ENGLISH

GXDP-700™

Digital Panoramic X-Ray System

User Manual

207723 rev. 7

Reviewed: Nieminen Timo Antero 2016-12-02 15:31
Approved: Laihonen Tuuli 2016-12-02 16:41

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The original language of this manual is English.

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Table of Contents

Reviewed: Nieminen Timo Antero 2016-12-02 15:31
Approved: Laihonen Tuuli 2016-12-02 16:41
D507729, 7

Reviewed: Nieminen Timo Antero 2016-12-02 15:31
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D507729, 7

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D507729, 7

1 Introduction

1.1 GXDP-700™

GXDP-700 is a dental X-ray system for producing high quality digital images of dentition, TM-joints and skull. In order to take images with GXDP-700, you need a suitable PC hardware connected to the GXDP-700 unit and imaging software to capture and manage images.

GXDP-700 performs the following procedures:

Panoramic

- Standard panoramic
- Small panoramic
- Wide arch panoramic
- Bitewing
- Frontal TMJ, PA projection
- TMJ, lateral projection (axially corrected)
- Maxillary sinus
- Frontal dentition
- Orthogonal panoramic

Cephalometric (optional)

- Cephalometric latero-lateral (LL) projection
- Cephalometric PA/AP projection
- Carpus program (optional)
  (Not available in USA and Canada)

3D H x W (optional)

- 61x41 mm Field of View
- 61x78 mm Field of View

NOTICE! *The FOV heights are maximum values measured at the center of the FOV, the measured height at the edges of the FOV are smaller.*

1.2 Intended use

The unit is intended for dental radiographic examination of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as x-ray projection images of an examined volume for the reconstruction of a 3D view.

The unit is also intended for carpus imaging in assisting cephalometric analyses (Not in USA).

CAUTION! *USA only: Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.*

1.3 Intended user profile

Only for professionally qualified dental / medical personnel.

Typical user is a dental assistant with specific training for using dental x-ray units.

1.4 Associated documentation

- GXDP-700 user manual
- GXDP-700 installation manual
- GxPicture Driver software installation manual
- The user manual supplied with the dental imaging software (e.g. VixWin)
- The installation manual supplied with the dental imaging software (e.g. VixWin)
- The user manual supplied with the 3D imaging software (e.g. InVivo)
- The installation manual supplied with the 3D imaging software (e.g. InVivo)

1.5 References

The following instructions are delivered with in the GXDP-700 installation manual:

- Firmware update instructions
- Calibration instructions
- Cephalostat upgrade instructions
- Cephalostat side changing instructions

- 3D upgrade instructions are delivered with the 3D upgrade kit.

1.6 Abbreviations used in this manual

FOV = Field Of View. The cylindrical 3D volume that is reconstructed by the system.

ROI = Region Of Interest. The anatomical area or region of the patient that you are interested to examine.

FH = Frankfort-Horizontal

H = Horizontal

DRT = Dose Reduction Technology

SRT = Scatter Reduction Technology™ reduces the effect of metal and other dense radiopaque objects, which typically create artifacts that are seen as stripes and shadows.

1.7 Warnings and precautions

1.7.1 Warnings to be observed during use

The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.

The unit must only be used to take the dental x-ray exposures described in this manual. The unit must NOT be used to take any other x-ray exposures. It is not safe to use the unit to take x-ray exposures, that it is not designed for.

Only professionally qualified dental and/or medical personnel are allowed to operate the unit and carry out any diagnoses based on output from the unit.

Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.

When taking an x-ray exposure of a patient with exceptional anatomy (typically very tall or large) use the Test-mode (no x-rays) first to make sure that patient can be positioned correctly to the unit and for checking that the unit doesn't hit the patient.

Operator should maintain visible contact with the patient and technical factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.

It is the responsibility of the doctor to decide whether x-ray exposure or any additional exposures are justified and necessary.

The minimum height of patient that can be x-rayed in standing position is 120cm (3.9ft/47.2in) and the maximum is 200cm (6ft/78in). Taller patients must be seated. These heights only apply to patients with normal anatomy.

Always use the lowest suitable x-ray dose to obtain the desired level of image quality.

Always follow the instructions for patient positioning and imaging procedures instructed in the User Manual.

Avoid taking x-ray exposures of pregnant women.

When taking an x-ray exposure of a child always use the lowest possible x-ray dose, the smallest possible image area and the lowest possible resolution that allows you to perform the required diagnostic task.

If the patient is using a pacemaker, consult the manufacturer of the pacemaker before taking an exposure to confirm that the x-ray unit will not interfere with the operation of the pacemaker.

Decontaminate all the surfaces that the patient is in contact with after every patient to prevent cross infection.

Decontaminate all device accessories that contact the patient during a radiographic examination.

Check that the power supply cable is properly attached to the mains socket and visually check the cable for damage. If the cable is damaged, it shall be replaced by authorized service technician only.

Do not open or remove any of the unit's enclosures. No user serviceable parts inside.

Do not touch the patient and any exposed electrical connector, such as sensor connector or Ethernet port, simultaneously.

The customer must ensure that the siting environment fulfills the requirements listed in the Installation manual. Special attention must be paid to the strength of the floor and wall materials, electrical mains and radiation protection. It is the responsibility of the customer to ensure that the site is large enough for the patients.

The unit contains toxic materials that need to be handled properly when disposing the unit. Return the unit to the dealer in the end of its life cycle.

Excessive dust should be cleaned from the unit for free airflow and cooling. Switch the unit OFF before cleaning.

In case of water damage/water dropping over the product, call for service technician to ensure the product is fully operational according to specification.

1.7.2 Warnings for cross infection

Always use available hygienic barriers with the patient positioning accessories:
- Bite guide hygienic barrier
- Chin support hygienic barrier
- Temple support hygienic barrier
- Ear plug cover

1.7.3 General warnings

Personnel operating the device must be adequately trained with respect to the technological principles of operation and radiation protection when using cone beam computed tomography (CBCT) imaging.

This unit complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could influence the performance of the unit.

Always ensure to fulfill the requirements of the local and national regulations.

The correct software and settings in the workstation are essential to the performance of the unit. Consult technical support to ensure correct setup.

Danger: Explosion hazard - do not use in the presence of flammable anesthetics, gases or vapors.

The unit is factory set to operate using a 230-240 ±10 VAC power supply. Never connect the unit to a power supply different to the voltage marked on the unit.

If the unit needs to be connected to a multiple socket-outlet, the socket shall not be placed on the floor.

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

The site must fulfill the environmental requirements in the installation manual chapter technical specifications.

There should be free space around the unit for safe operation.

The PC / Ethernet switch to which the unit is connected, should be approved appropriately (e.g. EN 60950, IEC 60950, UL 60950). After installation, check that the IEC 60601-1 leakage current levels are not exceeded.

This product itself complies with IEC 60601-1 medical safety standard but in order to the system incorporating also a PC to comply the standard, EITHER the PC has to be a medical PC OR the PC has to be located over 1,5 meters apart from the unit. The installer and the user of the system shall confirm that at least one of the above requirements is fulfilled. A PC is a medical one if it complies IEC 60601-1 standard and that is indicated in the accompanying documents of the PC.

The unit shall be connected directly to the acquisition PC with an Ethernet cable. Connection through the LAN-network of the site is not allowed. Two network ports are needed in the PC in order to connect also to the site network.

All service operations must be made by authorized service personnel only.

The annual service as described in manual is mandatory for the correct and safe operation of the unit.

When taking exposures, operators and service personnel must protect themselves from radiation and remain at least two meters (six feet) away from the unit during exposure. Protect the patient from scattered radiation by placing a protective lead apron over the patient.

The unit must be installed and serviced according to the unit Installation & adjustments manual by a qualified technician.

Only personnel trained and approved by the manufacturer of the unit are allowed to service the unit.

3D imaging should not be used for routine or screening examinations in which a radiograph is taken regardless of the presence or absence of clinical signs and symptoms. 3D imaging examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.

Where it is likely that evaluation of soft tissues will be required as part of the patient’s radiological assessment, the imaging should be done using conventional medical CT or MR, rather than 3D imaging using Cone Beam technology.

Cone beam computed tomography images are not adequate for the analysis of soft tissue.

Panoramic and 3D exposures should not be used if conventional intra-oral radiographic images (like bitewing exposures) would be sufficient.

Make sure that patient’s thyroid glands are protected by a lead apron during the exposure.

The place where the unit is to be installed and the position from where the user will take exposures must be correctly shielded from the radiation that is generated when the unit is operated. Ensure to fulfill or exceed the requirements of your local regulations.

The unit or its parts must not be changed or modified in any way without approval and instructions from the manufacturer.

When servicing use only approved replacement parts supplied by the manufacturer.

The use of accessories not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

If this device is used with 3rd party imaging application software not supplied by the manufacturer, the 3rd party imaging application software must comply with all local laws on patient information software. This includes the Medical Device Directive 93/42/EEC and/or relevant legal requirements in the USA.

Do not connect any equipment to the unit that has not been supplied with the unit or that is not recommended by the manufacturer. The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

All protective covers must be properly installed before handing unit to the user or when operating the unit.

The user must always ensure, especially after a system crash or break in the x-ray unit - PC connection, or when scanning 2D images without patient ID, that images retrieved from the unit are associated to the correct patient.

1.8 Disclaimer

The manufacturer shall have no liability for consequential damages, personal injury, loss, damage or expense directly or indirectly arising from the use of its products. No agent, distributor or other party is authorized to make any warranty or other liability on behalf of the manufacturer with respect to its products.

1.9 Disposal

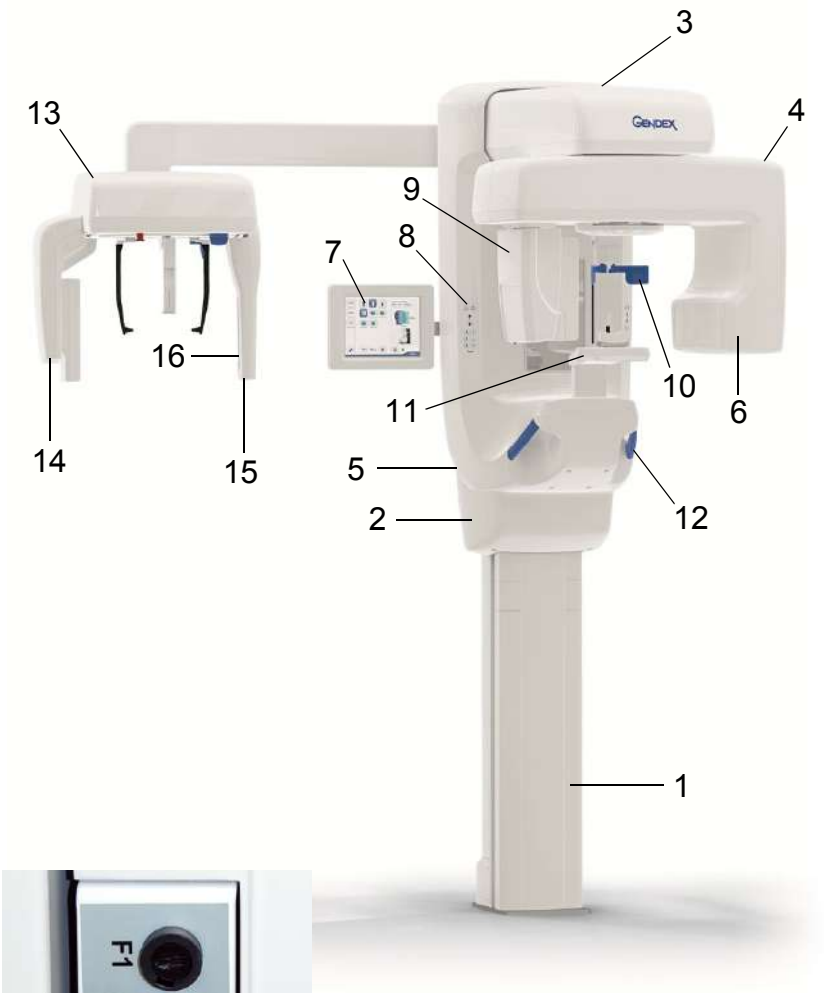
The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

Unit has at least the following parts that should be regarded as non-environmental friendly waste products:

- Tubehead (Pb, oil)
- Collimator (Pb)
- All electronic circuits, electronic boards inside
- Sensor covers (EMC painted)

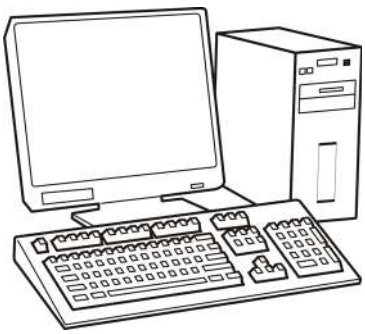
2 Unit description

2.1 Main parts and controls



1. Column
2. Carriage
3. Main support
4. Rotating unit
5. On / off switch (rear of carriage) and main fuses
6. Tubehead assembly
7. Touchscreen display
8. Control panel
9. Sensor head
10. Head support
11. Chin rest
12. Handgrips
13. Cephalometric unit
14. Cephalometric sensor
15. Secondary collimator
16. Positioning panel

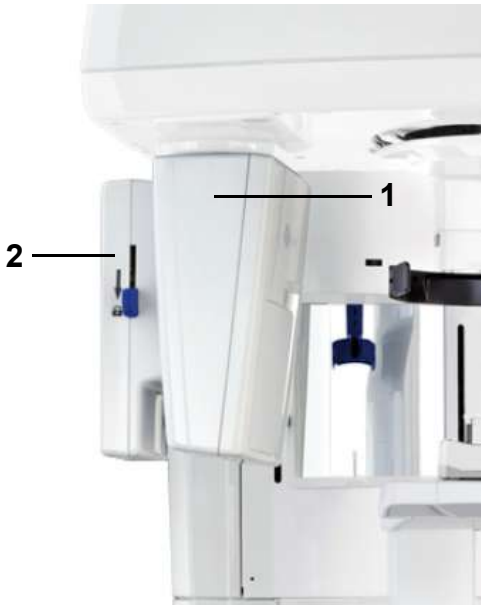
On/off switch (used to power the unit on and off) and main fuses.



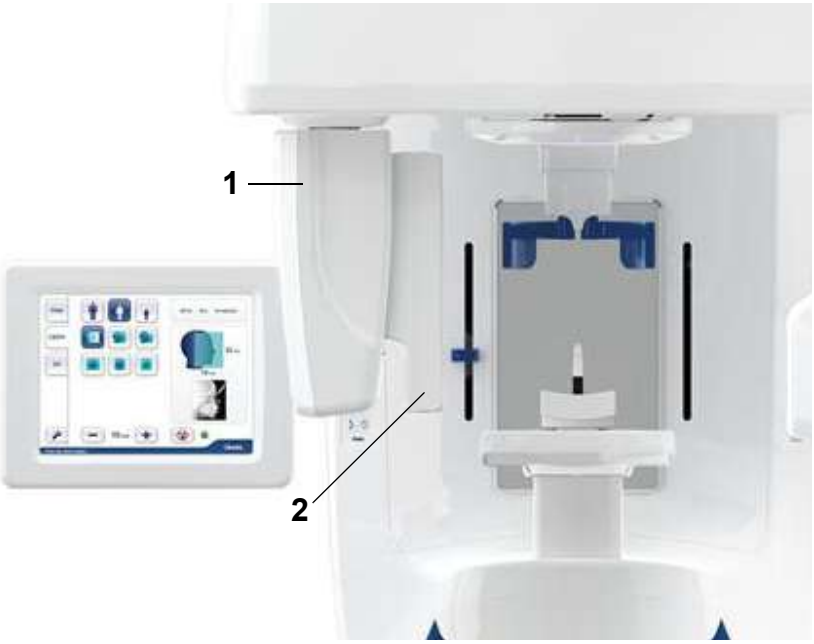
PC with MDD approved dental imaging software and 3D viewing software (not included).

All software must conform to the MDD and the relevant legal requirements in the USA.

The PC must conform to all the unit and dental imaging software requirements.



1. Sensor holder (panoramic units without 3D option)
2. Panoramic sensor

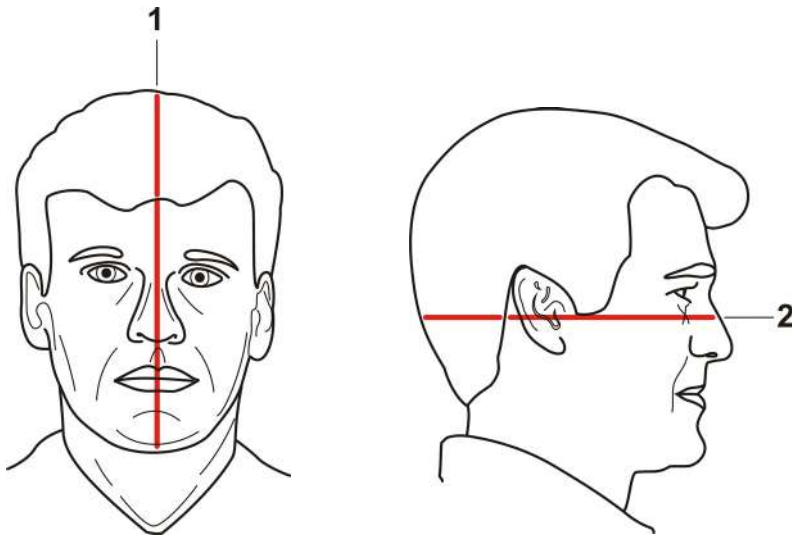


1. 3D sensor (units with 3D option)
2. Panoramic sensor

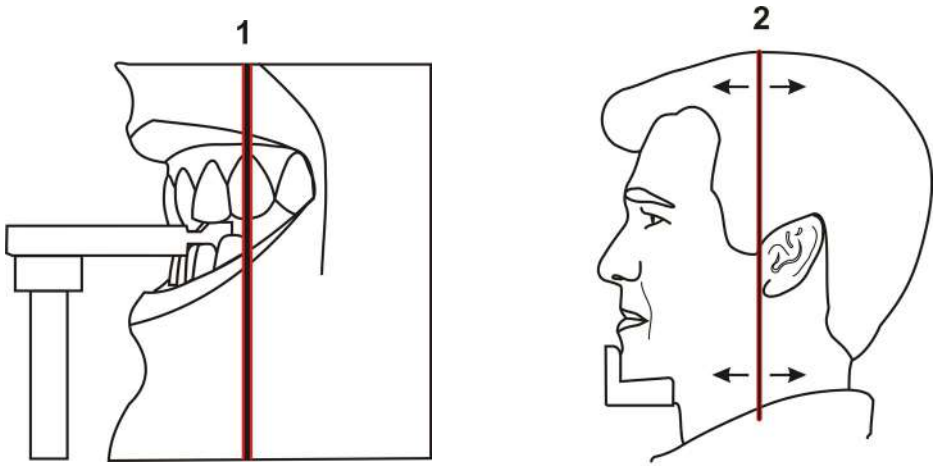
2.2 Patient positioning lasers

1. Midsagittal laser
2. Frankfort-horizontal plane laser (FH)
3. Image layer laser
4. Cephalometric Horizontal laser
5. TMJ laser
6. Horizontal laser, top of FOV (3D option only)
7. Horizontal laser, bottom of FOV (3D option only)

Panoramic lasers

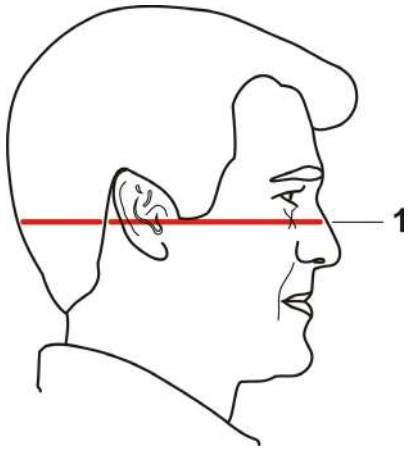


1. Midsagittal laser
2. FH laser (Frankfort Horizontal)



1. Image layer laser
2. TMJ laser

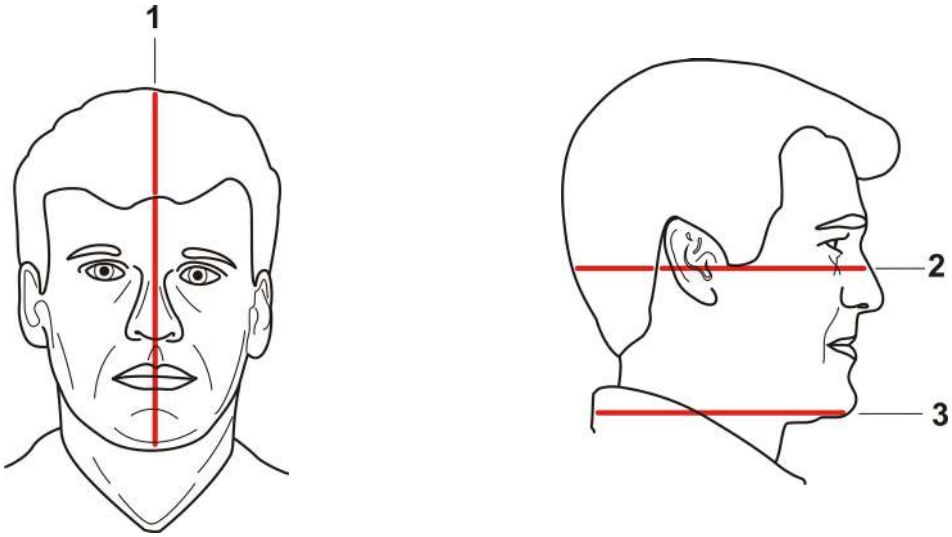
Cephalometric lasers



1. FH laser (Frakfort Horizontal)

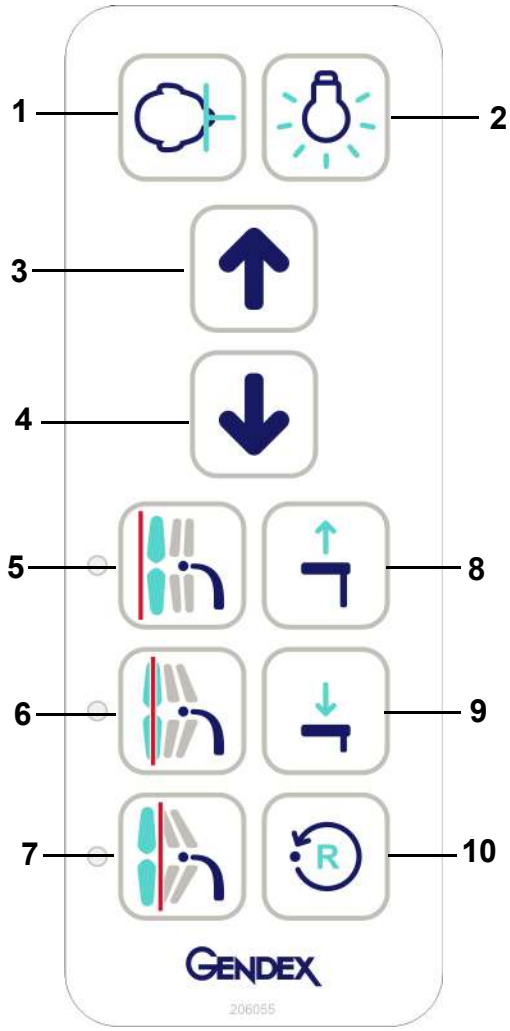
3D lasers (optional)

NOTICE! *Appropriate* lasers *are turned automatically on based on selected FOV.*



1. Midsagittal laser
2. Horizontal (H) light, top of FOV
3. Horizontal (H) laserlight, bottom of FOV

2.3 Control panel



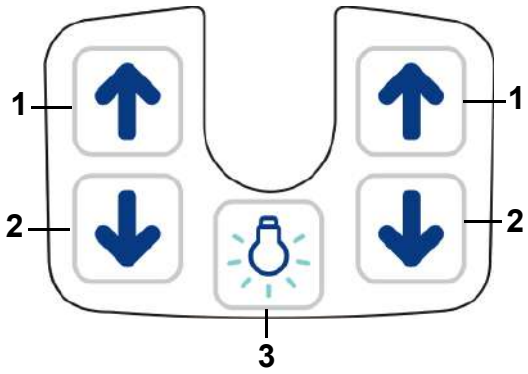
1. Patient In key - moves the Rotating Unit to allow patient better access when entering the unit.
2. Positioning lasers ON/OFF
3. Carriage UP
4. Carriage DOWN
5. Image Layer Control - Retrusion.
6. Image Layer Control - 'Normal' position; also use to reset position
7. Image Layer Control - Protrusion
8. Chin support UP
9. Chin support DOWN
10. Reset button

2.3.1 Image layer controls

Image Layer corresponds to the width of the x-ray capture area (focal trough) in relation to the position of the teeth. Typically, this trough completely encompasses the anterior teeth. However, in the case of a retruded bite, the teeth may be behind the trough. Conversely, with the protruded bite, the teeth may extend in front of the trough. The result of either is a non-optimal image.

