EzRay Air W (Model: VEX-S300W)

User Manual | Version 1.0

English

innovation inside

"i" stands for 'innovation', one of the core values of VATECH, which aims to expand accessibility of medical solutions to more people.

Notice

The **VEX-S300W** is an intra-oral dental X-ray system.

This manual contains descriptions, operational instructions, imaging procedures for the **VEX-S300W** dental X-ray system. It is recommended that you thoroughly familiarize yourself with this manual in order to make the most effective use of this equipment. Read and understand all cautions, safety messages and warnings in this manual.

Keep this manual with the equipment at all times, 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:

Phone: (+82) 1588 9510

E-mail: gcs@vatech.co.kr

This document is originally written in English.

The **VEX-S300W** is referred to as **Equipment** or **System** in this manual.

Manual Name: EzRay Air W (Model: VEX-S300W) User Manual

Version: 1.0

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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 product only when:

- Genuine VATECH approved equipment and components have been used at all times.
- All maintenance and repairs have been performed by a VATECH authorized agent.
- 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.

1.2 Owner and Operator's Obligations

- The owner of this equipment shall perform constancy tests at regular intervals in order to ensure patient and operator safety. These tests must be performed in accordance with local X-ray safety regulations.
- The owner of this equipment shall 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 shall ensure inspection and cleaning work is performed in accordance with the maintenance schedule outlined in **Chapter 6 User Maintenance.**

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.
	**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.

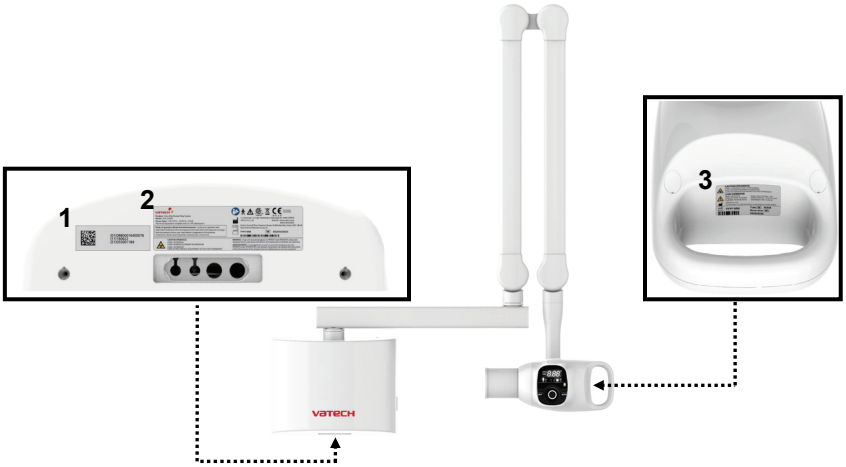
1.4 Marks and Symbols

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

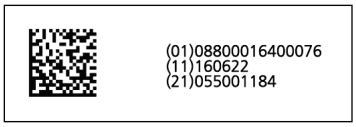
Mark/Symbol	Description	Location
	Alternate current	Main Label
	Attention: consult accompanying documents	Main Label
	Dangerous voltage	Power board, X-ray Generator, Generator Label
	Protective earth (Ground)	Power Box Base
	Off (power: disconnected to the **Main Power Switch**)	Main Power Switch
	On (power: connected to the **Main Power Switch**)	Main Power Switch
	IEC60601-1 Degree of Protection from Electric Shock TYPE B Equipment	Main Label
	Radiation hazard	Main Label, Generator Label
	Authorized European Representative name and address	Main Label
	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Main Label
	CSA mark No.266436	Main Label

Mark/Symbol	Description	Location
	Prescription Requirement label ***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
	Serial Number	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
	This symbol indicates the direction of cover attachment/detachment.	Cone's upper part

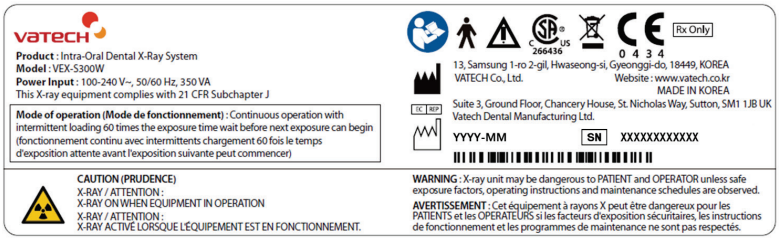
1.4.1 Label Locations



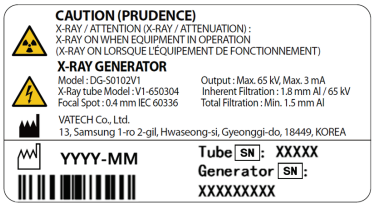
1. UDI Label



2. Main Label



3. Generator Label



NOTE

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

1.5 Standards and Regulations

Standards:

The VEX-S300W is designed and manufactured to meet the following standards:

- IEC 60601-1, IEC/EN 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-65, IEC 62366
- X-RAY EQUIPMENT for DENTAL INTRA-ORAL RADIOGRAPHY VEX-S300W 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 0434

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

2. Safety Instructions

2.1 General Safety Guidelines

- Mode of operation: Continuous operation with intermittent loading—This equipment needs a rest time of at least 60 times the exposure time before starting the next exposure.
- 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 only be operated 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.
- 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.
- Don’t keep the equipment or its parts in a humid place or near a liquid substance.
- Avoid placing the equipment near chemical storage and gas-filled storage facilities.

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.
 WARNING	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
 WARNING	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 Section A.3 Electromagnetic Compatibility (EMC) Information.
- Never try to modify this equipment, including the wires or cables. Modifying this equipment may damage it beyond repair.
- 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.
- Serious dangers may occur from electromagnetic interference (i.e. noise) between other equipment in the area during specific examinations or medical treatment.

Radiation Safety

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.

- This equipment should be operated by a trained and qualified dentist or a dental technician in a controlled environment.
- All users and patients should wear protective equipment, such as a lead apron, thyroid collar, etc.
- 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.
- Any person or organization who installs an external Door Interlock Switch is responsible for ensuring that the Switch has a radiation indicator or an equivalent alarm system to show the state of current.
- This equipment should be operated at least 2 m away from the operator when operated in or outside of the room. For details on the Scattered Dose data, please see ‘Scattered Dose’ on *page A-9* in Appendix.

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3. System Overview

The VEX-S300W is an intra-oral dental X-ray system intended for intra-oral imaging. It consists of X-ray generator, X-ray controller, beam limiting device, operation panel and mechanical arm. The X-ray controller allows for accurate exposure control, and the adjustable mechanical arm allows for easy positioning. The system can be used with an imaging system.

3.1 Indications for Use

The EzRay Air W (Model: VEX-S300W) is an intra-oral dental X-ray system (extra-oral X-ray source system) intended for use by a trained and qualified dentist or dental technician for both adult 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, 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.

3.4 Components

No.	Item	Standard	Option	Qty.
1	Power Box Assembly	●		1
2	Scissor Arm Assembly	●		1
3	X-ray Generator Assembly	●		1
4	User Manual	●		1
5	Installation Manual	●		1
6	Round Cover	●		1
7	Remote Exposure Switch*	●	●	1
8	Remote Exposure Switch (Doorbell type)		●	1
9	Remote Exposure Switch Cable (Doorbell type)		●	1
10	Door Interlock Cable		●	1
11	AC Power Cable		●	1
12	Rectangular Cover (2x3)		●	1
13	Rectangular Cover (4x3)		●	1
14	Double Stud		●	1
15	Horizontal Arm Assembly 450 mm		●	1
16	Horizontal Arm Assembly 600 mm		●	1
17	Horizontal Arm Assembly 900 mm		●	1

* The standard **Remote Exposure Switch** can be additionally provided as an optional item if needed. For details on the Remote Exposure Switch and Power Cable Connections, please see ‘Section 4.4.1’ on *page 37 and 38*.

