

**ENGLISH**

# **Orthopantomograph® OP300**

## **Installation Manual**

204389 rev. **2**



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**Manufactured by**

Instrumentarium Dental  
Nahkelantie 160 (P.O. Box 20)  
FI-04300 Tuusula  
FINLAND  
Tel. +358 10 270 2000  
Fax. +358 9 851 4048

For service, contact your local distributor.



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# 1 Introduction

## 1.1 General

Instrumentarium Dental **Orthopantomograph® OP300** x-ray unit (hereafter called “OP300”) is a software controlled diagnostic dental X-ray equipment for producing high quality digital images of dentition, TM-joints and skull. In order to take images with OP300 you need a suitable PC hardware connected to the OP300 unit and ClinView software to handle images.

## 1.2 Intended use

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

USA only

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

## 1.3 About this manual

This manual describes how to set up OP300 X-ray unit. Please read this installation manual before installing the unit.

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

## 1.4 Abbreviations used in this manual

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

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

ADC = Automatic Dose rate Control

## 1.5 Associated documents

The CliniView software installation manual or the installation manual for the dental imaging software you are using. The installation instructions supplied with the 3D imaging software you are using.

## 1.6 Warnings and precautions

### To be observed during installation

- When installing a dental X-ray unit always observe local and national safety, radiation control and electrical regulations.
- There should be enough space around the installation place of the unit.
- The place where the unit is to be installed and the position from where the user will take exposures must be correctly shielded from the radiation that is generated when the unit is operated.
- The unit or its parts must not be changed or modified in any way without approval and instructions from Instrumentarium Dental.
- When servicing use only approved replacement parts supplied by Instrumentarium Dental.
- Mains selection should be correct and site environment. No explosive vapors.
- Be aware of hot surfaces and sharp edges when removing covers during installation and maintenance.
- The Ethernet cable shall be unshielded CAT6, so that multiple chassis are not connected. To maintain patient safety it is mandatory to use an unshielded CAT6 Ethernet cable between the unit and the network or workstation. Non-medical grade PC should not be used in patient environment.
- If this device will be used with 3rd party imaging application software not supplied by Instrumentarium Dental, 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 Instrumentarium Dental.  
The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.
- The aperture plate and tubehead housing are made of lead (Pb), which is a toxic material. Do not touch these parts with your bare hands.
- OP300 must be installed and serviced according to the OP300 installation & Adjustments manual by a qualified and trained technicians.
- This product itself complies IEC 60601-1 medical safety standard but in order to the system incorporating also a PC to comply the standard, EITHER the PC has to be a medical PC OR the PC has to be located over 1,5 meters apart from the OP300 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.

### To be observed during use

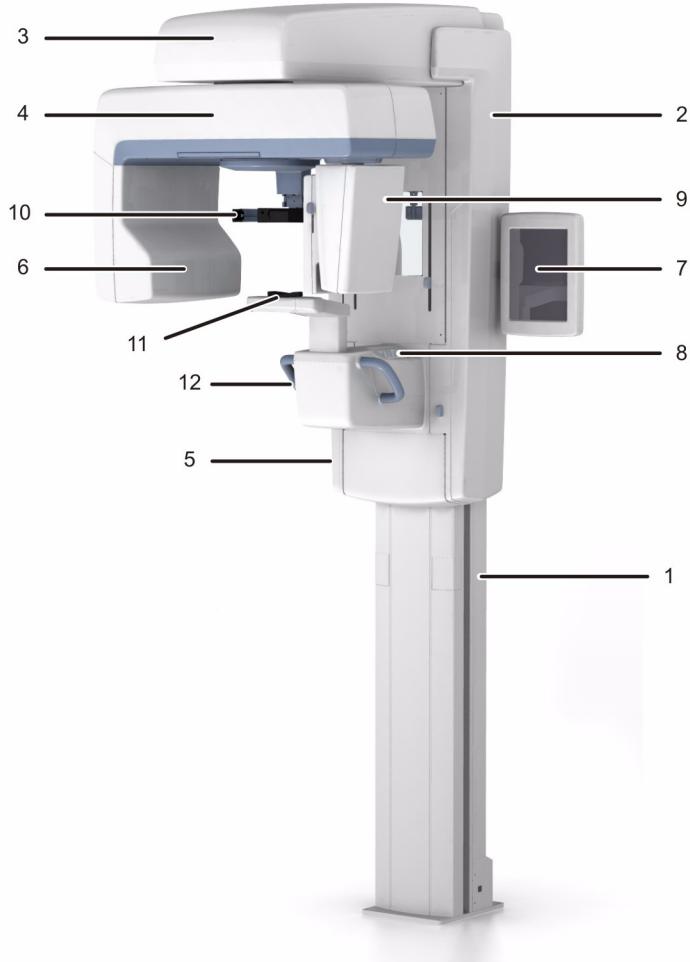
- There should be free space around the unit for safe operation.
- The unit must only be used to take the dental x-ray exposures described in this manual. The unit must NOT be used to take any other x-ray exposures. It is not safe to use the unit to take an x-ray exposures, that it is not designed for.
- Only professionally qualified dental and/or medical personnel are allowed to operate the unit and carry out any diagnoses based on output from the unit.
- The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.
- This unit complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could

influence the performance of the unit.

- Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.
- In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can also be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam.
- Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.
- It is the responsibility of the doctor to decide if the x-ray exposure is necessary.
- The minimum height of patient that can be xrayed is 113 cm (3.7ft / 44.5in) and the maximum is 200 cm (6ft /78in). These heights only apply to patients with normal anatomy.
- When taking an x-ray exposure of a patient with exceptional anatomy (typically very tall or large) use the Test-mode (no x-rays) first to make sure that patient can be positioned correctly to the unit and for checking that the unit doesn't hit the patient.
- Always use the lowest suitable x-ray dose to obtain the desired level of image quality.
- Avoid taking x-ray exposures of pregnant women.
- When taking an x-ray exposure of a child always use the lowest possible x-ray dose, the smallest possible image area and the lowest possible resolution that allows you to perform the required diagnostic task.
- If the patient is using a pacemaker, consult the manufacturer of the pacemaker before taking an exposure to confirm that the x-ray unit will not interfere with the operation of the pacemaker.
- Always use disposable protective covers with the chin supports, chin rests, TMJ nose support and bite blocks.

- Disinfect all the surfaces that the patient is in contact with after every patient.
- The annual service as described in OP300 manuals is mandatory for the correct and safe operation of the unit.
- Danger: Explosion hazard - do not use in the presence of flammable anesthetics.

## 1.7 Main parts and controls



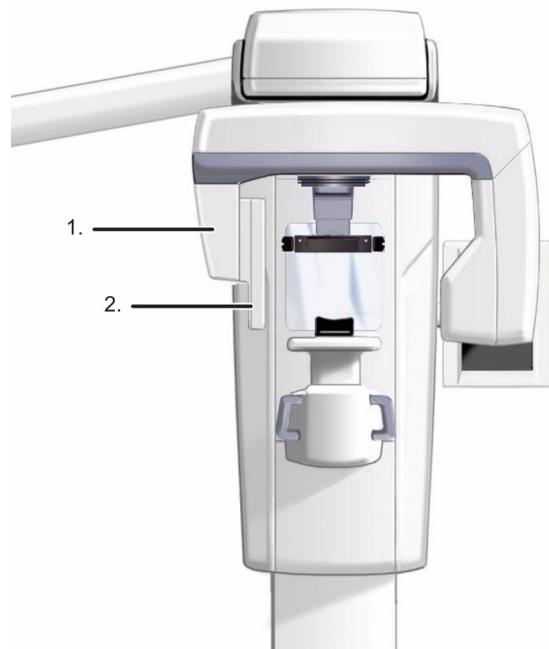
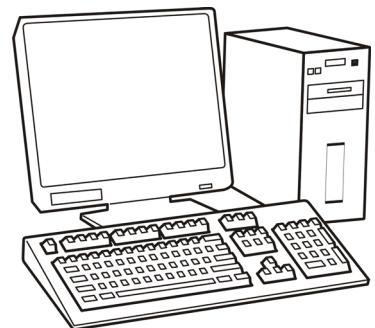
- 1.** Column
- 2.** Carriage
- 3.** Main support
- 4.** Rotating unit
- 5.** On / off switch (rear of column) and main fuses \*)
- 6.** Tubehead assembly
- 7.** GUI
- 8.** Positioning panel
- 9.** Sensor head
- 10.** Head support
- 11.** Chin rest
- 12.** Handles

\*) On / off switch and main fuses



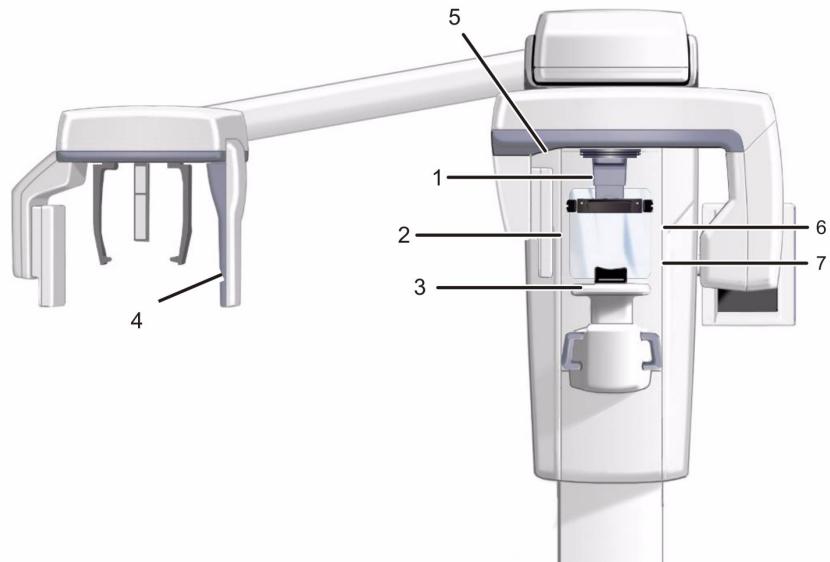
PC with MDD approved dental imaging software and 3D viewing software.

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



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

## 1.8 Patient positioning lights



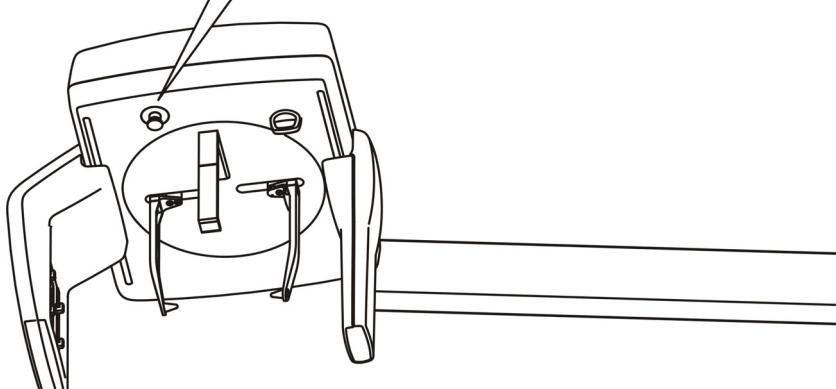
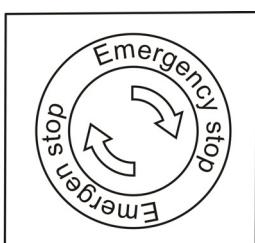
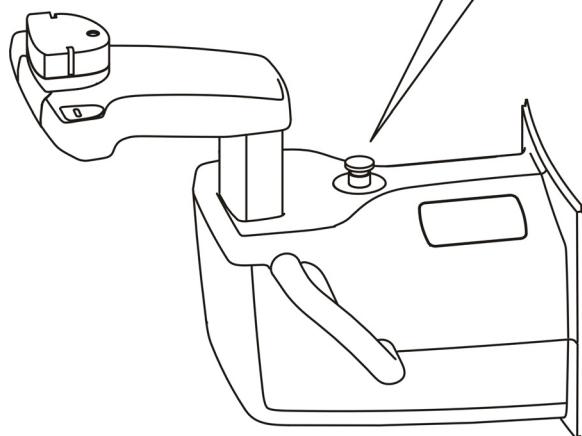
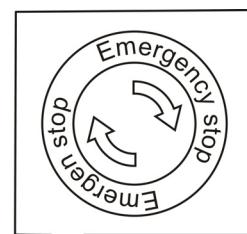
- 1.** Midsagittal light
- 2.** FH light
- 3.** Image layer light
- 4.** Cephalometric FH light
- 5.** TMJ light
- 6.** Horizontal light, top of FOV (3D option only)
- 7.** Horizontal light, bottom of FOV (3D option only)

## 1.9 Emergency stop switch

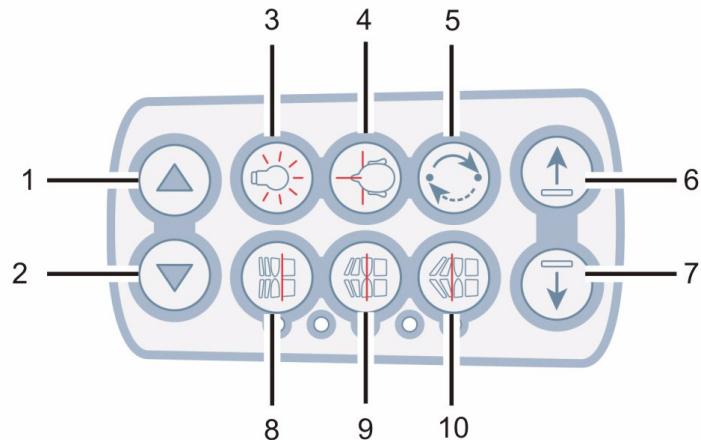
In case of malfunction of the exposure button or other protective devices of the unit, an emergency stop switch is provided near the handles and on the roof of the cephalostat head so that the patient can reach it.

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

Press to stop the unit,  
rotate to release.

