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OPERATOR'S MANUAL
ProXIma X6

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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 ProXIma X6 family:
- ProXIma X6 REF. 70EA (2D version)
- ProXIma X6 REF. 70EB (2D/3D version)
- ProXIma X6 REF. 70EC (2D 70 kV version)

Unless otherwise specified, the instructions contained in this manual refer to all the above-mentioned models of ProXIma X6 family (from now on named “ProXIma X6”).

In the continuation of this manual, the instructions referring only to the ProXIma X6 REF. 70EA / 70EC model device are identified with the description “For 2D machine only”.

3D The instructions referring only to the ProXIma X6 REF. 70EB model device are identified with the following icon, the description “For 3D machine only” or both.

2. INTRODUCTION

2.1. INTENDED USE

ProXIma X6 is an extra-oral X-ray equipment for digital panoramic, tomographic and cephalometric X-rays exams, indicated for the following:

1. production of orthopanoramic images of the maxillofacial area, diagnostic dental exams on teeth, dental arches and other structures of the oral cavity;
2. production of X-ray images of the dental arches, parts of the cranium and of the carpus in support of cephalometric examination, where the configuration includes the CEPH arm;
3. production of tomographic images of the structures of the maxillofacial area and oral cavity for diagnostic dental exams on teeth, dental arches, the structures of the oral cavity including some cranial bones, where the configuration includes the CBCT option.

The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.

The equipment performs tomographic examinations through the acquisition of X-ray images through a rotational sequence and the reconstruction of a three-dimensional matrix of the volume examined, producing two- and three-dimensional views of this volume. This technique is known as CBCT.

ProXIma X6 is a digital X-ray unit, suitable for professionals in the sector, allowing them to obtain dental imaging in a simple, automated manner. The image is acquired through the use of an X-ray detector and a constant-voltage X-ray source, powered by a high-frequency high-voltage generator. The image is then transferred to a computer in real time for subsequent processing.

ProXIma X6 allows the following acquisitions to be made:
- paediatric panoramic or standard views (PAN);
- complete or partial view of the teeth, selected by the user (DENT);
- frontal and lateral views of the maxillary sinus (SIN);
- lateral and posterior-anterior views of the temporomandibular joints (TMJ).

Where equipped with CEPH arm, ProXIma X6 offers the following projections:
- cephalographies in latero-lateral view, in different formats;
- cephalographies in anteroposterior and posteroanterior view;
- hand (carpus) X-ray.

If the configuration includes CBCT exams, ProXIma X6 also allows the acquisition of tomographic images.

ProXIma X6 is indicated for use in the following sectors of dentistry:
- endodontics;
- periodontology;
- dental prosthetics;
- functional diagnosis and therapy of craniomandibular disorders;
- dental surgery;
- 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.
It is recommended to use this device with patients whose weight does not exceed 190 kg. If the patient is shorter than 109 cm or taller than 191 cm, it is advisable to use footrests or seating devices that can be stabilised in height and not provided with backrest to allow the 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.

For operators in Europe: any serious accident occurred in relation to the device must be reported to CEFLA s.c. and to the competent authority of the Member State where the user and/or patient lives.

For users in Canada: Where it is likely that an evaluation of soft tissues will be required as part of the patient X-ray evaluation, the appropriate imaging should follow the "Diagnostic Imaging Referral Guidelines of the Canadian Association of Radiologists", instead of using the cone-beam technology.

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 radiographies as i.e. the ones referred on the website Image Gently (www.imagegently.org), for dental X-rays, 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.

2.2. EXPECTED CLINICAL BENEFITS

The device uses X-ray imaging for the production of orthopanoramic images of the maxillofacial area, diagnostic dental exams on teeth, dental arches and other structures of the oral cavity; production of X-ray images of the dental arches, parts of the cranium and of the carpus in support of cephalometric examination, where the configuration includes the CEPH arm; production of tomographic images of the structures of the maxillofacial area and oral cavity for diagnostic dental exams on teeth, dental arches, the structures of the oral cavity and some cranial bones, where the configuration includes the CBCT option.

Clinical benefits include enabling the physician to identify and/or rule out medical problems and diagnose illnesses; determining when surgery is needed; reducing the need for exploratory surgery; reducing the length of hospitalisation; guiding the treatment of common conditions; and improving patient positioning in appropriate care areas.
The devices make it possible to obtain high-quality images of many parts of the body easily and automatically and enable precise diagnostic testing.
The availability of good quality images leads to a more precise clinical assessment by physicians, thus enabling them to plan a more precise intervention or treatment and achieve a better final clinical performance and outcome for the patient.

2.3. MANUAL DESCRIPTION

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

2.4. GENERAL WARNINGS

The digital X-ray device with its drivers and software have been developed and manufactured by CEFLA s.c. - via Selice Provinciale 23/A - 40026 Imola (BO) Italy, hereinafter referred to as the Manufacturer, in compliance with the European Union Regulation on medical devices.

In order to use the device, 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. 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.
- Optional equipment/applications and their availability may vary based on the reference markets and/or model.

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.

2.5. NECESSARY ELEMENTS, NOT SUPPLIED WITH THE PRODUCT

For correct operation, the product requires a connection to a Personal Computer (indicated as PC) and the relevant software. 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.

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 or IEC 62368-1

2.6. STANDARDS AND REGULATIONS

The device has been designed to meet the following standards:
- (EU) Regulation 2017/745 on Medical Devices;
- Directive 2006/42/EEC - Machinery Directive.

Technical Standards:
IEC 60601-1:2005 + A1:2012
IEC 60601-1-2:2014 + A1:2020
IEC 60601-1-3:2008 + A1:2013
IEC 60601-2-63:2012 + A1:2017 + A2:2021
IEC 60601-1-6:2010 + A1:2013
IEC 62366-1:2015 + A1:2020
IEC 62304:2006 + A1:2015
IEC 60825-1:2014

2.7. CLASSIFICATIONS

The device is classified as Class I Type B as far as safety is concerned, under IEC 60601-1.

The device is classified as a Class IIB medical electrical X-ray equipment in accordance with (EU) Regulation 2017/745 on Medical Devices.

2.8. 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.

 The operator’s manual is provided in electronic format.

CE 0051 Equipment in compliance with the essential requirements of (EU) Regulation 2017/745 on Medical devices.
Notified body: IMQ spa.

UDI Unique device identifier.

 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 Product/equipment identification code.

I Unit ON.

O Unit OFF.

Mark of conformity with technical regulations of Ukraine.

MD Medical device.

\# Model number.

2.9. GENERAL SAFETY WARNINGS

The instructions inform the user on how to properly operate the device. 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 device 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.

2.9.1. INSTALLATION CONDITIONS

- The device 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 device must be installed by a technician authorised by the Manufacturer under supervision of a Qualified Expert.
- The room where the device 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 device 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 device 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 device 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.

2.9.2. USE CONDITIONS

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.**
- **For patients, the use of leaded aprons with collar for thyroid protection is required, except when the specialist detects possible risks of artefacts or possible overlapping on concerned anatomical structures.**
- **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

Note for users in Canada: SIN 3D examinations and the 3D fields of view (FOVs) [11x11], [8x10], [10x6], [10x7] described in this document may not be available for dento-alveolar applications in all Canada regions.

2.9.3. 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.*

2.9.4. MAINTENANCE AND DISPOSAL

Never take the covers off the equipment.

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 device malfunctioning, do not attempt to carry out any type of maintenance operation and do not use the device on a patient, but directly contact your local distributor.

The user cannot carry out maintenance on any mechanical or electronic part of the x-ray device.

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 device 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 “ProXIma X6 - 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.

2.9.5. CLEANING AND DISINFECTION

Cleaning is the first step required for any disinfection process. Physically scrubbing with detergents and surface-active substances and rinsing with water removes a considerable amount of micro-organisms. If the surface is not first cleaned, the disinfection process cannot be successful.

If a surface cannot be adequately cleaned, it should be covered with barriers.

The outer parts of the equipment must be cleaned and disinfected using a product for hospital use with indications for HIV, HBV and tuberculocidal (medium-level disinfectant) specific for small surfaces.

The various drugs and chemical products used in dental surgeries may damage the painted surfaces and the plastic parts. Researches and tests performed show that the surfaces cannot be fully protected against the harsh action of all products available on the market. We therefore recommend protecting with barriers whenever possible.

The harsh actions of chemical products also depend on the amount of time they are left on the surfaces. It is therefore important not to leave the product on the surfaces longer than the time specified by the manufacturer.
It is recommended to use the specific medium-level disinfectant, STER 1 PLUS (CEFLA s.c.), which is compatible with painted surfaces, plastic parts and unpainted metal surfaces. As an alternative, we recommend to use products containing:

- 96% ethanol. Concentration: maximum 30 g per 100 g of disinfectant.
- 1-Propanol (n-propanol, propyl alcohol, n-propyl alcohol). Concentration: maximum 20 g per 100 g of disinfectant
- Combination of ethanol and propanol. Concentration: the combination of the two should be maximum 40 g per 100 g of disinfectant.

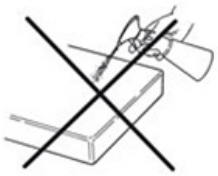
Coated surfaces and plastic parts.

- Incidin Spezial (Henkel Ecolab);
- Omnizid (Omnident);
- Plastisept (Alpro) (not tuberculocide as not an alcohol-based disinfectant);
- RelyOn Virkosept (DuPont);
- Green & Clean SK (Metasys) (not tuberculocide as not an alcohol-based disinfectant).

- **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.**
- **All products must be used as directed by the manufacturer.**
- **Do not mix the STER 1 PLUS disinfectant with other products.**
- **Do not spray the selected product directly on the surfaces**

Clean and disinfect with disposable non-abrasive paper (avoid using recycled paper) or sterile gauze.

- **Turn off the device prior to cleaning and disinfecting the external parts.**
- **All materials used for cleaning and disinfection must be thrown away upon completing the procedure.**



2.9.6. 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 cephalometric examinations, 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.

2.10. SAFETY WARNINGS

2.10.1. USE CONDITIONS

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

2.10.2. 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.

2.10.3. 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.

2.10.4. EMERGENCY STOP BUTTON

The device is equipped with a red emergency stop button, positioned near the power button, in order to be pressed by the patient or the operator to stop the X-ray device operation.

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, 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.

2.10.5. CONDENSATION

Condensate may form in the X-ray device after high temperature fluctuations. Activate the X-ray device only after an appropriate ambient temperature has been reached. See the chapter "Environmental characteristics".

2.10.6. 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.

2.10.7. EXPOSURE TO LASER RADIATION

The device 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 traces.
- **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.

2.10.8. ELECTROMAGNETIC SAFETY

The device is intended for use in environments recognised as professional health facilities, as described in IEC 60601-1-2:2014 + A1:2020. The device belongs to CISPR 11 Class A Group 1 and complies with immunity test levels specified by IEC 60601-1-2:2014 + A1:2020 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.
For users residing in China only		
RF emissions CISPR 11	Class A (The device in combination with the shielded area)	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. The device must only be used in a shielded room with a minimum RF shielding effectiveness and, for each cable coming out of the shielded position, a minimum RF filter attenuation of 20 dB from 30 MHz to 1 GHz. If installed in a shielded room, the device is suitable to be used in all spaces other than the domestic ones and those directly connected to a public low-voltage network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

For users residing in China only: It is essential to check the actual effectiveness of RF shielding and the filter attenuation from the shielded position to ensure that they meet or exceed the minimum values specified.

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**	**Degree 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 relevant 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 power supply 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.
Over-voltage IEC 61000-4-5	± 1 kV differential mode ± 2 kV common 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% for 1 cycle Ut = 70% (at 0°) for 25/30 cycles Ut = 0% for 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. 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 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	d = 1.2 x √P 80 MHz at 800MHz d = 2.3 x √P 800 MHz at 2.5GHz
Conducted RF EN 61000-4-6	3 V 150 kHz to 80 MHz 6 V ISM frequencies	IEC 60601-1-2 Test level	d = 1.2 x √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:  **For users residing in China only:** The device must only be used in a shielded room with a minimum RF shielding effectiveness and, for each cable coming out of the shielded position, a minimum RF filter attenuation of 20 dB from 30 MHz to 1 GHz. The field intensities outside the position shielded by fixed RF transmitters, defined by a measurement of the electromagnetic site, must be lower than 3 V/m.

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)**		
	150 KHz to 80 MHz $d = 1.2 \times \sqrt{P}$	**80 KHz to 800 MHz** $d = 1.2 \times \sqrt{P}$	**800 KHz to 2.5 MHz** $d = 2.3 \times \sqrt{P}$
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.
3. **For users residing in China only:** It is essential to check the actual effectiveness of RF shielding and the filter attenuation from the shielded position to ensure that they meet or exceed the minimum values specified.

For users residing in China only: The field intensity of fixed transmitters, such as base stations for radio (mobile / cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot theoretically be accurately predicted. To evaluate the electromagnetic environment caused by fixed RF transmitters, an investigation of the electromagnetic site must be taken into account. If the field intensity measured outside the shielded position where the device is used exceeds 3 V/m, the device must be monitored to check its normal operation. If abnormal performance is observed, additional measures could be required, such as device transfer or use in a shielded place with greater RF shielding efficiency and filter attenuation.

For users residing in China only: The emission characteristics of other equipment permitted inside the shielded room must meet the pertinent levels set out by the technical standards applied. It is recommended to publish a notice containing this information at the entrance to the protected area.

2.10.9. PROTECTION AGAINST RADIATIONS

The device is an X-ray equipment. 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 device 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, additional components, and procedures available to protect the patient and operator from X-ray radiation, especially for children.**
- **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 (FOV) with reduced dimensions, such as: 6x6 (6 cm volume diameter, 6 cm height), 8x6, 8x8, 10x6, 5x4. Possibility of scanning in Low Dose mode, a low-dose protocol characterised by reduced scanning time. The field of view (FOV) must be selected to irradiate the minimum area required for the examination, in order to minimise the radiation exposure for the patient.**

2.10.10. APPLIED PARTS

The parts of the equipment that, during standard use, necessarily come into contact with the patient, so that the device may carry out its functions correctly, are: chin rest, bite and hygienic covers, headrest, handles, ceph nasion and ear protections.
Not applied parts that might come into contact with the patient are the external casings and the patient arm.

2.10.11. CONSIDERATIONS FOR PAEDIATRIC 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 could also approximately correspond to that of an average 12 years old or that of a 5th percentile U.S. adult female.

ProXIma X6 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): https://www.fda.gov/radiation-emitting-products/medical-imaging/pediatric-x-ray-imaging
- "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 devices.

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 contributes to significantly reduce the dose to the thyroid in all radiodiagnostic dental examinations, 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.

ProXIma X6 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), 8x6, 8x8, 10x6, 5x4. 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
Indications 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)	"Dose declaration and acceptance test" attachment.

2.10.12. CYBERSECURITY INFORMATION

Medical devices capable of connecting (e.g. Via Ethernet port) to another device are vulnerable to cybersecurity.

The intended use of the device (generation of radiologic two-dimensional and three-dimensional images) limits for its nature the intended use environment (health care facility, medical facility, hospital, etc.) and the intended users (health care worker, paediatrician, etc.).

This condition limits the probability that the device may be subject to cyber-attack.

In every case some precautions are recommended:

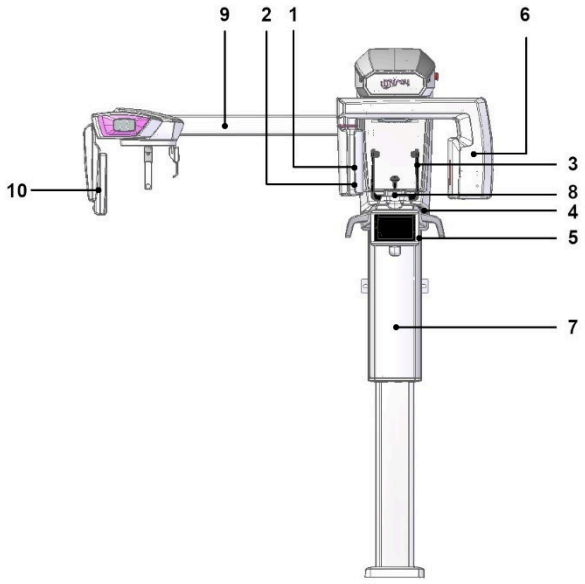
- the scanner and the workstations must be used in a controlled access environment (e.g. radiology department) so that they are accessible to authorised personnel only;
- the workstations must belong to a medical network, where the cybersecurity countermeasures are correctly and effectively implemented in accordance with national and regional regulations in force;
- the infrastructure must manage functions for access protection, therefore a login must be executed to access the workstation with correct User Id and Password. The passwords must be maintained reserved, not easily identifiable and they must be changed periodically;
- the infrastructure must provide the protection from unauthorised accesses with firewall;
- the infrastructure must manage functions for data protection;
- the infrastructure must manage functions for logging and detecting accesses.

3. DESCRIPTION OF THE OPERATION

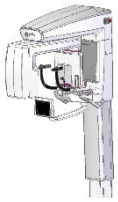
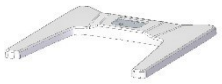
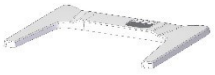
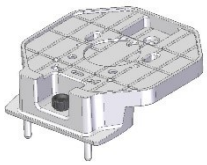
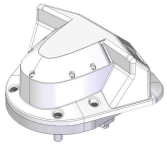
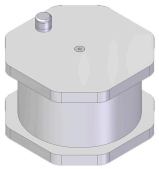
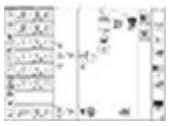
The X-ray device consists of a rotary arm fitted on a column support for carrying out panoramic X-rays or tomographic examinations. The rotary arm features roto-translation motorised movements which allow moving X-ray emission system and image detector around the patient, according to complex orbits 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.

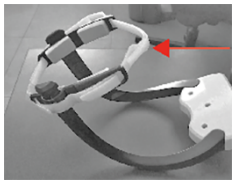
The X-ray device can feature a cephalometric examination arm, fitted on the column support. The arm houses a cephalostat, which keeps the patient position during the exam, and the image detector which translates in synchronisation with the X-ray source movement.
At user's choice, the X-ray device can be equipped with a single image detector (thus the operator must position it on the rotary arm for panoramic X-rays or on the cephalometric examination 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 cephalometric examination arm).

