VistaVox S

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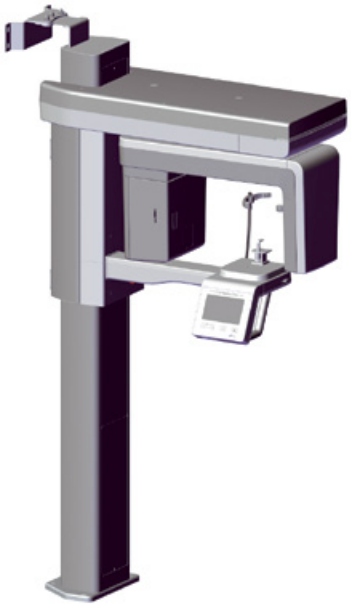

Operating Instructions

CE 0297

2210200378L02

DÜRR DENTAL

1802V006

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1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

This translation was prepared to the best of our knowledge. The original German language version of the manual is the definitive version.

Refer to the separate installation instructions for information about assembly, installation and configuration of the unit.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:


General warning symbol


Warning – dangerous high voltage


Warning – X-rays

The warnings are structured as follows:

SIGNAL WORD

Description of the 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 four levels of danger:

– **DANGER**
  Immediate 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

Other symbols

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


Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

Order number

Serial number

CE labelling with the number of the notified body


Manufacturer


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


Type BF application part


Do not reuse

Not sterile

Steam sterilise 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

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This way up / store and transport in an upright position


Keep away from sunlight


Comply with the Operating Instructions.


Wear hand protection.


Switch off and de-energise the unit (e.g. unplug from mains).


Notice


Emergency stop switch

Laser class 1


Warning – X-rays


Warning – dangerous high voltage


Warning – X-rays

1.2 Copyright information

All names of circuits, processes, names, software programs and units used in this document are protected by copyright.

The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürr Dental.

2 Safety

The unit has been developed and designed in such a way that dangers are effectively ruled out if used in accordance with the proper, intended use. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose and indication

Creation of 3D, panoramic and optionally cephalometric X-ray images in dental radiography for adult and adolescent patients.

2.2 Intended use

The unit must only be used by dentists or dental assistants who have been trained in the use of X-ray radiation in accordance with the applicable legal requirements.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

2.4 Contraindication

The radiobiological effects of X-ray beams in tissue result in the following contraindications:

– Pregnancy
– Pre-existing illnesses that make it impossible to take a CBCT image
– Absence of a justified indication

Exceptions can be formulated at the discretion of the physician.

2.5 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.6 Radiation protection

› Comply with all applicable X-ray protection rules and take all required X-ray protection measures.
› Use the prescribed X-ray protection equipment.
› In order to reduce the level of X-ray exposure, we recommend the use of bismuth, lead shielding or protective aprons, especially for children and teenagers.
› The persons operating the equipment must keep away from the X-ray unit while the exposure is being taken. The minimum distance required by law must be maintained (e.g. Germany 1.5 m, Austria 2.0 m).
› Children and pregnant women must consult a doctor before having an X-ray taken.
› Nobody else must be in the radiation room without X-ray protection measures apart from the patient. 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.
› The radiation room must be lockable to prevent entry by unauthorised persons.
› If a fault occurs, cancel the exposure immediately by letting go of the trigger button.

2.7 Qualified 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

› Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.8 Protection from electric shock

› When working on the units observe all the relevant electrical safety regulations.
› Never touch the patient and unshielded plug connections on the device at the same time.
› Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

› Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "12 Information about EMC in accordance with EN 60601-1-2".

2.9 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
› Only use only genuine working parts and spare parts.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

The use of non-approved accessories, special accessories or non-genuine working parts / spare parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

The following accessories can influence EMC:

– Mains cable (3.6 m; order no.: 2210200243)
– Exposure switch (order no.: 2210200313)

2.10 Transport

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

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

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Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

› Only transport the device 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.

2.11 Disposal

Unit

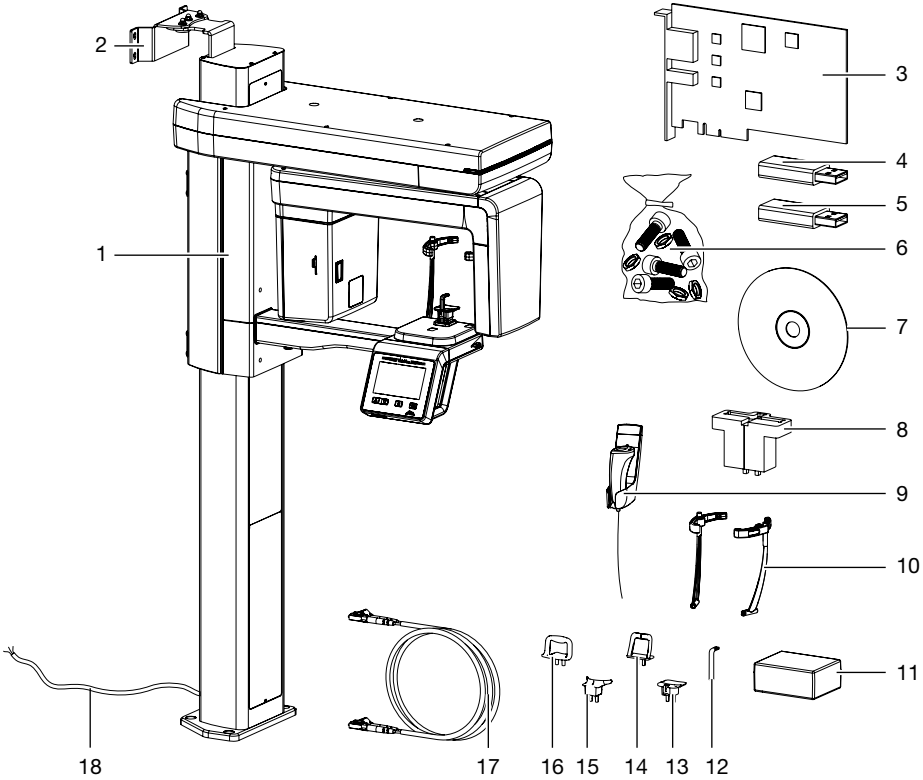
The unit must be properly disposed of. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

› If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

X-ray emitter

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

3 Overview



1 3D and panoramic X-ray device
2 Wall bracket
3 Frame grabber card
4 USB dongle
5 USB stick with device-specific calibration data
6 Small parts
7 VistaSoft imaging software DVD
8 Test body holder
9 Exposure switch (with holder)
10 Head support with cushion
11 Hygienic protective covers for bite block
12 Bite block
13 Adapter bite block
14 Chin holder for maxillary joint image
15 Chin holder for edentulous jaws
16 Chin holder for sinus image
17 Fibre optic cable
18 Mains cable for permanent connection

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3.1 Scope of delivery

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

VistaVox 2210200403
– VistaSoft imaging software DVD
– Fibre optic cable 10 m
– Exposure switch and holder
– Adapter bite block
– Bite block
– Chin holder for edentulous jaws
– Chin holder for maxillary joint image
– Chin holder for sinus image
– Head support with cushion
– Hygienic protective covers for bite block
– Test body holder (Germany, Switzerland and Austria only)
– Top wall bracket set, short
– Small parts (e.g. screws, nuts etc.)
– Various housing parts
– Operating instructions
– Installation instructions
– PCI Express frame grabber card
– USB dongle
– USB stick with device-specific calibration data

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

3.2 Accessories

The following articles are necessary for the operation of the unit, depending on the application:

Hygienic protective cover bite block
(100 pieces) 2207-010-50

Positioning aids

Adapter bite block. 2207-050-50
Bite block piece (3 pieces) 2210200399
Chin holder for toothless 2207-052-50
Head support with cushion 2210200700
Cushion for head supports 2210200701
Chin holder for
mandibular joint image 2207-053-50
Chin holder for sinus image. 2207-054-50

3.3 Special accessories

The following optional items can be used with the device:

Bottom wall bracket set, short
(wall/wall installation) 2210200553
Top wall bracket set, long 2210200611
Bottom wall bracket set, long
(wall/wall installation) 2210200439
Fibre optic cable 5 m 9000100494
Fibre optic cable 20m 9000100495

Acceptance and consistency check

Test body set for Pano 2121-060-55
Consistency test body 3D set 2210200527
Acceptance test body 3D 2210200526
Ball phantom 2207-021-50
Primary absorber set
Pano/Ceph 2207100047

3.4 Disposable materials

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

Hygienic protective cover bite block
(100 pieces) 2207-010-50

Cleaning and disinfection

FD 350 Classic
disinfection wipes CDF35CA0140
FD 333 rapid
surface disinfectant CDF333C6150
FD 322 rapid
surface disinfectant CDF322C6150
FD 366 rapid
disinfectant for sensitive
surfaces CDF366C6150

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

4 Technical data

Electrical data for the unit		
Voltage	V AC	200 - 240
Max. mains voltage fluctuation	%	±10
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*	A	T 10.0 AH / 250 V~ (IEC 60127-2, Sheet 5)

* The fuses must only be replaced by Dürr Dental or or by a company authorised by Dürr Dental.