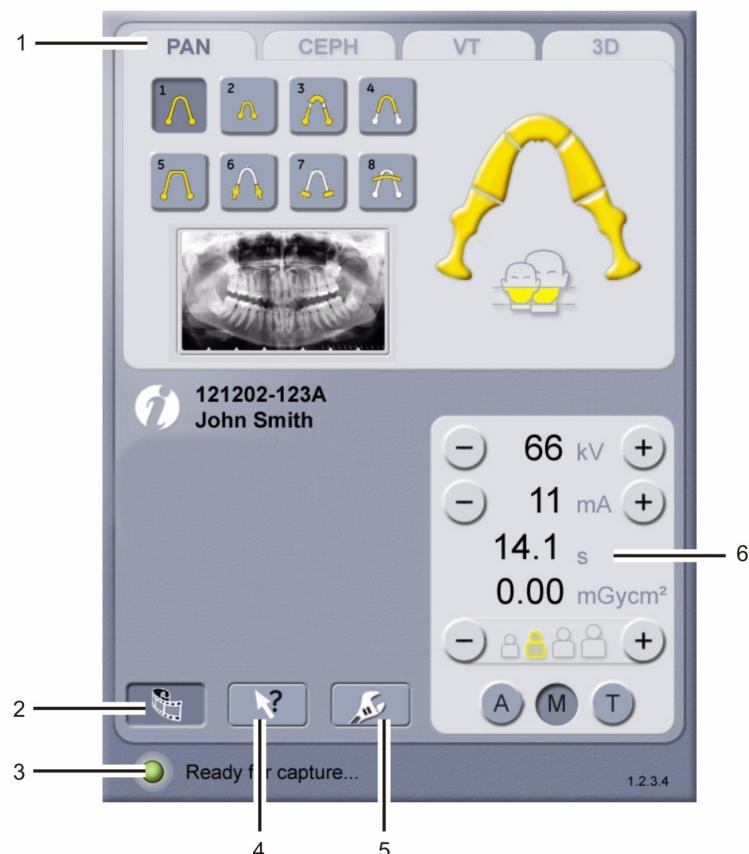


## 1.10 Patient positioning panel



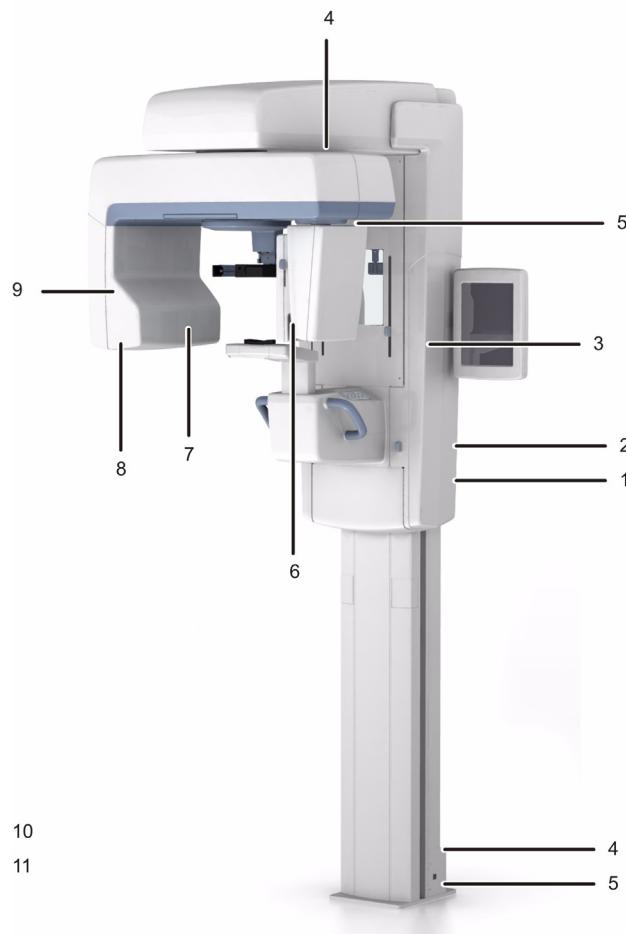
- 1.** Carriage UP
- 2.** Carriage DOWN
- 3.** Positioning lasers ON/OFF
- 4.** Patient positioning
- 5.** Start position
- 6.** Chin support UP
- 7.** Chin support DOWN
- 8.** move the image layer anterior before exposure  
3 mm, with sinus program 10 mm
- 9.** normal occlusion/ reset position
- 10.**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

## 1.11 Main control panel (GUI)



1. Modality / imaging program section
2. Patient positioning guide
3. Status of the unit
4. Help
5. Settings
6. Exposure settings

## 1.12 Unit identification labels



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

## 2 Pre-installation requirements

### 2.1 The unit

- See chapter 5, OP300 Pre-sales check list.
- The unit is supplied:

OP300 Packages	COLUMN (card board)	MAIN SUPPORT AND ROTATION UNIT (card board)	CEPH (card board)
Size (LxWxH) cm:	230 x 33 x 42 cm	100 x 100 x 70 cm	120 x 70 x 71 cm
Gross weight approx.:	105 kg/232 lbs	106 kg/234 lbs	51 kg/112 lbs
Net weight approx.:	87 kg/192 lbs	83 kg/183 lbs	25 kg/55 lbs

- Unit weights:

**OP300 PAN    OP300 CEPH    OP300 3D**

210 kg            245 kg            212 kg  
(463 lb.)        (540 lb.)        (467 lb.)

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

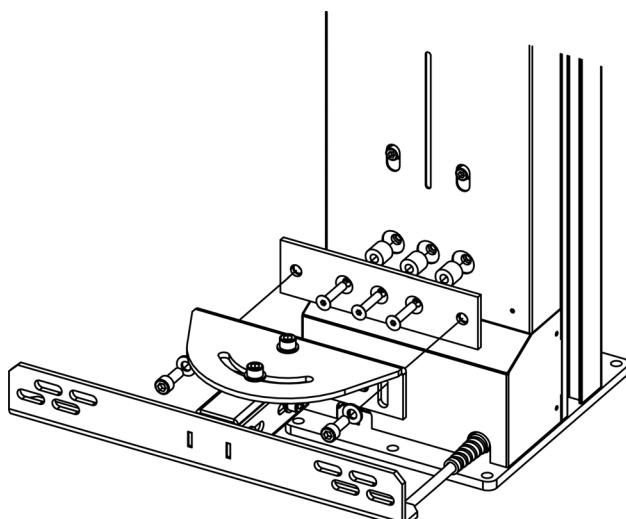


Fig 2.1. Additional wall support

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

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

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

## 2.2 The PC

<b>Minimum PC requirements:</b>	
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Operating system	Windows 7 or Windows Vista (32 or 64-bit), Windows XP Professional (32-bit)
Processor	2.0 GHz Core i5 or i7 CPU or equivalent processor
Main memory (RAM)	3 Gigabytes RAM
Hard disk	500 GB HDD or larger
Network adapter	2x 1Gb Ethernet network interface
Graphics card	GTX 460 GEFORCE NVIDIA GPU, FX 3800 GEFORCE NVIDIA Contact <a href="mailto:techsupp@instrumentarium.com">techsupp@instrumentarium.com</a> for update information about the approved graphics cards
PCI board connection	Full-length PCIe x16 slot (for GPU board)
USB	USB ports (for HASP Dongle keys) • 1 for reconstruction system (Dongle supplied with Mercury GPU Kit) • 1 for OnDemand3D (Dongle supplied with CD Kit)
Color monitor size	20" 2MP LCD display, 1600 x 1200 (19" 1.3MP LCD 1280 x 1024, minimum)
Power supply	550 watt power supply with two 6-pin power cables (for GPU)
Mouse	Mouse with scroll wheel



- The PC to be used with the unit must be installed in a location that meets all local and national safety requirements with regards the connection of a PC to an x-ray device.
- The connection of the unit to the PC must meet IEC 60601-1 requirements.
- The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Consideration relating to the choice shall include:

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

## 2.3 The dental imaging software

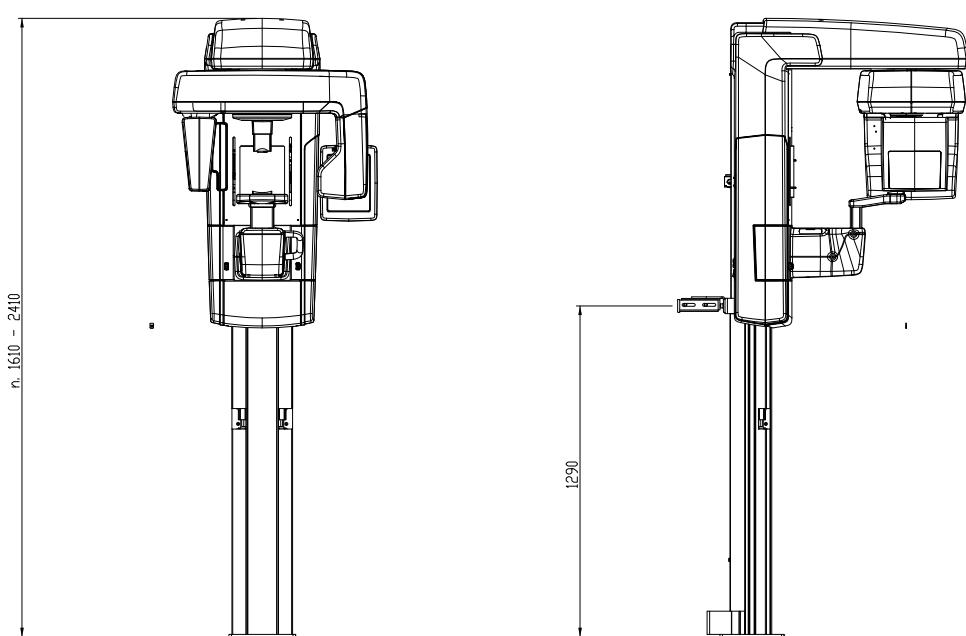
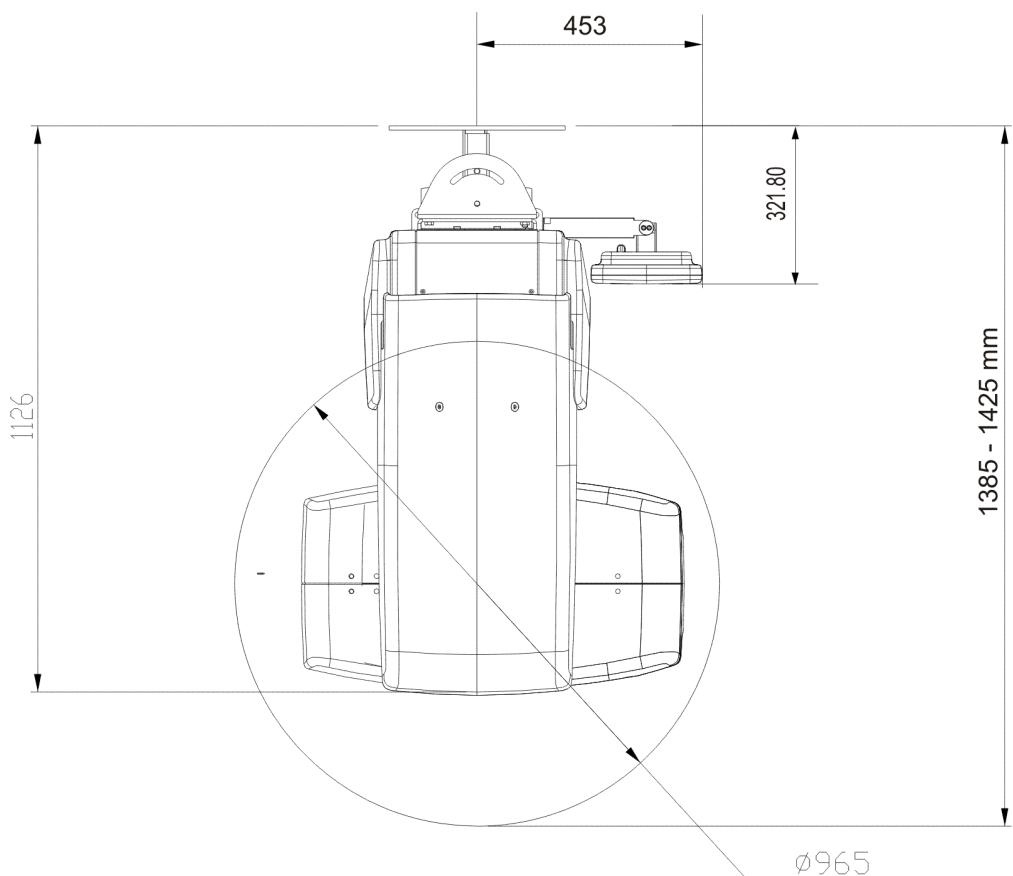
The dental imaging software installed in the PC that is used with the unit must be MDD approved, for example Cliniview.

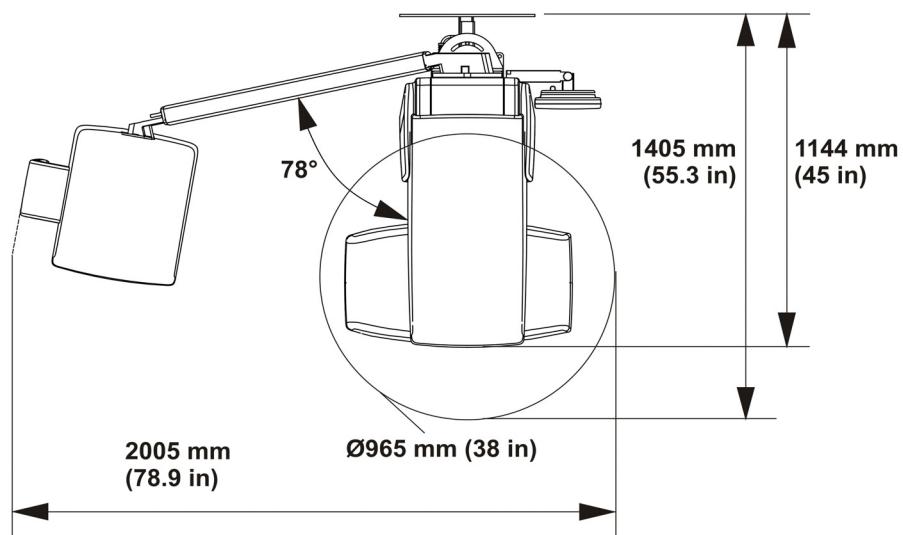
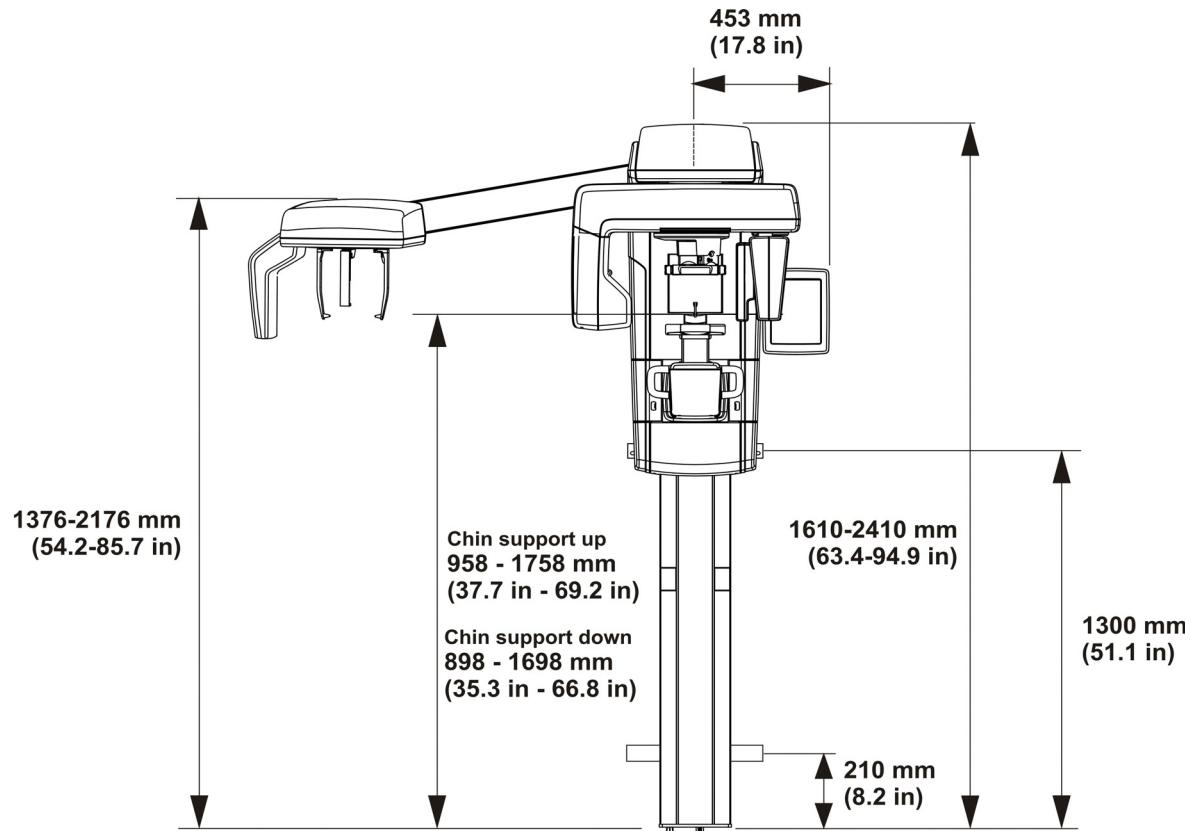
## 2.4 Space requirements

