Beyes CANADA

OPERATING INSTRUCTIONS

DURAY 2D / DURAY 2D Ceph

English

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FOREWORD

Dear Customer,

Thank you for choosing DURAY 2D / DURAY 2D Ceph as your new Panoramic and Cephalometric solution! Our patients, dentists and partners are inspiring us every day. With all our knowledge, passion and experience, we provide complete modern dental solutions to improve global dentistry. We hope that DURAY 2D / DURAY 2D Ceph will help you to provide happy and healthy smiles to your patients, every day.

DURAY 2D / DURAY 2D Ceph combines Panoramic and One-Shot Cephalometric imaging functionality in one compact device. Switching between sensors is done automatically, without need of manual handling, thus saving your time and securing your investment. Select desired 2D exposure program, simply with a push of a button, on device control panel or remotely from the computer. Your smooth workflow is guaranteed, since the unit is completed by powerful DURAY DG Suite imaging software. Fast, easy to use and fully loaded - your ultimate diagnostic solution, DURAY 2D / DURAY 2D Ceph.

System with 2-sensors automatically and quickly adjusts its position to your 2D Pano or Ceph program selection. This saves time and secures your investment. Innovative sensor technology acquires the cephalometric image in less than 1 second, thus preventing patient movement and increasing image quality. Setting of exposure was never easier - Pano or Ceph in just 2 clicks. Simply select the program, patient size and you are ready to go.

You can select from 9 panoramic programs including Sinus, TMJ, dentition and bitewings. Child panoramic and partial arch scans are available to allow patient dose reduction including Left-side, Right-side and Anterior dentition.
Quickly acquired and distortion-free One-Shot Ceph images are immediately ready to be traced and evaluated, with detailed diagnostic information in both soft and hard tissue.

To keep your system in top shape, consult regular maintenance checks with your distributor (please refer to paragraph §12. Inspection and maintenance).

1. SYMBOLS

This is a list of symbols used in this manual and in the labeling of the devices.


Consult the enclosed documentation before using the device relevant part.


This symbol can be found on device labeling. It means that before operating the unit the user must observe the instruction given in this operating manual.


Warning. A possible dangerous situation can result in injury for patient or operator user.


Disposal. The product must be disposed according to law in force.


Note: Is used for a possibly harmful situation which could lead to damage of the product or an object in its environment. Also used for other important information.


Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without ESD protective measures.


Do not spray liquids such as disinfectants into the ventilation slots.


Single use device.


IEC classification: class I, type B.


Manufacturer address.


Manufacturing date.

Serial number.

Reference number.


OFF (disconnected from mains supply).

ON (connected to mains supply).


Fuse.


Alternate Current.


Protective Earth.


Inherent Filtration.

Transport and storage temperature.

Transport and storage humidity.

Transport and storage pressure.

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

2. GENERAL INFORMATION

2.1. General information about this manual

This Operating Instructions, supplied together with the unit, are integral parts of the product. They contain instructions for the proper use of this X-Ray unit. Please read it carefully to become familiar with the device before its use and taking radiographs on the patient.
Keep these operating instructions for easy and quick reference, in case you or another user require information at a later point in time.

The original language of the Operating Instructions is English.

The manual information are subject to changes without any notice, justification or notification to the persons concerned.

The manufacturer is not responsible for direct, indirect or accidental damage resulting from or relating to the provision or use of this information.

This document may not be reproduced, adapted or translated, in part or in full, without the prior written permission of the manufacturer.

In order to prevent injury to persons and damage to the equipment you must also read the warning and safety notes given in these Operating Instructions.

This operating instruction manual refers to models:

- DURAY 2D.
- DURAY 2D Ceph.

2.2. Other valid document

For a correct use of the X-Ray system please also read Software manual and take into account instructions, warning and safety information included there.

The technical literature is provided together with the equipment, to be used by technician for correct installation and maintenance of the equipment and it includes one technical manual.

2.3. Responsabilities of system owner and personnel

The user has the following responsibilities:

- Verify compliance with the local regulations in force and/or ask a Qualified Expert for advice.
- Pay attention to fulfill the obligations of the law regarding the protection of workers, the population and patients against radiation.
- Use the system following the instructions and recommendations contained in this user manual.
- Keep the machine in perfect working condition following the maintenance instructions given by the manufacturer. Failure to observe the instructions relieves the manufacturer or his agent from any responsibility for injury, damage or non-conformities that may derive there from.
- Promptly notify the competent Health Authority and the manufacturer in the event of an accident involving this medical device and/or operations that may cause death or put the patient and/or the user at risk. The type and serial numbers of the components involved, indicated on the external labels, are to be communicated to the manufacturer.
- Prior to the exposure, please ask women of a childbearing age as to whether they are pregnant or not. If the patient is pregnant, a risk/benefit analysis must be performed.

2.4. Indication for use

DURAY 2D: extraoral source dental X-ray system intended to perform panoramic exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry.

DURAY 2D Ceph: extraoral source dental X-ray system intended to perform panoramic and cephalometric exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry, as well as carpal images for dental clinical investigations.

2.5. Indication and contraindications

There are no contraindications to the use of the equipment within the indication for use other than those related to exposure of the patient to ionizing radiation, which should be limited as much as possible.

The unit must not be used for any other purpose.
This unit must not be operated in areas subject to explosion hazards.
Operating and Maintenance Instructions must be observed.

℞Only Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

2.6. Essential performance

The purpose of this paragraph is to establish the particular essential performance requirements for DURAY 2D and DURAY 2D Ceph devices.
The performance of the clinical functions of the device necessary to achieve its intended use are:

- Accuracy of loading factors.
- Reproducibility of the radiation output.

The essential performances are guaranteed by the manufacturer through both an embedded electronics and embedded FW system that allows the control of effective value of loading factors, making sure that they are within the established range, and with specific tests carried out during the device production phase.

3. WARNING AND SAFETY NOTES

3.1. General safety information

As manufacturer of medical devices, we can assume responsibility for safety-related performance of the equipment only if maintenance, repair and modifications are carried out only by our service network and components are replaced with only original parts.
We suggest that you request a certificate showing the nature and extent of the work performed, from those who carry out such work, and specify that the certificate show any changes in rated parameters or working ranges, as well as the date, the name of the firm, and a signature.
Only use original accessories indicated in this Operating Instructions. It is the user's risk when using non-approved accessories.
Exposures of patients may only be taken if the unit functions fault-free. Never leave the unit unattended during its functioning.

3.2. Installation

The system is fully tested in manufacturing and can be operated once the major modules are mechanically assembled at installation and then connected to the power line.

The system must not be used if it shows any electrical, mechanical or radiation defect. Like for all medical electrical systems, this device requires proper installation, use, maintenance and service with the aim of assuring safe and efficient operation. The entire system must be installed by two technicians and at least one of them is a Qualified Expert, authorized by the Manufacturer.
All the installation instructions are given in the Installation manual, provided with the equipment.

3.3. Qualification of operating personnel

The system may only be operated by skilled or properly trained personnel.
Qualification Personnel, who are to be trained, taught, instructed or are taking part in a general training, may operate the device only under the supervision of an experienced person. To operate the unit, the operating personnel must:

- have read and understood the Operating Instructions;
- be familiar with the fundamental structure and functions of the unit;
- be able to recognize irregularities in the functioning of the unit and implement the appropriate measures where necessary;
- have read and understood Radiation Protection Guidelines on this manual.

3.4. Equipment

a. Condensation

Following extreme temperature fluctuations, condensate formation may occur; therefore please do not switch on the device until normal room temperature has been reached.

b. Electrostatic discharge (ESD)

Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without ESD protective measures.

c. Ventilation slots

The ventilation slots on the unit must never be covered, since otherwise the air circulation will be obstructed. This can cause the unit to overheat.

Do not spray liquids such as disinfectants into the ventilation slots. This may lead to malfunctions. Use wipe disinfection only in the vicinity of the ventilation slots.

d. Laser light localizers used

This product incorporates Class 1 lasers as light localizers for the positioning of the patient. They must not be used for other purposes. A minimum distance of 100 mm must be maintained between the eye and the laser. Avoid unnecessary exposure of the eyes and pay attention that the beams are not intercepted by any optical device.
The light localizers may be switched on only when functioning perfectly. Repair work must be carried out by authorized staff only. Do not use the system with any other lasers, and do not make any changes to settings or processes that are not described in these operating instructions. This may lead to a dangerous exposure to radiation.

e. Touchscreen

The device is equipped with touch-sensitive control technology. The touchscreen must not be operated with pointed objects such as ballpoint pens, pencils, etc. Such objects could damage or scratch its surface. Always operate the touchscreen by pressing it gently with your fingertip. Please refer to paragraph §12.1 “care of the surfaces” for cleaning instructions.

f. Patient positioning

No patient shall be positioned in the unit while it is booting up. In case of an error that requires switching the unit off and back on again, the patient must be removed from the unit, at the latest before the unit is switched back on.

3.5. Hygiene

a. Protective sleeves

The protective sleeves must be exchanged and all auxiliary exposure equipment must also be disinfected for each new patient in order to prevent any possible transmission of infective agents which might cause serious illnesses.

b. Cleaning and disinfection

Suitable hygienic measures must be taken to prevent cross contamination between patients, users and other persons. More information about sterilization and hygienic protective sleeves can be found in chapter §12. Inspection and maintenance.

3.6. Trouble-free operation

Use of this system is permissible only if it works properly without malfunctions. If trouble-free operation cannot be ensured, the unit must be taken out of service, checked by technicians for malfunctions and, if necessary, repaired. X-rays of patients shall be taken only when the system is working troublefree. The movements of the unit must not be obstructed by physical constitution, clothing, dressings, wheelchairs or hospital beds. The travel range of the unit must be kept free from foreign matter. Do not leave the patient at the unit unattended. The device may only be operated with a complete cover and protective hood.

3.7. Combination with other equipment

Any person, who assembles or modifies a medical electrical system complying with the standard IEC 60601-1 (safety requirements for medical electrical equipment) by combining it with other equipment is responsible for ensuring that the requirements of this regulation are met to their full extent for the safety of the patients, the operators and the environment. If any devices not approved by BEYES are connected, they must comply with the applicable standards:

- IEC 60950-1 for information technology equipment and/or
- IEC 60601-1 for electrical medical devices.

3.8. Electromagnetic Compatibility

This unit may be operated in a residential/hospital area, provided it is used under the responsibility of a trained medical operator, and following the recommendations reported in chapter 15, Electromagnetic Compatibility.
DURAY 2D / DURAY 2D Ceph needs special precautions regarding EMC, and needs to be installed and put into service according to the EMC information provided in Chapter 15.
Use of accessories, transducers and cables other than those specified or provided by BEYES could result in increased electromagnetic emissions or decreased electromagnetic immunity of the DURAY 2D / DURAY 2D Ceph and result in improper operation.

In the following table a list of the interface cables of the equipment is provided:

Designation of interface cables	**Code**
Hand switch spiral cable, 3 m, unshielded	76 190 25580
2 x LAN cables, cat. 5e, 10 m, shielded	42 914 00006
Mains cable, 2.4 m, 3 x AWG 16, unshielded	62 680 15400

Use of the DURAY 2D / DURAY 2D Ceph adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the DURAY 2D / DURAY 2D Ceph and the other equipment should be observed to verify that they are operating normally.
The presence of electromagnetic disturbances may degrade the diagnostic performance of the equipment (e.g. exam interruption, presence of artifacts…). The need of repetition of an X-Ray exam must be justified for each patient in order to demonstrate that the benefits outweigh the risks.

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

3.9. Interference with electronic devices

Portable and mobile Radio Frequency communications equipment can affect medical electrical equipment like DURAY 2D / DURAY 2D Ceph.
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closed than 30 cm (12 inches) to any part of the DURAY 2D / DURAY 2D Ceph, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment.

3.10. Malfunction of electronic units / devices which are worn on the patient's body

In order to prevent failure of electronic units and data storage devices, e.g. radio-controlled watch and telephone card, etc., it is essential that these be removed prior to X-ray exposure.

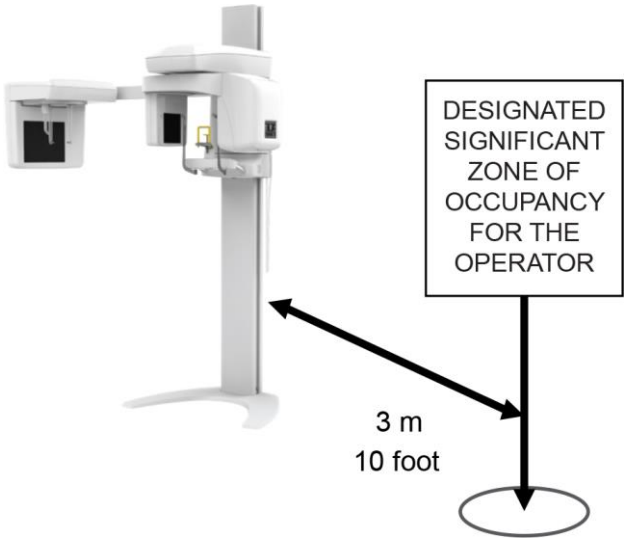
3.11. Electrical safety

Trained and qualified technicians only are authorized to remove covers and have access to power circuits.
Power supply lines must comply with safety legislation and have ground terminals for protective earth connection.

3.12. Explosion

This unit cannot be used in presence of flammable gases or vapors.

3.13. Radiation protection guidelines



X-ray equipment produces ionizing radiation that may be harmful if not properly controlled. It is therefore recommended that the equipment be operated by trained personnel only, in accordance with existing law.
Exposure to ionizing radiation is of particular concern in pediatric patients. It is thus recommended to follow the specific pediatric protocol available on the unit. Refer also to the Image Gently in Dentistry Campaign materials (http://www.imagegently.org/Roles-What-can-I-do/Parent/Dentist) for best practices in pediatric X-ray imaging.
Observe the applicable health physics regulations. The radiation protection facilities should be used.
During the exposition the operator should remain as far away from the X-ray tube as the cable of the release button permits (in the designated significant zone of occupancy for the operator).
With the exception of the patient, no other persons may remain in the room while the exposure is being made. Under exceptional circumstances a third person, however not belonging to the dental practice, may then assist.
Maintain visual contact with the patient and the unit during the exposure and in case of faulty operation, immediately discontinue the exposure by releasing the X-ray button.

3.14. Modifications to the unit

Modifications to this unit which might affect the safety of the system owner, patients or other persons are prohibited. For reasons of product safety, this product may be operated only with original accessories or third-party accessories expressly approved by BEYES. The user is responsible for any damage resulting from the use of non-approved accessories.

3.15. Structural alterations

If structural changes are made in the vicinity of the X-ray unit which result in the device being exposed to very high levels of vibration or even impact, the device must be inspected by a service engineer and readjusted and re-calibrated if necessary.