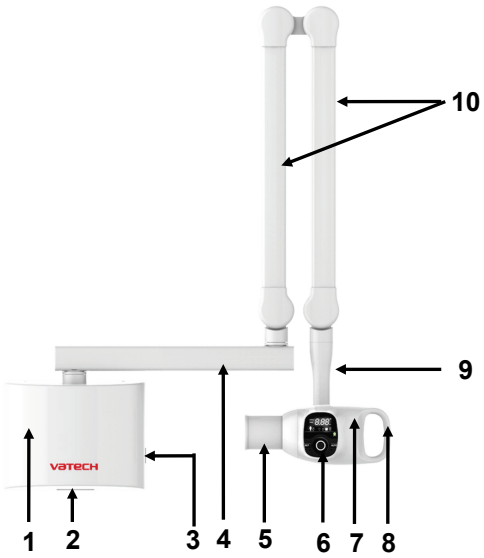
3.5 Features

The VEX-S300W is an intra-oral dental X-ray system that offers safety, reliability, and greater functionality:

- Ergonomic design and shape for safety and comfort of patients
- Easy-to-use Control Panel that provides a straightforward process
- Full-swivel revolution in all directions
- Tube head revolves freely around the sphere
- Compact, lightweight components

3.6 General View of the Equipment

Main Body



No.	Item	Description
1	Power Box Assembly	Controls the electrical power of the system.
2	Remote Exposure Switch and Power Cable Connectors	Connect the X-ray Exposure Switch cable and AC power cable (manufacturing option). Please refer to Section 4.4.1 Remote Exposure Switch and Power Cable Connections.
3	Main Power Switch	Main Power On/Off switch
4	Horizontal Arm	Connection arm between the power box assembly and the scissor arm assembly. (3 length options: 450 mm, 600 mm, 900 mm)
5	X-ray Beam Limiting Device	Limits the X-ray exposure area. Default type: Round Cone + Round Cover (FOV: Ø 6 cm)
6	Control Panel	Display for the X-ray exposure settings and operation conditions
7	X-ray Generator	Includes the X-ray tube and the high-voltage generator.
8	Handle	Grip the handle securely when using the system.
9	X-ray Generator Arm	Connection arm between the X-ray generator and the scissor arm assembly

No.	Item	Description
10	Scissor Arm Assembly	Adjusts the length of the entire arm by folding and unfolding the scissor arm assembly. Connection arm assembly between the horizontal arm and the X-ray generator assembly.

Control Panel

No.	Item	Description
1	Tube Voltage/Current Indicator	Indicates the tube voltage and tube current of the system.
2	Angle/Time Display	Displays the X-ray exposure time, error code, cooling time and exposure angle.
3	Adult/Child Selection	Indicates a patient type (adult or child).
4	Tooth Type Selection	Indicates a tooth type (incisor, canine, molar/premolar, bitewing).
5	X-ray Exposure Indicator	Indicates the X-ray exposure status. (Green: Ready / Yellow: X-ray ON)
6	SET Button (with LED lamp)	Resets the X-ray exposure angle. (SET button is pressed. → LED lamp flickers one time.)
7	Jog Dial	Turn the jog dial left (-) or right (+) to select X-ray exposure settings, press the jog dial to confirm the operating settings.
8	AUTO Button (with LED lamp)	Selects a tooth and exposure time automatically based on the X-ray exposure angle. (1. If the AUTO button is pressed, the LED lamp flickers one time. 2. If the AUTO Mode is ON, the LED lamp is ON.)
9	Speaker	Sound alarm for X-ray exposures

Available Option Items

No.	Illustration/Photo	Option name	Usage	Material
1		Rectangular Cover 2x3 (FOV: 2x3 / 3x2 cm)	Used for limiting the X-ray exposure area by covering the X-ray Beam Limiting Device except for the 2x3 (3x2) rectangular area	ABS (Acrylonitrile butadiene styrene) copolymer
2		Rectangular Cover 4x3 (FOV: 4x3 / 3x4 cm)	Used for limiting the X-ray exposure area by covering the X-ray Beam Limiting Device except for the 4x3 (3x4) rectangular area	ABS (Acrylonitrile butadiene styrene) copolymer
3		Remote Exposure Switch (if the Control Panel is installed to the wall framework)	Used to remotely perform exposure by pressing the Remote Exposure Switch	ABS (Acrylonitrile butadiene styrene) copolymer
4		Remote Exposure Switch (Doorbell type)	Used with the standard ‘Remote Exposure Switch’ (only if needed)	Steel (painted)
5		Remote Exposure Switch Cable (Doorbell type)	Used to connect the Remote Exposure Switch to the Remote Exposure Switch Connector on the bottom of the Power Box Assembly	PVC
6		Door Interlock Cable	Used to connect the Door Interlock Switch to the Door Interlock Cable Connector on the bottom of the Power Box Assembly	PVC

No.	Illustration/Photo	Option name	Usage	Material
7		AC Power Cable	Used to connect the power (AC 220 V) to the Power Box Assembly	PVC
8		Double Stud	Used for fixing the power box to the wall (when installing the power box on the wooden wall in the North America regions)	ABS (Acrylonitrile butadiene styrene) copolymer + SPCC
9		Horizontal Arm 450 mm	Used as a connection arm (length: 450 mm) between the Power Box Assembly and the Scissor Arm Assembly	AL6061 + ABS (Acrylonitrile butadiene styrene)
10		Horizontal Arm 600 mm	Used as a connection arm (length: 600 mm) between the Power Box Assembly and the Scissor Arm Assembly	AL6061 + ABS (Acrylonitrile butadiene styrene)
11		Horizontal Arm 900 mm	Used as a connection arm (length: 900 mm) between the Power Box Assembly and the Scissor Arm Assembly	AL6061 + ABS (Acrylonitrile butadiene styrene)

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4. Operation

4.1 Power On/Off

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

Main Power On/Off switch

Symbol	Power On/Off Status
	Power On
	Power Off

2. The following displays light up. For further information, see ‘Control Panel’ on *page 15*.

1) Current Angle/Time Display

2) Adult/Child Selection Display

3) Tooth Type Selection Display

4) X-ray Exposure Indicator

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.

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.

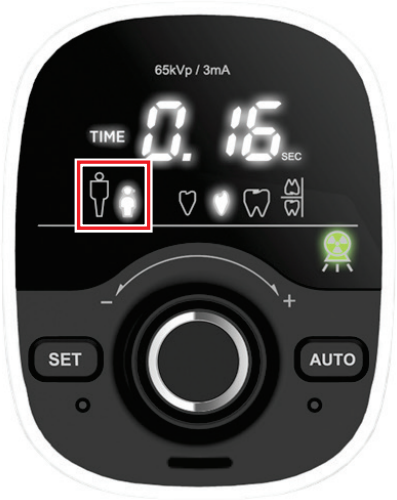
Before tooth type selection **After tooth type selection**

Tooth Type

Symbol	Type
	Incisor
	Canine
	Molar/Premolar
	Bitewing

3. After tooth type selection, patient type should be selected. When the Adult/Child 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
	Adult
	Child

NOTE

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 0.5 s. (increments: 0.01 s)

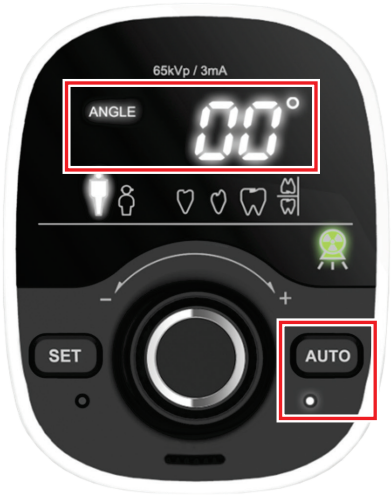
NOTE

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.

Auto Mode

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



NOTE

To set the starting point during exposure, press **SET**.

2. Position the system to the teeth to perform exposure. To see how to perform the patient positioning, refer to Section 4.3 Positioning. (The following figure is an example of the maxilla incisor.)

3. When tooth types are selected, the exposure angles are automatically set according to the tooth type. To check the default exposure angles, refer to the following table.

Tooth Type	Angle of Inclination
Incisor	Maxilla: +40° ~ +50°
	Mandible: -22° ~ -28°
Canine	Maxilla: +40° ~ +50°
	Mandible: -17° ~ -23°
Molar/Premolar	Maxilla: +25° ~ +35°
	Mandible: -2° ~ -8°
Bitewing	+3° ~ +12°

NOTE

Since the angles of inclination for the maxilla incisor and canine are same, the exposure time of the canine is applied for both the maxilla incisor and canine.