When installing the unit make sure that:

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

## 2.5 Unit dimensions





## 2.6 Fixing hardware and Installation and Setup tools

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

### Fixing hardware

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

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

### Installation tools

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

### Pan calibration and setup tools

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

### 3D calibration and setup tools

- 3D calibration phantom
- QC phantom

## 2 Pre-installation requirements

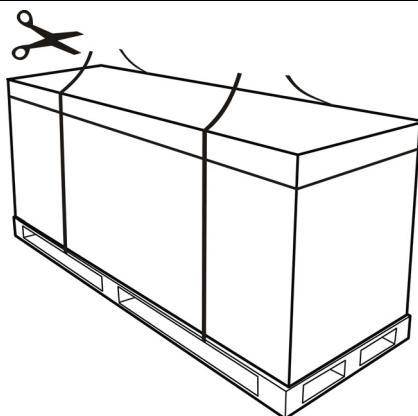
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# 3 Installing the unit

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

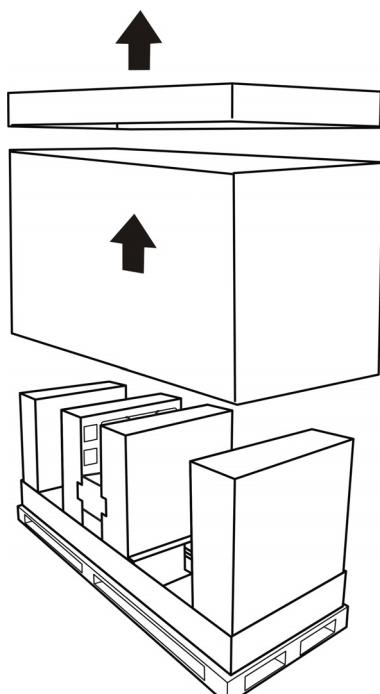
## 3.1 Content of delivery

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



### The column

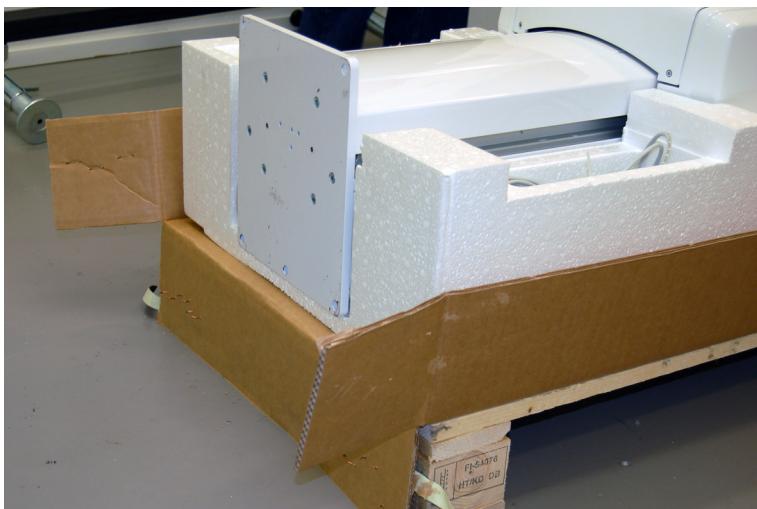
1. Transport the column box (the longest one) to the location where the unit is to be installed.
  2. Remove the straps that hold the box to the pallet.
3. Lift off the top of the box and then the sides.



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



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



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

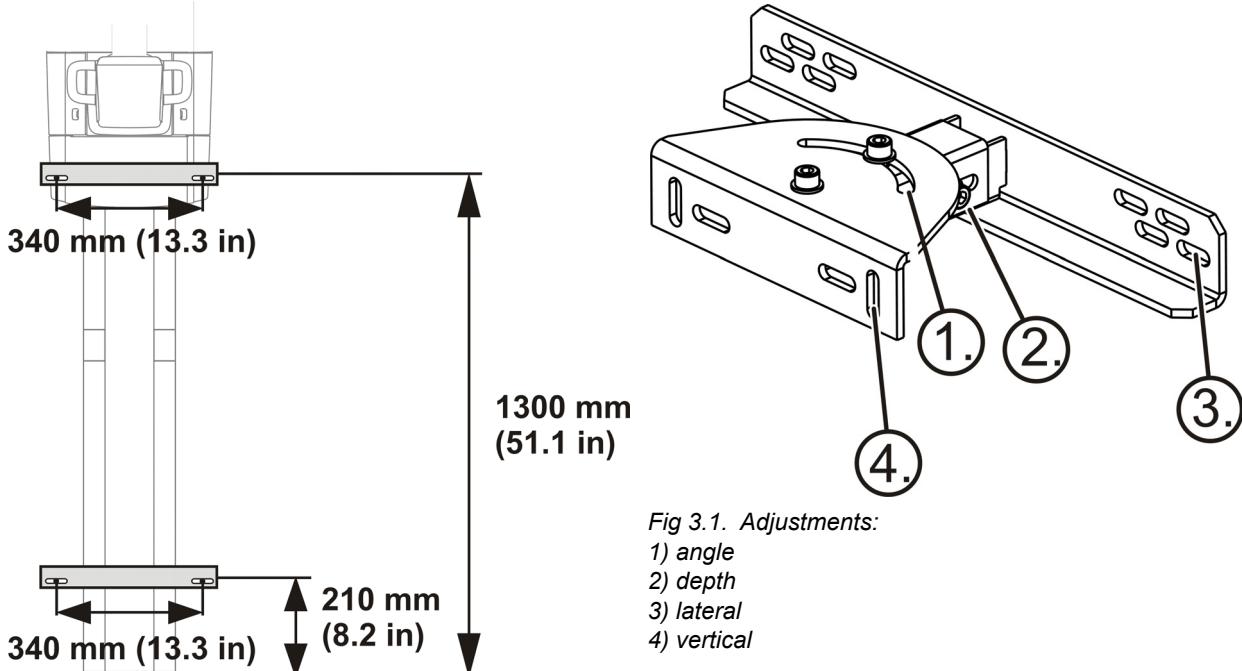


Fig 3.1. Adjustments:

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

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

## **8. CAUTION - HEAVY OBJECT 87 KG**

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

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

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

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



- 9.** Remove the styrofoam supports.
- 10.** Remove the transport supports behind the column.



- 11.** Install the unit to the upper wall bracket on the wall.

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

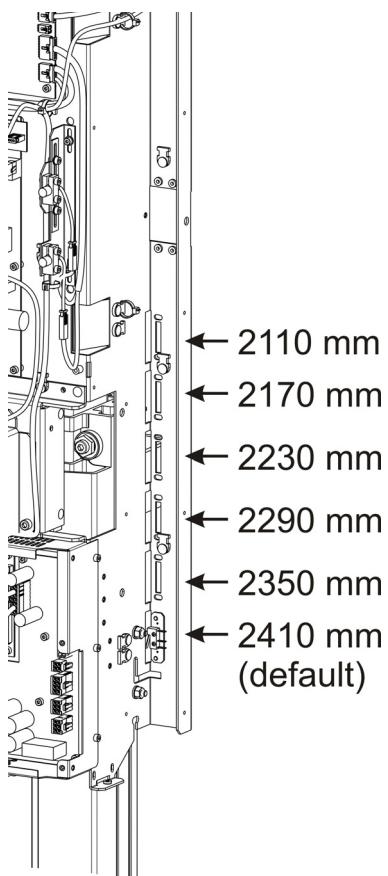


**13.** Drill the floor and bolt the unit to the floor.  
If two wall brackets are used, tighten the lower one  
to the unit.

---

**14.** Remove the plastic wrap from top of the column.  
Remove the side covers by removing two screws  
from the cabin.





**15.** 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 microswitch.

Step 1. Remove the sheet-metal cable guide from the right (11 screws).

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

Step 3. Open 2 screws of the microswitch and move the microswitch to appropriate position.

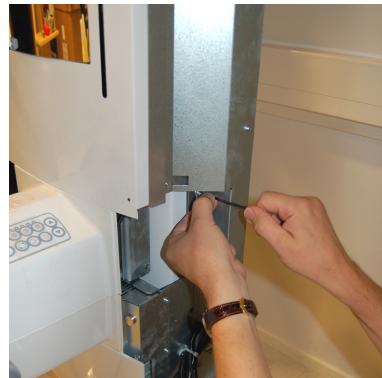


Fig 3.2. Step 1

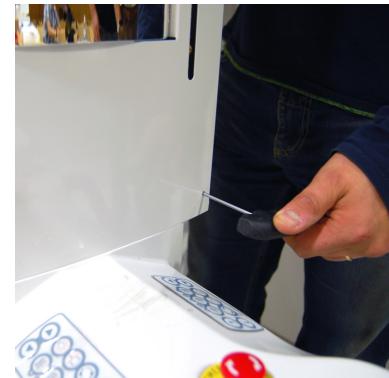
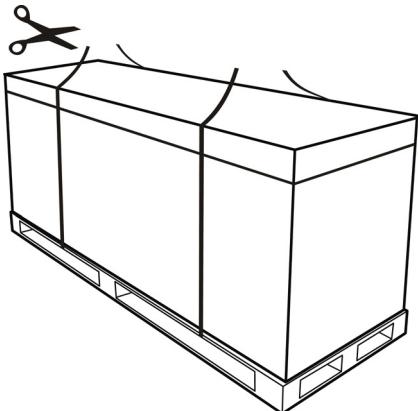


Fig 3.3. Step 2



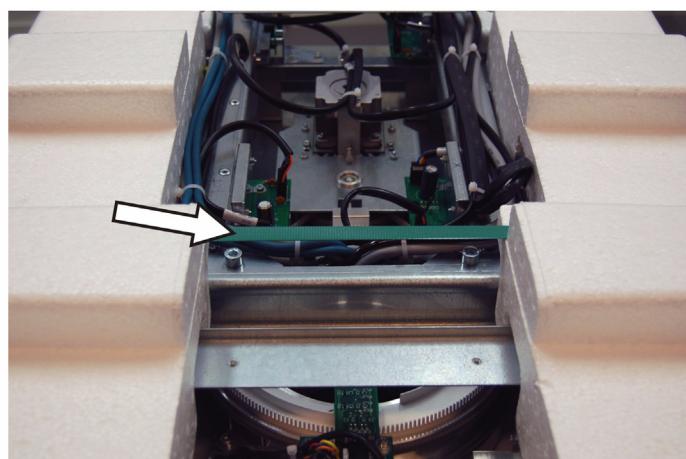
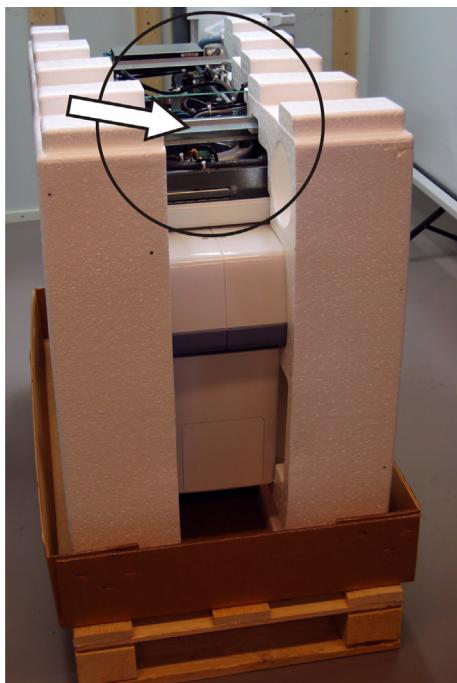
### 3.3 The carriage

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



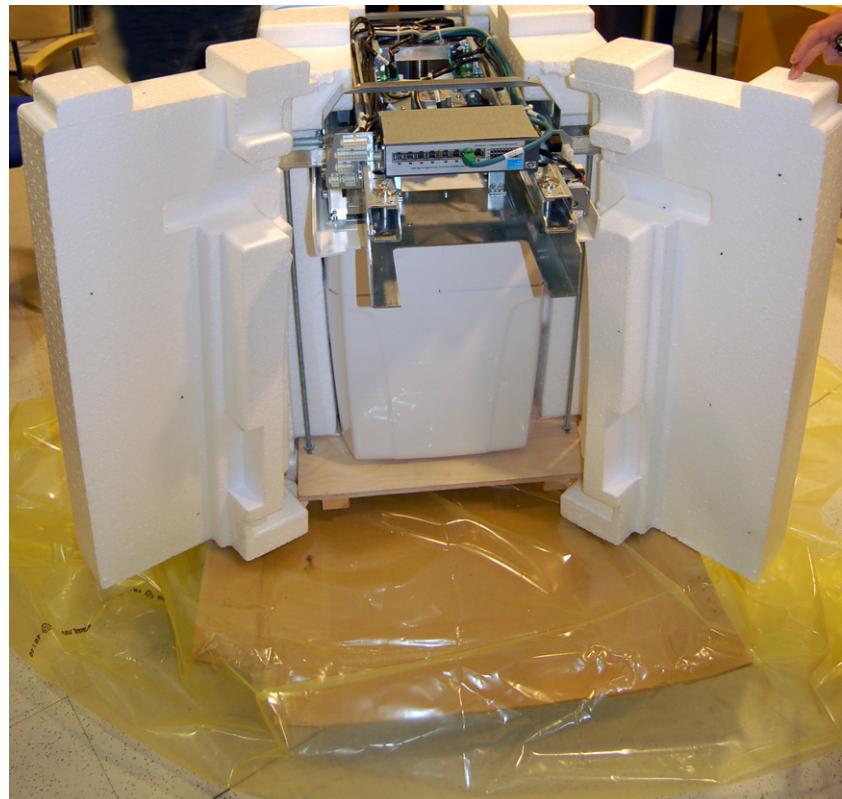
3. Lift off the top of the box and then the sides. Remove plastic wrap.

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



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

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



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

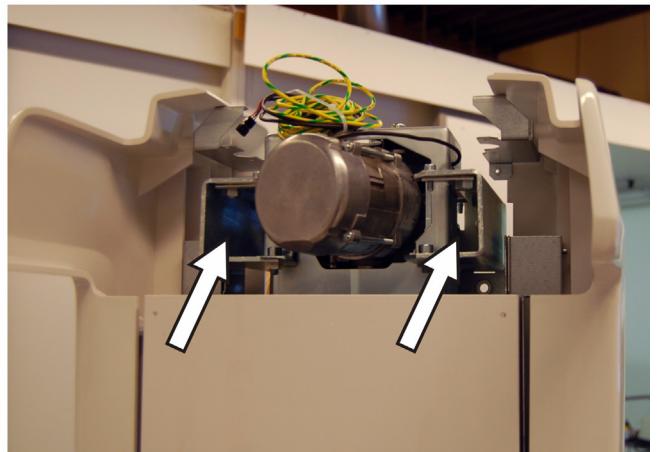
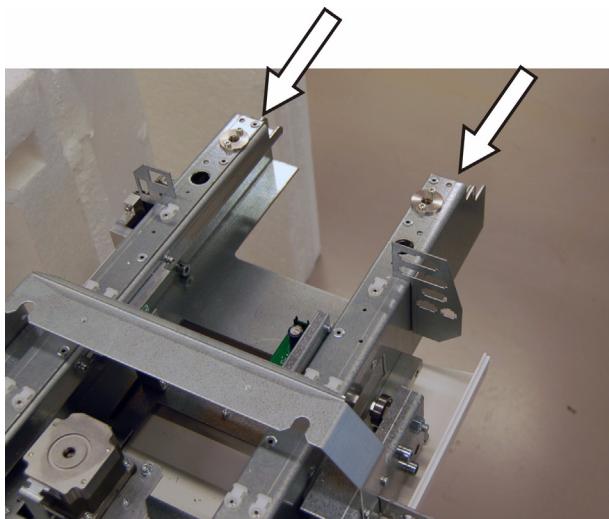
A minimum of two persons are required for the following task.