3.16. Maintenance

The device does not contain parts that can be repaired directly by the user. If you find or suspect any kind of system malfunctioning, do not attempt to carry out any type of maintenance operation and do not use the system on a patient, but directly contact your local distributor.
The user may not carry out maintenance on any mechanical or electronic part of the X-ray system. Opening the cases to access the internal circuits may cause device breakage and failure of the electrical safety devices and will lead to forfeiture of the warranty. Any maintenance, repairs and modifications to the device must be carried out only by personnel directly authorized by the manufacturer and must be carried out according to the laws in force and the generally accepted technical standards. All the system components must be checked and replaced if necessary by qualified personnel. For any maintenance operation, please contact the dealer.

3.17. Disassembly and reinstallation

For disassembly and reinstallation of the unit please proceed as described in the installation instructions to ensure perfect function of the unit and its stability. This operation must be performed by two technicians. In case, please contact the dealer.

3.18. Disposal

It generally applies that any disposal of this product must comply with the relevant national regulations. Please observe the regulations applicable in your country.
Within the European Economic Community, Council Directive 2012/19/EU (WEEE) requires environmentally sound recycling / disposal of electrical and electronic devices.
Your product is marked with the adjacent symbol. Disposal of your product with domestic refuse is not compatible with the objectives of environmentally sound recycling / disposal. The black bar underneath the garbage can symbol means that it was put into circulation after Aug. 13, 2005 (see EN 50419:2005).
Please note that this product is subject to Council Directive 2012/19/EU (WEEE) and the applicable national law of your country and must be recycled or disposed of in an environmentally sound manner.
The X-ray tube assembly of this product contains a tube with a potential implosion hazard, a lead lining and mineral oil.
Please contact your dealer if final disposal of your product is required.

3.19. Recommendations for pediatric population

Caution: use special care when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range.

Children are three times more at risk from radiation with respect to adults. Exposure to ionizing radiation is of particular concern in pediatric patients for three reasons:

- younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients);
- younger patients have a longer expected lifetime for the effects of radiation exposure to manifest as cancer;
- use of equipment and exposure settings designed for adult use can result in excessive radiation exposure to the smaller patient.

X-ray exams must be prescribed only when benefits outweigh the risks posed by radiation and only when necessary to answer a medical question or help treat a disease. Use the lowest radiation dose that still produces image with adequate quality for diagnosis or intervention (refer §6. EXPOSURE PROGRAMS). Always use exposure settings designed for children to avoid an excessive and unnecessary radiation exposure.

The following resources provide information about pediatric imaging radiation safety and/or radiation safety for dental radiography devices:

- FDA's pediatric x-ray Imaging website: https://www.fda.gov/radiation-emitting-products/medical-imaging/pediatric-x-ray-imaging,
- FDA's medical x-ray imaging website: https://www.fda.gov/radiation-emitting-products/medical-imaging/medical-x-ray-imaging.

3.20. IT / CYBERSECURITY

- Set a "private LAN" between the X-ray unit and the X-ray image PC with PC software.
- Assign a fixed IP address to the unit.
- The firmware updates can only be performed by qualified technicians.
- The device is designed to allow the detection of security compromises events.
- It is recommended to use a Windows 10 operating system with long term support to achieve an optimum and safe IT environment.
- The IT structure should be limited to authorized users only.
- The access to devices is limited through the authentication of users (user ID and password) and there is a layered authorization model by differentiating privileges based on the user role. Authentication is used to prevent unauthorized access to device functions and to prevent unauthorized software execution.
- Take measures against computer viruses and verify antivirus measures.
- It is recommended the installation of the latest Windows networks security tools on the PC for an effective protection against malware and cyberattacks.
- It is recommended to install the PC operating system security updates immediately. Use strong passwords to protect your PC.
- It is recommended to avoid the installation of additional software on the PC.
- It is recommended to avoid the use of virtual machines for operating systems.

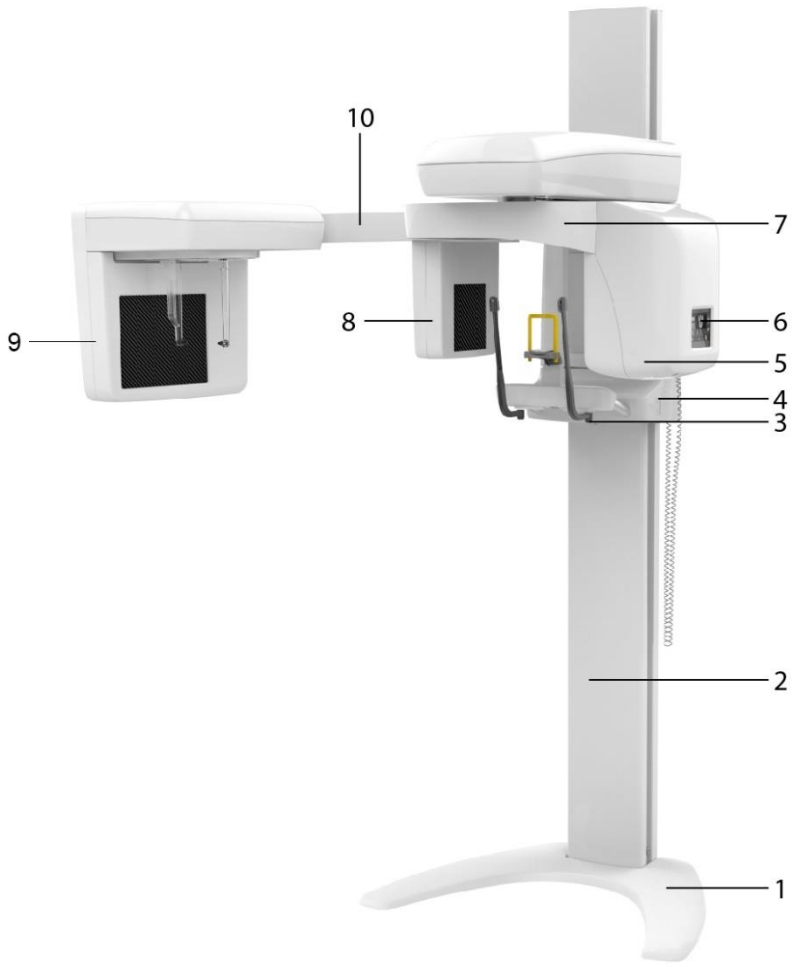
4. GENERAL DESCRIPTION

Two configurations are available: DURAY 2D and DURAY 2D Ceph.

DURAY 2D has a rotating arm mounted on a column support. The rotating arm performs motor-driven rototranslatory movements that allow moving the X-ray emission system and the image detector around the patient according to different orbits that follow the morphologic profile of the patient.

DURAY 2D Ceph, in addition, is equipped with a tele-X-ray arm coupled to the column support. The arm hosts a one shot X-Ray sensor for the detection of X-Ray image and a cephalostat to hold the patient in position during the examination.

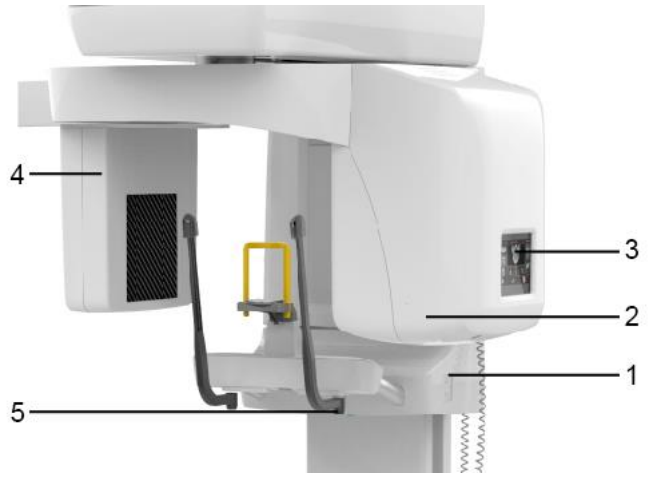
The main parts of the equipment are illustrated below:



1. Self standing base (optional)
2. Column
3. ON/OFF button
4. Height adjustment buttons
5. X-Ray Generator
6. Control panel (touchscreen)
7. Rotational carriage
8. Panoramic X-Ray image sensor
9. Cephalometric X-Ray image sensor (only DURAY 2D Ceph)
10. Cephalometric arm (only DURAY 2D Ceph)

4.1. Rotational carriage

The rotational carriage contains following parts:

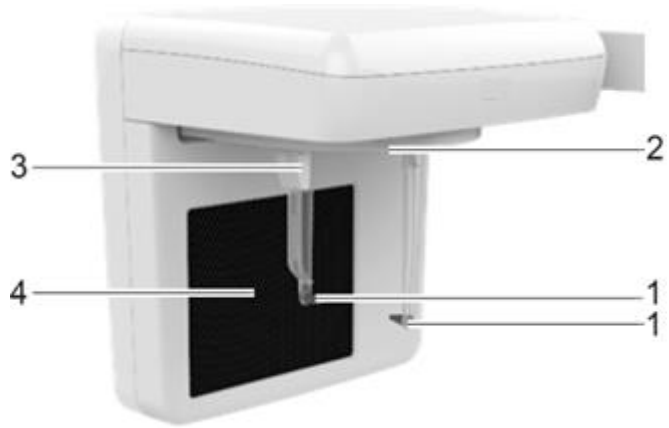


1. Height adjustment buttons.
2. X-Ray Generator.
3. Control panel (touchscreen).
4. Panoramic X-Ray image sensor.
5. ON/OFF button.

6. Hand grips.
7. Patient positioning mirror.
8. X-Ray button.
9. Temple support.
10. Accessories for patient positioning.

4.2. Cephalometric arm (only DURAY 2D Ceph)

The cephalometric arm contains following parts:



1. Ear plugs.
2. Cephalostat.
3. Nasion.
4. Cephalometric X-Ray image sensor.

The cephalometric arm can be ordered anytime as option.

4.3. PC connected to the equipment

A PC is provided with the device (optional), which already has installed the software DURAY DG Suite for image acquisition and database.

The provided PC is specifically configured for DURAY 2D / DURAY 2D Ceph acquisition and reconstruction. Unauthorized hardware or software modification will void all warranties of the PC.

4.4 Software DURAY DG Suite

The software DURAY DG Suite is a complete and simple to use tool for the management of the dental cabinet and enhancement of digital radiographic images.
The software allows to manage all data of the Dental cabinet in a very simple and intuitive way. Moreover, it allows to acquire the images from a wide range of electronic devices: video radio X-Ray system, telecameras, digital extraoral units, scanners, cameras, slides scanner, etc.
All the acquired images, independently from their origin, can be saved and elaborated. A series of measurement functions exist (distance, angles, areas, etc.) for reliable treatment planning.

The software DURAY DG Suite allows the acquisition of panoramic and cephalometric X-ray images and X-Ray images for 3D reconstruction, managing also the associated patient data records.
The images acquired by DURAY DG Suite can be saved in DICOM format.
For more information on the use of the application, refer to the DURAY DG Suite user manual.

The use of DURAY DG Suite software is not mandatory, the devices could be used in combination with other software that allows the viewing and management of radiographic images in DICOM format.

4.5. Control panel (touchscreen)

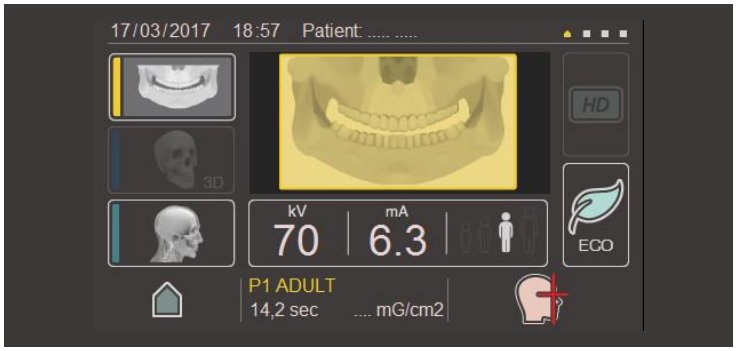
The control panel, with touch screen technology, allows the control of the device.

To make a selection in the touch screen it is sufficient to gently touch the button with a finger.

After a certain period of inactivity, the touch-screen switches to stand-by mode. Touch any part of the touchscreen to activate it again.

When an icon is selected, it becomes highlighted, as in side image.

If the icon is not selected, it is not highlighted.



From the home page it is possible to select the exam type (panoramic or cephalometric), patient size, manually correct technical parameters, etc.

The icon “home” allows to go back to the main view.

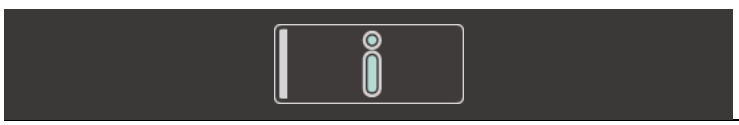
The icons “Right arrow” and “Left arrow” allow to scroll the options (i.e. in selection of the programs or in changing technical parameters).

The icons “Plus” and “Minus” allow to increase or decrease technical parameters value (i.e. mA, kV, mAs).

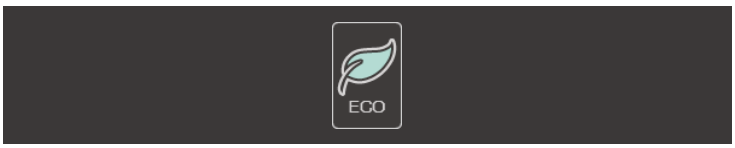
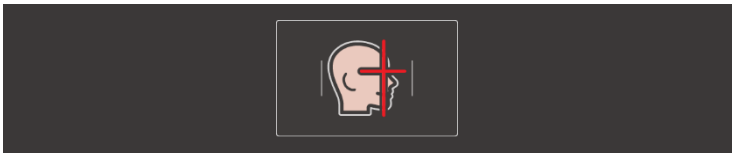
The icon “Confirm” allows to accept the configuration set.

The icon “Return” allows to return the system from “start position” to “patient entry position”.

Icon “Carriage Initialization” allows to reset the system.



Icon “info” shows the main technical information concerning the system (i.e. Serial number, SW version, etc.).

	“User Settings” Icon.
	Icon “Service”: for technicians only (Password required).
	Icon “Child”.
	Icon “ECO” (active for panoramic exams).
	Icon “Patient Positioning”.
	Icon “Test” (test of carriage rotation, without X-Ray).
	Icon “Go to Start position” (with X-Ray).
	Icon “Go to Start position” (Test modality, without X-Ray).
	Icon “Warning”.
	Icon “Error”.
	Icon "Positioning tool".
	Icon “Cooling” is shown when the device needs a cooling time.

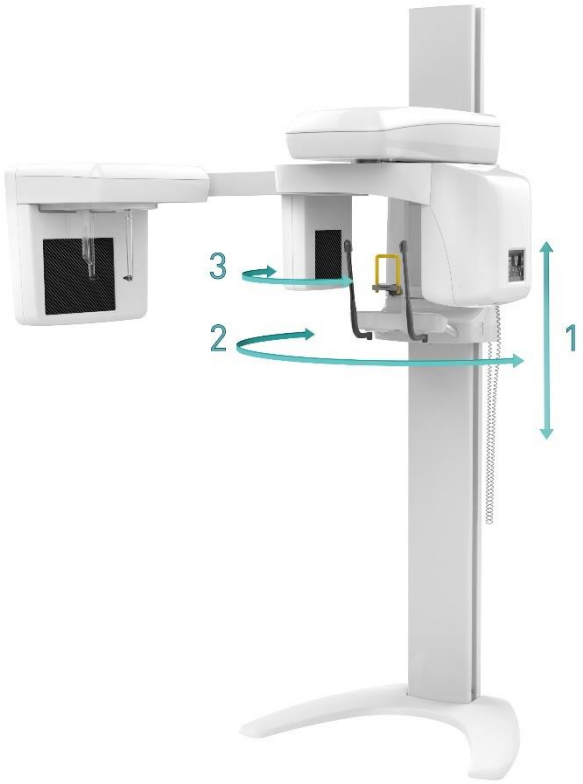
4.6. X-Ray Button

The X-Ray button is located on the right of the unit, attached with a magnetic connection.