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

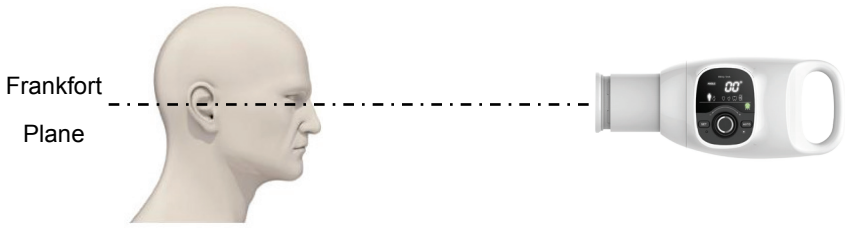
4.3 Positioning

Positioning the Patient

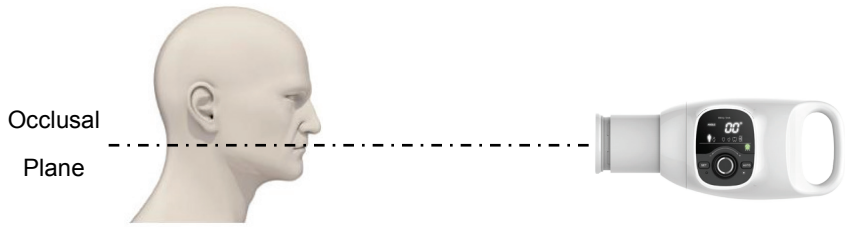
To obtain high-quality intra-oral radiography with maximum details, take extra care in all steps of the radiography process: positioning the patient and the X-ray imaging system; exposing the intra-oral sensor.

1. Place a protective lead apron on the patient's chest.
2. Have the patient sit on the chair with the sagittal plane vertical.

   - For radiography of the upper maxillary, the Frankfort Plane must be horizontal.



   - For radiography of the lower maxillary, the Occlusal Plane must be horizontal.

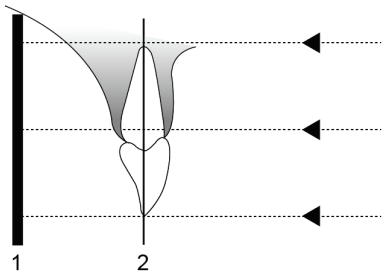


3. Place the tube head cone on the area you want to take an image.

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

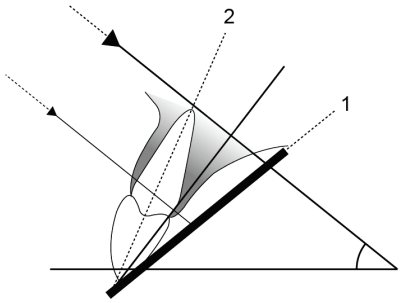
Positioning Instructions

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

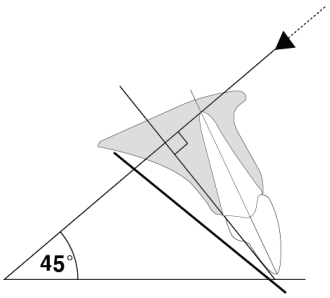
Position the tube head to the patient using the accepted standard positioning procedures.

Here are the specific angulations and directions for the tube head in order to take the best images of a particular 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 Incisor**

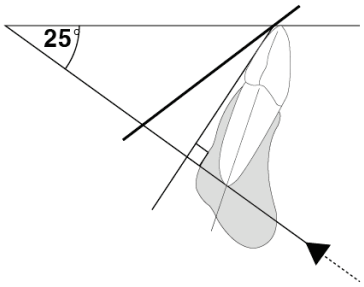
  X-ray beam is directed downward at 45°.



Teeth		Angle of inclination
Incisor	Maxilla	+45°

- **Mandibular Incisor**

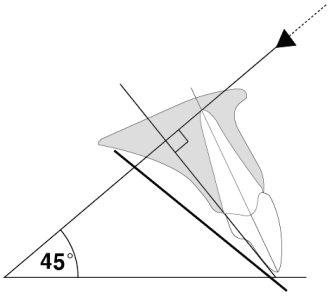
  X-ray beam is directed upward at 25°.



Teeth		Angle of inclination
Incisor	Mandible	-25˚

- **Maxillary Canine**

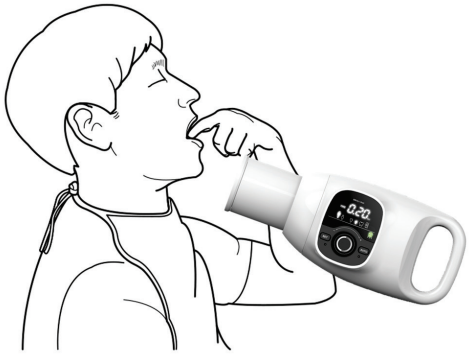
  X-ray beam is directed downward at 45°.

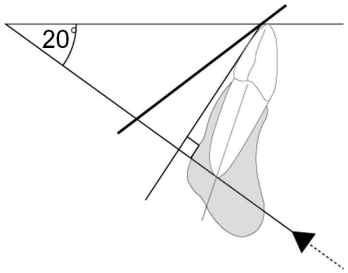


Teeth		Angle of inclination
Canine	Maxilla	+45˚

- **Mandibular Canine**

X-ray beam is directed upward at 20°.

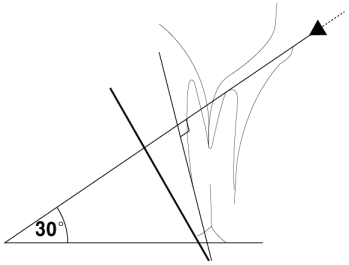




Teeth		Angle of inclination
Canine	Mandible	-20˚

- **Maxillary Molar and Premolar**

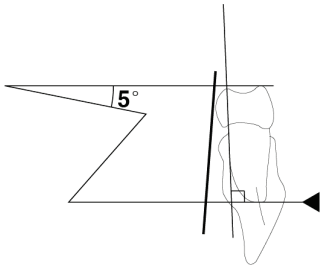
  X-ray beam is directed downward at 30°.



Teeth		Angle of inclination
Molar and Premolar	Maxilla	+30˚

- **Mandibular Molar and Premolar**

X-ray beam is directed upward at 5°.



Teeth		Angle of inclination
Molar and Premolar	Mandible	-5°

- **Bitewing**

  For a bitewing exposure, the patient closes their teeth during exposure on the sensor holder.

  X-ray beam is directed downward at 5° ~ 8°.

Teeth	Angle of inclination
Bitewing exposure	+5˚~ +8˚

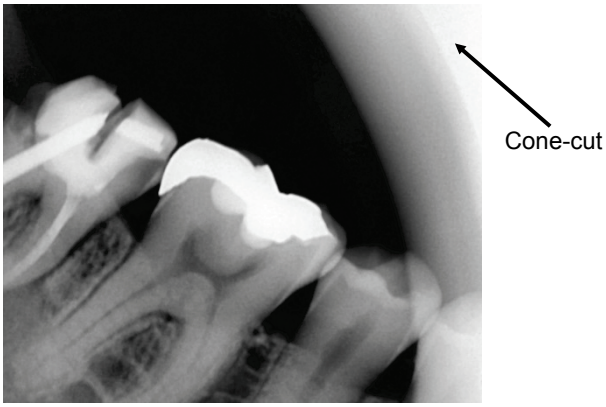
Positioning the Imaging Sensor

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' on *page 26*.

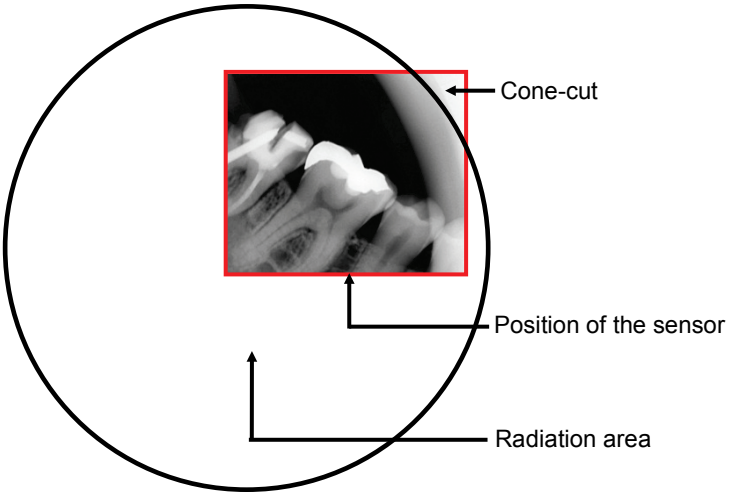
- Failure to position the imaging sensor properly can result in errors on the radiograph, such as distorted teeth and roots, elongation, magnification, and overlapping contacts.

NOTE	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.