Lift the carriage and push it towards the column.

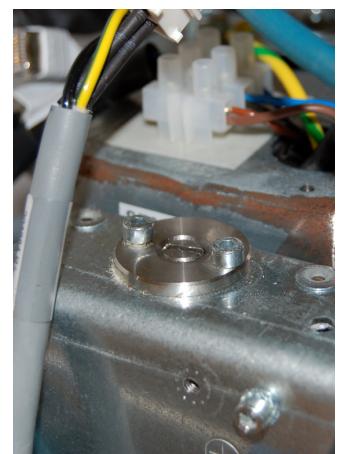
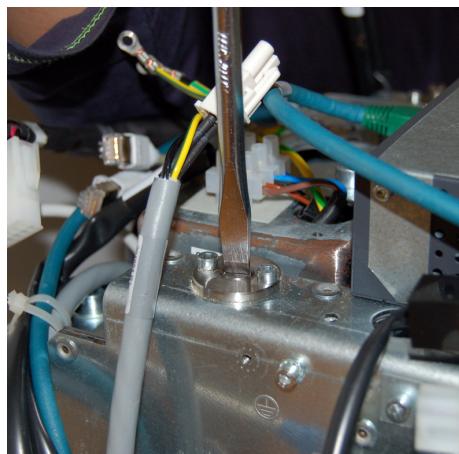
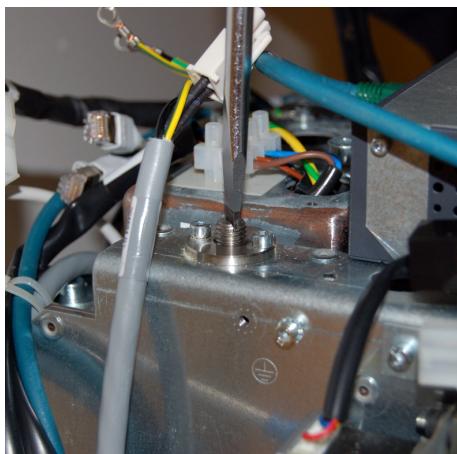
Lifting places pointed.



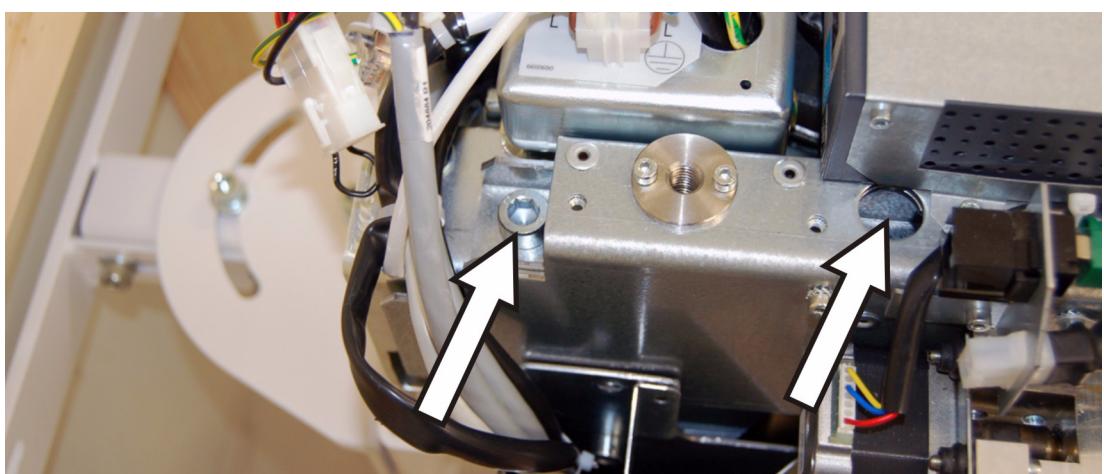
**NOTE!** Do not put the carriage down on the chin rest or on the patient handles!



7. Fasten the main support to the column counterpart with 2 thread cones without force. The cones align the main support. Cones are in the screw bag.



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

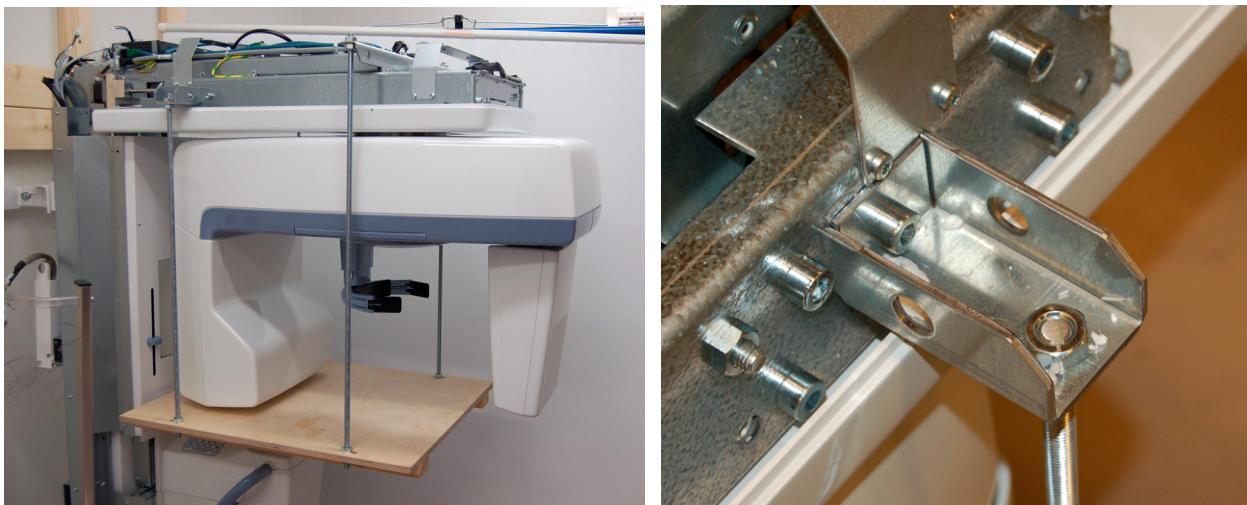


**9.** Remove the styrofoam material.

**10.** Remove the metal transport supports on the main support, thread bars and the holding overhead brackets, and the sheet of plywood.

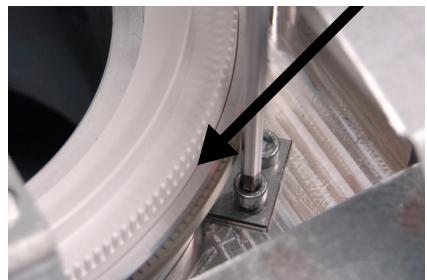
**11.** Remove plastic wrap around the sensor.

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



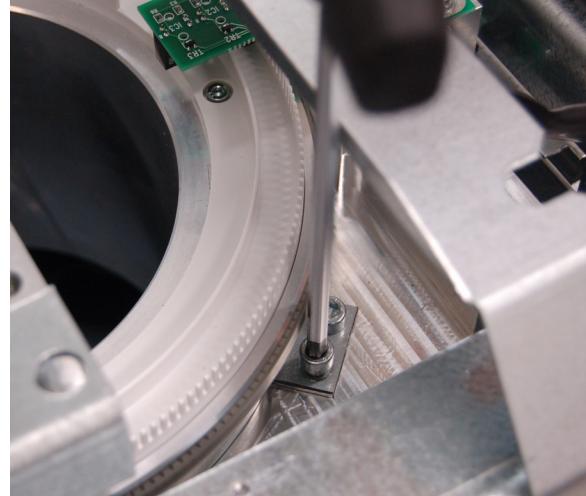
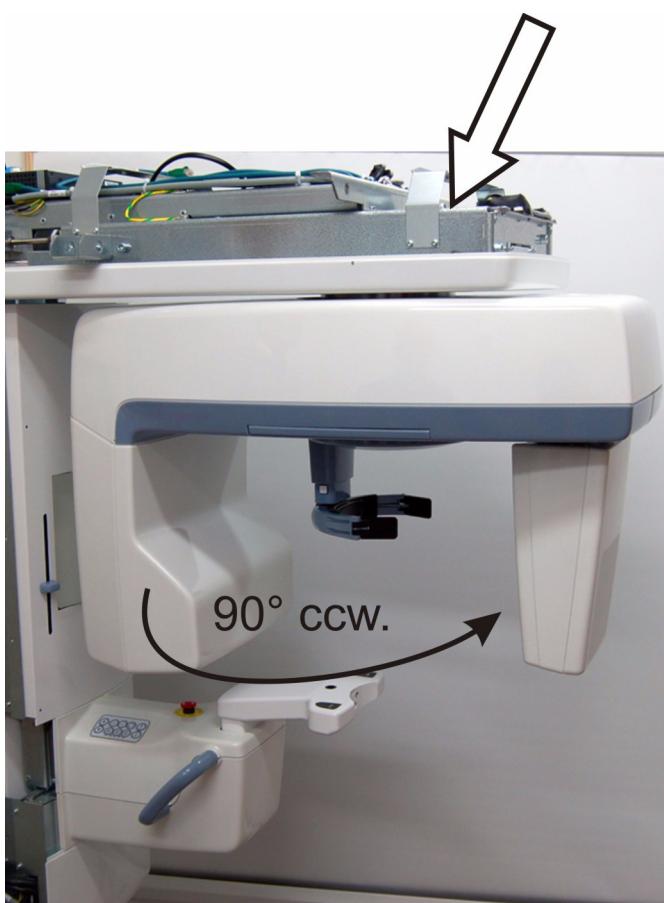
### 3.4 Stopper plate

**WARNING!** Do not damage  
the teeth of the encoder!



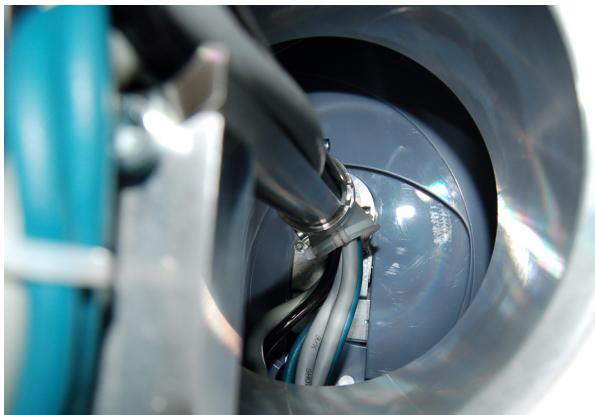
*Rotation unit is secured. To release the rotation unit:*

1. Remove the stopper plate on the main support by removing 2 screws.



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

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



*Fig 3.4. Fully rotated clockwise, from left side view*

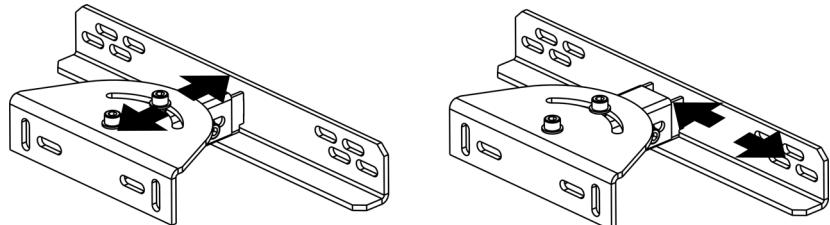


*Fig 3.4. Fully rotated ccw, from right side view*

### 3.5 Check leveling

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

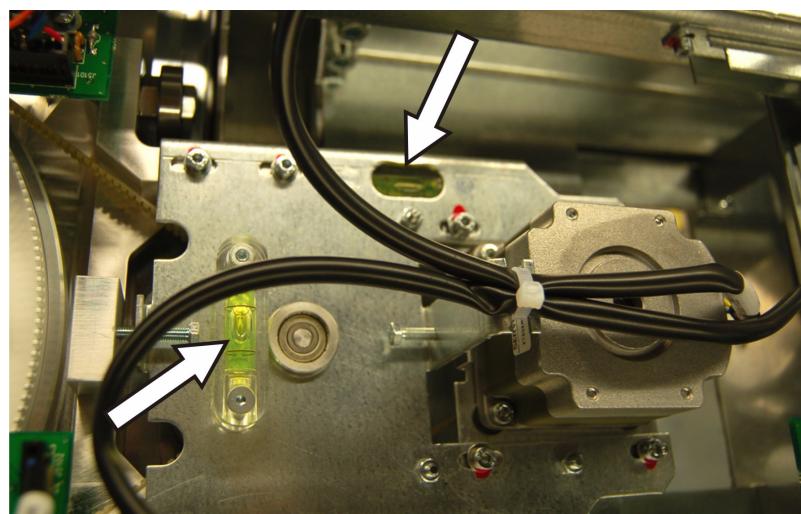
The wall bracket is adjustable so that the unit can be adjusted in all directions.



Before adjusting the tubehead must be turned to front position.

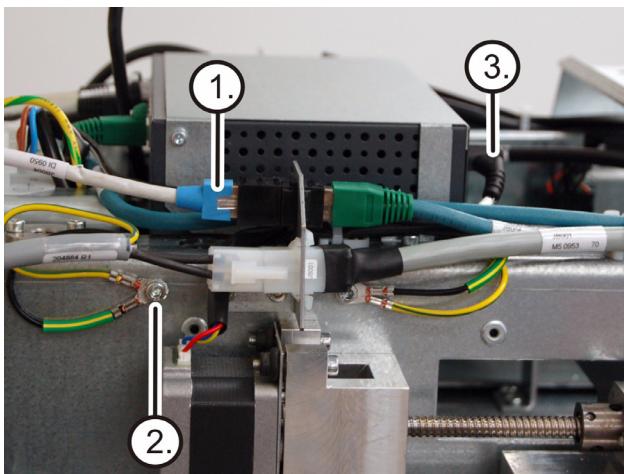


Use the spirit levels on the top of the main support.



