ORTHOPANTOMOGRAPH™ OP 3D Pro

3D Dental X-Ray System

Installation Manual

ENGLISH

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The original language of this manual is English.

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CE 0537

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1 Introduction

1.1 ORTHOPANTOMOGRAPH™ OP 3D Pro

ORTHOPANTOMOGRAPH™ OP 3D Pro is a dental X-ray system for producing high quality digital images of dentition, TM-joints and skull. In order to take images with OP 3D Pro you need a suitable PC hardware connected to the OP 3D Pro unit and CLINIVIEW™ imaging software to capture and manage images. The OP300 performs the following procedures:

Panoramic

- Standard panoramic
- Pediatric panoramic
- Wide arch panoramic
- Bitewing
- TMJ, posterior-anterior (PA) projection
- TMJ, lateral projection (axially corrected)
- Ortho TMJ, axial corrected lateral projection
- Maxillary sinus
- Ortho Zone enhanced panoramic
- Orthogonal panoramic

Cephalometric (optional)

- Cephalometric lateral projection
- Cephalometric pediatric lateral projection
- Cephalometric postero-anterior (PA) projection
- Reverse Towne projection
- Waters view
- Carpus program (optional) (Not available in USA and Canada)

3D Small panel (optional) H x W

- 61 x 41 mm Field of View
- 61 x 78 mm Field of View

3D Medium panel, H x W (optional)

- 50 x 50 mm Field of View
- 61 x 78 mm Field of View
- 78 x 78 mm Field of View
- 78 x 150 mm Field of View
- 130 x 150 mm Field of View (optional)

NOTICE! *The FOV heights are maximum values measured at the center of the FOV, the measured heights 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 Associated documentation

- OP 3D Pro User manual
- OP 3D Pro Service manual
- CLINIVIEW software user manual
- CLINIVIEW software installation manual
- The user manual supplied with the 3D imaging software
- The installation manual supplied with the 3D imaging software

1.4 References

The following instructions are delivered with in the OP 3D Pro installation manual:

- Firmware update instructions

- Calibration instructions
- Cephalostat upgrade instructions
- Cephalostat side changing instructions

1.5 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

ADC = Automatic Dose Control

LDT = Low Dose Technology™

MAR = Metal Artifact Reduction

1.6 Warnings and precautions

1.6.1 Warnings for cross infection

Always use available disposable protective covers with the patient positioning accessories:
- Bite fork cover
- Chin support cover
- Head support cover
- Nose support cover
- Ear holder cover

1.6.2 Warnings to be observed during installation and service

In case the transportation package has been damaged, make sure the actual product is fully intact.

Before attempting to service the device make sure that you know how to operate it. Read the user's manual.

Read and familiarize yourself with the warnings and precautions listed in the user's manual.

Only use original spare parts from the manufacturer when repairing the device or replacing parts.

Warning - Radiation Safety

Before servicing the unit familiarize yourself with local and national radiation safety standards and requirements relating to dental x-ray equipment.

Warning - Electrical Safety

Disconnect the unit from the main power supply before removing any covers.

Disconnect the unit from the main power supply before repairing or replacing mechanical parts or installing accessories.

Be careful when operating the unit not to get body parts or clothing trapped between moving parts.

Disconnect the unit from the mains power connection before servicing the unit, e.g. replacing circuit boards or other electrical components.

If there are capacitors on a circuit board or electrical device wait ten (10) minutes, after disconnecting the unit from the power supply, before handling the board or device.

If you have to leave the unit unattended with covers removed during servicing or maintenance, disconnect the unit from main power supply so that anyone who inadvertantly touches the unit does not receive an electric shock.

This unit should only be used in areas that are provided with a protective earth connection to ensure an equipotential ground connection.

Warning - Explosion hazard

Some disinfectants and cleaning agents may vaporize to form an explosive vapour. If such disinfectants and cleaning agents are used the vapour should be allowed to disperse before switching the unit on.

Warning - Cleaning the unit

Switch the unit off and disconnect it from the main power supply before cleaning or disinfecting the unit.

The aperture plate and the tube housing are made of lead (Pb), which is a toxic material. Do not touch it with your bare hands.

The installer must ensure that:

- The fixing screws are suitable for the wall material.
- The wall for fixing the unit is strong enough for attaching the unit. It must withstand loads of 5000N or more.
- Pull out strength of the screws is 5000N or more.
- The wall fixing screws are adequately tightened.

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.

The installer must ensure that the upper shelf attachment screws are tightened.

The unit should be installed in a place with enough space for safe operation. See the unit installation manual for recommended minimum site dimensions. It is the responsibility of the customer to ensure that the site is large enough for the patients.

Be aware of hot surfaces when removing covers during installation and maintenance.

When installing a dental X-ray unit always observe local and national safety, radiation control and electrical regulations.

1.6.3 Cautions for Electrostatic discharge

Electrostatic Discharge (ESD) can damage or destroy electronic components.

When servicing the device take precautions to avoid electrostatic build up and discharge (ESD). Follow the recommendations for the prevention of ESD that are used in the country in which you are working. If no recommendations are available follow the guide lines below.

Leave all new or replacement circuit boards and electrical parts in their protective packaging until the boards are needed.

Before handling circuit boards and electrical parts make sure that any static electricity charge that has built up in you body is discharged.

When handling circuit boards hold them by their edges and do not touch any connectors or components.

When examining and checking circuit boards use an elasticated wrist wrap which is connected to a ground point through a 1 Mohm current limiting cable. For a ground point use water pipes, radiators or other objects that are known to be connected to the ground. Also use a cable to connect the x-ray unit to the same ground potential as the wrist wrap.

If an antistatic mat is used, connect the wrist wrap to the mat and the mat to the ground potential.

Wash the wrist wrap and check that it is in good condition frequently.

1.6.4 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 intraoral 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.

1.7 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.

1.8 Disposal

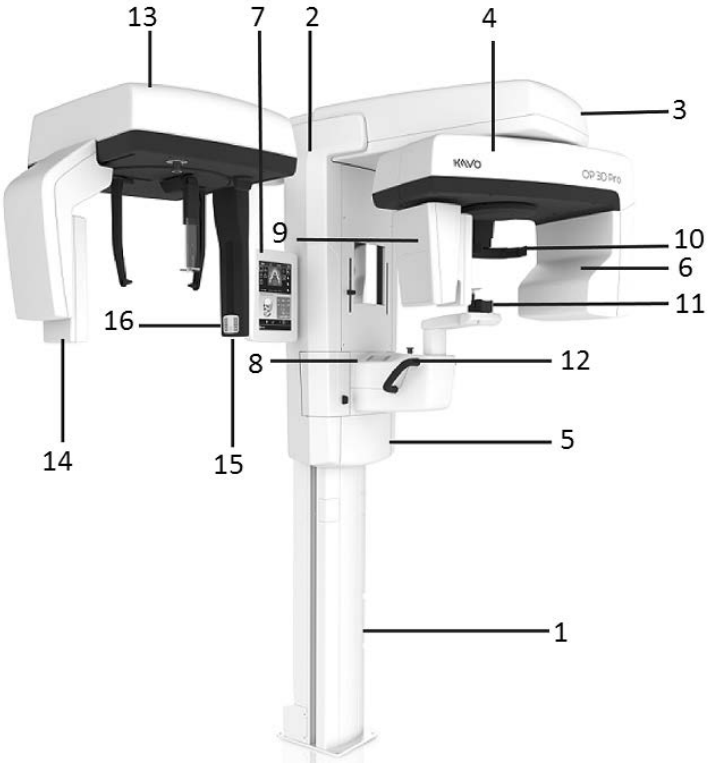
The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal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

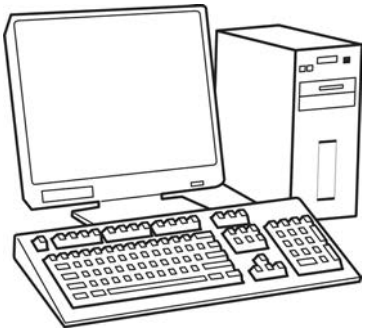
2 Unit description

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. Touch screen display
8. Patient positioning panel
9. Sensor head
10. Head support
11. Chin rest
12. Handles
13. Cephalostat unit
14. Cephalostat sensor
15. Secondary collimator
16. Patient positioning panel

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

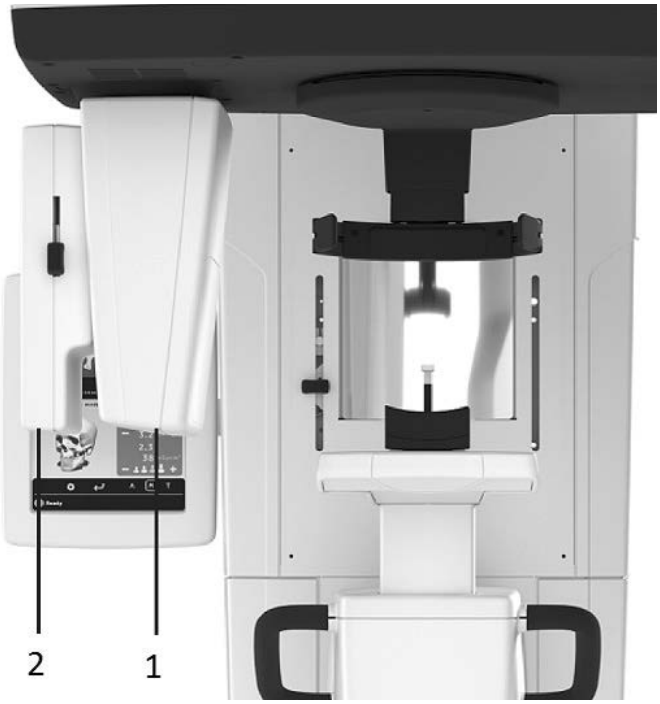


PC with MDD approved dental imaging software and 3D viewing software (not included).

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

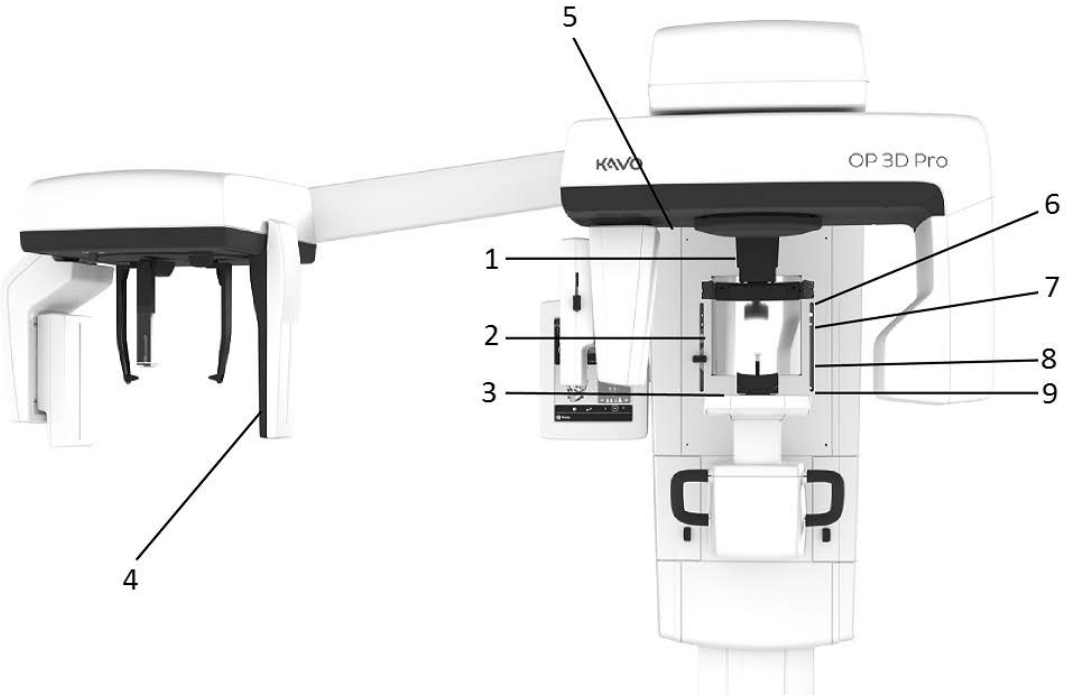
The PC must conform to all the unit and dental imaging software requirements.

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



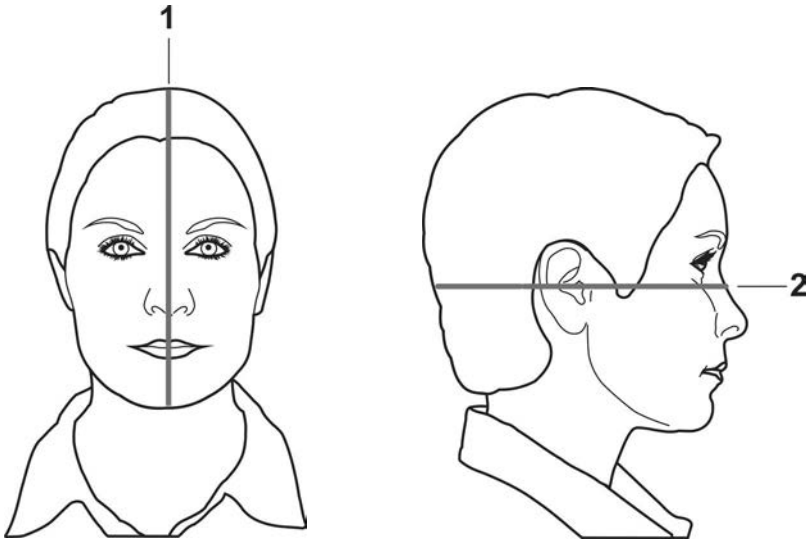
1. 3D sensor (units with 3D option)
2. Panoramic sensor

2.2 Patient positioning lights

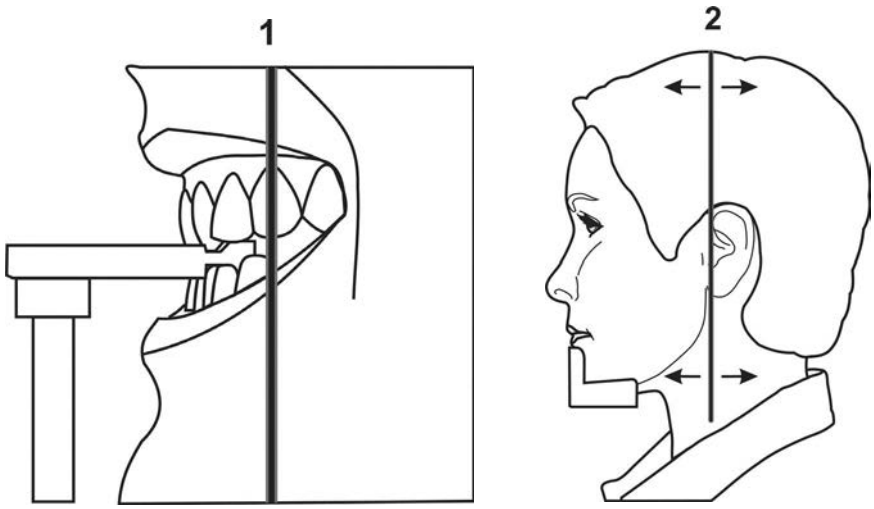


1. Midsagittal light
2. Frankfort horizontal (FH) light /
   Horizontal light, top of 130 mm high FOV (Medium Panel 3D option only)
3. Image layer light
4. Cephalometric FH light
5. TMJ light
6. Horizontal light, top of 78 mm high FOV
7. Horizontal light, top of 61 mm high FOV
8. Horizontal light, top of 50 mm FOV
9. Horizontal light, bottom of FOV

Panoramic lights

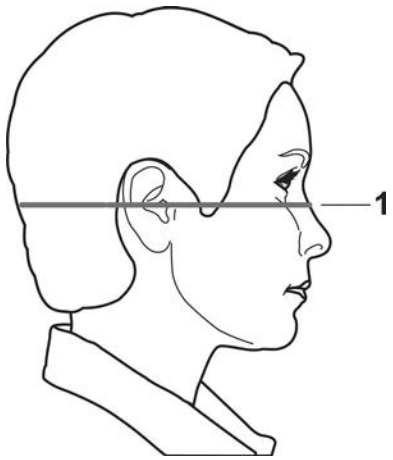


1. Midsagittal light
2. FH light



1. Image layer
2. TMJ light

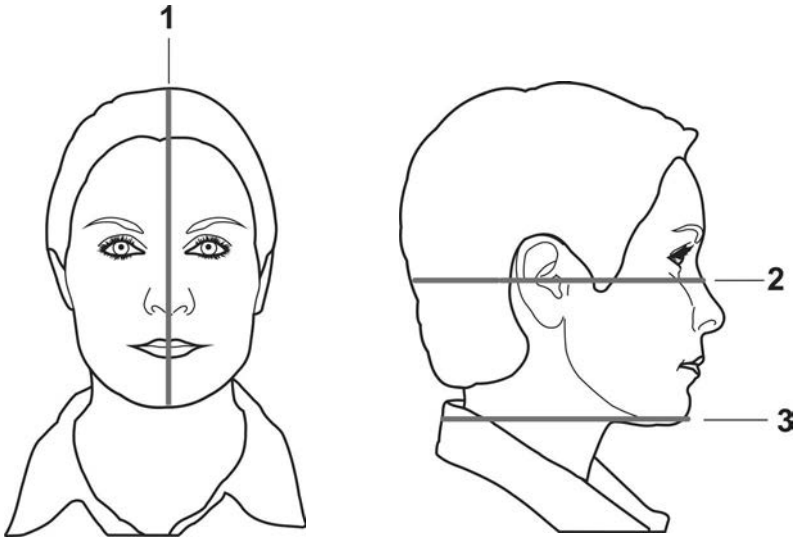
Cephalometric lights (optional)



1. FH light

3D lights (optional)

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

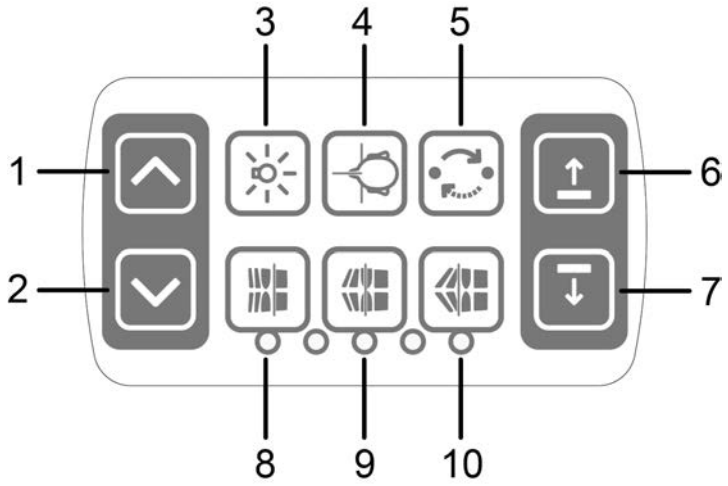


1. Midsagittal light

2. Horizontal light, top of FOV
   NOTICE! *With Medium Panel 3D option, Optional 130 mm height is indicated with Frankfort horizontal (FH) light. Move FH light to 130 mm position (locked in up-position).*

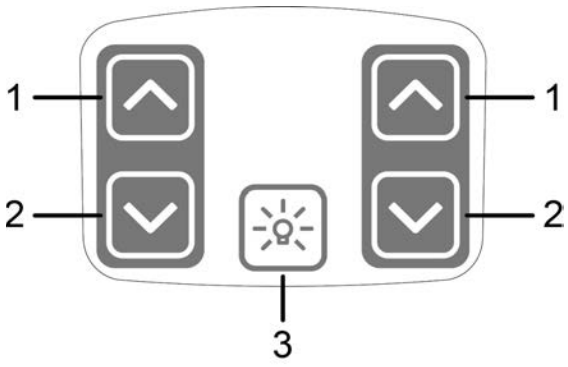
3. Horizontal light, bottom of FOV

2.3 Patient positioning panel



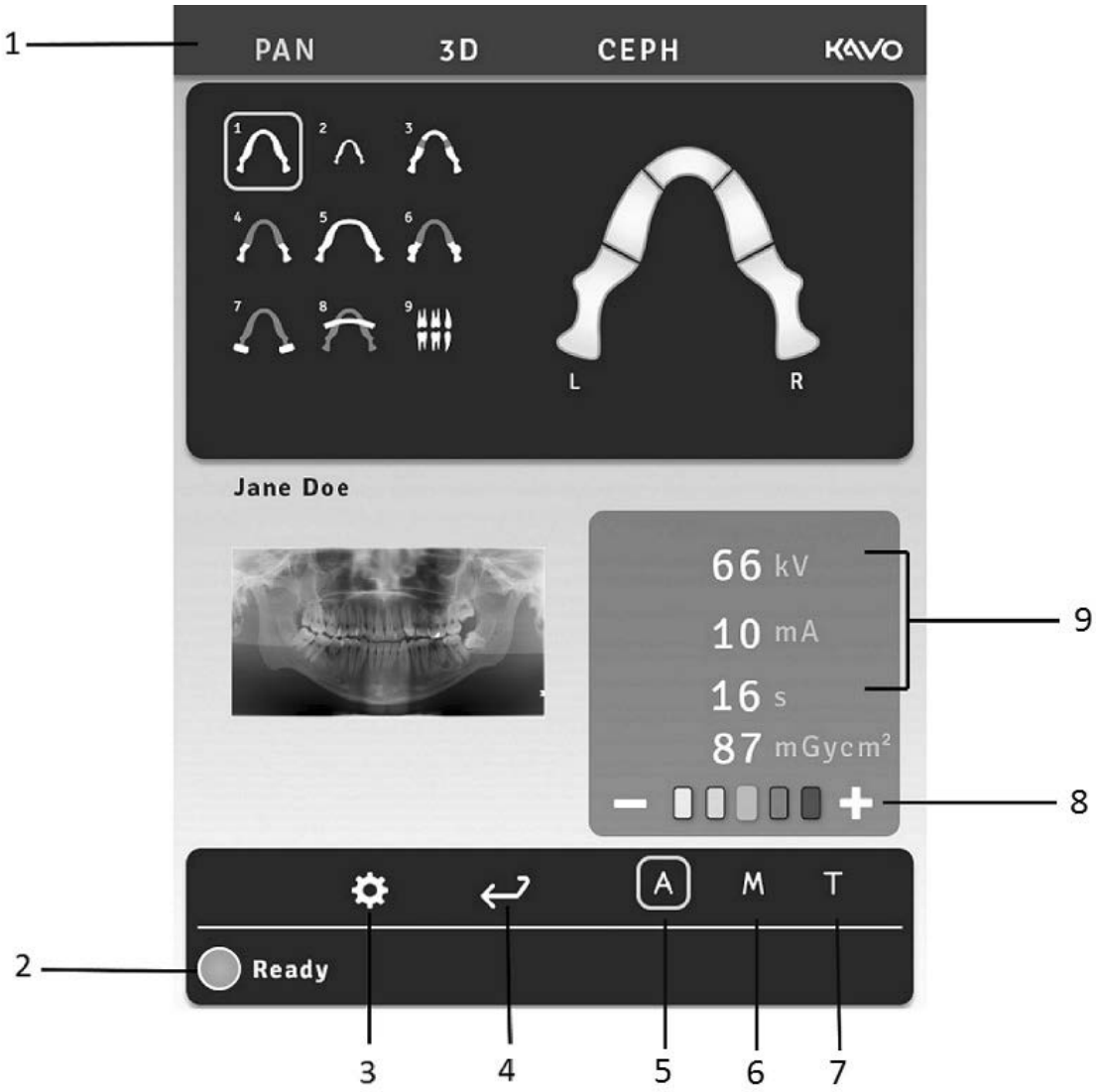
1. Carriage UP
2. Carriage DOWN
3. Positioning lights ON/OFF
4. Patient positioning
5. Start position
6. Chin support UP
7. Chin support DOWN
8. Move the image layer anterior before exposure 3 mm, with sinus program 10 mm
9. Normal occlusion/ reset position
10. Move the image layer posterior before exposure 3 mm, with sinus program 10 mm.

2.3.1 Cephalometric unit positioning panel



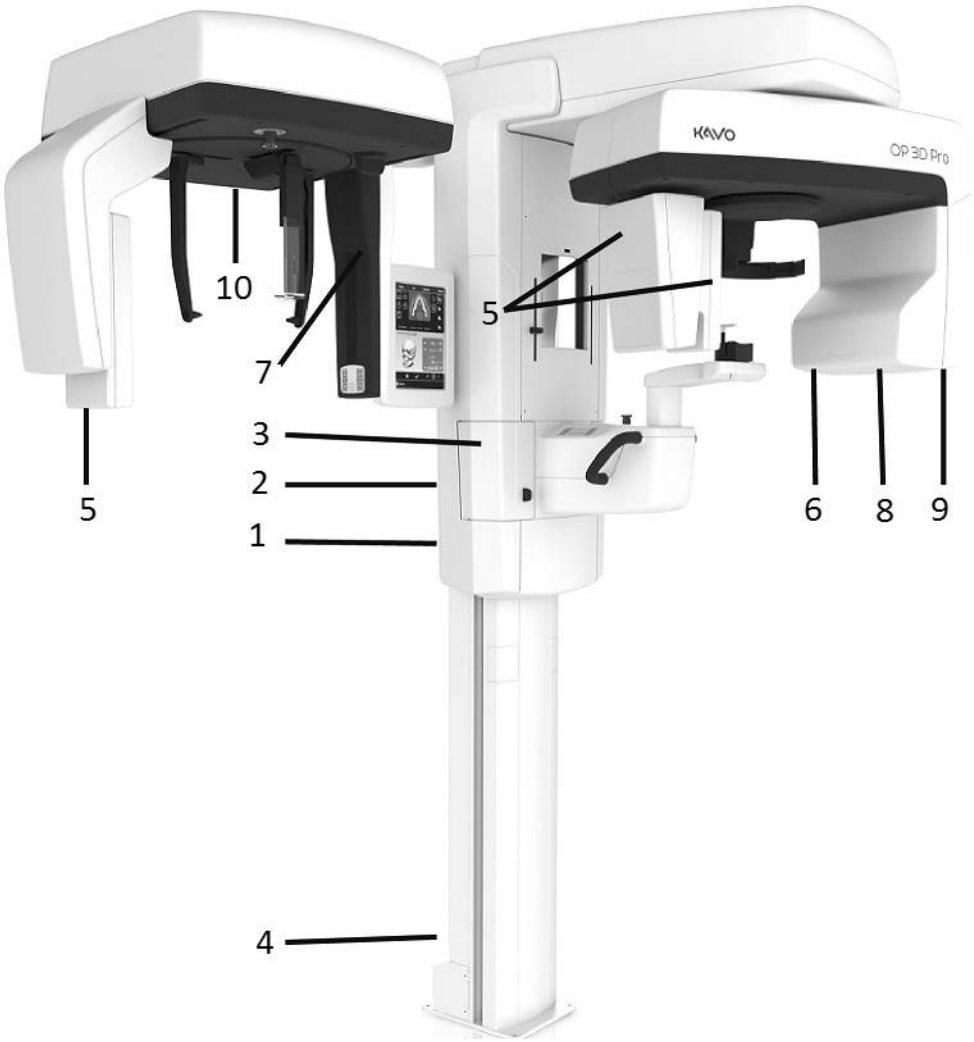
1. Carriage UP
2. Carriage DOWN
3. Positioning lights ON/OFF

2.4 Main control panel



1. Modality / imaging program section
2. Status of the unit
3. Settings
4. End examination
5. Automatic Dose Control
6. Manual mode
7. Test mode
8. Patient size selection
9. Exposure settings

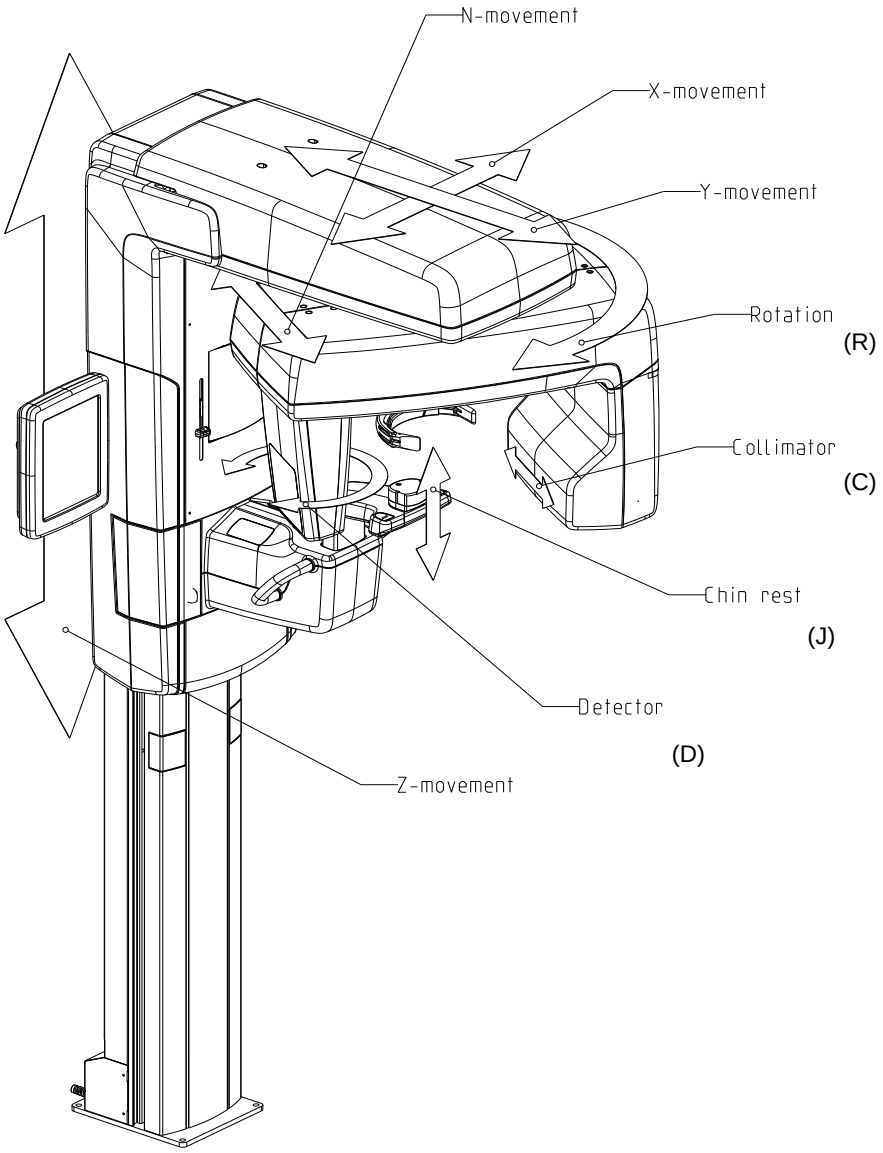
2.5 Unit identification labels



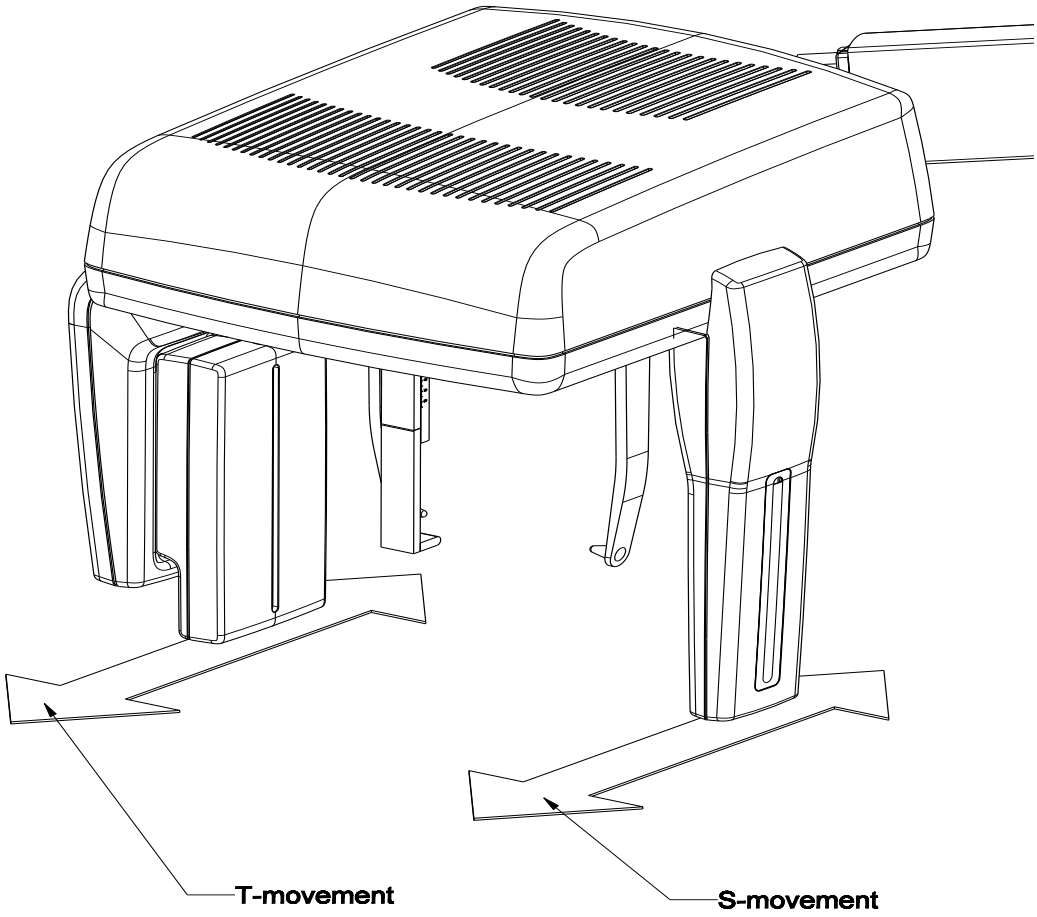
1. Main label
2. 10A & 15A Fuse labels (next to the fuse holder)
3. Laser class 1 warning label IEC 60825-1:2007
4. Ethernet label
5. Sensors
6. (Primary) collimator label
7. (Secondary) cephalostat collimator label
8. Tubehead label
   (on the tubehead and on the tubehead cover)
9. Warning label for deadly voltages
   (inside the tubehead cover)
10. Cephalostat main label

2.6 Unit movements

Panoramic unit movements



Cephalometric unit movements

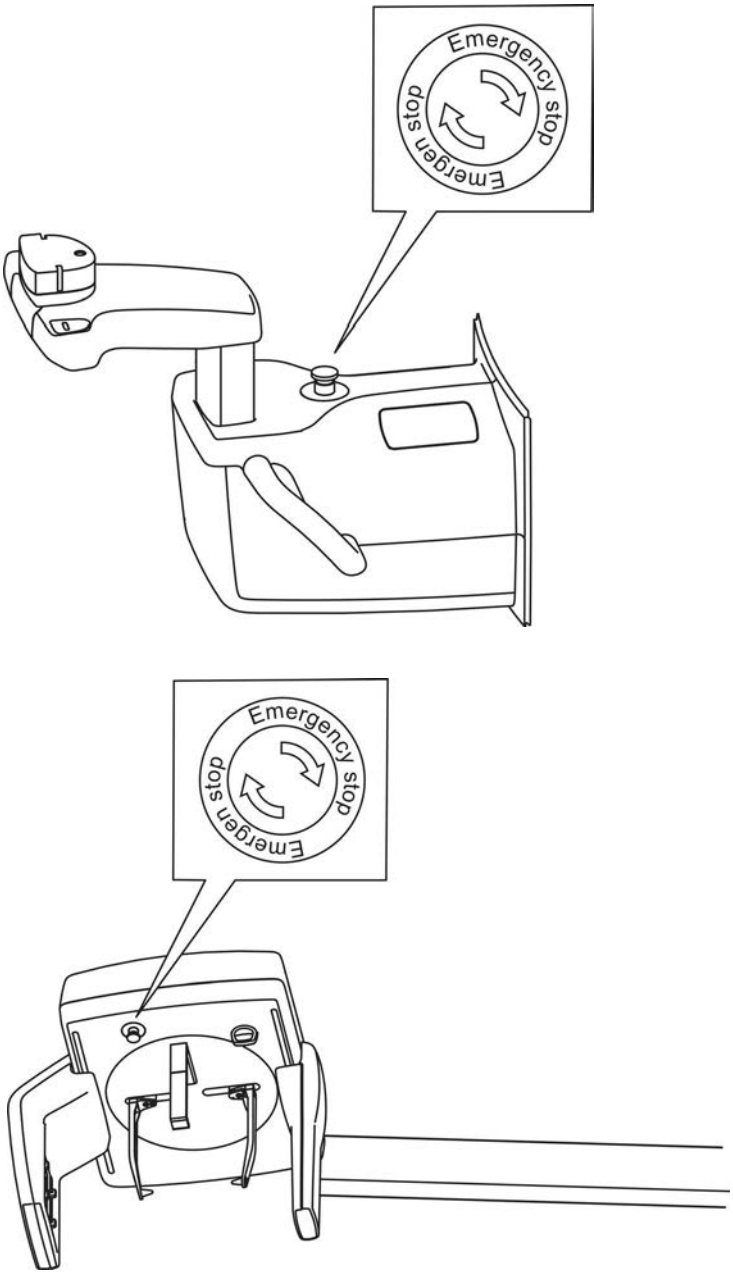


2.7 Emergency stop switch

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.


