CTOMAPT
DENTAL SOLUTIONS

Green X™

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ZIP Code : 18449
www.vatech.com

Green X™

User Manual

English

Green X™

User Manual
English   v 1.22

vatech

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.

Phone: +82-1588-9510

E-mail: gcs@vatech.co.kr

This document is originally written in English.

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

Manual Name: Green X™ (Model: PHT-75CHS) User Manual

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1. Introduction

1.1 Overview

Green X^{TM} (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^{TM} (Model: PHT-75CHS), a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography, **Green X^{TM} (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^{TM}(Model: PHT-75CHS) can also acquire 2D diagnostic image data in conventional panoramic and cephalometric modes.

1.2 Indications for Use

Green X^{TM} (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.

English

1.3   Intended Purposes

- 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 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

1.4 Intended User Profiles

Considerations	Requirement Description
Qualification	▪ Legally qualified persons such as dentists and healthcare professionals for X-ray device operation
Knowledge	▪ Understanding the treatment and diagnosis of dental disease ▪ Understanding the terms and guidance of hardware and software of a diagnostic medical radiation device and recognizing device connection, installation, and operating conditions
Language understanding	▪ Understanding how to use manuals (English/Korean) or ▪ Understanding other languages provided
Experience	▪ Understanding the objectives and effects of the diagnosis and treatment of dental disease using diagnostic medical radiation devices ▪ Understanding of the normal operation of diagnostic medical radiation equipment ▪ Understanding the contents of the **User Manual**

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

1.5 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.

English

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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.

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

English

2.4   Marks and Symbols

Symbols	Description	Location
⚡	Dangerous voltage	Powerboard /Inverter board /Monoblock
⏚	Protective earth (Ground)	Column
○	Off (power: disconnected to the **Main Power Switch**)	Main Power Switch
		On (power: connected to the **Main Power Switch**)	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
EC REP	Indicates the authorized representative in the European Community.	Label
CE 2460	The CE symbol indicates that this product complies with the European Regulation for Medical Devices Regulation 2017/745 as a class IIb device.	Label
cULus E476672	UL mark No. E476672	Label
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Label

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
CLASS 1 LASER PRODUCT	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 **User Manual**.	Label
	Indicates the date of manufacture.	Label
SN	Indicates the manufacturer's serial number to identify the specific equipment.	Label
MD	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.
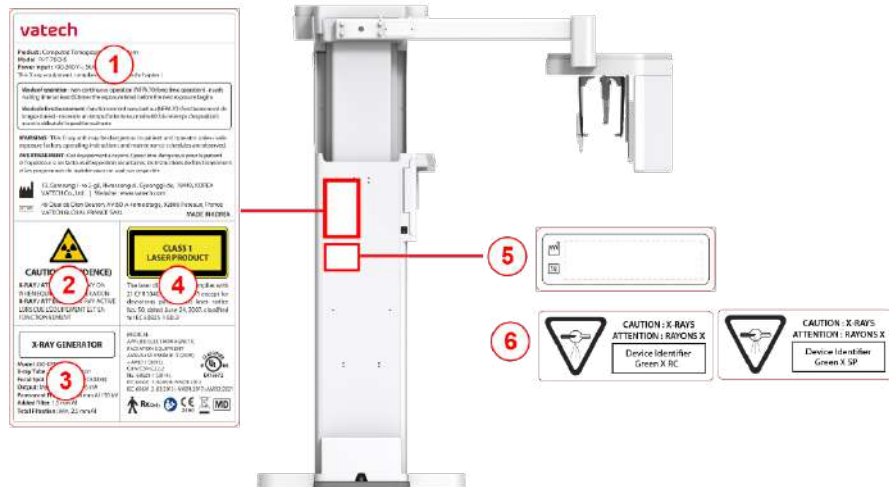
No.	Item
1	**Main Label**
2	**CAUTION Label** - X-ray / Attention: X-ray is on when equipment is in operation.
3	**X-RAY GENERATOR Label** : 1.6 kW Generator
4	**CLASS 1 LASER PRODUCT Label**
5	**Manufacturer Label** : The date of manufacture / Serial Number
6	**Device Identifier Label** • Green X RC: CEPH included. • Green X SP: CEPH not included

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

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)

- 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.

⚠ **WARNING**	Follow all the manual's warnings and safety instructions to ensure a safe operation.
⚠ **WARNING**	Follow precautions and conduct regular inspections to work safely around the X-ray equipment. Ignoring the precautions may endanger both patients and operators.

Hygiene

⚠ **CAUTION**	Turn off the equipment before you start cleaning.
⚠ **CAUTION**	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 3rd 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)

- 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

> ⚠ **WARNING** | 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
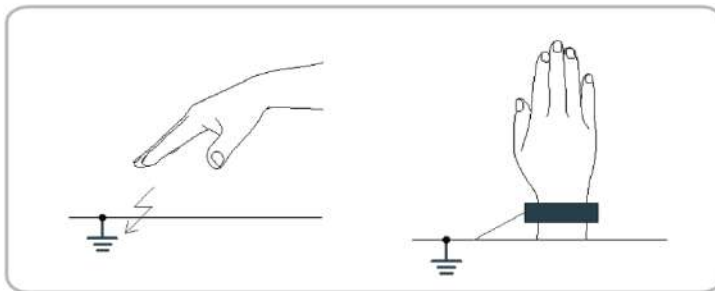
3.3   Radiation Safety

- 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 the 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 before image acquisition for thyroid protection.

- Women who are pregnant or might be pregnant, and children should minimize X-ray exams unless absolutely 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.

- 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.

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

English

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.

⚠ WARNING	▪ 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.
⚠ WARNING	▪ 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.
⚠ WARNING	▪ **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.
① CAUTION	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

⚠ **CAUTION**	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 3rd 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

- Multi-FOV support: Selectable FOV among Double Scan(16x15), 16x9, 12x9, 8x8, 8x5. 5x5, and 4x4 (cm)

- **Endo Mode:** the option that provides high-resolution 3D images essential for root canal treatment, including nerves, pulp structure, and blood vessels inside the tooth.

- **Double Scan:** Algorithm to reconstruct large FOV CT images by stitching upper and lower FOV CT images.

- **Insight PAN** is a multi-image acquisition option that reconstructs the panoramic image into multiple focal images in depth regions. Its main purpose is to diagnose depth regions that cannot be confirmed with ordinary panoramic. The option also provides images of user-specified areas in the Console software.

- The multi-imaging solution for Accurate Diagnostics

- Conventional 2D (PANO and CEPH) image acquisition

- 3D scanning for Plaster Cast with FOV 8x8 (cm)

- Control Panel implemented for easy use

- DICOM (Digital Imaging Communication in Medicine) format supported

- Differentiated Console Software Interface

- MAR(Metal Artifact Reduction) supported

English

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

$C\epsilon$ 2460	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)
CLASSIFIED c(UL)us E476672	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.

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.

English

4.6 Imaging System Configuration
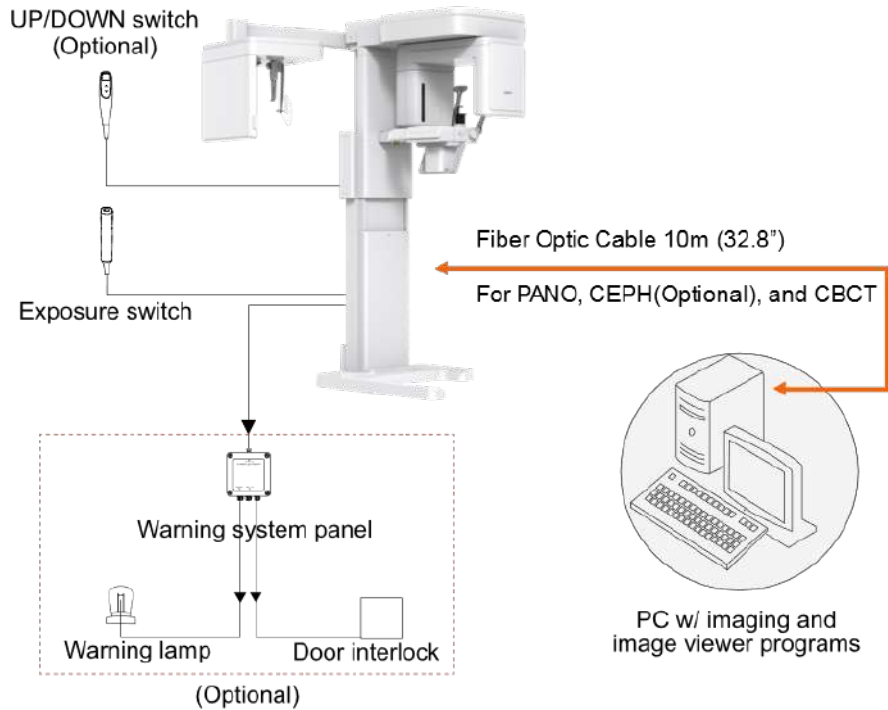
| IMPORTANT | Ensure to use the PC outside the patient environment, such as X-ray (Radiology room). |

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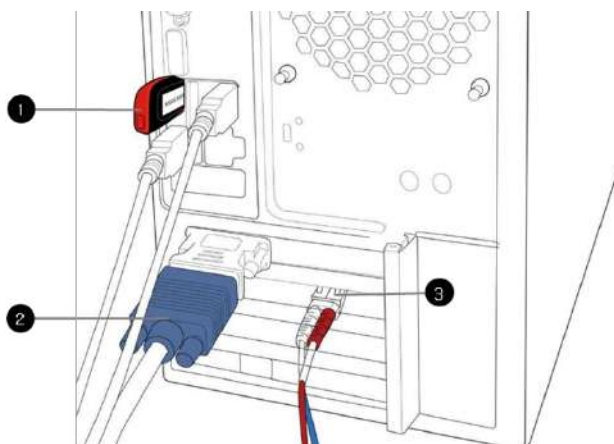
No.	Item
1	3D viewer License Key
2	Video output
3	Fiber optic cable (Data in/out: UART communication)

Ports and Cable Connections
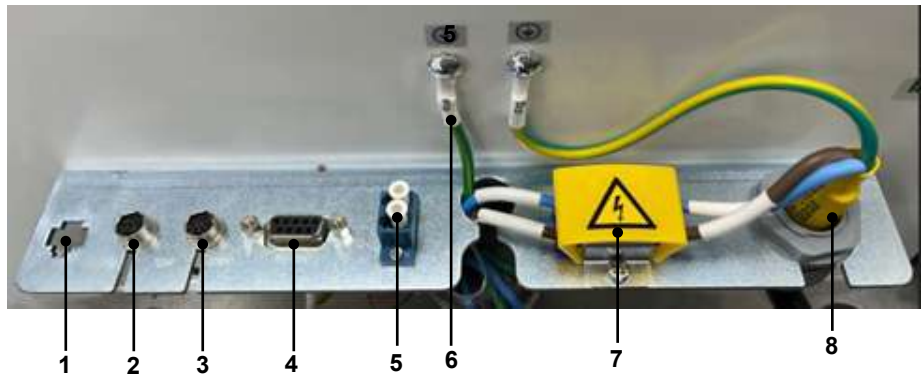
No.	Item	Description
1	Emergence Stop Switch Port*	Connects the emergency stop switch to the equipment.
2	Door Lock Port	Connects the door lock cable to the equipment when installing a door lock.
3	Exposure Switch Port	Connects the exposure switch to the equipment.
4	RS232 Port	Used for testing and repairing 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
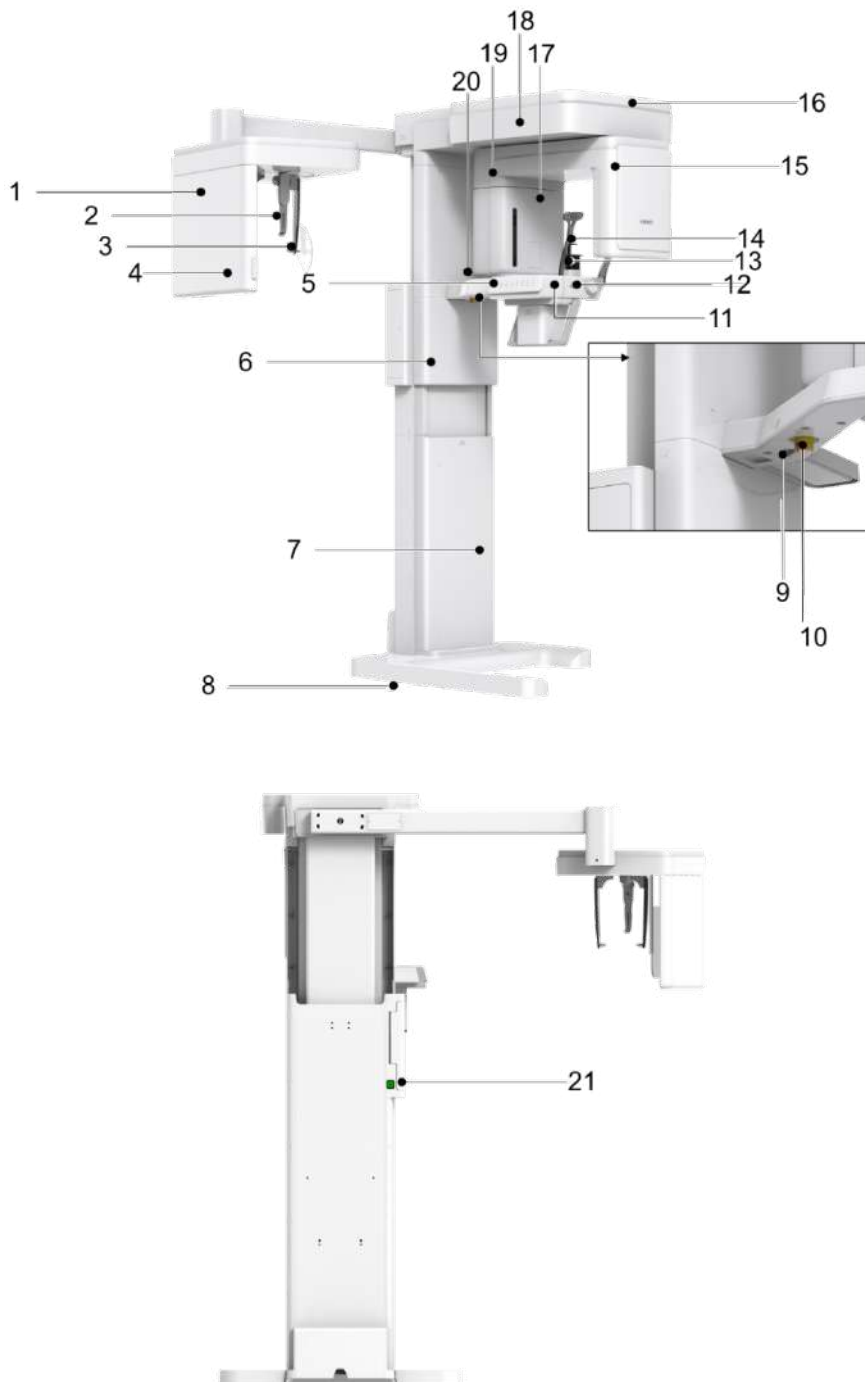
No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor.
2	Nasal Positioner	Corrects the patient's position for the CEPH imaging procedure.
3	Ear Rods	Secures the patient's head during CEPH imaging.
4	Column up/down button (CEPH Part)	Adjusts the column's height
5	Control Panel	Controls the laser beam, rotating unit, and column's height. For more information, go to **4.7.1 Control Panel**.
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 **column up/down** switch.
10	Emergency Stop Switch	Stops the equipment in an emergency. For more information, go to **4.7.2 Emergency Stop Switch**.
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. ▪ **Green**: X-ray is on standby ▪ **Yellow**: X-ray is on
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
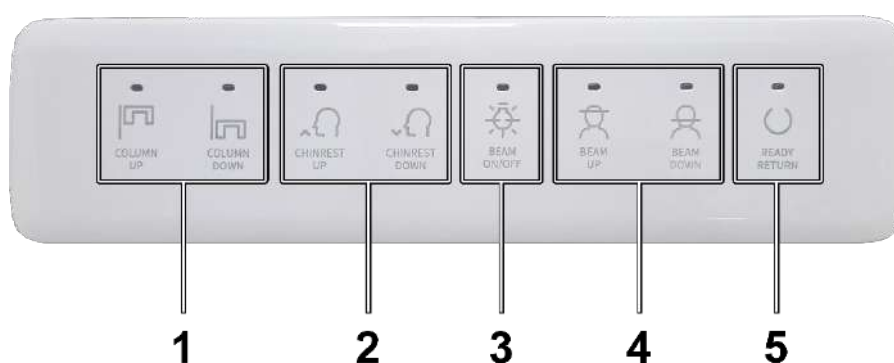
No.	Buttons	Description
1	Column Up/Down	Adjusts the column's height by moving the moving column up and down.
2	Chinrest Up/Down	Adjusts the chinrest's height for the CBCT imaging.
3	Beam On / Off	Turns on or off the laser beams for patient positioning.
4	Beam Up/Down	Adjusts the horizontal beam's location 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.
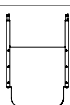
Press and hold the **exposure switch** down until the acquisition is completed. Premature release of the **exposure switc**h will abort image acquisition.

Pressing the exposure switch activates the LED indicator to turn yellow. This color indicates that the X-ray is being emitted.
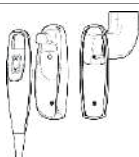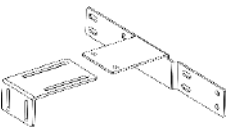
IMPORTANT	Ensure the **exposure switch** cable is not detached from the equipment during the operation.
IMPORTANT	Keep vocal/visual contact with the patient during exposure. In an emergency, release the **exposure switch** immediately.

