

EzRay™ Chair

User Manual

English v 1.46



vatech

Notice

The **EzRay Chair (Model: VEX-S300C)** is an intra-oral dental X-ray system.

This manual contains descriptions, operational instructions, imaging procedures for the **EzRay Chair (Model: VEX-S300C)** dental X-ray system. It is recommended that you thoroughly familiarize yourself with this manual 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 always and review the operating procedures and safety instructions if needed.

The illustrations/photos of the equipment in this manual are only for illustration purposes. The 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 Chair (VEX-S300C)** is referred to as **Equipment** or **System** in this manual.

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1. General and Regulatory Information

1.1 Manufacturer's Liability

The manufacturers and retailers of this equipment assume responsibility for the safe and healthy operation of this product only when:

- Genuine VATECH approved equipment and components have always been used.
- A VATECH authorized agent has performed all maintenance and repairs.
- The equipment has been used generally by 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 maintenance at regular intervals to ensure patient and operator safety. These tests must be performed by 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 by 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 damage to the equipment, please observe all warnings and safety information included in this document.








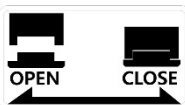
| | |
|--|---|
|  WARNING | Indicates a potentially hazardous situation and improper handling may result in: <ul style="list-style-type: none">• Serious bodily injury (User or veterinary patient)• Substantial property damage |
|  CAUTION | Indicates a potentially hazardous situation and improper handling may result in: <ul style="list-style-type: none">• Light injury• Property damage |
| IMPORTANT | Indicates a potentially harmful situation, and improper handling may result in: <ul style="list-style-type: none">• Property damage |
| NOTICE | Indicates a usage and other valuable information. |

1.4 Marks and Symbols

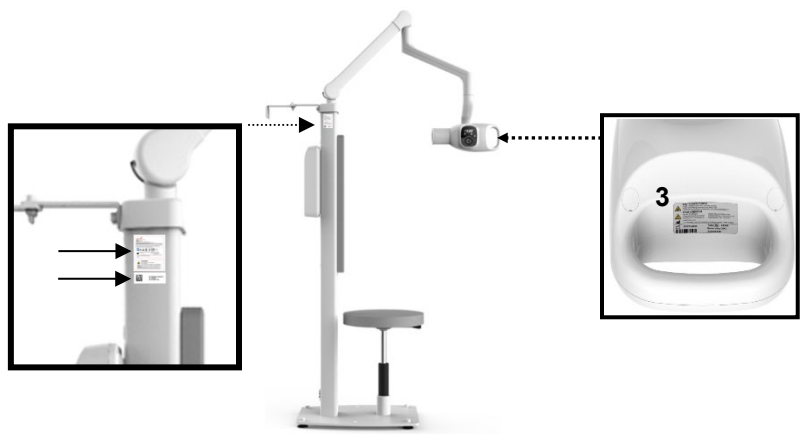
The following table describes the purpose and location of safety symbols and other valuable information provided on the equipment.

| 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 The 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 |
|  | UL mark No. E476672 | Main Label |

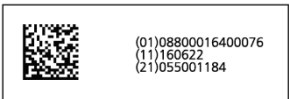
1. General and Regulatory Information

| 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 | Generator Label |
|  | Serial Number | Generator Label |
|  | This symbol indicates that electrical and electronic equipment should not be treated 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

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Product : Dental X-ray System
Model : VEX-S300C
Power Input : 100-240 V~, 50/60 Hz, 4-2A
This X-ray equipment complies with 21 CFR Subchapter J.

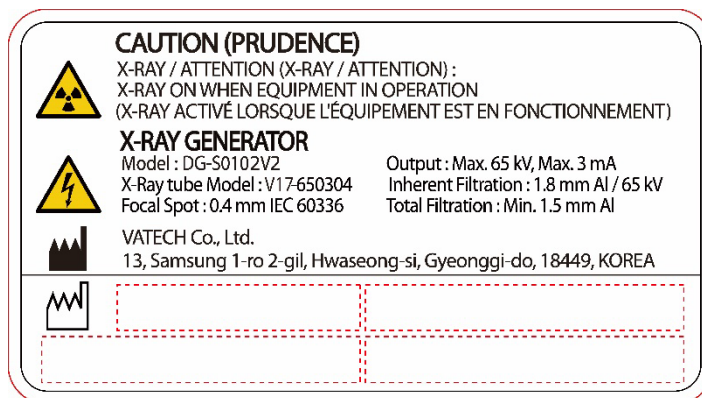
Mode of operation (Mode de fonctionnement) : Continuous operation with intermittent loading—This equipment needs a rest time of at least 60 times the exposure time before starting the next exposure. (Fonctionnement en continu avec chargement intermittent — Cet équipement nécessite une période de repos d'au moins 60 fois le temps d'exposition avant de commencer l'exposition suivante.)

WARNING : X-ray unit may be dangerous to PATIENT and OPERATOR unless safe exposure factors, operating instructions and maintenance schedules are observed.
AVERTISSEMENT : Cet équipement à rayons X peut être dangereux pour les PATIENTS et les OPERATEURS si les facteurs d'exposition sécuritaires, les instructions de fonctionnement et les programmes de maintenance ne sont pas respectés.

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Vatech Global France (SARL)

CAUTION (PRUDENCE)
X-RAY / ATTENTION :
X-RAY ON WHEN EQUIPMENT IN OPERATION
X-RAY / ATTENTION :
X-RAY ACTIVE LORSQUE L'EQUIPEMENT EST EN FONCTIONNEMENT

3. Generator Label



NOTICE



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

1.5 Standards and Regulations

Standards:

The **EzRay Chair (Model:VEX-S300C)** is designed and manufactured to meet the following standards:

- MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012),
CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-1-3:2008 + AMD1:2013, IEC 60601-2-65:2012 + AMD1:2017
- 21 CFR 1020.30 & 1020.31
- ISO 13485

| | |
|--|---|
|  | This is Class IIb equipment and obtained CE marking in April 2007 for regulations compliance by the revised European Union's MDD (Medical Devices Directive) 93/42 EEC. |
|  | This equipment received the UL certification mark in accordance with ANSI/AAMI, CAN/CSA-C22.2 No. 60601-1 regulation. |

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: Conehead






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2. Safety Instructions

2.1 General Safety Guidelines

- Mode of operation: Continuous operation with cyclic 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 | <p>This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed.</p> <p>It is essential to read this user manual carefully and strictly abide by all warnings and cautions stated within it.</p> |
|  WARNING | <p>To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.</p> |
|  WARNING | <p>Since rules and regulations concerning radiation safety differ between countries, it is the responsibility of the owner and operator of this equipment to comply with all applicable rules and regulations concerning radiation safety and protection in their area.</p> |

- DO NOT open or remove the cover panels on this equipment.
- DO NOT use spray cleaners on this equipment, as this could cause a fire.
- DO NOT place flammable materials near 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.
- Never use this equipment in an environment that is susceptible to explosion.
- 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 1.A.4 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 for 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.
- Grave 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 for all users comply with the following radiation safety guidelines 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, et cetera.
- 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 67* in Appendix.

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3. System Overview

The **EzRay Chair (Model: VEX-S300C)** is an intra-oral dental X-ray system intended for intra-oral imaging. It consists of an X-ray generator, X-ray controller, beam limiting device, an operation panel, and a 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 Chair (Model: VEX-S300C)** is a 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 a high voltage is supplied to the X-ray tube assembly which frees electrons from the cathode. They hit anode to produce X-rays. The equipment acquires images by emitting X-rays continuously on the human tooth.

