vatech A9

User manual

Model : PHT-30CSS
Version : 1.05

• English

Full version

vatech

Notice

Thank you for purchasing the **vatech A9 (PHT-30CSS)** extra-oral imaging system.

vatech A9 (PHT-30CSS) is one of the manufacturer's product series for aiding dental professionals in providing excellent care in a safe environment that promotes healing.

vatech A9 (PHT-30CSS) is an advanced digital diagnostic system that incorporates PANO, CEPH (Optional), CBCT imaging capabilities into a single system.

This manual describes how to operate the **vatech A9 (PHT-30CSS)** system. It is recommended that you thoroughly familiarize yourself with this manual to make the most effective use of this equipment.

Observe all cautions, safety messages, and warnings 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.com

This document is originally written in English.

vatech A9 (PHT-30CSS) is referred to as "equipment" in this manual.

Manual Name: vatech A9 (PHT-30CSS) User Manual

Version: 1.05

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1. Introduction

1.1 Overview

vatech A9 (PHT-30CSS) is an advanced 3-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), and CBCT scan imaging capabilities into a single system.

vatech A9 (PHT-30CSS), a digital radiography imaging system, exposure an X-ray to a sitting patient and acquires and processes diagnostic images for dentists.

Designed explicitly for dental radiography, **vatech A9 (PHT-30CSS)** 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.

1.2 Indications for Use

vatech A9 (PHT-30CSS) is intended to produce panoramic, cone beam computed tomography, or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The equipment is to be operated by healthcare professionals.

1.3 Intended Purposes

- Determination of the extent of lesions, tumors, cysts, etc., which cannot be fully visualized on plain films.
- Identifying the relationship of the inferior dental canal to a tooth / lesion that is to be removed.
- Visualization of 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.
- Assessment of complex root canal anatomy.
- Diagnosis of periapical pathology.
- Diagnosis of vertical root fracture.
- Assessment of fractures on maxilla, mandible and fractures of teeth where plain film imaging is equivocal.
- Reconstruction of position, malformations and fractures of maxilla & mandible bones and nasal bone as 3D pictures for operational planning and patient education.

1.4 Intended User Profiles

Considerations	Requirement Description
Education	▪ Licensed dentists or dental hygienists, radiologists, and graduates of relevant bachelor's degree (national qualifications)
Knowledge	▪ Understanding the treatment and diagnosis of dental disease ▪ Understanding the terms and guidance of hardware and software of a diagnostic medical radiation equipment and recognizing equipment connection, installation, operating conditions
Language understanding	▪ Understanding how to use manuals (English/Korean) or ▪ Understanding other language provided
Experience	▪ Understanding the objectives and effects of the diagnosis and treatment of dental disease using diagnostic medical radiation equipment ▪ Understanding of the normal operation of diagnostic medical radiation equipment ▪ Understanding the contents of the **User Manual**

IMPORTANT	Qualified personnel should use X-ray CBCT (dentists, dental hygienists, or radiologists only).

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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 by all the cautions and conditions required for installation.
- The good **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(Disinfection) work is performed by the maintenance schedule outlined in **11. Cleaning and Disinfection** and **12. Maintenance**.

2.3 Conventions in this Manual

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

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

	**WARNING**	Indicates information that should be followed with the utmost care. Failure to comply with a warning may result in severe damage to the equipment or physical injury to the operator and patient.
	**CAUTION**	Indicates a situation that demands prompt and careful action, a specific remedy, or emergency attention.
	**IMPORTANT**	Indicates a situation or action that could potentially cause problems to the equipment and its operation.
	**NOTICE**	Emphasizes essential information or provides useful tips and hints.
	**RADIATION**	Indicates a possible danger from exposure to radiation.
	**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.

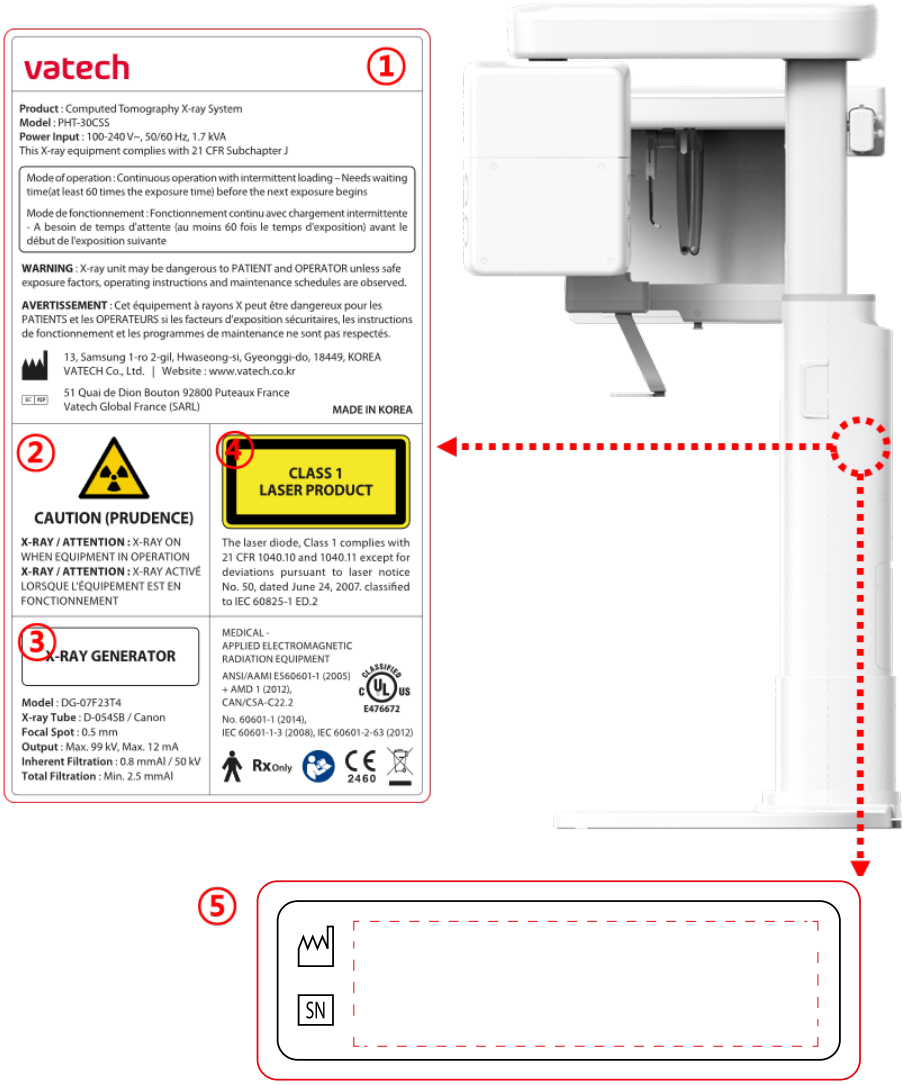
2.4 Marks and Symbols

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
	Indicates the authorized representative in the European Community.	Label
	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Label
	UL mark No. E476672	Label
	Caution: Federal law restricts this equipment to sale by or on the order of a licensed healthcare practitioner.	Label
	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

Symbols	Description	Location
	Warns ESD hazard.	MCU board /Board package
	Indicates that this equipment is classified as a CLASS 1 LASER PRODUCT by IEC 60825-1 ED. 2 regulations.	Label
	Indicates that the user needs to refer to the **User Manual**.	Label
	Indicates the date of manufacture.	Label
	Indicates the manufacturer's serial number so that the specific equipment can be identified.	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 on when equipment in operation.
3	**X-RAY GENERATOR Label** : 1.0 kW Generator
4	**CLASS 1 LASER PRODUCT Label**
5	**Manufacturer Label** : The date of manufacture / Serial Number of the equipment

3. Warnings and Precautions

WARNING	Be sure to observe all warnings and safety instructions included in this manual.
WARNING	This x-ray unit may be dangerous to patients and operators unless safe exposure factors, operating instructions, and maintenance schedules are observed.

3.1 General Safety Guidelines

Operator qualifications

This equipment may only be operated by personnel trained in its operation.

- To operate this equipment, the operator must:
  - Read and understood the **User Manual**.
  - Be familiar with the fundamental structure and functions of this equipment.
  - Be able to recognize the intermittent operation of this equipment and implement appropriate measures to remedy such irregularities.

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 conduct inspection and maintenance of 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.
- Do not push or pull the equipment. Overbalances of the equipment may cause the risk of physical injuries or property damage.
- 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 that this equipment is kept away from water, moisture, or foreign substances always.
- If this product is exposed to water, moisture, or a foreign substance, immediately turn off the main power of the equipment and contact your **VATECH** technical support representative.
- If there are signs of oil leakage, immediately cease all operations of this equipment and contact your **VATECH** technical support representative.
- External equipment intended for connection to signal input, signal output, or other connectors, shall comply with relevant IEC Standard (e.g., IEC 60950 for IT equipment and IEC 60601-1 series for medical electrical equipment).
- Also, all such combination-system-shall comply with the standard IEC 60601-1, and IEC 60601-1-1 harmonized national standard or the combination. If, in doubt, contact a qualified technician or your local representative.
- 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.

Ventilation

- Do not close the equipment's ventilation slots in any case. The obstruction of ventilation could result in the equipment overheating due to a lack of air circulation.
- Do not spray any liquid or disinfectant on this equipment. The penetration of these substances may damage the electrical and mechanical components inside. Use a soft cloth to disinfect the ventilation slots.
- Always leave enough space around the PC to allow for proper ventilation.

Hygiene

⚠CAUTION	Always disconnect the equipment from the power outlet when disinfecting the surfaces of the equipment. Never expose this equipment to liquids, mists, or sprays. Exposing this equipment to liquids may cause an electric shock or otherwise damage the system. Do not use spray cleaners on the equipment, as this could cause a fire.

- All movable patient support components (the Bite, the Chinrest, and the Ear Rods) can be cleaned using non-alcohol based, non-corrosive cleaning solution
- Clean the Support Handles by using non-alcohol based, non-corrosive cleaning solution before taking photos of the next patient.
- Other surfaces of the equipment, including the Control Panel, can be cleaned using a soft cloth dampened with a mild cleaning solution.

- New hygiene cover must be provided for each new patient to prevent the transmission of communicable diseases.

⚠CAUTION	Do not use aerosol or spray cleaning agents directly on the surface of the equipment.

Condensation

- Extreme fluctuation in temperature may cause condensation to develop inside the equipment. Do not turn on the equipment until it has reached room temperature.

Cooling

- Allow the proper amount of cooling downtime (for the X-ray tube to cool down) before the acquisition of the next image.
  - Mode of operation: Continuous operation with intermittent loading - 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)
- If the temperature inside the tube head reaches 60 °C (140 °F), X-ray exposure will cease, and an error message will be displayed. Normal X-ray capabilities will resume after the generator reaches 58 °C (136.4 °F).
- The fan automatically operates when the temperature surrounding the tube head reaches the pre-defined level: 35 °C (95 °F). The setpoint temperature is configurable.

Turning the equipment on/Adjusting the height of the equipment

- Do not position the patient near the equipment while it is initiating as the patient could be injured if the equipment malfunctions.
- Ensure that the patient is kept clear of the equipment while adjusting its height.

Emergency stop

- If a problem occurs during image acquisition, press the red **Emergency Stop Switch** to immediately stop all moving parts and cut off all power to the equipment. (**Emergency Stop Switch** is located under the bottom of the Handle Frame. Turn the switch in the direction of the arrow to reboot the equipment.)

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 the 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 it has been 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 which may affect the safety of the operator, patients, or other persons is prohibited by law.
- 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 **Main Power Switch** is set to off when the equipment is not in use.
- 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.
- Use the same power circuit for the PC and the equipment.

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 systems, radio link systems, 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, the use of mobile wireless phones in medical offices or hospital environments must be prohibited.
- For more details, refer to **15.3 Electromagnetic Compatibility (EMC) Information**.
- Please also observe the Electro-Static Discharge (ESD) protective measures described.

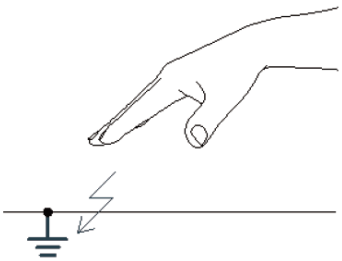
Static Discharge

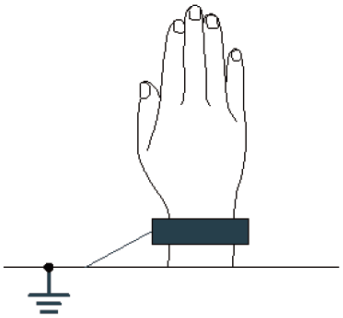
- Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without observing ESD protective measures.


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

WARNING	Since rules and regulations concerning radiation safety differ between countries, it is the responsibility of the owner and operator of this equipment to comply with all applicable rules and regulations concerning radiation safety and protection in his/her area.

- This equipment must be housed inside an X-ray shielded room.
- The operator must remain outside a shielded room during X-ray exposure to protect himself/herself from radiation.
- During imaging, the operator must maintain vocal/visual contact with the patient from outside the shielded area.
- The operator should continuously check the status of the patient and the equipment during imaging.
- The operator should be at least 2 m (6 feet) away from the equipment during imaging.
- The operator must immediately stop imaging if the equipment malfunctions.
- The patient must wear a lead apron with neck and thyroid protection during X-ray exposure.
- Children and pregnant women must consult with a doctor before X-ray exposure.

WARNING	As a manufacturer of radiology equipment that conforms to stringent protection standards around the world, we guarantee the maximum degree of protection against radiation hazards for our equipment.

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. ▪ It is essential to read this **User Manual** carefully and abide by all warnings and cautions stated within it.
⚠WARNING	▪ The 3D image should not be used for screening examinations. Each exam must be justified by demonstrating that the benefits outweigh the risk. ▪ Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, conventional medical CT or MR should be used instead of dental cone beam imaging.
⚠WARNING	▪ **vatech A9 (PHT-30CSS)** system, like other medical equipment, uses high-frequency electrical signals that can interfere with implantable green devices such as pacemakers and Implantable Cardioverter Defibrillators (ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately power off the Dental X-ray system. ▪ **vatech A9 (PHT-30CSS)** system is designed to withstand the effects of defibrillation. However, when possible, disconnect the Dental X-ray system during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.
⚠CAUTION	Federal law restricts this equipment to sale by or on the order of a dentist or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices using or order the use of the equipment.

Lasers

- The system incorporates Class 1 laser products. The light localizers used in this product are intended for correct patient positioning and must not be used for any other purpose.
- For maximum safety, advise the patient not to look directly at the laser beam.
- 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 and do not make any changes to the settings or processes that are described in these operating instructions.

Cleaning

- Never expose this equipment to liquids, mists, or sprays. Exposing this equipment to liquids may cause an electric shock or otherwise damage 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 the operator is touching the SIP/SOP connectors.
- The medical electrical equipment or medical electrical system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the medical electrical equipment or medical 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 of EQUIPMENT or SYSTEM.

In case of an electrical fire

- Use only fire extinguishers designed for electrical fires to extinguish fires on this equipment.

  Liquid extinguishers, such as those which use water, could damage the equipment and cause physical injury.

- Unplug the equipment's power cable before extinguishing any fire.

Installation

- To avoid improperly balanced equipment, install the equipment 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.
- Equipment should only be installed by an authorized technician, complying with proper installation procedures.

NOTICE	For further details on installation, refer to the **vatech A9 (PHT-30CSS) 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 and 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 update through a third party, not the manufacturer, is prohibited. For cybersecurity issues related to the software and medical devices, please contact the manufacturer.

4. Imaging System Overview

4.1 System Components

- **vatech A9 (PHT-30CSS)** X-ray equipment
- PC system
- Console Software: PANO, CEPH (Optional), and CBCT Scan
- **EzDent-i**: 2D viewer and patient management software
- **Ez3D-i**: 3D viewer software

4.2 Features

- FOV 8x8 support (Anatomically 9.3x8.0) (cm)
- The multi-imaging solution for Accurate Diagnostics
- Conventional 2D (PANO and CEPH) image acquisition
- Control Panel implemented for easy use
- DICOM (Digital Imaging Communication in Medicine) format supported
- Differentiated Console Software Interface

4.3 Imaging System Options

Configuration	Item	Sensor	
SP	PANO +CBCT	PANO/CBCT	Xmaru1404CF-Plus
RC	PANO +CBCT +CEPH	PANO/CBCT	Xmaru1404CF-Plus
		CEPH	Xmaru2602CF

4.4 Standards and Regulations

Standards

vatech A9 (PHT-30CSS) 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), IEC 60601-2-63 (2012)

- 21 CFR 1020.30, 31, 33

- NEMA Standard publication PS 3.1-3.18

CE 2460	This is Class IIb equipment and obtained CE marking in April 2007 for regulations compliance by the revised European Union's MDD (Medical Devices Directive) 93/42 EEC.
CLASSIFIED c UL us E476672	UL symbol grants this equipment compliance with the CAN/CSA C22.2 No.601.1.

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

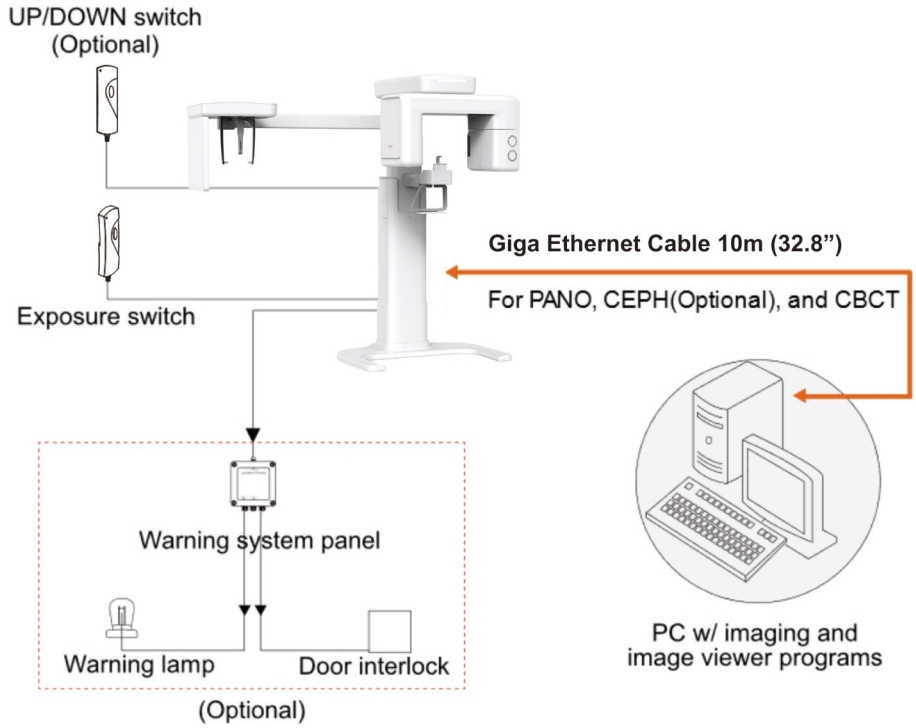
4.5 Operating Principles

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

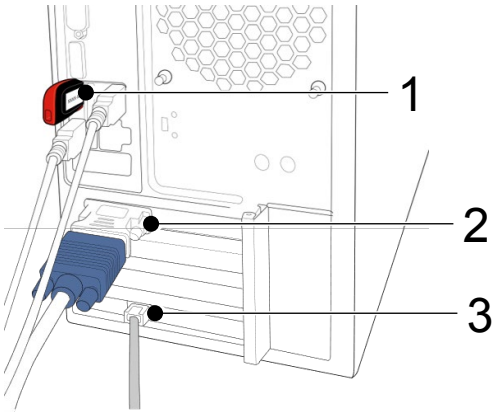
They hit anode to produce an X-ray. The machine acquires images by emitting X-ray continuously and rotates on the human tooth at different angles.

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

4.6 Imaging System Configuration

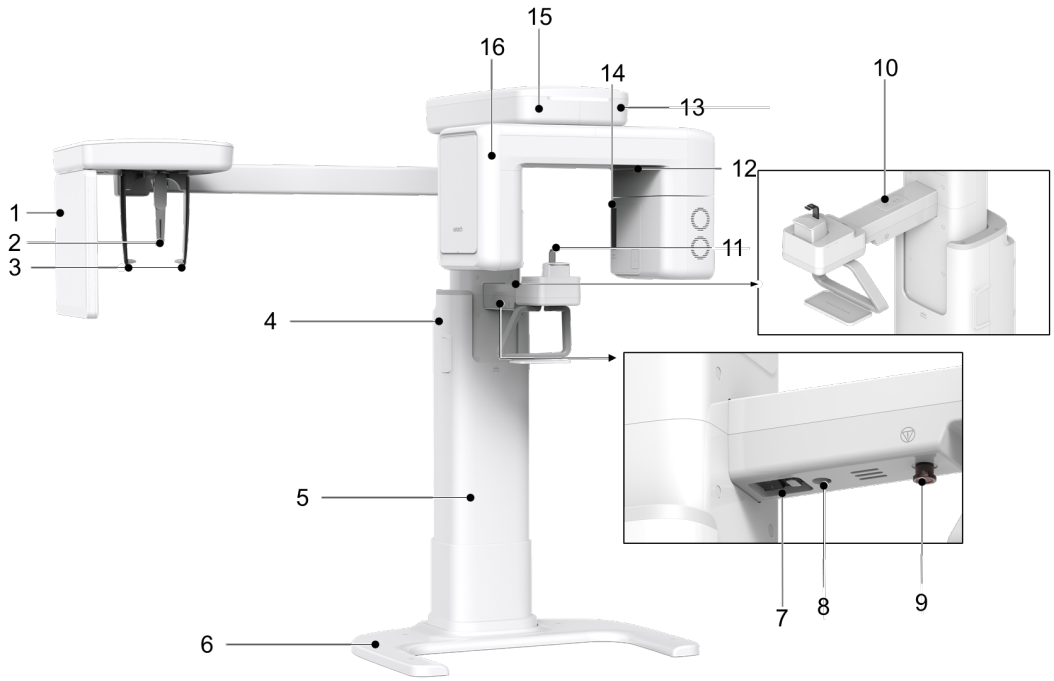


PC Signal Input/Output



No.	Item
1	3D viewer License Key
2	Video output
3	Giga Ethernet Cable

4.7 Equipment Overview



< Perspective View>

No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor
2	Nasal Positioner	Positions the patient during CEPH imaging. The ruler used for reference in an acquired image that is different from the actual size
3	Ear Rods	Secure the patient's head during CEPH imaging.
4	Column UP/DOWN Switch (optional)	Adjust column height to adjust the height of the vertical frame.
5	Stationary Column	Supports the whole part of the equipment.
6	Base (Optional)	Balances the equipment and maintains its safety.
7	Main Power Switch	Turns on/off the main power of the equipment.
8	D-Sub Connector	The input signal port for **Column UP/DOWN** Switch
9	Emergency Stop Switch	Immediately stops the moving parts and cuts off all power to the equipment's electrical components.
10	Column UP/DOWN button	Adjust column height to adjust the height of the vertical frame.