Classification	
Medical product class	IIb

General technical data		
Dimensions (W x D)	mm	990 x 1130
Height	mm	1406 - 2206
Vertical radius	mm	700
Weight	kg	180

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

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

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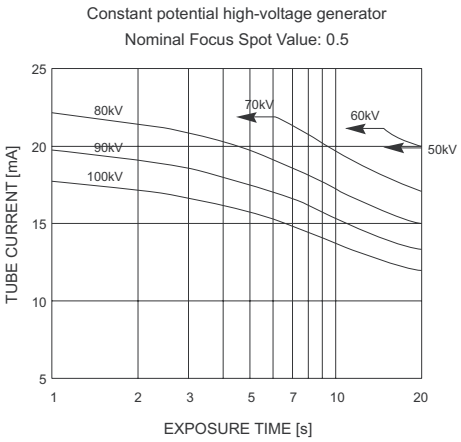
X-ray emitter		
Model		DG-07C11T2 (H)
Rated power	kW	1.6 (for 1 s)
Type: high-voltage generator		Inverter
Nominal voltage, high-voltage generator	kV	50 - 99 (±10 %)
Nominal current, high voltage generator	mA	4 - 16 (± 10%, max. 75 kV 16 mA, max. 99 kV 10 mA)
Cooling, high-voltage generator		Automatic monitoring Shut-off at ≥ 60°C
Additional filtering at 50 kV	mm Al	2.0 + 3.0 (autom. added for CBCT)
Integrated filtering at 50 kV	mm Al	0.8
Total filtering at 50 kV	mm Al	2.8 + 3.0 (autom. added for CBCT)
X-ray tube model		Toshiba D-052SB
Focal spot size as per IEC 60336 X-ray tube	mm	0.5
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 (with 75 kV/16 mA)

4.1 X-ray tube performance data

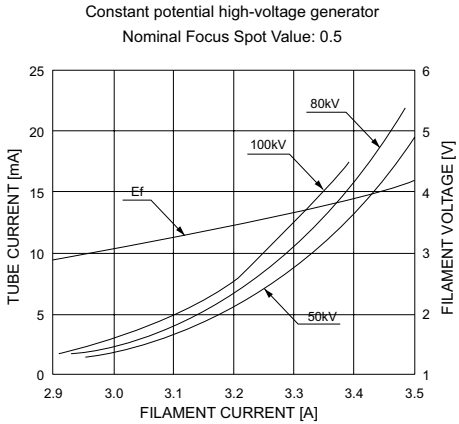
– Maximum deviation of the voltage peak from the displayed value ± 10%
– Maximum deviation of the tube current from the displayed value ± 20%
– Maximum deviation of the exposure time from the displayed value ± 10%
– The device complies with the standards IEC 60601-1, IEC 60601-1-3 and IEC 60601-2-63.
– The lowest possible stress factor is obtained with a combination of the settings 50 kV and 4 mA.

Maximum Rating Charts

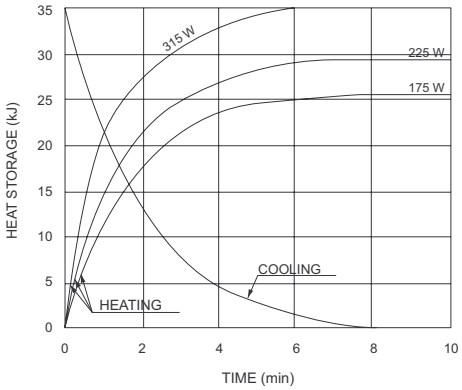
DC (Center Grounded)



Emission and Filament Characteristics



Anode Thermal Characteristics



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

Acquisition mode	FDD mm	FOD mm	ODD mm	Image capture scale (magnification factor)
Panoramic	600	477.7	122.3	1.26

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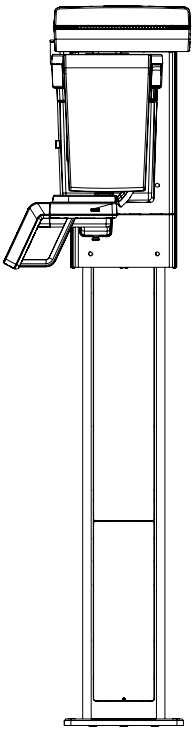
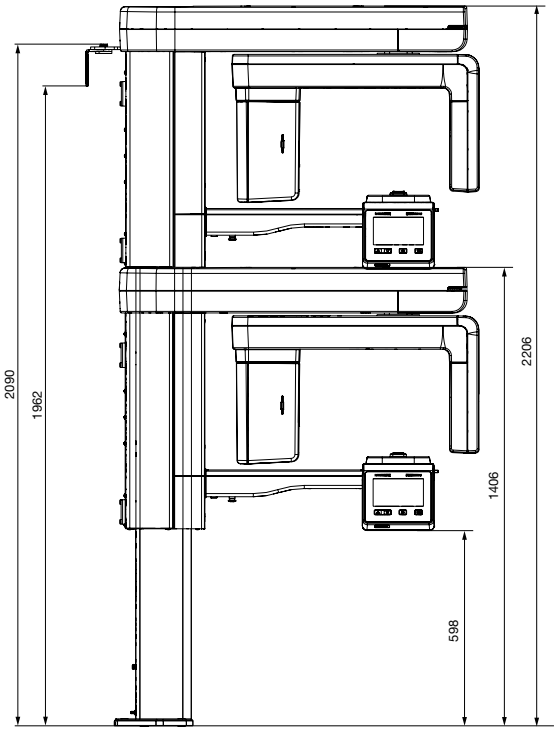
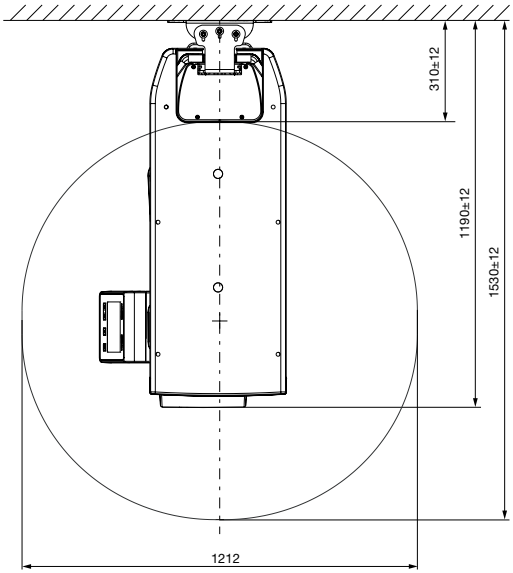
FDD: distance from focal spot to detector
FOD: distance from focal spot to object
ODD: distance from object to detector (ODD = FDD - FOD)
Image capture scale = FDD/FOD