3.3 Intended User Profile

| Considerations | Requirement Description |
|------------------------|---|
| Education | A licensed dentist or dental hygiene, radiologist, and graduates of relevant bachelor's degree (national qualifications) |
| Knowledge | The operator must have understood: <ul style="list-style-type: none"> ▪ 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: <ul style="list-style-type: none"> ▪ the English or Korean manuals (or other languages provided). |
| Experience | The operator must have understood: <ul style="list-style-type: none"> ▪ 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 | Middle Arm Assembly | • | | 1 |
| 4 | X-ray Generator Assembly | • | | 1 |
| 5 | Column Assembly | • | | |
| 6 | User Manual | • | | 1 |
| 7 | Installation Manual | • | | 1 |
| 8 | Round Cover | • | | 1 |
| 9 | Remote Exposure Switch* | • | | 1 |
| 10 | Remote Exposure Switch (Doorbell type) | | • | 1 |
| 11 | Remote Exposure Switch Cable (Doorbell type) | | • | 1 |
| 12 | Door Interlock Cable | | • | 1 |
| 14 | Rectangular Cover (2x3) | | • | 1 |
| 15 | Rectangular Cover (4x3) | | • | 1 |
| 16 | Rotating rectangular cover (2x3) | | • | 1 |
| 17 | Rotating rectangular cover (4x3) | | • | 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 **4.5.1 Remote Exposure Switch and Power Cable**.

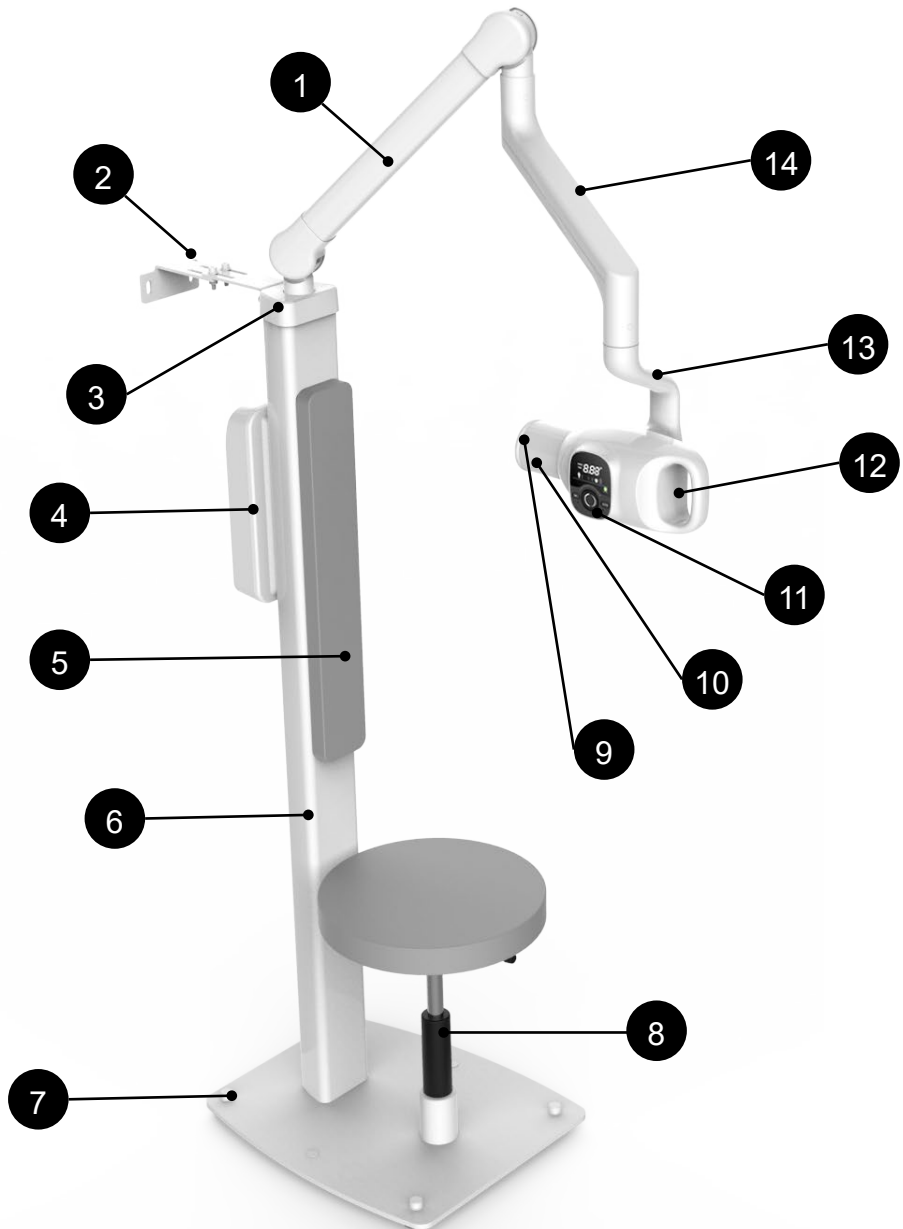
3.5 Features

EzRay Chair (Model: VEX-S300C) is a 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 | Scissor Arm Assembly | Adjusts the length and height of the entire arm by folding and unfolding the scissor arm assembly. |
| 2 | Wall Bracket Assembly | Use to fix the equipment on the wall |
| 3 | Column cap | Support the arm assembly shaft\ |
| 4 | Power Box Assembly | Controls the electrical power of the system |
| 5 | Back Cushion | Support the back of the patient |
| 6 | Column Unit | Supports the whole part of the equipment. |
| 7 | Base Unit | Balances the equipment and maintains its safety. |
| 8 | Chair | The chair is used for patient positioning |
| 9 | X-ray Generator Assembly | Includes the X-ray tube and the high-voltage generator. |
| 10 | X-ray Beam Limiting Device | Limits the X-ray exposure area. Default type: Round Cone + Round Cover (FOV: Ø 6 cm) |
| 11 | Control Panel | Display for the X-ray exposure settings and operation conditions |
| 12 | Handle | Grip the handle securely when using the system. |
| 13 | Generator Arm | Connection arm between the X-ray generator and the scissor arm assembly |
| 14 | Middle Arm | Adjust location of rotational direction |

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.) |

Available Option Items

| No. | Illustration/Photo | Option name | Usage | Material |
|-----|---|--|---|---|
| 1 |  | 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 |
| 2 |  | 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 |
| 3 |  | Rotating rectangular cover 4x3 (3x4) FOV: 4x3cm, 3x4cm (This adaptor can be used as both 4x3 and 3x4.) | Performs the same function as the Rectangular Cover. Moreover, Rectangular Cover rotates in 360 degrees and adjustable in 90-degree and 10-degree increments. | ABS (Acrylonitrile butadiene styrene) copolymer |
| 4 |  | Rotating rectangular cover 2x3 (3x2) FOV: 2x3cm, 3x2cm (This adaptor can be used as both 2x3 and 3x2.) | Performs the same function as the Rectangular Cover. Moreover, Rectangular Cover rotates in 360 degrees and adjustable in 90-degree and 10-degree increments. | ABS (Acrylonitrile butadiene styrene) copolymer |
| 5 |  | Remote Exposure Switch (Doorbell type) | Used with the standard 'Remote Exposure Switch' (only if needed) | Steel (painted) |
| 6 |  | 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 |

| No. | Illustration/Photo | Option name | Usage | Material |
|-----|---|----------------------|---|----------|
| 7 |  | 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 |

NOTICE

Refer to the **Appendix A.1 'Using the rotating rectangular cover** for instructions for use.

EzRayTM Chair

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

www.vatech.com

4. Operation

4.1 Power On/Off

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



| Symbol | Power On/Off Status |
|--------|---------------------|
| | Power On |
| ○ | Power Off |

2. The following displays light up. For further information, see 'Control Panel' on page 17.



- 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.