No.	Item	Description
11	Chinrest	The place to rest the chin.
12	X-ray Detector for PANO/CBCT	Xmaru1404CF-Plus for PANO/CBCT imaging sensor
13	LED Lamp	Displays the status of X-ray exposure. ▪ **Green**: Standby ▪ **Yellow**: In operation (X-ray on)
14	X-ray Generator	The X-ray tube where the X-ray is produced.
15	Vertical Frame	Holds the Rotating Unit. It can be controlled with the **Column UP/DOWN** switch.
16	Rotating Unit	Rotates around the patient's head while the image is being acquired. (Its movement is different according to the scan mode.)

4.7.1 Control Panel

No.	Buttons	Description
1	COLUMN UP/DOWN Button	Moves the Vertical Frame up or down. (For adjusting the height of the Chinrest)

4.7.2 Emergency Stop Switch

During operation, the following emergencies may occur:

- X-ray emission even after the **Exposure Switch** has been released
- Physical injury to the patient or damage to the equipment
- Other emergencies

If a problem occurs during image acquisition, press the red **Emergency Stop Switch** to immediately stop the moving parts and cut off all power to the equipment's electrical components. To restart the equipment, turn the **Emergency Stop Switch** clockwise until it pops up.

The **Emergency Stop Switch** is located under the bottom of the Handle Frame.

4.7.3 Exposure Switch

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

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

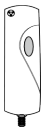
Pressing the **Exposure Switch** activates the LED indicator to turn yellow. This color indicates that the X-ray is being emitted.

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

4.7.4 Enclosed Components

The enclosed components can be disassembled and cleaned. All enclosed components that are used to support the patient (the Bite, the Chinrest, and the Ear Rods) should be cleaned with non-alcohol based, non-corrosive cleaning solution and wiped with clean towels.

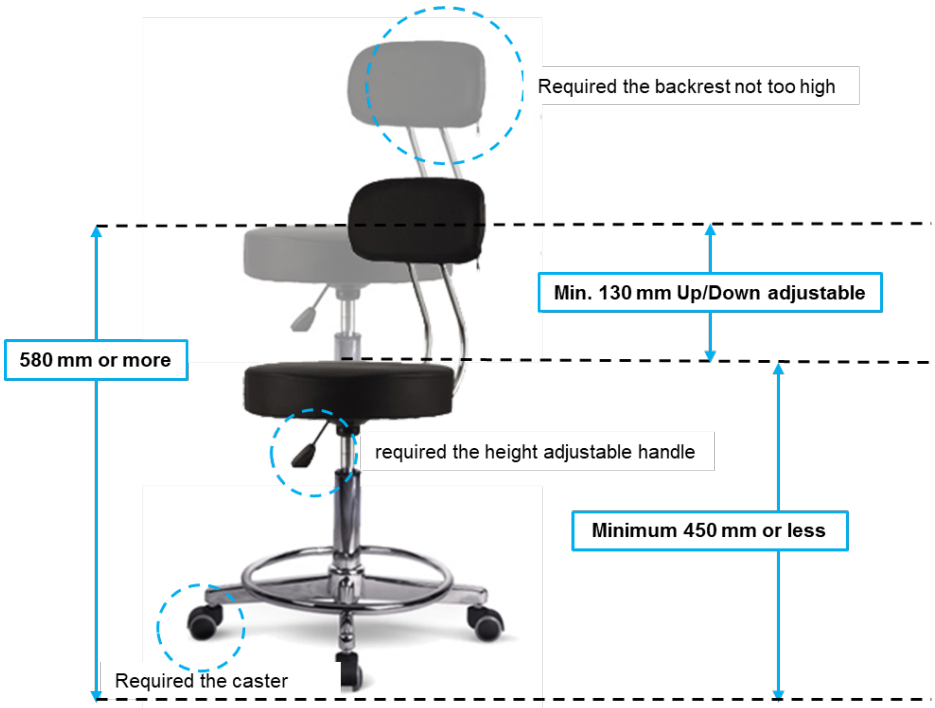
Components	Name and Function	Materials
	Normal Bite - For PANO and CBCT normal patients	PC (Polycarbonate)
	Deep Bite Block *. Deep Bite Block is only available in some Asian countries.	PC (Polycarbonate)
	Special Bite A - For PANO TMJ LAT and Sinus PA modes	PC (Polycarbonate)
	Special Bite B - For PANO edentulous patients - For PANO TMJ PA and Sinus LAT modes.	PC (Polycarbonate)
	Special Chinrest	ABS (Acrylonitrile butadiene styrene) copolymer
	Normal Chinrest	ABS (Acrylonitrile butadiene styrene) copolymer
	Ear Rods (1 set)	Silicone
	Nasal Positioner Cover - For CEPH	Silicone
	Carpus Plate	PC (Polycarbonate)
	Sanitary Vinyl Covers (disposable) for the Bite	PP+PE (PolyPropylene + PolyEthylene)

Components	Name and Function	Materials
	Protractor (1 set) - For positioning the patient's body in CEPH mode.	PC (Polycarbonate)
	Up/Down Switch and Holder (Option)	ABS (Acrylonitrile butadiene styrene) copolymer

4.7.5 Chair purchase recommendations (The item that must be purchased separately)

This equipment is designed for the patient to sit in a chair and positioning. Therefore, Use this equipment after purchasing a separate chair. Here are some recommendations for choosing which chair to purchase.

- Chair with a backrest (not too high)
- Up/Down available chair (requires height adjustment handle)
- When the chair is lowered to the lowest level or the upper part of the chair without vertical movement should be 450 mm or less from the ground
- When the chair is raised to the top level or the upper part of the chair without vertical movement should be 580 mm or more from the ground.
- Must have casters to facilitate chair movement
- Do not use a chair equipped with a seat break, which automatically brakes when a load is applied, because it is not convenient to use when entering the equipment and may cause a safety accident.



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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), and CBCT Scan

5.1 PC Specifications (Recommended)

NOTICE

- The PC system plays a vital role in image processing and verification. Configure the PC environment to meet the following specifications. If the PC specifications are not met, the image quality can be lower.
- Do not place patients near the equipment and PC.

Item	Specifications
CPU	Intel® Core i3-9100 3.6 4C
RAM	16GB (2x8 GB) DDR4-2666 UDIMM NECC Memory APJ
HDD	1TB SATA 7200 rpm 3.5in WKS
Graphics board	GEFORCE GTX1050 Ti DUAL D5 4G
Ethernet Interface	Intel Ethernet I210-T1 PCIe x1 Gb NIC
Serial Port (RS232)	HP Serial Port Adapter Kit
Power Supply	500 W internal power module, up to 90% efficiency, active PFC
Slots	M.2 PCIe x1 2230 (for WLAN) M.2 PCIe x4 2280/2230 Combo (for storage) PCI Express v3.0 x1 PCI Express v3.0 x16 (wired as x4) PCI Express v3.0 x16
CD/DVD drive	DVD-ROM, DVD+/-RW, Blu-Ray
Monitor	19” 1280x1024 screen resolution
Operating System	Windows 10 Professional 64-Bit OS
Recommended System	HP Z1G5

*. If an ethernet card is not installed in your PC, purchase an Ethernet card separately.

5.2 EzDent-i

EzDent-i is imaging software that manages patient images to make faster and more accurate diagnoses. **EzDent-i**, linked with the console software and 3D viewer, makes it convenient for the operator to use and process necessary images. Various functions enable the acquired images to be processed quickly and conveniently from the console software.

NOTICE	Please refer to **EzDent-i User Manual** for more information.
NOTICE	**Security Capabilities** ▪ It is recommended to install and operate **EzDent-i** SW within a secure operating environment that allows only authorized users to access and 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 update through a third party, not the manufacturer, is prohibited. For cybersecurity issues related to the software and medical devices, please contact the manufacturer.

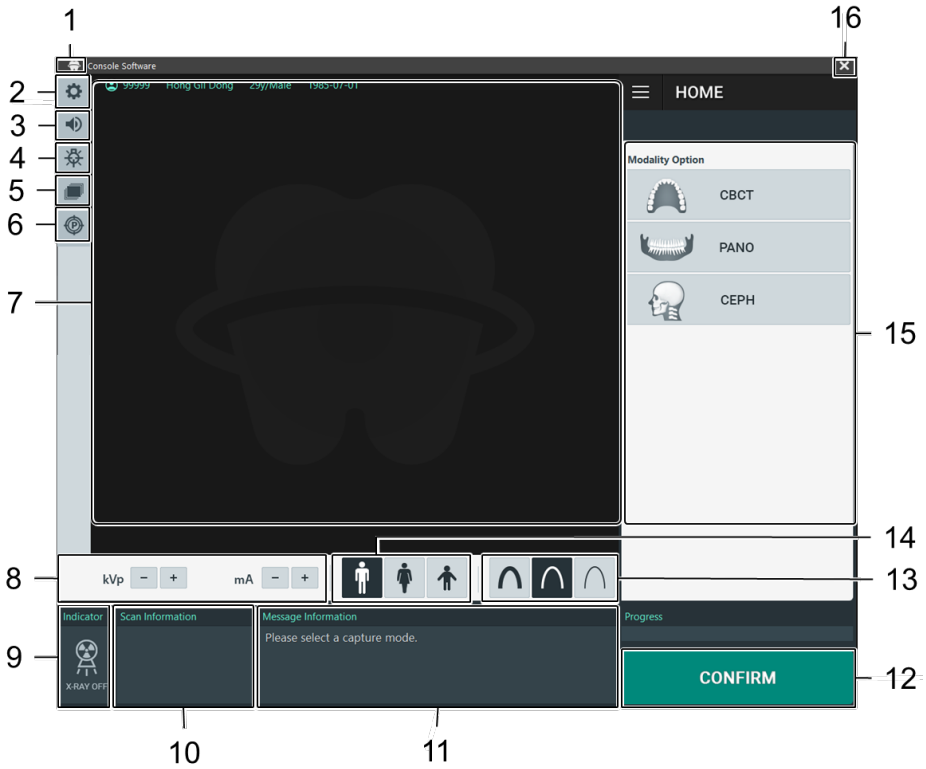
5.3 Console Software

Use the Console Software to configure the imaging environment according to the mode.

NOTICE

- It is able to set the imaging parameters on the Console Software running on the PC. (They are synchronized and display the same environmental settings.)
- To improve program functions, the Console Software may change without notice

The Main Screen of the Console Software consists as follows. Each imaging mode will be described later.



No.	Item	Description
1	Tooth icon	Click the tooth icon to view the Open Source Announcement and the Console Software version information.
2	**Settings** button	Displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, etc.
3	**Speaker Volume** button	This button is used to adjust the speaker volume. Clicking on the speaker icon brings up the volume control bar, and you can adjust the volume by clicking and moving the volume control bar with your mouse. After moving the bar,

No.	Item	Description
		release the mouse to play the current volume and save the current volume.
4	**Laser Beam ON/OFF** button	Turns the Laser Beam on or off for patient positioning. Enabled when the **CONFIRM** button is clicked after the imaging conditions are configured.
5	**Manual Reconstruction** button	Reconstructs the image manually when automatic image reconstruction fails: 1. Click this button and select a Modality. 2. Click the **Search** button. 3. Select an image to reconstruct. Click the **Reconstruction** button.
6	**Phantom** button	This function is used to acquire Phantom images. **NOTICE** **Image acquisition using the Phantom Jig:** 1. Click the **Phantom** button. 2. Select the Modality and click the **Capture** button. 3. Check the parameters displayed in the main GUI window and align the Phantom Jig, and then click the **READY** button. 4. Press and hold down the **Exposure Switch**.
7	Patient Information window	Displays information on the selected patient. **NOTICE** The user can freely control the mouse in the guide area and specify the exposure range.
8	Tube Voltage and Current Adjustment	If the patient is selected in **EzDent-i**, the default kVp/mA, according to the patient's information (gender/age), is displayed. This tool adjusts the kVp and mA values and controls the power of the X-ray to improve image quality. If necessary, adjust the kVp and mA values manually using the arrows. **NOTICE** For the tube voltage and its correspondence with the selected patient, refer to **16.1 Recommended X-ray Exposure Table**.
9	X-ray indicator	The radiation mark turns yellow, and the lamp image changes to colored.

<table>
<tr><th>No.</th><th>Item</th><th>Description</th></tr>
<tr><td>10</td><td>Scan Information window</td><td>Displays estimated DAP (Dose Area Product), scan time, and exposure time after exposure parameter settings are completed.</td></tr>
<tr><td>11</td><td>Guide Message window</td><td>Displays various text instructions for the operator.</td></tr>
<tr><td>12</td><td>CONFIRM /READY button</td><td>CONFIRM
Applies the selected settings and moves to the next step.
(Exposure parameter setting and patient positioning > Ready for exposure)

NOTICE
When you click the CONFIRM button, estimated DAP (Dose Area Product), scan time, and exposure time would be displayed DAP, Scan Time, and Exposure Time Display window.

READY
It is activated when you click the CONFIRM button after the patient positioning is completed. Click the button when all aspects of preparation are completed for image acquisition.</td></tr>
<tr><td>13</td><td>X-ray intensity</td><td>Selects X-ray intensity.

NOTICE
Depending on the circumference of the patient’s head, X-ray intensity may be classified as Hard, Normal, or Soft:
Soft ≤ Normal ≤ Hard
<table>
<tr><th>Age Group</th><th>Average Head Circumference (cm)</th><th>Range (cm)</th><th>X-ray Intensity</th></tr>
<tr><td rowspan="3">Child</td><td rowspan="3">53±3</td><td>>53±3</td><td>Hard</td></tr>
<tr><td>53±3</td><td>Normal</td></tr>
<tr><td><53±3</td><td>Soft</td></tr>
<tr><td rowspan="3">Adult</td><td rowspan="3">56±3</td><td>>56±3</td><td>Hard</td></tr>
<tr><td>56±3</td><td>Normal</td></tr>
<tr><td><56±3</td><td>Soft</td></tr>
</table></td></tr>
<tr><td>14</td><td>Patient’s gender/age group</td><td>Displays the current patient’s gender/age group as entered in EzDent-i’s patient information fields. If necessary, the gender/ age group can be manually selected.</td></tr>
</table>

<table>
<tr><th>No.</th><th>Item</th><th>Description</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Gender / Age Group</th><th></th><th>VATECH's Standard</th></tr>
<tr><td colspan="2">Child</td><td>2 ~ 12 years of age</td></tr>
<tr><td rowspan="2">Adult</td><td>Man</td><td rowspan="2">> 12 years of age</td></tr>
<tr><td>Woman</td></tr>
</table>
</td></tr>
<tr><td>15</td><td>Modality Selection button</td><td>Selects the imaging parameters for each mode: PANO, CEPH (Optional), and CBCT Scan

NOTICE
Selecting Modality changes the Modality Selection screen to the Imaging Parameters Configuration panel.</td></tr>
<tr><td>16</td><td>EXIT button</td><td>Exits the console software.</td></tr>
</table>

NOTICE	After completing the X-Ray survey, a pop-up message appears to show the progress of the image acquisition and displaying a preview of the acquired image.

6. Getting Started

6.1 Turning on the Equipment

WARNING

- Do not place the patient close to the equipment when it is being turned on. Doing so may cause physical injury to the patient and damage to the equipment.
- Do not operate the PC while the equipment is in operation. Doing so may cause an error in the equipment.

1. Press the **Main Power Switch** that is located under the Handle frame to turn on the equipment.

NOTICE

Main Power Switch isolates its circuits electrically from the supply mains on all poles simultaneously.

2. Make sure that the White LED light at the top of the equipment is on.

6.2 Running the Image Viewer (EzDent-i)

The Imaging Program is interfaced with **EzDent-i,** and the user can analyze the image acquired from the Console Software easily and rapidly. On your desktop, double-click **the EzDent-i** icon. The **EzDent-i** main window will be displayed.

NOTICE	For **vatech A9 (PHT-30CSS)** dental computed tomography X-ray system, both 3D viewer (**Ez3D-i**) and Console Software are being accessed through 2D viewer (**EzDent-i**) SW. 3D viewer and Console Software do not have an image storage capacity of their own, and both programs will not be able to keep patient information.

6.2.1 Creating a New Patient Record

To create a new patient record, follow the procedure outlined below:

1. Click the **PATIENT** tab and click the **Add Patient** icon from the main GUI window.

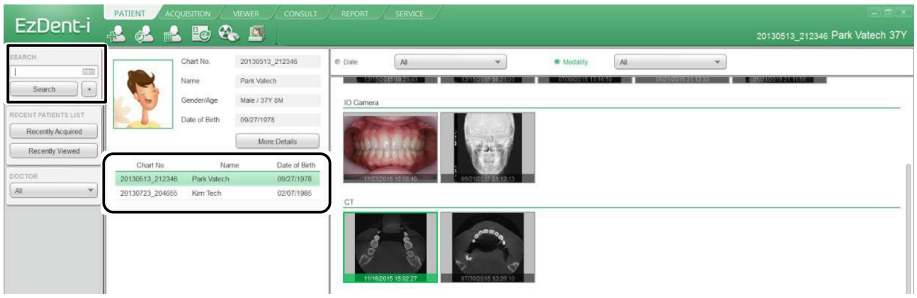
2. Enter the required patient information. **Chart Number**, **E-Mail address, First Name**, and **Last Name** are required fields that must be filled in. (The Chart Number is filled in automatically.)

3. Click the **Add** button to save the patient record.

6.2.2 Searching the Patient Records

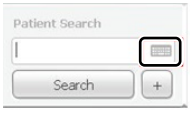
You can search through the patient database using a patient's Chart Number, First Name, or Last Name.

1. Enter the Name or Chart Number of the patient to be searched on the **Patient Search** panel and then click the **Search** button. The information on the patient that fits the search condition appears.

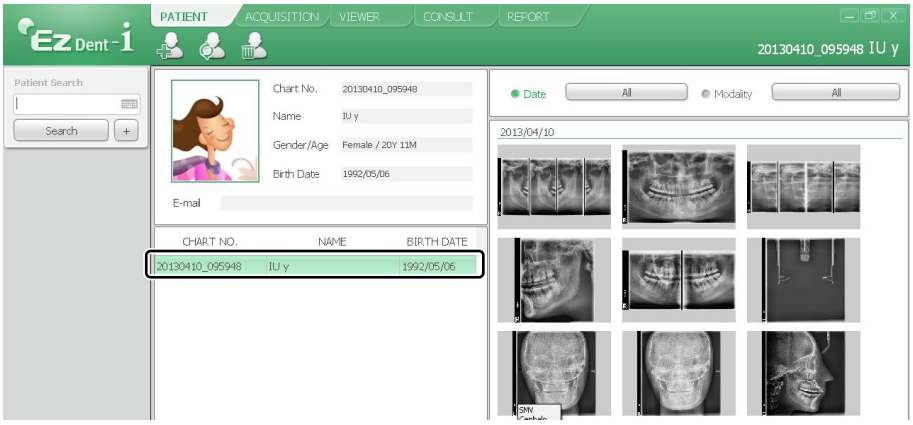


NOTICE

Double-click the Keyboard icon to display the virtual keyboard. You may search for patient information using the virtual keyboard.



2. Double-click the patient information to see more details about the patient, as shown below.

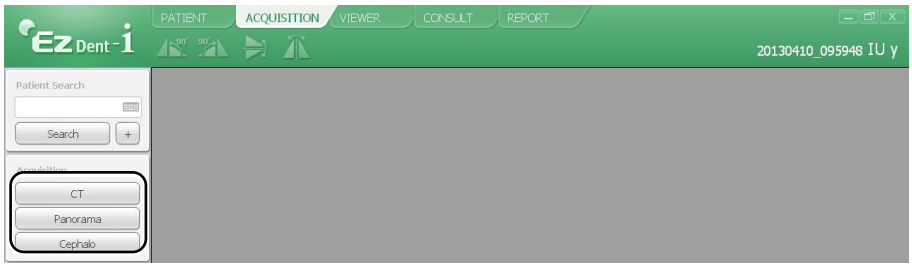


6.3 Initiating the Console Software

NOTICE	For a new patient, the patient information needs to be registered first.

1. Search and select the patient to be captured.

2. Click the **ACQUISITION** tab and select the imaging mode (CT, Panorama, or Cephalo).



3. The Main Screen for the selected mode appears. From the Main Screen, you can configure the imaging parameter settings before acquiring an image.

NOTICE	Refer to the following **chapters (7~9)** for more information on image acquisition.

7. Acquiring PANO Images

7.1 PANO Imaging Program Overview

■ Result Images

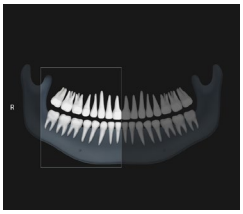
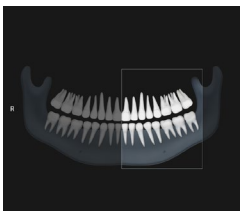
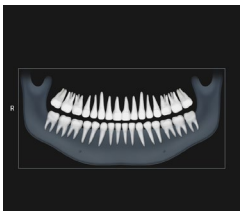
It provides conventional 2D panoramic images.

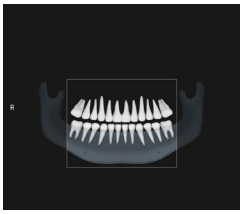
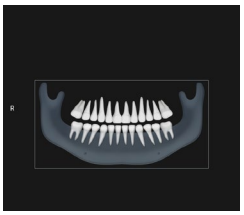
■ Image Acquisition Method

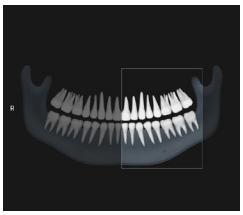
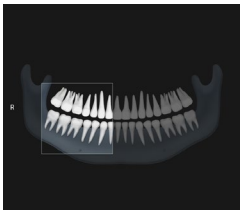
It reconstructs U-shaped arch data to a single 2D image utilizing multiple images taken with the X-ray beam scanning specific oral & maxillofacial regions at different angles.

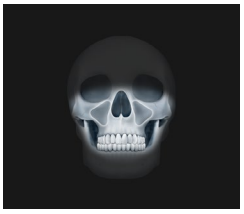
■ Examination Programs

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

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

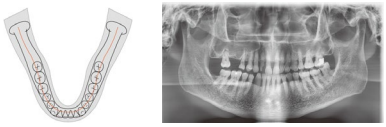
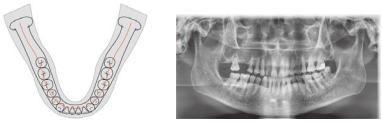
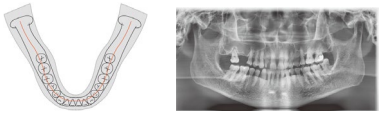
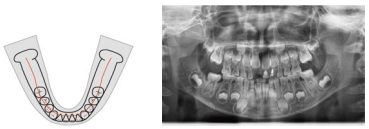
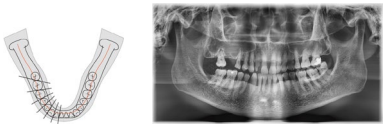
Examination Type	Arch Selection	ROI	Example
PANO Examination	Child	Right	
		Front	
	Child	Left	
		Standard	
	Orthogonal	Right	
		Front	

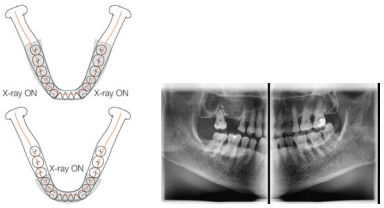
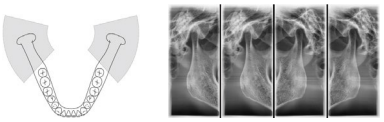
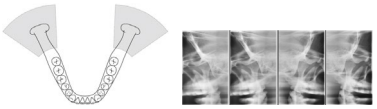
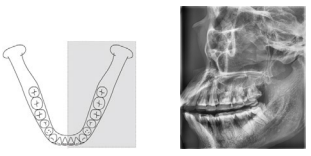
Examination Type	Arch Selection	ROI	Example
		Left	
		Bitewing Right*	
		Standard	
		Bitewing Left*	
		Bitewing*	
PANO Examination	Orthogonal	Bitewing Incisor* (Optional)	

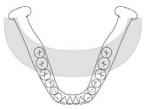
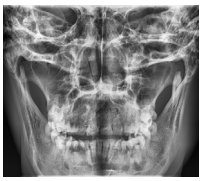
Examination Type	Arch Selection	ROI	Example
SPECIAL Examination	N/A	TMJ LAT Open	
		TMJ LAT Close	
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

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

■ 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, which is beamed perpendicularly between teeth. 

