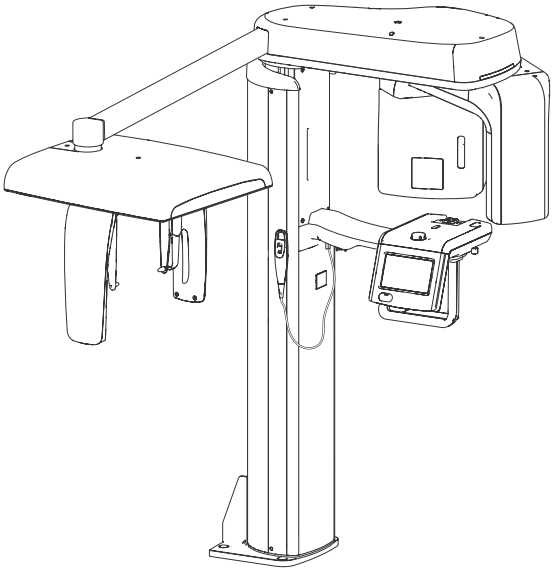
PRO▸VECTA® S-Pan Ceph

*Panoramic **Cephalometric** X-ray System*

Operating Instructions



AIR TECHNIQUES equipped for life®

CE 2460

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Important information

1 Documentation

This document forms an integral part of the unit. It provides setup and operating information that conforms to the relevant version of the equipment and the status of technology valid at the time of the first operation. All operators must read and understand this manual prior to using the device.

Air Techniques cannot guarantee smooth operation and safe function of the unit and will not accept any liability when the instructions and notes contained in this installation and operating instructions are not strictly observed.

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 ignoring the 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 the danger of minor injuries

– **NOTICE**
Risk of serious damage

Federal law restricts this device to sale by or on the order of a dentist licensed by the law of the State in which he practices to use or order the use of the device. Use of this device, other than as described in this manual, may result in injury.

Additional 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.

UL certification mark.
IEC/EN 60601-1 (3rd Ed.)
UL 60601-1 (1st), IEC/EN 60601-1-2
IEC/EN 60601-1-3, IEC/EN 60601-2-63

CE 2460 CE Labeling

Manufacturer

Date of Manufacture

Indicates the authorized representative in the European Community.

EC REP EC Representative; Vatech Global France (SARL)
51 Quai de Dion Bouton 92800 Puteaux France

Class I type B

Only use once.

Wear protective gloves

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

Laser class 1 product

1.2 Notes on copyright

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

Any reprinting of the technical documentation, in whole or in part, is subject to prior approval of Air Techniques 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.

2.2 Incorrect use

Any use of this device 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 device observe any and all guidelines, laws, regulations and other restrictions which may apply to the device.
- Before each use check the function and condition of the device.
- Do not convert or change the device 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.
- 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.
- The status LED indicates when and X-ray image is triggered.
  Optionally, it is possible that the triggering of an X-ray image is enabled or interrupted by a door switch.

2.5 Qualified personnel

Instructions for use

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

- Ensure personnel is trained in the correct usage of the device.

Installation and repair

- Installation, resetting, alterations, extensions and repairs must be carried out by qualified personnel specifically approved and authorized by Air Techniques.
- Equipment not suitable for use in the presence of flammable anaesthetic mixture with air or oxygen or nitrous oxide.

2.6 Protection against electrical current

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

Observe guidelines for electro-magnetic compatibility for medical devices

- Follow special precautionary measures with regard to electromagnetic comparability (EMC) for medical products, see "13 Information on EMC according to EN 60601-1-2".

2.7 Only use original parts

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

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

2.8 Transport

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

Air Techniques 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 device 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 device to any strong shocks.
- Do not bump or pull the unit.

2.9 Disposal

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

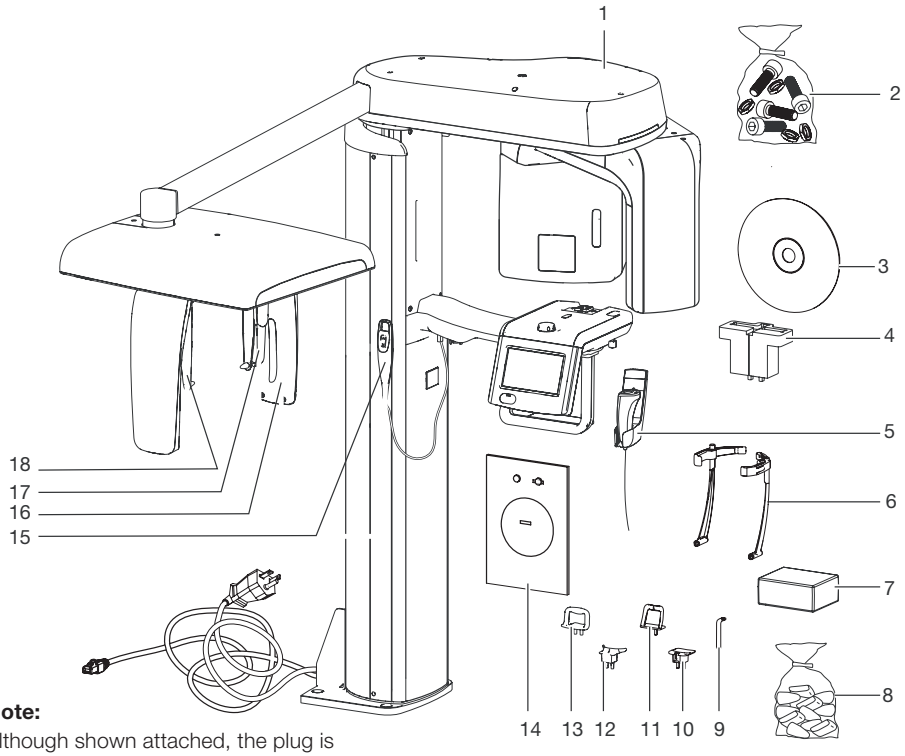
Tubehead:
Non-biodegradable plastic materials, metals, glass, dielectric oil, lead, tungsten.

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

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

Product description

3 Overview



Note:
Although shown attached, the plug is supplied separately and must be installed when connecting to a power outlet.

1 X-ray system
2 Installation Mounting Hardware
3 Provecta S-Pan Ceph Utility Disk
4 2-D X-ray test phantom holder
5 Exposure switch
6 Temple support plus*
7 Bite block covers*
8 Ear cushions and nose support covers*
9 Bite block*
10 Holder for a bite block
11 Chin support for maxillary joint image*
12 Chin support for edentulous jaws*
13 Chin support for sinus image*
14 Carpus plate*
15 Manual switch for height adjustment
16 Secondary aperture
17 Nose support
18 Ear cushions with holder

* Denotes parts in contact with patient

3.1 Delivery Contents

The following articles are included in the scope of delivery:

Provecta S-Pan Ceph A7550

– ProVecta S-Pan Utility Disk
– Mains cable, 8 ft. (2.5 m)
– Mains Plug, NEMA 6-20
– Network cable, 33 ft. (10 m)
– Exposure Switch
– Holder for a bite block
– Bite block
– Chin support for edentulous jaws
– Chin support for maxillary joint image
– Chin support for sinus image
– Temple support plus
– Ear cushions and nose support covers
– Carpus plate
– Nose support
– Ear cushions with holder
– Bite block covers
– Installation mounting hardware
– Operating Instructions
– Installation instructions
– PCI Express Gigabyte Ethernet card
– Manual switch for height adjustment includes a holder

3.2 Accessories

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

Laser test tool. A7385
Ball phantom A7330
Bite block cover A7395

Positioning aids

Holder for bite block A7375
Bite block (3 pieces). A7751
Chin support for edentulous jaws A7390
Temple support plus (1 pair) A7800
Chin support for mandibular joint image A7391
Chin support for sinus image. A7392
Ear cushions with holder A7514
Nose support A7513
Carpus plate A7511
Hygienic protective covers for bite block A7395

3.3 Special accessories

The following items can be optionally used with the device:

2-D X-ray test phantom Set A7556
Floor Stand A7355

3.4 Disposable materials

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

Bite block cover A7395

Ear cushions and nose support covers . . A7510

4 Technical data

Electrical data, unit	
Nominal voltage	200 - 240 V AC
Maximum voltage fluctuation	±10 %
Frequency	50/60 Hz
Power rating	170 W
Maximum power	2.2 kVA
Classification	
FDA 21 CFR Device Classification	Class II
This X-ray system complies with US - FDA:	21 CFR Part 1010.2 and 21 CFR Part 1020.30/31
Degree of protection against ingress of water	Ordinary
Manufacturer: VATECH Co., Ltd. for Air Techniques	
13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, 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	3 V/m
Radiated HF interference E_1 in accordance with IEC 61000-4-3	3 V_{eff}
Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. *See also 12 Information on EMC according to EN 60601-1-2"	

X-ray generator electrical data	
Generator Model	DG-07C11T2 (H)
X-ray Tube Model	Canon D-052SB
Tube voltage * Values below 60 kV are not intended for human use in USA and Canada	60 - 99 kV (±10%)
Tube current	4 - 16 mA (for 1 kVp)
Focal spot size as per IEC 60336	0.5 mm
Anode angle	5 degrees
Inherent filtration at 50 kV	0.8 mm Al
Total filtration at 50 kV	2.8 mm Al
Duration of the X-ray Exposure	1.9 - 13.5 sec
Pulse to pause ratio	1:60 or greater

General technical data		
Height	62.48 to 89.88 in.	1587 to 2283 mm
Operating Dimensions (W x D)	77 x (48-51) in.	1938 x (1223-1284) mm
Vertical radius	28 in.	700 mm
Weight without optional stand assembly	286 lb.	130 kg
Weight with optional stand assembly	396 lb.	180 kg
Ambient temperature during operation		
Temperature	50 to 95 °F	10 to 35 °C
Relative humidity	30 to 75 %	
Air pressure	21 to 31 in of mercury (860 to 1060 hPa)	
Ambient conditions during storage and transport		
Temperature	14 to 140 °F	-10 to +60 °C
Relative humidity	10 to 75%	
Air pressure	25 to 31 in of mercury (860 to 1060 hPa)	

Detector		**Panoramic**	**Ceph**
Model		Xmaru 1501CF	Xmaru 2301CF
Brand		Xmaru 1501CF-HS	Xmaru 2301CF-HS
Type		CMOS photodiode array	
Pixel size		100 µm	
Active surface		6 x 150.4 mm	5.9 x 230.4 mm
Frame rate		300 fps	200 fps
Greyscales		14 bit	

Exposer mode	**FDD mm**	**FOD mm**	**ODD mm**	**Image capture scale (magnification factor)**
Panoramic	490.2	375.0	115.2	1.3
Ceph	1745	1525	220	1.14

FDD = Focal spot - detector distance

FOD = Focal spot - object distance

ODD = Object - detector distance (ODD = FDD - FOD

FDD/FOD = Image capture scale

4.1 X-ray tube performance data

– Maximum deviation of peak tube potential from indicated value: ±10 %.