1 3D/2D panel
(For 3D machine only)
2 2D sensor for panoramic images
(For 2D machine only)
3 Craniostat
4 Control panel
5 Touch control console (optional)
6 X-ray source
7 Lifting telescopic column
8 Chin rest and bite
9 Cephalometric examination arm
10 2D sensor for cephalometric examinations



4. MAIN COMPONENTS

Basic machine		Support for carpus scans (optional)	
Remote X-ray button (optional)		Standard stand (optional)	
Patient positioning unit (craniostat)		Standard stand for machine including cephalometric examination arm (optional)	
Sensor for panoramic images		Support for 3D scans of models, impressions, X-ray templates, phantoms for quality checks / consistency tests (optional)	
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.		Phantom for 2D quality checks (optional)	
Cephalometric examination arm (optional)		Phantom for 3D quality checks (optional)	
Sensor for panoramic and cephalometric X-ray images (optional)		22” / 24” medical monitor for image displaying (optional)	
CBCT detector for 3D image acquisition		2D or 3D image acquisition workstation (optional)	
Long sticks for patient positioning (optional)		Multiple-workstation hardware keys for the activation of additional licenses (1, 5, 10, 25, 50, 250) on LAN network (optional)	
Quick Start Guide (summary of the main functions of the machine)		Ergonomic bite and chin rest (3 pieces)	

Hygienic covers in the version with cephalometric examination arm: set of 5 pairs of autoclavable earpieces, disposable infection control sheaths			Disposable infection control sheaths for bite and soft bite inserts for edentulous patients	
Strap for craniostat			Disposable infection control sheaths and silicone cover for ergonomic bite	
Touch control console onboard the machine (optional)*			Subnasal supports for SIN and TMJ / TMJ 3D	

** Some optional features of the device may or may not be available depending on your reference market. For more details, please contact your local distributor.*

5. CONTROL PANEL

5.1. TOUCH CONTROL PANEL ONBOARD THE MACHINE

Each button on the control panel has a white LED: if the LED is off, the corresponding button is disabled; if the LED is on, the button is active.

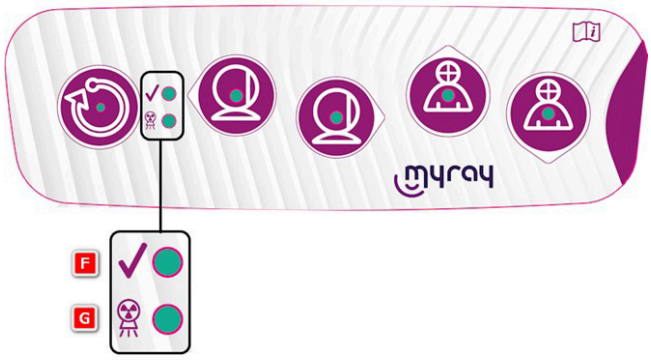
Control panel area:

A Confirmation Button
Performs different functions depending on the status of the machine (indicated by the colour of the status LED **F**):

With RED LED: clears any error.
With BLUE LED FLASHING: wake-up function from stand-by device.
With BLUE LED STEADY ON (short press < 2s): start device setup.
With BLUE LED STEADY ON (long press (>2s): performs the parking function (if configured).
With GREEN LED STEADY ON (long press (>2s): start demo mode.
With GREEN LED STEADY ON/FLASHING (short press < 2s): start SETUP mode.

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 device:

F BLUE LED STEADY ON: X-ray device turned on.
BLUE LED FLASHING:
X-ray device in pause mode (Standby).
GREEN LED STEADY ON:
X-ray device ready for the X-ray emission; referred to as “Ready status”: if pressed, the remote X-ray button makes the X-ray examination start.
GREEN LED FLASHING:
devices 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).
LIGHT BLUE LED:
Device reset in progress.
RED LED:
device in error.

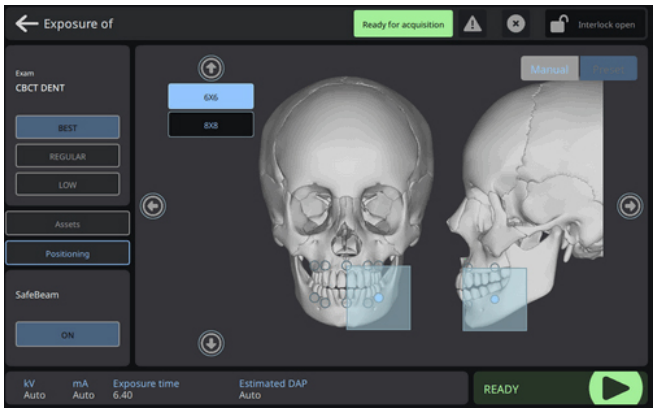
G YELLOW LED STEADY ON:
X-ray emission in progress
YELLOW LED FLASHING:
device in motion during an examination

5.2. CONTROL CONSOLE

The control console* is an interface that allows managing the operating functions of the X-ray device.

The operator can use the control console to set the examination in a guided manner, as described in details inside the following dedicated chapters.

** Some optional features of the device may or may not be available depending on your reference market.*
For more details, please contact your local distributor.



5.3. CONTROL PANEL ON CEPHALOMETRIC EXAMINATION ARM

For all the units equipped with cephalometric examination arm, such arm features a control panel which allows moving the device vertically.

H Column upward movement

I Column downward movement

J Confirmation Button

Performs the same functions, which change depending on the status of the machine (indicated by the colour of the status LED): refer to the functions described above for the button **A**.

LED
Indicates the status of the device: refer to the statuses described above for the LED **F**.

5.4. X-RAY EMISSION REMOTE CONTROL

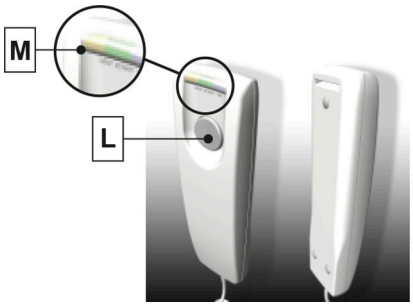
The device is equipped with a remote control to enable the X-ray emission.

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 device 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.

BUTTON PRESSED

BUTTON RELEASED

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

During the execution of panoramic or cephalometric examinations, 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.

Comply with the safety standards on ionising radiation for the operator (for further information, see the paragraph on Radiation Safety).

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 simulate an examination without radiation emission (dummy run):

- Select the desired examination;
- Wait until the status LED turns steady GREEN if in READY status or flashing GREEN if the interlock is enabled (door open);
- Press and hold the Confirmation button (**A**) (see para. CONTROL PANEL ONBOARD THE MACHINE) during the entire simulation of he examination.

This simulation can be useful for patients who are particularly emotional, children, showing the patient what the examination consists of.

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 (> 2s) (see par. CONTROL PANEL ONBOARD THE MACHINE) until the status LED turns BLUE and is STEADY ON.
This function is configurable (positions and enabling/disabling).

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

6. LIGHTING AND PATIENT MONITORING SYSTEMS

6.1. DEVICE STATUS BACKLIGHTING

The device can be equipped with a backlighting system*, integrated behind the mirror, which can take on 5 different colours, immediately showing the operator and patient the status of the machine from start to finish of the examination.
Settings can be made via the control console.

** Some optional features of the device may or may not be available depending on your reference market.*
For more details, please contact your local distributor.

BLUE BACKLIGHTING:
X-ray device in pause mode (Standby)

GREEN BACKLIGHTING:
X-ray device ready for the X-ray emission; referred to as “Ready status”

LIGHT BLUE BACKLIGHTING:
device reset in progress

RED BACKLIGHTING:
device in error

YELLOW BACKLIGHTING:
X-ray emission in progress

6.2. AMBIENT LIGHTING

The ambient lighting system* allows the user customisation in terms of colour and light intensity, so that the device is perfectly suited to the style and furniture of the practice.
Settings can be made via the control console.

** Some optional features of the device may or may not be available depending on your reference market.*
For more details, please contact your local distributor.

6.3. LOGO LIGHTING

The device can be equipped with a logo lighting system*, which can take on different colours and brightness levels.
Settings can be made via the control console.

** Some optional features of the device may or may not be available depending on your reference market.*
For more details, please contact your local distributor

6.4. PATIENT MONITORING SYSTEM

The patient monitoring system* consists of an integrated camera under the mirror and a intercom system that allows remote communication between the operator and the patient in real time.

** Some optional features of the device may or may not be available depending on your reference market.*
For more details, please contact your local distributor.

7. PERFORMING A 2D X-RAY EXAMINATION

The steps to follow to properly perform a 2D X-ray examination are:
1. Switching on of device and PC where the acquisition driver is installed
2. Selection of X-ray examination (from Neowise software)
3. Preparation of X-ray examination (from the control console or Neowise software)
4. Patient positioning
5. Execution of the X-ray examination
6. Image display and processing

7.1. SWITCHING ON THE DEVICE

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.

7.2. EXAMINATION SELECTION AND PATIENT DATA ENTRY

7.2.1. 2D EXAMINATIONS AVAILABLE

1. Turn on the PC and run the Neowise software. The identification image of your device will be displayed. If the device is inactive, the disconnected status icon will be displayed.

2. After switching on the PC, the connection to the device will be established. The device ready status is indicated by a green icon.

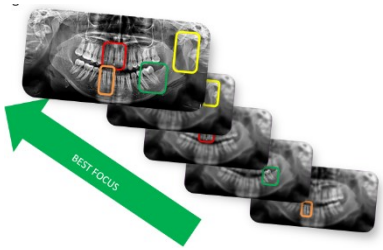
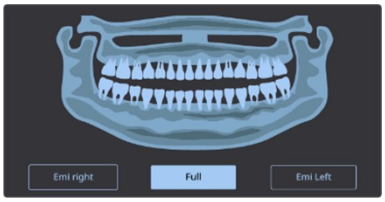
3. Enter the patient data to which the examination will be associated (or in the case of already existing data within the programme, search for the correct patient).

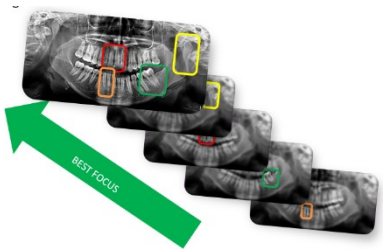
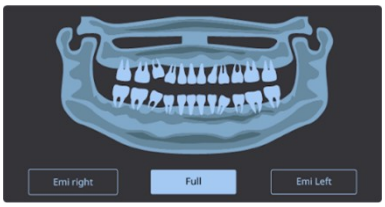
   For more details on patient data records, please refer to the Neowise User Manual.

DO NOT allow the patient to access the X-ray device during the examination selecting procedure, but only at the end of the procedure described in this paragraph.

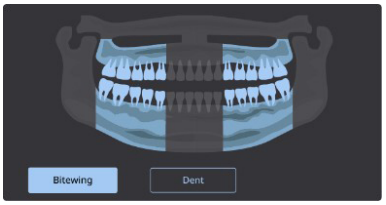
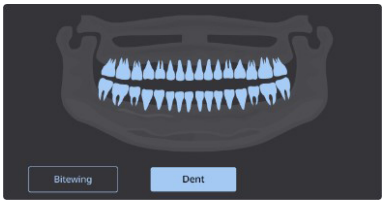
4. At this point, it will be possible to choose the type of 2D examination to be performed: the examinations foreseen for the "2D" category are:

Panoramic 2D examinations (PAN):

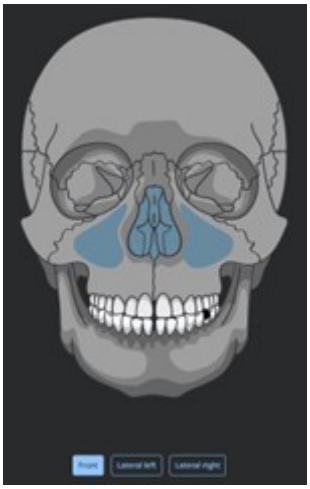
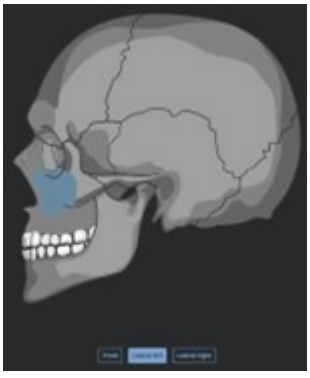
NAME	DESCRIPTION	PREVIEW
PAN ADULT	**PAN (FULL):** High-definition projection for the view of the complete dental arch and of TMJs (temporomandibular joints). Optionally, it can be limited to: • **HALF PAN RIGHT** (limited to right lateral) • **HALF PAN LEFT** (limited to left lateral) Options available for dose profile selections: • **ECO** (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 and to pay special attention to the correct patient positioning.* 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) • **iPAN (BEST FOCUS)*** (new intelligent feature providing a single image with optimised focus for the patient's morphology. The final result is a single PAN automatically created by the device with the anatomical areas of each layer more in focus thanks to the Focus-Free mode).  **Only for PAN REGULAR (FULL) examinations*	

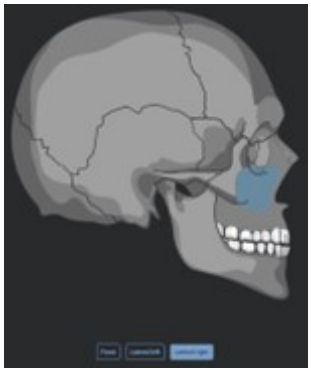
NAME	DESCRIPTION	PREVIEW
PAN CHILD	**PAN (FULL):** Projection for the view of the complete dental arch and of TMJs (temporomandibular joints), optimised for paediatric version, which adapts to child's morphology. Options available for dose profile selections: • **ECO** (projection with reduced doses 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) • **iPAN (BEST FOCUS)*** (new intelligent feature providing a single image with optimised focus for the patient's morphology. The final result is a single PAN automatically created by the device with the anatomical areas of each layer more in focus thanks to the Focus-Free mode).  **Only for PAN REGULAR (FULL) examinations*	

Dentition 2D examinations (BITEWING and DENT):

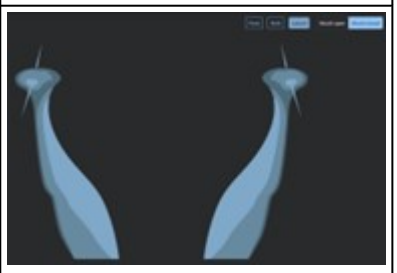
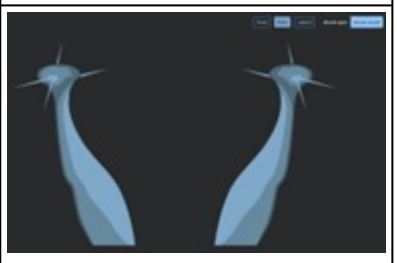
NAME	DESCRIPTION	PREVIEW
BTW	**BTW (FULL):** Series of 4 images optimised for a complete representation of the crowns of the entire dentition. Optionally, it can be limited to: • **BTW RIGHT** (limited to right lateral - 2 images) • **BTW LEFT** (limited to left lateral - 2 images)	
DENT	**DENT (FULL):** Projection of the complete dental arch excluding TMJs (temporomandibular joints), with improved orthogonality to reduce crown overlapping. Optionally, it can be limited to: • **DENT RIGHT** (1st and 4th arch quadrant) • **DENT LEFT** (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 2D examinations (SIN):

NAME	DESCRIPTION	PREVIEW
SIN FRONT	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.	

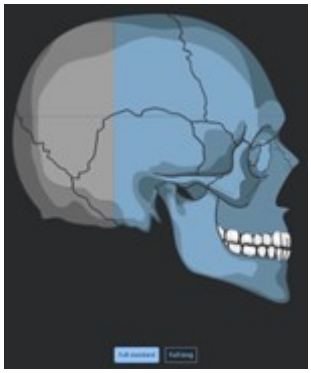
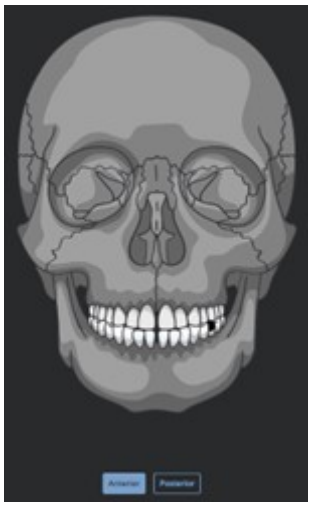
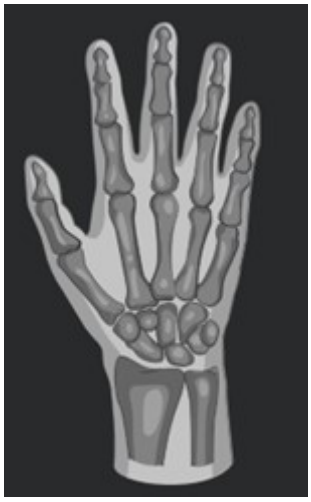
NAME	DESCRIPTION	PREVIEW
SIN R	Linear projection of the cranium with lateral view, at the level of right maxillary sinuses only.	

Temporomandibular joint 2D examinations (TMJs):

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

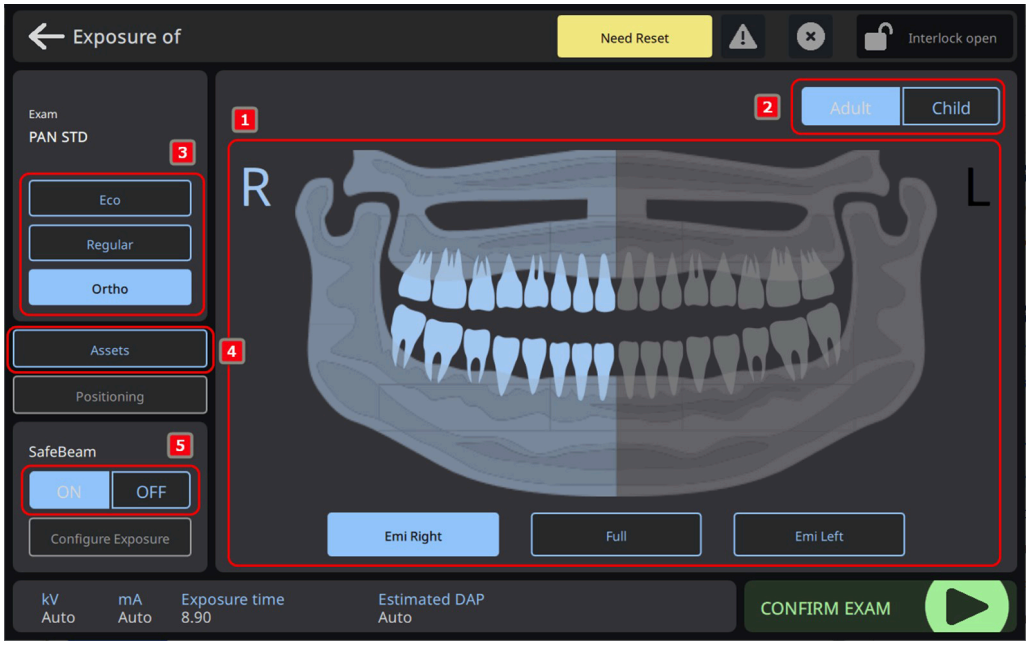
For each one of the TMJ diagnostic programs it is possible to perform the same examination with the mouth closed, at rest or open.

