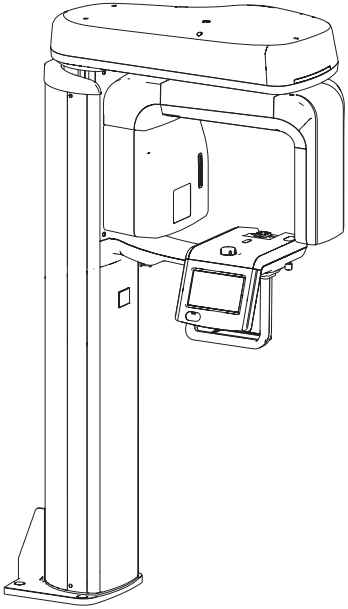
PRO▸VECTA® S-Pan

Panoramic X-Ray System

Installation Instructions



AIR TECHNIQUES equipped for life®

CE 2460

Contents

Important information

Product description

Mounting

Annex

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 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 these 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 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.


Refer to instruction manual/booklet

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

Indicates the authorized representative in the European Community.

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


Manufacturer


Date of Manufacture


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 X-ray unit 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.
- Make sure to follow the instructions precisely.
- Keep this document in an accessible place so that the operator has instant access.

2.4 Radiation protection

- Observe all mandatory current X-ray protection rules and take all necessary X-ray protection measures.
- Use the prescribed 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 and 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 are 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 section 12 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.
- For continued protection against risk of fire, replace only with the same type and rating of circuit breakers and fuses.

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.

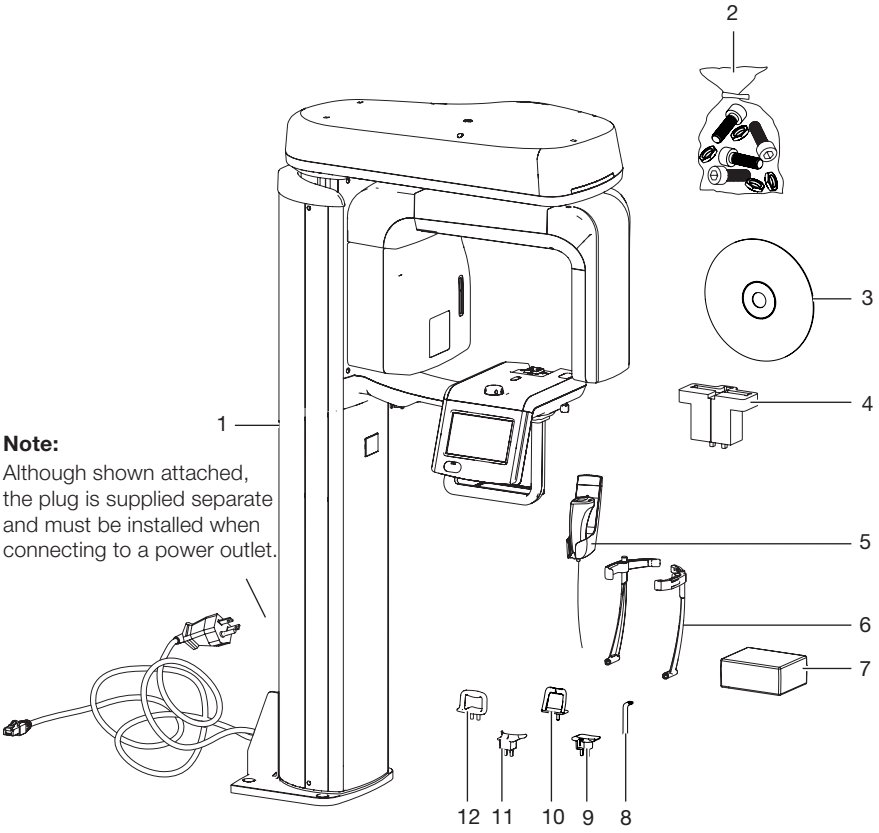
Other parts:

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 separate and must be installed when connecting to a power outlet.

1 Panoramic X-ray unit
2 Installation Mounting Hardware
3 Provecta S-Pan Utility Disk
4 2-D X-ray test phantom holder
5 Exposure Switch
6 Temple support plus*
7 Bite block covers*
8 Bite block*
9 Holder for bite block*
10 Chin support for maxillary joint image*
11 Chin support for edentulous jaws*
12 Chin support for sinus image*

* Denotes parts in contact with patient

3.1 Delivery Contents

The following articles are included in the scope of delivery:

Provecta S-Pan A7350

– 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 bite block
– Bite block
– Chin support for edentulous jaws
– Chin support for maxillary joint image
– Chin support for sinus image
– Temple support plus
– Bite block covers
– Installation Mounting Hardware
– Operating Instructions
– Installation instructions
– PCI Express Gigabyte Ethernet card

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 covers 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
Hygienic protective covers for bite block A7395

3.3 Special accessories

The following items can be optionally used with the device:

Manual switch for height adjustment include holder A7340
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 covers A7395

3.5 Required tools

– Wrench set, hexagon socket wrench, AF1.5 to 10 mm
– Cable cutter
– Spirit level
– Multimeter
– Impact drills

4 Technical data

Electrical technical data	
Nominal voltage	200 - 240 V AC
Max. 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
	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	
Model	DG-07C11T2(H)
X-Ray Tube Model	Canon D-052SB
Tube voltage	60 - 99 kV (±10%)
* Values below 60 kV are not intended for human use in USA and Canada.	
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 50kV	0.8 mm Al
Total filtration at 50kV	2.8 mm Al
Duration of the X-ray Exposure	1.9 - 13.5 sec
Pulse to pause ratio	1:60 or greater

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

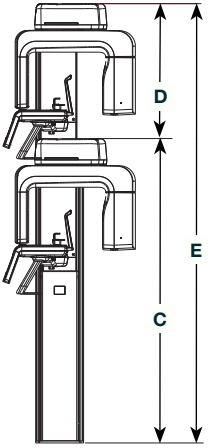
General technical data		
Height	62.48 to 89.88 in.	1587 to 2283 mm
Operating Dimensions (W x D)	38.97 x (44.88 - 45.67) in.	990 x (1140 - 1160) mm
Vertical radius	27.56 in.	700 mm
Weight	231 lb.	105 kg
Weight with base (optional)	342 lb.	155 kg
Image capture scale (magnification)	1.3	

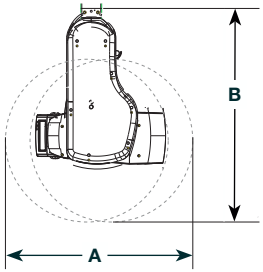
Ambient temperature during operation		
Temperature	50 to 95 °F	10 - 35 °C
Relative humidity	30 to 75 %	
Air pressure	21 to 31 in of mercury (860 to 1060 hPa)	

