VATECH

Pax-i3D *Premium* (Model: PCT-90LH)

User Manual | Version 1.2

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 **PaX-i3D Green Premium™ (Model: PCT-90LH)** extra-oral imaging system.

PaX-i3D Green Premium™ is an advanced digital X-ray imaging system that incorporates PANO, i-CEPH (Optional), 3D CT (Dental / ENT) and 3D PHOTO (Optional) imaging capabilities into a single system for Dental and ENT(Ear, Nose and Throat) diagnostics.

PaX-i3D Green Premium™ may be used by dentists, X-ray technicians and other professionals who are licensed to perform X-rays by the law of the region in which it is being used.

This manual describes how to operate the **PaX-i3D Green Premium™** system. It is recommended that you thoroughly familiarize yourself with this manual in order 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 **PaX-i3D Green Premium™** is referred to as “equipment” in this manual.

Manual Name: PaX-i3D Green Premium™ (Model: PCT-90LH) User Manual

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1. Introduction

1.1 Overview

PaX-i3D Green Premium™ (Model: PCT-90LH) is an advanced 4 in 1 digital X-ray imaging system that incorporates PANO, i-CEPH (Optional), 3D CT (Dental / ENT) and 3D PHOTO (Optional) imaging capabilities into a single system for Dental and ENT (Ear, Nose and Throat) diagnostics.

PaX-i3D Green Premium™ a digital radiographic imaging system, acquires and processes multi FOV diagnostic images for dentists and ENT specialists. Specifically designed for dental and ENT radiography, **PaX-i3D Green Premium™** 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 head, neck and craniofacial anatomy for ENT, oral surgery, implant and orthodontic treatment. **PaX-i3D Green Premium™** can also acquire 2D diagnostic image data in panoramic and cephalometric mode.

1.2 Indications for use

PaX-i3D Green Premium™ (Model: PCT-90LH) is intended to produce panoramic, cephalometric or 3D digital x-ray images.

It provides diagnostic details of the dento-maxillofacial, ENT, 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 facial bones, mandible, condylar neck, orbital floor and fractures of teeth where plain film imaging is equivocal

- Visualization of 3D anatomy of the alveolar clefts

- Diagnosis of un-erupted teeth, impacted teeth and odontomas

- Diagnosis of root resorption of teeth

- Assessment of cleft palate

- Planning any craniofacial surgery where 3D models of the jaw/facial skeleton/skull are required

- Diagnosis of most malformations and dysplasia, traumatic lesions and thin osseous labyrinthine wall erosion or dehiscence through CBCT inner ear imaging

- Visualization of eustachian tube obstruction

- Reconstruction of position, malformations and fractures of nasal and facial bones and paranasal sinuses as 3D pictures for operational planning and patient education

- Air-mucosa-bone contrast for detailed study of air cavity anatomy and ventilation

- Instant diagnosis of CRS (chronic rhinosinusitis)

- Examinations of the airways for measuring the volume and dimensions of air passages

1.4 Intended User Profile

Considerations	Requirement Description
Education	▪ Licensed dentists or dental hygienists, radiologists and graduates of relevant bachelor's degree (national qualifications)
Knowledge	▪ Understanding of 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 of 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/or 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 in accordance with 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 in accordance with 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 in order to ensure patient and operator safety. These tests must be performed in accordance with 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 are performed in accordance with the maintenance schedule outlined in **Chapter 13. 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/or 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/or 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/or its operation.
	NOTE	Emphasizes important 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
	Warns ESD hazard.	MCU board / Board package
	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/or electric shock: Class 1 equipment)	Label
	Radiation hazard	Label
	Indicates the authorized representative in the European Community.	Label
	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Label
	UL mark : UL 60601-1 / CAN / CSA C22.2 No.601.1	Label
	Addresses where the equipment was manufactured.	Label

Symbols	Description	Location
	Indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Label
	Indicates that this equipment is classified as a CLASS 1 LASER PRODUCT in accordance with IEC 60825-1 ED.2 regulations.	Label
	Indicates the date when the equipment was manufactured..	Label
	Indicates that the user needs to refer to the **Instruction Manual.**	Label

2.4.1 Label Locations

No.	Item
1	PaX-i3D Green Premium™ (Model: PCT-90LH) Main Label
2	X-ray GENERATOR Label - This part has two types according to the X-ray Tube model implemented. * Type 1: Superior tube (SXR-130-15-0.5) * Type 2: C.E.I tube (OX/115-05)
3	CLASS 1 LASER PRODUCT Label

No.	Item
4	X-ray CAUTION Label - X-ray / Attention: X-ray on when equipment in operation.
5	Wheelchair Height Limit CAUTION Label - In case a wheelchair must be used, the overall height of the wheelchair must not exceed the designated line.

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:
  - has read and understood the **User Manual**.
  - be familiar with the fundamental structure and functions of this equipment.
  - be able to recognize 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 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).
- In addition, 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 external door interlock switch is responsible for ensuring that it has 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 type of 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 Block, the Chinrest, the Headrest) can be cleaned using alcohol-based cleaning solutions.
- Clean the Support Handles by using alcohol-based cleaning solutions before taking photos of 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 acquisition of next image.
  - Mode of operation: Continuous operation with intermittent loading
  - Exposure time: Max. 18 s / Resting time: 10 min.
  - Column operation time: 1 min / Resting time: 9 min.
- 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).

Turning the equipment on / Adjusting the height of the equipment

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

Emergency stop

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

Trouble-free operation

- Never use this equipment in an environment that is susceptible to explosion.
- Always operate the equipment within a temperature range of 10 °C to 35 °C (50 °F to 95 °F) for the safe operation. Image quality may deteriorate if the equipment is operated outside of this range.
- Always allow the equipment 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 system is in full working order.
- Always ensure that equipment movement is not obstructed by the patient's clothing, medical device (such as a wheelchair), or the patient themselves.
- 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 affects 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 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 in the immediate vicinity of the patient.
- The equipment and PC should be connected to a common protective earth.
- Never overload the equipment's circuit by sharing it with too many appliances.
- Use the same power circuit for the PC and the equipment.

Combining this equipment with other devices

- Do not connect this equipment to devices 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 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.

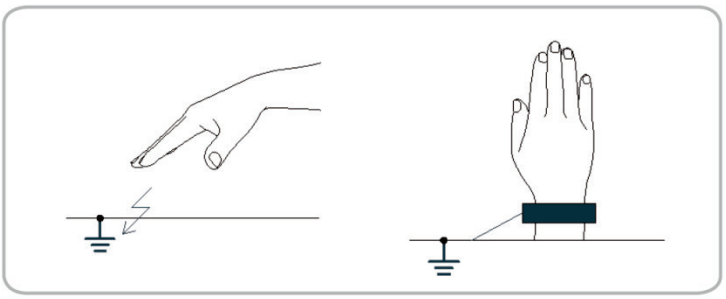
Static Discharge

- 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 wrist band 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 their area.

- This equipment must be housed inside an X-ray shielded room.
- The operator must remain outside a shielded room during X-ray exposure in order 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.

- X-ray equipment is hazardous to 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.

- 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.

- **PaX-i3D Green Premium™** system, like other medical equipments, 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.
- **PaX-i3D Green Premium™** 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.

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.

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 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 performing an operation. 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, with the exception of 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 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

- In order 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.

Security Capabilities

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

4. Imaging System Overview

4.1 System Components

- **PaX-i3D Green Premium™** digital X-ray equipment
- PC system
- Console Software: PANO, i-CEPH (Optional), Dental CT, ENT CT and 3D PHOTO
- **EzDent-i**: 2D viewer and patient management software
- **Ez3D-i**: 3D viewer and image analysis software

4.2 Features

- Extensive Diagnosis with Large FOV (Maximum FOV 21x19 (cm))
- Multi FOV support: Selectable FOV from 8x8 (cm) to 21x19(cm)
- Multi Imaging Solution for Accurate Diagnostics
- Conventional 2D (PANO) image acquisition
- 3D and 2D (Auto Pano*, Auto Ceph**) image acquisition by single scan
- 3D for ENT Specialists: Optimized FOV for ENT Diagnosis
- Multi-purpose camera equipped for patient positioning and 3D PHOTO acquisition (Optional)
- Touch Screen implemented for easy use
- Digital Imaging Communication in Medicine (DICOM) 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 Standard mode in DICOM or BMP format.)
Auto Pano option is available under DENTAL CT (FOV: 21x19, 17x15) and ENT CT (FOV: 21x19) modality.

****Auto Ceph**
Auto Ceph 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 cephalometric images offer. (It provides images for PA, Lateral, SMV and Waters' view modes in DICOM or BMP format.)

	Auto Ceph option is available under DENTAL CT (FOV: 21x19) and ENT CT (FOV: 21x19) modality. * When selected, Auto Pano and/or Auto Ceph image is automatically acquired and can be seen on the **EzDent-i** Viewer.

4.3 Standards and Regulations

Standards

PaX-i3D Green Premium™ was designed and developed to comply with the following international standards and regulations:

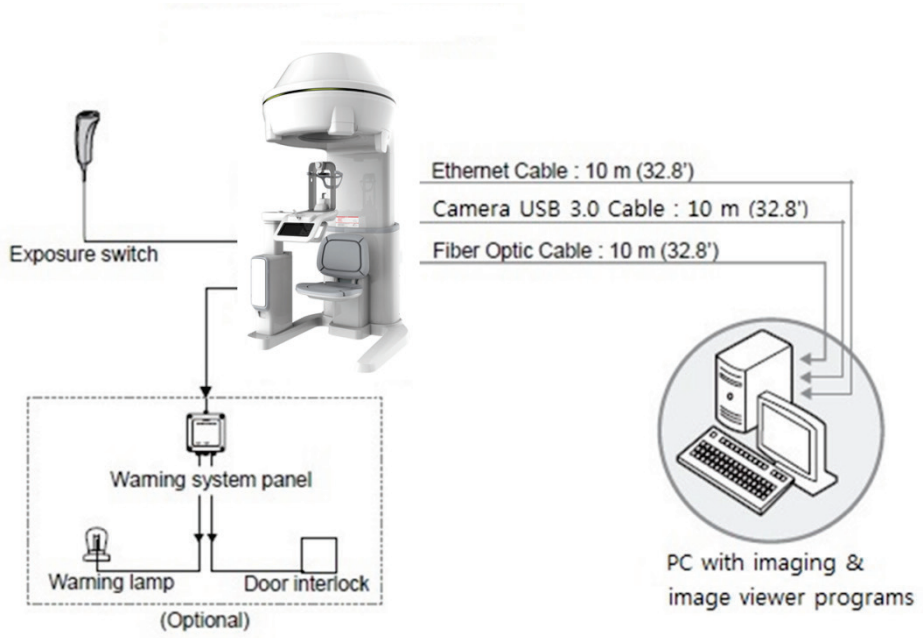
- IEC/EN 60601-1(3rd), UL 60601-1(1st), IEC/EN 60601-1-3, IEC 60601-2-63
- 21 CFR 1020.30, 31, 33
- NEMA Standard publication PS 3.1-3.18, 2008

CE 0434	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.
CLASSIFIED c UL us Medical equipment UL 60601-1 / CAN/CSA C22.2 No. 601.1 E330656	This equipment received the UL certification mark in accordance with UL 60601-1/CAN/CSA C22.2 No.601.1 regulations.

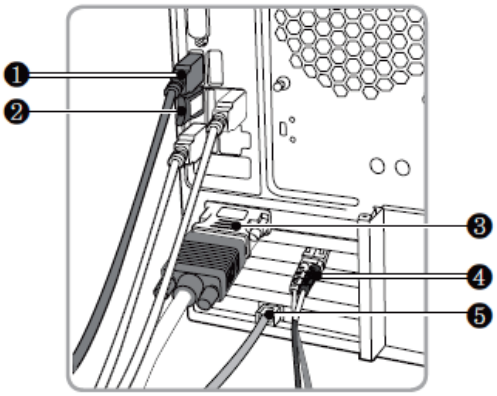
Classifications (IEC 60601-1 6.1)

- Degree of protection against water ingress: Ordinary Equipment: IPX0
- Degree of protection against electric shock: Class 1 equipment, Type B Applied Parts: Headrest, Chinrests and Bites

4.4 Imaging System Configuration

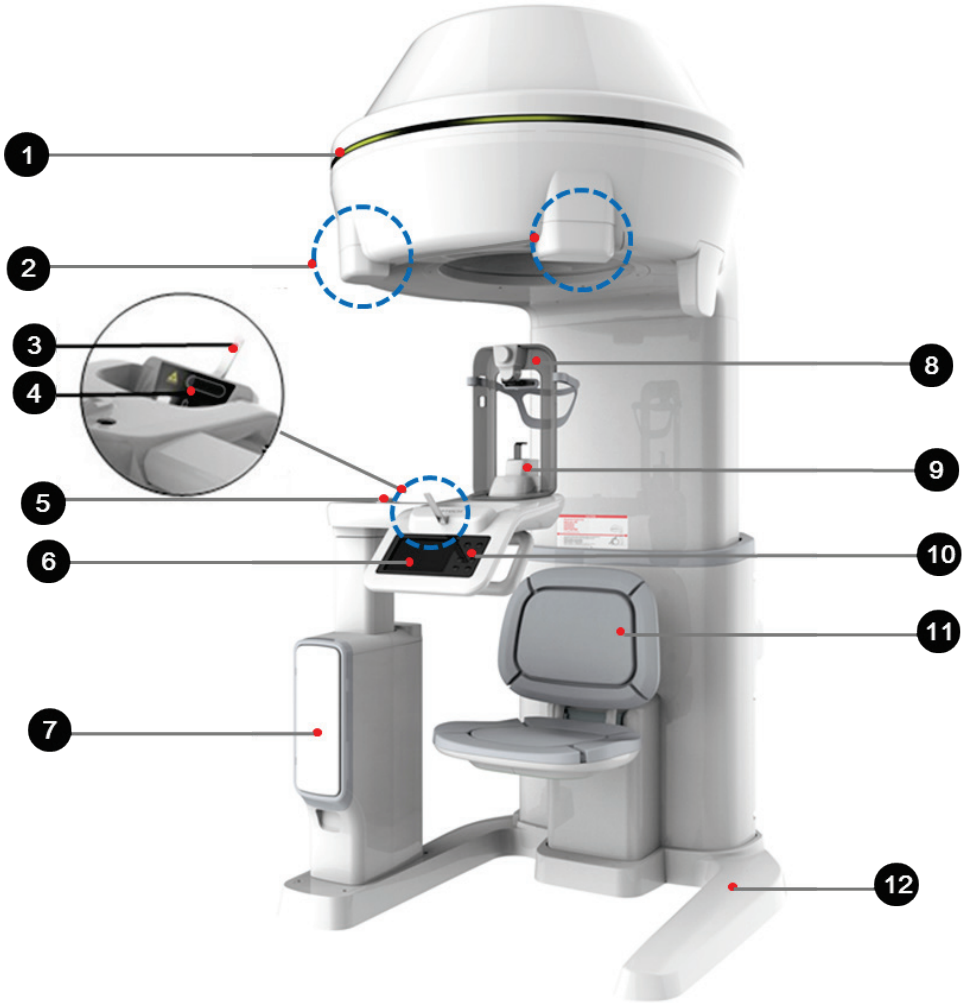


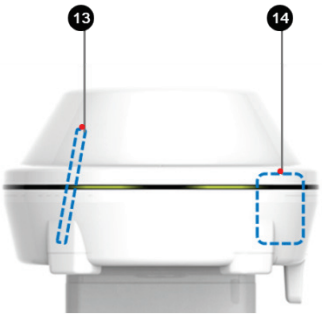
PC Signal Input / Output



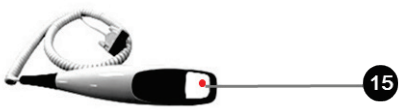
No.	Item
1	USB Camera input (USB 3.0 Cable) NOTE: To avoid any connection problem, it is highly recommended to install a USB 3.0 PCI card for USB 3.0 cables.
2	3D Viewer License Key
3	Video output
4	Fiber optic cable (Data in / out)
5	Ethernet cable (LCD in / out)

4.5 Equipment Overview





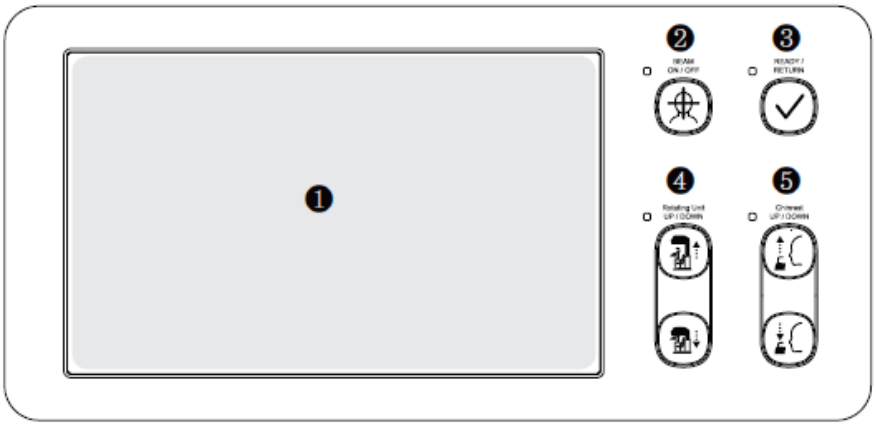
<Front view>



No.	Item	Description
1	LED Lamp	Displays the status of X-ray exposure. - Green: Ready - Yellow: X-ray ON
2	LED lights (TOP) & Eye marks (#2,#3)	▪ LED Lamps provide enough light for 3D Photography. ▪ Eye marks help to position the patient' head correctly when taking a 3D photograph.
3	Eye mark (#1)	Helps to position the patient' head correctly when taking a 3D photograph.
4	LED light (BOTTOM) & 3D PHOTO Camera	▪ LED Lamp provides enough light for 3D photography. ▪ 3D PHOTO Camera takes 3D photograph.
5	Handle Frame **Open/Close** button	Opens/closes the Handle Frame.
6	Touch Screen	▪ Sets imaging condition according to a capture mode. ▪ Displays the status of patient positioning.
7	Enclosed Component Storage	The place where Bite Blocks, Chinrest Ass'y and the other components can be stored.
8	Headrest	Holds the patient's head during i-CEPH mode imaging.
9	Chinrest	The place to rest the chin.
10	Control Panel	Controls the height of the Rotating Unit and Chinrest, Laser Beam On/Off. Prepares exposure by clicking **READY** button after setting the capture conditions and patient's positioning. For the details, refer to **3.5.1 Control Panel**.
11	Chair	A Chair used for patient positioning Maximum weight allowed: 180 Kg or Under IMPORTANT: In case a wheelchair must be used for specific patients, the overall height of the wheelchair must not exceed the designated line. For the details, refer to the **Wheelchair Height Limit CAUTION Label** attached on the equipment.
12	Base	Balances the equipment and maintains its safety.
13	X-ray Detector	Xmaru3104CF for PANO, i-CEPH and CT
14	X-ray Generator	The vacuum tube where the X-ray is produced.

No.	Item	Description
15	Chinrest Up/Down Switch	Adjusts the height of the Chinrest.

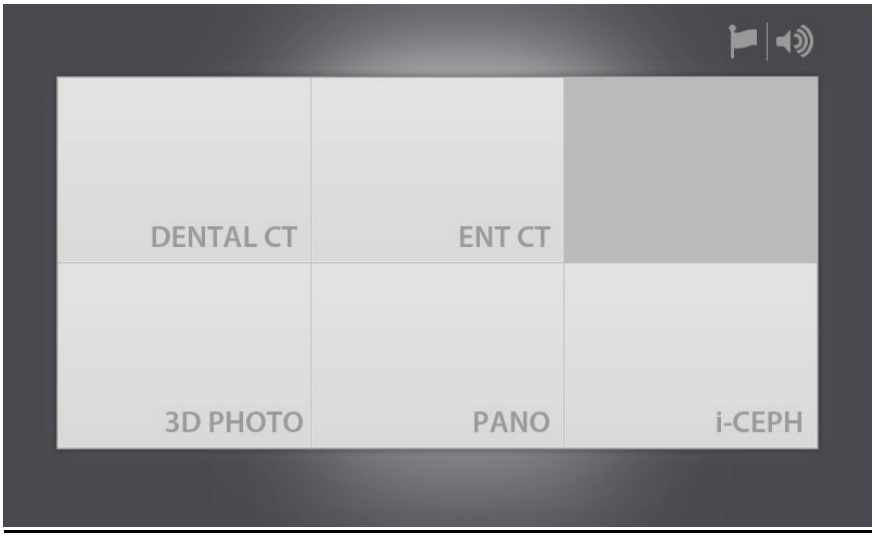
4.5.1 Control Panel



No.	Buttons	Description
1	Touch Screen	Configures the parameter settings in each imaging mode. For more information, refer to **4.5.2 Touch Screen**.
2	Laser Beam **ON/OFF** button	Turns on/off the vertical Laser Beam.
3	**READY** button	Indicates that imaging is ready after parameter settings and the patient positioning are complete.
4	Rotating Unit **UP/DOWN** button	Moves the Rotating Unit up or down.
5	Chinrest **UP/DOWN** button	Moves the Chinrest up or down.

4.5.2 Touch Screen

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.

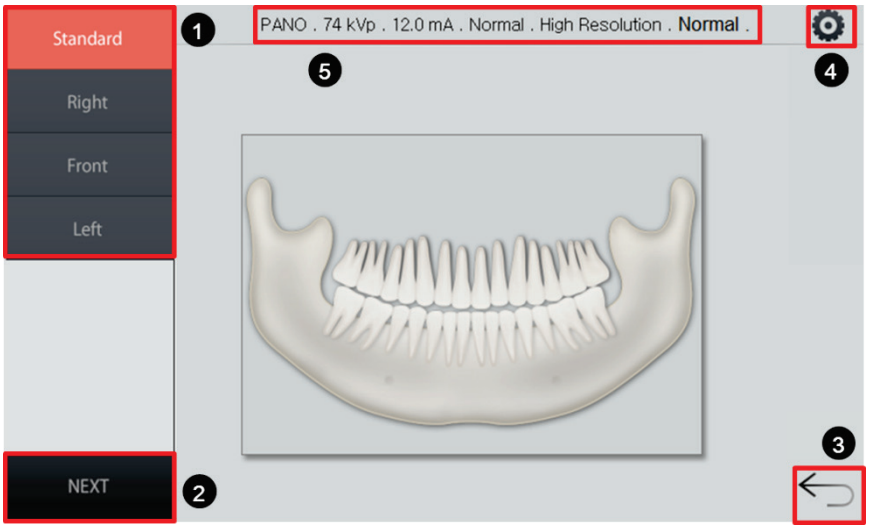


** i-CEPH and 3D PHOTO are Optional modalities.

CAUTION

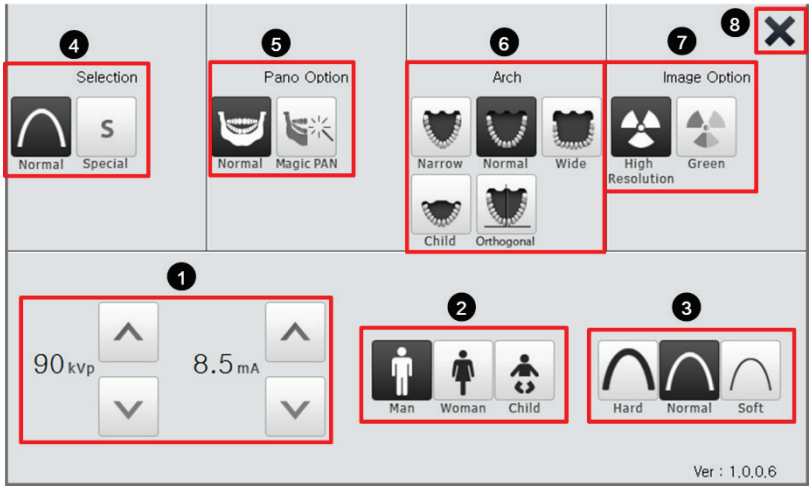
- Do not allow patient to control Touch Screen. Doing so may cause physical injury to the patient or damage to the equipment.
- Always operate the Touch Screen by pressing it gently with your fingertip.
- Do not use pointed objects such as ballpoint pens or pencils. Doing so may cause damage to the screen.

PANO Main Screen



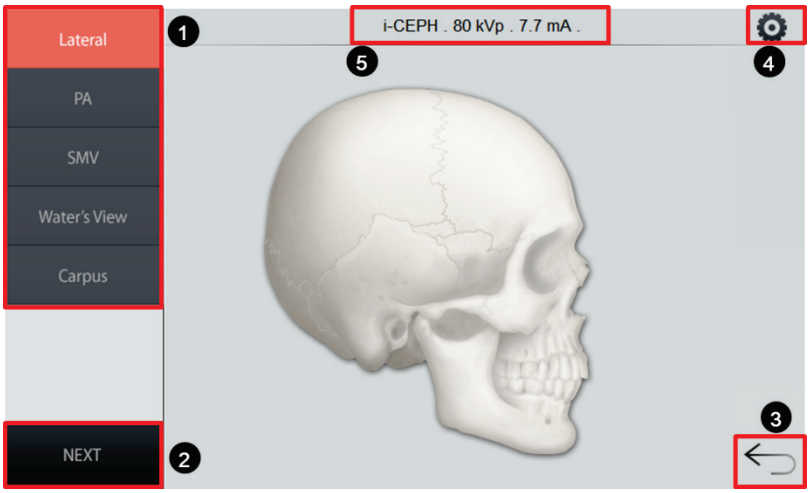
No.	Function	Description
1	Examination mode selection panel	Displays available PANO Examination programs. (In PANO – Orthogonal mode, press **UP/DOWN** button to scroll through next/previous ROI option)
2	**NEXT** button	Moves to the next step.
3	**BACK** button	Moves back to the modality (PANO, i-CEPH (Optional), Dental CT, ENT CT and 3D PHOTO (Optional)) selection screen.
4	**Settings** button	Adjusts kVp/mA , Arch type, etc..
5	Imaging parameter settings information	Displays currently set information such as kVp/mA, Type, Arch and Quality.