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	- For normal patients - For Pano and CBCT image acquisition	PC (Polycarbonate)
Special Bite A	- For both edentulous and normal patients - For TMJ (open, close) and Sinus image acquisition.	PC (Polycarbonate)
Special Bite B	- For edentulous patients. - For Pano and CBCT image acquisition	PC (Polycarbonate)
Chinrest	- To rest the patient's chin	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
Sanitary Vinyl Cover (disposable)	To cover the normal bite	PP+PE
Protractor	To position the patient's body correctly for a cephalometric image acquisition	PC (Polycarbonate)
Model Scan Jig	To store the model scan jig used for 3D model scan	ABS (Acrylonitrile butadiene styrene) copolymer
Up/Down Switch and Holder	To adjust the column's height	ABS (Acrylonitrile butadiene styrene) copolymer
Wall Bracket	To fix the equipment to the wall	SPCC

English

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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 Xeon W-2223 3.6 GHz 4 Core Processor
RAM	16 GB DDR4 2666 ECC Registered RAM or larger
HDD	1 TB SATA
Graphics board	ZOTAC GAMING GTX1660Ti 6GB or greater
Ethernet Interface	Integrated Intel I218LM PCIe GbE
Serial Port (RS232)	NEXT-SL601 PCI-E
Power Supply	≥ 700 Watts (90% efficient)
Slots	2 PCI Express Gen3 x 16 Slots 1 PCI Express Gen3 x 8 Slot 1 PCI Express Gen2 x 4 Slot 1 PCI Express Gen2 x 1 Slot
	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 Z4G4

English

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 antispyware 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.
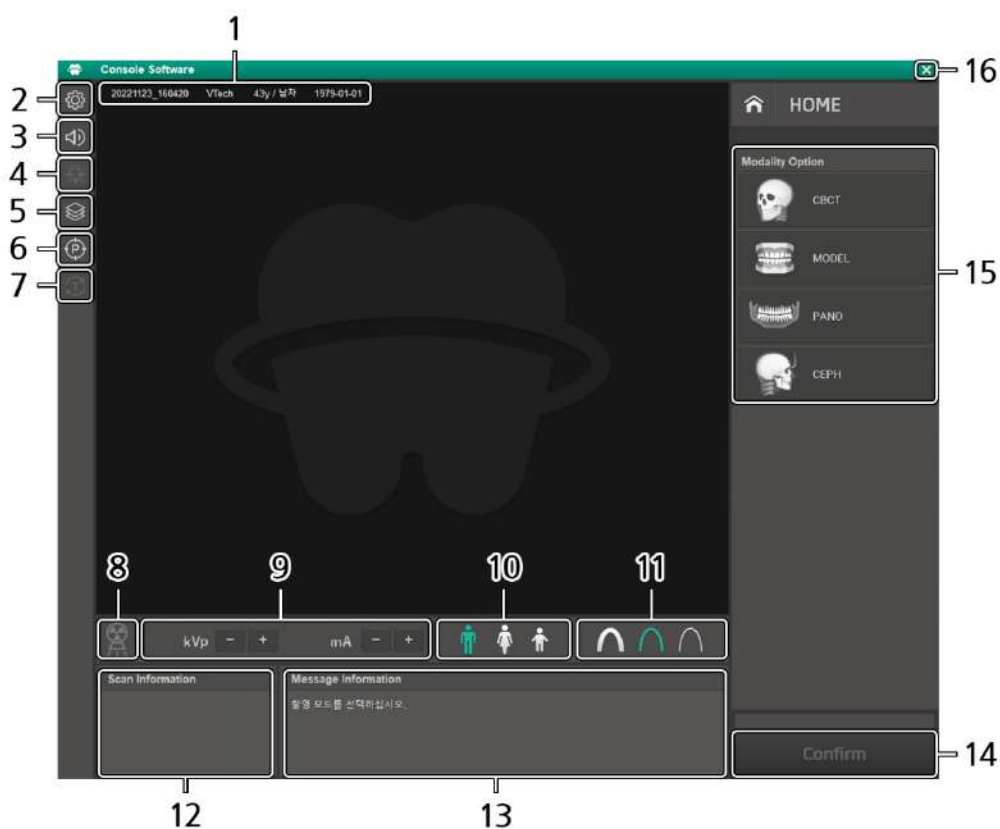
<table>
<tr><td>**NOTICE**</td><td>The console software's UI and features can be updated without notice due to product enhancement.</td></tr>
</table>

No.	Item	Description
1	**Patient information**	Displays the selected patient's information.
2	**Setting button**	Sets user environments for the console software and capture modes such as auto-save option or language.
3	**Volume button**	Changes audio message's volume level.
4	**Laser on/off button**	Turns on or off the laser beams.
5	**Manual reconstruction button**	Reconstructs the captured image after the system fails automatic reconstruction. **How to Start a Manual Reconstruction** 1) Click the **manual reconstruction button**. 2) Select a modality. 3) Click **Search**. 4) Select an image for reconstruction. 5) Click the button again.
6	**Phantom Button**	Captures a phantom image. **How to Capture a Phantom Image** 1) Click the **phantom button**. 2) Select a modality and click **Capture**. 3) Set exposure parameters and place a phantom jig. 4) Click **Ready**. 5) Press the **exposure switch**.
7	**Test Rotation Button**	Performs a test rotation to check before scanning if the equipment hits the patient. **How to Start a Test Rotation:** 1) To start a test rotation: 2) Ask the patient to enter the unit. 3) Select a modality. 4) Click Confirm. 5) Click the test rotation button. After clicking, the button turns green.
8	**X-ray exposure indicator**	Indicates the X-ray exposure status. ▪ **Gray**: X-ray is off ▪ **Yellow**: X-ray is on
9	**Exposure condition menu**	Select exposure conditions (tube current and voltage).

No.	Item	Description
10	**Patient selection menu**	Selects or changes a patient type.
11	**X-ray level selection menu**	Selects or changes an X-ray level intensity.
12	**Scan information window**	Shows the estimated DAP(Dose Area Product), scan, and exposure times for the exposure settings you selected.
13	**Message information window**	Shows guide in text for the user.
14	**Confirm (Ready) button**	This button performs a dual role**.** ▪ **Confirm:** finalizes the capture mode and settings you selected. ▪ **Ready:** Prepares the equipment ready for X-ray exposure. The Ready button appears after the user clicks the Confirm button.
15	**Modality Option**	Selects a capture mode: PANO, CEPH (Optional), CBCT, and Model.
16	**Exit button**	Leaves the console window.

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.

ON

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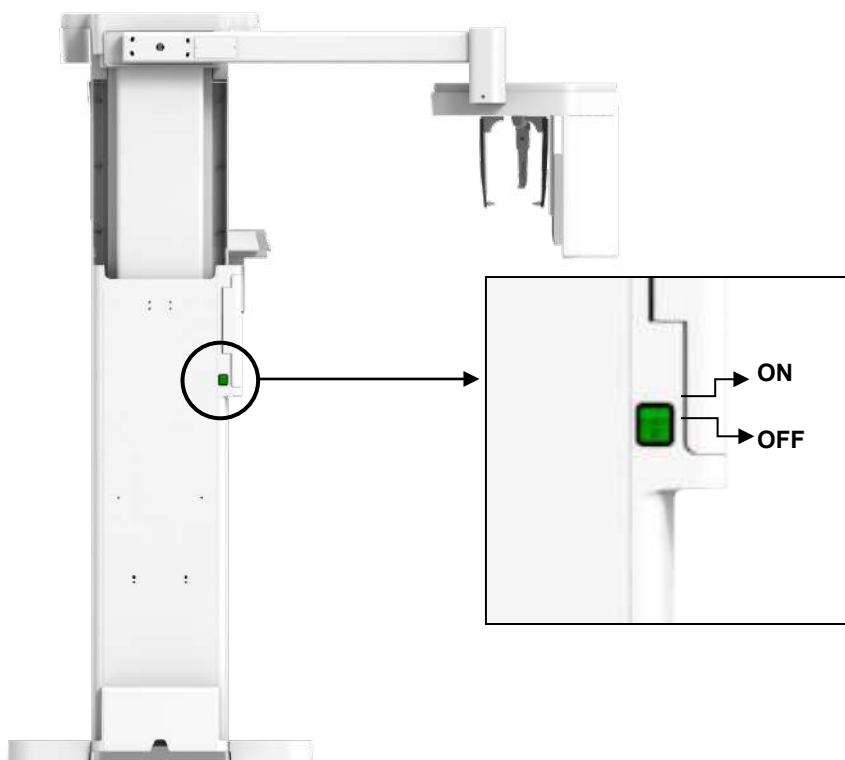
2.   Check if the green light comes on the LED light in front of the rotating unit.

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 Creating a New Patient Record

To create a new patient record with **EzDent-i**:

EzDent-i Main Window

1. Select the **PATIENT** tab and click ![icon]. After clicking the button, a dialog box appears as below.

2. In the dialog box, fill out **Chart No**. And **Name**. If necessary, fill out other areas such as social ID and mobile.

3. Click ![Add] to save the new patient record.

NOTICE	The chart number and name are required fields. You cannot leave them as blanks.

6.2.2 Retrieving Existing Patient Information

To retrieve the patient record saved in **EzDent-i**:

1. Go to the search box and enter the **patient's name** or **chart number**.

If necessary, click the keyboard icon next to the SEARCH to use the virtual keyboard.

2. Click Search .
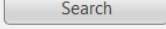
3. Check and double-click the patient record with the matching chart number or name.

6.2.3 Starting Console Software

To initiate the console software:

> **NOTICE**
>
> Before starting the console software, you must create new patient information. Go to **6.2.1 Creating a New Patient Information** for more information.

1. Search and select the patient record.

2. Click the **ACQUISITION** tab.
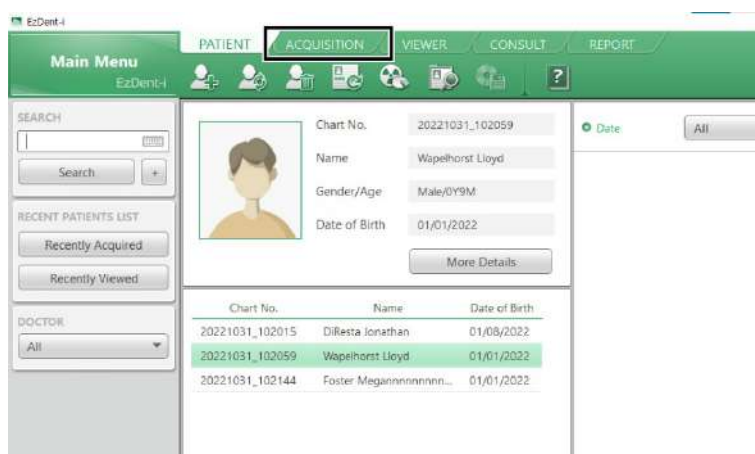
3. Select a modality you want to capture the image. The displayed options can be different depending on your equipment's option.
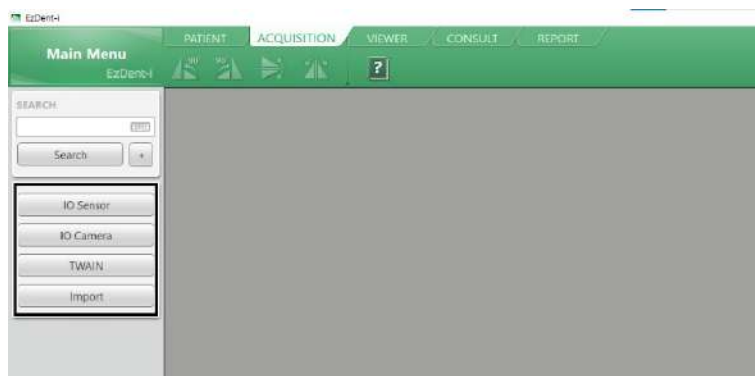
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7. How to Acquire PANO Images

7.1 Program Overview

■ **Role**
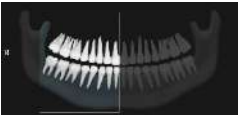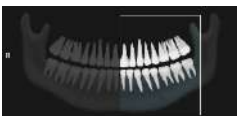
It provides 2D panoramic images.

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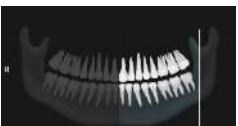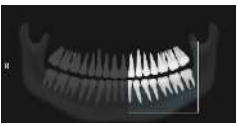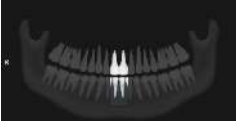
It reconstructs U-shaped arch data to a single 2D image utilizing multiple images taken with the X-ray beam scanning specific oral & maxillofacial regions at different angles.
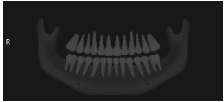
■ **Examination Programs**

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

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

Examination Type	Arch Selection	ROI	Example
		Standard	
	Orthogonal	Right	
		Front	
		Left	
		Bitewing Right*	
		Standard	
		Bitewing Left*	
		Bitewings*	
PANO Examination	Orthogonal	Bitewing Incisor* (Optional)	
PANO Examination (Insight PAN**)	Normal	-	
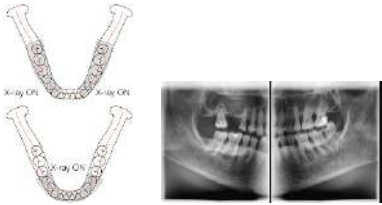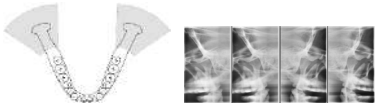
Examination Type	Arch Selection	ROI	Example
	Child	-	
SPECIAL Examination	N/A	TMJ LAT Open	
		TMJ LAT Close	
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

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

■ **Main Imaging Programs**

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

English

Examination Type	Arch Selection	ROI	Description & Sample Image
			which is beamed perpendicularly between teeth.
		Bitewings** (Bitewing Incisor mode is Optional)	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.)
SPECIAL Examination	N/A	TMJ LAT Open/Close	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)
		TMJ PA Open/Close (Optional)	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.
		Sinus LAT (Optional)	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.

Examination Type	Arch Selection	ROI	Description & Sample Image
		Sinus PA	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.

** 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 featured in Green X, designed to protect patients from the rotating unit's sudden movement during the exposure parameter configuration. When the system detects a patient inside the equipment during the configuration, it will halt the procedure, and the following audio message will be played: "During the system preparation, a patient has been detected at the imaging location." Guide the patient out of the equipment to a safe location, then restart the image capture program.
IMPORTANT	**Patient motion detection** is **disabled in certain countries, including the United States.** For more information, contact your local Vatech Representative.

7.2.1 Normal Tab

To set the exposure settings on the Normal tab:

1.   Select **PANO** from the **Modality Option**.

After clicking PANO, the main window looks as below.

2. Click the **Normal** tab.

Normal	Special

3. Select a **PANO option**.
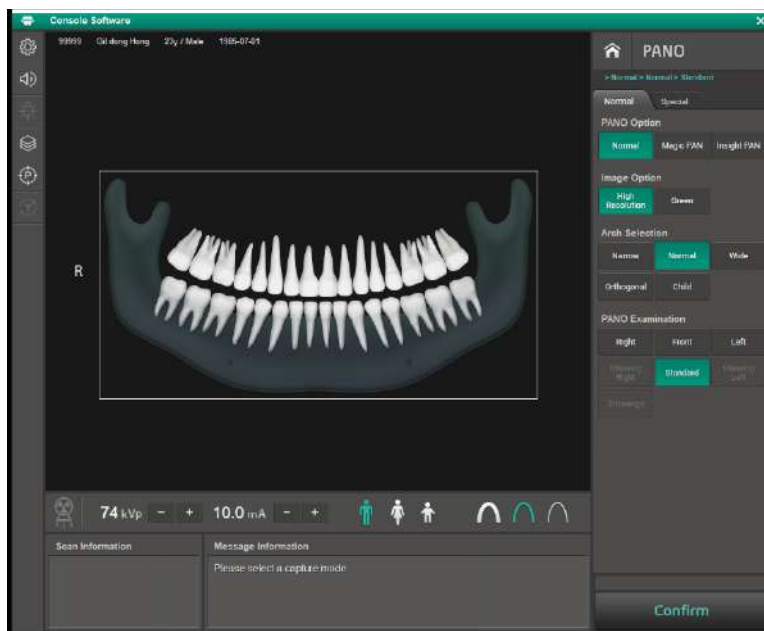
    PANO Option

Normal	Magic PAN	Insight PAN
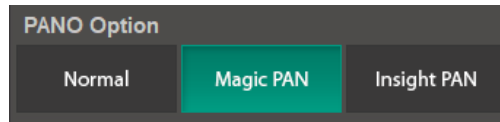
NOTICE	For **Insight PAN**, you can specify the X-ray exposure range.
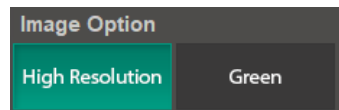
4. Select an **Image Option**.

    Image Option

High Resolution	Green

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

NOTICE	Once the Insight PAN or Magic PAN is selected, the image options menu is disabled.

5. Select an option from the **Arch Selection.**

    Arch Selection

Narrow	Normal	Wide
Orthogonal	Child	
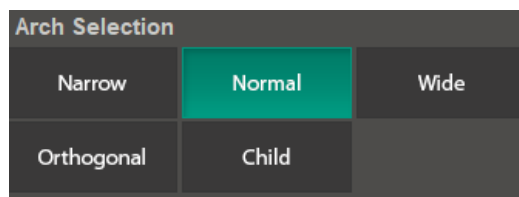
NOTICE	To enable Bitewing options (Bitewings, Bitewing Left, Bitewing Right, Bitewing Incisor), select **Orthogonal** from the arch selection menu.

---

6. Select an option from the **PANO Examination**.
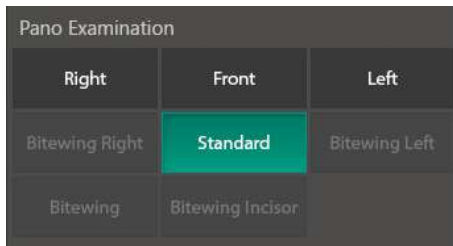
7. Select a **patient type**.

Man   **Women**   **Child**

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

8. 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

9. The system automatically configures the exposure condition based on previous parameters chosen by the user. However, you can customize the preselected condition by using the plus-minus buttons.

74 kVp [−] [+] 10.0 mA [−] [+]

With each click of the plus-minus buttons, the voltage adjusts by **± 1.0 kVp**, and the current by **±1.0 mA**.

10. Click **Confirm**. Once the button is clicked, you cannot change the parameters and the system will operate as follows:

Confirm

- ▪ The rotating unit moves to a scanning position.
- ▪ Laser beams are turned on.
- ▪ The **scan information window** shows DAP (Dose Area Product), scan time, and exposure time.

| **NOTICE** | When the progress bar reaches 100%, the **Confirm** button turns into the **Ready** button. |

11. Guide the patient to the X-ray room when you see the message below.

Message Information

Please position the patient for image capturing, and then click OK.

Ok
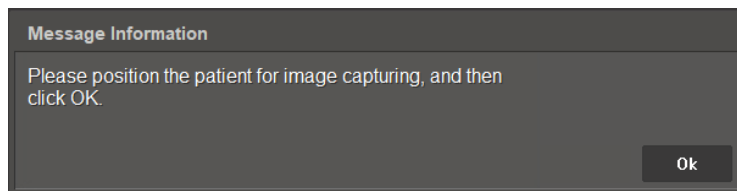
| ⚠ **CAUTION** | Do not allow the patient to enter the X-ray room until the equipment stops moving. |

7.2.2 Special Tab

To set the exposure settings on the Special tab:

1. Select **PANO** from the **Modality Option**.

After clicking the **PANO**, the main window looks as below:
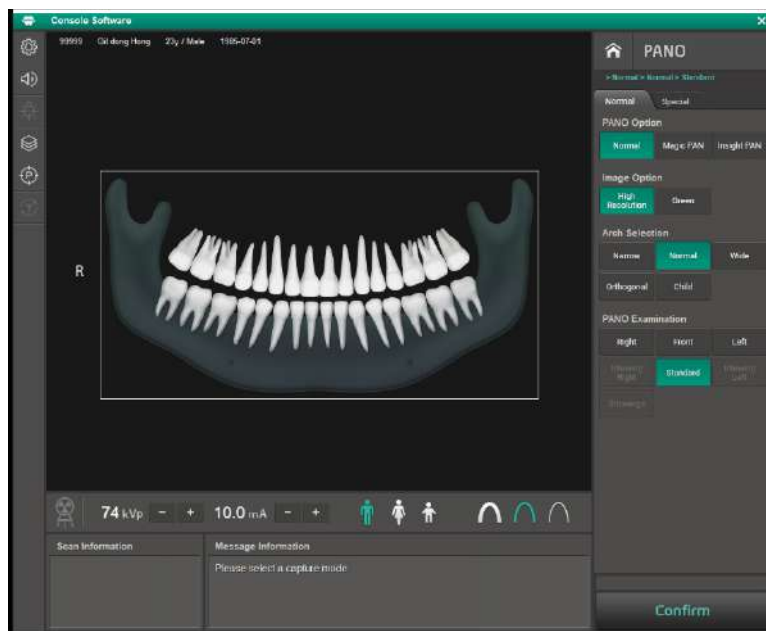
2. Click the **Special** tab.

After clicking the **Special** tab, the main window looks as below:

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

4. Select a **patient type**.

Man   Women   Child

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

5. 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

6. The system automatically configures the exposure condition based on previous parameters chosen by the user. However, you can customize the preselected condition by using the **plus-minus buttons**.

With each click of the plus-minus buttons, the voltage adjusts by **± 1.0 kVp**, and the current by **±1.0 mA.**

7. Click **Confirm**. Once the button is clicked, you cannot change the parameters and the system will operate as follows:

- The rotating unit moves to a scanning position.
- Laser beams are turned on.
- The **scan information window** shows DAP (Dose Area Product), scan time, and exposure time.

8. Guide the patient to the equipment.

Message Information

Please position the patient for image capturing, and then click OK.

