



Gendex Orthoralix® 9200 DDE



Operator's Manual

This manual in English is the original version.
Due to the constant engagement of Gendex to the
technical improvement of its products, all data and
information in this Operator's Manual are subject to
change without prior notice.

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Introduction

The Gendex Orthoralix 9200 DDE is a system for X-ray images acquisition in real time and by a computer. It allows to realize all the radiographic projections which are of greater interest for dentist, surgeon and maxillo-facial radiologist.

A new CCD sensor (Charge Coupled Device) makes possible the image acquisition in real time and with the best diagnostic quality.

Gendex Vixwin software creates a simple interface giving immediate access to different functions: capture, vision, analysis and eventual treatment of the radiographic images.

The system for patient positioning is provided with an efficient optical centering system (with three lasers) and with a full motorized ultrasensitive moving system; it ensures a careful positioning of the patient.

A friendly control panel with functional keys (it has a simple use and an easy access) is controlled by a microprocessor and shows the used technical factors (kV, mA, s) and positioning data (mm) in order to make easy the reproducibility of the tests.

Near the control panel, on the right side of the column, there is a reference pictographic guide: it indicates the options/actions necessary to perform a Standard Panoramic Exposure.

1.1 Graphic methods

Three graphic methods are used in this manual:

Normal For information about the machine employment.



This icon indicates the notes.



This icon indicates the security warnings.



This manual is intended to assist the user in the safe and efficient operation of the equipment described. The equipment must be used in accordance with the procedures contained in the manual and must not be used for purposes other than those which are described herein.

The equipment should only be used by persons having recognized qualifications and, if relevant, having adequate training on the particular equipment, especially regarding protective measures such as radiation protection.

It is the responsibility of the user to ensure that existing legal regulations regarding installation of the equipment are observed. Moreover, the legal regulations regarding operation of the equipment must be observed.

Incorrect operation or failure of the user to maintain the equipment in accordance with the maintenance schedule, relieves the manufacturer or his agent from all the responsibilities for consequent non-compliance, damage, injury, defect and/or other malfunction.

Safety procedures

Aims

- Indicating standards and safety regulations
- Observing the main safety procedures in the interest of patient and user

Contents

- **Introduction**
General description of the Orthoralix 9200 DDE system.
- **Standards and Regulations**
Regulations and standards, which Orthoralix 9200 DDE is in compliance with.
- **Safety procedures**
Instructions to observe in the interest of patient and user.

Standards and Regulations

Orthoralix 9200 DDE unit is designed to meet the following standards:

- IEC 60601-1 (1988) (amendment 1991 and 1995)
- IEC 60601-1-4 (1996) (amendment 1999)
- IEC 60601-2-7 (1998)
- IEC 60601-2-28 (1993)
- CSA-C22.2 n. 114
- UL 187

Radiation protection:

- IEC 60601-1-3 (1994)

Electro-magnetic interference:

- IEC 60601-1-2 Ed. 2 2001-09

Lasers:

- IEC 60825-1 (2001)

CE 0051 The CE symbol ensures that the product herein described meets the provisions of European Council Directive 93/42 concerning medical devices.

Gendex Dental System, Cusano Milanino Italy, is the manufacturer and dealer in accordance with European Council Directive for medical devices 93/42/CEE.

Classification

Orthoralix 9200 DDE is a Class I and Type B electromedical X-ray equipment according to IEC 60601-1.

Orthoralix 9200 DDE is classified in class IIB according to the European Council Directive for medical devices 93/42/CEE.

Explanation of symbols

The following symbols are used in the equipment and/or in this manual:



Equipment classified as Type B by IEC 60601.1



Consult written instructions in this Operator's Manual.



General X-ray radiation warning



General laser radiation warning



Warning in this Operator's Manual



Notes in this Operator's Manual



Beware of moving mechanical parts.

Mandatory reporting according to the European Directive for 93/42 medical devices:

In order to fulfil the obligations foreseen by the CE marking, the user is obliged to report any accident involving the medical device; any alterations to its features or in its performance – including insufficient user's instructions – which could cause death, injuries or health hazards to patient and/or operator, to the competent Health Authorities. Such reporting must also be promptly notified to the manufacturer or his agent, in order to permit the fulfillment of the obligations foreseen for said manufacturer in the a.m. European Directive.

Safety Procedures



In the interest of the safety of patient and user, the following points should be observed:

General

The equipment must never be used if it shows any electrical, mechanical or radiation defects whatsoever. As all electromedical devices, Orthoralix 9200 DDE requires correct installation, handling, maintenance and servicing in order to ensure safe and efficient operation. The unit features continuous operation (stand-by) with intermittent loading (X-rays).

Refer to the Service Manual for the recommended programmed maintenance activities. Modifications and additions to the equipment must be carried out only by Gendex personnel or third parties that are expressly authorized by Gendex, and must comply with the applicable legal requirements as well as with the generally accepted technical regulations.

The tubehead contains mineral insulating oil. Such oil is potentially harmful in case of ingestion or contact with skin or mucosa. In case of a defect or fault, an oil leak can occur. Avoid direct contact with the oil and do not inhale its vapors.

In case of minor leaks, the oil can be wiped away with a dry cloth, wearing protective gloves.



Radiation protection

Orthoralix 9200 DDE implements various built-in measures to prevent excess radiation (leakage, secondary and scattered) from reaching the patient, the operator, and other persons.

It is the responsibility of the qualified Radiation Protection Inspector to ensure that the proper measures are taken to prevent undue radiation exposure to personnel and to the public at large.

All personnel in the examination room must exercise radiation safety procedures.

To protect the patient against unnecessary radiation, other accessories can be used whenever necessary, in addition to those provided on the Orthoralix 9200 DDE (for example, filters).

Care must be taken, however, that these accessories do not interfere with the proper radiographic operation of the apparatus.

For instance, lead shield collars should be avoided as they may block the useful X-ray beam.

The following points must be always be observed:

Maintain a safety distance of at least 2m from the X-ray tube during exposure;

All persons not directly involved with the patient should be outside the examination room, or behind lead or leadglass shielding, during exposure;

A film badge should be carried for personal monitoring.

Electrical safety

Only qualified service personnel should be authorized to remove the covers of, or otherwise obtain access to, parts of the equipment that include line voltage powered circuits, included the provision for an additional security earth terminal which permits an equipotential connection.

The equipment may only be used in rooms which comply with the relevant national and/or international legislation and recommendations (e.g. CE and others) concerning electrical safety in rooms used for medical purposes.

Always disconnect or switch off the equipment before cleaning or disinfecting.

No water or any other liquid should be allowed to enter the equipment, as they could cause short-circuits and corrosion.

Mechanical Safety

Due care must be taken when the system is used to ensure that neither patient nor personnel reach into the equipment or get their clothing caught in it.

The equipment contains mechanical components such as cables, rubber belts and gears, which are subject to operational wear and tear.

To prevent any risk of injury to patient and operator due to components which no longer comply to normal safety standards (e.g. worn cables subject to movement), the equipment must be subject to regular technical testing and maintenance.



Explosion Safety

This equipment is not suitable for use in the presence of flammable gases or vapors. Certain disinfectants vaporize and form explosive mixtures. If such disinfectants are used, the vapors must be left to disperse before the equipment is powered-up again.

Positioning safety

During Panoramic procedures, the patient is positioned facing the positioning mirror in front of him. On reset position, the DMU will be at his right and the tubehead at his left.

Once the exposure has been performed, positioning references (L and R) will be displayed on the acquired image:

- L (Left) to indicate the left side of the patient's mouth,
- R (Right) to indicate the right side of the patient's mouth.

On symmetrical images both L and R are displayed, on half-exposure images only one letter (L or R), indicating the side of the mouth, will be displayed. No letter is placed in correspondence of the centre of the mouth.

It's strongly recommended to pay attention to the L and R letters to identify the anatomical side and to avoid any mistake during the its evaluation.

During Cephalometric symmetrical projections, neither L nor R is displayed on the image, due to the impossibility for the system to detect if the patient is placed in Antero-Posterior or Postero-Anterior position. It's user responsibility to pay attention to the anatomical side.

Laser Safety

This equipment is designed in accordance with IEC 60825-1:2001.

The position of laser sources are emphasised by mean of the following warning labels (black on yellow).



Although compliant to the safety rules, it is a good practice for the operator to avoid to expose his eyes and patient's eyes directly to the LASER beam.

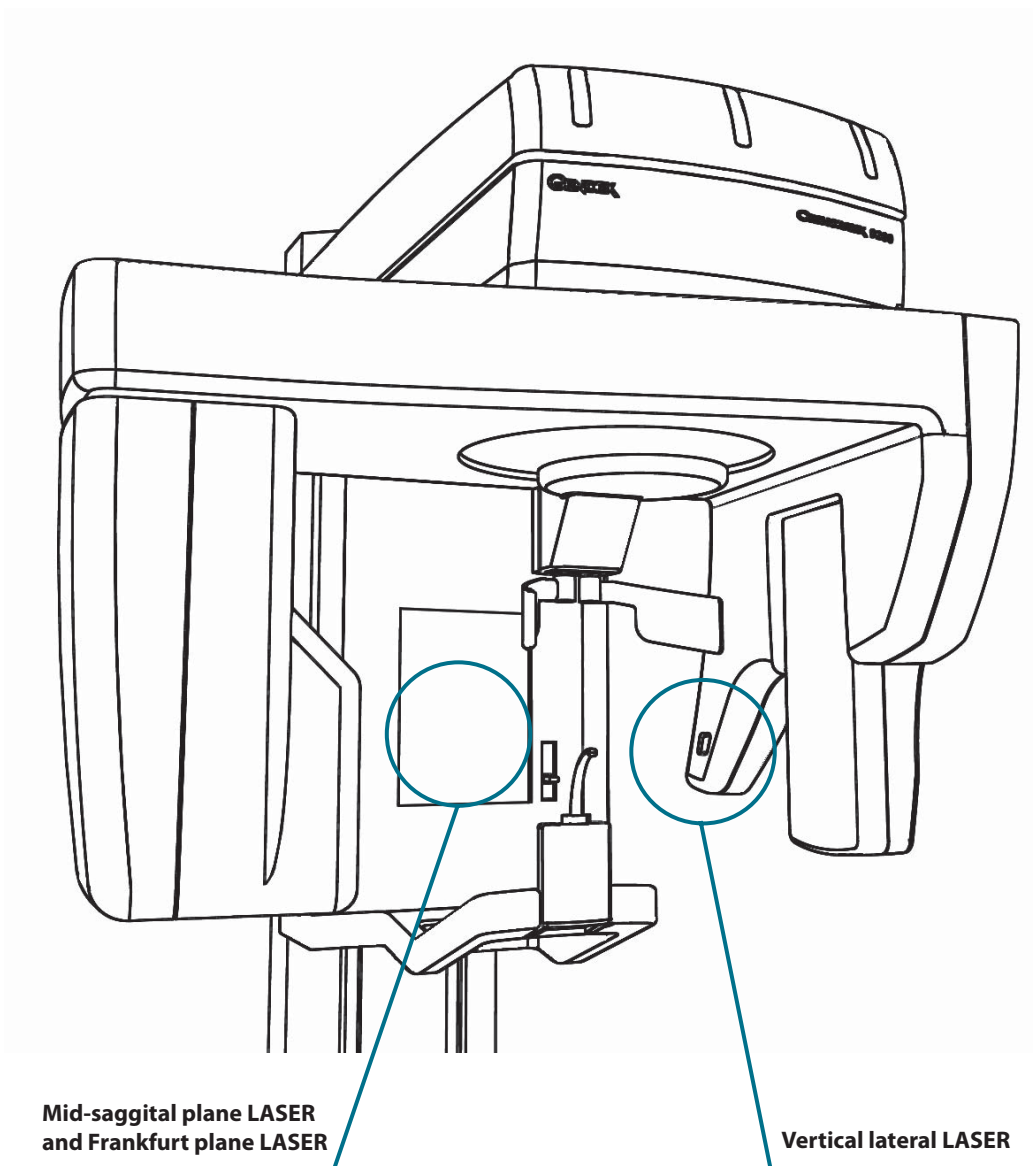
Location of lasers apertures:

Two lasers for the lighting of the mid-sagittal plane (vertical laser beam) and the lighting of the Frankfurt plane (horizontal laser beam) are positioned behind the mirror.

The laser for the lighting of the roots of the lateral incisors (vertical lateral laser beam) is positioned on the rotating arm, on the left of the sensor.



Use of controls or adjustments or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.



Characteristics and installation

Aims

- Indication of the functional characteristics of the panoramic radiography system.
- Correct installation and configuration of the parts necessary for the regular performance of Orthoralix 9200 DDE.

Contents

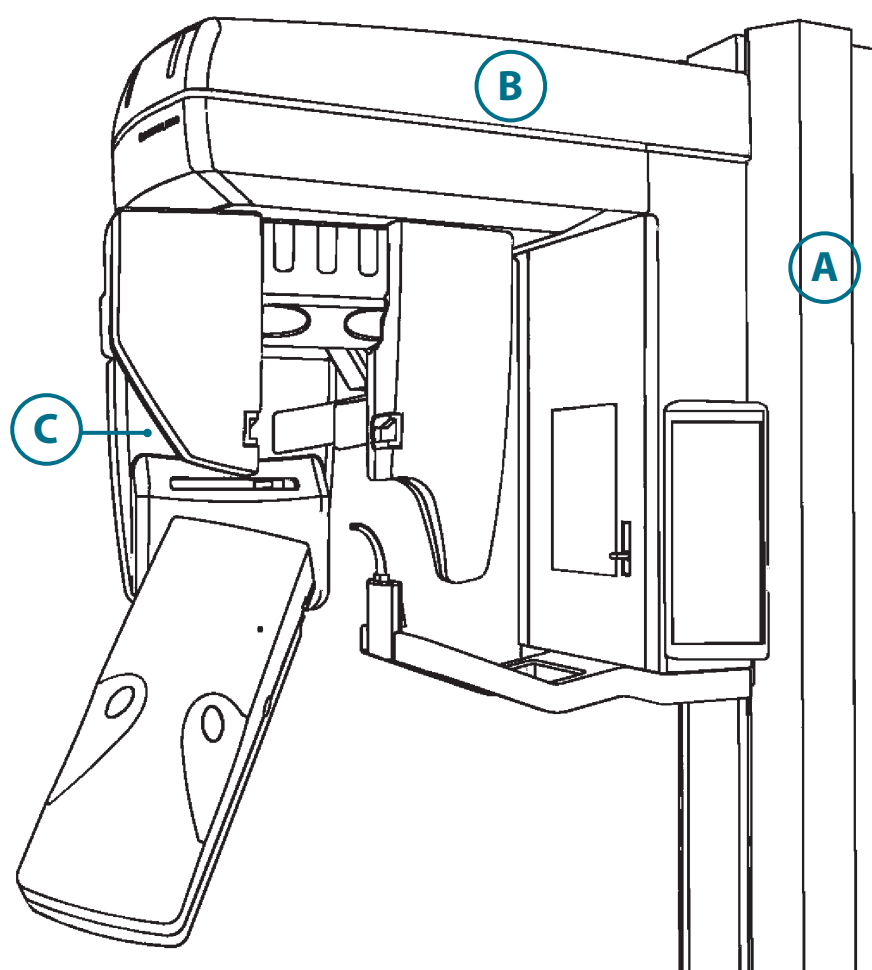
- **General description**
Main characteristics and programs of panoramic radiology available in the Orthoralix 9200 DDE system.
- **Preliminary procedures**
Operations necessary for the correct configuration of the external parts, Personal Computer, in connection with Orthoralix 9200 DDE.
- **Installation of driver and software**
Instructions for installation, configuration and examination of driver and software necessary to obtain the digital radiographic image.

Panoramic system

General Description

4

Orthoralix 9200 DDE is a system for panoramic radiography of the dento-maxillo-facial area.

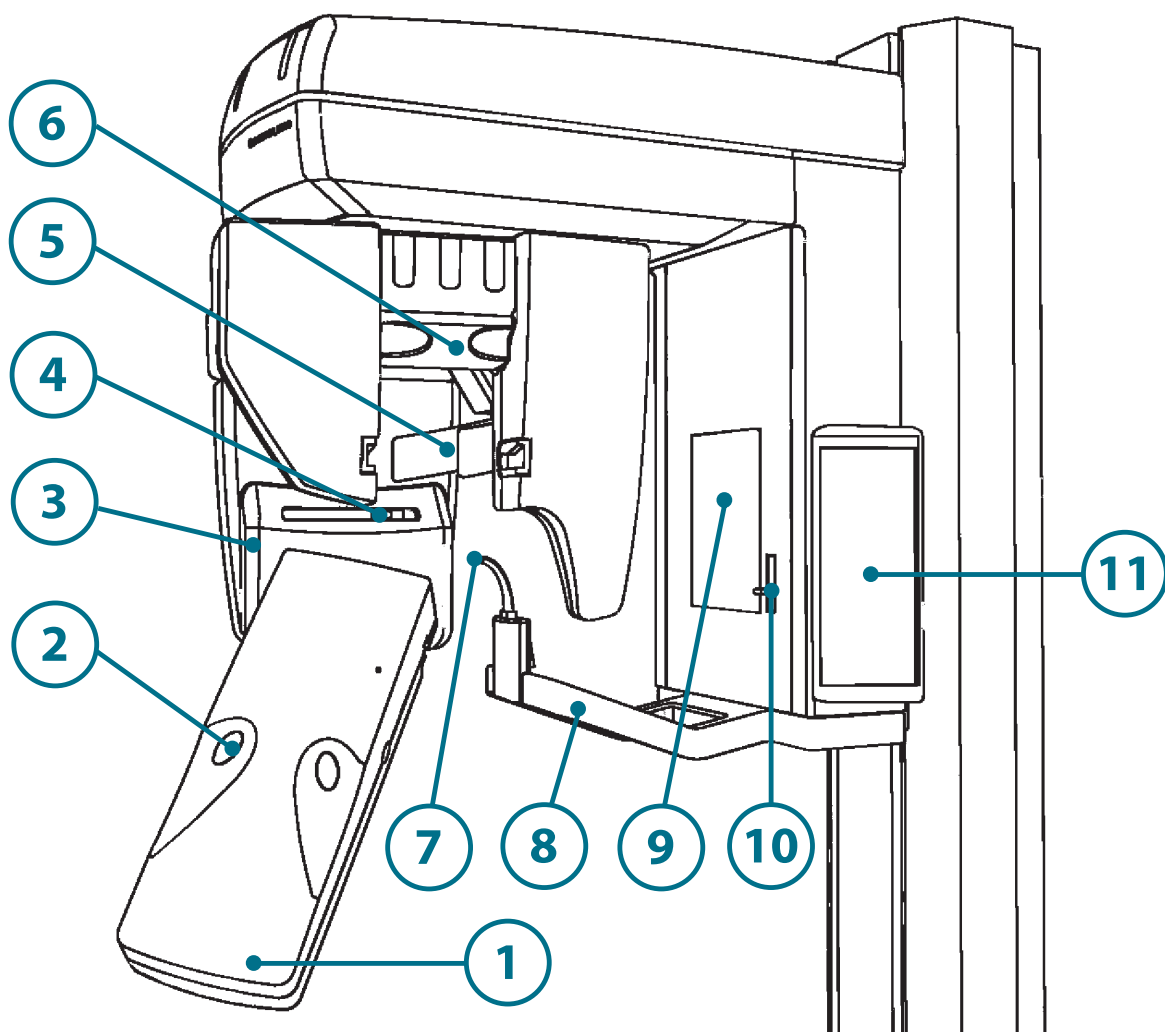


The system is made by:

- A** A counter-balanced motorized column to be fixed to wall, or to an optional free standing base;
- B** A motorized carriage, with patient positioning system, technical factors and radiographic projection geometry;
- C** An X-ray tubehead, with DC power supply to the X-ray tube via electronic converter;

System components:

- 1** Digital module unit (DMU)
- 2** DMU release buttons
- 3** X-ray tubehead
- 4** Primary collimator
- 5** Motorized head-rest
- 6** DMU housing
- 7** Bite block (can be replaced with the chin rest)
- 8** Handgrip
- 9** Positioning mirror
- 10** Frankfurt plane laser setting
- 11** Main keyboard



Exposure automatism

During a panoramic exposure, the X-ray tube and digital sensor are moving on a trajectory around the patient head. The beam from the X-ray tube is collimated by a slit diaphragm.

All movements for the radiographic panoramic projection are performed by three independent, microprocessor controlled stepper motors. Various projection geometries for panoramic exposures and for different diagnostic purposes are possible.

Patient positioning is simple, accurate and consistent thanks to the motorized headrest, the motorized displacement of the X-ray generator assembly while the patient stands still, the indication of the positioning data and various other available positioning devices.

Thanks to the robotized movement technology, various exposure modalities with different projection geometry can be executed.

The digital radiographic images are displayed by the monitor of a personal computer connected with Orthoralix 9200 DDE.

For common panoramic radiography the Standard Pan modality should be selected. With this projection program the entire dental and alveolar region as well as the rami and the TMJ can be depicted.

In addition to the Standard Pan modality the following projections are available:

Available basic programs:

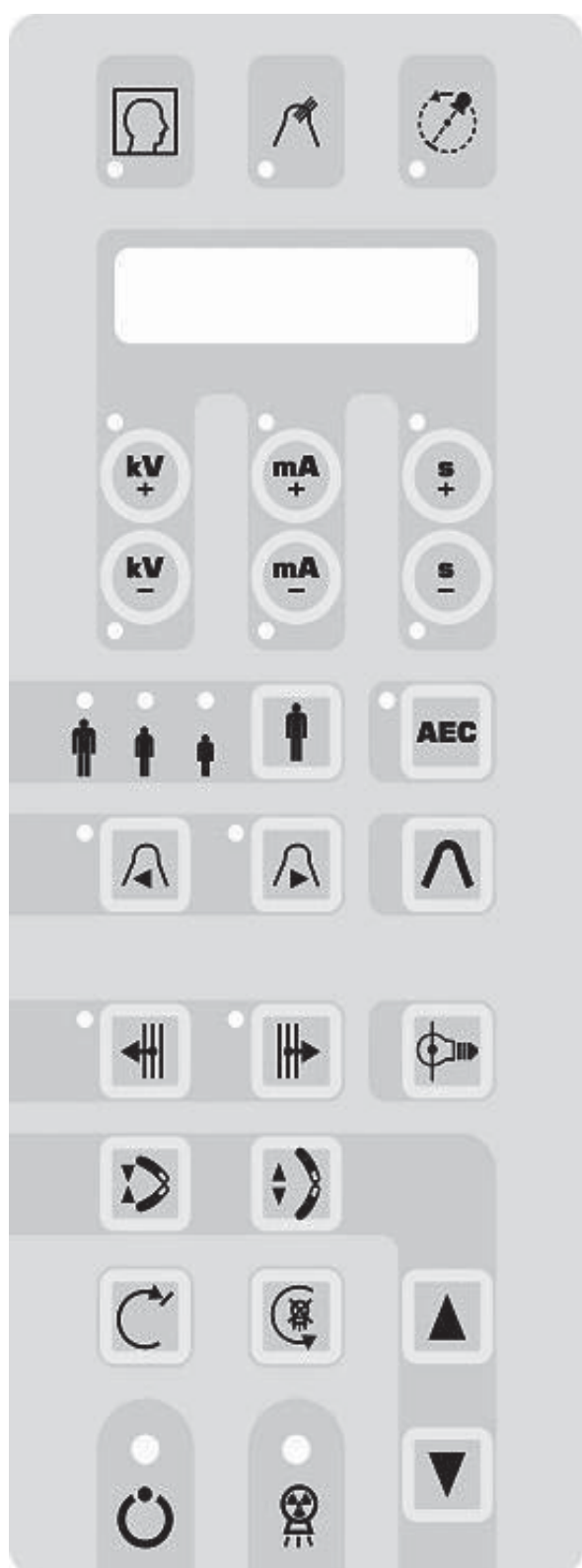
- Standard Panoramic
- Child Panoramic
- Orthogonal Dentition
- Half-panoramic
- Lateral TMJ
- Frontal dentition




















Dento-Maxillo-facial projections programs:

- Frontal TMJ
- Frontal sinus
- Lateral sinus
- Half-orthogonal dentition

Control panel

Each keystroke is associated with one and only one function and operation: the operator, therefore, does not use more than one key to initiate a given function. Where applicable, each keystroke is confirmed by an associated LED light and/or a buzzer. Each key is labeled with a pictogram related to the performed function.



