VistaPano S 2.0
VistaPano S Ceph 2.0

EN-US Installation instructions

CE 2460 Rx Only

DÜRR DENTAL

220810005211 A9302 2604V003

The latest version of the instructions is available in this page:

https://bit.ly/m/air-techniques-imaging-manuals

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Important information

1 About this document

These installation instructions apply to:
VistaPano S 2.0
REF: A9350
VistaPano S Ceph 2.0
REF: A9550
These installation instructions are an integral part of the unit.

Air Techniques shall not be held liable and offers no guarantees of the safe and smooth operation of this unit if you fail to comply with notes and instructions contained in these Instructions.

For use of the unit, note the separate operating instructions (document no. A9301).

1.1 Warnings and symbols

Warnings

The warning notes in this document highlight possible injury to persons or damage to machinery.
They are marked with the following warning symbols:

General warning symbol

Warning – risk of dangerous electric voltages

Warning – X-rays

The warnings are structured as follows:

SIGNAL WORD

Description of type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between different levels of danger:

- **DANGER**
  Direct danger of severe injury or death
- **WARNING**
  Possible danger of severe injury or death
- **CAUTION**
  Risk of minor injuries
- **NOTICE**
  Risk of extensive material/property damage

Miscellaneous symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding the efficient use of the unit.

Take note of the accompanying electronic documents.

Refer to Operating Instructions.

MD Medical device

REF Part number

SN Serial number

CE xxxx CE labeling with the number of the notified body

UL classification

EC REP Authorized EU representative

Rx Only Caution: By virtue of Federal Law (US-FDA 21CFR801.109), the device may only be sold to dentists or bought on behalf of a dentist.

Manufacturer

Date of manufacture

Distributor

Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).


Type B Applied Part


Do not reuse

Sterilize with steam at 134 °C


Wear hand protection.


Disconnect all power from the unit.


Off

On


Class 1 laser product


Protective ground connection


Warning – risk of dangerous electric voltages


Alternating Current


Warning against electrostatic discharge

1.2 Copyright information

All circuits, processes, names, software programs, and devices mentioned in this document are protected by copyright.
Any reprinting of the installation and operating instructions, in whole or in part, is only permitted with the written approval of the owner of the corresponding rights.

2 Safety

The unit has been developed and designed appropriately such that hazards are largely excluded if the unit is used in accordance with its Normal Use.
Despite this, the following residual risks can remain:

- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to electric shock
- Personal injury due to radiation
- Personal injury due to fire
- Personal injury due to thermal effects to skin
- Personal injury due to lack of hygiene, e.g. infection

2.1 Indications for use

The unit is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians.

2.2 Improper use

Any use of this appliance/these appliances above and beyond that described in the Installation and Operating Instructions is deemed to be incorrect usage. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.

2.3 General safety information

- Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
- Check the function and condition of the unit prior to every use.
- Do not convert or modify the unit.
- The unit must only be checked and repaired by a technician authorized by Vatech.
- Comply with the specifications of the Installation and Operating Instructions.
- The Installation and Operating Instructions must be accessible to all operators of the unit at all times.
- It is prohibited by law to modify the unit in any way that could endanger the safety of persons.
- Only use accessories and parts for this unit that have been supplied by Vatech or a third-party supplier approved by Vatech.

2.4 Systems, connection with other devices

Additional devices connected to medical electrical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1).
Anyone connecting additional devices to medical electrical devices is a system configurer and is therefore responsible for ensuring that the system meets the standard requirements for systems. It shall be noted that local laws take precedence over the requirements outlined above.

2.5 Radiation protection

- Comply with all applicable X-ray protection regulations and X-ray protection measures.
- Use the prescribed X-ray protection equipment.
- In order to reduce the level of X-ray exposure, we recommend the use of bismuth, lead shielding or protective aprons, especially for children and teenagers.
- The persons operating the equipment must keep away from the X-ray unit while the exposure is being taken. The minimum distance required by the law must be maintained
- Children and pregnant women must consult a doctor before recording an X-ray image.
- No person other than the patient is permitted to be present in the radiation room without X-ray protection measures. In exceptional circumstances another person may be present to provide assistance, but this must not be a member of the surgery staff. When the exposure is being taken, make sure that you have visual contact to the patient and to the unit.
- The radiation room must be lockable to prevent entry by unauthorized persons.
- If a fault occurs, abort the exposure immediately by releasing the trigger button.
- The status LED displays when an X-ray image acquisition has been triggered.
  It is optionally also possible to enable or interrupt X-ray exposures via a door contact.
- The parts connected to the unit, e. g. cables, must comply with the relevant IEC standards (e. g. IEC 60950 for IT equipment and IEC 60601-1 for medical electrical equipment)

2.6 Specialist personnel

Qualification

Legally qualified persons such as a dentist and healthcare professional for X-ray device operation.

Knowledge

- Understand the diagnosis and treatment of dental diseases.
- Understand specific terminology and instructions for the hardware and software of medical diagnostic X-ray equipment.
- Understanding of the connection, installation and operating conditions of the devices.

Language understanding

Understands English or other languages provided in the manual.

Experience

- Understands the objective and effect of diagnosing and treating dental diseases with diagnostic medical radiation devices.
- Understands how to operate diagnostic medical radiation equipment.
- Understands the contents of the user manual.

2.7 Protection from electric shock

- Comply with all the relevant electrical safety regulations when working on the unit.
- Never touch the patient and unshielded plug connections of the device at the same time.
- Replace damaged cables or plugs immediately.
- If the user of this unit requires continuous operation during power failure, an uninterruptible power supply may be required to maintain operation.

WARNING

Contraindication due to radio frequency signals

Electrical radio frequency signals can interfere with the function of pacemakers and defibrillators.

› Patients with pacemakers or defibrillators should not be treated with this unit.

WARNING

Electric shock due to missing protective earth

› To avoid the risk of electric, this equipment must only be connected to a supply mains with protective earth.

Comply with the EMC rules concerning medical devices

The unit meets the requirements according to IEC 60601-1-2:2020.

- The quality of the mains voltage should correspond to that of a typical commercial or hospital environment.
- Electromagnetic disruptions can lead to a loss of system performance. Therefore it may be necessary to remove devices that generate static electricity in the surrounding area, or to remove the user's static electricity before use.
- The unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the unit is operated in any other environment, potential effects on the electromagnetic compatibility must be taken into account.
- Do not operate the unit in the vicinity of RF surgical instruments or MRT equipment.
- Maintain a minimum distance of at least 30 cm (12 in) between the unit and other electronic devices.
- Maintain a distance of at least 20 cm (8 in) between the device and wireless devices such as RFID/NFC with 134.2 kHz and 13.56 MHz.
- Note that cable lengths and cable extensions have effects on electromagnetic compatibility.

No maintenance measures are required to maintain the basic EMC safety.

- Floor coverings should be made of wood, concrete or ceramic tile. If synthetic material is installed, then the relative humidity must be at least 30%.
- The emissions characteristics of this unit make it suitable for use in industrial areas and hospitals (CISPR 11, Class A). When used in a residential environment (which normally requires Class B in accordance with CISPR 11), this device may not provide adequate protection from radio communication services. The operator may need to take corrective measures such as relocating or reorienting the device.

NOTICE

Negative effects on the EMC due to non-authorized accessories

› Only use accessories that have been specified or approved by the manufacturer.

› The use of any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an faulty operation mode.

NOTICE

Erroneous operation mode due to use immediately adjacent to other devices or with other stacked devices

› Do not stack the unit together with other devices.
› If this is unavoidable, the unit and other devices should be monitored in order to ensure that they are working correctly.

WARNING

Reduced performance characteristics due to insufficient distance between unit and portable RF communication devices

› Portable RF communication devices, including peripheral devices such as antenna cables and external antennae, should not be used closer than 30 cm (12 inches) to any part of the VistaPano S or VistaPano S Ceph, including cables specified by the manufacturer. Otherwise this can impair the performance of this device.

2.8 Elements that patients will come into contact with

Type B Applied Part

– Protective covers for bite block
– Temple support plus
– Comfort bite foam set
– Comfort bite block
– Bite block
– Holder for bite block
– Chin support for maxillary joint image
– Chin holder for edentulous jaws
– Chin support for sinus image
– Ear cushions and nose support covers
– Carpus plate

2.9 Protection from cybersecurity threats

The unit is to be connected to a computer that can be connected to the Internet. Therefore, the system needs to be protected from threats from the Internet.
– Use antivirus software and update it regularly.
– Look for evidence of possible virus infection and, if applicable, check with the antivirus software and remove the virus.
– Perform regular data backups.
– Restrict access to units to trustworthy users, e.g. via a user name and password.
– Make sure that only trustworthy content is downloaded. Install manufacturer-authenticated software and firmware updates only.

2.10 Notification requirement of serious incidents

The operator/patient has to report any serious incident related the product to the manufacturer and the competent authority of the Member State, in which the operator and/or patient is established/resident.

2.11 Only use genuine parts

– Only use accessories and optional items that have been recommended or specifically approved by the manufacturer.
– Only use original working parts and spare parts.

Manufacturer and distributor accept no liability for damage or injury resulting from the use of non-approved accessories or optional accessories, or from the use of non-original wear parts or replacement parts.

The use of non-approved accessories, optional items or non-genuine wear parts / replacement parts (e. g. mains cable) can adversely affect the electrical safety and EMC.

The following accessories may affect EMC:
– Power Cable
– Exposure switch

2.12 Transport

The original packaging provides optimum protection for the unit during transport.

If required, original packaging for the unit can be ordered.

Manufacturer and distributor shall not accept any responsibility or liability for damage occurring during transport due to the use of faulty packaging, even where the unit is still under guarantee.

- Only transport the unit in its original packaging.
- Keep the packing materials out of the reach of children.
- Reattach the transport locking devices.
- Do not expose the unit to any strong vibrations or shocks.
- Do not bump or pull the unit.

2.13 Disposal

The equipment contains - in some of its parts - solid and liquid substances which must be disposed of at appropriate recycling centers conforming to all local, state and federal regulations. In particular, the equipment contains the following materials and/or components.

X-ray emitter

Non-biodegradable plastic materials, metals, glass, dielectric oil, lead, tungsten.

Other components

Non-biodegradable plastics, metals, printed circuits, and electronic components.

Air Techniques is not responsible for disposal of the apparatus or parts thereof and for the related expenses.

Product description

3 Overview

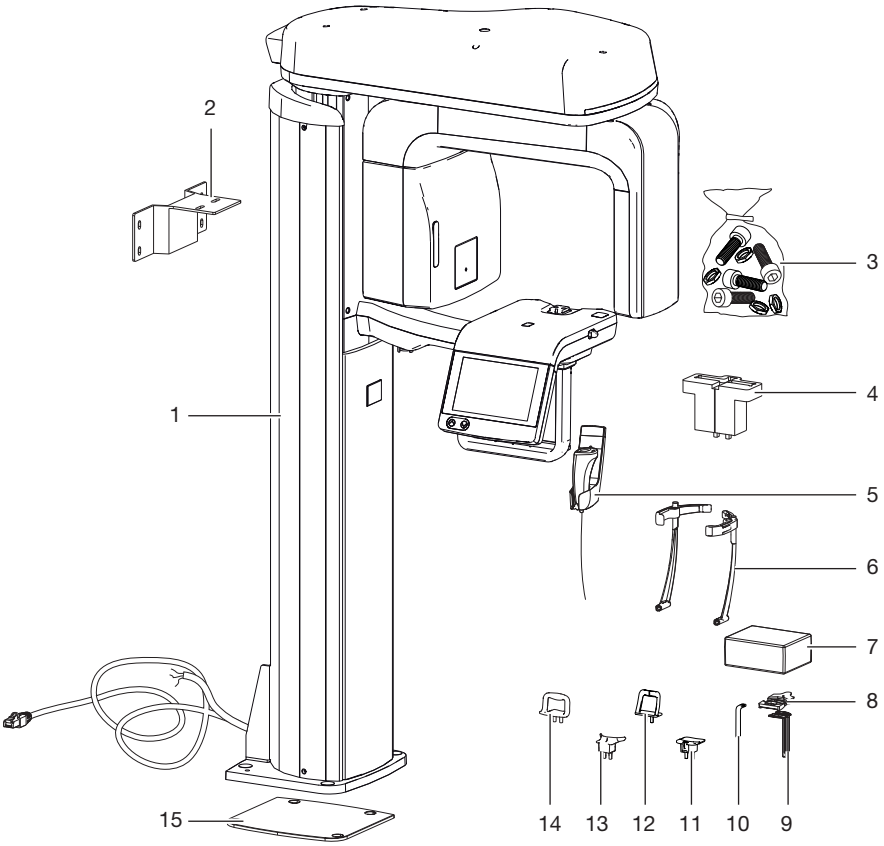

Fig. 1: VistaPano S 2.0

1 Panoramic X-ray device
2 Wall bracket
3 Installation mounting hardware
4 Test phantom holder for ProVecta S-Pan
5 Exposure switch
6 Temple support plus*
7 Protective bite block covers*
8 Comfort bite foam set*
9 Comfort bite block*
10 Bite block*
11 Holder for bite block*
12 Chin support for maxillary joint image*
13 Chin holder for edentulous jaws*
14 Chin support for sinus image*
15 Aligning plate

*These parts will be in direct contact with the patient.

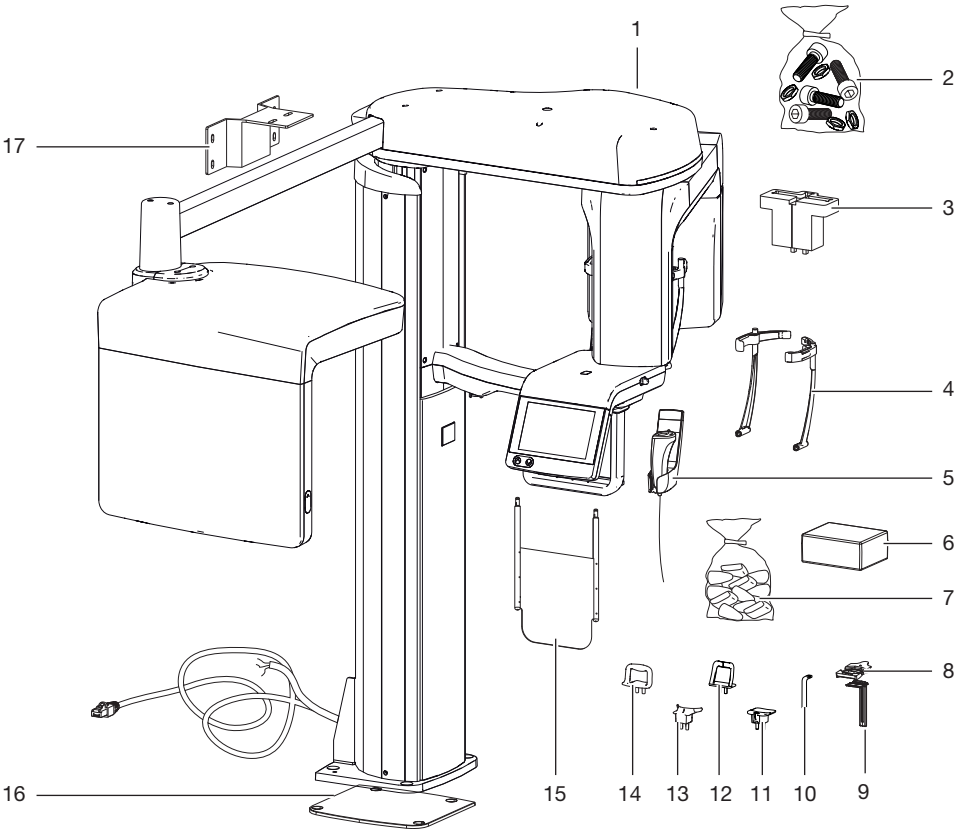

Fig. 2: VistaPano S Ceph 2.0

1 X-ray system
2 Installation mounting hardware
3 Test phantom holder for ProVecta S-Pan
4 Temple support plus*
5 Exposure switch
6 Protective bite block covers*
7 Ear cushions and nose support covers*
8 Comfort bite foam set*
9 Comfort bite block*
10 Bite block*
11 Holder for bite block*
12 Chin support for maxillary joint image*
13 Chin holder for edentulous jaws*
14 Chin support for sinus image*
15 Carpus plate*
16 Aligning plate
17 Wall bracket

*These parts will be in direct contact with the patient.

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations may apply due to country-specific requirements and/or import regulations):

VistaPano S 2.0 . . . . . A9350

- Voucher for VistaSoft imaging software
- Network cable, 10 m
- Exposure switch and holder
- Holder for bite block
- Bite block
- Comfort bite block
- Chin support for edentulous jaws
- Chin holder for maxillary joint image
- Chin holder for sinus image
- Temple support plus
- Protective bite block covers (100 pieces)
- Comfort bite foam set (10 pcs.)
- Installation mounting hardware
- Silicone cap-set
- Wall bracket set
- Aligning plate
- Quick start guide
- PCI Express Gigabit Ethernet card

VistaPano S Ceph 2.0 . . . . . A9550

- Voucher for VistaSoft imaging software
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- Comfort bite block set (10 pcs.)
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- Installation mounting hardware
- Silicone cap-set
- Carpus plate
- Wall bracket set
- Aligning plate
- Quick start guide
- PCI Express Gigabit Ethernet card

3.2 Accessories

The following items are required for operation of the device, depending on the application:

Laser test tool A7385
Ball phantom A7330
Protective bite block covers (100 pieces) . A7395
Test phantom holder (can be used with test phantom set for Pano 2121-060-55 and with test phantom 2121-060-54) . . . A7366
Test phantom holder for cephalometric projections (can be used with test phantom set for Pano 2121-060-55 and with test phantom 2121-060-54) A7557

Positioning aids

Holder for bite block A7747
Bite block (3 pieces) A7751
Comfort bite foam set (10 pcs.) A7745
Comfort bite foam set (100 pcs.) A7746
Chin support for edentulous jaws A7390
Head supports with cushion A7800
Chin holder for mandibular joint image . . A7391
Chin holder for sinus image A7392

3.3 Optional items

The following optional items can be used with the device:

Floor stand A7355
Laser test tool A7385
Ball phantom A7330
Silicone Cap-set A9347

Acceptance and consistency check

2-D X-ray test phantom set A7556
Primary absorber, Copper filter A7466

3.4 Consumables

The following materials are consumed during operation of the device and must be re-ordered:

Protective bite block covers (100 pieces) . A7395
Comfort bite foam set (100 pieces) A7746

4 Technical data

Electrical data of the device		
Nominal Voltage	V AC	200 - 240
Max. mains voltage fluctuation	%	±10
Frequency	Hz	50/60
Maximum power	kVA	2.2
Type of protection		IP X0
Operating mode height adjustment		max 2 min ON / 18 min OFF (Ratio 1:9 switch-on/switch-off time)
Operating mode		Non-continuous operation (NFPA 70: long time operation) Needs waiting time (at least 60 times the exposure time) before the next exposure begins.