Ok
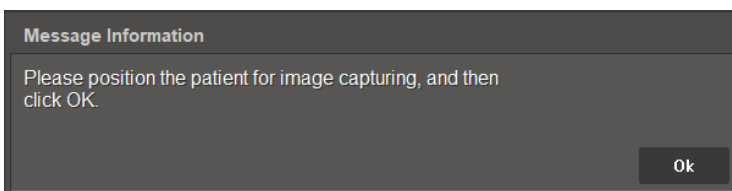
⚠ **CAUTION**	Do not allow the patient to enter the X-ray room until the equipment stops moving.
NOTICE	Insight PAN allows users to capture an image of the user-selected area only. By capturing a specific area, this mode minimizes the amount of radiation that the patient is exposed to.

< 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^2.

- 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.

7.3   Patient Positioning

To prepare patients for imaging:

1. Remove metal objects that the patient wears or carries, such as glasses.

2. Cover the patient with a lead apron, blanket, or protective clothing.

⚠ WARNING	- Cover patients with a lead apron or a blanket to protect their bodies from radiation exposure. - Do not shine the laser beam directly into the person's eyes. This can cause vision loss. - Pregnant women must consult a doctor before taking an X-ray
IMPORTANT	- Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition. - Metal implants or bridges may reduce the quality of the images.

7.3.1   Normal Mode

To position the patient for a normal panoramic image:

IMPORTANT	If you are positioning edentulous patients, insert **special bite B** into the normal chinrest instead of the normal bite block.
⚠ **CAUTION**	Chinrest, bite, and other accessories that had contact with the patient should be cleaned between patients with a chlorine dioxide-based alcohol-free product.

1.   Insert a normal bite into the normal chinrest.

2.   Cover the **normal bite** with a sanitary vinyl cover.

⚠ **CAUTION**	When the sanitary vinyl covers provided by VATECH runs out of stock, contact the manufacturer.
⚠ **CAUTION**	If you use the sanitary vinyl covers provided by the 3rd 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

3. Turn the **temple support knob** to open the temple supports.

4. Press the **column up/down button** to adjust the column's height for the patient.

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

5. Ask the patient to enter the equipment and give the following instructions:

    ▪ Stand straight.
    ▪ Grab handles with both hands.
    ▪ Place the chin on the chinrest.
    ▪ Gently bite on the bite block's groove with the front teeth.

6. When the patient positioning is complete, ask the patient to:

    ▪ Close their mouth.
    ▪ Close their eyes.
    ▪ Place the tongue on the roof of the mouth.

7. Turn the **temple support knob** to close the temple supports.

Laser Beam Positioning

After clicking **Confirm** on the console software, the following beams are turned on:

- ▪ Horizontal beam
- ▪ Vertical beam
- ▪ Canine Teeth beam
- ▪ Shoulder beam

Follow the steps below to position each beam:

1. Check if the **vertical beam** is aligned with the **patient's mid-sagittal line** (plane). Adjusts the patient's head position if necessary.

2. Check if the **horizontal beam** is in line with the patient's Frankfurt line (plane). Use the **beam up/down button** to adjust the beam's height if necessary.

3. Check if the **canine teeth beam** hits the patient's canine. If necessary, use the **canine teeth beam lever** to adjust the beam's location.
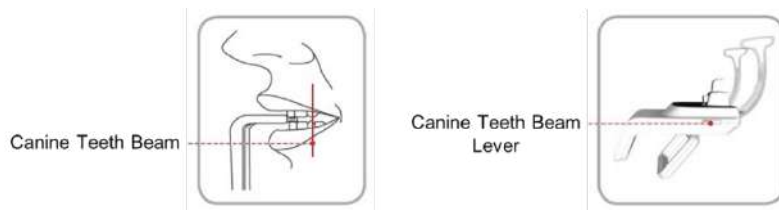
4. Check if the **shoulder beam** touches any part of the patient's shoulder. Ask the patient to lower his or her shoulder if necessary.

⚠ WARNING	Ensure that the laser beam does not hit the patient's eyes. Direct contact with the laser beam may cause vision loss.
NOTICE	The laser up/down button works only in panoramic mode. In other modes, you cannot move the horizontal beam.

Finishing Patient Positioning

After finishing the patient positioning:

1. Click **Ready**. X-ray is not emitted until you press the exposure switch.

2. Now go to **7.4 Acquiring Images** to start the exposure.

7.3.2   TMJ Open Mode

IMPORTANT	In the TMJ mode, the chinrest automatically goes down by 20 mm. Ensure to adjust the column's height after the chinrest is fully moved.
IMPORTANT	Check if the special bite A and chinrest are clean before using the parts.
⚠ CAUTION	Chinrest, bite, and other accessories that had contact with the patient should be cleaned between patients with a chlorine dioxide-based alcohol-free product.

To position patients for TMJ open mode:

1.   Insert the **special bite A** into the normal chinrest.

2.   Turn the **temple support knob** to open the temple supports.

3.   Press the **column up/down button** to adjust the column's height for the patient.

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

4.   Ask the patient to enter the equipment and give the following instructions:

- Stand straight.
- Grab handles with both hands.
- Place the chin on the chinrest.
- Gently bite on the bite block's groove with the front teeth.

---

5. Ask the patient to rest the acanthion point on the **special bite A** and tilt the head **forward at 5**˚. Ensure that the patient's jaw does not touch the equipment.

6. When the patient positioning is complete, ask the patient to:

   - Close their mouth.
   - Close their eyes.
   - Place the tongue on the roof of the mouth.

7. Turn the **temple support knob** to close the temple supports.

8. When the patient positioning is complete, ask the patient to:

   - Open their mouth.
   - Close their eyes.
   - Place the tongue on the roof of the mouth.

Laser Beam Positioning

NOTICE	The canine beam is turned off in **TMJ open, close,** and **Sinus mode.**

After clicking **Confirm** on the console software, the following beams are turned on:

- Horizontal beam
- Vertical beam
- Canine Teeth beam
- Shoulder beam

Follow the steps below to position each beam:

1. Check if the **vertical beam** is aligned with the **patient's mid-sagittal line** (plane). Adjusts the patient's head position if necessary.

2. Check if the **horizontal beam** is in line with the patient's Frankfurt line (plane). Use the **beam up/down butto**n to adjust the beam's height if necessary.
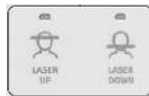
3. Check if the **shoulder beam** touches any part of the patient's shoulder. Ask the patient to lower his or her shoulder if necessary.

WARNING	Ensure that the laser beam does not hit the patient's eyes. Direct contact with the laser beam may cause vision loss.
NOTICE	**The laser up/down button** works only in the panoramic mode. In other modes, you cannot move the horizontal beam.

Finishing Patient Positioning

After finishing the patient positioning.

1. Click **Ready**. X-ray is not emitted until you press the exposure switch.

2. Now go to **7.4 Acquiring Images** to start the exposure.

7.3.3   TMJ Close Mode

Acquire a TMJ close image after taking a TMJ open image.

NOTICE	To acquire a TMJ close image, you must complete TMJ open imaging procedure.

To position the patient for TMJ close mode:

1. After you capture a TMJ open image, the message "Do you want to capture a TMJ close image" appears on the console software.

    Click **O.K**. to capture a TMJ close image,
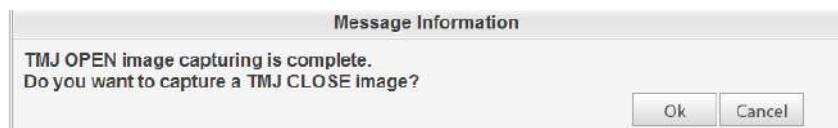
2. Guide the patient to the equipment.

3. Ask the patient to rest the acanthion point on the **special bite A** and tilt the head **forward at 5**˚. Ensure that the patient's jaw does not touch the equipment.

4. When the patient positioning is complete, ask the patient to

    ▪   Close the Mouth
    ▪   Close the eyes.
    ▪   Place the tongue on the roof of the mouth.
    ▪   Swallow
    ▪   Breath with noses

Positioning Laser Beams

This part is the same as the TMJ open mode.

Finishing Patient Positioning

This part is the same as the TMJ open mode.

7.3.4 Sinus Mode (LAT / PA)

To position the patient for sinus mode:

1. Insert the **special bite A** into the normal chinrest.

2. Turn the **temple support knob** to open the temple supports.

3. Press the **column up/down button** to adjust the column's height for the patient.

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

4. Ask the patient to enter the equipment and give the following instructions:

   - Stand straight.
   - Grab handles with both hands.
   - Place the chin on the chinrest.
   - Gently bite on the bite block's groove with the front teeth.

5. Ask the patient to rest the acanthion point on the **special bite A** and tilt the head **forward at 5˚**. Ensure that the patient's jaw does not touch the equipment.

6. When the patient positioning is complete, ask the patient to:

   - Close their mouth.
   - Close their eyes.
   - Place the tongue on the roof of the mouth.

7. Turn the **temple support knob** to close the temple supports.

Positioning Laser Beams

This part is the same as the TMJ open mode.

Finishing Patient Positioning

This part is the same as the TMJ open mode.

7.4   Acquiring Images

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

⊘ CAUTION	Do not use the PC while capturing an image. This can cause a problem with equipment or software's operation.
⚠ WARNING	In an emergency, release the **exposure switch** and press the **emergency stop switch**. The equipment immediately stops after pressing the switch.
⊘ CAUTION	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 **Ready** on the console software.

2.   Press the exposure switch when the message information window says, "Please press and hold the X-ray exposure switch until image capturing is completed."

Yellow : X-ray On

When you press the exposure switch,

- The LED on the vertical unit turns yellow.
- The LED on the exposure switch flickers yellow.
- The X-ray exposure status on the console software turns yellow.

3.   Release the exposure switch when the message information window says, "**Image capturing is complete**."

IMPORTANT	Do not release the exposure switch until you see the message. Early release of the exposure switch can disturb the image capture.

7.5 After Acquiring Images

Follow the steps below after the image acquisition.

⚠ **WARNING**	The equipment returns to its initial position after capturing the image. Ensure that the patient does not leave the equipment until it stops moving.

1. Use the **temple support knob** to open the temple supports.

2. Guide the patient to leave the X-ray room.

3. Remove the sanitary vinyl cover from the bite block.

7.6 Checking the Acquired Images

Follow the steps below to check the acquired images.

1. Click **Save** to store the acquired images. You may skip this step if you selected the **Auto Save option** before image acquisition.

2. Select the **PATIENT** tab on the **EzDent-i** window. Select and double-click the image you want to view.

NOTICE	You can select one image at a time.

3. The selected image is open on the **VIEWER** tab of the **EzDent-**

English
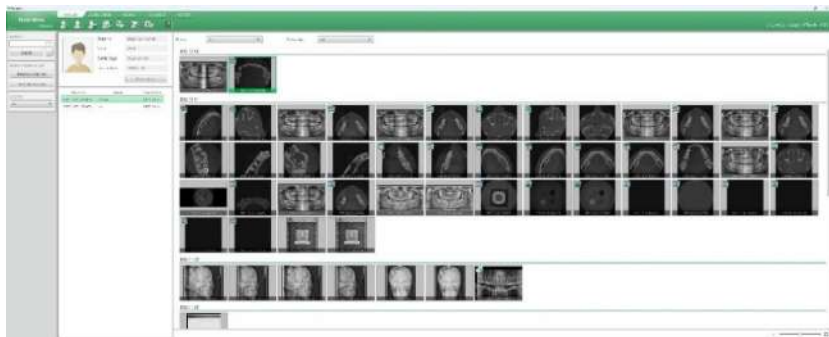
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8. How to Acquire CEPH Images (Optional)

8.1 Program Overview

■ **Role**

It provides conventional 2D cephalometric images.
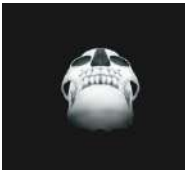
■ **Image Acquisition Method**

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)	- Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate. - 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.	 <Lateral> <Full Lateral>
PA	- The radiation is directed from the posterior of the skull to the anterior. - It is used to examine cranial diseases, trauma, and congenital malformations. - 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	 <PA>

Examination Area	Description	Position
	sinus, antrum ethmoidal olfactory pits, and optic disc pits. ■ 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.	
SMV	■ 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.	 <SMV>
Waters' View	■ 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.	 <Waters' view>
Carpus	■ Used to assess hand bone age to compare the changes in the skull.	 <Carpus>

8.2 Selecting Exposure Settings

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

English
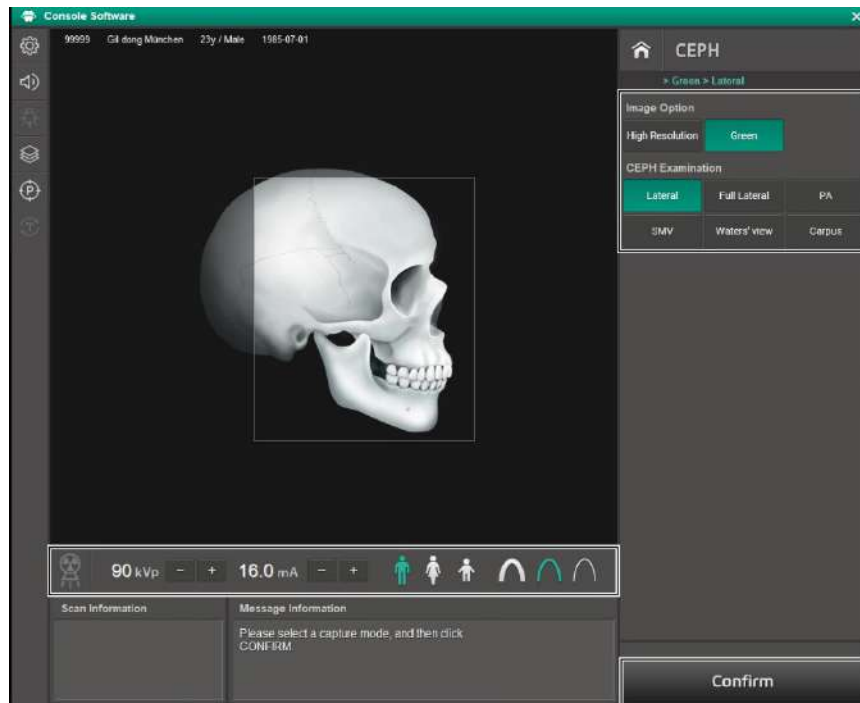
1. Select **CEPH** from the **Modality Option**.

2. Select an **image option**.
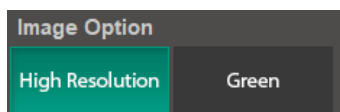
Mode	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

3. Select a **CEPH examination** option.

4. Select a patient type.

Man   Women   Child

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

5. 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

6. The system automatically configures the exposure condition based on previous parameters chosen by the user. However, you can customize the preselected condition by using the **plus-minus buttons**.

90 kVp [-] [+]   16.0 mA [-] [+]

With each click of the plus-minus buttons, the voltage adjusts by **± 1.0 kVp**, and the current by **±1.0 mA**.

7. Click **Confirm**. Once the button is clicked, you cannot change the parameters and the system will operate as follows:

Confirm

- The progress bar appears above the Confirm button.
- **The scan information window** shows DAP (Dose Area Product), scan, and exposure time.

NOTICE	When the progress bar reaches 100%, Confirm turns into Ready.

8. Guide the patient to the equipment.

English

8.3 Patient Positioning

To prepare patients for imaging:

1. Remove metal objects that the patient wears or carries, such as glasses.

2. Cover the patient with a lead apron, blanket, or protective clothing.

⚠ WARNING	- Cover patients with a lead apron or blanket to protect their bodies from radiation exposure. - Do not shine the laser beam directly into the person's eyes. This can cause vision loss. - Pregnant women must consult a doctor before taking an X-ray
IMPORTANT	- Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition. - Metal implants or bridges may reduce the quality of the images.

8.3.1   Lateral / Full Lateral (Optional) Mode

Follow the steps below to position the patient for the lateral 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 Lateral / Full lateral mode marker.

3.   Use the **column up/down butto**n 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 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.
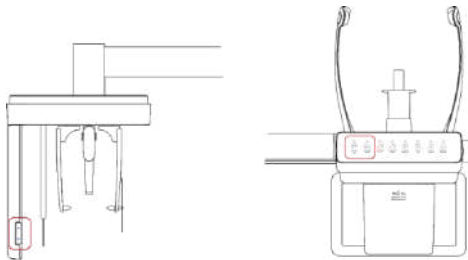
> **CAUTION** Ensure that the patient does not collide with the equipment while it is moving.

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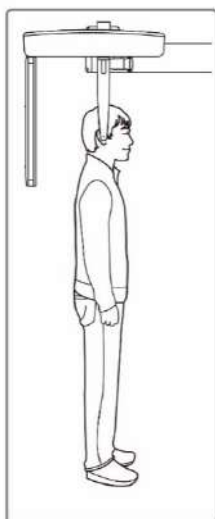
5. Slid the ear rods until their tips gently touch the patient's outer ear canals.

> ⚠ **CAUTION** | 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.
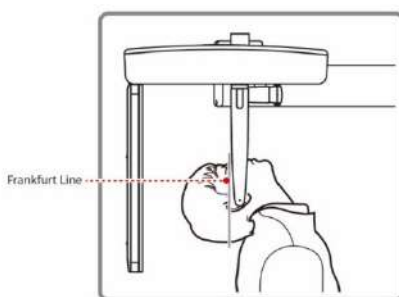
Frankfurt Line

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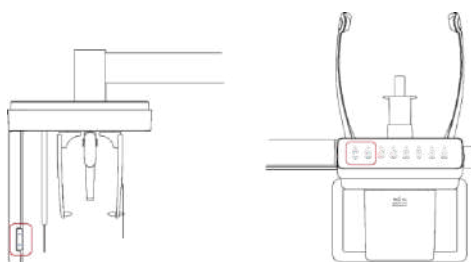
| CAUTION | Ensure that the patient does not collide with the equipment while it is moving. |

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.

English
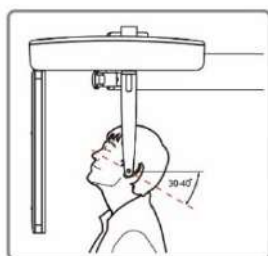
8. Give the patient the following instructions:

    ▪ 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:

| ⚠ **CAUTION** | Ensure that the carpus plate is installed and secured before positioning the patient. |

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 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**.

    | **IMPORTANT** | 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.

ⓘ CAUTION	Do not use the PC while capturing an image. This can cause a problem with equipment or software's operation.
⚠ WARNING	In an emergency, release the **exposure switch** and press the **emergency stop switch**. The equipment immediately stops after pressing the switch.
ⓘ CAUTION	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 **Ready** on the console software.

Ready

2. Press the exposure switch when the message information window says, "Please press and hold the X-ray exposure switch until image capturing is completed."

Yellow : X-ray On

When you press the exposure switch,

- The LED on the vertical unit turns yellow.
- The LED on the exposure switch flickers yellow.
- The X-ray exposure status on the console software turns yellow.

3. Release the exposure switch when the message information window says, "**Image capturing is complete**."

IMPORTANT	Do not release the exposure switch until you see the message. Early release of the exposure switch can disturb the image capture.

8.5   After Acquiring Images

Follow the steps below after the image acquisition.

⚠ **WARNING**	The equipment returns to its initial position after capturing the image. Ensure that the patient does not leave the equipment until it stops moving.

1.   Slid the ear rods back to their pre-scanning position.

2.   Fold up the nasal positioner if necessary.

3.   Remove the carpus plate, if necessary.

4.   Instruct the patient to leave the X-ray room.

8.6   Checking the Acquired Images

Follow the steps below to check the acquired images.

1.   Click **Save** to store the acquired images. You may skip this step if you selected the **Auto Save option** before image acquisition.

2.   Select the **PATIENT** tab on the **EzDent-i** window. Select and double-click the image you want to view.
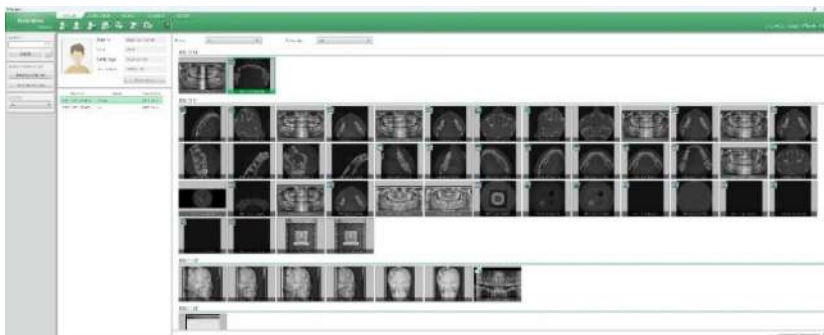
NOTICE	You can select one image at a time.

