ProVecta 3D Prime and ProVecta 3D Prime Ceph

EN-US Operating instructions

CE 0297

Rx Only

equipped for life
AIR TECHNIQUES

2210200979L29 A7866 2607V011

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

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

Contents

Important information

Product description

Usage

Troubleshooting

Appendix

Important information

1 About this document

These installation and operating 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 Installation and Operating Instructions.

The German version of the operating instructions is the original manual. All other languages are translations of the original manual.
These operating instructions apply to:
ProVecta 3D Prime
REF: A7761
ProVecta 3D Prime Ceph
REF: A7861
Refer to the separate installation instructions for information about assembly, installation and configuration of the unit (document no. A7867).

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

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.

REF Part number

SN Serial number

MD Medical device

CE xxxx CE labeling with the number of the notified body

SGS xxxxxx SGS marking with number

Manufacturer

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.

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

Type BF applied part

Do not reuse

NON STERILE Not sterile

Sterilize with steam at 134 °C


Protective ground connection


Equipotential bonding


Fragile, handle with care


Lower and upper atmospheric pressure limits


Lower and upper temperature limits


Lower and upper humidity limits


Stacking limits


Recycling


Keep dry


This way up / store and transport in an upright position


Keep away from sunlight during storage


Refer to Operating Instructions.


Wear hand protection.


Wear eye protection.


Use a mask.


Wear protective clothing.


Disconnect all power from the unit.


Notice


Emergency stop switch


Class 1 laser product


Warning – X-rays


Warning – risk of dangerous electric voltages


Warning – X-rays

1.2 Copyright information

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

ProVecta 3D Prime

ProVecta 3D Prime is computed tomography x-ray unit intended to generate 3D and panoramic X-ray images in dental radiography for adult and pediatric patients. It provides diagnostic details of the maxillofacial areas for a dental treatment.
The device is operated and used by physicians, dentists, and x-ray technicians.
Not intended for mammography use.

ProVecta 3D Prime Ceph

ProVecta 3D Prime Ceph is a computed tomography x-ray unit intended to generate 3D, panoramic and cephalometric X-ray images in dental radiography for adult and pediatric patients. It provides diagnostic details of the maxillofacial areas for a dental treatment.
The device is operated and used by physicians, dentists, and x-ray technicians.
Not intended for mammography use.

2.2 Contraindications

The radiobiological effects of X-ray beams in tissue result in the following contraindications:
– Pregnancy
– Pre-existing illnesses preventing the recording of a CBCT image
– Absence of a justified indication

Exceptions can be formulated at the discretion of the physician.

2.3 Intended use

ProVecta 3D Prime Ceph

ProVecta 3D Prime Ceph is a computed tomography x-ray unit intended to generate 3D, panoramic and cephalometric X-ray images in dental radiography for adult and pediatric patients. It provides diagnostic details of the maxillofacial areas for a dental treatment. The device is operated and used by physicians, dentists, and x-ray technicians.
Not intended for mammography.

ProVecta 3D Prime

ProVecta 3D Prime is computed tomography x-ray unit intended to generate 3D and panoramic X-ray images in dental radiography for adult and pediatric patients. It provides diagnostic details of the maxillofacial areas for a dental treatment.
The device is operated and used by physicians, dentists, and x-ray technicians.
Not intended for mammography use.

2.4 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.

2.5 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.
– 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.

The sale or prescription of this device by a medical practitioner is subject to the restrictions of the applicable Federal Acts. The device may be used only under permanent supervision by a dentist or licensed medical practitioner.

RxOnly 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.

2.6 Radiation protection

1. Comply with all applicable X-ray protection regulations and X-ray protection measures.
2. Use the prescribed X-ray protection equipment.
3. 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.
4. 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.
5. Children and pregnant women must consult a doctor before recording an X-ray image.
6. 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 maintain visual contact with the patient and the unit and keep talking to the patient.
7. The radiation room must be lockable to prevent entry by unauthorized persons.
8. If a fault occurs, abort the exposure immediately by releasing the trigger button.

2.7 Specialist personnel

Operation

Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

– Instruct or have every user instructed in handling the unit.

Installation and repairs

– The manufacturer recommends that installation, readjustments, alterations, upgrades and repairs be carried out either by the manufacturer itself or by qualified personnel authorized by the manufacturer.

2.8 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.

Comply with the EMC rules concerning medical devices

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

– 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 between the unit and other electronic devices.
– Note that cable lengths and cable extensions have effects on electromagnetic compatibility.

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

– 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.

NOTICE

Reduced performance features due to insufficient distance between unit and mobile HF communication devices

› Keep at least 30 cm distance between the unit (including parts and cables of the unit) and mobile HF communication devices (wireless units) (including their accessories such as antenna cables and external antennas).

2.9 Essential performance characteristics

The unit does not have any essential performance characteristics as set out in IEC 60601-1 section 4.3.

2.10 Notification requirement of serious incidents

The user / patient is required to report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established any serious incident that has occurred in relation to the device.

Report any serious incidents to the manufacturer under incidents@duerrdental.com.

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.

1. Only use accessories and optional items specified or approved by Air Techniques.
2. Only use original working parts and spare parts.

The following accessories may affect EMC:
– Mains cable (3.6 m; order no.: A7782)
– Exposure switch (order no.: A7801)

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

Device

The units and electronic circuits may be disposed of only in proper facilities for recycling and recovery. Make sure to dispose of these objects in compliance with the applicable laws and regulations of the federal, national, state and municipal authorities.

X-ray emitter

The X-ray emitter contains a tube that is potentially capable of imploding, lead cladding and mineral oil.

2.14 Protection from cybersecurity threats

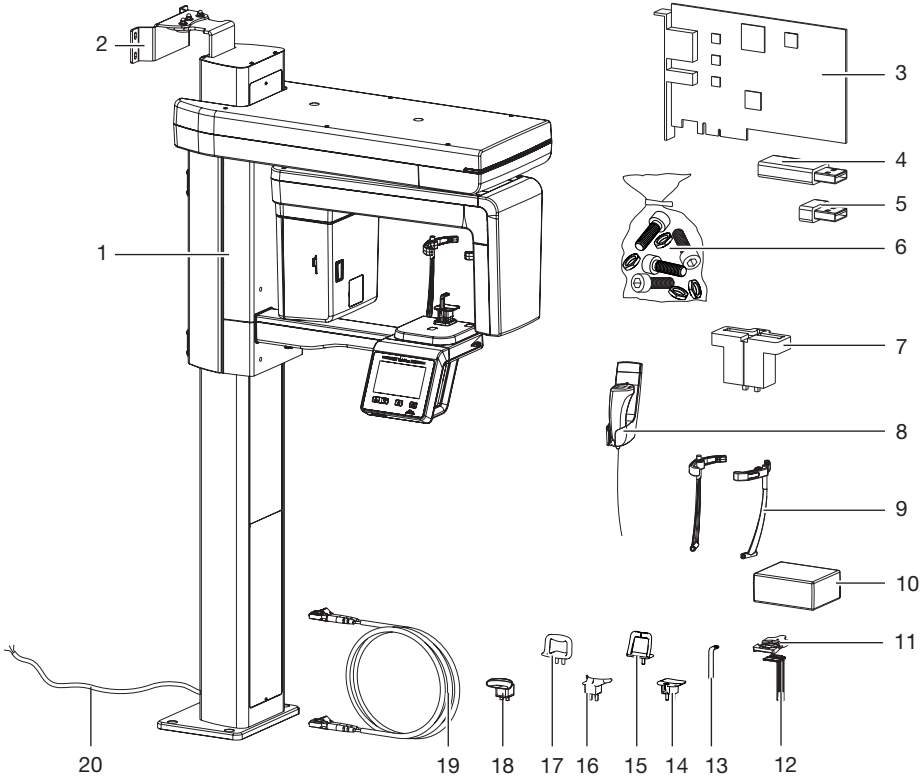
The unit is to be connected to a computer that can be connected to the Internet. Therefore, the system needs to be protected from threats from the Internet.

- 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.

Product description

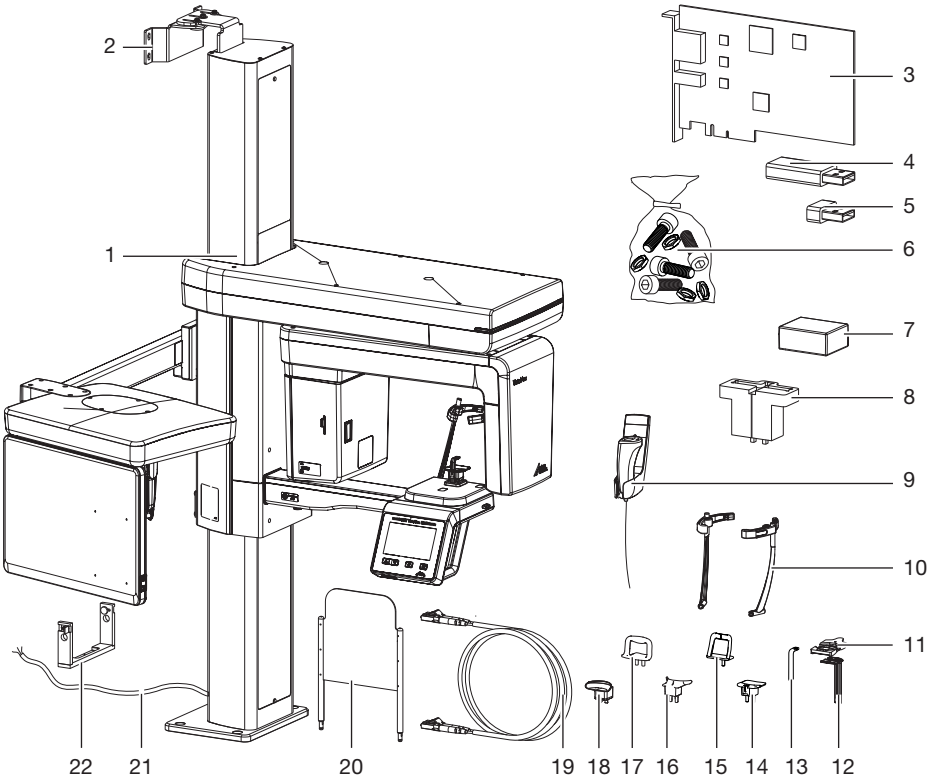
3 Overview

3.1 ProVecta 3D Prime



1	3D and panoramic X-ray unit	11	Comfort bite block foam pad
2	Wall bracket	12	Comfort bite block
3	Frame grabber card	13	Bite block
4	USB dongle	14	Holder for bite block
5	USB stick with calibration data	15	Chin rest for maxillary joint image
6	Small parts	16	Chin rest for edentulous patients
7	Pano test body holder	17	Chin rest for sinus image
8	Exposure switch (with holder)	18	Chin rest, universal
9	Head supports Plus with cushion	19	Fiber optic cable
10	Hygienic protective covers for bite block	20	Mains cable for permanent connection

3.2 ProVecta 3D Prime Ceph



1 3D, Ceph and panoramic X-ray unit
2 Wall bracket
3 Frame grabber card
4 USB dongle
5 USB stick with calibration data
6 Small parts
7 Hygienic protective covers for bite block
8 Pano test body holder
9 Exposure switch (with holder)
10 Head supports Plus with cushion
11 Comfort bite block foam pad
12 Comfort bite block
13 Bite block
14 Holder for bite block
15 Chin rest for maxillary joint image
16 Chin rest for edentulous patients
17 Chin rest for sinus image
18 Chin rest, universal
19 Fiber optic cable
20 Positioning plate for projections of the hand/ wrist (carpus)
21 Mains cable for permanent connection
22 Ceph test body holder

3.3 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):

ProVecta 3D Prime

ProVecta 3D Prime A7750

- Fiber optic cable 10 m / 33 ft
- Exposure switch and holder
- Holder for bite block
- Bite block (3 pieces)
- Comfort bite block (3 pcs.)
- Comfort bite block foam pads (10 pcs.)
- Chin rest for edentulous patients
- Chin rest for maxillary joint image
- Chin rest for sinus image
- Chin rest, universal
- Head supports Plus with cushion
- Top wall bracket, short (16 in)
- Hygienic protective covers for bite block
- Small parts (e.g. screws, nuts, etc.)
- Various housing parts
- Voucher for VistaSoft imaging software
- Operating instructions
- Installation instructions
- Framegrabber 3
- USB dongle for 3D reconstruction
- USB stick with calibration data

ProVecta 3D Prime Ceph

ProVecta 3D Prime Ceph A7850

- Fiber optic cable 10 m / 33 ft
- Exposure switch and holder
- Holder for bite block
- Bite block (3 pieces)
- Comfort bite block (3 pcs.)
- Comfort bite block foam pads (10 pcs.)
- Chin rest for edentulous patients
- Chin rest for maxillary joint image
- Chin rest for sinus image
- Chin rest, universal
- Head supports Plus with cushion
- Top wall bracket set, long
- Positioning plate for projections of the hand/wrist (carpus)
- Hygienic protective covers for bite block
- Nose support set
- Holder for ear rods set
- Small parts (e.g. screws, nuts, etc.)
- Various housing parts
- Operating instructions
- Installation instructions
- Voucher for VistaSoft imaging software
- Framegrabber 3
- USB dongle for 3D reconstruction
- USB stick with calibration data

If the mains cable of this unit is damaged it must only be replaced by an original mains cable from the manufacturer.

3.4 Optional items

The following optional items can be used with the device:

Top wall bracket set, long (wall/wall installation) A7764
Bottom wall bracket set, long (wall/wall installation) A7755
Fiber optic cable 5 m A7757
Fiber optic cable 20 m A7758
Stand A7815
Silicone pads for head support Plus A7803

Acceptance and consistency check

2D X-ray Pan phantom set A7556
Consistency check test phantom 3D set . A7759
Acceptance test phantom 3D set A7760
Ball phantom A7330
2D X-ray test phantom holder A7366

ProVecta 3D Prime only

Bottom wall bracket set, 16 inch, short (wall/wall installation) A7754

ProVecta 3D Prime Ceph only

Set of silicone pads Ear rods and nose support A7910

3.5 Consumables

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

Hygienic protective cover bite block (100 pieces) A7395
Silicone pads for head support Plus A7803
Comfort bite block foam pads (100 pcs.) . A7746

Cleaning and disinfection

Monarch surface disinfection wipes (hundred pcs. - 7" x 9") H6171
Monarch enzymatic cleaner (84.5 oz. bottle) H6201

Information on replacement part is available at the portal for specialist dealers: *www.airtechniques.com*.

ProVecta 3D Prime Ceph only

Set of silicone pads Ear rods and nose support A7910

4 Technical data

Electrical data for the device		
Nominal voltage	V AC	200 - 240
Frequency	Hz	50/60
Protection class		I
Operating mode X-ray tube		S6 = 6.3% 320 s duty cycle 20 s / 5 min (switch-on/switch-off time)
Operating mode height adjustment		S3 = 9% duty cycle 1 min / 9 min (switch-on/switch-off time)
Rated power	W	170
Maximum power	kVA	2.2
Fuses* (2 pcs.)	A	T 10.0 AH / 250 V~ (IEC 60127-2, Sheet 5)

* We recommend only having the device fuses changed by Air Techniques or by a technician/company authorized by Air Techniques.