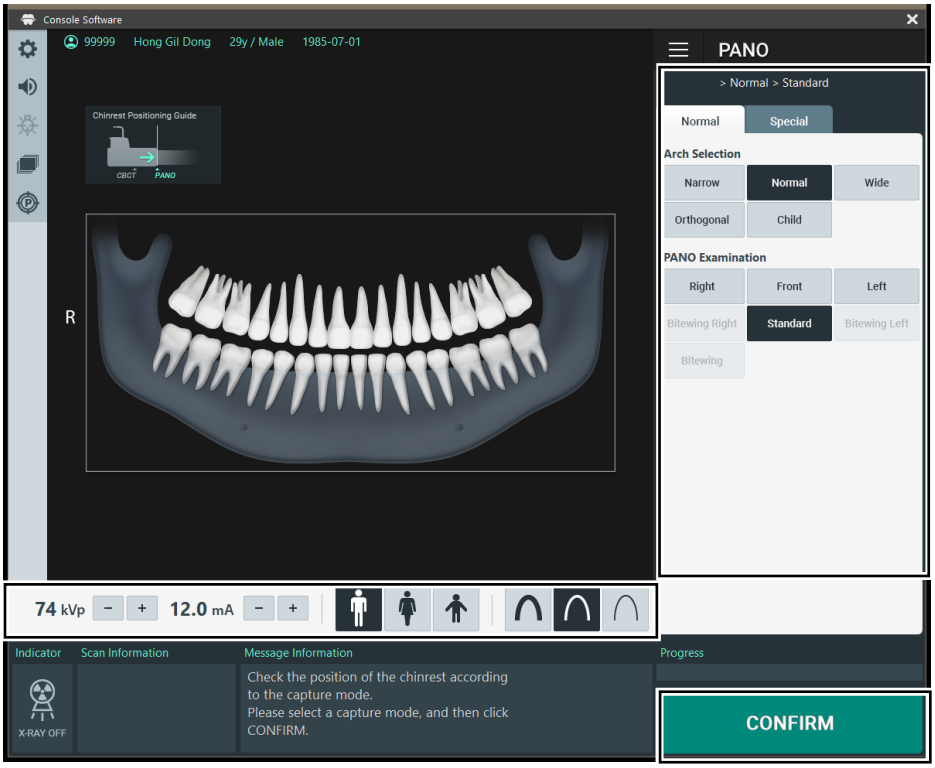
Examination Type	Arch Selection	ROI	Description & Sample Image
		Bitewing** (Bitewing Incisor mode is Optional)	A panoramic imaging mode to acquire an image only for the region of interest through the orthogonal trajectory. (Pros: less X-ray exposure than the Normal mode. /Cons: TMJ and some parts of 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 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 close. 
		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 on the frontal region of the maxillary sinus.  

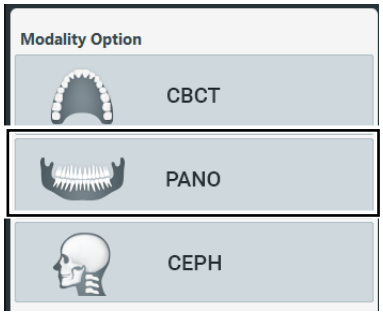
** Bitewing imaging mode is activated only when Orthogonal is selected in Arch Selection.

7.2 Configuring Exposure Parameters

To acquire PANO Images, **6. Getting Started** must be completed first. If not, you must return to the **6. Getting Started** and finish the step first.



1. Click the **PANO** button on the Main Screen.

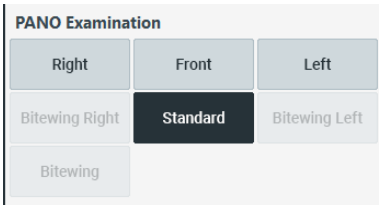


NOTICE	**The CEPH** button exists only when the CEPH imaging program is included in the equipment.

2. Make an Arch Selection.

Arch Selection	Description
Narrow	Panoramic image of V-shaped palatal arches (Small number of adult females)
Normal	Panoramic image of normal adult palatal arches
Wide	Panoramic image of square-shaped palatal arches (some number of adult males)
Orthogonal	The panoramic image where the x-ray angle enters vertically in between the teeth, so overlapping images is minimized. NOTICE: If Orthogonal Arch is selected, Bitewing examinations (Bitewing, Bitewing Incisor (Optional), Bitewing Right, Bitewing Left) are activated.
Child	Panoramic image of child palatal arches, more than 40% less X-ray dose than in Normal mode.

3. Select an Examination Program in the Pano Examination or Special Examination panel.



NOTICE

- To activate Bitewing examination options- **Bitewing**, **Bitewing Incisor** (Optional), **Bitewing Right**, **Bitewing Left**, select **Orthogonal** in the Arch Selection panel.

- When a Special Examination option is clicked, the **PANO Examination** panel is disabled. If you want to select a PANO Examination option, please conduct Arch selection again.
- For more information about the Examination Program, refer to the **7.1 PANO Imaging Program Overview**.

4. The Gender/Age group of the patient is selected automatically based on the patient information. If necessary, you can select the option manually.

NOTICE

Gender / Age Group		VATECH's Standard
Child		2 ~ 12 years of age
Adult	Man	> 12 years of age
	Woman	

5. Select X-ray intensity.

NOTICE

Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft:

Soft ≤ Normal ≤ Hard

Age Group	Average Head Circumference (cm)	Range (cm)	X-ray Intensity
Child	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

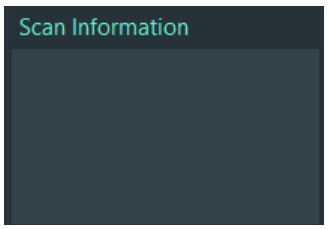
6. The values of tube voltage and current are configured automatically according to the patient's gender/age group and X-ray intensity. Click the **UP/DOWN** arrow to adjust kVp and mA. The dose is adjustable by ±1 kVp and ±1 mA, respectively.

7. Click the **CONFIRM** button when the exposure parameter setting is completed.

NOTICE

When you click **CONFIRM** button,

- The Rotating Unit will move to its initial scanning position.
- The Vertical Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below the Scan Information window.



8. Guide the patient to the equipment.

7.3 Patient Positioning

WARNING	▪ Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation. ▪ Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
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. ▪ Be sure to adjust the laser beam correctly. Otherwise, the quality of images can be lower due to ghost images or expansion/reduction of the images.
IMPORTANT	▪ Since the patient needs to sit in a chair and position, the action that the user has to lower the upper body when positioning the patient is a necessary motion.
NOTICE	There is a horizontal beam laser for the guide that points the patient's shoulder in the rotator section. This laser allows you to proactively identify the possibility of moving the rotator and touching the patient's shoulder. If the laser is pointing at the patient's shoulder, it can be lowered further to prevent the rotator from touching the patient's shoulder.
NOTICE	The manufacturer recommends using a chair that can be adjusted to a height of at least 450 mm and up to 580 mm.

Getting prepared

1. Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button in the Handle frame or use the switch option to adjust the equipment to match the sitting height of the patient.

Chinrest position adjustment

Before patient alignment, adjust the Chinrest position to the PANO mode. (If the Chinrest position is already set to PANO mode, there is no need to adjust again.)

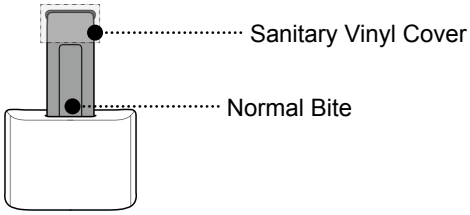
NOTICE	The installation angle of the Chinrest attachment part may be distorted by 2 degrees. This is intended for calibration purposes. 

1. Push the Chinrest attachment part on the handle frame towards the machine until the end of the Chinrest attachment part is printed in "-PANO-" silk. Push until you hear a “click” sound.

7.3.1 PANO Examination Mode (Standard/Right/Left/Front/Orthogonal)

Normal Patient Positioning

1. Insert the Normal Bite and cover it with a Sanitary Vinyl Cover.



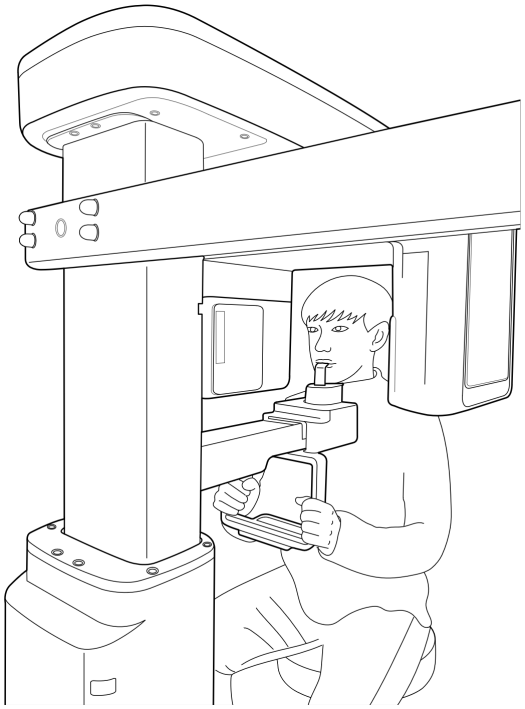
⚠CAUTION

- The Sanitary Vinyl Cover is for sole use only. It should be replaced for each patient. Be sure to use the approved vinyl cover.

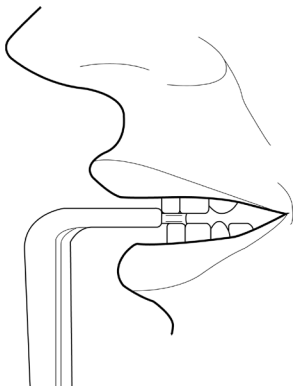
- Clean the Chinrest and the Bite with non-alcohol based, non-corrosive cleaning solution and wipe with a dry towel before the next patient.

2. Guide the patient to a chair (sold separately) in the center of the equipment.

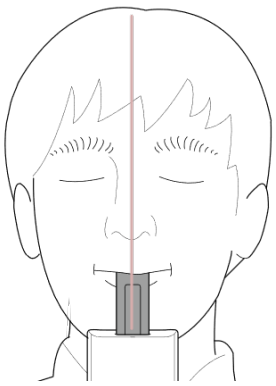
3. Adjust the instrument to the patient's sitting height using the **Column UP/DOWN** on the Handle frame or the optional UP/DOWN switch.



4. Guide the patient to sit in the center of the equipment and maintain the position described below.
   - Hold the handle firmly.
   - Make sure the patient's chest is in contact with the equipment.
   - Keep both shoulders parallel.
   - Straighten the patient's cervical spine and sit still.
   - Let the patient bite the Bite along its grooves with his/her front teeth.



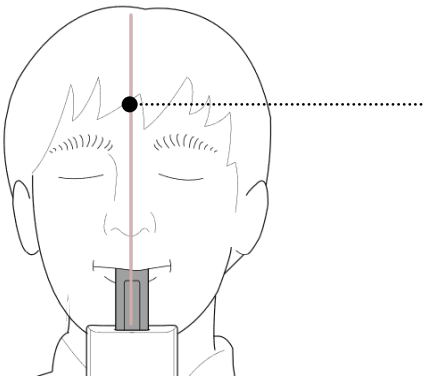
5. Let the patient maintain the posture as follows:
   - Close the mouth.
   - Place the tongue to the roof of the mouth.
   - Close the eyes.



Laser Beam Aligning

WARNING	Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the laser beam properly.

1. Align the Vertical Beam with the center of the face (Mid-sagittal Line). (It is to prevent the horizontal expansion of the image)
2. Align the Horizontal Beam in a straight line to the Frankfurt Line on the patient's face. Use the **Horizontal Beam** button on the control panel to position it. Make sure that the Horizontal Beam is aligned to the patient's face horizontally.



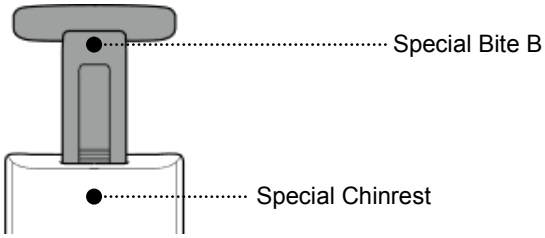
Finishing Patient Positioning

1. Click the **READY** button. X-ray exposure has not started yet.

2. Now go to **7.4 X-ray Exposure** to start the exposure.

Edentulous Patient Positioning

1. Insert the **Special Bite B**.



⚠CAUTION	Clean the Special Bite B with non-alcohol based, non-corrosive cleaning solution and wipe with a dry towel before the next patient.

2. Guide the patient to a chair (sold separately) in the center of the equipment.
3. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.

4. Guide the patient to sit in the center of the equipment and maintain the position described below.
   - Hold the handle firmly.
   - Make sure the patient's chest is in contact with the equipment.
   - Keep both shoulders parallel.
   - Straighten the patient's cervical spine and sit still.
   - Let the patient bite the Bite along its grooves with his/her front teeth.

5. Let the patient maintain the posture as follows:

- Close the mouth.
- Place the tongue to the roof of the mouth.
- Close the eyes.

Finishing Patient Positioning

1. Click the **READY** button. X-ray exposure has not started yet.

2. Now go to **7.4 X-ray Exposure** to start the exposure.

7.3.2 SPECIAL Examination Mode (TMJ/Sinus)

TMJ OPEN Mode (LAT)

The TMJ Close image can be acquired after the TMJ Open image is acquired.

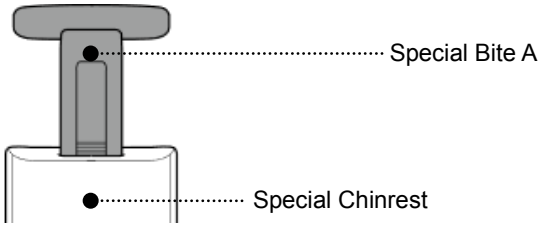
NOTICE

Steps for TMJ Mode

Patient positioning for TMJ Open > Laser Beam Aligning > X-ray Exposure > Patient positioning for TMJ Close > Laser Beam Aligning > X-ray Exposure

Patient Positioning

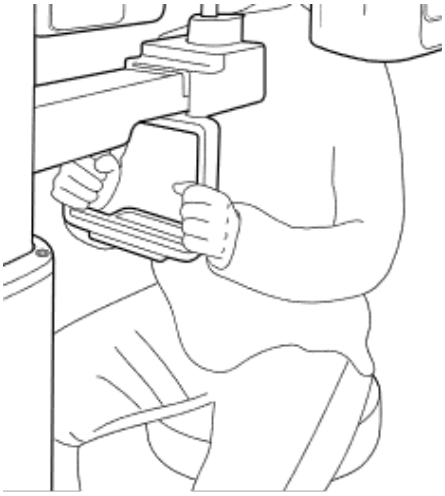
1. Remove the **Normal Chinrest** and insert the **Special Chinrest** into the equipment.
2. Insert the **Special Bite A** into the **Special Chinrest**



⚠CAUTION

Clean the Chinrest and the Bite with non-alcohol based, non-corrosive cleaning solution and wipe with a dry towel before the next patient.

3. Guide the patient to a chair (sold separately) in the center of the equipment.
4. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.

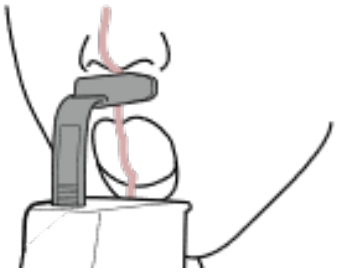


5. Guide the patient to sit in the center of the equipment and maintain the position described below.
   - Hold the handle firmly.
   - Make sure the patient's chest is in contact with the equipment.
   - Keep both shoulders parallel.
   - Straighten the patient's cervical spine and sit still.
   - Let the patient bite the Bite along its grooves with his/her front teeth.
6. Guide the patient to press the base of the nose (acanthion point) against the Chinrest and tilt the head forward about 5˚. At this point, make sure the patient's jaw does not touch the equipment.

IMPORTANT

- If the jaw touches the equipment, it is difficult to maintain the proper position to get good images.
- Be careful; the patient does not touch the equipment with his/her jaw.

7. Let the patient maintain the posture as follows:
   - Open the mouth.
   - Place the tongue to the roof of the mouth.
   - Close the eyes.



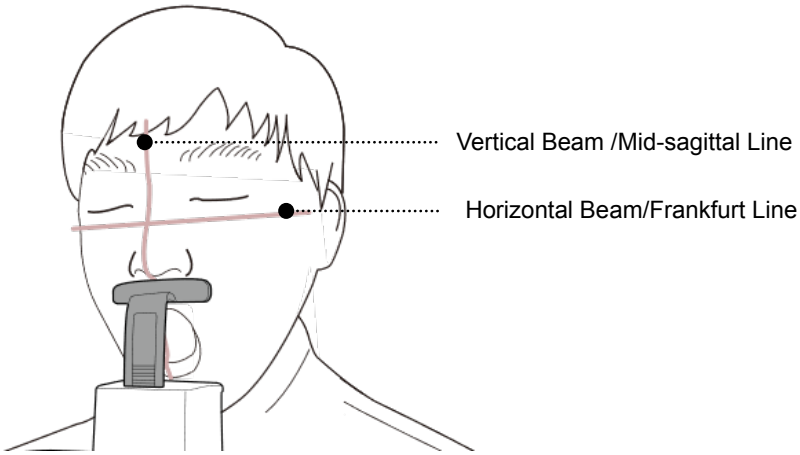
NOTICE

- As shown in the picture, the support unit of the integrated Chinrest should touch the patient's acanthion point.
- Ask the patient to maintain his/her position until the operation is completed.

Laser Beam Aligning

WARNING	Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the laser beam properly.

1. Align the Vertical Beam with the center of the face (Mid-sagittal Line). (It is to prevent the horizontal expansion of the image)
2. Align the Horizontal Beam in a straight line to the Frankfurt Line on the patient's face. Use the **Horizontal Beam** button on the control panel to position it. Make sure that the Horizontal Beam is aligned to the patient's face horizontally.



Finishing Patient Positioning

1. Click the **READY** button. X-ray exposure has not started yet.

2. Now go to **7.4 X-ray Exposure** to start the exposure.

TMJ CLOSE Mode (LAT) and SINUS (PA) Mode

The TMJ Close image can be acquired after the TMJ Open image is acquired.

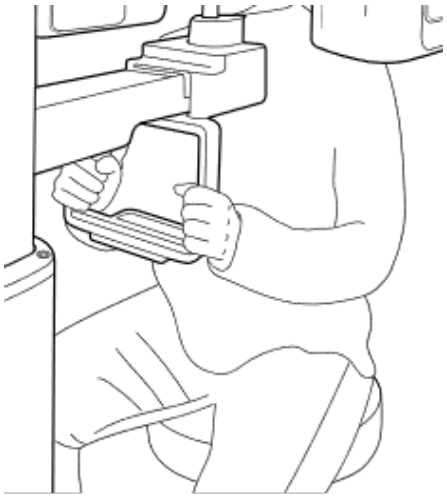
NOTICE

Steps for TMJ Mode

Patient positioning for TMJ Open > Laser Beam Aligning > X-ray Exposure > Patient positioning for TMJ Close > Laser Beam Aligning > X-ray Exposure

Patient Positioning

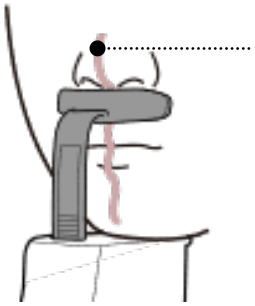
1. "Do you want to capture a TMJ Close image?" message will appear when the TMJ Open mode is completed. Press/Click **OK** button to begin TMJ Close mode.
2. Guide the patient to a chair (sold separately) in the center of the equipment.
3. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.



4. Guide the patient to sit in the center of the equipment and maintain the position described below.
   - Hold the handle firmly.
   - Make sure the patient's chest is in contact with the equipment.
   - Keep both shoulders parallel.
   - Straighten the patient's cervical spine and sit still.
   - Let the patient bite the Bite along its grooves with his/her front teeth.
5. Guide the patient to place the base of his/her nose (acanthion point) against the Chinrest and bend the head forward about 5˚.

6. Let the patient maintain the posture as follows:

- Close the mouth.
- Place the tongue to the roof of the mouth.
- Close the eyes.



NOTICE	▪ As shown in the picture, the support unit of the integrated Chinrest should touch the patient's acanthion point. ▪ Let the patient maintain his/her position until the operation is completed.

Laser Beam Aligning

This is the same as the one for TMJ Open mode.

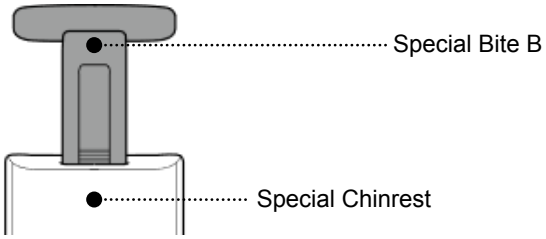
Finishing Patient Positioning

This is the same as the one for TMJ Open mode.

TMJ CLOSE Mode (PA) and Sinus Mode (LAT)

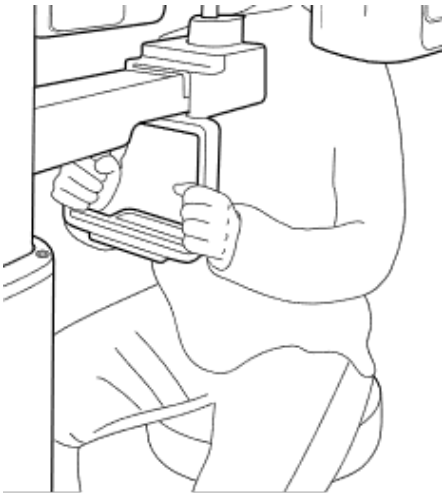
Patient Positioning

1. Remove the **Normal Chinrest** and insert the **Special Chinrest** into the equipment.
2. Insert the **Special Bite B** into the **Special Chinrest**



⚠CAUTION	Clean the Chinrest and the Bite with non-alcohol based, non-corrosive cleaning solution and wipe with a dry towel before the next patient.

3. Guide the patient to a chair (sold separately) in the center of the equipment.
4. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.



5. Guide the patient to sit in the center of the equipment and maintain the position described below.
   - Hold the handle firmly.
   - Make sure the patient's chest is in contact with the equipment.
   - Keep both shoulders parallel.
   - Straighten the patient's cervical spine and sit still.