3.   The selected image is open on the **VIEWER** tab of the **EzDent-i**

9. How to Acquire CBCT Images

9.1 CBCT Imaging Program Overview

■ **Role**
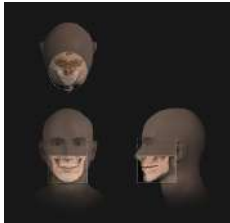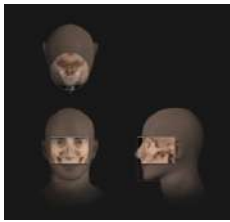
It provides conventional 3D CT sliced images.
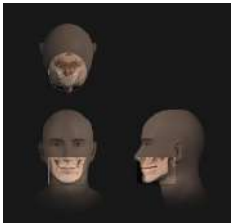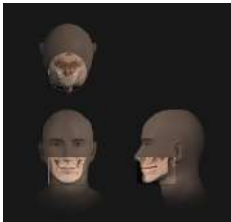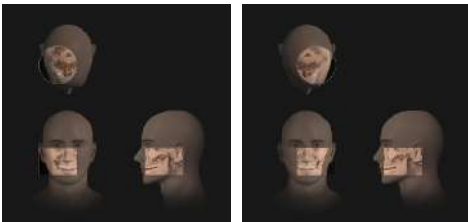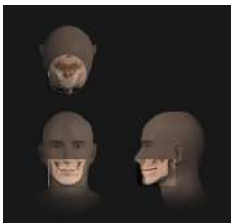
■ **Image Acquisition Method**
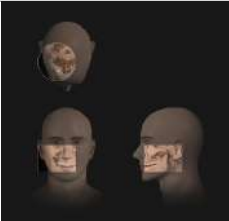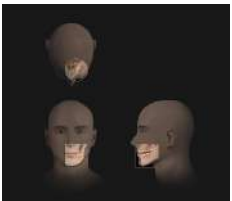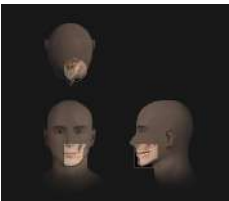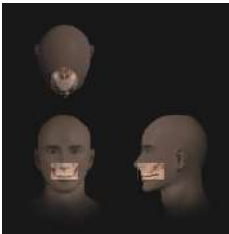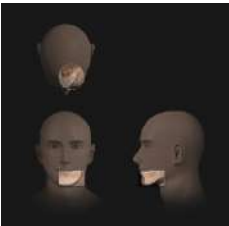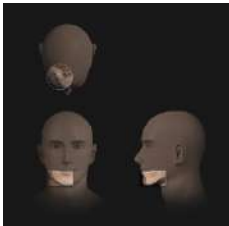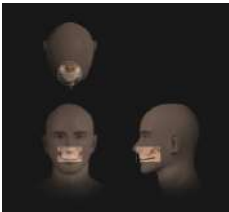
It acquires images with the X-ray beam scanning specific oral & maxillofacial regions and reconstructs them into 3D sliced images.

■ **Examination Programs**
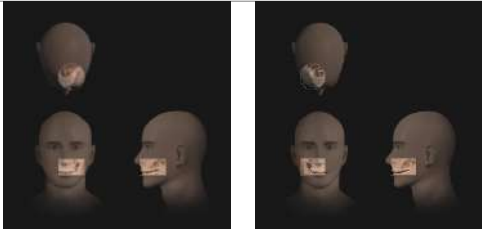
It is classified as below based on the FOV.

Available FOVs (cm)	ROI	Description
Double Scan (Optional)	 <Mandible/Center> <Maxilla/Center> NOTICE — After taking two consecutive exposures in the order of "1 → 2", it is automatically synthesized and displayed as one full image.	- Full arch, sinus, left and right TMJ area can be checked - Suitable for most intra-oral surgery, including multiple implant placement

Available FOVs (cm)	ROI	Description
16x9	<Occlusion/Center>	- Covers full arch region, sinus, and left/right TMJ. - Suitable for most oral surgery cases as well as multiple implant surgery.
12x9	<Occlusion/Center> <TMJ/Right> <TMJ/Left> <Airway/Center>	- Covers both maxillary and mandibular structures, including the 3rd molar region. - TMJ Right/Left and Airway modes are available.
8x8	<Occlusion/Center>	- Selectable FOV for the region (left/center/right). - Covers both maxillary and mandibular areas and left/right TMJ.

Available FOVs (cm)	ROI		Description
	<TMJ/Left>	<TMJ/Right>	
	<Occlusion/Left>	< Occlusion/Right>	
8x5	<Mandible/Center> <Mandible/Left>	<Mandible/Right>	- Selectable FOV for the region (left/ center/right). - Covers both maxillary and mandibular areas.
	<Maxilla/Center>		

Available FOVs (cm)	ROI	Description
	< Maxilla/Left> < Maxilla/Right>	
5x5		- Covers 3~4 areas through capturing ROI. - Can acquire 3~4 teeth at once. - Voxel Size: 0.08/0.12 applied.
Endo (4x4)		- Covers 3~4 areas through capturing ROI. - Can acquire 3~4 teeth at once. - Voxel Size: 0.05 applied.

NOTICE	The Endo mode FOV size is 40 x 40 mm^2, 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.

English

9.2 Selecting Exposure Settings

Complete the steps in **6. Getting Started** before configuring exposure settings in console software.
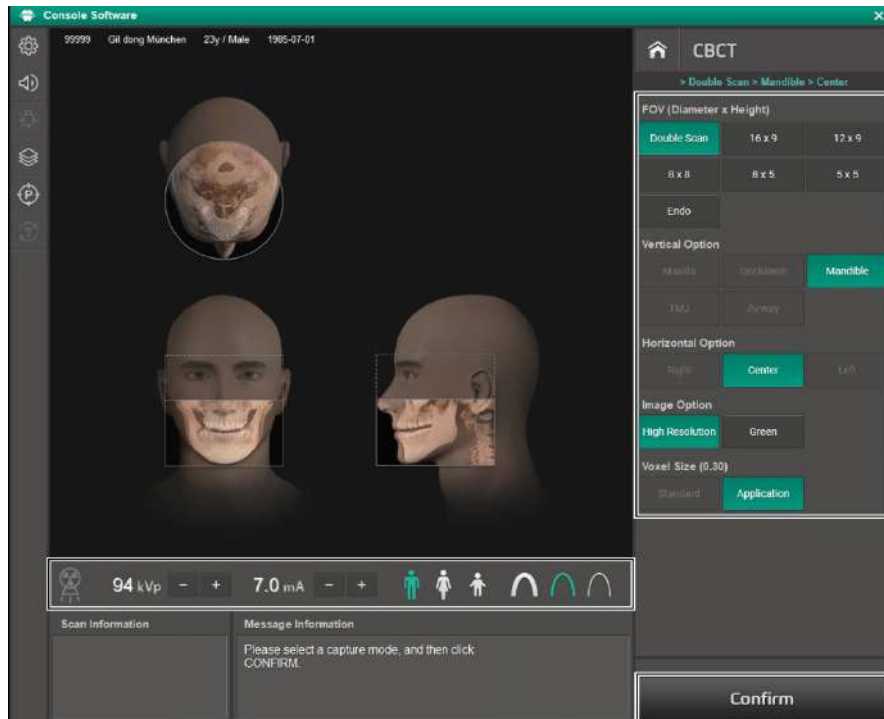
Console Software Window

IMPORTANT	**Patient Motion Detection** is featured in Green X, designed to protect patients from the rotating unit's sudden movement during the exposure parameter configuration.
	When the system detects a patient inside the equipment during the configuration, it will halt the procedure, and the following audio message will be played: "During the system preparation, a patient has been detected at the imaging location."
	Guide the patient out of the equipment to a safe location, then restart the image capture program.
IMPORTANT	**Patient motion detection** is a feature that is **disabled in certain countries, including the United States.** For more information, contact your local Vatech Representative.

1. Select **CBCT** from the **Modality Option**.

2. Select a **FOV**. the vertical options and horizontal options are selected according to the FOV you chose.
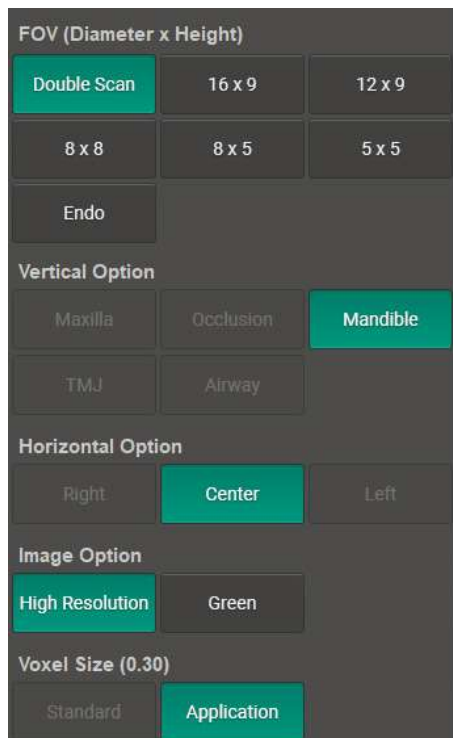
See the Table below for the vertical and horizontal options corresponding to each FOV.

Available FOV (cm)	Vertical option	Horizontal option
16x15 (Double Scan; 16x9 stitching)	Mandible (First Scan) Maxilla (Second Scan)	Center
16x9	Occlusion	Center
12x9	Occlusion	Center
	TMJ	Right
		Left
	Airway	Center
8x8	Occlusion	Right
		Center
		Left
	TMJ	Right
		Left
8x5	Maxilla	Right
		Center
		Left
	Mandible	Right
		Center
		Left
5x5	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)
Endo (4x4)	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)

3. Select an **image option**.
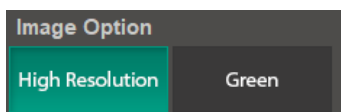
Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

4. Select a **voxel size**.
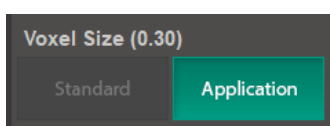
5. Select a **patient type**.

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

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. The system automatically configures the exposure condition based on previous parameters chosen by the user. However, you can customize the preselected condition by using the **plus-minus buttons**.

94 kVp [– | +] 13.0 mA [– | +]

With each click of the plus-minus buttons, the voltage adjusts by **± 1.0 kVp,** and the current by **±0.1 mA**.

8. Click **Confirm**. Once the button is clicked, you cannot change the parameters and the system will operate as follows:

Confirm

- The rotating unit moves to a scanning position.
- Laser beams are turned on.
- The progress bar appears above the **Confirm** button.
- The **scan information window** shows DAP (Dose Area Product), scan time, and exposure time.

9. Guide the patient to the X-ray room when you see the message below.

Message Information

Please position the patient for image capturing, and then click OK.

Ok
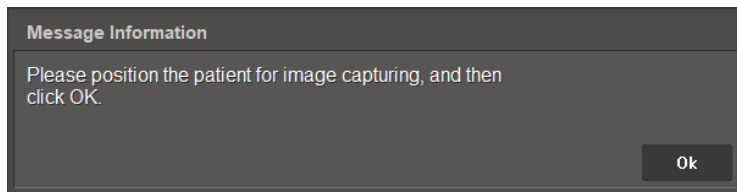
⚠ **CAUTION** | Do not allow the patient to enter the X-ray room until the equipment stops moving.

9.3 Double Scan Mode

In Double Scan mode, the mandible (lower jaw) is first scanned followed by the maxilla (upper jaw). But you need to select exposure settings only once. Once the first scan is completed, the system automatically sets the condition for the second scan.

IMPORTANT	Patient anatomy that is within a central 6 cm tall region of the FOV [comprising 25 % of the total FOV] may receive an increased X-ray dose depending on the FOV setting.
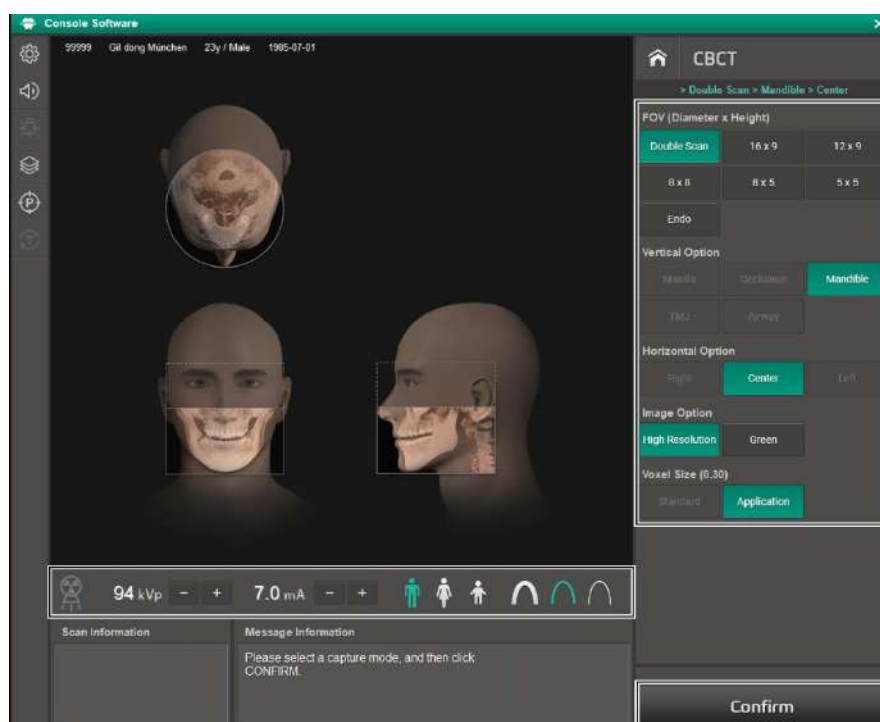
9.3.1 First Scan (Mandible)

To start the first scan for double scan mode:

1. Select **Double Scan** from the **FOV** menu. Once selected, the system automatically sets the vertical option (Mandible), the horizontal option (Center), and the voxel size (Application)

FOV (Diameter x Height)		
Double Scan	16 x 9	12 x 9
8 x 8	8 x 5	5 x 5
Endo		

2. Select an **image option**.

Image Option	
High Resolution	Green

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 under the age of 12

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. The system automatically configures the exposure condition based on previous parameters chosen by the user. However, you can customize the preselected condition by using the **plus-minus buttons**.

With each click of the plus-minus buttons, the voltage adjusts by **± 1.0 kVp**, and the current by **±0.1 mA**.

6. Click **Confirm**. Once clicked you cannot change the selected settings and the system operates as below:

- The rotating unit moves to a scanning position.
- Laser beams are turned on.
- The progress bar appears above the **Confirm** button.
- The **scan information window** shows DAP (Dose Area Product), scan time, and exposure time.

7. Guide the patient to the X-ray room when you see the message below.
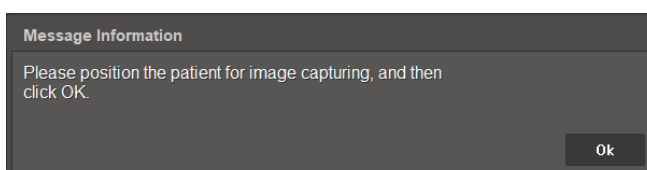
⚠ **CAUTION**	Do not allow the patient to enter the X-ray room until the equipment stops moving.

8. Click **Ready**.

9. Start an X-ray exposure according to **9.6 Acquiring Image**.

10. Ask the patient to step outside of the equipment.

⚠ **CAUTION**	Until the equipment stops moving, do not allow the patient to leave the equipment.

9.3.2 Second Scan (Maxilla)

For the second scan, the vertical option (Maxilla), the patient type, X-ray intensity level, and exposure condition are automatically selected by the system.

1. Click **Confirm**. Once clicked you cannot change the selected settings and the system operates as below:

> ## Confirm

- ▪ The rotating unit moves to the scanning position.
- ▪ Laser beams are turned on.
- ▪ The progress bar appears above the Confirm button.
- ▪ The **scan information window** shows the estimated DAP(Dose Area Product), scan time, and exposure time.

NOTICE	When the progress bar reaches 100%, the **Confirm** button turns into the **Ready** button.

2. Guide the patient to the equipment and position the patient according to **9.5 Patient Positioning**.

3. Click **Ready**.

> ## Ready

4. Starts an X-ray exposure following **9.6 Acquiring Images**.

9.4 Scout View

For Endo and 5x5 mode, you can take a scout image before acquiring a CBCT image. To start a scout scan:

1. Select 5x5 or Endo from FOV.

5x5   **Endo**
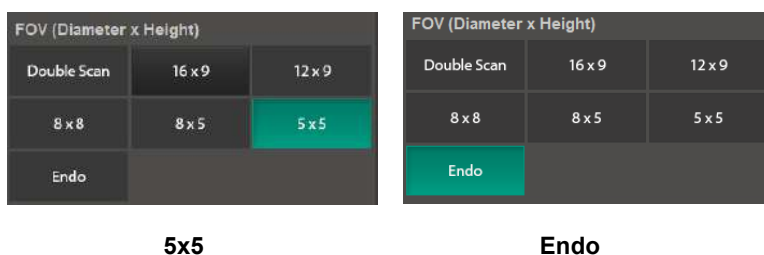
2. Select the exposure settings for the **5x5** or **End**o mode.

3. Position the patient according to the selected FOV. Once the patient positioning is completed, click **Confirm**.

4. When you see the message information window says, 'Do you want to proceed with SCOUT capturing?', click '**Yes**'.
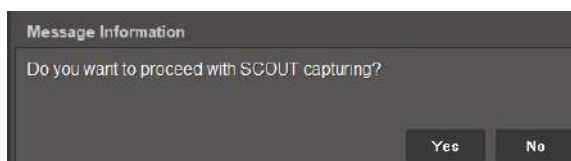
NOTICE	Click **No** if you want to skip the scout view imaging.
IMPORTANT	If the patient moves during Scout mode imaging, the capture location you selected may become incorrect. Please guide the patient to maintain their original position until the end.

5. Check the capture location in the scout image. To change the location, follow the steps below:

   1) Click the guideline(green lines) on the screen.

   2) Drag the guideline to the desired location. you can move the line **up and down** to set a new capture location.

6. Click **Set** after selecting the capture location. The chinrest will move down according to the adjusted location.
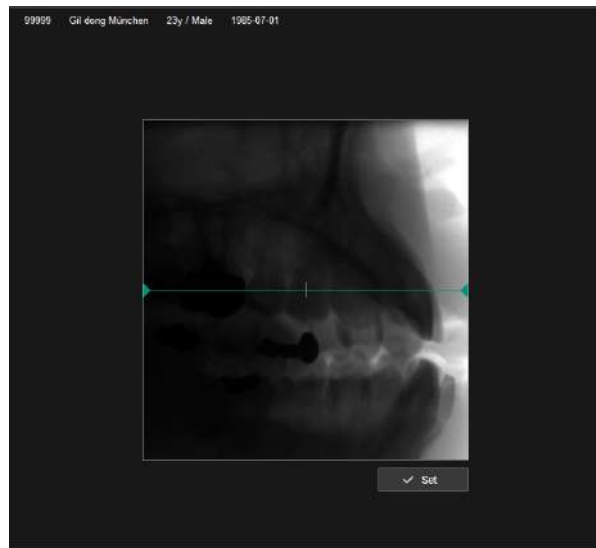
Preview Image

IMPORTANT	Please guide the patient to maintain their position before clicking Set.
NOTICE	Do not click Set until you finalize the selection. You can use the Set button only once.