4.2 Dimensions







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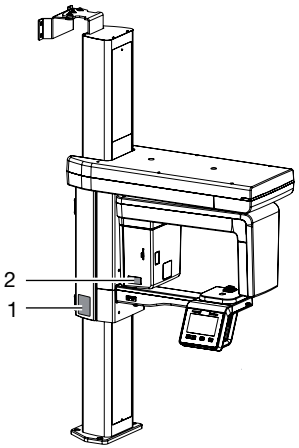
4.3 Type plate

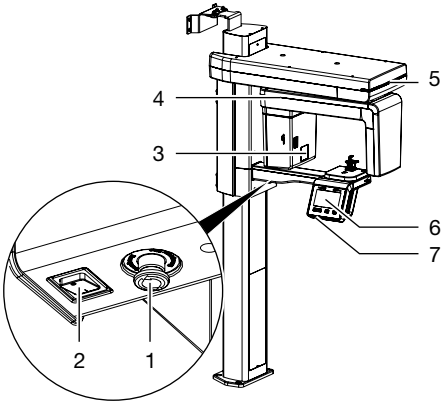


1 Type plate for the complete system
2 X-ray tube type plate

4.4 Conformity assessment

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

5 Operation

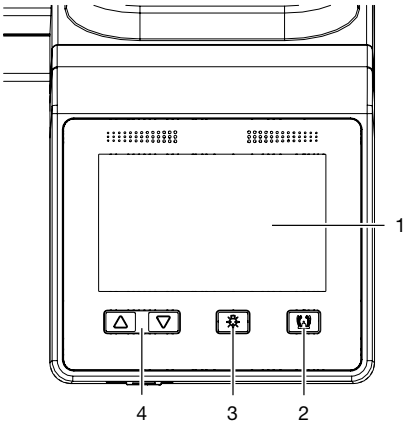


1 Emergency stop switch
2 On/off switch
3 X-ray tube
4 C-shaped elbow
5 Status LED
6 Operating elements
7 Memory card slot

5.1 Functional description

Similarly to computed tomography or magnetic resonance imaging, 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-ray radiation passes through the region under investigation and is measured for image generation via a detector as an attenuated X-ray image based on grey values. 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. Based on this volume, it is then possible to generate sectional images (tomograms) in all spatial dimensions as well as 3D views.

5.2 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. Information can be entered on the touch screen with the tip of a finger.

Figure 1: Screen, unit ready to acquire image

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

The *Help* button can be used to open a help page for the relevant screen. The *Messages* button can be used to recall current messages.

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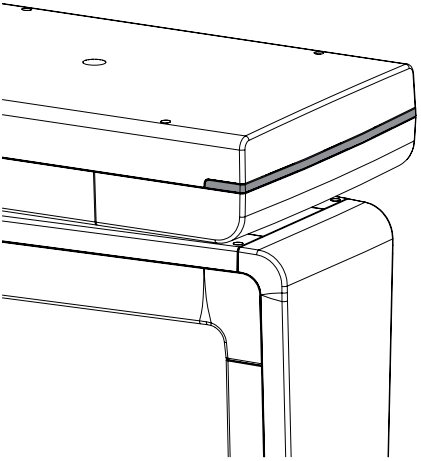
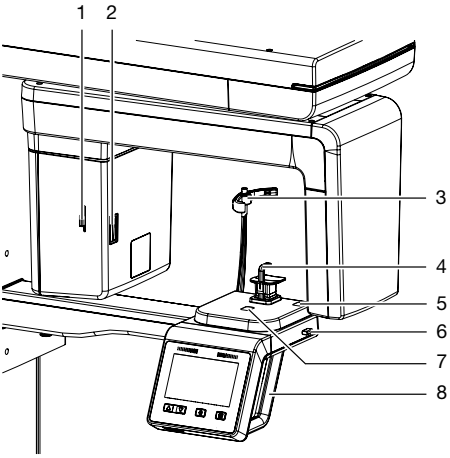
5.3 Status LED



The status LED uses different colours to display the different operating modes:

– Blue: unit ready for operation
– Green: unit ready to acquire image
– Yellow: X-ray beam active

5.4 Positioning aids



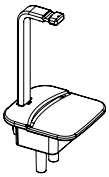
1 Lever for positioning the Frankfurt plane positioning beam
2 Frankfurt plane of the X-ray positioning beam
3 Head support with cushion
4 Positioning aid, e. g. chin support with bite block
5 Upper canine positioning beam
6 Lever for positioning the upper canine positioning beam
7 Mid-sagittal positioning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

The applied parts in accordance with IEC 60601-1 are:

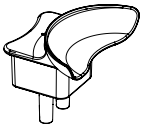
– Grips
– Head support with cushion
– Positioning aids (e.g. bite block and mounting for bite block, chin support for edentulous patients)

Description of the positioning aids

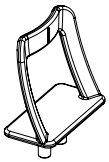
The positioning aids are used to correctly position the patient in the unit. The suitable positioning aid is selected according to the selected image. The head supports gently keep the head of the patient in place.



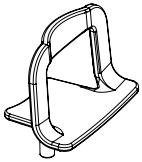
Bite block and adapter bite block



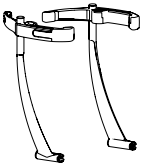
Chin holder for edentulous jaws



Chin holder for maxillary joint image



Chin holder for sinus image



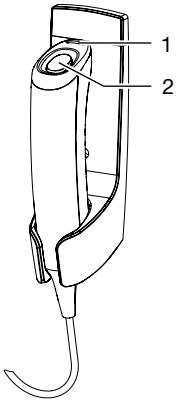
Head support with cushion

5.5 Exposure button

Exposure switch

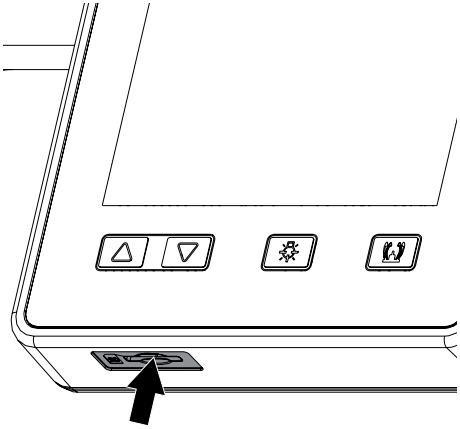
The exposure switch is used to trigger the prepared image acquisition and start the X-ray exposure. The LED indicates the unit status, as does the LED on the unit.

– Green: The unit is ready
– Yellow: X-radiation active



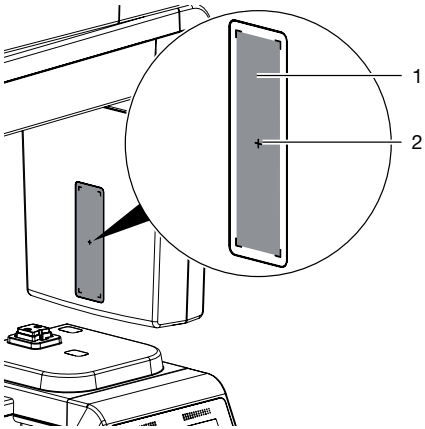
1 Indicator lamp (LED)
2 Exposure button

5.6 Memory card slot



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

5.7 Sensor window



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

The active sensor surface area is displayed via the markings in the corners of the sensor window. The cross indicates the geometric mid-point of the active sensor surface area.

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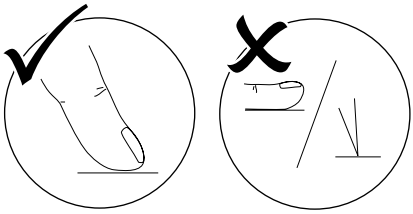
6 Operating the touch screen

NOTICE
Damage to the touch screen due to incorrect handling

- Only touch the touch screen with your fingertips.
- Do not use a sharp instrument (e.g. ballpoint pen) to operate the touch screen.
- Protect the touch screen against water.

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



› 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.

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

6.2 Using menus

The menus integrated in the main window contain additional commands, which can be selected as required.

› To open the menu, touch ▶.