Classification	
Medical device class	IIb
FDA classification (CFR Title 21)	II
Health Canada Classification (SOR/98-282)	II
Protection against electric shock	Class I

CLASSIFIED C UL US
E476672

UL classification
MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005 + AMD1:2012 + AMD2:2021,
CAN/CSA-C22.2 No. 60601-1:14 (Amendment 2:2022)
IEC 60601-1-3:2008 + AMD1:2013 + AMD2:2021
IEC 60601-1-6:2010 + AMD1:2013 + AMD2:2020
IEC 60601-2-63:2012 + AMD1:2017 + AMD2:2021

Manufacturer:
VATECH Co., Ltd. on behalf of Air Techniques
13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do,
Korea

Authorized EU representative:
VATECH GLOBAL FRANCE SARL
49 Quai de Dion Bouton, AVISO A 4ème étage, 92800
Puteaux, France

Product	Digital X-ray imaging system
Model	VistaPano S VistaPano S Ceph

General technical data		VistaPano S 2.0	VistaPano S Ceph 2.0
Height Height incl. stand (optional)	mm in mm in	1587 - 2287 62.48 - 90.04 1615 - 2315 63.58 - 91.14	
Dimensions (W x D)	mm in	990 x 1160 38.97 x 45.67	1900 x (1145 - 1160) 74.80 x (45.08 - 45.67)
Vertical adjustment travel of telescopic column	mm in	700 27.56	700 27.56
Weight Weight incl. stand (optional)	kg lbs kg lbs	112.5 248.0 158 348.3	134.8 297.2 180.3 397.5

Ambient conditions during operation		
Temperature	°C °F	10 - 35 50 - 95
Relative humidity	%	30 - 75
Air pressure	hPa	860 - 1060

Ambient conditions during storage and transport		
Temperature	°C °F	-10 to +60 14 to 140
Relative humidity	%	10 - 75
Air pressure	hPa	860 - 1060

X-ray emitter		
Model		DG-07E22T2
Rated power	kW	1.6 (at 1 sec)
Type		Inverter
Tube voltage**	kV	60 - 99 (1 kV increment)
Tube current**	mA	4 - 16 (1 mA increment)
Duration of radiation exposure**	sec	1.9 - 13.4
Duty Cycle		1:60 or more (exposure time : interval duration)
Cooling		Automatic monitoring Shut-off at ≥ 60°C
Additional filters	mm Al	1.5
Permanent filtration (minimum)	mm Al	1.0
Total filtration (minimum)	mm Al	2.5
X-ray tube permanent filtration	mm Al	Minimum 0.8 (at 50 kV)
X-ray tube model		D-052SB / Canon
Focal spot size as per IEC 60336 X-ray tube	mm	0.5
Anode angle	°	5

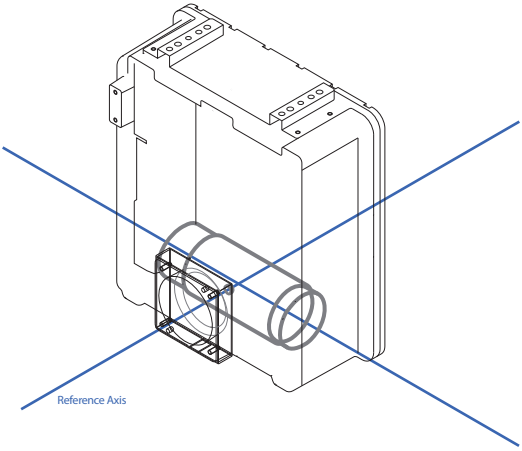
*The reference axis is the perpendicular of the X-ray exit window at the level of the side marker for the focal point on the cover of the X-ray emitter
**Tube voltage/current range and exposure time depend on the type of exposure:
– Panorama (Voltage: 60 - 90 kVp, Current: 4 - 14 mA; Exposure time: 2.4 - 13.4 s)
– Remote X-ray (Voltage: 60 - 99 kVp, Current: 4 - 16 mA; Exposure time: 1.9 - 7.7 s)
– For further information, refer to sections "10 Default values", "11 Panoramic program parameters", and "12 Ceph program parameters"

Detector		Panorama	Ceph
Model		Xmaru1501CF-PLUS	Xmaru2602CF
Type		CMOS photodiode array	
Pixel size	µm	100	100 200 (2x2 binning)
Active surface area	mm	6 x 151.2	15.6 x 259.2
Frame rate	fps	~287	~ 109 ~ 330 (2x2 binning)
Gray scales	bit	14	14

Exposure Mode	FDD mm	FOD mm	ODD mm	Image capture scale (magnification factor)
Panorama	490.2	375.0	115.2	1.3
Ceph	1745	1524	221	1.14

FDD: distance from focal spot to detector
FOD: distance from focal spot to object
ODD: distance from object to detector (ODD = FDD - FOD)
Image capture scale = FDD/FOD

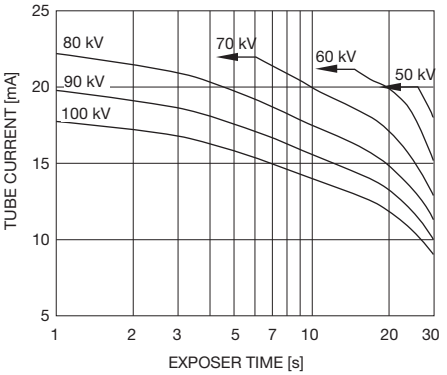
4.1 X-ray tube performance data



– Maximum deviation of the voltage peak from the displayed value ±10 %
– Maximum deviation of the tube current from the displayed value ±20 %
– Maximum deviation of the exposure time from the displayed value ± (5 %+ 50 ms)
– The lowest possible load factor is obtained with a combination of the settings 60 kV und 4 mA.

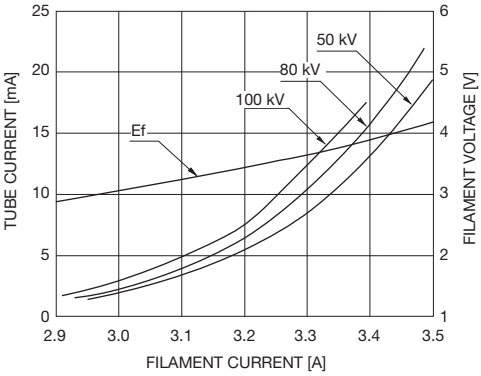
Maximum Rating Charts

Constant Potential High-Voltage Generator
Nominal Focal Spot Value: 0.5x0.5

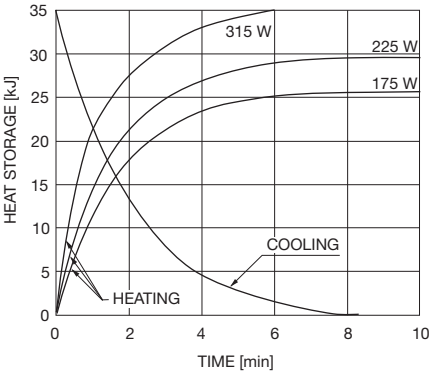


Emission and Filament Characteristics

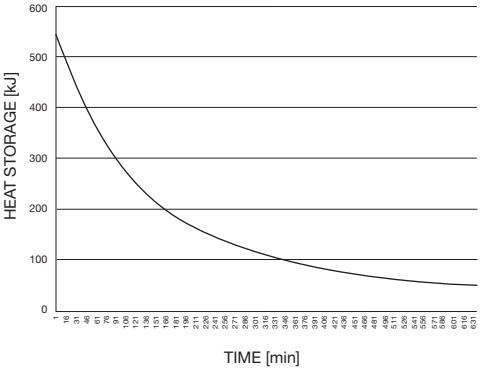
Constant Potential High-Voltage Generator
Nominal Focal Spot Value: 0.5x0.5



Anode Heating/Cooling Characteristics



X-ray Housing Assembly Tube Characteristics



4.2 Electromagnetic compatibility (EMC)

Phenomenon Basic EMC standard or test procedure	Mode of operation	Tested connector	Test voltage	Test category / requirement
Interference voltage at the power supply connection CISPR 11:2015+A1:2016+A2:2019 EN 55011:2016/A11:2020	– Mode of operation – Standby	Voltage supply unit AC	220 V AC, 60 Hz 230 V AC, 50 Hz	CISPR11 Group 1, Class A
Electromagnetic interference radiation CISPR 11:2015+A1:2016+A2:2019 EN 55011:2016/A11:2020	– Mode of operation – Standby	Housing	220 V AC, 60 Hz 230 V AC, 50 Hz	CISPR11 Group 1, Class A
Emission of harmonics IEC 61000-3-2:2018+A1:2020 EN IEC 61000-3-2:2019/A1:2021	– Mode of operation – Standby	Voltage supply unit AC	230 V AC, 50 Hz	Class A

Phenomenon Basic EMC standard or test procedure	Mode of operation	Tested connector	Test voltage	Test category / requirement
Voltage changes, voltage fluctuations and emission of flicker IEC 61000-3-3:2013+A1:2017+A2:2021 EN 61000-3-3:2013+A1:2019	– Mode of operation – Standby	Voltage supply unit AC	230 V AC, 50 Hz	Pst: 1 Plt: 0.65 dmax: 4% dc: 3.3%
Immunity to interference, discharge of static electricity IEC 61000-4-2:2008 EN 61000-4-2:2009	– Mode of operation – Standby	Housing	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	± 8 kV / contact ±2, ±4, ±8, ±15 kV/air
Immunity to interference, high-frequency electromagnetic fields IEC 61000-4-3:2020 EN IEC 61000-4-3:2020	– Mode of operation – Standby	Housing	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz
Immunity to interference by near fields of wireless RF communication devices IEC 61000-4-3:2020 EN IEC 61000-4-3:2020	– Mode of operation – Standby	Housing	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	Table 9 in IEC 60601-1-2
Immunity to interference by rapid transient bursts IEC 61000-4-4:2012 EN 61000-4-4:2012	– Mode of operation – Standby	Voltage supply cable AC Data cables	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	AC current cable: ±2 kV Signal: ±1 kV 100 kHz repetition rate
Immunity to interference by surges IEC 61000-4-5:2014+A1:2017 EN 61000-4-5:2014+A1:2017	– Mode of operation – Standby	Voltage supply unit AC	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	Line-vs-line: ±0.5 kV, ±1 kV Line to earth: ±0.5 kV, ±1 kV, ±2 kV
Immunity to interference by conducted disturbances induced by high-frequency fields IEC 61000-4-6:2013 EN 61000-4-6:2014	– Mode of operation – Standby	Voltage supply cable AC Data cables	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	AC current and signal line: 3 V, 0.15 – 80 MHz 6 V ISM frequency bands Ranging from 0.15 MHz to 80 MHz : 80% AM at 1 kHz
Immunity to power frequency magnetic fields IEC 61000-4-8:2009 EN 61000-4-8:2010	– Mode of operation – Standby	Housing	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	30 A/m 50 Hz & 60 Hz

Phenomenon Basic EMC standard or test procedure	Mode of operation	Tested connector	Test voltage	Test category / requirement
Immunity to interference by voltage dips IEC 61000-4-11:2020 EN IEC 61000-4-11:2020	– Mode of operation – Standby	Voltage supply unit AC	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	0 % U_T: 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
				0 % U_T; 1 period and 70% U_T; 25/30 periods Single phase: at 0°
Immunity to short-term interruptions IEC 61000-4-11:2020 EN IEC 61000-4-11:2020	– Mode of operation – Standby	Voltage supply unit AC	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	0% U_T; 250/300 periods
Inference immunity in magnetic near field IEC 61000-4-39:2017 EN IEC 61000-4-39:2017	– Mode of operation – Standby	Housing	– 220 V AC, 60 Hz – 230 V AC, 50 Hz	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m

The strength of the RF field that is fed into the network of the unit should be less than 3 V in the frequency range 0.15 to 80 MHz.