6. Guide the patient to press the base of the nose (acanthion point) against the Chinrest and tilt the head forward about 5˚. At this point, make sure the patient's jaw does not touch the equipment.

IMPORTANT

- If the jaw touches the equipment, it is difficult to maintain the proper position to get good images.
- Be careful; the patient does not touch the equipment with his/her jaw.

7. the patient maintains the posture as follows:

- Close the mouth.
- Place the tongue to the roof of the mouth.
- Close the eyes.

NOTICE

- As shown in the picture, the support unit of the integrated Chinrest should touch the patient's acanthion point.
- Ask the patient to maintain his/her position until the operation is completed.

Laser Beam Aligning

WARNING	Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the Laser Beam properly.

1. Align the Vertical Beam with the center of the face (Mid-sagittal Line). (It is to prevent the horizontal expansion of the image)
2. Align the Horizontal Beam in a straight line to the Frankfurt Line on the patient's face. Use the **Horizontal Beam** button on the control panel to position it. Make sure that the Horizontal Beam is aligned to the patient's face horizontally.

Finishing Patient Positioning

1. Click the **READY** button. X-ray exposure has not started yet.

2. Now go to **7.4 X-ray Exposure** to start the exposure.

7.4 X-ray Exposure

WARNING	▪ If an emergency occurs during image acquisition, release the **Exposure Switch** to cease X-ray emission. ▪ The operator shall always observe the X-ray safety regulations applicable to his/her area during the operation of this equipment.
CAUTION	▪ The operator must always keep vocal/visual contact with the patient during the image acquisition process. ▪ Do not operate the PC during exposure. Doing so may cause the system to malfunction.
IMPORTANT	▪ Let the patient close the eyes during the operation. ▪ To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move.

1. Get out of the X-ray room and close the door.

IMPORTANT	The operator must always keep vocal/visual contact with the patient during image acquisition.

2. Press and hold down the **Exposure Switch** until image acquisition is completed.

NOTICE	The image appears on the screen.
NOTICE	During X-ray exposure, the status appears as follows. ▪ The LED light of the **Exposure Switch** turns yellow. ▪ The LED light on the top of the equipment turns yellow. ▪ An alert sound comes out to indicate that X-ray emission is currently underway. ▪ On Console Software, the radiation mark turns Yellow.  

3. Release the **Exposure Switch** when “Image capturing is completed” message appears on the screen.

7.5 Finishing the Scan

1. Guide the patient out of the equipment.
2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.

7.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

The exported images can be confirmed in **EzDent-i**.

NOTICE	Refer to the **EzDent-i User Manual** for more information.

1. The images are transferred to **EzDent-i** automatically.
2. The images are automatically saved if the automatic save option is configured as default. If it is not configured as default, click the **Save** button to save the images.
3. To check the image, double-click the one on the **Patient List**.

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8. Acquiring CEPH Images (Optional)

8.1 CEPH Imaging Program Overview

- **Result Images**

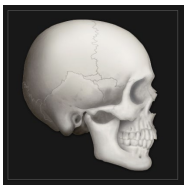
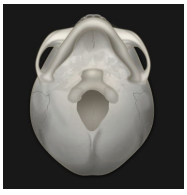
  It provides conventional 2D cephalometric images.

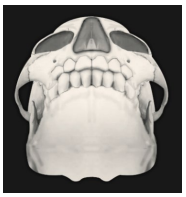
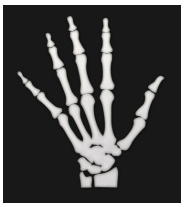
- **Image Acquisition Method**

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

■ Examination Programs

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

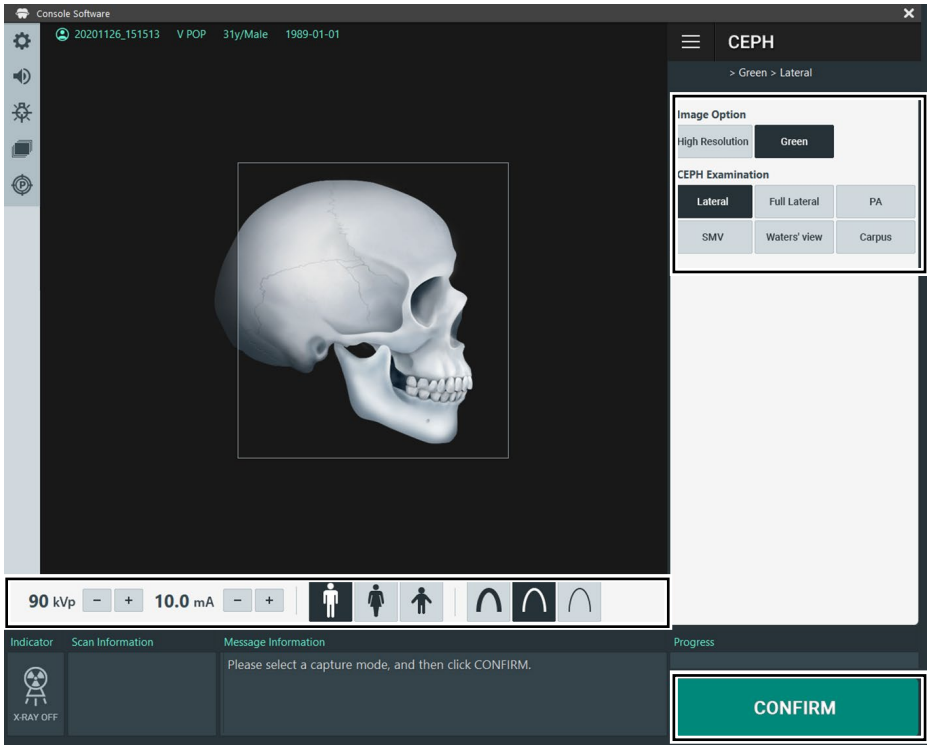
Examination Area	Description	Position
Lateral/ Full Lateral (Optional)	▪ Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate. ▪ Measures the angles formed by the connecting lines between the cranial measurement points to further assess the growth of the facial region. 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 sinus, antrum ethmoidal, olfactory pits, and optic disc pits. ▪ Measures the angles formed by the connecting lines between the cranial measurement points to further assess the growth of the facial region. It is widely used in Orthodontics and Oral and Maxillofacial Surgery.	 <PA>
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>

Examination Area	Description	Position
Waters' view	▪ Used to study the frontal sinus, the antrum ethmoidal, the optic disc pit, the frontozygomatic suture, the nasal cavity, 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 Configuring Exposure Parameters

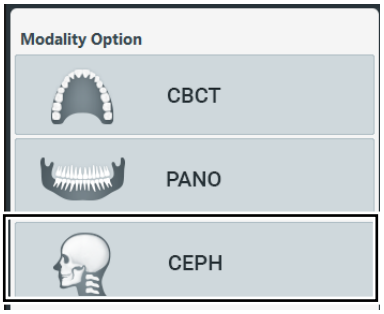
To acquire CEPH images, **6. Getting Started** must be completed first.

NOTICE	It is able to set the imaging parameters on the Console Software running on the PC. They are synchronized and display the same environmental settings.



8. Acquiring CEPH Images (Optional)

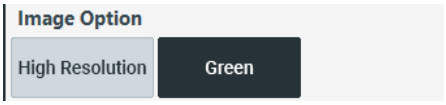
1. Click the **CEPH** button on the Main Screen.



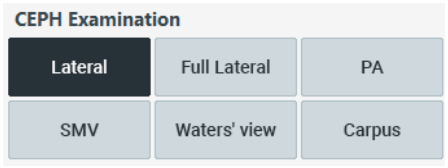
NOTICE

The CEPH button exists only when the CEPH imaging program is included in the equipment.

2. Select an Image Option.



3. Select an examination program in the CEPH Examination panel.



4. The Gender/Age group of the patient is selected automatically based on the patient information. If necessary, you can select the option manually.

NOTICE

Gender / Age Group		VATECH's Standard
Child		2 ~ 12 years of age
Adult	Man	> 12 years of age
	Woman	

5. Select X-ray intensity.

NOTICE

Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft:

Soft ≤ Normal ≤ Hard

Age Group	Average Head Circumference (cm)	Range (cm)	X-ray Intensity
Child	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

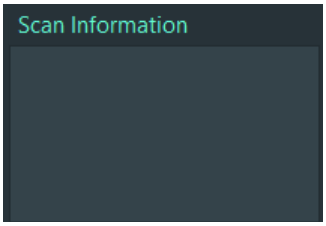
6. The values of tube voltage and current are configured automatically according to the patient's gender/age group and X-ray intensity. Click the **UP/DOWN** arrow to adjust kVp and mA. The dose is adjustable by ±1 kVp and ±1 mA, respectively.

7. Click the **CONFIRM** button when the exposure parameter setting is completed.

NOTICE

When you click **CONFIRM** button,

- The Rotating Unit will move to its initial scanning position.
- The Vertical Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below the Scan Information window.



8. Guide the patient to the equipment.

8.3 Patient Positioning

WARNING	▪ Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation. ▪ Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	Ensure that the Nasal Positioner is left unfolded, before adjusting the Ear Rods in the proper direction.
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.
NOTICE	The manufacturer recommends using a chair that can be adjusted to a height of at least 450 mm and up to 580 mm.

Getting prepared

1. Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button in the Handle frame or use the switch option to adjust the equipment to match the sitting height of the patient.

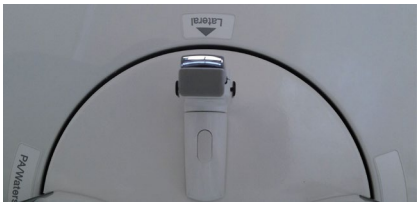
8.3.1 Lateral/Full Lateral (Optional) Mode

NOTICE

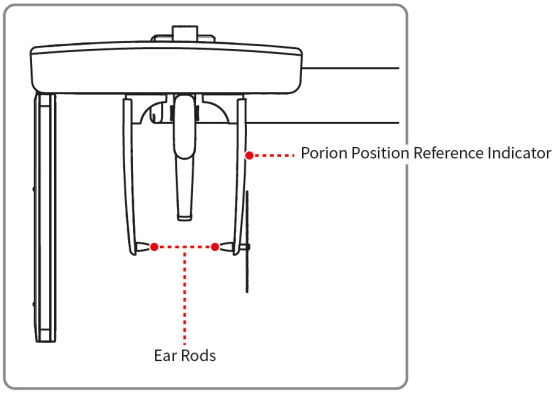
Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.

Patient Positioning

1. Turn the Nasal Positioner to the **Lateral** mode Positioning Marker, as shown below.



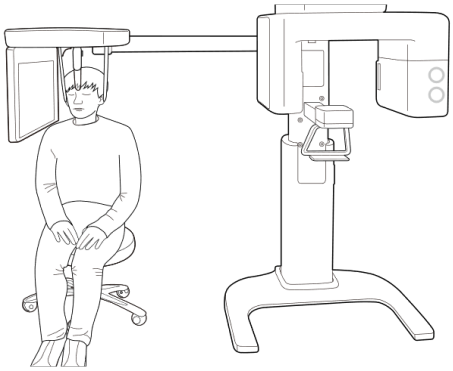
2. Leave enough space between the Ear Rods.



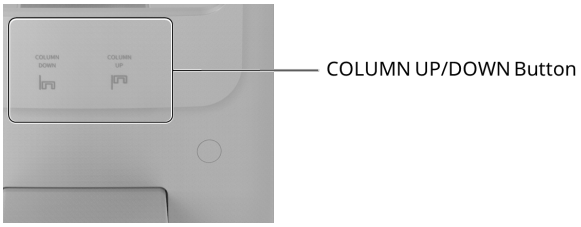
NOTICE

Use the Porion Position Reference Indicator that appears in the acquired image to confirm the location of Porion quickly.

3. Guide the patient to the CEPH unit.
4. Instruct the patient to relax the neck and shoulders and sit upright.

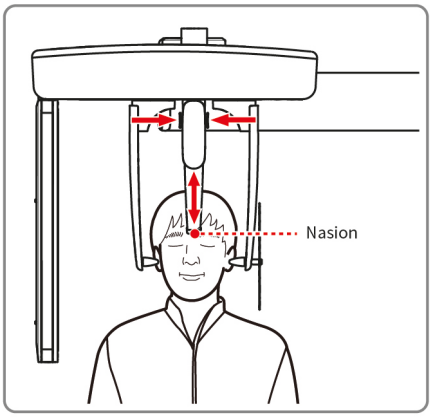


5. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.

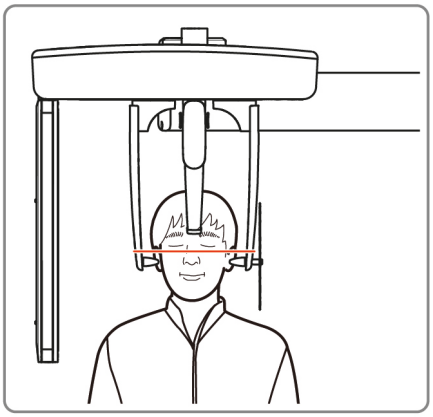


WARNING	After adjusting the height of the column, align the Ear Rods and Nasal Positioner to the patient.

6. Align the Ear Rods into the patient's ears properly so that the head does not move during the operation. Moreover, aligning the Nasal Positioner with the patient's nasion by adjusting its height.



7. Align horizontally, so the patient's Frankfurt Line is parallel with the floor.



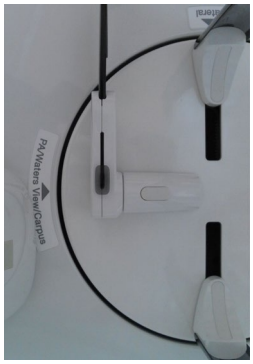
8. Direct the patient to swallow first before closing the mouth and to remain in his/her current position until image acquisition is completed.
9. Click the **READY** button. The x-ray exposure has not started yet.

10. Now go to **8.4 X-ray Exposure** to start the exposure.

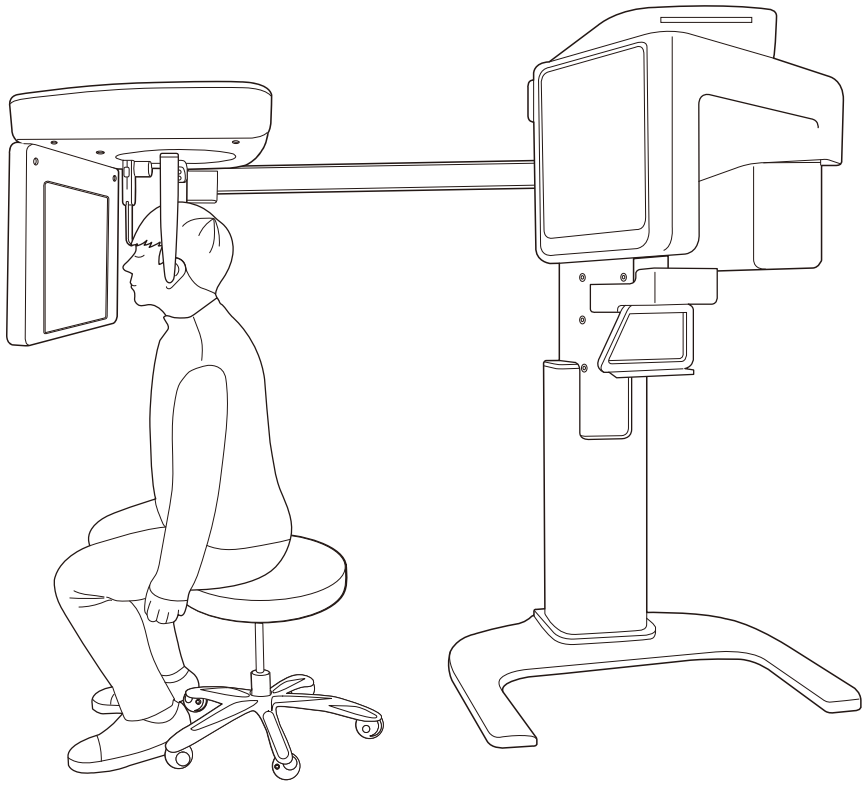
8.3.2 PA Mode

Patient Positioning

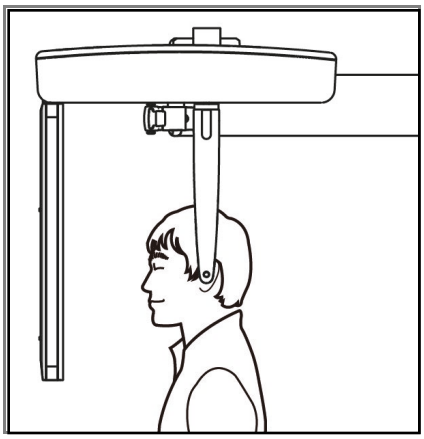
1. Turn the Nasal Positioner to the **PA/Waters' view/Carpus** mode Positioning Marker, as shown below.



2. Fold the Nasal Positioner up. The Nasal Positioner is not used in PA mode.
3. Guide the patient to the CEPH unit.



4. Ask the patient to sit upright towards the sensor. Make sure the patient's shoulders are flat and the neck is relaxed.

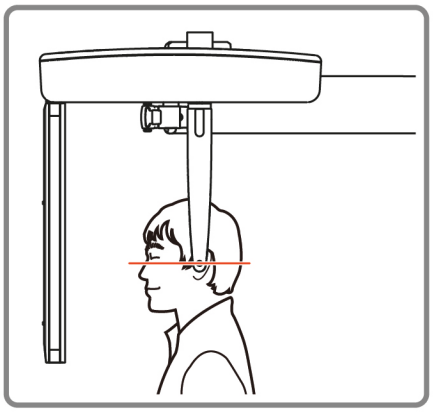


5. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.

WARNING	After adjusting the height of the column, align the Ear Rods to the patient.

6. During the operation, correctly align the Ear Rods to the patient's ears, so his/her head does not move.

7. Align horizontally, so the patient's Frankfurt Line is parallel with the floor.



8. Direct the patient to swallow first before closing his/her mouth and to remain in his/her current position until image acquisition is completed.

9. Click the **READY** button. The x-ray exposure has not started yet.

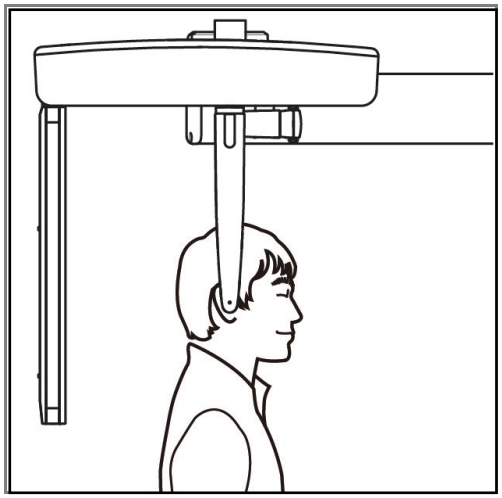
10. Now go to **8.4 X-ray Exposure** to start the exposure.

8.3.3 SMV Mode

Patient Positioning

1. Turn the Nasal Positioner to the **SMV** mode Positioning Marker, as shown below.

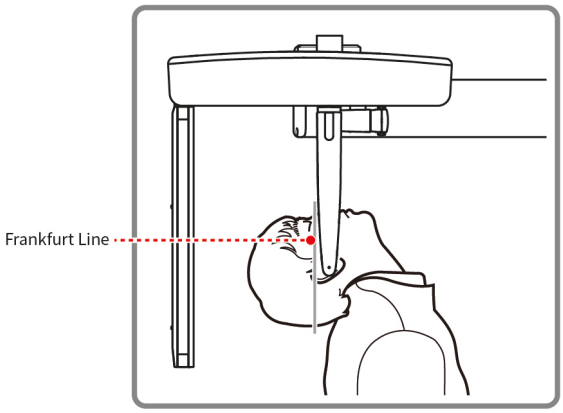
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in SMV mode.
3. Guide the patient to the CEPH unit.
4. Guide the patient to face the X-ray tube and sit upright.



5. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.

WARNING	After adjusting the height of the column, align the Ear Rods to the patient.

6. During the operation, correctly align the Ear Rods to the patient's ears, so his/her head does not move.
7. Carefully tilt the patient's head back and adjust so his/her Frankfurt Line is vertical with the floor.
8. Direct the patient to swallow first before closing his/her mouth and to remain in his/her current position until image acquisition is completed.



9. Click the **READY** button. The x-ray exposure has not started yet.

10. Now go **to 8.4 X-ray Exposure** to start the exposure.

8.3.4 Waters' view Mode

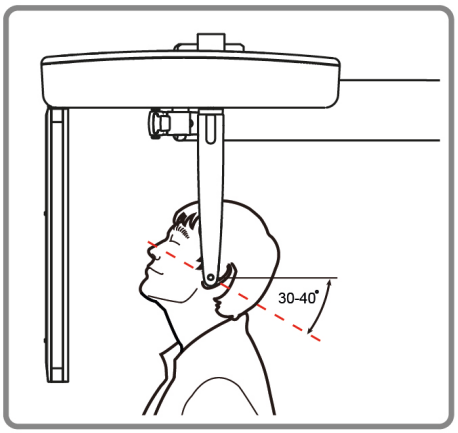
Patient Positioning

1. Turn the Nasal Positioner to the **PA/Waters' view/Carpus** mode Positioning Marker, as shown below.

2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Waters' view mode.
3. Guide the patient to the CEPH unit.
4. Ask the patient to sit upright facing the sensor. Make sure that the patient's shoulders are level and that his/her neck is relaxed.
5. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.

⚠WARNING	After adjusting the height of the column, align the Ear Rods to the patient.

6. During the operation, correctly align the Ear Rods to the patient's ears, so his/her head does not move.
7. Direct the patient to swallow first before closing his/her mouth and guide the patient to bend the head backward 30˚ - 40˚. Direct the patient to remain in the current position until image acquisition is completed.



8. Click the **READY** button. The x-ray exposure has not started yet.

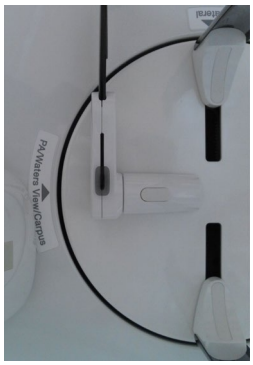
9. Now go **to 8.4 X-ray Exposure** to start the exposure.

8.3.5 Carpus Mode

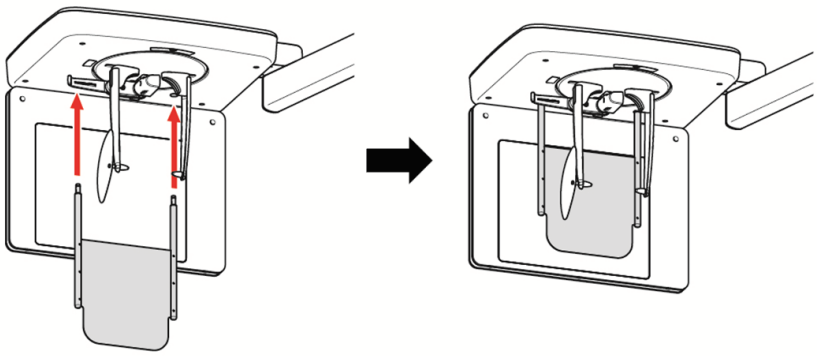
For Carpus Mode, install the Carpus Plate first before positioning the patient.