-  Cephalography mode
-  Transcan mode
-  The unit is in Panoramic mode
- +kV** Increase kV for the next exposure
- kV** Decrease kV for the next exposure
- +mA** Increase mA for the next exposure
- mA** Decrease mA for the next exposure
- +s** Increase exposure time (s) for the next exposure (disabled)
- s** Decrease exposure time (s) for the next exposure (disabled)
-  Patient size indicator (small, medium, large)
-  Patient size selector
- AEC** AEC mode
-  Select the available projection modalities
-  Select the available projection modalities
-  Select the Standard Panoramic Program
-  Move backward the motorized X-ray carriage
-  Move forward the motorized X-ray carriage
-  Switch on the timed centering lasers
-  Close the headrest
-  Open the headrest
-  Reset position, moves the motorized X-ray carriage into start position
-  Dummy run, execute a simulation of the selected program by performing the movements without X-ray emission
-  Move the X-ray carriage up
-  The equipment is ready for an X-ray emission
-  X-rays are being emitted
-  Move the X-ray carriage down

5.1 AEC MODE

For a number of the panoramic projections it is possible to activate the Automatic Exposure Control (AEC) mode.

AEC is a real-time control of the dosage necessary to obtain the correct exposure of the radiography, varying the preimposed technical factors for the selected patient type (kV).

The AEC function uses the detector sensor to measure residual dosage during the scanning and allows real time correction of technical factors in order to ensure optimum balance between contrast and image blackening.

At the end of the exposure, and in case of any correction during the exposure time, the operator can verify the maximum value reached by pressing either the **kV+** (LED on) key in case of an increment or the **kV-** (LED on) key in case of a reduction. The value will be indicated on the control panel.

The correction limit of the "AEC" mode is set at **+/- 6kV from the selected value.**

In case the system will automatically disable the "AEC" mode (display of the "AEC DISACTIVATED" message in the control panel), the system will use the preset values selected for patient size.

The possibility to manually change the technical factors for exposure is inhibited when the AEC function is activated.

The AEC mode can be selected for the following projections:

- Standard panoramic
- Child Panoramic
- Orthogonal dentition
- Lateral TMJ
- Frontal sinus
- Ceph LL H
- Ceph LL MAX
- Ceph LL V
- Ceph AP/PA V
- Ceph AP/PA MAX

Recovery of images

In case of PC crash during an exposure, Orthoralix 9200 DDE gives the possibility to recover the acquired image.

In this case simply restart the PC without switching off the Orthoralix.

Then restart the PC and from the tab in the OCX panel ask to “resend last image”.

This feature allows the user to avoid the administration of any useless additional dose to the patient, increasing in this way the high level of safety of the Orthoralix system.

Preliminary procedures

Before positioning the patient and executing radiographic exposure some preliminary operations may be necessary.

In particular, it is important to configure a correct combination between Orthoralix 9200 DDE and Personal Computer.

Therefore, the other electrically connected parts (Computer and optional peripherals) shall be located outside from the patient area, and should be in conformity with IEC 950 and CE 89/336 Directive.

7.1 Peculiarities of Personal Computer

- Processor: Pentium III or higher (500MHz min).
- 256 MB RAM recommended.
- Video card/graphic controller for Super-VGA 4 MB mode RAM screen.
- Ethernet card 10/100 base T.
- CD-ROM driver.
- Hard disk.
- Keyboard, mouse.
- Multisync colored monitor with high resolution: 800x600 min. or 1024x768
- Operating system: Microsoft Windows 98, Windows 2000, Windows ME, Windows XP.



Video card

For a correct radiographic image a video mode with at least 1024x768 pixels x 16Millions of colors (24bit, True color) should be chosen, the related scale has 256 gray-levels (If a mode with 15 or 16 bit is chosen, the gray-levels are 32).

For the S-VGA 1024x728 mode it is necessary to have a video card with 4 MB RAM, the installation and the use of the software provided with the installed video card or those available in Microsoft Windows.

Monitor

To ensure a correct view of the images, it is recommended a multisync colored monitor. This monitor can give a resolution in S-VGA mode of 640 x 480, 800 x 600 and 1024x768 pixels. Such resolution is related to the mode selected by the video card. A 15" or 17"screen is recommended, with dot-pitch not higher than 0.28 mm. Ensure to correctly adjust contrast and brightness.



Hard disk

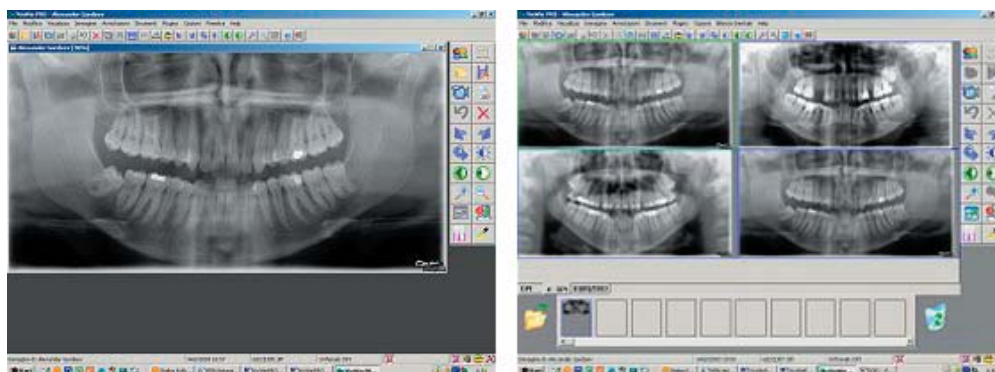
The choice of the hard disk depends on the number and dimension of images to store. Hard disk with 8GB is usually able to satisfy user's requirements. However, for data security it is better to duplicate the stored information and diagnostic images.

Back up (security copy in order to recover the lost data)

It is recommended to often duplicate image and-patient data (for instance weekly) on a removable device for a general storage (e.g. removable hard disk, CD-Rom, etc.). You can use the back-up functions provided in the Microsoft software, or copy data and images directly on the removable storage device.

7.2 Application software

The Orthoralix 9200 DDE system is provided with the Gendex software VixWin.



VixWin is an application software program; it operates into Microsoft Windows for diagnostic imaging in dento-maxillo-facial area.

Its main function is the control of capture, vision, eventual treatment^(*), analysis and storage of radiographic dental images obtained by CCD sensors (Charge Coupled Device); in addition, it supplies these functions for various other diagnostic images, for instance for those obtained by radiographic films (panoramic and others) and by a back-lit scanner, phosphor plates obtained by Gendex DenOptix or colored images realized by an endoral or extraoral dental camera (for example AcuCam Concept IV).

VixWin includes functions to store images in permanent storage devices, such as hard disks, floppy disk, writable cd-rom, which are local or in common with other points of LAN (Local Area Network).

The functionality is in accordance with the standard graphic interface of Microsoft Windows. The functions can be selected by mouse and/or keyboard.

VixWin can be also interfaced by an external database software, for instance a program for the global administration of the odontologic office. This interface is based on a protocol DDE client-server (DDE, Dynamic Data Exchange is a standard protocol of Microsoft Windows for data-exchange among different programs).

In this case, capture, vision, treatment and analysis of the images are performed within VixWin, whereas the storage in database is controlled by the administration software.

(*) Among the image treatments available with VixWin, it is possible to measure the lengths (length measures) on the obtained images; in particular, this treatment is useful for the panoramic images. The length measuring gauge allows to calibrate the length of an object with known dimension. (Refer to the paragraph about the calibration of length in Operator's Manual VixWin).

Installation

What is mentioned in this chapter is a quick overview of the steps to be followed during the installation (installation of the imaging software, network connection, installation of the driver). Please, refer to the Service manual for the complete installation procedure.

8.1 Installation of the software for diagnostic imaging

Install on the Personal Computer(s) that will be connected to the Orthoralix the application software VixWin for diagnostic imaging (contained in the VixWin packing supplied with the system), and follow the video instructions.

To have other information, refer to section 2 "Installation, configuration and preferences" in the Operator's Manual VixWin.

8.2 Data cable connection Computer(s) Panoramic System

After installing VixWin, plug the Orthoralix in the network where the PC(s) that will be connected to the panoramic system are plugged.

In case of stand-alone modality, the PC and the Orthoralix DDE have to be connected through a crossover network cable or by means of a standard cable plus hub between the computer and the Panoramic System.

8.3 Installation of the ActiveX driver

When the Orthoralix DDE and the computer(s) are plugged in the network and the imaging software VixWin is running on the PC(s), the connection PC(s)-Orthoralix DDE has to be completed by running the ActiveX driver on the PC(s). To install the ActiveX driver, insert the ActiveX CD-Rom and follow the CD instructions.



Notes for testing or installation of the software driver are contained in Microsoft Windows Manual. If the user is unskilled, he must not install the software driver, but apply to a trained personnel.

8.4 Status icon

In the System Tray of Windows (in “application bar” near the “system clock” available in all the versions of the Microsoft Windows operating systems) there is one ICON, which represent the operation of Orthoralix 9200 DDE and CCD sensor. The colours of the icon represents a different operation status.

The different status and the related icons are indicated in the following list.

GREEN Icon: it indicates the correct operation of electronics, CCD sensor and connection.



Orthoralix 9200 DDE is ready to capture the images



Hardware faulty condition



DMU not present



Connection status

RED Icon: Orthoralix 9200 DDE is not able to acquire the images.



System not connected.

YELLOW Icon



The PC does not have the control, but is connected

DRIVER icon



Gendex products:

By clicking on this icon with right key of the mouse, a menu is displayed, in which it is possible to view and to modify both data and parameters common to all the Dentsply Gendex imaging system products (VisualiX, Concept, DenOptix).

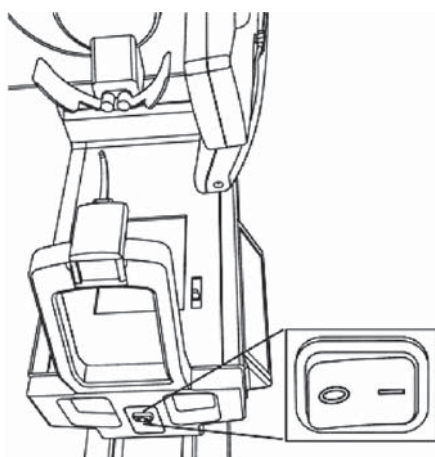
If the status icon is not visible, verify the correct installation of the software driver.



Double click on the status icon allows to enter a configuration panel which contains information about the operation of electronics, the software version, and the characteristics of sensor (that is a useful information to ask for the Technical Service).

Preparation

9.1 Switching on the system



Switch on the Orthoralix 9200 DDE by pressing the power-on switch under the handgrip.

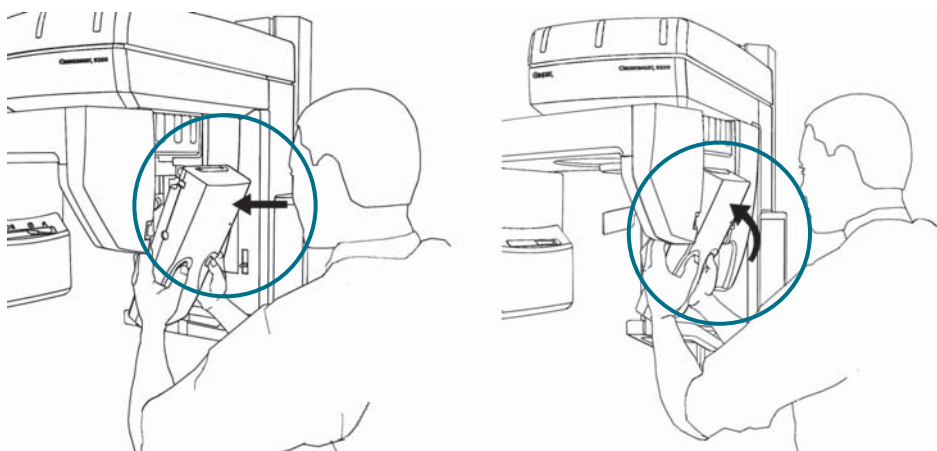


Switch on the personal computer connected to the Orthoralix 9200 DDE unit and start the application program VixWin2000 (refer to Operator's Manual VixWin 2000).

9.2 Coupling/releasing of the sensor module

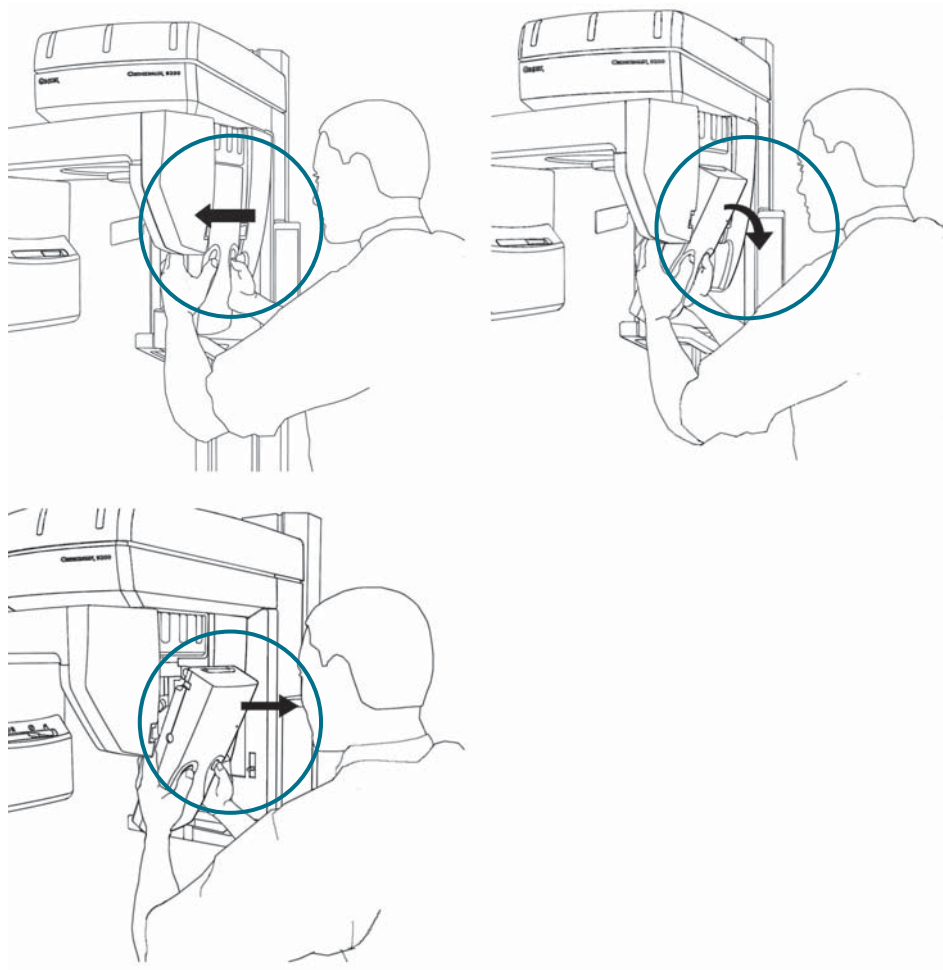
The Orthoralix 9200 DDE is equipped with an ergonomic sensor module, replacing the traditional film cassette for the direct reconstruction of the image. The sensor, extremely compact, can be easily handled by the user and the electromechanical coupling assures the maximum precision and safety during the coupling and the release, simply driven by two frontal buttons and confirmed by a tactile and audible feed-back.

To insert the sensor in the system, keep it firmly through the ergonomic handle and insert it towards the housing with a 25-30° inclination. When the two lateral pins will reach the end of the housing, rotate the top of the sensor module in the direction of the rotating arm. At that time it will be possible to hear the double click of the electromechanical coupling and the sensor will be automatically fixed in the correct position.



To release the sensor, keep it firmly through the ergonomic handle and press the two frontal release buttons. While turning briefly the top of the sensor in the direction of the rotating arm, it will be possible to hear the double click of the release mechanism.

At that time, it will be possible to remove the sensor from the housing.



The advanced safety system prevents the sensor from accidentally falling down during the releasing.

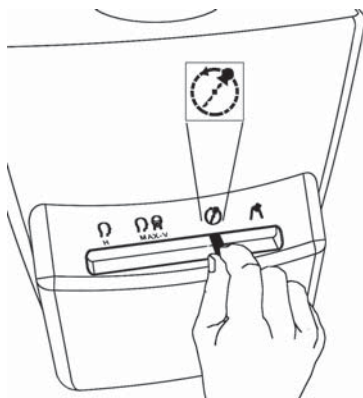


It's important to pay the maximum attention during the coupling and the releasing of the sensor module, as it's containing the CCD detector which is extremely fragile. To prevent any possible falling during the electromechanical coupling/releasing, the advanced safety system prevents the sensor from accidentally falling down during this phase, by keeping the module secured to the housing even if it's left falling.

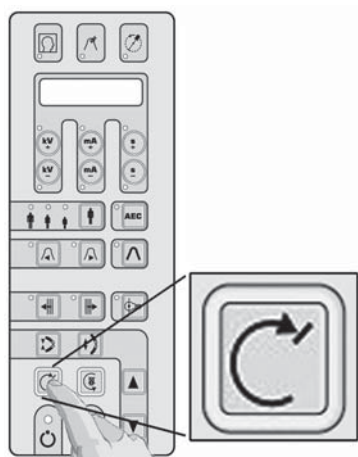


The coupling/releasing mechanism works in the same way on both the pan and the ceph housings. Obviously, if the Orthoralix DDE is not equipped with the digital ceph assembly, it's not necessary to move the digital module out of the carriage, as the system will work simply in panoramic mode. If the system is equipped with the digital ceph assembly, the procedure of coupling/releasing has to be performed exactly in the same way on the pan and ceph housings.

9.3 Setting the primary collimator



Make sure that the lever of the collimator in the tubehead is on the 'Panoramic mode' position. If not, move it into this position. The symbol on the control panel will light up.

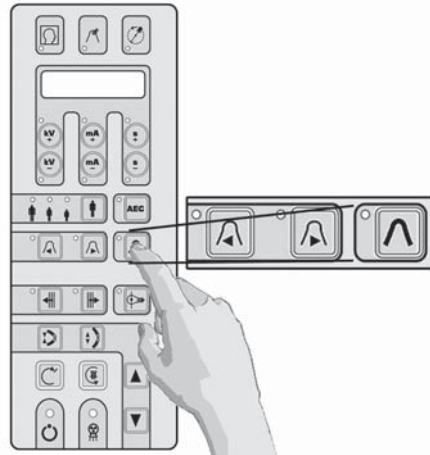


Press the Reset key.


Please note that the equipment must always be in the reset condition as pre-requisite for starting the execution of any exposure program.



If the above mentioned operations have been carried out correctly, the current projection modality and default exposure data are displayed, and the symbol will light up.

9.4 Selection of the projection

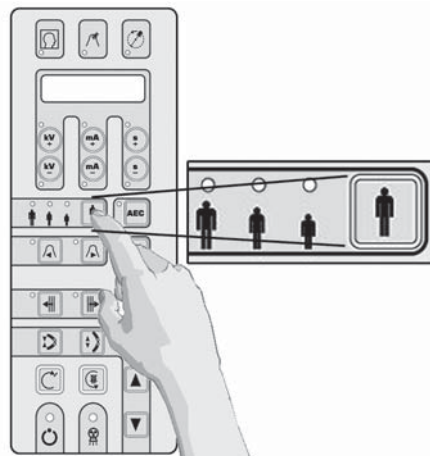


On power-on the Standard Pan modality is set and the relevant led  lights up.

You can go to Standard Pan anytime by pressing the key .

To select the other exposure modalities press the keys  or .

9.5 Selection of the patient size



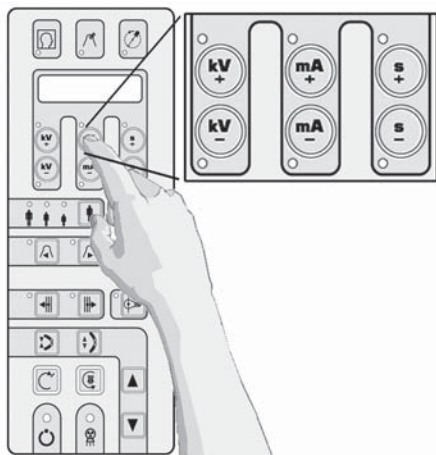
Press the select patient key and choose between small, medium and large.

Medium size patient is proposed by default.



Big adult male or elderly person with strongly calcified dentition are classified as large size.

9.6 Setting the technical parameters



The exposure technical factors related to the chosen selection (kV, mA, s) will be set and displayed.

If the operator deems it necessary, kV and mA can be individually modified (each in the whole range) by pressing the following keys: **+kV**, **-kV**, **+mA**, **-mA**, in the upper part of the control panel.

If the selected technical factor is different from the default value, the related led will light up.

The exposure time (technical factor: s) is exclusively determined by the chosen program.

9.7 Use of the AEC (Automatic Exposure Control) in panoramic mode

For the panoramic projections where the AEC option can be selected (see page 16), the user can activate the AEC function by pressing the AEC button on the main keyboard.

Once the AEC button has been selected, the three LEDs indicating the various patient sizes will light up intermittently and the message "CHOOSE PATIENT SIZE" will be displayed. The AEC mode can be activated only by pressing the AEC marked key.

Press the select patient size key and choose between small, medium and large, as shown in the previous paragraph. The relevant exposure technique factors (kV, mA, s) will be set and displayed.

The user doesn't have to select any other button, as the system will regulate by itself the best technical factors for that exposure.

At the end of the exposure, and in case of any correction during the exposure time, the operator can verify the maximum value reached by pressing either the kV+ (LED on) key in case of an increment or the kV- (LED on) key in case of a reduction. The value will be indicated on the control panel, only when the lighted button (kV+ or kV-) is pressed.

In case the system will automatically disable the "AEC" mode (display of the "AEC DISACTIVATED" message in the control panel), the system will use the preset values selected for patient size.

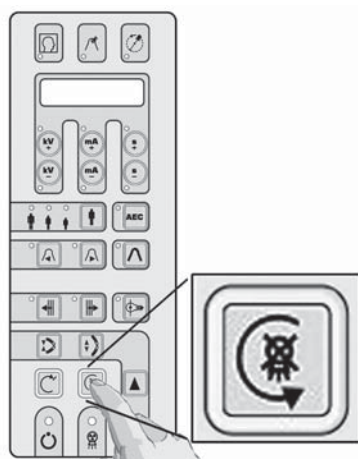
With the deactivated AEC mode kV and mA can be individually adjusted (in the whole range), if the operator deem it necessary to do so, through the keys +kV, -kV, +mA, -mA in the upper part of the control panel. The possibility to manually change the technical factors for exposure is inhibited when the AEC function is activated.




Increasing mA manually from the preset value will result in an increment of image density, or blackening, with constant contrast. The opposite result is obtained by decreasing mA, the image contrast remaining constant. Increasing kV manually from the pre-programmed value will result in an increase in image blackening with a decrease in the contrast. Therefore, in order to obtain a low-contrast image with constant image blackening, kV must be increased and mA must be decreased accordingly. A percent change in kV affects the image blackening proportional to a power two (square) law respect to a percent change in mA. Please note that, in accordance with the requirements in the IEC standards, the kV value displayed for panoramic exposure is the maximum value during exposure.

This is the kV value necessary to compensate for spine absorption at the centre of the image, whereas the actual momentary kV in other parts of the exposure may be different from this maximum value in order to account for the different absorption therein.


9.8 Performing a “dummy run”



To perform a ‘dummy run’ (a no-radiation simulation of the currently selected projection program or modality), press the key .

This key must be pressed throughout the whole run time (key operates in “dead man” mode), otherwise, the movement will stop.

Return to the start position by pressing the reset key .

In case of emergency, the movement during this operation can be stopped by pressing the key .



Before positioning the patient, all metal articles (glasses, removable dentures, earrings, etc) must be removed. If he/she is to be fitted with a lead-lined apron for radiation protection, make sure that the neck is not covered, because this will cause unexposed areas in the radiograph.