4.3 Dimensions

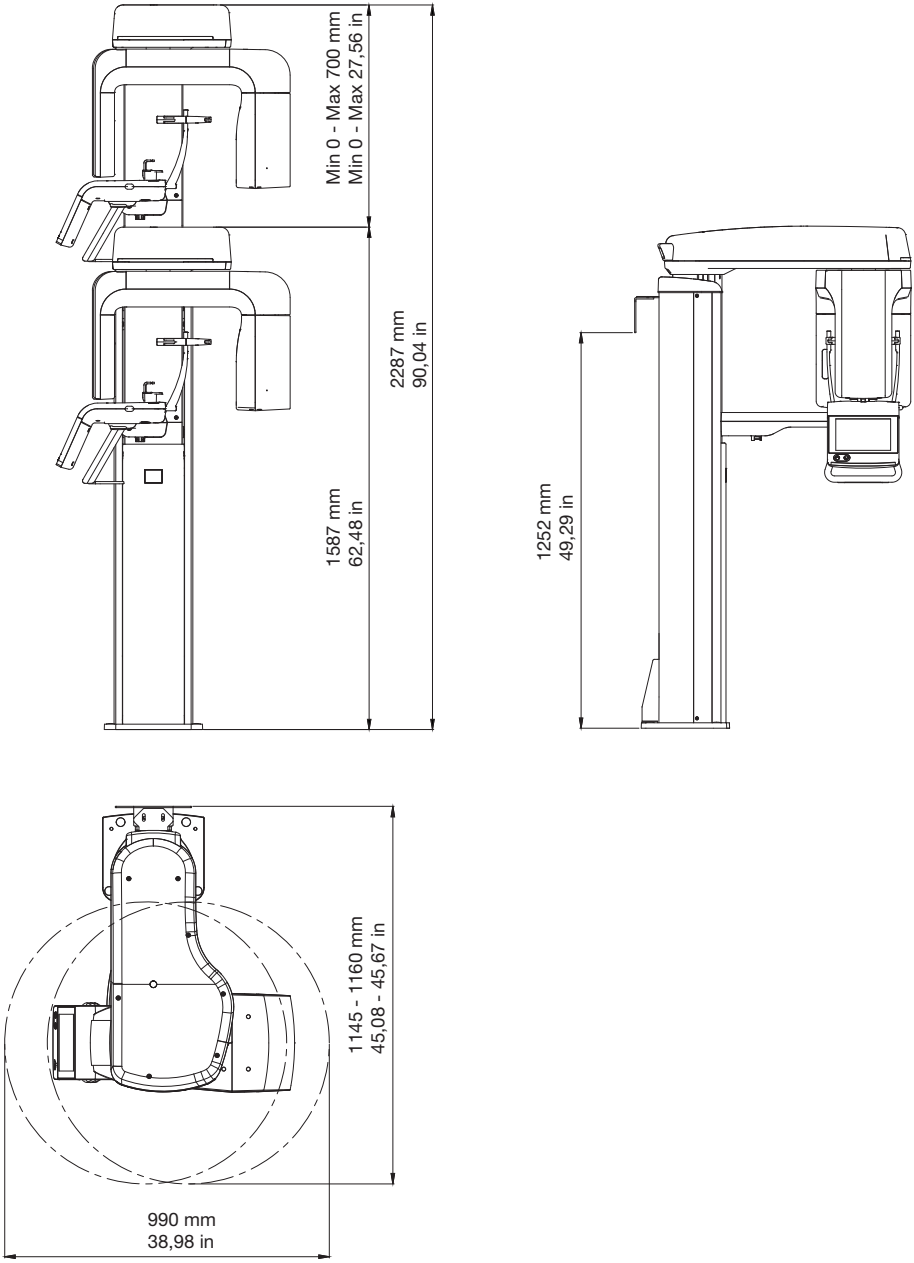


Fig. 3: VistaPano S 2.0

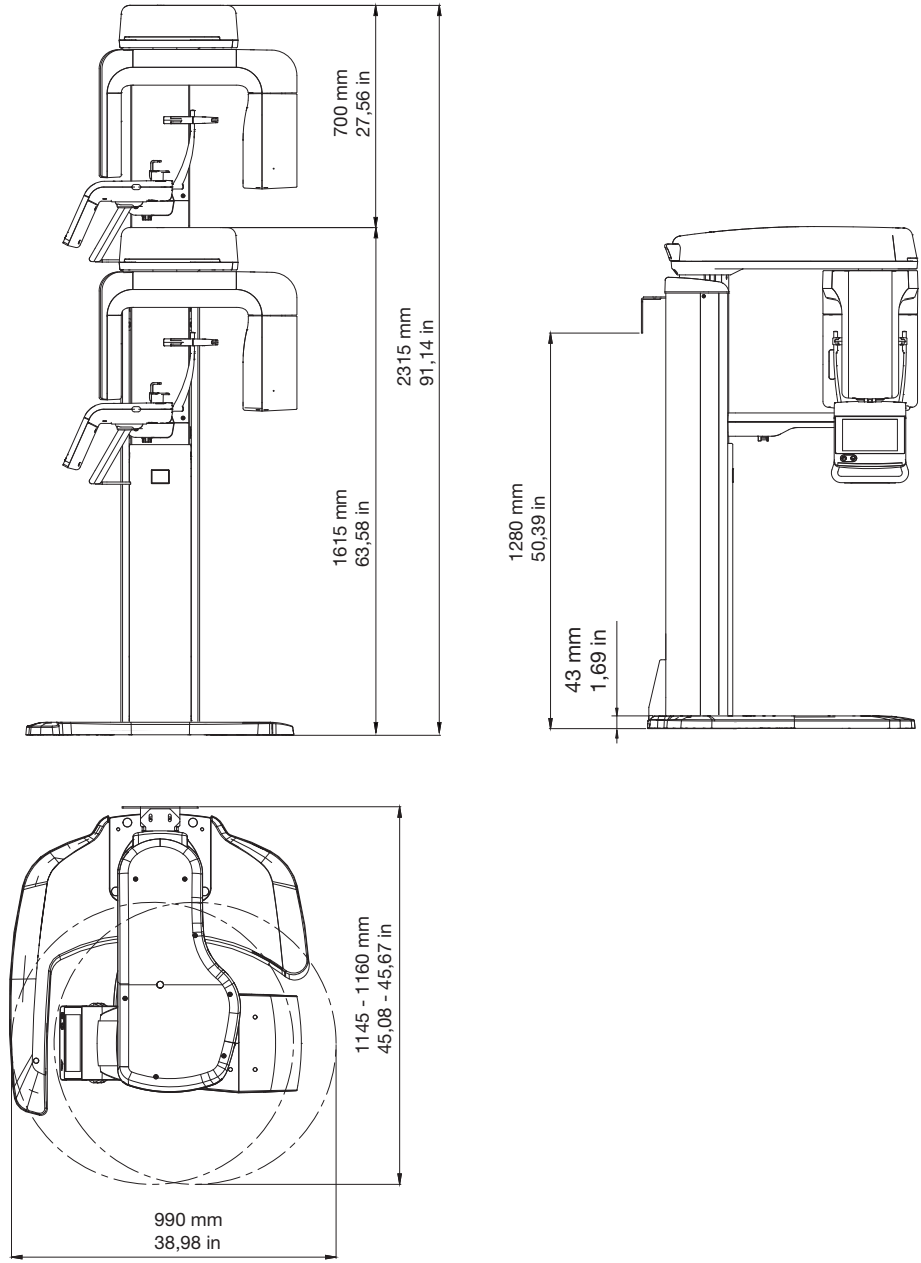


Fig. 4: VistaPano S 2.0 with floor stand

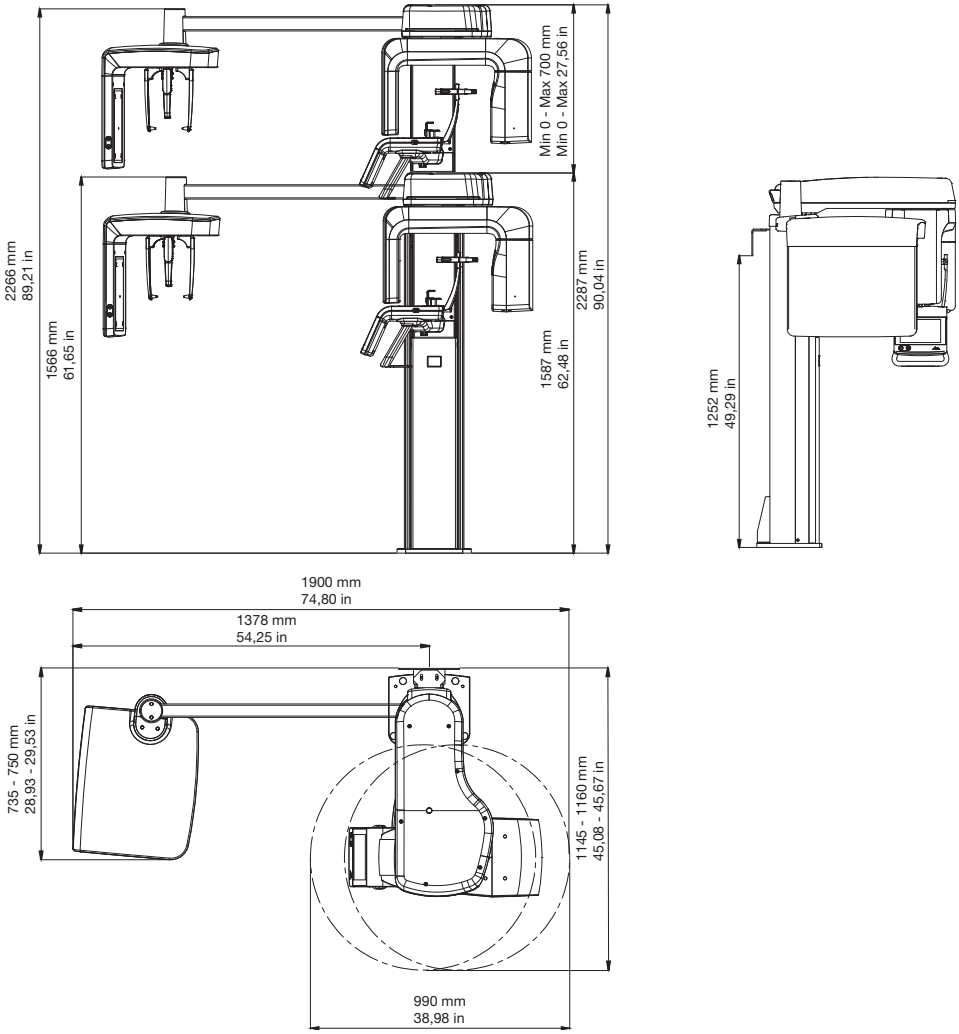


Fig. 5: VistaPano S Ceph 2.0

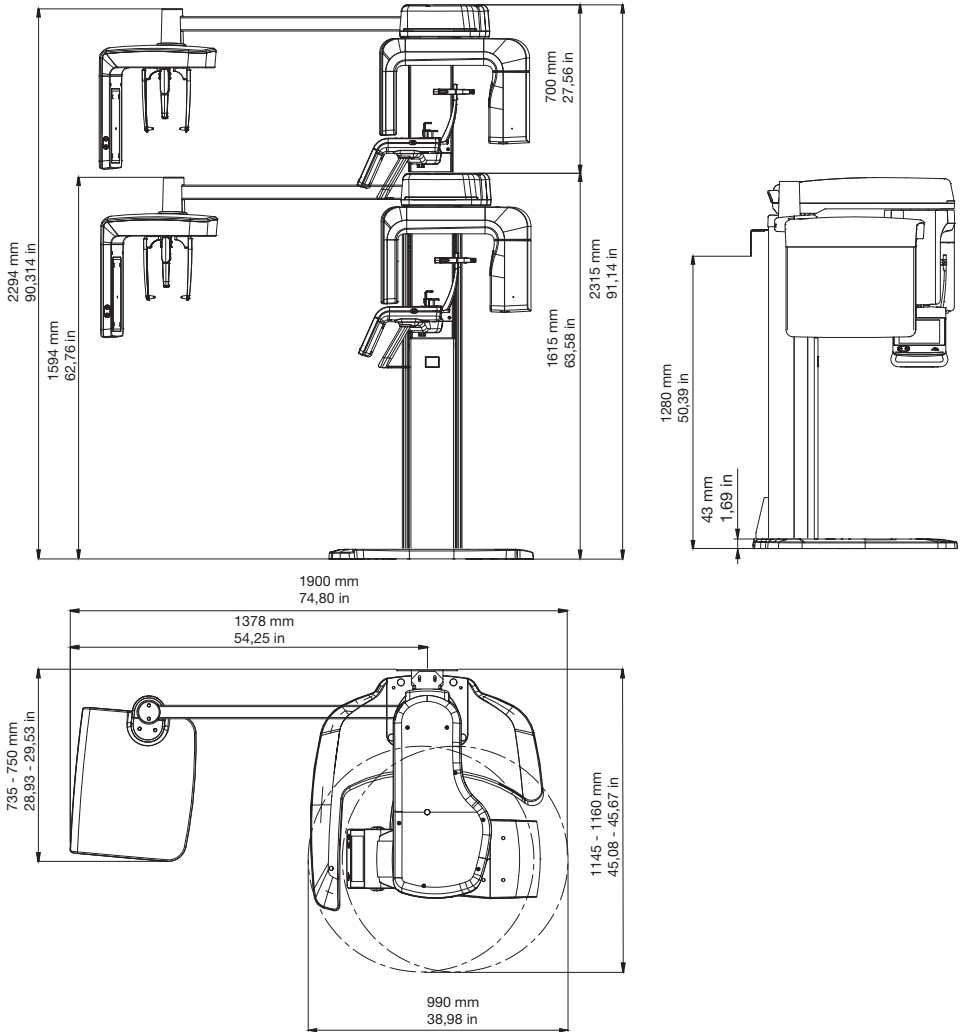
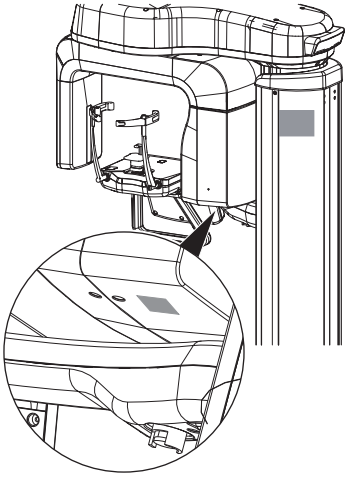


Fig. 6: VistaPano S Ceph 2.0 with floor stand

4.4 Model identification plate

The identification plates are located on the X-ray emitter and on the telescopic column.

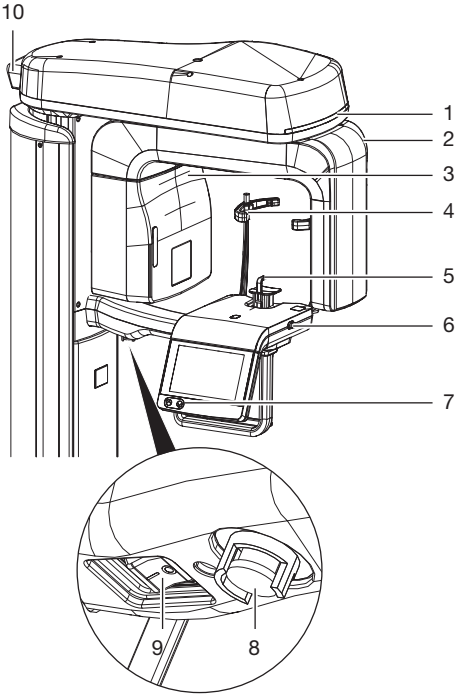


4.5 Conformity assessment

This device has been subjected to conformity acceptance testing in accordance with the current relevant guidelines of the European Union. This equipment conforms to all relevant requirements.

5 Function

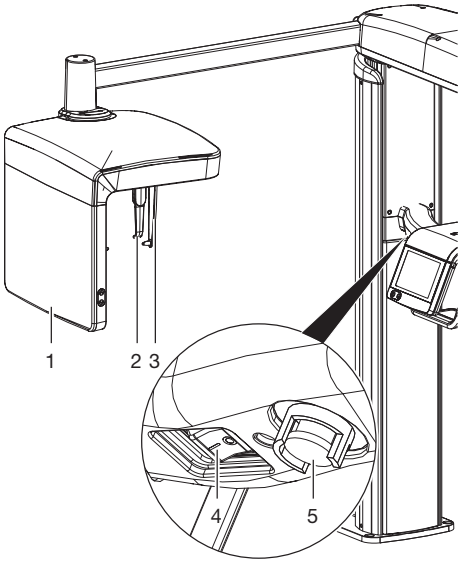
5.1 Panoramic X-ray device



1 Status LED
2 C-shaped arm
3 X-ray tube
4 Head support with cushion
5 Chin holder and bite block
6 Lever for adjustment of the upper canine positioning beam
7 Buttons for height adjustment
8 EMERGENCY OFF button
9 On/off switch
10 Ambient Light

The panoramic X-ray unit is used to take digital panoramic images that enable diagnostics in the oral area.
The X-ray task is started via the imaging software and activated via the touch screen.

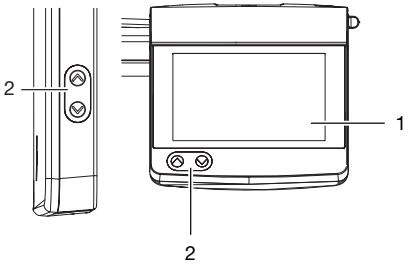
5.2 Cephalometric X-ray unit



1 Sensor (Ceph)
2 Nose support
3 Ear rods with holder
4 On/off switch
5 EMERGENCY OFF button

The cephalometric unit digitally records the anatomy of the cranium.
The X-ray task is started via the imaging software and activated via the touch screen.

5.3 Operating elements



1 Touch screen
2 Buttons for height adjustment

The touch screen can be used to operate the unit. Information can be entered on the touch screen with the tip of a finger.

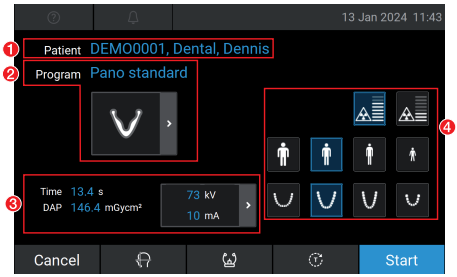
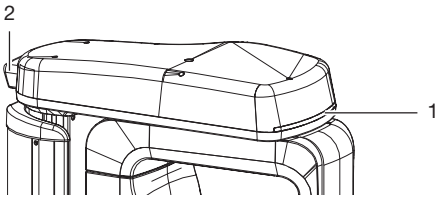


Fig. 7: Monitor, unit ready to acquire image

1 Logged-in patient
2 Selected X-ray image
3 Display of the X-ray parameters (duration, DAP value, voltage and current)
4 Selected parameters

The *Messages* button can be used to recall current messages.

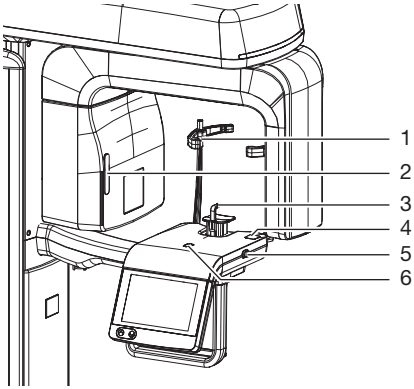
5.4 Status LED



1 Status LED
2 Ambient Light

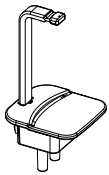
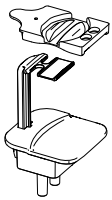
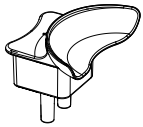
Mode of operation	Status LED	Ambient Light
Unit ready for operation	Blue	Blue can be customized, except red or white
Unit ready to acquire image X-ray confirmation required	Green	Green
X-ray image is generated	Yellow	Yellow

5.5 Positioning aids panoramic image

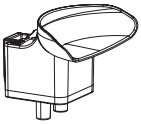


1 Head support with cushion
2 Frankfurt plane of the X-ray positioning beam
3 Positioning aid, e. g. chin support with bite block
4 Upper canine positioning beam
5 Lever for positioning the upper canine positioning beam
6 Mid-sagittal positioning beam

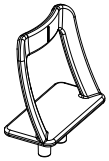
The positioning aids are used to correctly position the patient in the unit. The appropriate positioning aid is selected according to the selected image. The head supports gently keep the head of the patient in place.

Panorama	
	Bite block and adapter bite block
	Comfort bite block incl. foam pad and bite block adapter
	Chin support for edentulous jaws

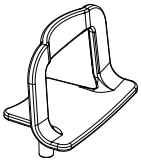
Panorama



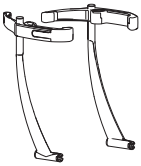
Chin rest, universal



Chin rest for maxillary joint image

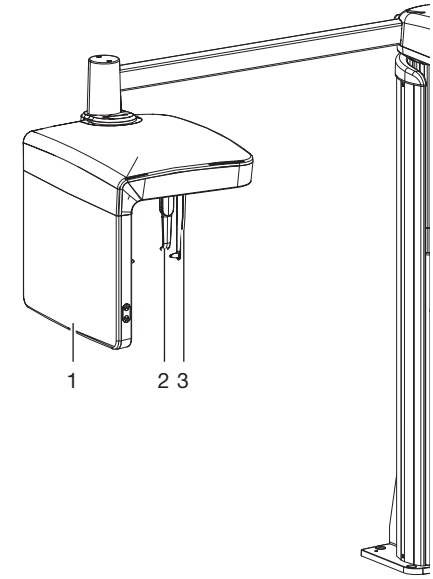


Chin rest for sinus image



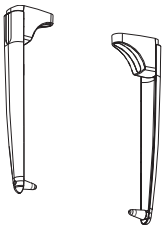
Head supports with cushion

5.6 Positioning aids for cephalometric projections



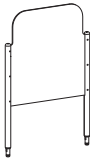
1 Sensor (Ceph)
2 Ear rods with holder
3 Nose support

Cephalometric projections



Ear rods with holder

Nose support



Carpus plate

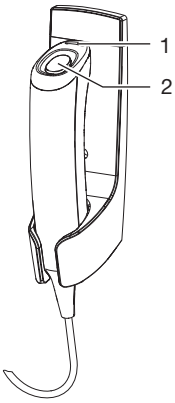
The applied parts in accordance with IEC 60601-1 are:
- Grips
- Head supports with cushion
- Positioning aids (e.g. bite block and mounting for bite block, chin support for edentulous patients)

The applied parts in accordance with IEC 60601-1 for the cephalometric unit are:
- Nose support
- Ear rods with holder
- Carpus plate

5.7 Exposure button

Exposure switch

The exposure switch is used to trigger the prepared image acquisition and start the X-ray exposure. The LED indicates the status of the unit, as does the LED on the unit.
- Green: unit ready for recording
- Yellow: X-ray beam active

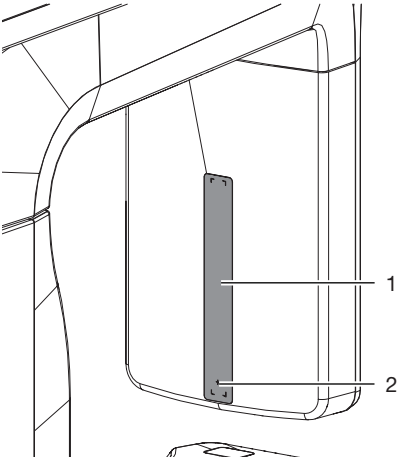


1 Indicator lamp (LED)
2 Exposure button

5.8 Sensor window

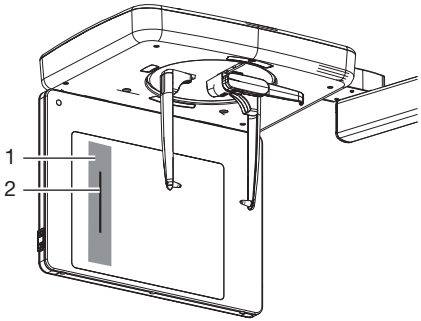
The active sensor surface is indicated by the markers in the corners of the sensor window. The cross indicates the geometric mid-point of the active sensor surface.

Panoramic X-ray device



1 Active sensor surface
2 Geometric mid-point of the active sensor surface

Cephalometric X-ray unit



1 Line sensor housing
2 Active sensor surface

Usage

6 Quality control

The manufacturer recommends carrying out a quality control procedure.
This is divided into acceptance testing and consistency testing.
It is advisable – and in some countries legally required – that the image display system be checked before the acceptance testing of the X-ray device.
During acceptance testing, X-ray images must be displayed and evaluated, which is why optimal prior adjustment and inspection of the monitor is necessary.
The acceptance test is performed by trained personnel at the end of device installation and calibration. The acceptance test ensures that image quality, X-ray dose, and regulatory requirements comply with a defined standard.
During the acceptance test, reference images of the test phantom are created and stored in VistaSoft Inspect.
Consistency tests are performed by the operator. Consistency checking is carried out by taking X-ray exposures of the test phantom using the same dosing parameters as used for the acceptance test (benchmark values).
The requisite tests are determined by local rules and regulations. Carry out testing in accordance with local rules and regulations.

6.1 Applicable standards in Germany

The following standards are primarily applicable with the acceptance test:
– DIN 6868-151 Acceptance testing of dental X-ray equipment according to the X-Ray Ordinance (RöV)
– DIN 6868-157: Acceptance test and consistency check of the image playback system

The following standards are primarily applicable in the consistency check:
– DIN 6868-5: Consistency check according to X-Ray Ordinance (RöV) on dental X-ray equipment
– DIN 6868-157: Acceptance test and consistency check of the image playback system

The following guidelines and ordinances apply as well:
– Radiation Protection Act (Strahlenschutzgesetz, StrlSchG)
– Radiation Protection Ordinance (Strahlenschutzverordnung, StrlSchV)
– Guidelines for Expert Qualifications (Sachverständigen-Richtlinie, SV-RL)
– Quality Assurance Guidelines (Qualitätssicherung-Richtlinie, QS-RL)
– Specialist Knowledge Guidelines (Fachkunde-Richtlinie, FK-RL)

6.2 Applicable standards in other countries

The following standards are primarily applicable with the acceptance test outside of Germany:
– IEC 61223-3-4 (2000-03) Imaging performance of dental X-ray equipment

6.3 Acceptance check

The acceptance check must be performed prior to commissioning an X-ray system.

The acceptance test of the X-ray system must be performed by a certified service technician with proven expertise and specialist knowledge.

An access code (technician password) is required in order to perform an acceptance test and a partial acceptance test. The access code is required once after every restart of the software if an acceptance test or partial acceptance test is being processed.

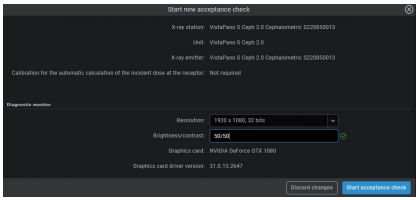
The access code is made up of the current date (day and month) in reverse sequence. For example: May 3 = 03.05. Access code: "5030"

Aim of the acceptance check
– Ensuring that the required image quality is achieved with the lowest possible radiation exposure
– Defining the operator and device data
– Defining reference values for the consistency test

Panoramic

✓ Acceptance check of the image reproduction system (IRS) successfully completed
✓ Device is calibrated
✓ All positioning aids are removed

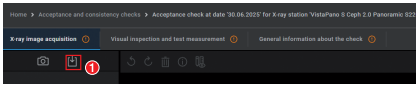
1. If all of the data has been correctly entered, click *Start acceptance test*.



The acceptance test opens with the *X-ray image acquisition* registration tab.

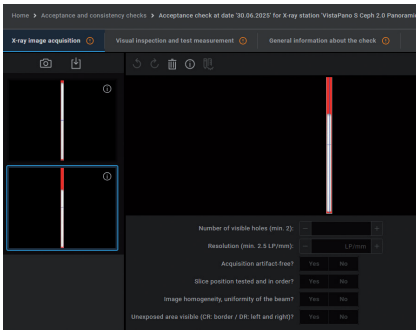
2. Import aperture images.

Aperture images were created during calibration by the service tool.



1 Importing aperture images

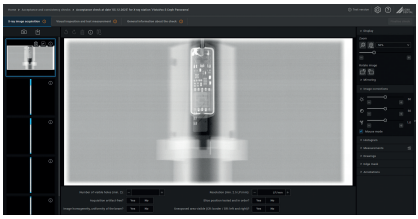
The aperture image for children and adults is displayed in the column on the left.



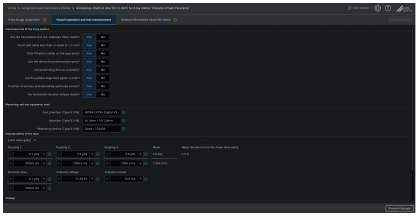
Performing the dose measurement

The test phantom set for Pano and the test phantom holder for VistaPano S are required for this step. These items are not included in the standard scope of delivery and need to be ordered separately.

1. Attach the primary absorber set for Pano/Ceph Cu 1.8 mm and Al 6 mm to the exit of the X-ray tube.
2. Place the dosimeter in the layer position. The measuring probe points toward the X-ray tube.
3. Align the canine tooth laser centrally on the measuring probe.
4. Click *Start X-ray image recording*.