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

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

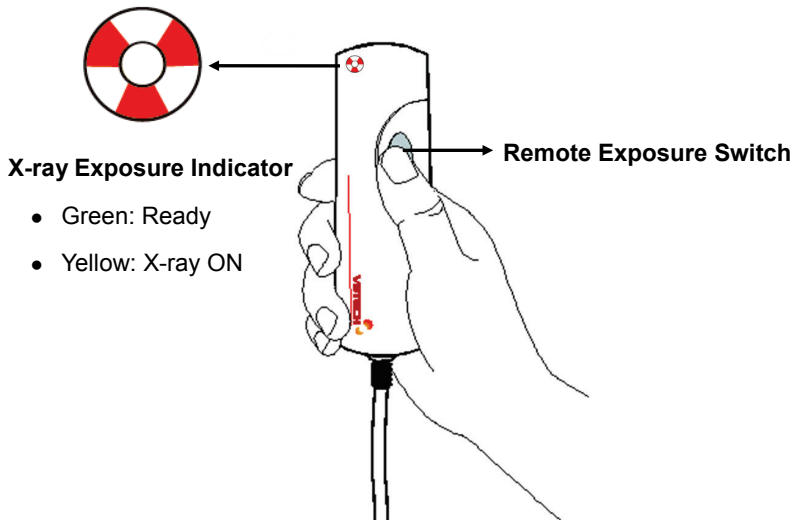
NOTE	Once the PID is properly aligned, instruct the patient not to move.

4.4 Exposure

IMPORTANT

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

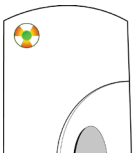
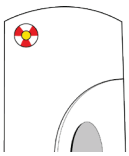
1. Instruct the patient not to move.
2. Press and hold the **Remote Exposure Switch** for exposure duration. The **Remote Exposure Switch** allows the operator to control image acquisition from outside of the X-ray room. Pressing the **Remote Exposure Switch** activates the X-ray Exposure Indicator to turn yellow. This color indicates that the X-ray is being emitted.



IMPORTANT

Press and hold the **Remote Exposure Switch** as long as the acoustic signal can be heard. Otherwise the exposure will be faulty and there will be an error message on the Control Panel.

3. While X-ray is being exposed, the X-ray Exposure Indicators on the **Control Panel** and the **Remote Exposure Switch** are turned on and an audible sound is produced. Keep pressing until the X-ray Exposure Indicator lights are turned off and the audible sound stops.

Location of the X-ray Exposure Indicator	X-ray Exposure Indicator's Status	
	Green: Ready	Yellow: X-ray ON
Control Panel		
Remote Exposure Switch		

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.

IMPORTANT

If the **Door Interlock Switch (option)** has been installed, X-ray exposure will be stopped once the door of the X-ray room is opened.

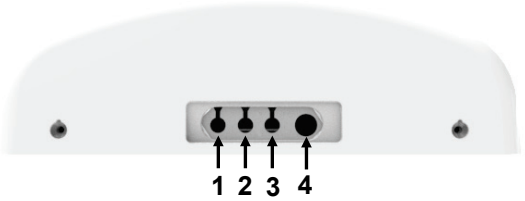
NOTE

As described in step 2 and 3 above, the X-ray Exposure Indicator is included both on the **Control Panel** and the **Remote Exposure Switch**.

4.4.1 Remote Exposure Switch and Power Cable Connections

There are four connectors on the bottom of the Power Box Assembly as described below.

- **Connector 1, 2, 3:** Remote Exposure Switch Connectors
- **Connector 4:** AC Power Cable Connector



The standard and optional **Remote Exposure Switches**, and the **Door Interlock Cable** are connected to the **Connector 1, 2, and 3**. Please check all seven possible options in the table below.

Option No.	Description	Connector 1	Connector 2	Connector 3	Connector 4
Option 1	Press (1).	 (1) Remote Exposure Switch **(Standard)**	N/A	N/A	AC Power Cable **(Option)**
Option 2	Press (1) **and** (2) at the same time.	 (1) Remote Exposure Switch **(Standard)**	N/A	 (2) Remote Exposure Switch **(Option)**	AC Power Cable **(Option)**

Option No.	Description	Connector 1	Connector 2	Connector 3	Connector 4
Option 3	Press (1) **and** (2) at the same time.	 (1) Remote Exposure Switch **(Standard)**	N/A	 (2) Remote Exposure Switch (Doorbell type) **(Option)**	AC Power Cable **(Option)**
Option 4	Press (1).	 (1) Remote Exposure Switch **(Standard)**	N/A	 (2) Door Interlock Cable **(Option)**	AC Power Cable **(Option)**
Option 5	Press (1) **or** (2).	 (1) Remote Exposure Switch **(Standard)**	 (2) Remote Exposure Switch **(Option)**	N/A	AC Power Cable **(Option)**
Option 6	Press (1) **or** (2).	 (1) Remote Exposure Switch **(Standard)**	 (2) Remote Exposure Switch (Doorbell type) **(Option)**	N/A	AC Power Cable **(Option)**

Option No.	Description	Connector 1	Connector 2	Connector 3	Connector 4
Option 7	Press (2) **and** (3) at the same time. (1): Not used in this option.				AC Power Cable **(Option)**
		(1) Remote Exposure Switch **(Standard)**	(3) Remote Exposure Switch (Doorbell type) **(Option)**	(2) Remote Exposure Switch (Doorbell type) **(Option)**	

5. 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.

Error Messages

Error Code	Check Parameter	Description
E.02	X-ray Generator	The kV feedback is lower than the set value during X-ray irradiation.
E.03	X-ray Generator	The kV feedback is higher than the set value during X-ray irradiation.
E.04	X-ray Generator	The mA feedback is lower than the set value during X-ray irradiation.
E.05	X-ray Generator	The mA feedback is higher than the set value during X-ray irradiation.
E.06	X-ray Generator	The mono-tank block temperature exceeds the error limit.
E.07	System	The Remote Exposure Switch was pressed when the system power is turned on.
E.08	User	1) The Remote Exposure Switch was turned off earlier than the exposure time. 2) The door of the X-ray room was opened during X-ray exposure when the door has the Door Interlock Switch (option) installed.

Troubleshooting

Problem	Cause	Solution
Equipment is not turned on.	Power button is not turned on properly.	Turn the equipment power switch off and turn it back on.
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' on *page 51*.)
	Remote Exposure Switch is pressed, but X-ray exposure does not work.	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 short.	Increase 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 long.	Decrease the exposure time.

6. User Maintenance

To ensure that the equipment operates at maximum efficiency, it is recommended to perform the following procedures for the customer's routine maintenance activities.

Maintenance Task Checklist

Always turn off the equipment before performing any maintenance.

Tasks	Period
Sterilize all components that come into contact with the patient and operator by using an alcohol-based solution.	Daily
Wipe the outer covers of the equipment with a dry cloth at the end of each day's operation.	Daily
Ensure that the main power button has been turned off after using the equipment.	Daily
Ensure the audible signal is audible and the X-ray exposure light is visible when you perform an exposure.	Daily
Ensure that the wall framework is securely attached to the wall.	Daily
Ensure that the yellow (exposure) indicator light turns on when the exposure button is pressed.	Daily
Ensure that the power cable does not have cuts or abrasions.	Monthly
Ensure that all cable connectors are not mechanically defective.	Monthly
Ensure that the control panel has no defects.	Monthly
Ensure that the power cable does not have cuts or abrasions.	Monthly
Ensure that all visible labels are intact and legible.	Monthly

DO NOT use detergents or solvents to clean the outer covers of the equipment.

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

Cleaning the Equipment

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.

 CAUTION	DO NOT spray any cleaner or disinfectant directly into the equipment, as this could cause a fire.
 NOTE	The soft cloth should be damp, but not dripping wet.
 NOTE	The cloths or wipes cannot be re-used.

7. Disposing of the Unit

In order 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				●
Other parts			●	

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

This symbol on the product 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 product, please contact your local authorities or dealer and ask for the correct method of disposal.

