



Digital Panoramic X-ray System

REF DP700IM

206757 rev 3

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1 Introduction

1.1 General

GXDP-700TM x-ray unit (hereafter called “the unit”) is a software controlled diagnostic dental X-ray equipment for producing high quality digital images of dentition, TM-joints and skull. In order to take images with the unit you need a suitable PC hardware connected to the unit and the imaging software to handle images.

1.2 Intended use

The unit must only be used and operated by dentist and other qualified professionals. The unit must only be used to take panoramic, cephalometric and 3D images of the dento-maxillofacial complex of the human skull. It must not be used to take images of any other part of the human body.

USA only

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

1.3 About this manual

This manual describes how to set up the unit. Please read this installation manual before installing the unit.

CAUTION! *It is important to read the warnings and precautions, listed in section 1.6, before installing the unit. It is also important to observe these warnings and precautions whenever the unit is used.*

1.4 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

1.5 Associated documents

The installation manual for the dental imaging software you are using.

The installation instructions supplied with the 3D imaging software you are using.

1.6 Warnings and precautions

To be observed during installation

- When installing a dental X-ray unit always observe local and national safety, radiation control and electrical regulations.
- There should be enough space around the installation place of the unit.
- 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.
- The unit or its parts must not be changed or modified in any way without approval and instructions from Gendex Dental Systems.
- When servicing use only approved replacement parts supplied by Gendex Dental Systems.
- Mains selection should be correct and site environment. No explosive vapors.
- Be aware of hot surfaces and sharp edges when removing covers during installation and maintenance.
- The Ethernet cable shall be unshielded CAT6, so that multiple chassis are not connected. To maintain patient safety it is mandatory to use an unshielded CAT6 Ethernet cable between the unit and the network or workstation. Non-medical grade PC should not be used in patient environment.

-
- If this device will be used with 3rd party imaging application software not supplied by Gendex Dental Systems, 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 Gendex Dental Systems.
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.
 - The aperture plate and tubehead housing are made of lead (Pb), which is a toxic material. Do not touch these parts with your bare hands.
 - The unit must be installed and serviced according to the unit installation & Adjustments manual by a qualified and trained technician.
 - This product itself complies 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.
 - All service operations are performed by Gendex Dental Systems authorized service personnel.

To be observed during use

- There should be free space around the unit for safe operation.
- 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 exposure 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.
- 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.
- 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.
- 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.
- 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 also be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray 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.
- It is the responsibility of the doctor to decide if the x-ray exposure is necessary.
- The minimum height of patient that can be x-rayed is 113 cm (3.7ft / 44.5in) and the maximum is 200 cm (6.5ft /78in). These heights only apply to patients with normal anatomy.

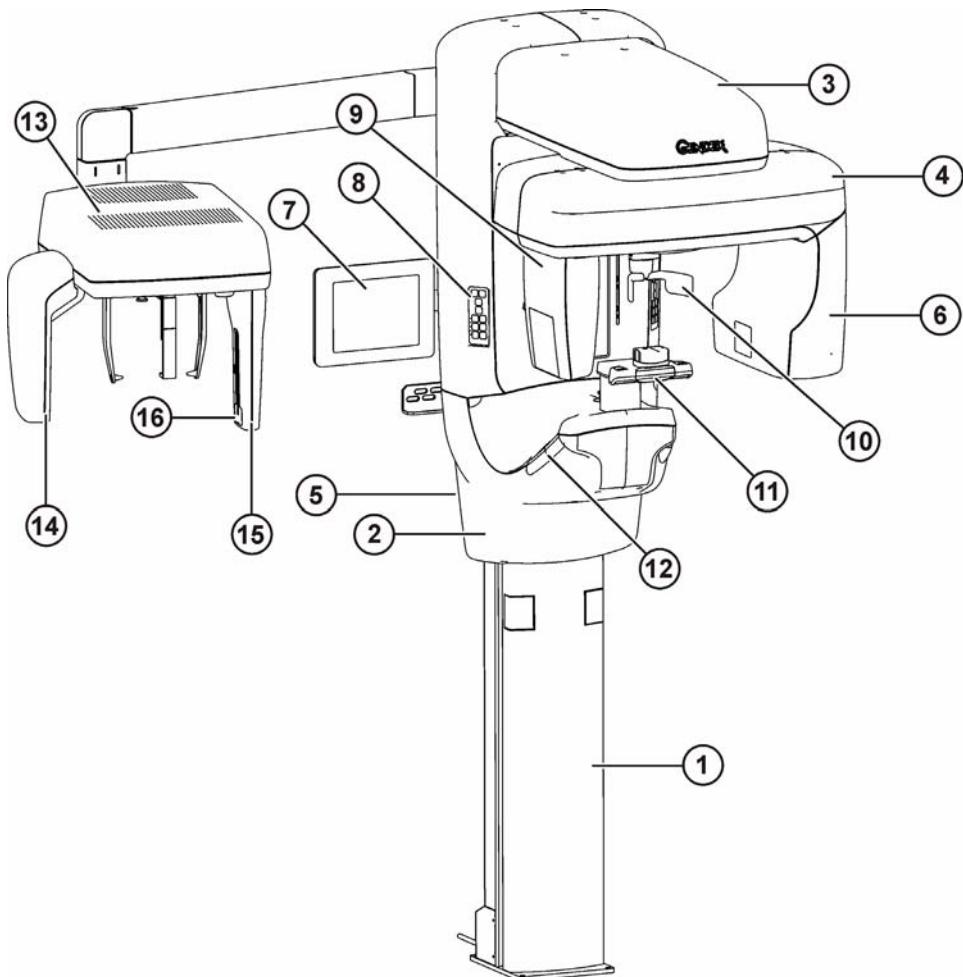
-
- When taking an x-ray exposure of a patient with exceptional anatomy (typically very tall or large) use the test program (no x-rays) first to make sure that patient can be positioned correctly in the unit.
 - Always use the lowest suitable x-ray dose to obtain the desired level of image quality.
 - 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.
 - Always use available disposable protective covers with the patient positioning accessories:
 - Bite block disposable cover
 - Chin support disposable cover
 - Temple support disposable cover
 - Ear plug cover
 - Disinfect all the surfaces that the patient is in contact with after every patient.
 - Disinfect all device accessories that contact the patient during a radiographic examination.
 - Danger: Explosion hazard - do not use in the presence of flammable anesthetics.

General warnings

- There should be enough space around the installation place of the unit.
- 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.
- The unit or its parts must not be changed or modified in any way without approval and instructions from Gendex Dental Systems.
- When servicing use only approved replacement parts supplied by Gendex Dental Systems.

- The Ethernet cable shall be unshielded CAT6, so that multiple chassis are not connected.
- If this device is used with 3rd party imaging application software not supplied by Gendex Dental Systems, 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.
- 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.
- Do not connect any equipment to the unit that has not been supplied with the unit or that is not recommended by Gendex Dental Systems.
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.
- The aperture plate and tubehead housing are made of lead (Pb), which is a toxic material. Do not touch these parts with your bare hands.
- The unit must be installed and serviced according to the unit Installation & adjustments manual by a qualified technician.
- This product itself complies with IEC 60601-1 medical safety standard, but in order for the system incorporating a PC to comply with 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 with IEC 60601-1 standard and that is indicated in the accompanying documents of the PC.
See chapter 5.6, Computer Specifications, Minimum PC Requirements.

1.7 Main parts and controls



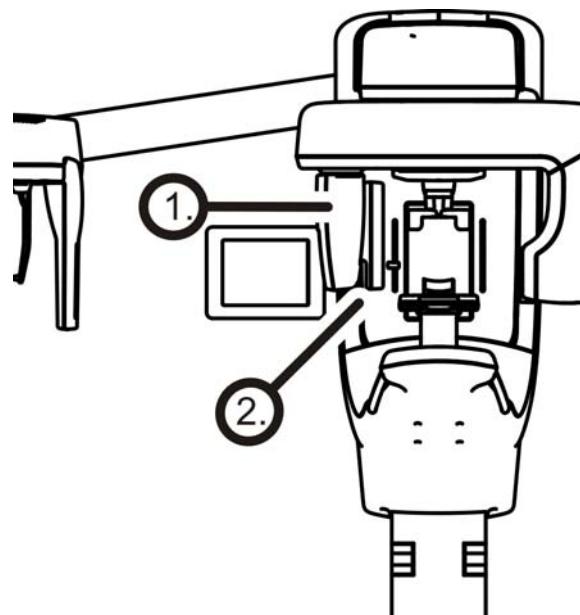
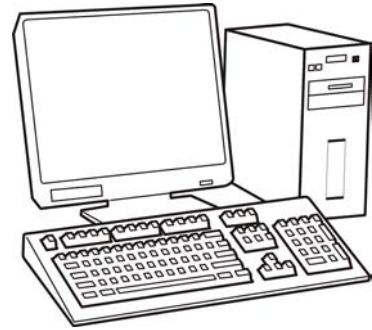
- 1.** Column
- 2.** Carriage
- 3.** Main support
- 4.** Rotating unit
- 5.** On / off switch (rear of column) and main fuses
- 6.** Tubehead assembly
- 7.** Touch screen display
- 8.** Positioning panel
- 9.** Sensor head
- 10.** Head support
- 11.** Chin rest
- 12.** Handles
- 13.** Ceph unit
- 14.** Ceph sensor
- 15.** Secondary collimator
- 16.** Positioning panel

On / off switch and
main fuses



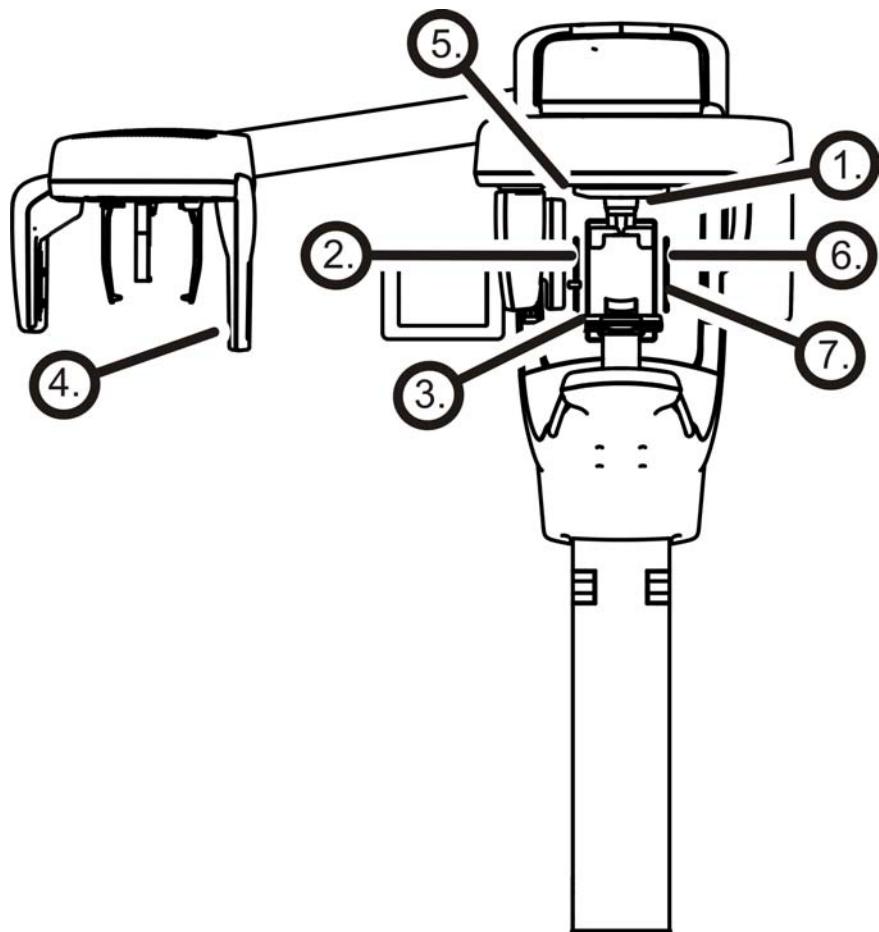
PC with MDD approved
dental imaging software and
3D viewing software.

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



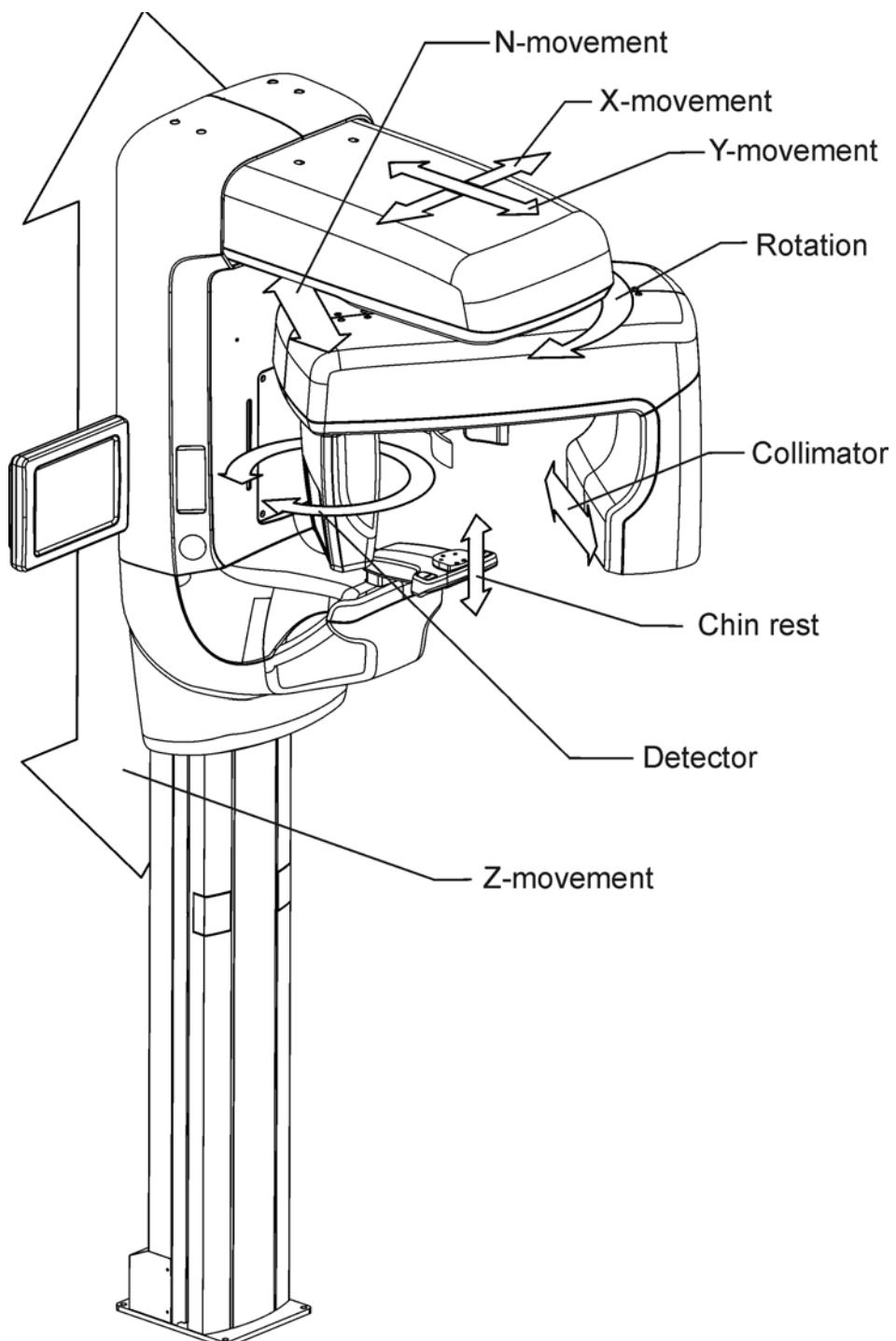
- 1.** Sensor holder (units without 3D option)
- 2.** Panoramic sensor

1.8 Patient positioning lasers



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

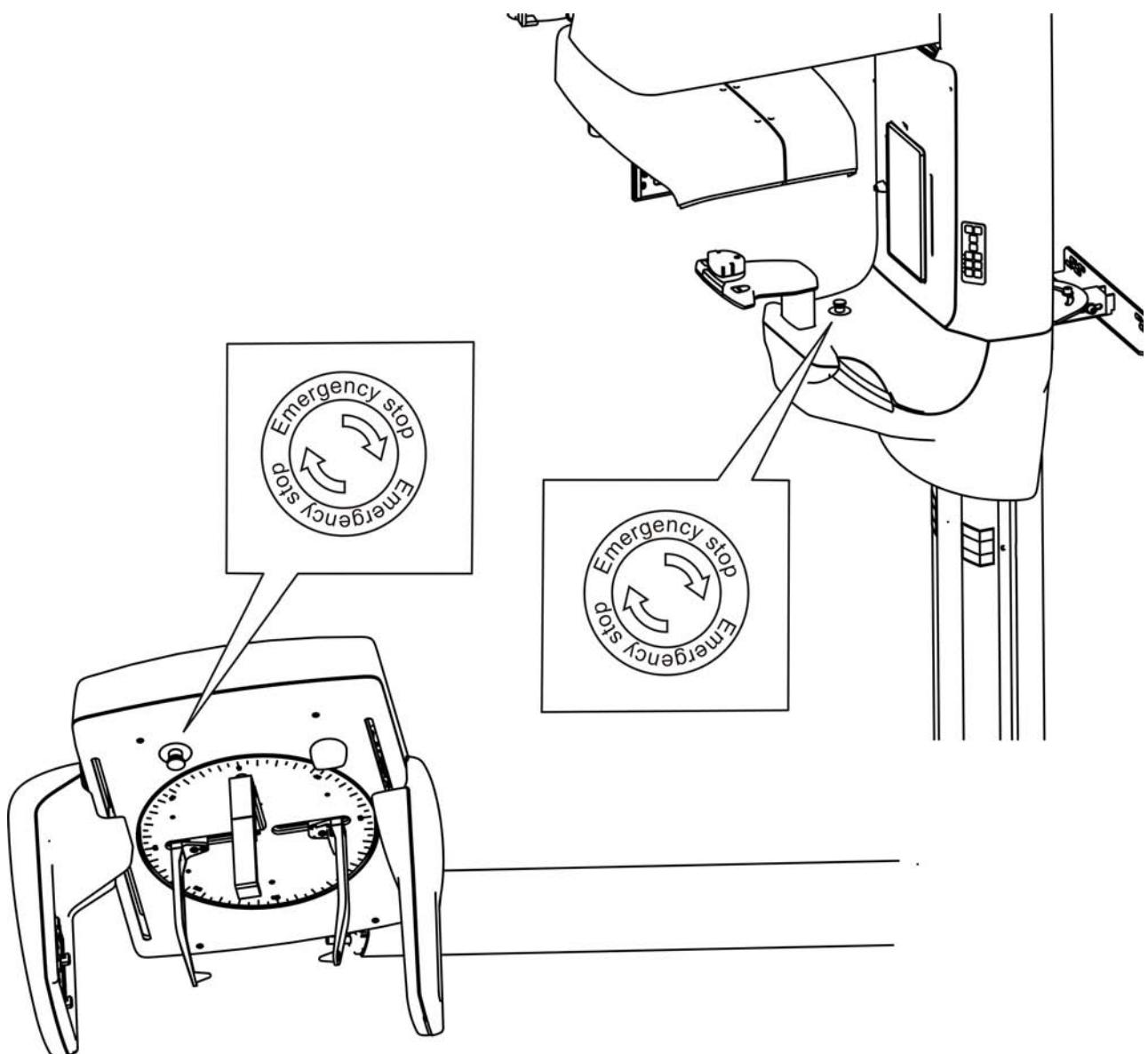
1.9 Unit movements



1.10 Emergency stop switch

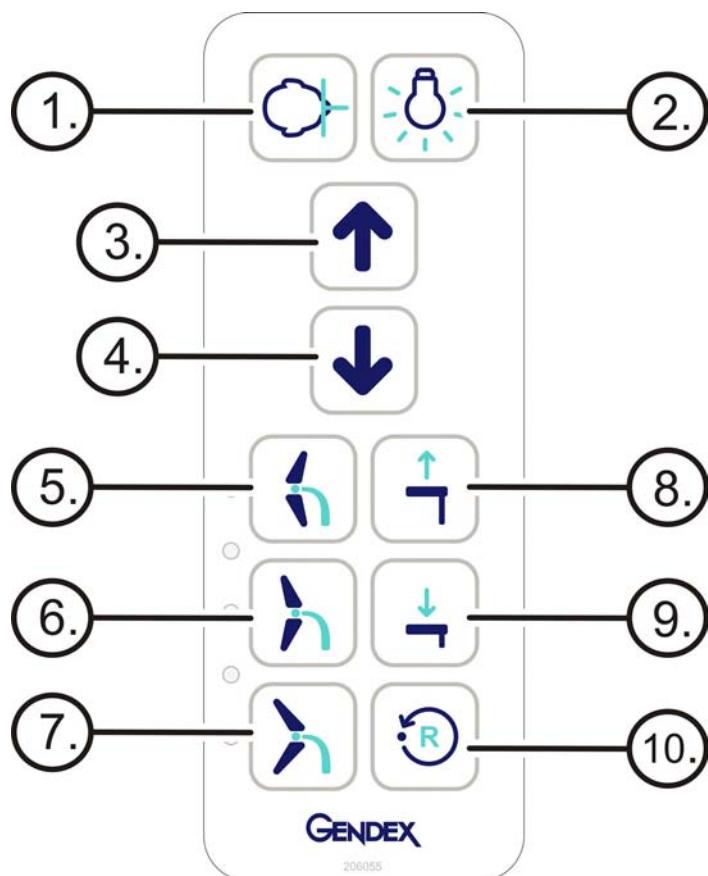
In case of malfunction of the exposure button or other protective devices of the unit, an emergency stop switch is provided near the handles and on the roof of the cephalostat head so that the patient can reach it.

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.

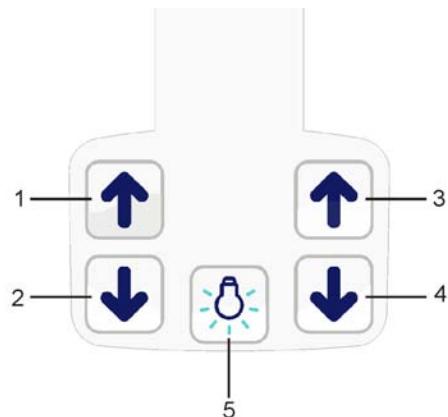


Press to stop the unit, rotate to release.