Whatever panoramic projection modality is used, one notable feature of Orthoralix 9200 DDE is that the magnification at the center of the image focal layer is constant through the whole image. The focal layer is fashioned as to adapt to the theoretical average jaw shape, as reported and published in the scientific literature by independent studies.

Panoramic exposure

Aims

- Indicating the parameters for a correct panoramic exposure.
- Using correctly the patient positioning devices.
- Performing a panoramic exposure.

Contents

- **Preparation**

Operations to arrange the system or to modify the programmed technical factors, before executing a panoramic exposure.

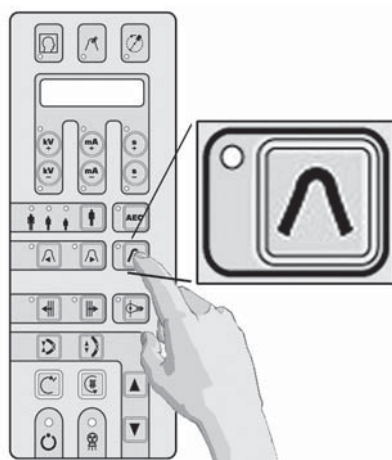
- **Patient positioning**

Instructions for a correct patient positioning by using the centering optical devices and the motorized system.

- **Acquisition of an image**

Operation modality during the radiographic exposure, vision and storage of the acquired digital images.

10.1



Press the standard panoramic key on the control panel to select the standard panoramic projection mode.

The LED on the side of icon lights up and the message STANDARD PANORAMIC is displayed.

If not, verify the position of the collimator lever and/or press the standard panoramic key in order to select this mode.

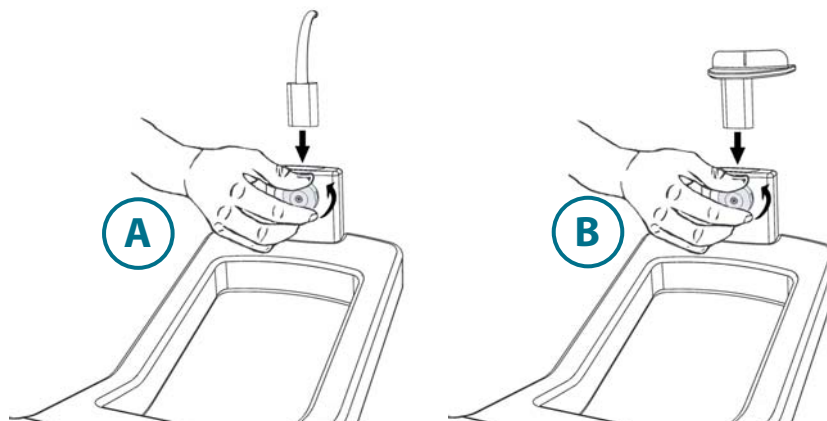
Verify that the unit is in the start position by pressing the reset key. Select the patient size with the key **and**, if necessary, modify the preset exposure factors (see "PREPARATION").

Now, you can proceed with the patient positioning.

10.2 Patient positioning

10.2.1 Use of the bite block / chin rest

Insert the supplied bite block **(A)** in the related seat. Tighten it firmly by rotating the knob (clockwise=tighten anticlockwise = loose).

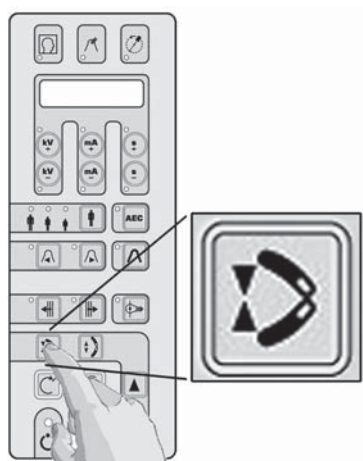


In case of edentulous patient, it is possible to use the supplied transparent chin rest **(B)**.
For hygienic reasons, the bite block must be covered with a new bag before using it again.



It's strongly recommended the use of the Gendex disposable bite-block covers which have been designed and developed for the use with the Orthoralix system.

10.2.2 Placing the patient in the system



Open the motorized headrest, if not already so, by pressing the key.

Specially with nervous patients (e.g. children), you have the possibility to perform a test run, to prepare them for the actual exposure procedure and to show them that it will not be harmful.

Place the patient under the headrest and in front of the handgrip.



Position the motorized X-ray carriage by pressing the related keys on the control panel.

Then, place the patient close to the bite block or chin rest; the bite block must be at the level of patients' mouth (occlusal plane), or the chin rest must be aligned with the patient's chin.

10.3 Vertical movement of the column

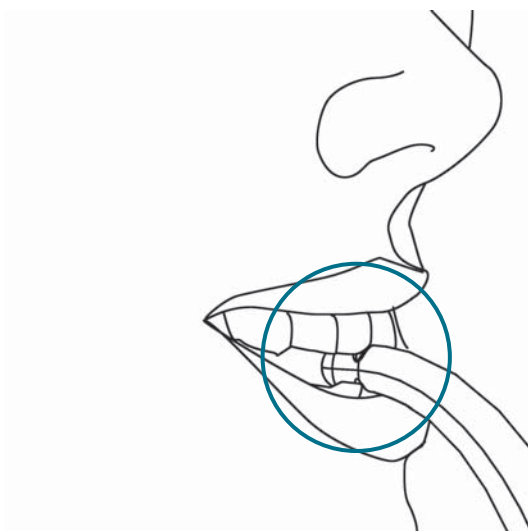
The vertical movement of the unit on the column is controlled by the keys ▲ (up) and ▼ (down) on the control panel. The CONSTANT pressure on one of these keys causes after 2s a gradual acceleration and the movement of the unit at the maximum speed; for a millimetric movement, press lightly the keys.



The patient should firmly grasp the handgrip with both hands as far forward as from the bite block holder possible. Patient's feet should be moved forward and brought together, so that the patient's body is straight and slanted, he/she should slightly hang from the handgrip (compatible with his/her physical possibility to maintain this uncomfortable position during the examination). The purpose of this position is to stretch the spine as much as possible, in order to decrease the artifact shadow that would be cast into the image.

In any case, patients may also stand in natural and more comfortable position if they cannot hold the above described position (e.g. elderly people).

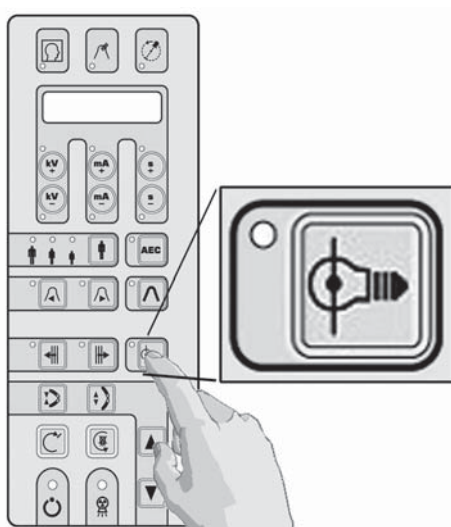
Patients in wheelchairs can also be positioned.



Make sure that the patient is not biting too forward, beyond the grooves.

Edentulous patients should use the chin rest. If the chin rest is used for dentate patients, he/she should bite so as to align lower and upper incisors.

10.4 Use of the positioning lasers



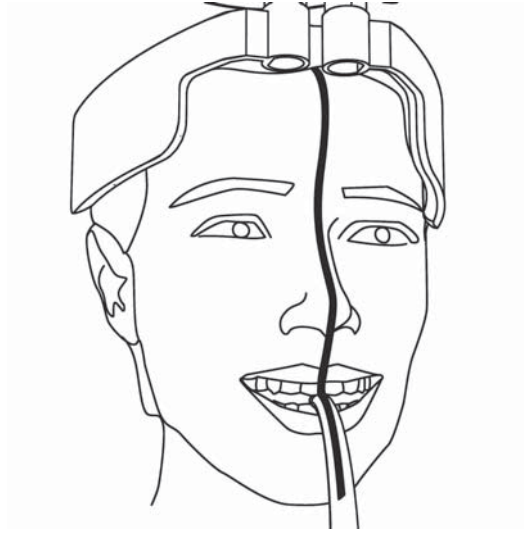
Switch the positioning lights on by pressing the appropriate key. The lasers are timed and they will switch off automatically after 30 sec.

Although compliant to the safety rules, it is a good practice for the operator to avoid to expose his eyes and patient's eyes to the LASER beam; the position of laser sources are emphasized by mean of warning labels.



Caution – Use of controls or adjustments or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.

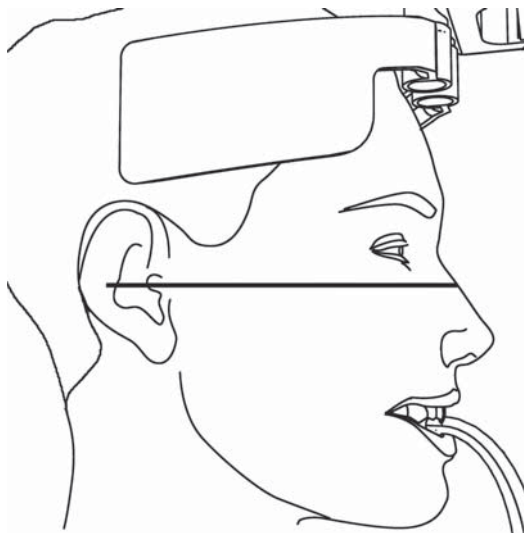
10.5 Vertical light beam



Gently displace or tilt patient's head sideways until the front **vertical light beam** coincides with the mid-sagittal plane, for instance the midline of the face.

Remember that the center of the dentition should correspond to the midline of the bite block or chin rest.

10.6 Horizontal light beam



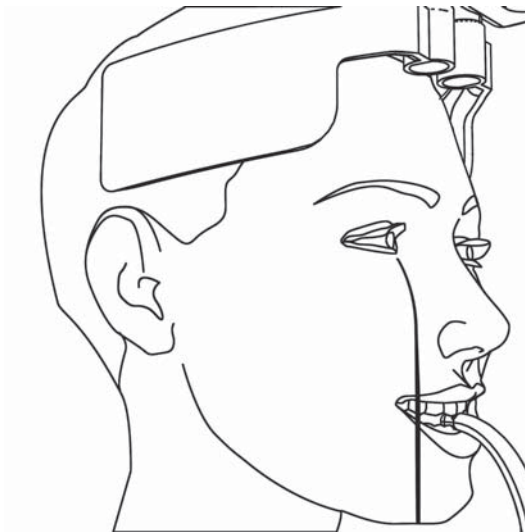
The **horizontal light beam** should coincide with the lower margin of the orbit by using the lever at the right side of the mirror.

Tilt patient's head backwards or forwards by gently raising or lowering the unit, so as to horizontally align the Frankfurt plane (for instance the line from the lower margin of the orbits to the tragus at the external auditory meatus).



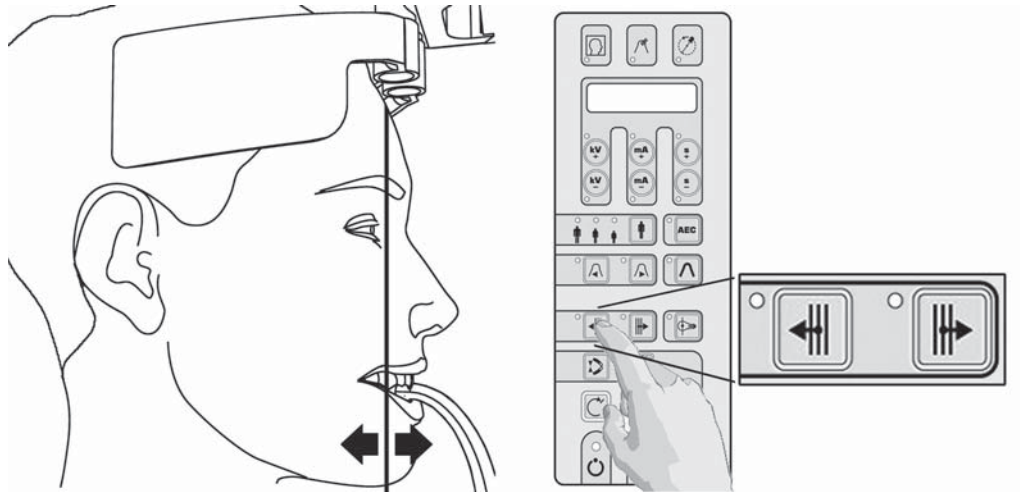
Beware not to hurt the patient by raising or lowering the carriage too fast (keystroke for more than 2s on the up or down key) .

10.7 Vertical lateral light beam and movement on the Y axis



The vertical lateral light beam indicates the foremost position that the focal layer will reach during the exposure. This should be made to correspond to the roots of the lateral incisors, which is normally equivalent to the alignment of the light beam into the center of the cuspid.

If it is not already so, attain this by displacing the entire overhead carriage, and the lateral vertical light beam with it, from the nominal position (7mm) by pressing the key (forwards) or the key (backwards).



During this operation do not move the patient.

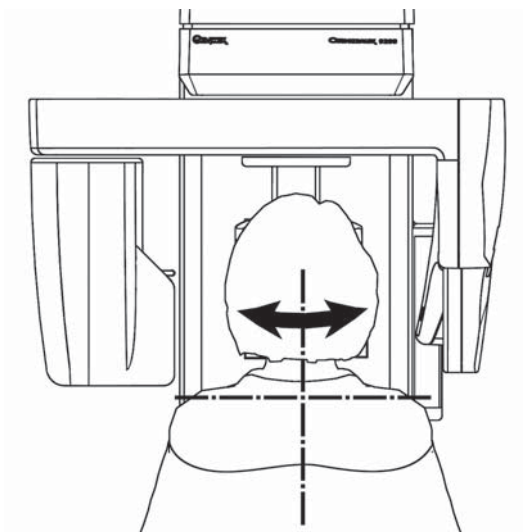
The actual Y position in mm (longitudinal axis) is momentarily displayed whenever the light-on key or the Y displacement key are operated.

When the bite block is used, the motorized unit and the lateral vertical light beam must be moved some mm backwards ($Y > 7$ mm) in case of protruding incisors, and some mm forwards ($Y < 7$ mm) if the incisors are straight.



The nominal position on the longitudinal axis Y of the motorized unit and of the lateral vertical light beam, is 7 mm, that means that the most frontal point of the focal layer during exposure is 7 mm behind the groove of the bite block. The width of the movement is from 0 (forwards) to 14 mm (backwards).

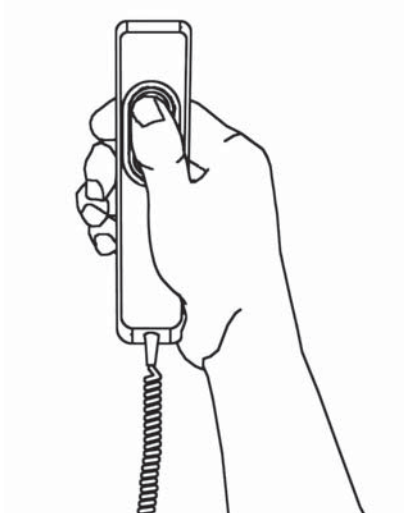
10.8 Exposure



When the patient's head has been properly positioned use the keys to close the headrest flippers until the forehead leans to them, and make sure the patient does not shift position during the exposure process.

Ask the patient to press his/her tongue to the palate and to stay still during the exposure.

Verify that in the System tray of Personal Computer is displayed the GREEN icon: it indicates that the system is ready to capture radiographic images.

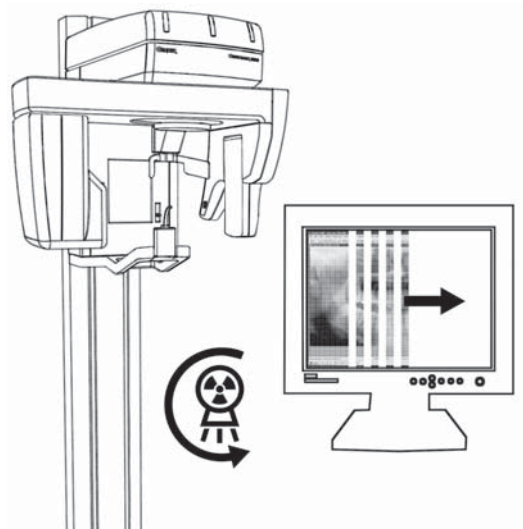


Make the exposure by pressing the exposure handswitch.

Do not forget to observe the applicable radiation safety procedure.



The exposure handswitch must be kept firmly pressed during the whole exposure procedure, otherwise X-ray emission and carriage movements will be stopped ("dead man" exposure mode). If this should happen, the unit must be reset and the patient positioning re-done.



During X-ray emission, verify (whereas possible) on monitor the correct image acquisition in the built-in preview-window of the program VixWin: it will be automatically displayed when the X-rays reach the electronic sensor.

During the emission of the X-rays (which takes place only during part of the cycle, because part of the time is used for re-positioning the machine) the yellow signal lights up and an audible buzz is emitted, both at the unit and at the remote station, if installed.

When the exposure cycle has been concluded, release the X-ray handswitch.

The preview is immediately transferred from the system as VixWin image.

When the cycle has been concluded, the headrest will automatically open.

Then, the patient can be moved away and the machine reset.

The radiographic image will be displayed on the monitor.

Now, it is possible to save the image or to perform treatments (refer to VixWin Manual).



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

Other panoramic and DMF projections

Aims

- Indicating the available basilar panoramic radiology programs and the dento-maxillo-facial radiology programs

Contents

- **Basilar panoramic radiology programs**
Description of basilar panoramic projections and technical specifications of the different projections
- **Dento-maxillo-facial radiology programs**
Description of dento-maxillo- facial projections and technical specifications of the different projections

Other panoramic projections

11

11.1 Child panoramic

Child panoramic is a common panoramic projection adapted to the specific infantile morphology.

By taking advantage of the shorter shape of child's jaw, it's possible to achieve a good orthogonality of the X-ray beam to the dentition in the premolar area, and as a consequence un-deformed images of those teeth with little crown overlap, while covering the whole dento-maxillary complex including TMJ.

The operation and the patient positioning are the same as for the Standard Panoramic.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

11.2 Orthogonal dentition

Orthogonal dentition is a panoramic modality projection limited to the sole dentition, without the rami and the TMJ. The orthogonality of the X-ray beam to each single element of the dentition is better than in a conventional Standard Panoramic standard in the whole dento-maxillo-facial area.

As consequence, the images of teeth (specially in premolar area) are nearly undeformed and with little crown overlap.



This modality requires a more careful patient positioning (it is less tolerant of positioning mistakes), because the image layer is about twice thinner than in Standard Panoramic. An improper patient positioning would also cause artifacts in the shape of vertical dark bands, more evident than with Standard Panoramic. This program might not be adequate for patients having very protruded incisors, and should not be used whenever there are amalgam fillings, bridges, implants or other radio-opaque (metallic) objects in the most posterior molars, as these would cause white artifacts to the image.

Operation and patient positioning are otherwise the same as for the Standard Panoramic.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

11.3 Left Jaw and Right jaw (Left Half-panoramic and Right Half panoramic)

These programs are specific projections of the respective sides of the mouth.

The movement and consequent projection geometry are different from those in Standard Panoramic (they are not just a Standard Panoramic divided into two exposures). That provides a better X-ray beam orthogonality to dentition (with less apparent crown overlap in premolar areas) and the radiographic shadow from the spine is almost entirely outside the useful image area.

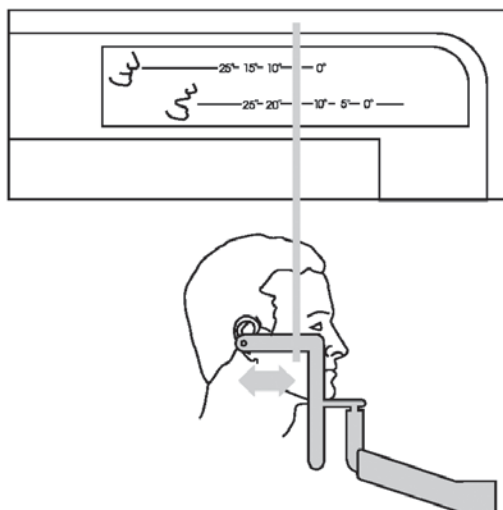
This modality is recommended for a careful reproduction and also for a reduced radiological load, whenever the diagnosis object is included in one of the dental arches.

Operation and patient positioning are the same as for the Standard Panoramic.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

11.4 Lateral exposure TMJ



The Lateral TMJ program is a projection modality of the Temporo-Mandibular Joint, both right and left side, where the TMJ is viewed with projections along the major axis of the condyles (sagittal view of the condyle). This is not exactly a lateral projection, as the condyle is generally not perpendicular to the mid-sagittal plane of the skull.

The patient can be positioned by means of the special skull cephalostat for TMJ examinations (optional). If this is not available, the positioning can be performed using the chin rest without ridge (white) and the TMJ ruler. The ear plug of the ruler must be put into the right auditory meatus. Switch on the positioning lights by pressing the key .

Patient's head must be moved back and forth until the vertical lateral light coincides with the vertical line in the TMJ ruler. The center of the fossa should be about 75 mm behind this light beam.



The assumption for this standard positioning is that the angle between the major condylar axis and the perpendicular to the median/sagittal plane is 10°. If the exact angle is known (this can be determined using the submento vertex exam), patient positioning should be done by moving the vertical lateral light beam to coincide with the reference values indicated on the TMJ ruler – for both open and closed mouth projections. This procedure optimizes the orthogonal incidence of the X-ray beam relative to the major condylar axis, ensuring the highest possible diagnostic value of the exposure.

In the TMJ program, the longitudinal pre-positioning displacement of the overhead carriage is inhibited, and the equipment always starts the exposure cycle from the reset position at Y = 7 mm. Operation is otherwise the same as for Standard Panoramic.

It is possible to repeat the exposure of the same patient with open and closed mouth, whenever necessary, in order to examine the condyle displacement caused by the protrusion. For optimal image congruence (careful positioning and reproducibility), it is recommended the use of the special skull cephalostat for TMJ.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

DMF projections

12.1 Frontal dentition

The frontal dentition program reproduces the anterior elements of the frontal arch with a focused image stratum which is larger than that of a standard examination. This mode is recommended for patients in orthodontic treatment or for patients with off-center occlusions.

The larger focal layer makes sure that the position of not perfectly aligned incisors, as required by the standard and orthogonal modalities, does not prejudice the results.

Operation and patient positioning are the same as for the Standard Panoramic.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

12.2 Left and right half-orthogonal (Left and Right Orthogonal Half-Dentition)

These programs are based on the orthogonal dentition projection and represent the whole dentition.



As the hemi-orthogonal is derived from the orthogonal dentition projection, it guarantees excellent results (orthogonality of the projection beam) but requires the same attention in patient positioning.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

12.3 Maxillary Sinuses, Frontal view

The Frontal Sinus Program provides a linear scannography of the skull in postero-frontal view, at the level of the nasal sinuses.

The chin rest without ridge (in white plastic) should be used for patient positioning.

Operation and patient positioning are the same as for the Standard Panoramic. You can displace the position of the image layer on the frontal and posterior side, by pressing the keys and, depending on the area of interest in the sinus.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

12.4 Left and Right Maxillary Sinus, Lateral view

The Lateral Sinus program provides a linear scannography of the skull in lateral view, limited to the nasal sinuses of the chosen side.

The chin rest without ridge (in white plastic) should be used for patient positioning.

In the Sinuses programmes the longitudinal pre-positioning displacement of the overhead carriage is inhibited and the equipment always starts the exposure cycle from the rest position at $Y = 7\text{mm}$.

Therefore, the patient must be positioned so as to direct the lateral vertical light on the canine.

Operation and patient positioning are otherwise the same as for the Standard Panoramic.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

12.5 Frontal TMJ

The frontal projection of the Temporo-Mandibular Joint is obtained by means of the so-called Reverse Geometry Projection. A frontal view of both the right and left TMJ is depicted on a single exposure.

This radiographic projection permits the assessment of the exact shape of the condyle, with coronal view, i.e. for the diagnosis of arthritis. In combination with the lateral TMJ projection, it allows a complete diagnosis assessment of the TMJ.

