

Green X™

User Manual  
English v1.26



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Green X™

User Manual

English

Green X™

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## Notice

Thank you for purchasing the **Green X™ (Model: PHT-75CHS)** extra-oral imaging system.

**Green X™ (Model: PHT-75CHS)** is one of the manufacturer's Green CT product series for aiding dental professionals in providing excellent care in a safe environment that promotes healing.

**Green X™ (Model: PHT-75CHS)** is an advanced digital diagnostic system that incorporates PANO, CEPH (Optional), CBCT, and 3D MODEL Scan imaging capabilities into a single system.

This manual describes how to operate the **Green X™ (Model: PHT-75CHS)** system. You must thoroughly familiarize yourself with this manual to effectively use this equipment.

Observe all cautions, safety messages, and warnings in this manual.

Due to constant technological improvement, the manual may not contain the most updated information and is subject to change without prior notice to the persons concerned. For further information not covered in this manual, please contact us at:

**VATECH Co., Ltd.**

**E-mail:** [gcs@vatech.co.kr](mailto:gcs@vatech.co.kr)

This document is originally written in English.

**Green X™ (Model: PHT-75CHS)** is referred to as “equipment” in this manual.

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# 1. Introduction

## 1.1 Overview

**Green X™ (Model: PHT-75CHS)** is an advanced 4-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), CBCT, and 3D MODEL Scan imaging capabilities into a single system.

**Green X™ (Model: PHT-75CHS)**, a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography, **Green X™ (Model: PHT-75CHS)** is a complete digital X-ray system equipped with imaging viewers, an X-ray generator, and a dedicated SSXI detector.

The digital CBCT system is based on a CMOS digital X-ray detector. The CMOS CT detector is used to capture 3D radiographic images of the head, neck, oral surgery, implant, and orthodontic treatment.

**Green X™ (Model: PHT-75CHS)** can also acquire 2D diagnostic image data in conventional panoramic and cephalometric modes.

## 1.2 Intended Purpose (Indications for Use)

**Green X™ (Model: PHT-75CHS)** is intended to produce panoramic, cephalometric, or 3D digital x-ray images. It provides diagnostic details of the dental-maxillofacial, sinus, TMJ, and ENT for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.



It enables:

- Determination of the extent of lesions, tumors, cysts, etc., which cannot be adequately visualized on plain films.
- Diagnosis of foreign bodies or displaced roots involving the maxillary sinus
- Diagnosis of bone diseases, cysts, etc., affecting the temporomandibular joints
- Identifying the relationship of the inferior dental canal to a tooth/lesion that is to be removed
- Assessment of fractures on the maxilla, mandible, condylar neck, and fractures of teeth where plain film imaging is equivocal.
- Visualization of the 3D anatomy of the alveolar clefts
- Diagnosis of un-erupted teeth impacted teeth and odontomas.
- Diagnosis of root resorption of teeth
- Assessment of the cleft palate
- Diagnosis of CRS (chronic rhinosinusitis)
- Assessment of complex root canal anatomy
- Diagnosis of Periapical Pathology
- Diagnosis of vertical root fracture
- Examinations of the airways for measuring the volume and dimensions of air passages
- Planning any surgery where a 3D analysis of the jaw is required.
- Storing Plaster Casts in 3D data

### 1.3 Intended User Profiles

Considerations	Requirement Description
Qualification	<ul style="list-style-type: none"> <li>Legally qualified persons such as dentists and healthcare professionals for X-ray device operation</li> </ul>
Knowledge	<ul style="list-style-type: none"> <li>Understanding the treatment and diagnosis of dental disease</li> <li>Understanding the terms and guidance of hardware and software of a diagnostic medical radiation device and recognizing device connection, installation, and operating conditions</li> </ul>
Language understanding	<ul style="list-style-type: none"> <li>Understanding how to use manuals (English/Korean) or</li> <li>Understanding other languages provided</li> </ul>
Experience	<ul style="list-style-type: none"> <li>Understanding the objectives and effects of the diagnosis and treatment of dental disease using diagnostic medical radiation devices</li> <li>Understanding of the normal operation of diagnostic medical radiation equipment</li> <li>Understanding the contents of the <b>User Manual</b></li> </ul>

#### **IMPORTANT**

Only qualified personnel such as dentists, dental hygienists, or radiologists can use X-ray devices.

### 1.4 Contraindications

DO NOT use this device other than the intended purpose.

There are no other contraindications to it since the technology is at a controllable level in accordance with global standards. It can be used on adult and pediatric patients, but infants (1 month to 2 years) are excluded.

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## 2. General Information

### 2.1 Manufacturer's Liability

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






- A **VATECH**-authorized technician has installed the equipment.
- The equipment has been installed following all the cautions and according to the required conditions.
- **VATECH**-approved equipment and components have always been used.
- A **VATECH**-authorized agent has performed all maintenance and repairs.
- The **user manual** has typically used the equipment.
- The equipment damage or malfunction is not the result of an error on the part of the owner or the operator.

### 2.2 Owner and Operator's Obligations












- The owner of this equipment shall perform constancy tests at regular intervals to ensure patient and operator safety. Local X-ray safety regulations must perform these tests.
- 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 12: Cleaning and Disinfection**.

## 2.3 Conventions in This Manual









The following conventions are used in this manual to inform users. Ensure to understand the meaning of each convention and follow accompanying instructions.

 <b>WARNING</b>	<b>WARNING</b>	Failure to comply with the given information may result in severe injuries to the people or damages to the equipment.
 <b>CAUTION</b>	<b>CAUTION</b>	Requires the user's immediate attention or action due to the possibility of safety issues.
<b>IMPORTANT</b>	<b>IMPORTANT</b>	Requires the user's attention because the stated action and environment may cause trouble.
<b>NOTICE</b>	<b>NOTICE</b>	Indicates useful information for users.
	<b>RADIATION</b>	Indicates a possible danger from radiation exposure.
	<b>SINGLE-USE</b>	Indicates a component that must be replaced for each new patient.
	<b>ESD susceptibility</b>	Indicates that an item is susceptible to damage from electrostatic discharges.

## 2.4 Marks and Symbols

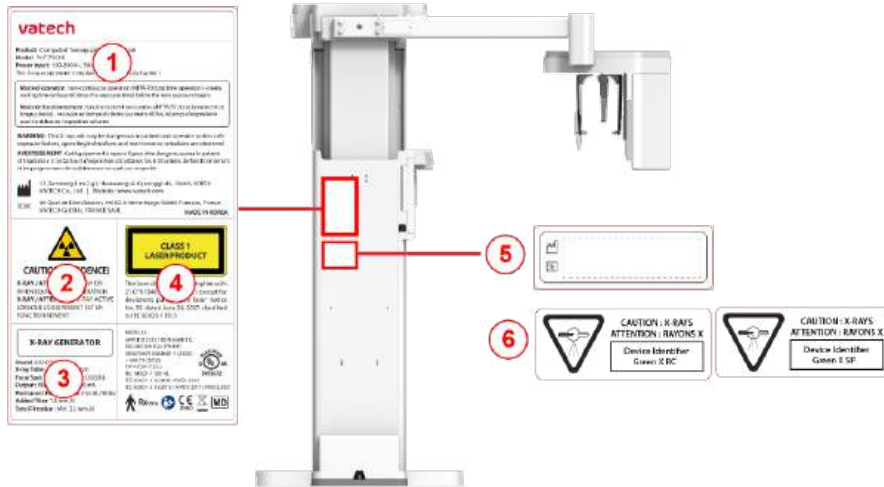
Symbols	Description	Location
	Dangerous voltage	Powerboard /Inverter board /Monoblock
	Protective earth (Ground)	Column
	Off (power: disconnected to the <b>Main Power Switch</b> )	Main Power Switch
	On (power: connected to the <b>Main Power Switch</b> )	Main Power Switch
	Alternate Current	Label
	Type B Applied Equipment (IEC 60601-1: Degree of protection against leakage current and electric shock: Class 1 equipment)	Label
	Radiation hazard	Label
	Indicates the authorized representative in the European Community.	Label
	The CE symbol indicates that this product complies with the European Regulation for Medical Devices Regulation 2017/745 as a class IIb device.	Label
	UL mark No. E476672	Label
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Label

## 2. General Information

Symbols	Description	Location
	Addresses where the equipment was manufactured.	Label
	Indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Label
	Warns ESD hazard.	MCU board / Board package
	Indicates that this equipment is classified as a CLASS 1 LASER PRODUCT by IEC 60825-1 ED. 3 regulations.	Label
	Indicates that the user needs to refer to the <b>User Manual</b> .	Label
	Indicates the date of manufacture.	Label
	Indicates the manufacturer's serial number to identify the specific equipment.	Label
	Indicates the device is a medical device	Label

### 2.4.1 Label Locations

The label is attached on the right side of the equipment, and it consists of 5 parts, as below.



No.	Item
1	<b>Main Label</b>
2	<b>CAUTION Label</b> - X-ray / Attention: X-ray is on when equipment is in operation.
3	<b>X-RAY GENERATOR Label</b> : 1.6 kW Generator
4	<b>CLASS 1 LASER PRODUCT Label</b>
5	<b>Manufacturer Label</b> : The date of manufacture / Serial Number
6	<b>Device Identifier Label</b> <ul style="list-style-type: none"> <li>• Green X RC: CEPH included.</li> <li>• Green X SP: CEPH not included</li> </ul>

### NOTICE

The design and contents of the labels may be different in some countries based on local regulations and standards

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## 3. Warnings and Precautions

### 3.1 General Safety Guidelines

#### Operator Qualifications

This equipment must be operated by a qualified person who is trained in proper operating procedures and satisfies the following qualifications:

- Read and understand the **user manual**.
- Have full knowledge of the structure and functions of the equipment.
- Recognize problems in the equipment and implement appropriate solutions to resolve the issues.

#### General Safety Precautions

- Follow the instructions specified in this manual to ensure the safety of both the patient and the operator.
- The operator must always maintain vocal/visual contact with the patient during imaging.
- Do not open or remove the cover panels on this equipment. Always have a trained and authorized service technician to inspect and maintain this equipment.
- Do not place any heavy objects on this equipment at any time.
- Do not place any objects within this equipment's field of operation. It may cause property damage.
- Ensure to install equipment with a wall bracket or other connecting parts. Both operators and patients can receive injuries from the equipment tip-over if it is not securely mounted to the wall or the floor.
- The operator must instruct the patient to remain still until the equipment arm has stopped moving and the reset motion is completed.
- Observe all local fire regulations. Always keep a fire extinguisher near the equipment.
- The operator of this equipment must be familiar with this equipment's emergency protocols.
- Ensure to keep this equipment away from water, moisture, or foreign substances. This equipment is an IPX0 device and is not intended to be used near liquids.
- Ensure that liquid does not enter the equipment when you are taking an X-ray image of the patient who has the following conditions:
  - The patients with a urinary catheter (drainage bag)

### 3. Warnings and Precautions

- Patients who have implants or underwent oral anesthesia or other procedures can cause drooling during the imaging procedure.
- If this equipment is exposed to water, moisture, or a foreign substance, turn off the equipment and contact your **VATECH** technical support representative.
- If there is a sign of oil leakage, stop the equipment immediately and contact your **VATECH** technical support representative.
- The external parts connected to the outside of equipment such as cables must comply with relevant IEC Standards. (e.g., IEC 60950 for IT equipment and IEC 60601-1 series for medical electrical equipment)
- Likewise, these parts must comply with IEC 60601-1, IEC 60601-1-1, and the national regulations of the country where the equipment is installed. Please contact **VATECH** or its area representative if you have questions.
- Any person or organization that installs an external door interlock switch is responsible for ensuring that it has a radiation indicator or equivalent alarm system to show the state of the current.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user or patient is established.

#### Ventilation

- Do not block the equipment's ventilation slot. Blocking the slot may lead to overheating and equipment malfunction.
- Do not spray a cleaning product into the ventilation slot. The air-sprayed liquid may damage the electrical and mechanical components inside. Use a soft cloth to disinfect the ventilation slot.
- Leave enough space around the PC system to avoid overheating.



Follow all the manual's warnings and safety instructions to ensure a safe operation.



Follow precautions and conduct regular inspections to work safely around the X-ray equipment. Ignoring the precautions may endanger both patients and operators.

## Hygiene



Turn off the equipment before you start cleaning.



Do not use a spray-type cleaner on the equipment. Spraying liquids may cause a fire and bring other damage to the equipment.

- Clean the handle frame with a non-alcoholic product when the patient leaves the X-ray room.
- Clean the removable accessories that directly contact the patients, such as the bite and temple support, using a non-alcoholic product.
- Clean the equipment's surface with a soft fabric damped in a non-alcoholic product.
- Always provide a new sanitary vinyl cover for each patient to prevent transmissible diseases.



- When the sanitary vinyl covers provided by VATECH runs out of stock, contact the manufacturer.
- If you use sanitary vinyl covers provided by a 3<sup>rd</sup> party, ensure that the product conforms to one of the following standards:
  - ISO 10993-1 (Biological Evaluation of Medical Devices)
  - FDA
  - CE
  - Local regulations in your area

## Condensation

- Condensation can occur inside the equipment when the temperature difference is great between the outside and inside of the X-ray shielding room where the equipment is installed. To avoid condensation, store the equipment at room temperature.

## Cooling

- Allow the X-ray tube to cool down before starting the next X-ray exposure. The continuous operation without a cooling time may cause an overload.
  - **Mode of operation:** non-continuous operation (NFPA 70: long time operation) - needs waiting time (at least 60 times the exposure time) before the next exposure begins.
  - **Column operation time:** Max. 2 min. On / 18 min. Off (Ratio 1:9)

### 3. Warnings and Precautions

- The X-ray exposure stops, and an error message is displayed on the control panel when the tube head temperature rises to 60 °C (140 °F). The equipment starts working again when the tube head temperature drops to 58 °C (136.4 °F).

#### Turning the Equipment On / Adjusting Equipment's Height

- Ensure that the patient does not stand near the equipment when the staff is turning on the system or adjusting the equipment's height to avoid injuries from the rotating unit or vertical frame's movement.

#### Conducting Emergency Stop

- Press the **emergency stop switch** when you detect a problem with the equipment during the operation. The equipment stops as you press the switch. The emergency stop switch is located under the handle frame. If the problem is resolved, turn the switch in the direction of the arrow to reboot the system.

#### Trouble-Free Operation

- Never use this equipment in an environment that is susceptible to explosion.
- Always operate the equipment within a temperature range of 10 °C to 35 °C (50 °F to 95 °F) for safe operation. Image quality may deteriorate if the equipment is operated outside of this range.
- Always allow the equipment enough time to warm up (while switched on) if exposed to temperatures below 10 °C (50 °F).
- Only perform X-rays of patients if the system is in full working order.
- Always ensure that equipment movement is not obstructed by the patient's clothing, a medical device (such as a wheelchair), or the patient.
- Do not leave the patient unattended around the equipment.
- Remove all radio-controlled devices, mobile phones, etc., from the X-ray room before image acquisition, as these objects may cause the equipment to malfunction.

#### Modifying the Equipment

- Modifying the equipment in any way that may affect the safety of the operator, patients, or other persons is prohibited.
- No part of this equipment is serviceable by the operator. A **VATECH**-qualified service technician must perform all maintenance and repair of this equipment.
- This product may only be operated with original **VATECH** accessories or third-party accessories expressly approved by **VATECH**.

## 3.2 Electricity-related Safety Precautions



To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

- Check the status of the power source, PC, and cables before operating the equipment.
- Ensure that **the main power switch** is turned off when the equipment is not used.
- Always disconnect the power supply before cleaning the equipment.
- Always keep electrical cords away from hot appliances or radiators.
- Do not place the PC or peripheral equipment connected to the PC near the patient.
- The equipment and PC should be connected to a common protective earth.
- Never overload the equipment's circuit by sharing it with too many appliances.
- PC must be used outside the patient environment, such as the X-ray room.

### Combining this equipment with other devices

- Do not connect this equipment to devices that are not designated as a part of the system.
- Do not connect this equipment to a Multiple Portable Socket-Outlet (MPSO) or extension cord, which is not provided with the equipment.

### Electromagnetic compatibility

- This X-ray equipment complies with IEC standard 60601-1-2.
- Medical electrical equipment is subject to special Electromagnetic Compatibility (EMC) preventive measures. It must be installed and operated as specified in EMC information.
- If high-voltage, radio link, or MRI systems are located within 5 m of the unit, please observe the specifications stated in the installation requirements.
- Portable Radio Frequency (RF) communications equipment may interfere with medical electrical equipment. Therefore, mobile wireless phones in medical offices or hospital environments must be prohibited.
- For more details, refer to **16.3 Electromagnetic Compatibility (EMC) Information**.
- Please also observe the Electro-Static Discharge (ESD) protective measures described.

#### **Static Discharge**

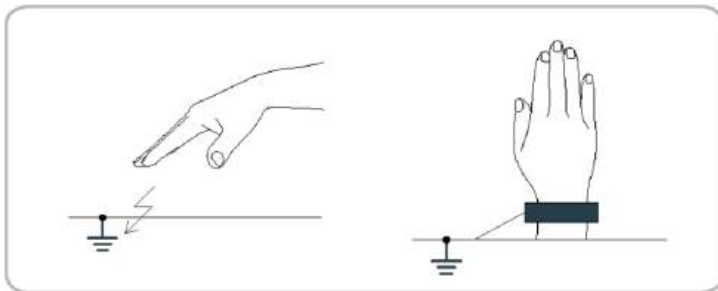
- Without observing ESD protective measures, connector pins or sockets bearing ESD warning labels must not be touched or interconnected.



Electrostatic discharge (ESD)

#### **ESD protective measures include**

- Procedures for preventing electrostatic charge build-up (e.g., temperature control, humidification, conductive floor coverings, and non-synthetic clothing)
- Electrostatic discharge of your own body with the frame of the equipment, the protective ground wire, or large metallic objects
- Use of the wristband for grounding



### 3.3 Radiation Safety

- Ensure to install this equipment inside an X-ray room.
- The operator must stay outside of the X-ray room while acquiring an X-ray image to protect himself or herself from radiation exposure.
- The operator must be able to communicate with his or her patient either visually or verbally while the equipment is in operation.
- Check the status of the patient and the equipment until the image acquisition is completed.
- Stay at least 2 m (7 ft) away from the equipment during image acquisition.
- Stop the equipment immediately when a problem occurs during image acquisition.
- Guide the patient to wear a lead apron with a neck collar to protect thyroid gland prior to imaging. Wearing lead glasses is also recommended. Note, however, that the lead glasses may cause an image artifact in the acquired image.
- Women who are pregnant or might be pregnant, and children should minimize X-ray exams unless necessary.
- Women who are pregnant or might be pregnant, and children should check the need for an X-ray exam through consultation with a radiologist before taking an X-ray scan. If they need an X-ray exam, we recommend that they wear lead shielding or protective aprons.
- Younger patients are more radio-sensitive than adults (the cancer risk per unit dose of ionizing radiation higher for younger patients).
- Younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.
- Check if your patients have an electrical medical device implanted in their body or are currently under radioactive iodine seed treatment. Patients who meet one of these conditions must be informed before X-ray scanning about the danger associated with radiation exposure.
- Guide the following patients to consult their doctor before taking an X-ray:
  - 1) the patients with the implanted medical device
  - 2) the patients under the radioactive iodine seed treatment.
- The implanted medical devices that require a doctor's consultation before X-ray scanning are insulin pumps, cardiac implantable electronic devices (pacemaker and implantable cardioverter defibrillators), and neurostimulators.





As a manufacturer of radiology equipment, **VATECH** guarantees the maximum degree of protection against radiation hazards for its product.



Because the radiation safety regulations differ across countries, both equipment owners and users are responsible for following radiation safety regulations and protective measures in their areas.

## 3.4 Warnings

The following warning statements should be obeyed with the utmost care. Failure to follow these warnings may cause severe damage to the equipment or physical injuries to the patient and the operator.



- X-ray equipment is hazardous to the patient and the operator if proper exposure safety measures and operating instructions are not observed.
- Read this **user manual** carefully and follow all warnings and cautions in the manual.



- Do not use 3D images for screening examination.
- Taking an X-ray is justified only when its benefits outweigh its risks.
- Use the medical CT or MRI to examine the patient's soft tissue, instead of the dental CT.



- **Green X (Model: PHT-75CHS)** uses high-frequency electrical signals like other medical devices, so it may interfere with implanted medical devices such as pacemakers or implantable cardioverter-defibrillators (ICDs). If a patient is using such an implanted medical device, please be aware of this and immediately turn off the device if interference occurs.
- If there is a concern about electromagnetic interference (EMI) with a patient's implanted medical device, please guide them to consult with the physician in charge of the implanted medical device.



Federal law restricts the sale of this device to dentists, or the personnel licensed by the law of the state where he or she uses or orders the use of the device.

### Lasers

- The system incorporates Class 1 laser products. The light localizers in this product are intended for correct patient positioning and must not be used for any other purpose.
- Advise the patient not to look directly at the laser beam for maximum safety.
- While adjusting the patient, ensure that the laser beam is not directed at the patient's eyes.
- Wavelength: 650 nm, Radiant power: Max. 039 mW



Risk of eye injury!

Do not use this equipment with any other laser sources; do not make any changes to the settings or processes described in these operating instructions.

### Cleaning

- Never expose this equipment to liquids, mist, or sprays. Exposing this equipment to liquids may cause an electric shock or damage to the system.
- Do not use spray cleaners on this equipment, as this could cause a fire.

### During the Operation

- Never use this equipment in an environment that is susceptible to explosion.
- Do not place flammable materials near this equipment.
- Do not operate the PC while the equipment is operating. Failure to comply with this instruction may result in system malfunction.
- Immediately stop imaging if the equipment malfunctions in any way.
- If a problem occurs during imaging, press the red **Emergency Stop Switch** to immediately stop all moving parts and cut off all power to the equipment's electrical components.
- Never touch the patient while he or she is touching the SIP/SOP connectors.
- The medical electrical equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the medical equipment or electrical system should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories and cables other than those specified, except cables sold by **VATECH** of the medical electrical equipment or medical electrical system as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY EQUIPMENT or SYSTEM.

### In case of an electrical fire

- Ensure to use the fire extinguisher for electrical fire only. Using a fire extinguisher that uses water, foam, or other wet chemicals can damage the equipment and cause electrical shock or burns.

### Installation

- To avoid improperly balanced equipment, install the device on a flat surface to maintain stability.
- If the equipment is not stable, property damage and personal injury may occur.
- Do not push or pull the equipment.
- An authorized technician should only install equipment, complying with proper installation procedures.

### **NOTICE**

For further details on installation, refer to the **Green X™ (Model: PHT-75CHS) Installation Manual**.

### Security Capabilities

- It is recommended to install and operate **EzDent-i** SW within a secure operating environment that allows only authorized users to access a system network equipped with Windows built-in firewall, Windows Defender antispyware tools, and other commonly used 3<sup>rd</sup> party security tools and application systems.
- The latest updates for anti-virus software and a firewall are recommended.
- The software can be updated by the manufacturer only. Unauthorized software updates through a third party, not the manufacturer, is prohibited. Please contact the manufacturer for cybersecurity issues related to the software and medical devices.

#### **3.4.1 Side Effects**

- X-ray imaging exams should be performed only after careful consideration of the patient's health needs.
- X-ray imaging should be performed only when it is deemed necessary by a healthcare professional to guide the treatment of a patient's disease within the scope of Indications for use and Intended purpose of the X-ray device.
- The operator must understand the well-known risks which can occur during X-ray exposure and minimize them by preventing unnecessary radiation exposure for patients.

## 4. Imaging System Overview

### 4.1 System Components

- **Green X (Model: PHT-75CHS)** X-ray equipment
- PC system
- Console Software: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan
- **EzDent-i:** 2D viewer and patient management software
- **Ez3D-i:** 3D viewer software

### 4.2 Features

- 2D panoramic and cephalometric imaging capabilities
- A variety of FOV options for CBCT imaging: Double Scan, 16x9, 12x9, Smart Focus(12x9), 8x8, 8x5, 5x5, and Endo (4x4) (unit: cm)
- 3D scan option for plaster cast at FOV 8x8 (unit: cm)
- **Smart Focus:** a CBCT capture mode that reconstructs the user-selected areas into multiple high-resolution 4x4 images. The system first acquires a 12x9 CT image, then reconstructs the acquired image into 4x4 images based on user's selection. The user can select up to three reconstruction areas.
- **Double Scan:** a CBCT capture mode that scans the mandible and maxilla and reconstructs their images into a single 16x15 image.
- **Endo:** a CBCT capture mode that acquired an image of tooth selected by the user and reconstructs the image into a high-resolution 4x4 image consisting of details such as nerves and blood vessels. .
- **Insight PAN:** a PANO capture mode that captures only the user-selected target and reconstructs the acquired image into multiple images with multiple focal points. In the Insight PAN mode, the radiation exposure to the patient is minimized because the X-ray only hits the areas selected by the user.
- **Magic PAN:** a PANO image reconstruction algorithm that minimizes the differences between the actual shape of the patient's arch and the reconstructed image. The user can obtain an optimized panoramic image of different arches.
- **Auto Pano:** an optional feature for the Smart Focus, Double Scan, 16x9, and 12x9 modes that provides a 2D panoramic image of the patient's arch along with the CT image.
- **Full Arch:** an optional feature of the Smart Focus mode that provides a high-resolution 3D image of the patient's entire arch.
- **Scout View:** an optional feature for 8x5, 5x5, and Endo modes that allows the user to preview the image areas before capturing the actual image.

## 4. Imaging System Overview

- Easy-to-use and intuitive console software.
- DICOM (Digital Imaging Communication in Medicine) format supported
- MAR(Metal Artifact Reduction) supported

### 4.3 Imaging System Options



Model Name	Brand Name	Device Identifier	System Configuration (X-ray Detector)	
PHT-75CHS	Green X	Green X SP	CBCT / PANO	Xmaru1314CF
		Green X RC	CBCT / PANO	Xmaru1314CF
			CEPH	Xmaru2602CF

## 4.4 Standards and Regulations

### Standards

**Green X (Model: PHT-75CHS)** is designed and developed to comply with the following international standards and regulations:

- 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 60601-2-63:2012+AMD1:2017+AMD2:2021.
- 21 CFR 1020.30, 31, 33
- NEMA Standard publication PS 3.1-3.18

	<p>This is class IIb equipment and obtained CE marking in May 2017 for regulation compliance by the enacted European Union's MDR (Medical Device Regulation)</p>
	<p>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 60601-2-63:2012+AMD1:2017+AMD2:2021.</p>

### Classifications (IEC 60601-1 6.1)

- The degree of protection against water ingress: Ordinary Equipment: IPX0
- The degree of protection against electric shock: Class 1 equipment, Type B applied parts (chinrest, bite and cover, nasal positioner and cover, ear rod and cap, carpus plate).



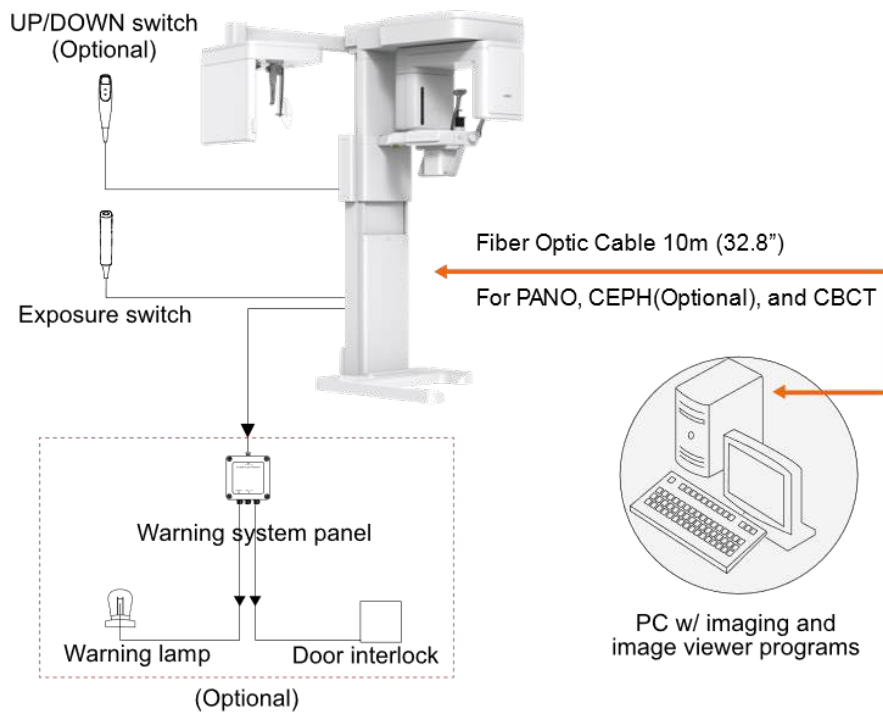
## 4.5 Operating Principles

X-ray is emitted when a high voltage is supplied to the X-ray tube assembly, which frees electrons from the cathode.

They hit an anode to produce an X-ray. The machine acquires images by emitting X-rays continuously and rotates on the human tooth at different angles.

Images are acquired, computed, and recompiled to reproduce 2D or 3D images.

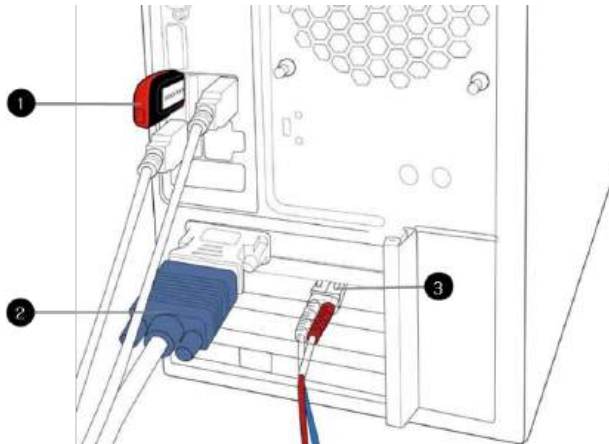
## 4.6 Imaging System Configuration



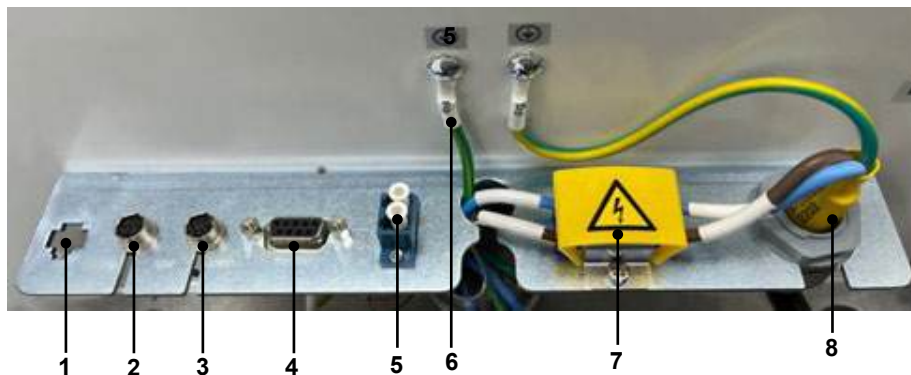
**IMPORTANT**

Ensure to use the PC outside the patient environment, such as X-ray (Radiology room).