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)	

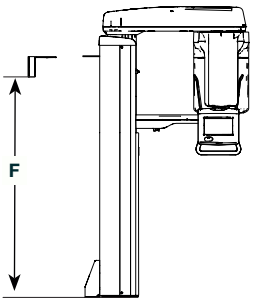
Dimensions

4.1 Dimensions

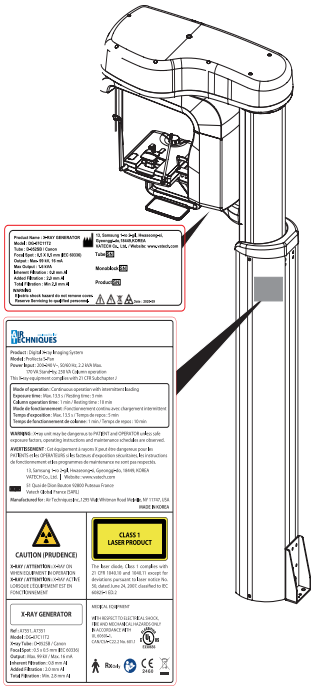




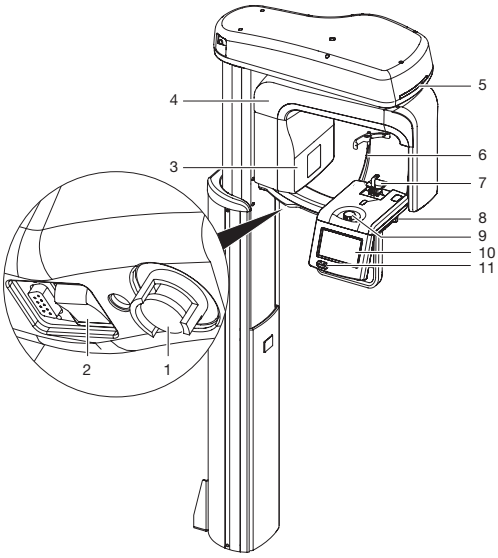
Height	**F**	49.29 in. (1252 mm)
	E	89.88 in. (2283 mm)
	D	27.56 in. (700 mm)
	C	62.48 in. (1587 mm)
Depth	**B**	44.88 to 45.67 in. (1140 to 1160 mm)
Width	**A**	38.97 in. (990 mm)



4.2 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.



4.3 Controls and indicators. The operating controls and indicators are shown below. Refer to the Operating Instructions manual supplied with the device to operate the Provecta S-pan.



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.

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

NOTICE

Danger of damage to the device

Do not push or pull the device during installation by the rotating unit or by the handle for the patients.

- Move the device carefully and only grip it by the telescopic column.

5 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 section 4 Technical data.

5.1 System requirements

The system requirements of computer systems are provided as part of the Annex of this manual. See page 34.

5.2 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.

6 Installation

6.1 Checking before unpacking

- Visually inspect the packaging for damage.
- Check that the Shockwatch or TiltWatch display has been enabled.

- If the Shockwatch or TiltWatch display is triggered or there is damage to the packaging, do not unpack and contact the shipping company.

6.2 Installations options

The Provecta S-Pan is fully pre-installed and provided with carrying handles.

There are three ways of installing the device:

– Wall mounting on level ground
– Wall mounting on uneven ground
– Pedestal mounting (optional)

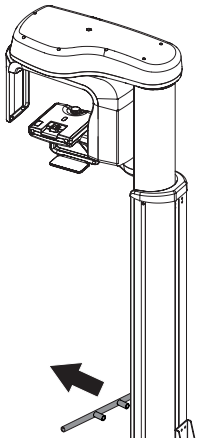
6.3 Wall mounting on level ground

Requirements:

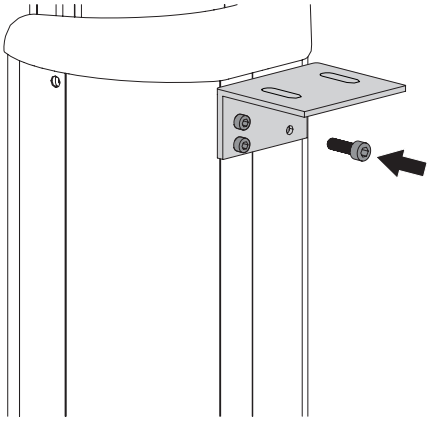
✓ The socket-outlet must be easily accessible
✓ The wall material must be able to absorb a tensile force of 72 lb ft (320 N) for each screw

- Place the device upright at the installation site on the wall.

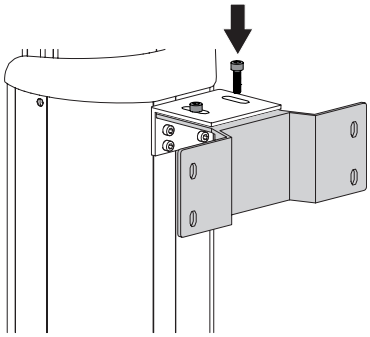
- Remove the carrying handle at the bottom of the device.



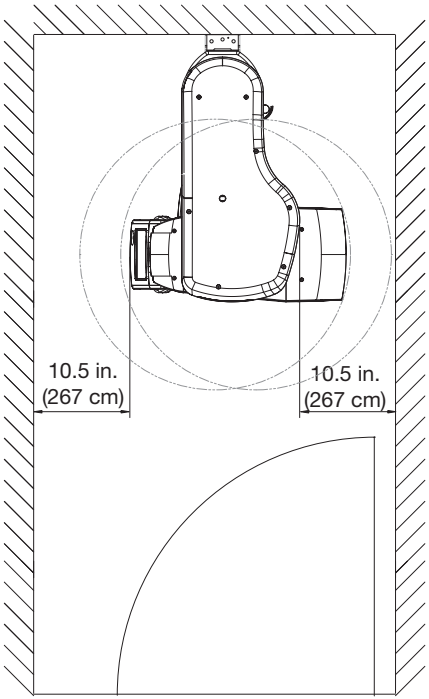
- Attach the bracket at the pre-drilled holes on the telescopic column with four M8x20 screws.