Classification	
Medical Device Class (MDR)	IIb
FDA classification (CFR Title 21)	II

General technical data		ProVecta 3D Prime	ProVecta 3D Prime Ceph
Dimensions (W x D)	mm in	572.5 x 1181 ± 12 22.54 x 46.50 ± 0.47	1940.8 x 1251 ± 12 76.41 x 49.25 ± 0.47
Height	mm in	1406 - 2206 55.35 x 86.85	1406 - 2206 55.35 x 86.85
Weight	kg lbs	180 397	202 445

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

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

X-ray emitter		
Model		DG-07E22T2
Rated power	kW	1.6 (for 1 s)
Type of high-voltage generator		Inverter

X-ray emitter		
Nominal voltage, high-voltage generator	kV	60 - 99 (±10 %)
Nominal current, high voltage generator	mA	4 - 16 (± 10%, max. 75 kV 16 mA, max. 99 kV 10 mA)
Cooling, high-voltage generator		Automatic monitoring Shut-off at ≥ 60°C
Additional filtration	mm Al in Al	1.5 + 3.0 (added automatically for CBCT) 0.06 + 0.12 (added automatically for CBCT)
Inherent filtration	mm Al in Al	0.8 0.03
Total filtration	mm Al in Al	2.5 + 3.0 (added automatically for CBCT) 0.09 + 0.12 (added automatically for CBCT)
X-ray tube model		D-052SB / Canon (Toshiba)
Focal spot size as per IEC 60336 X-ray tube	mm in	0.5 0.02
Anode angle*	°	5
Anode heat capacity	kJ	35
Pulse/break ratio		1:60 or more
Duration of radiation exposure	s	0.5 - 20
Maximum current-time product per hour	mAs	960 (at 75 kV/16 mA)

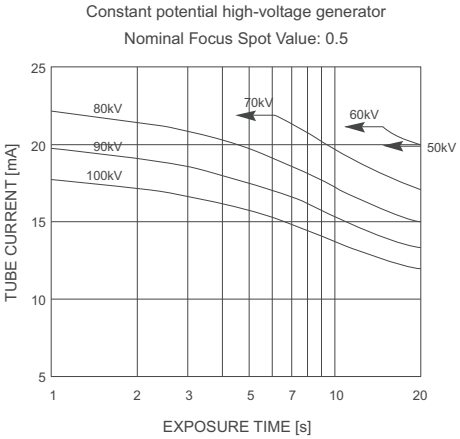
*The reference axis is the perpendicular of the X-ray exit window at the level of the side marker for the focal point on the cover of the X-ray emitter

4.1 X-ray tube performance data

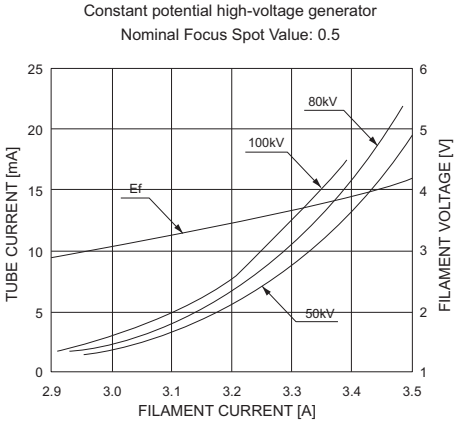
– Maximum deviation of the peak voltage from the displayed value ± 10%
– Maximum deviation of the tube current from the displayed value ± 20%
– Maximum deviation of the exposure time from the displayed value ± 10%
– The device complies with the standards IEC 60601-1, IEC 60601-1-3 and IEC 60601-2-63.
– The lowest possible load factor is obtained with a combination of the settings 60 kV and 4 mA.

Maximum Rating Charts

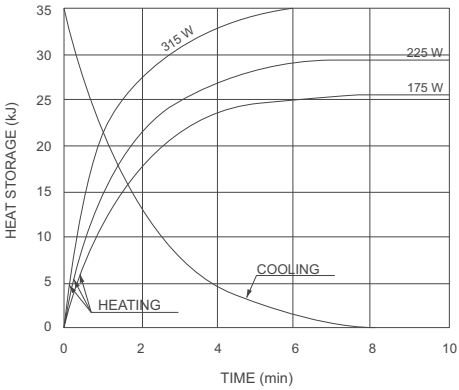
DC (Center Grounded)



Emission and Filament Characteristics



Anode Thermal Characteristics



Detector Pano/CBCT		
Brand		Xmaru1404CF
Type		CMOS photodiode array
Pixel size	µm	49.5 99 (2x2 binning) 198 (4x4 binning)
	in	0.001949 0.003898 (2x2 binning) 0.007795 (4x4 binning)
Sensor size	mm in	230 x 160 x 26 9.06 x 6.30 x 1.02
Active surface area	mm in	135.8 x 36.4 5.35 x 1.43
Frame rate	fps	53.5 107 (2x2 binning) 308 (4x4 binning)
Greyscale	bit	14

Exposure mode	FDD mm in	FOD mm in	ODD mm in	Image capture scale (magnification factor)
CBCT	600 23.62	428.6 16.87	171.4 6.75	-
Panorama	600 23.62	477.7 18.81	122.3 4.81	1.26
Cephalometric projections	1745 68.70	1524 60.00	221 8.70	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

Electromagnetic compatibility (EMC) Interference emission measurements	
High-frequency emissions in accordance with CISPR 11	Group 1
Interference voltage at the power supply connection CISPR 11	Class A
Electromagnetic interference radiation CISPR 11	Class A
Emission of harmonics IEC 61000-3-2	Class A
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements on the cover	
Immunity to electrostatic discharge IEC 61000-4-2 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Conforms
Immunity to high-frequency electromagnetic fields IEC 61000-4-3 3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz	Conforms
Immunity to near fields of wireless HF communication devices IEC 61000-4-3 Refer to the table with immunity to interference levels for near fields of wireless HF communication devices.	Conforms

Immunity to interference levels by near fields of wireless HF communication devices

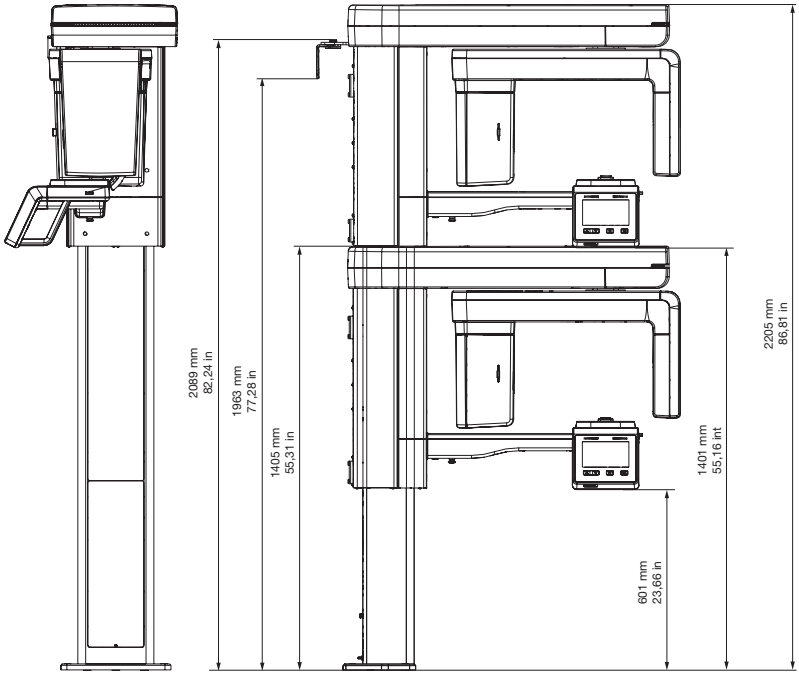
Radio service	Frequency band MHz	Test level V/m
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE bands 1, 3, 4, 25 UMTS	1700 - 1990	28

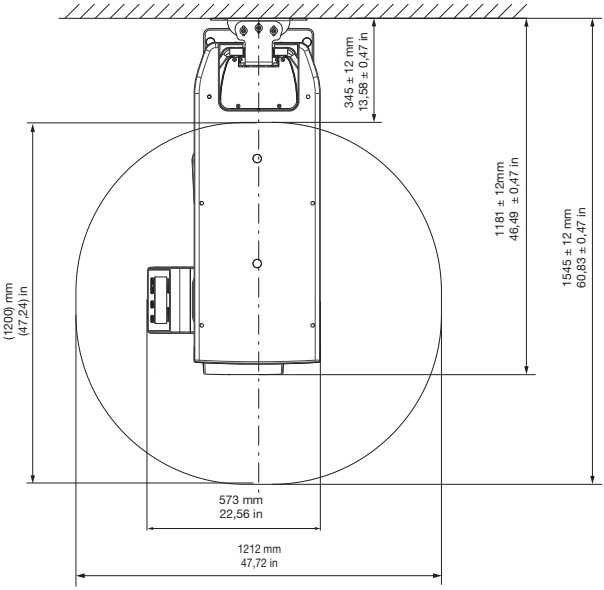
Immunity to interference levels by near fields of wireless HF communication devices		
Radio service	**Frequency band MHz**	**Test level V/m**
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input	
Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4 ± 2 kV 100 kHz repetition frequency	Conforms
Immunity to surges, line-to-line IEC 61000-4-5 ± 0.5 kV, ± 1 kV	Conforms
Immunity to surges, line-earth IEC 61000-4-5 ± 0.5 kV, ± 1 kV, ± 2 kV	Conforms
Immunity to conducted disturbances, induced by radio-frequency fields – AC mains voltage IEC 61000-4-6 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Conforms
Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11 0% U_T for 0.5 period 0% U_T for 1 period 70% U_T for 25/30 periods (50/60 Hz) 0% U_T for 250/300 periods (50/60 Hz)	Conforms

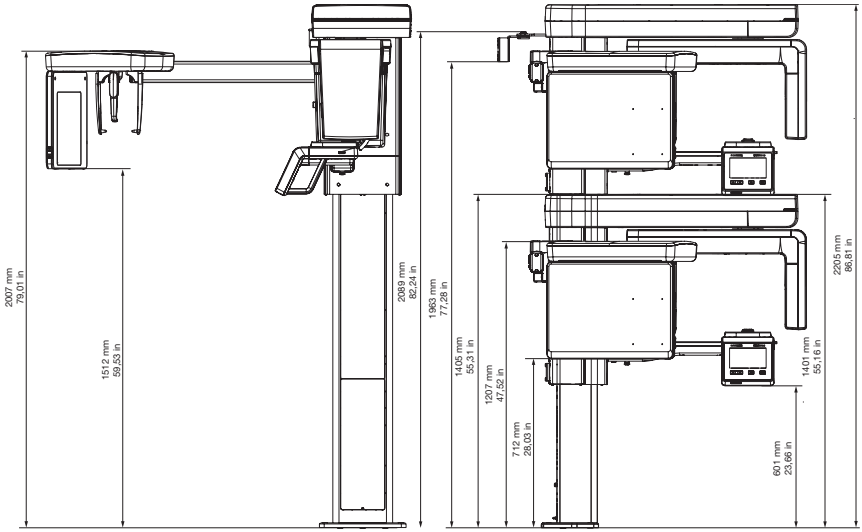
4.2 Dimensions

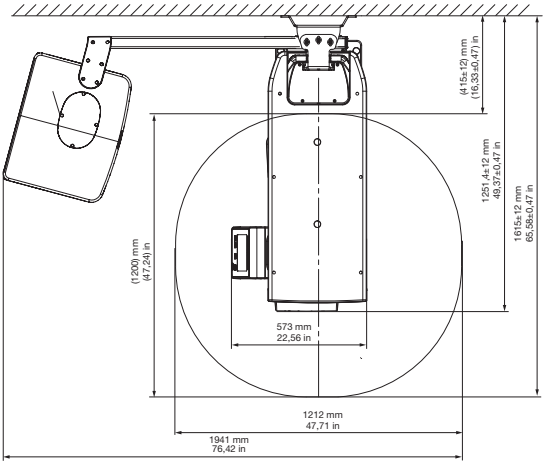
ProVecta 3D Prime



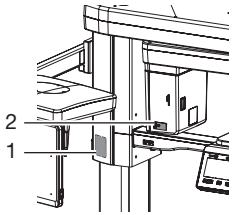


ProVecta 3D Prime Ceph





4.3 Model identification plate



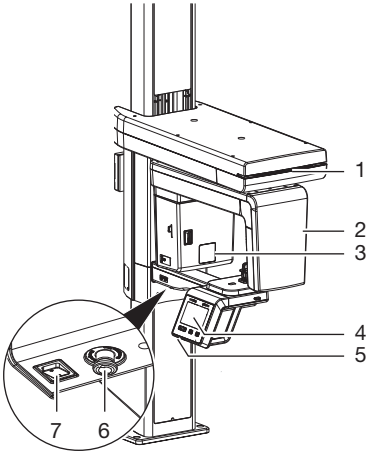
1 Type plate of the unit
2 Type plate of the X-ray tube

4.4 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

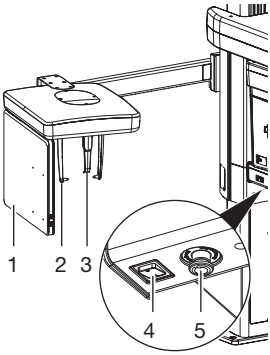
5.1 3D and panoramic X-ray unit



1 Status LED
2 Rotating unit
3 X-ray tube
4 User interface
5 Memory card slot
6 Emergency stop switch
7 On/off switch

Similar to computer tomography or magnetic resonance tomography, sectional images can be generated with CBCT. With CBCT, an X-ray tube and an imaging sensor opposite it rotate around a seated or standing patient. The X-ray tube rotates through 180°-540° and emits a conical X-ray beam. The X-rays pass through the region under investigation and are measured for image generation by a detector as an attenuated grey scale X-ray image. Here, a large series of two-dimensional individual images is acquired during the revolution of the X-ray tube. Using a mathematical calculation on the rotating image series via a reconstruction computer, a grey value coordinate image is generated in the three spatial dimensions. This three-dimensional coordinate model corresponds to a volume graphic that is made up of individual voxels. This volume can be used to generate sectional images (tomograms) in all spatial dimensions as well as 3D views.
The X-ray job is started via the imaging software and activated via the touch screen.