The special skull cephalostat for TMJ examinations is strongly recommended for patient positioning. If this is not available, then he/she must be positioned with the help of the chin rest. The lateral vertical light must be in correspondence with the lower canine.

The patient should keep the mandible as protruded as possible, or open, so as to displace the condylar head forward, under the eminence.

The head must be tilted forward so as to have the Frankfurt plane slightly (approximately 5°) beyond the horizontal (cervical spine slightly more extended than with the positioning for a standard radiograph). Excessive tilt backwards may involve the overlap of the orbital base/palatine vault on the diagnostically interesting parts of the condyle.

In TMJ program the longitudinal pre-positioning displacement of the overhead carriage is inhibited and the equipment always starts the exposure cycle from the rest position at Y = 7mm

Operation is otherwise the same as for the Standard Panoramic.



Please, refer to appendix B for the technical specifications of this modality program and to appendix C for the X-ray projection geometry.

Image Quality

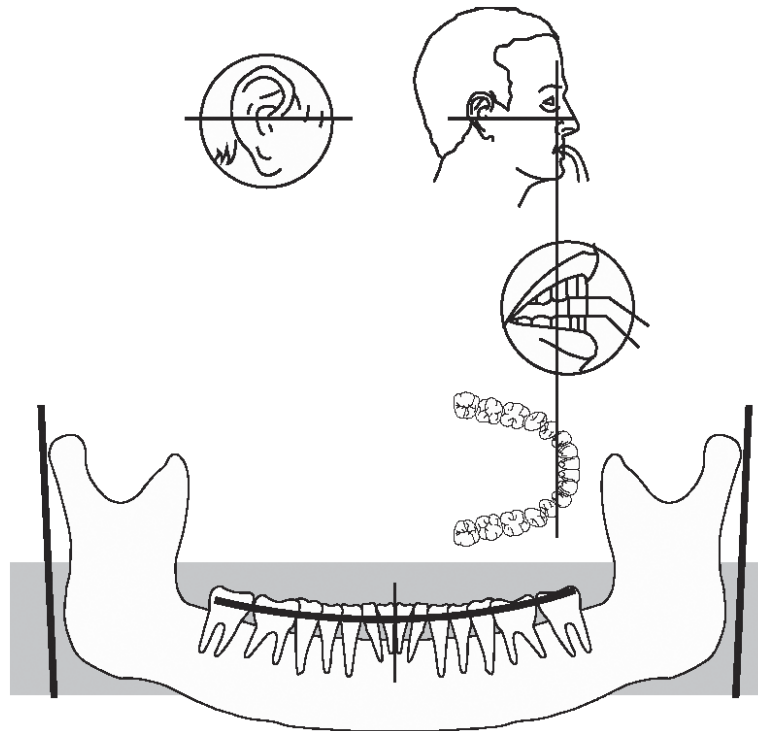


Fig.1

Correct position

The occlusion plane is slightly curved, ascending rami are nearly parallel

Signs of incorrect positioning

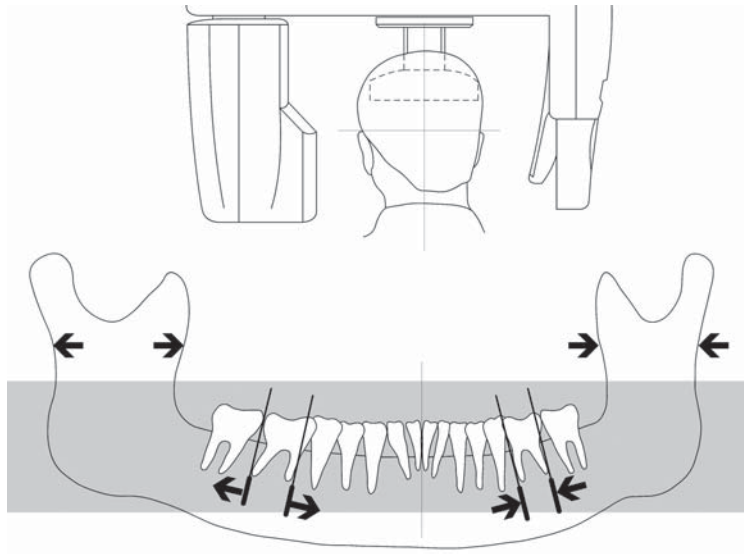


Fig. 2

Incorrect position

Head turned to left: the left side is broadened, the right one is diminished.

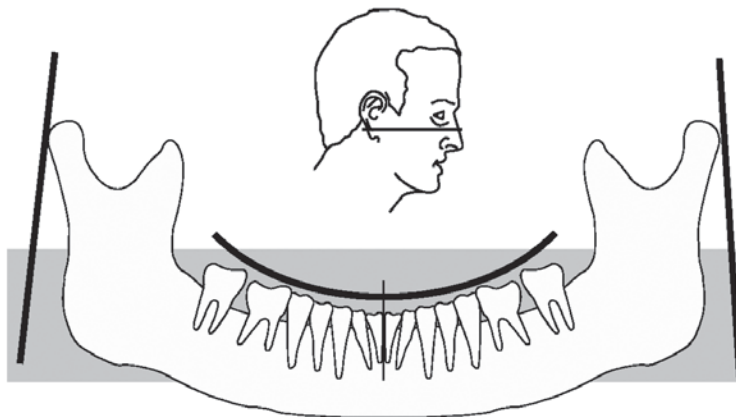


Fig. 3

Incorrect position

Head tilted forward: the occlusion plane is very curved, ascending rami sloping together.

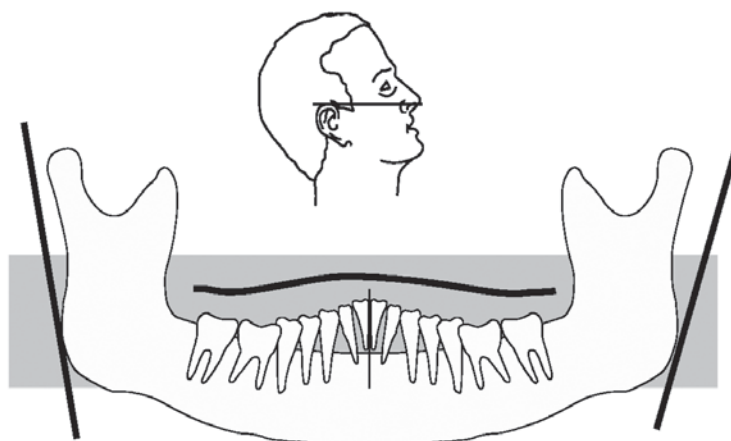


Fig. 4

Incorrect position

Head tilted backward, the occlusion plane is corrugated, ascending rami diverging.

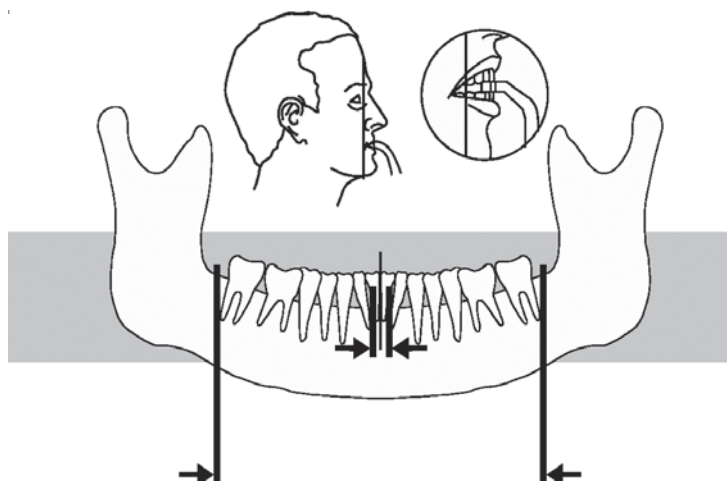


Fig. 5

Incorrect position

Vertical light beam shifted backward: the teeth are diminished and rows together

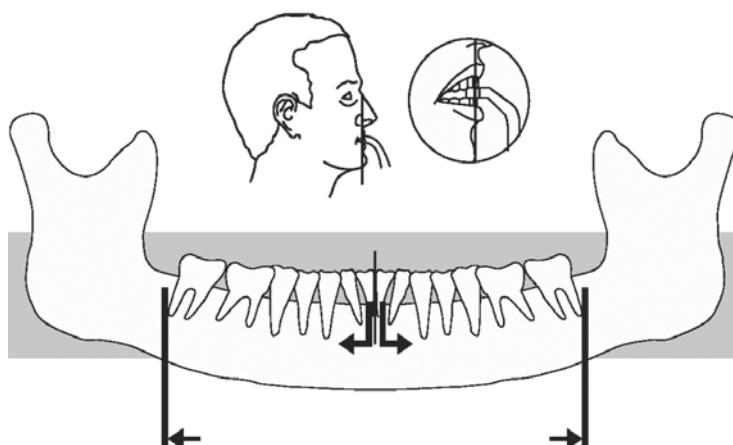


Fig. 6

Incorrect position.

Vertical light beam shifted forward: the teeth are enlarged, the rows separated

Use of the Orthoralix 9200 DDE in Cephalometric mode

Aims

- Explaining the use of the Cephalometric mode on the Orthoralix 9200 DDE

Contents

- **Introduction of the Ceph system**
Description of Cephalometric attachment (arm with Cephalostat and Ceph CCD sensor)
- **Preparation of the system**
Inserting the Ceph CCD sensor and setting the primary collimator
- **AEC modality in Cephalometric mode**
Use of the Automatic Exposure Control with Ceph projections

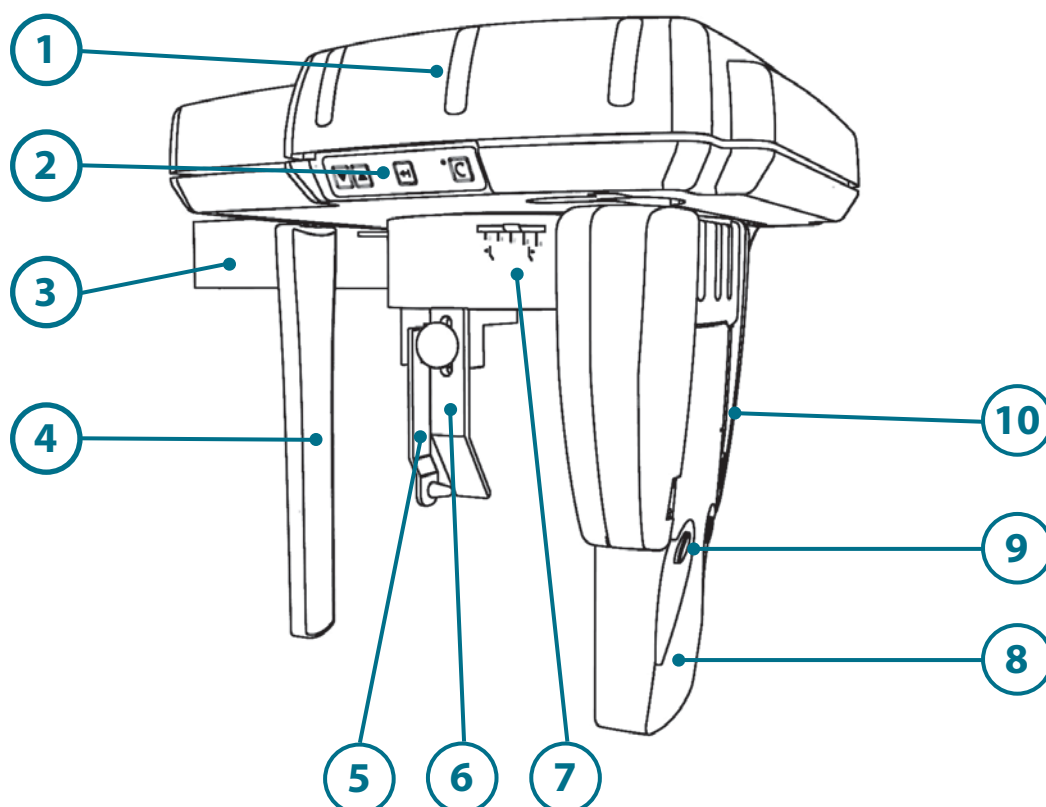
Cephalometric system general description

14

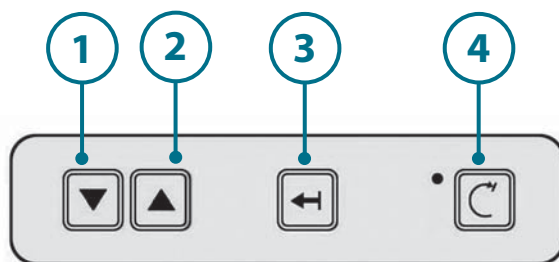
This mode is accessible only if the optional cephalometric attachment (arm with cephalostat and Ceph CCD sensor) is installed on the system.

14.1 Description of the Ceph arm

- | | |
|--|---|
| 1 Ceph assembly | 2 Ceph keyboard |
| 3 Arm | 4 Secondary collimator |
| 5 Ear rods | 6 Nasion support |
| 7 Cephalostat | 8 Ceph CCD sensor (installed on the Cephalostat) |
| 9 Release buttons on the Sensor | 10 Power led |



14.2 Description of the Ceph keyboard



- 1** down button
- 2** up button
- 3** positioning button
- 4** reset button

Down button

It moves the whole X-ray carriage down.

Up button

It moves the whole X-ray carriage up.

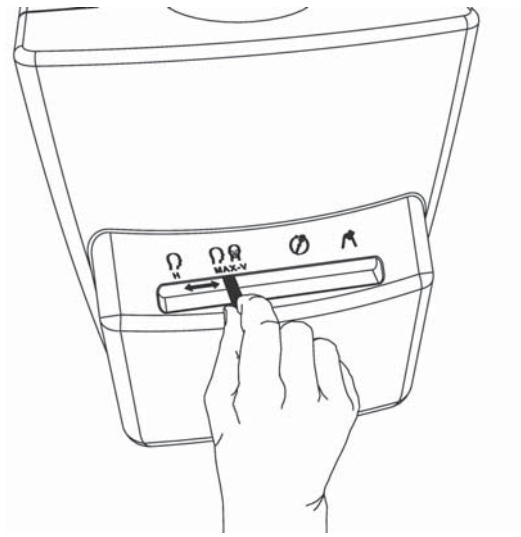
Positioning button

It allows a more comfortable positioning of the patient: by pressing the button the sensor and the secondary collimator are moved away on the distal part of the cephalometer assembly (typically, they are moved closed to the wall if the Orthoralix is wall-mounted).

Reset button

It moves the motorized X-ray system in the start position. To be pressed every time before starting the exposure.

14.3 Description of the primary collimator



The primary collimator is located in the front of the tubehead on the rotating arm of the system. When used in Ceph modality, the collimator has to be positioned on one of the two following positions:

H (horizontal):

it allows to perform the Ceph projections obtaining an horizontal format (18x24 cm):
(LL Horizontal)

V/MAX (vertical/max):

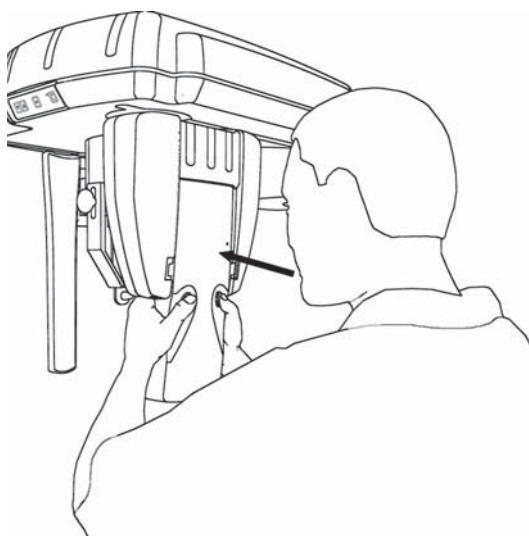
it allows to perform the Ceph projections obtaining a vertical format (22x18 cm):
(LL Vertical, AP/PA Vertical) or the maximum format (22x24 cm): **(LL Max, AP/PA Max)**

The type of projection has to be selected through the control panel.

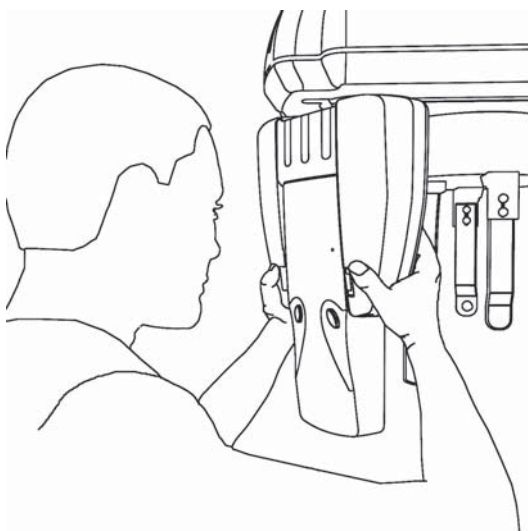
Preparation of the system

15.1 Inserting the Ceph CCD sensor

The Ceph CCD sensor that equips the Orthoralix 9200 DDE Ceph systems has been developed for use with both the panoramic and Ceph projections.



When the Ceph CCD sensor is used for Ceph exposures, it has to be installed on the housing of the Ceph assembly, following the same procedure described for its insertion on the panoramic housing (chapter 9.2 of this manual).



In order to facilitate the coupling/release of the Ceph CCD sensor when the Ceph assembly is installed in cramped spaces (typically, when the lateral side of the Ceph assembly is closed to the wall), there is the possibility to manually turn of 90° the housing of the sensor in order to have it in the front of the user. This rotation of the housing of the sensor is allowed only if it is positioned on the proximal step of its stroke, as shown in the picture.

Make sure that the equipment is powered-up, or switch it on by pressing the power-on button.

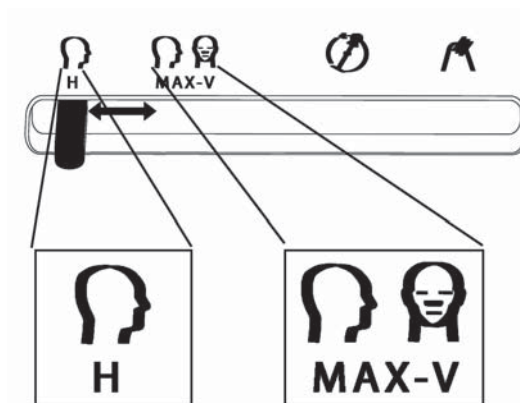
Then, make sure the Ceph CCD sensor is installed in the housing in the Cephalostat and not in the housing in the panoramic rotating arm. If not, move the sensor from the panoramic rotating arm to the Cephalostat. The CCD sensor is inserted in the Ceph housing exactly as it happens for the use with the Panoramic exposures.

When the system is powered-up and the Ceph CCD sensor is correctly installed in the Cephalostat, the green led indicator on the front of the CCD sensor lights up.



The Orthoralix 9200 DDE is intended to be used with only one digital module unit (DMU), which in the Ceph version (Ceph CCD sensor) has to be installed on the Panoramic assembly or in the Ceph assembly according to the exposure to be performed. The system is not intended for use with 2 DMUs installed simultaneously; in this case only the DMU installed on the Panoramic assembly will be working.

15.2 Setting the collimator in the tubehead assembly



Make sure that the lever of the collimator in the tubehead assembly corresponds to the one of the two Ceph mode positions indicated by **H** (Horizontal 18 cm) and **MAX-V** (Vertical /Max 22 cm). If not, press the lever and slide it there. Make sure that the chosen position of the collimator is consistent with the selected projection.

The Ceph symbol on the control panel will light up and the message CEPH LL-MAX will be displayed.

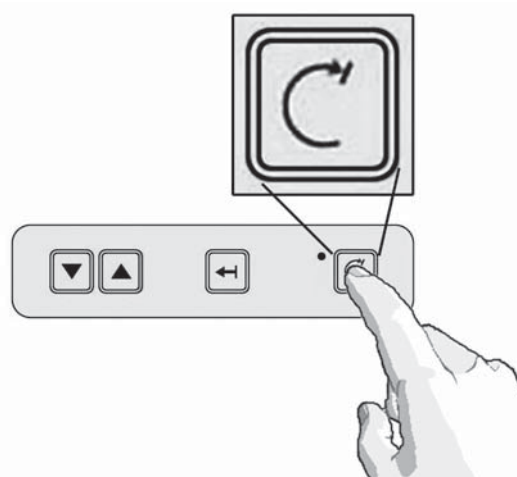


When switching the system on the cephalometric mode, the default projection shown on the display is CEPH LL-MAX, independently from the position of the collimator in H or V/MAX. Always make sure that the chosen position of the collimator is consistent with the selected projection.

If the position of the collimator and the position of the sensor are not congruent, then the message COLLIMATOR is displayed. Position the sensor on the Ceph carriage or move the collimator lever to the proper position to correct this.



Remember that, despite what happens with the analogical Orthoralix 9200 systems, on the Orthoralix 9200 DDE systems it is not required to manually turn the tubehead in order to make it parallel to the Ceph carriage.



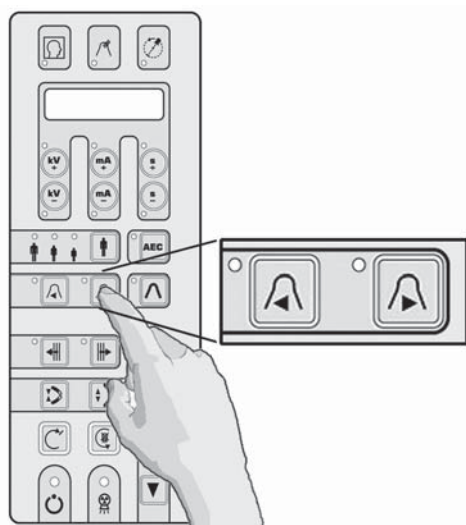
Press the reset key.

Remember that the equipment must always be in the reset condition as a pre-requisite to making any exposure.

If the above mentioned operations have been carried out correctly, the message LATERO-LATERAL plus the technical factors for the exposure to be made are displayed, and the ready symbol lights up. It is possible to set the ANTERIOR-POSTERIOR mode using the select projections keys.

Should the AEC option be enabled when powering up the unit, the three LED's indicating the various patient sizes will light up and the message "SELECT PATIENT SIZE" will be displayed. The AEC mode can also be enabled using the relevant key on the control panel.

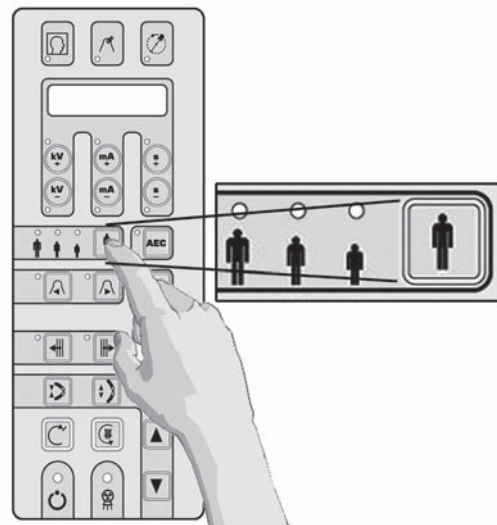
15.3 Selection of the projection



On power-on of the Ceph arm the LL Max modality is set.

To select the other exposure modalities press the projections keys ◀ or ▶.

15.4 Selection of the patient size

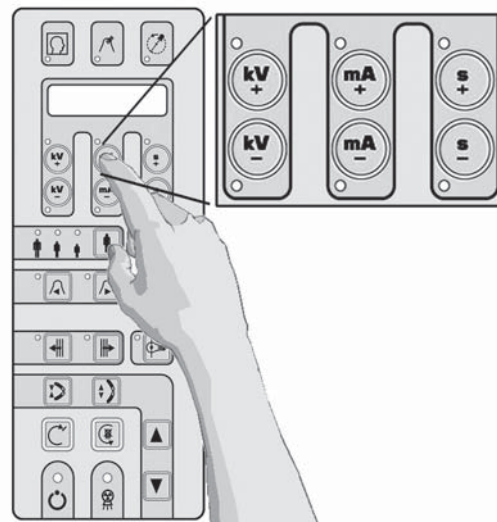


Press the select patient key and choose between small, medium and large.
Medium size patient is proposed by default.