PANO Settings Screen



No.	Function	Description
1	kVp/mA control button	Adjusts kVp and 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 type	Selects between Normal and Special.
5	Imaging type	Selects between Normal and Magic Pan (Optional).
6	Arch selection	Selects available patient's arch types.
7	Image Option	Selects between High Resolution and Green. (Image quality: High Resolution > Green)
8	**EXIT** button	Closes the Settings Screen and moves back to PANO Main Screen.

i-CEPH Main Screen

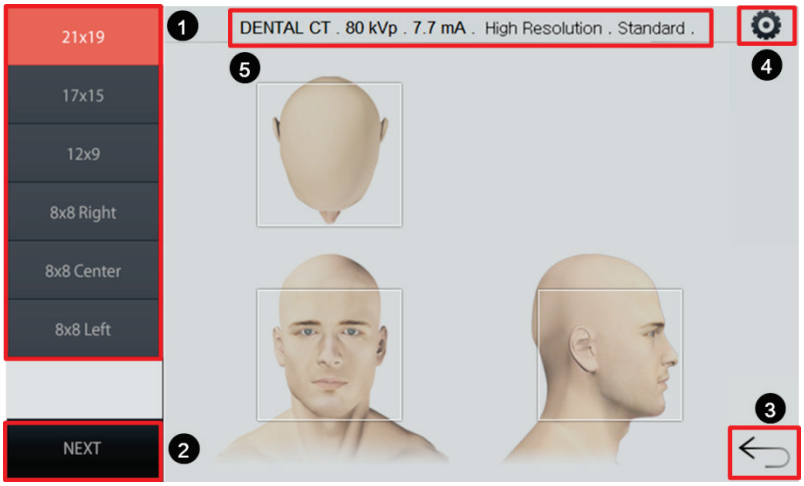


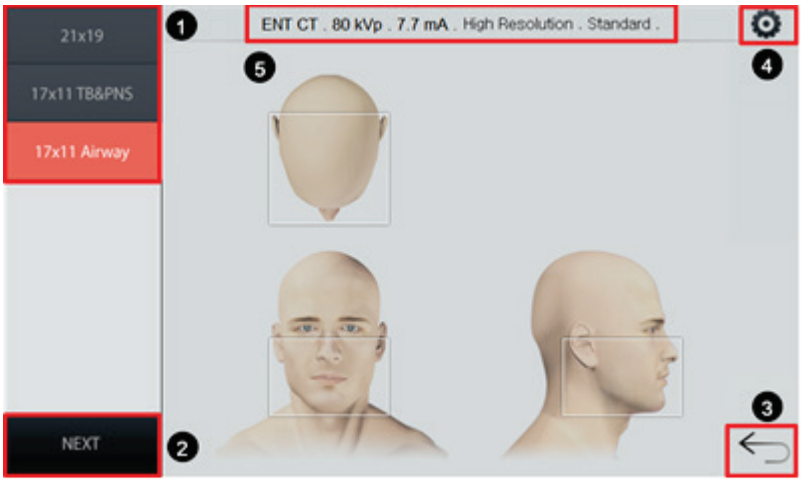
No.	Function	Description
1	Examination selection panel	Displays available i-CEPH Examination programs.
2	**NEXT** button	Moves to the next step.
3	**BACK** button	Moves back to the modality (PANO, i-CEPH (Optional), Dental CT, ENT CT and 3D PHOTO (Optional)) selection screen.
4	**Settings** button	Adjusts kVp/mA, Gender and X-ray Intensity etc..
5	Imaging parameter settings information	Displays currently set information such as kVp/mA.

i-CEPH Settings Screen

No.	Function	Description
1	kVp/mA control button	Adjusts kVp and 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	**EXIT** button	Closes the Settings Screen and moves back to i-CEPH Main Screen.

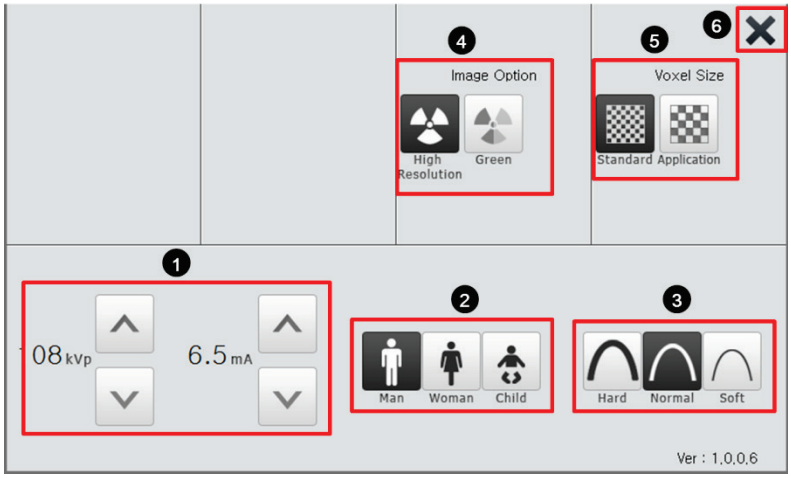
CT (Dental / ENT) Main Screen





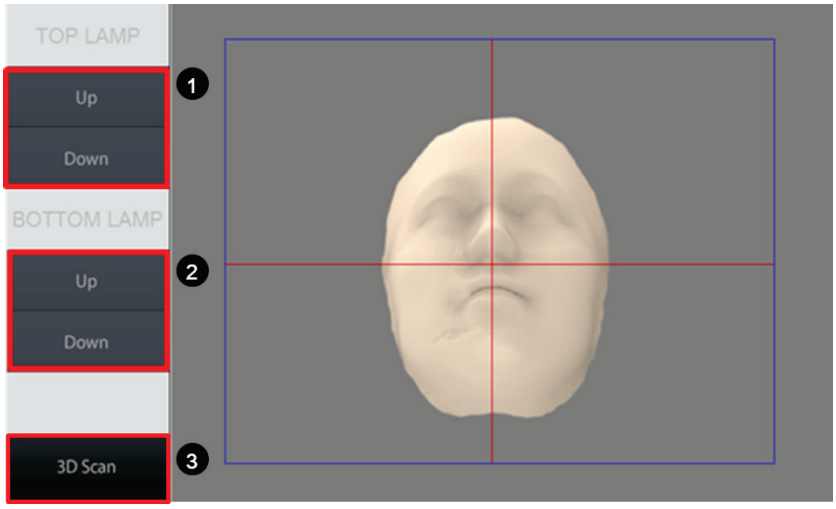
No.	Function	Description
1	FOV selection panel	Displays available FOV modes.
2	**NEXT** button	Moves to the next step.
3	**BACK** button	Moves back to the modality (PANO, i-CEPH (Optional), Dental CT, ENT CT and 3D PHOTO (Optional)) selection screen.
4	**Settings** button	Adjusts kVp/mA and Voxel size, etc..
5	Imaging parameter settings information	Displays currently set information such as kVp/mA, Image Option and Voxel size.

CT (Dental / ENT) Settings Screen



No.	Function	Description
1	kVp/mA control button	Adjusts kVp and 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 CT (Dental / ENT) Main Screen.

3D PHOTO Main Screen



No.	Function	Description
1	TOP LED light Brightness control panel	Press **UP/DOWN** button to adjust brightness of the LED lights on the top.
2	BOTTOM LED light Brightness control panel	Press **UP/DOWN** button to adjust brightness of the LED light on the bottom.
3	3D Scan button	Starts 3D photography.

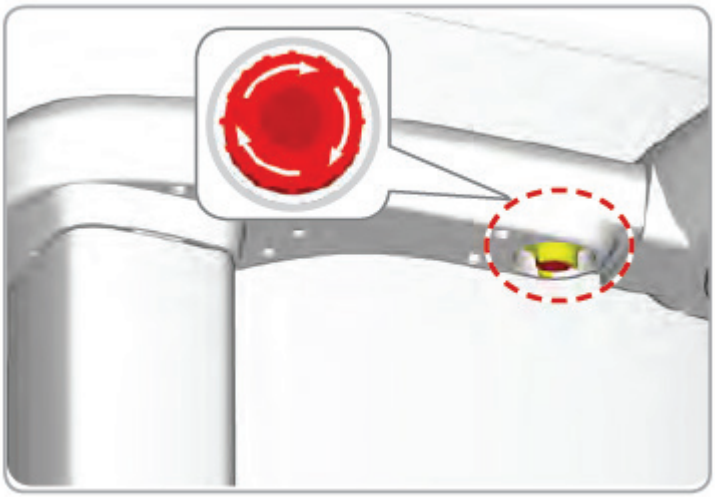
4.5.3 Emergency Stop Switch

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 under the Handle Frame.

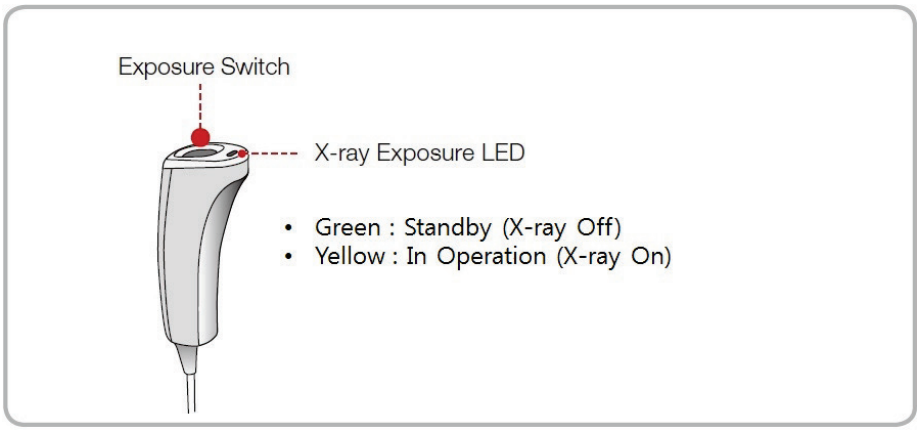


4.5.4 Exposure Switch

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 complete. 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.

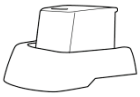


IMPORTANT

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

4.5.5 Enclosed Components

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

Components	Name and Function	Contact (duration)
	Bite Block	Skin (≤ 24 h)
	TMJ Bite	Skin (≤ 24 h)
	Sinus / Edentulous Bite	Skin (≤ 24 h)
	Chinrest Ass'y (Upper part: Chinrest Lower part: Chinrest Base)	Skin (≤ 24 h)
	Sanitary vinyl covers (disposable) for the Bite Block	Intraoral (≤ 24 h)
	Headrest	Skin (≤ 24 h)

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5. Imaging Software Overview

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

- **EzDent-i**: 2D viewer and patient management
- **Ez3D-i**: 3D viewer
- **Console software**: PANO, i-CEPH (Optional), Dental CT, ENT CT and 3D PHOTO image acquition

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	Intel Xeon E5-1620v3 3.5GHz 2133 10MB cache CPU
RAM	32GB DDR4-2133 ECC RAM
HDD	1TB SATA 1st HDD
Graphics board	NVIDIA GEFORCE GTX980 Ti OC D5 6GB or greater
Ethernet interface	Broadcom 5761 Gigabit PCIe NIC
Serial Port (RS232)	HP Serial Port Adapter Kit
Power Supply	≥ 700 Watts (90% Efficiency)
Slots	1 PCI Express Gen3 x 8 Slot 2 PCI Express Gen3 x 16 slot 1 PCI Express Gen2 x 8 Slot 1 PCI Express Gen2 x 4 Slot
	1 PCI Slot
CD/DVD Drive	DVD-ROM, DVD+/-RW, Blu-Ray
Monitor Resolution	1280 x 1024 screen resolution
Operating System	Windows 8.1 Professional 64-Bit OS
Recommended system	HP Z440

5.2 EzDent-i

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

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

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

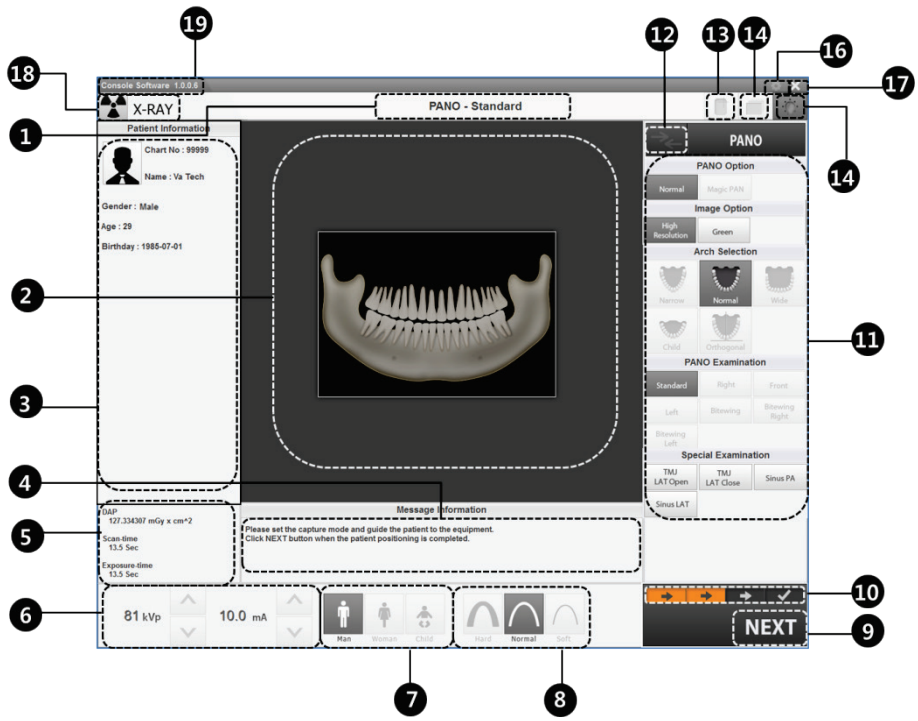
5.3 Console Software

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

NOTE

- You can set the imaging parameters on either the Touch Screen or the Console Software running on the PC. They are synched and display the same environmental settings. For more details on the Touch Screen, refer to **3.3.2 Touch Screen**.
- 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.



<table>
<tr><th>No.</th><th>Item</th><th>Description</th></tr>
<tr><td>1</td><td>Imaging Mode Display</td><td>Displays the current imaging mode.</td></tr>
<tr><td>2</td><td>Scanning Status and Image Preview window</td><td>Shows image acquisition progression and displays preview of the images acquired.</td></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, 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 in order 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 gender / age group</td><td>Displays the current patient's gender / age group as entered in EzDent-i'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</td></tr>
</table>

<table>
<tr><th>No.</th><th>Item</th><th>Description</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Age Group</th><th>Average Head Circumference (cm)</th><th>Range (cm)</th><th>X-ray Intensity</th></tr>
<tr><td rowspan="3">Child</td><td rowspan="3">53±3</td><td>>53±3</td><td>Hard</td></tr>
<tr><td>53±3</td><td>Normal</td></tr>
<tr><td><53±3</td><td>Soft</td></tr>
<tr><td rowspan="3">Adult</td><td rowspan="3">56±3</td><td>>56±3</td><td>Hard</td></tr>
<tr><td>56±3</td><td>Normal</td></tr>
<tr><td><56±3</td><td>Soft</td></tr>
</table>
</td></tr>
<tr><td>9</td><td>NEXT / READY button</td><td>NEXT
Moves to the next step.
(Exposure parameter setting > Patient positioning > Ready for exposure)
READY
Activated when you click NEXT 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>Progress indicator</td><td>Shows the image acquisition progress.
<Before selecting an imaging mode (with 3D PHOTO)>

<Before selecting an imaging mode (without 3D PHOTO)>

< After selecting an imaging mode and exposure parameters>

< After completing patient positioning>
 </td></tr>
<tr><td>11</td><td>Imaging parameters configuration panel</td><td>Selects the imaging parameters for each mode: PANO, i-CEPH (Optional), Dental CT, ENT CT and 3D PHOTO (Optional)</td></tr>
<tr><td>12</td><td>Modality Selection button</td><td>Returns to Modality Selection (PANO, i-CEPH (Optional), Dental CT, ENT CT and 3D PHOTO (Optional)) screen.</td></tr>
<tr><td>13</td><td>Phantom button</td><td>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 READY button.</td></tr>
</table>

No.	Item	Description
		4. Press and hold down the **Exposure Switch**.
14	**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.
15	**Laser Beam ON/OFF** button	Turns the Laser Beam on or off for patient positioning. Enabled when **NEXT** button is clicked after the imaging conditions are configured.
16	**Settings** button	Displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, etc..
17	**EXIT** button	Exits the console software.
18	X-ray indicator	The radiation mark turns yellow and “X-RAY” changes to “X-RAY ON”.
19	Version Information	Displays the Console Software version.

Left blank intentionally

6. Getting Started

6.1 Turning on the Equipment

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

CAUTION	▪ Extreme fluctuation of temperature may cause condensation inside the equipment. Do not switch 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 worm-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 wormed 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 the equipment and PC installed correctly.

1. Turn on the PC.
2. Press the **Main Power Switch** that is located at the back of the unit 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)

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

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

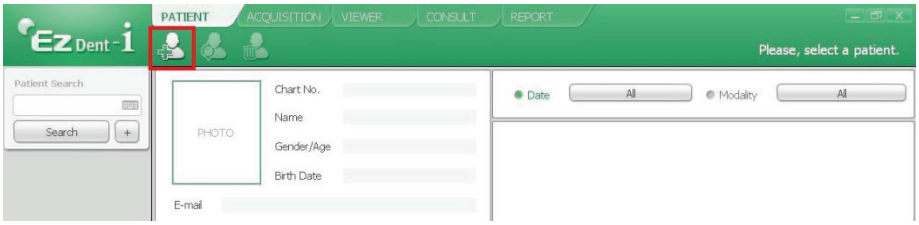
NOTE	**Security Capabilities** ▪ It is recommended to install and operate **EzDent-i** SW within a secure operating environment that allows only authorized users to access and a system network equipped with Windows built-in firewall, Windows Defender antispyware tools and other commonly used 3rd party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

NOTE	For **PaX-i3D Green Premium™** computed tomography X-ray system, both 3D Viewer (**Ez3D-i**) and Console Software are being accessed through 2D Viewer (**EzDent-i**) SW. 3D Viewer and Console Software do not have image storage capability of their own and both programs will not be able to keep patient information.

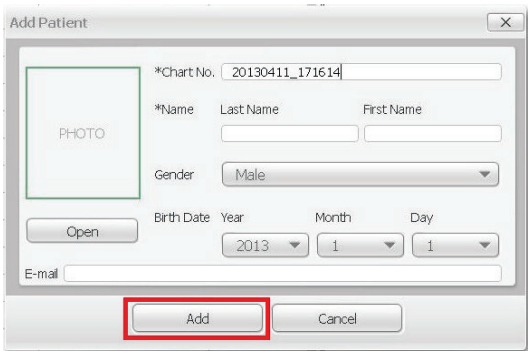
6.2.1 Creating a New Patient Record

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

1. 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 **Add** button to save the patient record.

IMPORTANT

Limit Access to Trusted Users Only

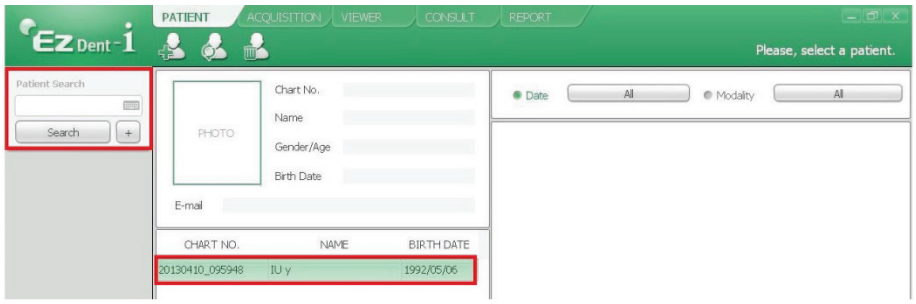
- **EzDent-i** software requires each operator to set up a unique user ID and Password to prevent any unauthorized access to patients' confidential information.
- User ID and Password can be assigned to give permission to register, add, delete and modify patient information and diagnostic images. The application of User ID and Password authentication assures the accountability that the prescribed access process is being done by an authorized user.
- According each operator's privilege level, the login enables the user to search, register, modify and delete the patient information or diagnostic images. Different search criteria suggest availability of the patient information being sought.
  − Search by ID: Search by ID is possible if the patient id is known.

	− Search by Name: Search by the name of the patient is possible. − Search by Gender / Age group can be used to divide the search results further, for patients with the same name. ▪ The user's Login/Logout time and work duration can be traced via log data.

6.2.2 Retrieving Patient Records

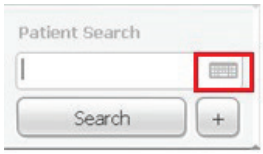
You can search through the patient database using a patient's Chart Number, First Name, or Last Name.

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

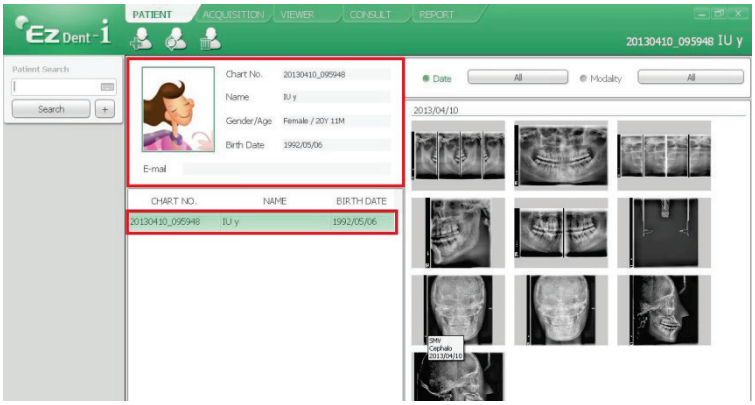


NOTE

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.

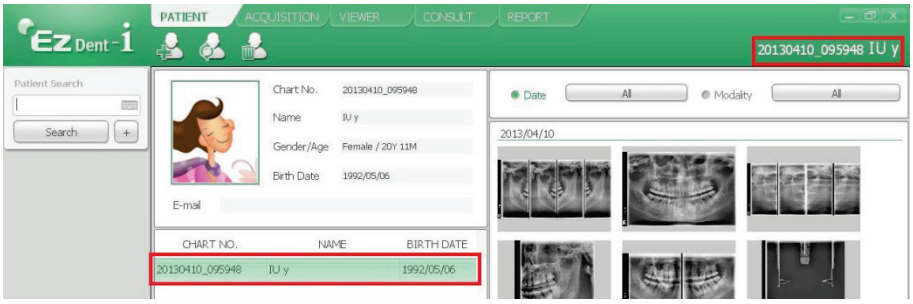


6.3 Initiating the Console Software

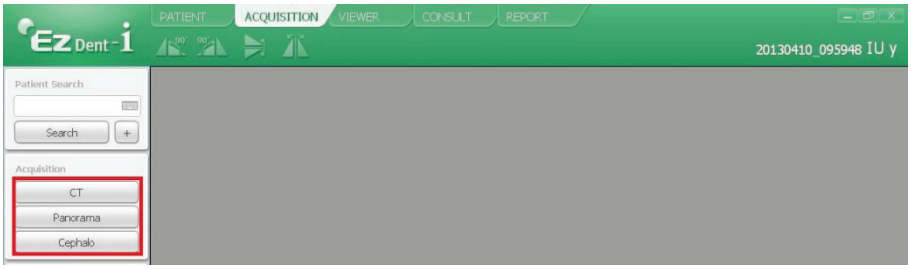
NOTE

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

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. (Refer to **4.3 Console Software)** From the Main Screen, you can configure the imaging parameter settings prior to acquiring an image.

NOTE

Refer to the following **chapters (6 ~ 10)** for the more information on the image acquisition.

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7. Acquiring PANO Images

7.1 PANO Imaging Program Overview

Result Images

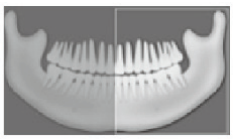
It provides conventional 2D panoramic images.

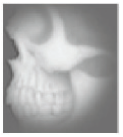
Image Acquisition Method

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

Examination Programs

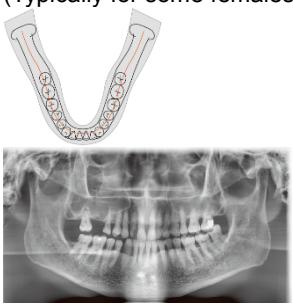
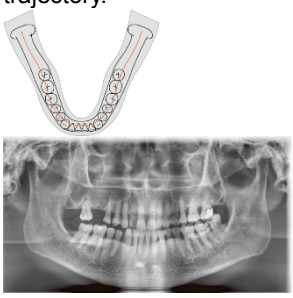
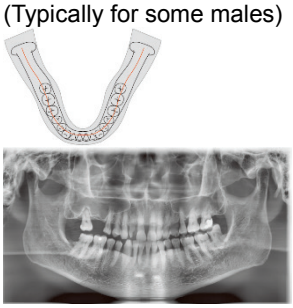
It is classified as below based on the ROI (Region of Interest).