The X-Ray button can alternatively be mounted remotely in case the unit is located in an X-ray room which has a door and enables visual contact with the patient.
An optional kit is available for remote mounting of the hand switch.

The X-Ray button allows to change the device position (one click).
It permits also to perform X-Ray exposure by pressing and holding the x-Ray button until the end of the exam. When the examination is started, the yellow LED on the remote control comes on and simultaneously an acoustic signal is emitted by the equipment.

4.7. Device movable parts



Possible movements of the equipment are:

1. Up / down of the system (rotational carriage + cephalometric arm) along the column.
   This movement allows to bring the system to proper height according to patient height through height adjustment buttons.

2. Rotation of the rotational carriage.
   This movement takes place during panoramic exams and allows the complete scanning of the patient.

3. Rotation of the Panoramic X-Ray image sensor.
   This movement takes place when cephalometric exam is selected, and equipment status changes from “Patient entry position” to “Ceph exam start position” (refer to paragraph §5.2 Operating position – Cephalometric exams).

4.8. Ambient light

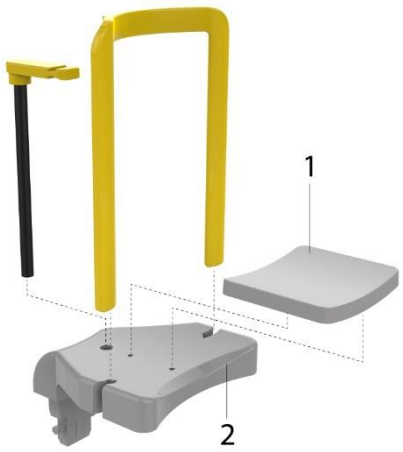
The equipment has an ambient light, positioned back of the carriage, which gives information about the equipment status, as illustrated in table below.

LIGHT COLOR		LIGHT STATUS		MEANING
	Green		Floating	Carriage in patient entry position.
	Green		Fixed	Carriage in start exam position.
	Yellow		Fixed	Caution - See message on touch screen display.
	Blue		Fixed	Carriage in patient exit position / end exam position.
	Blue		Blinking	Carriage moving from one position to another.
	Violet		Fixed	Service function active / System boot.
	Orange		Fixed	X-Ray ON.
	Red		Fixed	Warning – See error message on touch screen display.

4.9. Positioning tools

A set of positioners are provided with the equipment.
Please refer to table in paragraph §4.9.f. Positioning tool – resuming table to choose right positioner and position for selected exam.
Please refer to the paragraph 12.1 Care of the surfaces for cleaning and sterilization procedures.

a. Chin rest



A chin rest to be used for 2D panoramic exams. It is possible to use the stick with bite accessory or the yellow arch (for edentulous) for positioning of the patient, according needs.

The additional support (1) must be mounted on the chin rest (2) if the patient is a child.

b. 1 bite block and 1 nasal suppot (yellow)

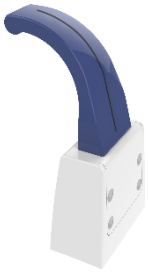
Yellow bite block

Yellow Nasal support

The yellow bite block positioner can be used for patient with complete dentition for panoramic exams.
The yellow nasal support positioner can be used for patient with complete / incomplete dentition, for panoramic exams.

c. 1 bite block and 1 nasal support (blue)

Blue bite block



Blue Nasal support

The blue bite block positioner can be used for patient with complete dentition for panoramic exams (only maxillary sinuses).
The blue nasal support positioner can be used for patient with complete / incomplete dentition (for, 2D maxillary sinuses or 2D TMJ programs).

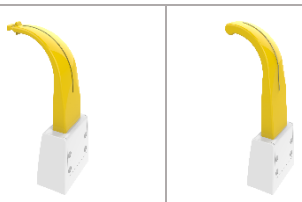
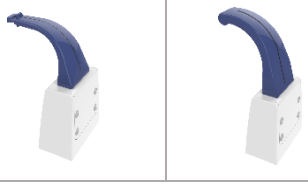
d. Temple support

Temple support can be used as an additional positioning tool, in order to fix the head in the desired position.

e. Craniostat for cephalometric exams

It is used for patient positioning for cephalometric exams (Only for DURAY 2D Ceph).
It is composed by a removable nasion and two auricular rods.

f. Positioning tool – resuming table

	Modality		Programs		
Positioner	**2D**	**Ceph**	**P1→P6, P8**	**P7, P9**	**C1→C4**
	X		X (Pos.0)		
	X		X		
	X			X	
		X			X
	X		X	X	

4.10. Hygienic protective sleeves

Prior to each exposure, the appropriate hygienic protective sleeve (single use devices) must be fitted. Single use devices are identified with the symbol shown on the left.

Hygienic protective sleeves are not provided with the equipment and must be biocompatible according to ISO 10993 requirements.

They must be disposed of immediately after use. Do not use single use devices more than once.

5. OPERATING POSITIONS

5.1. Panoramic Exams

- **PATIENT ENTRY** position

  Control panel and X-ray source on the right of the patient and the image receiver on the left.

  Ambient light is **green (floating).**

- **START** position

  System ready to start the exposure. When the unit reaches the START position the green light of the READY indicator on the control panel is turned ON.

  Ambient light is **green (fixed).**

- **PATIENT EXIT** position

  Control panel and X-ray source on the left of the patient and the image receiver on the right.

  Ambient light is **blue (fixed).**

5.2. Cephalometric Exams

- **PATIENT ENTRY** position

  Control panel and X-ray source in front of the Panoramic X-Ray image sensor.

  Ambient light is **green (floating).**

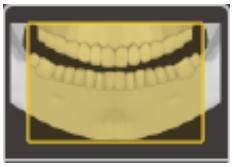
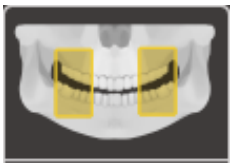
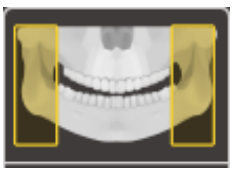
- **CEPHALOMETRIC** position

  Panoramic sensor is in front of the mirror, the X-ray source in front of the cephalometric sensor.

  Ambient light is **green (fixed).**

6. EXPOSURE PROGRAMS

6.1. Panoramic program exposures

Ref	Description	Exam duration	Icon	ECO option
P1	ADULT FULL This panoramic exposure displays the full tooth region with ascending rami.	14.8 s (X-Ray: 14.2 s)		
P2	CHILD FULL The exposure represents a reduced tooth region without ascending rami, for children. For this exposure the radiation dose is considerably reduced.	14.8 s (X-Ray: 11.6 s)		
P3	ADULT PARTIAL FRONT The exposure shows the anterior tooth region.	14.8 s (X-Ray: 4.9 s)		
P4	ADULT PARTIAL LEFT This panoramic exposure displays the left part of the tooth region with left ascending rami.	14.8 s (X-Ray: 7.4 s)		
P5	ADULT PARTIAL RIGHT This panoramic exposure displays the right part of the tooth region with right ascending rami.	14.8 s (X-Ray: 7.4 s)		
P6	ADULT DENTITION The exposure represents a reduced tooth region without ascending rami.	14.8 s (X-Ray: 11.6 s)		
P7	SINUSES This exposure shows the paranasal sinuses.	14.8 s (X-Ray: 14.2 s)		
P8	BITEWING The exposure displays the posterior tooth regions with an image height restricted to the bite wing and an optimized projection.	14.8 s (X-Ray: 8.7 s)		
P9	TMJ OPEN/CLOSED MOUTH This exposure displays the temporomandibular joints from a lateral aspect with the mouth open and closed and provides 4 views in one image.	14.8 s (X-Ray: 4.6 s)		

The image at receptor's plane is approximately 29% higher than real size: the vertical magnification on adult standard profile is 1.29:1 approximately with constant vertical magnification on dental arch.

6.2. Cephalometric programs (Only DURAY 2D Ceph)

Ref.	Description	Image dimension	Icon
C1	LL (Latero-Lateral) LARGE VIEW This program displays a full-format lateral view (approx. 30 x 24 cm). This program displays the whole of the patient's head.	30 x 24	
C2	LL (Latero-Lateral) SMALL VIEW This program displays a full-format lateral view (approx. 18 x 23 cm). This program omits the front of the patient's head.	18 x 24	
C3	AP (Antero-Posterior) / PA (Postero-Anterior) VIEW The program takes a full-format exposure from anterior to posterior or from posterior to anterior.	30 x 24	
C4	CEPH Carpus The program displays a Carpus view. The Carpus view is used to determine the growth stage of the body or the jaw.	30 x 24	

The image at receptor's plane is approximately 10% higher than real.

7. PREPARING FOR EXPOSURE

7.1. Switching ON the Unit

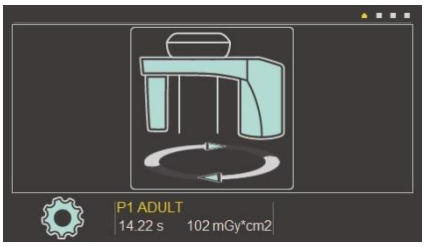
By pressing the mains switch in the lower part of the vertical carriage under the mirror, the unit is supplied as indicated by the green light of the mains switch.

ATTENTION
Following extreme temperature fluctuations, condensate formation may occur; therefore please do not switch on the device until normal room temperature has been reached.

ATTENTION
When switching on the unit there must NOT be a patient positioned in the unit.
If a fault which requires switching the unit off and then back on again occurs, the patient must be taken out of the unit at the latest before switching it on again!

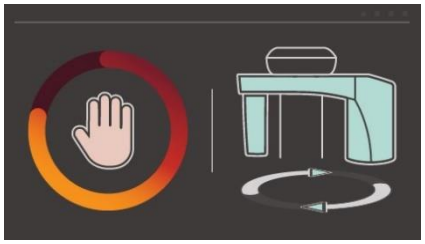
- The display on the control panel turns on.
- System boot starts.

7.2. Carriage initialization



After system boot, the setting page is displayed on the control panel.

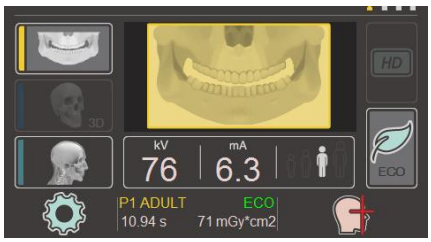
Select the Icon “Carriage Initialization” in order to have the device ready for use; the rotation arm moves to the PATIENT ENTRY position.



During system initialization the image to the side is shown on the display.

Ambient light is **blue (blinking).**

ATTENTION:
Pay attention not to be in the trajectory of the carriage during its movement.



At the end of carriage initialization, the home page is displayed.

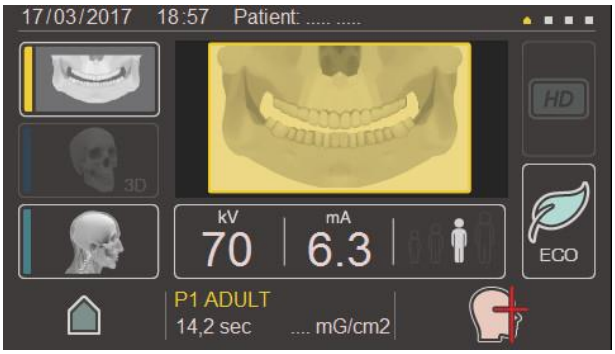
7.3. Running image acquisition software on the PC

A. Starting

On the PC connected to DURAY 2D / DURAY 2D Ceph with DURAY DG Suite installed, start DURAY DG Suite, select your account and insert your password.

Select the patient from the list or insert a new patient and click on “DURAY 2D / DURAY 2D Ceph” button from the list.

B. Acquisition module



The content of the touchscreen of the equipment will be displayed on PC.
You can select functions from touchscreen representation on PC or from the touchscreen of equipment.

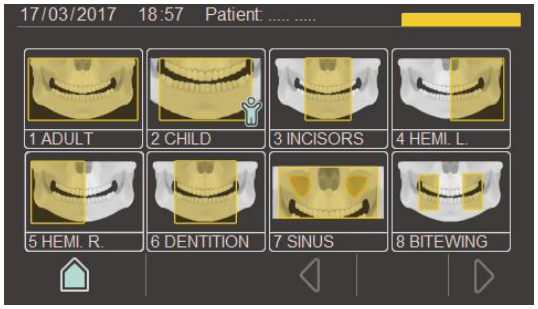
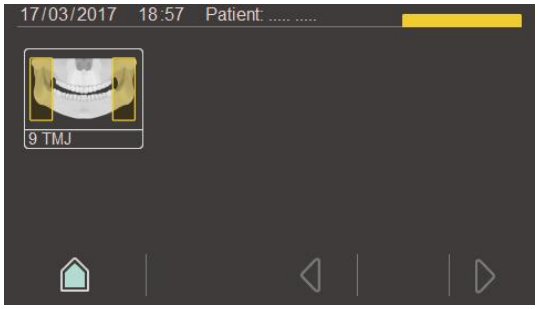
7.4. Exam type selection

Please select the exam type from the home page.
1. Panoramic exams.
2. Cephalometric exams.

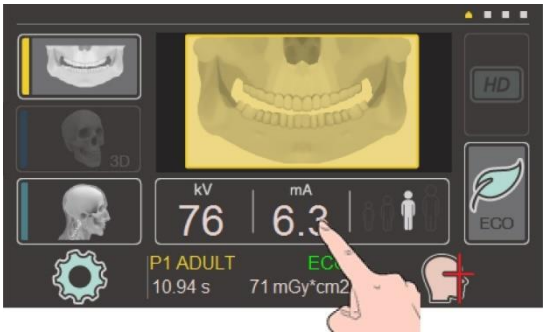
It is possible to select ECO modality from this page, by clicking on the relevant icon. In case the ECO modality is not selected, the Standard (STD) modality will be applied.

If the ECO modality is available for selected exam the relevant icon is highlighted.

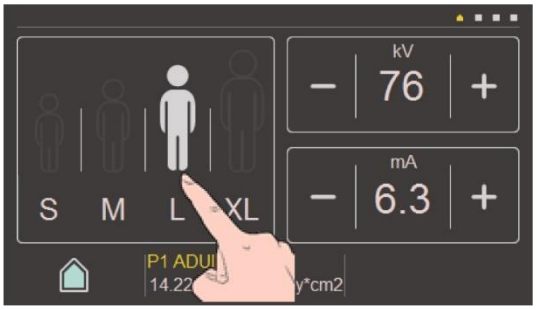
For each selected modality, the exam list is available. Scroll pages with arrows and select the desired exam by touching the correspondent icon. The selected exam will be displayed in the home page, with relevant technical parameter (default patient size 3 or customized ones).