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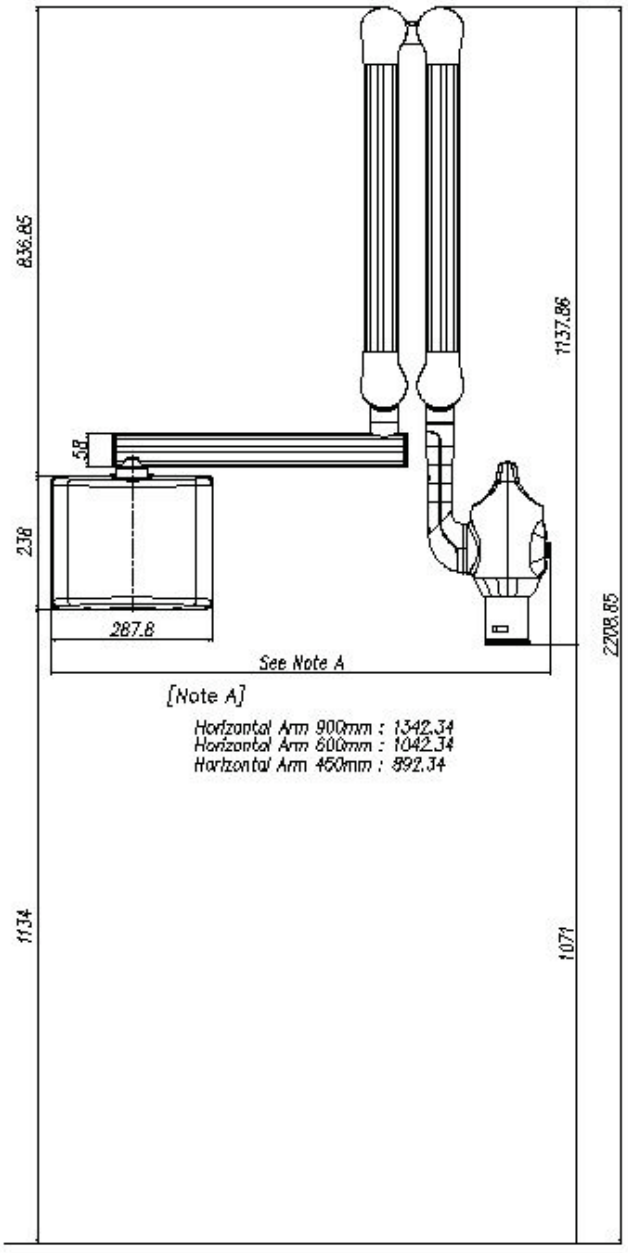
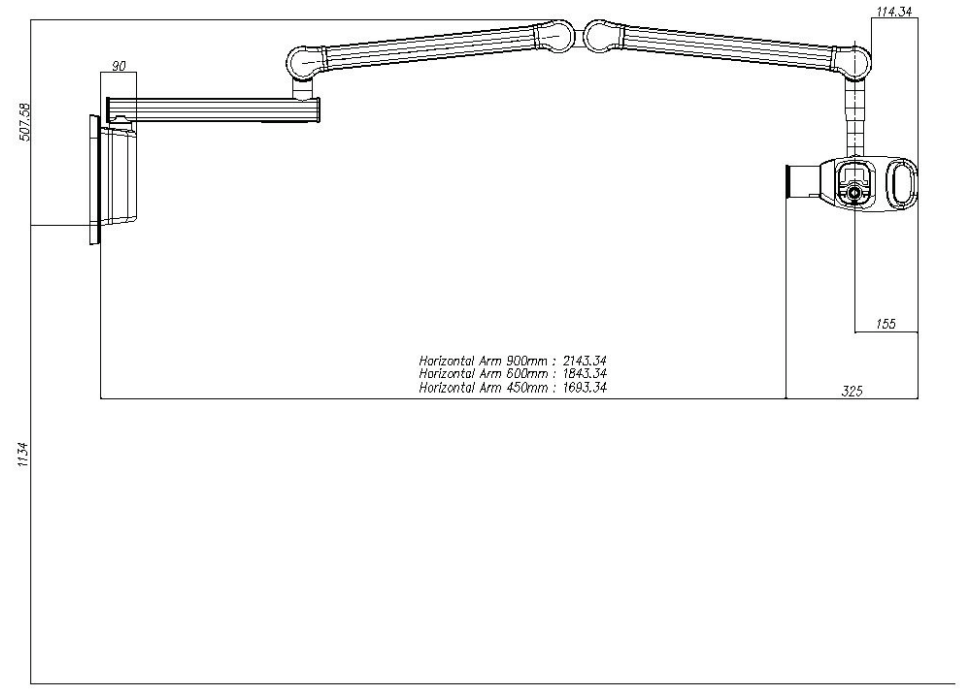
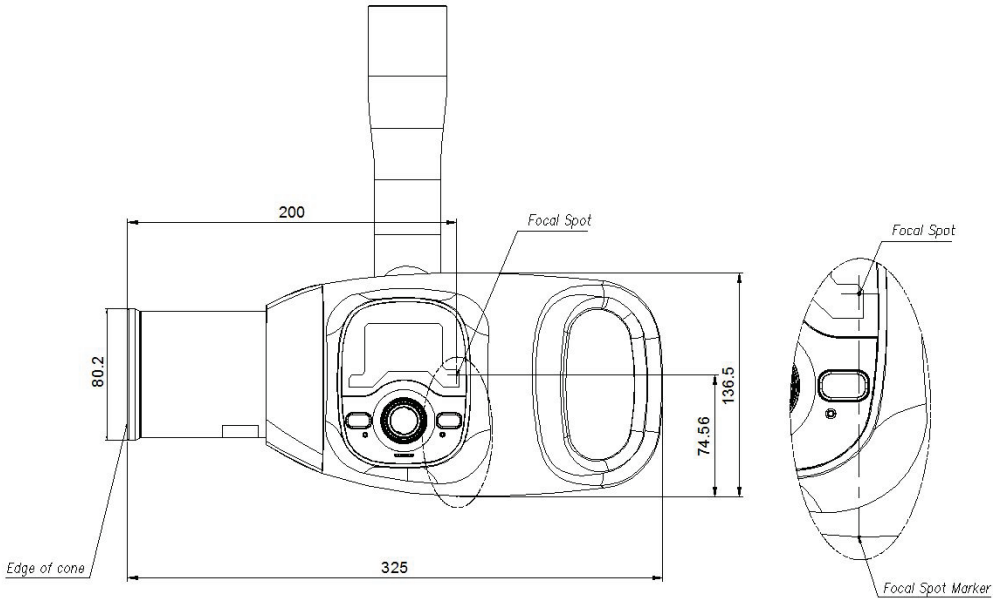
8. Product Specifications

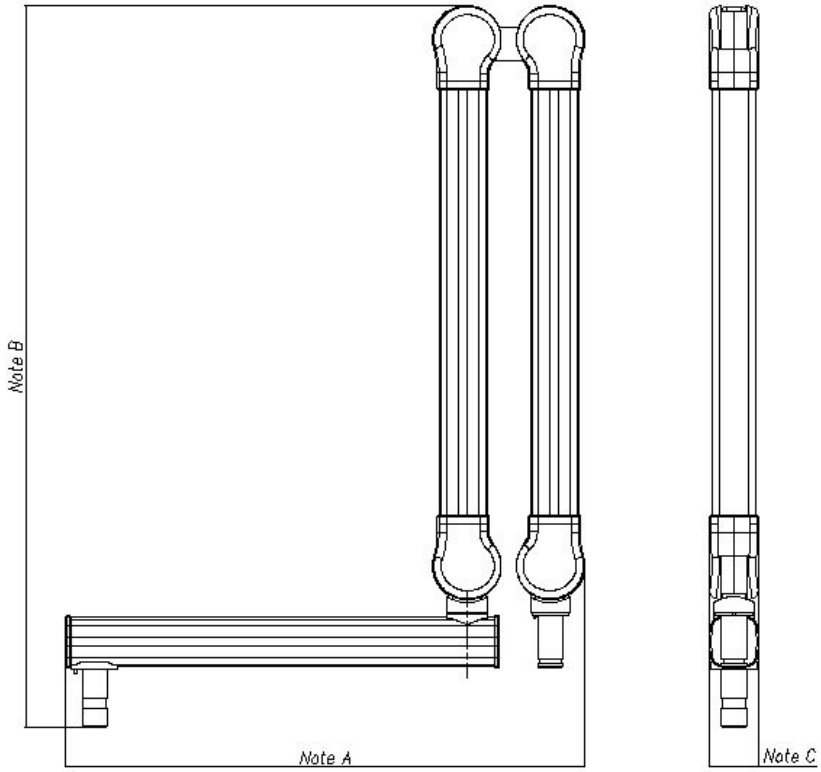
8.1 Mechanical Specifications

Dimensions

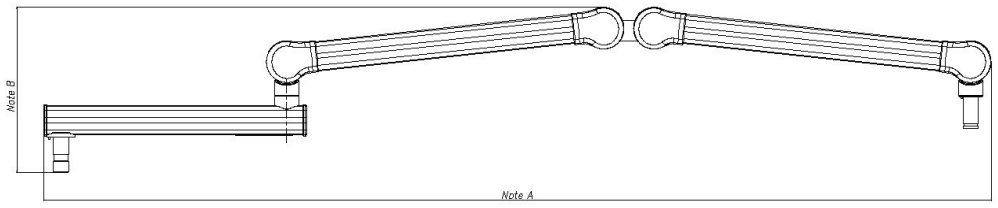



114.34
90
507.58
155
Horizontal Arm 900mm : 2143.34
Horizontal Arm 600mm : 1843.34
Horizontal Arm 450mm : 1693.34
325
1134


