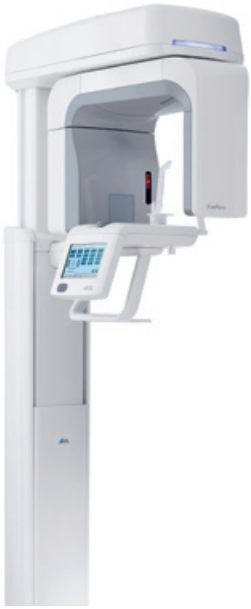
VistaPano S

EN



Operating instructions

CE 0120

9000-618-256/02

DÜRR DENTAL

1403V003

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Important information

EN

1 Documentation

These Installation and Operating Instructions form an integral part of the unit. They conform to the relevant version of the equipment and the status of technology valid at the time of first operation.

Dürr Dental cannot guarantee smooth operation and safe function of the unit and will not accept any liability where the instructions and notes contained in these installation and operating instructions are not strictly observed.

This translation has been carried out in all good faith. The original German version is decisive. Dürr Dental accepts no liability for incorrect translation.

1.1 Warnings and symbols

Warnings

The warnings in this document are there to point out possible injury to persons or damage to machinery.

The following warning symbols are used:


General warning symbol


Warning - dangerous electrical voltage


Warning - X-rays

The warnings are structured as follows:

SIGNAL WORD

Description of type and source of danger

Possible consequences of ignoringthe safety warning here

- Measures to be taken to avoid any possible danger.

The signal word differentiates between different levels of danger:

– **DANGER**
  High risk of danger of serious injury or death
– **WARNING**
  Possible risk of danger of serious injury or death
– **CAUTION**
  Risk of danger of minor injuries
– **NOTICE**
  Risk of serious damage

Further symbols

These symbols are used within the documentation and on the unit itself:


Notes, e.g. special instructions concerning economical use of the unit.


Observe the accompanying documentation.

CE-Labeling

UL Classification


Manufacturer


Dispose of product correctly and in accordance with EU directive (2002/96/EG-WEEE).


Part type B


Only use once.

Authorised EU representative


Wear protective gloves


Switch off the appliance (i. e. unplug and disconnect from mains).


Laser class 1 product

EN

1.2 Notes on copyright

All circuits, processes, names, software and appliances quoted are protected under industrial property rights.

Any reprinting of the technical documentation, in whole or in part, is subject to prior approval of Dürr Dental being given in writing.

2 Safety

This unit has been so designed and developed that under normal and proper usage any possibility of damage or injury can be virtually ruled out. However, there is always a small margin of risk. Please observe the following instructions carefully.

2.1 Correct use

The unit is designed exclusively for taking panoramic X-ray images for the inspection and diagnosis of diseases of the oral cavity and craniofacial anatomy.

2.2 Incorrect use

Any use of this appliance above and beyond that specifically described in these instructions will be deemed to be as not according to the intended use. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The user bears all risks.

2.3 General safety notes

- Before using the appliance observe any and all guidelines, laws, regulations and other restrictions which may apply to the appliance.
- Before each use check the function and condition of the appliance.
- Do not convert or change the appliance in any way.
- Observe the Installation and Operating Instructions precisely.
- Keep the Installation and Operating Instructions in an accessible place so that the operator has instant access to them.

2.4 Radiation protection

- Observe all mandatory current X-ray protection rules and take all necessary X-ray protection measures.
- Use the proscribed X-ray protection equipment.
- In order to reduce the amount of X-ray exposure, we recommend the use of bismuth, lead shielding or protective aprons, especially for children and teenagers.
- Any operative personnel must keep away from the X-ray unit when taking an exposure. The legally specified minimum distance must be maintained (e. g. Germany 1.5 m, Austria 2.0 m).

- As well as the patient, any other person present in the X-ray room must wear X-ray protection. In exceptional circumstances a third party may be present to give assistance, but this must not be a member of the surgery personnel. Ensure visual contact with the patient and the unit during exposure.
- In the case of any interruption when taking an exposure, stop the procedure immediately by letting go of the release switch.

2.5 Qualified personnel

Instructions for use

Persons who operate the appliance must, on the basis of their training and knowledge, ensure safe and correct handling of the appliance.

- Ensure personnel are trained in the correct usage of the appliance.

Installation and repair

- Installation, resetting, alterations, extensions and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.6 Protection against electrical current

- When working on and with the appliance always observe the local electrical safety procedures.
- Never come into contact with patients and open plug-in connections on the appliance at the same time.
- Damaged supply lines and connections must be replaced immediately.

Observe guidelines for electro-magnetic compatibility for medical devices

- Heed special precautionary measures with regard to electromagnetic comparability (EMC) for medical products, see "12 Information on EMC according to EN 60601-1-2".

2.7 Only use original parts

- Only Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental may be used.
- Only use original working parts and spare parts.

Dürr Dental cannot accept any liability for damage caused by the use of accessories and special accessories not specifically approved by Dürr Dental or not using original working parts and spare parts.

2.8 Transport

The original packaging offers the optimum protection for the appliance during transport.

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

Dürr Dental cannot accept any liability for damage caused during transport by the use of unsuitable packaging, this is also valid during the warranty term.

- Only transport the appliance in its original packaging whenever possible.
- Keep the packing materials out of the reach of children.
- Attach the transport locking devices again.
- Do not expose the appliance to any strong shocks.

Do not bump or pull the unit.

2.9 Disposal

Appliance

Dispose of the appliance correctly. Within the European Union dispose of the appliance according to EU directive 2002/96/EG (WEEE).

- If you have any questions concerning correct disposal, please contact Dürr Dental or your usual dental supplier.

X-ray unit

The x-ray unit contains a tube which may implode, lead sheathing and mineral oil.

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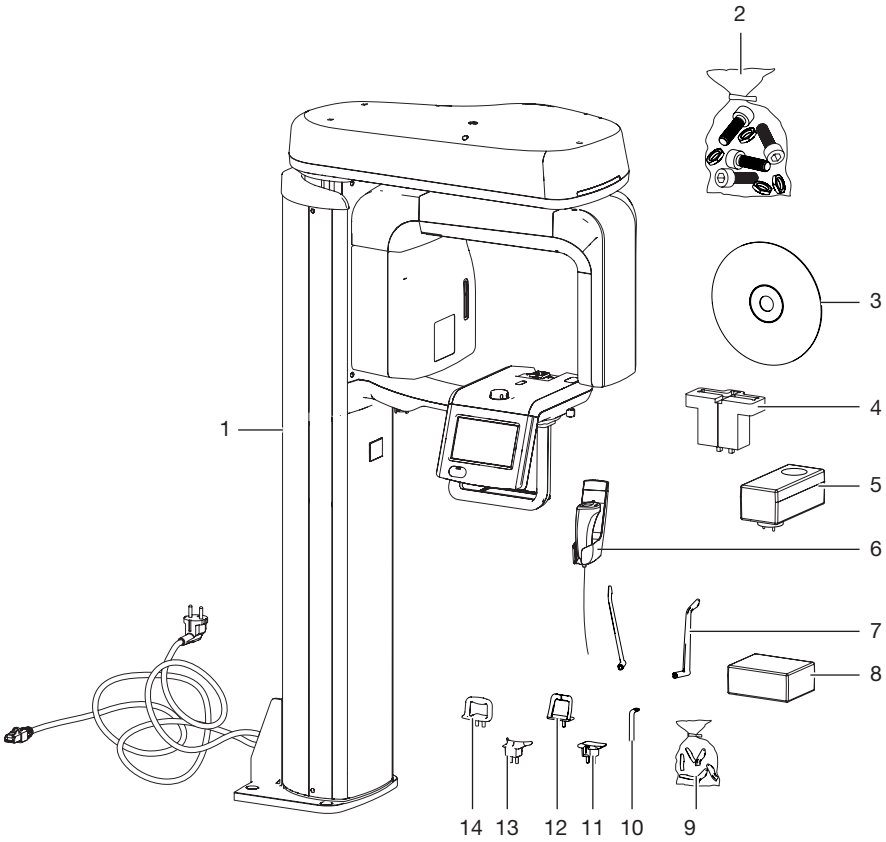
3 Overview