Cephalometric 2D examinations (CEPH):

NAME	DESCRIPTION	PREVIEW
LATERAL (LL)	**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** • **FULL LONG** Magnification equal to 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. Magnification equal to 1.13.	
CARPUS	It scans the carpus, using a suitable hand support.	

7.2.2. EXAMINATION SETTINGS

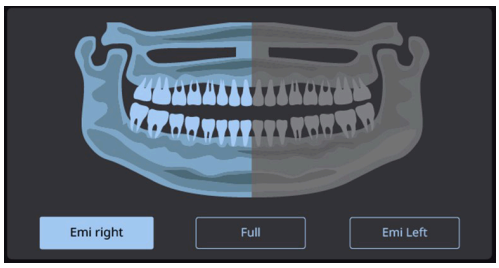
After selecting the desired type of examination, the SETTINGS page will be displayed on the console of the machine.
This screen includes:



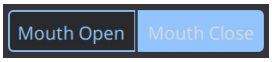
1 Summary of projection TYPE and chosen ANATOMIES:

By touching this area, you can select the desired ANATOMY.

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



For TMJ examinations, it is possible to select MOUTH OPEN or MOUTH CLOSED mode for every available anatomy.



2 Setting up the examination for ADULT/CHILD

Touch the ADULT/CHILD switch on the following page, if available.

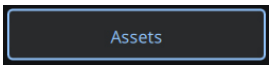
The reference anatomical model changes accordingly and dose profiles are set as reduced as compared to those for adults.

3 DOSE PROFILE selection

Allows selection of the dose profile between:

- **ECO** (projection with reduced doses and scanning times)
- **REGULAR** (projection with optimal scanning time for obtaining standard-resolution images)
- **ORTHO** (projection with increased orthogonality).

4 EQUIPMENT FOR PREPARATION OF THE EXAMINATION

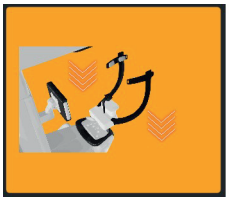


By touching the ASSETS button, the user is informed of the operations to be performed on the device in order to carry out the examination. This control consists of:

- indicate which devices are required for the patient positioning and how to position them;
- if necessary, be prepared to move removable sensors.

The screen shows the actions necessary to correctly prepare the machine.

The equipment images vary according to the type of examination chosen beforehand.

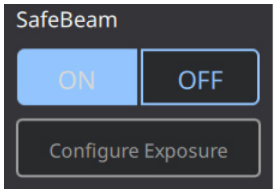


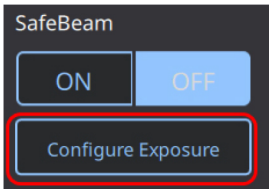
5 MRT settings (exposure meter):

In this area, it is possible to select the dose mode of administration. The available options are:

A **MRT ON:** technical features are automatically set to ensure the best possible quality of the final image, optimising the radiation dose to the patient.

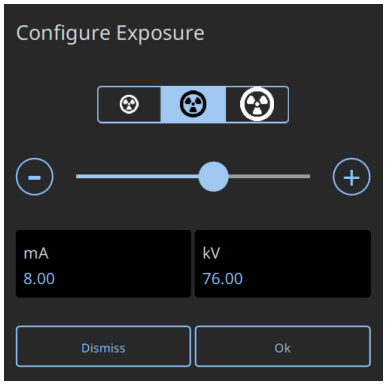
B **MRT OFF:** enables manual exposure meter configuration.





Sets parameters according to the preset values for three different profiles: low, medium, high.

Press on the icons “+” and “-” to increase or decrease the dose administered.



7.2.3. DEVICES FOR PATIENT POSITIONING

2D EXAMINATION TYPE	MOBILE SUPPORT	IMAGE
PAN – DENT – BTW	Craniostat, chin rest PAN bite and general bite	
TMJ	Under-nose support and craniostat	
SIN	Under-nose support and craniostat.	
CEPH	Cephalometric cephalostat for cranium positioning.	
CARPUS	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.

7.2.4. SENSOR MOVEMENT

This information is only addressed to users having a device equipped with removable sensors.

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 and it will be impossible to perform the examination chosen.
Do not 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.

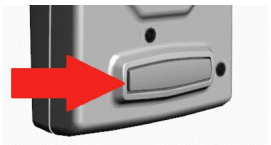
In the event of an X-ray device in 2D version equipped with a CEPH arm for cephalometric examinations, it is necessary to move the sensor from the CEPH position to the PAN position and vice versa, depending on the type of examination to be performed.
The X-ray device automatically detects the presence 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 device allows removing and moving it to the correct position.
The sensor coupling system contains electronic parts and a mechanical lock.

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. The two sensors can be distinguished by the height of the black stripe which identifies the area sensitive to X-rays. See images.

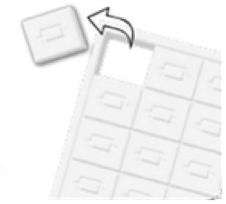
PAN SENSOR

PAN / CEPH SENSOR

7.2.5. DEVICES FOR EDENTULOUS PATIENTS

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

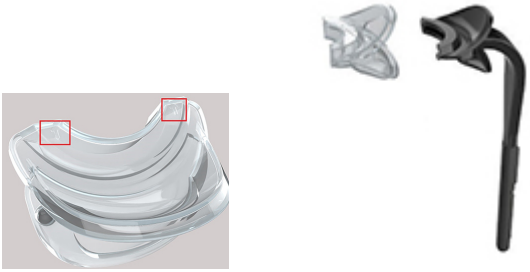
4. push the bite until the block of material is ejected

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

In the case of edentulous patients who require the use of an anatomic bite with autoclavable silicone cover:

1. after performing a sterilisation cycle of the silicone cover, insert the cover in the bite, making it adhere completely

Pay attention to the insertion direction, the arrows must point upwards.



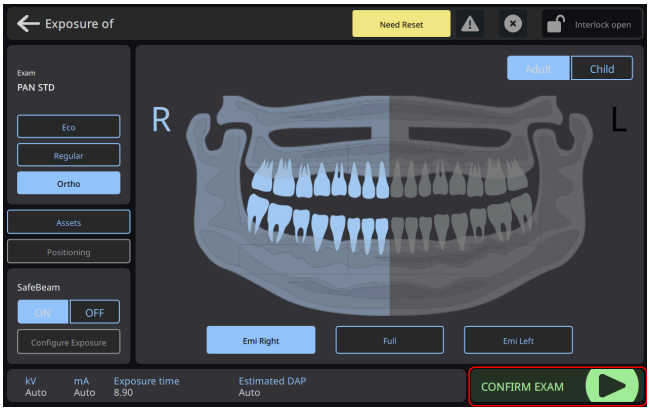
2. apply the disposable infection control sheath on the bite block

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, use disposable infection control sheaths for the parts in contact with the patient. Always insert / replace bite disposable hygienic infection control sheaths before positioning a new patient.

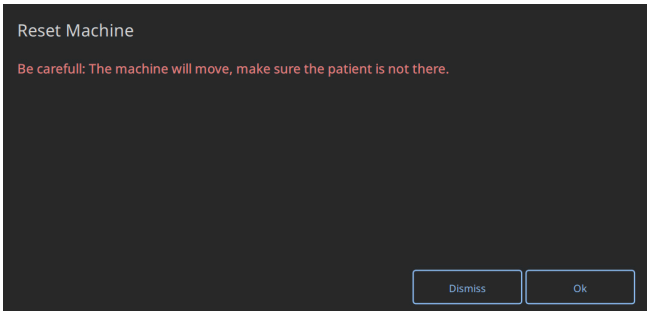
3. Carry out the normal positioning procedure for the examination making the patient press the silicone cover centre with mucous membranes.

7.2.6. EXAMINATION START CONFIRMATION

Once the settings for the examination have been confirmed, touch the CONFIRM EXAM button on the console physical keyboard.



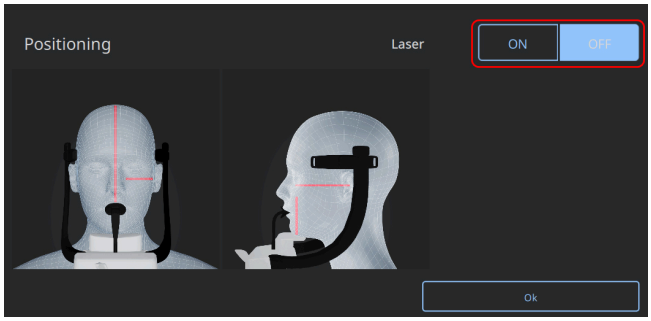
At this point, the machine will require a reset movement and automatically prepare for the PATIENT POSITIONING.



7.3. PATIENT POSITIONING

At this point, the POSITIONING button will be enabled on the console. 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 CONFIRM 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 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.



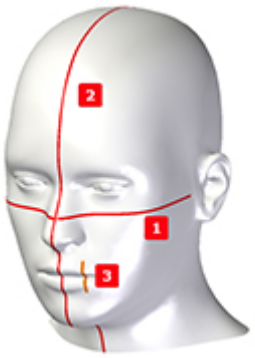
Lasers can be turned on and off by using the switch.

When the patient accesses the machine (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.

7.3.1. 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, SIN, TMJ, 3D examinations
2. **Sagittal Vertical Laser Trace**
   used in all PAN, DENT, SIN, TMJ, 3D examinations
3. **Vertical Focusing Laser Trace**
   used in PAN, DENT, SIN, TMJ examinations



Upper horizontal trace (1)
It is generated by a laser projector located on the side of the X-ray generator.
The adjustment is carried out using the wheel located on the lower part of the generator. It allows identifying the Frankfurt plane[1] on patients of different sizes, ensuring proper patient alignment.

The symbols on the side of the ruler refer to the positioning options available only on devices equipped with a 3D detector and/or a sensor for CEPH examinations.

For devices equipped with a 2D sensor, the central line of the ruler (6 cm) indicates the centre of the panel.

Sagittal vertical trace (2)
It is generated by a laser projector located beneath the mirror. 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 is generated by a laser projector located on the side of the X-ray generator. It indicates the focal sulcus position to achieve the optimal focusing.

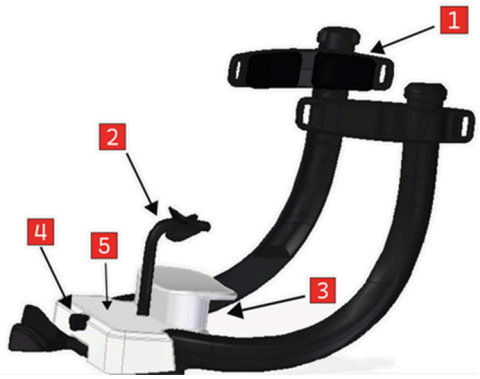
Each pressure of the CONFIRM button will move all the device mobile parts. Make sure NOT to press the button during the patient positioning and that the device can be safely moved.

[1] 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.

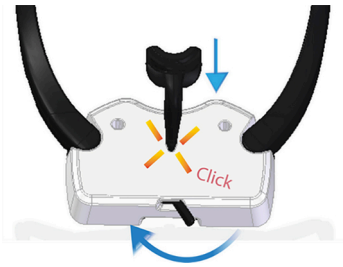
7.3.2. PATIENT POSITIONING DESCRIPTION (ERGONOMIC CRANIOSTAT)

Craniostat's components:

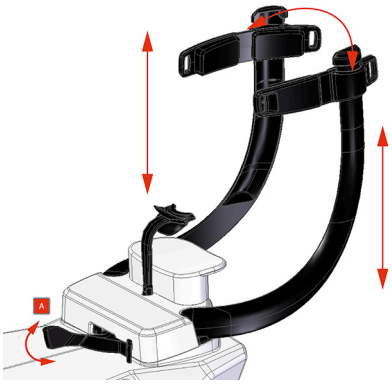
1. **Anatomical arches with temporal rubber elements**
2. **Bite**
3. **Chin rest**
4. **Bite locking lever**
5. **Base**



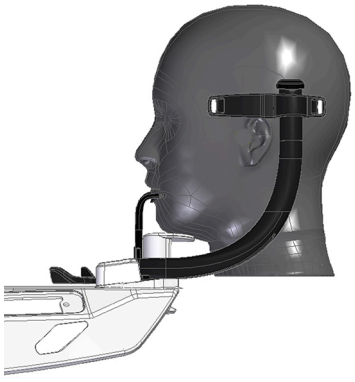
The bite (**2**) is inserted into the relevant hole of the seat (**1**): once it has been positioned at the desired height, pull the central lever (**4**) from the right (unlocking position) to the left (locking position) in order to centre and lock it into the required position.



The arches are usually closed with a spring mechanism. To open them fully and allow patient positioning, operate the lever (**A**).
Keeping the lever actuated, let the patient approach and ask him/her to rest his/her chin on the chin rest.
The arches are also adjustable in height.



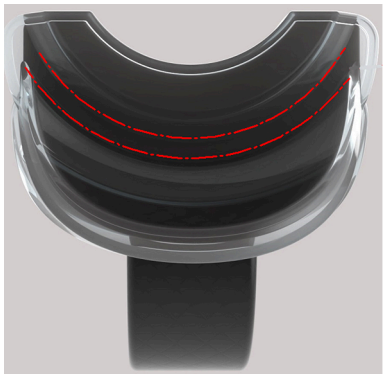
Then the lever is slowly released and the arches rest on the patient's temporal area, adapting to the conformation of the skull.
Positioning is completed by having the patient bite the bite block.



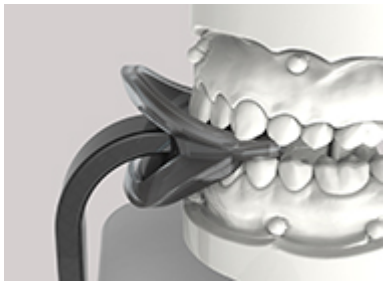
The entire craniostat assembly can be removed (e.g. for CEPH examinations) by simply taking it from the base and lifting it vertically.

7.3.3. INSTRUCTIONS FOR USE OF THE ERGONOMIC POSITIONING BITE

1. Insert the bite with film (disposable hygienic cover), adjusting its height.



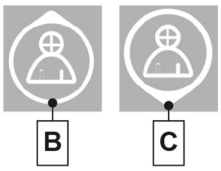
2. The patient must clamp the bite with the upper and lower dental arches in its grooves, as shown in the image.



3. Make sure that the lips stay fully inside the guards, as shown in the image.

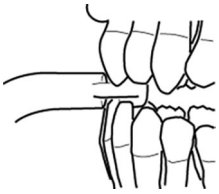
7.3.4. PAN, DENT AND BTW EXAMINATIONS

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.
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

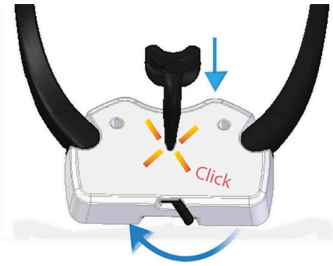
5. Adjust the height of the bite and rotate it inside the mouth, asking the patient to bite it as shown in the figure. The tip of upper and lower incisors must be in the bite groove. The interproximal space of incisors must be in the bite midline.



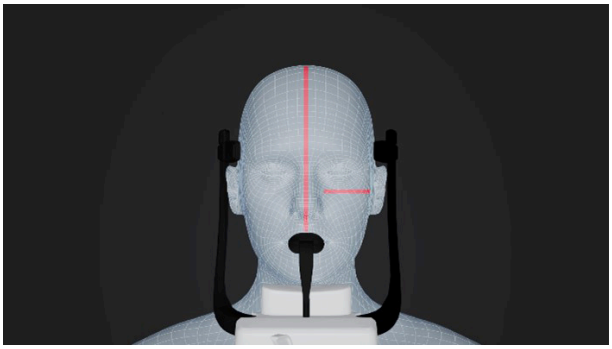
6. The correct positioning of the bite block is facilitated by the upward and downward sliding movement of the relevant support pillar.

   If a BTW examination is being performed, it is NECESSARY TO ADJUST THE BITE HEIGHT in a specific point. It is recommended to remove the chin rest.

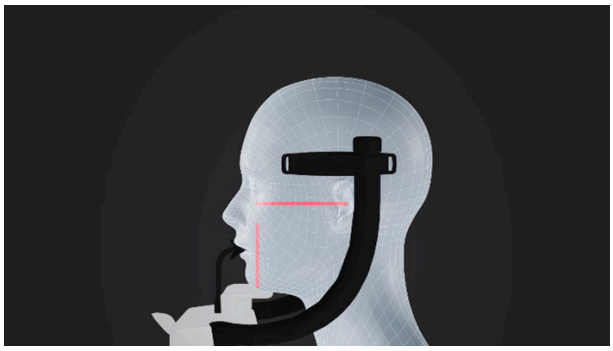
   Then adjust the bite vertical position in the point where an acoustic feedback ("clack") and a tactile feedback (slight resistance to the bite vertical sliding) are perceived. Once this position has been reached, lock the bite as described in the previous paragraph, turning the lever in the lock position.



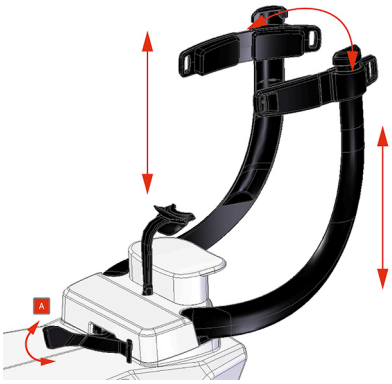
7. Check the symmetry of the patient's head using the sagittal vertical trace as a guide watching the mirror.



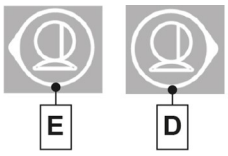
8. Check the correct positioning of the Frankfurt plane by overlapping the upper horizontal trace. To adjust the inclination of the patient's head, use the column upward and downward movement keys. Make sure that the patient's back is straight, relaxed and that the chin rests on the chin rest.



9. Once the correct orientation has been found, lock the craniostat as explained in the previous paragraph.
   Push the front support forward until it rests on the patient's forehead. The forehead's pressure on the support will automatically stabilise it.
   Close the arms until they touch the patient's cranium.
   Rotate the top levers downward until they are laterally locked.



10. Ask the patient to smile in order to show the upper dentition. Normally the vertical light trace falls on 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.



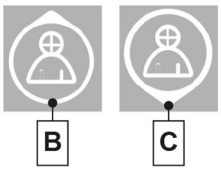
11. Before leaving the room to press the X-ray emission button, ask the patient to close his/her eyes, swallow and move the tongue against the palate.

