

PaX-i PlusTM PaX-i InsightTM

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PaX-i PlusTM InsightTM

User Manual

English

PaX-i PlusTM PaX-i InsightTM

User Manual

English v 1.43



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Notice

Thank you for purchasing the **PaX-i Plus / PaX-i Insight (Model: PCH-30CS)** extra-oral imaging system.

PCH-30CS is an advanced digital diagnostic system that incorporates PANO and CEPH (Optional) imaging capabilities into a single system. **PCH-30CS** is classified into two types – **PaX-i Plus** and **PaX-i Insight** - according to the availability of Insight PAN function.

This manual describes how to operate the **PCH-30CS** system and covers differences in the specifications between **PaX-i Plus** and **PaX-i Insight**. It is recommended that you thoroughly familiarize yourself with this manual to make the most effective use of this equipment.

Observe all cautions, safety messages, and warnings that 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.

PCH-30CS is referred to as “equipment” in this manual.

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1. Introduction

1.1 Overview

PaX-i Plus / PaX-i Insight (Model: PCH-30CS) is an advanced 2-in-1 digital X-ray imaging system that incorporates PANO and CEPH (Optional) imaging capabilities into a single system and acquires 2D diagnostic image data in conventional panoramic and cephalometric modes.

1.2 Indications for Use

PaX-i Plus / PaX-i Insight (Model: PCH-30CS) is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The equipment is to be operated by physicians, dentists, and x-ray technicians.

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.
- Diagnosis of un-erupted teeth impacted teeth and odontomas.
- Diagnosis of root resorption of teeth
- Diagnosis of CRS (Chronic Rhinosinusitis)
- Assessment of fractures on the maxilla, mandible, condylar neck, and fractures of teeth where plain film imaging is equivocal.
- Detailed verification of images in in-depth direction (**PaX-i Insight only**)

1.4 Contraindications

DO NOT use this device other than the intended purpose.

There are no other contraindications to it since the technology is at a controllable level in accordance with global standards.

1.5 Intended User Profiles

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

IMPORTANT

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

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 by all the cautions and conditions required for installation.
- Genuine **VATECH**-approved equipment and components have been used always.
- All maintenance and repairs have been performed by a **VATECH**-authorized agent.
- The equipment has been used normally by the **User Manual**.
- The equipment damage or malfunction is not the result of an error on the part of the owner or the operator.








2.2 Owner and Operator's Obligations

- The owner of this equipment shall perform constancy tests at regular intervals to ensure patient and operator safety. These tests must be performed by local X-ray safety regulations.
- The owner of this equipment shall perform regular inspection and maintenance of the mechanical and electrical components in this equipment to ensure safe and consistent operation (IEC 60601-1).
- The owner of this equipment shall ensure inspection and cleaning work is performed by the maintenance schedule outlined in **Chapter 10. Cleaning and Disinfection**.













2.3 Conventions in this Manual








The symbols below are used to inform the manual's readers about warnings, cautions, and useful tips related to using the equipment. Ensure that you understand the symbol's meaning and accompanying instructions for your safety.

Please observe all warnings and cautions in this manual to prevent injuries and property damages.

	WARNING	This 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	This indicates a situation that demands prompt and careful action, a specific remedy, or emergency attention.
	IMPORTANT	This indicates a situation or action that could potentially cause problems to the equipment and/or its operation.
	NOTE	This emphasizes important information or provides useful tips and hints.
	RADIATION	This indicates a possible danger from radiation exposure.
	SINGLE-USE	This indicates a component that must be replaced for each new patient.
	ESD susceptibility	This indicates that an item is susceptible to damage from electrostatic discharges.

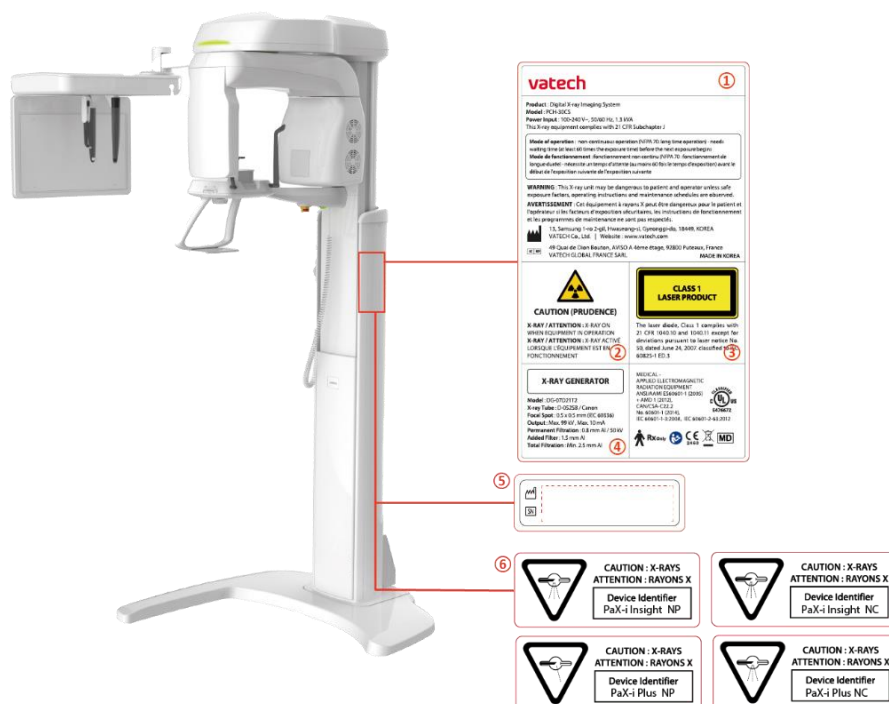
2.4 Marks and Symbols

Symbols	Description	Location
	Dangerous voltage	Power board / Inverter board / Monoblock
	Protective earth (Ground)	Column
	Off (power: disconnected to the Main Power Switch)	Main Power Switch
	On (power: connected to the Main Power Switch)	Main Power Switch
	Alternate Current	Label
	Type B Applied Equipment (IEC 60601-1: Degree of protection against leakage current and/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 Regulation for Medical Devices Regulation 2017/745 as a class IIb device.	Label
	UL mark No. E476672	Label
	Caution: Federal law restricts this equipment to sale by or on the order of a licensed healthcare practitioner.	Label
	Addresses where the equipment was manufactured.	Label

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

2.4.1 Label Locations



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



No.	Item
1	PaX-i Plus / PaX-i Insight (Model: PCH-30CS) Main Label
2	CAUTION Label - X-ray / Attention: X-ray on when equipment is in operation.
3	X-RAY GENERATOR Label : 1.0 kW Generator
4	CLASS 1 LASER PRODUCT Label
5	Manufacturer Label - The date of manufacture / Serial Number
6	Device Identifier Label <ul style="list-style-type: none"> PaX-i Insight NP / PaX-i Plus NP: CEPH not included PaX-i Insight NC / PaX-i Plus NC: CEPH included.

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3. Warnings and Precautions

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

3.1 General Safety Guidelines

Operator qualifications

This equipment must be operated by a qualified person who is trained in proper operating procedures. To operate the equipment, the operator must meet the following standards:

- Read and understand the **user manual**.
- Understand this equipment's structure and function.
- Recognize problems in the equipment and implement appropriate solutions.

General safety precautions

- Follow the instructions in this manual to ensure the safety of the patient and the operator.
- The operator must maintain vocal/visual contact with the patient always during imaging.
- Do not open or remove the cover panels on this equipment. Always have a trained and authorized service technician to carry out the 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.
- Ensure to install equipment with a wall bracket or other connecting parts. Both operators and patients can receive injuries from the equipment tip-over if it is not securely mounted to the wall or the floor.
- The operator must instruct the patient to remain still until the equipment arm has stopped moving and the reset motion is completed.
- Observe all local fire regulations. Always keep a fire extinguisher near the equipment.
- The operator of this equipment must be familiar with this equipment's emergency protocols.

3. Warnings and Precautions

- Ensure to keep this equipment away from water, moisture, or foreign substances. This equipment is an IPX0 device and is not intended to use near liquids.
- Ensure that a liquid does not enter the equipment when you are taking an X-ray image of the patient who has the following conditions:
 - Patients with a urinary catheter (drainage bag)
 - Patients who have implants or underwent oral anesthesia or other procedures can cause drooling during the image acquisition.
- When this equipment is exposed to water, moisture, or a foreign substance, turn off the equipment immediately and contact your **VATECH** technical support representative.
- When there is a sign of oil leakage, stop the equipment immediately and contact your **VATECH** technical support representative.
- The external parts connected to the outside of equipment such as cables must comply with relevant IEC Standards. (e.g., IEC 60950 for IT equipment and IEC 60601-1 series for medical electrical equipment).
- Likewise, these parts must comply with IEC 60601-1, IEC 60601-1-1, and the national regulations of the country where the equipment is installed. Please contact **VATECH** or its area representative if you have questions.
- Any person or organization that installs an external door interlock switch is responsible for ensuring that the switch has a radiation indicator or equivalent alarm system to show the state of the current.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Ventilation

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

Hygiene



Turn off the equipment before you start cleaning.



DO NOT use a cleaner spray on the equipment. Spraying liquid directly over the equipment can cause a fire or damage the electrical parts inside the equipment.

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



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

Condensation

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

Cooling

- Allow the proper amount of cool downtime (for the X-ray tube to cool down) before the acquisition of the next image.
 - **Mode of Operation:** non-continuous operation (NFPA 70: long time operation) - needs waiting time (at least 60 times the exposure time) before the next exposure begins.
 - **Column Operation Time:** Max. 2 min. On / 18 min. Off (Ratio 1:9)

- If the temperature inside the tube head reaches 60 °C (140 °F), X-ray exposure will cease, and an error message will be displayed. Normal X-ray capabilities will resume after the generator reaches 58 °C (136.4 °F).
- If the fan (optional) is installed, it operates automatically when the temperature surrounding the tube head reaches the pre-defined level: 40 °C (104 °F). The setpoint temperature is configurable.

Turning the equipment on / Adjusting the height of the equipment

- Do not position the patient near the equipment while it is getting ready for scanning. The patient could be injured if the equipment malfunctions.
- Ensure that the patient is kept clear of the equipment while adjusting its height.

Emergency stops

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

Trouble-free operation

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

Modifying the equipment

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

3.2 Electricity-Related Safety Precautions



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

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

Combining this equipment with other devices

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

Electromagnetic compatibility

- This X-ray equipment complies with IEC standard 60601-1-2.
- Medical electrical equipment is subject to special Electromagnetic Compatibility (EMC) preventive measures. It must be installed and operated as specified in EMC information.
- If high-voltage systems, radio link systems, or MRI systems are located within 5 m of the unit, please observe the specifications stated in the installation requirements.
- Portable Radio Frequency (RF) communications equipment may interfere with medical electrical equipment. Therefore, the use of mobile wireless phones in medical offices or hospital environments must be prohibited.
- For more details, refer to **14.3 Electromagnetic Compatibility (EMC) Information**.
- Please also observe the Electro-Static Discharge (ESD) protective measures described.

Static Discharge

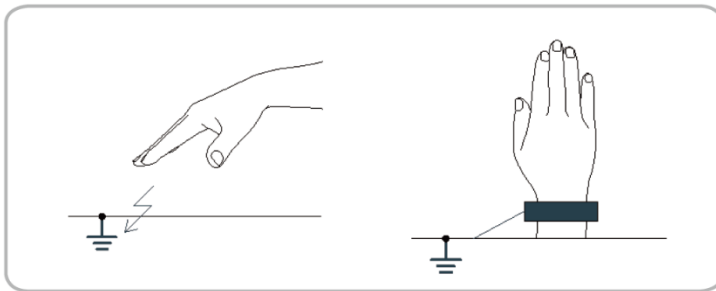
- Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without observing ESD protective measures.



Electrostatic discharge (ESD)

ESD protective measures include

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



3.3 Radiation Safety

- Ensure to install this equipment inside an X-ray room.
- The operator must stay outside of the X-ray room while acquiring an X-ray image to protect himself or herself from radiation exposure.
- The operator must be able to communicate with his or her patient either visually or verbally while the equipment is in operation.
- Check the status of the patient and the equipment until the image acquisition is completed.
- Stay at least 2 m (7 ft) away from the equipment during the image acquisition.
- Stop the equipment immediately when a problem occurs during image acquisition.
- Guide the patient to wear a lead apron with a neck collar before image acquisition for thyroid protection.
- Women who are pregnant or might be pregnant, and children should minimize X-ray exams unless absolutely necessary.
- Women who are pregnant or might be pregnant, and children should check the need for an X-ray exam through consultation with a radiologist before taking an X-ray scan. If they need an X-ray exam, we recommend that they wear lead shielding or protective aprons.
- Check if your patients have an electrical medical device implanted in their body or are currently under radioactive iodine seed treatment. Patients who meet one of these conditions must be informed before X-ray scanning about the danger associated with radiation exposure.
- Guide the following patients to consult their doctor before taking an X-ray:
 - 1) the patients with the implanted medical device.
 - 2) the patients under the radioactive iodine seed treatment.
- The implanted medical devices that require a doctor's consultation before X-ray scanning are insulin pumps, cardiac implantable electronic devices (pacemaker and implantable cardioverter defibrillators), and neurostimulators.







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



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


3.4 Warnings

Follow the warnings below to ensure your safety. Failure to follow these warnings can cause injuries or damage to the equipment.

 WARNING	<ul style="list-style-type: none"> ▪ X-ray equipment is hazardous to the patient and the operator if proper exposure safety measures and operating instructions are not observed. ▪ Read this user manual and follow all warnings and cautions in the manual.
 WARNING	<ul style="list-style-type: none"> ▪ Taking an X-ray is justified only when its benefits outweigh its risks.
 WARNING	<ul style="list-style-type: none"> ▪ PaX-i Plus / Insight (Model: PCH-30CS) uses high-frequency electrical signals like other medical devices, so it may interfere with implanted medical devices such as pacemakers or implantable cardioverter-defibrillators (ICDs). If a patient is using such an implanted medical device, please be aware of this and immediately turn off the device if interference occurs. ▪ If there is a concern about electromagnetic interference (EMI) with a patient's implanted medical device, please guide them to consult with the physician in charge of the implanted medical device.
 CAUTION	<p>Federal law restricts the sale of this device to dentists, or the personnel licensed by the law of the state where he or she uses or orders the use of the device.</p>

Lasers

- The system incorporates Class 1 laser products. The light localizers used in this product are intended for correct patient positioning and must not be used for any other purpose.
- For maximum safety, advise the patient not to look directly at the laser beam.
- While adjusting the patient, ensure that the laser beam is not directed at the patient's eyes.
- Wavelength: 650 nm, Radiant power: Max. 0.39 mW

 CAUTION	<p>Risk of eye injury!</p> <p>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.</p>
----------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Cleaning

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

During the Operation

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

In case of an electrical fire

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

Installation

- To avoid improperly balanced equipment, install the equipment 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.

NOTICE

For further details on installation, refer to the **PaX-i Plus / PaX-i Insight (Model: PCH-30CS) Installation Manual**.

Security Capabilities

- It is recommended to install and operate **EzDent-i** SW within a secure operating environment that allows only authorized users to access a system network equipped with Windows built-in firewall, Windows Defender antispware 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 by a third party, not the manufacturer, is strictly prohibited. For cybersecurity issues related to software and medical devices, please contact the manufacturer.

3.4.1 Side effects

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

4. Imaging System Overview

4.1 System Components

- **PaX-i Plus / PaX-i Insight (Model: PCH-30CS)** X-ray equipment
- PC system
- Console Software: PANO and CEPH (Optional)
- **EzDent-i:** 2D viewer and patient management software

4.2 Features

- The multi-imaging solution for Accurate Diagnostics
- Conventional 2D (PANO and CEPH (Optional)) image acquisition in high quality
 - **PANO:** Optionally implemented improved multi-image acquisition technology that reconstructs the panoramic image into multiple images with different focal planes in one take.
 - **CEPH:** Minimized motion artifact through short scan time.
- Supports DICOM (Digital Imaging Communication in Medicine) format.

4.3 Imaging System Options



Model Name	Brand Name	Device Identifier	System Configuration (X-ray Detector)	
PCH-30CS	PaX-i Plus	PaX-i Plus NP	PANO	Xmaru1501CF-Plus
		PaX-i Plus NC	PANO	Xmaru1501CF-Plus
			CEPH	Xmaru2602CF
	PaX-i Insight	PaX-i Insight NP	PANO	Xmaru1404CF-Plus
		PaX-i Insight NC	PANO	Xmaru1404CF-Plus
			CEPH	Xmaru2602CF

4.4 Standards and Regulations

Standards

PaX-i Plus / PaX-i Insight (Model: PCH-30CS) is designed and developed to comply with the following international standards and regulations:

- MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-1-3:2008, IEC 60601-2-63:2012
- 21 CFR 1020.30, 31, 33
- NEMA Standard publication PS 3.1-3.18

	<p>This is class IIb equipment and obtained CE marking in May 2017 for regulation compliance by the enacted European Union's MDR (Medical Device Regulation)</p>
	<p>MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-1-3:2008, IEC 60601-2-63:2012</p>

Classifications (IEC 60601-1 6.1)

- The degree of protection against water ingress: Ordinary Equipment: IPX0
- The degree of protection against electric shock: Class 1 equipment, Type B Applied Parts (Chinrest, Bite and cover, Nasal Positioner and cover, Ear Rod and cap, Carpus Plate)



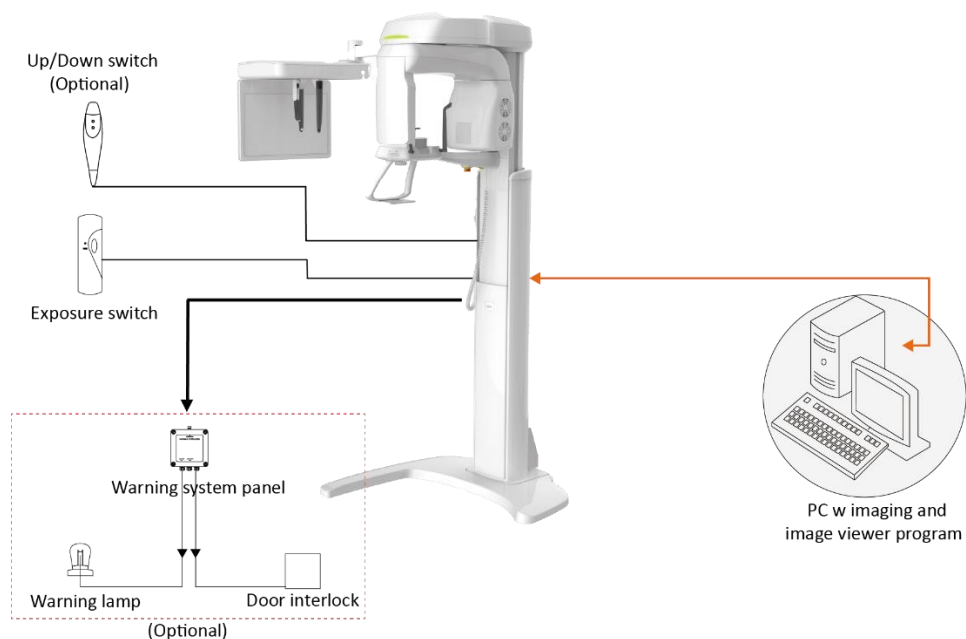
4.5 Operating Principles

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

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

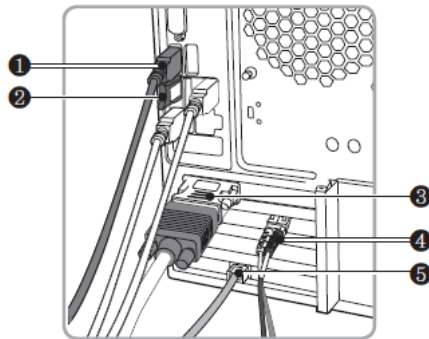
Images are acquired, computed, and recompiled to reproduce 2D images.

