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EzRay Air Vet™

EzRay Air Vet User manual

EzRay Air Vet™

User manual

Model : VEX-P300
Version : 1.43

• English



Full version

ZIP Code : 18449
14, Samsung 1 ro 2 gil, Hwaseong si, Gyeonggi do, Republic of Korea
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"i" stands for 'innovation', one of the core values of VATECH, which aims to expand accessibility of medical solutions to more people.

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Notice

The **EzRay Air VET™(VEX-P300)** is a portable dental X-ray system.

This manual contains descriptions, operational instructions, imaging procedures for the **EzRay Air VET™(VEX-P300)** Veterinary dental X-ray system. It is recommended that you thoroughly familiarize yourself with this manual to make the most effective use of this equipment. Observe all cautions, safety messages and warnings that appear in this manual.

Keep this manual with the equipment always and review the operation procedures and safety instructions if needed.

The illustrations/photos of the equipment in this manual are only for illustration purposes. Actual equipment may differ.

Due to continuous technological improvements, the manual may not contain the most updated information. For further information not covered in this manual, please contact us at:

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This document is originally written in English.

The **EzRay Air VET™(VEX-P300)** is referred to as Equipment in this manual.

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1. General and Regulatory Information

1.1 Manufacturer's Liability

The manufacturers and/or retailers of this equipment assume responsibility for the safe and normal operation of this equipment only when:

- Genuine **Woorien** approved equipment and components have been used always.
- All maintenance and repairs have been performed by a **Woorien** authorized agent in accordance with instructions contained in this manual.
- The equipment has been used normally in accordance with the user's manual.
- The equipment damage or malfunction is not the result of an error on the part of the owner or operator.



RADIATION HAZARD

Disclaimer:

EzRay Air VET™(VEX-P300) is sold with the understanding that the user assumes sole responsibility for radiation safety (as well as any state, provincial, or local regulatory compliance) and that **Woorien**, its agents or representatives, do not accept responsibility for:

1) any injury or danger to personnel from X-ray exposure,
2) image over/under exposure due to poor operating techniques or procedures,
3) equipment which has been damaged, modified, or tampered with in any way.

1.2 Owner and Operator's Obligations

- The owner of this equipment must perform constancy tests at regular intervals to ensure patient and operator safety. These tests must be performed in accordance with local X-ray safety regulations.
- The owner of this equipment must perform regular inspection and maintenance of the mechanical and electrical components in this equipment to ensure safe and consistent operation (IEC 60601-1).
- The owner of this equipment must ensure inspection and cleaning work is performed in accordance with the maintenance schedule outlined in **Chapter 7 Cleaning and Maintenance.**

⚠WARNING DO NOT operate this equipment until you have read this manual and reviewed the accompanying materials.

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1.3 Conventions Used in this Manual

The following symbols are used throughout this manual. Make sure that you fully understand each symbol and follow the instructions which accompany it.

To prevent personal injury and/or damage to the equipment, please observe all warnings and safety information included in this document.

	**WARNING**	Indicates that a specific hazard is known to exist which through inappropriate conditions or actions may cause: • Severe personal injury (to the operator and/or patient) • Substantial property damage.
	**RADIATION HAZARD**	Indicates a possible danger from exposure to radiation.
	**CAUTION**	Indicates that a potential hazard may exist which through inappropriate conditions or actions will or can cause: • Minor injury • Property damage.
	**IMPORTANT**	Indicates that a potential problem may exist which through inappropriate conditions or actions can cause: • Property damage.
	**NOTE**	Indicates precautions or recommendations that should be used in the operation of the system, specifically: • Using this Manual • Notes to emphasize or clarify a point.

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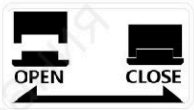
1.4 Marks and Symbols

The following table describes the purpose and location of safety symbols and other important information provided on the equipment.

Mark/Symbol	Description	Location
	Alternate current	Battery Charger Label
	Direct current	Main Label
	Attention: consult accompanying documents	Main Label
	Dangerous voltage	Power board, X-ray Generator, Generator Label
OFF	Off (power: disconnect from the main switch)	Battery bay access door (outside)
ON	On (power: connect to the main switch)	Battery bay access door (outside)
	IEC60601-1 Degree of Protection from Electric Shock TYPE B Equipment	Main Label
	Radiation hazard	Generator Label
EC REP	Authorized European Representative address	Main Label
CE	The CE symbol indicates that this equipment complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Main Label
C US 266436	CSA mark No.266436	Main Label

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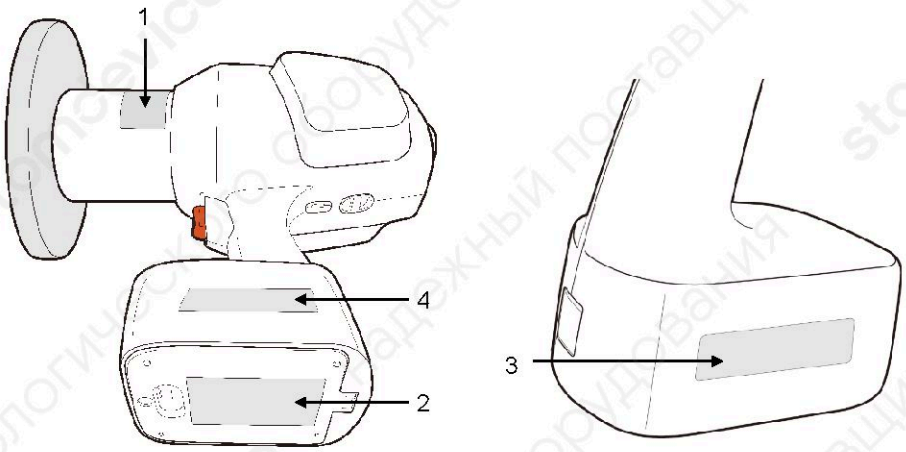
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Mark/Symbol	Description	Location
	***Caution:*** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Main Label
	Manufacturer's name and address	Main Label, Generator Label
	Date of manufacture	Main Label, Generator Label
	This symbol indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Main Label
	ESD susceptibility symbols indicate that an item is susceptible to damage from electrostatic discharges.	Board package
	Refer to the User Manual.	Main Label
	Using a torx wrench, unscrew the battery bay access door.	Main Label
	Lift the door after removal of the screw.	Main Label
	Battery replacement procedure	Battery bay access door (inside)
	This symbol indicates the direction of cover attachment/detachment.	Cone's upper part

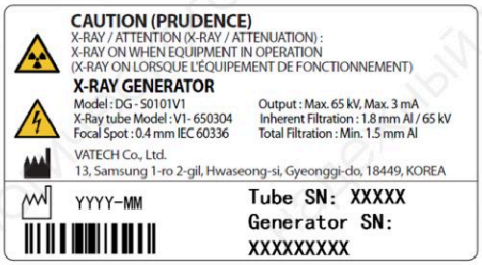
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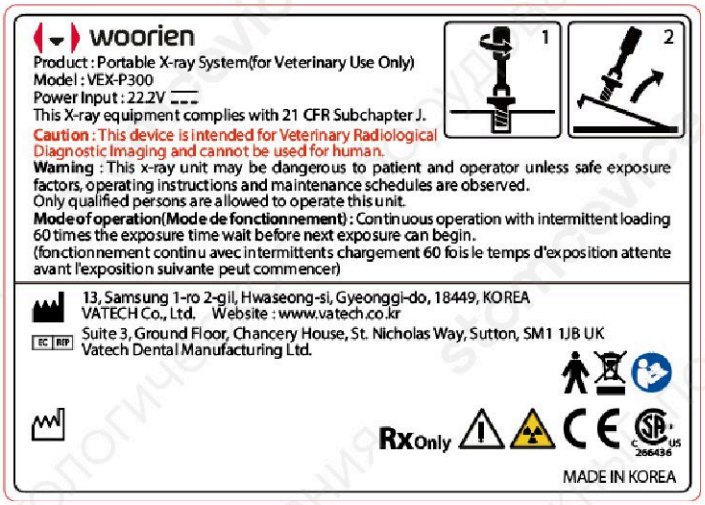
1.4.1 Label Locations



1. Generator Label



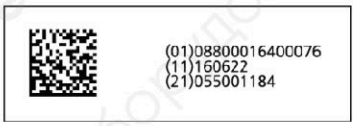
2. Main Label



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3. UDI Label



4. Warning Label



NOTICE	The labels in this manual are only for illustration purposes. Actual labels may differ.

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1.5 Standards and Regulations

Standards:

The **EzRay Air VET™(VEX-P300)** is designed and manufactured to meet the following standards:

- IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-65
- X-RAY EQUIPMENT for DENTAL INTRA-ORAL RADIOGRAPHY VEX-P300 IEC 60601-2-65:2012
- CAN/CSA-C22.2 No. 60601-1:14, CAN/CSA-C22.2 No. 60601-1-3:09, CAN/CSA-C22.2 No. 60601-1-6:11, CAN/CSA-C22.2 No. 60601-2-65:15, CAN/CSA-IEC 62366:14
- ANSI/AAMI ES60601-1:2005 / (R)2012, AND A1:2012, C1:2009 / (R)2012 AND A2:2010 / (R)2012 (Consolidated text - edition 3.1)
- ISO 13485
- 21 CFR 1020.30 & 1020.31

CE **The CE symbol grants this equipment compliance with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.**

Classifications (IEC60601-1 6.1):

Protection against the ingress of water: Ordinary Equipment (IPX0)

Protection against electric shock: Class I equipment, Type B Applied Parts: Cone head



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2. Safety Instructions

2.1 General Safety Guidelines

⚠WARNING	• This equipment is designed and manufactured to ensure maximum safety of operation. Operate and maintain it in strict compliance with the safety precautions and operating instructions contained in this manual. • This equipment must be operated only by legally qualified persons. • Observe all local fire regulations. Always keep a fire extinguisher near the equipment. • The equipment must be installed, maintained, and serviced by qualified service personnel according to the procedures and preventive maintenance schedules. Only battery replacement can be performed by users. • Ensure that the on/off switch is set to off when the equipment is not in use. • Always disconnect the power supply before cleaning the equipment. • DO NOT keep the equipment or its parts in a humid place or a liquid substance. • Avoid placing the equipment near chemical storage and gas-filled storage facilities. • The backscatter shield protects users from backscatter radiation that they might be exposed during X-ray exposure. Operating the equipment with the backscatter shield allows the users to be exposed to less radiation compared to when operating without. For details on the scatter data of the device configured both with, and without the backscatter shield, please review '10.2.3 Scattered Dose'.
IMPORTANT	This equipment is shipped with the backscatter shield attached (firmly fixed), so the backscatter shield cannot be replaced by users. If it is damaged or defective, contact your Service Representative for replacement.
NOTICE	Mode of operation: Continuous operation with intermittent loading—This equipment needs a rest time of at least 30 times the exposure time before starting the next exposure.

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2.2 Warnings and Safety Instructions

WARNING

- This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

  It is important to read this user manual carefully and strictly abide by all warnings and cautions stated within it.
- To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
- Since rules and regulations concerning radiation safety differ between countries, it is the responsibility of the owner and/or operator of this equipment to comply with all applicable rules and regulations concerning radiation safety and protection in their area.
- DO NOT open or remove the cover panels on this equipment.
- Never expose this equipment to liquids, mists or sprays. Exposing this equipment to liquids may cause an electrical shock or otherwise damage the system.
- DO NOT use spray cleaners on this equipment, as this could cause a fire.
- Never use this equipment in an environment that is susceptible to explosion.
- DO NOT place flammable materials near this equipment.
- Never touch the patient while also touching the SIP/SOP connectors.

