PROVECTA® HD

Intraoral Dental X-Ray System

Operating Instructions

CE 2460

AIR TECHNIQUES equipped for life®

Contents

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 where 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.

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 60601-2-65

CE 2460 CE Labeling

Manufacturer

Date of Manufacture

Class I Type B

Wear protective gloves

Indicates the authorized representative in the European Community.
EC REP
EC Representative; Vatech Global France (SARL)
51 Quai de Dion Bouton 92800 Puteaux France

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

1.2 Notes on copyright

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

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

This unit is designed solely for using intraoral x-rays in the examination and diagnosis of diseases and illnesses of teeth, jaw and the oral cavitiy.

2.2 Incorrect use

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

2.3 General safety notes

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

2.4 Radiation protection

- Observe all mandatory current x-ray protection rules and take all necessary x-ray protection measures.
- Use 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 remain at least 1.5 m from the x-ray unit when taking any radiographs.
- Within the radiation room there must be no other person present beside the patient without x-ray protection measures. In exceptional circumstances a third party may be present to give assistance, but this must not be a member of the surgery staff. Ensure visual contact during exposure with the patient and the unit.
- In the case of any interruption when taking an exposure, stop the procedure immediately by letting go of the release switch.

2.5 Qualified personnel

Instructions for use

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

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

Installation and repair

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

2.6 Protection against electrical current

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

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 appliance during transport.

If required, the original packaging for the unit can be ordered at Air Techniques.

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 appliance in its original packaging whenever possible.
- Keep the packing materials out of the reach of children.

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:

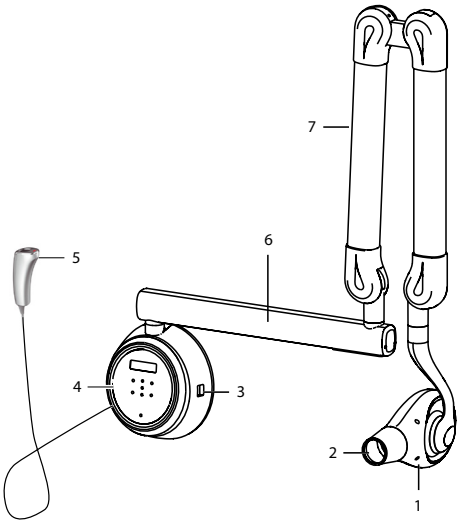
Tubehead:
Non-biodegradable plastic materials, metals, glass, dielectric oil, lead, tungsten.

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



1 X-ray tube head
2 Cone (collimator)
3 Main power switch
4 Control unit with control panel
5 Handheld exposure button
6 Horizontal Arm
7 Scissor Arm

3.1 Delivery Contents

The following articles are included in the scope of delivery.

Provecta HD X-ray unit with short extension arm. A6350-15

Provecta HD X-ray unit with medium extension arm A6350-24

Provecta HD X-ray unit with long extension arm. A6350-33

– X-ray tubehead
– Scissor arm
– Horizontal arm
– Control unit with control panel
– Exposure button and holder
– X-ray collimator 1.2 x 1.6 in ^{2}
– Mains cable (110 V)
– Installation Mounting Hardware
– Installation and Operating Instructions

3.2 Special accessories

The following items can be optionally used with the appliance:

Single stud wall mount plate kit A6336

16 on center wall mount plate kit. A6330

X-ray collimator, rectangular
0.8 x1.2 in ^{2} A6346

Extension cone, 12 inches (300 mm). . . . A6395

Wallplate exposure pushbutton switch kit . . A6320

Control panel remote mounting kit. A6400

Commissioning and intraoral constancy checks

2-D X-ray test phantom. G8795

4 Technical data

Unit electrical data

Nominal voltage	100 to 240 V AC
Max. voltage fluctuation	±10%
Frequency	50/60 Hz
Power rating	500 W
Maximum power	750 VA

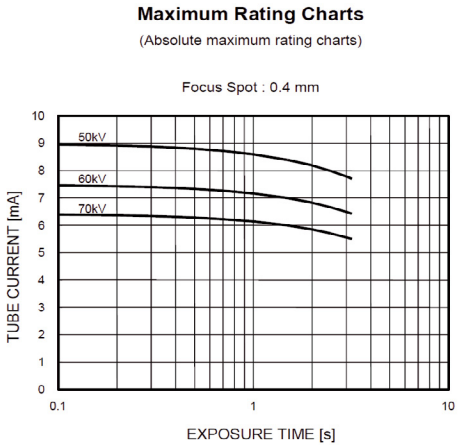
Classification

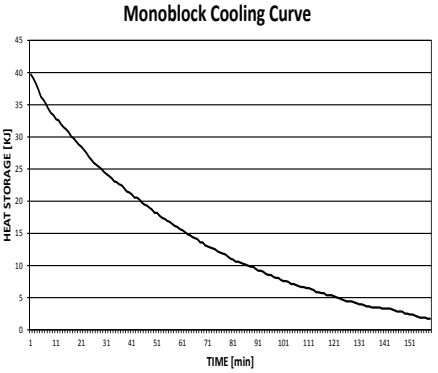
FDA 21 CFR Device Classification	Class II
This X-ray system complies with US - FDA:	21 CFR Part 1010.2
	21 CFR Part 1020.30/31
Degree of protection against ingress of water	Ordinary
Medical products directive (93/42/EEC) manufacturer: VATECH Co., Ltd. 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea	