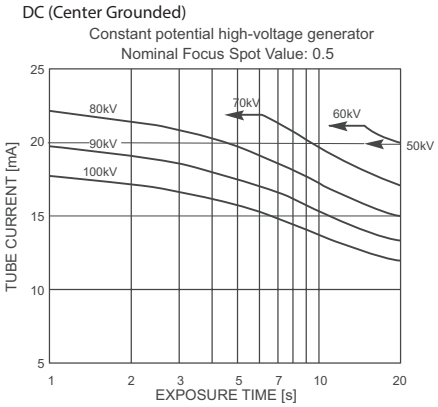
– Maximum deviation of tube current from indicated value: ±20 %.

– Maximum deviation of exposure time from indicated value: ±

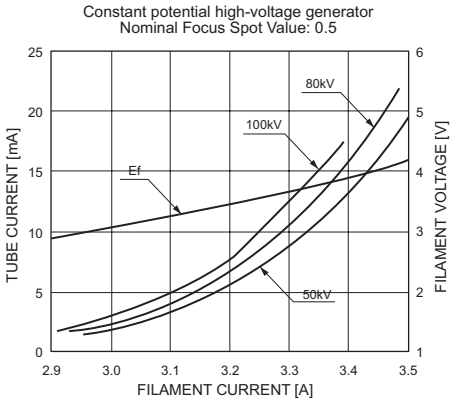
– This device is compliance with IEC 61223-3-4 and IEC 60601-1.

– The combinations of loading factors resulting in the lowest current time product: 50kV and 4mA.

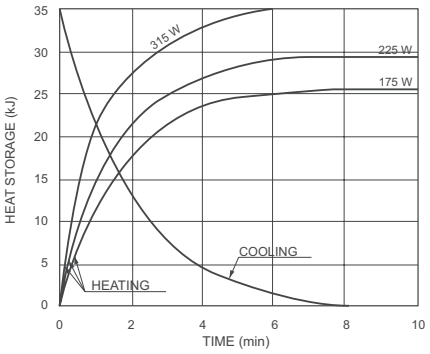
Maximum Rating Charts



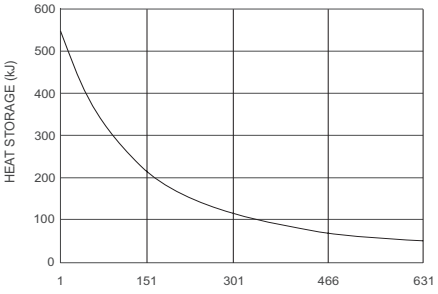
Emission and Filamant Characteristics



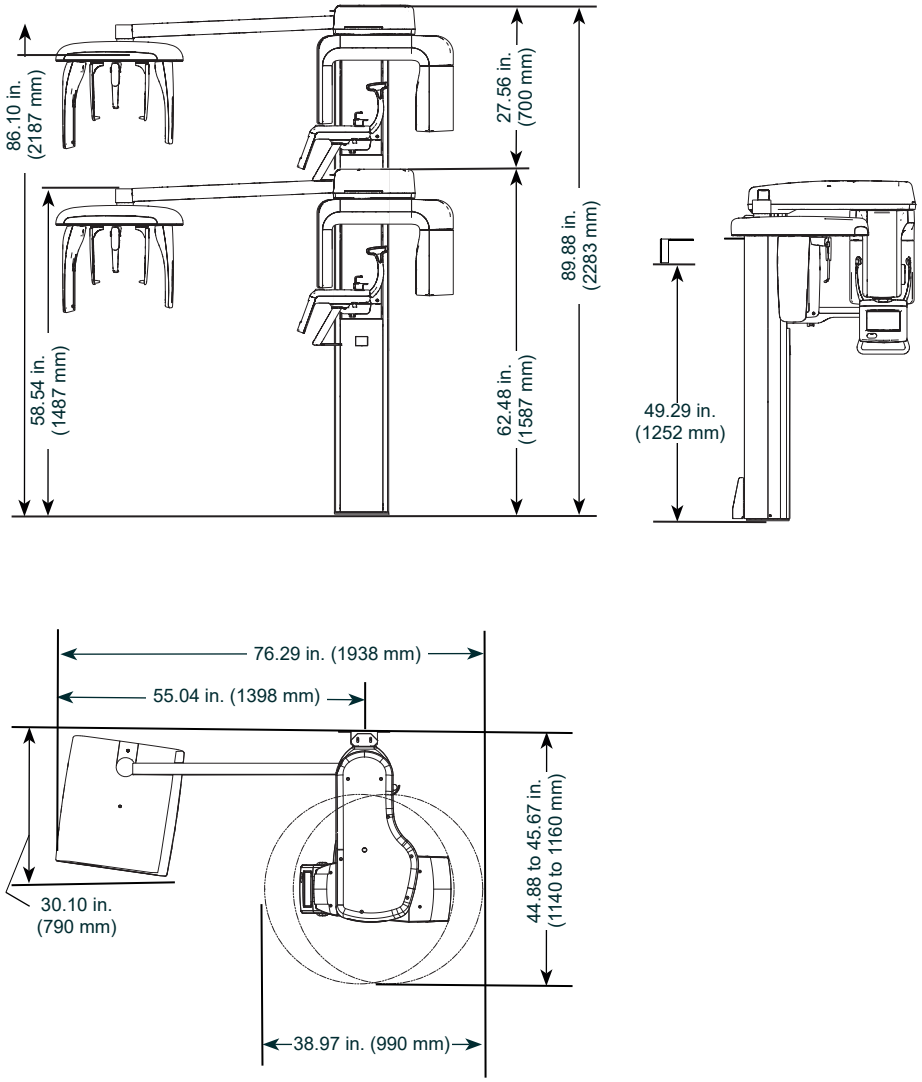
Anode Thermal Characteristics



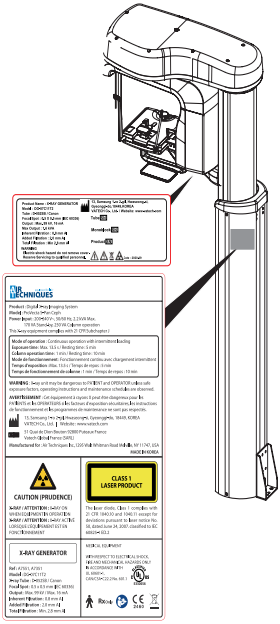
Monoblock Cooling Curve



4.2 Dimensions

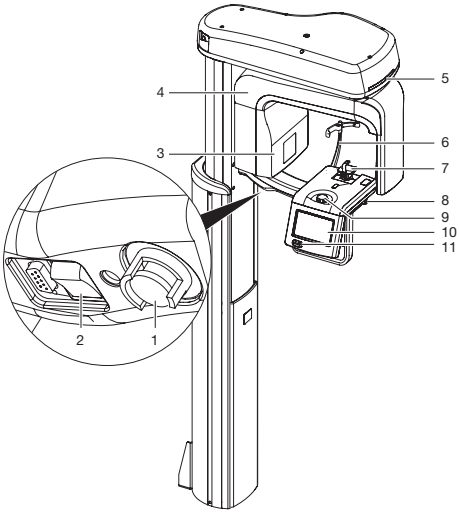


4.3 Model identification plate. As shown below, the model and serial numbers are affixed on the X-ray tube and on the telescopic column via identification plates.



5 Function

5.1 Panorama X-ray unit

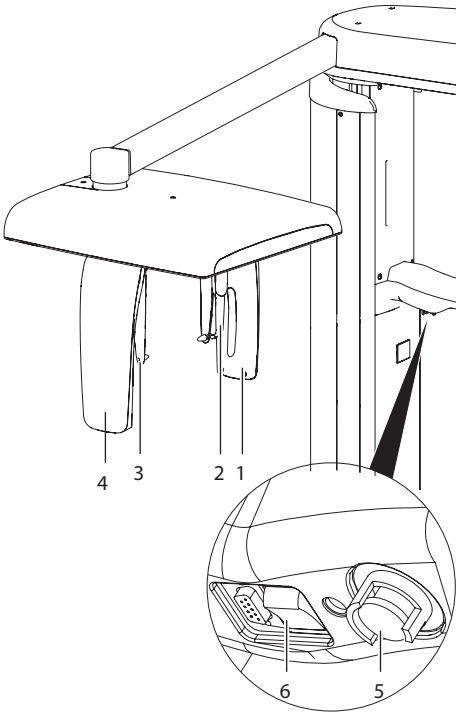


1 EMERGENCY OFF button
2 On/Off switch
3 X-ray tube
4 Rotating unit
5 Status LED
6 Head support with cushion
7 Chin support and bite block
8 Switch to set the beam localizer to the maxillary canine
9 Setting wheel to adjust the head support
10 Touch LCD display
11 Buttons for the height adjustment

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

The X-ray process is started and image acquired via the third party imaging software and the touch screen.