Medical electrical equipment is subject to special EMC preventive measures. For more details, refer to '10.3 Electromagnetic Compatibility (EMC) Information'.



RADIATION HAZARD

- We recommend that the patient and the operator wear protective lead-lined aprons, unless other Radiation Protection Protocols apply locally.
- Children and pregnant women must consult with a doctor before X-ray exposure.

IMPORTANT

- Never try to modify this equipment, including the wires or cables. Modifying this equipment may damage it beyond repair.
- Serious dangers may occur from electromagnetic interference (i.e. noise) between other equipment in the area during specific examinations or medical treatment.

NOTICE

Battery chargers must be in the accessible area where they can be easily unplugged from the power source.

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Battery Use

⚠WARNING

- Make sure to charge the battery in the external environment from the patient.
- Make sure to use the battery only provided or approved by **Woorien**. If non-standard or damaged batteries are used, there is risk of fire and explosion.
- Make sure to use the battery charger only provided or approved by **Woorien**. Using an unauthorized charger may result in battery damage.
- DO NOT expose batteries to heat or fire. Avoid storage in direct sunlight.
- DO NOT short-circuit, crush, puncture, mutilate, or disassemble the battery.
- DO NOT store batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.
- Observe the plus (+) and minus (-) marks on the battery and equipment and ensure correct use.
- DO NOT subject batteries to mechanical shock.
- In the event of a cell leaking, do not allow the liquid to meet the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- Keep the battery away from Children and pets.
- DO NOT make the battery wet or let it be in water. Keep batteries clean and dry.
- Seek medical advice immediately if a battery has been swallowed.
- Make sure to turn off the device before replacing the battery.

⚠CAUTION

- DO NOT remove a battery from its original packaging until required for use.
- DO NOT dispose of batteries with ordinary trash. Turn in discharged batteries to local supply or discard or recycle batteries according to your local government regulations.

IMPORTANT

- DO NOT leave a battery on prolonged charge when not in use.
- If the equipment has not been used for long periods of time, it is recommended to charge the battery before use.
- After extended periods of storage, it may be necessary to charge and discharge the cells or batteries several times to obtain maximum performance.

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IMPORTANT	If the equipment not in use has been turned on for long periods of time, the battery may be fully discharged. - Depending upon the battery discharge status, it takes about 1 day for charging the battery. If the device is not turned on after charging the battery for about 1 day, it indicates that the battery has been fully discharged. Contact your Service Representative for battery replacement. - DO NOT charge a fully discharged battery, as this may cause fire or explosion. Be sure to replace the battery (provided by **Woorien**).
NOTICE	• Batteries can be replaced by users. • When charging the battery, the exposure function is locked. • Be sure to turn off the equipment when not in use. This helps to ensure the life of the battery. • Be sure to charge the battery frequently. This helps to ensure the life of the battery.

Radiation Safety

⚠WARNING	• This equipment must be operated only by properly trained, fully qualified personnel in a controlled environment. • When using the equipment, it is recommended that all users comply with the following radiation safety guidance for the safety of the users and the patients.
 RADIATION HAZARD	• All users and patients should wear protective equipment, such as a lead apron, thyroid collar, etc. • This equipment should be operated in the area that is more than 6 feet away from other personnel, such as assistants or other patients. If they should stay closer than 6 feet, it is recommended that they wear a lead apron, thyroid collar, or stay behind a lead shield. • Pregnant women should not be exposed to X-rays unless it is strictly necessary. • All users should comply with the Radiation Protection Policies established by the government. • When selecting a Position Indicating Device, it should be considered if the PID can be used with the back-scatter shield attached at the outer end of the cone for maximum operator protection.

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3. System Overview

The **EzRay Air VET™(VEX-P300)**, a portable dental X-ray system, operates on 21.6 V dc. supplied by a rechargeable Li-ion polymer battery pack. The portable X-ray system is an X-ray generating device which is mainly designed for dental examination (teeth and jaw). The portable X-ray system is composed of an X-ray generating part with an X-ray tube including a device controller, a power controller, a user interface, a beam limiting part, a backscatter shield, and an optional Remote Exposure Switch. The **EzRay Air VET™(VEX-P300)** is designed to diagnose teeth and jaw through X-ray exposure using intra-oral image receptors.

3.1 Indications for Use

The **EzRay Air VET™(VEX-P300)** is a portable dental X-ray system intended for use by a trained and qualified dentist or dental technician for both Large and pediatric subjects for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.

3.2 Principles of Operation

X-rays are emitted when high voltage is supplied to the X-ray tube assembly which frees electrons from cathode. They hit anode to produce X-rays. The equipment acquires images by emitting X-rays continuously on human tooth.

3.3 Intended User Profile

Considerations	Requirement Description
Education	Licensed dentist or dental hygiene, Veterinary dentist, radiologist and graduates of relevant bachelor's degree (national qualifications)
Knowledge	The operator must have understood: • treatment and diagnosis of dental disease • terms and guidance of diagnostic medical radiation devices • device connection, installation and operating conditions.
Language understanding	The operator must have understood: • the English or Korean manuals (or other languages provided).
Experience	The operator must have understood: • objectives and effects of treatment and diagnosis of dental disease using diagnostic medical radiation devices • normal operation of diagnostic medical radiation devices • the contents of the user manual.

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3.4 Components

No.	Item	Standard	Option	Qty.
1	**EzRay Air VET™(VEX-P300)** Main Body	●		1
2	Battery Charger (power cord included)	●		1
3	User Manual	●		1
4	Backscatter Shield	●		1
5	Round Cover	●		1
6	Cradle	●		1
7	Rectangular Cover (4x3)	●		1
8	Rectangular Cover (2x3)		●	1
9	Remote Exposure Switch		●	1
10	Base Holder		●	1
11	Hand/Neck Strap		●	1
12	Rotating Rectangular Cover (4x3)		•	1
13	Rotating Rectangular Cover (2x3)		•	1

3.5 Features

The **EzRay Air VET™(VEX-P300)** is an intra-oral portable X-ray system that offers safety, reliability, and greater functionality:

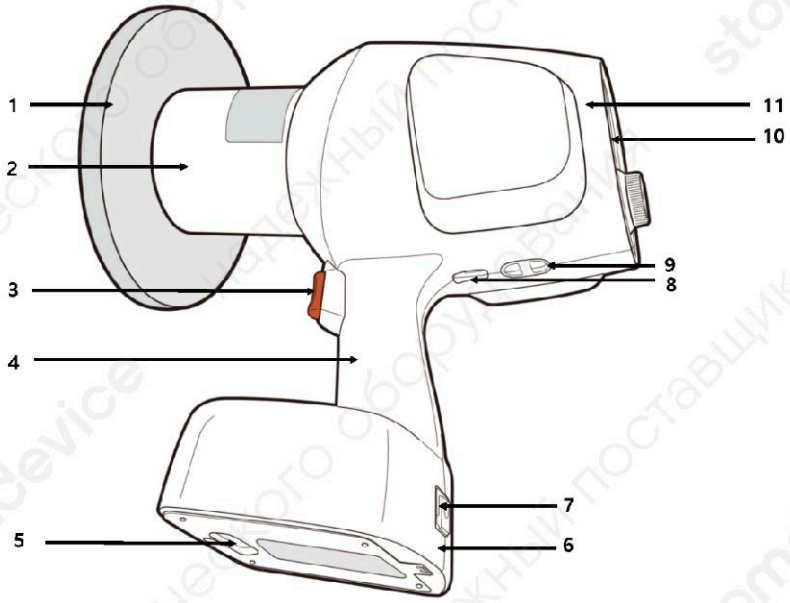
- Lightweight and ergonomic design
- Convenience of cordless design by using battery-pack
- Micro-computer and specialized circuit that monitors and precisely regulates the exposure technique factors (kV, mA, and exposure time)
- Pre-programmed exposure time makes the operation fast and easy.

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3.6 General View of the Equipment

Main Body

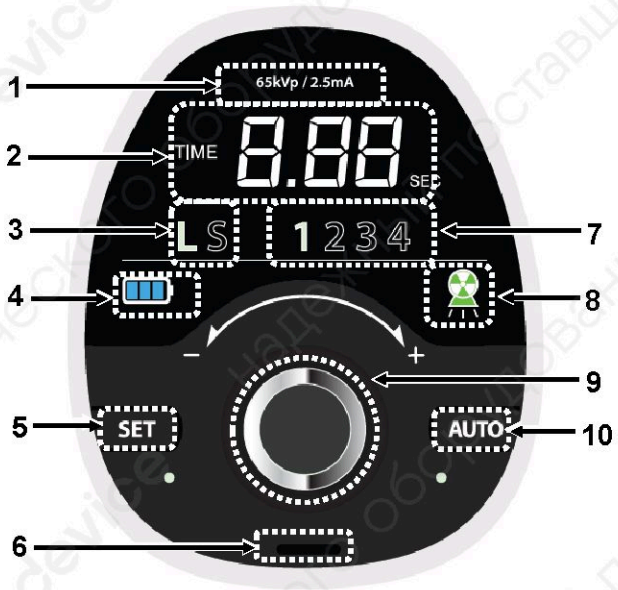


No.	Item	Description
1	Backscatter Shield	Shields from the back-scattering radiation.
2	X-ray Beam Limiting Device	Limits the X-ray exposure area. Default type: Round Cone + Round Cover (FOV: Ø 6 cm)
3	X-ray Exposure Button	Press the button for X-ray exposure.
4	Handle	Grip the handle securely when using the system.
5	Power Button	Power On/Off button
6	Battery	Rechargeable Lithium ion battery
7	Adaptor Connector	Connect the charging adaptor.
8	Remote X-ray Exposure Switch Port	Connect the X-ray exposure cable switch. Or can be used as a service port
9	Strap Loop	Connect the strap.
10	Control Panel	Display for the X-ray exposure settings and operation conditions
11	X-ray Generator	Includes the X-ray tube and the high-voltage generator.

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Control Panel



No.	Item		Description
1	65kVp / 2.5mA	Tube Voltage/Current Indicator	Indicates the tube voltage and tube current of the system.
2	8.88	Angle/Time Display	Displays the X-ray exposure time, error code, cooling time and exposure angle.
3	L S	Large/Small Selection	Indicates a patient type (Large or small).
4		Remaining Battery Indicator	Indicates remaining battery level.
		Battery Charging Indicator	1) Indicates the battery charger is connected to the device. 2) Indicates the battery needs to be charged **when it flickers**.
5	SET	SET Button	Resets the X-ray exposure angle.
6		Speaker	Sound alarm for the X-ray exposure
7	1 2 3 4	Tooth Type Selection	Selects the tooth type.

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No.	Item		Description
8		X-ray Exposure Indicator	Indicates the X-ray exposure status. (Green: Ready / Yellow: X-ray On)
9		Jog Dial	Turn the jog dial left (-) or right (+) to select an X-ray exposure setting, press the jog dial to confirm the operating setting.
10		AUTO Button	Selects a tooth and exposure time automatically based on the X-ray exposure angle.

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Available Option Items

No.	Figure	Option name
1		Rectangular Cover 2x3 (3x2) FOV: 2x3 cm, 3x2 cm (This cover can be used as both 2x3 and 3x2.)
2		Remote Exposure Switch
3		Rotating Rectangular Cover 4x3 (3x4) FOV: 4x3cm, 3x4cm (This adaptor can be used as both 4x3 and 3x4.)
4		Rotating Rectangular Cover 2x3 (3x2) FOV: 2x3cm, 3x2cm (This adaptor can be used as both 2x3 and 3x2.)
5		Base Holder*

*** In case a tripod is used with the Base Holder, refer to the specifications below.**

- Fixing bolt size: 3/8 inch
- Maximum supportable weight: about 5 kg
- Minimum height: > 130 cm
- More than 3 columns are required.
- When using a tripod with 3 columns, make sure to have space of at least 1 min width on the bottom.