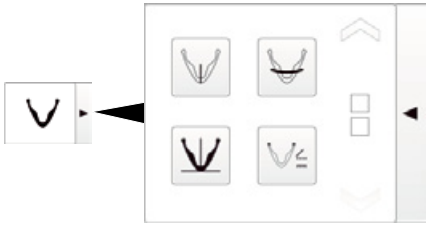


Figure 2: Example: expanded menu

› Select a command.

6.3 Calling up messages on the touch screen

The *Messages* view shows an overview of all previous messages. Here, the messages are divided into the following categories:

Malfunction	Unit will no longer function. When the error has been remedied, it may be necessary to acknowledge the error message.
Notice	After acknowledgement 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.
Normal operation	

› Tap on *Messages*.

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

› For more information about the message, touch *Help*.

7 Operation

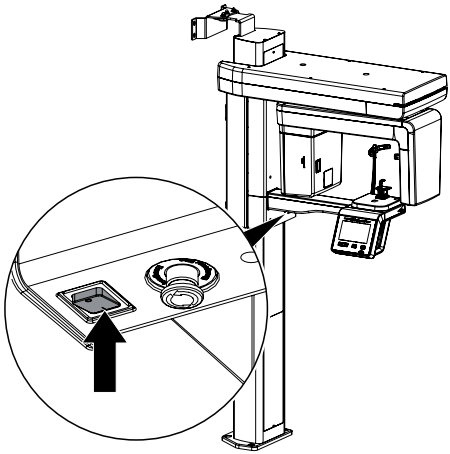
7.1 Switch on the unit.

CAUTION
Danger of injury due to movement of the the C-shaped angle connector piece

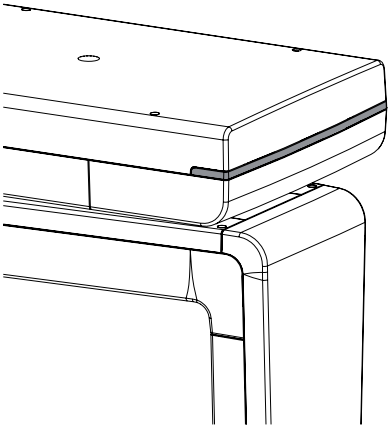
After switching on the unit and confirming the parameters on the touch screen, the C-shaped angle connector piece is positioned. Persons can be injured during this.

› Nobody must remain in the area of the C-shaped angle connector piece while the unit is being switched on.

› Switch on the device at the main power switch.



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



7.2 Adjusting the imaging software

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

Preparing an X-ray image in VistaSoft

Requirements:

– VistaSoft is started.
– Patient is logged-in.
– No other image acquisitions are in progress (X-ray or video).

› In the menu bar click on the required image (e.g. for a CBCT image).
Via you can call up further acquisition types that belong to the grouping e. g. for 5x5 Maxilla 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.

› If image acquisition does not begin automatically, select the X-ray station.
The parameters, imaging volume and patient shape, are preselected according to the patient.

EN

› Check the parameters.
Single-click on  to open the flyout for setting the parameters. The changed parameters are immediately synchronised with the device.
› If the preselected parameters are correct, continue to work directly on the unit.

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 acquisition volume

The selected image volume influences the height of the image volume. The image volume "Child" has a reduced height. The diameter is identical.

	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 An improved signal/noise ratio is achieved via an extended exposure time.
	SQ image This setting is used for standard images.

Patient type

Selection of patient type will depend on the patient's size or their head circumference. This means that the preset patient type may need to be changed if necessary.

The X-ray parameters are preset using 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)

Arch

The selected jaw form influences the rotational behaviour of the C-shaped angle connector piece during image acquisition. This enables an image with an ideal layer position to be captured even on a particularly narrow or wide jaw.

	Normal arch
	Narrow arch
	Wide arch
	Child 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 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 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 unit.

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.

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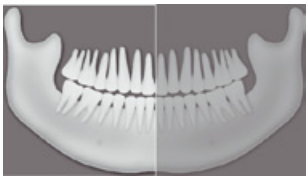
Panoramic images


Default

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

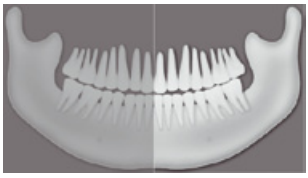

Front

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

Right

The image only shows the right dental area.

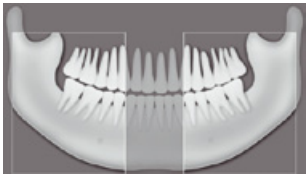



Left

The image only shows the left dental area.

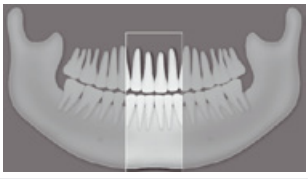

Orthogonal

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

Bite wing

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

Bite wing front

The image shows the anterior area with a size limited to the bite wings.

Panoramic images

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.

Maxillary joint imaging

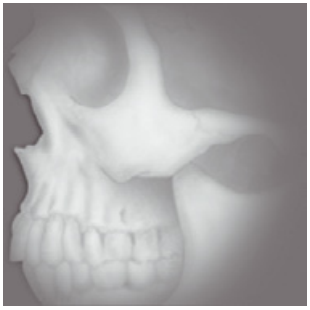
Maxillary joint, lateral

The image shows the lateral maxillary joints with an open and closed mouth in 4-fold depiction on one image.

Maxillary joint, PA

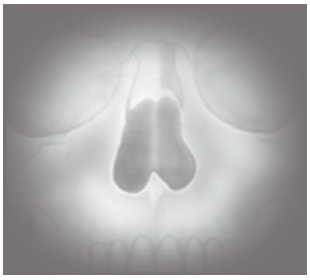
The image shows the posterior-anterior maxillary joints with an open and closed mouth in 4-fold depiction on one image.

Sinus images



Sinus, lateral

The image shows the lateral sinuses.



Sinus, PA

The image shows the posterior-anterior sinuses.

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7.3 Inserting the positioning aids

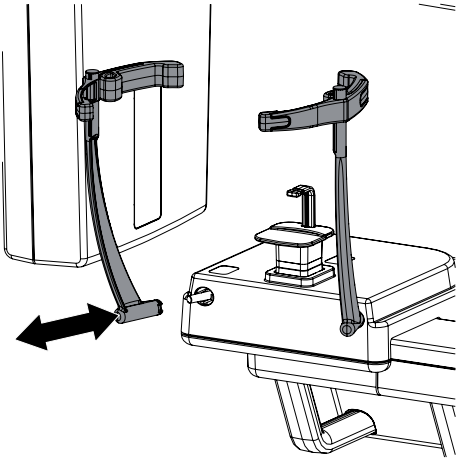
For the X-ray image, the patient is positioned in the unit using the corresponding positioning aids and then accurately aligned using the positioning beams.

WARNING
Danger due to non-reprocessed products
Risk of infection for operator and patient
› Reprocess the product correctly and sterilise it as required prior to first use and after every subsequent use.
› Do not reprocess disposable items.

Inserting the head supports

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

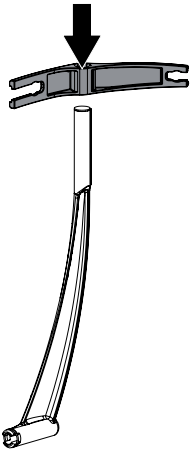
› Remove any dirty head supports by pulling them out.
› Insert new head supports.
When doing this, make sure that the cushions of the head supports face inwards.