Emergency stop
Emergency stop
Emergency stop
Emergency stop

3 Pre-installation requirements

3.1 The unit

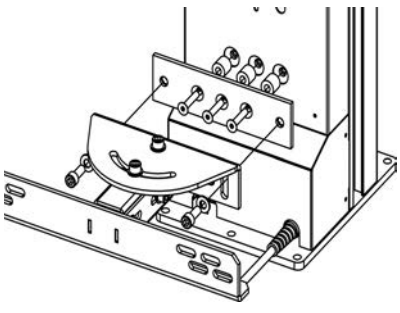
- See chapter 9 OP 3D Pro Pre-sales check list.
- The unit is supplied:

OP 3D Pro Packages	COLUMN (card board)	MAIN SUPPORT AND ROTATION UNIT (card board)	CEPHALOSTAT (card board)
Size (LxWxH) cm:	171 x 65 x 97 cm	118 x 65 x 97 cm	140 x 78 x 88 cm
Size (LxWxH) in:	67.3 x 25.5 x 38.1 in	46.4 x 25.5 x 38.1 in	55.1 x 30.7 x 34.6 in
Gross weight approx.:	170 kg/ 372.5 lbs	114 kg/ 251.3 lbs	66 kg/ 145.5 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, either use additional wall support (ordered separately) or use the exhibition stand and one wall mounting bracket. 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.

NOTICE! *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.

- It is recommended for the installation site to have supply mains over-current releases:
  100-120V: 20A
  220-240V: 15A

- 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 0.2 ohms.

3.2 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:

Depth: 1700 mm, 66.9 inches
Width: 1500 mm, 59 inches
Height: 2410 mm, 94.8 inches at minimum
(max height adjustable from 2110 to 2410 cm, from 83 to 94.8 inches)

Cephalostat:

Depth: 1700 mm, 66.9 inches
Width: 2500 mm, 98.4 inches
Height: 2410 mm, 94.8 inches at minimum
(max height adjustable from 2110 to 2410 cm, from 83 to 94.8 inches)

3.3 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

NOTICE! *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), see chapter 6.5.14 Panoramic Quality Check (optional).

3D calibration and setup tools

- 3D calibration phantom
- QC phantom

4 PC requirements

4.1 Minimum PC requirements

Minimum PC requirements for 2D and 3D acquisition workstation	
Processor	Intel Core i5, i7 or Xeon, 4-cores or more
GPU (graphics processing unit)	NVIDIA Quadro M2000 4GB or GeForce GTX 1050 Ti 4GB
Memory	8 Gigabytes RAM, or more
Hard disk	1 TB or more RAID 1 or RAID 5 recommended for data redundancy, plus backup
Network	Gigabit Ethernet 1000 Mb/s
Operating system	Windows 10 Pro or Enterprise, 64-bit, Windows 8.1 Pro or Enterprise, 64-bit, Windows 7 Professional, Ultimate or Enterprise, 64-bit, with SP1
Display	1920 x 1080 resolution (Full HD) or higher, at least 300 cd/m2 brightness for typical room lighting, native contrast ratio 100:1 or better, 8-bit panel strongly recommended.
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Other	OpenCL 1.1 support DVD-ROM drive Anti-virus software

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 card	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 xray 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.

4.2 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, for example CLINIVIEW™ software.

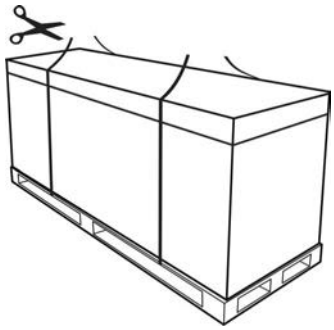
5 Installing the unit

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

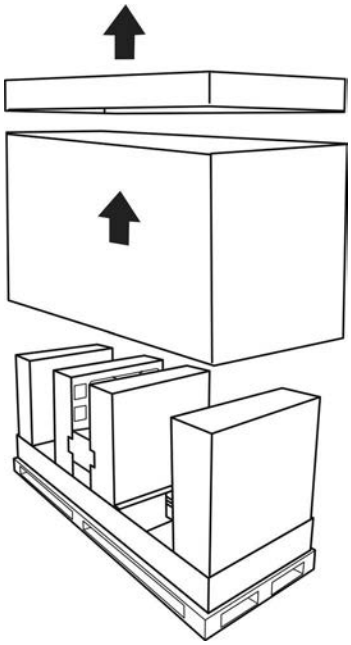
5.1 Content of delivery

COLUMN BOX	CARRIAGE BOX	CEPHALOSTAT BOX (optional)
■ Column ■ Main support top cover ■ Accessories ■ Wall bracket	■ Main support ■ Rotation unit	■ Cephalostat arm ■ Cephalostat head ■ Cephalostat sensor (optional) ■ Accessories

5.2 The column

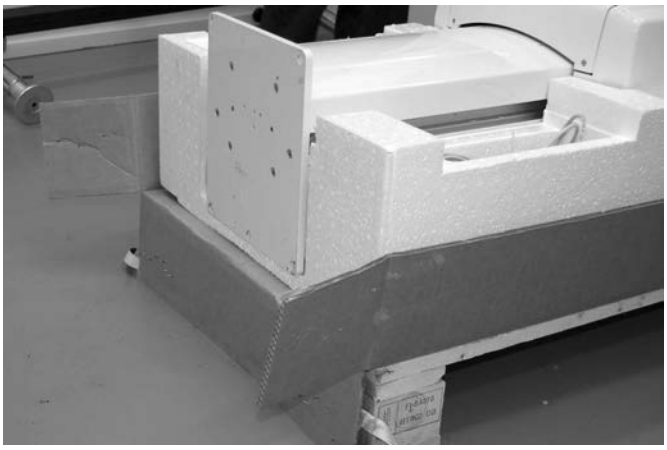


1. Transport the column box (2) to the location where the unit is to be installed.
2. Remove the straps that hold the box to the pallet.

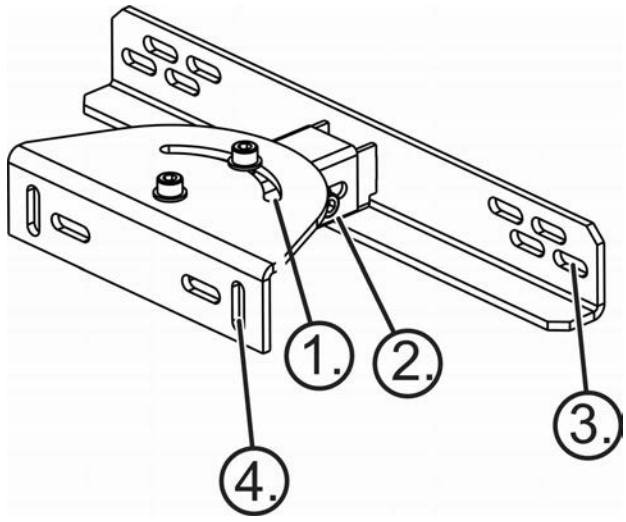


3. Lift off the top of the box and then the sides.

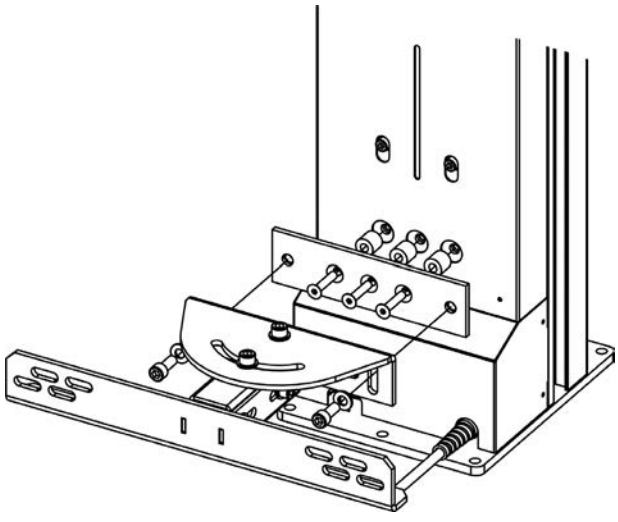
4. Remove the plastic wrap.
5. Remove the accessory boxes and the main support cover.
6. Fold down the bottom end of the box and slide the unit over the edge of the pallet.



7. Attach the wall bracket(s) to wall. The upper bracket is mandatory. The lower bracket is optional.
   • Drill holes according to figure below.
   • Position the wall bracket in the middle of (lateral and lengthwise) the holes in the bracket.



Adjustments:
1) angle
2) depth
3) lateral
4) vertical



Additional wall bracket (lower)

NOTICE! *The unit is normally 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, an additional wall bracket (lower) or exhibition stand*

(206908) is required (ordered separately). At least one wall mount bracket is needed for all installations.

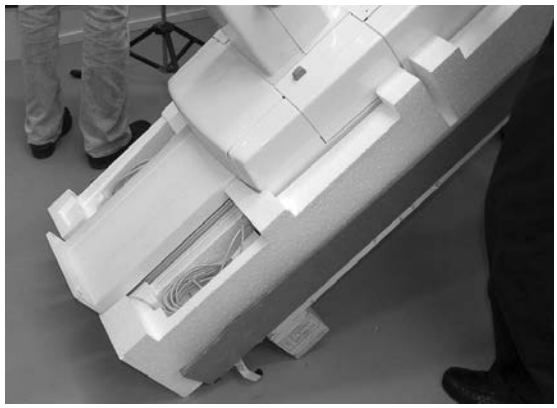
8. Erect the column by lifting from the top. Move the unit to the place where it is installed and set it beside the wall.

   HEAVY OBJECT 87 KG 191.8 LBS
   A minimum of two persons are required for the following task.

   NOTICE! *Follow the local regulations considering lifting heavy objects.*

   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!*



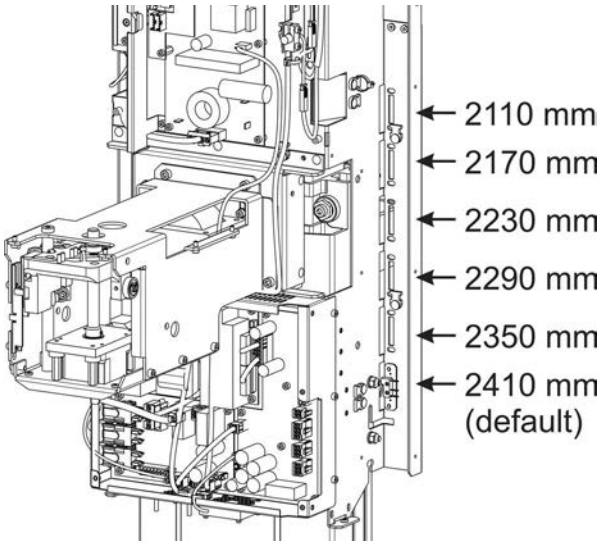
9. Remove the Styrofoam supports.

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

11. Use a spirit level to ensure the column is plumb in both directions.

12. Remove the plastic wrap from top of the column. Remove the side covers by removing two bottom screws and loosening two top screws from the cabin.

13. The default maximum height of the unit is 2410 mm. If the room height is less, the column maximum height must be adjusted.
    The height is adjustable from 2410 mm to 2110 mm by 60 mm steps. Adjust by changing the position of the micro-switch.

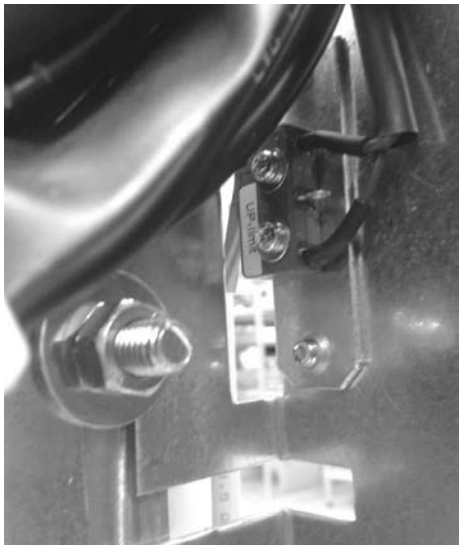


A. Loosen the 2 screws (bottom and upper) of the mirror plate from the right side.

B. Remove the sheet-metal cable guide from the right (11 screws).

C. Open 2 screws holding the micro-switches “UP-LIMIT” and “HEIGHT-DET”. Move the micro-switches to appropriate position.

Microswitches “UP-LIMIT” and “HEIGHT-DET” are attached with the same screws.

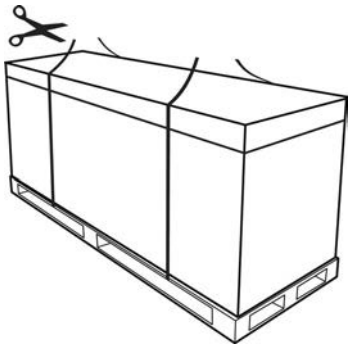


Microswitch UP-LIMIT is inside the cable guide.

5.3 The carriage

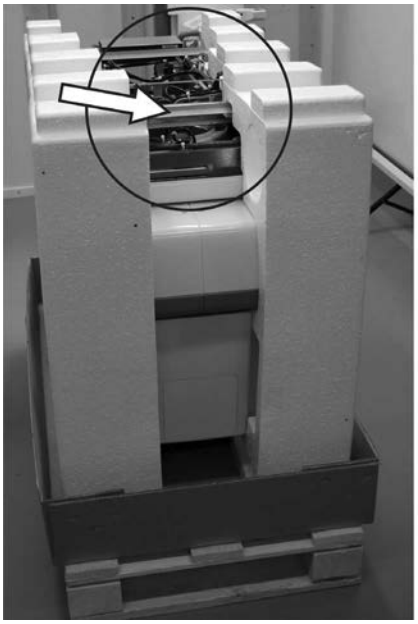
1. Transport the carriage box (number 1) to the location where the unit is to be installed.

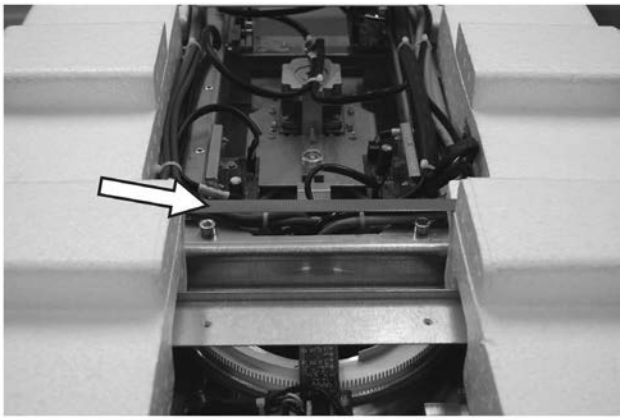
2. Remove the straps that hold the box to the pallet.



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

   NOTICE! *DO NOT cut the strap between the styrofoam supports!*

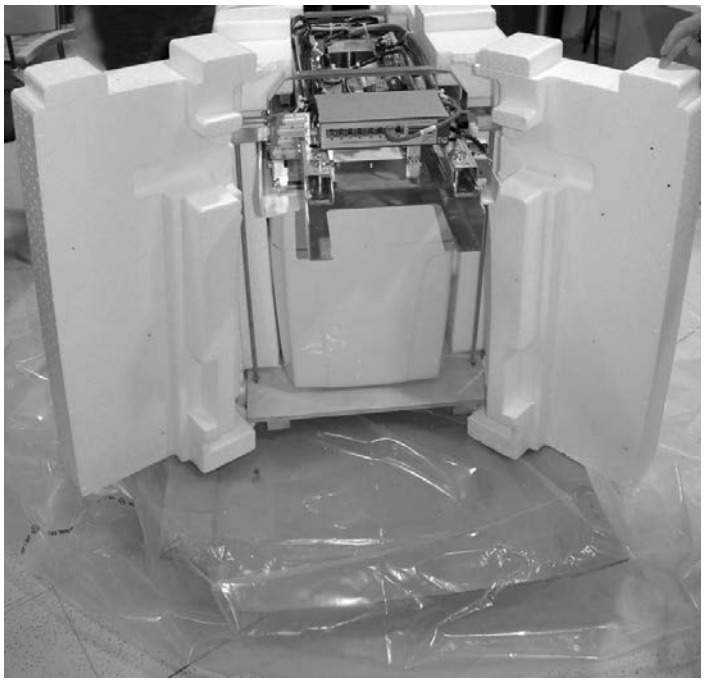




NOTICE! *DO NOT remove the styrofoam material that protects the main support and the rotating unit.*

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.

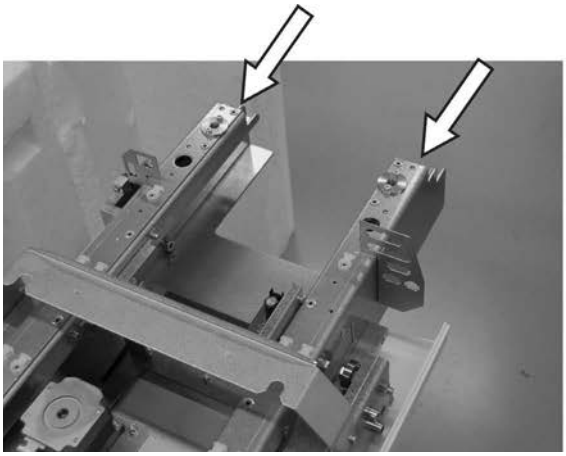


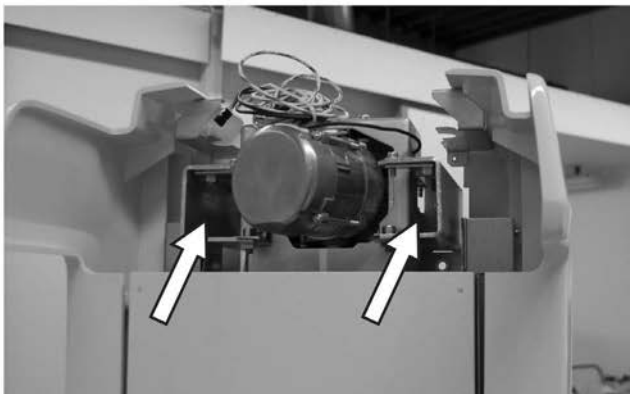
6. Lift the carriage and push it towards the column.
   The lifting places are shown by arrows in the picture.

   CAUTION - HEAVY OBJECT 83 KG 182.9 LBS
   A minimum of two persons are required for the following task.

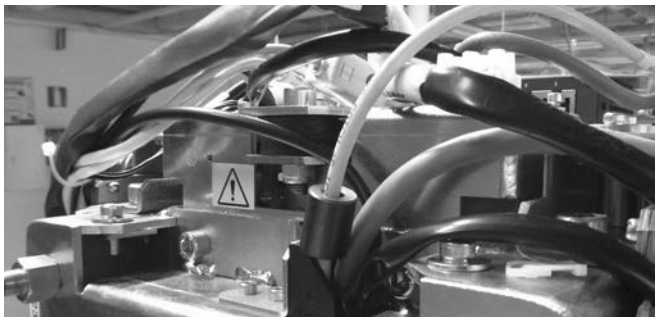
   NOTICE! *Follow the local regulations considering lifting heavy objects.*

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

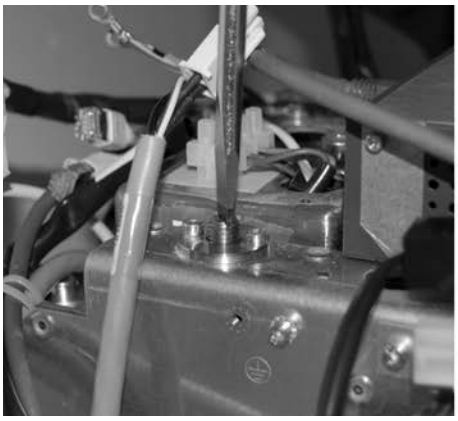


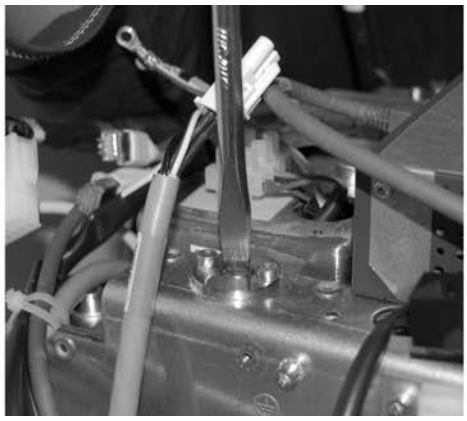


NOTICE! *Caution marking located near the Z-lift motor, indicates, that it contains a mechanical protective device. If the mechanical protective device is activated the part shall be replaced by service personnel.*

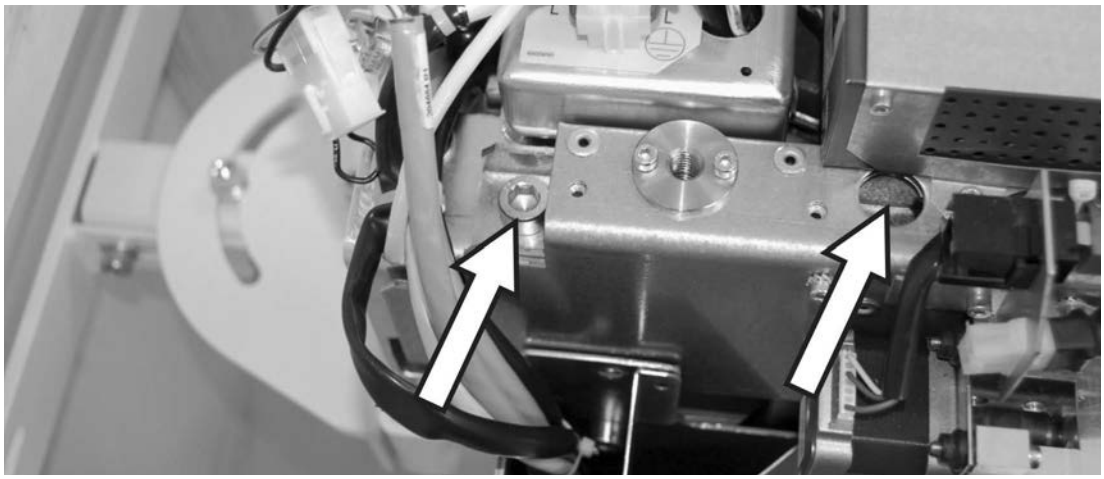


7. Fasten the main support to the column counterpart with 2 guide pins without force. The pins align the main support. Pins are located in the box with the cone phantom.



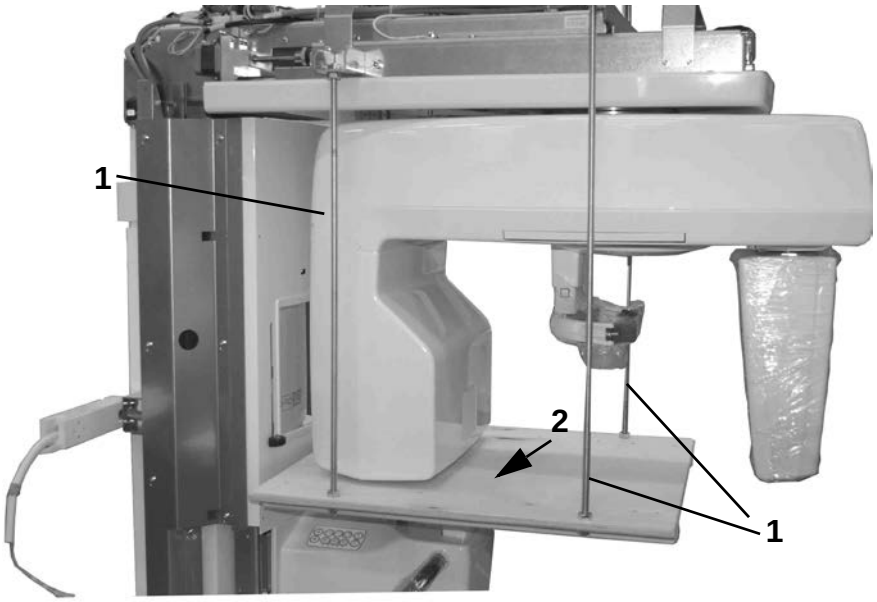


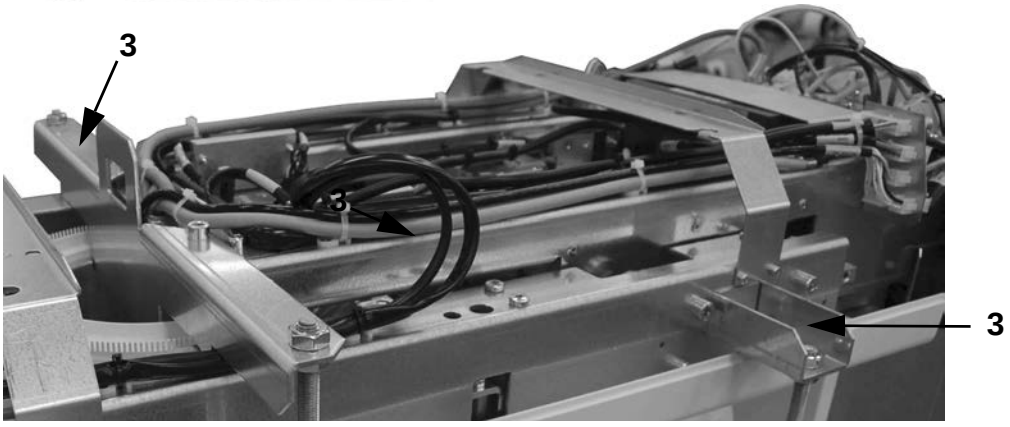
8. Fasten the main support to the column counterpart with 4 screws (M10 x 20mm).



9. Remove the styrofoam material.

10. Remove the transport supports on the main support:
    1) thread bars (4 pcs)
    2) the sheet of plywood
    3) the overhead shipping brackets (3 pcs) and screws.



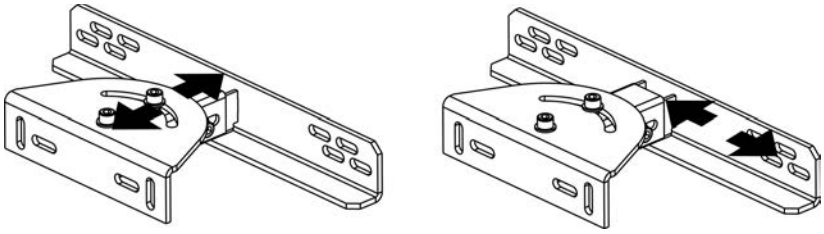


11. Remove the plastic wrap around the sensor.

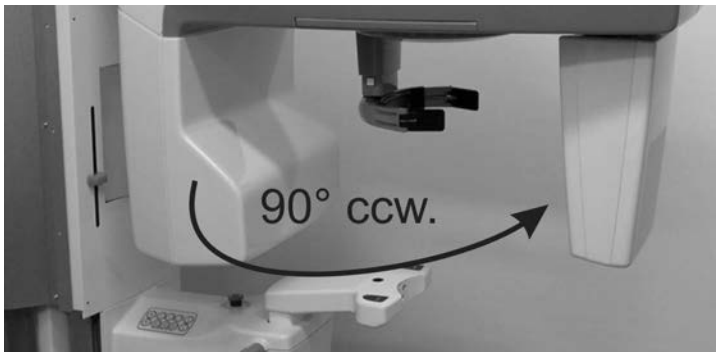
    NOTICE! *The plywood may scratch the chin support. Remove carefully!*

5.4 Check leveling

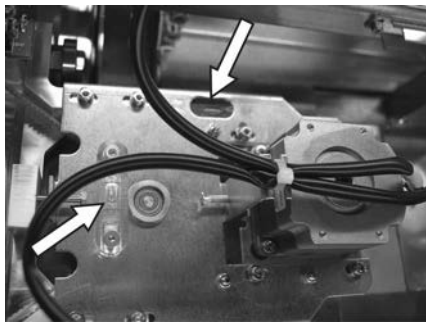
Ensure the unit is level by adjusting the wall bracket(s). The wall bracket allows for the unit to be adjusted all directions.



Before adjusting the tubehead must be turned to front position.



Use the precision spirit levels on the top of the main support. Straighten the unit as accurately as possible to ensure the best image quality

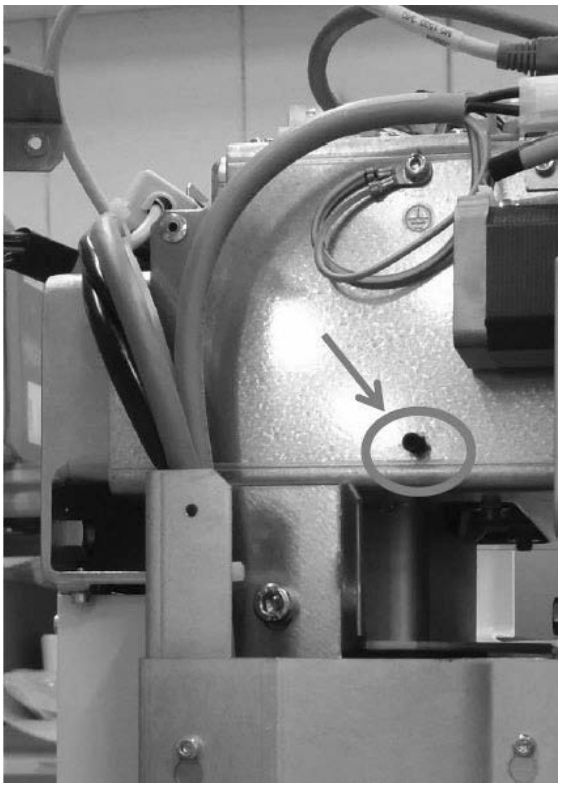


Drill holes and bolt the unit to the floor.
If two wall brackets are used, tighten the lower one to the unit.

5.5 Installing additional set screws and connecting cables

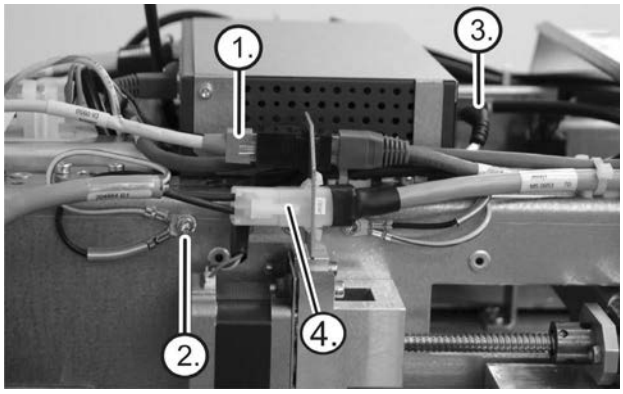
1. Locate 2pcs M6X20 DIN913 set screws from the screw bag.

2. Screws are installed both sides of the unit, close to column and upper shelf joint.



3. Use 3mm hex driver/key to install the set screws on both sides. After both screws are in place, tighten them to final torque of 1Nm.