The Image Layer keys allow the operator to match the patient's actual anatomy by using the cuspid as a guide. When the Image Layer laser is initiated, look for its position relative to the cuspid; then, match it to one of the three Image Layer keys--Retrusion, Normal, Protrusion.

2.3.2 Cephalometric unit control panel (optional)

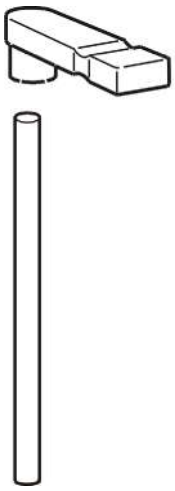


Located in Cephalostat secondary collimator enclosure.

1. Carriage UP
2. Carriage DOWN
3. Positioning lasers ON/OFF

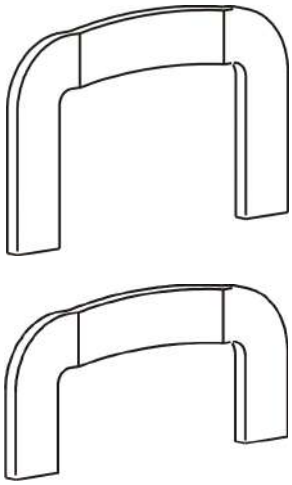
2.4 Accessories

Bite rod with the bite guide

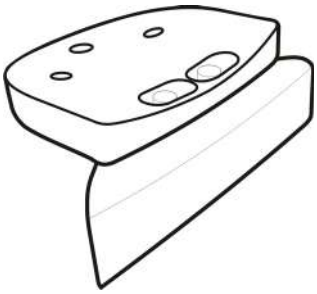


Bite rod with the edentulous bite positioner

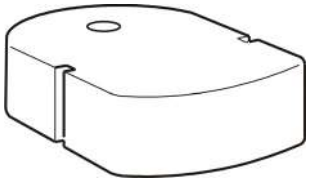
Chin support for edentulous patients



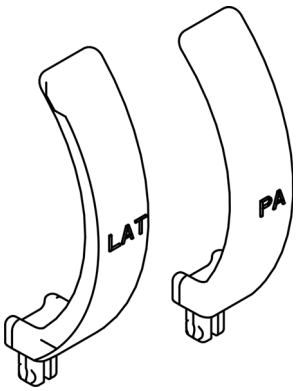
Sinus rest



Chin rest



TMJ nose support

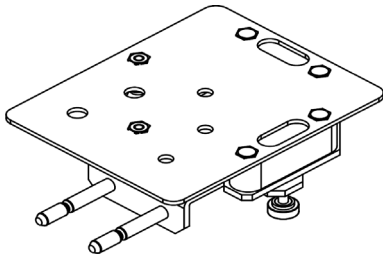


Disposable covers for patient positioning devices

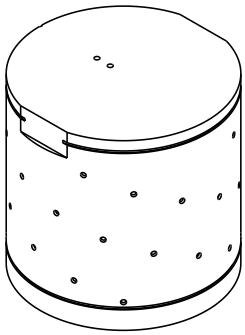
- Bite guide disposable covers
- Chin support disposable covers
- Temple support disposable covers
- Nasion support disposable covers
- Ear holder disposable covers

2.5 Other detachable parts

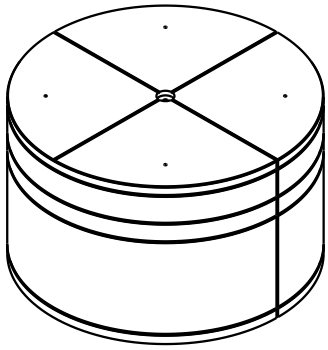
Bubble level



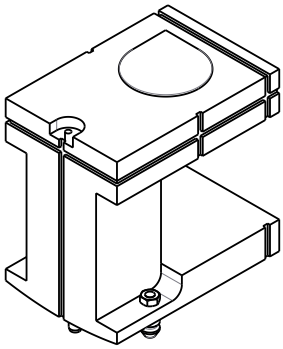
3D calibration phantom



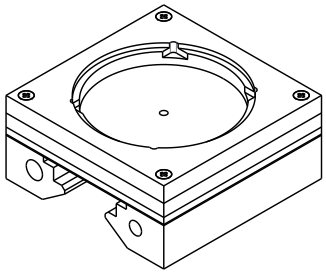
QC phantom



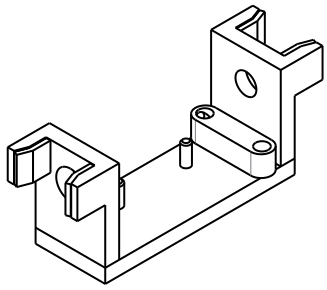
Cone phantom



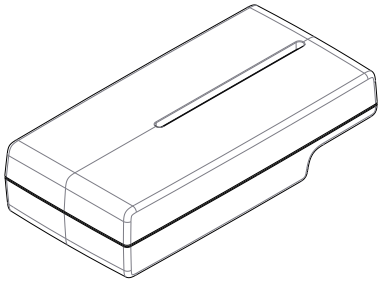
Panoramic quality check tool (option)



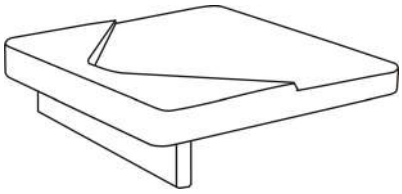
Panoramic quality check tool adapter for ceph (option)



Sensor (Pan & Ceph)



Platform for dental model

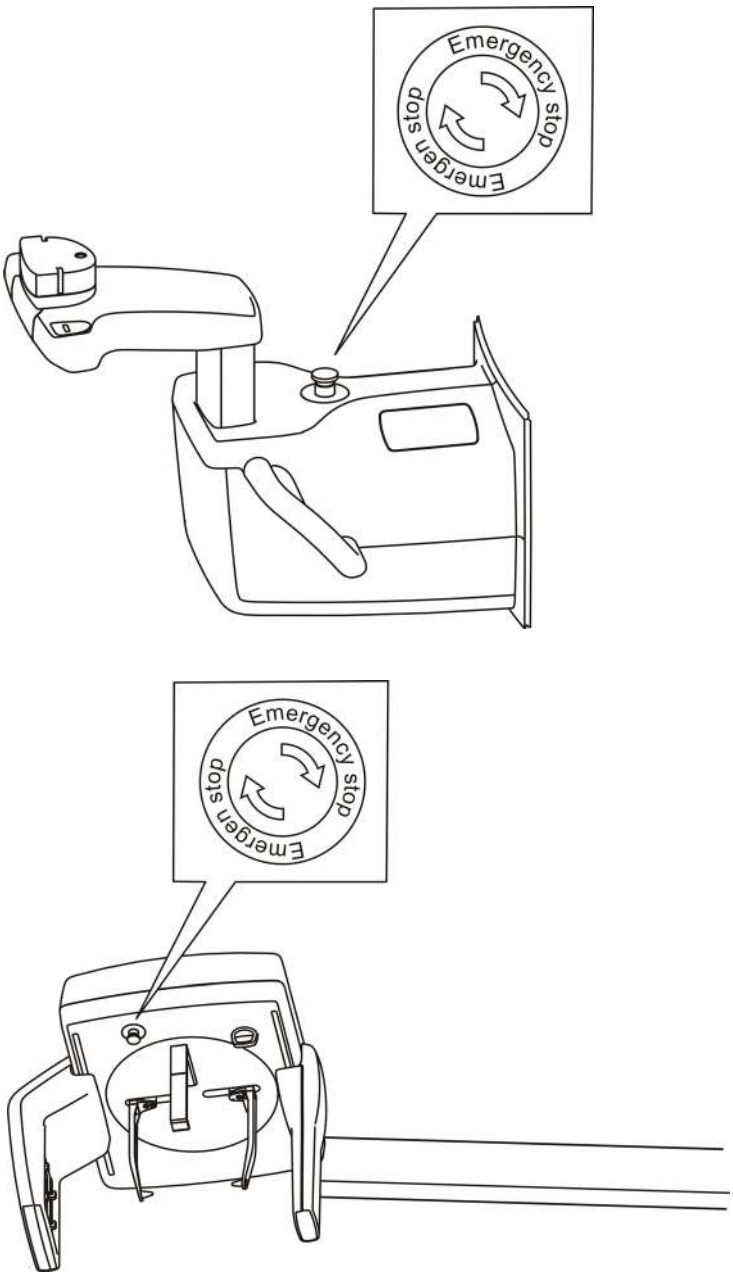


2.6 Emergency stop switch

In case of malfunction of the exposure button or other protective devices of the unit, an emergency stop switches are located near the handles and on the cephalostat unit, so that the patient can easily reach them.

If the emergency stop switch is pressed during an exposure, the exposure is terminated immediately and the x-ray unit is completely stopped. An interrupted exposure cannot be continued later, but has to be retaken from the beginning after the emergency stop switch is released.

Press to stop the unit, rotate to release.



2.7 Patient contacting parts

Applied parts/ parts in contact with patient	Part type	Type of contact	Contact duration
	Chin support	Skin	<5 min
	Disposable cover for chin support	Skin	<5 min
	Bite guide	Mucosal membrane	<5 min
	Disposable cover for bite guide	Mucosal membrane	<5 min
	Handle	Skin	<5 min
	Ear rod	Skin	<5 min
	Disposable cover for ear rod	Skin	<5 min
	Sinus/Chin rest	Skin	<5 min
	Nose support	Skin	<5 min
	Disposable cover for Nose support	Skin	<5 min
	Temple support	Skin	<5 min
	Disposable cover for Temple support	Skin	<5 min

3 Imaging programs

3.1 Standard Panoramic programs

The following standard programs are available under the **Pan** tab on the unit LCD screen.

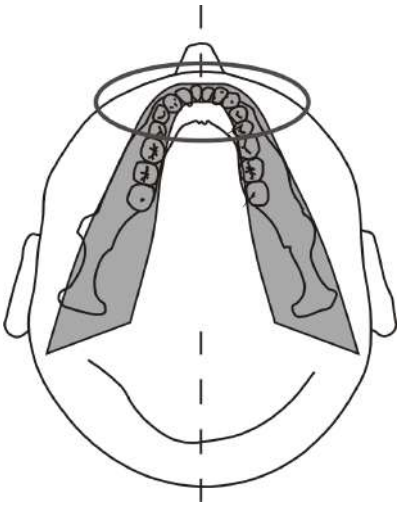


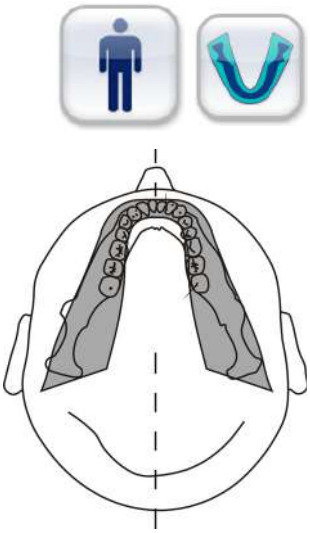
Image Layer corresponds to the thickness of the x-ray capture area (focal trough) in relation to the position of the teeth. Typically, this trough completely encompasses the anterior teeth. However, in the case of a retruded bite, the teeth many be behind the trough. Conversely, with the protruded bite, the teeth may extend in front of the trough. The result of either is a non-optimal image.

The Image Layer Adjustment buttons allow the operator to match the patient's actual anatomy by using the canine as a guide. When the Image Layer laser is used, look for its position relative to the cuspid; then, match its position to one of the three Image Layer Adjustment buttons--Retrusion, Normal, Protrusion.

If the light is behind the canine on the patient, click this button to have the unit compensate during image captured.
The unit will automatically make a 3-mm anterior adjustment.

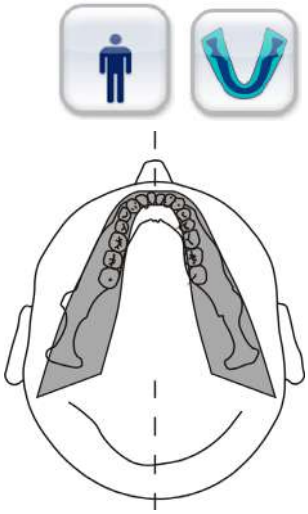
If the light is in front of the canine on the patient, click this button to have the unit compensate during image captured.
The unit will automatically make a 3-mm posterior adjustment.

Select the patient size from the three icons at the top of the LCD screen. From left to right, the icons represent large, medium, and small-sized patients. The dose is increased towards left and decreased towards right. Selecting different size patient settings may also affect some panoramic program trajectories or collimation settings, as described in individual program descriptions.



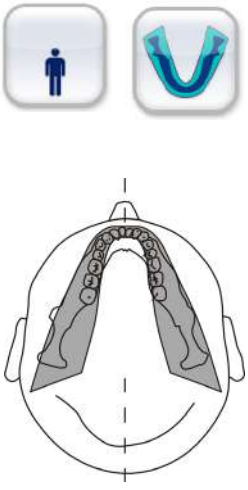
Wide Arch Panoramic: Magnification 1.3

Selecting panoramic and large patient keys gives you a panoramic image that is full height vertically and can image a large skull. The exposure factors are designed for a large skull. This program produces a slightly wider panoramic arch trajectory in the anterior region.



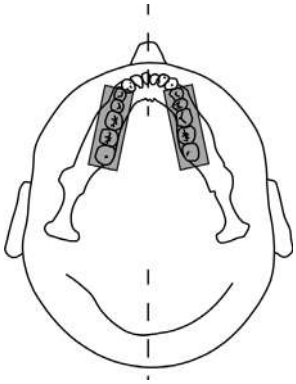
Standard Panoramic: Magnification 1.3

Selecting panoramic and medium patient keys gives you a panoramic image that is full height vertically and can image an average-sized skull. The exposure factors are designed for an average skull. This program produces a typical panoramic arch trajectory throughout the entire scan.



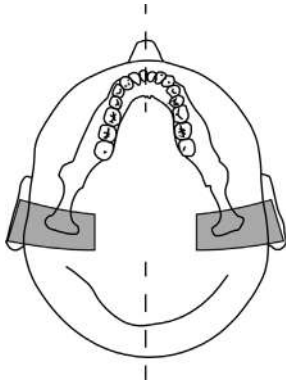
Small Panoramic: Magnification 1.3

Selecting panoramic and small patient keys gives you a panoramic image that is collimated slightly from the top down, and has a shorter trajectory from left to right. The exposure factors are reduced as well. This program may also be suitable for patients with jaw shapes that are more narrow than average.



Bitewing: Magnification 1.3

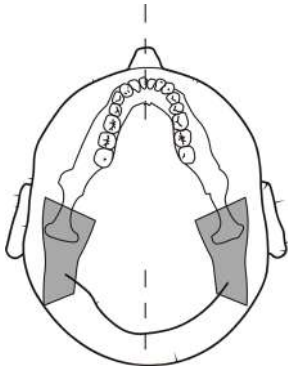
The Bitewing Program provides two segmented orthogonal views of the dentition, one for the left and one for the right side. Each view extends approximately from the canine to the 3rd molar posterior, with the Y-axis of the rotation path changed to improve the beam angle, and to be closer to perpendicular to the interproximal surfaces. The Bitewing images are collimated from the top down and bottom up, to show only the dentition.



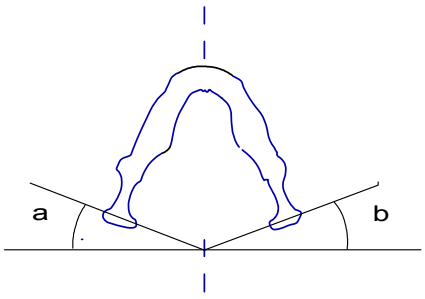
Frontal TMJ: Magnification 1.55

The Frontal TMJ program provides wide layer, corrected frontal views of the patient's left and right temporomandibular joints.

Clicking on the same key for the TMJ Programs will alternate between the Frontal and Lateral TMJ Programs, as designated by the letter F or the letter L.



Lateral TMJ: Magnification 1.23



The Lateral TMJ program provides wide layer, corrected lateral views of the patient's left and right temporomandibular joints.

Clicking on the same key for the TMJ Programs will alternate between the Lateral and Frontal TMJ Programs, as designated by the letter L or the letter F.

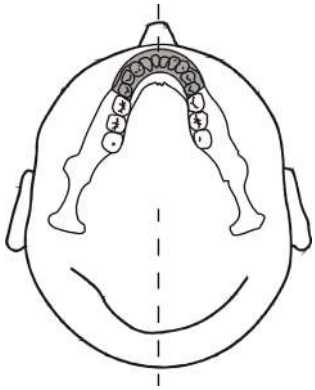
3.2 Advanced Panoramic programs

Advanced Panoramic Programs can be accessed by going to the LCD display and clicking on the tool tab in the lower left corner. From the menu that appears, check the box that says "Advanced PAN Mode," and then return to the Pan tab. You will then see an additional set of advanced panoramic programs. You can return to the basic set of panoramic programs by selecting the tool tab and removing the check mark from the Advanced PAN Program box.

Select the patient size from the three icons at the top of the LCD screen. From left to right, the icons represent large, medium, and small-sized patients. The dose is increased towards left and decreased towards right. Selecting different size patient settings may also affect some panoramic program trajectories or collimation settings, as described in individual program descriptions.

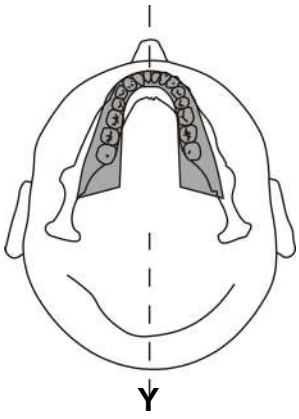
Frontal Dentition: Magnification 1.25

The Frontal Dentition Program provides a vertically and horizontally collimated panoramic image, approximately 50mm in length and centered on the anterior teeth. Typical coverage will be the upper and lower dentition from canine to canine.



Orthogonal Dentition: Magnification 1.3

An optimized view of the dentition only, with corrected angulation and reduced radiation. The Orthogonal Program produces a panoramic view with modified projection geometry. The Y-axis of the rotation path is changed to improve the beam angle, to be closer to perpendicular to the interproximal surfaces. With this improvement, other tradeoffs must be made: the ascending rami may be lost, and, in adult patients, the redundant shadows will be increased.



(L/R) Half Panoramic: Magnification 1.3

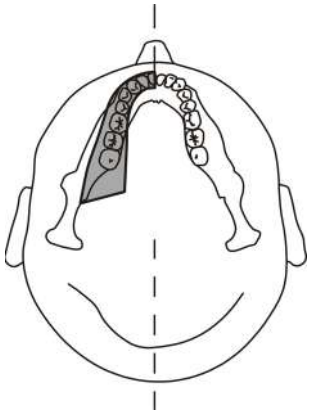
The Half-Panoramic Program gives you a full height half-panoramic image, selecting either the left or the right half of the patient's jaw only, with reduced radiation.

Clicking on the same key for the Half-Panoramic Program will alternate between imaging the patient's left or right sides, as designated by the icon and the letters R and L. The same technique factors and trajectories that apply to a full panoramic image will also apply to the half-panoramic image, when you select a Small, Medium, or Large Patient.

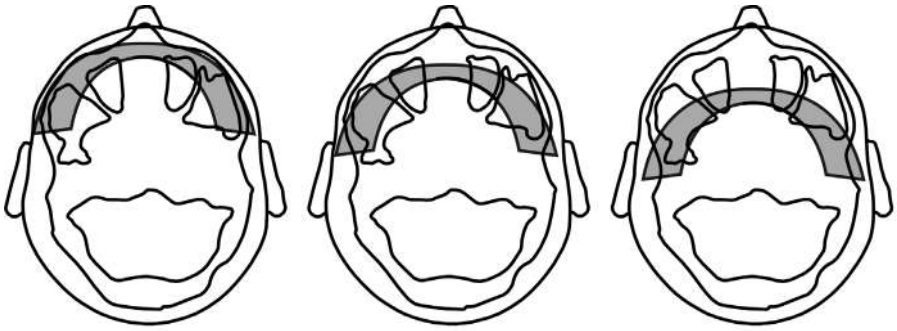
L/R) Half -Orthogonal Dentition: Magnification 1.3

The Half-Orthogonal Program gives you a full height half-Orthogonal image, selecting either the left or the right half of the patient's dentition only, with corrected angulation and reduced radiation.

Clicking on the same key for the Half-Orthogonal Program will alternate between imaging the patient's left or right sides, as designated by the icon and the letters R and L. The same technique factors, trajectories, and trade-offs that apply to a full Orthogonal image will also apply to the half-Orthogonal image.



Maxillary Sinus: Magnification 1.3

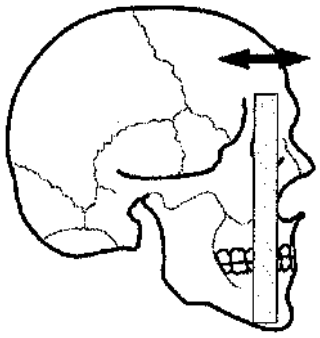


Anterior 10 mm Start Posterior 10 mm

The maxillary Sinus Program produces a pan - tomographic layer through the posterior maxillary sinus. The layer is flatter than the standard panoramic programs, and is moved 18mm backward. These images are helpful in visualizing the mid and posterior maxillary sinus.

You can shift the Sinus Program image layer 10 mm in an anterior direction by pressing Image Layer Retrusion button.

You can shift the Sinus Program image layer 10 mm in a posterior direction by pressing the Image Layer- Protrusion button.



3.3 Default exposure settings

User Configurable Panoramic mA Level

Default mA level for panoramic programs can be set using the touch screen display. To change the setting:

1. Start an exam and select a panoramic program.

2. Select **Settings** on the touch screen.

3. Select *Imaging program defaults*.

4. Select *Set current PAN mA level* as default.

The selected mA value is used as default value for the current program. The default mA level is adjusted by an equal amount also for other panoramic programs.

3.4 User Configurable Default Program

Default imaging program (pan/ceph/3D) can be set using the touch screen display. To change default program:

1. Start an exam and select the desired program.

2. Press the Settings button on the touch screen.

3. Select Imaging program defaults.

4. Select Set current program as default.

The selected program is automatically activated when an exam is started for a new patient and at startup.

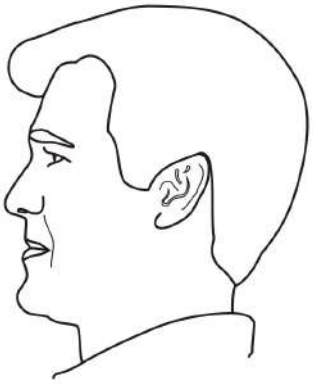
3.5 Cephalometric programs

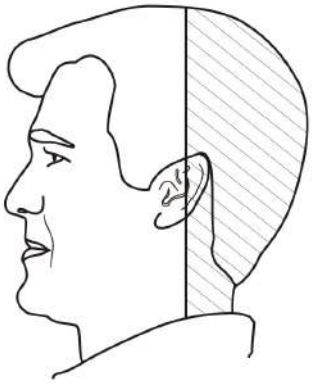
Cephalometric latero-lateral (LL) projections

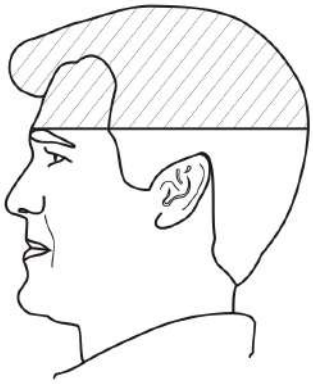
The most common use of the cephalometric extension is to take latero-lateral radiographs of the skull, mostly used to trace a cephalogram for the purpose of orthodontic treatment. There are different methods to achieve this, however it is generally accepted that the following three points must be visible 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.

There are three LL cephalometric programs available. The programs can be combined with exposure values for different patient sizes by selecting the appropriate patient size key or adjusting the kV or mA settings manually.

