

PaX-i3D GreenTM

User Manual

Model : PHT-60CFO

Version : 1.71

-
- English



Full Version

vatech

Notice

Thank you for purchasing the **PaX-i3D Green™** extra-oral imaging system.

The **PaX-i3D Green™** is an advanced digital dental diagnostic system that incorporates PANO, CEPH, and 3D CBCT imaging capabilities into a single system.

This manual describes how to operate the **PaX-i3D Green™** system. It is recommended that you thoroughly familiarize yourself with this manual in order to make the most effective use of this equipment.

Observe all cautions, safety messages and warnings which appear in this manual.

The **QR** code linked to video file about image capture for the **PANO Standard** and **CEPH Lateral** is provided in the manual. The smart phone and pad which have the QR code reader application program can be used to watch video.

Due to a constant technological improvement, the manual may not contain the most updated information, subjecting to change without prior notice to the persons concerned. For further information not covered in this manual, please contact us at:

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This document is originally written in English.

The PaX-i3D Green™ is referred to as Equipment in this manual.

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General Information

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1 General Information

1.1 Manufacturer's Liability

The manufacturers and/or retailers of this equipment assume responsibility for the safe and normal operation of this product only when:

- The equipment has been installed by a VATECH authorized technician.
- The equipment has been installed in accordance with all of the cautions and conditions for installation.
- Genuine VATECH approved equipment and components have been used at all times.
- All maintenance and repairs have been performed by a VATECH authorized agent.
- The equipment has been used normally in accordance with the user's manual.
- The equipment damage or malfunction is not the result of an error on the part of the owner or operator.

1.2 Owner and Operator's Obligations

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

1.3 Conventions in this Manual

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

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

	WARNING	Indicates information that should be followed with the utmost care. Failure to comply with a warning may result in severe damage to the equipment or physical injury to the operator and/or patient.
	CAUTION	Indicates a situation that demands prompt and careful action, a specific remedy, or emergency attention.
	X-ray	Indicates a possible danger of exposure to radiation.
	IMPORTANT	Indicates a situation or action that could potentially cause problems to the equipment and/or its operation.
	NOTE	Emphasizes important information or provide useful tips and hints.
	SINGLE USE	Indicates a component which must be replaced for each new patient.

2

Warnings and Precautions

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2. Warnings and Precautions



Be sure to strictly observe all warnings and safety instructions included in this manual.

2.1 General Safety Precautions

Operator qualifications

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

- To operate this equipment, all operators must:
 - have read and understood the user's manual
 - be familiar with the fundamental structure and functions of this equipment
 - be able to recognize irregularities in the operation of this equipment and implement appropriate measures to remedy such irregularities.

General safety precautions

- Follow the instructions specified in this manual to ensure the safety of both the patient and the operator.
- The operator must maintain visual contact with the patient at all times during imaging.
- Do not open or remove the cover panels on this equipment. Always have a trained and authorized service technician carry out inspection and maintenance of this equipment.
- Do not place foreign objects on this equipment at any time.
- Do not place any objects within this equipment's field of operation.
- Do not push or pull the equipment. If equipment overbalances, resulting in the risk of physical injuries or property damage.
- Operators must ask the patient to remain still until the equipment arm has stopped moving and the reset motion is complete.

- Observe all local fire regulations. Always keep a fire extinguisher near the equipment.
- The operator of this equipment must be familiar with this equipment's emergency protocols.
- Ensure that this equipment is kept away from water, moisture, or foreign substances at all times.
- If this product is exposed to water, moisture, or a foreign substance, immediately turn off all power to the equipment and contact your VATECH technical support representative.
- Immediately cease all operation of this equipment if there are signs of oil leakage and contact you VATECH technical support representative.

Ventilation

- Do not obstruct the equipment's ventilation for air opening. Improper ventilation could result in the equipment overheating due to a lack of air circulation.
- Do not spray any type of liquid or aerosol on this equipment as this may penetrate the system and damage the electrical and mechanical components inside.
- Always leave a sufficient amount of space around the PC to allow for proper ventilation.