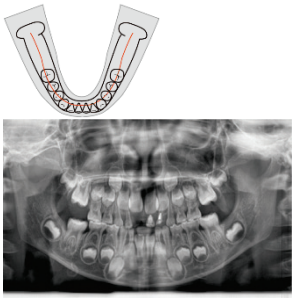
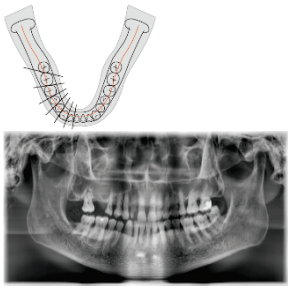
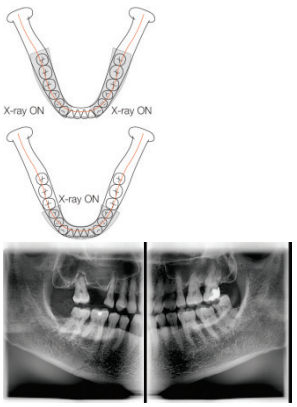
Examination Type	Arch Selection	ROI	Example
PANO Examination	Narrow Normal Wide Child Orthogonal	Standard	
		Right	
		Front	
		Left	
	Orthogonal	Bitewing*	
		Bitewing Right*	

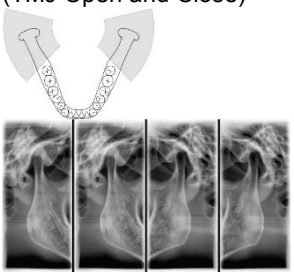
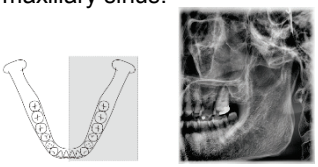
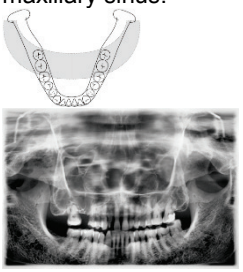
Examination Type	Arch Selection	ROI	Example
		Bitewing Left*	
SPECIAL Examination	N/A	TMJ LAT Open	
		TMJ LAT Close	
		Sinus LAT	
		Sinus PA	

* 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 the child trajectory. (Less X-ray exposure than the Normal mode by approximately more than 40%)

Examination Type	Arch Selection	ROI	Description & Sample Image
			
	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**	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.) 

Examination Type	Arch Selection	ROI	Description & Sample Image
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) 
		Sinus LAT	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. 

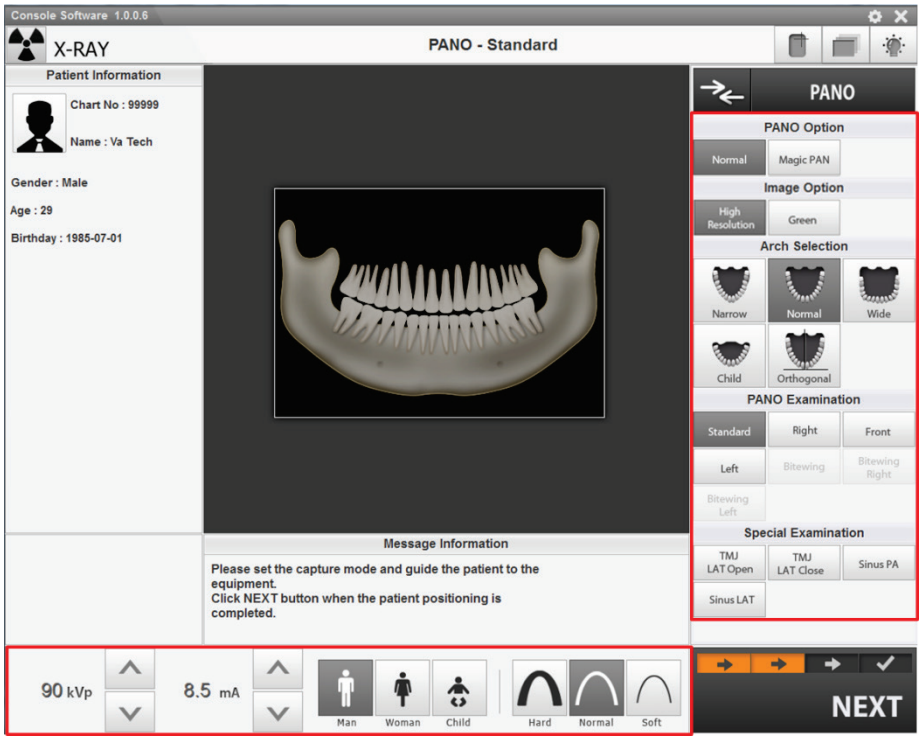
** Bitewing imaging mode is activated only when Orthogonal is selected in Arch Selection.

7.2 Configuring Exposure Parameters

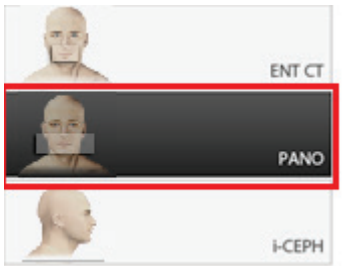
To acquire PANO Images, **6. Getting Started** must be completed first. If not, you must return to the **6. Getting Started** and finish the step first.

NOTE

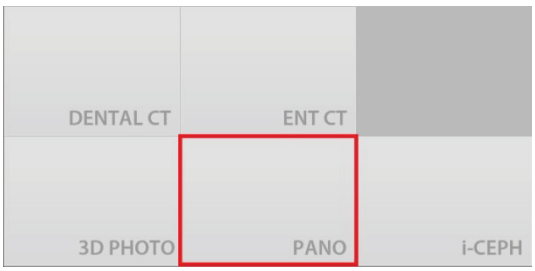
You can set the imaging parameters either on the Touch Screen or through the Console Software running on the PC. They are synched and display the same environmental settings.



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



<Console Software>



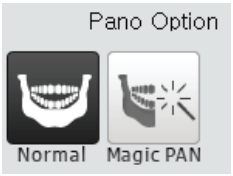
<Touch Screen>

NOTE

"i-**CEPH**" and "**3D PHOTO**" buttons exist only when each imaging program is included in the equipment.

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

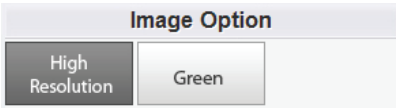
<Console Software>



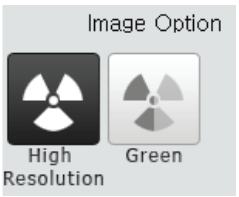
<Touch Screen>

Mode	Description
Normal	Normal option
Magic PAN (Optional)	Reconstructs the image with optimized focus (autofocus) from the entire panorama to acquire high quality images. (Any errors caused by issues with the patient's position and tooth trajectory can be minimized.)

3. Select an Image Option.



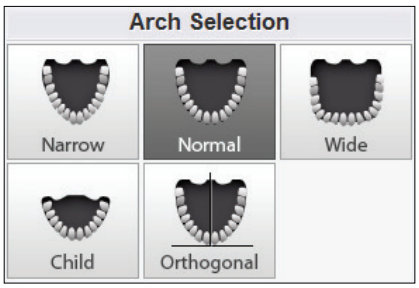
<Console Software>



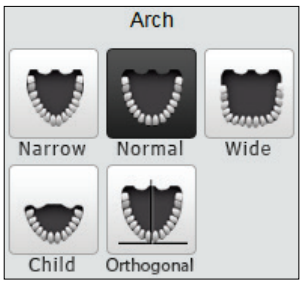
<Touch Screen>

Mode	Description
High Resolution	High Resolution image
Green	Normal quality image

4. Make an Arch Selection.



<Console Software>

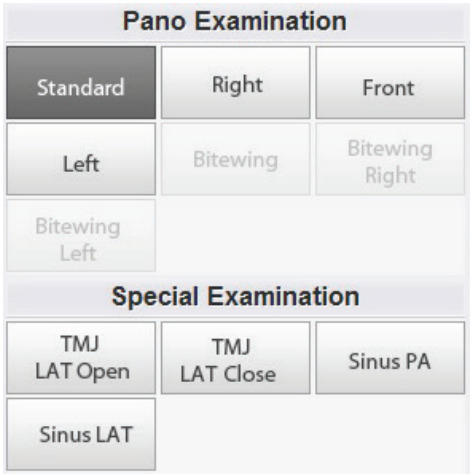


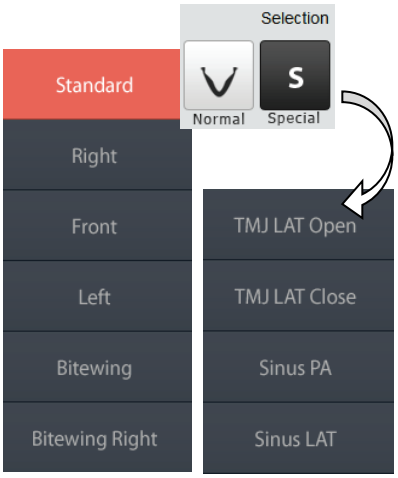
<Touch Screen>

NOTE

For more information about Arch type, refer to **7.1.2 Main Imaging Program**.

5. Select an Examination Program.





<Console Software> <Touch Screen>

NOTE

- To activate three Bitewing examination options- Bitewing, Bitewing Right and Bitewing Left, select Orthogonal Arch in the Arch Selection panel.

- For more information about PANO Examination Program, refer to **7.1.2 Main Imaging Program**.

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 **Arrow** button to zoom in. The dose is adjustable by the ±1 kVp and ±0.5 mA respectively.

9. When the exposure parameter setting is completed, guide the patient to the equipment for positioning the patient. (Go to **7.3 Getting Prepared for Patient Positioning**.)

IMPORTANT

On the Console Software, do not click **NEXT** button before completing patient positioning.

On the Touch Screen, it's ok to press **NEXT** button after competing parameter setting. (When **NEXT** button is pressed, a confirmation window will appear.) But do not press **OK** button before completing patient positioning.

7.3 Getting Prepared for Patient Positioning

WARNING

- Have patients (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to direct the Laser Beam into the patient's eyes. Doing so may result in a permanent loss of vision.

WARNING

When the equipment is not operable while the Rotating Unit is in operation or in exposure location, bring the patient out of the equipment immediately as follows.

① **[When the patient is biting the Bite Block]** Ask the patient to open the mouth.

② Ask the patient to back off a bit.

③ **[When the Headrest is attached]** Detach it. (The operator or the patient must keep holding the Headrest until the Handle Frame is opened and take it out after the Handle Frame is opened.)

④ **[When the Chinrest Ass'y is attached]** Take out the Chinrest and the Chinrest Base in turn separately.

⑤ Open the Handle Frame.

⑥ Guide the patient out of the equipment.

* For ①, ③ and ⑤, each step can be skipped if it's not necessory according to the existence of each accessory.

IMPORTANT

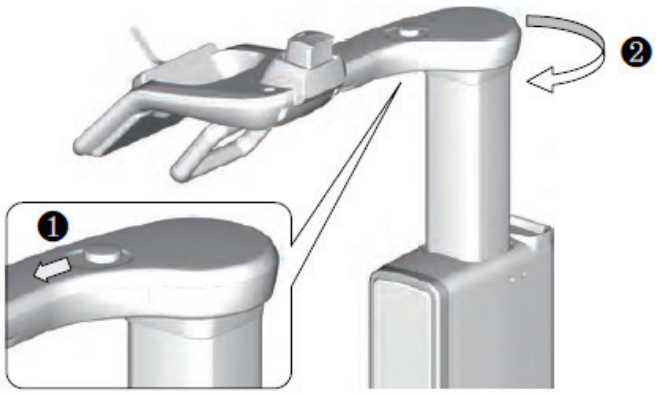
- Correct posture reduces the shadow casted by the patient's cervical spine and allows clear image acquisition.
- Metal implants or bridges may reduce the quality of the images.
- Be sure to adjust Laser Beam correctly. Otherwise, the quality of images can be lower due to ghost images or expansion /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

NOTE

To minimize the time that the patient spending inside the equipment, it is highly recommended to complete configuring exposure parameters first before to start positioning the patient's posture.

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. Let the patient wear a lead apron to protect themselves from residual radiation.
3. Push the Handle Frame's **Open/Close** button inward and open the Handle Frame.



4. Let the patient sit on the chair.
5. Close the Handle Frame.

7.4 Patient Positioning

7.4.1 PANO Standard and Bitewing mode

For Normal patients

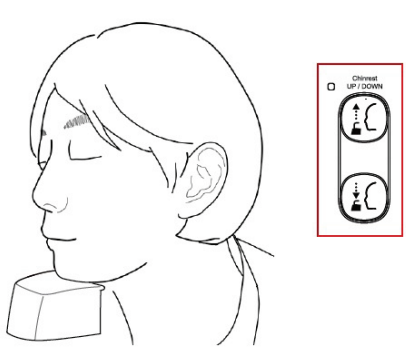
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

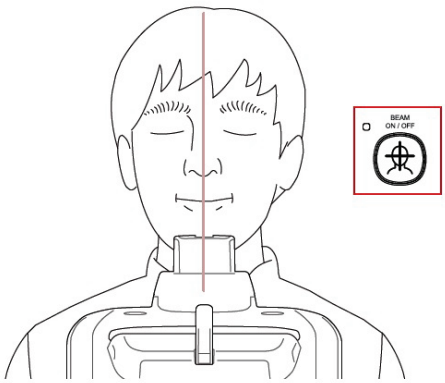
Patients need to keep the following poses during imaging process.

- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the Cervical Vertebra.

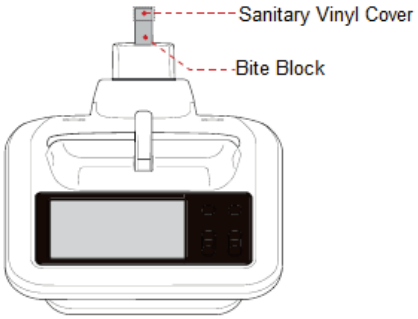
2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. Align the Vertical Beam to the center of the patient's face. (It can prevent the acquired image from being expended left or right.)



4. Insert the Bite Block into the Chinrest and cover it with a sanitary vinyl cover.

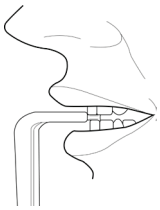


CAUTION

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

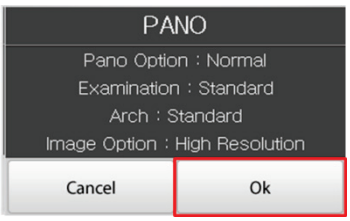
- Clean the Chinrest and the Bite Block with ethanol and wipe with a dry towel before the next patient.

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



6. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

(In case **NEXT** button has been already clicked, you will see pop-up window directly.)



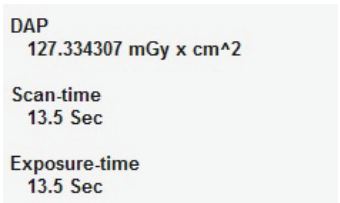
<Console Software> <Touch Screen>

NOTE

When you click **NEXT** (**OK** in Touch Screen) button,

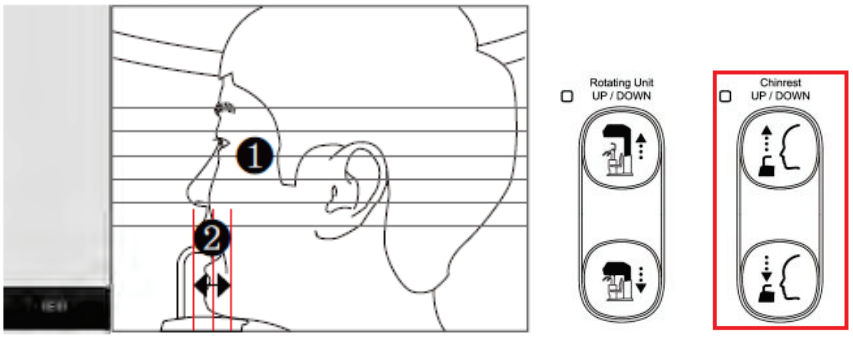
- The Rotating Unit will come down to the positioning location.

- The vertical Laser Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below Patient Information window.



7. You can see the patient through the Touch Screen.

- Make sure that the horizontal lines displayed in the screen are parallel to the patient's Frankfurt line by using the Chinrest **UP/DOWN** button.
- Let the patient smile and make sure that the patient's canine teeth are positioned on the center of the vertical line or between the other two vertical lines.



8. Let the patient maintain the posture as follows:

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

IMPORTANT

Before conduct the next step, be sure to let the patient know that the Rotating Unit will be lower to the exposure location and instruct him or her to relax down.

9. Click **NEXT** button when the patient positioning is completed. The Rotating Unit will come down to the exposure location. Then, **READY** button will be activated on the Touch Screen and the Console Software.

WARNING

When the equipment is not operable while the Rotating Unit is in the exposure location, detach the Chinrest from the equipment and open the Handle Frame to bring out the patient immediately.

10. Press **READY** button. No X-ray will be emitted at this point.

<Console Software>

<Touch Screen>

11. Go to **7.5 X-ray Exposure** to start the exposure.

For Edentulous Patients

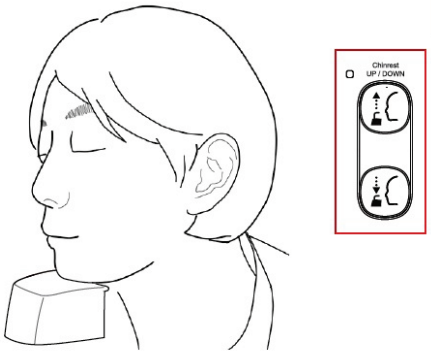
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

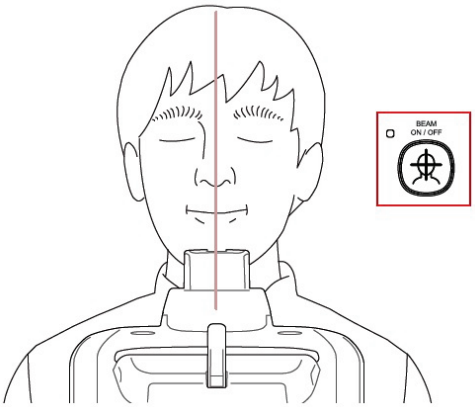
Patients need to keep the following poses during imaging process.

- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the Cervical Vertebra.

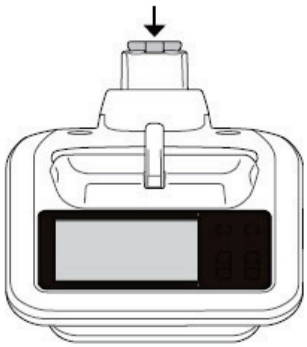
2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. Align the Vertical Beam to the center of the patient's face. (It prevented the acquired image from being expended left or right.)



4. Insert the Sinus / Edentulous Bite into the Chinrest.



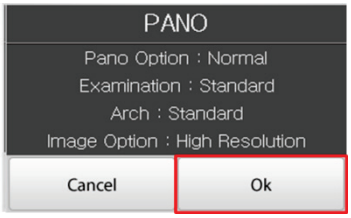
Sinus / Edentulous Bite

CAUTION

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

5. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

(In case **NEXT** button has been already clicked, you will see pop-up window directly.)

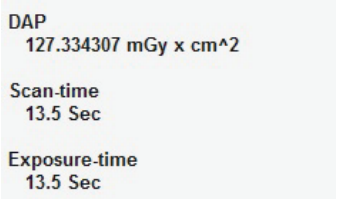


<Console Software> <Touch Screen>

NOTE

When you click **NEXT** (**OK** in Touch Screen) button,

- The Rotating Unit will come down to the positioning location.
- The vertical Laser Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below Patient Information window.



6. You can see the patient through the Touch Screen.
   - Make sure that the horizontal lines displayed in the screen are parallel to the patient's Frankfurt line by using the Chinrest **UP/DOWN** button.
   - Let the patient smile and make sure that the patient's canine teeth are positioned on the center of the vertical line or between the other two vertical lines.
7. Let the patient maintain the posture as follows:
   - Close the mouth.
   - Place the tongue to the roof of the mouth.
   - Close the eyes.

IMPORTANT	Before conduct the next step, be sure to let the patient know that the Rotating Unit will be lower to the exposure location and instruct him or her to relax down.

8. Click **NEXT** button when the patient positioning is completed. Then, **READY** button will be activated on the Touch Screen and the Console Software.

WARNING	When the equipment is not operable while the Rotating Unit is in the exposure location, detach the Chinrest from the equipment and open the Handle Frame to bring out the patient immediately.

9. Press **READY** button. No X-ray will be emitted at this point.

<Console Software>

<Touch Screen>

10. Go to **7.5 X-ray Exposure** to start the exposure.

7.4.2 TMJ Mode

NOTE

Steps for TMJ Mode

Patient's positioning for TMJ Open > X-ray Exposure > Patient's positioning for TMJ Close > X-ray Exposure

TMJ Open mode

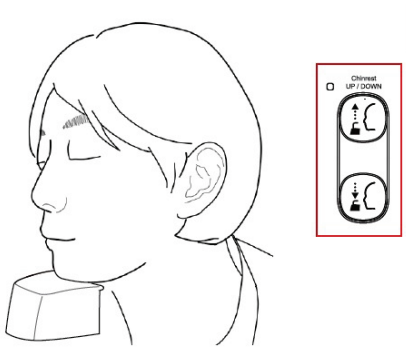
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

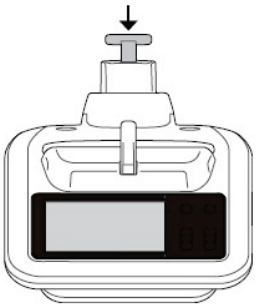
Patients need to keep the following poses during imaging process.

- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the Cervical Vertebra.

2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. Insert the TMJ Bite into the Chinrest.



CAUTION

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

4. Let the patient place the base of their nose (acanthion point) against the Chinrest and bend the head forward about 5˚.

IMPORTANT

Be careful the patient does not to touch the equipment with their jaw.

Doing so may cause difficulty to maintain the proper position to get images of good quality.

5. Align the Vertical Beam to the center of the patient's face. (It can prevent the acquired image from being expended left or right.)

6. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

(In case **NEXT** button has been already clicked, you will see pop-up window directly.)

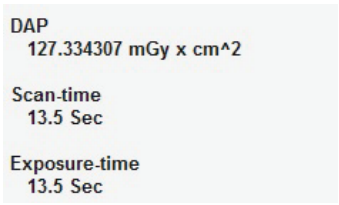
<Console Software>

<Touch Screen>

NOTE

When you click **NEXT** (**OK** in Touch Screen) button,

- The Rotating Unit will come down to the positioning location.
- The vertical Laser Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below Patient Information window.



7. You can see the patient through the Touch Screen.

   Make sure that the patient's Frankfurt line is tilted about 5˚ from the horizontal lines of the screen.

8. Let the patient maintain the posture as follows:

   - After swallowing once, open your mouth as wide as possible.
   - Close the eyes.

IMPORTANT

Before conduct the next step, be sure to let the patient know that the Rotating Unit will be lower to the exposure location and instruct him or her to relax down.

9. Click **NEXT** button when the patient positioning is completed. The Rotating Unit will come down to the exposure location. Then, **READY** button will be activated on the Touch Screen and the Console Software.

WARNING

When the equipment is not operable while the Rotating Unit is in the exposure location, detach the Chinrest from the equipment and open the Handle Frame to bring out the patient immediately.

10. Press **READY** button. No X-ray will be emitted at this point.

<Console Software>

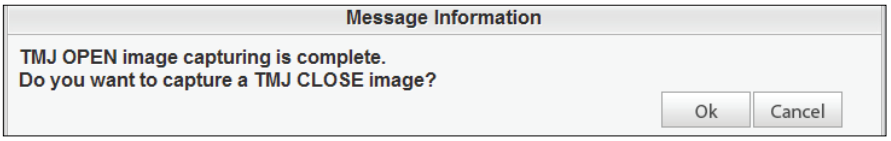
<Touch Screen>

11. Go to **7.5 X-ray Exposure** to start the exposure.

TMJ Close mode

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

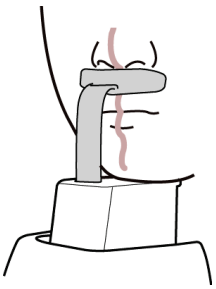
1. "Do you want to capture a TMJ Close image?" message will appear when the TMJ Open mode is completed. Press/Click **OK** button to begin TMJ Close mode.



<Console Software>

<Touch Screen>

2. Let the patient place the base of their nose (acanthion point) against the Chinrest and bend the head forward about 5˚.
3. Align the Vertical Beam to the center of the patient's face.



4. You can see the patient through the Touch Screen. Make sure that the patient's Frankfurt line is tilted about 5˚ from the horizontal lines of the screen.
5. Let the patient maintain the posture as follows:
   - Close the mouth.
   - Close the eyes.
6. Click **NEXT** button when the patient positioning is completed. The Rotating Unit will come down to the exposure location.
7. When the Rotating Unit is in exposure location, **READY** button will be activated in the Touch Screen and the Console Software.
8. Press **READY** button. No X-ray will be emitted at this point.
9. Go to **7.5 X-ray Exposure** to start the exposure.

7.4.3 Sinus Mode

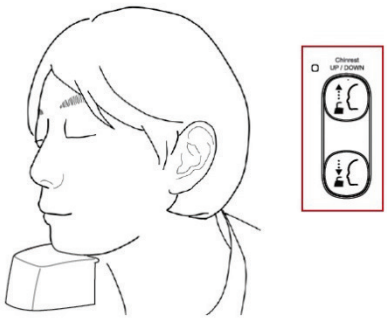
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

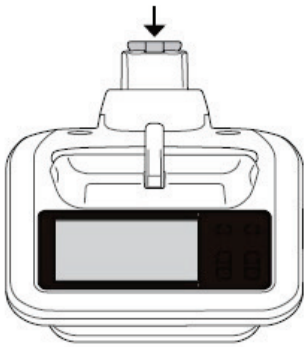
Patients need to keep the following poses during imaging process.

- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the Cervical Vertebra.

2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. Insert the Sinus / Edentulous Bite into the Chinrest.



Sinus / Edentulous Bite

CAUTION

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

4. Let the patient bend the head backward around 10˚-15˚.

IMPORTANT

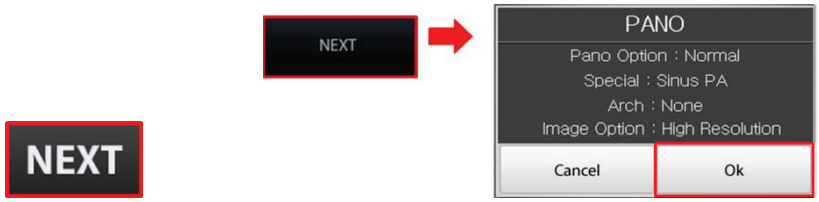
Be careful the patient does not to touch the equipment with their jaw.

