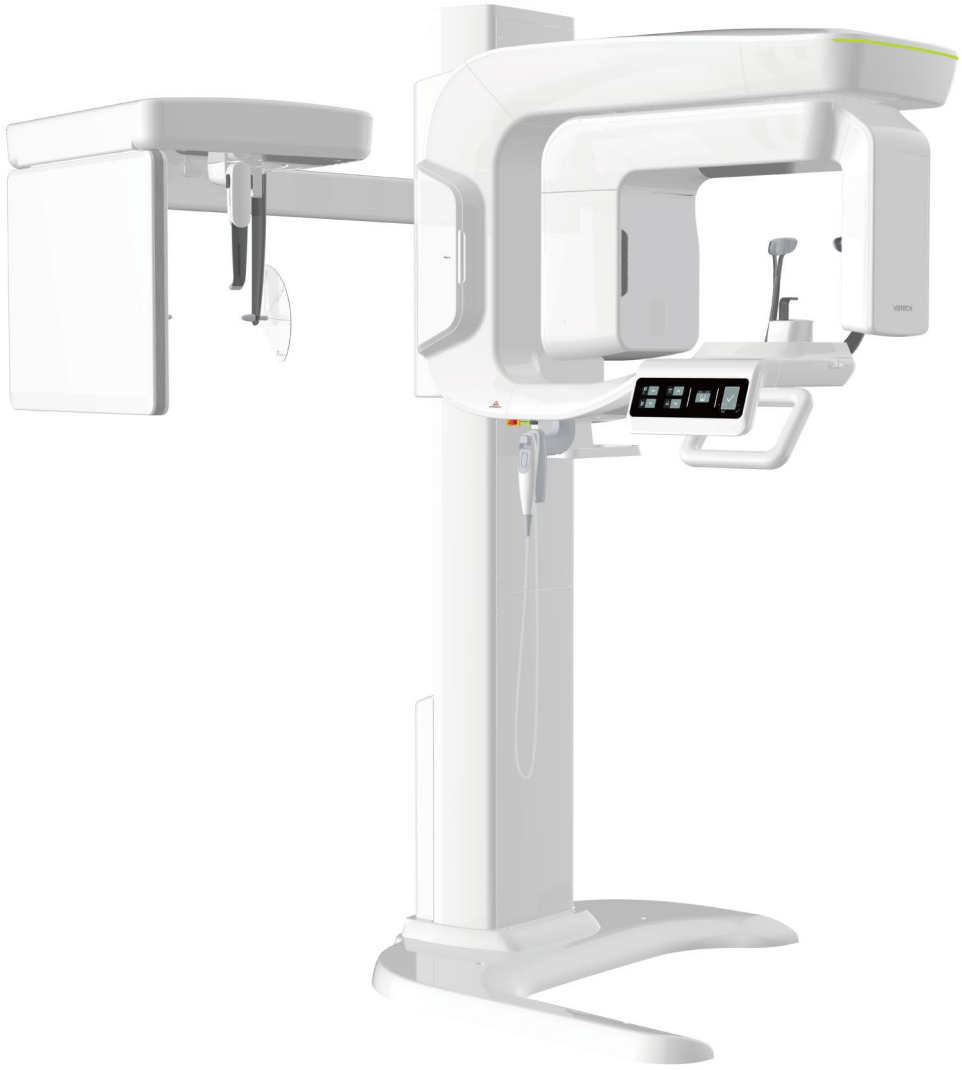
GREEN CT

vatech



GREEN SMART (Model:PHT-35LHS)

User Manual | **Version 1.23**

English

innovation inside

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

Notice

Thank you for purchasing the **Green Smart (Model: PHT-35LHS)** extra-oral imaging system.

Green Smart is an advanced digital diagnostic system that incorporates PANO, CEPH (Optional), CBCT and 3D MODEL Scan imaging capabilities into a single system.

This manual describes how to operate the **Green Smart** 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 which appear 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:

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This document is originally written in English.

The **Green Smart** is referred to as “equipment” in this manual.

Manual Name: Green Smart (Model: PHT-35LHS) User Manual

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1. Introduction

1.1 Overview

Green Smart (Model: PHT-35LHS) is an advanced 4-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), CBCT and 3D MODEL Scan imaging capabilities into a single system.

Green Smart, a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography, **Green Smart** is a complete digital X-ray system equipped with imaging viewers, 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. With Auto Pano function, it also reconstructs the 3D CT data and produces 2D panoramic images without an additional scan.

Green Smart can also acquire 2D diagnostic image data in conventional panoramic and cephalometric modes.

1.2 Indications for Use

Green Smart (Model: PHT-35LHS) is intended to produce panoramic, cephalometric or 3D 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 device 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

- Diagnosis of foreign bodies or displaced roots involving the maxillary sinus

- Diagnosis of bone diseases, cysts, etc., affecting the temporomandibular joints

- Identifying the relationship of the inferior dental canal to a tooth/lesion that is to be removed

- Assessment of fractures on maxilla, mandible, condylar neck, orbital floor and fractures of teeth where plain film imaging is equivocal

- Visualization of the 3D anatomy of the alveolar clefts

- Diagnosis of un-erupted teeth impacted teeth and odontomas

- Diagnosis of root resorption of teeth

- Assessment of cleft palate

- Planning any surgery where 3D analysis of the jaw is required

- Storing Plaster Casts in 3D data

- Detailed verification of images in depth direction

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 device and recognizing device connection, installation, operating conditions
Language understanding	▪ Understanding how to use manuals (English / Korean) Or ▪ Understanding other language provided
Experience	▪ Understanding of the objectives and effects of the diagnosis and treatment of dental disease using diagnostic medical radiation devices ▪ Understanding of the normal operation of diagnostic medical radiation equipment ▪ Understanding the contents of the **User Manual**

The dental X-ray CT should be used by qualified personnel (dentists, dental hygienists or radiologists) only.

2. General Information

2.1 Manufacturer's Liability

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

- The equipment has been installed by a **VATECH**-authorized technician.
- The equipment has been installed by all of the cautions and conditions required for installation.
- The genuine **VATECH** approved equipment and components have been used at all times.
- All maintenance and repairs have been performed by a **VATECH**-authorized agent.
- The equipment has been used normally by the **User Manual**.
- 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. These tests must be performed by local X-ray safety regulations.
- The owner of this equipment shall perform regular inspection and maintenance of the mechanical and electrical components in this equipment to ensure safe and consistent operation (IEC 60601-1).

The owner of this equipment shall ensure inspection and cleaning work is performed by the maintenance schedule outlined in **Chapter 12 Cleaning and Maintenance.**

2.3 Conventions in this Manual

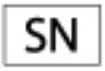
The following symbols are used throughout this manual. Make sure that you fully understand each symbol and follow the instructions accompanied.

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.
	**NOTE**	Emphasizes essential information or provides useful tips and hints.
	**RADIATION**	Indicates a possible danger from exposure to radiation.
	**SINGLE USE**	Indicates a component which must be replaced for each new patient.
	**ESD susceptibility**	Indicates that an item is susceptible to damage from electrostatic discharges.

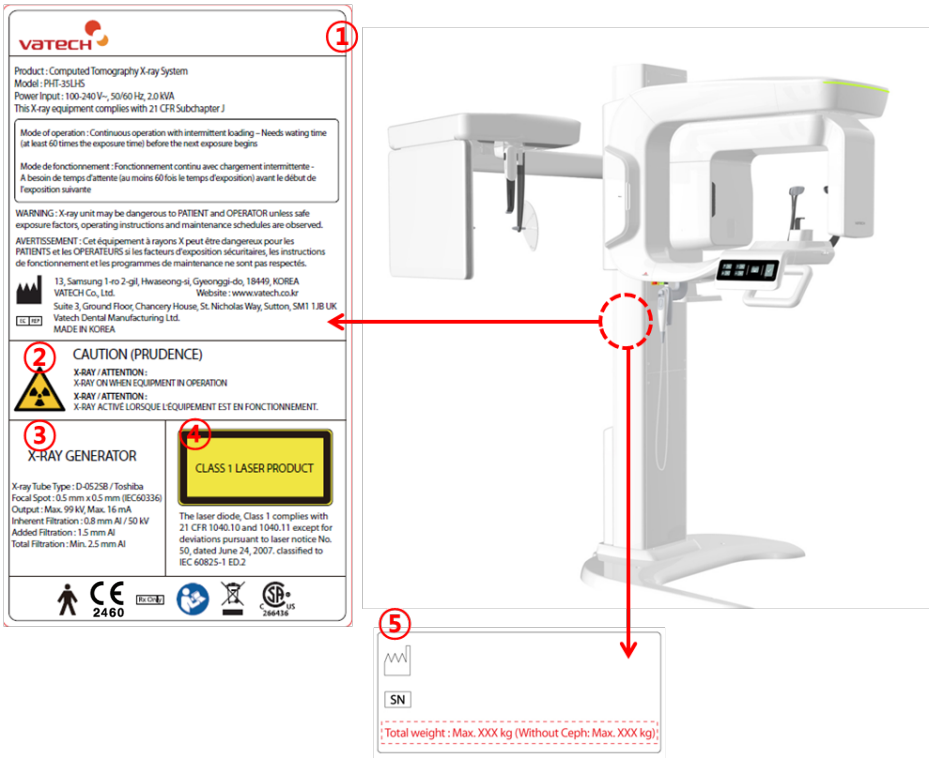
2.4 Marks and Symbols

Symbols	Description	Location
	Dangerous voltage	Power board / 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
	CSA mark No.266436	Label
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Label

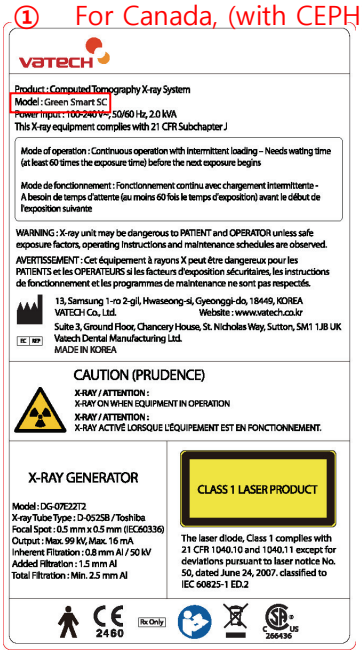
Symbols	Description	Location
	Addresses where the equipment was manufactured.	Label
	Indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Label
	Warns ESD hazard.	MCU board / Board package
	Indicates that this equipment 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 **Instruction Manual.**	Label
	Indicates the date when the equipment was manufactured.	Label
	Indicates the manufacturer's serial number so that specific equipment can be identified.	Label

2.4.1 Label Locations

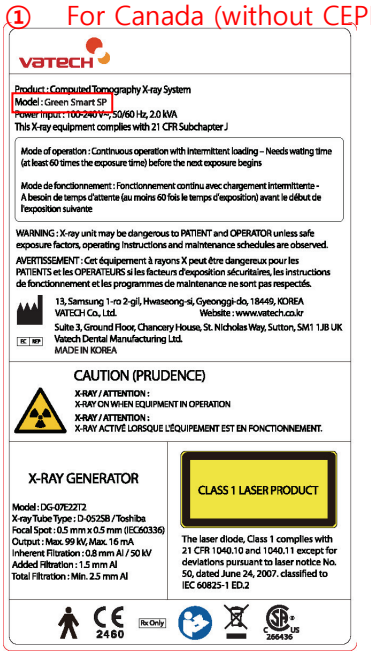
The label is attached to the right side of the equipment, and it consists of 5 parts as below.



① For Canada, (with CEPH)



① For Canada (without CEPH)



No.	Item
①	**Green Smart (Model: PHT-35LHS) Main Label** For Canada, the Model is distinguished by Green Smart SC and Green Smart SP. ● Green Smart SC: CEPH included ● Green Smart SP: CEPH not included
②	**CAUTION Label** - X-ray / Attention: X-ray on when equipment in operation.
③	**X-RAY GENERATOR Label** : 1.6 kW Generator
④	**CLASS 1 LASER PRODUCT Label**
⑤	**Manufacturer Label** - The date of manufacture / Serial Number / Weight of the equipment

3. Warnings and Precautions

	Be sure to strictly observe all warnings and safety instructions included in this manual.
	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 fully trained in its operation.

- To operate this equipment, the operator must:
  - Have read and understood the **User Manual**.
  - Be familiar with the fundamental structure and functions of this equipment.
  - Be able to recognize the irregular 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 maintain vocal/visual contact with the patient at all times during imaging.
- Do not open or remove the cover panels on this equipment. Always have a trained and authorized service technician to carry out 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 at all times.
- 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 60601-1series for medical electrical equipment).
- Also, all such combination-system-shall comply with the standard IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative.
- Any person or organization who 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 a current.

Ventilation

- Do not close the equipment's ventilation slots in any cases. 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. Penetration of these substances may damage the electrical and mechanical components inside. Use a soft cloth to disinfect the ventilation slots.
- Always leave a sufficient amount of 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 removable patient support components (the Bite, the Chinrest, the Temple Supports, and the Ear Rods) can be cleaned using alcohol-based cleaning solutions.
- Clean the Support Handles by using alcohol-based cleaning solutions before taking photos of the next patient.

- Other surfaces of the equipment, including the Touch Screen, 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 disease.

 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 cool down time (for the X-ray tube to cool down) before the acquisition of 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).
- If the fan (optional) is installed, it operates automatically when the temperature surrounding the tube head reaches the pre-defined level: 40 °C (104 °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 at the bottom of the Vertical 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 sufficient time to warm up (while switched on) if it has been exposed to temperatures of 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 prior to 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. All maintenance and repair of this equipment must be performed by a VATECH qualified service technician.
- This product may only be operated with original VATECH accessories or third-party accessories expressly approved by VATECH.

3.2 Electricity-related Safety Precautions

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

- Check the status of the power source, PC, and cables prior to 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 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 which 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.

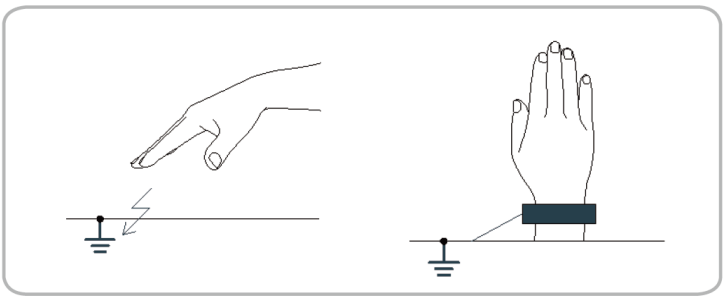
Static Discharge

- 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/or 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/or the operator.

 WARNING	▪ X-ray equipment is hazardous to the patient and the operator if proper exposure safety measures and/or operating instructions are not observed. ▪ It is important to read this **User Manual** carefully and strictly 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	▪ **Green Smart** system, like other medical equipment, uses high-frequency electrical signals that can interfere with implantable 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. ▪ **Green Smart** 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 device to sale by or on the order of dentist or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device.

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

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 he or she 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/or cause physical injury.

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

Installation

- To avoid improperly balanced equipment, install the device on a flat surface to maintain stability.
- If the equipment is not stable, property damage and/or 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.

For further details on installation, refer to the **Green Smart (Model: PHT-35LHS) Installation Manual**.

Security Capabilities

- It is recommended to install and operate **EzDent-i / EasyDent** 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 strictly prohibited. For cybersecurity issues related to the software and medical devices, please contact the manufacturer.

4. Imaging System Overview

4.1 System Components

- **Green Smart (Model: PHT-35LHS)** X-ray equipment
- PC system
- Console Software: PANO, CEPH (Optional), CBCT and 3D MODEL Scan
- EzDent-i / EasyDent: 2D viewer and patient management software
- Ez3D-i / Ez3D Plus: 3D viewer and image analysis software

4.2 Features

- Multi-FOV support: Selectable FOV - 10x8.5, 10x7 and 5x5 (cm)
- The multi-imaging solution for Accurate Diagnostics
- Conventional 2D (PANO and CEPH) image acquisition
- 3D and 2D (*Auto Pano) image acquisition by a single scan
- 3D scanning for Plaster Cast with FOV 10x8.5 (cm)
- Touch Screen implemented for easy use (Optional)
- DICOM (Digital Imaging Communication in Medicine) format supported

NOTE	***Auto Pano** Auto Pano is a feature used to acquire reconstructed 2D images during 3D CT scans without additional X-ray exposure. It has the same region that conventional panoramic images offer. (It provides images for the Standard mode in DICOM or BMP format.) Auto Pano option is available when FOV 10x8.5 or 10x7 is selected. When Auto Pano option is selected, Auto Pano image is automatically acquired and can be seen on the **EzDent-i / EasyDent** Viewer.

4.3 Standards and Regulations

Standards

Green Smart is designed and developed to comply with the following international standards and regulations:

- IEC 60601-1, IEC/EN 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-63
- CAN/CSA-C22.2 No. 60601-1:14, CAN/CSA-C22.2 No. 60601-1-3:09, CAN/CSA-C22.2 No. 60601-1-6:11, CAN/CSA-C22.2 No. 60601-2-63:15, CAN/CSA-IEC 62366:15
- ANSI/AAMI ES60601-1:2005 / (R)2012, AND A1:2012, A2:2010 / (R)2012 (Consolidated text - edition 3.1)
- 21 CFR 1020.30, 31, 33
- NEMA Standard publication PS 3.1-3.18, 2008

CE 2460	This is Class IIb equipment and obtained CE marking in April 2007 for regulations compliance in accordance with the revised European Union's MDD (Medical Devices Directive) 93/42 EEC.
C SA US 266436	This equipment received the CSA certification mark in accordance with CAN/CSA C22.2 No.601.1 regulations.

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: Temple Supports, Chinrests, and Bites.

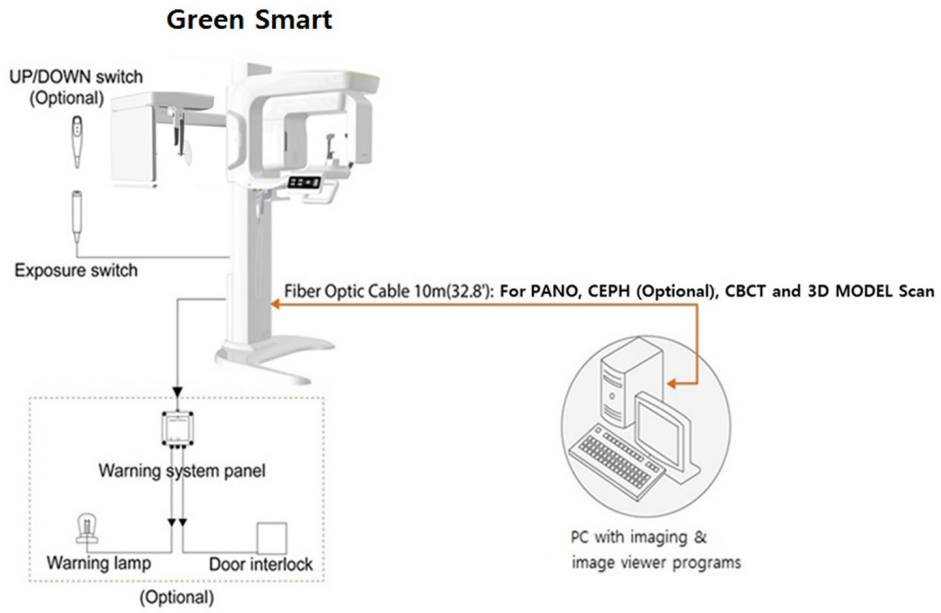
4.4 Operating Principles

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

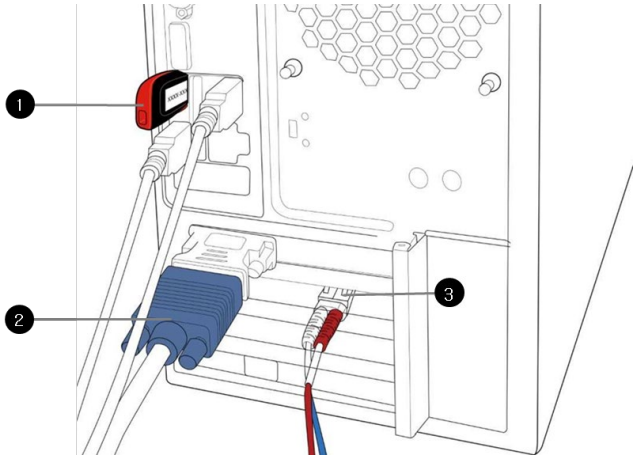
They hit anode to produce X-ray. The machine acquires images by emitting X-ray continuously and rotates on the human tooth at different angles.

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

4.5 Imaging System Configuration

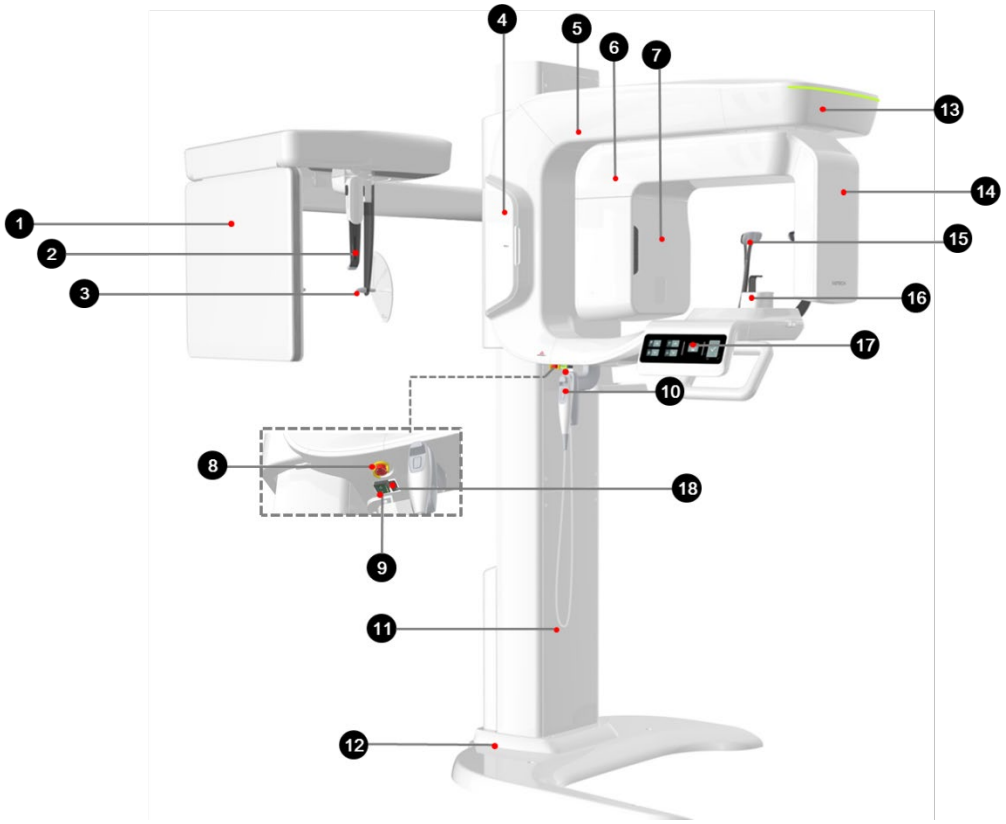


PC Signal Input / Output

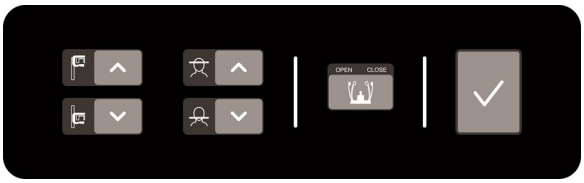
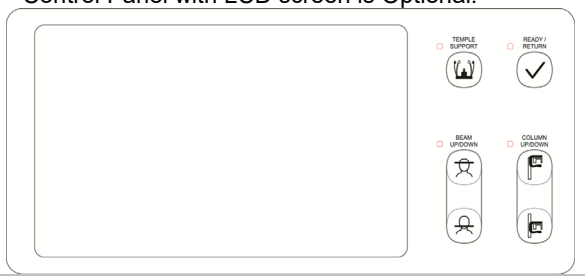


No.	Item
1	3D viewer License Key
2	Video output
3	Fiber optic cable (Data in / out)

4.6 Equipment Overview

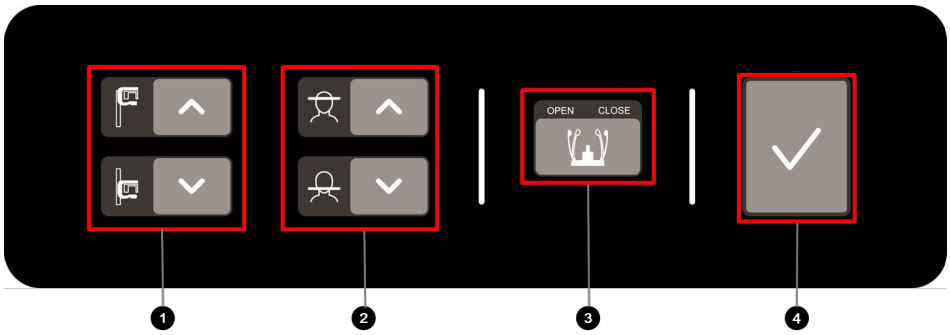


No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor
2	Nasal Positioner	− Positions the patient during CEPH imaging. − The ruler used for reference in an acquired image that is different from the actual size
3	Ear Rods	Secure the patient's head during CEPH imaging.
4	Enclosed Component Storage	The place where Bites, Chinrest Ass'y, and the other components can be stored.
5	Vertical Frame	Holds the Rotating Unit. Can be controlled by **Column UP/DOWN** switch.
6	Rotating Unit	Rotates around the patient's head while the image is being acquired. (Its movement is different according to the scan mode.)
7	X-ray Generator	The vacuum tube where the X-ray is produced.