1.11 Patient positioning panel



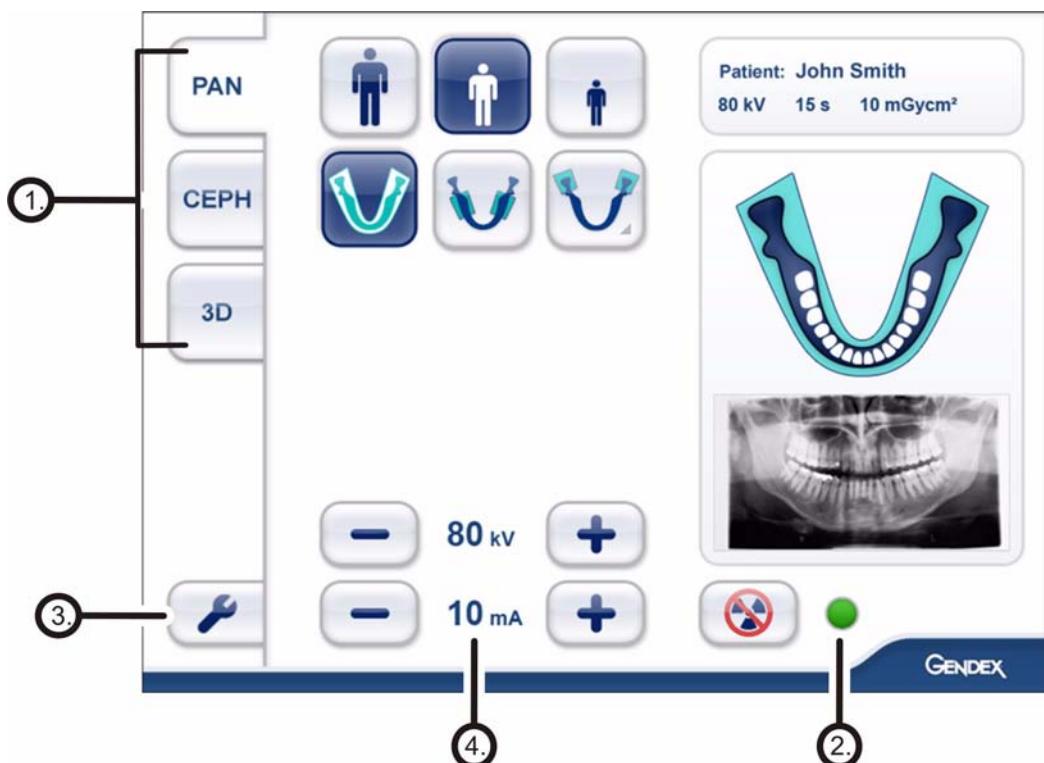
Cephalometric unit



- 1.** Carriage up
- 2.** Carriage down
- 3.** Carriage up
- 4.** Carriage down
- 5.** Positioning lasers ON/OFF

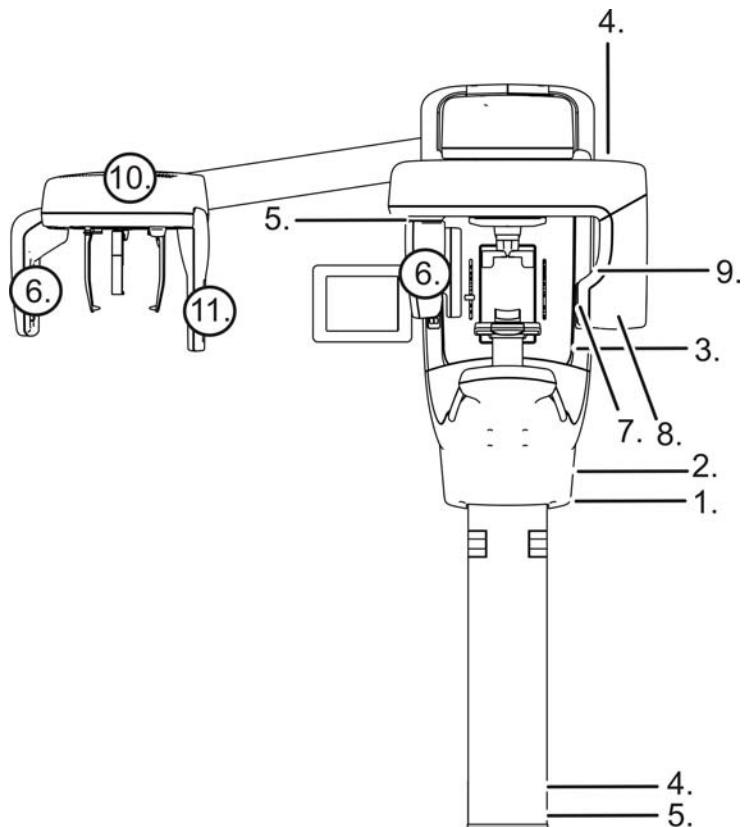
1.12 Main control panel

Touch screen display



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

1.13 Unit identification labels



- 1.** Main label
- 2.** 10A & 15A Fuse label (next to the fuse holders)
- 3.** Laser class 1 warning label IEC 60825-1:2007 (in the accessory box)
- 4.** Ethernet and remote exposure button label
- 5.** Warning label for line voltage connection (on the power cord)
- 6.** Sensors (on the sensor)
- 7.** (Primary) collimator label (on the collimator and on the tubehead cover)
- 8.** Tubehead label (on the tubehead and on the tubehead cover)
- 9.** Warning label for deadly voltages (inside the tubehead cover)
- 10.** Cephalostat (outside on the cover)
- 11.** Secondary collimator (on the secondary collimator and on the collimator cover)

2 Pre-installation requirements

2.1 The unit

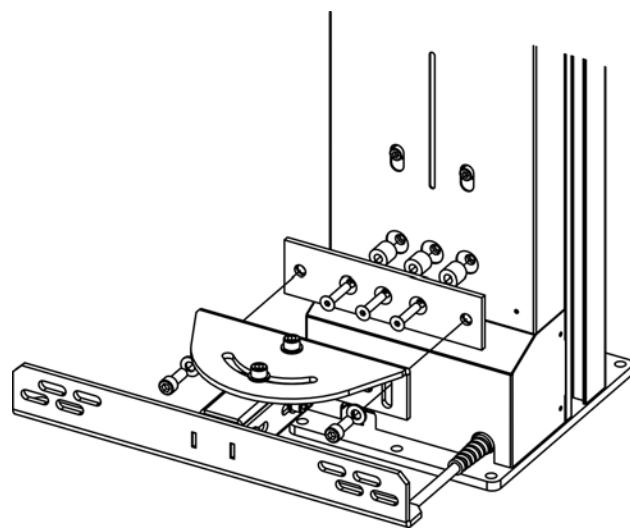
- See chapter 5, The unit Pre-sales check list.
- The unit is supplied:

The unit Packages	COLUMN (card board)	MAIN SUPPORT AND ROTATION UNIT (card board)	CEPH (card board)
Size (LxWxH) cm:	230 x 33 x 42 cm	100 x 100 x 70 cm	120 x 70 x 71 cm
Gross weight approx.:	105 kg/232 lbs	106 kg/234 lbs	51 kg/112 lbs
Net weight approx.:	87 kg/192 lbs	83 kg/183 lbs	25 kg/55 lbs

- Unit weights:

PAN	CEPH	3D
210 kg (463 lb.)	245 kg (540 lb.)	212 kg (467 lb.)

- Make sure that the floor where the unit is to be installed can support this weight. To avoid the unit from tipping over, fix the unit with floor bolts appropriate to the surface the unit is mounted on. The bolts and the floor material must endure force of 5000 N on the base plate.
- The unit must be permanently attached to the wall and the floor. If floor attachment is not possible, use additional wall support (ordered separately). Wall mount screws should be tightened.



Additional wall support

- Make sure that the fixing hardware and wall can withstand pull-out strengths of at least 5000 N.

NOTE! *Mounting bolts for floor and wall fastening are not included in the delivery. The fixing hardware used to permanently attach the unit to the wall must be correct type for the wall and wall material.*

- Wall material should be suitable for fixing the unit. If the wall is made of weak material, you may have to use a reinforcing plate on the rear side of the wall to hold the fixing hardware.
- The place where the unit is to be installed and the position from where the user takes exposures must be correctly shielded from the radiation that is generated when the unit is operated. Follow the local radiation and safety requirements.
- Do not install the unit in environments where there are corrosive or explosive vapours.
- Special steps regarding EMC need to be taken when installing the unit. For more information refer to the EMC declaration in user's manual.
- The unit must be installed at least 1.85m (73 in) away from any non-medical electrical or electromechanical equipment.
- Mains extension cables MUST NOT be used with the unit.
* Maximum allowed mains line impedance is 0.2ohms.

2.2 The PC

Minimum PC requirements:	
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Processor	2.0 GHz Core i5 or i7 CPU or equivalent processor
Main memory (RAM)	3 Gigabytes RAM
Hard disk	500 GB HDD or larger
Network adapter	2x 1Gb Ethernet network interface
Graphics card	Type examples: GTX 460 Nvidia GPU, FX 3800 Nvidia Quadro or Nvidia Quadro 4000 (Supplied by Instrumentarium if workstation not ordered, model is updated regularly, model might change)
PCI board connection	One available full length and double width PCI Express x16 slot for a GPU card
USB	USB ports (for HASP Dongle keys) <ul style="list-style-type: none"> • 1 for reconstruction system (Dongle supplied with Mercury GPU Kit) • 1 for OnDemand3D (Dongle supplied with CD Kit)
Color monitor size	20" 2MP LCD display, 1600 x 1200 (19" 1.3MP LCD 1280 x 1024, minimum)
Power supply	550 watt power supply with two 6-pin power cables (for GPU)
Mouse	Mouse with scroll wheel

2.3 The dental imaging software

The dental imaging software installed in the PC that is used with the unit must be MDD approved.

2.4 Space requirements

When installing the unit make sure that:

- there is enough space at the front and sides of the unit to allow patients to enter and exit the unit easily. Patients in wheelchairs will require more space than standing patients.
- the unit is positioned at least 1.85m (73 in) away from any non-medical electrical or electromechanical equipment.
- the unit is positioned so that the operator, when protected from radiation, can see and hear the patient during an exposure.

Minimum installation space requirements:

Pan/3D:

Minimum installation space

Depth: 1700 mm

Width: 1500 mm

Height: 2410 mm at minimum

(max height adjustable from 2110 to 2410)

Ceph:

Minimum installation space

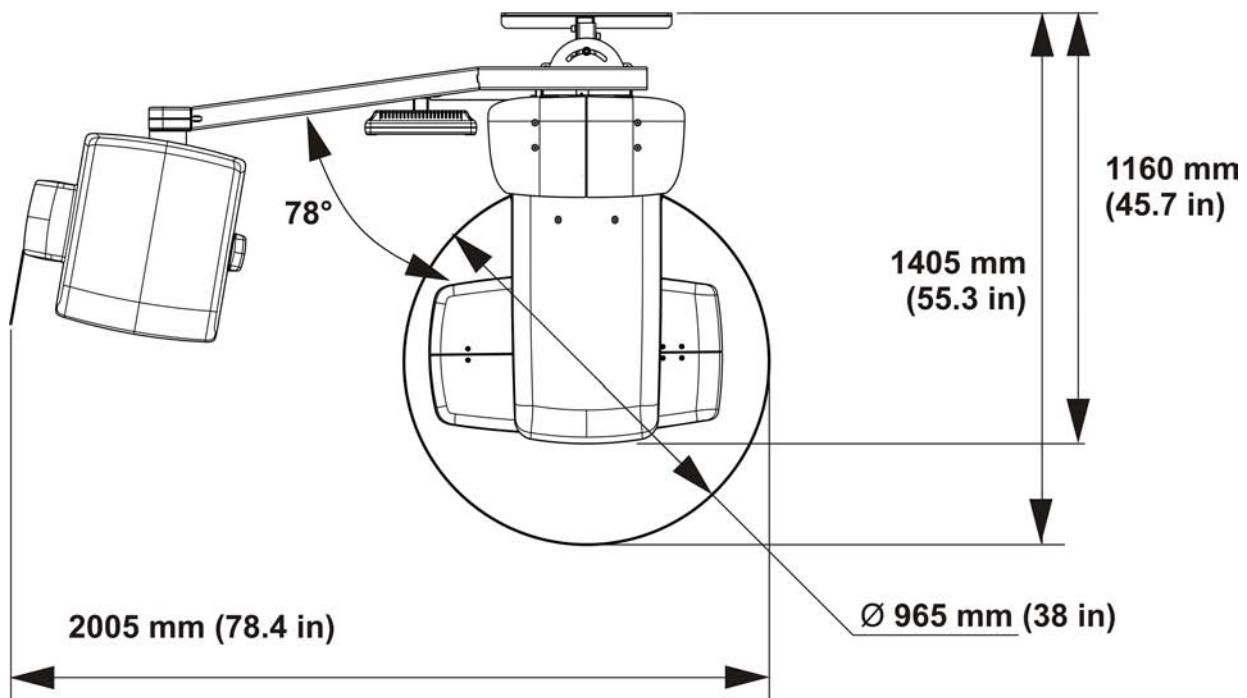
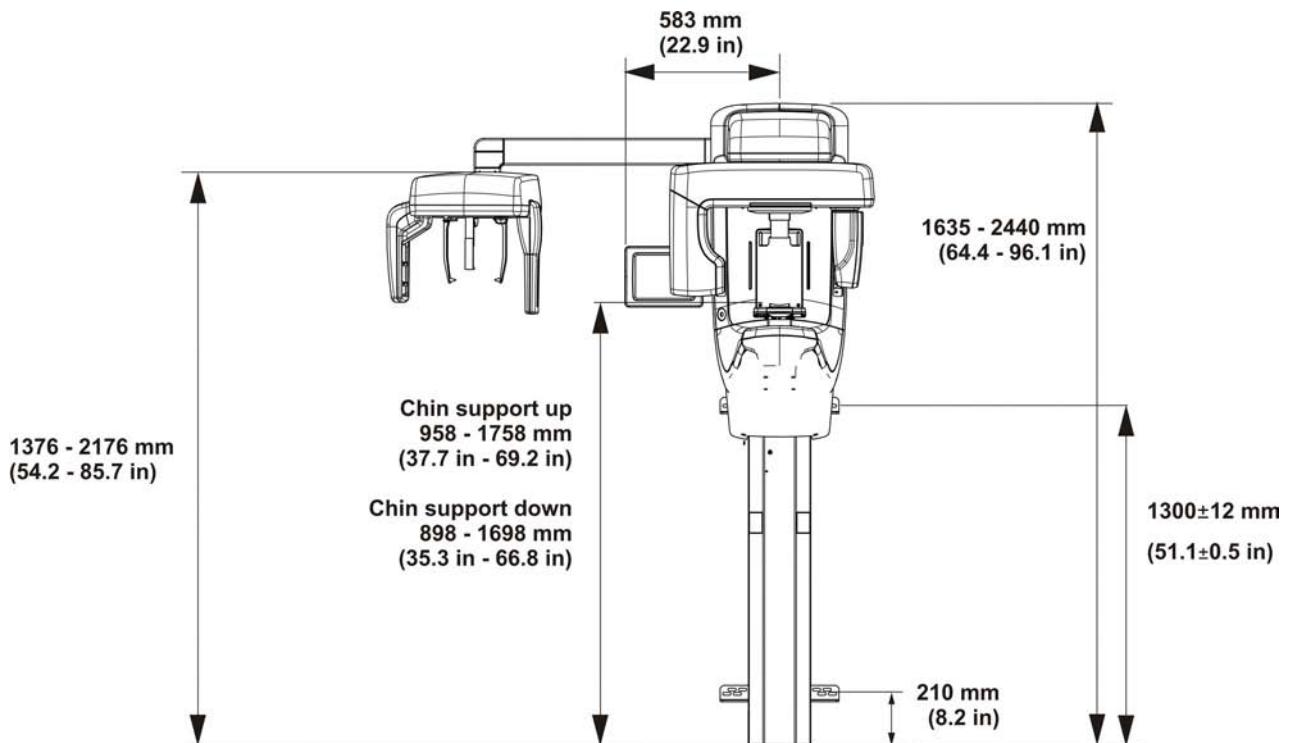
Depth: 1700 mm

Width: 2500 mm

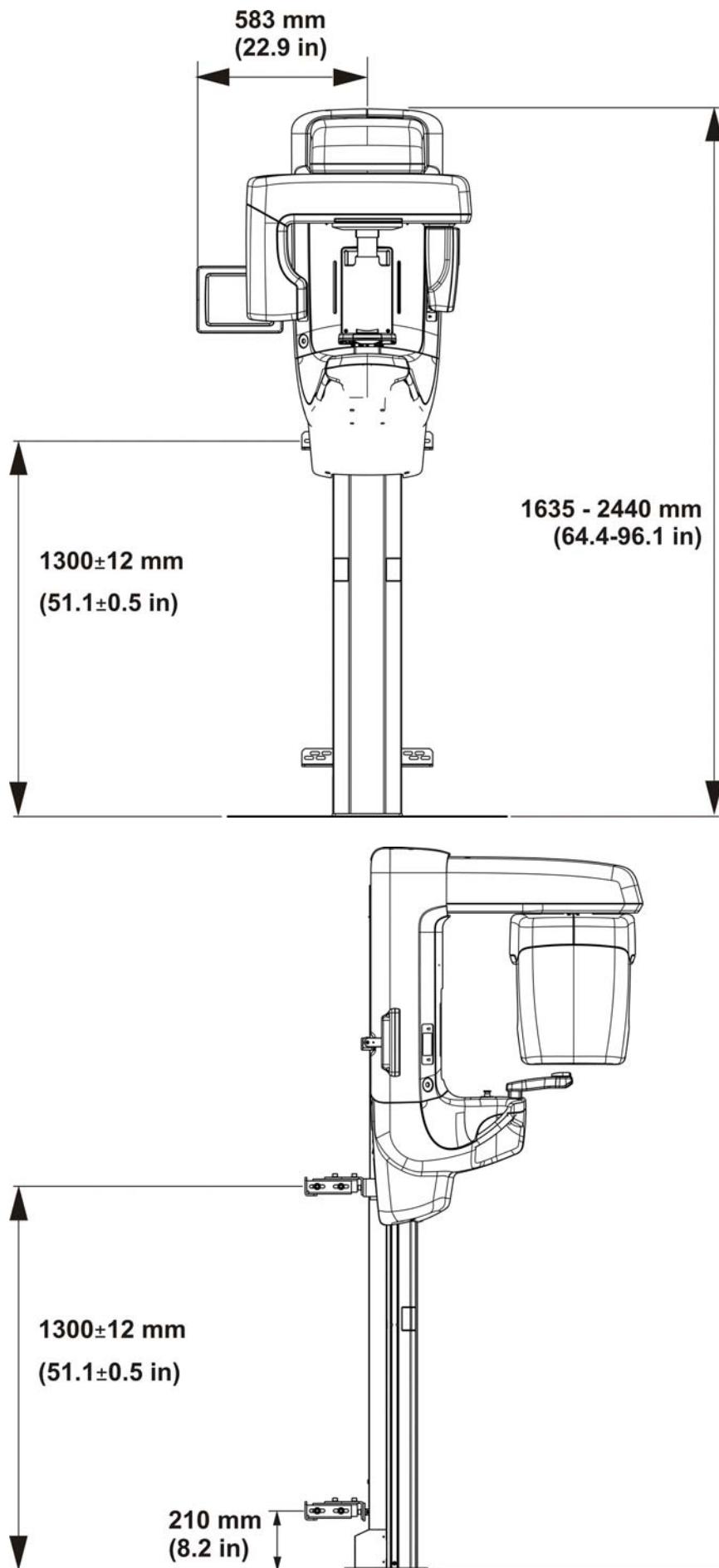
Height: 2410 mm at minimum

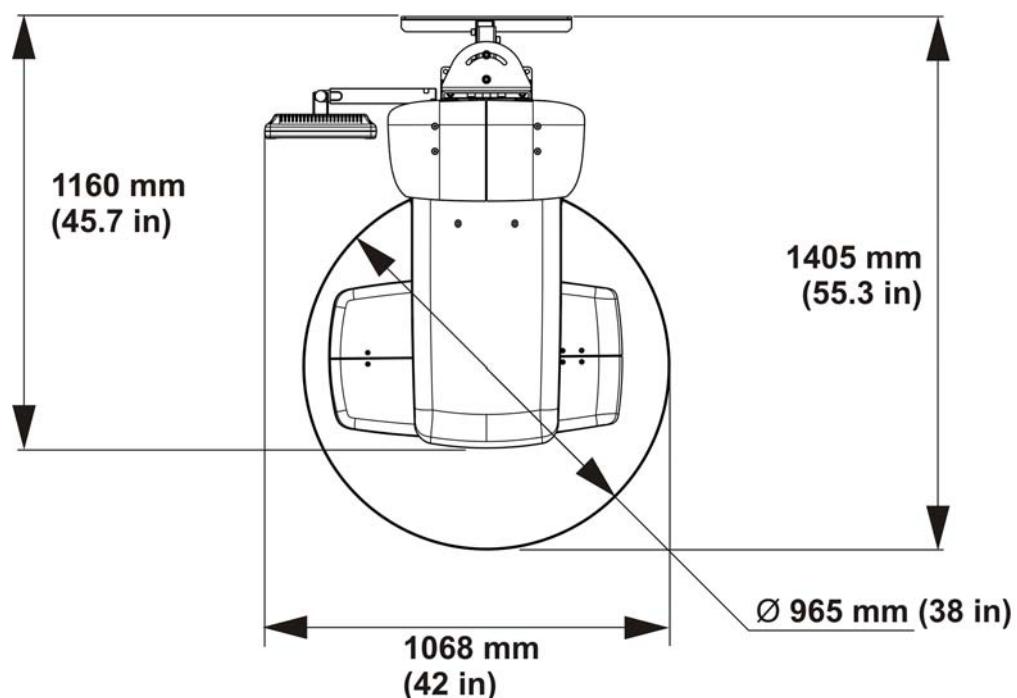
(max height adjustable from 2110 to 2410)

2.5 Unit dimensions



NOTE! The cephalostat arm and the touch screen can be on either side (L/R).





NOTE! The touch screen can be on either side (L/R).

2.6 Fixing hardware and Installation and Setup tools

The following tools and hardware are required to install and set up the unit. These are not included in the delivery of the unit, unless otherwise stated.

Fixing hardware

NOTE! *Mounting bolts for floor and wall fastening are not included in the delivery.*

The type and length of hardware to be used depends on the wall material and floor material to which the unit is to be attached.

Installation tools

- Electric drill
- Spanners (wrenches) 10, 17 (x 2) mm AF
- Allen keys (Hexagon socket wrenches) 1.5-8mm
- Flat blade screwdrivers
- Spirit level
- Pliers and wire cutters
- Scissors/Knife
- Service tools set

Pan calibration and setup tools

- Alignment cone assembly
- Prüfkörper digital test tool for countries where this test is required (optional, not supplied with the unit)

3D calibration and setup tools

- 3D calibration phantom
- QC phantom

3 Installing the unit

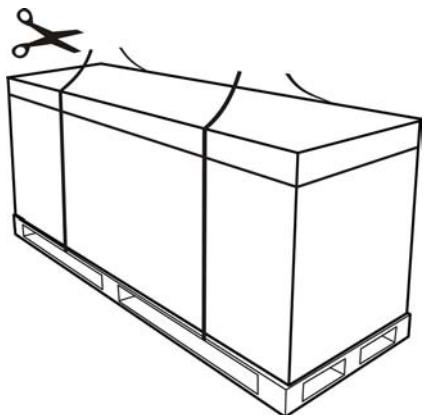
NOTE! Save the packaging materials as they may be needed if you move the unit to a new location.

3.1 Content of delivery

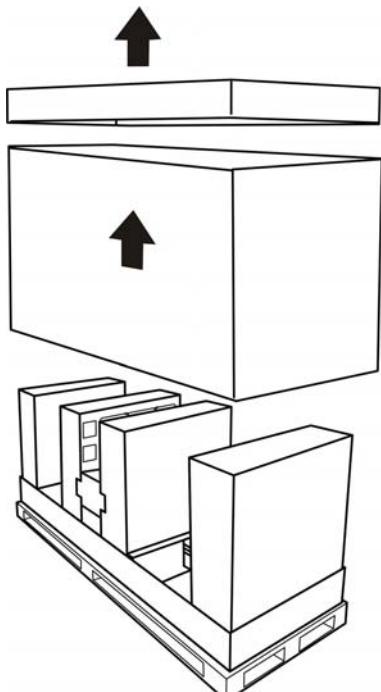
COLUMN (card board)	MAIN SUPPORT AND ROTATION UNIT (card board)	CEPH (card board)
<ul style="list-style-type: none">– Column– Main support top cover– Accessories– Wall bracket	<ul style="list-style-type: none">– Main support– Rotation unit	<ul style="list-style-type: none">– Ceph arm– Ceph head– Ceph sensor– Accessories

3.2 The column

1. Transport the column box (the longest one) to the location where the unit is to be installed.
2. Remove the straps that hold the box to the pallet.



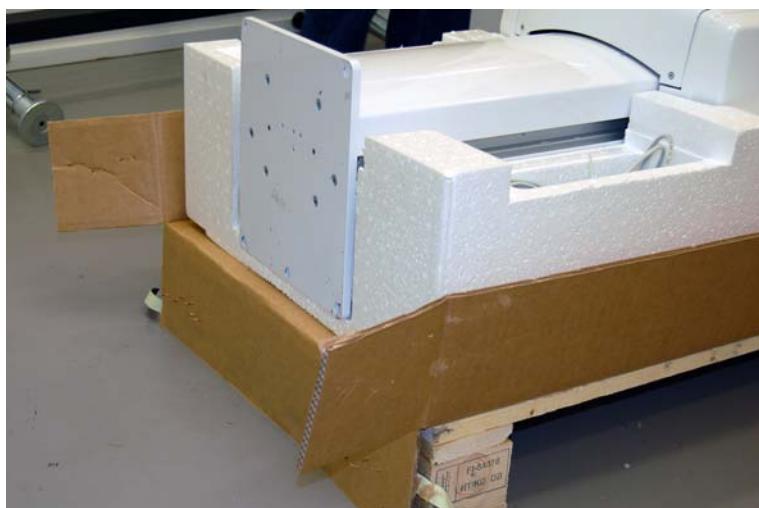
3. Lift off the top of the box and then the sides.