1 Panorama X-ray unit
2 Sundries
3 DBSWIN imaging software DVD
4 Test body holder
5 Switch-on current limiter
6 Manual release
7 Temple support
8 Hygienic protective covers for bite block piece
9 Hygienic protection silicone for temple support
10 Bite block piece
11 Holder for bite block piece
12 Chin support for maxillary joint image
13 Chin support for edentulous jaws
14 Chin support for sinus image

3.1 Delivery Contents

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

VistaPano S 2207-01

– DBSWIN imaging software DVD
– Mains cable, 2.5 m, country-specific plug
– Network cable, 10 m
– Manual release and holder
– Holder for bite block piece
– Bite block piece
– Chin support for edentulous jaws
– Chin support for maxillary joint image
– Chin support for sinus image
– Temple support
– Hygienic protection silicone for temple support (3 pairs)
– Hygienic protective covers for bite block piece (300 pieces)
– Test body holder (only Germany, Switzerland, Austria)
– Sundries
– Operating Instructions
– Installation instructions
– PCI Express Gigabyte Ethernet card
– Switch-on current limiter

3.2 Accessories

The following items are required for operating the appliance, depending on the application:

Laser test tool. 2207-020-50
Ball phantom 2207-021-50
Hygienic protection silicone for temple support (3 pairs) 2207-011-50
Hygienic protective cover bite block (300 pieces) 2207-010-50
Test body holder for VistaPano S (usable with test body set for Pano S 2121-060-55) 2207-900-50
Activation of the DBSWIN X-ray module 2100-725-04FC

Positioning aids

Holder for bite block piece 2207-050-50
Bite block piece (3 pieces) 2207-051-50
Chin support for edentulous jaws . 2207-052-50
Temple supports (1 pair) 2207-060-50
Chin support for mandibular joint image 2207-053-50
Chin support for sinus image. 2207-054-50

3.3 Special accessories

The following items can be optionally used with the appliance:

Foot 2207-100-50
Manual switch for height adjustment incl. holder 2207-070-50

Commissioning and constancy test

Test body set for Pano 2121-060-55

3.4 Disposable materials

The following materials are used when operating the appliance and must be ordered separately:

Hygienic protection silicone for temple support (3 pairs) 2207-011-50
Hygienic protective cover bite block (300 pieces) 2207-010-50

Cleaning and disinfecting

FD 350 Classic disinfectant wipes CDF35CA0140
FD 333 surface disinfectant. . . . CDF333C6150
FD 322 surface disinfectant. . . . CDF322C6150
FD 366 Sensitive surface quick disinfectant CDF366C6150

4 Technical data

EN

Electrical data, unit

Nominal voltage	V AC	100 - 240
Max. voltage fluctuation	%	±10
Frequency	Hz	50/60
Rated power	W	170
Maximum power	kVA	2.2

Classification

Medical products class	IIb
Manufacturer: VATECH Co., Ltd. for Dürr Dental 23-4, Seogu-dong, Hwaseoung-si, Gyeonggi-do, Korea	

Electromagnetic compatibility (EMC)*

HF emissions in accordance with CISPR 11		Group 1 Class B
Harmonic oscillations in accordance with IEC 61000-3-2		Class A
Voltage fluctuations/flicker in accordance with IEC 61000-3-3		Not applicable
Conducted HF interference V_1 in accordance with IEC 61000-4-6	V/m	3
Radiated HF interference E_1 in accordance with IEC 61000-4-3	V_{eff}	3

*See also "12 Information on EMC according to EN 60601-1-2"

X-ray tube electrical data

Model		Toshiba D-052SB
Tube voltage	kV DC	50 - 90
Tube current	mA	4 - 16 (for 1 kVp)
Focal spot size as per IEC 60336	mm	0,5
Anode angle	°	5
Inherent filtration	mm Al	0,8
Total filtration	mm Al	2,8
Pulse to pause ratio		1:60 or greater

Detector

Brand		Xmaru 1501CF
Model		Xmaru 1501CF-HS
Model		CMOS photodiode array
Pixel size	µm	100
Active surface	mm	6 x 150.4
Frame rate	fps	300
Grey scales	bit	14

General technical data		
Height	mm	1580 - 2280
Dimensions (W x D)	mm	990 x 1130
Vertical radius	mm	700
Weight	kg	90
Weight with foot (optional)	kg	135
Image capture scale (magnification)		1,3

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

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

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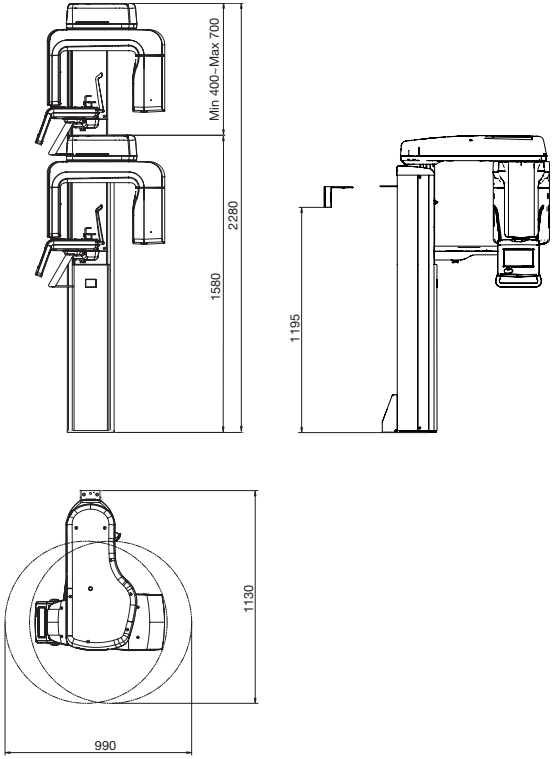
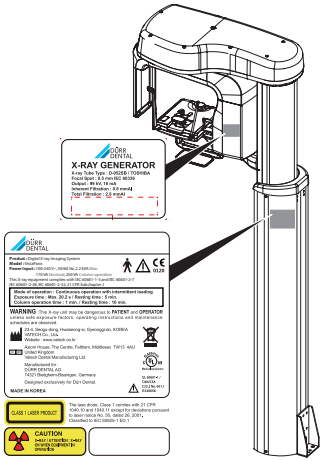
4.1 Dimensions



4.2 Model identification plate

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



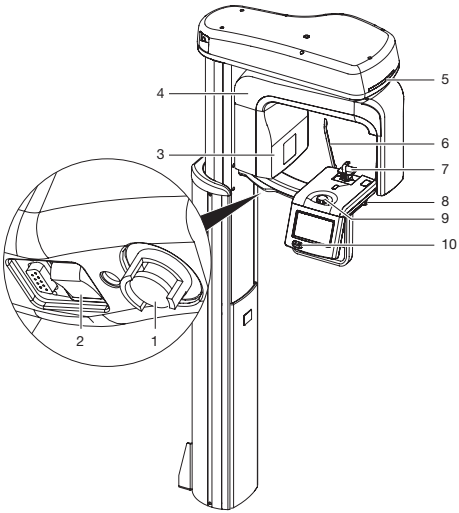
REF Order number

SN Serial number

4.3 Note on Conformity

This appliance has been tested according to the relevant directive of the European Union and the required conformity acceptance procedure. This appliance meets all the necessary requirements.

5 Function



1 EMERGENCY OFF button
2 On/Off switch
3 X-ray tube
4 C angle connector piece
5 Status LED
6 Temple support
7 Chin support and bite block piece
8 Switch to set the beam localiser to the maxillary canine
9 Setting wheel to adjust the temple support
10 Buttons for the height adjustment

The panoramic X-ray unit takes digital panoramic images which enable diagnostics in the oral area.

The X-ray job is started via the imaging software and activated via the touch screen.