Big adult male or elderly person with strongly calcified dentition are classified as large size.

15.5 Setting the technical parameters



The exposure technical factors related to the chosen selection (kV, mA, s) will be set and displayed.

If the operator deems it necessary, kV and mA can be individually modified (each in the whole range) by pressing the following keys: **+ kV**, **- kV**, **+ mA**, **- mA**, in the upper part of the control panel.

If the selected technical factor is different from the default value, the related led will light up.

You can always reset back to the default technique factors by pressing the relevant patient size key.

15.6 Use of the AEC (Automatic Exposure Control) in cephalometric mode

For all the cephalometric projections (except the Carpus program), the user can activate the AEC function by pressing the AEC button on the main keyboard.

Once the AEC button has been selected, the three LEDs indicating the various patient sizes will light up intermittently and the message "CHOOSE PATIENT SIZE" will be displayed. The AEC mode can be activated only by pressing the AEC marked key.

Press the select patient size key and choose between small, medium and large, as shown in the previous paragraph. The relevant exposure technique factors (kV, mA, s) will be set and displayed.

The user doesn't have to select any other button, as the system will regulate by itself the best technical factors for that exposure.

At the end of the exposure, and in case of any correction during the exposure time, the operator can verify the maximum value reached by pressing either the kV+ (LED on) key in case of an increment or the kV- (LED on) key in case of a reduction. The value will be indicated on the control panel, only when the lighted button (kV+ or kV-) is pressed.

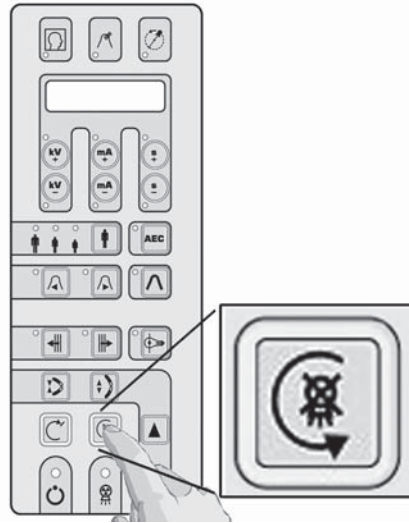
In case the system will automatically disable the "AEC" mode (display of the "AEC DISACTIVATED" message in the control panel), the system will use the preset values selected for patient size.


With the deactivated AEC mode kV and mA can be individually adjusted (in the whole range), if the operator deem it necessary to do so, through the keys +kV, -kV, +mA, -mA in the upper part of the control panel. The possibility to manually change the technical factors for exposure is inhibited when the AEC function is activated.



Increasing mA manually from the preset value will result in an increment of image density, or blackening, with constant contrast. The opposite result is obtained by decreasing mA, the image contrast remaining constant. Increasing kV manually from the pre-programmed value will result in an increase in image blackening with a decrease in the contrast. Therefore, in order to obtain a low-contrast image with constant image blackening, kV must be increased and mA must be decreased accordingly. A percent change in kV affects the image blackening proportional to a power two (square) law respect to a percent change in mA. Please note that, in accordance with the requirements in the IEC standards, the kV value displayed for panoramic exposure is the maximum value during exposure. This is the kV value necessary to compensate for spine absorption at the centre of the image, whereas the actual momentary kV in other parts of the exposure may be different from this maximum value in order to account for the different absorption therein.


15.7 Performing a “dummy run”



To perform a ‘dummy run’ (a no-radiation simulation of the currently selected projection program or modality), press the key .

This key must be pressed throughout the whole run time (key operates in “dead man” mode), otherwise, the movement will stop.

Return to the start position by pressing the reset key .

In case of emergency, the movement during this operation can be stopped by releasing the key .



Before positioning the patient, all metal articles (glasses, removable dentures, earrings, etc) must be removed. If he/she is to be fitted with a lead-lined apron for radiation protection, make sure that the neck is not covered, because this will cause unexposed areas in the radiograph.

Latero-lateral radiography

Aims

- Indicating the parameters for a correct LL Ceph exposure.

Contents

- **Patient positioning**
Operations to arrange the system before executing a LL Ceph exposure.
- **Use of the soft tissue filter**
Instructions for a correct use of the soft tissue filter.
- **Exposure**
Operation modality during the radiographic exposure.


Latero-lateral projection

The most common use of the cephalometric extension is to take latero-lateral radiographs of the skull, mostly used to trace a cephalogram for the purpose of orthodontic treatment. There are different methods to achieve this, however it is generally accepted that the following three points must be visible in the radiogram: the pogonion, the nasion, and the porion. In addition, the frontal profile of the soft tissues, including the chin and the nose tip, as well as the Bolton point and the last vertebrae of the spine should preferably also be visible.

16.1 Patient positioning in latero-lateral radiography

16.1.1 Positioning the Cephalostat

Make sure that the Ceph sensor is correctly installed in the housing in the Ceph assembly.

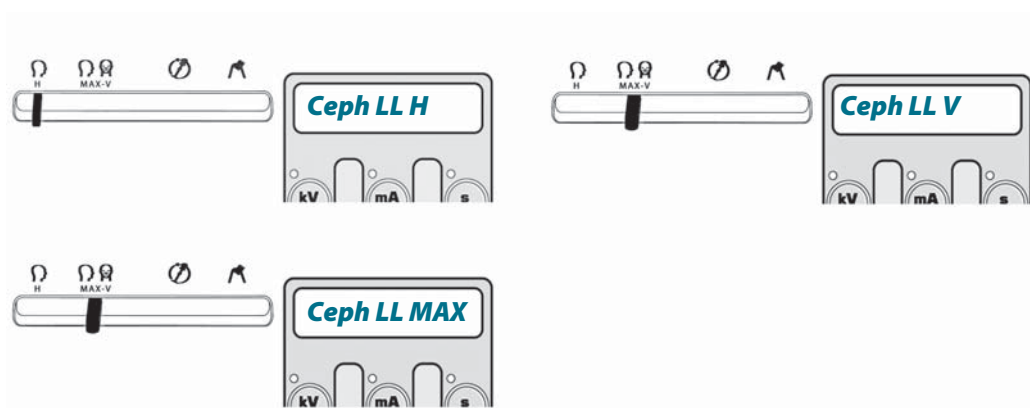
Make sure that the collimator lever on the tubehead is in one of the two Ceph positions, indicated by the symbol .

By using the keys and on the control panel you can choose among three formats of LL image:

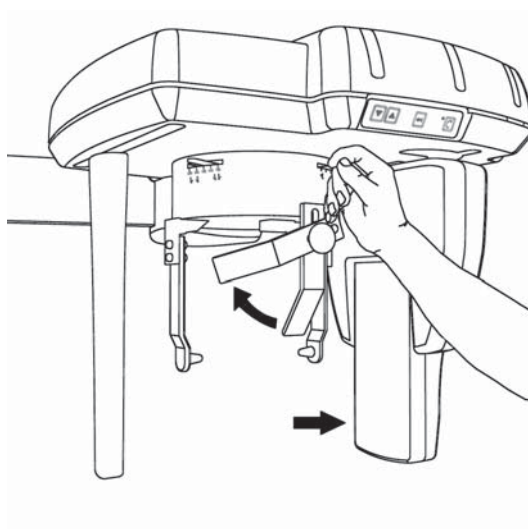
- LL Max (22x24 cm)
- LL Vertical (22x18 cm)
- LL Horizontal (18x24 cm)



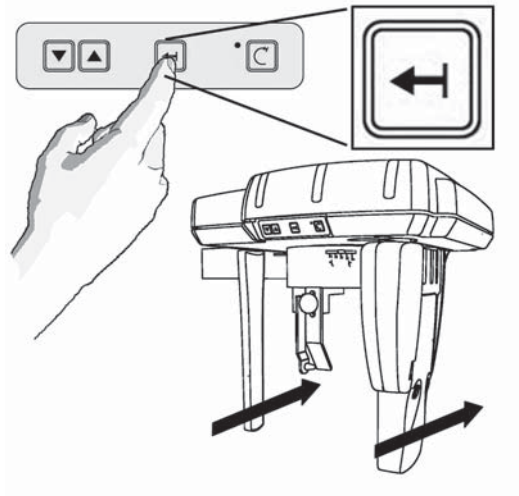
Make sure that the position of the collimator on the tubehead is consistent with the format of the chosen image.



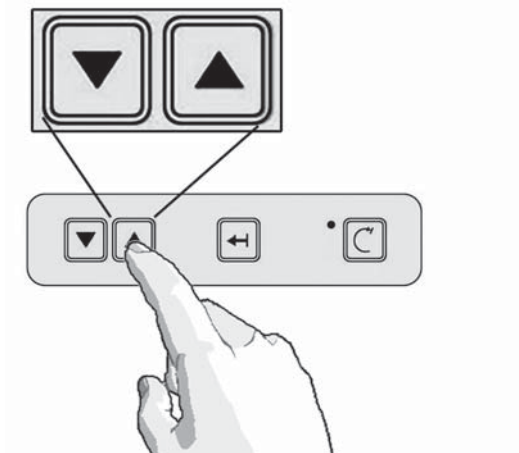
Manually turn the cephalostat, if not already in position, by firmly grasping its circular cover, so that the patient's head will look away from the wall (sagittal plane parallel to the plane of the sensor). Fully open the ear rods of the cephalostat, using the lever to the right of the cephalostat. Extract the nasion support fully, using the lever to the left of the cephalostat, and turn upwards the support itself.



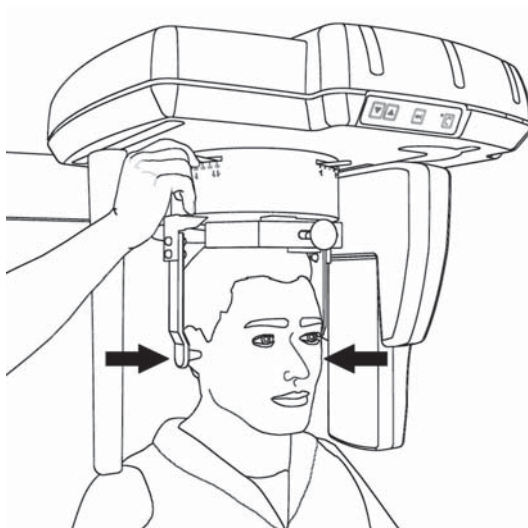
16.2 Placing the patient in the system



If the Ceph CCD sensor and the secondary collimator are standing on the front of the assembly, in order to facilitate the positioning of the patient the user can press the button on the Ceph keyboard. In this way the Ceph sensor moves away, leaving more space in order to achieve a more comfortable patient positioning.



Move the cephalostat arm to the proper height, using the appropriate "up" and "down" keys on the control panel or those on the keyboard on the top of the Cephalostat, so that the ear plugs are approximately in level with the patient's acoustic meati (ears).

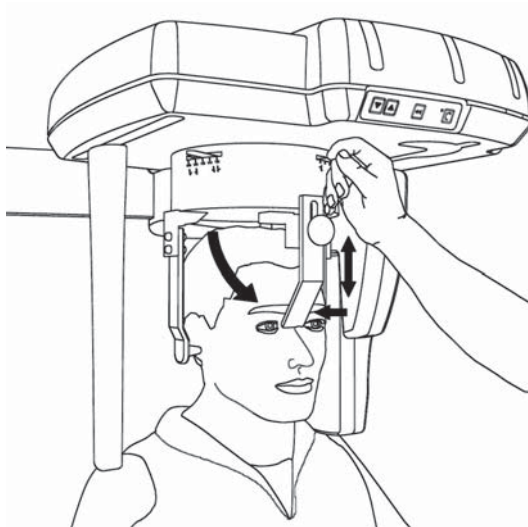


Make sure that the hygienic covers have been inserted into the ear plugs.

Place the patient's head in the cephalostat, carefully adjusting the height of the cephalometric arm, making sure that the patient is standing in a for him/her natural posture, eyes to front having the Frankfort plane on the horizontal.

Make sure that the ear plugs are covered with the hygienic protections.

Gently close the ear rods, by means of the lever, so the ear plugs enter into the acoustic meati.



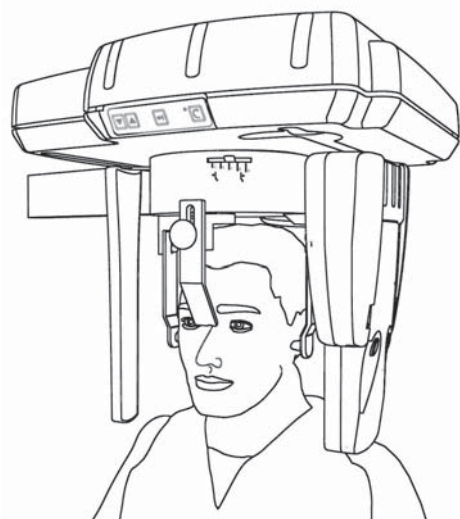
Stabilisation of the head can be aided using the nasion support (useful for the positioning of the soft tissue filter) which can be rotated vertically, adjusted longitudinally (using the lever at the side of the cephalostat) and raised by releasing the knob at its front.

Use of the soft tissue filter



For Latero Lateral exposure, an adjustable soft-tissue filter is provided, to gradually decrease the intensity of the radiation in the front part of the X-ray field, so that the profile of soft tissues of the face can be seen on the radiography, which would otherwise be radiographically burned out by the more intense dose necessary for the hard and denser parts of the skull.

Five numbered and graduated segments of increasing size are marked on the Craniostat, in correspondence of the adjustment lever of the nasion support.

Having completed the patient positioning, the value indicated on the craniostat corresponds to the value of the soft tissue filter that has to be set on the system through the control panel.



Looking at the control panel, the last two characters of the first line on the display are showing F=0, F=1, F=2, F=3 or F=4 where the number is the value of the soft tissue filter position.

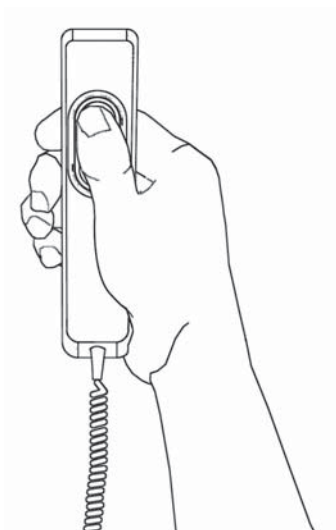
By pressing the keys  and  it is possible to increase or decrease the value until the number on the display is the same of the one present on the Craniostat.



Stabilisation of the head can be aided using the nasion support (useful for the positioning of the soft tissue filter) which can be rotated vertically, adjusted longitudinally (using the lever at the side of the cephalostat) and raised by releasing the knob at its front.

Now the patient is positioned and is ready for the exposure. Ask the patient to close the mouth, i.e. teeth and lips.

17.1 Exposure



Make the exposure by pressing the exposure handswitch.

Do not forget to observe the applicable radiation safety procedure.



The exposure handswitch must be kept firmly pressed during the whole exposure procedure, otherwise X-ray emission and carriage movements will be stopped ("dead man" exposure mode). If this should happen, the unit must be reset and the patient positioning re-done.

During the exposure the Sensor Module Carriage and the Secondary Collimator move inside their slits, very close to the patient; the operator must be careful that:

- **the patient does not insert his fingers in the slits;**
- **parts of patient's body do not interfere with the overall movement;**

in case this occurs the operator must release the handswitch button, and the movement (and X-Rays emission) will stop immediately.

During the emission of X-rays (which takes place only during part of the entire cycle) the yellow signal lights up, and an audible buzz is emitted, both at the unit itself and at the remote attachment, if installed.

Please, refer to appendix B for the technical specifications of this modality program.

Antero-Posterior Postero-Anterior radiography

Aims

- Indicating the parameters for a correct AP/PA Ceph exposure.

Contents

- **Patient positioning**
Operations to arrange the system before executing a AP/PA Ceph exposure.
- **Exposure**
Operation modality during the radiographic exposure.

Antero-Posterior Postero-Anterior projection

18

18.1 Patient positioning in Antero-Posterior / Postero-Anterior radiography

18.1.1 Positioning the Cephalostat

Make sure that the Ceph sensor is correctly installed in the housing in the Ceph assembly.

Make sure that the collimator lever on the tubehead is in one of the two Ceph positions

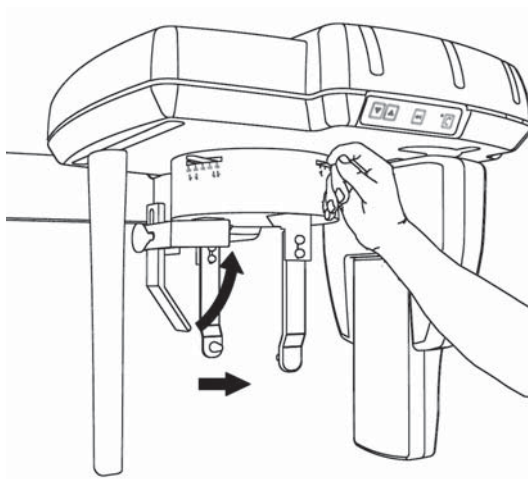
By using the select projections keys on the control panel you can choose among two formats of AP/PA image:

- AP/PA Max (22x24 cm)
- AP/PA Vertical (22x18 cm)

Make sure that the position of the collimator on the tubehead is consistent with the format of the chosen image.

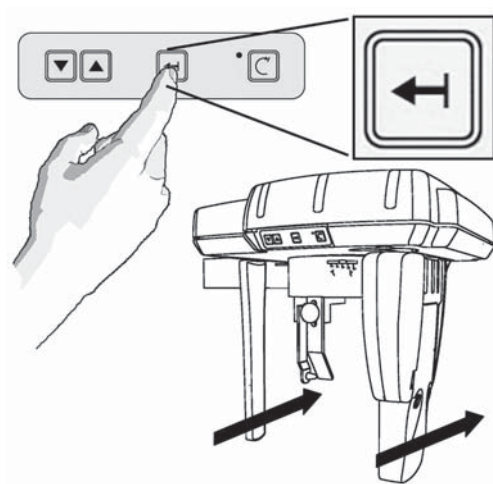


Manually turn the cephalostat, if not already in position, by firmly grasping its circular cover, so that the patient's head will look in the direction of the tubehead (sagittal plane perpendicular to the plane of the sensor).



Fully open the ear rods of the cephalostat, using the lever to the right of the cephalostat. Extract the nasion support fully, using the lever to the left of the cephalostat, and turn upwards the support itself.

18.1.2 Placing the patient in the system

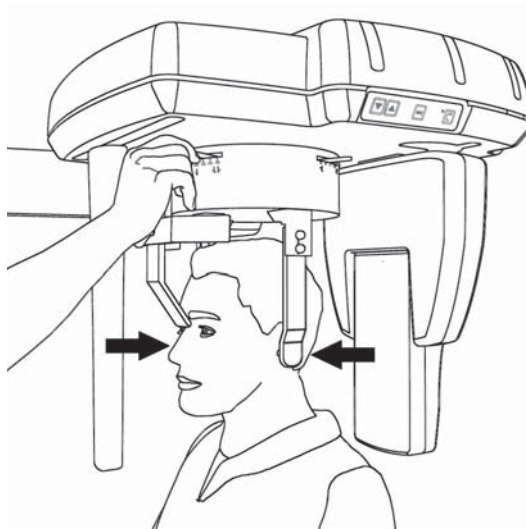


If the Ceph CCD sensor and the secondary collimator are standing on the front of the assembly, in order to facilitate the positioning of the patient the user can press the button on the Ceph keyboard. In this way the Ceph sensor moves away, leaving more space in order to achieve a more comfortable patient positioning.

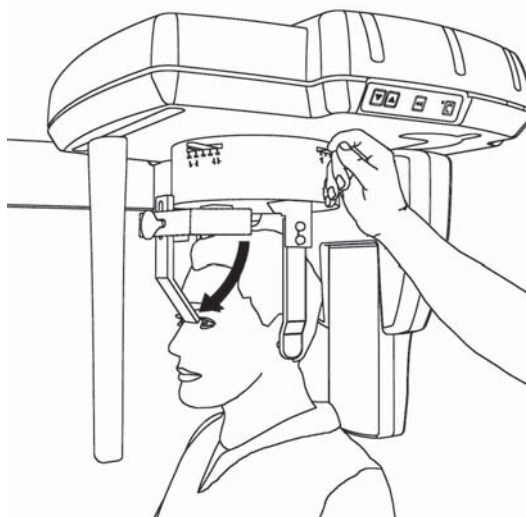
Move the cephalostat arm to the proper height, using the appropriate “up” and “down” keys on the control panel or those on the keyboard on the top of the Cephalostat, so that the ear plugs are approximately in level with the patient’s acoustic meati (ears).

Make sure that the hygienic covers have been inserted into the ear plugs.

Place the patient’s head in the cephalostat, carefully adjusting the height of the cephalometric arm, making sure that the patient is standing in a for his/her natural posture, eyes to front having the Frankfort plane on the horizontal.



Make sure that the ear plugs are covered with the hygienic protections. Gently close the ear rods, by means of the lever, so the ear plugs enter into the acoustic meati.



Stabilisation of the head can be aided using the nasion support (useful for the positioning of the soft tissue filter) which can be rotated vertically, adjusted longitudinally (using the lever at the side of the cephalostat) and raised by releasing the knob at its front.

No soft tissue filter is used for the ANTERO-POSTERIOR projection

A Postero Anterior projection can be obtained following the procedure described above, by simply turning the patient by 180°, so that he/she looks towards the CCD sensor and away from the tubehead.

The nasion support must be removed from its normal position (for L.L.), by releasing the screw knob, and fixed on the opposite side (patient's face side).

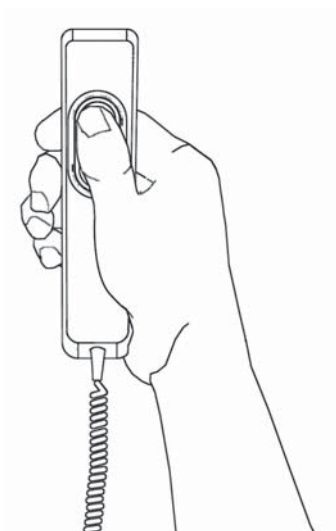


In this position Submento-vertex projections can also be obtained, positioning the patient's head appropriately inclined away from the moving sensor module. For patient comfort we recommend a seated position in an appropriate chair.



For the patient safety, we strongly recommend to pay the maximum attention in the patient positioning, in order to avoid any possible impact between the secondary collimator and the patient's chest. In order to make sure that the secondary collimator will not hurt the patient's chest during the exposure, a dummy run before the real exposure is strongly recommended.

18.2 Exposure



Make the exposure by pressing the exposure handswitch.

Do not forget to observe the applicable radiation safety procedure.



The exposure handswitch must be kept firmly pressed during the whole exposure procedure, otherwise X-ray emission and carriage movements will be stopped ("dead man" exposure mode). If this should happen, the unit must be reset and the patient positioning re-done.

During the exposure the Sensor Module Carriage and the Secondary Collimator move inside their slits, very close to the patient; the operator must be careful that:

- the patient does not insert his fingers in the slits;
 - parts of patient's body do not interfere with the overall movement;
- in case this occurs the operator must release the handswitch button, and the movement (and X-Rays emission) will stop immediately.**

The actual X-ray emission starts 1 s after pressing the handswitch. During the emission of X-rays (which takes place only during part of the entire cycle) the yellow signal lights up, and an audible buzz is emitted, both at the unit itself and at the remote attachment, if installed.



Please, refer to appendix B for the technical specifications of this modality program.

Carpus radiography

Aims

- Indicating the parameters for a correct Carpus exposure.

Contents

- **Setting of the system and patient positioning**
Operations to arrange the system before executing a Carpus exposure.
- **Exposure**
Operation modality during the radiographic exposure.

Carpus projection

The most common use of the carpus projection is the evaluation of the status of the epiphysis and the diaphysis of the fingers of the patient, in order to evaluate the ossification during the treatment. The analysis of the sesamoid bone of the hand is also used for the evaluation of the bone growth.

19.1 Preparing the system

19.1.1 Setting the collimator

Make sure that the Ceph sensor is correctly installed in its housing in the Ceph assembly.