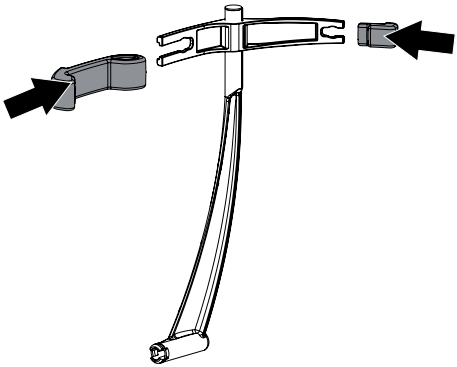
Inserting the cushions of the head supports

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

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



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



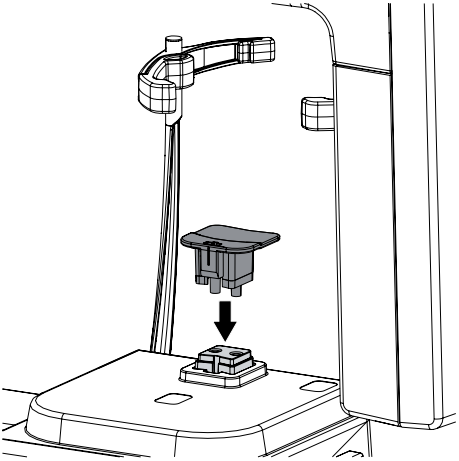
Inserting the positioning aid for CBCT images

We recommend using the mounting for the bite block on CBCT images. The bite block can be used optionally in addition to this.

On edentulous patients the chin support for edentulous patients can be used.

The other positioning aids can be used depending on the application scenario.

› Insert the mounting for the 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 "7.3 Inserting the positioning aids" and the reprocessing instructions under "9 Reprocessing".

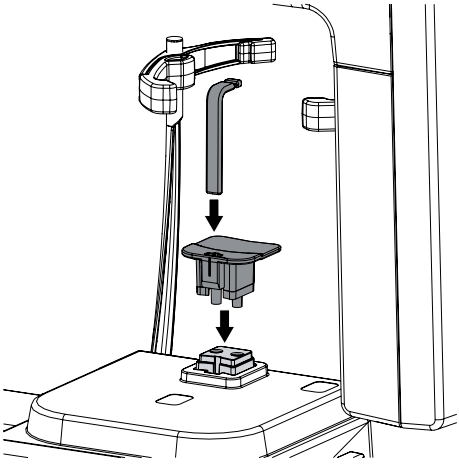
WARNING

There is a danger of cross contamination if hygienic protective covers are not used or they are used more than once.

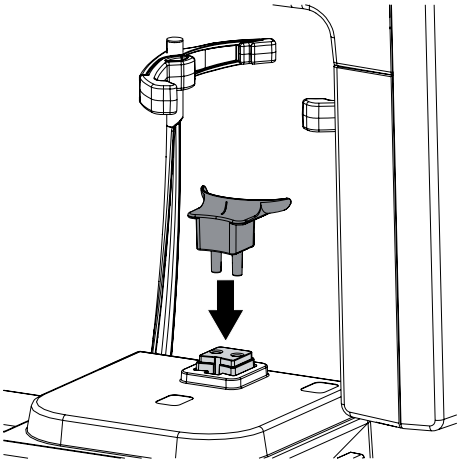
› Reprocess the bite block without the hygienic protective cover after use.

› Do not use the hygienic protective cover more than once (disposable item).

› Optionally insert the bite block.



› On edentulous patients the chin support for edentulous patients can be used.



EN

Inserting the positioning aid for panoramic images

We recommend using the mounting for the bite block and the bite block on panoramic images.

On edentulous patients the chin support for edentulous patients can be used.

The other positioning aids can 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.

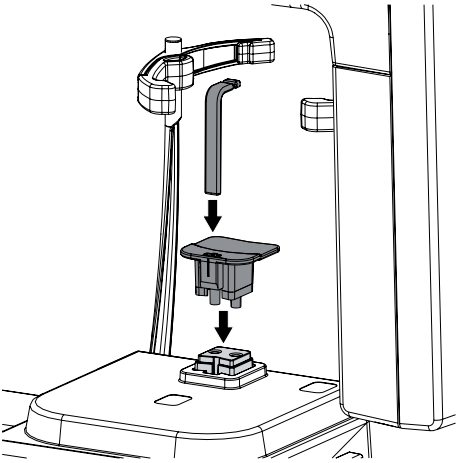
If the bite block is used without a hygienic protective cover, observe the instructions under "Inserting the positioning aid for panoramic images with hygienic protective cover (optional)" and the reprocessing under "9 Reprocessing".

WARNING
There is a danger of cross contamination if hygienic protective covers are not used or they are used more than once.

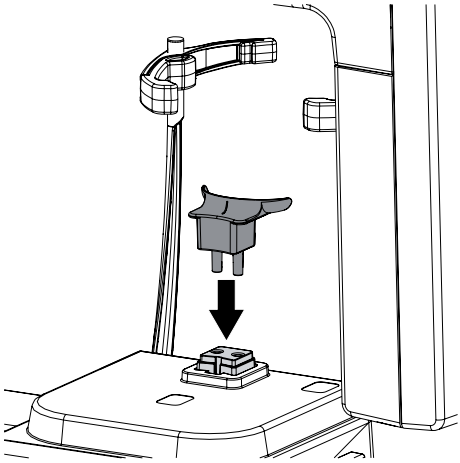
› Reprocess the bite block without the hygienic protective cover after use.

› Do not use the hygienic protective cover more than once (disposable item).

› Insert the mounting for the bite block and the bite block.



› On edentulous patients the chin support for edentulous patients can be used.

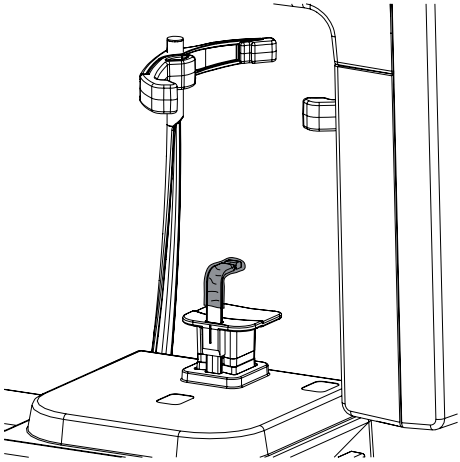


Inserting the positioning aid for panoramic images with hygienic protective cover (optional)

WARNING
Risk of cross contamination due to non-reprocessed bite block

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

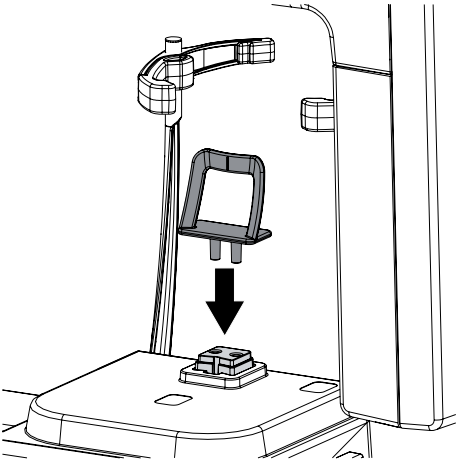
› Optionally place a hygienic protective cover over the bite block.



Inserting the positioning aid for the maxillary joint image

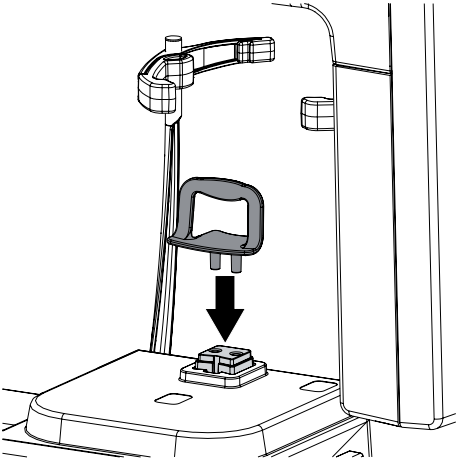
Correct image acquisition is only possible with the chin support for maxillary joint images.

› Insert the chin support for the maxillary joint image.



Inserting the positioning aid for sinus images

› Insert the chin support for sinus images.



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 jewellery 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 X-ray procedure.
- 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, they can close their 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 has to place his tongue against the roof of his mouth during the X-ray.
- The patient has been informed that he has to keep his 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 due to movement of the the C-shaped angle connector piece

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

› Nobody must remain in the area of the C-shaped angle connector piece while the unit is being switched on.