200
Focal Spot
80.2
136.5
74.56
Edge of cone
325
Focal Spot
Focal Spot Marker



Horizontal Arm Length	Note A(W)	Note B (L)	Note C(H)
Horizontal Arm 900mm	1077	870.06	58.4
Horizontal Arm 600mm	777	870.06	58.4
Horizontal Arm 450mm	627	870.06	58.4



Horizontal Arm Length	Note A(W)	Note B (L)	Note C(H)
Horizontal Arm 900mm	2338.7	326.98	58.4
Horizontal Arm 600mm	2038.7	326.98	58.4
Horizontal Arm 450mm	1888.7	326.98	58.4

Item			Dimension (mm)	Weight (kg)
Total Assembly (including Power Box Assembly and X-ray Generator Assembly)	Horizontal Arm 900 mm	With folded Scissor Arm (minimum)	1342.34	15.45
		With unfolded Scissor Arm (maximum)	2155.38	
	Horizontal Arm 600 mm	With folded Scissor Arm (minimum)	1042.34	14.6
		With unfolded Scissor Arm (maximum)	1855.38	
	Horizontal Arm 450 mm	With folded Scissor Arm (minimum)	892.34	14.15
		With unfolded Scissor Arm (maximum)	1705.38	
Total Arm Assembly	Horizontal Arm 900 mm	With folded Scissor Arm (minimum)	1077.0(W)x892.56(L)x58.4(H)	11.45
		With unfolded Scissor Arm (maximum)	2338.7(W)x326.98(L)x58.4(H)	
	Horizontal Arm 600 mm	With folded Scissor Arm (minimum)	777.0(W)x892.56(L)x58.4(H)	10.6
		With unfolded Scissor Arm (maximum)	2038.7(W)x326.98(L)x58.4(H)	

<table>
<tr><th colspan="4">Item</th><th>Dimension (mm)</th><th>Weight (kg)</th></tr>
<tr><td rowspan="2">Total Arm Assembly</td><td colspan="2" rowspan="2">Horizontal Arm 450 mm</td><td>With folded Scissor Arm (minimum)</td><td>627.0(W)x892.56(L)x58.4(H)</td><td rowspan="2">10.15</td></tr>
<tr><td>With unfolded Scissor Arm (maximum)</td><td>1888.7(W)x326.98(L)x58.4(H)</td></tr>
<tr><td rowspan="3">Horizontal Arm Assembly</td><td colspan="3">900 mm</td><td>976.0(W) x 151.24(L) x 58.3(H)</td><td>3.65</td></tr>
<tr><td colspan="3">600 mm</td><td>676.0(W) x 151.24(L) x 58.3(H)</td><td>2.8</td></tr>
<tr><td colspan="3">450 mm</td><td>526.0(W) x 151.24(L) x 58.3(H)</td><td>2.35</td></tr>
<tr><td colspan="4">Scissor Arm Assembly</td><td>797.6(W) x 184.0(L) x 58.4(H)</td><td>7.8</td></tr>
<tr><td colspan="4">Power Box Assembly</td><td>287.8(W) x 238.0(L)</td><td>1.6</td></tr>
<tr><td colspan="4">X-ray Generator Assembly</td><td>325.0(W) x 299.5(L) x 222.7(H)</td><td>2.4</td></tr>
<tr><td rowspan="3">X-ray Beam Limiting Device</td><td rowspan="2">X-ray Beam Area (mm)</td><td colspan="2">Round Type</td><td>FOV: < ⌀ 60</td><td>0.013</td></tr>
<tr><td colspan="2">Rectangular Type</td><td>FOV: 20 x 30 (30 x 20),
40 x 30 (30 x 40)</td><td>0.013</td></tr>
<tr><td colspan="3">SSD(Source to Skin Distance) (mm)</td><td>Min. 200</td><td>-</td></tr>
</table>

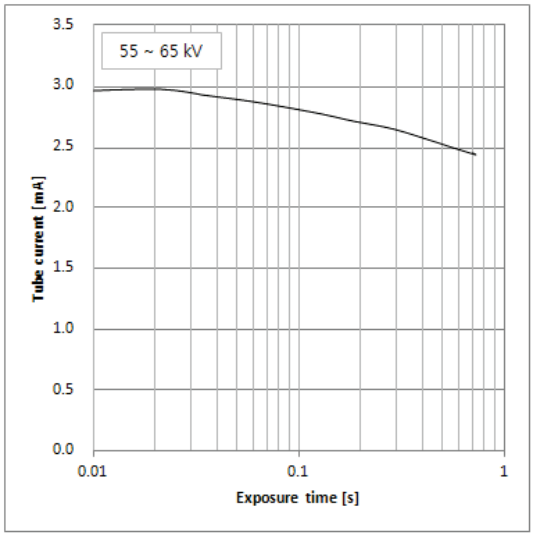
8.2 Technical Specifications

X-ray Generator

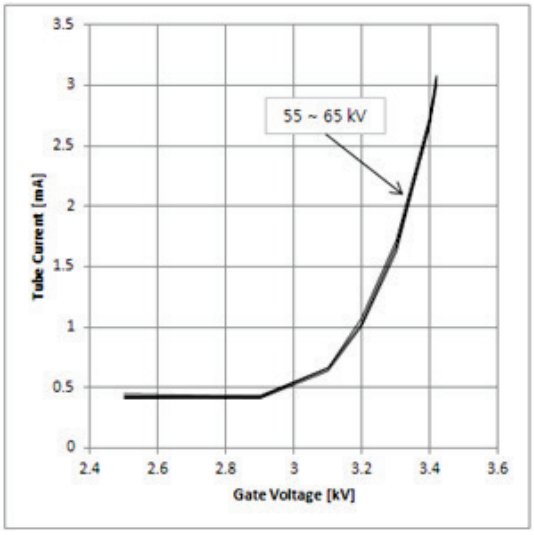
Item		Description
High Voltage Generator (Assembly)	Model	DG-S0102V1
	Rated output power	Max. 0.2 kW
	Duty Cycle	1:60 or more (Exposure time: Interval time)
	Cooling Protection	Thermistor ≥ 60 °C
	Inherent Filtration	1.8 mm Al / 65 kV
	Total Filtration	Min. 1.5 mm Al
	Type	Inverter Type
	Tube Voltage	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	0.8 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