No.	Item	Description
8	Emergency Stop Switch	Immediately stops the moving parts and cuts off all power to the equipment's electrical components.
9	Main Power Switch	Turns on / off the main power of the equipment.
10	Column UP/DOWN Switch (optional)	Adjusts the height of the Vertical Frame.
11	Stationary Column	Supports the whole part of the equipment.
12	Base (Optional)	Balances the equipment and maintains its safety.
13	LED Lamp	Displays the status of X-ray exposure. - Green: Standby - Yellow: In operation
14	X-ray Detector for PANO / CBCT	Xmaru1404CF-Plus for PANO / CBCT imaging sensor
15	Temple Supports	Supports the patient's head by holding the temples. Used in PANO and CBCT modes.
16	Chinrest	The place to rest the chin.
17	Control Panel	Operates the Horizontal Beam, opens/closes Temple Supports, adjusts the height of the Vertical Frame and prepares for operation when the **READY** button is pressed. (For the details, refer to **4.6.1 Control Panel**.) * The Membrane type control panel below is the default.  * Control Panel with LCD screen is Optional. 
18	D-Sub Connector	The input signal port for **Column UP/DOWN** Switch

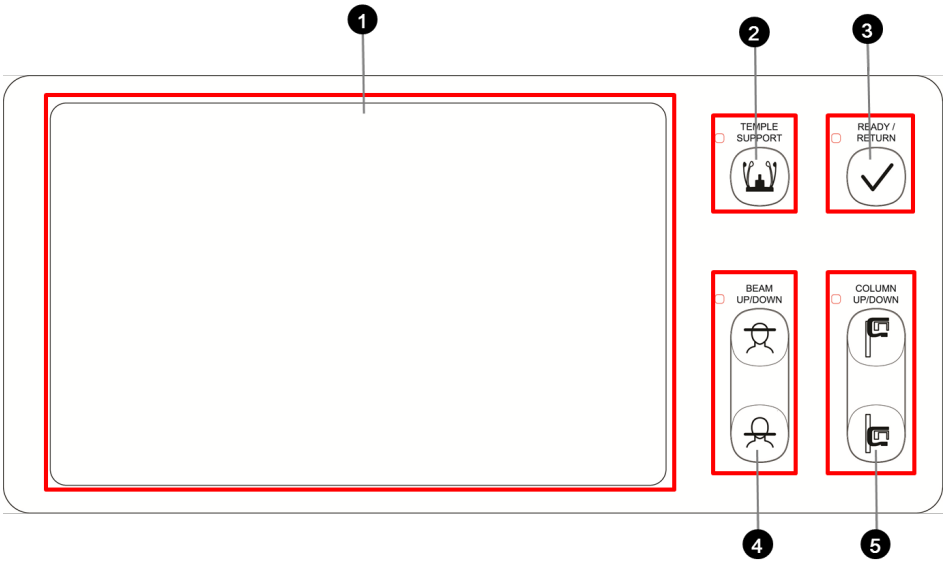
4.6.1 Control Panel

Membrane type



No.	Item	Description
1	Column UP/DOWN button	Moves the Vertical Frame up or down. (For adjusting the height of the Chinrest)
2	Horizontal Beam UP/DOWN button	Aligns the Horizontal Beam in PANO mode.
3	Temple Supports OPEN/CLOSE button	Adjusts the Temple Supports for patient positioning.
4	READY / RETURN button	Indicates that imaging is ready after parameter settings and the patient positioning are complete. Initializes the positioning of the Rotating Unit.

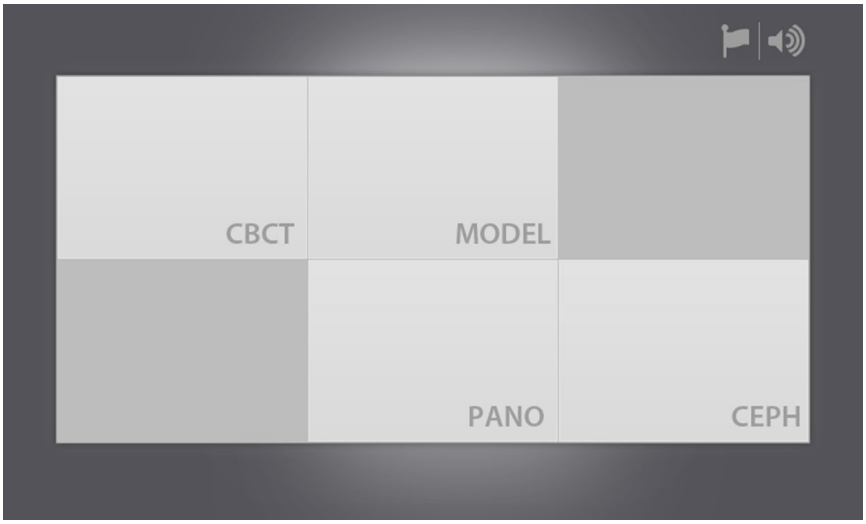
LCD type



No.	Buttons	Description
1	Touch Screen (LCD)	Configures the parameter settings in each imaging mode. For more information, refer to **4.6.2 Touch Screen**.
2	Temple Supports OPEN/CLOSE button	Adjusts the Temple Supports for patient positioning.
3	READY / RETURN button	Indicates that imaging is ready after parameter settings and the patient positioning are complete. Initializes the positioning of the Rotating Unit.
4	Horizontal Beam UP/DOWN button	Aligns the Horizontal Beam in PANO mode.
5	Column UP/DOWN button	Moves the Vertical Frame up or down. (For adjusting the height of the Chinrest)

4.6.2 Touch Screen (Optional)

Set options for imaging of each mode by using Touch Screen. It provides the same function as the PC's Console Software. Touch Screen and Console Software (**5.3. Console Software**) are interlocked mutually, therefore, indicate the same environment setting values always.



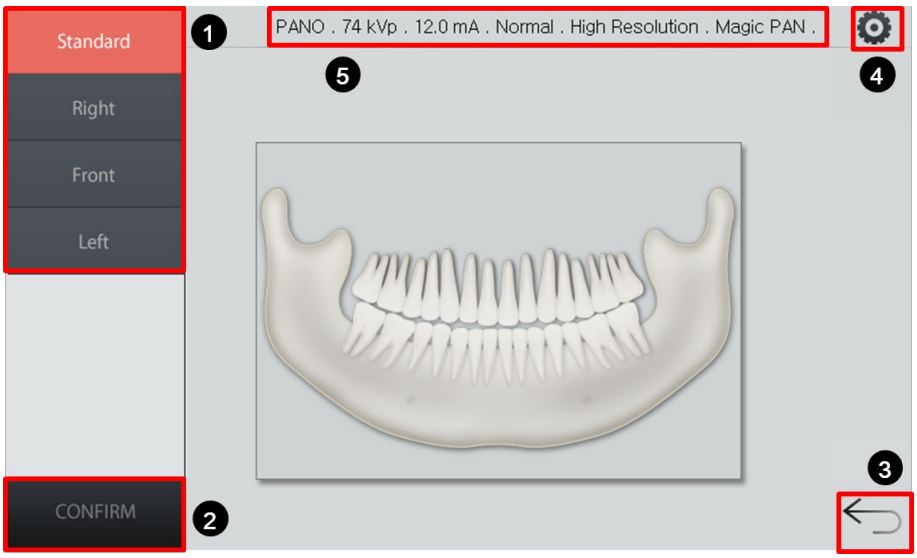
NOTE

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

CAUTION

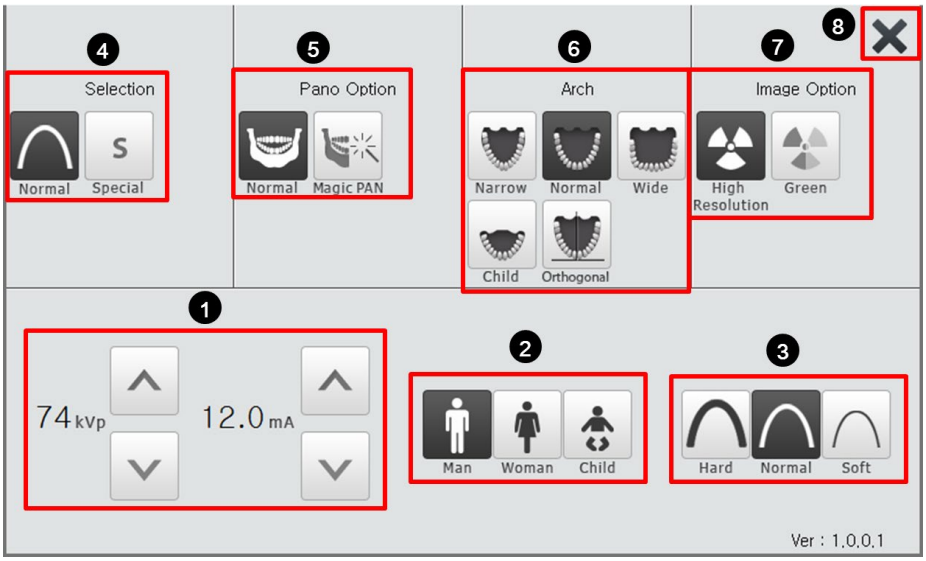
- Do not allow the patient to control Touch Screen. Doing so may cause physical injury to the patient or damage to the equipment.
- Always operate the Touch Screen by pressing it gently with your fingertip.
- Do not use pointed objects such as ballpoint pens or pencils. Doing so may cause damage to the screen.

PANO Main Screen



No.	Function	Description
1	Examination mode selection panel	Displays available PANO Examination programs. (In PANO – Orthogonal mode, press **UP/DOWN** button to scroll through next/previous ROI option.)
2	**CONFIRM** button	Confirms the settings and moves to the next step.
3	**BACK** button	Moves back to the modality (PANO / CEPH (Optional) / CBCT / MODEL) selection screen.
4	**Settings** button	Adjusts Tube voltage, Tube current, Gender / Age group, X-ray Intensity, Examination type, Imaging type, Arch selection, and Image option.
5	Imaging parameter settings information	Displays the current setting information. (Modality, Tube voltage, Tube current, Arch type, Image option, and Pano option.)

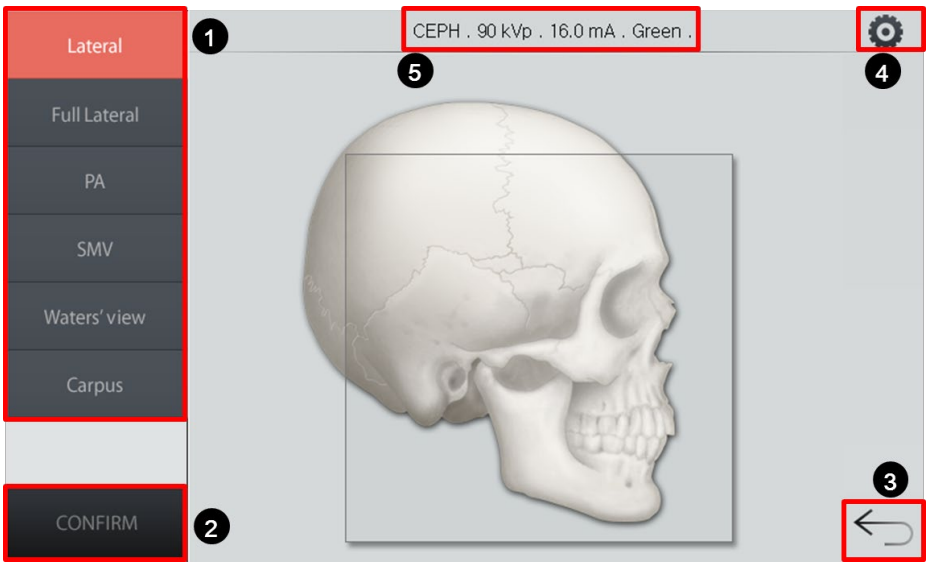
PANO Settings Screen



No.	Function	Description
1	kVp / mA control button	Adjusts Tube voltage (kVp) and Tube current (mA).
2	Patient's Gender / Age group	Selects patient's Gender / Age group.
3	X-ray intensity	Selects X-ray intensity. NOTE: Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft : Soft ≤ Normal ≤ Hard
4	Examination Program	Selects between Normal and Special.
5	Pano Option	Selects between Normal, Insight PAN and Magic PAN (Optional).
6	Arch	Selects available patient's Arch types.
7	Image Option	The default is "High Resolution." "Green" is optional. - When "Green" is enabled, Image Option is selectable between "High Resolution" and "Green." When "Green" is disabled, Image Options section is invisible. (Image quality: High Resolution > Green)

No.	Function	Description
8	**EXIT** button	Closes the Settings Screen and moves back to **PANO** Main Screen.

CEPH Main Screen

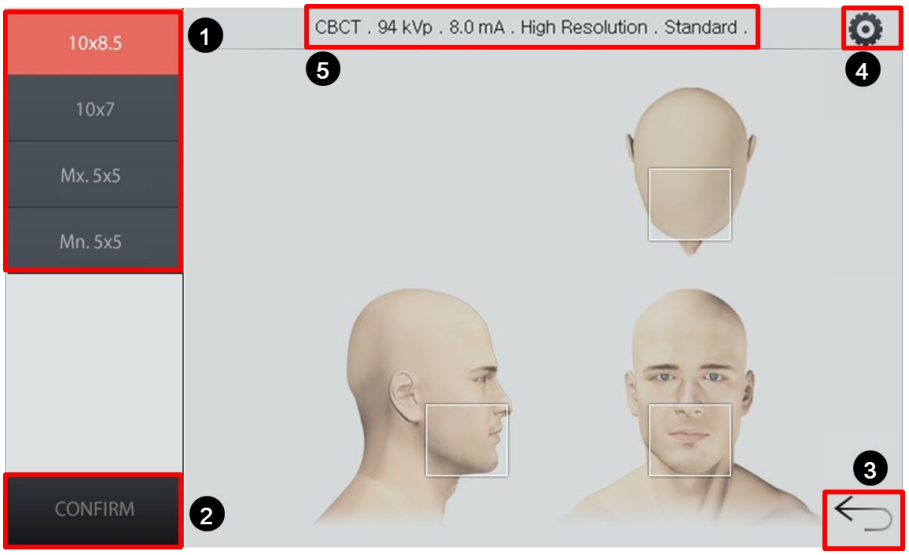


No.	Function	Description
1	Examination selection panel	Displays available CEPH Examination programs.
2	**CONFIRM** button	Confirms the settings and moves to the next step
3	**BACK** button	Moves back to the modality (PANO / CEPH (Optional) / CBCT / MODEL) selection screen.
4	**Settings** button	Adjusts Tube voltage, Tube current, Gender / Age Group, X-ray Intensity, and Image Option.
5	Imaging parameter settings information	Displays the current setting information. (Modality, Tube voltage, Tube current, and Image option)

CEPH Settings Screen

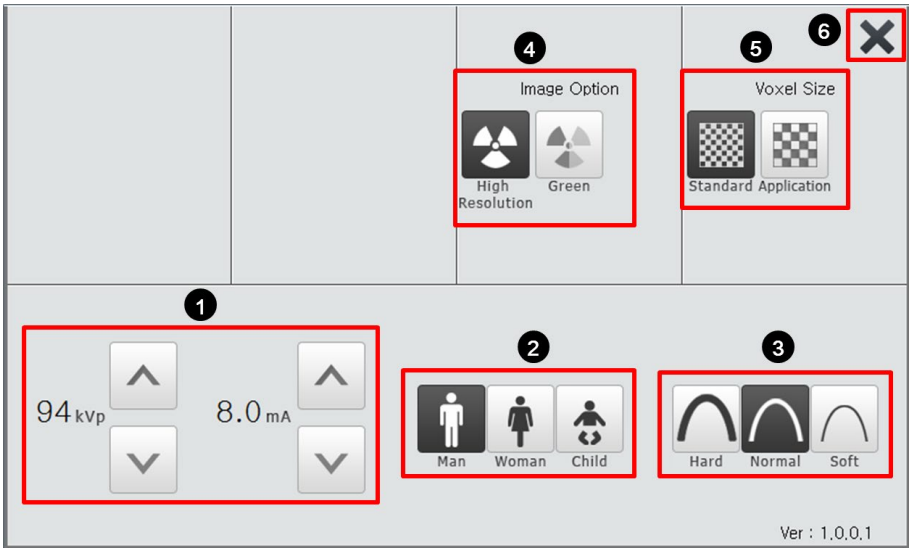
No.	Function	Description
1	kVp / mA control button	Adjusts Tube voltage (kVp) and Tube current (mA).
2	Patient's Gender / Age group	Selects patient's Gender / Age group.
3	X-ray intensity	Selects X-ray intensity. NOTE: Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft : Soft ≤ Normal ≤ Hard
4	Image Option	Selects between "High Resolution" and "Green." (Image quality: High Resolution > Green)
5	**EXIT** button	Closes the Settings Screen and moves back to CEPH Main Screen.

CBCT Main Screen



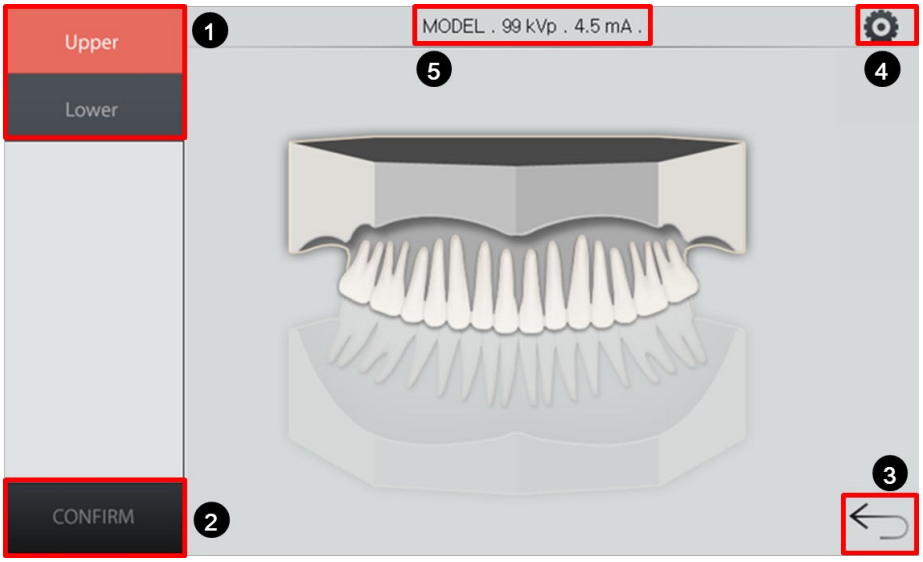
No.	Function	Description
1	FOV selection panel	Displays available FOV modes.
2	**CONFIRM** button	Confirms the settings and moves to the next step.
3	**BACK** button	Moves back to the modality (PANO / CEPH (Optional) / CBCT / MODEL) selection screen.
4	**Settings** button	Adjusts Tube voltage, Tube current, Gender / Age group, X-ray intensity, Image Option, and Voxel Size.
5	Imaging parameter settings information	Displays the current setting information. (Modality, Tube voltage, Tube current, Image option, and Voxel size)

CBCT Settings Screen



No.	Function	Description
1	kVp / mA control button	Adjusts Tube voltage (kVp) and Tube current (mA).
2	Patient's Gender / Age group	Selects patient's Gender / Age group.
3	X-ray intensity	Selects X-ray intensity. NOTE: Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft : Soft ≤ Normal ≤ Hard
4	Image Option	Selects between "High Resolution" and "Green." (Image quality: High Resolution > Green)
5	Voxel size	Selects between Standard and Application.
6	**EXIT** button	Closes the Settings Screen and moves back to CBCT Main Screen.

3D MODEL Scan Main Screen



No.	Function	Description
1	Examination selection panel	Displays available 3D MODEL Scan Examination programs.
2	**CONFIRM** button	Confirms the settings and moves to the next step
3	**BACK** button	Moves back to the modality (PANO / CEPH (Optional) / CBCT / MODEL) selection screen.
4	**Settings** button	Adjusts Tube voltage, Tube current, Gender / Age group, and X-ray intensity.
5	Imaging parameter settings information	Displays the current setting information. (Modality, Tube voltage, and Tube current)

3D MODEL Scan Settings Screen

No.	Function	Description
1	kVp / mA control button	Adjusts Tube voltage (kVp) and Tube current (mA).
2	Patient's gender / age group	Selects patient's gender / age group.
3	X-ray intensity	Selects X-ray intensity.
4	**EXIT** button	Closes the Settings Screen and moves back to 3D MODEL Scan Main Screen.

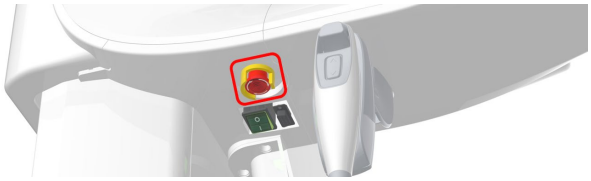
4.6.3 Emergency Stop Switch

During operation, the following emergency situations may occur:

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

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 at the bottom of the Vertical Frame.

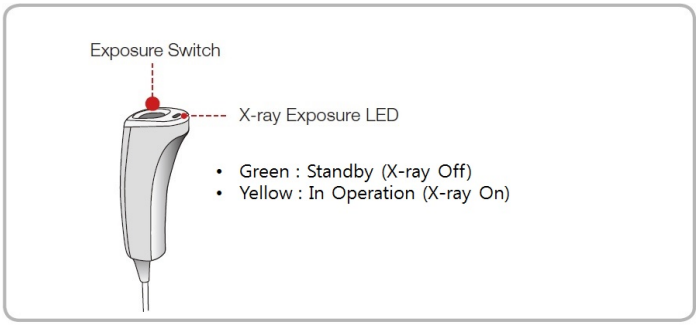


4.6.4 Exposure Switch

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.

4.6.5 Enclosed Components

The enclosed components can be disassembled and cleaned. All enclosed components that are used to support the patient (the Bite, the Chinrest, the Ear Rods, and the Temple Supports) should be cleaned with ethanol and wiped with clean towels.

Components	Name and Function	Materials
	Normal Bite : For PANO and CBCT normal patients	PC (Polycarbonate)
	Special Bite A : For PANO TMJ and Sinus modes : For CBCT TMJ patients	PC (Polycarbonate)
	Special Bite B : For PANO edentulous patients	PC (Polycarbonate)
	Normal Chinrest : For Normal Bite	ABS (Acrylonitrile butadiene styrene) copolymer
	Special Chinrest : For Special Bite A and Special Bite B	ABS (Acrylonitrile butadiene styrene) copolymer
	Temple Supports (1 set)	PC (Polycarbonate)
	Ear Rods (1 set)	Silicone
	Nasal Positioner Cover : For CEPH	Silicone
	Carpus Plate	PC (Polycarbonate)
	Sanitary Vinyl Covers (disposable) for the Bite	LDPE (Low-density polyethylene)
	Protractor (1 set) : For positioning the patient's body in CEPH mode.	PC (Polycarbonate)
	Model Scan Jig	ABS (Acrylonitrile butadiene styrene) copolymer

5. Imaging Software Overview

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

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

5.1 PC Specifications (Recommended)

NOTE

- The PC system plays an important 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 (HP)
CPU	E5-1607v4 4C 3.1GHz 2133 10MB
Chipset	Intel® C612
RAM	2X8GB DDR4-2400 Registered RAM
HDD	1TB SATA 7200 rpm
Graphics board	NVIDIA GeForce GTX1060 6GB
Ethernet Interface	Integrated Intel I218LM PCIe GbE Controller Intel Ethernet I210-T1 PCIe NIC (Option)
Serial Port (RS232)	HP Serial Port Adapter Kit (Option)
Power Supply	≥ 700 Watts (90% efficient)
Slots	2 PCI Express Gen3 x16 slot 1 PCI Express Gen3 x 8 Slot 1 PCI Express Gen2 x 4 Slot 1 PCI Express Gen2 x 1 Slot
	1 PCI 32bit/33MHz
CD/DVD drive	DVD Writer 5.25"
Operating System	Windows 7 Professional 64-bit (available through downgrade rights from Windows 10 Pro)
Recommended System	HP Z440

5.2 EzDent-i / EasyDent

EzDent-i / EasyDent is imaging software from **VATECH Co., Ltd.** that manages patient images to make faster and more accurate diagnoses. **EzDent-i / EasyDent**, 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.

NOTE

Please refer to **5.2.1 Creating a New Patient Record** and **5.2.2 Retrieving Patient Records** and **EzDent-i / EasyDent User Manual** for more information.