Hygiene



Always disconnect the equipment from the power outlet when disinfecting the surfaces of the equipment.

- All removable patient support components (bite block, chin support, temple supports) can be cleaned using alcohol-based cleaning solutions.
- Patient support handles can be cleaned using alcohol-based cleaning solutions.
- Other surfaces of the equipment, including the touch screen, can be cleaned using a soft cloth dampened with a mild cleaning solution.



- Disinfect the components (bite block, temple supports etc.) of the equipment that come into contact with the patient or the operator after each exposure.
- New hygiene cover must be provided for each new patient to prevent the transmission of communicable disease.



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

Condensation

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

Cooling

- Allow the proper amount of cool down time (for the X-ray tube to cool down) to elapse between each image acquisition.
 - Mode of operation: Continuous operation with intermittent loading.
 - Exposure time: Max. 20.2 s / Resting time: 5 min.
 - Column operation time: 1 min / Resting time: 9 min
- If the temperature inside the tube head reaches 60 °C, 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 set point temperature is configurable.

Turning the equipment on / adjusting the height of the equipment

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

Emergency stop

- If a problem occurs during image acquisition, press the red emergency stop button to immediately stop all moving parts and cut off all power to the equipment.

Trouble-free operation

- Never use this equipment in an environment that is susceptible to explosion.
- Always operate the equipment within a temperature range of 10 °C to 35 °C (50 °F to 95 °F) for the safe operation. Image quality may deteriorate if the equipment is operated outside of this range.
- Always allow the equipment sufficient time to warm up (while switched on) if it has been exposed to temperatures of below 10 °C (50 °F).
- Only perform X-rays of patients if system is in full working order.
- Always ensure that equipment movement is not obstructed by the patient's clothing, medical device (such as a wheelchair), or the patient themselves.
- Do not leave the patient unattended around the equipment.
- Remove all radio-controlled devices, mobile phones, etc. from the X-ray room prior to image acquisition as these objects may cause the equipment to malfunction.

Modifying the equipment

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

2.2 Electricity-related Safety Precautions

- Check the status of the power source, PC and cables prior to operating the equipment.
- Ensure that the on/off switch is set to off when the equipment is not in use.
- Always disconnect the power supply before cleaning the equipment.
- Always keep electrical cords away from hot appliances or radiators.
- DO NOT place the PC or peripheral equipment connected to the PC in the immediate vicinity of the patient.
- The equipment and PC should be connected to a common protective earth.
- Never overload the equipment's circuit by sharing it with too many appliances.
- Use the same power circuit for the PC and the equipment.

Combining this equipment with other devices

- Do not connect this equipment to devices which are not part of the system.
- Do not connect this equipment to a Multiple Portable Socket-Outlet (MPSO) or extension cord.

Electromagnetic compatibility

- The PaX-i X-ray unit complies with IEC standard 60601-1-2.

Medical electrical equipment is subject to special EMC preventive measures. It must be installed and operated as specified in the **Installation Requirements** document.

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 and mobile 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 the document **Electromagnetic Compatibility Information**.



ElectroStatic Discharge

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

2.3 Radiation Safety



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

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



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

2.4 Warnings

The following warning statements should be obeyed with the utmost care. Failure to follow these warnings may cause severe damage to the equipment or physical injuries to the patient and/or operator.



X-ray equipment is hazardous to patient and the operator if proper exposure safety measures and/or operating instructions are not observed.

It is important to read this user manual carefully and strictly abide by all warnings and cautions stated within it.



- **3D image should not be used for screening examinations. Each exam must be justified by demonstrating that the benefits outweigh the risk.**

- **Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, conventional medical CT or MR should be used instead of dental cone beam imaging.**



- **PaX-i3D Green system, like other medical equipment, uses high-frequency electrical signals that can interfere with implantable devices such as pacemakers and implantable cardioverter-defibrillators(ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately power off the Dental X-ray system.**

- **PaX-i3D Green system is designed to withstand the effects of defibrillation. However, when possible, disconnect the Dental X-ray systems during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.**

Lasers

- The system incorporates Class 1 laser products. The light localizers used in this product are intended for correct patient positioning and must not be used for any other purpose.
- For maximum safety, advise the patient not to look directly at the Laser Beam.
- While adjusting the patient, ensure that the Laser Beam is not directed at the patient's eyes.