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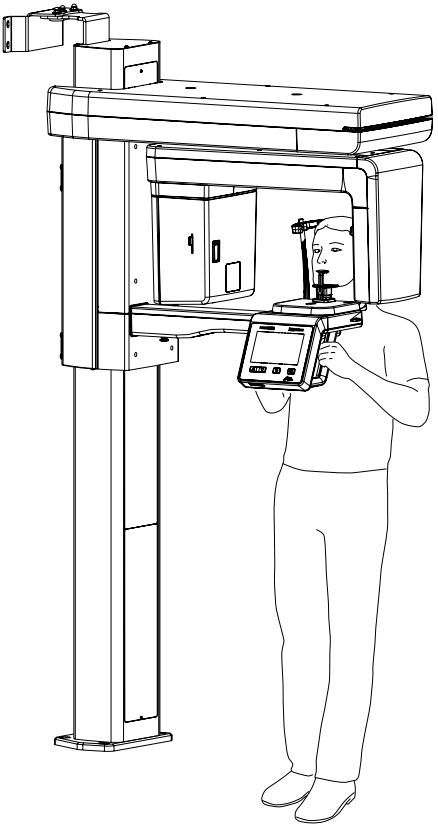
› Bring the patient into an upright position at the unit.

It is also possible to position patients in a seated position (e.g. wheelchair users, tall patients).

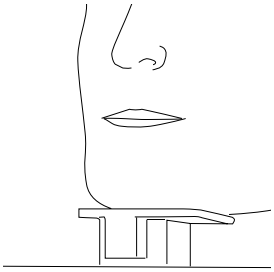


› Use the ▲ ▼ buttons to set the height of the unit.

CBCT image acquisition

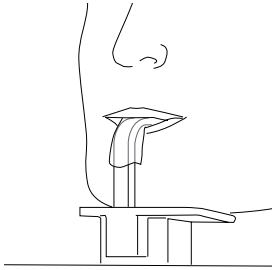
› The patient places his/her chin on the mounting for the bite block.

The bite block is not required.



Panoramic image

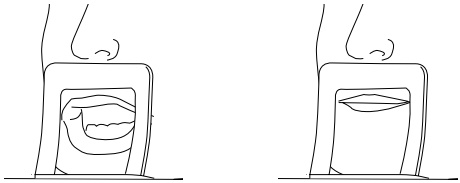
› The patient bites onto the bite block, with the upper and lower incisors resting in the grooves provided.



› 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.

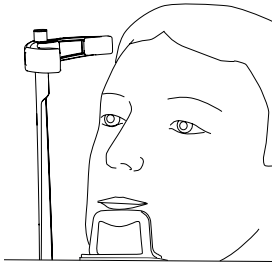
Maxillary joint image

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



Sinus image

› Position the patient so that their bottom lip presses lightly against the chin support.



Adjusting the position with the positioning beams

The positioning beams use class 1 laser beams. Although these can dazzle the patient, they are safe and will not damage the eye.

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

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

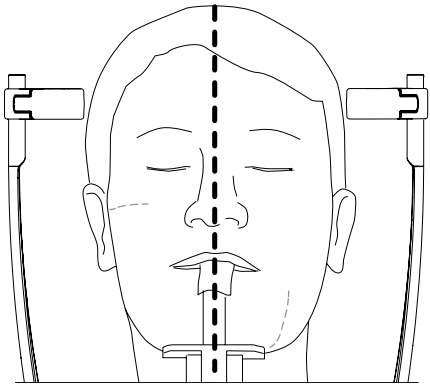
The alignment of the upper canine X-ray positioning beam is crucial for the image quality of panoramic images.

› Check to make sure that the patient has closed his/her eyes.

› If necessary, correct the height of the unit again.

› Activate the positioning beams with the button.

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



› 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°.

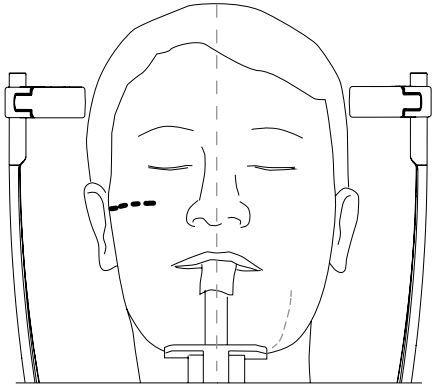
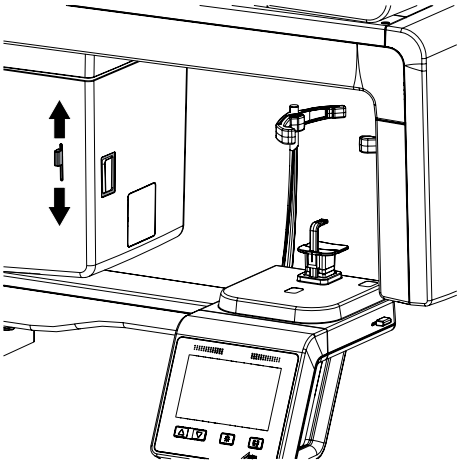


Figure 3: Frankfurt plane: laser height to the lower edge of the eyes

› Correct any inclination of the head via the height of the unit.

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



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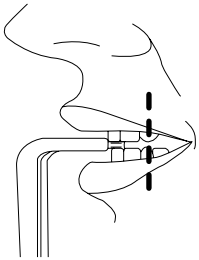
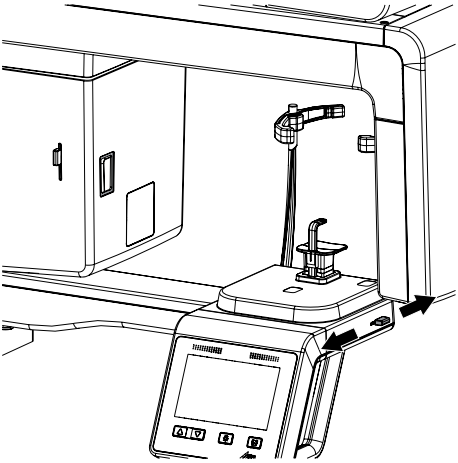
› Direct the "upper canine" X-ray positioning beam as exactly as possible to the middle of the upper canine.

Have the patient smile so the upper canine is visible.



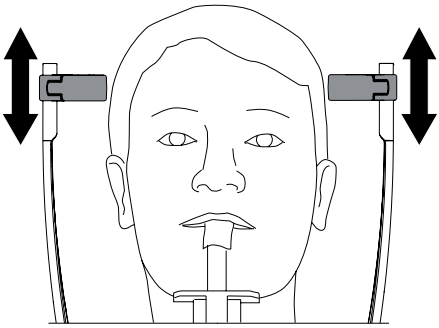
› If necessary, correct the X-ray positioning beam manually.



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

Adjusting the head supports

› Adjust the height of the head supports.

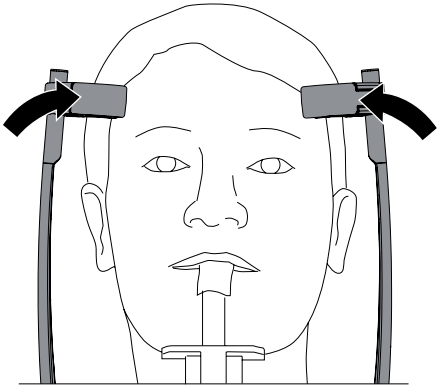


› Carefully press the head supports by hand towards the head in order to check that they are in the right position. The device or the head supports are not damaged in the process.

Ideally, the head supports should make contact slightly above the eye brows; correct the position as required.

› Close the head supports with the button.

To do this, just press the button briefly – don't press and hold.



The head supports automatically close against the head of the patient with a defined pressure.

7.5 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.

› Touch *Test run* on the touch screen.
› Touch *Run* and hold.

While doing this, constantly monitor the movements of the unit. If the unit is obstructed in its movements, let go of the *Run* button. The unit will stop immediately. Reposition the patient.

› Press *Return run* to perform the return run.