Make sure that the collimator lever on the tubehead is in the Ceph position showed in the picture below MAX-V.



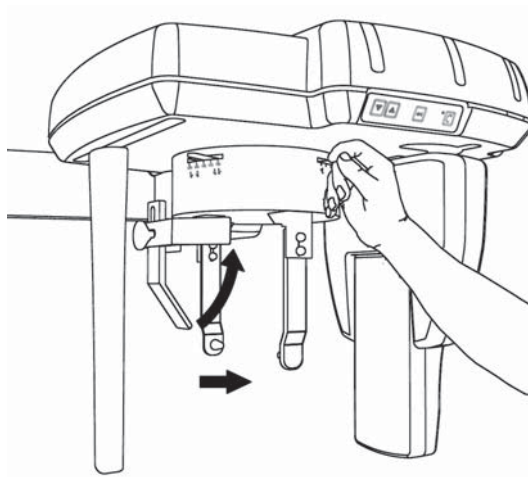
If the primary collimator is erroneously set in the “Panoramic” or “Transcan” position, the system will not give the possibility to start the projection and a error message will be showed on the display.

If the primary collimator is erroneously positioned in the LL Horizontal position, the system can take the image, but, due to the smaller X-ray field, the result will be an image not completely exposed.

19.1.2 Placing the carpus positioner

The carpus positioner has to be installed and screwed to the rotateable cephalostat of the Ceph assembly, in a position parallel to the DMU.

To place the carpus positioner, the cephalostat has to be rotated as in the AP/PA projection: i.e. with the ear rods parallel to the plane of the sensor and the nasion bar remaining on the left of the cephalostat.



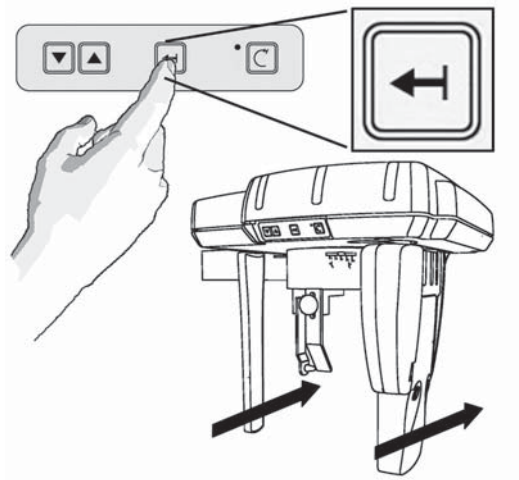
Fully open the ear rods of the cephalostat, using the lever to the right of the cephalostat. Extract the nasion support fully, using the lever to the left of the cephalostat, and turn upwards the support itself.

The graduated bar used for the setting of the Soft Tissue Filter will be positioned on 0.

Viewing from underneath the cephalostat, it's possible to see an hole to fix the positioner in a position symmetrical to the screw fixing the nasion bar. Similarly, on the top of the carpus positioner, it's possible to see an hole to be used for fixing the positioner to the cephalostat.

Holding the positioner parallel to the DMU with one hand, place the positioner so that the hole at its top it's placed in correspondence to the hole on the cephalostat. Then, with the other hand, lock it with the provided screw.

19.2 Placing the patient in the system



If the Ceph CCD sensor and the secondary collimator are standing on the front of the assembly, the user can press the button on the Ceph keyboard in order to facilitate the positioning of the patient.

In this way the Ceph sensor moves away, leaving more space for achieving a more comfortable patient positioning.

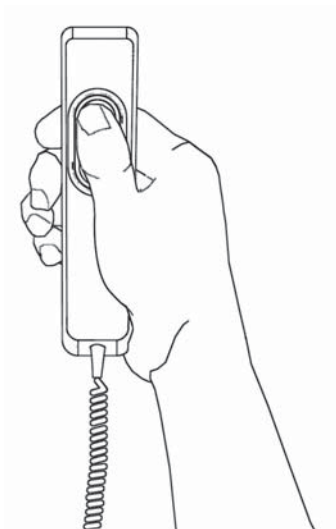
The patient can firmly place his hand on the positioner, with the target zone in correspondence of the transparent zone of the positioner.

The patient has to stand in a comfortable position, compatible to his/her physical possibility to maintain it during the examination. If not, the system can be slightly moved up or down in order to increase the comfort of the patient.



By using the appropriate "up" and "down" keys on the control panel (or those on the keyboard on the top of the Cephalostat), it's possible to move carefully the cephalostat arm and consequently the capus positioner to the proper height.

19.3 Exposure



Make the exposure by pressing the exposure handswitch.

Do not forget to observe the applicable radiation safety procedure.



The exposure handswitch must be kept firmly pressed during the whole exposure procedure, otherwise X-ray emission and carriage movements will be stopped ("dead man" exposure mode). If this should happen, the unit must be reset and the patient positioning re-done.

During the exposure the Sensor Module Carriage and the Secondary Collimator move inside their slits, very close to the patient; the operator must be careful that:

- the patient does not insert his fingers in the slits;
 - parts of patient's body do not interfere with the overall movement;
- in case this occurs the operator must release the handswitch button, and the movement (and X-Rays emission) will stop immediately.**

During the emission of X-rays (which takes place only during part of the entire cycle) the yellow signal lights up, and an audible buzz is emitted, both at the unit itself and at the remote attachment, if installed.

The carpus positioner, like all the other parts coming in direct contact with the patient, must be kept cleaned and disinfected. The positioner can be cleaned with a 2% ammonia solution, or other appropriate solutions.

To improve the level of disinfection, it's also recommendable the use of a polythene sheet to cover the positioner during the contact with the patient.



Please, refer to appendix B for the technical specifications of this modality program.

Use of the Orthoralix 9200 DDE in Transcan mode

Aims

- explaining the use of the Transcan mode on the Orthoralix 9200 DDE

Contents

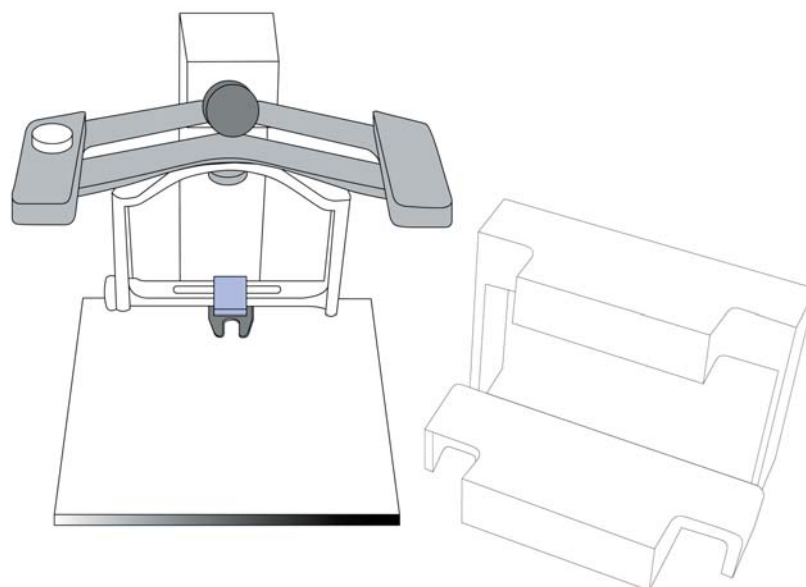
- Introduction of the Transcan programs and description of the components
- Use of the Transcan workbench
- Procedures for X-ray exposure
- Patient positioning for Transcan exposure

Transcan mode

The Transcan mode is accessible only if the optional Transcan assembly is installed on the system.

The TRANSCAN option is a radiographic projection mode that employs scannagraphic technology to acquire layered images of 8 mm thickness perpendicular to the dental arch (transversal plane). This option is specifically intended to be used for implantology.

The use of the TRANSCAN positioning device is a prerequisite to assure reliable and reproducible patient positioning. The device, combined with the patient's dentition impression or a dedicated bite block, is employed during preliminary alignment procedures on the workbench, and subsequently during exposure in Transcan mode.



The positioning device with patient impression alignment templates (positioning guides) and workbench support are shown in the picture above.



The patient impression must be taken using the supplied components (tray and molding compound).

20.1 Transcan programs

Four programs can be selected on the control panel, offering a complete examination of the dental arches and corresponding alveolar bone sections:

- RR posterior molars, premolars, right cuspids
- RR incisors right incisors
- LL posterior molars, premolars, left cuspids
- LL incisors left incisors.

Each program permits a transversal slicing of 8 mm focal trough width, symmetrically disposed relative to the image's center plane in mesial and distal direction.

Three scans are executed per program and are depicted on the same film plate, with a 7 mm displacement between each image. The magnification factor is 1.40 relative to the central plane of the scannographic scan.

The mathematic model for the dental arch & dentition according to Welander and Nummikoski has been applied.

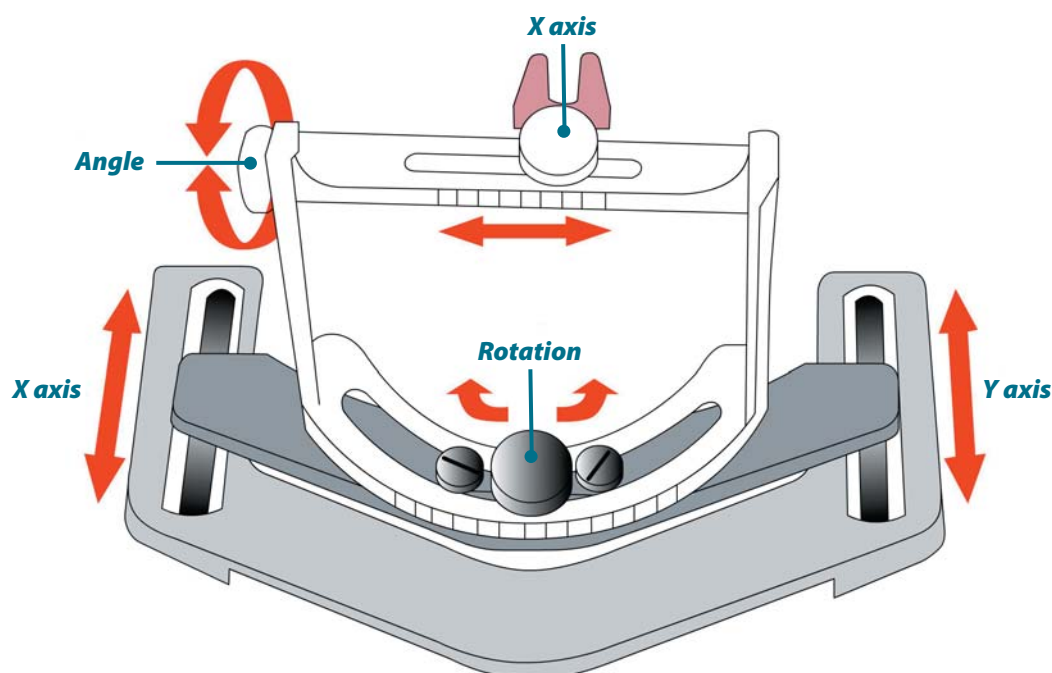


Please, refer to appendix B for the technical specifications of this modality

20.2 Description of Components

20.2.1 Dentition impression Positioning Device

The function of the positioning device is to set the diagnostic target zone, aligning the patient's dentition impression (previously obtained with the supplied impression material), relative to reference points on the supplied alignment templates.

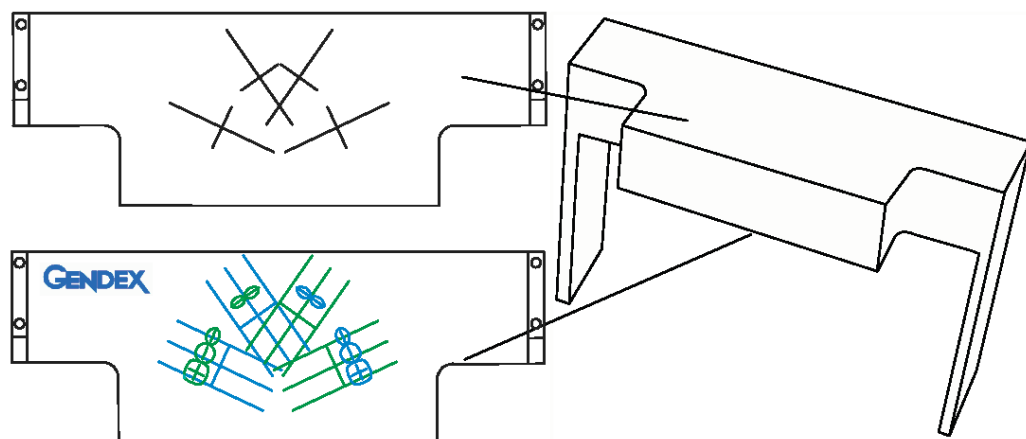


The possible movements of the positioning device are shown below:

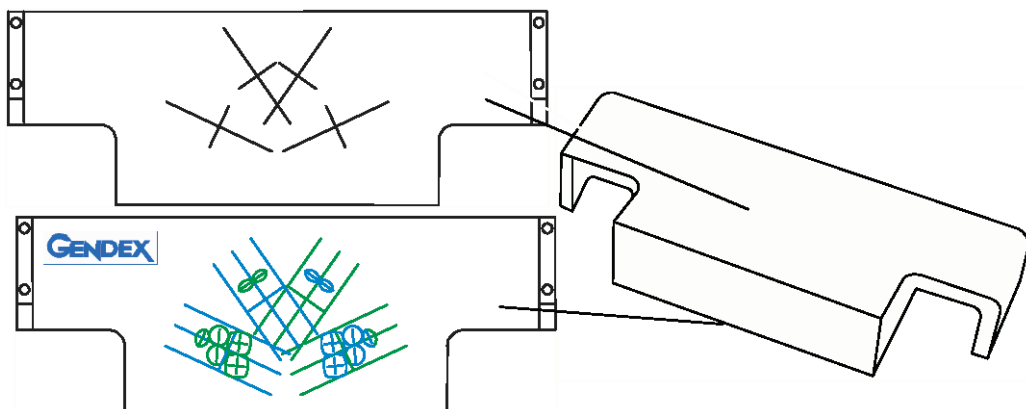
The two transparent plastic templates are required to align the patient's dentition impression for the examination of a target zone in the upper or lower jaw. Four guide pins are used to couple each template to the positioning device.

The reference icons on the template represent the effective position of TRANSCAN layers relative to the corresponding target zone on the dental arch. Each icon is associated to a programme which can be selected from the control panel. Appropriately colour coded reference lines mark Right (blue) or Left (green) jaw.

Maxilla template

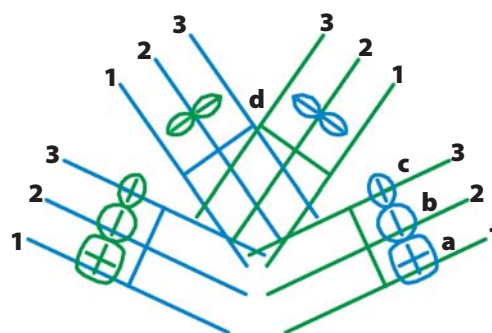


Mandible template



Left side (green)
Anterior (central&lateral incisor)

Right side (blue)
Anterior (central&lateral incisor)



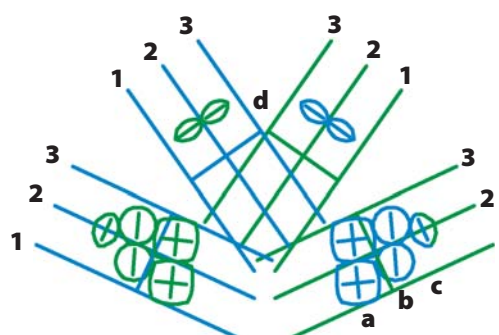
Left side (green)
Posterior (molar, pre-molar, canine)

Right side (blue)
Posterior (molar, pre-molar, canine)

Fig.1 Upper jaw alignment template

Right side (green)
Anterior (central&lateral incisor)

Left side (blue)
Anterior (central&lateral incisor)



Right side (green)
Posterior (molar, pre-molar, canine)

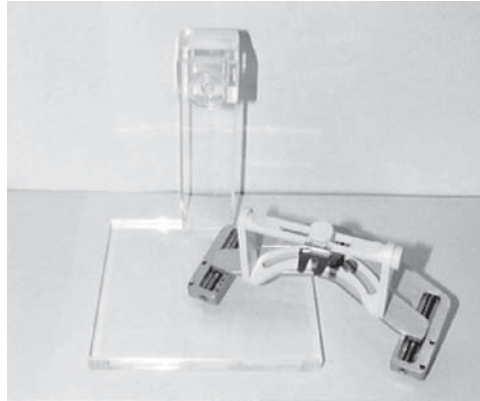
Left side (blue)
Posterior (molar, pre-molar, canine)

Fig.2 Lower jaw alignment template

- 1** = distal slice
- 2** = central slice
- 3** = mesial slice
- a** = molars
- b** = premolars
- c** = cuspidis
- d** = incisors

20.2.2 Workbench support for the positioning device

The workbench support is equipped with a suited coupling and a fastening screw to secure the positioning device in the pre-examination phase for impressions of both the upper or lower jaw.



20.2.3 Trays for dentition impression

The set of 24 trays supplied with the positioning device contains 12 trays for the upper and 12 trays for the lower jaw (3 different sizes).



20.2.4 Molding compound

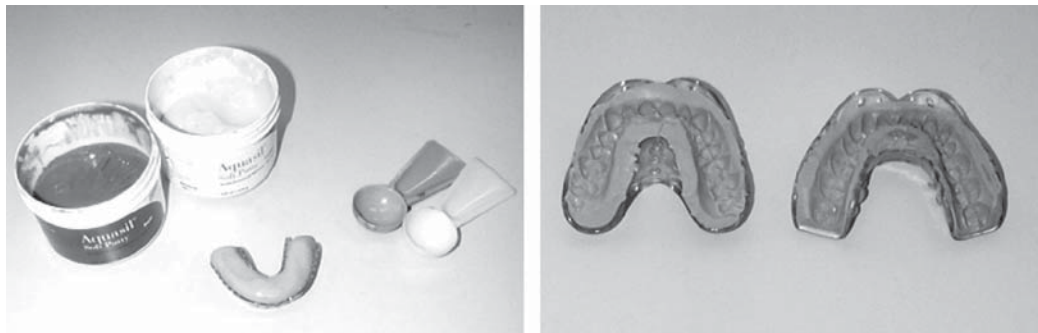
The set contains 2 jars containing base and catalyst paste plus appropriate spoons.



20.3 Taking dentition impression

Pick the appropriate tray for the mandibular or maxillary arch choosing from the three different sizes according to patient size (small, medium or large).

To prepare the impression material, mix equal amounts (half a spoonful) of base and catalyst, place the resulting compound in the tray and make the dentition impression according to the manufacturer's instructions.



The quantity of compound used should be just enough to ensure that the patient can again accurately place the dentition impression during X-ray exposure as described in the following pages. Remove any excess compound using an appropriate cutter or other sharp edged tool.

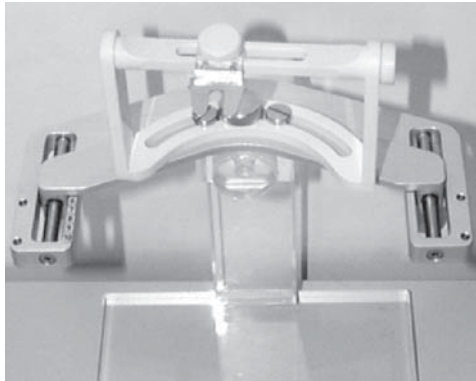


If possible place and fix a marker (small steel ball-bearing, or suitable gutta-percha cone) in the diagnostic target zone of the dentition impression. As an alternative mark up the target zone with a non-toxic pen (water soluble ink) to facilitate preliminary alignment on the workbench.

The steel ball-bearing or gutta-percha cone are extremely useful markers for diagnosis of the radiographic results.

20.4 Preliminary alignment on workbench

Insert the positioning device into the workbench support, locking it into place with the appropriate fastening screw. For mandibular examinations turn the positioning device upside-down before locking into place.

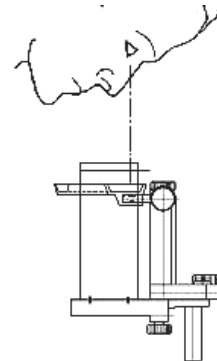
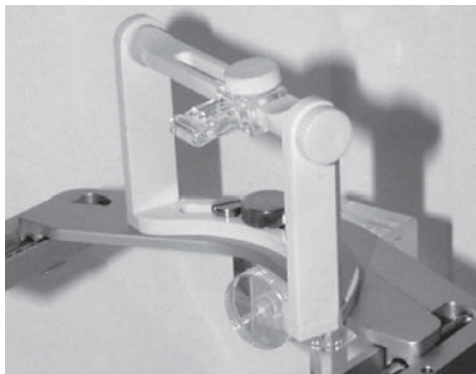


Insert the tray into the forked tray holder on the positioning device.



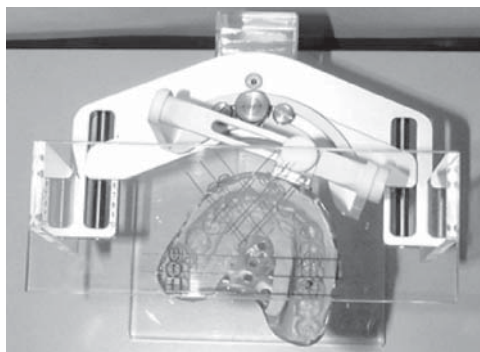
The necessary angle of rotation for examinations of the mandibular depends on the position of the occlusal plane relative to the lower mandibular base; deviation from the horizontal plane normally lies in a range between -5° to -10° .

To obtain the best result for the upper jaw, the forked tray holder should be adjusted to the horizontal plane (0°). For mandibular examinations the forked tray holder should be inclined below the horizontal plane.



In order to ensure an accurate alignment of the dentition impression relative to the icons on the alignment templates, the angle of observation must be perpendicular to the template itself.

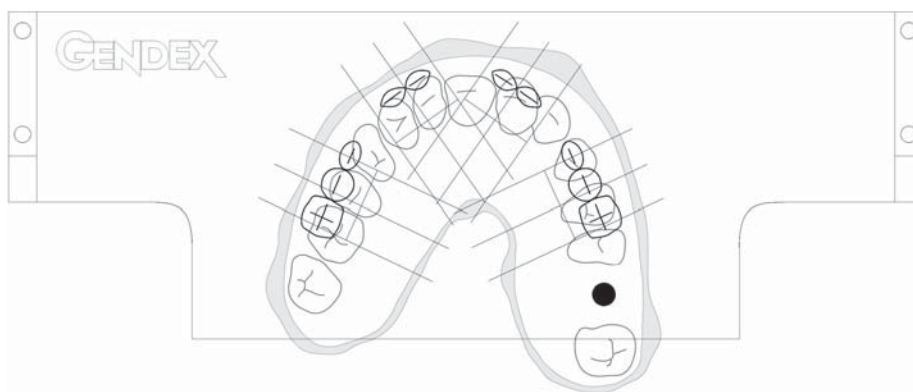
20.4.1 Alignment for the dentition impression of the upper jaw



Loosen all fastening screws and ensure that all components of the positioning device are free to move as needed.

Insert the dentition impression into the forked tray holder on the positioning device.

Fit the alignment template for the **upper** jaw to the holder, inserting the guide pins into the appropriate holes on the positioning device.



Molars, premolars & cuspids

While observing the dentition impression through the transparent template, and using the vernier slides and rotating carriage (X- & Y-axis, rotation) of the positioning device, maneuver it into a position so that the diagnostic target zone is aligned with the corresponding central tooth icon on the template (see figure).