Installing the Carpus Plate

1. Turn the Nasal Positioner to the **PA/Waters' view/Carpus** mode Positioning Marker, as shown below.



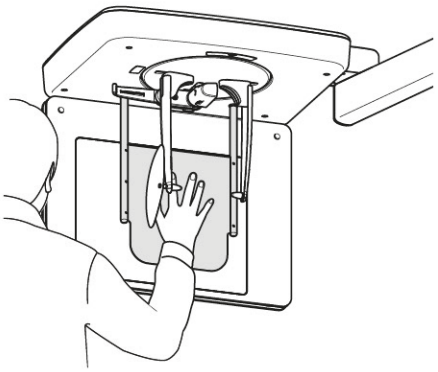
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Carpus mode.
3. Fit the two ends of the Carpus Plate into the two holes of the CEPH unit as below.



4. Confirm that the Carpus Plate is safely mounted.

Patient Positioning

1. Let the patient put his/her right hand splayed on the Carpus Plate, as shown below. Make sure that the patient does not bend his/her fingers.



2. Ask the patient to close his/her eyes and sit still until the image acquisition is completed.
3. Click the **READY** button. The x-ray exposure has not started yet.

4. Now go **to 8.4 X-ray Exposure** to start the exposure.

8.4 X-ray Exposure

⚠WARNING	▪ If an emergency occurs during image acquisition, release the **Exposure Switch** to cease X-ray emission. ▪ The operator shall always observe the X-ray safety regulations applicable to his/her area during the operation of this equipment.
⚠CAUTION	▪ The operator must always keep vocal/visual contact with the patient during the image acquisition process. ▪ Do not operate the PC during exposure. Doing so may cause the system to malfunction.
IMPORTANT	▪ Let the patient close the eyes during the operation. ▪ To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move.

1. Get out of the X-ray room and close the door.
2. Press and hold down the **Exposure Switch** until image acquisition is completed.

NOTICE	The image appears on the screen.
NOTICE	During X-ray exposure, the status appears as follows. ▪ The LED light of the **Exposure Switch** turns yellow. ▪ The LED light on the top of the equipment turns yellow. ▪ An alert sound comes out to indicate that X-ray emission is currently underway. ▪ On Console Software, the radiation mark turns Green.  

3. Release the **Exposure Switch** when “Image capturing is completed” message appears on the screen.

8.5 Finishing the Scan

1. Leave enough space between the Ear Rods.
2. Fold the Nasal Positioner up in case it is unfolded.
3. Guide the patient out of the equipment.

8.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

The exported images can be confirmed in **EzDent-i.**

NOTICE	Refer to the **EzDent-i User Manual** for more information.

1. The images are transferred to **EzDent-i** automatically.
2. The images are automatically saved if the automatic save option is configured as default. If it is not configured as default, click the **Save** button to save the images.
3. To check the image, double-click the one on the **Patient List**.

9. Acquiring CBCT Images

9.1 CBCT Imaging Program Overview

■ Result Images

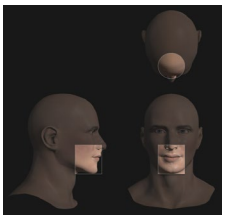
It provides conventional 3D CT sliced images.

■ Image Acquisition Method

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

■ Examination Programs

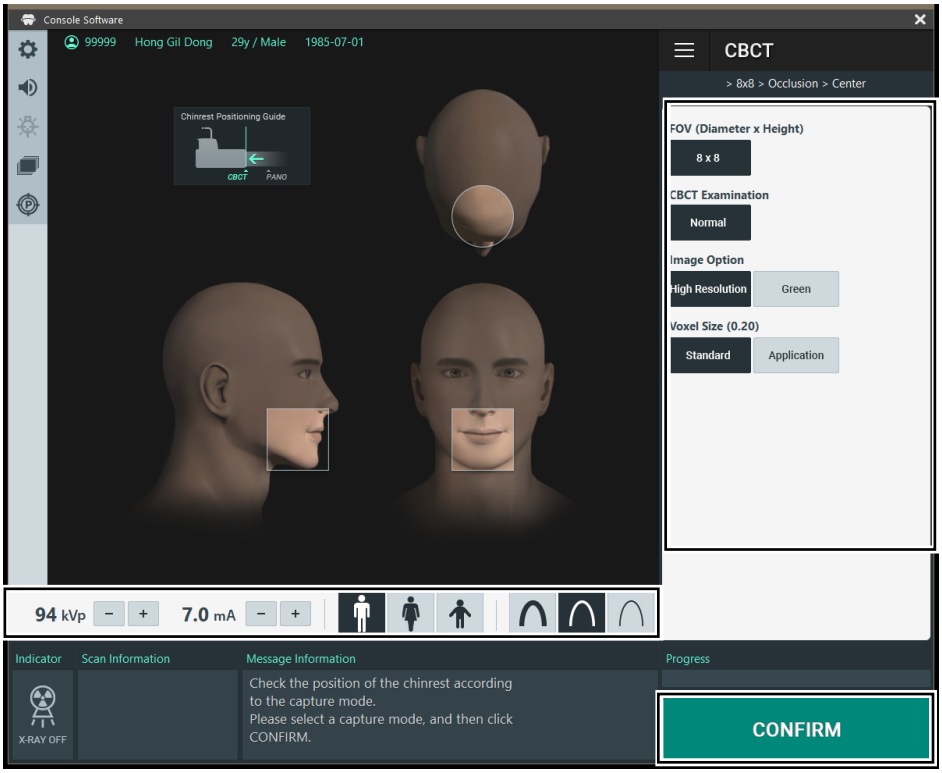
It is classified as below based on the FOV.

Available FOVs (cm)	ROI	Description
8x8	 <Occlusion/Center>	- Covers both maxillary and mandibular areas.

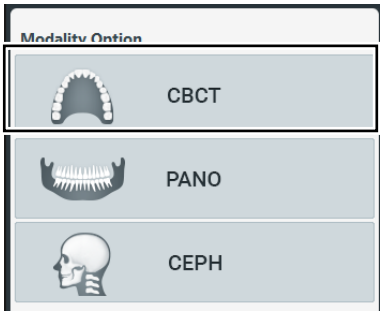
9.2 Configuring Exposure Parameters

To acquire CBCT Images, **6. Getting Started** must be completed first.

NOTICE	You can set the imaging parameters on the Console Software running on the PC. They are synchronized and display the same environmental settings.



1. Click the **CBCT** button on the Main Screen.

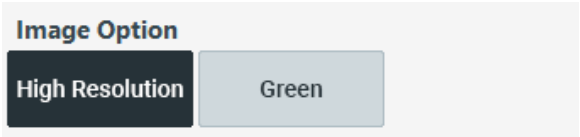


NOTICE	The **CEPH** button exists only when the CEPH imaging program is included in the equipment.
NOTICE	Make sure FOV (Diameter x Height) is 8x8.

◆ Available options for each FOV are as below.

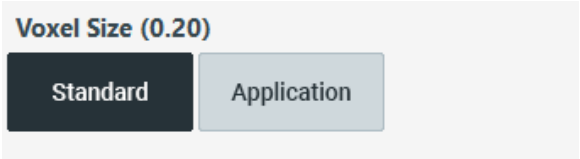
Available FOV (cm)	Vertical option	Horizontal option
8x8	Occlusion	Center

2. Select an Image Option.



3. Select a Voxel Size.

NOTICE	MAR (Metal Artifact Reduction) function is applied automatically if there are metal objects in the image. MAR may increase image reconstruction time.



4. The Gender/Age group of the patient is selected automatically based on the patient information. If necessary, you can select the option manually.

NOTICE

Gender / Age Group		VATECH's Standard
Child		2 ~ 12 years of age
Adult	Man	> 12 years of age
	Woman	

5. Select X-ray intensity.

NOTICE

Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft:

Soft ≤ Normal ≤ Hard

Age Group	Average Head Circumference (cm)	Range (cm)	X-ray Intensity
Child	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

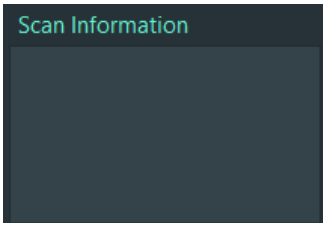
6. The values of tube voltage and current are configured automatically according to the patient's gender/age group and X-ray intensity. Click the **UP/DOWN** arrow to adjust kVp and mA. The dose is adjustable by ±1 kVp and ± 0.1 mA, respectively.

7. Click the **CONFIRM** button when the exposure parameter setting is completed.

NOTICE

When you click **CONFIRM** button,

- The Rotating Unit will move to its initial scanning position.
- The Vertical Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below the Scan Information window.



8. Guide the patient to the equipment.

9.3 Patient Positioning

WARNING	▪ Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation. ▪ Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
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. ▪ Be sure to adjust the laser beam correctly. Otherwise, the quality of images can be lower due to ghost images or expansion/reduction of the images.
NOTICE	There is a horizontal beam laser for the guide that points the patient's shoulder in the rotator section. This laser allows you to proactively identify the possibility of moving the rotator and touching the patient's shoulder. If the laser is pointing at the patient's shoulder, it can be lowered further to prevent the rotator from touching the patient's shoulder.
NOTICE	The manufacturer recommends using a chair that can be adjusted to a height of at least 450 mm and up to 580 mm.
IMPORTANT	Since the patient needs to sit in a chair and position, the action that the user has to lower the upper body when positioning the patient is a necessary motion.

9.3.1 Getting prepared

1. Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button in the Handle frame or use the switch option to adjust the equipment to match the sitting height of the patient.

9.3.2 Chinrest position adjustment

Before patient alignment, adjust the Chinrest position to the CBCT mode. (If the Chinrest position is already set to CBCT mode, there is no need to adjust again.)

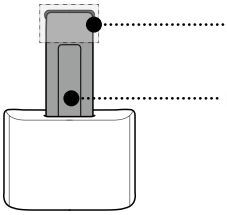
NOTICE

The installation angle of the Chinrest attachment part may be distorted by 2 degrees. This is intended for calibration purposes.

1. Pull the Chinrest attachment part on the handle frame towards the machine until the end of the Chinrest attachment part is printed in "-CBCT-" silk. Pull until you hear a “click” sound.

9.3.3 Patient Positioning - Normal

1. Insert the Normal Bite into the Normal Chinrest and cover it with a Sanitary Vinyl Cover.

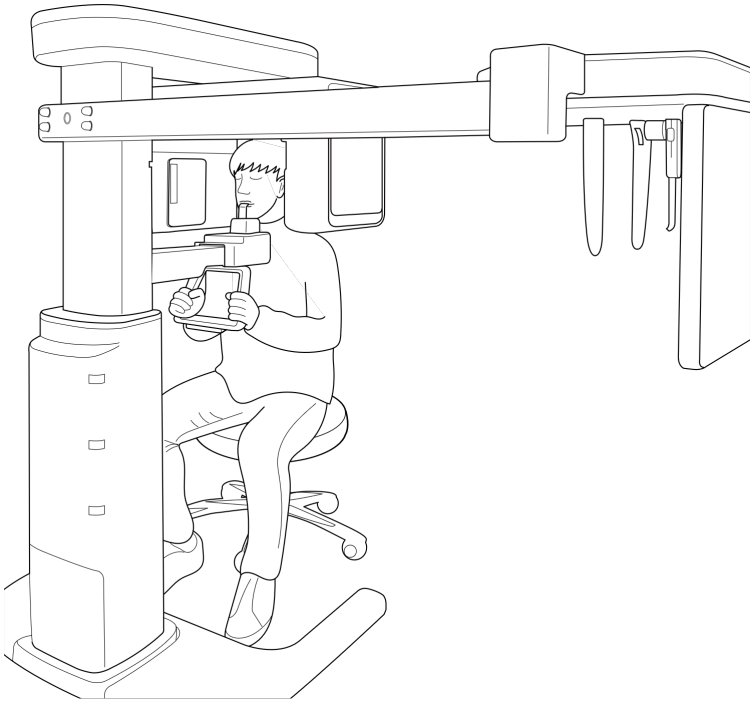


⚠CAUTION

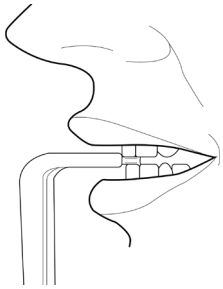
- The Sanitary Vinyl Cover is for sole use only. It should be replaced for each patient. Be sure to use the approved vinyl cover.

- Clean the Chinrest and the Bite with non-alcohol based, non-corrosive cleaning solution and wipe with a dry towel before the next patient.

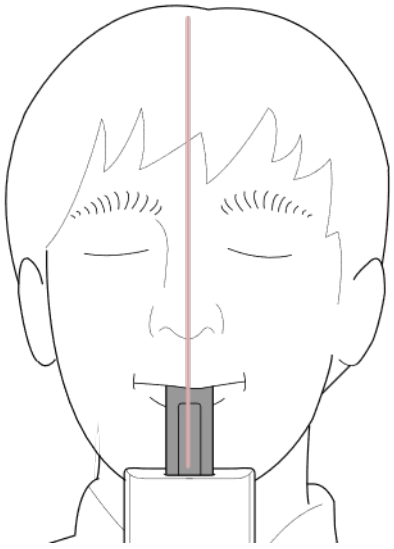
2. Guide the patient to a chair (sold separately) in the center of the equipment.
3. Adjust the instrument to the patient's sitting height using the Column UP/DOWN on the Handle frame or the optional UP/DOWN switch.



4. Guide the patient to sit in the center of the equipment and maintain the position described below.
   - Hold the handle firmly.
   - Make sure the patient's chest is in contact with the equipment.
   - Keep both shoulders parallel.
   - Straighten the patient's cervical spine and sit still.
   - Let the patient bite the Bite along its grooves with his/her front teeth.

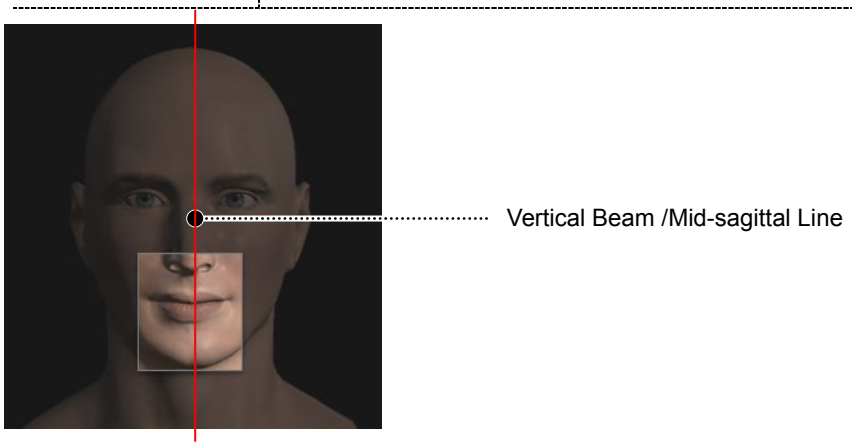


5. Let the patient maintain the posture as follows:
   - Close the mouth.
   - Place the tongue to the roof of the mouth.
   - Close the eyes.



9.3.4 Laser Beam Aligning – Normal

WARNING	Be careful not to shine the Laser Beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	If the Laser Beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align Laser Beam properly.



NOTICE	This is a sample illustration for reference only. Actual FOV may vary from the image, as shown above.

1. Align the Vertical Beam with the center of the face (Mid-sagittal Line). (It is to prevent the horizontal expansion of the image)

9.3.5 Finishing Patient Positioning

1. After checking the positions of the patient and the Laser Beam, prevent the patient's head from moving.
2. Click the **READY** button. X-ray exposure has not started yet.

3. Now go to **9.5 X-ray Exposure** to start the exposure.

9.4 X-ray Exposure

WARNING	▪ If an emergency occurs during image acquisition, release the **Exposure Switch** to cease X-ray emission. ▪ The operator shall always observe the X-ray safety regulations applicable to his/her area during the operation of this equipment.
CAUTION	▪ The operator must always keep vocal/visual contact with the patient during the image acquisition process. ▪ Do not operate the PC during exposure. Doing so may cause the system to malfunction.
IMPORTANT	▪ Let the patient close the eyes during the operation. ▪ To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move.

1. Get out of the X-ray room and close the door.

IMPORTANT	The operator must always keep vocal/visual contact with the patient during image acquisition.

2. Press and hold down the **Exposure Switch** until image acquisition is completed.

NOTICE	The image appears on the screen.
NOTICE	During X-ray exposure, the status appears as follows. ▪ The LED light of the **Exposure Switch** turns yellow. ▪ The LED light on the top of the equipment turns yellow. ▪ An alert sound comes out to indicate that X-ray emission is currently underway. ▪ On Console Software, the radiation mark turns Green.  

3. Release the **Exposure Switch** when “Image capturing is completed” message appears on the screen.

9.5 Finishing the Scan

1. Guide the patient out of the equipment.
2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.

9.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

The exported images can be confirmed in **EzDent-i**.

NOTICE	Refer to the **EzDent-i User Manual** for more information.

1. The images are transferred to **EzDent-i** automatically.
2. The images are automatically saved if the automatic save option is configured as default. If it is not configured as default, click the **Save** button to save the images.
3. To check the image, double-click the one on the **Patient List**.
4. Then, **Ez3D-I** automatically starts a 3D viewing of the saved image.

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10. Troubleshooting

10.1 Troubleshooting

If a problem occurs while operating the equipment, perform the corresponding troubleshooting measures outlined in the table below. If the problem persists, please contact our customer support staff.

If the equipment is not working

Cause	Actions to be taken
Failure of power supply	Check the equipment's power supply.
Initialization status	Wait until the equipment has been initialized and then try again.
Failure of the Control PC's connection	Check the connection status of Communication Port (Optic), which connects the PC to the equipment.

If the Exposure Switch is not functioning

Cause	Actions to be taken
Failure of readiness	Check whether the Console Software is ready for imaging.

If imaging cannot be performed

Cause	Actions to be taken
Failure of initialization	Wait until the equipment is initialized and then try again. If this problem persists, restart the equipment.

If the Laser Beam has shut off and patient positioning cannot be performed

Cause	Actions to be taken
Expiration of the time allotted for patient positioning	Press the Laser Beam button to turn on the Laser Beam.

10.2 Error Codes

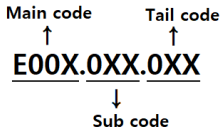
In instances of abnormal operation, error messages appears with error codes on the Console Software and Control Panel. If a problem persists, please request assistance from the customer support information services.

NOTICE

Error messages will be displayed in the format written below.

[Code: E00X.0XX.0XX]

The code consists of three parts: Main code, Subcode, Tail code.



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

10.2.1 Main code - Hardware (001)

10.2.1.1 Subcode – Generator related error (001)

Tail code	Description
001	Appears when the tube is not ready for use
002	Appears when cable between tube tank and Inverter board are disconnected
003	Appears when a current of the inverter board exceeds 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 current feedback compared to the average value
008	Appears when the temperature of the mono tank is above the setting temperature

Tail code	Description
009	Appears when the inverter output current is higher than 1A during X-ray irradiation (In EP, IP condition)
010	Appears when inverter board falsely recognizes the exposure switch signal as OFF after the irradiation On command
011	Appears when X-ray OFF command is not sent to 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.

10.2.1.2 Subcode - Motor related error (002)

Tail code	Description
021	Appears during rotator-axis motor origin movement
027	Appears during Cephalo sensor motor origin movement
037	Appears during generator tilting

10.2.1.3 Subcode – Exposure switch related error (003)

Tail code	Description
060	It appears if the exposure switch is pressed when turning on the equipment.
061	It appears if X-ray exposure is stopped by releasing the exposure switch.

10.2.1.4 Subcode – Other error (004)

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

10.2.2 Main code – Software (002)

10.2.2.1 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

10.2.2.2 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

10.2.2.3 Subcode – PC Network related error (024)

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

10.2.3 Main code - Acquisition Module (003)

10.2.3.1 Subcode – Initialization Failure related error (010)

Tail code	Description
000	Appears when 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

10.2.3.2 Subcode – Capture Failure related error (020)

Tail code	Description
000	Appears when there is a capture error

10.2.3.3 Subcode – Reconstruction Failure related error (030)

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

10.2.3.4 Subcode – Hardware related error (061)

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

Left blank intentionally

11. Cleaning and Disinfection

⚠WARNING	Always turn off the power to the equipment and disconnect it from the power outlet before cleaning.
⚠CAUTION	The liquid can cause damage to the equipment. When cleaning or disinfecting, liquids may enter the equipment or the release button via the ventilation slots. ▪ Do not spray the equipment with Cleaners or disinfectant agents. Apply the Cleaners or disinfectant agents to a clean cloth and wipe it. ▪ Make sure that no liquids run along the surface into the ventilation slots or release button. ▪ Remove any soiling with a soft, wet, lint-free cloth. ▪ Please follow the Cleaners or disinfectant agents' instructions for use. ▪ When cleaning or disinfect the surfaces, always disconnect the equipment from mains. Do not use spray cleaner or disinfectant directly onto the equipment, as this could cause a fire.

- Cleaners or disinfectant agents may contain powerful ingredients. Unsuitable cleaning and disinfectant agents are detrimental to health and attack the surface of the equipment.
- Do not use cleaners or disinfectant agents containing Phenol, acetic acid, peroxide, or other oxygen splitting agents, sodium hypochlorite, isopropyl alcohol (2-propanol, isopropanol) or iodine- splitting agents.
- Comply with the specifications contained in the operating instructions of the Cleaners or disinfectant agents.
- Wear safety gloves.

11.1 Cleaning

- Thoroughly clean the areas of the equipment that come in direct contact with the patient, such as the Chinrest and the Bite.
- The equipment surfaces can be cleaned with a soft cloth damped in an non-alcohol based, non-corrosive cleaning solution. Do not use sponges or, in any case, any material that can be reused.

- Do not use spray cleaners or solvents as they could flow into the equipment and damage the electrical components or cause a fire.
- Do not use any cleaning products which contain silicon. They could potentially damage the equipment's electrical components.

The following table summarizes the standard cleaning procedures to be performed by the operator.

Components	Cleaning Process
Bite (Normal Bite, Special Bite A, and Special Bite B)	Clean with non-alcohol based, non-corrosive cleaning solution and gently wipe with a dry towel before the next patient.
Chinrest	Clean with non-alcohol based, non-corrosive cleaning solution and gently wipe with a dry towel before the next patient.
Computer and peripherals	Follow the manufacturers' instructions found in the accompanying manuals.
Outer covers of equipment	Wipe the unit with a dry cloth at the end of each day.

IMPORTANT	Do not use cleaning agents in aerosol or spray form directly on the surface of the equipment.

11.2 Disinfection

- Use only disinfectants that comply with the valid requirements of the respective national regulatory body or whose bactericidal, fungicidal, and virucidal properties have been verifiably tested and approved accordingly.
- Sterilization and disinfection should be performed thoroughly for items that have been in frequent contact with patients and operators.
- Do not use UV systems to disinfect the equipment, as exposed parts of the equipment can turn yellow or discolor.
- The use of unsuitable Cleaners or disinfectant agents and methods can damage the equipment and accessories. Only use the Cleaners or disinfectant agents specified or approved by VATECH
- The following Cleaners or disinfectant agents have been evaluated for safe use on the surfaces.
- Never combine products with each other or with liquids other than the products listed above.
- Damages to surfaces and materials due to the use of different products cannot be excluded even if they are not included in the exceptions mentioned above.
- Use a non-alcoholic chlorine dioxide-based disinfectant.