7.3.5. TMJ EXAMINATION

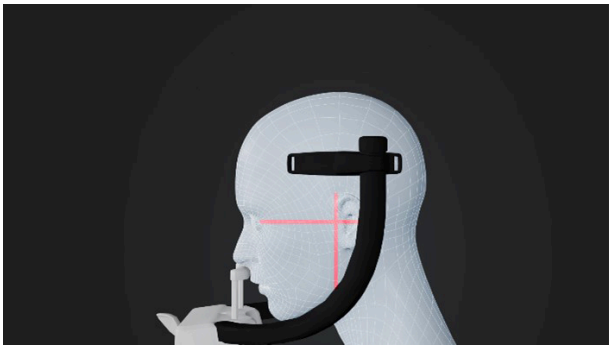
7.3.5.1. LATERAL TMJ

1. Remove the chin rest and the bite, insert the reduced under-nose support (**A2**) and adjust the height of the anatomic arches of the craniostat.

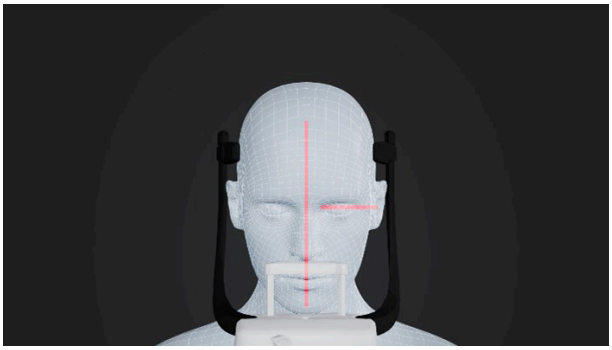
2. Adjust the unit height, in order to facilitate the patient's access, using the keys (**B**) and (**C**) to move the column upward or downward (see par. CONTROL PANEL ONBOARD THE MACHINE) until the under-nose support reaches the height of the nose base. The telescopic column will move slowly at first,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



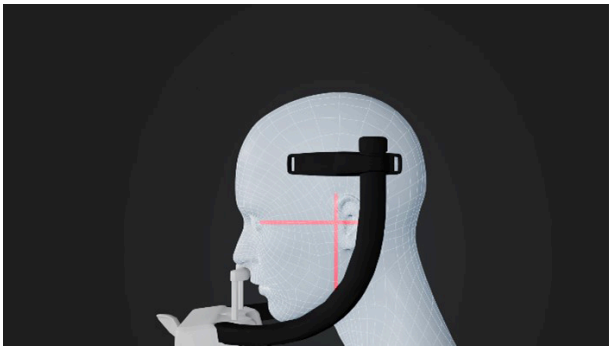
3. Guide the patient toward the unit so that he/she faces the under-nose support and can grab the wide handles. The patient will rest the nose base on the under-nose support, as in the figure.



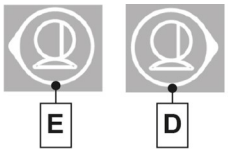
4. Check the symmetry of the patient's head using the sagittal vertical trace as a guide; check the correct positioning of the Frankfurt plane by overlapping the upper horizontal light trace, as shown in the previous figure. If required for the examination and if necessary, slightly tilt the patient's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



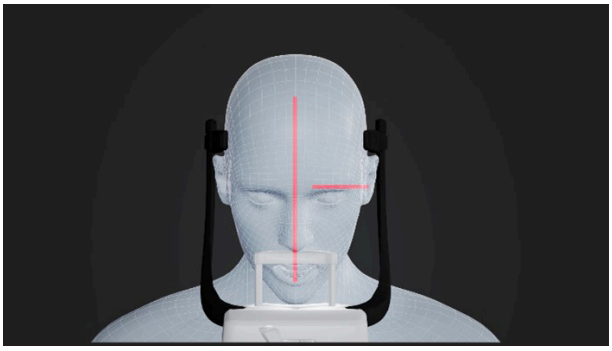
6. Make sure that the examination required is selected correctly.
   Use keys (**E**) and (**D**) (see par. CONTROL PANEL ONBOARD THE MACHINE) to position the vertical focusing light trace exactly on the condyle head, as shown in the figure.



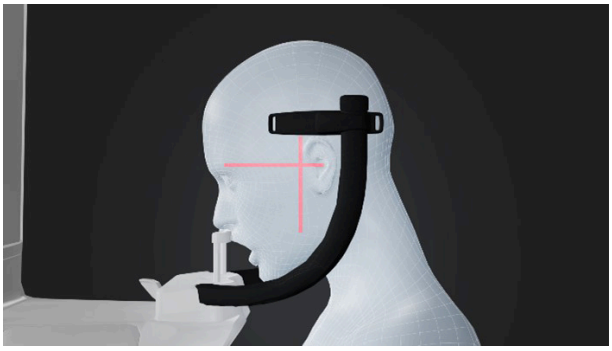
7. Before leaving the room to press the X-ray emission button, ask the patient to close his/her eyes and to remain still.

7.3.5.2. FRONTAL TMJ

1. Repeat the steps of lateral TMJ examination from number **1** to number **3**.

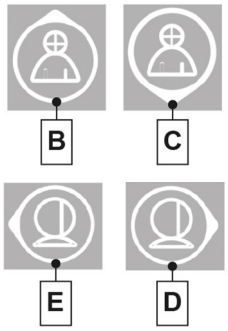


2. Check the symmetry of the patient's head using the sagittal vertical light trace as a guide; tilt the patient's head forward until the upper horizontal light trace passes through the lower part of the auditory meatus and under the eyebrow arch, as shown in the figure on the side.



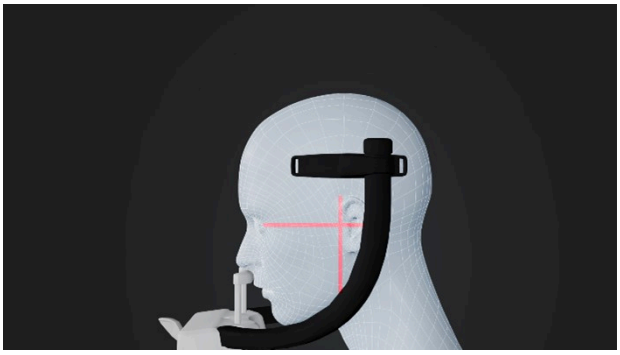
3. To adjust the head's inclination, just lift or lower the unit using the height adjusting buttons (**B**) and (**C**) (see par. CONTROL PANEL ONBOARD THE MACHINE).

4. 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.

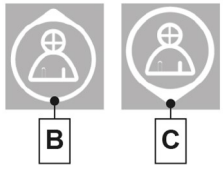


7.3.5.3. TMJ BOTH

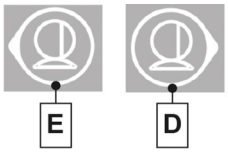
1. Repeat the steps of front TMJ examination.



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).



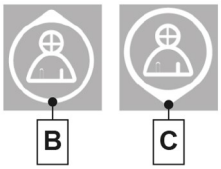
3. Use keys (**E**) and (**D**) (see par. CONTROL PANEL ONBOARD THE MACHINE) to position the vertical focusing light trace exactly on the condyle head, as shown in the figure.



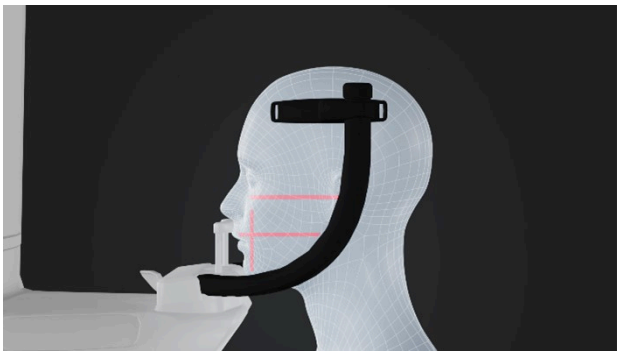
7.3.6. MAXILLARY SINUSES EXAMINATION

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.

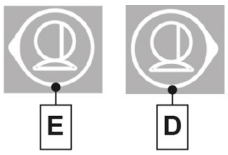


3. Guide the patient toward the unit so that he/she faces the under-nose support and can grab the wide handles. The patient will rest the nose base on the special support for sinuses, as in the figure.



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 CONFIRM 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.



7.3.7. CEPHALOMETRIC EXAMINATIONS (CEPH)

Cephalometric examinations can be performed only if the device features a cephalometric examination 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.

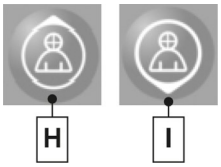
If a seat is used, make sure that the backrest or the armrests do not interfere with the correct movement of the machine.

Remove the bite and the chin rest 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.

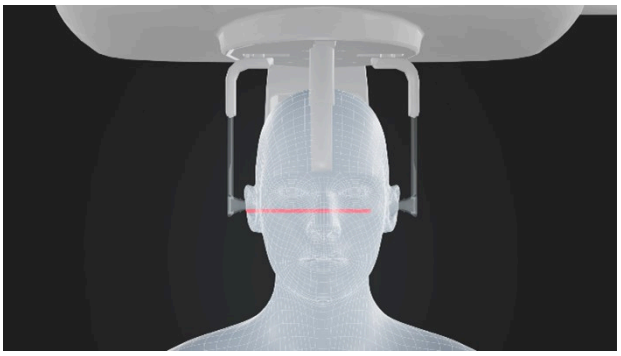
3. Adjust the motorised column height by using the suitable keys (**H**) and (**I**) (see par. CONTROL PANEL ON CEPHALOMETRIC EXAMINATION ARM) until the ear loops reach the height of the patient's external auditory canal.



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.

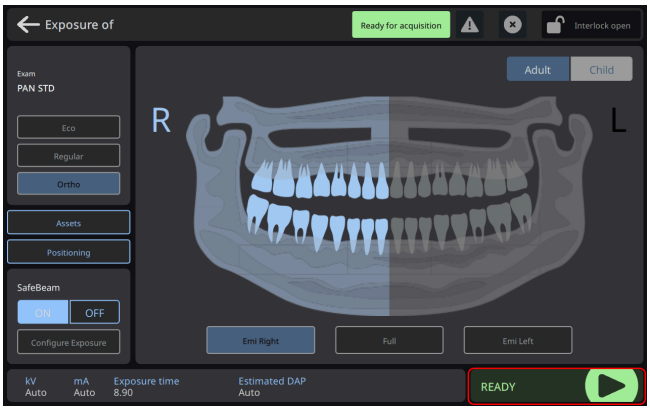


7. Rotate the NASION support downward and adjust its depth and height in order to make it rest on the patient's Nasion point, without pushing it or modifying the previously set position.

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.

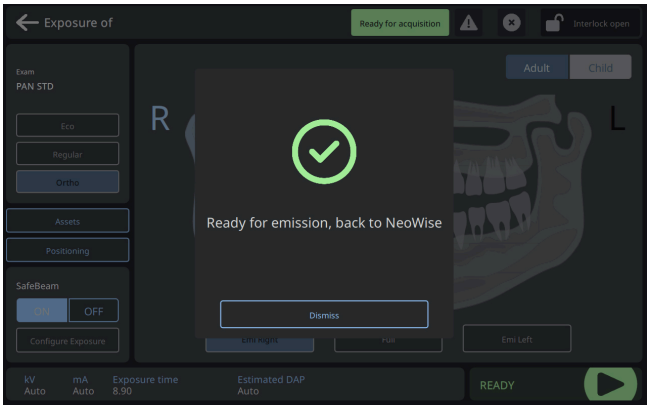
7.4. EXECUTION OF EXAMINATION

Once the patient's positioning is confirmed, touch the READY button on the console physical keyboard.



The window indicating to proceed with the examination using the Neowise software will be displayed

- 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 (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.

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.
For more details on the scanning procedure, please refer to the Neowise User Manual.

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 CONFIRM button.

7.5. DISPLAYING AND SAVING

The X-ray device features the Neowise program for displaying and saving the examinations; if using this software, refer to the Neowise 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 Neowise software is optional in case of 2D examinations (e.g.: panoramic and cephalometric).
The use of Neowise 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, Neowise provides an automatic guide for the creation of a DVD, which includes a redistributable copy of Neowise for displaying images (Neowise 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. 3D TOMOGRAPHIC EXAMINATION (CBCT) EXECUTION

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 Neowise 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 device and PC where the acquisition driver is installed
2. Selection of 3D examination (from Neowise software)
3. Preparation of 3D examination (from the control console or Neowise software)
4. Patient positioning
5. Execution of the 3D examination
6. Image display and processing

8.1. SWITCHING ON THE DEVICE

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.

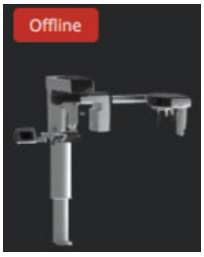
If the X-ray device is in Standby mode, press the Confirmation button (A) to restore its functions.
Once it has correctly started, the LED (F) (see par. CONTROL PANEL ONBOARD THE MACHINE) is blue and steadily on.

8.2. EXAMINATION SELECTION AND PATIENT DATA ENTRY

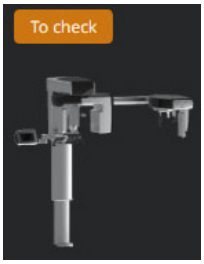
8.2.1. 3D EXAMINATIONS AVAILABLE AND SELECTION

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

1. Turn on the PC and run the Neowise software. The identification image of your device will be displayed. If the device is inactive, the disconnected status icon will be displayed.



2. A Daily Check procedure must be completed, upon the first start-up of the day, before performing any 3D Examination. The request for daily check is indicated by a green icon.

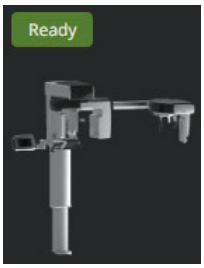


The daily check procedure is a service procedure with X-ray emission and must be performed WITHOUT PATIENT.

Before starting the daily check procedure, remove bite and chin rest.

DO NOT allow the patient to access the X-ray device during the examination selecting procedure, but only at the end of the procedure described in this paragraph.

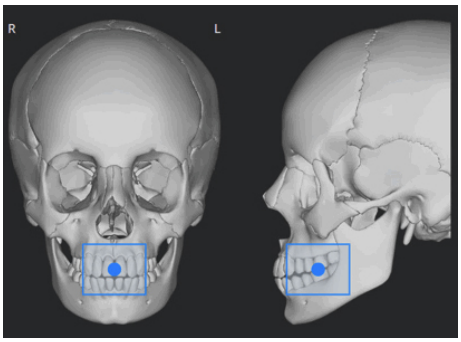
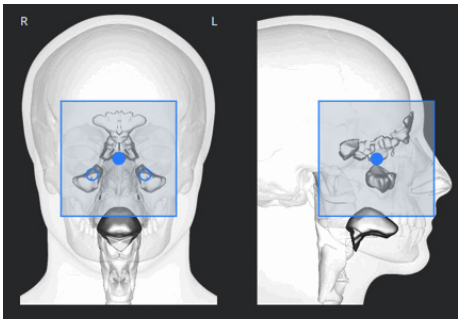
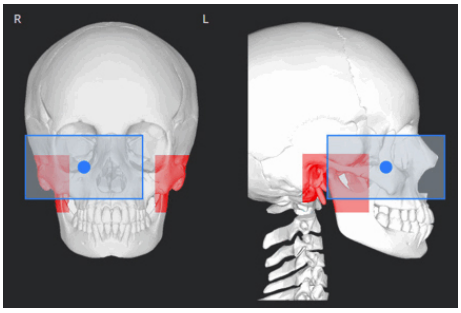
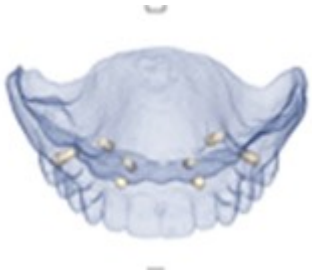
3. At the end of the daily check, the device will become available for examination. The device ready status is indicated by a green icon.



4. Enter the patient data to which the examination will be associated (or in the case of already existing data within the programme, search for the correct patient).

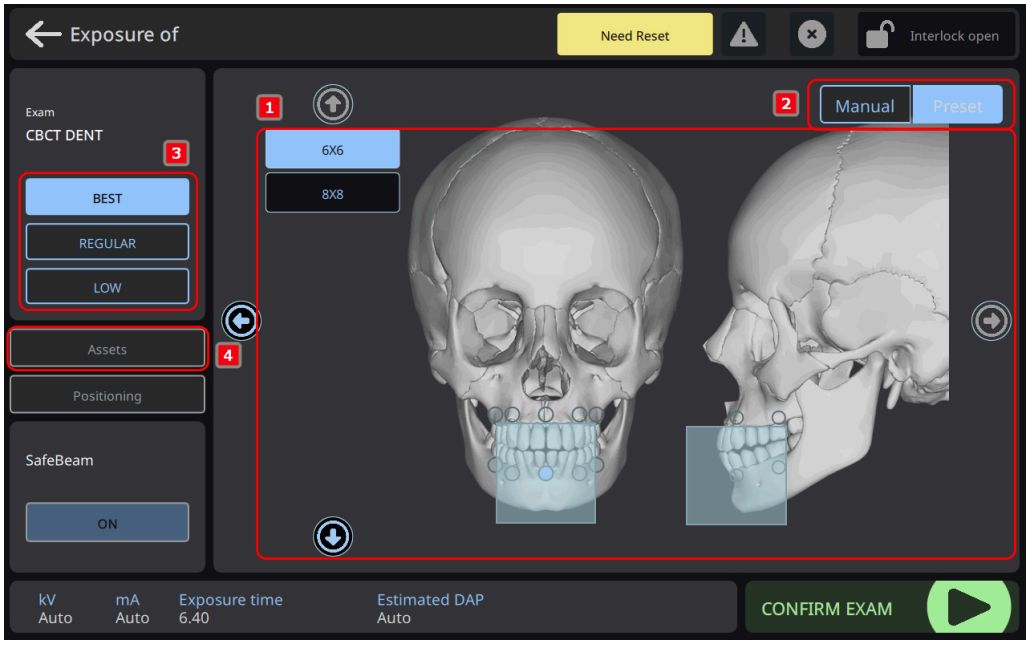
   For more details on patient data records, please refer to the Neowise User Manual.