### PC Signal Input/Output



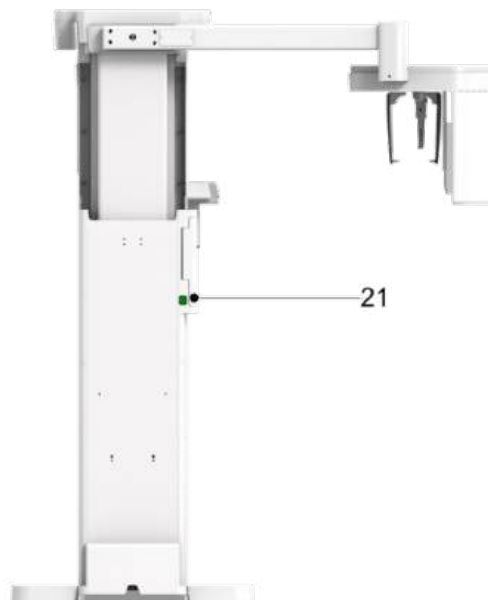
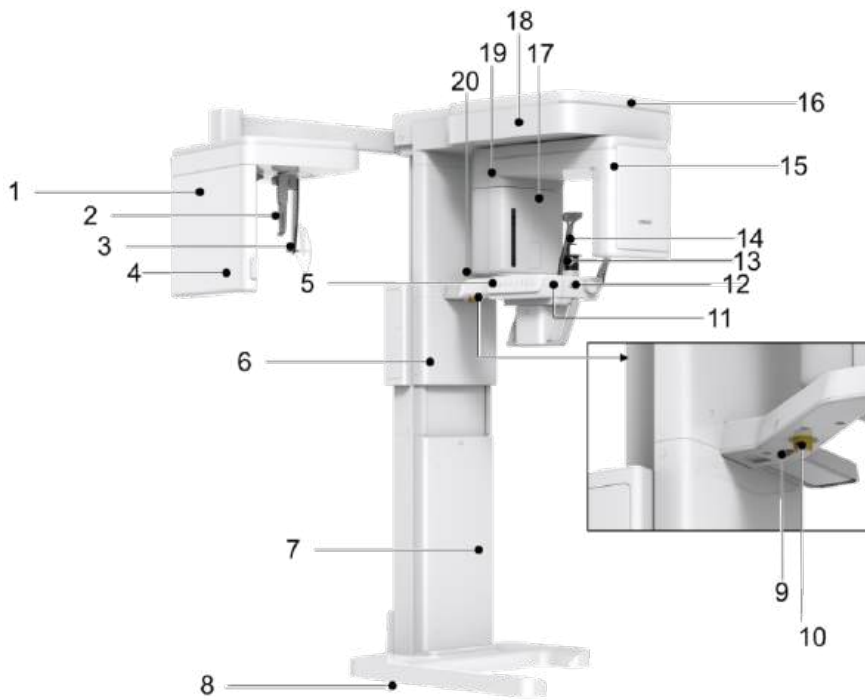
No.	Item
1	3D viewer License Key
2	Video output
3	Fiber optic cable (Data in/out: UART communication)

**Ports and Cable Connections**

No.	Item	Description
1	Emergence Stop Switch Port*	Connects the emergency stop switch to the equipment.
2	Door Lock Port	Connects the door lock cable to the equipment when installing a door lock.
3	Exposure Switch Port	Connects the exposure switch to the equipment.
4	RS232 Port	Used for testing and repairing equipment.
5	Optic Port	Connects the main MCU and the sensor with the PC.
6	Frame Ground Cable	Connects the external FG with the internal FG.
7	Terminal	Connects the external power cable with the internal power cable.
8	Power Cable	Supplies the power to the equipment.

\*Emergency stop switch port is used in Russia only.

## 4.7 Equipment Overview



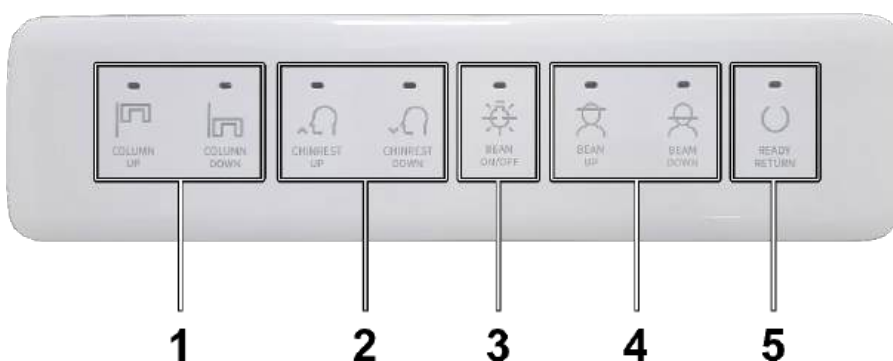
## 4. Imaging System Overview

No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor.
2	Nasal Positioner	Corrects the patient's position for the CEPH imaging procedure.
3	Ear Rods	Secures the patient's head during CEPH imaging.
4	Column up/down button (CEPH Part)	Adjusts the column's height
5	Control Panel	Controls the laser beam, rotating unit, and column's height. For more information, go to <b>4.7.1 Control Panel</b> .
6	Column up/down button (optional)	Adjusts the column's height
7	Column	Supports the whole part of the equipment.
8	Base (Optional)	Balances the equipment and maintains its safety.
9	D-Sub Connector	Serves as the input signal port for the <b>column up/down</b> switch.
10	Emergency Stop Switch	Stops the equipment in an emergency. For more information, go to <b>4.7.2 Emergency Stop Switch</b> .
11	Canine Teeth Beam Lever	Changes the canine beam's location to align the beam with the patient's Frankfurt line(plane).
12	Temple Supports Knob	Opens or closes the temple supports.
13	Chinrest	Places the patient's chin for the imaging procedure.
14	Temple Supports	Holds the patient's head in position for PANO and CBCT imaging.
15	X-ray Detector for PANO/CBCT	Xmaru1314CF for PANO and CBCT imaging sensor.
16	LED Lamp	Indicates the X-ray exposure status. <ul style="list-style-type: none"> <li>▪ <b>White:</b> The equipment is in an idle state</li> <li>▪ <b>Green:</b> X-ray is stand by</li> <li>▪ <b>Yellow:</b> X-ray is on</li> </ul>
17	X-ray Generator	The X-ray tube where the X-ray is produced.
18	Vertical Frame	Holds the rotating units
19	Rotating Unit	Rotates around the patient's head to acquire an X-ray image.
20	Enclosed Component Storage	Stores bites, chinrest, and other accessories.
21	Main Power Switch	Turns on or off the equipment.

### 4.7.1 Control Panel

You can do the following tasks on the control panel:

- Adjusting the column's height
- Adjusting the chinrest's height (for CBCT mode only)
- Turning on or off the laser beams.
- Adjusting the horizontal beam's location (for PANO mode only)
- Changing the rotating unit's position for image acquisition



No.	Buttons	Description
1	Column Up/Down	Adjusts the column's height by moving the moving column up and down.
2	Chinrest Up/Down	Adjusts the chinrest's height for the CBCT imaging.
3	Beam On / Off	Turns on or off the laser beams for patient positioning.
4	Beam Up/Down	Adjusts the horizontal beam's location for panoramic imaging.
5	Ready/Return	Indicates that the X-ray is ready for exposure with the LED. Moves the rotating unit's position to its initial place.

### 4.7.2 Emergency Stop Switch

The emergency stop switch is located under the handle frame. Press the switch to stop the equipment in an emergency. The emergency may include the following situation but is not limited to:

- When the X-ray emission continues after releasing the exposure switch
- When the equipment hits the patient, a mechanical failure occurs.

To restart the equipment after the situation is resolved, turn the switch until it pops up again.

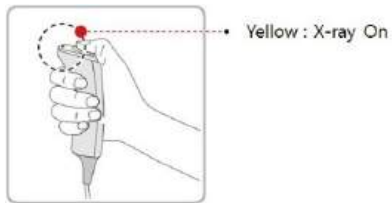


### 4.7.3 Exposure Switch

The **exposure switch** allows the operator to control image acquisition outside the X-ray room.

Press and hold the **exposure switch** down until the acquisition is completed. Premature release of the **exposure switch** will abort image acquisition.

Pressing the exposure switch activates the LED indicator to turn yellow. This color indicates that the X-ray is being emitted.



#### IMPORTANT

Ensure the **exposure switch** cable is not detached from the equipment during the operation.

#### IMPORTANT

Keep vocal/visual contact with the patient during exposure. In an emergency, release the **exposure switch** immediately.

#### 4.7.4 Accessories

The following accessories are used to position the patient and support the equipment. The accessories that have contact with the patient must be disinfected between each patient. For more information about cleaning accessories, go to **Chapter 12. Cleaning and Disinfection**.












Image / Name	Usage	Materials
 Normal Bite	<ul style="list-style-type: none"> <li>For normal patients</li> <li>For Pano and CBCT image acquisition</li> </ul>	PC (Polycarbonate)
 Special Bite A	<ul style="list-style-type: none"> <li>For both edentulous and normal patients</li> <li>For TMJ (open, close) and Sinus image acquisition.</li> </ul>	PC (Polycarbonate)
 Special Bite B	<ul style="list-style-type: none"> <li>For edentulous patients.</li> <li>For Pano and CBCT image acquisition</li> </ul>	PC (Polycarbonate)
 Chinrest	<ul style="list-style-type: none"> <li>To rest the patient's chin</li> </ul>	ABS (Acrylonitrile butadiene styrene) copolymer
 Temple Supports (1 set)	To secure the patient's head during the image acquisition.	Temple Supports : PA(Polyamide) Temple Support Pad : Silicone
 Ear Rod Caps (1 set)	To protect patient's ears when using the ear rods.	Silicone
 Nasal Positioner Cover	To protect the nasal positioner from contamination	Silicone
 Carpus Plate	To place a hand to capture a carpus X-ray Image	PC (Polycarbonate)

Image / Name	Usage	Materials
 <p>Sanitary Vinyl Cover (disposable)</p>	To cover the normal bite	PP+PE
 <p>Protractor</p>	To position the patient's body correctly for a cephalometric image acquisition	PC (Polycarbonate)
 <p>Model Scan Jig</p>	To store the model scan jig used for 3D model scan	ABS (Acrylonitrile butadiene styrene) copolymer

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## 5. Imaging Software Overview

Three programs are included in this equipment to acquire, process, and view the image:

- **EzDent-i** 2D viewer and patient management software
- **Ez3D-i** 3D viewer software
- Console software: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan

### 5.1 PC Specifications (Recommended)

#### IMPORTANT

If your PC does not meet the recommended specifications provided below, it may result in degraded image quality.

#### CAUTION

Prior to using the PC, ensure that Windows Defender Firewall is enabled to protect your PC and data from network security threats.

Item	Specifications
CPU	Intel XeonW-2223 3.6 4C
RAM	32GB DDR4-2666 ECC REG APJ or higher
HDD	1TB SATA 7200 rpm * 2EA
Graphics board	RTX 3050 6GB or higher
Ethernet Interface	Broadcom 5761 Gigabit PCIe NIC
Serial Port (RS232)	HP Serial Port Adapter Kit
Power Supply	750 W internal power module, up to 90% efficiency, active PFC
Slots	2 ports PCIe 3 x4 2 ports M.2 PCIe 3 x4 1 port PCIe x8 2 ports PCIe x16 1 PCI Slot
CD/DVD drive	DVD-ROM, DVD+/-RW, Blu-Ray
Monitor	19" 1280x1024 screen resolution
Operating System	Windows 10 or higher
Recommended System	HP Z4

### 5.2 EzDent-i

**EzDent-i** is imaging software that manages the acquired images for faster and more accurate diagnoses. The software is linked with the console software and the 3D viewer, allowing users to save the acquired images and view them in three dimensions.

#### **NOTICE**

To use EzDent-i, please read the EzDent-i user manual.

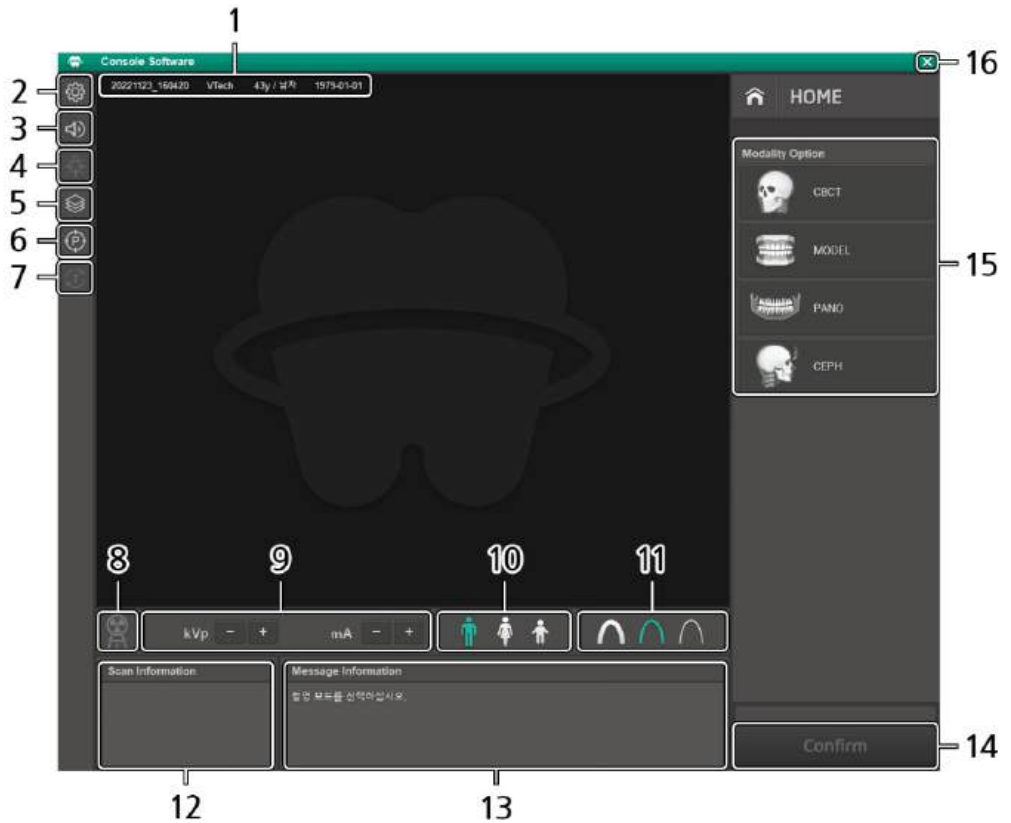
#### **NOTICE**

#### **Security Capabilities**

- Ensure to install and operate **EzDent-i** under a secure environment where only authorized users can access the system network with defender antispysware tools and a built-in firewall.
- Ensure to use the latest anti-virus software and firewall. Update them regularly for cyber security.
- A cover is installed on the back of the equipment to prevent unwarranted persons from accessing the communication port. Do not remove the back cover unless you are an authorized VATECH technician.
- Contact VATECH for inquiries about the cyber security issues of the equipment and its software.


### 5.3 Console Software

Using the console software, you can set and change exposure parameters.



#### NOTICE

The console software's UI and features can be updated without notice due to product enhancement.

No.	Item	Description
1	<b>Patient information</b>	Displays the selected patient's information.
2	<b>Setting button</b>	Sets user environments for the console software and capture modes such as auto-save option or language.
3	<b>Volume button</b>	Changes audio message's volume level.
4	<b>Laser on/off button</b>	Turns on or off the laser beams.
5	<b>Manual reconstruction button</b>	Reconstructs the captured image after the system fails automatic reconstruction. <b>How to Start a Manual Reconstruction</b> <ol style="list-style-type: none"> <li>1) Click the <b>manual reconstruction button</b>.</li> <li>2) Select a modality.</li> <li>3) Click <b>Search</b>.</li> <li>4) Select an image for reconstruction.</li> <li>5) Click the button again.</li> </ol>
6	<b>Phantom Button</b>	Captures a phantom image. <b>How to Capture a Phantom Image</b> <ol style="list-style-type: none"> <li>1) Click the <b>phantom button</b>.</li> <li>2) Select a modality and click <b>Capture</b>.</li> <li>3) Set exposure parameters and place a phantom jig.</li> <li>4) Click <b>Ready</b>.</li> <li>5) Press the <b>exposure switch</b>.</li> </ol>
7	<b>Test Rotation Button</b>	Performs a test rotation to check before scanning if the equipment hits the patient. <b>How to Start a Test Rotation:</b> <ol style="list-style-type: none"> <li>1) To start a test rotation:</li> <li>2) Ask the patient to enter the unit.</li> <li>3) Select a modality.</li> <li>4) Click Confirm.</li> <li>5) Click the test rotation button. After clicking, the button turns green.</li> </ol> 
8	<b>X-ray exposure indicator</b>	Indicates the X-ray exposure status. <ul style="list-style-type: none"> <li>▪ <b>Gray:</b> X-ray is off</li> <li>▪ <b>Yellow:</b> X-ray is on</li> </ul>
9	<b>Exposure condition menu</b>	Select exposure conditions (tube current and voltage).

No.	Item	Description
10	<b>Patient selection menu</b>	Selects or changes a patient type.
11	<b>X-ray level selection menu</b>	Selects or changes an X-ray level intensity.
12	<b>Scan information window</b>	Shows the estimated DAP(Dose Area Product), scan, and exposure times for the exposure settings you selected.
13	<b>Message information window</b>	Shows guide in text for the user.
14	<b>Confirm (Ready) button</b>	<p>This button performs a dual role.</p> <ul style="list-style-type: none"> <li>▪ <b>Confirm:</b> finalizes the capture mode and settings you selected.</li> <li>▪ <b>Ready:</b> Prepares the equipment ready for X-ray exposure. The Ready button appears after the user clicks the Confirm button.</li> </ul>
15	<b>Modality Option</b>	Selects a capture mode: PANO, CEPH (Optional), CBCT, and Model.
16	<b>Exit button</b>	Leaves the console window.

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## 6. Getting Started

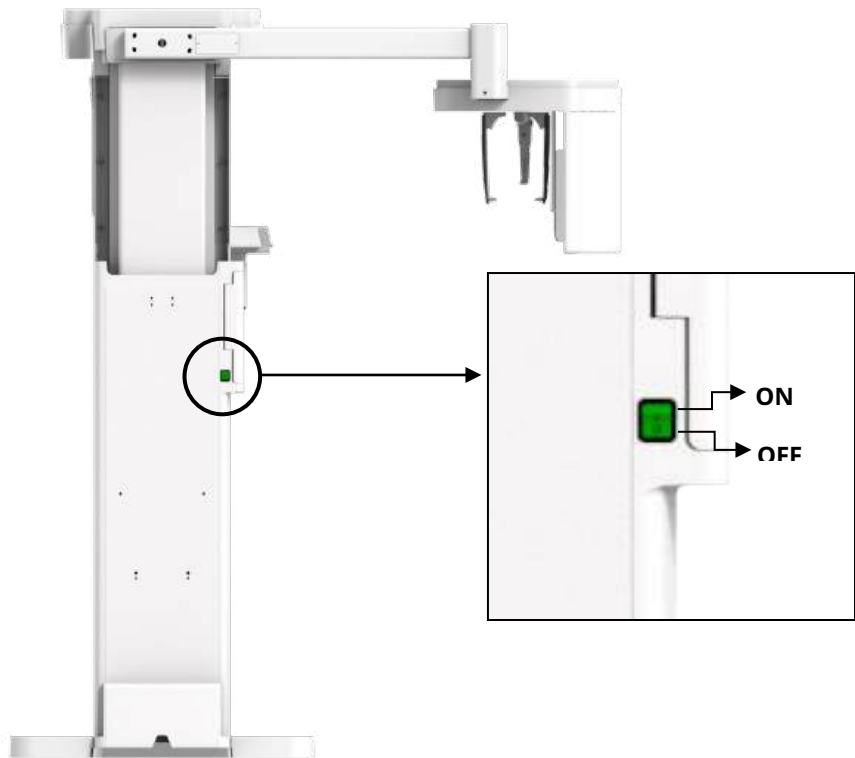
### 6.1 Turning on the Equipment

**WARNING**

Do not turn on the equipment when people stand near the equipment.

Follow the steps below to turn on the equipment:

1. Press the main power switch located behind the column.



2. Check if the green light comes on the LED light in front of the rotating unit.

## 6.2 Running the Image Viewer (EzDent-i)

**NOTICE**

Read the **EzDent-i User Manual** to learn how to use the image viewer. This manual is provided separately from the **Green X** user manual.

**NOTICE**

**Green X's** 3D viewer(Ez3D-i) and console software must be accessed through the 2D viewer (EzDent-i). 3D viewer and console software do not have storage to save captured images and the patient's information.


**NOTICE**

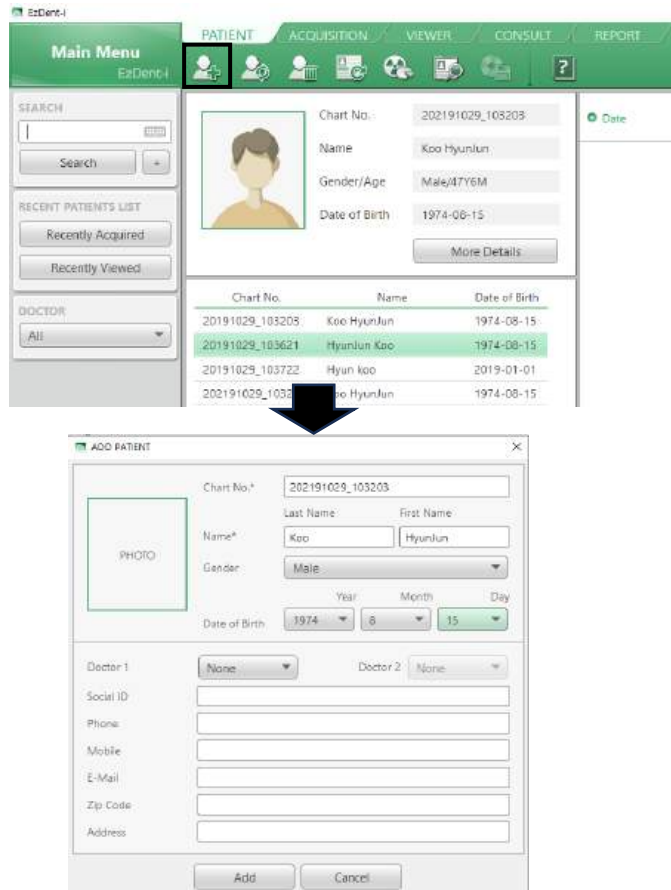
### Security Capabilities


- Ensure to install and operate EzDent-i under a secure environment that only authorized users can access the system network.
- The system network for EzDent-i must be protected with a Windows firewall, defender antivirus, and other programs commonly recognized for cyber security.
- Update antivirus software and firewall to maintain the latest version.
- The security cover is installed on the back of the equipment. Do not remove or open this cover unless you are a VATECH-authorized engineer.
- VATECH must update all software provided by VATECH.
- For inquiries about cyber security issues for VATECH's equipment and software, contact your nearest VATECH representative.

## 6.2.1 Adding a New Patient

To create a new patient account in EzDent-i.

1. Launch EzDent-i.
2. Select the **Patient** tab and click . After clicking the button, a dialog box will appear.

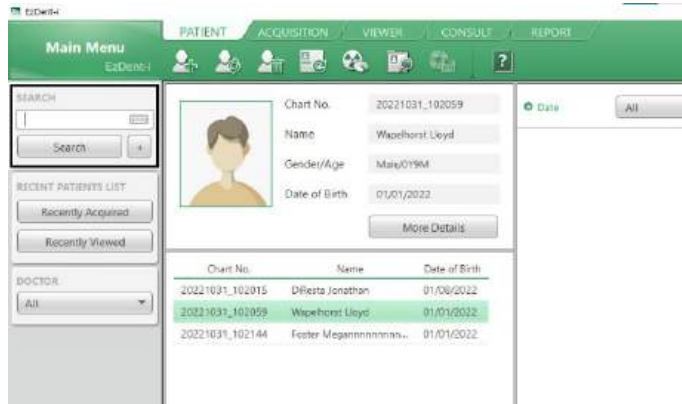


3. In the dialog box, fill out the required fields(\*) such as the chart number and patient's name.
4. Click  to save the new patient information.

## 6.2.2 Searching for a Patient

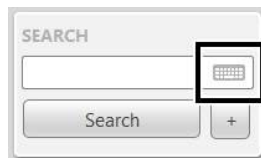
To search for a patient in EzDent-i,

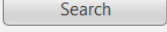
1. Launch EzDent-i.
2. Enter the patient's name or chart number in the search box.

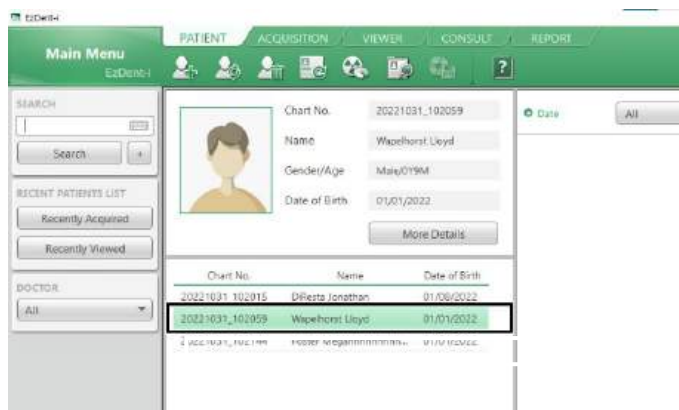


To use the virtual keyboard, click the keyboard icon next to the search box

**NOTICE**



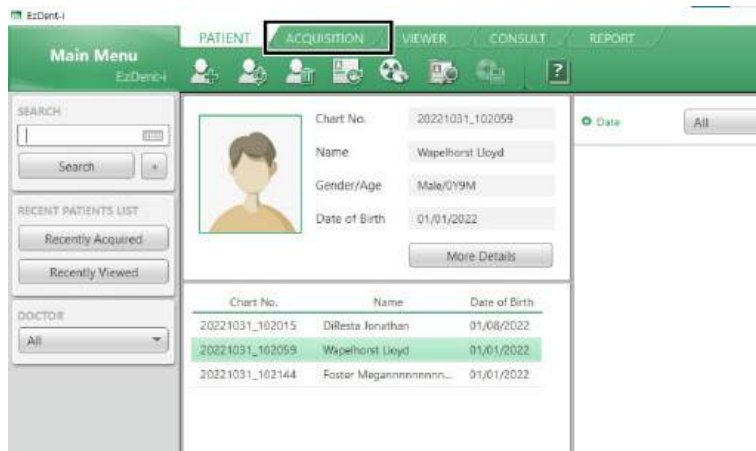
3. Click .
4. From the list displayed, select the patient information you want to retrieve.



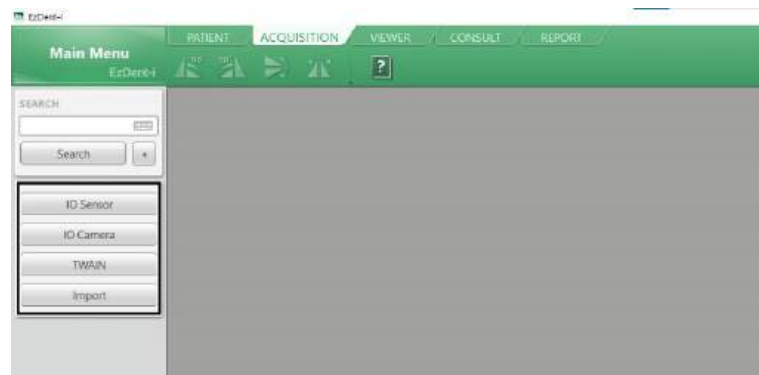
### 6.2.3 Starting the Console Software

To start the console software,

1. Launch the Ezdent-i.
2. Add a new patient or select existing patient information.
3. Select the **Acquisition tab**.



4. From the **Modality menu**, select the capture mode in which you want to acquire the image. The options displayed on the menu may vary depending on the configuration of your equipment.



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## 7. How to Acquire PANO Images

### 7.1 Program Overview

- **Role**



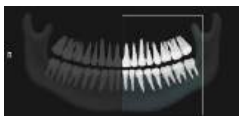



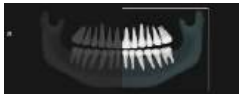
It provides 2D panoramic images.

- **Image Acquisition Method**


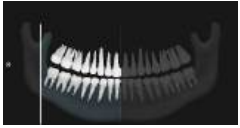







It reconstructs U-shaped arch data to a single 2D image utilizing multiple images taken with the X-ray beam scanning specific oral & maxillofacial regions at different angles.








- **Examination Programs**

It is classified below based on the ROI (Region of Interest).

Examination	Arch Selection	ROI	Example
Normal	Narrow Normal Wide Orthogonal	Right	
		Front	
		Left	
		Standard	
Normal	Child	Right	
		Front	
Normal	Child	Left	

## 7. How to Acquire PANO Images

Examination	Arch Selection	ROI	Example
		Standard	
	Orthogonal	Right	
		Front	
		Left	
		Bitewing Right	
		Standard	
		Bitewing Left	
		Bitewings	
Normal		Orthogonal	Bitewing Incisor (Optional)
Insight Pan	Normal	-	

Examination	Arch Selection	ROI	Example
	Child	-	
Special	N/A	TMJ LAT Open	
		TMJ LAT Close	
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

### NOTICE

- The bitewing option is activated when you select 'Orthogonal' on the arch selection menu.
- Once the Insight PAN is selected, the user can freely choose the area for an X-ray exposure before the image acquisition

### NOTICE

Insight PAN allows users to capture an image of the user-selected area only. By capturing a specific area, this mode minimizes the amount of radiation that the patient is exposed to.



< Image Capture Area Selection window >





### NOTICE





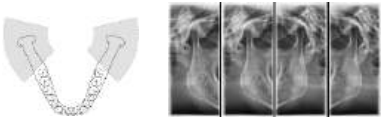
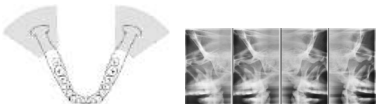
<Insight PAN image>

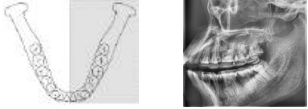
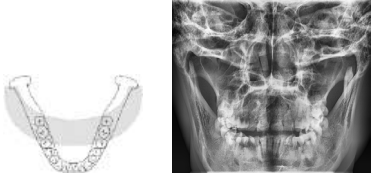
- When you want to capture a single tooth only, ensure to select the teeth left and right in addition, to the teeth you chose because each patient's arch is different.
- The minimum size of the areas that you capture with the Insight PAN is 50 x 50 mm<sup>2</sup>.
- You can view the captured image with the Insight PAN, using Insight NAVI. connected to EzDent-i
- Read the EzDent-i user manual to learn more information about the Insight PAN.

### ■ Main Imaging Programs

Examination Type	Arch Selection	ROI	Description & Sample Image
Normal	Narrow	Standard	<p>A panoramic imaging mode for patients with a V-shaped arch trajectory. (Typically for some females)</p> 
	Normal	Standard	<p>A panoramic imaging mode for adult patients with a typical arch trajectory.</p> 
	Wide	Standard	<p>A panoramic imaging mode for the patients with a square-shaped arch trajectory. (Typically for some males)</p> 
	Child	Standard	<p>A panoramic imaging mode for child trajectory. (Less X-ray exposure than the Normal mode by more than 40%)</p> 
	Orthogonal	Standard	<p>A panoramic imaging mode to minimize the overlapped region of the teeth from the X-ray exposure, which is beamed perpendicularly between teeth.</p>

## 7. How to Acquire PANO Images

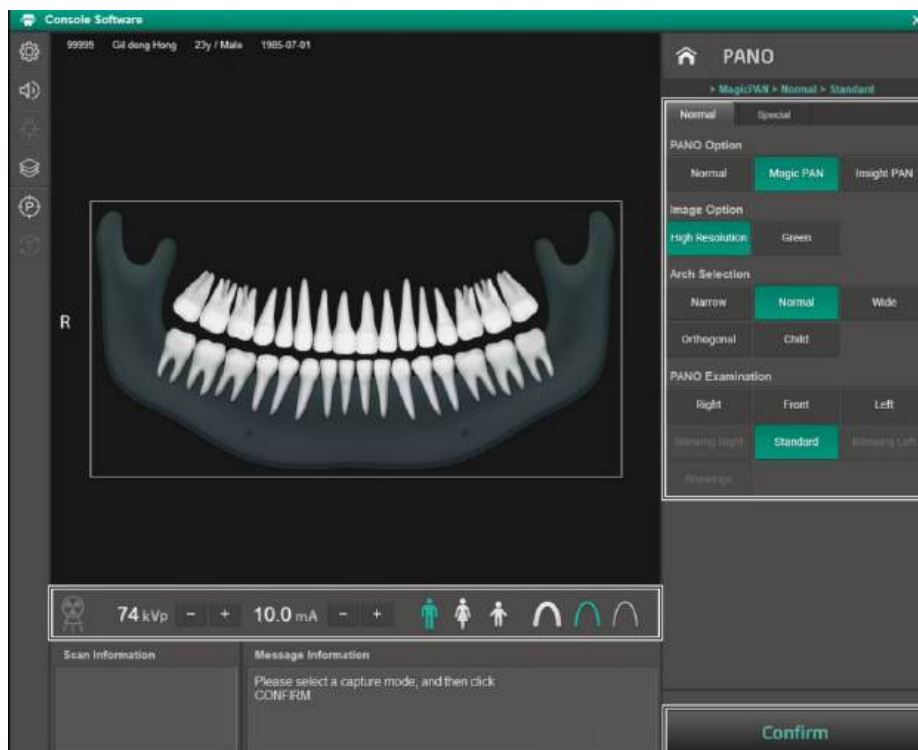
Examination Type	Arch Selection	ROI	Description & Sample Image
			
		<p>Bitewings** (Bitewing Incisor mode is Optional)</p>	<p>A panoramic imaging mode to acquire an image only for the region of interest through the orthogonal trajectory. (Pros: less X-ray exposure than the Normal mode. /Cons: TMJ and some parts of the maxillary sinus cannot be acquired.)</p> 
Special	N/A	<p>TMJ LAT Open/Close</p>	<p>An imaging mode to acquire a lateral image of the TMJ, in which the X-ray beam is directed on the lateral TMJ region. (TMJ Open and Close)</p> 
		<p>TMJ PA Open/Close (Optional)</p>	<p>An imaging mode is to acquire a TMJ image, in which the X-ray beam is directed on the frontal TMJ, with the patient's mouth open fully and closed.</p> 
		<p>Sinus LAT (Optional)</p>	<p>A special imaging mode to acquire a Sinus image, in which an X-ray beam is directed on the lateral region of the maxillary sinus.</p>

Examination Type	Arch Selection	ROI	Description & Sample Image
			
		Sinus PA	<p data-bbox="797 469 1167 595">A special imaging mode to acquire a Sinus image, in which an X-ray beam is directed at the frontal region of the maxillary sinus.</p> 

\*\* Bitewing mode is activated only when Orthogonal is selected in Arch Selection.