NOTE

Security Capabilities

- It is recommended to install and operate **EzDent-i / EasyDent** 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 strictly prohibited. For cybersecurity issues related to the software and medical devices, please contact the manufacturer.

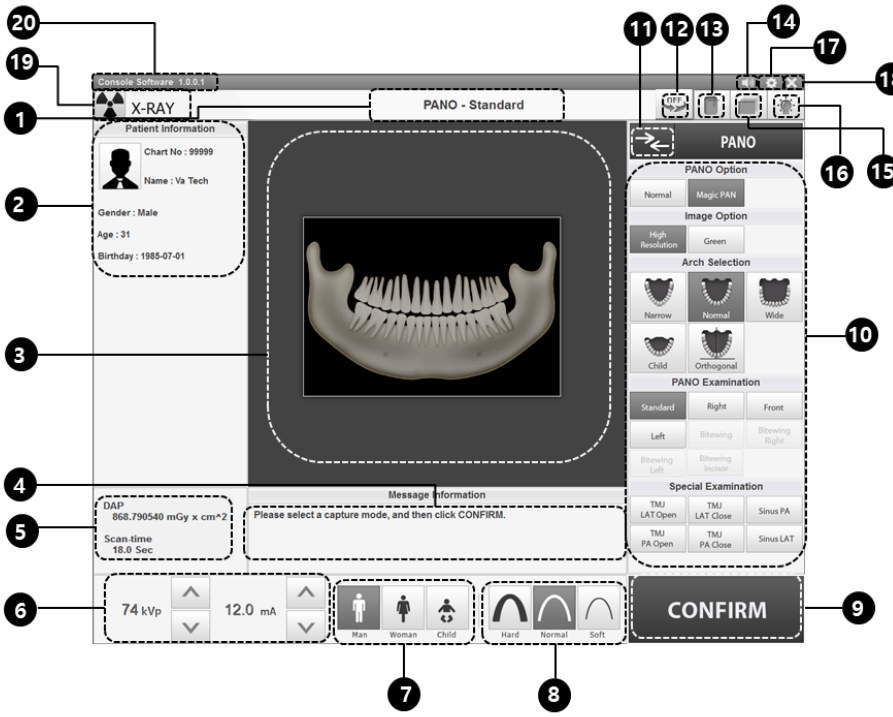
5.3 Console Software

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

NOTE

- You can set the imaging parameters on Console Software running on the PC. (Touch Screen is Optional. In case the Touch Screen is included in the equipment, Touch Screen and Console Software 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	Imaging Mode Display	Displays the current imaging mode.
2	Scanning Status and Image Preview window	Shows image acquisition progression and displays preview of the images acquired.

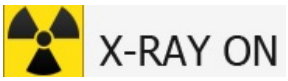
<table>
<tr><th>No.</th><th>Item</th><th>Description</th></tr>
<tr><td>3</td><td>Patient Information window</td><td>Displays information on the selected patient.</td></tr>
<tr><td>4</td><td>Guide Message window</td><td>Displays various text instructions for the operator.</td></tr>
<tr><td>5</td><td>DAP, Scan Time and Exposure Time Display window</td><td>Displays estimated DAP (Dose Area Product), scan time and exposure time after exposure parameter settings are completed.</td></tr>
<tr><td>6</td><td>Tube Voltage and Current Adjustment</td><td>If the patient is selected in EzDent-i / EasyDent, 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.
 
NOTE
For the tube voltage and its correspondence with the selected patient, refer to 15.1 Recommended X-ray Exposure Table.</td></tr>
<tr><td>7</td><td>Patient's gender/age group</td><td>Displays the current patient's gender/age group as entered in EzDent-i / EasyDent's patient information fields. If necessary, gender/ age group can be manually selected.
<table>
<tr><th colspan="2">Gender / Age Group</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>8</td><td>X-ray intensity</td><td>Selects X-ray intensity.
 
NOTE
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>
</table>

<table>
<tr><td>9</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)

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

READY
Activated when you click 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>10</td><td>Imaging parameters configuration panel</td><td>Selects the imaging parameters for each mode: PANO, CEPH (Optional), CBCT and 3D MODEL Scan</td></tr>
<tr><td>11</td><td>Modality Selection button</td><td>Returns to Modality Selection (PANO, CEPH (Optional), CBCT and MODEL) screen.</td></tr>
<tr><td>12</td><td>Rotation Test
button</td><td>Switches to the Rotation Test mode to check if any part of the patient’s body reaches the surface of the equipment before the actual exposure.
To change to the Rotation test mode,
1. Align the patient to the equipment. (For the details, refer to the “Positioning the Patient” section of each modality chapter.)
2. Select a modality.
3. Click CONFIRM button.
4. Click Rotation Test button. Then, the button is changed to OFF state and icon.
 
● To start the rotation test, press BEAM ON/OFF button on the Control Panel.
● To finish the test mode, click Rotation Test button or READYbutton.

NOTE
This function is applied to PANO and CBCT modalities only.</td></tr>
</table>

13	**Phantom** button	This function is used to acquire Phantom images. NOTE **Image acquisition using the Phantom Jig:** 1. Click **Phantom** button. 2. Select the Modality and click **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**.
14	**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, release the mouse to play the current volume and save the current volume.
15	**Manual Reconstruction** button	Reconstructs the image manually when automatic image reconstruction fails: Select a Modality after clicking this button. > Click **Search** button. > Select an image to reconstruct. > Click **Reconstruction** button.
16	**Laser Beam ON/OFF** button	Turns the Laser Beam on or off for patient positioning. Enabled when **CONFIRM** button is clicked after the imaging conditions are configured.
17	**Settings** button	Displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, etc.
18	**EXIT** button	Exits the console software.
19	X-ray indicator	The radiation mark turns yellow and “X-RAY” changes to “X-RAY ON.” 
20	Version Information	Displays the Console Software version.

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6. Getting Started

6.1 Turning on the Equipment

WARNING	▪ Do not place the patient close to the equipment when it's 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.

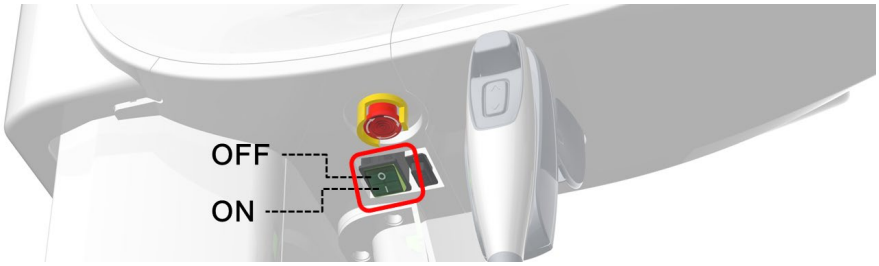
CAUTION	▪ Extreme fluctuation of temperature may cause condensation inside the equipment. Do not switch on the equipment until it has reached normal room temperature. ▪ Rebooting the equipment: After turning it off, wait for approx. 20 seconds before turning it on again. ▪ Warm-up the equipment for at least 5 minutes before the operation. For the best image quality, it is recommended to have a warm-up phase for more than 30 minutes.

IMPORTANT	If the equipment has not been used for a long time, please let it have enough time to be warmed up. It extends the life of the X-ray tube.

The imaging system mainly consists of the imaging equipment and the PC.

Before turning on the equipment, please confirm that the equipment and PC have been installed correctly.

1. Turn on the PC.
2. Press the **Main Power Switch** that is located at the bottom of the Vertical Frame to turn on the equipment.



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

3. Make sure that the green LED light at the top of the equipment is on.

6.2 Running the Image Viewer (EzDent-i / EasyDent)

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

For further details on this subject, refer to the **EzDent-i / EasyDent User Manual**.

Security Capabilities

- It is recommended to install and operate **EzDent-i / EasyDent** 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 strictly prohibited. For cybersecurity issues related to the software and medical devices, please contact the manufacturer.

For **Green Smart** dental computed tomography X-ray system, both 3D viewer (**Ez3D-i / Ez3D Plus**) and Console Software are being accessed through 2D viewer (**EzDent-i / EasyDent**) SW. 3D viewer and Console Software do not have 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

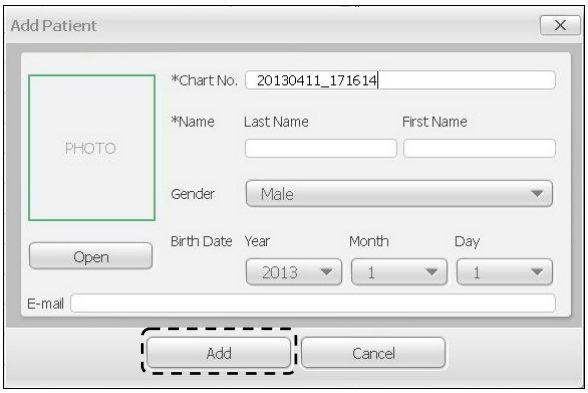
To create a new patient record, follow the procedure outlined below:

EzDent-i

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 which must be filled in. (The Chart Number is filled in automatically.)

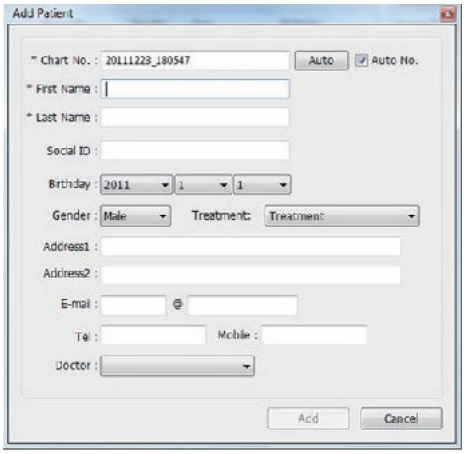
3. Click the **Add** button to save the patient record.



EasyDent

1. Click the Patient icon in the upper left corner of the EasyDent's main GUI window.

2. Enter the required patient information. **Chart Number**, **First Name**, and **Last Name** are required fields which must be filled in. All other fields are optional, but it is recommended that they are filled in.



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

6.2.2 Retrieving Patient Records

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

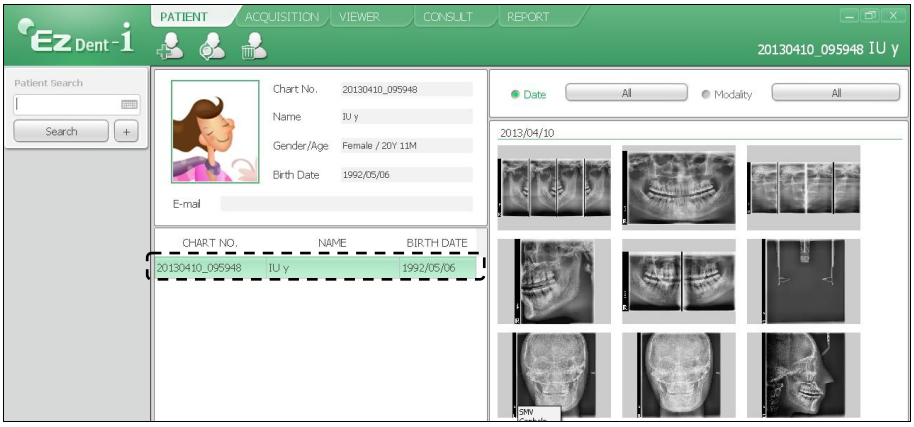
EzDent-i

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.

NOTE

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

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

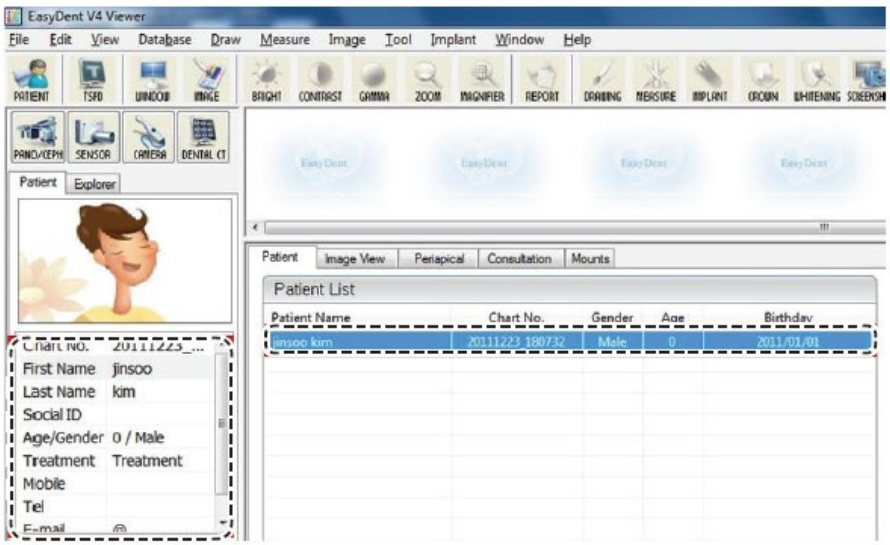


EasyDent

1. On the **Patient Information** pane, double-click the Chart No., First name, or Last name of the patient and the virtual keyboard will pop up.

2. Enter the **Chart No.**, **First name**, or **Last name** of the patient by clicking the mouse on the virtual keyboard and click the **Enter** key. (The physical keyboard can be used to do the same job)

3. Patient information can be displayed on the **Patient Information** panel and **Patient List**.



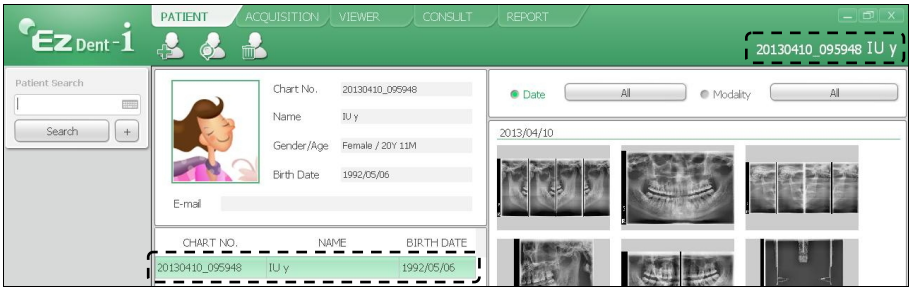
6.3 Initiating the Console Software

NOTE

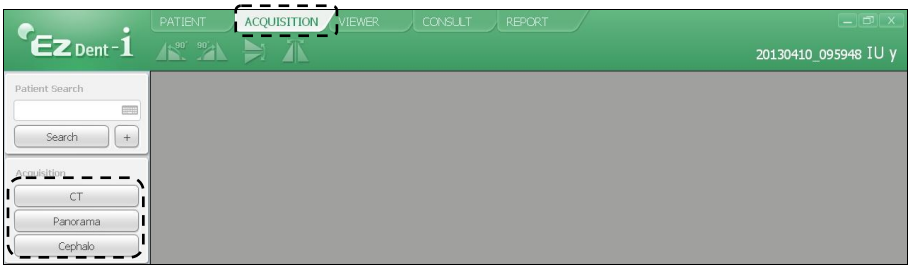
For a new patient, the patient information needs to be registered first.

EzDent-i

1. Search and select the patient to be captured.



2. Click **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 prior to acquiring an image.

NOTE

Refer to the following **chapters (7 ~ 10)** for the more information on the image acquisition.

EasyDent

1. First, click the patient information in the **Patient List**, and click an imaging modality button to select on the upper left corner.

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

NOTE

Refer to the following **chapters (7 ~ 10)** for the more information on the image acquisition.

7. Acquiring PANO Images

7.1 PANO Imaging Program Overview

■ Result Images

It provides conventional 2D panoramic images.

■ Image Acquisition Method

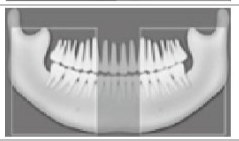
It reconstructs U-shaped arch data to a single 2D image utilizing multiple images taken with the X-ray beam scanning specific oral & maxillofacial regions at different angles.

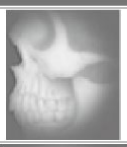
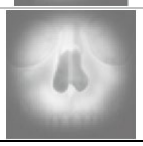
■ Available PANO Options

Mode	Description
Normal	- Provides a normal panoramic image.
Magic PAN (Optional)	- Provides a single optimal panoramic image having multiple focal images combined. - Minimizes the difference in the quality of images varied according to the patient's positioning and the arch shape.
Insight PAN	Multi-image acquisition option that reconstructs the panoramic image into multiple focal images in depth regions. Its main purpose is to diagnose depth regions, which cannot be confirmed with ordinary panoramic images.

■ Examination Programs

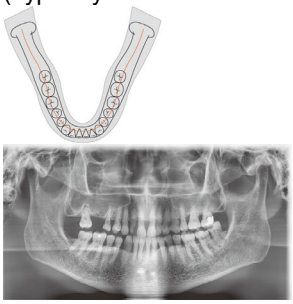
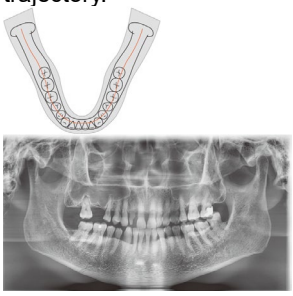
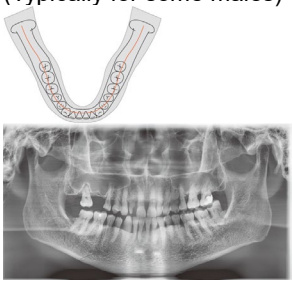
It is classified as below based on the ROI (Region of Interest).

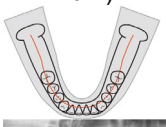
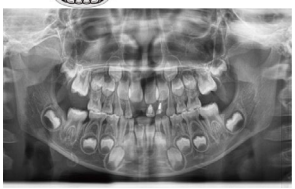
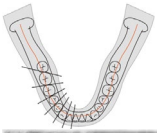
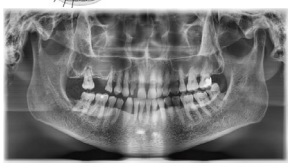
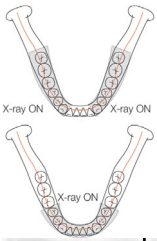
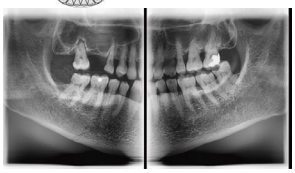
Examination Type	Arch Selection	ROI	Sample Image
PANO Examination	Narrow Normal Wide Child Orthogonal	Standard	
		Right	
		Front	
		Left	
	Orthogonal	Bitewing*	
		Bitewing Incisor* (Optional)	
		Bitewing Right*	
		Bitewing Left*	
SPECIAL Examination	N/A	TMJ LAT Open	
		TMJ LAT Close	

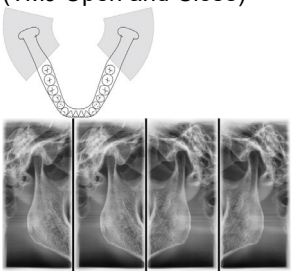
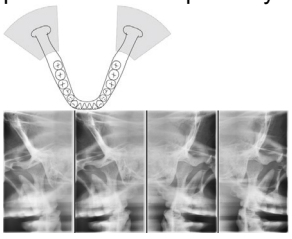
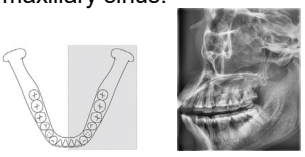
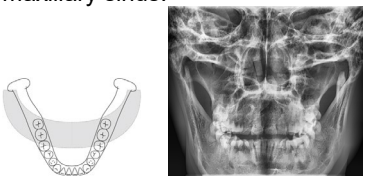
Examination Type	Arch Selection	ROI	Sample Image
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

* 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 normal 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 approximately 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.  
		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.)  

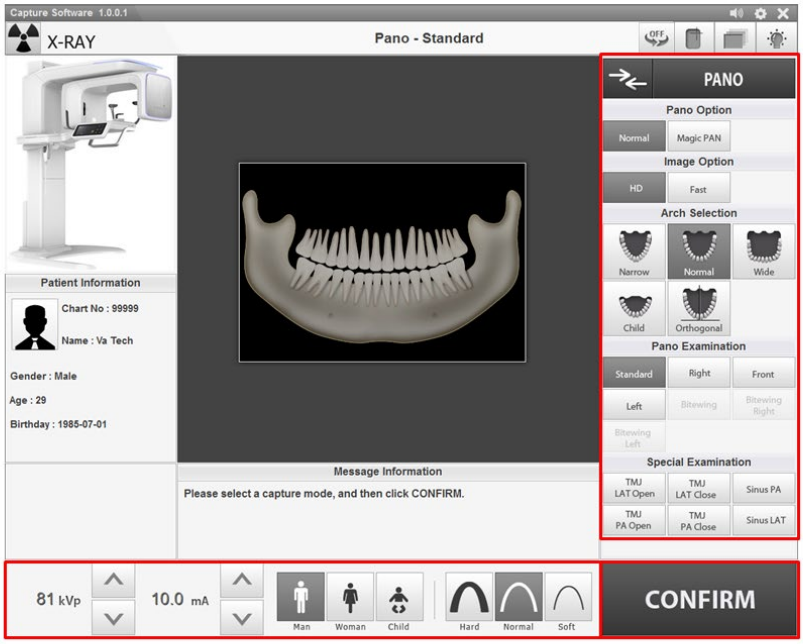
SPECIAL Examination	N/A	TMJ LAT Open / Close	An imaging mode to acquire a lateral image of the TMJ, in which the X-ray beam is directed on the lateral TMJ region. (TMJ Open and Close) 
		TMJ PA Open / Close (Optional)	An imaging mode to acquire a TMJ image, in which the X-ray beam is directed on the 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 X-ray beam is directed on the lateral region of the maxillary sinus. 
		Sinus PA	A special imaging mode to acquire a Sinus image, in which 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.

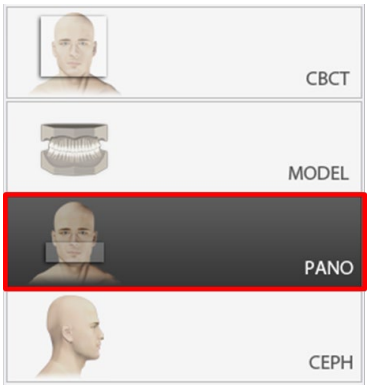
7.2 Configuring Exposure Parameters

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.

NOTE	You can set the imaging parameters on Console Software running on the PC. (Touch Screen is Optional. In case the Touch Screen is included in the equipment, Touch Screen and Console Software are synchronized and display the same environmental settings.)



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



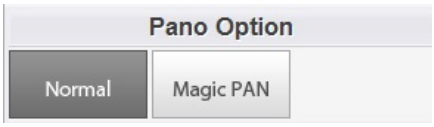
<Console Software>

<Touch Screen>

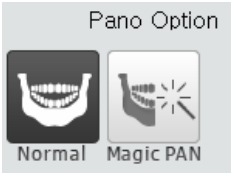
NOTE

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

2. Select a Pano Option. (On Touch Screen, click **Settings** button before selecting options.)



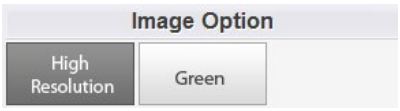
<Console Software>



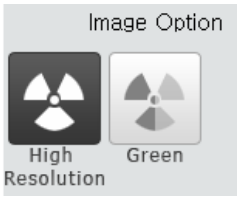
<Touch Screen>

Mode	Description
Normal	- Provides a normal panoramic image.
Magic PAN (Optional)	- Provides a single optimal panoramic image having multiple focal images combined. - Minimizes the difference in the quality of images varied according to the patient's positioning and the arch shape.
Insight PAN	- Provides multiple panoramic images having different focal planes along with a normal panoramic image together. - Enables detailed verification of images in depth direction.

3. Select an Image Option.



<Console Software>



<Touch Screen>

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

NOTE

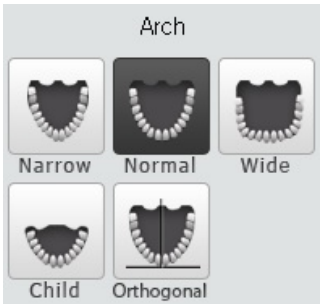
The default is “High Resolution.” “Green” is optional.

When “Green” is enabled, Image Option is selectable between “High Resolution” and “Green.” When “Green” is disabled, Image Options section is invisible.

When “Insight PAN” is selected among Pano Options, Image Options are disabled.

4. Make an Arch Selection.

<Console Software>



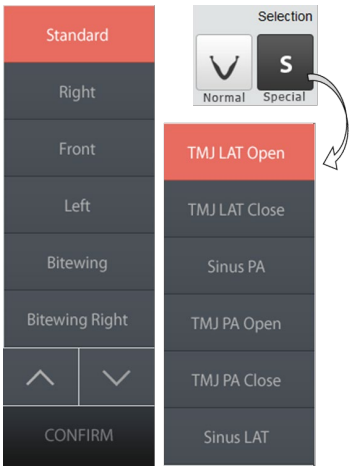
<Touch Screen>

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)
Child	Panoramic image of child palatal arches, approximately more than 40% less X-ray dose than in Normal mode.
Orthogonal	Panoramic image where the x-ray angle enters vertically in between the teeth, so overlapping images are minimized.