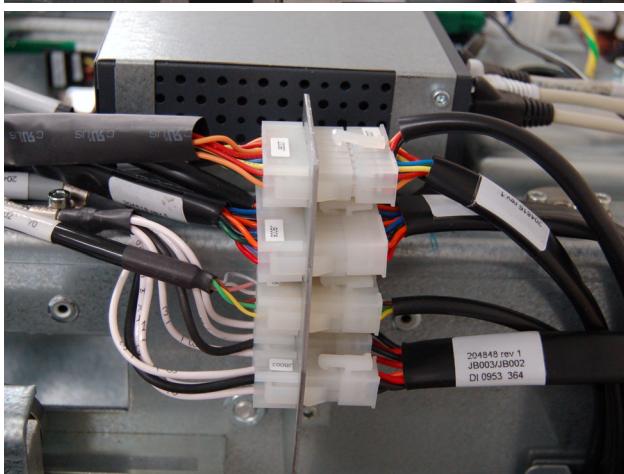
## 3.6 Connect all cables

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

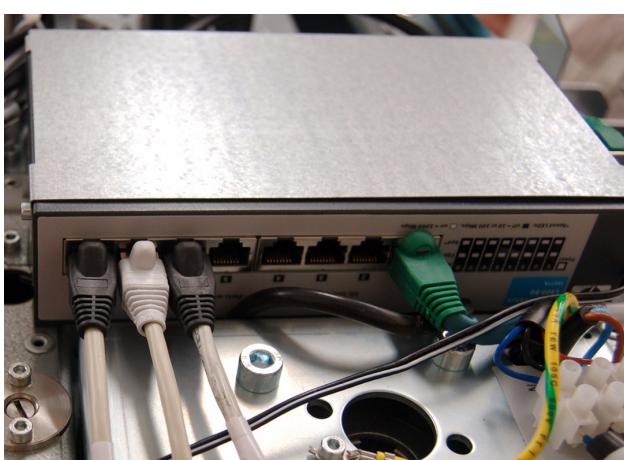


On the right side

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



On the left side



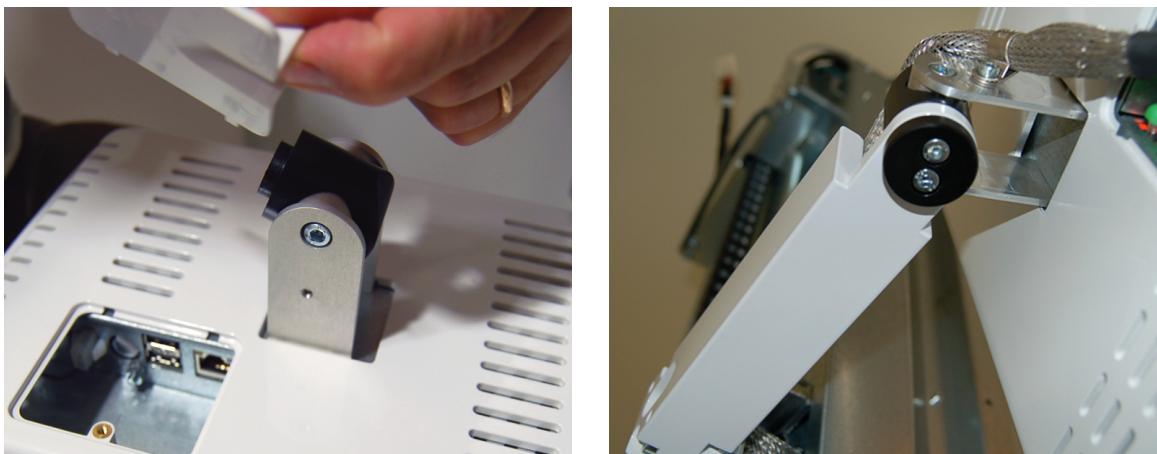
On the top

### 3.7 Attaching the touch panel to the column

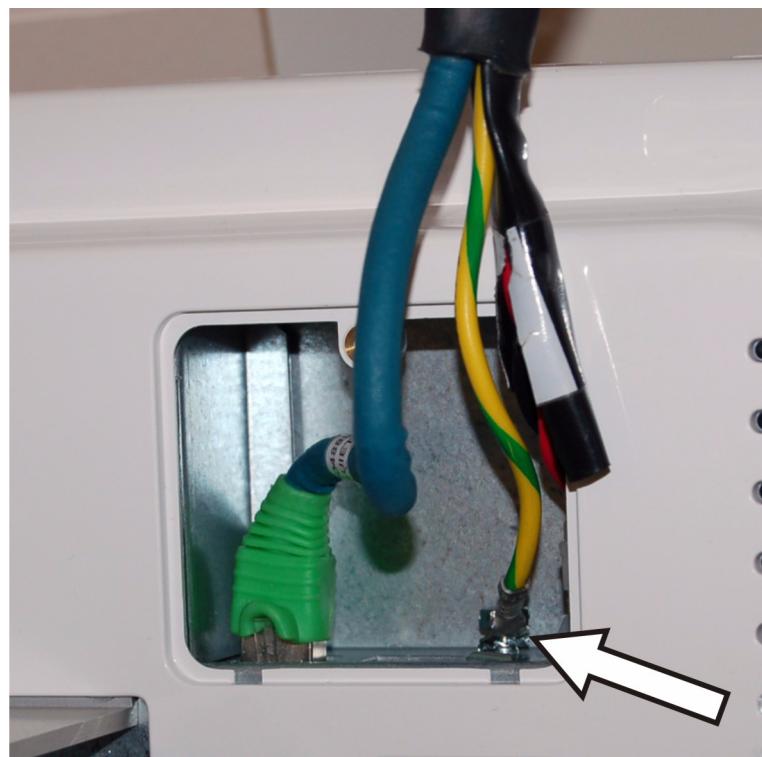
1. Unfasten the touch panel arm (1 screw) and re-fasten it to the horizontal position.



2. Fasten the touch panel to the arm by 2 screws. (One screw is pre-installed and another is in the screw bag).



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



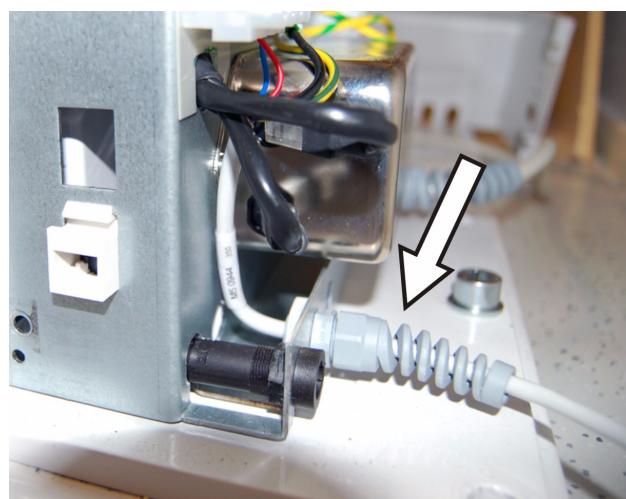
### 3.8 Exposure button

**NOTE!** *Exposure button is factory installed with 10 m cable. The following installation is done only, if other exposure button is needed.*

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



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

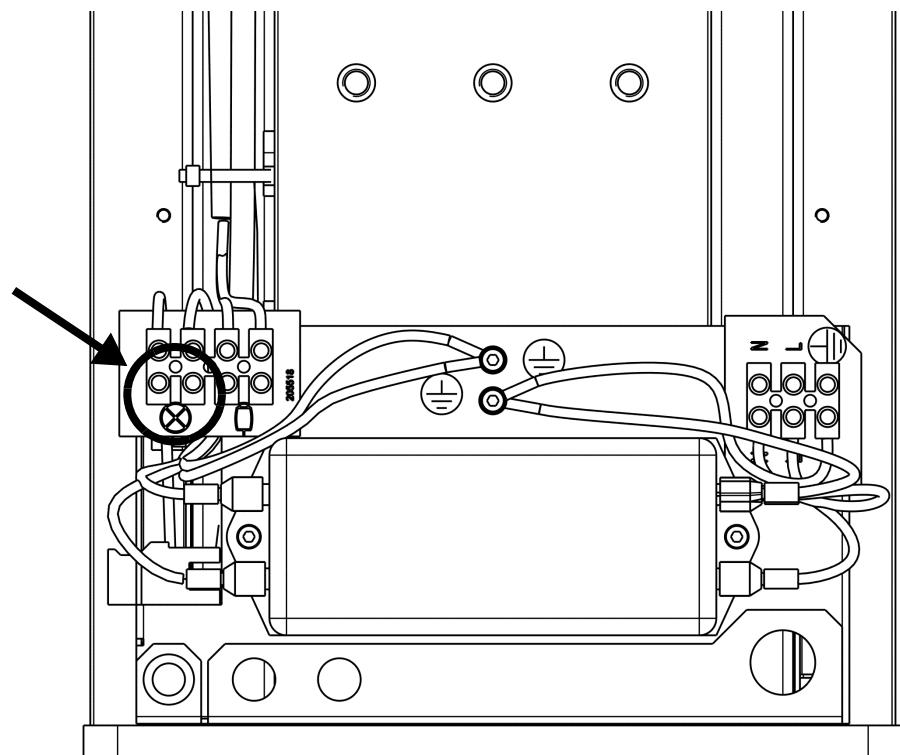
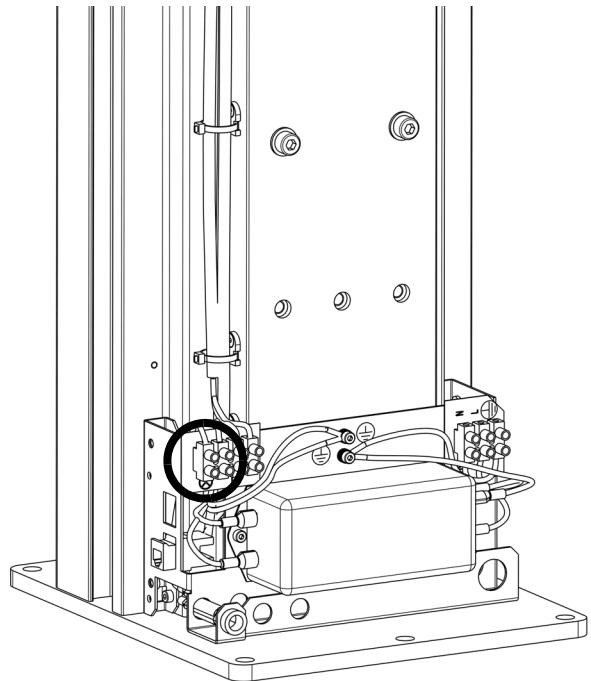
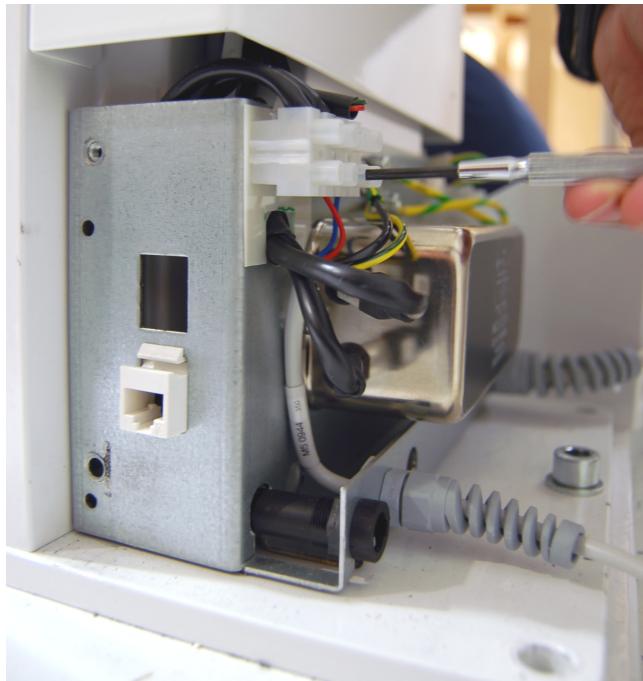


### 3.9 External warning light

Attach the external warning light cable to the cable terminal x, y (see figures below).

Specification for the external warning light:

- max 20W/240Vac/24VDC/2A
- 2A T 250V 6.3x32mm



### 3.10 Connecting the unit to the mains

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

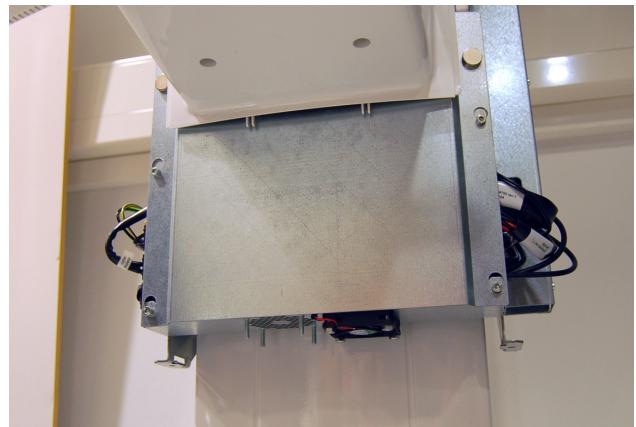
**WARNING!** Do not connect the unit to the mains voltage until instructed to do so.

**NOTE!** OP300 units are delivered from the factory with 230Vac line voltage settings. If your mains voltage is 100/120Vac, read this chapter for instructions how to change the line voltage setting of the unit.

The unit can be set to operate at:

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

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



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

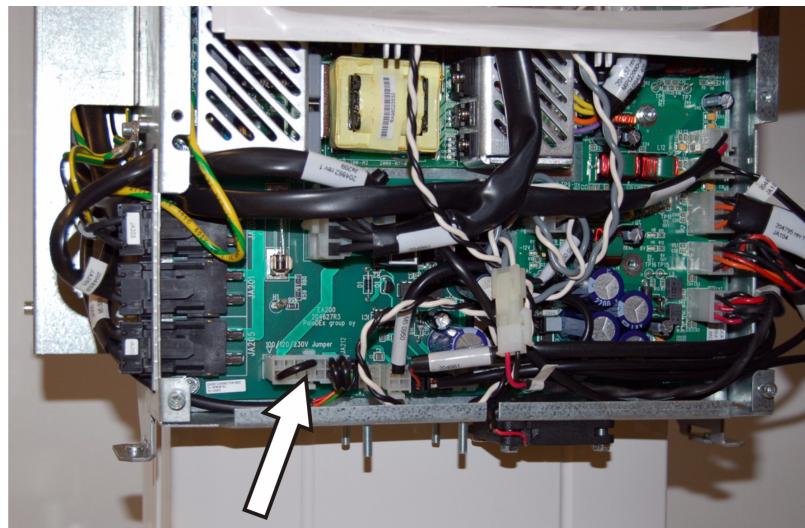


Fig 3.5. Jumper



- 3.** Make sure that you have correct main fuses (F1 & F2) in the unit.
- For 220-240Vac use two 10A fuses, type T10A H 250V (Littelfuse 326 010)
  - For 100-120Vac use two 15A fuses, type T15A H 250V (Littelfuse 326 015)

- 4.** For 100-120Vac operation an additional 10uF starting capacitor (located on the main support) needs to be added in parallel with the 30uF capacitor of the z-motor. This can be done by removing the metal cover on the top of the column and connecting JA005 connector to the low voltage cap connection of JA004.



Fig 3.6. Connector JA005 connected to the low voltage cap connection of JA004.

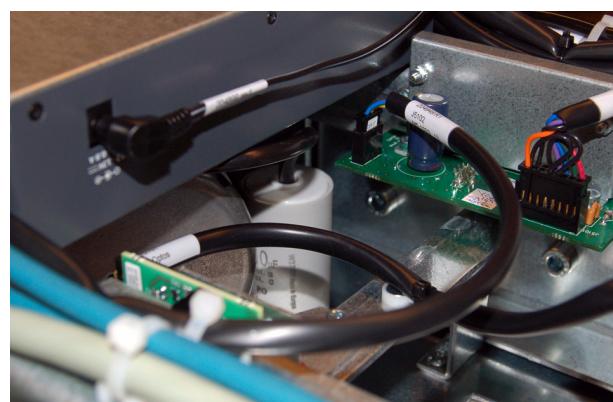


Fig 3.7. JA005 and JA004 connection is hidden under the box with the additional 10uF starting capacitor.

### 3 Installing the unit

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- 
5. Install correct mains power cord to the connection on the base of the column
    - For EU 230Vac: H05VV-F 3G 1.5mm<sup>2</sup> with a Schuko plug (CEE 7/7)
    - For USA/CAN 115Vac: SJT AWG14 with a hospital grade NEMA 5-20 plug
    - For USA/CAN 230Vac: SJT AWG14 with a hospital grade NEMA 6-15 plug
  6. Install all the covers back on.

**WARNING!** *Before connecting the mains voltage to the unit, check that the installation environment's temperature and humidity complies with allowed operating conditions of the unit. Make sure that the power line meets the requirements set by the manufacturer. See chapter Technical Specifications in the OP300 User Manual for more details.*

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

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

### 3.11 Preparing the PC

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

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

2. Switch the PC on and install Cliniview or the dental imaging software that will be used with the device.

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

**NOTE!** During the Cliniview installation when the Select Features window appears, make sure that you select the OP300 option.