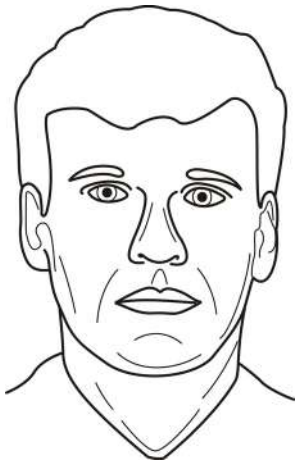
- LL Max (22 x 24 cm) 
- LL Vertical (22 x 18 cm) 
- LL Horizontal (18 x 24 cm) 







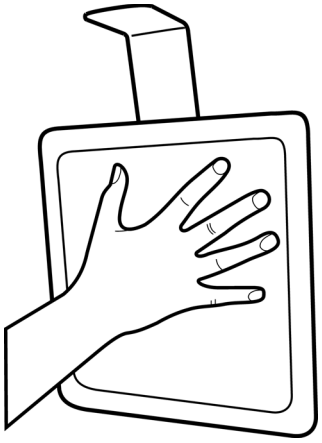
Cephalo postero-anterior/ antero-posterior (PA/AP) projections



The unit provides two different size PA/AP projections:

- AP/PA Max (22 x 24 cm)

- AP/PA Vertical (22 x 18 cm)



Cephalometric Carpus projection (Not available in USA and Canada)

The Carpus view uses a full height image field (22 cm height x 20 cm wide). 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. The Carpus view program should not be used for imaging a skull, as the reduced dose will not be sufficient to achieve good image quality for a Lateral or PA ceph view. The Carpus view should only be used where local laws and regulations permit its use.

3.6 3D programs

Cone beam 3D imaging enables seeing dentomaxillofacial anatomy of selected Field of View, FOV, helping with diagnostics and treatment planning. With 3D viewing software, user is able to analyze FOV area from multiple directions and see cross-sectional images from the area of interest.

61 x 41 mm FOV

High resolution (133µm voxel size)

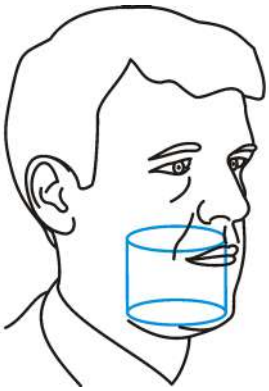
Standard resolution (200µm voxel size)

Dose Reduction Technology DRT (290µm voxel size)

Program for optimized endodontic imaging:

Endo program (85µm voxel size)

61 x 78 mm FOV (optional)



High resolution (200µm voxel size)

Standard resolution (300µm voxel size)

Dose Reduction Technology DRT (330µm voxel size)

3.7 SRT™, Scatter Reduction Technology

SRT™, Scatter Reduction Technology software can be used to reduce the effect of metals and other dense radiopaque objects on the 3D image. These create artifacts that are seen typically as stripes and shadows from the above-mentioned objects. To utilize SRT™ on a CBCT image may have affect to image reconstruction time

SRT™-button is ON. SRT™-button becomes visible on the 3D modality.

SRT™-button is OFF.

3.8 Exposure settings for 3D imaging

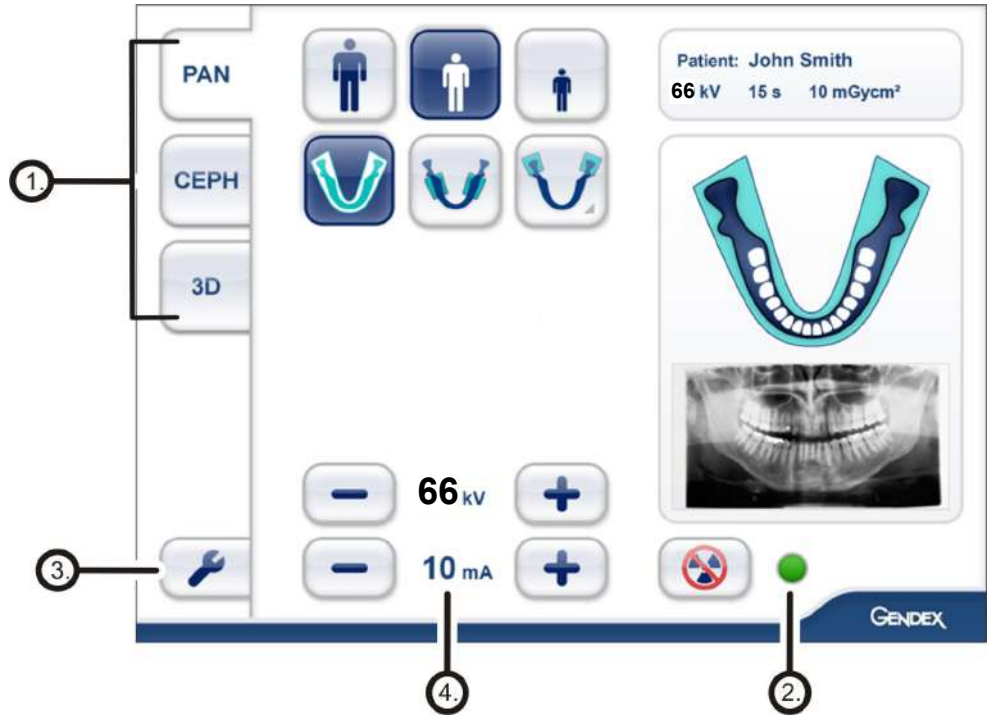
Exposure settings for 3D imaging (default values)							
NOTICE! *Voltage setting is always 90kV with the unit 3D modality.*							
FOV	**Resolution**	**Exposure time**	**Scanning time**	**Voxel size (µm)**	**Default mA**	**mAs**	**DAP (mGycm2)**
61 x 41 mm	DRT	1,2 s	11,0 s	290	3.2	3,8	30
	Std Res	2,3 s	15,6 s	200	10	23	184
	High Res	6,1 s	11,5 s	133	8	48,8	384
	Endo Res	6,1 s	11,5 s	85	10	61	480
61 x 78 mm (optional)	DRT	2,4 s	21,1 s	330	3.2	7.7	61
	Std Res	4,9 s	21,1 s	300	10	49	383
	High Res	12,6 s	21,0 s	200	6.3	79,4	626

Available mA ranges for each field of view sizes and resolution settings															
FOV	**Resolution**	**3.2 mA**	**3.6 mA**	**4 mA**	**4.5 mA**	**5 mA**	**5.6 mA**	**6.3 mA**	**7.1 mA**	**8 mA**	**9 mA**	**10 mA**	**11 mA**	**12.5 mA**	**14 mA**
61 x 41 mm	DRT	x	x	x	x	x	x	x	x						
	Std Res							x	x	x	x	x	x	x	
	High Res			x	x	x	x	x	x	x	x	x	x	x	
	Endo Res			x	x	x	x	x	x	x	x	x	x	x	
61 x 78 mm (optional)	DRT	x	x	x	x	x									
	Std Res							x	x	x	x	x	x	x	
	High Res			x	x	x	x	x	x	x	x	x			

Exposure settings for scout imaging (default values)				
FOV (h x w)	**Resolution**	**kV**	**mA**	**Scan-ning time**
61 x 41 mm	Scout	90	12.5	0,02 s
61 x 78 mm (optional)	Scout	90	12.5	0,04 s

4 Controlling the unit

4.1 Main control panel



1. Modality / imaging program section
2. Status of the unit
3. Settings
4. Exposure settings

4.2 Modality section

Select the modality tab; PAN, CEPH or 3D.

When panoramic modality is selected, a program specific dental arch is shown.

Cephalometric programs have their own, program specific model heads and setting buttons for the start position of lateral scanning.

3D programs have buttons for selecting standard resolution, high resolution, Dose Reduction Technology resolution and scout image mode.

The FOV for 3D imaging can be positioned on the XY-plane by selecting the center point of the FOV on the dental arch of the touch screen display. The FOV is positioned in the Z-direction by using the chin rest movement and positioning lights.

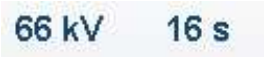
4.3 Exposure settings

4.3.1 Exposure indicators and settings

kV value

mA value

Patient name



Exposure value and time

Dose value (DAP)

Patient size settings

Test mode (No radiation)

4.3.2 Patient size settings

Select the patient size from the three icons at the top of the LCD screen. From left to right, the icons represent large, medium, and small-sized patients. The dose is increased towards left and decreased towards right. Selecting different size patient settings may also affect some panoramic program trajectories or collimation settings, as described in individual program descriptions. Incremental changes to kV and mA for each program can be made by pressing the +/- keys at the bottom of the LCD screen.

4.4 Status section

Status field shows when the unit is ready for capturing or any trouble occurs. Green or red color indicate the status in question. Green means ready to capture and red means not ready. During actual exposure, a large radiation warning symbol will fill the Touchscreen display.

Exposure Indicator

4.5 Other sections

General settings

- Local Pan Preview
  - When activated, the Pan image is shown on the device Touchscreen

- Advanced Panoramic Mode
  - When activated, the advanced Pan programs are available

- SmartLogic™ Keys
  - When activated, the patient size and program selections on each tab will default to the most frequently used selections
  - Press and hold to reset the counter

- Retrieve Last Image
  - Use this to retrieve the last image from the device memory e.g. after a system crash
  - Please make sure that the retrieved image is associated with the correct patient

- Retrieve With SRT
  - After taking a 3D image with SRT either on or off, image can be re-reconstructed with different setting by selecting either “Retrieve last image” or “Retrieve With SRT” from the general settings on the touch screen. If reconstruction with SRT is unavailable for the last captured image, e.g. last taken image is cephalometric, “Retrieve With SRT”-button will not be visible.

NOTICE! *Only the last taken x-ray image is saved in the unit until the power is switched off. This image data is used in the retrieve procedure.*

- Show System Data
  - System IP address and other system related data
- Quality Assurance
  - Use this to reach the programs for periodical maintenance
- Languages
  - Use this to select language on the touch screen

5 Using the unit

5.1 Attaching and removing the sensor

NOTICE! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

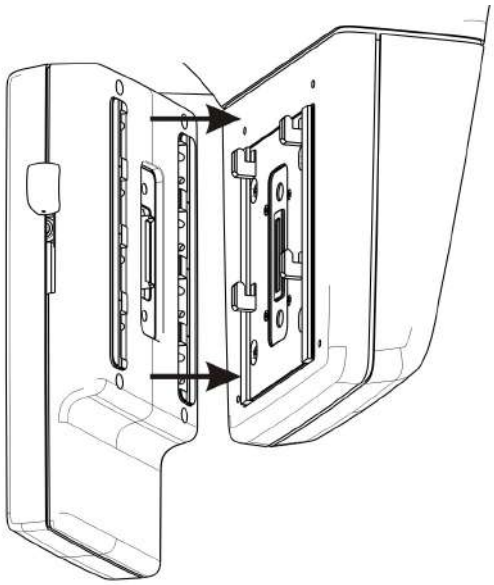
Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.

WARNING!
Handle the sensor with care as instructed in this manual. The sensor must not be dropped or exposed to impacts. A shock indicator inside the sensor shows if the sensor has been exposed to excess impact.

5.1.1 Attaching the sensor

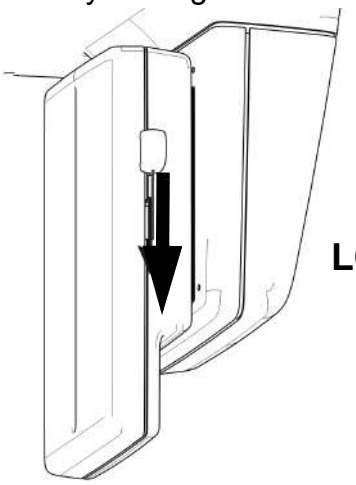
NOTICE! *Normally there is no need to remove the sensor.*

1. Insert the four slots on the rear of the sensor, into the four hooks in the sensor holder.



2. Pull the sensor downwards firmly until it stops and then slide the locking knob down on the side of the sensor to lock the sensor in position.

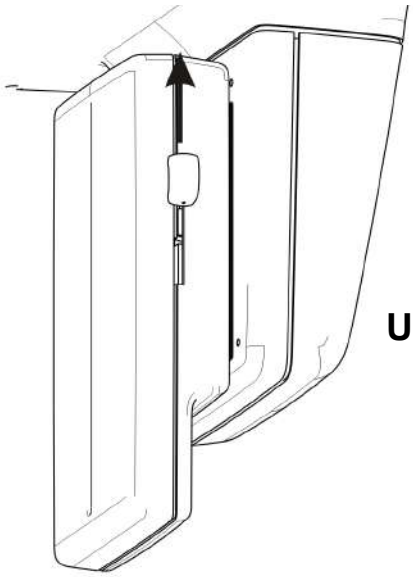
   NOTICE! Make sure that the sensor is seated properly before sliding the locking knob down. Forcing the locking knob down when the sensor is not in correct position may damage the sensor connectors!



LOCKING

5.1.2 Removing the sensor

1. Slide the locking knob upwards on the side of the sensor to unlock the sensor.



UNLOCKING

2. Slide the sensor up and remove it.

5.2 Preparing the system

1. Switch on the unit and the PC, allowing both time to boot up. At startup, the unit produces a test sound to confirm that the beeping sound produced during exposure is functioning properly.
2. **PC:** Start viewing software.
3. **PC:** Select a patient and schedule acquisition.

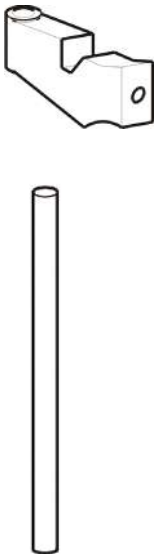
5.3 Panoramic exposures

- Standard Panoramic:
  Standard PAN program + medium patient size
- Small Panoramic:
  Standard PAN program + small patient size
- Wide arch Panoramic:
  Standard PAN program + large patient size
- Orthogonal programs
- Bitewing
- Ortho TMJ axial corrected lateral projection
- TMJ PA projection
- Maxillary sinus view

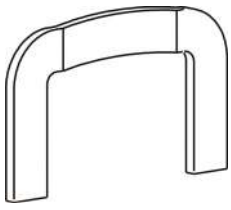
5.3.1 Positioning devices

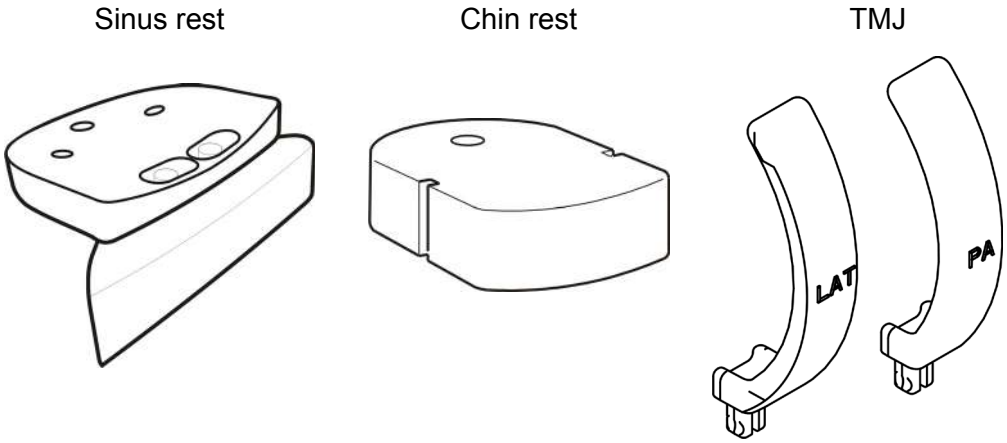
Bite rod with the bite guide

Bite rod with the edentulous bite positioner

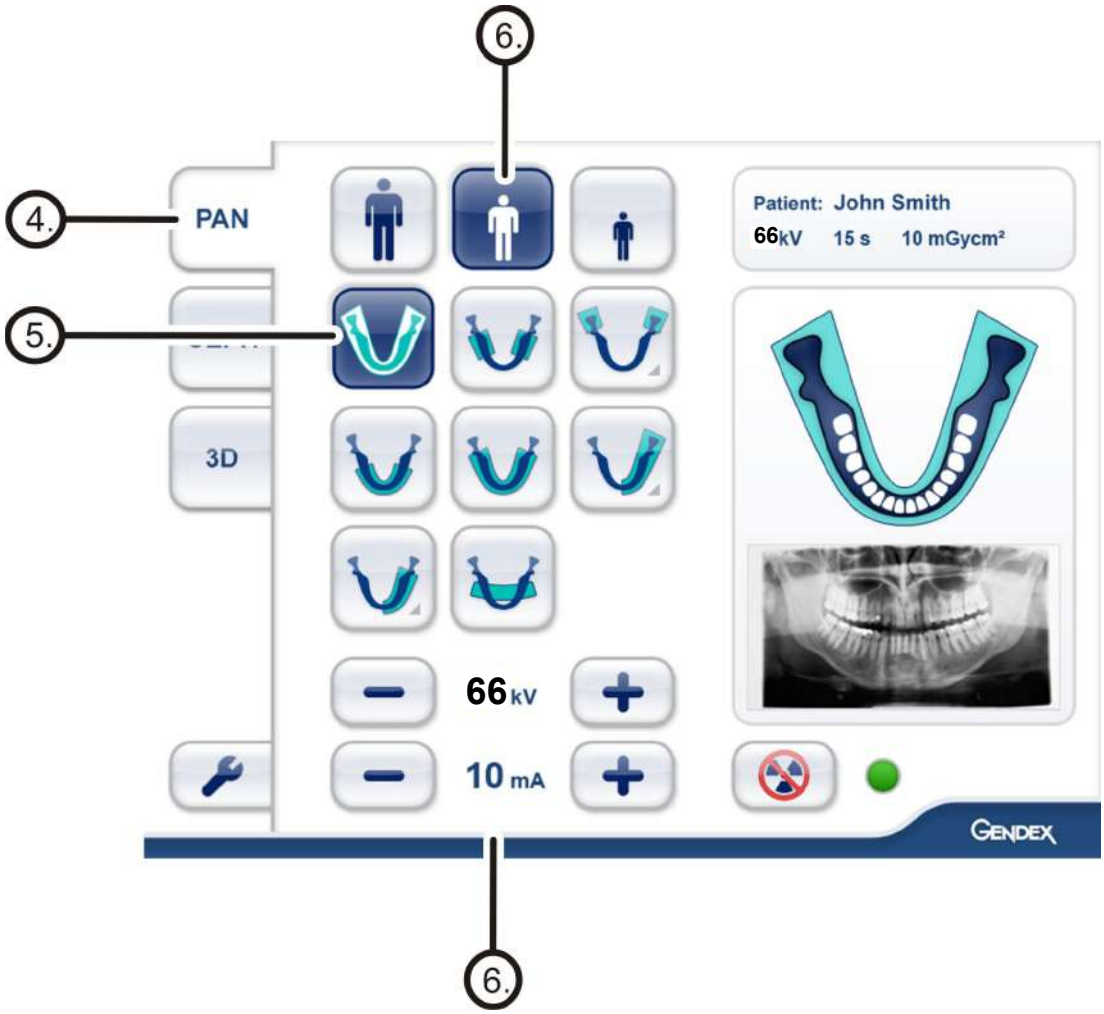


Chin support for edentulous patients





5.3.2 General instructions



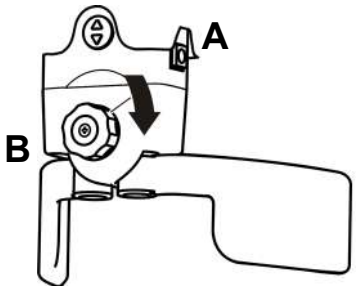
1. Open the imaging software on the acquisition computer.

NOTICE! *You can also scan a patient without the viewing software running for 2D scans. You receive an image*

without the patient ID. In this case ensure that you associate the image with the correct patient.

2. Enter or select a patient on the computer.
3. Click the schedule acquisition icon in the imaging software.
4. Select PAN tab on the touchscreen display.
5. Select the imaging program on the touchscreen display.
6. Set the kV and mA or
   select the patient size (small, medium, large) on the touchscreen display.

7. Press **Patient In** on the carriage to rotate the unit to *'patient in'* position.
8. Open the temple supports. Raise and pull the head support assembly forward and up. To give the patient greater access to the unit, move the head support unit out of the way by depressing the **A** buttons on either side and pulling back. Releasing the buttons locks the assembly. Have the patient enter the machine at this point, standing fully upright and grasping the handgrips. Next, turn the **B** knob to close the temple supports.



9. Remove eye glasses, hearing aids, removable dentures, jewelry (necklaces, tongue rings, lip rings, etc.) and hair clips, and pins.

   Place a protective lead apron on the patient.

10. After completing setup and positioning, ask the patient to swallow, place their tongue firmly against the roof of their mouth, and remain still for the duration of the exposure.

NOTICE! *Local country regulations may set different standard for lead apron usage needs.*

5.3.3 Patient positioning

5.3.3.1 Panoramic exposure

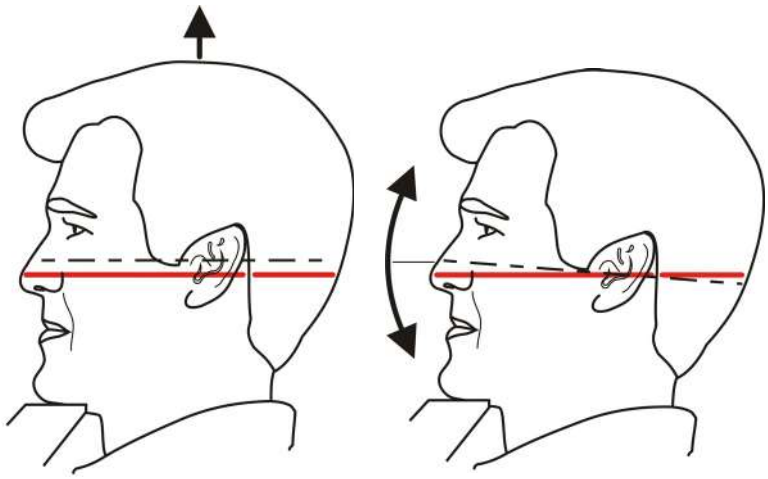
1. Insert the sinus rest, chin rest and bite rod with the bite guide. Place the hygienic barriers.

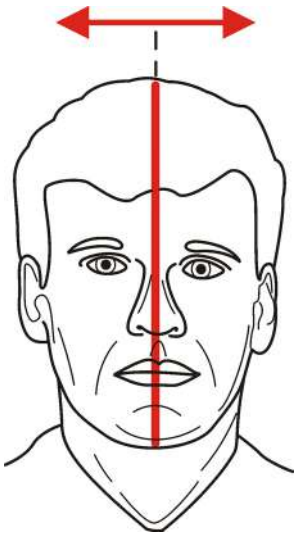
   NOTICE! *Use a new hygienic barrier for every patient.*

2. Adjust the unit height using the carriage Up/Down keys on the column control panel to slightly higher than the patient's chin.

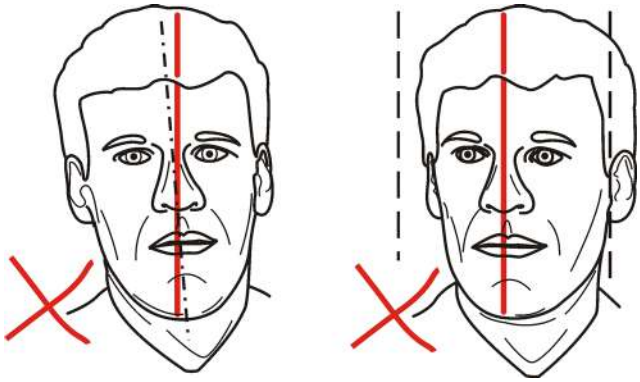
3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Exposure can also be taken in a sitting position, including from a wheelchair. Ask the patient to grip the handgrips and bite on the bite guide, so that the upper and lower anterior teeth are in the grooves of the bite guide. Use the edentulous bite positioner or the chin support for an edentulous patient.

4. Adjust the unit height to get the Frankfort plane laser passing over the orbitale and porion.

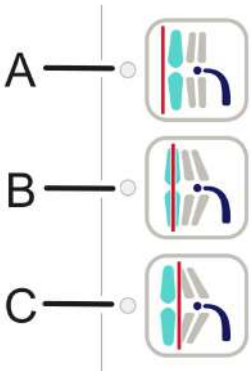




5. Check the position of the midsagittal laser. If it is not on the midsagittal plane of the patient, gently adjust the patient´s head.
   Make sure the patient´s head is not turned or tilted. If the patient appears to be slumped forward, ask them to stand up straight and gently stretch the patient's neck from the back of the skull while tilting the chin down.