Arch Selection	Description
	NOTE If Orthogonal Arch is selected, Bitewing examinations (Bitewing, Bitewing Incisor (Optional), Bitewing Right, Bitewing Left) are activated.

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

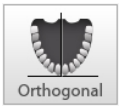
<Console Software>



<Touch Screen>

NOTE

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



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

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

<Console Software>

<Touch Screen>

NOTE

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

7. Select X-ray intensity.

<Console Software>

<Touch Screen>

NOTE

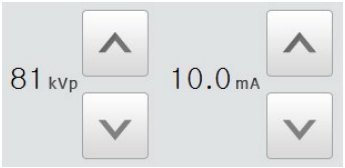
Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft :

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

8. 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.

<Console Software>



<Touch Screen>

9. Click **CONFIRM** button when exposure parameter setting is completed.

<Console Software>

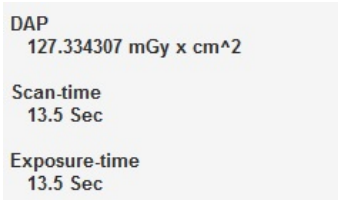
<Touch Screen>

When you click **CONFIRM** button:

NOTE

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 Patient Information window.



10. Guide the patient to the equipment.

7.3 Patient Positioning

WARNING

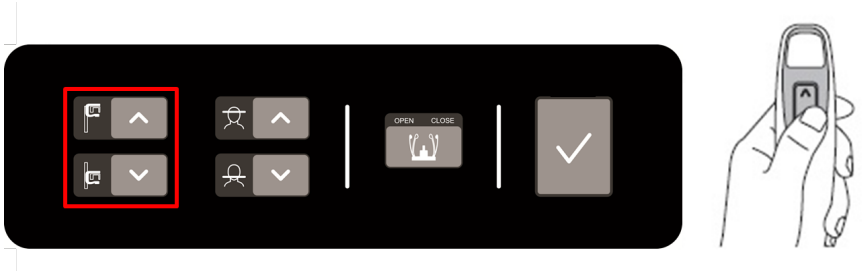
- Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.

IMPORTANT

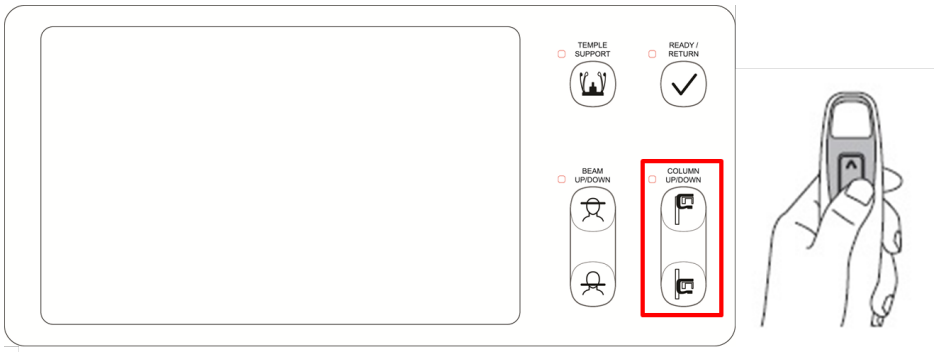
- Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.
- Metal implants or bridges may reduce the quality of the images.
- Be sure to adjust laser beam correctly. Otherwise, the quality of images can be lower due to ghost images or expansion/reduction of the images.

Getting prepared

1. Let the patient remove all the metal objects (glasses, earrings, hair pins, braces, false teeth, etc.). Metal objects may induce ghost images and lower the image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button or switch option to adjust the equipment to match the height of the patient.
4. Press the **Rotation test** button in the Console program and check that the equipment touches a part of the patient while the equipment is running.



< Control Panel – Membrane type>

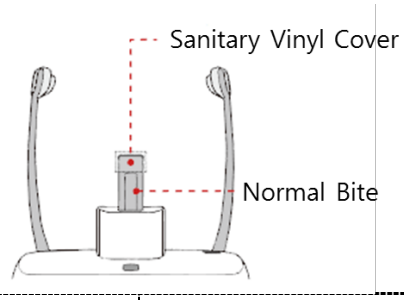


<Control Panel – LCD type>

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

Normal Patient Positioning

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



CAUTION

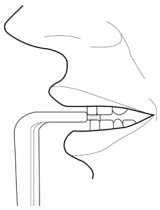
- The Sanitary Vinyl Cover is for single use only. It should be replaced for each patient. Be sure to use the approved vinyl cover.

- Clean the Chinrest and the Bite with ethanol and wipe with a dry towel before the next patient.

2. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.

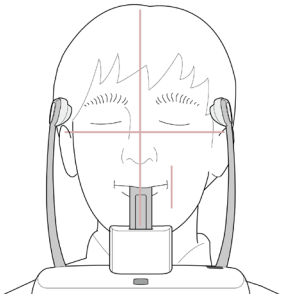
3. Guide the patient to the inside of the equipment.
4. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
   - Hold the handles tightly.
   - Press the chest against the equipment.
   - Keep both feet close to the inside of the base.
   - Keep both shoulders parallel.
   - Straighten the Cervical Spine and stand still.

6. Let the patient bite the Bite along its grooves with his/her front teeth.



7. Let the patient maintain the posture as follows:

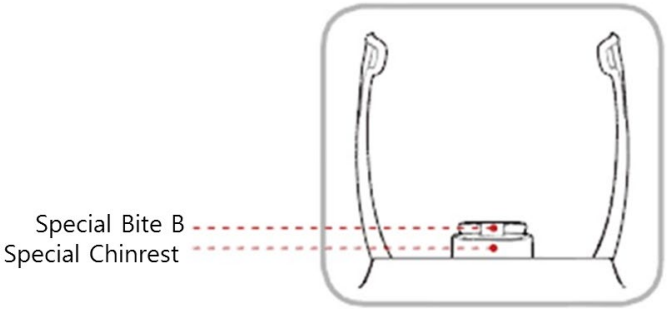
- Close the mouth.
- Place the tongue on the roof of the mouth.
- Close the eyes.



Edentulous 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 ethanol and wipe with a dry towel before the next patient.

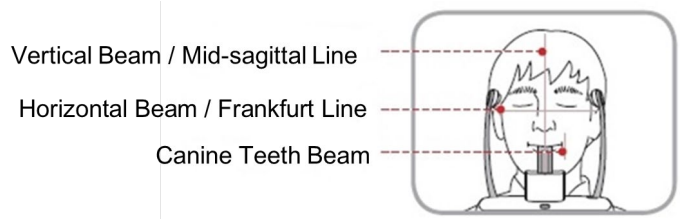
3. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.

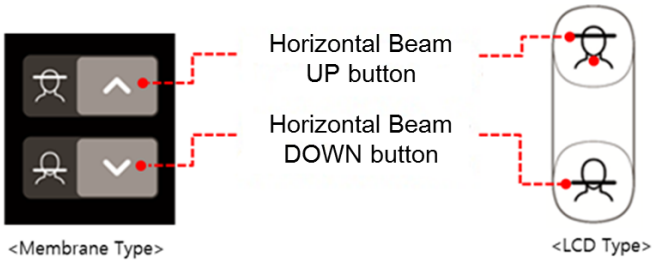
4. Guide the patient to the equipment.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
   - Hold the handles tightly.
   - Press the chest against the equipment.
   - Keep both feet close to the inside of the base.
   - Keep both shoulders parallel.
   - Straighten the Cervical Spine and stand still.
7. Let the patient maintain the posture as follows:
   - Close the mouth.
   - Place the tongue on the roof of the mouth.
   - Close the eyes.

Laser Beam Aligning

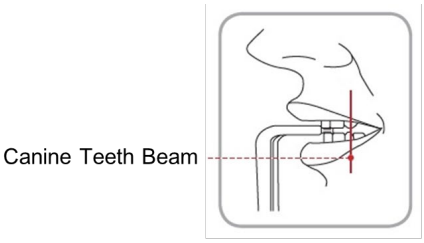
WARNING	Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure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

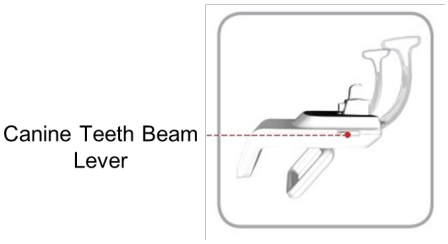
1. Align the Vertical Beam with the center of the face (Mid-sagittal Line). (It's to prevent horizontal expansion of the image.)
2. Align the Horizontal Beam in a straight line to the Frankfurt Line on the patient's face. Use the **Horizontal Beam** button on the control panel to position it. Make sure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





3. Direct the patient to smile and align the Canine Teeth Beam to the center of the canines. Use the Canine Teeth Beam Lever to adjust the position of the beam.





Finishing Patient Positioning

1. After checking the positions of the patient and the laser beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.

CAUTION	Make sure that the Temple Supports are in CLOSE position before clicking the **READY** button.

2. Click the **READY** button. The X-ray exposure has not started yet.
3. Now go to **7.4 X-ray Exposure** to start the exposure.

7.3.2 SPECIAL Examination Mode (TMJ / Sinus)

<TMJ Open Mode (LAT / PA)>

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

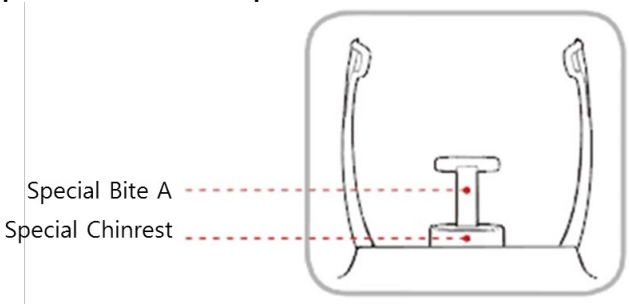
NOTE

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 ethanol and wipe with a dry towel before the next patient.

3. Use the **Temple Supports Open/Close** button on the control panel to widen the Temple Supports.

4. Guide the patient to the equipment.
5. Use the **Vertical Frame UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
   - Hold the handles tightly.
   - Press the chest against the equipment.
   - Keep both feet close to the inside of the base.
   - Keep both shoulders parallel.
   - Straighten the Cervical Spine and stand still.

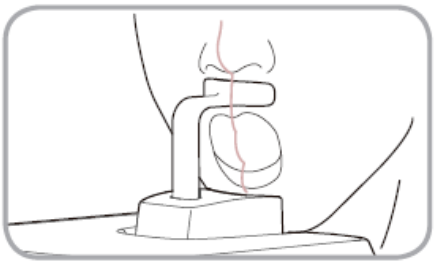
7. Guide the patient to press the base of the nose (acanthion point) against the Chinrest and tilt the head forward about 5˚. At this point, make sure the patient's jaw does not touch the equipment.

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.

8. Let the patient maintain the posture as follows:

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



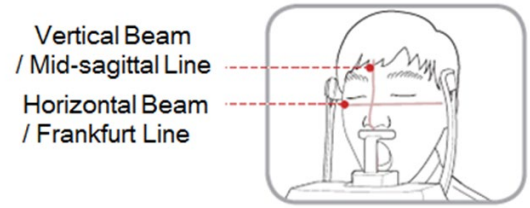
NOTE

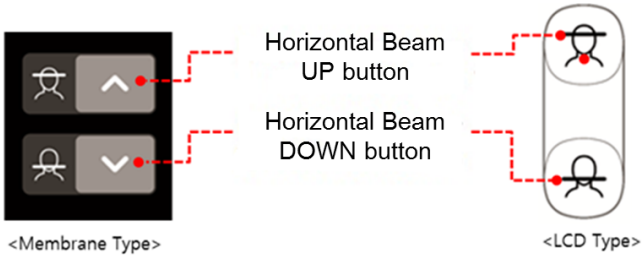
- As shown in the picture, the support unit of the integrated Chinrest should touch the patient's acanthion point.
- Ask the patient to maintain his/her position until the operation is completed.

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's to prevent 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. After checking the positions of the patient and the laser beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.

CAUTION	Make sure that the Temple Supports are in CLOSE position before clicking the **READY** button.

2. Click the **READY** button. The X-ray exposure has not started yet.
3. Now go to **7.4 X-ray Exposure** to start the exposure.

<TMJ Close Mode (LAT / PA)>

The TMJ Close image can be acquired after the TMJ Open image has been acquired.

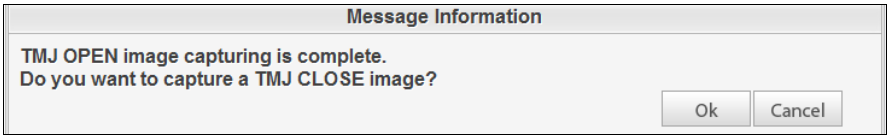
NOTE

Steps for TMJ Mode

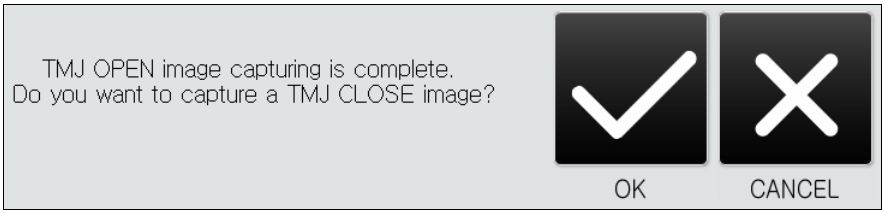
Patient positioning for TMJ Open > Laser Beam Aligning > X-ray Exposure > Patient positioning for TMJ Close > Laser Beam Aligning > X-ray Exposure

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.

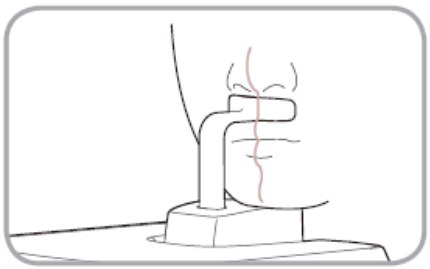


<Console Software>



<Touch Screen>

2. Guide the patient to the inside of the equipment.
3. Guide the patient to place the base of his/her nose (acanthion point) against the Chinrest and bend the head forward about 5˚.
4. Let the patient maintain the posture as follows:
   - Close the mouth.
   - Place the tongue on the roof of the mouth.
   - Close the eyes.



NOTE

- 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.

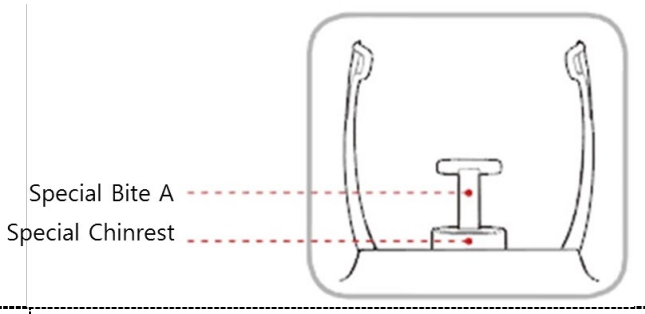
Finishing Patient Positioning

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

<Sinus Mode (LAT / PA)>

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 ethanol and wipe with a dry towel before the next patient.

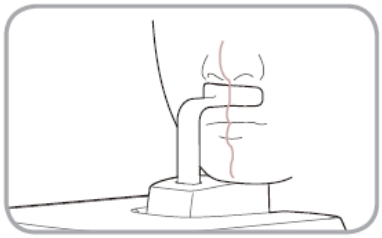
3. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.

4. Guide the patient to the equipment.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
   - Hold the handles tightly.
   - Press the chest against the equipment.
   - Keep both feet close to the inside of the base.
   - Keep both shoulders parallel.
   - Straighten the Cervical Spine and stand still.
7. 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.

8. Let the patient maintain the posture as follows:

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



NOTE

- 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's to prevent 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. After checking the positions of the patient and the Laser Beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.

CAUTION	Make sure that the Temple Supports are in CLOSE position before clicking the **READY** button.

2. Click the **READY** button. The X-ray exposure has not started yet.
3. 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 observe the X-ray safety regulations applicable to his/her area at all times during the operation of this equipment.

CAUTION

- The operator must keep vocal/visual contact with the patient at all times during the image acquisition process.
- Do not operate the PC during exposure. Doing so may cause the system to malfunction.

IMPORTANT

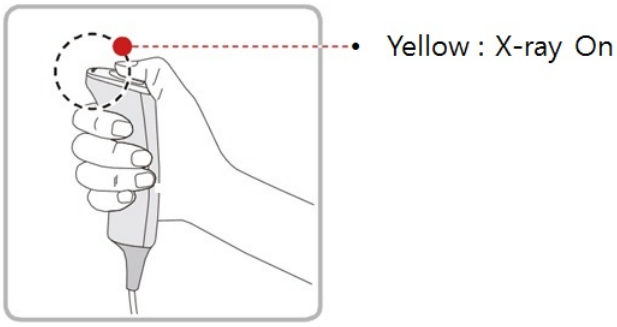
- Let the patient close the eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, don't let the patient move until the Temple Supports are open.

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

IMPORTANT

The operator must keep vocal/visual contact with the patient at all times during image acquisition.

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



NOTE

The image appears on the screen.

NOTE

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 and “X-RAY” changes to “X-RAY ON.”

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

7.5 Finishing the Scan

1. Open the Temple Supports and guide the patient out of the equipment.
2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.
3. Press **READY** button to bring the Rotating Unit back to its initial position.

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 / EasyDent**.

NOTE

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

1. The images are transferred to **EzDent-i / EasyDent** automatically.
2. The images are automatically saved if 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

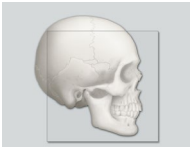
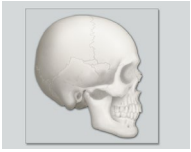
It provides conventional 2D cephalometric images.

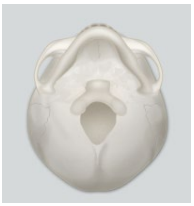
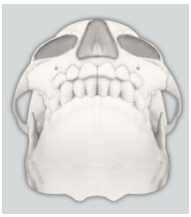
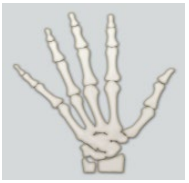
■ Image Acquisition Method

It acquires multiple images by scanning the specific oral & maxilocial regions with the linear movement of the narrow 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).

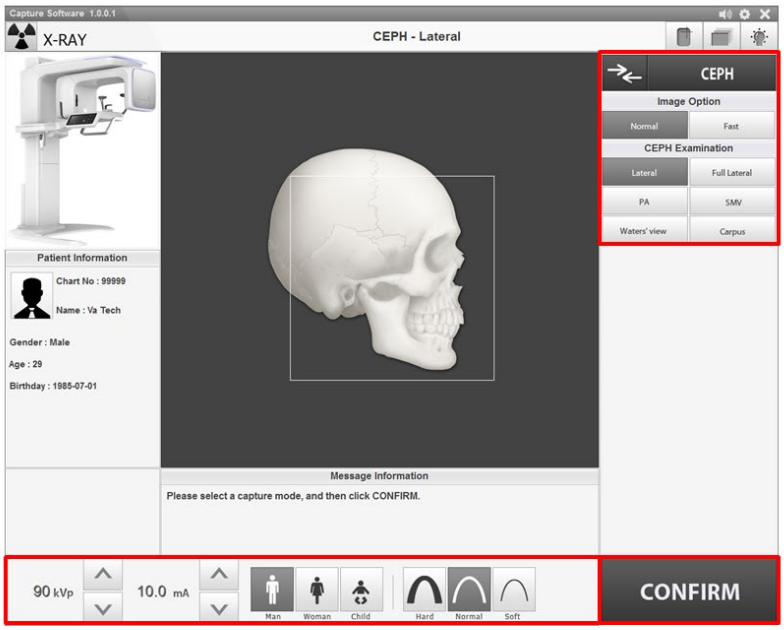
Examination Area	Description	Position
Lateral / Full Lateral (Optional)	▪ Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate. ▪ Measures the angles formed by the connecting lines between 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. ▪ Used to examine cranial diseases, trauma, and congenital malformations. ▪ 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 ethmoidale, 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>

Examination Area	Description	Position
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 side wall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull.	 <SMV>
Waters' view	▪ Used to study the frontal sinus, the antrum ethmoidale, 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>

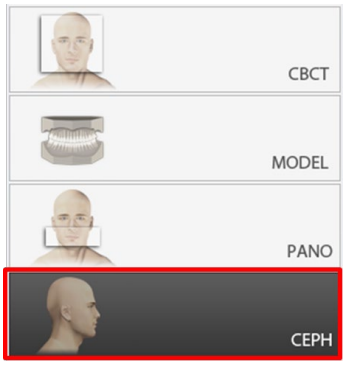
8.2 Configuring Exposure Parameters

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

NOTE	You can set the imaging parameters on Console Software running on the PC. (Touch Screen is Optional. In case the Touch Screen is included in the equipment, Touch Screen and Console Software are synchronized and display the same environmental settings.)



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



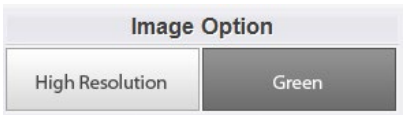
<Console Software>

<Touch Screen>

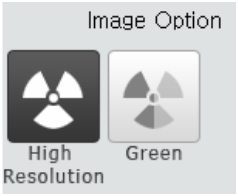
NOTE

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

2. Select an Image Option. (On Touch Screen, click **Settings** button before selecting options.)

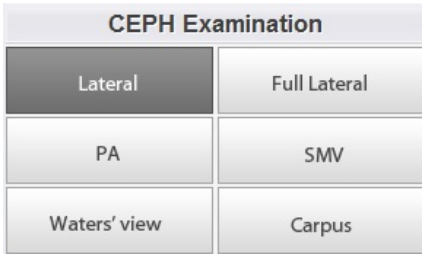


<Console Software>

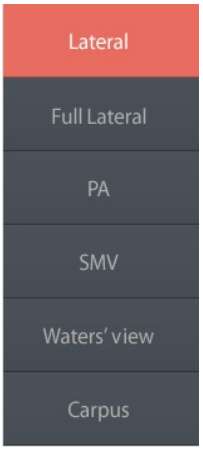


<Touch Screen>

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



<Console Software>



<Touch Screen>

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

<Console Software>

<Touch Screen>

NOTE

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

5. Select X-ray intensity.

<Console Software>

<Touch Screen>

NOTE

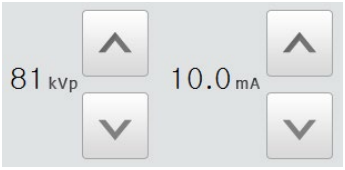
Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft :

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.

<Console Software>



<Touch Screen>

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

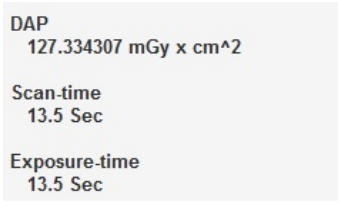
<Console Software>

<Touch Screen>

NOTE

When you click **CONFIRM** button,

- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below the Patient Information window.



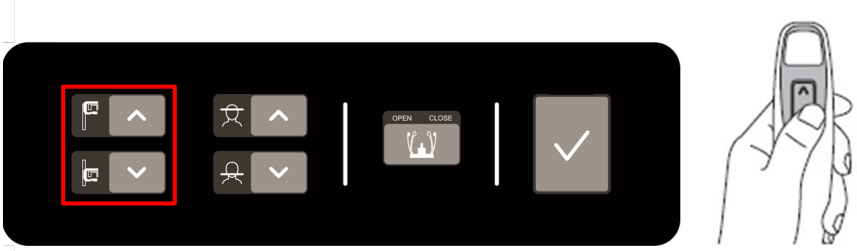
8. Guide the patient to the equipment.

8.3 Patient Positioning

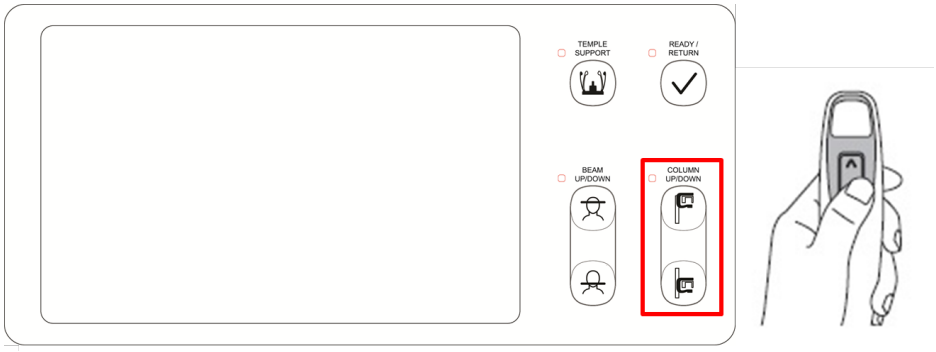
WARNING	▪ Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation. ▪ Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	Ensure that the Nasal Positioner is left unfolded, before 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.