4.6 Imaging System Configuration



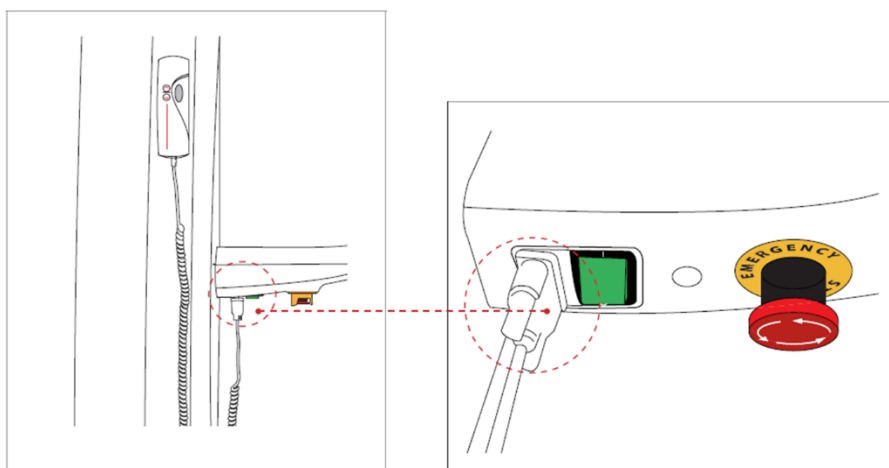
IMPORTANT

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

Input / Output for PC

No.	Item
1	USB Camera input (USB 3.0 Cable) <hr/> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;">NOTICE</div> <p>To avoid any connection problems, it is highly recommended to install a USB 3.0 PCI card for USB 3.0 cables.</p> </div> <hr/>
2	2D viewer License Key
3	Video Output
4	Fiber Optic Cable (Data in / out)
5	Ethernet Cable

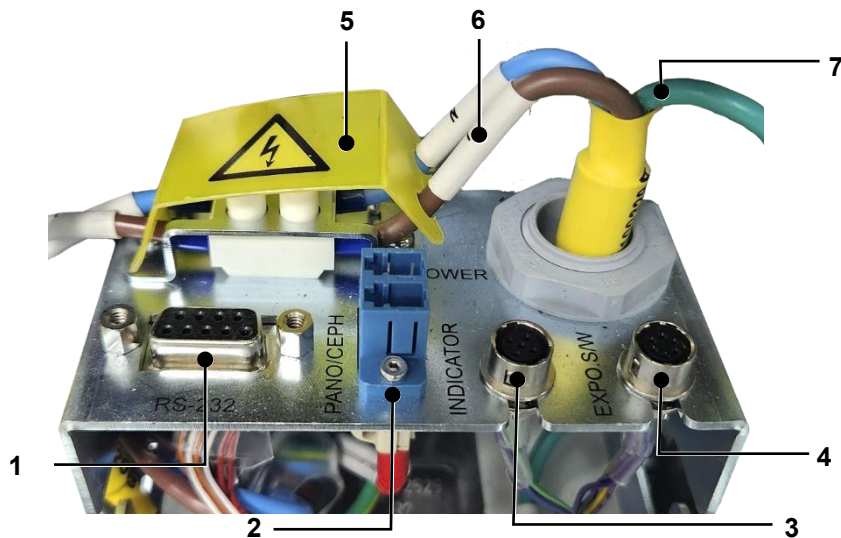
Signal Input & Output for Column UP/DOWN Switch



NOTICE

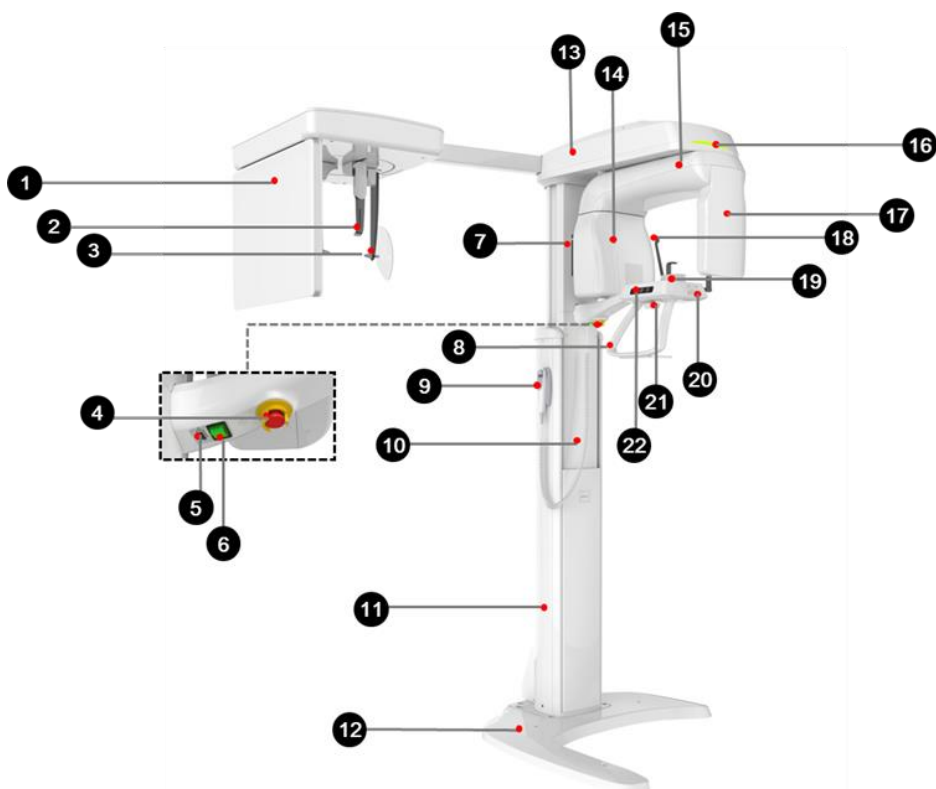
The equipment connected to the signal input, signal output, or other connectors must comply with the relevant IEC standards (e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment).

Besides, all such combination systems must comply with IEC60601-1 and/or relevant combination standards. If in doubt, contact a qualified technician or your local VATECH representative.


Port and Cable Connection

No.	Item	Description
1	RS-232 Port	Used for test and C/S support.
2	Optic Port	Connects the MCU and the sensor with the PC.
3	Indicator Port	Connects the warning system (lamp, door lock to the equipment.
4	Exposure Switch Port	Connects the exposure switch to the equipment.
5	Terminal	Connects the external power cable with the internal power cable.
6	Power Cable	Supplies power to the equipment.
7	Frame Ground Cable	Connects the external FG with the internal FG.

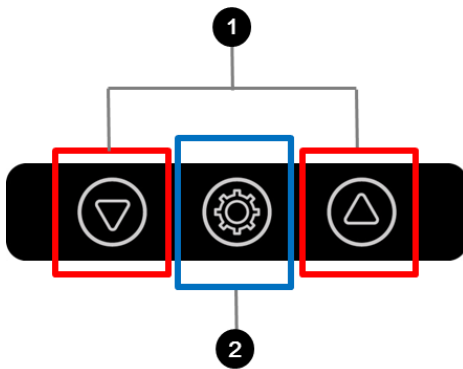
4.7 Equipment Overview



No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor
2	Nasal Positioner	<ul style="list-style-type: none"> Positions the patient during CEPH imaging. The ruler is used for reference in an acquired image that is different from the actual size
3	Ear Rods	Secure the patient's head during CEPH imaging.
4	Emergency Stop Switch	Immediately stops the moving parts and cuts off all power to the equipment's electrical components.
5	D-Sub Connector	The input signal port for Column UP/DOWN Switch
6	Main Power Switch	Turns on/off the main power of the equipment.
7	Horizontal Beam Lever	Aligns the Horizontal Beam in PANO mode.
8	Handle Frame	Held firmly by the patient during imaging to stabilize his /

No.	Item	Description
		her position.
9	Column UP/DOWN Switch (optional)	Adjusts the height of the Vertical Frame.
10	Telescopic Column	Moves by the Column UP/DOWN button or switch for patient positioning.
11	Stationary Column	Supports the whole part of the equipment.
12	Base (Optional)	Balances the equipment and maintains its safety.
13	Vertical Frame	Holds the Rotating Unit. Can be controlled by the Column UP/DOWN switch.
14	X-ray Generator	The vacuum tube where the X-ray is produced.
15	Rotating Unit	Rotates around the patient's head while the image is being acquired. (Its movement is different according to the scan mode.)
16	LED Lamp	Displays the status of X-ray exposure. - Green: Standby - Yellow: In operation
17	X-ray Detector for PANO	<ul style="list-style-type: none"> ▪ PaX-i Plus: Xmaru1501CF-PLUS ▪ PaX-i Insight: Xmaru1404CF-PLUS
18	Temple Supports	Supports the patient's head by holding the temples. Used in the PANO mode.
19	Chinrest	The place to rest the chin.
20	Canine Teeth Beam Lever	Aligns the Canine Teeth Beam in PANO mode.
21	Temple Supports OPEN/CLOSE Wheel	Adjusts the Temple Supports for patient positioning.
22	Control Panel	<p>Operates the Laser Beam and adjusts the height of the Vertical Frame. (For the details, refer to 4.6.1 Control Panel.)</p> 

4.7.1 Control Panel



No.	Item	Description
1	Column UP/DOWN button	Moves the Vertical Frame up or down. (For adjusting the height of the Chinrest)
2	Laser Beam ON/OFF button	Turns the Laser Beam on / off.

4.7.2 Emergency Stop Switch

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

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

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

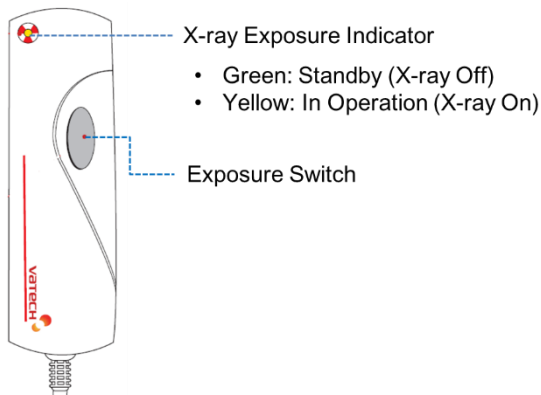


4.7.3 Exposure Switch

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

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

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



IMPORTANT









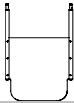



The **Exposure Switch** is detachable. Ensure the **Exposure Switch** cable is not detached from the unit accidentally during the operation.

IMPORTANT

Keep vocal/visual contact with the patient during exposure. If any problem occurs during exposure, release the **Exposure Switch** immediately.

4.7.4 Enclosed Components

The following accessories are used to position the patient and support the equipment. The accessories that have contact with the patient must be disinfected between each patient.

Components	Name and Function	Materials
	Normal Bite : For PANO	PC (Polycarbonate)
	Deep Bite Block*	PC (Polycarbonate)
	SINUS/TMJ bite	PC (Polycarbonate)
	Edentulous Bite : For PANO edentulous patients	PC (Polycarbonate)
	Normal Chinrest : For Normal Bite	ABS (Acrylonitrile butadiene styrene) copolymer
	Temple Supports (1 set)	PC (Polycarbonate)
	Ear Rods (1 set)	Silicone
	Nasal Positioner Cover : For CEPH	Silicone
	Carpus Plate	PC (Polycarbonate)
	Sanitary Vinyl Covers (disposable) for the Bite 	PP+PE
	Protractor (1 set) : For positioning the patient's body in CEPH mode.	PC (Polycarbonate)

*. Deep Bite Block is only available in some Asian countries.

5. Imaging Software Overview

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

- **EzDent-i:** 2D viewer and patient management software
- **Console software:** PANO and CEPH (Optional)
- PC Specifications (Recommended)

IMPORTANT

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

CAUTION

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

■ PaX-i Plus

Item	Specifications
CPU	Intel Core i3-7100 3.9GHz 3MB Cache, 2cores
Chipset	Intel Q270
RAM	2X4GB DDR4-2400 DIMM NECC UNB
Hard disk drive	500GB SATA 7200 rpm
Graphics board	Integrated Intel HD 630 Graphics
Ethernet interface	Integrated Intel I219LM Gigabit Network Intel Ethernet I210-T1 PCIe x1 Gb NIC (Option)
Serial Port (RS232)	1 (Onboard)
Power supply	≥ 400 Watts (93% Efficiency)
Slots	2 PCI Express x 1 Slot 2 PCI Express x 16 Slot
CD/DVD drive	DVDRW
Operating system	Windows 10 Professional 64 bit

WARNING

If you need to install a grabber card, plug it into the x4 express slot.

■ PaX-i Insight

Item	Specifications
CPU	Intel Core i5-7500 3.4 2133 4C CPU
Chipset	Intel C236 Chipset
RAM	16GB DDR4-2400 ECC (2X8GB) Unbuffered RAM
Hard disk drive	1TB SATA 7200 1st HDD
Graphic board	NVIDIA GTX 1050Ti
Ethernet interface	Integrated Intel® I218LM PCIe GbE Controller
Serial Port (RS232)	PCIe type RS232 Port
Power supply	400W (90% efficiency)
Slots	2 PCIe Gen3 x 16 slots
	1 PCIe Gen3 x 8 slot
	1 PCIe Gen2 x 4 slot
	1 PCIe Gen2 x 1 slot
	1 PCIe 32bit/33MHz
CD/DVD drive	DVDRW
Operating system	Windows 10 Professional 64 bit

5.1 EzDent-i

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

NOTICE

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

NOTICE

Security Capabilities

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

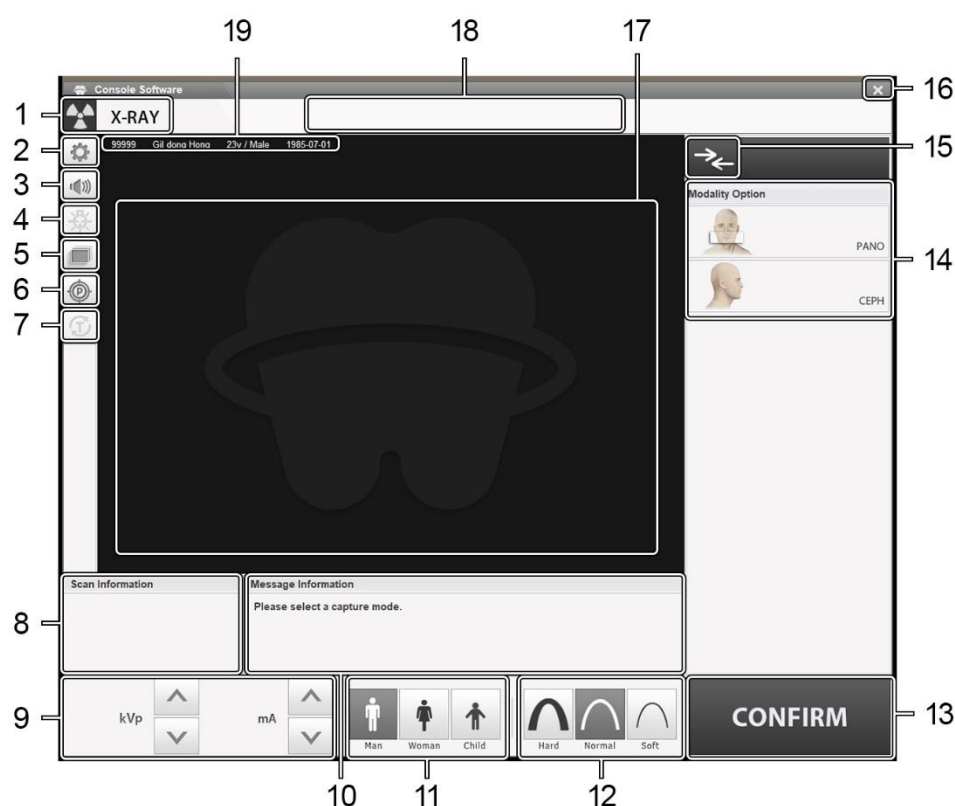
5.2 Console Software




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

NOTICE

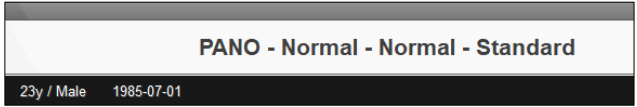
- You can set the imaging parameters on the Console Software running on the PC. They are synchronized and display the same environmental settings.)
- To improve program functions, the Console Software may change without notice

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



No.	Item	Description
1	X-ray indicator	<p>The radiation mark turns yellow and “X-RAY” changes to “X-RAY ON”.</p> 
2	Settings button	Sets user environments for console software, including language, automatic save, DAP display unit, etc.
3	Volume button	Changes the volume level of audio message.
4	Laser Beam ON/OFF button	Turns the Laser Beam on or off for patient positioning. Enabled when the CONFIRM button is clicked after the imaging conditions are configured.
5	Manual Reconstruction button	<p>Reconstructs the image manually when automatic image reconstruction fails:</p> <p><u>How to Start a Manual Reconstruction</u></p> <ol style="list-style-type: none"> 1) Click the manual reconstruction button. 2) Select a modality. 3) Click Search. 4) Select an image for reconstruction. 5) Click the button again.
6	Phantom button	<p>This function is used to acquire Phantom images.</p> <div>  <p> Captures a phantom image. <u>How to Capture a Phantom Image</u> <ol style="list-style-type: none"> 1) Click the phantom button. 2) Select a modality and click Capture. 3) Set exposure parameters and place a phantom jig. 4) Click Ready. 5) Press the exposure switch. </p> </div>
7	Test Rotation button	<p>Performs a test rotation to check before scanning if the equipment hits the patient.</p> <p><u>How to Start a Test Rotation</u></p> <ol style="list-style-type: none"> 1) Ask the patient to enter the unit. 2) Select a modality. 3) Click Confirm. 4) Click the test rotation button. After clicking, the button turns green. <div>  <p>This function is applied to PANO mode only.</p> </div>
8	Scan Information button	Shows the estimated DAP(Dose Area Product), scan, and exposure times for the exposure settings you selected.