- When the tooth type selection area is blinking, turn the jog dial to select the tooth type. Refer to the figure below before and after selecting the control panel.





Before tooth type selection



After tooth type selection



Tooth Type

| Symbol | Type |
|---|----------------|
|  | Incisor |
|  | Canine |
|  | Molar/Premolar |
|  | Bitewing |

3. After tooth type selection, the 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 |

NOTICE

After the tooth type and patient type are selected, the 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)

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.

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 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 Sleep Mode

When the device remains inactive for 5 minutes, the system enters 'sleep mode', and all displays, except for the LEDs under the SET and AUTO buttons, are turned off as illustrated below.



NOTICE

During sleep mode, the LEDs under the SET and AUTO buttons will blink at every one second.



To leave the sleep mode, take one of the following actions:

- Press the SET button or AUTO button.
- Press or turn the jog dial.
- Move the device's head up or down.
- Press the X-ray exposure button on the device.

WARNING

Pressing the X-ray exposure button activates X-ray emission. When exiting sleep mode by pressing the button, ensure that the X-ray emitter (head) is not directed toward a person.

3. Positioning. (The following figure is an example of the maxilla incisor.)



4. 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° |

NOTICE

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

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



4.3 Sleep Mode

When the device remains inactive for 5 minutes, the system enters 'sleep mode', and all displays, except for the LEDs under the SET and AUTO buttons, are turned off as illustrated below.



NOTICE

During sleep mode, the LEDs under the SET and AUTO buttons will blink at every one second.



To leave the sleep mode, take one of the following actions:

- Press the SET button or AUTO button.
- Press or turn the jog dial.
- Move the device's head up or down.
- Press the X-ray exposure button on the device.

WARNING

Pressing the X-ray exposure button activates X-ray emission. When exiting sleep mode by pressing the button, ensure that the X-ray emitter (head) is not directed toward a person.

4.4 Positioning

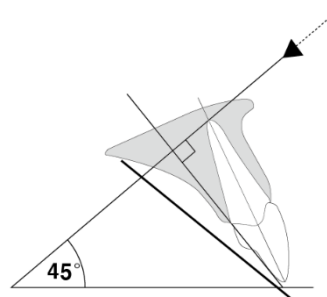
Here are the specific angulations and directions for the tube head to take the best images of a tooth (i.e., **Bisected angle technique**).



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

▪ Maxillary Incisor

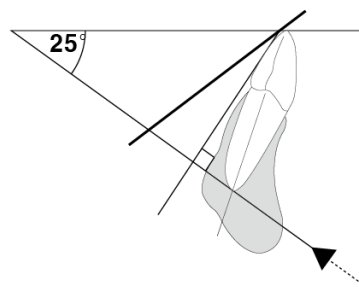
The x-ray beam is directed downward at 45°.



| Teeth | | Angle of inclination |
|---------|---------|----------------------|
| Incisor | Maxilla | +45° |

▪ Mandibular Incisor

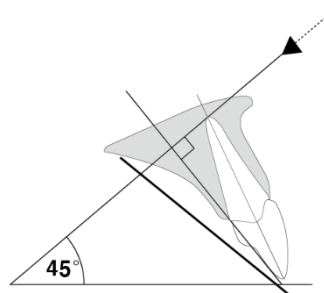
The x-ray beam is directed upward at 25°.



| Teeth | | Angle of inclination |
|---------|----------|----------------------|
| Incisor | Mandible | -25° |

▪ Maxillary Canine

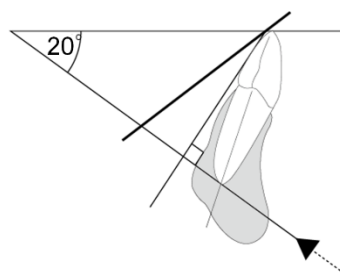
The x-ray beam is directed downward at 45°.



| Teeth | | Angle of inclination |
|--------|---------|----------------------|
| Canine | Maxilla | +45° |

▪ Mandibular Canine

The x-ray beam is directed upward at 20°.



| Teeth | | Angle of inclination |
|--------|----------|----------------------|
| Canine | Mandible | -20° |

- **Maxillary Molar and Premolar**

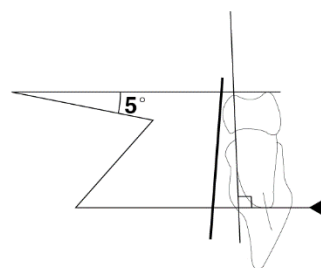
The x-ray beam is directed downward at 30°.



| Teeth | | Angle of inclination |
|--------------------|---------|----------------------|
| Molar and Premolar | Maxilla | +30° |

- **Mandibular Molar and Premolar**

The x-ray beam is directed upward at 5°.

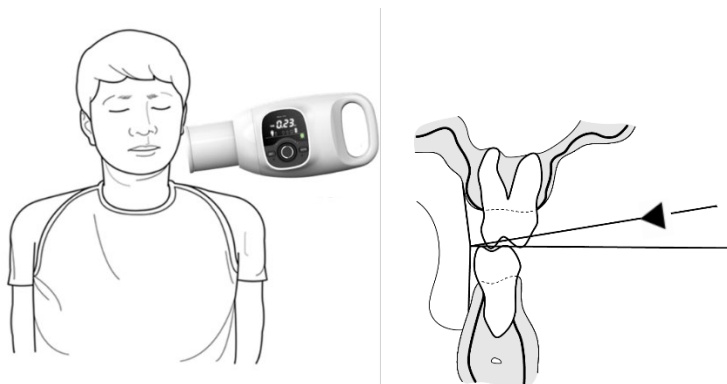


| Teeth | | Angle of inclination |
|--------------------|----------|----------------------|
| Molar and Premolar | Mandible | -5° |

▪ Bitewing

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

The x-ray beam is directed downward at $5^{\circ} \sim 8^{\circ}$.



| Teeth | Angle of inclination |
|-------------------|------------------------------|
| Bitewing exposure | $+5^{\circ} \sim +8^{\circ}$ |

Positioning the Imaging Sensor

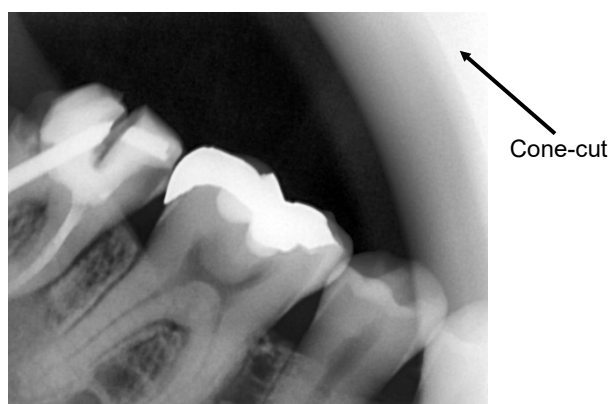
To ensure image quality, the digital imaging sensor must be positioned correctly (for information about the proper placement of the imaging sensor, please refer to 'Positioning Instructions' on page 26).

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

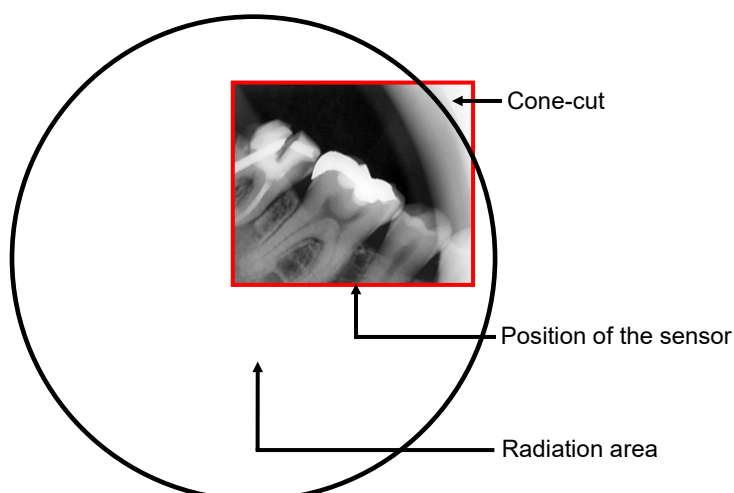
NOTICE

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 certain 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.