5.2 Cephalometric (Ceph) unit

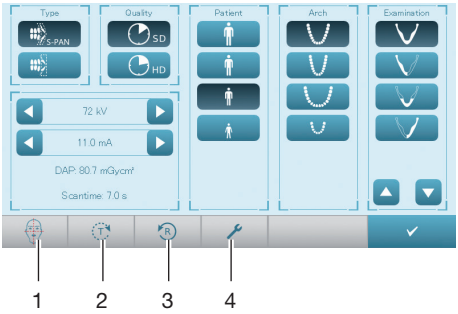


1 Secondary aperture
2 Nose support
3 Ear cushions with holder
4 Sensor (Ceph)
5 EMERGENCY OFF button
6 On/Off switch

The remote X-ray unit digitally records the anatomy of the cranium.

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

5.3 Touch screen

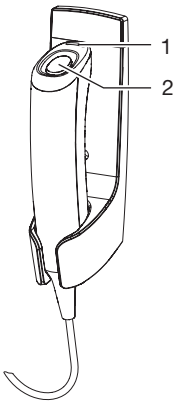


1 Activate/deactivate all beam localizers
2 Test circulation, keep the button pressed
3 Return
4 Set language, activate/deactivate audio

5.4 Exposure Switch

The prepared image is triggered by the exposure switch 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



1 Indicator lamp (LED)
2 Exposure button

Alternative exposure switch (optional)

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

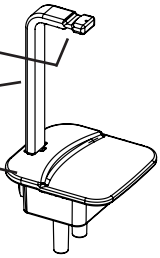
5.5 Positioning aids

The patient is properly positioned in the unit with the help of the positioning aids. Suitable positioning aid is selected according to the selected image. The head support gently keeps the head of the patient in place.

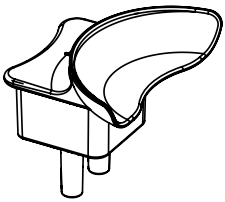
Handpiece protective cover for Bite Block, A7395

Bite Block, A7751

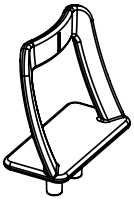
Holder for Bite Block, A7375



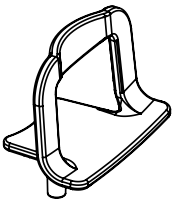
Chin support for edentulous patients A7390



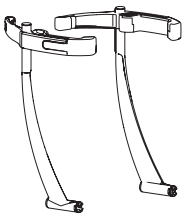
Support for maxillary joint image A7391



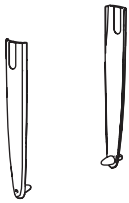
Support for sinus image, A7392



Temple support plus, A7800

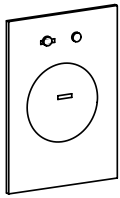


Ear cushions with holder, A7514



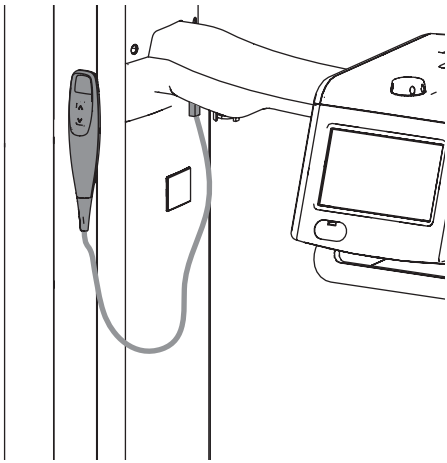
Nose support, A7513

Carpus plate, A7511



5.6 Manual switch for height adjustment

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



Setup

Only fully-qualified or from Air Techniques trained personnel may set-up, install or operate this device.

6 Prerequisites

The room chosen for set up should fulfill 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 section 4 Technical data".

6.1 System requirements

The system requirements of computer systems are provided as part of the Annex of this manual. (Section 18).

6.2 Monitor

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

Please note that strong ambient light, sunlight falling directly onto the monitor and associated reflections can reduce the X-ray image display detail.

7 Power Connection

7.1 Safety for the electrical connection

- The device may only be connected to a correctly installed grounded socket-outlet.
- Do not lay multi-socket units on the floor. Follow 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 device 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 section 4, Technical Data).

Important:
Short circuit due to build up of condensation
The appliance can only be put into operation once it has warmed up to room temperature and it is dry.

7.2 Connecting the device to power

Requirements:

✓ Correctly installed socket outlet in the vicinity of the unit (maximum length of mains cable 8 feet or 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.
- For continued protection against risk of fire, replace only with the same type and rating of circuit breakers and fuses.

7.3 Safe connection of device

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

DANGER
Electric shock because device is not connected with protective earth

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

- Only connect units when there can be no question of danger to the 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 device 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 ground fault protected components (e.g. computer, monitor, printer) that are electrically safety tested and bear safety markings.

  Connect the device and computer to a common protective earth.
- 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 minimum.

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 Operational check

The Provecta S-Pan 2-D X-ray test phantom set, as well as the suitable 2-D X-ray test phantom holder, is required.

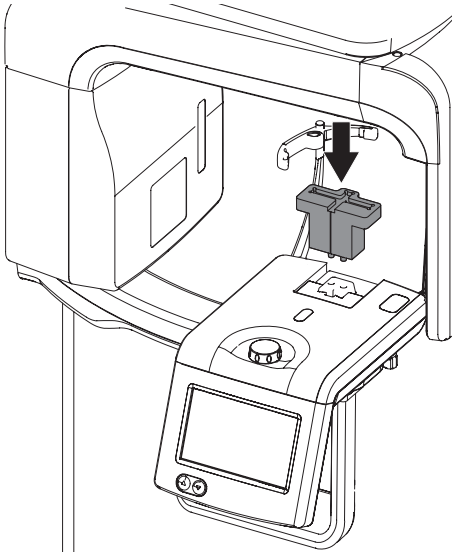
- Before commissioning, carry out the operational check of the X-ray system according to current regulations for the installation site.

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

Inserting the 2-D X-ray test phantom holder

The 2-D X-ray test phantom is used on the 2-D X-ray test phantom holder for the acceptance and consistency test.

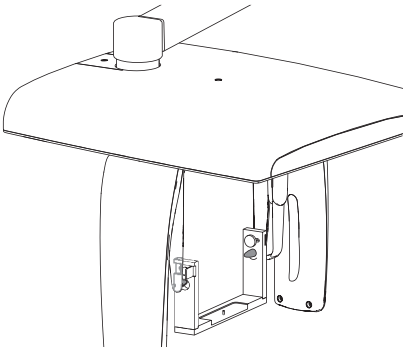
- Inserting the 2-D X-ray test phantom holder



Insert the Ceph 2-D X-ray test phantom holder

The 2-D X-ray test phantom is used on the 2-D X-ray test phantom holder for the acceptance and consistency test.

- Insert the 2-D X-ray test phantom holder.



8.2 Electrical safety check

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

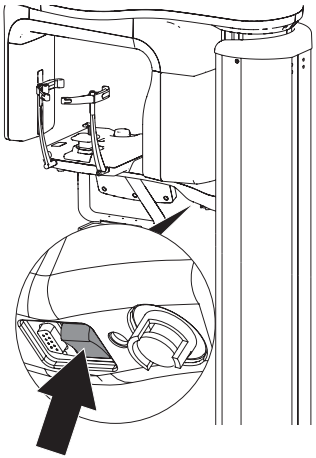
8.3 Switch unit on

CAUTION

Danger of injury due to the rotating unit moving

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

- No persons may remain in the area of the rotating unit 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 device

The unit supports authorized third-party imaging programs via the Twain interface. Refer to the Software Installation and Configuration Guide, P/N A7371, for additional information.

Setting up the network

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

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

9 Instructions for use

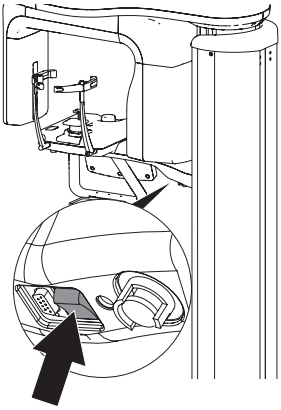
9.1 Switch unit on

CAUTION

Danger of injury due to the rotating unit moving

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

- No persons may remain in the area of the rotating unit 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 Provecta S-Pan TWAIN interface software. For further information on using the imaging software, see the respective manual.

Parameter overview in Provecta S-Pan

Patient type

The patient type selection is determined by the body or the head size of the patient. Although each patient type is set to default parameters, the available specifications can be changed as necessary to meet the patient requirements.

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

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

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

Large Adult | Average Adult | Small Adult/Youth | Child (< 13 years)

Provecta S-Pan type

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 extended exposure time.

SD: This setting is used for standard images.

HD - Panoramic image | SD - Panoramic image

Maxillary arch

The selected jaw form influences the rotational behavior of the rotating unit 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

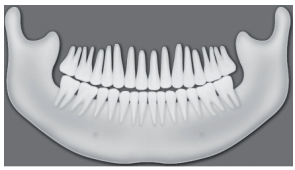
Wide jaw

Narrow jaw

Child/Deciduous teeth

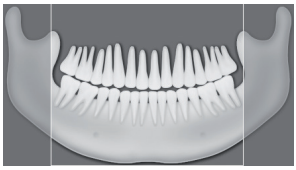
Imaging program

Panoramic image



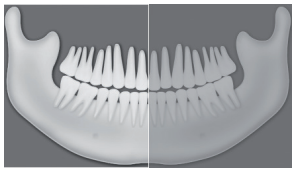
Standard

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



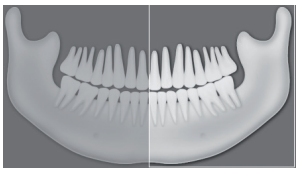
Front

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



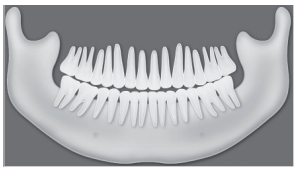
Right

The image only shows the right dental area.