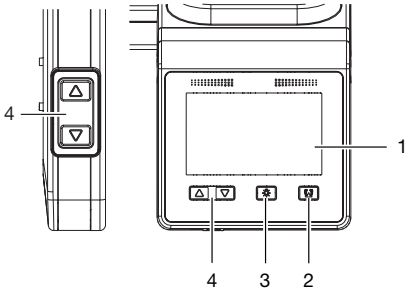
5.2 Cephalometric X-ray unit



1 Sensor (Ceph)
2 Ear rods with holder
3 Nose support
4 On/off switch
5 Emergency stop switch

Recording digital cephalometric radiographs, the patient's head is scanned line by line with a fan-shaped, flat X-ray beam.
The X-ray job is started via the imaging software and activated via the touch screen.

5.3 Operating elements



1 Touch screen
2 Button for opening/closing the head supports
3 Button for positioning beams on/off
4 Buttons for height adjustment

The touch screen can be used to operate the unit, see also "6 Operating the touch screen". Information can be entered on the touch screen with the tip of a finger.

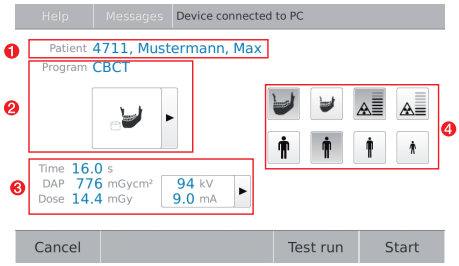
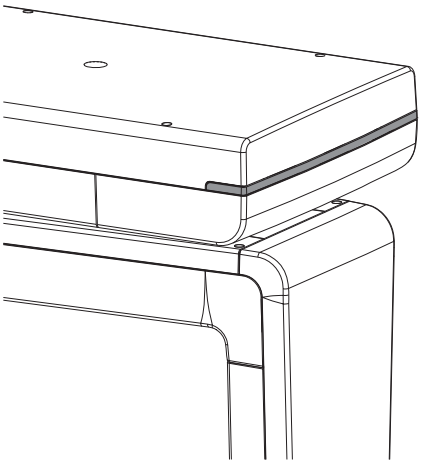


Fig. 1: Monitor, unit ready to acquire image

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

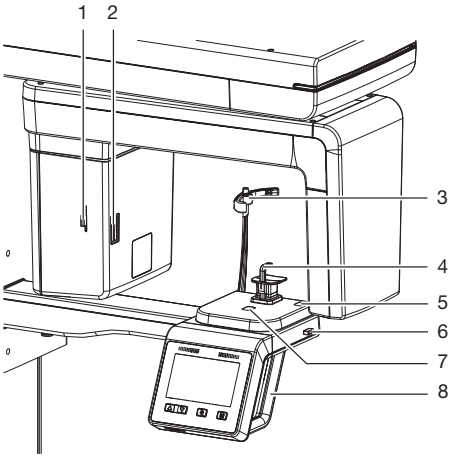
The *Messages* button can be used to call up current messages.

5.4 Status LED



The status LED uses different colors to display the different operating modes:
– Blue: unit ready for operation
– Green: unit ready to acquire image
– Yellow: X-ray beam active

5.5 Positioning aids

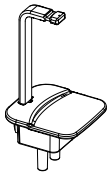


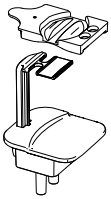
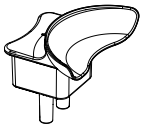
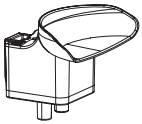
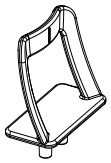
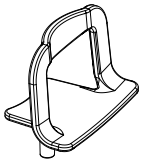
1 Lever for positioning the Frankfurt plane positioning beam
2 Frankfurt plane of the X-ray positioning beam
3 Head supports with cushion
4 Positioning aid, e. g. chin support with bite block
5 Upper canine positioning beam
6 Lever for positioning the upper canine positioning beam
7 Mid-sagittal positioning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

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)

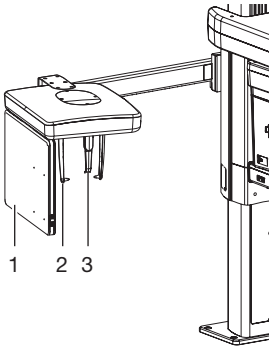
Description of the positioning aids

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.

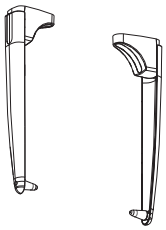
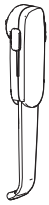
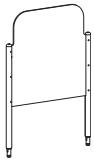
Panorama	
	Bite block and adapter bite block

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

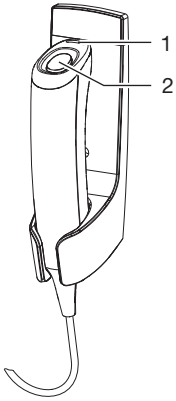
Cephalometric projections	
	Ear rods with holder
	Nose support
	Carpus plate

5.7 Exposure button

Exposure switch

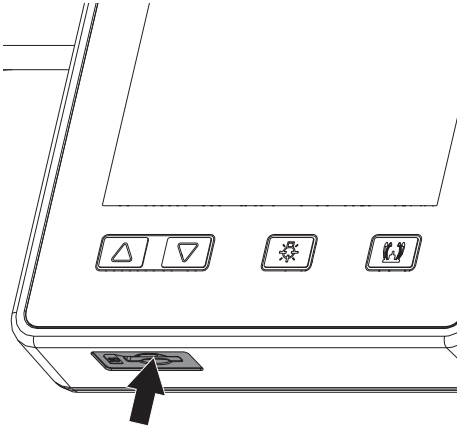
The exposure switch is used to trigger the prepared image acquisition and start the X-ray exposure. The LED indicates the status of the unit, as does the LED on the unit.

– Green: unit ready for recording
– Yellow: X-ray beam active



1 Indicator lamp (LED)
2 Exposure button

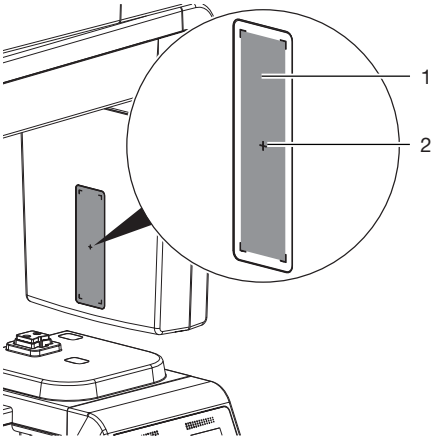
5.8 Memory card slot



The unit has a slot for a memory card. The slot is needed for service purposes only.

5.9 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.



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

Usage

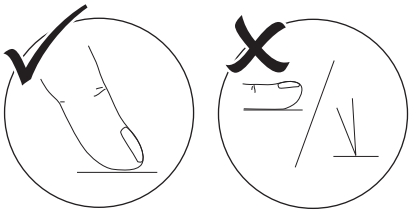
6 Operating the touch screen

NOTICE

Damage to the touch screen due to incorrect handling

- Only touch the touch screen with your fingertips.
- Do not use sharp objects (e.g. ball-point pen) to operate the touch screen.
- Protect the touch screen from water.

1. Operate the touch screen by tapping it with a fingertip to select a button or input field.



2. For further information about any window, tap on the *Help* field.

6.1 Navigating

If the contents of the window cannot be completely displayed on the touch screen, a scroll bar appears.

1. Tap or or to move the displayed section of the window.

6.2 Using menus

The menus integrated in a window contain additional commands that can be selected.

1. To open the menu, tap ▶.

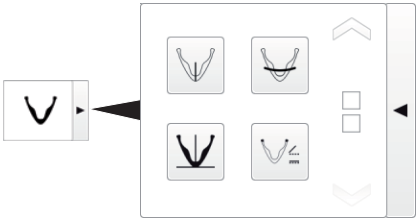


Fig. 2: Example: expanded menu

2. Select a command.

6.3 Calling up messages on the touch screen

The view on the touchscreen displays the current messages.
The *Messages* view at *Settings* > *Service menu* > *Messages* displays the history of all messages. A switch to the *Access level Technician* is required.
Messages are divided into the following categories:

	Fault	Unit will no longer function. When the error has been remedied, it may be necessary to acknowledge the error message.
	Notice	After acknowledgment the unit will continue to work, but only with limited functions.
	Note	Important information for the operator, e.g. about the current status of the device. The unit continues to operate.
	Information	Information for the operator. The unit continues to operate.
	Fault-free operation	

1. Tap .

   This displays the message. If there are several messages, the most current with the highest priority is displayed first.

2. For more information about the message, tap .

7 Operation

CAUTION

Health risks for the patient due to contraindications

› Before using the unit on the patient, make sure that none of the listed contraindications are evident.

In this section, the term "Child" is used for children and adolescents from the age of 7.

7.1 Switch the device on

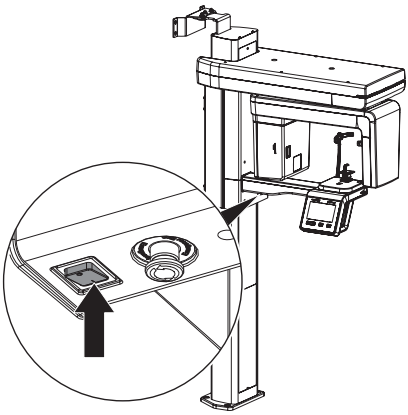
CAUTION

Danger of injury by moving rotating unit arm

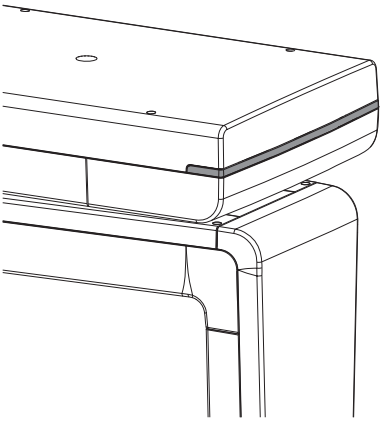
After the unit is switched on and the parameters are confirmed on the touch screen, the C-shaped angle connector piece is positioned. Persons can be injured during this.

› Nobody may be present in the area of the rotating unit arm while the unit is being switched on.

1. Use the main power switch to switch the unit on.



The main power switch lights up green after it is switched on. The status LED lights up blue.



7.2 Making settings in the imaging software

The settings are described using the VistaSoft imaging software for an example.
For further information regarding the use of the imaging software, refer to the relevant manual.

Children are more sensitive to radiation than adults. Keep the exposure parameters as low as possible taking into consideration the image quality. Refer also to the FDA information on pediatric X-ray imaging.
(refer to the FDA website on this topic, see https://tinyurl.com/FDAPediatric).

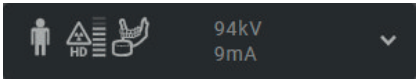
Preparing an X-ray image acquisition in VistaSoft

Requirements:
- ✓ VistaSoft has been opened.
- ✓ Patient is logged in.
- ✓ No other image acquisitions are in progress (X-ray or video).

1. Click on the required image in the menu bar (e.g. for a CBCT image).
   Use ❯ to call up further acquisition types that belong to the grouping. e.g. for 5x5 maxillary molar right (see "Image acquisition programs").

Depending on how the image acquisition types are configured, the acquisition of the X-ray image will start either immediately or you will first need to select an X-ray station.

2. If image acquisition does not begin automatically, select the X-ray station.
   The parameters, imaging volume, and patient shape are pre-selected according to the patient.
3. Check the parameters (see also "Parameter overview").



   Click on Parameters to open the flyout for setting the parameters. The changed parameters are immediately synchronized with the device.
4. If the pre-selected parameters are correct, continue to work directly on the device.

Parameter overview

Depending on the chosen image acquisition program, different parameters are available (e. g. the image volume is not available for panoramic images, but the jaw arch is instead).

Image volume

The selected image volume affects the height of the image volume. The image volume for children is reduced in height. The diameter remains the same.

	Image volume "Normal" Size (W x H): approx. 100 x 85 mm
	Image volume "Child" Size (W x H): approx. 100 x 70 mm

Image quality

	HQ image The preset parameters are recommended for standard CBCT images.
	SQ image This setting is applied for indication-based low-dose acquisition. Lower dose values are required with the same circulation time. SQ images exhibit a lower signal/noise ratio.
	HD acquisition A better signal/noise ratio is achieved through extended exposure time. Patient dose is thereby increased. Lateral full-format skull is not supported in HD.
	SD acquisition Setting is for pano standard images.

Patient type

The selection of patient type depends on the patient's size and/or head circumference. This means that the preset patient type may need to be changed, if necessary.
The X-ray parameters are preset based on the patient type (see "Appendix").

If a child is selected, then the X-ray parameters are different:
- Reduced dose
- Shorter circulation time
- Smaller radiation field

	Tall, well-built patient
	Average patient
	Small patient
	Child (< 13 years of age)

Jaw arch

The selected jaw shape affects the rotational behavior of the C-shaped arm during image acquisition. This enables an image with an ideal layer position to be captured even on a particularly narrow or wide jaw.

	Normal jaw arch
	Narrow jaw arch
	Wide jaw arch
	Child's jaw arch

Image acquisition programs

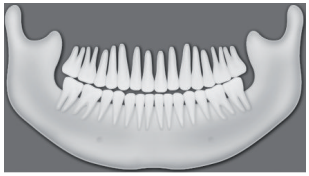
CBCT images	
	**CBCT** The CBCT image shows the jaw area. The size of the jaw area shown depends on the selected image volume. Resolution: 200 µm
	**CBCT maxilla** The image shows the maxilla. Resolution: 200 µm
	**CBCT mandible** The CBCT image shows the mandible. Resolution: 200 µm
	**CBCT 5x5 Maxilla Molar right** The X-ray image depicts the right molar region of the maxilla with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Maxilla Premolar right** The X-ray image depicts the right premolar region of the maxilla with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Maxilla Front** The X-ray image depicts the front region of the maxilla with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Maxilla Premolar left** The X-ray image depicts the left premolar region of the maxilla with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Maxilla Molar left** The X-ray image depicts the left molar region of the maxilla with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Mandible Molar right** The X-ray image depicts the right molar region of the mandible with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Mandible Premolar right** The X-ray image depicts the right premolar region of the mandible with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Mandible Front** The X-ray image depicts the front region of the mandible with a volume of 5x5 cm. Resolution*: 120 µm
	**CBCT 5x5 Mandible Premolar left** The X-ray image depicts the left premolar region of the mandible with a volume of 5x5 cm. Resolution*: 120 µm

CBCT images

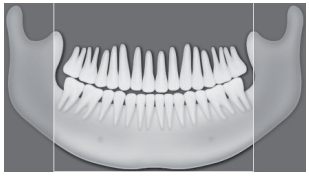
CBCT 5x5 Mandible Molar left
The X-ray image depicts the left molar region of the mandible with a volume of 5x5 cm.
Resolution*: 120 µm

* The resolution can be changed to 80 µm in the service menu of the device.
For panoramic images of children, the size of the radiation field is reduced with the aid of an additional collimator. The radiation dose is significantly reduced for this image.