NOTICE

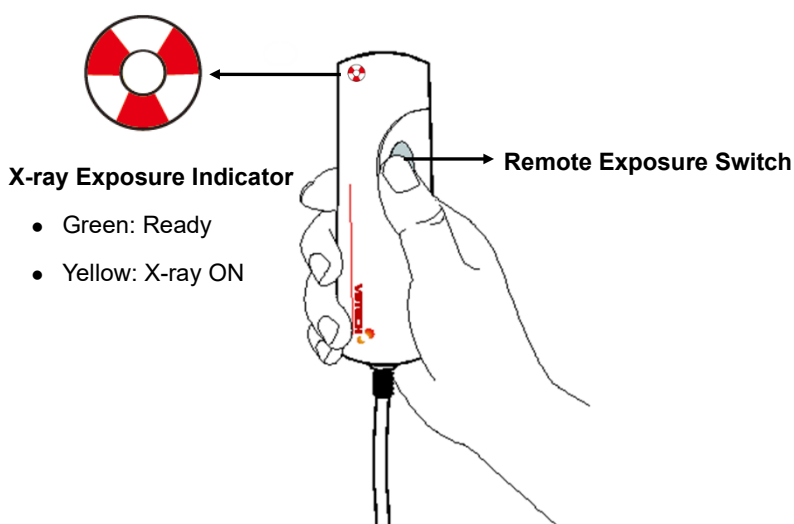
Once the PID is appropriately aligned, instruct the patient not to move.

4.5 Exposure

IMPORTANT

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



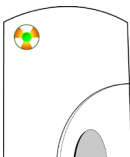
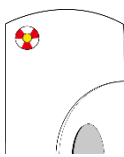
1. Instruct the patient not to move.
2. Press and hold the **Remote Exposure Switch** for exposure duration. The **Remote Exposure Switch** allows the operator to control image acquisition from outside of the X-ray room. Pressing the **Remote Exposure Switch** activates the X-ray Exposure Indicator to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



IMPORTANT

Press and hold the **Remote Exposure Switch** if 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.

NOTICE

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.


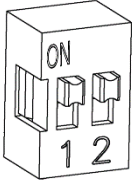


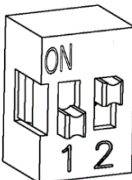
4.5.1 Remote Exposure Switch and Power Cable Connections

There are three connectors on the bottom of the Column Assembly as described below.

- **PORT 1, 2:** Remote Exposure Switch Connectors
- **POWER:** AC Power Cable Connector



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

| Option No. | Explanation DIP switch setting | Port 1 | Port 2 | Power |
|------------|---|---|---|----------------------------|
| Option 1 | Press (1). |  | Not applicable | AC power cable (option) |
| |  | (1) Remote Exposure Switch (standard) | | |
| Option 2 | Press (1). |  |  | AC power cable (option) |
| |  | (1) Remote Exposure Switch (standard) | (2) Door interlock cable (option) | |

| Option No. | Explanation DIP switch setting | Port 1 | Port 2 | Power |
|------------|---|--|--|----------------------------|
| Option 3 | Press (1). |   | Not applicable | AC power cable (option) |
| |  | (1) Remote Exposure Switch (Doorbell type) (Standard) | | |
| Option 4 | Press (1). |   |  | AC power cable (option) |
| |  | (1) Remote Exposure Switch (Doorbell type) (Standard) | (2) Door interlock cable (Option) | |
| Option 5 | Press (1), (2) simultaneously. |  |   | AC power cable (option) |
| |  | (1) Remote Exposure Switch (standard) | (2) Remote Exposure Switch (Doorbell type) (Option) | |

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5. Troubleshooting

In instances of abnormal operation, alarm/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 equipment is turned off and turned on, X-ray exposure is usually performed. |
| E.03 | | |
| E.04 | | |
| A.06 | X-ray Generator | The system needs cooling time due to continuous operation. (Duty Cycle: 1:60) This alarm clears when the system temperature goes down to normal. |
| A.07 | System | The Remote Exposure Switch has been held down. Release the switch. |
| A.08 | User | 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. |

Troubleshooting

| Problem | Cause | Solution |
|--|--|--|
| Equipment is not turned on. | The 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 | The generator is cooling. | Wait for the cooling time. (Duty Cycle: 1:60) |
| | 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. |
| | The receptor is facing the the wrong way. | Reposition the receptor. |
| X-ray emission works, but the exposure is too dark. | Exposure time is too long. | Decrease the exposure time. |

6. User Maintenance

For your equipment will operate as efficiently as possible, it is recommended that you perform the following procedures for your routine maintenance activities.

Maintenance Task Checklist



WARNING

Always turn off the equipment before performing any maintenance.

| Tasks | Period |
|--|---------|
| Sterilize all components that meet 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 |



WARNING

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



CAUTION

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

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7. Cleaning and Disinfection

7.1 Cleaning



Before cleaning, turn off the device for your safety.

When selecting a cleaner to clean the device, follow the cautions below:

- Your cleaner may contain powerful chemicals that could harm the equipment and the user's health. Verify the cleaner ingredients before using it.
- Do not use cleaners or disinfectant agents containing Phenol, acetic acid, peroxide, or other oxygen splitting agents, sodium hypochlorite, isopropyl alcohol(2-propanol, isopropanol) or iodine-splitting agents.
- Use cleaners or disinfectant agents that are alcohol-free and non-corrosive.

When cleaning the device, follow the precautions below:

- Wear safety gloves when handling cleaning or disinfectant agents.
- Before using chemicals, gently wipe away dust and dirt using a soft and lint-free cloth.
- Follow the provided instructions for the cleaning or disinfectant agent.
- Ensure that cleaning or disinfectant agent does not enter the device.
- Avoid directly spraying the cleaning or disinfectant agent onto the device. Always apply the agent to a clean cloth and gently wipe the device with it.
- Do not use sponge to clean the device.

7.2 Disinfection



Before disinfecting, turn off the device for your safety.

When disinfecting the device, follow the precautions below:

- Use disinfectants that comply with the regulations and requirements of the country where the device is used or those that have been verifiably tested and approved for their bactericidal, fungicidal, and virucidal properties.
- Sterilize and disinfect the device parts and its accessories that frequently come into contact with patients and operators.
- Avoid using UV systems to disinfect the device as this can cause discoloration.
- Using unsuitable cleaning or disinfectant agents and procedures can damage the device and its accessories.
- Avoid mixing different cleaning or disinfectant agents when cleaning the device as this can lead to damage.
- Use a non-alcoholic, chlorine dioxide-based disinfectant.

8. Disposing of the Unit

This equipment is designed to be as safe as possible to reduce environmental pollution. Many components of this equipment are environment-friendly and can be recycled.