12. Maintenance

NOTICE	The equipment must be installed and maintained on a flat surface.

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

Only **VATECH**-authorized technicians can perform inspection and service for the equipment. For technical assistance, contact the **VATECH** service center or your local **VATECH** representative.

12.1 Regular Maintenance

⚠WARNING	▪ Always turn off the equipment before performing any maintenance. ▪ Never remove equipment covers. There are no repairable parts inside. ▪ The only parts that can be replaced by the user are the input fuses, which must comply with the manufacturer's specifications. ▪ As a precaution against fire, the replacement should be one in the same type and range.
IMPORTANT	▪ There are no user-serviceable parts inside this equipment. ▪ If any service is required, please contact the **VATECH** service center or your local **VATECH** representative.

- Do not unplug cables by force.
- Do not expose the equipment or components in an area that is susceptible to water or humidity.
- Do not expose the equipment in an area of extreme fluctuation in temperature, poor ventilation, direct sunlight, dust, salt, etc.
- Keep all detachable components well organized and clean.
- Make sure that the equipment is well-grounded.
- Never try to modify this equipment, including the wires or cables. Doing so may damage it beyond repair.

12.2 Maintenance Task Checklist

Tasks	Period
Before the operation, ensure that the equipment is clean and ready for use. Make sure that all parts that come in direct contact with the patient have been cleaned thoroughly.	Daily
After using the equipment, make sure that the **Main Power Switch** has been turned off.	Daily
Ensure that the equipment is firmly plugged into a dedicated power source.	Daily
Ensure that the plug and the power cord are not heated abnormally.	Daily
Confirm that the LED indicator turns yellow when **the Exposure Switch** is pressed. Ensure that the LED indicator remains yellow for the entire duration of the exposure.	Daily
Ensure that the power cable is not kinked, broken, exposed, and free of all other defects.	Daily
Confirm that activating the **Emergency Stop Switch** ceases the unit's operation. Pressing the **Emergency Stop Switch** should stop all movement of the equipment and X-ray emission.	Weekly
Ensure that all visible labels are intact and legible.	Weekly
Check for damages to the **Exposure Switch** cable.	Monthly
Confirm that the audio message is audible throughout the exposure.	Monthly

12.3 QA Test

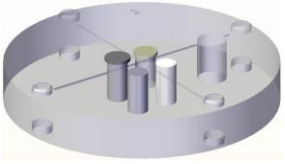
This section is intended to give information about PHT-30CSS PHANTOM KIT for 3D IMAGE QUALITY INSPECTION and CALIBRATION. It is recommended that you thoroughly familiarize yourself with this guide to perform the regular QA test effectively by using the PHANTOM KIT. QA tests should be done annually at the frequency specified by the manufacturer or state regulations in which the X-ray system is being used.

12.3.1 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

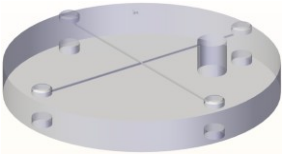
12.3.2 Specifications of Phantom Kit Contents

CT Number Check Phantom



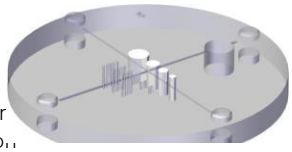
- Manufacturer
  - **VATECH Co., Ltd.**
- Intended Use
  - CT Number Inspection
  - CT Number Calibration
- Complies with
  - IEC 61223-2-6
  - IEC 61223-3-5

Uniformity Check Phantom



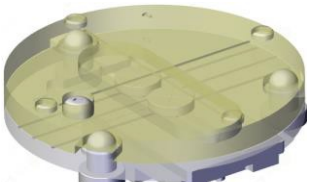
- Manufacturer
  - **VATECH Co., Ltd.**
- Intended Use
  - CT Image Homogeneity Inspection
  - CT Image Noise Inspection
- Complies with
  - IEC 61223-2-6
  - IEC 61223-3-5

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

12.4 QA Test Procedure

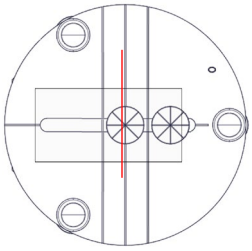
- Each facility shall establish a committee of individuals to be responsible for the Radiation Safety/Quality Assurance program. For a non-hospital facility, this committee might be composed of a dentist, an X-ray technician, an office manager, and a service representative who is certified to perform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

12.4.1 QA CT Number Test

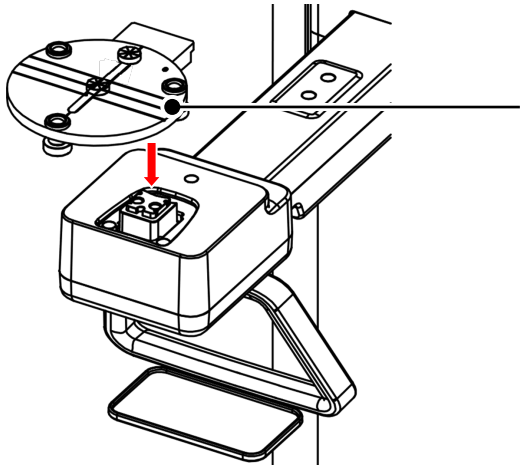
Follow the CT Number Test procedure below to produce correct images and analyze the User Phantom. Test results must be documented and maintained for at least one year. The CT number for water should be recorded and compared each day to the established specifications.

12.4.1.1 Setting up CT Number Phantom

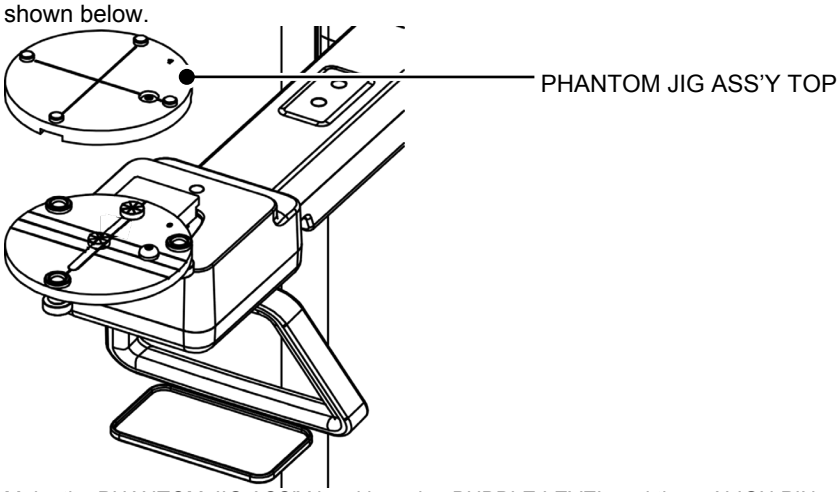
1. Remove Bite and Temple Supports from the Unit.
2. Align the PHANTOM FIXING BOLTs to the PHANTOM JIG BOTTOM base line as shown below and turn the bolts clockwise to tighten them.



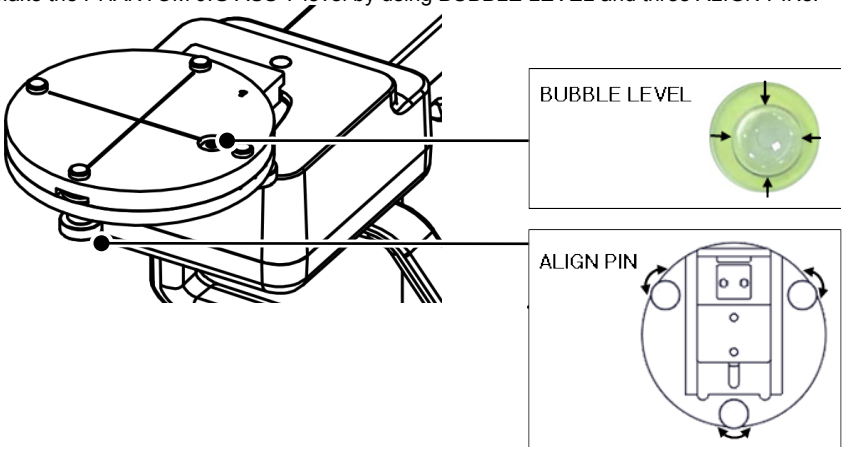
3. Insert the PHANTOM JIG BOTTOM into the Chinrest and then put the PHANTOM JIG TOP on the PHANTOM JIG BOTTOM.



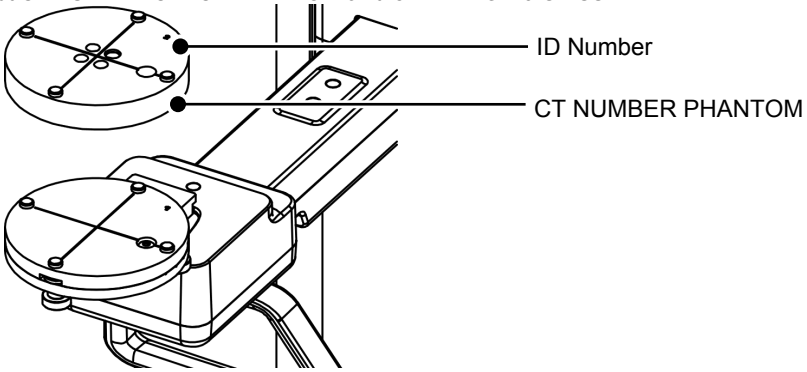
4. Put the PHANTOM JIG ASS'Y TOP on the PHANTOM JIG ASS'Y BOTTOM as shown below.



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



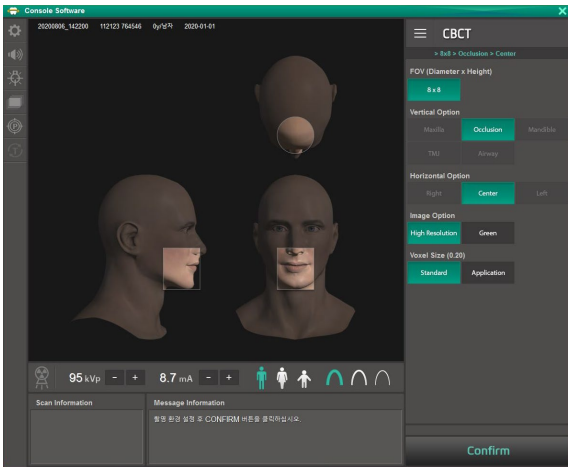
6. Put CT NUMBER CHECK PHANTOM on the PHANTOM JIG ASS'Y.



7. Run the EzDent-i and click to add a patient for QA TEST.

12.4.1.2 Imaging CT Number Phantom

1. Click CT to run Console Software in EzDent-i.
2. Choose the **CBCT** button in the Console Software.
3. Select an item below.

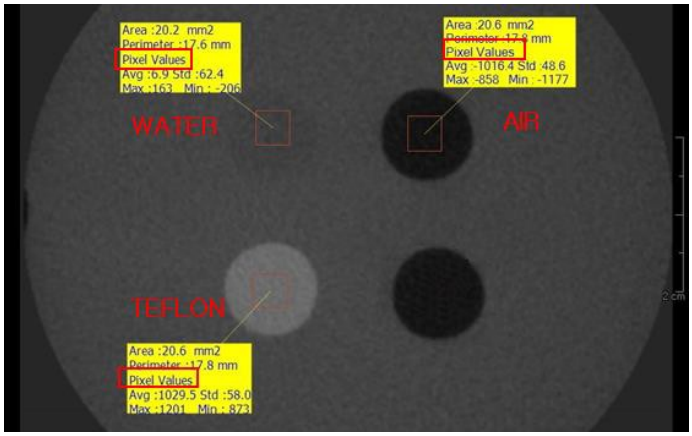


Item	Value
FOV (Diameter x Height)	8 x 8
Image Option	High Resolution
Voxel Size (0.20)	Standard
Gender/Age group	Man
X-ray Intensity	Hard

4. Click the **Confirm** button.
5. Click the **READY** button when enabled.
6. Capture the PHANTOM image according to Console Software instructions.
7. When image capturing is completed, save the image in EzDent-i.

12.4.1.3 Analyzing CT Number Phantom

1. Double-click the saved PHANTOM image in EzDent-i to run Ez3D-i.
2. In the Axial pane, double click the pane to maximize the Axial view.
3. Click  .
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.

5. Compare the CT NUMBER average values from the WATER, TEFLON, 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	

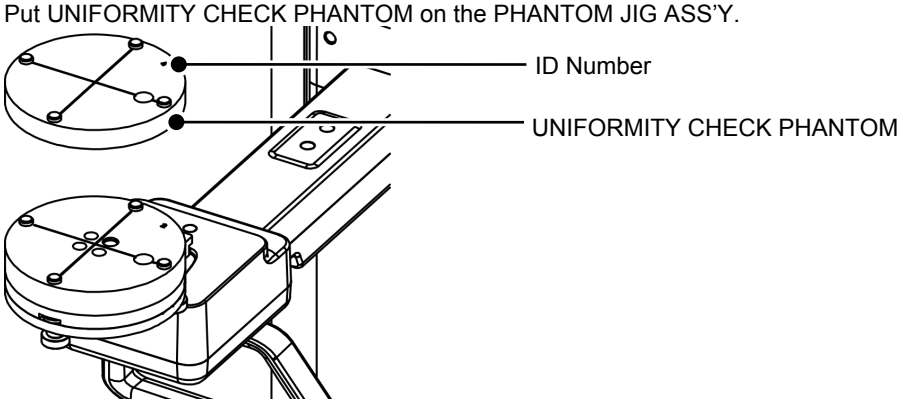
6. Record the mean CT Number value of each material.
7. Click  and save the captured screen in EzDent-i.
8. Remove User Phantom from the PHANTOM JIG ASS'Y.

12.4.2 QA CT Uniformity Test

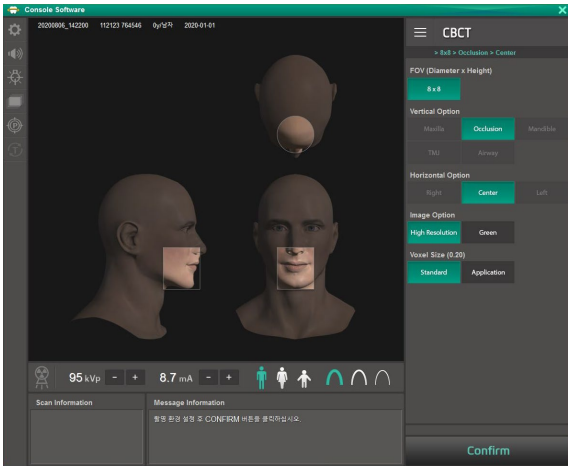
Follow the CT Uniformity Test procedure below to correctly image and analyze the CT Uniformity Check Phantom. Test results must be documented and maintained for at least one year.

12.4.2.1 Imaging 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 by using BUBBLE LEVEL and three ALIGN PINs.
4. Put UNIFORMITY CHECK PHANTOM on the PHANTOM JIG ASS'Y.



5. Click CT to run Console Software in EzDent-i.
6. Choose the **CBCT** button in the Console Software.
7. Select an item below.



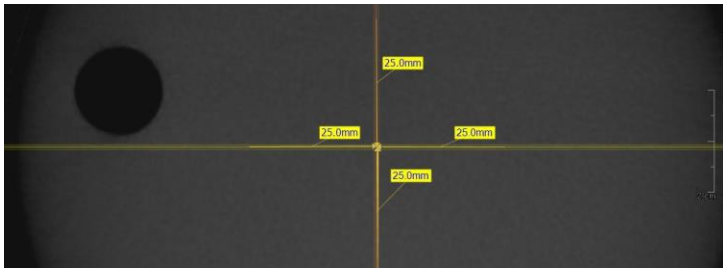
Item	Value
FOV (Diameter x Height)	8 x 8
Image Option	High Resolution

Item	Value
Voxel Size (0.20)	Standard
Gender/Age group	Man
X-ray Intensity	Hard

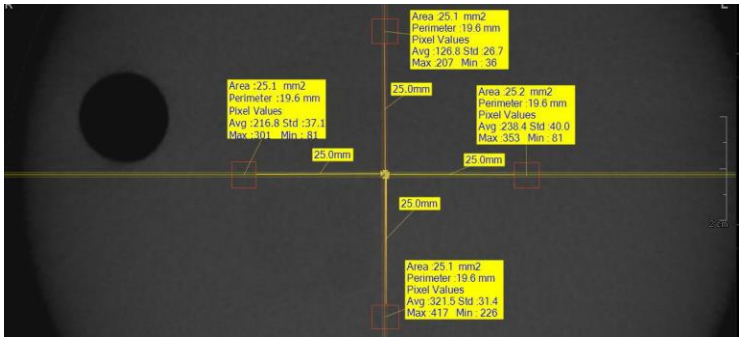
8. Click the **Confirm** button.
9. Click the **READY** button when enabled.
10. Capture the PHANTOM image according to Console Software instructions.
11. When image capturing is completed, save the image in EzDent-i.

12.4.2.2 Analyzing CT Uniformity Check Phantom

1. Double-click the saved PHANTOM image in **EzDent-i** to run **Ez3D-i**.
2. In the Axial pane, double click pane 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. Make the four boxes next to each 25mm line as shown below.



Try to make each box as close to 25.0 mm2 in the area as possible.

Put the 4 ROIs at the end of each 25mm line.

7. Measure the HOMOGENEITY by calculating the difference between Max. average value and min. average value among the 4 ROIs and compare it with its standard.

CALCULATION	EVALUATION	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  and save the captured screen in EzDent-i.
10. When finished, exit **EzDent-i.**

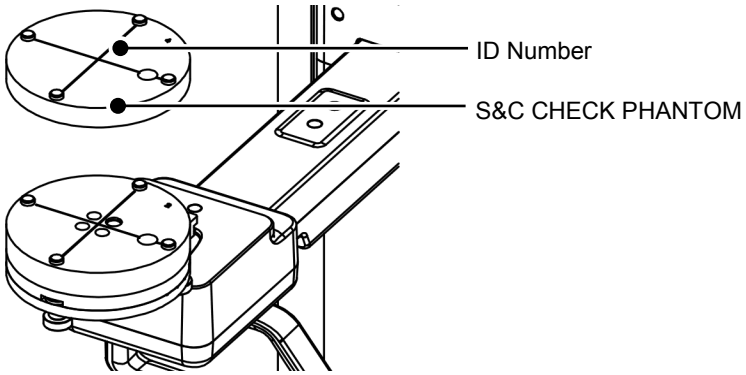
12.4.3 High Contrast and Low Contrast Resolution Tests

Test Frequency
- HIGH CONTRAST RESOLUTION: Initially and Yearly
- LOW CONTRAST RESOLUTION: Initially and Yearly

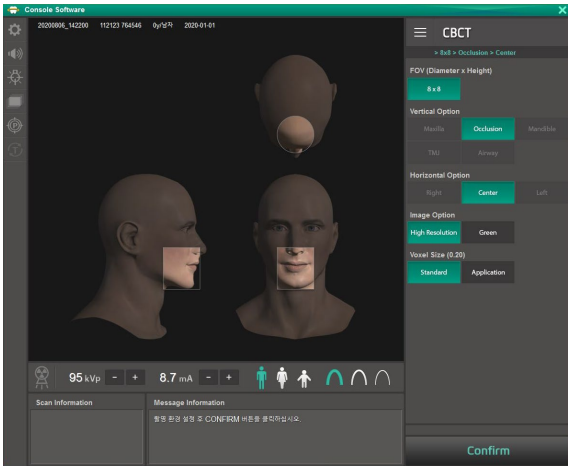
Follow the High and Low Contrast Resolution Test procedure below to correctly image and analyze the S&C Check Phantom. Test results must be documented and maintained for at least one year.

12.4.3.1 Imaging S&C 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 by using BUBBLE LEVEL and three ALIGN PINs.
4. Put S&C CHECK PHANTOM on the PHANTOM JIG ASS'Y.



5. Click CT to run Console Software in EzDent-i.
6. Choose the **CBCT** button in the Console Software.
7. Select an item below.



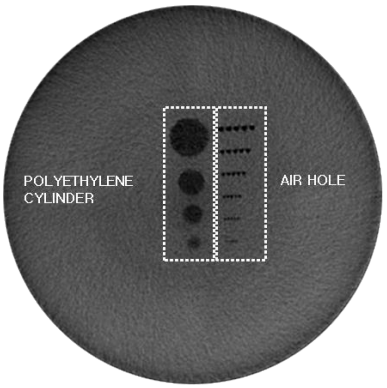
Item	Value
FOV (Diameter x Height)	8 x 8
Image Option	High Resolution
Voxel Size (0.20)	Standard
Gender/Age group	Man
X-ray Intensity	Hard

8. Click READY button when enabled.
9. Capture the PHANTOM image according to Console Software instructions.
10. When image capturing is completed, save the image in EzDent-i.

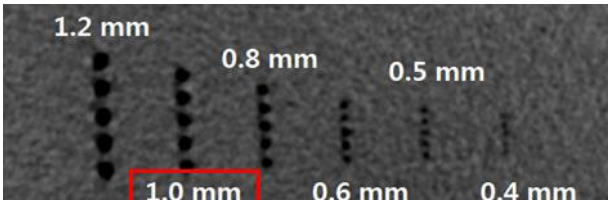
12.4.3.2 Analyzing S&C Check Phantom

1. Remove Bite and Temple Supports from the Unit.
2. Double-click the saved PHANTOM image in EzDent-i to run Ez3D-i.
3. Go to the Axial view and double click the pane for full-screen mode.
4. Adjust the contrast by using WINDOWING Icon.

5. Adjust the Brightness by using WINDOWING Icon.
6. Make sure that you can see the minimum size of the Airhole and the PE (Polyethylene) cylinder at a distance of 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



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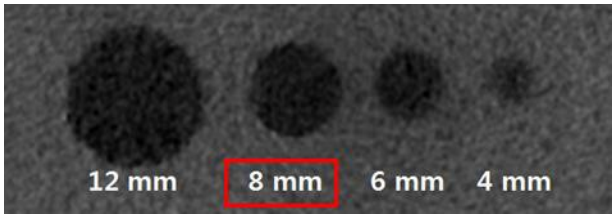

<Low Contrast Resolution>

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13. Disposing of the Equipment

To reduce environmental contamination, this equipment is designed to be as safe as possible to use and to be deposed. Many components of this equipment, except for some like the X-ray tube, are environment-friendly and can be recycled.

All parts and components which 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 it and disposing of its parts.
NOTICE	Observe all regulations relevant to the disposal of waste in your country.