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

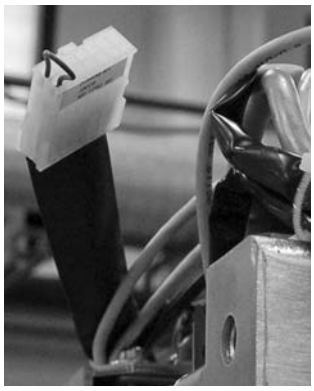


On the left side

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

On the right side

On the top



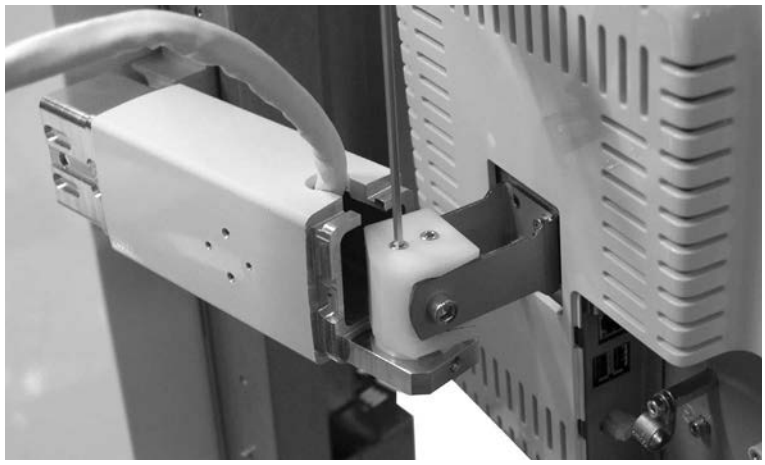
On the top

1 Connector JB006
2 Jumper JB006 (needed for pan/3D unit)

5.6 Attaching the touch screen display to the column (new model)

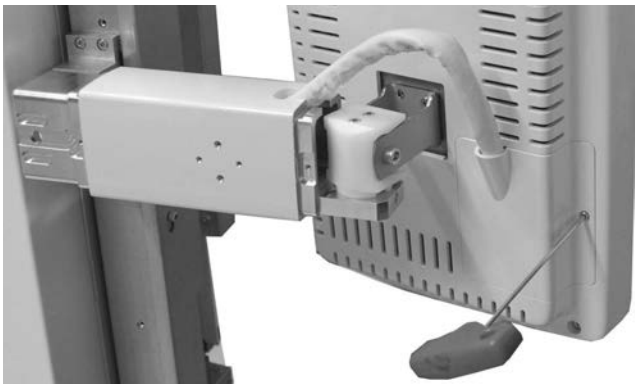
1. Unfasten the touch screen display arm (1 screw) from vertical position and re-fasten it to the horizontal position. One screw is pre-installed.

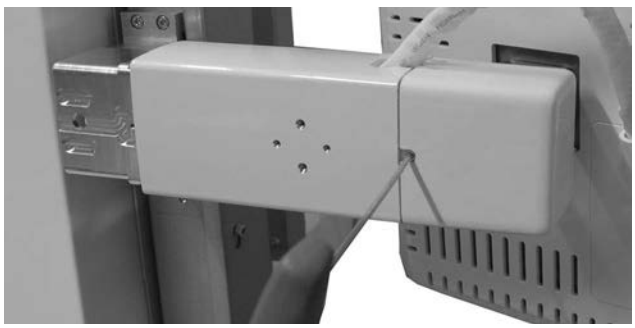
2. Fasten the touch screen display to the arm by 2 screws.

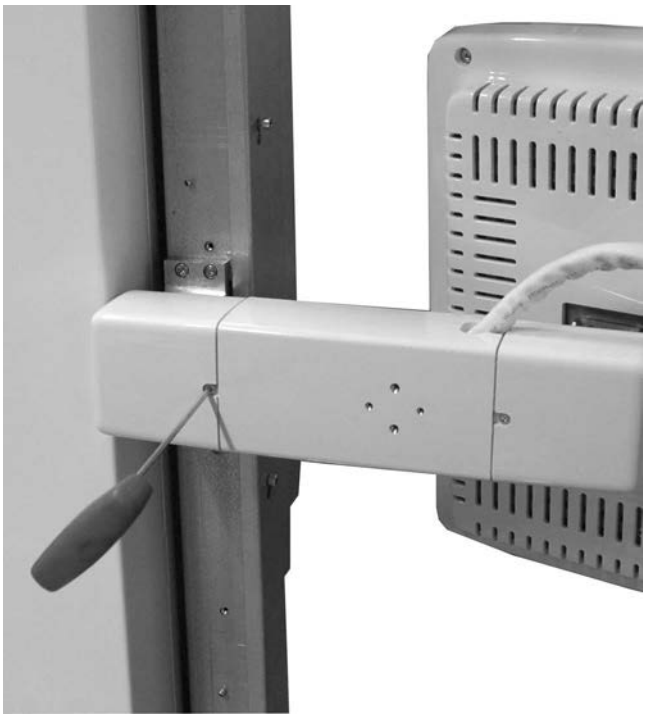


3. Connect the cables (Ethernet, PC power, the grounding cable). The grounding point is indicated in the figure below. Secure the cable with cable clamp on the touch screen display bracket.

4. Fasten the covers.







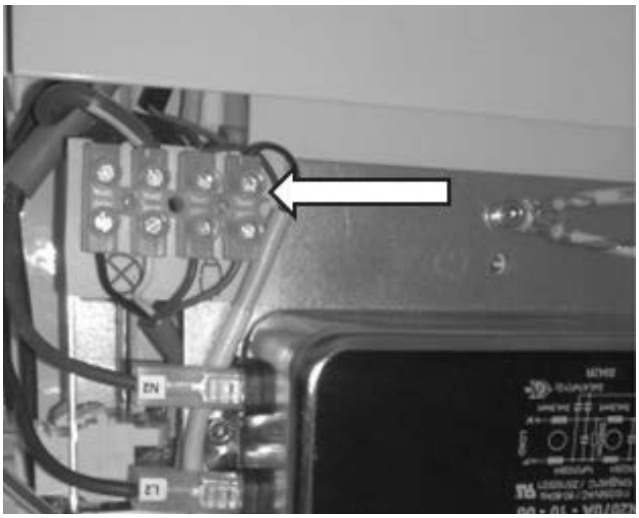
5.7 Exposure button

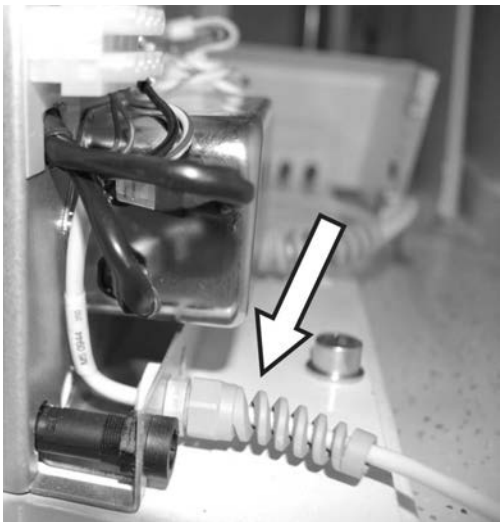
NOTICE! *Exposure button is factory installed with a flexible spiral cable. The following installation is done only if other exposure button (optional) is needed.*

1. Attach the exposure switch holder to the rear of the touch screen display arm.

2. Loosen the screws (DO NOT REMOVE) of the mains inlet cover and remove the cover.

3. Connect the exposure switch cable to the two connectors on the right side of the terminal block at the base of the unit.





4. Put the exposure switch into the exposure switch holder.

5.8 External warning light (optional)

NOTICE! *External max. 230V warning light can be connected only by doing internal modifications. Only authorized technician is allowed to do this.*

NOTICE! These instructions are intended only for the remote exposure button assembly (207502).

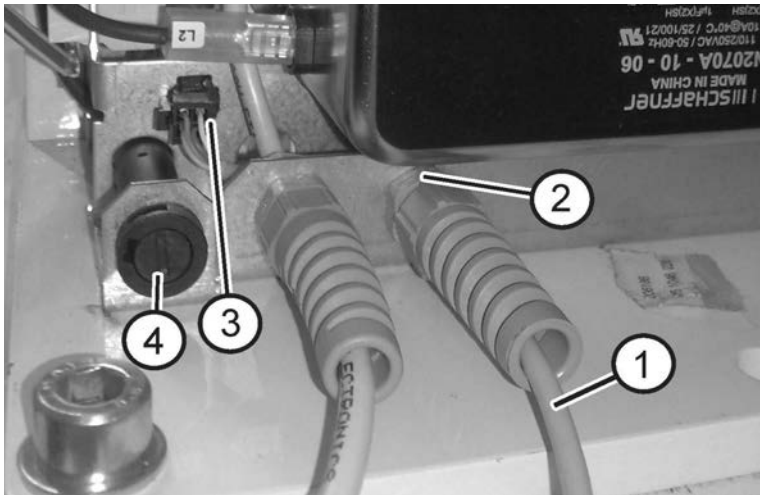
NOTICE! *12V voltage is supplied from the unit for the external warning light. Do not connect any external voltages to this connection.*

1. Attach the device end of the remote controller cable (207264) to its place and tighten the strain relief.

2. Connect the remote controllers cable connector J1004 to its place.

3. Make sure that correct F3 fuse **(T2A, 250V, Interrupting rating 100A@250Vac 10KA@125Vac, 6,3 x 3,2 mm, UR, CSA)** is in the units F3 fuse holder.

1. External warning light cable
2. Strain relief
3. Cable connection J1004
4. Fuse holder F3



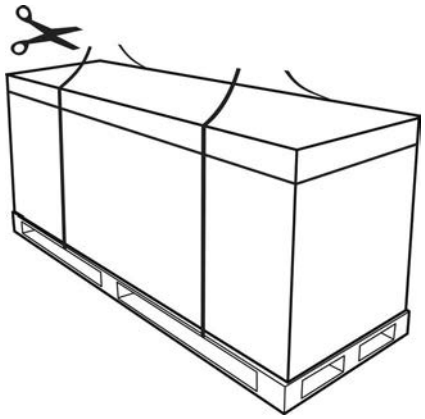
5.9 Installing the cephalometric unit

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

NOTICE! *Check the orientation of the nasion support and the ear holders so that the patient is always facing to the x-ray room.*

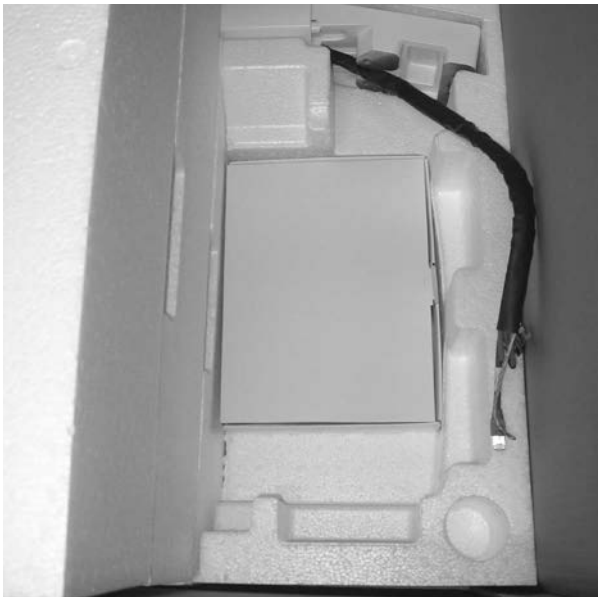
1. Transport the box to the location where the unit is to be installed.

2. Remove the straps that hold the box to the pallet.

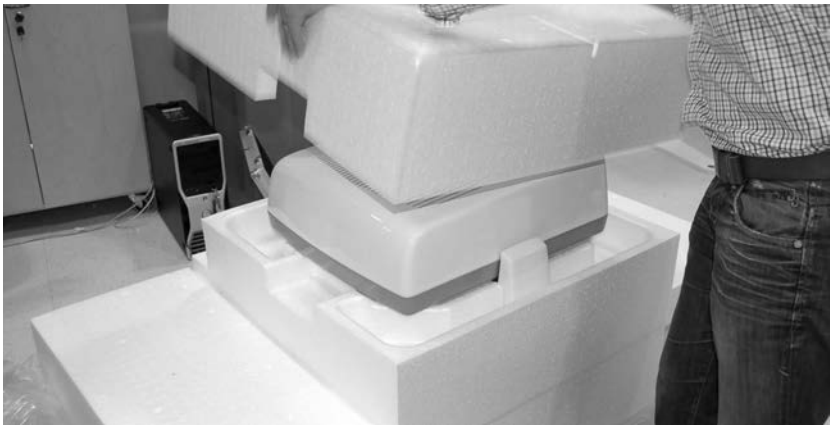


3. Lift off the top of the box and then the sides. Remove the plastic wrap.

4. **Cephalostat upgrade kit:**
   Remove the accessory box. The accessory box contains all the bolts required in the cephalostat unit installation.



5. Lift the upmost packaging styrofoam aside.



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

   NOTICE! Do not pull from the upper packaging cell to avoid causing any stress to the cephalostat head.

   CAUTION! *Lift the cephalostat together with its packing cells. Keep the cells together. Place on a level ground.*

   HEAVY OBJECT 25 KG 55 LBS

   NOTICE! *Follow the local regulations considering lifting heavy objects.*

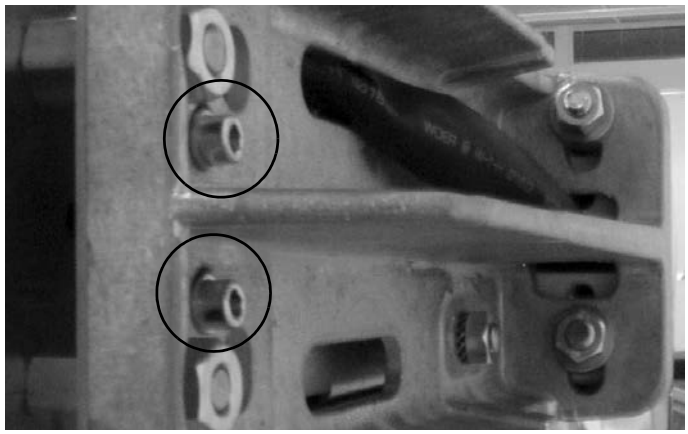
7. **CEPHALOSTAT UPGRADE KIT:**
   Attach the four cephalostat arm installation bolts to the back of the column.

8. Take the cephalostat arm from the box and lift it so that the installation bolts go through the four holes of the cephalostat arm.

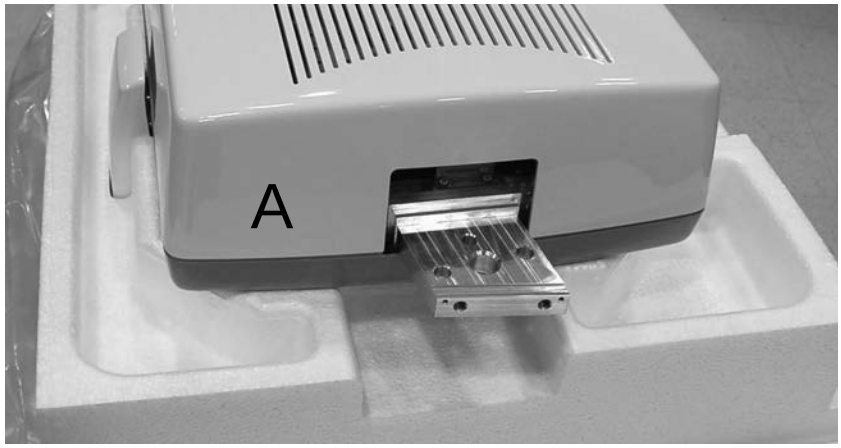
9. Attach and tighten the cephalostat arm to its place evenly with four nuts.

NOTICE! *If the cephalostat arm does not fit to its position, loosen all four nuts and also two screws to fit the arm properly.*

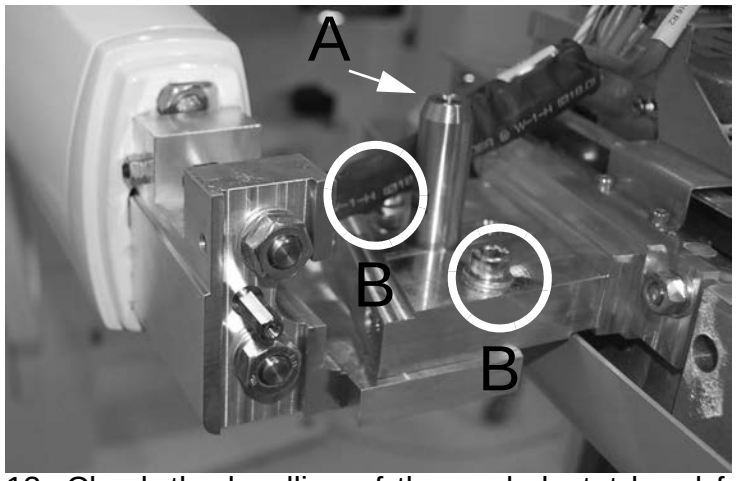
10. Adjust if needed. The correct position of the arm may sometimes be determined only during calibrations.



11. Remove the upper cover (A) from the cephalostat head and put it aside. Take the cephalostat head out of the styrofoam packaging and lift it carefully to the hook on the other end of the cephalostat arm.

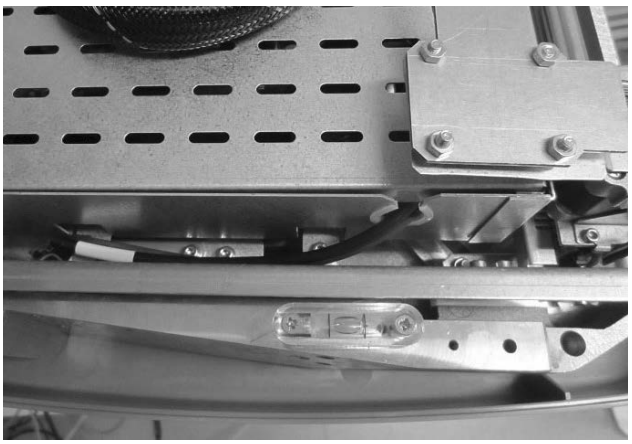


12. The pin (A) goes through the inlet.
    Attach the two bolts (B) to lock the cephalostat head to its place.



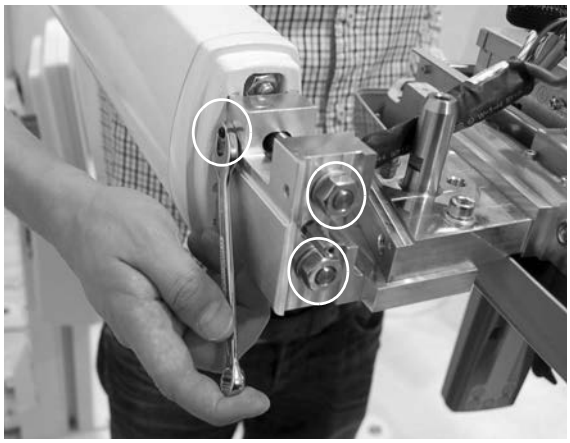
13. Check the levelling of the cephalostat head from the two spirit levels. If the cephalostat head is tilted or slightly hanging, straighten it as instructed below.

Side horizontal balance in terms of the cephalostat sensor.



Front horizontal balance in terms of the cephalostat sensor.

Side horizontal adjustment (slightly hanging)



Loosen the screws.

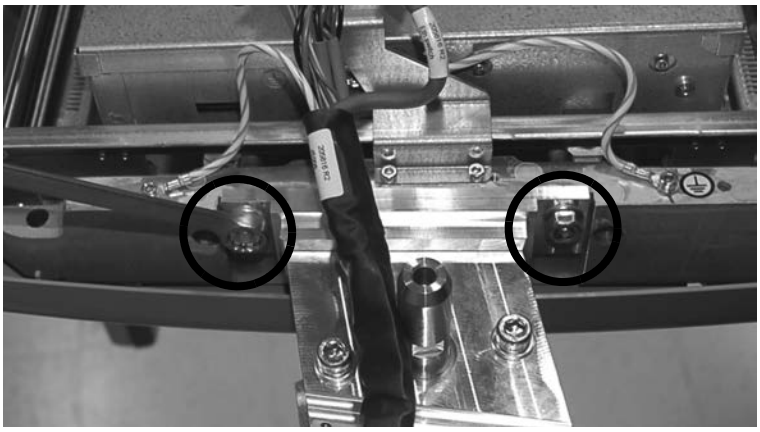
Adjust.

1) Loosen three nuts.

2) Lift the cephalostat head at the same time, when ad justing with the allen key, until the spirit level is levelled.

3) Use wrench to re-tighten the alignment screw first, and then the two big nuts.

Front horizontal adjustment (tilted sideways)



1) Use wrench to loosen the two nuts, then adjust by turning the cephalostat head, until the spirit level is levelled.

2) Re-tighten the nuts.

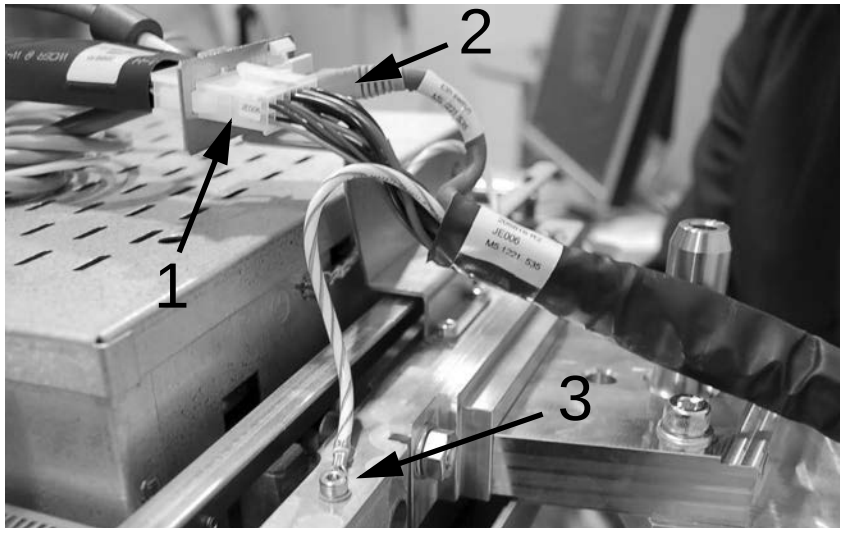
Horizontal adjustment (rotated on horizontal level)

NOTICE! *This adjustment is done only, if the calibration does not pass and the ceph head needs to be rotated. See chapter 7.2.4.4, Cephalostat fixation angle adjustment.*

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

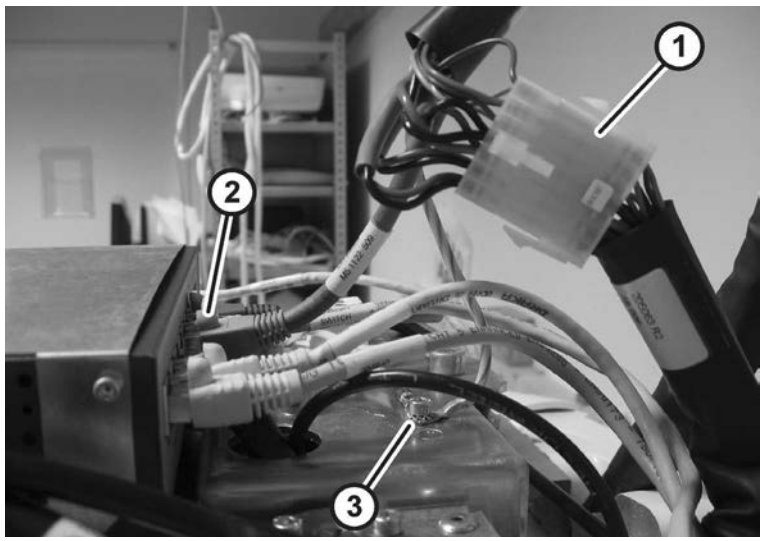
On the cephalometric head:

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



On top of the unit column:

1: Remove the jumper JB006.
Attach signal/Power cable.
2: Ethernet cable
3: Grounding point



15. Before installing the upper cover, take a cephalostat calibration image according to the cephalostat calibration instructions in this manual.

16. Install the covers (5 pieces).

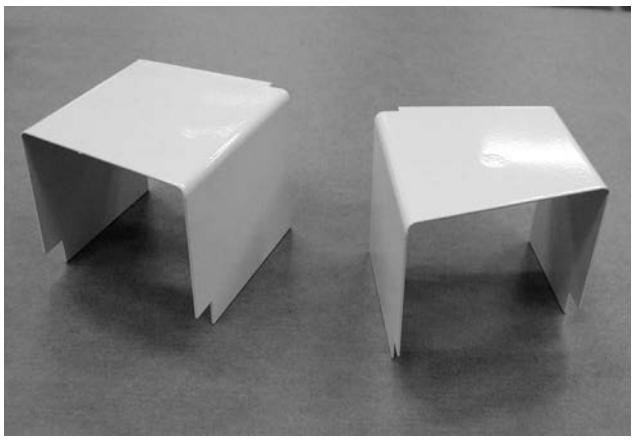
    A Joint cover between cephalostat head and arm

    B Upper cover of the cephalostat head

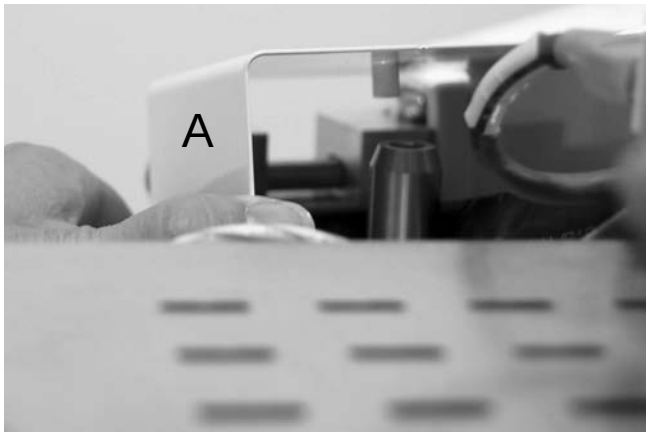
    C Cephalostat arm end cover (for head end)

    D Top cover of the column

    E Cephalostat arm end cover (for column end)



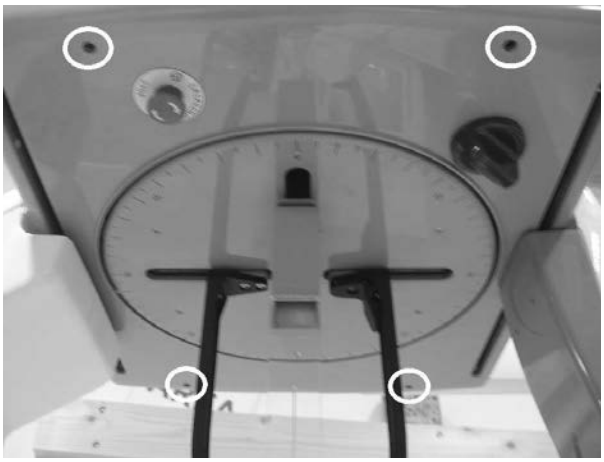
Joint cover for left and right handed cephalostat.



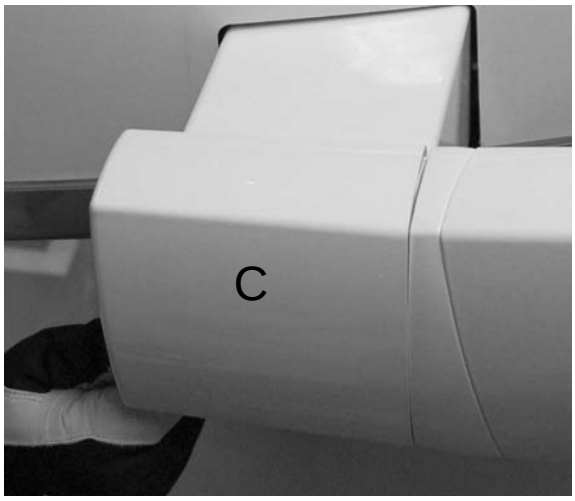
Joint cover (A).

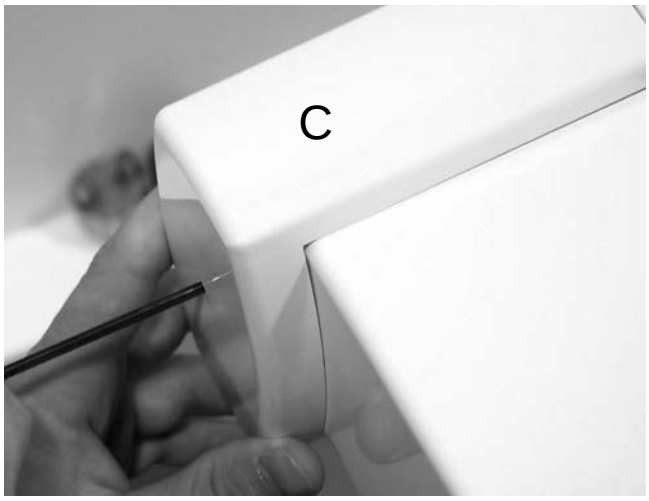
NOTICE! *Only one cover is used according to the handedness of the cephalostat.*

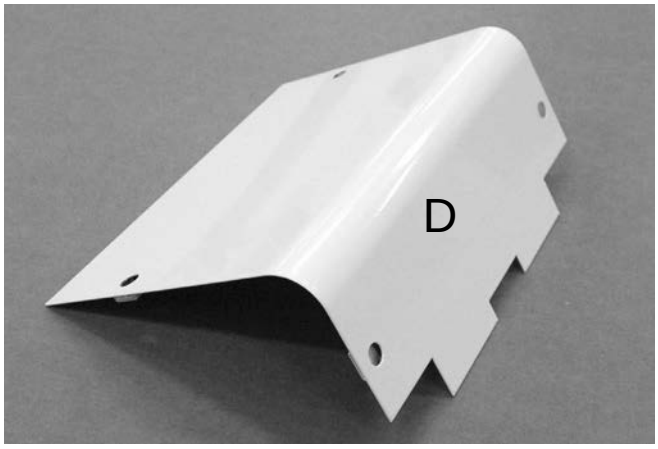
Upper cover of the cephalostat head.

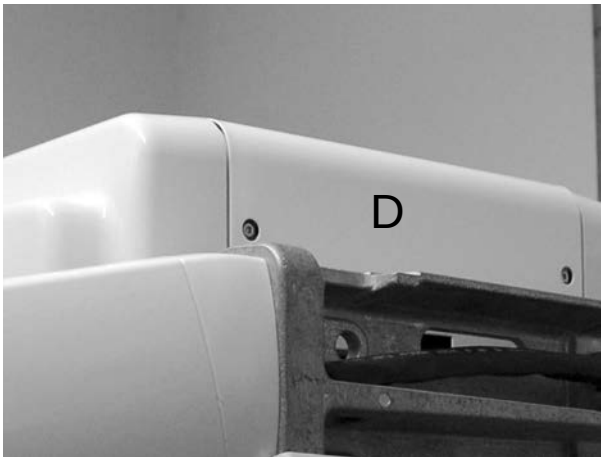


Fasten the upper cover to it's place with four bolts (M4x16) through the holes under the ceph head.

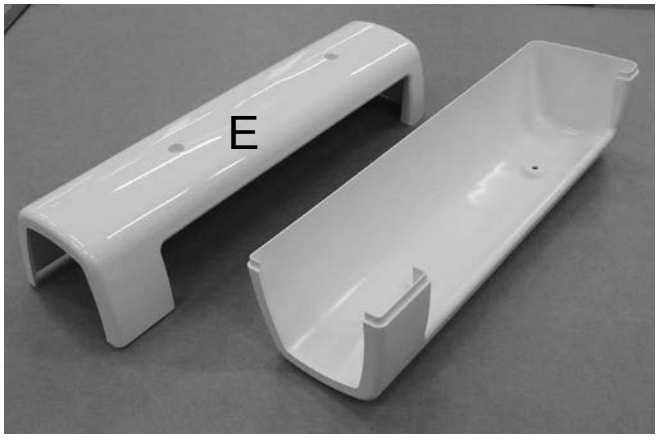








Top cover of the column.



17. Take the sensor out of its package and attach to the sensor holder. Make sure the sensor is properly seated down before pulling the lever.

18. Pull the lever down to lock the sensor to its place.

5.9.1 Enabling carpus imaging

Type in s2terminal in service mode: “carpus enable”.

By typing “carpus enabled” you get the status (enabled/ disabled). Disable it by typing “carpus disabled”.

6 Panoramic and 3D calibrations and adjustments

6.1 Introduction

The calibration procedure helps to maintain image quality and 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 R3220, 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…). Contact service if the problem persists after restarting the unit and PC.

NOTICE! *Panoramic and 3D calibration 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.*

NOTICE! *There are exclamation marks displayed at each calibration program key icon for programs that are yet not*

performed as a support for the installer. All calibrations must be done until the system informs they have passed. The exclamation marks disappear when a passed calibration has been saved.

NOTICE! *After calibrations place all the needed patient positioning accessories back to the chin rest.*

NOTICE! *Press* ***Save*** *on GUI after each calibration.*

6.2 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 re-calibrated 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.

NOTICE! *Also perform Quality Check when you replace the tubehead.*

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.

6.3 Reset maintenance counter

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

6.4 Preparing for calibration

1. Close the head support and lock it in its upmost position.
2. Install reconstruction dongle to PC (optional).
   Switch the PC and unit on.
3. **PC:** Open the s2terminal either by locating opens2.bat in the firmware package and double clicking it, or by doing the following:

   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 (normally **C:\Program Files (x86)\Palodex Group\IAM** or **C:\Program Files\Palodex Group\IAM**).

   _____

   cd C:\Program Files\Palodex Group\IAM

   _____

   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.

_____

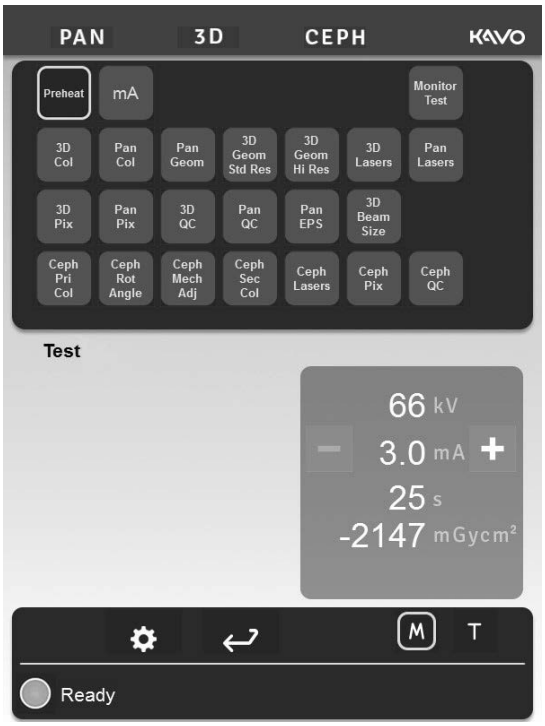
---- S2 Terminal Help ----------
xh help
xi receive image from the device
xr reserve device
xq quit

_____

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. **PC:** Click the image acquisition button to activate image capture.
6. Touch **Settings** on the Touch screen display.