Doing so may cause difficulty to maintain the proper position to get images of good quality.

5. Align the Vertical Beam to the center of the patient's face. (It can prevent the acquired image from being expended left or right.)

6. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

   (In case **NEXT** button has been already clicked, you will see pop-up window directly.)

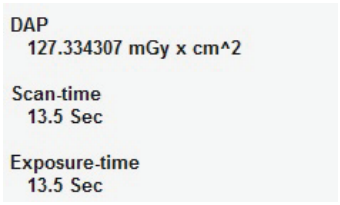


<Console Software> <Touch Screen>

NOTE

When you click **NEXT** (**OK** in Touch Screen) button,

- The Rotating Unit will come down to the positioning location.
- The vertical Laser Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below Patient Information window.



7. You can see the patient through the Touch Screen. Make sure that the patient's Frankfurt line is tilted about 10˚-15˚ from the horizontal lines of the screen.

8. Let the patient maintain the posture as follows:

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

IMPORTANT

Before conduct the next step, be sure to let the patient know that the Rotating Unit will be lower to the exposure location and instruct him or her to relax down.

9. Click **NEXT** button when the patient positioning is completed. The Rotating Unit will come down to the exposure location. Then, **READY** button will be activated on the Touch Screen and the Console Software.

WARNING

When the equipment is not operable while the Rotating Unit is in the exposure location, detach the Chinrest from the equipment and open the Handle Frame to bring out the patient immediately.

10. Press **READY** button. No X-ray will be emitted at this point.

<Console Software>

<Touch Screen>

11. Go to **7.5 X-ray Exposure** to start the exposure.

7.5 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 their area at all times during the operation of this equipment. ▪ During image acquisition (X-ray exposure), don't use the Chinrest UP/DOWN button or switch except for emergency situations. (The movement of the Rotating Unit is necessary only for the patient positioning in normal situation.) Doing so may lead the patient to be unsafe.

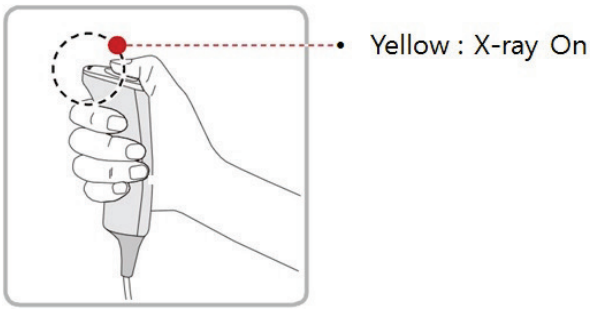
CAUTION	▪ The operator must keep vocal/visual contact with the patient at all times during image acquisition process. ▪ Do not operate the PC during exposure. Doing so may cause the system to malfunction.

IMPORTANT	▪ Let the patient close the eyes during operation. ▪ To acquire optimized images, let the patient hold his/her breath and not to swallow. Also don't let the patient move until the Rotating Unit moves up.

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 Green LED lights of the **Exposure Switch** and **Rotating Unit** turn yellow.
- An alert sound comes out to indicate that X-ray emission is currently underway.
- The X-ray Indicator icon of the Console Software turns yellow.

3. Release the **Exposure Switch** when “Image capturing is complete.” message appears on the screen.
4. The Rotating Unit will move up automatically when the image capturing is completed.
5. Push the Handle Frame’s **Open/Close** button inward and open the Handle Frame.
6. Guide the patient out of the equipment.
7. Remove the hygiene cover (optional) and the Bite Block from the Chinrest.

7.6 Checking the captured image

Acquired images can be reconstructed and converted to DICOM format.

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

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 **Save** button to save the images.
3. To check the image, double-click the one on the Patient list.

8. Acquiring i-CEPH Images (Optional)

8.1 i-CEPH Imaging Program Overview

Result Images

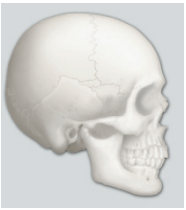
It provides 2D images similar to conventional cephalometric images.

Image Acquisition Method

It reconstructs specific oral & maxillofacial regions to a single 2D image utilizing the data acquired through CT imaging method..

Examination Programs

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

Examination Area	Description	Position
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 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.	
Lateral	▪ 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.	

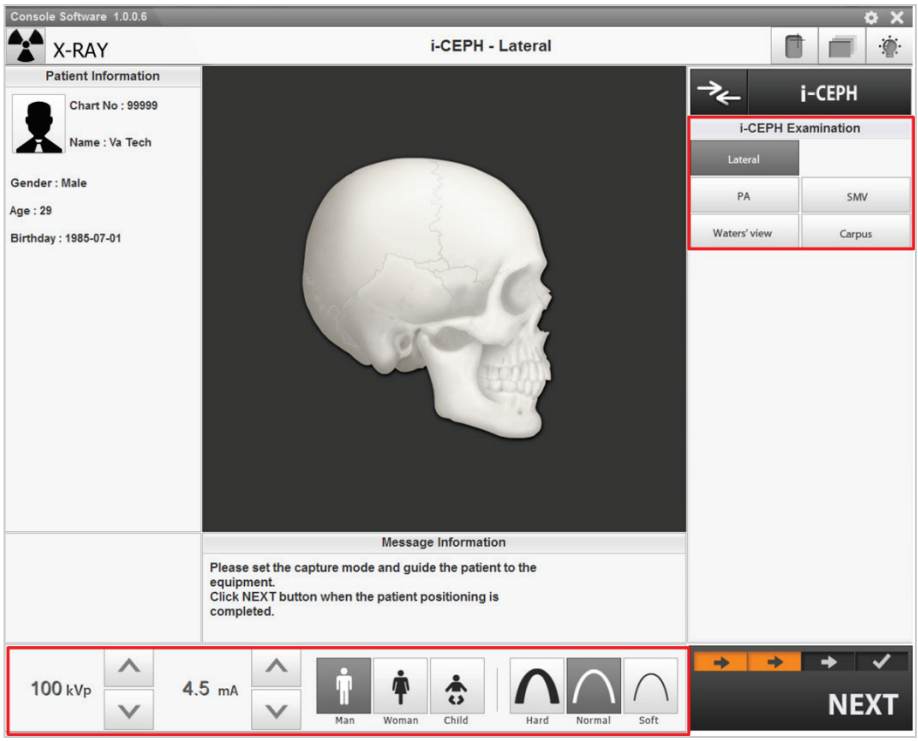
Examination Area	Description	Position
SMV	▪ Used to study the base of the skull, horizontal angulation of the mandibular condylar axis, the sphenoidal sinus, the curvature of the lower jaw, the side wall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at base of the skull.	
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.	
Carpus	▪ Used to assess hand bone age to compare the changes in the skull.	

8.2 Configuring Exposure Parameters

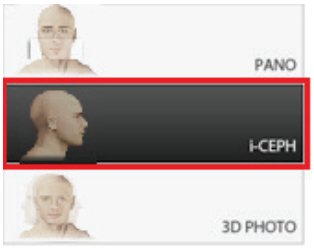
To acquire i-CEPH images, **6. Getting Started** must be completed first.

NOTE

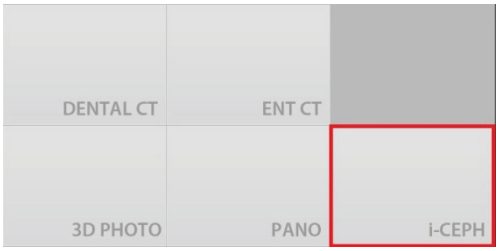
You can set the imaging parameters on either the Touch Screen or the Console Software running on the PC. They are synched and display the same environmental settings.



1. Click **i-CEPH** button in the Main Screen.



<Console Software>

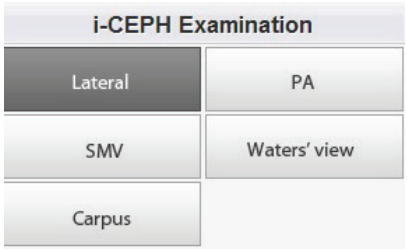


<Touch Screen>

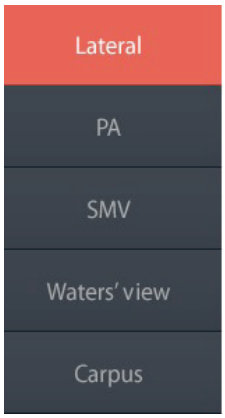
NOTE

"i-**CEPH**" and "**3D PHOTO**" buttons exist only when each imaging program is included in the equipment.

2. Select an i-CEPH Examination.



<Console Software>



<Touch Screen>

NOTE

For more information about i-CEPH examination, refer to **7.1 i-CEPH Imaging Program**.

3. The gender / age group of the patient is selected automatically based on the patient information. If necessary, you can select the gender / age group manually. (On Touch Screen, click **Settings** button before selecting options.)

<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>

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

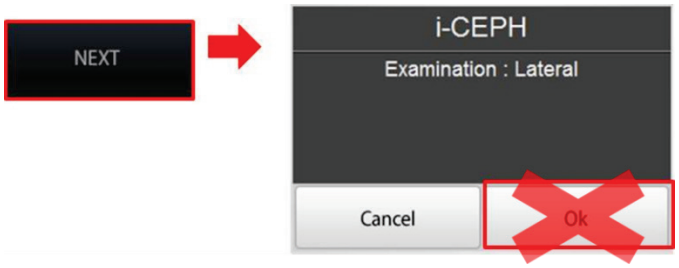
5. The values of tube voltage and current are configured automatically according to the patient's gender / age group and X-ray intensity. Click Arrow button to zoom in. The dose is adjustable by the ±1 kVp and ±0.5 mA respectively.

6. When the exposure parameter setting is completed, guide the patient to the equipment for positioning the patient. (Go to **8.3 Getting Prepared for Patient Positioning**.)

IMPORTANT

On the Console Software, do not click **NEXT** button before completing patient positioning.

On the Touch Screen, it's ok to press **NEXT** button after competing parameter setting. (When **NEXT** button is pressed, a confirmation window will appear.) But do not press **OK** button before completing patient positioning.



8.3 Getting Prepared for Patient Positioning

WARNING

- Have patients (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to direct the Laser Beam into the patient's eyes. Doing so may result in a permanent loss of vision.

WARNING

When the equipment is not operable while the Rotating Unit is in operation or in exposure location, bring the patient out of the equipment immediately as follows.

① **[When the patient is biting the Bite Block]** Ask the patient to open the mouth.

② Ask the patient to back off a bit.

③ **[When the Headrest is attached]** Detach it. (The operator or the patient must keep holding the Headrest until the Handle Frame is opened and take it out after the Handle Frame is opened.)

④ **[When the Chinrest Ass'y is attached]** Take out the Chinrest and the Chinrest Base in turn separately.

⑤ Open the Handle Frame.

⑥ Guide the patient out of the equipment.

* For ①, ③ and ⑤, each step can be skipped if it's not necessory according to the existence of each accessory.

IMPORTANT

<For Lateral, PA, SMV and Waters' view only>

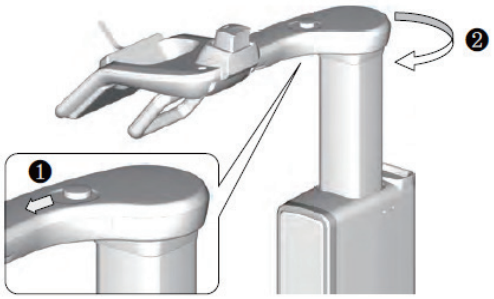
- Correct posture reduces the shadow casted by the patient's cervical spine and allows clear image acquisition.
- Metal implants or bridges may reduce the quality of the images.

NOTE

To minimize the time that the patient spending inside the equipment, it is highly recommended to complete configuring exposure parameters first before to start positioning the patient's posture.

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. Let the patient wear a lead apron to protect themselves from residual radiation.
3. Push the Handle Frame's **Open/Close** button inward and open the Handle Frame.



4. Let the patient sit on the chair and close the Handle Frame.
5. Close the Handle Frame.

8.4 Patient Positioning

Lateral, PA, SMV and Waters' view

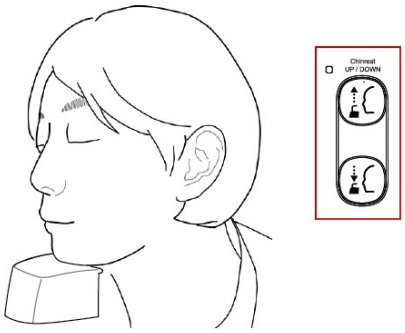
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

Patients need to keep the following poses during imaging process.

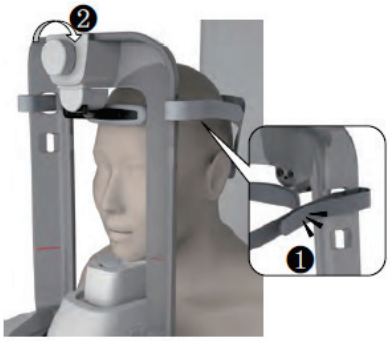
- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the cervical vertebra.

2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. Put the Headrest into the Chinrest.

4. Put the Headrest Strap on the patient's head and turn the knob clockwise to hold the head tightly.



5. Remove the Chinrest from the unit.

6. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

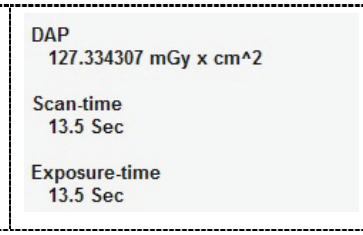
   (In case **NEXT** button has been already clicked, you will see pop-up window directly.)

<Console Software> <Touch Screen>

NOTE

When you click **NEXT** (**OK** in Touch Screen) button,

- The Rotating Unit will come down to the positioning location.
- The vertical Laser Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below Patient Information window.



7. You can see the patient through the Touch Screen. Make sure that the horizontal lines displayed in the screen are parallel to the patient's Frankfurt line by using the Chinrest **UP/DOWN** button.

8. Let the patient maintain the posture as follows:

   - Close the mouth.
   - Close the eyes.

IMPORTANT

Before conduct the next step, be sure to let the patient know that the Rotating Unit will be lower to the exposure location and instruct him or her to relax down.

9. Click **NEXT** button when the patient positioning is completed. The Rotating Unit will come down to the exposure location. Then, **READY** button will be activated on the Touch Screen and the Console Software.

WARNING

When the equipment is not operable while the Rotating Unit is in the exposure location, detach the Headrest from the equipment (detach the Chinrest as well when it's attached) and open the Handle Frame to bring out the patient immediately.

10. Press **READY** button. No X-ray will be emitted at this point.

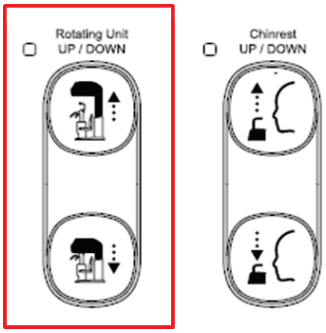
<Console Software>

<Touch Screen>

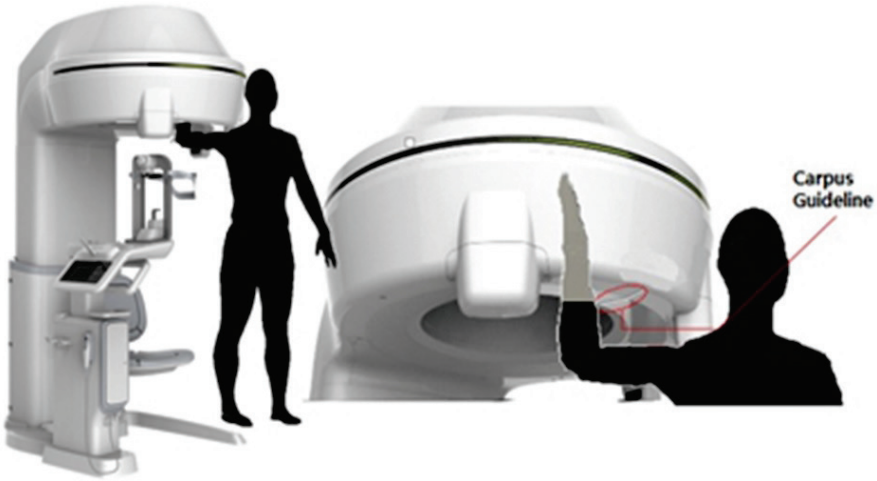
11. Go to **8.5 X-ray Exposure** to start the exposure.

Carpus

1. Make sure that the patient's upper arm is aligned with the Carpus Guideline engraved on the bottom surface of the Rotating Unit as shown below. If necessary, adjust the height by using the Rotating Unit **UP/DOWN** button on the Control Panel.



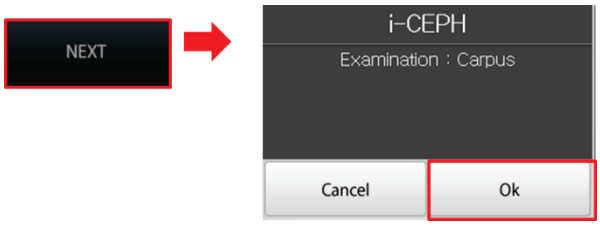
2. Let the patient put the right hand splaying on the inner side of the Rotating Unit as shown below. Make sure that the patient does not bend his / her fingers.



3. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

   (In case **NEXT** button has been already clicked, you will see pop-up window directly.)

<Console Software>



<Touch Screen>

4. Click **NEXT** button when the patient positioning is completed. Then, **READY** button will be activated on the Touch Screen and the Console Software.

5. Press **READY** button. No X-ray will be emitted at this point.

<Console Software>

<Touch Screen>

6. Go to **8.5 X-ray Exposure** to start the exposure.

8.5 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 their area at all times during the operation of this equipment.
- During image acquisition (X-ray exposure), don't use the Chinrest UP/DOWN button or switch except for emergency situations. (The movement of the Rotating Unit is necessary only for the patient positioning in normal situation.) Doing so may lead the patient to be unsafe.

CAUTION

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

IMPORTANT

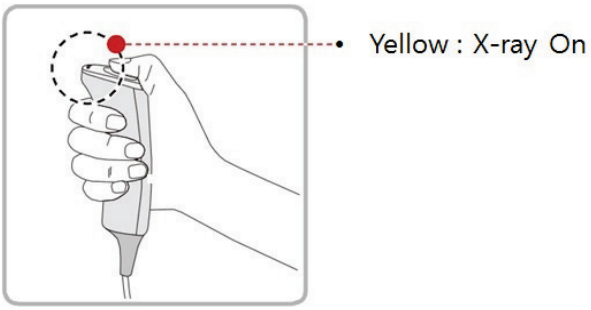
- Let the patient close the eyes during operation.
- To acquire optimized images, let the patient hold his/her breath and not to swallow. Also don't let the patient move until the Rotating Unit moves up.

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 Green LED lights of the **Exposure Switch** and **Rotating Unit**
  : [In Lateral, PA, SMV and Waters' view modes] become flashing for 6 seconds and turn yellow.
  : [In Carpus mode] turn yellow without flashing.
- An alert sound comes out to indicate that X-ray emission is currently underway.
- The X-ray Indicator icon of the Console Software turns yellow.

3. Release the **Exposure Switch** when "Image capturing is complete." message appears on the screen.
4. [For Lateral, PA, SMV and Waters' view mode only]
   ① The Rotating Unit will move up automatically when the image capturing is completed.
   ② Remove the Headrest Strap from the patient.
   ③ Push the Handle Frame's **Open/Close** button inward and open the Handle Frame.
5. Guide the patient out of the equipment.

8.6 Checking the captured image

Acquired images can be reconstructed and converted to DICOM format.

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

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 **Save** button to save the images.
3. To check the image, double-click the one on the Patient list.

Left blank intentionally

9. Acquiring Dental CT Images

9.1 Dental CT Imaging Program Overview

Result Images

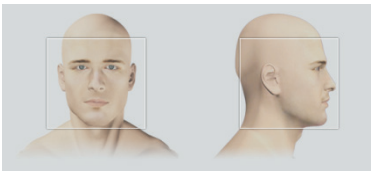
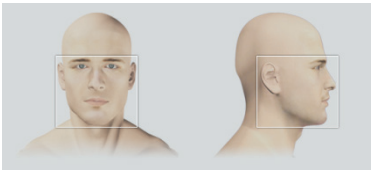
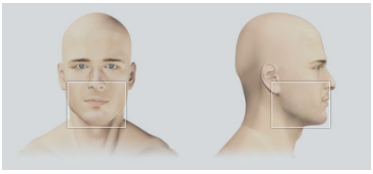
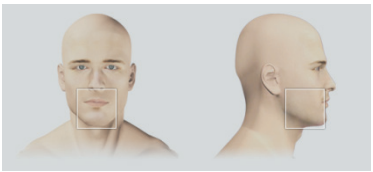
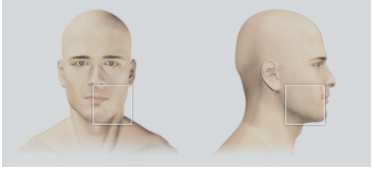
It provides conventional 3D CT sliced images

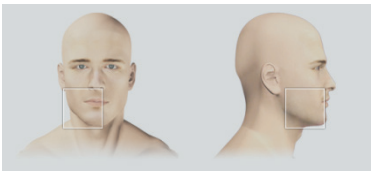
Image Acquisition Method

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.

FOV (cm)	Description	ROI
21x19	▪ For entire maxillofacial region diagnostics including frontal bone, frontal sinus, nasal, ethmoid, zygomatic, maxillary bones and mandible	
17x15	▪ Covering full arch region, sinus, left/right TMJ and nasal bone	
12x9	▪ Covering both maxillary and mandibular structures including the 3rd molar region ▪ Suitable for most oral surgery cases as well as multiple implant surgery	
8x8	▪ Selectable FOV for particular region (left/ center/right) ▪ Covering both maxillary and mandibular areas and left or right TMJ	 

FOV (cm)	Description	ROI
		

Special Mode

Dental CT + 3D PHOTO

: 3D PHOTO images can be acquired as well as Dental CT images at one time.

Special Option

Auto Pano / Auto Ceph

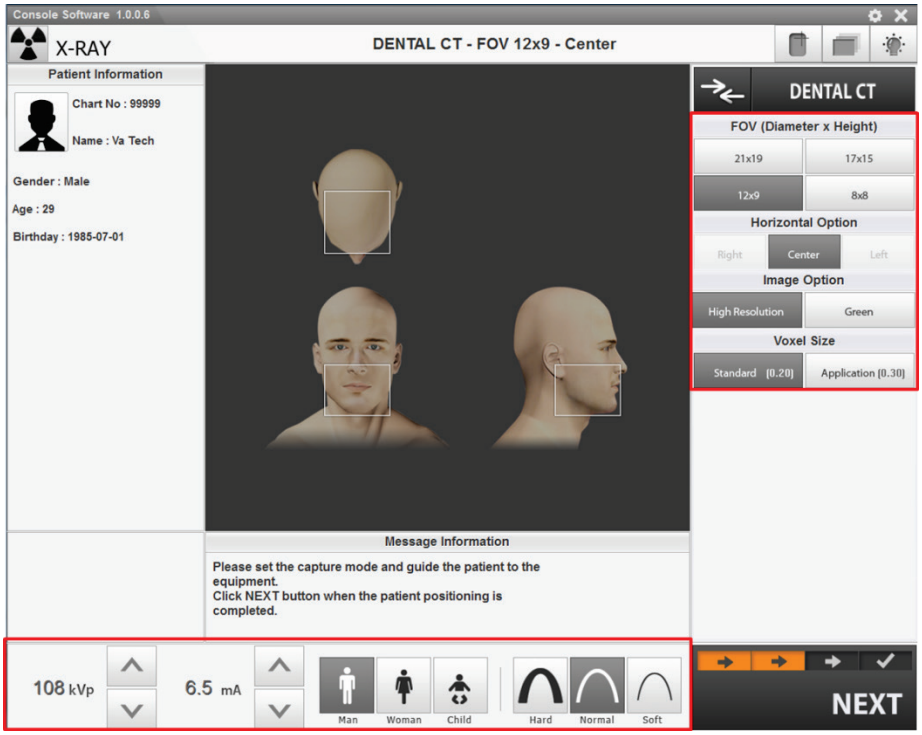
: 2D images of conventional panoramic / cephalometric view are available with the specific FOVs. For more details on Auto Pano / Auto Ceph, please refer to **9.2 Configuring Exposure Parameters**.

9.2 Configuring Exposure Parameters

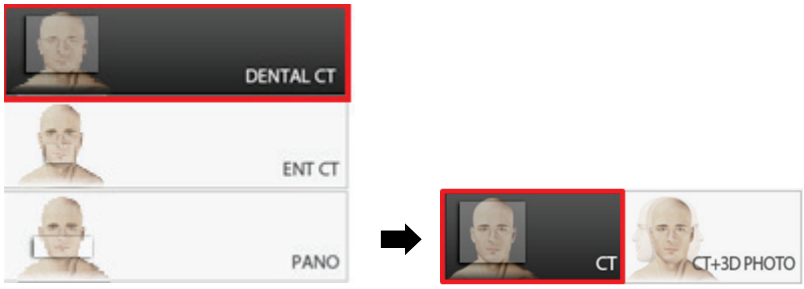
To acquire Dental CT Images, **6. Getting Started** must be completed first.

NOTE

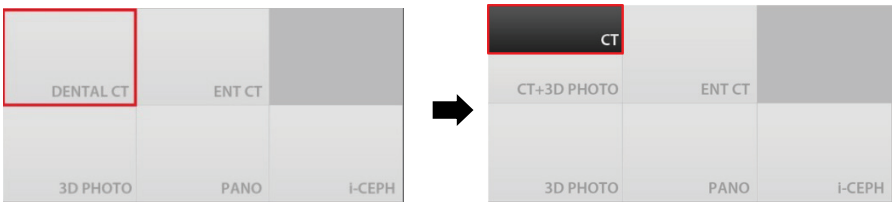
You can set the imaging parameters on either the Touch Screen or the Console Software running on the PC. They are synched and display the same environmental settings.