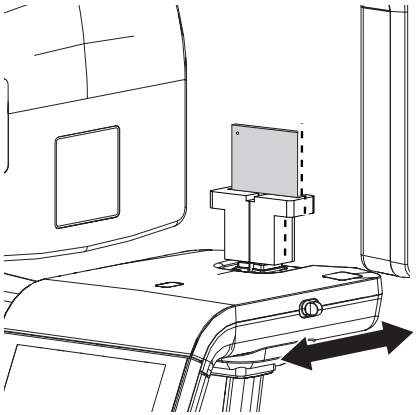
5. Determine measured values and enter them into the *Visual and measurement check* tab.



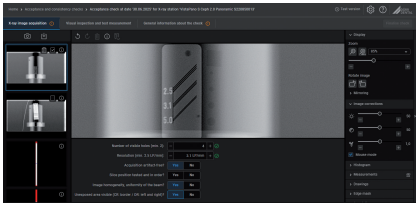
Typical measured values range between 2 and 5 µGy.

Reference X-ray image

1. Position the test phantom and align the canine laser.

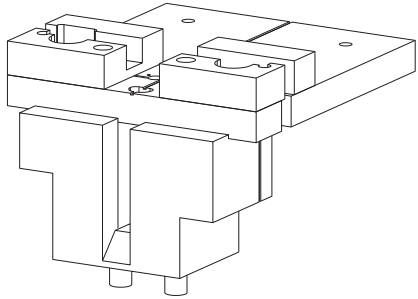


2. Attach the primary absorber set for Pano/Ceph Cu 1.8 mm to the exit of the X-ray tube.
3. Click *Start image acquisition*.
4. Reference recording found.
   Adjustments to the display of the X-ray image can be made under *Image corrections*.

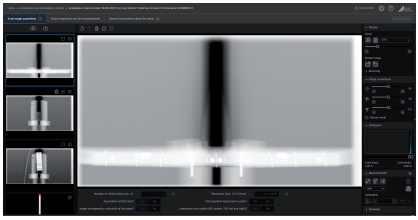


5. Mark reference recording.

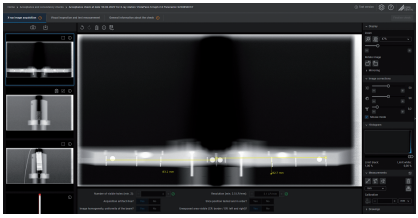
6. Check slice layer.
7. The calibration and test phantom set with special test phantoms is required for this step. The set is not included in the standard scope of delivery and needs to be ordered separately.
   Insert the spherical/needle phantom.



8. Click *Start image acquisition*.
9. Adjust the canine beam localiser, orientating it on the marking on the test phantom.
10. Confirm the acquisition on the touch screen of the unit by clicking on *Start*.
11. Visual assessment of the image.
    Adjustments to the display of the X-ray image can be made under *Image corrections*.



12. Perform *Measurements*.



    There may be a deviation of up to 5% between the measured values to the left and right of the centre.
13. Confirm *Slice layer tested and in order?*.
14. Check and confirm everything in the *Visual inspection and test measurement* tab in the *Functional test of the X-ray emitter* column.
15. Enter *Measuring and test equipment used*.

16. Enter *mains voltage*.
17. In the Panorama acceptance test, *Specification of voltage values is required:* need not be selected.

18. Fill out *General information about the test* registration tab.

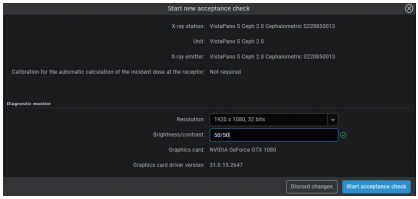
19. Click on *Finalize check*.

Subsequent editing is no longer possible!

Cephalometric

✓ Acceptance test of the image reproduction system (IRS) successfully completed
✓ Device is calibrated
✓ All positioning aids are removed

1. If all of the data has been correctly entered, click *Start acceptance test*.



The acceptance test opens with the *X-ray image acquisition* registration tab

2. Importing aperture images

Aperture images were created during calibration by the service tool.

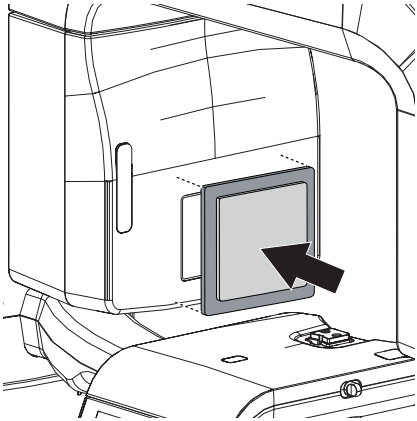
The aperture image for lateral, lateral full and SMV is displayed in the column on the left.

Performing the dose measurement

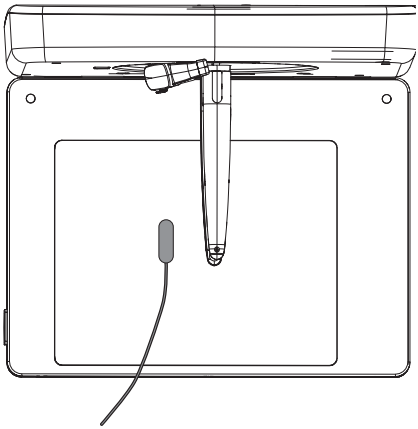
The test phantom set for panoramic image and the test phantom holder for VistaPano S are required for this step. These are not included in the standard scope of delivery and need to be ordered separately.

1. Remove all positioning aids and test phantoms from the beam path.

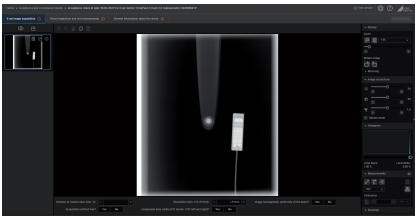
2. Attach the primary absorber set for Pano/Ceph Cu 1.8 mm and 6 mm Al to the exit of the X-ray tube.



3. Turn the positioning aid into the PA position.
4. Swivel the nose support to the side.
5. Place the dose measuring device.

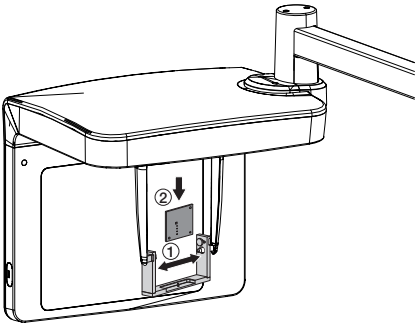


6. The manufacturer recommends performing the dose measurement at a voltage of 89 kV and 9 mA.
7. Click *Start image acquisition*.
8. Confirm and trigger the recording on the device touchscreen with *Start*.

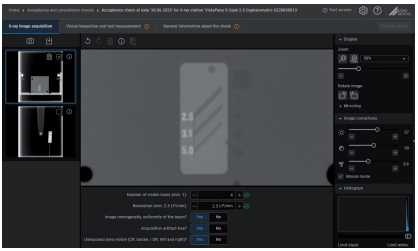


Reference X-ray image

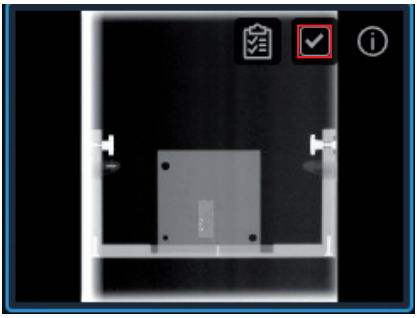
1. Bring the positioning aid into the lateral position.
2. Swivel the nose support to the side.
3. Position the test phantom holder and test phantom.



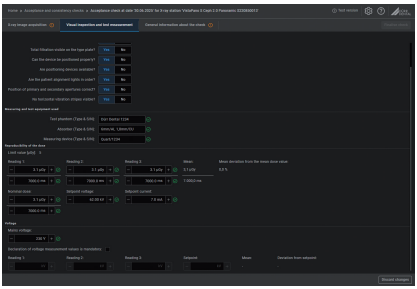
4. Click *Start image acquisition*.
5. Confirm and trigger the recording on the device touchscreen with *Start*.
6. Reference recording found.
   Adjustments to the display of the X-ray image can be made under *Image corrections*.



7. Mark reference recording.



8. Check and confirm everything in the *Visual inspection and test measurement* tab in the *Functional test of the X-ray emitter* column.
9. Enter *Measuring and test equipment used*.
10. Enter the values in the *Reproducibility of the dose* tab.
11. Enter value for mains voltage in the *Voltage* registration tab.



12. Fill out the *General information about the test* registration tab.
13. Click on *Finalize check*.

Subsequent editing is no longer possible!

6.4 Quality control measures

Descriptions and instructions to assist in the repair of parts are provided specifically by Air Techniques approved and authorized service personnel. For technical assistance with quality control procedures, contact your local service representative.

Pano

Test	Frequency	Testing tool	Permissible criteria			
Resolution of line pairs	Every six months	Test phantom/ VistaSoft VistaSoft Inspect	≥3.1 lp/mm			
Low contrast resolution	Every six months	Test phantom/ VistaSoft VistaSoft Inspect	2.0 mm			
Panoramic layer	Every six months	VistaSoft Inspect	Centering: 1382 ± 10 pixels Permissible range between left and right-hand pin: ±10 pixels			
Tube voltage	Annually	Voltmeter	≤ 10% of the specified value			
Limitation and alignment of the X-ray beam (4% slice)	Annually	VistaSoft Inspect	Adult			
			Collimator		Min. pixels	Max. pixels
			Threshold value 70%	Left	1	8
				Right		
				Top	5	20
				Bottom	10	40
			Child			
			Collimator		Min. pixels	Max. pixels
			Threshold value 70%	Left	1	8
				Right		
				Top	350	450
				Bottom	10	40

Ceph

Test	Frequency	Testing tool (Phantom/SW)	Permissible criteria
Resolution of line pairs	Every six months	Test phantom / VistaSoft VistaSoft Inspect	≥3.1 lp/mm

<table>
<tr><th>Test</th><th>Frequency</th><th>Testing tool (Phantom/SW)</th><th colspan="4">Permissible criteria</th></tr>
<tr><td>Low contrast resolution</td><td>Every six months</td><td>Test phantom / VistaSoft VistaSoft Inspect</td><td colspan="4">2.5 mm</td></tr>
<tr><td>Tube voltage</td><td>Annually</td><td>Voltmeter</td><td colspan="4">≤ 10% of the specified value</td></tr>
<tr><td rowspan="11">Limitation and alignment of the X-ray beam (4% slice)</td><td rowspan="11">Annually</td><td rowspan="11">VistaSoft Inspect</td><td colspan="4">HD</td></tr>
<tr><td colspan="2">Collimator</td><td>Min. pixels</td><td>Max. pixels</td></tr>
<tr><td rowspan="4">Threshold value 90 %</td><td>Left</td><td rowspan="2">1</td><td rowspan="2">20</td></tr>
<tr><td>Right</td></tr>
<tr><td>Top</td><td rowspan="2">40</td><td rowspan="2">80</td></tr>
<tr><td>Bottom</td></tr>
<tr><td colspan="4">SD</td></tr>
<tr><td colspan="2">Collimator</td><td>Min. pixels</td><td>Max. pixels</td></tr>
<tr><td rowspan="4">Threshold value 90 %</td><td>Left</td><td rowspan="2">1</td><td rowspan="2">10</td></tr>
<tr><td>Right</td></tr>
<tr><td>Top</td><td rowspan="2">20</td><td rowspan="2">40</td></tr>
<tr><td>Bottom</td></tr>
</table>

Installation

Only qualified specialists or persons trained by Air Techniques may install, connect, and commission the unit.

7 Requirements

7.1 Installation/setup room

The room chosen for set up should fulfil the following requirements:

- Closed, dry room.
- It should not be a room made for another purpose (e.g. boiler room or wet cell).
- There should be no major fields of interference (e.g. strong magnetic fields) present that can interfere with the proper operation of the unit.
- The required environmental conditions are met (refer to "Technical Data" in the operating instructions).

Portable and mobile HF communication appliances can interfere with the effectiveness of electrical medical devices.

1. Do not stack the unit next to or together with other appliances.
2. If, however, this unit is operated next to other units or stacked with other units, monitor the unit carefully in the configuration selected in order to ensure normal operation.

WARNING

Risk of explosion due to inflammation of combustible materials

› Do not use the unit in rooms in which combustible mixtures may be present, e.g. in operating rooms.

Radiation protection

- Comply with all applicable X-ray protection regulations and X-ray protection measures.
- Use the prescribed X-ray protection equipment.
- In order to reduce the level of X-ray exposure, we recommend the use of bismuth, lead shielding or protective aprons, especially for children and teenagers.
- The persons operating the equipment must keep away from the X-ray unit while the exposure is being taken. The minimum distance required by the law must be maintained
- Children and pregnant women must consult a doctor before recording an X-ray image.
- No person other than the patient is permitted to be present in the radiation room without X-ray protection measures. In exceptional circumstances another person may be present to provide assistance, but this must not be a member of the surgery staff. When the exposure is being taken, make sure that you have visual contact to the patient and to the unit.
- The radiation room must be lockable to prevent entry by unauthorized persons.
- If a fault occurs, abort the exposure immediately by releasing the trigger button.
- The status LED displays when an X-ray image acquisition has been triggered.
  It is optionally also possible to enable or interrupt X-ray exposures via a door contact.
- The parts connected to the unit, e. g. cables, must comply with the relevant IEC standards (e. g. IEC 60950 for IT equipment and IEC 60601-1 for medical electrical equipment)

7.2 Information about electrical connections

WARNING

Electric shock due to incorrectly connected device

› Never install a mains plug instead of the fixed connection.

– Ensure that the electrical connections to the mains power supply are established in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.
– The connection to the mains supply must be a fixed connection that can only be released using a tool. Plug-in connections (power outlet/plug) are not permissible.
– Install an all-pole disconnection unit (all-pole switch) in the electrical connection to the mains power supply. This must include the clearance and creepage distances defined in IEC 61058-1 for a mains voltage peak of 4 kV.

It must be possible to secure the disconnect switch so that it cannot be inadvertently switched back on again.
The disconnection unit (switch) must be easily accessible without danger.

– Observe the current consumption of the devices that are to be connected.

7.3 Information about connecting cables

The wire cross-section depends on the current consumption, line length and ambient temperatures of the units. For information concerning the current consumption, see the Technical Data enclosed with the units to be connected.
The following table lists the minimum diameters of the connections in relation to the current consumption:

Current consumption of unit [A]	Cross-section [mm^2]
> 10 and < 16	1.5
> 16 and < 25	2.5
> 25 and < 32	4
> 32 and < 40	6
> 40 and < 50	10
> 50 and < 63	16

Mains supply cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Plastic sheathed cable (e.g., type NYM-J)
flexible	– PVC flexible line (e.g., H05 VV-F) or – Rubber connection (e.g., H05 RN-F or H05 RR-F)

8 Installation

NOTICE

Danger to components due to electrostatic discharge (ESD)

› Establish equipotential bonding between the person carrying out the work and the surroundings, e. g. via a wrist strap that is connected to the unit. Here, the unit must be earthed via the earth terminal.

NOTICE

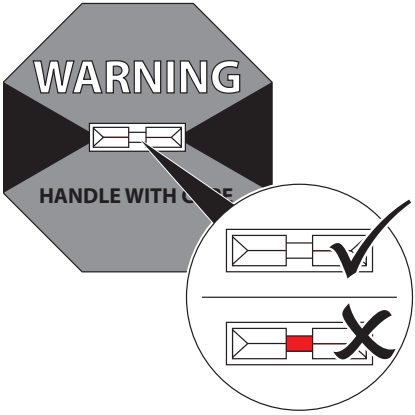
Risk of equipment damage

Do not push or pull the unit during installation by holding on to the C-shaped arm or the handle for the patient.

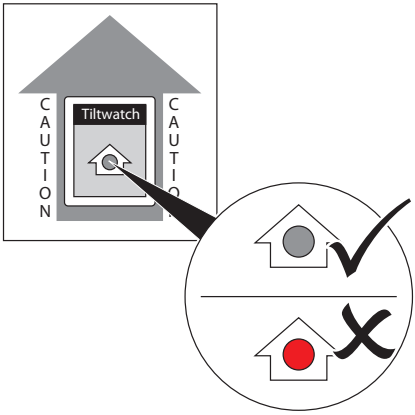
› Move the unit carefully and only grip it by the telescopic column.

8.1 Checks before unpacking

1. Visually inspect the packaging for damage.
2. Check to see if the Shockwatch display has been activated.



3. Check to see if the Tiltwatch display has been activated.



4. If the Shockwatch or Tiltwatch display is activated or there is damage to the packaging, do not unpack the unit; contact the shipping company.

8.2 Possible unit installations

The panoramic and cephalometric units are pre-assembled. The panoramic unit has carrying handles.

There are two ways of installing the unit:

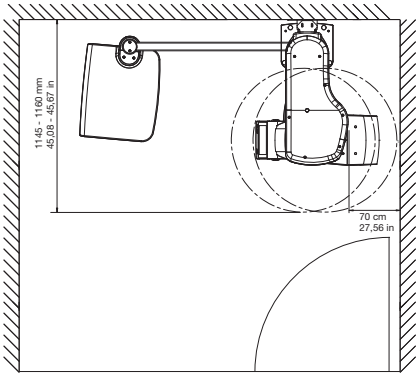
– Wall mounting
– Floor stand mounting (optional)

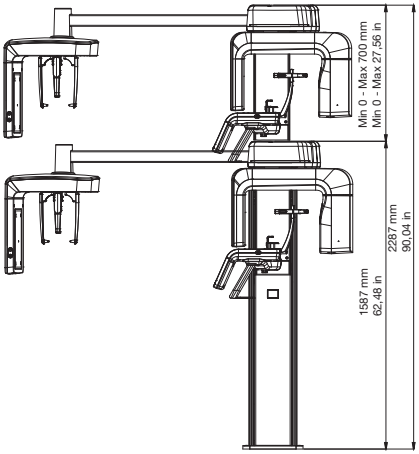
8.3 Wall mounting

Requirements:

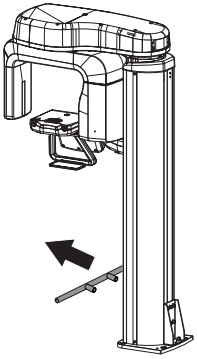
✓ Easily accessible electrical connections
✓ The wall material must be able to absorb a tensile force of 1360 N for each screw.

1. Place the panoramic unit upright at the installation site on the wall. A distance of 70 cm (27.56 in) to the wall on the right is recommended for patient access and the operating personnel.



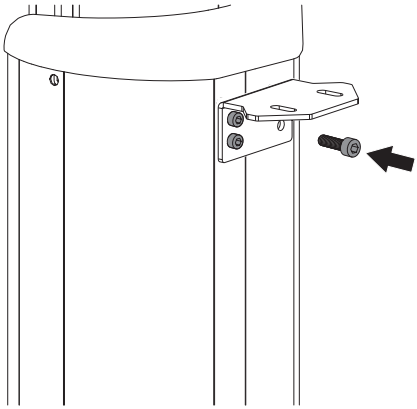


2. Remove the lower carrying handle.

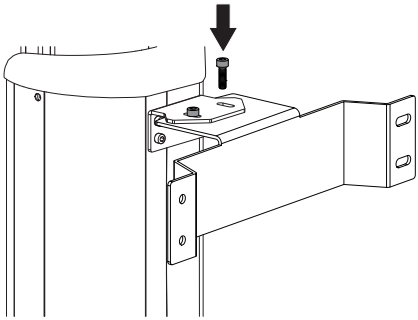


3. If the column with the column slide cannot be screwed to the floor (e.g. in the case of underfloor heating) or of the wall lacks the appropriate strength, then the lower wall mounting bracket also needs to be installed "3.3 Optional items".

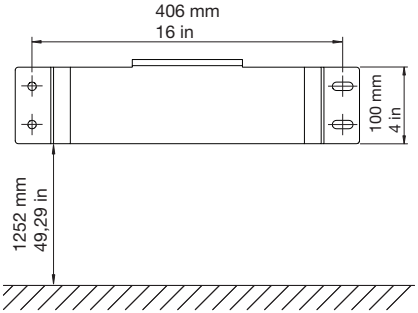
4. Attach the bracket at the pre-drilled holes on the telescopic column with four M8x20 screws.