No.	Item	Description																				
9	Exposure Condition menu	<p>If the patient is selected, the default kVp / mA according to the patient's information is displayed. If necessary, adjust the kVp and mA values manually.</p> <div><div>NOTICE</div><p>For the tube voltage and its correspondence with the selected patient, refer to the 14.1 Recommended X-ray Exposure Tables.</p></div>																				
10	Message Information window	Shows guide in text for the user.																				
11	Patient Type menu	<p>Displays the current patient's gender/age group as entered in EzDent-i's patient information fields. If necessary, the gender/ age group can be manually selected.</p> <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>	Gender / Age Group		VATECH's Standard	Child		2 ~ 12 years of age	Adult	Man	> 12 years of age	Woman										
Gender / Age Group		VATECH's Standard																				
Child		2 ~ 12 years of age																				
Adult	Man	> 12 years of age																				
	Woman																					
12	X-ray intensity	<p>Selects X-ray intensity.</p> <div><div>NOTICE</div><p>Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft: Soft ≤ Normal ≤ Hard</p><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></div>	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
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																			
13	CONFIRM / READY button	<p>This button performs a dual role.</p> <ul style="list-style-type: none">Confirm: finalizes the capture mode and settings you selected. <div>CONFIRM</div> <ul style="list-style-type: none">Ready: Prepares the equipment ready for X-ray exposure. The Ready button appears after the user clicks the Confirm button. <div>READY</div>																				
14	Modality option	Selects a capture mode : PANO, CEPH (optional)																				
15	Return to Modality option button	Returns to Modality Selection (PANO and CEPH (optional)) screen.																				
16	EXIT button	Exits the console software.																				

No.	Item	Description
17	Image Preview window	Shows image acquisition progression and displays a preview of the images acquired.
18	Imaging Mode Display	<p>Displays the current imaging mode.</p> 
19	Patient Information window	Displays information on the selected patient.

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6. Getting Started

6.1 Turning on the Equipment



WARNING

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



CAUTION

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

IMPORTANT

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

- The imaging system mainly consists of imaging equipment and the PC.
- Before turning on the equipment, please confirm that the equipment and PC have been installed correctly.
- Turn on the PC.
- Press the **Main Power Switch** that is located at the bottom of the Vertical Frame to turn on the equipment.



NOTICE

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

- 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 the **EzDent-i** icon. The **EzDent-i** main window will be displayed.

NOTICE

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

NOTICE

Security Capabilities

- The latest updates for anti-virus software and a firewall are recommended.
- The software can be updated by the manufacturer only. Unauthorized software update through a third party, not the manufacturer, is strictly prohibited. For cybersecurity issues related to software and medical devices, please contact the manufacturer.
- Ensure to install and operate EzDent-i under a secure environment that only authorized users can access the system network.
- The system network for EzDent-i must be protected with a Windows firewall, defender antivirus and other programs commonly recognized for cyber security.
- Update antivirus software and firewall to maintain the latest version.
- The security cover is installed on the back of the equipment. DO NOT remove or open this cover unless you are a VATECH-authorized engineer.
- All software provided by VATECH must be updated by VATECH.
- For inquiries about cyber security issues for VATECH's equipment and software, contact your nearest VATECH representative.

NOTICE

For the **PCH-30CS** dental computed tomography X-ray system, the Console Software is being accessed through 2D viewer (**EzDent-i**) SW. The Console Software does not have an image storage capacity of its 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 with **EzDent-i**:

EzDent-i Main Window

The screenshot shows the EzDent-i software interface. The top navigation bar includes tabs for PATIENT, ACQUISITION, VIEWER, CONSULT, and REPORT. The PATIENT tab is active. On the left, there is a 'Main Menu' with a search bar and a 'RECENT PATIENTS LIST' with buttons for 'Recently Acquired' and 'Recently Viewed'. Below this is a 'DOCTOR' dropdown menu set to 'All'. The main area displays patient details for a selected patient (Koo HyunJun) with fields for Chart No., Name, Gender/Age, and Date of Birth. A 'More Details' button is also present. At the bottom, a table lists recent patient records.

Chart No.	Name	Date of Birth
20191029_103203	Koo HyunJun	1974-08-15
20191029_103621	HyunJun Koo	1974-08-15
20191029_103722	Hyun koo	2019-01-01
202191029_103203	Koo HyunJun	1974-08-15

EzDent-i Main Window

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

ADD PATIENT

The dialog box contains the following fields and controls:

- Chart No.*: 202191029_103203
- PHOTO: Placeholder box
- Name*: Last Name (Koo), First Name (HyunJun)
- Gender: Male (dropdown)
- Date of Birth: Year (1974), Month (8), Day (15)
- Doctor 1: None (dropdown), Doctor 2: None (dropdown)
- Social ID: Text field
- Phone: Text field
- Mobile: Text field
- E-Mail: Text field
- Zip Code: Text field
- Address: Text field
- Buttons: Add, Cancel

2. In the dialog box, fill out **Chart No.** and **Name**. If necessary, fill out other areas such as social ID and mobile.
3. Click to save the new patient record.

NOTICE

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

6.2.2 Retrieving Patient Records

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

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

NOTICE

You can use a virtual keyboard to search for the patient record. Click the keyboard icon next to the search box to use the virtual keyboard:



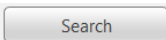
2. Click .
3. Check and double-click the patient record with the matching chart number or name.

Chart No.	Name	Date of Birth
20191029_103203	Koo HyunJun	1974-08-15
20191029_103621	HyunJun Koo	1974-08-15
20191029_103722	Hyun koo	2019-01-01
202191029_103203	Koo HyunJun	1974-08-15

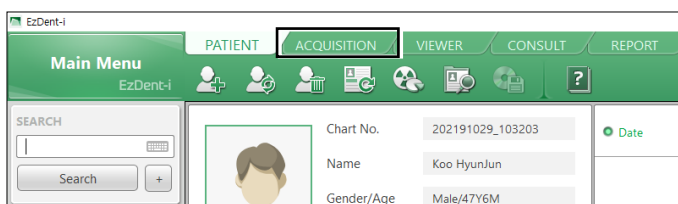
6.2.3 Initiating the Console Software

To initiate the console software:

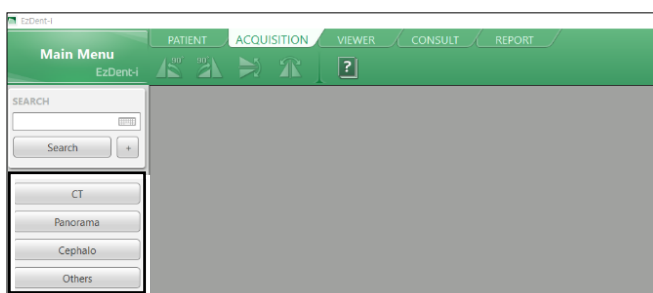
NOTICE

Before starting the console software, you must create new patient information. Go to **2.3.1 Creating a New Patient Record** for more information.

1. Search and select the patient record.
2. Click the **ACQUISITION** tab.



3. Select a modality you want to capture the image. The displayed options can be different depending on your equipment's option.



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7. Acquiring PANO Images

7.1 PANO Imaging Program Overview

■ Result Images

It provides conventional 2D panoramic images.

■ Image Acquisition Method

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


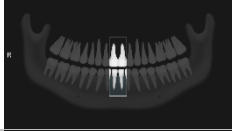
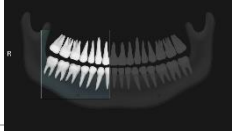
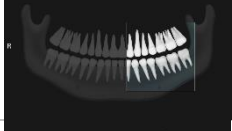





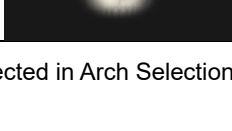
■ Available PANO Options

Mode	Description
Normal	Ordinary panoramic image acquisition option.
Auto-Focusing (Optional)	Multi-image acquisition option that reconstructs the panoramic image as multiple focal images.
Insight PAN	Multi-image acquisition option that reconstructs the panoramic image into multiple focal images in depth regions. Its main purpose is to diagnose depth regions, which cannot be confirmed with ordinary panoramic images.

■ Examination Programs

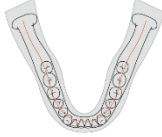

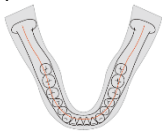

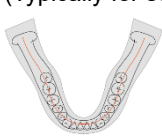

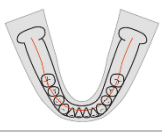

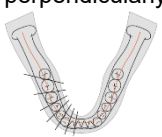

It is classified as below based on the ROI (Region of Interest).

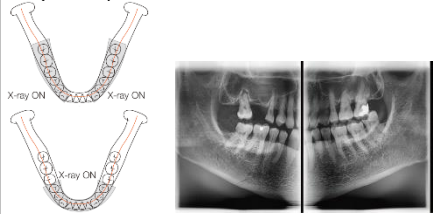
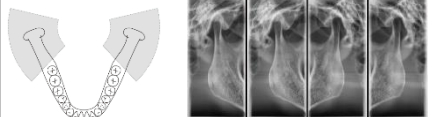
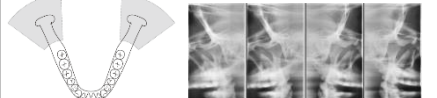


Examination Type	Arch Selection	ROI	Example
PANO Examination	Narrow Normal Wide Child Orthogonal	Standard	
		Right	
		Front	
		Left	

Examination Type	Arch Selection	ROI	Example
	Orthogonal	Bitewings*	
		Bitewing Incisor* (Optional)	
		Bitewing Right*	
		Bitewing Left*	
SPECIAL Examination	N/A	TMJ LAT Open	
		TMJ LAT Close	
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

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

■ Main Imaging Programs

Examination Type	Arch Selection	ROI	Description & Sample Image
PANO Examination	Narrow	Standard	A panoramic imaging mode for patients with a V-shaped arch trajectory. (Typically for some females)  
	Normal	Standard	A panoramic imaging mode for adult patients with a normal arch trajectory.  
	Wide	Standard	A panoramic imaging mode for the patients with a square-shaped arch trajectory. (Typically for some males)  
	Child	Standard	A panoramic imaging mode for child trajectory. (Less X-ray exposure than the Normal mode by approximately more than 40%)  
	Orthogonal	Standard	A panoramic imaging mode to minimize the overlapped region of the teeth from the X-ray exposure which is beamed perpendicularly between teeth.  
		Bitewing** (Bitewing Incisor mode is Optional)	A panoramic imaging mode to acquire an image only for the region of interest through the orthogonal trajectory. (Pros: less X-ray exposure than the Normal mode. / Cons: TMJ and some parts of the maxillary sinus cannot be

Examination Type	Arch Selection	ROI	Description & Sample Image
			<p>acquired.)</p> 
SPECIAL Examination	N/A	TMJ LAT Open / Close	<p>An imaging mode to acquire a lateral image of the TMJ, in which the X-ray beam is directed on the lateral TMJ region. (TMJ Open and Close)</p> 
		TMJ PA Open / Close (Optional)	<p>An imaging mode is to acquire a TMJ image, in which the X-ray beam is directed on the frontal TMJ, with the patient's mouth open fully and close.</p> 
		Sinus LAT (Optional)	<p>A special imaging mode to acquire a Sinus image, in which an X-ray beam is directed on the lateral region of the maxillary sinus.</p> 
		Sinus PA	<p>A special imaging mode to acquire a Sinus image, in which an X-ray beam is directed on the frontal region of the maxillary sinus.</p> 

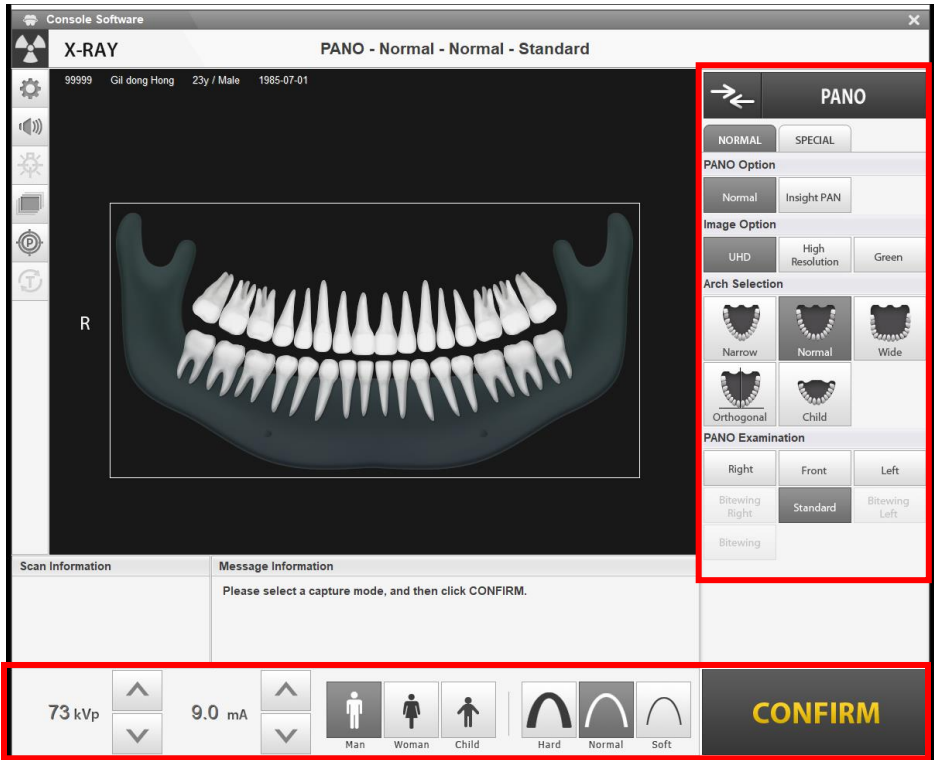
** Bitewing imaging mode is activated only when Orthogonal is selected in Arch Selection.

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.

NOTICE

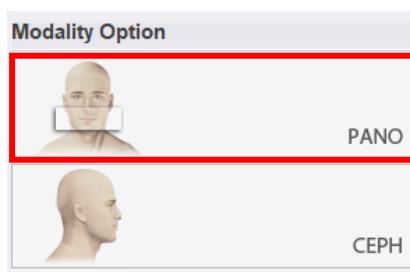
You can set the imaging parameters on the Console Software running on the PC. They are synchronized and display the same environmental settings.



7.2.1 Normal Tab

To set the exposure settings on the Normal tab:

1. Select PANO from the Modality Option.



NOTICE

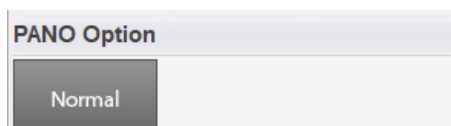
The "CEPH" button exists only when each imaging program is included in the equipment.

2. Click the **Normal** tab.



3. Select a PANO Option.

PaX-i Plus

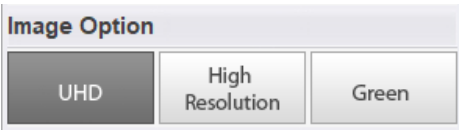


PaX-i Insight



Mode	Description
Normal (Default)	<ul style="list-style-type: none"> Provides a normal panoramic image.
Insight PAN (For PaX-i Insight Only)	<ul style="list-style-type: none"> Provides multiple panoramic images having different focal planes along with a normal panoramic image together. Enables detailed verification of the image's in-depth direction.

4. Select an Image Option.



Mode	Description
UHD (Optional)	Ultra-High-Definition image
High Resolution (Default)	High Resolution image
Green	Normal quality image

NOTICE

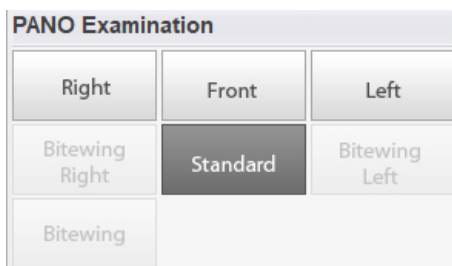
When “Insight PAN” is selected with **PaX-i Insight**, Image Options are disabled.

5. Select an Arch Selection.



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

6. Select an Examination Program in the PANO Examination panel.



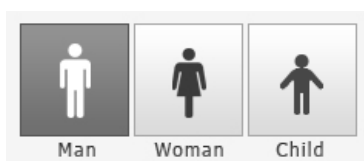
NOTICE

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



- For more information about the Examination Program, refer to the **7.1 PANO Imaging Program Overview**.

7. Select a patient type.



NOTICE

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

8. Select an X-ray intensity level.



NOTICE

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

Soft ≤ Normal ≤ Hard

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

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

73 kVp	▲	9.0 mA	▲
	▼		▼

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

CONFIRM

NOTICE

When you click **CONFIRM** button,

- The Rotating Unit will move to its scanning position.
- The **READY** button will be activated. (This means that the equipment is ready for X-ray exposure.)
- Three Laser Beams (Vertical Beam, Horizontal Beam, and Canine Teeth Beam) will be activated.
 - The Laser Beams are turned off automatically after 20 minutes or when the **READY** button is clicked.
- The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Patient Information window.

DAP
127.334307 mGy x cm²

Scan-time
13.5 Sec

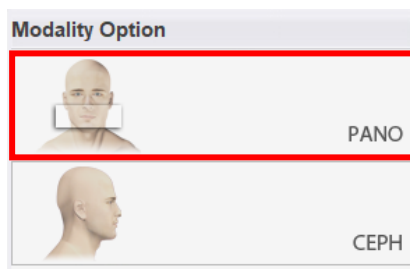
Exposure-time
13.5 Sec

11. Guide the patient to the equipment.

7.2.2 Special Tab

To set the exposure settings on the Special tab:

1. Select PANO from the Modality Option.



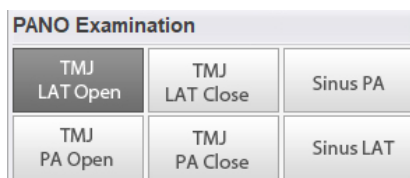
NOTICE

The “**CEPH**” button exists only when each imaging program is included in the equipment.

2. Click the **Special** tab.



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



4. Select a patient type.



NOTICE

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

5. Select an X-ray intensity level.



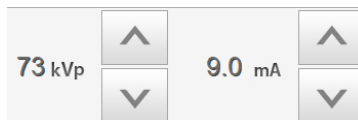
NOTICE

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

Soft ≤ Normal ≤ Hard

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

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



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

CONFIRM

NOTICE

When you click **CONFIRM** button,

- The Rotating Unit will move to its scanning position.
- The **READY** button will be activated. (This means that the equipment is ready for X-ray exposure.)
- Three Laser Beams (Vertical Beam, Horizontal Beam, and Canine Teeth Beam) will be activated.
 - The Laser Beams are turned off automatically after 20 minutes or when the **READY** button is clicked.
- The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Patient Information window.

DAP 127.334307 mGy x cm ²
Scan-time 13.5 Sec
Exposure-time 13.5 Sec

8. Guide the patient to the equipment.

7.3 Patient Positioning



WARNING

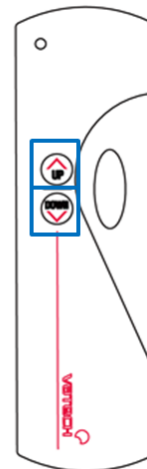
- Have patience (especially for pregnant women and children) and wear a lead apron to protect themselves from residual radiation.
- Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.