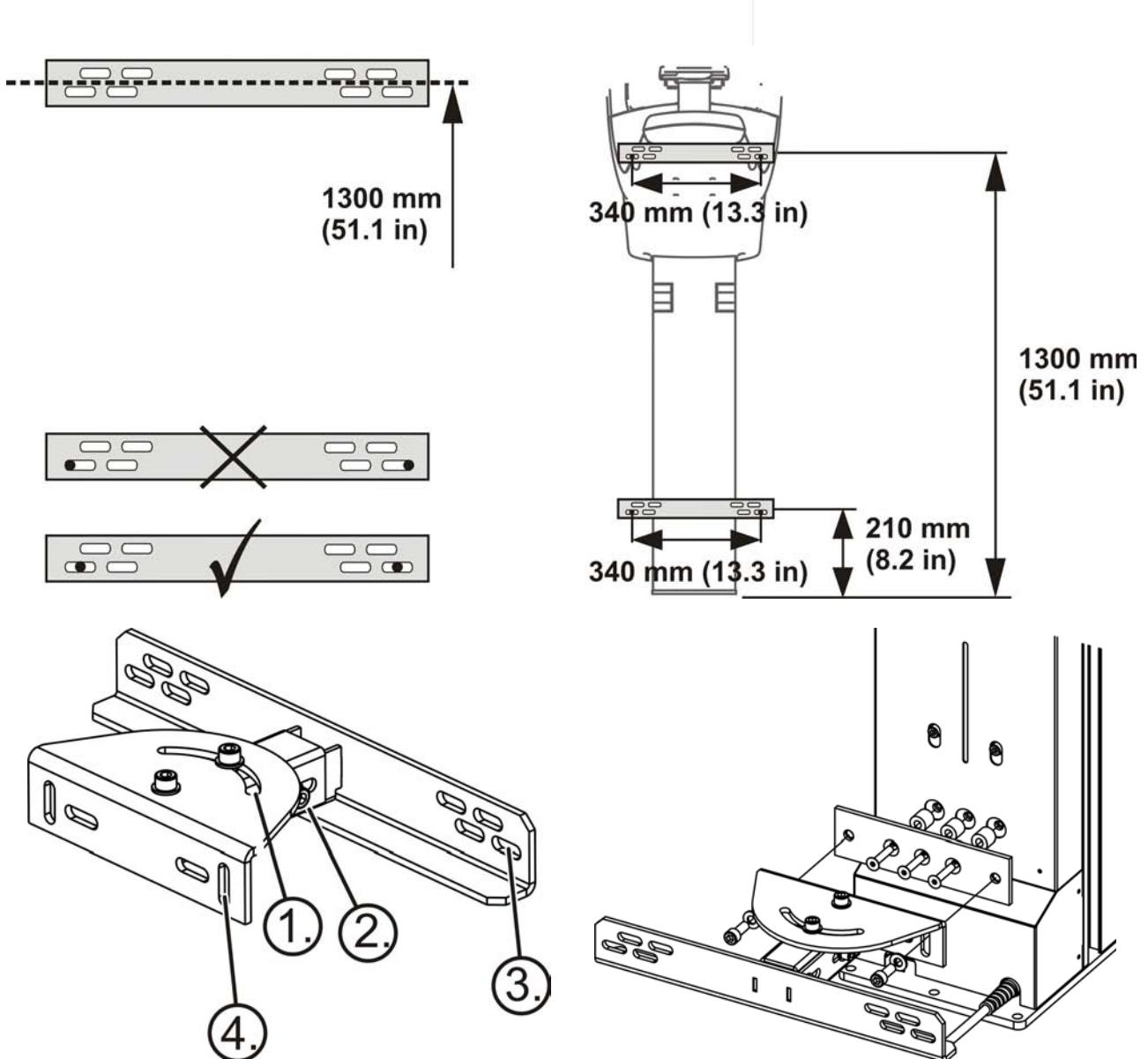
- 4.** Remove plastic wrap.
- 5.** Remove accessory boxes and the main support cover.



- 6.** Fold down the bottom end of the box.
Slide the unit over the edge of the pallet



- 7.** Install the wall bracket(s) to wall. Upper bracket is mandatory, and lower bracket is optional.
Drill holes to wall according to figure below.
Position the wall bracket in the middle of (lateral and lengthwise) adjustments.

**Adjustments:**

- 1) angle
- 2) depth
- 3) lateral
- 4) vertical

Additional wall bracket (lower)

NOTE! Normally unit is installed with one wall bracket (upper) and one base plate, which is bolted to the floor. If the unit cannot be bolted to the floor, additional wall bracket (lower) is required (ordered separately).

8. CAUTION - HEAVY OBJECT 87 KG

A minimum of two persons are required for the following task.

Erect the column by lifting from the top. Move the unit to the place where it is installed and set it beside the wall.

CAUTION! Do not lift the unit from the patient handles!

CAUTION! Always support the unit before it is attached to the wall! The unit will not stay in the upright position unsupported!



9. Remove the styrofoam supports.

10. Install the unit to the upper wall bracket on the wall with screws and washers .

11. Use spirit level and straighten the column tilt by sliding the base plate on the floor.



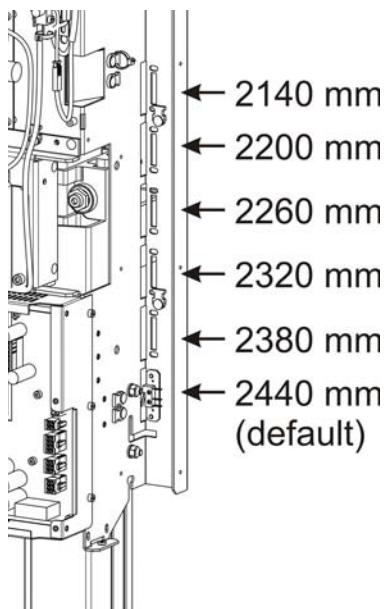
12. Drill the floor and bolt the unit to the floor.

If two wall brackets are used, tighten the lower one to the unit.

13. Remove the plastic wrap from top of the column.

Remove the side covers by removing the screws. Before detaching the side covers, remove the positioning panels attached to them with two bolts and nuts. Hang the panels to the holes at the side plates to prevent them from breaking down.





14. The default maximum height of the unit is 2440 mm. If the room height is less, the column maximum height must be adjusted. The height is adjustable from 2440 mm to 2140 mm by 60 mm steps. Adjust by changing the position of the microswitch.

Step 1. Remove the bottom cover.

Step 2. Remove the front cover.

Step 3. Remove the right hand side cover.

Step 4. Remove the EMC shield.

Step 5. Remove the right hand sheet metal bracket.

Step 6. Open 2 screws of the microswitch and move the microswitch to appropriate position.



Step 1



Step 2



Step 3



Step 4



Step 5



Step 6



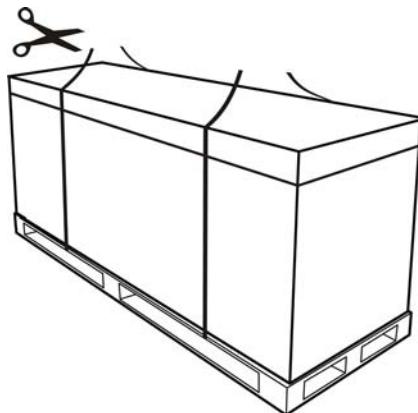
Step 6



Step 6

3.3 The carriage

1. Transport the carriage box to the location where the unit is to be installed.
2. Remove the straps that hold the box to the pallet.



3. Lift off the top of the box and then the sides. Remove plastic wrap.

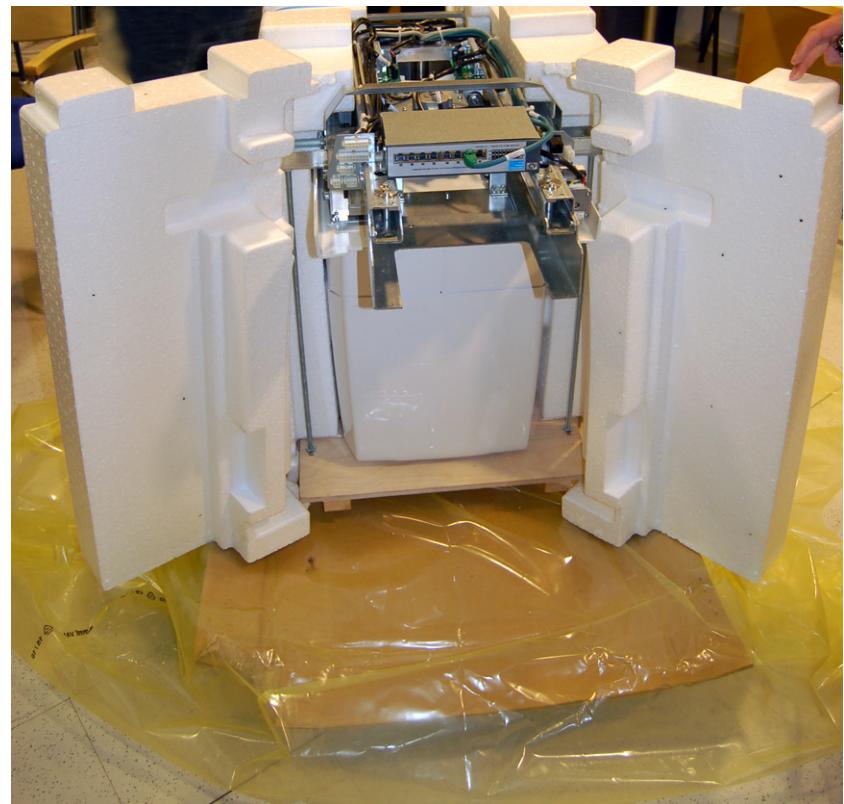
NOTE!

DO NOT cut the strap between the styrofoam supports!



NOTE! DO NOT remove the styrofoam material that protects the main support and the rotating unit.

4. Fold down the edges of the box.
5. Fold the side parts of the styrofoam away, so that the end of the main support, that connects to the column, is fully accessible.



6. **CAUTION - HEAVY OBJECT 83 KG**

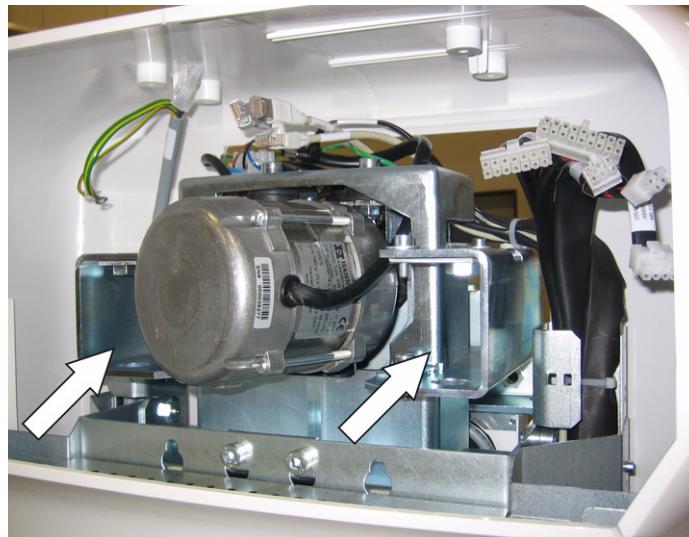
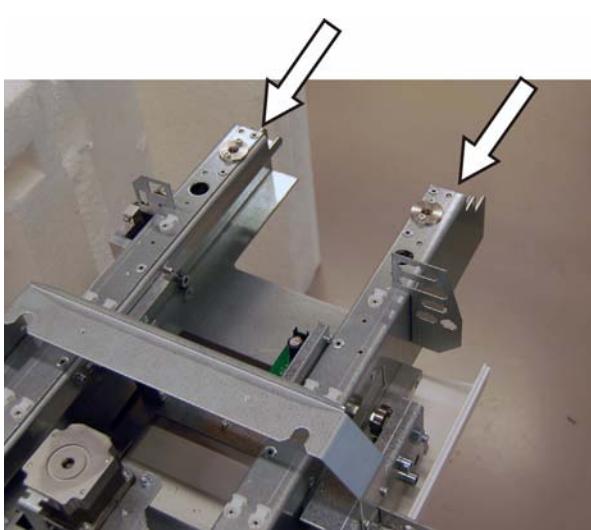
A minimum of two persons are required for the following task.

Lift the carriage and push it towards the column.

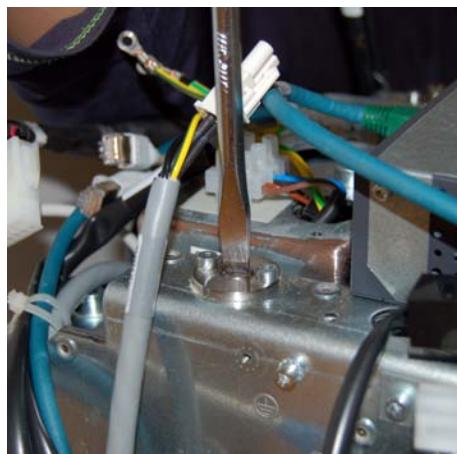
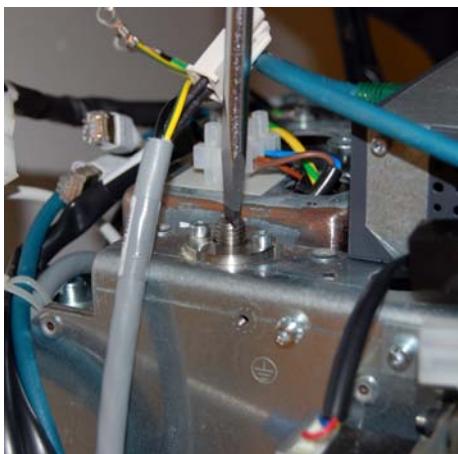
Lifting places pointed.



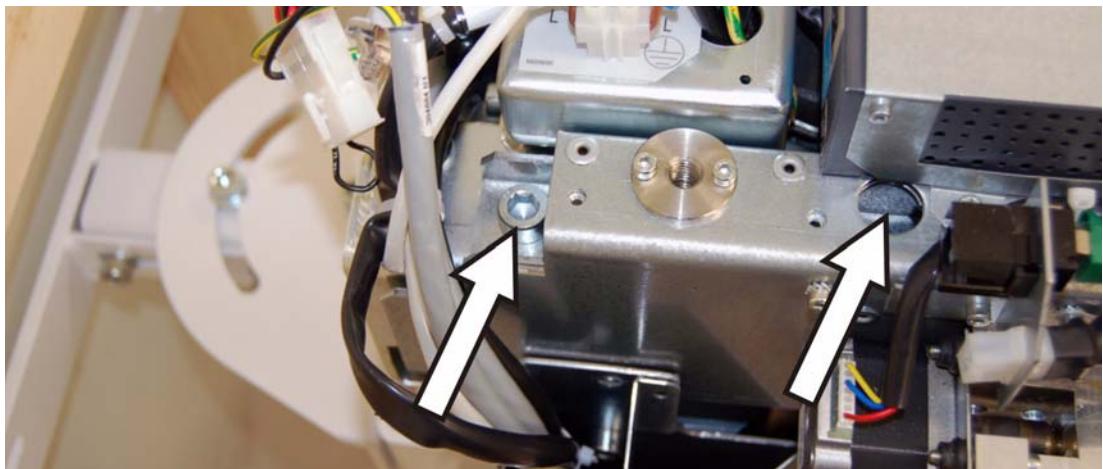
NOTE! Do not put the carriage down on the chin rest or on the patient handles!



7. Fasten the main support to the column counterpart with 2 guide pins without force. The pins align the main support. Pins are in the screw bag.



8. Fasten the main support to the column counterpart with 4 screws (M10 x 20 mm).



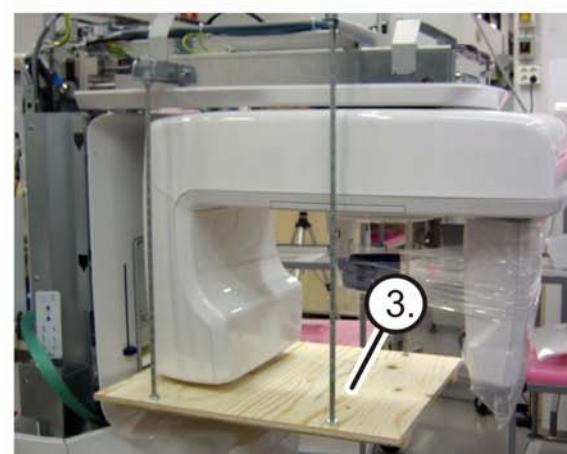
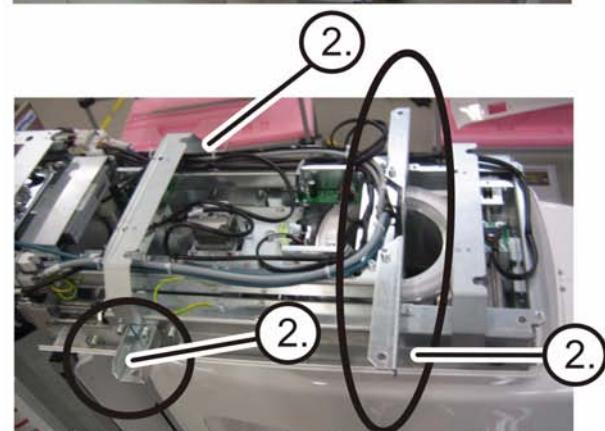
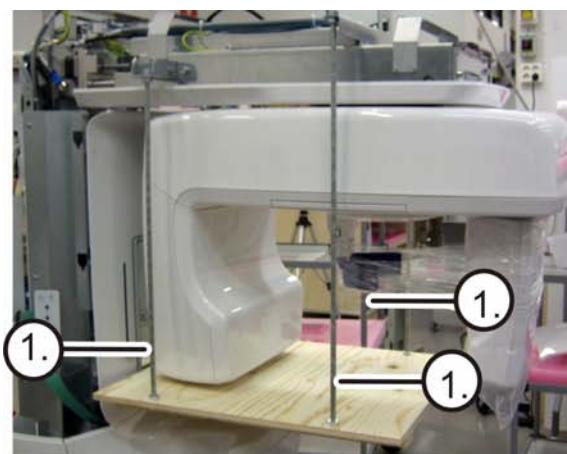
9. Remove the styrofoam material.

10. Remove the transport supports on the main support:

- 1) thread bars (4 pcs)
- 2) the holding overhead brackets (3pcs)
- 3) the sheet of plywood.

11. Remove plastic wrap around the sensor.

WARNING! *The plywood may scratch the chin support. Remove carefully!*

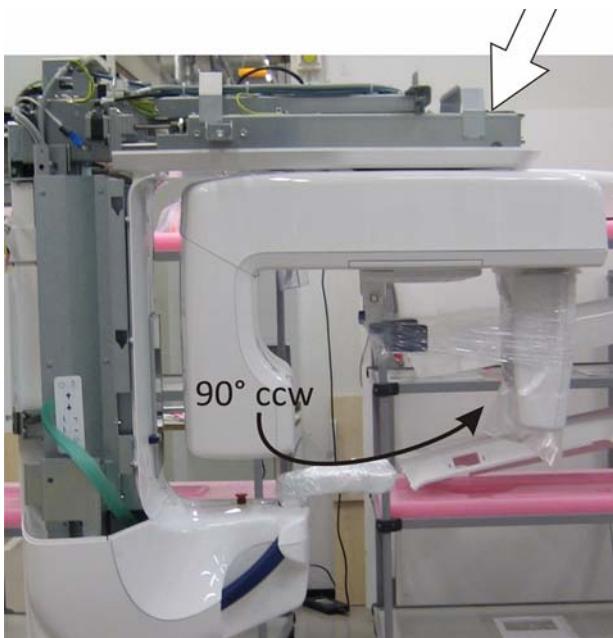


3.4 Stopper plate

WARNING! Do not damage the teeth of the encoder!

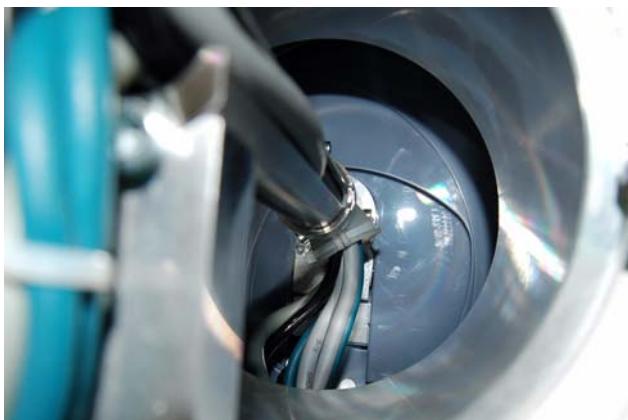


1. Rotation unit is secured. To release the rotation unit remove the stopper plate on the main support by removing 2 screws.



2. Rotate the rotating unit 90° counterclockwise.
3. Fasten the stopper plate back on it's place by 2 screws.

NOTE! When the rotation unit is released correctly, the cables should run like on the figures below.



Fully rotated clockwise, from left side view

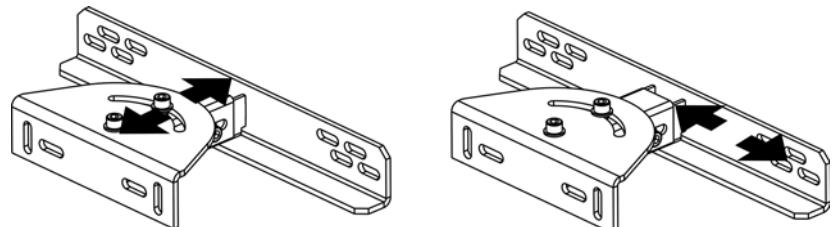


Fully rotated ccw, from right side view

3.5 Check leveling

Ensure the straightness of the unit by adjusting the upper wall bracket.

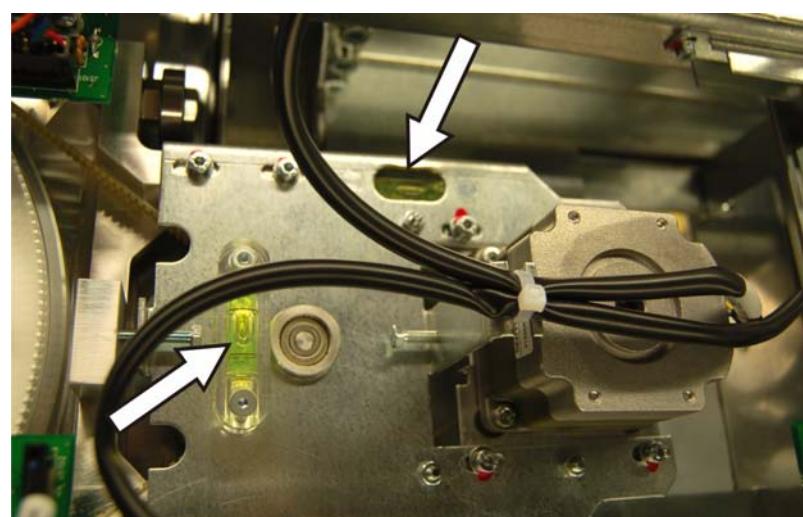
The wall bracket is adjustable so that the unit can be adjusted in all directions.



Before adjusting the tubehead must be turned to front position.

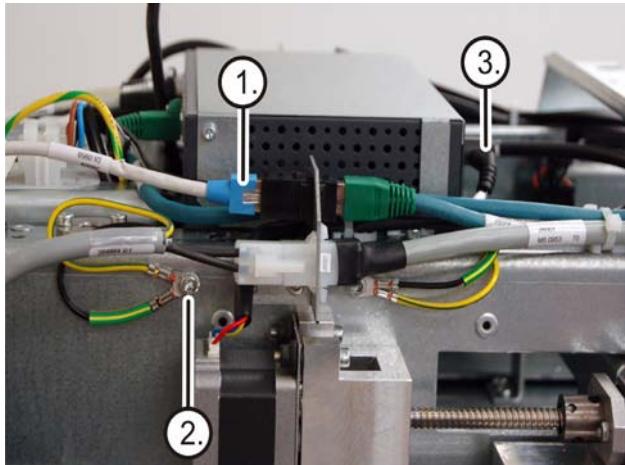


Use the spirit levels on the top of the main support.



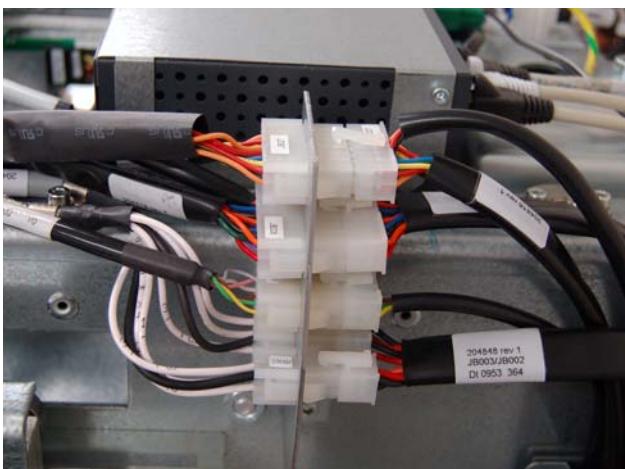
3.6 Connect all cables

1. Attach the cables on both sides and top of the column.



On the left side

- 1 Gigabit ethernet (marked with “Gigabit”)
- 2 Grounding point
- 3 Switch power cable



On the right side



On the top

3.7 Attaching the touch screen display to the column

NOTE!