All parts and components that contain hazardous materials must be disposed of by 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 | | | • | |

IMPORTANT

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



This symbol on the product and accompanying documents mean 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

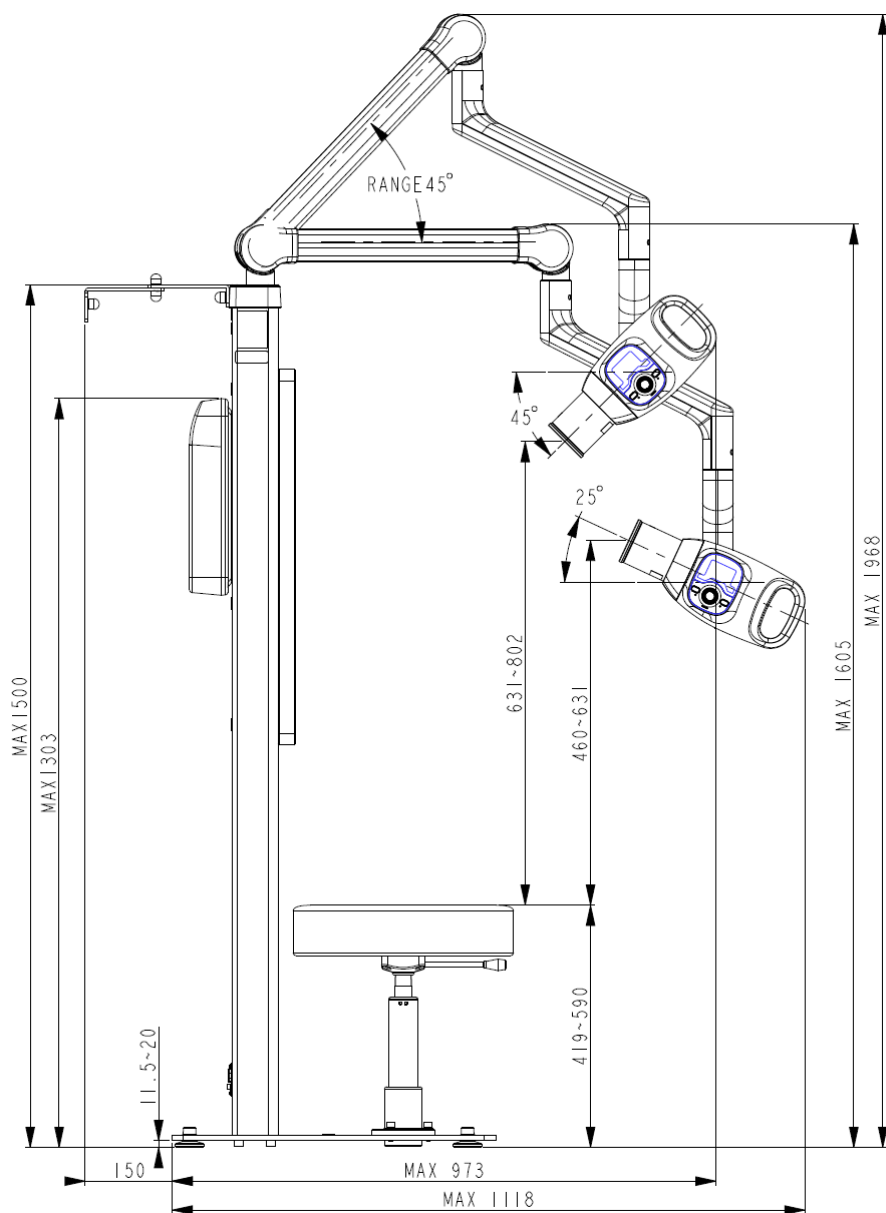
This symbol is only valid in the European Union (EU). If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

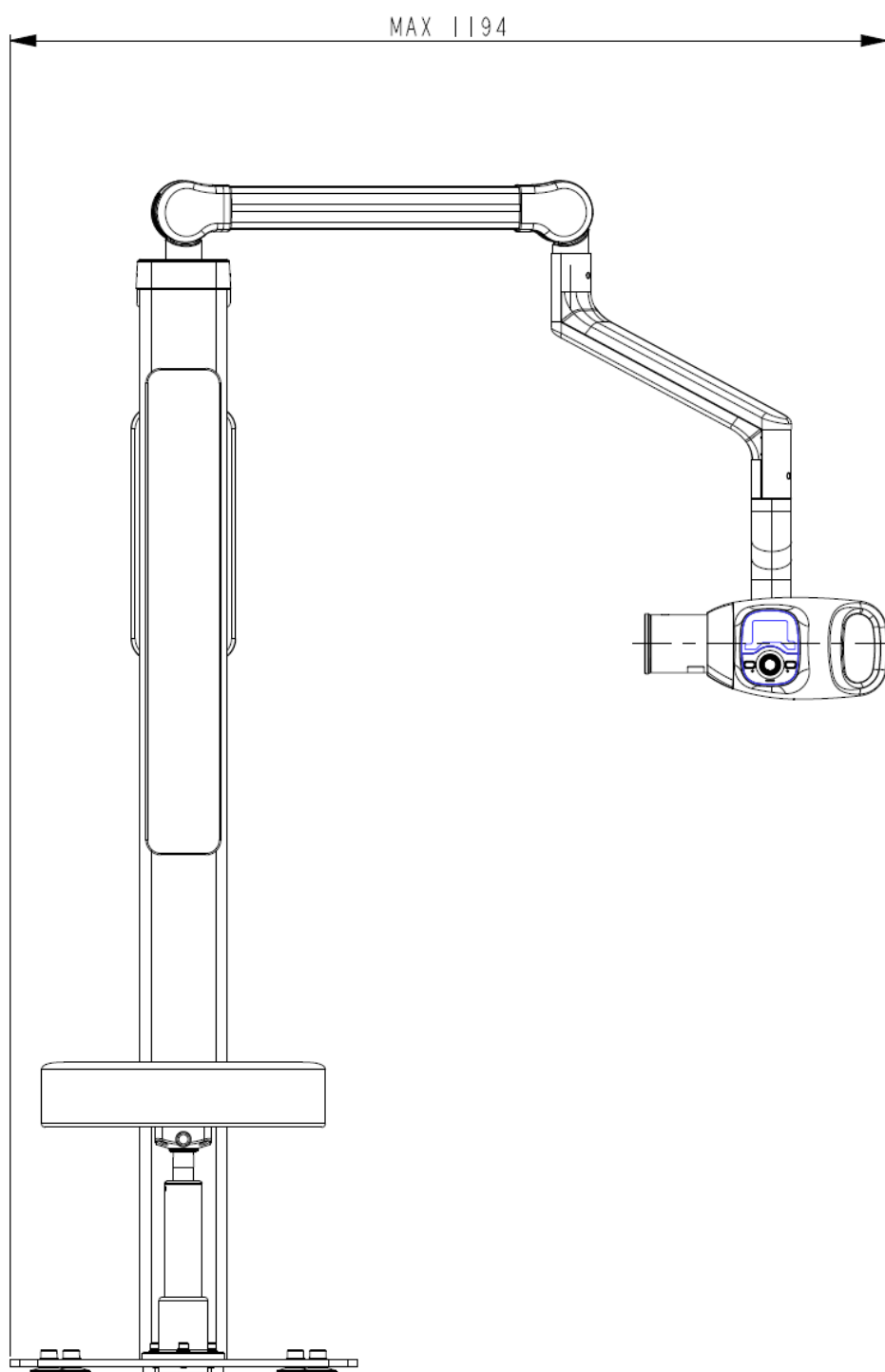
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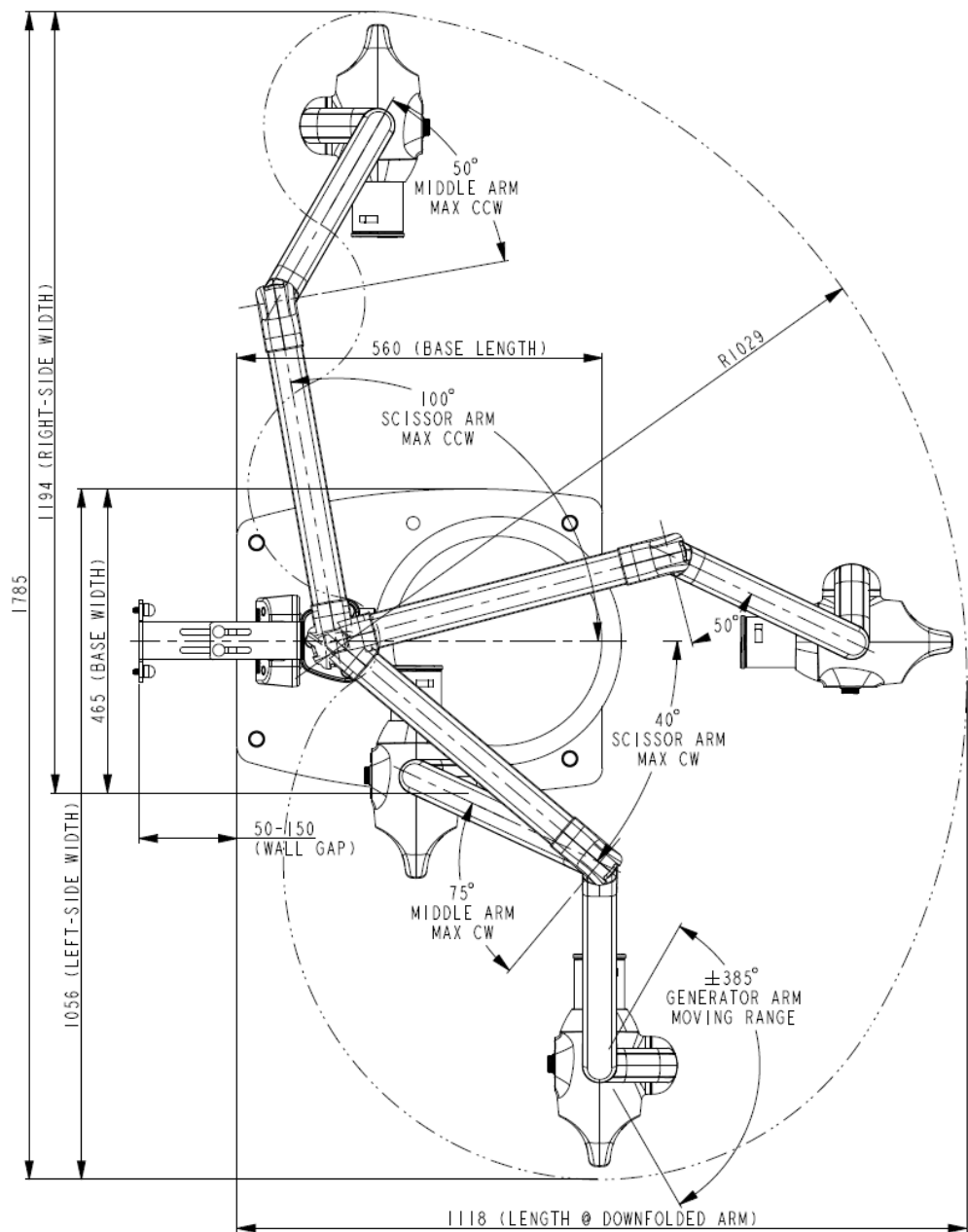
9. Product Specifications