## 7.2 Selecting Exposure Settings

Before Selecting exposure settings, finish the steps in **Chapter 6. Getting Started**.



### IMPORTANT

**Patient Motion Detection** is intended to protect patients from the rotating unit's sudden movement during the exposure parameter configuration.

When the system detects a patient inside the equipment, it halts the parameter configuration and sends out an audio message saying, "During the system preparation, a patient has been detected at the imaging location".

When the patient's motion detection is activated, guide the patient out of the equipment then restart the console software.

In some countries including the United States, this feature could be disabled. For more information, contact the VATECH representative in your region.

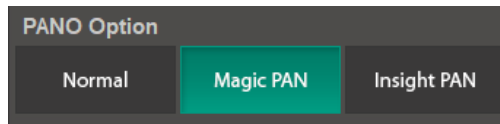
### 7.2.1 Normal / Insight PAN Mode

To select the exposure settings for the Normal and Insight PAN modes,

1. Click the Normal tab.

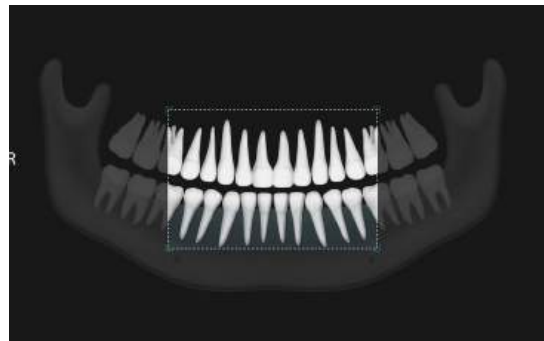


2. Select a PANO option.

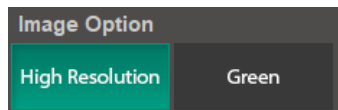


When selecting the Insight PAN mode, you need to select the exposure area on the screen by moving or resizing the crop box.

#### NOTICE



3. Select an Image Option.



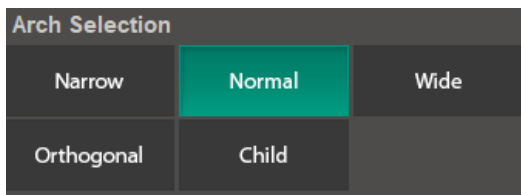
Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

#### NOTICE

The image option menu is disabled in Insight PAN mode.

## 7. How to Acquire PANO Images

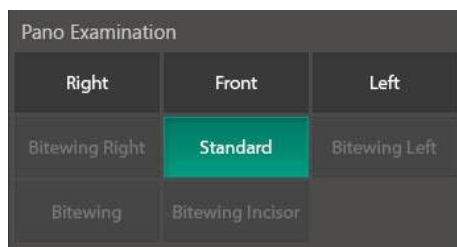
- Select an **Arch**.



### NOTICE

In the Insight PAN mode, the Arch Selection menu is disabled except for normal and child

- Select an option from the **PANO Examination**.



- Select a patient type.



Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females at the age of 12 or under

- Select an X-ray intensity level.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

8. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or current (mA); each click changes the values by  $\pm 1.0$ .



9. Click the **Confirm** button. Once the button is clicked, you cannot change the selected settings.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

10. After the equipment finishes moving, guide the patient to the X-ray room and follow instructions in **7.3 Patient Positioning**.

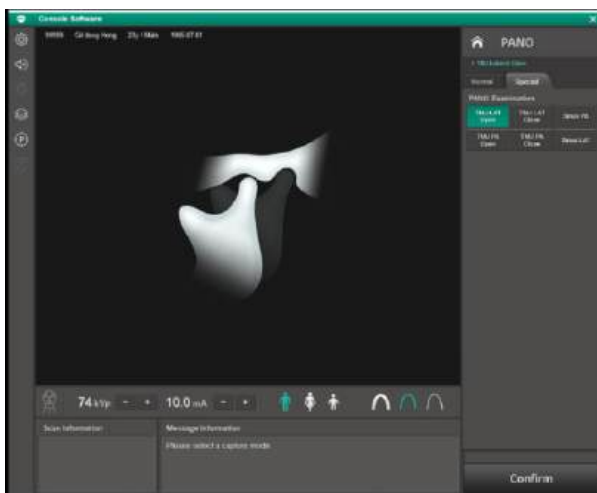
### 7.2.2 TMJ / SINUS Mode (LAT / PA)

To select the exposure settings for TMJ and Sinu modes

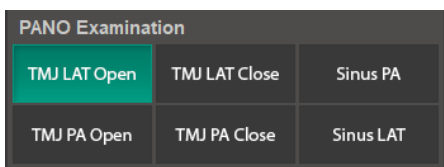
1. Click the **Special** tab.



the main window of the Special tab as shown as below:



2. Select an option from the **PANO Examination**.



3. Select a patient type.



**Man Woman Child**

Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females at the age of 12 or under

4. Select an X-ray intensity level.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

5. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or current (mA); each click changes the values by  $\pm 1.0$ .



6. Click the **Confirm** button. Once the button is clicked, you cannot change the selected settings.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

7. After the equipment finishes moving, guide the patient to the X-ray room and follow instructions in **7.3 Patient Positioning**.

## 7.3 Patient Positioning

### 7.3.1 Normal / Insight PAN mode

Follow the steps below to position patient for normal and Insight PAN mode.



Do not invite the patient to the X-ray room until the equipment stops moving.



Before positioning the patient, select and insert the correct bite block for your patient.

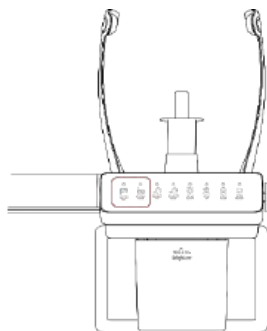
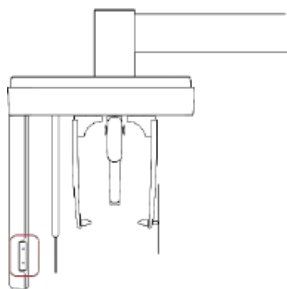
- **Normal Bite block** for dentate patients
- **Special bite B** for edentulous patients.

1. Ask the patient to remove all metal objects and wear a lead apron.



Metal objects can cause ghosts or shadows in the acquired X-ray image.

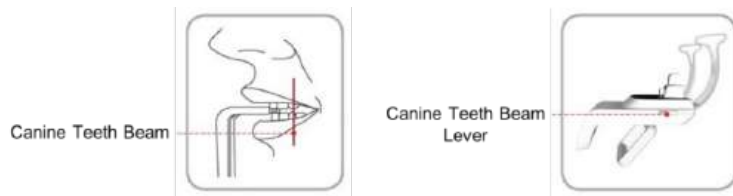
2. Have the patient stand in the X-ray unit and use the **column up/down button** to adjust the column height for the patient.



Ensure that the patient stays still while you adjust the column height.

3. Open the temple supports by turning the temple support knob clockwise, then ask the patient to do:
  - Bite into the groove of the normal bite block with their front teeth or rest their chin on the edentulous application (**Special bite B**).
  - Grab the handles with both hands.

4. Review the patient's position checking on the laser beams. If necessary, adjust the patient's position as follows:
  - Center the patient's head with the vertical laser beam.
  - Align the patient's Frankfurt plane to the horizontal laser beam. If necessary, use the **chinrest up/down button**.
  - Ensure that the canine teeth beam is aligned with the patient's canine. If necessary, use the **canine teeth beam lever** to adjust the position of the beam.



- Ensure that the patient's shoulders remain below the shoulder beam.



Ensure that the laser beam does not meet with the patient's eyes during positioning. Direct contact with beams can cause vision loss.

5. Close the temple supports by turning the temple support knob counterclockwise.
6. Ask the patient to stand still with closed eyes.
7. Leave the X-ray room and follow the instructions in **7.4 Acquiring Images**.

**IMPORTANT**

Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

### 7.3.2 TMJ / SINUS Mode (LAT / PA)

Follow the steps to position the patient for TMJ and SINUS mode.

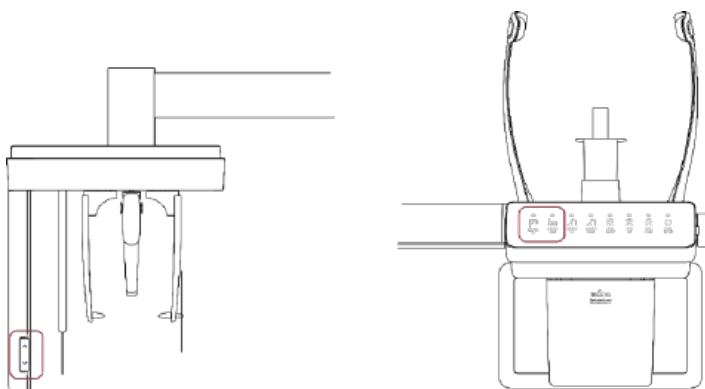
<b>⚠ CAUTION</b>	Do not invite the patient to the X-ray room until the equipment stops moving.
<b>NOTICE</b>	Before positioning the patient, insert the Special Bite A into the chinrest.
<b>IMPORTANT</b>	In the TMJ mode, the chinrest automatically lowers 20 mm. For accurate positioning, adjust the column height after the chinrest is fully lowered.

1. Ask the patient to remove all metal objects and wear a lead apron.

**NOTICE**

Metal objects can cause ghosts or shadows in the acquired X-ray image.

2. Have the patient stand in the X-ray unit and use the **column up/down button** to adjust the column height for the patient.



**⚠ CAUTION**

Ensure that the patient remains still while you adjust the column height.

3. Open the temple supports by turning the temple support knob clockwise, then have the patient to do:
  - For TMJ Open and Sinus mode, have the patient press the philtrum against the Special Bite A and open the mouth.
  - For TMJ Close mode, have the patient close the mouth while pressing the philtrum against the Special Bite A.

4. Review the patient's position checking on the laser beams. If necessary, adjust the patient's position as follows:
  - Center the patient's head with the vertical laser beam.
  - Align the patient's Frankfurt plane to the horizontal laser beam. If necessary, use the chinrest up/down button.
  - Ensure that the patient's shoulders remain below the shoulder beam.



Ensure that the laser beam does not meet with the patient's eyes during positioning. Direct contact with beams can cause vision loss.

5. Close the temple supports by turning the temple support knob counterclockwise.
6. Ask the patient to stand still with closed eyes.
7. Leave the X-ray room and follow the instructions in **7.4 Acquiring Images**.

**IMPORTANT**

Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

## 7.4 Acquiring Images

Follow the steps below to acquire an X-ray image.



Do not use the PC while capturing an image. This can cause a problem with equipment or software's operation.



In an emergency, release the **exposure switch** and press the **emergency stop switch** under the handle frame.

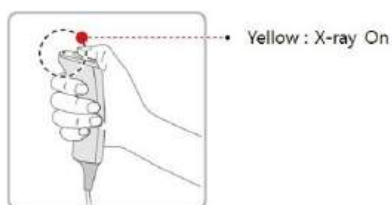


Stay in communication with the patient during the image capture. The user must be able to communicate with the patients visually or verbally for their safety.

1. Click the **Ready** button in the console window.



2. When the progress bar above the Ready button reaches 100%, press the exposure switch.



3. Release the exposure switch when the switch's LED light turns off.

**IMPORTANT**

Releasing the exposure switch before the LED light turns off may cause image acquisition to fail.

4. Wait until the sensor returns to its starting position. Then guide the patient out of the X-ray unit after opening the temple support.

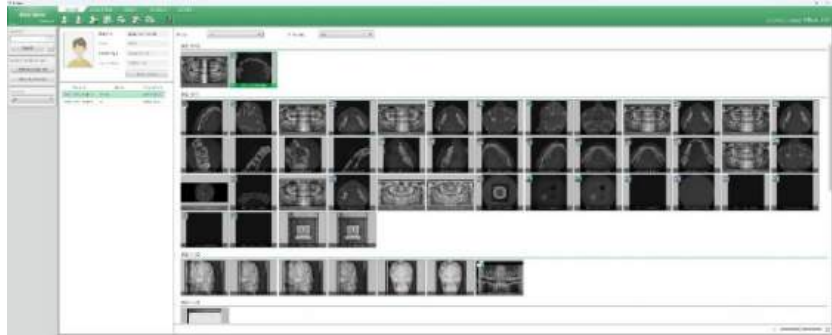


Do not approach the equipment until the sensor stops moving.

## 7.5 Viewing the Acquired Images

To save and review the acquired images,

1. Click the **Save** button to save the acquired images. If you have selected the auto save option, skip this step.
2. In the EzDent-i window, select the **Patient tab** and click the image you want to review from the displayed list.



### NOTICE

You can select only one image at a time.

3. When the selected image is displayed in the **Viewer tab**, review the image and make any necessary adjustments. In the Viewer tab, you can crop, resize, or adjust the quality of the image.

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## 8. How to Acquire CEPH Images (Optional)

### 8.1 Program Overview

#### ■ Role



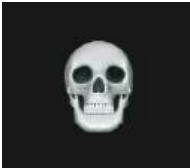
It provides conventional 2D cephalometric images.

#### ■ Image Acquisition Method




It acquires multiple images by scanning the specific oral & maxillofacial regions with the linear movement of the linear detector and reconstructs them into a single 2D image through computer calculations.

#### ■ Examination Programs

It is classified below based on the ROI (Region of Interest).

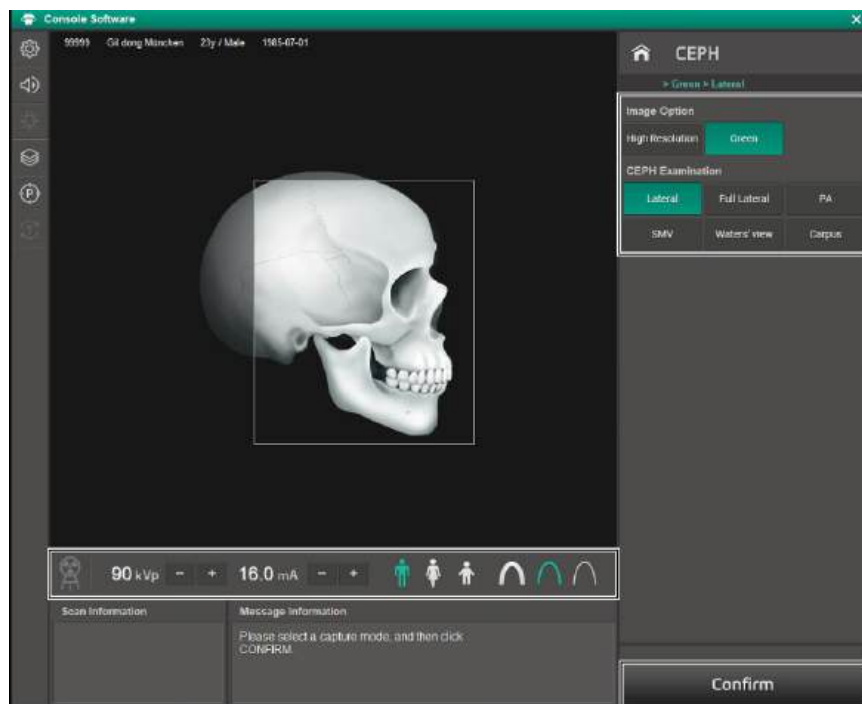
Examination Area	Description	Position
Lateral/ Full Lateral (Optional)	<ul style="list-style-type: none"> <li>Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate.</li> <li>Measures the angles formed by the connecting lines between the cranial measurement points to assess the growth of the facial region further. It's widely used in Orthodontics and Oral and Maxillofacial Surgery.</li> </ul>	 <p>&lt;Lateral&gt;</p>  <p>&lt;Full Lateral&gt;</p>
PA	<ul style="list-style-type: none"> <li>The radiation is directed from the posterior of the skull to the anterior.</li> <li>It is used to examine cranial diseases, trauma, and congenital malformations.</li> <li>It is used to assess the growth of the lateral side of the face. It is also used to examine the ramus mandibulae, the posterior region of the third-largest molar in the lower jaw, the sidewall of the maxillary sinus, the frontal</li> </ul>	 <p>&lt;PA&gt;</p>

## 8. How to Acquire CEPH Images (Optional)

Examination Area	Description	Position
	<p>sinus, antrum ethmoidal olfactory pits, and optic disc pits.</p> <ul style="list-style-type: none"> <li>Measures the angles formed by the connecting lines between the cranial measurement points to assess the growth of the facial region further. It is widely used in Orthodontics and Oral and Maxillofacial Surgery.</li> </ul>	
SMV	<ul style="list-style-type: none"> <li>Used to study the base of the skull, horizontal angulation of the mandibular condylar axis, the sphenoid sinus, the curvature of the lower jaw, the sidewall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull.</li> </ul>	 <p>&lt;SMV&gt;</p>
Waters' View	<ul style="list-style-type: none"> <li>Used to study the frontal sinus, the antrum ethmoidal, the optic disc pit, the frontozygomatic suture, the nasal cavity, and the coronoid process between the upper jaw and the zygomatic arch.</li> </ul>	 <p>&lt;Waters' view&gt;</p>
Carpus	<ul style="list-style-type: none"> <li>Used to assess hand bone age to compare the changes in the skull.</li> </ul>	 <p>&lt;Carpus&gt;</p>

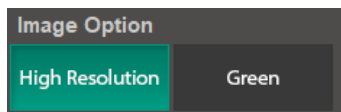
## 8.2 Selecting Exposure Settings

Before selecting exposure settings, finish the steps in **Chapter 6. Getting Started**.



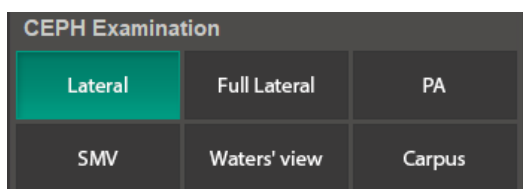
## 8. How to Acquire CEPH Images (Optional)

1. Select an **image option**.



Mode	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

2. Select a **CEPH examination** option.



3. Select a patient type.



Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Male or Female at the age of 12 or under

4. Select an X-ray intensity level.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft

Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

5. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or current (mA); each click changes the values by  $\pm 1.0$ .



6. Click the **Confirm** button. Once the button is clicked, you cannot change the selected settings.



7. Guide the patient to the X-ray room.

## 8.3 Patient Positioning

### 8.3.1 Lateral / Full Lateral (Optional) Mode

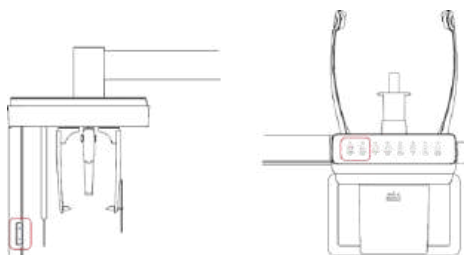
Follow the steps below to position the patient for the lateral mode.

1. Remove all the metal objects that the patient wears.

#### NOTICE

Metal objects can cause ghosts or shadows on the X-ray image and lower the image quality.

2. Turn the nasal positioner to the Lateral / Full lateral mode marker.
3. Use the **column up/down button** to adjust the equipment's height.



#### CAUTION

Ensure that the patient does not collide with the equipment while it is moving.

4. Make space between two ear rods for the patient's head.
5. Ask the patient to stand straight under the CEPH unit, facing the sensor.
6. Slid the ear rods until their tips gently touch the patient's outer ear canals.

#### CAUTION

Do not slide ear rods until adjusting the equipment's height is finished.

7. Give the patient the following instructions:
  - Close his or her eyes.
  - Swallow
  - Stay in the same position.
8. Leave the X-ray room and follow the instructions in **8.4 Acquiring Images**.

#### IMPORTANT

Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

### 8.3.2 PA Mode

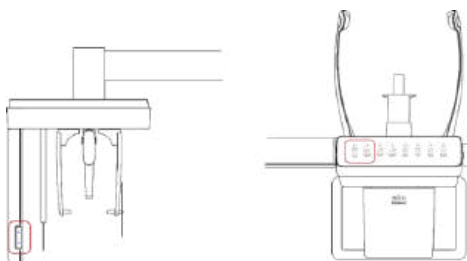
Follow the steps below to position the patient for the PA mode.

1. Remove all the metal objects that the patient wears.

#### NOTICE

Metal objects can cause ghosts or shadows on the X-ray image and lower the image quality.

2. Turn the nasal positioner to the PA / Waters' view / Carpus marker and fold the positioner up.
3. Use the **column up/down button** to adjust the equipment's height.



#### CAUTION

Ensure that the patient does not collide with the equipment while it is moving.

4. Make space between two ear rods for the patient's head.
5. Ask the patient to stand straight under the CEPH unit, facing the sensor.
6. Slid the ear rods until their tips gently touch the patient's outer ear canals.

#### CAUTION

Do not slide ear rods until adjusting the equipment's height is finished.

7. Give the patient the following instructions:
  - Close his or her eyes.
  - Swallow
  - Stay in the same position.
8. Leave the X-ray room and follow the instructions in **8.4 Acquiring Images**.

#### IMPORTANT

Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

### 8.3.3 SMV Mode

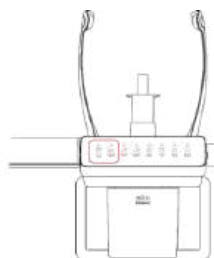
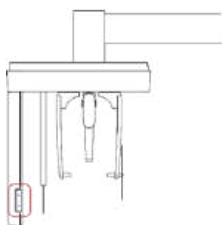
Follow the steps below to position the patient for the SMV mode:

1. Remove all metal objects that the patient wears.

#### NOTICE

Metal objects can cause ghosts or shadows on the X-ray image and lower the image quality.

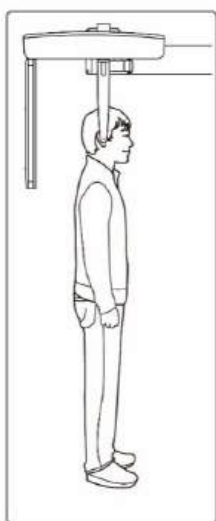
2. Use the **column up/down button** to adjust the equipment's height.



#### CAUTION

Ensure that the patient does not collide with the equipment while it is moving.

3. Make space between two ear rods for the patient's head.
4. Ask the patient to stand straight in the opposite direction of the sensor.

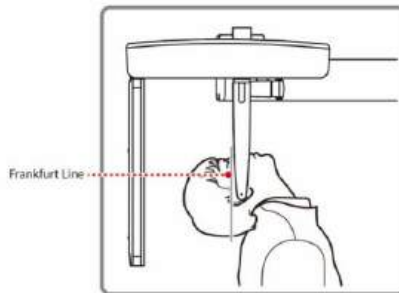


5. Slid the ear rods until their tips gently touch the patient's outer ear canals.



Do not slide ear rods until adjusting the equipment's height is finished.

6. Carefully tilt the patient's head back until his or her Frankfurt line (plane) lies vertical to the floor.



7. Give the patient the following instructions:
  - Close his or her eyes.
  - Swallow
  - Stay in the same position.
8. Leave the X-ray room and follow the instructions in **8.4 Acquiring Images**.

**IMPORTANT**

Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

### 8.3.4 Waters' View Mode

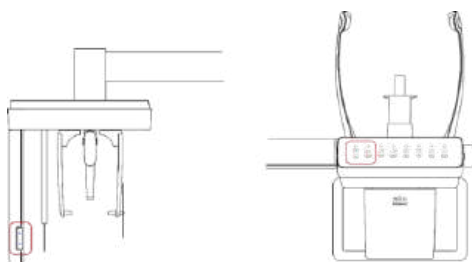
Follow the steps below to position the patient for the water's view mode:

1. Remove all metal objects that the patient wears.

#### **NOTICE**

Metal objects can cause ghosts or shadows on the X-ray image and lower the image quality.

2. Turn the nasal positioner to the Water's view marker and fold the positioner up.
3. Use the column up/down button to adjust the equipment's height.



#### **CAUTION**

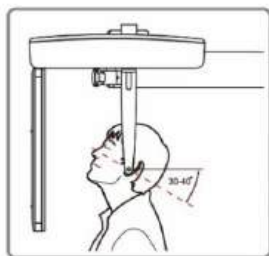
Ensure that the patient does not collide with the equipment while it is moving.

4. Make space between two ear rods for the patient's head.
5. Ask the patient to stand straight, facing the X-ray sensor.
6. Slid the ear rods until their tips gently touch the patient's outer ear canals.

#### **CAUTION**

Do not slide ear rods until adjusting the equipment's height is finished.

7. Ask the patient to tilt his or her neck back to 30°~ 40°, as shown in the image below.



8. Give the patient the following instructions:
  - Close his or her eyes.
  - Swallow
  - Stay in the same position.
9. Leave the X-ray room and follow the instructions in **8.4 Acquiring Images**.

**IMPORTANT**

Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

### 8.3.5 Carpus Mode

Follow the steps below to position the patient for the carpus mode:



Ensure that the carpus plate is installed and secured before positioning the patient.

1. Remove all metal objects that the patient wears.



Metal objects can cause ghosts or shadows on the X-ray image and lower the image quality.




2. Turn the nasal positioner to the PA / Water's view / Carpus mode marker and fold it up.
3. Ask the patient to place the right-hand on the carpus plate. Ensure that all five fingers are fully stretched out and the patient's palm lies flat on the plate.
4. Give the patient the following instructions:
5. Instruct the patient to:
  - Stay in the same position.
  - Close his or her eyes.
6. Leave the X-ray room and follow the instructions in **8.4 Acquiring Images**.



Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

## 8.4 Acquiring Images

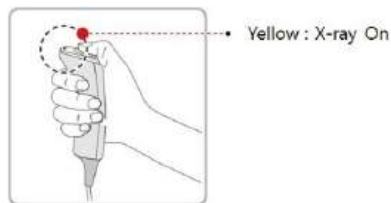
Follow the steps below to acquire an X-ray image.

 <b>CAUTION</b>	Do not use the PC while capturing an image. This can cause a problem with equipment or software operation.
 <b>WARNING</b>	In an emergency, release the <b>exposure switch</b> and press the <b>emergency stop switch</b> under the handle frame.
 <b>CAUTION</b>	Stay in communication with the patient during the image capture. The user must be able to communicate with the patients visually or verbally for their safety.

1. Click the **Ready** button in the console window.



2. When the progress bar above the Ready button reaches 100%, press the exposure switch.



3. Release the exposure switch when the switch's LED light turns off.

<b>IMPORTANT</b>	Releasing the exposure switch before the LED light turns off may cause image acquisition to fail
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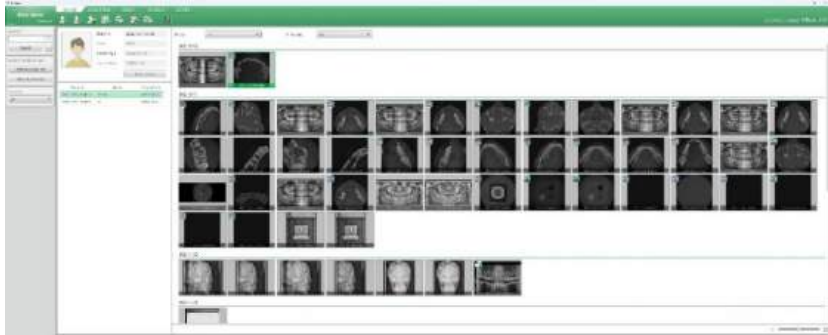
4. Make a space between the ear rods and fold up the nasal positioner. Then guide the patient out of the CEPH unit.

<b>IMPORTANT</b>	If you captured the carpus image, remove the carpus plate.
------------------	--

### 8.5 Viewing the Acquired Images

To save and review the acquired images,

1. Click the **Save** button to save the acquired images. If you have selected the auto save option, skip this step.
2. In the EzDent-i window, select the **Patient tab** and click the image you want to review from the displayed list.



#### **NOTICE**

You can select only one image at a time.

3. When the selected image is displayed in the **Viewer tab**, review the image and make any necessary adjustments. In the Viewer tab. You can crop, resize, or adjust the quality of the image.

## 9. How to Acquire CBCT Images

### 9.1 CBCT Imaging Program Overview

#### ■ Role


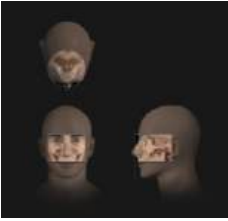
It provides conventional 3D CT sliced images.

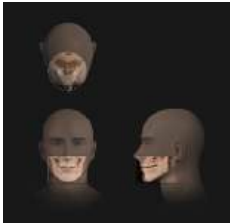
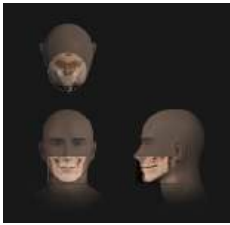
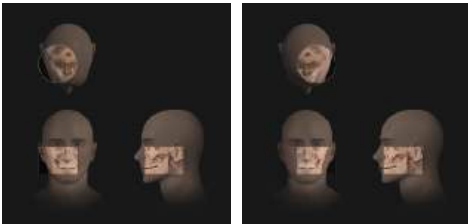
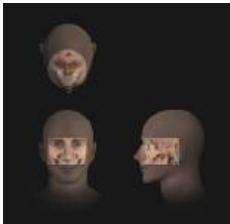

#### ■ Image Acquisition Method

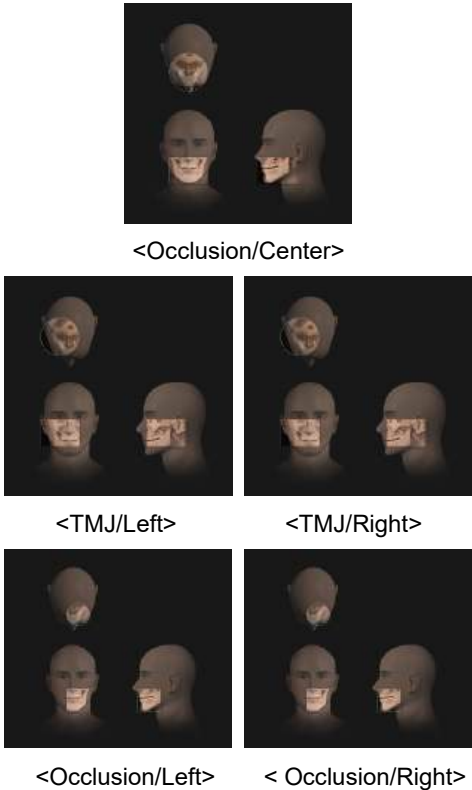
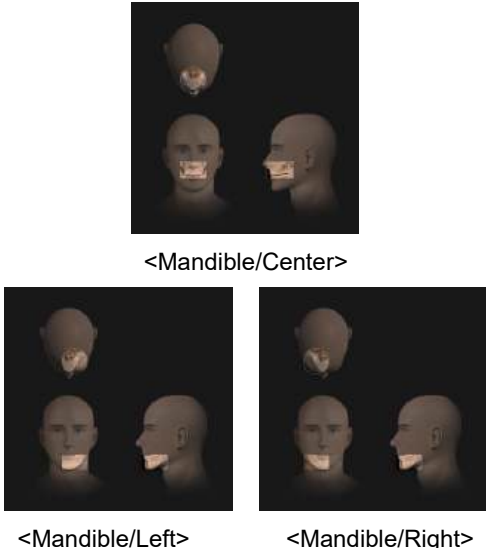
It acquires images with the X-ray beam scanning specific oral & maxillofacial regions and reconstructs them into 3D sliced images.