IMPORTANT

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

Getting prepared

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



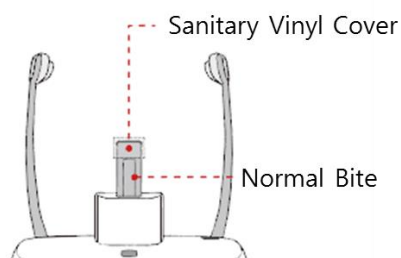
NOTICE

- In general, imaging is performed with the patient in an upright position. However, a stool may be used for imaging patients with special circumstances. If a stool is used, ensure that the beams and movement of the unit are not obstructed by the stool.

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

Normal Patient Positioning

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



Chinrest, bite blocks, and other accessories that have direct contact with the patients must be cleaned before scanning with chlorine dioxide-based alcohol-free products.



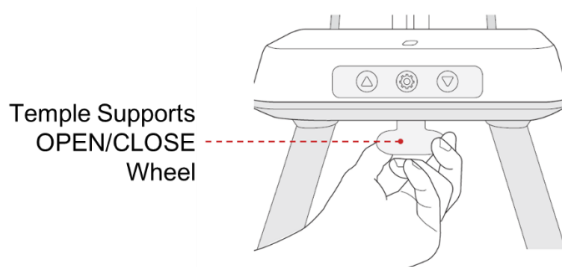
Using sanitary covers provided by VATECH is highly recommended. Contact VATECH or the nearest CS support for a new supply when the provided stock runs out.



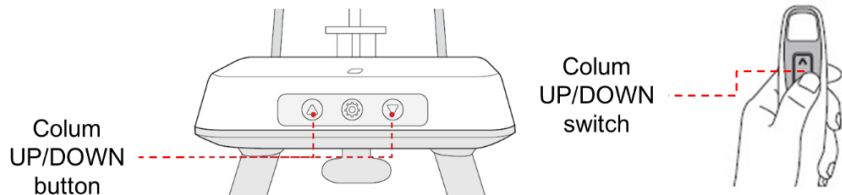
Ensure that your product conforms to one of the following standards if you are using a 3rd party product for sanitary cover:

- ISO 10993-1(Biological evaluation of medical devices)
- FDA
- CE
- Local regulations in your area

2. Loosen the **Temple Supports OPEN/CLOSE Wheel** under the control panel to widen the Temple Supports.



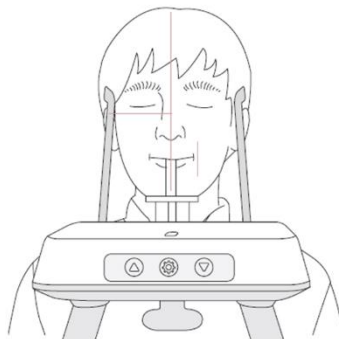
3. Guide the patient to the inside of the equipment.
4. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.



5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
6. Let the patient bite the Bite along its grooves with his/her front teeth.



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

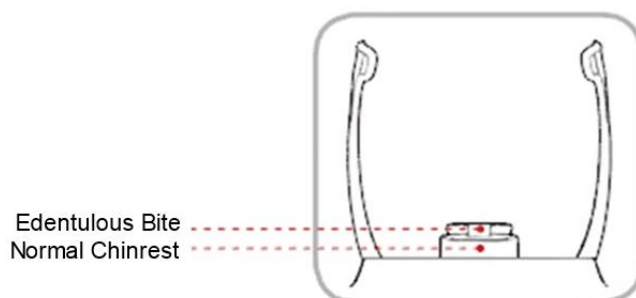


To acquire the best image possible, ask the patient not to:

- Breathe or swallow saliva during image acquisition
- Move during image acquisition

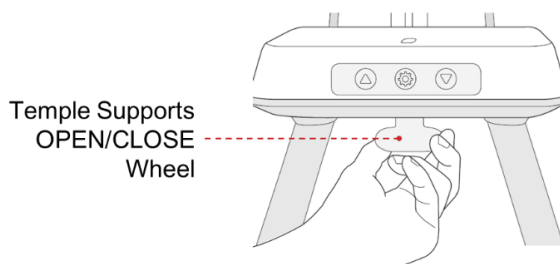
Edentulous Patient Positioning

1. Insert the **Edentulous Bite** into the **Normal Chinrest**.

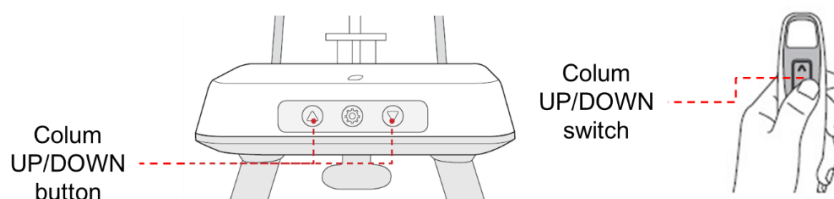


Clean the Chinrest and the Bite with ethanol and wipe with a dry towel before the next patient.

2. Loosen the **Temple Supports OPEN/CLOSE Wheel** under the control panel to widen the Temple Supports.



3. Guide the patient to the equipment.
4. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.





5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.

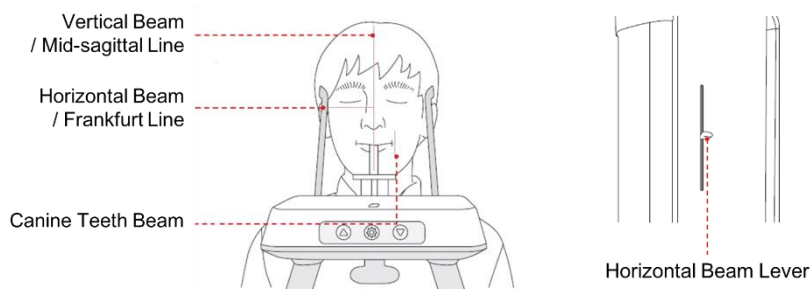
6. Let the patient maintain the posture as follows:
- Close mouth.
 - Place the tongue on the roof of the mouth.
 - Close eyes.



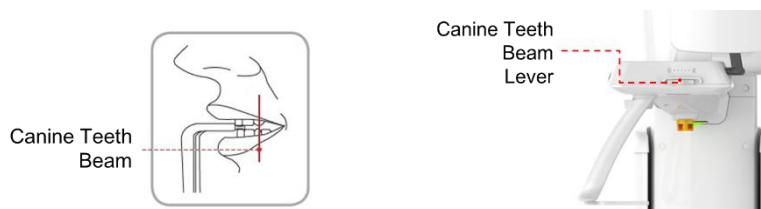
Laser Beam Aligning

WARNING	Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
CAUTION	If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the laser beam properly.
NOTICE	<ul style="list-style-type: none"> After clicking the CONFIRM button, laser beams will be turned on. Laser beams will be turned off when you click the READY button. To turn the Laser beams on/off manually, click the  icon on the Control Panel of the Handle Frame or the  icon on the Console Software.

- The Vertical Beam is fixed. Align the center of the patient's face (Mid-sagittal Line) with the Vertical Beam. (It's to prevent the horizontal expansion of the image)
- Align the Horizontal Beam in a straight line to the Frankfurt Line on the patient's face. Use the **Horizontal Beam** lever on the column (left side of the Control Panel) to position it. Make sure that the Horizontal Beam is aligned to the patient's face horizontally.



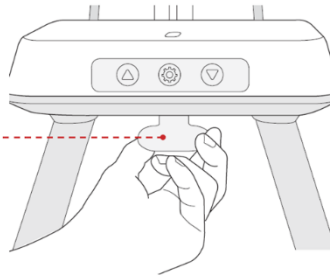
- Direct the patient to smile and align the Canine Teeth Beam to the center of the canines. Use the Canine Teeth Beam Lever (left side of the Control Panel) to adjust the position of the beam.



Finishing Patient Positioning

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

Temple Supports
OPEN/CLOSE
Wheel



2. Click the **READY** button on the Console Software. X-ray exposure has not started yet.



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

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

7.3.2 SPECIAL Examination Mode (TMJ / Sinus)

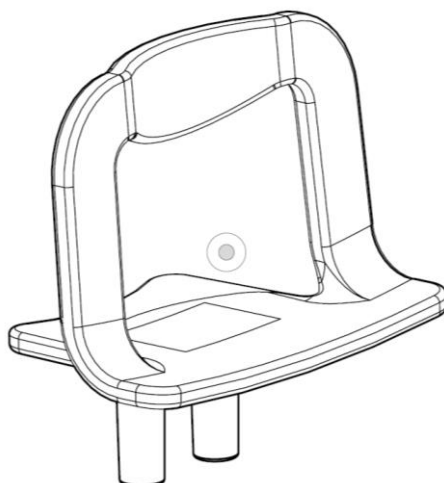
7.3.2.1 TMJ Open Mode (LAT /PA)

You need to take three steps to acquire a TMJ open image: 1) positioning the patient, 2) aligning the laser beam, and 3) X-ray exposure. You must complete the procedure for the TMJ open mode first before taking a TMJ close image.

Follow the steps below to acquire a TMJ open image.

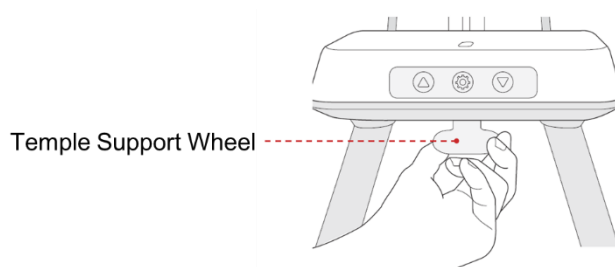
Step 1: Patient Positioning

1. Remove the **Normal Chinrest** and Insert the **SINUS/TMJ bite** into the chinrest receptacle.



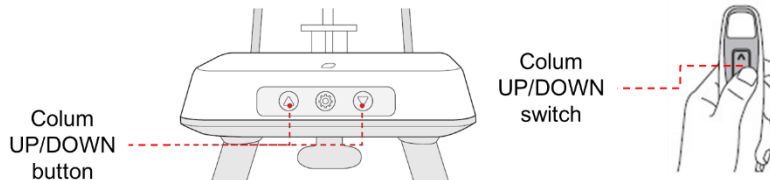
Ensure to clean Sinus/TMJ bite with ethanol and dry it with a towel each time before taking an image of the patient.

2. Turn the **Temple Support Wheel** under the control panel to open the Temple Support wide for the patient.



3. Guide the patient to the inside of the equipment.

4. Press the **Column UP/DOWN** button on the control panel or switch to adjust the height of the equipment until you see the patient's chin touches the **SINUS/ TMJ** bite.

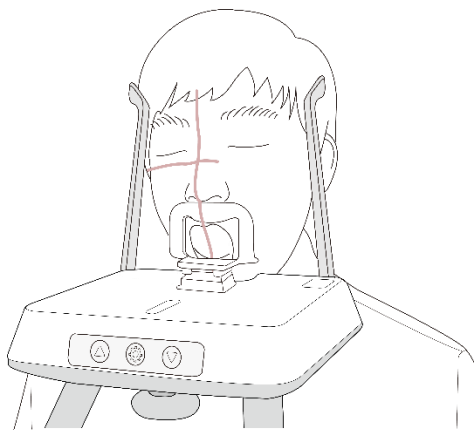


5. Ask the patient to stand in the center of the equipment and do the following:
 - Grab the handles on both sides.
 - Press the chest against the equipment.
 - Place feet inside of the base.
 - Keep both shoulders parallel.
 - Stand upright and stretch the neck straight.
6. Ask the patient to press the acanthion against the **SINUS/TMJ bite** and tilt the head forward by 5°.

IMPORTANT

Ensure that the patients do not touch the equipment with their jaws to maintain the proper position.

7. Ask the patient to maintain the posture below, until the scanning is completed :
 - Keep your mouth open.
 - Keep both eyes closed.
 - Place the tongue on the roof of the mouth.
 - Breath with the nose





Step 2: Laser Beam Alignment**WARNING**

DO NOT shine the laser beam directly into the person's eyes. This can cause vision loss or other serious damage to the eyes.

**CAUTION**

Ensure that the patient's position is properly aligned with laser beams before starting an X-ray exposure. The wrong positioning of a laser beam or person can create shadows or distortions in the image.

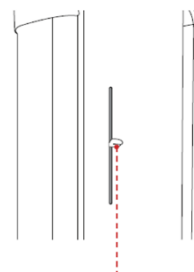
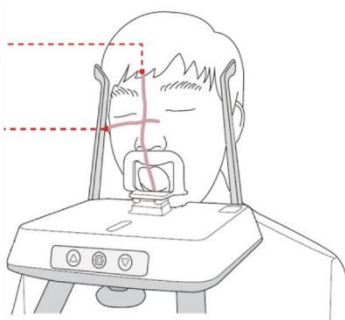
NOTICE

- When you click the **CONFIRM** button, three laser beams (vertical, horizontal, and canine teeth) are activated at once.
- All beams are turned off automatically after 20 minutes or when you click the **READY** button.
- If you want to turn on or off the laser beams manually, click the  icon on the Control Panel of the Handle Frame or the  icon on the Console Software.

1. The Vertical Beam is fixed. Align the center of the patient's face (Mid-sagittal Line) with the Vertical Beam. (It's to prevent the horizontal expansion of the image)
2. Align the Horizontal Beam in a straight line to the Frankfurt Line on the patient's face. Use the **Horizontal Beam** lever on the column (left side of the Control Panel) to position it. Make sure that the Horizontal Beam is aligned to the patient's face horizontally.

Vertical Beam
/ Mid-sagittal Line

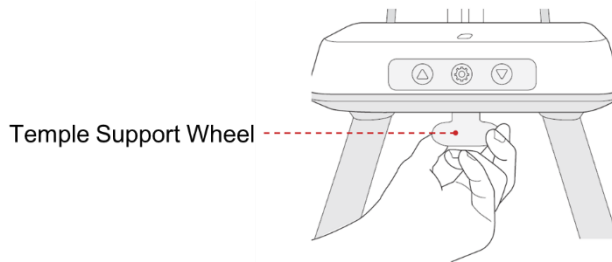
Horizontal Beam
/ Frankfurt Line



Horizontal Beam Lever

Step 3: Finishing Patient Positioning

1. After checking the positions of the patient and the laser beam, turn the Temple Support Wheel again to close temple supports to keep the patient's head from moving.



2. Click the **READY** button on the Console Software. X-ray exposure has not started yet.



Ensure that the Temple Supports are in the closed position before clicking the **READY** button.

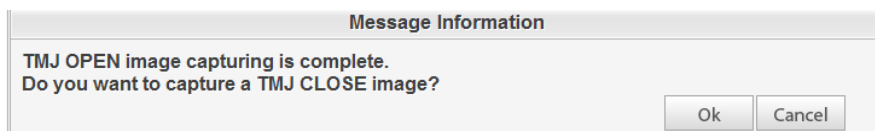
3. Now go to **7.4 X-ray Exposure** to start the exposure.

7.3.2.2 TMJ Close Mode (LAT / PA)

When you completed the procedure for TMJ open mode, the system will be ready for the TMJ close mode. Follow the steps below to acquire a TMJ close image.

Step 1: Patient Positioning

1. When you see the message "Do you want to capture a TMJ Close image?" Click the **OK** to start the TMJ close mode.



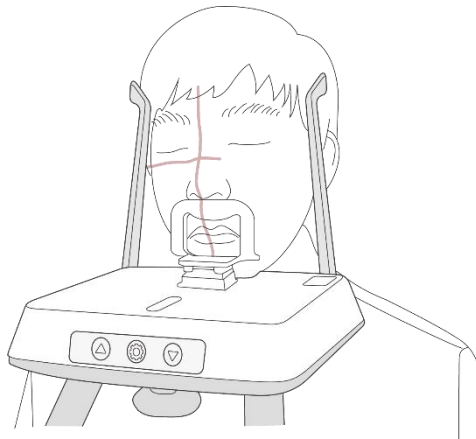
2. Turn the **Temple Support Wheel** under the control panel to open the temple support wide for the patient.
3. Guide the patient to the inside of the equipment.
4. Ask the patient to stand in the center of the equipment and do the following:
 - Grab the handles on both sides
 - Press the chest against the equipment
 - Place feet inside of the base.
 - Keep both shoulders parallel.
 - Stand upright and stretch the neck straight
5. Ask the patient to press the acanthion against the **SINUS/TMJ bite** and tilt the head forward by 5°.

IMPORTANT

Ensure that the patient does not touch the equipment with their jaws to keep the proper position.

6. Ask the patient to maintain the posture as follows until the scanning is completed:

- Close the mouth
- Place the tongue on the roof of the mouth
- Close eyes
- Breath with nose

**NOTICE**

The support unit of the integrated Chinrest must touch the patient's acanthion.

Step 2: Laser Beam Alignment

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

Step 3: Finishing Patient Positioning

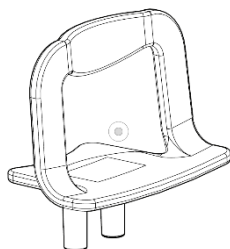
This is the same as the one for TMJ Open mode.

7.3.2.3 Sinus Mode (LAT / PA)

Follow the steps below to acquire an image in Sinus mode.

Step 1: Patient Positioning

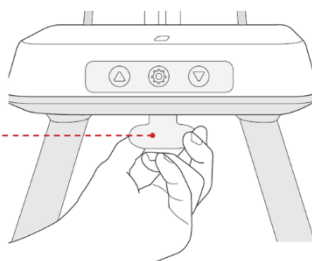
1. Remove the **Normal Chinrest** and Insert the **SINUS/TMJ bite**.



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

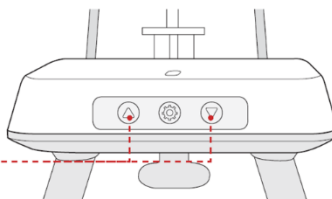
2. Turn the **Temple Supports Wheel** under the control panel to open the Temple Supports wide for the patient.

Temple Support Wheel



3. Guide the patient to the inside of the equipment.
4. Press the **Column UP/DOWN** button on the control panel or switch to adjust the height of the equipment until you see the patient's chin touches the **SINUS/ TMJ bite**.

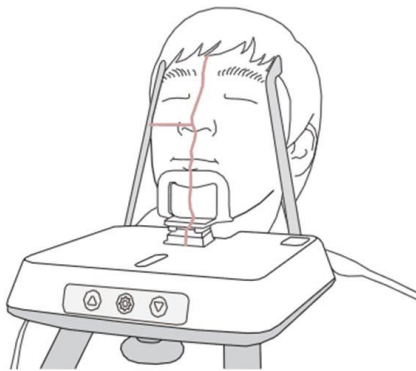
Column
UP/DOWN
button



Column
UP/DOWN
switch



5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Grab the handles on both sides
 - Press the chest against the equipment
 - Place feet inside the base
 - Keep both shoulders parallel
 - Stand upright and stretch the neck straight
6. Guide the patient to press the acanthion against the SINUS/TMJ bite and tilt the head backward about 10° ~ 15°.
7. Ask the patient to maintain the posture below until the scanning is completed :
 - Close the mouth
 - Place the tongue on the roof of the mouth
 - Close eyes
 - Breath with nose and stop swallowing



Step 2: Laser Beam Alignment



WARNING

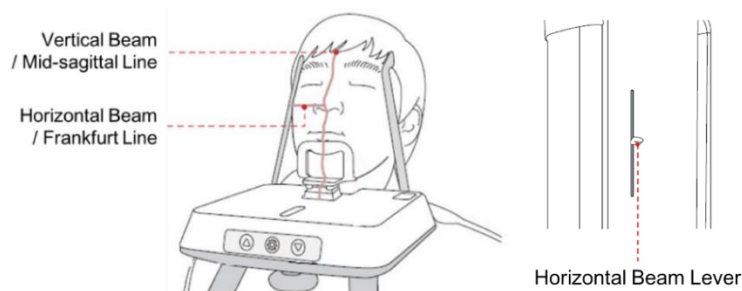
Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.