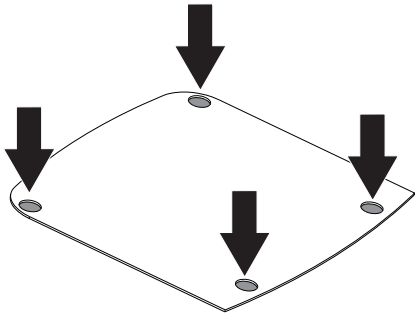
5. Mount the wall holder on this bracket with two M8x20 screws and two nuts. Do not tighten the screws yet.



6. Mark four holes for drilling on the wall.



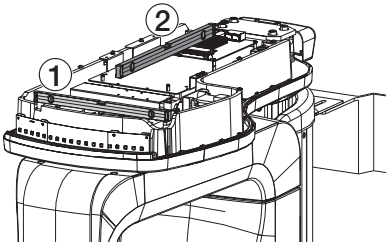
7. Use the aligning plate to mark four holes on the floor.



8. Drill four holes in the wall and four holes in the floor.

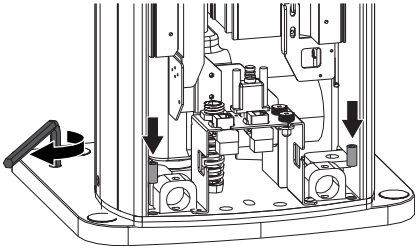
9. Place the unit in the intended position on the aligning plate and loosely attach it with four screws on the floor and four screws on the wall.

10. Use a spirit level to check that the unit is level.



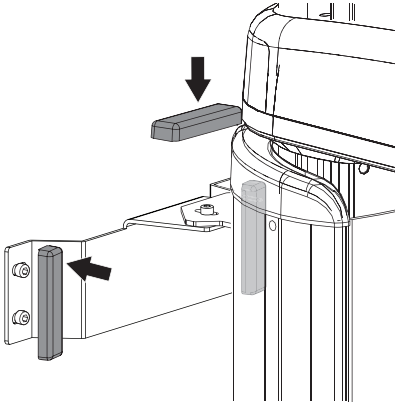
11. Screw four threaded pins M10 x 30 into the holes provided in the floor plate until they make contact with the aligning plate.

12. Screw in the corresponding threaded pins as required to align the unit.

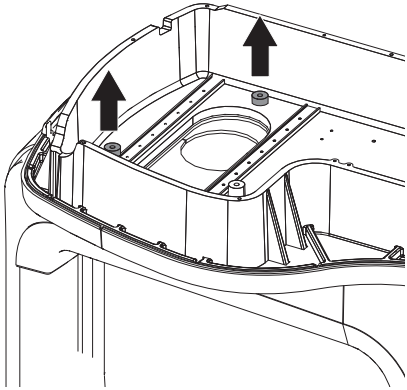


13. Tighten all screws.

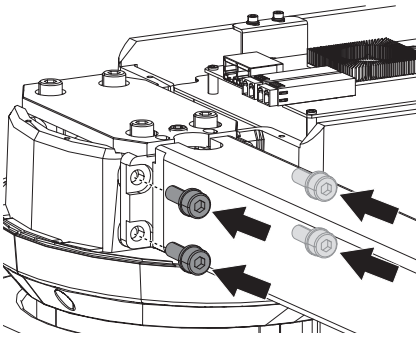
14. Fit the screw covers.



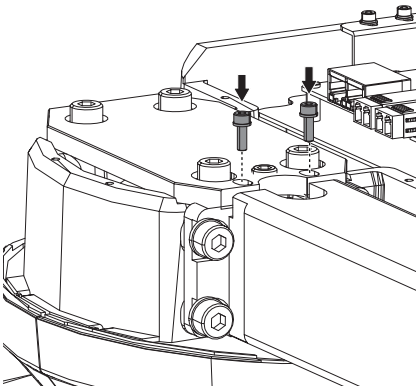
15. Remove the two screws that act as transport locks to secure the C-shaped arm and put them in a safe place.



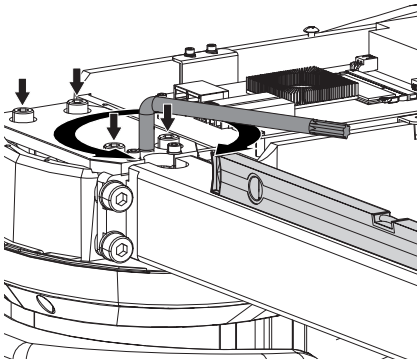
16. Attach the cephalometric unit with four M8x25 screws. Do not tighten the screws yet.



17. Install two more M6x20 screws from above. Do not tighten the screws yet.

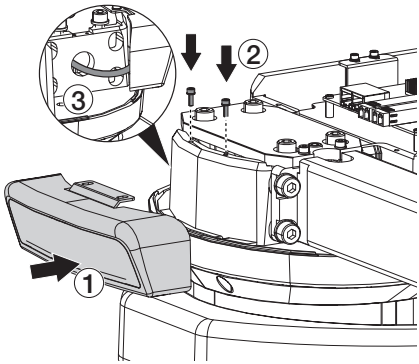


18. Align the cephalometric assembly by loosening four screws, if necessary.



19. Tighten all M8x25 and M6x20 screws.

20. Install ambient light.



Make the electrical connections to the cephalometric unit.

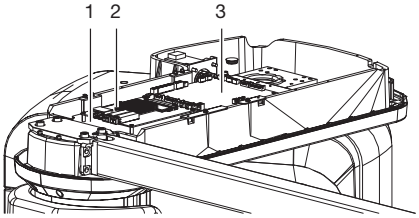
NOTICE

Equipment damage due to trapped cables

› When laying the Ambient Light cable H003552B, make sure that the cable is laid in such a way that it is not pinched when the housing cover is installed.

1. Connect the Ambient Light cable H003552B to the corresponding connection on the device.

2. Connect optical cable H003548A with SFP module to e-grabber card.
3. Connect cable H003537A with “Ceph” on the MCU board.



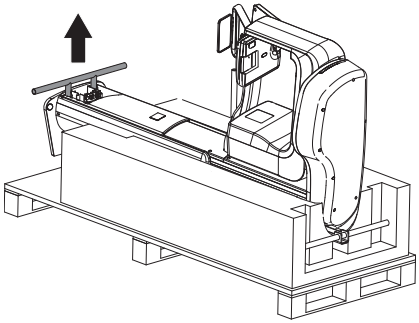
1 Ambient Light connection
2 E-grabber card
3 MCU board

4. Attach the upper panel.

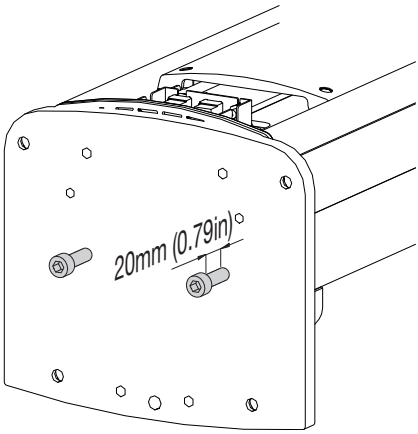
8.4 Floor stand mounting (optional)

When installing the floor stand make sure that the mains cable and the other cables of the unit are not damaged.

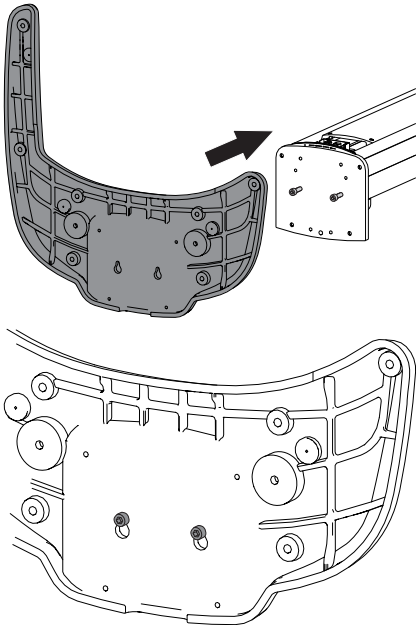
1. Remove the lower carrying handle on the unit.



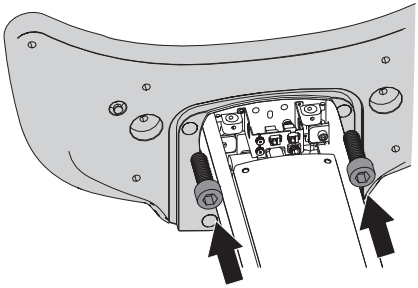
2. Screw two M10 x 30 screws into the floor stand.



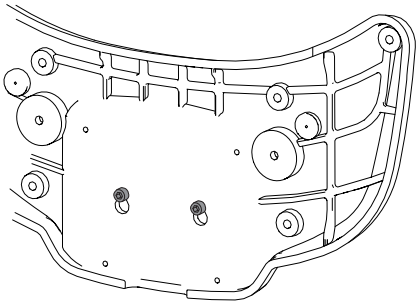
3. Mount the floor stand on the two screws.



4. Tighten the floor stand using two M10 x 20 screws.

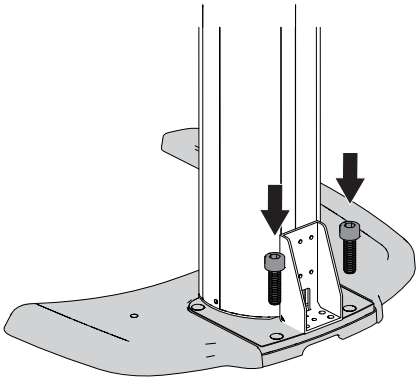


5. Tighten the two screws under the floor stand.

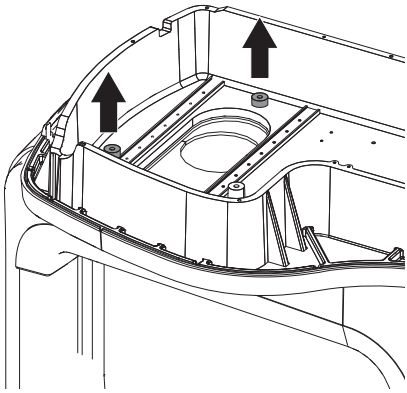


6. Set up the unit upright.

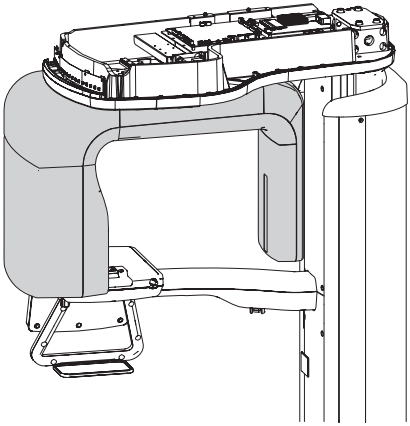
7. Tighten the floor stand onto the unit using another two M10 x 20 screws.



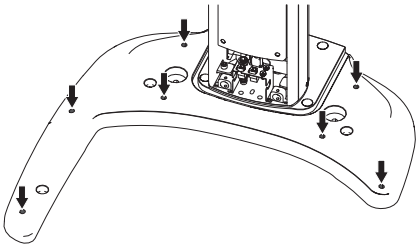
8. Remove the two screws that act as transport locks to secure the C-shaped arm and put them in a safe place.



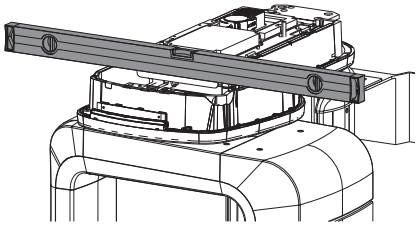
9. Slowly rotate the C-shaped arm through 180° so that it reaches the position shown.



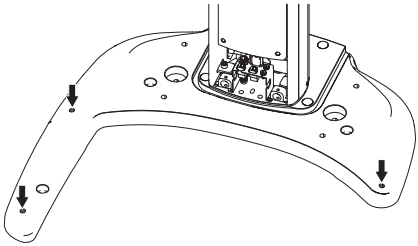
10. Slightly loosen the screws in the floor stand for levelling.



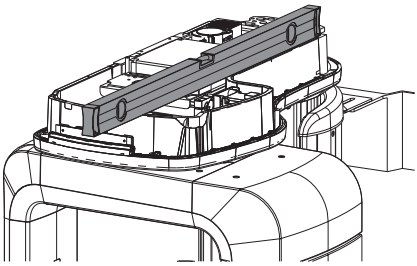
11. Use a spirit level to align the unit crossways.



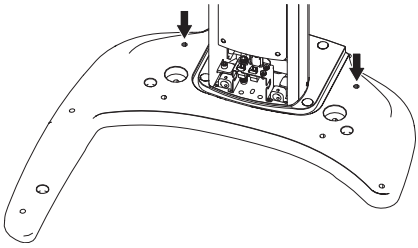
12. Screw in the corresponding screws as required to align the unit.



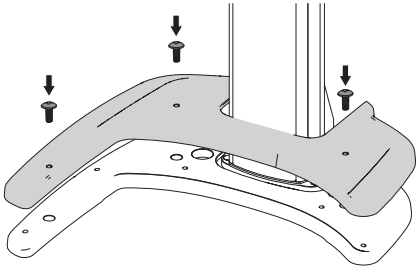
13. Use a spirit level to align the unit lengthways.



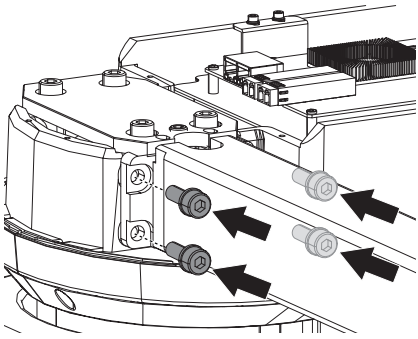
14. Screw in the corresponding screws as required to align the unit.



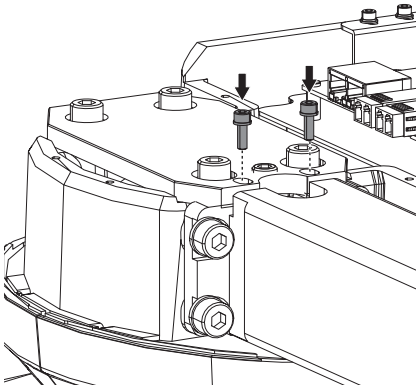
15. Attach the floor stand cover with three M5 x 8 screws.



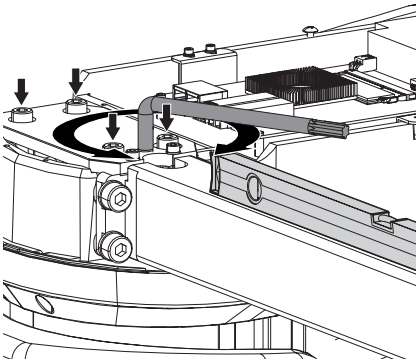
16. Attach the cephalometric unit with four M8x25 screws. Do not tighten the screws yet.



17. Install two more M6x20 screws from above. Do not tighten the screws yet.

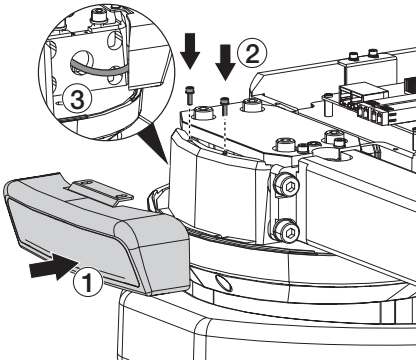


18. Align the cephalometric assembly by loosening four screws, if necessary.



19. Tighten all M8x25 and M6x20 screws.

20. Install ambient light.



Make the electrical connections to the cephalometric unit.

NOTICE

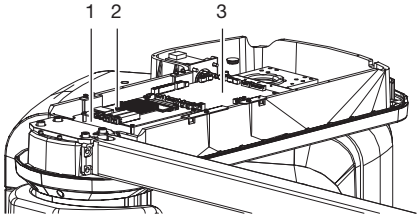
Equipment damage due to trapped cables

› When laying the Ambient Light cable H003552B, make sure that the cable is laid in such a way that it is not pinched when the housing cover is installed.

1. Connect the Ambient Light cable H003552B to the corresponding connection on the device.

2. Connect optical cable H003548A with SFP module to e-grabber card.

3. Connect cable H003537A with “Ceph” on the MCU board.



1 Ambient Light connection
2 E-grabber card
3 MCU board

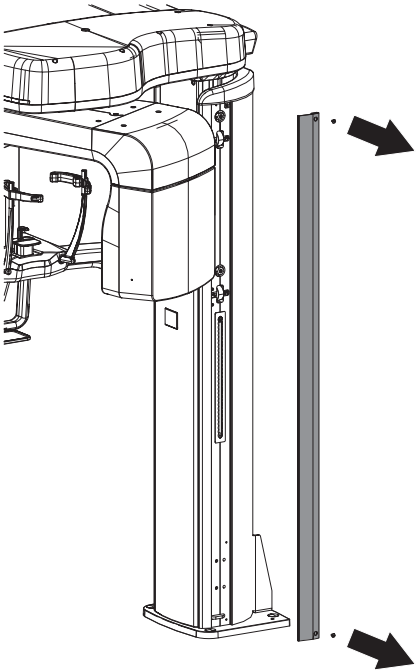
4. Attach the upper panel.

8.5 Limiting the height adjustment

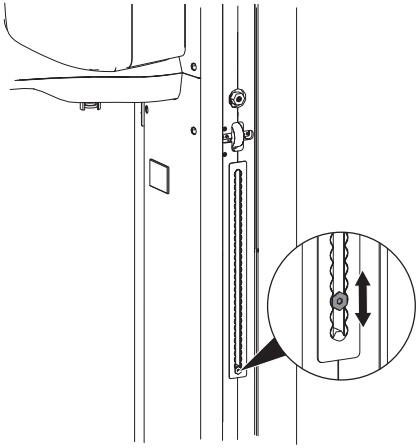
The height of the unit can be freely adjusted between 1.59 m (62.60 in) and 2.29 m (19.16 in) to match the height of the patient. The maximum height can be limited.
To open the unit for servicing, a minimum distance of 30 cm (11.81 in) should be maintained between the fully extended unit and the ceiling.

1. Loosen the two screws on the side cover.

2. Remove the side cover.



3. Loosen the screw on the adjustment scale. Do not loosen completely.



The values on the scale correspond to the height of the unit.

4. Move the screw to the desired unit height.
5. Retighten the screw.

8.6 Preparing the imaging PC

The unit supports the following imaging programs:
– VistaSoft distributed by Air Techniques

Always use the current version of the imaging program in the commissioning of the device. Check the version of the enclosed imaging program versus the versions available at www.airtechniques.com.

Computer settings

The system requirements for computer systems can be found in the download area at www.airtechniques.com/drivers (document no. E7201).

Windows configuration:

1. Deactivate all power saving functions in the energy options or set the Power Plan to *Maximum Performance*.
2. It is recommended to make the paths *C:\ProgramData\Duerr* and *C:\Program Files (x86)\Duerr* an exception in the anti-virus software (e.g. Windows Defender).
3. *Adjust the settings for User Account Control* to *Never notify*.
   To do this, pull the slider right to the bottom.