X-ray Tube Characteristics

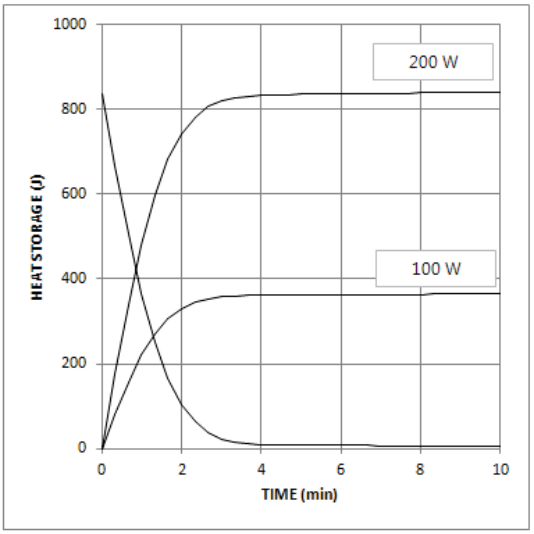
1) Maximum rating chart



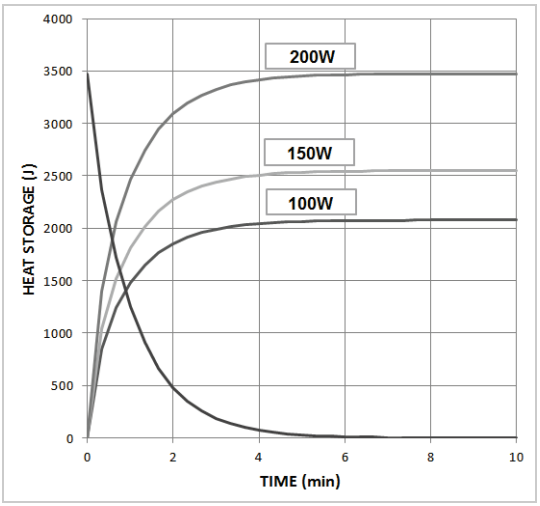
2) Emission characteristics



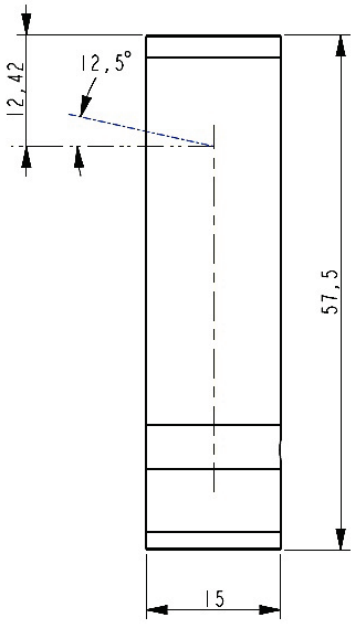
3) Heating and cooling curves of X-ray tube



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



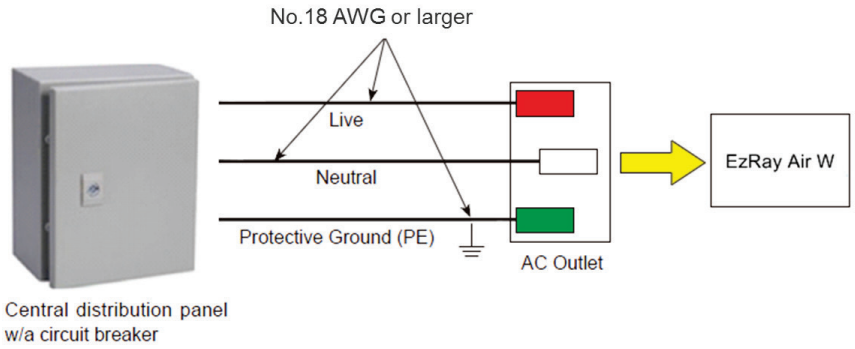
5) Tube Dimensions [mm]

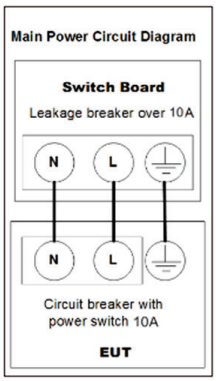


8.3 Electrical Specifications

Item	Description
Power Supply Voltage	100-240 V ~
Frequency	50/60 Hz (Single phase)
Power Rating	Max. 350 VA
Tube Voltage	65 kV fixed (± 3 %)
Tube Current	• Option A: 2.5 mA • Option B: 3.0 mA
Accuracy Error	< kVp +10 %, < mA + 20 %, < s ± 5 % or 20 ms

- The input line voltage depends on the local electrical distribution system.
- Allowable input voltage fluctuation requirement: ± 10 %
- Mode of operation: Continuous operation with intermittent loading—This equipment needs a rest time of at least 60 times the exposure time before starting the next exposure.
- Standard: Permanently installed, Option: AC Power Cable





NOTE	▪ To assure line voltage quality, a separate 3-core grounded power cable connected directly to central distribution panel with over-current circuit breaker rated for 10A must be used. ▪ The mains resistance should not exceed 0.5 Ω.
NOTE	The system will be available with a fixed tube current specification based on the user selection.
NOTE	Power Supply is specified as a part of ME EQUIPMENT.
NOTE	Power plugs may have various specifications for each country.

8.4 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

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Appendix

A.1 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.

- Option A: 65 kV, 2.5 mA

Receptor	Patient	Teeth		Angle of inclination	SSD: 200 mm (8 inch)		
					kV	mA	s
Sensor	Adult	Incisor		Maxilla: +45˚ Mandible: -25˚	65	2.5	0.20
		Canine		Maxilla: +45˚ Mandible: -20˚	65	2.5	0.22
		Molar/ Premolar		Maxilla: +30˚ Mandible: -5˚	65	2.5	0.24
		Bitewing		+5˚~ +8˚	65	2.5	0.25
	Child	Incisor		Maxilla: +45˚ Mandible: -25˚	65	2.5	0.16
		Canine		Maxilla: +45˚ Mandible: -20˚	65	2.5	0.18
		Molar/ Premolar		Maxilla: +30˚ Mandible: -5˚	65	2.5	0.20
		Bitewing		+5˚~ +8˚	65	2.5	0.22

➢ Option B: 65 kV, 3.0 mA

Receptor	Patient	Teeth		Angle of inclination	SSD: 200 mm (8 inch)		
					kV	mA	s
Sensor 	Adult 	Incisor		Maxilla: +45˚ Mandible: -25˚	65	3.0	0.18
		Canine		Maxilla: +45˚ Mandible: -20˚	65	3.0	0.20
		Molar/ Premolar		Maxilla: +30˚ Mandible: -5˚	65	3.0	0.22
		Bitewing		+5˚~ +8˚	65	3.0	0.23
	Child 	Incisor		Maxilla: +45˚ Mandible: -25˚	65	3.0	0.14
		Canine		Maxilla: +45˚ Mandible: -20˚	65	3.0	0.16
		Molar/ Premolar		Maxilla: +30˚ Mandible: -5˚	65	3.0	0.18
		Bitewing		+5˚~ +8˚	65	3.0	0.19

A.2 X-ray Dose Data

The X-ray dose data is extracted from the X-ray Dose Test Report for the VEX-S300W. The X-ray doses of VEX-S300W in the test report have been measured in accordance with the IEC collateral standards. The VEX-S300W has been designed in accordance with Part 1. General Requirements for Safety, IEC 60601-1-3.

Test Condition	
Model Name	VEX-S300W
Tube Model Name	V1-650304
Generator Model Name	DG-S0102V1 (Inverter type)
Loading Factor	· Option A: 65 kV, 2.5 mA · Option B: 65 kV, 3.0 mA

1. X-ray Dose Table

Test Equipment			
Instrument	Manufacturer	Model	S/N
Multi Dose Meter	UNFORS	Unfors Xi R/F&MAM	161834

Dose Table (65 kVp, 2.5 mA, FOV: Ø 6 cm, SSD 200 mm, at Al 6 mm)	
t (s)	**Dose (µGy)**
0.20	107
0.22	118
0.24	128
0.25	134

Dose Area Product (DAP) Table (65 kVp, 2.5 mA, SSD 200 mm)			
	FOV: Ø 6 cm	**FOV : 4 x 3 cm**	**FOV : 2 x 3 cm**
t (s)	**Dose (mGy.cm^2)**		
0.05	2.19	0.93	0.47
0.08	3.92	1.67	0.83
0.10	5.08	2.16	1.08
0.15	7.96	3.38	1.69
0.20	10.84	4.30	2.60
0.25	13.73	5.83	2.91

Dose Area Product (DAP) Table (65 kVp, 2.5 mA, SSD 200 mm)			
	FOV: Ø 6 cm	FOV : 4 x 3 cm	FOV : 2 x 3 cm
t (s)	Dose (mGy.cm^2)		
0.30	16.61	7.05	3.53
0.45	25.26	10.73	5.36
0.50	28.15	11.95	5.98

Dose Table (65 kVp, 3.0 mA, FOV: Ø 6 cm, SSD 200 mm, at Al 6 mm)	
t (s)	Dose (µGy)
0.18	116
0.20	128
0.22	141
0.23	148

Dose Area Product (DAP) Table (65 kVp, 3.0 mA, SSD 200 mm)			
	FOV: Ø 6 cm	FOV : 4 x 3 cm	FOV : 2 x 3 cm
t (s)	Dose (mGy.cm^2)		
0.05	2.63	1.12	0.56
0.08	4.71	2.00	1.00
0.10	6.09	2.59	2.29
0.15	9.55	4.06	2.03
0.20	13.01	5.53	2.76
0.25	16.47	6.99	3.50
0.30	19.93	8.45	4.23
0.45	30.32	12.87	6.44
0.50	33.78	14.34	7.17