6. Check the position of the image layer laser. If it is not on the buccal of the maxillary canine (or base of the nose, if edentulous), adjust the image layer by matching the keys with the laser position on the patient's actual canine.



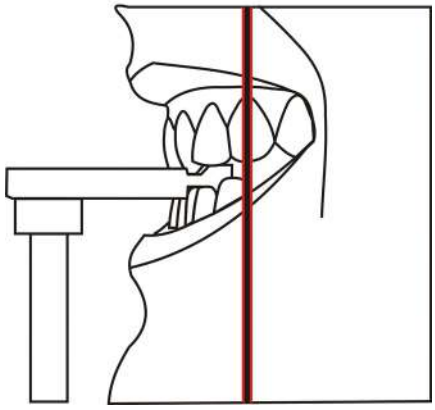
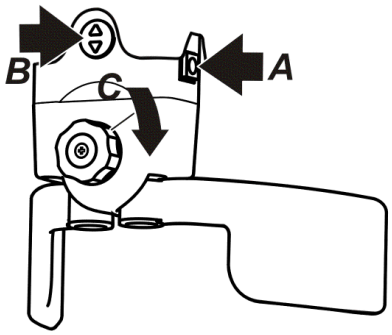


Image Layer Adjustment button:

A Retrusion.
If the light is behind the canine on the patient, click this button to have the unit compensate during image capture. The unit will automatically make a 3-mm anterior adjustment.

B Normal occlusion (default). Leave at this setting if the laser hits the center of the canine.

C Protrusion.
If the light is in front of the canine on the patient, click this button to have the unit compensate during image capture. The unit will automatically make a 3-mm posterior adjustment.



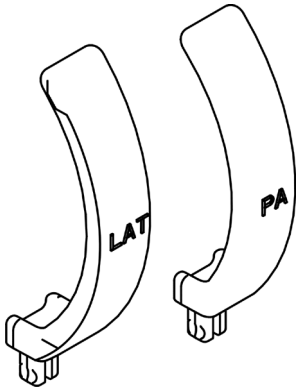
7. With the patient´s head already at the correct tilt, bring the head support unit toward the patient by depressing the A buttons on either side, and up and down by depressing the B button. Releasing the buttons locks the assembly. Next, turn the C knob to close the temple supports.

8. Ask the patient to take one step forward to straighten the spinal column. The patient is slightly leaning backwards during the imaging while maintaining a secure hold of the handgrips. If the patient´s neck is slumped forward, gently stretch up the patient´s neck from the base of the skull.

9. Ask the patient to swallow, place their tongue firmly against the roof of their mouth, and remain still for the duration of the exposure.

5.3.3.2 TMJ exposure

Nose support



1. Insert the required positioning devices, including the TMJ nose support.

   NOTICE! *Lateral or PA projections require different nose supports.*

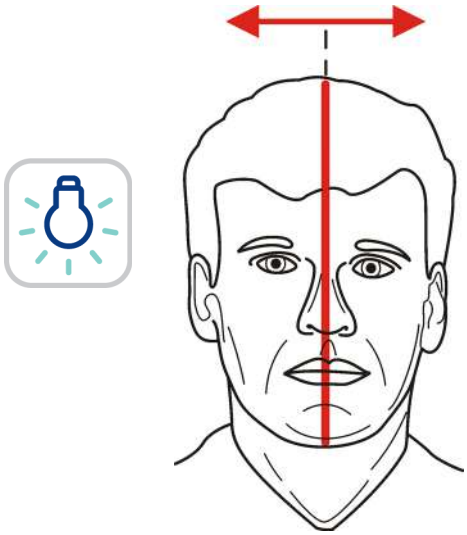
   NOTICE! *Use a new hygienic barrier for every patient.*

2. Adjust the unit height using the carriage Up/Down keys on the column controls to slightly higher than the patient's chin.

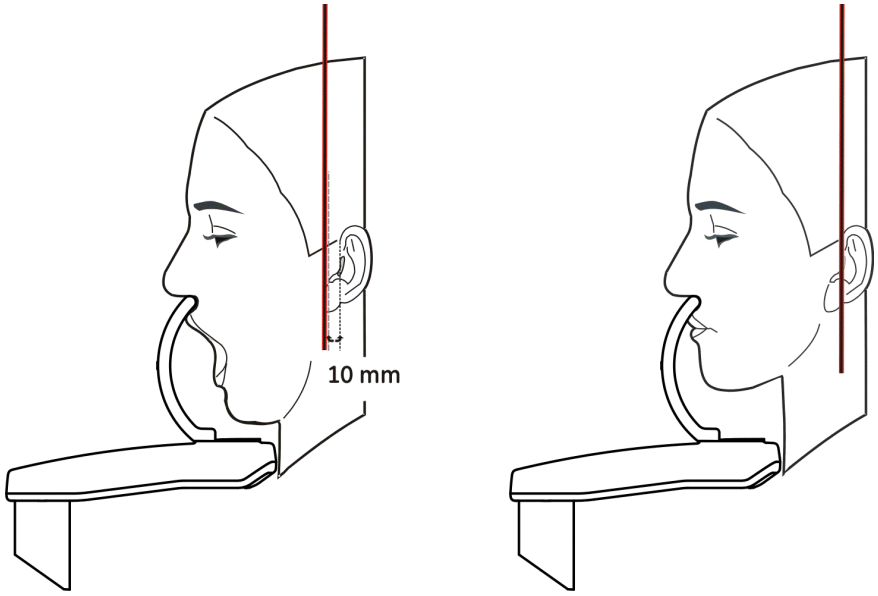
3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to take grip of the handgrips and set the nose against the TMJ nose support.

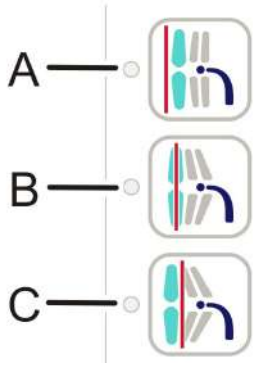
4. Adjust the unit height to get the Frankfort plane laser passing over the orbitale and porion.

5. Check the position of the midsagittal laser. If it is not on the midsagittal plane of the patient, gently adjust the patient´s head.



6. Adjust the position of the TMJ laser until it aligns with the middle of the condyle by using the Image Layer Adjustment laser buttons.. In this case, the light will reposition on the patient's TMJ area.





TMJ laser adjustment keys:

A Forward or Anteriorly (towards the mirror)

B Reset

C Backward or posteriorly (away from the mirror)

7. Utilized the head supports as previously described.

8. a) TMJ closed
   Ask the patient to close their teeth together, ask the patient to swallow, place their tongue firmly against the roof of their mouth, and remain still for the duration of the exposure.

   b) TMJ open
   Ask the patient to open their mouth to the fullest extent possible and remain still for the duration of the exposure.

5.3.3.3 Maxillary Sinus exposure

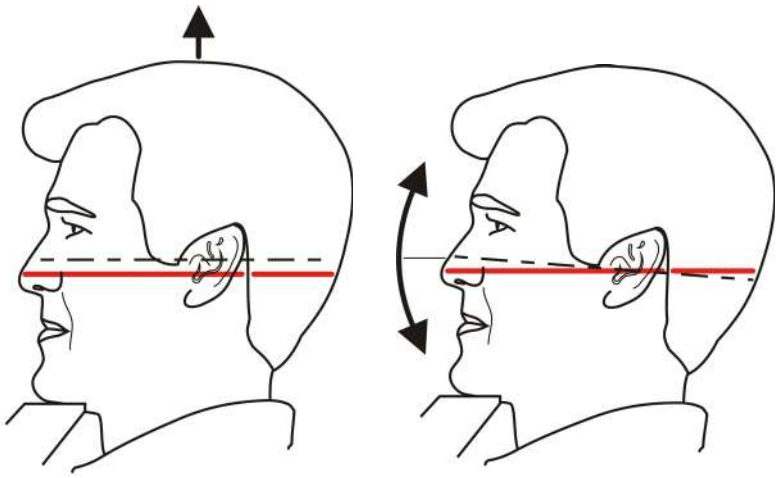
1. Insert the required positioning devices, bite rod with the bite guide on the sinus rest. Place the hygienic barriers.

   NOTICE! *Use a new hygienic barrier for every patient.*

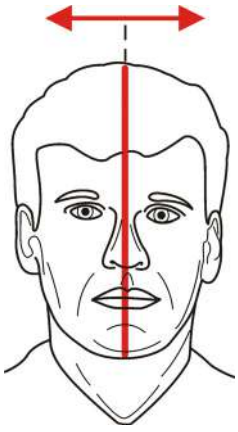
2. Adjust the unit height using the carriage Up/Down keys on the column control panel to slightly higher than the patient's chin.

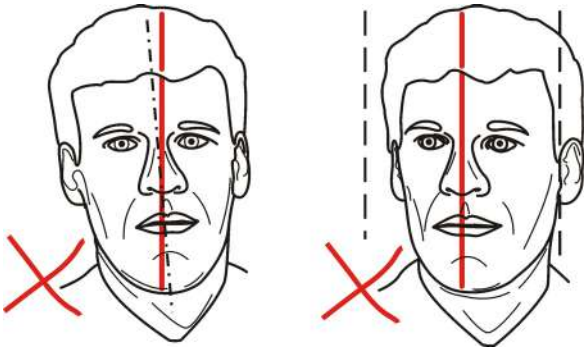
3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to grip the handgrips and bite on the bite guide.

4. Adjust the unit height to get the Frankfort plane laser passing over the orbitale and porion.



5. Check the position of the midsagittal laser. If it is not on the midsagittal plane of the patient, gently adjust the patient's head.





6. Adjust the position of the image layer as necessary. The image layer is 18 mm posterior compared to standard panoramic procedure. Adjust the image layer laser using the Cuspid light keys.

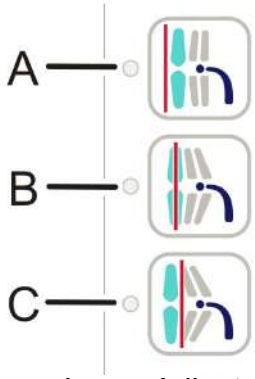


Image Layer Adjustment buttons:

A 10 mm anterior

B Center

C 10 mm posterior

7. Utilized the head supports as previously described.
8. Ask the patient to swallow, place their tongue firmly against the roof of their mouth, and remain still for the duration of the exposure.

5.3.3.4 Taking a panoramic exposure

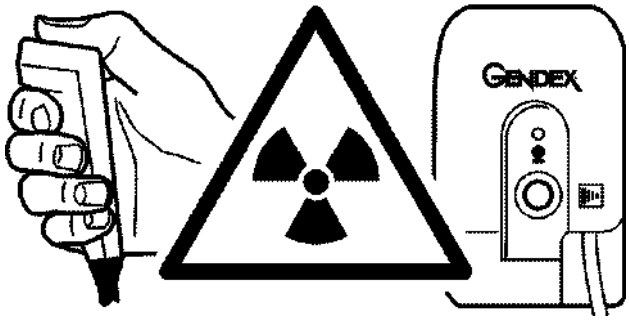
1. Verify the patient's position. Before leaving the area, press **Reset**. Although this action is not required, it lessens the amount of time the patient must remain still.

   Protect yourself from radiation by standing behind a suitable x-ray radiation shield and clearing the area. Make sure that you can see and hear the patient during the exposure.

   NOTICE! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (6 ft) from the focal spot and the X-ray beam. Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

NOTICE! *If the patient is apprehensive about the x-ray, you can demonstrate how the unit works to reassure them. Press the Test key and then press and hold the exposure button. The unit completes an exposure cycle without generating x-rays.*

2. Press and hold down the exposure button (on either the hand-held trigger or the wall unit) until the entire process is complete, and the rotating unit circles the patient's head and comes to a complete stop. During the exposure, you will hear an audible signal and the exposure warning symbol is displayed on the touchscreen.



3. After the exposure, release the temple supports and move the head support assembly away from the patient. Carefully guide the patient out of the unit. Remove hygienic barriers and decontaminate the necessary parts of the unit with approved methods and products.
4. **PC**: The image can be viewed at the PC using the viewing software.

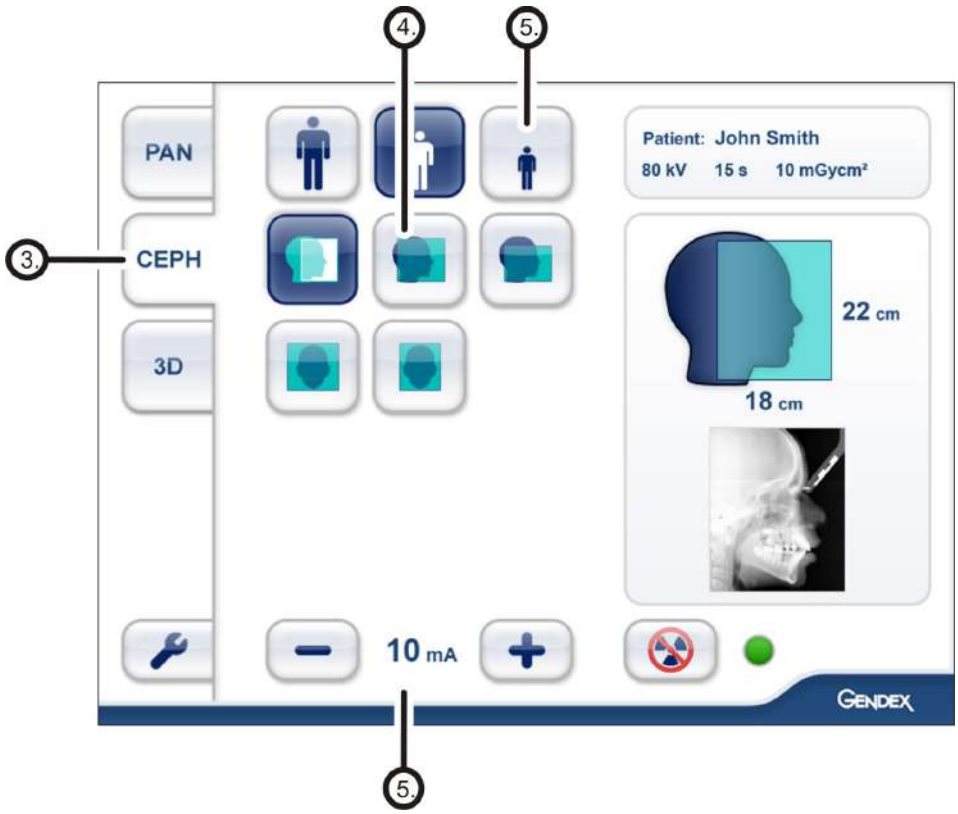
5.4 Cephalometric exposures

- Lateral projections
- PA projections
- Carpus view (Not available in USA and Canada)

WARNING! *Remove all calibration tools, Pan and 3D patient positioning accessories before taking any cephalomateric exposures!*

5.4.1 General instructions

1. Move the ceph sensor to the ceph sensor holder.
2. **PC:** Open the viewing software, select a patient and schedule acquisition.
3. Select CEPH tab at the touchscreen display.



4. Select the imaging program.
5. Set the kV and mA or select the patient size (small, medium, large).

6. Press **Patient In** to drive the unit to '*patient in*' position.

7. Ask the patient to remove any eye glasses, hearing aids, removable dentures, jewelry (necklaces, tongue rings, lip rings, etc.) and hair clips, and pins. Place a protective lead apron on the patient.

5.4.2 Patient positioning

5.4.2.1 LL projections

1. Unlock the lever and turn the ear rods to the LL projection position. Lock the position. Tilt the nasion support aside. Place the hygienic barriers.

Figure 1.1 Unlock first the lever, turn the ear rods and lock the lever again.

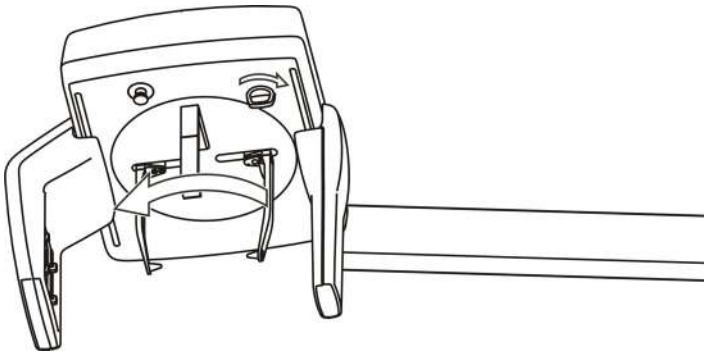
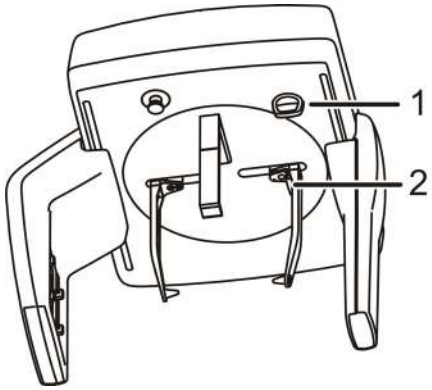


Figure 1.2 Locking lever (1), ear holder brake (2)



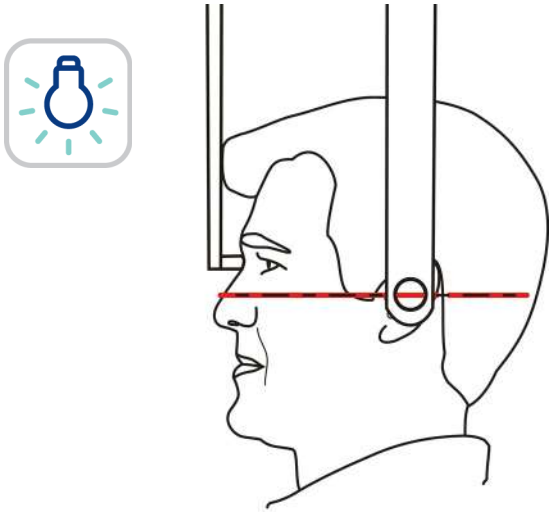
NOTICE! *Use a new hygienic barrier for every patient.*

2. Adjust the unit height.

3. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear plugs in the patient's ears. Tall patients can also sit on a chair.

4. Adjust the unit height to get the Frankfort plane laser passing over the orbitale and porion.

   NOTICE! *The shown laser line is a horizontal reference line.*



5. Tilt the nasion support down and slide it towards patient's nasion.

5.4.2.2 PA-AP projections

1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the hygienic barriers.

   NOTICE! *Use a new hygienic barrier for every patient.*

2. Adjust the unit height.

3. Guide the patient to the unit facing the sensor. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear rods towards patient's ears. Tall patients can also sit on a chair.

Unlock first the lever, turn the ear rods and lock the lever again.

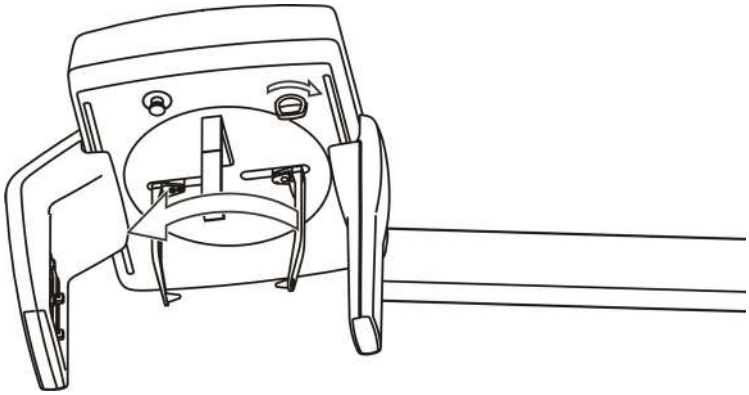
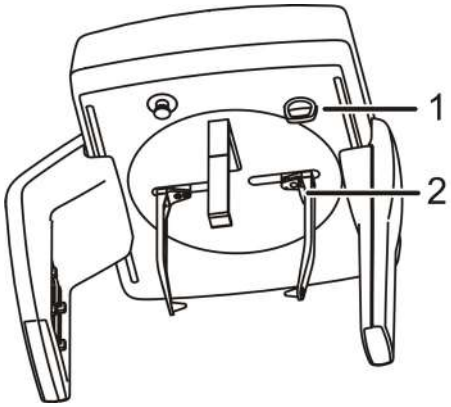


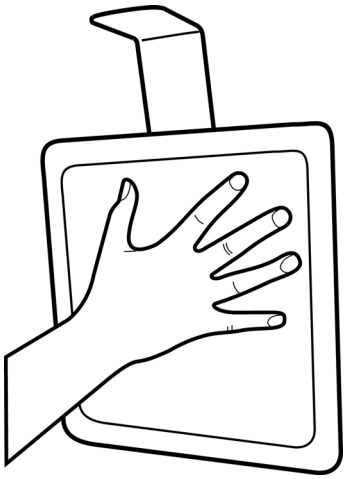
Figure 1.3 Locking lever (1), ear holder brake (2)



NOTICE! *Use a new hygienic barrier for every patient.*

5.4.2.3 Carpus view (Not available in USA and Canada)

CAUTION! *Before taking Carpus image make sure this imaging method is approved by local authorities of your country.*

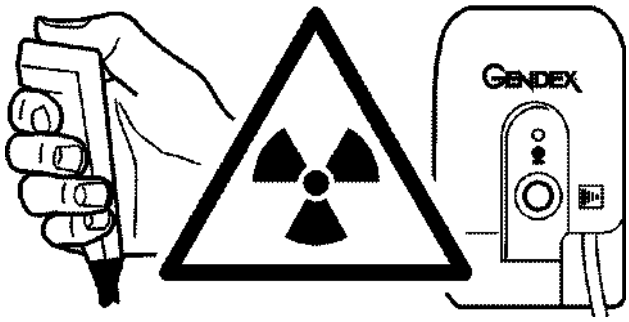


1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the carpus holder to the nasion support holder.
2. Adjust the unit height if needed.
3. Ask the patient to remove rings and metal objects and to place hand on the carpus holder.

5.4.2.4 Taking a cephalometric exposure

1. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.

2. Press and hold down the exposure button (on either the hand-held trigger or the wall unit) until the audible signal and the exposure warning symbol displayed on the touch screen discontinue.



3. Release the ear rods and guide the patient out. Remove disposable covers and decontaminate the unit.

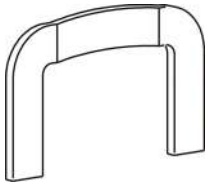
4. **PC:** The image can be examined using the imaging software. See the imaging software user manual.

   NOTICE! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the x-ray beam. Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

5.5 3D exposures

5.5.1 Positioning devices

Chin support



5.5.2 General instructions

1. **PC:** Select Patient, click **Schedule acquisition**.
2. Select the 3D modality tab at the touch screen display.

3. Select the FOV size:
   - 61 x 41 mm
   - 61 x 78 mm (optional)
4. Select scout or resolution selection:
   - DRT
   - Standard
   - High
   - Endo

5. Select patient size and adjust mA if needed.
6. Select the area of interest dragging the 'target' on the dental arch display while centering the crosshairs on the region of interest. The 3D FOV is positioned more accurately by using the scout image mode. The area of interest can be adjusted on the touch screen display after the scout image has been taken.

7. Press **Patient In** to rotate the unit to *'patient in'* position.
8. Ask the patient to remove eye glasses, hearing aids, removable dentures, jewellery (necklaces, tongue rings, lip rings, etc.) and hair clips, and pins.

5.5.3 Patient positioning

1. Insert the sinus rest, chin rest and chin support. Place the hygienic barrier.

   NOTICE! *Use a new hygienic barrier for every patient.*

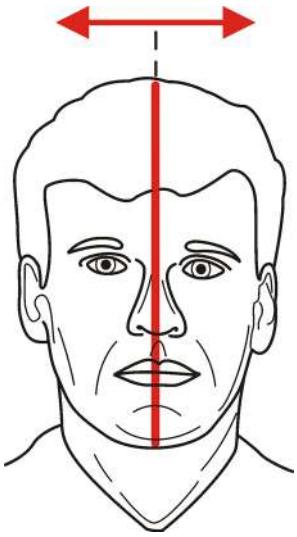
2. Select patient size, and adjust mA if needed.