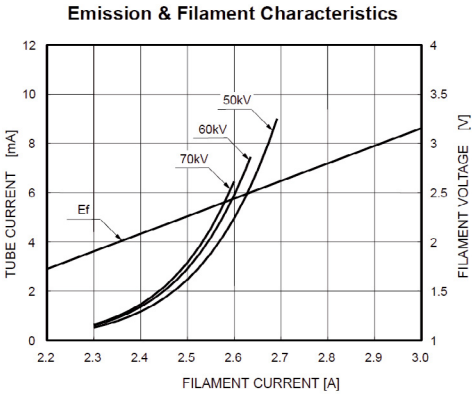
X-ray unit technical data

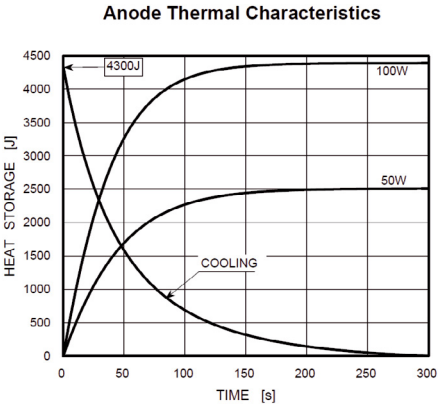
X-ray Tube Type	Canon D-041SB (Stationary Anode Type)
Model	DG-10A05T3
Generator size and weight	5.5 x 6 x 3 in. (140 x 150 x 70 mm) 5.5 lbs. (2.5 kg)
Source to skin distance	8 in. (200 mm) 12 in. optional (300 mm)
Generator performance	0.5 kW
Nominal voltage (Accuracy)	50 to 70 kVp (±10%) Values below 60 kV are not intended for human use in USA and Canada
Nominal current (Accuracy)	4 to 7 mA (±20%)
X-ray tube cooling	Automatically controlled ≥ 50 °C Air cooling: optional
Inherent filtration	1.0 mm Al
Total filtration	Min. 2.0 mm Al
Focal spot size according to IEC 60336	0.4 mm
X-ray field collimation	∅ 2.4 in./1.2 x 1.6 in^2 (∅ 60 mm/30 x 40 $mm^{2)}$ Optional 0.8 x 1.2 in^2 (20 x 30 mm^2)
Exposure time (Accuracy)	0.04 to 2 seconds (±5% or ±20 ms)
Anode material	Tungsten
Anode angle	12.5 degrees
Duty cycle	1:60 or greater

4.1 X-ray tube performance data







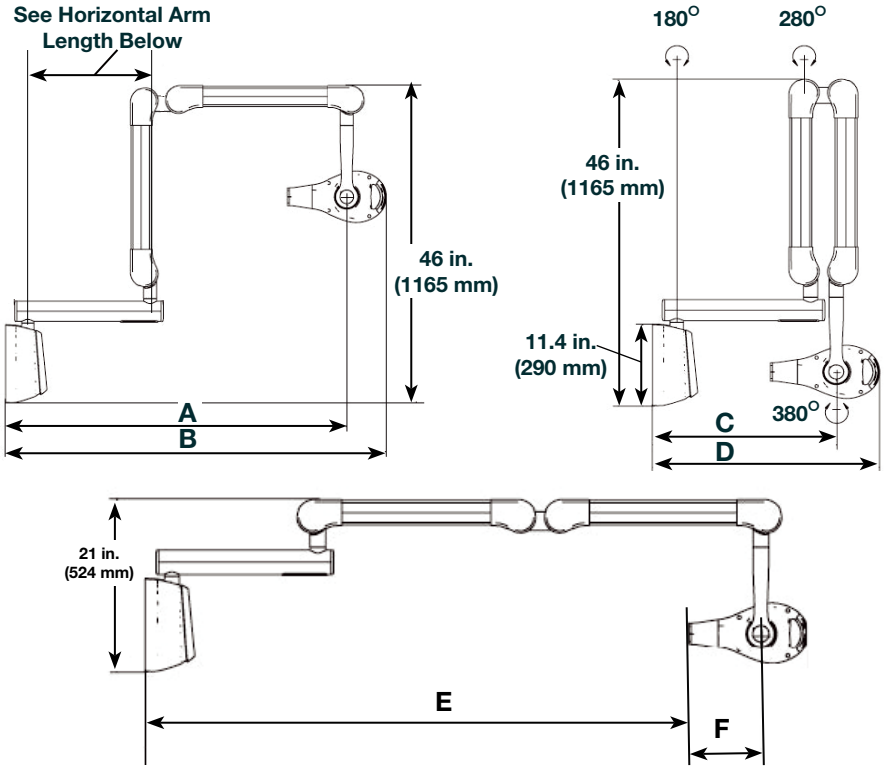


General technical data	A6350-15	A6350-24	A6350-33
Arm length	17.7 in. (450 mm)	23.6 in. (600 mm)	35.4 in. (900 mm)
Storage height		46 in. (1165 mm)	
Weight	55 lbs (24.9 kg)	56 lbs (25.4 kg)	59 lbs (26.7 kg)