7. Follow the instructions in **9.6 Acquiring Images**.

9.5 Patient Positioning

To prepare patients for imaging:

1. Remove metal objects that the patient wears or carries, such as glasses.

2. Cover the patient with a lead apron, blanket, or protective clothing.

⚠ WARNING	- Cover patients with a lead apron or a blanket to protect their bodies from radiation exposure. - Do not shine the laser beam directly into the person's eyes. This can cause vision loss. - Pregnant women must consult a doctor before taking an X-ray
IMPORTANT	- Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition. - Metal implants or bridges may reduce the quality of the images.

9.5.1 Normal Mode

To position the patient for a normal panoramic image:

IMPORTANT	If you are positioning edentulous patients, insert **special bite B** into the normal chinrest instead of the normal bite block.
⚠ **CAUTION**	Chinrest, bite, and other accessories that had contact with the patient should be cleaned between patients with a chlorine dioxide-based alcohol-free product.

1. Insert a normal bite into the normal chinrest.

2. Cover the normal bite with a sanitary vinyl cover.

⚠ **CAUTION**	When the sanitary vinyl covers provided by VATECH runs out of stock, contact the manufacturer.
⚠ **CAUTION**	If you use the sanitary vinyl covers provided by the 3rd 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

3. Turn the **temple support knob** to open the temple supports.

4. Press the **column up/down button** to adjust the column's height for the patient.

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

5. Ask the patient to enter the equipment and give the following instructions:

   ▪ Stand straight.
   ▪ Grab handles with both hands.
   ▪ Place the chin on the chinrest.
   ▪ Gently bite on the bite block's groove with the front teeth.

6. When the patient positioning is complete, ask the patient to:

   ▪ Close their mouth.
   ▪ Close their eyes.
   ▪ Place the tongue on the roof of the mouth.

7. Turn the **temple support knob** to close the temple supports.

8. Leave the X-ray room and follow the instructions in **9.6 Acquiring Images**.

English

9.5.2 Double Scan Mode

First Scan (Mandible Scan)

To position the patient for the first (mandible) scan:

1. Insert the normal bite into the normal chinrest. Cover the bite with a sanitary vinyl cover.
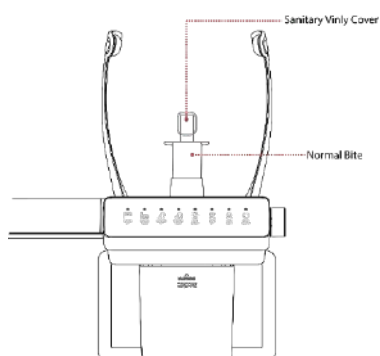
2. Press the column up/down button to adjust the column's height for the patient.
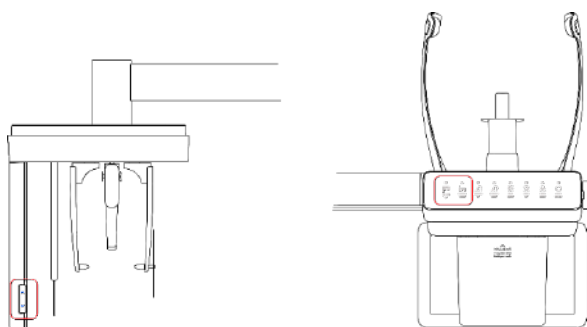
⚠ CAUTION	Ensure that the patient does not collide with the equipment while it is moving.

3. Turn the **temple support knob** to open the temple supports.

4. Ask the patient to stand inside the equipment and give the following instructions:

   - Stand straight.
   - Grab handles with both hands.
   - Place the chin on the chinrest.
   - Gently bite on the bite block's groove with the front teeth.

5. Adjust the patient's position according to the laser beam's location.

    ▪ The **vertical beam** must be aligned with the patient's **mid-sagittal plane**. If necessary, center the patient's head.

    ▪ The **horizontal beam** must be aligned with the patient's **Frankfurt plane** Use the **chinrest up/down button** to align the patient with the beam.

    ▪ Check if the **shoulder beam** touches the patient's **shoulder**. If necessary, ask the patient to lower his or her shoulder.

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

6. Ask the patient to place the tongue on the roof of the mouth and close the eyes.

7. Turn the **temple supports knob** to close the temple supports to secure the patient's head.

8. Leave the X-ray room and follow the instructions in **9.6 Acquiring Images**.

Second Scan (Maxilla Scan)

Follow the steps below to position the patient for the second scan.

NOTICE	After the first (mandible) scan, the system automatically sets exposure settings for the second (maxilla) scan.

1. After the first scan is complete, ask the patient to exit the equipment.

ⓘ **CAUTION**	Instruct the patient to exit only after the equipment made a complete stop.

2. Click **Confirm** on the console window.

ⓘ **CAUTION**	After clicking **Confirm**, the rotating unit will spin, and both the chinrest and column will move down for the maxilla scan.

3. After the first scan, the chinrest goes down. Guide the patient to open his or her mouth while the chin is placed on the chinrest.

   - Grab handles with both hands and stand with your neck straight.
   - Place the chin on the chinrest.
   - Gently bite the bite block with the front teeth.

4. Adjust the patient's position according to the laser beam's location.

   - The **vertical beam** must be aligned with the patient's **mid-sagittal plane**. If necessary, center the patient's head.
   - The **horizontal beam** must be aligned with the patient's **Frankfurt plane** Use the **chinrest up/down button** to align the patient with the beam.
   - Check if the **shoulder beam** touches the patient's **shoulder**. If necessary, ask the patient to lower his or her shoulder.

5. Follow the instructions in **9.6 Acquiring Images** to complete the second (maxilla) scan.

9.6   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**. The equipment immediately stops after pressing the switch.
	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 **Ready** on the console software.

2. Press the exposure switch when the message information window says, "Please press and hold the X-ray exposure switch until image capturing is completed."

When you press the exposure switch,

- The LED on the vertical unit turns yellow.
- The LED on the exposure switch flickers yellow.
- The X-ray exposure status on the console software turns yellow.

3. Release the exposure switch when the message information window says, "**Image capturing is complete**."

IMPORTANT	Do not release the exposure switch until you see the message. Early release of the exposure switch can disturb the image capture.

9.7 After Acquiring Images

Follow the steps below after the image acquisition.

⚠ **WARNING**	The equipment returns to its initial position after capturing the image. Ensure that the patient does not leave the equipment until it stops moving.

1. Use the temple support knob to open the temple supports.

2. Guide the patient to leave the X-ray room.

3. Remove the sanitary vinyl cover from the bite block.

9.8 Checking the Acquired Images

Follow the steps below to check the acquired images.

1. Click **Save** to save the captured images. You can skip this step if you already select the Auto Save option before scanning.

NOTICE	Click **Retake** to capture another image.
NOTICE	**How to Select the Auto Save Option** 1) Select the Settings button on the console window. 2) Select **User > Image Save option** and check the box to apply the Auto Save. 3) Click **Save**.
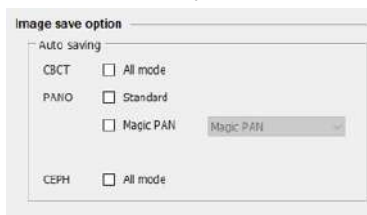
2. Select the **PATIENT** tab on the **EzDent-i** window. Select and double-click the image you want to view.
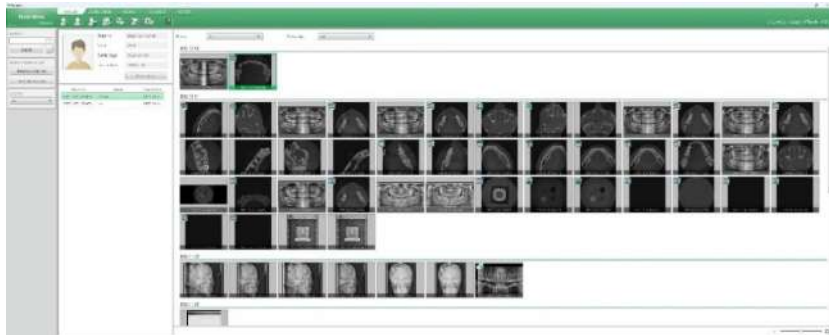
| **NOTICE** | You can select one image at a time. |

3. When you select a 3D image, the **Ez3D-i window** is open and you can view the captured images through **Ez3D-i**.

| **NOTICE** | Check if the Ez3D-i or the 3rd party 3D viewer is linked to EzDent-i to access 3D images. Go to **EzDent-i** and select *Environment > Linkage* to check the linkage status. |

English

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10. How to Acquire 3D Model Scan Images

10.1 Program Overview

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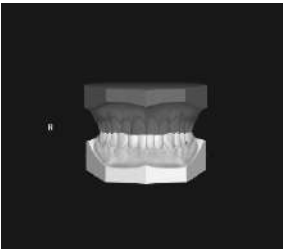
It provides 3D modeling surface data of the Plaster Cast. (STL file)

■ **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 configure exposure settings for 3D model scan:

1. Select **MODEL** from the **Modality Option**.

2. Select an area to acquire an image.
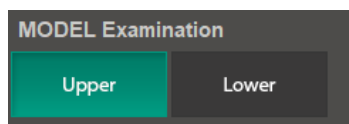
3. The system automatically configures the exposure condition based on previous parameters chosen by the user. However, you can customize the preselected condition by using the **plus-minus buttons**.

With each click of the plus-minus buttons, the voltage adjusts by **± 1.0 kVp,** and the current by **±0.1 mA**.

4. Click **Confirm**. Once the button is clicked, you cannot change the parameters and the system will operate as follows:

- The rotating unit moves to a scanning position.
- Laser beams are turned on.
- The progress bar appears above the Confirm button.
- The **scan information window** shows DAP (Dose Area Product), scan time, and exposure time.

5. Bring a plaster cast to the equipment.

English

10.3 Model Positioning

MODEL Scan Jig Installation

1. Remove the Temple Supports and the Chinrest

2. Insert the MODEL Scan Jig.
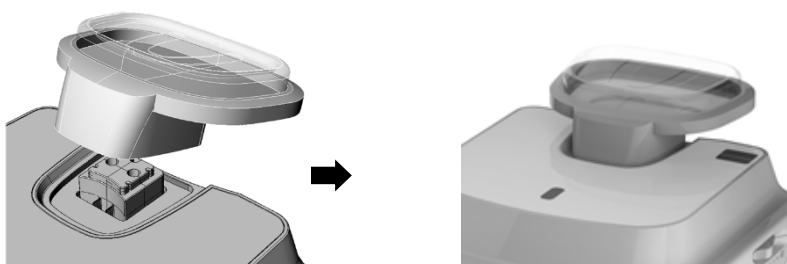
Laser Beam Positioning

1. Put the Plaster Cast on the MODEL Scan Jig. (Whether the Plaster Cast is for Maxilla or Mandibular, place it flat side down.)

2. Align the Mid-sagittal plane Laser Beam to the center of the Plaster Cast. (To prevent the horizontal expansion of the image)

3. Click the **Ready** button. X-ray is not emitted until you press the exposure switch.

4. Now go to **10.4 Acquiring Imagee** to start the exposure.

10.4   Acquiring Images

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

⚠ CAUTION	DO NOT use the PC while capturing an image. This can cause a problem with equipment or software's operation.
⚠ WARNING	In an emergency, release the **exposure switch** and press the **emergency stop switch**. The equipment immediately stops after pressing the switch.
⚠ CAUTION	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 **Ready** on the console software.

2. Press the exposure switch when the message information window says, "Please press and hold the X-ray exposure switch until image capturing is completed."

When you press the exposure switch,

- The LED on the vertical unit turns yellow.
- The LED on the exposure switch flickers yellow.
- The X-ray exposure status on the console software turns yellow.

3. Release the exposure switch when the message information window says, "**Image capturing is complete**."

IMPORTANT	DO NOT release the exposure switch until you see the message. Early release of the exposure switch can disturb the image capture.

English

10.5   Checking the Acquired Images

Follow the steps below to check the acquired images.

1.   Click **Save** to save the images you captured. You can skip this step if you select the auto-save option before scanning.

2.   Open the **EzDent-i** and select the **PATIENT** tab. Select and double-click one of the images displayed next to the patient information.
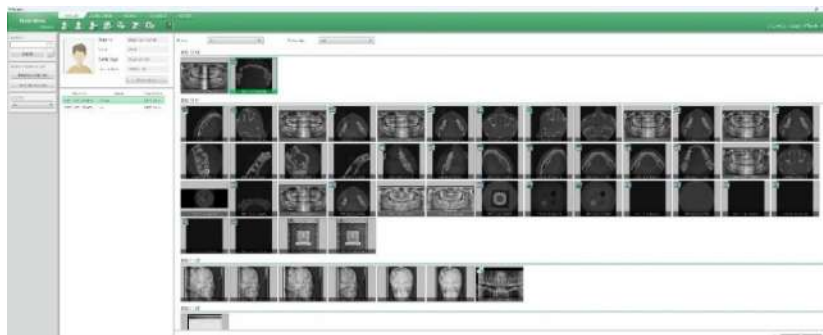
3.   The STL viewer linked to the EzDent-i is open after you click the image.

NOTICE	You can select one image at a time.
NOTICE	Ensure that the STL viewer is linked to the **EzDent-i** before checking the captured images.

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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	1. Check the exposure switch's connection status. 2. Check if the console software is ready to capture an image.

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 **Beam on/off button** on the control panel.

11.2   Error Codes

When a problem occurs during the operation, an error code appears on the message information window. When you see the code, contact VATECH for assistance.

NOTICE	Error code is written in the following format:
	[Code: E00X.0XX.0XX]
	The code consists of three parts: Main, Sub, and Tail.
	Main code Tail code ↑ ↑ **E00X.0XX.0XX** ↓ Sub code
	▪ **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.
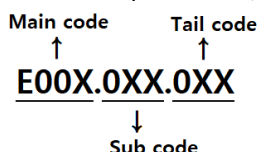
11.2.1   Main code - Hardware (001)

11.2.1.1 Subcode – Generator-Related Error (001)

Tail code	Description
001	Appears when the tube is not ready for use
002	Appears when the cable between the tube tank and Inverter board is disconnected
003	Appears when the current of the inverter board exceeds the maximum allowable level during X-ray irradiation
004	Appears when there is ±10kV or more voltage difference in tube voltage compared to a reference value
005	Appears when there is ±0.5mA or more current difference in tube current compared to a reference value
006	Appears when there is ±20kV or more voltage difference in tube voltage feedback compared to the average value
007	Appears when there is ±1mA or more current difference in tube

Tail code	Description
	current feedback compared to the average value
008	Appears when the temperature of the mono tank is above the setting temperature
009	Appears when the inverter output current is higher than 1A during X-ray irradiation (In EP, IP conditions)
010	Appears when the inverter board falsely recognizes the exposure switch signal as OFF after the irradiation. On command
011	Appears when the X-ray OFF command is not sent to the inverter board in 0.5 seconds after turning off the exposure switch
012	Appears when kV feedback is over -20kV compared to the setting value during X-ray irradiation
013	Appears when kV feedback is over +20kV compared to the setting value during X-ray irradiation.
014	Appears when the mA feedback value is less than 50% compared to setting conditions during X-ray irradiation.
015	Appears when the mA feedback value is higher than 150% compared to setting conditions during X-ray irradiation.

11.2.1.2 Subcode - Motor-Related Error (002)

Tail code	Description
021	Appears when rotator-axis motor origin movement fails
027	Appears when CEPH sensor motor origin movement fails
030	Appears when quadruple axis collimator left origin movement fails
031	Appears when quadruple axis collimator right origin movement fails
032	Appears when quadruple axis collimator up origin movement fails
033	Appears when quadruple axis collimator down origin movement fails

Tail code	Description
036	Appears when an error occurs during the collimator filter axis motor initialization
037	Appears when the generator tilting fails
039	Appears when X-axis motor origin movement fails
040	Appears when Y-axis motor origin movement fails

11.2.1.3 Subcode – Exposure Switch-Related Error (003)

Tail code	Description
060	It appears that the exposure switch is pressed when turning on the equipment.

11.2.1.4 Subcode – Other Errors (004)

Tail code	Description
102	Appears when there is no response during CAN communication.

11.2.2 Main code – Software (002)

11.2.2.1 Subcode – Sequence-Related Error (001)

Tail code	Description
001	Appears when the packing mode is enabled
002	Appears when the door is open
003	Appears when the exposure switch is pressed

11.2.2.2 Subcode – PC Resolution Related Error (010)

Tail code	Description
001	Appears when the resolution is less than 1280x1024
002	Appears when the resolution is less than 1200x960

11.2.2.3 Subcode – PC Network-Related Error (024)

Tail code	Description
002	Appears when the port is invalid
003	Appears when the time is out

11.2.3 Main code - Acquisition Module (003)

11.2.3.1 Subcode – Initialization Failure-Related Error (010)

Tail code	Description
000	Appears when the COM port cannot be opened
001	Appears when the frame grabber interface cannot be initialized, or memory for acquisition cannot be reserved
002	Appears when the MCU is not communicable, or the modem ring signal is in an improper state

11.2.3.2 Subcode – Capture Failure-Related Error (020)

Tail code	Description
000	Appears when there is a capture error

11.2.3.3 Subcode – Reconstruction Failure-Related Error (030)

Tail code	Description
001	Appears when bugs exist in the VXM file or there is insufficient memory

11.2.3.4 Subcode – Hardware-Related Error (061)

Tail code	Description
HW Error No	Appears when the error occurs during the acquisition module operation

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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:

    - Chorine-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.

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

12.2   Cleaning

Before capturing an image, clean the accessories or parts that have contact with the patient's skin. The list below shows examples of accessories and parts that require cleaning:

- Normal / Special A / Special B bite
- Temple Supports
- Chinrest
- Nasal Positioner
- Ear rods

Accessory /Part	Procedure
Bite (Normal / Special A / Special B)	1) Remove visible soil with a paper wipe or disposable cloth. 2) Use a soft cloth dampened with a cleaning agent. And gently wipe the target area with the cloth. 3) Dry the cleaned parts and accessories with a dry cloth until no liquid is left.
Temple Supports	
Chinrest	
PC and its peripherals	Clean each part following the manufacturer's instructions
Outer covers	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

13.1 Regular 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.

English

13.2 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 **main power switch** is turned off after the operation.	Daily
Check for the temperature of the power cords.	Daily
Ensure that the LED indicator turns yellow when you press **the exposure switch**.	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 **emergency stop switch**	Weekly
Ensure that all labels on the equipment are intact and legible.	Weekly
Check the condition of the **exposure switch**.	Monthly
Check the sound of the audio messages from the equipment.	Monthly

13.3   QA Test

This section is intended to give information about PHT-75CHS PHANTOM KIT for 3D IMAGE QUALITY INSPECTION and CALIBRATION. You must thoroughly familiarize yourself with this guide to perform the regular QA test effectively by using the PHANTOM KIT. QA tests should be done annually at the frequency specified by the manufacturer or state regulations in which the X-ray system is being used.

13.4   Phantom Kit Contents

- CT NUMBER CHECK PHANTOM x 1
- UNIFORMITY CHECK PHANTOM x1
- S&C CHECK PHANTOM x1
- PHANTOM JIG A'SSY x 1
- PHANTOM KIT User Manual x 1

13.4.1   Specifications of Phantom Kit Contents

CT Number Check Phantom

- Manufacturer

    - VATECH Co., Ltd.

- Intended Use
    - CT Number Inspection
    - CT Number Calibration

- Complies with

    - IEC 61223-2-6
    - IEC 61223-3-5
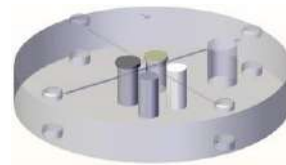
Uniformity Check Phantom

- Manufacturer

    - VATECH Co., Ltd.

- Intended Use

    - CT Image Homogeneity Inspection

    - CT Image Noise Inspection

- Complies with

    - IEC 61223-2-6
    - IEC 61223-3-5
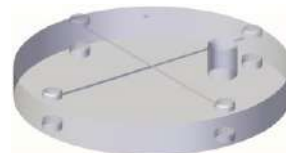
S&C Check Phantom

- Manufacturer

  - VATECH Co., Ltd.