7. Select the **Quality Assurance** button.
   The calibration display appears.



6.5 The calibration sequence

6.5.1 Calibration of the preheat of the tube

NOTICE! *Calibration of the preheat of the tube takes a while. The audible signal starts and stops several times.*

Do this calibration if there has been long time between installation and final testing of the unit or if the other calibrations won't pass.

1. Select the **Preheat** program.

2. Take an exposure.
3. Touch screen display and s2terminal inform you when the calibration is done. Repeat the calibration until calibration result "passed" is achieved.

6.5.2 Calibration of the tube current

NOTICE! *Calibration of the tube current takes approximately 10 to 15 minutes. The audible signal starts and stops several times during the calibration.*

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

1. Select the **mA** program.

2. Take an exposure.
3. Touch screen display informs when the calibration is done. Repeat the calibration until calibration result "passed" is achieved.

6.5.3 3D collimator calibration

NOTICE! *Only needed with 3D units.*

1. Select the **3D Col** program.

2. Press **Patient Positioning**.

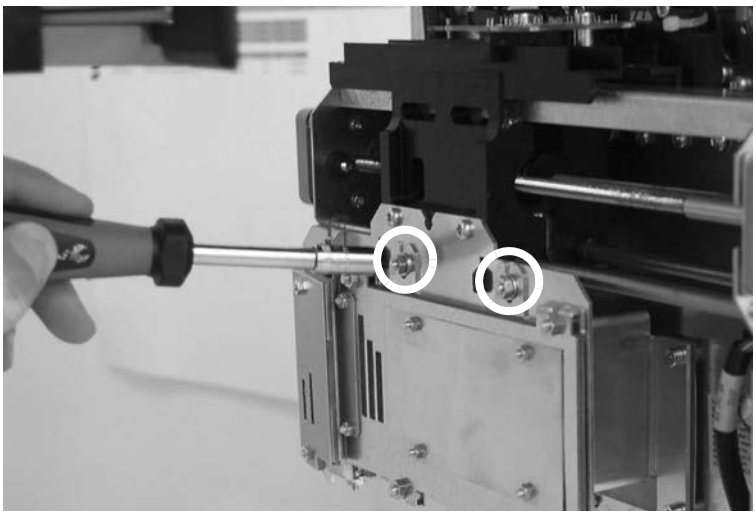
3. Take an exposure.

   NOTICE! Adjust the height and tilt of the collimator manually.

4. The status is displayed on the image captured in the imaging software, how much the height needs to be adjusted and in which direction.
5. Make adjustments and take new exposures until calibration result “**passed**” is achieved.

6.5.3.1 Adjustment of the height of the collimator "BLD-NGEO-M"

1. Loosen two locking nuts.



2. Adjust the height with one screw on the bottom of the collimator.

Clockwise (cw) = Collimator upwards
Counterclockwise (ccw) = Collimator downwards

3. Re-tighten the two locking nuts and take a new image.

6.5.4 3D Beam size verification (optional)

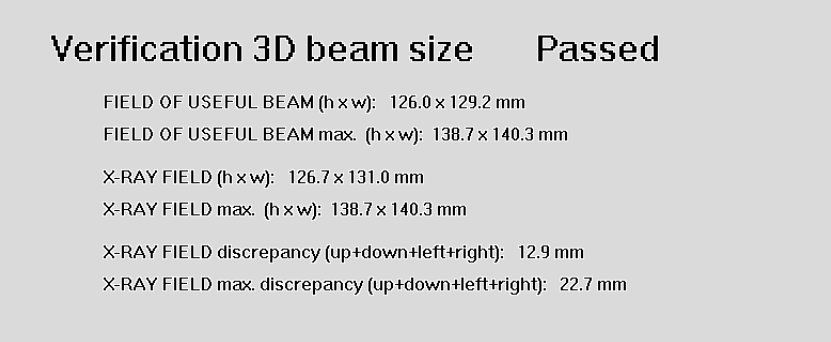
This program can be used to verify that the size of the 3D X-ray beam does not exceed limits defined in IEC 60601-1-3 and DIN 6868-161, if required by local regulations. The result of the program only gives information and does not affect the calibration of the unit. Perform the 3D Col calibration before using this program (redo the 3D Col if not done recently, or if it was done with a different driver version).

The panoramic sensor is used to measure the X-ray beam dimensions. To have the whole beam visible on the sensor you may have to adjust the panoramic sensor downwards (and possibly 3D collimator upwards if the sensor adjustment is not enough). Should this be the case, re-do collimator calibrations after beam size verification has been carried out.

1. Attach the panoramic sensor.
2. Select the **3D Beam Size** program.

3. Press **Patient Positioning**.

4. Take an exposure.
5. The beam dimensions and calibration result are presented in the result image.



First two lines are for DIN and the rest for the IEC standard.

Field of useful beam (h x w): 126.0 x 129.2 mm result according to DIN.
Field of useful beam max. (h x w): 138.7 x 140.3 mm DIN limit.
X-ray field (h x w): 126.7 x 131.0 mm result according to IEC.
X-ray field max. (h x w): 138.7 x 140.3 mm IEC limit.
X-ray field discrepancy (up+down+left+right): 12.9 mm result according to IEC.
X-ray field discrepancy (up+down+left+right): 22.7 mm IEC limit.

6.5.5 Panoramic collimator calibration

NOTICE! *With Pan unit (no 3D option) this calibration is done by adjusting the collimator.*

NOTICE! *There is a 6-8 second delay after initially pressing the exposure button before exposure occurs.*

1. Attach the panoramic sensor.
2. Select the **PAN Col** program.

3. Press **Patient Positioning**.

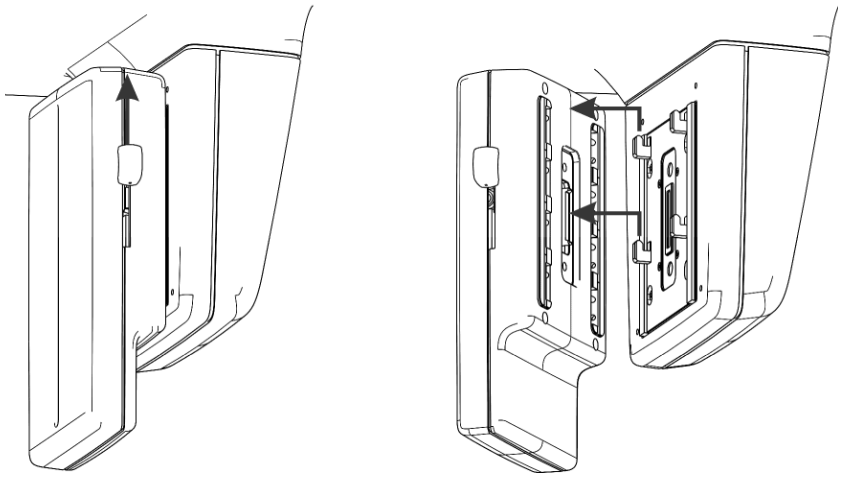
4. Take an exposure.
5. The status is displayed on the image captured in the imaging software, how much the height needs to be adjusted and in which direction.
6. Adjust the height of the PAN sensor and check the tilt and position of the collimator. Make adjustments and take new exposures until calibration result “passed” is achieved.

6.5.5.1 Adjustment of the height of the PAN sensor

NOTICE! *This adjustment is only available on 3D devices.*

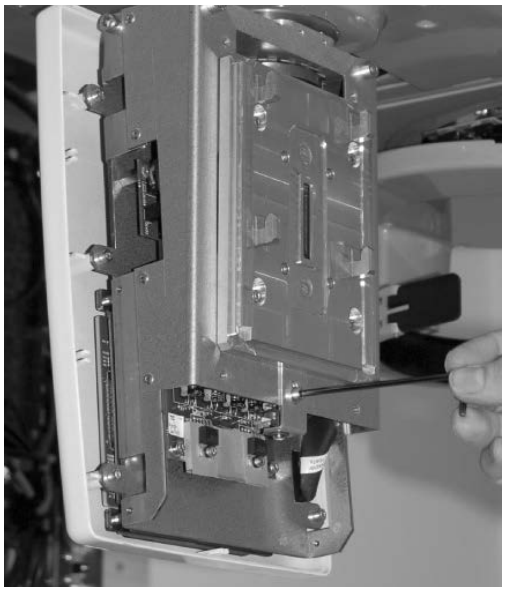
Do the adjustment with the sensor holder.

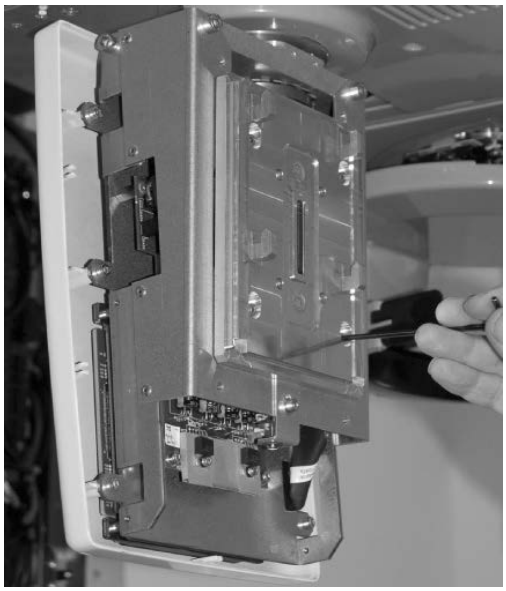
1. Remove the sensor.



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

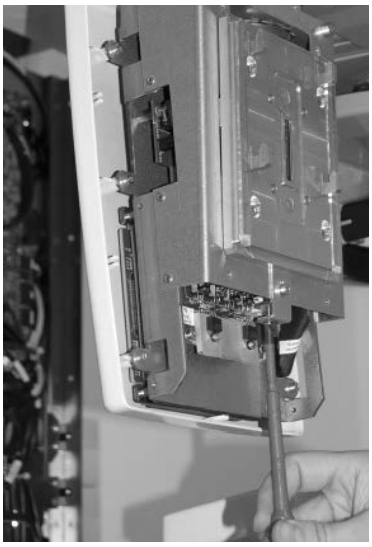
3. Loosen five screws of the sensor holder.





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

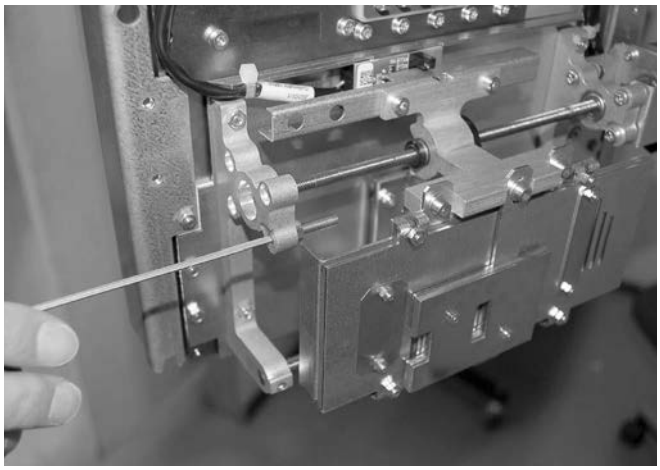
   Clockwise (cw) = Collimator upwards
   Counterclockwise (ccw) = Collimator downwards



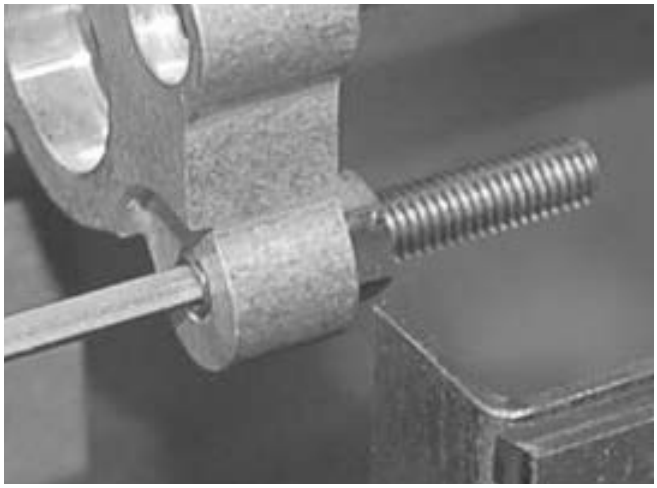
6.5.5.2 Horizontal adjustment of the collimator "BLD-NGEO-S-2"

NOTICE! *This is an optional procedure. The horizontal position of the collimator assembly can be adjusted slightly for example in cases when the VT slot cannot be found.*

1. Adjust the Allen screw of the collimator.



2. Open the nut when adjusting the Allen screw.



Hold the nut when adjusting the Allen screw.

3. Re-tighten the nut after Allen screw is adjusted. Take a new image.

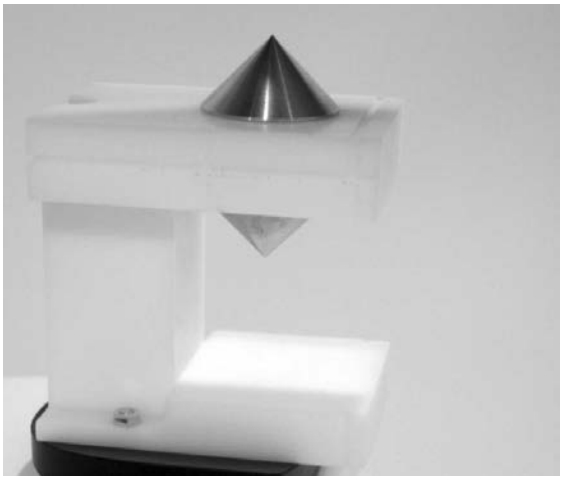
NOTICE! *3D collimator calibration should be checked if the collimator is moved horizontally.*

6.5.6 Panoramic geometry calibration

1. Select the **Pan Geom** program.

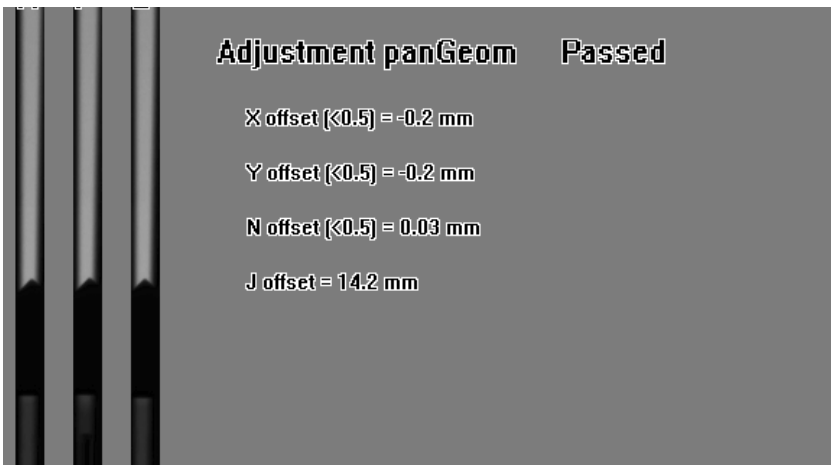
2. Press **Patient Positioning**.

3. Install the chin rest and **double cone calibration tool**.



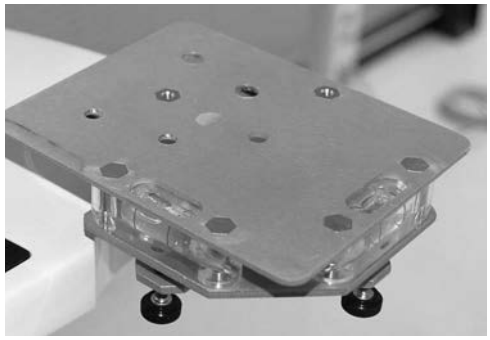
Chin rest and double cone calibration tool.

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

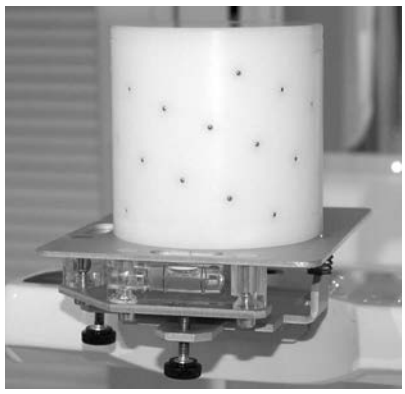


6.5.7 3D geometry calibration

1. Attach the adjustable phantom holder to the lower shelf. Level it with the bubble on the adjustable phantom holder.



2. Install the **3D calibration phantom**. Check that the phantom is level by using a spirit level.



3. Select the **3D Geom Std Res** or **3D Geom Hi Res** program. There is a calibration procedure for both 3D imaging modes, standard and high resolution. Standard geometry calibration has to be done first.

4. Press **Patient Positioning**.

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

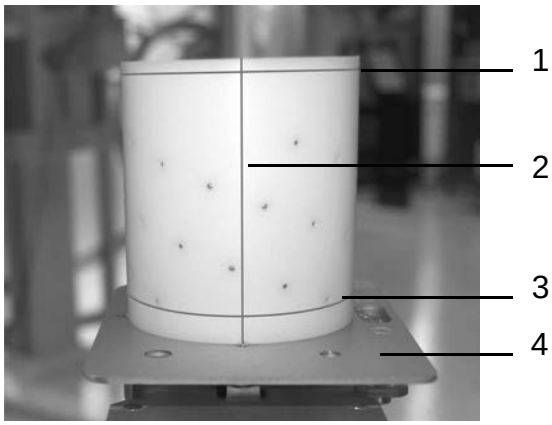
6.5.8 SFOV (Small panel) 3D lasers alignment

NOTICE! *With MFOV unit (Medium panel) see the instructions in chapter 6.5.9.*

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

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

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



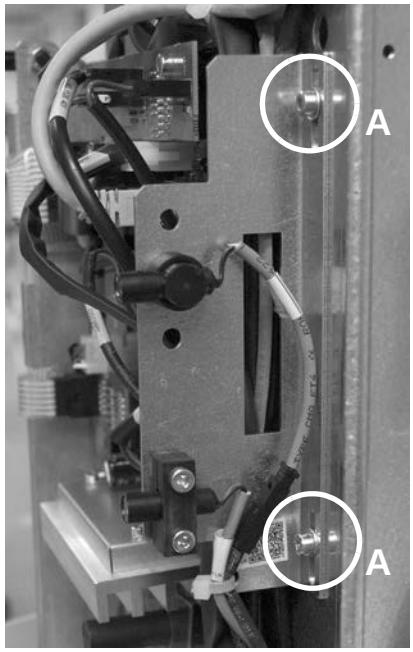
2. Select the **3D lasers** program.

3. Press **Patient Positioning**.

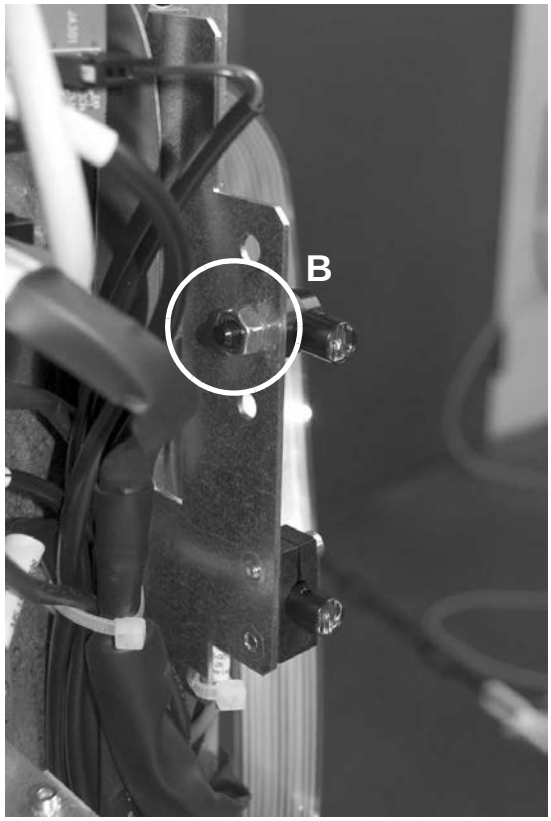
NOTICE! *Lasers can be turned on by pushing the light button. Lasers stay on approx. 30 seconds.*

4. If adjustment is needed, remove the mirror plate by loosening four M4 screws. Lift the plate first and pull.

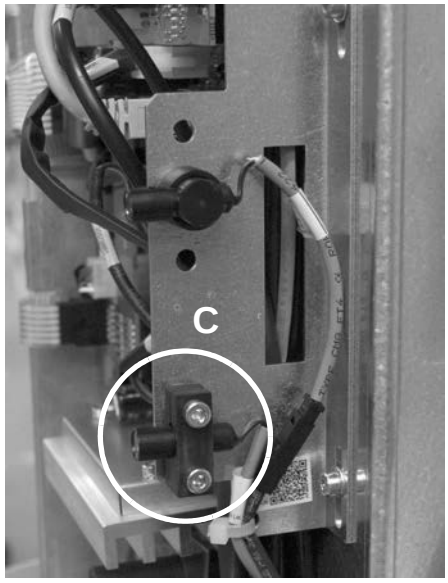
5. Loosen the two screws (A) of the bottom laser. Align the height of the laser by moving it up or down.



6. Loosen the screw (B) of the upper laser. Align the tilt of the laser by rotating it.



7. Loosen the two screws (C) of the bottom laser. Align the tilt of the laser by rotating.



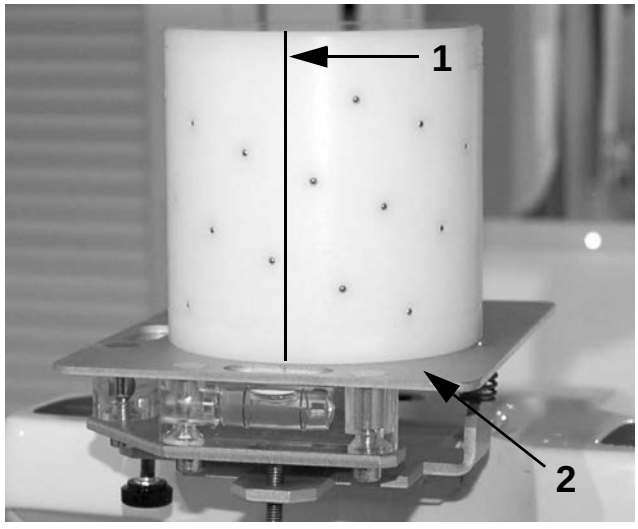
8. Briefly press the exposure button (no X-rays are generated) to acknowledge that the check has been carried out.

6.5.9 MFOV (Medium panel) 3D lasers alignment

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

1. Attach the 3D geometry calibration phantom to the unit. Use the 3D calibration phantom with grooves for aligning the mid-sagittal laser.

   1 Mid-sagittal
   2 Adjustable phantom holder

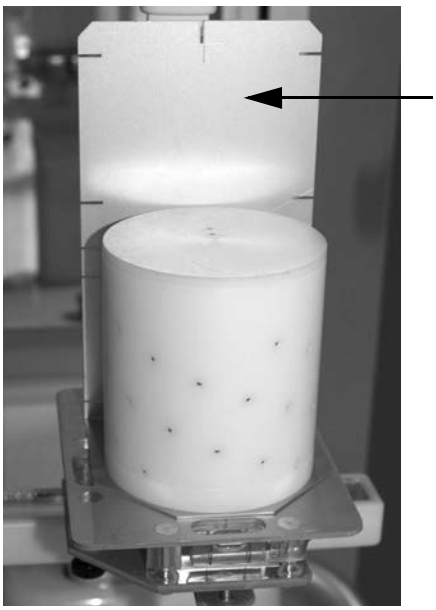


2. Select the **3D lasers** program.

3. Press **Patient Positioning**.

NOTICE! *Lasers can be turned on by pushing the light button. Lasers stay on approx. 30 seconds.*

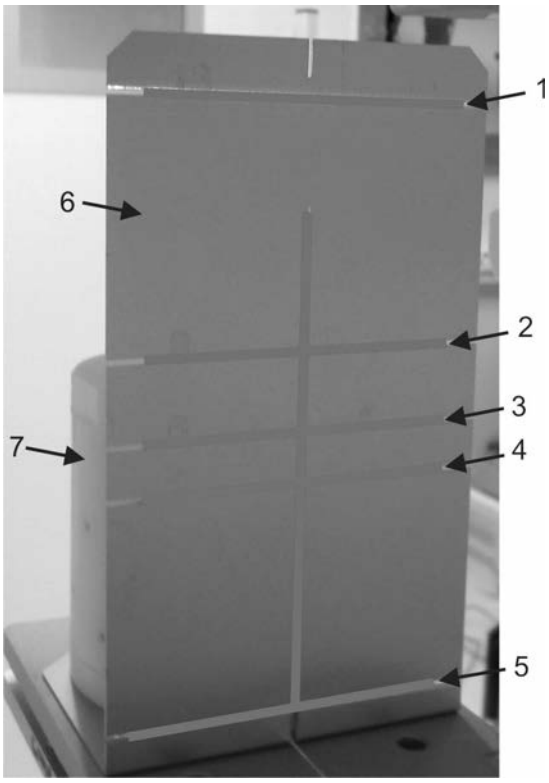
4. Align the 3D lasers of MFOV (Maxio) by using the MFOV 3D lasers alignment tool (L-shaped metal plate). This tool is fixed to the phantom holder by using the 3D geometry calibration phantom.



3D lasers alignment tool

5. Locations of the lasers and tools:

1 FH-laser of FOV 130 x 150 mm
2 Top of FOV 78 mm
3 Top of FOV 61 mm
4 Top of FOV 50 mm
5 Bottom of FOV
6 MFOV3D lasers alignment tool
7 3D geometry calibration phantom

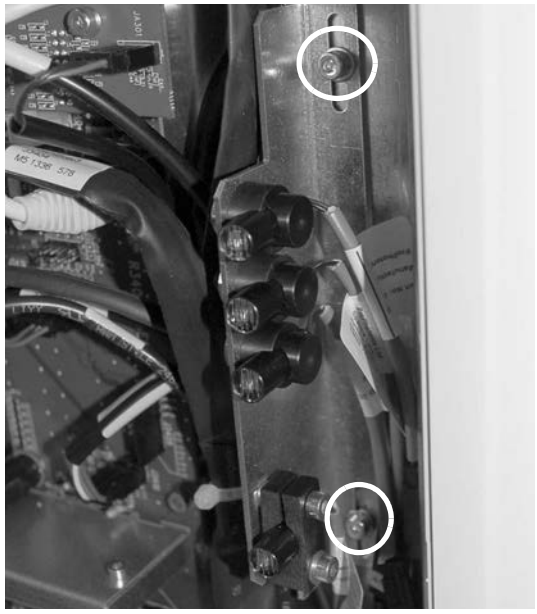


6. Remove the mirror plate and the knob of the FH-laser.

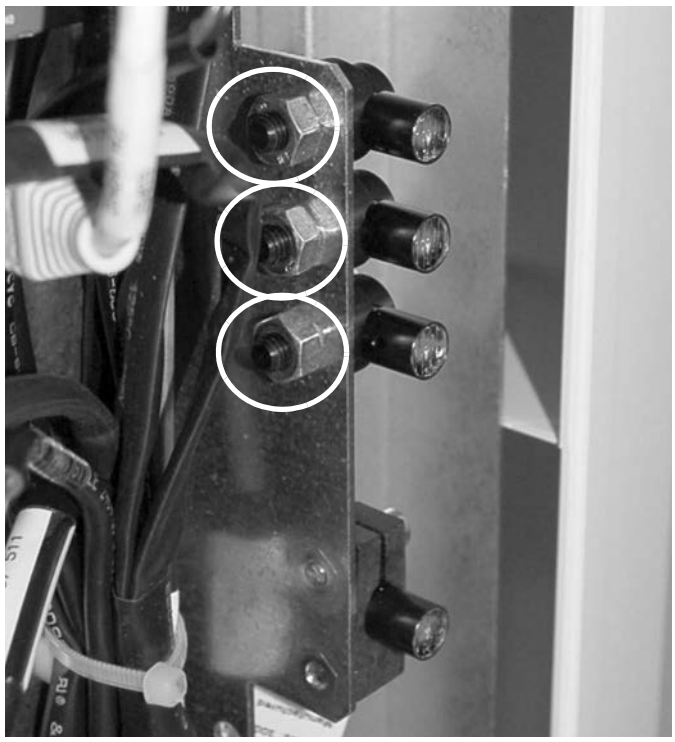
   Adjust four lasers from bottom to up.

   Adjust the lowest laser first. Loosen the upper screw. The laser starts to rotate. Align the laser horizontally. Tighten the screw.

7. Adjust the lowest laser vertically. Loosen the two screws. Move the plate vertically. Tighten the screws.



8. Adjust the three upper lasers from bottom to up. Loosen the screw next to the laser. Align the laser first horizontally and then vertically. Tighten the screw. Repeat with the two upper lasers.



9. Adjust the FH-laser used for 130 x 150 FOV to the corresponding grooves by mechanically adjusting the lasers.
10. Briefly press the exposure button (no X-rays are generated) to acknowledge that the check has been carried out.

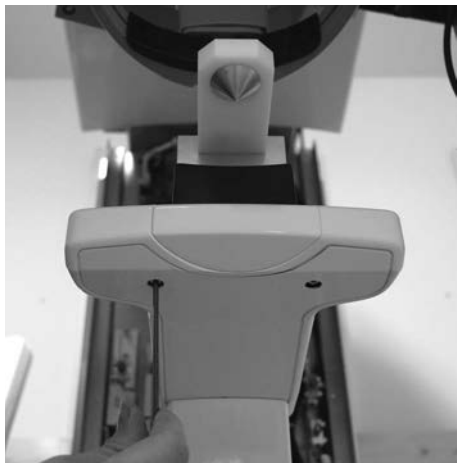
6.5.10 Panoramic laser alignment

1. Attach the PAN geometry calibration tool (double cone) to the unit.

2. Select the **Pan Lasers** program.

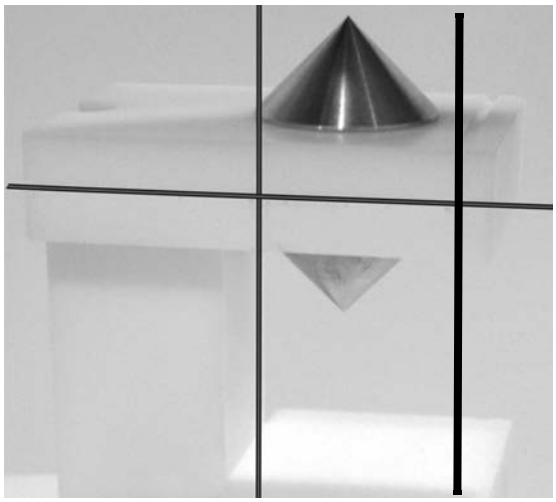
3. Press **Patient Positioning**.

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. The layer laser is adjusted by the screws below the chin rest.

   Adjustment of the laser located in the rotator is software based. Use the chin support adjustment buttons to adjust the angle of the laser and occlusion correction buttons to adjust the Y-position of the laser to match the backmost groove on the calibration tool.



NOTICE! *Lasers can be turned on by pushing the light button. Lasers stay on approx. 30 seconds.*

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.

6.5.11 3D pixel calibration

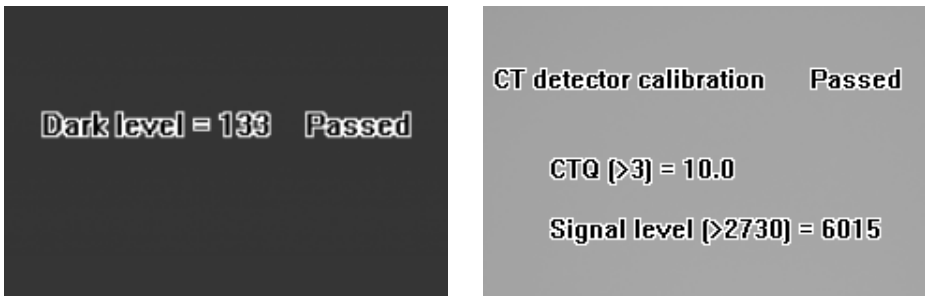
1. Remove all phantoms (if attached).

2. Select the **3D Pix** program.

3. Press **Patient Positioning**.

4. Take an exposure.

5. The resulting image informs when the calibration is passed.



6.5.12 Panoramic pixel calibration

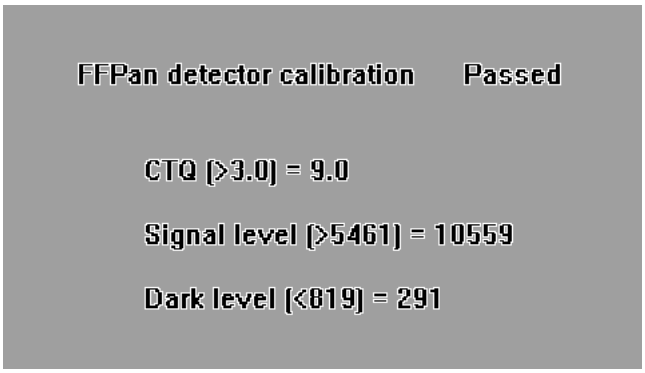
NOTICE! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

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

1. Attach the tube head covers.
2. Remove the calibration tools.
3. Select the **Pan Pix** program.

4. Press **Patient Positioning**.

5. Take an exposure.
6. Check that the calibration result is “passed”.



6.5.13 3D Quality Check

The x-ray unit has integrated 3D quality check program, which verifies following values from the reconstructed volume automatically:

- Image noise
- Grey values
- Uniformity (Driver Update Package 15.1 or newer required)

Following properties can be inspected visually by the user from the reconstructed volume:

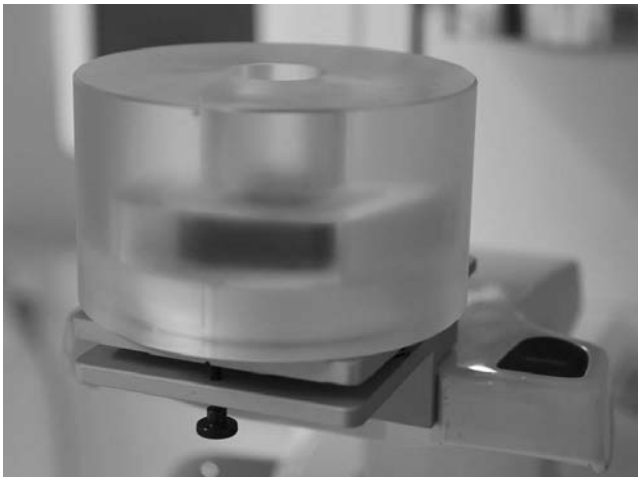
- Artefacts

The results of the periodical checks below should be recorded and the check images filed. To do this, it is recommended that a “Constancy Test” “Patient” record is created under which the test images can be recorded.