7.6 Taking the X-ray

CAUTION
Injuries through 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.

› Check all parameters on the touch screen and change them if necessary.

The changed parameters are immediately synchronised with the imaging software. The parameters can then no longer be changed in the imaging software.

› Remind the patient to press his/her tongue against the gums during image acquisition.
› Press *Start* to confirm the parameters.

The C-shaped arm is 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.

EN

› 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 scanning times depend on the patient type, imaging program and image quality (see "13 Program parameters").

Image acquisition is started. While the image is being taken, 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) then the ongoing image acquisition will stop. The X-ray image will be unusable as a result and should be retaken as required. In this case the operator 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.

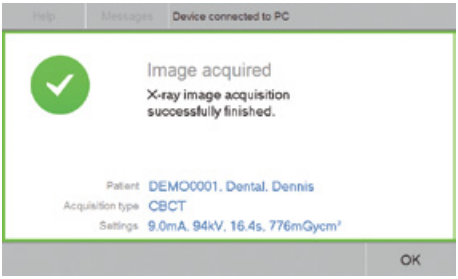
While an X-ray is being taken, this is indicated on the touch screen with:

On maxillary joint images, it is then necessary to acknowledge a message on the touch screen and trigger a second image acquisition. The images are then joined together to a single image.

The LED on the unit lights up blue when the X-ray acquisition has been completed.

The C-shaped arm does not automatically move back to the starting position after the trigger button is released.

› Click *OK* to confirm the message.



› Release the head support.
The patient can leave the X-ray room.
› Remove the hygienic protective cover.
› Remove and disinfect the positioning aids.
› The unit can be positioned back in its start position by touching *Start position*. Otherwise, the C-shaped arm is positioned via VistaSoft during adjustment of the parameters.

7.7 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.

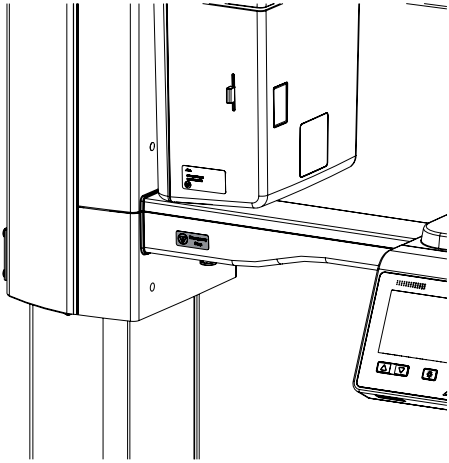


Figure 4: Emergency stop switch on the operator side

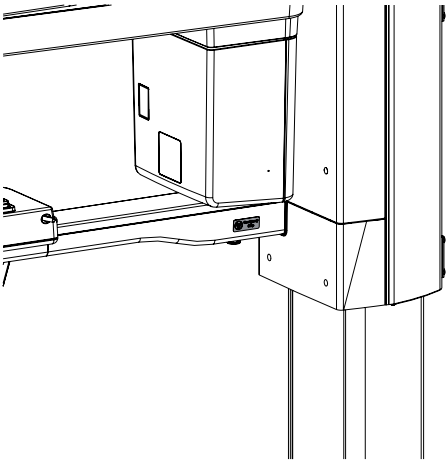
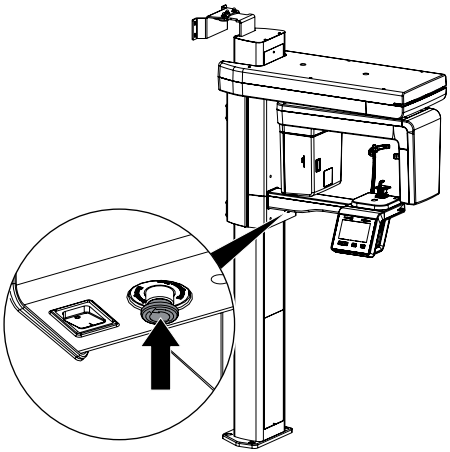


Figure 5: Emergency stop switch on the patient side

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

› Press the emergency stop switch.



Device is switched off.

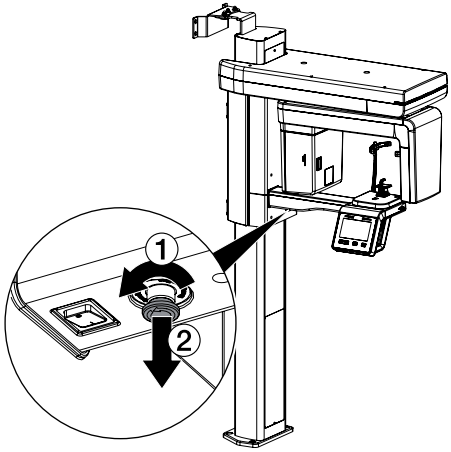
Releasing the emergency stop switch

CAUTION
Danger of injury due to movement of the the C-shaped angle connector piece

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

› Nobody must remain in the area of the C-shaped angle connector piece while the unit is being switched on.

› Twist the emergency stop switch to release it.



The unit will automatically restart.

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8 Cleaning and disinfection

NOTICE
The use of unsuitable agents and methods can damage the unit and accessories.
› Only use the disinfectants and cleaning agents specified or approved by Dürr Dental.
› Comply with the specifications contained in the the operating instructions of the disinfectants and cleaning agents.

Wear safety gloves.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

8.1 Unit surfaces

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 unit surface must be cleaned and disinfected of any contamination or soiling. Use the following cleaning and disinfectant agents:

– FD 322 Rapid surface disinfectant
– FD 333 Rapid surface disinfectant
– FD 350 Disinfectant wipes
– FD 366 Rapid disinfectant for sensitive surfaces

NOTICE
Liquid can cause damage to the unit.
› Do not spray the unit with cleaning and disinfectant agents.
› Make sure that liquid does not get inside the unit.

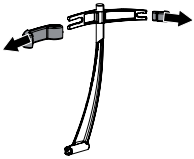
› Remove any soiling with a soft, damp, lint-free cloth.
› Disinfect the surfaces using a disinfection wipe. Alternatively, use a rapid surface disinfectant on a soft, lint-free cloth. Comply with the operating instructions for the disinfectant when doing this.

8.2 Positioning aids

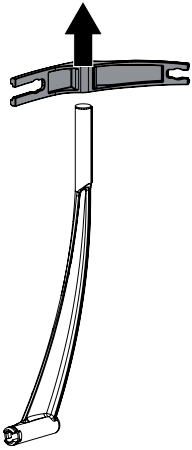
The positioning aids must be cleaned and disinfected if they are contaminated or soiled. Use the following cleaning and disinfectant agents:

– FD 322 Quick-acting surface disinfection
– FD 333 Quick-acting surface disinfection
– FD 350 Disinfection wipes
– FD 366 Quick-acting disinfectant for sensitive surfaces

Head support with cushion
› Pull off the head supports from the device.
› Remove the cushions from the head supports.



› Removal of the cushion holder.



› Remove any soiling with a soft, damp, lint-free cloth.
› 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 for the disinfectant when doing this.

Chin support, chin holder and bite block holder

› Pull the chin support, chin holder or bite block holder off the device.
› Remove any soiling with a soft, damp, lint-free cloth.
› 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 for the disinfectant when doing this.

EN

9 Reprocessing

The following accessories need to be reprocessed:

– Bite block:
  - Manual cleaning
  - Manual disinfection
  - Automatic cleaning and disinfection
  - Steam sterilisation

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

9.1 Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives, standards and specifications such as e. g. the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".

Accessories of the medical device are also subject to reprocessing.

Classification recommendation

Classification recommendation given proper use of the product:

semi-critical A to critical A

The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

9.2 Reprocessing procedure in accordance with EN ISO 17664

The reprocessing procedure after each patient treatment is carried out according to the reprocessing procedure established by EN ISO 17664.

Important information!

The reprocessing notes in accordance with EN ISO 17664 have been independently tested by Dürr Dental for the preparation of the device and its components for their reuse.