- Intended Use

  - Low Contrast Resolution Inspection

  - High Contrast Resolution Inspection

- Complies with

  - IEC 61223-2-6

  - IEC 61223-3-5
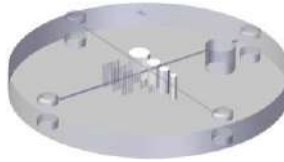
Phantom Jig Assembly

- Manufacturer

  - VATECH Co., Ltd.

- Intended Use

  - CT Image Inspection

  - CT Image Calibration
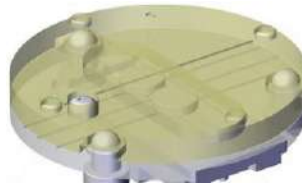
13.5 QA Test Procedure

- 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.

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

- If the test criteria are not met, contact your local VATECH service representative.

13.5.1 QA CT Number Test

Follow the CT Number Test procedure below to produce correct images and analyze the User Phantom. Test results must be documented and maintained for at least one year. The CT number for water should be recorded and compared each day to the established specifications.

13.5.1.1 Setting up CT Number Phantom

To set a CT number Phantom:

1. Remove the **bite block,** and the **temple supports** from the unit.

2. Align the **phantom fixing bolts** to the **phantom jig bottom baseline,** as shown below, and turn the bolts clockwise to tighten them.
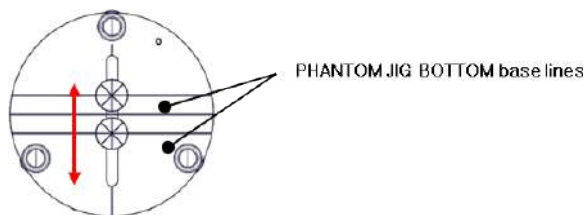
3. Insert the phantom jig bottom into the chinrest and then put the phantom jig top on the inserted bottom.
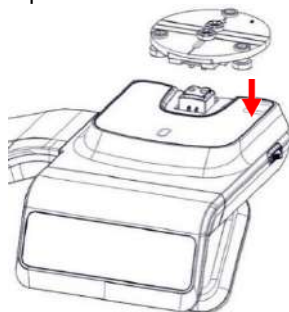
4. Place the phantom jig ass'y top on the phantom jig ass'y bottom, as shown below.
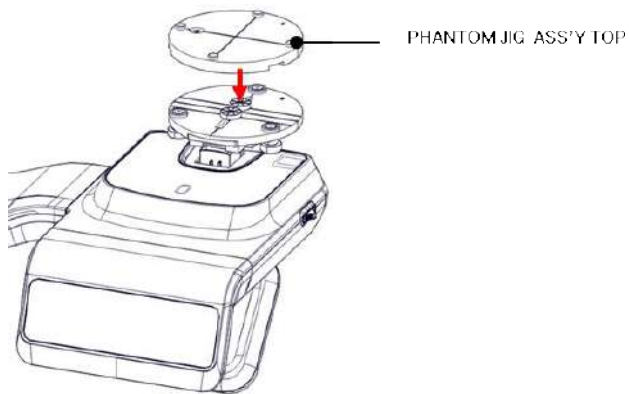
5. Make the **phantom jig ass'y** level using a bubble level, and three align pins.
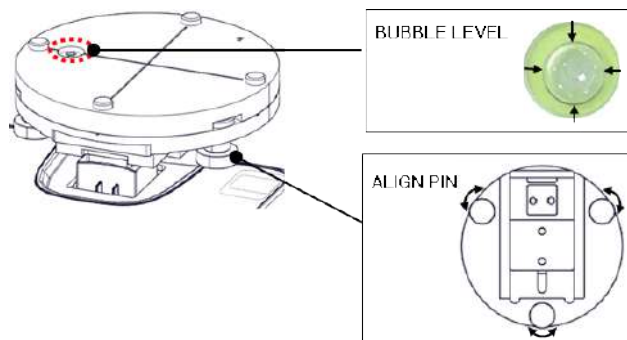
6. Place a CT number check phantom on the phantom jig ass'y.
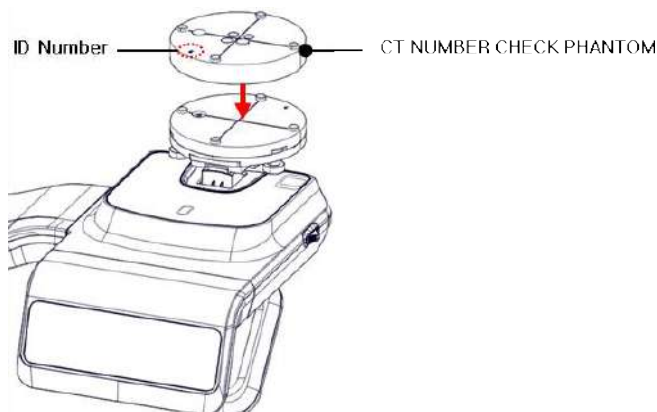
7. Run the 2D viewer and click to add a patient for the QA test.

English

13.5.1.2 Imaging CT Number Phantom

To capture an image with the CT number phantom:

1. Click [icon] to run Capture Software in EzDent-i.

2. Click [icon] to enter Phantom Capture mode.

3. Click the **CT** check box and click **Capture**.

4. Click the **NEXT** button at the bottom of the Capture Software screen.

5. Click the **Ready** button after the button is enabled.

6. Capture a PHANTOM image.

7. When the image capturing is completed, save the image in **EzDent-i**.

13.5.1.3 Analyzing CT Number Phantom

To analyze the test with the CT number phantom:

1. Double-click the saved PHANTOM image in EzDent-i to run Ez3D-I Plus.

2. Click / in the upper-right corner in the Axial pane to maximize the Axial view.

3. Click [ ] > [ ] Rectangle .
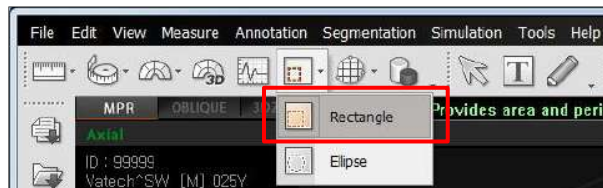
4. Make the boxes on the WATER, TEFLON, and AIR area as shown below.
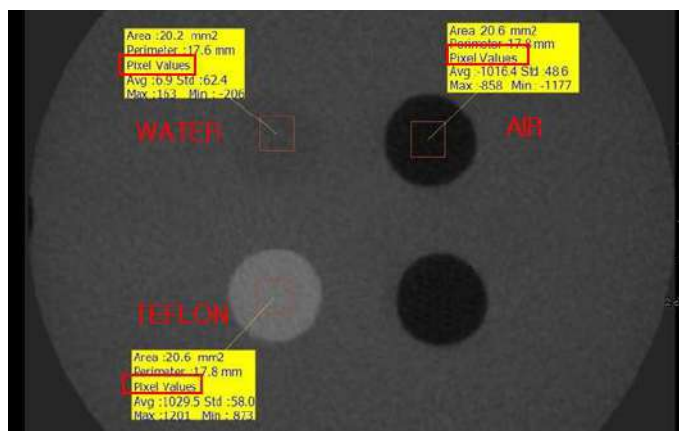
| NOTICE | Try to make each box as close to 20.0 mm^2 in the area as possible. |

English

5. Compare the CT NUMBER average values from the WATER, TEFLON, and AIR areas with the standard.

MATERIAL	MEAN	LOWER LIMIT	UPPER LIMIT	Scope
AIR	-990 HU	-1030 HU	-900 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	

6. Record the mean CT Number value of each material.

7. Click > and save the captured screen in EzDent-i.

8. Remove User Phantom from the PHANTOM JIG ASS'Y.

13.5.2 QA CT Uniformity Test

Follow the CT Uniformity Test procedure below to image and analyze the CT Uniformity Check Phantom correctly. Test results must be documented and maintained for at least one year.

13.5.2.1 Imaging CT Uniformity Check Phantom

To capture an image with CT uniformity, check Phantom:

1. Remove Bite and Temple Supports from the Unit.

2. Insert the PHANTOM JIG BOTTOM into the Chinrest and then put the PHANTOM JIG TOP on the PHANTOM JIG BOTTOM.

3. Make the PHANTOM JIG ASS'Y level using the BUBBLE LEVEL and three ALIGN PINs.

4. Put UNIFORMITY CHECK PHANTOM on the PHANTOM JIG ASS'Y.
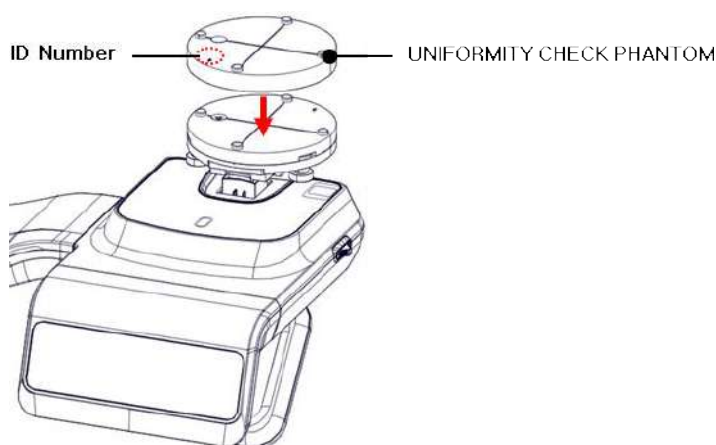
5. Click ![DENTAL CT] to run Capture Software in EzDent-i.

6. Click ![icon] to enter Phantom Capture mode.

7. Click the **CT** check box and click Capture.

8. Click the **NEXT** button at the bottom of the Capture Software screen.

9. Click the **Ready** button after the button is enabled.

10. Capture the PHANTOM image according to the capture software instructions.

11. When the image capturing is completed, save the image in **EzDent-i**.

13.5.2.2 Analyzing CT Uniformity Check Phantom

To analyze the test with the CT uniformity check phantom:

1. Double-click the saved PHANTOM image in **EzDent-i** to run **Ez3D-i**.

2. In the Axial pane, click in the upper-right corner to maximize the Axial view.

3. Click > .

4. Make 25mm lines from the center to UP/DOWN/LEFT/RIGHT directions as shown below.
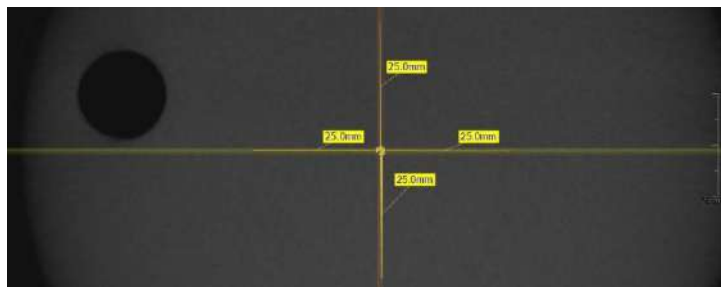
5. • Click > .
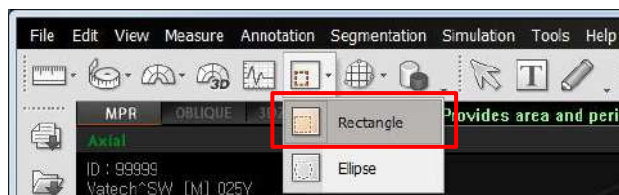
6. As shown below, make the four boxes next to each 25mm line.
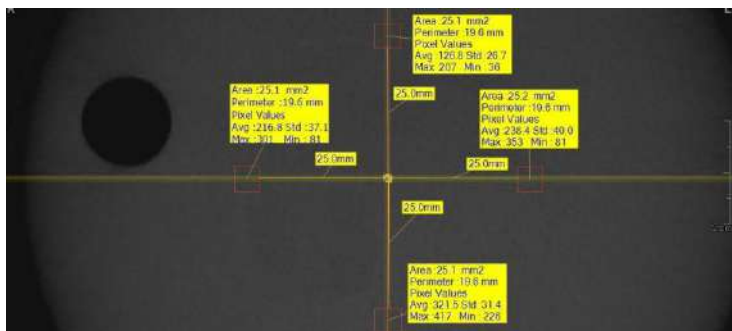
    1) Try to make each box as close to 25.0 mm2 in the area as possible.

    2) Put the 4 ROIs at the end of each 25mm line

7. Measure the HOMOGENEITY by calculating the difference between the maximum and minimum average values among the 4 ROIs and compare it with its standard.

Calculation	Standard	Scope
Subtract the minimum average value from the Maximum average value among the 4 ROIs	The difference should be less than 400 HU	61223.3.5 INTRODUCTION

8. Record the mean CT Number value of each material.

9. Click [camera icon] > [Full screen...] and save the captured screen in **EzDent-i**.

10. When finished, exit **EzDent-i**

13.5.3 High and Low Contrast Resolution Tests

Perform a high/low contrast resolution test at the following interval:

- **High contrast resolution test**: Initially and Yearly
- **Low contrast resolution test**: Initially and Yearly

13.5.3.1 Imaging S&C Check Phantom

To perform a high and low contrast resolution with S&C check phantom:

1. Remove the bite and the temple support from the unit.

2. Insert the PHANTOM JIG BOTOTM into the chinrest

3. Place the PHANTOM JIG TOP over the phantom jig bottom.

4. Make the PHANTOM JIG ASS'Y level using the BUBBLE LEVEL and three ALIGN PINs.

5. Put S&C CHECK PHANTOM on the PHANTOM JIG ASS'Y.
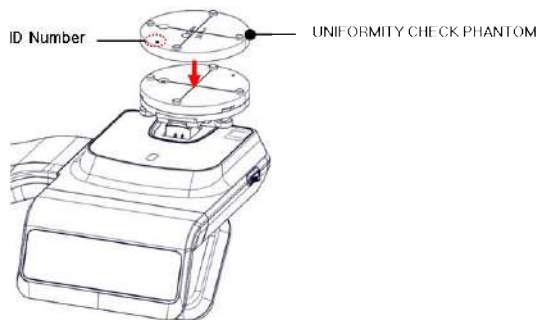
6. Click to start Capture Software in 2D viewer.

7. Click to enter Phantom Capture mode.

8. Click the CT check box and click Capture.

9. Click 'NEXT' at the bottom of the Capture Software screen.

10. Click 'READY' after the bottom is enabled.

11. Follow the capture software's instructions to capture the phantom image.

12. Save the captured image on EzDent-i after taking the image.

13.5.3.2 Analyzing S&C Check Phantom

To analyze the test with an S&C check phantom:

1. Remove the bite and temple support from the unit.

2. Double-click the saved phantom image in EzDent-i to run Ez3D-i.

3. Go to the Axial view and click ⬚ for full-screen mode.

4. Click ⚙ and ⬚ All to adjust the brightness and contrast in the saved image. Drag the icon left and right to change the contrast or up and down to adjust the brightness.

5. Make sure you can see the minimum size of the Airhole and the PE (Polyethylene) cylinder at 50 cm (20 inches) from the monitor.
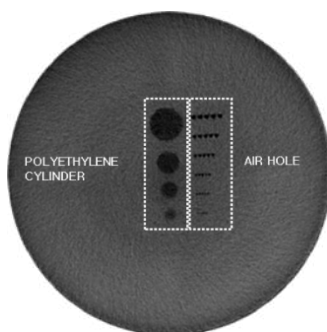
Parameters	Material	Minimum visible size
High Contrast Resolution	Air Hole	1.0mm
Low Contrast Resolution	PE cylinder	8.0mm

<High Contrast Resolution>

<Low Contrast Resolution>

English
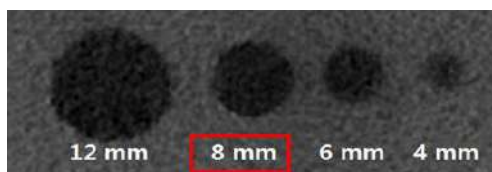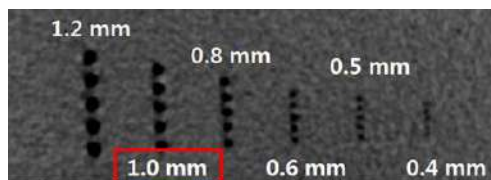
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14.   Disposing of the Equipment

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 **VATECH**			
Other parts			●	

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

English

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15. Technical Specifications

15.1 Mechanical Specifications

15.1.1 Dimensions

*unit = mm(")

	With CEPH	Without CEPH
Top view (With Base)		
Front View (With Base)		

	With CEPH	**Without CEPH**
Top view (Without Base)		
Front View (Without Base)		

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)

15.1.2 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

15.2   Technical Specifications

15.2.1   X-ray Generator Specifications

<u>Specifications</u>

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)
	Normal/ Pulse — 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)

English

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

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

Constant potential high-voltage generator
Nominal Focus Spot Value: 0.5
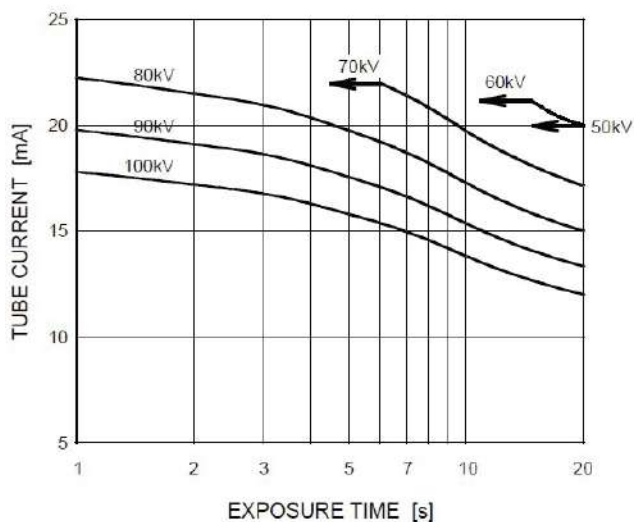
▌▌ Emission & Filament Characteristics