3. Select the area of interest dragging the 'target' on the dental arch display while centering the crosshairs on the region of interest. The 3D FOV is positioned more accurately by using the scout image mode. The area of interest can be adjusted on the touch screen display after the scout image has been taken.

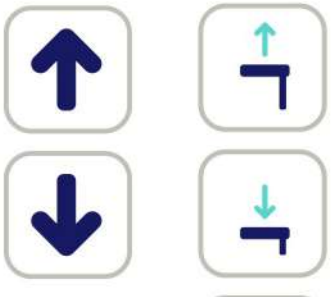
4. Press **Patient In** to rotate the unit to *'patient in'* position.
5. Adjust the unit height using the carriage Up Down buttons on the column control panel to slightly higher than the patient's chin.

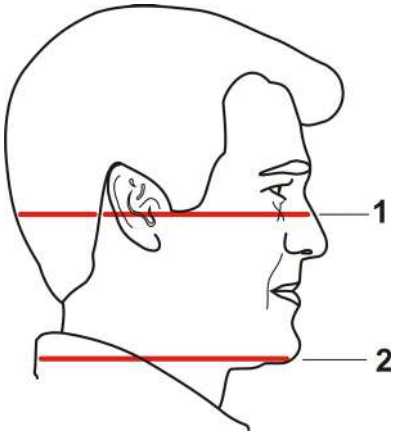
6. Guide patient to the unit. Instruct patient to stand as straight and tall as possible in the unit. The patient can also be imaged in sitting position in certain cases, for example, if the patient is wheelchair-bound, or too tall to stand in the unit. Ask the patient to take grip of the hand grips and place chin on the chin cup.

7. Check the position of the midsagittal laser. If it is not on the midsagittal plane of the patient, gently adjust the patient's head.



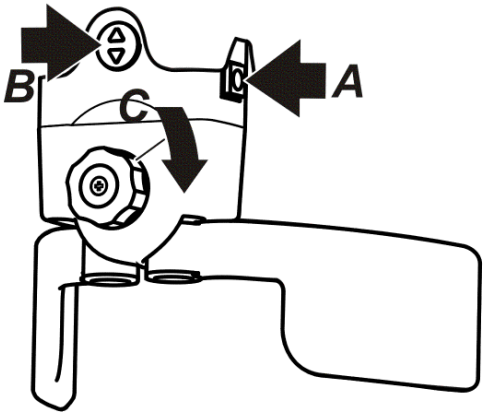
8. Adjust the unit height and chin rest height to get the Region of Interest between the top and bottom FOV lasers. Position the patient so that the occlusal plane is horizontal. A horizontal line from the superior border of the tragus to the inferior border of the ala is a close approximation for occlusal plane horizontal.





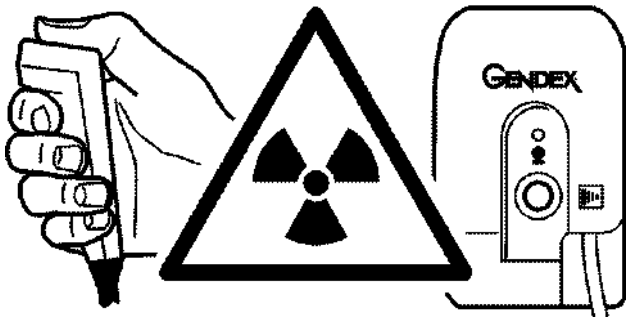
1. Horizontal laser, top of FOV
2. Horizontal laser, bottom of FOV

9. Bring the head support unit toward the patient by depressing the A buttons on either side, and up and down by depressing the B button. Releasing the buttons locks the assembly. Next, turn the C knob to close the temple supports.



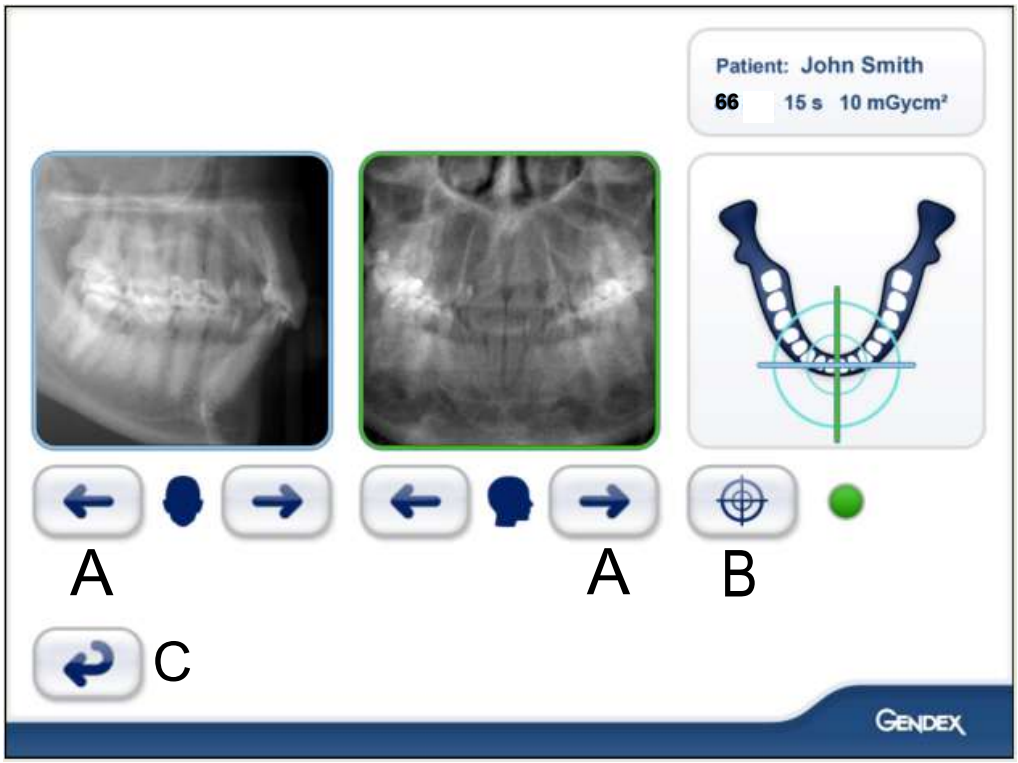
5.5.4 Taking a Scout image

1. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.
2. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the touch screen display appears.



Continue to hold down the exposure button until the audible signal ends and the machine has come to a complete stop.

3. Two scout preview images appear on the touchscreen display.



4. Fine adjust scout position using the side arrow keys (A), so that the Region of Interest is centred in each Scout Image.

5. If a vertical adjustment is needed to center the Region of Interest higher or lower, you will need to raise or lower the chinrest with the Chin Support Up/Down buttons found on the Column Control Panel; and you may also have to adjust the carriage height using the Carriage UP/DOWN buttons. Lowering the Chin Support will allow you to see higher into the upper arch, and raising the Chin Support will allow you to see lower into the lower arch. An additional Scout View may be needed for a major adjustment to Patient positioning.

6. Trigger the exposure button to capture the 3D image or, if needed, take a new scout by pressing the Scout button (B) and trigger the exposure button. Use the Back button (C) to return to the previous screen to make changes to capture settings.

5.5.5 Taking a 3D image

1. Select image resolution:

DRT 3D image quality

Standard 3D image quality

High resolution 3D image quality

Endo program

2. Select mA.
3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the touch screen display appears.

4. Select **SRT™** ON or OFF based on your estimation of the need. See chapter 3.7 SRT™, Scatter Reduction Technology Reduction.

5.5.6 Stone model and radiographic guide scan

For scanning of stone models and radiographic guides, a positioning plate is available for the system.

1. Scan the patient with an open bite by securing the bite with cotton pads.
2. Install the positioning plate. Position stone model.

NOTICE! *It is recommended to use a sponge or a foam under radiographic guide during the scan.*

3. Take scout image with default values. Correct position if needed.

4. Select same resolution and parameters as in patient scan.

NOTICE! *Position the radiographic guide in similar way.*

5.6 Warnings and error messages

The unit responds to error situations by showing a dialog box containing an error code and descriptive text on the touch screen.

When an error code appears on the display the unit will stop working and cannot be operated while the error code is on the display. In less severe cases a warning message will be displayed, leaving the unit operable.

5.6.1 Acknowledging errors

Most errors may be acknowledged by closing the dialog box the error is reported in. Some errors require the unit to be rebooted. If such an error occurs, or if the unit fails to operate as described in the user's manual, switch the unit off, wait a few seconds and switch the unit on again.

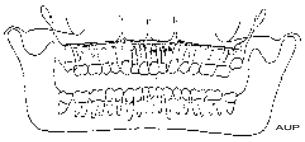
5.6.2 Image transfer errors

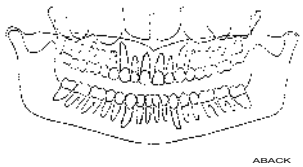
If an image is not transferred successfully to the PC, close and then reopen the dental imaging software and/or restart the PC. DO NOT restart the unit as this will erase any image that is stored in the unit memory and this retrievable image will be lost. If restarting the PC and/or restarting the dental imaging software does not allow you to retrieve the images, contact technical support without restarting the unit.

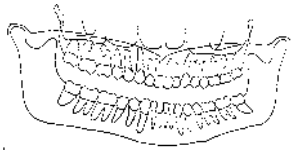
6 Troubleshooting

High quality images with sharp contrast and good detail provide optimum diagnostic information. Images with less quality are usually the result of one or more common problems.

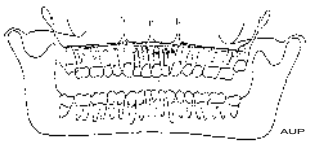
6.1 Patient positioning

Problem	Possible cause	Remedy
Incisors and canines narrow and unsharp. Overshadow in molar and premolar areas. Rows of teeth are compressed. 	1. Patient is too far forward or anterior. 2. Image Layer laser instruction was not followed. 3. Bite guide was not used or the anterior teeth are not in the notches.	1. Check patient positioning with laser lines and Image Layer laser and Adjustment buttons. 2. Insert bite guide. Verify that the anterior teeth are in the notches.

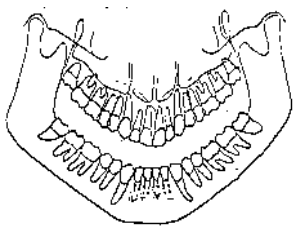
Problem	Possible cause	Remedy
Incisors and canines wide and unsharp. Rows of teeth widened. 	1. Patient is too far back or posterior. 2. Image Layer laser instruction was not followed.	1. Check patient positioning with Image Layer laser and Adjustment buttons. 2. Insert bite guide.

Problem	Possible cause	Remedy
Teeth appear wider on one side and narrower on the opposite. Ramus widths are different on opposite sides. 	1. Patient's head not in center position. 2. Midsagittal line not utilized correctly.	1. Check patient's midsagittal plane with laser-line. 2. Check that patient's head is centered, and that the head support temple supports positioned correctly and closed enough to keep the head straight.

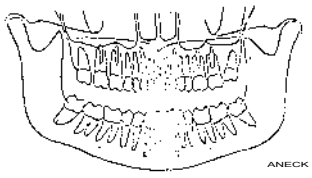
Problem	Possible cause	Remedy
The shadow of hard palate is exposed over maxillary molars. Row of teeth has a wavy appearance. TM joints are exposed outward. Image has a "frowning" shape. Mandible is imaged sharper than maxilla.	Patient head tilted back	Check FH plane using the horizontal laser.



Problem	Possible cause	Remedy
Rows of teeth curved upwards. Mandibular incisors are unsharp. TMJ joints exposed high and are often cut off from the image. Image has an exaggerated "smiling" shape.	Patient head tilted forward.	Check FH plane using the horizontal laser.



Problem	Possible cause	Remedy
Middle area of the image too bright and unsharp. Spine shadow.	Patient's neck was not stretched.	Stretch patient's neck by having him or her step forward while maintaining a secure hold of the handgrips.



Problem	Possible cause	Remedy
Black shadow over maxillary teeth apex area.	Tongue was not against the roof of palate.	Ask patient to swallow and place tongue against the roof of palate during the exposure.

Problem	Possible cause	Remedy
TMJ's exposed on different heights on image. Bilateral distortion in molar and premolar regions.	1. Patient tilted to one side. 2. Mid-sagittal line not utilized correctly.	1. Check midsagittal plane and center patient's head.

Problem	Possible cause	Remedy
Rows of teeth exposed too high. TMJs are cut off.	1. Chin was not resting on chin support 2. Patient positioned too high	Check patient positioning.

Problem	Possible cause	Remedy
Rows of teeth exposed too low. Mandible not exposed completely in the image.	Chin rest was not used with bite rod.	Install chin rest.

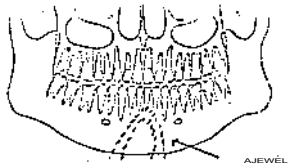
6.2 Image appearance

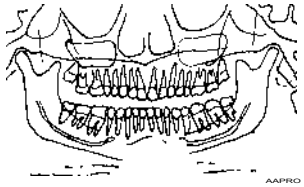
Problem	Possible cause	Remedy
Images are too light	1. Imaging software: Contrast and brightness not optimum 2. Imaging software: Gamma not set correctly 3. Manual technique factors used too low.	1. Adjust contrast and brightness. 2. Select a more fitting histogram type and check gamma setting. 3. Increase technique factors (mA).

Problem	Possible cause	Remedy
Images are too dark	1. Imaging software: Contrast and brightness not optimum. 2. Manual technique factors used too high.	1. Adjust contrast and density. 2. Decrease technique factors.

Problem	Possible cause	Remedy
Lack of image contrast	1. Imaging software: Contrast and brightness not optimum. 2. kV used is too high. 3. Gamma value is not correct for the monitor being used.	1. Adjust contrast and brightness. 2. Lower the kV setting. 3. Adjust Gamma value

6.3 Artifacts

Problem	Possible cause	Remedy
Irregular, bright shadows or artifacts 	Patient is wearing metal objects, such as earrings, necklace etc.	Ask patient to remove objects.

Problem	Possible cause	Remedy
An unexposed area is shown down in the lower middle section of the image. 	Lead apron misplaced (too high on back of neck).	Check the lead apron positioning.

Problem	Possible cause	Remedy
Partial lack of detail and motion artifacts. Irregular vertical bright lines on image.	Patient has moved during the exposure.	Retake the image.

Problem	Possible cause	Remedy
Vertical dark lines on image.	Patient's shoulder in contact with machine parts.	Check patient positioning.

Problem	Possible cause	Remedy
Patient's right side teeth are not exposed.	Exposure button released prematurely.	Retake the image.

Problem	Possible cause	Remedy
Right and left image sides are incomplete. TMJs are not shown.	Orthogonal procedure was mistakenly used.	Select correct panoramic procedure.

Problem	Possible cause	Remedy
A light horizontal line on QA image.	bite guide was left on place.	Remove the bite guide and re-take QA image.

Problem	Possible cause	Remedy
Horizontal lines on image.	Sensor problem.	Consult the dealer.

Problem	Possible cause	Remedy
CEPH: Lateral view has 2 ear plugs.	1. Cephalostat lock not locked 2. Ear plugs misaligned	1. Lock it 2. Call service

6.4 Unit operation

Problem	Possible cause	Remedy
Back of the patient's head is touching the x-ray tube during the exposure.	1. Patient's head inclination not correct (chin up) 1. Patient is too big for the unit. 1. Patient has slumped.	If the image is not acceptable then 1. Check the head position and retake the image. 2. Check the patient positioning. Make the exposure even though the head may touch the tube head. 3. Check the patient positioning. Stretch the patient´s neck. Make the exposure even though the head may touch the tube head. Have patient take ½ step forward, so they are leaning back during scan.

Problem	Possible cause	Remedy
Patient's shoulders are touching the x-ray tube or sensor.	Patient is too big for the unit. Wide and high shoulders. Shoulders tensed unit is positioned too low.	Reverse patient's hands on Handgrips, left to right side handle and vice versa, to pull the shoulders in. Alternately, ask the patient to round the shoulders, and if needed, to drop the shoulders as much as possible. Ask patient to relax shoulders, raise machine slightly and stretch neck.

7 Maintenance

7.1 Maintenance procedure

The maintenance procedure described below shall be seen as a minimum requirement and can be made more stringent to comply with regulations regarding the use and maintenance of dental x-ray devices that are in force in the country in which the unit is installed.

For more maintenance related details, refer to service program manual delivered with the unit.

7.1.1 Annual maintenance

An annual maintenance procedure must be carried out at least once a year by qualified service personnel. Contact your local distributor for details.

7.1.2 Calibration intervals

To keep the image quality at best possible level, calibrations and quality checks shall be carried out at regular intervals according to the table below.

Modality	Minimum requirement	Recommendation
3D	Two (2) times annually	Four (4) times annually
Panoramic	Annually during normal maintenance	Two (2) times annually
Cephalometric	Annually during normal maintenance	Two (2) times annually

NOTICE! *The calibrations mentioned in this manual can be done by the user or qualified service personnel.*

7.2 Changing the fuses

Main fuses are located next to the on/off power switch. Push inward on the fuse base and twist it counterclockwise with a screwdriver. The fuse with the base comes out.

Remove the fuse from the base and replace it with the new one. Repeat this with each blown fuse. Fasten both fuses by pushing the base in and twisting it clockwise with a screwdriver.

Use only appropriate fuses:

- Line voltage 220-240 Vac: 326 Littelfuse 10A (slow blow) or Cooper Bussman MDA-10 (time delay)
- Line voltage 100-120 Vac: 326 Littelfuse 15A (slow blow) or Cooper Bussman MDA-15 (time delay)

7.3 Cleaning and decontaminating the unit

CAUTION! *Switch the unit off or disconnect it from mains before cleaning the unit. If you use a spray cleaner do not spray into any ventilation grills. Do not allow water or other cleaning liquids to enter the unit interior since these may cause short-circuits or corrosion. The unit should be cleaned after every usage.*

CAUTION! *Clean the dust off the unit regularly. The unit might overheat if excess dust is gathered on the cooling grilles.*

Unit surfaces

All surfaces can be wiped clean with a soft cloth dampened with a mild detergent, e.g. soapy water. DO NOT use abrasive cleaning agents or polishes on this equipment.

Positioning light covers

The positioning light covers are made of clear plastic. Use a soft cloth dampened with a mild detergent, e.g. soapy water. NEVER use abrasive cleaning agents or polishes to clean the covers.

Surfaces that the patient touches

All surfaces and parts that the patient touches or comes into contact with must be decontaminated after each patient. Use a disinfectant that is formulated specifically for decontaminating dental equipment and use the disinfectant in accordance with the instructions supplied with the disinfectant. All items and surfaces should be dried before next usage.

NOTICE! *Clean the dust off the unit regularly. The unit might overheat if excess dust is gathered on the cooling grilles.*

WARNING! *Do not use any disinfecting sprays since the vapor could ignite causing injury.*

Decontamination techniques for both the unit and the room must comply with all laws and regulations within the local jurisdiction.

Examples of cleaning agents that can be found in disinfectant products which are allowed or prohibited **when cleaning the unit**:

Allowed: Methanol (metyl alcohol), Soap, Isopropyl alcohol, distilled water.

Not allowed: Bentzene, Chlorine bentzene, Acetone, Acetic ether, agents containing phenol, paracetic acid, peroxide and other oxygen-cleaving agents, sodium hypochlorite and iodine-cleaving agents.

Autoclave

Some removable parts in contact with the patient may be autoclaved. These parts are: bite rods, bite guides and chin supports.

If autoclaving is performed for these items, disinfection by alternate methods is not needed.s

Steam sterilization

Recommended parameters for sterilizable parts are:

- Gravity-displacement steam sterilization

  "Flash" sterilization:
  Temperature: 270 F (132°C)
  Exposure time: 3 minutes

- Prevacuum steam sterilization

  "Flash" sterilization:
  Temperature: 270 F (132°C)
  Exposure time: 3 minutes

- Steam-flush pressure-pulse steam sterilization

  Temperature: 270 F to 275 F (132°C to 135°C)
  Exposure time: 3 to 4 minutes

8 Calibration and adjustment

8.1 Introduction

Calibrations and quality checks are performed by taking exposures of calibration tools. The system does needed adjustments according to the image data captured. For panoramic and cephalometric quality checks the quality is visually evaluated by the operator.

Resulting from the each calibration is an image containing calibration results, telling the operator how to proceed with the calibration and adjustment procedure. In addition to the calibration name (e.g. Adjustment panCol) the images contain image data sampled during the calibration, adjustment instructions and a "Passed / Not Passed / Failed" calibration status.

- **Passed** means that the calibration program is successfully done. Move on to next calibration.
- **Not passed** means that adjustment is still needed. Follow the instructions the image (if any) and take another exposure. Some calibration programs are iterative and demand a few repetitions.
- **Failed** means that the system could not decide what adjustment should be done in order for the calibration to succeed. This calibration status is always the result of some error condition. Taking another exposure will not help. The image may give a hint on what the problem is (e.g. no radiation, collimator severely tilted, image data corrupted…). Contact service if the problem persists after restarting the unit and PC.

8.2 Preparing for calibration

1. Close the head support and lock it in its upmost position.

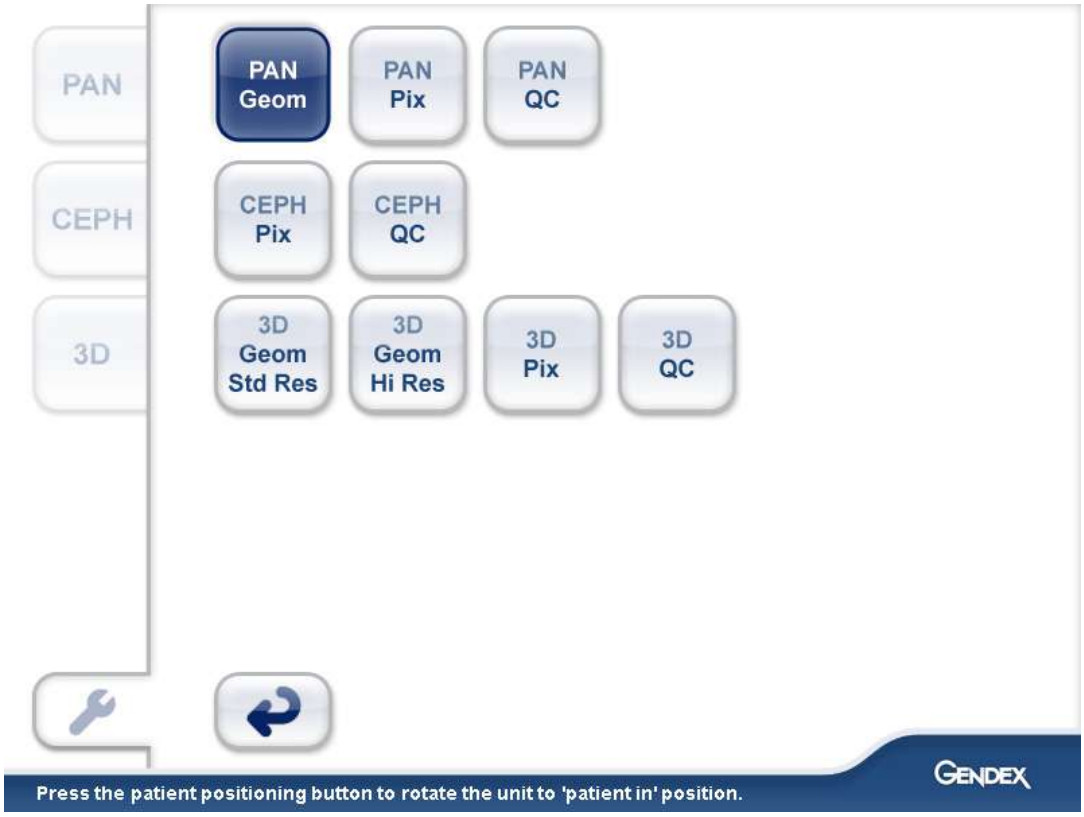
2. Switch the PC and unit on.

3. **PC:** Open the dental imaging software and then open a patient (card) and give it an identifiable name, for example: calibration (refer to the user's manual supplied with the dental imaging software for more information).

4. **PC:** Click the image acquisition button to activate image capture.