Risk of eye injury!

Do not use this equipment with any other laser sources and do not make any changes to the settings or processes that are described in these operating instructions.

Cleaning

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

During Operation

- Never use this equipment in an environment that is susceptible to explosion.
- Do not place flammable materials near this equipment.
- Do not operate the PC or Touch screen while the equipment is performing an operation. Failure to comply with this instruction may result in system malfunction.
- Immediately stop imaging if the equipment malfunctions in any way.
- If a problem occurs during imaging, press the red emergency stop button to immediately stop all moving parts and cut off all power to the equipment's electrical components.
- Never touch the patient while also touching the SIP/SOP connectors.

In case of electrical fire

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

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

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

Installation

- In order to avoid improperly balanced equipment, install the device on a flat surface to maintain stability.
- If the equipment is not stable, property damage and/or personal injury may occur.
- Do not push or pull the equipment.
- Equipment should only be installed by an authorized technician, complying with proper installation procedures.

PaX-i3D Green Imaging System Overview

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3 PaX-i3D Green Imaging System Overview

3.1 Introduction

The **PaX-i3D Green** is an advanced digital dental diagnostic system that incorporates Panoramic (PANO), Cephalometric (CEPH), and 3D CBCT imaging capabilities into a single system.

The **PaX-i3D Green** system is intended for use to take a panoramic, cephalometric and CT image of the oral and craniofacial anatomy to provide diagnostic information for adult and pediatric patients. The **PaX-i3D Green** system uses the advanced sensors to produce the higher quality of image in 2D and 3D of the head region, including the dental/maxillofacial regions.

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

3.1.1 System Components

- PaX-i3D Green digital X-ray equipment
- PC
- EasyDent / EzDent-i: 2D viewer and patient management software
- Ez3D plus / Ez3D-i: 3D viewer
- Imaging software

3.1.2 Features

- A 3-in-1 imaging solution: PANO, CEPH and CBCT imaging combined in single equipment.
- Improved image processing algorithms:
 - Magic PAN (Optional): A high quality image reconstructed from the optimal auto-focused images in each segment throughout the panoramic region to correct the improper patient positioning and rotating unit's trajectory.
- Metal Artifact Reduction: Metal artifacts are minimized to improve image quality.

- Fast CEPH: CEPH imaging with low X-ray dose and high speed
- Control Panel: to allow an easy handling of the equipment
- Multi-FOV (Field Of View): FOV is selected, based on the most suitable ROI.
- Provides an auto-switching between 2 sensors for the PANO and CBCT imaging, without the intervention of the operator.
- 3D Viewer **Ez3D plus / Ez3D-i**: Enables 3D images to be analyzed accurately, leading to greater diagnostic precision.
- DICOM file support: The standard file format for medical applications.

3.1.3 The PaX-i3D Green Model Series (Optional)

Model	Item	Sensor		FOV (mm)
SP	PANO +CBCT	PANO	Xmaru1501CF	-
		CBCT	Xmaru1215CF MP	100 X 80, 80 X 80, 80 X 50, 50 X 50
			Xmaru1524CF MP	160 X 100, 120 X 90, 80 X 80, 80 X 50, 50 X 50
				150 X 150, 120 X 90, 80 X 80, 80 X 50, 50 X 50
SC	PANO +CBCT +CEPH	PANO	Xmaru1501CF	-
		CBCT	Xmaru1215CF MP	100 X 80, 80 X 80, 80 X 50, 50 X 50
			Xmaru1524CF MP	160 X 100, 120 X 90, 80 X 80, 80 X 50, 50 X 50
				150 X 150, 120 X 90, 80 X 80, 80 X 50, 50 X 50
				170 x 150, 120 x 90, 80 x 80, 80 x 50, 50 x 50
		CEPH	Xmaru2301CF	Scan Type
OP	PANO +CBCT +CEPH	PANO	Xmaru1501CF	-
		CBCT	Xmaru1215CF MP	100 X 80, 80 X 80, 80 X 50, 50 X 50
			Xmaru1524CF MP	160 X 100, 120 X 90, 80 X 80, 80 X 50, 50 X 50
				150 X 150, 120 X 90, 80 X 80, 80 X 50, 50 X 50
		CEPH	1210SGA	One shot Type 304.8x254.0, 228.6x254.0, 203.2x203.2 (mm) 12 X 10, 9 X 10, 8 X 8 (inch)