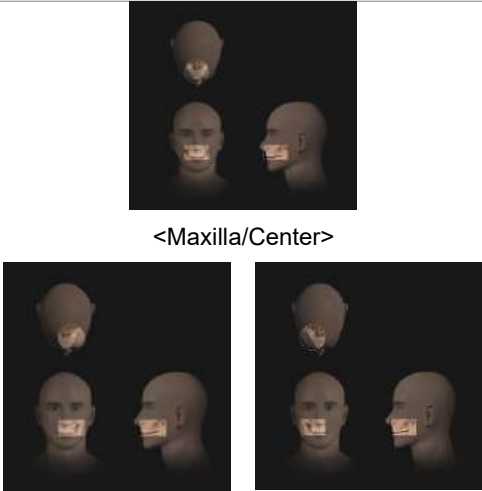


#### ■ Examination Programs

It is classified as below based on the FOV.

Available FOVs (cm)	ROI	Description
Double Scan	 <p data-bbox="587 1070 794 1097">&lt;Mandible/Center&gt;</p>	<p data-bbox="985 1087 1174 1205">- Full arch, sinus, left and right TMJ area can be checked</p> <p data-bbox="985 1219 1185 1336">- Suitable for most intra-oral surgery, including multiple implant placement</p>
	 <p data-bbox="587 1333 794 1360">&lt;Maxilla/Center&gt;</p>	
	<div data-bbox="443 1454 618 1499" style="border: 1px solid black; padding: 2px; display: inline-block;"><b>NOTICE</b></div> <p data-bbox="653 1387 927 1570">After taking two consecutive exposures in the order of "1 → 2", it is automatically synthesized and displayed as one full image.</p>	

Available FOVs (cm)	ROI	Description
16x9	 <p data-bbox="546 542 757 571">&lt;Occlusion/Center&gt;</p>	<ul style="list-style-type: none"> <li>- Covers full arch region, sinus, and left/right TMJ.</li> <li>- Suitable for most oral surgery cases as well as multiple implant surgery.</li> </ul>
12x9	 <p data-bbox="546 823 757 852">&lt;Occlusion/Center&gt;</p>  <p data-bbox="467 1093 605 1122">&lt;TMJ/Right&gt;</p> <p data-bbox="710 1093 847 1122">&lt;TMJ/Left&gt;</p>  <p data-bbox="559 1363 743 1392">&lt;Airway/Center&gt;</p>	<ul style="list-style-type: none"> <li>- Covers both maxillary and mandibular structures, including the 3<sup>rd</sup> molar region.</li> <li>- TMJ Right/Left and Airway modes are available.</li> </ul>
Smart Focus		<ul style="list-style-type: none"> <li>-Users can select up to three areas to view the selected areas in a 4x4 high-resolution image.</li> </ul>

Available FOVs (cm)	ROI	Description
8x8	 <p>&lt;Occlusion/Center&gt;</p> <p>&lt;TMJ/Left&gt;                      &lt;TMJ/Right&gt;</p> <p>&lt;Occlusion/Left&gt;              &lt; Occlusion/Right&gt;</p>	<ul style="list-style-type: none"> <li>- Selectable FOV for the region (left/center/right).</li> <li>- Covers both maxillary and mandibular areas and left/right TMJ.</li> </ul>
8x5	 <p>&lt;Mandible/Center&gt;</p> <p>&lt;Mandible/Left&gt;              &lt;Mandible/Right&gt;</p>	<ul style="list-style-type: none"> <li>- Selectable FOV for the region (left/center/right).</li> <li>- Covers both maxillary and mandibular areas.</li> </ul>

Available FOVs (cm)	ROI	Description
	 <p style="text-align: center;">&lt;Maxilla/Center&gt;</p> <p style="display: flex; justify-content: space-around;"> <span>&lt; Maxilla/Left&gt;</span> <span>&lt; Maxilla/Right&gt;</span> </p>	
5x5		<ul style="list-style-type: none"> <li>- Covers 3~4 areas through capturing ROI.</li> <li>- Can acquire 3~4 teeth at once.</li> <li>- Voxel Size: 0.08/0.12 applied.</li> </ul>
Endo (4x4)		<ul style="list-style-type: none"> <li>- Covers 3~4 areas through capturing ROI.</li> <li>- Can acquire 3~4 teeth at once.</li> <li>- Voxel Size: 0.05 applied.</li> </ul>

**NOTICE**

The Endo mode FOV size is 40 x 40 mm<sup>2</sup>, which is an area including 3~4 teeth. Before starting the X-ray exposure, check the status of wisdom teeth. Then select the location of the tooth for imaging to provide a scout function for accurate exposure.

## 9.2 Selecting Exposure Settings



### IMPORTANT

**Patient Motion Detection** is intended to protect patients from the rotating unit's sudden movement during the exposure parameter configuration.

When the system detects a patient inside the equipment, it halts the parameter configuration and sends out an audio message saying, "During the system preparation, a patient has been detected at the imaging location".

When the patient motion detection is activated, guide the patient out of the equipment then restart the console software.

In some countries including the United States, this feature could be disabled. For more information, contact the VATECH representative in your region.

### 9.2.1 Normal Mode

Follow the steps below to select exposure settings for a normal CBCT image.

1. Select a **FOV** other than 'Double Scan', Smart Focus', or 'Endo'. Based on your selection, the system determines **vertical**, **horizontal**, and **sub options**.



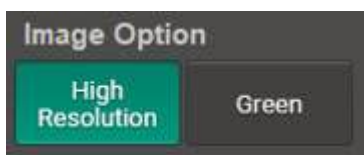
Available FOV (Unit: cm)	Vertical option	Horizontal option	Sub option
Double Scan	Maxilla Mandible	Center	Auto Pano
16x9	Occlusion	Center	Auto Pano
12x9	Occlusion	Center	Auto Pano
	TMJ	Right	
		Left	
Airway	Center		
Smart Focus	Occlusion	Center	Auto Pano Full Arch
8x8	Occlusion	Right	N/A
		Center	
		Left	
	TMJ	Right	
		Left	
8x5	Maxilla	Right	N/A
		Center	
		Left	
	Mandible	Right	

		Center	
		Left	
5x5	Maxilla Mandible	Selectable FOV by Teeth (Total: 32)	N/A
Endo (4x4)	Maxilla Mandible	Selectable FOV by Teeth (Total: 32)	N/A

2. Select whether to use the **Auto Pano** option. If you want to acquire a CT image only, leave the option box unchecked.



3. Select an **image option**.

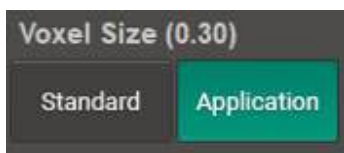


Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

**NOTICE**

**Patient, X-ray intensity, and exposure condition** are automatically selected based on the patient information you retrieved from the EzDent-i DB. However, you can manually customize the selected options to your preference.

4. Select a **voxel size**.



5. Select a **patient type**.



**Man Woman Child**

Patient	VATECH standard
Man	Male over the age of 12
Woman	Female over the age of 12
Child	Male or Female at the age of 12 or under

6. Select an **X-ray intensity level**.



**Hard Normal Soft**

Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

7. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or the current (mA); each click changes the voltage by  $\pm 1.0$  kVp and the current by  $\pm 0.1$  mA.



8. Click the **Confirm** button. Once the button is clicked, you cannot change the selected settings.





When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

9. After the equipment finishes moving, guide the patient to the X-ray room and follow the instructions in **9.3 Patient Positioning**.

### 9.2.2 Double Scan Mode

For the double scan mode, select the exposure settings once. After the first scan, the second scan begins automatically.

1. Select 'Double Scan' in the FOV menu.



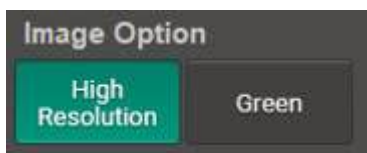
#### NOTICE

After 'Double Scan' is selected, the vertical option, horizontal option, and voxel size are automatically set by the system.

2. Select whether to use the **Auto Pano** option. If you want to acquire a CT image only, leave the option box unchecked.



3. Select an **image option**.



Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

#### NOTICE

**Patient, X-ray intensity, and exposure condition** are automatically selected based on the patient information you retrieved from the EzDent-i DB. However, you can manually customize the selected options to your preference.

4. Select a **patient type**.



Patient	VATECH standard
Man	Male over the age of 12
Woman	Female over the age of 12
Child	Male or Female at the age of 12 or under

5. Select an **X-ray intensity level**.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

6. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or the current (mA); each click changes the voltage by  $\pm 1.0$  kVp and the current by  $\pm 0.1$  mA.



- Click the **Confirm** button. Once the button is clicked, you cannot change the selected settings.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

- After the equipment finishes moving, guide the patient to the X-ray room and follow instructions in **9.3 Patient Positioning**.

### 9.2.3 Smart Focus Mode

To select exposure settings for the Smart Focus mode:

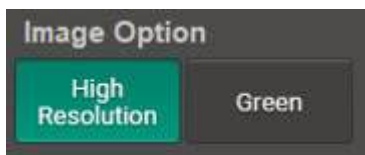
1. Select **'Smart Focus'** in the **FOV menu**.



2. Select whether to use the Auto Pano or Full Arch options. If you only want to acquire a CT image, leave the option boxes unchecked.

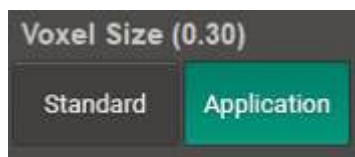


3. Select an **image option**.



Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

4. Select a **voxel size**.



#### **NOTICE**

**Patient, X-ray intensity, and exposure condition** are automatically selected based on the patient information you retrieved from the EzDent-i DB. However, you can manually customize the selected options to your preference.

5. Select a **patient type**.



Patient	VATECH standard
Man	Male over the age of 12
Woman	Female over the age of 12
Child	Male or Female at the age of 12 or under

6. Select an **X-ray intensity level**.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

7. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or the current (mA); each click changes the voltage by  $\pm 1.0$  kVp and the current by  $\pm 0.1$  mA.



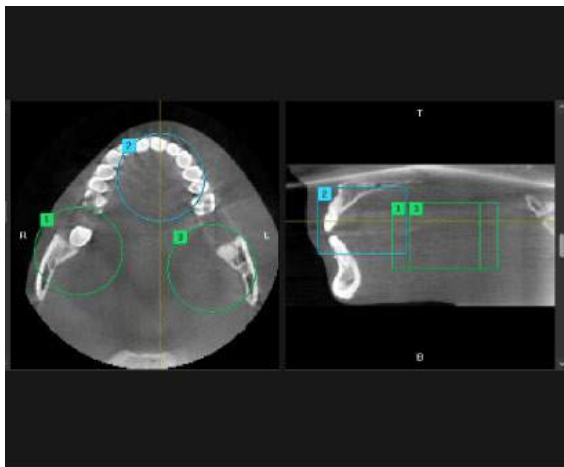
8. Click the **Confirm** button. Once the button is clicked, you cannot change the selected settings.



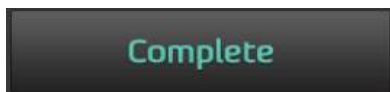


When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

9. Position the patient according to **9.3 Patient Positioning** and acquire an image according to **9.4 Acquiring Images**.
10. **[Selecting Reconstruction Region]** Select one or more regions for image reconstruction from the displayed image. You can select up to three regions.



11. After selecting the reconstruction regions, click the **Complete** button.



### 9.2.4 Endo Mode

To select exposure settings for the Endo mode.

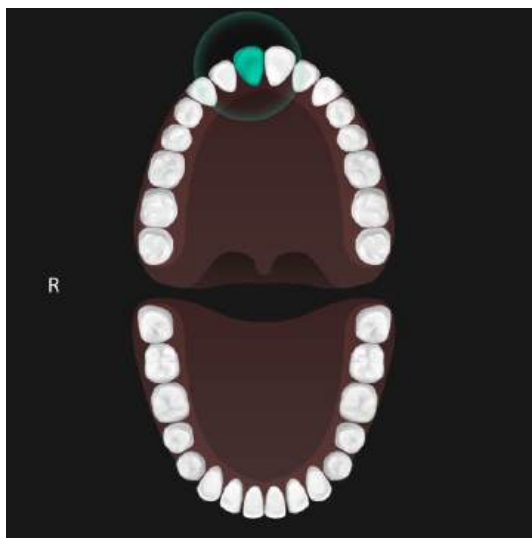
1. Select 'Endo' in the FOV menu.



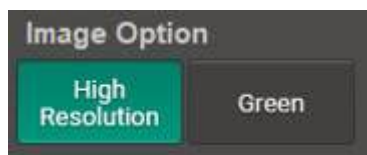
**NOTICE**

After 'Endo' is selected, the vertical and horizontal options are disabled.

2. Select a tooth for image acquisition.



3. Select an **image option**



Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

4. Select a **patient type**.



Patient	VATECH standard
Man	Male over the age of 12
Woman	Female over the age of 12
Child	Male or Female at the age of 12 or under

5. Select an **X-ray intensity level**.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

## 9. How to Acquire CBCT Images

6. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or the current (mA); each click changes the voltage by  $\pm 1.0$  kVp and the current by  $\pm 0.1$  mA.



7. Click the **Confirm** button. Once the button is clicked, you cannot change the selected settings.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

8. After the equipment finishes moving, guide the patient to the X-ray room and follow the instructions in **9.3 Patient Positioning**.

## 9.2.5 Scout View

When selecting an FOV of **8x5**, **5x5**, or **Endo**, you have the option to capture a scout image to preview and reselect the imaging target. Follow the steps below to capture a scout image.

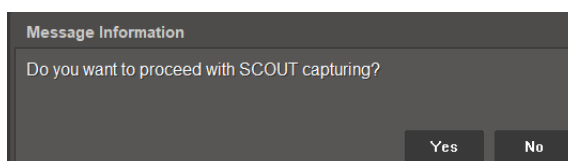
1. Select **8x5**, **5x5** or **Endo** in the FOV menu.



2. Select the rest of exposure settings according to **9.2 Selecting Exposure Settings**. Then click the **Confirm** button.



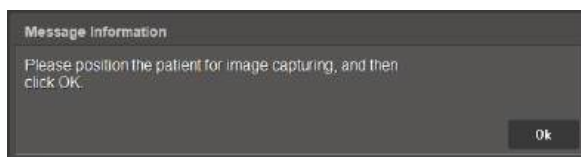
3. When the system asks, "Do you want to proceed with SCOUT capturing?", click the **Yes** button.



### NOTICE

Click the **No** button to skip the scout image acquisition.

4. After the chinrest finishes moving, position the patient according to **9.3 Patient Positioning**.
5. Click the **OK** button to start a scout image acquisition.



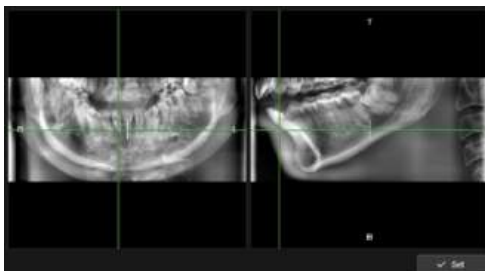
### NOTICE

Ask the patient to maintain his or her position until the image acquisition ends.

- In the preview image, verify that your imaging target is centered in the image, if not, drag the guidelines (green lines) to relocate the target.
  - In the **8x5** scout image, click and drag the horizontal green line up or down.



- In the **Endo** and **5x5** scout image, click and drag the horizontal or vertical green lines up, down, left or right.



- After relocating the imaging target, click the **Set** button to confirm the new location.



- Click the **Ready** button in the console window and acquire image following the steps in **9.4 Acquiring Images** to complete the remaining image acquisition.



### 9.3 Patient Positioning

Follow the steps below to position patient for image acquisition.



Do not invite the patient to the X-ray room until the equipment stops moving.



Before positioning the patient, select and insert the correct bite block for your patient.

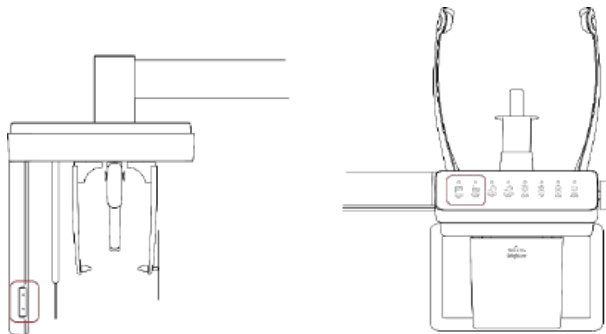
- **Normal Bite block** for dentate patients
- **Special bite B** for edentulous patients.

1. Ask the patient to remove all metal objects and wear a lead apron.



Metal objects can cause ghosts or shadows in the acquired X-ray image.

2. Have the patient stand inside the X-ray unit and use the **column up/down button** to adjust the column's height for the patient.



Ensure that the patient stays still while you adjust the column height.

3. Open the temple supports by turning the temple support knob clockwise, then ask the patient to do:
  - Bite into the groove of the normal bite block with their front teeth or rest their chin on the edentulous application (**Special bite B**).
  - Grab the handles with both hands.

## 9. How to Acquire CBCT Images

4. Review the patient's position based on the laser beams. If necessary, adjust the patient's position as follows:
  - Center the **patient's head** with the **vertical laser beam**.
  - Align the **patient's Frankfurt plane** to the **horizontal laser beam**. If necessary, use the chinrest up/down button.
  - Ensure that the **patient's shoulders** remain below the **shoulder beam**.



Ensure that the laser beam does not meet with the patient's eyes during positioning. Direct contact with beams can cause vision loss.




5. Close the temple supports by turning the temple support knob counterclockwise.
6. Ask the patient to stand still with closed eyes.
7. Leave the X-ray room and follow the instructions in **9.4 Acquiring Images**.

**IMPORTANT**

Review the patient's position before leaving the X-ray room. If necessary, reposition the patient.

## 9.4 Acquiring Images

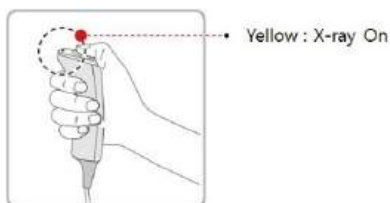
Follow the steps below to acquire an X-ray image.

 <b>CAUTION</b>	Do not use the PC while capturing an image. This can cause a problem with equipment or software's operation.
 <b>WARNING</b>	In an emergency, release the <b>exposure switch</b> and press the <b>emergency stop switch</b> under the handle frame.
 <b>CAUTION</b>	Stay in communication with the patient during the image capture. The user must be able to communicate with the patients visually or verbally for their safety.

1. Click the **Ready** button in the console window.




2. When the progress bar above the Ready button reaches 100%, press the exposure switch.



3. Release the exposure switch when the switch's LED light turns off.

<b>IMPORTANT</b>	Releasing the exposure switch before the LED light turns off may cause image acquisition to fail
------------------	--

4. Wait until the sensor returns to its starting position. Then guide the patient out of the X-ray unit after opening the temple support.

 <b>WARNING</b>	Do not approach the equipment until the sensor stops moving.
--	--

## 9.5 Viewing the Acquired Images

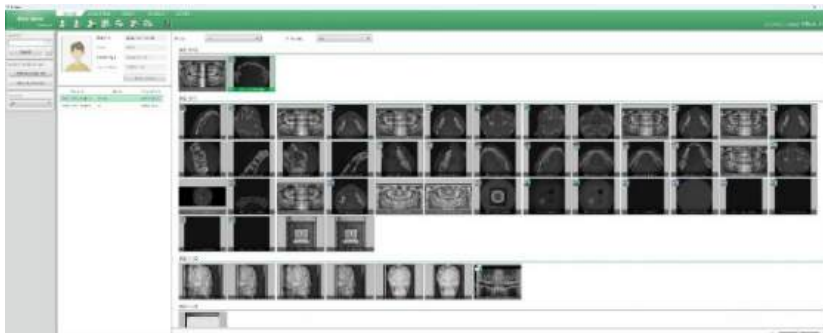
Follow the steps below to check the acquired images.

1. Check the image on the screen and click the **Save** button.

### NOTICE

If you have selected the **Auto Save** option, you may skip this step.

2. Select the Patient tab and click on the image to review. Once the image is selected, Ez3D-i will start.



### NOTICE

You can select one image at a time.

3. Review the selected image in the Viewer tab of the Ez3D-i, if necessary, use the tools in the toolbar to edit the image.

## 10. How to Acquire 3D Model Scan Images

### 10.1 Program Overview

- **Role**


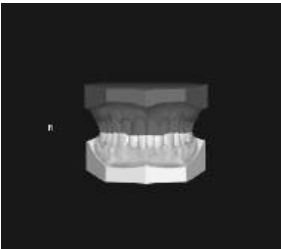
It provides 3D modeling surface data of the Plaster Cast. (STL file)

- **Image Acquisition Method**

It acquires images with the X-ray beam scanning the Plaster Cast and reconstructs them into 3D sliced images and converts the sliced images into 3D modeling surface data.

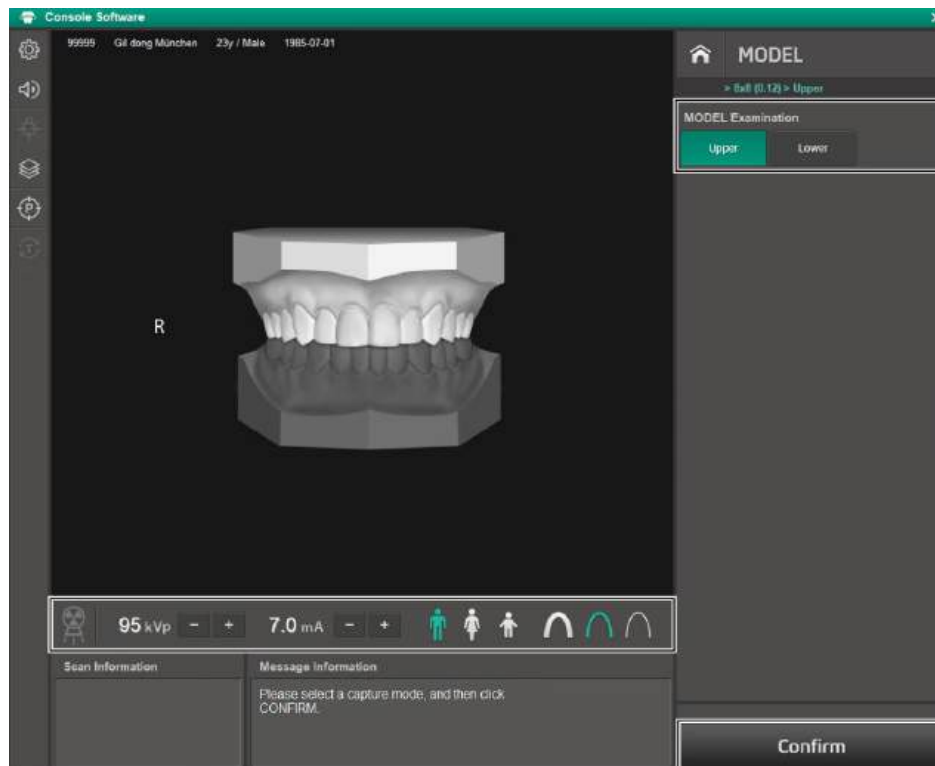
- **Examination Programs**

It is classified as below based on the MODEL type.

Applied FOV (cm)	Vertical Option	ROI	Description
8x8	Upper (Maxilla)		Captures a whole maxillary Plaster Cast.
	Lower (Mandible)		Captures a whole mandibular Plaster Cast.

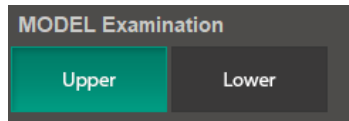
## 10.2 Selecting Exposure Settings

Before configuring exposure settings, finish the steps in **6. Getting Started**.



To select exposure settings for the MODEL mode,

1. Select a model examination option.



2. Check the exposure settings. To adjust, click the plus-minus button next to the tube voltage (kVp) or the current (mA); each click changes the voltage by  $\pm 1.0$  kVp and the current by  $\pm 0.1$  mA.



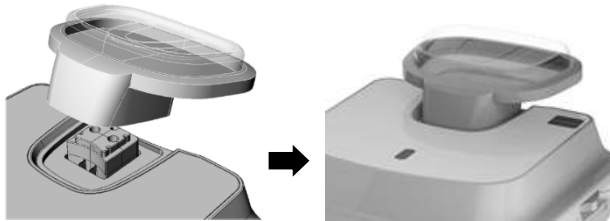
3. Click the **Confirm** button. Once the button is clicked, you cannot change the parameters



### 10.3 Model Positioning

Follow the steps below to position the plaster cast for the MODEL mode.

1. Insert the model scan jig on the handle frame after removing the chinrest and temple support.



2. Place the plaster cast on the jig. Whether the plaster caster is for maxilla or Mandibular, make sure that the flat side of the cast is facing down.



3. Align the center of the plaster cast to the vertical laser beam.



## 10.4 Acquiring Images

Follow the steps below to acquire an X-ray image.



Do not use the PC while capturing an image. This can cause a problem with equipment or software operation.



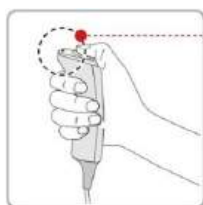
In an emergency, release the **exposure switch** and press the **emergency stop switch** under the handle frame.

1. Click the **Ready** button in the console window.



Do not approach the equipment until the sensor stops moving.

2. When the progress bar above the Ready button reaches 100%, press the exposure switch.



Yellow : X-ray On

3. Release the exposure switch when the switch's LED light turns off.

**IMPORTANT**

Releasing the exposure switch before the LED light turns off may cause image acquisition to fail

4. Wait until the sensor returns to its starting position. Then guide the patient out of the X-ray unit after opening the temple support.



Do not approach the equipment until the sensor stops moving.

## 10.5 Viewing the Acquired Images

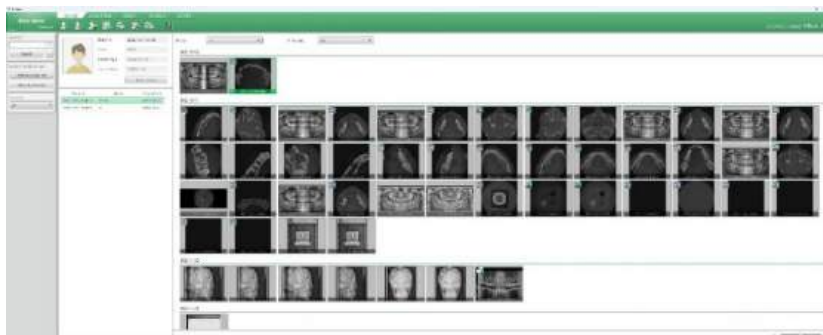
Follow the steps below to check the acquired images.

1. Check the image on the screen and click the **Save** button.

### NOTICE

If you have selected the **Auto Save** option, you may skip this step.

2. Select the **Patient tab** and click on the image for review. Once the image is selected, the STL viewer you have linked to EzDent-i will start.



### NOTICE

Prior to image acquisition, ensure that STL viewer is connected to the **EzDent-i**.

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# 11. Troubleshooting

## 11.1 Troubleshooting

If a problem occurs during the operation, follow the guide in the table below to solve the issue. If the problem persists, contact VATECH customer service.

### When the equipment is not working

Description	Action
Fail to turn on	Check the equipment's power connection status.
Fail to initialize	Check the error code on the console window and contact customer service.
Fail to communicate with the PC	Check the communication port (optic) that connects the PC to the equipment.

### When the system cannot capture the image

Description	Action
Fail to capture an image	<ol style="list-style-type: none"> <li>1. Check the exposure switch's connection status.</li> <li>2. Check if the console software is ready to capture an image.</li> </ol>

### When the system cannot capture the image after clicking Confirm

Description	Action
Fail to capture an image	Check the error code on the console window and contact customer service.

### When the laser beam is turned off before completing patient positioning

Description	Action
Lasers are turned off	Press the <b>Beam on/off button</b> on the control panel.

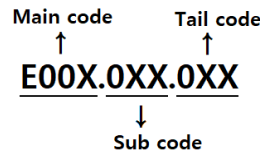
## 11.2 Error Codes

The error code appears in the message information window of the console software when a problem occurs during the operation of device. If you see the code, please contact VATECH for assistance.

Error code is written in the following format:

**[Code: E00X.0XX.0XX]**

The code consists of three parts: Main, Sub, and Tail.



### NOTICE

- **The main code** indicates the source of error codes. The source is categorized as hardware, software, an acquisition module, etc.
- **The subcode** describes the area where the error occurred according to the main code.
- **The tail code** explains the specific symptoms and causes of the errors mentioned in the subcode.

### 11.2.1 Main code - Hardware (001)

#### 11.2.1.1 Subcode – Generator-Related Error (010)

Tail code	Description
001	The tube is not ready for use
002	The tube tank cable is not connected the inverter board
003	The tube current has exceeded the maximum limit during image acquisition.
004	The tube voltage value is $\pm 10\text{kV}$ or more from the reference value
005	The tube current value is $\pm 0.5\text{mA}$ or more from the reference value
006	The tube voltage feedback value is $\pm 20\text{kV}$ or more from the average value
007	The tube current feedback value is $\pm 1\text{mA}$ or more from the average value
008	Mono tank temperature is higher than the setup value

Tail code	Description
009	Inverter's output current is higher than 1A during the X-ray exposure (both in EP and IP conditions)
010	Inverter board incorrectly receives the X-ray exposure switch signal as "OFF" after X-ray exposure
011	The "X-ray OFF" command is not sent to the inverter board within 0.5 seconds after the X-ray exposure switch is turned off.
012	Tube voltage feedback value exceeds -20kV from the setup value during X-ray exposure
013	Tube voltage feedback value exceeds +20kV from the setup value during X-ray exposure
014	Tube current feedback value is less than 50% of the setup value during X-ray exposure
015	Tube current feedback value exceeds 150% of the setup value during X-ray exposure

### 11.2.1.2 Subcode - Motor-Related Error (020)

Tail code	Description
003	The axis of the rotator motor has failed to move to the origin
009	CEPH sensor motor has failed to move to the origin
012	The left axis of the collimator's has failed to move to the origin
013	The right axis of the collimator's has failed to move to the origin
014	The top axis of the collimator's has failed to move to the origin
015	The bottom axis of the collimator's has failed to move to the origin
018	The generator tilting failed
019	The temple support motor has run into a problem while moving
020	The X-axis of the motor has failed to move to the origin
021	The Y-axis of the moto has failed to move to the origin
022	The X-axis of the sensor has failed to move to the origin
023	Column position sensor does not respond
024	Column auto-calibration does not respond

**11.2.1.3 Subcode – Exposure Switch-Related Errors (030)**

Tail code	Description
001	X-ray exposure switch is pressed while turning on the equipment
002	Image acquisition is halted due to early release of the X-ray exposure.

**11.2.1.4 Subcode – Other Errors (040)**

Tail code	Description
000	The main MCU is unable to carry out CAN communication.
001	The tube is unable to carry out CAN communication.
002	The collimator is unable to carry out CAN communication.
003	The sensor MCU is unable to carry out CAN communication.
004	The keypad (control panel) MCU is unable to carry out CAN communication.