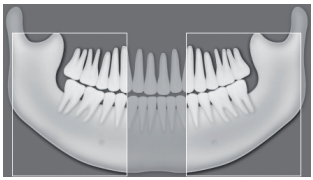
Left

The image only shows the left dental area.



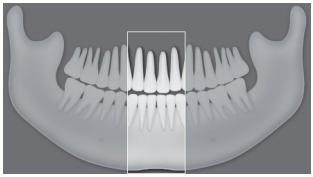
Orthogonal

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



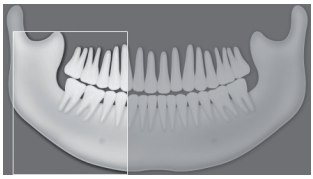
Bite wing

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



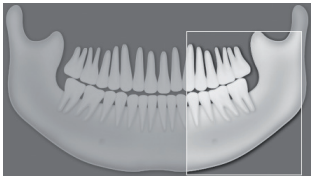
Bite wing front

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

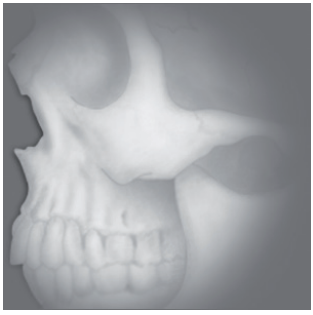
The image shows the left posterior region with a size limited to the bite wings.

Lateral maxillary joint

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

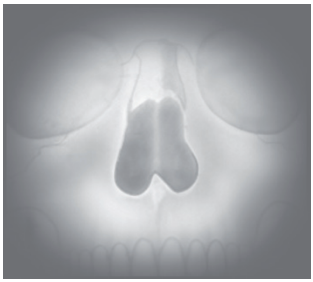
Maxillary joint PA

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



Lateral sinus

The image shows the lateral sinuses.

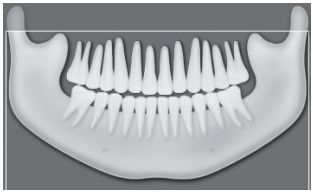


PA sinus image

The image shows the posterior-anterior sinuses.

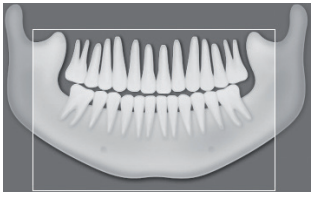
Panoramic image, child

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



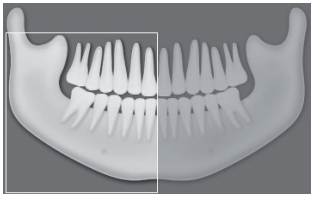
Standard

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



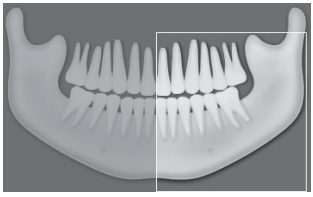
Front

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



Right

The image only shows the right dental area.



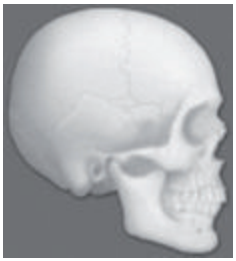
Left

The image only shows the left dental area.

Preparing an X-ray image in Provecta S-Pan Ceph

Select acquire image via Twain third party applications.

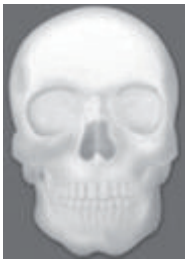
Cephalometric (Ceph) image



Lateral head

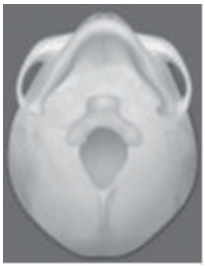
The image shows the skull and profile of the head of the patient.

The **Full lateral head** option is also available. (Changeable mode is not supported.)



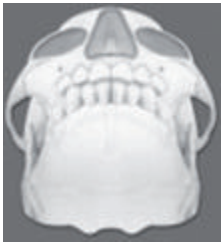
Head PA

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



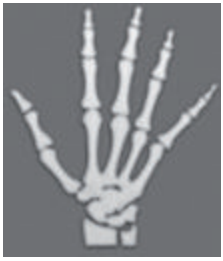
SMV

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



Waters View

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



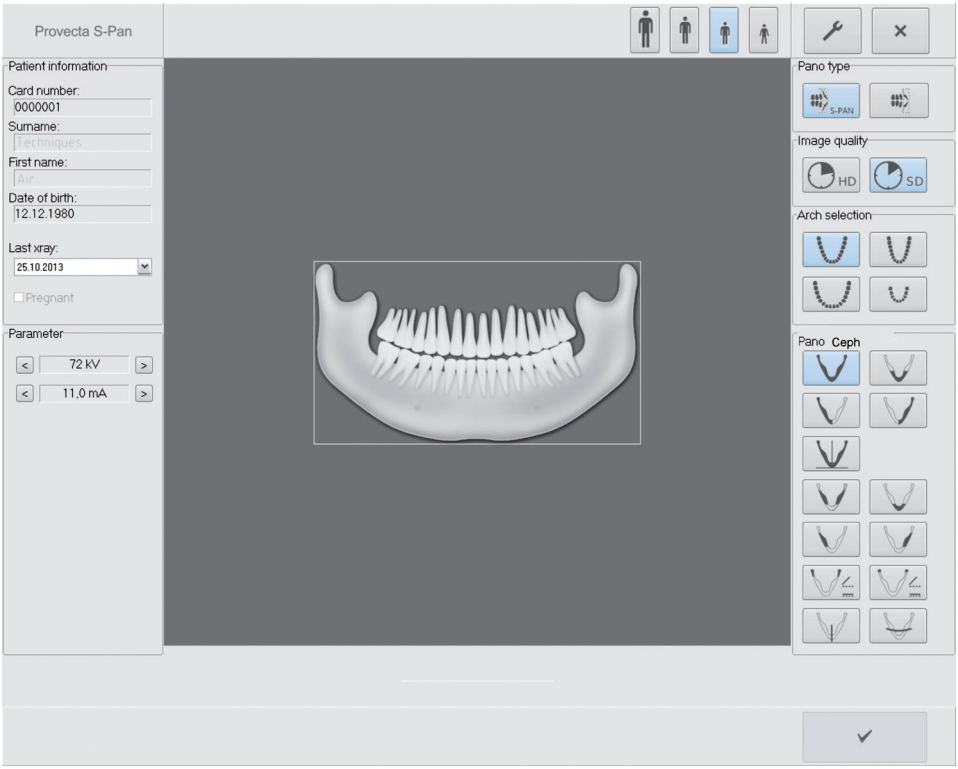
Carpus

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

The control window shown below opens.

- Check the patient type, maxillary arch and imaging parameters.
- If necessary, change the parameters and confirm with button ✓.
- Continue to work directly on the unit.

Refer to section 19, Image Transfer Retrieval if an image transfer is terminated prematurely.



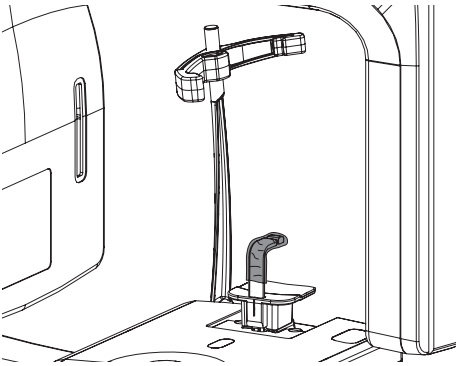
9.3 Setting up the unit

WARNING

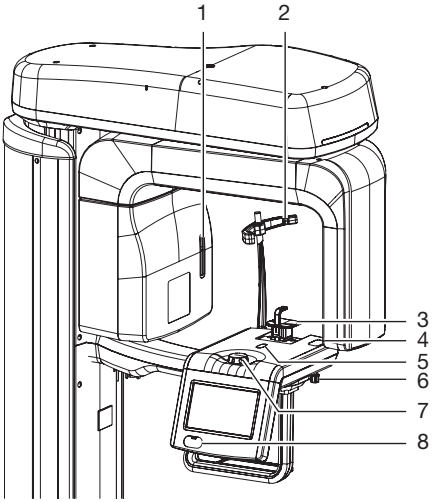
Danger of cross contamination if hygienic protective covers are not used or are used more than once

- Do not use the bite block without a bite block cover.
- Do not use a bite block cover more than once (single use).

- Disinfect the positioning aids, see "10 Cleaning and disinfecting".
- Equip the bite block with a bite block cover and insert.



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



1 Frankfort horizontal plane of the X-ray positioning beam
2 Head support with cushion
3 Positioning aids, e. g. chin support with the bite block
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 head support
8 Buttons for the height adjustment

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.

Requirements:

✓ Make sure the patient is not wearing jewellery and metal objects, e. g. earrings, hair clips, glasses, artificial dentures or orthodontic aids.

✓ Make sure the patient is wearing a protective lead apron.

✓ Inform the patient about the X-ray procedure.

✓ Instruct the patient to place his/her tongue against the roof of the mouth during the X-ray.

✓ Inform the patient to keep eyes closed during the positioning of the X-ray positioning beam.

✓ Make sure the patient knows not to move during the X-ray and until the device is back in the starting position.

CAUTION

Danger of injury due to the rotating unit moving

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

- No persons may remain in the area of the rotating unit 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.