NOTICE

Refer to the **Appendix 10.2 Using the Rotating Rectangular Cover** for instructions for use.

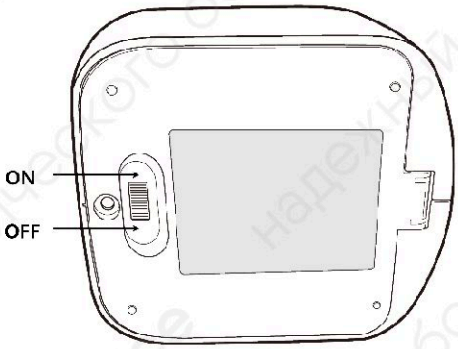
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4. Operation

4.1 Power On/Off

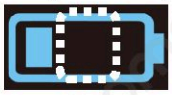
1. Turn on the system referring to the following figure.



2. The following displays and indicators light up:
   - Current Angle/Time display
   - Tooth type selection display
   - Large/Small selection display
   - Remaining battery indicator
   - X-ray exposure indicator
3. Make sure that at least one battery indicator light comes on.



Battery level 1

NOTICE	When the battery indicator has one flickering light, charge the battery immediately by using the battery charger.  For more information, refer to '**4.5 Remote Exposure Switch**".

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4.2 Operation Mode

This system can be operated with Manual Mode and Auto Mode, and you can set up the mode by using the **AUTO** button.

Manual Mode

1. To start the Manual Mode, check if the lamp under the **AUTO** button is turned off.



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2. When the tooth type selection area flickers, turn the jog dial to select the tooth type. To see the Control Panel before and after selection, refer to the figures below.

Before tooth type selection **After tooth type selection**



Tooth Type

Symbol	Type
1	Incisor
2	Canine
3	Premolar
4	Molar

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3. After tooth type selection, a patient type should be selected. When the Large/Small selection area flickers, turn the jog dial to select the patient type. To see the Control Panel after selection, refer to the figure below.

After patient type selection



Patient Type

Symbol	Type
L	Large 10~25kg
S	Small <10kg

NOTICE	After the tooth type and patient type are selected, exposure time is automatically displayed.

4. If you want to change the exposure time, turn the jog dial to adjust the exposure time from 0.05 to 1.0 s. (increments: 0.01 s)

NOTICE	If you press the jog dial after adjusting the exposure time in Manual Mode, the exposure time is returned to the default setting. To save the exposure time as default in Manual Mode, press and hold the jog dial for about 3 seconds.

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Auto Mode

1. When the Auto Mode is turned on by pressing **AUTO**, the default angle is displayed as shown in the following figure.



NOTICE	To set the starting point (0°) during exposure, press **SET**.

2. Select the patient type by turning the jog dial.
3. Perform patient positioning, and press **SET**.

   To check how to perform patient positioning, refer to '4.3 Positioning'.

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When tooth types are selected, the exposure angles are automatically displayed according to canine's tooth type. To check the default exposure angles, refer to the following table.

Exposure time is automatically set according to the Canine's tooth type.

Tooth type	Angle of inclination
Incisor (Occlusal View)	Maxilla: +50° ~ +60°
	Mandible: +60° ~ +70°
Canine (Lateral View)	Maxilla: +60° ~ +70°
	Mandible: +60° ~ -+70°
Premolar (Rostral View)	Maxilla: +35° ~ +45°
	Mandible: +40° ~ +50°
Molar (Caudal View)	+50° ~ +60°
	0° ~ +5°

NOTICE

Refer to the following figure to see the angle for olar/premolar.



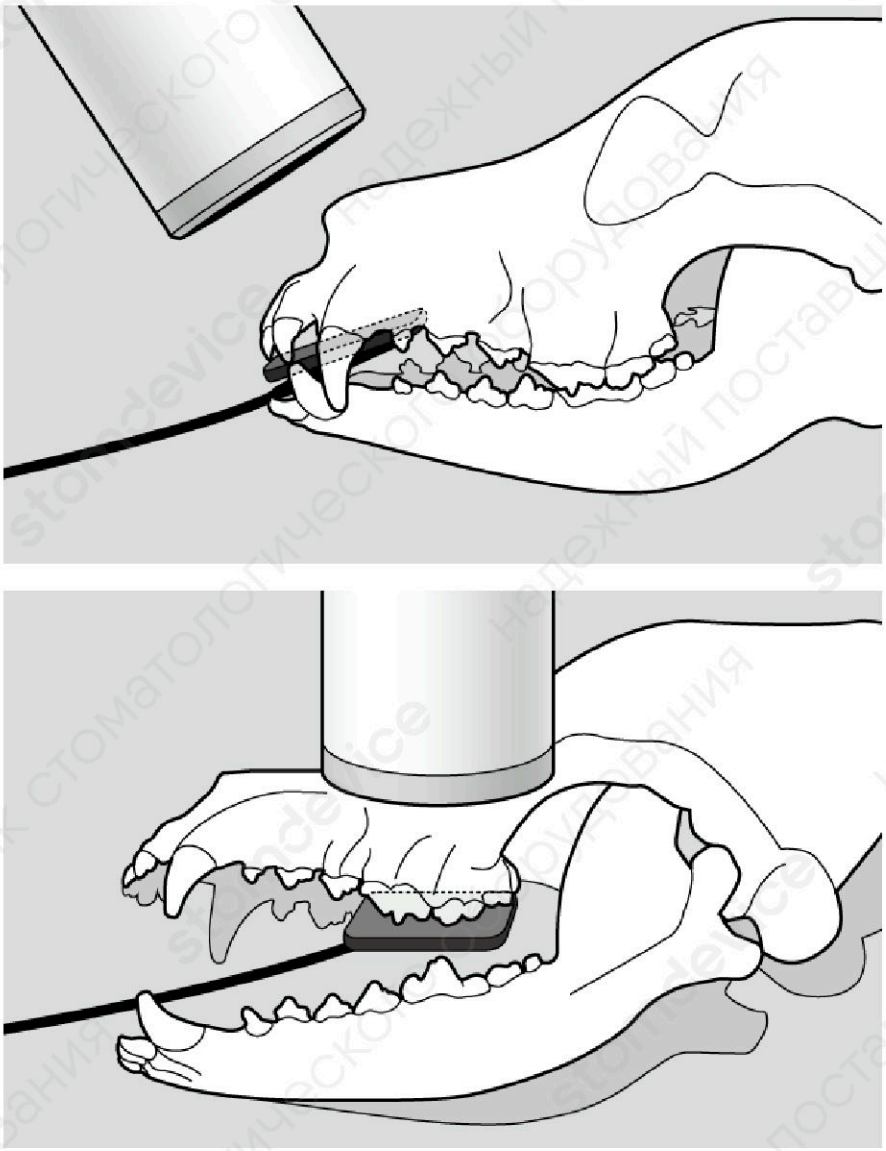
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4.3 Positioning

Positioning the Patient

To obtain high-quality intra-oral radiography with maximum details, take extra care in all steps of the radiography process: positioning the patient and the X-ray imaging system; exposing the intra-oral sensor.



Place the tube head cone on the area need to take an image.

When hold the device, it is recommended to grip the handle by one hand and place the other on the underside between the Exposure Button and the cone.

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NOTICE	Depending on the imaging angles, exposure times vary. Since it is necessary to keep the patient with low X-ray doses and the user in the protected area, have the patient's head slightly tilted, and raise or lower the chin if needed. Please refer to '2.2 Warnings and Safety Instructions'.

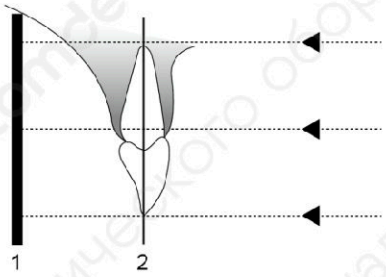
For further information about the patient positioning and beam angle for each mode, refer to the following **Positioning Instructions**.

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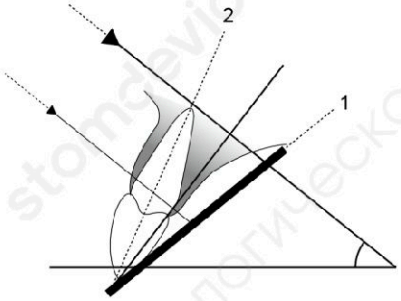
Positioning Instructions

Paralleling technique: The sensor is placed in a holder which is used to align the sensor parallel to the long axis of the teeth.



1. Sensor
2. Long axis of the tooth

Bisected angle technique: The patient holds the sensor in place with his/her finger. The X-ray beam is directed perpendicularly towards an imaginary line, which bisects the angle between the sensor plane and the long axis of the tooth.



1. Sensor
2. Long axis of the tooth

Position the tube head to the patient using the accepted standard positioning procedures.

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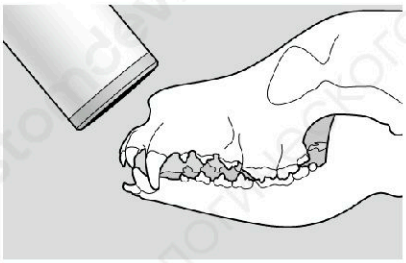
Here are the specific angulations and directions for the tube head to take the best images of a tooth (i.e. **Bisected angle technique**).

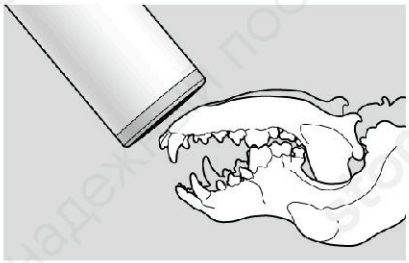
⚠CAUTION	Position the receptor carefully not to damage the soft tissue of the patient's intra-oral area.