1. Click **DENTAL CT** > **CT** button in the Main Screen.



<Console Software>



<Touch Screen>

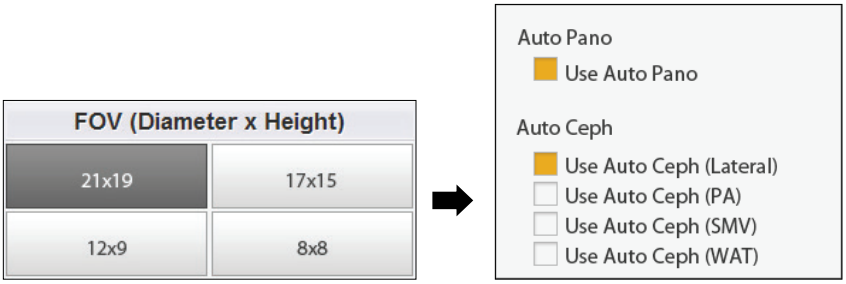
NOTE

- "i-**CEPH**" and "**3D PHOTO**" buttons exist only when each imaging program is included in the equipment.
- To acquire 3D PHOTO with CT images, click **DENTAL CT** > **CT+3D PHOTO** button.

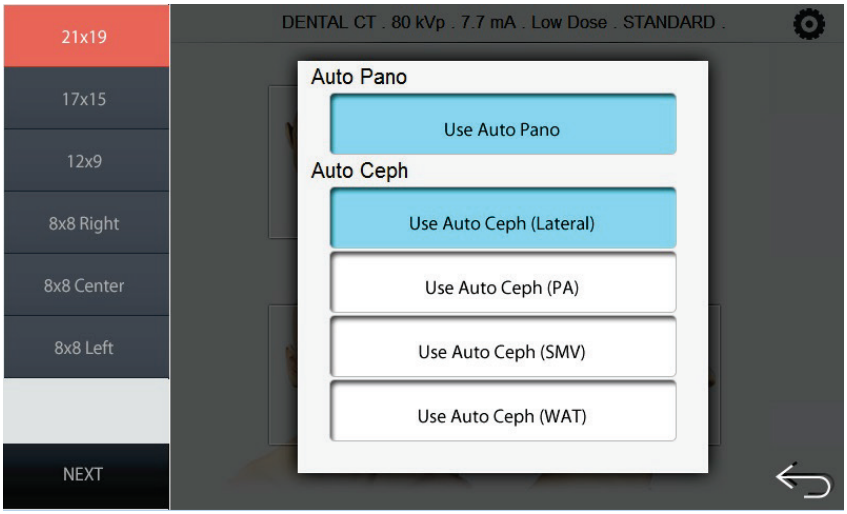
2. Select FOV size.

- You can configure **Auto Pano** and **Auto Ceph** options when **21x19** is selected.

  (On the Touch Screen) Press button to close **Auto Pano** / **Auto Ceph** option window.



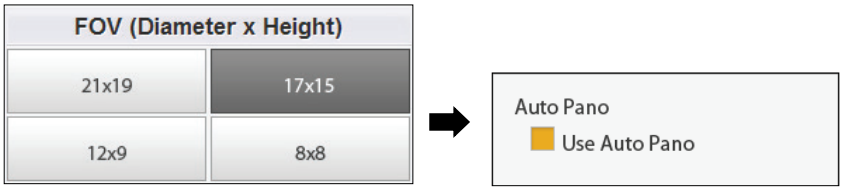
<Console Software>



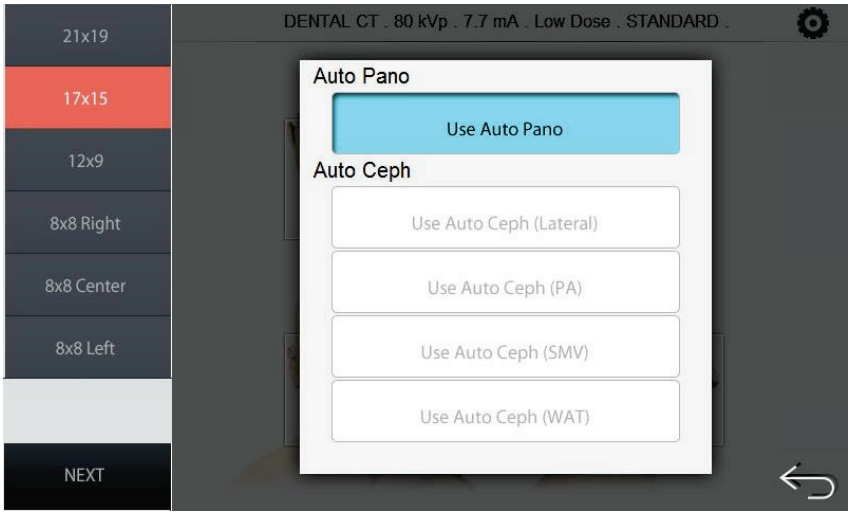
<Touch Screen>

- You can configure the **Auto Pano** options when **17x15** is selected.

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

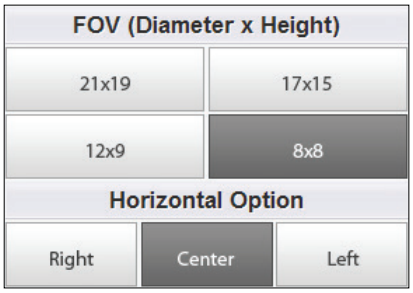


<Console Software>

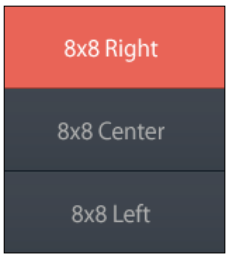


<Touch Screen>

- You can configure Horizontal options when **8x8** is selected.



<Console Software>



<Touch Screen>

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

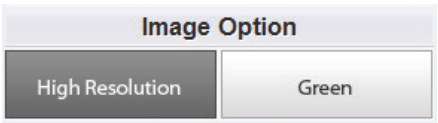
for Standard mode in DICOM or BMP format.)

**** Auto Ceph**

Auto Ceph 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 cephalometric images offer. (It provides images for PA, Lateral, SMV and Waters' view modes in DICOM or BMP format.)

- When selected, Auto Pano and/or Auto Ceph image is automatically acquired and can be seen on the **EzDent-i** Viewer.

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



<Console Software>

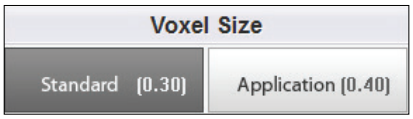
<Touch Screen>

NOTE

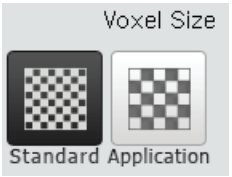
The Green mode produces approximately 20 % ~ 65 % lower DAP value than the High Resolution mode during X-ray exposure.

Mode	DAP ($mGy \cdot cm^2$)	Exposure Condition
High Resolution	2010	FOV: 21x19 (cm) (108 kVp / 6.5 mA / 18.0 sec)
	1470	FOV: 17x15 (cm) (108 kVp / 6.5 mA / 16.6 sec)
	740	FOV: 12x9 (cm) (108 kVp / 6.5 mA / 13.9 sec)
	620	FOV: 8x8 (cm) (108 kVp / 6.5 mA / 11.0 sec)
Green	1610	FOV: 21x19 (cm) (95 kVp / 6.5 mA / 18.0 sec)
	1010	FOV: 17x15 (cm) (90 kVp / 6.5 mA / 16.6 sec)
	380	FOV: 12x9 (cm) (85 kVp / 5.5 mA / 13.9 sec)
	230	FOV: 8x8 (cm) (80 kVp / 4.5 mA / 11.0 sec)

4. Select a Voxel Size.



<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

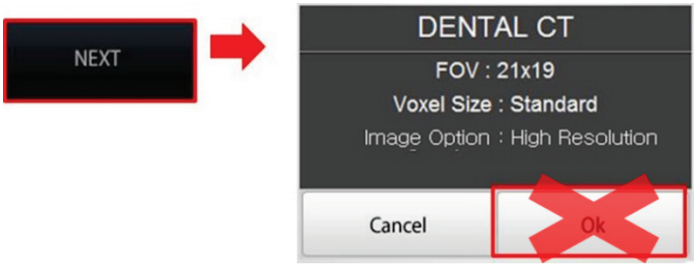
7. The values of tube voltage and current are configured automatically according to the patient's gender / age group and X-ray intensity. Click Arrow button to zoom in. The dose is adjustable by the ±1 kVp and ±0.1 mA respectively.

8. When the exposure parameter setting is completed, guide the patient to the equipment for positioning the patient. (Go to **9.3 Getting Prepared for Patient Positioning**.)

IMPORTANT

On the Console Software, do not click **NEXT** button before completing patient positioning.

On the Touch Screen, it's ok to press **NEXT** button after competing parameter setting. (When **NEXT** button is pressed, a confirmation window will appear.) But do not press **OK** button before completing patient positioning.



9.3 Getting Prepared for Patient Positioning

WARNING

- Have patients (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to direct the Laser Beam into the patient's eyes. Doing so may result in a permanent loss of vision.

WARNING

When the equipment is not operable while the Rotating Unit is in operation or in exposure location, bring the patient out of the equipment immediately as follows.

① **[When the patient is biting the Bite Block]** Ask the patient to open the mouth.

② Ask the patient to back off a bit.

③ **[When the Headrest is attached]** Detach it. (The operator or the patient must keep holding the Headrest until the Handle Frame is opened and take it out after the Handle Frame is opened.)

④ **[When the Chinrest Ass'y is attached]** Take out the Chinrest and the Chinrest Base in turn separately.

⑤ Open the Handle Frame.

⑥ Guide the patient out of the equipment.

* For ①, ③ and ⑤, each step can be skipped if it's not necessory according to the existence of each accessory.

IMPORTANT

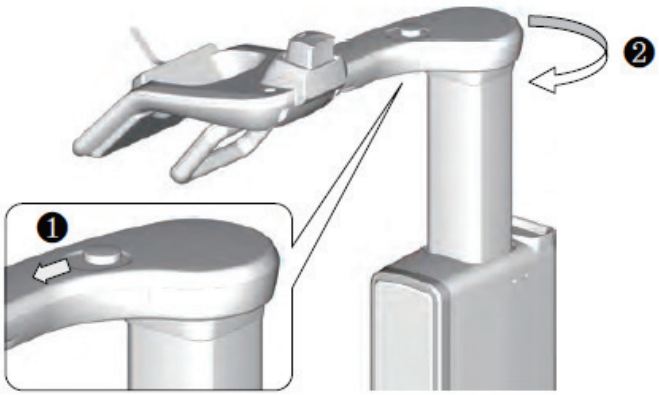
- Correct posture reduces the shadow casted by the patient's cervical spine and allows clear image acquisition.
- Metal implants or bridges may reduce the quality of the images.

NOTE

To minimize the time that the patient spending inside the equipment, it is highly recommended to complete configuring exposure parameters first before to start positioning the patient's posture.

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. Let the patient to wear a lead apron to protect themselves from residual radiation.
3. Push the Handle Frame's **Open/Close** button inward and open the Handle Frame.



4. Let the patient sit on the chair.
5. Close the Handle Frame.

9.4 Patient Positioning

9.4.1 Dental CT mode

Patient Positioning

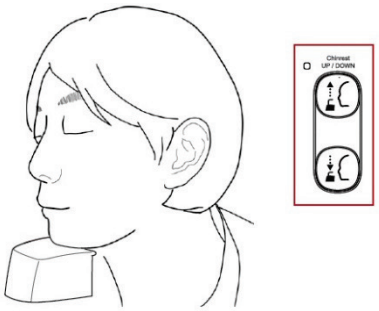
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

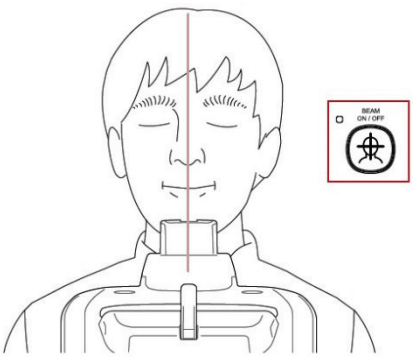
Patients need to keep the following poses during imaging process.

- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the Cervical Vertebra.

2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. Align the Vertical Beam to the center of the patient's face.



4. Install the Headrest. (Only when Auto Ceph option selected.)

① Put the Headrest into the Chinrest.

② Put the Headrest Strap on the patient's head and turn the knob clockwise to hold the head tightly.

NOTE

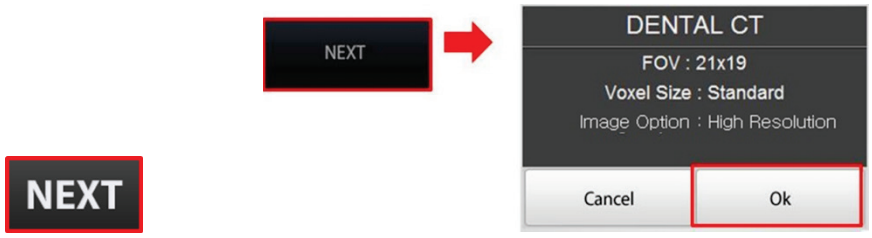
It is not mandatory to install the Headrest for CT mode. But it is highly recommended to acquire the images with higher quality.

NOTE

For more information about using the Headrest, refer to **8.3 Patient Positioning** for i-CEPH mode.

5. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

(In case **NEXT** button has been already clicked, you will see pop-up window directly.)

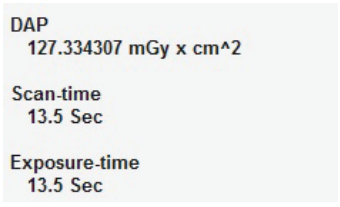


<Console Software> <Touch Screen>

NOTE

When you click **NEXT** (**OK** in Touch Screen) button,

- The Rotating Unit will come down to the positioning location.
- The vertical Laser Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below Patient Information window.



6. You can see the patient through the Touch Screen. Make sure that the horizontal lines displayed in the screen are parallel to the patient's Frankfurt line by using the Chinrest **UP/DOWN** button.

7. Let the patient maintain the posture as follows:

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

IMPORTANT	Before conduct the next step, be sure to let the patient know that the Rotating Unit will be lower to the exposure location and instruct him or her to relax down.

8. Click **NEXT** button when the patient positioning is completed. The Rotating Unit will come down to the exposure location. Then, **READY** button will be activated on the Touch Screen and the Console Software.

WARNING	When the equipment is not operable while the Rotating Unit is in the exposure location, detach the Chinrest or/and the Headrest from the equipment and open the Handle Frame to bring out the patient immediately.

9. Press **READY** button. No X-ray will be emitted at this point.

<Console Software>

<Touch Screen>

10. Go to **9.5 X-ray Exposure** to start the exposure.

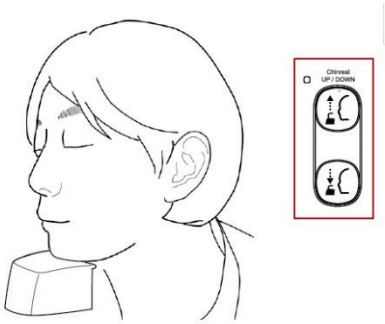
9.4.2 Dental CT + 3D PHOTO mode

Patient Positioning

1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT	Patients need to keep the following poses during imaging process. ▪ Sit close against the chair. ▪ Hold the handle. ▪ See front. ▪ Close the mouth. ▪ Breathe through the nose. ▪ Keep both shoulders parallel. ▪ Relax the body. ▪ Straighten the Cervical Vertebra.

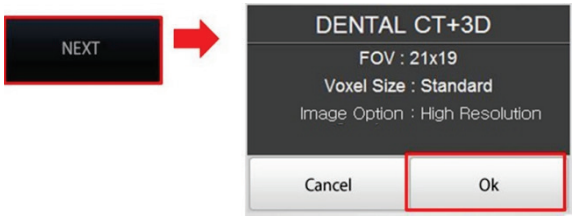
2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

   (In case **NEXT** button has been already clicked, you will see pop-up window directly.)

<Console Software>

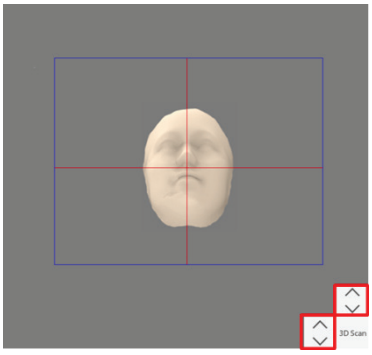


<Touch Screen>

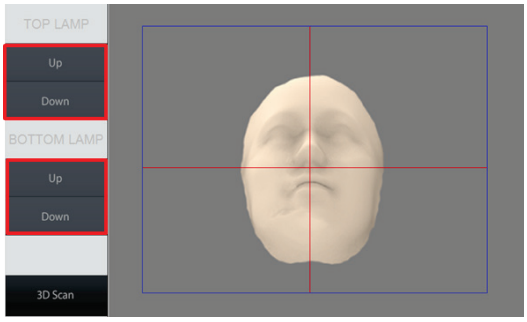
4. Remove the Chinrest from the unit.

5. You can see the patient through the Image Preview Window or Touch Screen.

- Make sure that the horizontal lines displayed in the screen are parallel to the patient's nasal base
- If necessary, click or press LED light **UP/DOWN** button to adjust LED light brightness to have proper lighting for the photograph.



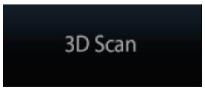
<Console Software>



<Touch Screen>

6. Click **3D Scan** button when ready.

<Console Software>



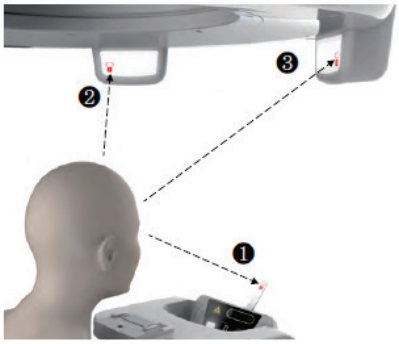
<Touch Screen>

7. Let the patient see the Eye mark #1.

8. Let the patient see the Eye mark #2 when you hear the beep sound.

IMPORTANT	Make sure that the patient turns his/her head, not eyes when he/she sees the eye mark.

9. Let the patient see the Eye mark #3 when you hear the beep sound.



10. Put the Chinrest into the unit when 3D photography is completed.

11. Click/Press **NEXT** button to continue with Dental CT Imaging. For more information, refer to **9.4.1 Dental CT mode (No.3 ~ No.10)**.

9.5 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 their area at all times during the operation of this equipment.
- During image acquisition (X-ray exposure), don't use the Chinrest UP/DOWN button or switch except for emergency situations. (The movement of the Rotating Unit is necessary only for the patient positioning in normal situation.) Doing so may lead the patient to be unsafe.

CAUTION

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

IMPORTANT

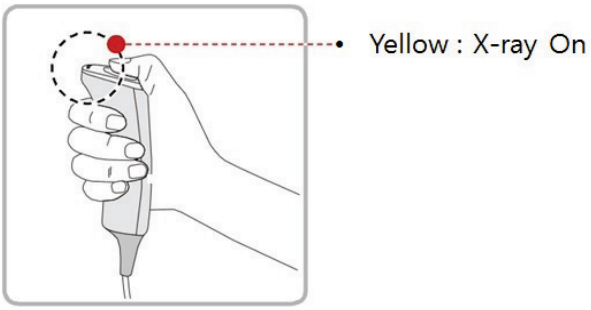
- Let the patient close the eyes during operation.
- To acquire optimized images, let the patient hold his/her breath and not to swallow. Also don't let the patient move until the Rotating Unit moves up.

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.



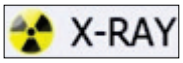
NOTE

The image appears on the screen.

NOTE

During X-ray exposure, the status appears as follows.

- The Green LED lights of the **Exposure Switch** and **Rotating Unit** become flashing for 6 seconds and turn yellow.
- An alert sound comes out to indicate that X-ray emission is currently underway.
- The X-ray Indicator icon of the Console Software turns yellow.



3. Release the **Exposure Switch** when “Image capturing is complete.” message appears on the screen.
4. The Rotating Unit will move up automatically when the image capturing is completed.
5. Remove the Headrest Strap from the patient if needed.
6. Push the Handle Frame’s **Open/Close** button inward and open the Handle Frame.
7. Guide the patient out of the equipment.
8. Put the Chinrest into the unit if it was removed from the unit.

9.6 Checking the captured image

Acquired images can be reconstructed and converted to DICOM format.

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

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 **Save** button to save the images.
3. To check the image, double-click the one on the Patient list.
4. Then, **Ez3D-i** will run automatically for 3D viewing.

Left blank intentionally

10. Acquiring ENT CT Images

10.1 ENT CT Imaging Program Overview

Result Images

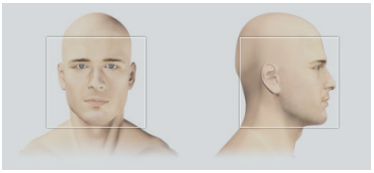
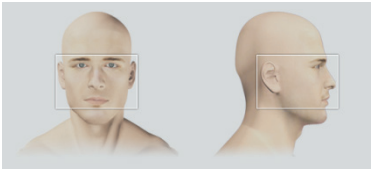
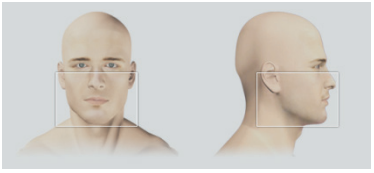
It provides conventional 3D CT sliced images.

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.

FOV (cm)	Description	ROI
21x19	▪ For entire ENT (Ear, Nose and Throat) region diagnostics including PNS (Para nasal sinus), TB (Temporal bone), TMJ (Temporomandibular Joint) and Airway	
17x11	▪ Covering for both PNS, TB and TMJ areas or Airway diagnostics selectively	 PNS & TB  Airway

Special Mode

ENT CT + 3D PHOTO

: 3D PHOTO images can be acquired as well as ENT CT images at one time.

Special Option

Auto Pano / Auto Ceph

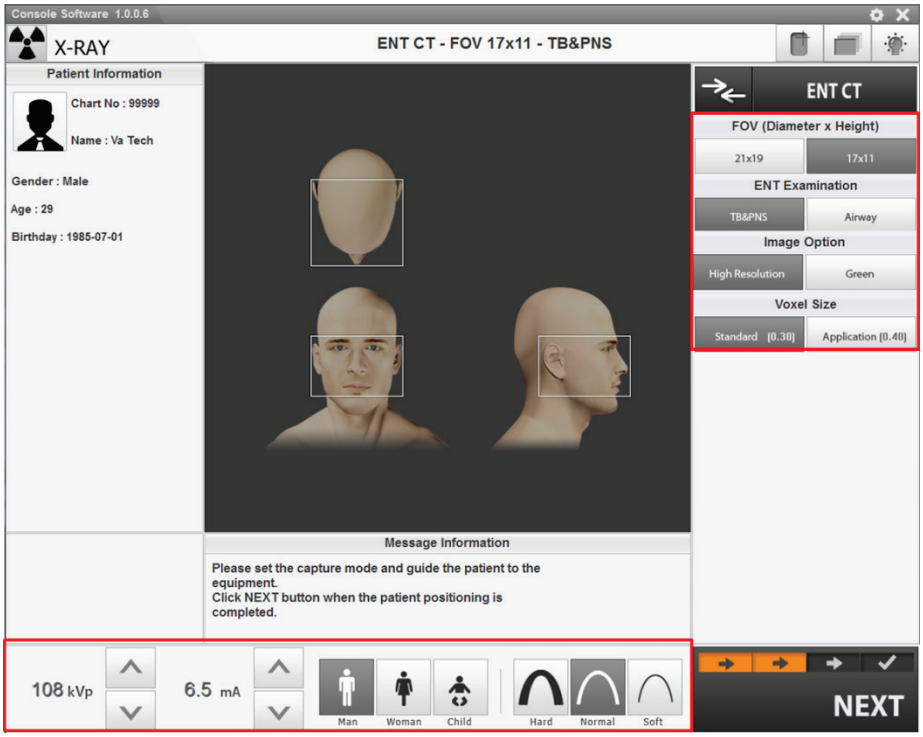
: 2D images of conventional panoramic / cephalometric view are available with the specific FOV. For more details on Auto Pano / Auto Ceph, please refer to **10.2 Configuring Exposure Parameters**..

10.2 Configuring Exposure Parameters

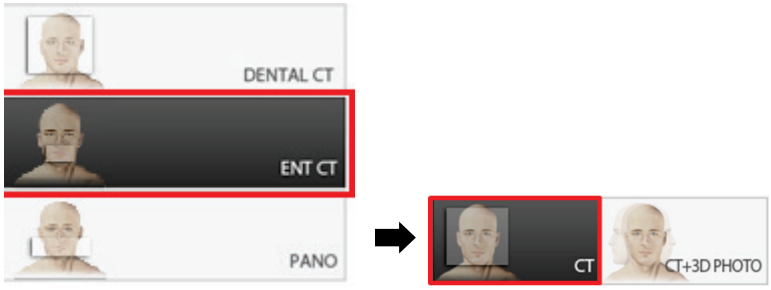
To acquire ENT CT Images, **6. Getting Started** must be completed first.

NOTE

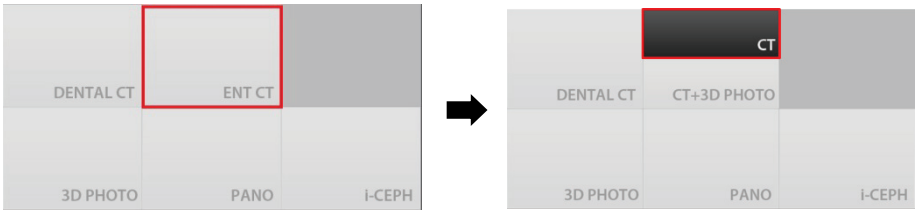
You can set the imaging parameters on either the Touch Screen or the Console Software running on the PC. They are synched and display the same environmental settings.