5. At this point, it will be possible to choose the type of 3D examination to be performed: the examinations foreseen for the "3D" category are:

NAME	DESCRIPTION	PREVIEW
DENT 3D	Examinations on dentition and surrounding bone areas	
SIN 3D	Specific examinations of maxillary sinuses that can be viewed in a field with maximum diameter of 11 cm.	
TMJ 3D	Specific examinations of temporomandibular joints that can be viewed within a maximum width of 15 cm *If the relevant software option is enabled, scanning in eFOV (extra Field of View) mode is available, namely an acquisition mode that uses several adjacent exposures, based on the dimensions of the selected volume. The eFOV scanning is characterised by the letter "e" next to the selected FOV (e.g. [15x11e]).*	
MODEL 3D	Acquisition of dentition models in plaster, silicone, resin or other materials typically used in the dentistry field, or of masks or surgical guides. DO NOT select this type of examination on real patients.	

8.2.2. EXAMINATION SETTINGS

After selecting the desired type of examination, the SETTINGS page will be displayed on the console of the machine.
This screen includes:



1 Choosing ANATOMY:

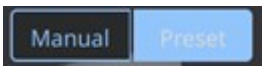
To help the user's choice, example 3D models are displayed, representing the type of examination to be performed.
Depending on the circumstances, a reference anatomical model consistent with the examination field chosen will be displayed. The DENT case is shown on the side.

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

The highlighted box identifies the field of view (FOV) and its position with respect to the anatomical model.

To change the FOV size, touch directly the selection buttons next to the 3D models to enlarge/reduce the diameter and increase/decrease the cylindrical FOV height.

2 Selecting PRESET or MANUAL



Selecting the MANUAL button, 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.

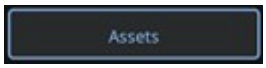
By selecting the PRESET button, a cursor can be placed on preset points

3 DOSE PROFILE selection

Allows selection of the dose profile between:

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

4 EQUIPMENT FOR PREPARATION OF THE EXAMINATION

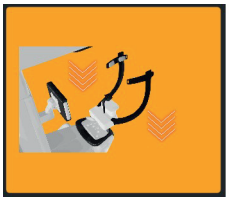


By touching the ASSETS button, the user is informed of the operations to be performed on the device in order to carry out the examination. This control consists of:

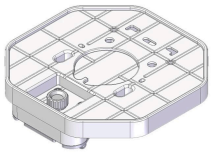
- indicate which devices are required for the patient positioning and how to position them;
- if necessary, be prepared to move removable sensors.

The screen shows the actions necessary to correctly prepare the machine.

The equipment images vary according to the type of examination chosen beforehand.



8.2.3. DEVICES FOR PATIENT POSITIONING

3D EXAMINATION TYPE	MOBILE SUPPORT	IMAGE
DENT 3D	Craniostat, chin rest PAN bite and general bite	
SIN 3D	Under-nose support and craniostat.	
TMJ 3D	Under-nose support and craniostat.	
MODEL 3D	Support for 3D scans of models, impressions, X-ray templates, phantoms for quality checks / consistency tests (optional)	

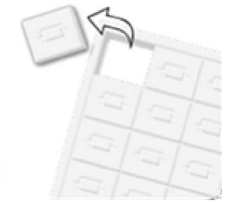
Remember to change the disposable infection control sheaths before positioning a new patient.

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.

8.2.4. DEVICES FOR EDENTULOUS PATIENTS

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

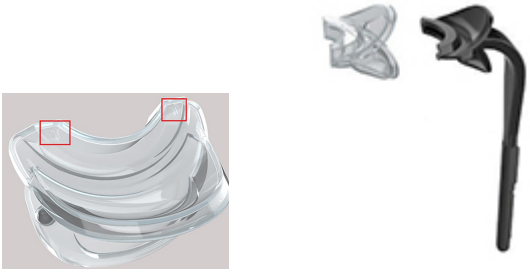
4. push the bite until the block of material is ejected

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

In the case of edentulous patients who require the use of an anatomic bite with autoclavable silicone cover:

1. after performing a sterilisation cycle of the silicone cover, insert the cover in the bite, making it adhere completely

Pay attention to the insertion direction, the arrows must point upwards.



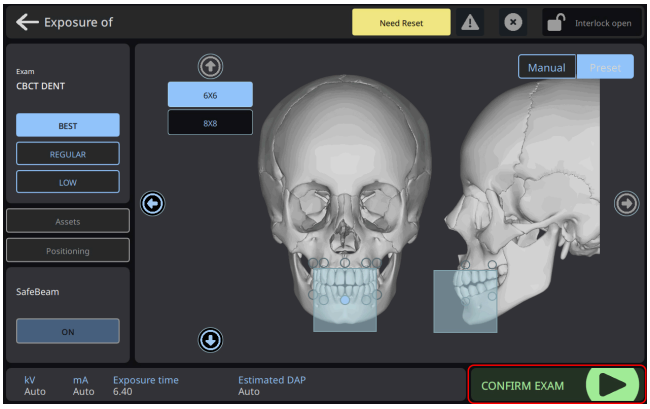
2. apply the disposable infection control sheath on the bite block

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, use disposable infection control sheaths for the parts in contact with the patient. Always insert / replace bite disposable hygienic infection control sheaths before positioning a new patient.

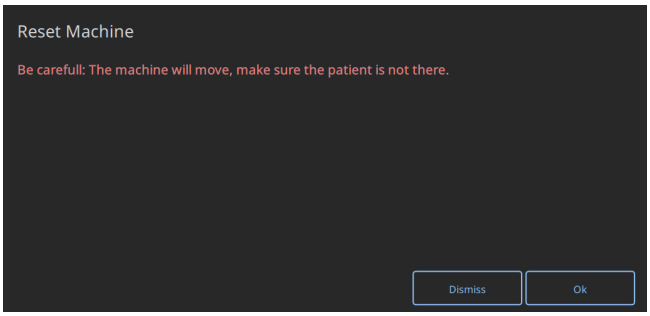
3. Carry out the normal positioning procedure for the examination making the patient press the silicone cover centre with mucous membranes.

8.2.5. EXAMINATION START CONFIRMATION

Once the settings for the examination have been confirmed, touch the CONFIRM EXAM button on the console physical keyboard.



At this point, the machine will require a reset movement and automatically prepare for the PATIENT POSITIONING.

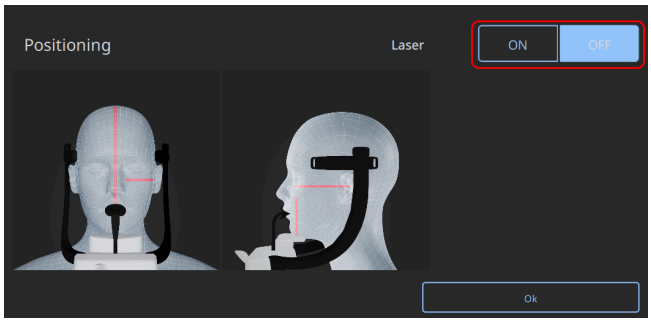


8.3. PATIENT POSITIONING FOR 3D EXAMINATIONS

3D For 3D machines only.

At this point, the POSITIONING button will be enabled on the console. 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 CONFIRM 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 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.

When the patient accesses the machine (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.

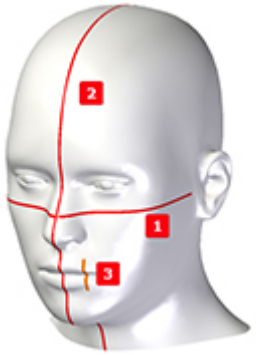
8.3.1. LASER TRACES

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

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

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

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



Upper horizontal trace (1)
It is generated by a laser projector located on the side of the X-ray generator.
The adjustment is carried out using the wheel located on the lower part of the generator and allows identifying the Frankfurt plane[2] on patients of different sizes, ensuring proper patient alignment; moreover, it allows identifying the FOV height most suitable for the acquisition of the clinically relevant region by means of a ruler on the generator and the corresponding marked icons:

6 Ruler position 7 cm Position indicated for 3D DENT examinations of the upper arch in adults (FOV 6x6 up, 8x6 up, 11x6 up) and for 3D TMJ examinations (FOV 15x6, 13x6)

5 Ruler position 5 cm Position indicated for 3D DENT examinations of both arches in adults (FOV 11x11 low, 13x10, 10x10) and for 3D TMJ/ SIN examinations (FOV 15x11, 11x11 low)

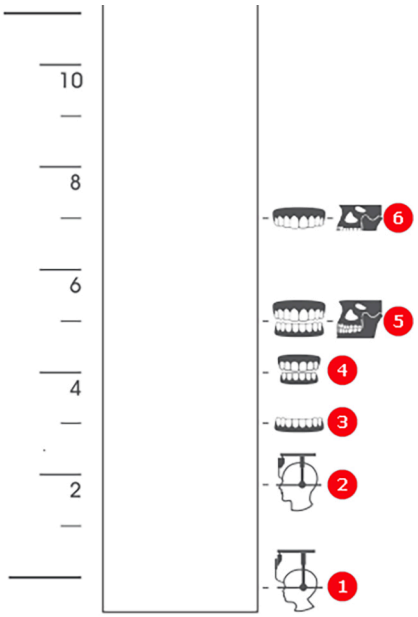
4 Ruler position 4 cm Position indicated for 3D DENT examinations of both arches in children (FOV 8x8 low, 11x8 low)

3 Ruler position 3 cm Position indicated for 3D DENT examinations of the lower arch in adults (FOV 6x6 low, 8x6 low, 11x6 low)

2 Ruler position 2 cm Position indicated for CEPH examinations in adults (short brackets)

1 Ruler position 0 cm Position indicated for CEPH examinations in children (long brackets)

Other:
Ruler position 6 cm
3D DENT FOV 5x4 up



The symbols on the side of the ruler refer to the positioning options available only on devices equipped with a 3D detector and/or a sensor for CEPH examinations.

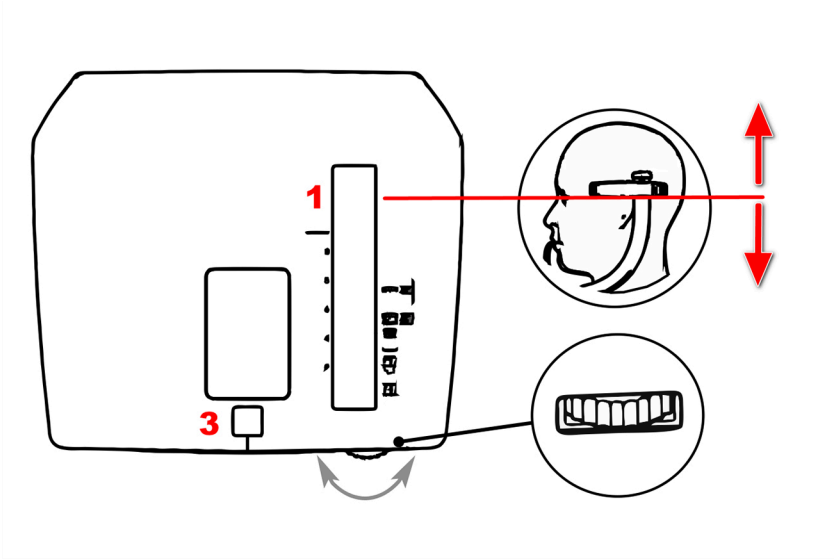
For devices equipped with a 2D sensor, the central line of the ruler (6 cm) indicates the centre of the panel.

Sagittal vertical trace (2)
It is generated by a laser projector located beneath the mirror. 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 is generated by a laser projector located on the side of the X-ray generator. It indicates the focal sulcus position to achieve the optimal focusing.

Each pressure of the CONFIRM 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.

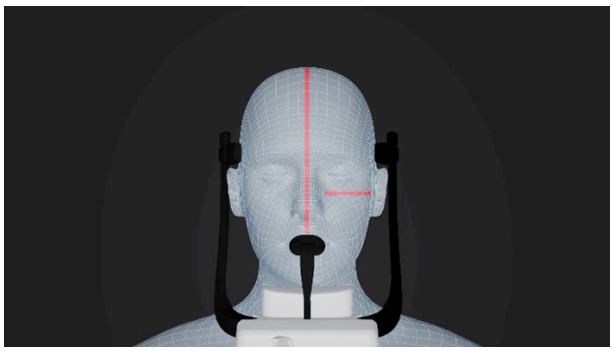
[2] The Frankfurt plane is represented by an imaginary line running from the upper edge of the auditory meatus to the lower edge of the orbit.

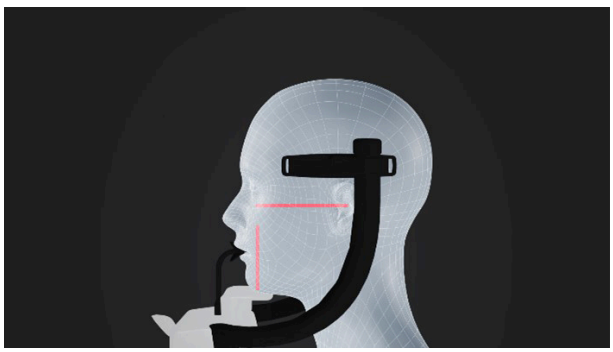

1
3

8.3.2. DENT 3D 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.

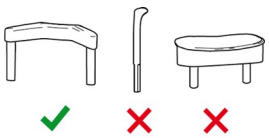
4. Adjust the height of the bite and rotate it inside the mouth, asking the patient to bite it as shown in the figure. The tip of upper and lower incisors must be in the bite groove. The interproximal space of incisors must be in the bite midline.
5. Adjust the patient's head position using, as a guide, the front laser trace that identifies the sagittal plane passing through the centre of the selected FOV.
6. Go to the PC workstation.



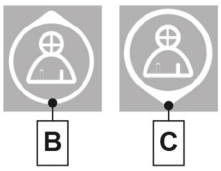


8.3.3. MAXILLARY SINUSES 3D EXAMINATIONS

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



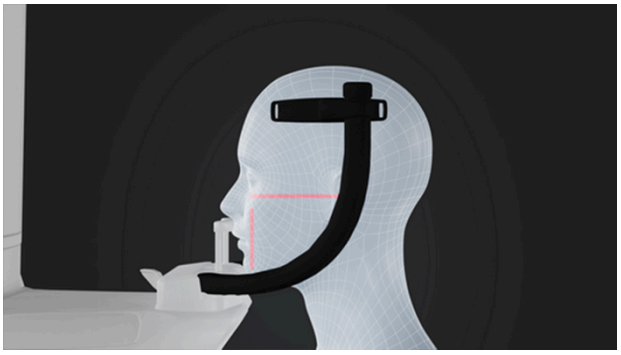
3. The patient must grab the handles with both hands and keep a standing position.

4. In 3D examinations, patient's head is in fixed central position.

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.

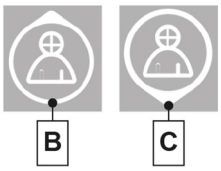
7. Go to the PC workstation.



8.3.4. TMJ 3D EXAMINATIONS

1. Remove the chin rest and the bite, and insert the under-nose support for TMJ 3D. 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.



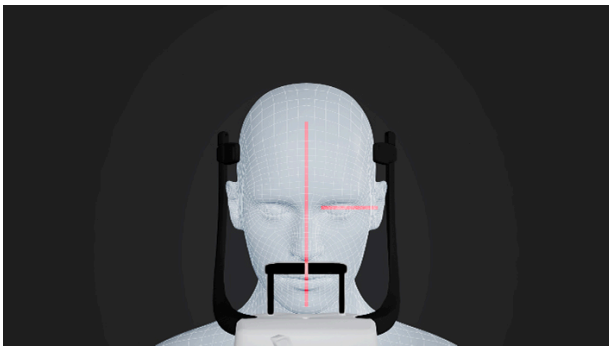
3. The patient must grab the handles with both hands and keep a standing position.

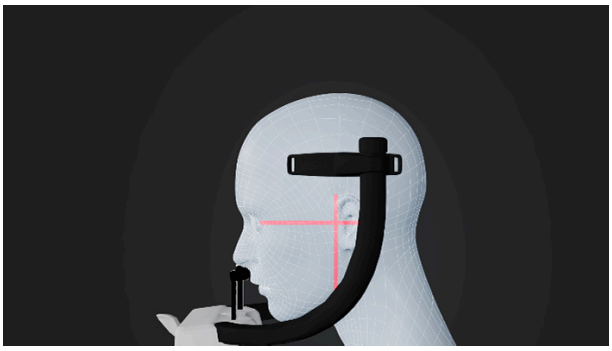
4. In 3D examinations, patient's head is in fixed central position.

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.

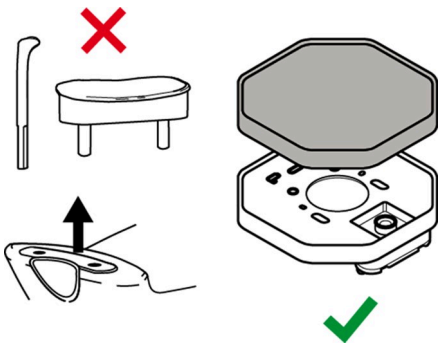
7. Go to the PC workstation.



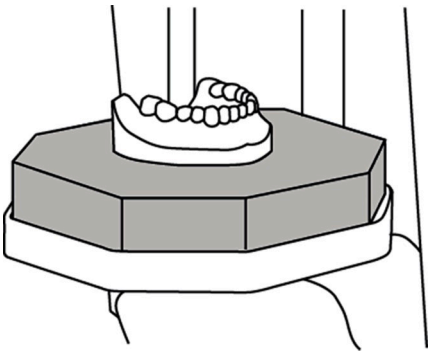


8.3.5. MODEL 3D EXAMINATION

1. Remove the chin rest and the bite, and insert the relevant support.



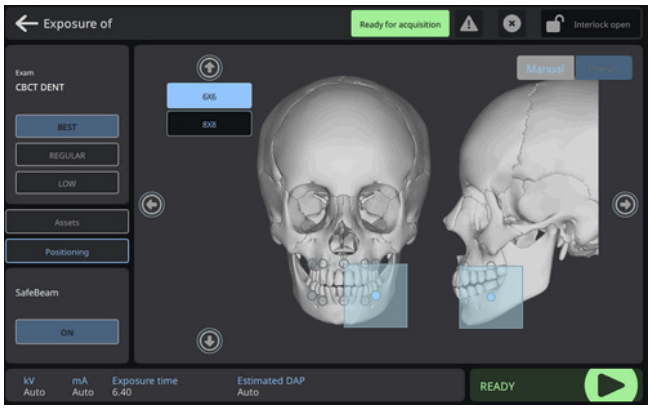
2. Position the model (impression / X-ray template) on the support.