CAUTION

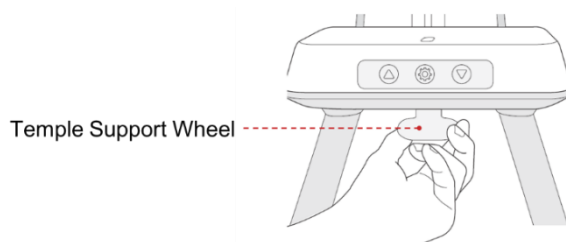
If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the Laser Beam properly.

1. The Vertical Beam is fixed. Align the center of the patient's face (Mid-sagittal Line) with the Vertical Beam. (It's to prevent the horizontal expansion of the image)
2. Align the Horizontal Beam in a straight line to the Frankfurt Line on the patient's face. Use the **Horizontal Beam** lever on the column (left side of the Control Panel) to position it. Make sure that the Horizontal Beam is aligned to the patient's face horizontally.



Step 3: Finishing Patient Positioning

1. After confirming that both patients and laser beams are properly positioned, turn the **Temple Support Wheel** to close the part to keep the patient's head from moving.



2. Click the **READY** button on the Console Software. X-ray exposure has not started yet.






CAUTION

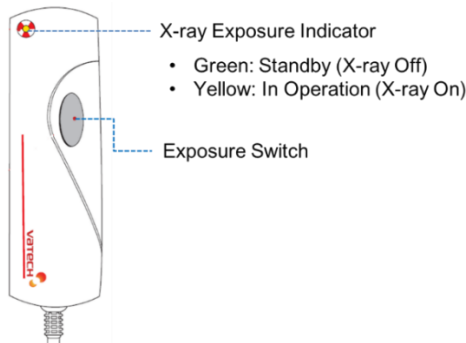
Ensure that the Temple Supports are in the closed position before clicking the **READY** button.




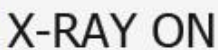
3. Now go to **7.4 X-ray Exposure** to start the exposure.

7.4 X-ray Exposure

	<ul style="list-style-type: none">▪ If an emergency occurs during image acquisition, release the Exposure Switch to cease X-ray emission.▪ The operator shall observe the X-ray safety regulations applicable to his/her area always during the operation of this equipment.
	<ul style="list-style-type: none">▪ The operator must keep vocal/visual contact with the patient always during the image acquisition process.▪ Do not operate the PC during exposure. Doing so may cause the system to malfunction.
	<ul style="list-style-type: none">▪ Ask patients to close their eyes during the operation.▪ To acquire optimized images, instruct the patient to hold his/her breath and not swallow. Also, don't let the patient move until the Temple Supports are open.

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



	The image appears on the screen.
	<p>During X-ray exposure, the status appears as follows.</p> <ul style="list-style-type: none">▪ The X-ray Exposure Indicator of the Exposure Switch and the LED light on the top of the equipment turn yellow.▪ An alert sound comes out to indicate that X-ray emission is currently underway.▪ On Console Software, the radiation mark turns yellow, and "X-RAY" changes to "X-RAY ON".  

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

7.5 Finishing the Scan

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

7.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.
The exported images can be confirmed in **EzDent-i**.

NOTICE

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

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

8. Acquiring CEPH Images (Optional)

8.1 CEPH Imaging Program Overview

■ Result Images




It provides conventional 2D cephalometric images.

■ Image Acquisition Method




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

■ Examination Programs

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

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

8. Acquiring CEPH Images (Optional)

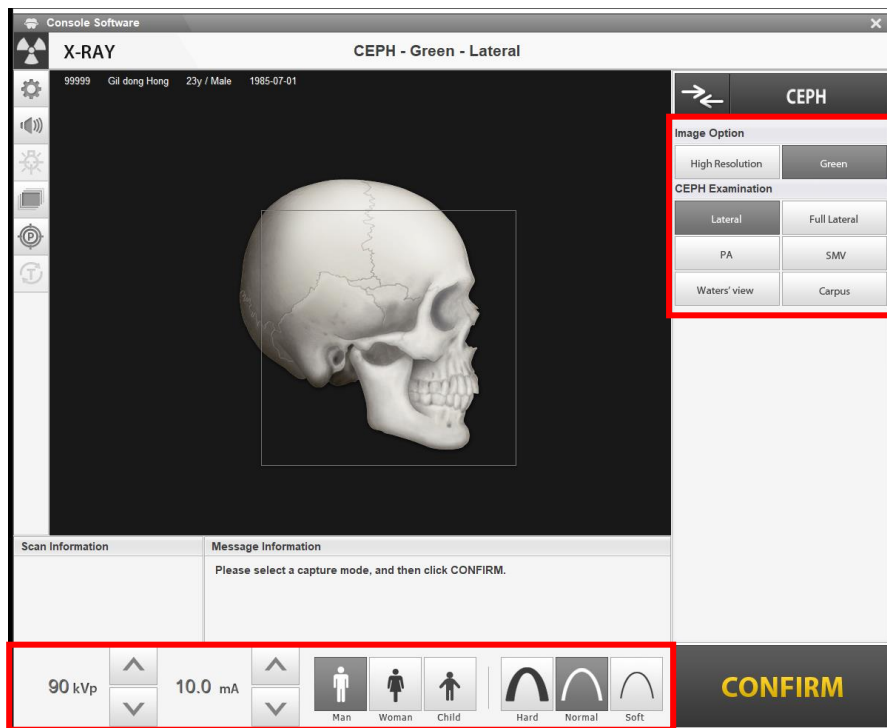
Examination Area	Description	Position
	in Orthodontics and Oral and Maxillofacial Surgery.	
SMV	<ul style="list-style-type: none"> Used to study the base of the skull, horizontal angulation of the mandibular condylar axis, the sphenoid sinus, the curvature of the lower jaw, the side wall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull. 	 <SMV>
Waters' view	<ul style="list-style-type: none"> Used to study the frontal sinus, the antrum ethmoidale, the optic disc pit, the frontozygomatic suture, the nasal cavity, and the coronoid process between the upper jaw and the zygomatic arch. 	 <Waters' view>
Carpus	<ul style="list-style-type: none"> Used to assess hand bone age to compare the changes in the skull. 	 <Carpus>

8.2 Configuring Exposure Parameters

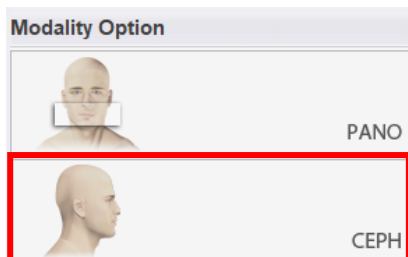
To acquire CEPH images, **6. Getting Started** must be completed first.

NOTICE

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



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

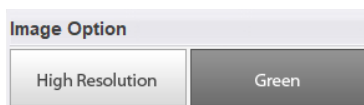


NOTICE

The “**CEPH**” button exists only when each imaging program is included in the equipment.

8. Acquiring CEPH Images (Optional)

2. Select an Image Option.



Mode	Description
High Resolution	High quality image
Green	Low dose image

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



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



NOTICE

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

5. Select X-ray intensity.



NOTICE

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

Soft ≤ Normal ≤ Hard

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

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

90 kVp	↑	10.0 mA	↑
	↓		↓

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

CONFIRM**NOTICE**

When you click **CONFIRM** button,

- The **READY** button will be activated. (This means that the equipment is ready for X-ray exposure.)
- The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Patient Information window.

DAP
127.334307 mGy x cm²

Scan-time
13.5 Sec

Exposure-time
13.5 Sec

8. Guide the patient to the equipment.

8.3 Patient Positioning



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



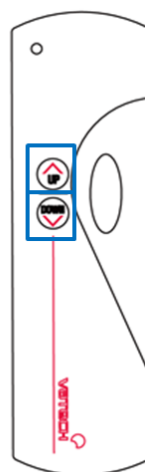
Ensure that the Nasal Positioner is left unfolded, before adjusting the Ear Rods in the proper direction.



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

Getting prepared

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



NOTICE

- In general, imaging is performed with the patient in an upright position. However, a stool may be used for imaging patients with special circumstances. If a stool is used, ensure that the beams and movement of the unit are not obstructed by the stool.

8.3.1 Lateral / Full Lateral Mode

NOTICE

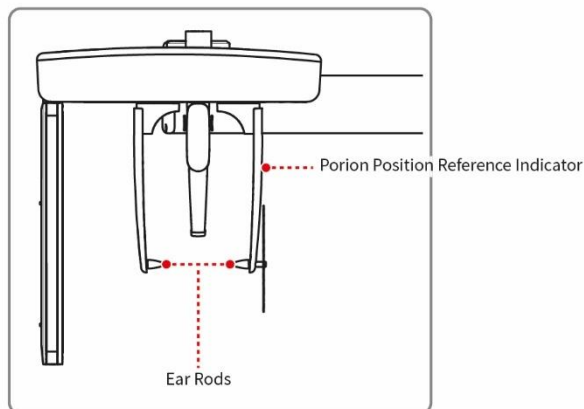
Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.

Patient Positioning

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



2. Leave enough space between the Ear Rods.



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

! CAUTION

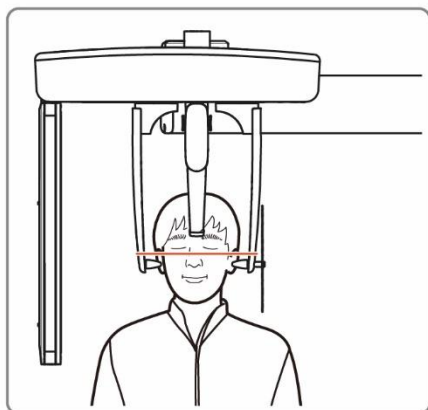
Before securing the patient's head with ear rods and the nasal positioner, ensure that you have finished adjusting the column's height for the patient.

8. Acquiring CEPH Images (Optional)

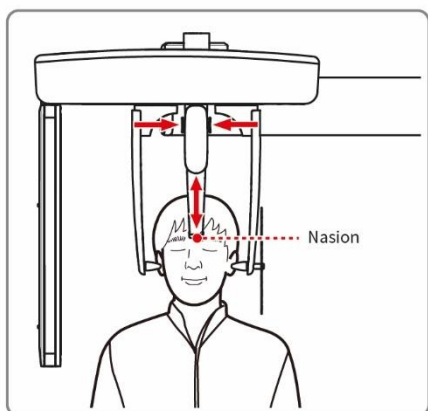
6. Push the ear rods inward to secure patient's head, ensuring the tips of both ear rods slightly overlap the patient's ear canal.

NOTICE

Ensure that the patient's Frankfurt plane is parallel to the floor.



7. Place the nasal positioner at the patient's nasion point.



8. Direct the patient to swallow first before closing the mouth and to remain in his/her current position until image acquisition is completed.
9. Click the **READY** button on Console Software. No X-ray will be emitted at this point.
10. Now go to **8.4 X-ray Exposure** to start the exposure.

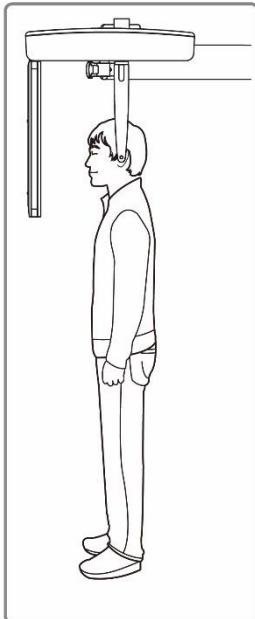
8.3.2 PA Mode

Patient Positioning

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



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



8. Acquiring CEPH Images (Optional)

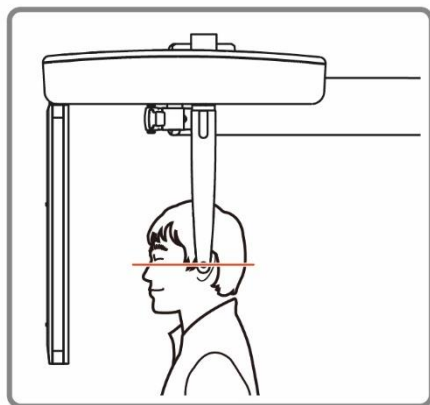
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to approximately match the height of the patient.



WARNING

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

6. During the operation, properly align the Ear Rods to the patient's ears so his/her head does not move.
7. Align horizontally so the patient's Frankfurt Line is parallel to the floor.



8. Direct the patient to swallow first before closing his/her mouth and to remain in his/her current position until image acquisition is completed.
9. Click the **READY** button on Console Software. No X-ray will be emitted at this point.
10. Now go to **8.4 X-ray Exposure** to start the exposure.

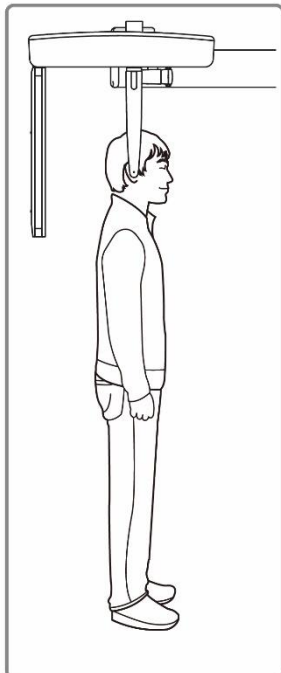
8.3.3 SMV Mode

Patient Positioning

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



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



8. Acquiring CEPH Images (Optional)

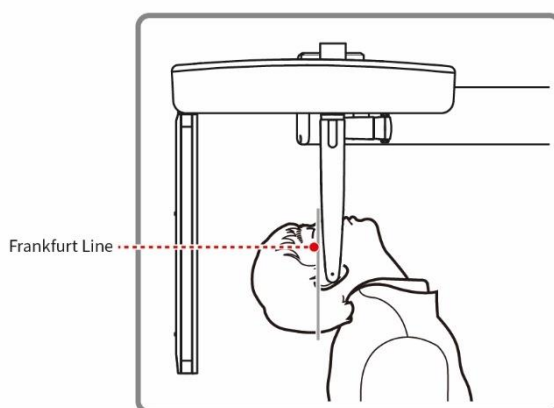
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to approximately match the height of the patient.



WARNING

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

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



9. Click the **READY** button on Console Software. No X-ray will be emitted at this point.
10. Now go to **8.4 X-ray Exposure** to start the exposure.

8.3.4 Waters' View Mode

Patient Positioning

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

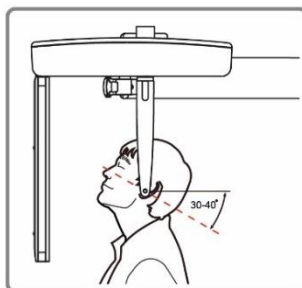


2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Waters' view mode.
3. Guide the patient to the CEPH unit.
4. Ask the patient to stand upright facing the sensor. Make sure that the patient's shoulders are level and that his/her neck is relaxed.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to approximately match the height of the patient.



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

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



8. Click the **READY** button on Console Software. No X-ray will be emitted at this point.
9. Now go to **8.4 X-ray Exposure** to start the exposure.

8.3.5 Carpus Mode

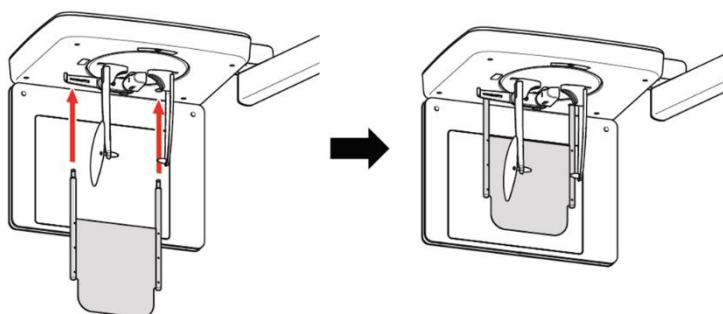
For Carpus Mode, install the Carpus Plate first before positioning the patient.

Installing the Carpus Plate

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



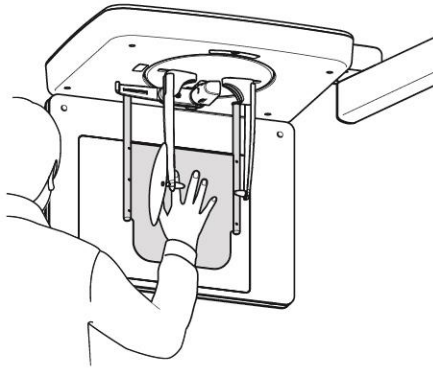
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Carpus mode.
3. Fit the two ends of the Carpus Plate into the two holes of the CEPH unit as below.



4. Confirm that the Carpus Plate is safely mounted.

Patient Positioning

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



2. Ask the patient to close his/her eyes and stand still until the image acquisition is completed.
3. Click the **READY** button on Console Software. No X-ray will be emitted at this point.
4. Now go to **8.4 X-ray Exposure** to start the exposure.

8.4 X-ray Exposure



- If an emergency occurs during image acquisition, release the **Exposure Switch** to cease X-ray emission.
- The operator shall observe the X-ray safety regulations applicable to his/her area always during the operation of this equipment.

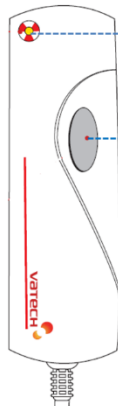


- The operator must keep vocal/visual contact with the patient always during the image acquisition process.
- Do not operate the PC during exposure. Doing so may cause the system to malfunction.



- Ask the patients to close their eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not swallow.

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



X-ray Exposure Indicator

- Green: Standby (X-ray Off)
- Yellow: In Operation (X-ray On)

Exposure Switch

NOTICE

The image appears on the screen.

NOTICE

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

- The X-ray Exposure Indicator of the Exposure Switch and the LED light on the top of the equipment turn yellow.
- An alert sound comes out to indicate that X-ray emission is currently underway.
- On Console Software, the radiation mark turns yellow, and "X-RAY" changes to "X-RAY ON".



X-RAY ON

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

8.5 Finishing the Scan

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

8.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

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

NOTICE

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

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

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9. Troubleshooting

9.1 Troubleshooting

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

If the equipment is not working

Cause	Actions to be taken
Failure of power supply	Check the equipment's power supply.
Initialization status	Wait until the equipment has been initialized and then try again.
Failure of the Control PC's connection	Check the connection status of the 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.