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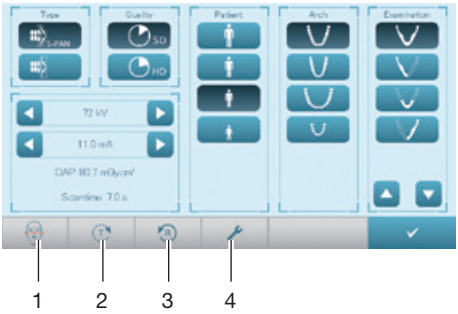
5.1 Touch screen



1 Activate/deactivate all beam localisers
2 Test circulation, keep the button pressed
3 Return
4 Set language, activate/deactivate audio

5.2 Trigger

Manual release

The prepared image is triggered by the manual trigger and X-ray radiation is activated. The LED indicates the unit status, as does the LED on the unit.

– Blue: Unit is switched on
– Green: Unit is ready to take images
– Orange: Unit takes an X-ray

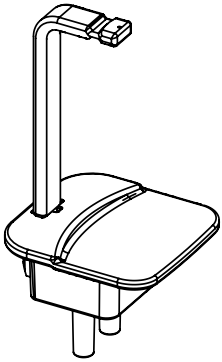
Alternative trigger (optional)

This trigger is usually mounted outside the X-ray room. The prepared image is triggered via the trigger and X-ray radiation is activated.

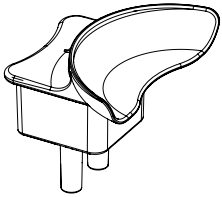
5.3 Positioning aids

The patient is properly positioned in the unit with the help of the positioning aids. The suitable positioning aid is selected according to the selected image. The temple supports gently keep the head of the patient in place.

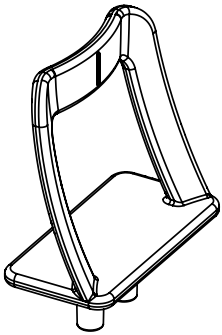
Chin support and bite block piece



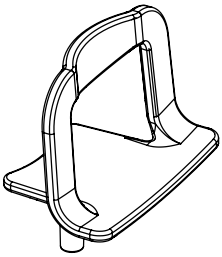
Chin support for edentulous patients



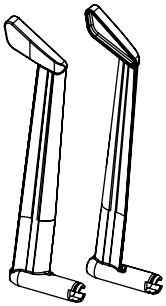
Support for maxillary joint image



Support for sinus image

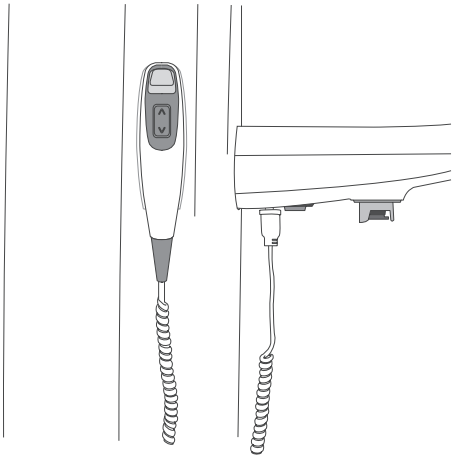


Temple supports



5.4 Manual switch for height adjustment (optional)

The manual switch can be used as an alternative to the buttons on the touch screen for adjusting the height of the unit.



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Only fully-qualified or from Dürr Dental trained personnel may set-up, install or operate this appliance.

6 Prerequisites

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

– Closed, dry room.
– Should not be a room made for another purpose (e. g. boiler room or wet cell).
– No large fields of interference (e. g. strong magnetic fields) present, that can interfere with the function of the unit.
– Take environmental conditions into consideration "4 Technical data".

6.1 System requirements

The system requirements of computer systems can be found in the download area at www.duerr.de (document no. 9000-618-148).

6.2 Monitor

The monitor must comply with the requirements for digital X-ray with higher light intensity and high contrast range.

Strong ambient light, sunlight falling directly onto the monitor and reflections can reduce the diagnosability of the X-ray images.

7 Installation

7.1 Safety for the electrical connection

- The appliance may only be connected to a correctly installed socket-outlet.
- Do not lay multi-socket units on the floor. Heed the requirements of Section 16 of IEC 60601-1 (EN 60601-1).
- Do not operate any other systems using the same multiple socket-outlet strip.
- Make sure the connection lines to the appliance are not subject to any mechanical tension.
- Before initial start-up, check the supply voltage with the voltage information on the model identification plate (see also "4. Technical Data").

7.2 Connecting the appliance to the power supply

Requirements:

✓ Correctly installed socket outlet in the vicinity of the unit (max. length of mains cable 2.5 m).
✓ The socket outlet must be easily accessible.
✓ Rated current to conform with information on the model identification plate of the power unit.

- Now connect the power cable to the electric mains socket.

If a fast-blow fuse was used, the switch-on current limiter included in the delivery must be interposed between the plug of the unit and the socket outlet.

7.3 Safe connection of appliance

Danger can arise when connecting units with each other or to parts of the system (e.g. through discharge current).

- Only connect units when there can be no question of danger to operator or to patient.
- Only connect units when there can be no environmental impairment through such interconnection.
- When it is not clear from the unit data sheets that such connection will cause no danger, then a qualified expert should be consulted to ensure no danger (e.g. one of the product manufacturers).
- When connecting the appliance to other equipment,such as a PC system,heed the specifications of Section 16 of IEC 60601-1 (EN 60601-1).
- When setting up the PC system in the vicinity of the patients:

  Only connect components (e.g. computer, monitor, printer) that comply with the standard IEC 60601-1 (EN 60601-1).
- During the set-up of the PC system outside the vicinity of the patients:

  Connect components (e.g. computer, monitor, printer) that comply to standard IEC 60950-1 (EN 60950-1) at least.

A master copy of the system manufacturer‘s declaration according to Article 12 of Directive 93/42/EWG can be found in our download section under www.duerr.de (Document No. 9000-461-264).

8 Operation

The necessary tests (e. g. acceptance test) are regulated by the locally applicable national law.

- Find out which tests are to be made.
- Carry out tests in accordance with national law.

8.1 Acceptance test

The Pano test body set, as well as the suitable test body holder, is required.

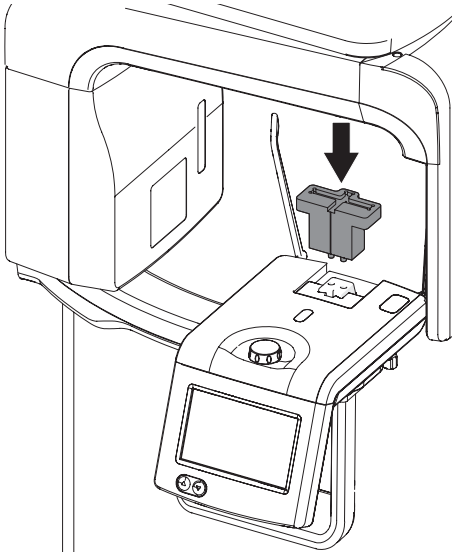
- Before commissioning, carry out the acceptance test of the X-ray system according to national regulations.

The tests of constancy, that must be carried out at regular intervals by the surgery personnel, are based on the results of the acceptance test.

Inserting the test body holder

The test body is used on the test body holder for the acceptance and consistency test.

- Inserting the test body holder



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8.2 Electrical safety check

- Carry out an electrical safety check according to all national regulations (e.g. patient conductivity, conductivity of housing).
- Document the results.

8.3 Switch unit on

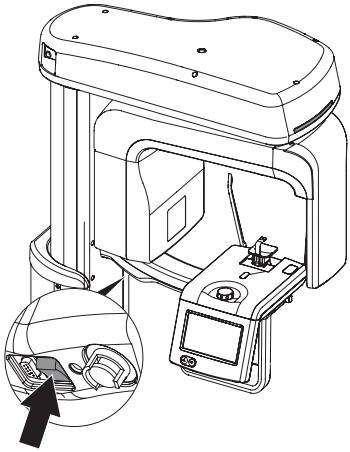
CAUTION

Danger of injury due to the C angle connector piece moving

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

- No persons may remain in the area of the C angle connector piece when switching on.

- Switch on the unit.



The LED on the unit flashes blue during the start process. If the unit is operational, the LED on the unit flashes blue.

8.4 Installing and configuring the appliance

The unit supports the following imaging programs:

– DBSWIN from Dürr Dental
– VistaEasy from Dürr Dental
– Imagebridge from Dürr Dental
– Third-party software on request

Setting up the network

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

- Install the Ethernet card in the PC.
- Connect the network cable with the network connection of the Ethernet card.