Ambient conditions during operation	
Temperature	50 to 95 °F (+10 to +35 °C)
Relative humidity	30 to 75%
Air pressure	25 to 31 inHg (860 to 1060 hPa)

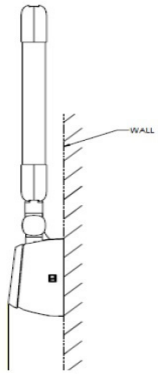
Ambient conditions during storage and transport		
Temperature	14 to 140 °F	(-10 to +60 °C)
Relative humidity		10 to 75%
Air pressure		25 to 31 inHg (860 to 1060 hPa)

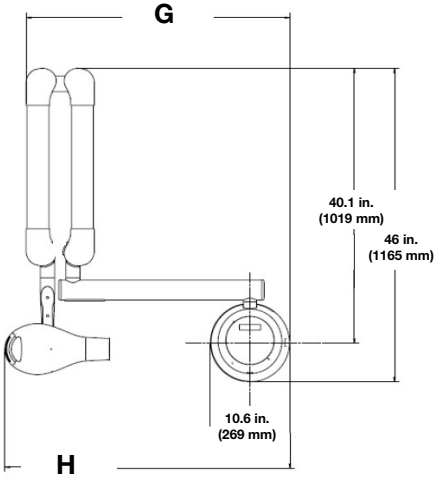
4.2 Dimensions



DIMENTIONS 'A' THRU 'E' :
SINGLE POST WALL MOUNTING PLATE (P/N A6389) - ADD 0.5" (13mm)
16 CENTER TO CENTER WALL MOUNTING PLATE (P/N A6341) - ADD 1.0" (26mm)

Horizontal Arm length	A	B	C	D	E	F
17.7 inches (450 mm) **PN A6350-15**	50.3 inches (1278 mm)	56 inches (1422 mm)	24.4 inches (620 mm)	30.2 inches (767 mm)	66.5 inches (1689 mm)	8.6 inches (220 mm)
23.6 inches (600 mm) **PN A6350-24**	56.25 inches (1429 mm)	61.75 inches (1568 mm)	31 inches (787 mm)	36.5 inches (927 mm)	71.75 inches (1823 mm)	8.6 inches (220 mm)
35.4 inches (900 mm) **PN A6350-33**	68.5 inches (1740 mm)	73 inches (1854 mm)	42 inches (1068 mm)	48 inches (1219 mm)	83.3 inches (2118 mm)	8.6 inches (220 mm)



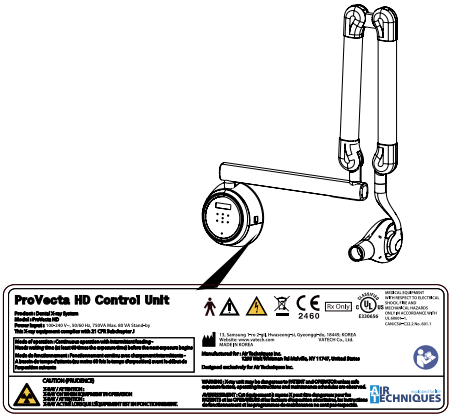


Horizontal Arm length	G	H (Head Turned in) H (Head Turned out)
17.7 inches (450 mm) **PN A6350-15**	29.2 inches (742.5 mm)	32.1 inches (814.7 mm) 35.0 inches (890 mm)
23.6 inches (600 mm) **PN A6350-24**	35.1 inches (892.5 mm)	37 inches (940 mm) 41 inches (1040 mm)
35.4 inches (900 mm) **PN A6350-33**	48 inches (1219.2 mm)	50 inches (1270 mm) 53 inches (1346 mm)

4.3 Model identification plate

Appliance

The model identification plate is located on the rear side of the control unit housing.



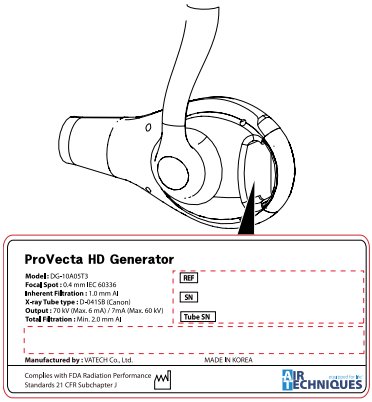
REF Order number

SN Serial number

UDI Unique device identification code

X-ray unit

The model identification plate is located on the rear side of the x-ray unit.