1. Click **ENT CT** > **CT** button in the Main Screen.



<Console Software>



<Touch Screen>

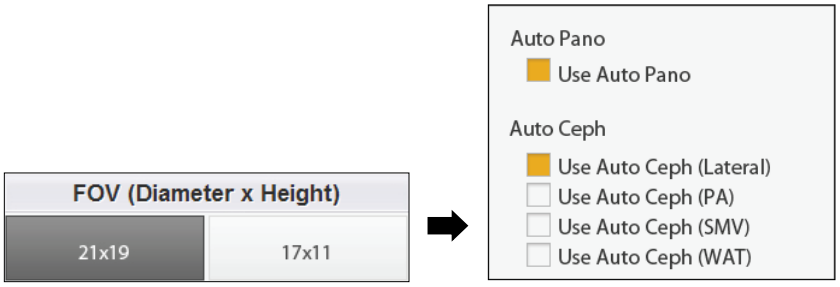
NOTE

- "i-**CEPH**" and "**3D PHOTO**" buttons exist only when each imaging program is included in the equipment.
- To acquire 3D PHOTO with ENT CT images, click **ENT CT** > **CT+3D PHOTO** button.

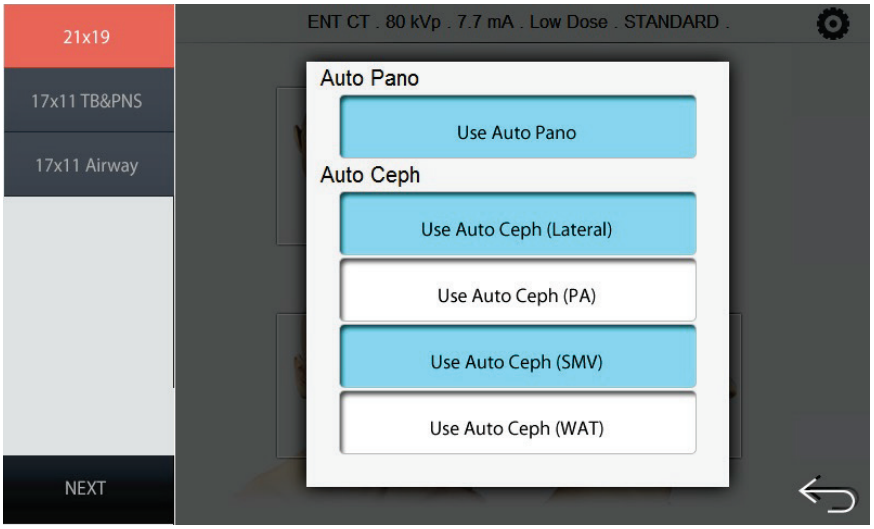
2. Select FOV size.

- You can configure **Auto Pano** and **Auto Ceph** options when **21x19** is selected.

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



<Console Software>



<Touch Screen>

NOTE

*** Auto Pano**

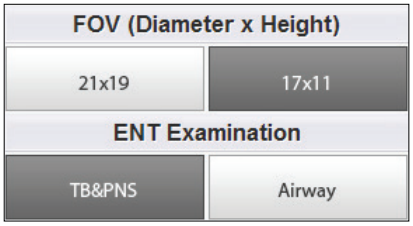
Auto Pano is a feature used to acquire reconstructed 2D images during 3D CT scans without additional X-ray exposure. It has the same region that conventional panoramic images offer. (It provides images for Standard mode in DICOM or BMP format.)

*** * Auto Ceph**

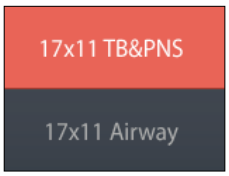
Auto Ceph is a feature used to acquire reconstructed 2D images during 3D CT scans without additional X-ray exposure. It has the same region that conventional cephalometric images offer. (It provides images for PA, Lateral, SMV and Waters' view modes in DICOM or BMP format.)

When selected, Auto Pano and/or Auto Ceph image is automatically acquired and can be seen on the **EzDent-i** Viewer.

- You can configure the **ENT Examination** option when **17x11** is selected.

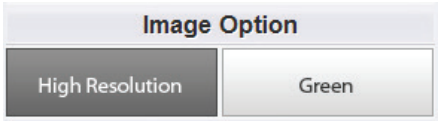


<Console Software>

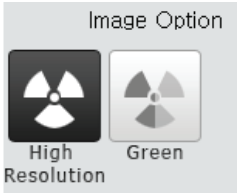


<Touch Screen>

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



<Console Software>



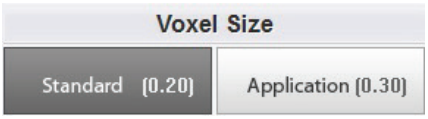
<Touch Screen>

NOTE

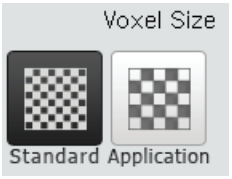
The Green mode produces approximately 20 % ~ 40 % lower DAP value than the High Resolution mode during X-ray exposure.

Mode	DAP ($mGy \cdot cm^2$)	Exposure Condition
High Resolution	2010	FOV: 21x19 (cm) (108 kVp / 6.5 mA / 18.0 sec)
	1130	FOV: 17x11 (cm) (108 kVp / 6.5 mA / 16.6 sec)
Green	1610	FOV: 21x19 (cm) (95 kVp / 6.5 mA / 18.0 sec)
	770	FOV: 17x11 (cm) (90 kVp / 6.5 mA / 16.6 sec)

4. Select a Voxel Size.



<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

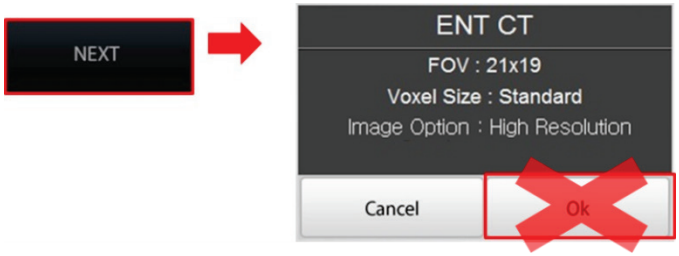
7. The values of tube voltage and current are configured automatically according to the patient's gender / age group and X-ray intensity. Click Arrow button to zoom in. The dose is adjustable by the ±1 kVp and ±0.1 mA respectively.

8. When the exposure parameter setting is completed, guide the patient to the equipment for positioning the patient. (Go to **10.3 Getting Prepared for Patient Positioning**.)

IMPORTANT

On the Console Software, do not click **NEXT** button before completing patient positioning.

On the Touch Screen, it's ok to press **NEXT** button after competing parameter setting. (When **NEXT** button is pressed, a confirmation window will appear.) But do not press **OK** button before completing patient positioning.



10.3 Getting Prepared for Patient Positioning

WARNING

- Have patients (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to direct the Laser Beam into the patient's eyes. Doing so may result in a permanent loss of vision.

WARNING

When the equipment is not operable while the Rotating Unit is in operation or in exposure location, bring the patient out of the equipment immediately as follows.

① **[When the patient is biting the Bite Block]** Ask the patient to open the mouth.

② Ask the patient to back off a bit.

③ **[When the Headrest is attached]** Detach it. (The operator or the patient must keep holding the Headrest until the Handle Frame is opened and take it out after the Handle Frame is opened.)

④ **[When the Chinrest Ass'y is attached]** Take out the Chinrest and the Chinrest Base in turn separately.

⑤ Open the Handle Frame.

⑥ Guide the patient out of the equipment.

* For ①, ③ and ⑤, each step can be skipped if it's not necessory according to the existence of each accessory.

IMPORTANT

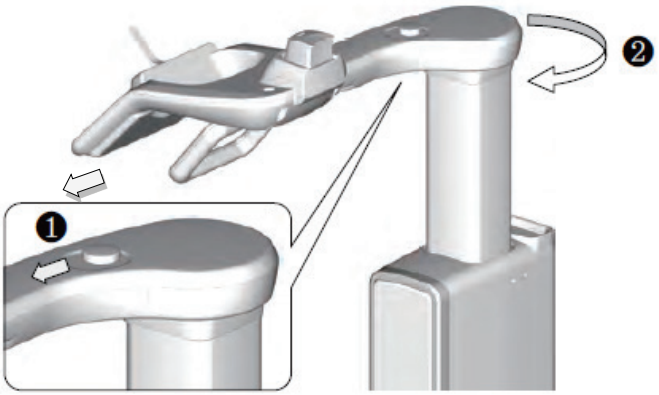
- Correct posture reduces the shadow casted by the patient's cervical spine and allows clear image acquisition.
- Metal implants or bridges may reduce the quality of the images.

NOTE

To minimize the time that the patient spending inside the equipment, it is highly recommended to complete configuring exposure parameters first before to start positioning the patient's posture.

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. Let the patient wear a lead apron to protect themselves from residual radiation.
3. Push the Handle Frame's **Open/Close** button inward and open the Handle Frame.



4. Let the patient sit on the chair
5. Close the Handle Frame.

10.4 Patient Positioning

10.4.1 ENT CT mode

Patient Positioning

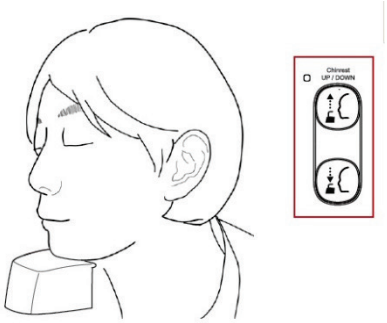
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

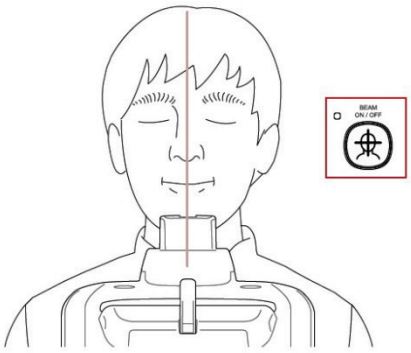
Patients need to keep the following poses during imaging process.

- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the Cervical Vertebra.

2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



3. Align the Vertical Beam to the center of the patient's face.



4. Install the Headrest. (Only when Auto Ceph option selected.)

① Put the Headrest into the Chinrest.

② Put the Headrest Strap on the patient's head and turn the knob clockwise to hold the head tightly.

NOTE

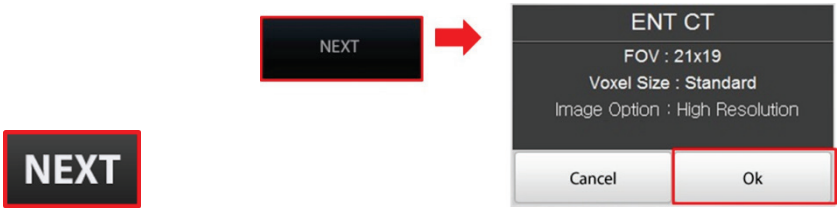
It is not mandatory to install the Headrest for CT mode. But it is highly recommended to acquire the images with higher quality.

NOTE

For more information about using the Headrest, refer to **8.3 Patient Positioning** for i-CEPH mode.

5. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

(In case **NEXT** button has been already clicked, you will see pop-up window directly.)

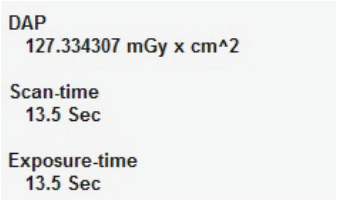


<Console Software> <Touch Screen>

NOTE

When you click **NEXT** (**OK** in Touch Screen) button,

- The Rotating Unit will come down to the positioning location.
- The vertical Laser Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time and Exposure Time will be displayed below Patient Information window.



6. You can see the patient through the Touch Screen. Make sure that the horizontal lines displayed in the screen are parallel to the patient's Frankfurt line by using the Chinrest **UP/DOWN** button.

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

IMPORTANT	Before conduct the next step, be sure to let the patient know that the Rotating Unit will be lower to the exposure location and instruct him or her to relax down.

8. Click **NEXT** button when the patient positioning is completed. The Rotating Unit will come down to the exposure location. Then, **READY** button will be activated on the Touch Screen and the Console Software.

WARNING	When the equipment is not operable while the Rotating Unit is in the exposure location, detach the Chinrest or/and the Headrest from the equipment and open the Handle Frame to bring out the patient immediately.

9. Press **READY** button. No X-ray will be emitted at this point.

<Console Software>

<Touch Screen>

10. Go to **10.5 X-ray Exposure** to start the exposure.

10.4.2 ENT CT + 3D PHOTO mode

Patient Positioning

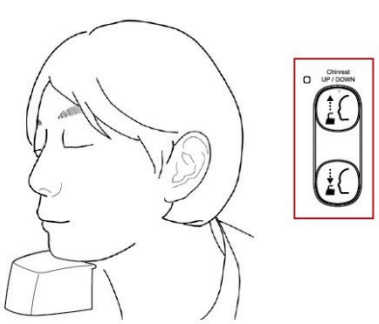
1. Let the patient hold the handle in comfortable posture and see front.

IMPORTANT

Patients need to keep the following poses during imaging process.

- Sit close against the chair.
- Hold the handle.
- See front.
- Close the mouth.
- Breathe through the nose.
- Keep both shoulders parallel.
- Relax the body.
- Straighten the Cervical Vertebra.

2. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



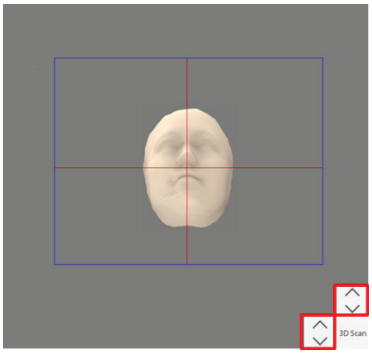
3. On the Console Software, Click **NEXT** button when the exposure parameter setting is completed. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button if the setting is correct.

(In case **NEXT** button has been already clicked, you will see pop-up window directly.)

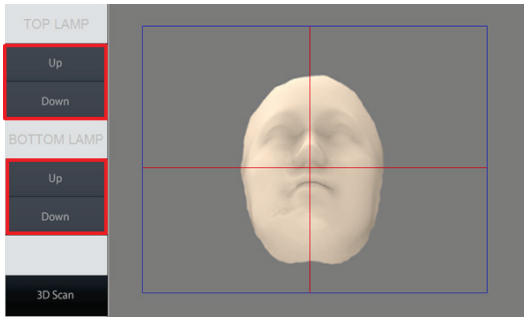
<Console Software> <Touch Screen>

4. Remove the Chinrest from the unit.

5. You can see the patient through the Image Preview Window or Touch Screen.
   - Make sure that the horizontal lines displayed in the screen are parallel to the patient's nasal base.
   - If necessary, click or press LED light **UP/DOWN** button to adjust LED light brightness to have proper lighting for the photograph.



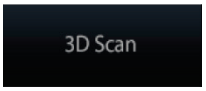
<Console Software>



<Touch Screen>

6. Click **3D Scan** button when ready.

<Console Software>

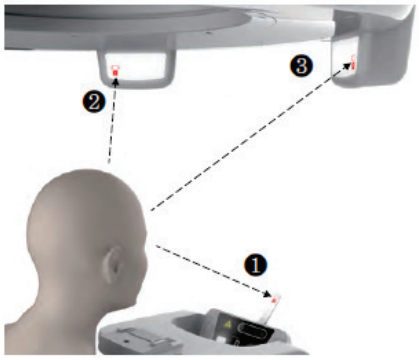


<Touch Screen>

7. Let the patient see the Eye mark #1.
8. Let the patient see the Eye mark #2 when you hear the beep sound.

IMPORTANT	Make sure that the patient turns his/her head, not eyes when he/she sees the eye mark.

9. Let the patient see the Eye mark #3 when you hear the beep sound.



10. Put the Chinrest into the unit when 3D photography is completed.

11. Click/Press **NEXT** button to continue with ENT CT Imaging. For more information, refer to **10.4.1 ENT CT mode (No.3 ~ No.10)**.

10.5 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 their area at all times during the operation of this equipment.
- During image acquisition (X-ray exposure), don't use the Chinrest UP/DOWN button or switch except for emergency situations. (The movement of the Rotating Unit is necessary only for the patient positioning in normal situation.) Doing so may lead the patient to be unsafe.

CAUTION

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

IMPORTANT

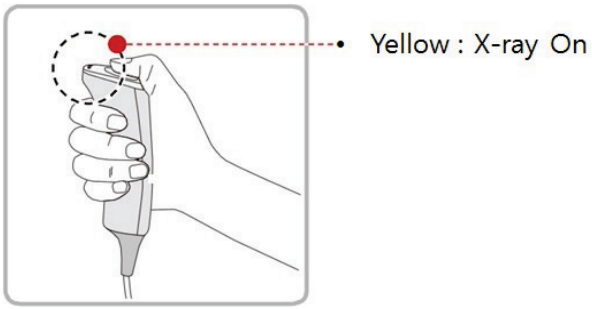
- Let the patient close the eyes during operation.
- To acquire optimized images, let the patient hold his/her breath and not to swallow. Also don't let the patient move until the Rotating Unit moves up.

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 Green LED lights of the **Exposure Switch** and **Rotating Unit** become flashing for 6 seconds and turn yellow.
- An alert sound comes out to indicate that X-ray emission is currently underway.
- The X-ray Indicator icon of the Console Software turns yellow.

3. Release the **Exposure Switch** when “Image capturing is complete.” message appears on the screen.
4. The Rotating Unit will move up automatically when the image capturing is completed.
5. Remove the Headrest Strap from the patient if needed.
6. Push the Handle Frame’s **Open/Close** button inward and open the Handle Frame.
7. Guide the patient out of the equipment.
8. Put the Chinrest into the unit if it was removed from the unit.

10.6 Checking the captured image

Acquired images can be reconstructed and converted to DICOM format.

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

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 **Save** button to save the images.
3. To check the image, double-click the one on the Patient list.
4. Then, **Ez3D-i** will run automatically for 3D viewing.

11. Acquiring 3D PHOTOs (Optional)

11.1 3D PHOTO Imaging Program Overview

Result Images

It provides 3D PHOTO images.

Image Acquisition Module

A separate Intel Sense SDK module utilizing a 3D PHOTO camera is used.

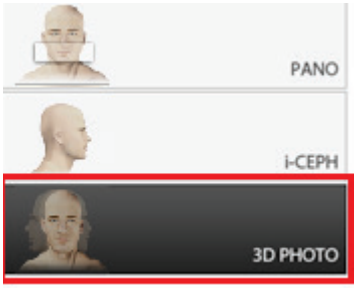
Scan Area

It covers the surface of the face.

NOTE	3D PHOTO images themselves have no diagnostic purposes. But they can be used for consultation or reference purposes such as before-surgery simulation by mapping them on CT images in the same position.

11.2 Taking 3D PHOTOs

1. Click **3D PHOTO** button in the Main Screen.



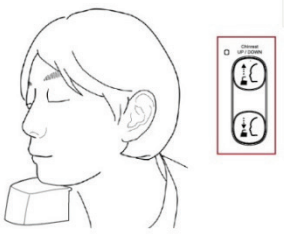
<Console Software>

<Touch Screen>

NOTE

"i-**CEPH**" and "**3D PHOTO**" buttons exist only when each imaging program is included in the equipment.

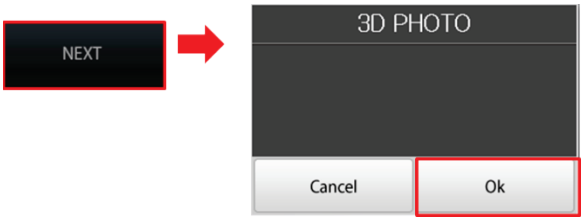
2. Guide the patient to the equipment.
3. Push the Handle Frame's **Open/Close** button inward and open the Handle Frame.
4. Let the patient sit on the chair and close the Handle Frame.
5. Let the patient hold the handle in comfortable posture and see front.
6. Adjust the height of the Chinrest by using the Chinrest **UP/DOWN** button on the Control Panel until the patient's chin is placed comfortably on the Chinrest.



7. On the Console Software, Click **NEXT** button. On the Touch Screen, a confirmation window will appear after **NEXT** button is clicked. Click **OK** button.

   (In case **NEXT** button has been already clicked, you will see pop-up window directly.)

<Console Software>

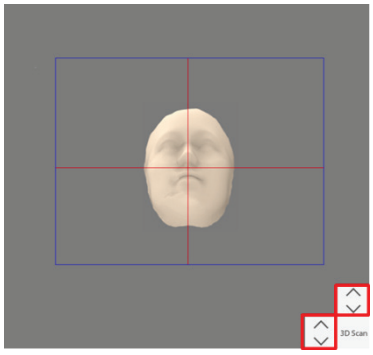


<Touch Screen>

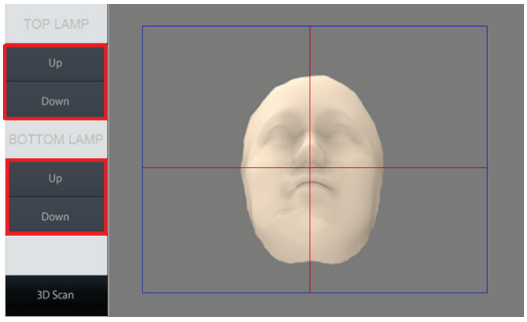
8. Remove the Chinrest from the unit.

9. You can see the patient through the Image Preview Window or Touch Screen.

- Make sure that the horizontal lines displayed on the screen are parallel to the patient's nasal base.
- If necessary, click or press LED lamp **UP/DOWN** button to adjust the brightness to have proper lighting for the photograph.



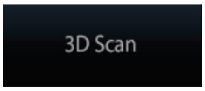
<Console Software>



<Touch Screen>

10. Click **3D Scan** button when ready.

<Console Software>



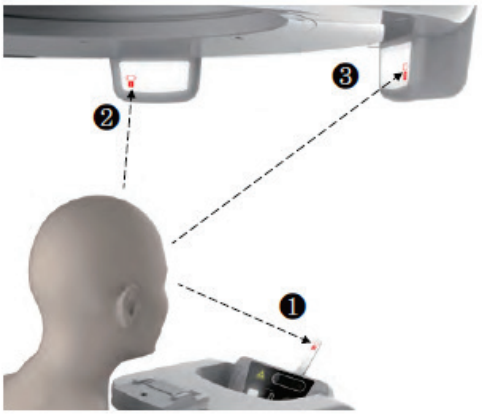
<Touch Screen>

11. Let the patient see the Eye mark #1

12. Let the patient see the Eye mark #2 when you hear the beep sound.

IMPORTANT	Make sure that the patient turns his/her head, not eyes when he/she sees the eye mark.

13. Let the patient see the Eye mark #3 when you hear the beep sound.



14. Put the Chinrest into the unit when 3D photography is completed.

15. Push the Handle Frame's **Open/Close** button inward and open the Handle Frame.

16. Guide the patient out of the equipment.

11.3 Checking 3D PHOTOs

1. The images are transferred to **EzDent-i** automatically when the image capturing is completed.
2. Double-click the image to confirm on the Patient list.
3. You can check the captured image (.OBJ file) with a 3rd party 3D PHOTO viewer after exporting the image from **EzDent-i**

NOTE

- You cannot use **Ez3D-i** as a 3D PHOTO viewer. Use a 3rd party 3D PHOTO viewer instead.
- Refer to the **EzDent-i** and **3rd party 3D PHOTO viewer User Manual** for more information.

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12. 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.

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's electrical components. You may then safely release the patient from the equipment. To restart the equipment, turn the **Emergency Stop Switch** clockwise until it pops up.

Do not allow any liquid in the vicinity of the machine. Moisture may cause extensive damage to the equipment's electrical components.

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13. Cleaning and Maintenance

NOTE

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

13.1 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 comes in direct contacts with the patient, such as the Handle Frame, the Chinrest and the Bite Block.
- 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 Block	Clean with ethanol and gently wipe with a dry towel before the next patient.
Headrest	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.

13.2 Maintenance

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

13.2.1 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 the one in the same type and range.

- There are no user serviceable parts inside this equipment.
- If any service is required, please contact **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 sun light, 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.