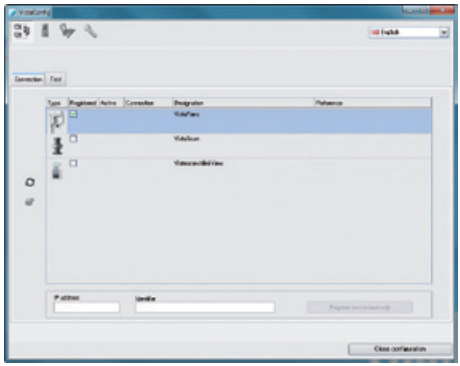
The IP settings of the appliance are:
Appliance IP address: 10.42.43.10
Appliance subnet: 255.255.255.0

- Configure the Ethernet card on the PC
  – IP address: 10.42.43.15
  – Subnet: 255.255.255.0
- Check that Port 20130 is released in the Firewall of the TCP used; release if necessary.
- Open the console via *Start* > *Execute* > *cmd*.
- Check the connection with the command *ping 10.42.43.10*.

Configuring the appliance

Configuration is carried out using VistaNetConfig, which is automatically installed on installation of DBSWIN or VistaEasy.

- Click *Start* > *All Programs* > *Dürr Dental* > *VistaConfig* > *VistaNetConfig*.



- Click on ⟳ once.
  The list of units connected will be brought up to date.
- The unit connected can be activated in *Registered* column.

9 Instructions for use

9.1 Switch unit on

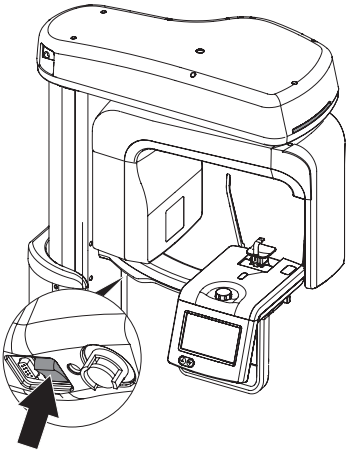
CAUTION

Danger of injury due to the C angle connector piece moving

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

- No persons may remain in the area of the C angle connector piece when switching on.

- Switch on the unit.



The LED on the unit flashes blue during the start process. If the unit is operational, the LED on the unit flashes blue.

9.2 Setting the imaging software

The settings are described using the example of the DBSWIN imaging software.
For further information on using the imaging software, see the respective manual.

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Parameter overview in DBSWIN

Patient type

The selection of the patient type depends on the size of the patient or the head size of the patient. The preset patient type must also be adjusted if necessary.

The X-ray parameters are preset using the patient type (see Appendix).

If it is set for a child, the X-ray parameters change:

– Reduced dose
– Shorter circulation time
– Radiation field is smaller

Large, powerful patient

Adult male

Adult female

Child (< 13 years)

Panotype

Several layers are recorded by the S-Pan technology. The optimum OPG recording is produced by the sharpest layer being selected for the horizontal and vertical image area respectively, and merging these image areas into a single image.

S-Pan is preset.

S-Pan

Standard OPG

Image quality

HD: A better signal/noise ratio is achieved by an extended exposure time.

SD: This setting is used for standard images.

HD - Panorama image

SD - Panorama image

Maxillary arch

The selected jaw form influences the rotational behaviour of the C angle connector piece during the recording. This enables an image with an ideal layer position to be achieved, even for a specially narrow or wide jaw.

Normal maxillary arch

Narrow jaw

Wide jaw

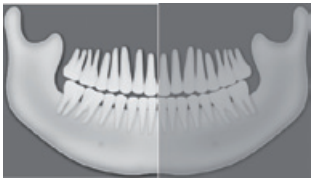
Child/milk teeth

Imaging program

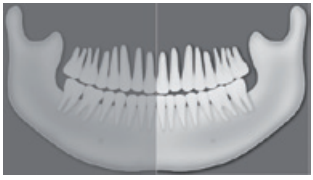
EN

Standard
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.



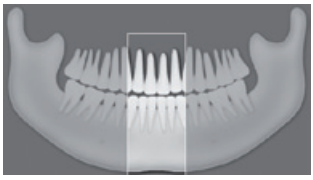
Right
The image only shows the right dental area.



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.

Bite wing right

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

Bite wing left

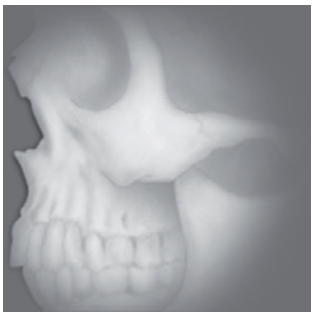
The image shows the left posterior region with a size limited to the bite wings.

Lateral maxillary joint

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

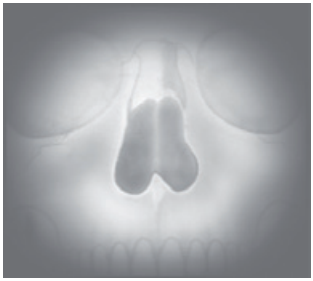
Maxillary joint PA

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



Lateral sinus

The image shows the lateral sinuses.



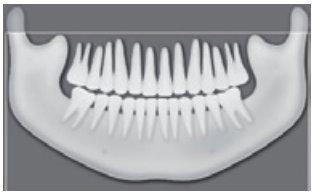
Sinus PA

The image shows the posterior-anterior sinuses.

EN

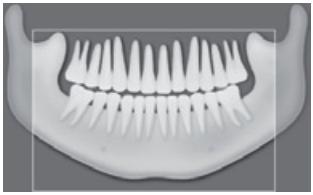
Child images

For panoramic images of children, the radiation field is made smaller by an additional aperture. The radiation dose is significantly reduced for this image.



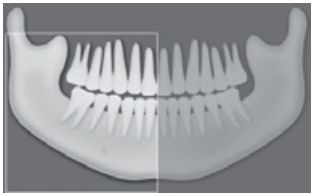
Standard

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



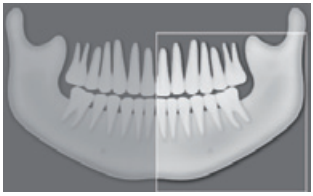
Front

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.

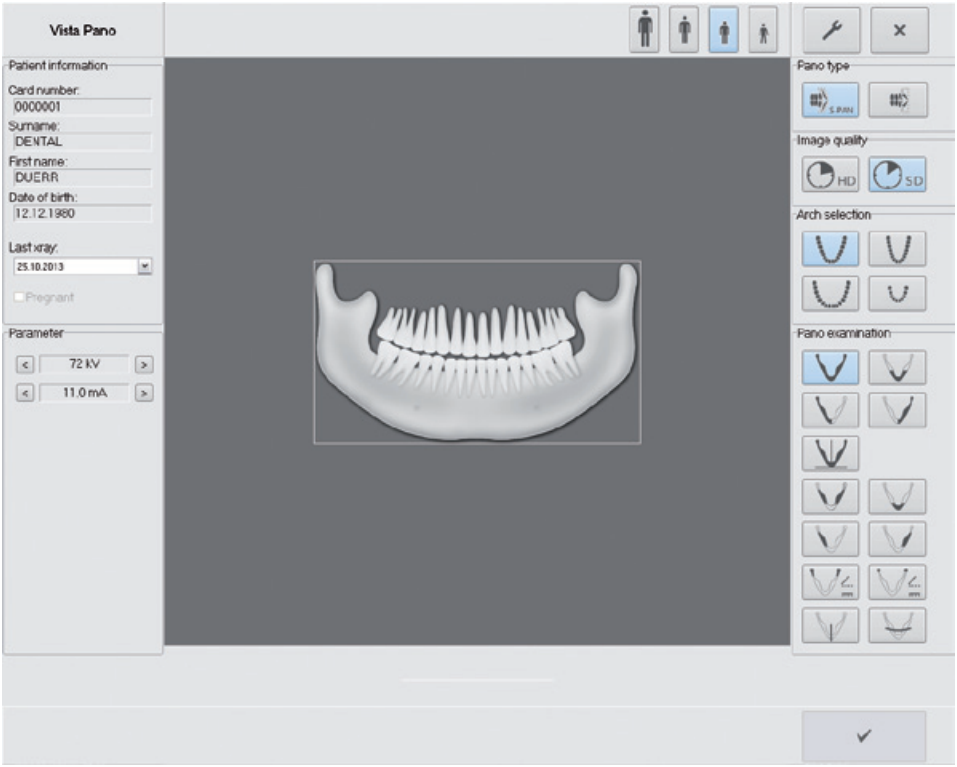
EN

Preparing an X-ray image in DBSWIN

✓ DBSWIN is started.