REF Order number

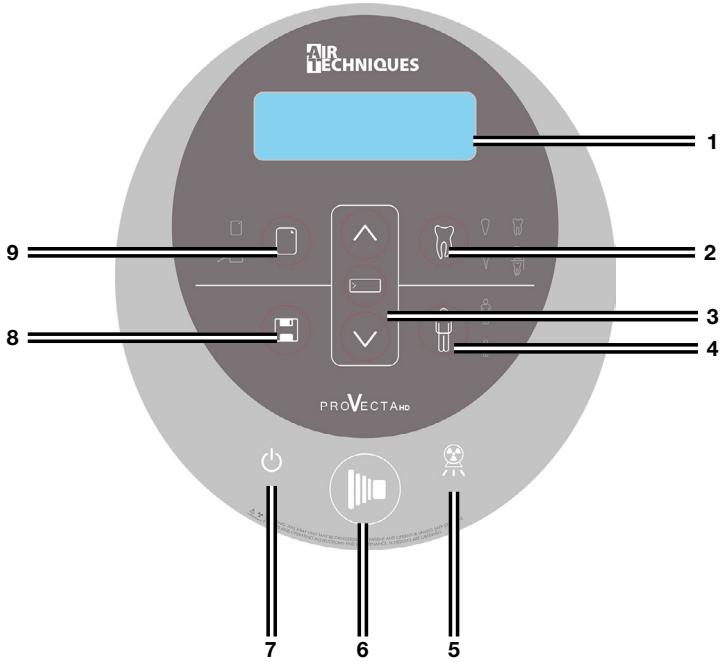
SN Serial number

5 Function

Provecta HD is an extraoral x-ray unit and is factory set at the correct x-ray dosage for each dental area required using Air Techniques image plates and sensors. It consists of a control unit, an arm extension system and an x-ray tube assembly.

The handle on the x-ray head unit allows the x-ray tube to be positioned precisely.

5.1 Control panel



1	LED Display	**6**	Exposure button
2	Anatomical selector	**7**	Stand-by/Power indicator
3	Parameter adjustment key	**8**	Save key
4	Adult/Child selector	**9**	Image plate/sensor selector
5	X-Ray emission indicator		

Menu tooth symbol

Front tooth

Molar

Pre-molar

Bite wing exposure

Menu x-ray parameter

kV -> mA -> sec

To enter the following parameters press ^ or v

kV: 60 to 70, 50 to 70 (optional)

mA: 4 to 7

secs: 0.04 to 2

Menu Adult/Child

Adult

Child

Menu image plate/sensor

Image plate

Sensor

5.2 Exposure switch

The exposure switch can be used as alternative to using the control panel to activate irradiation.

5.3 Radiation field collimation

The radiation field collimator reduces the useful x-ray field to the required dimensions. This reduces the x-ray exposure to the patient. Observe any national regulations.

5.4 Wall mounting plate

A wall mounting plate must be used for Provecta HD installations. There are two mounting plates available; one for single stud installations and a 16 on center plate used when there are dual studs. Refer to the Installation manual for instructions to install the Provecta HD unit.

Setup

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

6 Prerequisites

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

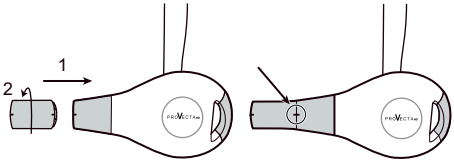
Closed, dry room.

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

7 Tube and Power Setup

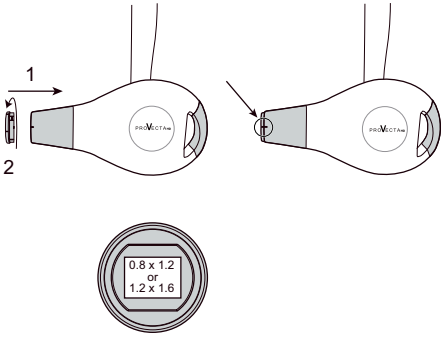
7.1 Mount tube (optional)

• Place the 12 in. (30 cm) tube extension in position and check whether the grooves match correctly.



7.2 Mount radiation field collimation

• Slide the radiation field collimator piece onto the tube and adjust according to the image plate or the sensor.



7.3 Safety for electrical connection

• The appliance may only be connected to a correctly installed electrical socket outlet.
• Do not lay multi-socket units on the floor. Specifications of UL 60601-1 (1st) apply.
• Other systems should not be plugged into the same multi-socket unit.
• All cables, etc. must be laid so that no mechanical tension is exerted on them.
• Before start-up or first use, check the mains voltage against the voltage indicated on the model identification plate (see also "4. Technical Data").

7.4 Connecting the appliance to the power supply

Requirements:

✓ A correctly installed socket-outlet in the vicinity of the unit must be available (maximum length of mains cable 6 ft. (1.8 m)
✓ The socket-outlet must be easily accessible
✓ Voltage is identical to that given on the model identification plate
✓ Insert plug into electrical socket

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

When carrying out the commissioning tests where the image plate and sensor are used as receiver, the 2-D X-ray test phantom is required and possibly the appropriate 2-D X-ray test phantom holder.

- Before initial unit operation the commissioning test of the x-ray system must be carried out according to national regulations.

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

8.2 Electrical safety check

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

8.3 Switch unit on

The display will show the standard values for x-ray exposures or the setting values used for the last exposure carried out.

– Operational display lamps,
– LED for menu tooth symbol,
– LED for menu Adult/Child and
– LED for menu image plate/sensor all light up.