Constant potential high-voltage generator
Nominal Focus Spot Value: 0.5
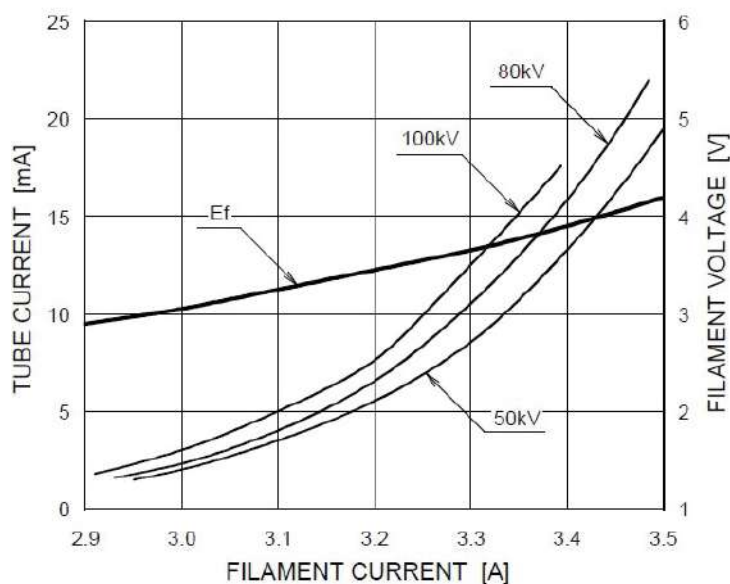
▌▌ Anode Thermal Characteristics
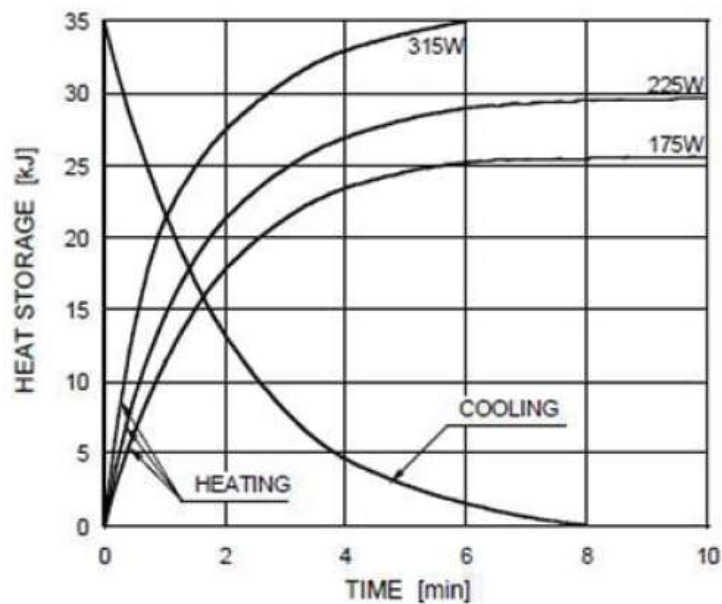
▌▌ X-ray Housing Assembly Tube Characteristics
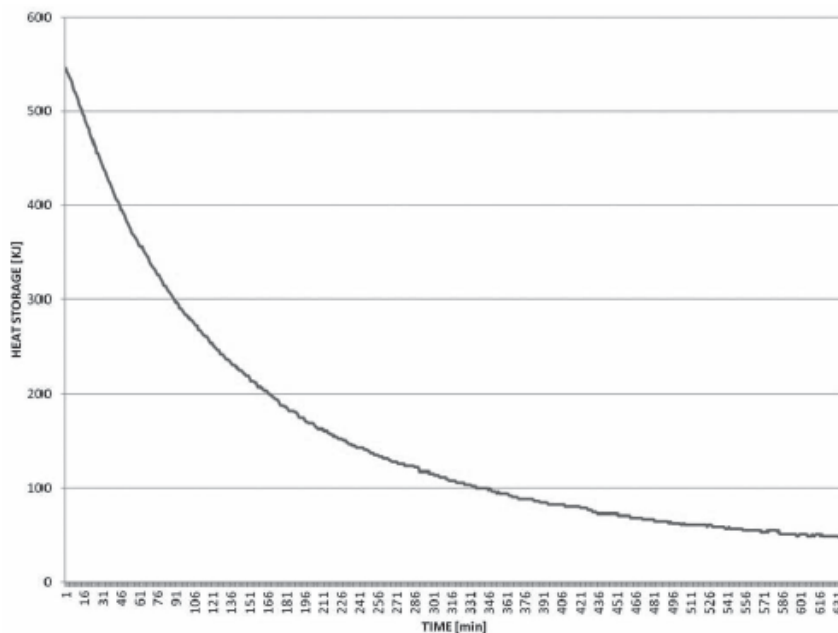
15.2.2　Detector Specifications

Item	Description	
	PANO & CBCT	**CEPH**
Model	Xmaru1314CF	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 μm @ 4x4 binning 99 μm @ 2x2 binning (49.5 μm @ no binning)	200 μm @ 2x2 binning
Active area	PANO: 135.8 x 5.9 (mm) CBCT: 135.8 x127.5 (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 ℃ (Temperature) 10~75 % (Humidity)	
Storage condition	-10~60 ℃ (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	≥ 2 %@ 2.5 lp/mm
Dynamic Range	> 80 dB	≥ 68 dB

15.3   Electrical Specifications

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

- The input line voltage depends on the local electrical distribution system.

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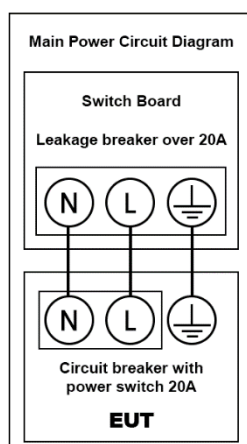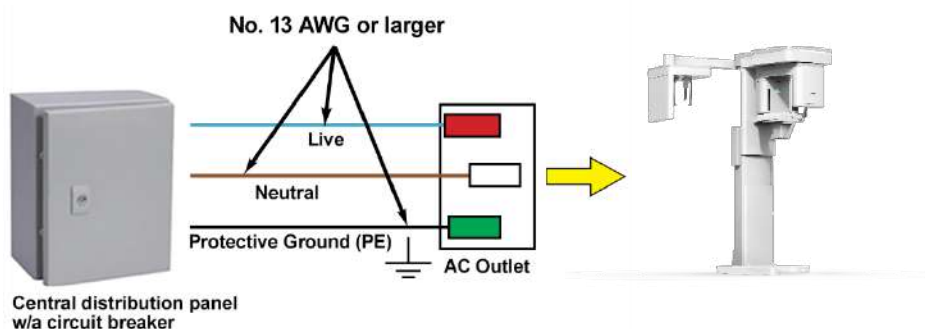
NOTICE	
	▪ A separate 3-core grounded power cable connected directly to the central distribution panel with an over-current circuit breaker rated for 20A must be used to assure line voltage quality.
	▪ Maximally allowed deviation of the tube voltage/tube current/exposure time:
	Tube Voltage (kVp) ± 10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

15.4   Environmental Specifications

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

English

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16. Appendices

16.1   Recommended X-ray Exposure Tables

16.1.1   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
PANO Examination (Insight PAN; Optional)	High Resolution	Man	Normal	70	6.0
		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

Mode	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
		Woman	Hard	74	10.0
			Normal	73	10.0
			Soft	72	10.0
		Child	Hard	70	10.0
			Normal	69	10.0
			Soft	68	10.0

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

Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
		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
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.

- **Scan Time**: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.
- **Exposure Time**: The actual time that the patient is exposed to the X-ray emission.

English

16.1.2   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

- Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.
- Exposure Time: The time the patient is exposed to the X-ray emission.

16.1.3 CBCT Mode

<u>Exposure Area</u>

FOV (cm)	Vertical Position	Horizontal Position		
		Right	**Center**	**Left**
16x9	Occlusion	X	O	X
12x9	Occlusion	X	O	X
	TMJ	O	X	O
	Airway	X	O	X
8x8	Occlusion	O	O	O
	TMJ	O	X	O
8x5	Maxilla/Mandible	O	O	O
5x5	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)		
Endo	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)		
Double scan (Optional)	First Exposure: Mandible Second Exposure: Maxilla	X		

English

Exposure Condition

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
16x9 & 12x9 & Double scan (Optional)	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

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
			Soft	93	12.7
		Child	Hard	95	12.4
			Normal	94	12.4
			Soft	93	12.4
	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
		Man	Hard	88	9.3
			Normal	87	9.3

English

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
5x5	Green		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	High Resolution	Man	Hard	98	12.0
			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 (Optional)	18.0	18.0
16x9	9.0	9.0
12x9	9.0	9.0
8x8	2.9	2.9
8x5	2.9	2.9
5x5	2.9	2.9
Endo	18.0	18.0

- Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.
- Exposure Time: The time the patient is exposed to the X-ray emission.

Reconstruction Time/File Size (Measured Object: Skull)

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)		File Size (MB)
		Fast	HD	
Double scan (Optional)	0.3	29	-	282
16x9	0.2	35	149	550
	0.3	15	80	163
12x9	0.2	22	96	309
	0.3	9	61	92
8x8	0.12	36	120	635
	0.2	8	36	138
8x5	0.12	21	72	359
	0.2	4	24	77
5x5	0.08	26	89	466
	0.12	7	32	138
Endo	0.05	61	-	976

- The above data is obtained from a computer system based on Intel E5-1607 v3@3.10GHz (16GB of RAM) and NVIDIA GeForce GTX1060 6GB.
- Image reconstruction time varies depending on computer specifications and working conditions.
- When compression is applied, the image file size is reduced to 40% of its original size. Compression is available in all modes.

16.1.4 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	9.0	9.0

- Scan Time: The actual time that the equipment shoots the plaster cast except for the initial acceleration and late deceleration stages.
- Exposure Time: The time the plaster cast is exposed to the X-ray emission.

Reconstruction Time/File Size

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)	File Size (MB)
8x8	0.12	269	635

- The above data is obtained from a computer system based on Intel i7-6700 and NVIDIA GeForce GTX1060 6GB.
- Image reconstruction time varies depending on computer specifications and working conditions.

16.2 X-ray Dose Data

16.2.1 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)	**Green X (Model: PHT-75CHS)**
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 ($mGy·cm^2$). 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

DAP[mGy · cm²]=Dose[mGy] x Exposed Area[cm²]

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
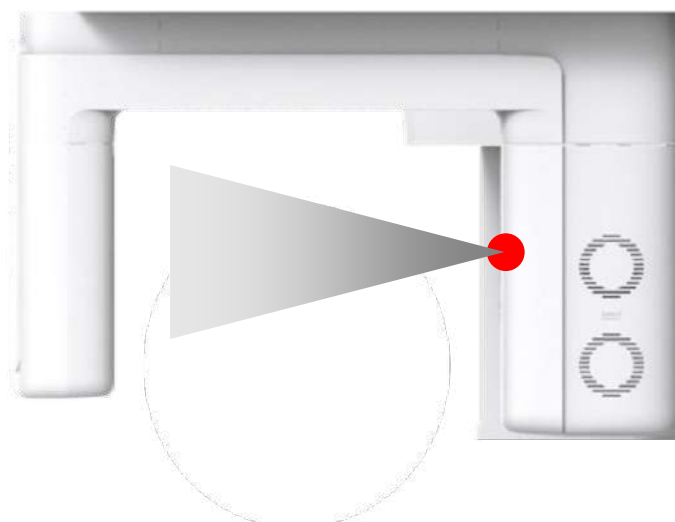
Results

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 / 8.0mA / 11.5 s	54.64
		Green	Man	84 kVp / 14.0 mA / 3.9 s	58.17
			Child	67 kVp / 11 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 mA / 3.9 s	35.27
			Child	86 kVp / 15 mA / 3.9 s	32.55
		Green	Man	90 kVp / 16 mA / 1.9 s	21.36
			Child	86 kVp / 16 mA / 1.9 s	19.75

CBCT	Double Scan	High Resolution	Man	94 kVp / 7.0 mA / 9.0 s	2771.92
			Child	94 kVp / 6.4 mA / 9.0 s	2545.61
		Green	Man	87 kVp / 6.1 mA /9.0 s	2009.77
			Child	87 kVp / 5.5 mA / 9.0 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 / 8.0mA / 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.

16.2.2 Leakage Dose

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.

16.2.2.1 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

16.2.2.2 Measurement Overview

16.2.2.3 PANO Mode Results

Test Condition	
Test Mode	- PANO - Adult(Man) - Pano option: Normal - Image option: High Resolution - Pano examination: Standard - Arch selection: Normal
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

Mode Direction [°]	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

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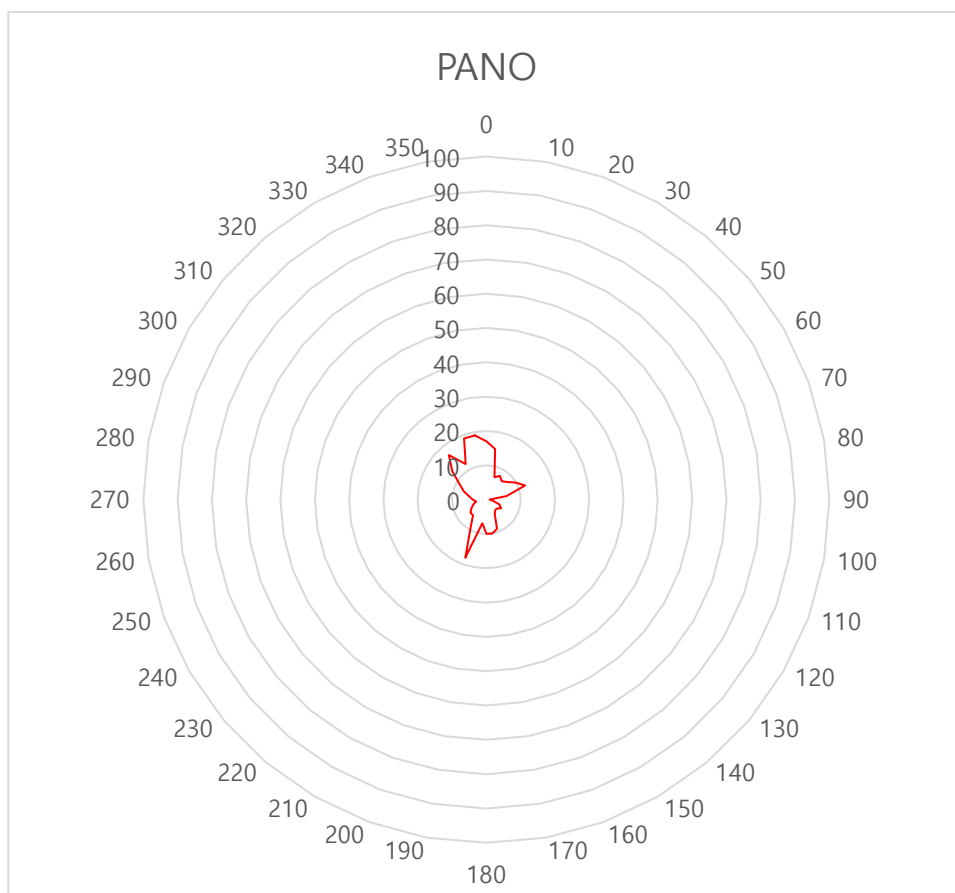
PANO (Normal, High Resolution) Leakage Dose Test Graph

English

16.2.2.4 PANO Mode Results (Insight PAN)

Test Condition	
Test Mode	- PANO - Adult(Man) - Pano option: Insight PAN - Image option: N/A - Pano examination: N/A - Arch selection: Normal
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	11

Mode Direction [°]	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

Mode Direction [°]	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
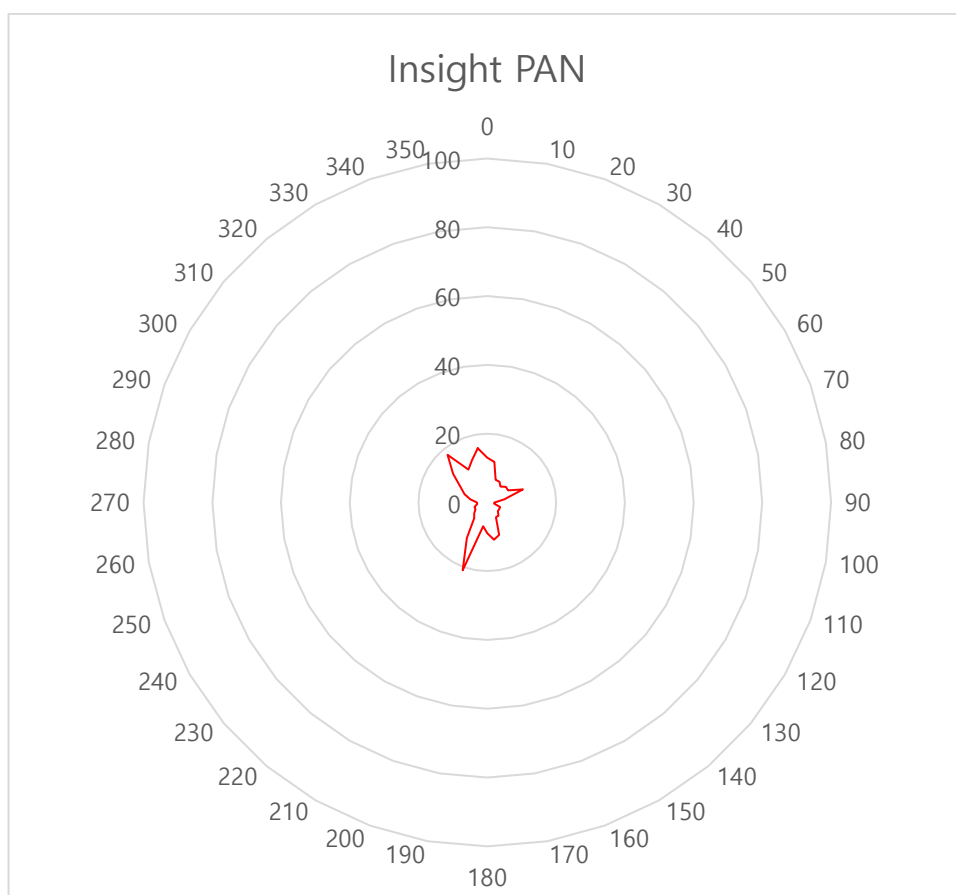
PANO (Insight PAN, High Resolution) Leakage Dose Test Graph

16.2.2.5 CEPH Mode Results

Test Condition	
Test Mode	- CEPH - Adult (Man) - Image option: Green - CEPH Examination: Lateral
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	99
Tube Current [mA]	16
Exposure Time [s]	1.9

Mode Direction [°]	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

Mode	CEPH	
Direction [°]	[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
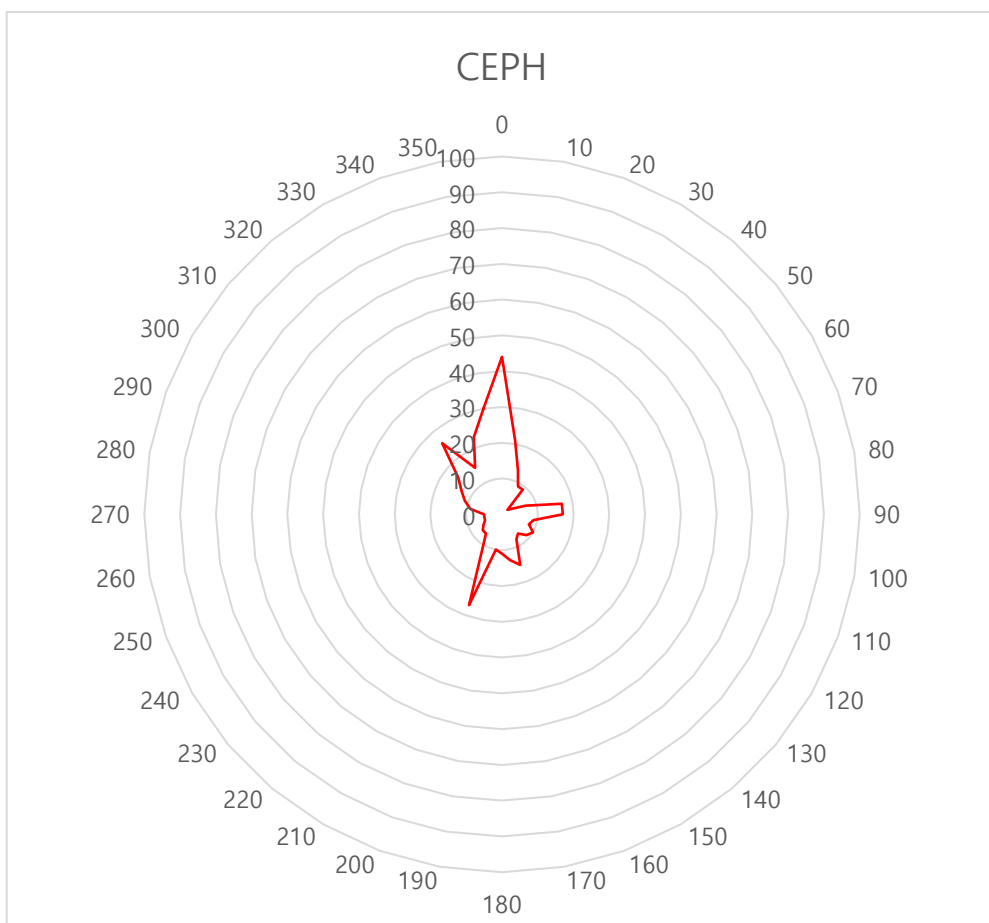
CEPH (Lateral, Green) Leakage Dose Test Graph

CBCT Mode Results

Test Condition	
Test Mode	**Test Mode 1** - CBCT - Adult (Man) - FOV: 16x9, - Vertical option: Occlusion - Horizontal option: Center - Image option: High resolution - Voxel Size: Standard (0.20) **Test Mode 2** - CBCT - Adult (Man) - FOV: Endo (Tooth no.:11) - Vertical option: N/A - Horizontal option: N/A - Image option: High resolution - Voxel Size: Standard (0.05)
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

Mode / Direction [°]	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
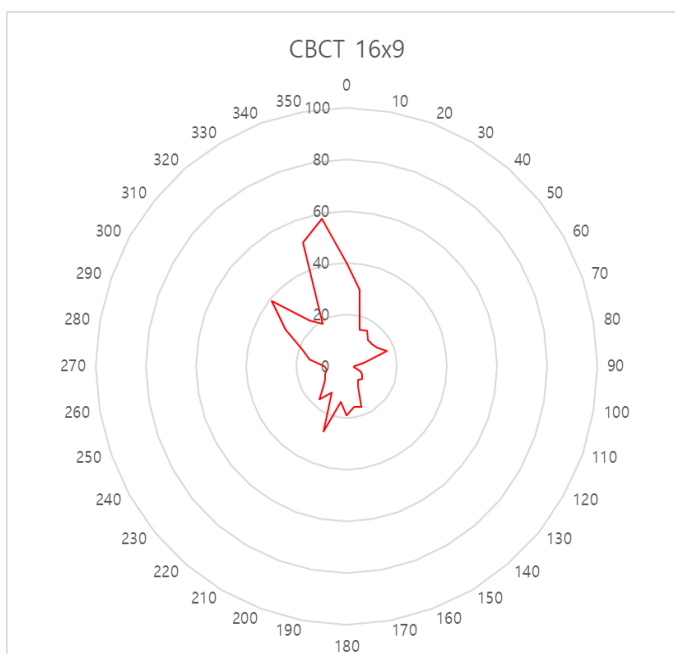
CBCT (16x9, High Resolution) Leakage Dose Test Graph
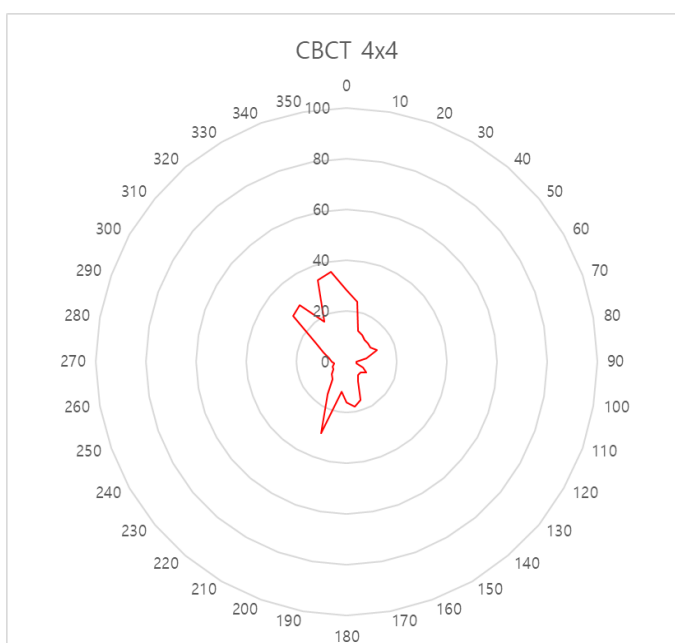
CBCT (Endo, High Resolution) Leakage Dose Test Graph

16.2.3 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.