## 3.12 Configuring the communication link to the PC

### Using an IP address

1. Connect one end of the Ethernet cable to the unit (the connector at the rear of the column) and the other end to the PC or the network.
2. Switch the unit on and carry out initialization.
3. PC: Start the PC and then open Cliniview or the dental imaging software that you installed.
4. PC: After Cliniview has opened, it automatically starts the OP300 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 (OP300 and PC are required to be on same subnet).

**NOTE!** If the the Unit is part of a network, you will have to get an IP address for the unit from your local IP administrator. Refer to s2terminal usage instructions in the OP300 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.

### 3 Installing the unit

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# 4 Calibration and adjustment

## 4.1 Introduction

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

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

During the calibration procedure calibration data is produced. This data, which is stored in the GUI PC and on the R3210, is used for unit calibration and image processing. Resulting from the calibration programs are also calibration images containing calibration results, telling the operator how to proceed with the calibration and adjustment procedure. In addition to the calibration name (e.g. Adjustment panCol) the images contain image data sampled during the calibration, adjustment instructions and a "Passed / Not Passed / Failed" calibration status.

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

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

## 4.2 Preparing for calibration

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

**cd c:\program files\s2terminal**

---

- c) Press **ENTER**.
  - d) Key in **s2terminal** and then the **IP address** of the unit. Press **Settings** on the GUI. 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 -----

<b>xh</b>	<b>help</b>
<b>xi</b>	<b>receive image from the device</b>
<b>xr</b>	<b>reserve device</b>
<b>xq</b>	<b>quit</b>

---

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 the settings button on the GUI.

7. Select the service button.

The calibration display appears.



## 4.3 The calibration sequence

### 4.3.1 Calibration of the preheat of the tube



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



1. Select the program.
2. Press the patient positioning button.
3. Take an exposure. GUI and s2terminal inform you when the calibration is done.



### 4.3.2 Calibration of the tube current

 mA

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



1. Select the program.
2. Press the patient positioning button.
3. Take an exposure.
4. GUI informs when the calibration is done.



The screenshot shows a software window titled "PREVIEW". In the center, under the heading "Tube\_mA calibration", the following data is displayed:

**Calibrated ref value 4mA : 65**  
**Calibrated ref value 15mA : 223**  
**Measured Fb peak value 4mA : 55**  
**Measured Fb peak value 15mA : 214**

At the bottom of the window, a small yellow-bordered box contains the following text:

```
4mA calibration done  
Calibration reference 4mA  
Calibration reference 15mA  
Measured Fb peak value 4mA  
Measured Fb peak value 15mA
```

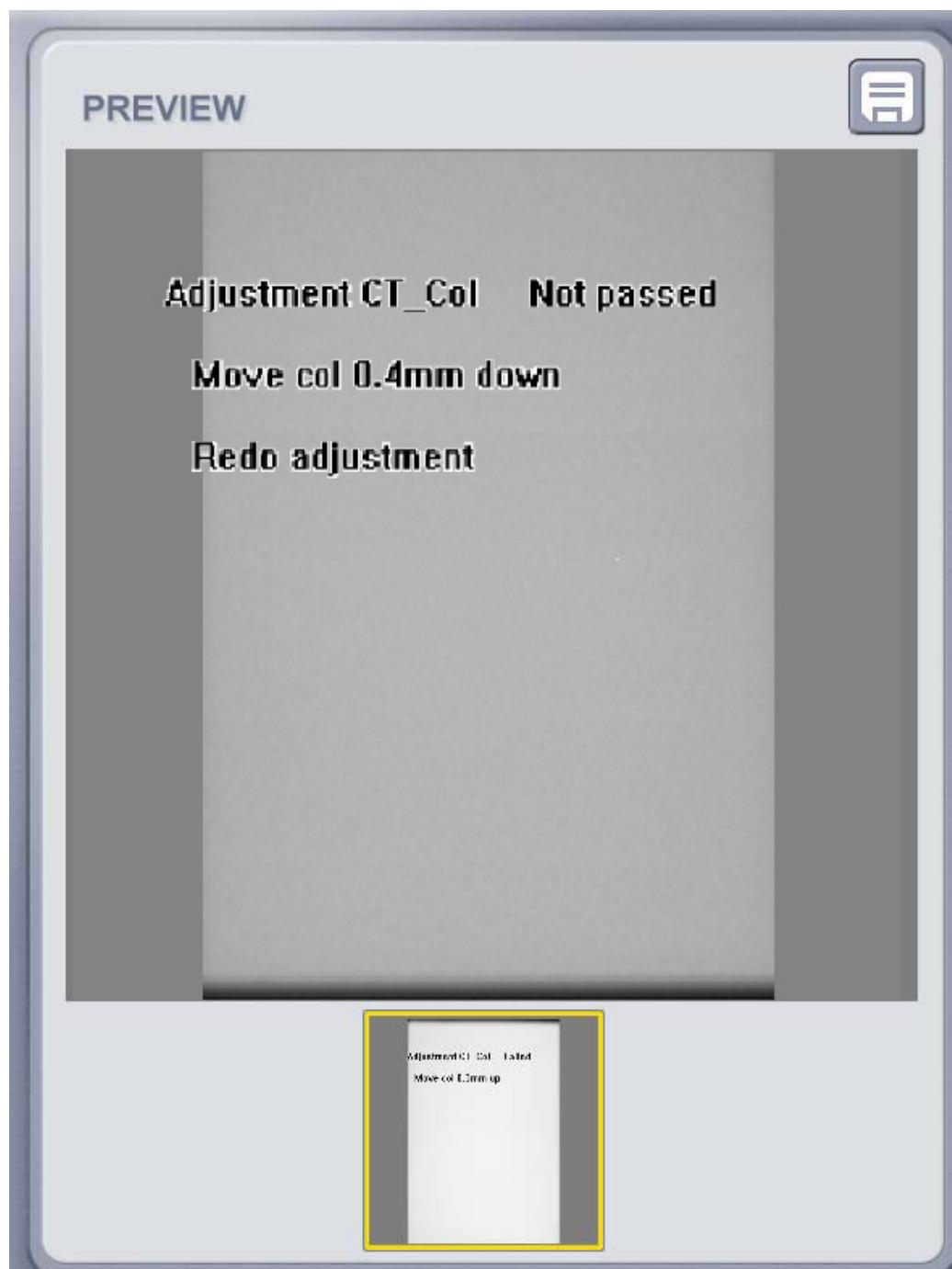
### 4.3.3 CT collimator calibration



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

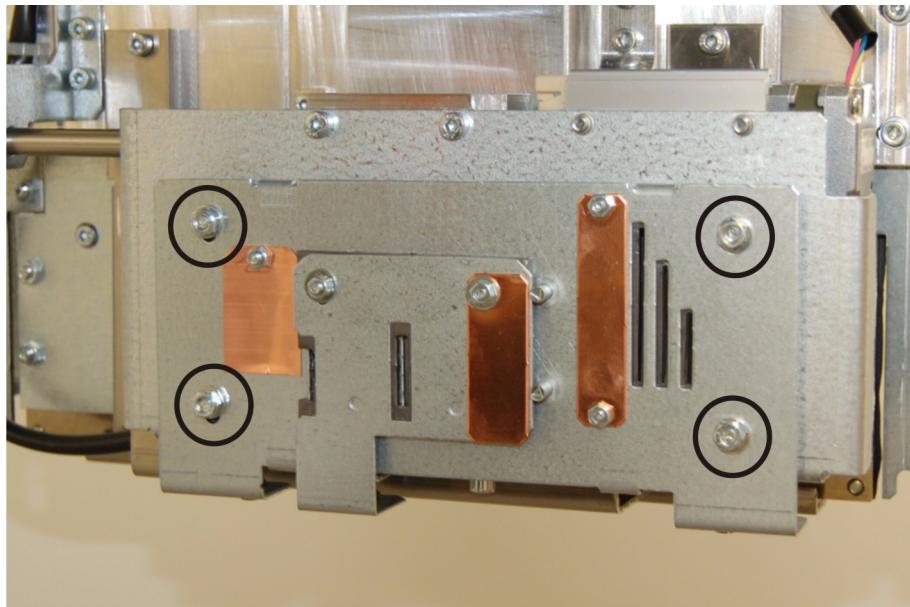


1. Select the program.
2. Press the patient positioning button.
3. Take an exposure, on which the manual adjustments are based. GUI informs how much the height needs to be adjusted and in which direction.



#### 4.3.3.1 Adjustment of the height and tilt of the collimator

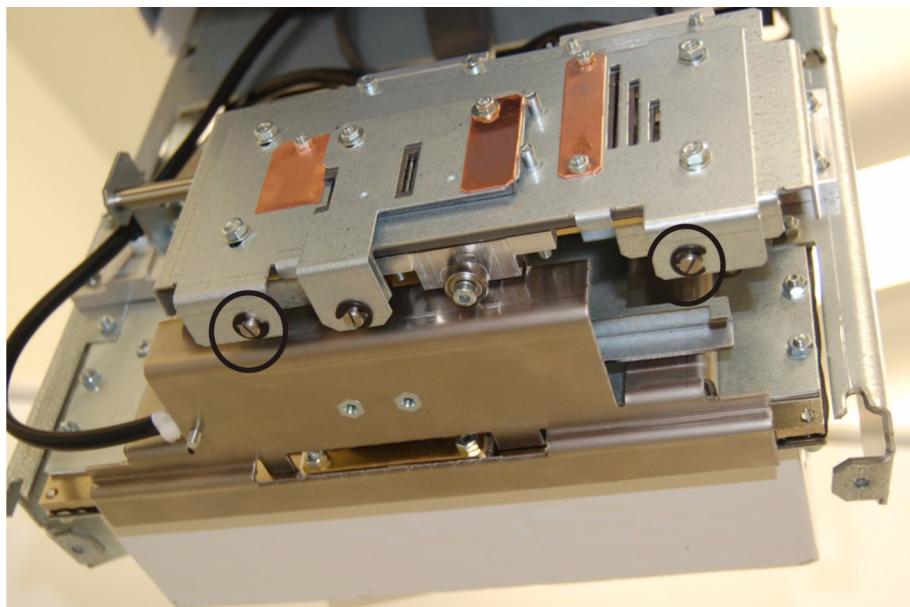
1. Loosen four M4 nuts to be able to adjust the plate.



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

Clockwise (cw) = Collimator upwards

Counterclockwise (ccw) = Collimator downwards

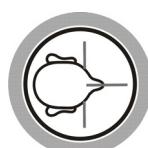


3. Re-tighten the four M4 nuts and take a new image.

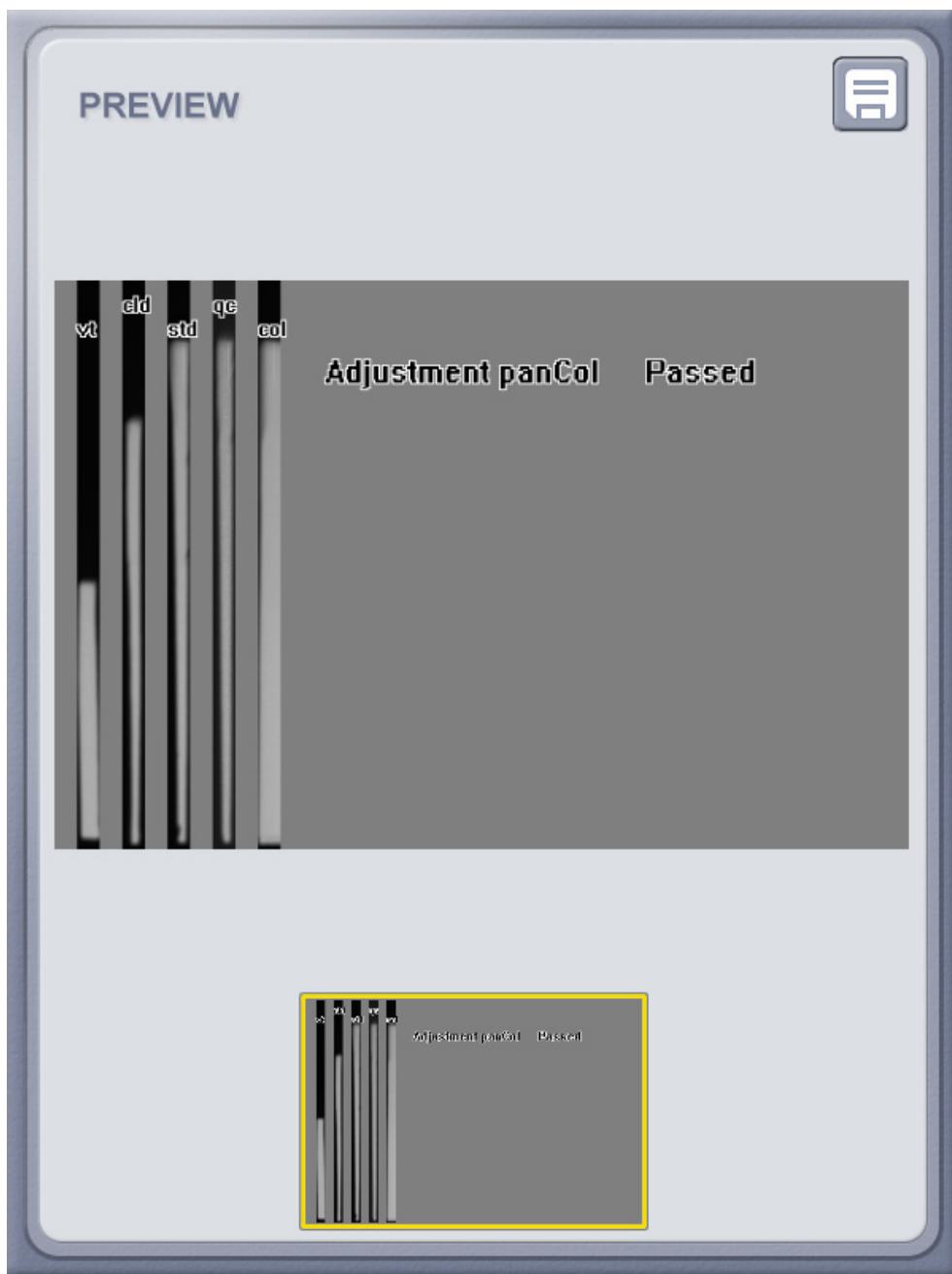
#### 4.3.4 PAN collimator calibration



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



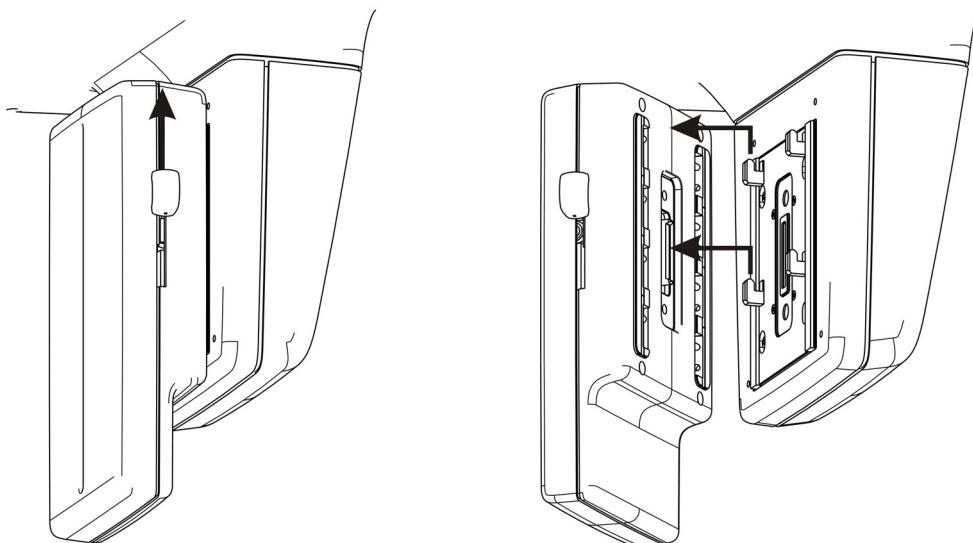
1. Select the program.
2. Press the patient positioning button.
3. Take an exposure, on which the manual adjustments are based. GUI informs how much the height needs to be adjusted and in which direction.