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

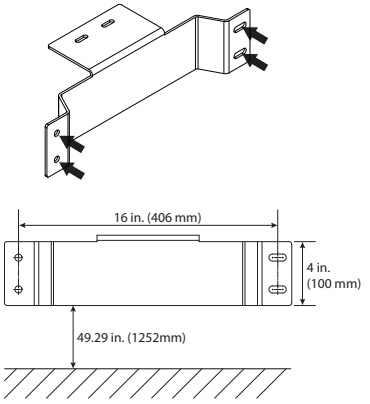


- Push the device to the intended position on the wall. A minimum distance of 10.5 inches (267 cm) to adjacent wall is recommended for patient access and the operating personnel.

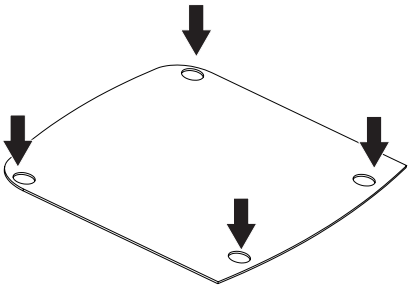


Caution: Always drill new holes. Do not reuse mounting holes

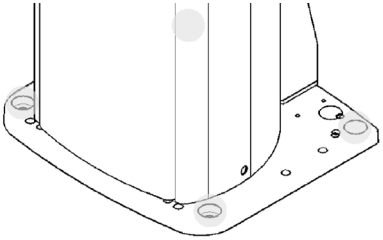
- Mark four new drill holes on the wall.



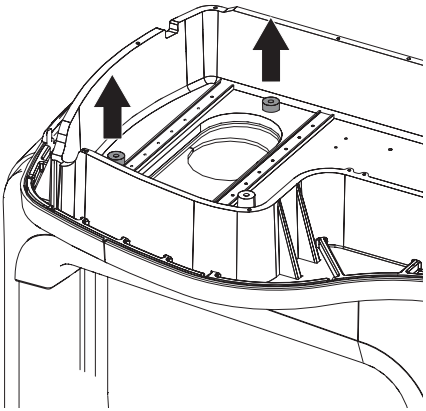
- Drill four holes in the wall and four holes in the floor.



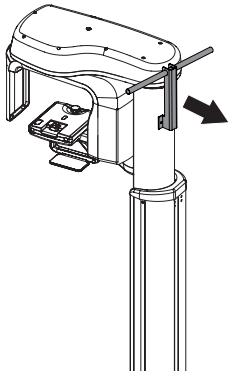
- Loosely attach the device with four screws on the ground and four screws on the wall.
- Use a spirit level to check that the device is level.
- Tighten all screws



- Remove the top cover.
- Remove and safeguard the two screws that fix the rotating unit as transport locks.



- Place the upper panel in position.
- Remove the carrying handle at the top of the device.



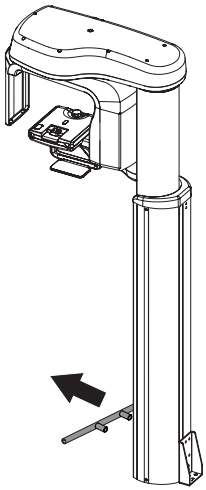
6.4 Wall mounting on uneven ground

Requirements:

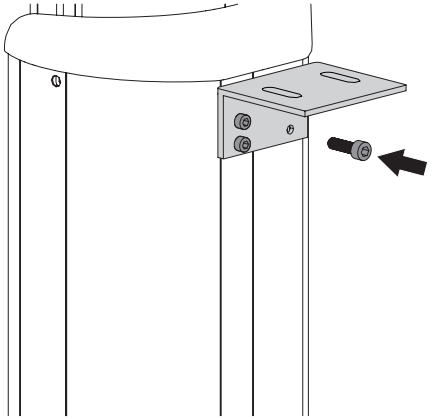
✓ The socket-outlet must be easily accessible

✓ The wall material must be able to absorb a tensile force of 72 lb ft (320 N) for each screw

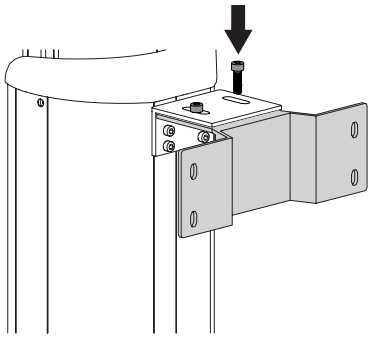
- Place the device upright at the installation site on the wall.
- Remove the carrying handle at the bottom of the device.



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

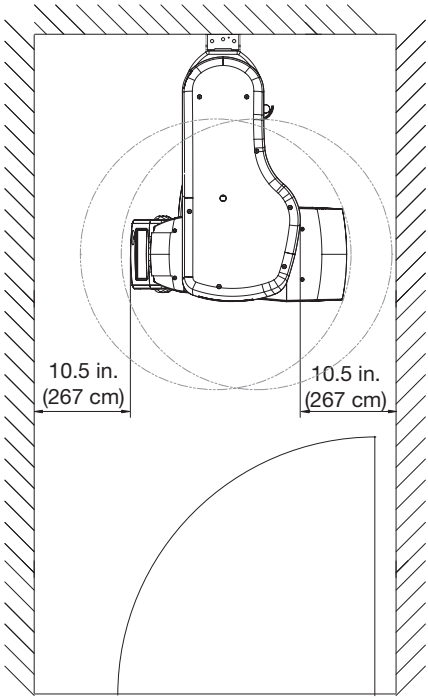


- Mount the wall holder on this bracket with two M8x20 screws and two nuts. Do not tighten the screws yet.



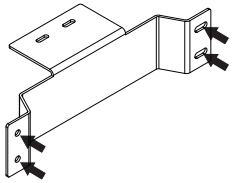
- Push the device to the intended position on the wall. A minimum distance of 28 inches (70 cm) o

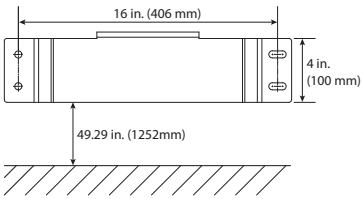
adjacent wall is recommended for patient access and the operating personnel.



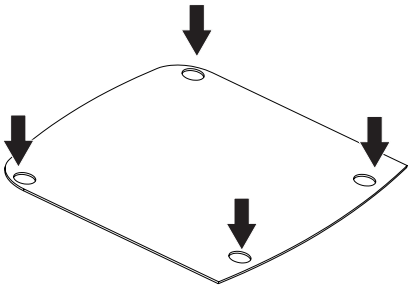
Caution: Always drill new holes. Do not reuse mounting holes

- Mark four new drill holes on the wall.