8.4 Service menu settings

- While pressing the button and additionally the button a little longer in order to switch to the Service-menu.
- Under menu option 1. *Cone Type* move to appropriate value with or scroll through and then use to confirm.
- Under menu option 2. *Cone Type* move to appropriate value with or scroll through and then use to confirm.
- Under menu option 3. *Default Value Reset*, press to confirm reset.
- Under menu option 4. *kV Option* move to appropriate value with or scroll through, 50-70 kV are permissible in countries with no x-ray limit regulations. Use to confirm.
- Under menu option 5. *X-ray Count* move to appropriate value with or scroll through. Use to confirm.

  Resetting the counter is password protected.
- Under menu option 6. *Version* the current Firmware Version can be called up. Use to confirm.
- Under menu option 7. *Demo* the Demo-Version can be started by pressing .
- After entering all required values press to exit the Service Menu.

Usage

9 Instructions for use

NOTICE

Exerting force on the unit can lead to it becoming damaged

- Do not lean against or support yourself using the unit.

9.1 Standard settings on switch-on

The tube length can be preset in the Service-Menu "8.4 Service menu settings".
An extension of the tube influences the image quality and the dose area product displayed.

Standard settings on switch-on

– Image plate
– Adult, Pre-molar
– 60 kV, 7 mA

The following table shows the standard values for the image plate exposure time of an adult patient.

	DC radiator, 7 mA Tube length 8 in. (20 cm)		DC radiator, 6 mA Tube length 12 in. (30 cm)	
	60 kV	**µGy**	**70 kV**	**µGy**
Incisor	0.08 s	107	0.13 s	109
Pre-molar	0.12 s	156	0.18 s	147
Molar	0.17 s	215	0.25 s	207
Bite wing	0.18 s	227	0.27 s	223

The following table shows the standard values for the image plate exposure time of a child patient.

	DC radiator, 7 mA Tube length 8 in. (20 cm)		DC radiator, 6 mA Tube length 12 in. (30 cm)	
	60 kV	**µGy**	**70 kV**	**µGy**
Incisor	0.05 s	67	0.08 s	67
Pre-molar	0.07 s	94	0.11 s	93
Molar	0.11 s	146	0.14 s	144
Bite wing	0.11 s	146	0.14 s	144

- Check and adjust X-ray appliances in accordance with the following standard equipment-specific values.

The following table shows the standard values for the sensor exposure times for an adult patient.

	DC radiator, 7 mA Tube length 8 in. (20 cm)		DC radiator, 6 mA Tube length 12 in. (30 cm)	
	60 kV	**µGy**	**70 kV**	**µGy**
Incisor	0.07 s	93	0.11 s	91
Pre-molar	0.10 s	132	0.16 s	131
Molar	0.13 s	162	0.20 s	164
Bite wing	0.14 s	174	0.21 s	172

The following table shows the standard values for the sensor exposure time of a child patient.

	DC radiator, 7 mA Tube length 8 in. (20 cm)		DC radiator, 6 mA Tube length 12 in. (30 cm)	
	60 kV	**µGy**	**70 kV**	**µGy**
Incisor	0.04 s	51	0.07 s	58
Pre-molar	0.06 s	81	0.10 s	82
Molar	0.08 s	108	0.13 s	107
Bite wing	0.09 s	121	0.14 s	115

• Check and adjust X-ray appliances in accordance with the following standard equipment-specific values.
Pre-programmed exposure times for films with class E sensitivity on an adult patient

	DC radiator, tube length 8 in. (20 cm)		DC radiator, tube length 12 in. (30 cm)	
	7 mA 60 kV	**6 mA 70 kV**	**7 m A 60 kV**	**6 mA 70 kV**
Incisor	0.16 s	0.08 s	0.32 s	0.16 s
Pre-molar	0.20 s	0.10 s	0.40 s	0.20 s
Molar	0.25 s	0.12 s	0.50 s	0.25 s
Bite wing	0.32 s	0.16 s	0.64 s	0.32 s

Pre-programmed exposure times for films with class E sensitivity on a child patient

	DC radiator, tube length 8 in. (20 cm)		DC radiator, tube length 12 in. (30 cm)	
	7 mA 60 kV	**6 mA 70 kV**	**7 mA 60 kV**	**6 mA 70 kV**
Incisor	0.10 s	0.05 s	0.20 s	0.10 s
Pre-molar	0.12 s	0.06 s	0.25 s	0.12 s
Molar	0.16 s	0.08 s	0.32 s	0.16 s
Bite wing	0.20 s	0.10 s	0.40 s	0.20 s

• Check and adjust X-ray appliances in accordance with the following standard equipment-specific values.
• Press selection key image plate/sensor.
• Press selection key tooth symbol.
• Press selection key Adult/Child patient.
• Press selection key imaging parameters
– kV, and ∧ ∨ to select other values
• Press selection key imaging parameters
– mA, and ∧ ∨ to select other values
• Press selection key imaging parameters
– secs, and ∧ ∨ to select other values
• Press key Save for 2 secs.

The individual settings have now been saved and can be read on the display.

To reset the unit to the factory settings please contact your Service Technician.