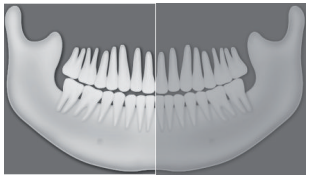
Panoramic images

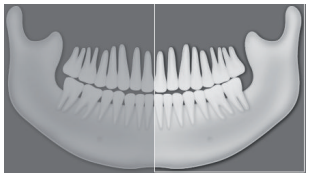
Standard
The standard panoramic image records the complete dental area with ascending dental branches and jaw joints.

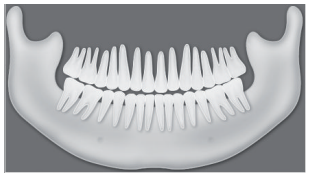
Front
The image shows a reduced dental area without ascending dental branches.

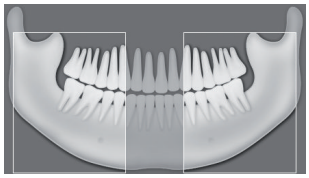
Right
The image only shows the right dental area.

Left
The image only shows the left dental area.

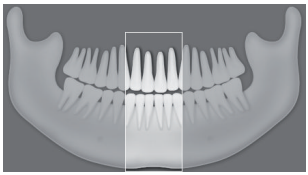



Orthogonal
The image shows the complete dental area and is generated perpendicular to the maxillary arch. This prevents overlapping crowns.

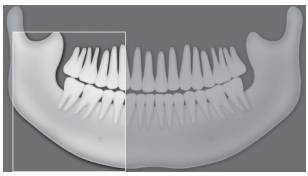



Bitewing
The image shows the lateral dental area with a size limited to the bite wings.

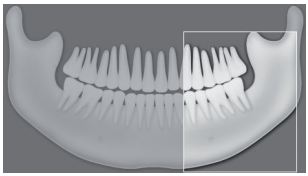
Panoramic images



Bite wing front
The image shows the anterior dental area with a size limited to the bite wings.



Bite wing right
The image shows the right posterior region with a size limited to the bite wings.



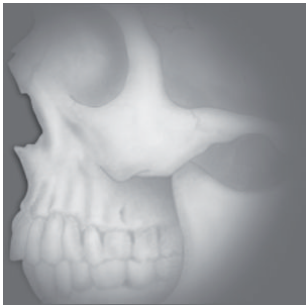
Bite wing left
The image shows the left posterior region with a size limited to the bite wings.

Temporomandibular imaging

Maxillary joint, lateral
The image shows the lateral maxillary joints for an open and closed mouth in 4-fold depiction in one image.

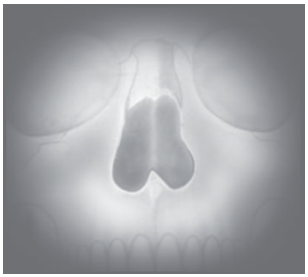
Maxillary joint, PA
The image shows the posterior-anterior maxillary joints for an open and closed mouth in 4-fold depiction in one image.

Sinus images



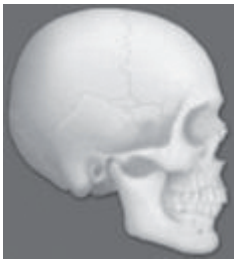
Sinus, lateral
The X-ray image shows the lateral sinuses.

Sinus images

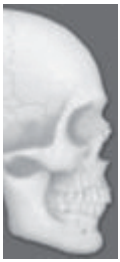


Sinus, PA
The X-ray image shows the posterior-anterior sinuses.

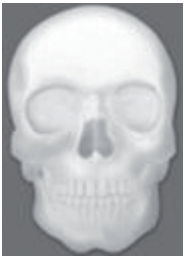
Cephalometric exposures



Head Lateral Full format
The X-ray image shows the entire head of the patient in a lateral view.
This image recording program can be selected in some versions.

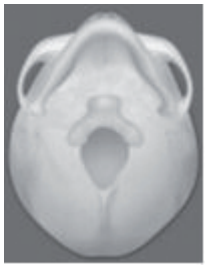


Head Lateral
The X-ray image shows the facial skull of the patient in a lateral view.
This image recording program can be selected in some versions.

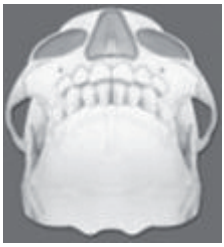


Head PA
The image shows the posterior/anterior cranium. It is suitable for semi-axial cranial images and provides a cranial eccentric overview.

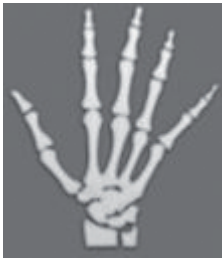
Cephalometric exposures



SMV
The image shows the cranium in a submentovertex projection. It is suitable for recording the jaw arch and the jaw joints, for example.



Waters View
This view is suitable for recording the articular head in the mandibular joint socket, for example.



Carpus
The image shows the carpus of the patient. It is suitable for providing conclusions on the growth stage of the body/jaw.

7.3 Inserting the positioning aids

For the acquisition of the X-ray image, the patient is positioned in the unit using the corresponding positioning aids and then accurately aligned using the positioning beams.

WARNING

Danger due to non-reprocessed products

Risk of infection for operator and patient

› Reprocess the product correctly and sterilize it as required prior to the first use and after every subsequent use.
› Do not reprocess disposable items.

WARNING

Danger from the re-use of products intended for single use

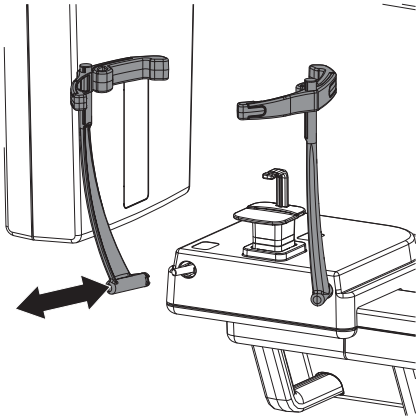
Single-use article is damaged after use and cannot be reused.

› Dispose of single-use articles after use.

Inserting the head supports

If no head supports are inserted or if they are dirty, insert new head supports before positioning the patient.

1. Remove any dirty head supports by pulling them out.
2. Insert new head supports.
   When doing this, make sure that the cushions of the head supports face inwards.

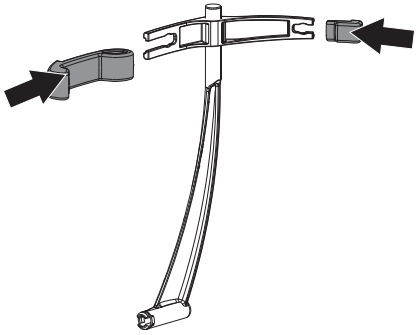


Inserting the cushions of the head supports

If no cushions are inserted in the head supports or if they are dirty, insert new cushions before you position the patient.

1. Remove any dirty cushions by pulling them out.
2. Inserting the cushion holder.

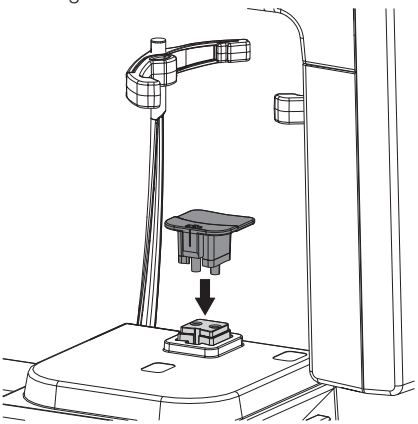
3. Insert new cushions in the cutout provided on the head supports.



Inserting the positioning aid for CBCT images

We recommend using the holder for bite block on CBCT images. The bite block can be used optionally in addition to this.
In the case of edentulous patients, the chin support for edentulous jaws can be used.
The other positioning aids can also be used, depending on the application scenario.

1. Inserting the holder for bite block.



The bite block can be used with or without a hygienic protective cover.

We recommend using the bite block with a hygienic protective cover.

If the bite block is used without a hygienic protective cover, refer to the instructions under "Inserting the positioning aid for panoramic images with hygienic protective cover (optional)" and the reprocessing instructions under "9 Reprocessing".

WARNING

There is a danger of cross contamination if hygienic protective covers are not used or if they are re-used

- › Reprocess the bite block after using it without the hygienic protective cover.
- › Do not re-use the hygienic protective cover (disposable item).

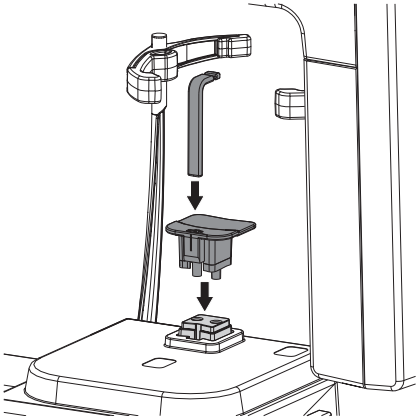
WARNING

Danger from the re-use of products intended for single use

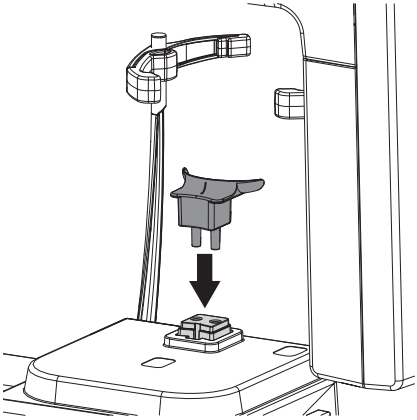
Single-use article is damaged after use and cannot be reused.

- › Dispose of single-use articles after use.

2. Optionally insert the bite block.



3. In the case of edentulous patients, the chin support for edentulous jaws can be used.



Inserting the positioning aid for panoramic images

We recommend using the holder for the bite block together with the bite block itself, or the comfort bite block with foam padding.
The Universal Chin Rest provides greater patient stability and added comfort in the chin area, as well as an optimized FOV in the maxillary region.
In the case of edentulous patients, the chin support for edentulous jaws can be used.
The other positioning aids can also be used, depending on the application scenario.

The bite block can be used with or without a hygienic protective cover.

We recommend using the bite block with a hygienic protective cover.

If the bite block is used without a hygienic protective cover, refer to the information under "Inserting the positioning aid for panoramic images with hygienic protective cover (optional)" and the reprocessing instructions under "9 Reprocessing".

If the Comfort bite block is to be used with the foam pad, refer to the information under "7 Operation" and the reprocessing instructions under "9 Reprocessing".

WARNING

There is a danger of cross contamination if hygienic protective covers are not used or if they are re-used

- › Reprocess the bite block after using it without the hygienic protective cover.
- › Do not re-use the hygienic protective cover (disposable item).

WARNING

There is a risk of cross contamination when the light protection cover is not used or when the light protection cover is re-used

- › Reprocess the Comfort bite block after using it without the foam pad.
- › Do not re-use the light protection cover (disposable item).

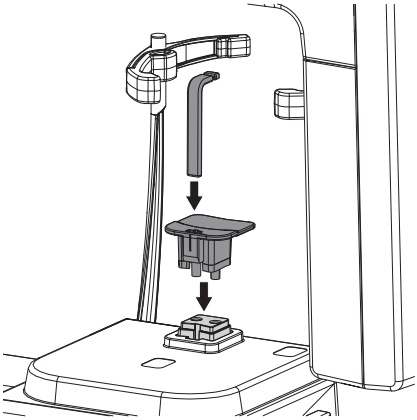
WARNING

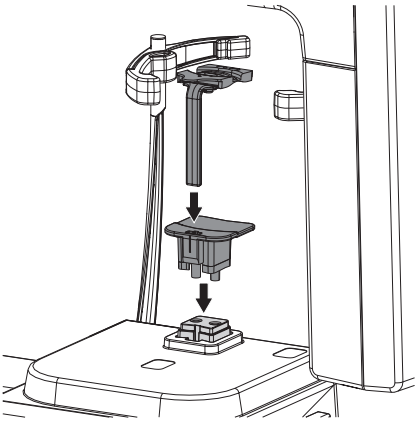
Danger from the re-use of products intended for single use

Single-use article is damaged after use and cannot be reused.

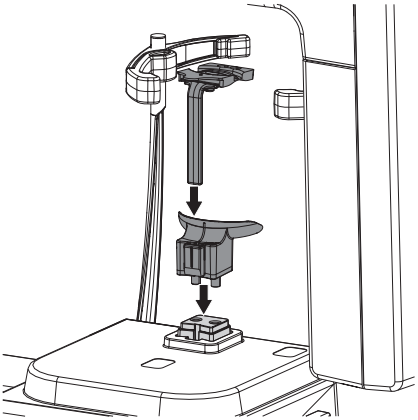
- › Dispose of single-use articles after use.

1. Insert the bite block holder with bite block or the Comfort bite block with foam pad.

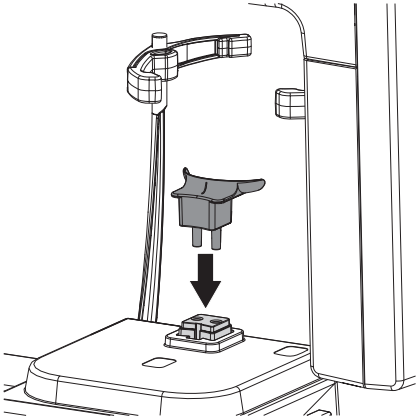




2. Use the Universal Chin Rest together with the comfort bite block with foam padding.



3. In the case of edentulous patients, the chin support for edentulous jaws can be used.



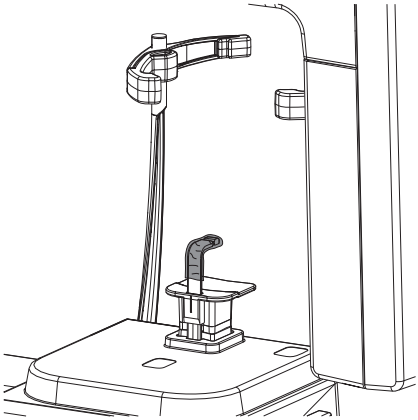
Inserting the positioning aid for panoramic images with hygienic protective cover (optional)

WARNING

Risk of cross contamination due to non-reprocessed bite block

› Reprocess the bite block in accordance with the reprocessing instructions.

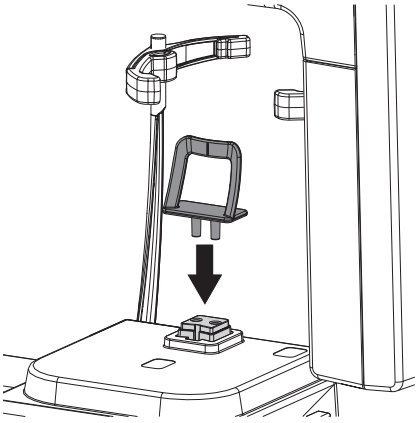
1. Optionally place a hygienic protective cover over the bite block.