Please note that the reference levels may change with x-ray unit firmware / driver updates. Upon such updates, new reference levels for measured values for the unit should be established. Always refer to the limiting values that are specified with current 3D QC test.

3D Quality Check program execution

1. Attach the QC phantom to the unit.



2. Select the **3D QC** program.

3. Press **Patient Positioning**.

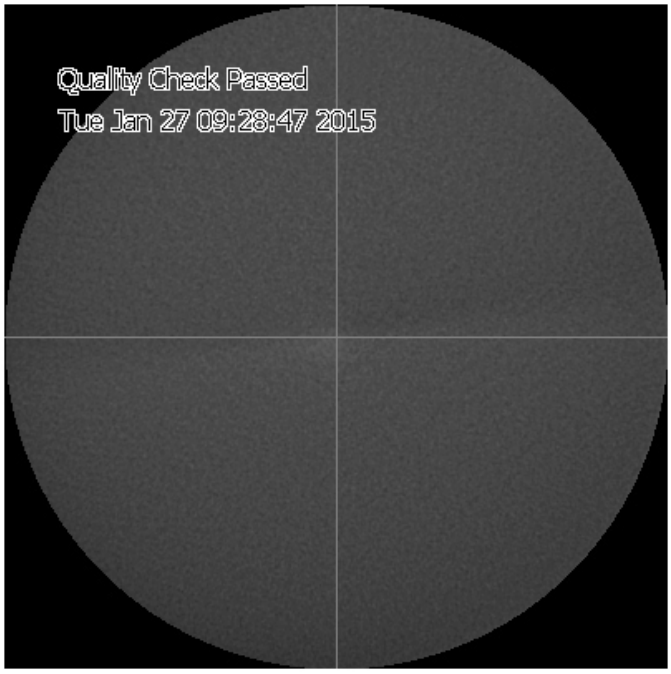
4. Take an exposure.

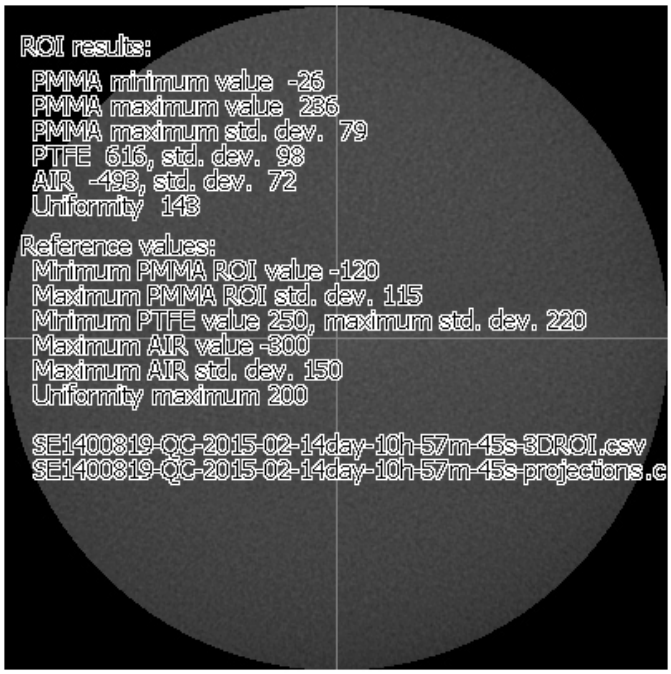
> ***NOTICE!*** *Reference your 3D imaging program manual for instructions on viewing the 3D volume.*

3D QC program result evaluation

NOTICE! *Reference your 3D imaging program manual for instructions on viewing the 3D volume.*

To check results, open resulting image in a 3D viewer. One axial slice of the volume contains Pass/Fail status and one axial slice measurement results and used reference values. If “Passed” is not achieved, redo the 3D collimator, 3D pixel and 3D geometry calibrations before retrying 3D QC.





Pass/Fail calculation is based on ROI (Region of Interest) measurement result verification against reference values.

"ROIs" are smaller volumes inside the 3D QC reconstructed volume that are used to calculate noise or average grey values, for example. ROIs are marked with thin circular lines inside the reconstructed volume.

Last lines of text on the image tell the file name of the measurement results stored in a csv table. Path for this file is typically C:\ProgramData\DXR120\. It is not necessary, but the "3DROI" file can be copied to be archived as constancy check results or imported to a spreadsheet program to closer examine measured values. In case of failed QC result, this file can be attached for technical support request.

Description for the measurements

Noise measurement

Noise is defined as standard deviation of the 3D measurement ROI in the volume. Noise is determined from several materials in the phantom:

- PMMA std. dev.
- PTFE std. dev.
- Air std. dev.

Grey values measurement

Grey values of several materials in the reconstructed volume are measured. There must be difference in grey values in different materials to ensure adequate low contrast resolution and consequently to make sure that good tissue/bone separation is achieved in the 3D volume.

Following grey values are measured from the volume:

- PMMA average value
  - Corresponds closely water x-ray absorption
- PTFE average value
- Air average value

Field Uniformity

Field uniformity measurement calculates max difference in grey values between centre and border regions of the PMMA material in the phantom.

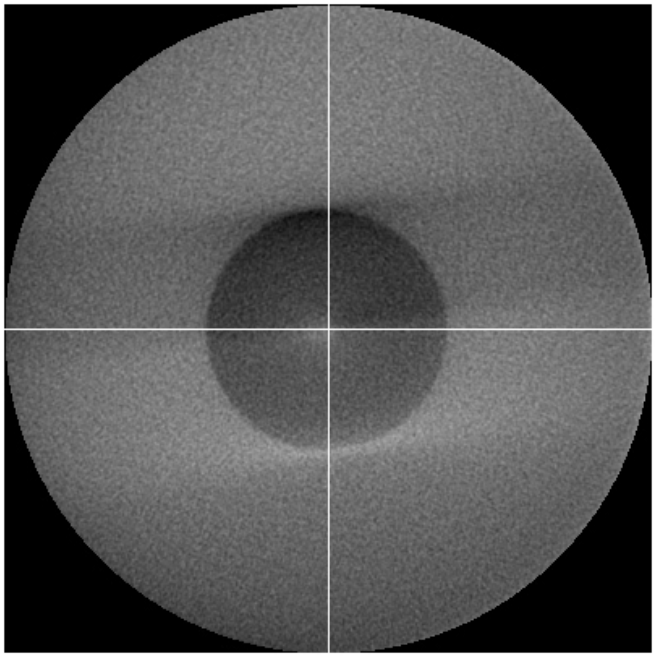
Artefacts

This check is carried out visually. Person with experience on interpreting 3D images should perform the check. Examine the axial slices of 3D QC volume taken in the previous QC steps. Be aware of artefacts which do not originate from the object or from the projection conditions. Please note that there will be some circles drawn in the volume to indicate areas used for 3D QC program result calculations.

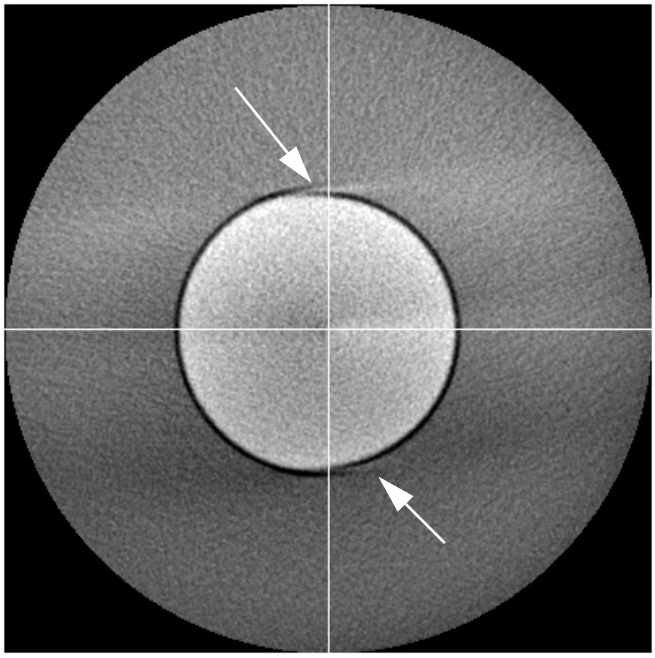
Requirements:

Absence of artefacts, except for those that may be expected due to phantom or projection conditions.

Examples:



Acceptable, shadowing may appear around straight horizontal material interfaces.



Not acceptable; discontinuity in circular shape due to geometry mismatch between scans with different offset. In similar artefacts are observed, redo 3D geometry calibrations before retrying 3D QC.

6.5.14 Panoramic Quality Check (optional)

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

   NOTICE! *Not required in North America.*

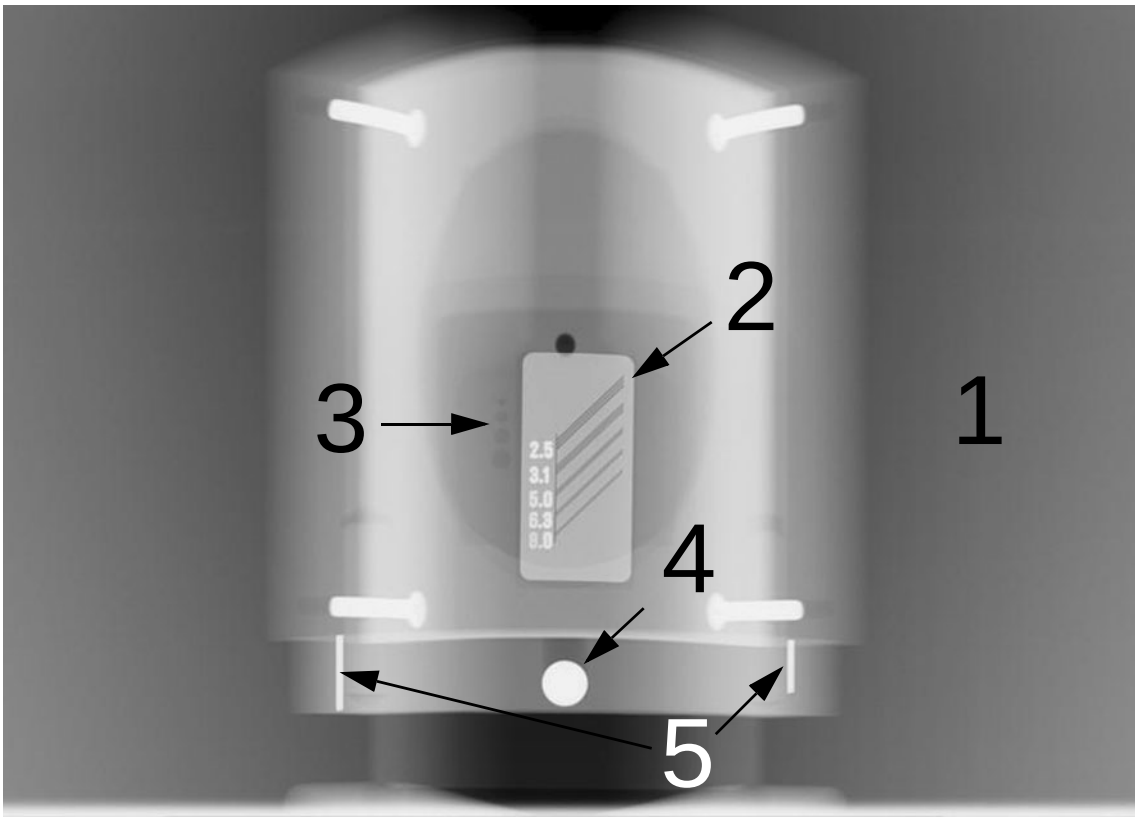
   NOTICE! *Use the same tool for cephalostat Quality Check.*

2. Select the **Pan QC** program.

3. Press **Patient Positioning**.

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.

Re-do panoramic geometry calibration if above conditions are not met.

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 using service command* ***copperthickness****. Refer to service command* ***help copperthickness*** *for further instructions.*

7 Cephalometric calibration and alignment

7.1 Preparations

NOTICE! *The nasion support and the ear holders must be turned out of the way for cephalostat calibrations, so they are not in front of the x-ray beam.*

NOTICE! *Check the orientation of the nasion support and the ear holders so that the patient is always facing to the x-ray room.*

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

NOTICE! *Before calibrating the cephalostat update the unit firmware. See Firmware update instructions.*

Take an exposure.

7.2 Cephalometric calibration sequence

1. Balance the cephalostat.
2. Do the primary collimator horizontal adjustment (automatic). Adjust the rotator angle to have the x-ray beam directed exactly towards the cephalometric sensor.
3. Do the rotation angle adjustment (automatic). Adjust the rotator angle to have the x-ray beam directed exactly towards the cephalometric sensor.
4. Do the mechanical collimator adjustments and check the cephalostat fixation angle (manual, software guided), which you can adjust if necessary.
5. Do the secondary collimator horizontal adjustment (automatic). Fine tune the position of the secondary collimator for optimal alignment with the sensor and X-ray source.
6. Do the cephalostat laser adjustment.
7. Do the cephalometric pixel calibration. Capture sensor calibration data for performing image corrections.
8. Check the cephalometric quality (optional). Verify that the image quality is appropriate.
9. Align the ear holders.

These steps are described in more detail in the following sections. The adjustments are to be carried out in the described order.

7.2.1 Balancing the cephalostat

See chapter 5.9 Installing the cephalometric unit, step 9.

7.2.2 Primary collimator calibration

1. Attach cephalostat or pan sensor to the rotating unit sensor holder.
2. Touch **Settings** on the Touch screen display.

3. Select the **Quality Assurance** button.
   The calibration display appears.
4. Select **CEPH Pri Col** calibration.

5. Press **Patient Positioning**.

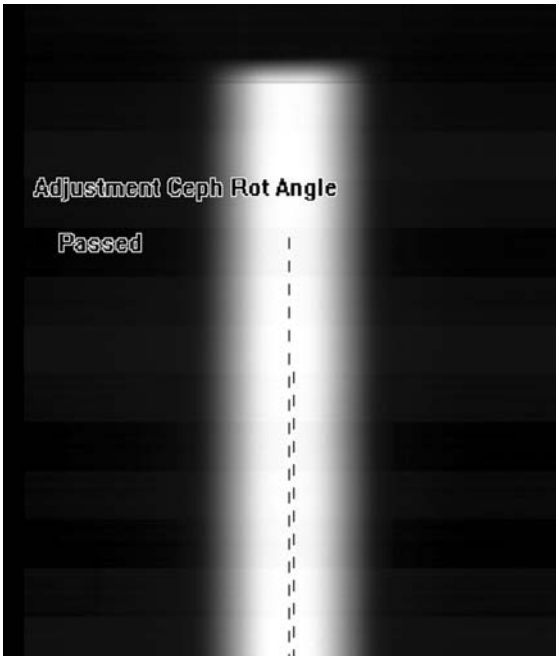
6. Take an exposure.
7. Check that the calibration result is “passed”. If “passed” is not achieved, check the sensor fastening and remove all calibration tools and phantoms. If “passed” is still not achieved, call the service personnel.

7.2.3 Rotation angle calibration

1. Attach the cephalostat sensor to cephalostat sensor holder.
2. Select **CEPH Rotate Angle** calibration.

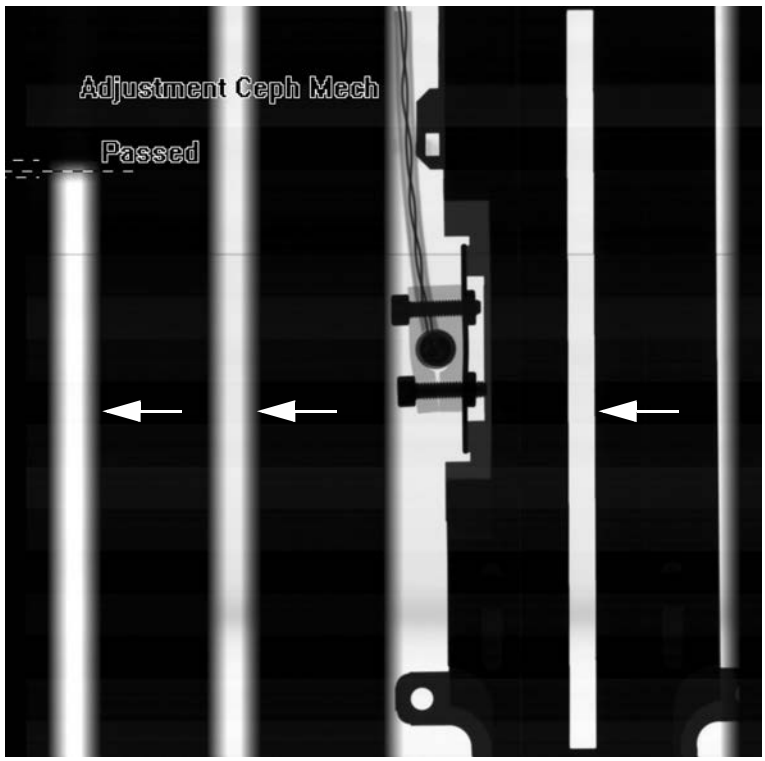
3. Press **Patient Positioning**.

4. Take an exposure.
5. Check that the calibration is “passed”. If it is not, redo the calibration.


Adjustment Ceph Rot Angle
Passed

7.2.4 Mechanical adjustment program

Mechanical adjustments of primary and secondary collimator, as well as adjustment of the cephalostat fixation angle, are guided by a mechanical adjustment program. This program gives an image with three exposed areas of interest (marked with arrows in the figure).



Example of a Cephalostat Mechanical Adjustment image.

- The leftmost area is exposed with the cephalometric collimator having reduced height. This area is used for adjusting the vertical position of the X-ray beam (primary collimation vertical position).
- The area in the middle is exposed with the full height cephalometric collimator. This area is used for checking X-ray beam integrity, and shall be equally exposed in the whole height of the image.
- The rightmost area is the beam after secondary collimation. This area is used for checking secondary collimator vertical position and tilt. This area being too far left or right in the image indicates that the fixation angle of the cephalostat is incorrect and that the cephalostat must be turned.

To complete this calibration:

1. Select the **CEPH Mech Adj** program.

2. Press **Patient Positioning**.

3. Take an exposure.
4. Follow the instructions in the calibration result image. Possible instructions and references to further information are found in table “instructions for adjustment”.
5. Take new exposures until the calibration result is “Passed”.

Table 8.1 Instructions for adjustment

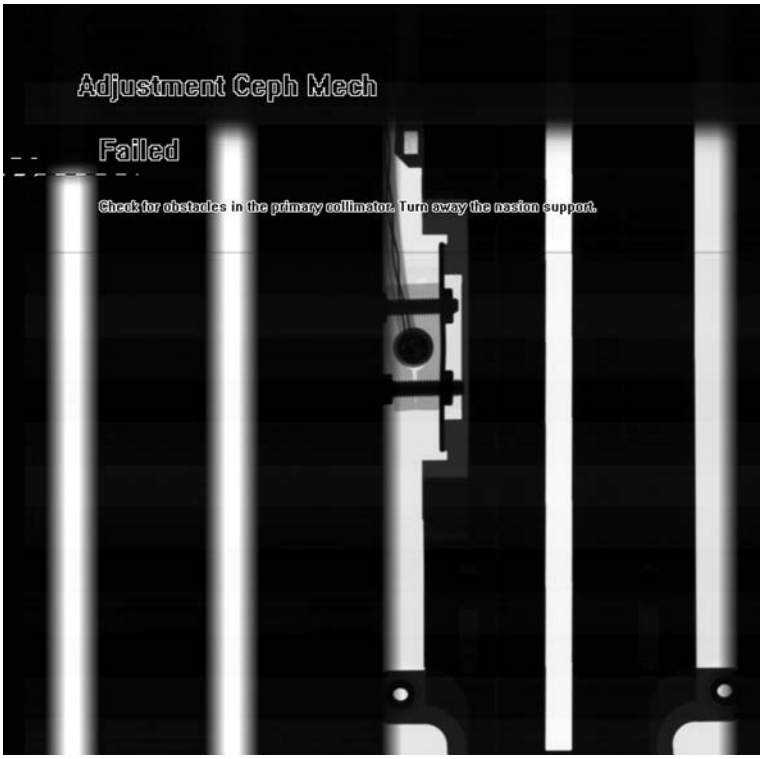
Instruction	Additional information
Check for obstacles in the primary collimator. Turn away the nasion support. 	Something is blocking the X-ray beam. Check for wrong nasion support position, loose parts in the collimator assembly or calibration tools attached to the panoramic/3D chin support. ***NOTICE!*** *After turning the cephalostat, the Ceph Rot Angle calibration must be redone. The x-ray beam will otherwise not be central at the cephalostat sensor.*

Table 8.1 Instructions for adjustment

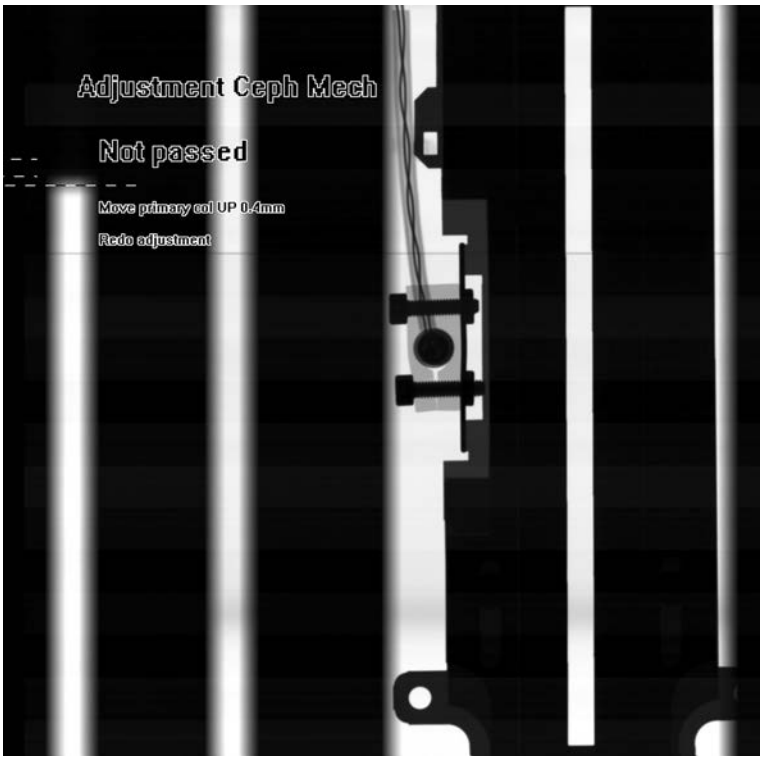
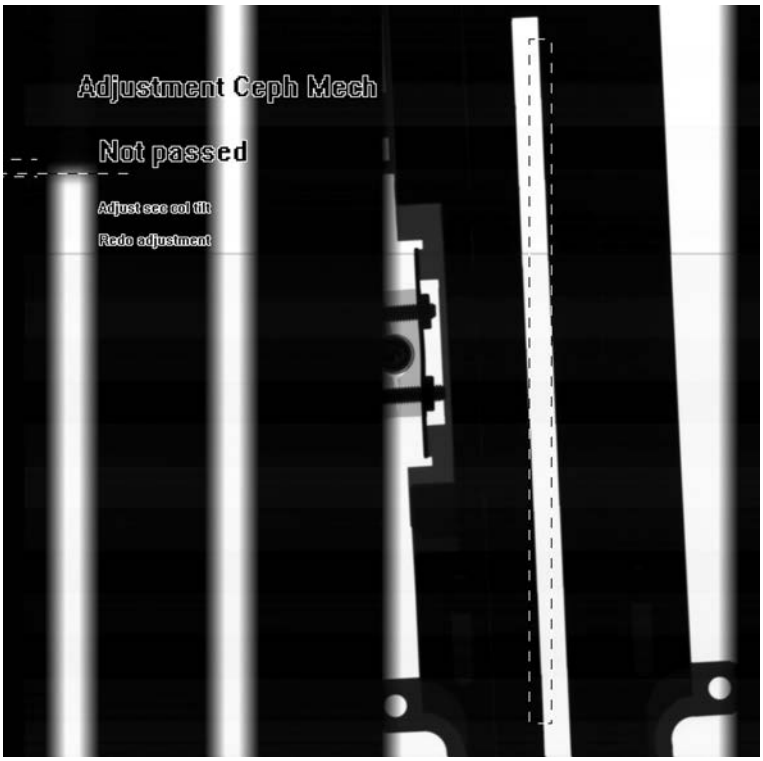
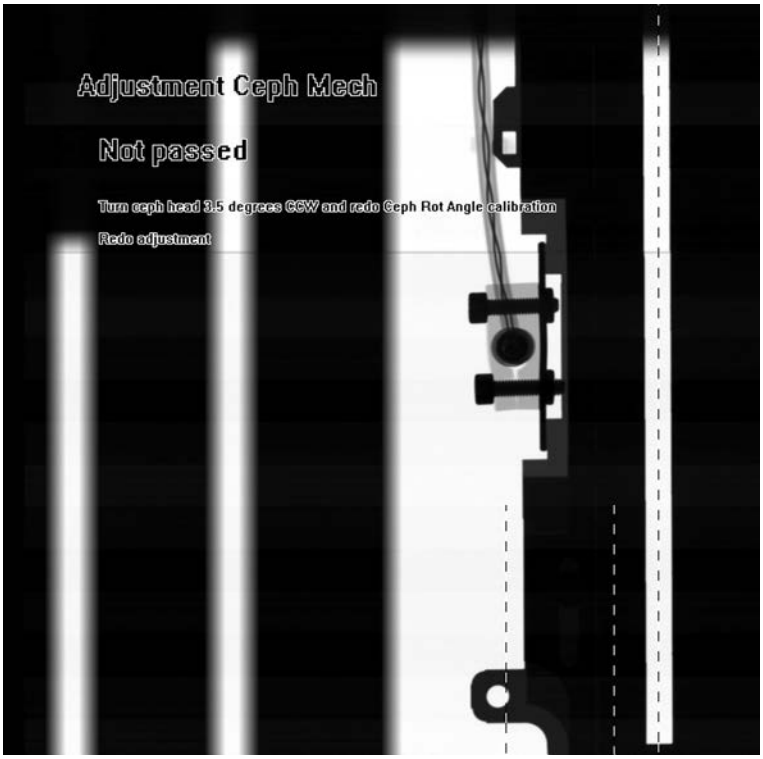
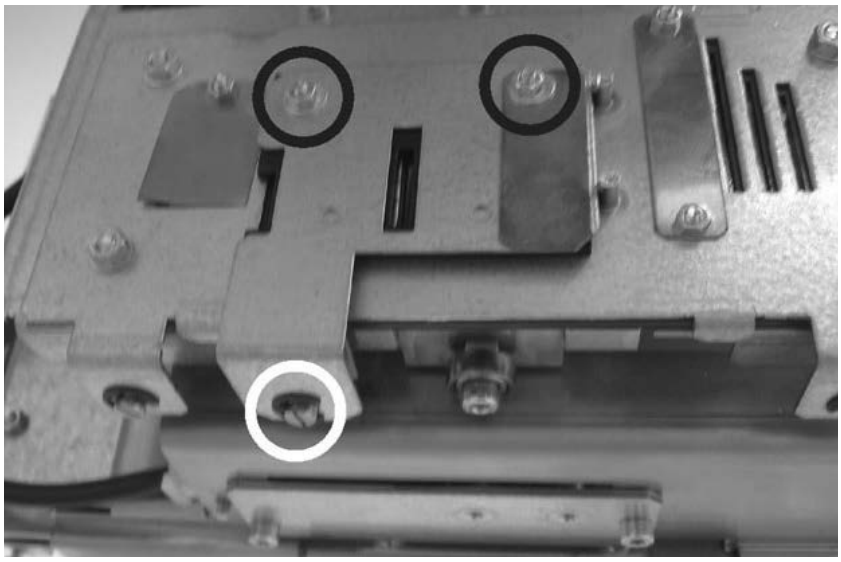
Instruction	Additional information
Move primary collimator UP/DOWN. 	The vertical position of the primary collimator must be adjusted in order to have the X-ray beam aligned to correct height. See chapter 8.2.4. Primary collimator vertical adjustment for details.
Adjust secondary collimator tilt. 	Secondary collimator is tilted. Adjust the tilt so that the secondary collimator fits within the dotted lines drawn next to it. In the example case (left), the lower part of the secondary collimator shall be turned towards the laser holder (seen to the left of the dotted lines in the picture). See chapter 8.2.4.5. Removing secondary collimator covers and 8.2.4.7. Secondary collimator tilt adjustment for details.

Table 8.1 Instructions for adjustment

Instruction	Additional information
Turn cephalostat head CW/CCW and redo Ceph Rot angle calibration. 	The fixation angle of the cephalostat must be adjusted in order to have the secondary collimator and sensor aligned with the X-ray source. See chapter 8.2.4.4. Cephalostat fixation angle adjustment for details.

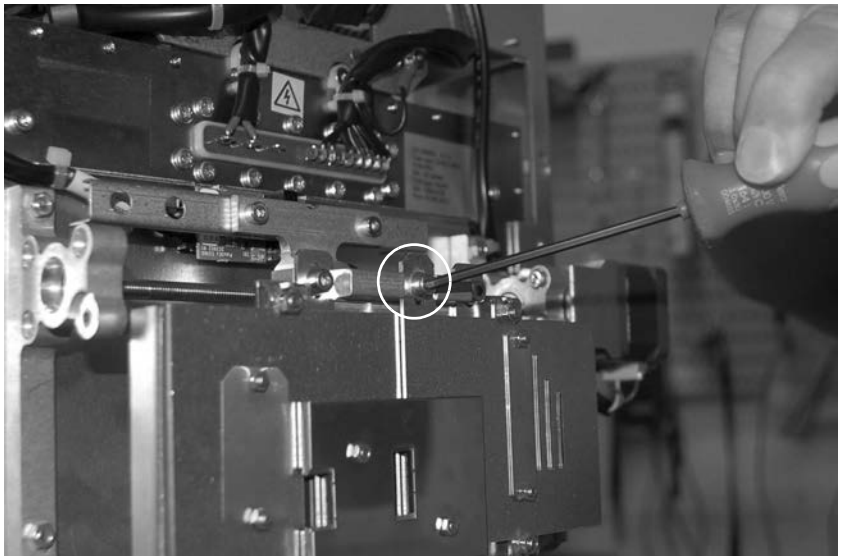
7.2.4.1 Primary collimator "BLD-NGEO-S" vertical adjustment

1. Loosen the two locking nuts (black circles in the picture).
2. Adjust the vertical position of the collimator using the adjustment screw (a white circle in the picture).
3. Tighten the locking nuts.



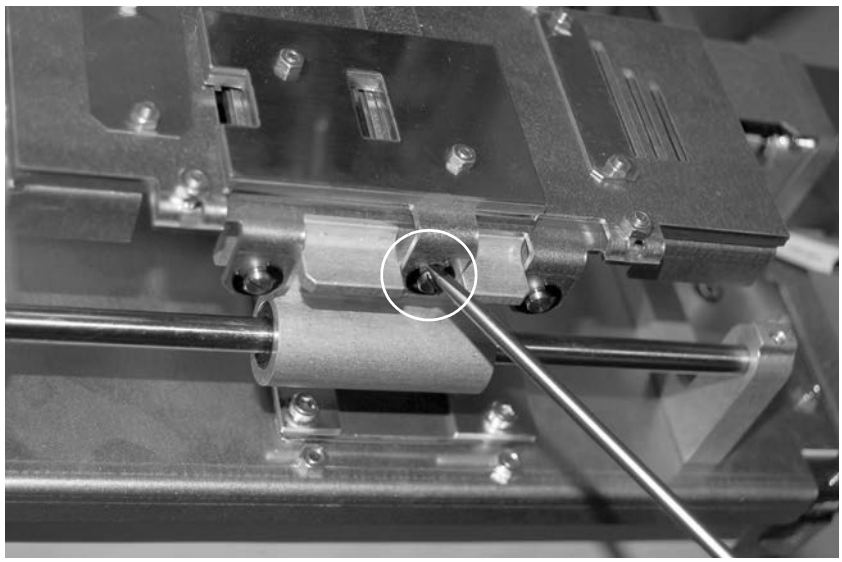
7.2.4.2 Primary collimator "BLD-NGEO-S-2" vertical adjustment

1. Loosen the locking nut.



2. Adjust the vertical position of the collimator using the adjustment screw.

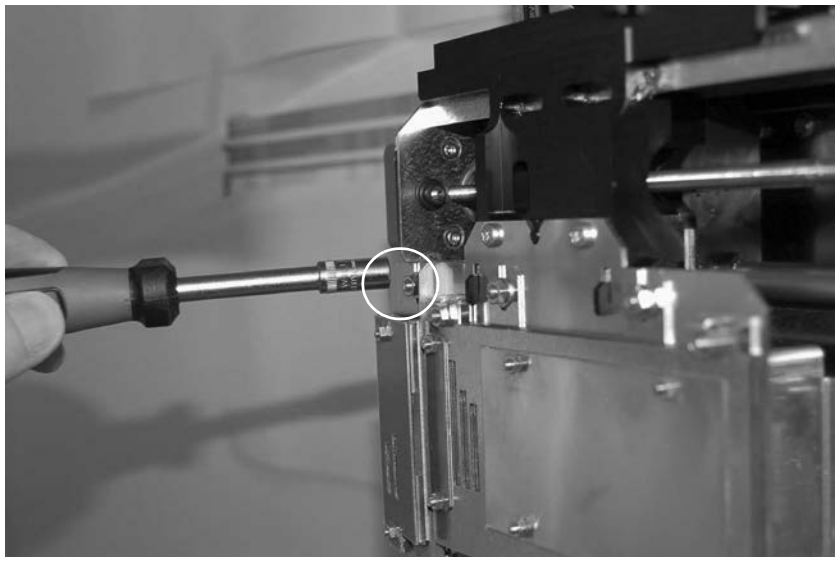
   Clockwise (cw) = Collimator upwards
   Counterclockwise (ccw) = Collimator downwards.