9.2 Error Codes

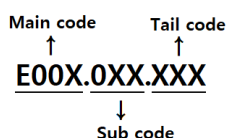
In instances of abnormal operation, error messages will be displayed on the Control Panel. Error Code Guide is intended to assist technicians to understand and deal with error codes. Follow the instructions described in the tables below to resolve the problem.

IMPORTANT

Error messages will be displayed in the format written below.

[Code: E00X.0XX.XXX]

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



The **main code** indicates the source of error codes. The source is categorized as hardware, software, acquisition module, etc.

Subcode describes the specific area where an error has occurred according to the Main code.

Tail Code explains the detailed symptoms and causes of the errors mentioned in the subcode.

IMPORTANT

The tables of the following chapter consist of four parts: Tail Code, Description, Solution, and CS Part List.

Tail Code	Description	Solution

Tail Code explains the detailed symptoms and causes of the errors mentioned in the subcode.

The description provides a brief cause of the problems according to each error code.

The solution provides instructions to solve the problem according to each error code.

It is categorized into three parts: Essential, Recommended, and Optional.

9.2.1 Hardware

9.2.1.1 Main code (001)

9.2.1.1.1 Subcode – Generator-related error (001)

Tail Code	Description
001	Appears when the tube is not ready for use
002	Appears when the cable between the tube tank and Inverter board is disconnected
003	Appears when the current of the inverter board exceeds the maximum allowable level during X-ray irradiation
004	Appears when there is $\pm 10\text{kV}$ or more voltage difference in tube voltage compared to the reference value
005	Appears when there is $\pm 0.5\text{mA}$ or more current difference in tube current compared to the reference value
006	Appears when there is $\pm 20\text{kV}$ or more voltage difference in tube voltage feedback compared to the normal value
007	Appears when there is $\pm 1\text{mA}$ or more current difference in tube current feedback compared to the normal value
008	Appears when the temperature of the mono tank is above the setting temperature
009	Appears when the inverter output current is higher than 1A during X-ray irradiation (In EP, IP condition)
010	Appears when the inverter board falsely recognizes the exposure switch signal as OFF after the irradiation On command
011	Appears when the X-ray OFF command is not sent to the inverter board in 0.5 seconds after turning off the exposure switch
012	Appears when kV feedback is over -20kV compared to the setting value during X-ray irradiation
013	Appears when kV feedback is over $+20\text{kV}$ compared to the setting value during X-ray irradiation
014	Appears when the mA feedback value is less than 50% compared to setting condition during X-ray irradiation
015	Appears when the mA feedback value is higher than 150% compared to setting conditions during X-ray irradiation

9.2.1.1.2 Subcode - Motor-related error (002)

Tail Code	Description
020	Appears during p-axis motor origin movement
021	Appears during rotator-axis motor origin movement
027	Appears during Cephalo sensor motor origin movement
036	Appears during mono-axis collimator left/right origin movement
037	Appears during generator tilting
039	Appears during X-axis motor origin movement

9.2.1.1.3 Subcode – Exposure switch-related error (003)

Tail Code	Description
060	Appears if the exposure switch is pressed when turning on the equipment.

9.2.1.1.4 Subcode – Other error (004)

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

9.2.2 Software

9.2.2.1 Main code (002)

9.2.2.1.1 Subcode – Sequence-related error (001)

Tail Code	Description
001	Appears when the Packing Mode is not enabled
002	Appears when the door is open
003	Appears when the exposure switch is pressed

9.2.2.1.2 Subcode – PC Resolution related error (010)

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

9.2.2.1.3 Subcode – PC Network-related error (02X)

Tail Code	Description
N/A (0XX)	Appears when there is a problem related to the PC Network connection

9.2.2.1.4 Subcode – PC Network-related error (03X)

Tail Code	Description
N/A (0XX)	Appears when there is a library-related error

9.2.2.1.5 Subcode – File-related error (06X)

Tail Code	Description
N/A (0XX)	Appears when the Patient.ini file cannot be found

9.2.3 Acquisition Module

9.2.3.1 Main code (003)

9.2.3.1.1 Subcode – Initialization Failure-related error (010)

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

9.2.3.1.2 Subcode – Capture Failure related error (020)

Tail Code	Description
000	Appears when there is a capture error

9.2.3.1.3 Subcode – Reconstruction Failure-related error (030)

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

9.2.3.1.4 Subcode – Hardware-related error (061)

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

10. Cleaning and Disinfection

10.1 Before Cleaning

Before cleaning, ensure to take the following actions:

- Turn off the equipment.
- Wear safety gloves

When you select a product, ensure that the product meets the following condition:

- Silicone-free and Alcohol-free
- Chlorine dioxide base.
- Does not contain oil and gas that can be abrasive and corrosive.
- Does not contain the following chemicals: acetone, phenol, acetic acid, peroxide, sodium hypochlorite, isopropyl alcohol (2-propanol, isopropanol), iodine-splitting agents, and oxygen-splitting agents.
- An FDA-approved product that also satisfies local regulations on the chemical product.



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

10.2 Cleaning

Clean the accessories and parts that directly contact the patient's mucous membranes, each time you use them. These parts include but are not limited to

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

When you clean these accessories, ensure to use the product outlined in **10.1 Before Cleaning**. The table below shows the cleaning procedure for some accessories and parts.

Accessory /Part	Procedure
Bite (Normal / Special A / Special B)	1) Remove all visible soil with a paper wipe or disposable cloth. 2) Using a soft cloth dampened with a cleaning product, gently wipe the areas you target to clean. 3) Dry the components or accessories with a paper wipe or clean, dry cloth until no liquid is left.
Temple Supports	
Chinrest	
Computer and peripherals	Clean the components following the manufacturer's instructions
Outer covers	Wipe the covers with a dry cloth once a day.



DO NOT spray or pour the cleaning product directly into the equipment. Direct contact with liquids can damage the equipment and cause a fire.

IMPORTANT

DO NOT soak the cloth in liquids to prevent dripping into the equipment. Always dampen the cloth with a cleaning agent.

10.3 Disinfection

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

- Use disinfectants that satisfy national and regional standards. The product you chose must be approved for its safety by your region's regulatory body.
- Use a disinfectant product for the parts that are frequently touched or come to contact with the patients and staff.
- Do not use UV sterilizer to disinfect the equipment. UV light can discolor the surface of the equipment.
- Always follow the directions on the label.

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11. Maintenance

11.1 Regular Maintenance

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

11.2 Maintenance Task Checklist

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

12. Disposing of the Equipment

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

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

Parts	Materials	Recyclable	To the special disposal site	Hazardous waste; Needs Separate Collection
Frame and Covers	Aluminum and plastics	•		
Motors		•		
Circuit Boards		•		
Cables and Transformer	Copper	•		
	Steel	•		
	Oil		•	
Packing	Wood	•		
	Cardboard	•		
	Paper	•		
X-ray Tube				•
Sensor Head	Return the Sensor Head to VATECH			
Other parts			•	



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.

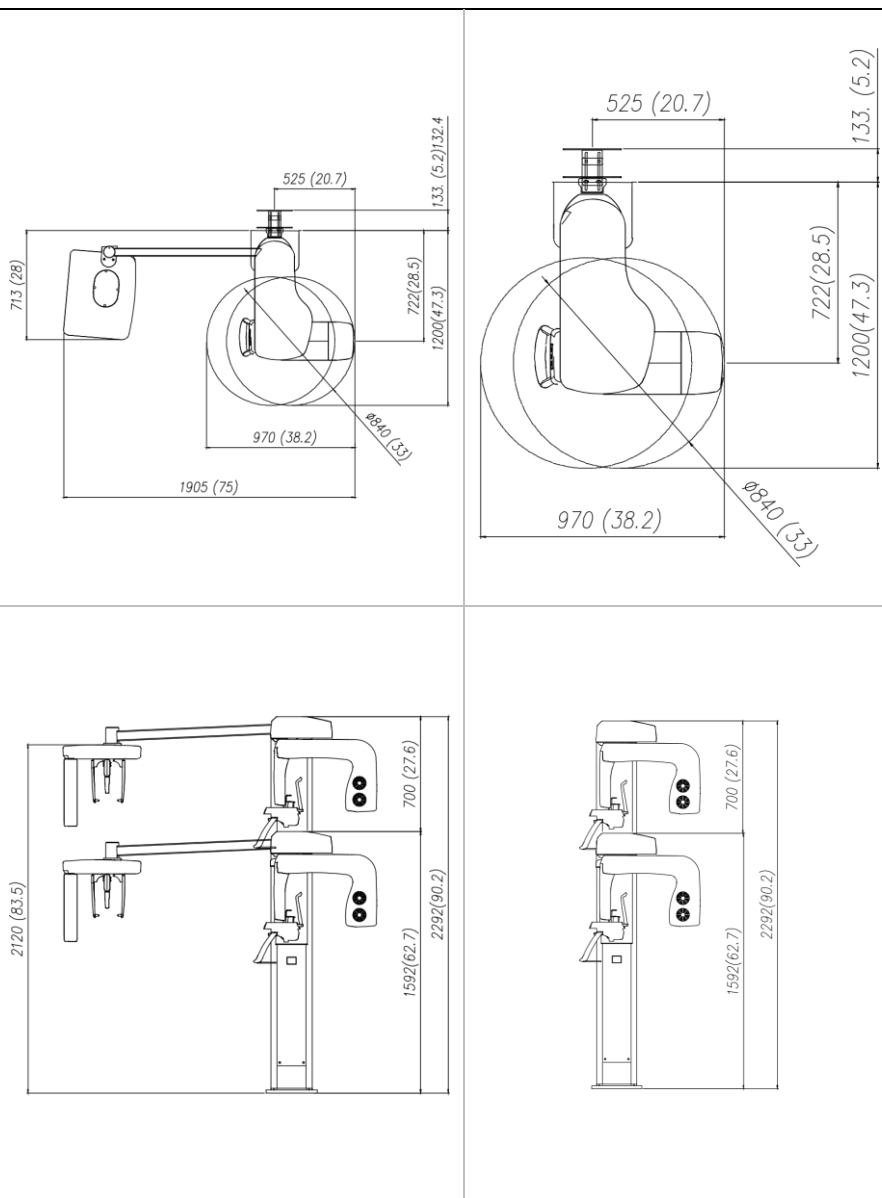
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13.1 Mechanical Specifications

13.1.1 Dimensions (unit = mm)

PaX-i Plus / PaX-i Insight (Model: PCH-30CS) User Manual

Without Base



Item		Description
Weight	Without CEPH unit	95 kg (209.4 lbs. – without Base)
		135 kg (297.6 lbs. – with Base)
	With CEPH unit	120 kg (264.5 lbs. - without Base)
		160 kg (352.7 lbs. - with Base)
Total Height	Without Base	Max. 2292 mm
	With Base	Max. 2320 mm
Dimensions during operation (Length x Width x Height)	Without CEPH unit	970 mm (L) x 1333 mm (W) x 2292 mm (H) (without Base)
		990 mm (L) x 1333 mm (W) x 2320 mm (H) (with Base)
	With CEPH unit	1905 mm (L) x 1333 mm (W) x 2292 mm (H) (without Base)
		1905 mm (L) x 1333 mm (W) x 2320 mm (H) (with Base)
Rotating Unit Vertical Movement		Max. 700mm
Installation type		Base Stand / Wall Mount (Default: Wall Mount type)
Packing Box Organization		Main Box, CEPH Box (Optional), Base Box (Optional)

13.1.2 Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	490.3	375.5	114.6	1: 1.3
CEPH	1745	1524	221	1: 1.14

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

13.2 Technical Specifications

13.2.1 X-ray Generator Specifications

Specifications

Item			Description
Generator	Model		DG-07D21T2
	Rated output power		1.0 kW
	Inverter model name		INV-21
	Type		Inverter
	Normal/ Pulse	kVp	60 kV ~ 99 kV (1 kV increment)
		mA	4 mA ~ 10 mA (1 mA increment)
	Cooling		Air Cooling / Protect $\geq 60^{\circ}\text{C}$ 1:60 or more (Exposure time: interval time)
	Total filtration		Min. 2.5 mm Al
Tube	Added filter		1.5 mm Al (Fixed)
	Manufacturer		Canon Electron Tubes & Devices
	Model		D-052SB (Stationary Anode type)
	Focal spot size		0.5 mm x 0.5 mm (IEC 60336)
	Target Angle		5 degrees
	Permanent Filtration		At least 0.8 mm Al equivalent at 50 kV
	X-ray Coverage		95 mm x 380 mm at SID 550 mm
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time: Interval time)

Test Condition

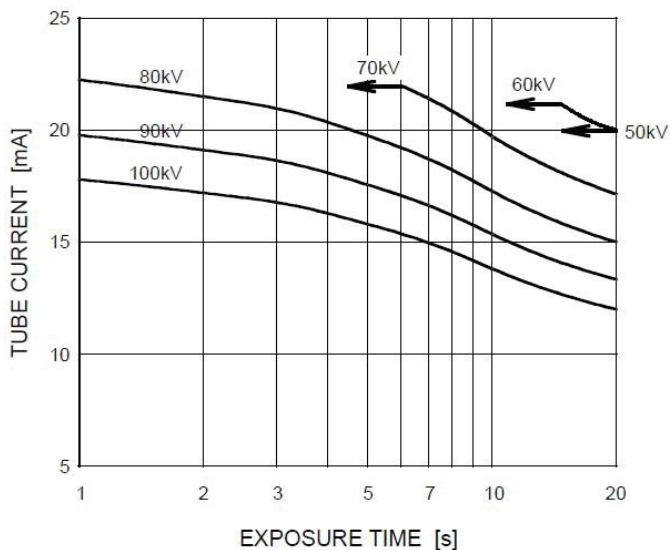
Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	60 ~ 99	4 ~ 10	20.2
	60 ~ 99	4 ~ 10	17.2
	60 ~ 99	4 ~ 10	16.7
	60 ~ 99	4 ~ 10	14.5
	60 ~ 99	4 ~ 10	13.8
	60 ~ 99	4 ~ 10	13.5
	60 ~ 99	4 ~ 10	11.5
	60 ~ 99	4 ~ 10	11.2
	60 ~ 99	4 ~ 10	11.1
	60 ~ 99	4 ~ 10	10.3
	60 ~ 99	4 ~ 10	10.1
	60 ~ 99	4 ~ 10	9.7
	60 ~ 99	4 ~ 10	9.2
	60 ~ 99	4 ~ 10	8.6
	60 ~ 99	4 ~ 10	8.4
	60 ~ 99	4 ~ 10	7.3
	60 ~ 99	4 ~ 10	7.2
	60 ~ 99	4 ~ 10	6.8
	60 ~ 99	4 ~ 10	6.7
	60 ~ 99	4 ~ 10	6.2
	60 ~ 99	4 ~ 10	6.1
	60 ~ 99	4 ~ 10	6.0
	60 ~ 99	4 ~ 10	5.9
	60 ~ 99	4 ~ 10	5.7
	60 ~ 99	4 ~ 10	5.2
	60 ~ 99	4 ~ 10	5.1

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
	60 ~ 99	4 ~ 10	5.0
	60 ~ 99	4 ~ 10	4.9
	60 ~ 99	4 ~ 10	4.8
	60 ~ 99	4 ~ 10	4.3
	60 ~ 99	4 ~ 10	3.7
	60 ~ 99	4 ~ 10	3.6
	60 ~ 99	4 ~ 10	3.1
	60 ~ 99	4 ~ 10	2.6
	60 ~ 99	4 ~ 10	2.5
	60 ~ 99	4 ~ 10	1.8
	60 ~ 99	4 ~ 10	1.3
	60 ~ 99	4 ~ 10	1.9
CEPH	60 ~ 99	4 ~ 10	2.4
	60 ~ 99	4 ~ 10	3.9
	60 ~ 99	4 ~ 10	4.9
	60 ~ 99	4 ~ 10	5.4
	60 ~ 99	4 ~ 10	

Maximum Rating Charts

Constant potential high-voltage generator

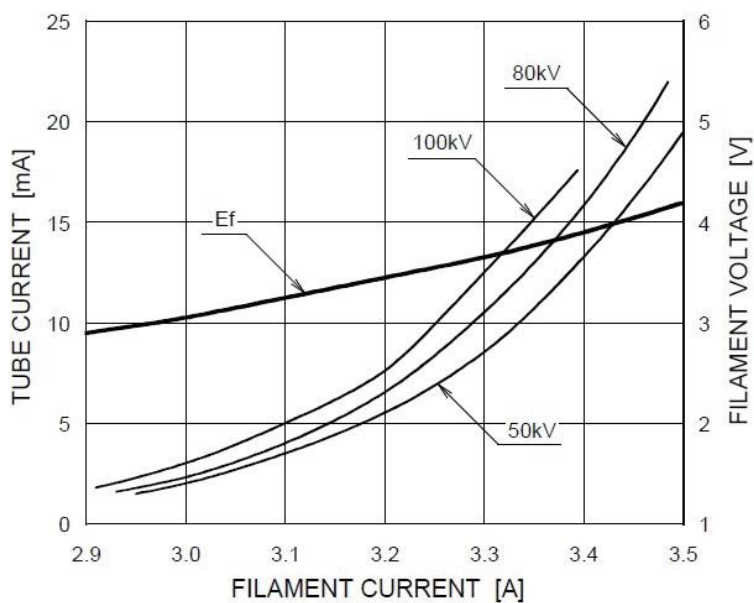
Nominal Focus Spot Value: 0.5



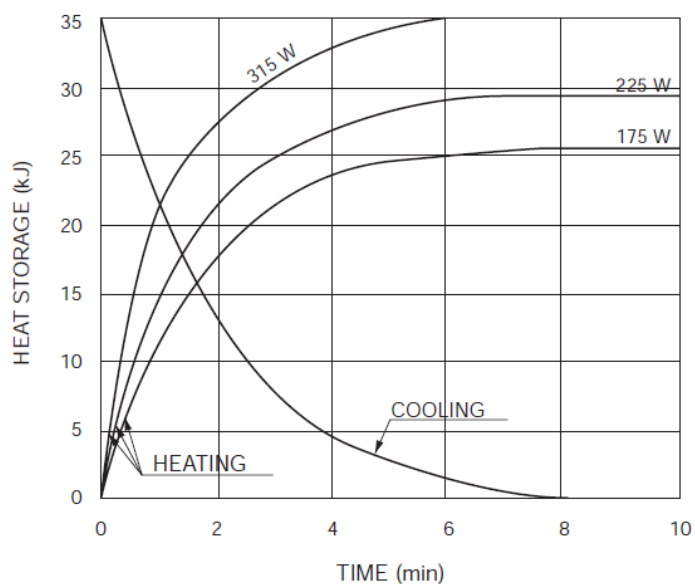
Emission & Filament Characteristics

Constant potential high-voltage generator

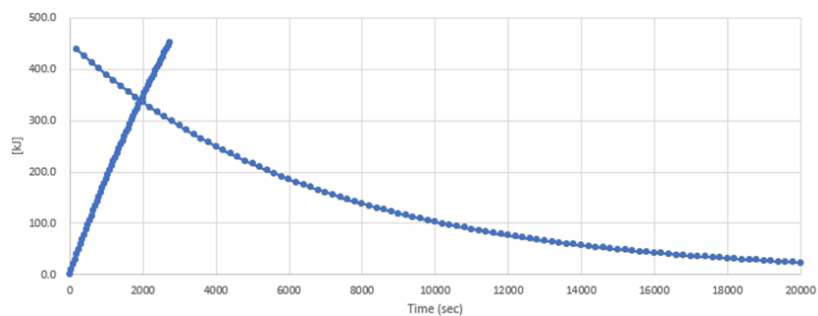
Nominal Focus Spot Value: 0.5



■ ■ Anode Thermal Characteristics



■ ■ X-ray Tube Assembly Heating / Cooling Curve



13.2.2 Detector Specifications

■ PaX-i Plus

Item	Description	
	PANO	CEPH
Model	Xmaru1501CF-PLUS	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	100 μm @ Full Resolution	200 μm @ 2X2 Binning
Active area(mm)	151.20 x 6.0	259.20 x 15.60
Frame Rate	~ 287 fps @ Full Resolution	~ 320 fps @ 2x2 binning
Analogue-Digital Conversion	14 bits	
Operating Condition	10 ~ 35 °C (Temperature) 10 ~ 75 % (Humidity)	
Storage Condition	-10 ~ 60 °C (Temperature) 10 ~ 75 % (Humidity)	
Sensor Size(mm)	79 (L) x 174 (W) x 30.2 (H)	110 (L) x 279 (W) x 20 (H)
Sensor Weight(kg)	0.45	<1.0
Converter	Csl: TI	
Energy Range(kVp)	50 - 120	40 - 120
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 55 % @ 1 lp/mm > 13 % @ 2.5 lp/mm	> 2 % @ 2.5 lp/mm
Dynamic Range	$\geq 70\text{dB}$	$\geq 68\text{dB}$