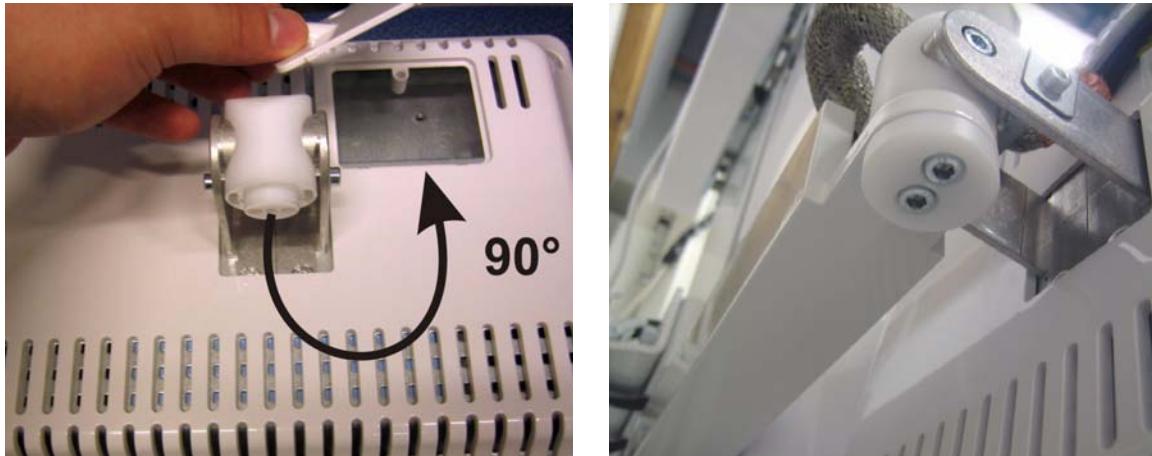
Remove the transport support of the touch screen arm.



1. Unfasten the touch screen display arm (1 screw) and re-fasten it to the horizontal position from the holes with counterbore. One screw is pre-installed and another is in the screw bag.



2. Fasten the touch screen display to the arm by 2 screws.



Remove screw and rotate 90°.

2. Connect the cables
(Ethernet, PC power, the grounding cable).
The grounding point is indicated in the figure below.

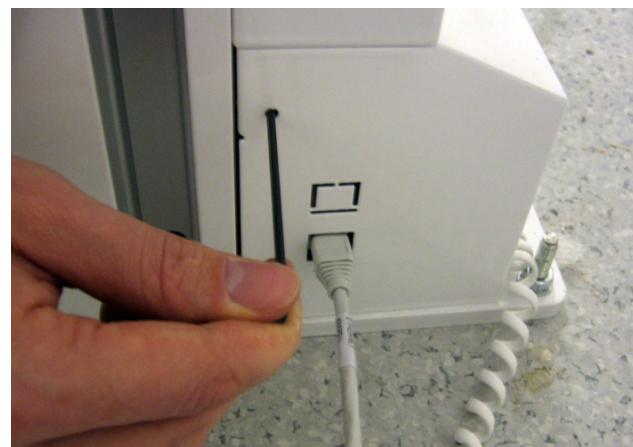


3. Secure cable with cable clamp on touch screen display bracket.

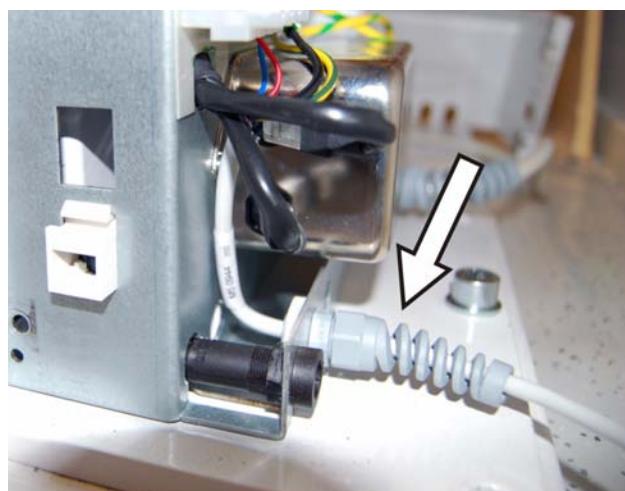
3.8 Exposure button

NOTE! *Exposure button is factory installed with flexible spiral cable. The following installation is done only, if a remote exposure button is needed.*

1. Attach the exposure switch holder to the rear of the touch screen display arm.
2. Loosen the screws of the mains inlet cover and remove the cover.



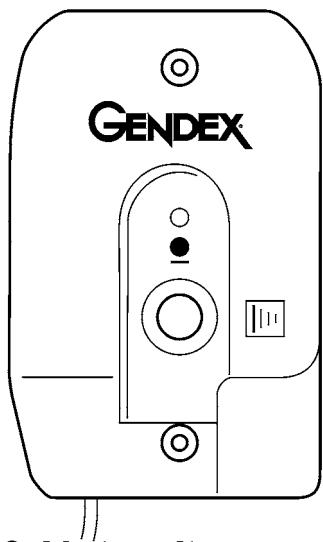
3. Connect the exposure switch cable to the connector at the base of the unit.
4. Put the exposure switch into the exposure switch holder.



3.9 Connecting the remote exposure switch

NOTE! The unit is shipped with an exposure switch connected to the device. Depending on the preference of the customer and the site layout, the Remote exposure switch (provided in shipment) may be needed in lieu of the factory connected switch. The Remote switch must also be installed if the customer wants an external warning light.

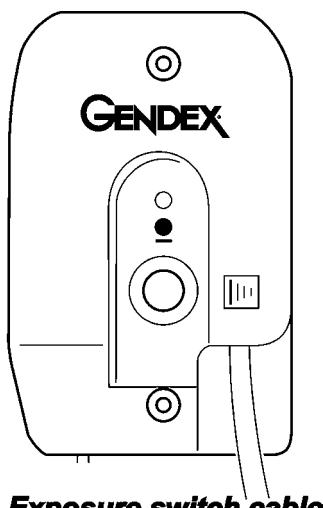
1. Remove the factory connected exposure switch.
2. Connect one end of the remote controller extension cable to connector J2 inside the remote exposure switch.
3. Attach the remote assembly to the wall in the required position (2 screws). Make sure that the cable from J2 is positioned in the small cut-out in the bottom of the remote exposure switch housing.



Cable to unit



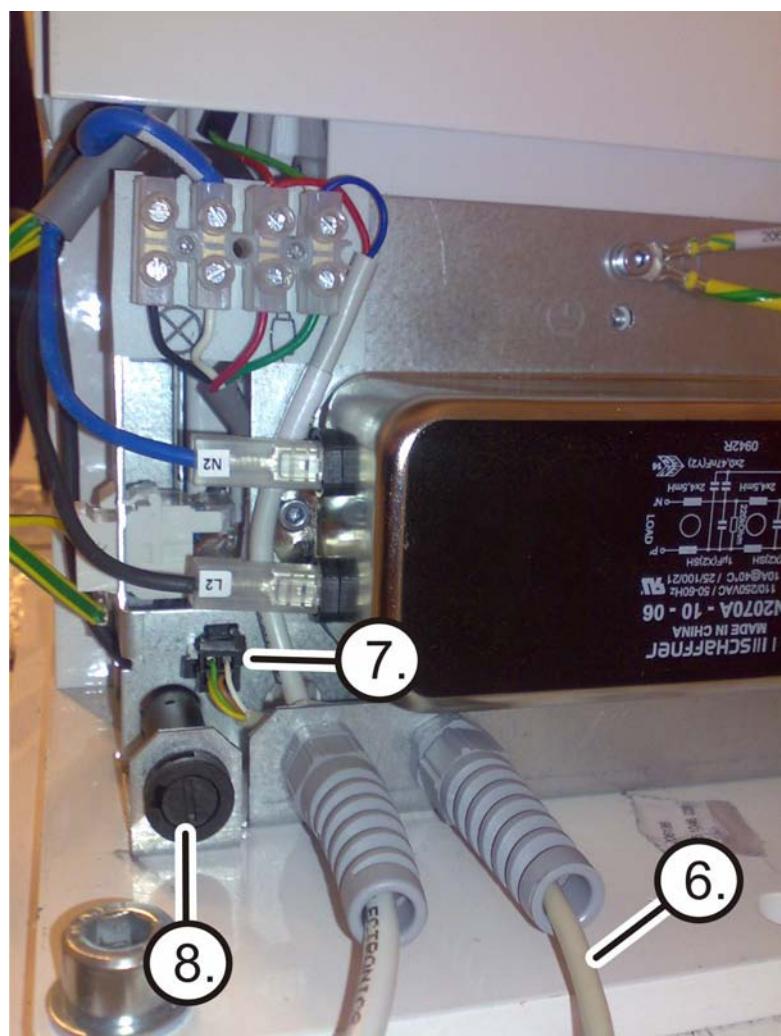
4. Attach the exposure switch hook to any flat smooth vertical surface. The exposure switch hook has double-backed tape. Make sure that exposure switch is positioned so that the user can protect them self from radiation and can see the patient during a exposure.



Exposure switch cable

5. Connect the exposure switch to the remote assembly. Exposure can be taken either with the exposure switch or the button on the remote assembly.

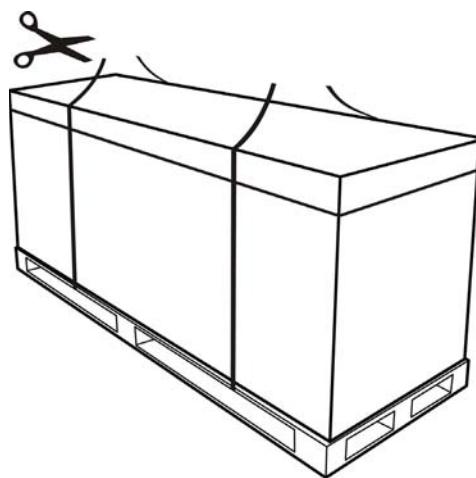
6. Attach the remote controller cables 207264 device end to its place and tighten the strain reliefs backend holder screw.
7. Connect remote controllers cable connector J1004 to its place.
8. Make sure that correct F3 fuse (2A 250V 6.3x32mm UR, CSA) is in the units F3 fuseholder.



3.10 Installing the cephalometric unit

NOTE! Save the packaging materials as they may be needed if you move the unit to a new location.

1. Transport the box (box number 3) to the location where the unit is to be installed.
2. Remove the straps that hold the box to the pallet.



3. Lift off the top of the box and then the sides. Remove the plastic wrap.

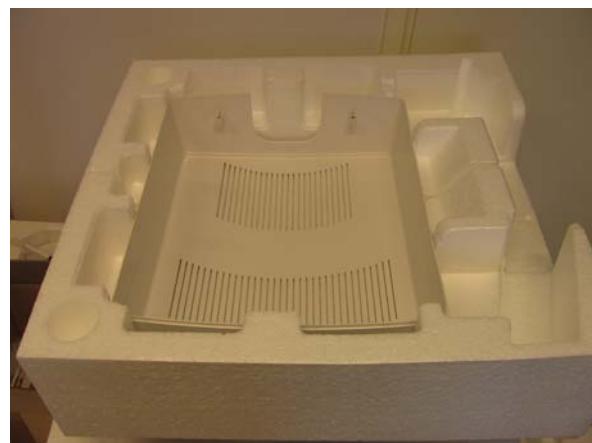


4. Ceph upgrade kit only:

Remove both the sensor box and the accessory box from both ends. The accessory box contains all the bolts required in the ceph unit installation.



5. Lift the upmost packaging styrofoam carefully and turn it around to get the ceph upper cover. Put the cover in its styrofoam aside.

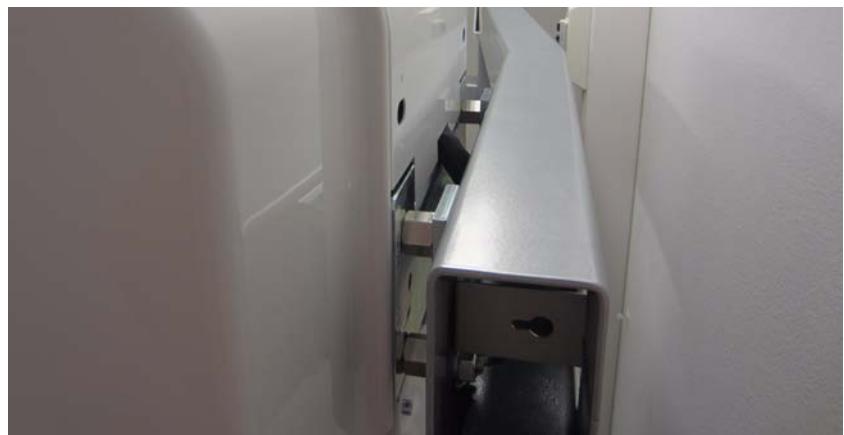




- 6.** To pull the ceph unit from the box, grab the lower packaging styrofoam cell from both sides. Lift the front end slightly and pull the unit out of the box carefully, leaving the ceph arm to its place.

NOTE! *Do not pull from the upper packaging cell to avoid causing any stress to the cephalo head*

- 7.** Ceph upgrade kit only:
Attach the four ceph arm installation bolts to the back of the column.
- 8.** Take the ceph arm from the box and lift it so that the installation bolts go through the four holes of the ceph arm.



- 9.** Attach and tighten the ceph arm to it's place evenly with four nuts



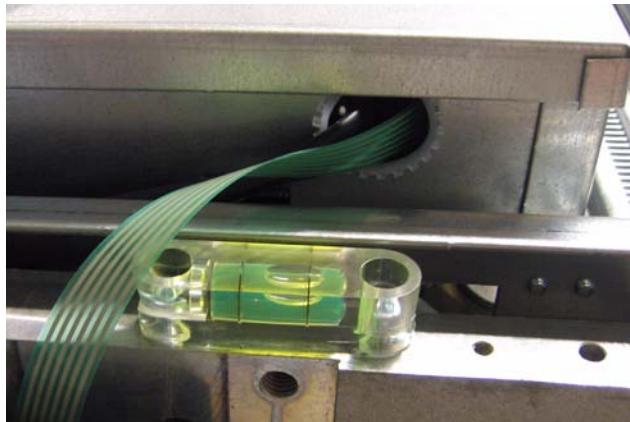
-
- 10.** Attach the ceph arm end by tightening it to its place with two screws



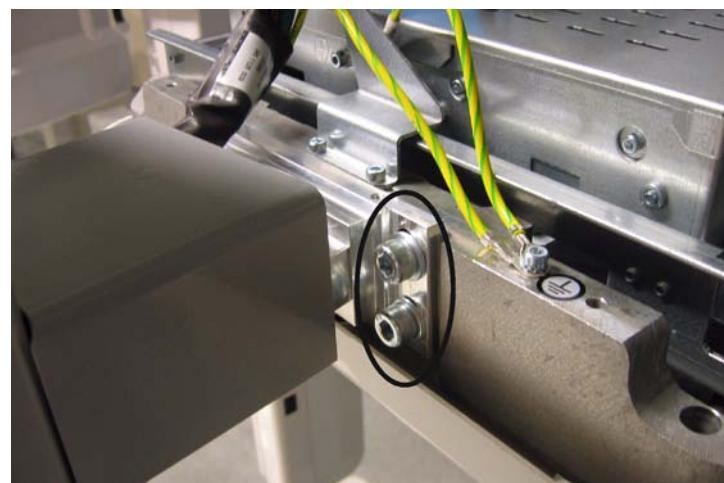
- 11.** Take the ceph unit out of the styrofoam packaging and lift it carefully to the hook on the other end of the ceph arm. Lift the unit so that the pin goes through the inlet at the ceph head and attach the two bolts to lock the ceph head to its place.



12. Check the leveling of the ceph unit from the two spirit levels. If the spirit levels indicate that the unit is straight proceed to the next section. If the unit is tilted, it has to be straightened. For information how to do this, look section **4.4.2 Cephalometric unit balance adjustment**



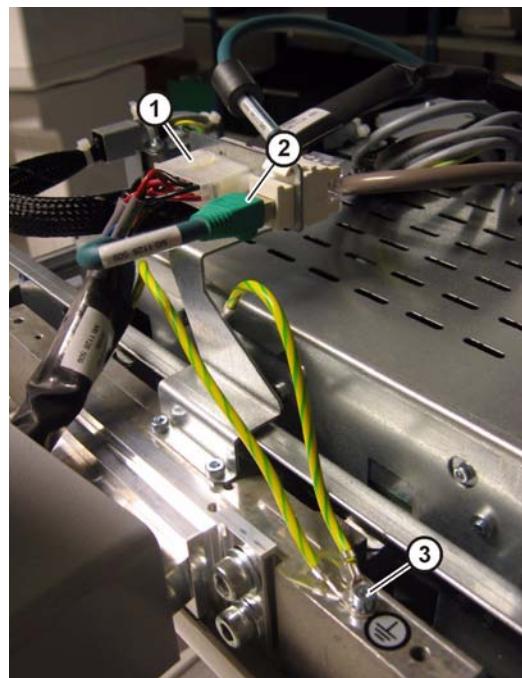
13. If the ceph head is leveled properly, check that all of the ceph attachment bolts are tight and that the ceph head stays in its place



14. Attach the cables of the ceph arm as shown.

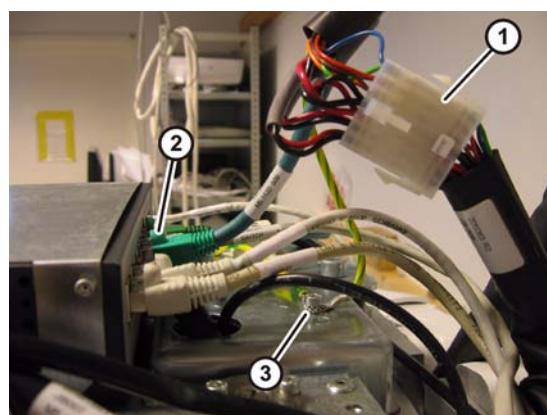
On the cephalometric unit:

- 1: Signal/Power cable
- 2: Ethernet cable
- 3: Grounding cable



On top of the unit column:

- 1: Signal/Power cable
- 2: Ethernet cable
- 3: Grounding point



15. Before installing the upper cover, calibrate the ceph unit according to instructions on chapter
4.4 Cephalometric calibration and alignment

16. Install the upper cover of the ceph unit by placing the cover over the ceph head and fasten the upper cover to its place with four bolts (M4x16) through the holes under the ceph unit.



17. Install the ceph arm covers on.

18. Take the sensor out of it's package and place it to the sensor holder



Pull the lever down to lock the sensor to it's place



3.11 Connecting the unit to the mains

WARNING! Only an authorized technician is allowed to perform the mains voltage change of the unit.

WARNING! Do not connect the unit to the mains voltage until instructed to do so.

NOTE! The units are delivered from the factory with 230Vac line voltage settings. If your mains voltage is 100/120Vac, read this chapter for instructions how to change the line voltage setting of the unit.

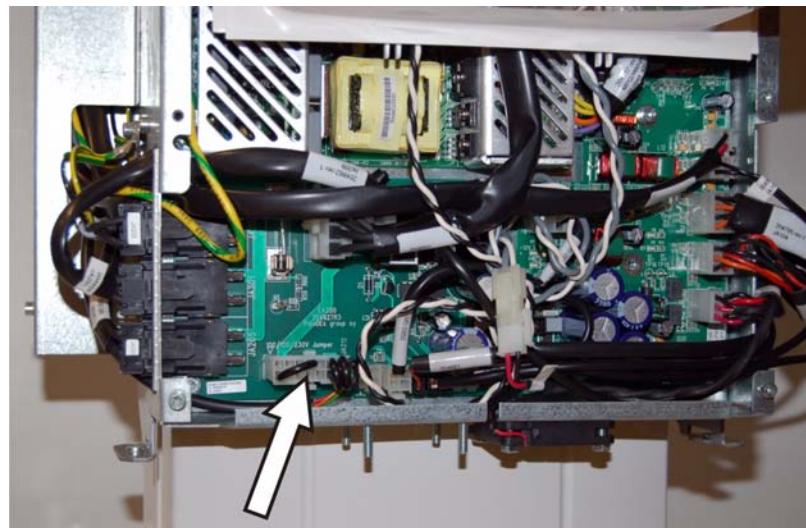
The unit can be set to operate at:

- 100 VAC (100...110VAC)
- 120 VAC (110...120VAC)
- 230 VAC (220...240VAC)

1. Remove the two covers under the lower shelf to access the power supply boards.



2. On the EA200 board there is a jumper (J1) for line voltage selection. If you have 220-240Vac mains voltage, you should install jumper marked with 230Vac to the J1 position. If you have 100-110Vac mains voltage, you should use the 100Vac jumper and if you have 110-120Vac mains voltage, use the 120Vac jumper.



Jumper

3. Make sure that you have correct main fuses (F1 & F2) in the unit.
 - For 220-240Vac use two 10A fuses, type T10A H 250V (Littelfuse 326 010)
 - For 100-120Vac use two 15A fuses, type T15A H 250V (Littelfuse 326 015)
4. For 100-120Vac operation an additional 10uF starting capacitor (located on the main support) needs to be added in parallel with the 30uF capacitor of the z-motor. This can be done by removing the metal cover on the top of the column and connecting JA005 connector to the low voltage cap connection of JA004.



Connector JA005 connected to the low voltage cap connection of JA004.



JA005 and JA004 connection is hidden under the box with the additional 10uF starting capacitor.

5. Install correct mains power cord to the connection on the base of the column
 - For EU 230Vac: H05VV-F 3G 1.5mm² with a Schuko plug (CEE 7/7)
 - For USA/CAN 115Vac: SJT AWG14 with a hospital grade NEMA 5-20 plug
 - For USA/CAN 230Vac: SJT AWG14 with a hospital grade NEMA 6-15 plug
6. Install all the covers back on.

WARNING! *Before connecting the mains voltage to the unit, check that the installation environment's temperature and humidity complies with allowed operating conditions of the unit. Make sure that the power line meets the requirements set by the manufacturer. See chapter Technical Specifications in the unit User Manual for more details.*

7. Now the unit can be connected to the mains and be switched on.

NOTE! *If the unit is moved to a new location, check that the voltage at the new location is the same as the unit is configured to. If not, the unit needs to be configured to that particular mains voltage.*

3.12 Preparing the PC

- 1.** Position the PC to be used with the unit at least 1.85m (73 in) away from the unit.

NOTE! If the unit and PC are to be part of a dental system make sure that all the other system components and devices are installed, connected and configured correctly. Refer to the documentation supplied with the other components and devices for information on how to do this.

- 2.** Switch the PC on and install the GxPicture software driver and the dental imaging software that will be used with the device.

For information on how to do this refer to the installation/configuration manual supplied with the dental imaging software you are installing.

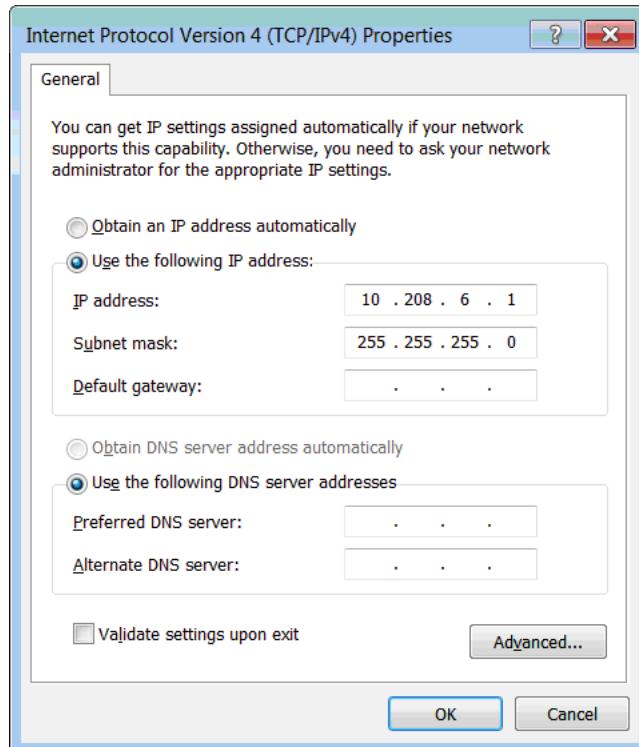
NOTE! During the imaging software installation when the Select Features window appears, make sure that you select the unit option.

3.13 Configuring the communication link to the PC

In this step, the IP address of the unit will be configured. Both the IP address used by the x-ray unit and the driver configuration can be updated. For point-to-point installations, it is not necessary to change the IP address of the unit (step 5).