3. Tighten the locking nut.

7.2.4.3 Primary collimator "BLD-NGEO-M" vertical adjustment

1. Loosen the locking nut.



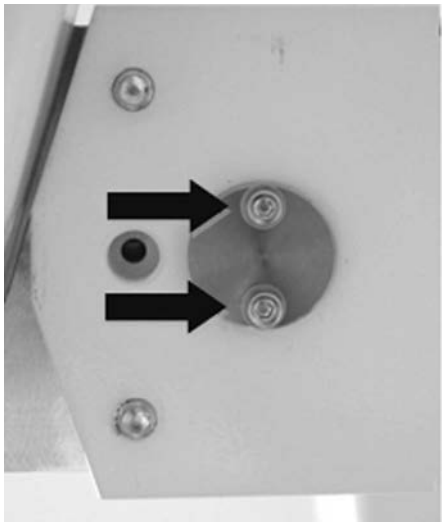
2. Adjust the vertical position of the collimator using the adjustment nut.

   Clockwise (cw) = Collimator upwards
   Counterclockwise (ccw) = Collimator downwards.

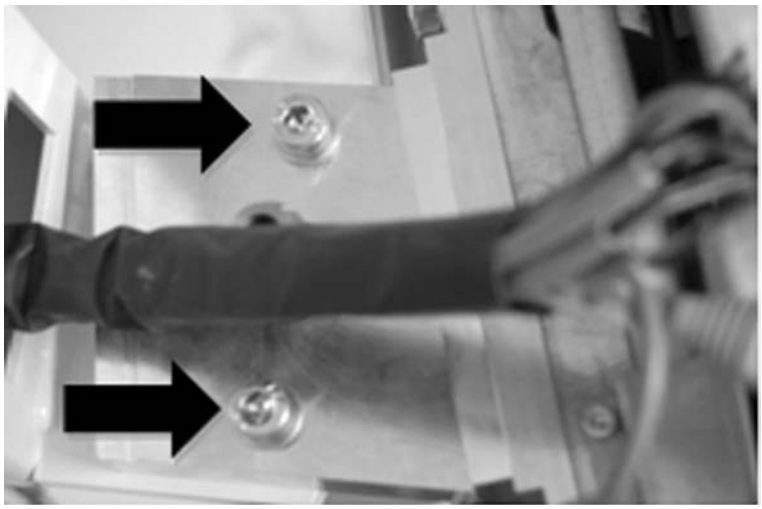
3. Tighten the locking nut.

7.2.4.4 Cephalostat fixation angle adjustment

1. Loosen two locking screws located in the bottom of the cephalostat, next to the cephalostat arm.



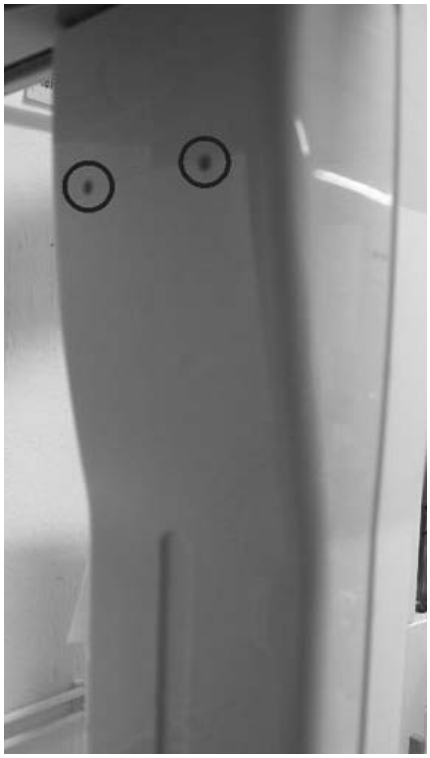
2. Slightly loosen two more locking screws, located next to the cephalostat arm.

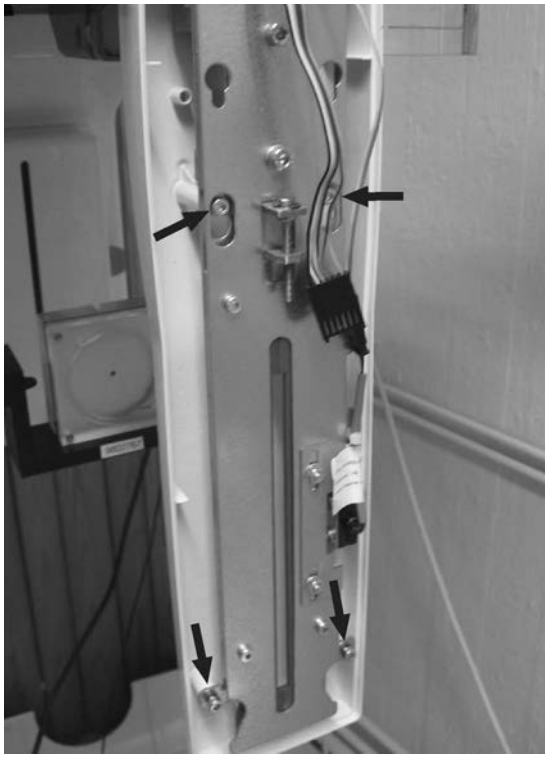


3. Turn the cephalostat.
4. Tighten the locking screws on the up side of the cephalostat. Also tighten the locking screws in the bottom of the cephalostat if you are done adjusting.
5. Re-calibrate Ceph Rotation Angle (see chapter 8.2.3).
6. Re-calibrate Mechanical Adjustment (see chapter 8.2.4).

7.2.4.5 Removing secondary collimator covers

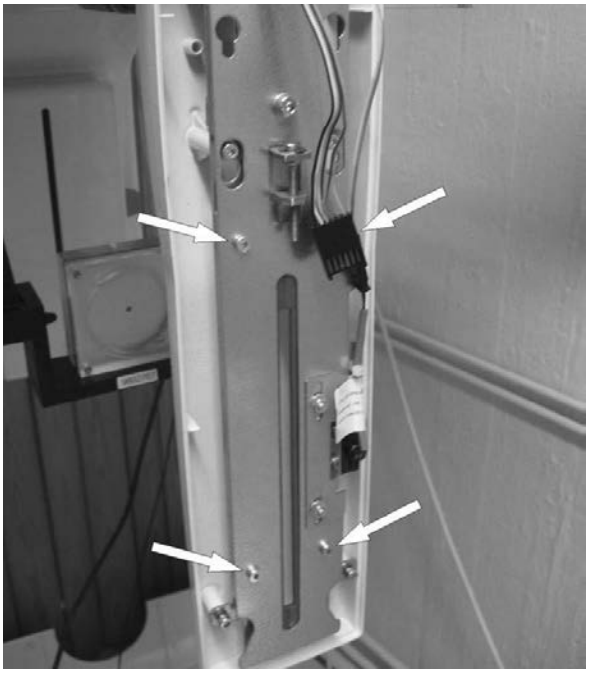
1. Loosen the counter piece screws (2 pcs) through the holes in the cover.
2. Lift the cover to have it removed.
3. Remove the two lower screws and loosen the two upper screws (marked with arrows in the picture) to remove the second cover.





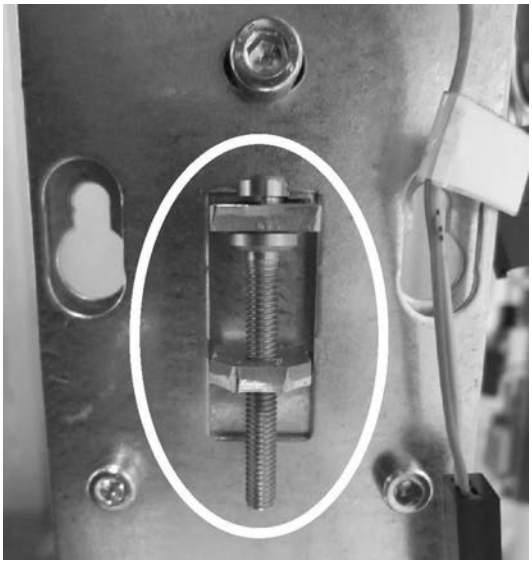
7.2.4.6 Secondary collimator vertical adjustment

1. Loosen four locking screws.



Collimator vertical locking screws.

2. Adjust the vertical position of the lead plates using the adjustment screw.

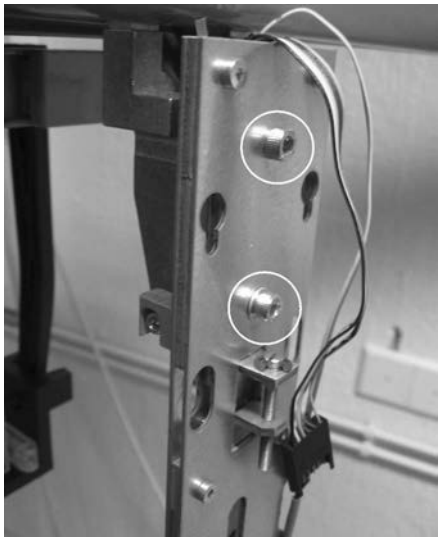


Vertical adjustment screw.

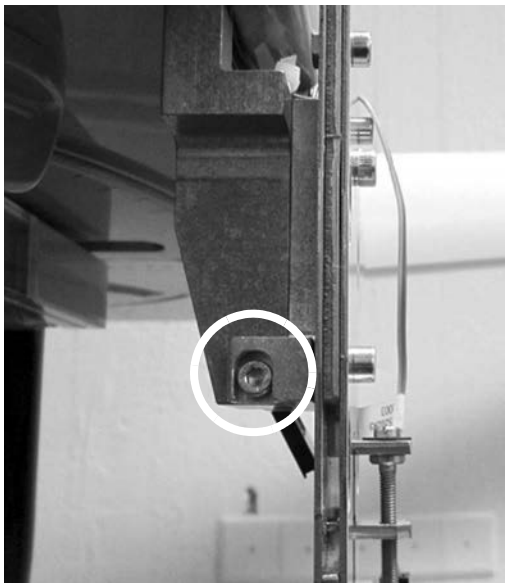
3. Tighten the locking screws.

7.2.4.7 Secondary collimator tilt adjustment

1. Loosen two locking screws.



2. Adjust the tilt of the secondary collimator using the tilt adjustment screw.



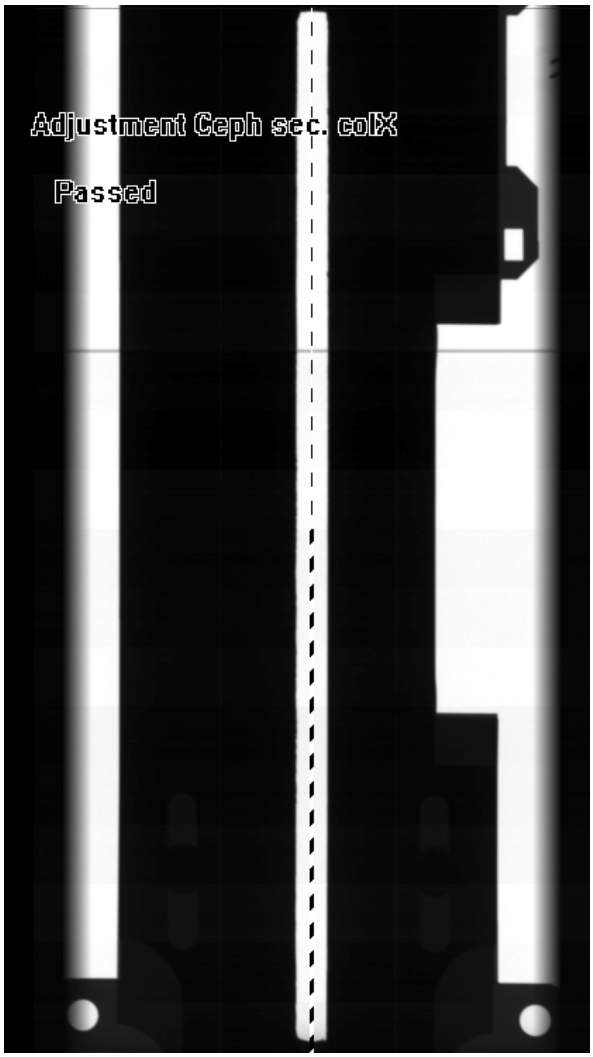
3. Tighten the locking screws.

7.2.5 Secondary collimator horizontal adjustment

1. Select Secondary Collimator Horizontal adjustment.

2. Press **Patient Positioning**.

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


Adjustment Ceph sec. colX
Passed

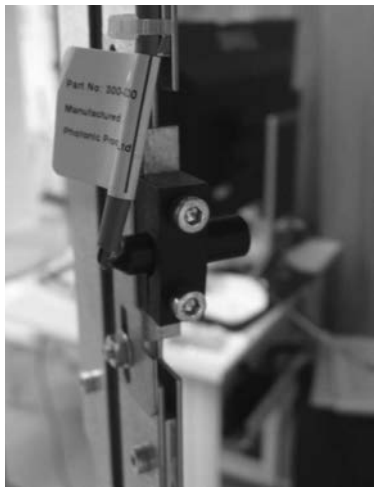
7.2.6 Cephalostat laser alignment

1. Select the **CEPH Lasers** program.

2. Press **Patient Positioning**.

3. Check that the laser beam is horizontal and that it goes through the center of the ear rod.

4. 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.



The laser is on the secondary collimator, see chapter 2.2. Patient positioning lights.

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

7.2.7 Cephalostat pixel calibration

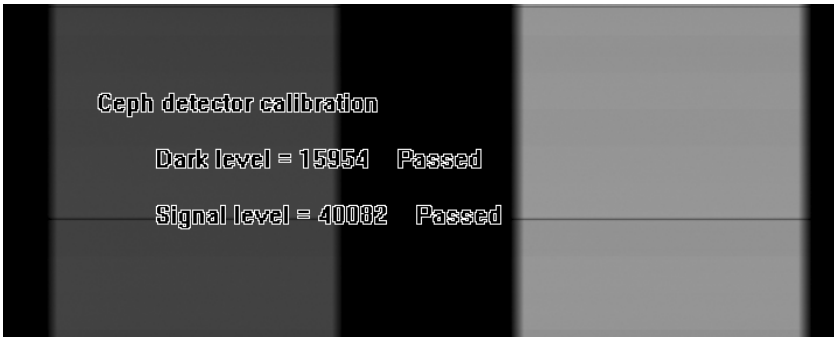
1. Attach secondary collimator and tubehead covers.
2. Rotate the ear holders into PA view position and move them completely apart.

   NOTICE! *Turn nasion support up out of the way.*

3. Select **CEPH Pix** Calibration program.

4. Press **Patient Positioning**.

5. Take an exposure.
6. This calibration should always be passed.

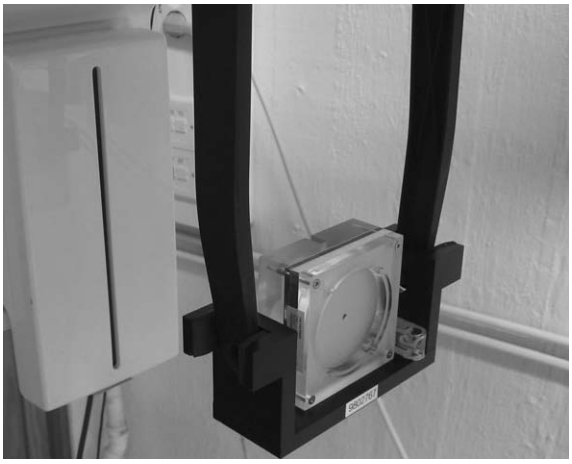


7.2.8 Cephalostat Quality Check (optional)

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

NOTICE! *Not required in North America.*

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

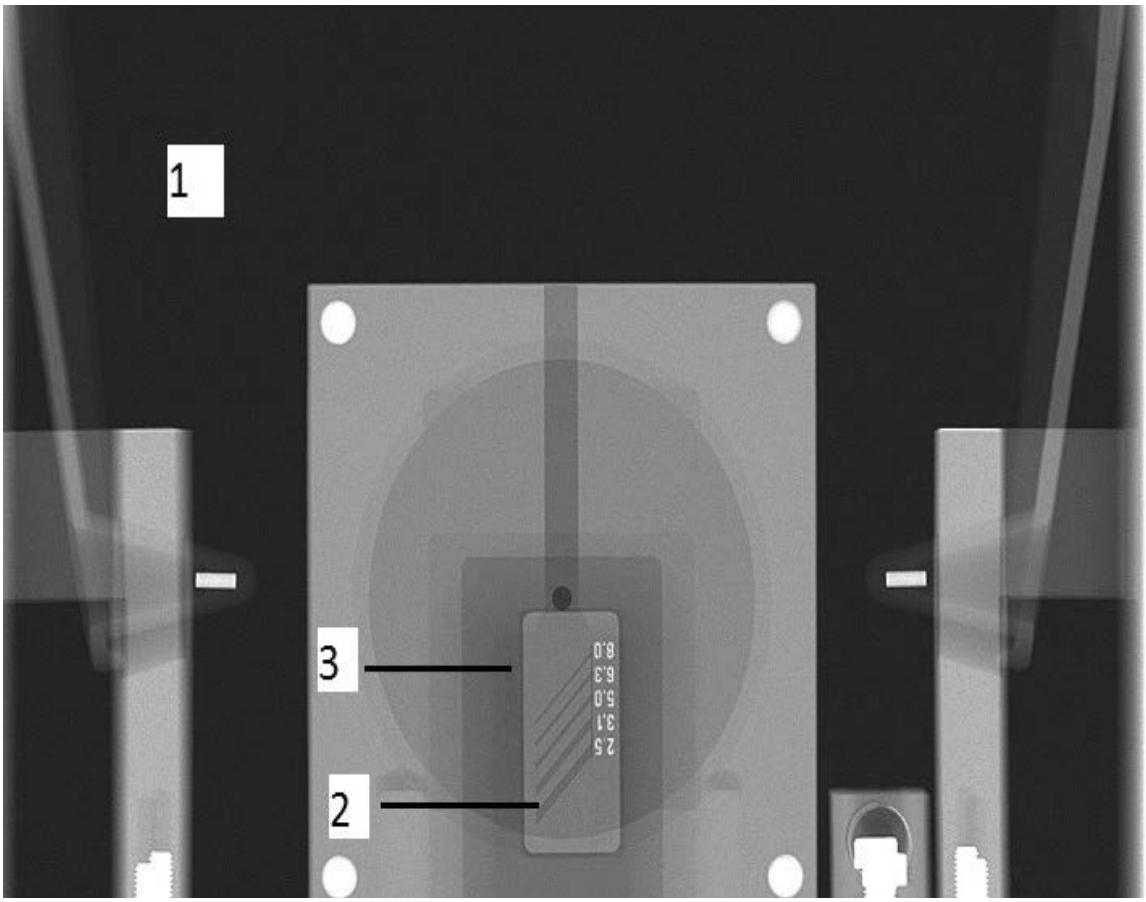


2. Select the **CEPH QC** program.

3. Press **Patient Positioning**.

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.

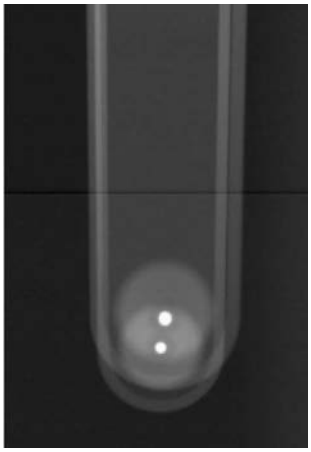
7.2.9 Ear holder alignment

NOTICE! *Rotate the ear holders into lateral view position and move them completely apart. Push nasion support as in as it go.*

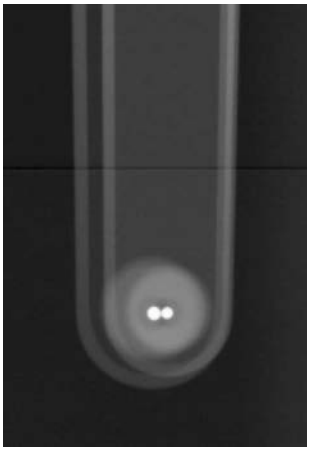
The ear holder center pins and the x-ray focal spot must be in line.

1. Turn the ear holders into the lateral view position and move them completely apart.
2. Select the cephalometric exposure program.

3. Take an exposure.
4. 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.
5. If the balls do not merge into a single ball, the ear holders must be adjusted.



Vertical adjustment needed



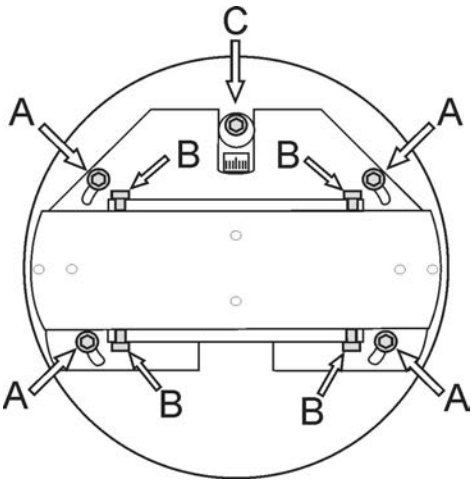
Horizontal adjustment needed

The balls merge; no adjustment needed

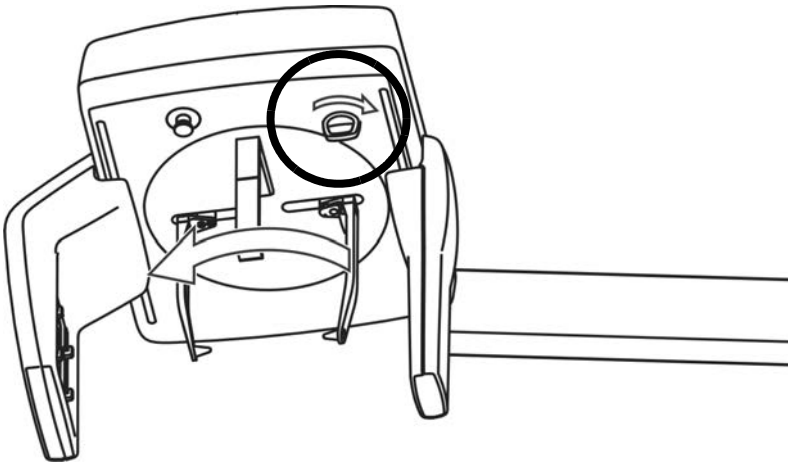
7.2.10 Horizontal adjustment

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

1. Loosen the 4 locking screws (A) on the ear holder assembly.

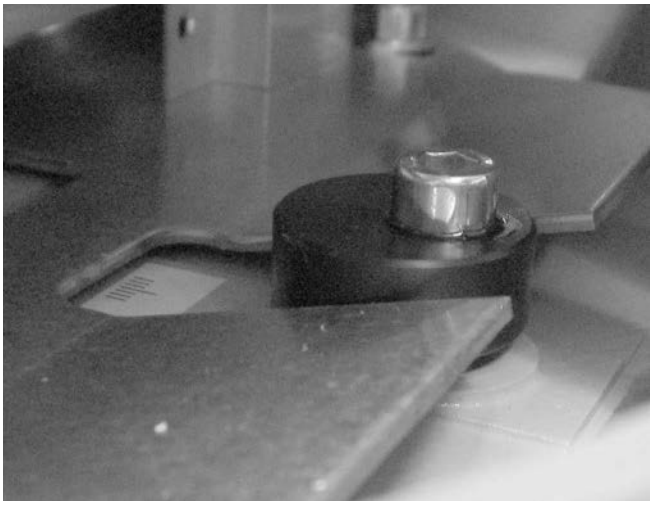


Top view of ear holder assembly.



To ease the loosening, lock the ear holder assembly to its place with the locking switch.

Locking screw (A)



Adjustment screw (C)

2. Make adjustments by turning the eccentric cam screw (C).

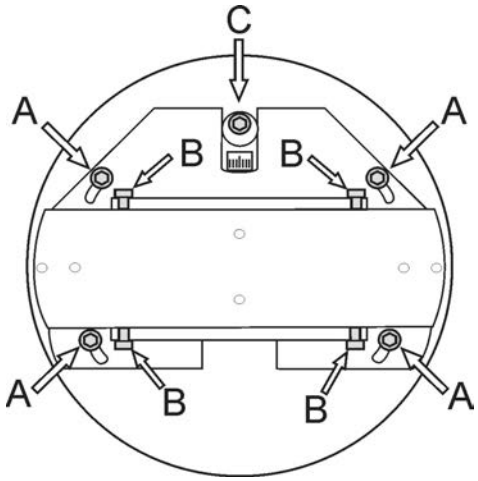
   Mark the starting position to the scale beside the screw. The amount of rotation can be seen on the scale.

3. Tighten at least two locking screws when adjustment is done and verify by taking a test image.

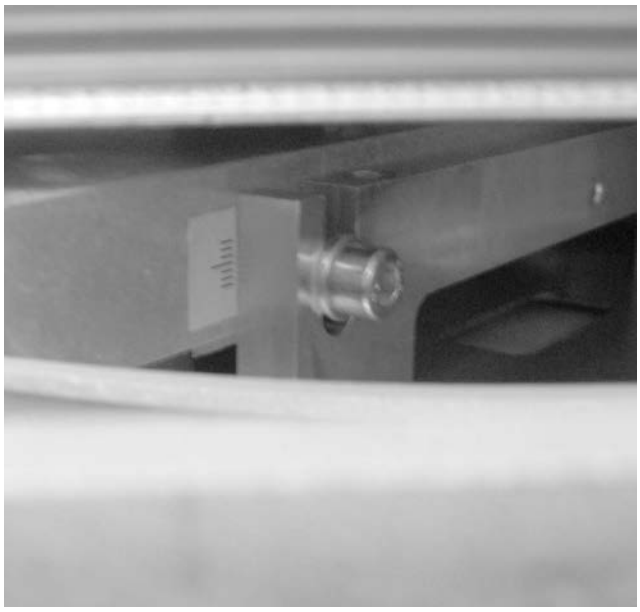
4. When the horizontal adjustment is complete, tighten all locking screws.

7.2.11 Vertical adjustment

1. Loosen the 4 locking screws (B) on the ear holder assembly.



Top view of ear holder assembly.



Locking screw (B)

Vertical adjustment screw

2. Mark the starting position to the scale beside the screw.
3. Make adjustments by turning the vertical adjustment screw at the end of the ear holder assembly.

   The amount of rotation can be seen on the scale.
4. Tighten at least two locking screws when adjustment is done and verify by taking a test image.
5. When the vertical adjustment is complete, tighten all locking screws.

8 Special procedures

8.1 General

When updating the unit, e.g. with a cephalometric or 3D option, it is always recommended to update the unit with latest firmware and the image capturing PC with the latest driver software (KaVo Driver Update CD). Please contact the manufacturer's Technical Support for further information.

NOTICE! *It is compulsory to update the earlier units with a cooling kit for the CPU before making firmware updates (R1.05 or newer).*

8.2 Cephalometric upgrade kit

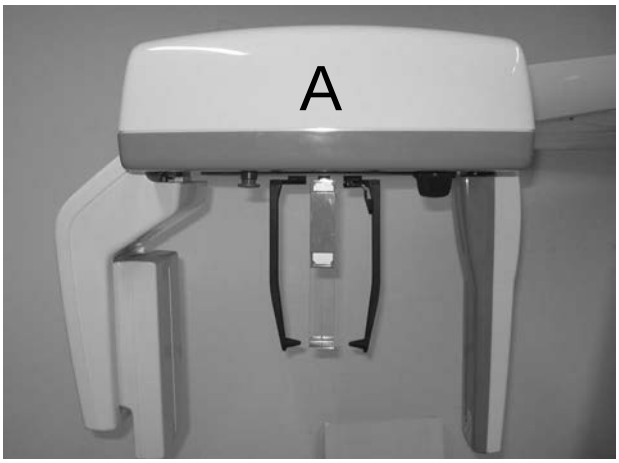
For the installation of the cephalometric upgrade kit see chapter 5.9 Installing the cephalometric unit.

For changing the handedness of the unit see chapter 8.3 Changing the cephalostat arm side.

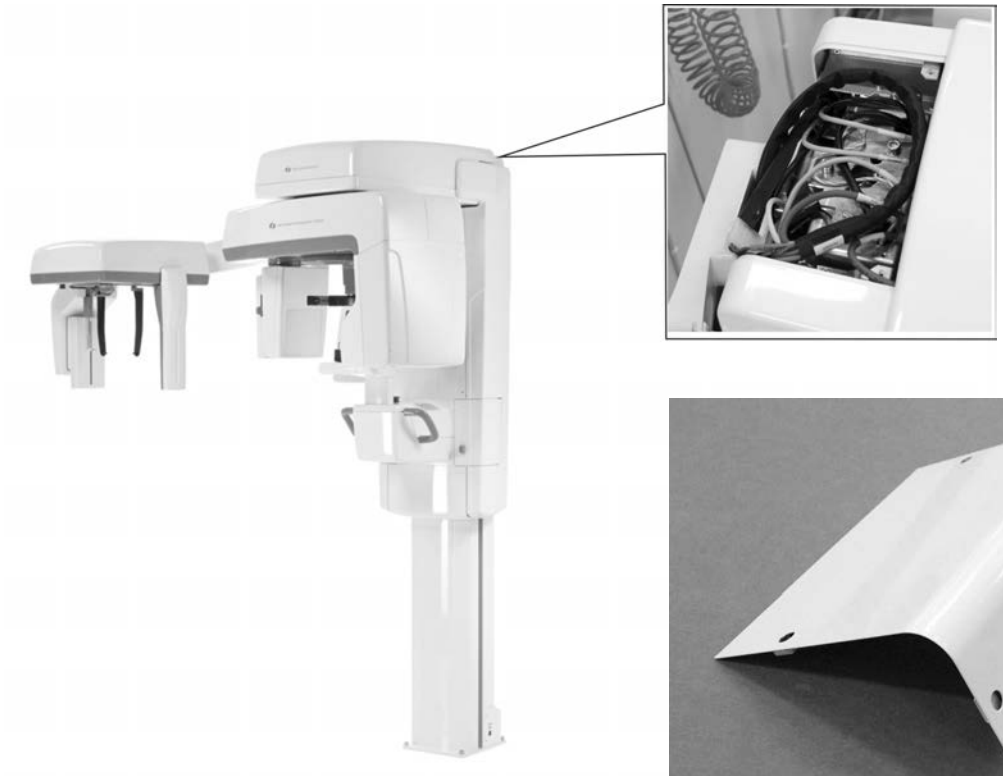
8.3 Changing the cephalostat arm side

Left hand cephalostat arm is on the left when standing in front of the unit. In these instructions left handed cephalostat is changed to be right handed.

1. Remove the upper cover (A) from the cephalostat head.

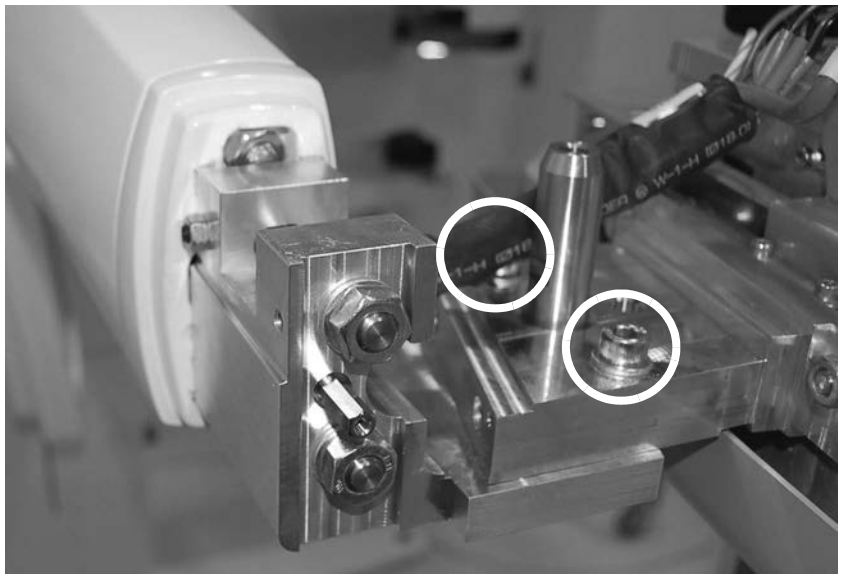


2. Remove the top cover of the column.



3. Remove the cables that go from the cephalostat head to the cephalostat arm. The cables can be left inside the arm.

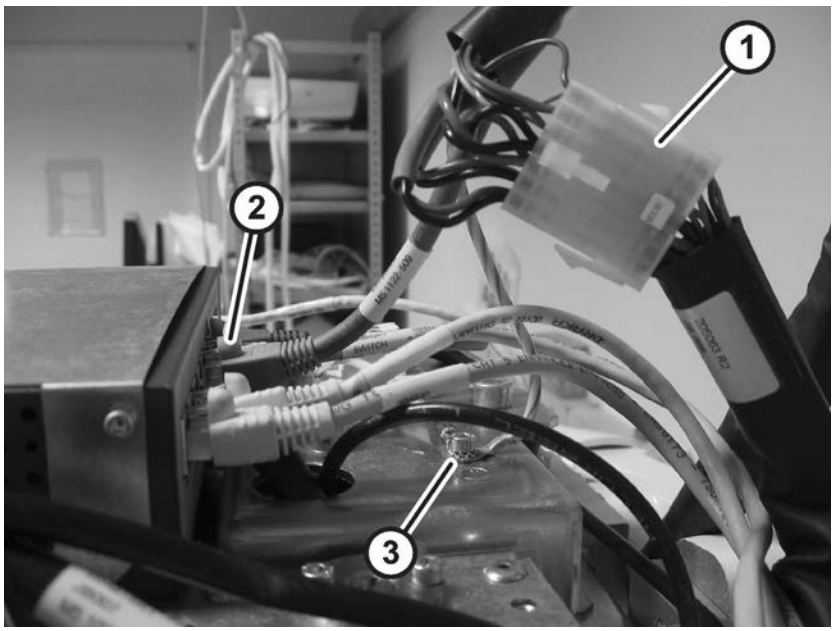
4. Loosen two screws, lift the cephalostat head and remove it from the arm.