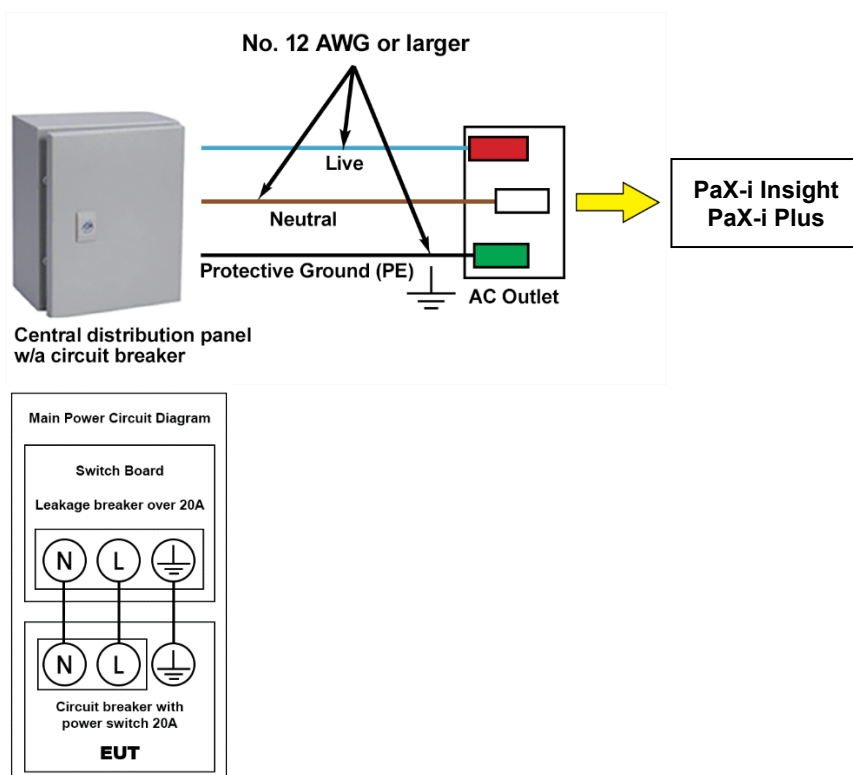
■ PaX-i Insight

Item	Description	
	PANO	CEPH
Model	Xmaru1404CF-PLUS	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 μm @ 4X4 Binning	200 μm @ 2X2 Binning
Active area (mm)	135.8 x 5.9	259.20 x 15.60
Frame Rate	~ 308 fps @ 4x4 binning	~ 320 fps @ 2x2 binning
Analogue-Digital Conversion	14 bits	
Operating condition	10 ~ 35 $^{\circ}\text{C}$ (Temperature) 10 ~ 75 % (Humidity)	
Storage condition	-10 ~ 60 $^{\circ}\text{C}$ (Temperature) 10 ~ 75 % (Humidity)	
Sensor Size (mm)	160 (L) x 230 (W) x 26 (H)	110 (L) x 279 (W) x 20 (H)
Sensor weight (kg)	1.6	<1.0
Converter	Csl: TI	
Energy Range (kVp)	40 – 120	
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 45% @ 1.0 lp/mm @ 4X4 binning	>2% @ 2.5 lp/mm
Dynamic Range	> 80dB @ 4X4 binning	\geq 68dB

13.3 Electrical Specifications

Item	Description
Power supply voltage	100 - 240 V ~
Frequency	50 / 60 Hz
Power rating	1.3 kVA
Accuracy	Tube Voltage (kVp) $\pm 10 \%$ Tube Current (mA) $\pm 20 \%$ Exposure Time (s) $\pm (5 \% + 50 \text{ ms})$

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



NOTICE

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

13.4 Environmental Specifications

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

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14. Appendices

14.1 Recommended X-ray Exposure Tables

14.1.1 PANO Mode

Exposure Condition

■ PANO Option > Normal

Mode	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	UHD (Optional) / HD	Man	Hard	74	9
			Normal	73	9
			Soft	72	9
		Woman	Hard	73	9
			Normal	72	9
			Soft	71	9
		Child	Hard	68	9
			Normal	67	9
			Soft	66	9
	Normal	Man	Hard	74	7
			Normal	73	7
			Soft	72	7
		Woman	Hard	73	7
			Normal	72	7
			Soft	71	7
		Child	Hard	68	7
			Normal	67	7
			Soft	66	7
SPECIAL Examination	N/A	Man	Hard	74	9
			Normal	73	9
			Soft	72	9
		Woman	Hard	73	9
			Hard	73	9

Mode	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
			Normal	72	9
			Soft	71	9
		Child	Hard	68	9
			Normal	67	9
			Soft	66	9

■ PANO Option > Auto Focusing (Optional)

Mode	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	UHD (Optional) / HD	Man	Hard	74	9
			Normal	73	9
			Soft	72	9
		Woman	Hard	73	9
			Normal	72	9
			Soft	71	9
		Child	Hard	68	9
			Normal	67	9
			Soft	66	9
	Normal	Man	Hard	74	7
			Normal	73	7
			Soft	72	7
		Woman	Hard	73	7
			Normal	72	7
			Soft	71	7
		Child	Hard	68	7
			Normal	67	7
			Soft	66	7

- Auto Focusing is not available for SPECIAL Examination programs.

■ PANO Option > Insight PAN (PaX-i Insight only)

Mode	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination / SPECIAL Examination	N/A	Man	Hard	71	5
			Normal	70	5
			Soft	69	5
		Woman	Hard	71	5
			Normal	70	5
			Soft	69	5
		Child	Hard	68	5
			Normal	67	5
			Soft	66	5

Scan Time / Exposure Time**■ PANO Examination**

Arch Type	Examination Mode	Image Option					
		UHD (Optional)		HD		Normal	
		Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
Narrow	Standard	21.0	20.2	14.0	13.5	10.4	10.1
	Right	21.0	10.1	14.0	6.7	10.4	5.0
	Front	21.0	16.7	14.0	11.2	10.4	8.4
	Left	21.0	10.1	14.0	6.7	10.4	5.0
Normal	Standard	21.0	20.2	14.0	13.5	10.4	10.1
	Right	21.0	10.1	14.0	6.7	10.4	5.0
	Front	21.0	16.7	14.0	11.2	10.4	8.4
	Left	21.0	10.1	14.0	6.7	10.4	5.0
Wide	Standard	21.0	20.2	14.0	13.5	10.4	10.1
	Right	21.0	10.1	14.0	6.7	10.4	5.0
	Front	21.0	16.7	14.0	11.2	10.4	8.4
	Left	21.0	10.1	14.0	6.7	10.4	5.0
Child	Standard	18.1	17.2	12.1	11.5	8.9	8.6
	Right	18.1	8.6	12.1	5.7	8.9	4.3
	Front	18.1	13.8	12.1	9.2	8.9	6.8
	Left	18.1	8.6	12.1	5.7	8.9	4.3
Ortho goal	Standard	21.0	20.2	14.0	13.5	10.4	10.1
	Right	21.0	10.1	14.0	6.7	10.4	5.0
	Front	21.0	16.7	14.0	11.2	10.4	8.4
	Left	21.0	10.1	14.0	6.7	10.4	5.0
	Bitewings	21.0	14.5	14.0	9.7	10.4	7.3
	Bitewing Incisor (Optional)	21.0	3.7	14.0	2.5	10.4	1.8
	Bitewing Right	21.0	7.3	14.0	4.8	10.4	3.6
	Bitewing Left	21.0	7.3	14.0	4.8	10.4	3.6

- For Insight PAN mode, only "Normal" is applied to Image Options.

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

■ SPECIAL Examination

Examination Mode	Scan Time (s)	Exposure Time (s)
TMJ LAT Open / TMJ LAT Close	14.0	6.2
TMJ PA Open (Optional) / TMJ PA Close (Optional)	13.0	10.1
Sinus LAT (Optional)	6.5	5.9
Sinus PA	10.9	10.3

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

14.1.2 CEPH Mode

Exposure Condition

Examination Program	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
Lateral Full Lateral PA SMV Waters' view	Normal / Fast	Man	Hard	92	10.0
			Normal	90	10.0
			Soft	88	10.0
		Woman	Hard	90	10.0
			Normal	88	10.0
			Soft	86	10.0
		Child	Hard	88	10.0
			Normal	86	10.0
			Soft	84	10.0
Carpus	Normal / Fast	Man	Hard	90	6.0
			Normal	88	6.0
			Soft	86	6.0
		Woman	Hard	88	6.0
			Normal	86	6.0
			Soft	84	6.0
		Child	Hard	86	6.0
			Normal	84	6.0
			Soft	82	6.0

Scan Time / Exposure Time

Examination Program	Image Option			
	Normal		Fast	
	Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
Lateral	3.9	3.9	1.9	1.9
Full Lateral	5.4	5.4	3.9	3.9
PA	4.9	4.9	2.4	2.4
SMV	4.9	4.9	2.4	2.4
Waters' view	4.9	4.9	2.4	2.4
Carpus	4.9	4.9	2.4	2.4

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

14.2 X-ray Dose Data

14.2.1 DAP (Dose Area Product)

The X-ray dose data is extracted from the X-ray Dose Test Report for **PaX-i Plus / PaX-i Insight (Model: PCH-30CS)**.

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

Test Hardware	
Brand Name (Model)	PaX-i Plus / PaX-i Insight (Model: PCH-30CS)
Sensor Type	<PaX-i Plus> PANO: Xmaru1501CF-PLUS CEPH: Xmaru2602CF
	<PaX-i Insight> PANO: Xmaru1404CF-PLUS CEPH: Xmaru2602CF
X-ray Generator	DG-07D21T2
Tube	D-052SB

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

Accuracy of Radiation

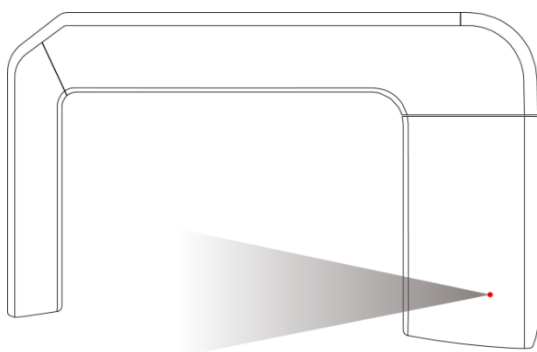
Information of the overall uncertainty of the indicated values of the AIR KERMA and DOSE AREA PRODUCT shall be provided in the ACCOMPANYING DOCUMENT and shall not exceed 50 %

DAP (Dose Area Product) Calculation

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

NOTICE

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

Measurement Overview**Results**

■ PaX-i Plus

<PANO>

PANO Option	Image Option	Arch Selection	Gender / Age group	Tube Voltage (kVp)	Tube Current (mA)	DAP (mGy·cm2)
Normal	UHD	Normal	Adult	73	9	220
			Child	67	9	127
	HD	Normal	Adult	73	9	148
			Child	67	9	85
	Normal	Normal	Adult	73	7	88
			Child	67	7	49

<CEPH>

CEPH Examination	Image Option	Gender / Age group	Tube Voltage (kVp)	Tube Current (mA)	DAP (mGy·cm ²)
Lateral	Normal	Adult	90	10	23
		Child	86	10	21
	Fast	Adult	90	10	13
		Child	86	10	12

■ PaX-i Insight

<PANO>

PANO Option	Image Option	Arch Selection	Gender / Age group	Tube Voltage (kVp)	Tube Current (mA)	DAP (mGy·cm ²)
Normal	UHD	Normal	Adult	73	9	204
			Child	67	9	127
	HD	Normal	Adult	73	9	138
			Child	67	9	85
	Normal	Normal	Adult	73	7	81
			Child	67	7	50
Insight PAN	Normal	Normal	Adult	70	5	374
			Child	67	5	245

<CEPH>

CEPH Examination	Image Option	Gender / Age group	Tube Voltage (kVp)	Tube Current (mA)	DAP (mGy·cm ²)
Lateral	Normal	Adult	90	10	23
		Child	86	10	21
	Fast	Adult	90	10	13
		Child	86	10	12

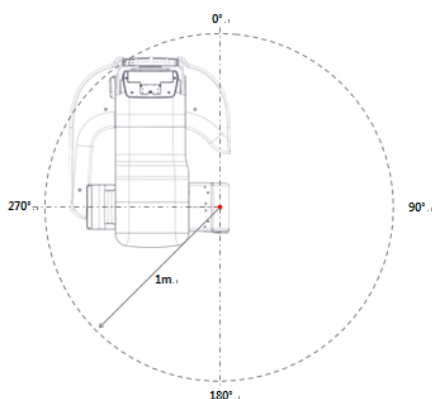
14.2.2 Leakage Dose

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 the 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 1.0 mGy in 1hr

Measurement Overview



■ PaX-i Plus

Test Condition

Test Mode	Tube Voltage (kVp)	Tube Current (mA)
PANO Adult / Normal	99	10
PANO Child / Normal	99	10
CEPH	99	10

Results

Direction [°]	PANO Adult / Normal [mGy/hr]	PANO Child / Normal [mGy/hr]	CEPH [mGy/hr]
0	0.044	0.035	0.053
45	0.035	0.053	0.026
90	0.096	0.096	0.114
100	0.079	0.079	0.096
110	0.088	0.088	0.096
120	0.202	0.272	0.254
130	0.105	0.114	0.123
140	0.105	0.105	0.114
150	0.114	0.105	0.114
160	0.114	0.114	0.114
170	0.123	0.132	0.132
180	0.158	0.167	0.167
190	0.184	0.175	0.184
200	0.360	0.272	0.342
210	0.325	0.333	0.316
220	0.263	0.281	0.263
230	0.228	0.237	0.211
240	0.307	0.289	0.281

Direction [°]	PANO Adult / Normal [mGy/hr]	PANO Child / Normal [mGy/hr]	CEPH [mGy/hr]
250	0.228	0.219	0.211
260	0.228	0.272	0.325
270	0.421	0.439	0.456
315	0.158	0.096	0.114
340	0.430	0.132	0.140

■ PaX-i Insight

Test Condition

Test Mode	Tube Voltage (kVp)	Tube Current (mA)
PANO Adult / Normal	99	10
PANO Child / Normal	99	10
PANO Adult / Insight PAN	99	10
PANO Child / Insight PAN	99	10
CEPH	99	10

Results

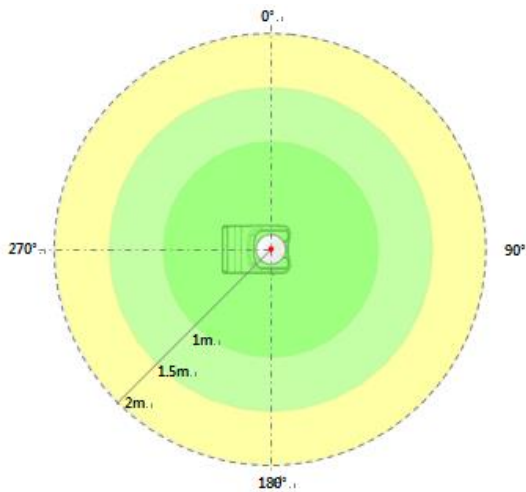
Direction [°]	PANO Adult / Normal [mGy/hr]	PANO Child / Normal [mGy/hr]	PANO Adult / Insight PAN [mGy/hr]	PANO Child / Insight PAN [mGy/hr]	CEPH [mGy/hr]
0	0.026	0.096	0.035	0.026	0.018
45	0.053	0.018	0.035	0.026	0.018
90	0.088	0.096	0.088	0.079	0.096
100	0.088	0.096	0.088	0.088	0.088
110	0.211	0.246	0.219	0.158	0.140
120	0.123	0.132	0.114	0.123	0.114
130	0.114	0.132	0.114	0.105	0.105
140	0.114	0.114	0.105	0.114	0.105

Direction [°]	PANO Adult / Normal [mGy/hr]	PANO Child / Normal [mGy/hr]	PANO Adult / Insight PAN [mGy/hr]	PANO Child / Insight PAN [mGy/hr]	CEPH [mGy/hr]
150	0.132	0.123	0.123	0.123	0.123
160	0.132	0.149	0.140	0.149	0.140
170	0.158	0.167	0.158	0.167	0.149
180	0.175	0.263	0.237	0.219	0.219
190	0.351	0.342	0.333	0.351	0.333
200	0.298	0.316	0.289	0.298	0.298
210	0.219	0.237	0.211	0.237	0.219
220	0.184	0.202	0.184	0.184	0.184
230	0.228	0.254	0.184	0.193	0.219
240	0.175	0.193	0.158	0.167	0.167
250	0.219	0.272	0.219	0.237	0.228
260	0.237	0.237	0.211	0.219	0.219
270	0.325	0.316	0.281	0.298	0.289
315	0.123	0.219	0.088	0.079	0.079
340	0.228	0.088	0.123	0.158	0.263

14.2.3 Scattered Dose

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

Measurement Overview



■ PaX-i Plus

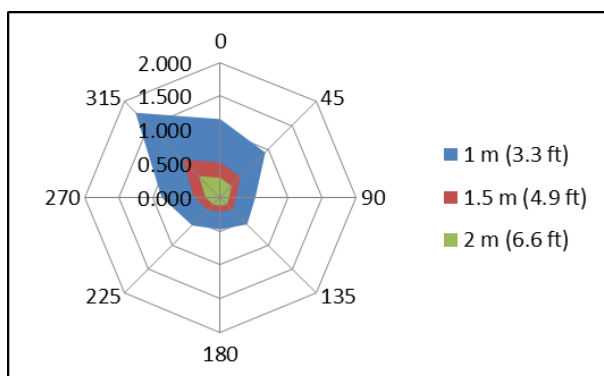
Test Condition

Test Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO Adult (UHD) / Normal	99	10	20.2
PANO Adult (HD) / Normal	99	10	13.5

Results

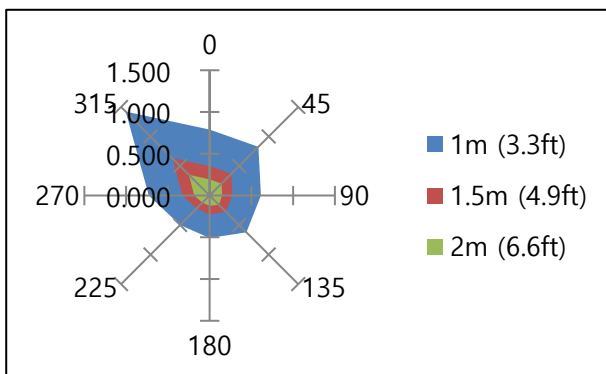
◆ PANO Adult (UHD) / Normal

Direction [°]	1 m [mGy/hr]	1.5 m [mGy/hr]	2 m [mGy/hr]
0	1.158	0.518	0.289
45	0.939	0.421	0.237
90	0.518	0.237	0.132
135	0.561	0.254	0.140
180	0.474	0.211	0.123
225	0.588	0.263	0.149
270	0.868	0.386	0.219
315	1.772	0.789	0.447



◆ PANO Adult (HD) / Normal

Direction [°]	1 m [mGy/hr]	1.5 m [mGy/hr]	2 m [mGy/hr]
0	0.789	0.351	0.193
45	0.825	0.368	0.202
90	0.614	0.272	0.149
135	0.623	0.272	0.158
180	0.509	0.228	0.123
225	0.500	0.219	0.123
270	0.728	0.325	0.184
315	1.421	0.632	0.351



■ PaX-i Insight

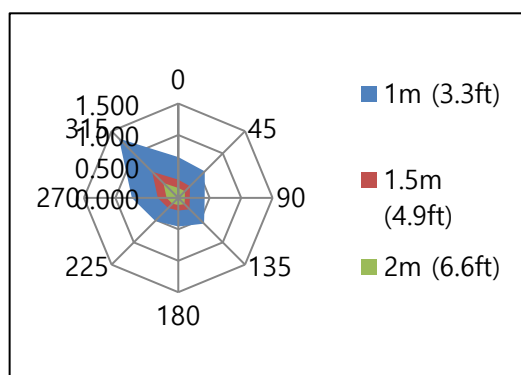
Test Condition

Test mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO Adult (UHD) / Normal	99	10	20.2
PANO Adult (HD) / Normal	99	10	13.5
PANO Adult (Normal) / Insight PAN	99	10	10.1.