3. Go to the PC workstation.

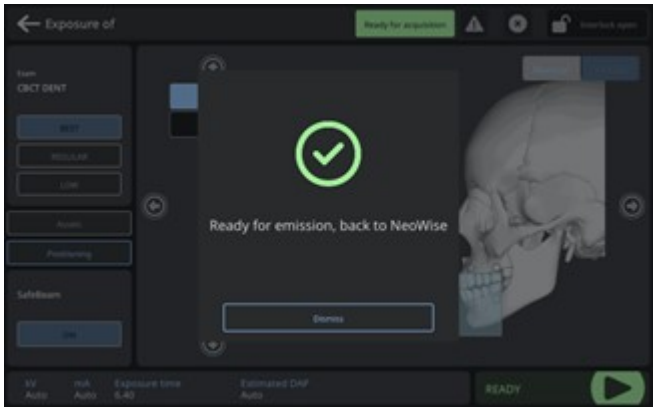
8.4. EXECUTION OF EXAMINATION

Once the patient's positioning is confirmed, touch the READY button on the console physical keyboard.



The window indicating to proceed with the examination using the Neowise software will be displayed:

- 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 (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.

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.

For more details on the scanning procedure, please refer to the Neowise User Manual.

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 CONFIRM button.

8.5. DISPLAYING AND SAVING

The X-ray device features the Neowise program for displaying and saving the examinations; if using this software, refer to the Neowise 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 Neowise 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, Neowise provides an automatic guide for the creation of a DVD, which includes a redistributable copy of Neowise for displaying images (Neowise 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.

9. 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

To properly perform these procedures, consult Neowise “Acquisition operations” manual and the technical manual.

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

9.1. COOLING SYSTEM

If the X-ray generator is equipped with a cooling system, the device performance can be improved, allowing for the following:
- Performing a panoramic exam every ~7 minutes for 8 hours/day (equivalent to 66 panoramic exams / day)* (without cooling system)
- Performing a panoramic exam every ~3.5 minutes for 8 hours/day (equivalent to 146 panoramic exams / day)* (with cooling system)

*The conditions above refer to an ambient temperature of 25°C. The reference exam considered is the Standard Panoramic exam on an average-sized patient with the following exposure parameters: 76 kV, 6 mA.

The tests were conducted during the Pan Standard exam, as it is more energy-consuming, and the data provided above also include 3D examinations.

9.2. TYPICAL 2D IMAGES

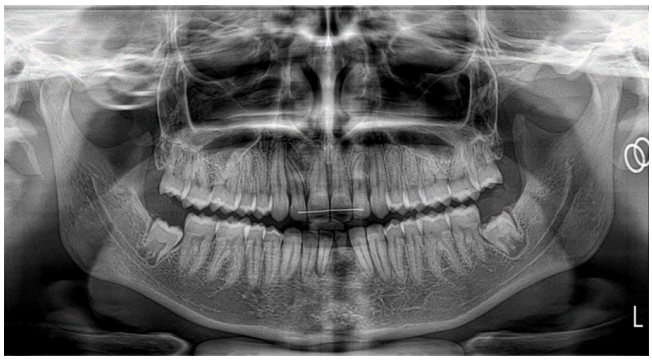
The following images derive from the acquisition on anthropomorphic phantoms and real patients.

9.2.1. ADULT PANORAMIC IMAGING

9.2.1.1. STANDARD PANORAMIC X-RAY

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

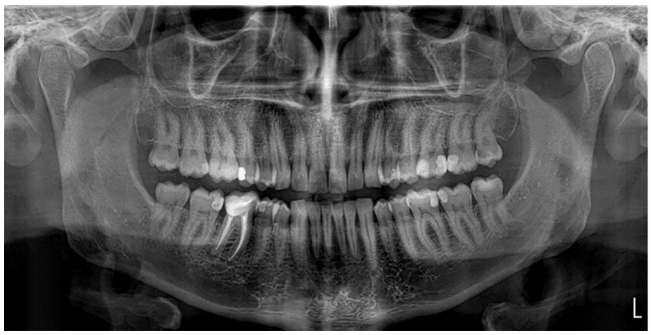
The image on the right shows a typical image with PAN standard exposure.



9.2.1.2. HIGH ORTHOGONALITY PANORAMIC X-RAY

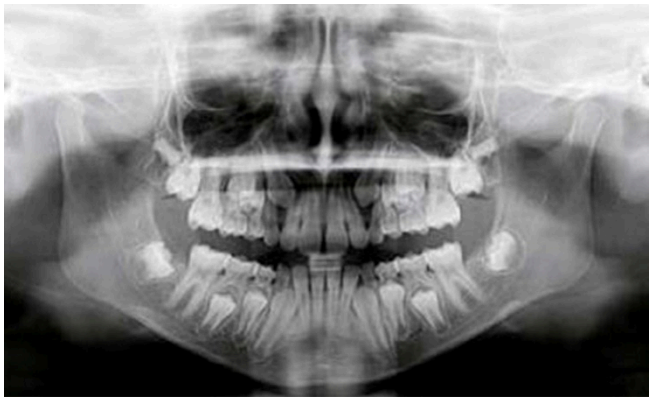
Compared to standard panoramic X-ray, this exposure aims at obtaining a greater orthogonality, minimising the overlapping of adjacent tooth crowns.

It is recommended not to use this projection on patients with metal prostheses or implants in the posterior area or on the mandibular ramus and to pay special attention to the correct patient positioning.



9.2.2. 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.



9.2.3. TMJ EXAMINATION (TEMPOROMANDIBULAR JOINT)

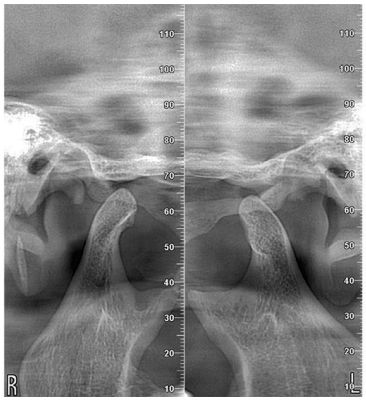
Programs for the X-ray of temporomandibular joints (TMJ) allow a study of the temporomandibular state in the following modes:

9.2.3.1. 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 temporomandibular joints is shown in latero-lateral view.

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

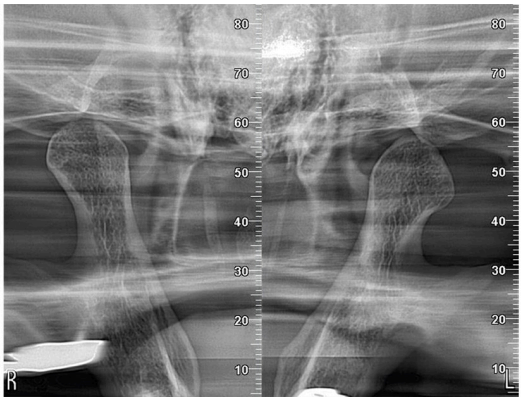


9.2.3.2. FRONT VIEW OF BOTH CONDYLES (2 IMAGES)

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

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

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

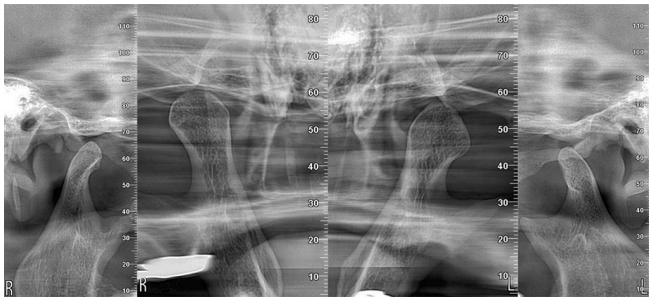


9.2.3.3. COMBINED VIEW OF BOTH CONDYLES (4 IMAGES)

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

The entire structure of temporomandibular 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.

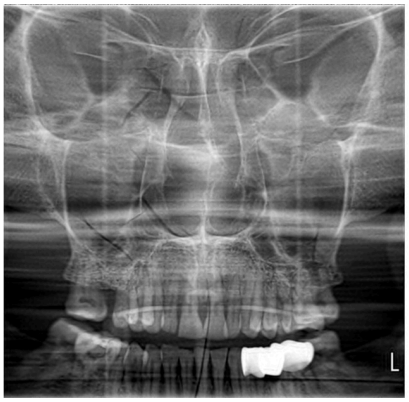


9.2.4. SIN EXAMINATIONS

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.

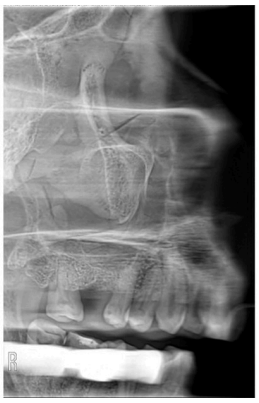
9.2.4.1. FRONT VIEW

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



9.2.4.2. LATERAL VIEW

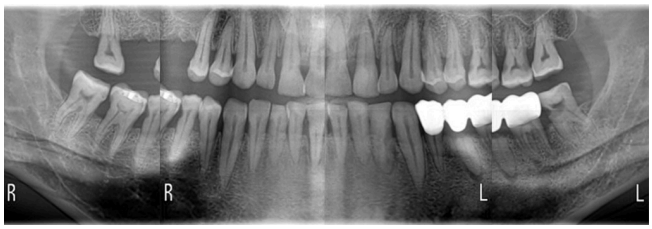
The image on the right shows a typical image with SIN LAT exposure.



9.2.5. 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.

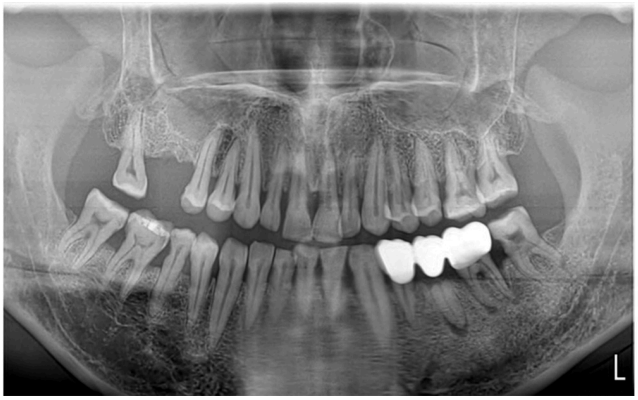
The image on the right shows a typical 4-image BITEWING standard exposure.



9.2.6. 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 PAN standard.

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



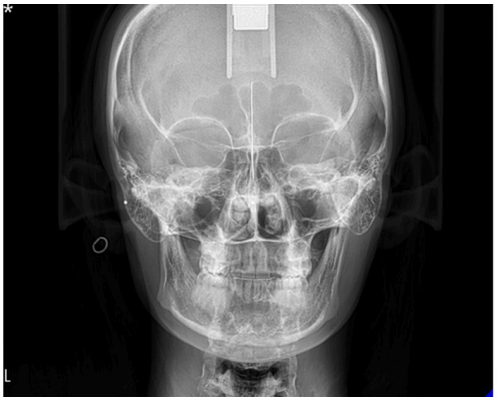
9.2.7. CEPH EXAMINATIONS

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

9.2.7.1. 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.

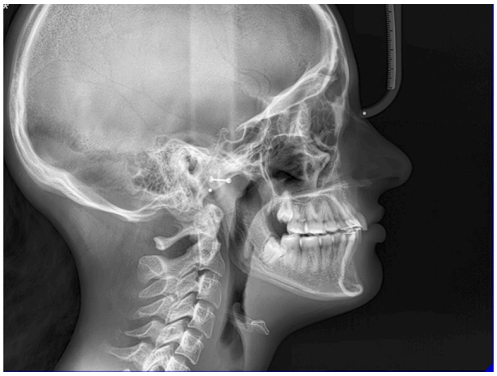


9.2.7.2. CEPH LATERAL

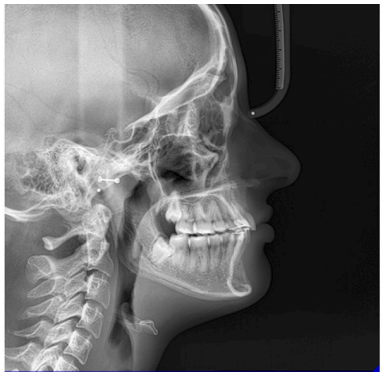
With the programs of Ceph LATERAL exposure, an image of the cranium with a latero-lateral view is produced.

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.

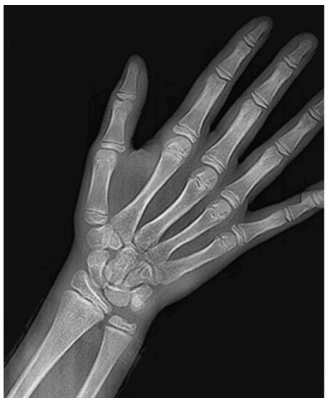


The image on the right shows a typical image with CEPH LATERAL - FULL STANDARD exposure, where only the cranium front part is acquired.



9.2.7.3. CEPH CARPUS

The program of CEPH carpus exposure allows viewing the carpus bones of the left hand, or in any case the hand not usually dominant, typically used to determine the patient's skeletal age.



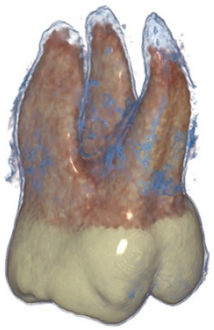
9.3. TYPICAL 3D IMAGES

9.3.1. DENTAL (DENT) 3D EXAMINATIONS - ADULTS and CHILDREN

DENT examinations, with FOV protocols available from 6x6 to 11x11 in Low Dose/Quick, Regular of Best Quality/High Res mode, allow obtaining sectoral tomographic images of partial or complete dentition, of single maxillary or mandibular arches or both, also including the low maxillary sinus floor.

9.3.1.1. DENTAL (DENT) 3D EXAMINATIONS - SINGLE TOOTH, SINGLE IMPLANT SITE

6x6 and 5x4 typical FOVs available for studying root and coronal morphology, dysmorphism, lesions or fractures, for upper and lower arch teeth respectively, reducing exposure to only the area of interest, with resolution suitable for endodontic investigations.

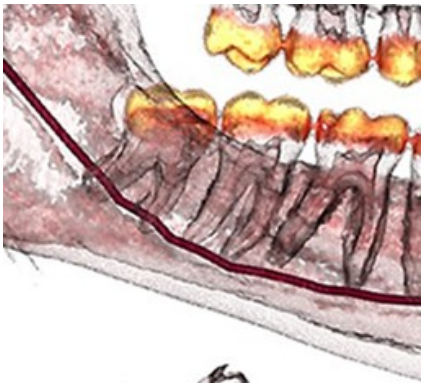


Main available programs:

DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Position of teeth, impacted teeth, supernumerary teeth, granulomas, cavities	6x6 (quadrant 1 and 2) 6x6 (quadrant 3 and 4)	Quick/Low dose	6x6 (quadrant 1 and 2) 6x6 (quadrant 3 and 4)	Quick/Low dose
Implants or edentulous sites (bone or nearby structures, positioning and osseointegration follow-up, bone regeneration status, extraction)	6x6 (quadrant 1 and 2) 6x6 (quadrant 3 and 4)	Quick/Low dose	6x6 (quadrant 1 and 2) 6x6 (quadrant 3 and 4)	Quick/Low dose
Third molars, tooth resorption, impacted tooth	6x6 (quadrant 3 and 4)	Regular/Best	6x6 (quadrant 3 and 4)	Regular/Best
Endo (apical lesions, root canals, fractures), periodontal structures, mandibular canal	6x6 (quadrant 1 and 2) 6x6 (quadrant 3 and 4) 5x4 (quadrant 1 and 2) 5x4 (quadrant 3 and 4)	Best	6x6 (quadrant 1 and 2) 6x6 (quadrant 3 and 4) 5x4 (quadrant 1 and 2) 5x4 (quadrant 3 and 4)	Best

9.3.1.2. DENTAL (DENT) 3D EXAMINATIONS - DENTITION

Typical FOV: 8x6 (upper arch) and 8x6 (lower arch) for post-surgical evaluation, position, shape, cyst size, position of impacted teeth, supernumerary teeth and nearby structures such as mandibular canal and nearby teeth. 6X6 FOVs are also available to allow further reducing the exposure of the concerned area by lowering the dose.

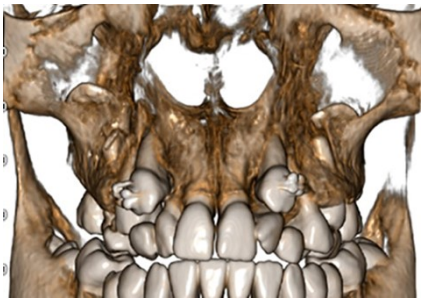


Main available programs:

DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Position of teeth, impacted teeth, supernumerary teeth, granulomas, cavities	6x6 (quadrant 1 and 2) 6x6 (quadrant 3 and 4) 8x6 (quadrant 1 and 2 hemiarch) 8x6 (quadrant 3 and 4 hemiarch)	Quick/Low dose	6x6 (quadrant 1 and 2 hemiarch) 6x6 (quadrant 3 and 4 hemiarch)	Quick/Low dose
Implants or edentulous sites (bone or nearby structures, positioning and osseointegration follow-up, bone regeneration status, extraction, sinus lift)		Quick/Low dose		Quick/Low dose
Roots/canal ratio		Regular/Best		Regular
Endo (apical lesions, root canals, fractures), periodontal structures, mandibular canal		Best		Best

9.3.1.3. DENTAL (DENT) 3D EXAMINATIONS - SINGLE DENTAL ARCH

Typical FOV: 11x6 (upper jaw) and 11x6 (lower jaw) for post-surgical evaluation, position, shape, cyst size, position of impacted teeth, supernumerary teeth and nearby structures such as mandibular canal and nearby teeth. Additional 8x6 (upper jaw) and 8x6 (lower jaw) FOVs are also available to reduce the dose in case of small patients.

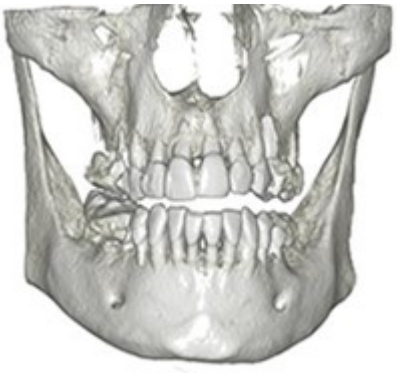


Main available programs:

<table>
<tr><th rowspan="2">DIAGNOSTIC NEED</th><th colspan="2">ADULT</th><th colspan="2">CHILD</th></tr>
<tr><th>FOV</th><th>PROTOCOL</th><th>FOV</th><th>PROTOCOL</th></tr>
<tr><td>Position of teeth, impacted teeth, supernumerary teeth, granulomas, cavities</td><td rowspan="4">11x6 (upper jaw)
11x6 (lower jaw)</td><td>Quick/Low dose</td><td rowspan="4">8x6 (upper jaw)
8x6 (lower jaw)</td><td>Quick/Low dose</td></tr>
<tr><td>Implants or edentulous sites, generation of surgical guides (complete bone and nearby structures, positioning and osseointegration follow-up, bone regeneration, sinus lift)</td><td>Regular/ Best in lower jaw</td><td>Regular/ Best in lower jaw</td></tr>
<tr><td>Roots/canal ratio</td><td rowspan="2">Best</td><td rowspan="2">Best</td></tr>
<tr><td>Endo (apical lesions, root canals, fractures), periodontal structures, mandibular canal</td></tr>
</table>

9.3.1.4. DENTAL (DENT) 3D EXAMINATIONS - DENTITION (2 ARCHES) AND MAXILLARY SINUSES

Typical FOV: 10x10 or 11x11 or 11x8 and reduced 8x8 for patients with smaller head size, for post-surgical evaluation, position, shape, cyst size, position of impacted teeth, supernumerary teeth and nearby structures such as mandibular canal and nearby teeth, for implant planning.