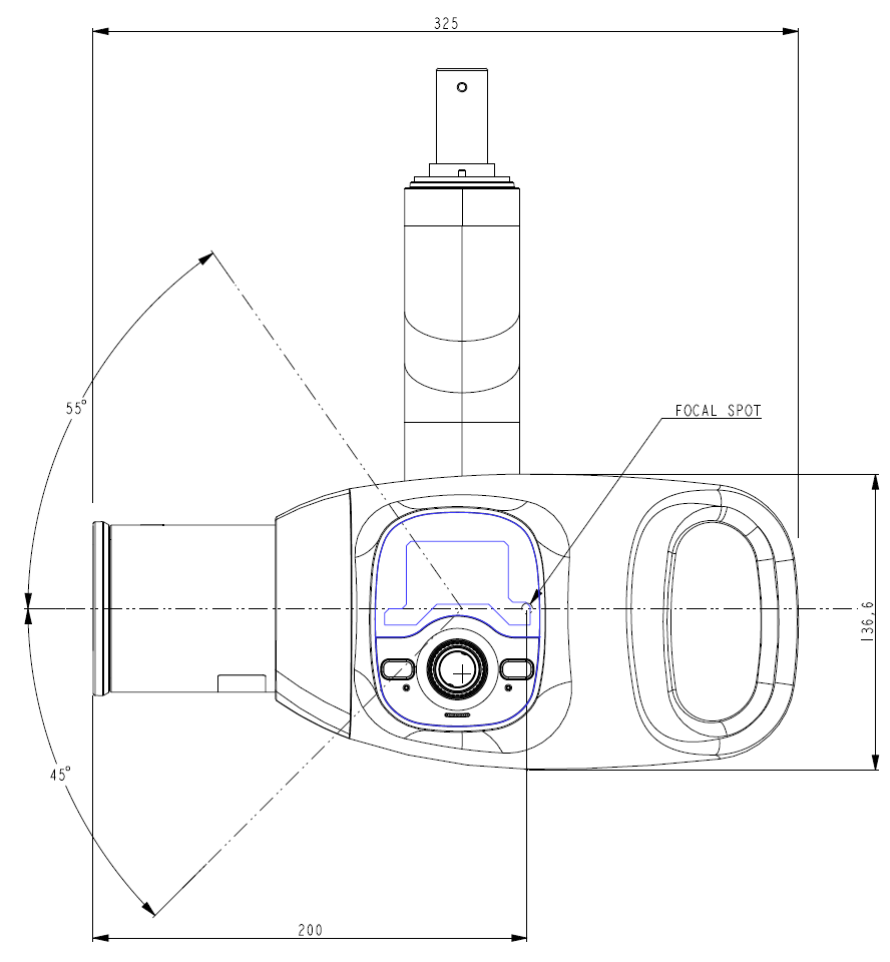
9.1 Mechanical Specifications

Dimensions









9. Product Specifications

| Item | | | Dimension (mm) | Weight (kg) |
|--------------------------------|--|-----------------------------|---|----------------|
| Total Assembly | With upstretched Scissor Arm | | Max 973(L) x 1968(H) | 41.5 |
| | With downfolded Scissor Arm | | Max 1116(L) x 1659(H) | |
| | With right-sided Scissor Arm | | Max 1192(W) | |
| | With left-sided Scissor Arm | | Max 1054(W) | |
| | Max Rotational Radius @ Column Center | | Max 1026(R) | |
| Base Assembly | | | 465(W) x 589(L) x 1500(H) | 31 |
| Arm Assembly (Released Status) | | | 845(L) x 694(H) | 7.8 |
| Power Box Assembly | | | 140(W) x 73(L) x 340(H) | 1.7 |
| X-ray Generator Assembly | | | 194(W) x 325(L) x 324(H) | 2.7 |
| X-ray Beam Limiting Device | X-ray Beam Area (mm) | Round type | ø80.15 x 7.7(T) FOV: < ø 60mm | 0.013 |
| | | Rectangular type (Optional) | ø80.15 x 10.2(T) FOV: 20 x 30mm (30 x 20), 40 x 30mm (30 x 40) | 0.038 0.044 |
| | | | SSD(Source to Skin Distance) | |