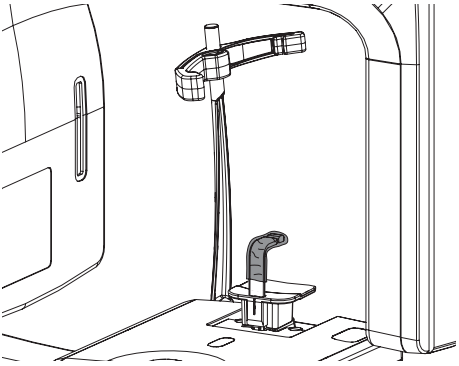
Preparing the panoramic imaging

WARNING

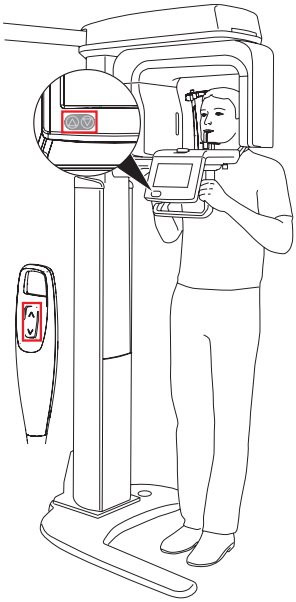
There is a danger of cross contamination when hygienic protective covers are not used or are used more than once

- Do not use the bite block without the bite block cover.
- Do not use the bite block cover more than once (single use).

- Equip the bite block with a bite block cover.
- Insert the bite block.



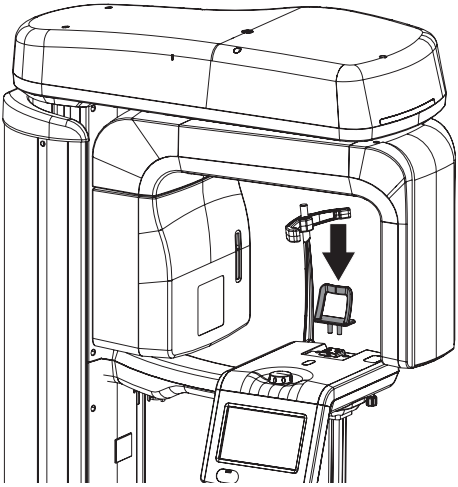
- The patient bites in the grooves provided on the bite block with the upper and lower incisors. (Use the chin support for edentulous patients in the case of patients who do not have any teeth.)



- Correct the height of the unit again if necessary.

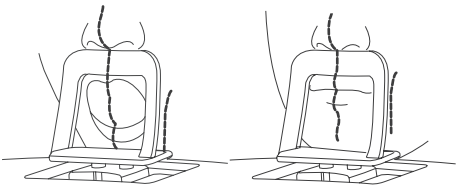
Preparing the maxillary joint image

- Insert the chin support for maxillary joint image.



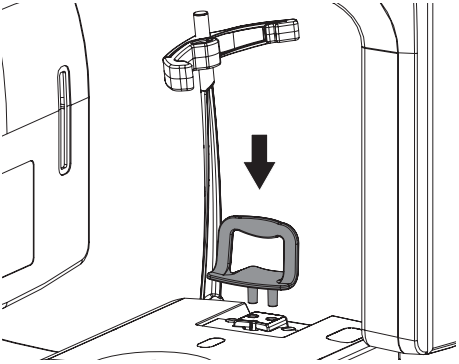
- Position the patient with the upper lip against the chin support.

- The 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

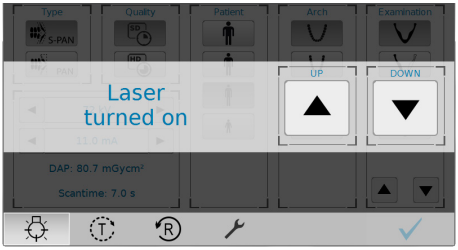
Danger of glare due to the laser beam

- 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 the button .



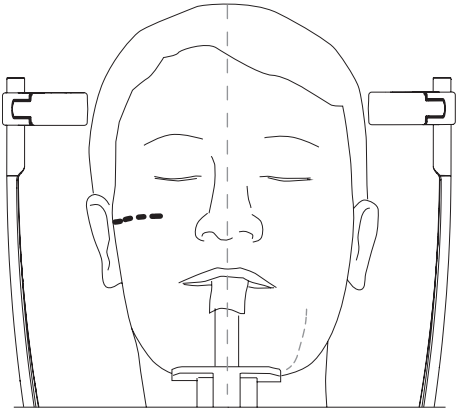
- Align the head of the patient according to the Frankfort horizontal plane with the aid of the X-ray positioning beam.

  Laser height to the lower edge of the eyes.

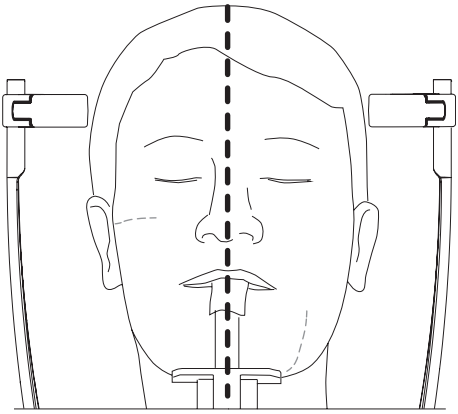
  Correct the inclination of the head according to the auditory canal using the Up and Down buttons.

- **For a sinus image:**

  Patient over-stretches the cervical vertebral column by approx. 10° to 15°.

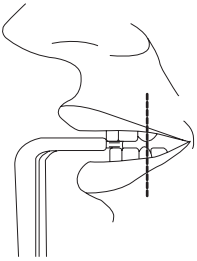


- Check the X-ray positioning beam is in the mid-saggital plane and correct if necessary.

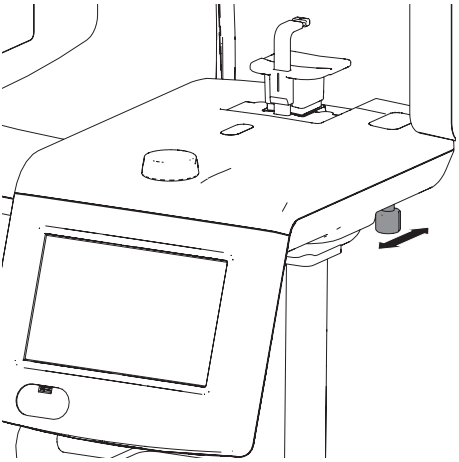


- Have the patient smile so the upper maxillary canine is visible.

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

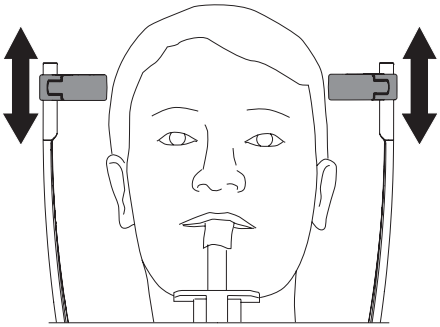


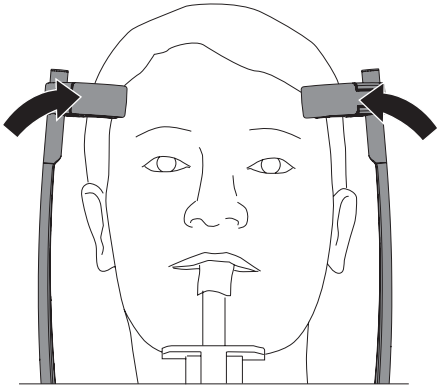
- If necessary, correct the X-ray positioning beam manually.



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

- Deactivate the X-ray positioning beam on the touch screen, using the button  .
- Use the setting wheel to adjust the head support 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  .

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

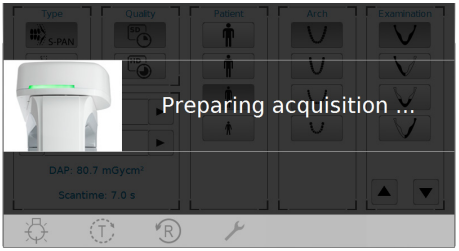
- Prior to an image being triggered, all data entered on the PC must be checked on the touch screen.

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

  The changed parameters are immediately synchronised with Provecta S-Pan.
- Make sure the patient's tongue is pressed against the palate.
- Activate the image using button ✔.

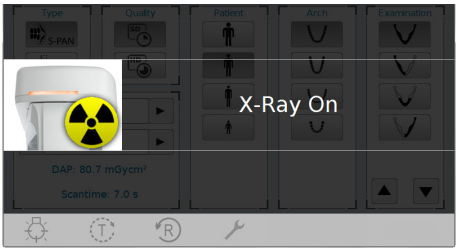
The rotating unit is positioned. The LED on the exposure switch and on the unit lights green.

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 "14 Panorama Program parameters".

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



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

The rotating unit 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.

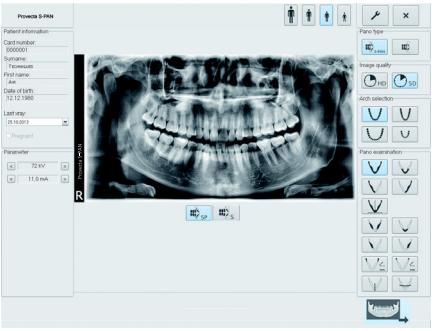
- Release the head support.

  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, Provecta S-Pan 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.

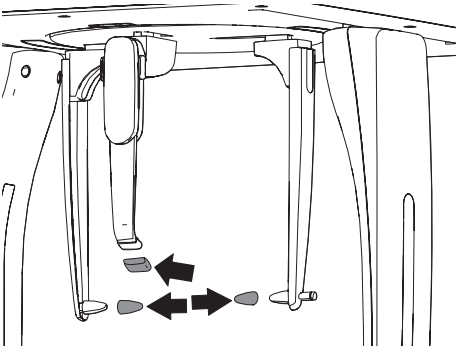


- Check the image and optimise if necessary.
- Use the button SP to preselect S-Pan if required.
- Use the button S to preselect the Standard OPG if required.
- Use the button to accept the image in Provecta S-Pan.