13.2.2 Maintenance Task Checklist

Tasks	Period
Before operation, ensure that the equipment is clean and ready for use. Make sure that all parts that come in direct contacts 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 duration of the exposure.	Monthly

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14. Disposing of the Equipment

In order 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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15. Technical Specifications

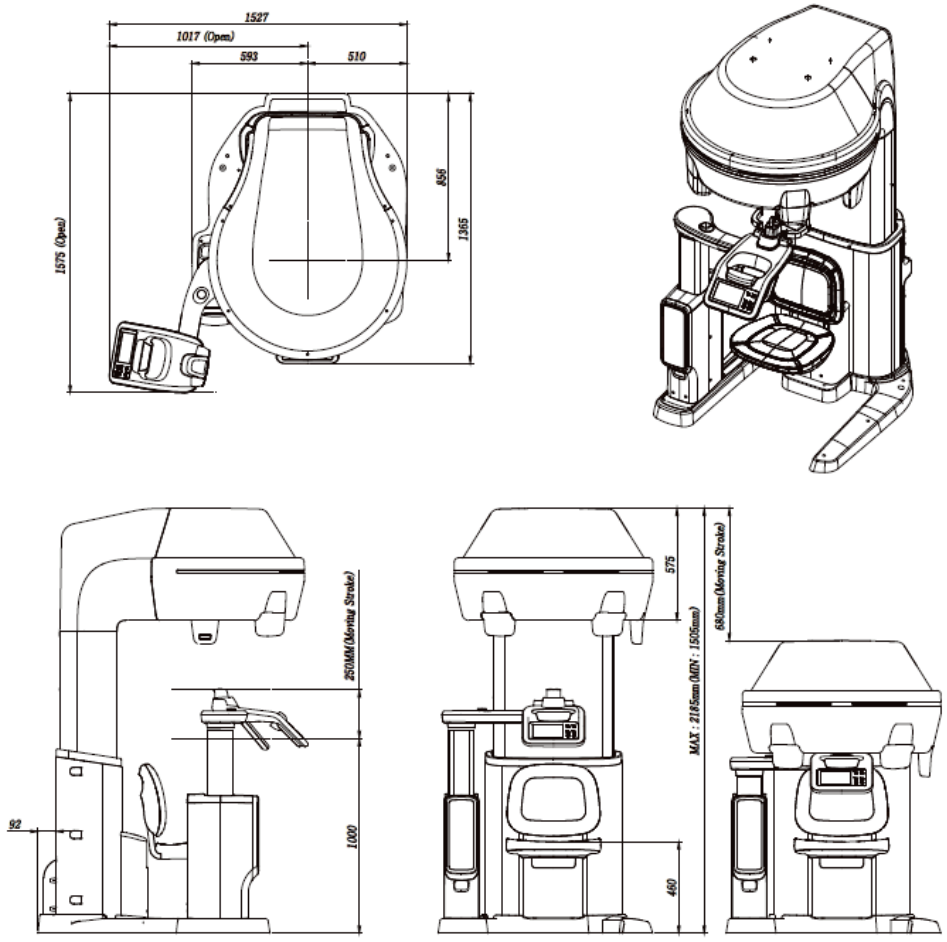
15.1 Mechanical Specifications

Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
CT	672.72	384.12	288.60	1.75
PANO	672.72	446.13	226.59	1.51
i-CEPH (PA and Lateral)	672.72	384.12	288.60	1.75 (Virtual : 1)
i-CEPH (Carpus)	672.72	626.20	46.50	1.07

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

Dimensions (unit=mm)



Item	Description
Weight	321 kg (708 lbs. with the Base)
Total Height	Max. 2185 mm (86.0 inch)
Rotating Unit Vertical Movement	Max. 680 mm (26.8 inch)
Dimensions (Length(L) x Width(W) x Height(H))	1575(L) x 1527(W) x 2185(H) mm (62.0(L) x 60.1(W) x 86.0(H) inch)
Installation type	Base stand

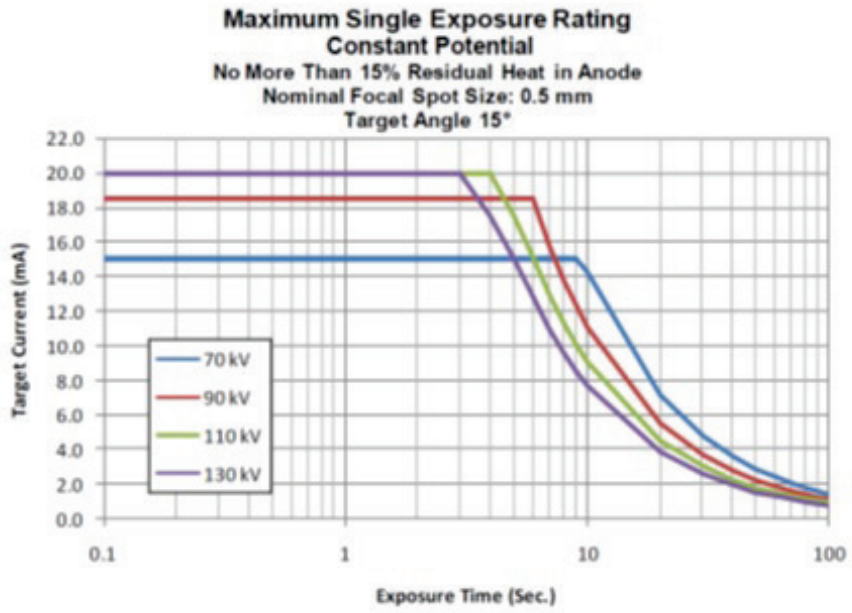
15.2 Technical Specifications

15.2.1 X-ray Generator Specifications

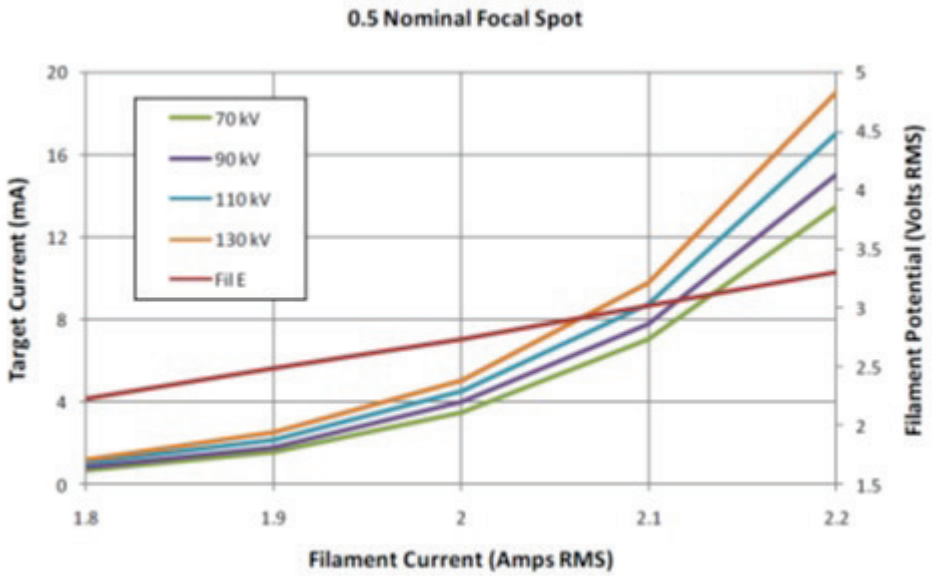
A-type: Superior Tube Option

Item			Description
High Voltage Generator	Model		DG-08C22S1
	Rated output power		1.2 kW
	Type		Inverter
	Normal/ Pulse	kVp	60 ~ 120 kV (1 kV increment ±10 %)
		mA	4 ~ 10 mA (1 mA increment ±20 %) (PANO & i-CEPH: 0.5 mA increment, CT: 0.1 mA increment ±10 %)
	Cooling		Cooling Protect (Optional fan cooling ≥ 60 ℃)
	Total filtration		Min. 2.5 mm Al
	Added filtration		2.0 mm Al
X-ray Tube	Manufacturer		Superior
	Model		SXR-130-15-0.5 (Stationary Anode type)
	Focal spot size		0.5 mm (IEC 60336)
	Target Angle		15 degree
	Inherent Filtration		At least 1.1 mm Al equivalent at 80kV
	Anode Heat Content		21 kJ
	Duty Cycle		1:20 or more (Exposure time : Interval time)

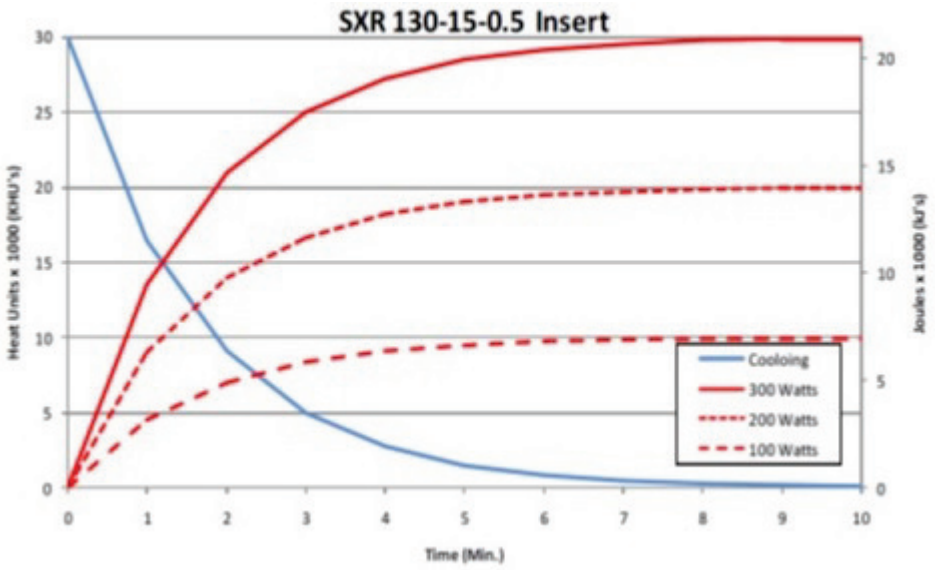
Maximum Rating Charts



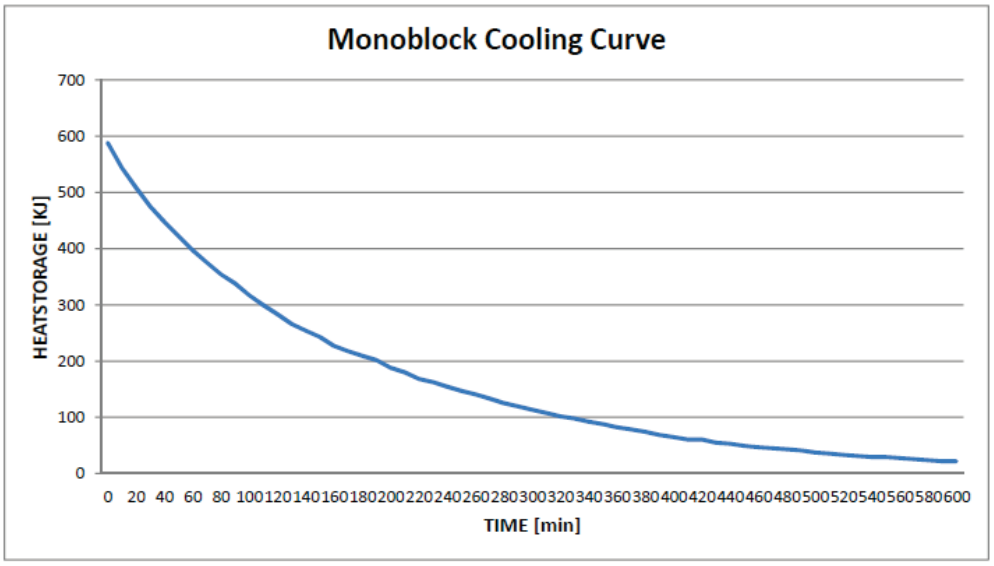
Emission & Filament Characteristics



Anode Thermal Characteristics



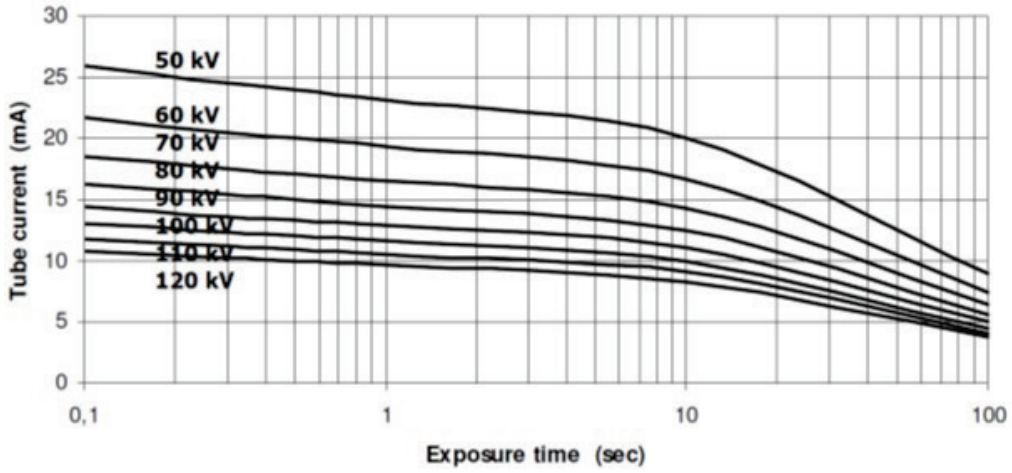
Tube Housing Assembly Thermal Characteristics



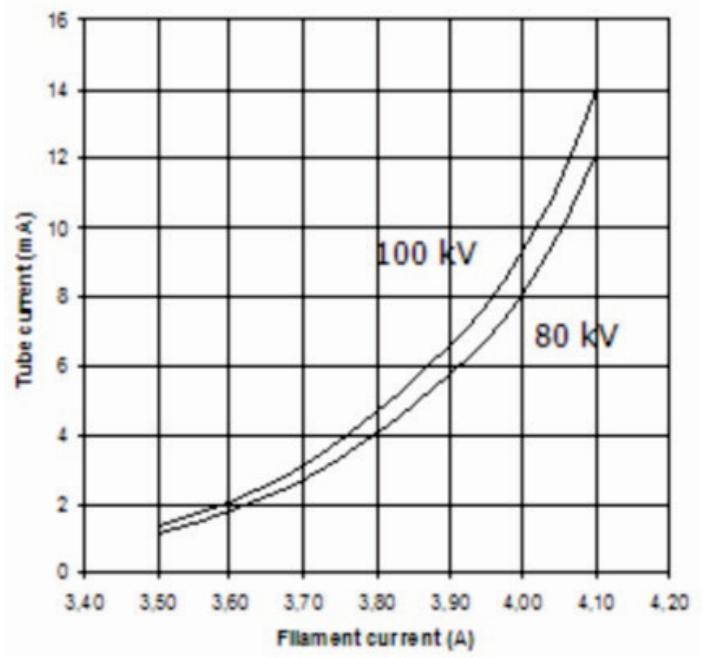
B-type: C.E.I Tube Option

Item			Description
High Voltage Generator	Model		DG-08C22C2
	Rated output power		1.2 kW (0.1 sec)
	Type		Inverter
	Normal/ Pulse	kVp	60 ~ 120 kV (1 kV increment ±10 %)
		mA	4 ~ 10 mA (1 mA increment ±20 %) (PANO & i-CEPH: 0.5 mA increment, CT: 0.1 mA increment ±10 %)
	Cooling		Cooling Protect (Optional fan cooling, ≥ 60 ℃)
	Total filtration		Min. 2.5 mm Al
	Added filtration		2.0 mm Al
X-ray Tube	Manufacturer		CEI
	Model		OX/115-05 (Stationary Anode type)
	Focal spot size		0.5 mm (IEC 60336)
	Target Angle		15 degree
	Inherent Filtration		0.5mm Al
	Anode Heat Content		30 kJ
	Duty Cycle		1:60 or more (Exposure time : Interval time)

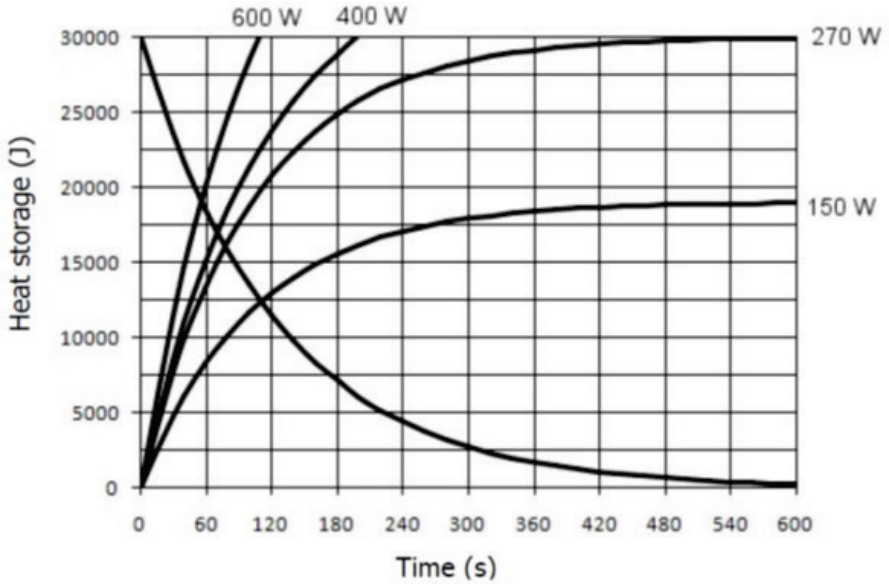
Maximum Rating Charts



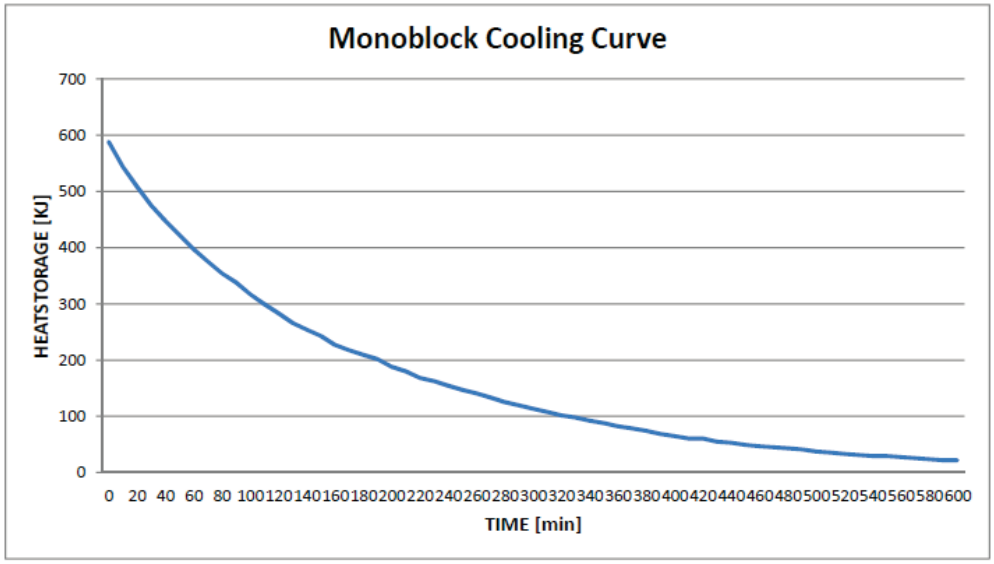
Emission & Filament Characteristics



Anode Thermal Characteristics



Tube Housing Assembly Thermal Characteristics



15.2.2 Detector Specifications

Item	Description (PANO, CT and i-CEPH)
Model	Xmaru3104CF
Detector Type	CMOS photodiode array
Pixel size	99 μm @ 2X2 Binning : PANO 198 μm @ 4X4 Binning : CT (Dental / ENT), i-CEPH
Active area	310.4 mm x 36.4 mm
Frame Rate	107 fps (2x2 Binning) : PANO 308 fps (4x4 Binning) : CT (Dental / ENT), i-CEPH
Analogue-Digital Conversion	14 bits
Operating condition	10 ~ 35 ℃ (Temperature) 10 ~ 75 % (Humidity)
Storage condition	-10 ~ 60 ℃ (Temperature) 10 ~ 75 % (Humidity)
Sensor size	350 mm x 300 mm
Converter	CsI:Ti
Energy Range	60 ~ 120 kVp
Readout	Charge amplifier array
Video Output	Optic

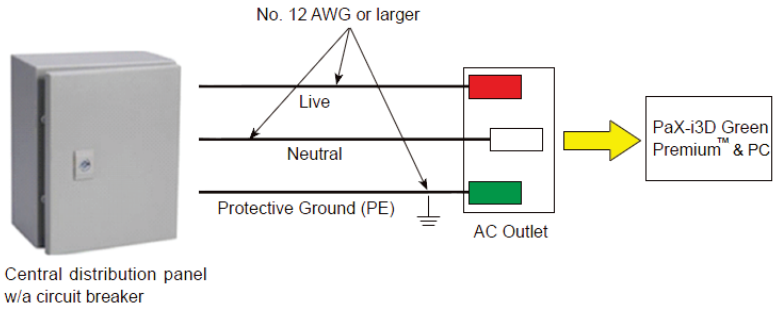
15.3 Electrical Specifications

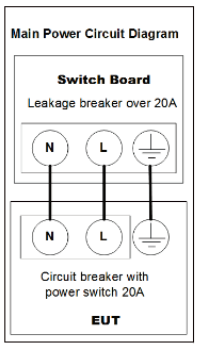
Item	Description
Power supply voltage	AC 100 - 240 V
Frequency	50 / 60 Hz
Power rating	1.3 - 1.6 kVA

- 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

  Exposure time: Max. 18 s / Resting time: 10 min.

  Column operation time: 1 min. / Resting time: 9 min.





NOTE

- To assure line voltage quality, a separate 3-core grounded power cable connected directly to central distribution panel with over-current circuit breaker rated for 20/15A must be used.
- The mains resistance should not exceed 100 V at 0.045 ohm, 240 V at 0.19 ohm.

15.4 Environmental Specifications

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

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16. Appendices

16.1 Recommended X-ray Exposure Table

16.1.1 PANO mode

Exposure Condition

Image Option	Gender / Age Group	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
High Resolution	Man	90 / 9.0	90 / 8.5	90 / 8.0
	Woman	90 / 8.5	90 / 8.0	90 / 7.5
	Child	85 / 8.0	85 / 7.5	85 / 7.0
Green	Man	85 / 7.5	85 / 7.0	85 / 6.5
	Woman	85 / 7.0	85 / 6.5	85 / 6.0
	Child	85 / 6.5	85 / 6.0	85 / 5.5

Scan Time / Exposure Time

Examination	Arch Selection	Mode	Scan Time (s)		Exposure Time (s)	
			High Resolution	Green	High Resolution	Green
Pano Examination	Narrow, Normal, Wide, Orthogonal	Standard	13.5	13.5	13.5	13.5
		Right	13.5	13.5	6.8	6.8
		Front	13.5	13.5	11.2	11.2
		Left	13.5	13.5	6.8	6.8
	Child	Standard	11.9	11.9	11.9	11.9
		Right	11.9	11.9	6.0	6.0
		Front	11.9	11.9	9.5	9.5
		Left	11.9	11.9	6.0	6.0
	Orthogonal	Bitewing	13.5	13.5	9.6	9.6
		Bitewing Right	13.5	13.5	4.8	4.8
		Bitewing Left	13.5	13.5	4.8	4.8
Special Examination	-	TMJ LAT Open	13.5	N/A	6.0	N/A
		TMJ LAT Close	13.5		6.0	

Examination	Arch Selection	Mode	Scan Time (s)		Exposure Time (s)	
			High Resolution	Green	High Resolution	Green
		Sinus LAT	9.0		9.0	
		Sinus PA	13.5		11.2	

16.1.2 i-CEPH mode

Exposure Condition

Examination	Gender / Age Group	Hard (kVp/mA)	Normal (kVp/mA)	Soft (kVp/mA)
Lateral, PA	Man	102 / 4.5	100 / 4.5	98 / 4.5
	Woman	100 / 4.5	98 / 4.5	96 / 4.5
	Child	98 / 4.5	96 / 4.5	94 / 4.5
Carpus	Man	90 / 6.0	90 / 5.5	90 / 5.0
	Woman	90 / 6.0	90 / 5.5	90 / 5.0
	Child	90 / 6.0	90 / 5.5	90 / 5.0

Scan Time / Exposure Time

Examination	Scan Time (s)	Exposure Time (s)
Lateral	18.0	18.0
PA	18.0	18.0
Carpus	8.4	8.4

16.1.3 CT (Dental / ENT) mode

Exposure Condition (FOV: 21x19 (cm))

Mode		High Resolution		Green	
		kVp	mA	kVp	mA
Man	Hard	110	6.5	97	6.5
	Normal	108	6.5	95	6.5
	Soft	106	6.5	93	6.5
Woman	Hard	108	6.5	95	6.5
	Normal	106	6.5	93	6.5
	Soft	104	6.5	91	6.5
Child	Hard	106	6.5	93	6.5
	Normal	104	6.5	91	6.5
	Soft	102	6.5	89	6.5

Exposure Condition (FOV: 17x15, 17x11 (cm))

Mode		High Resolution		Green	
		kVp	mA	kVp	mA
Man	Hard	110	6.5	92	6.5
	Normal	108	6.5	90	6.5
	Soft	106	6.5	88	6.5
Woman	Hard	108	6.5	90	6.5
	Normal	106	6.5	88	6.5
	Soft	104	6.5	86	6.5
Child	Hard	106	6.5	88	6.5
	Normal	104	6.5	86	6.5
	Soft	102	6.5	84	6.5

Exposure Condition (FOV: 21x19 (cm))

Mode		High Resolution		Green	
		kVp	mA	kVp	mA
Man	Hard	110	6.5	87	5.5
	Normal	108	6.5	85	5.5
	Soft	106	6.5	83	5.5
Woman	Hard	108	6.5	85	5.5
	Normal	106	6.5	83	5.5
	Soft	104	6.5	81	5.5
Child	Hard	106	5.5	83	5.5
	Normal	104	5.5	81	5.5
	Soft	102	5.5	79	5.5

Exposure Condition (FOV: 8x8 (cm))

Mode		High Resolution		Green	
		kVp	mA	kVp	mA
Man	Hard	110	6.5	82	4.5
	Normal	108	6.5	80	4.5
	Soft	106	6.5	78	4.5
Woman	Hard	108	6.5	80	4.5
	Normal	106	6.5	78	4.5
	Soft	104	6.5	76	4.5
Child	Hard	106	5.5	78	4.5
	Normal	104	5.5	76	4.5
	Soft	102	5.5	74	4.5

Scan Time / Exposure Time

FOV (cm), Scan Area		Scan Time (s)		Exposure Time (s)	
		High Resolution	Green	High Resolution	Green
21x19		18.0	18.0	18.0	18.0
17x15 (Dental CT)		18.0	18.0	16.6	16.6
17x11 (ENT CT)		18.0	18.0	16.6	16.6
12x9		18.0	18.0	13.9	13.9
8x8	Right	18.0	18.0	11.0	11.0
	Left	18.0	18.0	11.0	11.0
	Center	18.0	18.0	11.0	11.0

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

NOTE

- Maximally allowed deviation of the tube voltage / current: kVp ± 10 % / mA ± 20 % according to IEC 60601-2-63.
- Due to image optimization performed prior to shipping, equipment data may differ slightly from those specified in the table.

16.2 X-ray Dose Data

16.2.1 DAP (Dose Area Product)

Dose Area Product (DAP) 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 limitation, Dose Area Product (DAP) is the best way to predict effective dose value and currently the most convenient method for patient doses monitoring.