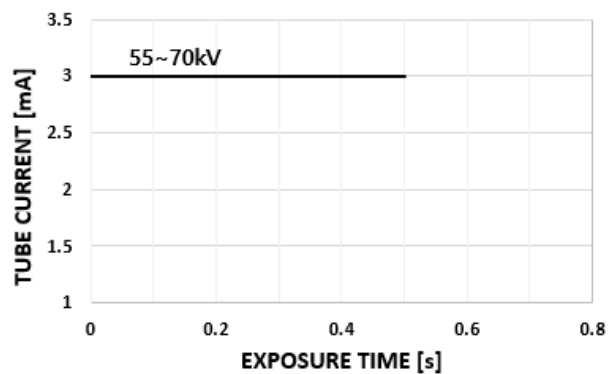
9.2 Technical Specifications

X-ray Generator

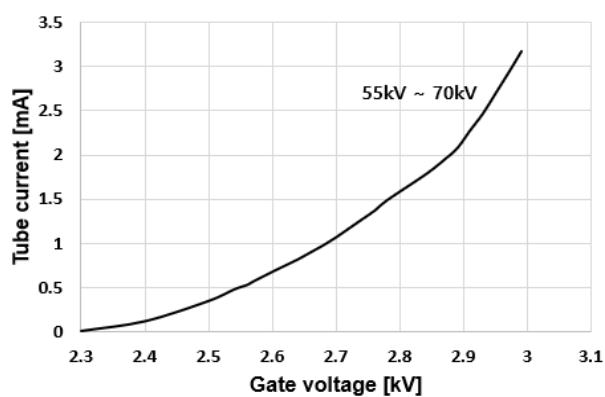
| | Item | Description |
|--------------------------------------|--------------------------------|--|
| High Voltage Generator (Assembly) | Model | DG-S0102V1 |
| | Rated output power | Max. 0.2 kW |
| | Duty Cycle | 1:60 or more (Exposure time: Interval time) |
| | Cooling Protection | Thermistor $\geq 65^{\circ}\text{C}$ |
| | 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 |

X-ray Tube Characteristics

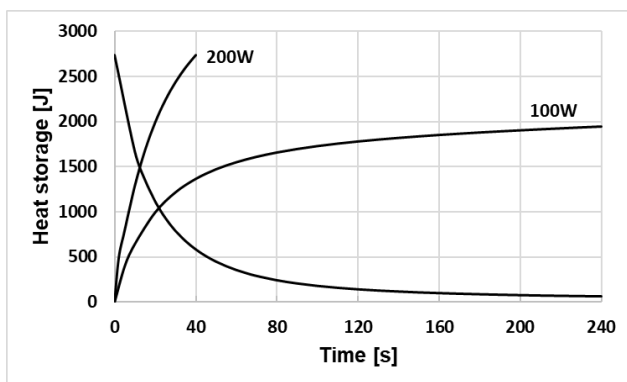
1) Maximum rating chart



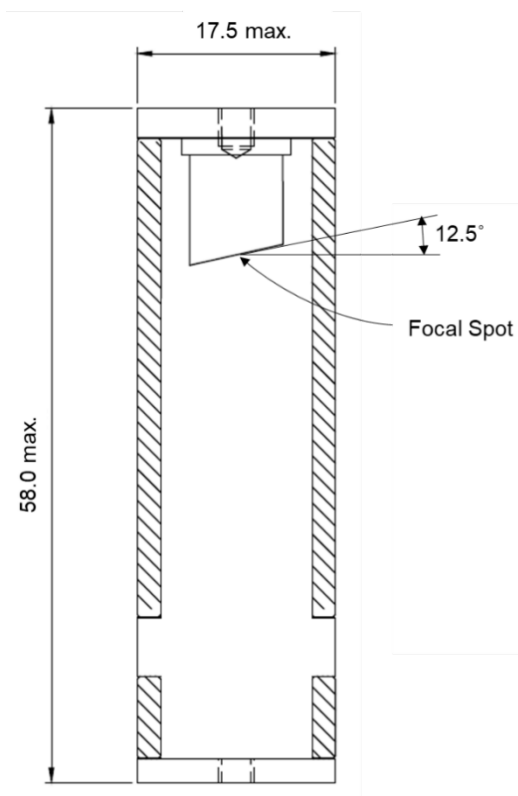
2) Emission characteristics



3) Heating and cooling curves of the X-ray tube



4) Tube Dimensions [mm]



9.3 Electrical Specifications

| Item | Description |
|----------------------|--|
| Power Supply Voltage | 100-240 V ~ |
| Frequency | 50/60 Hz (Single phase) |
| Power Rating | 4-2 A |
| Tube Voltage | 65 kV fixed ($\pm 3\%$) |
| Tube Current | 3.0 mA (fixed) |
| Accuracy Error | < kVp +10 %, < mA + 20 %, < s $\pm 5\%$ or 20 ms |

- The input line voltage depends on the local electrical distribution system.
- Allowable input voltage fluctuation requirement: $\pm 10\%$
- Mode of operation: Continuous operation with cyclic 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

NOTICE

- To ensure line voltage quality, you must use a separate 3-core grounded power cable directly connected to the central distribution panel with a 10 A class overcurrent breaker.
- The mains resistance should not exceed $0.5\ \Omega$.

NOTICE

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

NOTICE

Power Supply is specified as a part of ME EQUIPMENT.

NOTICE

Power plugs may have various specifications for each country.

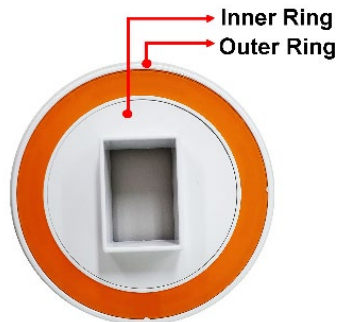
9.4 Environmental Specifications

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

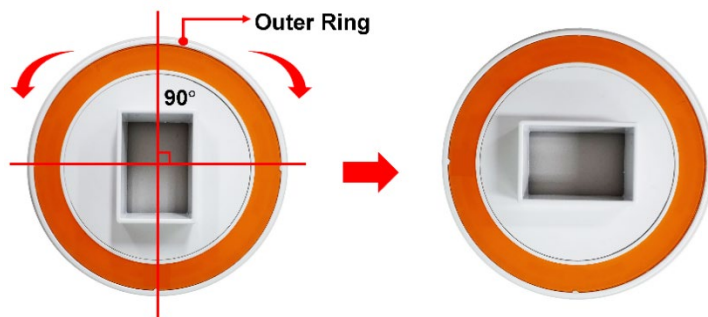
Appendix

A.1 Using the rotating rectangular cover

The rotating rectangular cover rotates 360 degrees. The cover consists of the outer and inner rings as illustrated below.

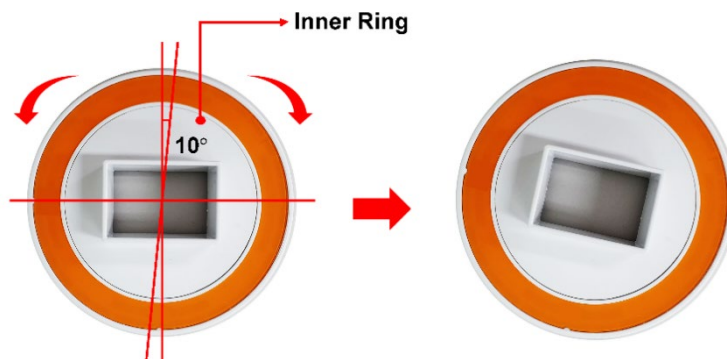


The outer ring rotates in 90-degree increments.



IMPORTANT

The inner ring rotates in 10-degree increments.



To use the rotating rectangular cover:

1. Assemble the rotating rectangular cover to the device's cone.

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

Disassembling rotating rectangular cover is the same as the assembly method. Refer to the NOTE mentioned below stage 1.