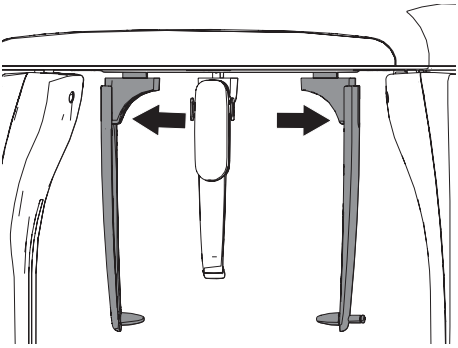
9.7 Cephalometric images

Setting up the unit

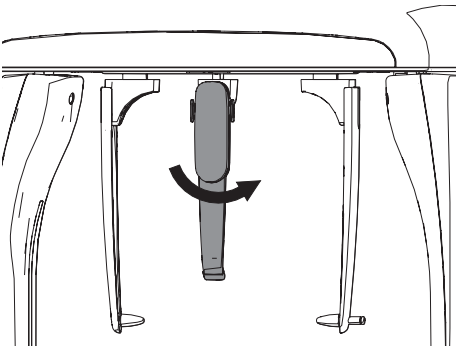
- Disinfect the positioning aids, see "10 Cleaning and disinfecting".
- Provide ear cushions with protective caps and nose support with protective cover.



- Grasp the holder for the ear cushions at the top and push outwards.



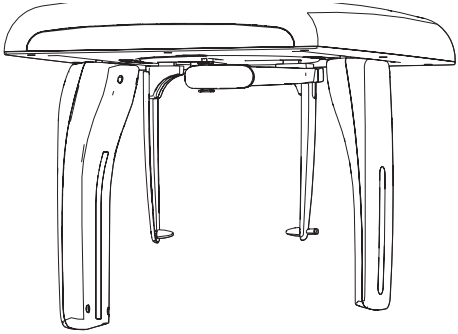
- Swivel the nose support to the side.



- Use ▲ ▼ to roughly pre-set the appliance height to the height of the patient.

Positioning the patient

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



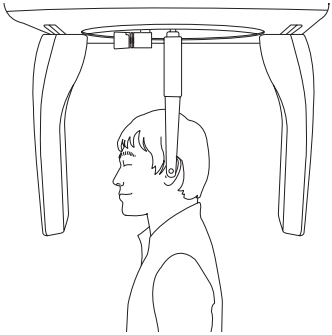
Prerequisite:

- ✓ 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 is not allowed to move during the X-ray until the device is back in the starting position.
- Use the ▲ ▼ buttons to set the height of the appliance.

Preparations for the head PA image

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

- Place the patient vertical with his/her face towards the sensor. The Frankfort horizontals of the patient are parallel to the floor.

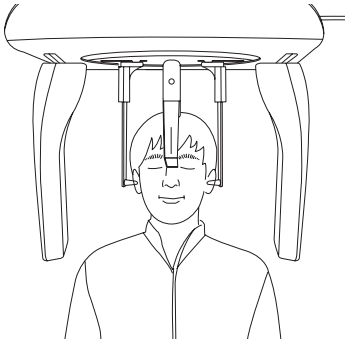


- Adjust the holders for the ear cushions to the height of the external auditory canals of the patient.

Preparations for the lateral head image

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

- Place the patient with his/her face towards the nose support. The Frankfort horizontals of the patient are parallel to the floor.



- Adjust the holders for the ear cushions to the height of the external auditory canals of the patient.

CAUTION

Danger of injury due to nose support not being positioned

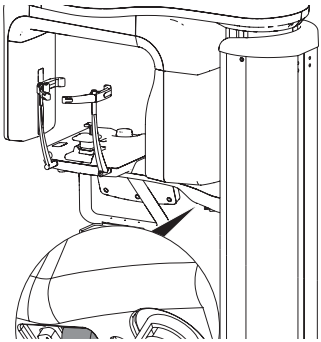
The moving secondary aperture causes injury and damage to the machine if the nose support is folded to the side

- Correctly position the nose support.
- Position the nose support at the height of the nasal bridge.

Preparations for the SMV image

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

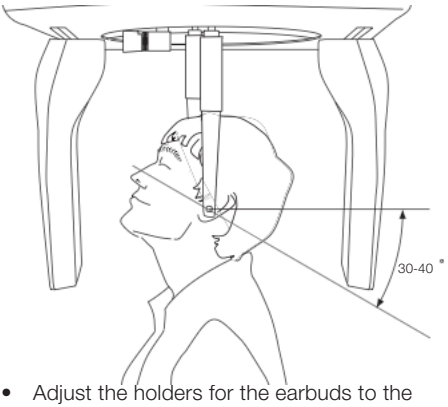
- Place the patient upright, with his/her face to- wards the secondary aperture.
- Instruct the patient to tilt the head backwards.
- Adjust the holders for the ear cushions to the height of the external auditory canals of the patient.



Preparations for the Waters View image

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

- Place the patient vertical with his/her face towards the sensor.
- Instruct the patient to tilt the head backwards.



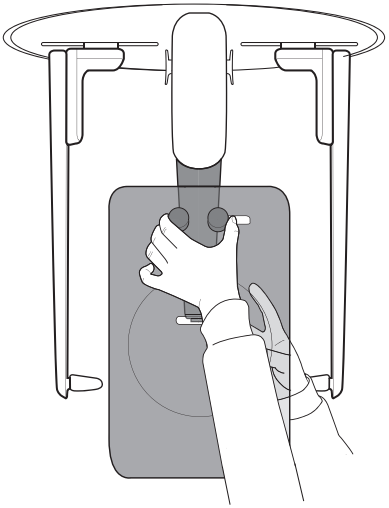
- Adjust the holders for the earbuds to the height of the external auditory canals of the patient.

Preparations for the carpus image

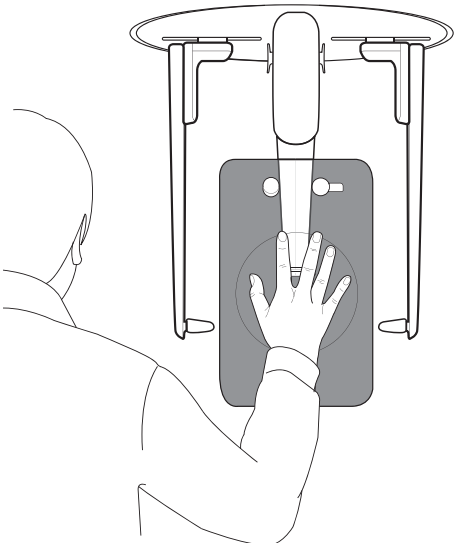
✓ The holders for the earbuds are pushed apart.

✓ The holders for the earbuds are rotated by 90° to the sensor.

- Insert the carpus plate into the nose positioner.
- Secure the carpus plate onto the nose support with the movable screw.
- Screw both screws tight.



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



Create radiographs

CAUTION

Injuries through X-rays

X-rays can cause tissue damage.

- Observe the regulations for radiation protection.
- Maintain the minimum distance.

CAUTION

Danger of too high a radiation dose

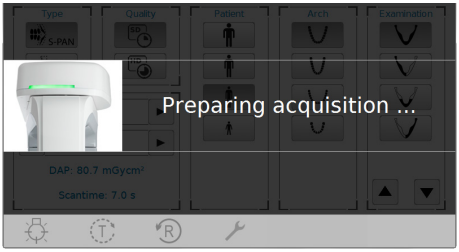
- Prior to an image being triggered, all data entered on the PC must be checked on the touch screen.

- Check all parameters on the touch screen and change if necessary.
  The changed parameters are immediately synchronised with Provecta S-Pan.
- Activate the image using the button ✓.

✓ The rotating unit is positioned.

✓ The LED on the exposure switch 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 "15 Ceph Program parameters."

- While the image is being taken, the LED on the exposure switch and on the unit lights orange. An acoustic signal sounds.

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

✓ The rotating unit moves back to the starting position after the trigger button is released.

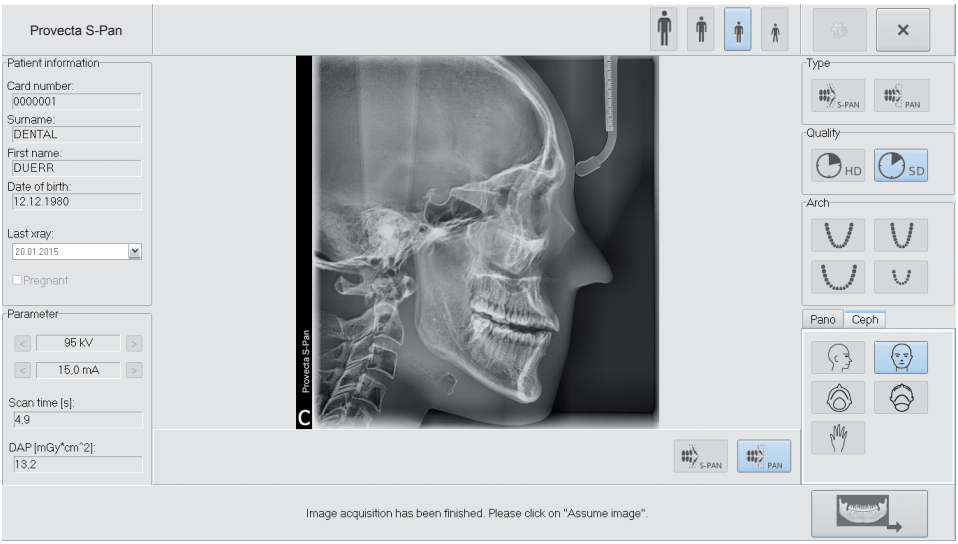
✓ The LED on the unit lights blue if the X-ray recording has been completed.

- Release the head support.
  The patient can leave the X-ray room.
- Remove the hygienic protective cover.
- Remove and disinfect the positioning aids.