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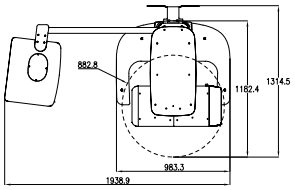
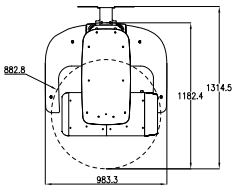
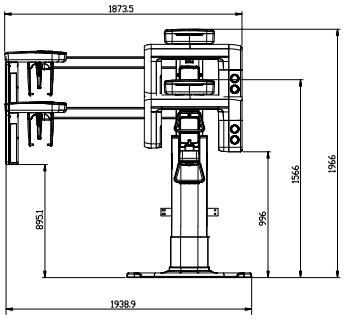
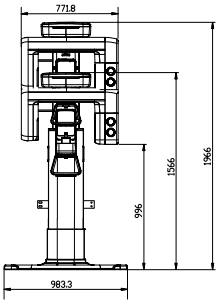
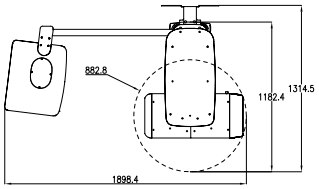
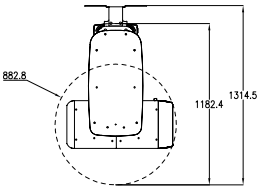
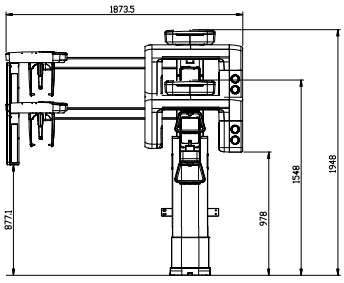
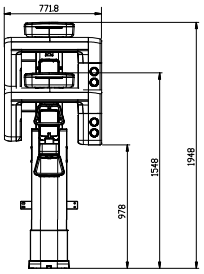
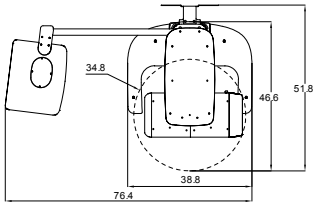
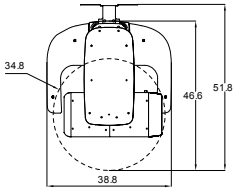
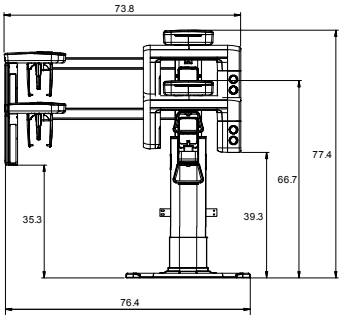
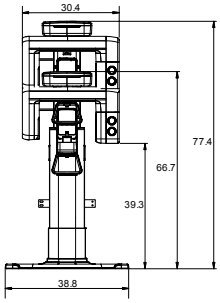
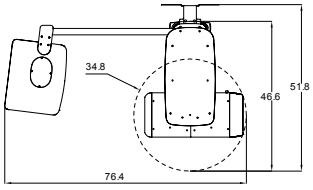
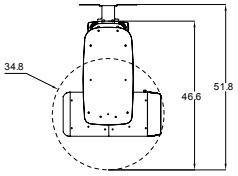
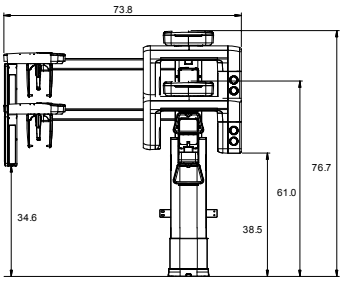
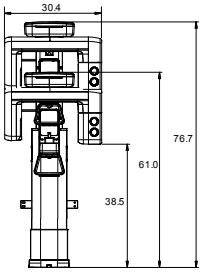
14. Technical Specifications

14.1 Mechanical Specifications

14.1.1 Dimensions

unit = mm	With CEPH	Without CEPH
Top view (with Base)		
Front View (with Base)		
Top view (without Base)		
Front View (without Base)		

unit = inch	With CEPH	Without CEPH
Top view (with Base)		
Front View (with Base)		
Top view (without Base)		
Front View (without Base)		

Item		Description
Weight	Without CEPH unit	108.3 kg (238.76 lbs. - without Base)
		160.5 kg (353.84 lbs. – with Base)
	With CEPH unit	134.3 kg (296.08 lbs. - without Base)
		186.5 kg (411.16 lbs. - with Base)
Total Height	Without Base	Max. 1948 mm (76.7”)
	With Base	Max. 1966 mm (77.4”)
Dimensions during operation (Length x Width x Height)	Without CEPH unit	without Base: 882.8 (L) x 1314.5 (W) x 1948.0 (H) (mm) 34.8 (L) x 51.8 (W) x 76.7 (H) (inch)
		with Base: 983.3 (L) x 1314.5 (W) x 1966.0 (H) (mm) 38.8 (L) x 51.8 (W) x 77.4 (H) (inch)
	With CEPH unit	without Base: 1898.4 (L) x 1314.5 (W) x 1948.0 (H) (mm) 76.4 (L) x 51.8 (W) x 76.7 (H) (inch)
		with Base: 1938.9 (L) x 1314.5 (W) x 1966.0 (H) (mm) 76.4 (L) x 51.8 (W) x 77.4 (H) (inch)
Installation type		Base Stand/Wall Mount (Default: Wall Mount type)
Packing Box Organization		Main Box, CEPH Box (Optional), Base Box (Optional)

14.1.2 Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	584.6	425.6	159	1.374
CBCT	584.6	353.6	231	1.653
CEPH	1745	1524	221	1.145

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

14.2 Technical Specifications

14.2.1 X-ray Generator Specifications

Specifications

Item			Description
Generator	Model		DG-07F23T4
	Rated output power		1.0 kW
	Inverter model name		INV-23
	Type		Inverter
	Normal/ Pulse	kVp	60 kV ~ 99 kV (1 kV increment)
		mA	4 mA ~ 12 mA (for 60 kV ~ 80 kV) 4 mA ~ 10 mA (for 60 kV ~ 99 kV) (0.1 mA increment for CBCT, 1 mA increment for PANO and CEPH)
	Cooling		Thermal protect (fan cooling ≥ 35 ℃ (95 °F))
	Total filtration		Min. 2.5 mmAl
	Default filtration		1.0 mm Al
	Added filtration		1.5 mm Al (Fixed)/PANO and CEPH mode 1.5 mm Al (Fixed) + 3.0 mm Al (Automatically added)/CBCT mode
Tube	Manufacturer		Canon Electron Tubes & Devices
	Model		D-054SB (Stationary Anode type)
	Focal spot size		0.5 mm
	Target Angle		5 degree
	Inherent Filtration		At least 0.8 mm Al equivalent at 50 kV
	X-ray Coverage		75 mm x 380 mm at SID 550 mm
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time: Interval time)

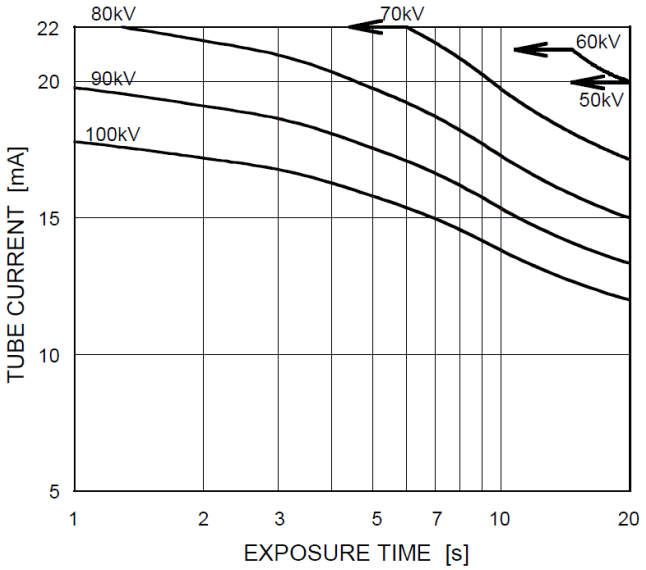
Test Condition

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	60~80	4~12	2.7
	60~80	4~12	4.4
	60~80	4~12	5.7
	60~80	4~12	6.4
	60~80	4~12	6.7
	60~80	4~12	8.5
	60~80	4~12	8.8
	60~80	4~12	9.2
	60~80	4~12	9.4
	60~80	4~12	11.2
	60~80	4~12	11.4
	60~80	4~12	13.5
CEPH	60~99	4~10	1.9
	60~99	4~10	2.4
	60~99	4~10	3.9
	60~99	4~10	4.9
	60~99	4~10	5.4
CBCT	60~99	4~10	15.5

Maximum Rating Charts

Constant Potential High-voltage Generator

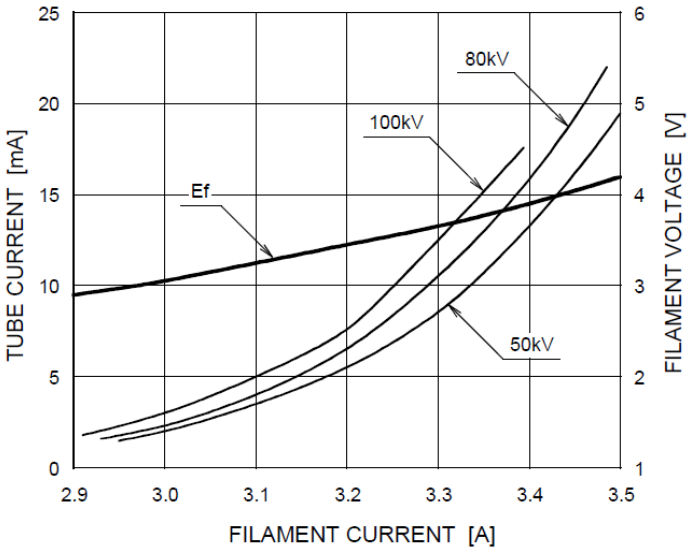
Nominal Focal Spot Value: 0.5



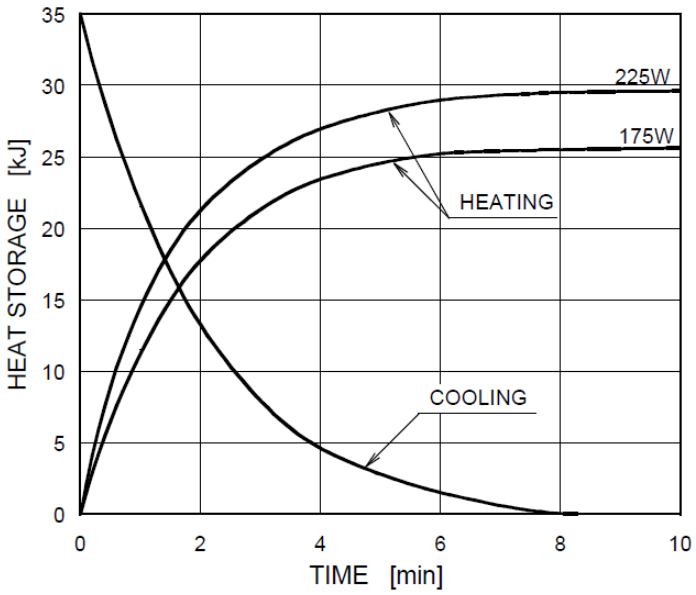
Emission & Filament Characteristics

Constant Potential High-voltage Generator

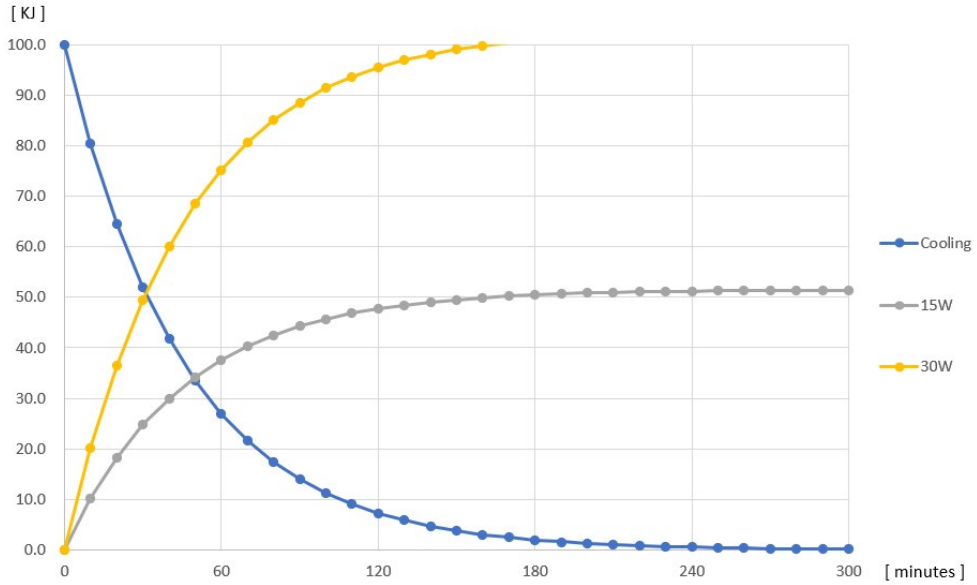
Nominal Focal Spot Value: 0.5



Anode Thermal Characteristics



X-ray Housing Assembly Tube Characteristics



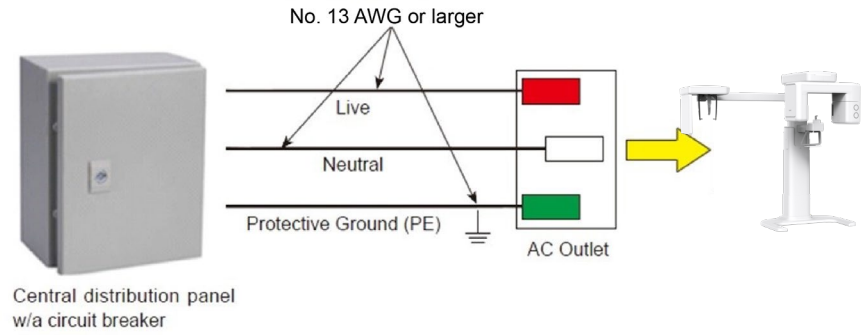
14.2.2 Detector Specifications

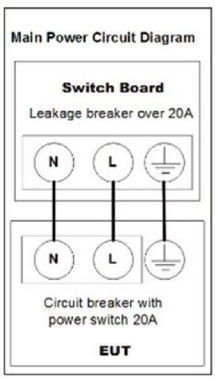
Item	Description	
	PANO & CBCT	CEPH
Model	Xmaru1404CF-Plus	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 μm @ 4x4 binning	200 μm @ 2x2 binning
Active area	135.8 x 36.4 (mm)	259.2 x 15.6 (mm)
Frame Rate	~ 308 fps @ 4x4 binning	~330 fps @ 2x2 Binning
Analogue-Digital Conversion	14 bits	
Operating condition	10~35 ℃ (Temperature) 10~75 % (Humidity)	
Storage condition	-10~60 ℃ (Temperature) 10~75 % (Humidity)	
Sensor size	160(L) x 230(W) x 26(H) (mm)	110(L) x 279(W) x 20(H) (mm)
Sensor weight	1.5 kg	Less than 1.3 kg
Converter	CsI : Ti	
Energy Range	50~120 kVp	
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 45 % @ 1 lp/mm	> 8 % @ 2.5 lp/mm
DQE	> 60 % @~0 lp/mm	> 70 % @~0 lp/mm
Dynamic Range	> 80 dB	> 70 dB

14.3 Electrical Specifications

Item	Description
Power supply voltage	100-240 V~
Frequency	50/60 Hz
Power rating	1.7 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: Continuous operation with intermittent loading - Needs waiting time (at least 60 times the exposure time) before the next exposure begins.





NOTICE

- To assure line voltage quality, 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.
- 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 ohms at 100 V and 0.19 ohm at 240 V.

14.4 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

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15. Appendices

15.1 Recommended X-ray Exposure Tables

15.1.1 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	12
			Normal	74	12
			Soft	73	12
		Woman	Hard	74	12
			Normal	73	12
			Soft	72	12
		Child	Hard	68	10
			Normal	67	10
			Soft	66	10
SPECIAL Examination	N/A	Man	Hard	75	12
			Normal	74	12
			Soft	73	12
		Woman	Hard	74	12
			Normal	73	12
			Soft	72	12
		Child	Hard	68	10
			Normal	67	10
			Soft	66	10

Scan Time/Exposure Time

Examination Mode	Arch Type	Examination Mode	High Resolution	
			Scan Time (s)	Exposure Time (s)
PANO Examination	Narrow	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
	Normal	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
	Wide	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
	Child	Standard	11.9	11.4
		Right	11.9	5.7
		Front	11.9	9.2
		Left	11.9	5.7
	Orthogonal	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
		Bitewing	14.1	8.8
		Bitewing Incisor (Optional)	14.1	2.7
		Bitewing Right	14.1	4.4
		Bitewing Left	14.1	4.4
SPECIAL Examination	-	TMJ LAT Open	14.1	6.4
		TMJ LAT Close		
		TMJ PA Open (Optional)	13.6	9.4
		TMJ PA Close (Optional)		
		Sinus LAT (Optional)	6.2	5.6
		Sinus PA	9.6	8.5

- 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.

15.1.2 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	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
	Green	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
Full Lateral (Optional)	High Resolution/ Green	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10

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	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
	Green	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
Carpus	High Resolution / Green	Man	Hard	90	6
			Normal	88	6
			Soft	86	6
		Woman	Hard	88	6
			Normal	86	6
			Soft	84	6
		Child	Hard	86	6
			Normal	84	6
			Soft	82	6

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 actual time that the patient is exposed to the X-ray emission.

15.1.3 CBCT Mode

Exposure Area

FOV (cm)	Vertical Position	Horizontal Position		
		Right	Center	Left
8x8	Occlusion	X	O	X

Exposure Condition

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
8x8	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	81	6.1
			Normal	80	6.1
			Soft	79	6.1
		Woman	Hard	81	5.8
			Normal	80	5.8
			Soft	79	5.8
		Child	Hard	81	5.5
			Normal	80	5.5
			Soft	79	5.5

Scan Time/Exposure Time

FOV (cm)	Scan Time (s) (High Resolution/Green)	Exposure Time (s) (High Resolution/Green)
8x8	18.0	15.5

- 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.

Reconstruction Time/File Size (Measured Object: Skull)

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)	File Size (MB)
8x8	0.2	110	154.0
	0.3	88	45.6

- The above data is obtained from a computer system which is 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.

15.2 X-ray Dose Data

15.2.1 DAP (Dose Area Product)

The X-ray dose data is extracted from the X-ray Dose Test Report for **vatech A9 (PHT-30CSS)**.

X-ray Dose Test Report for the **vatech A9 (PHT-30CSS)** maintains dosimetric evaluation that the **VATECH** dental diagnostic system meets all requirements specified in the IEC Collateral Standard. To limit unnecessary exposure to the patient, operator, or other staff, **vatech A9 (PHT-30CSS)** is designed to comply with IEC 60601-1-3 Part 1 General Requirements for Safety.

Test Hardware	
Brand Name (Model)	**vatech A9 (PHT-30CSS)**
Sensor Type	PANO & CBCT: Xmaru1404CF-Plus CEPH: Xmaru2602CF
X-ray Generator	DG-07F23T4
Tube	D-054SB

DAP (Dose Area Product) is a quantity used in assessing 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 ($mGy \cdot cm^2$). Despite the limitation, DAP is the best way to predict effective dose value and currently the most convenient method for patient doses monitoring.

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

Mode	Exposure Condition	DAP [mGy·cm²]
PANO Adult Man Normal (High Resolution)	74 kVp/12.0 mA/13.5 s	133
PANO Child Normal (High Resolution)	67 kVp/10.0 mA/11.4 s	82
CEPH Adult Man LAT (High Resolution)	90 kVp/10.0 mA/3.9 s	24
CEPH Child LAT (High Resolution)	86 kVp/10.0 mA/3.9 s	22
CEPH Adult Man LAT (Green)	90 kVp/10.0 mA/1.9 s	13
CEPH Child LAT (Green)	86 kVp/10.0 mA/1.9 s	12
CBCT 8x8 Adult Man (High Resolution)	94 kVp/7.0 mA/15.5 s	676
CBCT 8x8 Adult Man (Green)	80 kVp/6.1 mA/15.5 s	414

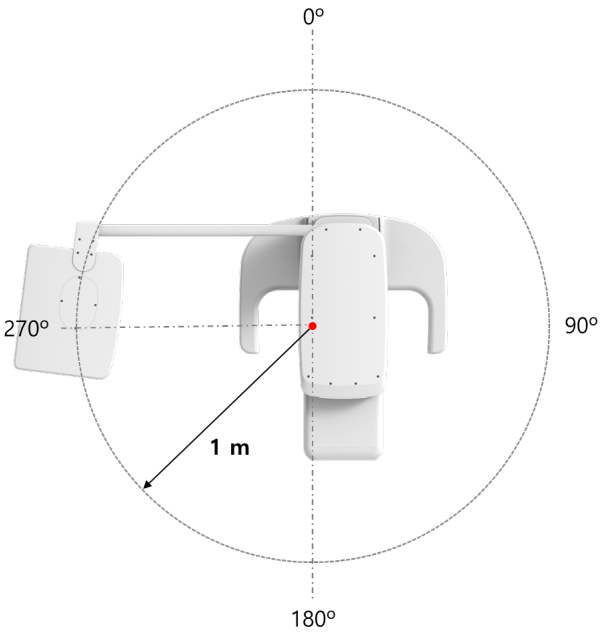
15.2.2 Leakage Dose

X-ray Leakage Dose Test Report for PHT-30CSS maintains dosemetric evaluation of the Vatech dental diagnostic system to meet requirements in IEC Collateral Standard. To limit unnecessary exposure to the patient, the operator, and other staff, PHT-30CSS is designed to fulfill IEC 60601-1 (IEC 60601-1-3, IEC 60601-2-63) and this document provides leakage test report with the evaluation condition and procedure.