2. Leakage Dose

Scope

IEC 60601-2-65 203.12.4

Requirements

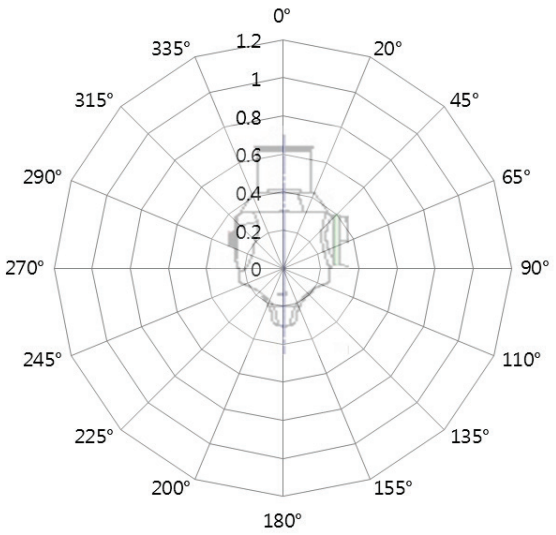
In the LOADING STATE, the AIR KERMA due to LEAKAGE RADIATION from X-RAY SOURCE ASSEMBLIES, 1 m from the FOCAL SPOT, average over any area of 100 cm^2 of which no principal linear dimension exceeds 20 cm, when operated at the NOMINAL X-RAY TUBE VOLTAGE under condition of LOADING corresponding to the reference LOADING conditions, shall not exceed 0.2 mGy in one hour.

Leakage Dose	Permissive Range
65 kVp, 3.0 mA, 0.5 s (Max. Exposure Condition) At Focal Spot to Distance 1 m Duty Cycle 1 : 60	< 0.2 mGy/h

Results

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. 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 is shown in the table below.

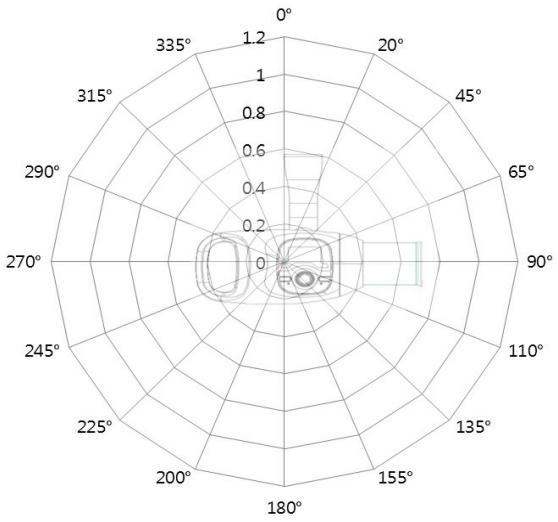
Result (Horizontal Plane)



Direction	Default type	Rectangular 2x3	Rectangular 4x3
	[mGy/h]	[mGy/h]	[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

Direction	Default type	Rectangular 2x3	Rectangular 4x3
	[mGy/h]	[mGy/h]	[mGy/h]
245°	ND	ND	ND
270°	ND	ND	ND
290°	ND	ND	ND
315°	ND	ND	ND
335°	ND	ND	ND

Result (Vertical Plane)



Direction	Default type	Rectangular 2x3	Rectangular 4x3
	[mGy/h]	[mGy/h]	[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

Direction	Default type	Rectangular 2x3	Rectangular 4x3
	[mGy/h]	[mGy/h]	[mGy/h]
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. Detection limit is 0.00001 mGy per exposure.

3. Scattered Dose

Scope

IEC 60601-2-65 203.13

Requirements

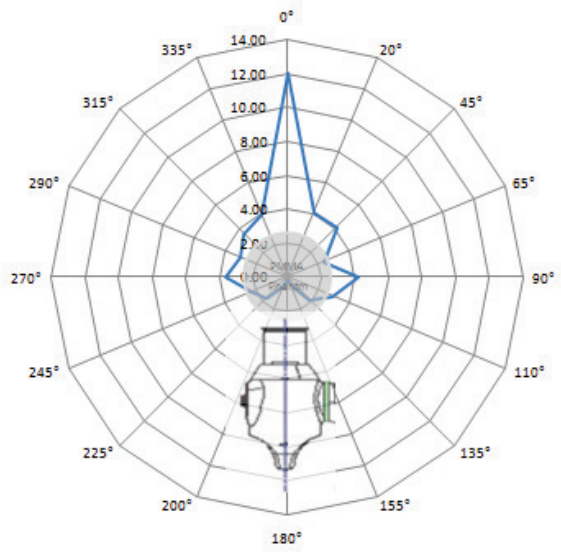
ME EQUIPMENT shall be provided with means to optionally allow actuation of the IRRADAIATION from a PROTECTED AREA after installation.
Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

Results

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.

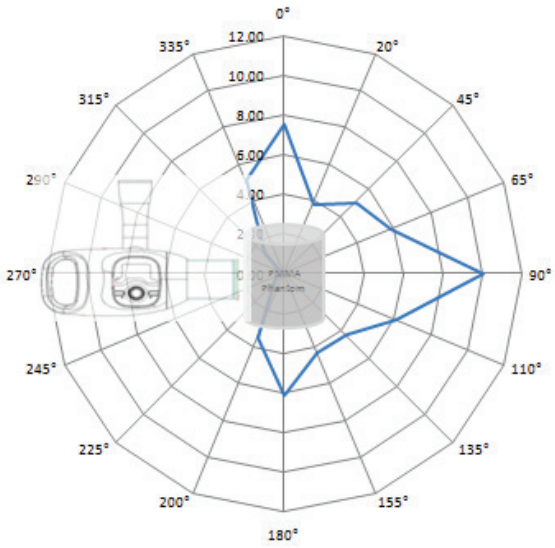
Method
PMMA Phantom aligned to 280 mm away from Focal Spot
(with Position Indicating Device (80 mm))
65 kVp, 3.0 mA, 0.5 s (Max. Exposure Condition)
Measure point: 2,000 mm from PMMA Phantom

Result (Horizontal Plane)



Direction [°]	[µGy/h]
0°	11.41
20°	3.90
45°	3.97
65°	2.24
90°	4.02
110°	2.75
135°	1.80
155°	0.46
180°	0.17

Direction [°]	[µGy/h]
200°	0.48
225°	1.62
245°	2.20
270°	3.50
290°	2.87
315°	3.44
335°	3.78

Result (Vertical Plane)	
	
Direction [°]	**[µGy/h]**
0°	7.20
20°	3.58
45°	4.83
65°	5.48
90°	9.52
110°	5.77
135°	4.15
155°	4.12

Direction [°]	[µGy/h]
180°	5.86
200°	3.35
225°	0.89
245°	0.43
270°	0.09
290°	0.31
315°	1.43
335°	4.85

A.3 Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions

<table>
<tr><td colspan="3">The VEX-S300W is intended for use in the electromagnetic environment specified below. The customer or the user of the VEX-S300W should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The VEX-S300W 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The VEX-S300W is suitable for use in all establishments 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Applicable</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Applicable</td></tr>
<tr><td colspan="3">NOTE) It is essential that the actual RF shielding effectiveness and filter attenuation of the shielded location be verified to ensure that they meet or exceed the specified minimum values.</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity

The VEX-S300W is intended for use in the electromagnetic environment specified below. The customer or the user of the VEX-S300W 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-S300W image intensifier requires continued operation during power mains interruptions, it is recommended that the VEX-S300W be 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 V a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The VEX-S300W is intended for use in the electromagnetic environment specified below. The customer or the user of the VEX-S300W 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	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	The VEX-S300W must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 20 dB from 30 MHz to 230 MHz, 20 dB from 230 MHz to 1 GHz. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m.a Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V /m 80 MHz to 2.5 GHz	

NOTE 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

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-S300W is used exceeds 3V/m, the VEX-S300W should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the VEX-S300W or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

A.4 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	PolyMethylMethAcrylate
RF	Radio Frequency
SID	Source to Image receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SSD	Source to Skin Distance

Manufactured by VATECH Co., Ltd.

Tel: (+82) 1588 9510

Email: gcs@vatech.co.kr

Website: www.vatech.co.kr

Head Quarters Address: 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea

Factory Address: 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea

CE 0434	The CE symbol grants this product 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:** **Name: Vatech Dental Manufacturing Ltd.** **Address: 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**

VATECH Co., Ltd.

Postal Code: 18449
13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, Korea

www.vatech.co.kr