Transmitting and saving the image

While the image is being triggered, the software displays a preview of the image.
For further information on the software, see associated software manual.

- Check the image and optimize if necessary.
- Use the  button to accept the image



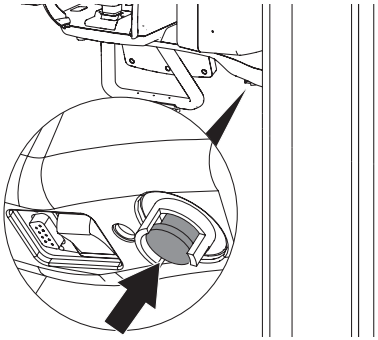
9.8 Restoring the last image

- If required, the last image can be restored by performing the procedure of paragraph 19.2, Retrieving the last image taken

9.9 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.

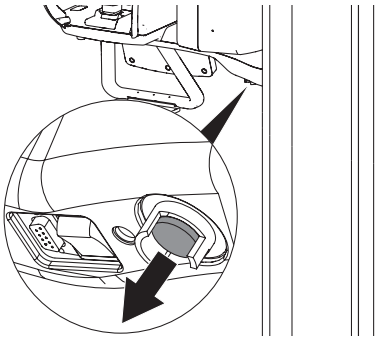


EMERGENCY OFF button lights red.
The unit is switched off.

Unlock the EMERGENCY OFF

Unlock the EMERGENCY OFF to restart the unit.

- Pull the EMERGENCY OFF down to unlock.



- Switch on the unit again.

9.10 RETURN run

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

- Button  On the touch screen, press. The rotating unit moves back to the starting position.

10 Cleaning and disinfecting

NOTICE

Unsuitable agents and methods can damage the device and accessories

- Only use the disinfection and cleaning agents specified or approved by Air Techniques.
- Observe the instructions for use of the disinfection and cleaning agents.
- Do not use the prohibited chemicals listed below as they may degrade the finish of the unit surface.

Wear protective gloves

Prior to working on the device 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.

Clean the outside surfaces of the unit by wiping with a soft lint-free cloth dampened with a mild non-abrasive household dish detergent or use a use a quick-acting cleaning agent such as Birex, or Isopropyl II Alcohol 70% wipes. Be careful not to allow liquids to run or pool

The following should not be used:

CaviWipes towelettes,

CaviWipes 1 towelettes,

Sani-Cloth wipes, Volo Surface wipes,

Opti Cide 3 surface wipes,

Optim 33TB wipes,

Clorox germicidal wipes,

Maxiwipe germicidal cloth.

NOTICE

The liquid can cause damage to the device

- Do not spray the device with cleaning and disinfectant agents.
- Make sure that liquid does not get inside the device.
- Remove any soiling with a soft, wet, lint-free cloth.

10.2 Positioning aids

Clean the head support using the method recommended for the device (see "10.1 Unit surfaces") using approved cleaning solutions.

Disinfect the surfaces using a disinfectant wipe registered with the EPA. Chin support and bite block are washable and can be disinfected in a disinfectant washer. Alternatively use a spray disinfectant on a soft, lint-free cloth. Observe the instructions for use of the disinfectant.

The following disinfectants can be used on the bite block, chin supports and head support:

Birex wipes

Discide Ultra Towelettes

Volo surface wipes

Opti Cide 3 surface wipes

Optim 33TB wipes

Maxiwipe germicidal cloth

Do not use disinfectant wipes listed below, they will cause deterioration of the bite block, chin supports and head support plastic.

CaviWipes towelettes

CaviWipes 1 towelettes

Clorox germicidal wipes

Sani-Cloth wipes

Maintenance

11 Recommended maintenance schedule

Contact your local Air Techniques authorized dealer for service. Only trained technicians from an authorized dealer may service the unit.

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

- Do not keep the device and parts in a humid place.
- Keep the device and parts in an appropriate place to maintain them in good condition.
- They may be influenced by environmental factors such as temperature, lights, ventilation, dust, salt and so on.
- For items needed for image capturing, please arrange them and put them in proper places for the next image capturing.
- Please check the ground connection of the device.
- Do not try to fix the device including wires and cables by yourself. It may cause accidents and damage to the device.

Inspection interval	**Inspection work**
Daily	• Prior to commissioning, ensure that the unit and the positionaing aids have been cleaned or disinfected, see "10 Cleaning and disinfecting".
	• Functional test of the display. Are all symbols displayed?
	• Verify the various status LEDs light
Weekly	• Functional test of the EMERGENCY OFF button. Is the EMERGENCY OFF button easy to operate mechanically and does it light when pressed?.
	• Check that the head support and nose support mechanisms function correctly. Are the head supports and nose support easy to detach and put on.
	• Optically check the light visors. Check the proper functioning of the cuspid light visor adjusting lever.
Monthly	• Inspect the X-ray images for artifacts. If necessary, adjust the aperture and/ or calibrate the sensor.
	• Functional testing of the voice response.
	• Make sure that all signs and the model identification plates are not damaged and are easy to read.
	• Carry out a Dose Area Product (DAP) measurement and compare the values with the commissioning.

Maintenance interval	**Maintenance work**
Every year	• Visually and acoustically check the linear movement on the rotating unit connector piece. If necessary, clean the slide rails with alcohol and grease with Vaseline.
	• Check the lift motor is functioning properly. Does the appliance lift and lower without any noise. If necessary, clean with alcohol and grease with Vaseline.

Troubleshooting

12 Tips for Operators and Technicians

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
The Unit does not start up	No mains supply	• Check mains cable and sockets and change if necessary. • Inform service technician.
		• Check the main fusing in building.
	On / off switch is a defect	• Inform service technician.
The 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 device in the firewall settings.

Error Code	Comments	Solution
#0	Wrong or missing firewall configuration for S-Pan	Check firewall settings: enable TCP port 20130
#3	Failed to acquire an image	1. Check the network cable connection 2. Check the Gigabit Ethernet adapter card 3. Check that the Windows power savings mode is disabled 4. Verify all network security programs are turned off, including Windows firewall and anti-virus programs.
#8	Mono block temperature is higher than nominal temperature (55°C)	Cool down tube
#10	After X-ray exposure, allowable command receive, exposure switch off.	The button at the exposure switch released too early: push and hold the button until the red light is off. If the same error occurs again then check the cable for malfunction or change the exposure switch board.
#11	No connection to the device.	1. Check the network cable connection 2. Check that the device is switched on
#11	After exposure switch is off during X-ray exposure, no X-ray off command received within 0.5 second	The exposure button is pressed too long. Make sure to release the button after exposure is done.
#60	Exposure switch is pressed while the device is being turned on.	Wait until the light is green before pressing the exposure switch.

Annex

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

13.1 General notes

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

13.2 Abbreviations

EMC	Electro-magnetic compatibility
HF	High frequency
U_T	Voltage rating of device (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 the transmitter in watts (W) according to the manufacturer's information
d	Recommended safety distance in metres (m)

13.3 Guidelines and manufacturer's information

Electromagnetic transmissions for all devices and systems

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

Interference measurements	According to	Electro-magnetic environment – guidelines
HF transmissions according to CISPR 11	Group 1	The device 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 device must transmit electromagnetic energy in order to fulfil the functions for which it has been designed. Other electronic devices in the vicinity could be affected.
HF transmissions according to CISPR 11	Class [A or B]	The device 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 devices and systems

Electromagnetic resistance for all devices and systems

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

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 device requires continued function even during a power out, we recommend that the device 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 devices and systems

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

Portable and cordless radio devices should not be used close to the device, 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 devices 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 devices 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 land-line 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 device is used exceeds the above level of consistency, the device should be observed in order to demonstrate the intended function. If any unusual behaviour of the device is observed, additional steps will be required, e.g. changing the orientation or location of the device.

[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 device

The device 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 device can help to prevent electromagnetic interference by maintaining minimum distances as recommended between portable and mobile HF communications devices (transmitters) and the device as outlined below according to the maximum output of the communications device.

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 device

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.

13.4 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			

14 Panorama program parameters

Digital X-ray imaging System is an index of a representative dose is based on the IEC 60601-2-63 standard in DAP. Dosimetry is measured directly without DAP meter Phantom. DAP measurement is determined using a typical DAP meter. Dose meter located on the XRay Detector and irradiates the X-ray. It is possible to measure the DAP (Dose Area Product).

Test equipment: RaySafe Xi dosemeter.

14.1 Large Adult, S-Pan and PAN

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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 (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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

14.2 Average Adult, S-Pan and PAN

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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 (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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

14.3 Small Adult/Youth, S-Pan and PAN

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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 (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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

14.4 Child, S-Pan and PAN

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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 (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (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

14.5 Patient Type Preset Guidelines Based on Head Circumference

Patient Type	Head Circumference
Large Adult	> 56 ±3 cm
Average Adult	56 ±3 cm
Small Adult/Youth	<56 ±3 cm
Child	53 ±3 cm

14.6 Arch Type Presets

Arch Type	Distance between the two lower second premolars
Narrow	Under 43 mm
Normal	43 ~ 49 mm
Wide	Over 49 mm

15 Ceph program parameters

Digital X-ray imaging System is an index of a representative dose is based on the IEC 60601-2-63 standard in DAP. Dosimetry is measured directly without DAP meter Phantom. DAP measurement is determined using a typical DAP meter. Dose meter located on the XRay Detector and irradiates the X-ray. It is possible to measure the DAP (Dose Area Product).