15.2.2.1 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

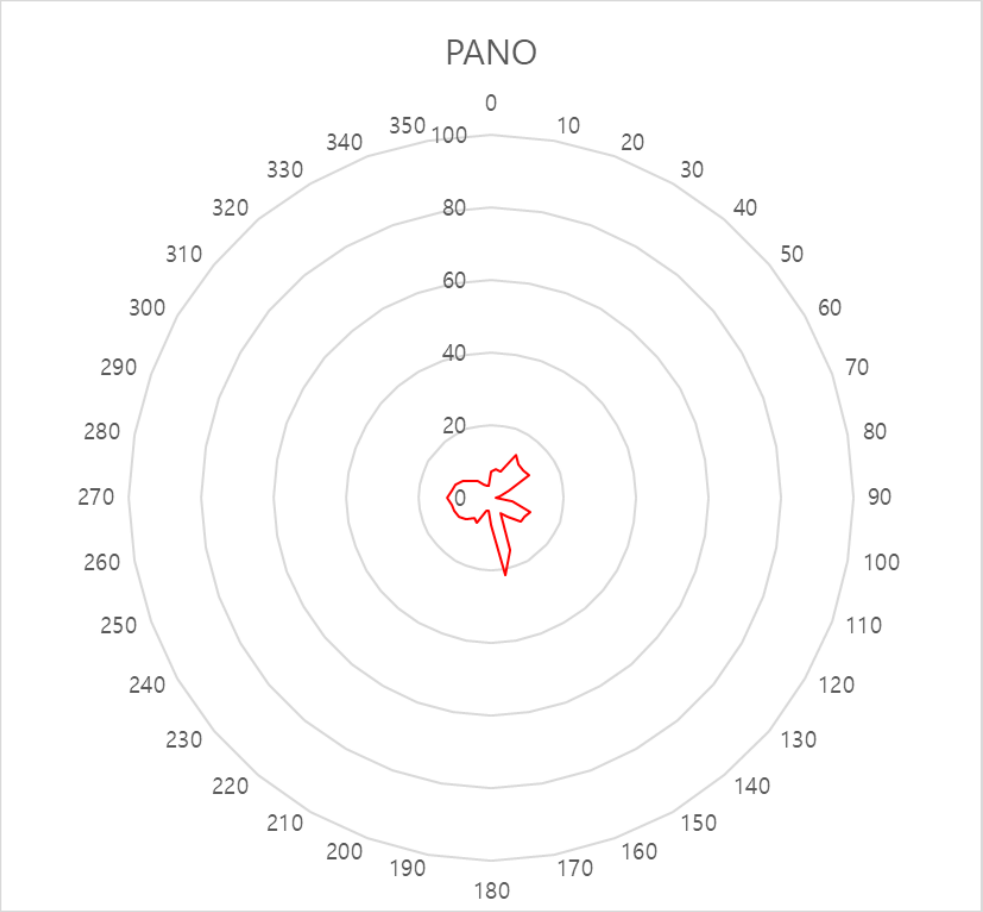
15.2.2.2 Measurement Overview



15.2.2.3 PANO Mode Results

Test Condition	
Tested Mode	PANO
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	80
Applied Tube Current [mA]	12

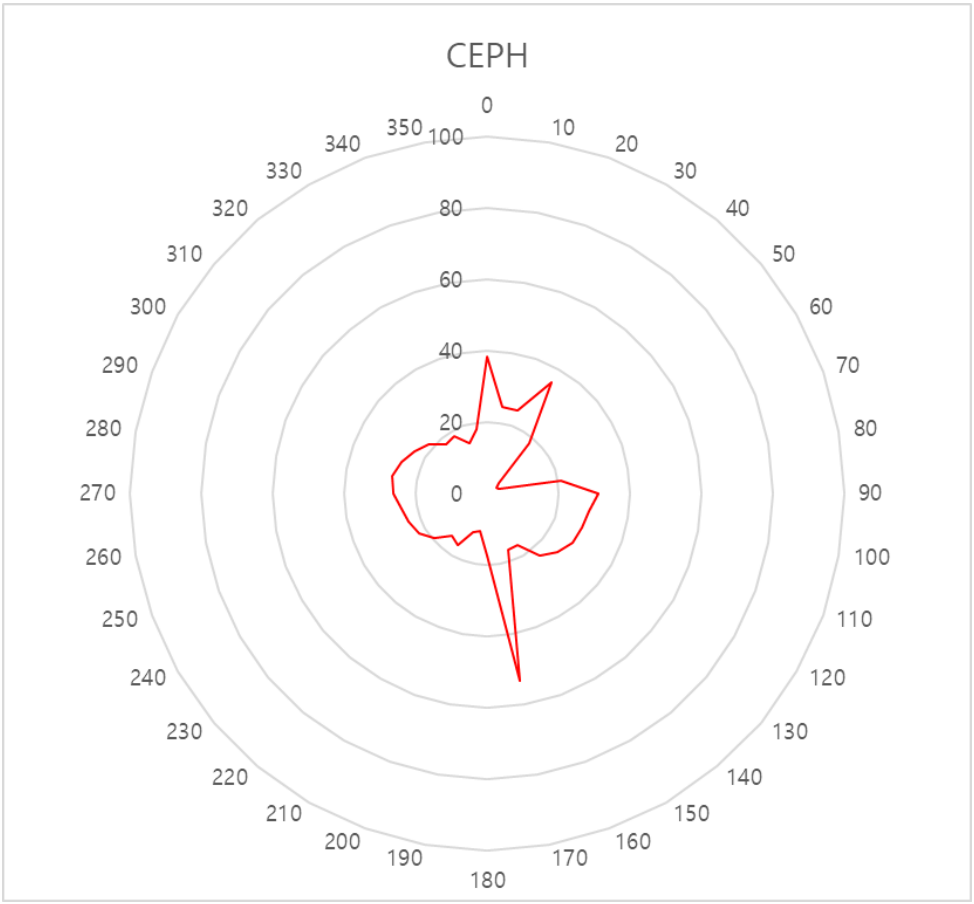
Mode / Direction [°]	PANO	
	[mR/hr]	[mGy/hr]
0	7	0.062
10	8	0.069
20	8	0.068
30	13	0.117
40	12	0.103
50	11	0.100
60	12	0.107
70	5	0.046
80	2	0.020
90	1	0.011
100	6	0.051
110	11	0.101
120	11	0.094
130	10	0.091
140	7	0.062
150	5	0.043
160	15	0.136
170	22	0.190
180	8	0.066
190	4	0.034
200	4	0.035
210	8	0.070
220	7	0.065
230	9	0.081
240	10	0.091
250	11	0.096
260	11	0.098
270	12	0.108
280	11	0.098
290	11	0.093
300	9	0.079
310	7	0.061
320	6	0.050
330	4	0.037
340	3	0.029
350	3	0.029



15.2.2.4 CEPH Mode Results

Test Condition	
Tested Mode	CEPH
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	10

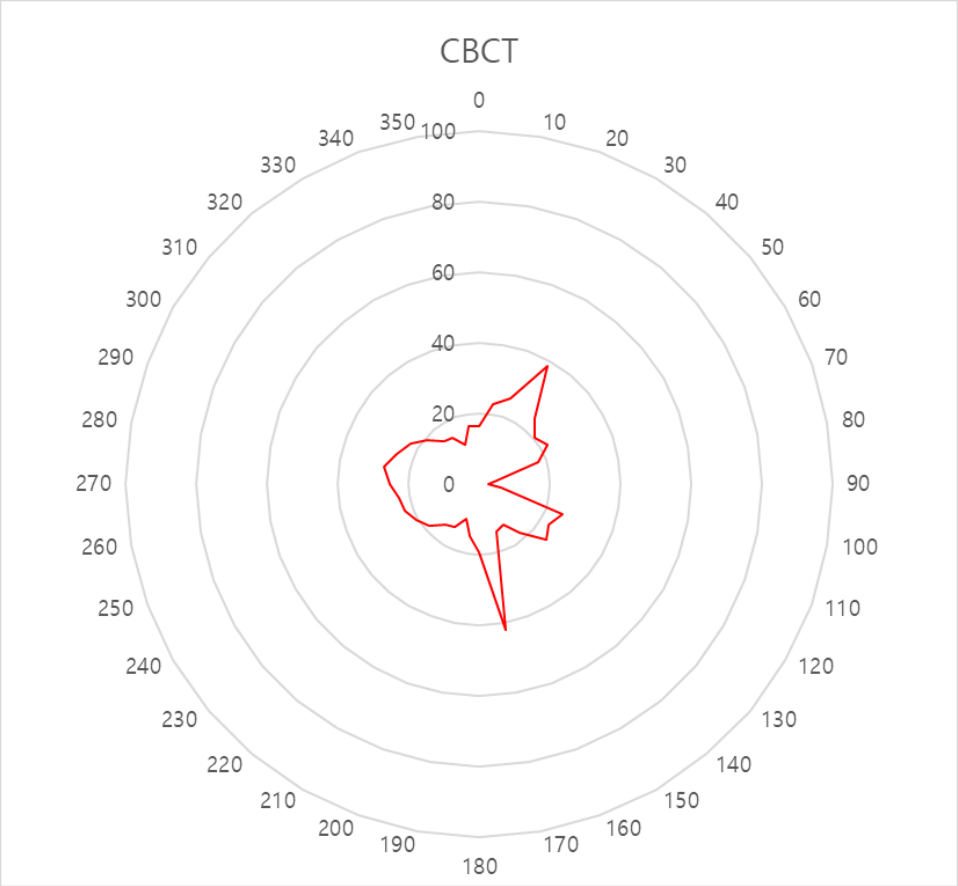
Mode / Direction [°]	CEPH	
	[mR/hr]	[mGy/hr]
0	38	0.337
10	25	0.216
20	25	0.218
30	36	0.316
40	18	0.161
50	4	0.037
60	3	0.027
70	3	0.030
80	21	0.185
90	31	0.274
100	29	0.254
110	28	0.246
120	28	0.242
130	26	0.225
140	23	0.199
150	17	0.146
160	17	0.148
170	53	0.467
180	17	0.153
190	11	0.095
200	11	0.101
210	17	0.147
220	16	0.137
230	19	0.171
240	22	0.195
250	24	0.207
260	24	0.215
270	26	0.231
280	27	0.238
290	25	0.224
300	23	0.206
310	22	0.189
320	18	0.157
330	18	0.162
340	15	0.130
350	18	0.160



15.2.2.5 CBCT Mode Results

Test Condition	
Tested Mode	CBCT
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	10

Mode / Direction [°]	CBCT	
	[mR/hr]	[mGy/hr]
0	16	0.143
10	23	0.200
20	26	0.226
30	39	0.338
40	24	0.212
50	20	0.179
60	22	0.196
70	18	0.157
80	5	0.043
90	3	0.023
100	6	0.055
110	25	0.221
120	23	0.200
130	25	0.218
140	18	0.157
150	13	0.118
160	14	0.126
170	42	0.369
180	19	0.171
190	15	0.133
200	10	0.092
210	14	0.125
220	15	0.133
230	18	0.162
240	21	0.180
250	22	0.196
260	23	0.203
270	25	0.223
280	27	0.239
290	25	0.219
300	23	0.198
310	19	0.168
320	16	0.137
330	15	0.132
340	12	0.103
350	17	0.146

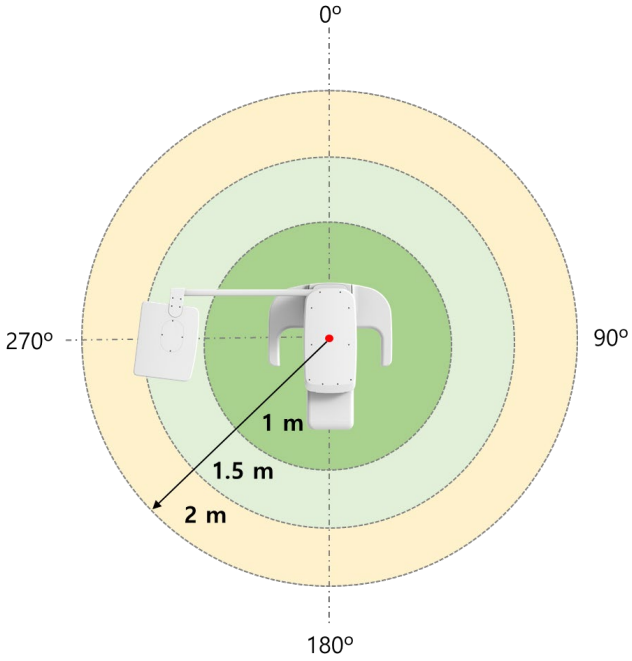

CBCT
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
150
160
170
180
190
200
210
220
230
240
250
260
270
280
290
300
310
320
330
340
350
100
80
60
40
20
0

15.2.3 Scattered Dose

X-ray Scattered Dose data concerning different angle and distance 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.

For Dental diagnosis equipment PHT-30CSS, controlled area is suggested to be a satisfied adequate condition that high level of scattered radiation within the room during exposures to restrict the exposure of the operator and staffs.

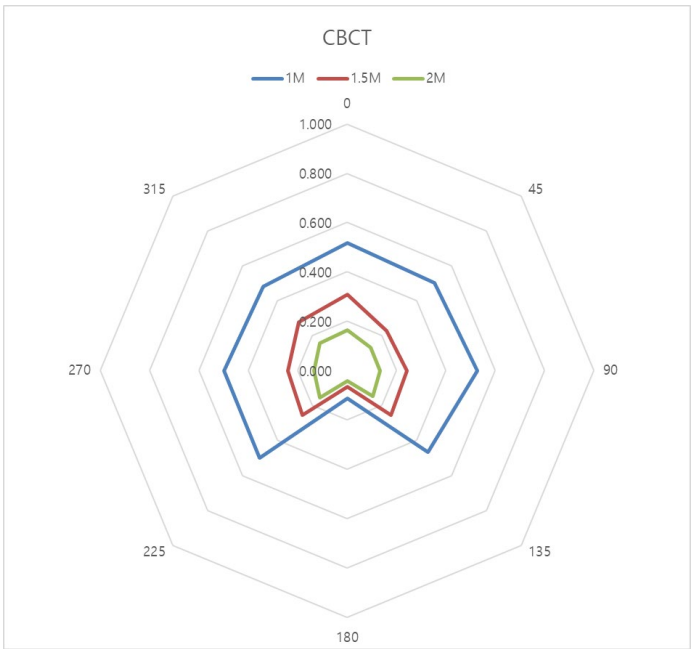
15.2.3.1 Measurement Overview



15.2.3.2 CBCT Mode Results

Test Condition	
Tested Mode	CBCT
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12
Applied Exposure time [sec]	15.5

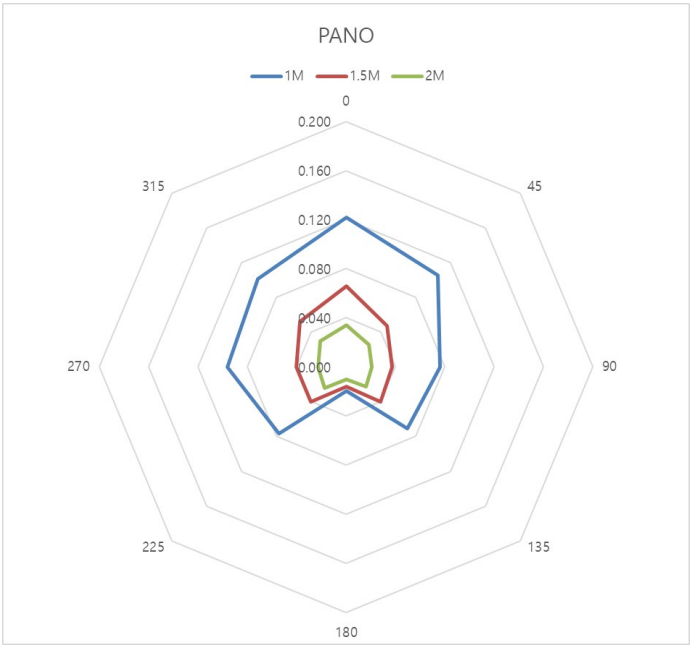
Direction [°] \ Mode		CBCT FOV 8x8 [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Occiput	0.517	0.307	0.166
45		0.502	0.229	0.133
90	Left ear	0.527	0.242	0.134
135		0.466	0.253	0.147
180	Nose	0.113	0.066	0.042
225		0.502	0.254	0.154
270	Right ear	0.500	0.239	0.135
315		0.483	0.276	0.158



15.2.3.3 PANO Mode Results

Test Condition	
Tested Mode	PANO
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	80
Applied Tube Current [mA]	12
Applied Exposure time [sec]	13.5

Direction [°] \ Mode		PANO Adult Normal [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Occiput	0.122	0.066	0.034
45		0.105	0.047	0.026
90	Left ear	0.077	0.038	0.021
135		0.071	0.040	0.023
180	Nose	0.019	0.016	0.010
225		0.077	0.040	0.024
270	Right ear	0.096	0.041	0.023
315		0.101	0.053	0.030

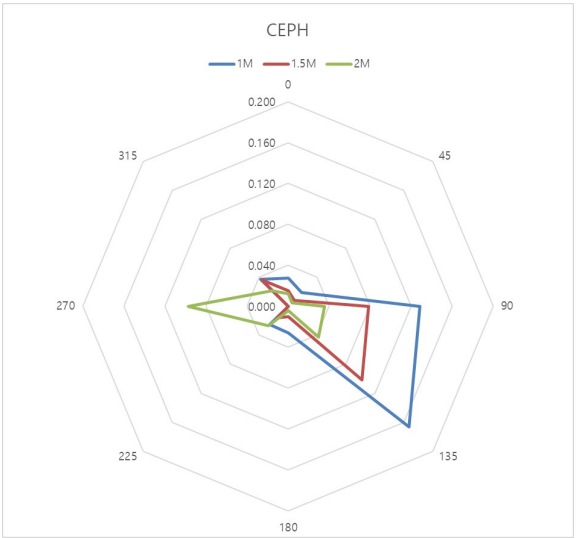


15.2.3.4 CEPH Mode Results

Test Condition	
Tested Mode	Ceph
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	10
Applied 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	0.027	0.015	0.012
45		0.019	0.009	0.005
90	Right ear	0.129	0.079	0.036
135		0.167	0.102	0.042
180	Occiput	0.026	0.010	0.004
225		0.025	0.016	0.027
270	Left ear	-	-	0.097
315		0.038	0.036	0.022

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.



15.3 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 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 power supply unit	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 power supply unit	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 Communic	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

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
ations Equipment					
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012 IEC 61000-4-4:2012	IDLE mode CT mode PANO mode CEPH mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line: ± 2 kV Signal: ±1 kV 100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2014 IEC 61000-4-5:2014	IDLE mode CT mode PANO mode CEPH mode	AC Mains of 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 EN 61000-4-8:2010 IEC 61000-4-8:2009	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
			Hand piece cable		
Power Frequency Magnetic Field Immunity	EN 61000-4-11:2004 IEC 61000-4-11: 2004	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 power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°,

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
				AC 240 V, 60 Hz	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 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

15.4 Acquiring Images for Pediatric Dental Patients

15.4.1 Age Group: Classification Table

Ages are classified loosely into the following correspondence between FDA definition and 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	

15.4.2 Positioning the Pediatric Dental Patients

1. Use a laser light beam guide to locate the midsagittal plane. Direct patient focusses on mirroring reflection. Affix decal to mirror to aid the patient in maintaining the correct position throughout the exposure.
2. Move the Chinrest into a position that is 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 that resembles the erect stance of a soldier.
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 in 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 product 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 growth and development of the pediatric patient and for evaluation of 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 skill.[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 the assessment of the pediatric patient while minimizing the occurrence of retakes that result from the 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.

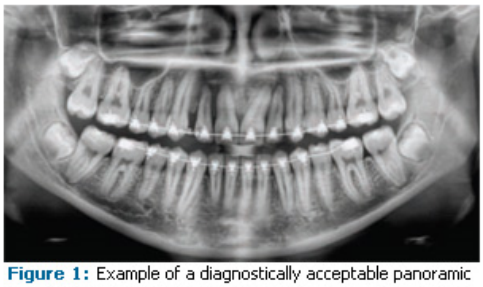


Figure 1: Example of a diagnostically acceptable panoramic radiograph of an adolescent patient undergoing orthodontic intervention. (Courtesy of Jamie Mace and Will Wright of Schick Technologies Inc.)

The most critical component in producing a diagnostically acceptable panoramic image is patient positioning. 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.

FEBRUARY 2009 Dimensions OF DENTAL HYGIENE

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, may be 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.

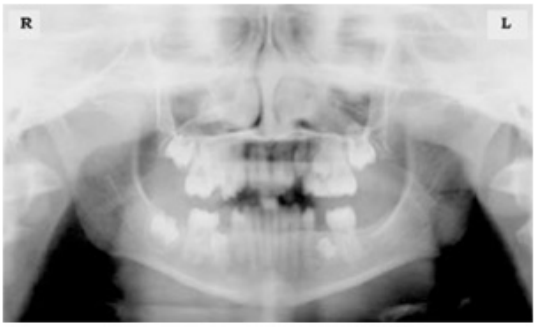


Figure 3: Incorrect position too far anteriorly. Note the narrow anterior teeth and superimposition of the spinal column over the condyles. The radiolucency superior to the maxillary apices indicates that the tongue was not placed against the palate. An open lip line can also be detected.

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 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 the pediatric patient 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.

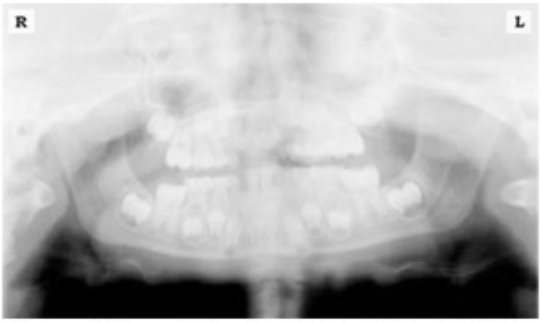


Figure 4: Incorrect lateral position tilted to the right. Note the teeth on the left are wide and poorly defined, while the teeth on the right are narrowed and severely overlapped. The inferior border of the mandible is distorted and the condyles appear asymmetrical.

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.

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.

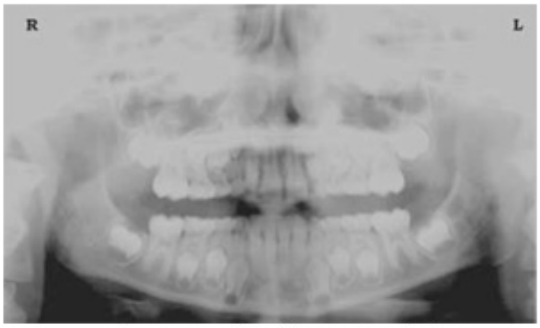


Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

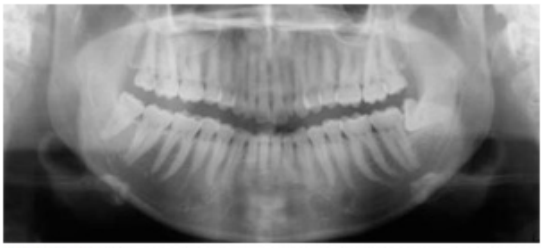


Figure 6: Chin positioned too far down. Note the characteristic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

Correct positioning of the arches in the superior-inferior dimension requires that the patient stands with 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 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 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 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 the pediatric patient, 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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15.4.3 Setting Exposure Values to the Age Group

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

15.4.4 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 is 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 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 the 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 to 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 of 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/

15.5 Abbreviations

3D	Digital Dental Design
AC	Alternating Current
AF	Auto-Focusing
AMPT	Adaptive layer Mode Panoramic Tomography
CAN	Controlled Area Network
CBCT	Cone-Beam Computed Tomography
CEPH	Cephalogram
CMOS	Complementary Metal-Oxide -Semiconductor
CRS	Chronic rhinosinusitis
CT	Computed Tomography
DAP	Dose Area Product
DC	Direct Current
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
EUT	Equipment Under Test
FDD	A focal spot to Detector Distance
FOD	A focal spot to Object Distance
FOV	Field of View
FPD	Flat Panel Detector
IEC	International Electrotechnical Commission
ISO	International Standards Organization

3D	Digital Dental Design
AC	Alternating Current
LCD	Liquid Crystal Display
LED	Light-Emitting Diode
MAR	Metal Artifact Reduction
MPSO	Multiple Portable Socket-Outlet
ODD	Object to Detector Distance
PA	Posterior/Anterior
PANO	Panoramic
PC	Personal computer, a general-purpose computer for individuals
RF	Radio Frequency
ROI	Region of Interest
SID	Source to Image Receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SPCC	Steel plate cold commercial
SMV	Submento-Vertical
SSXI	Solid State X-ray Imaging Device
STL	Stereo Lithography
SW	Software
TMJ	Temporomandibular Joint
UHD	Ultra-High Definition

Tel: (+82) 1588-9510

Email: gcs@vatech.com

Website: www.vatech.com

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

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

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EC REP

EC Representative; Vatech Global France (SARL)
51 Quai de Dion Bouton 92800 Puteaux France
Tel: +33 1 64 11 43 30
Fax: +33 1 64 11 43 39

vatech A9

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

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