Unit connection and software

– Install the second network card supplied
– Assign a fixed IP address for IPv4
– IP address of imaging PC: 10.100.200.100
– Subnet mask: 255.255.255.0
– Control connection manager
– Connection manager is installed with the VistaPano install package
– Runs automatically when the PC is started
– Establishes the connection between the PC and VistaPano S 2.0
– Connection state
  – gray M: Unit off or not connected
  – red M: Unit connected

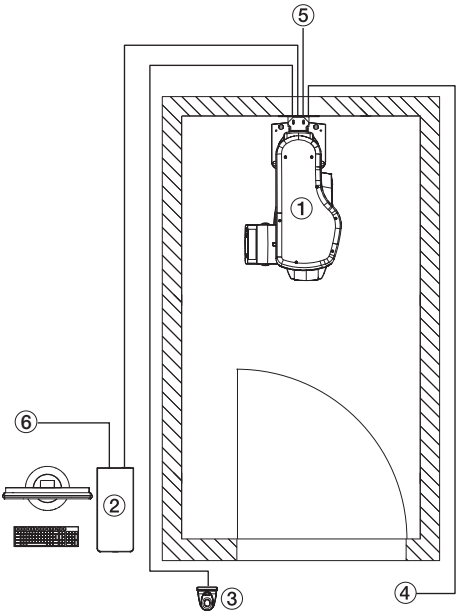
8.7 Connecting the unit

Overview of connection

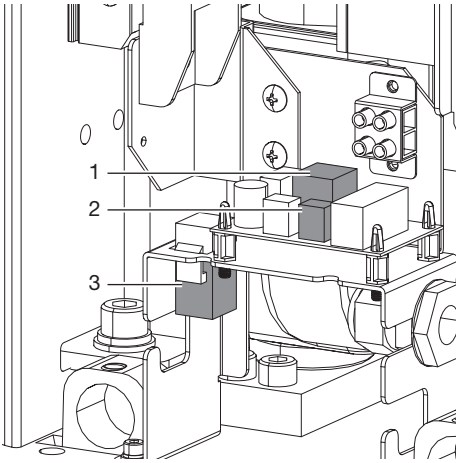
NOTICE

Equipment damage due to the electric voltage being too high

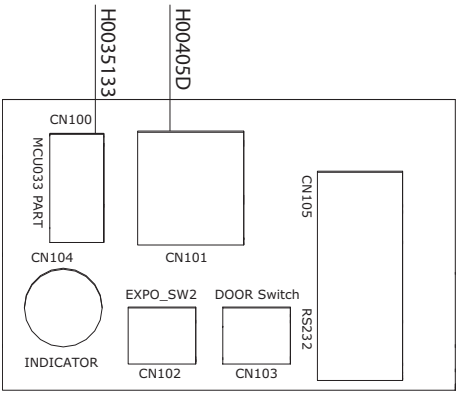
› The voltage connected to the door contact switches and exposure switches must not exceed 24 V.



1 VistaPano S 2.0
2 VistaPano S 2.0 Acquisition PC
3 Exposure switch
4 Door contact
5 Mains connection
6 Network connection to the practice network



1 CN101 Exposure switch
2 CN103 Door contact switch
3 Ethernet connection for VistaPano S 2.0 Acquisition PC

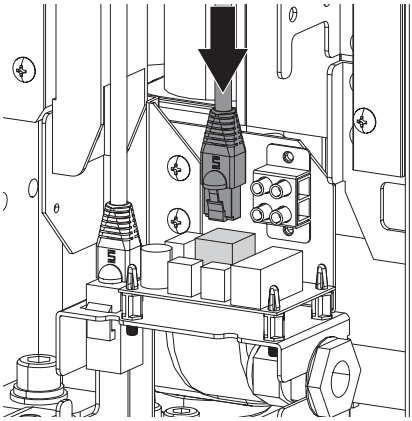


CN101	Exposure switch
CN103	Door contact switch

Installing the exposure switch

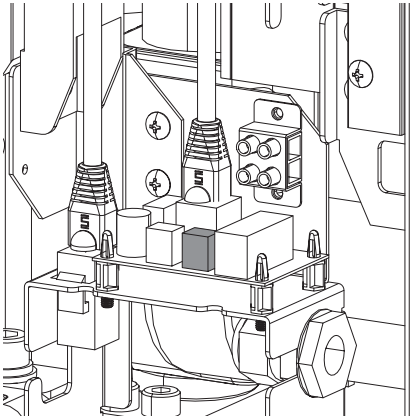
1. Route the cable of the exposure switch though the cable bushing to the front into the column.

2. Connect the cable to Slot CN101.



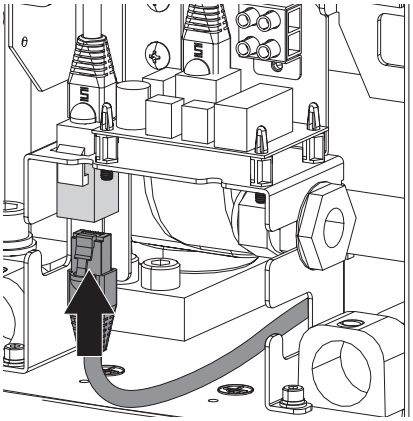
Installing the door contact switch (optional)

1. Route the cable of the door contact switch through the cable bushing to the front into the column.
2. Door contact switch can be connected to the unit via a 2-pole terminal connection.



Connecting the device to a computer

1. Route the ethernet cable through the cable bushing to the front into the column.
2. Established ethernet connection.



8.8 Network connection

Purpose of the network connection

The network connection is used to exchange information or control signals between the unit and a software installed on a computer, in order to, e. g.:

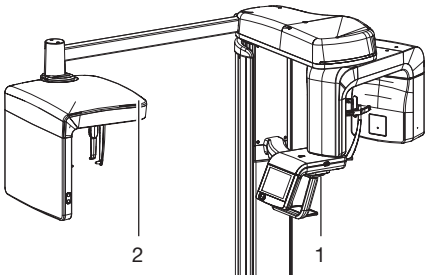
- Display parameters
- Select operating modes
- Indicate messages and error situations
- Change device settings
- Activate test functions
- Transmit data for archiving
- Provide documents concerning the devices

9 Commissioning and first start-up

9.1 Electrical safety checks

1. Carry out the electrical safety check according to national law (e. g. in accordance with IEC 62353).
2. Document the results.

We recommend a test current of 10 A in order to remove any contamination and establish a good contact without contact resistance. When measuring with a test current of 200 mA, make sure that the measuring point is bare and free of grease and that the measuring probe has low contact resistance to the measuring point. Otherwise incorrect measurements can result.



1 Measuring point patient handle
2 Measuring point cephalometric unit

The unit supports the following imaging programs:
– VistaSoft distributed by Air Techniques

Always use the current version of the imaging program in the commissioning of the device. Check the version of the enclosed imaging program versus the versions available at www.airtechniques.com.

9.2 Installing and configuring the unit

Device report

Call up the device report to check or contact the service department

1. Click ⚙.
2. Click on *Devices* > *Configuration VistaPano S Ceph 2.0* > *Report*.

   The device report is displayed.

Configuring the network

Data transmission between the unit and PC is carried out over a dedicated network connection. The required network cable and the Ethernet card are included in the scope of delivery of the unit.

1. Install the Ethernet card in the PC.
2. Connect the network cable to the network connection of the Ethernet card and the connection at the front of the column.
3. Install Ethernet card on the PC
   IP address: 10.100.200.100
   Subnet: 255.255.255.0
4. Check whether the following ports are enabled in the firewall.

The IP settings of the unit are as follows:
Unit IP address: 10.100.200.252
Unit subnet: 255.255.255.0
This address cannot be changed. The address on the PC is important.

Report	Port	Program
TCP	54466	Manager (PC LAN)
TCP	31175	E-grabber

Configuring the unit in VistaSoft

Always download calibration files in AISU 2.0 before creating an X-ray station. Press *Connect* > *Service* > *Packing Mode* > *Release*. Click *Bright File Upload/Download* > *Download*. Start *Download*.

Creating an X-ray station

1. Click *Automatic search*.

   The wizard will open.
2. Select an X-ray station from the list.
   If the X-ray station is not in the list, this means that the device still needs to be connected to the software.
3. Enter the name and address of the operator.
   The data for the current practice is preassigned to the operator information.

4. Click *OK* to close the wizard.

Result:
The X-ray station will be displayed in the list of X-ray stations.
The information about the X-ray emitter for the created X-ray station has been automatically generated. The X-ray station can be configured via *Configure*.
If an X-ray station already exists with this X-ray device the system will not overwrite the configuration of the X-ray station; instead, a further X-ray station will be created.

Configuring image acquisition types

The list of image acquisition types is predefined. For every image acquisition type you can set which acquisition source (image acquisition device) and which image acquisition mode are to be used to generate the image.

1. Click ⚙.
2. Click *Acquisition types*.
3. Select the required image acquisition type in the list.
4. Click *Configure*.
5. Under *acquisition source* select whether the device is to be manually selected for each image acquisition, or whether a specific device or the last used device should be selected.
   If the image acquisition device is not in the list, this means that the device still needs to be connected to the software.
6. The selected mode is displayed under *Image acquisition mode*. Click *...* to change the mode. The image acquisition mode depends on the selected acquisition source.
7. If the image acquisition type is to be displayed in the menu bar, tick the check box next to *Favorite*.

Result:
The configuration is active for the next image acquisition with this image acquisition type.
The option *Restore default settings* can be used to reset the configuration of an image acquisition mode.

9.3 Calibrating the unit

The unit must be calibrated in order to obtain homogeneous, defect-free and reproducible X-ray images.
Here, the radiation field on the sensor is adjusted by adjustment of the collimators.

AISU 2.0 tool

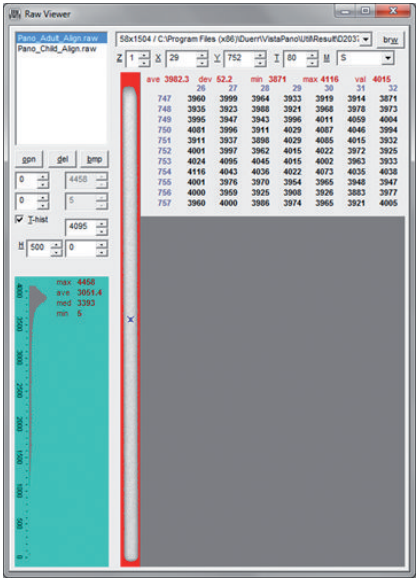
The AISU 2.0 tool is needed for, among other things, calibration of the sensor and adjustment of the collimators. It is a component of the VistaPano InstallPackage. It is automatically installed with VistaSoft. Details of the currently installed version of the VistaPano InstallPackage can be found under *Control Panel\Programs and Features\VistaPano Version x.x.x.*
The AISU 2.0 tool can only be updated by updating the VistaPano InstallPackage.

Pano

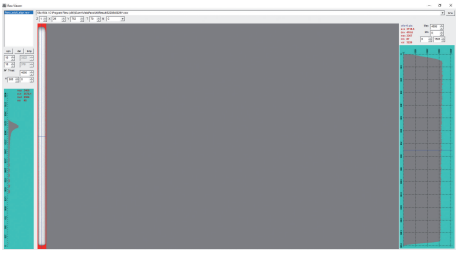
Call up the AISU tool in VistaSoft:

1. Press *Devices* > *Configuration VistaPano S Ceph 2.0* > *Maintenance* > *AISU*.
   The AISU tool is open.
2. First adjust the adult collimator.
   Press *Image Calibration* > *Collimator Alignment (Adult)* > *Go*.
   Press *Initialize* > *AutoAlign*.
   The current position of the adult collimator is displayed.
   VistaPano S 2.0
   Empirical value adult collimator pano: 2270.
   Empirical value child collimator panoramic image: 4190.
   VistaPano S Ceph 2.0
   Empirical value adult collimator panoramic image: 9950.
   Empirical value child collimator pano: 12030.
   Ceph collimator: 4110
3. Press *Capture*.
   An X-ray image is captured with the current collimator position.
4. Continue to use AutoAlign until the AISU tool tells you that the calibration has been successful.

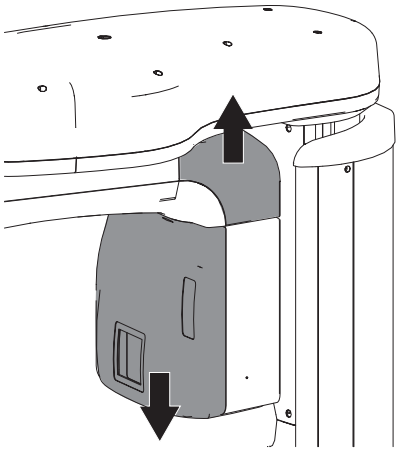
5. The collimator adjustment has been successful if the red background for the adult collimator is visible all around.



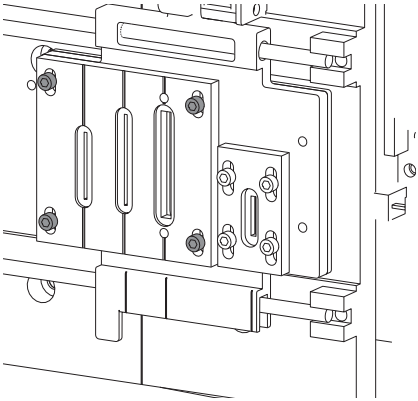
If the radiation field does not strike the sensor at right angles, the collimator will need to be manually corrected on the unit.



6. Remove the collimator covers.



7. Slightly loosen the four screws on the collimator.

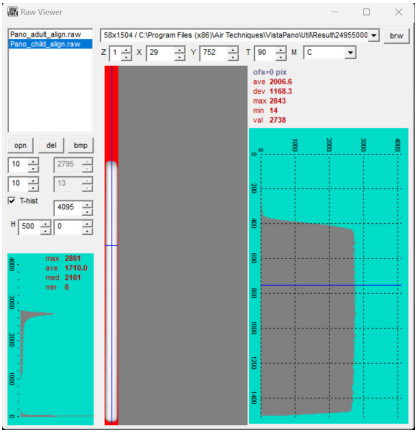


8. Carefully turn the collimator in the corresponding direction.

9. Realign the collimator with the AISU tool.

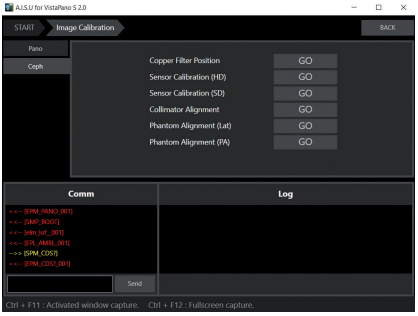
   The collimator adjustment has been successful if the radiation field strikes the sensor at right angles.

10. Adjust the child collimator in the same way. The collimator adjustment has been successful if the red background for the child collimator looks like the following.



Ceph

1. Press *Ceph* > *Collimator Alignment* > *GO*.



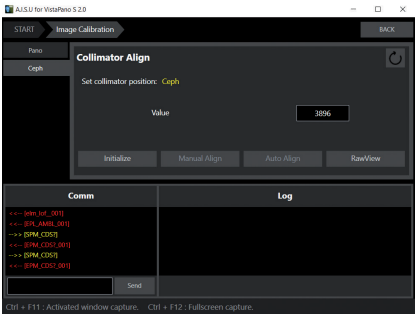
2. Click *Initialize*.
3. Press *AutoAlign*.
4. Press *Capture*.

   An X-ray image is captured with the current collimator position.

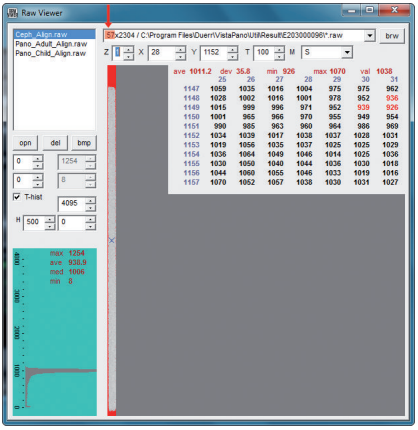
5. To check the position of the collimator press *Check align*.

Check the calibration of the collimators with the RAW viewer.

6. End the calibration. To do so, press *Close*.
7. Press *RawViewer*.



8. Adjust the pixel width of the sensor if necessary.
   Change the first value ahead of the specified path to "57".

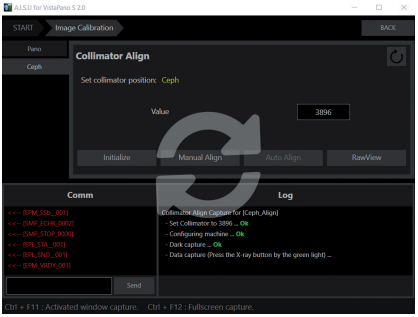


   The current position of the collimator is displayed.

   Default values are 4000

Collimator too far left or right

1. If the collimator is too far to the left or right, adjust the value for the collimator.

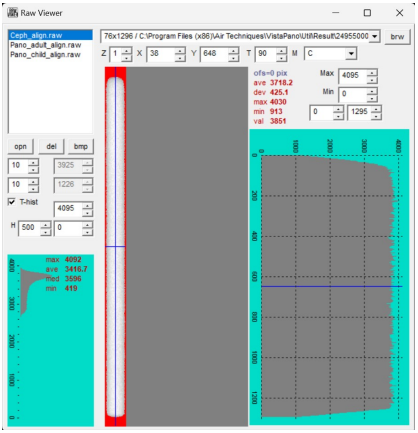


2. Press *Capture*.

   An X-ray image is captured with the current collimator position.

3. To check the position of the collimator press *AutoAlign*.

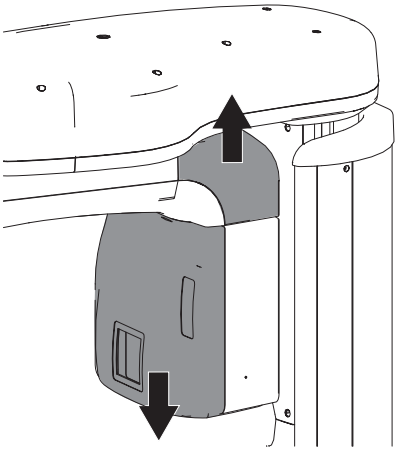
4. The collimator adjustment has been successful if the red background for the ceph collimator looks like the following.



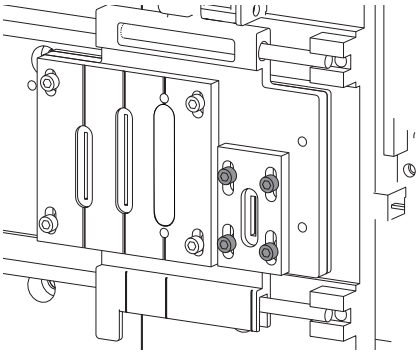
Collimator too low or too high

1. If the collimator is too high or too low you will need to manually adjust the collimator.

2. Remove the collimator cover.



3. Slightly loosen the four screws on the collimator.



4. Carefully move the collimator in the corresponding direction.

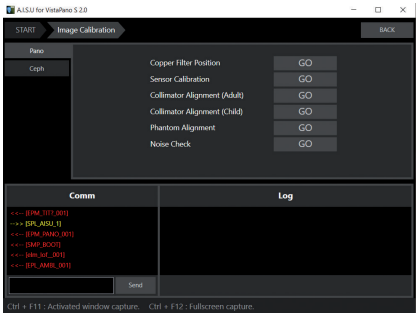
5. Realign the collimator with the AISU tool.

6. Repeat the procedure of capturing images and checking with AISU until the collimator has been successfully positioned.

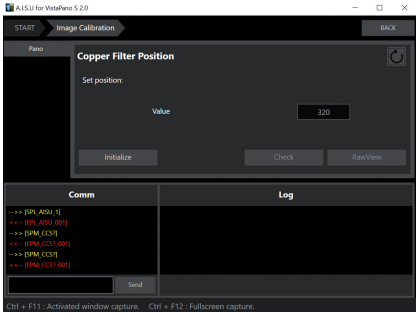
Determining the position of the copper filter

1. Launch the AISU tool.

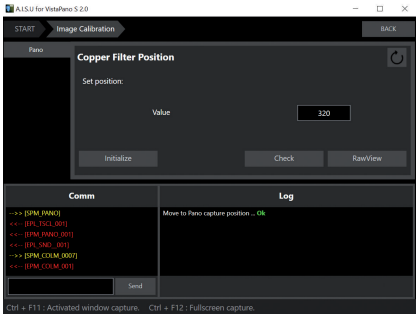
2. Determine position of the copper filter.
Press *Pano* > *Copper filter position* > *GO*.