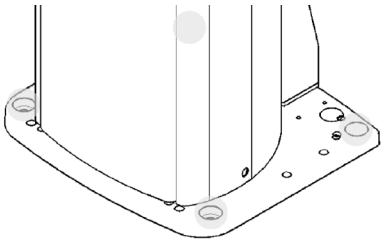




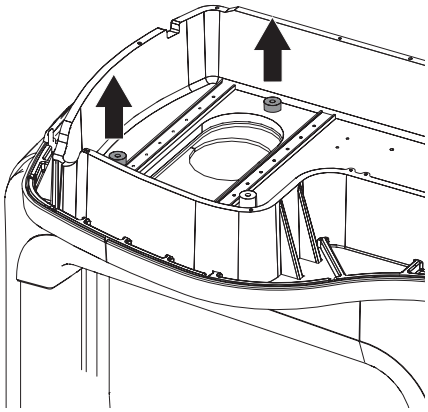
- Drill four holes in the wall and four holes in the floor.



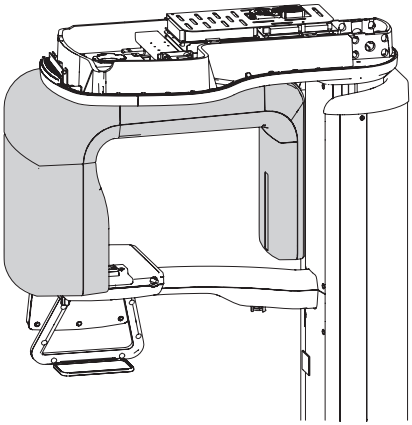
- Loosely attach the device with four screws on the ground and four screws on the wall.
- Use a spirit level to check that the device is level.
- Tighten all screws



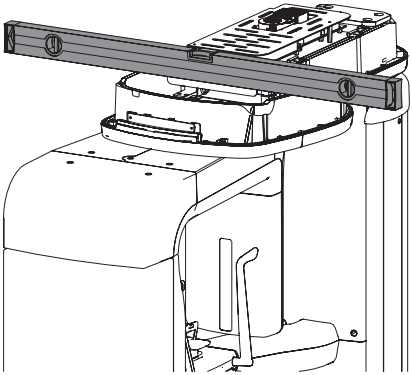
- Remove the top cover.
- Remove and safeguard the two screws that fix the rotating unit as transport locks.



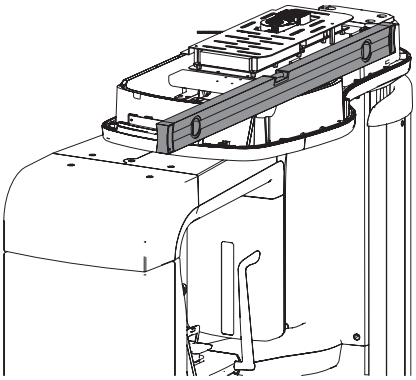
- Rotate the rotating unit by 180° so that it reaches the position shown.



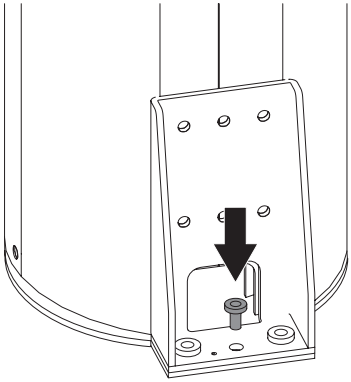
- Use a spirit level to align the device cross-ways.



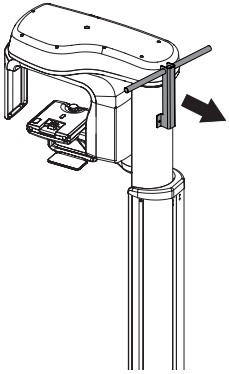
- Use a spirit level to align the device lengthways.



- Insert a M12x15 screw on the back of the telescopic column and hence align the device.



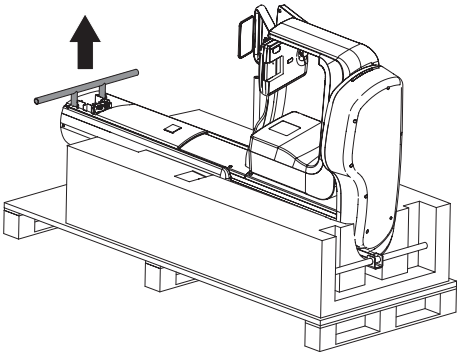
- Screw the fastening screws tight on the wall and floor.
- Place the upper panel in position.
- Remove the carrying handle at the top of the device.



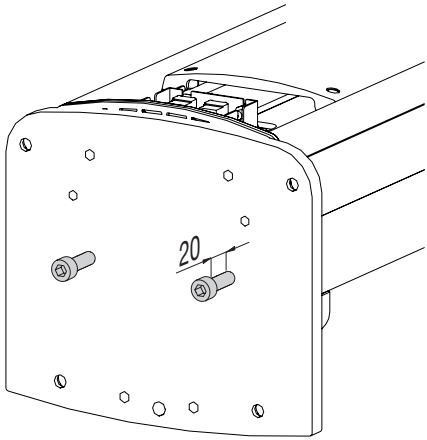
6.5 Floor stand mounting (optional)

When installing the stand, make sure that the mains and device cables are not damaged.

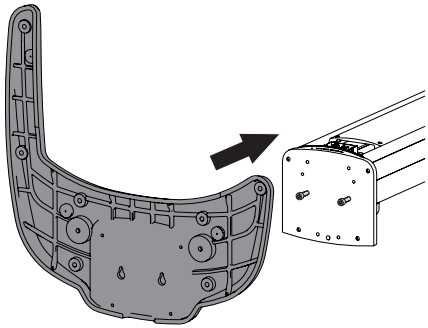
- Remove the lower carrying handle on the device.

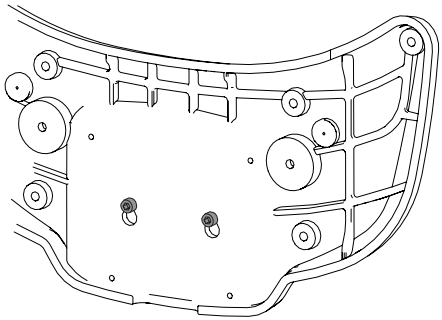


- Screw two M10x30 screws into the adapter plate.

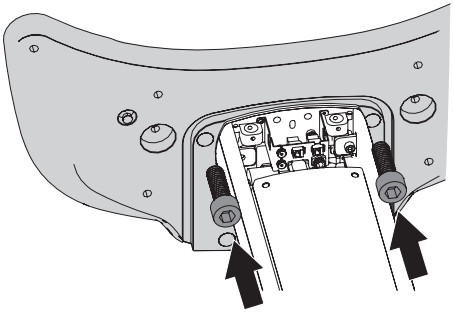


- Mount the stand on the two screws.