- Select the patient.
- Select the *X-ray* tab.

The configuration window opens.



The patient type, maxillary arch and imaging program parameters are preselected according to the patient.

- Check the parameters.
- If the preselected parameters are correct, continue to work directly on the unit.
- If necessary, change the parameters and confirm with button ✓.

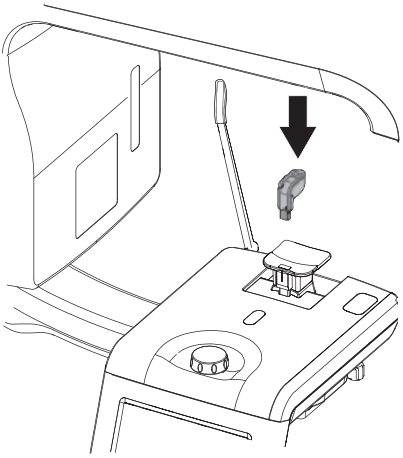
9.3 Setting up the unit

WARNING

Danger of cross contamination if hygienic protective covers are not used or are used more than once

- Do not use the bite block piece without a hygienic protective cover.
- Do not use a hygienic protective cover more than once (disposable item).

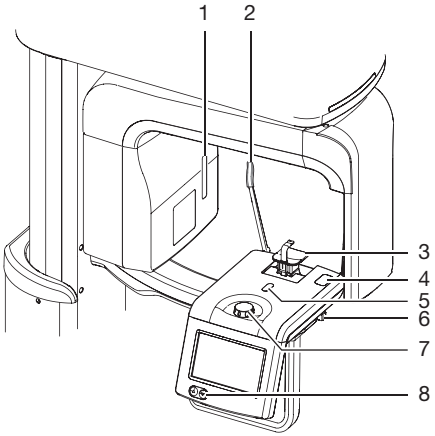
- Disinfect the positioning aids, see "10 Cleaning and disinfecting".
- Equip the bit block piece with a hygienic protective cover and insert.



- Use arrows to roughly set the unit height to the height of the patient.

9.4 Positioning the patient

For the X-ray image, the patient is positioned in the unit using the respective positioning aids and exactly aligned using the X-ray positioning beam. The patient must not move while the image is taken.



1 Frankfurter horizontal plane of the X-ray positioning beam
2 Temple support with silicone protective caps
3 Positioning aids, e. g. chin support with bite block piece
4 Maxillary canine X-ray positioning beam
5 Mid-sagittal X-ray positioning beam
6 Switch to position the maxillary canine X-ray positioning beam
7 Setting wheel for positioning the temple supports
8 Buttons for the height adjustment

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 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 the positioning of the X-ray positioning beam.
- ✓ The patient has been informed that he is not allowed to move during the X-ray until the device is back in the starting position.

CAUTION

Danger of injury due to the C angle connector piece moving

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

- No persons may remain in the area of the C angle connector piece when switching on.

- Bring the patient into an upright position at the unit.
- Use the Up and Down buttons to set the height of the unit.

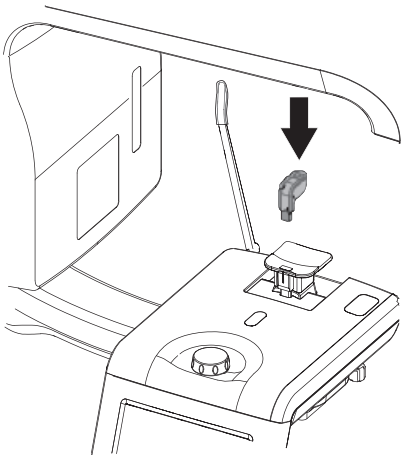
Preparing the panoramic imaging

WARNING

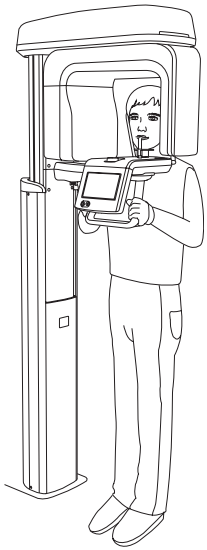
There is a danger of cross contamination when hygienic protective covers are not used or are used more than once

- Do not use the bite block piece without the hygienic protective cover.
- Do not use the hygienic protective cover more than once (disposable item).

- Equip the bite block piece with a hygienic protective cover.
- Insert the bite block piece.



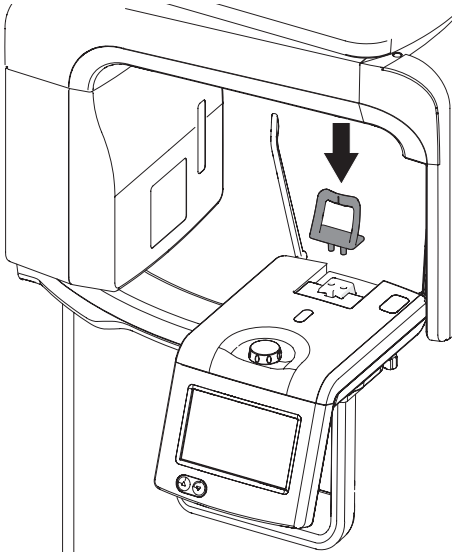
- The patient bites in the grooves provided on the bite block piece with the upper and lower incisors. (Use the chin support for edentulous patients in the case of patients who do not have any teeth.)



- Correct the height of the unit again if necessary.

Preparing the maxillary joint image

- Insert the chin support for maxillary joint image.



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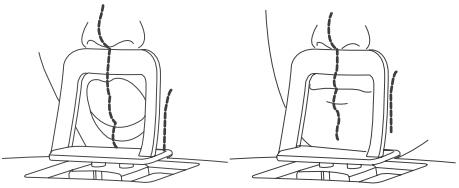
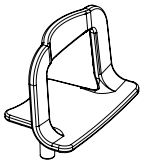
- Position the patient with the upper lip against the chin support.
- Patient opens and closes the mouth.



Preparing a sinus image

- Insert the chin support for a sinus image. "Preparing the maxillary joint image"



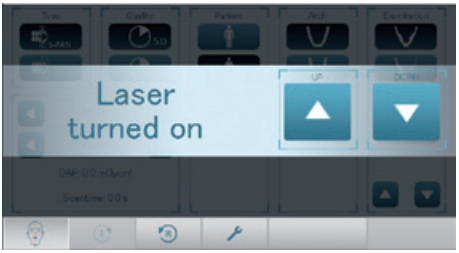
Adjusting the position with the X-ray positioning beam

WARNING
Danger of glare due to laser beam

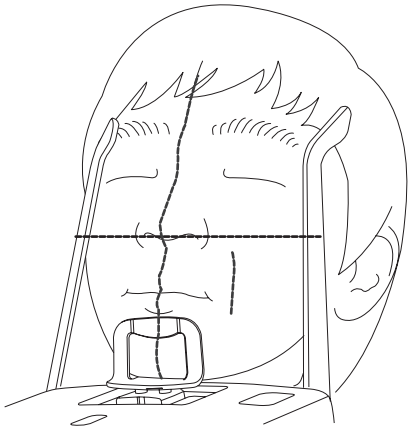
- Avoid the laser beam projecting directly into the eyes of the patient.
- Only activate the X-ray positioning beam when the patient has closed his eyes.

The alignment of the X-ray positioning beam to the maxillary canine is decisive for the image quality.