**11.2.2 Main code – Software (002)****11.2.2.1 Subcode – User-Related Caution (001)**

Tail code	Description
001	ROI (Focus item) is not assigned
002	Image acquisition is canceled by user
003	User setting information has been changed

**11.2.2.2 Subcode – PC Resolution Related Error (010)**

Tail code	Description
001	The PC monitor resolution is less than 1280x1024
002	The PC monitor resolution is less than 1200x960

**11.2.2.3 Subcode- PC Storage Error (011)**

Tail code	Description
001	Low disk space (less than 1GB)
002	Low disk space (less than 2GB)
003	Low disk space (less than 3GB)

### 11.2.2.4 Subcode – Network Error (023)

Tail code	Description
009	The packing mode is enabled
010	The X-ray room door is opened
011	The X-ray exposure switch is pressed too early

### 11.2.2.5 Subcode – File Loading Failure (061)

Tail code	Description
002	The INI section cannot be found
003	The name of INI key cannot be found

### 11.2.2.6 Subcode –File Opening Failure (062)

Tail code	Description
001	The file path is incorrect

### 11.2.2.7 Subcode – File Reading Error (063)

Tail code	Description
001	The file path is incorrect
009	Null (No patient information)
012	The name of INI key cannot be found

## 11.2.3 Main code - Acquisition Module (003)

### 11.2.3.1 Subcode – Initialization Failure-Related Error (010)

Tail code	Description
001	Unable to open the COM port
002	Unable to initialize frame grabber interface or Reserve memory for image capture
003	Unable to communicate with the MCU or the modem signal has improper state

**11.2.3.2 Subcode – Capture Failure-Related Error (020)**

Tail code	Description
001	Image acquisition runs into a problem

**11.2.3.3 Subcode – Reconstruction Failure-Related Error (030)**

Tail code	Description
002	Unable to open program files
003	Missing projection file
004	Missing geometry file
005	Missing Aircal file
006	Projection file size error
007	Geometry file size error
008	Aircal file size error
009	Writing to file failed
010	Saving slice files failed
100	Timeout
101	Failed to load submodule DLL
200	Invalid parameter value
201	Invalid Recon mode
300	Unknown GPU Error
301	GPU out of memory
400	CS normalization error
401	CS Thetabeta error

**11.2.3.4 Subcode – Hardware-Related Error (061)**

Tail code	Description
HW Error No	Acquisition module runs into a problem

## 12. Cleaning and Disinfection

### 12.1 Preparation

Before cleaning or disinfecting the equipment, you must:

- Turn off the equipment.
- Wear safety gloves.
- Select the product that satisfies the following conditions:
  - Chlorine-Dioxide based.
  - Non-alcoholic
  - Contains none of the following chemicals: silicone, acetone, phenol, acetic acid, peroxide, sodium hypochlorite, isopropyl alcohol (2-propanol, isopropanol), iodine-splitting agents, and oxygen-splitting agents.
  - Not an oil or gas type.
  - Approved by FDA and local regulations for chemical products.



DO NOT clean the equipment while the power is still on. This can cause electrical shock, burns, and other injuries to you or other people near the equipment.



Oil or gas-type cleaning agents can cause corrosion and deterioration.

## 12.2 Cleaning

Before and after imaging, clean the accessories and parts that contact the patient or user. The accessories and parts that require cleaning are:

- Normal / Special A / Special B bites
- Temple Supports
- Chinrest
- Nasal positioner covers
- Ear rods caps
- Carpus plate
- Protractor
- Model scan jig

Accessory / Part	Procedure
Bite (Normal / Special A / Special B) Temple Supports Chinrest Carpus plate Protractor Model scan jig	<ol style="list-style-type: none"> <li>1) Remove visible soil with a paper wipe or disposable cloth.</li> <li>2) Use a soft cloth dampened with a cleaning agent. And gently wipe the target area with the cloth.</li> <li>3) Dry the cleaned parts and accessories with a dry cloth until no liquid is left.</li> </ol>
PC and its peripherals	Clean each part following the manufacturer's instructions
Accessory covers and caps	Wipe the outer covers with a dry cloth once a day.

### NOTICE

Contact **VATECH**'s customer service for more information on cleaning the equipment.

### WARNING

DO NOT spray or pour the cleaning agent over the equipment. Liquid can damage equipment or cause a fire.

### IMPORTANT

DO NOT use the cloth soaked in the cleaning agent to clean the equipment. Liquids may slip into the equipment. Put a little amount of the cleaning agent on the cloth to avoid the incident for use.

### 12.3 Disinfection

Follow the precautions below when you choose a disinfectant and use it for the equipment.

- Use the product approved by the safety regulations of the country where the equipment is installed.
- Follow the directions on the product's label.
- Disinfect the accessories and parts that are frequently touched by people including patients.
- DO NOT use UV sterilizer to disinfect the equipment. UV light can discolor the equipment's surface.

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## 13. Maintenance

- **VATECH** requires periodic constancy tests to assure image quality and safety for its patients and users.
- Only **VATECH**-authorized technicians can inspect and repair the equipment. Contact the service center or your local **VATECH** representative for technical assistance.
- Users cannot inspect or repair the equipment. Contact the service center or your local **VATECH** representative for technical assistance.
- Users cannot remove the equipment's cover. There are no repairable parts inside.
- Users cannot reform or modify the equipment, cables, or wires. Modification can damage the equipment beyond repair.
- Ensure to turn off the equipment before inspection or repair.
- Ensure to inspect and repair the equipment on a flat surface.
- DO NOT pull cables by force.
- Ensure that the equipment is well-grounded.
- Ensure that all detachable parts are clean.
- Avoid the following places when storing the equipment or its components:
  - Susceptible to water or humidity
  - Prone to extreme fluctuation in temperature
  - Exposed to direct sunlight, salt, dust, and other pollutants.

### 13.1 Maintenance Task Checklist

Tasks	Period
Ensure that the equipment is clean and ready for use before the operation.	Daily
Ensure that all parts directly contacting the patients are clean.	Daily
Ensure that the <b>main power switch</b> is turned off after the operation.	Daily
Ensure that the LED indicator turns yellow when you press <b>the exposure switch</b> .	Daily
Ensure that the LED indicator remains yellow during the operation.	Daily
Check for defects on the cables inside and outside the equipment.	Daily
Check the correct operation of the <b>emergency stop switch</b>	Weekly
Ensure that all labels on the equipment are intact and legible.	Weekly
Check the condition of the <b>exposure switch</b> .	Monthly
Check the sound of the audio messages from the equipment.	Monthly

## 14. QA Test

### 14.1 Who Performs a QA Test

Each facility shall establish a committee of individuals responsible for the Radiation Safety/Quality Assurance program. For a non-hospital facility, this committee might be composed of a dentist, an X-ray technician, an office manager, and a service representative certified to perform radiological functions by the law in the state where the X-ray system is being used.

Each facility shall make the radiation safety/quality assurance program, including the following tests, at the frequency specified by the manufacturer or state regulations and maintain data records.

Test	Recommended Period
CT Number Test	Yearly
CT Uniformity Test	Yearly
High & Low Contrast Test	Initially and yearly

For technical assistance for QA tests, contact your local VATECH service representative.





## 14.2 Phantom Kit Information

We strongly recommend regularly performing three tests (CT number, CT uniformity, high & low contrast) explained in this chapter at the interval and time specified by the manufacturer or the state law where the X-ray system is installed.

To conduct tests, you need to use the phantom kit consisting of a user manual and the phantoms as specified in the table below.

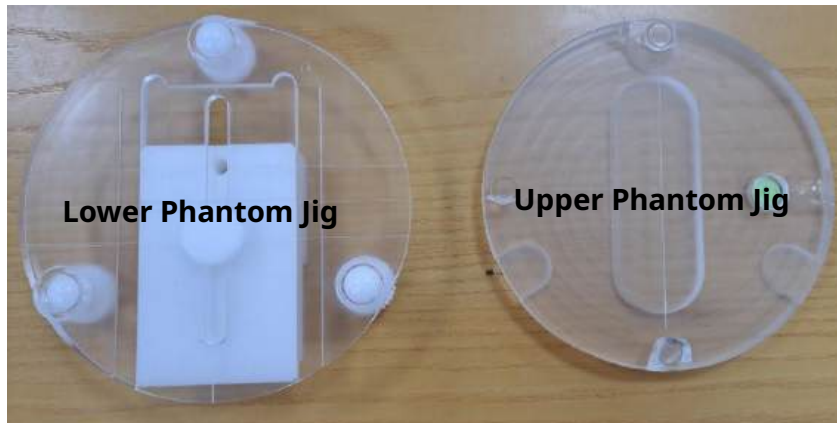
Kit Contents	Qty.
CT number check phantom	1
Uniformity check phantom	1
S&C check phantom	1
Phantom jig	1
Phantom kit user manual	1

The table below shows the specifications for each phantom inside the kit.

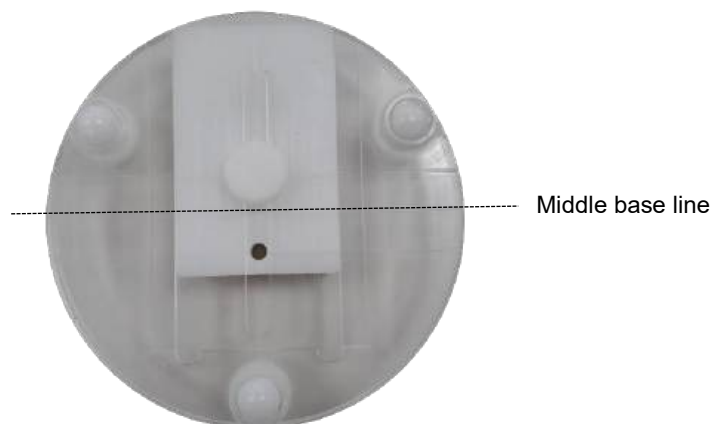
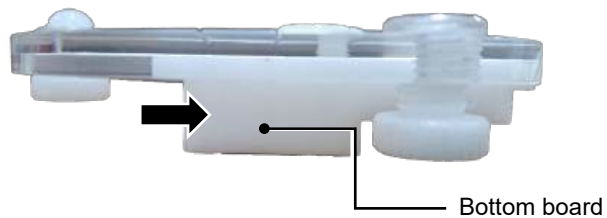
Image	Name	Intended use	Manufacturer
	CT Number Check Phantom	CT number inspection and calibration	VATECH Co., Ltd.
	Uniformity Check Phantom	CT Image Homogeneity and noise inspection	VATECH Co., Ltd.
	S&C Check Phantom	Low and high contrast resolution inspection	VATECH Co., Ltd.
	Phantom Jig	CT image inspection and calibration	VATECH Co., Ltd.

### 14.3 Installing Phantom Jig

Installing the phantom jig is the first key step in a QA test. Follow the steps below to install the phantom jig and calibrate it for the QA test.



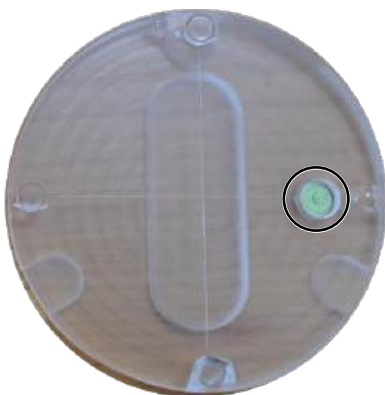
1. Remove the **chinrest**, **bite block**, and **temple supports** from the handle frame.
2. Calibrate the lower phantom jig as illustrated below:
  - 1) Slide the bottom board until the groove on the board is aligned with the middle base line.



- 2) When the alignment is complete, turn the bolt clockwise to fix the bottom board in place.



3. Insert the lower phantom jig on the handle frame where you have removed the chinrest and bite block.
4. Assemble the upper phantom jig on the top of the lower phantom jig.
5. [Leveling the phantom jig ] Check the bubble level on the upper phantom jig. If the jig is level, the bubble inside the device should stay at the center.



If it does not, use the align pins of the lower phantom jig to adjust the phantom until the bubble comes to the center.

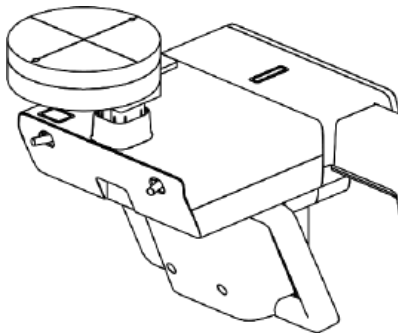
## 14.4 Performing QA Test

### NOTICE

Before performing a QA test, ensure that the phantom jig is properly installed.

### 14.4.1 CT Number Test

1. Place the **CT number check phantom** on the phantom jig,



2. Double-click the **EzDent-i** icon on your PC.



3. Go to the **AQUISITION** tab and select 'CT' from the modality menu to open the DENTAL CT console window.




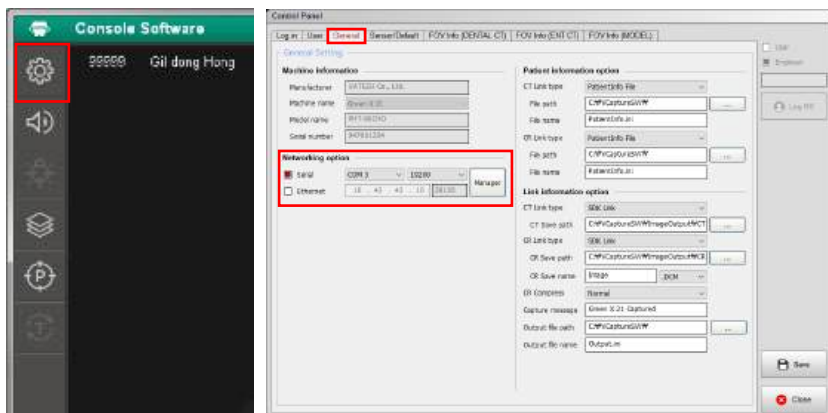
4. In the DENTL CT console window, select '21x19' on the FOV menu.



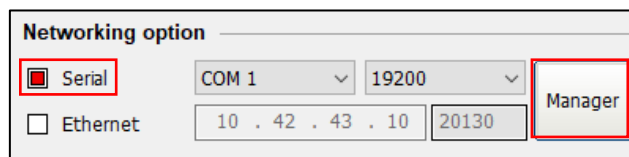
5. Click the **Confirm** button.

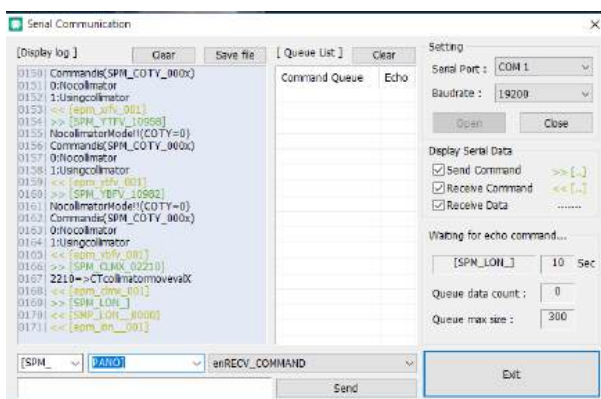


6. Click  on the console software to open the **control panel window**. Then select the **General** tab > **Networking Option** > **Serial**.



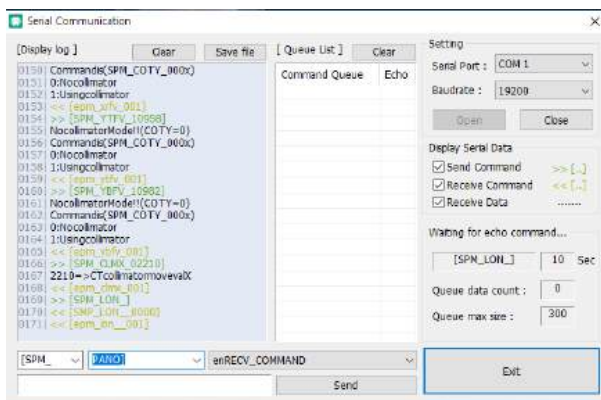
7. Click the **Manager** button to open a **serial communication window**.



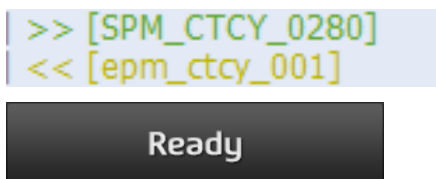


Serial Communication Window

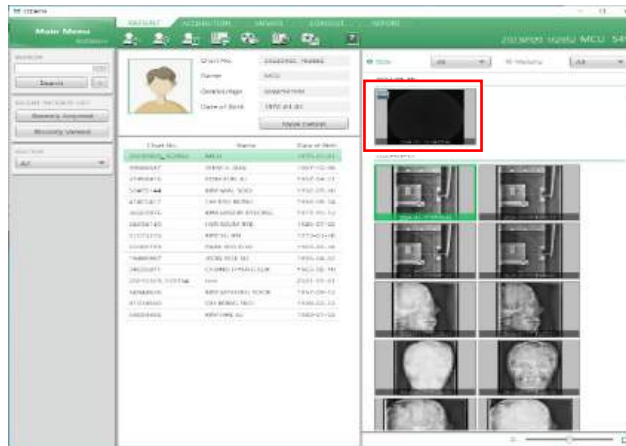
- In the window, enter “[SPM\_CTCY\_0282]” to capture the center of the phantom. Click the **Send** button once entering the command.



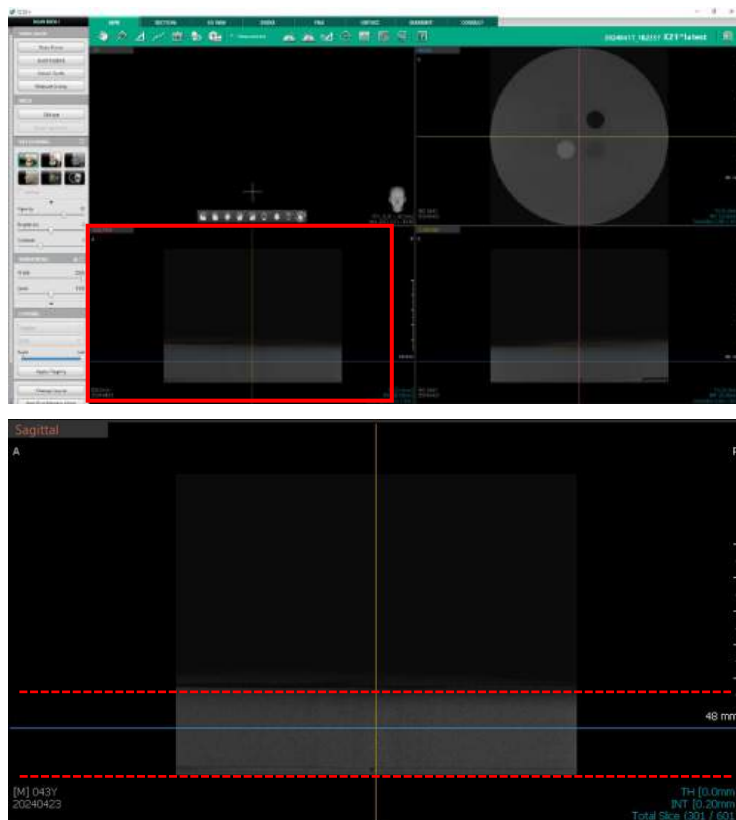
- When the “[epm\_ctcy\_001]” appears in the Display log, click the **Ready** button in the console window.



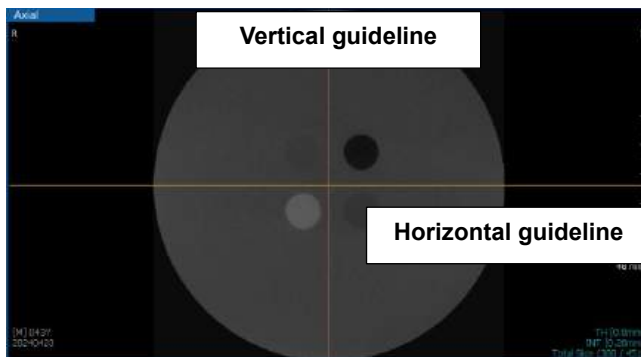
- Press the X-ray exposure switch according to the instructions in the Message Information window.
- Return to the Ezdent-i window and click the captured image. Once the image is clicked, Ez3D-i will automatically start.




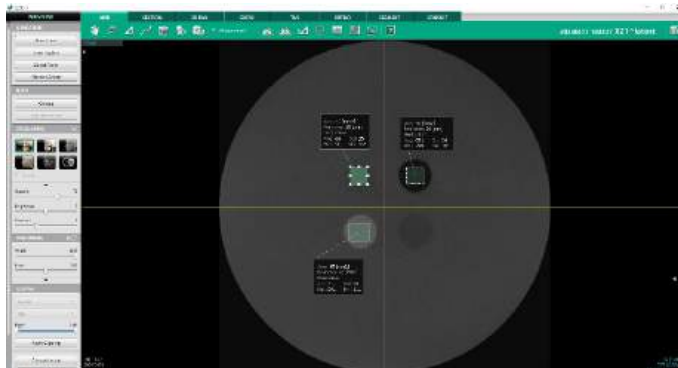
12. In the Ez3D-i window, go to the 'Sagittal' screen, and drag the guideline down to the middle between the top and bottom of the phantom.



13. Go to the Axial window and check if the vertical and horizontal guidelines are placed as illustrated below. Then double-click the 'Axial' label for the full-screen mode.




14. Select  from the toolbar and click the “Water”, “Air”, and “Teflon” areas as illustrated below. When clicking each area, a pop-up will appear.



15. Check the average (avg) pixel value in the pop-up and compare the value with standards in the table below. The pixel value for each material should fall within the standard range.

Material	Mean	Lower Limit	Upper Limit	Scope
Air	-900 HU	-1030 HU	-990 HU	IEC 61223-2-6: 5.5.4, 5.5.5
Water	0 HU	-50 HU	50 HU	
Teflon	980 HU	900 HU	1100 HU	

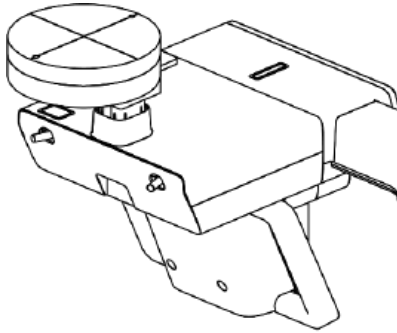


16. Click  to capture and save the Ez3D-i screen with pixel value information.
17. Remove the **CT number check phantom** from the phantom Jig.

### 14.4.2 CT Uniformity Test

Follow the steps below to perform a CT uniformity test.

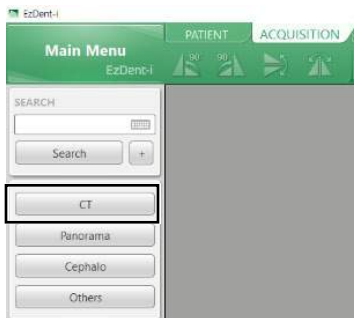
1. Place the **uniformity check phantom** over the phantom jig.



2. Double-click the EzDent-i icon on your PC.



3. Go to the **AQUISITION** tab and select 'CT' from the modality menu to open the DENTAL CT console window.




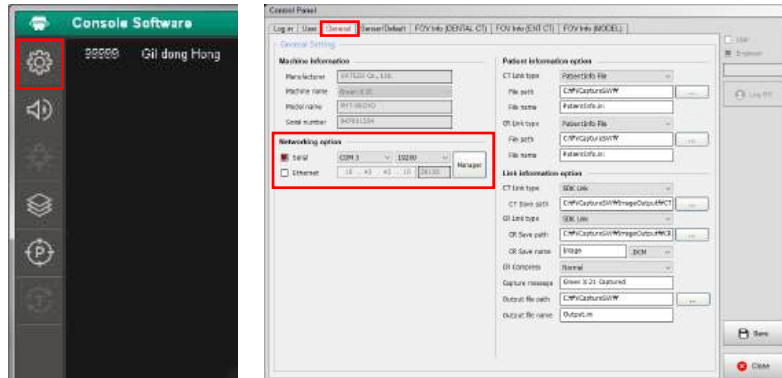
4. In the DENTAL CT console window, select '21x19' on the FOV menu.



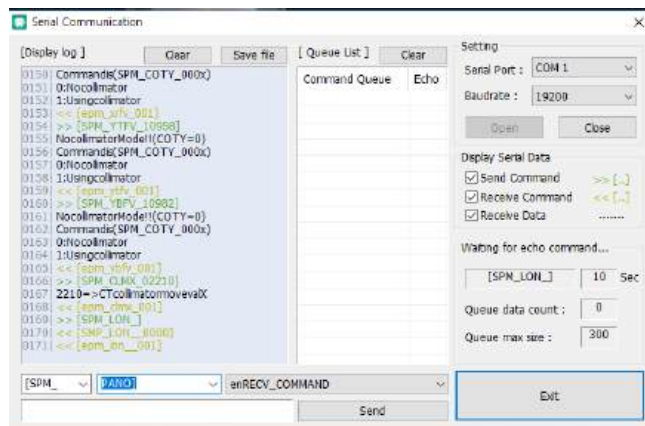
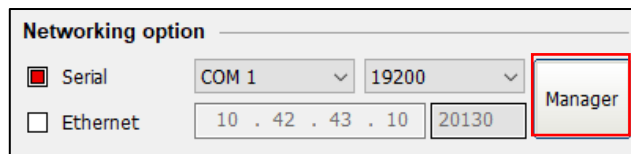
5. Click the **Confirm** button.



6. Click  on the console software to open the **control panel window**. Then select the **General** tab > **Networking Option** > **Serial**.

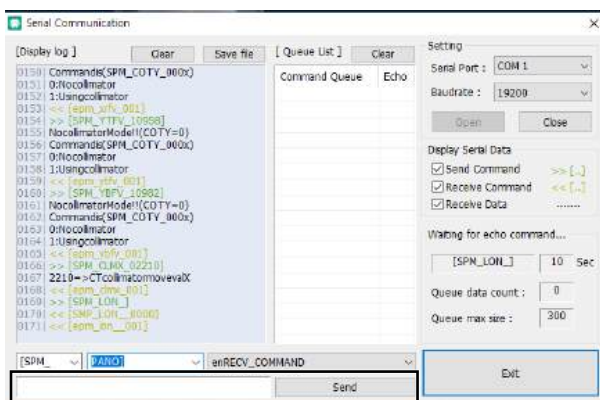


7. Click the **Manager** button to open a **serial communication window**.

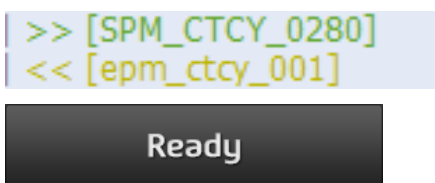


**Serial Communication Window**

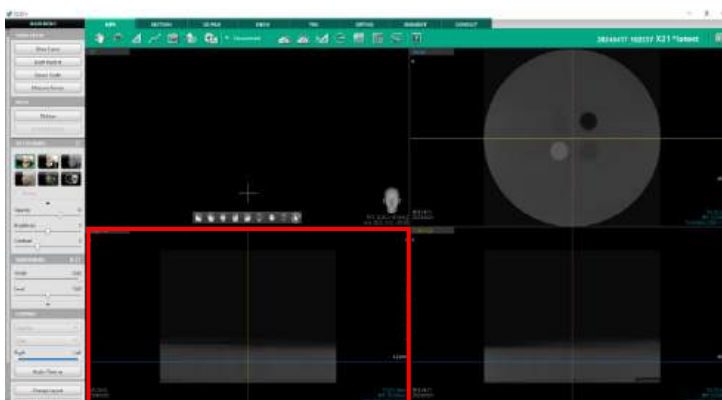
- In the window, enter “[SPM\_CTCY\_0282]” to capture the center of the phantom. Click ‘Send’ after entering the command.

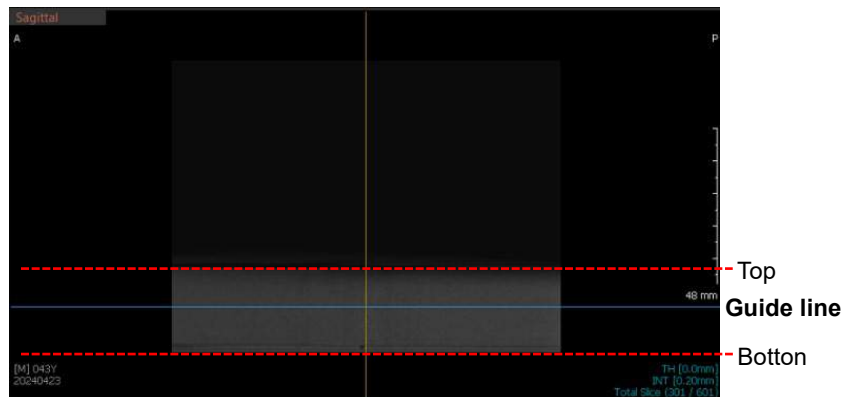


- When the “[epm\_ctcy\_001]” appears in the display log, click the **Ready** button in the console window.

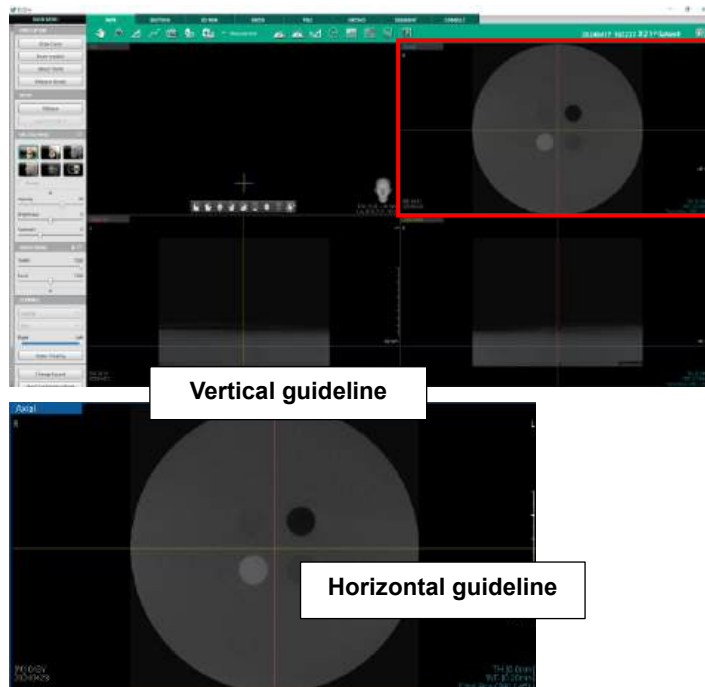



- Press the X-ray exposure switch according to the instructions in the Message Information window.
- Return to the Ezdent-i window and select the captured image. The selected image will be opened in the Ez3D-i window.
- In the Ez3D-i window, go to the 'Sagittal' window, and drag the guideline down to the middle between the top and bottom of the phantom.



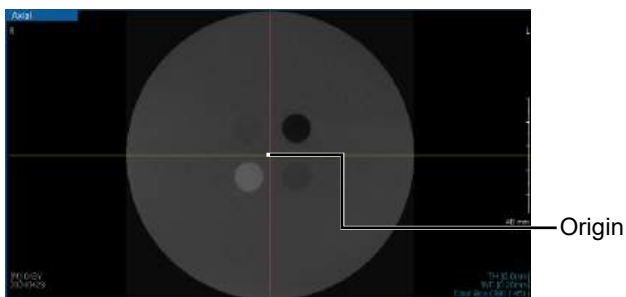



13. Go to the Axial window and check if the vertical and horizontal guidelines are placed as illustrated below. Then double-click the 'Axial' label for the full-screen mode.

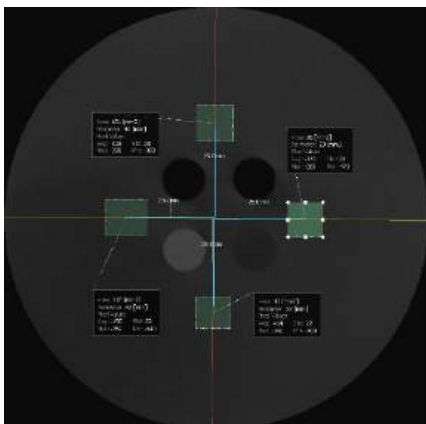


14. Click  and draw 25.0 mm lines in four directions from the origin.

## 14. QA Test



15. Click  and select the end of each of the four lines. Once selected, a pop-up will appear as illustrated below.




16. Check the average in the pixel value pop-up and repeat it for all four ROIs.

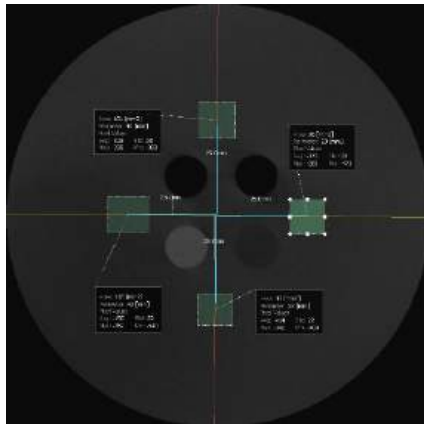


17. **[Measuring Homogeneity]** Among the average values of four ROIS, select the largest and the smallest. Then calculate the difference between two values and compare the result with the standard in the table below.

Calculation	Standard	Scope
Subtract the smallest value from the largest value among the average values of four ROIs	The difference should be less than 400 HU	61223.3.5 INTRODUC TION



18. Click  to capture and save the Ez3D-i screen with pixel value information.

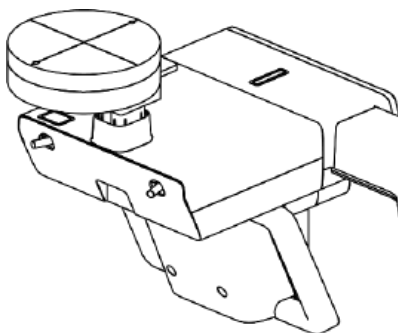


19. Remove the **uniformity check phantom** from the phantom Jig.

### 14.4.3 High and Low Contrast Resolution

Follow the steps below to perform a high and low contrast resolution test.