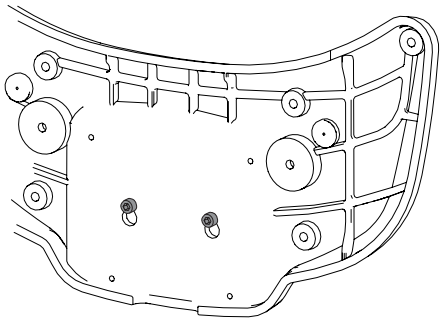




- Tighten the stand using two M10x20 screws.

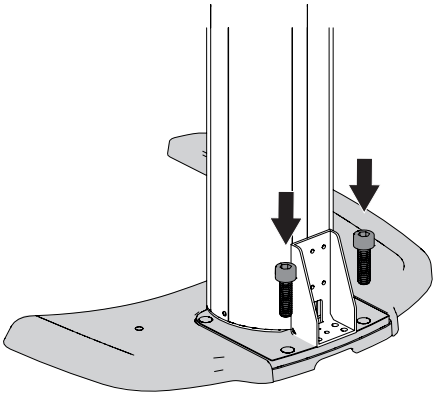


- Tighten the two screws under the stand.

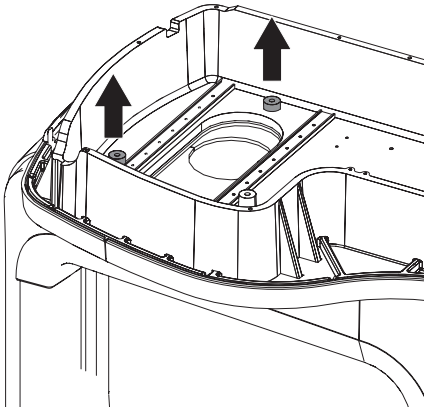


- Install the device upright.

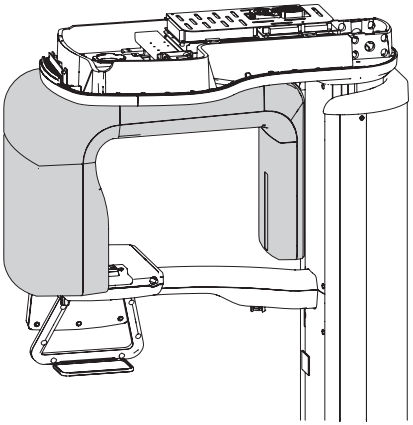
- Tighten the stand onto the device using another two M10x20 screws.



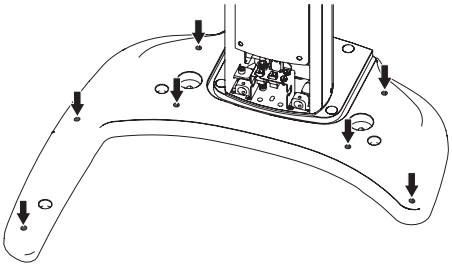
- Remove the top cover.
- Remove and safeguard the two screws that fix the rotating unit as transport locks.



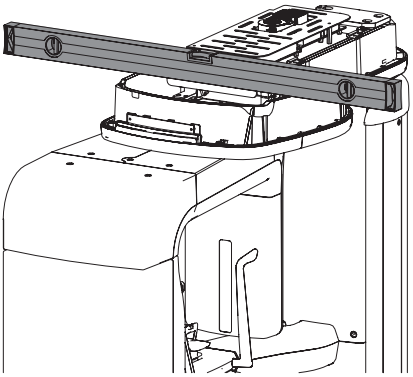
- Rotate the rotating unit by 180° so that it reaches the position shown.



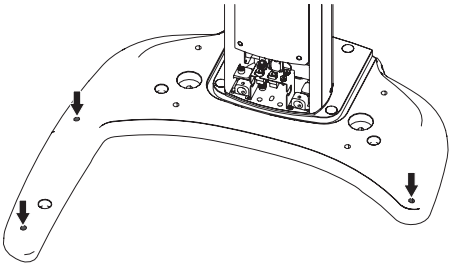
- Slightly loosen the screws in the stand for levelling.



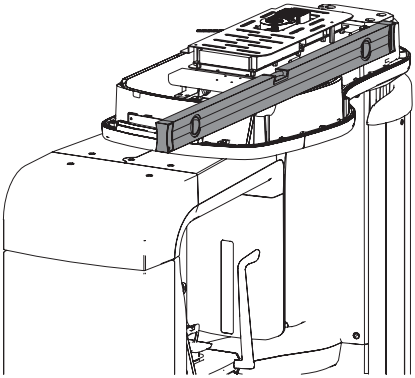
- Use a spirit level to align the device crossways.



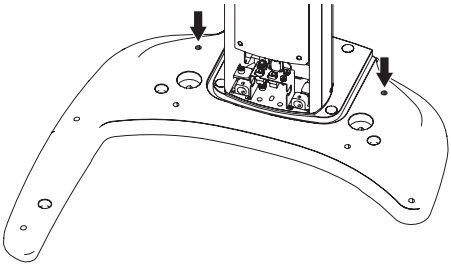
- As required, screw in the corresponding screws and hence align the device.



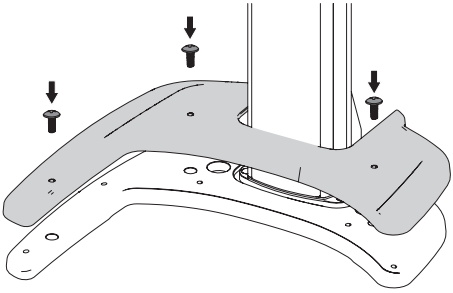
- Use a spirit level to align the device lengthways.



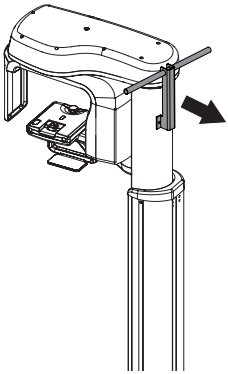
- As required, screw in the corresponding screws and hence align the device.



- Attach the stand cover with three M5x8 screws.



- Place the upper panel in position.
- Remove the carrying handle at the top of the device.