Inserting the positioning aid for the maxillary joint image

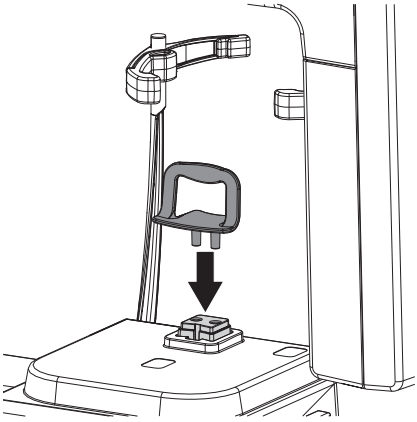
Correct image acquisition is only possible with the chin support for maxillary joint images.

1. Inserting the chin support for the maxillary joint image.

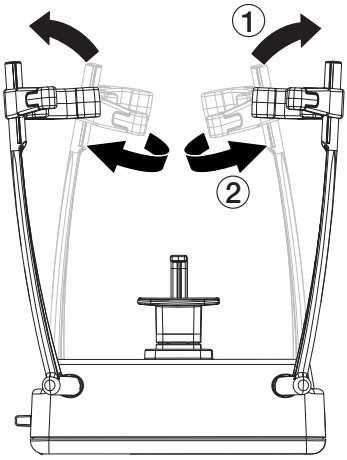


Inserting the positioning aid for sinus images

1. Inserting the chin support for sinus images.



Opening the head supports



1. Open the head supports by pressing the "Close/open head supports" button on the touch screen.
2. Open the cushion holder with cushions properly such that the patient can be positioned.

7.4 Positioning the patient

For the X-ray image, the patient is accurately aligned using the positioning beams.

Requirements:

- ✓ The patient has taken off jewelry and metal objects, e.g. earrings, hair slides, glasses, artificial dentures or orthodontic aids.
- ✓ The patient has put on a protective lead apron.
- ✓ The patient has been informed about the recording of the X-ray image.
- ✓ The patient has been informed that the unit may pass by close to his/her head (including through the field of vision). If patients feel uncomfortable with this, he or she can close his/her eyes while the image is being taken.
- ✓ The patient has been informed that he/she can press the emergency stop switch in the event of anxiety during image acquisition.
- ✓ The patient has been informed that he/she has to place his/her tongue against the roof of the mouth during the X-ray.
- ✓ The patient has been informed that he/she has to keep his/her eyes closed during positioning of the X-ray positioning beam.
- ✓ The patient has been told not to move while the X-ray is being taken until the unit is back in the starting position.

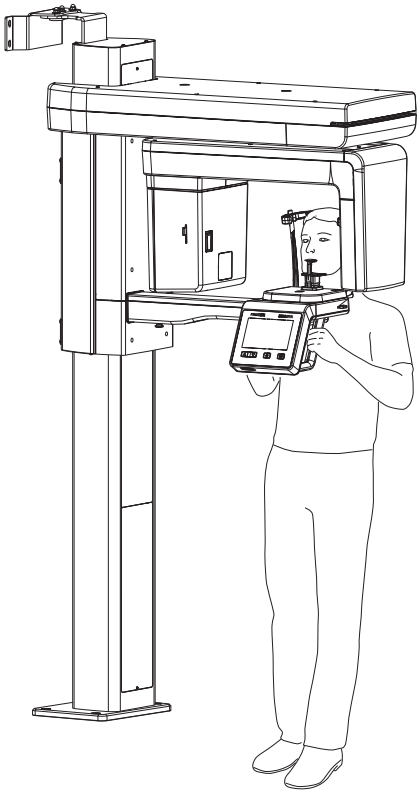
CAUTION

Danger of injury by moving rotating unit arm

After the unit is switched on and the parameters are confirmed on the touch screen, the C-shaped angle connector piece is positioned. Persons can be injured during this.

› Nobody may be present in the area of the rotating unit arm while the unit is being switched on.

1. Move the patient into an upright position at the unit.
   It is also possible to position patients in a seated position (e.g. wheelchair users, tall patients).

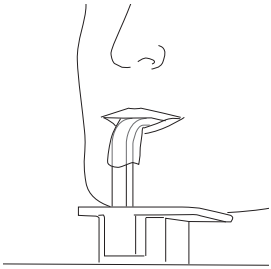


2. Use the ▲ ▼ buttons to set the height level of the unit.

CBCT image acquisition

The patient is positioned as follows depending on the indication:

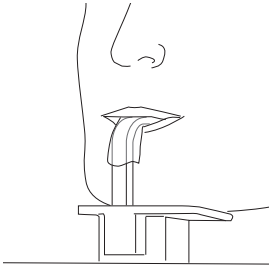
1. The patient bites onto the bite block, with the upper and lower incisors resting in the grooves provided.



2. Use of the chin support for edentulous patients. Here, the patient places his/her chin on the chin support.

Panoramic image acquisition

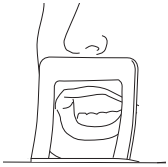
1. The patient bites onto the bite block, with the upper and lower incisors resting in the grooves provided.

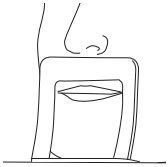


2. Use the chin support for edentulous patients in the case of patients who do not have any teeth. Here, the patient places his/her chin on the chin support.

Maxillary joint image

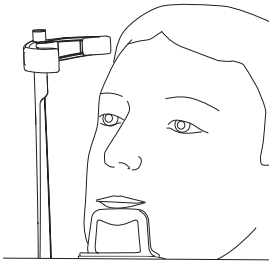
1. Position the patient with the upper lip against the chin support.





Sinus image acquisition

1. Position the patient so that his/her bottom lip presses lightly against the chin support.



Adjusting the position with the positioning beams

The positioning beams consist of class 1 laser beams. They can produce a glare for patients but are not dangerous for eyes.

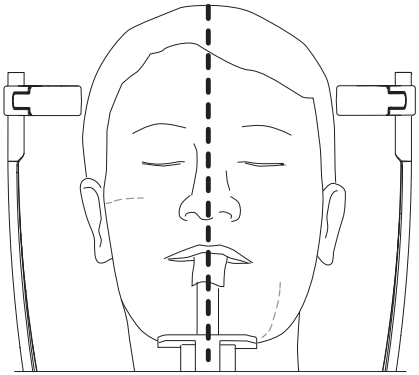
For CBCT images it is sufficient to perform positioning based on the mid-sagittal plane.

For all other image types the patient needs to be positioned more accurately with the aid of the following steps.

The alignment of the upper canine X-ray positioning beam is crucial for the image quality of panoramic images.

1. Check to make sure that the patient has closed his/her eyes.
2. If necessary, correct the height of the unit again.
3. Activate the positioning beams with the button.

4. Check the X-ray positioning beam for the mid-sagittal plane and correct the position of the patient if necessary.



5. Align the head of the patient according to the Frankfurt horizontal plane with the aid of the X-ray positioning beam.
Exception: sinus image. Patient over-extends the cervical vertebral column to the rear by approx. 10° to 15°.

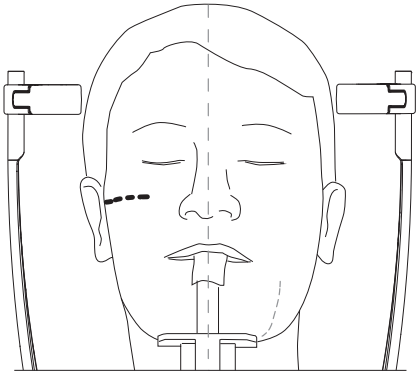
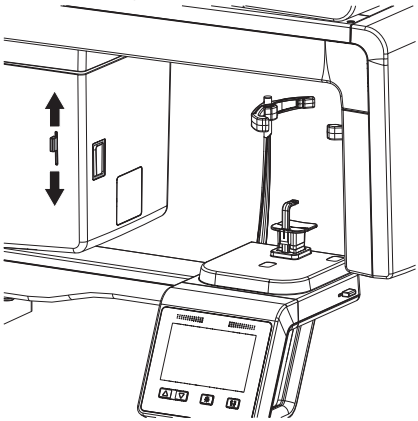
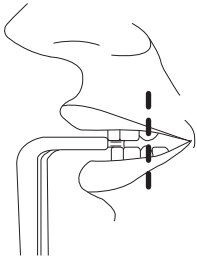


Fig. 3: Frankfurt plane: laser height at the lower edge of the eyes

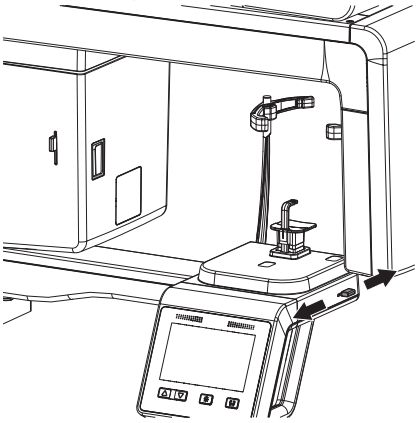
6. Correct any inclination of the head via the height of the unit.
If necessary, correct the X-ray positioning beam manually.



7. Direct the "upper canine" X-ray positioning beam as exactly as possible to the middle of the upper canine.
Have the patient smile so the upper canine is visible.



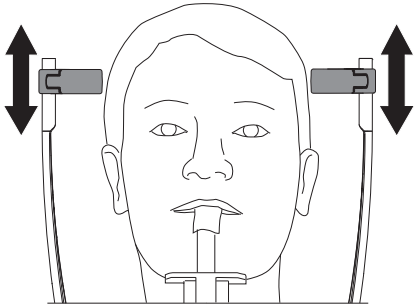
8. If necessary, correct the X-ray positioning beam manually.



9. Once the patient has been correctly positioned using the positioning beams, deactivate the positioning beams using the button.

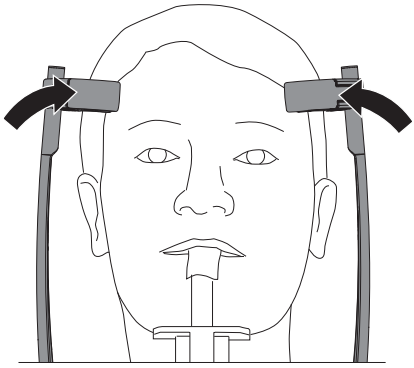
Adjusting the head supports

1. Adjust the height of the head supports.



2. Carefully press the head supports by hand towards the head in order to check if they are in the right position. The device or the head supports are not damaged in the process.
   Ideally, the head supports should make contact slightly above the eye brows; correct the position as required.

3. Close the head supports with the button.
   To do this, just press the button briefly – don't press and hold.



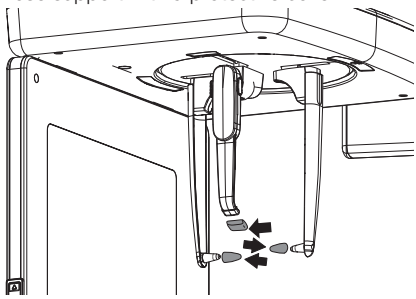
   The head supports automatically touch against the head of the patient at a defined pressure.

7.5 Cephalometric exposures

Setting up the unit

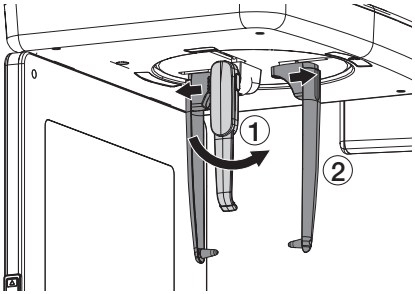
1. Disinfect the positioning aids, see "8 Cleaning and disinfection".

2. Fit the ear rods with protective caps and the nose support with a protective cover.



3. Grasp the holder for the ear rods at the top and push outwards.

4. Swivel the nose support to the side.



5. Use the ▲ ▼ buttons to adjust the unit to the height of the patient.

Positioning the patient

For recording of the X-ray image, the patient is positioned in the unit using the relevant positioning aids. The patient must not move while the image is being taken.

Requirements:

- ✓ The patient has taken off jewelry and metal objects, e.g. earrings, hair slides, glasses, artificial dentures or orthodontic aids.
- ✓ The patient has put on a protective lead apron.
- ✓ The patient has been informed about the recording of the X-ray image.
- ✓ The patient has been told not to move while the X-ray is being taken until the unit is back in the starting position.

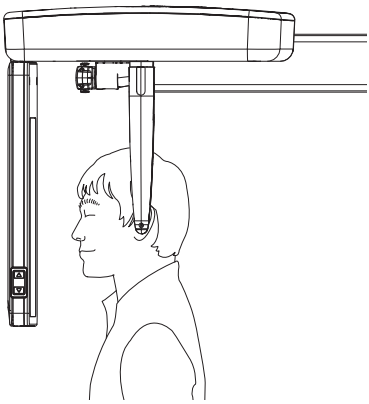
1. Use the ▲ ▼ buttons to set the unit to the height of the patient.

Preparations for the head PA image

- ✓ The holders for the ear rods are pushed apart.
- ✓ The nose support is swiveled upwards.
- ✓ The holders for the ear rods are rotated by 90° toward the sensor.
- ✓ The ear rods are fitted with protective caps and the nose support is fitted with a protective cover.
- ✓ The unit is adjusted to the height of the patient

1. Place the patient vertical with his/her face towards the sensor. The Frankfurt plane of the patient is parallel to the floor.

2. Adjust the holders for the ear rods to the height of the external auditory canals of the patient.



Preparations for the lateral head image

- ✓ The holders for the ear rods are pushed apart.
- ✓ The nose support is swiveled upwards.
- ✓ The holders for the ear rods are in a line with the sensor.
- ✓ The ear rods are fitted with protective caps and the nose support is fitted with a protective cover.
- ✓ The unit is adjusted to the height of the patient

1. Place the patient with his/her face towards the nose support. The Frankfurt plane of the patient is parallel to the floor.

WARNING

Risk of injury when positioning the ear rods

If the ear rods are positioned with jerky movements on the patient, there is a risk that the patient's eardrum will be damaged.

› Grasp the ear rod holder at the top with both hands and gently squeeze it together until it is placed in the patient's auditory canal.

2. Adjust the holders for the ear rods to the height of the external auditory canals of the patient.

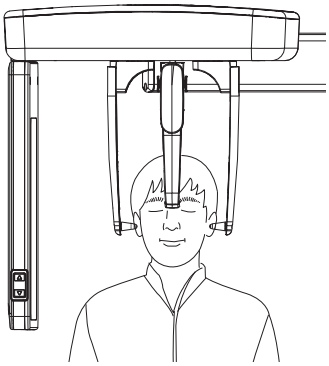
CAUTION

Danger of injury due to nose support not being positioned

The moving secondary collimator causes injury and damage to the machine if the nose support is folded to the side

› Correctly position the nose support.