Incisors

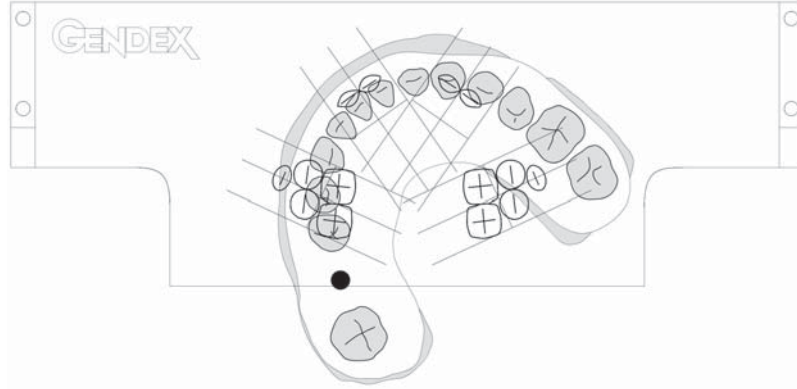
Proceed as above until the diagnostic target zone coincides with the respective icon of the incisors on the template.

Fix the position of the tray by tightening the appropriate fastening screws on the vernier slides and rotating carriage.

Remove the alignment template

20.4.2 Alignment for the dentition impression of the lower jaw

Fit the alignment template for the **lower** jaw to the holder, inserting the guide pins into the appropriate holes on the positioning device (positioning device is **upside-down**).



Molars, premolars & cuspids

While observing the dentition impression through the transparent template, and using the vernier slides and rotating carriage (X- & Y-axis, rotation) of the positioning device, maneuver it into a position so that the diagnostic target zone is centered on the cross-hairs created by the intersection of the depicted central slice line and the longitudinal axes of the tooth icon under examination on the template (see figure).

Incisors

Refer to procedure as described for incisors of the upper jaw (see above).

Fix the position of the tray by tightening the appropriate fastening screws on the vernier slides and rotating carriage.

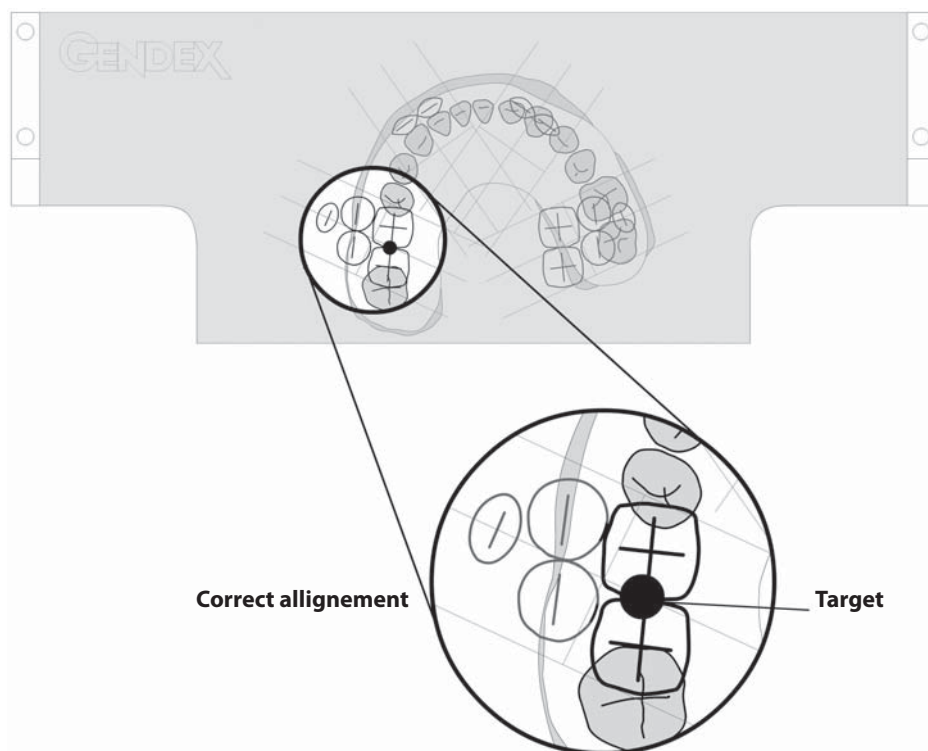
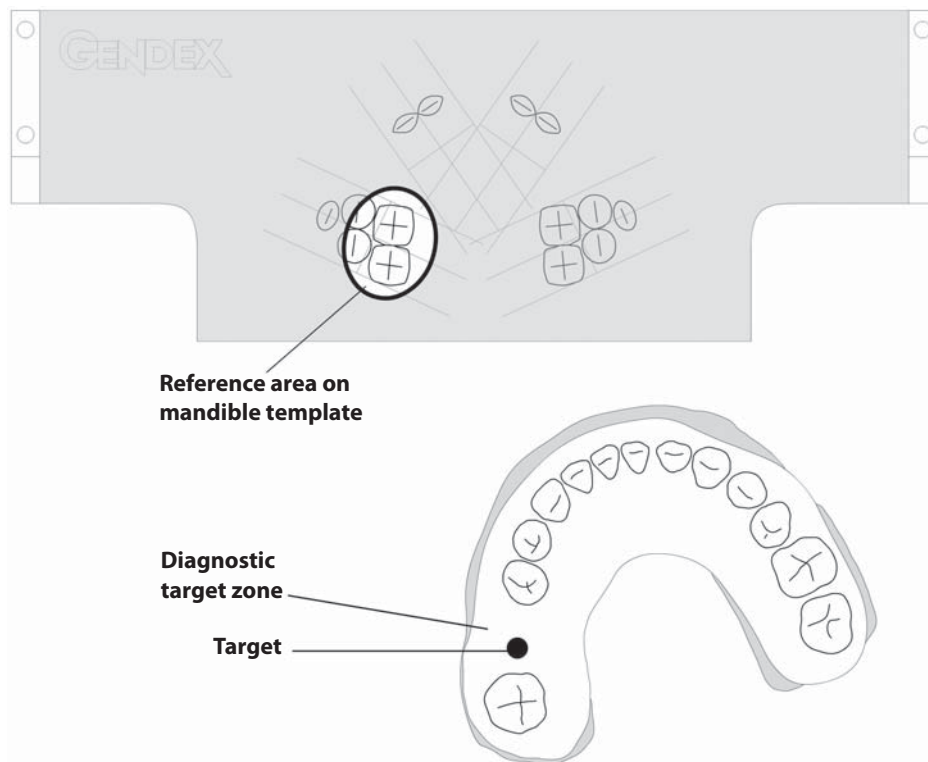
Remove the alignment template



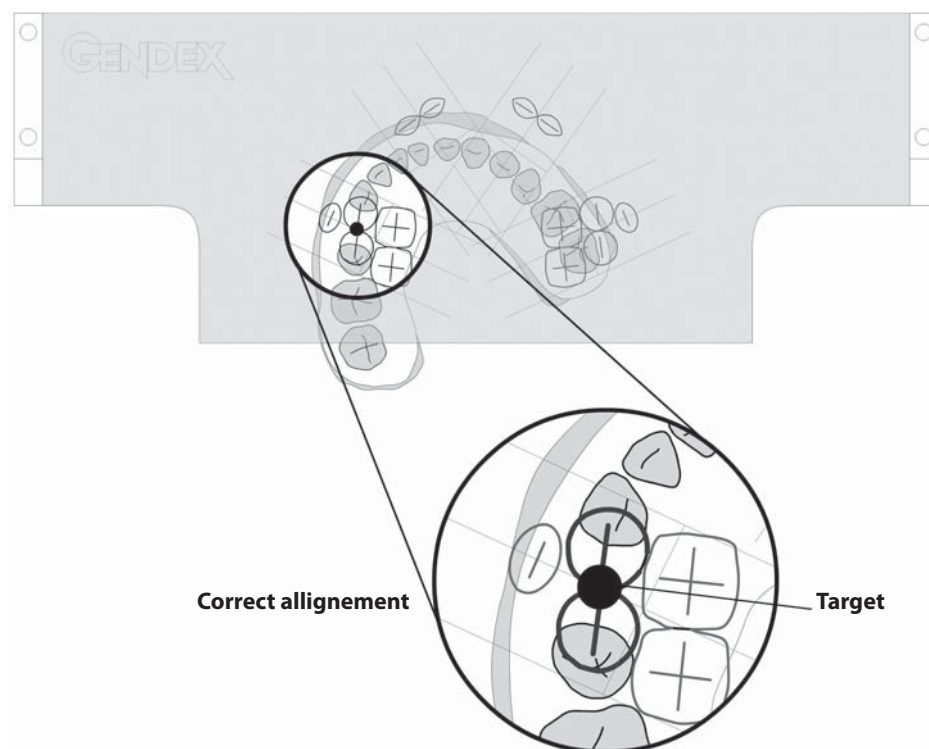
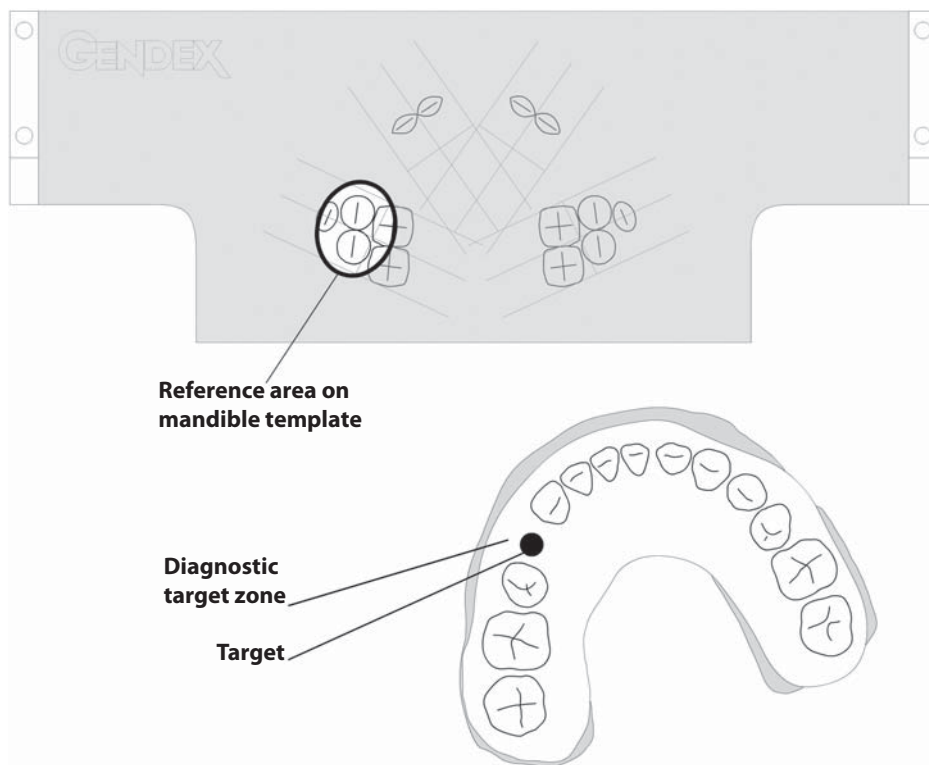
The position of the tooth icons on the template, which lie outside the sagittal axis, reflect the effective position of single elements relative to jaw morphology. In all cases it is of fundamental importance to verify that the impression tray and above all the section comprising the diagnostic target is aligned with the inscribed longitudinal axis passing through each tooth icon on the templates.

20.4.3 Align mandibular profile

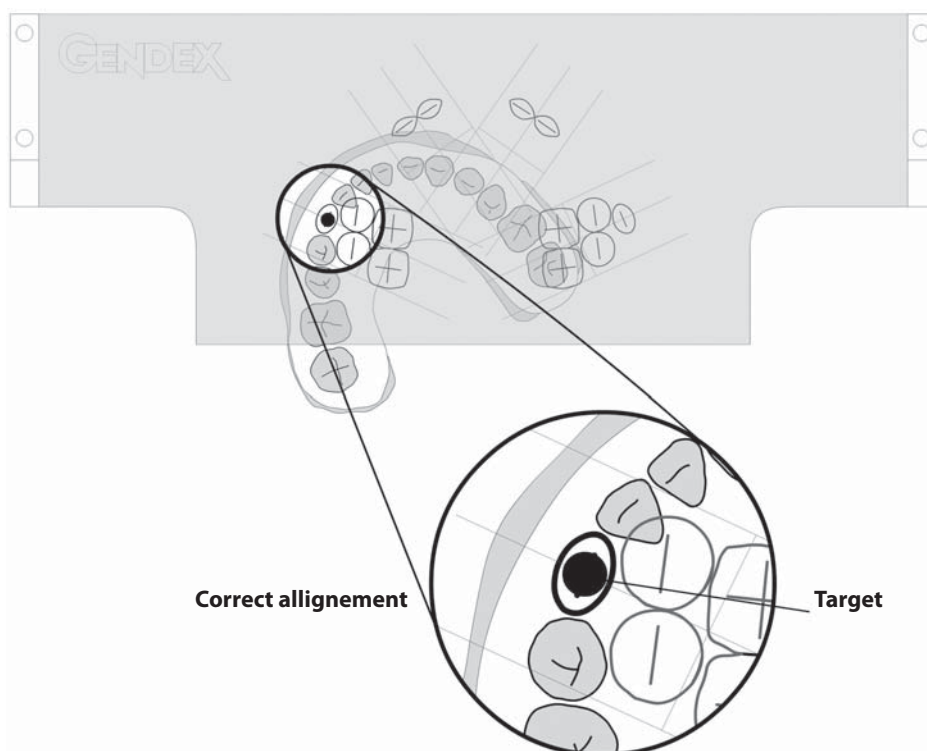
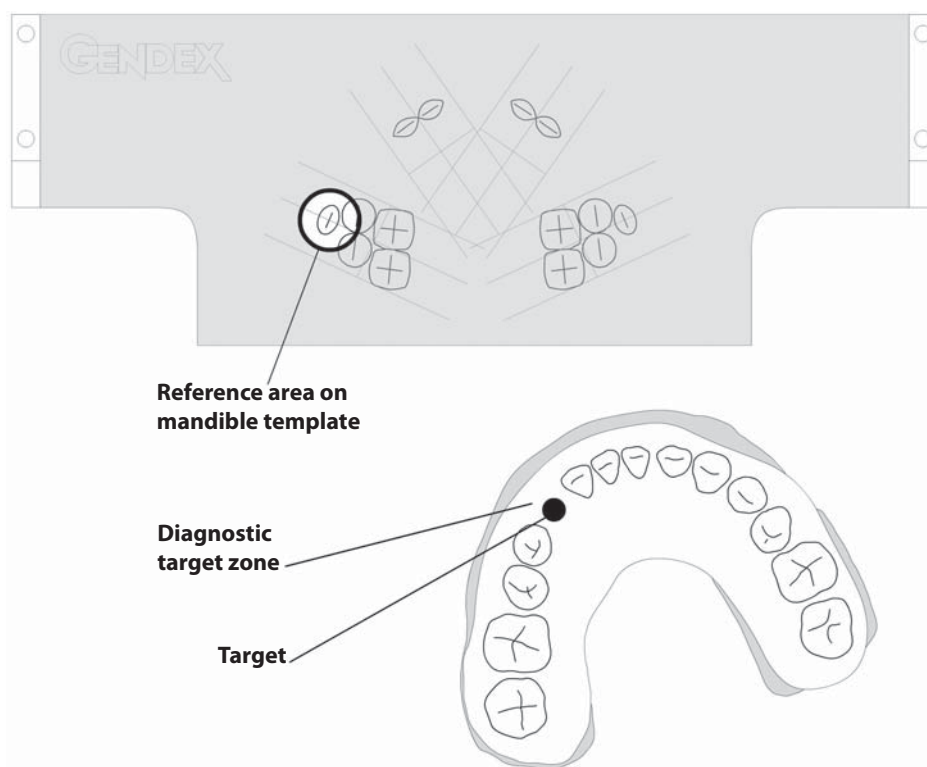
Alignment molar region



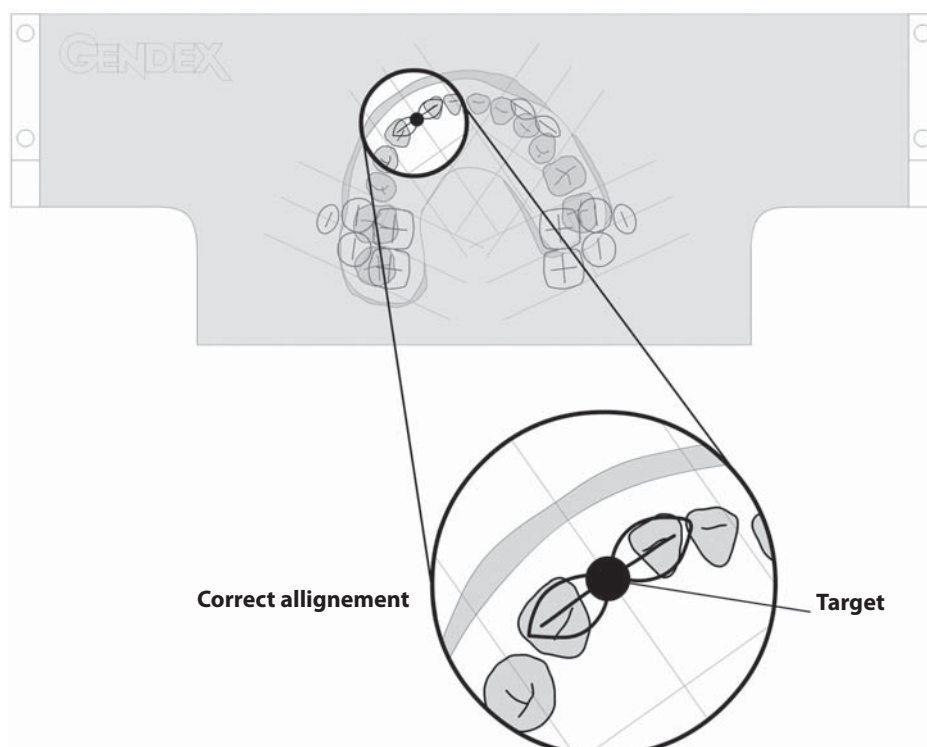
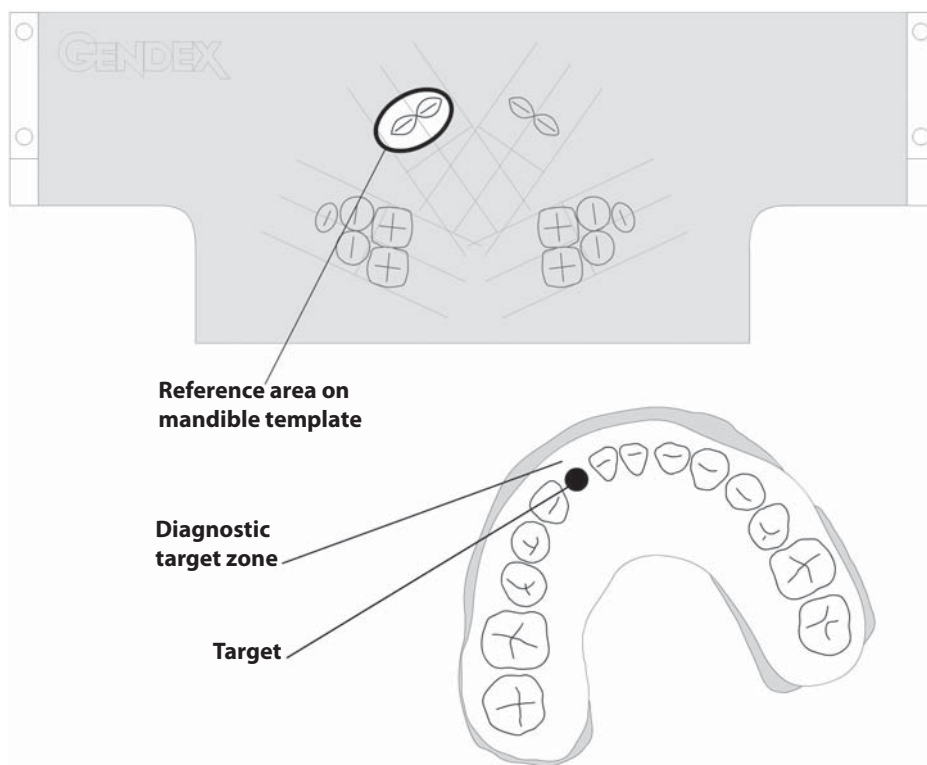
Alignment pre-molar region



Alignement canine region



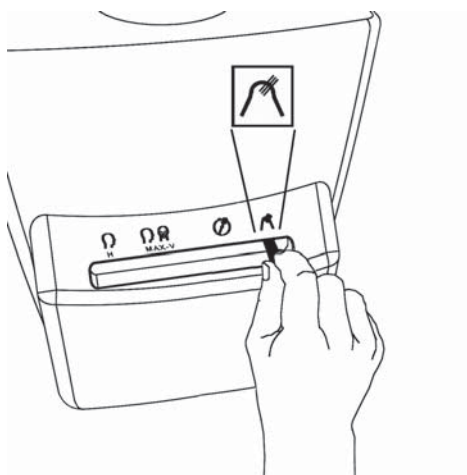
Alignement incisive region



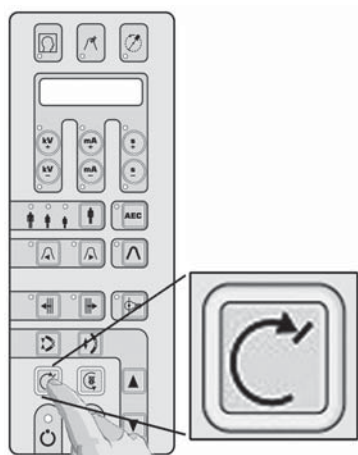
20.5 Preliminary procedures for X-ray exposure

To perform Transcan exposures, make sure the sensor module is inserted on the bay on the panoramic rotating arm.

20.5.1 Setting the primary collimator



Make sure that the lever of the collimator in the tubehead is on the 'Transcan mode' position. If not, move it into this position. The symbol on the control panel will light up.

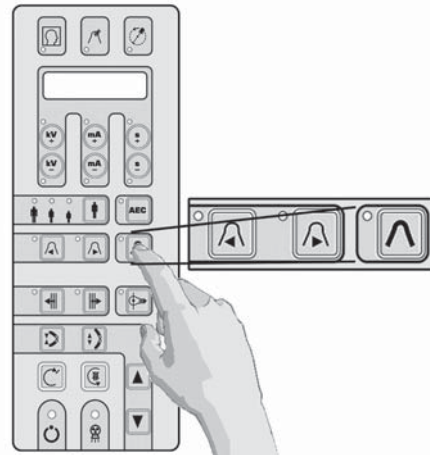


Press the Reset key.

Please note that the equipment must always be in the reset condition as pre-requisite for starting the execution of any exposure program.

If the above mentioned operations have been carried out correctly, the current projection modality and default exposure data are displayed, and the symbol will light up.

20.5.2 Selection of the projection




Select the Transcan program on the control panel using the selection keys. The display will show the sector of the layer among:

RR Posterior

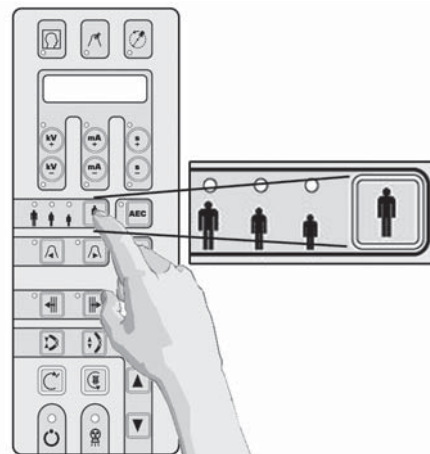
LL Posterior

RR Incisors

LL Incisors

To select the different exposure modalities press the keys ◀ or ▶. Please consider that in Transcan mode the key  doesn't have any recalling function.

20.5.3 Selection of the patient size



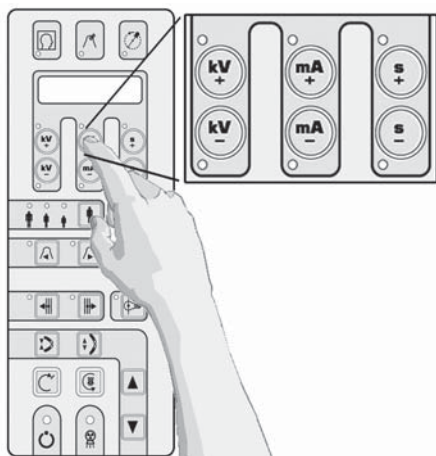
Press the select patient key and choose between small, medium and large.

Medium size patient is proposed by default.