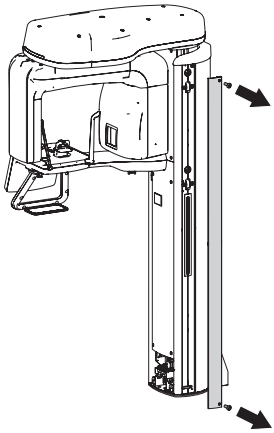


6.6 Limiting the height adjustment

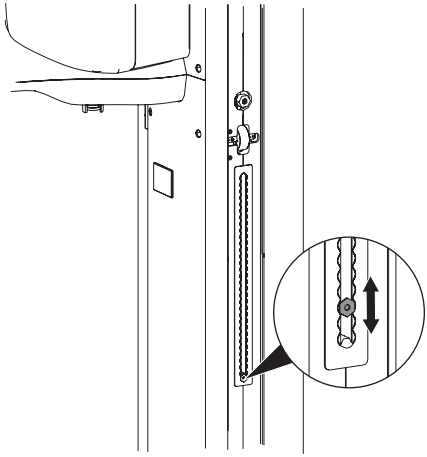
The height of the device can be varied between 5 feet (1.58 m) and 7.5 feet (2.28 m), according to the height of the patient. The maximum height can be limited.

To open the device for servicing, a minimum distance of 12 inches (30 cm) should be maintained between the fully extended device and the ceiling.

- Loosen the two screws on the side cover.
- Remove the side cover.



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



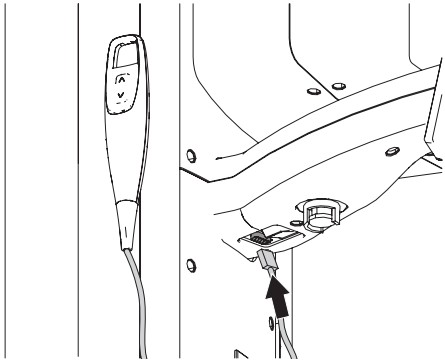
The values on the scale correspond to the device height.

- Move the screw to the desired device height.
- Retighten the screw.

6.7 Installing the manual switch for height adjustment (optional)

As an alternative to the buttons on the touch screen, the device height can be adjusted with a manual switch.

- Insert the connector of the hand switch next to the switch for switching on the device.

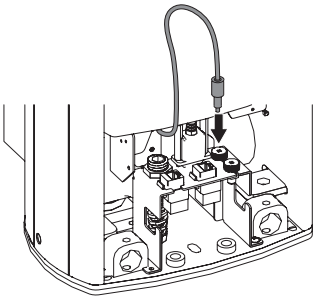


6.8 Installing the Exposure Switch

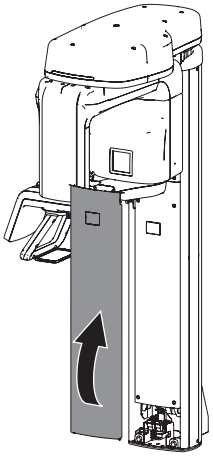
Exposure switch

The X-ray image is triggered in the X-ray room. If required, the exposure switch can be placed on the outside.

- Insert the cable on the foot of the telescopic column from behind and plug the connector into the marked socket.



- Install the front cover of the telescopic column.



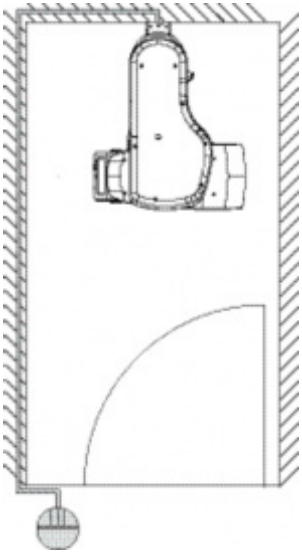
Optional remote exposure switch

The X-ray image is normally triggered in the X-ray room using the exposure switch. If required, the image can be triggered remotely from outside the X-ray room via an optional exposure switch placed outside the X- ray room.

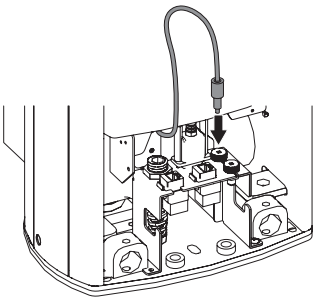
The switch installation requires a 2-wire with shielded AWG-24 cable for proper connection to selected switch. The switch and cable are provided by the user

Make sure to observe all local, state and federal guidelines, laws, regulations and other restrictions that may apply to the use of X-ray exposure switches. Perform the following to install an exposure switch.

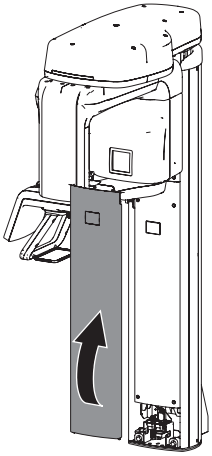
- Insert the cable on the foot of the telescopic column from behind and plug the connector into the marked socket.



- Insert one end of the remote exposure switch adapter (A7318) into the marked socket located within the foot of the telescopic column.



- Connect the two wires on the other end of the remote exposure switch adapter (A7318) to the two wires of the remote exposure switch.
- Install the front cover of the telescopic column.



6.9 Safety for the electrical connection

- The device may only be connected to a correctly installed outlet.
- Do not lay extension cords units on the floor. Follow the requirements of Section 16 of IEC 60601-1 (EN 60601-1).
- Do not operate any other systems connected via same outlet strip.
- Make sure there is slack in the connection lines to the S-Pan ensuring a secure connection that is 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").
- Ensure that electrical connections to the mains power supply are carried out according to current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.

6.10 Connecting the device to the power supply

Requirements:

- ✓ Correctly installed socket outlet in the vicinity of the unit (max. length of mains cable 8 feet (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.

6.11 Safe connection of device

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 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 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.

7 Operation

Tests such as operational check, electrical safety tests are regulated by the local and federal code.

- Find out which tests are to be made and the required intervals for your specific installation.
- Conduct tests in accordance with code.

7.1 Electrical safety check

Perform an electrical safety check according to local code to check patient and housing conductivity. Document the results.

7.2 Generator warm up

This Procedure prolongs tube life and avoids damage to the generator. Make sure to perform warm-up procedure at installation and whenever the X-Ray unit has not been used for a month.

Warm-up procedure

1. Current set to 4mA.
2. Voltage set to 50kVp.
3. One time Pano(SD) acquistion.

7.3 Installing and configuring the software

The unit supports authorized third party imaging programs via the TWAIN interface. Refer to instructions, P/N A7371, provided on the supplied CD for the steps to install the software and configure the device.

The tasks are summarized below.