16.2.3.1 Measurement Overview

16.2.3.2   CBCT Mode Results

Test Condition	
Test Mode	- CBCT - Adult(Man) - FOV: 16x9, - Vertical option: Occlusion - Horizontal option: Center - Image option: High resolution - Voxel Size: Standard (0.20)
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
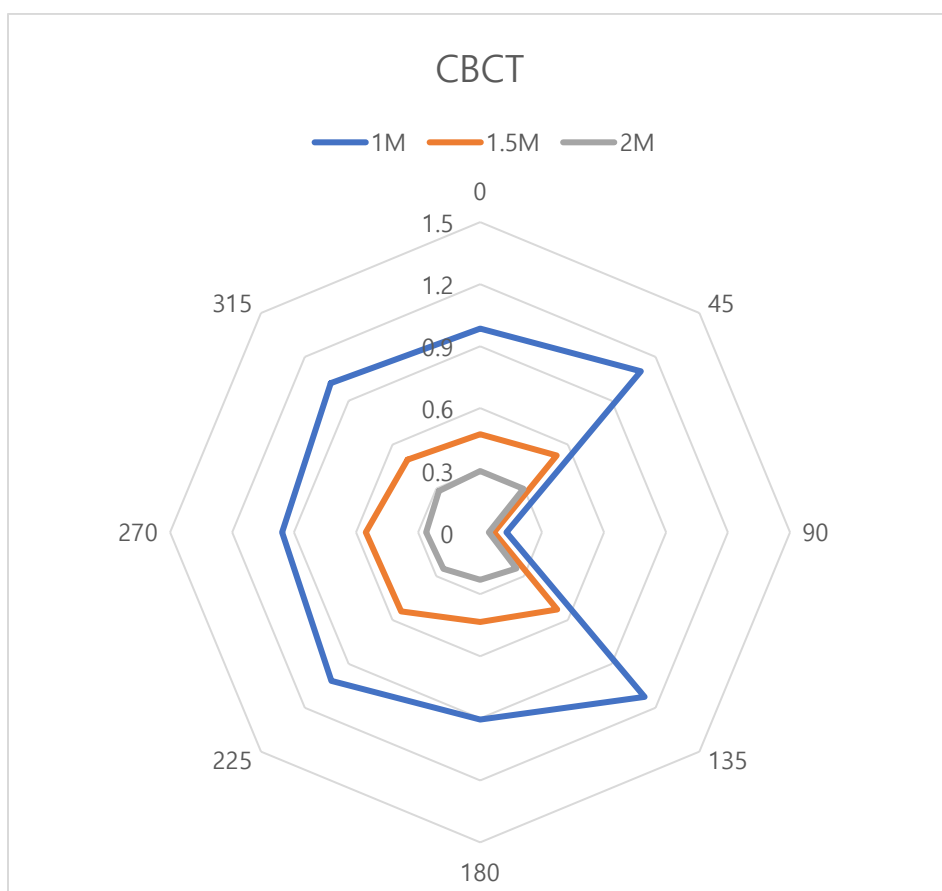
CBCT (16x9, High Resolution) Scattered Dose Test Graph

16.2.3.3 CBCT Endo Mode Results

Test Condition	
Test Mode	- CBCT - Adult (Man) - FOV: Endo (Tooth no.:11) - Vertical option: N/A - Horizontal option: N/A - Image option: High resolution - Voxel size: Standard (0.05)
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
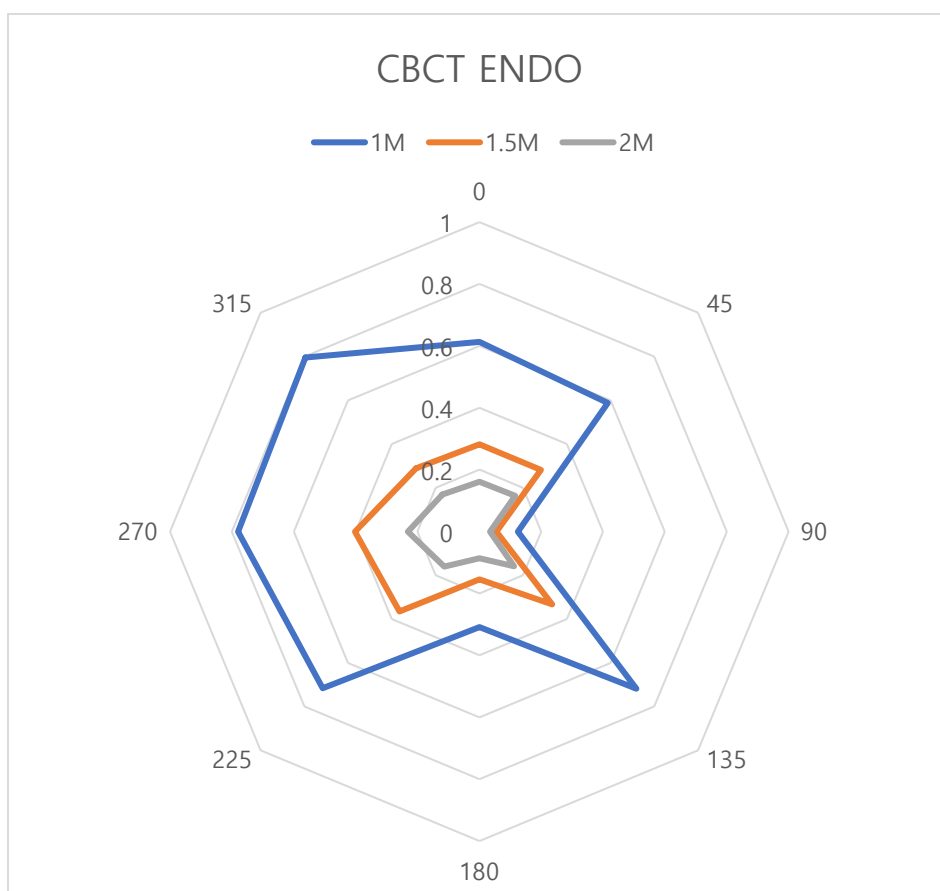
CBCT (Endo, High Resolution) Scattered Dose Test Graph

16.2.3.4 PANO Mode Results

Test Condition	
Test Mode	- PANO - Adult (Man) - Pano option: Normal - Image option: High Resolution - Pano examination: Standard - Arch selection: Normal
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
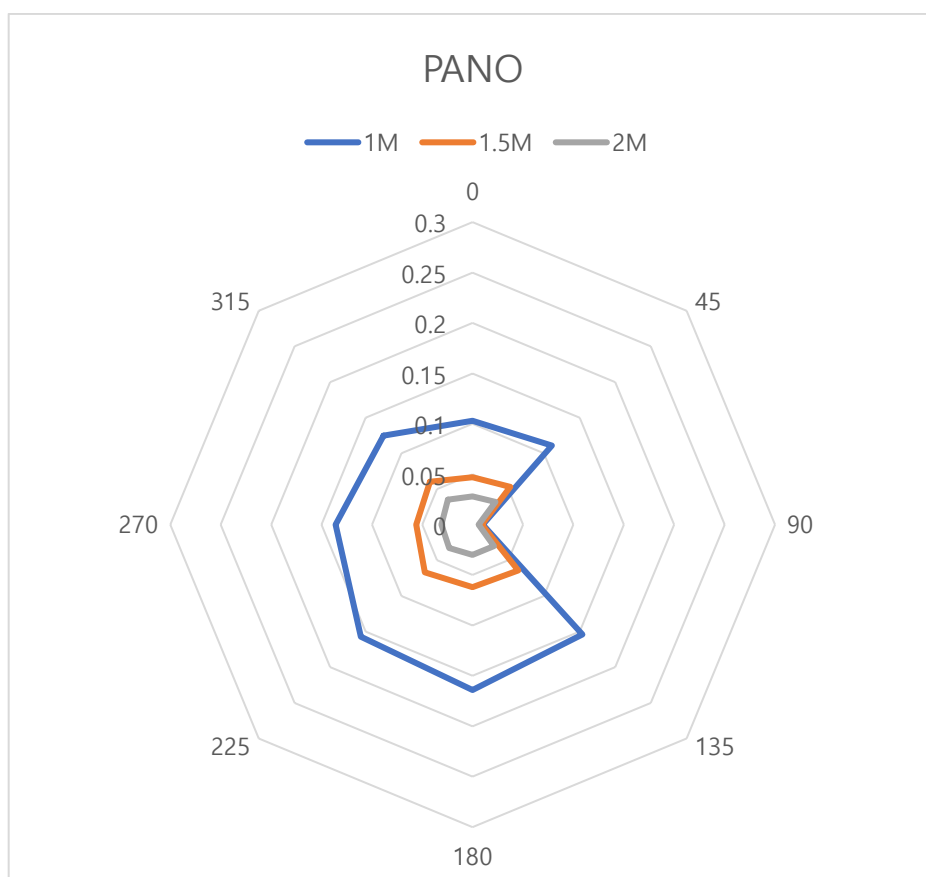
PANO (Normal, High Resolution) Scattered Dose Test Graph

16.2.3.5 PANO Mode (Insight PAN) Results

Test Condition	
Test Mode	- PANO - Adult (Man) - Pano option: Insight PAN - Image option: N/A - Pano examination: N/A - Arch selection: Normal
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
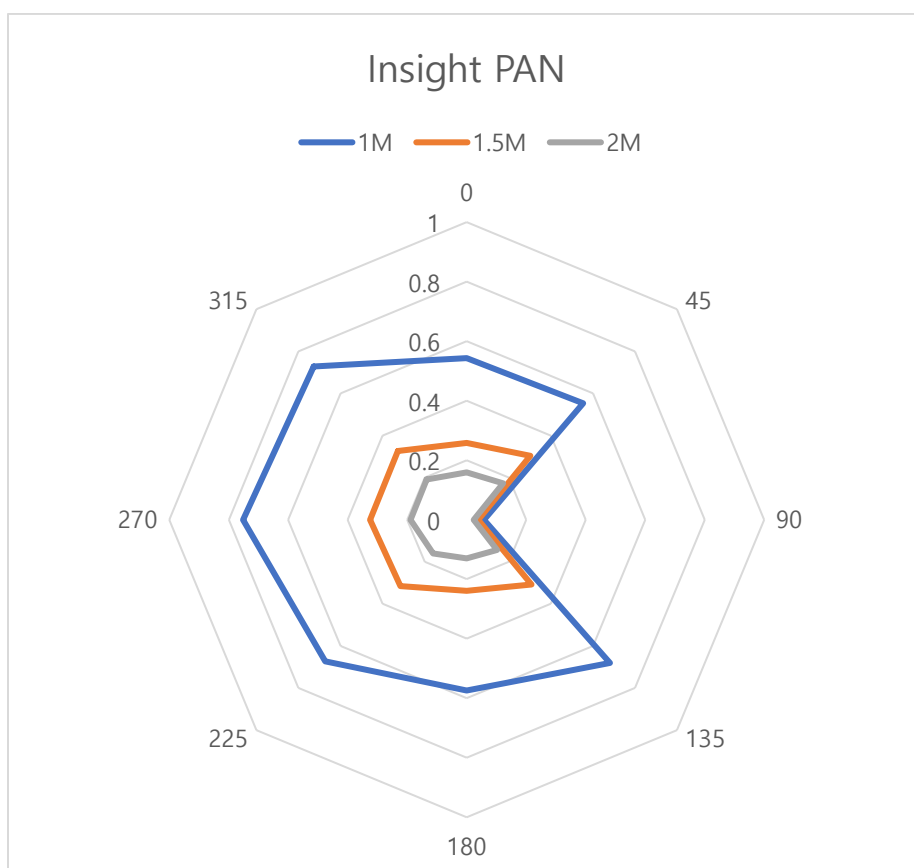
PANO (Insight PAN, High Resolution) Scattered Dose Test Graph

16.2.3.6 CEPH Mode Results

Test Condition	
Test Mode	- CEPH - Adult (Man) - Image option: High resolution - CEPH Examination: Full Lateral
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.
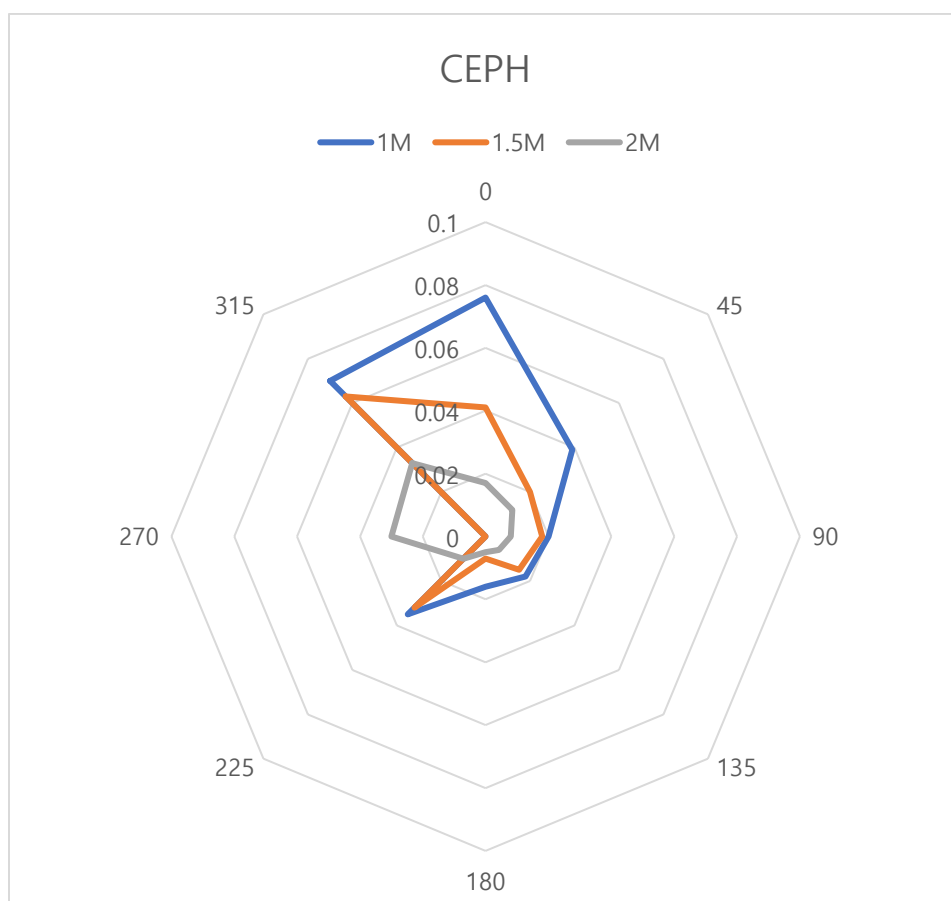
CEPH (Full Lateral, High Resolution) Scattered Dose Test Graph

16.3   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 Communications Equipment	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	Table 9 in IEC 60601-1-2: 2014
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012,	IDLE mode CT mode PANO	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz	AC Line: ± 2 kV Signal: ±1 kV

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
	IEC 61000-4-4:2012	mode CEPH mode		AC 220 V, 60 Hz AC 230 V, 50 Hz	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 ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 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 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
			Exposure switch cable		
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 0º
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

16.4   Acquiring Images for Pediatric Dental Patients

16.4.1   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	

16.4.2   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.[1-3] While the panoramic technique seems relatively straightforward, producing a diagnostic-quality image of the pediatric patient requires a mastery of technical skills.[4] Modern panoramic x-ray equipment is designed for ease of use, yet studies continue to demonstrate a high incidence of errors.[5-7] Positioning errors may occur at an even higher rate in pediatric panoramic radiographs.[7] 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.[8,9] 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.[4,10] 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 Hyoid 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.

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.[11] 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.[9]

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.[11]

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.
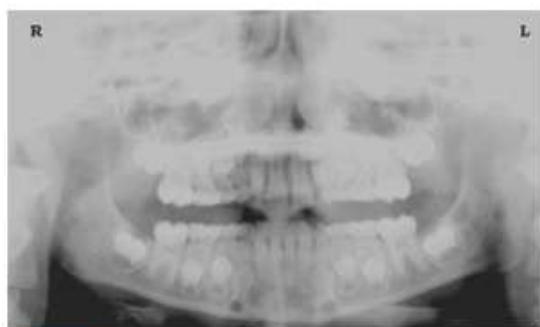

Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.
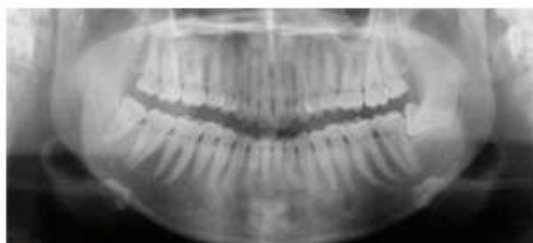
Figure 6: Chin positioned too far down. Note the characte-istic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

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.[7] 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.[7]

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.[6] 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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16.4.3 Setting Exposure Values to the Age Group

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

16.4.4 The References Pertinent to the Potential Risks for the Pediatric Patients

1) Literature

- ▪ I. ESPELID, I. MEJÀRE, 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/

16.5   Abbreviations

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

English

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

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CE 2460	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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