5. Touch the **settings** button on the touch screen display.

6. Select the **Quality assurance** button.
   The calibration display appears.



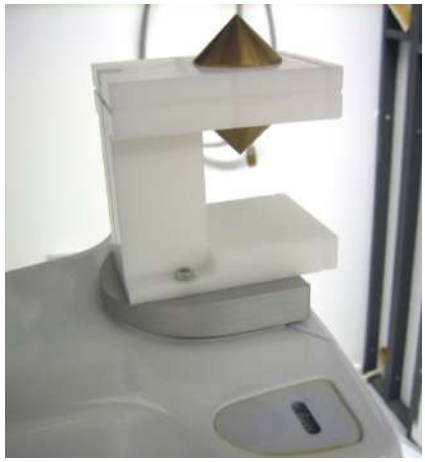
8.3 Panoramic calibration

8.3.1 Panoramic geometry calibration

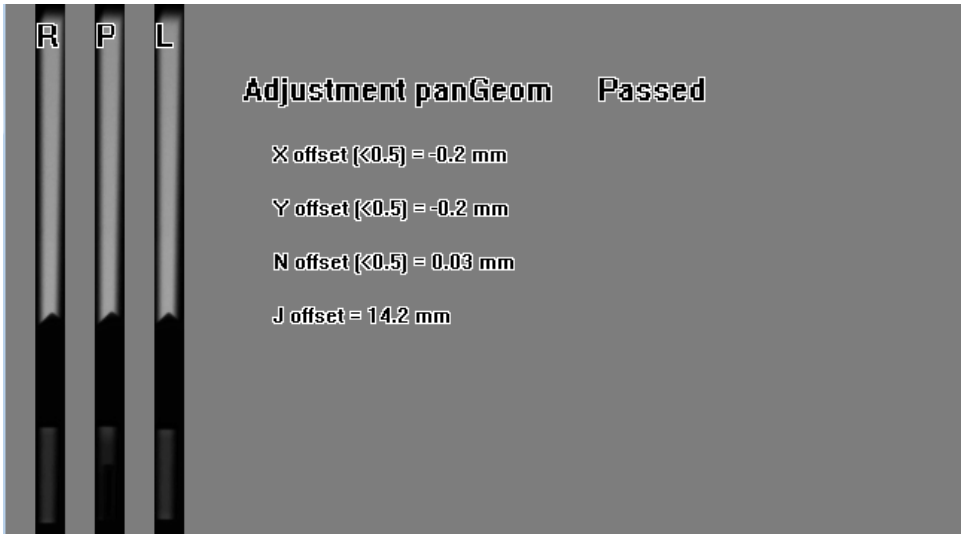
1. Select the program.

2. Press **Patient In.**

3. Install the double cone calibration tool.



4. Take an exposure.
5. Repeat the calibration until calibration result “passed” is achieved.



8.3.2 Panoramic pixel calibration

NOTICE! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

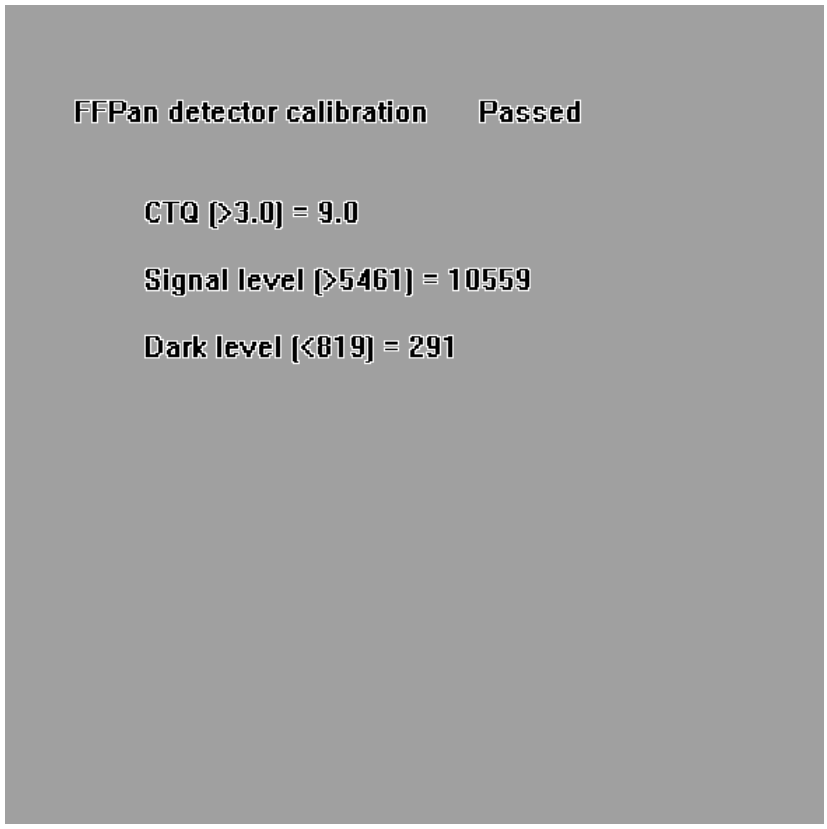
NOTICE! *Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.*

1. Remove the double cone calibration tool.

2. Select the program.

3. Press **Patient In.**

4. Take an exposure. Touch screen display informs when the calibration is passed.



8.3.3 Panoramic Quality Check (optional)

NOTICE! *Use the same tool for cephalostat Quality Check.*

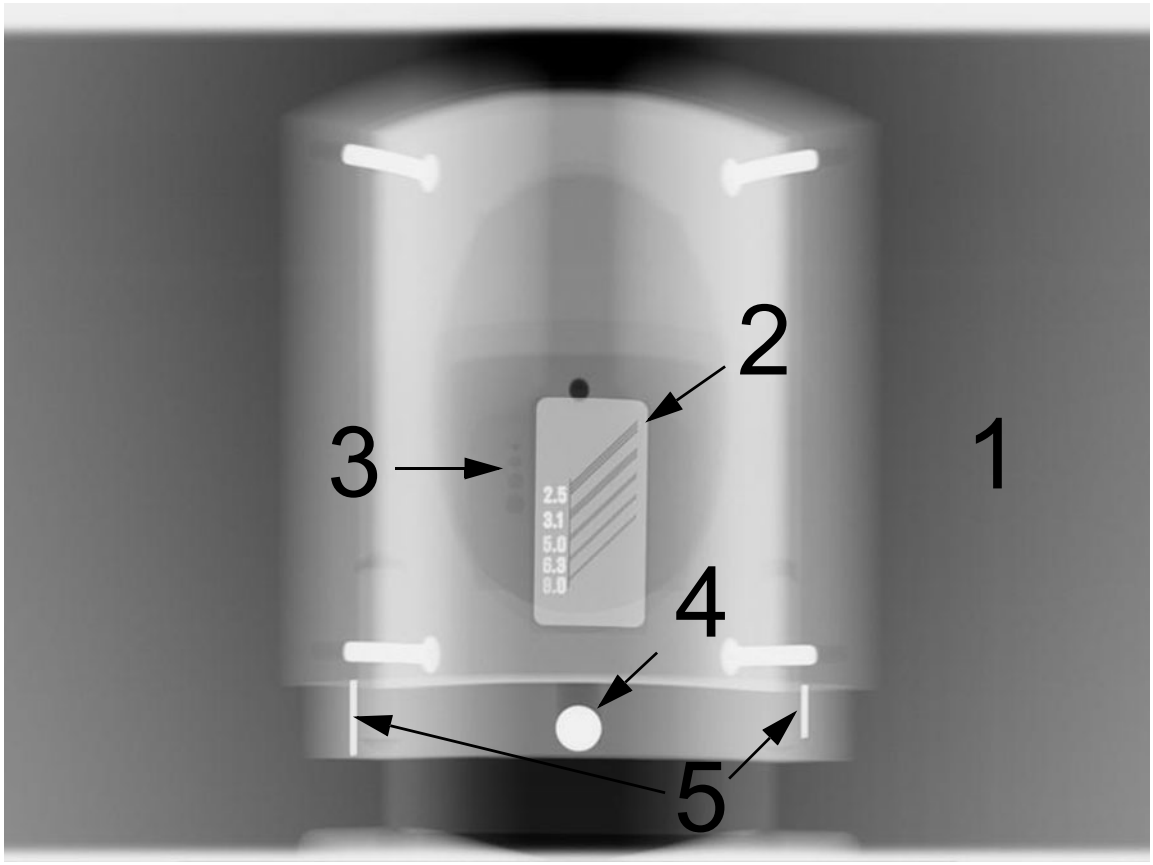
1. Attach a panoramic Quality Check Tool (optional) to the chin support.

2. Select the Pan QC program.

3. Press **Patient In.**

4. Take an exposure.

5. Visually evaluate the result using the installed imaging software.



Subjects to be evaluated:

1. Smoothness of the exposed area. Non-exposed area surrounds the whole image.
2. High contrast resolution; minimum 3.1LP/mm must be distinguishable.
3. All four low contrast holes must be visible.
4. Roundness of the ball.
5. The ball should be placed symmetrically between the two pins. The distance from both pins to center should be equal length.

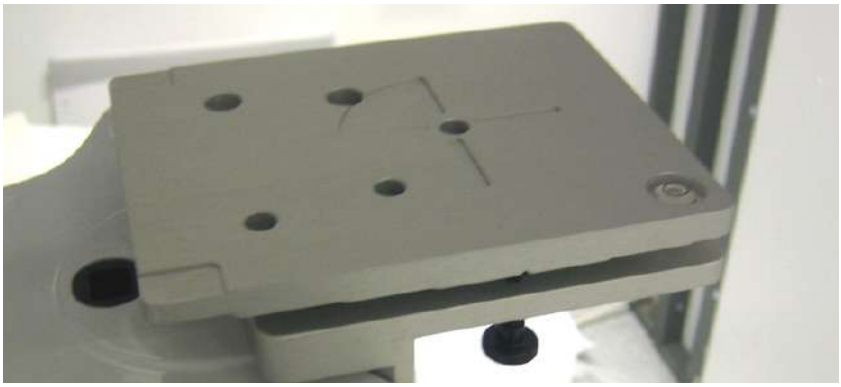
NOTICE! *The panoramic QC collimator is equipped with a 0.8 mm copper filter. If more filtration is required, additional filtration may be attached to the tubehead cover. The unit may be configured to use higher exposure values to compensate for an additional 1 mm copper filter.*

Ask Technical Support to adjust the copper thickness setting as required.

8.4 3D calibration

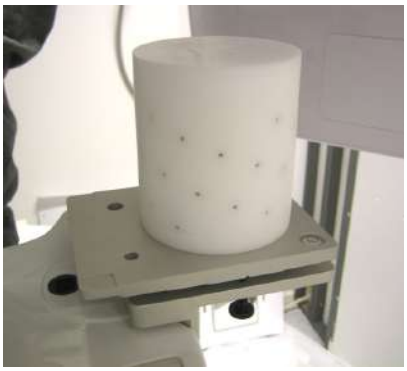
8.4.1 3D geometry calibration

1. Attach the 3D phantom base (bubble level assembly) to the lower shelf. Level it using the screws on the bottom of the phantom base and the bubble on top of the phantom base.



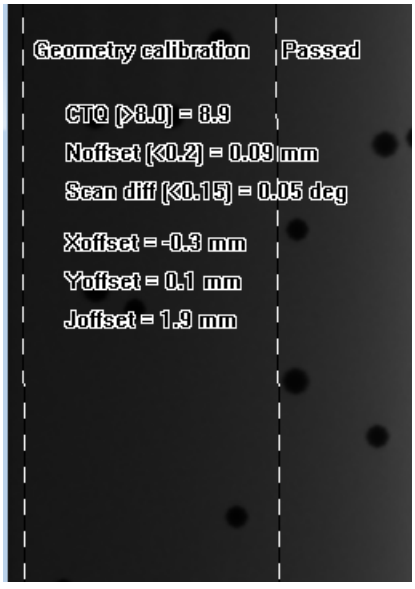
2. Select the program.There is a calibration procedure for both 3D imaging modes, standard and high resolution. Standard geometry calibration has to be done first.

3. Press **Patient In.**



4. Install the 3D calibration phantom.

5. Take an exposure.



6. Repeat the calibration until calibration result “passed” is achieved. This calibration is only needed with 3D units.

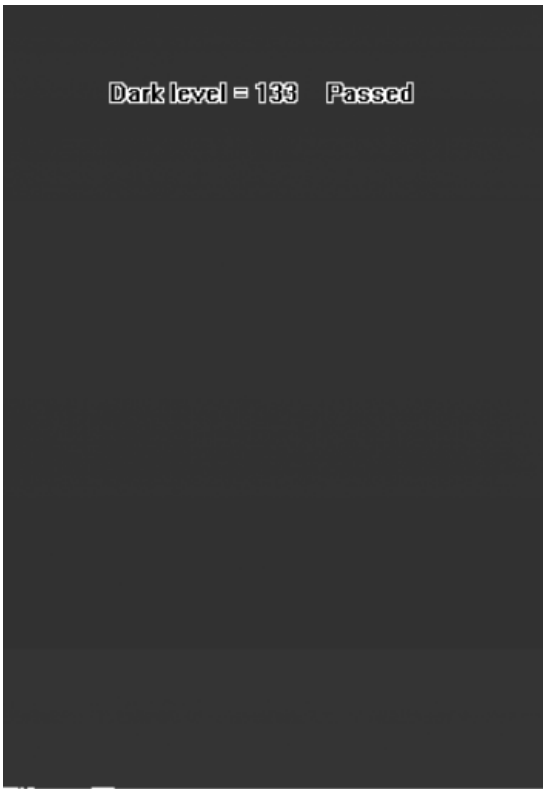
8.4.2 3D pixel calibration

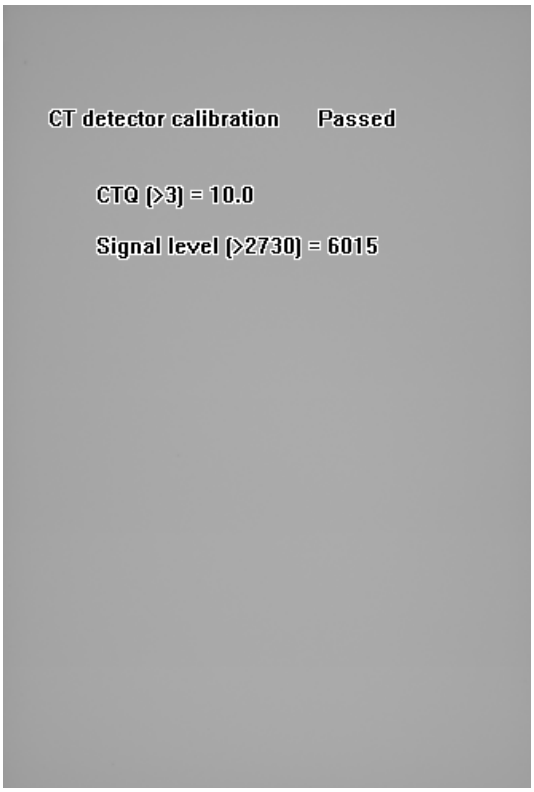
1. Remove the 3D calibration phantom.

2. Select the program.

3. Press **Patient In.**

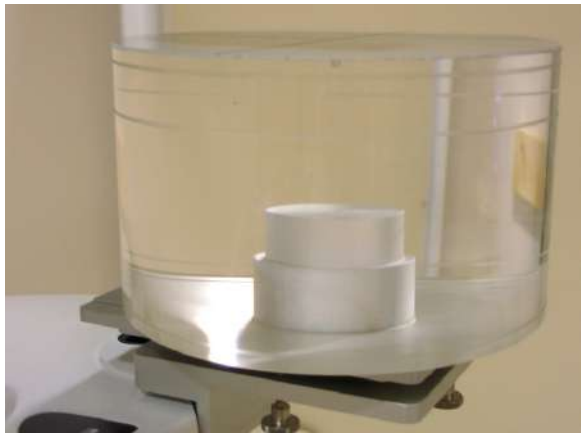
4. Take an exposure. The result image informs when the calibration is passed.





8.4.3 3D Quality Check program

1. Attach the QC phantom to the 3D phantom base.



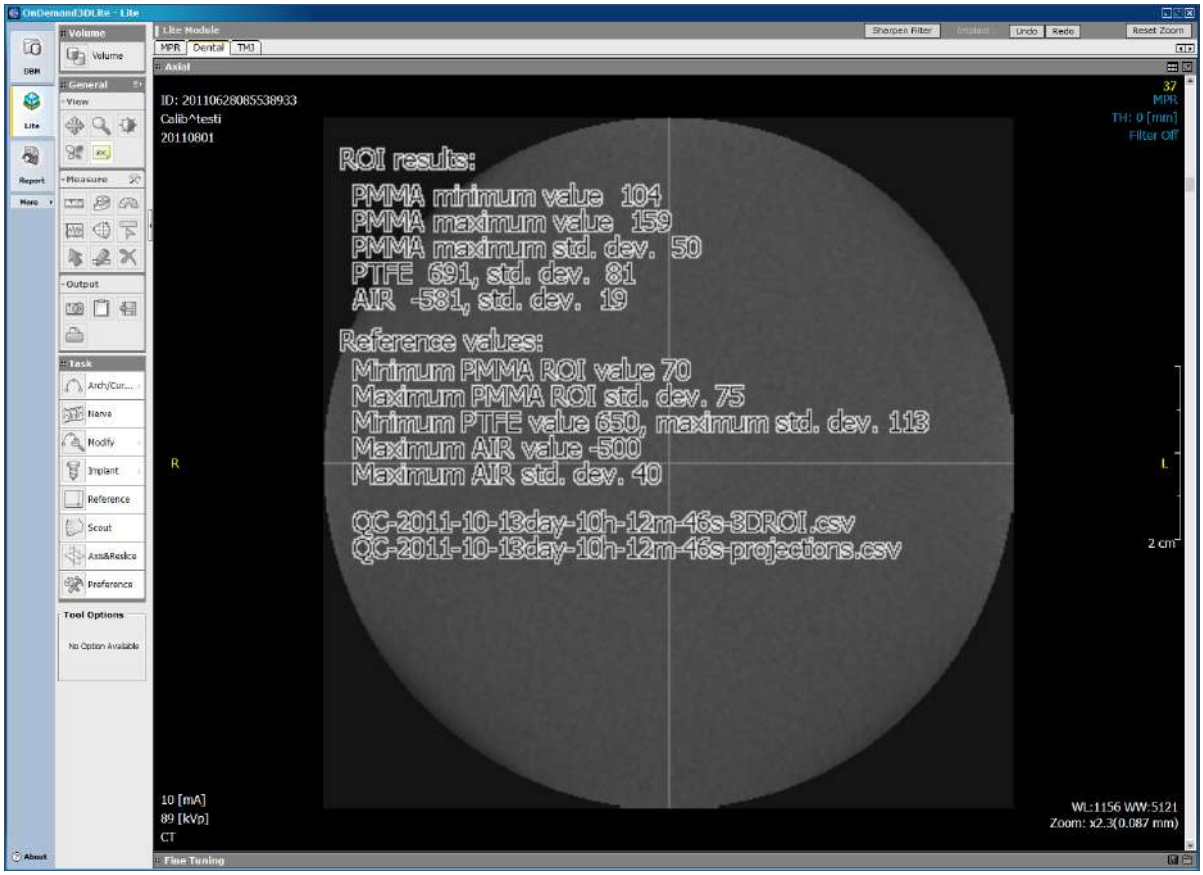
2. Ensure that QC phantom is aligned with the spirit level on the phantom base. If it's not, level it using the screws on the bottom of the phantom base.

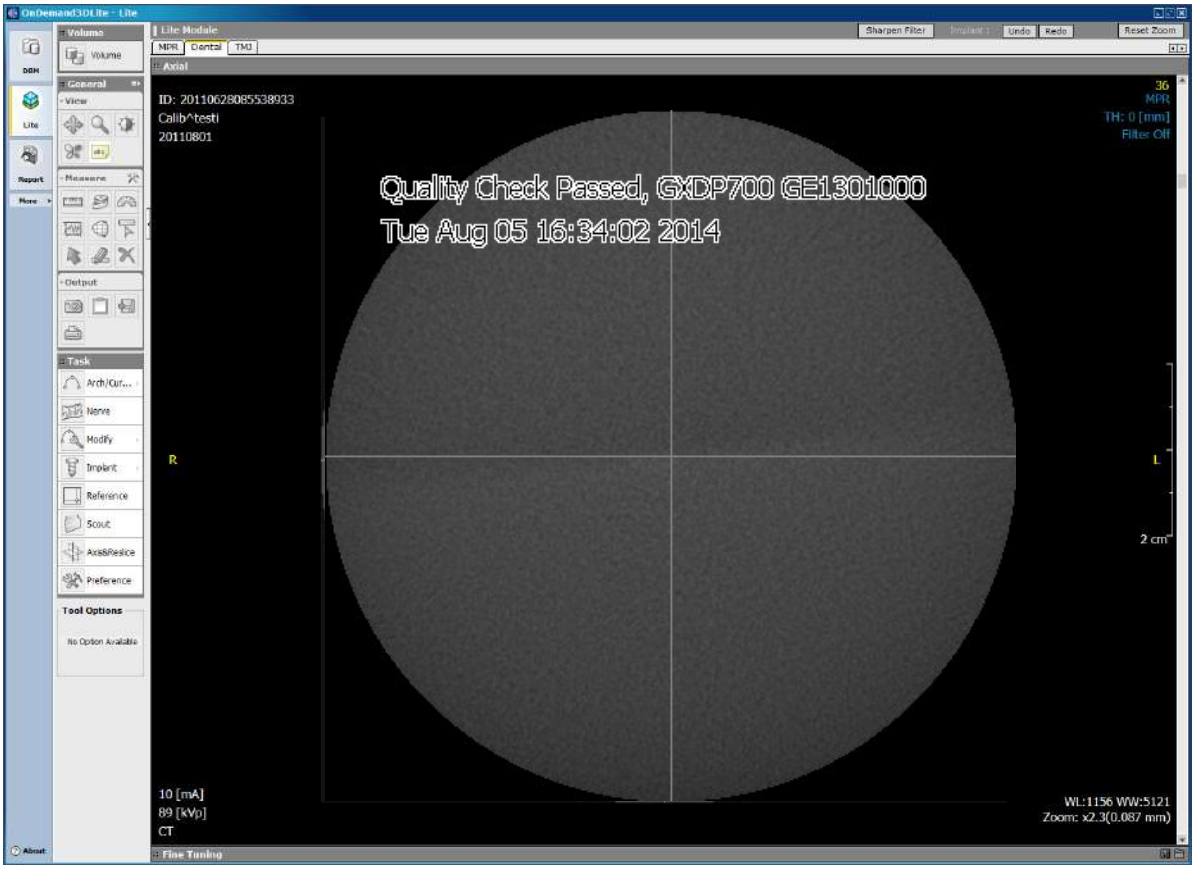
3. Select the 3D QC program.

4. Press **Patient In.**

5. Take an exposure.

6. Quality check measurement information and pass/fail result can be found in the reconstructed volume from axial view. Use 3D viewing software from to find the axial slices containing the information. If quality check is not passed, unit may need recalibration. Please redo 3d geometry and 3d pixel calibrations. If the quality check is still not passed, contact service.