HPA recommends that any national reference dose that achievable dose (DAP) value of 250 [mGy·cm^2] for clinical protocol for a standard male patient.

Standard

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

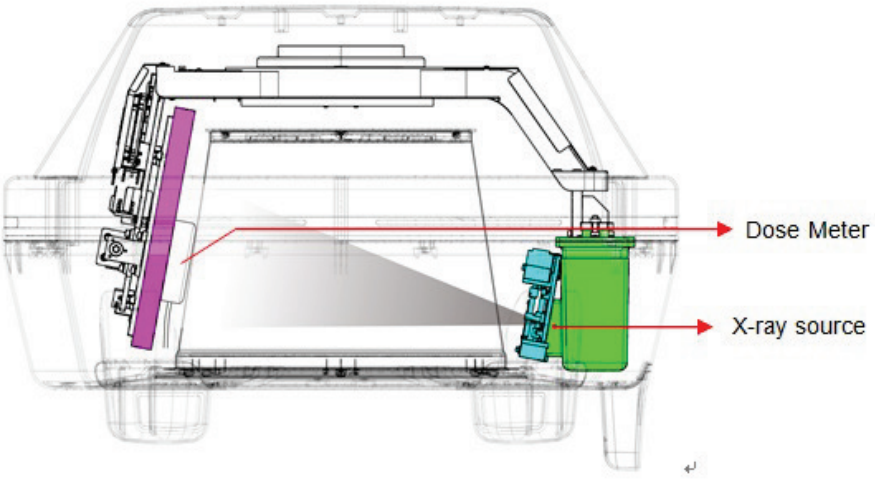
DAP (Dose Area Product) Calculation

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 Normal	85 kVp / 7.0 mA / 13.5 sec	84
PANO Child Normal	85 kVp / 6.0 mA / 11.9 sec	50
Dental CT 21 x 19 (High Resolution)	108 kVp / 6.5 mA / 18.0 sec	2010
Dental CT 21 x 19 (Green)	95kVp / 6.5 mA / 18.0 sec	1610
Dental CT 8 x 8 (High Resolution)	108 kVp / 6.5 mA / 11.0 sec	620
Dental CT 8 x 8 (Green)	80 kVp / 4.5 mA / 11.0 sec	230
ENT CT 21 x 19 (High Resolution)	108 kVp / 6.5 mA / 18.0 sec	2010
ENT CT 21 x 19 (Green)	95 kVp / 6.5 mA / 18.0 sec	1610
i-CEPH	100 kVp / 4.5 mA / 18.0 sec	1200

16.2.2 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.

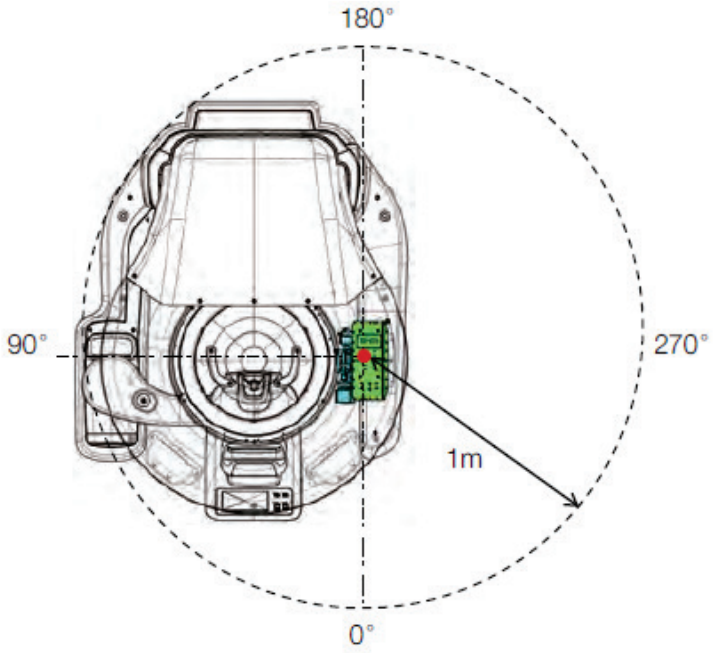
Standard

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

Test Condition

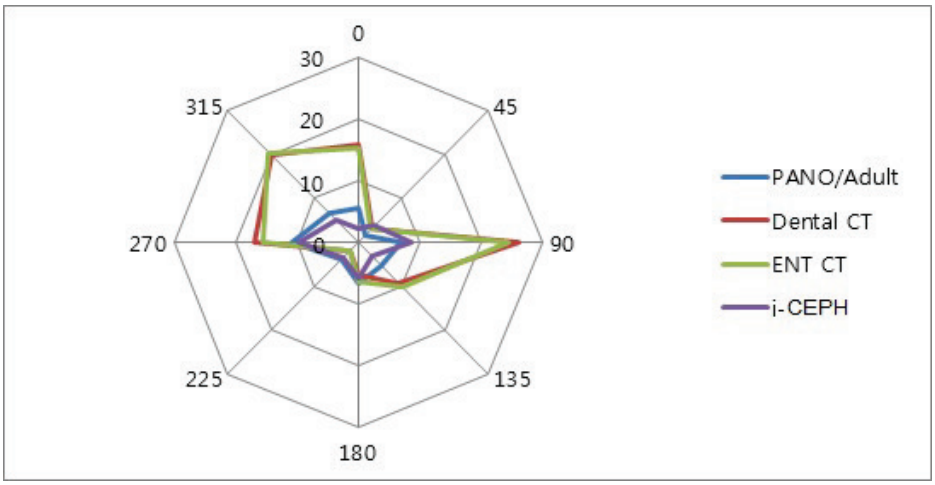
Test mode	kVp	mA	sec
PANO / Adult	90	9.6	13.5
Dental CT (21 x 19)	110	6.5	18.0
ENT CT (21 x 19)	110	6.5	18.0
i-CEPH	102	4.5	18.0

Measurement Overview



Results

Direction [°]	PANO/Adult [mR/h]	Dental CT 21 x 19 [mR/h]	ENT CT 21 x 19 [mR/h]	i-CEPH [mR/h]
0	4.5	12.2	11.4	4.4
45	1.2	2.4	3.8	7.2
90	5.8	20.0	15.4	16.4
135	4.4	7.1	5.8	6.2
180	5.6	4.0	3.7	11.4
225	3.2	1.5	4.2	6.5
270	8.8	12.9	8.8	18.4
315	5.5	15.3	21.4	9.9



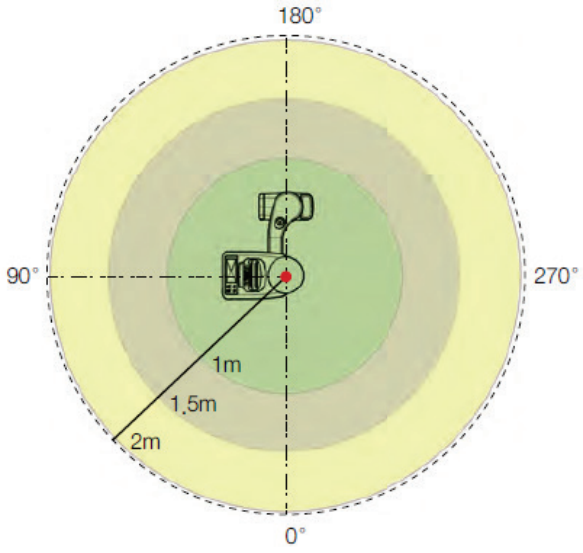
16.2.3 Scattered Dose

X-ray Scattered Dose data with respect to varied angle and distance is examined for recommendations about appropriate radiation level in significant zones of occupancy and the effectiveness of protective shielding facility around the patient's position. This information states the identity and intended position of tested phantom and scattered dosimetric evaluation under defined scope and test circumstances to ensure magnitude of risks to the operator and staffs, during both accident situation and routine work.

Test Condition

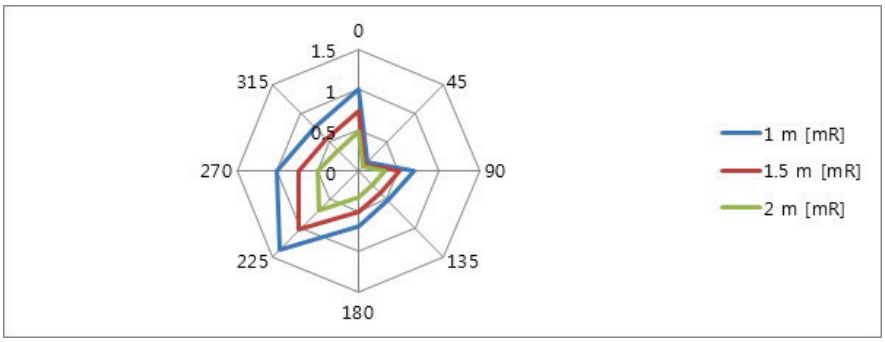
Test mode	kVp	mA	sec
PANO / Adult	90	9.5	13.5
Dental CT (21 x 19)	110	6.5	18.0
ENT CT (21 x 19)	110	6.5	18.0
i-CEPH	102	4.5	18.0

Measurement Overview



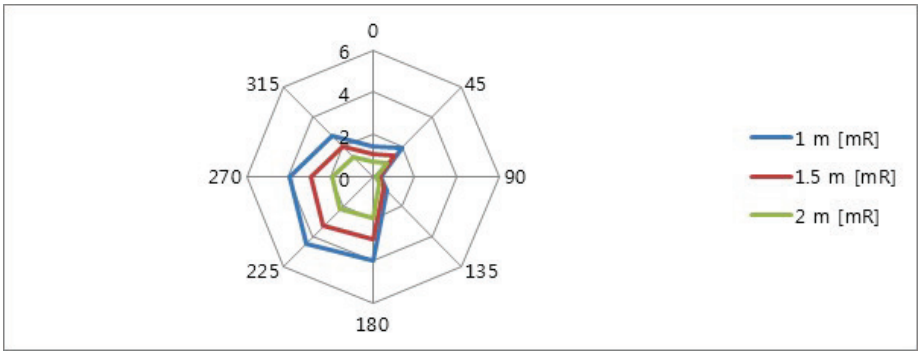
Results (PANO / Adult)

Direction [°]	1 m [mR]	1.5 m [mR]	2 m [mR]
0	1.00	0.74	0.49
45	0.15	0.11	0.08
90	0.69	0.51	0.34
135	0.51	0.38	0.25
180	0.68	0.50	0.33
225	1.38	1.03	0.68
270	1.00	0.74	0.49
315	0.75	0.56	0.36



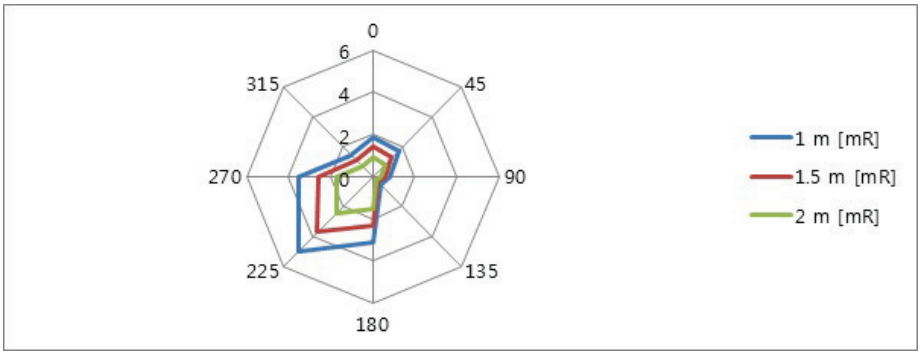
Results (Dental CT - 21 x 19)

Direction [°]	1 m [mR]	1.5 m [mR]	2 m [mR]
0	1.46	1.09	0.72
45	1.94	1.45	0.95
90	0.37	0.28	0.19
135	0.95	0.70	0.47
180	4.01	2.99	1.96
225	4.48	3.33	2.18
270	3.92	2.91	1.91
315	2.71	2.01	1.32



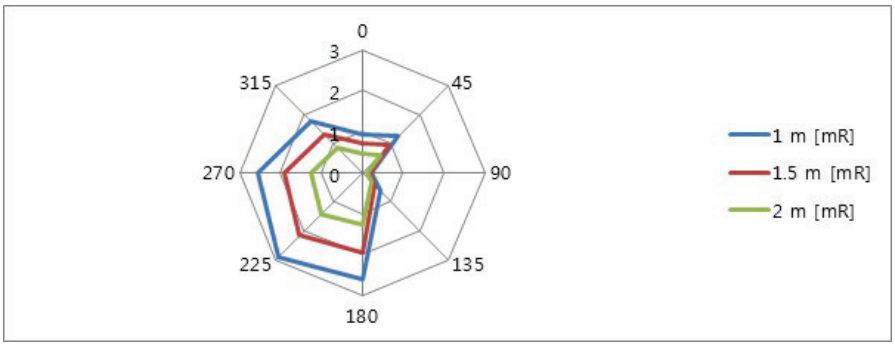
Results (ENT CT - 21 x 19)

Direction [°]	1 m [mR]	1.5 m [mR]	2 m [mR]
0	1.88	1.40	0.92
45	1.74	1.29	0.84
90	0.84	0.62	0.40
135	0.50	0.37	0.25
180	3.08	2.29	1.49
225	4.98	3.70	2.43
270	3.50	2.60	0.92
315	1.46	1.09	0.84



Results (i-CEPH)

Direction [°]	1 m [mR]	1.5 m [mR]	2 m [mR]
0	0.95	0.71	0.47
45	1.26	0.94	0.62
90	0.24	0.18	0.12
135	0.62	0.45	0.31
180	2.60	1.94	1.27
225	2.91	2.16	1.42
270	2.55	1.89	1.24
315	1.76	1.31	0.86



16.3 Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions

The **PCT-90LH** is intended for use in the electromagnetic environment specified as below. The customer or the user of the **PCT-90LH** should assure that it is used in such an environment.

Immunity test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The **PCT-90LH** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A (The **PCT-90LH** in combination with the shielded location)	The **PCT-90LH** 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 **PCT-90LH** or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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.

Guidance and manufacturer's declaration - electromagnetic immunity

The **PCT-90LH** is intended for use in the electromagnetic environment specified below. The customer or the user of the **PCT-90LH** 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 **PCT-90LH** image intensifier requires continued operation during main power interruptions, it is recommended that the **PCT-90LH** 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 **PCT-90LH** is intended for use in the electromagnetic environment specified below. The customer or the user of the **PCT-90LH** 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	3 Vrms 150 kHz to 80MHz	V_1=3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the **PCT-90LH**, 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 :
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	E_1=3V/m	

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.

[a] 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 **PCT-90LH** is used exceeds the applicable RF compliance level above, the **PCT-90LH** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PCT-90LH**.

[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 PCT-90LH

This is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **PCT-90LH** can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PCT-90LH** as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter [m]

IEC 60601-1-2

Frequency of Transmitter Equation Rated maximum output power of 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 **PCT-90LH** is used exceeds the applicable RF compliance level above, the **PCT-90LH** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PCT-90LH**

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

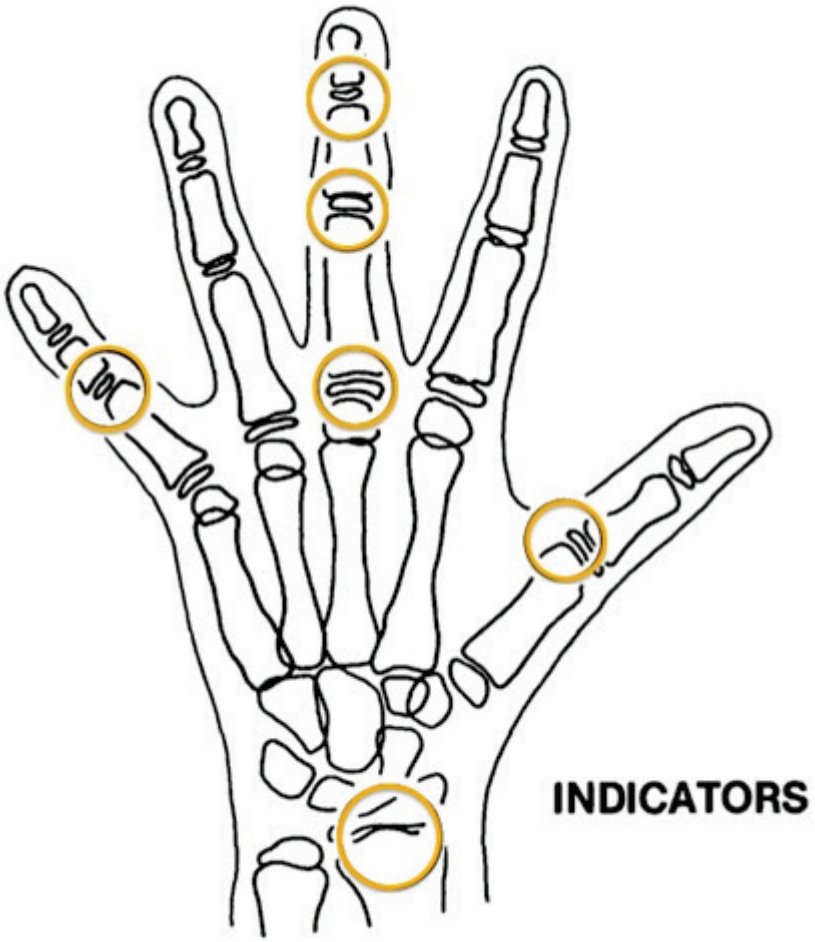
16.4 Hand-wrist Image Evaluation References

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

Fishman LS. 1982

System of Skeletal Maturation Assessment (SMA)

The System uses only four stages of bone maturation, all found at six anatomical sites located on 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.

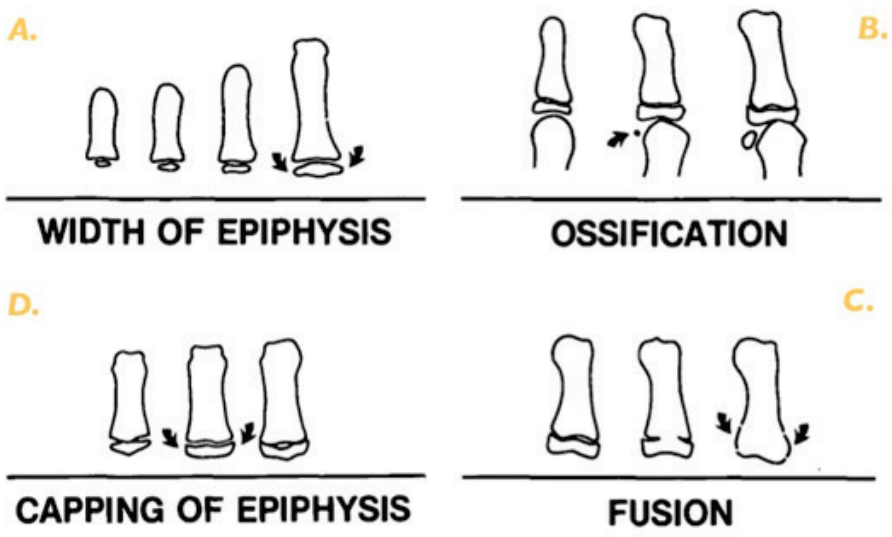


Fig. 2 Radiographic identification of skeletal maturity indicators.
A. Epiphysis equal in width to diaphysis.
B. Appearance of adductor sesamoid of the thumb.
C. Capping of epiphysis.
D. Fusion of epiphysis.

[Fig2. Radiographic identification of skeletal maturity indicators]]

A. 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

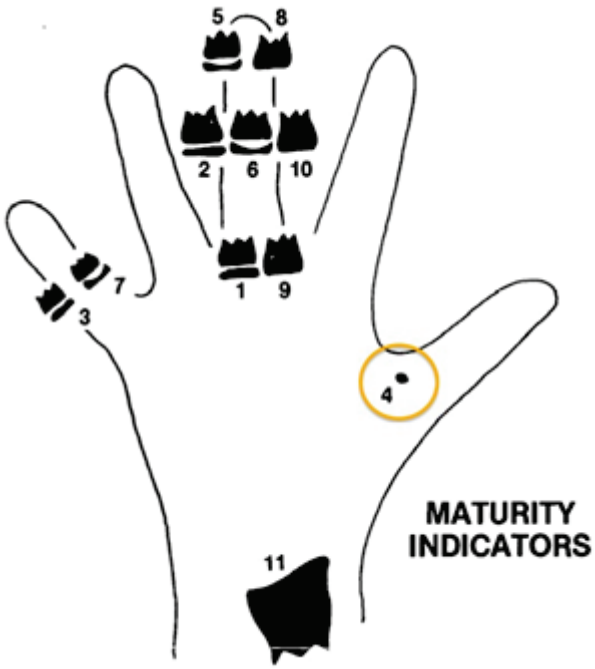
2. Third finger – Proximal phalanx

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 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

16.5 Acquiring Images for Pediatric Dental Patients

16.5.1 Age Group: Classification Table

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

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

16.5.2 Positioning the Pediatric Dental Patients

1. Use laser light beam guide to locate mid sagittal plane. Direct patient focus to mirror reflection. Affix decal to mirror to aid patient in maintaining the correct position throughout 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 onto the rest. Direct the patient to assume a position that resembles the erect stance of a soldier.
3. Direct the patient to stick out the chest while dropping the chin down. While holding the unit handles for stability, direct the patient to take a half step in toward the vertical column of the X-ray device into a position that feels as if he/she is slightly leaning backward.
4. Direct the patient to close lips around the Bite Block during the exposure.
5. Direct the patient to swallow and note the flat position of the tongue. Request that the patient suck 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 straight forward, 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 radiographic error.

Producing A Quality Panoramic Image

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

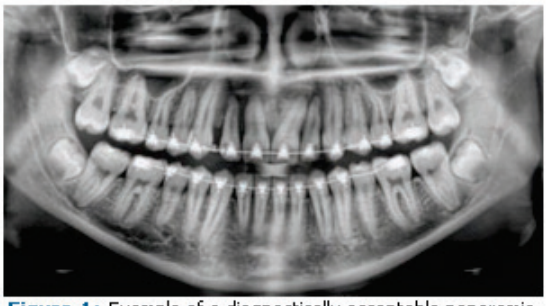


Figure 1: Example of a diagnostically acceptable panoramic radiograph of an adolescent patient undergoing orthodontic intervention. (Courtesy of Jamie Mace and Will Wright of Schick Technologies Inc.)

The most 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 a 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.

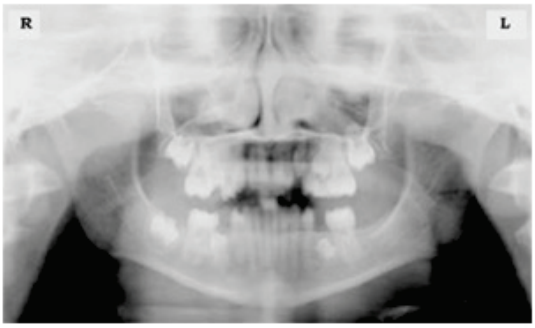

Figure 3: Incorrect position too far anteriorly. Note the narrow anterior teeth and superimposition of the spinal column over the condyles. The radiolucency superior to the maxillary apices indicates that the tongue was not placed against the palate. An open lip line can also be detected.

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.

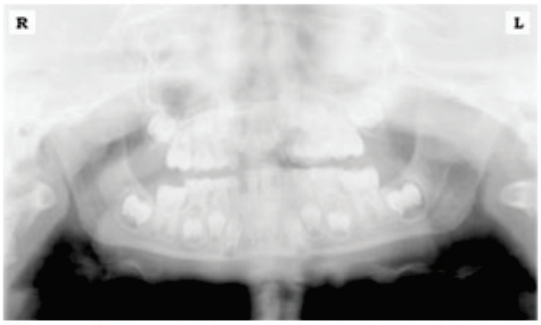

Figure 4: Incorrect lateral position tilted to the right. Note the teeth on the left are wide and poorly defined, while the teeth on the right are narrowed and severely overlapped. The inferior border of the mandible is distorted and the condyles appear asymmetrical.

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.

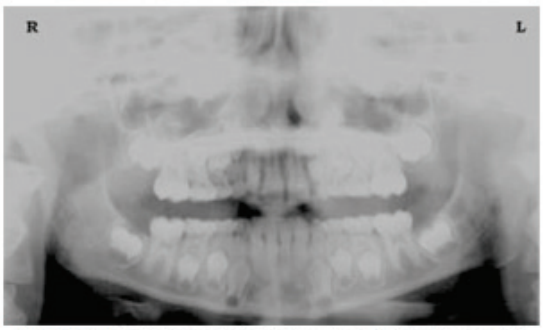

Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

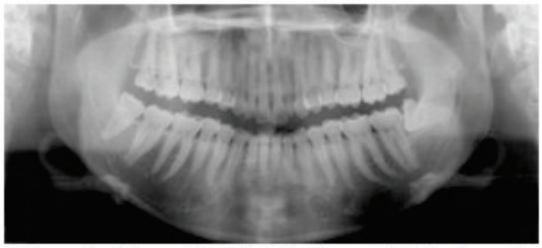

Figure 6: Chin positioned too far down. Note the characteristic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

Correct positioning of the arches in the superior- inferior dimension requires that the patient stand 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 maxillary anterior 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 into 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 empty 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 interfere 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.

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

16.5.3 Setting Exposure Values to the Age Group

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

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

1) Literature

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

  EAPD guidelines for use of radiographs in children, P40-48. European Journal of Pediatric Dentistry 1/2003 Guidelines in dental radiology are designed to avoid unnecessary exposure to X-radiation and to identify individuals who may benefit from a radiographic examination. Every prescription of radiographs should be based on an evaluation of the individual patient 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 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. 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, with a view 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 thermo luminescent 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 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 siliconphotodiode 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 brain. Maximum values of mean doses for the radiosensitive lens and thyroid were 32.7 mGy for 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) Websites

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

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

16.6 Abbreviations

AC	Alternating Current
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 Electro technical 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
TMJ	Temporomandibular Joint

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CE 0434

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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