- **Maxillary / Mandibular Incisor – Occlusal View**

1. X-ray beam is directed downward at 60° for the maxillary occlusal view2. X-ray beam is directed downward at 45° for the mandibular occlusal view

Teeth		Angle of inclination
Incisor	Maxilla	+60°
	Mandible	+45°





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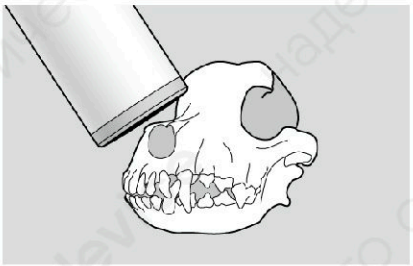
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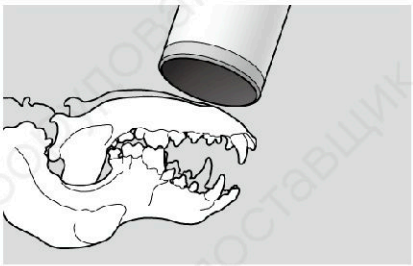
Maxillary / Mandibular Canine – Lateral View

1. X-ray beam is directed downward at 70° for the maxillary lateral view

2. X-ray beam is directed downward at 70° for the mandibular lateral view

Teeth		Angle of inclination
Canine	Maxilla	+70°
	Mandible	+70 °





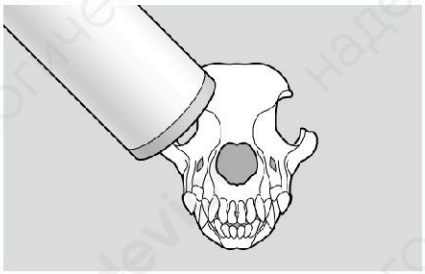
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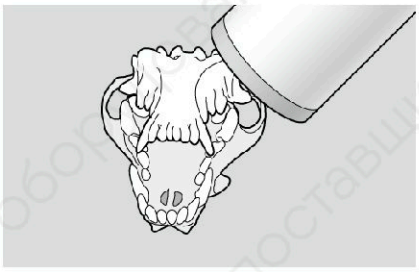
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- **Maxillary / Mandibular Pre-Molar – Rostral View**

1. X-ray beam is directed downward at 45° for the maxillary rostral view
2. X-ray beam is directed downward at 50° for the mandibular rostral view

Teeth		Angle of inclination
Pre-molar	Maxilla	+45°
	Mandible	+50°





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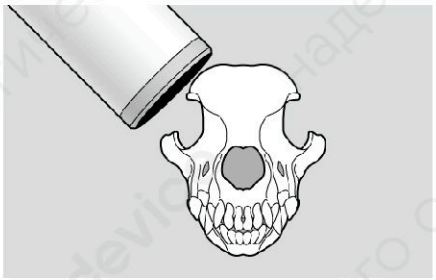
stomdevice

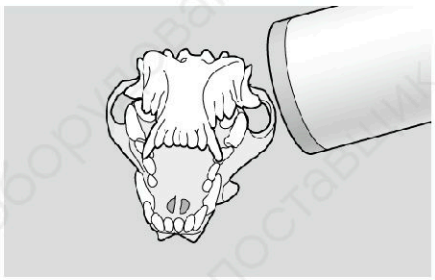
Maxillary / Mandibular Molar – Occlusal View

1. X-ray beam is directed downward at 60° for the maxillary occlusal view

2. X-ray beam is directed downward at 5° for the mandibular occlusal view

Teeth		Angle of inclination
Moral	Maxilla	+60°
	Mandible	+5 °





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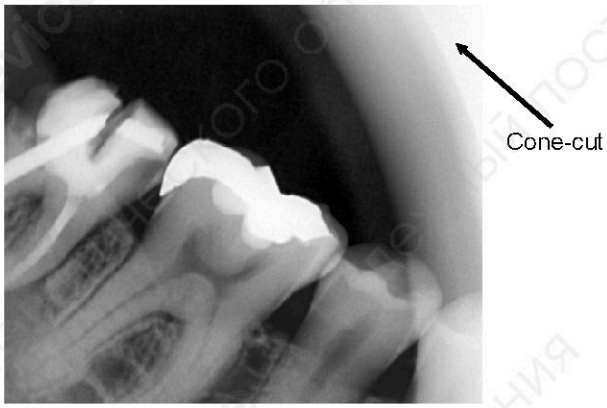
Positioning the Imaging Sensor

To ensure image quality, the digital imaging sensor must be positioned properly (for information about the proper placement of the imaging sensor, please refer to 'Positioning Instructions'.

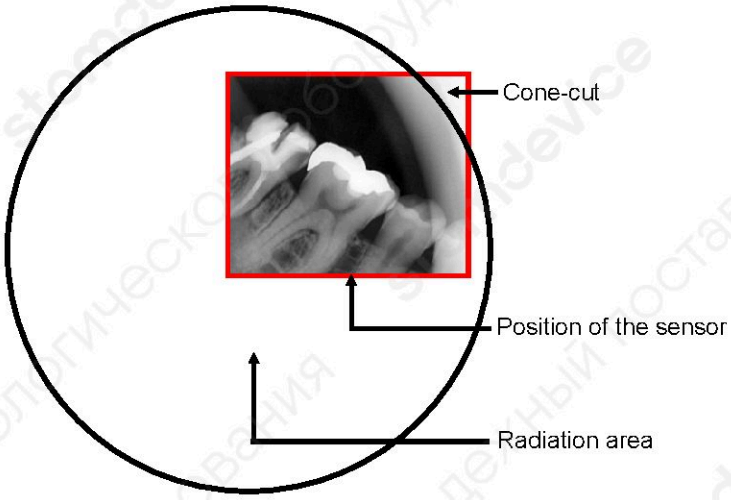
- Failure to position the imaging sensor properly can result in errors on the radiograph, such as distorted teeth and roots, elongation, magnification, and overlapping contacts.

NOTICE	The paralleling technique generally reduces the risk of such errors, but if you position the sensor improperly, angulation errors may occur (angulation of the sensor to the tooth itself).

- Failure to align the imaging sensor with the exit pattern of the X-ray beam can result in cone-cuts on the radiograph. The cone-cuts are clear areas that are shown on the radiograph when part of the radiograph is not exposed to radiation. Please refer to the following figure as an example of cone-cuts.



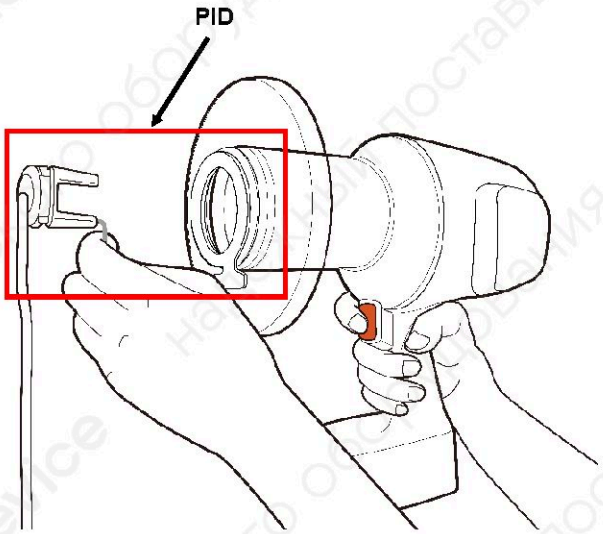
The following figure indicates how the cone-cut occurred by showing the position of the imaging sensor and the radiation area.



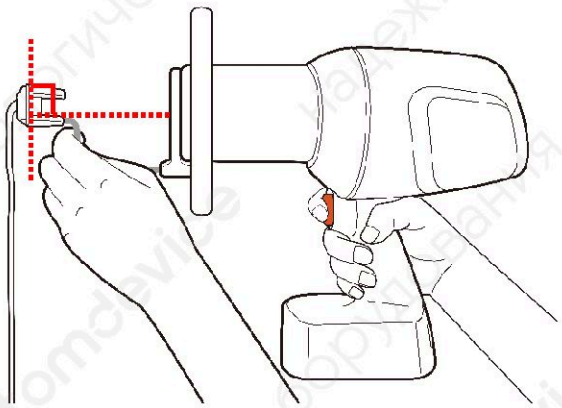
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To ensure proper alignment between the imaging sensor and the X-ray beam, it is recommended to use a PID (Position Indicating Device) as shown in the following figure.



When using the PID, the exit pattern of the X-ray device should be aligned perpendicular to the target receptor as shown in the following figure.



NOTICE	Once the PID is properly aligned, instruct the patient not to move.

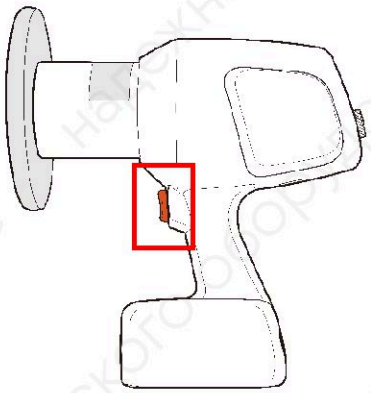
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4.4 Exposure

IMPORTANT	The operator **MUST** instruct the patient to refrain from moving during the entire exposure.

1. Instruct the patient not to move.
2. Press the Exposure Button for exposure duration.



3. While X-ray is being exposed,
   - The X-ray Exposure Indicator lights up and an audible sound is produced.
   - Keep pressing until the X-ray Exposure Indicator light goes out and the audible sound stops.

	
Green: Ready	**Yellow**: X-ray On

IMPORTANT	Hold the Exposure Button or switch if the acoustic signal can be heard. Otherwise the exposure will be faulty and there will be an error message on the Control Panel.

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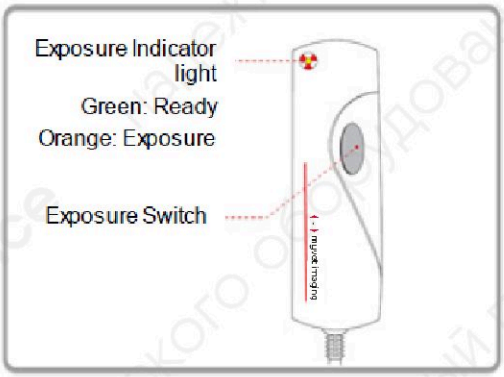
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4.4.1 Remote Exposure Switch

The **Remote Exposure Switch** allows the operator to control image acquisition from outside of the X-ray room.

Press and hold the **Remote Exposure Switch** until acquisition is completed. Premature release of the **Remote Exposure Switch** will abort image acquisition.

Pressing the **Remote Exposure Switch** activates the X-ray Exposure Indicator to turn yellow. This color indicates that the X-ray is being emitted.



IMPORTANT	The **Remote Exposure Switch** is detachable. Ensure that the **Remote Exposure Switch** cable is not detached out from the unit accidentally during the operation.
IMPORTANT	Keep vocal/visual contact with the patient during exposure. If any problem occurs during exposure, release the **Remote Exposure Switch** immediately.

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4.5 Using the Battery

Battery level indicator with residual quantity is shown on the left side of the Control Panel. When the battery indicator has one flickering light (level 1), charge the battery immediately. Refer to the battery levels as shown below.



Level 3 **Level 2** **Level 1**

If the battery is not charged for about an hour, the battery voltage becomes low. At this level, all displays are turned off except for the error code **E.10** as shown in the following figure, so exposure cannot be performed. After the device is connected to the battery charger, and the battery level becomes 'Level 1', all functions are returned to normal operation.

IMPORTANT



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System Status depending on Battery Levels

Item		System Status			
		Battery Level 3, 2	Battery Level 1		Low Battery
When turning on the system	Operation	Normal	Normal	Normal	Not operated
	Battery Level Indicator	Normal	Normal	Flickers	Not displayed
	Battery Charging Indicator	Not displayed	Not displayed	Flickers	Not displayed
	Control Panel Brightness	Normal	Normal	Dark	Normal (Error code **E.10** is only displayed)
When operating the system	Operation	Normal	Normal	Normal	Not operated
	Battery Level Indicator	Normal	Normal	Flickers	Not displayed
	Battery Charging Indicator	Not displayed	Not displayed	Flickers	Not displayed
	Control Panel Brightness	Normal	Normal	Normal	Normal (Error code **E.10** is only displayed)

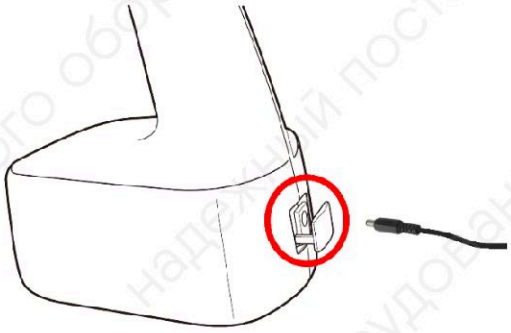
⚠CAUTION	Make sure to charge the battery if the Battery Charging Indicator flickers (or the error code E.10 is displayed). If the device has been turned on for long periods of time with the error code E.10, the battery may be discharged.
⚠CAUTION	DO NOT charge a fully discharged battery, as this may cause fire or explosion. Be sure to replace the battery (provided by **Woorien**).
NOTICE	When the device is connected to the battery charger, the Battery Charging Indicator is displayed always except that the battery is fully discharged.