Setting IP addresses for the PC and the x-ray unit

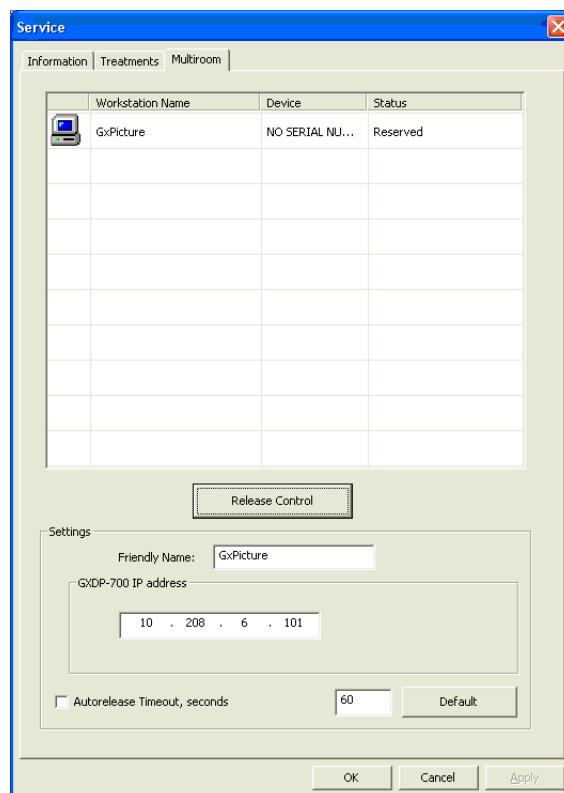
1. Connect one end of the Ethernet cable to the unit (the connector at the rear of the column) and the other end to the PC or the network.
2. Switch the unit on and carry out initialization (press a position panel key as requested on the unit GUI).
3. PC: Start the PC.
4. PC: Set the IP address of the PC to 10.208.6.1 (using windows control panel). If required, a different address may be used, as long as the unit and PC are on the same subnet and no other device on the network has the same address.



NOTE! If the unit is part of a network, you have to get an IP address for the unit from your local IP administrator.

5. To modify IP address of GXDP-700:

PC: Locate the Gendex GXDP-700 icon on the windows taskbar, right click and select "Multiroom" tab. Close Exam (Release Control key). Status changes to "Available".



PC: Type in the IP address to be assigned to the unit in GXDP-700 IP address field. For stand-alone configurations, use the default IP address 10.208.6.101.

Note! This is the factory default IP address, and usually there is no need to do this step.



UNIT: Press and hold, for a few seconds, keys **Positioning lasers** and **Patient positioning**. The unit accepts IP configuration for 60 seconds.

PC: Click on **Change** to configure the unit with the new IP address.

Status changes as follow:

- Configure
- Disconnected
- Available

6. To connect to GXDP-700 with specific (default) IP address:

PC: Locate the Gendex GXDP-700 icon on the windows taskbar, right click and select "Multiroom" tab. Close Exam (Release Control key). Status changes to "Available" (see pictures above).

PC: Type in the IP address of the unit (default is 10.208.6.101) in GXDP-700 IP address field. Click on "Change" button.

Status changes as follow:

- Configure
- Disconnected
- Available

4 Calibration and adjustment

4.1 Introduction

The calibration procedure helps to maintain the image quality and maintain the correct operation of the unit.

When carrying out the full or partial calibration procedure the calibration and check steps must be carried out in the order in which they are listed.

During the calibration procedure calibration data is produced. This data, which is stored in the Touch screen display PC and on the R3210, is used for unit calibration and image processing. Resulting from the calibration programs are also calibration images 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...).

NOTE! *Images are shown on the screen as viewed from the x-ray tube. All adjustment instructions contained in the calibration images also refers to this perspective.*

4.2 Preparing for calibration

1. Close the head support and lock it in its upmost position.
 2. Install reconstruction dongle to PC.
Switch the PC and unit on.
 3. PC: Open the s2terminal.
 - a) Open the **Command Prompt** (**Start\Programs\Accessories**).
 - b) In the Command prompt key in **cd** and then path where the s2terminal application has been installed (e.g. **c:\program files\s2terminal**).
-

cd c:\program files\s2terminal

- c) Press **ENTER**.
 - d) Key in **s2terminal** and then the **IP address** of the unit. Press **Settings** on the Touch screen display. The IP address of the unit is shown in the settings window.
-

s2terminal 10.208.6.101

- e) Press **ENTER** to open the s2terminal and make a connection to the unit.

The s2terminal version number appears together with a list of commands.

---- S2 Terminal Help -----

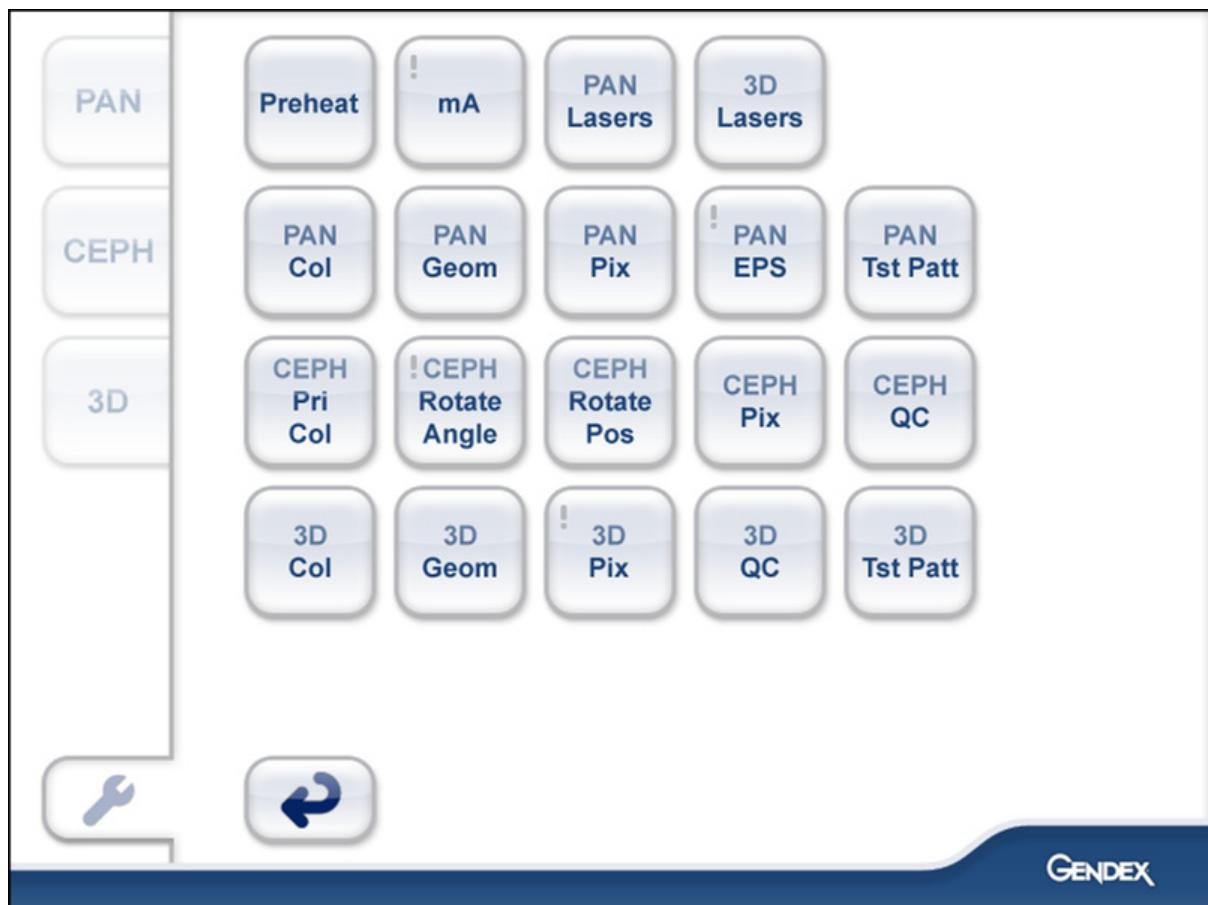
xh	help
xi	receive image from the device
xr	reserve device
xq	quit

Software and firmware version numbers appear after the basic list of commands.

4. 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).



5. Touch **Settings** on the Touch screen display.
6. Select the Quality Assurance key.
The calibration display appears.



4.3 The calibration sequence

4.3.1 Calibration of the preheat of the tube

NOTE! Calibration of the preheat of the tube lasts very long. The audible signal starts and stops several times. You can see when the calibration is finished from s2terminal.



Do this if there has been long time between installation and final testing of the unit.



1. Select the program.
2. Press **Patient positioning**.
3. Take an exposure. Keep exposure button pressed until program is finished. Touch screen display and s2terminal inform you when the calibration is done.

Tube_preheat calibration

Calibrated ref value 4mA : 54

Calibrated ref value 15mA : 207

Measured Fb peak value 4mA : 45

Measured Fb peak value 15mA : 235

4.3.2 Calibration of the tube current

NOTE! Calibration of the tube current lasts very long. the audible signal starts and stops several times. You can see when the calibration is finished from s2terminal.



Do this if there has been long time between installation and final testing of the unit.



1. Select the program.
2. Press **Patient positioning**.
3. Take an exposure.
4. Touch screen display informs when the calibration is done.

Tube_mA calibration

Calibrated ref value 4mA : 43

Calibrated ref value 15mA : 234

Measured Fb peak value 4mA : 44

Measured Fb peak value 15mA : 230

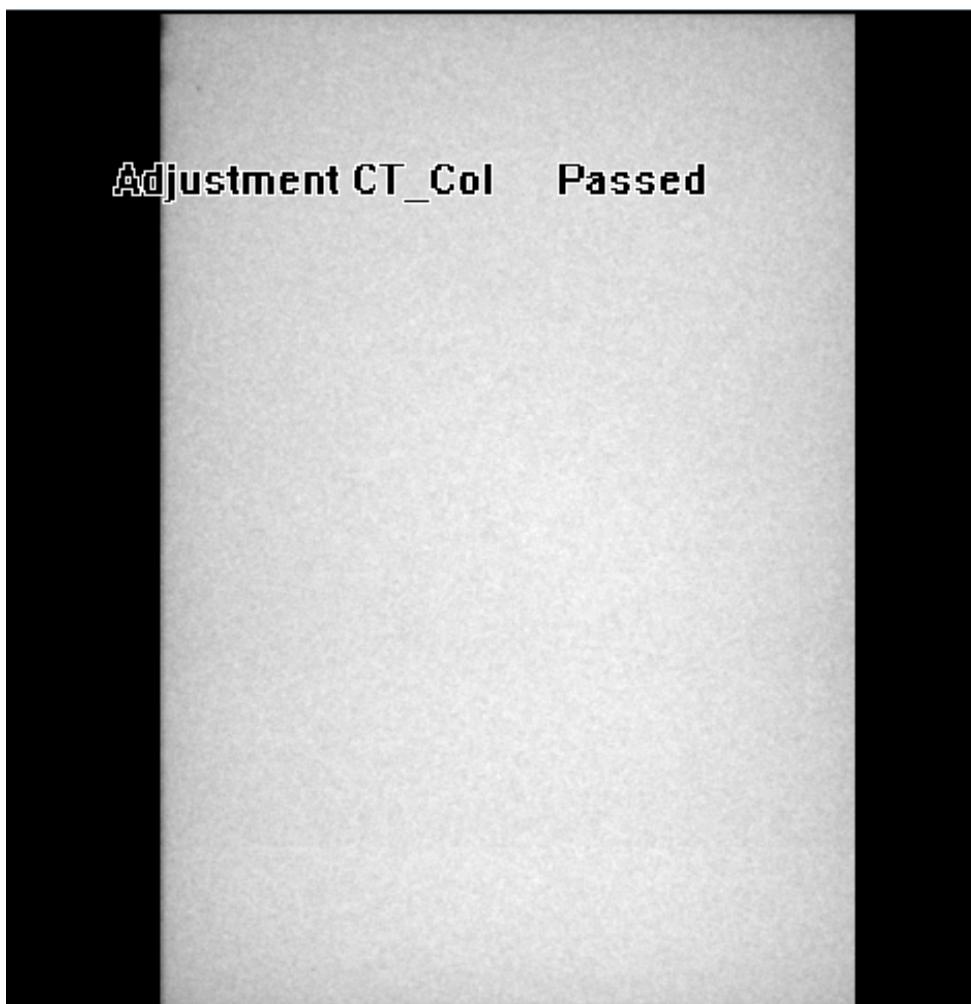
4.3.3 3D collimator calibration



Adjust the height and tilt of the collimator manually.
Only needed with 3D units.

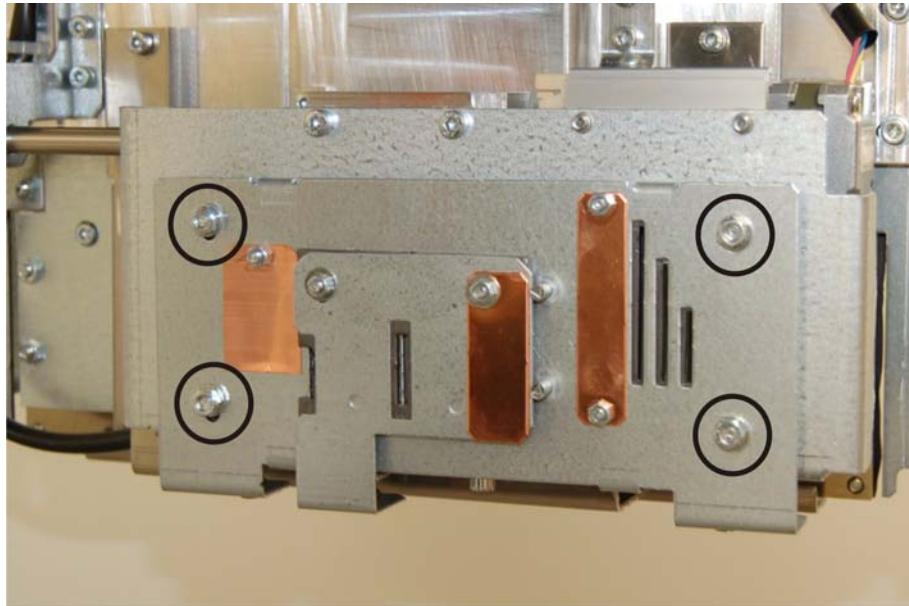


1. Select the program.
2. Press **Patient positioning**.
3. Take an exposure, on which the manual adjustments are based. Touch screen display informs how much the height needs to be adjusted and in which direction.



4.3.3.1 Adjustment of the height and tilt of the collimator

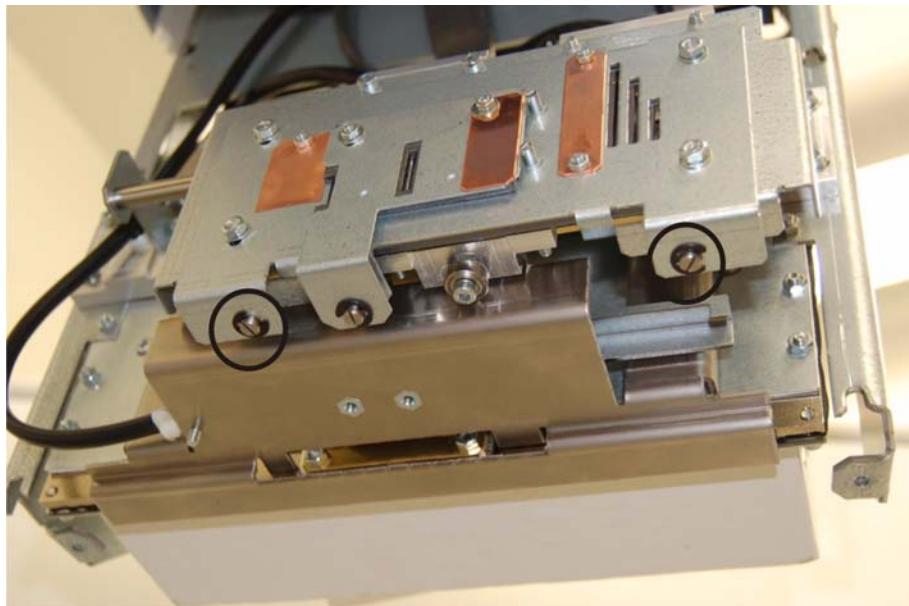
1. Loosen four M4 nuts to be able to adjust the plate.



2. Adjust the height/tilt with two screws on the bottom of the collimator.

Clockwise (cw) = Collimator upwards

Counterclockwise (ccw) = Collimator downwards



3. Re-tighten the four M4 nuts and take a new image.

4.3.4 Panoramic collimator calibration

NOTE! With Pan unit (no 3D option) this calibration is done by adjusting the collimator (not the sensor), as in chapter 4.3.3.1, Adjustment of the height and tilt of the collimator.

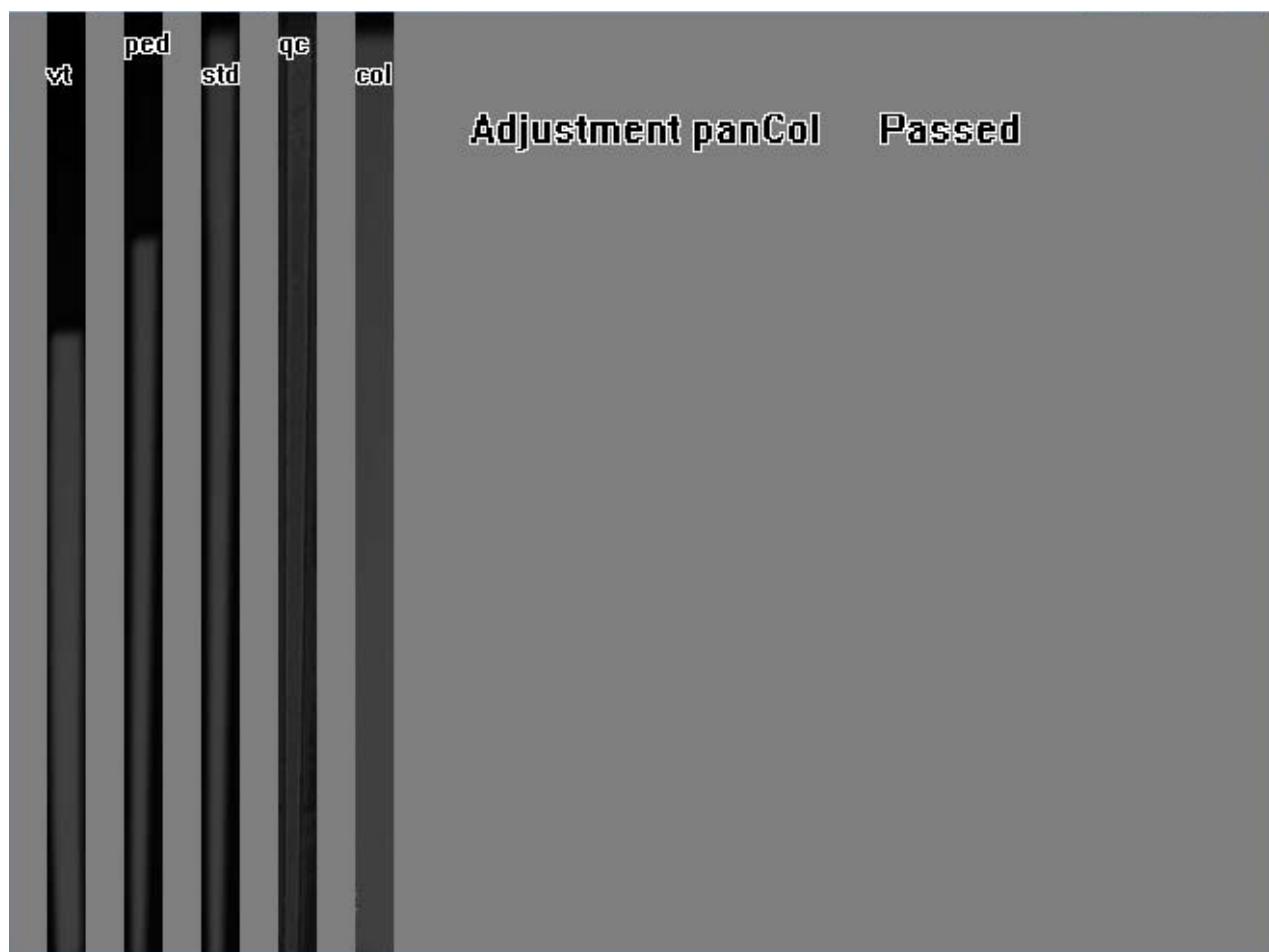
Adjust the height of the Pan sensor and check the tilt and position of the collimator.



1. Attach the panoramic sensor.



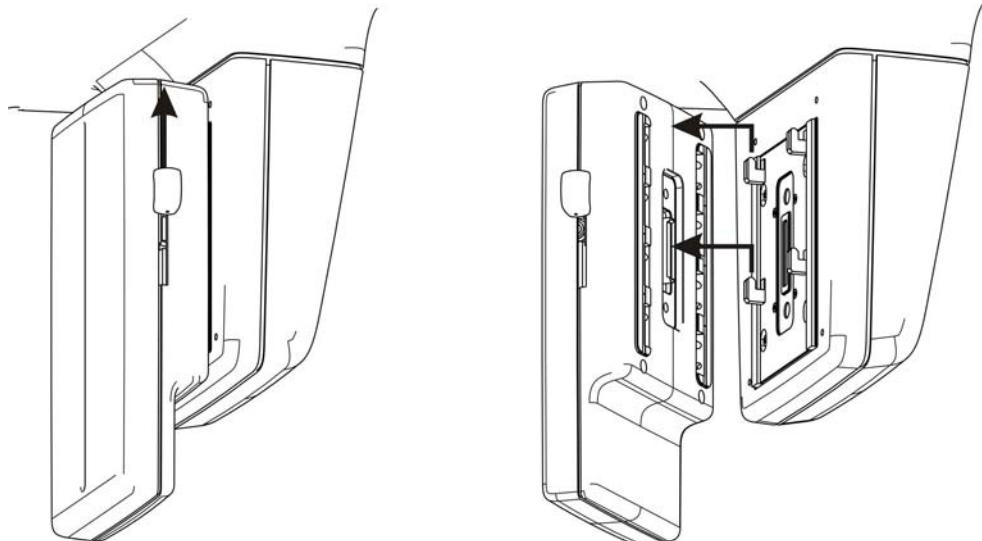
2. Select the program.
3. Press **Patient positioning**.
4. Take an exposure, on which the manual adjustments are based. Touch screen display informs how much the height needs to be adjusted and in which direction.



4.3.4.1 Adjustment of the height of the PAN sensor

Do the adjustment with the sensor holder.

1. Remove the sensor.



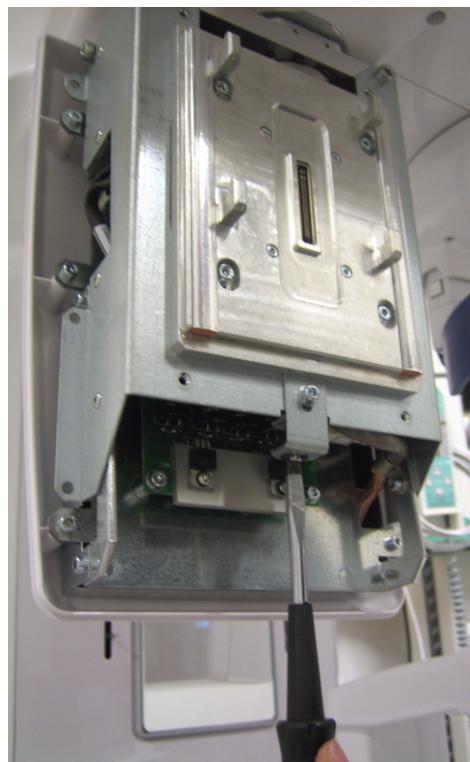
2. Remove the sensor holder cover by removing four M4 screws.



- 3.** Loosen five screws of the sensor holder.

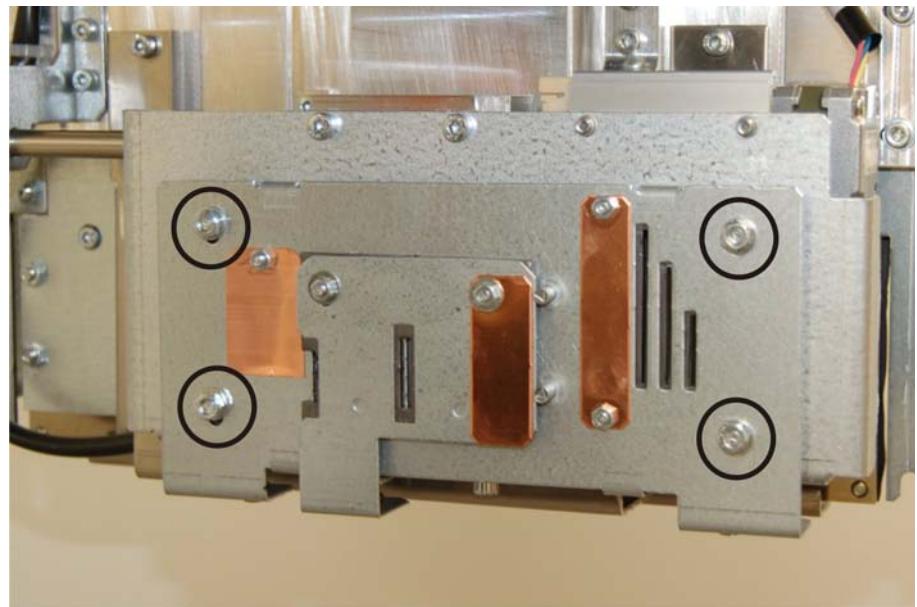


- 4.** Adjust the height with an adjustment screw on the bottom of the holder.