Big adult male or elderly person with strongly calcified dentition are classified as large size.

20.5.4 Setting the technical parameters



The exposure technical factors related to the chosen selection (kV, mA, s) will be set and displayed.


If the operator deems it necessary, kV and mA can be individually modified (each in the whole range) by pressing the following keys: **+ kV**, **- kV**, **+ mA**, **- mA**, in the upper part of the control panel.

If the selected technical factor is different from the default value, the related led will light up.

The exposure time (technical factor: s) is exclusively determined by the chosen program.


20.5.5 Performing a “dummy run”



To perform a ‘dummy run’ (a no-radiation simulation of the currently selected projection program or modality), press the key .

This key must be pressed throughout the whole run time (key operates in “dead man” mode), otherwise, the movement will stop.

Return to the start position by pressing the reset key .

In case of emergency, the movement during this operation can be stopped by pressing the key .

20.6 Patient positioning

Depending on the difficulties and conditions which may be encountered during each examination (patient's emotive state, patient morphology, problematic examination, available time etc...) choose one of the two following application methods:

20.6.1 Use of the impression tray



With the aim making the patient as comfortable as possible during the X-ray examination, the tray can be cropped laterally with an appropriate tool (see the product instructions).



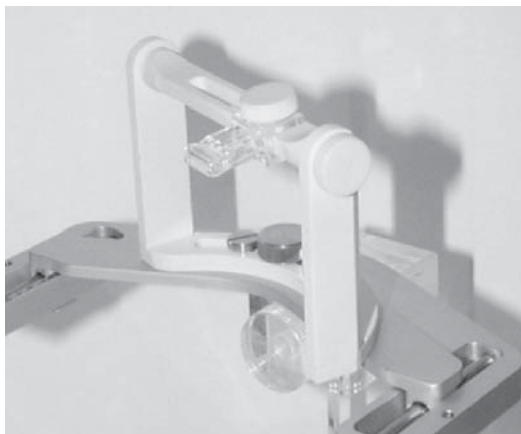
Reposition the impression on the patient's dental arch, making certain that all the teeth are in their correct position.

Move the patient into a position so that the impression tray in the patients mouth can be coupled to the tray-holder-fork in the positioning device.

20.6.2 Use of the special TRANSCAN bite block

Conclude alignment procedure and remove the impression tray from the positioning device

Substitute the metal tray-holder-fork with the supplied special TRANSCAN bite block, making sure that the bite block is in the same position as was the tray-holder-fork.



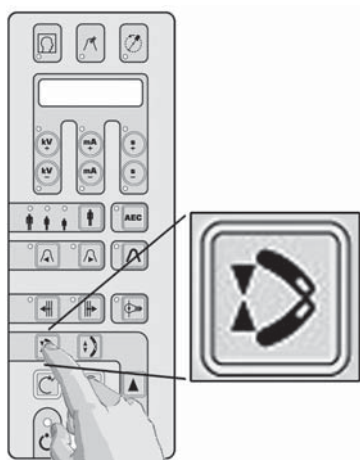
Have the patient bite on the special bite block, making sure that incisors fit into the appropriate splines on the bite block.

Make sure that the patient's "diastema" is aligned with the central reference on the bite block, verifying that the mid-sagittal plane is centered on the reference line (patient's head should not be inclined from vertical).

Verify that the head is neither turned away or inclined, using the positioning light beams if necessary.

For both of the above described methods (use of the impression tray or bite block) position the mandibular profile horizontally for examinations of the lower jaw. For upper jaw examinations verify that the ala-trago plane is in a horizontal position. Set the necessary head inclination by cautiously raising or lowering the overhead of the panoramic unit.

Before proceeding make sure to loosen the appropriate screws on the positioning device to permit this movement.

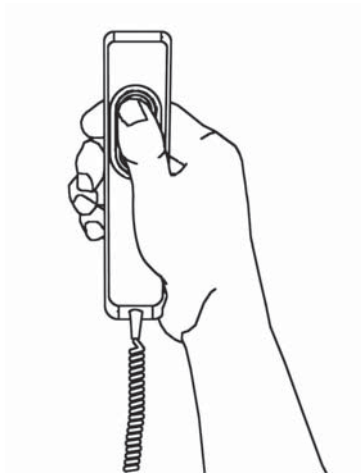


Close the head rest flippers using the appropriate key on the control panel until one of these touches the head of the patient, offering a reference point when holding the position during exposure.



The use of the headrest is possible only for certain modes and depends on the patient's morphology.

Verify that in the System tray of Personal Computer is displayed the GREEN icon: it indicates that the system is ready to capture radiographic images.

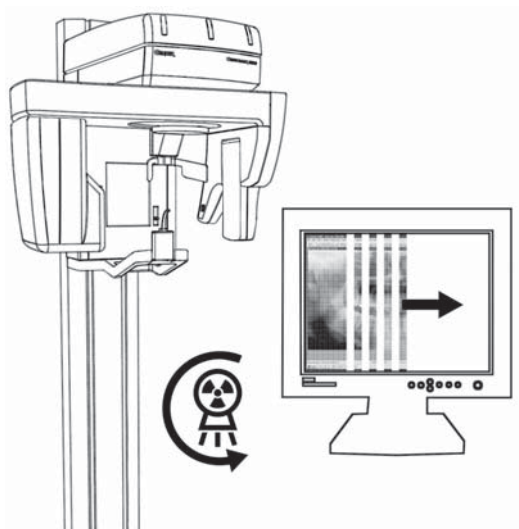


Make the exposure by pressing the exposure handswitch.

Do not forget to observe the applicable radiation safety procedure.



The exposure handswitch must be kept firmly pressed during the whole exposure procedure, otherwise X-ray emission and carriage movements will be stopped ("dead man" exposure mode). If this should happen, the unit must be reset and the patient positioning re-done.



During X-ray emission, verify (whereas possible) on monitor the correct image acquisition in the built-in preview-window of the program VixWin: it will be automatically displayed when the X-rays reach the electronic sensor.

During the emission of the X-rays (which takes place only during part of the cycle, because part of the time is used for re-positioning the machine) the yellow signal lights up and an audible buzz is emitted, both at the unit and at the remote station, if installed.

When the exposure cycle has been concluded, release the X-ray handswitch.

The preview is immediately transferred from the system as VixWin image.

Use of the special TMJ Cephalostat

21

The special patented skull cephalostat for TMJ examinations (pt. nr. 9801 401 30004) is designed for stable, accurate, and repeatable positioning of the patient's head during a TMJ x-ray examination with Orthoralix 9200 DDE.

With this cephalostat, patient positioning is not done with reference to the dentition but rather to his/her acoustic meati, a landmark very close to the Temporo-Mandibular Joint itself. The chin is completely free to move, so two consecutive radiographs with closed and open mouth (or protruded jaw) can be taken, if necessary, without moving the patient's head. Radiographs of the same patient taken in this way are geometrically congruent, i.e. shape and measurements of the anatomic objects therein are directly comparable between different radiographs.

The TMJ cephalostat plugs into the clamp for the positioning aids, and determines the patient position via three adjustable support points: two ear plugs in the acoustic meati, and one nasion support. It accommodates patient heads with inter-temporal width in the range 120-200 mm, and a nasion-meatus distance (projected onto the sagittal plane) in the range 70-110 mm. In case of a frontal projection, the head must be oriented with the Frankfurt plane slightly tilted downwards in order to reduce the shadow cast by the zygomatic bone onto the condyle head.

Make sure that the Orthoralix 9200 DDE is in reset position. Select the suitable TMJ projection and the technique factors. Open the motorised headrest completely. Remove the bite block or the chin rest from the clamp, and insert the TMJ cephalostat instead. Make sure the plug is firmly clamped in. Displace the ear plugs as far apart as possible, by using the lever under the cephalostat. Release the nasion support by loosening the knob at its side, and move it forward as much as possible. Move the overhead carriage to the proper height so that the ear plugs are level with the patient's ears.

Use hygienic protections (pt. nr. 4519 128 20952, set of 280 pieces) on the ear plugs. Place the patient between the ear plugs so that he/she looks at the mirror. Ask him/her to grasp the handgrip. Adjust the ear plugs, gently closing them into the patient's ears. The patient should stand in a natural, comfortable stance, but with the neck as stretched as possible. Adjust the head inclination by resting onto the nasion support, and lock this last in position by turning its knob. Make the exposure(s) by following the relevant instructions in this manual.

References:

Welander U, Tronje G, McDavid WD

Layer thickness in rotational panoramic radiography: some specific aspects.

Dentomaxillofac Radiol 1989; 18:119-127.v

Use of the technical test phantom

22

A patented universal technical test phantom (code nr. 4519 124 20471) is available, and supplied as an accessory with every Orthoralix 9200, for measuring the most important geometrical parameters of images in panoramic mode.

The phantom consists of a moulded object that incorporates a radio-opaque curved line reproducing shape and position of a line passing through the midpoint of the teeth roots in the average human maxilla. Short radio-opaque segments of fixed length and inclination are equally spaced along this line. The most frontal position of the curve is fitted with a set of pseudo-spherical objects, to check the exact position of the focal trough. Structures simulating position and inclination of the condyles, in occluded jaw condition, are also included.

With Orthoralix 9200, the phantom should be fixed by screws in the two holes of the included transparent chin rest. The phantom and chin rest set can then be inserted into the positioning aids clamp.

Use the minimum possible technique factors, i.e. 60 kV 3 mA; place the supplied 1.3 mm copper plate on the middle area of the inner side of the sensor module (where the small blue dots are showing the position of the CCD), in order to cover the whole surface of the CCD itself.

Make an exposure with the projection modality that you want to verify. Properly process the film.

The following information can be elicited from the image so exposed:

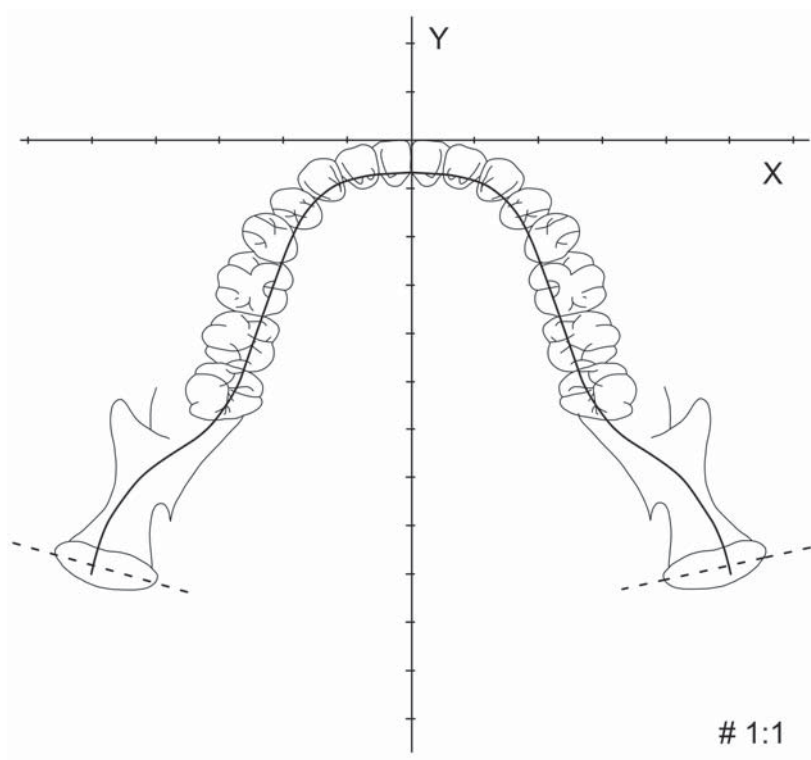
- Symmetry of the x-ray projection.
- The exact position of the focal trough in the most frontal part of the image layer corresponds to the one blot that is perfectly round in the series of oval blots at the center of the image. The blots that are closer to the projection center (respect to the focal trough) are shown elongated horizontally, those more external (farther away from the projection center towards the sensor) are shown elongated vertically. If the whole series of blots is shown almost round, it means that the image layer is broad and well centred respect to the average jaw shape.

Please note that the lateral vertical light, indicating the most frontal position of the focal trough, should coincide with the most frontal position of the curve, and the center of the series of blots.

- The deviation of the image layer provided by the equipment, respect to the average standard curve for the dentition, can be assessed by observing the radiographic shape of the vertical segments. In case of perfect coincidence (both in shape and position), the segments will be shown focused at their center, corresponding with the intersection with the average standard curve, and gradually defocused at their extremes.
- The horizontal and vertical magnification in different parts of the image can be measured on the image from the horizontal spacing between each pair of adjacent segments (it is 5 mm in reality), and from the projection to the vertical of the segments length (would correspond to magnification one), respectively.
- The angle, in different parts of the image, between the x-ray beam and the average standard curve of dentition can be measured as the angle to the vertical of the segments image.

References:

1. Nummikoski P, Prihoda T, Langlais RP, McDavid WD, Welander U
Dental and mandibular arch width in three ethnic groups in Texas: a radiographic study.
Oral Surg Oral Med Oral Pathol 1988; 64:609-617.
2. Welander U, Nummikoski P, Tronje G, McDavid WD, Legrell PE, Langlais RP
Standard forms of dentition and mandible for application in rotational panoramic radiography.
Dentomaxillofac Radiol 1989;18:60-67.
3. Molteni R
A universal test phantom for dental panoramic radiography
MedicaMundi 1991; 36/3:212-217.



Standard average jaw shape for dentition.

Hygienic procedures and cleaning

23

Always substitute the disposable hygienic covers of the bite block and ear plugs before positioning a new patient. These covers should be stored in a clean, dry environment and not exposed to direct sunlight or UV radiation.

Bite block and chin rest can be disinfected by immersion in a cold sterilizer, and can be steam sterilized in autoclave up to 125°C.

The other parts that may come into direct contact with the patient, such as the handgrip, the transcan positioning aids or the front rest flaps, must be kept clean and disinfected. These can be cleaned with a 2% ammonia solution, or other appropriate solutions. The ear plugs should also be kept clean and disinfected.





Always disconnect the unit from the mains supply before cleaning or disinfection. No water or any other liquids should be allowed to enter the equipment, as this can cause short-circuits and corrosion. The unit, including accessories and connecting cables, should be cleaned or disinfected only using a damp cloth, followed by rubbing down with a dry cloth. Do not use solvents (toluene, benzene, etc.), corrosive cleaning agents or abrasive polishing materials. Spray disinfectants are not recommended, as the disinfectants may permeate into the unit and cause short circuits or corrosion. If sprays are unavoidable, the following precautions must be taken: should the room in which the equipment is installed have to be disinfected by means of an atomizer, the unit should be carefully covered with a plastic sheet before proceeding.

The equipment should be switched off and allowed to cool down well in advance in order to prevent convection currents drawing the disinfectant vapours into the equipment. After dispersal of the vapours, the plastic sheeting can be removed and the unit powered-up for use. The equipment must not be used in the presence of disinfectants which vaporize to form explosive mixtures, these vapours must be allowed to disperse before the equipment is returned to use. The method of disinfection used should comply with current regulations and recommendations, including those concerning the prevention of explosive hazards.

The Orthoralix contains substances which may be harmful to the environment. In particular, the tubehead contains approximately 2.5 kg of insulating mineral oil. Therefore, disposal of discarded parts must be done through a company specialized in industrial wastes.

User programs





Users can pre-configure certain parameters via a special operation mode - the User's Configuration Programme. Another special operation mode is the Service Programme, for the benefit of the Service Engineer during installation, maintenance and repairs. Refer to the Technical Service Manual for information regarding the Service Programme.

To start the User's Configuration Programme, keep key  pressed for a few seconds when powering-up the unit, until the message "WAIT" disappears from the display. The available functions can be selected by using keys  or  and are shown in the display; each selection must be confirmed using the key . The functions are:

Set language

English, Français, Italiano, Deutsch, Espanol.

Set exposure factors

With this function, it is possible to individually alter each one of the preset technical factors in any of the projection modalities and patient sizes (except the exposure time in the Pan and Transcan modes, where it is determined by the projection kinematics itself). To change the preset technique factors, while this function is active and shown on the display, simply navigate through the various projection modalities and patient sizes in the normal way via keys , ,  then change the technique factor as desired, in the normal way via keys +kV, -kV, +mA, -mA, +s, -s, and confirm via key . If the general SENSITIVITY is changed, this will also affect in a linear way the altered mA values.

Density test

Enable/disable the density test (in addition to the normal projection modalities.)

AEC default (Y/N)

Enable/disable the AEC default function when powering-up the Orthoralix 9200 DDE.

Default Values

Resetting of the default values on the Orthoralix 9200 DDE

Messages and alarms

A number of warning messages may be displayed in case of certain anomalous conditions:

Collimator

The collimator is not properly set in a position corresponding to any of the possible projection modes. To correct move the collimator lever to the proper position, as indicated by the symbols on the tubehead cover above the collimator.

Tubehead

The position of the tubehead is not congruent with the selected mode, which is determined by the position of the collimator. To correct turn the tubehead, or re-select the mode via the collimator.

Operator release

The operator has released the x-ray handswitch too soon before the conclusion of an x-ray exposure. Press any key to cancel the message.

Movement halted

The operator has halted the movement during a reset or a dummy run cycle, before its conclusion. Press any key to cancel the message. Do reset again.

Cooling down

The tubehead has reached its estimated thermal load limits, because of heavy radiographic workload, and just cool down before another x-ray emission. The number of seconds to go for the thermal recovery is shown and continuously updated on the display. Wait until this number reaches zero and the message disappears.

DMU not present

The Digital Module Unit (DMU) is not properly inserted on the housing. Check the presence of the DMU.

DMU misplaced

The Orthoralix 9200 DDE is detecting a wrong correspondence between the position of the DMU and the position of the primary collimator level.

Check the correct correspondence for the projections the system has to perform

CEPH BAY rotated

The Ceph DMU housing is rotated. Turn it parallel to the secondary collimator before making the exposure.

DMU Fault

No image is acquired under x-ray.

No Connection

The physical connection between the Host PC and the Orthoralix is lost.

DMU Not Detected

The Serial number of the DMU is not detected

Transfer Error

A DMU transmission error is not recovered after 3 image resend.

HW Fault:

(Where #### is a specific error code)

An HW fault in one of internal Orthoralix communication bus (IPU-LPC-ORTH-IPU-PA7)

Host Unavailable

It doesn't exist any logical connection between the Host PC and the Orthoralix (Multi Room Management).

Host Busy

Host PC is not ready for exposure.

Other alarm messages might be displayed because of technical faults of the equipment.

For these refer to the Technical Service Manual.

Appendix A :

Technical data

A

For diagrams and detailed technical information, refer to the Service Manual.

Power supply:	230 VAC nominal, operating range 115 - 250 V
Frequency:	48-62Hz
Max. line voltage regulation at 115V:	4%
Max. line power rating:	10A at 230V, 15A at 115V
Line current absorption in stand-by:	< 0.5A (230V) < 1A (115V)
High voltage waveform:	true DC, via square-wave power electronic converter (25 kHz) and voltage multiplier/rectifier
from 60kV to 84kV, in 2 kV steps:	max. tolerance from nominal value ± 3 kV
from 3mA to 15mA, in 1 mA steps:	max. tolerance from nominal value $\pm 5\%$
Backup timer:	14,4s (pan)
Tube type number:	GX 100-20DC
Anode angle:	5°
Anode material:	Tungsten
Rated peak tube potential:	100kV
Duty factor:	1:20 at full power operation
Inherent filtration:	2.5 mm Al equivalent (84 kV)
Half Value Layer (HVL):	2.4 mm Al equivalent (typical) at 60 kV 2.9 mm Al equivalent (typical) at 70 kV 3.2 mm Al equivalent (typical) at 80 kV
Focal spot:	0.5 according with IEC 336 (1993)
Output dose rate:	approximate average 0.325 mGy/s at 70 kV, 10mA, 1000mm
Leakage radiation from tubehead:	less than 250 μ Gy/hour (84kV) at 1 m in any direction
Leakage technique factors:	84 kV, 15 mA, duty factor 1:20.
Primary X-ray beam shielding : (behind the sensor holder)	1.5mmPb
Focus to collimator distance:	94mm
Source to Detector Distance (SID):	505mm (pan) 1500mm (ceph)

Beam limiting device:

Vertical slit collimator:

- 0.7x25mm Pan
- 0.7x13.8mm Ceph vertical
- 1.4x11.2mm Ceph horizontal
- 3x160mm Ceph secondary

Image acquisition device:

CCD (Charge Coupled Device)

• **CCD sensor resolution:**

10,4 LP / mm

• **CCD sensor pixel size:**

48 µm

• **image resolution:**

5,2 LP / mm

• **image pixel size:**

96 µm

Lasers:• **Class**

2, conform to IEC 60825-1:2001

• **Wavelength**

650nm

• **beam divergence for collimated beam**

< 1 mrd

• **pulse duration**

30 seconds

• **maximum output**

< 1 mW

Weight:

186 kg

Environmental conditions:

Operational temperature +15/+35°C

Storing temperature:

-30/+60°C

Minimum atmospheric pressure:

50,000 Pa

Any electrically connected part (Computer and eventual optional peripherals) outside from the patient area, shall be in conformity with IEC 950 and CE 89/336 Directive.

Appendix B :

Technical factors

B

Modality: BASIC

	Total exposure Time (seconds)	Total Cycle Time (seconds)	Magnification	Movement range of the focal layer, related to the jaw morphology (mm)	Preset technical factors small patient (kV)	Preset technical factors medium patient (kV)	Preset technical factors big patient (kV)	mA
Standard panoramic	12	24	1.25	0-14 (ref.7)	66	70	74	4
Child panoramic	11	24	1.25	0-14 (ref.7)	62	66	70	4
Orthogonal dentition	9.6	24	1.25	0-14 (ref.7)	64	68	72	4
Left Jaw (Left Half-panoramic)	8	24	1.25	0-14 (ref.7)	66	70	74	4
Right Jaw (Right Half-panoramic)	8	24	1.25	0-14 (ref.7)	66	70	74	4
Lateral TMJ (open/close mouth)	8	27	1.23		66	70	74	4
Frontal Dentition	6.4	24	1.25	0-14 (ref.7)	64	68	72	4

Modality: DMF

	Total exposure Time (seconds)	Total Cycle Time (seconds)	Magnification	Movement range of the focal layer, related to the jaw morphology (mm)	Preset technical factors small patient (kV)	Preset technical factors medium patient (kV)	Preset technical factors big patient (kV)	mA
Left Half-Orthogonal (Left Orthogonal Half-dentition)	6	32	1.25	0-14 (ref.7)	64	68	72	4
Right Half-Orthogonal (Right Orthogonal Half-dentition)	6	16	1.25	0-14 (ref.7)	64	68	72	4
Frontal sinuses	6.2	22	1.24	0-14 (ref.7)	68	72	74	4
Lateral sinus - Left	2.5	26	1.27		66	70	74	4
Lateral sinus - Right	2.5	18	1.27		66	70	74	4
Frontal TMJ	6	27	1.64		68	72	76	4

Modality: CEPH

	Total exposure Time (seconds)	Total Cycle Time (seconds)	Magnification		Preset technical factors small patient (kV)	Preset technical factors medium patient (kV)	Preset technical factors big patient (kV)	mA
Latero – Lateral (LL)	8	20	1.1		72	76	80	7
Antero – Posterior (AP)	8	20	1.1		74	78	82	10
Carpus	6	18	1.03		62	64	66	5

Modality: TRANSCAN

	Total exposure Time (seconds)	Total Cycle Time (seconds)	Magnification		Preset technical factors small patient (kV)	Preset technical factors medium patient (kV)	Preset technical factors big patient (kV)	mA
RR posterior	5,2	45	1.337		68	72	76	4
LL posterior	5,2	45	1.337		68	72	76	4
RR incisors	5,2	50	1.337		68	72	76	4
LL incisors	5,2	45	1.337		68	72	76	4

Appendix C : X-ray projections geometry

C

Standard panoramic



Child panoramic



Orthogonal dentition



Left jaw

(left half-panoramic)



Right Jaw

(right half-panoramic)



Lateral TMJ

(open / close mounth)



Frontal dentition**Left half-orthogonal****Right half-Orthogonal****Frontal sinuses****Lateral sinus - left****Lateral sinus - right****Frontal TM**