9.2 Positioning patient, X-ray unit and image receptor

CAUTION

Injuries to the oral cavity

Sharp-edged receptors can cause injuries to the oral cavity.

- Careful positioning of the image receptor into the patient's oral cavity.

- Allow the patient to sit down.
- Position the image receptor inside the oral cavity
- Position the x-ray unit.

CAUTION

Image quality insufficient

If the x-ray unit is moved or if the patient moves during exposure then the images will not be usable.

- The patient should sit quite still during x-ray exposure.
- The x-ray unit must not be moved in any way during exposure.

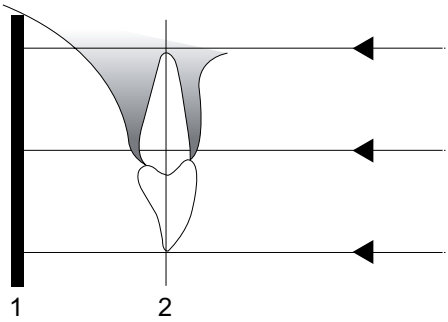
The image receptor can be any of the following:

– Film
– Sensor
– Image plate

Ensure that the image receptor is placed within the x-ray field.
Place the tube close to the skin.

Parallel techniques

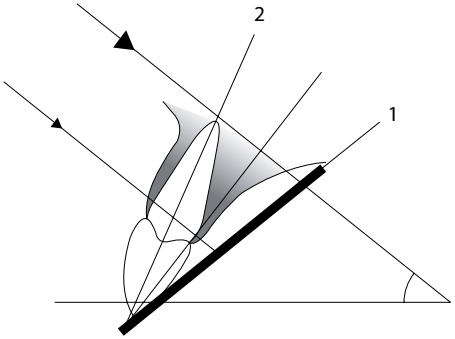
Position the image receptor using a holder system for parallel techniques.



1 Image receptor
2 Tooth axis

Bisection angle technique

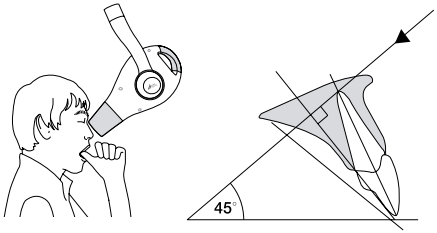
The patient should hold the image receptor in the mouth in the correct position. The middle of the radiation ray is set at right angles to an (estimated) plane at half the angle between tooth axis and image receptor.



1 Image receptor
2 Tooth axis

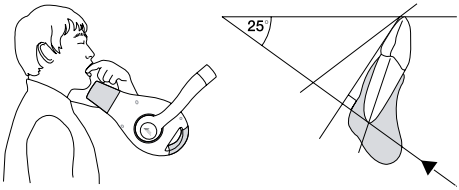
Upper jaw front tooth exposure

X-ray is projected 45° downwards



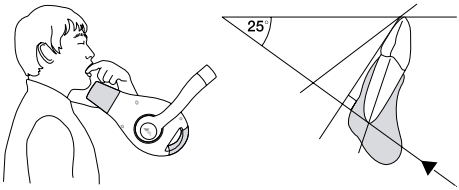
Lower jaw front tooth exposure

X-ray is projected 25° upwards



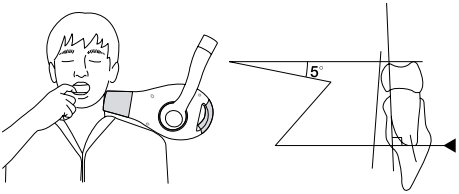
Upper jaw molar and premolar exposure

X-ray is projected 25° upwards



Lower jaw molar and premolar exposure

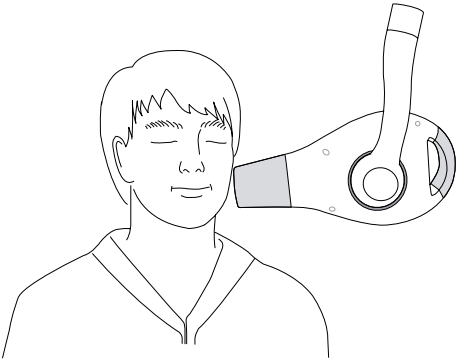
X-ray is projected 5° upwards



Bite wing technique

During the bite wing exposure the patient needs to bite on a bite wing holder.

X-ray is projected 5 to 8° upwards



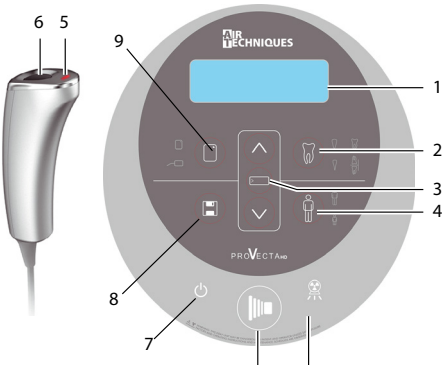
9.3 Activate exposure

CAUTION

Injuries through x-rays

X-rays can cause tissue damage.

- Observe all x-ray regulations.
- Keep a minimum safety distance of 5 feet (1.5 m.)