3.1.4 Standards and Regulations

Standards:

The PaX-i3D Green is designed and manufactured to meet the following standards:

IEC/EN/UL 60601-1, IEC/EN 60601-1-1, IEC/EN 60601-1-2, IEC/EN 60601-1-3, IEC/EN 60601-2-7, IEC/EN 60601-2-28, IEC/EN 60601-2-32, IEC/EN 60601-2-44, ISO 9001, ISO 13485

NEMA standard publication PS 3.1-3.18, 2008

X-ray source assembly [DG-07C11T2 / DG-07C11C1] IEC 60601-2-28 (1993)



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



The symbol grants this equipment received the CSA certification mark in accordance with CAN/CSA C22.2 No.601.1 regulations.

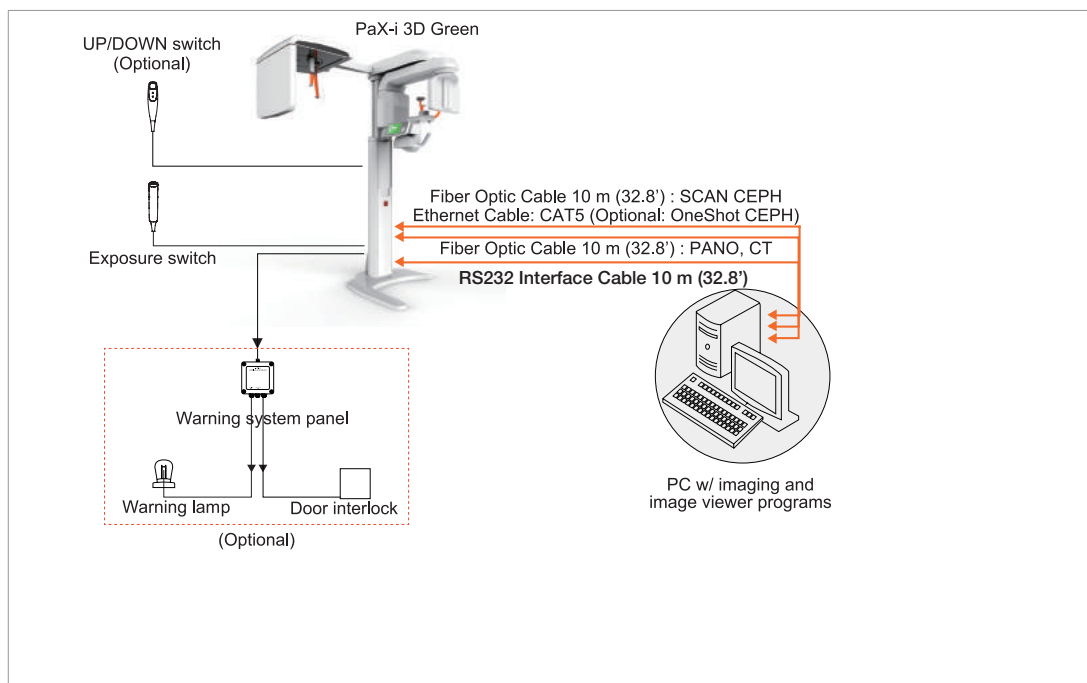
Classifications (IEC60601-1 6.1):