#### 4.3.4.1 Adjustment of the height of the PAN sensor

Do the adjustment with the sensor holder.

1. Remove the sensor.



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



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

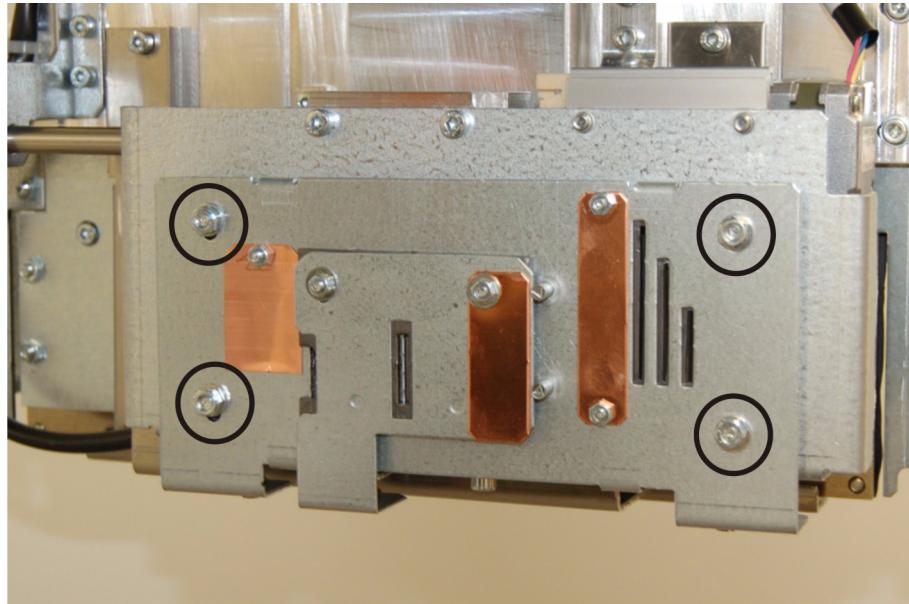


- 4.** Adjust the height with an adjustment screw on the bottom of the holder.

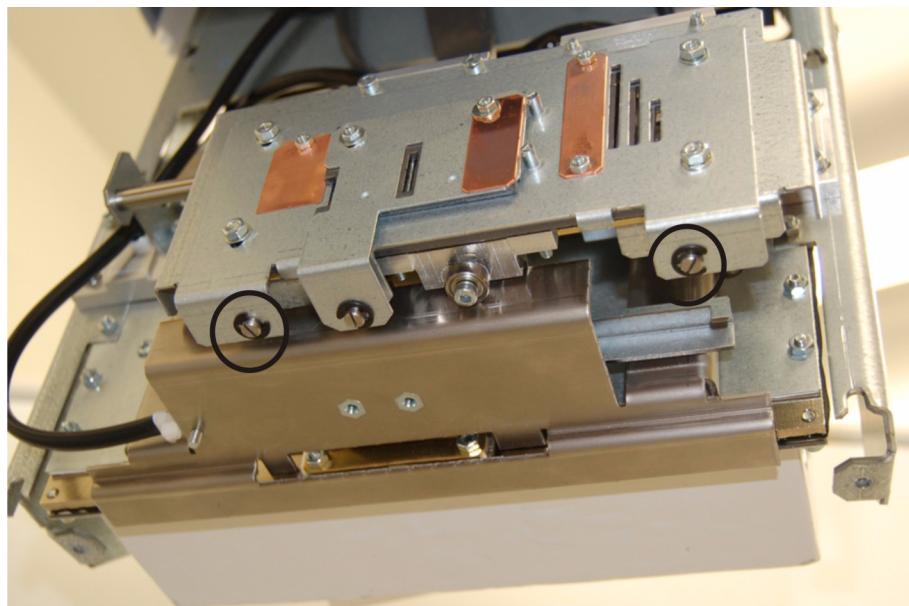


#### 4.3.4.2 Adjustment of the tilt of the collimator

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



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



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

**NOTE!** CT collimator calibration should be checked if the tilt is adjusted.

#### 4.3.5 PAN geometry calibration



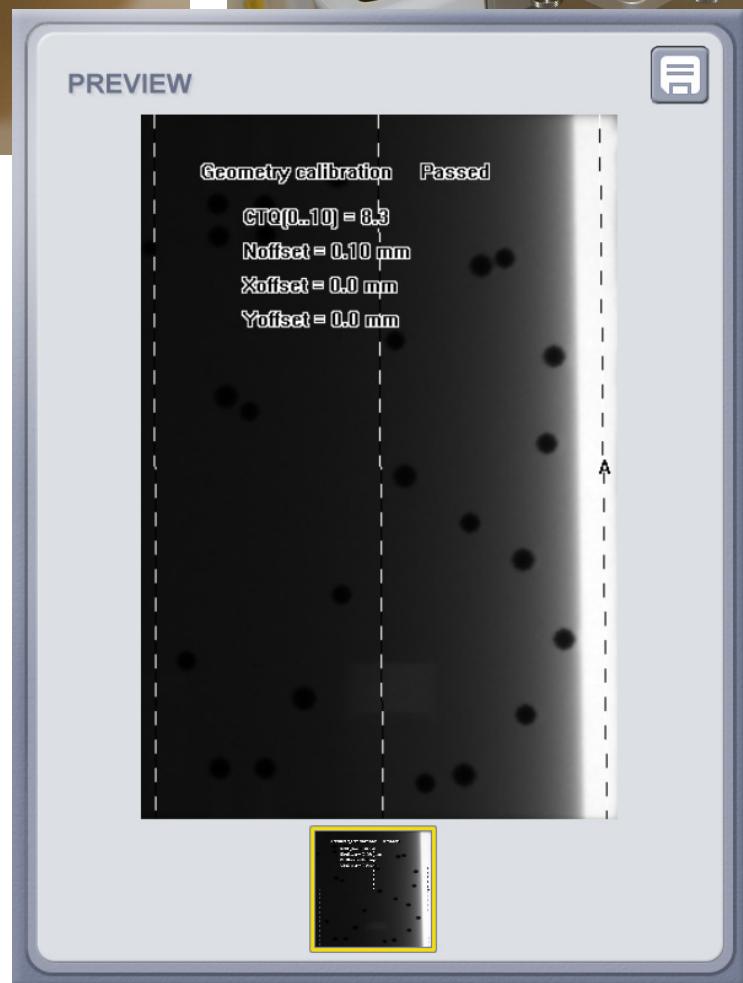
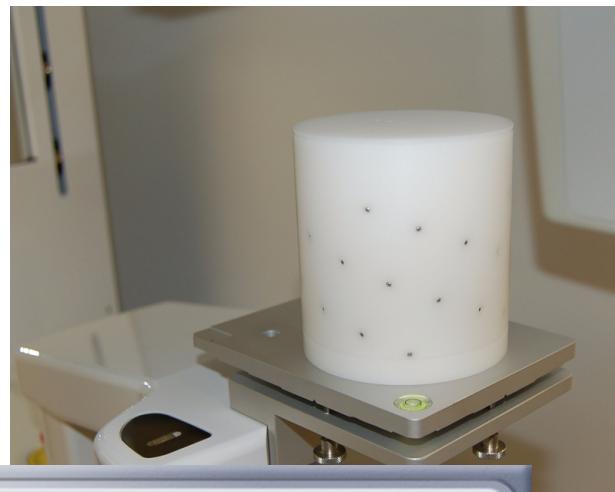
1. Select the program.
2. Press the patient positioning button.
3. Install the double cone calibration tool.
4. Take an exposure. GUI informs when the calibration is passed. Repeat the calibration if it fails.



#### 4.3.6 CT geometry calibration



1. Place the base of the phantom to the lower shelf.  
Level it with the bubble.
2. Select the program.
3. Press the patient positioning button.
4. Install the 3D calibration phantom.
5. Take an exposure. GUI informs when the calibration is passed. Repeat the calibration if it fails.  
This calibration is only needed with 3D units.



#### 4.3.7 CT lasers alignment

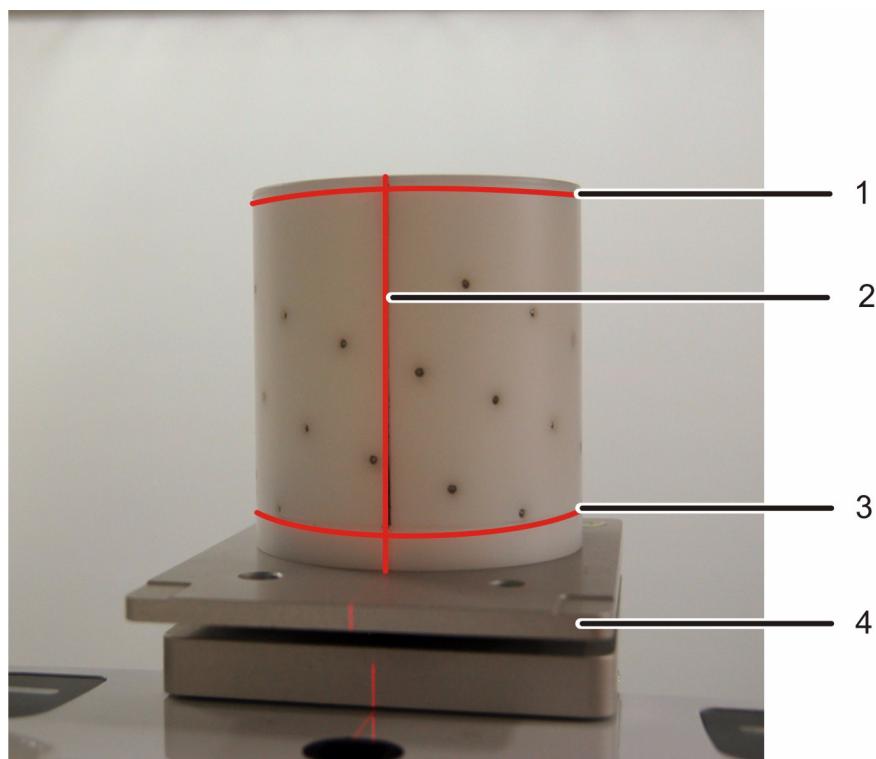
Remove the mirror plate by loosening four M4 screws.  
Lift the plate first and pull.

1. Attach the CT geometry calibration tool to the unit.  
Use the 3D calibration phantom with grooves for aligning the FOV and mid-sagittal lasers.
2. Select the CT lasers program in the service mode.
3. Press the patient positioning button.



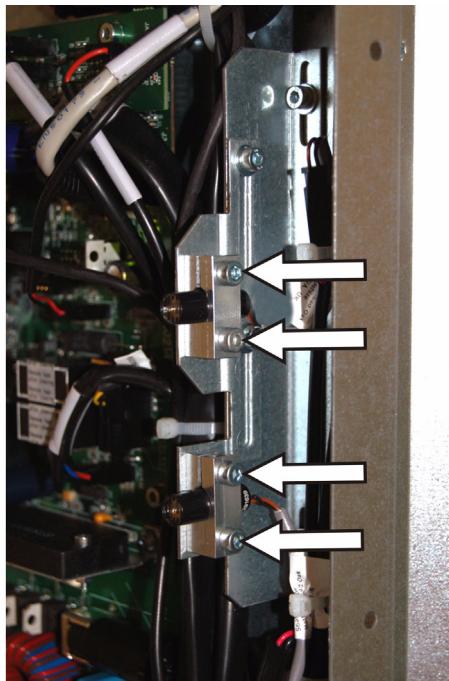
**NOTE!** Lasers can be turned on by pushing the light button. Lasers stay on approx. 30 seconds.

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



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

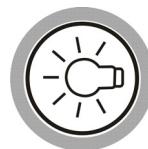
5. Align bottom laser first by two screws.
6. Align top laser second by two screws.



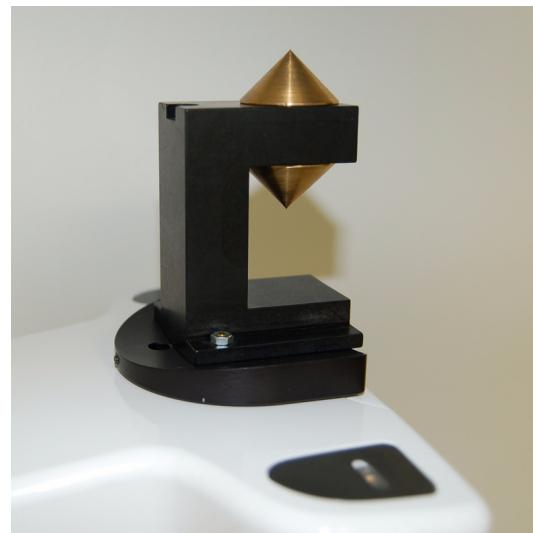
#### 4.3.8 PAN laser alignment

To align patient positioning lasers used in panoramic imaging:

1. Attach the PAN geometry calibration tool (double cone) to the unit.
2. Select the PAN lasers program.
3. Press the patient positioning button.
4. Align the layer laser, FH-laser and mid-sagittal lasers to the corresponding grooves by mechanically adjusting the lasers. Adjustment of the laser located in the rotator is software based. Use the chin support adjustment 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.
5. Briefly press the exposure button (no X-rays are generated) to acknowledge the adjustment has been carried out. The rotation and Y-position are also saved.