1 LED Display
2 Anatomical selector
3 Parameter adjustment key
4 Adult/Child selector
5 X-Ray emission indicator
6 Exposure button
7 Stand-by/Power indicator
8 Save key
9 Image plate/sensor selector

NOTICE

Unit damage due to switching frequency being too high

If sufficient cooling of the x-ray unit is not ensured, this can lead to damage.

- Only activate the subsequent x-ray image after the displayed cooling time has elapsed.

- Check x-ray settings on control panel and change if necessary
  - Change the tooth region using menu tooth symbol
  - Change to adult or child using patient menu
- Check x-ray parameter and change if necessary
- Depress exposure button

– The x-ray unit control lamp lights green -> unit is warming up

– The control lamp lights orange and an acoustic signal is heard -> unit is exposing

Hold the exposure button at least as long as the acoustic signal can be heard. Otherwise the exposure will be faulty and there will be an error message in the display.

– The image is ready as soon as the exposure time has passed. The x-ray unit control lamp goes out and the acoustic signal is no longer heard.
– The dose area product is shown on the display, when this function is enabled in the service menu

The unit cools down after every exposure. The cooling time is clearly displayed as it reduces. During this time the activation release can no longer be operated. The x-ray unit control lamp blinks.

– The unit is ready again.

10 Cleaning and disinfecting

NOTICE

Unsuitable agents and methods can damage the appliance and accessories

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

Wear protective gloves

Prior to work on the appliance, pull the mains plug.

The unit surface must be cleaned and disinfected of contamination or soiling. Using approved cleaning and disinfectant agents.

NOTICE

Liquid can cause damage to the appliance

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

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

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.

Troubleshooting

11 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
E01	Electrical connection between the control panel and PCB (main board) is interrupted	• Switch the appliance off. • Check the connection cable. • Inform service technician.
E02	Electrical connection between the x-ray unit and PCB (main board) is interrupted	• Switch the appliance off and on. • Inform service technician.
E03	Current strength exceeded maximum permitted value during exposure	• Switch the appliance off and on. • Inform service technician.
E08	X-ray unit temperature too high	• Switch off the x-ray unit until it has cooled down sufficiently. • Switch the appliance on again.
E09	Current strength outside permitted value during exposure	• Switch the appliance off and on. • Inform service technician.
E10	X-ray exposure not activated despite key being pressed	• Quit by pressing key "Menu x-ray parameter" • If the fault repeats, inform your Service Technician.
E11	Exposure continues more than 0.5 secs, even though activation switch no longer pressed	• Switch the appliance off. • Inform service technician.
E12	Displayed kV-value is lower than the value actually set	• Switch the appliance off and on. • If the fault continues to be displayed, inform your Service Technician.
E13	Displayed kV-value is higher than the value actually set	• Switch the appliance off and on. • If the fault continues to be displayed, inform your Service Technician.
E14	Displayed mA-value is lower than the value actually set	• Switch the appliance off and on. • If the fault continues to be displayed, inform your Service Technician.
E15	Displayed mA-value is higher than the value actually set	• Switch the appliance off and on. • If the fault continues to be displayed, inform your Service Technician.

Problem	Probable cause	Solution
E60	Activation switch is released while unit is being turned on	• Switch the appliance off and on. Take care that the activation key is not being pressed. • Inform service technician.
E61	Activation switch is released, before the set exposure time has been expired	• Quit by pressing key "Menu x-ray parameter" • If the fault repeats, inform your Service Technician.
Value over	Operating error kV value or time entered is too high	• Correct the value.

Problem	Probable cause	Solution
Unit does not start up	No mains supply	• Check mains cable and sockets and change if necessary. • Inform service technician.
		• Check main fusing in building.
	On / off switch is defect	• Inform service technician.
No x-ray irradiation	X-ray unit temperature too high	• Wait until x-ray unit has cooled down sufficiently.
	Activation key on control panel is defect	• Inform service technician.
	Activation key on manual release is defect	• Cable is defect or not connected to unit. • Inform service technician.
X-ray image too bright	Image receptor being used not compatible with unit settings	• Use different X ray receptor or change unit setting
	X-ray unit not positioned correctly	• Correct the position of the x-ray unit
	X-ray parameters not set correctly	• Check x-ray parameters and, if necessary, set correctly. Increase exposure time. • Inform service technician.
	Image receptor not correctly placed in patient's mouth	• Correct the position of the image receptor
X-ray image too dark	Image receptor being used not compatible with unit settings	• Use different image receptor or change unit settings.
	X-ray parameters not set correctly	• Check x-ray parameters and, if necessary, set correctly. Reduce exposure time. • Inform service technician.

Annex

12 Leakage Dose Test Report

12.1 General notes

The X-ray does data is extracted from the X-ray Dose Test Report for the ProVecta HD. The X-ray doses of ProVecta HD in the test report were measured in accordance with the IEC collateral standards. ProVecta HD was designed in accordance with Part 1. Generatl Requirements for Safety, IEC 60601-1-3.