1. Place the **S&C check phantom** on the phantom jig.



2. Start **EzDent-i** by double-clicking the desktop icon.



3. Go to the **AQUISITION** tab and select 'CT' from the modality menu to open the DENTAL CT console window.




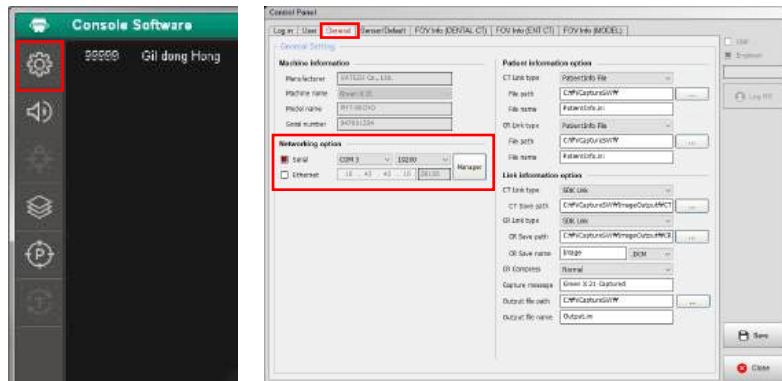
4. In the DENTL CT console window, select '**21x19**' on the FOV menu.



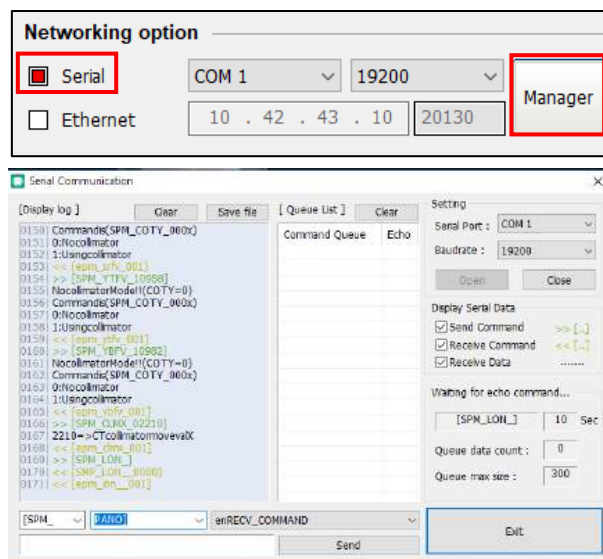
5. Click the **Confirm** button.



6. Click  on the console software to open the control panel window. Then select the **General tab > Networking Option > Serial**.

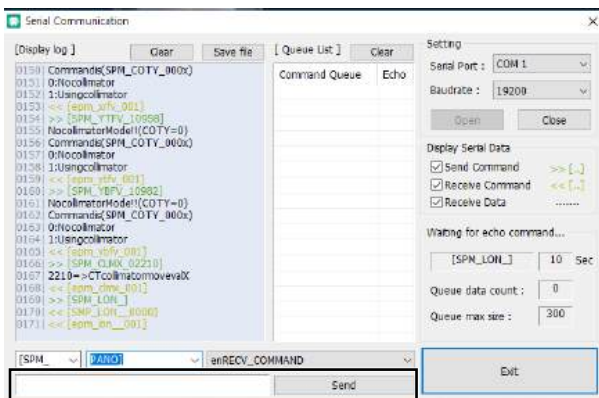


7. Click the **Manager** button to open a **serial communication window**.

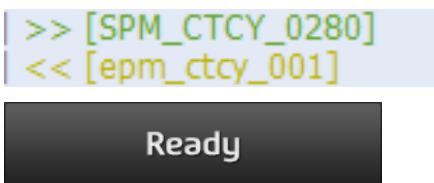


**Serial Communication Window**

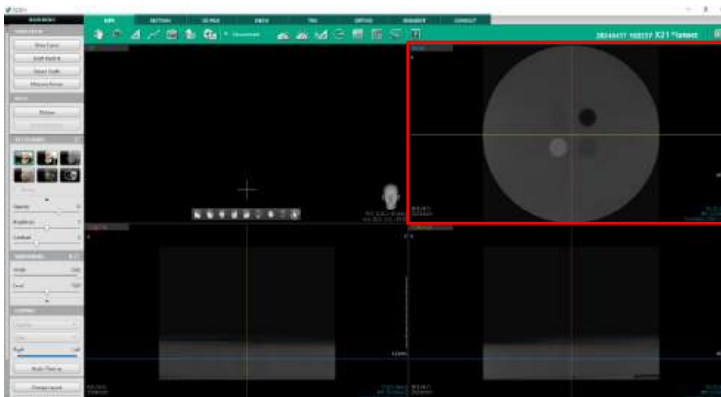
- In the window, enter “[SPM\_CTCY\_0282]” to capture the center of the phantom. Click the **Send** button after entering the command.



- When the “[epm\_ctcy\_001]” appears in the display log, click the **Ready** button in the console window.

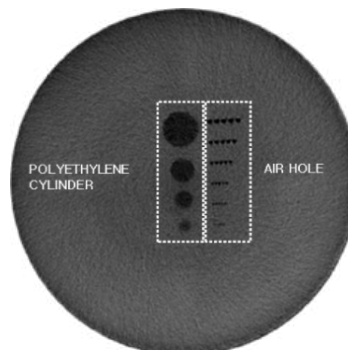


- Press the X-ray exposure switch according to the instructions in the Message Information window.
- Return to the Ezdent-i window and click the captured image. Once the image is clicked, Ez3D-i will automatically start.
- Go to the Axial window and click the 'Axial' label for the full-screen mode.

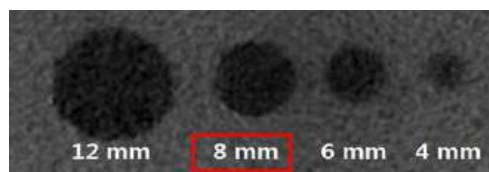




13. **[Checking high & low contrast]** To evaluate the high contrast resolution, check the visibility of the **0.1 mm air hole**. To evaluate the low contrast resolution, check the visibility of the **8.0 mm PE(Polyethylene) cylinder** at 50 cm from the monitor.

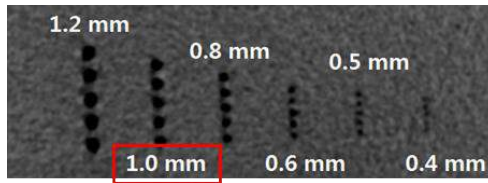


Parameters	Material	Minimum visible size
High Contrast Resolution	Air Hole	1.0mm
Low Contrast Resolution	PE cylinder	8.0mm




<High Contrast Resolution>

## 14. QA Test



<Low Contrast Resolution>

14. Click  to capture and save the Ez3D-i screen with pixel value information.
15. Remove the **S&C check phantom** from the phantom Jig.

# 15. Disposing of the Equipment

This equipment is designed for safe use and disposal to reduce environmental contamination. Many components, except parts like the X-ray tube, are environmentally friendly and recyclable.

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

Parts	Materials	Recyclable	To the special disposal site	Hazardous waste; Needs Separate Collection
Frame and covers	Aluminum and plastics	•		
Motors		•		
Circuit boards		•		
Cables and transformer	Copper	•		
	Steel	•		
	Oil		•	
Packing	Wood	•		
	Cardboard	•		
	Paper	•		
X-ray tube				•
Sensor head	Return the sensor head to <b>VATECH</b>			
Other parts			•	

<b>⚠ CAUTION</b>	This dental equipment shall not be disposed of as domestic garbage materials.
<b>IMPORTANT</b>	Clean/Disinfect/Sterilize the equipment before disassembling and disposing of its parts.
<b>NOTICE</b>	Observe all regulations relevant to the disposal of waste in your country.

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Item		Description
Weight	Without CEPH unit	162.9 kg (359.13 lbs. - without Base)
		217.9 kg (480.38 lbs. – with Base)
	With CEPH unit	187.9 kg (414.25 lbs. - without Base)
		242.9 kg (535.50 lbs. - with Base)
Total Height	Without Base	Max. 2317.4 mm (91.24")
	With Base	Max. 2345.4 mm (92.34")
Dimensions during operation (Length x Width x Height)	Without CEPH unit	Without Base: 1085.0(L) x 1457.8(W) x 2317.4(H) (mm) 42.72(L) x 57.39(W) x 91.24(H) (")
		With Base: 1085.0(L) x 1457.8(W) x 2345.4(H) (mm) 42.72(L) x 57.39(W) x 92.34(H) (")
	With CEPH unit	Without Base: 1905.5(L) x 1457.8(W) x 2317.4(H) (mm) 75.02(L) x 57.39(W) x 91.24(H) (")
		With Base: 1905.5(L) x 1457.8(W) x 2345.4 (H) (mm) 75.02(L) x 57.39(W) x 92.34(H) (")
Rotating unit's vertical movement		Max. 800 mm (31.50")
Installation type		Base Stand/Wall Mount (Default: Wall Mount type)
Packing box organization		Main Box, CEPH Box (Optional), Base Box (Optional)

### 16.1.2 Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	560	414.81	145.19	1:1.35
CEPH	1745	1524.00	221.00	1:1.14
CBCT	560	350.00	210.00	1:1.60

- **FDD:** Focal Spot to Detector Distance
- **FOD:** Focal Spot to Object Distance
- **ODD:** Object to Detector Distance (ODD = FDD - FOD)
- **Magnification** = FDD/FOD

## 16.2 Technical Specifications

### 16.2.1 X-ray Generator Specifications

#### Specifications

Item		Description	
Generator	Model	DG-07E22T2	
	Rated output power	1.6 kW	
	Inverter model name	INV-22	
	Type	Inverter	
	Normal/ Pulse	kVp	60 kV~99 kV (1 kV increment)
		mA	4 mA~16 mA (0.1 mA increment for CBCT, 1 mA increment for PANO and CEPH)
	Cooling	Thermal protection	
	Total filtration	Min. 2.5 mm Al	
	Permanent filtration	Min. 1.0 mm Al	
Added filter	PANO and CEPH: 1.5 mm Al (Fixed) CBCT: 1.5 mm Al (Fixed) + 3.0 mm Al (Automatically added)		
Tube	Manufacturer	Canon Electron Tubes & Devices	
	Model	D-052SB (Stationary Anode type)	
	Focal spot size	0.5 mm (IEC 60336)	
	Target Angle	5 degrees	
	Permanent Filtration	At least 0.8 mm Al equivalent at 50 kV	
	X-ray Coverage	95 mm x 380 mm at SID 550 mm	
	Anode Heat Content	35 kJ	
	Duty Cycle	1:60 or more (Exposure time: Interval time)	

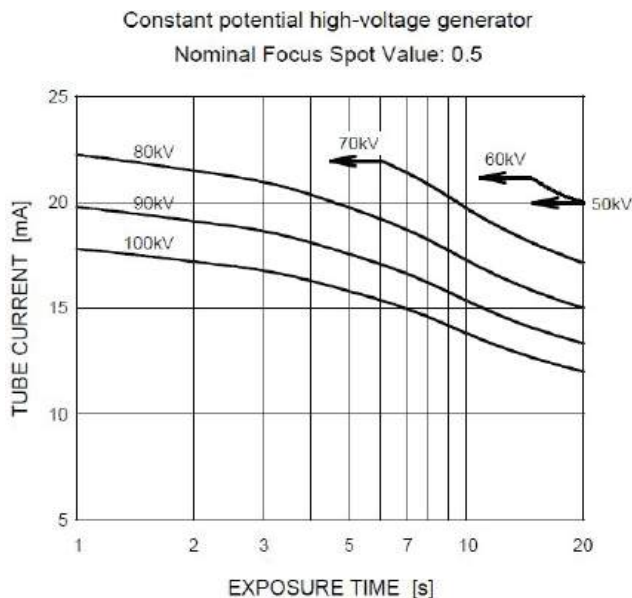
**Test Condition**

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	60~90	4~14	13.5
	60~90	4~14	11.5
	60~90	4~14	11.2
	60~90	4~14	9.2
	60~90	4~14	9.0
	60~90	4~14	8.0
	60~90	4~14	6.8
	60~90	4~14	6.7
	60~90	4~14	6.7
	60~90	4~14	6.2
	60~90	4~14	5.7
	60~90	4~14	5.5
	60~90	4~14	4.5
	60~90	4~14	3.9
	60~90	4~14	3.7
	60~90	4~14	3.4
	60~90	4~14	3.2
	60~90	4~14	3.0
	60~90	4~14	2.8
	60~90	4~14	2.0
60~90	4~14	1.5	
60~90	4~14	0.8	
CEPH	60~99	4~16	1.9
	60~99	4~15	2.4
	60~99	4~15	3.9
	60~99	4~14	4.9
	60~99	4~14	5.4

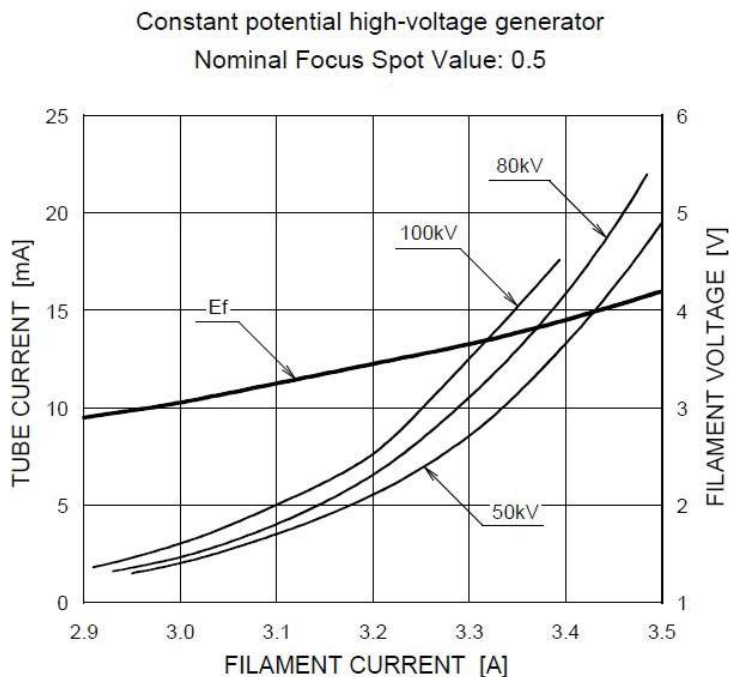
## 16. Technical Specifications

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
CBCT	60~99	4~12	9.0
	60~99	4~16	2.9
	60~99	4~12	18.0

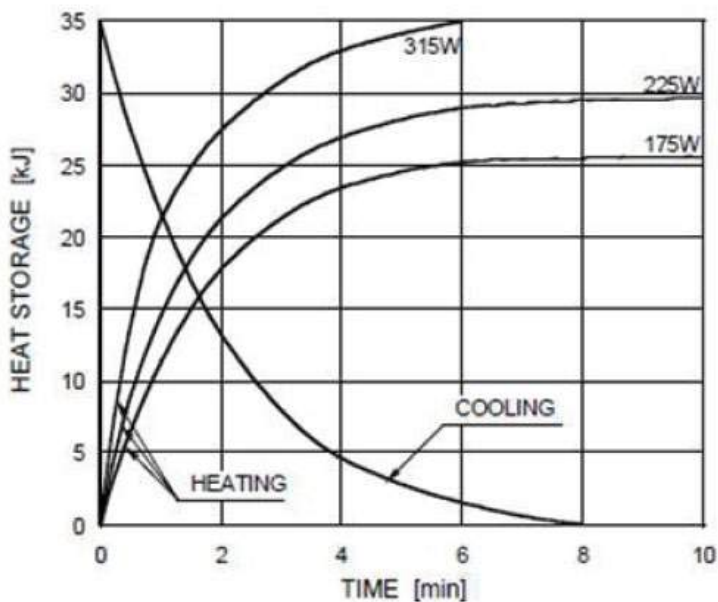
## Maximum Rating Charts



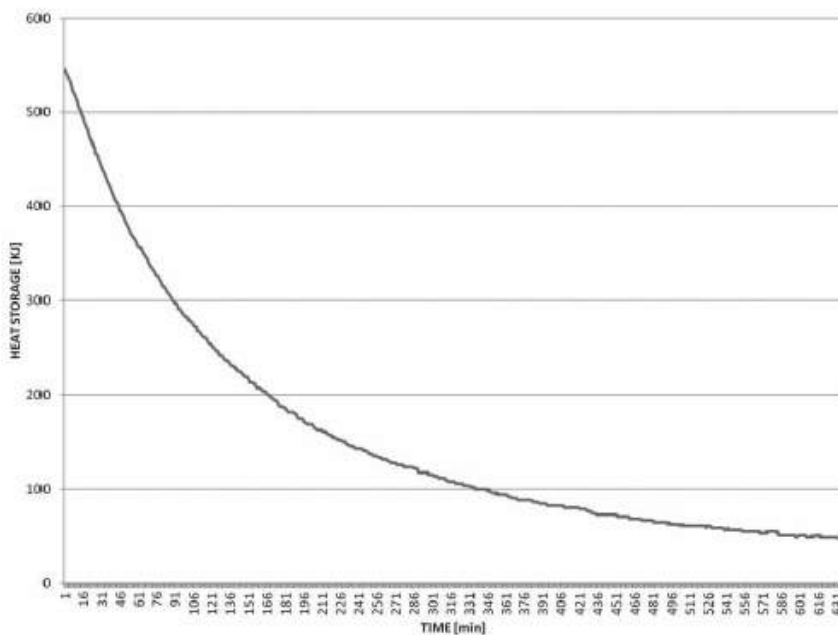
## Emission & Filament Characteristics



### ■ Anode Thermal Characteristics



### ■ X-ray Housing Assembly Tube Characteristics



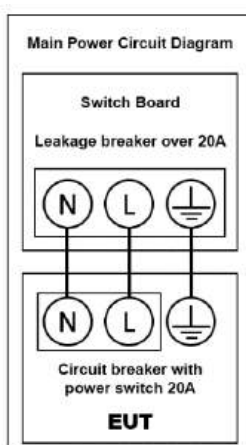
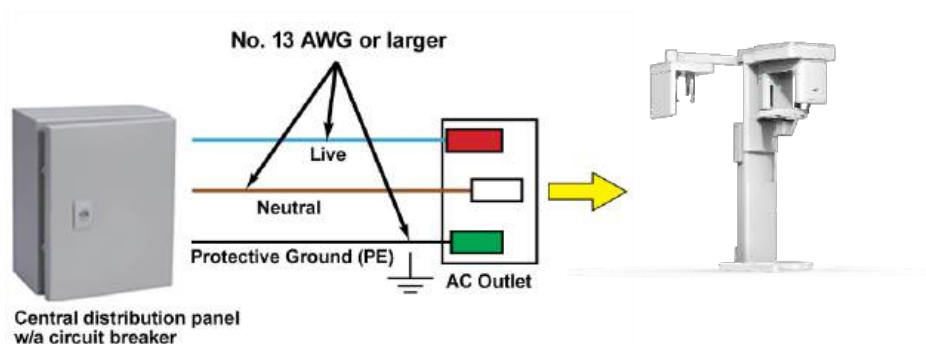
## 16.2.2 Detector Specifications

Item	Description	
	PANO & CBCT	CEPH
Model	Xmaru1314CF	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 $\mu\text{m}$ @ 4x4 binning 99 $\mu\text{m}$ @ 2x2 binning (49.5 $\mu\text{m}$ @ no binning)	200 $\mu\text{m}$ @ 2x2 binning
Active area	PANO: 135.8 x 5.9 (mm) CBCT: 135.8 x 127.5 (mm)	259.20 x 15.60 (mm)
Frame Rate	~ 108 fps @ 4x4 binning ~ 32 fps @ 2x2 binning	~ 320 fps @ 2x2 binning
Analogue-Digital Conversion	14 bits	
Operating condition	10~35 $^{\circ}\text{C}$ (Temperature) 10~75 % (Humidity)	
Storage condition	-10~60 $^{\circ}\text{C}$ (Temperature) 10~75 % (Humidity)	
Sensor size	165 (L) x 230 (W) x 27 (H) (mm)	110 (L) x 279 (W) x 20 (H) (mm)
Sensor weight	1.45 kg	<1.0 kg
Converter	Csl : TI	
Energy Range	50~120 kVp	40~120 kVp
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 45 % 1.0 lp/mm, > 10 % @ 2.5 lp/mm	$\geq$ 2 % @ 2.5 lp/mm
Dynamic Range	> 80 dB	$\geq$ 68 dB

### 16.3 Electrical Specifications

Item	Description
Power supply voltage	100-240 V~
Frequency	50 / 60 Hz
Power rating	2.2 kVA
Accuracy	Tube Voltage (kVp) < $\pm 10\%$ , Tube Current (mA) < $\pm 20\%$ , Exposure Time (s) < $\pm (5\% + 50\text{ ms})$

- The input line voltage depends on the local electrical distribution system.
- Allowable input voltage fluctuation requirement:  $\pm 10\%$ .
- **Mode of operation:** non-continuous operation (NFPA 70: long time operation) - needs waiting time (at least 60 times the exposure time) before the next exposure begins.
- Column operation time: Max. 2 min. On /18 min. Off (Ratio 1:9)



**NOTICE**

- A separate 3-core grounded power cable connected directly to the central distribution panel with an over-current circuit breaker rated for 20A must be used to assure line voltage quality.
- Maximally allowed deviation of the tube voltage/tube current/exposure time:  
Tube Voltage (kVp)  $\pm 10\%$  / Tube Current (mA)  $\pm 20\%$  /  
Exposure Time (s)  $\pm (5\% + 50\text{ ms})$  according to IEC 60601-2-63.
- The mains resistance should not exceed  $0.045\ \Omega$  at 100 V and 0.19 ohms at 240 V.

## 16.4 Environmental Specifications

	Item	Description
During Operation	Temperature	10~35 °C
	Relative humidity	30~75 %
	Atmospheric pressure	860~1060 hPa
During Transport and Storage	Temperature	-10~60 °C
	Relative humidity	10~75 %
	Atmospheric pressure	860~1060 hPa

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## 17. Appendices

### 17.1 Recommended X-ray Exposure Tables

#### NOTICE

- **Scan time** : the time in which the equipment acquires image data excluding the initial acceleration and late deceleration stages.
- **Exposure time** : the time in which the patient is exposed to X-ray emission.

#### 17.1.1 PANO Mode

##### Exposure Condition

Mode	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	High Resolution	Man	Hard	75	10.0
			Normal	74	10.0
			Soft	73	10.0
		Woman	Hard	74	10.0
			Normal	73	10.0
			Soft	72	10.0
		Child	Hard	70	8.0
			Normal	69	8.0
			Soft	68	8.0
	Green (Optional)	Man	Hard	85	14.0
			Normal	84	14.0
			Soft	83	14.0
		Woman	Hard	84	14.0
			Normal	83	14.0
			Soft	82	14.0
Child		Hard	68	11.0	
		Normal	67	11.0	
		Soft	66	11.0	
		Man	Normal	70	6.0

Mode	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination (Insight PAN; Optional)	High Resolution	Woman	Normal	70	6.0
		Child	Normal	67	6.0
SPECIAL Examination	N/A	Man	Hard	75	10.0
			Normal	74	10.0
			Soft	73	10.0
		Woman	Hard	74	10.0
			Normal	73	10.0
			Soft	72	10.0
		Child	Hard	70	8.0
			Normal	69	8.0
			Soft	68	8.0

**Scan Time /Exposure Time**

Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
PANO Examination	Narrow	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
	Normal	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
	Wide	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
	Child	Standard	12.0	11.5	7.0	6.8
		Right	12.0	5.7	7.0	3.3
		Front	12.0	9.2	7.0	5.5
		Left	12.0	5.7	7.0	3.3
	Orthogonal	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
		Bitewings	14.1	9.0	4.0	3.0
		Bitewing Incisor (Optional)	14.1	2.8	4.0	0.8
		Bitewing Right	14.1	4.5	4.0	1.5
		Bitewing Left	14.1	4.5	4.0	1.5

Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
SPECIAL Examination	-	TMJ LAT Open	14.1	6.7	n/a	n/a
		TMJ LAT Close				
		TMJ PA Open (Optional)	10.0	6.1	n/a	n/a
		TMJ PA Close (Optional)				
		Sinus LAT (Optional)	4.0	3.7	n/a	n/a
		Sinus PA	8.8	8.0	n/a	n/a

*\*Green, Insight PAN, Bitewing Incisor, TMJ PA open/close, and Sinus LAT are optional in some countries.*

## 17.1.2 CEPH Mode

**Exposure Condition**

Examination Program	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
Lateral	High Resolution	Man	Hard	92	15.0
			Normal	90	15.0
			Soft	88	15.0
		Woman	Hard	90	15.0
			Normal	88	15.0
			Soft	86	15.0
		Child	Hard	88	15.0
			Normal	86	15.0
			Soft	84	15.0
	Green	Man	Hard	92	16.0
			Normal	90	16.0
			Soft	88	16.0
		Woman	Hard	90	16.0
			Normal	88	16.0
			Soft	86	16.0
Child		Hard	88	16.0	
		Normal	86	16.0	
		Soft	84	16.0	
Full Lateral (Optional)	High Resolution/ Green	Man	Hard	92	14.0
			Normal	90	14.0
			Soft	88	14.0
		Woman	Hard	90	14.0
			Normal	88	14.0
			Soft	86	14.0
		Child	Hard	88	14.0
			Normal	86	14.0
			Soft	84	14.0

Examination Program	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PA SMV Waters' view	High Resolution	Man	Hard	92	14.0
			Normal	90	14.0
			Soft	88	14.0
		Woman	Hard	90	14.0
			Normal	88	14.0
			Soft	86	14.0
		Child	Hard	88	14.0
			Normal	86	14.0
			Soft	84	14.0
	Green	Man	Hard	92	15.0
			Normal	90	15.0
			Soft	88	15.0
		Woman	Hard	90	15.0
			Normal	88	15.0
			Soft	86	15.0
		Child	Hard	88	15.0
			Normal	86	15.0
			Soft	84	15.0
Carpus	High Resolution / Green	Man	Hard	90	6.0
			Normal	88	6.0
			Soft	86	6.0
		Woman	Hard	88	6.0
			Normal	86	6.0
			Soft	84	6.0
		Child	Hard	86	6.0
			Normal	84	6.0
			Soft	82	6.0

**Scan Time/Exposure Time**

Examination Program	High Resolution		Green	
	Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
Lateral	3.9	3.9	1.9	1.9
Full Lateral (Optional)	5.4	5.4	3.9	3.9
PA	4.9	4.9	2.4	2.4
SMV	4.9	4.9	2.4	2.4
Waters' view	4.9	4.9	2.4	2.4
Carpus	4.9	4.9	2.4	2.4

### 17.1.3 CBCT Mode

#### Exposure Area

FOV (cm)	Vertical Position	Horizontal Position		
		Right	Center	Left
Double Scan	Maxilla	X	O	X
	Mandible	X	O	X
16x9	Occlusion	X	O	X
12x9	Occlusion	X	O	X
	TMJ	O	X	O
	Airway	X	O	X
Smart Focus	Maxilla	Selectable FOV by Teeth (Unlimited)		
	Mandible			
8x8	Occlusion	O	O	O
	TMJ	O	X	O
8x5	Maxilla	O	O	O
	Mandible	O	O	O
5x5	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)		
ENDO	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)		

**Exposure Condition**

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
16x9 & 12x9 & Smart Focus Double scan	High Resolution	Man	Hard	95	7.0
			Normal	94	7.0
			Soft	93	7.0
		Woman	Hard	95	6.7
			Normal	94	6.7
			Soft	93	6.7
		Child	Hard	95	6.4
			Normal	94	6.4
			Soft	93	6.4
	Green	Man	Hard	88	6.1
			Normal	87	6.1
			Soft	86	6.1
		Woman	Hard	88	5.8
			Normal	87	5.8
			Soft	86	5.8
		Child	Hard	88	5.5
			Normal	87	5.5
			Soft	86	5.5
8x8 8x5	High Resolution	Man	Hard	95	13.0
			Normal	94	13.0
			Soft	93	13.0
		Woman	Hard	95	12.7
			Normal	94	12.7
			Soft	93	12.7
		Child	Hard	95	12.4
			Normal	94	12.4
			Soft	93	12.4

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
	Green	Man	Hard	88	9.6
			Normal	87	9.6
			Soft	86	9.6
		Woman	Hard	88	9.3
			Normal	87	9.3
			Soft	86	9.3
		Child	Hard	80	8.0
			Normal	79	8.0
			Soft	78	8.0
5x5	High Resolution	Man	Hard	95	13.0
			Normal	94	13.0
			Soft	93	13.0
		Woman	Hard	95	12.7
			Normal	94	12.7
			Soft	93	12.7
		Child	Hard	95	12.4
			Normal	94	12.4
			Soft	93	12.4
	Green	Man	Hard	88	9.3
			Normal	87	9.3
			Soft	86	9.3
		Woman	Hard	88	9.0
			Normal	87	9.0
			Soft	86	9.0
Child		Hard	80	8.0	
		Normal	79	8.0	
		Soft	78	8.0	
Endo		Man	Hard	98	12.0

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
	High Resolution		Normal	97	12.0
			Soft	96	12.0
		Woman	Hard	98	11.7
			Normal	97	11.7
			Soft	96	11.7
		Child	Hard	98	11.4
			Normal	97	11.4
			Soft	96	11.4

### Scan Time / Exposure Time

FOV (cm)	Scan Time (s) (High Resolution/Green)	Exposure Time (s) (High Resolution/Green)
Double scan	22.0	18.0
16x9	11.0	9.0
12x9	11.0	9.0
Smart Focus	11.0	9.0
8x8	2.9	2.9
8x5	2.9	2.9
5x5	2.9	2.9
Endo	18.0	18.0

### 17.1.4 3D MODEL Scan Mode

#### Exposure Area

FOV (cm)	MODEL Type	Horizontal Position		
		Right	Center	Left
8x8	Upper (Maxilla)	X	O	X
	Lower (Mandible)	X	O	X

#### Exposure Condition

FOV (cm)	Gender/Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
8x8	Man/Woman/Child	Hard/Normal /Soft	95	7.0

#### Scan Time/Exposure Time

FOV (cm)	Scan Time (s)	Exposure Time (s)
8x8	11.0	9.0

### 17.1.5 X-ray Dose Data

### 17.1.6 DAP (Dose Area Product)

The X-ray dose data is extracted from the X-ray Dose Test Report for **Green X (Model: PHT-75CHS)**.

X-ray Dose Test Report for the **Green X (Model: PHT-75CHS)** maintains dosimetric evaluation that the **VATECH** dental diagnostic system meets all requirements specified in the IEC Collateral Standard. Green X (Model: PHT-75CHS) is designed to comply with IEC 60601-1-3 Part 1 General Requirements for Safety to limit unnecessary exposure to the patient, operator, or other staff.

Test Hardware	
Brand Name (Model)	<b>Green X (Model: PHT-75CHS)</b>
Sensor Type	PANO & CBCT: Xmaru1314CF CEPH: Xmaru2602CF
X-ray Generator	DG-07E22T2
Tube	D-052SB

DAP (Dose Area Product) is used to assess the radiation risk from diagnostic X-ray examination procedures. It is defined as the absorbed dose multiplied by the area irradiated, expressed in gray square centimeters ( $\text{mGy}\cdot\text{cm}^2$ ). Despite the limitation, DAP is the best way to predict effective dose value and is currently the most convenient method for patient dose monitoring.