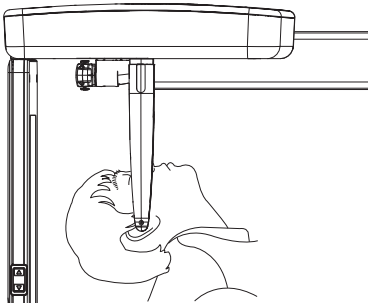
3. Position the nose support at the height of the nasal bridge.



Preparations for the SMV image

✓ The holders for the ear rods are pushed apart.
✓ The nose support is swiveled upwards.
✓ The holders for the ear rods are rotated by 90° toward the sensor.
✓ The ear rods are fitted with protective caps.
✓ The unit is adjusted to the height of the patient

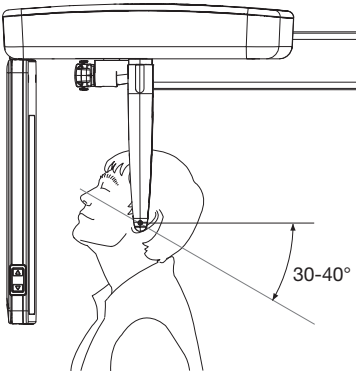
1. Place the patient upright, with his/her face towards the secondary collimator.
2. Instruct the patient to tilt his/her head backwards.
3. Adjust the holders for the ear rods to the height of the external auditory canals of the patient.



Preparations for the Waters View image

✓ The holders for the ear rods are pushed apart.
✓ The nose support is swiveled upwards.
✓ The holders for the ear rods are rotated by 90° toward the sensor.
✓ The ear rods are fitted with protective caps.
✓ The unit is adjusted to the height of the patient

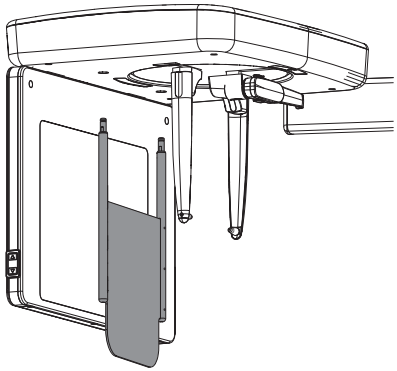
1. Place the patient vertical with his/her face towards the sensor.
2. Instruct the patient to tilt his/her head backwards.
3. Adjust the holders for the ear rods to the height of the external auditory canals of the patient.



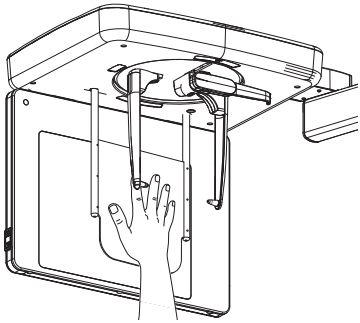
Preparations for the carpus image

✓ The holders for the ear rods are pushed apart.
✓ The holders for the ear rods are rotated by 90° toward the sensor.

1. Insert the carpus plate into the holes provided until it clicks into place.



2. Place the patient sideways to the unit.
3. Adjust the height of the unit so the patient can lay his/her hand on the carpus plate with the arm bent.
4. The patient lays his/her right hand on the carpus plate with the fingers outstretched.



7.6 Start a test run

The test run ensures that the unit can perform the image acquisition without any problems. This prevents unnecessary exposure of the patient to radiation.

No radiation is generated during the test run.

Requirements:
✓ The patient is correctly positioned in the unit using the positioning aids and the positioning beams.
✓ The required imaging program has been selected.

1. Touch *Test run* on the touch screen.
2. Tap *Run* and hold.
   While doing this, constantly monitor the movements of the unit. If the unit is obstructed in its movements, release the *Run* button. The unit stops immediately. Reposition the patient.
3. Press *Return run* to perform the return run.

7.7 Taking the X-ray image

CAUTION

Injuries due to X-rays

X-rays can cause tissue damage.

› Comply with the radiation protection regulations.
› Maintain the minimum distance.

CAUTION

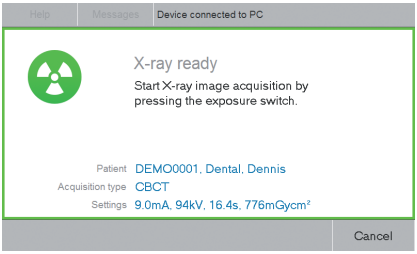
Danger of excessively high radiation dose

› Before an image acquisition is triggered, all data entered on the PC must be checked on the touch screen.

1. Check all parameters on the touch screen and change them if necessary.
   The changed parameters are immediately synchronized with the imaging software. The parameters can then no longer be changed in the imaging software.
2. Remind the patient to press his/her tongue against the roof of the mouth during image acquisition.

3. Press *Start* to confirm the parameters.

   The rotating unit is being positioned. The LED on the exposure switch and the status LED on the unit light up green.
   The touch screen displays that the unit is ready to take an image.



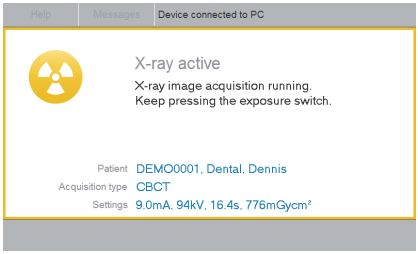
4. Trigger the image by pressing and holding the button on the exposure switch until the acoustic signal stops and the control lamp goes out. The scan times depend on the patient type, imaging program and image quality (see "13 Program parameters").

   Image acquisition is started. During the acquisition, the LED on the exposure switch and on the unit illuminates yellow. An acoustic signal is issued.

   If the button on the exposure switch is released before the control lamp goes out or the emergency stop switch is pressed (e.g. if there is a danger to the patient or to anyone else in the area), the ongoing image acquisition is aborted. The X-ray image will be unusable as a result and should be retaken as required. In this case, the operators must use their skills and training to decide on the risks of a repeated image acquisition.

   In addition, an error messages appears on the touch screen.

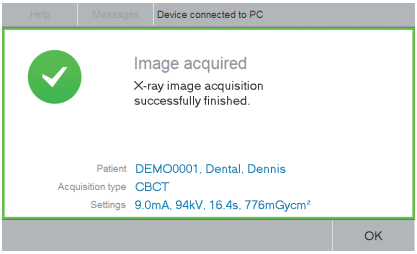
   While an X-ray is being taken, this is indicated on the touch screen by:



   After the acquisition of maxillary joint images, it is necessary to confirm a message on the touch screen and trigger a second image acquisition. The images are then combined into a single image.

   The LED on the unit lights up blue when the X-ray acquisition has been completed.
   The rotating unit does not automatically move back to the starting position after the trigger button is released.

5. Click *OK* to confirm the message.



6. Release the head supports.
   The patient can leave the X-ray room.
7. Remove the hygienic protective cover.
8. Remove and disinfect the positioning aids.
9. The unit can be returned to its starting position by touching *Start position*. Otherwise, the C-shaped arm is positioned via the imaging software during adjustment of the parameters.

7.8 Emergency stop switch

The emergency stop switch stops the unit and switches it off. It can be used if the unit is taking an X-ray even though the exposure button is no longer being pressed, or if the patient is injured or the unit is damaged. It can also be used to avert an unwanted collision.
The yellow stickers on the patient positioning system with the symbol show the location of the emergency stop switch.

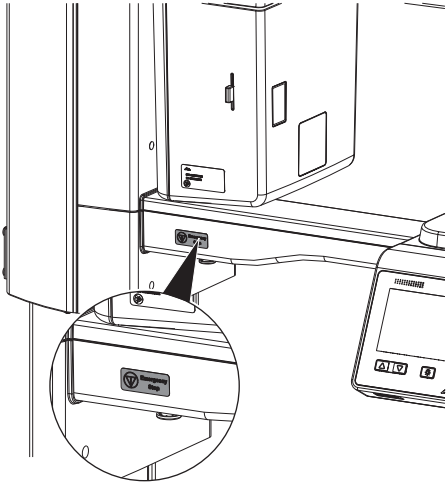


Fig. 4: Emergency stop switch sticker on the operator side

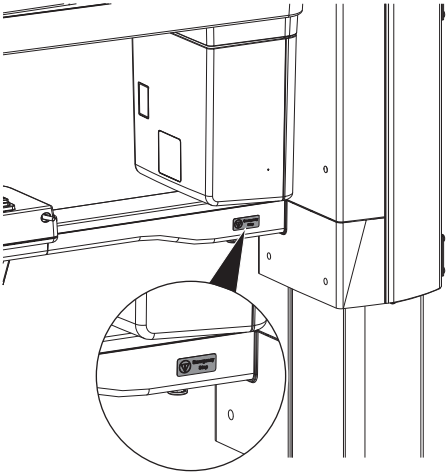
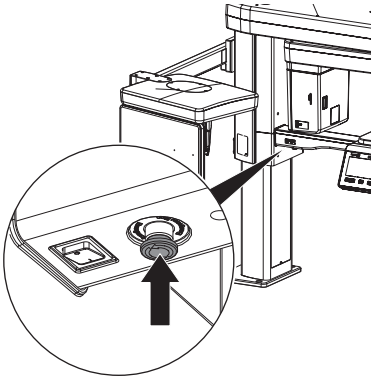


Fig. 5: Emergency stop switch sticker on the patient side

Misuse of the emergency stop switch can lead to data loss.

1. Press the emergency stop switch.



Device is switched off.

Releasing the emergency stop switch

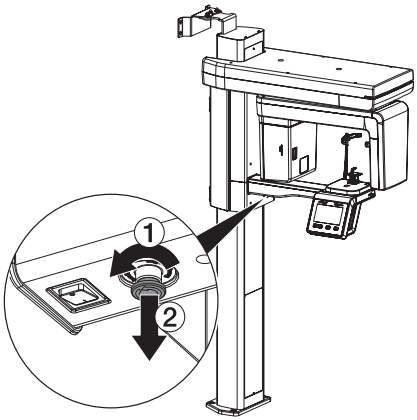
CAUTION

Danger of injury by moving rotating unit arm

After the unit is switched on and the parameters are confirmed on the touch screen, the C-shaped angle connector piece is positioned. Persons can be injured during this.

› Nobody may be present in the area of the rotating unit arm while the unit is being switched on.

1. Twist the emergency stop switch to release it.



The unit automatically restarts.

8 Cleaning and disinfection

NOTICE

The use of unsuitable agents and methods can damage the unit and accessories

› Only use the disinfection and cleaning agents specified or approved by Air Techniques and the EPA.

› Comply with the operating instructions of the disinfectants and cleaning agents.

Wear hand protection.

Prior to working on the unit or in case of danger, disconnect it from the mains.

The following cleansers and disinfection agents have been tested for the compatibility of materials:

- Birex wipes
- Discide Ultra Towelettes
- Opti Cide 3 surface wipes
- Optim 33TB wipes
- Maxiwipe germicidal cloth
- Cavi Wipes
- Cavi Wipes 1
- PDI Sani-Cloth
- Clorox
- Monarch

8.1 Surface of the unit

NOTICE

Damage to the touch screen caused by cleaning it with disinfectant

› Only clean the touch screen with a soft cloth and a commercially available cleaning agent.

The surface of the unit must be cleaned and disinfected if it is contaminated or soiled.

NOTICE

Liquid can cause damage to the unit

› Do not spray the unit with cleaning agents or disinfectants.

› Make sure that no liquid penetrates into the unit.

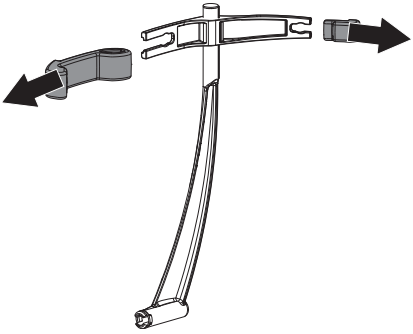
1. Remove any soiling with a soft, damp, lint-free cloth.
2. Disinfect the surfaces with a disinfection wipe. Alternatively, use a quick-acting surface disinfectant on a soft, lint-free cloth. Comply with the operating instructions of the disinfectant.

8.2 Positioning aids

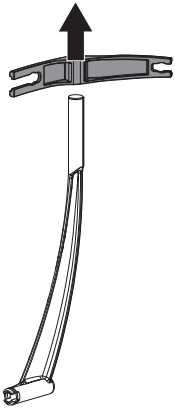
The positioning aids must be cleaned and disinfected if they are contaminated or soiled.

Head supports with cushion

1. Pull the head supports off the device.
2. Remove the cushions from the head supports.



3. Remove the cushion holder.



4. Remove any soiling with a soft, damp, lint-free cloth.
5. Disinfect the surfaces using a disinfection wipe. Alternatively, use a quick-acting surface disinfectant on a soft, lint-free cloth. Comply with the operating instructions of the disinfectant.
6. Reprocessing the cushions (see "9 Reprocessing").

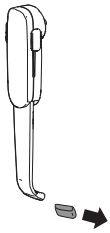
Ear rod holder with ear rods

1. Remove the ear rods from the ear rod holder.

2. Remove any soiling with a soft, damp, lint-free cloth.
3. Disinfect the surfaces using a disinfection wipe. Alternatively, use a quick-acting surface disinfectant on a soft, lint-free cloth. Comply with the operating instructions of the disinfectant.
4. Reprocess the ear rods (see "9 Reprocessing").

Nose support with protective cover

1. Remove the protective cover from the nose support.



2. Remove any soiling with a soft, damp, lint-free cloth.
3. Disinfect the surfaces using a disinfection wipe. Alternatively, use a quick-acting surface disinfectant on a soft, lint-free cloth. Comply with the operating instructions of the disinfectant.

4. Reprocess the protective cover (see "9 Reprocessing").

Carpus plate and grips

1. Clean and disinfect the carpus plate and grips (see "8 Cleaning and disinfection").

9 Reprocessing

The following accessories need to be reprocessed:

- Bite block:
  - Manual cleaning
  - Automatic cleaning and disinfection
  - Steam sterilization
- Holder for bite block, chin rest for TMJ imaging, universal chin rest, chin support for edentulous patients, and chin rest for sinus imaging
  - Manual cleaning
  - Manual disinfection
  - Automatic cleaning and disinfection
- Cushion for head supports Plus
  - Manual cleaning
  - Manual disinfection
  - Automatic cleaning and disinfection

In order to prevent damage to the accessories, only the methods described above must be used.

9.1 Risk analysis and classification

A risk analysis and classification of medical devices that are common in dentistry must be performed before they are reprocessed by the operator. Comply with the country-specific guidelines, standards and regulations.
Accessories of the medical device are also subject to reprocessing.

Classification recommendation according to EN ISO 17664-1, Annex C

Recommended classification given proper use of the bite block:

- **semi-critical**

Classification recommendation for the intended use of the holder for the bite block, chin rest for TMJ imaging, universal chin rest, chin support for edentulous patients, chin rest for sinus imaging, and Plus headrest pads:
non-critical
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

9.2 Reprocessing procedure according to EN ISO 17664-1

Perform the reprocessing procedure after each patient treatment and according to the reprocessing procedure established by EN ISO 17664-1.