12.2 Leakage Dose Test

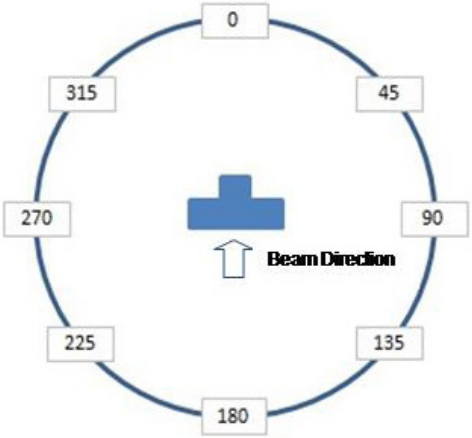
Test Equipment Information			
Instrument	**Manufacture**	**Model**	**S/N**
Dose Meter	Victoreen	660	101114 / 101377

Test Condition	
Distance from focal point [m]	1
Applied tube Voltage Peak [kVp]	70
Applied Tube Current [mA]	6.0
Applied Exposure time [s]	0.5

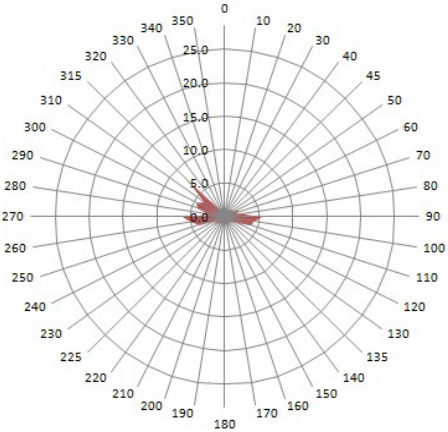
Direction [°]	Basic Cone [mGy/hr]	
	Transverse	**Longitudinal**
0	0.0018	0.0605
45	0.0140	0.0395
90	0.0482	0.0535
135	0.0105	0.0561
180	0.0035	0.0947
225	0.0105	0.0561
270	0.0544	0.0614
315	0.0702	0.0509

The tested area on the plane of radiation is defined within a radius at a distance of 1m from the focal spot.

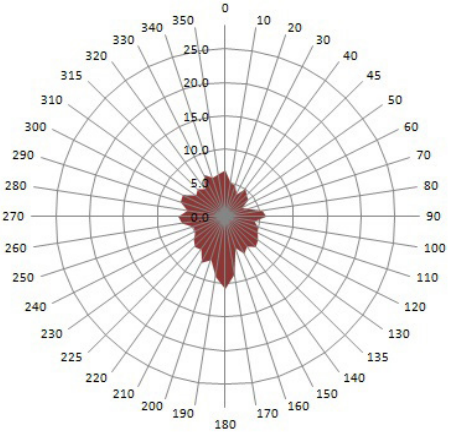
[Measurement Points (Transverse / Longitudinal)]



[Measurement Values (Transverse)]



[Measurement Values (Longitudinal)]



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 appliances. The information reproduced here should be observed during the installation of individual appliances and when combining Air Techniques appliances 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 appliance (supply voltage)
V_1, V_2	Level of consistency for testing according to IEC 61000-4-6
E_1	Level of consistency for testing according to IEC 61000-4-3
P	Rated power of transmitter in watts (W) according to manufacturer's information
d	Recommended safety distance in metres (m)

13.3 Guidelines and manufacturer's information

Electromagnetic transmissions for all appliances and systems

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

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

Table 1: Electromagnetic transmissions for all appliances and systems

Electromagnetic resistance for all appliances and systems

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

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

Table 2: Electromagnetic resistance for all appliances and systems

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

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

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

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

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

d Recommended safety distance in metres (m)

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

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

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

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

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

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

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

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

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

Table 4: Recommended safety distances between portable and mobile HF communications devices and the appliance

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

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

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

13.4 Table of calculation

If the measured values deviate from the standard, the values in Section 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. 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.
- 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.

Maintenance interval	Maintenance work
Daily	• Clean all components that come into contact with the patient and operator with and alcohol-based solution.
	• Wipe the outer covers of the equipment with a dry cloth at the end of each day's operation. **Do not use detergents or solvents to clean the outer covers of the equipment.**
	• Ensure that the main power switch has been turned off after using the equipment.
	• Ensure that the equipment is firmly plugged into a dedicated power source.
	• Ensure that there are no oil leaks.
	• Ensure that the wall framework is securely attached to the wall.
	• Ensure that the plug and power cord are not hot.
	• Ensure that the power supply cable is in good condition.
	• Ensure that the audible signal is audible and the x-ray emission light is visible when you make an exposure.
	• Ensure that the orange(exposure) indicator light turns on when the exposure switch is pressed.
Weekly	• Ensure that the power cable is not kinked, broken, exposed and that it is free of all other defects.
Monthly	• Ensure that all visible lables are intact and legible.
	• Ensure that the equipment is well grouned.
	• Ensure that there is no wear or damage to the exposure switch cable

Provecta HD 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 HD 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 HD 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 HD 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.

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

❑ Digital Imaging

- Digital Radiography
- Intraoral Camera
- Caries Detection Aid
- Intraoral X-ray
- Panoramic 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

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