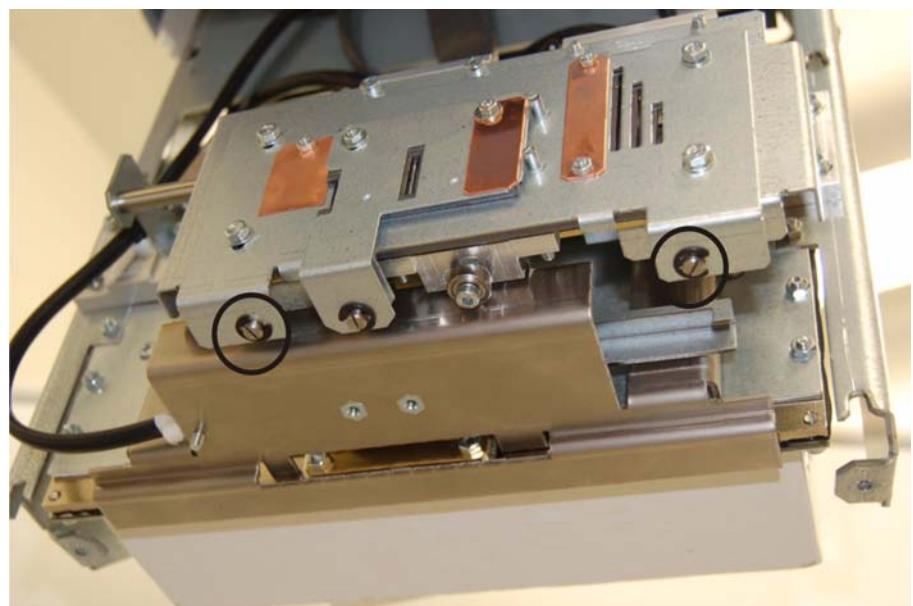


4.3.4.2 Adjustment of the tilt of the collimator

1. Loosen four M4 nuts of the collimator.
Adjust the tilt with left and right lower screws.



2. Use the two bottom screws to adjust the height/ tilt of the collimator.
Clockwise (cw) = Collimator upwards
Counterclockwise (ccw) = Collimator downwards



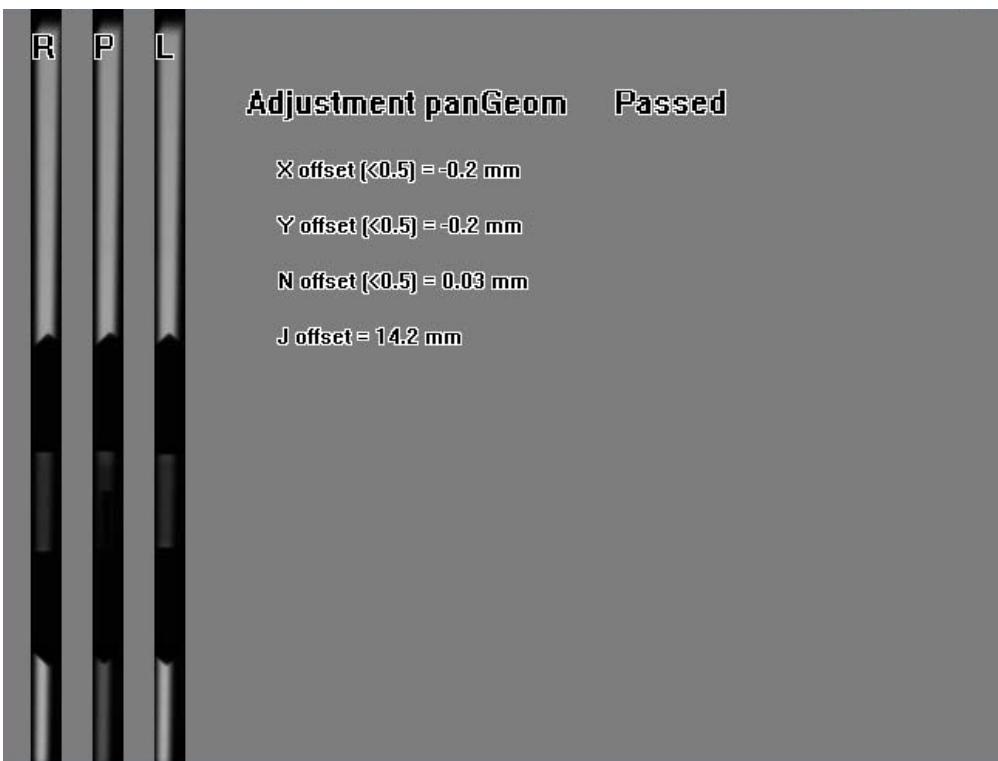
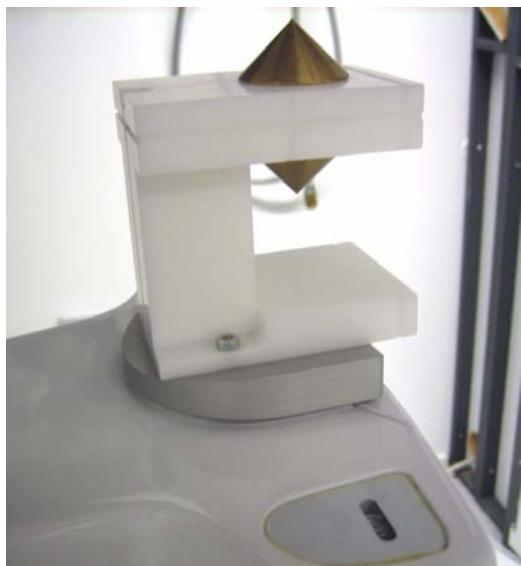
3. Re-tighten the four M4 nuts and take a new image.

NOTE! 3D collimator calibration should be checked if the tilt is adjusted.

4.3.5 Panoramic geometry calibration

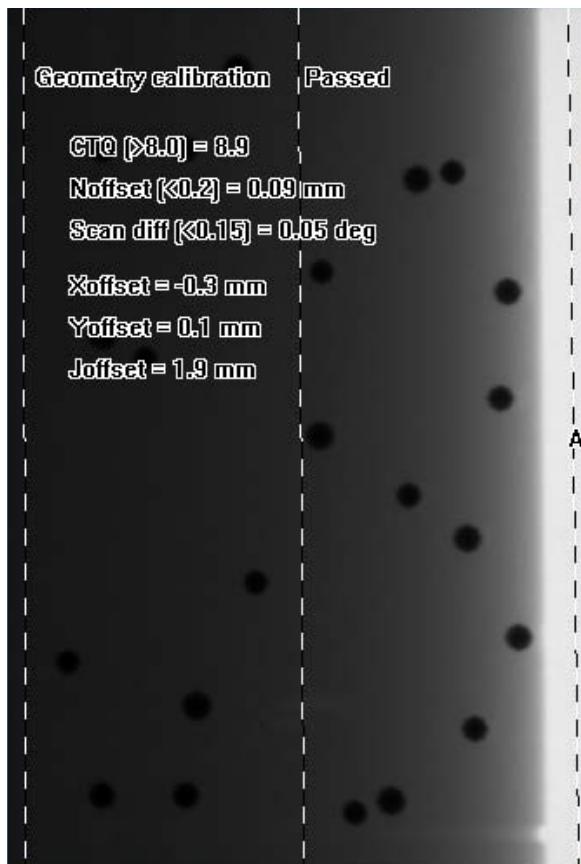
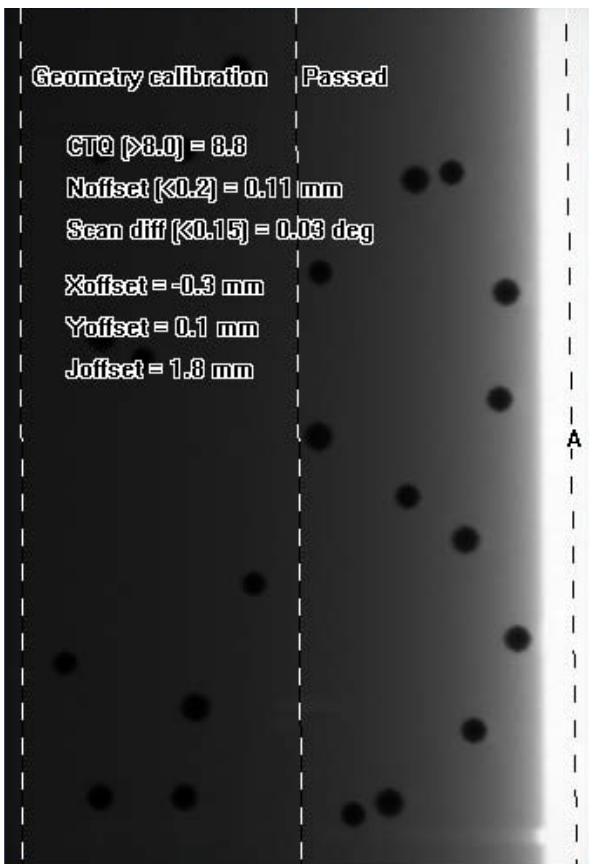
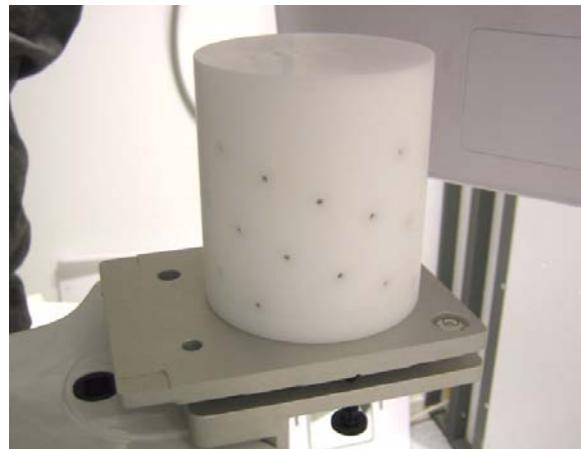
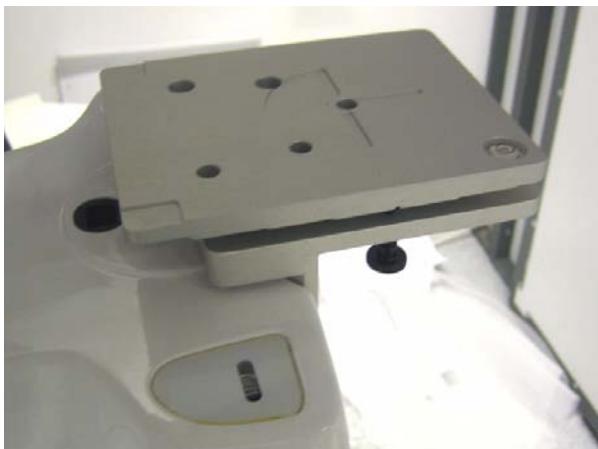


1. Select the program.
2. Press **Patient positioning**.
3. Install the double cone calibration tool.
4. Take an exposure. Repeat the calibration until calibration result "passed" is achieved.



4.3.6 3D geometry calibration

1. Place the base of the phantom to the lower shelf.
Level it with the bubble.
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 positioning**.
4. Install the 3D calibration phantom.
5. Take an exposure. Repeat the calibration until calibration result "passed" is achieved. This calibration is only needed with 3D units.



4.3.7 3D lasers alignment

Remove the mirror plate by loosening two M4 screws.
Lift the plate first and pull.



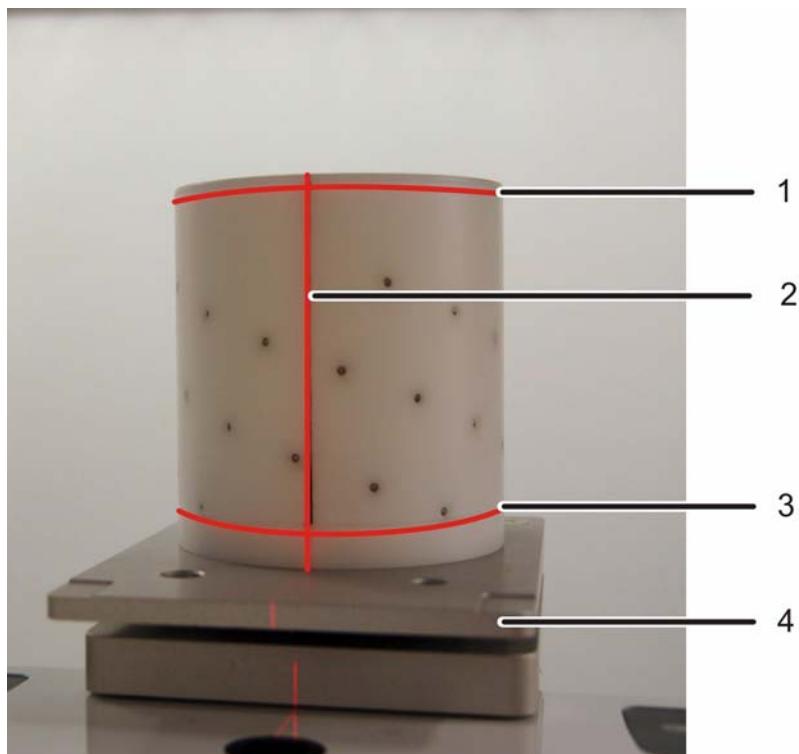
1. Attach the 3D geometry calibration tool to the unit.
Use the 3D calibration phantom with grooves for aligning the FOV and mid-sagittal lasers.

2. Select the 3D lasers program in the service mode.

3. Press **Patient positioning**.

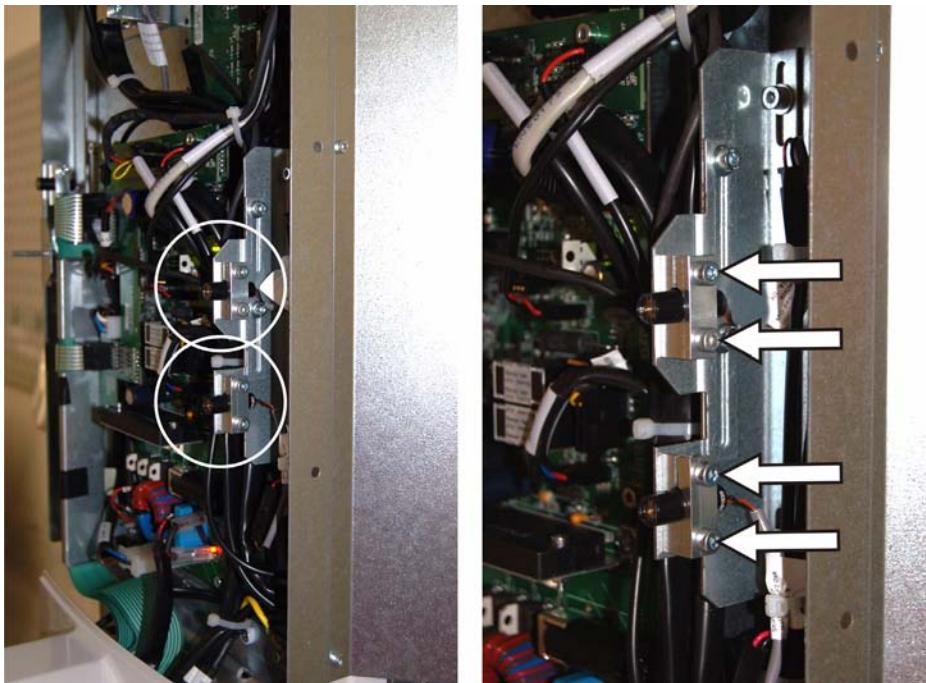
NOTE! Lasers can be turned on by pushing the light key.
Lasers stay on approx. 30 seconds.

4. Briefly press the exposure button (no X-rays are generated) to acknowledge that the check has been carried out.



1. Top of FOV
2. Mid-sagittal
3. Bottom of FOV
4. Adjustable phantom holder

5. Align bottom laser first by two screws.
6. Align top laser second by two screws.



4.3.8 Panoramic laser alignment

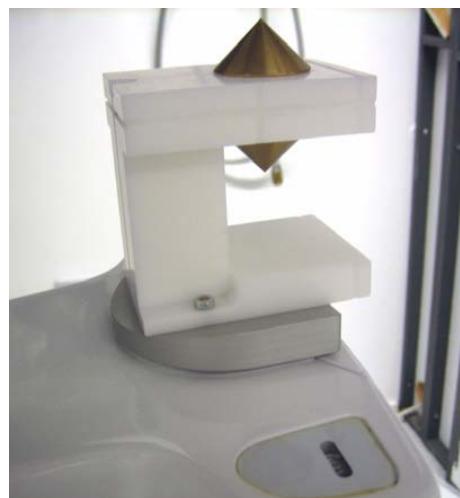
To align patient positioning lasers used in panoramic imaging:



1. Attach the PAN geometry calibration tool (double cone) to the unit.
2. Select the PAN lasers program.
3. Press **Patient positioning**.
4. Remove the lower shelf bottom cover.
5. Align the layer laser, FH-laser and mid-sagittal lasers to the corresponding grooves by mechanically adjusting the lasers. Adjustment of the laser located in the rotator is software based. Use the chin support adjustment keys to adjust the angle of the laser and occlusion correction keys to adjust the Y-position of the laser to match the backmost groove on the calibration tool.
6. Briefly press the exposure button (no X-rays are generated) to acknowledge the adjustment has been carried out. The rotation and Y-position are also saved.



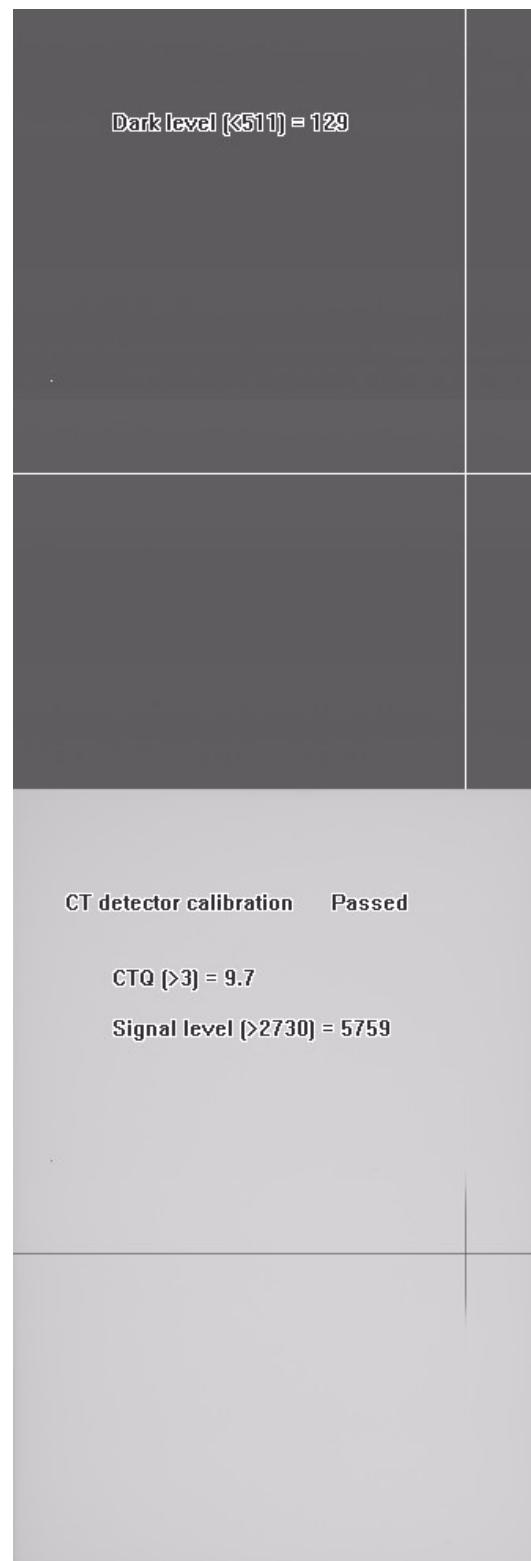
NOTE! Lasers can be turned on by pushing the light key. Lasers stay on approx. 30 seconds.



4.3.9 3D pixel calibration



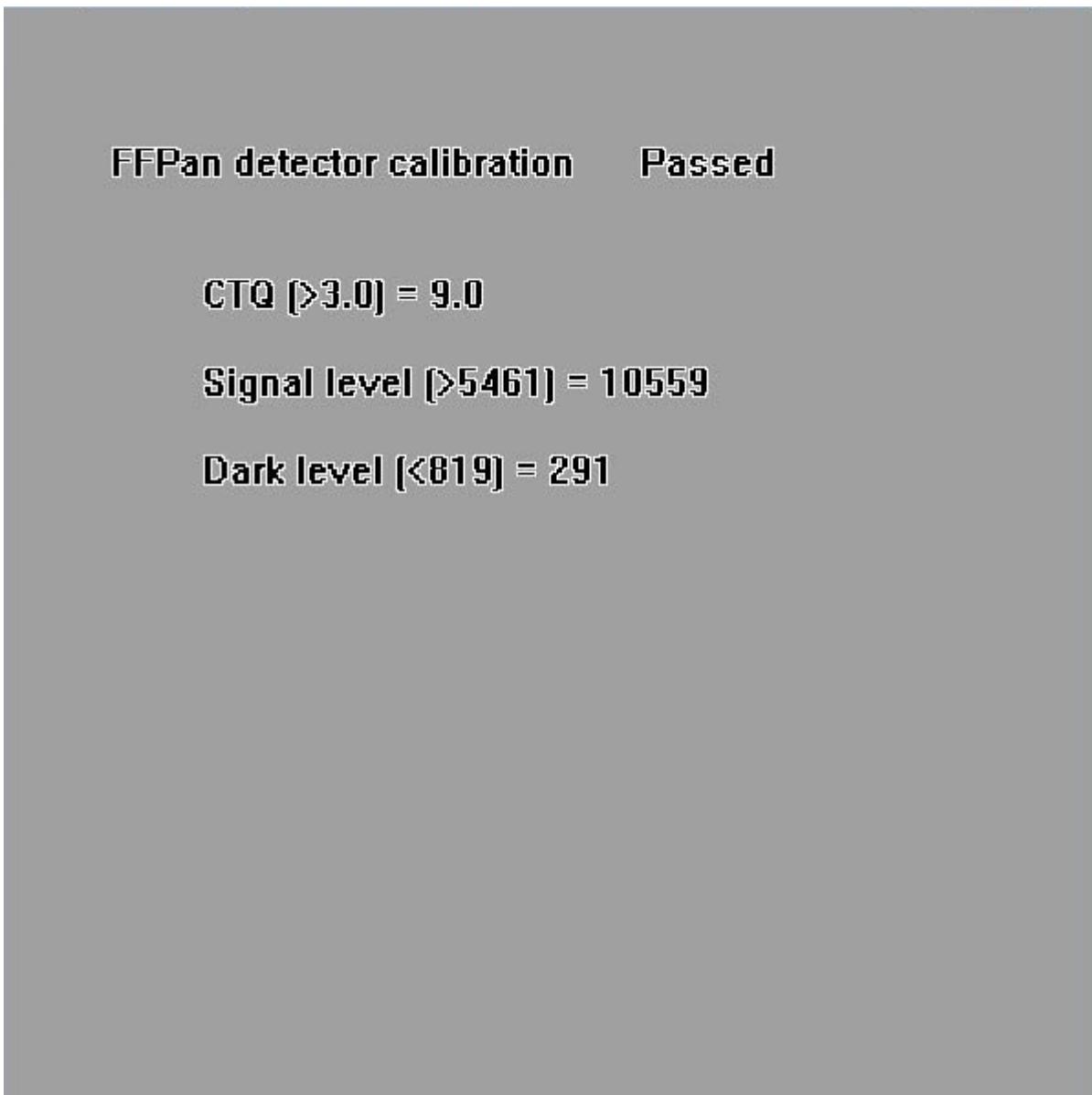
1. Attach the tube head covers.
2. Remove the 3D calibration phantom.
3. Select the program.
4. Press **Patient positioning**.
5. Take an exposure. The result image informs when the calibration is passed.



4.3.10 Panoramic pixel calibration



1. Attach the tube head covers.
2. Remove the double cone calibration tool.
3. Select the program.
4. Press **Patient positioning**.
5. Take an exposure.
Touch screen display informs when the calibration is passed.



4.3.11 3D Quality Check



1. Attach the QC phantom to the unit.
2. Select the 3D QC program.
3. Press **Patient positioning**.
4. Take an exposure.
5. The resulting image contains information on whether the quality check was passed.



4.3.12 Panoramic Quality Check



1. Attach a line pair calibration tool to the chin support.
2. Select the Pan QC program.
3. Take an exposure.
4. Visually evaluate the result using the installed imaging software.