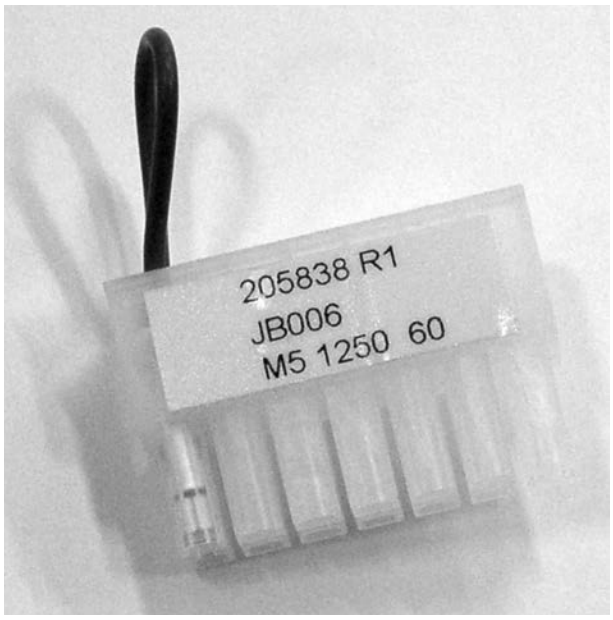
5. Remove the cables that go from the arm to the column.

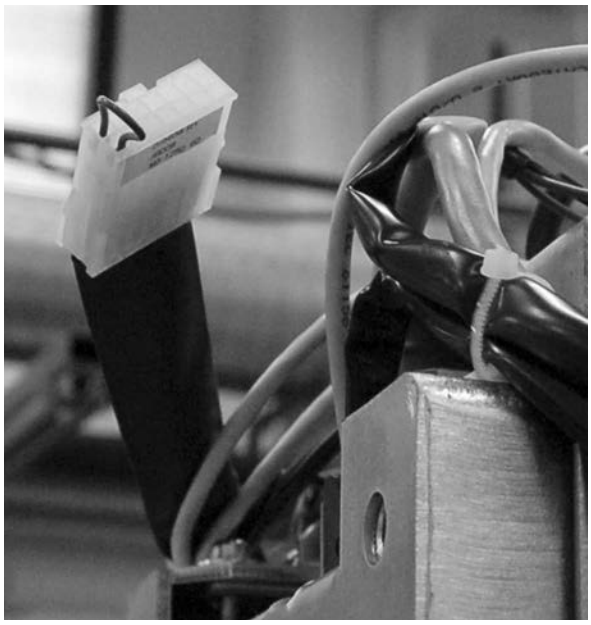
   On top of the unit column:

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



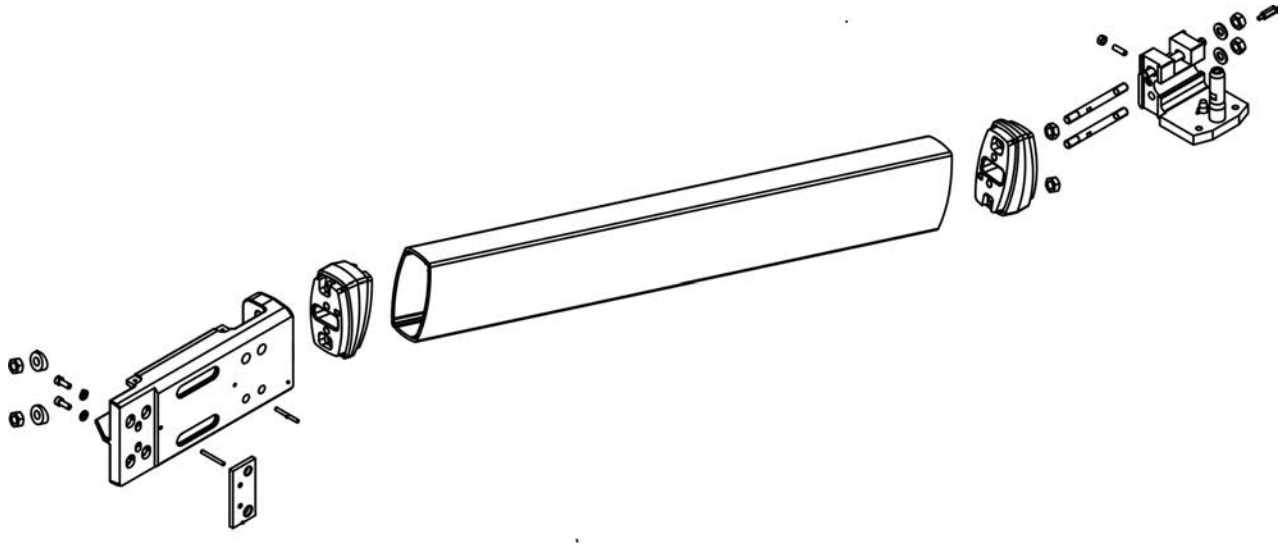
NOTICE! *There should be jumper JB006 connected to the connector JB006, when cephalometric unit is NOT installed.*





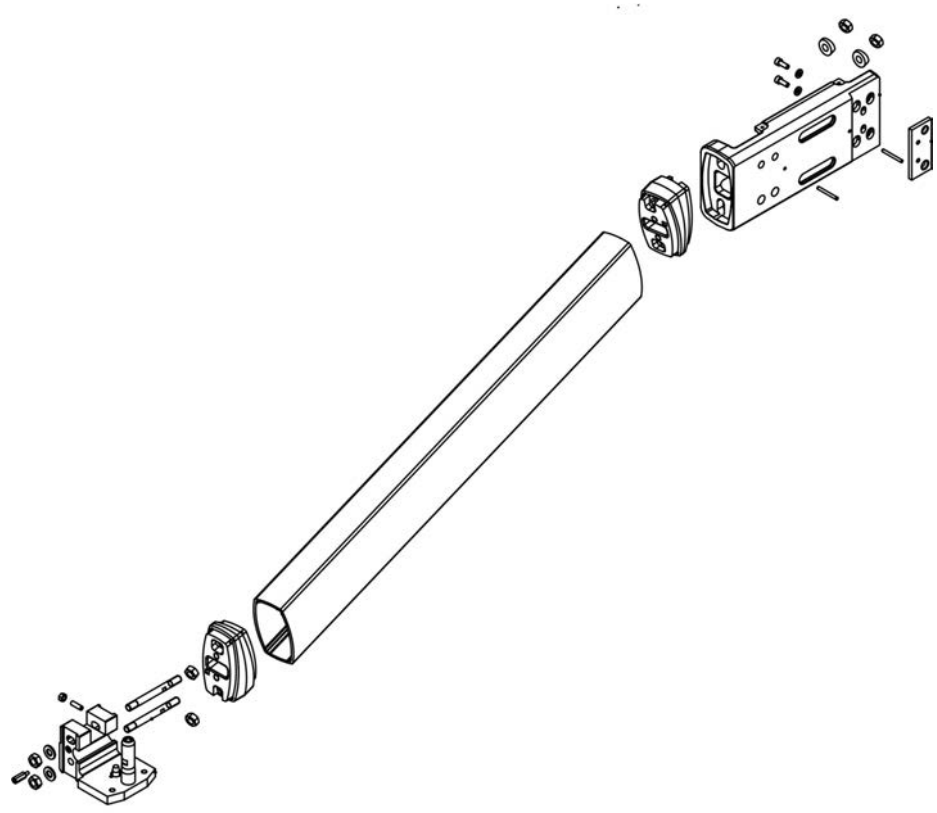
6. Remove the arm from the column (4 nuts).

7. Disassemble the arm.

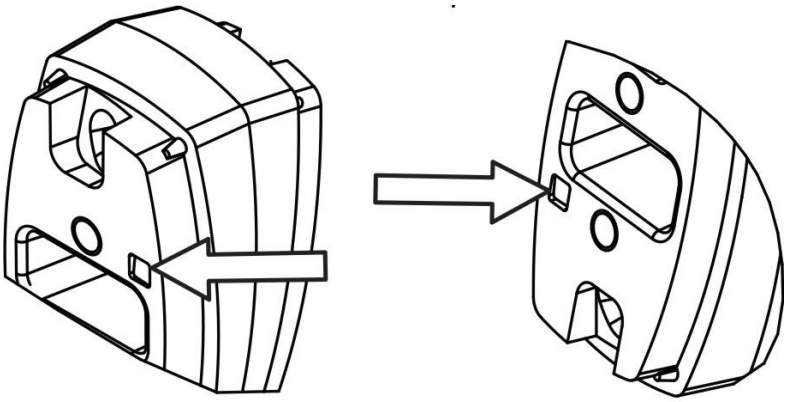


Right handed cephalostat arm.

8. Rotate the arm 180° with the cable inside. Re-assemble the arm from left handed to right handed (or vice versa when needed).

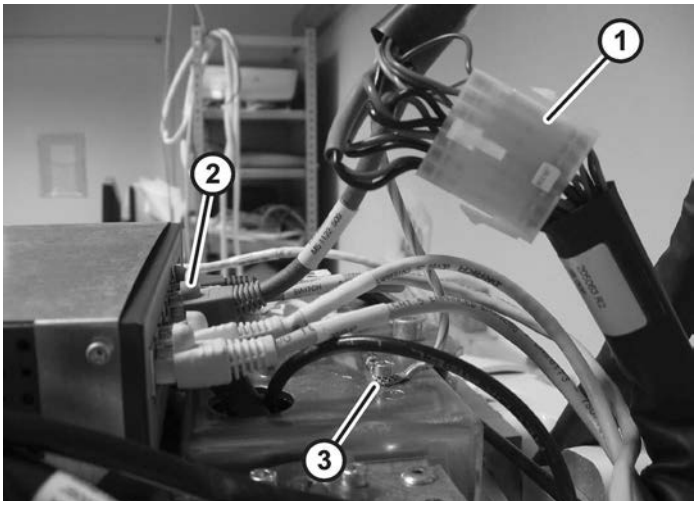


Left handed cephalostat arm.



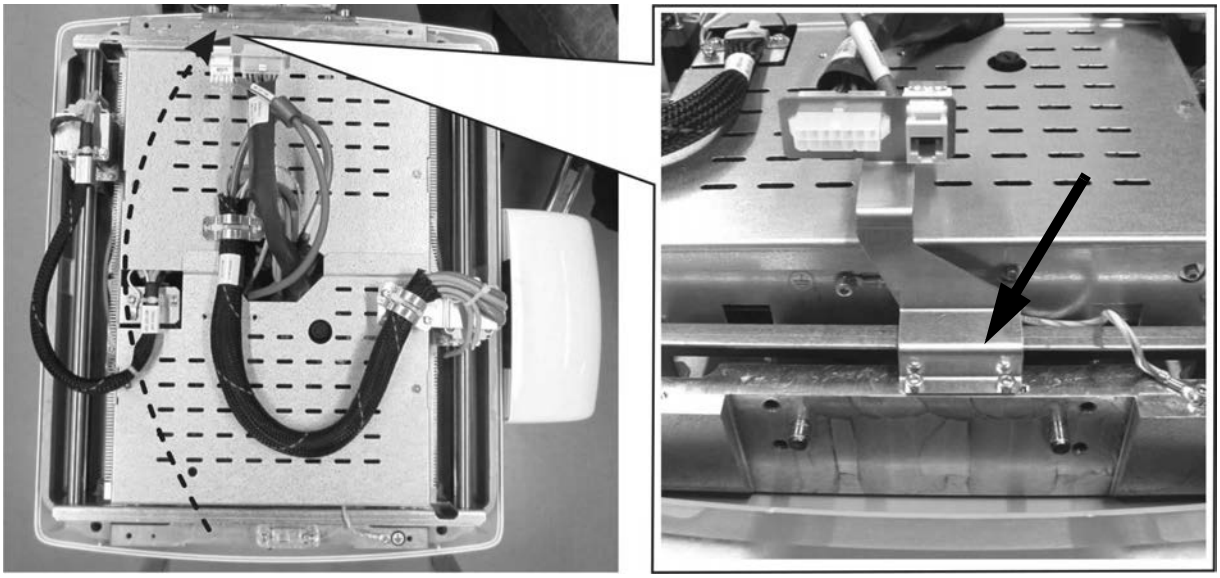
Notice the side of the square apertures in both arm ends.

9. Re-attach the cables from the column to the arm.



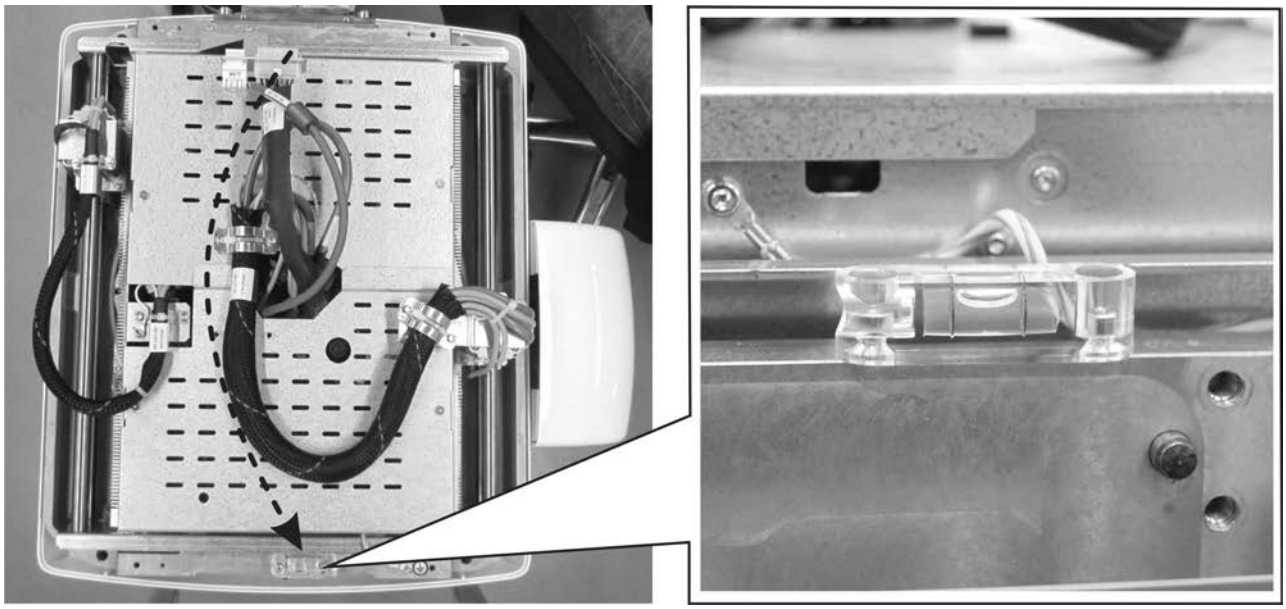
1: Signal/Power cable, 2: Ethernet cable, 3: Grounding point

10. Rotate the cephalostat head. Move the fastening plate of the cables to the other side of the cephalostat head.



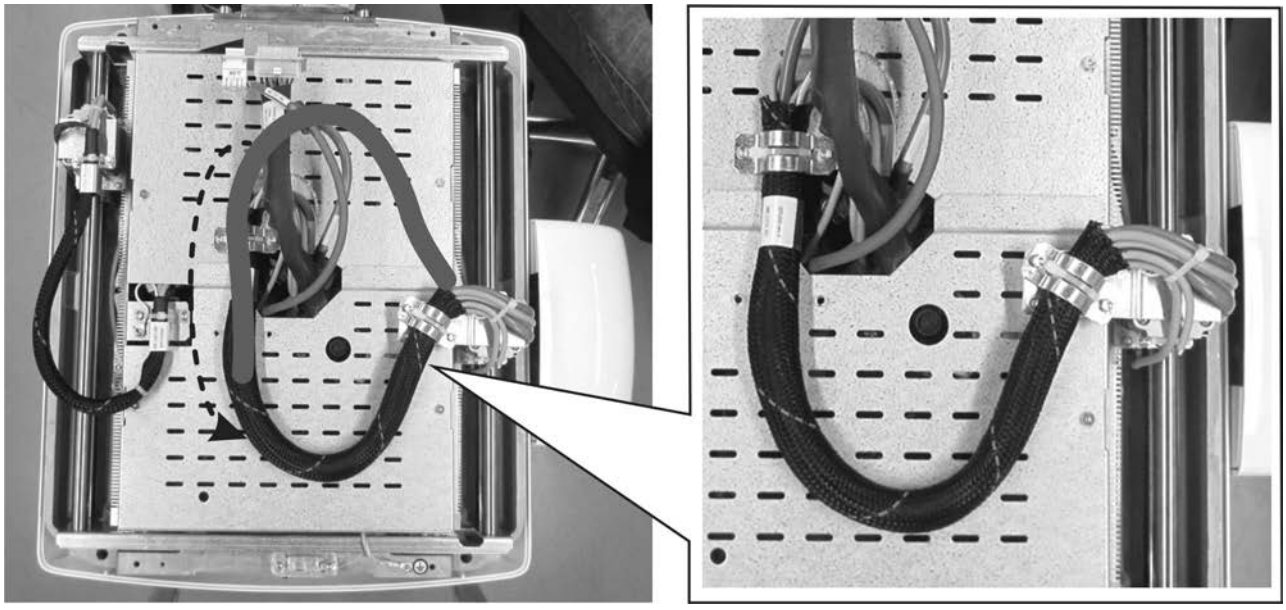
(right handed assembly)

11. Move the bubble level to the other side of the cephalostat head.



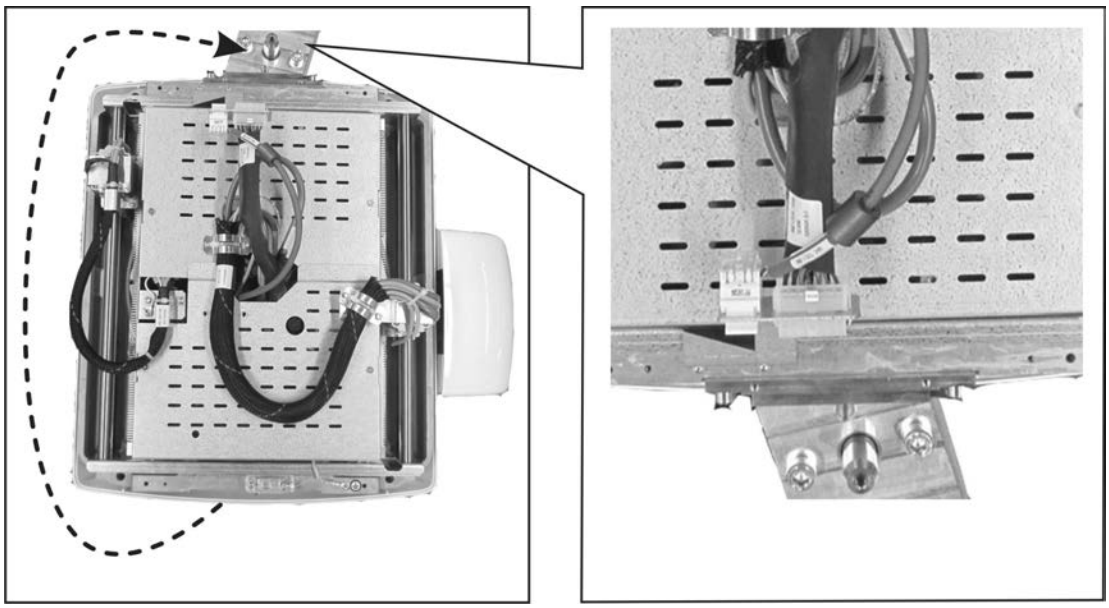
(right handed assembly)

12. Re-route the cables from the sensor to the other side of the cephalostat head.

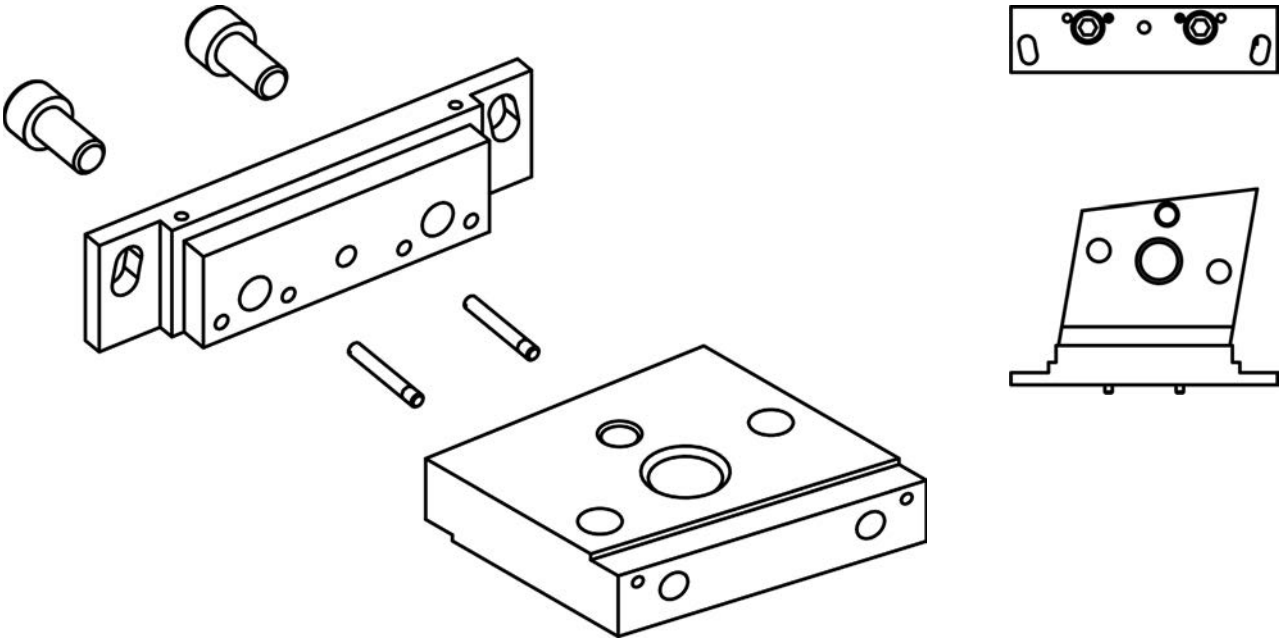


(right handed assembly)

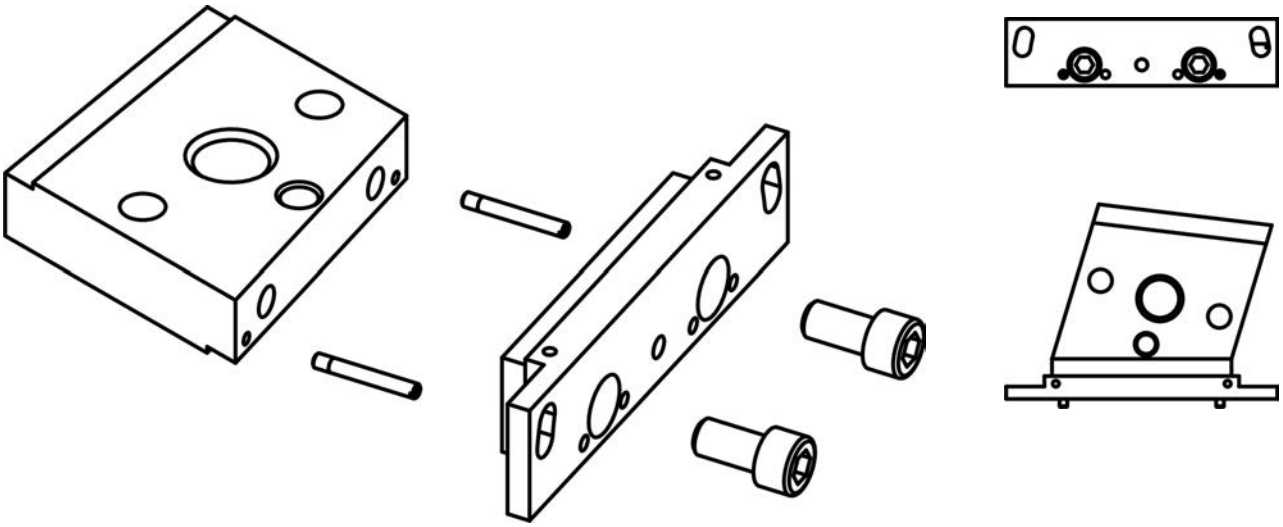
13. Move the prism assembly to the other side of the cephalostat head.



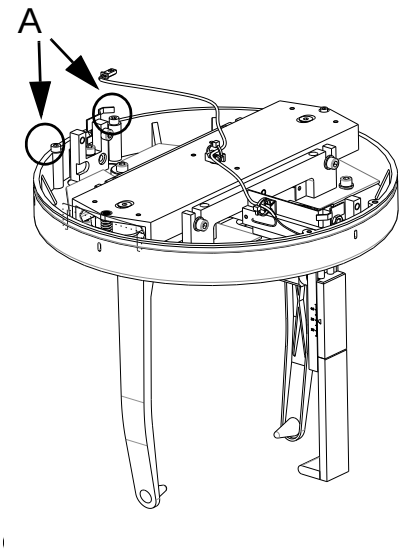
(right handed assembly)



Prism assembly for the left handed cephalostat.

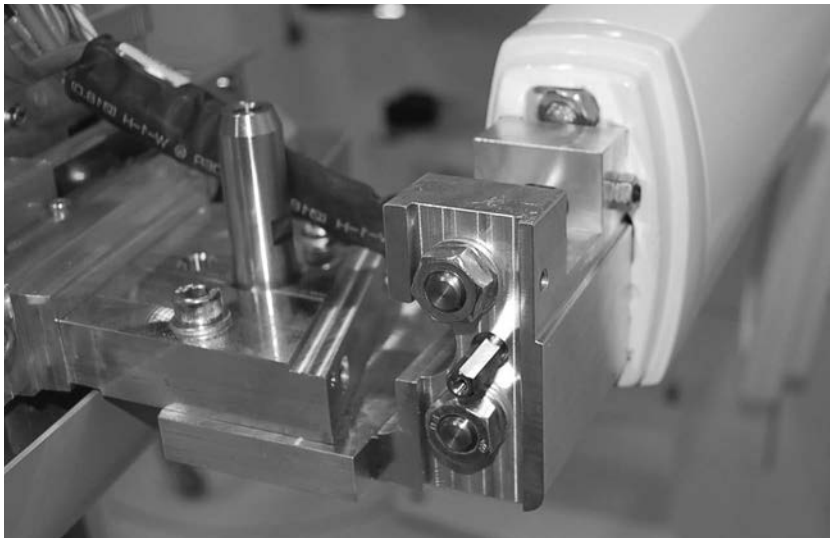


Prism assembly for the right handed cephalostat.



14. Move the 2 stop screws (A) to the other side so that when the patient is in the unit, they will be facing forwards to the room.

15. Re-attach the cephalostat head to the arm.



16. Re-connect the cables from the arm to the cephalostat head.

17. Re-attach the unit covers.

8.4 Changing the cephalostat arm side in service mode

Usage: **unithandedness** [**main**|**ceph**|**all**] [**l**|**r**]

main: Sets handedness for main unit

ceph: Sets handedness for cephalostat unit

all: Sets handedness for both cephalostat and main units

l: The GUI and/or cephalostat are on the left side of the unit

r: The GUI and/or cephalostat are on the right side of the unit

Use this to define the handedness options of the unit.

Usage examples:

unithandedness ceph l => cephalostat is on the left side of the unit

unithandedness main r => GUI is on the right side of the unit

unithandedness all r => cephalostat and GUI are on the right side of the unit

8.5 Adjusting and calibrating the cephalostat

For adjustments and calibrations see chapter 7.2 Cephalometric calibration sequence.

8.6 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.*

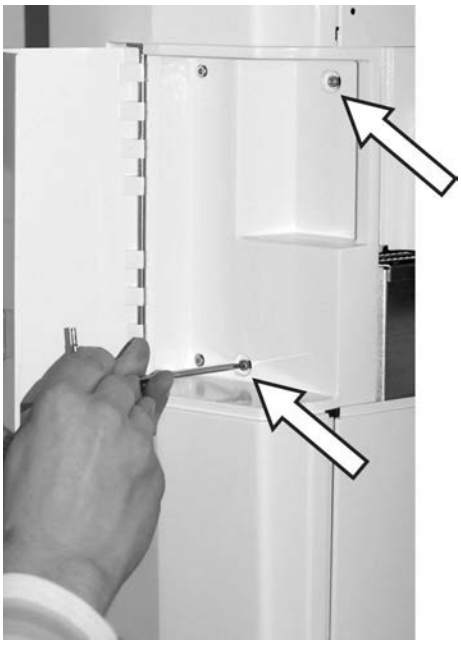
NOTICE! *Units are delivered from the factory with 230Vac line voltage settings. If your mains voltage is 100/120Vac, read this chapter for instructions how to change the line voltage setting of the unit.*

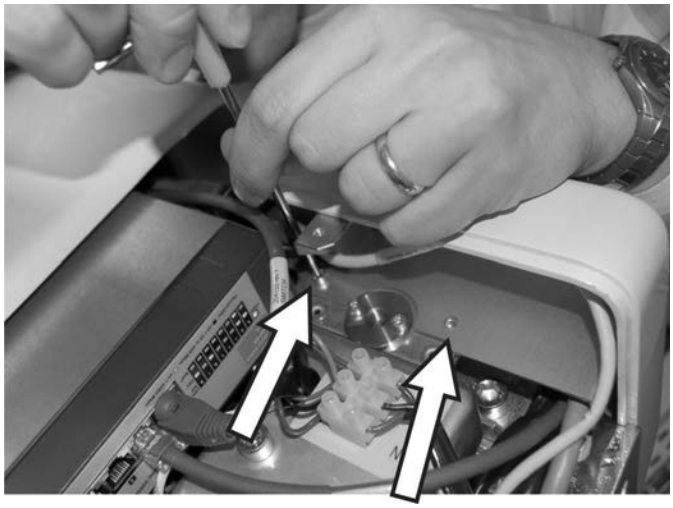
The unit can be set to operate at:

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

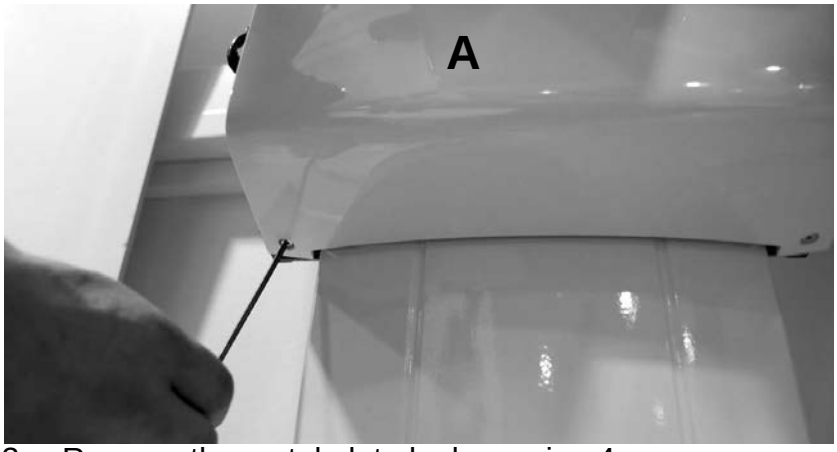
Mains voltage change

1. Open the side covers.





2. Remove the cover (A) under the lower shelf.



3. Remove the metal plate by loosening 4 screws.

4. 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.

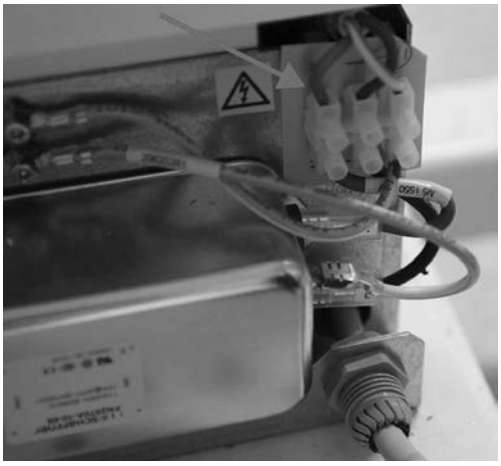
Jumper

5. 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)

6. Loosen the screws (DO NOT REMOVE) of the mains inlet cover and remove the cover.

7. Install the mains power cord wires to the terminal block on the base of the column and route the cable through the strain relief.



- 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

8. Install all the covers.

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 the Technical Specifications in the User Manual for more details.*

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

   NOTICE! 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.

8.6.1 Preparing the PC

NOTICE! *See the Service Manual for instructions on changing the IP address.*

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

   NOTICE! *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. If only the graphic card (GPU) was delivered with the device, install the GPU. For graphic card installation, refer to graphic card manufacturer's instruction delivered with the package or to manufacturer support site on the internet.

3. Switch the PC on and install the CLINIVIEW™ software driver and the dental imaging software that will be used with the device.

   Ensure that the provided Driver Updater is installed (see installation disk).

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

   NOTICE! *During the CLINIVIEW™ software installation when the Select Features window appears, make sure that you select the* OP 3D Pro *unit option.*

4. Install "Driver Update" from the Driver Update CD.

8.6.2 Configuring the communication link to the PC

NOTICE! *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.*

NOTICE*! Static IP address needs to be defined for the 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.

2. Switch the unit on and carry out initialization.

3. PC: Start the PC and then open CLINIVIEW™ or the dental imaging software that you installed.

4. PC: After CLINIVIEW™ software has opened, it automatically starts the driver. Locate “CBCT Driver” icon on the Windows taskbar, hold CTRL key down and click on the icon with right mouse button. A menu opens; click “Driver setup”-item to continue.

5. PC: IP address of the unit can be entered in the assigned field.

   For stand-alone configurations use the default IP address of the Unit (10.208.6.101). Set the IP address of the PC to 10.208.6.1. If required different addresses can be used (the unit and PC are required to be on same subnet).

Setting an IP address to the unit

NOTICE! *If the Unit is part of a network, you will have to get an IP address for the unit from you local IP administrator. Refer to s2terminal usage instructions in the Service Manual for instructions on changing the IP address.*

UNIT: Press and hold keys “Positioning lasers” and “Patient positioning”. The unit accepts IP configuration for 60 seconds.