1. Setting up the ProVecta S-Pan network.
2. ProVecta S-Pan Utilities Installation.
3. Configure the Client IP.
4. Download Prerequisite Files.
5. Testing ProVecta S-Pan Setup.
6. Third Party Imaging Management Application Setup.
7. Advanced Procedures (DDIPS Software and retrieving interrupted image acquisition).

7.4 Collimator Calibration Check

The device must be calibrated in order to obtain homogeneous, defect-free and reproducible X-ray images. To do so, the radiation field of the sensor as well as the collimator aperture for children and adults is checked and adjusted.

7.5 AISU2 Program and Device Connection

a. From the start menu, select the AISU2 item from the Air Techniques–>ProVecta S-Pan submenu.

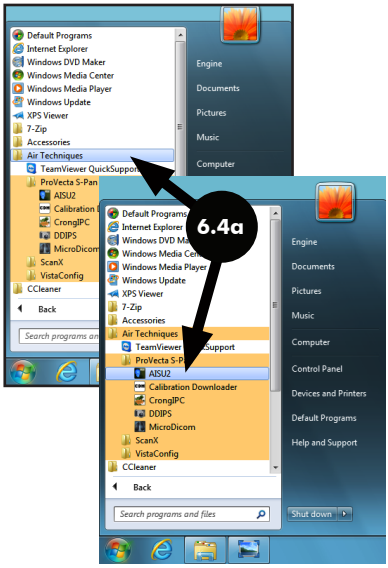
b. Observe that the AISU window opens showing that the device is Disconnected.

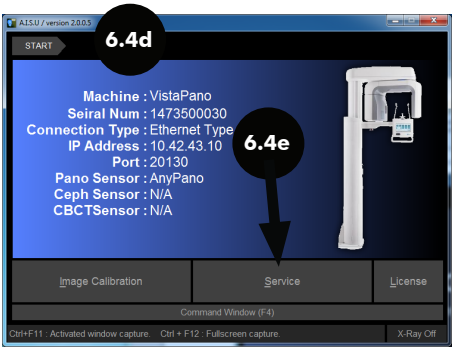
c. Press the Connect tab located at the bottom center of the window.

d. Observe that a new AISU window opens showing that the device is connected (Disconnected removed) and four new tabs are available at the bottom center of the window.

e. Press the center Service tab.

f. Observe that the AISU utility window opens.





7.6 Calibration Data Backup File

a. Make sure the Service tab is selected.

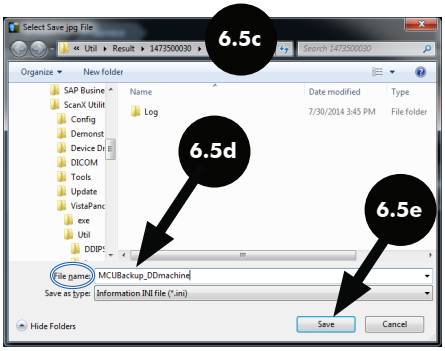
b. Under the Machine information section, press the Backup (Save) Info tab.

c. Observe that a new window opens.

d. Select a location for the backup file and name the file.

e. Press the Save button.

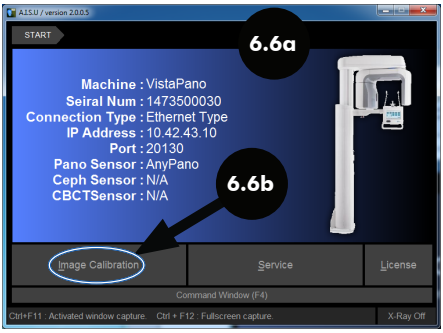
f. Return to the AISU utility start window by pressing Back button.



7.7 Adult and Child Collimator Adjustment for S-Pan

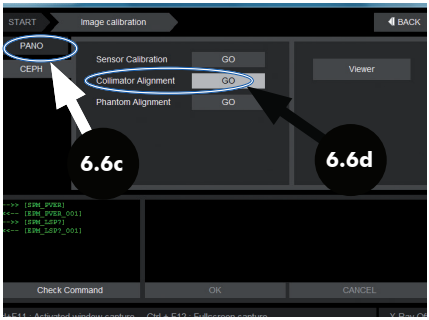
a. Verify the program returns to the AISU utility start window.

b. Press the Image Calibration tab located on the lower left.



c. Observe that the Image Calibration window opens. Select the PANO tab.

d. Select the Collimator Alignment's Go button.

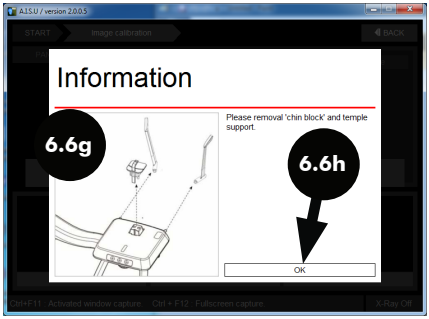


e. Observe that the Collimator Align window opens.

f. Press the Initialize tab.

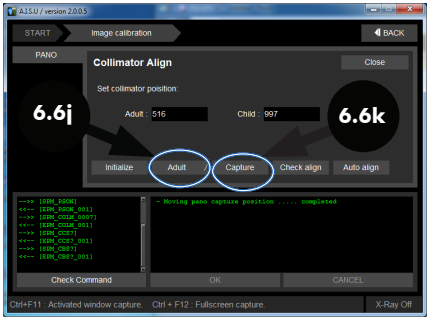
g Verify that a reminder window appears to remove chin block and temple support.

h. Press the OK button to return to the Collimator Align window and continue the calibration.

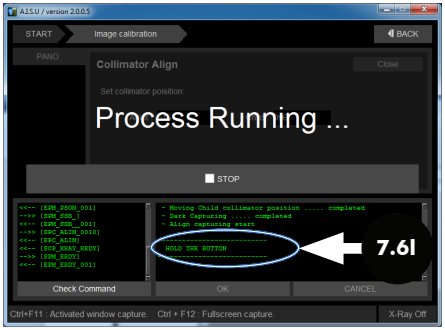


j. From the Collimator Align window, select Adult.

k. Press the Capture tab.



l. Observe that a Process Running window opens and the status screen displays the Hold the button message.

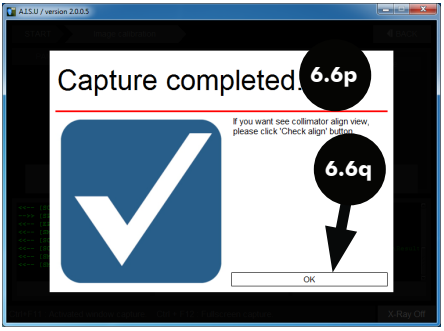


m. Depress and hold the exposure button on the exposure switch.

n. Observe that the exposure switch button LED illuminates green, turns off and finally illuminates amber. Keep the exposure switch pressed until three beeps are heard.

p. Observe that a Capture completed status window appears and release the exposure button.