2D		
CEPH		

7.5. Selection of patient SIZE



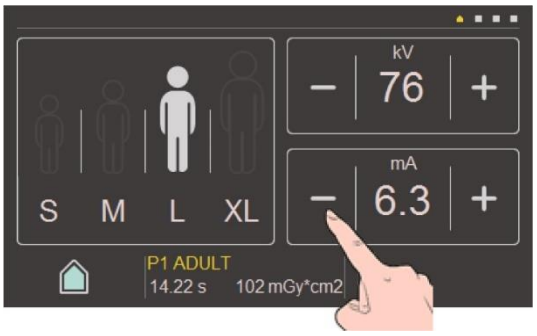
It is possible to select patient size or adjust manually the technical parameters kV and mA (mAs only for cephalometric programs) by pressing the “kV/mA/size” button, in the middle of the display home page.



Select the desired patient size, from S to XL, by touching the correspondent icon.
Preset kV/mA combinations are assigned to the patient symbols, which are selected according to the patient's size and weight. The symbols correspondence is listed below:
Size S: small.
Size M: medium.
Size L: large.
Size XL: extra large.

Select Home icon to go back on home page.

7.6. Setting of technical parameters

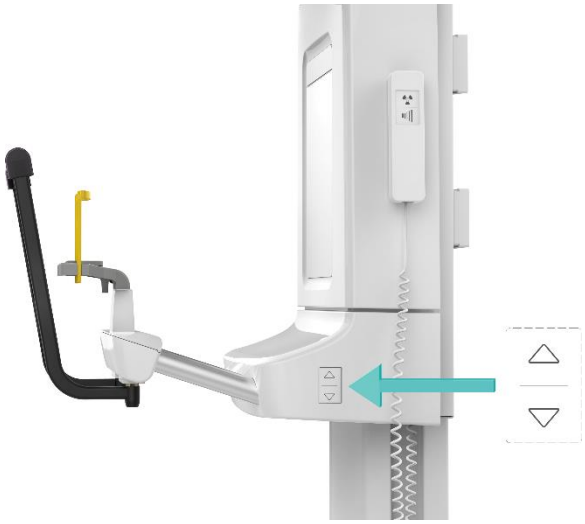


If the preset kV/mA combinations do not provide a satisfactory result, it is possible to set the kV/mA values manually in all programs. Increase or decrease kV and mA values by touching icons “+” or “-”.

Select Home icon to go back on home page.

8. PATIENT POSITIONING

8.1. Preparing patient before positioning

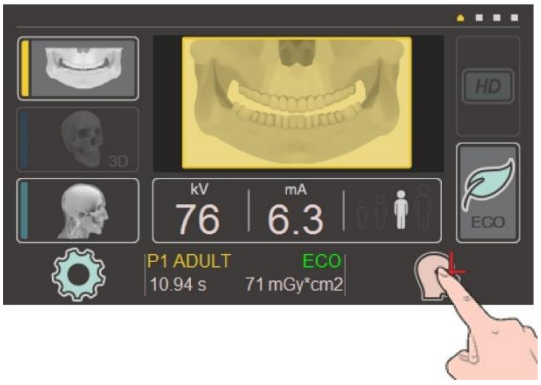


Ask the patient to remove from head and neck all metallic items such as removable denture, earrings, necklaces, glasses which might cause ghost images on the radiograph.

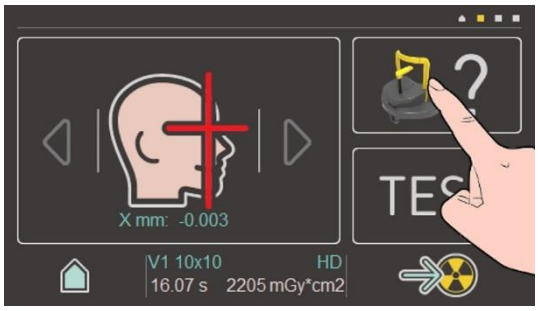
- Physical constitution, clothing, bandages, etc. must not interfere with the movement of the arm.
- If in doubt, perform a test rotation without radiation by having selected before the TEST mode.
- In case a protective apron is used leave the neck free not to interfere with the X-ray beam: radiation enters from sides and from back.
- With the arm in “PATIENT ENTRY” position, have the patient stand in front of the mirror, close to the unit.
- Bring the unit the proper height using UP or DOWN keys.

NOTE:

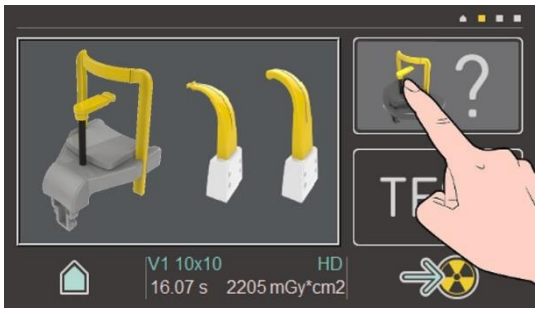
The height adjustment motor starts slowly and then increases its speed. Press the height adjustment key until the unit has reached the desired height.



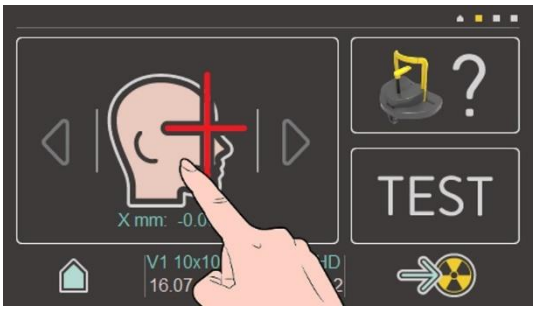
Select Icon “Patient positioning” on the bottom right part of the display.
The light laser beams automatically switch ON; they switch off after 60 s.



Press and keep pressed the button "positioning tool" in the upper right part of the touchscreen.



Check that the positioning tool inserted in the device is one of those needed for the selected exams, shown in the main window of the touchscreen.
If not, replace it; pull the accessories upwards and out of the holder and insert the new one.

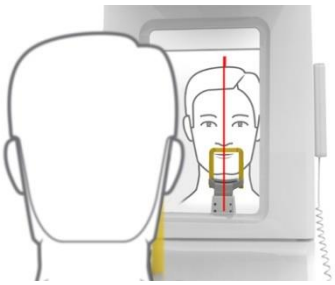


Select icon “Patient positioning” to switch OFF/ON the light beam localizers.

ATTENTION:
The light beams are LASER lights. Avoid unnecessary exposure of the eyes of the patient or of the operator to the laser radiation and pay attention that the laser beams are not intercepted by any optical device.

8.2. Panoramic images - reference laser beam

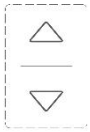
a. Mid sagittal laser beam



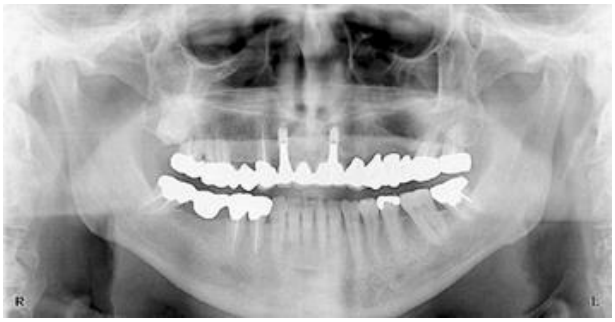
The Mid-sagittal laser beam should fall in the mid-sagittal plane of the patient. Stand behind the patient and check in the mirror if the vertical mid-sagittal laser beam (red line in the side image) is aligned with the patients mid-sagittal plane. Adjust the position by moving patients’ head, if needed.

b. Frankfurt Horizontal laser beam

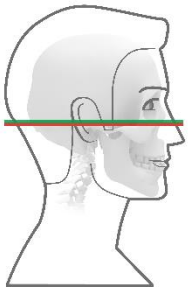
The FH (Frankfurt Horizontal) beam should be falling between the upper edge of the external auditory meatus and the lower edge of the infra-orbital rim.
The height of the FH horizontal beam can be adjusted with a dedicated knob on the right side of the tubehead.
Adjust the height of the unit to have the Frankfurt plane Horizontal (FH) and the cervical vertebrae straight (not bent forward) and stretched.
In the images below the Frankfurt plane on the patient is represented by a green line, the laser beam for Frankfurt plane alignment (emitted by equipment) is represented by a red line.

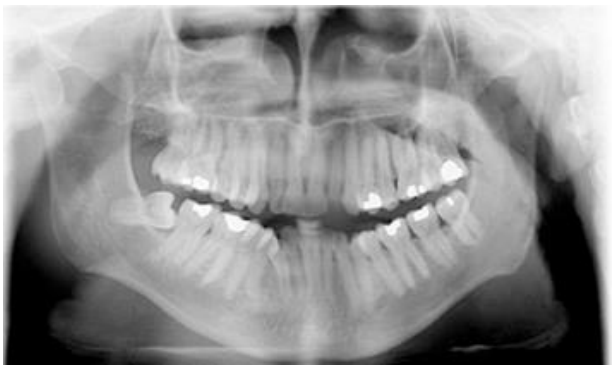


Fine tune the head inclination for the FH setting by briefly touching the UP or DOWN height adjustment key.
Verify side rotation of the head with reference to the Midsagittal light using the mirror from the back of the patient and correct in case.
Ask the patient to swallow and keep the tongue lightly pressed to the palate.
Eventually recommend to avoid movements till the end of the exposure.

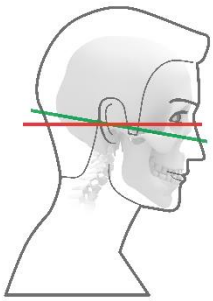


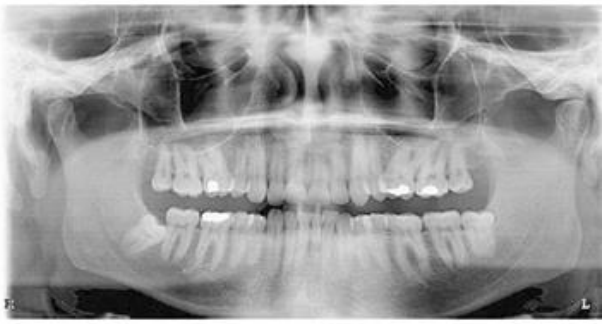
Correct position:
Frankfurt plane is horizontal.



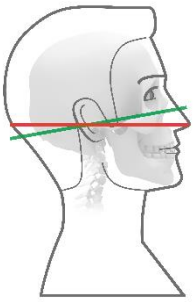


Wrong position:
Frankfurt plane is NOT horizontal.
The head is tilted forward thus resulting in a V shaped dental arch on the X-Ray image.



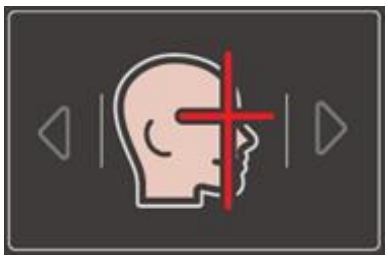


Wrong position:
Frankfurt plane is NOT horizontal.
The head is tilted backward, thus resulting in a flat dental arch on the X-Ray image.



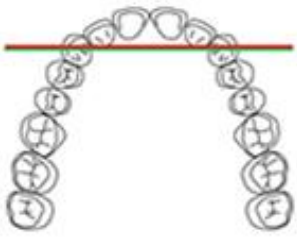
The correct positioning of the Frankfurt plane is of particular importance. A wrong position of the Frankfurt plane of the patient may result in an incorrect volume area acquisition, with the risk that the patient must repeat the X-Ray acquisition.

c. Canine laser beam

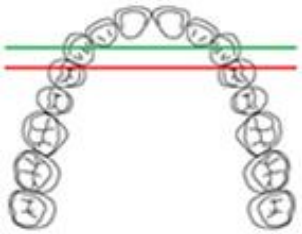


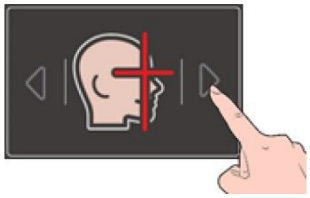
The lateral light beam does not need to be corrected for patients with normal occlusion.

In cases of overjet with class II or III malocclusion, move the carriage with the two arrows on the touch screen until the lateral light beam is on the distal part of the canine, to have the roots of the incisors within the layer in focus (the movement in mm is shown on the control panel).
The procedure is described here below.

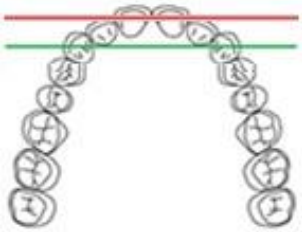


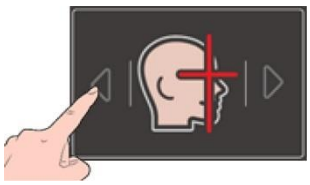
- Layer correctly centered.
  - The light beam (red line) falls on the distal part of the canine (green line).
  - The roots of the incisors fall exactly in the center of the layer in focus.
  - The front teeth appear sharp.





- The light beam (red line) falls behind the canine (green line).
  - The roots of the incisors fall outside the layer in focus.
  - The front teeth appear blurred and proportionally smaller.
  - Move the rotating arm forward (towards the column) to correct.





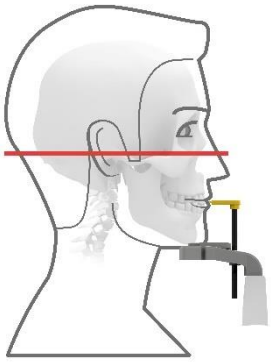
- The light beam (red line) falls in front of the canine (green line).
  - The roots of the incisors fall outside the layer in focus.
  - The front teeth appear blurred and proportionally larger.
  - Move the rotating arm backward (away from the column) to correct.

8.3. Panoramic images - positioning the patient

Patient positioning must be done according to positioning tool selected. The available tools for each exam type are summarized in paragraph §4.9.f Positioning tool – resuming table. Reference laser beams must be positioned according to indication given in previous paragraph, unless otherwise stated.

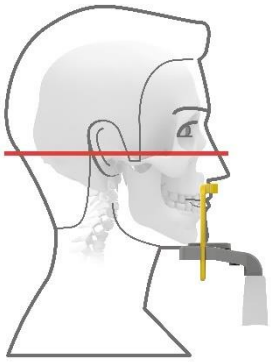
a. Positioning with chin rest

- Bring the carriage to have the bite block or the chin rest slightly higher.
- The patient must stay with lowered shoulders and advanced feet, close to the column, to favor spine stretching at cervical level for a better beam penetration, holding firmly the handles.