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Charging the Battery

1. Connect the battery charger to the battery charger connector as shown in the following figure.



2. When the battery charger is connected, the battery charging LED indicator light comes on. Charge the battery until all the three LED indicators are filled up.



NOTICE	Usually it takes about 3 hours to fully charge the battery after complete discharge.

3. When the battery charge is completed, remove the battery charger from the device.

NOTICE	You cannot perform an exposure while the battery charger is connected to the device.

Battery Use Cycle

Battery is a consumable part. It is expected to degrade gradually, so it should be recharged more frequently. When the battery duration decreases to half or less than half compared to when the battery was new, contact your Service Representative to get a new battery.

To check how to replace the battery, see 'Battery Replacement'.

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Battery Replacement

NOTICE	Batteries can be replaced by users. To replace the battery, contact your Service Representative to get a battery kit (including a new battery and a torx wrench).

1. Manpower

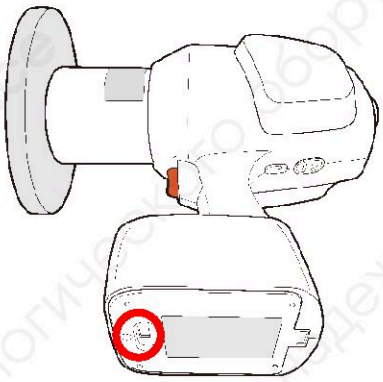
   One person, 3 minutes

2. Tools required

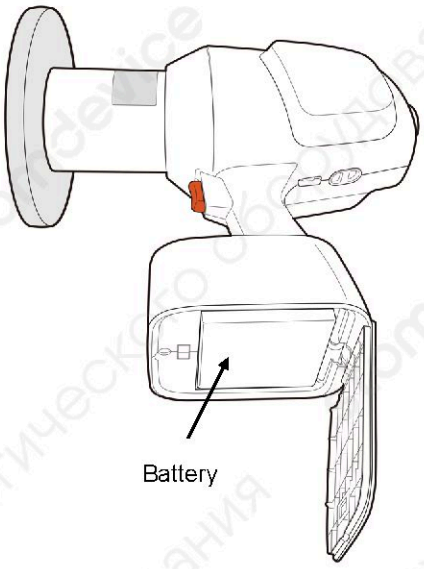
   Torx wrench (size: T20)

3. Removal Procedure

   1) Using a torx wrench, unscrew the battery bay access door.



   2) Lift the door and remove the battery.



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3) Disconnect the battery cable from the device by pressing the battery cable connector as shown in the following figure.



⚠CAUTION	DO NOT pull excessively on the battery cable.

4) Install the new battery in the reverse order of removal.

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Sleep Mode

To reduce battery consumption, the Sleep Mode is started when the system is not in use for one minute. (To see how to change the default waiting time for the Sleep Mode, see 'Waiting Time Setting for the Sleep Mode'.)

1. When the Sleep Mode is started, the Control Panel becomes dark as shown in the following figure (right).



Brightness: Normal **Brightness: Dark**

2. To return to normal operation, move the system or press any button (except for the X-ray Exposure Button).
3. If you do not use the system, turn it off to reduce battery consumption.

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Power Off Mode

If the system (not in use) has been turned on for 30 minutes since the Sleep Mode was started, the Power Off Mode is started.

1. 'Off' is flickering on the Control Panel. If you need to be notified by an alarm when the Power Off Mode is started, change the setting referring to 'Buzzer On/Off'.



2. To return to normal operation, move the system or press any button (except for the X-ray Exposure Button).
3. If you do not use the system, turn it off to reduce battery consumption.

Power Save Mode

If the system (not in use) has been turned on for 4 hours since the Power Off Mode was started, the Power Save Mode is started.

1. All displays are turned off on the Control Panel.
2. To return to normal operation in the Power Save Mode, you **MUST** turn off the system and turn it back on.



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5. Service Mode

5.1 Overview

In the Service Mode, you can view and change the following settings.

- Factory Default Settings (See '5.3.1 Factory Default Settings'.)
- Exposure Time Settings (for each patient and tooth type) (See '5.3.2 Exposure Time Settings (for each patient and tooth type)'.)
- User Default Settings (for each patient and tooth type) (See '5.3.3 User Default Settings (for each patient and tooth type)'.)
- Password Mode On/Off (See '5.3.4 Password Mode On/Off.)
- Angle Increments Setting (See '5.3.5 Angle Increments Setting'.)
- Waiting Time Setting for the Sleep Mode (See '5.3.6 Waiting Time Setting for the Sleep Mode'.)
- Waiting Time Setting for the Power Off Mode (See '5.3.7 Waiting Time Setting for the Power Off Mode'.)
- Waiting Time Setting for the Power Save Mode (See '5.3.8 Waiting Time Setting for the Power Save Mode'.)
- Buzzer On/Off (See '5.3.9 Buzzer On/Off'.)
- Power Off Mode On/Off (See '5.3.10 Power Off Mode On/Off'.)
- Password Setting (See '5.3.11 Password Setting'.)

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5.2 Changing System Parameters

To change system parameters:

1. Press and hold the **SET button** and **jog dial** at the same time (for about 3 seconds).



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2. Enter the 3 digit numeric password using the jog dial. (default password: 000)



3. Press the jog dial to enter the next digit then press and hold the jog dial.



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4. After entering the password is completed, the Service Mode is started as shown in the following figure.



5. There are a total of 24 modes. To select the first mode, press **AUTO** as shown on the left, then the Service Mode number **n.01** is displayed on the Control Panel as shown on the right.



6. Turn the jog dial to select the Service Mode number that has information you want to change. To see the functions of each Service Mode menu, refer to '5.3 Service Mode Menu'.
7. To save the changes, press and hold the jog dial for about 3 seconds.
8. After saving the changes, press and hold the **SET button** and **jog dial** at the same time (for about 3 seconds) to return to radiography.

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5.3 Service Mode Menu

Perform the Service Modes described in this section referring to '5.2 Changing System Parameters'.

5.3.1 Factory Default Settings

Perform this mode to restore the system to the factory default settings (it initializes all the parameters except for **n.24**).

Service Mode No.	Item
n.01	Factory default settings

To restore the system to the factory default settings,

1. Select **n.01** by pressing the jog dial, then **"YES"** is displayed on the Control Panel. It restores the system to the factory default.



2. Save the setting, and check if the system is restored to the factory default.

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5.3.2 Exposure Time Settings (for each patient and tooth type)

Perform each mode to set the exposure time for each patient and tooth type referring to the table below.

Service Mode No.	Item
n.02	Large Incisor
n.03	Large Canine
n.04	Large Premolar
n.05	Large Molar
n.06	Small Incisor
n.07	Small Canine
n.08	Small Premolar
n.09	Small Molar

To set the exposure time for a specific patient and tooth type as described above,

1. Select the Service Mode number according to the patient and tooth type you need to take an image. (i.e. **n.06** for Small Incisor)



2. After entering the mode, turn the jog dial to adjust the exposure time you want.
3. Save the exposure time, and check if it has been correctly saved.

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5.3.3 User Default Settings (for each patient and tooth type)

Perform each mode to set the default settings for a specific patient and a tooth type referring to the table below.

Service Mode No.	Item
n.10	Large
n.11	Small
n.12	Incisor
n.13	Canine
n.14	Premolar
n.15	Molar

To set the default setting for a specific patient type and a tooth type,

1. Select the Service Mode number between **n.10** (Large) and **n.11** (Small) for a specific patient type, and from **n.12** to **n.15** for a tooth type. For instance, if you select **n.10** by pressing the jog dial to set the patient type 'Large' as default, then **"YES"** is displayed on the Control Panel.



2. Save the setting, and check if the patient type 'Large' has been saved as default.
3. If you want to perform other settings, follow the same procedure.

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5.3.4 Password Mode On/Off

Perform this mode to turn on/off the password mode.

Service Mode No.	Item
n.16	Password On
n.17	Password Off

To turn on the password mode,

1. Select **n.16** by pressing the jog dial, then **"YES"** is displayed on the Control Panel.



2. Save the setting, and check if the system requires a password when turning on the system.

To turn off the password mode, select **n.17** and follow the same procedure as described above.

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5.3.5 Angle Increments Setting

Perform this mode to set the angle increments when using the **Auto Mode**.

Service Mode No.	Item
n.18	Angle increments setting

When using the Auto Mode, the angle value increases and decreases according to the increments setting (default: 1 degree).

The angle increments can be set **from 1 to 5 degrees**.

To change the angle increments setting,

1. Select **n.18** by pressing the jog dial, then the default angle increments **"001°"** is displayed on the Control Panel as shown in the following figure.



2. Turn the jog dial to adjust the angle increments you want and save the setting.
3. Check if it has been correctly saved.

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5.3.6 Waiting Time Setting for the Sleep Mode

Perform this mode to set up the waiting time that takes before the Sleep Mode is started. (default: 1 minute)

Service Mode No.	Item
n.19	Waiting time setting for the Sleep Mode

To change the waiting time for the Sleep Mode,

1. Select **n.19** by pressing the jog dial, then the default time **"001"** (1 minute) is displayed on the Control Panel as shown in the following figure (right).



2. The waiting time can be modified **from 1 to 999 minutes**.

   Turn the jog dial to set the time, and save the setting.

3. Check if it has been correctly saved.

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5.3.7 Waiting Time Setting for the Power Off Mode

Perform this mode to set up the waiting time for the Power Off Mode. (default: 30 minutes)

Service Mode No.	Item
n.20	Waiting time setting for the Power Off Mode

To change the waiting time for the Power Off Mode,

1. Select **n.20** by pressing the jog dial, then the default time **"030"** (30 minutes) is displayed on the Control Panel as shown in the following figure (right).



2. The waiting time can be modified **from 1 to 999 minutes**.
   Turn the jog dial to set the time, and save the setting.
3. Check if it has been correctly saved.

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5.3.8 Waiting Time Setting for the Power Save Mode

Perform this mode to set up the waiting time for the Power Save Mode. (default: 4 hours)

Service Mode No.	Item
n.21	Waiting time setting for the Power Save Mode

To change the waiting time for the Power Save Mode,

1. Select **n.21** by pressing the jog dial, then the default time **"240"** (240 minutes) is displayed on the Control Panel as shown in the following figure (right).



2. The waiting time can be modified **from 1 to 999 minutes**.

   Turn the jog dial to set the time, and save the setting.

3. Check if it has been correctly saved.

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5.3.9 Buzzer On/Off

Perform this mode to turn On/Off the buzzer. In case of 'buzzer On', there are three options: battery level 1 (flickering) warning only, Power Off Mode warning only, or both. (For details about battery levels, see '4.4.1Remote Exposure Switch'.

Service Mode No.	Item
n.22	Buzzer On/Off

To change the buzzer On/Off setting,

1. Select **n.22** by pressing the jog dial, then the default setting **"000"** (buzzer Off) is displayed on the Control Panel as shown in the following figure (right).



2. Turn the jog dial to select an option out of the four options as described below.

- "000" = Buzzer Off (default)
- "001" = Buzzer On for battery level 1 (flickering) warning only
- "002" = Buzzer On for Power Off Mode warning only
- "003" = Buzzer On for both

3. Save the setting, and check if it has been correctly saved.

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5.3.10 Power Off Mode On/Off

Perform this mode to turn on/off the Power Off Mode.