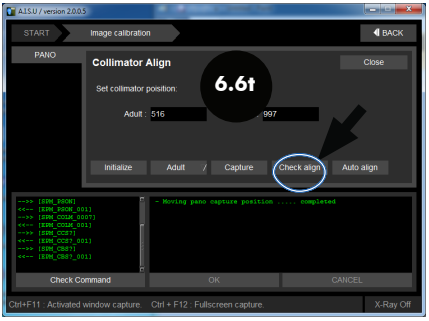
q. Press the OK button to return to the Collimator Align window. Go to step r to perform a child collimator adjustment, otherwise proceed to step s.



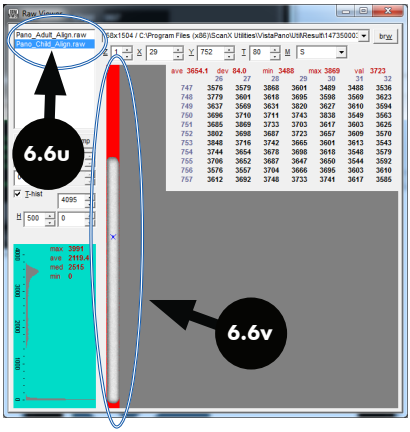
r. Select Child in step j and perform steps k through q when adjusting the child collimator.

s. Press the OK button to return to the Collimator Align window.

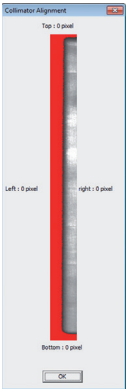
t. At the Collimator Align window, press the Check align tab.



u. The Raw Viewer screen opens after alignment. Both adult and child can be seen by highlighting the file name in the upper left corner.



v. Observe the red area around the collimator. If the area to the left or right of the collimator is ≤1 pixel, repeat the exposure.

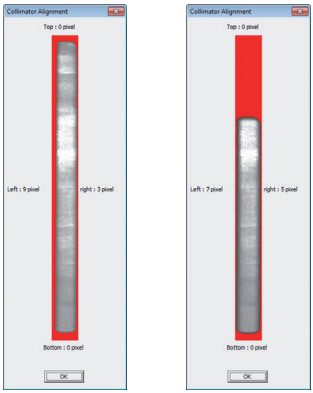


Note:

Unsuccessful calibration - red area is more than one pixel, repeat the exposure.

- Child position value should be in the 975 and 1020 range.
- Adult position value should be between 494 and 538.

w. Repeat exposures until the collimators are successfully calibrated, i. e. the active sensor surface has a red area with ≥1 pixel all around as shown below. A child collimator is somewhat shorter.

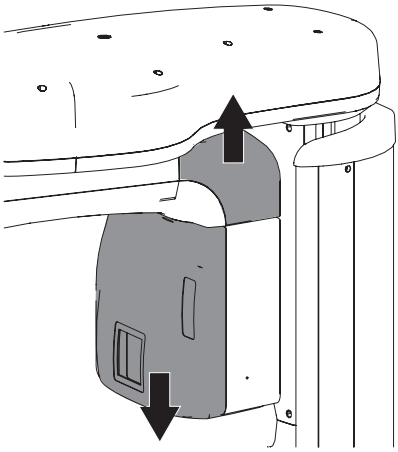


Adult Child

Successfully Calibrated Collimators

x. If the collimator lies "inclined" in the radiation field, the collimator must be corrected manually on the device by performing the following steps.

1. Remove the collimator covers.



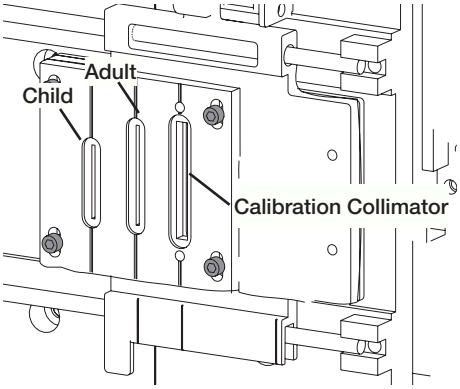
Note:

Based on failed collimator position shown by the Raw Viewer screen, adjust as follows.

Decrease value to move position right.
Increase value to move position left
Adjust in small increments.

2 Slightly loosen the four screws on the collimator.

3 Carefully shift the collimator in the corresponding direction.



4 Continue to adjust the collimator using the AISU tool until successfully calibrated.

Annex

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

8.1 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 Dürr Dental devices with products of other manufacturers. If there is any question of doubt, the complete standard must be checked.

8.2 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 transmitter in watts (W) according to manufacturer's information
d	Recommended safety distance in metres (m)

8.3 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 an 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 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 2: 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 3: 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.

8.4 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			

9 Program parameters

9.1 Large Adult, S-Pan

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

9.2 Average Adult, S-Pan

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
SD	Standard pan-oramic	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 pan-oramic	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

9.3 Small Adult/Youth, S-Pan

Image quality	Program	Voltage	Current	DAP	Scanning time
		kV	mA	mGycm²	s
SD	Standard pan-oramic	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 pan-oramic	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

9.4 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

9.5 Patient Type Preset Guidelines Based on Head Circumference

Patient Type	Head Circumference	KvP	mA	Mode
Large Adult	> 56±3	74	15	SD
		74	10	HD
Average Adult	56±3	73	12	SD
		73	10	HD
Small Adult/Youth	56±3 <	72	11	SD
		72	10	HD
Child	53±3	67	10	SD
		67	8	HD

10 Computer System Requirements

10.1 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)

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.

Notes

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.

Air Techniques' family of quality products for the dental professional include:

❑ Digital Imaging
- Digital Radiography
- Intraoral Camera
- Caries Detection Aid
- Intraoral X-ray
- Film Processors

❑ 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
- Imaging Accessories
- Chemistry
- Processor Accessories

Manufactured for / Distributed by

Air Techniques, Inc. | 1295 Walt Whitman Road | Melville, New York 11747- 3062

Phone: 1-800-247-8324 | Fax: 1-888-247-8481

Manufactured by

Vatech, Co., LTD | 13, Samsung 1-ro 2-gil | Hwaseong-si Gyeonggi-do | 18449 | KOREA

Australian Sponsor

Emergo Australia | Level 20 Tower II | Darling Park | 201 Sussex Street | Sydney | NSW 2000 | Australia

www.airtechniques.com

Platinum Green Business Certified

equipped for life®