Getting prepared

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



< Control Panel – Membrane type>



<Control Panel – LCD type>

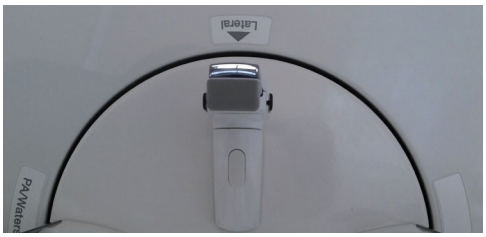
8.3.1 Lateral / Full Lateral (Optional) Mode

NOTE

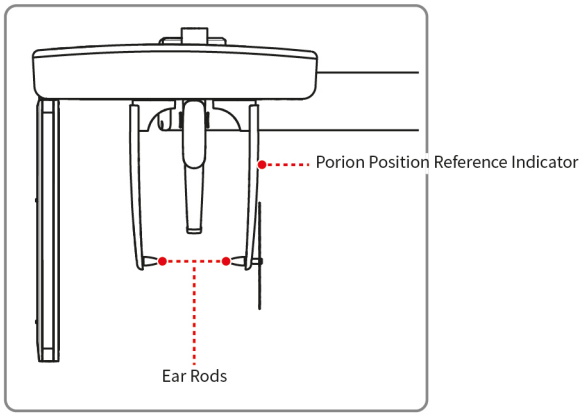
Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.

Patient Positioning

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



2. Leave enough space between the Ear Rods.



NOTE

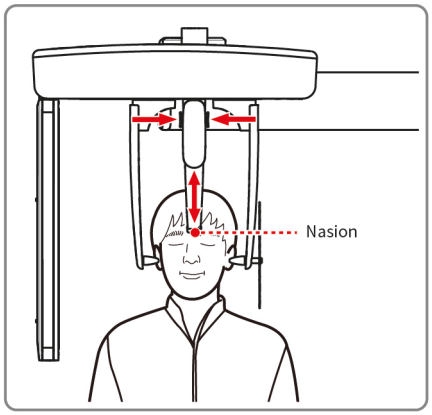
Use the Porion Position Reference Indicator that appears in the acquired image to easily confirm the location of Porion.

3. Guide the patient to the CEPH unit.
4. Direct the patient to relax his/her neck and shoulders and stand upright.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to approximately match the height of the patient.

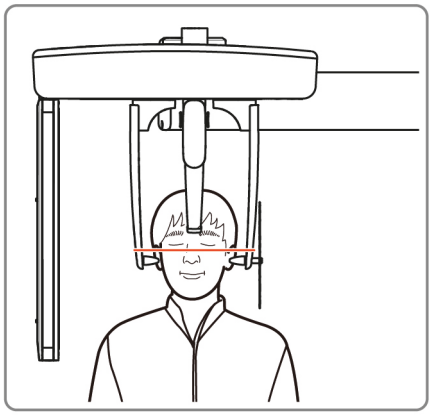
WARNING

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

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



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

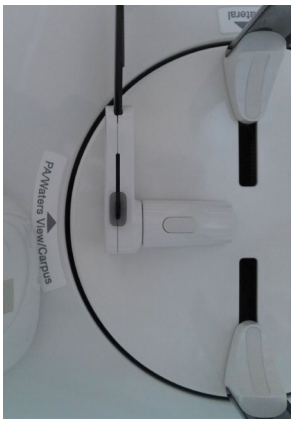


8. Direct the patient to swallow first before closing the mouth and to remain in his/her current position until image acquisition is completed.
9. Click the **READY** button. The x-ray exposure has not started yet.
10. Now go to **8.4 X-ray Exposure** to start the exposure.

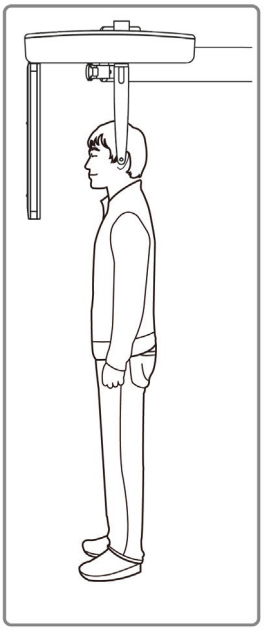
8.3.2 PA Mode

Patient Positioning

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



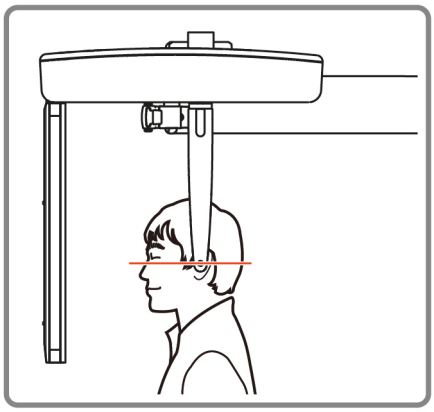
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in PA mode.
3. Guide the patient to the CEPH unit.
4. Ask the patient to stand upright facing the sensor. Make sure that the patient's shoulders are level and that his/her neck is relaxed.



5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to approximately match the height of the patient.

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

6. During the operation, properly 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 to the floor.



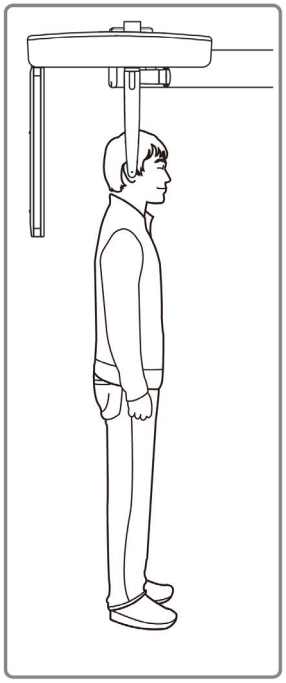
8. Direct the patient to swallow first before closing his/her mouth and to remain in his/her current position until image acquisition is completed.
9. Click the **READY** button. The x-ray exposure has not started yet.
10. Now go **to 8.4 X-ray Exposure** to start the exposure.

8.3.3 SMV Mode

Patient Positioning

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

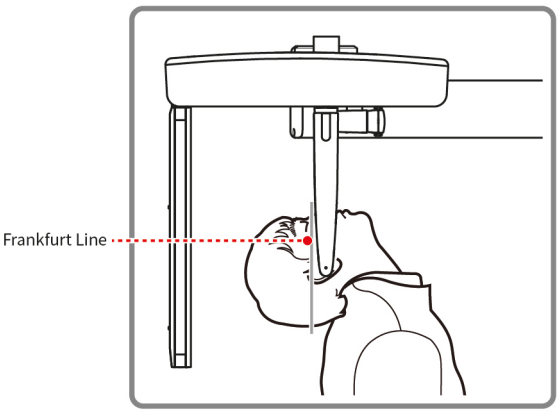
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in SMV mode.
3. Guide the patient to the CEPH unit.
4. Guide the patient to face the X-ray tube and stand upright.



5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to approximately match the height of the patient.

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

6. During the operation, properly 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.

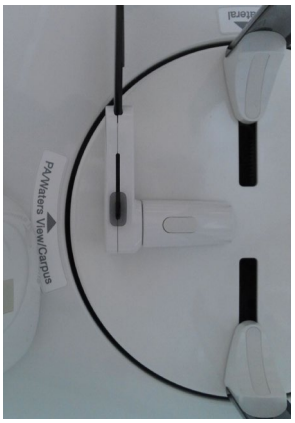


9. Click the **READY** button. The x-ray exposure has not started yet.
10. Now go **to 8.4 X-ray Exposure** to start the exposure.

8.3.4 Waters' view Mode

Patient Positioning

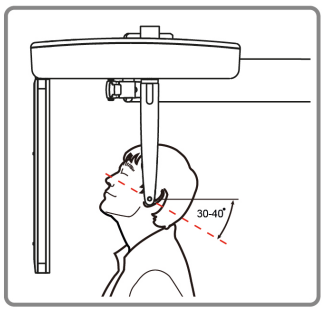
1. Turn the Nasal Positioner to the **PA / Waters' view / Carpus** mode Positioning Marker as shown below.



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 stand upright facing the sensor. Make sure that the patient's shoulders are level and that his/her neck is relaxed.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to approximately match the height of the patient.

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

6. During the operation, properly 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.



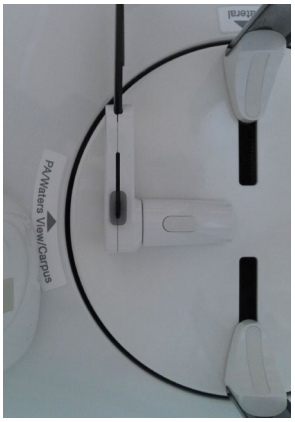
8. Click the **READY** button. The x-ray exposure has not started yet.
9. Now go **to 8.4 X-ray Exposure** to start the exposure.

8.3.5 Carpus Mode

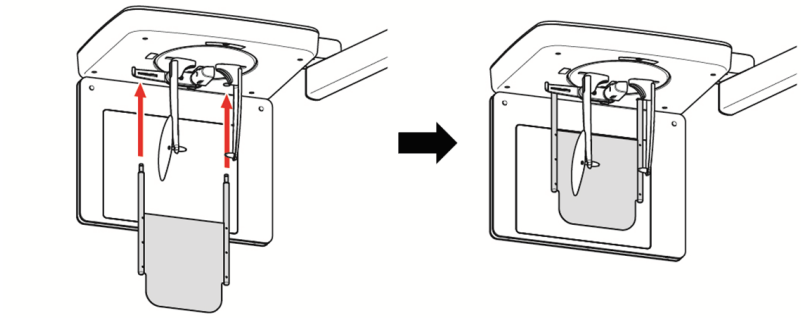
For Carpus Mode, install the Carpus Plate first before positioning the patient.

Installing the Carpus Plate

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



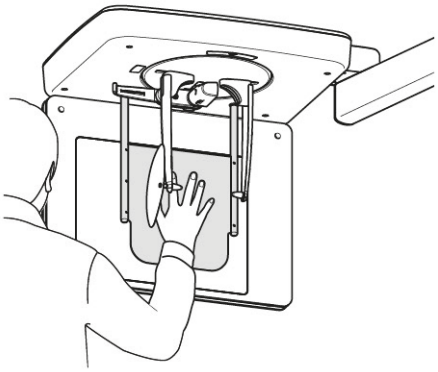
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Carpus mode.
3. Fit the two ends of the Carpus Plate into the two holes of the CEPH unit as below.



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 stand 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 observe the X-ray safety regulations applicable to his/her area at all times during the operation of this equipment.

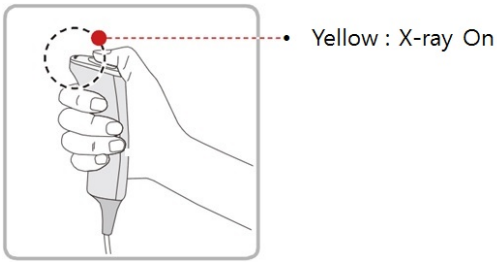
CAUTION

- The operator must keep vocal/visual contact with the patient at all times 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, don't let the patient move until the Temple Supports are open.

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.



NOTE

The image appears on the screen.

NOTE

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 and "X-RAY" changes to "X-RAY ON."

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's 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 / EasyDent**.

NOTE

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

1. The images are transferred to **EzDent-i / EasyDent** automatically.
2. The images are automatically saved if 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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9. Acquiring CBCT Images

9.1 CBCT Imaging Program Overview

■ Result Images

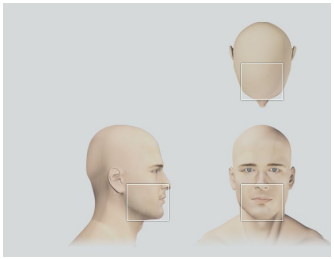
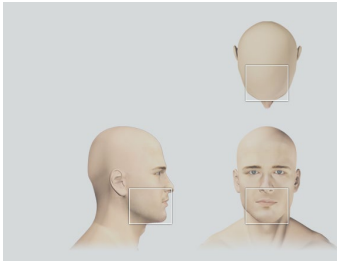
It provides conventional 3D CT sliced images.

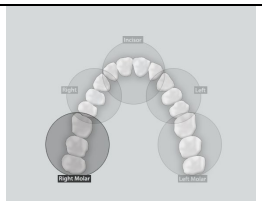
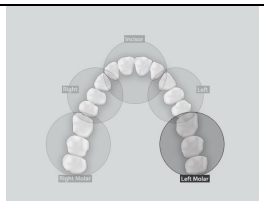
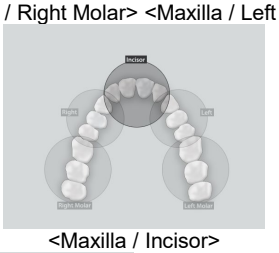
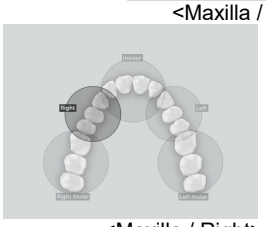
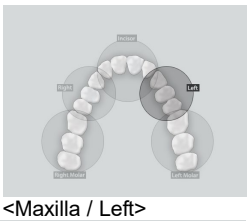
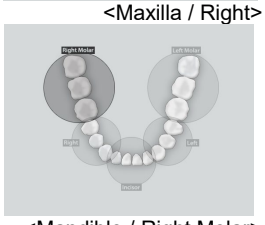
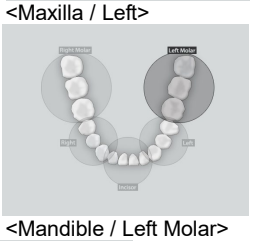
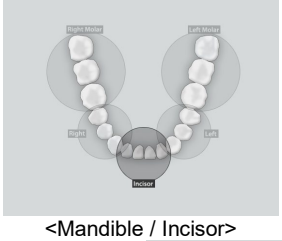
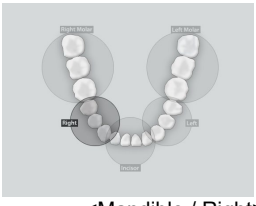
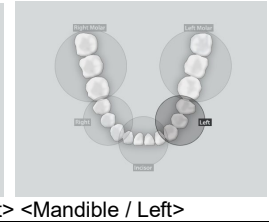
■ Image Acquisition Method

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
10x8.5	 <Occlusion / Center>	▪ Covers both maxillary and mandibular structures including the 3rd molar region. ▪ Suitable for most oral surgery cases as well as multiple implant surgery.
10x7	 <Occlusion / Center>	▪ For children aged between 0 and 13. ▪ Covers both maxillary and mandibular structures including the 3rd molar region. ▪ Suitable for most oral surgery cases as well as multiple implant surgery.

5x5	  <Maxilla / Right Molar> <Maxilla / Left Molar>  <Maxilla / Incisor>   <Maxilla / Right> <Maxilla / Left>   <Mandible / Right Molar> <Mandible / Left Molar>  <Mandible / Incisor>   <Mandible / Right> <Mandible / Left>	▪ Covers 3 ~ 4 areas through capturing ROIs. ▪ Can acquire 3 ~ 4 teeth at once. ▪ Endo mode (Voxel Size: 0.08) applied.

■ Special Option

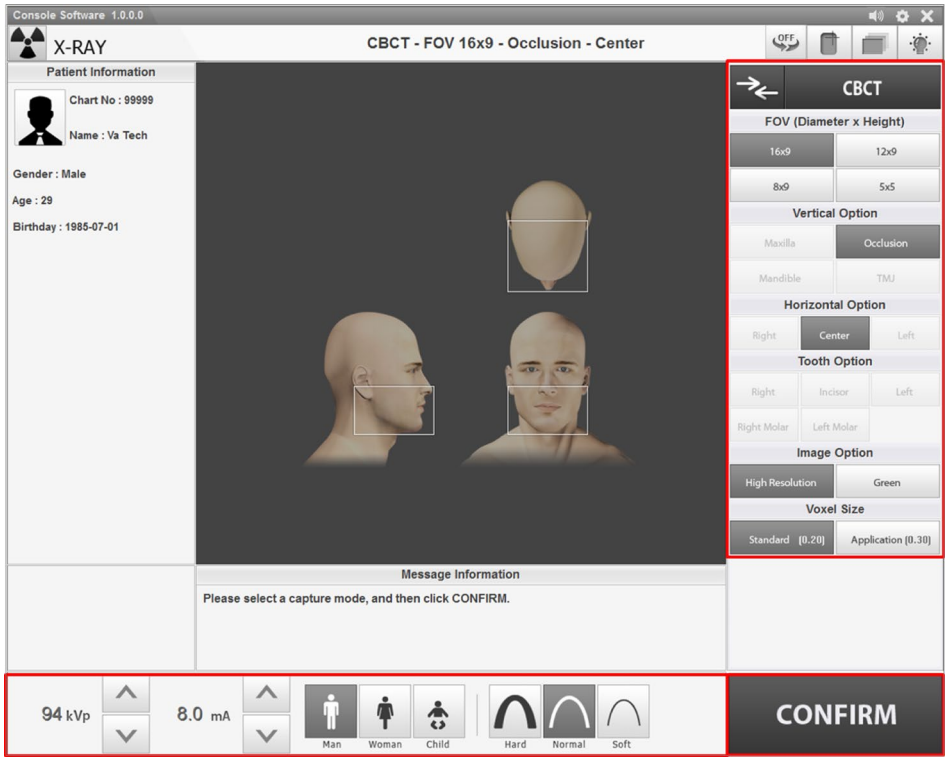
Auto Pano

: 2D images of conventional panoramic view are available with the specific FOVs. For more details on Auto Pano, please refer to **9.2 Configuring Exposure Parameters**.

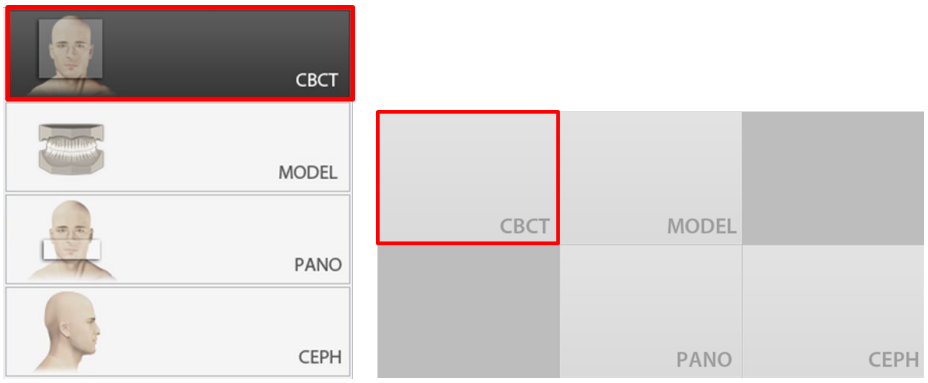
9.2 Configuring Exposure Parameters

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

NOTE	You can set the imaging parameters on Console Software running on the PC. (Touch Screen is Optional. In case the Touch Screen is included in the equipment, Touch Screen and Console Software are synchronized and display the same environmental settings.)



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



<Console Software> <Touch Screen>

NOTE

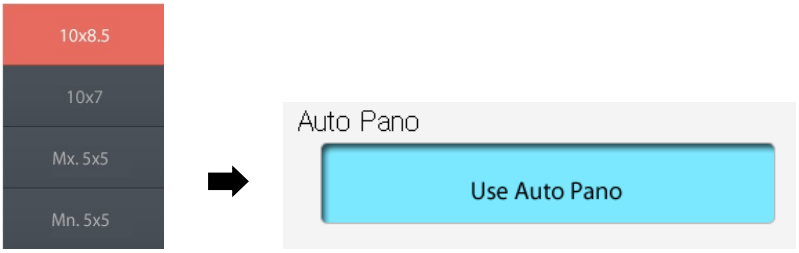
CEPH button exists only when the CEPH imaging program is included in the equipment.

2. Select FOV Size.

- You can configure **Auto Pano** options when **10x8.5 or 10x7** is selected.

  (On the Touch Screen, press  button to close Auto Pano option window.)

<Console Software>



<Touch Screen>

- For both 10x8.5 and 10x7 FOVs, Vertical option and Horizontal option are set as below by default.
- For FOV 5x5, Vertical option and Tooth option are available.

Available FOV (cm)	Vertical option	Horizontal option	Tooth option
10x8.5	Occlusion	Center	N/A
10x7	Occlusion	Center	N/A
5x5	Maxilla / Mandible	N/A	Right Molar
			Right
			Incisor
			Left
			Left Molar

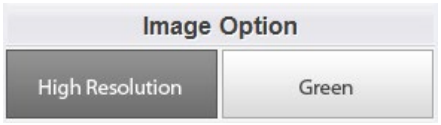
NOTE

***Auto Pano**

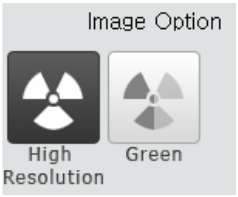
Auto Pano is a feature used to acquire reconstructed 2D images during 3D CT scans without additional X-ray exposure. It has the same region that conventional panoramic images offer. (It provides images for the Standard mode in DICOM or BMP format.)

	Auto Pano option is available when FOV 10x8.5 or 10x7 is selected. When Auto Pano option is selected, Auto Pano image is automatically acquired and can be seen on the **EzDent-i / EasyDent** Viewer.

3. Select an Image Option. (On Touch Screen, click **Settings** button before selecting options.)



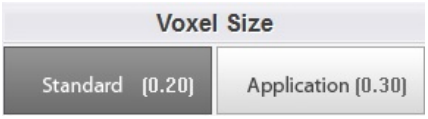
<Console Software>



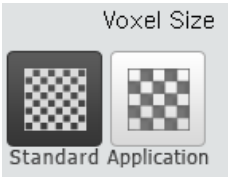
<Touch Screen>

4. Select a Voxel Size.

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



<Console Software>



<Touch Screen>

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

<Console Software>

<Touch Screen>

NOTE

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

6. Select X-ray intensity.

<Console Software>

<Touch Screen>

NOTE

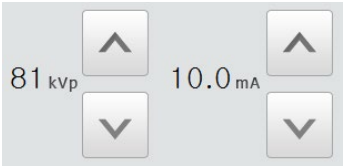
Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft :

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

7. 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.

<Console Software>



<Touch Screen>

8. Click **CONFIRM** button when exposure parameter setting is completed.

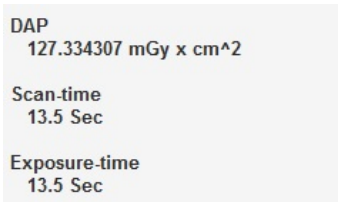
<Console Software>

<Touch Screen>

NOTE

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 Patient Information window.



9. Guide the patient to the equipment.

9.3 Patient Positioning

WARNING

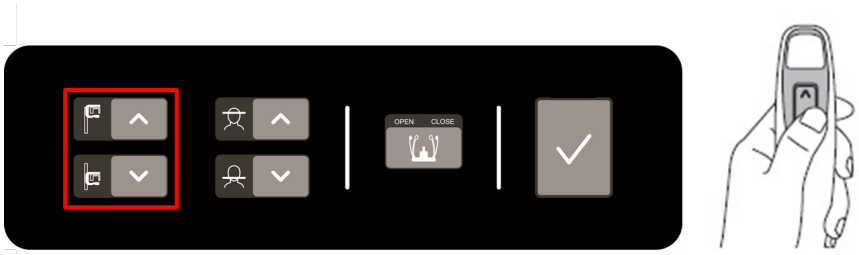
- Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.

IMPORTANT

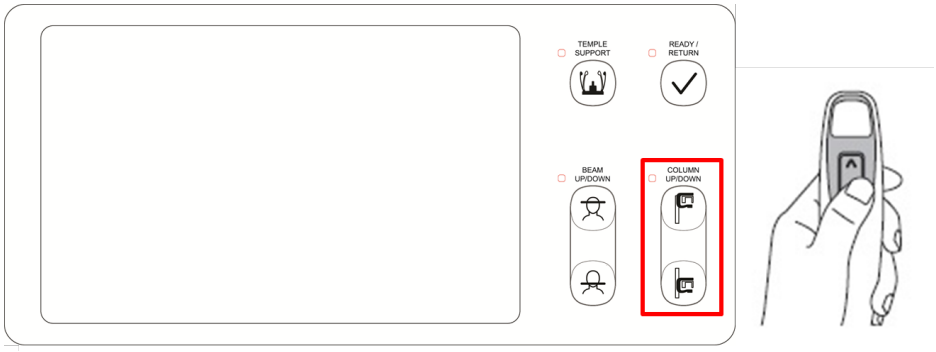
- Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.
- Metal implants or bridges may reduce the quality of the images.
- Be sure to adjust laser beam correctly. Otherwise, the quality of images can be lower due to ghost images or expansion/reduction of the images.

Getting prepared

1. Let the patient remove all the metal objects (glasses, earrings, hair pins, braces, false teeth, etc.). Metal objects may induce ghost images and lower the image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button or switch option to adjust the equipment to match the height of the patient.
4. Press the **Rotation test** button in the Console program and check that the equipment touches a part of the patient while the equipment is running.