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any negative consequences resulting from deviation from these instructions by the person performing the reprocessing are the responsibility of the member of staff performing the reprocessing.

Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially 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:
  - FD 333 Quick-acting disinfection (Dürr Dental)
– Manual cleaning:
  - ID 213 Instrument disinfection (Dürr Dental)
– Manual disinfection:
  - ID 213 Instrument disinfection (Dürr Dental)
– Automatic cleaning and disinfection:
  - Washer-disinfector: G 7836 CD (Miele, Gütersloh, Germany)
  - Cleaning agent: neodisher MediClean Dental
  - Program: *D-V-MEDICLEAN*
– Steam sterilisation:
  - Steam steriliser HST 6x6x6 (Zirbus technology GmbH, Bad Grund, Germany)

9.3 General information

› Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.
› Comply with the specifications in "9.5 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "9.6 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying" when selecting the cleaning and disinfectant agents to be used.
› Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
› Do not use any cleaning and disinfectant agents which contain chlorine, solvents, strong bases (pH >11) and oxidising agents.
› Use non-foaming, non-fixing and aldehyde-free cleaning and disinfectant agents.
› Do not use any rinse aid (danger of toxic residue on the components).
› Only use freshly-produced solutions.
› Use only distilled or de-ionised water with a low bacteria count (≤ drinking water quality).
› Use clean, dry, oil and particle-free compressed air.
› Do not exceed temperatures of 138 °C.
› Subject all the devices used (ultrasonic bath, washer-disinfector, sealing device, steam steriliser) to regular maintenance and inspections.

9.4 Preparation at the operating location


Wear hand protection.


Wear protective goggles.


Use a face mask.


WARNING
Risk of infection from contaminated products
Danger of cross contamination
› Reprocess the product correctly and promptly before its first use and after every subsequent use.

› Transport the device from the treatment location to the reprocessing location in such a way as to protect against contamination.
› Remove course organic and inorganic soiling with a disinfectant cloth.

9.5 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying

A combined cleaning and disinfectant agent is required for manual cleaning and disinfection. It must have the following properties:

– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)
– without chlorine, solvents, strong alkaline solutions (pH >11) or oxidising agents

For further information, see: "8 Cleaning and disinfection".

Cleaning

› Place individual parts in a cleaning agent bath making sure that all parts are covered.
› Brush off all surfaces completely with a soft hygienic brush.
› Note the exposure times of the cleaning agent.

Intermediate rinsing

After the action time prescribed by the manufacturer:

› Rinse off all components under water for at least 1 minute (temperature < 35°C).

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Disinfection

› Place individual parts in a cleaning and disinfectant bath so that all parts are covered.
› Note the action time for the disinfectant.

Final rinse

After the action time prescribed by the manufacturer:

› Rinse off all components under water for at least 1 minute (temperature < 35°C).

Drying

› If necessary, re-dry at a clean location using a hygienic, lint-free cloth.
› 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 CD with the following properties and validated processes:

– Corresponds to and tested in accordance with EN ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 90°C)

Programme is suitable for the components and provides sufficient rinsing cycles.

For more information: "9.3 General information".

Selection of the cleaning agent automatic

The following properties are required:

– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

For further information, see: "9.3 General information".

Cleaning and disinfection

› Place all components in the cleaning and disinfection unit (follow the manufacturer's instructions).
› Make sure there are no hidden areas that are missed by the rinsing process.
› Secure the components with a suitable fixture of the cleaning and disinfection unit.

9.7 Check for function

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

9.8 Steam sterilising

Packing

For packaging of the components, only use transparent paper film sterilisation packaging that is approved for use in steam sterilisation according to the manufacturer's instructions. This includes:

– Temperature resistance up to 138°C
– Standards DIN EN ISO 11607-1/2
– The applicable sections of the standard series DIN EN 868

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

Steam sterilising

WARNING
Incorrect sterilisation reduces effectiveness and can damage the product.

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

Requirements placed on the steam steriliser:

– Corresponds to EN 13060 or EN 285 and/or ANSI AAMI ST79
– Suitable programme for the products listed (e. g. with hollow bodies, fractionated vacuum procedure in three vacuum steps)
– Sufficient product drying
– Validated process in accordance with DIN EN ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ)

Perform the following steps:

› Sterilise the parts for sterilisation (at least 20 minutes at 121°C, at least 4 minutes at 132°C or at least 5 minutes at 134°C).

Do not exceed 138 °C.

Marking

› Mark the packaged, treated medical product in such a way as to ensure safe application.

9.9 Issue clearance for the parts for sterilisation

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

› Document the clearance of the medical product after reprocessing.

9.10 Storing parts for sterilisation

› 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

  Packaging for a sterile medical device can suffer damage 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 Maintenance

10.1 Recommended maintenance schedule

EN

Only trained specialists or personnel trained by Dürr Dental may service the device.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

WARNING
Risk of infection from contaminated products
Danger 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 head supports mechanism functions correctly. Are the head supports easy to detach and put back on?
	› Functional test of the emergency stop switch. Is the emergency stop switch easy to operate mechanically, and does it light up when pressed?
	› Visually check the beams localisers. Check the operation of the levers for adjusting the beam localisers.
	› Check the X-ray images for artefacts. 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 (Germany, Switzerland and Austria only).
	› Recurring tests and tests after repairs to medical electrical equipment – DIN EN 62353 (VDE 0751-1).

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

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.

11 Tips for operators and service technicians

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

Fault	Probable cause	Solution
Unit does not switch on	EMERGENCY STOP SWITCH accidentally activated	› Release the EMERGENCY STOP SWITCH.
	No mains voltage	› Check the mains cable and electrical connection; replace if necessary. › Inform a Service Technician.
		› Check the mains fuse in the building.
	On/off switch is defective	› Inform a Service 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 fibre 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 COM port in the VistaVox service tool.

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Fault	Probable cause	Solution
Error messages during start 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 imBIOS 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 pack if necessary.
	PC and/or graphic card do not comply with the specified system requirements	› Set up system in accordance with the system requirements.
	User account control (UAC) has not been correctly configured	› Adjust user account control 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 -ray image	› Add the installation path from Dürr Dental, as exception, to 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 doors properly.

12 Information about EMC in accordance with EN 60601-1-2

12.1 General information

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

12.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_T	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E_1	Compliance level for the test in acc. with IEC61000-4-3
P	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)

12.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

The device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the device should ensure that the device is operated in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The unit uses HF energy exclusively for internal functions. For this reason, HF transmissions are very low and it is unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accordance with CISPR 11	Class A	The VistaVox unit is suitable for use in installations other than buildings used for residential purposes and in buildings that are directly connected to the PUBLIC MAINS ELECTRICITY GRID that also supplies buildings used for residential purposes.
Harmonics in acc. with IEC 61000-3-2	Class A	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Compliant	

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Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

Interference immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±1 kV voltage outer conductor/outer conductor ±2 kV voltage outer conductor/earth	±1 kV push-pull voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage in accordance with IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the operator of the device needs the unit to continue working even if the mains power supply is interrupted, we recommend powering the device from an uninterruptible power supply (UPS) or from a battery.
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at mains frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 1: Resistance to electromagnetic interference (immunity) for all devices and systems

Electromagnetic interference immunity for devices or systems that are not life-sustaining

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ = 3 V	$d = 1.2 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ = 3 V/m	$d = 1.2 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)

The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site[a].[b]

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

[a] The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[V_1]$ V/m.

EN

Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 2: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection on the building, objects and people.

12.4 Essential performance characteristics

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

13 Program parameters

The extraoral dental X-ray system meets the requirements set out in the standard IEC 60601-2-63. The dosage information complies with the requirements of the standard and is stated in mGycm².

The accuracy of the DAP/dose values is ± 30%.

EN

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	mGy-cm²	mGy	mGy-cm²	mGy	mGy-cm²	mGy	mGy-cm²	mGy	mGy-cm²
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

EN

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

EN

Test equipment: Dosimeter Victoreen 660

Test conditions	
Program parameters	HD / Adult, child / Standard Pano
Distance to 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

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