Service Mode No.	Item
n.23	Power Off Mode On/Off

To change the Power Off Mode On/Off setting,

1. Select **n.23** by pressing the jog dial, then the default setting **"001"** is displayed on the Control Panel. (**"001"** = On, **"000"** = Off)



2. To turn off the Power Off Mode, change the setting from **"001"** to **"000"** by turning the jog dial.



3. Save the setting, and check if it has been correctly saved.
4. To turn on the Power Off Mode again, follow the same procedure as described above.

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5.3.11 Password Setting

Perform this mode to change the password.

Service Mode No.	Item
n.24	Password setting

To change the password,

1. Select **n.24** by pressing the jog dial, then the default password **"000"** is displayed on the Control Panel as shown in the following figure (right).



2. When the first digit flashes, turn the jog dial to change the password, and then save it by pressing the jog dial.
3. Follow the same procedure for the next two digits.
4. Check if the new password has been correctly saved.

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6. Troubleshooting

In instances of abnormal operation, error messages will be displayed on the Control Panel. If a problem persists, please request assistance from the customer support information services.

Alarm/Error Messages

NOTICE

A.0X: A problem occurred, and the system performs the correction automatically. This alarm clears after the correction is completed.

E.0X: An error occurred. Turn the power off, and then turn it back on. If the error persists, contact your Service Representative.

Error Code	Check Parameter	Description
E.02	X-ray Generator	Error related to X-ray exposure is not possible to exposure X-ray in the state while "E.02", "E.03", "E.04", "E.05" where power is maintained. After X-ray exposure related error occurs, when the device is turned off and turned on, X-ray exposure is usually performed.
E.03		
E.04		
E.05		
A.06		Appears when the system needs cooling time due to continuous operation. This alarm clears when the system temperature goes down to normal.
A.07	System	Appears when the Remote Exposure Switch has been held down. Release the switch.
A.08	User	Appears when the exposure button has been pressed and released before the X-ray exposure finished with the default exposure time. Press and hold the exposure button for the duration of the exposure time.
A.09	Battery	Appears when the battery voltage is higher than the reference value. Check the battery.
A.10		Appears when the battery voltage is lower than the reference value during X-ray exposure. Charge the battery.
A.11		Appears when the battery is being charged. Operate the system after disconnecting the battery charger from the system.
E.12		Appears when the battery level is below the reference value during X-ray exposure.

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Troubleshooting

Problem	Cause	Solution
Equipment is not turned on.	Power switch is not turned on properly.	Turn the equipment power switch off and turn it back on.
	Battery discharged	Recheck after charging the battery with a charger.
	Battery cable is not properly connected.	Contact your Service Representative.
	Defective battery	Contact your Service Representative.
Control Panel is not turned on.	Defective main board	Contact your Service Representative.
	Internal cable disconnected	Contact your Service Representative.
No X-ray emission	Generator is cooling.	Wait for the cooling time (refer to 'Duty Cycle').
	Defective Remote Exposure Switch	Contact your Service Representative.
	Internal cable disconnected	Contact your Service Representative.
	Defective generator	Contact your Service Representative.
	Tube lifecycle termination	Contact your Service Representative.
X-ray emission works, but exposure is too light or completely white.	Equipment has been positioned incorrectly.	Adjust the position of the equipment.
	Exposure time is too long.	Decrease the exposure time.
	Receptor is facing the wrong way.	Reposition the receptor.
X-ray emission works, but exposure is too dark.	Exposure time is too short.	Increase the exposure time.

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7. Cleaning and Maintenance

7.1 Cleaning

WARNING	Before cleaning the equipment, make sure to turn off the equipment.

- The equipment surfaces can be cleaned with a soft cloth damped in an alcohol-based, non-corrosive cleaning solution. If necessary, wipe off surfaces with disinfectant.
- If necessary, wipe off surfaces with disinfectant.

CAUTION	When cleaning the surfaces, make sure that the equipment is not connected to the battery charger.

CAUTION	• DO NOT expose the equipment to any liquids. • DO NOT use spray cleaner or disinfectant directly into the equipment as this could cause a fire.

NOTICE	The soft cloth should be damp, but not dripping wet.

NOTICE	The cloths or wipes cannot be re-used.

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7.2 Maintenance

Woorien requires periodic constancy tests to ensure image quality and the safety for the patient and operator.

Only **Woorien** authorized technicians can perform inspection and service of this equipment. For the technical assistance, contact **Woorien** service center or your local **Woorien** representative.

Cautions and Notes

⚠CAUTION	DO NOT keep the equipment or its parts in a humid place or near a liquid substance.
⚠CAUTION	Avoid placing the equipment near chemical storage and gas-filled storage facilities.
NOTICE	When the equipment is not in use for a long time, fully charge the battery and remove it from the device before storage.

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7.2.1 Maintenance Task Checklist

⚠WARNING	Always turn off the equipment before performing any maintenance.

Tasks	Period
Before operation, ensure that the equipment is clean and ready for use.	Daily
After using the equipment, make sure that the equipment has been turned off.	Daily
Wipe the outer covers of the equipment with a dry cloth at the end of each day's operation. **⚠WARNING DO NOT use detergents or solvents to clean the outer covers of the equipment.**	Daily
Ensure that the signal is audible, and the X-ray emission light is visible when you make an exposure.	Daily
Ensure that the yellow (exposure) indicator light turns on when the Exposure Button is pressed.	Daily
Ensure that the battery charging LED indicator comes on when charging the battery.	Daily
Ensure that the battery level indicator displays at least two levels (Battery Level 2). For more information on the battery levels, see '4.5 Using the Battery'.	Daily
Ensure that all visible labels are intact and legible.	Monthly

⚠CAUTION	If any defects are found, do not operate the equipment since it has to be handled by a qualified person. Contact your Service Representative.

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8. Disposing of the Unit

To reduce environmental contamination, this equipment is designed to be as safe as possible to use and dispose of. Many components of this equipment are environment-friendly and can be recycled.

All parts and components that contain hazardous materials must be disposed of in accordance with disposal regulations. (IEC 60601-1 6.8.2 j)

Part	Material	Recyclable	Waste Disposal Site	Hazardous waste; Needs Separate Collection
Covers	Plastics	●		
Boards		●		
Cables and transformer	Copper	●		
Packing	Polystyrene	●		
	Cardboard	●		
	Paper	●		
X-ray tube				●
Battery				●
Other parts			●	

IMPORTANT Observe all regulations relevant to the disposal of waste in your country.



This symbol on the equipment and/or accompanying documents means that used electrical and electronic equipment (WEEE) should not be mixed with general household waste.

For professional users in the European Union:

If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.

For disposal in countries outside of the European Union:

This symbol is only valid in the European Union (EU). If you wish to discard this equipment, please contact your local authorities or dealer and ask for the correct disposal method.

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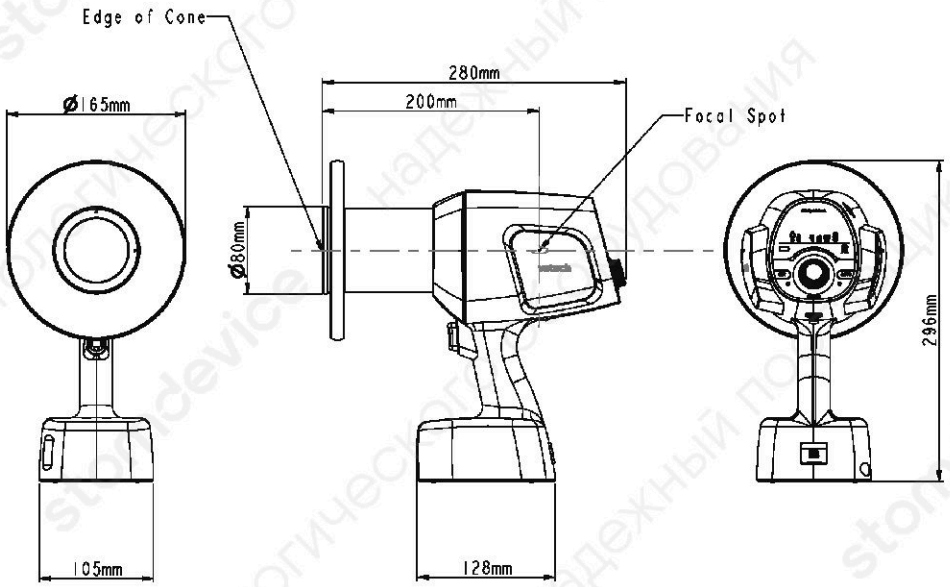
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9. Equipment Specifications

9.1 Mechanical Specifications

Dimensions



Item			Description
Main Body	Dimension (mm)		280(L) x 296(H) x ø 165
	Weight (kg)		2.14 (± 10 %)
X-ray Beam Limiting Device	X-ray Beam Area (mm)	FOV: < ø 60	FOV: < ø 60
		FOV: 20 x 30, 40 x 30	FOV: 20 x 30, 40 x 30
	SSD (Source to Skin Distance) (mm)		200

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9.2 Technical Specifications

X-ray Generator

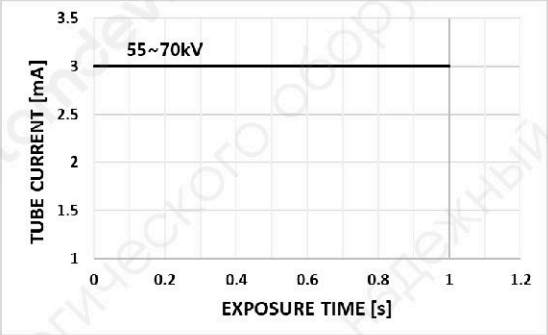
Item		Description
High Voltage Generator (Assembly)	Model	DG- S0101V1
	Rated output power	Max. 0.2 kW
	Duty Cycle	1:60 or more (Exposure time: Interval time)
	Cooling Protection	Thermistor ≥ 65 °C
	Inherent Filtration	1.8 mm Al / 65 kV
	Total Filtration	Min. 1.5 mm Al
	Type	Inverter Type
	Tube Voltage	55-65 kV
	Tube Current	1.0-3.0 mA
X-ray Tube	Manufacturer	VATECH Co., Ltd.
	Model	V1-650304 (Stationary Anode type)
	Focal spot size	0.4 mm (IEC 60336)
	Anode heat contents	Max. 2.7 kJ
	Maximum Anode Heat Dissipation	200 W
	Target Material	Tungsten
	Target Angle	12.5°
	Inherent Filtration	Min. 1.5 mm Al
	X-ray Coverage	70 mm at SID 200 mm
	Tube Voltage	Max. 65 kV
	Tube Current	Max. 3.0 mA

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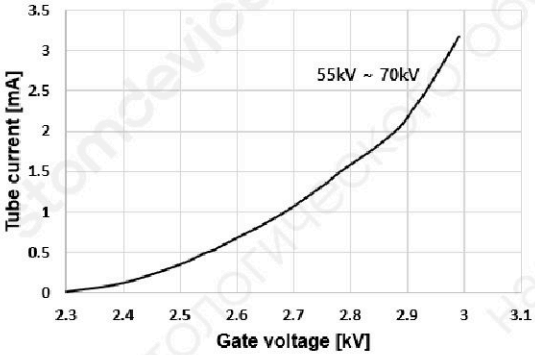
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X-ray Tube Characteristics