Test equipment: PTW Diamentor E2

15.1 Large Adult

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
SD	Lateral head	98	15	11.5	4.1
SD	Head PA	98	15	13.5	4.9
SD	SMV	98	15	13.5	4.9
SD	Waters View	98	15	13.5	4.9
SD	Carpus	60	6	2.5	4.9

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
HD	Full Lateral head (Option)	86	10	27.2	16.9
HD	Lateral head	86	10	21.9	12.9
HD	Head PA	86	10	21.9	12.9
HD	SMV	86	10	21.9	12.9
HD	Waters View	86	10	21.9	12.9
HD	Carpus	60	6	6.2	12.9

15.2 Average Adult

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
SD	Lateral head	97	15	11.45	4.1
SD	Head PA	97	15	13.4	4.9
SD	SMV	97	15	13.4	4.9
SD	Waters View	97	15	13.4	4.9
SD	Carpus	60	5	2.1	4.9

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
HD	Full Lateral head (Option)	85	10	26.5	16.9
HD	Lateral head	85	10	21.9	12.9
HD	Head PA	85	10	21.9	12.9
HD	SMV	85	10	21.9	12.9
HD	Waters View	85	10	21.9	12.9
HD	Carpus	60	6	6.2	12.9

15.3 Small Adult/Youth,

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
SD	Lateral head	95	15	11.2	4.1
SD	Head PA	95	15	13.2	4.9
SD	SMV	95	15	13.2	4.9
SD	Waters View	95	15	13.2	4.9
SD	Carpus	60	5	2.1	4.9

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
HD	Full Lateral head (Option)	84	10	25.7	16.9
HD	Lateral head	84	10	20.7	12.9
HD	Head PA	84	10	20.7	12.9
HD	SMV	84	10	20.7	12.9
HD	Waters View	84	10	20.7	12.9
HD	Carpus	60	5	5.2	12.9

15.4 Child

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
SD	Lateral head	90	15	10.5	4.1
SD	Head PA	90	15	12.5	4.9
SD	SMV	90	15	12.5	4.9
SD	Waters View	90	15	12.5	4.9
SD	Carpus	60	5	2.1	4.9

Image quality	Program	Voltage (kV)	Current (mA)	DAP (mGy cm²)	Scanning time (s)
HD	Full Lateral head (Option)	80	10	23.1	16.9
HD	Lateral head	80	10	18.6	12.9
HD	Head PA	80	10	18.6	12.9
HD	SMV	80	10	18.6	12.9
HD	Waters View	80	10	18.6	12.9
HD	Carpus	60	5	5.2	12.9

16 Information on the scattered radiation

Test equipment: Dosemeter Victoreen 660

Test conditions

Program parameters	HD/Adult/Standard Pano
Distance to focal spot	1 m
Voltage	80 kVp
Current	16 mA

R (Degrees)	1 m (mR/h)	HD, 13.5 s 1.5 m (mR/h)	2 m (mR/h)
0	98.4	37.8	19.8
45	34.7	17.6	9.3
90	15.4	6.2	3.5
135	14.9	7.1	4.5
180	0	0	0
225	37.2	14.4	8.9
270	51.4	21.5	12.9
315	86.1	34.7	18.2

17 Information on the leakage rate

Test equipment: Dosemeter Victoreen 660

Test conditions

Program parameters	HD/Adult, Child/ Standard Pano
Distance to focal spot	1 m
Voltage	90 kVp
Current	16 mA

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

18 Computer System Requirements

18.1 Computer System Requirements

Item	Recommended Specification
Processor/CPU	Dual core 2.0 GHz+ (i3 series Intel processor or equivalent AMD) or greater
RAM	4 GB or greater
Hard Disk Drive	200 GB
Display Adapter	1280 x 1024 32bit color video display adapter (True color) 128MB or greater Direct3D®-capable workstation-class graphics card
Network interface	Gigabit Ethernet adapter
Slots	1 PCI Express x 1
Optical Drive	SuperMulti DVD Drive
Operating System	Windows 10 Professional or Enterprise (64 bit) Windows 8.1 Professional or Enterprise (64 bit)

19 Image Transfer Retrieval

19.1 Premature termination of image transfer

If an image transfer is terminated prematurely, a message will appear when you next try to acquire an image. Please ensure that the image is properly assigned to the correct patient.

If the image belongs to the current patient record, click **OK** to accept the image into the patient record.

If the image does not belong to the current patient record, click **Cancel** to exit TWAIN, keeping the image for the next acquisition. This allows for the opportunity to select the correct patient record.

Important: Since the ProVecta S-Pan device only holds the last image acquired in RAM as long as it is turned on, image retrieval is only successful when the device has been continually turned on.

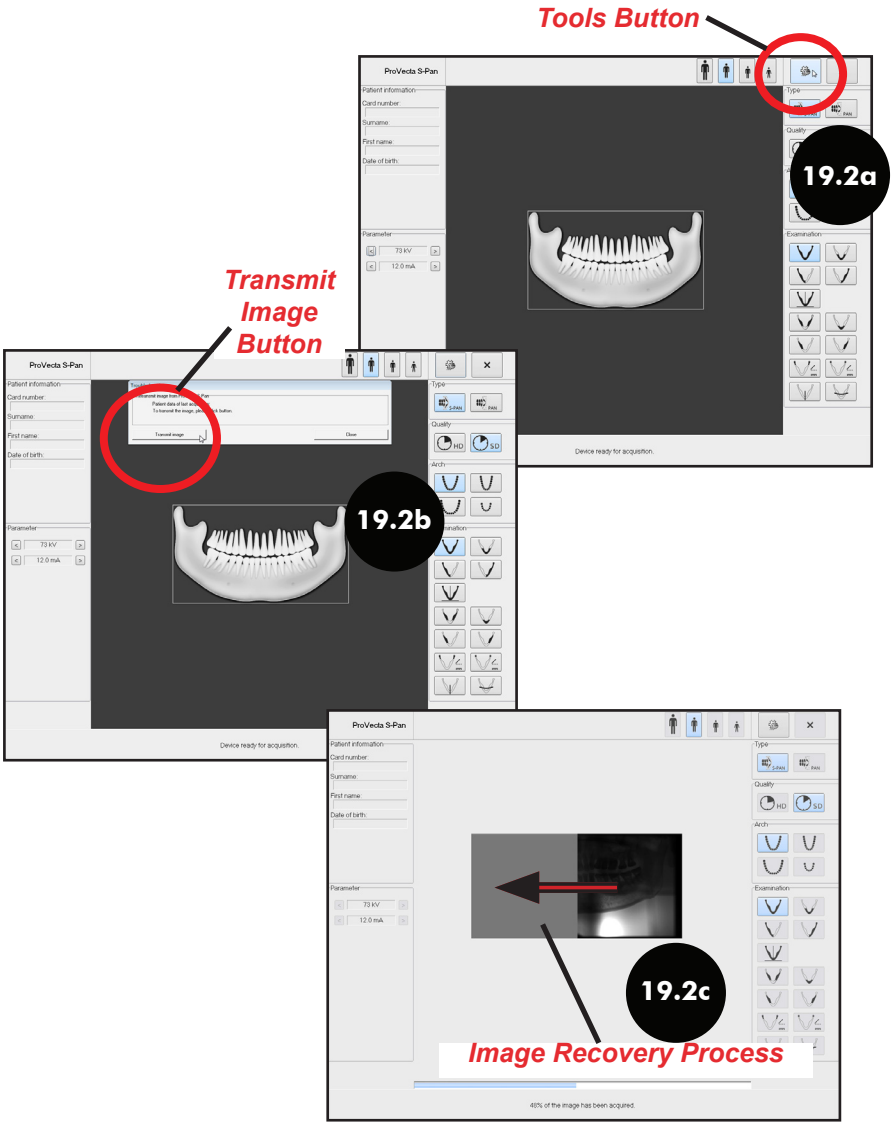
19.2. Retrieving the last image taken.

19.2a. Select the *Tools* button from the control window shown below.

19.2b. Select *Transmit Image* from the pop-up message window.

19.2c. Observe the image recovery progress and verify the successful acquisition of the image by the third party image application.

19.2d. Make sure that the image is properly assigned to the correct patient.



Warranty

Provecta S-Pan is warranted to be free from defects in material and workmanship from the date of installation for a period of 2 years (24 months). Provecta S-Pan is designed solely for use in a dental office environment and this warranty is not applicable to other applications.

All part and component returns and replacement of equipment under warranty require a Return Materials Authorization (RMA). Items returned without an RMA, or included with other products for which an RMA has been issued, may be returned to the customer at the discretion of Air Techniques.

Any item returned under warranty, will be repaired or replaced at our option at no charge provided that our inspection shall indicate it to have been defective. Air Techniques, Inc. is not liable for indirect or consequential damages or loss of any nature in connection with this equipment. Dealer labor, shipping and handling charges are not covered by this warranty.

Warranty credit will not be applied to product returns that exhibit damage due to shipping, misuse, careless handling or repairs by unauthorized service personnel. Credit, or partial credit, will not be issued until product/parts have been received and assessed. Warranty is void if product is installed or serviced by anyone other than authorized Air Techniques dealer service personnel. This warranty is void if Provecta S-Pan is operated with any covers removed.

This warranty is in lieu of all other warranties expressed or implied. No representative or person is authorized to assume for us any liability in connection with the sale of our equipment.

Online Warranty Registration

Quickly and easily register your new Provecta S-Pan online. Just have your product model and serial numbers available. Then go to the Air Techniques web site, **www.airtechniques.com**, click the *Warranty Registration* link at the top of the page and complete the registration form. This online registration ensures a record for the warranty period and helps us keep you informed of product updates and other valuable information.

For over 50 years, Air Techniques has been a leading innovator and manufacturer of dental products. Our priority is ensuring complete satisfaction by manufacturing reliable products and providing excellent customer and technical support. Whether the need is digital imaging, utility room equipment or merchandise, Air Techniques can provide the solution via our network of authorized professional dealers. Our products are helping dental professionals take their practices to the next level.

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- ❑ Utility Room
  - Dry Vacuums
  - Wet Vacuums
  - Air Compressors
  - Amalgam Separator
  - Utility Accessories
  - Utility Packages
- ❑ Merchandise
  - Surface Disinfectant
  - Enzymatic Cleaner
  - Hand Sanitizer and Lotion
  - Waterline Cleaner
  - Evacuation System Cleaner
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