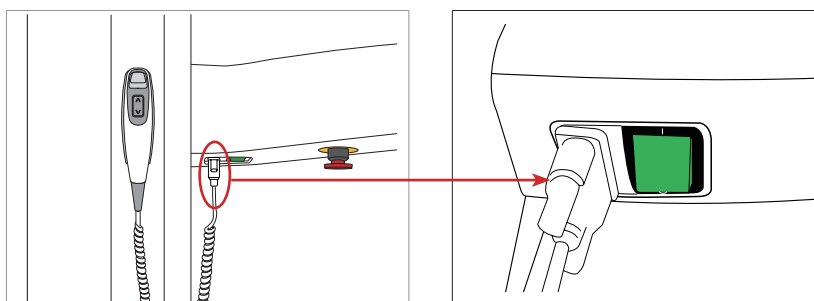
Protection against the ingress of water: Ordinary Equipment: IPX0

Protection against electric shock: Class 1 equipment, Type B Applied Parts

3.2 Imaging System Structure



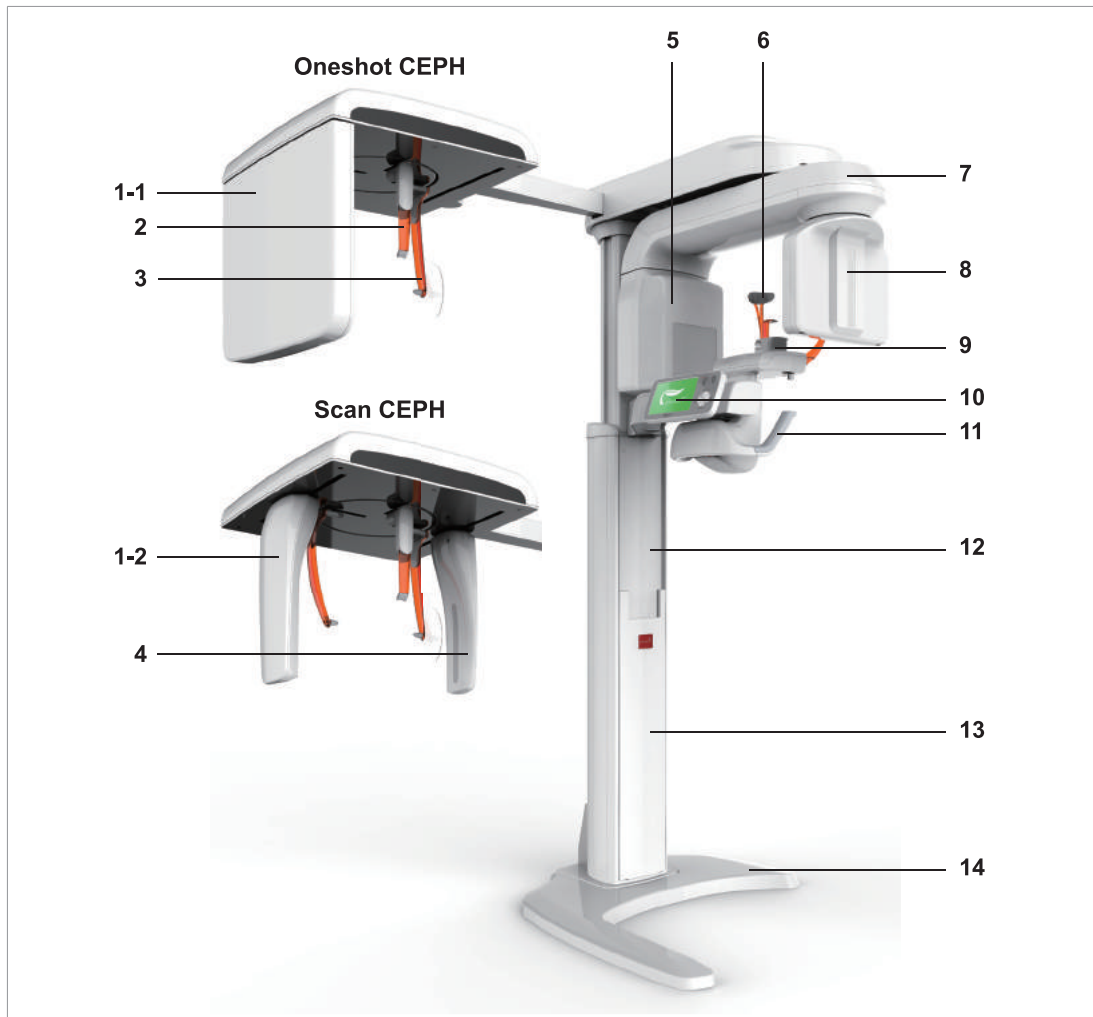
1. Signal input/output at the column up/down switch (optional)