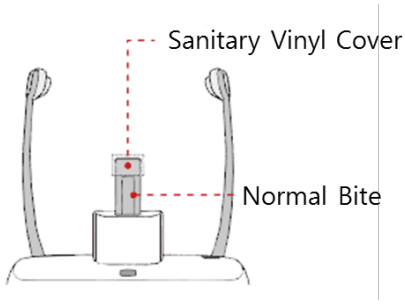
< Control Panel – Membrane type>



<Control Panel – LCD type>

Normal Patient Positioning

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



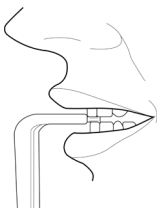
CAUTION

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

- Clean the Chinrest and the Bite with ethanol and wipe with a dry towel before the next patient.

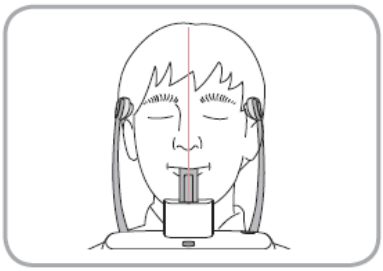
2. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.

3. Guide the patient to the equipment.
4. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
   - Hold the handles tightly.
   - Press the chest against the equipment.
   - Keep both feet close to the inside of the base.
   - Keep both shoulders parallel.
   - Straighten the Cervical Spine and stand still.
6. Let the patient bite the Bite along its grooves with his/her front teeth.



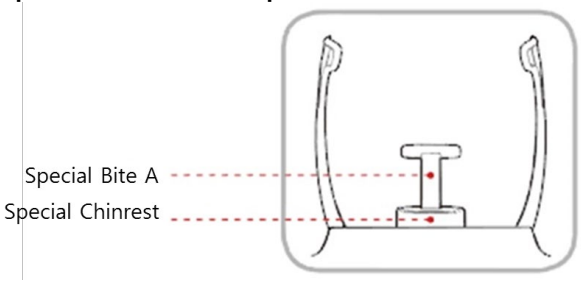
7. Let the patient maintain the posture as follows:

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



TMJ 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**



3. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.

4. Guide the patient to the equipment.
5. Use the **Vertical Frame Up/Down** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
   - Hold the handles tightly.
   - Press the chest against the equipment.
   - Keep both feet close to the inside of the base.
   - Keep both shoulders parallel.
   - Straighten the Cervical Spine and stand still.
7. Let the patient maintain the posture as follows:
   - Close the eyes.

NOTE

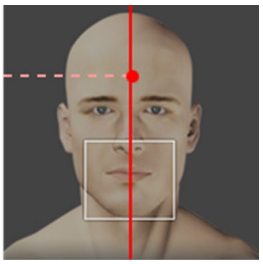
- Ask the patient to maintain his/her position until the operation is completed.

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 Laser Beam properly.

Vertical Beam / Mid-sagittal Line



FOV 10x8.5 (cm)

NOTE	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's to prevent horizontal expansion of the image.)

Finishing Patient Positioning

1. After checking the positions of the patient and the Laser Beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.

CAUTION	Make sure that the Temple Supports are in CLOSE position before clicking the **READY** button.

2. Click the **READY** button. The X-ray exposure has not started yet.
3. Now go to **9.4 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 observe the X-ray safety regulations applicable to his/her area at all times during the operation of this equipment.

CAUTION

- The operator must keep vocal/visual contact with the patient at all times during the image acquisition process.
- Do not operate the PC during exposure. Doing so may cause the system to malfunction.

IMPORTANT

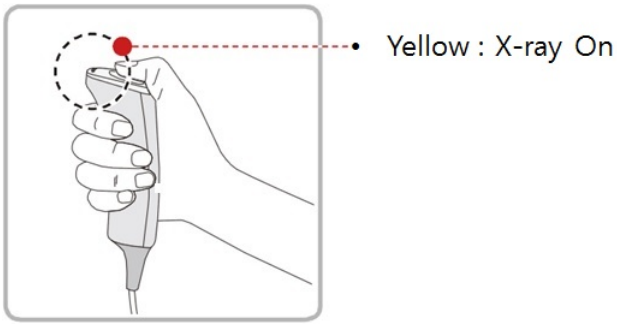
- Let the patient close the eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, don't let the patient move until the Temple Supports are open.

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

IMPORTANT

The operator must keep vocal/visual contact with the patient at all times during image acquisition.

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



NOTE

The image appears on the screen.

NOTE

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 and “X-RAY” changes to “X-RAY ON.”

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

9.5 Finishing the Scan

1. Open the Temple Supports and guide the patient out of the equipment.
2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.
3. Press **READY** button to bring the Rotating Unit back to its initial position.

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 / EasyDent**.

NOTE

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

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

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10. Acquiring 3D MODEL Scan Images

10.1 3D MODEL Scan Imaging Program

■ Result Images

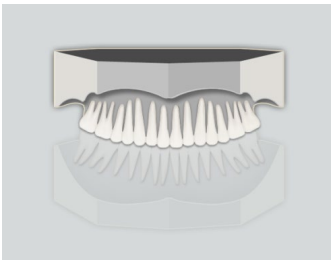
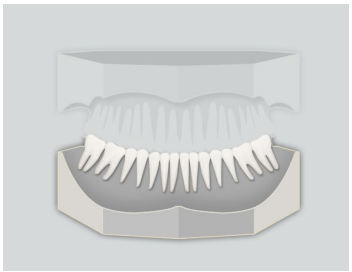
It provides 3D modeling surface data of the Plaster Cast. (STL file)

■ Image Acquisition Method

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

■ Examination Programs

It is classified as below based on the MODEL type.

Applied FOV (cm)	Vertical Option	ROI	Description
10x8.5	Upper (Maxilla)		Captures a whole maxillary Plaster Cast.
	Lower (Mandible)		Captures a whole mandibular Plaster Cast.

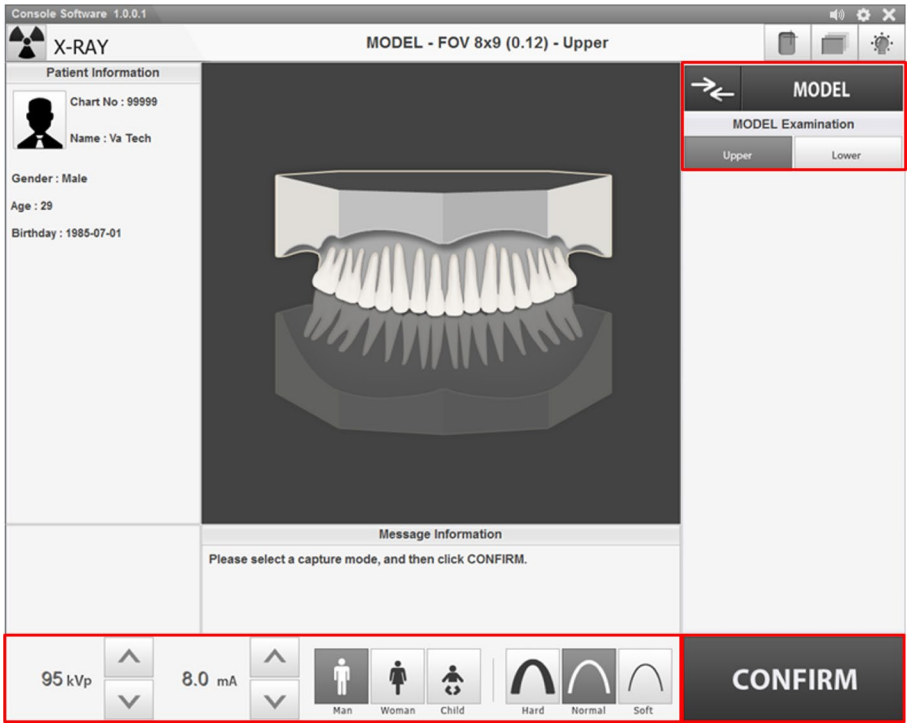
NOTE

The 3D MODEL Scan modality is not available for EasyDent / Ez3D Plus users.

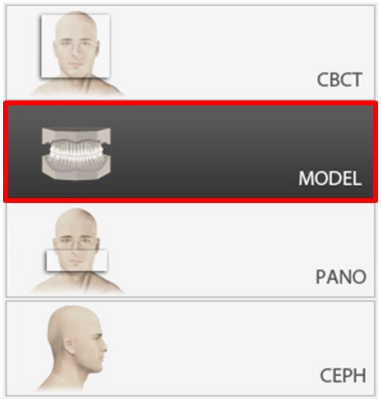
10.2 Configuring Exposure Parameters

To acquire 3D MODEL Scan Images, **6. Getting Started** must be completed first.

NOTE	You can set the imaging parameters on Console Software running on the PC. (Touch Screen is Optional. In case the Touch Screen is included in the equipment, Touch Screen and Console Software are synchronized and display the same environmental settings.)



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



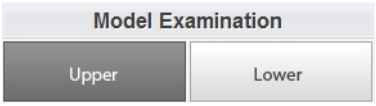
<Console Software>

<Touch Screen>

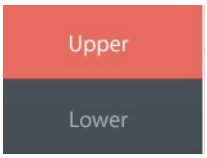
NOTE

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

2. Select Model Examination type.



<Console Software>



<Touch Screen>

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

<Console Software>

<Touch Screen>

NOTE

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

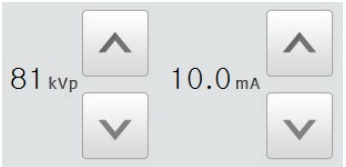
4. Select X-ray intensity.

<Console Software>

<Touch Screen>

5. 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.

<Console Software>



<Touch Screen>

6. Click **CONFIRM** button when exposure parameter setting is completed.

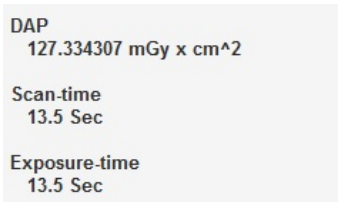
<Console Software>

<Touch Screen>

NOTE

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 Patient Information window.

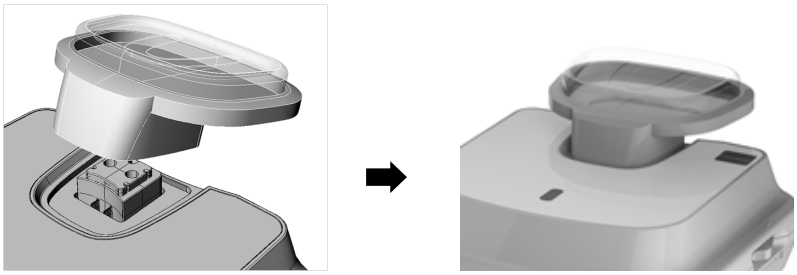


7. Bring the Plaster Cast to the equipment.

10.3 MODEL Positioning

MODEL Scan Jig Installation

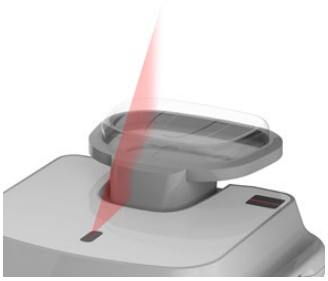
1. Remove the Temple Supports and the Chinrest
2. Insert the MODEL Scan Jig.



Laser Beam Aligning

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

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

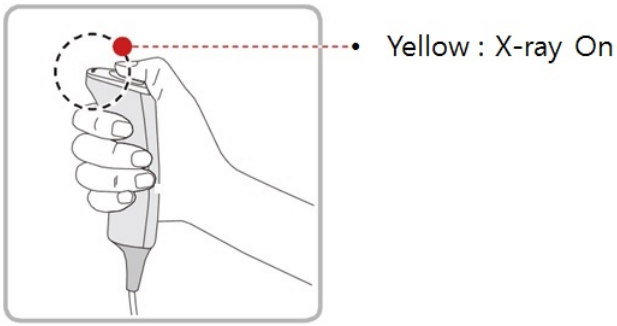


3. Click the **READY** button. The X-ray exposure has not started yet.
4. Now go to **10.4 X-ray Exposure** to start the exposure.

10.4 X-ray Exposure

CAUTION	Do not operate the PC during exposure. Doing so may cause the system to malfunction.

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.



NOTE	The image appears on the screen.

NOTE	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 and “X-RAY” changes to “X-RAY ON.” 

3. Release the **Exposure Switch** when “Image capturing is completed” message appears on the screen.
4. Remove the Plaster Cast out of the equipment.

10.5 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM or STL (Stereo Lithography) format.

NOTE

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 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. You can check the captured image with a 3rd party STL viewer.

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11. Troubleshooting

11.1 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.

11.2 Error Codes

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

Error Code	Description
H001	Error occurs when the tube state is not Ready. - Check the inverter board and such for CAN communication cable connections.
H002	Error occurs by disconnection of the cables for the monoblock and the inverter board. - Check the cables to the inverter and the monk tank.
H003	Error occurs by overcurrent of the inverter (upon X-ray emission). - Check the input power (DC 300 V) of the inverter board. - After replacing the inverter board, check for error after X-ray emission. If the same error occurs, replace the monk tank.
H008	Error occurs when the temperature of the monoblock is greater than or equal to the set value. When the temperature is less than or equal to the set value of -2 °C, the error is cleared. - Check the temperature of the monk tank. - When the temperature of the monk tank is greater than or equal to 55 °C, do not emit X-rays and cool down the mono tank before use.
H009	Error occurs when the inverter current has a problem during emission of X-rays (greater than or equal to the X-ray irradiation current by +1 A under the current EP and IP). - Check the input power (DC 300 V) of the inverter board.
H010	Error occurs when the Exposure Switch is "Off" after the exposure On command is sent. - Check the connection to the X-ray switch on the inverter. - Check for CAN communication status. - If there is any communication failure, replace the inverter board.
H011	Error occurs when exposure Off command is not received within 0.5 seconds after the Exposure Switch is changed to Off during X-ray emission. - Check the connection to the X-ray switch on the inverter. - Check for CAN communication status. - If there is any communication failure, replace the inverter board.
H012	Error occurs when the kV feedback is less than or equal to the set value by more than or equal to 20 kV during X-ray emission. (kV feedback ≤ set value - 20) The number "3" appears on the inverter board. - Check the input power (DC 300 V) of the inverter board. - Check that the input power (DC 300 V) is changed to less than or

Error Code	Description
	equal to 200 V upon X-ray emission. (In case of less than or equal to 200 V, replace the power source.) - After replacing the inverter board, check for error after X-ray emission. If the same error occurs, replace the monk tank.
H013	Error occurs when the kV feedback is greater than or equal to the set value by more than or equal to 20 kV during X-ray emission (kV feedback ≥ set value + 20). The number "4" appears on the inverter board. - After emitting X-rays again, check whether the same error occurs. - Check the input power (DC 300 V) of the inverter board. - Check that the input power (DC 300 V) is changed to less than 200 V upon X-ray emission. (In case of less than 200 V, replace the power source.) - After replacing the inverter board, check for error after X-ray emission. If the same error occurs, replace the monk tank.
H014	Error occurs when the mA feedback is less than or equal to the 50 % of the set value during X-ray emission (mA feedback ≤ set value x 0.5). The number "6" appears on the inverter board. - After emitting X-rays again, check whether the same error occurs. - Check the input power (DC 300 V) of the inverter board. - After replacing the inverter board, check for error after X-ray emission. If the same error occurs, replace the monk tank.
H015	Error occurs when the mA feedback is greater than or equal to the 150 % of the set value during X-ray emission (mA feedback ≥ set value x 1.5). The number "6" appears on the inverter board. - After emitting X-rays again, check whether the same error occurs. - Check the input power (DC 300 V) of the inverter board. - After replacing the inverter board, check for error after X-ray emission. If the same error occurs, replace the monk tank.
H020	Error occurs during movement from the P-axis motor's origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H021	Error occurs during movement from the rotator-axis motor's origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H024	Error occurs during movement from the CT horizontal laser up/down-axis motor's origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H027	Error occurs during movement from the Cephalo sensor motor's

Error Code	Description
	origin position. - Check the connection lines for motor and origin sensor. If any problem, replace the motor or sensor.
H030	Error occurs during movement from the 4-axis collimator's left origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H031	Error occurs during movement from the 4-axis collimator's right origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H032	Error occurs during movement from the 4-axis collimator's up origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H033	Error occurs during movement from the 4-axis collimator's down origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H036	Error occurs during movement from the 1-axis collimator's left/right origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H037	Error occurs during the generator tilting motion. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H038	Error occurs during the temple support motor's motion. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H039	Error occurs during the movement from the X-axis motor's origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H040	Error occurs during the movement from the Y-axis motor's origin position. - Check the connection lines for the motor and origin sensor. If any problem, replace the motor or sensor.
H060	Error occurs when the Exposure Switch has been pressed when the equipment is turned on. - Check the connection to the Exposure Switch and perform Reset the equipment.
H102	Error occurs when there is no response to CAN communication.

12. Cleaning and Maintenance

IMPORTANT

The equipment has to be installed and maintained on a flat surface.

12.1 Cleaning

WARNING

Always turn off the power to the equipment and disconnect it from the power outlet before cleaning.

- Thoroughly clean the areas of the equipment that come in direct contact with the patient, such as the Chinrest and the Bite.
- 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 abrasive liquids such as acetone, gas, or oil, which may cause corrosion on the surface of the equipment.
- 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 ethanol and gently wipe with a dry towel before the next patient.
Temple Supports	Clean with ethanol and gently wipe with a dry towel before the next patient.
Chinrest	Clean with ethanol 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.

12.2 Maintenance

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

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

12.2.1 Regular Maintenance

- 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.

- 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 which 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.

12.2.2 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 possible damages to the **Exposure Switch** cable.	Monthly
Confirm that the audio message is audible throughout the exposure.	Monthly

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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 dispose of. 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 in accordance with 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			●	

This dental equipment shall not be disposed of as domestic garbage materials.

Clean / Disinfect / Sterilize the equipment before disassembling it and disposing of its parts.

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

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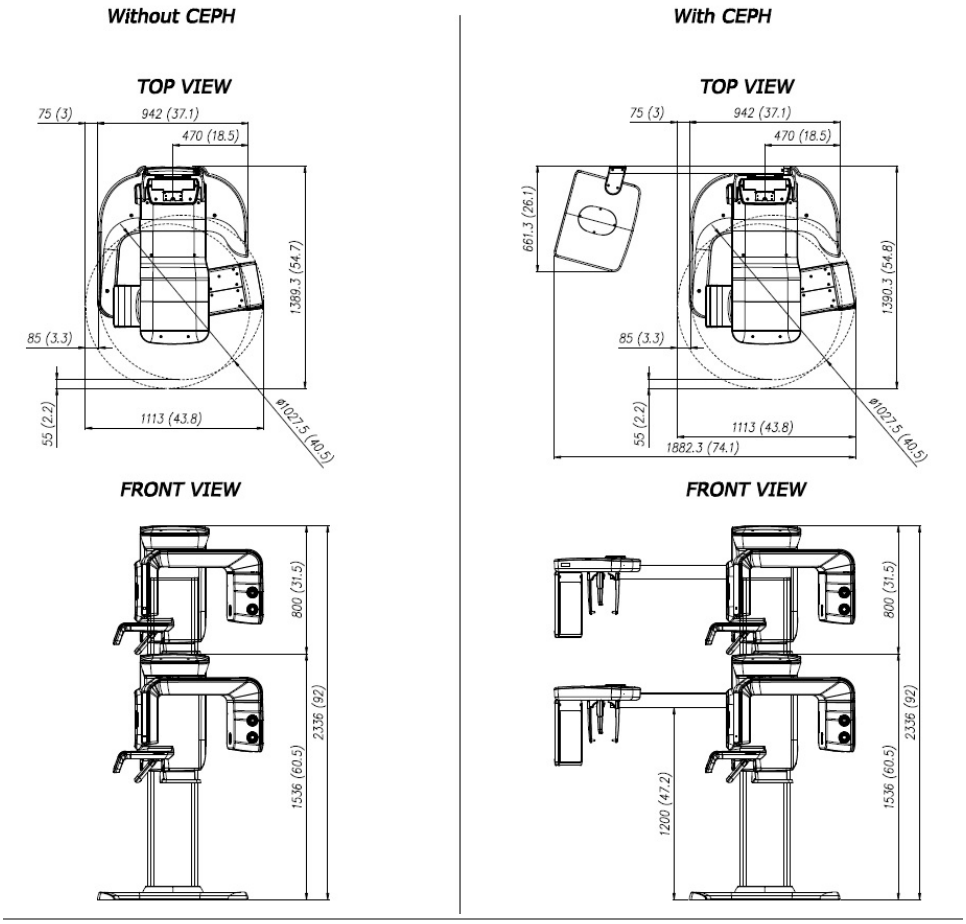
14. Technical Specifications

14.1 Mechanical Specifications

14.1.1 Dimensions (unit = mm)



Item		Description
Weight	Without CEPH unit	137 kg (302.0 lbs. – without Base)
		190 kg (418.9 lbs. – with Base)
	With CEPH unit	162 kg (357.1 lbs. – without Base)
		215 kg (474.0 lbs. – with Base)
Total Height	Without Base	Max. 2304.5 mm
	With Base	Max. 2336 mm
Dimensions during operation (Length x Width x Height)	Without CEPH unit	1389.3 mm (L) x 1113 mm (W) x 2304.5 mm (H) (without Base)
		1389.3 mm (L) x 1113 mm (W) x 2336 mm (H) (with Base)
	With CEPH unit	1390.3 mm (L) x 1882.3 mm (W) x 2304.5 mm (H) (without Base)
		1390.3 mm (L) x 1882.3 mm (W) x 2336 mm (H) (with Base)
Rotating Unit Vertical Movement		Max. 800 mm
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	600	477.7	122.3	1 : 1.25
CEPH	1745	1524	221.0	1 : 1.14
CBCT	600	428.6	171.4	1 : 1.40

- 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

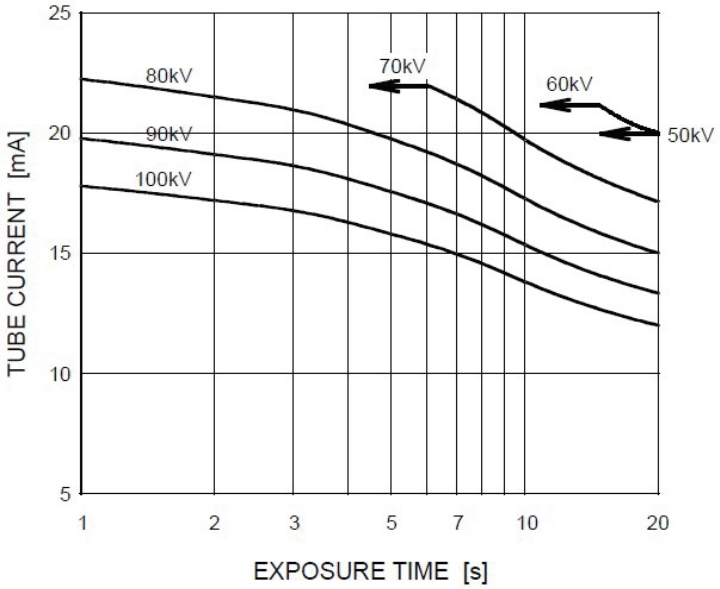
Item			Description
Generator	Model		DG-07E22T2
	Rated output power		1.6kW
	Inverter model name		INV-22
	Type		Inverter
	Normal/ Pulse	kVp	60 kV ~ 99 kV (1 kV increment)
		mA	4 mA ~ 16 mA (0.1 mA increment for CBCT, 1 mA increment for PANO and CEPH)
	Cooling		Cooling Protect (Optional fan cooling ≥ 60℃)
	Total filtration		Min. 2.5 mm Al
	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		Toshiba
	Model		D-052SB (Stationary Anode type)
	Focal spot size		0.5 mm (IEC 60336)
	Target Angle		5 degree
	Inherent Filtration		At least 0.8 mm Al equivalent at 50 kV
	X-ray Coverage		95 mm x380 mm at SID 550 mm
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time: Interval time)

Test Condition

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	60 ~ 90	4 ~ 14	13.5
	60 ~ 90	4 ~ 14	11.5
	60 ~ 90	4 ~ 14	11.3
	60 ~ 90	4 ~ 14	11.1
	60 ~ 90	4 ~ 14	9.2
	60 ~ 90	4 ~ 14	7.7
	60 ~ 90	4 ~ 14	7.0
	60 ~ 90	4 ~ 14	6.8
	60 ~ 90	4 ~ 14	6.7
	60 ~ 90	4 ~ 14	6.1
	60 ~ 90	4 ~ 14	5.8
	60 ~ 90	4 ~ 14	5.7
	60 ~ 90	4 ~ 14	5.2
	60 ~ 90	4 ~ 14	5.0
	60 ~ 90	4 ~ 14	3.7
	60 ~ 90	4 ~ 14	3.5
	60 ~ 90	4 ~ 14	3.3
	60 ~ 90	4 ~ 14	2.8
	60 ~ 90	4 ~ 14	1.4
CEPH	60 ~ 99	4 ~ 16	1.9
	60 ~ 99	4 ~ 15	2.4
	60 ~ 99	4 ~ 15	3.9
	60 ~ 99	4 ~ 14	4.9
	60 ~ 99	4 ~ 14	5.4
CBCT	60 ~ 99	4 ~ 12	16.4
	60 ~ 99	4 ~ 12	11.0