8.5 Cephalometric calibration

8.5.1 Ceph pixel calibration

NOTICE! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

NOTICE! *Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.*

1. Rotate the ear holders into PA view position and move them completely apart. Turn nasion support up out of the way.

2. Select Ceph Pix program.

3. Press **Patient In.**

4. Take an exposure.

5. This calibration should always be a pass.

8.5.2 Ceph Quality check program (Optional)

NOTICE! *Rotate the ear holders into PA view position. Turn nasion support up out of the way.*

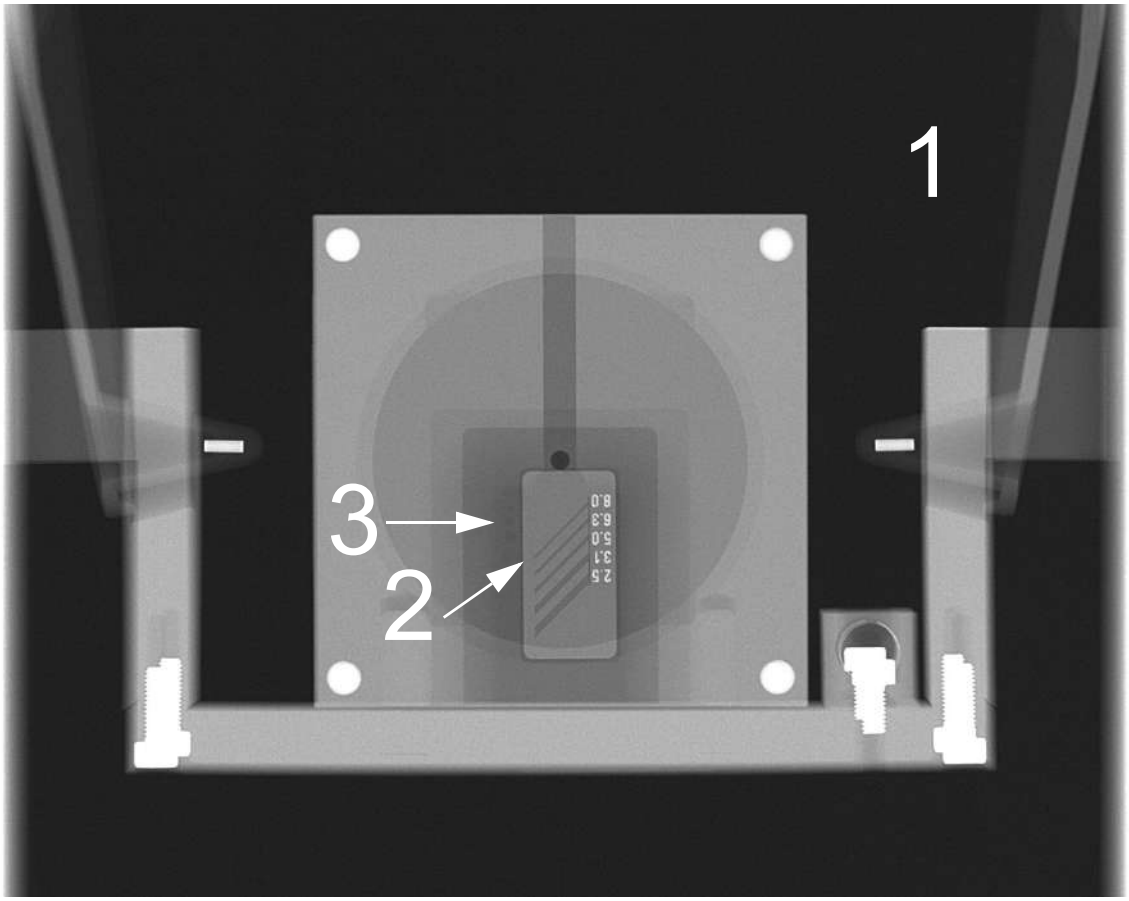
1. Attach the QC phantom to the ceph unit and ensure that it's leveled from the spirit level.

2. Select the Ceph QC program.

3. Press **Patient In.**

4. Take an exposure.

5. Visually evaluate the result using the installed imaging software.



Subjects to be evaluated:

1. Smoothness of the exposed area. Non-exposed area surrounds the whole image.
2. High contrast resolution; minimum 3.1LP/mm must be distinguishable.
3. All four low contrast holes must be visible.

9 Technical data

9.1 Technical specifications

Manufactured for:	Gendex Dental Systems
Quality system	In accordance with ISO13485 and ISO9001 standard
Environmental management system	In accordance with ISO14001 standard
Conformity to standards:	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-4 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-2-63 IEC 60601-1-2 IEC 60601-1-3 UL 60601-1 CAN/CSA –C22.2 No. 601-1-M90 This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture. GXDP-700 is in conformity with the provisions of Council Directive 93/42/EEC as amended by the Directive 2007/47/EC concerning medical devices. Performance Standards and European Union Directive 93/42/EEC (Medical Devices Directive).

Product name	**GXDP-700**
Model:	GXDP-700
Product type:	Digital dental imaging system with panoramic cephalometric and Cone Beam 3D imaging programs.

Unit data	
Protection against electric shock	Class I
Degree of protection	Type B applied with no conductive connection to the patient
Protection against the ingress of liquids	IP20
Disinfection methods	- mild soapy water (non-abrasive) - non-alcohol based disinfectant for the chin rest - disposable plastic covers for bite block, chin rest and chin support
For use	In environments where no flammable anaesthetics nor flammable cleaning agents are present
Mode of operation	continuous operation/intermittent loading
Safety	IEC 60601-1
Power supply	Mains plug connection

Tube head assembly	
Tube head assembly type	THA 300
Tube type	Toshiba D-052SB, D-054SB-C Stationary W anode
Tube voltage	57 - 90 kV In some countries, min. kV limited to 60 kV
Max. tube current	16 mA In some countries, max. mA limited to 15 mA
Max. electric output	1,44 kW
Target angle	5 degrees
Focal spot	0,5 x 0,5 mm (according to IEC 60336/2005)
Nominal anode input	1750 W
Reference axis	In the middle of the panoramic sensor’s active area
Max. anode heat content	35 kJ
Max. X-ray tube assembly heat content	385 kJ
Max. continuous heat dissipation of the X-ray tube assembly	38 W
Total filtration	min. 3.2 mm Al, 90kV
Leakage Technique Factors	5625 mAs/h @ 90kV/4mA

Electrical connections	
Nominal mains voltage	220-240V / 100-120V (Selectable)
Input power frequency	50 / 60 Hz
Nominal current	10A @ 230 VAC, 15A @ 110 VAC
Fuses	230 Vac: Littelfuse 326 (slow blow) 10A Cooper Bussman (time delay) MDA-10 110 Vac: Littelfuse 326 (slow blow) 15A Cooper Bussman (time delay) MDA-15
Power consumption	2.3 kVA @ 230 VAC, 1.65 kVA @ 110 VAC
Maximum impedance of main	0,2 Ω

2D modalities

The following charts represent technique factors that can be used with the selected line voltage and continuous radiation. One of the three technique factors is always fixed.

Table 1: 100 VAC											
mA											
16											
14											
12.5	x	x									
11	x	x	x	x	x						
10	x	x	x	x	x	x	x				
9	x	x	x	x	x	x	x	x	x		
8	x	x	x	x	x	x	x	x	x	x	
7.1	x	x	x	x	x	x	x	x	x	x	
6.3	x	x	x	x	x	x	x	x	x	x	
5.6	x	x	x	x	x	x	x	x	x	x	
5	x	x	x	x	x	x	x	x	x	x	
4.5	x	x	x	x	x	x	x	x	x	x	
4	x	x	x	x	x	x	x	x	x	x	
3.6	x	x	x	x	x	x	x	x	x	x	
3.2	x	x	x	x	x	x	x	x	x	x	
	57	**60**	**63**	**66**	**70**	**73**	**77**	**81**	**85**	**90**	**kV**

Table 2: 120 VAC											
mA											
16	x	x	x								
14	x	x	x	x	x						
12.5	x	x	x	x	x	x	x				
11	x	x	x	x	x	x	x	x	x	x	
10	x	x	x	x	x	x	x	x	x	x	
9	x	x	x	x	x	x	x	x	x	x	
8	x	x	x	x	x	x	x	x	x	x	
7.1	x	x	x	x	x	x	x	x	x	x	
6.3	x	x	x	x	x	x	x	x	x	x	
5.6	x	x	x	x	x	x	x	x	x	x	
5	x	x	x	x	x	x	x	x	x	x	
4.5	x	x	x	x	x	x	x	x	x	x	
4	x	x	x	x	x	x	x	x	x	x	
3.6	x	x	x	x	x	x	x	x	x	x	
3.2	x	x	x	x	x	x	x	x	x	x	
	57	**60**	**63**	**66**	**70**	**73**	**77**	**81**	**85**	**90**	**kV**

Table 3: 240 VAC											
mA											
16	x	x	x	x	x	x	x				
14	x	x	x	x	x	x	x	x	x		
12.5	x	x	x	x	x	x	x	x	x	x	
11	x	x	x	x	x	x	x	x	x	x	
10	x	x	x	x	x	x	x	x	x	x	
9	x	x	x	x	x	x	x	x	x	x	
8	x	x	x	x	x	x	x	x	x	x	
7.1	x	x	x	x	x	x	x	x	x	x	
6.3	x	x	x	x	x	x	x	x	x	x	
5.6	x	x	x	x	x	x	x	x	x	x	
5	x	x	x	x	x	x	x	x	x	x	
4.5	x	x	x	x	x	x	x	x	x	x	
4	x	x	x	x	x	x	x	x	x	x	
3.6	x	x	x	x	x	x	x	x	x	x	
3.2	x	x	x	x	x	x	x	x	x	x	
	57	**60**	**63**	**66**	**70**	**73**	**77**	**81**	**85**	**90**	**kV**

3D modalities

The following charts represent technique factors that can be used with the selected line voltage in 3D imaging mode. 3D modality uses pulsed x-rays with fixed 90 kV and exposure time.

Table 4: Exposure settings for 3D SFOV imaging

FOV	3D Program	DAP (mGycm2) & Available mA ranges													
		3.2 mA	3.6 mA	4 mA	4.5 mA	5 mA	5.6 mA	6.3 mA	7.1 mA	8 mA	9 mA	10 mA	11 mA	12.5 mA	14 mA
61x41 mm	Low Dose	30	33	37	42	46	52	58	65						
	Std Res							116	131	148	166	184	203	231	
	High Res			192	216	240	269	302	341	384	432	480	528	600	
	Endo			192	216	240	269	302	341	384	432	480	528	600	
61x78 mm (optional)	Low Dose	61	69	77	86	96									
	Std Res							241	272	306	345	383	421	479	
	High Res			397	447	497	556	626	705	795	894	993			

Positioning lights	
Panoramic, TMJ & Maxillary Sinus Programs Cephalostat FH light 3D imaging programs	laser light (CLASS 1 LASER PRODUCT) max output 100µW Warning symbols are placed next to the laser lights and the label describing the laser light classification is placed inside the carriage side cabinet. USA / Canada models have different types of laser light stickers according to local requirements. Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	IEC 60825-1:1993+A1:1997+A2:2001

X-ray generator	
Nominal power	1750 W nominal at 90 kV, 12.5 mA
Tube voltage	57 - 90 kV (+/- 5 kV)
Tube current	3,2 - 16 mA (+/- 1 mA)
Supply frequency	75 - 150 kHz
Spine compensation	kV / mA compensated
Spine compensation mode	Automatic (ASC), Pre-programmed

X-ray generator	
Coefficient of variation of DAP	< 5%
Automatic Dose Rate Control reproducibility	> 95%

User interface	
Program and technique factors selection, exposure control	Touch screen panel, optional remote exposure switchTouchscreen panel, removable exposure button with coiled, flexible cable (5 m), remote exposure button.
Patient positioning	Positioning panel, integrated
Connection cable (GXDP-700 - PC)	CAT6 UTP Ethernet cable

Panoramic programs & technique factors & magnification:		
Standard Adult Panoramic	57-90 kV/ 3.2-16 mA/2.5-16.4 s	30%
Small Panoramic	57-90 kV/ 3.2-16 mA/2.5-14.4 s	30%
Orthogonal Panoramic	57-90 kV/ 3.2-16 mA/2.0-12.9 s	30%
Lateral TMJ	57-90 kV/ 3.2-16 mA/5.3-10.6 s	23%
PA TMJ View	57-90 kV/ 3.2-16 mA/5.6-10.6 s	55%
Maxillary Sinus	57-90 kV/ 3.2-16 mA/12.5 s	30%
Bitewing	57-90 kV/ 3.2-16 mA/2.4-11.9 s	30%
Panoramic QC	57-90 kV/ 3.2-12.6 mA/16.4 s 66 kV /3,2 mA with 0,8 mm Cu filter, 70 kV / 8 mA with 1,8 mm Cu filter	30%

Exposure Control	
Exposure Control	Pre-programmed icons for all programs Automatic Spine Compensation

Cephalometric programs & technique factors:	
LL Max	85-90 kV / 8-12.5 mA / 10-20 s
LL Vertical	85-90 kV / 8-12.5 mA / 7.5-15 s
LL Horizontal	85-90 kV / 8-12.5 mA / 10-20 s
AP/PA Max	85-90 kV / 8-12.5 mA / 10-20 s
AP/PA Vertical	85-90 kV / 8-12.5 mA / 7.5-15 s
Exposure Control	Pre-programmed icons for all programs.
Magnification factor	1.15 (15%)

3D imaging programs:	
61 x 41 mm FOV Low Dose resolution	90 kV / 3.2 - 7.1 mA / 1.2 s
61 x 41 mm FOV standard resolution	90 kV / 6.3 - 12.5 mA / 2.3 s
61 x 41 mm FOV high resolution and Endo program	90 kV / 4 - 12.5 mA / 6.1 s
61 x 41 mm FOV scout	90 kV / 4 - 12.5 mA / 0.02 s
61 x 78 mm FOV Low Dose resolution	90 kV / 3.2 - 5 mA / 2.4 s
61 x 78 mm FOV standard resolution	90 kV / 6.3 - 12.5 mA / 4.9 s
61 x 78 mm FOV high resolution	90 kV / 4 - 10 mA / 12.6 s
61 x 78 mm FOV scout	90 kV / 4 - 12.5 mA / 0.04 s

NOTICE! *Accuracy of the imaging program factors that are shown in GUI are:*

- *kV: +- 5kV*
- *mA: +- 1mA / +-20%*
- *time: +- 10%*
- *DAP: +- 50%*

Image storing and retrieving:	
File formats	PNG (16-bit), JPG (12-bit)
File compression	PNG (lossless), JPG (100%-60% quality)
Typical panoramic file size	About 2-4 MB (PNG 16 bits)
Typical cephalometric file size	3-5 MB (PNG 16 bits)
Typical 3D file size	150-250 MB (DICOM)
Patient database	Standalone workstation (provided by customer) Server on local area network (LAN) (provided by customer)

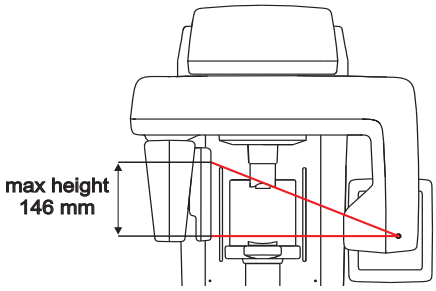
Panoramic patient positioning	
Operation	Left or right side of unit Motorised carriage movement
Positioning aids	Chin rest, bite guide, 3-point headrest mirror, 3 positioning lasers, Cuspid light keys

Cephalostat patient positioning	
Operation	Arm mounts on left or right side of the unit Interlocked pan/ceph sensor Motorised carriage buttons at cephalostat head assembly.
Positioning aids	Ear holders, Nasion support with vertical mm scale, Frankfort plane laser light, Contact plate (Carpus program).

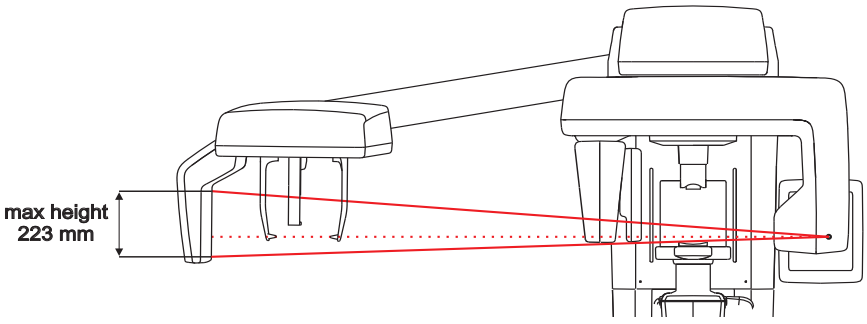
3D imaging patient positioning	
Operation	Left or right side of unit Motorised carriage movement
Positioning aids	Chin rest, chin support, 3-point headrest, mirror, 3 positioning laser lights

Cephalostat scanning	
Scanning method	Horizontal scan, synchronized sensor and secondary slot motion
Scanning time	10 - 20 s.

Panoramic image receptor	
Sensor unit	Pan sensor or interchangeable Ceph sensor
Technology/Sensor type	CMOS
Image pixel size and depth	100 x 100 µm and 14 bits
Active area height	5.8 inches / 148 mm / 1480 pixels
Resolution	5 LP/mm (panoramic)

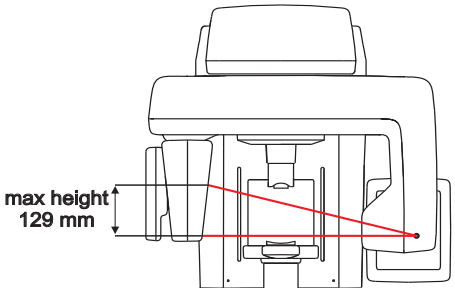


Cephalometric image receptor	
Sensor unit	interchangeable Ceph sensor
Technology/Sensor type	CMOS
Image pixel size and depth	100 x 100 µm and 14 bits
Active area height	223,2 mm / 2232 pixels
Image field width in lateral view	9.4 inches / 240 mm maximum 7.1 inches / 180 mm minimum
Image field width in PA view	9.4 inches / 240 mm maximum 7.1 inches / 180 mm minimum
Resolution	4 LP/mm (cephalometric)



3D image receptor	
Sensor unit	3D sensor
Technology/Sensor type	CMOS
Image pixel size and depth	200 x 200 µm and 13 bits

3D image receptor	
Photodiode area:	100 x 68.2 mm



Unit physical measures:	
source-image distance (SID)	500 mm (Panoramic) 570 mm (3D)
Installation	Standard wall mount with ±45° angled joint. Optional base for free standing unit (unit height is increased 25 mm).
Height x Width x Depth (inches/mm)	2440x960x1160mm (standard column) 96 x 37.8 x 45.7 inches -Max.
Weight	200 kg / 441 lbs. (Panoramic)

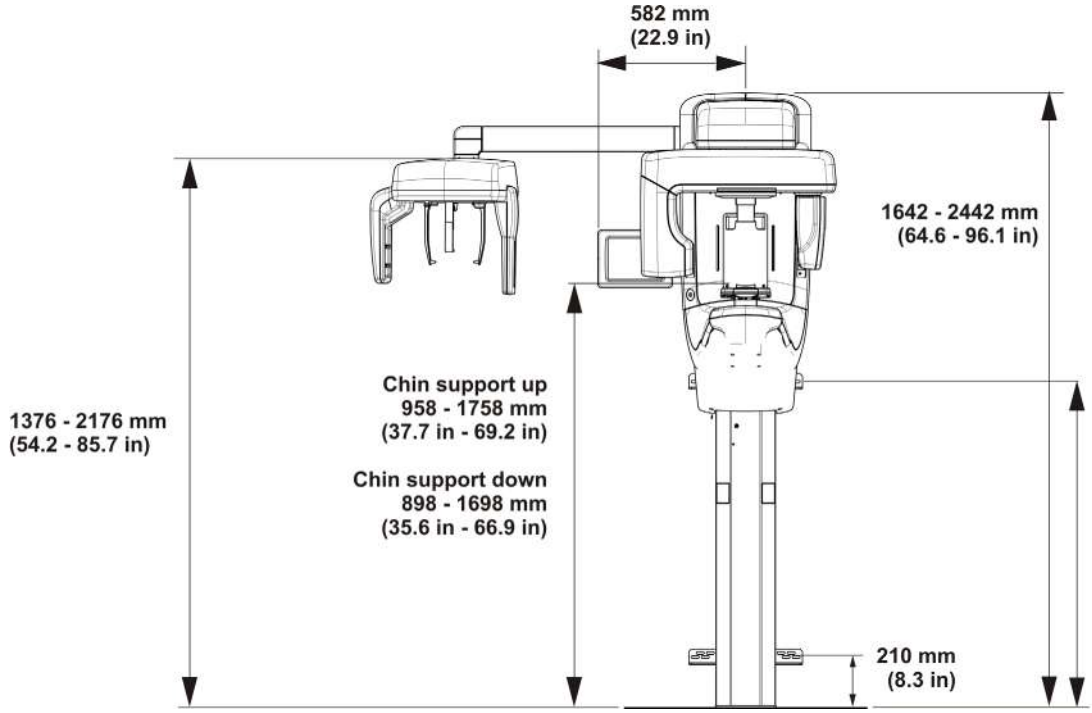
GXDP-700 ceph physical measures:	
source-image distance (SID)	1745 mm / 68.7 inches
source-object distance (SOD)	1520 mm / 60 inches
Installation	Standard wall mount with 45° angled joint. Optional base for free standing unit (unit height is increased 25 mm)
Height x Width x Depth (inches/mm)	2440 x 2065 x 1210 mm 96 x 81.3 x 47.6 inches
Weight	240 kg / 529 lbs. (Cephalometric)

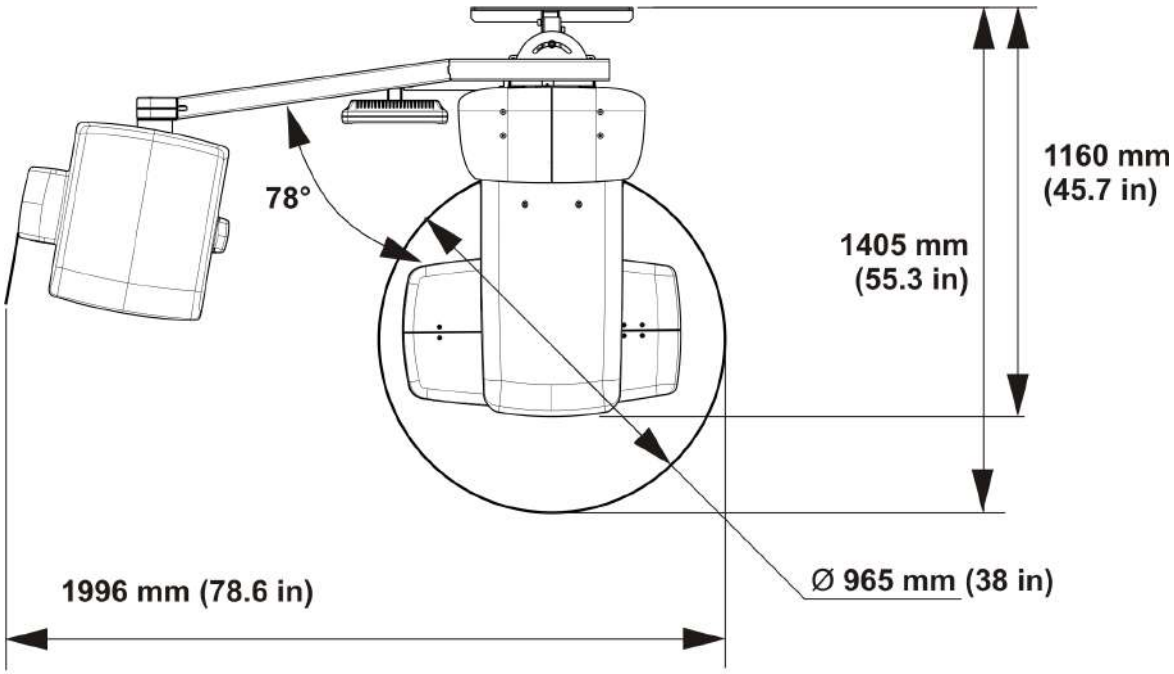
Ambient temperatures:	
Transportation and Storage	-10°…+50°C
Operation Temperature	+10°...+35°C, RH max. 85%, 700 - 1060 mbar

Ceph ready option (Ordered separately)	
Options	**Description**
Ceph Upgrade to GXDP-700 pan	Unit has the same sensor as ceph unit. Cost saving with future digital ceph upgrade.