Important information!

The reprocessing instructions in accordance with ISO 17664-1 have been independently tested by the manufacturer for the preparation of the device and its components for their reuse.

The person conducting the reprocessing is responsible for ensuring that the reprocessing is performed using equipment, materials and personnel that attains the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff reprocessing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible. Frequent reprocessing has little effect on the components of the device. The end of the product life cycle is mainly influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing procedure was validated as follows:
- Pre-cleaning:
  - Monarch surface disinfection wipes (Air Techniques)
  - Cleaning brush
- Manual cleaning:
  - Monarch enzymatic cleaner 2.0 % (v/v) (Air Techniques)
- Manual disinfection:
  - Monarch surface disinfection wipes (Air Techniques)
- Automated cleaning and disinfection was performed in accordance with EN ISO 15883 with tested efficacy:
  - Washer-disinfector PG 8536 CD (Miele, Gütersloh, Germany)
  - Cleaning agent: Neodisher MediClean Forte
  - Programs: *Cleaning without neutralization* and *THERMAL DES*
- Steam sterilization:
  - Steam sterilizer Systec DX-45 (Systec GmbH, Linden, Germany)

9.3 General information

1. Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilization of medical devices as well as the specific specifications for dental practices and clinics.
2. Comply with the specifications (in "9.5 Manual cleaning, intermediate rinsing, disinfection, drying" and "9.6 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying") when you select the cleaning agents and disinfectants to be used.
3. Comply with the concentrations, temperatures, residence times and post-rinsing specifications issued by the manufacturer of the cleaning agent and disinfectant.
4. Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
5. Only use disinfectants that are aldehyde-free and display material compatibility with the product.
6. Only process chemicals (cleaning agents, neutralizers and rinse aids) that do not affect the biocompatibility of the medical devices being treated may be used in washer-disinfectors (WDs).
7. Only use freshly-produced solutions.
8. Only use distilled or de-ionized water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. Legionella bacteria).
9. Use clean, dry, oil- and particle-free compressed air.
10. Do not exceed temperatures of 281 °F(138 °C).
11. Subject all devices used (e.g. ultrasonic bath, cleaning and disinfection device (washer-disinfector), sealing device, steam sterilizer) to regular maintenance and inspections.

9.4 Preparation at the operating location


Wear hand protection.


Wear eye protection.


Use a mask.


Wear protective clothing.

WARNING

Risk of infection from contaminated products

Risk of cross contamination

› Reprocess the product correctly and promptly before its first use and after every subsequent use.

1. Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

2. Brush off all surfaces below the water surface with a soft hygienic brush until they are clean to the eye.
3. Wipe off all surfaces for at least one minute with a disinfection wipe.

9.5 Manual cleaning, intermediate rinsing, disinfection, drying

Cleaning

1. Place individual parts in a cleaning agent bath making sure that all parts are covered.
2. Comply with the exposure times of the cleaning agent.

Intermediate rinsing

After the action time prescribed by the manufacturer has expired:

1. Rinse all components with water for at least 1 minute (temperature < 95°F).

Disinfecting

1. Wipe off all surfaces for at least one minute with a disinfection wipe.

Drying

1. If necessary, re-dry at a clean location using a hygienic, lint-free cloth.
2. Blow dry the components with compressed air in a clean location.

9.6 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:
– Satisfies ISO 15883, with verified efficacy
– Program is suitable for the components and includes sufficient rinsing cycles.
Further information: "9.3 General information".

Selection of the cleaning agents for automatic cleaning

The following properties are required:
– Material compatibility with the product
– Compliance with the washer-disinfector manufacturer's specifications

For further information, see "9.3 General information".

Cleaning and disinfection

1. Place all components in the washer-disinfector (follow the manufacturer's instructions).
2. Make sure there are no hidden areas that are missed by the rinsing process.
3. Secure the components with a suitable fixture of the washer-disinfector.

9.7 Check for function

1. After the end of the cleaning and disinfection cycle, check the components for any residual soiling and residual moisture. If necessary, repeat the cycle.
2. If necessary, replace any damaged parts.
3. The components should be packaged as soon as possible after drying and checking.

9.8 Steam sterilization

Packing

For packing of the components, only use transparent paper-film sterilization packaging that is approved for use in steam sterilization according to the manufacturer's instructions. This includes:
– Temperature resistance up to 281°F
– Standards DIN EN ISO 11607-1/2
– The applicable sections of the standard series DIN EN 868

The sterilization packaging must be sufficiently large. Once it is loaded, the sterilization packaging may not be under any strain.

Steam sterilization

WARNING

Incorrect sterilization reduces effectiveness and can damage the product

› Only steam sterilization is permitted.
› Comply with the specified process parameters.
› Comply with the manufacturer‘s instructions regarding use of the steam sterilizer.
› Do not use any other methods.

Steam sterilizer requirements:
- Complies with EN 13060 or EN 285 and/or ANSI AAMI ST79
- Suitable programs for the products listed (e. g. with hollow bodies: fractionated vacuum procedure including three vacuum steps)
- Sufficient drying of the product
- Validated processes in accordance with ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ))

Perform the following steps:

1. Sterilize the parts to be sterilized (at least 20 minutes at 250 °F (121 °C), at least 4 minutes at 270 °F (132 °C) or at least 5 minutes at 274 °F (134 °C)).
   Do not exceed a temperature of 281 °F (138 °C) in the process.

Marking

1. Mark the packaged, treated medical device appropriately such as to ensure its safe application.

9.9 Issue clearance for the parts for sterilization

The reprocessing of the medical device ends with the documented clearance for storage and renewed use.

1. Document the release of the medical device after reprocessing.

9.10 Storing parts for sterilization

1. Comply with the stated storage conditions:
   - Store the parts protected against contamination
   - Dust-protected, e.g. in a locked cabinet
   - Protected against moisture
   - Protected against excessive temperature fluctuations
   - Protected against damage

   The integrity of the packaging of a sterile medical device be lost as a result of a particular incident and the passage of time. Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

10 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.

10.1 Applicable standards in Germany

The following standards are primarily applicable to the acceptance test:
- DIN 6868-151 Acceptance test in accordance with German X-Ray Ordinance (RöV) on dental X-ray equipment
- DIN 6868-161: Acceptance test in accordance with German X-Ray Ordinance (RöV) of dental X-ray units for digital volume tomography
- DIN 6868-157: Acceptance test and consistency check of the image playback system

The following standards are primarily applicable to the consistency check:
- DIN 6868-5: Consistency check in accordance with German X-Ray Ordinance (RöV) of dental X-ray equipment
- DIN 6868-15: Consistency check in accordance with German X-Ray Ordinance (RöV) of dental X-ray equipment for digital volume tomography
- 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)

10.2 Applicable standards in other countries

The following standards are primarily applied during acceptance testing outside of Germany:
- IEC 61223-3-4 Imaging performance of dental X-ray equipment
- IEC 61223-3-7 Acceptance and constancy tests – Imaging performance of X-ray equipment for dental cone beam computed tomography

10.3 Consistency check

Inspection intervals

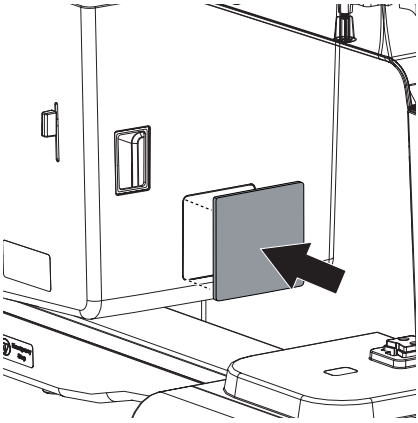
Authorities in each German federal state can set shorter or longer intervals! The tests have to be recorded and kept available for a period of two years. A chronologically-ordered X-ray control book must be kept and patient-relevant X-ray doses must be recorded.

Consistency testing of the X-ray system (according to DIN 6868-5) is carried out by the operator and must be repeated every 4 weeks (§88 StrlSchV).
Every 5 years, a recurring test has to be carried out by an expert.

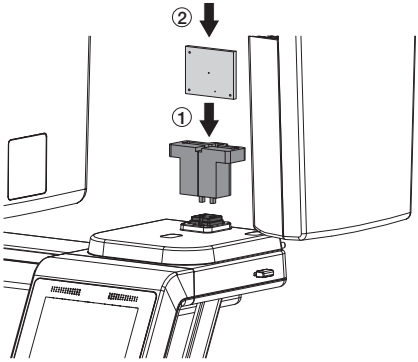
We recommend performing the acceptance and consistency tests using VistaSoft Inspect. VistaSoft Inspect detects which device is being tested and adapts the required test procedure to the device's specifications.
For information on how to perform the checks with VistaSoft Inspect, please refer to the VistaSoft Inspect software assistant.

Panoramic

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

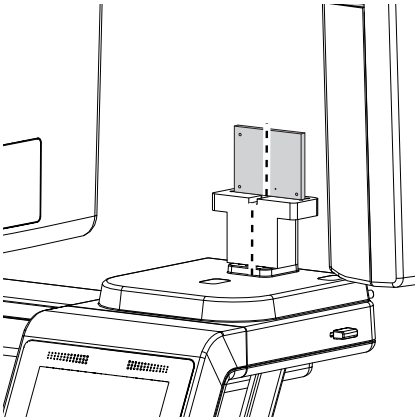


2. Remove the Intra/Extra test phantom for pano and take out the test element.
3. Place the test element holder and 6 mm Al between the X-ray tube and the detector.



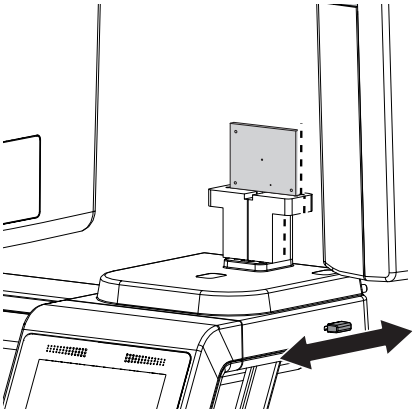
4. Activate the median-sagittal light beam.

5. Check the central alignment.

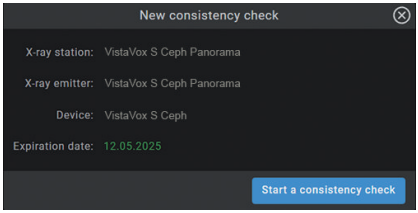


6. Set the canine light beam.

The canine light beam must pass over the notch in the test element holder.



7. Start the consistency test.

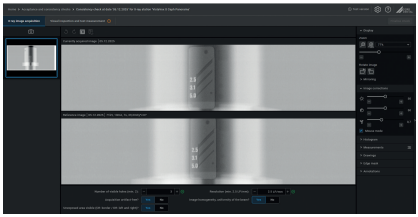


8. The reference image will be loaded.

9. Click "*Start* image acquisition.

10. Compare the generated image with the reference image.

11. Enter all information related to the image.

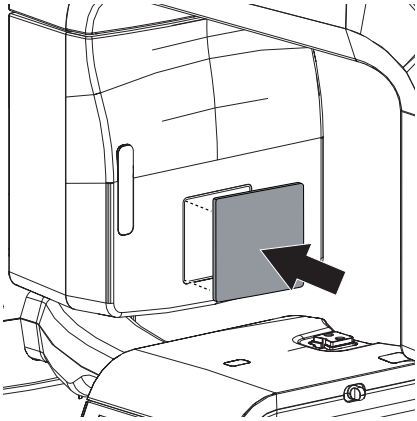


12. In the *Visual and Measurement Testing* tab, fill in the column titled *Additional information on the test*.

13. *Finalize check*

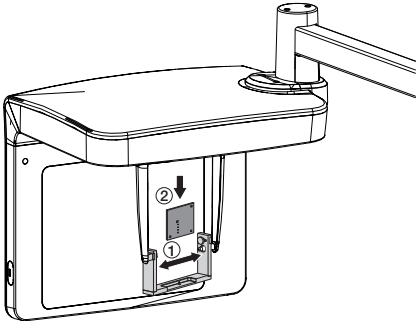
Cephalometric

1. Attach the primary absorber set for Pano/Ceph Cu 0.8 mm to the exit of the X-ray tube.

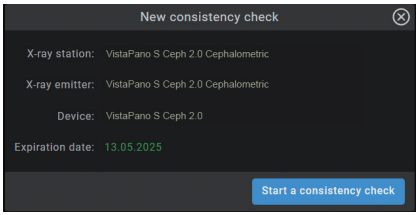


2. Remove the pano test phantom and take out the test element.

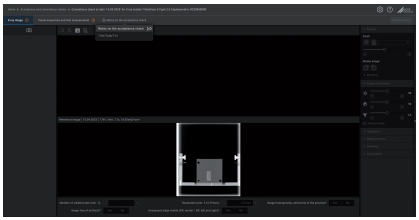
3. Place the test element holder and the test element.



4. Start the consistency test.



5. The reference image will be loaded.

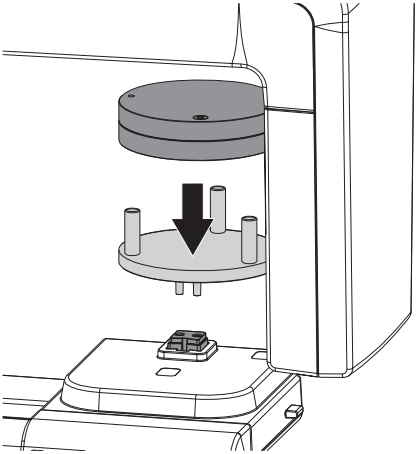


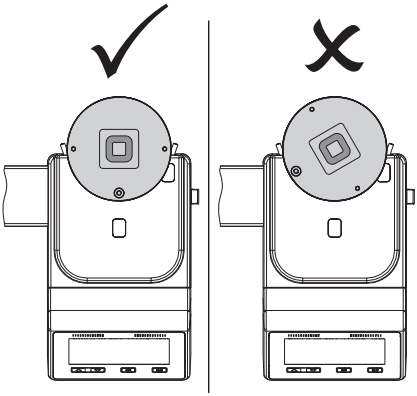
6. Click "***Start*** image acquisition.
7. Confirm the acquisition on the touch screen of the unit by clicking on ***Start***.
8. Determine the number of holes and the number of line pairs in the image.

9. Enter all values.
10. In the *Visual and Measurement Testing* tab, fill the column titled *Additional information on the test*.
11. *Finalize check*

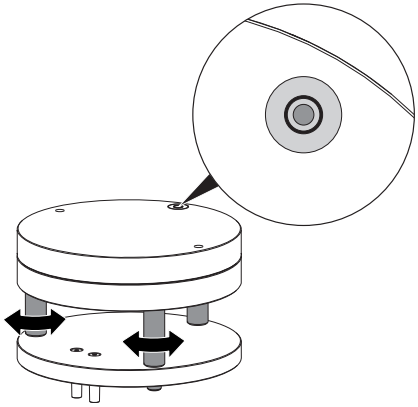
CBCT

1. Insert the test phantom consistency check CBCT.
   The test phantom must be placed as shown. Otherwise, automatic evaluation by VistaSoft Inspect will not work.