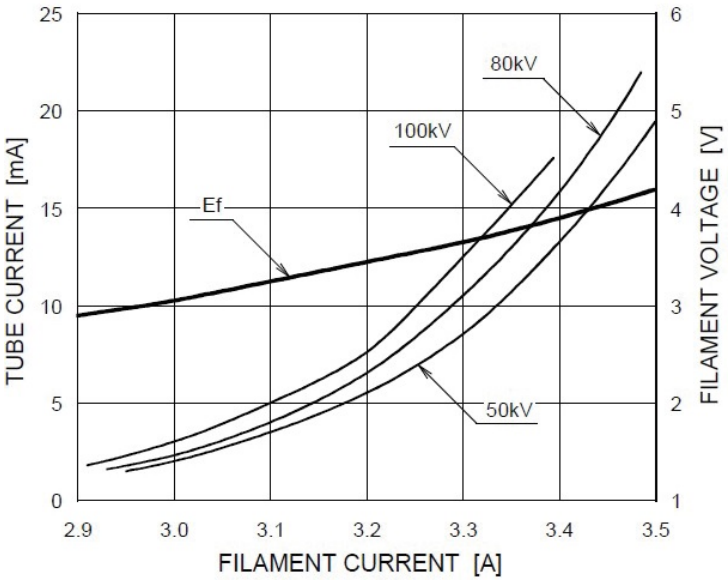
Maximum Rating Charts

Constant potential high-voltage generator
Nominal Focus Spot Value: 0.5

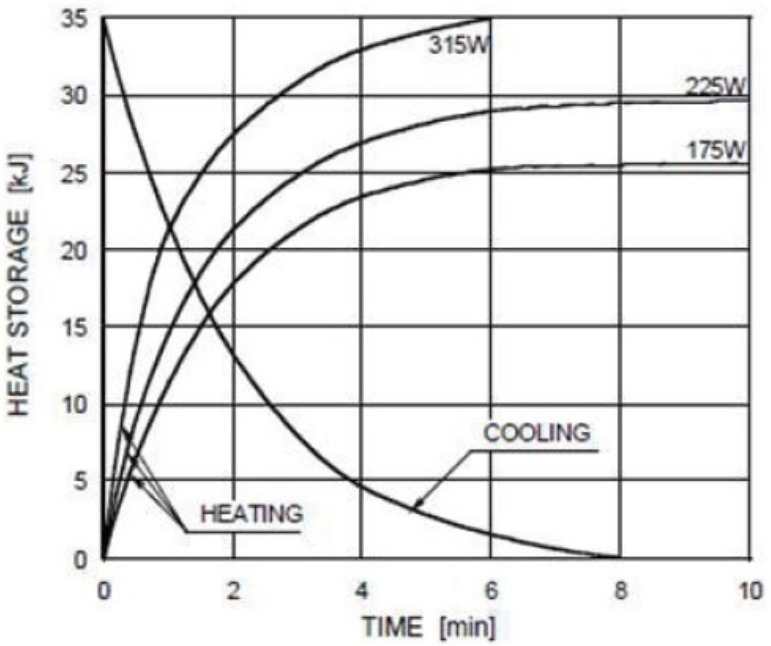


Emission & Filament Characteristics

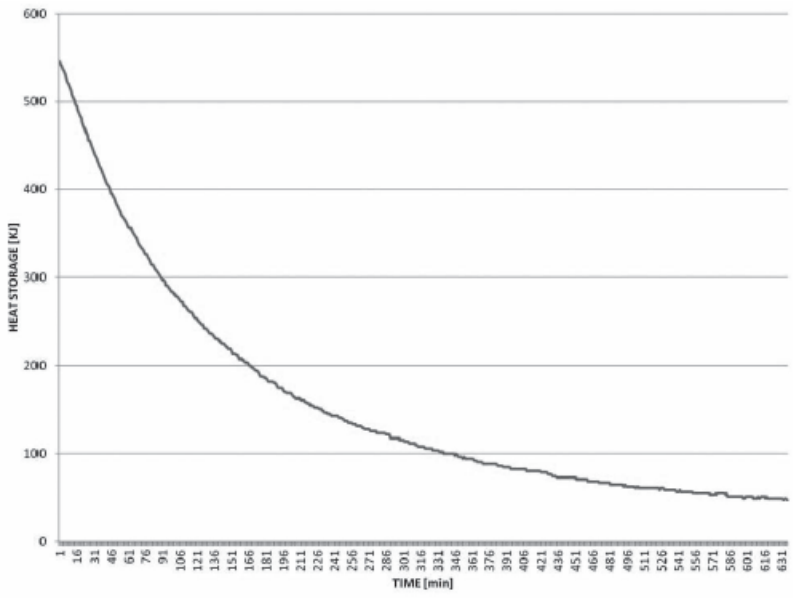
Constant potential high-voltage generator
Nominal Focus Spot Value: 0.5



Anode Thermal Characteristics



X-ray Housing Assembly Tube Characteristics



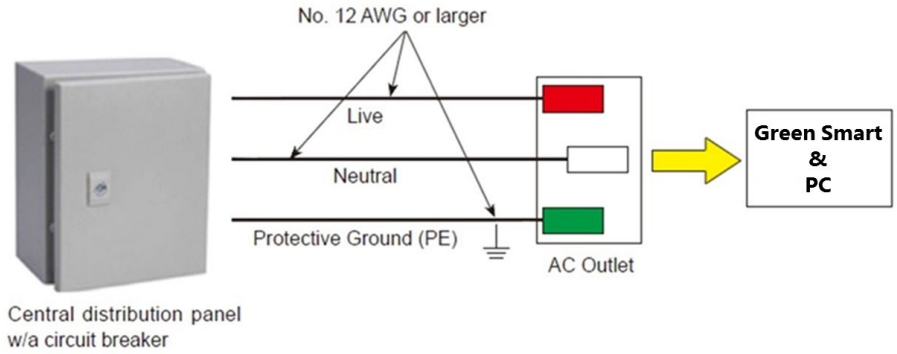
14.2.2 Detector Specifications

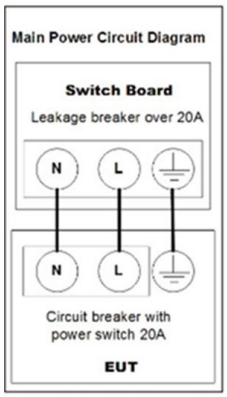
Item	Description	
	PANO & CBCT	**CEPH**
Model	Xmaru1404CF-Plus	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 μm @ 4X4 binning (49.5 μm @ no binning)	200 μm @ 2x2 binning (100 μm @ no binning)
Active area	CBCT - 36.4 mm X 135.8 mm PANO - 5.9 mm X 135.8 mm	15.6 mm x 259 mm
Frame Rate	~ 308 Hz @ 4X4 binning	~ 330 Hz @ 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 mm (L) x 230 mm (W) x 26 mm (H)	110 mm (L) x 279 mm (W) x 20 mm (H)
Sensor weight	450 g	1050 g
Converter	CsI:Ti	
Energy Range	50 ~ 120 kVp	
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 40 % @ 1 lp/mm > 8 % @ 2.5 lp/mm	
DQE	> 60 % @ ~ 0 lp/mm	> 60 % @ ~ 0 lp/mm
Dynamic Range	> 80 dB	> 80 dB

14.3 Electrical Specifications

Item	Description
Power supply voltage	100 - 240 V ~
Frequency	50 / 60 Hz
Power rating	2.0 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.
- Column operation time: Max. 2 min. On / 18 min. Off (Ratio 1:9)





NOTE

- To assure line voltage quality, a separate 3-core grounded power cable connected directly to 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

■ **PANO Option > Normal**

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
	Green (Optional)	Man	Hard	75	14
			Normal	74	14
			Soft	73	14
		Woman	Hard	74	14
			Normal	73	14
			Soft	72	14
		Child	Hard	68	12
			Normal	67	12
			Soft	66	12

SPECIAL Examination	N/A	Man	Hard	75	14
			Normal	74	14
			Soft	73	14
		Woman	Hard	74	14
			Normal	73	14
			Soft	72	14
		Child	Hard	68	12
			Normal	67	12
			Soft	66	12

■ **PANO Option > Insight PAN**

Mode	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination / SPECIAL Examination	N/A	Man	Hard	71	7
			Normal	70	7
			Soft	69	7
		Woman	Hard	71	7
			Normal	70	7
			Soft	69	7
		Child	Hard	68	7
			Normal	67	7
			Soft	66	7

Scan Time / Exposure Time

Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
PANO Examination	Narrow	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.8	7.0	3.5
		Front	14.1	11.3	7.0	5.8
		Left	14.1	6.8	7.0	3.5
	Normal	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.8	7.0	3.5
		Front	14.1	11.3	7.0	5.8
		Left	14.1	6.8	7.0	3.5
	Wide	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.8	7.0	3.5
		Front	14.1	11.3	7.0	5.8
		Left	14.1	6.8	7.0	3.5
	Child	Standard	12.0	11.5	6.8	6.7
		Right	12.0	5.7	6.8	3.3
		Front	12.0	9.2	6.8	5.2
		Left	12.0	5.7	6.8	3.3

	Ortho gonal	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.7	7.0	3.5
		Front	14.1	11.1	7.0	5.7
		Left	14.1	6.7	7.0	3.5
		Bitewing	14.1	9.2	7.0	5.0
		Bitewing Incisor (Optional),	14.1	2.8	7.0	1.4
		Bitewing Right	14.1	5.0	7.0	2.8
		Bitewing Left	14.1	5.0	7.0	2.8
SPECIAL Examination	-	TMJ LAT Open	14.1	6.7	14.1	6.7
		TMJ LAT Close				
		TMJ PA Open (Optional),	10.0	6.1	10.0	6.1
		TMJ PA Close (Optional),				
		Sinus LAT (Optional),	4.0	3.7	4.0	3.7
		Sinus PA	8.8	7.7	8.8	7.7

- *For Insight PAN mode, only "High Resolution" is applied to Image Options.*
- *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	15.0
			Normal	90	15.0
			Soft	88	15.0
		Woman	Hard	90	15.0
			Normal	88	15.0
			Soft	86	15.0
		Child	Hard	88	15.0
			Normal	86	15.0
			Soft	84	15.0
	Green	Man	Hard	92	16.0
			Normal	90	16.0
			Soft	88	16.0
		Woman	Hard	90	16.0
			Normal	88	16.0
			Soft	86	16.0
		Child	Hard	88	16.0
			Normal	86	16.0
			Soft	84	16.0
Full Lateral (Optional)	High Resolution / Green	Man	Hard	92	14.0
			Normal	90	14.0
			Soft	88	14.0
		Woman	Hard	90	14.0
			Normal	88	14.0
			Soft	86	14.0
		Child	Hard	88	14.0
			Normal	86	14.0
			Soft	84	14.0

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

Scan Time / Exposure Time

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

- *Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.*
- *Exposure Time: The 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
10x8.5	Occlusion	X	O	X
10x7	Occlusion	X	O	X
5x5	Maxilla / Mandible	Right Molar / Right / Incisor / Left / Left Molar		

- *10x8.5 (cm) and FOV 10x7 (cm) capture full arch area. (10x8.5 (cm) : Adult mode, FOV 10x7 (cm) :Child mode)]*

Exposure Condition (Scan Time: 18.0 s)

FOV (cm)	Image Option	Gender / Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
10x8.5 / 10x7 / 5x5	High Resolution	Man	Hard	95	8.7
			Normal	94	8.7
			Soft	93	8.7
		Woman	Hard	95	8.4
			Normal	94	8.4
			Soft	93	8.4
		Child	Hard	95	8.1
			Normal	94	8.1
			Soft	93	8.1
	Green	Man	Hard	80	5.0
			Normal	79	5.0
			Soft	78	5.0
		Woman	Hard	80	4.7
			Normal	79	4.7
			Soft	78	4.7
		Child	Hard	80	4.4
			Normal	79	4.4
			Soft	78	4.4

Scan Time / Exposure Time

FOV (cm)	Scan Time (s) (High Resolution / Green)	Exposure Time (s) (High Resolution / Green)
10x8.5	18.0	16.4
10x7	18.0	16.4
5x5	18.0	11.0

- *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)
10x8.5	0.2	113	260
	0.3	117	77
10x8.5 (with Auto Pano)	0.2	120	267
	0.3	125	84
10x7	0.2	90	202
	0.3	93	60
5x5	0.08	162	466
	0.12	128	139

- *The above data is obtained from a computer system which is based on Intel i7-6700 and NVIDIA Geforce GTX1060 6GB Graphics Card.*
- *Image reconstruction time varies depending on computer specifications and/or working conditions.*

NOTE

***Auto Pano**

Auto Pano is a feature used to acquire reconstructed 2D images during 3D CT scans without additional X-ray exposure. It has the same region that conventional panoramic images offer. (It provides images for the Standard mode in DICOM or BMP format.)

Auto Pano option is available when FOV 10x8.5 or 10x7 is selected. When selected, Auto Pano image is automatically acquired and can be seen on the **EzDent-i / EasyDent** Viewer.

15.1.4 3D MODEL Scan Mode

Exposure Area

FOV (cm)	MODEL Type	Horizontal Position		
		Right	Center	Left
10x8.5	Upper (Maxilla)	X	O	X
	Lower (Mandible)	X	O	X

Exposure Condition

FOV (cm)	Gender / Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
10x8.5	Man / Woman / Child	Hard / Normal / Soft	95	8.7

Scan Time / Exposure Time

FOV (cm)	Scan Time (s)	Exposure Time (s)
10x8.5	18.0	16.4

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

Reconstruction Time / File Size

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)	File Size (MB)
10x8.5	0.2	113	260

- *The above data is obtained from a computer system which is based on Intel i7-6700 and NVIDIA Geforce GTX1060 6GB.*
- *Image reconstruction time varies depending on computer specifications and/or 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 the **Green Smart**.

X-ray Dose Test Report for the **Green Smart** 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, the **Green Smart** is designed to comply with IEC 60601-1-3 Part 1 General Requirements for Safety.

Test Hardware	
Brand Name (Model)	Green Smart (Model: PHT-35LHS)
Sensor Type	PANO & CBCT: Xmaru1404CF-Plus CEPH: Xmaru2602CF
X-ray Generator	DG-07E22T2
Tube	D-052SB

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·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.

- *PHE (Public Health England) recommends that any national reference dose that achievable dose (DAP) value of 250 [mGy·cm2] for a clinical protocol for a standard male patient.*

Standard

National Deviations	Terminology	Permissive Range
PHE (GBR)	DAP (Pano, CEPH and CBCT)	**PANO**: ≤ 93 mGy·cm^2 (Adult) / 67 mGy·cm^2 (Child) **CEPH**: ≤ 40 mGy·cm² (Adult, Lateral) / 25 mGy·cm² (Child, Lateral) **CBCT**: ≤ 250 mGy·cm^2 (Basis of single implant)
AERB (IND)	Dose	All dose values must be within ± 20 % of the SPECIFIED values

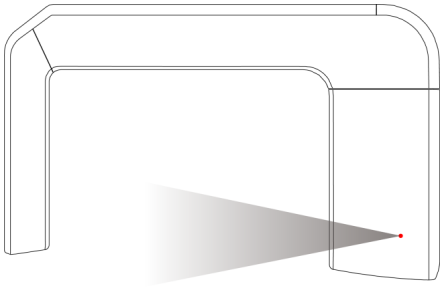
DAP (Dose Area Product) Calculation

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

NOTE

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·cm^2]
PANO Adult Man Normal (High Resolution)	74 kVp / 12.0 mA / 13.5 s	110
PANO Child Normal (High Resolution)	67 kVp / 10.0 mA / 11.5 s	55
PANO Adult Man Normal (Green)	74 kVp / 14.0 mA / 7.0 s	65
PANO Child Normal (Green)	67 kVp / 12.0 mA / 6.7 s	35
PANO Adult Man Insight PAN	67 kVp / 7.0 mA / 11.5 s	403
PANO Child Insight PAN	90 kVp / 15.0 mA / 3.9 s	295
CEPH Adult Man LAT (High Resolution)	90 kVp / 15.0 mA / 3.9 s	41
CEPH Child LAT (High Resolution)	86 kVp / 10.0 mA / 3.9 s	38
CEPH Adult Man LAT (Green)	90 kVp / 16.0 mA / 1.9 s	25
CEPH Child LAT (Green)	86 kVp / 16.0 mA / 1.9 s	23
CBCT FOV 10x8.5 Adult Man (High Resolution)	94 kVp / 8.7 mA / 16.4 s	646
CBCT FOV 10x8.5 Adult Man (Green)	79 kVp / 5.0 mA / 16.4 s	256

Mode	Exposure Condition	DAP [mGy·cm^2]
CT FOV 10x7 Adult Man (High Resolution)	94 kVp / 8.7 mA / 16.4 s	530
CT FOV 10x7 Adult Man (Green)	79 kVp / 5.0 mA / 16.4 s	210
CBCT FOV 5x5 Maxilla Adult Man (High Resolution)	94 kVp / 8.7 mA / 11.0 s	290
CBCT FOV 5x5 Maxilla Adult Man (Green)	79 kVp / 5.0 mA / 11.0 s	115
CBCT FOV 5x5 Mandible Adult Man (High Resolution)	94 kVp / 8.7 mA / 11.0 s	333
CBCT FOV 5x5 Mandible Adult Man (Green)	79 kVp / 5.0 mA / 11.0 s	132

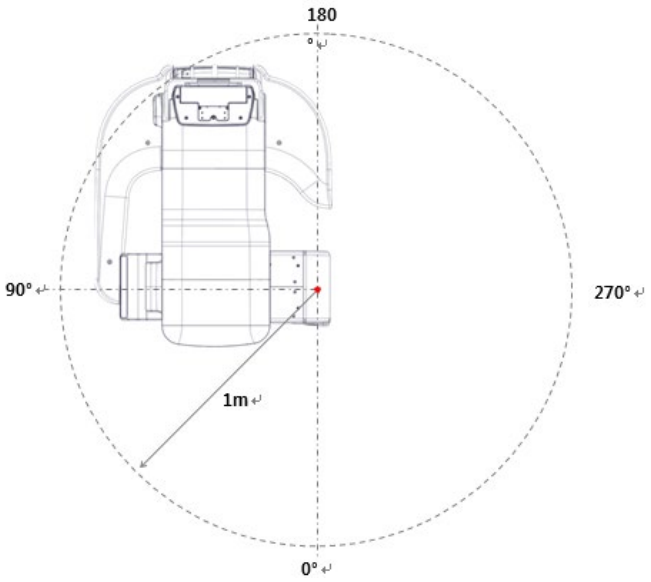
15.2.2 Leakage Dose

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

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

Measurement Overview



■ PANO Mode

<PANO Option: Normal>

Test Condition

Item	Condition
Tested Mode	PANO (Normal) Adult / Child
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

Results

Direction [°]	Adult		Child	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	9	0.079	8	0.070
22	7	0.061	7	0.061
45	3	0.026	4	0.035
75	2	0.018	3	0.026
90	1	0.009	1	0.009
100	3	0.026	2	0.018
110	3	0.026	3	0.026
120	4	0.035	4	0.035
130	4	0.035	4	0.035
140	5	0.044	5	0.044
150	3	0.026	3	0.026
160	2	0.018	2	0.018
170	9	0.079	9	0.079
180	6	0.053	6	0.053
190	4	0.035	4	0.035
200	9	0.079	8	0.070
210	5	0.044	5	0.044
220	4	0.035	4	0.035
230	3	0.026	2	0.018
240	3	0.026	3	0.026
250	3	0.026	4	0.035
260	3	0.026	3	0.026
270	3	0.026	3	0.026
315	9	0.079	6	0.053
340	7	0.061	5	0.044

<PANO Option: Insight PAN>

Test Condition

Item	Condition
Tested Model	PANO (Insight PAN) Adult / Child
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

Results

Direction [°]	Adult		Child	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	11	0.096	10	0.088
22	7	0.061	7	0.061
45	4	0.035	4	0.035
75	7	0.061	7	0.061
90	1	0.009	1	0.009
100	4	0.035	4	0.035
110	4	0.035	4	0.035
120	4	0.035	4	0.035
130	5	0.044	5	0.044
140	2	0.018	2	0.018
150	1	0.009	2	0.018
160	5	0.044	5	0.044
170	12	0.105	12	0.105
180	11	0.096	10	0.088
190	8	0.070	8	0.070
200	7	0.061	7	0.061
210	12	0.105	12	0.105
220	5	0.044	5	0.044
230	4	0.035	4	0.035
240	4	0.035	4	0.035
250	3	0.026	3	0.026
260	3	0.026	3	0.026
270	4	0.035	4	0.035
315	13	0.114	12	0.105
340	9	0.079	9	0.079

■ CEPH Mode

Test Condition

Item	Condition
Tested Model	CEPH
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

Results

Direction [°]	[mR/hr]	[mGy/hr]
0	9	0.079
22	7	0.061
45	3	0.026
75	2	0.018
90	1	0.009
100	3	0.026
110	3	0.026
120	4	0.035
130	4	0.035
140	5	0.044
150	3	0.026
160	2	0.018
170	9	0.079
180	6	0.053
190	4	0.035
200	9	0.079
210	5	0.044
220	4	0.035
230	3	0.026
240	3	0.026
250	3	0.026
260	3	0.026
270	3	0.026
315	9	0.079
340	7	0.061

■ CBCT Mode

Test Condition

Item	Condition
Tested Mode	CBCT (10x8.5 / 5x5), High Resolution
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12

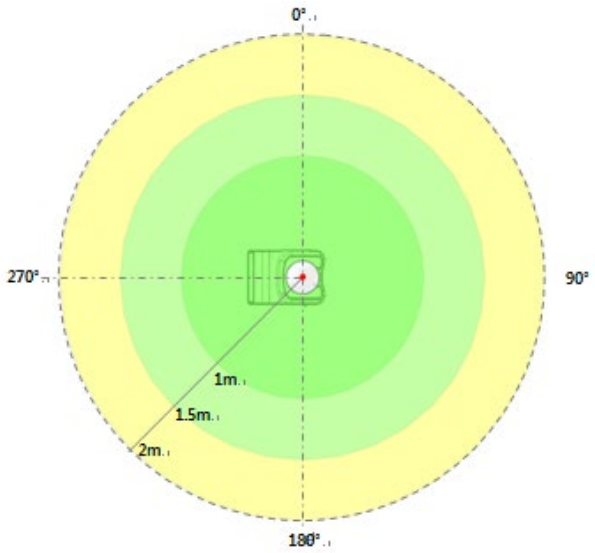
Results

Direction [°]	FOV 10x8.5		FOV 5x5	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	27	0.237	27	0.237
22	13	0.114	12	0.105
45	8	0.070	8	0.070
75	12	0.105	12	0.105
90	3	0.026	7	0.061
100	6	0.053	6	0.053
110	6	0.053	7	0.061
120	7	0.061	6	0.053
130	5	0.044	5	0.044
140	2	0.018	1	0.009
150	1	0.009	2	0.018
160	6	0.053	6	0.053
170	10	0.088	16	0.140
180	18	0.158	16	0.140
190	11	0.096	12	0.105
200	8	0.070	6	0.053
210	17	0.149	16	0.140
220	7	0.061	7	0.061
230	6	0.053	5	0.044
240	5	0.044	5	0.044
250	4	0.035	4	0.035
260	5	0.044	5	0.044
270	6	0.053	5	0.044
315	21	0.184	21	0.184
340	21	0.184	20	0.175

15.2.3 Scattered Dose

X-ray Scattered Dose data concerning varied 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 magnitude of risks to the operator and staffs, during both accident situation and routine work.