Results

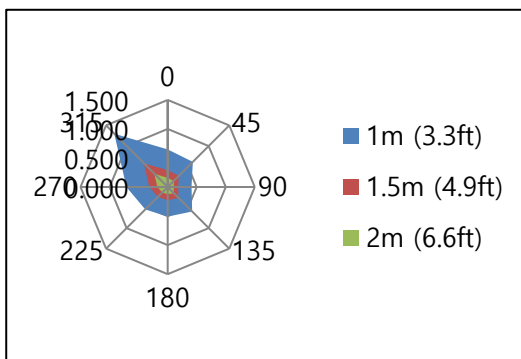
◆ PANO Adult (UHD) / Normal

Direction [°]	1 m [mGy/hr]	1.5 m [mGy/hr]	2 m [mGy/hr]
0	0.649	0.289	0.158
45	0.596	0.263	0.149
90	0.421	0.184	0.105
135	0.579	0.254	0.140
180	0.456	0.202	0.114
225	0.518	0.228	0.132
270	0.737	0.325	0.184
315	1.333	0.588	0.333



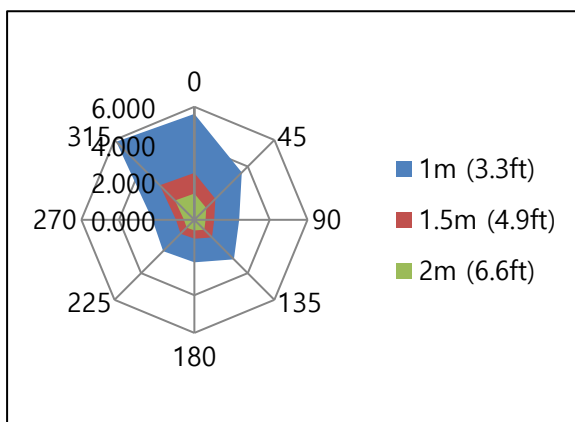
◆ PANO Adult (HD) / Normal

Direction [°]	1 m [mGy/hr]	1.5 m [mGy/hr]	2 m [mGy/hr]
0	0.649	0.289	0.158
45	0.614	0.272	0.149
90	0.412	0.184	0.105
135	0.596	0.263	0.149
180	0.509	0.228	0.123
225	0.544	0.237	0.132
270	0.711	0.316	0.175
315	1.298	0.579	0.325



◆ PANO Adult (Normal) / Insight PAN

Direction [°]	1 m [mGy/hr]	1.5 m [mGy/hr]	2 m [mGy/hr]
0	5.623	2.491	1.395
45	3.553	1.570	0.886
90	2.377	1.053	0.588
135	2.965	1.316	0.737
180	2.254	1.000	0.561
225	2.351	1.044	0.588
270	2.228	0.982	0.553
315	5.868	2.596	1.456



14.3 Electromagnetic Compatibility (EMC) Information

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Mains terminal disturbance voltage	CISPR 11:2009+A1:2010	IDLE mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Radiated disturbance	CISPR 11:2009+A1:2010	IDLE mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Harmonic Current Emission	EN 61000-3-2:2006+A1:2009, IEC 61000-3-2:2009	IDLE mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 230 V, 50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	EN 61000-3-3:2008, IEC 61000-3-3:2008	IDLE mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 230 V, 50 Hz	Pst: 1 Plt: 0.65 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	EN 61000-4-2:2009, IEC 61000-4-2:2008	IDLE mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3:2006 +A2:2010, IEC 61000-4-3:2010	IDLE mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communicati	EN 61000-4-3:2006 +A2:2010, IEC 61000-4-3:2010	IDLE mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Table 9 in IEC 60601-1-2: 2014

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

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
	IEC 61000-4-11:2004			AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles Single-phase: at 0°
Voltage interruptions	EN 61000-4-11:2004, IEC 61000-4-11:2004	IDLE mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % U_T ; 250/300 cycle

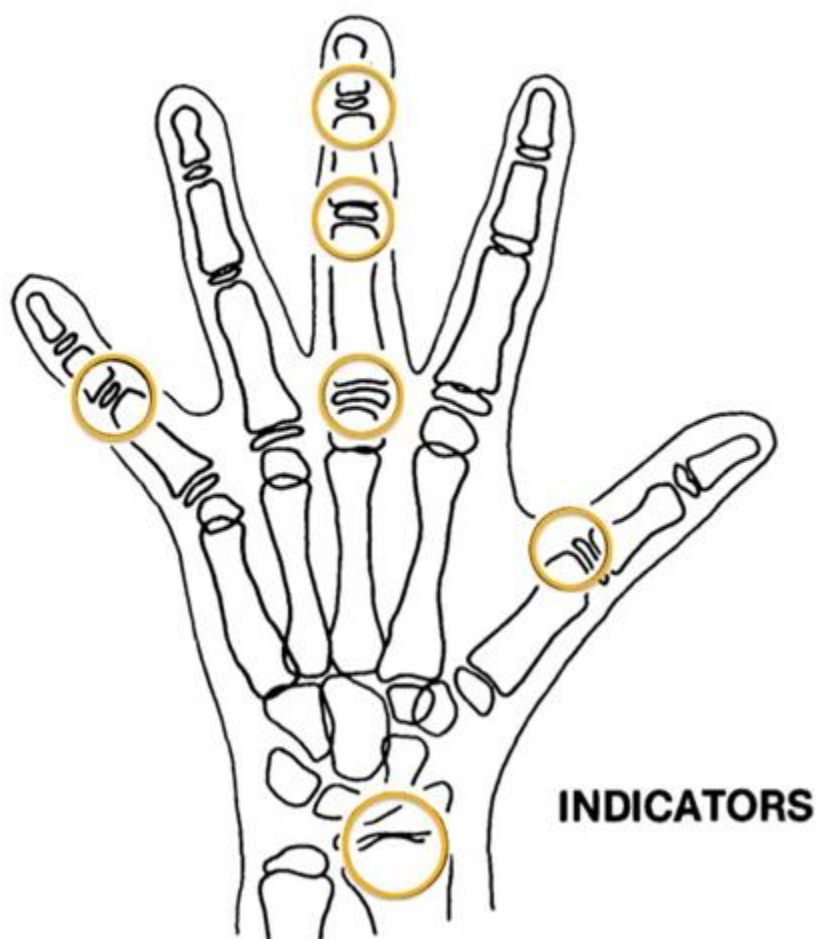
14.4 Hand-wrist Image Evaluation References

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

Fishman LS. 1982

The system of Skeletal Maturation Assessment (SMA)

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



[Fig1. The 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 and wrist.

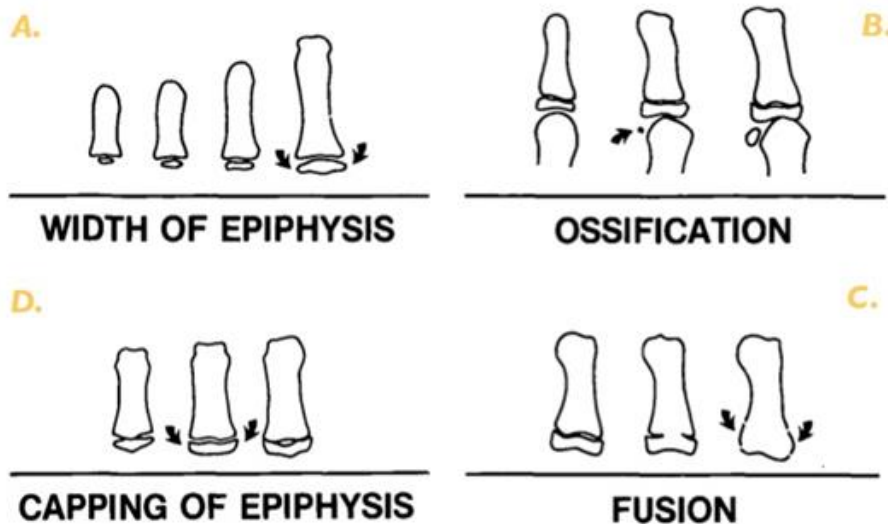


Fig. 2 Radiographic identification of skeletal maturity indicators.
 A. Epiphysis equal in width to diaphysis.
 B. Appearance of adductor sesamoid of the thumb.
 C. Capping of epiphysis.
 D. Fusion of epiphysis.

[Fig2. Radiographic identification of skeletal maturity indicators]

A. The width of the epiphysis as wide as the diaphysis

1. Third finger – a Proximal phalanx
2. Third finger – a middle phalanx
3. Fifth finger – a middle phalanx

B. Ossification

1. Adductor sesamoid of thumb

C. Capping of epiphysis

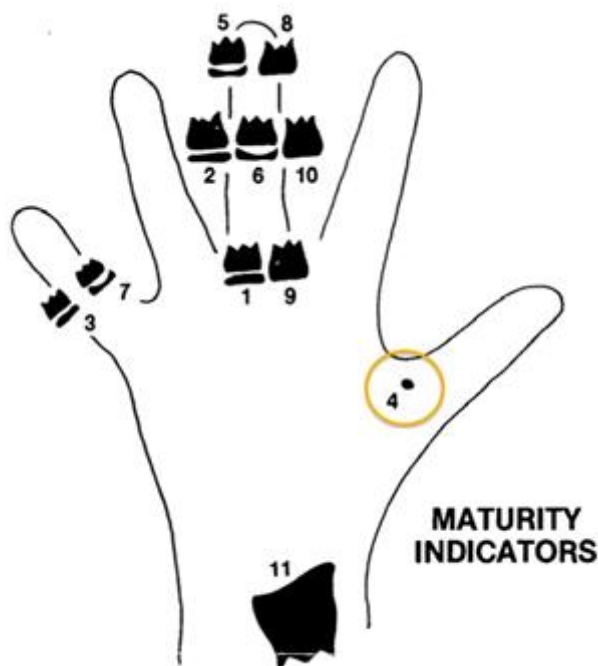
1. Third finger – a distal phalanx
2. Third finger – a middle phalanx
3. Fifth finger – a middle phalanx

D. Fusion

1. Third finger – a distal phalanx
2. Third finger – a Proximal phalanx
3. Third finger – a middle phalanx
4. Radius

Eleven Skeletal maturity indicators (SMIs)

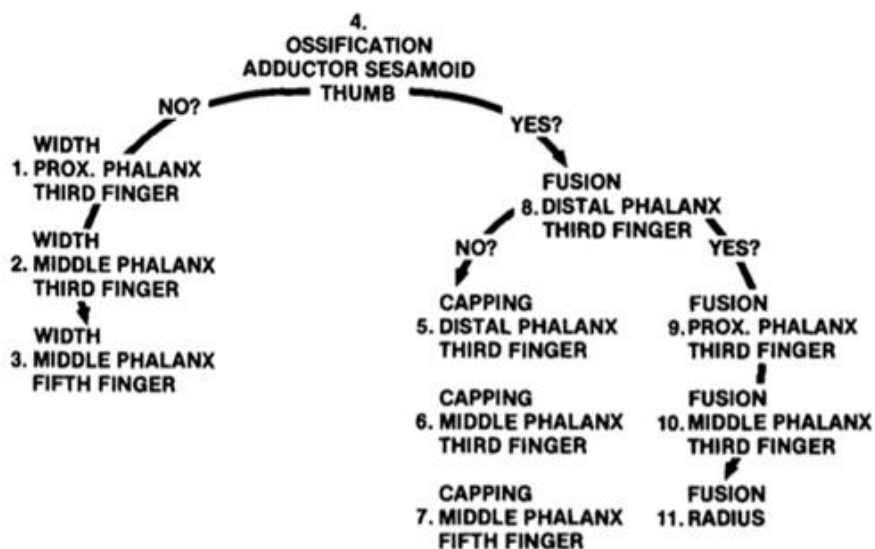
The System uses only four stages of bone maturation, all found at six anatomical sites located on the thumb, third finger, fifth finger, and radius, as seen in Fig.1. Eleven discrete adolescent skeletal maturational indicators (SMI), covering the entire period of adolescent development, are found on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



14.5 Acquiring Images for Pediatric Dental Patients

14.5.1 Age Group: Classification Table

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

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

14.5.2 Positioning the Pediatric Dental Patients

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

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

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

- By Evelyn M. Thomson, BSDH, MS

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

Producing A Quality Panoramic Image

A quality panoramic radiograph should image all 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 patient positioning. All panoramic X-ray machines have guidelines to assist

with positioning the dental arches within the three dimensions of the focal trough, an area where the anatomical structures will be imaged in relative clarity. Most panoramic X-ray machines have a bite block to indicate the correct anterior-posterior position or how far forward or back the patient should be positioned, side positioner guides for determining the correct lateral alignment, and chin rest to correctly locate the superior-inferior dimension or how far up or down the chin should be positioned.^{4,10} Panoramic X-ray machines are available with a mirror and laser light beam guide that shines on the patient's face to illustrate various anatomical planes (**Figure 2**). Incorrectly positioning the patient in any of these three dimensions will produce unique and distinct radiographic image errors (**Table 1**).



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

Table 1. Common Panoramic Positioning Errors

Error	Cause	Corrective action	Tips for pediatric patients
Anterior teeth narrow Severe posterior overlap Vertebrae superimposed over condyles	Arches positioned too far anterior	Position anterior teeth in appropriate position on bite guide. Locate appropriate position with anterior laser light guide.	Use a cotton roll to fill in missing primary teeth or partially erupted permanent teeth. Adapt adult recommendation for direction of laser light beam guide for use with primary teeth. Observe laser light beam guide on both the right and left sides.
Anterior teeth wide, blurred out of image Condyles not imaged	Arches positioned too far posterior	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 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 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.
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 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.
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 lips around the bite block.	Direct the patient to keep the lips closed around the bite block during the exposure.
Radiolucent shadow of the commissure superimposed over the teeth, mimicking caries	Lips not closed around bite block	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.
Radiolucency superimposed over the maxillary teeth apices	Tongue not placed against palate		

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 pediatric patients with primary or mixed dentition.

Lateral Left-Right Positioning Error

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



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

To avoid imaging errors that result from incorrect lateral positioning, the midsagittal plane must be positioned perpendicular to the floor. Most panoramic X-ray machines have a head positioner and/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.

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

Superior-Inferior (Up-Down) Positioning Error

Positioning the dental arches within the superior-inferior (up-down) dimension of the focal trough can be 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 the upward curve of the occlusal plane, with the condyles tilting inward toward the center of the image (**Figure 6**). Depending on the severity of the downward position, the vertebrae may also curve inward and appear superimposed over the condyles, and the hyoid bone may be superimposed over the mandible blocking a clear view of the erupted and unerupted mandibular teeth.

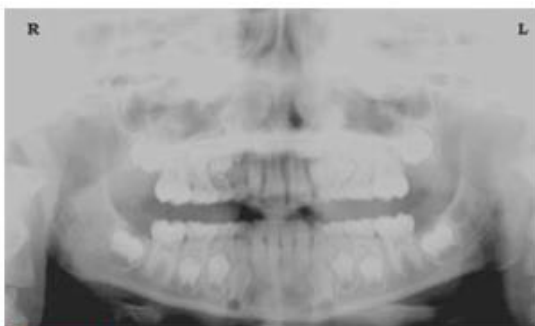


Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

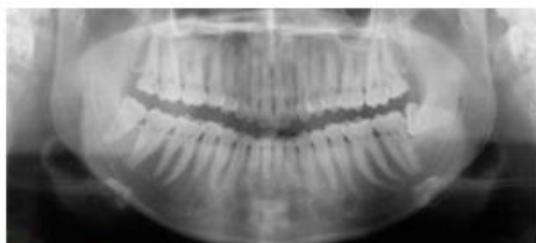


Figure 6: Chin positioned too far down. Note the characteristic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

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

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

producing a radiolucent shadow that diminishes the diagnostic quality of the radiograph (Figure 3).

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

Conclusion

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

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14.5.3 Setting Exposure Values to the Age Group

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

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

1) Literature

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

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

2) Website

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

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

14.6 Abbreviations

AC	Alternating Current
CAN	Controlled Area Network
CMOS	Complementary Metal-Oxide -Semiconductor
DAP	Dose Area Product
DC	Direct Current
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
FDD	Focal spot to Detector Distance
FOD	Focal spot to Object Distance
FPD	Flat Panel Detector
IEC	International Electrotechnical Commission
ISO	International Standards Organization
LED	Light-Emitting Diode
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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