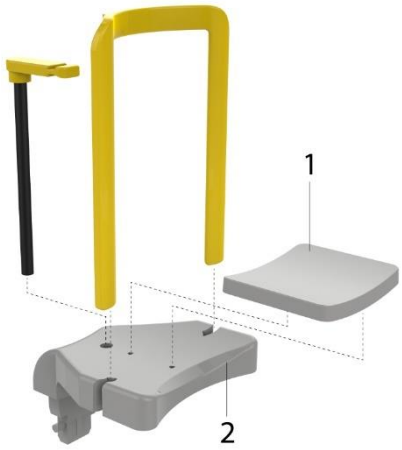
With bite block, and chin rest with bite block

- Have the patient bite into the indentation in the tip of the bite block. Mouth is closed but teeth are not superimposed.



With chin rest and support for patient without anterior teeth

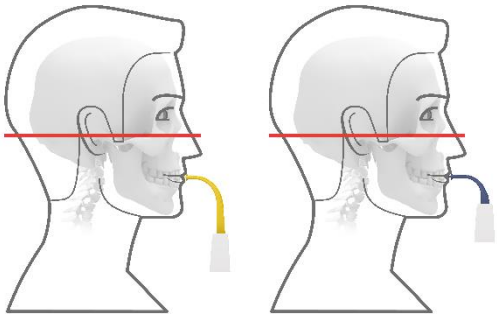
- Make sure the upper and lower jaws are lined up with each other. Use of a cotton roll to prevent superimposition of teeth.



NOTE

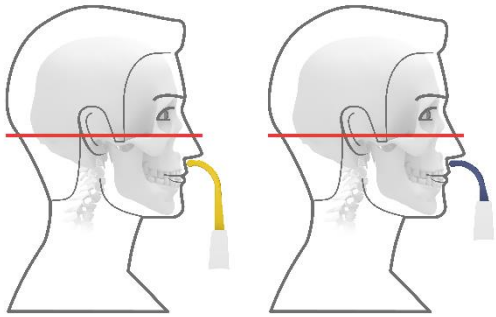
- In case the patient is a child:
  - The use of chin rest is recommended for greater stability.
  - The additional support (1) must be mounted on the chin rest (2).
  - Consider to seat the pediatric patient to have it still and stable.
  - Execute a free run in test mode for the pediatric patient to familiarize before the actual exposure.

b. Positioning with bite block



- Bring the carriage to have the bite block or the chin rest slightly higher.
- The patient must stay with lowered shoulders and advanced feet, close to the column, to favor spine stretching at cervical level for a better beam penetration, holding firmly the handles.
- Have the patient bite into the indentation in the tip of the bite block. Mouth is closed but teeth are not superimposed.

c. Positioning with nasal support

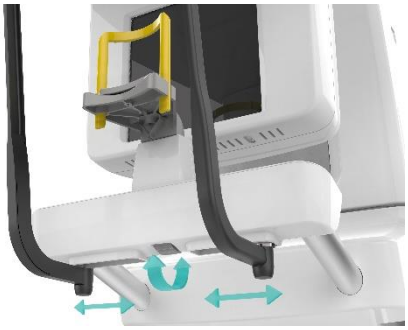


- Instruct the patient to place his subnasal (the base of his nose) against the contact segment.

d. Positioning with temple support

Temple support can be used in order to stabilize the head in the desired position.

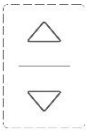
It is possible to remove the 2 temple support by pulling down the 2 bars, which are connected to the main structures through magnets.



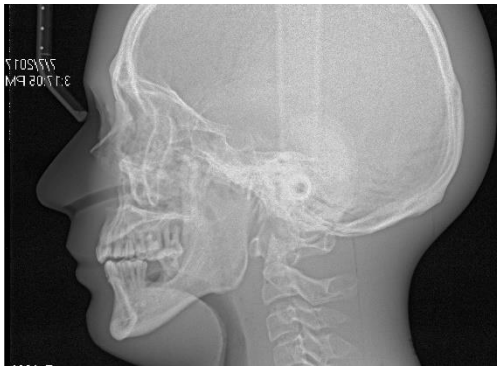
The regulation of the 2 lateral bars (opening / closing) can be done by moving the regulating wheel in the bottom part of the bite holder.

8.4. Cephalometric exams – refererence laser beam

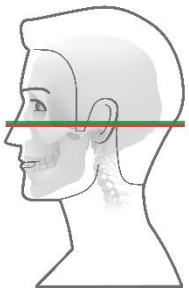
a. Frankfurt Horizontal laser beam

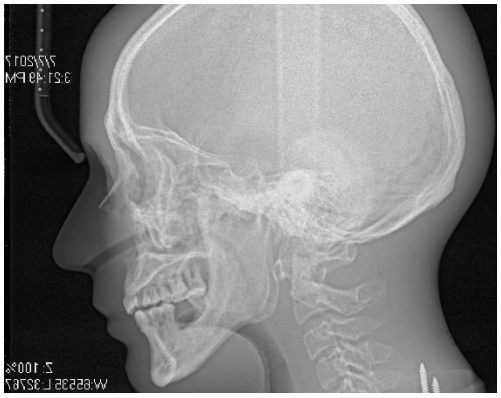


The FH (Frankfurt Horizontal) beam should be falling between the upper edge of the external auditory meatus and the lower edge of the infra-orbital rim.
The height of the FH horizontal beam can be adjusted with a dedicated knob on the right side of the tubehead.
Adjust the height of the unit to have the Frankfurt plane Horizontal (FH) and the cervical vertebrae straight (not bent forward) and stretched.
In the images below the Frankfurt plane on the patient is represented by a green line, the laser beam for Frankfurt plane alignment (emitted by equipment) is represented by a red line.
Fine tune the head inclination for the FH setting by briefly touching the UP or DOWN height adjustment key.
Verify side rotation of the head with reference to the Midsagittal light using the mirror from the back of the patient and correct in case.
Ask the patient to swallow and keep the tongue lightly pressed to the palate.
Eventually recommend to avoid movements till the end of the exposure.

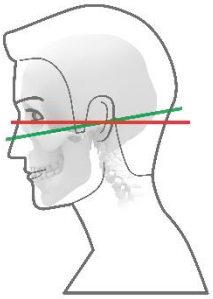


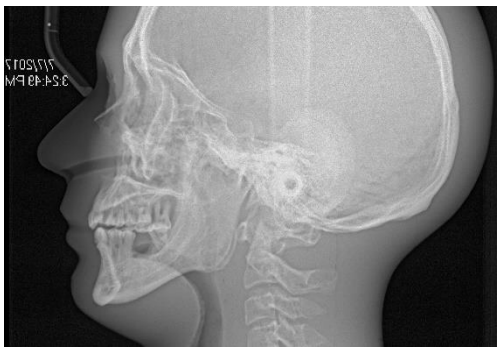
Correct position:
Frankfurt plane is horizontal.



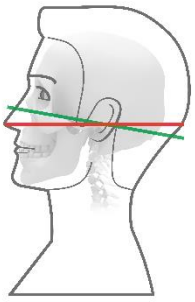


Wrong position:
Frankfurt plane is NOT horizontal, the head is tilted forward.





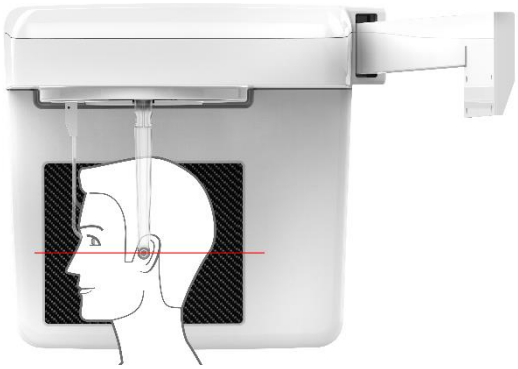
Wrong position:
Frankfurt plane is NOT horizontal, the head is tilted backward.



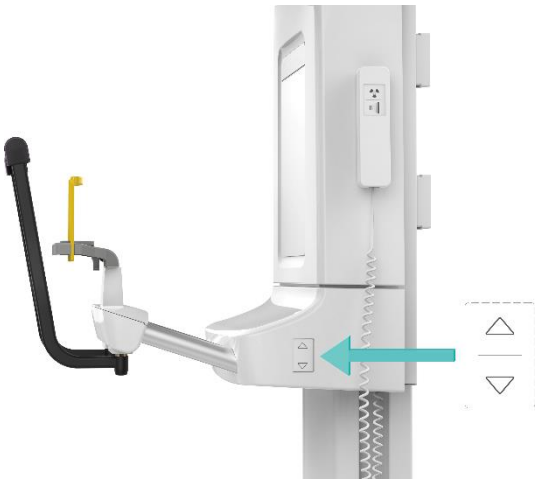
8.5. Cephalometric exams – positioning the patient

A craniostat with auricular rods is available for Latero-Lateral or Antero-Posterior projection and an adjustable nasion support.
Remove the nasion support by acting on the release pin in the case of Antero-Posterior or Carpus projection, as described in the relevant paragraph below.

a. Latero-Lateral program (30x24 / 18x24)



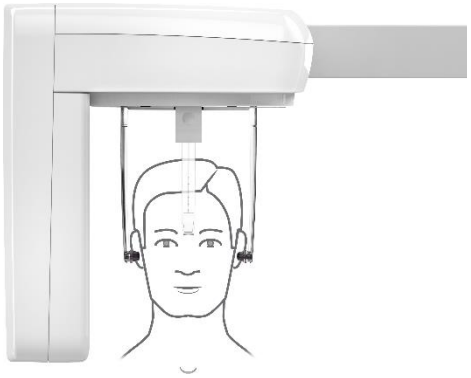
The configuration of the craniostat for Latero-Lateral program is indicated in the side image.
Turn the ear plug holder, in order to have ear plug and nasion as illustrated in side image.
Grasp the holders at the very top with both hands. Push the holders simultaneously outwards as far as they will go.
Insert the protective caps for ear plug.



Bring the unit the proper height using UP or DOWN keys.

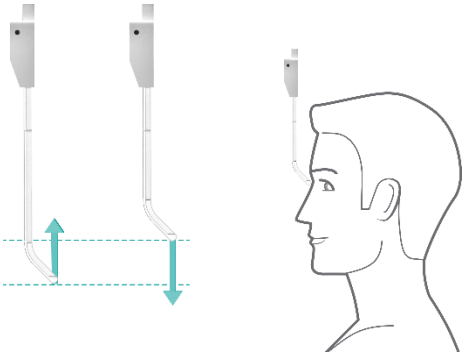
NOTE

The height adjustment motor starts slowly and then increases its speed. Press the height adjustment key until the unit has reached the desired height.
Ask the patient to stand with back to the cephalometric arm, and guide him between the two ear plug holders.



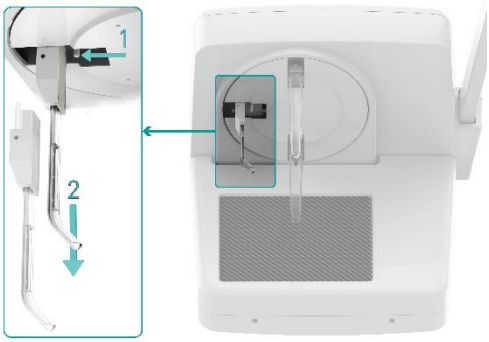
Grasp the ear plug holders at the top and simultaneously slide them together. The ear plugs are positioned on the patient's outer auditory passage.

Check that Frankfurt laser is positioned correctly in correspondence of the Frankfurt plane of the patient.

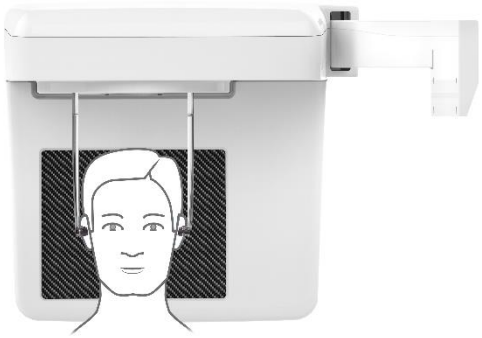


Grasp the plastic part of the nasion support and adjust the nasion support height by bringing it up/down.
The end of nasion support must be in contact with nasion of patient.
Instruct the patient to keep this position until the end of the exam.

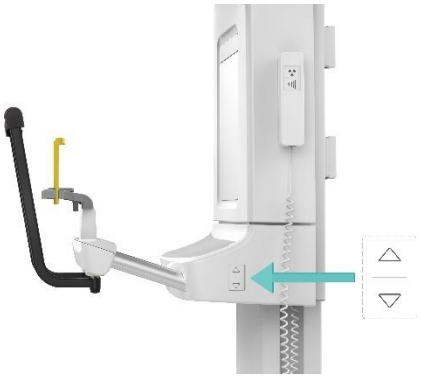
b. Antero-Posterior / Postero-Anterior program (AP/PA)



Remove the nasion support by acting on the release pin as illustrated in the side image.



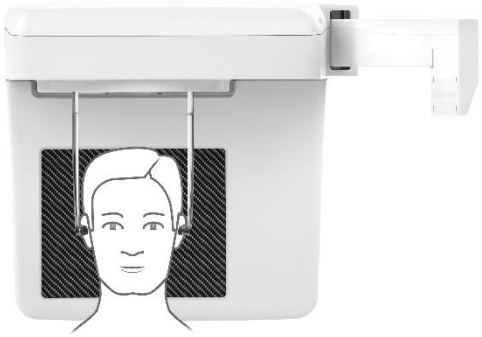
The configuration of the craniostat for Antero-Posterior program is indicated in the side image.
Turn the ear plug holder, in order to have ear plug as illustrated in side image.
Grasp the holders at the very top with both hands. Push the holders simultaneously outwards as far as they will go.
Insert the protective caps for ear plug.



Bring the unit the proper height using UP or DOWN keys.

NOTE

The height adjustment motor starts slowly and then increases its speed. Press the height adjustment key until the unit has reached the desired height.
Ask the patient to stand with back to the cephalometric arm, and guide him between the two ear plug holders.

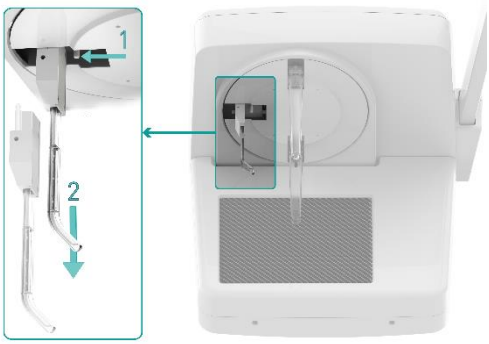


Grasp the ear plug holders at the top and simultaneously slide them together. The ear plugs are positioned on the patient's outer auditory passage.

Instruct the patient to keep this position until the end of the exam.

For postero-anterior exam the patient shall be positioned with the face in front of the sensor (see side image).

c. Carpus program (C4)



Remove the nasion support by acting on the release pin as illustrated in the side image.

Remove the ear plug from the ear plug holder, by unscrewing them. Pay attention not to lose the washer.

Grasp the holders at the very top with both hands. Push the holders simultaneously outwards as far as they will go.