A.2 Tables of Exposure Times (Default)

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 inch) respectively.

| Receptor | Patient | Teeth | Angle of inclination | SSD: 200 mm (8 inch) | | |
|---|--|---|---------------------------------|----------------------|-----|------|
| | | | | kV | mA | s |
| Sensor  | Adult  | Incisor  | Maxilla: +45° Mandible: -25° | 65 | 3.0 | 0.14 |
| | | 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 |
| | Child  | Incisor  | Maxilla: +45° Mandible: -25° | 65 | 3.0 | 0.11 |
| | | Canine  | Maxilla: +45° Mandible: -20° | 65 | 3.0 | 0.13 |
| | | Molar/ Premolar  | Maxilla: +30° Mandible: -5° | 65 | 3.0 | 0.15 |
| | | Bitewing  | +5° ~ +8° | 65 | 3.0 | 0.16 |

A.3 X-ray Dose Data

The X-ray dose data is extracted from the X-ray Dose Test Report for the EzRay Chair (VEX-S300C). The IEC collateral standards have measured the X-ray doses of EzRay Chair (VEX-S300C) in the test report. The EzRay Chair (VEX-S300C) has been designed by Part 1. General Requirements for Safety, IEC 60601-1-3.

| Test Condition | |
|----------------------|----------------------------|
| Model Name | EzRay Chair (VEX-S300C) |
| Tube Model Name | V1-650304 |
| Generator Model Name | DG-S0102V1 (Inverter type) |
| Loading Factor | 65 kV, 3.0 mA |

A.3.1 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, 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 |

A.3.2 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 any area of 100 cm² 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.

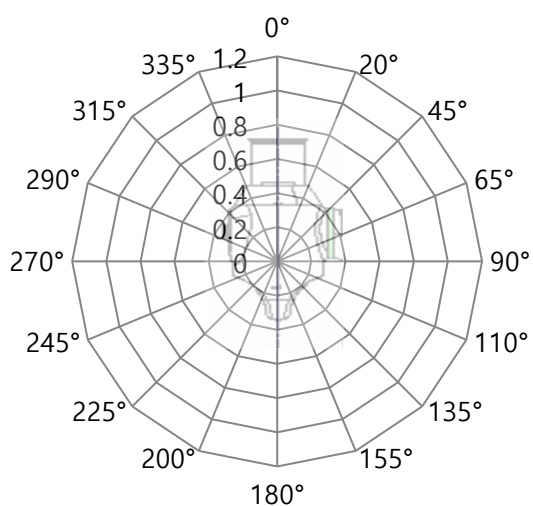
| Leakage Dose | Permissive Range |
|---|------------------|
| 65 kVp, 3.0 mA, 0.5 s (Max. Exposure Condition) At Focal Spot to Distance 1 m Duty Cycle 1 : 60 | < 0.2 mGy/h |

Results

The following exposure timetables 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).

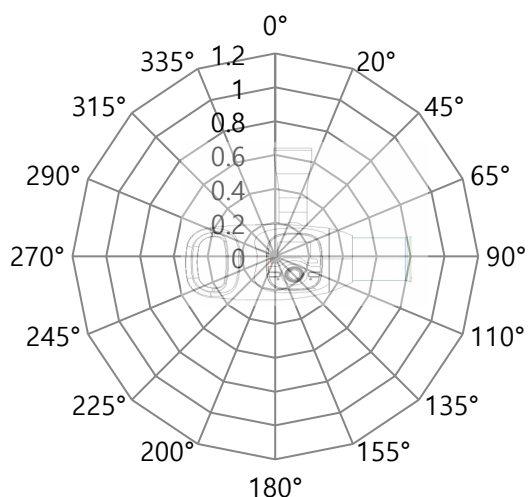
The raw data about the results are shown in the following table.

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

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

A.3.3 Scattered Dose

Scope

IEC 60601-2-65 203.13

Requirements

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

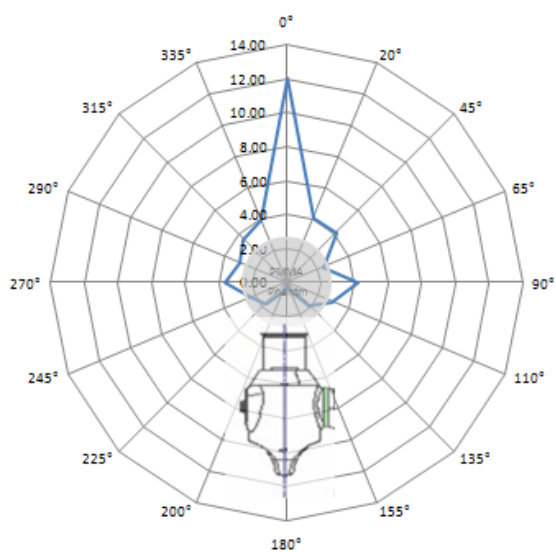
Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

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 inch) respectively.

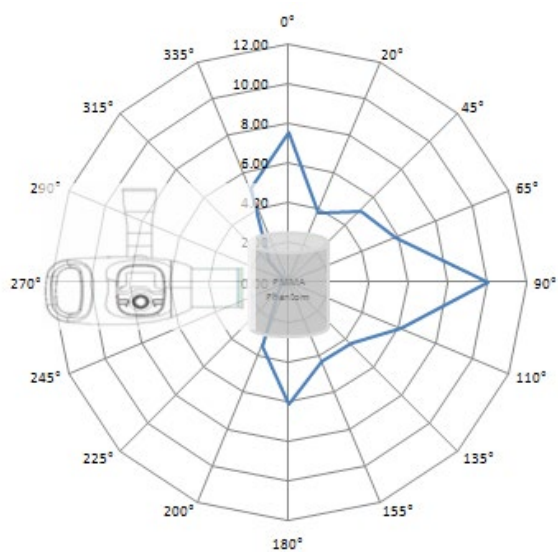
| Method |
|--|
| PMMA Phantom aligned to 280 mm away from Focal Spot (with Position Indicating Device (80 mm)) 65 kVp, 3.0 mA, 0.5 s (Max. Exposure Condition) Measure point: 2,000 mm from PMMA Phantom |

The 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 |

The 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.4 Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions

The EzRay Chair (VEX-S300C) is intended for use in the electromagnetic environment specified below. The customer or the user of the EzRay Chair (VEX-S300C) should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|--|------------|--|
| RF emissions CISPR 11 | Group 1 | The EzRay Chair (VEX-S300C) 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 EzRay Chair (VEX-S300C) 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. |
| Harmonic emissions IEC 61000-3-2 | Applicable | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Applicable | |

NOTE) It is essential to check the actual RF shielding effectiveness and filter attenuation of the shielded position to ensure that it meets or exceeds the specified minimum.

Guidance and manufacturer's declaration - electromagnetic immunity

The EzRay Chair (VEX-S300C) is intended for use in the electromagnetic environment specified below. The customer or the user of the EzRay Chair (VEX-S300C) 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 EzRay Chair (VEX-S300C) image intensifier is to continue to operate during mains interruption, it is recommended that the EzRay Chair (VEX-S300C) be powered from the 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 before application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The EzRay Chair (VEX-S300C) is intended for use in the electromagnetic environment specified below. The customer or the user of the EzRay Chair (VEX-S300C) 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 EzRay Chair (VEX-S300C) 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. 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 to verify that the actual shielding effectiveness of the shield position and filter attenuation meet the minimum specifications.

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. Electromagnetic field studies should be considered to evaluate the electromagnetic environment caused by fixed RF transmitters. If the measured field strength outside the shielded location in which the EzRay Chair (VEX-S300C) is used exceeds 3V/m, the EzRay Chair (VEX-S300C) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the EzRay Chair (VEX-S300C) or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

A.5 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 |

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This CE symbol indicates that this product complies with the European Directive for Medical Devices Directive 93/42 / EEC as amended by the IIb device by 2007/47 / EC.



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