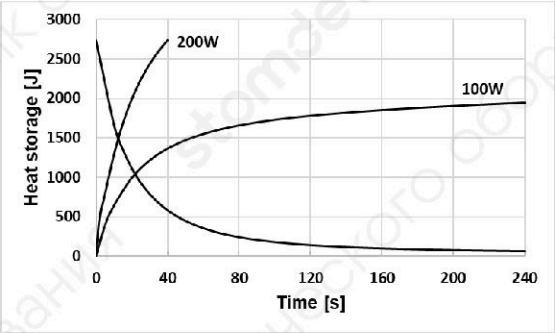
1) Maximum rating chart



2) Emission characteristics



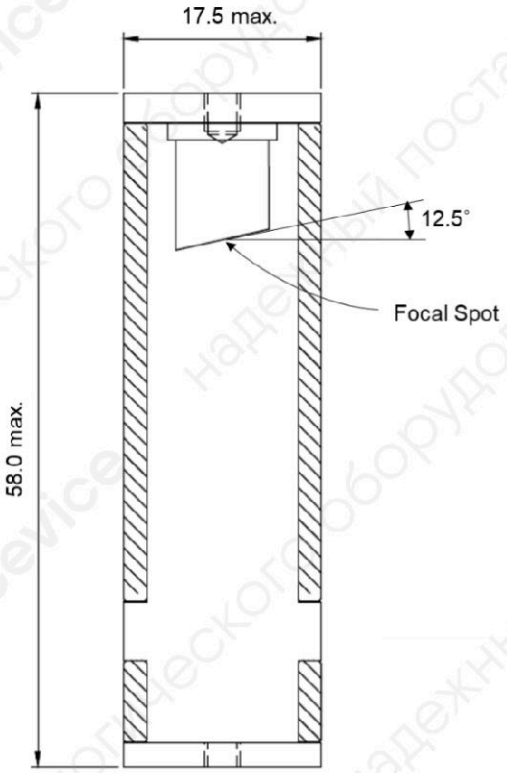
3) Heating and cooling curves of X-ray tube housing assembly



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4) Tube Dimensions [mm]



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Battery

Battery - HPL603163-6S1P

Item	Description
Type	Lithium Ion Rechargeable Battery
Nominal Capacity	2500 mAh
Nominal Voltage	21.6 V d.c.
Charging Voltage	25.2 V d.c. (4.2 V d.c./Cell)
Discharge Voltage	19.8 - 25.2 V d.c.

⚠WARNING

Make sure to use the battery only provided or approved by **Woorien**. Using an unauthorized battery may result in serious injury and equipment damage. For details on using the battery, see 'Battery Use'.

Battery Charger

Item	Description
Model	XVE-2520200
Manufacturer	JIN XIN YU POWER(SHENZHEN)SUPPLY CO.,LTD.
Rating	Input: 100-240 V~, 50/60 Hz, 1.5A
	Output: 25.2 V d.c., 2.0 A
Frequency	50/60 Hz
Standard	IEC 60950-1 (UL)
Power Cord	300 V, 2.5 A

⚠WARNING

Make sure to use the battery charger only provided or approved by **Woorien**. Using an unauthorized charger may result in serious injury and equipment damage. For details on using the battery charger, see 'Battery Use'.

NOTICE

- Power Supply is specified as a part of ME EQUIPMENT.
- Power plugs may have various specifications for each country.

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9.3 Electrical Specifications

Item	Description
Tube Voltage	65 kV fixed (± 5 %)
Tube Current	2.5 mA (± 10 %)
Exposure Time	0.05-1.0 s (± 3 % or 10ms)
Rated Voltage	21.6 V_{dc}

NOTICE	The system will be available with a fixed tube voltage specification based on the user selection.

NOTICE	Maximum exposures on a full charge: about 600 times at 65 kV, 2.5 mA, 0.2 s

9.4 Environmental Specifications

Item		Description
During operating	Temperature	10 ~ 35 ℃
	Relative humidity	30 ~ 75 %
	Atmospheric pressure	860 ~ 1060 hPa
Transport and storage	Temperature	-10 ~ 60 ℃
	Relative humidity	10 ~ 75 % non-condensing
	Atmospheric pressure	860 ~ 1060 hPa

⚠WARNING	Failure to follow the specifications above can result in serious injury and equipment damage.

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10. Appendix

10.1 Combining the Holder and the devices using tripod

NOTICE

Portable x-rays are not available in some countries. To be used in these countries, **Woorien** provides the holder with the exposure switch as an option.

The cradle is packed / shipped in a separate box as shown in the image below.



Remove all the components in the box and follow the procedure below to attach the cradle. (Note: Tripod not included)

NOTICE

To remove the holder, reverse the mounting procedure.

1. Using a Phillips screwdriver, connect the EzRay Air Portable and Gender cable with the supplied screws.





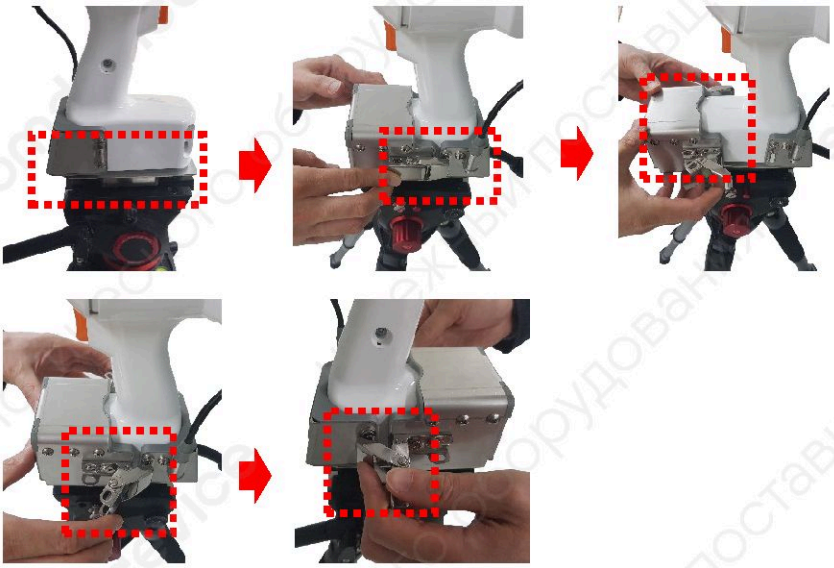
2. Attach the holder to a tripod. Refer to the Tripod manual for how to attach to a tripod.



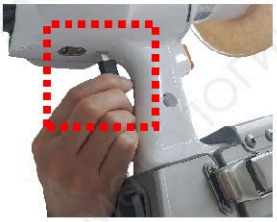
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3. Attach the EzRay Air Portable unit to the holder with the tripod as shown in the image below.



4. Connect one end of the Gender cable to the EzRay Air Portable device.



5. Connect the other end of the Gender cable connected to the holder to the supplied exposure cable.



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10.2 Using the Rotating Rectangular Cover

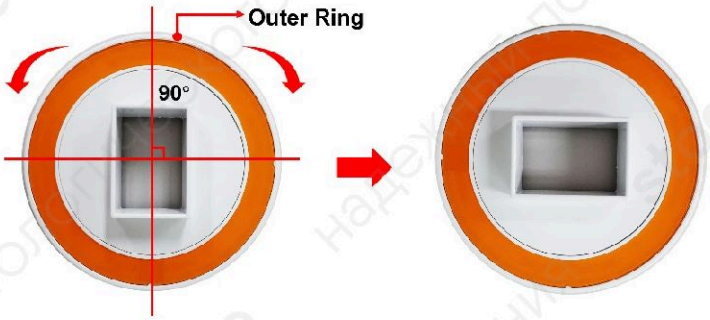
Rotating Rectangular Cover rotates in 360 degrees.

Rotating Rectangular Cover consists of the Outer Ring and the Inner Ring.

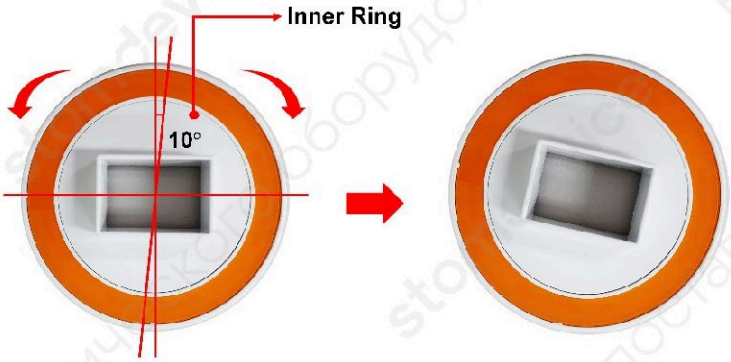


The Outer Ring rotates in 90-degree increments.

IMPORTANT



The Inner Ring rotates in 10-degree increments.



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1. Assemble the Rotating Rectangular Cover to the Cone of the Main body.

NOTICE	For assembling the Rotating Rectangular Cover to the Cone, turn the Rotating Rectangular Cover 45 degrees and check the Click sound to make sure the assembly is complete.

2. Turn the Outer Ring of the Rotating Rectangular Cover to adjust the angle roughly.
3. Turn the Inner Ring of the Rotating Rectangular Cover to fine-tune the angle.

NOTICE	Disassembly method of the Rotating Rectangular Cover is the same as the assembly method. Refer to the NOTE mentioned below stage 1.

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10.3 Tables of Exposure Times (Default)

The following exposure time tables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inch) respectively.

Patient		Teeth		Angle of inclination	SSD: 200 mm (8 inch)		
					kV	mA	S
Large 10 ~ 25kg	L	Incisor (Occlusal View)	1	Maxilla: +60˚	65	2.5	0.22
				Mandible: +45˚	65	2.5	0.20
		Canine (Lateral View)	2	Maxilla: +70˚	65	2.5	0.18
				Mandible: +70˚	65	2.5	0.18
		Pre- Molar (Rostral View)	3	Maxilla: +45˚	65	2.5	0.22
				Mandible: +50˚	65	2.5	0.22
		Molar (Caudal View)	4	Maxilla: +60˚	65	2.5	0.25
				Mandible: +5˚	65	2.5	0.25
Small < 10kg	L	Incisor (Occlusal View)	1	Maxilla: +60˚	65	2.5	0.16
				Mandible: +45˚	65	2.5	0.15
		Canine (Lateral View)	2	Maxilla: +70˚	65	2.5	0.14
				Mandible: +70˚	65	2.5	0.14
		Pre- Molar (Rostral View)	3	Maxilla: +45˚	65	2.5	0.16
				Mandible: +50˚	65	2.5	0.16
		Molar (Caudal View)	4	Maxilla: +60˚	65	2.5	0.18
				Mandible: +5˚	65	2.5	0.18

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10.4 X-ray Dose Data

The X-ray dose data is extracted from the X-ray Dose Test Report for the device. The X-ray doses of the device in the test report were measured by the IEC collateral standards. The device was designed by Part 1. General Requirements for Safety, IEC 60601-1-3.

Test Condition	
Model Name	VEX-P300
Tube Model Name	V1-650304
Generator Model Name	DG-S0101V1 (Inverter type)
Loading Factor	65 kV, 2.5 mA

10.4.1 X-ray Dose Table

Test Equipment			
Instrument	Manufacturer	Model	S/N
Dose Meter	Piranha	255	CB2-0750141

Dose Table (65 kVp, 2.5 mA, FOV: Ø 6 cm, SSD 200 mm, at Al 6 mm)	
t (s)	Dose (μGy)
0.16	132
0.19	156
0.21	173
0.23	189

Dose Area Product (DAP) Table (65 kVp, 2.5 mA, SSD 200 mm)			
	FOV: Ø 6 cm	FOV: 3 x 4 cm	FOV: 2 x 3 cm
t (s)	Dose ($mGy.cm^2$)		
0.16	13.63	5.79	2.89
0.19	15.78	6.70	3.35
0.21	17.21	7.31	3.65
0.23	17.93	7.61	3.81

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10.4.2 Leakage Dose

Scope

IEC 60601-2-65 203.12.4

Requirements

In the LOADING STATE, the AIR KERMA due to LEAKAGE RADIATION from X-RAY SOURCE ASSEMBLIES, 1 m from the FOCAL SPOT, average over an area of 100 cm^2 of which no principal linear dimension exceeds 20 cm, when operated at the NOMINAL X-RAY TUBE VOLTAGE under condition of LOADING corresponding to the reference LOADING conditions, shall not exceed 0.25 mGy in one hour.