4.4 Cephalometric calibration and alignment

4.4.1 Preparations

Ensure that 3D and panoramic collimator calibrations are done successfully. Otherwise primary collimator calibration may fail.

Remove every Pan/3D calibration tool before Ceph calibration.

Install the ceph unit and make sure that it is in balance using the spirit levels

4.4.2 Ceph firmware update

Updating is done by s2terminal. Check the unit's IP address from the GUI and then use s2terminal to connect to it. Your computer's IP address must be configured to be on the same subnet as the unit. Make sure no other computers are connected to the unit. Shut down the workstation software and image acquisition driver.

4.4.2.1 Preparing for the update

1. Power up the unit normally and connect to it using the s2terminal:
-

s2terminal <unit's IP address>

example: s2terminal 10.208.6.101

Make sure that your computer is configured to the same IP subnet as the unit.

2. Reserve the unit by typing the following command in the s2terminal prompt
-

xr

Make sure that s2terminal returns “**MODE RESERVE**“.

If not, repeat the procedure.

4.4.2.2 Updating the cephalostat core

1. Perform the update by typing in the following command in the s2terminal:
-

xfr <filename>.srec core

example: xfr cephcore.srec core

- 2.** Wait for the software package to be transferred
- 3.** Power the unit off, wait a few seconds and power the unit back on

4.4.2.3 Updating the cephalostat firmware

- 1.** Perform the update by typing in the following command in the s2terminal:
-

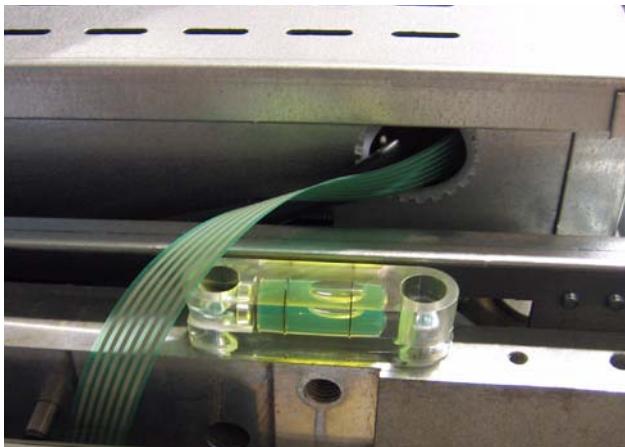
xfs <filename>.srec main

example: xfs cephfw.srec main

- 2.** Wait for the software package to be transferred and the ceph unit to reboot itself. The update is complete.

4.4.3 Cephalometric unit balance adjustment

1. Adjust the balance of the ceph unit according to the spirit levels.



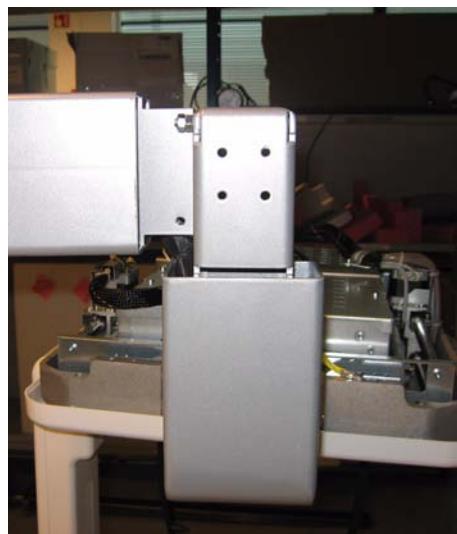
Vertical balance in terms of the ceph sensor



Horizontal balance in terms of the ceph sensor

4.4.3.1 Vertical balance adjustment

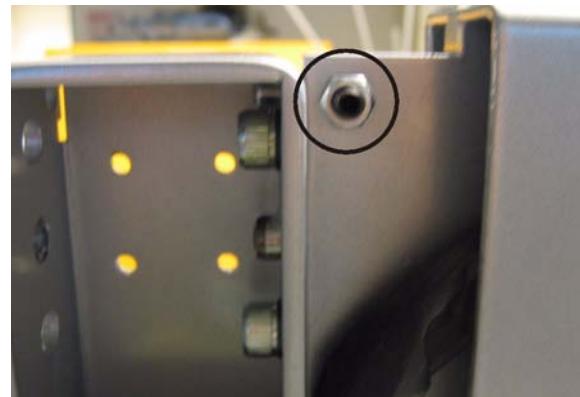
1. Remove the ceph arm cover piece to reveal the vertical balance adjustment screws



2. Loosen the two indicated screws from inside of the ceph arm



3. To adjust the ceph head vertically tighten or loosen the indicated screw. To raise the other end of the ceph head, tighten the screw and to lower the other end, loosen the screw.

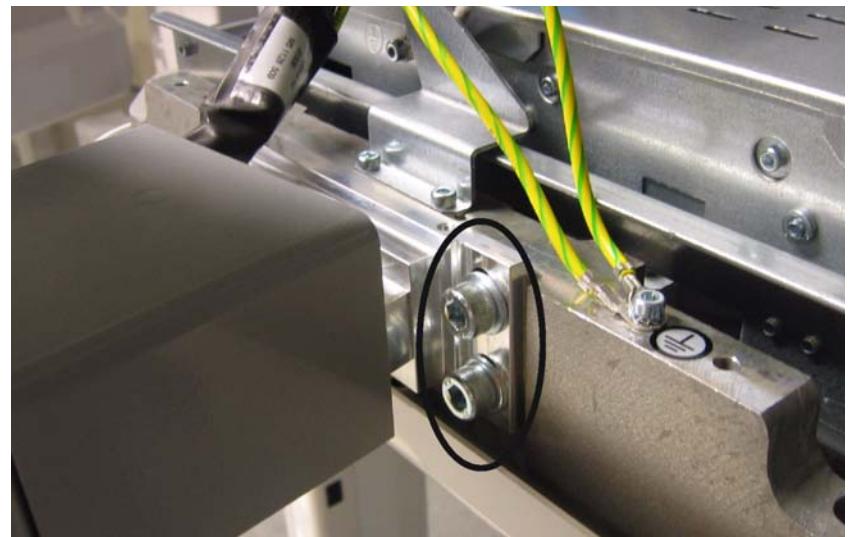


NOTE! Loosen the locking nut before tightening the screw and tighten it after the adjustment

4. Check the spirit level to ensure the balance of the ceph unit and tighten the screws.

4.4.3.2 Horizontal balance adjustment

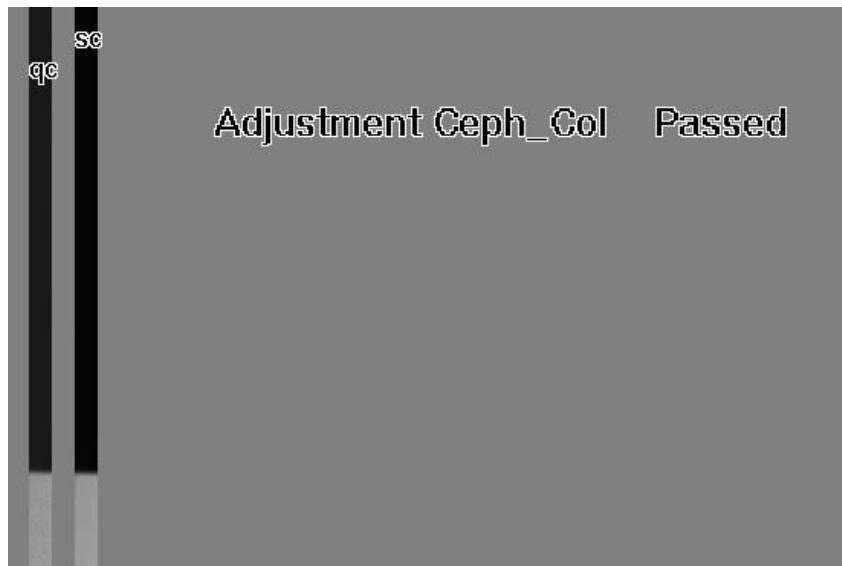
1. Loosen the ceph attachment bolts (4 pcs) slightly and twist the ceph head until it's balanced horizontally properly.



2. Check the spirit level to ensure the balance of the ceph unit and tighten the screws properly.
3. Install the ceph arm covers back on

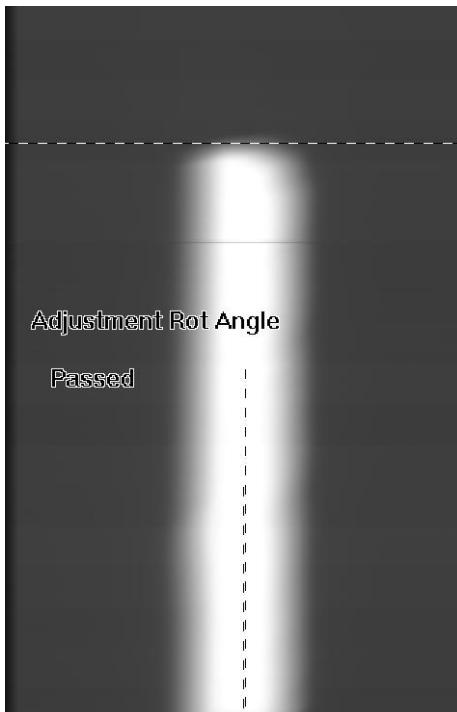
4.4.4 Primary collimator calibration

1. Attach ceph or pan sensor to the rotating unit sensor holder.
2. Select service state from GUI for cephalometric unit calibration
3. Select ceph primary collimator calibration from the GUI and press the patient positioning button.
4. Take an exposure.
5. If 3D/panorama collimator calibrations are done this calibration should always pass.



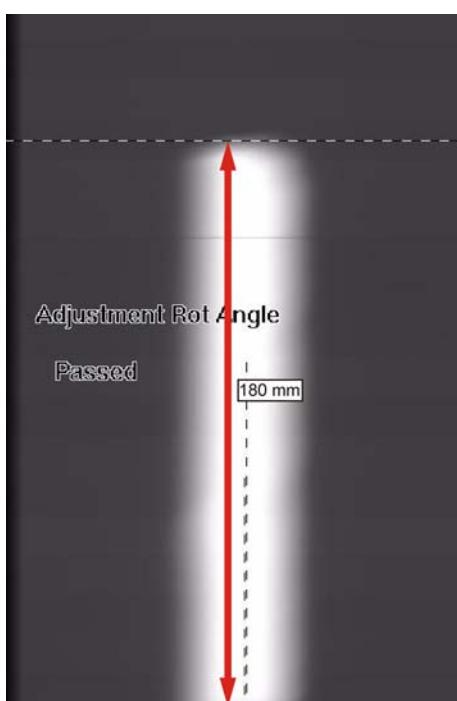
6. If calibration fails, redo 3D/panorama collimator calibrations and try again.

4.4.5 Rotation angle calibration



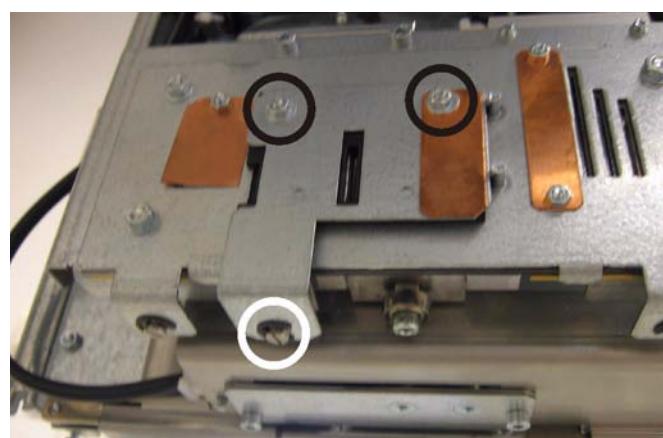
1. Attach the ceph sensor to ceph sensor holder
2. Open the ear holders and the temple holder as far as they go.
3. Select rotation angle calibration from the GUI and press the patient positioning button.

4.4.6 Collimator height calibration



1. Select rotation angle calibration from the GUI unit and press the patient positioning button.
2. Take an exposure.
3. Check from the image that the collimator height is 180 mm.
4. If it's not, adjust the ceph collimator from the primary collimator and retake a rotation angle calibration image
5. To adjust the collimator, loosen the M3 nuts marked with black, adjust the collimator using the screw marked with white and re-tighten the black nuts.

NOTE! This adjustment can be done during rotation angle calibration

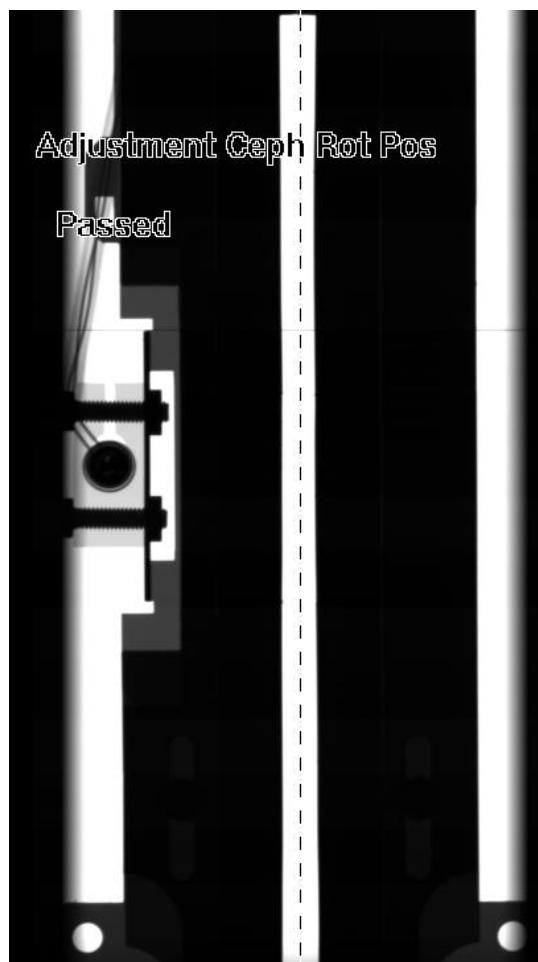


4.4.7 Cephalometric rotation position calibration



1. Select rotation position calibration from the GUI and press the patient positioning button.
2. Take an exposure.
3. Check that the calibration is passed.
4. If it's not, redo the calibration.

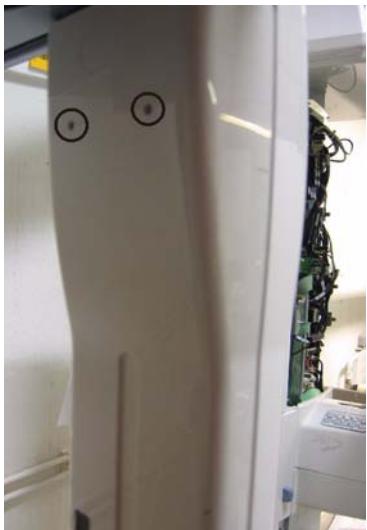
NOTE! It's recommended to repeat the rotation angle calibration and rotation position calibration couple of times by turns, to make sure, that the calibrations don't have any effect on each other.



4.4.8 Secondary collimator adjustment

4.4.8.1 Removing the covers

1. Loosen the counter piece screws (2 pcs) through the holes on the cover



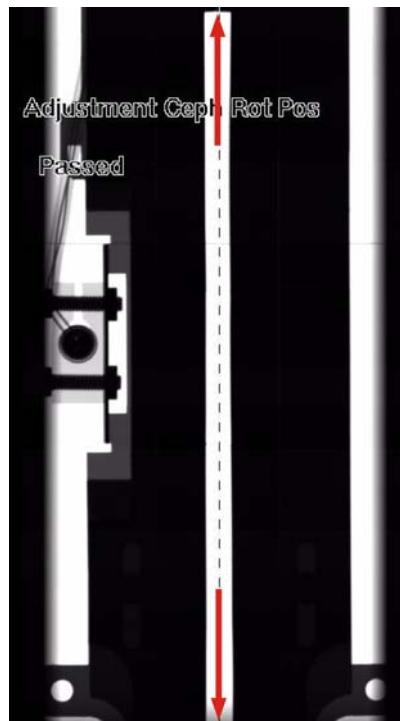
2. Lift the other half off the collimator
3. Remove the two lower screws and loosen the two upper screws to remove the other cover.



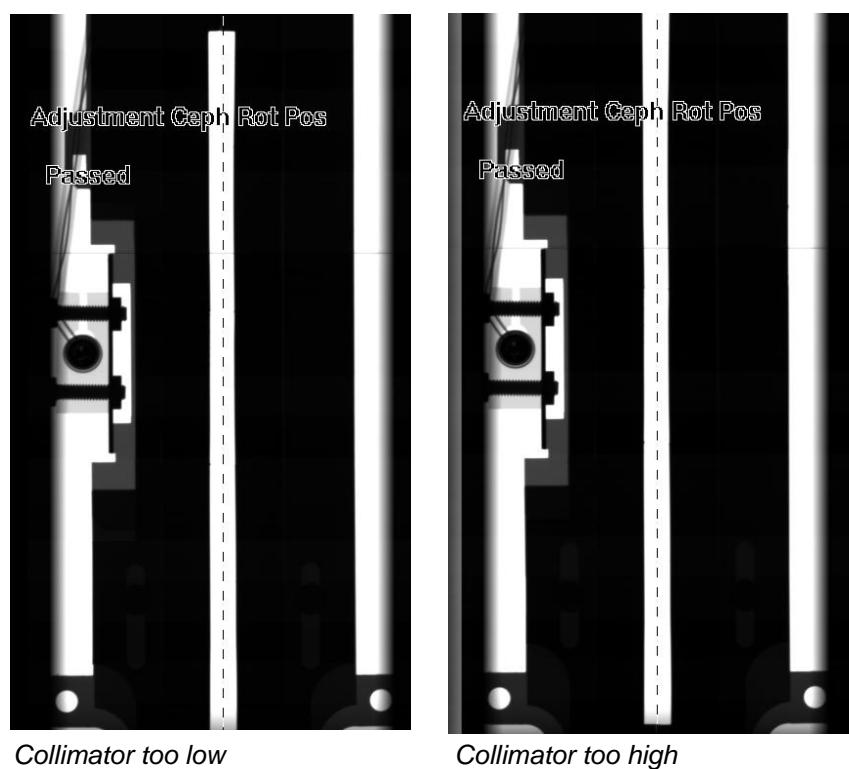
4. Detach the positioning panel connectors

4.4.8.2 Vertical alignment

1. Take a rotation position calibration image and check that the whole collimator slot fits to the calibration image.



If bottom or top line of the collimator is not seen on the image, adjust the collimator vertically by removing the shown locking screws and by using adjustment screw shown on image "Vertical adjustment screw".





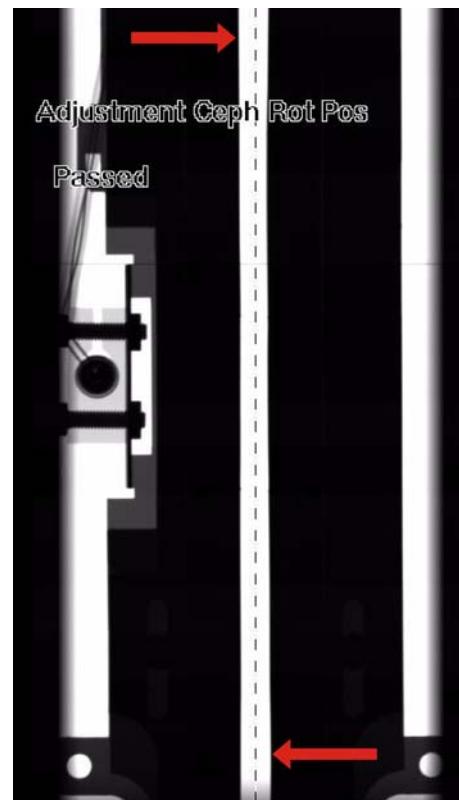
Collimator vertical locking screws



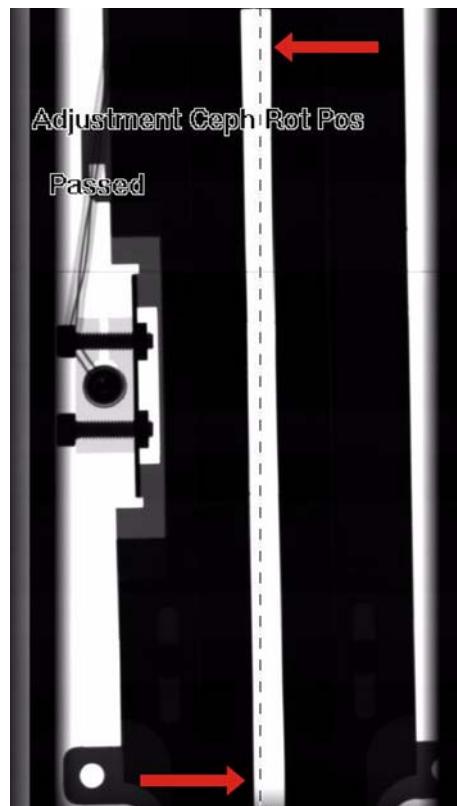
Vertical adjustment screw

4.4.8.3 Horizontal adjustment

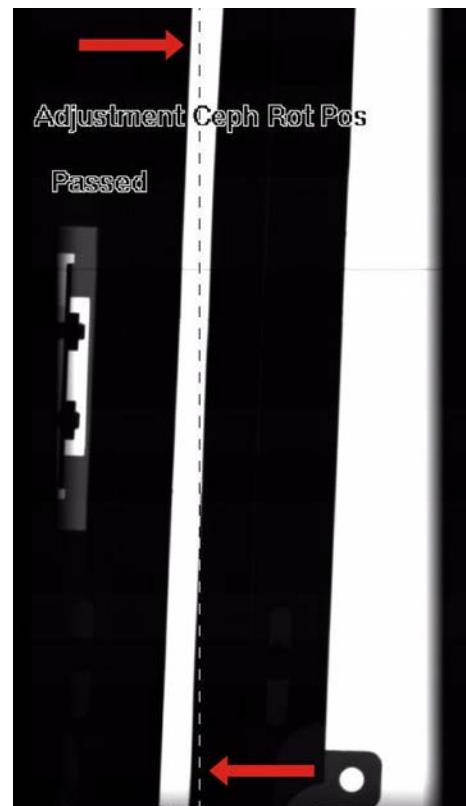
1. Take a rotation position calibration and check that the collimator slot is in line with the dashed line.



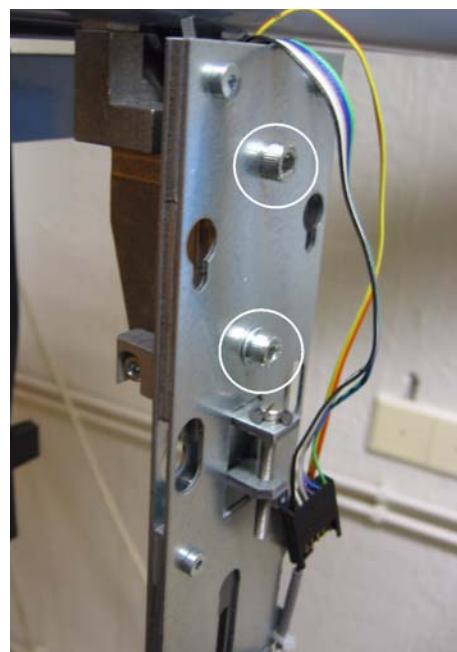
2. If collimator slot isn't in line with the dashed line, adjust the collimator horizontally by removing the lower screw of the indicated locking screws and then using the horizontal adjustment screw shown on image "horizontal adjustment screw".