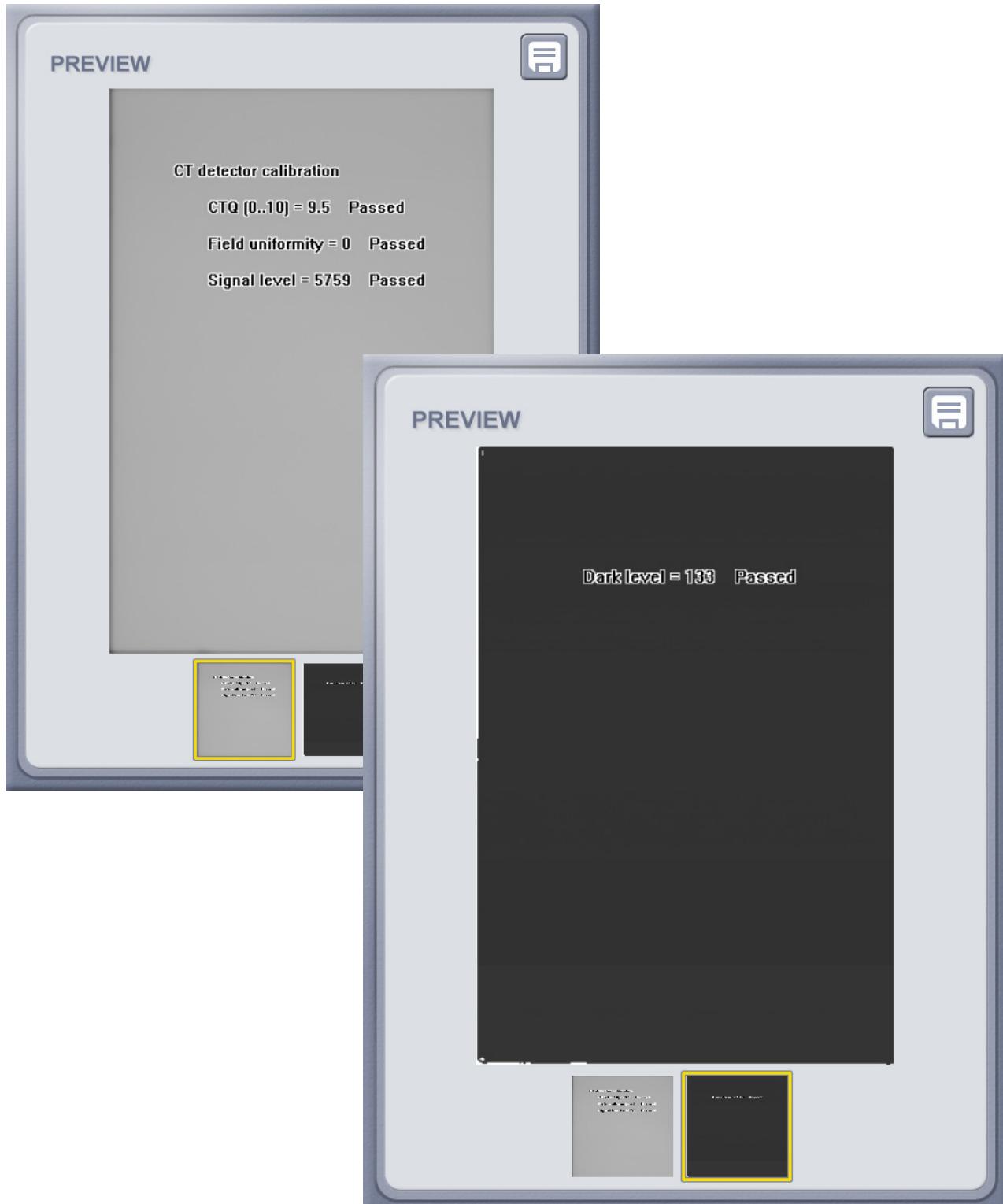
**NOTE!** Lasers can be turned on by pushing the light button. Lasers stay on approx. 30 seconds.



#### 4.3.9 CT pixel calibration



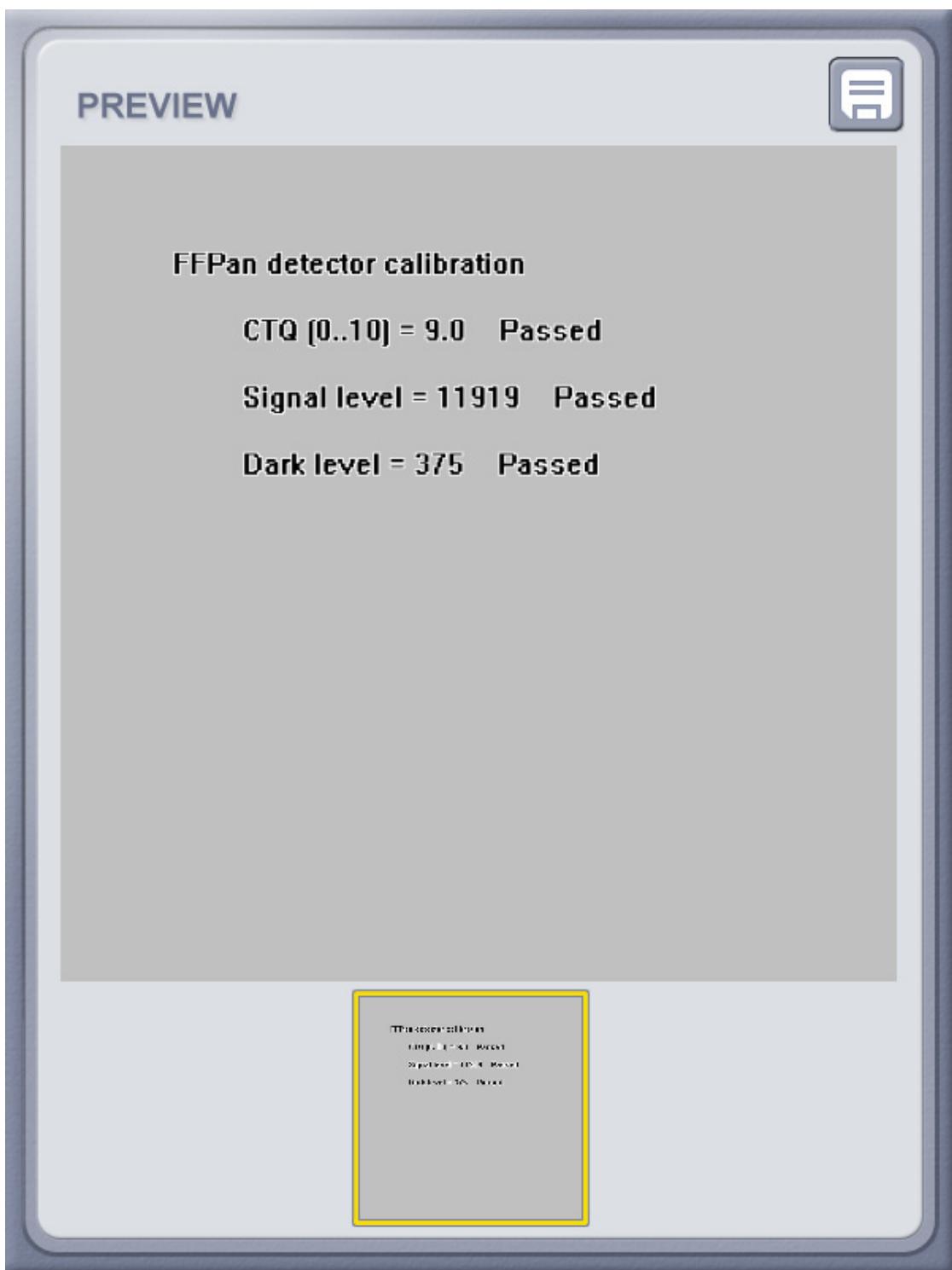
1. Attach the tube head covers.
2. Remove the 3D calibration phantom.
3. Select the program.
4. Press the patient positioning button.
5. Take an exposure.  
GUI informs when the calibration is passed.



#### 4.3.10 PAN pixel calibration



1. Attach the tube head covers.
2. Remove the double cone calibration tool.
3. Select the program.
4. Press the patient positioning button.
5. Take an exposure.  
GUI informs when the calibration is passed.



#### **4.3.11 CT QC program**

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

#### **4.3.12 Panoramic QC program**

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

## 4.4 When to calibrate the unit

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

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

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

### **Tubehead**

After replacing the tubehead the unit must be completely recalibrated.

### **R3800 X-ray generator**

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

### **Collimator assembly**

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

### **3D Panel**

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

### **Panoramic panel**

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

# 5 OP300 Pre-sales check list

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

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

## 5.1 Physical Environment Requirements

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

## 5.2 Radiation Shielding Requirements

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

(see image 1&amp;2)

Installation space:	Minimum installation space 2000 mm x 1500 mm. Height 2130 mm at minimum.	End User/Dealer				
Fixing hardware	Required fixing hardware depends on the wall and floor material and it is not delivered with the unit. The fixing hardware, as well as wall and floor materials must endure a pull-out force of 5000 N. Wall material should be suitable for fixing the unit. If the wall is made of weak material, you may have to use a reinforcing plate on the rear side of the wall to hold the fixing hardware. The person installing the unit is responsible for fixing hardware. Check that it is possible to drill holes in the floor without damage to any electrical or water pipes etc.	Dealer				
Weight:	The fully assembled unit with ceph weighs 245 kg / 450 lb (212 kg / 467 lbs without ceph). Make sure that the floor where the unit is to be installed can support this weight. The floor should be able to carry minimum 1000kg / m <sup>2</sup> .	End User/Dealer				

## 5.4 Electrical Specifications

Power network	100-240VAC, 50/60Hz (10A@230VAC, 15A@110VAC) dedicated power supply, max. 0.2Ω line impedance. Separate outlets for OP300 and Workstation PC.	End User/Dealer				
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## 5.5 Networking Specifications

		RESPONSIBILITY	APPROVAL LEVEL			
			OK	Does not meet the specs	Modification needed	Comment
1Gb/s network to all components involved with OP300 system	The connection between the unit and PC must meet EN60601-1 requirements.  OP300 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. If the OP300 is connected to the Workstation PC via a network switch, the switch and network configuration must allow 1Gb/s communication speed.	End User/Dealer				
IT Administrator available during installation	The end-user IT administrator shall be present during installation in order to keep promised installation schedule and guarantee successful set-up.	End User/Dealer				

## 5.6 Computer Specifications

Workstation	<p>The PC must meet the IEC 60950 standard.(minimum requirements)</p> <ul style="list-style-type: none"> <li>- Windows 7 or Windows Vista (32 or 64-bit), Windows XP Professional(32-bit)</li> <li>- 2.0 GHz Core i5 or i7 CPU or equivalent processor</li> <li>- 3 GB RAM</li> <li>- 500 GB HDD or larger</li> <li>- 2x 1Gb Ethernet network interface</li> <li>- one available full length PCI-Express x16 bus slot for a GPU card</li> <li>- GTX 460 NVIDIA QUADRO or FX 3800 NVIDIA QUADRO GPU (Contact techsupp@instrumentariumdental.com for update information about the approved graphics cards)</li> <li>- 2 available USB ports for hardware keylocks</li> <li>- 550 watt power supply with two 6-pin power cables (for GPU)</li> </ul>	<b>End User/Dealer or optionally Instrumentarium Dental</b>				
19" LCD display, 1280 x 1024 pixels, 32 bit color	<p>Displays (monitors) should be tested for quality on location.</p> <ol style="list-style-type: none"> <li>1. Brightness at least 120 cd/m<sup>2</sup>, recommended 200 cd/m<sup>2</sup>.</li> <li>2. Maximum static (NOT dynamic) contrast at viewing conditions: 1:400 (minimum), 1:1000 (recommended). We recommend the use of SMPTE-Test image to verify the resolution and high and low contrast 5% fields. In addition the real contrast should be measured in respect to the local environment conditions (ambient light) at the viewing station.</li> <li>3. If applicable, check local requirements</li> </ol>	<b>End User/Dealer or optionally Instrumentarium Dental</b>				

## 5.7 Backup Specifications

The Cliniview 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 Cliniview Installation Manual.	<b>End User</b>				
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## 5.8 DICOM Services SCP

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

## 5.9 Software configuration

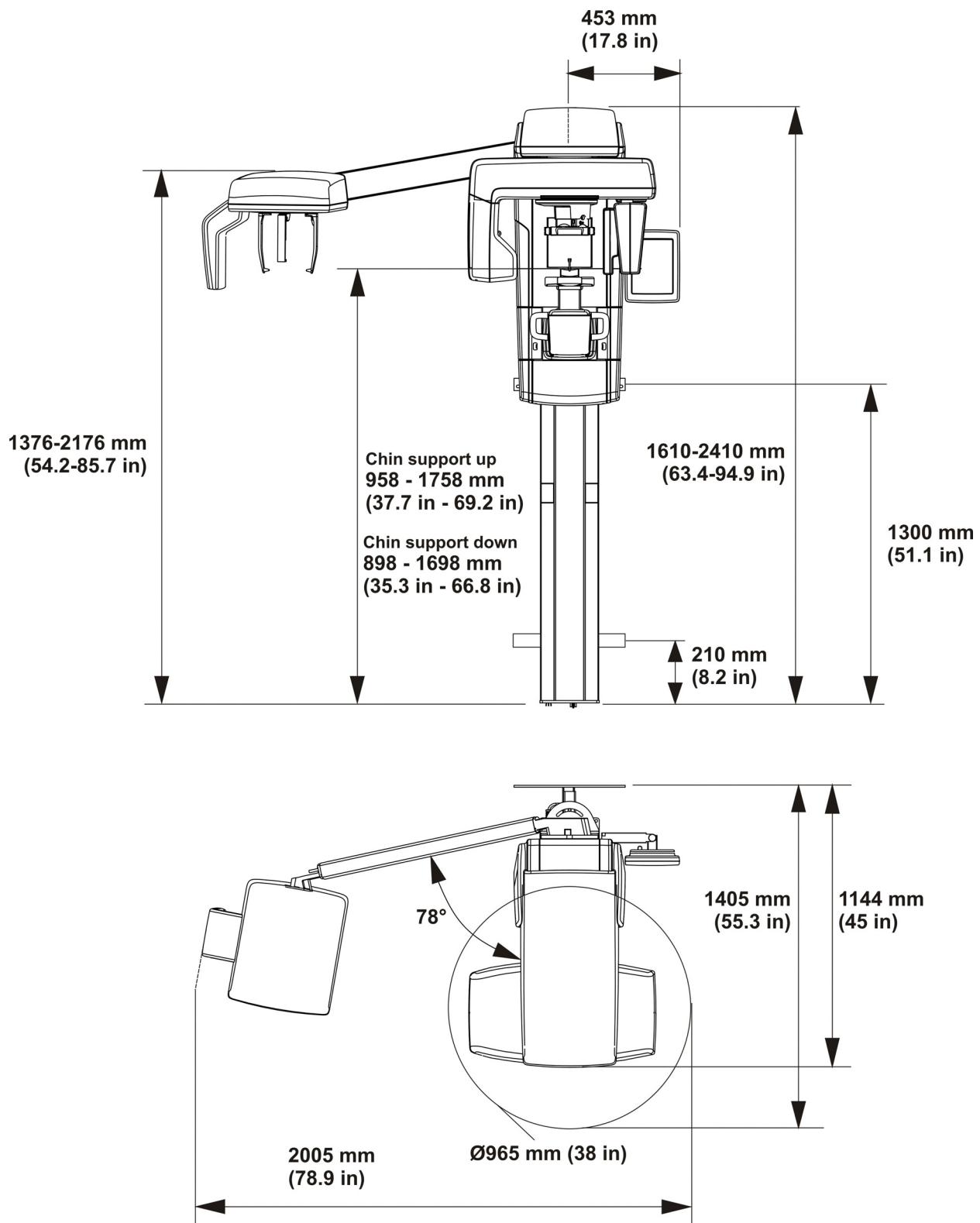
		YES	NO	DETAILS
Which software components are included in delivery?	CliniView software (required)	X		
	OnDemand3D Lite (3D visualization software)			
	CliniView software DICOM Option			NOTE: If full integration into a DICOM environment is needed, Cliniview software DICOM Option is required. This includes printing 2D images to DICOM printers, DICOM Storage, Modality Worklist, Query / Retrieve.
	FMS			Full Mouth Series option for Cliniview SW for intraoral use (not required for OP300)
	InVivoDental			Delivered in US only.

## 5.10 Other information

3rd party 3D software:	<p>Is Cliniview software going to be used with existing 3rd party 3D software?</p> <p>NOTE: Direct link between Cliniview and 3rd party 3D software is available for the following software:          Materialise Simplant, Cybermed OnDemand3D (Lite), Anatomage InVivoDental          Additionally, DICOM compatible 3D software (such as NobelGuide) is compatible with the OP300 system</p>			
DICOM Conformance statement	Have the DICOM conformance statement(s) been delivered to the end-user?			Can be downloaded from Instrumentarium Dental 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 Instrumentarium Dental X-ray units	Are any other Instrumentarium Dental digital imaging systems installed in the clinic?			
Imaging software already in use	Cliniview (please provide the version number)			
	Other			

## 5.11 Notes / comments


## 5.12 Image 1: Dimensions with ceph



## 5.13 Image 2: Dimensions of PAN/3D unit