NOTE

External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC60601-1series for medical electrical equipment). In addition, all such combination-system-shall comply with the standard IEC60601-1 and/or IEC60601-1-1 harmonized national standard or the combination.

3.3 General View of the PaX-i3D Green



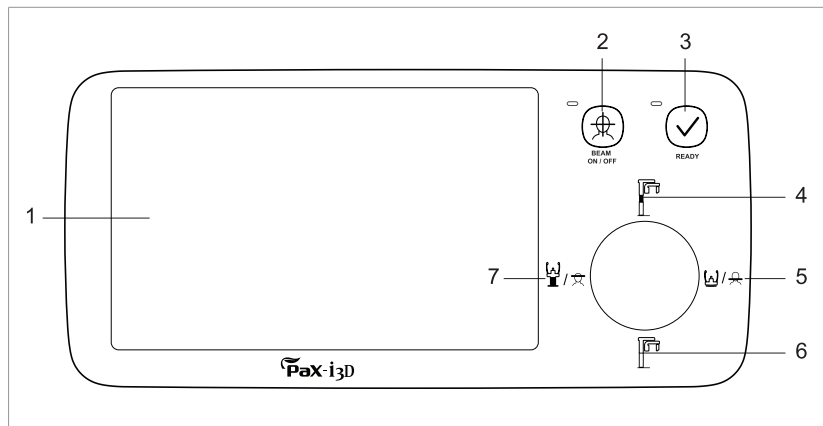
No.	Item	Details
1	X-ray SENSOR (CEPH)	CEPH imaging sensor (optional). - 1-1. One shot Type - 1-2. Scan Type
2	NASAL POSITIONER	- Positions the patient during CEPH imaging. - The ruler for use to compensate the acquired image that is different from actual size.
3	EAR RODS	Secure the patient's head during CEPH imaging.
4	SECONDARY COLLIMATOR	Limits the X-ray irradiation field for CEPH scanning.
5	X-ray TUBE	The source of X-ray emission.
6	TEMPLE SUPPORTS	Support the patient's temples during PANO scan.
7	ROTATING UNIT	Rotates around the patient's head during exposure (depending on the imaging mode).
8	X-ray SENSOR (PANO / CBCT)	Sensors: used for CBCT and PANO imaging. This module consists of two different sensors that perform different functions (CBCT and PANO). When you select a scanning mode, the sensor will be switched automatically (CBCT ↔ PANO, and vice versa).
9	CHINREST	Supports the patient's chin during imaging.
10	CONTROL PANEL	Allows the operator to control certain functions of the equipment and displays operational parameters. For more details, refer to 3.3.1 Control Panel and 3.3.2 Touch Screen
11	HANDLE FRAME	Held firmly by the patient during imaging to stabilize his / her position.
12	TELESCOPIC COLUMN	Moves the column up or down for patient positioning.
13	STATIONARY COLUMN	The portion of the column fixed to the base.
14	BASE	Used to balance and stabilize the equipment.



NOTE

The structural overview of the PaX-i3D Green may differ depending on the model. For more information, refer to section “3.1.3 The PaX-i3D Green Model Series”.