Measurement Overview



■ PANO Mode

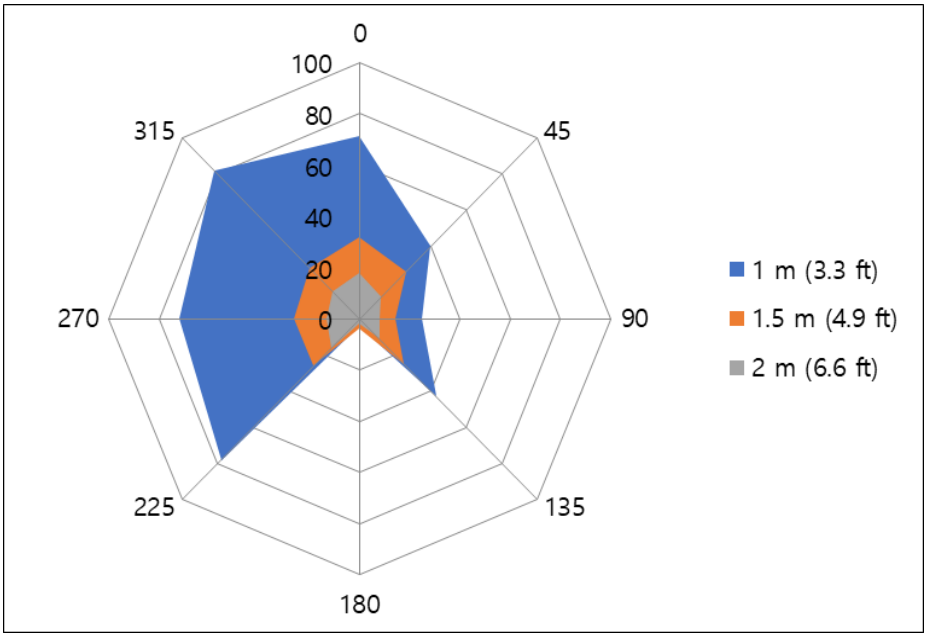
<PANO Option: Normal>

Test Condition

Item	Condition
Tested Model	PANO (Normal), High Resolution
Distance from focal point [m]	1 ~ 2
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

Results

Direction [°]	Normal, 13.5 s [mR/hr]		
	1 m *(3.3 ft)*	**1.5 m** *(4.9 ft)*	**2 m** *(6.6 ft)*
0	71	71	71
45	40	40	40
90	25	25	25
135	43	43	43
180	3	3	3
225	78	78	78
270	72	72	72
315	82	82	82



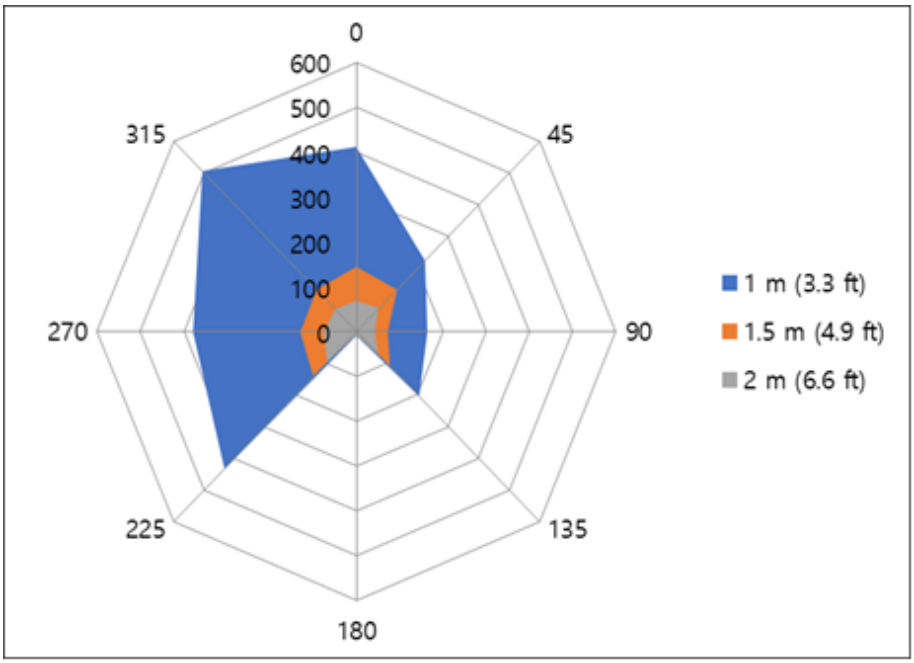
<PANO Option: Insight PAN>

Test Condition

Item	Condition
Tested Model	PANO (Insight PAN)
Distance from focal point [m]	1 ~ 2
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

Results

Direction [°]	Insight PAN, 13.5 s [mR/hr]		
	1 m *(3.3 ft)*	**1.5 m** *(4.9 ft)*	**2 m** *(6.6 ft)*
0	411	145	70
45	224	132	73
90	163	73	42
135	204	110	73
180	10	8	6
225	432	141	96
270	378	130	76
315	506	131	70



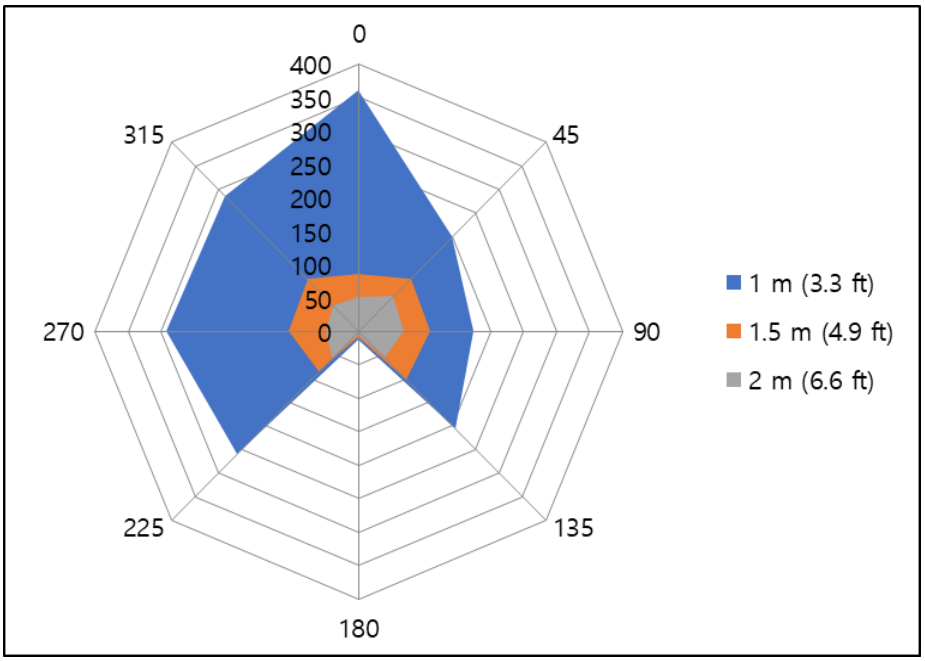
■ CBCT Mode

Test Condition

Item	Condition
Tested Mode	CBCT (10x8.5), High Resolution
Distance from focal point [m]	1 ~ 2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12

Results

Direction [°]	FOV 10x8.5, 16.4 s [mR/hr]		
	1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	361	85	51
45	200	112	74
90	173	109	68
135	206	102	55
180	13	9	6
225	260	85	57
270	291	106	50
315	287	110	55



15.3 Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions

<table>
<tr><td colspan="3">The PHT-35LHS is intended for use in the electromagnetic environment specified as below. The customer or the user of the PHT-35LHS should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>Compliance</th><th>Electromagnetic environment
- Guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The PHT-35LHS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The PHT-35LHS is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the PHT-35LHS or shielding the location.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">NOTE) It is essential that the actual RF shielding effectiveness and filter attenuation of the shielded location be verified to ensure that they meet or exceed the specified minimum values.</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity

The **PHT-35LHS** is intended for use in the electromagnetic environment specified below. The customer or the user of the **PHT-35LHS** should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV air	±6 kV Contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle 40 % U_T (60 % dip in U_T) for 5 cycle, 6 cycle 70 % U_T (30 % dip in U_T) for 25 cycle, 30 cycle <5 % U_T (< 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (< 95 % dip in U_T) for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the **PHT-35LHS** image intensifier requires continued operation during main power interruptions, it is recommended that the **PHT-35LHS** image intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The **PHT-35LHS** is intended for use in the electromagnetic environment specified below. The customer or the user of the **PHT-35LHS** should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80MHz 3 V/m 80 MHz to 2.5GHz	V_1=3Vrms E_1=3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **PHT-35LHS**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of the equipment marked with the following symbol : 

NOTE 1) At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the **PHT-35LHS** is used exceeds the applicable RF compliance level above, the **PHT-35LHS** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PHT-35LHS**.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than [V_1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PHT-35LHS

This is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **PHT-35LHS** can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PHT-35LHS** as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to the frequency of transmitter [m]
IEC 60601-1-2

Frequency of Transmitter Equation The rated maximum output power of the transmitter [W]	150kHz to 80MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ V_1=3Vrms Separation Distance (meters)	80MHz to 800MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ E_1=3V/m Separation Distance (meters)	800MHz to 2.5GHz $d = [\frac{7}{E_1}]\sqrt{P}$ E_1=3V/m Separation Distance (meters)
0.01	0.116	0.1166	0.2333
0.1	0.368	0.3687	0.7378
1	1.166	1.1660	2.3333
10	3.687	3.6872	7.3785
100	11.660	11.6600	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **PHT-35LHS** is used exceeds the applicable RF compliance level above, the **PHT-35LHS** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PHT-35LHS**.

b. Over the frequency range 150kHz to 80MHz, field strengths should be less than [V_1] V/m.

Immunity and Compliance Level

Immunity test	IEC 60601-1-2 Test level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	3Vrms
Radiated RF IEC 61000-4-3	3Vrms 80MHz to 2.5GHz	3V/m	3V/m

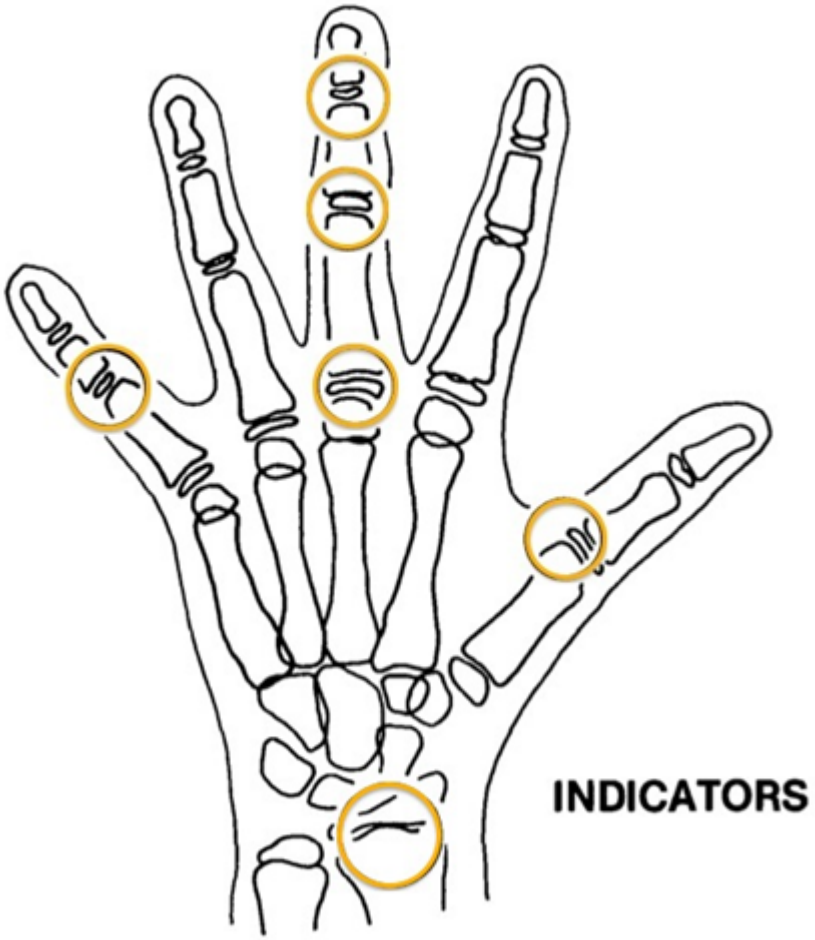
15.4 Hand-wrist Image Evaluation References

Radiographic Evaluation of Skeletal Maturation. A clinically oriented method based on hand-wrist films.

Fishman LS. 1982

- **The system of Skeletal Maturation Assessment (SMA)**

The System uses only four stages of bone maturation, all found at six anatomical sites located on the thumb, third finger, fifth finger, and radius, as seen Fig.1. Eleven discrete adolescent skeletal maturational indicators (SMI's), covering the entire period of adolescent development, are found on these six sites (Fig.1 orange circles).



[Fig1. Site of skeletal maturity indicators]

◆ Skeletal Maturity Indicators (SMI)

A system of skeletal maturation assessment based on four stages of bone maturation at six anatomical sites in the hand wrist.

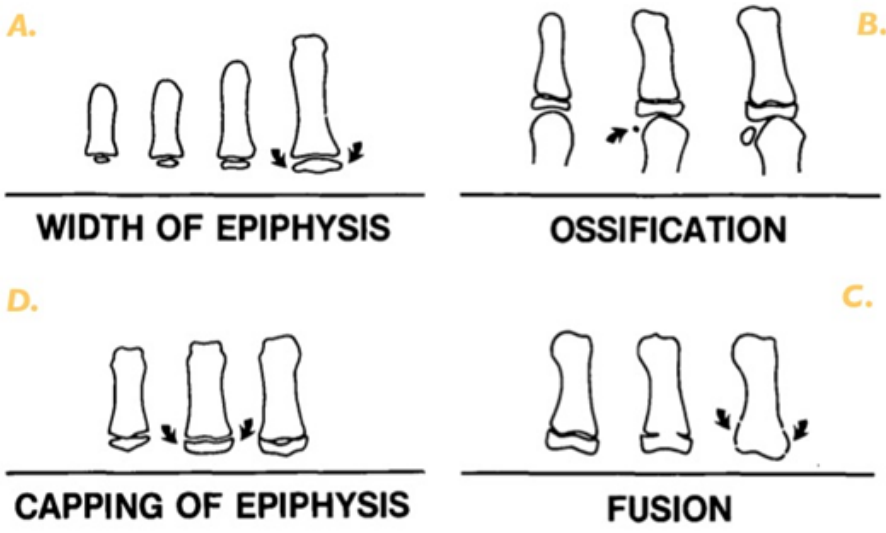


Fig. 2 Radiographic identification of skeletal maturity indicators.
A. Epiphysis equal in width to diaphysis.
B. Appearance of adductor sesamoid of the thumb.
C. Capping of epiphysis.
D. Fusion of epiphysis.

[Fig2. Radiographic identification of skeletal maturity indicators]

A. The width of epiphysis as wide as diaphysis

1. Third finger – Proximal phalanx

2. Third finger – middle phalanx

3. Fifth finger – middle phalanx

B. Ossification

1. Adductor sesamoid of thumb

C. Capping of epiphysis

1. Third finger –distal phalanx

2. Third finger –middle phalanx

3. Fifth finger – middle phalanx

D. Fusion

1. Third finger –distal phalanx

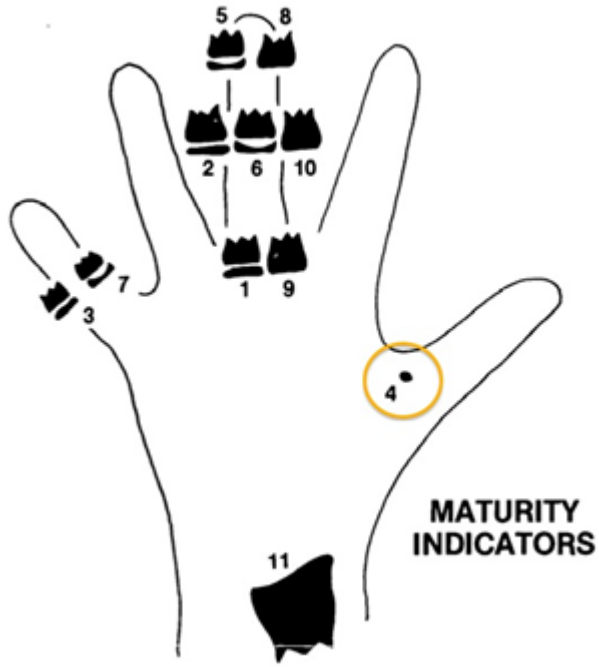
2. Third finger – Proximal phalanx

3. Third finger – middle phalanx

4. Radius

◆ Eleven Skeletal maturity indicators (SMIs)

The System uses only four stages of bone maturation, all found at six anatomical sites located on the thumb, third finger, fifth finger, and radius, as seen Fig.1. Eleven discrete adolescent skeletal maturational indicators (SMI's), covering the entire period of adolescent development, are found on these six sites (Fig.1 orange circles).



[Fig3. Eleven Skeletal maturity indicators (SMIs)]

A systematic observational scheme such as that shown in the figure above can further facilitate SMI evaluation. With this approach, key stages are checked first, rather than looking for maturity indicators in numerical order. A useful step is to determine if the adductor sesamoid of the thumb can be seen (orange circle). If not, then the applicable SMI will be one of those associated with early epiphyseal widening rather than capping. If the sesamoid is visible, then either the sesamoid or an SMI based on capping or fusion will be applicable.


HAND-WRIST OBSERVATION SCHEME
4. OSSIFICATION ADDUCTOR SESAMOID THUMB
NO?
YES?
WIDTH 1. PROX. PHALANX THIRD FINGER
WIDTH 2. MIDDLE PHALANX THIRD FINGER
WIDTH 3. MIDDLE PHALANX FIFTH FINGER
FUSION 8. DISTAL PHALANX THIRD FINGER
NO?
YES?
CAPPING 5. DISTAL PHALANX THIRD FINGER
CAPPING 6. MIDDLE PHALANX THIRD FINGER
CAPPING 7. MIDDLE PHALANX FIFTH FINGER
FUSION 9. PROX. PHALANX THIRD FINGER
FUSION 10. MIDDLE PHALANX THIRD FINGER
FUSION 11. RADIUS

15.5 Acquiring Images for Pediatric Dental Patients

15.5.1 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	

15.5.2 Positioning the Pediatric Dental Patients

1. Use a laser light beam guide to locate the midsagittal plane. Direct patient focus to mirror 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 patient place chin on 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 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 the overlapping of adjacent posterior teeth should be kept to a minimum.

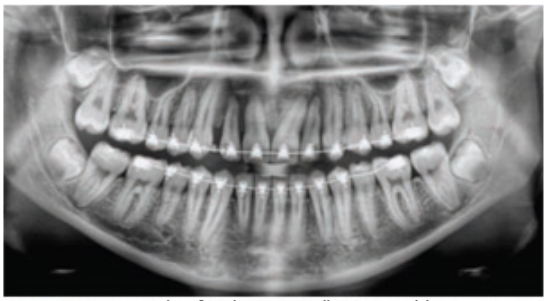


Figure 1: Example of a diagnostically acceptable panoramic radiograph of an adolescent patient undergoing orthodontic intervention. (Courtesy of Jamie Mace and Will Wright of Schick Technologies Inc.)

The most important component in producing a diagnostically acceptable panoramic image is the 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)**.

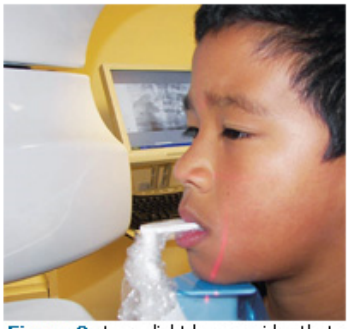


Figure 2: Laser light beam guides that assist with determining correct patient positioning.

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.

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Anterior-Posterior Positioning Error

When the arches are positioned incorrectly in the anterior-posterior direction, distortion or ghosting of the anterior anatomy occurs. Unerupted teeth in the anterior region may not be imaged on the radiograph if positioned outside of the focal trough. It is important to note that an error of only 3 mm to 4 mm in either direction will result in a significantly compromised image.[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 completely blurred from the image and the condyles may be cut off from the edges of the film.

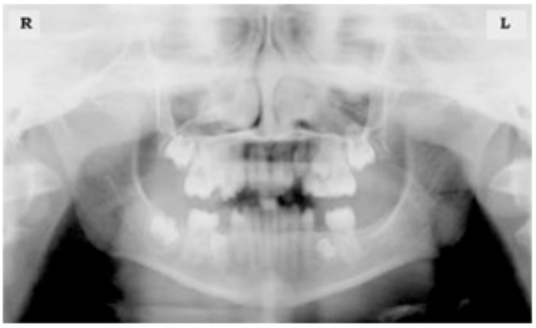

Figure 3: Incorrect position too far anteriorly. Note the narrow anterior teeth and superimposition of the spinal column over the condyles. The radiolucency superior to the maxillary apices indicates that the tongue was not placed against the palate. An open lip line can also be detected.

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 similar to 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.

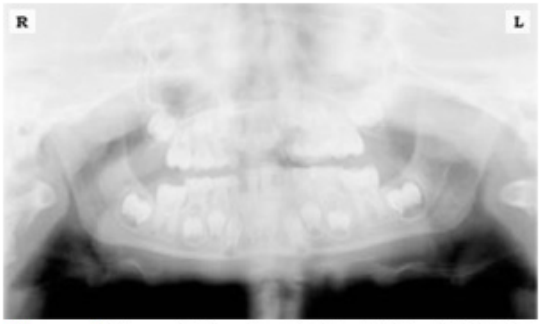

Figure 4: Incorrect lateral position tilted to the right. Note the teeth on the left are wide and poorly defined, while the teeth on the right are narrowed and severely overlapped. The inferior border of the mandible is distorted and the condyles appear asymmetrical.

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/or 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 difficult 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 overlapping 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 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.

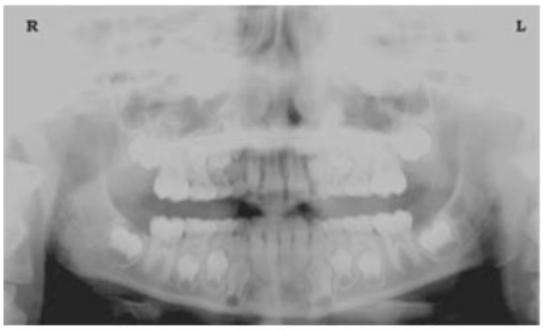

Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

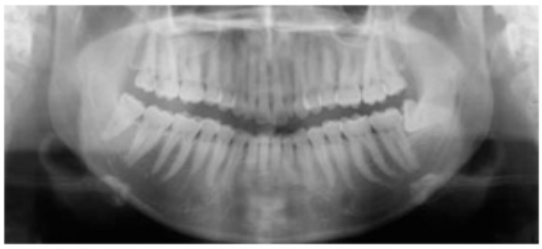

Figure 6: Chin positioned too far down. Note the characteristic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

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 in an attempt 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

Prior to 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 in spite of 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 panoramic equipment operation and pediatric patient management is more likely to produce radiographic images that result in higher diagnostic yields.

References

1. Public Health Service, Food and Drug Administration, American Dental Association Council on Dental Benefits Program, Council on Dental Practice, Council on Scientific Affairs. The Selection of Patients for Dental Radiographic Examinations. Washington, DC: United States Department of Health and Human Services; 1987 (revised 2005):1-23.

2. Pinkham PS, Casamassimo, Fields HW, McTigue DJ, Nowak AJ. Pediatric Dentistry Infancy through Adolescence. 4th ed. St. Louis: Elsevier Saunders; 2005:677.

3. Thomson EM. Panoramic radiographs and the pediatric patient. Dimensions of Dental Hygiene. 2008;6(2):26-29.

4. Rushton VE, Rout J. Panoramic Radiology. London: Quintessence Publishing Co Ltd; 2006:17, 84-85.

5. Kullman L, Joseph B. Quality of digital panoramic radiography in a newly established dental school. Swedish Dent Journal. 2006; 30: 165-170.

6. Akarslan ZZ, Erten H, Güngör K, et al. Common errors on panoramic radiographs taken in a dental school. J Contemp Dent Pract. 2003;4:24-34.

7. Rushton VE, Horner K, Worthington HV. The quality of panoramic radiographs in a sample of general dental practices. Br Dent J. 1999; 26: 630-633.

8. White SC, Heslop EW, Hollender LG, Mosier KM, Ruprecht A, Shrout MK. Parameters of radiologic care: an official report of the American Academy of Oral and Maxillofacial Radiology. Oral Surg Oral Med Oral Pathol. 2001;91:498-511.

9. McDonald RE, Avery DR, Dean JA. Dentistry for the Child and Adolescent. 8th ed. St. Louis:

Elsevier Mosby; 2000:71-72.

10. Johnson ON, Thomson EM. Essentials of Dental Radiography for Dental Assistants and Hygienists. 8th ed. Upper Saddle River, NJ: Prentice-Hall 2007:388-397.

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

15.5.3 Setting Exposure Values to the Age Group

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

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

1) Literature

- 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, that 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 years interval should be considered when caries activity/risk is low. A routine survey by radiographs, except for caries, has not been shown to provide sufficient 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 reducing 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 looked into 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 concern 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 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. 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/

15.6 Abbreviations

AC	Alternating Current
AF	Auto-Focusing
AMPT	Adaptive layer Mode Panoramic Tomography
CAN	Controlled Area Network
CBCT	Cone-Beam Computed Tomography
CMOS	Complementary Metal-Oxide -Semiconductor
CT	Computed Tomography
DAP	Dose Area Product
DC	Direct Current
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
ENT	Ear, Nose, and Throat
ESD	Electrostatic Discharge
EUT	Equipment Under Test
FDD	Focal spot to Detector Distance
FOD	Focal spot to Object Distance
FOV	Field of View
FPD	Flat Panel Detector
IEC	International Electrotechnical Commission
ISO	International Standards Organization
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
RF	Radio Frequency
ROI	Region of Interest
SID	Source to Image Receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SMV	Submento-Vertical

STL	Stereo Lithography
TMJ	Temporomandibular Joint
UHD	Ultra High Definition

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CE 2460

The CE symbol grants this product compliance to the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.

EC REP

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