PC: Click on the “Send to CBCT” button to configure the unit with the new IP address.

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).

8.7 Firmware update

8.7.1 Preparing for update

You need the following for a typical update:

The latest release package, available from Technical Support's extranet site.

A host PC for performing the update. The host PC may be a separate PC (e.g. a laptop computer) or the image acquisition workstation.

Also recommended is a spare CAT6 Ethernet cable and a USB Blaster (see chapter *Volatile installation*).

Preparing the update

1. Prepare a connection to the X-ray unit.

- When performing the update from the image acquisition workstation, close down any imaging application.

- When performing the update from a separate computer, connect an Ethernet cable directly between the computer and the X-ray unit. For this to work, you need to make the computer use the same subnet as the X-ray unit. On Windows 7 (similarly for other Windows versions), select **Control Panel** → **View Network Connections** → **Local Area Connection** → **Properties** → **Internet Protocol Version 4** and click the **Properties** button.

  Use the following settings:
  IP address: 10.208.6.102
  Subnet mask: 255.255.255.0

  NOTICE! *The settings above are valid if the X-ray unit is using the default IP address (10.208.6.101). If the unit's IP address is something else, set the first three numbers in the computer's IP address equal to the unit's, and make the last one differ. The unit's IP address is shown in the settings view in GUI.*

2. Copy the software release package to the host PC and unzip it.

3. Locate openS2.bat in the unzipped release package and double click it. You will be prompted for unit's IP address. Type it in (if other than default) and press enter.

4. An s2terminal connection is established to the unit. A list of command shortcuts (macros) is printed. These may be used to streamline the update process. Alternatively, the commands can be typed in manually.

8.7.2 Software update

The embedded software release package consist of a number of compatible software components. They can be updated either:

- manually - each software component is programmed separately or
- automatically - all software components are programmed using a single command.

Automatic update is recommended for normal updates. Manual update may be necessary in cases where the automatic update fails or for troubleshooting purposes.

8.7.2.1 Automatic update

Press the F10 button and press enter, or type in manually:

```
xu R<ver_major>.<ver_minor>
```

Example:

```
xu R2.00
```

An automatic update of the embedded software is performed. Follow the instructions printed in the s2terminal prompt and wait for the update to complete.

8.7.2.2 Manual update

When performing a manual update, the main/cephalostat CPU core and firmware must be updated in a given order. For other software components, the recommended order is the following:

1) Update the Main CPU R3220 core.

2) Power off and on again.

3) Update the Main CPU firmware.

4) Update the GUI software.

5) Update the R3400 firmware and core.

6) Update the R3300 firmware and core.

7) Update the Ceph R3210 core (units equipped with cephalostat).

8) Power off and on again.

9) Update the Ceph firmware (units equipped with cephalostat).

10) Set software release version.

After updating any software component, the unit must be restarted before normal operation is resumed. Reboot is not required between separate software component updates, unless otherwise stated in the component's update instructions.

Main CPU FPGA core update

1. Press the F2 button and press enter, or type in manually:

   ```
   xcc r3220 R<ver_major>.<ver_minor>
   ```

   Example:

   ```
   xcc r3220 R2.00
   ```

   This starts a R3220 core update. Wait until the software is transferred and the unit has restarted. Power off the unit before the countdown in the boot prompt ends.

2. Power on the unit again, this time type:

   ```
   safe
   ```

   and then press enter before the countdown in the boot prompt ends. This puts the unit in safe mode for R3220 firmware update.

Main CPU firmware update

Press the F3 button and press enter, or type in manually:

```
xf R<ver_major>.<ver_minor>
```

Example:

```
xf R2.00
```

Wait for the software package to be transferred and the unit to restart itself. If the update fails, try again.

GUI software update

Press the F4 button and press enter, or type in manually:

```
xcc gui R<ver_major>.<ver_minor>
```

Example:

```
xcc gui R2.00
```

Wait for the software package to be transferred. Make sure that the transfer is successful by following the messages printed in the s2terminal prompt. Try again in case of failure.

R3300 firmware and core update

1. Press the F5 button and press enter, or type in manually:

   ```
   xcc r3300 R<ver_major>.<ver_minor>
   ```

   Example:

   ```
   xcc r3300 R2.00
   ```

2. Wait for the software package to be transferred to the IO board. Make sure the transfer is successful by following the messages printed in the s2terminal prompt. Try again in case of failure.

3. The new software is taken into use the next time the unit is powered on.

R3400 firmware and core update

1. Press the F6 button and press enter, or type in manually:

   ```
   xcc r3400 R<ver_major>.<ver_minor>
   ```

   Example:

   ```
   xcc r3400 R2.00
   ```

2. Wait for the software package to be transferred to the IO board. Make sure the transfer is successful by following the messages printed in the s2terminal prompt. Try again in case of failure.

3. The new software is taken into use the next time the unit is powered on.

Cephalostat CPU FPGA core update

NOTICE! *The instructions below are valid when the cephalostat CPU is currently running a previous version of the cephalostat software. For instructions on programming a non-responsive or unprogrammed spare part CPU board, refer to chapter Special cases.*

1. Press the F7 button and press enter, or type in manually:

   ```
   xfr OP3DPRO_CEPHR3210_R<ver_major>_<ver_minor>.srec core
   ```

   Example:

   ```
   xfr OP3DPRO_CEPHR3210_R2_00.srec core
   ```

2. Wait until the update is completed, power off and power on again. Do not enter safe mode like in main CPU R3220 update.

Cephalostat firmware update

NOTICE! *The instructions below are valid when the cephalostat CPU is currently running a previous version of the cephalostat software. For instructions on programming a non-responsive or unprogrammed spare part CPU board, refer to chapter Special cases.*

1. Press the F8 button and press enter, or type in manually:

   ```
   xfs OP3DPRO_CEPHRFW_R<ver_major>_<ver_minor>.srec main
   ```

   Example:

   ```
   xfs OP3DPRO_CEPHFW_R2_00.srec main
   ```

2. Wait for the software package to be transferred and for the cephalostat CPU to boot itself. If the update fails, try again.

Verify and set the software version

1. Wait for the unit to start up and then type:

   ```
   login
   ```

   The unit should reply with a list of software versions. Check that they match the versions listed in the file ver-

sions.txt included in the software release package. If all versions match, proceed to the next step. Otherwise, you must first update the mismatching components.

2. Set the software release version by pressing F9, or by manually typing:

   ```
   pmode 0 <ver_major> <ver_minor>
   ```

   Example:

   ```
   pmode 0 2 00
   ```

   The unit should reply

   ```
   programming ended successfully, version now
   R2.00
   ```

   This command makes the unit store the versions of the software components currently loaded, so that the validity of the software release may be verified later. If one or more software component are manually changed without this step being carried out, the version will be displayed with an "M" postfix (as in "Modified"), e.g. R1.11M.

8.8 Volatile installation

Volatile installation is useful when a circuit board is not responsive to Ethernet communication, for example due to corrupted software. Using a JTAG programmer the software may then be loaded directly into the RAM of the circuit board, after which the software may be permanently installed the normal way through Ethernet. Volatile installation is available for all embedded software components except the GUI.

To perform a volatile installation you will need:

An Altera USB-Blaster Download Cable, available from Altera at:

http://www.altera.com/products/devkits/kit-cables.html

Alternatively, a Terasic USB Blaster Download Cable, available from Terasic can be used:

www.terasic.com.tw

Quartus II Programmer software, available for download from Altera at:

https://www.altera.com/download/software/prog-software

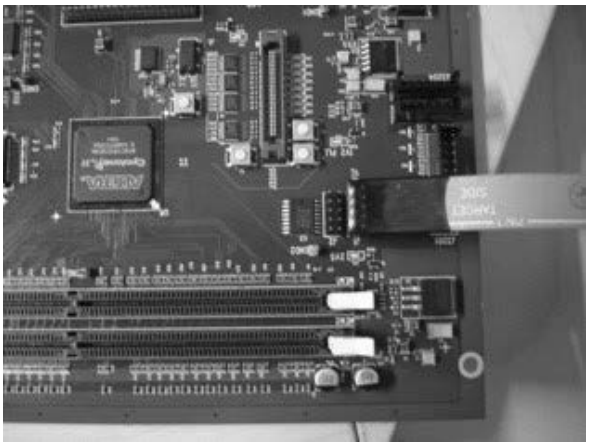
The jic/sof programming file for the circuit board to be programmed, included in the software update package.

8.8.1 Installation procedure

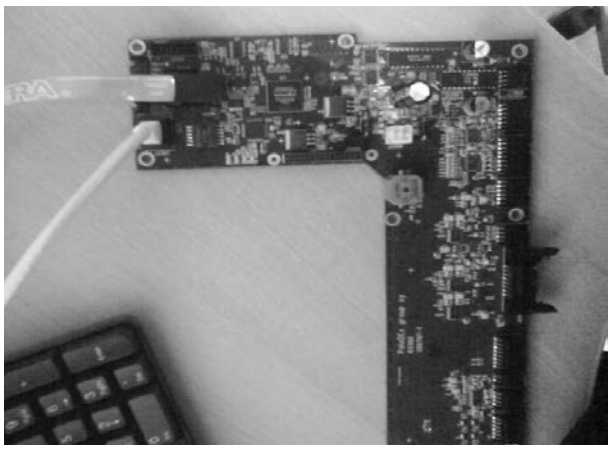
8.8.1.1 R3210, R3300, R3400

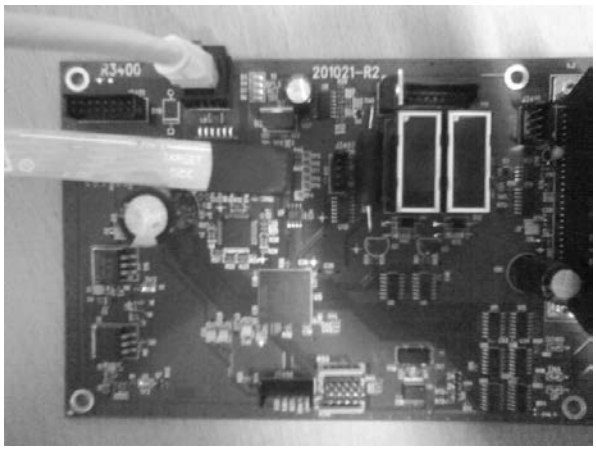
1. Connect the USB-Blaster's USB connector to a PC with the Quartus II Programmer software installed.
2. Connect the USB-Blaster's 10-pin connector to the JTAG port on the circuit board to be programmed (see circuit board specific connections below).

   NOTICE! See the orientation of the connector in figure below.



Connect to J1 on the R3210 board (Cephalostat CPU)



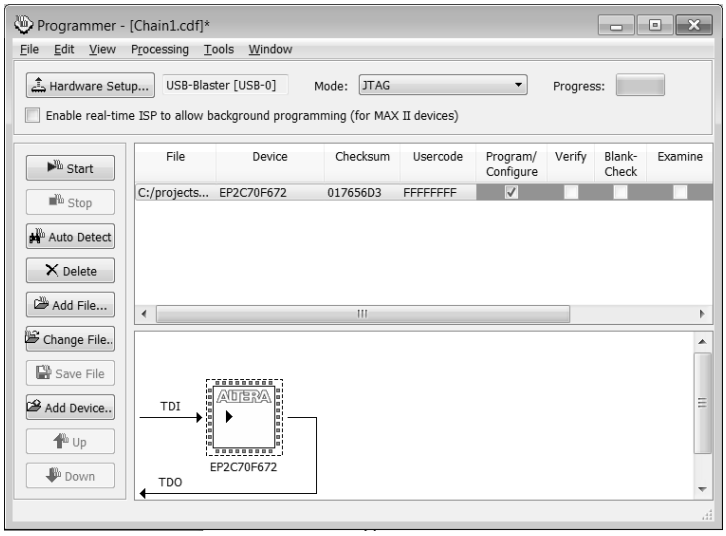


Left: Connect to J3304 on the R3300
Right: Connect to J3405 on the R3400

3. Start Quartus II programmer and click the Hardware Setup button in the upper left corner.
4. Select USB-Blaster from the Currently selected hard-

ware drop down list and click Close.

5. Click the Auto Detect button to have the programmer detect the device type and verify the connection to the circuit board.
6. Select the first row in the list and click the Change File… button.
7. Select the correct sof file for the circuit board (e.g. R3300_R2_00.sof for release R2.00 and R3300 circuit board).

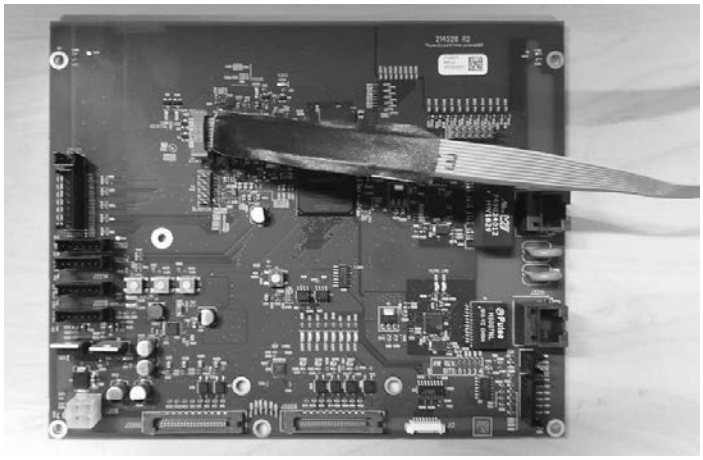


8. Mark the Program/Configure check box.
9. Click the Start button and wait for the download to complete (takes a few seconds).
10. Volatile installation is typically followed by a permanent install. Refer to chapter Manual update for instructions on how to do this. The volatile install is voided if the unit is powered off before the software is permanently installed.

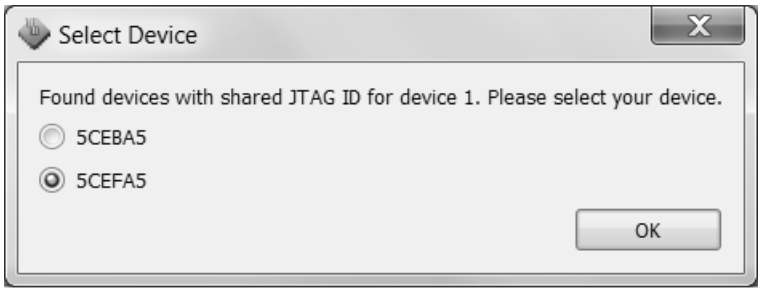
8.8.1.2 R3220

1. Connect the USB-Blaster's USB connector to a PC having the Quartus II Programmer software installed.
2. Connect the USB-Blaster's 10-pin connector to the JTAG port on the circuit board to be programmed (see circuit board specific connections below). Note the ori-

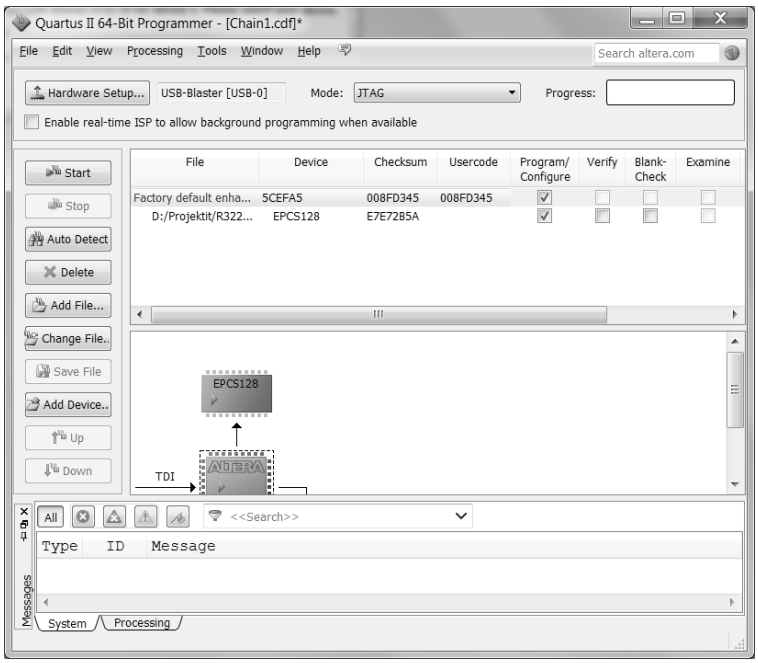
entation of the connector!



3. Start Quartus II programmer and click the Hardware Setup button in the upper left corner.
4. Select USB-Blaster from the Currently selected hardware drop down list and click Close.
5. Click the Auto Detect button and select 5CEFA5 device.



6. Select the first row in the list and click the Change File… button.
7. Select the correct sof file for the circuit board (e.g. R3220_R2_00.jic for release R2.00 and R3220 circuit board).



8. Mark the Program/Configure check box.
9. Click the Start button and wait for the download to complete (takes a few seconds).
10. Volatile installation is typically followed by a permanent install. Refer to chapter Manual update for instructions on how to do this. The volatile install is voided if the unit is powered off before the software is permanently installed.

8.9 Special cases

8.9.1 Programming a R3220 Main CPU board having wrong unit type configured

In case the CPU board is configured with wrong unit type or does not have a unit type configured, the s2terminal will not be able to locate the programming files properly. This is possible, for example, if a spare part R3220 board is used. To decide the unit type assumed by the s2terminal, follow the messages printed in the prompt right after a connection has been established.

If the board's unit type is not recognized by the s2terminal, it will prompt the user for the type to use. Enter the unit's type and program the board according to the instructions in chapter 8.7.2.2 Manual update.

If the board's unit type is not what it should be, programming must be done using an explicitly named programming file. See instructions below.

To program a R3220 Main CPU board using explicitly named programming files:

1. Establish a connection to the board as per instructions in Preparing for update.

2. Update the FGPA core using the command:

   ```
   xcpr 3220 OP3DPRO_R3220_R<ver_major>_<ver_minor>.pof
   ```

   Example:

   ```
   xcp r3220 OP3DPRO_R3220_R2_00.pof
   ```

   Wait until the software is transferred and power off the unit.

3. Power on the unit again. When a connection is established, type in

   ```
   safe
   ```

   and press enter before the countdown in the boot prompt ends. This puts the unit in safe mode for R3220 firmware update.

4. Update the firmware using the command

   ```
   xfp OP3DPRO_FW_R<ver_major>_<ver_minor>.srec
   ```

   Example:

   ```
   xfp OP3DPRO_FW_R2_00.srec
   ```

5. Wait for the software package to be transferred and the unit to restart itself. If the update fails, try again.

8.9.2 Programming a non-responsive cephalostat CPU

The cephalostat CPU must be running valid cephalostat software in order to be updateable using the normal approach.

- A non-responsive cephalostat CPU may be reprogrammed by doing a volatile installation using a USB Blaster download cable, followed by a permanent installation using a direct connection between the host PC and the CPU board.
- A cephalostat CPU board loaded with non-cephalostat software (e.g. a generic R3210 board used as spare part),may be programmed also without the help of a USB Blaster download cable.

The instructions below deal with these two cases separately.

8.9.2.1 Programming using a USB Blaster download cable

To program a non-responsive cephalostat CPU with the help of a USB Blaster download cable, proceed as follows:

1. Make a volatile installation of the cephalostat CPU FPGA core. Refer to chapter Volatile installation for more detailed instructions.

2. Connect an Ethernet cable between the host PC and the 100 Mb/s Ethernet port (J3211) on the cephalostat CPU board.

3. Run the openS2.bat file to have an s2terminal session started. Refer to chapter Preparing for update for more detailed instructions. Use the default IP address (10.208.6.101). A connection should be established and a boot prompt shown in the s2terminal, for example:

   CEPH R3200c boot-2.18R2798>

   otherwise redo the volatile installation.

4. Update the FGPA core using the command:

```
xcpr 3210 OP3DPRO_CEPHR3210_R<ver_major>_<ver_minor>.srec
```

   Example:

```
CEPH R3200c boot-2.18R2798>xcp r3210
OP3DPRO_CEPHR3210_R2_00.srec
Transferring OP3DPRO_CEPHR3210_R2_00.srec to Main CPU
Updating core...
transfer 864965 bytes from S-records...
update 0 864965 = 0x0..+864965
FRAMES:1205
Flashing image (864965 bytes) @0x0
Status command transfer error.
Login fail (no connection).
Login fail (no connection).
Login fail (no connection).
Verifying...
verified ok
Done.
```

   Wait until the update is completed, power off and power on again. You should again have a boot prompt coming up in the s2terminal, otherwise start over from step 1.

5. Update the cephalostat CPU FW using the command:

   `xfp OP3DPRO_CEPHRFW_R<ver_major>_<ver_minor>.srec`

   Example:

```
CEPH R3200c boot-2.18R2798>xfp
OP3DPRO_CEPHFW_R2_00.srec
Reading program file "OP3DPRO_CEPHFW_R2_00.srec" ...
Waiting for eraseErase time: 1342
Programming...
FRAMES:367
FRAMES:367
…
Checking embedded checksum...
checksum verified ok
```

```
;Flashing image (263148 bytes) @0x120000
Status command transfer error.
Verifying...
Error in login reply - command executed
verified ok
Done.
Connected to CBCT
CEPH R3200c boot-2.18R2798>
```

Wait for the software package to be transferred and for the cephalostat CPU to boot itself. If the update fails, try again.

6. Power off and power on again. Disconnect the Ethernet cable and reconnect it (needed since the MAC address of the CPU board has changed).

7. Verify that the version of the firmware matches the one listed for "Ceph FW" and "Ceph Core" in the release package's versions.txt file using command:

   ```
   login
   ```

   Example:

   ```
   ngeoceph> login
   main 1.4.4693/2012-08-10T15:32:43/TUULTESKELINEN
   core 2012-01-31T12:17:34/EP2C70F672C6/AUTO
   ```

8. Connect the cephalostat CPU board to the X-ray unit's internal network. Restart the unit and verify that the cephalostat is detected. This may be done by connecting the host PC to the X-ray unit's external Ethernet connector and following messages printed to the s2terminal or by verifying that the cephalostat tab is shown in the GUI.

8.9.2.2 Programming a cephalostat CPU board running non-cephalostat SW

If the R3210 board is loaded with other than cephalostat software, the procedure outlined below may be used. Note that the approach using the USB Blaster download cable is valid and recommended also in this case.

1. Connect an Ethernet cable between the host PC and the gigabit Ethernet port (J3210) on the R3210 board.

2. Run the openS2.bat file to have an s2terminal session started. Refer to chapter Preparing for update for more detailed instructions.

3. Update the FGPA core using command:

   `xcp r3210 OP3DPRO_CEPHR3210_R<ver_major>_<ver_minor>.srec`

   Example:

```
CEPH R3200c boot-2.18R2798>xcp r3210
OP3DPRO_CEPHR3210_R2_00.srec
Transferring OP3DPRO_CEPHR3210_R2_00.srec to Main CPU
Updating core...
transfer 864965 bytes from S-records...
update 0 864965 = 0x0..+864965
FRAMES:1205
Flashing image (864965 bytes) @0x0
Status command transfer error.
Login fail (no connection).
Login fail (no connection).
Login fail (no connection).
Verifying...
verified ok
    Done.
```

4. Wait until the update is completed, power off and power on again.
5. Connect the Ethernet cable to the 100 Mb/s port of the R3210 (J3211). The boot prompt should appear again in the s2terminal.
6. Update the cephalostat CPU FW using command:

   `xfp OP3DPRO_CEPHRFW_R<ver_major>_<ver_minor>.srec`

   Example:

```
CEPH R3200c boot-2.18R2798>xfp OP3DPRO_CEPHFW_R2_00.srec
Reading program file "OP3DPRO_CEPHFW_R2_00.srec" ...
Waiting for eraseErase time: 1342

Programming...
FRAMES:367
FRAMES:367
…
Checking embedded checksum...
checksum verified ok
;Flashing image (263148 bytes) @0x120000
Status command transfer error.
Verifying...
Error in login reply - command executed
verified ok
Done.
    Connected to CBCT
    CEPH R3200c boot-2.18R2798>
```

7. Wait for the software package to be transferred and for the cephalostat CPU to boot itself. If the update fails, try again.
8. Power off and power on again. Disconnect the Ethernet cable and reconnect it (needed since the MAC address

of the CPU board has changed).

9. Verify that the version of the firmware matches the one listed for "Ceph FW" and "Ceph Core" in the release package's versions.txt file using command:

   ```
   login
   ```

   Example:

   ```
   ngeoceph> login
   main 1.4.4693/2012-08-10T15:32:43/TUULTESKELINEN
   core 2012-01-31T12:17:34/EP2C70F672C6/AUTO
   ```

10. Connect the cephalostat CPU board to the X-ray unit's internal network. Restart the unit and verify that the cephalostat is detected. This may be done by connecting the host PC to the X-ray unit's external Ethernet connector and following messages printed to the s2terminal or by verifying that the cephalostat tab is shown in the GUI.

8.10 Troubleshooting

8.10.1 Problem: No connection to the X-ray unit / R3220 circuit board

Indication: A connection cannot be established. "Login fail (no connection)" is continuously printed in the s2terminal.

Possible reasons and solutions:

1. No physical connection to between the host PC and the X-ray unit. Check the link led next to the Ethernet port is lit. Check that the cable is not faulty and that the CPU board is powered.
2. Incorrect network settings. Check that the IP and subnet mask is correctly set in the host PC. Check that the X-ray unit's IP matches the IP you are trying to connect to. Refer to chapter Preparing for update for further instructions.
3. The Ethernet connector is connected to the wrong Ethernet port on the R3220 board. Connect to the correct port: J3210.
4. A software update has failed and left the CPU board in a non-responsive state. Perform a volatile installation as described in chapter Volatile installation.

The MAC address of the CPU board has changed due to a different type of software component being loaded. Disconnect and reconnect the Ethernet connector to have

the host PC notice the change and update its routing tables.

8.10.2 Problem: Automatic software update fails

Indication: Failure message from the automatic updater.

Possible reasons and solutions: Automatic software update may fail for example due to connectivity problems. Problems may also occur when updating from early embedded software versions. In case of failure, try to restart the automatic update. If it fails repeatedly, revert to manual update.

8.10.3 Problem: Manual update fails

Indication: Messages printed to the s2terminal indicate that the update did not succeed.

Possible reasons and solutions:

1. Faulty internal or external Ethernet cables. Retry the update. Don't power off the unit since this will typically leave it in a non-responsive state! Try to replace cables without powering off the unit.
2. Interference by another s2terminal or driver in the host PC. Make sure any imaging application is closed down. Close all other s2terminals than the one performing software update.

Faulty circuit board or insufficient power supply. Measure the voltage from the circuit board's power connector. Check that it matches the board's nominal voltage (typically 5V). Replace the board if faulty (if no other reason for found for the update to fail).

8.10.4 Problem: S2terminal is unable to find binary files

Indication: When trying to program, there is an error message in s2terminal:

```
Unable to locate binary file "OP3DPRO_fw_r2_00.srec"
or  ".\OP3DPRO_r2_00\OP3DPRO_fw_r2_00.srec"
```

Possible reasons and solutions:

1. Wrong command syntax or binary file name typed in. Check the syntax and filename.
2. The files are not found in the assumed location. Run the s2terminal using the openS2.bat file found in the software release package's root folder. Check that the file mentioned in the error message is really present. If not, unzip a new copy of the release package.

The unit type of the Main CPU board is incorrectly set. The unit type for which the s2terminal is trying to find binary files is indicated in the error message. See chapter Special cases / Programming a R3220 Main CPU board having wrong unit type configured for instructions on how to solve this issue.

8.11 Configurable panoramic mAs limit

A mAs (milliampere-seconds) limit of 250 mAs may be set for panoramic programs, if required by local regulations. When mAs limiting is enabled, the largest mA setting is removed for the imaging programs Standard panoramic, OrthoZone and Wide arch panoramic.

The mAs limiting feature is controlled by the s2terminal service program *limitmas*:

`limitmas` prints current setting

`limitmas on` enables limiting

`limitmas off` disables limiting

9 OP 3D Pro 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.

9.1 Physical Environment Requirements

		RESPONSIBILITY	APPROVAL LEVEL			
			OK	Does not meet the specs	Modifi-cation needed	Com-ment
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				

9.2 Radiation Shielding Requirements

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

9.3 Mechanical Specifications

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) Cephalostat: 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 m y 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 cephalostat weighs 245 kg/ 540 lbs (212 kg / 467 lbs without cephalostat). The area of the column base plate is 0,07 m^2. Make sure that the floor where the unit is to be installed can support this weight.	End User/Dealer				

9.4 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				

9.5 Networking Specifications

		RESPONSIBILITY	APPROVAL LEVEL			
			OK	Does not meet the specs	Modification needed	Comment
1Gb/s network to all components involved with OP 3D Pro system	The connection between the unit and PC must meet EN60601-1requirements. OP 3D Pro 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. OP 3D Pro should be connected to the Workstation PC directly.	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 succesful set-up.	End User/Dealer				

9.6 Computer Specifications

See chapter 4 for PC requirements.

9.7 Backup Specifications

The CLINI-VIEW™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 CLINI-VIEW™software Installation Manual.	End User				

9.8 DICOM Services SCP

	IDENTIFIERS		
	AE Title	**Port number**	**IP Address**
Worklist SCP			
Storage SCP			
Storage Commitment SCP			
Print SCP			
Query / Retrieve SCP			

9.9 Software configuration

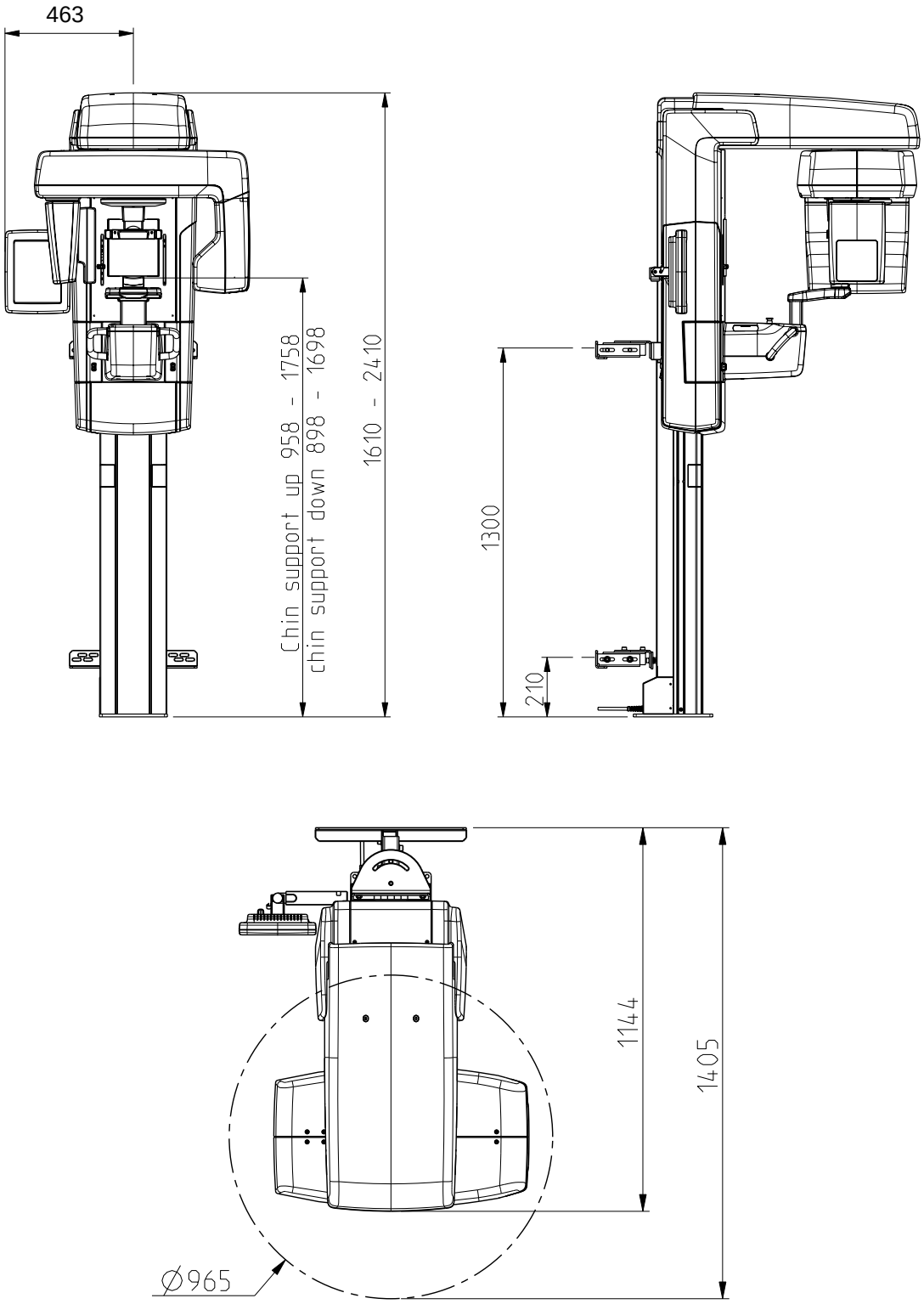
		YES	NO	DETAILS
Which software components are included in delivery?	CLINIVIEW™ software (required)	X		
	OnDemand3D Dental (3D visualization software)			
	CLINIVIEW™ software DICOM Option			NOTE: If full integration into a DICOM environment is needed, software DICOM Option is required. This includes printing 2D images to DICOM printers, DICOM Storage, Modality Worklist, Query / Retrieve.
	FMS			Full Mouth Series option for intraoral use
	InVivoDental			Delivered in US only.

9.10 Other information

3rd party 3D software:	Is CLINIVIEW™ software going to be used with existing 3rd party 3D software? NOTE: Direct link between CLINIVIEW™ and 3rd party 3D software is available for the following software: Materialise Simplant, Cybermed OnDemand3D, Anatomage InVivoDental. Additionally, DICOM compatible 3D software (such as NobelGuide) is compatible with the unit			
DICOM Conformance statement	Have the DICOM conformance statement(s) been delivered to the end-user?			Can be downloaded from the manufacturer 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 X-ray units	Are any other digital imaging systems installed in the clinic?			
Imaging software already in use	CLINIVIEW™ (please provide the version number)			
	Other			

9.11 Notes / comments

9.12 Dimensions



9.13 Dimensions with cephalostat