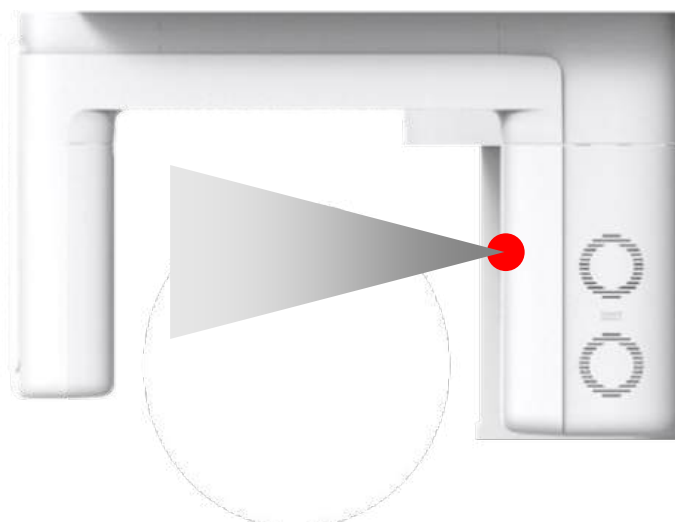
- **Accuracy of radiation:** *Information on the overall uncertainty of the indicated values of the AIR KERMA and DOSE AREA PRODUCT shall be provided in the ACCOMPANYING DOCUMENT and shall not exceed 50 %*

**DAP (Dose Area Product) Calculation**

$$\text{DAP}[\text{mGy} \cdot \text{cm}^2] = \text{Dose}[\text{mGy}] \times \text{Exposed Area}[\text{cm}^2]$$

**NOTICE**

When you need more information on DAP measurement procedures or test results for the equipment, please contact **VATECH** service center or your local **VATECH** representative and get assistance from **VATECH**-authorized technicians

**Measurement Overview****Results**

Modality	Modality Option	Image Option	Patient	Exposure Condition (kVp / mA / s)	DAP
PANO	Standard	High Resolution	Man	74 kVp / 10.0 mA / 13.5 s	112.06
			Child	69 kVp / 8.0 mA / 11.5 s	54.64
		Green	Man	84 kVp / 14.0 mA / 3.9 s	58.17
			Child	67 kVp / 11.0 mA / 6.8 s	49.14
	Insight PAN	High Resolution	Man	70 kVp / 6.0 mA / 7.5 s	112.47
			Child	67 kVp / 6.0 mA / 5.0 s	69.44
CEPH	Lateral	High Resolution	Man	90 kVp / 15.0 mA / 3.9 s	35.27
			Child	86 kVp / 15.0 mA / 3.9 s	32.55
		Green	Man	90 kVp / 16.0 mA / 1.9 s	21.36
			Child	86 kVp / 16.0 mA / 1.9 s	19.75

CBCT	Double Scan	High Resolution	Man	94 kVp / 7.0 mA / 18.0 s	2771.92
			Child	94 kVp / 6.4 mA / 18.0 s	2545.61
		Green	Man	87 kVp / 6.1 mA / 18.0 s	2009.76
			Child	87 kVp / 5.5 mA / 18.0 s	1821.25
	16x9	High Resolution	Man	94 kVp / 7.0 mA / 9.0 s	1385.96
			Child	94 kVp / 6.4 mA / 9.0 s	1272.81
		Green	Man	87 kVp / 6.1 mA / 9.0 s	1004.88
			Child	87 kVp / 5.5 mA / 9.0 s	910.63
	12x9	High Resolution	Man	94 kVp / 7.0 mA / 9.0 s	1090.87
			Child	94 kVp / 6.4 mA / 9.0 s	1001.82
		Green	Man	87 kVp / 6.1 mA / 9.0 s	790.97
			Child	87 kVp / 5.5 mA / 9.0 s	716.78
	8x8	High Resolution	Man	94 kVp / 13.0 mA / 2.9 s	815.63
			Child	94 kVp / 12.4 mA / 2.9 s	779.21
		Green	Man	87 kVp / 9.6 mA / 2.9 s	503.82
			Child	79 kVp / 8.0 mA / 2.9 s	330.64
	8x5	High Resolution	Man	94 kVp / 13.0 mA / 2.9 s	525.77
			Child	94 kVp / 12.4 mA / 2.9 s	502.29
		Green	Man	87 kVp / 9.6 mA / 2.9 s	324.78
			Child	79 kVp / 8.0 mA / 2.9 s	213.14
	5x5	High Resolution	Man	94 kVp / 13.0 mA / 2.9 s	349.60
			Child	94 kVp / 12.4 mA / 2.9 s	333.99
		Green	Man	87 kVp / 9.3 mA / 2.9 s	209.35
			Child	79 kVp / 8.0 mA / 2.9 s	141.72
Endo	High Resolution	Man	97 kVp / 12.0 mA / 18.0 s	1336.05	
		Child	97 kVp / 11.4 mA / 18.0 s	1279.95	
	Green	Man	97 kVp / 12.0 mA / 18.0 s	1336.05	
		Child	97 kVp / 11.4 mA / 18.0 s	1279.95	

- In Double Scan mode, expose the FOV 16x9 twice, and stitch the acquired images to provide one image.
- “Green” option is not available in the Insight PAN mode.

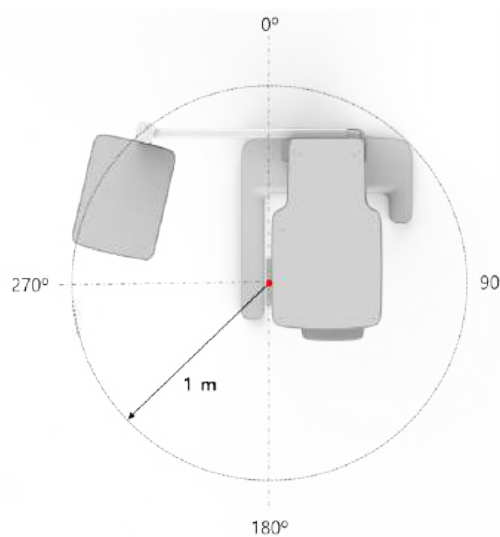
## 17.2 Leakage Dose

The X-ray Leakage Dose Test is performed to protect patients against excessive radiation that is not purposed, and this document evaluates the leakage dose amount based on the following standard defined by IEC regulation and has been performed by covering each collimator region in use.

### 17.2.1.1 Standard

National Deviation	Terminology	Permissive Range
International Standard IEC 60601-1-3	Leakage	limits leakage at 1m from the source to 100 mR in 1hr

### 17.2.1.2 Measurement Overview

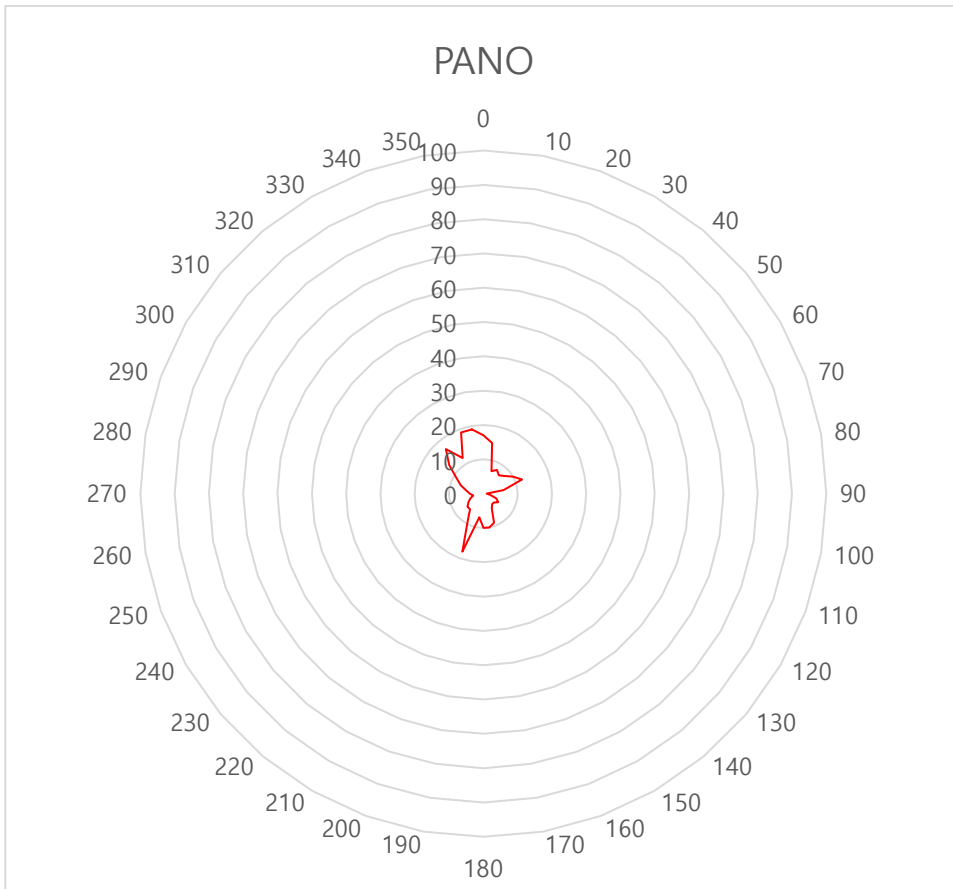


17.2.1.3 PANO Mode Results

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- PANO</li> <li>- Adult(Man)</li> <li>- Pano option: Normal</li> <li>- Image option: High Resolution</li> <li>- Pano examination: Standard</li> <li>- Arch selection: Normal</li> </ul>
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	13.5

Direction [°]	Mode	PANO	
		[mR/hr]	[mGy/hr]
0		17	0.149
10		15	0.132
20		7	0.061
30		8	0.070
40		7	0.061
50		8	0.070
60		10	0.088
70		12	0.105
80		6	0.053
90		1	0.009
100		2	0.018
110		4	0.035
120		5	0.044
130		4	0.035
140		4	0.035
150		5	0.044
160		9	0.079
170		10	0.088
180		10	0.088
190		7	0.061

Direction [°]	Mode	PANO	
		[mR/hr]	[mGy/hr]
200		18	0.158
210		9	0.079
220		6	0.053
230		6	0.053
240		5	0.044
250		4	0.035
260		3	0.026
270		4	0.035
280		5	0.044
290		7	0.061
300		9	0.079
310		13	0.114
320		17	0.149
330		12	0.105
340		19	0.167
350		19	0.167



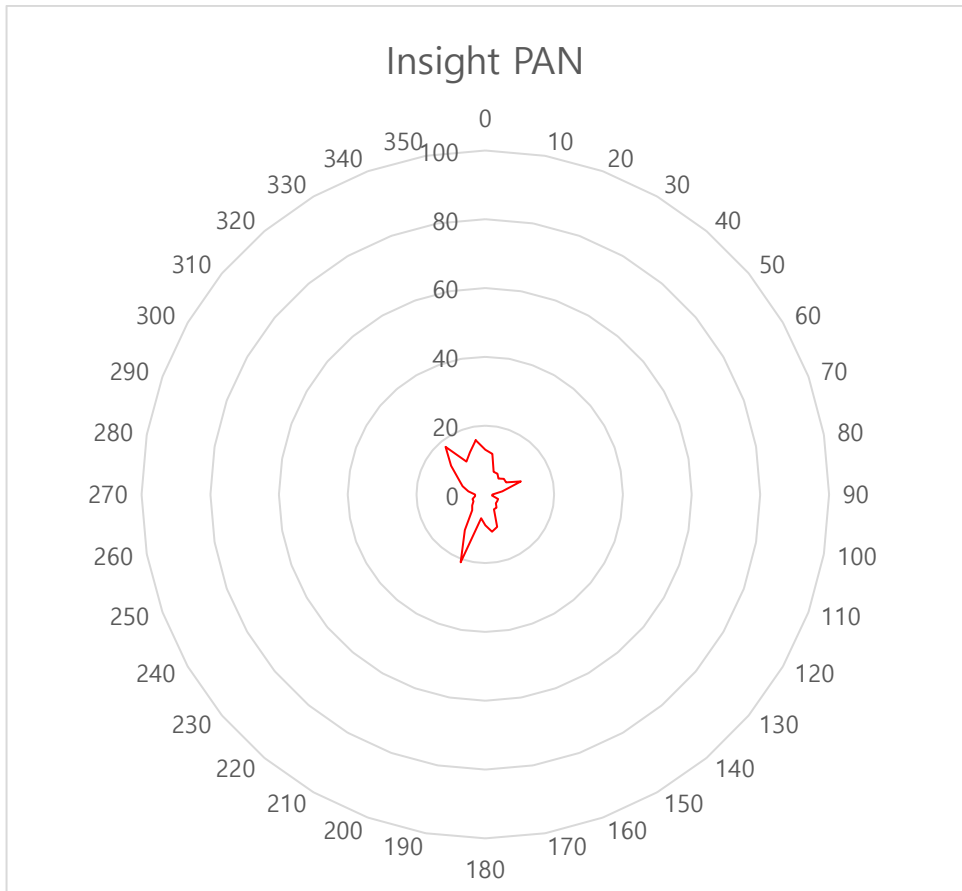
**PANO (Normal, High Resolution) Leakage Dose Test Graph**

## 17.2.1.4 PANO Mode Results (Insight PAN)

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- PANO</li> <li>- Adult(Man)</li> <li>- Pano option: Insight PAN</li> <li>- Image option: N/A</li> <li>- Pano examination: N/A</li> <li>- Arch selection: Normal</li> </ul>
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	11

Direction [°]	Mode	Insight PAN	
		[mR/hr]	[mGy/hr]
0		13	0.114
10		12	0.105
20		7	0.061
30		7	0.061
40		6	0.053
50		7	0.061
60		7	0.061
70		11	0.096
80		5	0.044
90		2	0.018
100		2	0.018
110		4	0.035
120		4	0.035
130		4	0.035
140		5	0.044
150		5	0.044
160		10	0.088
170		11	0.096

Direction [°]	Mode	Insight PAN	
		[mR/hr]	[mGy/hr]
180		9	0.079
190		7	0.061
200		21	0.184
210		12	0.105
220		6	0.053
230		5	0.044
240		4	0.035
250		4	0.035
260		3	0.026
270		3	0.026
280		5	0.044
290		7	0.061
300		9	0.079
310		13	0.114
320		18	0.158
330		11	0.096
340		13	0.114
350		16	0.140



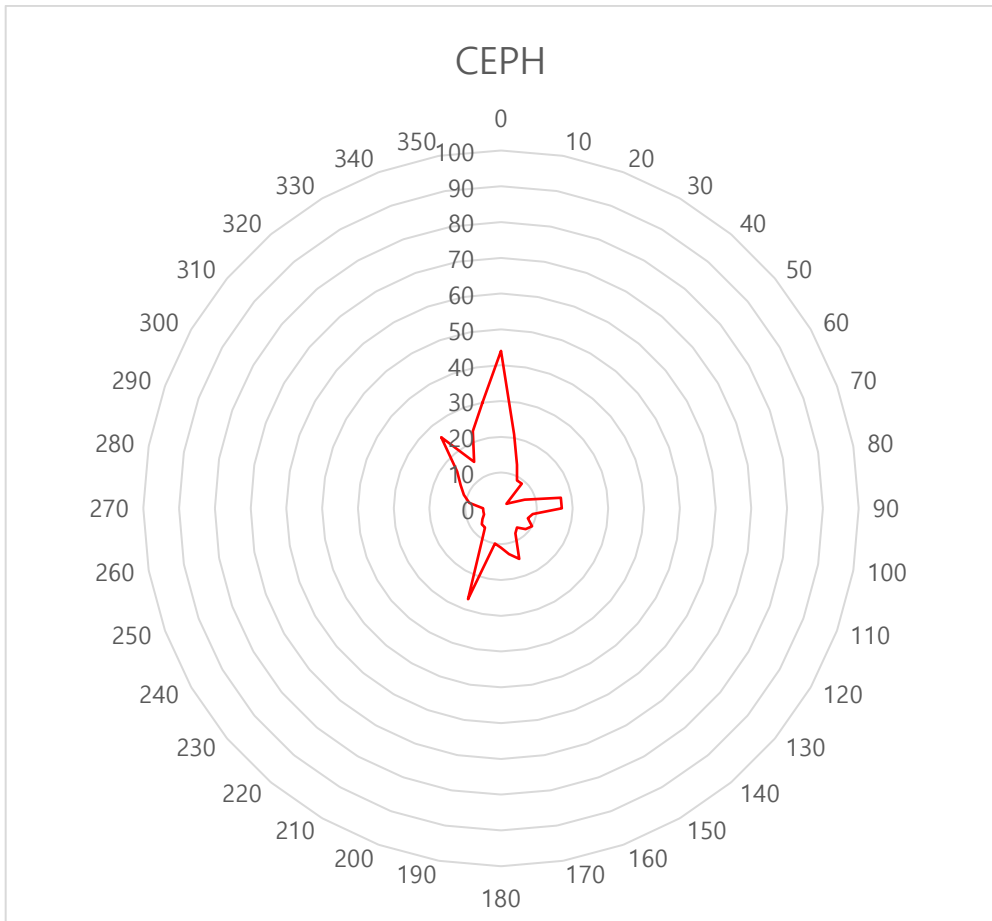
**PANO (Insight PAN, High Resolution) Leakage Dose Test Graph**

## 17.2.1.5 CEPH Mode Results

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- CEPH</li> <li>- Adult (Man)</li> <li>- Image option: Green</li> <li>- CEPH Examination: Lateral</li> </ul>
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	99
Tube Current [mA]	16
Exposure Time [s]	1.9

Direction [°]	Mode	CEPH	
		[mR/hr]	[mGy/hr]
0		44	0.386
10		21	0.184
20		13	0.114
30		9	0.079
40		9	0.079
50		2	0.018
60		3	0.026
70		7	0.061
80		17	0.149
90		17	0.149
100		9	0.079
110		8	0.070
120		10	0.088
130		9	0.079
140		7	0.061
150		8	0.070
160		15	0.132
170		13	0.114
180		11	0.096

Direction [°]	Mode	CEPH	
		[mR/hr]	[mGy/hr]
190		10	0.088
200		27	0.237
210		11	0.096
220		7	0.061
230		7	0.061
240		6	0.053
250		5	0.044
260		5	0.044
270		5	0.044
280		9	0.079
290		11	0.096
300		13	0.114
310		16	0.140
320		26	0.228
330		15	0.132
340		23	0.202
350		30	0.263



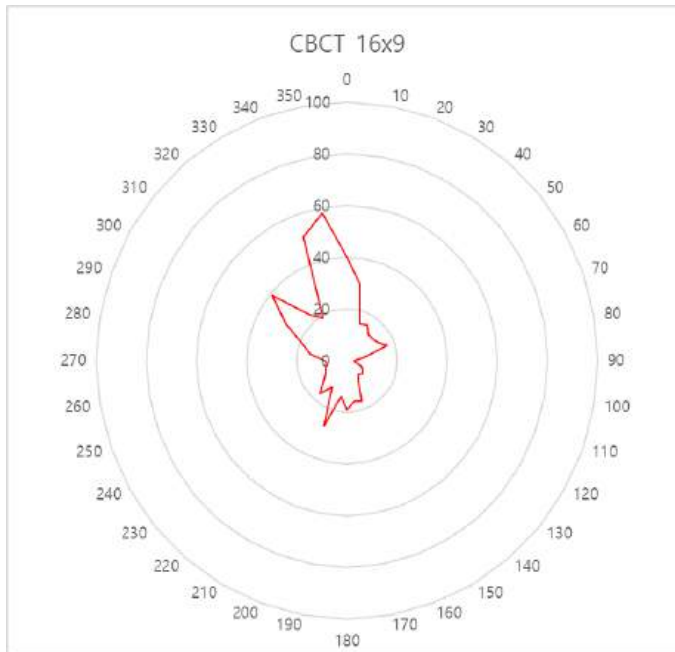
**CEPH (Lateral, Green) Leakage Dose Test Graph**

## CBCT Mode Results

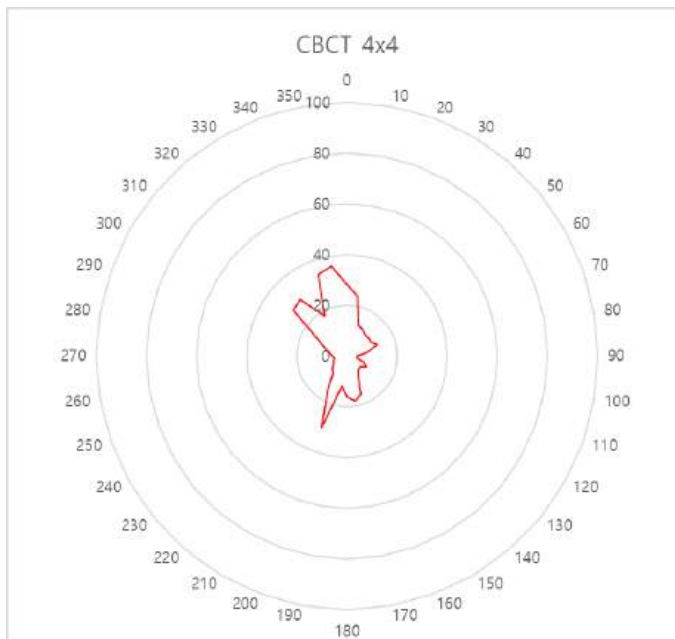
Test Condition	
Test Mode	<b>Test Mode 1</b> <ul style="list-style-type: none"> <li>- CBCT</li> <li>- Adult (Man)</li> <li>- FOV: 16x9,</li> <li>- Vertical option: Occlusion</li> <li>- Horizontal option: Center</li> <li>- Image option: High resolution</li> <li>- Voxel Size: Standard (0.20)</li> </ul>
	<b>Test Mode 2</b> <ul style="list-style-type: none"> <li>- CBCT</li> <li>- Adult (Man)</li> <li>- FOV: Endo (Tooth no.:11)</li> <li>- Vertical option: N/A</li> <li>- Horizontal option: N/A</li> <li>- Image option: High resolution</li> <li>- Voxel Size: Standard (0.05)</li> </ul>
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	99
Tube Current [mA]	12
Exposure Time [s]	9.0 (16x9) 18.0 (Endo)

Mode Direction [°]	16x9 High resolution		Endo 4x4 High resolution	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	40	0.351	28	0.246
10	30	0.263	24	0.211
20	15	0.132	13	0.114
30	16	0.140	12	0.105
40	13	0.114	11	0.096
50	13	0.114	11	0.096
60	14	0.123	11	0.096
70	17	0.149	13	0.114
80	7	0.061	8	0.070

Direction [°]	Mode	16x9 High resolution		Endo 4x4 High resolution	
		[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
90		3	0.026	4	0.035
100		3	0.026	4	0.035
110		6	0.053	7	0.061
120		7	0.061	9	0.079
130		8	0.070	7	0.061
140		7	0.061	7	0.061
150		9	0.079	9	0.079
160		17	0.149	16	0.140
170		16	0.140	18	0.158
180		19	0.167	16	0.140
190		14	0.123	12	0.105
200		27	0.237	30	0.263
210		12	0.105	15	0.132
220		17	0.149	9	0.079
230		12	0.105	8	0.070
240		10	0.088	6	0.053
250		9	0.079	6	0.053
260		8	0.070	5	0.044
270		9	0.079	6	0.053
280		15	0.132	7	0.061
290		19	0.167	10	0.088
300		28	0.246	14	0.123
310		39	0.342	28	0.246
320		23	0.202	29	0.254
330		19	0.167	18	0.158
340		51	0.447	34	0.298
350		58	0.509	36	0.316



**CBCT (16x9, High Resolution) Leakage Dose Test Graph**

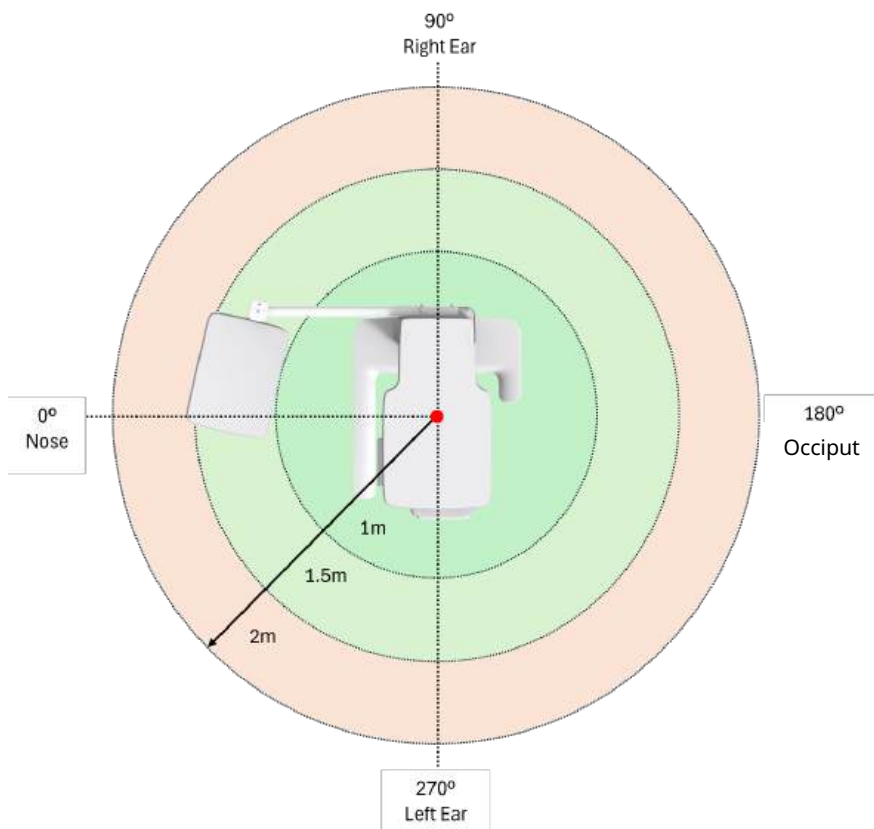


**CBCT (Endo, High Resolution) Leakage Dose Test Graph**

## 17.2.2 Scattered Dose

X-ray Scattered Dose data concerning different angles and distances is examined for recommendations about appropriate radiation level insignificant zones of occupancy and the effectiveness of protective shielding facility around the patient's position. This information states the identity and intended position of the tested phantom and scattered dosimetric evaluation under the defined scope and test circumstances to ensure the magnitude of risks to the operator and staff during both accident situations and routine work.

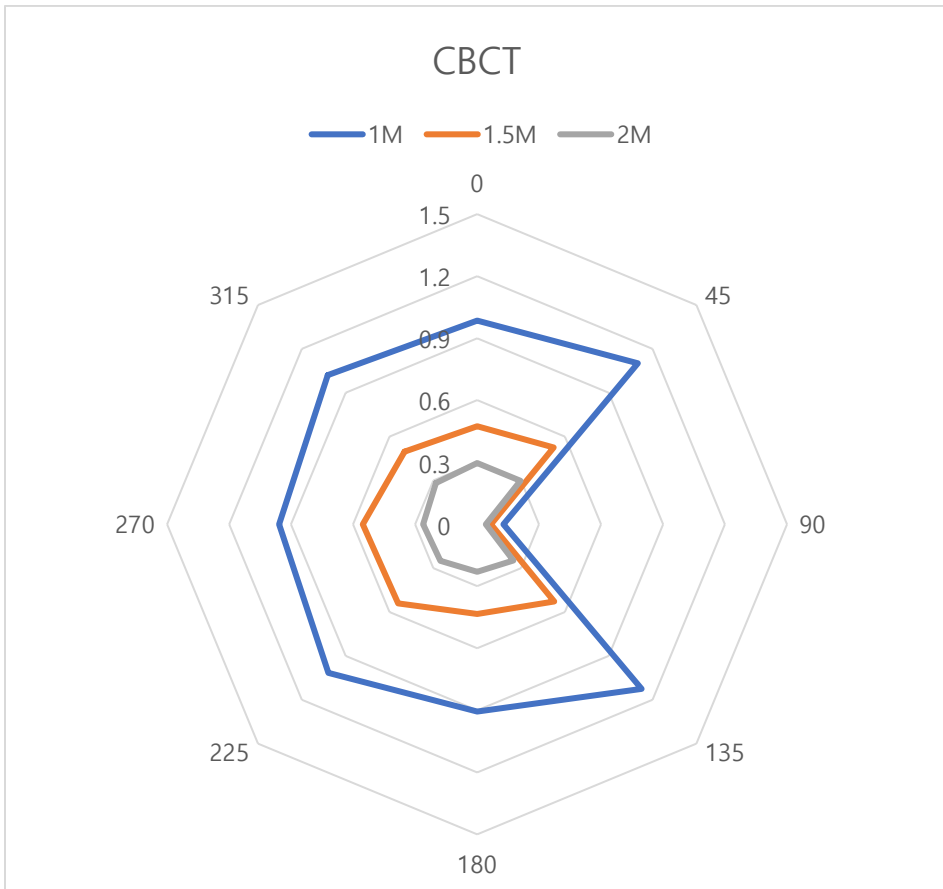
### 17.2.2.1 Measurement Overview



## 17.2.2.2 CBCT Mode Results

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- CBCT</li> <li>- Adult(Man)</li> <li>- FOV: 16x9</li> <li>- Vertical option: Occlusion</li> <li>- Horizontal option: Center</li> <li>- Image option: High resolution</li> <li>- Voxel Size: Standard (0.20)</li> </ul>
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	99
Tube Current [mA]	12
Exposure time [sec]	9.0

Direction [°] \ Mode		CBCT FOV 16x9 [mR]		
		1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.985	0.474	0.296
45		1.1	0.525	0.297
90	Right ear	0.127	0.067	0.043
135		1.126	0.528	0.249
180	Occiput	0.906	0.434	0.23
225		1.017	0.541	0.25
270	Left ear	0.958	0.553	0.261
315		1.021	0.497	0.282

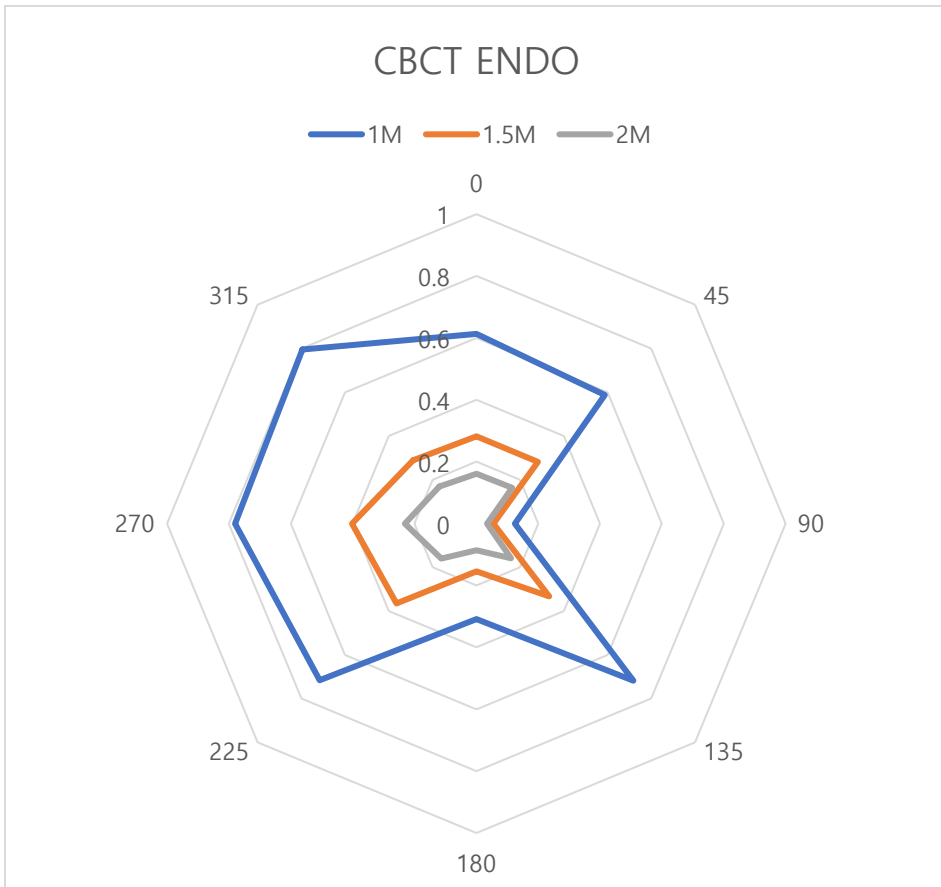


**CBCT (16x9, High Resolution) Scattered Dose Test Graph**

## 17.2.2.3 CBCT Endo Mode Results

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- CBCT</li> <li>- Adult (Man)</li> <li>- FOV: Endo (Tooth no.:11)</li> <li>- Vertical option: N/A</li> <li>- Horizontal option: N/A</li> <li>- Image option: High resolution</li> <li>- Voxel size: Standard (0.05)</li> </ul>
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	99
Tube Current [mA]	12
Exposure time [sec]	18.0

Direction [°] \ Mode		CBCT Endo [mR]		
		1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.613	0.282	0.161
45		0.588	0.282	0.164
90	Right ear	0.125	0.055	0.035
135		0.718	0.333	0.159
180	Occiput	0.309	0.154	0.086
225		0.716	0.365	0.16
270	Left ear	0.78	0.402	0.231
315		0.795	0.289	0.169