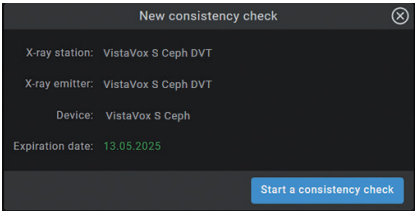




2. Use the circular spirit level to ensure that the test phantom is properly aligned. If necessary, correct the position using the leveling feet.

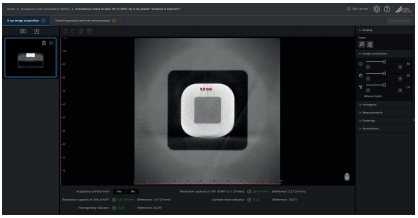


3. Start the consistency test.



4. Click "*Start* image acquisition.

5. Confirm the acquisition on the touch screen of the unit by clicking on *Start*.



6. Check the image for artifacts.
To do this, hold down the left mouse button and scroll within the image.

7. Confirm that the *image is free of artifacts*.
The other five values beneath the image must be displayed in green.

8. In the *Visual and Measurement Testing* tab, fill in the columns *Functional test of the X-ray emitter* and *Additional information on the test*.

Annual inspections are carried out by a technician.

9. *Finalize check*

11 Maintenance

11.1 Recommended maintenance schedule

Only qualified personnel or personnel trained by Air Techniques is allowed to service the unit.

WARNING

Risk of electric shock due to live parts

› Install an all-pole disconnect switch with a contact opening width of at least 3 mm in the electrical connection to the mains power supply. It must be possible to secure the disconnect switch so that it cannot be inadvertently switched back on again.

WARNING

Risk of infection from contaminated products

Risk of cross contamination

› Reprocess the product correctly and promptly before its first use and after every subsequent use.

NOTICE

Damage to the X-ray tube due to overheating

› Observe the cooling curves of the X-ray tube when working with the service tool.

Inspection interval	Inspection work
Every 3 years	› Functional test of the display. Are all symbols displayed?
	› Functional test of the exposure button.
	› Do the various status LEDs light up?
	› Check that the mechanism of the head supports works correctly. Are the head supports easy to detach and put back on?
	› Functional test of the EMERGENCY OFF button. Is the EMERGENCY OFF button easy to operate mechanically?
	› Light barrier test for all light barriers installed in the unit.
	› Visually check the positioning beams. Check the operation of the levers for adjusting the beam localizers.
	› Check the X-ray images for artifacts. If necessary, adjust the collimator and/or calibrate the sensor.
	› Check the firmware and software versions.
	› Perform a comparative dose measurement based on the requirements from the acceptance test.
	› Recurrent tests and tests after repairs of medical electrical equipment – IEC 62353 (VDE 0751-1).

Maintenance interval	Maintenance work
Every 3 years	› Visually and acoustically check the linear movement on the rotating unit.
	› Check the operation of the lift motor. Does the unit lift and lower with minimal noise?

Troubleshooting

CAUTION

Any oil leaking from the X-ray tube in the event of a fault is harmful.

- Wipe up any oil immediately.
- Do not swallow the oil.
- Stop using the unit and inform a service technician.

12 Tips for operators and service technicians

Any repairs above and beyond routine maintenance may only be done by suitably qualified personnel or by one of our service technicians.

Error	Possible cause	Remedy
Unit does not switch on	EMERGENCY STOP SWITCH accidentally activated	› Releasing the EMERGENCY STOP SWITCH.
	No mains voltage	› Check the mains cable and electrical connection; replace if necessary. › Contact technician.
		› Check the mains fuse in the building.
	On/off switch is defective	› Contact technician.
Unit not responding	The unit has not yet completed the startup procedure	› After switching on, wait until the booting process has finished.
	Cables not correctly connected	› Check the cable connections.
	Plug-in contacts of the fiber optic cable are contaminated	› Clean plug-in contacts and sockets.
	Driver for PCI Express frame grabber card is not installed or incorrectly installed	› Install driver or complete VistaVox Plugin once again.
	COM port incorrectly configured	› Check the COM port in the service tool.

Error	Possible cause	Remedy
Error messages during start of the acquisition of an X-ray image or during shut down of the PC	Energy-saving options incorrectly configured	› Deactivate the energy-saving options in Windows and the BIOS completely.
	Supply voltage for graphic card inadequate or incorrectly connected	› Check the plug connections. › Compare requirements of the graphic card with the power supply of the PC, use larger power supply if necessary.
	PC and/or graphic card fail to comply with the specified system requirements	› Set up the system in accordance with the system requirements.
	User account control (UAC) has not been correctly configured	› Make the user account control settings according to the information in the installation instructions.
	USB dongle not detected	› Check whether the USB dongle (included in scope of delivery) is plugged into the reconstruction computer, or check that the USB dongle is correctly plugged in.
	Virus scanner prevents the acquisition of an X-ray image	› Add the installation paths of the imaging software as exceptions in the virus scanner.
	Firmware of the device does not match the software version	› Check software versions and update if necessary.
	The device calibration has not been imported or incompletely imported	› Carry out initial commissioning using the service tool again/ initially.
	Door contact is not closed	› Check door contact and plug-in connections of the door contact, close door properly.

12.1 Error Codes

Messages that the device may display to the user.

Warning

– The device is temporarily not operational. Once the cause has been resolved, the device will be available again. Information

Information

– Information for the operator.

Note

– Information for the user providing guidance on the workflow.

Warning

Error	Possible cause	Remedy
4117001B	No connection to the device.	› Switch the device on › Check the connection to the device

Error	Possible cause	Remedy
47070022	Error during image acquisition.	› If available, start data recovery according to the imaging software instructions.
41270025	The device needs Windows administrator rights to continue.	› Make the user account control settings according to the information in the installation instructions
4122001D	Missing license dongle.	› Check whether the license dongle is inserted into the reconstruction PC.
4122001F	The system is not configured correctly. Calibration data is missing.	› Importing calibration data
412A001E	An internal error occurred.	› Restart the device and the PC
4708001C	Image acquisition was interrupted.	› Restart the image acquisition › Keep the hand trigger button pressed for the entire acquisition and release it only in an emergency
47090022	The reconstruction of the image data was aborted.	› Start data recovery according to the imaging software instructions. › Check the PC configuration.
41010026	Device initialization failed.	› Check the device and its surroundings › Restart unit › Contact technician
4707001D	The requested acquisition type is not supported.	› Use the correct acquisition program › Notify a technician if ceph images cannot be taken with the ceph device.
41228014	Device configuration was changed.	› Restart unit
4101001E	Internal device error.	› Restart unit

Information

Error	Possible cause	Remedy
66008010	Acquisition was aborted by user.	

Note

Error	Possible cause	Remedy
590A000F	Exposure switch was not triggered.	› Restart the acquisition if necessary
590A000E	The exposure switch is currently being pressed.	› Release the hand trigger button

Error	Possible cause	Remedy
511D000D	The door to the X-ray room is open.	› Close the X-ray room door
59050002	Temperature limit of the X-ray emitter reached.	› Allow the unit to cool down › Restart the image acquisition
570B8013	The last image acquisition was not completed.	› Start data recovery according to the imaging software instructions

Appendix

13 Program parameters

The digital 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 accuracy of the DAP/dose values is ± 50%.

The recording parameters are stored on the device. In the case of anatomical abnormalities such as an unusual jaw arch or body size, parameters can be adjusted.

13.1 CBCT program parameters

CBCT image acquisition, normal image volume, 16.4 s								
	4.0 mA		6.3 mA		8.0 mA		10.0 mA	
	mGy	mGycm²	mGy	mGycm²	mGy	mGycm²	mGy	mGycm²
75 kV	4.00	215.92	6.13	331.05	7.79	420.70	9.74	526.41
79 kV	4.50	242.90	6.89	372.41	8.76	473.26	10.96	592.17
90 kV	6.00	324.11	9.20	496.93	11.69	631.50	14.63	790.18
94 kV	6.55	353.92	10.04	542.63	12.77	689.58	15.97	862.85

CBCT image acquisition, normal image volume 5x5, 11 s										
	4.0 mA		6.3 mA		8.0 mA		10.0 mA		11.0 mA	
	mGy	mGycm²	mGy	mGycm²	mGy	mGycm²	mGy	mGycm²	mGy	mGycm²
79 kV	3.02	118.85	4.63	182.22	5.88	231.56	7.36	289.75	8.08	318.22
94 kV	4.40	173.17	6.74	265.51	8.57	337.41	10.72	422.19	11.78	463.68
98 kV	4.77	187.76	7.31	287.87	9.29	365.83	11.63	457.75	12.77	502.73

13.2 Panoramic program parameters

Pano image acquisition, normal jaw arch, normal patient, quality HQ, 13.5 s						
	4.0 mA		6.3 mA		10.0 mA	
	mGy	mGycm²	mGy	mGycm²	mGy	mGycm²
60 kV	3.85	24.28	6.06	38.15	9.57	60.31
67 kV	4.74	29.84	7.43	46.83	11.76	74.09
70 kV	5.12	32.24	8.03	50.59	12.70	80.03
74 kV	5.66	35.66	8.88	55.95	14.05	88.52
80 kV	6.47	40.79	10.16	64.00	16.07	101.25

	12.5 mA		14.0 mA	
	mGy	mGycm²	mGy	mGycm²
60 kV	11.77	74.18	13.21	83.23
67 kV	14.46	91.07	16.22	102.21
70 kV	15.61	98.37	17.52	110.40
74 kV	17.27	108.81	19.38	122.11
80 kV	19.76	124.46	22.17	139.68

13.3 Program parameters for cephalometric projections

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.

Image quality	Program	Voltage	Current	DAP	Kerma	Scan time
		kV	mA	mGycm²	mGy	s
SD	Head, lateral	90	14	21.73	0.34	1.9
SD	Head, full, lateral	90	14	54.33	0.86	3.9
SD	Head, PA	90	14	26.47	0.42	2.4
SD	SMV	90	14	26.47	0.42	2.4
SD	Waters View	90	14	26.47	0.42	2.4
SD	Carpus	88	6.3	11.44	0.18	2.4

Image quality	Program	Voltage	Current	DAP	Kerma	Scan time
		kV	mA	mGycm²	mGy	s
HD	Head, lateral	90	14	53.72	0.85	3.9
HD	Head, full, lateral	90	14	58.22	0.92	5.4
HD	Head, PA	90	14	53.72	0.85	4.9
HD	SMV	90	14	53.72	0.85	4.9
HD	Waters View	90	14	53.72	0.85	4.9
HD	Carpus	88	6.3	22.85	0.36	4.9

14 Information on scattered radiation

14.1 CBCT scattered radiation

Test equipment: Dosimeter Radcal 9015

Test conditions	
Program parameters	CBCT
Image acquisition volume	Normal
Voltage	99 kVp
Current	14 mA

R °	1 m mR/h	1.5 m mR/h	2 m mR/h
0	588.2	135.3	87.1
45	549.3	249.4	106.8
90	472.6	307.3	78.4
135	458.8	287.6	89.3
180	12.9	4.6	1.3
225	410.5	288.7	98.2
270	663.2	301.4	112.4
315	429.7	194.2	92.3

14.2 Pano scattered radiation

Test equipment: Dosimeter Radcal 9015

Test conditions	
Program parameters	Panoramic Standard
Patient size	Normal
Voltage	80 kVp
Current	14 mA

R °	1 m mR/h	1.5 m mR/h	2 m mR/h
0	60.9	17.7	8
45	19.6	12.4	5.8
90	10.6	6.8	4.1
135	22.1	12.5	5.6
180	1	0	0
225	45.4	21.4	9.4
270	47.6	21.9	9.2
315	76.4	19.4	8.6

15 Information on the leakage rate

Test equipment: Dosimeter Victoreen 660

Test conditions	
Program parameters	HD / Adult, child / Standard Pano
Distance from the focal spot	1 m
Voltage	90 kVp
Current	16 mA

Direction °	HD, Adult, 13.5 s	HD, Child, 11.5 s
0	0 mR/h	1.5 mR/h
10	3.9 mR/h	3.7 mR/h
20	4 mR/h	4.5 mR/h
30	0 mR/h	4.8 mR/h
40	0 mR/h	0.9 mR/h
45	0 mR/h	10.7 mR/h
50	4.8 mR/h	15.7 mR/h
60	0 mR/h	11.1 mR/h
70	0 mR/h	7.5 mR/h
80	4.6 mR/h	6.8 mR/h
90	2.1 mR/h	14.8 mR/h
100	0 mR/h	14.5 mR/h
110	0 mR/h	14.9 mR/h
120	0 mR/h	15.3 mR/h
130	0 mR/h	15.8 mR/h
135	0 mR/h	16.5 mR/h
140	0 mR/h	14.8 mR/h
150	0 mR/h	15 mR/h
160	0 mR/h	0 mR/h
170	0 mR/h	0 mR/h
180	0 mR/h	0 mR/h
190	0 mR/h	0 mR/h
200	0 mR/h	0.7 mR/h
210	0 mR/h	0.9 mR/h
220	0 mR/h	1.8 mR/h
225	1.3 mR/h	2.1 mR/h
230	6.2 mR/h	2.4 mR/h
240	1.2 mR/h	6.6 mR/h
250	1.6 mR/h	4 mR/h
260	7.6 mR/h	6.3 mR/h
270	14.8 mR/h	13 mR/h
280	35.4 mR/h	19.6 mR/h
290	19.2 mR/h	20.2 mR/h
300	8.8 mR/h	9.4 mR/h
310	7.1 mR/h	8.6 mR/h
315	6 mR/h	7.4 mR/h
320	6.3 mR/h	6.3 mR/h
330	5.1 mR/h	5.7 mR/h
340	6.3 mR/h	4.6 mR/h
350	4.5 mR/h	4 mR/h

16 Warranty

Air Techniques' Digital Products are warranted to be free from defects in material and workmanship from the date of installation for a limited period. Please visit the Air Techniques website for the most current Warranty Policies and Standard Terms and Conditions.
www.airtechniques.com/warranty

16.1 Online Warranty Registration

Quickly and easily register the new Air Techniques product online. Please have the part number and serial number available when logging into the Air Techniques online portal acount at www.airtechniques.com/portal.

Hersteller / Manufacturer:

DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
www.duerrdental.com

Manufactured for / Distributed by:
Air Techniques, Inc.
1295 Walt Whitman Road
Melville, New York 11747-3062, USA
Phone: +1 800-247-8324
Fax: +1 888-247-8481
www.airtechniques.com

AIR TECHNIQUES equipped for life