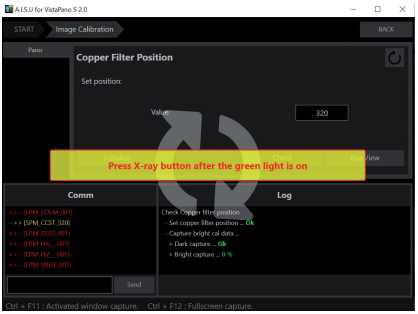
3. Click *Initialize*.



4. Press *Check*.



5. Start the X-ray image acquisition.



6. Stop the X-ray image acquisition when the message *Release X-ray button* is displayed.

7. Confirm the message *Bright capture*.

8. Press *RawViewer*.

9. Check the position of the copper filter:
Set value pano: 320
Set value pano and ceph: 8000

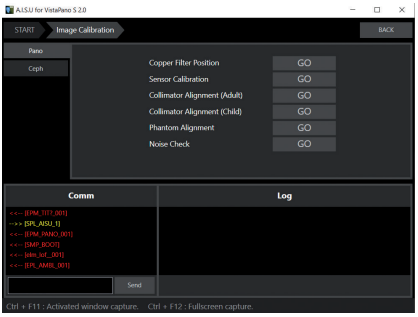
Sensor calibration

Pano

The sensor is calibrated at the factory. The sensor only needs to be calibrated if the image quality is unsatisfactory, i. e. if horizontal stripes or noise can be seen on the X-ray image.

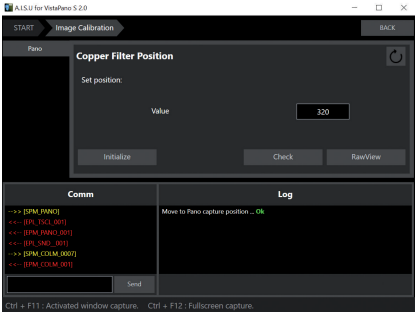
1. Launch the AISU tool.

2. Press *Image Calibration* > *Pano* > *Sensor Calibration* > *GO*.



3. Click *Initialize*.

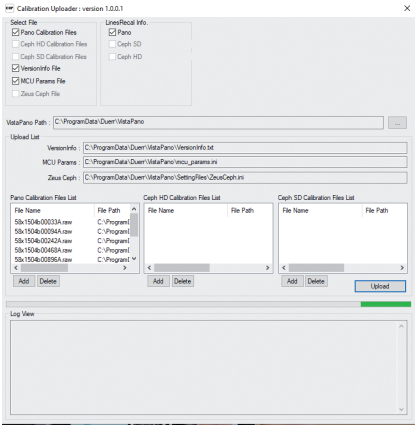
4. Press *Auto calibration* and follow the program.



5. After calibrating the sensor upload the data to the unit.
Start AISU *Service* > *Upload*.

6. Press *Select File* > *Pano Calibration Files*.

7. Upload the calibration data with *Upload*.



8. Start *Upload*.

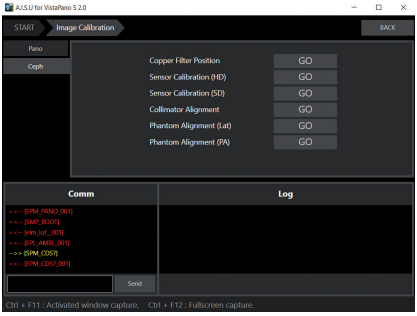
Ceph

With some images, the AISU tool will tell you that a 1 mm copper plate needs to be used.

1. Launch the AISU tool.

2. If necessary, mount a 1 mm copper plate on the X-ray emitter.

3. Press *Image calibration* > *Ceph* > *Sensor Calibration* > *GO*.



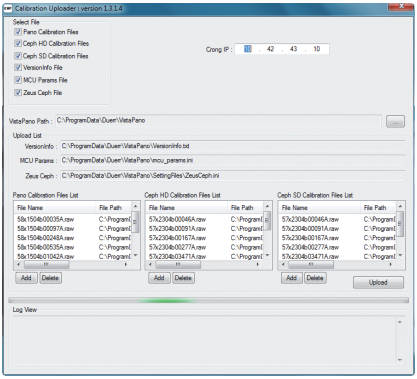
4. Click *Initialize*.

5. Click *Auto calibration*.

6. After calibrating the sensor upload the data to the unit.
Start AISU *Service* > *Upload*.

7. Press Select File *Ceph HD Calibration Files* and *Ceph SD Calibration Files*.

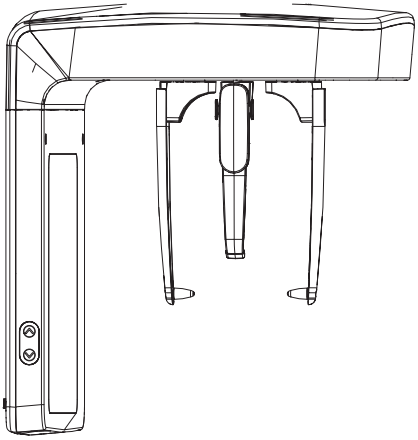
8. After successful calibration, upload the calibration data with *Upload*.



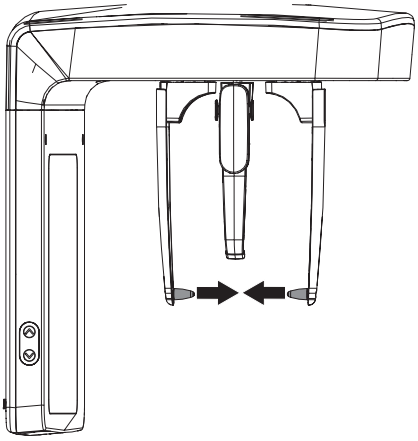
9. Start *Upload*.

Calibrate the ear rods

1. Set the ear rods for lateral mode.

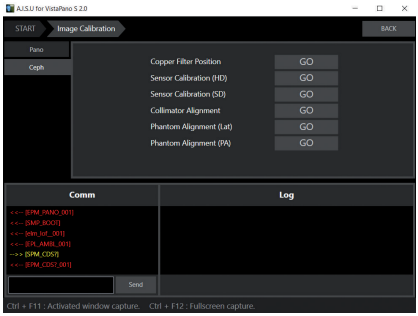


2. Remove the ear cushion.

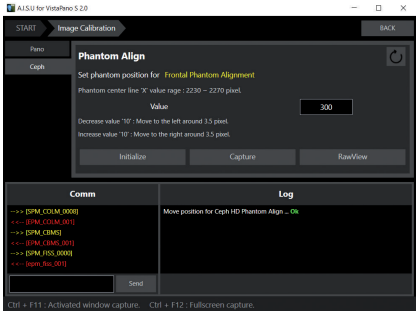


3. Launch the AISU tool.

4. Press *Image calibration* > *Pano* > *Phantom Alignment (Lat)* > *GO*.



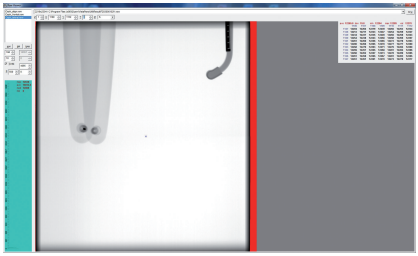
5. Click *Initialize*.



6. Press *Capture*.

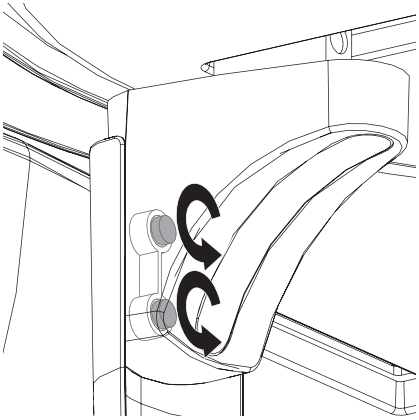
   An X-ray image is captured with the current collimator position.

7. The X-ray image can be viewed in RAW Viewer.
   To do so, press *Viewer*.

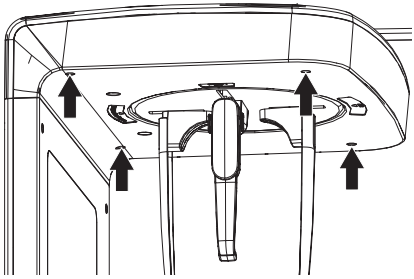


8. Repeat the procedure of capturing images and checking with AISU for *Phantom Alignment (PA)*.

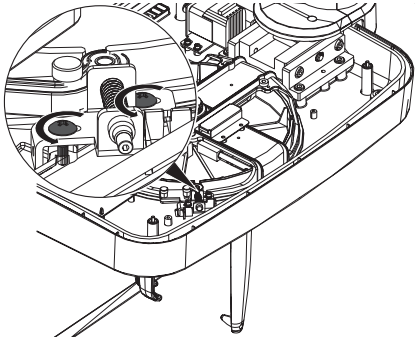
9. Loosen the screws lightly to set the ear rod bracket in the Y direction.



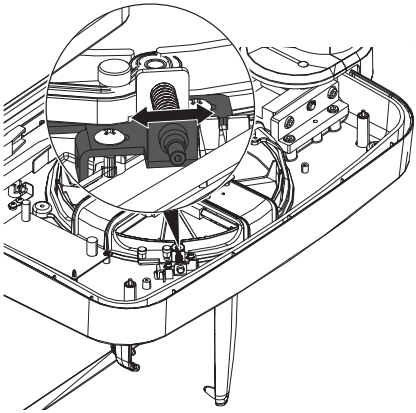
10. Slide the ear rod bracket in the Y direction.
11. Retighten the two screws.
12. Loosen the 8 screws lightly to set the ear rod bracket in the X direction.



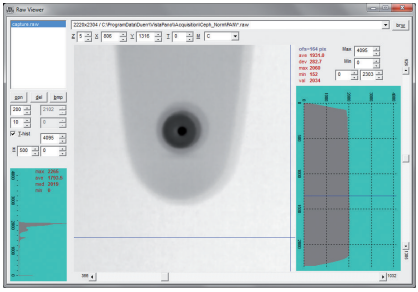
13. Remove the cover.
14. Loosen two screws lightly.



15. Adjust the angle a little.



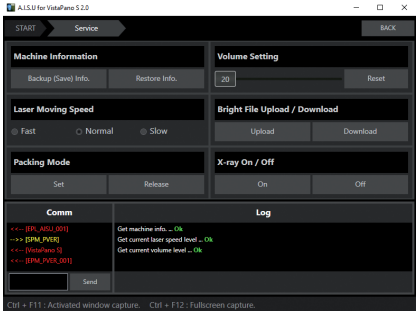
16. Set the X-ray image in the AISU tool again. If both ear rods are identical, the calibration was a success.



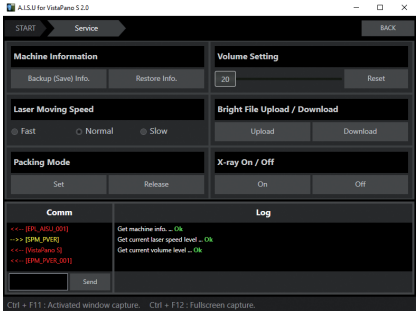
Backing up unit data

After successful calibration or maintenance save the MCU parameters.

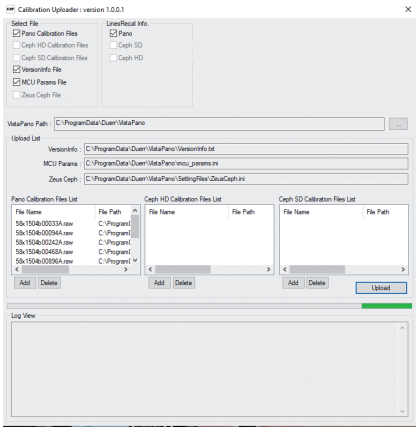
1. Call up the AISU tool.
2. Click *Service* > *Backup (Save) Info*.



3. Upload CAL files.
   Press *Service* > *Bright File Upload*.



4. Upload the calibration data with *Upload*.



9.4 Image reconstruction

The DDIPS tool is used for individual adaptation of image reconstruction parameters, such as e. g. brightness and contrast. With cephalometric images, DDIPS can be used to adjust the homogeneity of the images.

9.5 Acceptance check

The Intra/Extra Digital test phantom is required for performing acceptance tests for panoramic systems, together with the appropriate test phantom holder if necessary.

1. Before the unit is started up and used for the first time, the acceptance test of the X-ray system must be carried out in accordance with national regulations.

9.6 Monitoring the unit via the network

Combining devices safely

- Safety and essential performance features are independent of the network. The device is designed appropriately for operation independent of a network. However, some of the functions are not available in this case.
- Faulty manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
- The data connection utilizes part of the bandwidth of the network. Interactions with other medical devices cannot be completely excluded. Apply the IEC 80001-1 standard for risk assessment.
- The device is not suitable to be connected directly to the public internet.

1. When connecting the unit to other devices, e. g. a PC system, comply with the requirements set out in section 16 of IEC 60601-1 (EN 60601-1).
2. When setting up the PC system in the vicinity of the patient:
   Only connect components (e.g. computer, monitor, printer) that comply with the standard IEC 60601-1 (EN 60601-1).
3. When setting up the PC system outside of the vicinity of the patient:
   Connect components (e.g. computer, monitor, printer) that comply at least with the IEC 60950-1 (EN 60950-1) standard.

In various countries medical devices and electrical equipment are subject to regular checks at set intervals. The owner must be instructed accordingly.

1. Carry out and document the instruction and handover for the unit.

A sample handover report is included in the attachment.

Appendix

10 Default values

10.1 Pano

Scan and exposure times

Program	Arch	HD		SD	
		Exposure time	Scan time	Exposure time	Scan time
		s	s	s	s
Standard panoramic	Wide	13.5	14.0	7.2	7.5
	Normal	13.5	14.0	7.2	7.5
	Narrow	13.5	14.0	7.2	7.5
	Child	11.5	12.3	6.1	6.4
Right, Left	Wide	6.7	14.0	3.6	7.5
	Normal	6.7	14.0	3.6	7.5
	Narrow	6.7	14.0	3.6	7.5
	Child	5.7	12.3	3.1	6.4
Front	Wide	11.2	14.0	6.0	7.5
	Normal	11.2	14.0	6.0	7.5
	Narrow	11.2	14.0	6.0	7.5
	Child	9.2	12.3	4.9	6.4
Orthogonal	Standard	13.5	13.8	13.5	13.8
Bitewing		9.7	13.8	9.7	13.8
Bitewing Right, Left		4.8	13.8	4.8	13.8
Bitewing Front		2.4	13.8	2.4	13.8
Sinus, lateral	Wide	5.9	6.5	5.9	6.5
	Normal	5.9	6.5	5.9	6.5
	Narrow	5.9	6.5	5.9	6.5
	Child	5.9	6.5	5.9	6.5
Sinus, PA	Wide	10.3	10.9	10.3	10.9
	Normal	10.3	10.9	10.3	10.9
	Narrow	10.3	10.9	10.3	10.9
	Child	10.3	10.9	10.3	10.9
Maxillary joint, lateral	Wide	6.2	14.0	6.2	14.0
	Normal	6.2	14.0	6.2	14.0
	Narrow	6.2	14.0	6.2	14.0
	Child	6.2	14.0	6.2	14.0

Program	Arch	HD		SD	
		Exposure time	Scan time	Exposure time	Scan time
		s	s	s	s
Maxillary joint PA	Wide	5.3	11.6	5.3	11.6
	Normal	5.3	11.6	5.3	11.6
	Narrow	5.3	11.6	5.3	11.6
	Child	5.3	11.6	5.3	11.6

Scan time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.
Exposure time: The actual time that the patient is exposed to the X-ray emission.

Tube voltage and current

Mode	Patient	HD		SD	
		Voltage	Current	Voltage	Current
		kVp	mA	kVp	mA
Standard	Large	74	10.0	74	12.0
	Average	73	10.0	73	12.0
	Small	72	10.0	72	11.0
	Child	67	8.0	67	10.0
Right, Left	Large	74	10.0	74	12.0
	Average	73	10.0	73	12.0
	Small	72	10.0	72	11.0
	Child	67	8.0	67	10.0
Front	Large	74	10.0	74	12.0
	Average	73	10.0	73	12.0
	Small	72	10.0	72	11.0
	Child	67	8.0	67	10.0
Orthogonal	Large	74	10.0	74	10.0
	Average	73	10.0	73	10.0
	Small	72	10.0	72	10.0
	Child	67	8.0	67	8.0
Sinus, lateral	Large	74	10.0	74	10.0
	Average	73	10.0	73	10.0
	Small	72	10.0	72	10.0
	Child	67	8.0	67	8.0
Sinus, PA	Large	74	10.0	74	10.0
	Average	73	10.0	73	10.0
	Small	72	10.0	72	10.0
	Child	67	8.0	67	8.0

Mode	Patient	HD		SD	
		Voltage kVp	Current mA	Voltage kVp	Current mA
Maxillary joint, lateral	Large	74	10.0	74	10.0
	Average	73	10.0	73	10.0
	Small	72	10.0	72	10.0
	Child	67	8.0	67	8.0
Maxillary joint PA	Large	74	10.0	74	10.0
	Average	73	10.0	73	10.0
	Small	72	10.0	72	10.0
	Child	67	8.0	67	8.0

10.2 Ceph

Scan and exposure times

Program	HD		SD	
	Exposure time s	Scan time s	Exposure time s	Scan time s
Head lateral	7.7	8.4	1.9	2.1
Head lateral full format			3.9	4.2
Head PA / Waters View / SMV	7.7	8.3	2.4	2.6
Carpus	7.7	8.3	2.4	2.6

Tube voltage and current

Mode	Patient	HD		SD	
		Voltage kVp	Current mA	Voltage kVp	Current mA
Head lateral	Large	92	15.0	92	16.0
	Average	90	15.0	90	16.0
	Small	88	15.0	88	16.0
	Child	86	15.0	86	16.0
Head lateral full format	Large			92	14.0
	Average			90	14.0
	Small			88	14.0
	Child			86	14.0
Head PA / Waters View / SMV	Large	92	14.0	92	15.0

Mode	Patient	HD		SD	
		Voltage kVp	Current mA	Voltage kVp	Current mA
	Average	90	14.0	90	15.0
	Small	88	14.0	88	15.0
	Child	86	14.0	86	15.0
Carpus	Large	90	6.0	90	6.0
	Average	88	6.0	88	6.0
	Small	86	6.0	86	6.0
	Child	84	6.0	84	6.0

11 Panoramic program parameters

The X-rays generated by the X-ray focal spot pass through the X-ray beam limiter for each patient position to create an image receiving area.
The dose area product is calculated by a combination of the air kerma measured in the image receiver and the reception area.

Test conditions	
Model	VistaPano S
Brand	Xmaru1501CF-Plus
X-ray emitter model	DG-07E22T2
X-ray tube model	D-052SB
DAP measurement	If the mode has been set for each of the modes listed below and the dose meter for DAP measurement has been attached to the side of the X-ray detector, the dose value generated during X-ray exposure can be measured for each mode.