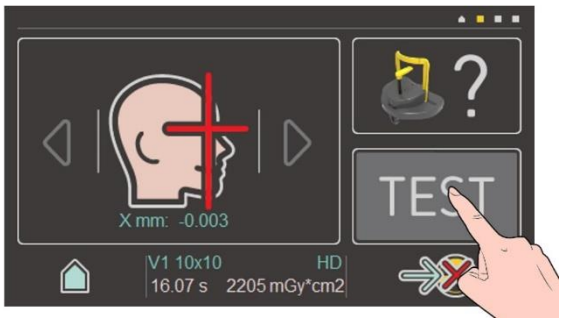
Guide the patient sideways into the unit.

Instruct the patient to place his hand on the carbonium surface of the sensor. Instruct the patient to only press lightly on the carbonium surface in order to not damage it.

Instruct the patient to keep this position until the end of the exam.

9. RELEASING THE EXPOSURE

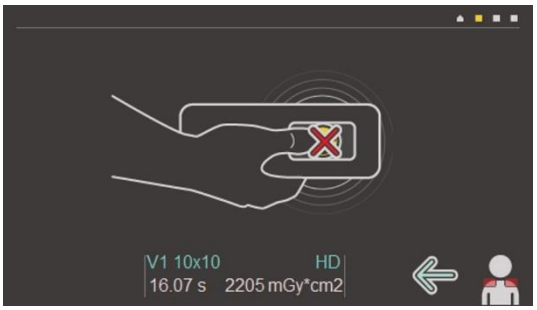
9.1. Test cycle (WITHOUT RADIATION) – Panoramic exams



The test cycle is executed without radiation. The test cycle is used to check that the unit is functioning correctly and to ensure that a complete, uninterrupted cycle is possible.

From the patient positioning page, select the button “Test”.

The icon “Go to start position” shows a red “X”, meaning that X-Ray are inhibited.



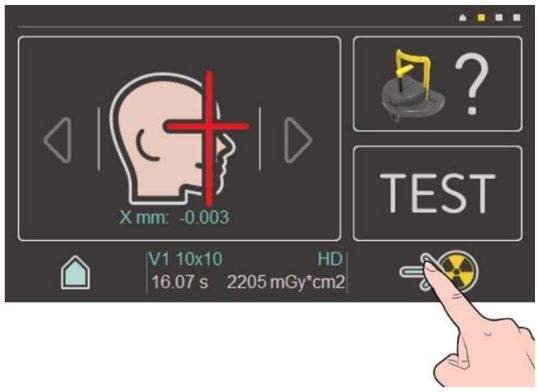
Click on X-Ray button in order to move the carriage from PATIEN ENTRY position to START EXAM POSITION.

Perform the test cycle by keeping pressed the X-Ray button.
During test cycle the ambient light is **blue blinking.**

After the cycle test the carriage is in PATIENT EXIT position. Click on X-Ray button in order to move the carriage to PATIENT ENTRY position.

9.2. Release X-RAY Exposure

a. Panoramic exams

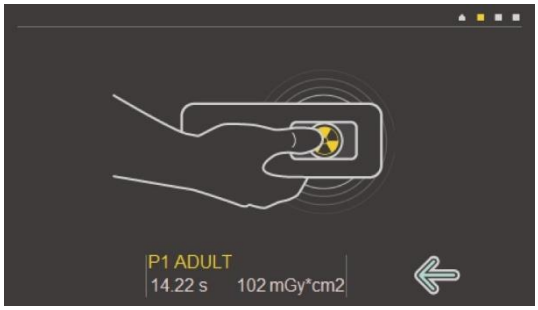


ATTENTION:
Operator: observe the radiation protection guidelines (see paragraph §3.13). Before releasing the exposure always check display for proper exposure data for the patient.

From the patient positioning page, select the icon “Go to Start position”. The carriage will move from the patient entry position to Start Exam Position, ready to start X-Ray exposure.
In alternative, click on the exposure button of the X-Ray button for a short time to reach same carriage position.

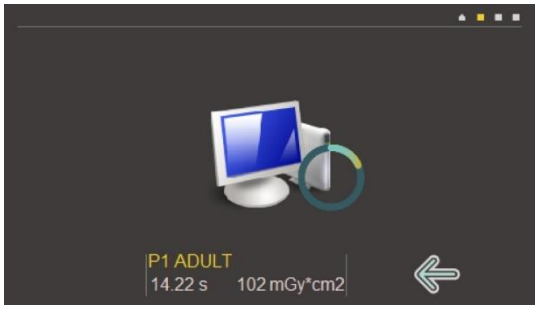

COOLING

NOTE
If the device is not ready for acquisition, the icon and text “Cooling” will be shown in the bottom right part of the touchscreen and it will not be possible to go to Start Exam position. Wait until the “Cooling” icon disappears to bring the carriage in Exam Start Position.



When carriage is in the start position the display shows the side image and ambient light is **green fixed.**

ATTENTION:
Should you need to reposition the patient, the arm has to be moved from the START position back to the PATIENT ENTRY (touch the icon “back” in the bottom right part of the display).
Go to the area designated for the operator behind the patient, three meters away from the column;
If the X-Ray button has been remotely installed, exit the room always keeping an eye on the patient, ready to immediately interrupt radiation if necessary.



NOTE
If the PC is not ready for X-Ray acquisition, the display shows side image. If the case check the status of the PC and be sure that acquisition SW is correctly set (refer to paragraph §7.3 Running image acquisition software on the PC).

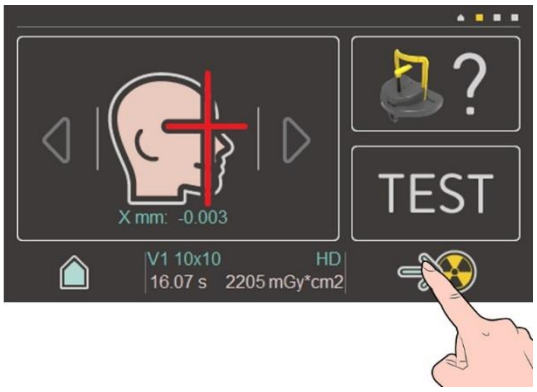
The exposure is released by keeping the exposure key pressed till end of movement.
The rotation movement runs automatically in accordance with the exposure program selected.
During exposure, the display shows the side image and the ambient light is **orange fixed.**

ATTENTION:
Keep pressed the release button until the end of the exposure. Note that radiation may be released several times in some exams during an exposure cycle.

ATTENTION:
For safety reasons the operator can terminate the exposure any time by releasing the exposure button. Premature termination is signaled by an error message (see details in the following).

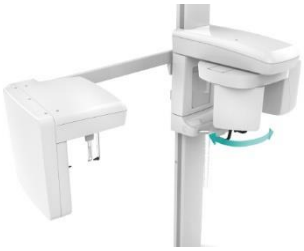
NOTE:
If acquisition is interrupted before it is complete, the entire portion of tissue analyzed will however be shown on the PC together with an error message on the equipment.
If the image is exhaustive, even if partial, the examination does not need to be repeated, thus avoiding subjecting the patient to a further dose of radiation.

b. Cephalometric exams



ATTENTION:
Operator: observe the radiation protection guidelines (see §3.13 Radiation protection guidelines). Before releasing the exposure always check display for proper exposure data for the patient.

From the patient positioning page, select the icon “Go to Start position”. The carriage will move from the patient entry position to Ceph exam Position, ready to start X-Ray exposure.

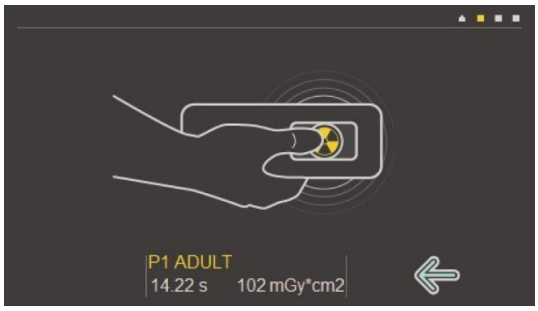


The panoramic sensor will move from its position (in front to the generator) to the new position (90° counterclock wise) which will allow the X-Ray beam to reach the cephalometric sensor.

In alternative, click on the exposure button for a short time to reach same carriage position.

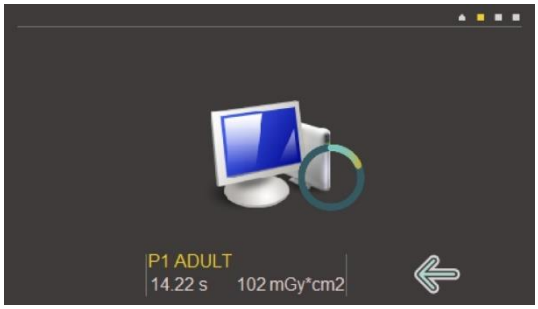
COOLING

NOTE
If the device is not ready for acquisition, the icon and text “Cooling” will be shown in the bottom right part of the touchscreen and it will not be possible to go to Start Exam position. Wait until the “Cooling” icon disappears to bring the carriage in Exam Start Position.



When carriage is in the start position the display shows the side image; ambient light is **green fixed.**

Go to the area designated for the operator behind the patient, three meters away from the column.
If the X-Ray button has been remotely installed, exit the room always keeping an eye on the patient, ready to immediately interrupt radiation if necessary.



NOTE:
If the PC is not ready for X-Ray acquisition, the display shows side image. If the case check the status of the PC and be sure that acquisition SW is correctly set (refer to paragraph §7.3 Running image acquisition software on the PC).

The exposure is released by keeping the exposure key pressed till end of movement.
The rotation movement runs automatically in accordance with the exposure program selected.
During exposure, the display shows the side image and the ambient light is **orange fixed.**

ATTENTION:
Take care not to let go of the exposure release button prematurely. Press the release button until the end of the exposure. Note that radiation may be released several times during an exposure cycle.

ATTENTION:
For safety reasons the operator can terminate the exposure any time by releasing the exposure switch. Premature termination is signaled by an error message (see details in the following).

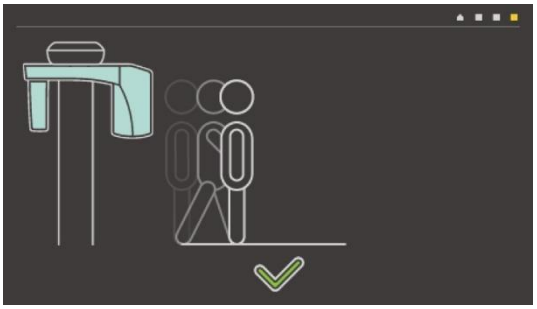
NOTE:
If acquisition is interrupted before it is complete, the entire portion of tissue analyzed will however be shown on the PC together with an error message on the equipment (valid only for panoramic and cephalometric exposure).
If the image is exhaustive, even if partial, the examination does not need to be repeated, thus avoiding subjecting the patient to a further dose of radiation.

9.3. Premature termination

Premature termination is signaled by an error message (Error 12: X-Ray exposure aborted before end of the exam) on the touch screen and by **red fixed** ambient light.

ATTENTION:
If the patient has been partially exposed, part of the radiograph will be available on PC. Examination may have to be repeated.

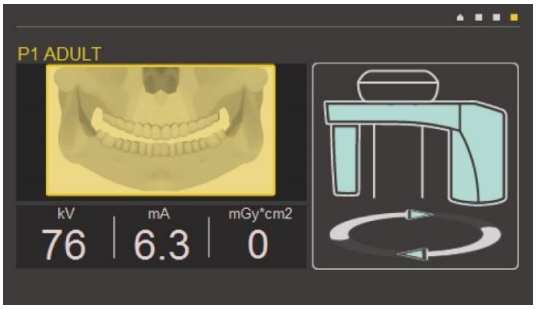
9.4. After the exposure



At the end of the X-Ray exposure the unit comes to a complete stop, in PATIENT EXIT position.

Open the temple support (optional) and have the patient stepping out.
The display shows the side image and the ambient light is blue fixed
Only after the patient left, move the arm to PATIENT ENTRY position for next exposure using by clicking on the X-Ray Button for short time.
The resulting X-Ray exam will be available on the PC in a short time.

9.5. Dose area product values



The value of the dose by area product (DAP) in mGy·cm^2 is indicated on display after each X-Ray exposure.

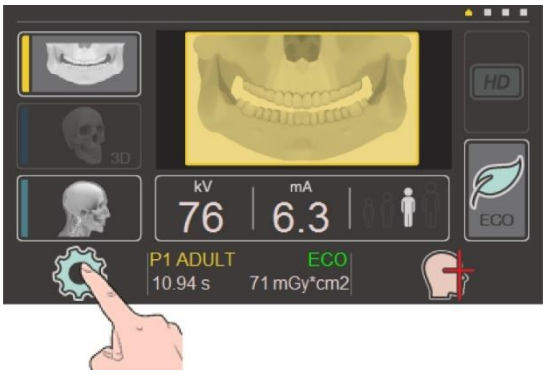
Do acknowledge the DAP value with RETURN or EXPOSURE key to proceed.

DAP computations can be enabled or disabled via service function.

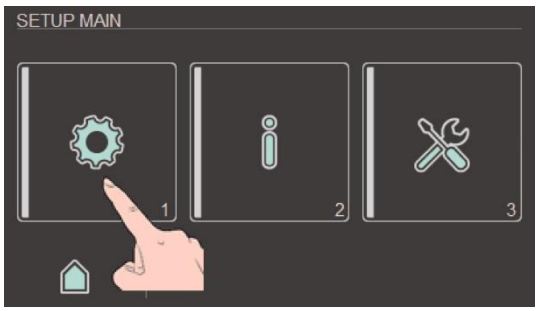
The DAP table showing the dose area product for all the examinations and all the settable kV / mA combinations is available, in digital format, on request.

The doses could be measured by using an appropriate instrument (SOLIDOSE DIGITAL DOSIMETER) which is suitably maintained and is calibrated annually.

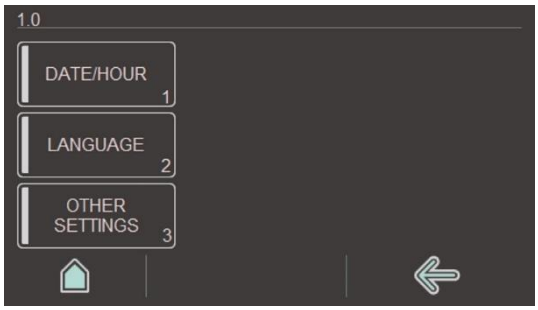
10. SETTINGS



By pressing the “user settings” icon it is possible to access to the setup menu.

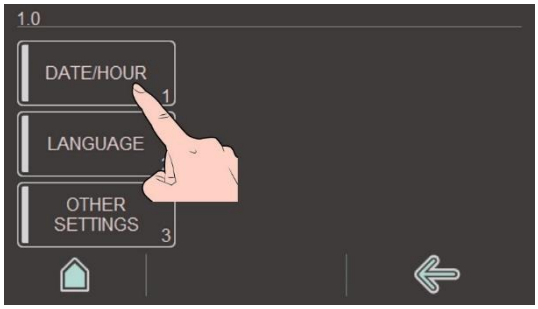


From the Setup main page, click on the “user settings” icon to have access to the settings page.