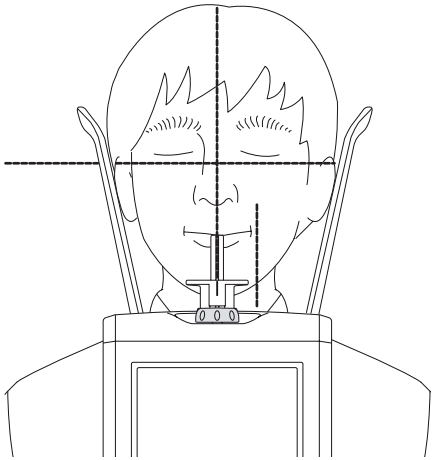
- Check that the patient has closed his eyes.
- Correct the height of the unit again if necessary.
- Deactivate the X-ray positioning beam on the touch screen, using button .



- Align the head of the patient according to the Frankfurter horizontal plane with the aid of the X-ray positioning beam.
  Laser height to the lower edge of the eyes.
  Correct the inclination of the head according to the auditory canal using the Up and Down buttons.
- **For a sinus image:**
  Patient over-stretches the cervical vertebral column by approx. 10° to 15°.

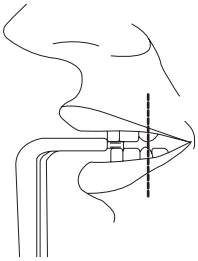


- Check the X-ray positioning beam is in the mid-saggital plane and correct if necessary.

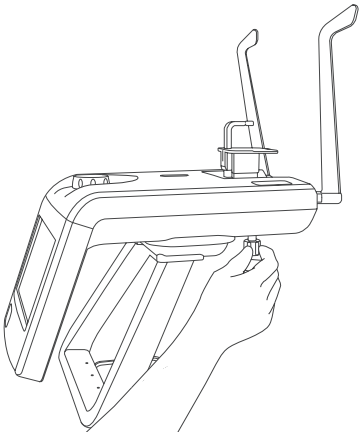


- Have the patient smile so the upper maxillary canine is visible.

  Align the "upper canine plane" X-ray positioning beam as exactly as possible to the middle of the upper maxillary canine.



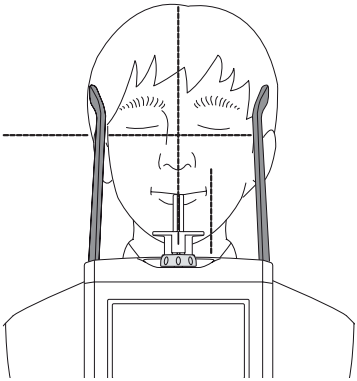
- If necessary, correct the X-ray positioning beam manually.

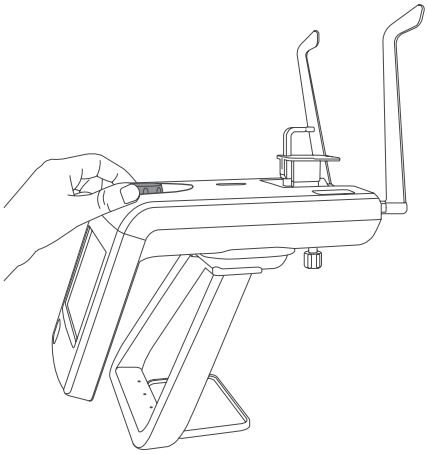


The patient is correctly positioned using the X-ray positioning beam.

- Deactivate the X-ray positioning beam on the touch screen, using button .

- Use the setting wheel to adjust the temple supports so they touch the head of the patient.





- Carry out the TEST circulation by pressing and holding the button .
- Carry out the RETURN run by pressing the button .

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9.5 Producing an X-ray exposure

CAUTION
Injuries through x-rays
X-rays can cause tissue damage.
- Observe the radiation protection regulations.
- Maintain the minimum distance.

CAUTION
Danger of too high a radiation dose
- Prior to an image being triggered, all data entered on the PC must be checked on the touch screen.

- Check all parameters on the touch screen and change if necessary.
  The changed parameters are immediately synchronised with DBSWIN.
- Check that the patient has placed his tongue against his palate.
- Activate the image using button ✓.

The C angle connector piece is positioned. The LED on the manual trigger and on the unit lights green.
The touch screen displays that the unit is ready to take an image.

- Trigger the image by pressing and holding the button until the acoustic signal and the control lamp go out. The scanning time depends on the patient type, imaging program and image quality, see "13 Program parameters".

While the image is being taken, the LED on the manual trigger and on the unit lights orange. An acoustic signal sounds.

An X-ray is indicated on the touch screen with:

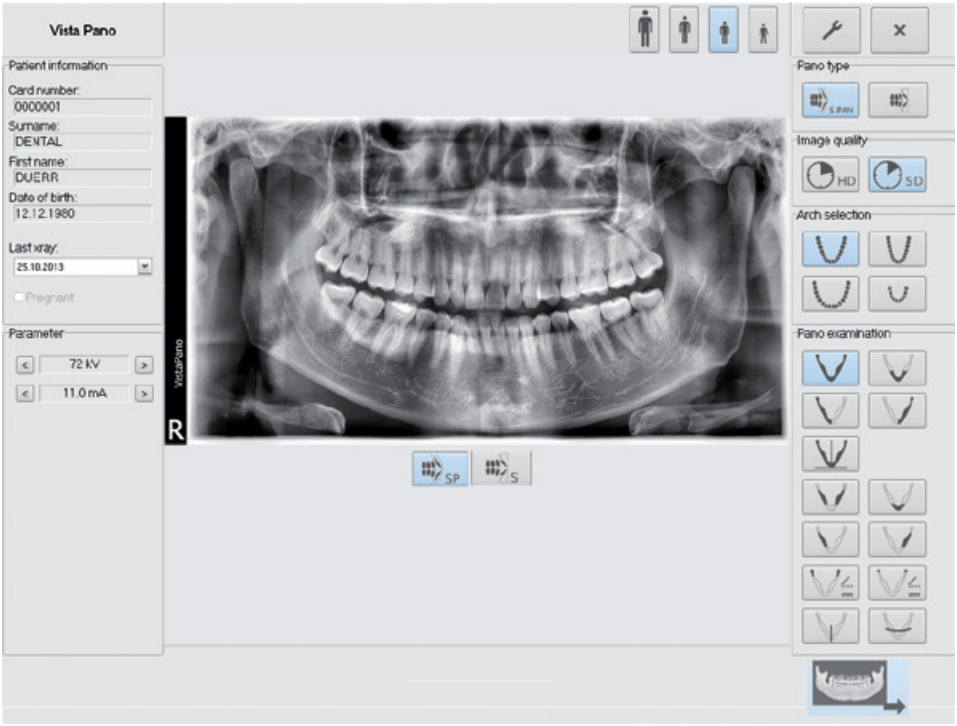
The C angle connector piece moves back to the starting position after the trigger button is released.
The LED on the unit lights blue if the X-ray recording has been completed.
- Release the temple supports.
  The patient can leave the X-ray room.
- Remove the hygienic protective cover.
- Remove and disinfect the positioning aids.

9.6 Transmitting and saving the image

While the image is being triggered, DBSWIN displays a preview of the image.
While the image preview is active, it is possible to select or deselect the S-Pan technology after taking the image. Without an image preview, the image is accepted directly in the database of the software.
For further information on the software, see "DBSWIN manual".

EN

- Check the image and optimise if necessary.



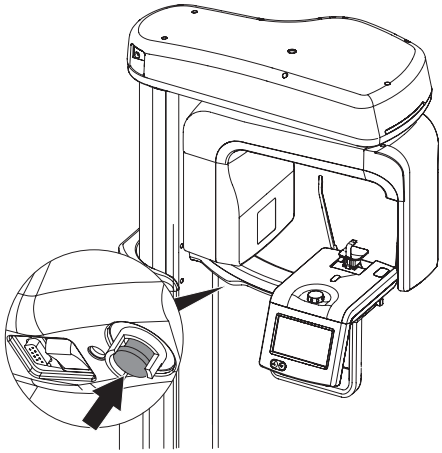
- Use the button  to preselect S-Pan if required.
- Use the button  to preselect the Standard OPG if required.
- Use the button  to accept the image in DBSWIN.