11.1 Large built patient

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm^2	s
SD	Standard panoramic	Wide	74	12	104.1	7.2
		Child	74	12	73.2	6.1
	Right, Left	Wide	74	12	52.1	3.6
		Child	74	12	36.6	3.1
	Front	Wide	74	12	87.4	6.0
		Child	74	12	55.5	4.9

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm^2	s
HD	Standard panoramic	Wide	74	10	160.1	13.5
		Child	74	10	101.9	11.5
	Right, Left	Wide	74	10	80.0	6.7
		Child	74	10	50.9	5.7
	Front	Wide	74	10	126.0	11.2
		Child	74	10	79.6	9.2

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
SD/HD	Bitewing	Wide	74	10	87.4	9.7
		Child	74	10	87.4	9.7
	Bitewing Right, Left	Wide	74	10	43.8	4.8
		Child	74	10	43.8	4.8
	Bitewing Front	Wide	74	10	22.2	2.4
		Child	74	10	22.2	2.4
	Orthogonal	Wide	74	10	160.1	13.5
		Child	74	10	123.4	13.5
	Sinus Lat	Wide	74	10	70.3	5.9
		Child	74	10	54.1	5.9
	Sinus PA	Wide	74	10	120.9	10.3
		Child	74	10	93.0	10.3
	Maxillary joint Lat	Wide	74	10	73.7	6.2
		Child	74	10	56.8	6.2
	Maxillary joint PA	Wide	74	10	64.0	5.3
		Child	74	10	49.1	5.3

11.2 Average built patient

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
SD	Standard panoramic	Wide	73	12	101.6	7.2
		Child	73	12	71.5	6.1
	Right, Left	Wide	73	12	50.8	3.6
		Child	73	12	35.8	3.1
	Front	Wide	73	12	85.3	6.0
		Child	73	12	54.2	4.9

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
HD	Standard panoramic	Wide	73	10	157.0	13.5
		Child	73	10	100.0	11.5
	Right, Left	Wide	73	10	78.4	6.7
		Child	73	10	49.9	5.7
	Front	Wide	73	10	123.6	11.2
		Child	73	10	78.1	9.2

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
SD/HD	Bitewing	Wide	73	10	85.2	9.7
		Child	73	10	85.2	9.7
	Bitewing Right, Left	Wide	73	10	42.7	4.8
		Child	73	10	42.7	4.8
	Bitewing Front	Wide	73	10	21.4	2.4
		Child	73	10	21.4	2.4
	Orthogonal	Wide	73	10	157.0	13.5
		Child	73	10	121.0	13.5
	Sinus Lat	Wide	73	10	68.6	5.9
		Child	73	10	52.8	5.9
	Sinus PA	Wide	73	10	117.7	10.3
		Child	73	10	90.6	10.3
	Maxillary joint Lat	Wide	73	10	71.8	6.2
		Child	73	10	55.3	6.2
	Maxillary joint PA	Wide	73	10	62.3	5.3
		Child	73	10	47.8	5.3

11.3 Small patient

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
SD	Standard panoramic	Wide	72	11	90.8	7.2
		Child	72	11	63.9	6.1
	Right, Left	Wide	72	11	45.4	3.6
		Child	72	11	32.0	3.1
	Front	Wide	72	11	76.2	6.0
		Child	72	11	48.5	4.9

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
HD	Standard panoramic	Wide	72	10	153.9	13.5
		Child	72	10	98.0	11.5
	Right, Left	Wide	72	10	76.9	6.7
		Child	72	10	48.9	5.7
	Front	Wide	72	10	121.2	11.2
		Child	72	10	76.5	9.2

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
SD/HD	Bitewing	Wide	72	10	83.1	9.7
		Child	72	10	83.1	9.7
	Bitewing Right, Left	Wide	72	10	41.6	4.8
		Child	72	10	41.6	4.8
	Bitewing Front	Wide	72	10	20.8	2.4
		Child	72	10	20.8	2.4
	Orthogonal	Wide	72	10	153.9	13.5
		Child	72	10	118.6	13.5
	Sinus Lat	Wide	72	10	66.9	5.9
		Child	72	10	51.5	5.9
	Sinus PA	Wide	72	10	114.6	10.3
		Child	72	10	88.2	10.3
	Maxillary joint Lat	Wide	72	10	70.0	6.2
		Child	72	10	53.9	6.2
	Maxillary joint PA	Wide	72	10	60.7	5.3
		Child	72	10	46.6	5.3

11.4 Child (<12 years)

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
SD	Standard panoramic	Wide	67	10	72.6	7.2
		Child	67	10	51.1	6.1
	Right, Left	Wide	67	10	36.2	3.6
		Child	67	10	25.5	3.1
	Front	Wide	67	10	61.1	6.0
		Child	67	10	38.8	4.9

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	mGycm²	s
HD	Standard panoramic	Wide	67	8	109.4	13.5
		Child	67	8	69.6	11.5
	Right, Left	Wide	67	8	54.7	6.7
		Child	67	8	34.8	5.7
	Front	Wide	67	8	86.2	11.2
		Child	67	8	54.4	9.2

Image quality	Program	Arch	Voltage	Current	DAP	Exposure time
			kV	mA	$mGycm^2$	s
SD/HD	Bitewing	Wide	67	8	58.4	9.7
		Child	67	8	58.4	9.7
	Bitewing Right, Left	Wide	67	8	29.2	4.8
		Child	67	8	29.2	4.8
	Bitewing Front	Wide	67	8	14.6	2.4
		Child	67	8	14.6	2.4
	Orthogonal	Wide	67	8	109.4	13.5
		Child	67	8	84.3	13.5
	Sinus Lat	Wide	67	8	47.0	5.9
		Child	67	8	36.2	5.9
	Sinus PA	Wide	67	8	80.5	10.3
		Child	67	8	61.9	10.3
	Maxillary joint Lat	Wide	67	8	49.1	6.2
		Child	67	8	37.8	6.2
	Maxillary joint PA	Wide	67	8	42.6	5.3
		Child	67	8	32.7	5.3

12 Ceph program parameters

The extraoral dental X-ray system meets the requirements set out in standard IEC 60601-2-63. The dosage information complies with the requirements of the standard and is stated in mGy.
Radiation accuracy: Information about the overall uncertainty of the stated values for air kerma and dose area product shall be noted in the accompanying document and must not exceed 50%.
If the operator changes the parameters “Voltage” and “Current”, the resulting radiation quantity may differ from the stated values.
The X-rays generated by the X-ray focal spot pass through the X-ray beam limiter for each patient position to create an image receiving area.
The dose area product is calculated by a combination of the air kerma measured in the image receiver and the reception area.

12.1 Large built patient

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	mGycm²	s
SD	Head, lateral	92	16	17.7	1.9
	Head lateral full format	92	14	30.5	3.9
	Head PA	92	15	20.5	2.4
	SMV	92	15	20.5	2.4
	Waters View	92	15	20.5	2.4
	Carpus	90	6	7.8	2.4

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	mGycm²	s
HD	Head, lateral	92	15	72.4	7.7
	Head PA	92	14	66.0	7.7
	SMV	92	14	66.0	7.7
	Waters View	92	14	66.0	7.7
	Carpus	90	6	27.3	7.7

12.2 Average built patient

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	mGycm²	s
SD	Head, lateral	90	16	23.5	1.9
	Head lateral full format	90	14	39.5	3.9
	Head PA	90	15	27.2	2.4
	SMV	90	15	27.2	2.4
	Waters View	90	15	27.2	2.4
	Carpus	88	6	11.3	2.4

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	mGycm²	s
HD	Head, lateral	90	15	90.9	7.7
	Head PA	90	14	87.4	7.7
	SMV	90	14	87.4	7.7
	Waters View	90	14	87.4	7.7
	Carpus	88	6	38.2	7.7

12.3 Small patient

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	mGycm²	s
SD	Head, lateral	88	16	22.5	1.9
	Head lateral full format	88	14	37.9	3.9
	Head PA	88	15	26.2	2.4
	SMV	88	15	26.2	2.4
	Waters View	88	15	26.2	2.4
	Carpus	86	6	10.9	2.4

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	mGycm²	s
HD	Head, lateral	88	15	87.4	7.7
	Head PA	88	14	84.4	7.7
	SMV	88	14	84.4	7.7
	Waters View	88	14	84.4	7.7
	Carpus	86	6	36.9	7.7

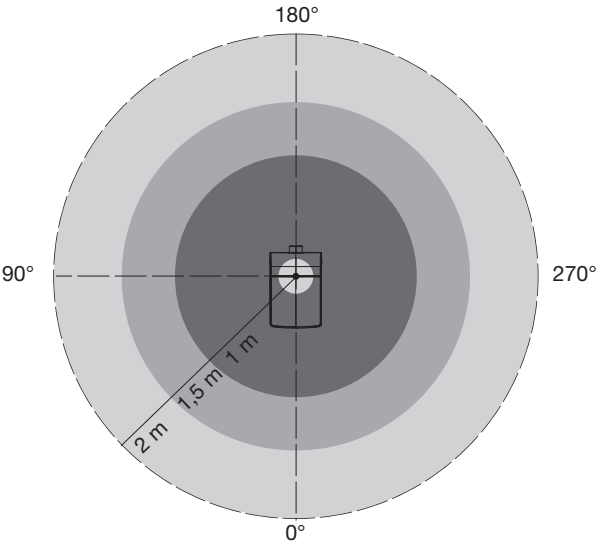
12.4 Child (<12 years)

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	mGycm²	s
SD	Head, lateral	86	16	21.5	1.9
	Head lateral full format	86	14	36.3	3.9
	Head PA	86	15	25.1	2.4
	SMV	86	15	25.1	2.4
	Waters View	86	15	25.1	2.4
	Carpus	84	6	10.4	2.4

Image quality	Program	Voltage	Current	DAP	Exposure time
		kV	mA	$mGycm^2$	s
HD	Head, lateral	86	15	84.0	7.7
	Head PA	86	14	81.5	7.7
	SMV	86	14	81.5	7.7
	Waters View	86	14	81.5	7.7
	Carpus	84	6	35.6	7.7

13 Information on scattered radiation

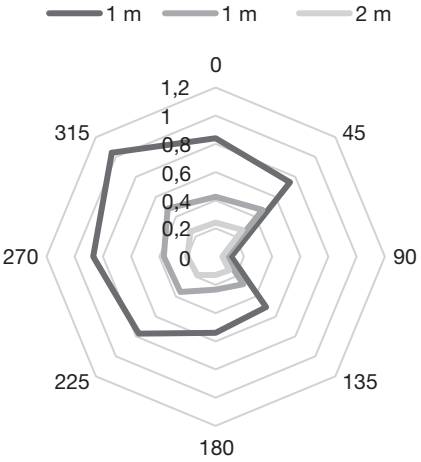
13.1 Measuring conditions



13.2 Pano, adult

Test conditions standard Pano, adult	
Distance from focal point	1 m, 1.5 m, 2 m
Generator voltage	90 kVp
Current	14 mA
Exposure time	13.5 s

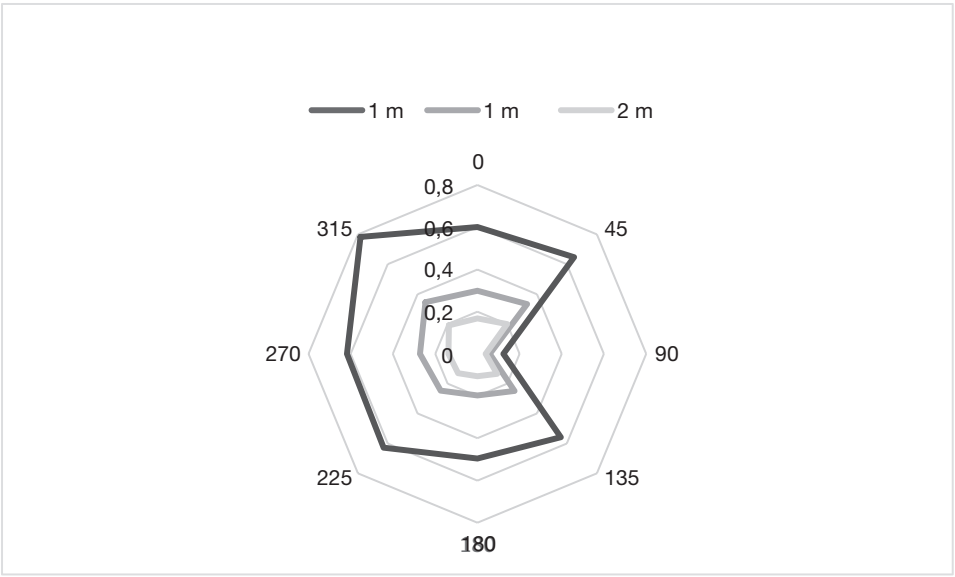
R °		HD, 13.5 s 1 m	1.5 m	2 m
0	Nose	0,84 µGy	0,425 µGy	0,242 µGy
45		0,764 µGy	0,47 µGy	0,268 µGy
90	Right ear	0,11 µGy	0,067 µGy	0,048 µGy
135		0,507 µGy	0,276 µGy	0,137 µGy
180	Back of the head	0,541 µGy	0,233 µGy	0,13 µGy
225		0,772 µGy	0,354 µGy	0,183 µGy
270	Left ear	0,869 µGy	0,368 µGy	0,202 µGy
315		1,041 µGy	0,482 µGy	0,252 µGy



13.3 Pano, pediatric

Test conditions standard Pano, child	
Distance from focal point	1 m, 1.5 m, 2 m
Generator voltage	90 kVp
Current	14 mA
Exposure time	11.4 s

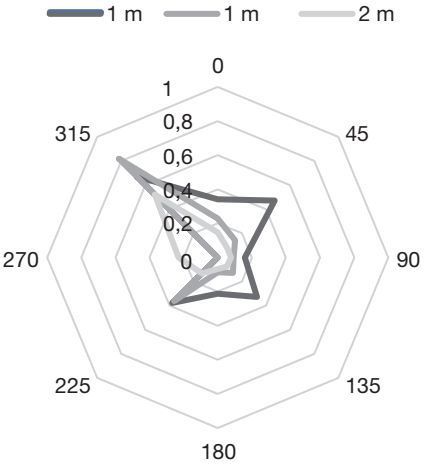
		HD, 11.5 s		
R °		1 m	1.5 m	2 m
0	Nose	0,601 µGy	0,299 µGy	0,168 µGy
45		0,648 µGy	0,333 µGy	0,199 µGy
90	Right ear	0,123 µGy	0,059 µGy	0,04 µGy
135		0,559 µGy	0,248 µGy	0,133 µGy
180	Back of the head	0,496 µGy	0,197 µGy	0,106 µGy
225		0,628 µGy	0,246 µGy	0,13 µGy
270	Left ear	0,618 µGy	0,272 µGy	0,137 µGy
315		0,784 µGy	0,347 µGy	0,191 µGy



13.4 Ceph, lat

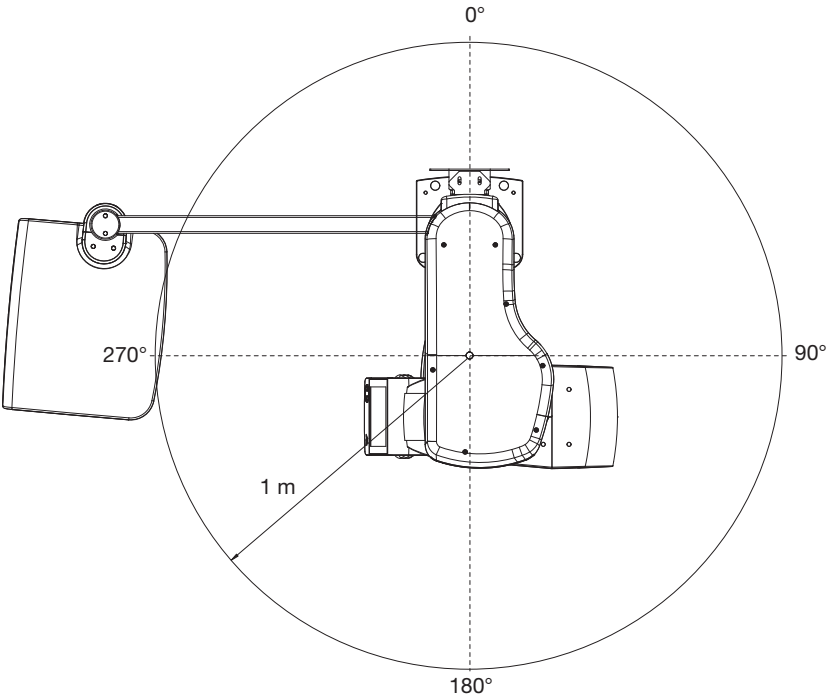
Test conditions Ceph, lat	
Distance from focal point	1 m, 1.5 m, 2 m
Generator voltage	99 kVp
Current	16 mA
Exposure time	7.7 s

R °		1 m	1.5 m	2 m
0	Nose	0.342 µGy	0.229 µGy	0.148 µGy
45		0.472 µGy	0.144 µGy	0.08 µGy
90	Right ear	0.159 µGy	0.094 µGy	0.078 µGy
135		0.326 µGy	0.127 µGy	0.076 µGy
180	Back of the head	0.212 µGy	0.086 µGy	0.068 µGy
225		0.377 µGy	0.362 µGy	0.132 µGy
270	Left ear	-	-	0.229 µGy
315		0.67 µGy	0.818 µGy	0.521 µGy


1 m
1 m
2 m
0
45
90
135
180
225
270
315
1
0,8
0,6
0,4
0,2
0

14 Information on the leakage rate

14.1 Measuring conditions

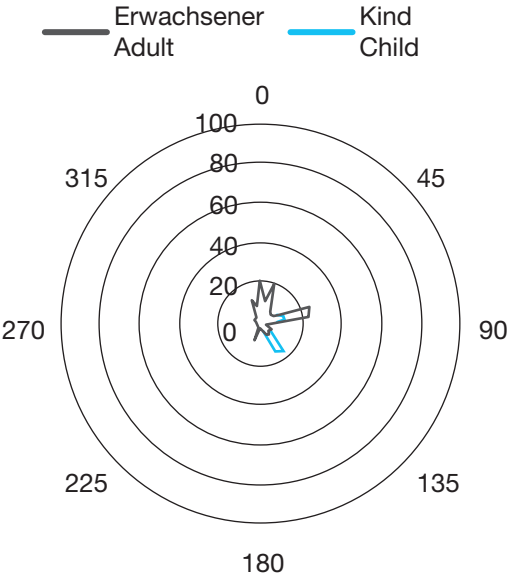


14.2 Standard Pano

Test conditions standard Pano, HD	Adult	Child
Distance from focal point	1 m 39.37 in	
Generator voltage	90 kVp	
Current	14 mA	
Exposure time	13.4 s	11.4 s

Direction °	Adult, dose mGy/h	Child, dose mGy/h
0	0.192	0.177
10	0.107	0.115
20	0.174	0.173
30	0.09	0.089
40	0.069	0.068
50	0.065	0.06

Direction °	Adult, dose mGy/h	Child, dose mGy/h
60	0.068	0.064
70	0.227	0.106
80	0.214	0.11
90	0.019	0.018
100	0.041	0.048
110	0.053	0.068
120	0.051	0.066
130	0.044	0.056
140	0.059	0.161
150	0.052	0.139
160	0.029	0.031
170	0.016	0.018
180	0.011	0.013
190	0.012	0.013
200	0.072	0.071
210	0.021	0.024
220	0.012	0.012
230	0.009	0.01
240	0.008	0.009
250	0.007	0.008
260	0.008	0.008
270	0.01	0.009
280	0.015	0.014
290	0.013	0.013
300	0.011	0.036
310	0.012	0.032
320	0.035	0.032
330	0.032	0.037
340	0.113	0.111
350	0.084	0.08

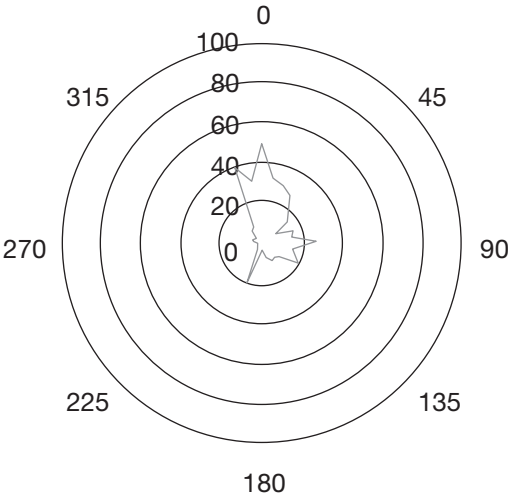


14.3 Ceph

Test conditions Ceph	
Distance from focal point	1 m 39.37 in
Generator voltage	99 kVp
Current	16 mA
Exposure time	7.7 s

Direction °	Adult, dose mGy/h
0	0.434
10	0.289
20	0.267
30	0.238
40	0.18
50	0.144
60	0.069
70	0.148
80	0.131
90	0.241
100	0.134
110	0.151
120	0.179

Direction °	Adult, dose mGy/h
130	0.092
140	0.086
150	0.096
160	0.075
170	0.051
180	0.031
190	0.035
200	0.184
210	0.047
220	0.027
230	0.021
240	0.018
250	0.019
260	0.021
270	0.025
280	0.039
290	0.038
300	0.029
310	0.03
320	0.069
330	0.069
340	0.34
350	0.272



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