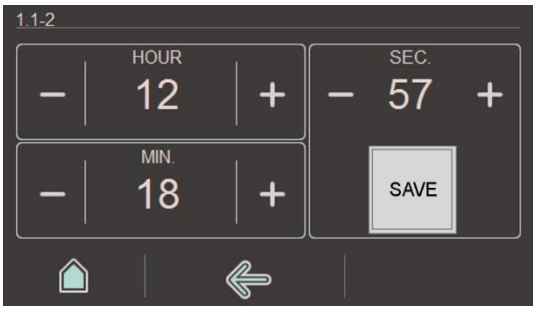
From this page it is possible to set date/time and change the language of the device.

10.1. Date and time



Click on the button “Date / Hour” to enter into this menu.

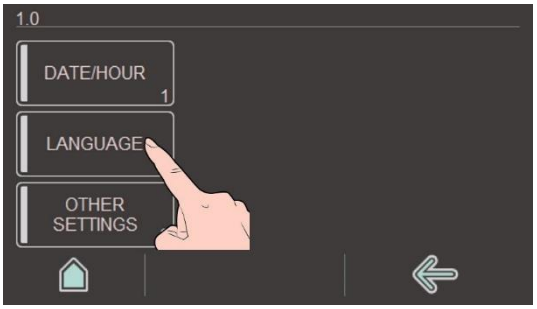
Click on button “EDIT”.
Adjust the date of the device by pressing the “+” and “–” button on the related sections.
Click on save button to save changes or click on the right arrow to adjust the time of the device.



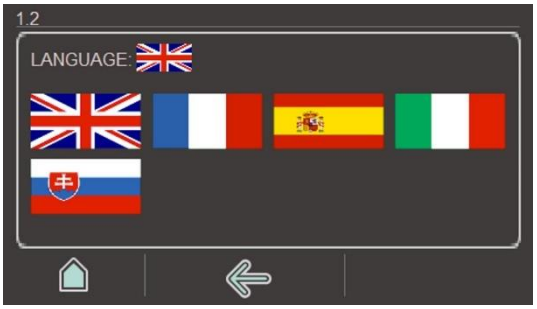
Adjust the time of the device by pressing the “+” and “–” button on the related sections.
Click on button “SAVE” to save changes to date and/or time.

Click on the left arrow to come back to the “user settings” page or click on icon “home” to go to “home page”.

10.2. Language

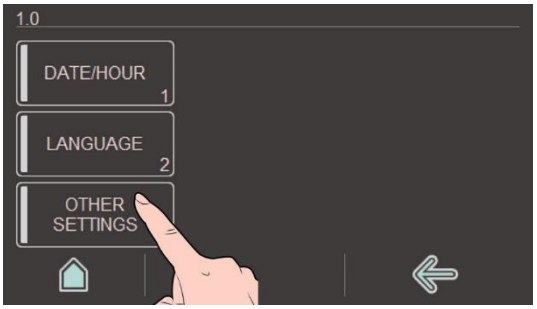


Click on the button “Language” to enter into this menu.

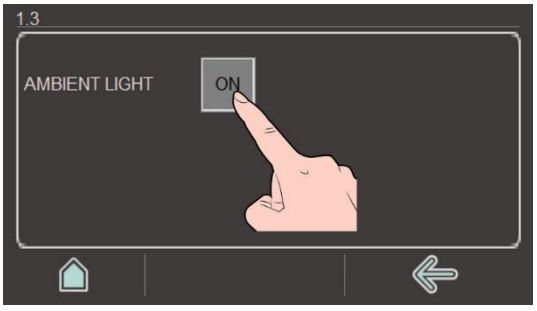


It is possible to select one of the available languages by pressing the corresponding flag.
Once touched the desired flag icon the system switches to the corresponding language and returns to SETTING HOME PAGE.

10.3. Other settings

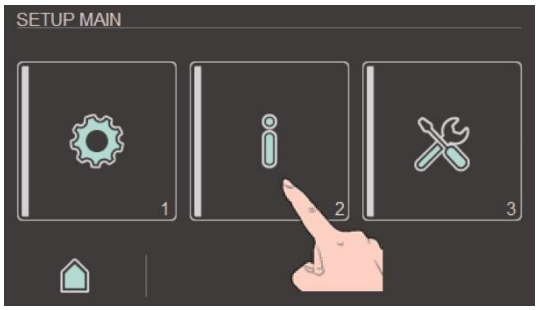


Click on the button “Other settings” to enter into this menu.



Click on button ON/OFF to enable / disable the ambient light.

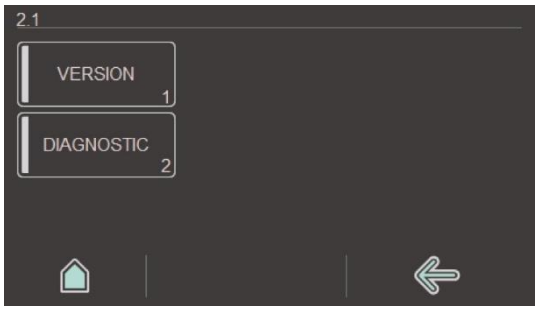
11. SYSTEM INFORMATION



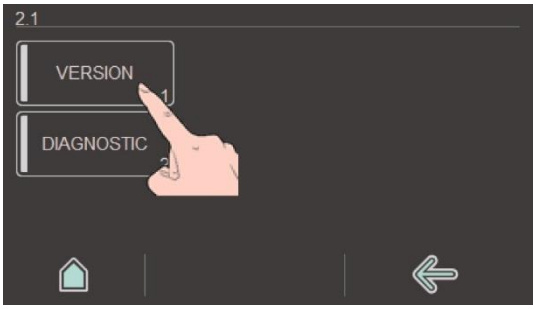
By pressing the icon “info” it is possible to access to the info menu.
This menu allows to have access to information related to the device or executed exams.

11.1. Device information

By pressing the icon on the left it is possible to access the menu containing the information of the specific unit (S/N, FW release, touch-screen FW release, etc.).



11.1.1.Version

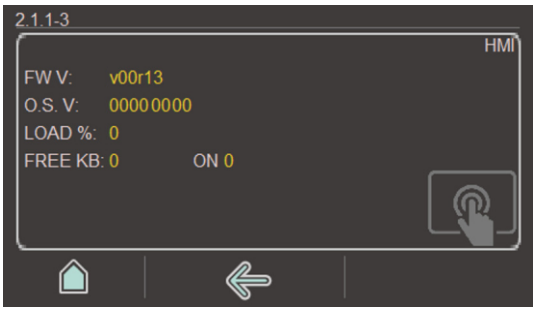


By clicking on the button “Version” it is possible to view the version information of the specific unit.

Use the arrows to move from one page to another.

First page shows model and serial number of equipment.

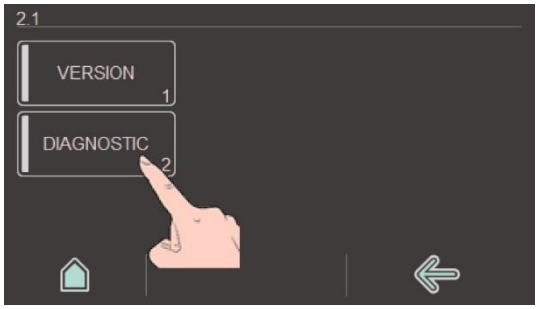
Second page shows information about CPU version.



Third page shows information about touchscreen version.

Click on icon “home” to go to “home page”.

11.1.2.Diagnostic



By clicking on the button “Diagnostic” it is possible to view some information regarding basic diagnostic of equipment.

Use the arrows to move from one page to another.

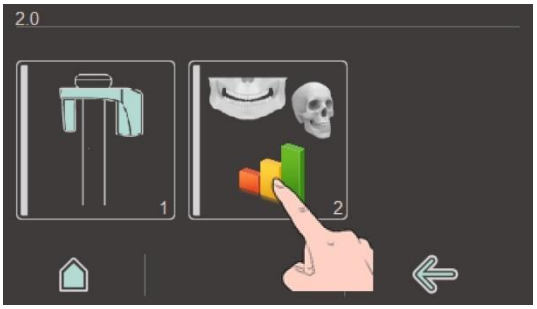
First page shows main voltages of equipment.

Second page shows status of the feedback signals for kV and mA signal.

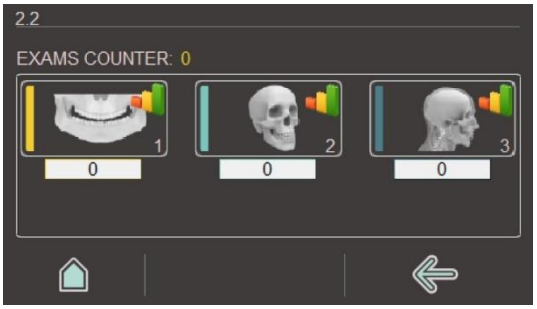
Third page shows status of the input signals.

Page 4 shows status of the output signals.

11.2. Exam information

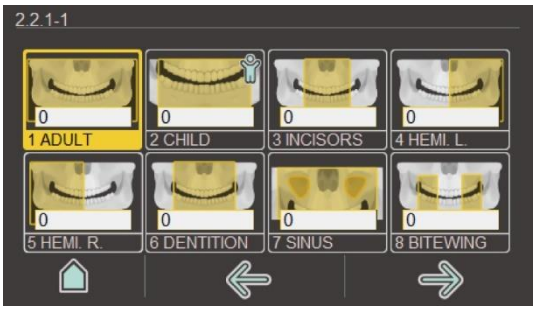


By pressing the icon on the right it is possible to view the statistics about the exams performed.



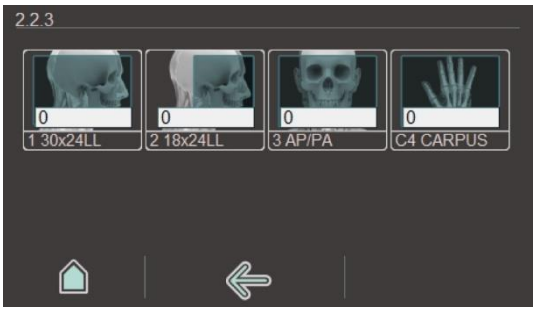
The statistics are divided into groups: Panoramics and Cephalometry (see the two icons in the side image).
The total number of exams, for each group, is displayed.

By clicking in each of the icons it is possible to see statistics related to each exam.



The total number of performed images is displayed near to related exam icon.
Use the arrows to see statistics related to other exams.

In the side image the statistics of Panoramic exams are shown.



The image on side shows the number of cephalometric exams performed, from C1 to C4.

12. INSPECTION AND MAINTENANCE

12.1. Care of the surfaces

ATTENTION:
Always disconnect the system from the mains by unplugging the plug from the wall socket before starting cleaning / disinfecting procedures.

a. Cleaning

Use a mild soap to remove fingerprints or other traces of dirt being careful not to let liquid substances penetrate the machine.
The plastic covers can be cleaned with a soft cloth and a mild detergent.
The touchscreen can be cleaned with a microfiber cloth (eventually slightly damp).

ATTENTION:
Electrical components of the system can be damaged by liquids.
Do not spray or pour any liquids into the ventilation slots or X-Ray release button.
First spray the liquid onto a cleaning cloth. Then wipe the ventilation slots or manual release button with the cleaning cloth. Make sure that no liquids run along the surface and into the ventilation slots or the manual release button.

b. Disinfecting

Only the external surfaces may be disinfected with chemical disinfectants. Use only disinfectants that comply with the valid requirements of the respective national regulatory body or whose bactericidal, fungicidal and virucidal properties have been verifiably tested and approved accordingly.

Cleaning and care agents may contain aggressive ingredients. Unsuitable cleaning and care agents are detrimental to health and attack the surface of the unit.
Do NOT use: Substances containing phenol, peracetic acid, peroxide or any other oxygen-splitting agents, sodium hypochlorite or iodine-splitting agents.

c. Sterilization

ATTENTION:
Infections can be transmitted from patient to patient. Positioning tools that are not sterilized correctly can cause illness in patients.

All positioning tools that are suitable for sterilization should only be sterilized in an autoclave at 134 °C (273° F), with at least 3 minutes holding time and at 2.1 bar (30.5 psi) overpressure. Other positioning tools must be disinfected (see point b above).
In addition, always use hygienic protective sleeves as suggested in paragraph “§4.10 Hygienic protective sleeves”.
The hygienic protective sleeves are single use devices. Unsterile hygienic protective sleeves can cause illness in patients. Replace the hygienic protective sleeves after each patient.

CAN BE STERILIZED	CAN NOT BE STERILIZED
	
- Chin rest - Additional support for children - Yellow and blue bite block - Yellow and blue nasal support	- Auricular rods and nasion of craniostat

12.2. Maintenance

To keep your system in top shape, consult regular maintenance checks with your distributor. This will ensure that your DURAY 2D / DURAY 2D Ceph will be updated, in good condition and performing according to highest standards.

Inspection and maintenance work must be performed at regular intervals to protect the safety and health of patients, users and third parties.

As the operator, you should ensure the safety and reliability of your system by performing maintenance on it at regular intervals (at least once annually) or having this work performed by your dental dealership.

In addition to the scheduled annual inspection by the user or persons contracted to perform this, a maintenance inspection must be performed by the service technician after 4, 7, 10 years and then every two years.

At regular intervals, however at least once a year, the quality image must be evaluated.

12.3. Dismantling and disposal

a. Dismantling and reinstallation

When dismantling and reinstalling the system, proceed according to the installation instructions for new installations in order to guarantee its proper functioning and stability.
The X-ray unit must be recalibrated whenever structural alterations in the area surrounding the X-ray room or new installations have been performed.

b. Disposal

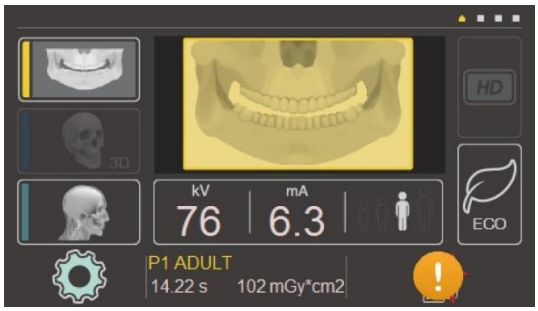
In accordance with Directive 2012/19/EU and national disposal regulations regarding old electrical and electronic devices, please be advised that such items must be disposed of in a special way within the European Union (EU). These regulations require environmental friendly usage / disposal of old electrical and electronic devices. Such items must not be disposed of as domestic refuse. This has been expressed using the icon of the “crossed out trash can” since March 24, 2006, amongst other methods.
For country-specific information on disposal, contact your local dental dealers. The X-ray tube assembly for this product contains an X-ray tube with a potential implosion hazard, a small amount of beryllium, a lead lining and mineral oil.

13. MESSAGES

13.1. Warning messages

During device functioning, auxiliary messages are displayed for certain actions, which call for the user to perform a specific action. These auxiliary messages are listed below.