EN

9.7 EMERGENCY OFF

The EMERGENCY OFF button stops the unit and switches it off. It can be used when the unit is taking X-rays, even though the trigger button is not pressed, the patient is injured or the unit is damaged.

- Press the EMERGENCY OFF button.

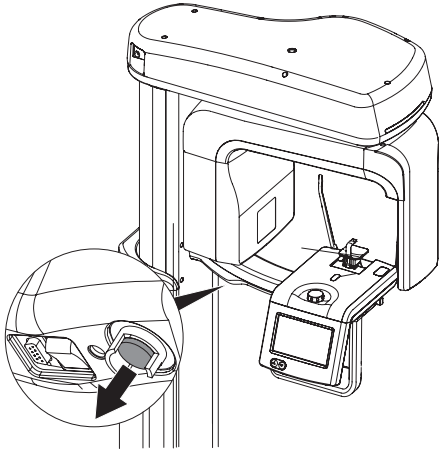


EMERGENCY OFF button lights red.
The unit is switched off.

Unlock the EMERGENCY OFF

Unlock the EMERGENCY OFF to restart the unit.

- Pull the EMERGENCY OFF down to unlock.



- Switch the appliance on again.

9.8 RETURN run

If the X-ray recording has been cancelled by pressing the EMERGENCY OFF button or after a TEST cycle, the C angle connector piece stops in its current position. The C angle connector piece must be moved into the starting position in order to start taking X-rays again.

- Button  On the touch screen, press .

The C angle connector piece moves back to the starting position.

10 Cleaning and disinfecting

NOTICE

Unsuitable agents and methods can damage the appliance and accessories

- Only use the disinfection and cleaning agents specified or approved by Dürr Dental.
- Observe the instructions for use of the disinfection and cleaning agents.

Wear protective gloves

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

10.1 Unit surfaces

NOTICE

Damage to the touch screen by cleaning 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 contamination or soiling. Use the following cleaning and disinfectant agents:

- ✓ FD 322 Quick-acting surface disinfectant
- ✓ FD 333 Quick-acting surface disinfectant
- ✓ FD 350 Disinfection wipes
- ✓ FD 366 Sensitive quick-acting surface disinfectant

NOTICE

Liquid can cause damage to the appliance

- Do not spray the appliance with cleaning and disinfectant agents.
- Make sure that liquid does not get inside the appliance.

- Remove any soiling with a soft, wet, lint-free cloth.
- Disinfect the surfaces using a disinfectant wipe. Alternatively use a spray disinfectant on a soft, lint-free cloth. Observe the instructions for use of the disinfectant.

10.2 Positioning aids

Clean the temple support using the method recommended for the device (see "10.1 Unit surfaces").

Chin support and bite piece are washable and disinfectable in a washer disinfector.

EN

11 Tips for Operators and Technicians

EN

Repairs above and beyond simple maintenance may only be carried out by a qualified technician or one of our service technicians.

Problem	Probable cause	Solution
Unit does not start up	No mains supply	• Check mains cable and sockets and change if necessary. • Inform service technician.
		• Check main fusing in building.
	On / off switch is defect	• Inform service technician.
Unit does not react	The unit has not yet completed the boot procedure	• After switching on, wait until the boot procedure has finished.
	Unit is blocked by the firewall	• Release the ports for the appliance in the firewall settings.

12 Information on EMC according to EN 60601-1-2

12.1 General notes

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical appliances. The information reproduced here should be observed during the installation of individual appliances and when combining Dürr Dental appliances with products of other manufacturers. If there is any question of doubt, the complete standard must be checked.

12.2 Abbreviations

EMC	Electro-magnetic compatibility
HF	High frequency
U_T	Voltage rating of appliance (supply voltage)
V_1, V_2	Level of consistency for testing according to IEC 61000-4-6
E_1	Level of consistency for testing according to IEC 61000-4-3
P	Rated power of transmitter in watts (W) according to manufacturer's information
d	Recommended safety distance in metres (m)

12.3 Guidelines and manufacturer's information

Electromagnetic transmissions for all appliances and systems

The appliance is designed for operation in one of the electromagnetic environments as outlined below. The customer/operator of such an appliance is obliged to ensure that the appliance is operated in such an environment.

Interference measurements	According to	Electro-magnetic environment – guidelines
HF transmissions according to CISPR 11	Group 1	The appliance employs HF energy exclusively for internal functions. Therefore, any HF transmissions are of extremely low nature and it is highly improbable that any other electronic components will receive any interference.
HF transmissions according to CISPR 11	Group 2	The appliance must transmit electromagnetic energy in order to fulfil the functions for which it has been designed. Other electronic appliances in the vicinity could be affected.
HF transmissions according to CISPR 11	Class [A or B]	The appliance is designed for use in all types of environment including those in residential areas and other suitable areas which are connected directly to the local power supply serving residential buildings.
Harmonic limits according to IEC 61000-3-2	[Class A, B, C, D or Not Applicable]	
Voltage fluctuations/flicker according to IEC 61000-3-3	[Fully compatible or not applicable]	

Table 1: Electromagnetic transmissions for all appliances and systems

Electromagnetic resistance for all appliances and systems

The appliance is designed for operation in one of the electromagnetic environments as outlined below. The customer/operator of such an appliance is obliged to ensure that the appliance is operated in such an environment.

EN

Resistance to interference checks	IEC 60601 - test levels	Level of consistency	Electro-magnetic environment – guidelines
Discharge of static electricity (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV discharge to air	±6 kV contact discharge ±8 kV discharge to air	Floors should be of wood or concrete or be covered by ceramic tiles. If the floor is covered by synthetic material, the relative humidity must be at least 30%.
Rapid transient electrical bursts according to IEC 61000-4-4	±2 kV for mains connections ±1 kV at input and output connections	±2 kV for mains connections ±1 kV at input and output connections	The quality of the supply voltage should be that of a typical office building or of a hospital environment.
Surges according to IEC 61000-4-5	±1 kV voltage external-external conductor ±2 kV voltage external-ground conductor	±1 kV push-pull voltage ±2 kV push-pull voltage	The quality of the supply voltage should be that of a typical office building or of a hospital environment.
Voltage drops, interruptions and fluctuations according to IEC 61000-4-11	< 5% U_T (> 95% retardation of U_T) for 1/2 period 40% U_T (60% retardation of U_T) for 5 periods 70% U_T (30% retardation of U_T) for 25 periods < 5% U_T (> 95% retardation of U_T) for 5 s	< 5% U_T (> 95% retardation of U_T) for 1/2 period 40% U_T (60% retardation of U_T) for 5 periods 70% U_T (30% retardation of U_T) for 25 periods < 5% U_T (> 95% retardation of U_T) for 5 s	The quality of the supply voltage should be that of a typical office building or of a hospital environment. Where the operator of the appliance requires continued function even during a power out, we recommend that the appliance is supplied by an uninterrupted power supply, e.g. battery power.
Magnetic field under supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the supply voltage should have the values found in a typical office building or of a hospital environment.

Table 2: Electromagnetic resistance for all appliances and systems

Electromagnetic resistance to interference for non life-supporting appliances or systems

Portable and cordless radio appliances should not be used close to the appliance, including any electrical supply lines, as the recommended safety distance which has been calculated from the transmission frequency.

Resistance to interference checks	IEC 60601 - test levels	Level of consistency	Recommended safety distance
Conductive HF interference factor according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ V	$d = [3.5 / V_1] \cdot \sqrt{P}$ $d = 1.2 \cdot \sqrt{P}$
Radiated HF interference factor according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ V/m	$d = [3.5 / E_1] \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = [7 / E_1] \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz

Table 3: Electromagnetic resistance to interference for non life-supporting appliances or systems

P Rated power of transmitter in watts (W) according to manufacturer's information

d Recommended safety distance in metres (m)

The field strength of stationary radio transmitters for all frequencies must be, according to investigation carried out on-site[a] lower than the consistency level.[b]

Some interference is possible in environments surrounding appliances where the following symbol is present.

Note 1 Where 80 MHz and 800 MHz are present, the higher frequency range becomes valid.