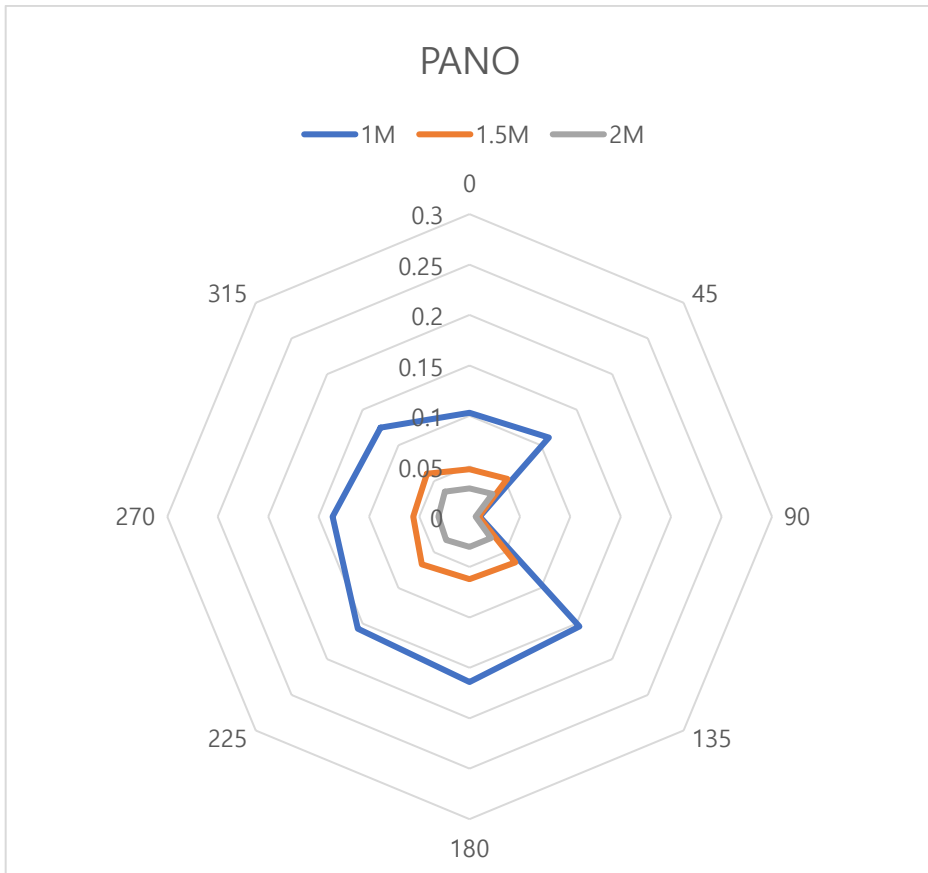


**CBCT (Endo, High Resolution) Scattered Dose Test Graph**

## 17.2.2.4 PANO Mode Results

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- PANO</li> <li>- Adult (Man)</li> <li>- Pano option: Normal</li> <li>- Image option: High Resolution</li> <li>- Pano examination: Standard</li> <li>- Arch selection: Normal</li> </ul>
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure time [sec]	13.5

Direction [°]	Mode	PANO (Normal) [mR]		
		1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.103	0.047	0.028
45		0.111	0.053	0.032
90	Right ear	0.01	0.009	0.006
135		0.154	0.064	0.03
180	Occiput	0.164	0.062	0.03
225		0.157	0.067	0.033
270	Left ear	0.136	0.056	0.031
315		0.125	0.06	0.035

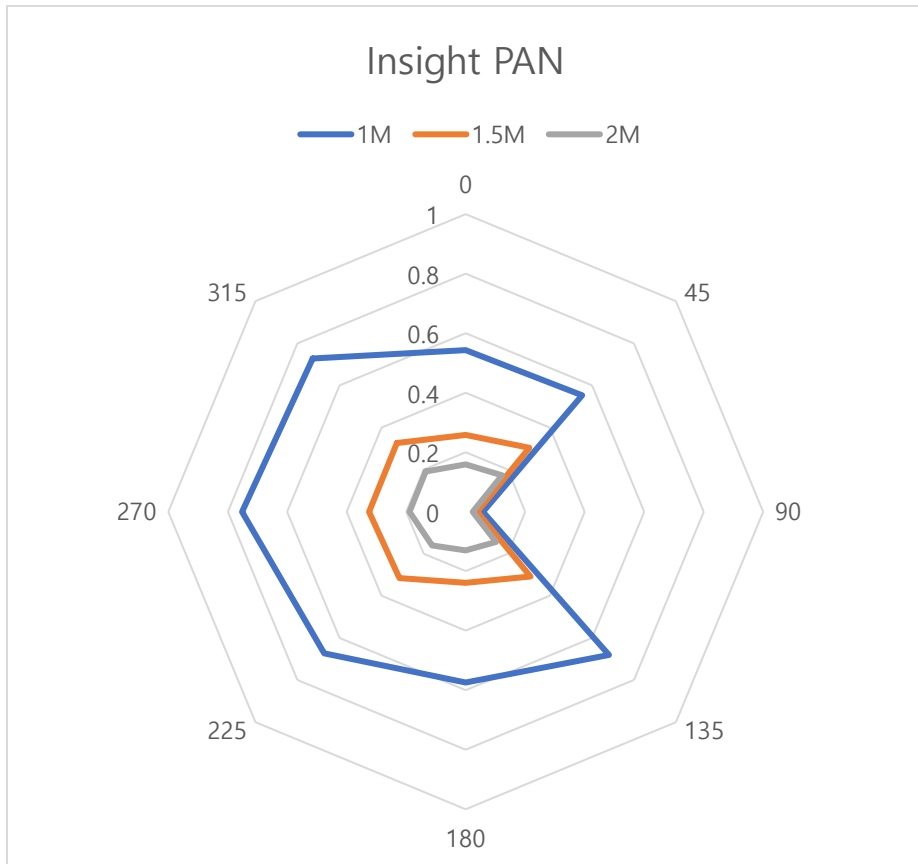


**PANO (Normal, High Resolution) Scattered Dose Test Graph**

## 17.2.2.5 PANO Mode (Insight PAN) Results

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- PANO</li> <li>- Adult (Man)</li> <li>- Pano option: Insight PAN</li> <li>- Image option: N/A</li> <li>- Pano examination: N/A</li> <li>- Arch selection: Normal</li> </ul>
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure time [sec]	11

Direction [°] \ Mode		PANO (Insight PAN) [mR]		
		1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.543	0.258	0.159
45		0.553	0.303	0.173
90	Right ear	0.058	0.039	0.024
135		0.681	0.308	0.144
180	Occiput	0.574	0.239	0.13
225		0.673	0.315	0.16
270	Left ear	0.752	0.325	0.189
315		0.728	0.327	0.191



**PANO (Insight PAN, High Resolution) Scattered Dose Test Graph**

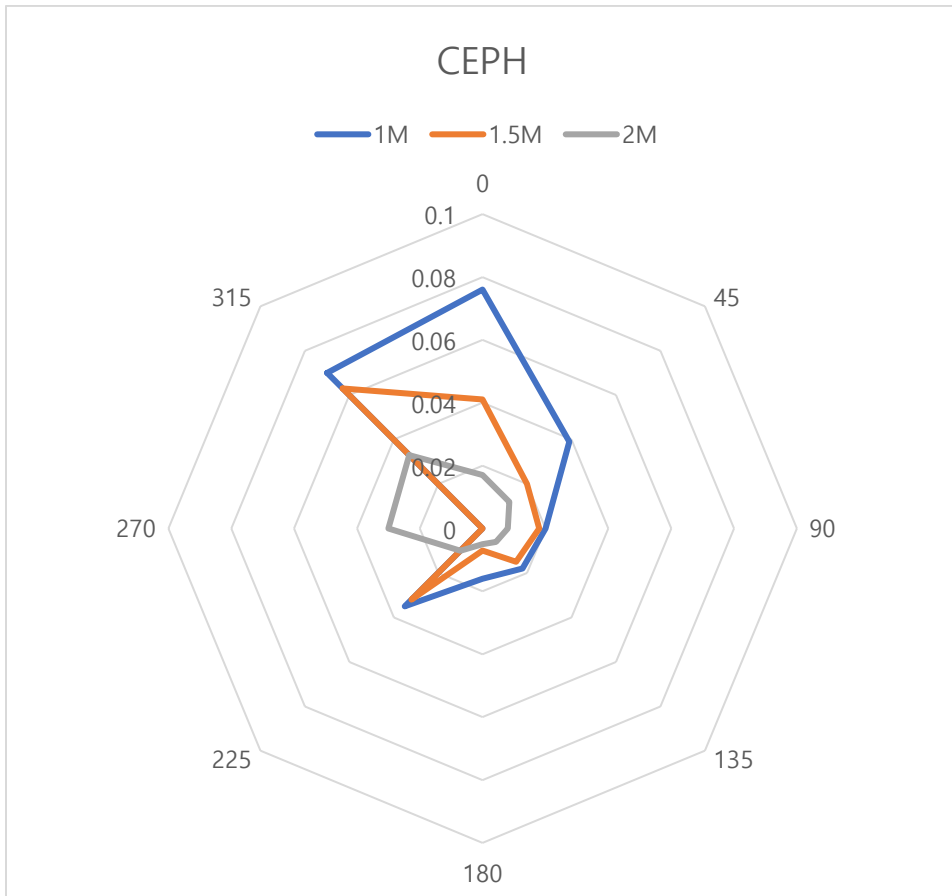
## 17.2.2.6 CEPH Mode Results

Test Condition	
Test Mode	<ul style="list-style-type: none"> <li>- CEPH</li> <li>- Adult (Man)</li> <li>- Image option: High resolution</li> <li>- CEPH Examination: Full Lateral</li> </ul>
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	99
Tube Current [mA]	14
Exposure time [sec]	5.4

Direction [°] \ Mode		CEPH Full Lateral [mR]		
		1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.076	0.041	0.017
45		0.039	0.02	0.012
90	Right ear	0.02	0.018	0.008
135		0.018	0.015	0.006
180	Occiput	0.016	0.007	0.005
225		0.035	0.032	0.01
270	Left ear	-	-	0.03
315		0.07	0.063	0.033

**NOTICE**

Since the Ion chamber is located between the generator and the object, Data of 1 m and 1.5 m at 270 ° are not measured.



**CEPH (Full Lateral, High Resolution) Scattered Dose Test Graph**

## 17.3 Electromagnetic Compatibility (EMC) Information

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Mains terminal disturbance voltage	CISPR 11:2015	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Radiated disturbance	CISPR 11:2015	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Harmonic Current Emission	EN 61000-3-2:2014, IEC 61000-3-2:2014	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 220 V, 60 Hz AC 230 V, 50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	EN 61000-3-3:2013, IEC 61000-3-3:2013	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 220 V, 60 Hz AC 230 V, 50 Hz	Pst: 1 Plt: 0.65 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	EN 61000-4-2:2009, IEC 61000-4-2:2008	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	± 8 kV/Contact  ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3:2006 +A2:2010, IEC 61000-4-3:2010	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless	EN 61000-4-3:2006 +A2:2010,	IDLE mode CT mode PANO mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Table 9 in IEC 60601-1-2: 2014

## 17. Appendices

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Communications Equipment	IEC 61000-4-3:2010	CEPH mode			
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012, IEC 61000-4-4:2012	IDLE mode CT mode PANO mode CEPH mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line: $\pm 2$ kV Signal: $\pm 1$ kV 100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2014, IEC 61000-4-5:2014	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Line to Line $\pm 0.5$ kV, $\pm 1$ kV  Line to Ground $\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV
Immunity to Conducted Disturbances Induced by RF fields	EN 61000-4-6:2014, IEC 61000-4-6:2013	IDLE mode CT mode PANO mode CEPH mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line & Signal: 3 V, 0.15-80 MHz
			Exposure switch cable		6 V in ISM bands Between 0.15 MHz and 80 MHz  80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	EN 61000-4-8:2010, IEC 61000-4-8:2009	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	30 A/m 50 Hz & 60 Hz
Voltage dips	EN 61000-4-11:2004, IEC 61000-4-11:2004	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % $U_T$ : 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
					0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles Single-phase: at 0°

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Voltage interruptions	EN 61000-4-11:2004, IEC 61000-4-11:2004	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % $U_T$ ; 250/300 cycle

## 17.4 Acquiring Images for Pediatric Dental Patients

### 17.4.1 Age Group: Classification Table

Ages are classified loosely into the following correspondence between the FDA definition and the one used in this manual.

Age Group	FDA's standard	VATECH's Standard
Infant	1 month to 2 years	N/A
Child	2 ~ 12 years of age	Child
Adolescent	12 ~16 years of age	Adult
Other	16 ~ 21 years of age	
Adult	> 21 years of age	

### 17.4.2 Positioning the Pediatric Dental Patients

1. Use a laser light beam guide to locate the midsagittal plane. Direct patient focuses on mirroring reflection. Affix the decal to the mirror to aid the patient in maintaining the correct position throughout the exposure.
2. Move the Chinrest into a position slightly higher than the patient's chin height before requesting that the weak place chin onto the rest. Direct the patient to assume a position resembling a soldier's erect stance.
3. Direct the patient to stick out the chest while dropping the chin down. While holding the unit handles for stability, direct the patient to take a half step toward the vertical column of the X-ray device into a position that feels as if he/she is slightly leaning backward.
4. Direct the patient to close lips around the Bite Block during the exposure.
5. Direct the patient to swallow and note the flat position of the tongue. Request that the patient sucks in the cheeks, pushing the tongue into the correct flat position against the palate and maintain this position throughout the exposure.

## <How to produce error-free radiographic images for the pediatric patient>

(<http://www.dimensionsofdentalhygiene.com/print.aspx?id=3612>)

- By Evelyn M. Thomson, BSDH, MS

Panoramic radiographs are often recommended for assessing the pediatric patient's growth and development and evaluating developing third molars during adolescence.<sup>1-3</sup> While the panoramic technique seems relatively straightforward, producing a diagnostic-quality image of the pediatric patient requires a mastery of technical skills.<sup>4</sup> Modern panoramic x-ray equipment is designed for ease of use, yet studies continue to demonstrate a high incidence of errors.<sup>5-7</sup> Positioning errors may occur at an even higher rate in pediatric panoramic radiographs.<sup>7</sup> The goal of the dental hygienist is to maximize the use of panoramic imagery in assessing the pediatric patient while minimizing the occurrence of retakes resulting from a radiographic error.

### Producing A Quality Panoramic Image

A quality panoramic radiograph should image all of the teeth, erupted and unerupted, in both the maxillary and mandibular arches from condyle to condyle in the horizontal dimension, and from the superior third of the orbit in the superior region to the inferior border of the mandible in the inferior region.<sup>8,9</sup> The arches should appear straight or slightly U-shaped, with the occlusal plane parallel to the horizontal edges of the film (**Figure 1**). The anterior teeth must not be magnified or diminished in size, and overlapping of adjacent posterior teeth should be kept to a minimum.



**Figure 1:** Example of a diagnostically acceptable panoramic radiograph of an adolescent patient undergoing orthodontic intervention. (Courtesy of Jamie Mace and Will Wright of Schick Technologies Inc.)

Patient positioning is the most critical component in producing a diagnostically acceptable panoramic image. All panoramic x-ray machines have guidelines to assist with positioning the dental arches within the three dimensions of the focal trough, an area where the anatomical structures will be imaged in relative clarity. Most

panoramic x-ray machines have a bite block to indicate the correct anterior-posterior position, or how far forward or back the patient should be positioned, side positioner guides for determining the correct lateral alignment, and chin rest to correctly locate the superior-inferior dimension or how far up or down the chin should be positioned.<sup>4,10</sup> Panoramic x-ray machines are available with a mirror and laser light beam guide that shines on the patient's face to illustrate various anatomical planes (**Figure 2**). Incorrectly positioning the patient in any of these three dimensions will produce unique and distinct radiographic image errors (**Table 1**).



**Figure 2:** Laser light beam guides that assist with determining correct patient positioning.

Table 1 Common Panoramic Positioning Errors			
Error	Cause	Corrective action	Tips for pediatric patients
Anterior teeth narrow Severe posterior overlap Vertebrae superimposed over condyles	Arches positioned too far anterior	Position anterior teeth in appropriate position on bite guide. Locate appropriate position with anterior laser light guide.	Use a cotton roll to fill in missing primary teeth or partially erupted permanent teeth. Adapt adult recommendation for direction of laser light beam guide for use with primary teeth. Observe laser light beam guide on both the right and left sides.
Anterior teeth wide, blurred out of image Condyles not imaged	Arches positioned too far posterior		
Teeth on the right side appear narrowed, severely overlapped Teeth on the left side appear broad, poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the right	Position the midsagittal plane perpendicular to the floor.	Use laser light beam guide to locate midsagittal plane. Direct patient focus to mirror reflection. Affix decal to mirror to aid patient in maintaining the correct position throughout exposure.
Teeth on the left side appear narrowed, severely overlapped Teeth on the right side appear broad and poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the left		
Flat, downward-turned, "frown" appearance to the occlusal plane Palate appears as a widened, thick, dense radiopacity Condyles flare out off the edges of the image Anterior teeth appear wide, elongated	Arches positioned too far superior	Position the Frankfort or the canthomeatal plane parallel to the floor, or the ala-tragus line 5° down toward the floor.	Move chin rest into a position that is slightly higher than the patient's chin height before requesting that the patient place chin onto the rest. Direct the patient to assume a position that resembles the erect stance of a soldier.
Exaggerated upward curve of the occlusal plane creating a "smile" appearance Broad bone superimposed over the mandible Condyles tilt inward Anterior teeth appear narrowed, elongated in the maxilla and foreshortened in the mandible	Arches positioned too far inferior		
Pyramid-shaped radiopacity superimposed over the anterior teeth	Patient in slumped position	Position the back and neck straight.	Direct the patient to stick out the chest while dropping the chin down. While holding the unit handles for stability, direct the patient to take a half step in toward the vertical column of the x-ray machine into a position that feels as if he/she is slightly leaning backward.
Radiolucent shadow of the commissure superimposed over the teeth, mimicking caries	Lips not closed around bite block	Position the lips around the bite block.	Direct the patient to keep the lips closed around the bite block during the exposure.
Radiolucency superimposed over the maxillary teeth apices	Tongue not placed against palate	Position the tongue flat against the roof of the mouth.	Direct the patient to swallow and note the flat position of the tongue. Request that the patient suck in the cheeks, pushing the tongue into the correct flat position against the palate and maintain this position throughout the exposure.

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### Anterior-Posterior Positioning Error

When the arches are positioned incorrectly in the anterior-posterior direction, distortion or ghosting of the anterior anatomy occurs. Unerupted teeth in the anterior region may not be imaged on the radiograph if positioned outside of the focal trough. It is important to note that an error of only 3 mm to 4 mm in either direction will result in a significantly compromised image.<sup>11</sup> When the arches are positioned too far anterior, the anterior teeth will appear narrow and diminished in size. The vertebrae of the spinal column may be superimposed over the condyles at the edges of the film and, depending on the size of the child, maybe superimposed over the rami of the mandible blocking a clear view of the posterior teeth (**Figure 3**). When the arches are positioned too far posteriorly, the anterior teeth will appear broad or widened. If the position is excessively posterior, anterior teeth may be blurred entirely from the image, and the condyles may be cut off from the edges of the film.



**Figure 3:** Incorrect position too far anteriorly. Note the narrow anterior teeth and superimposition of the spinal column over the condyles. The radiolucency superior to the maxillary apices indicates that the tongue was not placed against the palate. An open lip line can also be detected.

To avoid these imaging errors, the anterior teeth must occlude edge-to-edge onto the designated area of the bite block. Achieving this position is easily compromised during the exfoliation of primary teeth, making precise occlusion difficult when one tooth or multiple teeth are missing or partially erupted. A cotton roll may be attached to the bite block to fill in the space created by the missing tooth or teeth. Additionally, an adjustment may be necessary when using a laser light beam guide. The manufacturer's instructions for directing the laser light beam at a predetermined tooth or interproximal space usually apply to adult patients. These instructions may need to be modified for pediatric patients with primary or mixed dentition.

### Lateral Left-Right Positioning Error

When the arches are positioned incorrectly in the lateral left-right dimension, the posterior teeth on one side will appear broad or widened, while the teeth on the other side will appear narrowed or diminished in width and severely overlapped (**Figure 4**). This image distortion is like that which occurs with an incorrect anterior-posterior position. When the arches are rotated or tilted, the posterior teeth on one side move out of the focal trough to a position further away (back) from the image receptor, while the opposite side simultaneously moves closer (forward) to the image receptor. Depending on the severity of rotation or tilting, the inferior border of the mandible will appear distorted, and the condyles and rami will appear asymmetrical.



**Figure 4:** Incorrect lateral position tilted to the right. Note the teeth on the left are wide and poorly defined, while the teeth on the right are narrowed and severely overlapped. The inferior border of the mandible is distorted and the condyles appear asymmetrical.

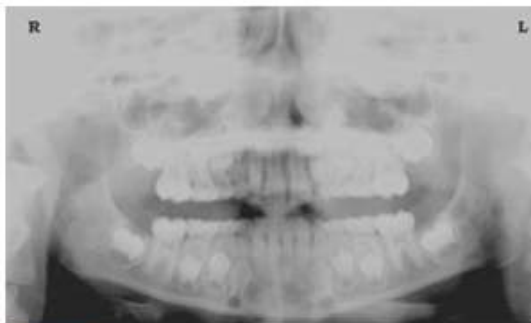
To avoid imaging errors that result from incorrect lateral positioning, the midsagittal plane must be positioned perpendicular to the floor. Most panoramic X-ray machines have a head positioner and laser light beam guide, along with a mirror, to assist in determining the correct lateral head position. The pediatric patient may need additional instructions to maintain the correct position throughout the exposure.

The movement of the tube head during exposure may pique the pediatric patient's curiosity, causing the head to rotate as the eyes follow the movement of the tube head. A vertical line decal affixed to the mirror can serve as a visual aid and a focus point. An eye-catching sticker, such as those purchased from a craft store, can be adhered to the mirror in a position that aligns with the midsagittal plane. The patient can be directed to position the head so that the sticker appears at the tip of the nose and to maintain focus on this reflection throughout the exposure. Pediatric patients may find looking at themselves in the mirror entertaining and a fun way to participate in the process.<sup>9</sup>

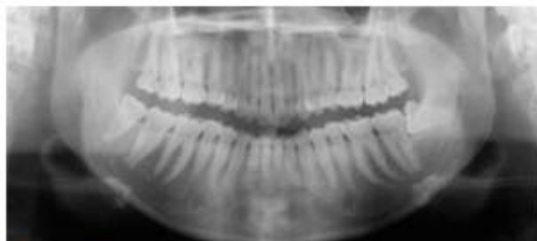
### Superior-Inferior (Up-Down) Positioning Error

Positioning the dental arches within the superior-inferior (up-down) dimension of the focal trough can be challenging to achieve, especially with children whose smaller size reduces the distance between the shoulders and the inferior border of the chin. When the arches are positioned incorrectly in the superior-inferior direction, the image exhibits multiple distortions, including increased overlap in the premolar regions. When the arches are positioned too far up or down, the teeth will simultaneously move into a position that is too far back or too far forward, respectively, out of the focal trough.<sup>11</sup>

Positioning the arches too far superiorly produces a characteristic "frown" or flat, downward-turned appearance to the occlusal plane (**Figure 5**). The condyles flare out and off the edges of the image, and the palate appears as a widened, thick, dense radiopacity. This positioning error results in a widened appearance of the palate and obliterates the apical regions of the maxillary teeth, compromising the images of the unerupted developing dentition. As the maxillary arch tips upward, the anterior teeth tilt backward, producing the same widened appearance that results from an incorrect anterior-posterior position. Positioning the arches too far inferior produces a characteristic "smile" appearance or the upward curve of the occlusal plane, with the condyles tilting inward toward the center of the image (**Figure 6**). Depending on the severity of the downward position, the vertebrae may also curve inward and appear superimposed over the condyles, and the hyoid bone may be superimposed over the mandible blocking a clear view of the erupted and unerupted mandibular teeth.



**Figure 5:** Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.



**Figure 6:** Chin positioned too far down. Note the characteristic “smile” or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

Correct positioning of the arches in the superior-inferior dimension requires that the patient stands with an erect posture while tucking the chin in and down slightly, a direction that both adults and pediatric patients often find difficult to follow without specific guidance. The result is often a slumped position with the patient hunching the neck and shoulders over to place the chin on the chin rest. The vertebrae collapse causing attenuation of the X-ray beam that produces a triangular radiopacity superimposed over the mandible and, if severe, over the anterior maxillary regions as well.

Depending on the manufacturer, panoramic x-ray machines direct the operator to position the Frankfort or the canthomeatal plane parallel to the floor or the ala-tragus line 5° down toward the floor. This is achieved by raising or lowering the chin rest so that the appropriate landmark lines up with the indicators on the machine (**Figure 2**). The patient should be directed to stand in front of the panoramic X-ray machine allowing the operator to place the chin rest in a position that is slightly higher than the patient's chin. The patient is then requested to move into the overhead assembly of the machine and remain standing tall. If further adjustment is needed, it is usually to a lowered chin position. Once the patient's chin is resting on the chin rest, it is easier to move to a lower position than to a higher one. To assist with placing the chin on the chin rest while maintaining an erect posture, the pediatric patient can be directed to stand like a soldier. Most children are familiar with the straight back, chest forward, and tucked chin position demonstrated by military persons, and can readily mimic this stance.

#### **Further Recommendations**

Before beginning the exposure, the patient should be directed to close the lips around the bite block and to place the tongue against the palate. Leaving the lips open will create a soft tissue shadow across the teeth that can be mistaken for caries.<sup>7</sup> Leaving the tongue at rest during the exposure allows the radiation to easily penetrate the

space of the oral cavity between the dorsal surface of the tongue and the palate, producing a radiolucent shadow that diminishes the diagnostic quality of the radiograph (Figure 3).

"Filling in" this space with the soft tissue of the tongue can increase the quality of the image by diminishing this radiolucent shadow. When directed to place the tongue on the roof of the mouth, the pediatric patient is likely to press only the tip of the tongue against the palate. While an adult patient can usually understand what is required when directed to swallow and note the position of the tongue, a child may be directed to suck in the cheeks, which results in pushing the tongue into a position flat against the palate.<sup>7</sup>

### Conclusion

In addition to these guidelines for producing error-free radiographic images for pediatric patients, panoramic machines should be evaluated periodically for accuracy. Changes may occur over time to the focal trough that interferes with the diagnostic quality of the machine.<sup>6</sup> If a decrease in image quality is noted despite following accurate patient positioning steps, the panoramic x-ray machine should be inspected, and the focal trough recalibrated. The dental hygienist who is skilled in understanding general equipment operation and pediatric patient management is more likely to produce radiographic images that result in higher diagnostic yields.

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11. *Serman N, Horrell BM, Singer, S. High-quality panoramic radiographs. Tips and tricks. Dentistry Today. 2003;22(1):70-73.*

### 17.4.3 Setting Exposure Values to the Age Group

For more information about this topic, refer to the Appendices **15.1 Recommended X-Ray Exposure Table**.

### 17.4.4 The References Pertinent to the Potential Risks for the Pediatric Patients

#### 1) Literature

- I. ESPELID, I. MEJÅRE, K. WEERHEIJM:

EAPD guidelines for the use of radiographs in children, P40-48. European Journal of Pediatric Dentistry, 1/2003 Guidelines in dental radiology are designed to avoid unnecessary exposure to X-radiation and to identify individuals who may benefit from a radiographic examination. Every prescription of radiographs should be based on an evaluation of the individual patient's benefit. Due to the relatively high frequency of caries among 5-year-old children, it is recommended to consider dental radiography for each child, even without any visible caries or restorations. Furthermore, radiography should be considered at 8-9 years of age and then at 12-14, which is 1-2 years after the eruption of premolars and second molars. Additional bitewing controls should be based on an overall assessment of the caries activity/risk. The high-risk patient should be examined radiographically annually, while a 2-3 year interval should be considered when caries activity/risk is low. A routine survey by radiographs, except for caries, has not been shown to provide enough information to be justified considering the balance between cost (radiation and resources) and benefit.

- MICHAEL L. TAYLOR, B.SC. TOMAS KRON, PH.D., AND RICK D. FRANICH, PH.D.:

ASSESSMENT OF OUT-OF-FIELD DOSES IN RADIOTHERAPY OF BRAIN LESIONS IN CHILDREN, Int. J. Radiation Oncology Biol. Phys., Vol. -, No. -, pp. 1–7, 2010 To characterize the out-of-field doses in pediatric radiotherapy and to identify simple methods by which out-of-field dose might be minimized, to reduce the risk of secondary cancers Out-of-field doses to pediatric patients can be minimized by using simple treatment

- C. THEODORAKOU, K. HORNER, K. HOWARD, A. WALKER:

Pediatric organ and effective doses in dental cone beam computed tomography Dental CBCT has been associated with higher radiation risk to patients compared to conventional dental X-ray imaging. Several studies have investigated the radiation doses involved in dental CBCT for adults, but none has investigated pediatric doses. This study estimates the organ and effective doses for two pediatric tissue-equivalent phantoms using thermoluminescent dosimeters for three dental CBCT units and six imaging protocols. The doses to the thyroid, salivary glands, and brain ranged from 0.068mSv to 1.131mSv, 0.708mSv to 2.009mSv, and 0.031mSv to 1.584mSv, respectively. The skin and red bone marrow have received much lower doses than the other three organs. The effective doses ranged from 0.022 mSv to 0.081 mSv. The effective doses calculated in this study were much higher than these of panoramic X-ray imaging but lower than conventional CT

- CHIYO YAMAUCHI-KAWAURA & KEISUKE FUJII & TAKAHIKO AOYAMA & SHUJI KOYAMA & MASATO YAMAUCHI:

Radiation dose evaluation in the head and neck MDCT examinations with a 6-year-old child anthropomorphic phantom, *Pediatr Radiol* (2010) 40:1206–1214 DOI 10.1007/s00247-009-1495-z

**Background:** CT examinations of the head and neck are the most commonly performed CT studies in children, raising concerns about radiation dose and their risks to children.

**Objective:** The purpose of this study was to clarify radiation dose levels for children 6 years of age undergoing head and neck multi-detector CT (MDCT) examinations.

**Materials and methods:** Radiation doses were measured with small-sized silicon photodiode dosimeters that were implanted at various tissue and organ positions within a standard 6-year-old anthropomorphic phantom. Organ and effective

doses of brain CT were evaluated for 19 protocols in nine hospitals on various (2–320 detector rows) MDCT scanners.

**Results:** The maximum value of the mean organ dose in brain CT was 34.3 mGy for the brain. Maximum values of mean doses for the radiosensitive lens and thyroid were 32.7 mGy for a lens in brain CT and 17.2 mGy for thyroid in neck CT. The seventy-fifth percentile of effective dose distribution in brain CT was approximately the same as the diagnostic reference level (DRL) in the 2003 UK survey.

### 2) Website

For additional information on pediatric X-ray imaging, please refer to the websites below.

- <http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm>
- <http://www.imagegently.org/>

## 17.5 Abbreviations

<b>AC</b>	Alternating Current
<b>CAN</b>	Controlled Area Network
<b>CBCT</b>	Cone-Beam Computed Tomography
<b>CMOS</b>	Complementary Metal-Oxide -Semiconductor
<b>CT</b>	Computed Tomography
<b>DAP</b>	Dose Area Product
<b>DC</b>	Direct Current
<b>DICOM</b>	Digital Imaging and Communications in Medicine
<b>EMC</b>	Electromagnetic Compatibility
<b>ESD</b>	Electrostatic Discharge
<b>FDD</b>	A focal spot to Detector Distance
<b>FOD</b>	A focal spot to Object Distance
<b>FOV</b>	Field of View
<b>IEC</b>	International Electrotechnical Commission
<b>ISO</b>	International Standards Organization
<b>LED</b>	Light-Emitting Diode
<b>MAR</b>	Metal Artifact Reduction
<b>MPSO</b>	Multiple Portable Socket-Outlet
<b>ODD</b>	Object to Detector Distance
<b>PA</b>	Posterior/Anterior
<b>RF</b>	Radio Frequency
<b>ROI</b>	Region of Interest

<b>SID</b>	Source to Image Receptor Distance
<b>SIP</b>	Signal Input Part
<b>SOP</b>	Signal Output Part
<b>SMV</b>	Submentovertex View
<b>STL</b>	Stereo Lithography
<b>TMJ</b>	Temporomandibular Joint

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This is class IIb equipment and obtained CE marking in May 2017 for regulation compliance by the enacted European Union's MDR (Medical Device Regulation)

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