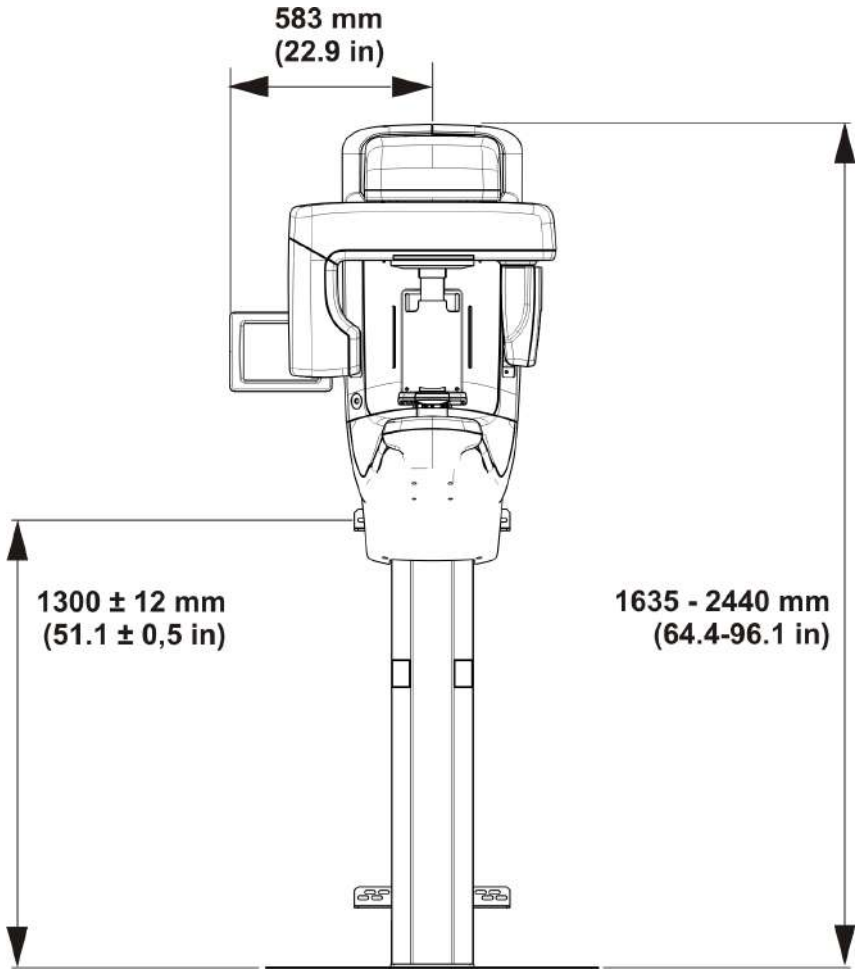
Field upgrades for model GXDP-700	
Upgrade	**Description**
Cephalostat Upgrade	Add ceph imaging to GXDP-700 pan
Left / right	Change handedness to pan ceph
3D Upgrade	Add 3D imaging: - Panoramic unit to 3D unit - Panoramic unit to 3D MFOV unit* - 3D unit to 3D MFOV unit* *availability based on unit serial number, contact your local distributor for more information.
3D Imaging Kit	Add 3D imaging capability to GXDP-700™ digital pan or pan and ceph. FOV 61 x 41 mm.
3D Large Field Of View Capability	Add optional 3D Large Field Of View (61 x 78mm) imaging to existing Standard 3D Field Of View (61 x 41mm). Must already have 3D capability.

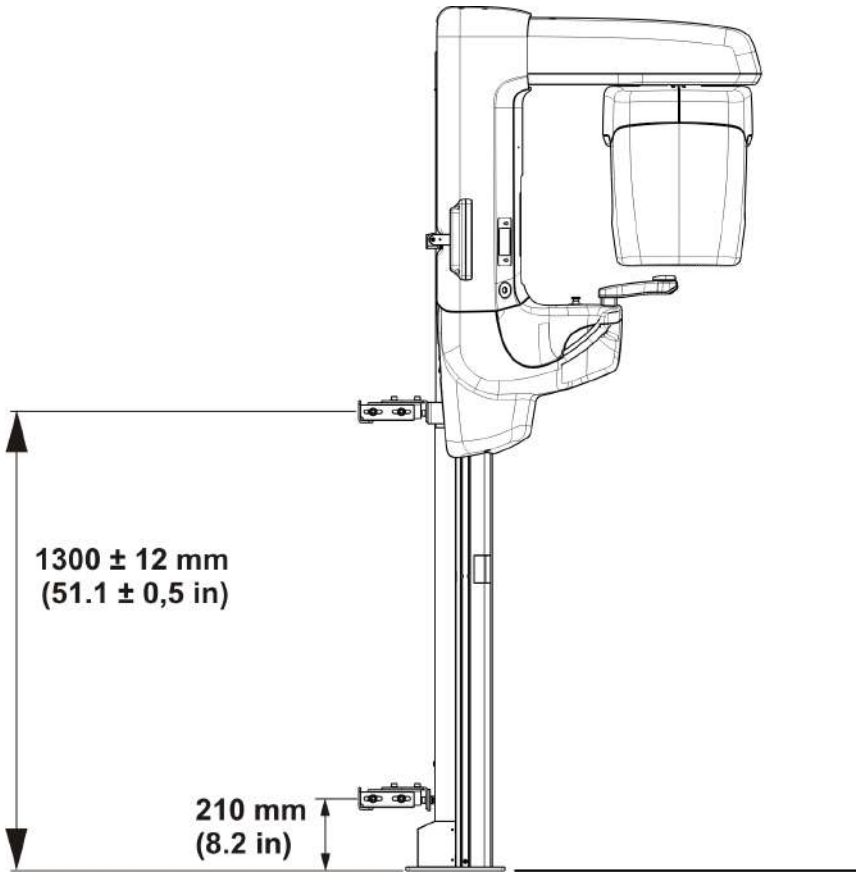
9.2 Unit dimensions

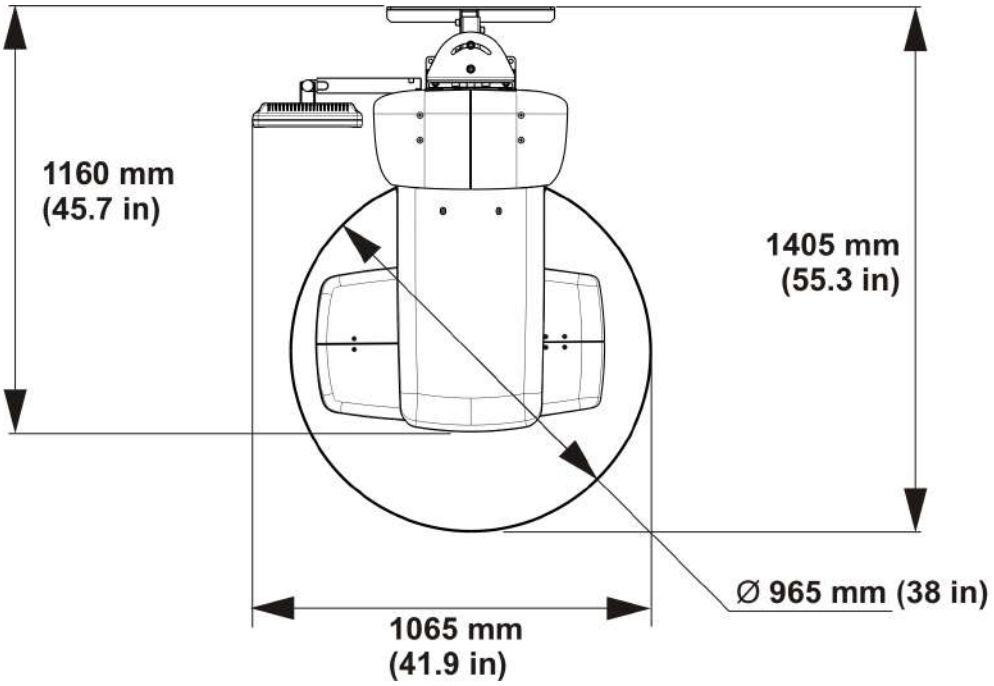




NOTICE! *The cephalostat arm and the touchscreen can be on either side (L/R).*







NOTE! *The touchscreen can be on either side (L/R).*

9.3 Symbols that may appear in the unit

Name and address of the manufacturer

Serial number

Radiation warning

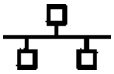
Dangerous voltage

On or enabled

Off or disabled

Exposure switch

Connector for exposure switch



Ethernet connector

Operating instructions
Refer to operating instructions for more information.
The operating instructions can be supplied electronically or in paper format.

Collision warning
Unit can collide with a seated patient when driving the carriage downwards. Pay attention on the unit movement.

Laser radiation (yellow label)

Attention,consult accompanying documents

Ground (Functional)

Protective ground

Focal spot

Filtration

Do not reuse

Recyclable

Laser class label (Patient positioning lights)

Rx only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Type B Applied part

CE (0537) symbol
MDD 93/42/EEC

ETL symbol
Conforms to UL STD 60601-1.
Certified to CSA.

9.4 Labels on the unit

The main label of the unit is located on the vertical carriage next to the on/off power switch. The unit is Class I, type B and with IP20 protection.

9.5 Electromagnetic Compatibility (EMC) tables

NOTICE! *Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.*

Table 1.1 Electromagnetic emissions IEC 60601-1-2 Ed3

GXDP-700 is suitable for use in the specified electromagnetic environment. The purchaser or user of GXDP-700 should assure that it is used in an electromagnetic environment as described below:		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Radio-Frequency Emissions CISPR11	Group 1	GXDP-700 uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR11	Class B	GXDP-700 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	IEC 61000-3-2 Class A	GXDP-700 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	GXDP-700 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 1.2 Electromagnetic immunity IEC 60601-1-2 Ed3

GXDP-700 is suitable for use in the specified electromagnetic environment. The purchaser or user of GXDP-700 should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT)	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT)	Mains power quality is that of a typical commercial and/or hospital environment. If the user of GXDP-700 requires continued operation during power mains interruptions, it is recommended that GXDP-700 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/ or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 1.3 RF immunity of non-life-support equipment or system IEC 60601-1-2

GXDP-700 is suitable for use in the specified electromagnetic environment. The purchaser or user of GXDP-700 should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6 Radiated RFIEC 61000-4-3	3 V150 kHz to80 MHz 3 V/m80 MHz to2,5 GHz	[V1] 3 V [E1] 3 V/m	Portable and mobile RF communications equipment are used no closer to any part of GXDP-700, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol: 

*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe GXDP-700 to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating GXDP-700.

Over the frequency range 150 kHz to 80 MHz, field strengths are less than [V1] V/m. The Recommended Separation Distances are listed in the next table.Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTICE! *RF communications equipment can effect medical electrical equipment.*

NOTICE! *This equipment generates, uses and can radiate radio frequency energy. If not installed and used in accordance with this manual, it may cause harmful interference to radio communications. Portable and mobile RF communications equipment can also affect the performance of* GXDP-700

Table 1.4 Table 4

Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
Frequency of Transmitter Equation Rated Maximum Output Power of Transmitter (watts)	150KHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ Separation Distance (meters)	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ Separation Distance (meters)	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ Separation Distance (meters)
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,34
10	3,69	3,69	7,38
100	11,67	11,67	23,34

USE LIMITATION:

External components

The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM

INSTALLATIONS REQUIREMENTS & ENVIRONMENT CONTROL:

In order to minimize interference risks, the following requirements shall apply.

Cables shielding & grounding

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

Electrostatic discharges environment & recommendations

In order to reduce electrostatic discharge interference, a charge dissipative floor should be installed to prevent charge accumulation.

- The dissipative floor material must be connected to the system reference ground, if applicable.
- Relative humidity must be maintained above 30 percent.

Stacked components & equipment

The GXDP-700 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the GXDP-700 should be observed to verify normal operation in the configuration in which it will be used.

Interference may occur in the vicinity of equipment marked with the following symbol:

No portable or mobile RF communications equipment may be used closer to any part of the GXDP-700 including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.
See Table 4.

9.6 X-ray tube assemblies

Duty cycle 1:8

Rectification type: Constant pot ential x-ray generator

Generator rating: Generator nominal power 1750W

Figure 1.4

Anode Thermal Characteristics

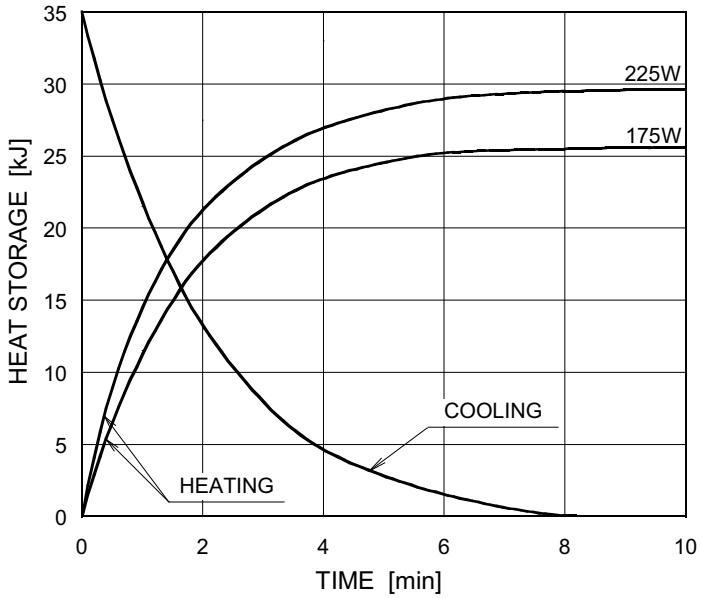


Figure 1.5

Maximum Rating Charts

(Absolute maximum rating charts)

DC (Center-Grounded)

Focal Spot : 0.5 mm

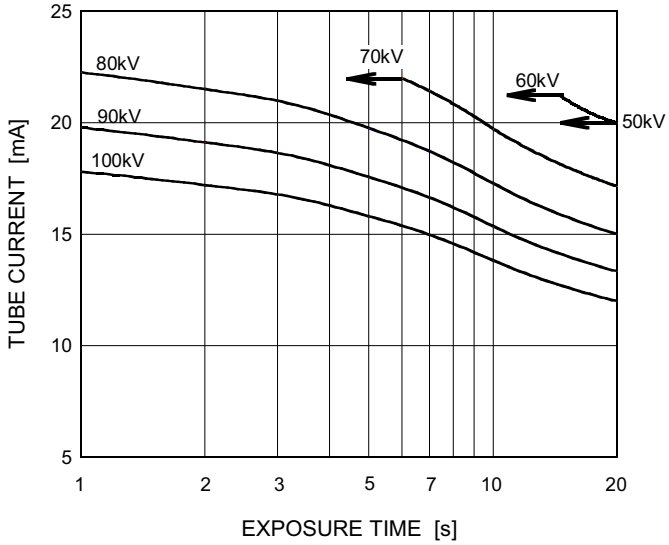
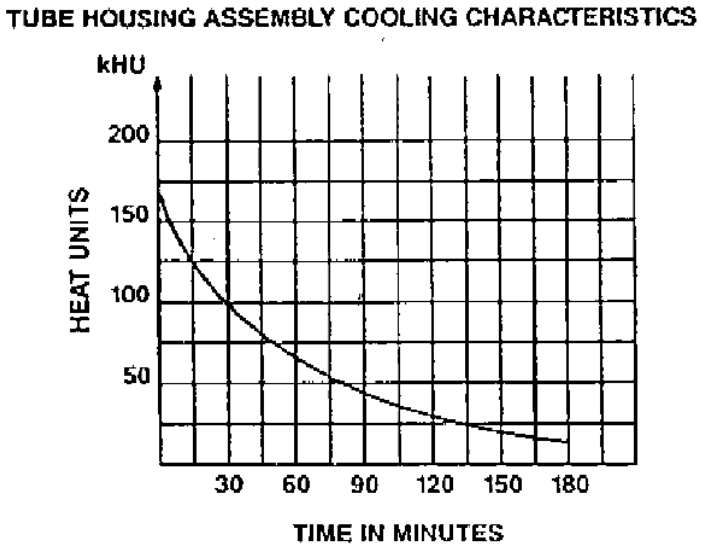


Figure 1.6



9.7 Scatter radiation measurement

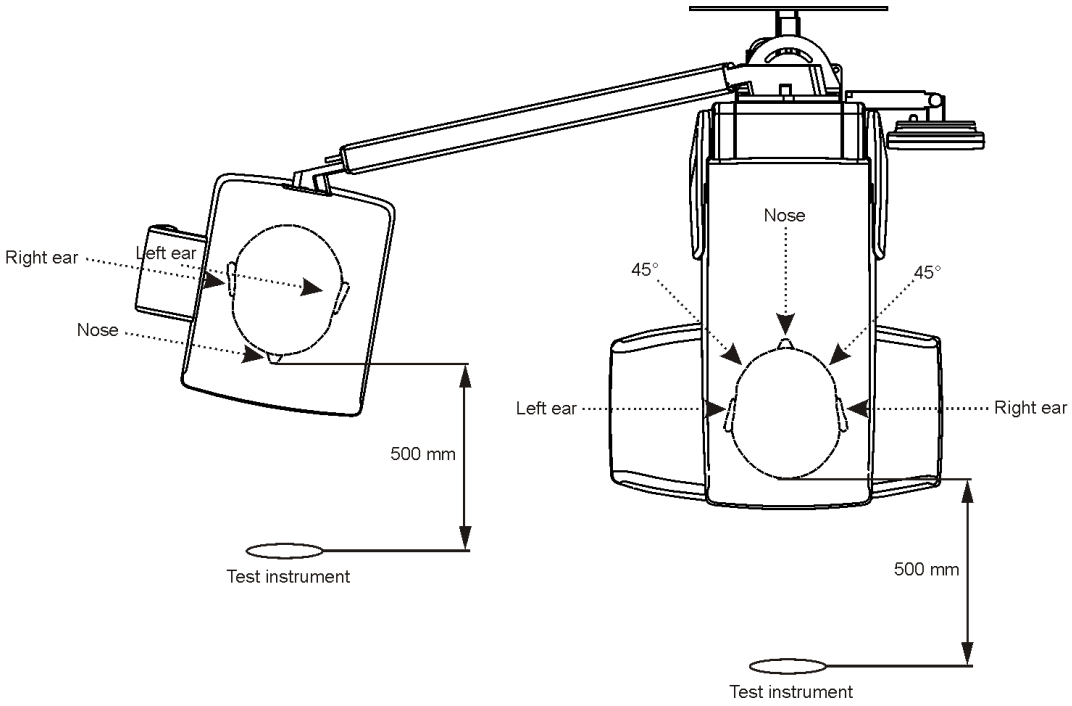
The scatter radiation was measured around the anthropomorphic skull phantom with the test instrument. Measurements were performed with both adult panoramic program and cephalometric, full lateral program. The height of the test instrument was altered to define the maximum scatter radiation direction.

The measurements in panoramic program were performed in panoramic-PIO position with the movement of the rotating unit. Exposure values were 90kV, 13mA and 16 sec. Reference measurement was measured first just in front of the skull to define the radiation level which is hitting the skull.

The measurements in cone beam programs were performed in CT-PIO position with the movement of rotation unit using hi-resolution option (maximum exposure time). Exposure values were 90kV, 13mA and 6.1 sec with small FOV and 90kV, 10mA and 13 sec with large FOV.

The measurements in cephalometric program were performed in ceph-PIO position with the movement of the ceph head. Exposure values were 90kV, 13mA and 10 sec. Reference measurement was measured first just in front of the skull to define the radiation hitting the skull.

The image shows the set-up of the tests and the arrows indicate the radiation direction.



9.7.1 Scatter radiation in panoramic program

The radiation hitting the skull is 481.8mR with values 90kV, 13mA,16sec.

Test instrument is positioned at 50 cm distance from the skull to measure the scattered radiation.

The following table shows the scatter radiation levels measured with the test instrument

Height	**Left ear**	**45deg**	**Nose**	**45deg**	Right ear
central beam	0.187mR	0.246mR	0.417mR	0.335mR	0.227mR
15cm up from central beam	0.158mR	0.134mR	0.161mR	0.144mR	0.158mR
15cm down from central beam	0.171mR	0.202mR	0.275mR	0.248mR	0.204mR

9.7.2 Scatter in cone beam programs

Test instrument was placed at 50 cm distance from the skull to measure the scattered radiation.

See the following illustration of the measured radiation levels.

Small FOV:

Height	**L-ear**	**45deg**	**Nose Skull**	**45deg**	R-ear
central beam	0.598mR	0.414mR	0.382mR	0.531mR	0.543
15cm up from central beam	0.531mR	0.406mR	0.241mR	0.409mR	0.462
15cm down from central beam	0.531mR	0.577mR	0.448mR	0.713mR	1.083

Large FOV:

Height	**L-ear**	**45deg**	**Nose Skull**	**45deg**	**R-ear**
central beam	0.826mR	0.661mR	0.603mR	0.735mR	0.861
15cm up from central beam	0.878mR	0.662mR	0.490mR	0.747mR	0.911
15cm down from central beam	1.285mR	0.944mR	0.800mR	1.019mR	1.380

9.7.3 Scatter radiation in ceph program

Ceph head was in ceph-PIO position (beam hitting the secondary collimator, ear posts and CCD-sensor). Radiation at technique factors 90kV, 13mA, 10sec was measured just below the ear ports (equivalent to radiation hitting the skull) to be 36mR.

Scatter radiation was measured during the scanning of the ceph head. Full lateral ceph images were taken with 90kV, 13mA, 10sec scanning/exposure time and scatter radiation was measured at 50 cm distance from the head.

The following table shows the scatter radiation levels measured with the test instrument

Height	Right ear	Nose	Left ear
central beam	0.025mR	0.034mR	0.066mR
15cm up from central beam	0.021mR	0.022mR	0.059mR
15cm down from central beam	0.038mR	0.029mR	0.081mR

10 PC requirements

10.1 Minimum PC requirements

Minimum PC requirements for 3D acquisition workstation	
Processor	2.5 GHz dual core, or better
Memory	8 Gigabytes RAM, or more
Hard disk	500 GB, or more
Power supply	500 watt minimum
Network	Gigabit Ethernet 1000Base-T
Operating system	Windows 7, Windows 8 / 8.1 or Windows 10 (64-bit)
Display	20" LCD display, 1600 x 1200 or 22" LCD wide-screen display, 1680 x 1050, or better
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Graphics board	The system is highly dependent on the used graphics board and graphics driver of the reconstruction workstation. Consult technical support for information on the supported boards and drivers. Examples of supported boards: NVidia Quadro 4000 NVidia GeForce GTX 660 The compatible graphics driver versions are found on the driver update DVD. 2 GB dedicated display memory is required.
PCI board connection	Full-length PCIe x16 slot (for GPU board)
USB	USB ports (for HASP Dongle keys) • 1 for reconstruction system • 1 for 3D viewing SW (if needed)
Mouse	Mouse with scroll wheel

Minimum PC requirements for 2D acquisition workstation	
Processor	2.5 GHz dual core, or better
Memory	3 Gigabytes RAM, or more
Hard disk	500 GB, or more
Graphics board	NVidia GeForce 6600 or ATI Radeon X700 or better; 256MB or more memory (integrated graphics are not supported)
Power supply	500 watt minimum
Network	Gigabit Ethernet 1000Base-T
Operating system	Windows 7, Windows 8 / 8.1 or Windows 10
Display	20" LCD display, 1600 x 1200 or 22" LCD wide screen display, 1680 x 1050, or better
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Mouse	Mouse with scroll wheel
OpenCL support	OpenCL 1.1 supported by either processor or graphics adapter

NOTICE! *This is an abbreviated list of requirements. Please refer to the software installation manual or contact your local dealer for detailed installation requirements.*

Minimum PC requirements for 2D/3D Viewing workstation *	
Processor	2.0 GHz dual core, or better
Memory	3 Gigabytes RAM, or more
Graphics board	1GB or more memory (integrated graphics are not supported)
Hard disk	3 GB free space, or more
Network	Gigabit Ethernet 1000Base-T (recommended) or Fast Ethernet 100Base-TX
Operating system	Windows 7, Windows 8 / 8.1 or Windows 10
Display	19" LCD display, 1280 x 1024, or better

* For the PC requirements of the 3D viewing software consult the 3D software manuals.

System requirements and connections

- The PC and any other external device(s) connected to the system must meet the IEC 60950 standard (minimum requirements). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.
- The PC and any other external devices must be connected in accordance with IEC 60601-1-1.
- The x-ray unit must be connected to it’s own separate power supply. The PC and any other external devices must NOT be connected to the same power supply as the x-ray unit.
- The unit shall be connected directly to the acquisition PC with an Ethernet cable. Connection through the LAN-network of the site is not allowed. Two network ports are needed in the PC in order to connect also to the site network.
- Position the PC and any other external device at least 1.5 m (60”) from the x-ray unit so that the patient cannot touch the PC or any other external device while being x-rayed.
- The PC and any other external devices shall not be connected to an extension cable.
- Multiple extension cables shall not be used.
- Do not position the PC where it could be splashed

with liquids.

- Clean the PC in accordance with the manufacturer's instructions.
- The PC to be used with the unit must be installed in a location that meets all local and national safety requirements with regards the connection of a PC to an x-ray device.
- The connection of the unit to the PC must meet IEC 60601-1 requirements.
- Connecting the unit to an IT-network that includes other equipment or changing the IT-network can cause unidentified risks to patients or operators. It is the responsibility of the organization controlling the IT-network to identify, analyse, evaluate and control these possible risks.

■ The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Consideration relating to the choice shall include:

- Use of the accessory in the PATIENT VICINITY.
- The safety certification of the accessory has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.

10.2 The dental imaging software

The dental imaging software installed in the PC that is used with the unit must have CE-mark according to Medical Device Directive.