Note 2 These guidelines are not applicable for all possible situations. The exact amount of electro-magnetic transmissions can be considerably influenced by the rate of absorption and reflection within the building, and the presence of objects and people.

[a] The field strength of stationary transmitters, e.g. base station of radio telephones or cordless landline phones, amateur radio stations, on AM and FM radio or TV, cannot be theoretically exactly calculated in advance. In order to establish the electromagnetic environment taking these stationary transmitters into account, a study of the electromagnetic phenomena of the actual location must be undertaken. If the field strength measured at the location where the appliance is used exceeds the above level of consistency, the appliance should be observed in order to demonstrate the intended function. If any unusual behaviour of the appliance is observed, additional steps will be required, e.g. changing the orientation or location of the appliance.

[b] The field strength is less than $[V_1]$ V/m over the frequency range of 150 kHz to 80 MHz.

Recommended safety distances between portable and mobile HF communications devices and the appliance

The appliance is designed for operation in one of the electromagnetic environments as outlined below in which the HF interference is controlled. The customer/operator of the appliance can help to prevent electromagnetic interference by maintaining minimum distances as recommended between portable and mobile HF communications devices (transmitters) and the appliance as outlined below according to the maximum output of the communications device.

EN

Rated power of transmitter (W)	Safety distance dependent on 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 4: Recommended safety distances between portable and mobile HF communications devices and the appliance

For transmitters whose maximum rated current is not included in the table above the recommended safety distance d in metres (m) can be calculated using the following mathematical formula and the appropriate column, where P is the maximum rated current of the transmitter in watts (W) according to the information of the manufacturer of the transmitter.

Note 1 Where 80 MHz and 800 MHz are present, the higher frequency range becomes valid.

Note 2 These guidelines are not applicable to all possible situations. The exact amount of electro-magnetic transmissions can be considerably influenced by the rate of absorption and reflection within the building and the presence of objects and people.

12.4 Table of calculation

If the measured values deviate from the standard, the values in chapter "4 Technical data" are specified.

The safety distances can then be calculated in the tables shown below.

P : .....

V_1: .....

E_1: .....

P Rated power of transmitter in watts (W) according to manufacturer's information

V_1 Level of consistency for testing according to IEC 61000-4-6

E_1 Level of consistency for testing according to IEC 61000-4-3

Resistance to interference checks	IEC 60601- test levels	Level of consistency	Recommended safety distances
Conductive HF interference factor according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	d = [3.5 / V_1] · √P
Radiated HF interference factor according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	d = [3.5 / E_1] · √P For 80 MHz to 800 MHz
			d = [7 / E_1] · √P For 800 MHz to 2.5 GHz

Rated power of transmitter (W)	Safety distance dependent on transmission frequency (m)		
	150 kHz to 80 MHz **d = [3.5/V_1] ·√P**	**80 MHz to 800 MHz** **d = [3.5/E_1]·√P**	**800 MHz to 2.5 GHz** **d = [7 / E_1] ·√P**
0.01			
0.1			
1			
10			
100			

13 Program parameters

13.1 Large, powerful man, S-Pan

EN

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
SD	Standard panoramic	74	15	116.0	7.0
SD	Right, left	74	15	57.5	3.5
SD	Front	74	15	95.3	6.0
SD	Bite wing	74	15	114.4	7.2
SD	Bite wing, right, left	74	15	57.4	3.6
SD	Bite wing, front	74	15	30.2	1.9
SD	Orthogonal	74	15	214.5	13.5
SD	Maxillary joint, lateral	74	15	96.8	6.1
SD	Maxillary joint, PA	74	15	111.0	7.0
SD	Sinus, lateral	74	15	95.3	6.0
SD	Sinus, PA	74	15	163.6	10.3

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
HD	Standard panoramic	74	10	143.0	13.5
HD	Right, left	74	10	71.0	6.7
HD	Front	74	10	117.4	11.1
HD	Bite wing	74	10	101.7	9.6
HD	Bite wing, right, left	74	10	50.8	4.8
HD	Bite wing, front	74	10	26.6	2.5
HD	Orthogonal	74	10	143.0	13.5
HD	Maxillary joint, lateral	74	10	64.6	6.1
HD	Maxillary joint, PA	74	10	74.0	7.0
HD	Sinus, lateral	74	10	63.6	6.0
HD	Sinus, PA	74	10	109.1	10.3

13.2 Adult, male, S-Pan

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
SD	Standard panoramic	73	12	90.4	7.0
SD	Right, left	73	12	44.8	3.5
SD	Front	73	12	74.3	6.0
SD	Bite wing	73	12	89.1	7.2
SD	Bite wing, right, left	73	12	44.7	3.6
SD	Bite wing, front	73	12	23.5	1.9
SD	Orthogonal	73	12	167.3	13.5
SD	Maxillary joint, lateral	73	12	75.5	6.1
SD	Maxillary joint, PA	73	12	86.6	7.0
SD	Sinus, lateral	73	12	74.4	6.0
SD	Sinus, PA	73	12	127.5	10.3

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
HD	Standard panoramic	73	10	139.4	13.5
HD	Right, left	73	10	69.2	6.7
HD	Front	73	10	114.5	11.1
HD	Bite wing	73	10	99.1	9.6
HD	Bite wing, right, left	73	10	49.5	4.8
HD	Bite wing, front	73	10	25.9	2.5
HD	Orthogonal	73	10	139.4	13.5
HD	Maxillary joint, lateral	73	10	62.9	6.1
HD	Maxillary joint, PA	73	10	72.2	7.0
HD	Sinus, lateral	73	10	62	6.0
HD	Sinus, PA	73	10	106.3	10.3

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13.3 Grown-up, female, S-Pan

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
SD	Standard panoramic	72	11	80.7	7.0
SD	Right, left	72	11	40.0	3.6
SD	Front	72	11	66.2	6.0
SD	Bite wing	72	11	79.5	7.2
SD	Bite wing, right, left	72	11	39.9	3.6
SD	Bite wing, front	72	11	21.0	1.9
SD	Orthogonal	72	11	149.2	13.5
SD	Maxillary joint, lateral	72	11	67.3	6.1
SD	Maxillary joint, PA	72	11	77.3	7.0
SD	Sinus, lateral	72	11	66.4	6.0
SD	Sinus, PA	72	11	113.8	10.3

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
HD	Standard panoramic	72	10	135.8	13.5
HD	Right, left	72	10	67.4	6.7
HD	Front	72	10	111.5	11.1
HD	Bite wing	72	10	96.5	9.6
HD	Bite wing, right, left	72	10	48.2	4.8
HD	Bite wing, front	72	10	25.2	2.5
HD	Orthogonal	72	10	135.8	13.5
HD	Maxillary joint, lateral	72	10	31.3	6.1
HD	Maxillary joint, PA	72	10	70.3	7.0
HD	Sinus, lateral	72	10	60.4	6.0
HD	Sinus, PA	72	10	103.6	10.3

13.4 Child, S-Pan

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
SD	Standard panoramic	67	10	48.9	6.1
SD	Right, left	67	10	20.4	3.1
SD	Front	67	10	33.0	5.2
SD	Bite wing	67	10	84.9	9.2
SD	Bite wing, right, left	67	10	42.4	4.8
SD	Bite wing, front	67	10	22.1	2.5
SD	Orthogonal	67	10	76.3	11.5
SD	Maxillary joint, lateral	67	10	54	6.1
SD	Maxillary joint, PA	67	10	61.9	7.0
SD	Sinus, lateral	67	10	53.1	6.0
SD	Sinus, PA	67	10	91.1	10.3

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
HD	Standard panoramic	67	8	62.0	11.5
HD	Right, left	67	8	30.7	5.7
HD	Front	67	8	49.6	9.2
HD	Bite wing	67	8	68.9	9.6
HD	Bite wing, right, left	67	8	34.5	4.8
HD	Bite wing, front	67	8	17.9	2.5
HD	Orthogonal	67	8	62.0	11.5
HD	Maxillary joint, lateral	67	8	43.9	6.1
HD	Maxillary joint, PA	67	8	50.3	7.0
HD	Sinus, lateral	67	8	43.1	6.0
HD	Sinus, PA	67	8	74.0	10.3

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