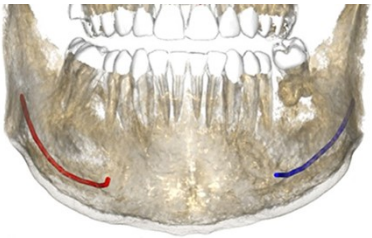


Main available programs:

DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Position of teeth, impacted teeth, supernumerary teeth, granulomas, cavities	10x10-11x11-11x8 (including maxillary sinuses or their lower portion)	Quick/Low dose	8x8-11x8	Quick/Low dose
Implants or edentulous site (complete bone and nearby structures, positioning and osseointegration follow-up, bone regeneration, sinus lift)		Regular		Regular
Roots/canal ratio		Regular/ Best		Regular
Endo (apical lesions, root canals, fractures), periodontal structures, mandibular canal		Best		Best

9.3.1.5. DENTAL (DENT) 3D EXAMINATIONS - LOWER JAW ASCENDING BRANCHES

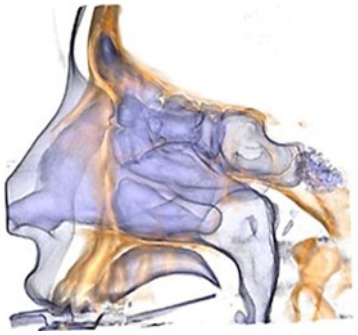
Typical FOV: 11x6 for post-surgical verification, position of impacted teeth and relationship with nearby structures such as mandibular canal and nearby teeth, for implant planning, with the additional 8x6 FOV, which allows further reduction of exposure to the area of interest only for patients with small head sizes.



DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Third molars, implant planning or follow-up	11x6	Quick/Low dose Regular Best	8x6 11x6	Quick/Low dose Regular Best

9.3.1.6. DENTAL (DENT) 3D EXAMINATIONS - DENTITION (UPPER JAW) AND MAXILLARY SINUSES

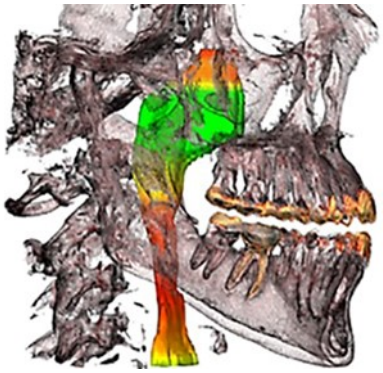
10x10 or 11x11 typical FOV, together with the additional 8x6 FOV, which allows reducing the dose for analysis of the upper respiratory tract or lower portion of maxillary sinuses (throat, nose, sinuses) together with the upper arch.



DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Analysis of upper respiratory tract (throat, nose, sinuses)	10x10 11x8 11x11	Regular	8x8-11x8 (upper jaw+sinuses low. portion)	Regular

9.3.1.7. DENTAL (DENT) 3D EXAMINATIONS - DENTAL ARCHES + ANALYSIS OF UPPER RESPIRATORY TRACT (THROAT, NOSE, SINUSES)

The 10x10 or 11x11 typical FOV allows acquiring both dental arches, together with the upper respiratory tract (nose, throat, sinuses), depending on the size of the patient's head. The 8x8 FOV is also available to limit the relevant exposed region in case of children or patients of small body size, together with Low Dose/Eco, Regular or Best Quality/High Res acquisition protocols for dose optimisation.



DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Dental arches + analysis of upper respiratory tract (nose-throat-sinuses)	10x10-11x11	Quick/Regular	10x10-11x11	Quick/Regular

9.3.2. SINUSES (SIN) 3D EXAMINATIONS - ADULTS and CHILDREN

SIN examinations, with 10x10 or 11x11 FOV protocol available in Low Dose/Eco, Regular of Best Quality/High Res mode, allow obtaining tomographic images of the maxillary sinuses region, also including nose and cheekbones, or of the paranasal sinuses area, according to the patient's build.

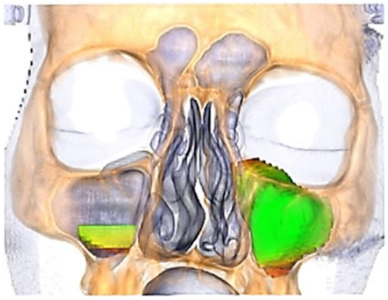
9.3.2.1. NOSE, CHEEKBONES AND MAXILLARY SINUSES

10x10 or 11x11 typical FOV for the evaluation of morphology, anomalies and diseases such as sinusitis, tumours, obstructions, genetic malformations, middle meatus opening.

DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Sinusitis, tumours, pathological obstructions, genetic malformations, middle meatus	10x10-11x11	Regular/Best	10x10-11x11	Regular

9.3.2.2. PARANASAL SINUSES

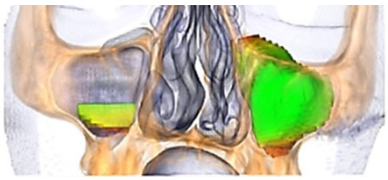
10x10 or 11x11 typical FOV for the evaluation of anomalies and diseases such as sinusitis, tumours, pathological obstructions, genetic malformations, middle meatus opening.



DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Sinusitis, tumours, pathological obstructions, genetic malformations, middle meatus	10x10-11x11 11x8	Quick-Low dose/Regular	8x8-10x10 11x8-11x11	Quick-Low dose/Regular

9.3.2.3. CHEEKBONES AND MAXILLARY SINUSES

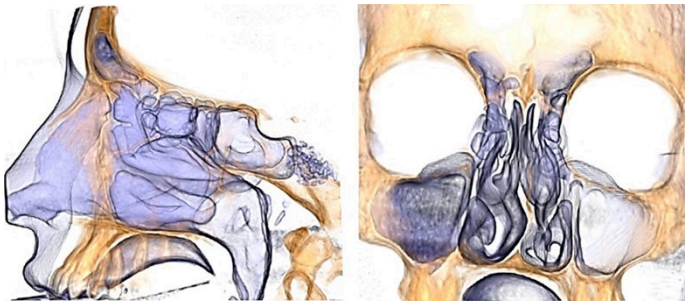
10x10 or 11x11 typical FOV for the evaluation of anomalies and diseases such as sinusitis, tumours, pathological obstructions, genetic malformations, middle meatus opening.



DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Screening/implants	10x10-11x11 11x8	Regular	8x8-10x10 11x8-11x11	Quick

9.3.2.4. MAXILLARY SINUSES

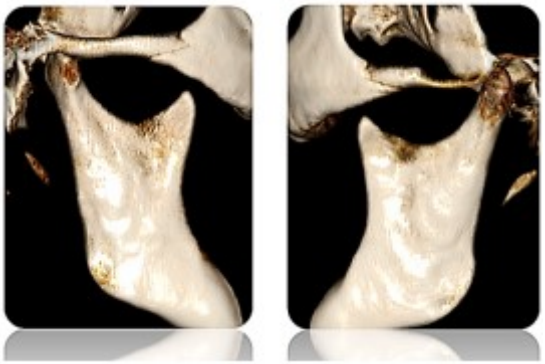
10x10 and 11x11 typical FOV for general screening and sinus lift study.



DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Maxillary sinuses (general screening, sinus lift)	8x8-10x10 11x8-11x11	Quick/Regular	8x8-10x10 11x8-11x11	Quick

9.3.3. TEMPOROMANDIBULAR JOINT (TMJ) 3D EXAMINATIONS - ADULTS and CHILDREN

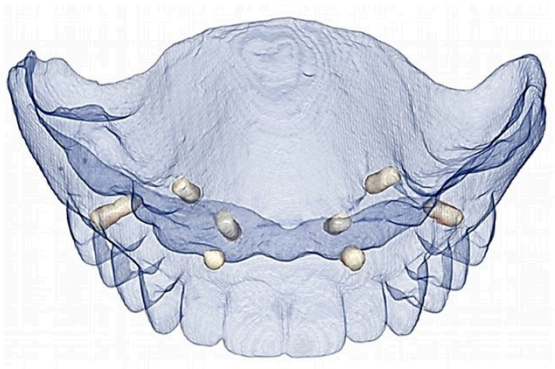
Typical FOV are 15x6 and 15x11 (13x6 or 13x10, children) and allow viewing, respectively, both condyles, the single condyle together with the fossa and temporomandibular joint including the sinus



DIAGNOSTIC NEED	ADULT		CHILD	
	FOV	PROTOCOL	FOV	PROTOCOL
Double TMJ with no ascending branches	15X6	Regular	13X6	Quick/Regular
Double TMJ with ascending branches	15X11	Regular	13X10	Quick/Regular
Single TMJ with no ascending branches	11x6	Regular	11x6	Quick/Regular
Single TMJ with ascending branches	11x11	Regular	10x10	Quick/Regular

9.3.4. MODEL (MODEL) 3D EXAMINATIONS

8x8 and 10x10 or 11x11 typical FOVs allow the 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.



DIAGNOSTIC NEED	FOV	PROTOCOL
Acquisition of dentition models in plaster, silicone, resin, X-ray guides.	8x8-10x10 11x6-11x8-11x11	Regular
Impression taking acquisition.		Best

9.4. QUALITY CONTROL

The quality control consists in the execution of the standard examination on a suitable quality check phantom, through an automatic procedure.

This control, that is recommended at least once a week, ensures the correct operation of the device and the validity of the obtained results.

The steps to follow to properly perform an X-ray examination are:

1 Switching on of device and PC where the acquisition driver is installed
2 CHECK → CONSTANCY CHECK menu selection (from Neowise software)
3 Preparation of the X-ray examination
4 Insertion of the quality check support
5 Positioning of the quality check phantom
6 Execution of the X-ray examination
7 Report display and processing

For more details on the test procedure, please refer to the Neowise User Manual.

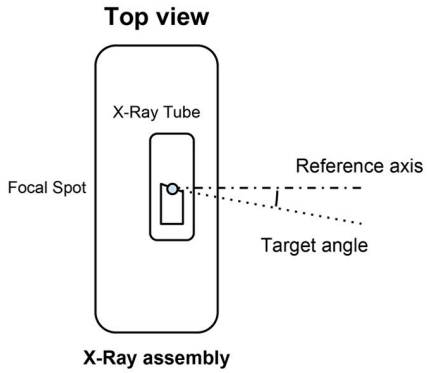
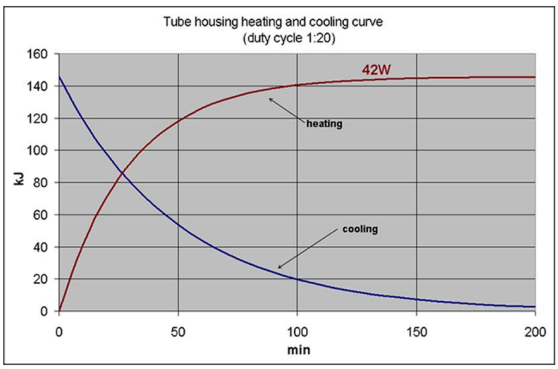
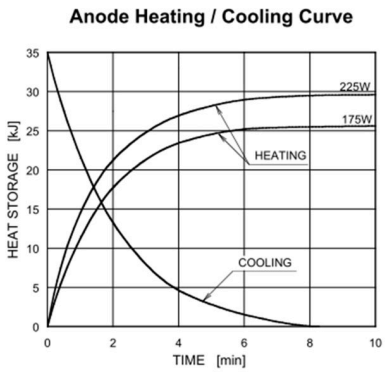
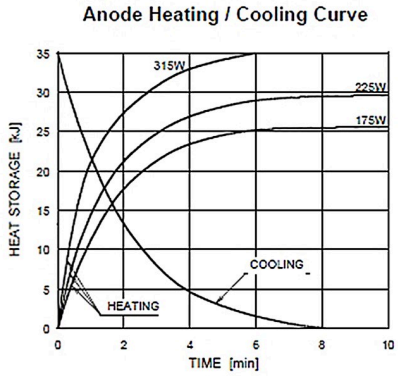
10. DATA SPECIFICATIONS

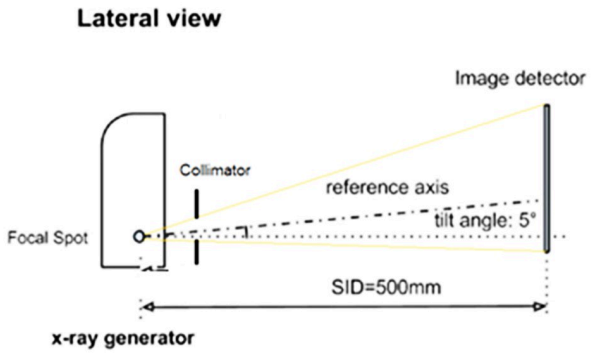
10.1. ELECTRICAL FEATURES

Input voltage	Single-phase 115 – 240 VAC 115 – 180 VAC (Fuse F20A) 180 – 240 VAC (Fuse F12A)
Power supply frequency	50 / 60 Hz
Current absorbed in rest conditions	2A @ 115V; 1A @ 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
Type of installation and use	Permanently installed
Connection to power supply	Permanently installed
Classification in terms of protection means	Class I
Applied part	Type B
Protection against liquid and dust entry	IPX0
Type of operation	Discontinuous, intermittent load

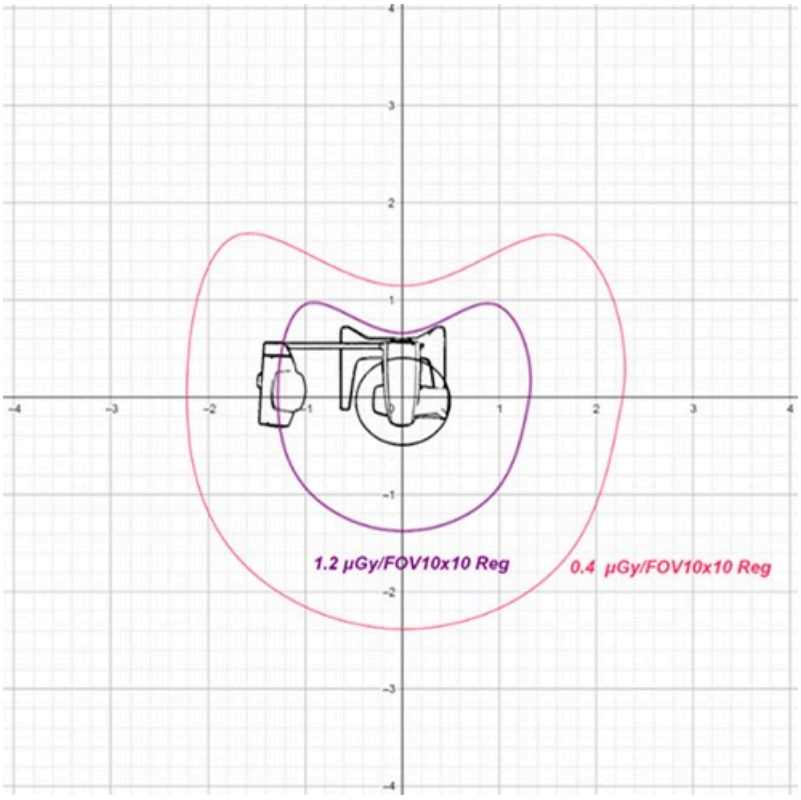
10.2. RADIOLOGICAL FEATURES

Type of generator	Constant potential (DC)
Generator voltage	60 – 90 Kv
Ripple on generator voltage	≤ 5 %
Anode current	2D: 4 - 15 mA 2D/3D: 2 - 16 mA
Maximum continuous input anode power	42 W
Leakage Technique Factor (LTF)	90kV; 0.47mA
Maximum peak input anode power	2D: 1080 W @ 72 kV - 15 mA 2D/3D: 1260 W @ 84 kV - 15 mA
Exposure time	2D mode: 1 - 15 s 3D mode (only 2D/3D models): 1 - 40
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 2D/3D machine only:* CANON / TOSHIBA D-067SB
Focal spot size	2D: 0.5 mm (IEC 60336) with CANON / TOSHIBA D-054SB 2D/3D: 0.6 mm (IEC 60336) with CANON / TOSHIBA D-067SB
Anode material	Tungsten (W)

Anode inclination	2D: 5° with CANON / TOSHIBA D-054SB 2D/3D: 12° with CANON / TOSHIBA D-067SB 
Anode thermal capacity	35 kJ = 49 kHU (CANON / TOSHIBA D-054SB - CANON / TOSHIBA D-067SB)
Anode cooling rate	35kJ / 8 min
Anode cooling mean	Oil
Temperature curves of cylinder block	
Anode thermal curves	2D: CANON / TOSHIBA D-054SB  2D/3D: CANON / TOSHIBA D-067SB 