Warning Code #	Message	Action required
WARN1	Battery low voltage.	Contact technical service.
WARN2	Free	Free
WARN3	Free	Free
WARN4	CPU Clock not working / stopped.	The Real Time Clock is stopped. Go to section “Setup Main – Date/Hour”, eventually adjust the time/date.
WARN5	Calibration files missing on PC.	Report to technical service.
WARN6	Upgrade CPU O.S.	CPU O.S. needs to be upgraded. Contact technical service.
WARN7	Missing CPU Data Backup.	CPU Backup never done. Contact technical service.



If a warning message is present, the icon “Warning” is shown in the bottom-right part of the home page of the control panel, as illustrated in the side image.

By clicking on the icon “Warning” it is possible to see the list of the warning messages.

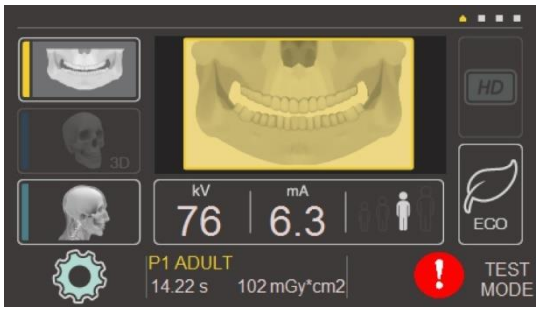
For each warning, please follow the instruction given in the table above.

By clicking on the icon “Home” it is possible to go to the home page.
The icon “Warning” will be shown in the bottom right part of the control panel until the situation which caused the warning is resolved.

13.2. Error messages

The error messages are displayed on the device in the form of an error code.
The display does not show any plain text error output. The error codes are structured according to the following pattern:

Error Code #	Message	Action required
ERR1	kV reference signal out of range.	Switch the unit off. Report to technical service.
ERR2	mA reference signal out of range.	Switch the unit off. Report to technical service.
ERR3	Carriage rotation encoder failure.	Switch the unit off. Report to technical service.
ERR4	Carriage displacement encoder failure.	Switch the unit off. Report to technical service.
ERR5	Carriage rotation sensor failure.	Switch the unit off. Report to technical service.
ERR6	Carriage displacement sensor failure.	Switch the unit off. Report to technical service.
ERR7	Main collimator plate displacement sensor failure.	Switch the unit off. Report to technical service.
ERR8	Cut-off collimator plate displacement sensor failure.	Switch the unit off. Report to technical service.
ERR9	Panoramic X-Ray rotation sensor group fault.	Switch the unit off. Report to technical service.
ERR10	Tube-head temperature exceeding limit.	Wait for tube cool down.
ERR11	Overhead limit position error.	Switch the unit off. Report to technical service.
ERR12	X-Ray exposure aborted before end of the exam.	Restart if termination was requested by the operator. Call for technical service if termination was spontaneous.
ERR13	38 V DC supply out of range.	Switch the unit off. Report to technical service.
ERR14	24 V DC supply out of range.	Switch the unit off. Report to technical service.
ERR15	15 V DC supply out of range.	Switch the unit off. Report to technical service.
ERR16	5 V DC supply out of range.	Switch the unit off. Report to technical service.
ERR17	High voltage failure.	Switch the unit off. Report to technical service
ERR18	User-unit collision.	Switch the unit off. Report to technical service.
ERR19	Missing trigger signal.	Switch the unit off. Report to technical service.
ERR20	X-Ray missing.	Switch the unit off. Report to technical service.
ERR21	No tube current.	Switch the unit off. Report to technical service.
ERR22	Sensor Boot mode.	Switch the unit off. Report to technical service.
ERR23	Filament current out of range.	Switch the unit off. Report to technical service.
ERR25	Tubehead thermal sensor failure.	Switch the unit off. Report to technical service.
ERR26	Control unit backup battery error.	Switch the unit off. Report to technical service.
ERR30	PC - Unit communication failure during exam.	Switch the unit off. Report to technical service.
ERR32	Control unit hardware fault.	Switch the unit off. Report to technical service.



If an error message is present, the icon “Error” is shown in the bottom-right part of the control panel, as illustrated in the side image.

By click on the red icon “Error” it is possible to see the list of the error messages.

To solve each error, please follow the instructions given in the table above.

By clicking on the icon “Confirm” the Alarm will be reset and the icon “Error” will not be shown in the home page.

By clicking on the icon “Home” it is possible to go to the home page. The icon “Error” will be shown in the bottom right part of the control panel until the situation which caused the error is resolved.

14. TECHNICAL DESCRIPTION

Equipment classification	IEC: Class I, type B equipment with Class I LASER sources (IEC 60825-1).

This product complies with the following standards:

IEC 60601-1:2005+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-3:2008+A1:2013	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
IEC 60601-2-63:2012+A1:2017	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.
IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices.
IEC 60825-1:2014	Safety of laser products. Part 1: Equipment classification, requirements and user's guide.
IEC 62304:2006+A1:2015	Medical device software – Software life cycle processes.
US FDA 21CFR1020.30	Performance Standards for Ionizing Radiation Emitting Products: Diagnostic X-ray Systems and their major Components.
US FDA 21CFR1020.31	Performance Standards for Ionizing Radiation Emitting Products: Radiographic Equipment.
US FDA 21CFR1040.10	Performance Standard for Light Emitting Products: Laser products.

Manufactured by	**BEYES DENTAL CANADA Inc.** 23-595 Middlefield Road Toronto, Ontario, M1V 3S2 Canada
Nominal line voltage	230 V ± 10%, 115 V ± 10%
Nominal line frequency	50/60 Hz
Nominal current absorption	MAX 10 A @ 230 V, MAX 16 A @ 115 V
Line fuse	T8 A 250 V for 230 V version; T15 A 250 V for 115 V version
Mains Resistance	≤ 0.8 ohm at 230 V, ≤ 0.4 ohm at 115 V
Rating	1450 W
Curve form of high voltage	High frequency multi-pulse, ripple ≤ 4%
Tube Voltage	60 - 86 kV ± 5%, constant potential
Tube Current	2.5 - 10 mA ± 10%, direct current (DC)
Focus size	0.5 IEC 60336
Total Filtration	> 2.5 mm Al/70 kV IEC 60522
Focus marking	Dot mark on generator's cover
Maximum beam size at image receptor (theoretical)	Pan mode: 142 x 4 mm^2 Cephalometric mode: 290 x 230 mm^2
Loading factor for leakage radiation	1.25 mA @ 85 kV
Leakage Radiation	≤ 1 mGy/h
Cool down pause	Variable pause depending on requested tube load
Maximum duty cycle	1/8
Column height	222 cm/87" (holes for wall plate at 210 cm/82.7" from floor)
Maximum height	229 cm/90.2"
Vertical displacement	92 cm/36.2", da 90 a 182 cm (da 35 a 71.7")
Vertical Movement	Motorized control with slow and quick motion
Weight	81 Kg (overhead) 28 Kg (cephalometric arm) 28 Kg (column)

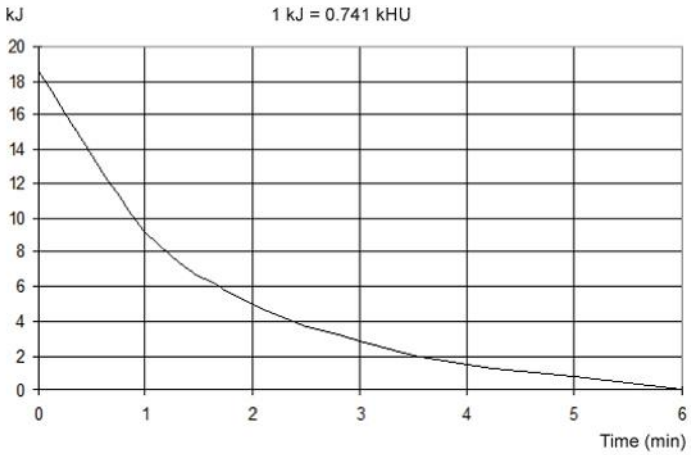
Self standing base	Optional on request
Panoramic Projections	P1 ADULT FULL P2 CHILD FULL P3 ADULT PARTIAL FRONT P4 ADULT PARTIAL LEFT P5 ADULT PARTIAL RIGHT P6 ADULT DENTITION P7 SINUSES P8 BITEWING P9 TMJ OPEN/CLOSED MOUTH
Cephalometric exams	C1 LL (Latero-Lateral) LARGE VIEW C2 LL (Latero-Lateral) SMALL VIEW C3 AP (Antero-Posterior) VIEW C4 CEPH Carpus
Anatomical Selection	4 Patient size levels: Small, Medium, Large, Extra Large
kV setting	14 positions in 2 kV steps: from 60 to 86 kV
mA setting	7 positions according to R'10 scale: 2.5, 3.2, 4, 5, 6.3, 8, 10 mA
mAs setting (Only for Ceph)	14 positions (10mA constant): 2, 2.5, 3.2, 4, 5, 6.3, 8, 10, 12, 16, 20, 25, 32, 40
Source-Image Receptor distance	Pan side: 52.02 cm Caphalometric side: 165.8 cm
Reproduction scale	Pan image at receptor's plane is approximately 29% higher than real size (vertical magnification on adult standard profile 1.29:1 approximately) Cephalometric images at receptor's plane is approximately 10% higher than real size (vertical magnification is approximately 1.10:1)
Computer requirements	• Operating system: minimum windows 8 64 bit system (10 recommended) • CPU: Minimum Amd Ryzen 3 3.5 GHz CPU • RAM: 8 GB DDR4 minimum • Hard disk: minimum 200 GB of free space • Drive: Minimum USB 3.0 gigabit port • Video card: At least AMD Radeon video • Display adapter monitor: minimum 0.25 dot pitch; • Contrast ratio 450:1, resolution 1024 x 768

Factory programmed technical parameter values:

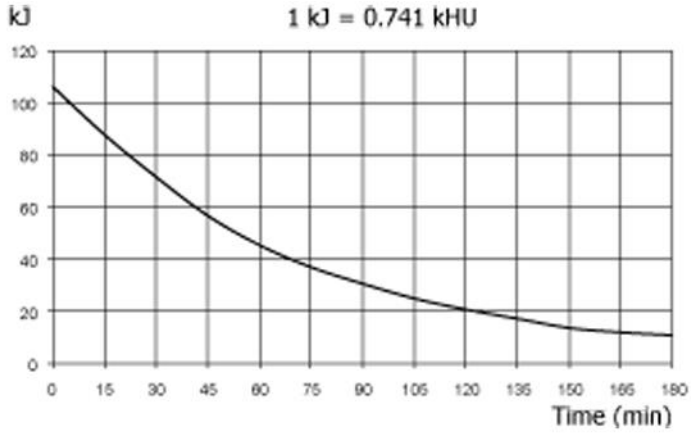
		Program	Factory programmed values							
			Size S		Size M		Size L		Size XL	
			kV	mA	kV	mA	kV	mA	kV	mA
Panoramic exams	P1	ADULT FULL	70	4	74	6.3	78	6.3	80	8
	P3	ADULT PARTIAL FRONT								
	P4	ADULT PARTIAL LEFT								
	P5	ADULT PARTIAL RIGHT								
	P6	ADULT DENTITION								
	P7	SINUSES								
	P8	BITEWING								
	P9	TMJ OPEN/CLOSED MOUTH								
	P2	CHILD FULL	62	3.2	64	4	68	6.3	70	8
		Program	**Size S**		**Size M**		**Size L**		**Size XL**	
			kV	**mAs**	**kV**	**mAs**	**kV**	**mAs**	**kV**	**mAs**
Ceph exams	C1	LL (Latero-Lateral) LARGE VIEW	82	4	82	5	84	5	86	6.3
	C2	LL (Latero-Lateral) SMALL VIEW	82	4	82	5	84	5	86	6.3
	C3	AP (Antero-Posterior) VIEW	82	4	82	5	84	5	86	6.3
	C4	CEPH Carpus	64	5	64	5	64	5	64	5

Aiming lights:	
Type	Class I LASER beam
Wavelength	650 nm
Output Power	< 0.15 mW at 100 mm
Reference planes	Median Sagittal Vertical, canine and Frankfurt Horizontal planes
Pulse duration	60 s
Image receptor Pan:	
Type	CMOS sensor
Active area	15 x 0.6 cm
Effective pixel size	99 micron
Spatial resolution	5 lpp/mm
A/D conversion	14 bits
Computer interface	2 Ethernet cables
Resulting image format Pano	About 3000x1500 pixels
Image receptor Ceph:	
Type	CsI flat panel
Active area	24.4 x 30.7 cm
Pizel size	120 µm
Spatial resolution	3.1 lpp/mm
A/D conversion	16 bits
Computer interface	1 Ethernet cable
Environmental data	
Operating conditions	Temperature: from 10 to 40 °C Humidity: from 30 to 75% Pressure: from700 to 1060 hPa
Transport and storage	Temperature: from –10 to +50 °C Humidity: from 20 to 80% Pressure: from 500 to 1060 hPa

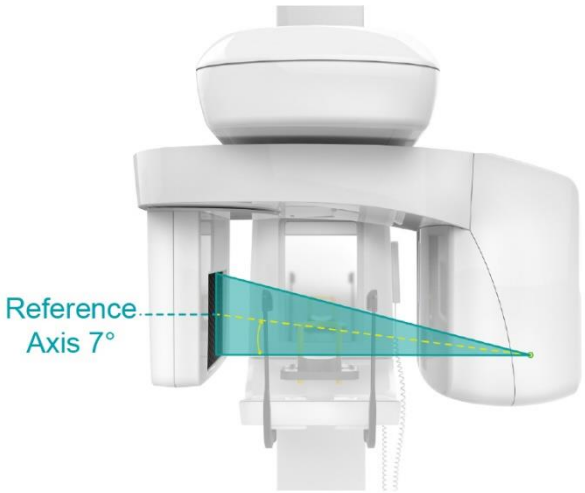
Cooling curve
X-ray tube



Cooling curve
Tube housing assembly



Reference axis



15. ELECTROMAGNETIC COMPATIBILITY

15.1. Electromagnetic emission

The DURAY 2D / DURAY 2D Ceph is suitable for use in the specified electromagnetic environment. The purchaser or user of the DURAY 2D / DURAY 2D Ceph should assure that it is used in an electromagnetic environment as described below:

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1 Class B	This DURAY 2D uses RF energy only for its internal function. Therefore the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Not applicable	This DURAY 2D is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 11	Group 1	

15.2. Electromagnetic immunity

The DURAY 2D is suitable for use in the specified electromagnetic environment. The purchaser or user of the DURAY 2D should assure that it is used in an electromagnetic environment as described below:

Immunity test	EN 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2/4/8/15 kV air	IEC 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material. The relative humidity should be at least 30%.
Radiated electromagnetic field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the DURAY 2D including cables. Minimum distance 30 cm
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3 m	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	0.5/1 kV differential mode 0.5/1/2 kV common mode	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 150 kHz to 80 MHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the DURAY 2D including cables. Minimum distance 30 cm.
Voltage dips. short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Un for 0.5 cycle 0 % Un for 1 cycle 70 % Un for 25 cycles 0 % Un for 5 s	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DURAY 2D requires continued operation during power mains interruptions. It is recommended that the DURAY 2D be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the states in which he or she practices to use or order the use of this device.

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File #: ENI070R1
10.04.24