Leakage Dose	Permissive Range
65 kVp, 2.5 mA, 1.0 s (Max. Exposure Condition) At Focal Spot to Distance 1 m 1 : 60 Duty Cycle	< 0.25 mGy/h

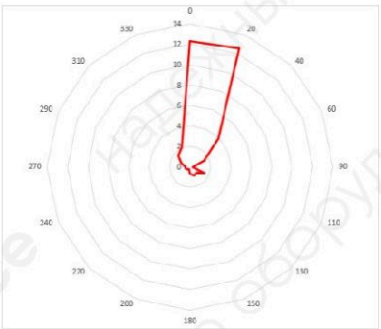
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Results

The following exposure timetables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inches) respectively. When the leakage doses have been measured with each cover type (default, rectangular 2x3, and rectangular 4x3), all the results have been ND (Not Detected).
The raw data about the results are shown in the table below.

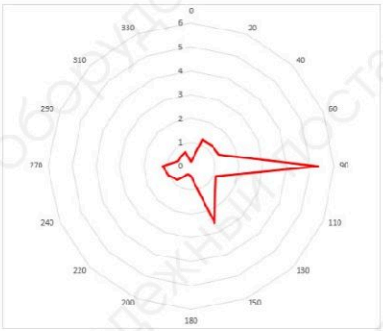
The result (Horizontal Plane)



Direction	Default type [mGy/h]	Rectangular 2x3 [mGy/h]	Rectangular 4x3 [mGy/h]
0°	ND	ND	ND
20°	ND	ND	ND
45°	ND	ND	ND
65°	ND	ND	ND
90°	ND	ND	ND
110°	ND	ND	ND
135°	ND	ND	ND
155°	ND	ND	ND
180°	ND	ND	ND
200°	ND	ND	ND
225°	ND	ND	ND
245°	ND	ND	ND
270°	ND	ND	ND
290°	ND	ND	ND
315°	ND	ND	ND
335°	ND	ND	ND

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The result (Vertical Plane)



Direction	Default type [mGy/h]	Rectangular 2x3 [mGy/h]	Rectangular 4x3 [mGy/h]
0°	ND	ND	ND
20°	ND	ND	ND
45°	ND	ND	ND
65°	ND	ND	ND
90°	ND	ND	ND
110°	ND	ND	ND
135°	ND	ND	ND
155°	ND	ND	ND
180°	ND	ND	ND
200°	ND	ND	ND
225°	ND	ND	ND
245°	ND	ND	ND
270°	ND	ND	ND
290°	ND	ND	ND
315°	ND	ND	ND
335°	ND	ND	ND

- ND: Not Detected. The detection limit is 0.00001 mGy per exposure.

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10.4.3 Scattered Dose

Scope

IEC 60601-2-65 203.13

Requirements

ME EQUIPMENT shall be provided with means to optionally allow actuation of the EXPOSURE from a PROTECTED AREA after installation.

Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

Results

The following exposure timetables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inches) respectively.

Method 1

PMMA Phantom aligned to 280 mm away from Focal Spot

(with Position Indicating Device)

Max. Exposure Condition

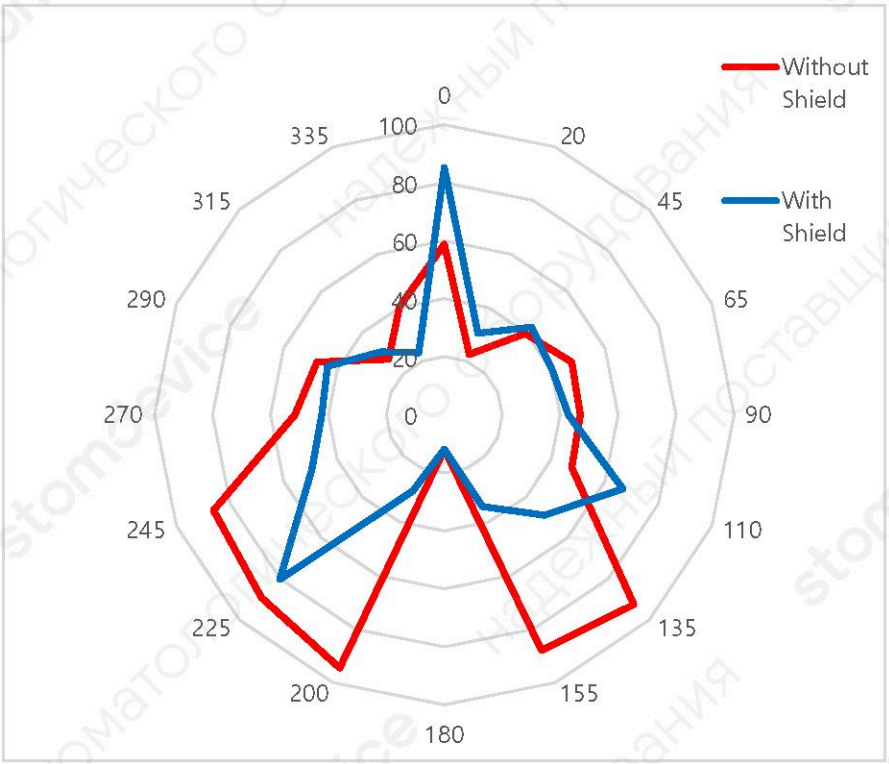
Measure point: 1000 mm from PMMA Phantom

Direction [°]	Result (Horizontal Plane) [μR]	
	Without Shield	With Shield
0°	58.8	85.2
20°	22.5	30.4
45°	39.6	42.7
65°	47.6	40.3
90°	46.9	42.9
110°	47.6	66.7
135°	92.5	48.9
155°	87.9	34.3
180°	11.9	11.9
200°	94.5	28.4
225°	89.2	80.3
245°	86.2	49.5
270°	51.6	42.3
290°	47.6	43.6

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Direction [°]	Result (Horizontal Plane) [μR]	
	Without Shield	With Shield
315°	27.1	30.7
335°	40.4	23.1

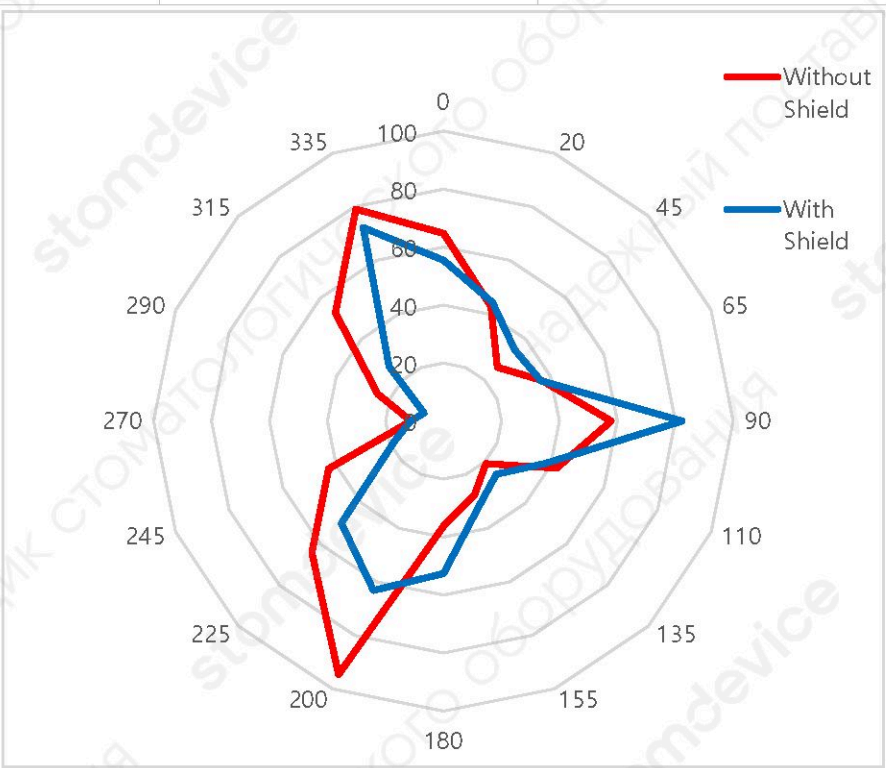


Direction [°]	Result (Vertical Plane) [μR]	
	Without Shield	With Shield
0°	64.7	55.4
20°	42.8	44.3
45°	26.3	34.8
65°	36.8	36.4
90°	57.9	82.4
110°	42.3	38.2
135°	20.7	25.9
155°	27.7	31.9

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10. Appendix

Direction [°]	Result (Vertical Plane) [μR]	
	Without Shield	With Shield
180°	36.2	52.6
200°	94.6	63.2
225°	64.2	49.8
245°	42.9	18.4
270°	11.2	11.3
290°	24.6	7.2
315°	52.8	26.5
335°	79.1	72.2



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10.5 Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions

The VEX-P300 is intended for use in the electromagnetic environment specified below. The customer or the user of the VEX-P300 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The VEX-P300 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The VEX-P300 is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, Provided the following warming is heeded: **Warning:** This VEX-P300 is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the VEX-P300 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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Guidance and manufacturer's declaration - electromagnetic immunity

The VEX-P300 is intended for use in the electromagnetic environment specified below. The customer or the user of the VEX-P300 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV air	±6 kV Contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle 40 % U_T (60 % dip in U_T) for 5 cycle, 6 cycle 70 % U_T (30 % dip in U_T) for 25 cycle, 30 cycle <5 % U_T (< 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle 40 % U_T (60 % dip in U_T) for 5 cycle, 6 cycle 70 % U_T (30 % dip in U_T) for 25 cycle, 30 cycle <5 % U_T (< 95 % dip in U_T) for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the VEX-P300 image intensifier requires continued operation during power mains interruptions, it is recommended that the VEX-P300 image intensifier is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE) U_T is the a.c. mains voltage prior to application of the test level.

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Guidance and manufacturer's declaration - electromagnetic immunity

The VEX-P300 is intended for use in the electromagnetic environment specified below. The customer or the user of the VEX-P300 should assure that it is used in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable mobile RF communications equipment should be used no closer to any part of the VEX-P300, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the VEX-P300 is used exceeds the applicable RF compliance level above, the VEX-P300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VEX-P300.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the VEX-P300

This is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VEX-P300 can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VEX-P300 as recommended below, according to the maximum output power of the communications equipment.

The rated maximum output power of the transmitter [W]	Separation distance according to the frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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10.6 Abbreviations

Acronym	Name
AL	Aluminum
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
FOV	Field of View
IEC	International Electro Technical Commission
ISO	International Standards Organization
LED	Light-Emitting Diode
ME	Medical Electrical
PMMA	PolymethylImethacrylate
RF	Radio Frequency
SID	Source to Image Receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SSD	Source to Skin Distance

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CE	The CE symbol grants this equipment compliance to the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.
EC REP	Authorized EU Representative: Vatech Dental Manufacturing Ltd. Suite 3, Ground Floor, Chancery House, St. Nicholas Way, Sutton, SM1 1JB UK Tel: (+44) 0208 652 1900, (+44) 0208 643 7109 Fax: (+44) 0208 652 1909

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