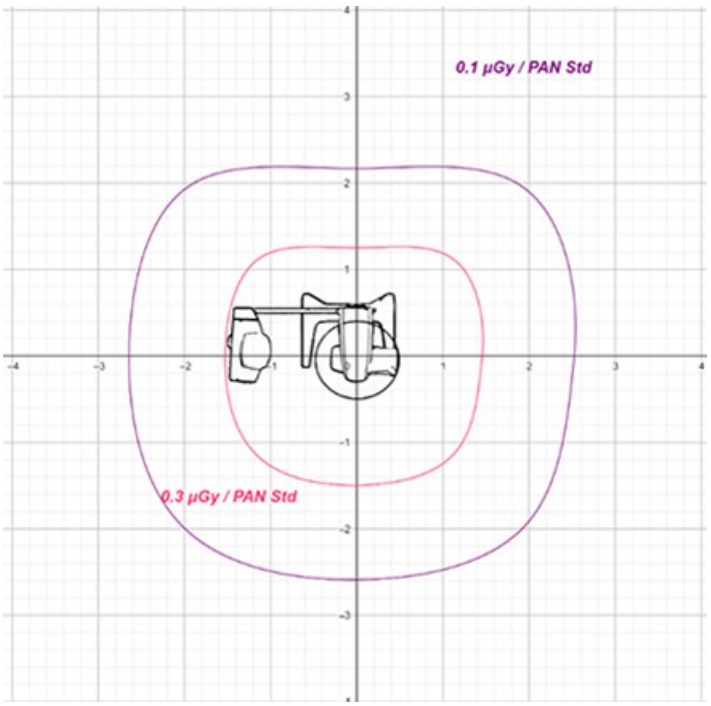
Inherent filtration (including supplementary filtration) / Total filtration	2D: >2.5 mm Al @ 90kV 2D/3D, 2D Examinations: >2.5 mm Al @ 90kV 2D/3D, 3D Examinations: >6 mm Al @ 90 kV (with additional automatic 5 mm Al filter)
Stray radiation	<0.88mGy / h at 1 metre from the focal spot at 90KV in conditions of maximum continuous input anode power equal to 42 W (in compliance with 21CFR and IEC)
Source distance - primary collimator	2D: 100 mm 2D/3D: 110 mm
Source - detector distance (SID)	2D PAN: 500 mm ± 5 mm 2D CEPH: 1610 mm ± 5 mm 3D CBCT: 500 mm ± 5 mm
Generator reference axis:	

10.3. ISODOSE CURVES FOR CBCT EXAMINATIONS

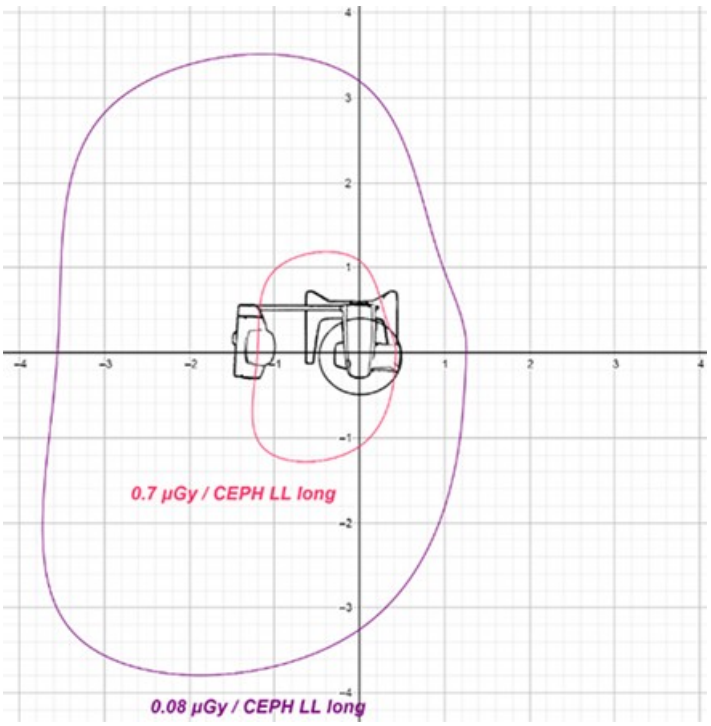


10.4. ISODOSE CURVES FOR PAN AND CEPH EXAMINATIONS

PAN



CEPH



10.5. CBCT DETECTOR FEATURES

Some technical features of the sensor may vary depending on the technology implemented and/or reference market; to know the detailed features of the sensor installed on your device, please refer to the Annex "Dose declarations and acceptance tests" or contact your local distributor if necessary.

Actual sensitive area dimensions	CBCT: 162 x 162 mm	CBCT: 161.3 x 161.3 mm	CBCT: 169.7 x 169.7 mm	CBCT: 159.544 x 159.544 mm
Pixel size	127 µm2	105 µm2	110.5 µm2	98 µm2
Sensor technology	Amorphous silicon	IGZO TFT		
Scintillator material & type	Direct Deposition CsI			
MTF (Modulation Transfer Function)	57% @ 1 lp/mm (1x1)	58% @ 1 lp/mm (1x1)	58% @ 1 lp/mm (1x1)	65% @ 1 lp/mm (1x1)
DQE (Detective Quantum Efficiency)	70% @ 0 lp/mm (1x1)	78% @ 0 lp/mm (1x1)	65% @ 0 lp/mm (1x1)	65% @ 0 lp/mm (1x1)
Sensor matrix dimensions	1280 x 1280 pixels	1536x1536 pixel (1x1) 768x768 pixel (2x2)	1532x1532 pixel (1x1) 766x766 pixel (2x2)	1628x1628 pixel (1x1) 814x814 pixel (2x2)
Gray level	16 bit	14 bit		
Connection	Gigabit Ethernet			

10.6. 2D DEDICATED PANORAMIC SENSOR FEATURES (PAN)

Some technical features of the sensor may vary depending on the technology implemented and/or reference market; to know the detailed features of the sensor installed on your device, please refer to the Annex "Dose declarations and acceptance tests" or contact your local distributor if necessary.

Active area dimensions	6 x 151.2 mm	6.7 x 152 mm	7.2 x 153.6 mm	6.2 x 149 mm
Actual sensitive area dimensions	6 x 148 mm	6 x 148 mm	6 x 148 mm	6.2 x 149 mm
Pixel size	100 µm2	99 µm2	100 µm2	97 µm2
Sensor technology	CMOS	CMOS	IGZO TFT	CMOS
Scintillator material & type	Direct Deposition CsI	Direct Deposition CsI	Direct Deposition CsI	High sensitivity CsI
MTF	58% @ 1 lp/mm (1x1)	60% @ 1 lp/mm (1x1)	63% @ 1 lp/mm (1x1)	57% @ 1 lp/mm (1x1)
DQE	65% @ 0 lp/mm (1x1)	70% @ 0 lp/mm (1x1)	77% @ 0 lp/mm (1x1)	70% @ 0 lp/mm (1x1)
Gray level	14 bit			
Connection	Gigabit Ethernet			

10.7. CEPHALOMETRIC EXAMINATION SENSOR FEATURES (CEPH)

Some technical features of the sensor may vary depending on the technology implemented and/or reference market; to know the detailed features of the sensor installed on your device, please refer to the Annex "Dose declarations and acceptance tests" or contact your local distributor if necessary.

Active area dimensions	6 x 223 mm	6.7 x 228 mm	7.2 x 230.4 mm	6.2 x 223 mm
Actual sensitive area dimensions	6 x 223 mm	6 x 223 mm	6 x 223 mm	6.2 x 223 mm
Pixel size	100 µm2	99 µm2	100 µm2	97 µm2
Sensor technology	CMOS	CMOS	IGZO TFT	CMOS
Scintillator material & type	Direct Deposition CsI	Direct Deposition CsI	Direct Deposition CsI	High sensitivity CsI
MTF	58% @ 1 lp/mm (1x1)	60% @ 1 lp/mm (1x1)	63% @ 1 lp/mm (1x1)	57% @ 1 lp/mm (1x1)
DQE	65% @ 0 lp/mm (1x1)	70% @ 0 lp/mm (1x1)	77% @ 0 lp/mm (1x1)	70% @ 0 lp/mm (1x1)
Gray level	14 bit			
Connection	Gigabit Ethernet			

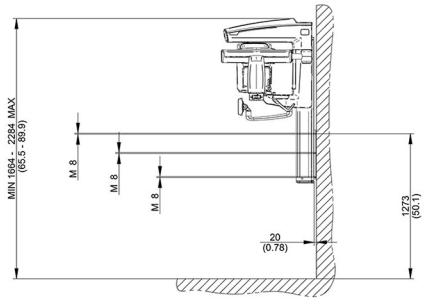
10.8. LASER FEATURES

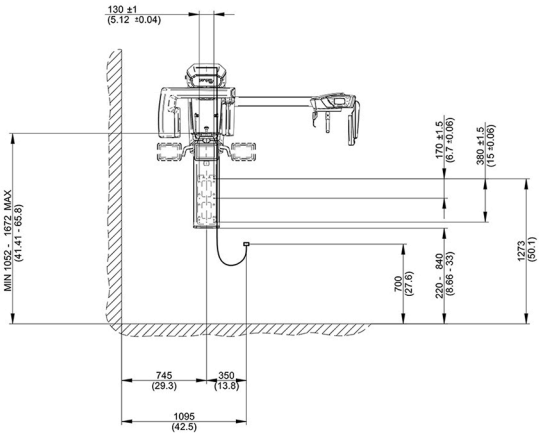
Classification	Class 1 according to IEC 60825-1:2014
Laser power	Max 3mW (without optics)
Diffractive optics	Aspheric lens; linear shape; 58° opening
Wave length	635-650 nm
Activation mode	Timed
Warning plate	

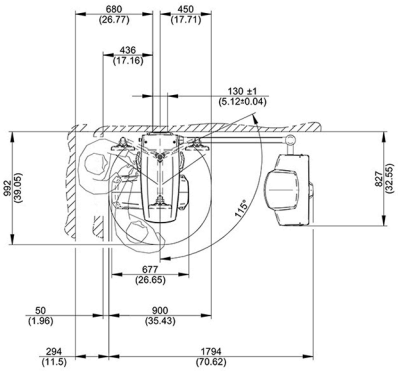
10.9. DIMENSIONAL FEATURES

Weight	3D basic machine: 56 Kg 2D basic machine: 51 Kg Telescopic column (floor version): 43 Kg Telescopic column (suspended version): 34 Kg Cephalometric examination arm with PAN/CEPH sensor: 21 Kg Standard stand (version for machine with cephalometric examination arm): 26 Kg Standard stand (version for machine without cephalometric examination arm): 20.5 Kg
Maximum overall dimensions in diagram	Floor version, without cephalometric examination arm: 1030 x 872 mm Floor version, with cephalometric examination arm: 1030 x 1785 mm Suspended version, without cephalometric examination arm: 983 x 872 mm Suspended version, with cephalometric examination arm: 983 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 and suspended version): 1860 x 355 x 350 mm Cephalometric examination arm with PAN/CEPH sensor: 1275 x 575 x 380 mm

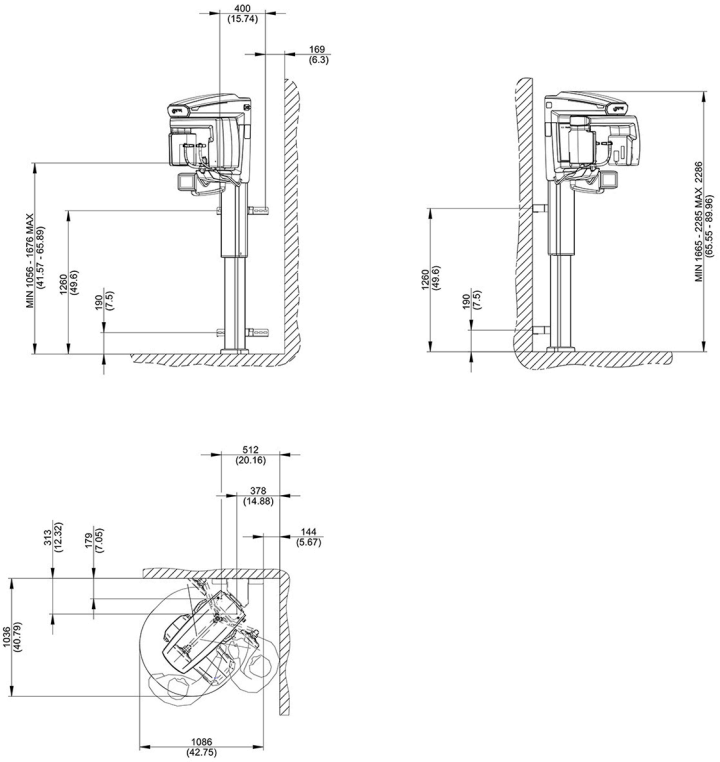
Suspended version with cephalometric examination arm



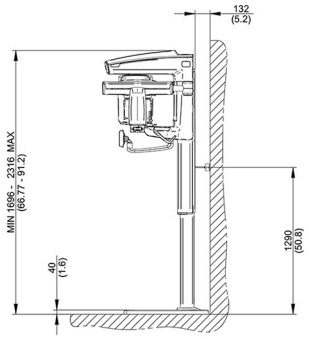


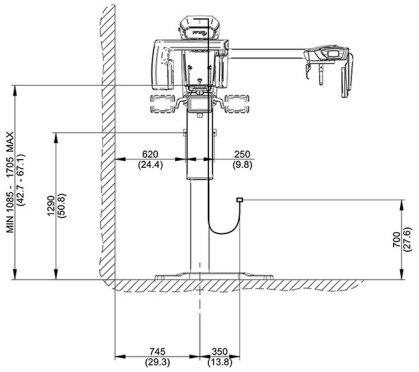


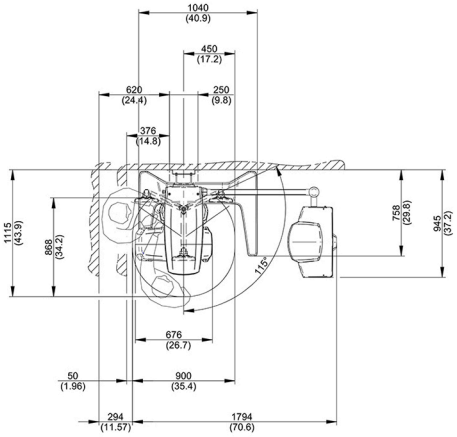
Floor version (without stand) with cephalometric examination arm



Floor version (with stand) and cephalometric examination arm







10.10. ENVIRONMENTAL CHARACTERISTICS

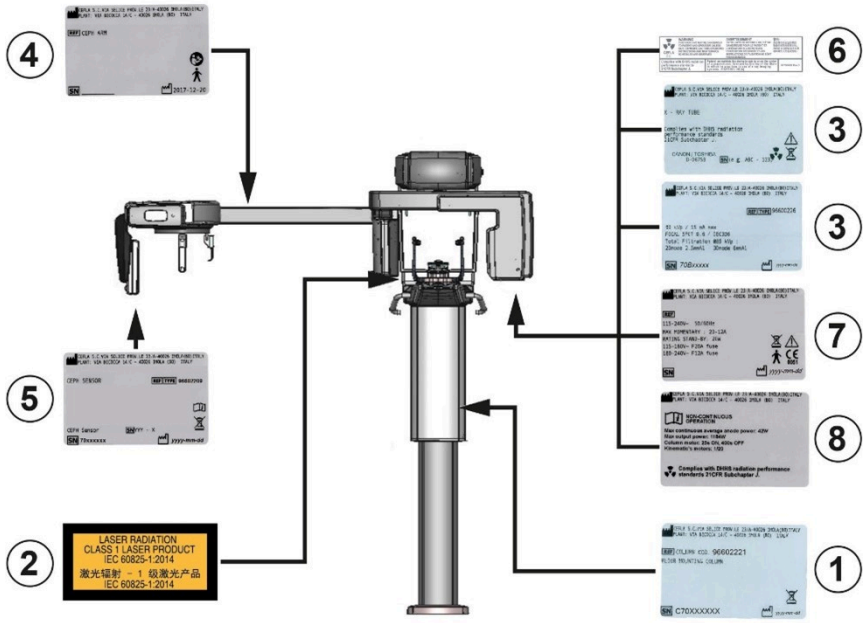
Operating conditions	Temperature +10 - +40 °C (max. +30 °C during the acquisition operations)
	Relative humidity between 10 - 90%
	Pressure 710 – 1060 hPa
	Altitude < = 3000 m
Transport and storage conditions	Temperature -10 - +60 °C
	Relative humidity between 10 - 90%
	Pressure 710 – 1060 hPa

10.11. PERSONAL COMPUTER 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.

10.12. IDENTIFICATION PLATE 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

11. 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 Neowise 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.

12. USER LICENCE AGREEMENT

IMPORTANT: READ CAREFULLY

12.1. 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 device and for its control, and to the image display and storage software, identified as a whole as “Neowise” and “Neowise viewer” (hereinafter referred to as “software”) processed by CEFLA s.c. - via Selice Provinciale 23/A - 40026 Imola (BO) (Italy), (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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   The author shall have the right to seek compensation for damage.

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The conditions of this licence shall be governed by Italian law. Notwithstanding any different connected regulations of the individual legal systems or International Conventions, any dispute that may arise between the parties on interpretation or execution of this licence agreement shall exclusively be assigned to Italian Jurisdiction with exclusive competence of the Court of Bologna.

12.1.7. WRITTEN FORM

Any modification shall be in written form on pain of invalidity. The parties hereto agree not to acknowledge any legal validity of previous, simultaneous or subsequent verbal declarations, by whoever made, henceforth renouncing the validity of any verbal agreements deemed to modify these general conditions. The author reserves the right, at any time and unilaterally, to modify these general conditions giving notice thereof in a way it sees fit.

12.1.8. TRANSLATION

For translations of this licence into another language, it is understood that, in the event of discordance of interpretation, the Italian version shall prevail.

12.1.9. SOFTWARE COMPLIANCE WITH THE REGULATIONS IN FORCE

If the author declares the compliance of his/her Software with specific laws or regulations, such compliance shall be deemed to exist on the date in which the author places the product on the market.
Since it is obvious that legislative or regulatory changes, as well as changes in the interpretation of regulations are always possible, and also considering that any changes and modifications would make the Software in the possession of the user no longer compliant with these regulatory provisions, the user undertakes from time to time to verify whether the use he/she intends to make of the Software is legitimate (or, in any case, is still legitimate), refraining from using it in case of doubt about compliance with the law for the use he/she intends to make of it, notifying the author of the circumstance at the earliest opportunity.

13. INSPECTION AND MAINTENANCE

13.1. USER INSPECTION

These instructions describe the maintenance procedures for the extraoral X-ray device.
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 operation**					
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 **Switching on the device**					
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 **Control panel onboard the machine**					
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 traces**					
9	Make sure that the detector is smoothly inserted inside the guides on Pan and CEPH sides - only for units with cephalometric examination arm and removable detector.	Section **Sensor movement**					
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. Section **Perform a simulation (dummy run)**					
11	If a cephalometric examination 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. Section **Perform a simulation (dummy run)**					
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. The 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” attachment**					
		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!

13.2. TECHNICAL MAINTENANCE

These instructions describe the maintenance procedures for the extraoral X-ray device. 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 (−)

			Inspection DATE		
Step	**Description**	**Reference in the manual**	**__/__/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 **Switching on the device**			
8	Check the touch screen console functionality: functions must respond to interrogation.	User Manual, section **Control panel onboard the machine**			
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 examination 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. User Manual, section **Perform a simulation (dummy run)**			
13	If a cephalometric examination 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. User Manual, section **Perform a simulation (dummy run)**			
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**			
15	Check the emergency stop button functionality. The 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 2D 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" attachment**			
		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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