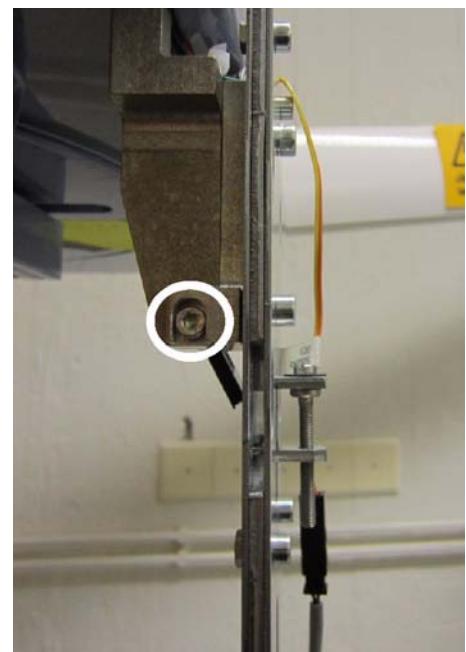
Collimator tilted left



Collimator tilted right



Collimator horizontal locking screws



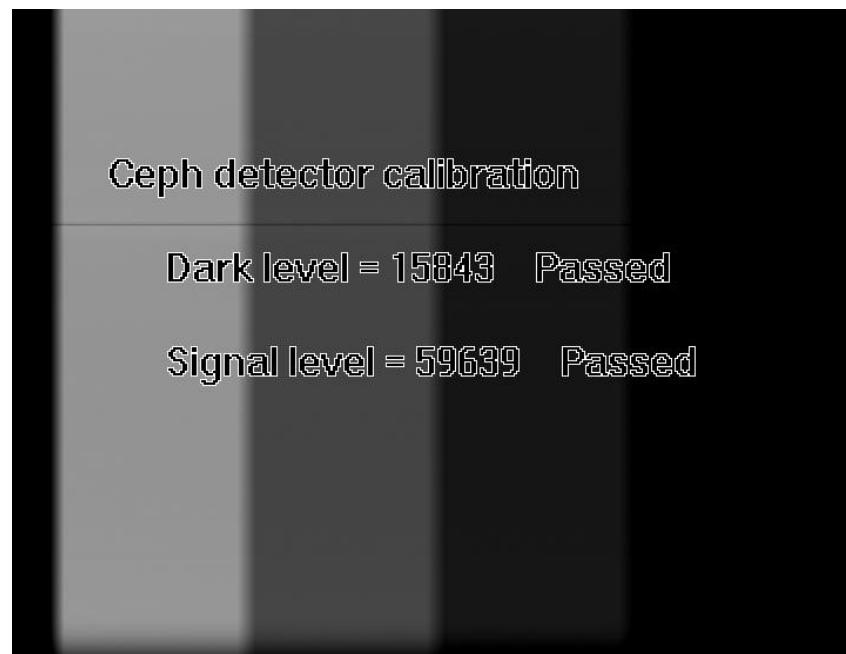
Horizontal adjustment screw

NOTE! Reattach and secure the collimator locking screws properly after every horizontal and vertical adjustment of the collimator

4.4.9 Ceph pixel calibration



1. Select pixel calibration program from the GUI unit and press the patient positioning button.
2. Take an exposure.
3. This calibration should always be a pass



4.4.10 Ceph QC program

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

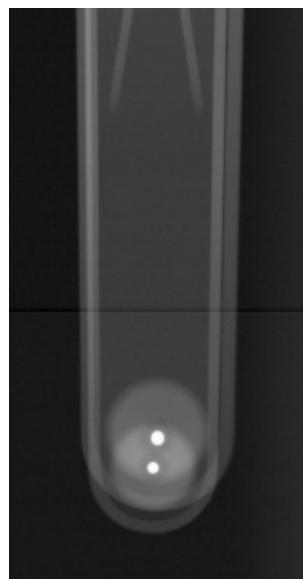


2. Select the Ceph QC program.
3. Take an exposure.
4. Visually evaluate the result using the installed imaging software.

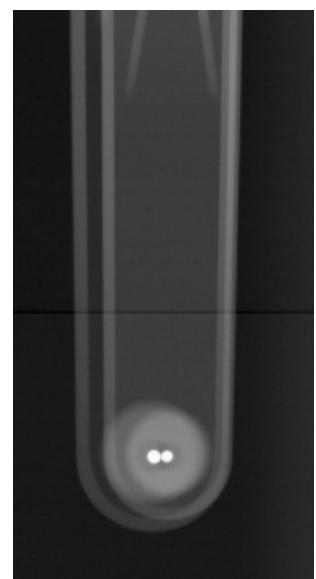
4.4.11 Ear holder alignment

The ear holder center pins and the x-ray focal spot must be in line. Adjust the ear holder alignment following the steps below.

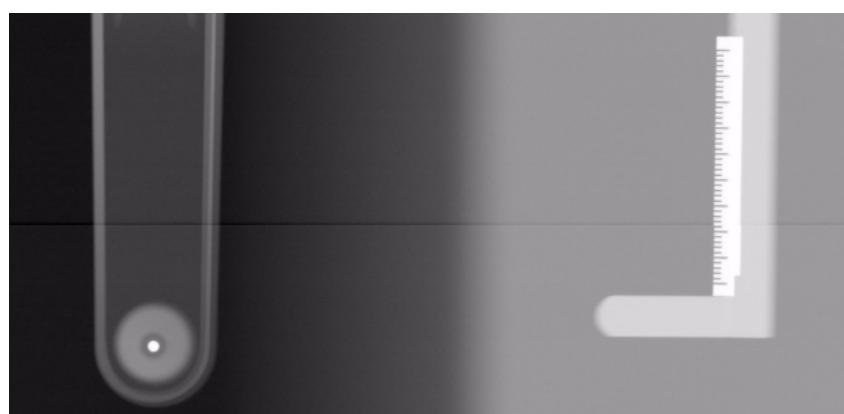
1. Turn the ear holders into the lateral view position and move them completely apart.
Exit the service state and select a cephalometric exposure program.
2. Prepare Cliniview for image capturing and take an exposure.
3. Both ear holders have a small metal ball that should be visible in the image: both balls should be displayed in the same point so that they merge into a single ball. The larger ball represents the tube side, and the smaller ball the cephalostat sensor side.
4. If the balls do not merge into a single ball, the ear holders must be adjusted.



Vertical adjustment needed



Horizontal adjustment needed

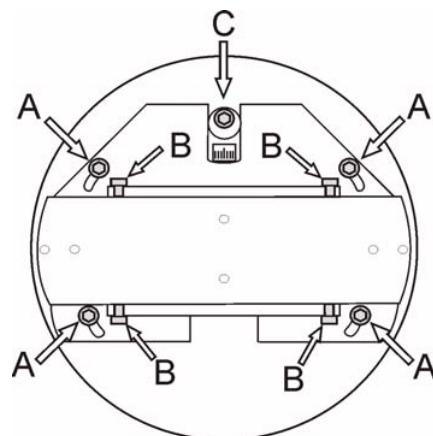


The balls merge; no adjustment needed

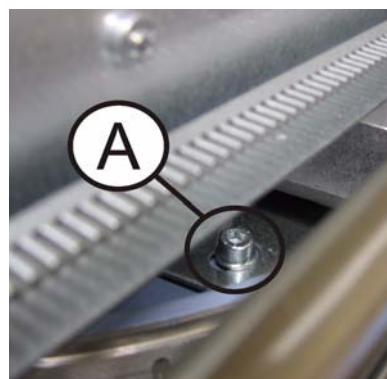
4.4.11.1 Horizontal adjustment

Rotate the ear holder assembly to access to all locking screws.

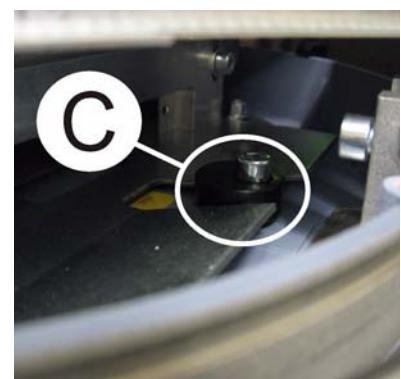
1. Loosen the 4 locking screws (A) on the ear holder assembly. To ease the loosening lock the ear holder assembly to its place with the locking switch to prevent it to move on its own.



Top view of ear holder assembly



Locking screw (A)

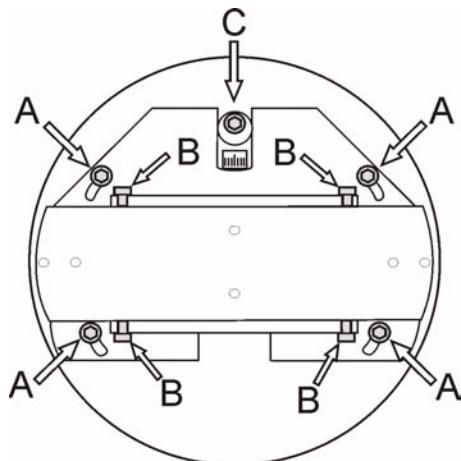


Adjustment screw (C)

2. Make adjustments by turning the eccentric cam screw (C). The amount of rotation can be seen on the scale after marking the starting position.
3. Tighten at least two locking screws when adjustment is done and verify by taking a test image.
4. When the horizontal adjustment is complete, tighten all locking screws.

4.4.11.2 Vertical adjustment

1. Loosen the 4 locking screws (**B**) located at the sides of the ear holder assembly. Make adjustments by turning the vertical adjustment screw at the end of the ear holder assembly. The amount of the vertical movement can be seen on the scale after marking the starting position.



Top view of ear holder assembly



Locking screw (B)



Vertical adjustment screw

2. Tighten at least two locking screws when adjustment is done and verify by taking a test image.
3. When the vertical adjustment is complete, tighten all locking screws.

4.4.12 Cephalometric lasers alignment



1. Select the cephalometric lasers program.
2. Press the patient positioning button.
3. Press the light button to turn on the patient positioning lasers.
4. Check that the laser beam is horizontal and that it goes through the center of the ear rod.



5. If the laser needs to be adjusted, loosen the screws of the laser shown on image and tighten it to its place when the laser is horizontal



6. When the adjustments are done press briefly the exposure button (no X-rays are generated) to acknowledge that the check has been carried out.

4.5 Reset maintenance counter

NOTE! Use the service mode to set the “Indicator service clear” command.

1. Open S2 terminal.
2. Type “indicator service clear” in the command prompt.
This resets the annual maintenance counter to zero.

NOTE! All unit covers must be re-installed after calibrations

4.6 When to calibrate the unit

The unit must be calibrated and, if necessary, adjusted at regular intervals in accordance with national regulations regarding the use, maintenance and service of dental x-ray devices that are in force in the country in which the unit is installed.

In any event, the unit must be completely recalibrated at least once a year.

The unit must also be fully or partially calibrated when parts are replaced. The calibration steps for the following replaced parts are as follows:

Tubehead

After replacing the tubehead the unit must be completely recalibrated.

R3800 X-ray generator

After replacing R3800 X-ray generator preheat and mA calibration must be redone.

Collimator assembly

After replacing or adjusting the collimator assembly redo all applicable collimator, pixel and geometry calibrations as well as the quality checks.

3D Panel

After replacing the 3D panel redo all the 3D calibrations and the 3D quality check. If the collimator is moved redo all collimator, pixel and geometry calibrations as well as the quality checks.

Panoramic panel

After replacing the panoramic panel redo all the panoramic calibrations. If the collimator is adjusted or replaced, redo all collimator, pixel and geometry calibrations as well as the quality checks.

5 The unit Pre-sales check list

Dealer	
Dealer contact person	
Clinic name	
Clinic contact person	
Clinic address	
Clinic tel.	
Clinic IT contact	
Targeted installation date	
Targeted application training date	
Signature & Date	Sales person
	End user

One copy to sales person and one copy to end user.

5.1 Physical Environment Requirements

	RESPONSIBILITY	APPROVAL LEVEL			
		OK	Does not meet the specs	Modification needed	Comment
Transport and short term storage:	Temperature -10°- +60°C Humidity 0-85 RH%	End User/Dealer			
Use:	Temperature +10°C - +35°C Humidity 0-85 RH%	End User/Dealer			

5.2 Radiation Shielding Requirements

Room:	Local regulatory requirements must be met. For more info, contact local regulatory office.	End User/Dealer				
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5.3 Mechanical Specifications

(see image 1&2)

Installation space:	Pan/3D: Minimum installation space Depth: 1700 mm Width: 1500 mm Height: 2410 mm at minimum (max height adjustable from 2110 to 2410) Ceph: Minimum installation space Depth: 1700 mm Width: 2500 mm Height: 2410 mm at minimum (max height adjustable from 2110 to 2410)	End User/Dealer				
Fixing hardware	Required fixing hardware depends on the wall and floor material and it is not delivered with the unit. The fixing hardware, as well as wall and floor materials must endure a pull-out force of 5000 N. Wall material should be suitable for fixing the unit. If the wall is made of weak material, you may have to use a reinforcing plate on the rear side of the wall to hold the fixing hardware. The person installing the unit is responsible for fixing hardware. Check that it is possible to drill holes in the floor without damage to any electrical or water pipes etc.	Dealer				
Weight:	The fully assembled unit with ceph weighs 245 kg / 450 lb (212 kg / 467 lbs without ceph). Make sure that the floor where the unit is to be installed can support this weight. The floor should be able to carry minimum 1000kg / m ² .	End User/Dealer				

5.4 Electrical Specifications

Power network	100-240VAC, 50/60Hz (10A@230VAC, 15A@110VAC) dedicated power supply, max. 0.2Ω line impedance. Separate outlets for the unit and Workstation PC.	End User/Dealer				
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5.5 Networking Specifications

	RESPONSIBILITY	APPROVAL LEVEL			
		OK	Does not meet the specs	Modification needed	Comment
1Gb/s network to all components involved with the unit system	<p>The connection between the unit and PC must meet EN60601-1 requirements.</p> <p>The unit shipment comes with a Cat6 UTP (unshielded twisted pair) network cable, 5m in length. Other "Cat6 UTP"- cables can also be used with the unit when necessary.</p> <p>If the unit is connected to the Workstation PC via a network switch, the switch and network configuration must allow 1Gb/s communication speed.</p>	End User/Dealer			
IT Administrator available during installation	The end-user IT administrator shall be present during installation in order to keep promised installation schedule and guarantee successful set-up.	End User/Dealer			

5.6 Computer Specifications

<p>Minimum PC requirements for Modality workstation (3D acquisition workstation):</p>	<p>Standard: The PC must meet the IEC 60950 standard (minimum requirements)</p> <p>Operating system: Windows 7 or Windows Vista (32 or 64-bit), Windows XP Professional (32-bit)</p> <p>Processor: 2.5 GHz dual core, or better</p> <p>Main memory (RAM): 3 Gigabytes RAM, or more</p> <p>Hard disk: 500 GB, or more</p> <p>Network adapter: Gigabit Ethernet network interface</p> <p>Graphics card: GTX 460 Nvidia Quadro GPU, FX 3800 Nvidia Quadro (Nvidia driver version 197.13 or newer)</p> <p>Contact TechSupport@gdex.com for update information about the approved graphics cards</p> <p>PCI board connection: Full-length PCIe x16 slot (for GPU board)</p>	<p>End User/Dealer or optionally Gdex Dental Systems</p>				
	<p>USB: Minimum 2 USB ports (for HASP Dongle keys) <ul style="list-style-type: none"> • 1 for reconstruction system (Dongle supplied with Mercury GPU Kit) • Spare </p> <p>Color monitor size: 20" 2MP LCD display, 1600 x 1200 (19" 1.3MP LCD 1280 x 1024, minimum)</p> <p>Power supply: 550 watt power supply with two 6-pin power cables (for GPU)</p> <p>Mouse: Mouse with scroll wheel</p>	<p>End User/Dealer or optionally Gdex Dental Systems</p>				

NOTE! This is an abbreviated list of requirements.
Refer to the software installation manual or contact your local dealer for detailed installation requirements.

5 The unit Pre-sales check list

20" 2MP LCD display, 1600 x 1200 pixels, (19" 1.3MP LCD 1280 x 1024, minimum) 32 bit color	<p>Displays (monitors) should be tested for quality on location.</p> <p>1. Brightness at least 120 cd/m², recommended 200 cd/m². 2. Maximum static (NOT dynamic) contrast at viewing conditions: 1:400 (minimum), 1:1000 (recommended). We recommend the use of SMPTE-Test image to verify the resolution and high and low contrast 5% fields. In addition the real contrast should be measured in respect to the local environment conditions (ambient light) at the viewing station. 3. If applicable, check local requirements</p>	End User				
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Minimum PC requirements for Viewing workstation for 2D/3D images:	<p>Standard: The PC must meet the IEC 60950 standard (minimum requirements)</p> <p>Operating system: Windows 7 or Windows Vista (32 or 64-bit), Windows XP Professional (32-bit)</p> <p>Processor: 2.0 GHz dual core, or better</p> <p>Main memory (RAM): 4 Gigabytes RAM, or more</p> <p>Graphics card: Ati Radeon HD4650 or higher, Ati Radeon HD5650 or higher, Nvidia GeForce 260, 460, 560, or higher, 256MB or more memory</p> <p>Hard disk: 3 GB free space, or more</p> <p>Network adapter: Gigabit Ethernet network interface</p>	End User				
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- 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.
- 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
 - evidence that 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.

5.7 Backup Specifications

The imaging software database must be backed up with an appropriate backup system.	It is recommended to use a suitable backup system that can easily be removed for off-site storage. For more info about database backup, please refer to the imaging software Installation Manual.	End User				
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5.8 Software configuration

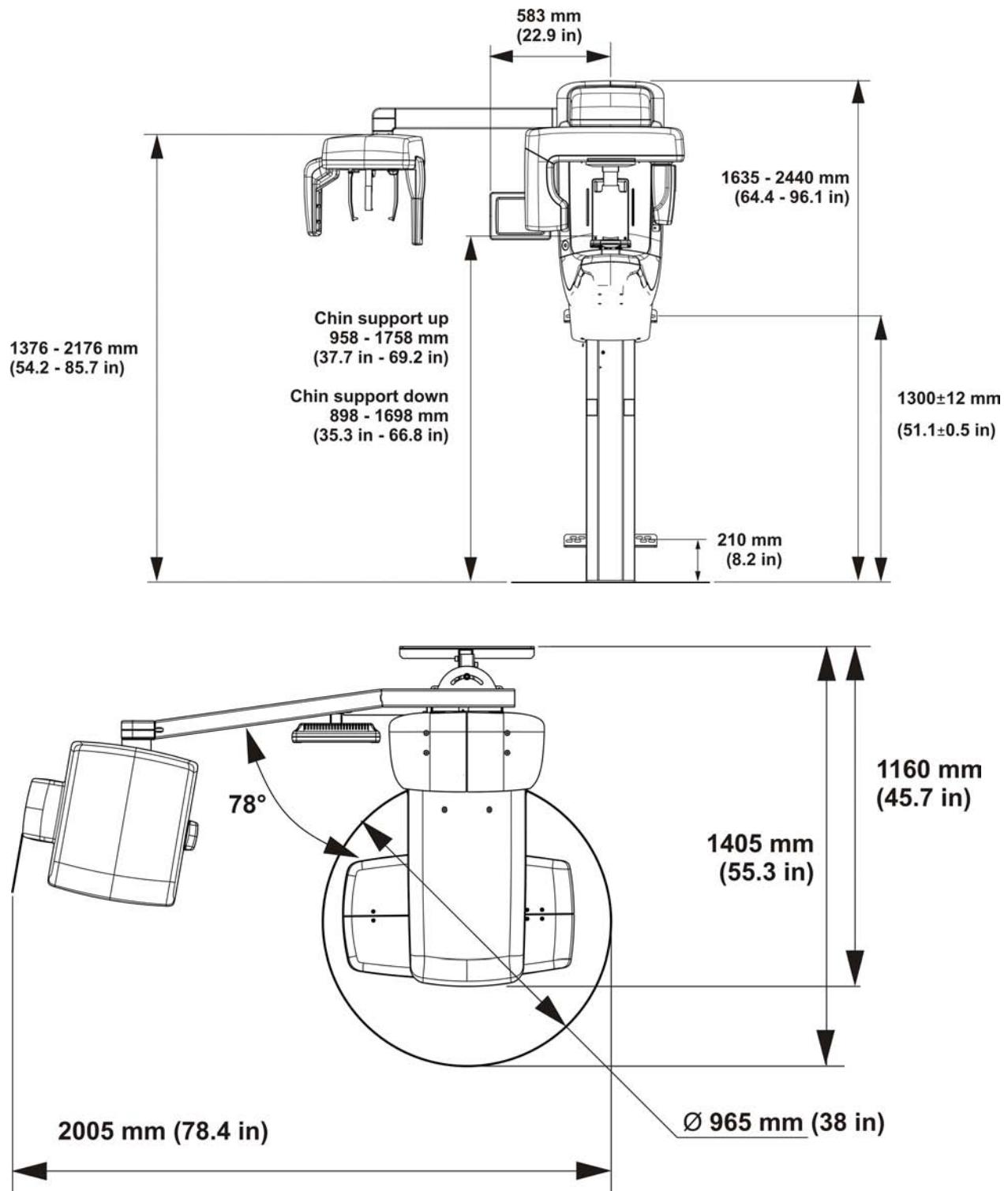
		YES	NO	DETAILS
Which software components are included in delivery?	The imaging software (required)	X		
	InVivoDental			Delivered in US only.

5.9 Other information

3rd party 3D software:	<p>Is the imaging software going to be used with existing 3rd party 3D software?</p> <p>NOTE: Direct link between the imaging software and 3rd party 3D software is available for the following software: Anatomage InVivoDental</p> <p>Additionally, DICOM compatible 3D software (such as NobelGuide) is compatible with the unit system</p>			
DICOM Conformance statement	Have the DICOM conformance statement(s) been delivered to the end-user?			Can be downloaded from Gendex Dental Systems extranet
High speed internet connection	Broadband internet connection to the workstation is mandatory. Software updates and support are handled through remote access (requires end-user confirmation before connection).			
Other Gendex Dental Systems X-ray units	Are any other Gendex Dental Systems digital imaging systems installed in the clinic?			
Imaging software already in use	<p>The imaging software (please provide the version number)</p> <p>Other</p>			

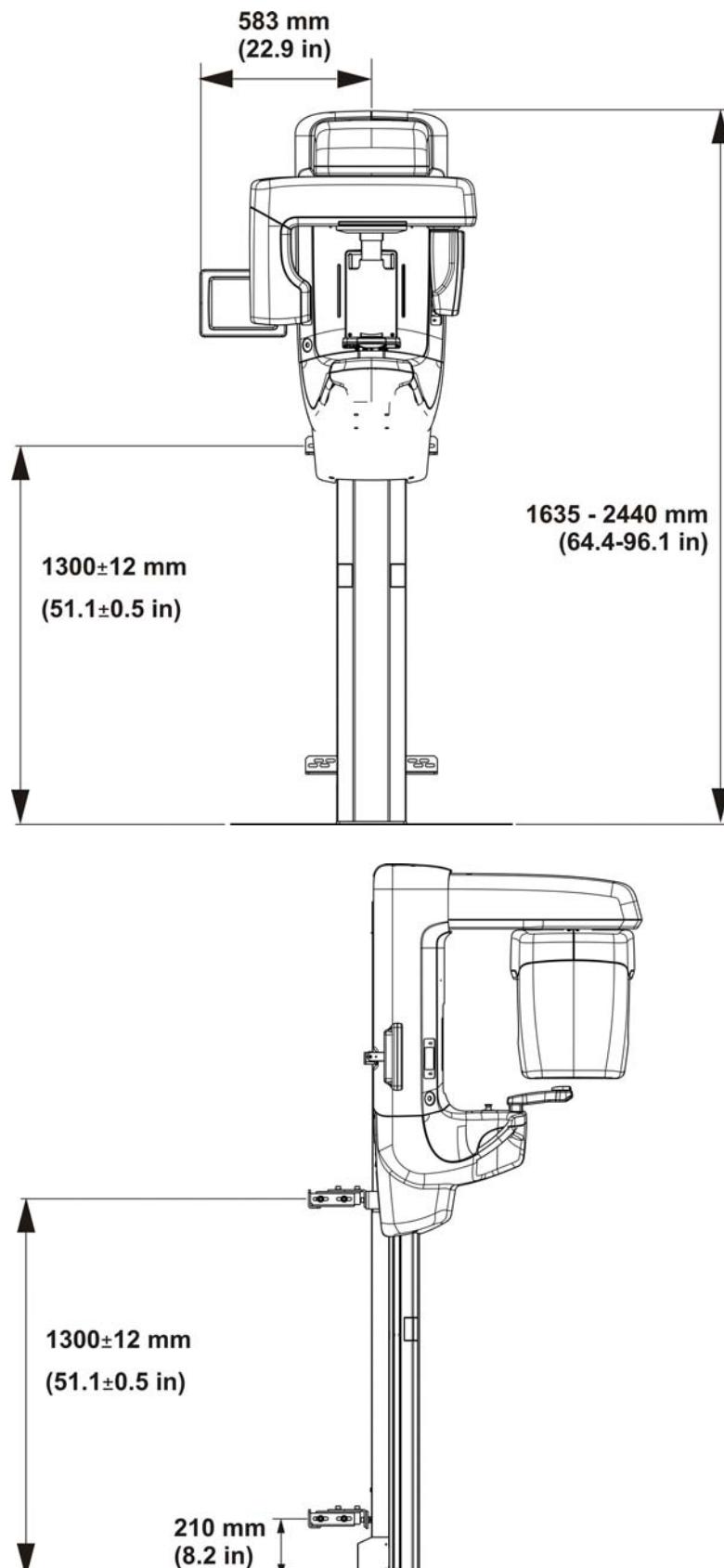
5.10 Notes / comments

5.11 Image 1: Dimensions with ceph



NOTE! The cephalostat arm and the touch screen can be on either side (L/R).

5.12 Image 2: Dimensions of PAN/3D unit



NOTE! The touch screen can be on either side (L/R).