3.3.1 Control Panel



Buttons		Functions
1	Touch Screen	Configures the parameter settings in each imaging mode. For more information on this, refer to 3.3.2 Touch Screen .
2	Laser Beam ON / OFF	Turns ON or OFF the Laser Beam.
3	READY	Indicates that parameter settings and the patient alignment are finished and imaging is ready.
4	Column UP	Moves the column up.
5	Chinrest DOWN	Lowest the chinrest. - Functions only in the CBCT imaging mode.
	Frankfurt plane Laser Beam DOWN	Moves Frankfurt plane Laser Beam down. - Functions only in the PANO imaging mode.
6	Column DOWN	Lowest the column.
7	Chinrest UP	Moves the chinrest up. - Functions only in the CBCT imaging mode.
	Frankfurt plane Laser Beam UP	Moves Frankfurt plane Laser Beam up. - Functions only in the PANO imaging mode.

3.3.2 Touch Screen

You can configure the parameter settings in each mode using the touch screen. The **touch screen** on the equipment and the **imaging program** (See 4.3 **Imaging Software Overview**) on the PC are synchronized in real time, and display the same parameter settings.

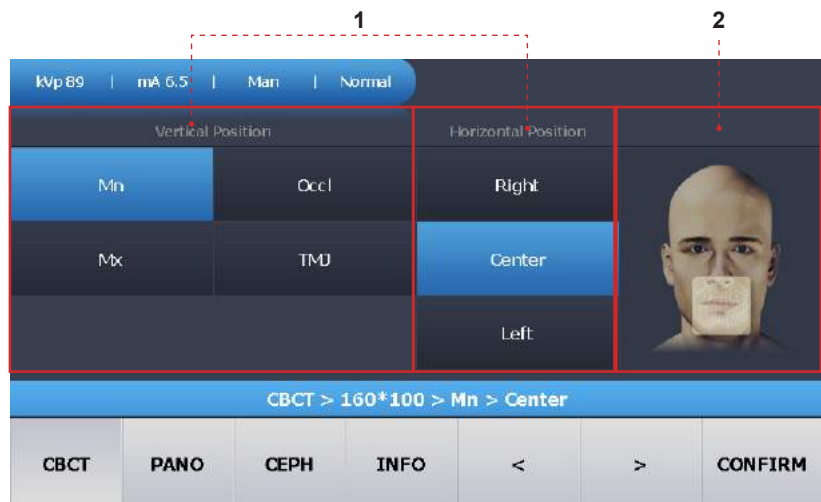


Never use pointed objects, such as a ballpoint pen or pencil, to manipulate the LCD screen as they could scratch or damage the LCD screen.

CBCT

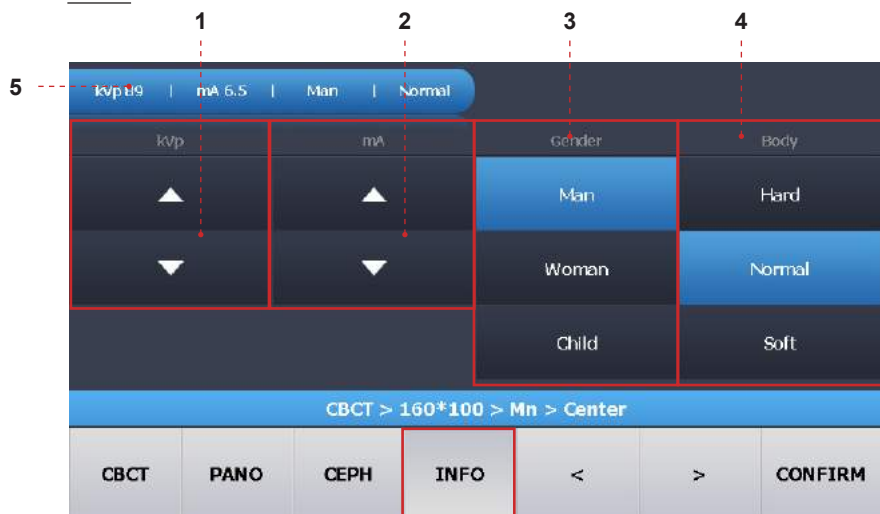


No.	Function	Description
1	Imaging parameter settings information	Displays currently set information such as patient type and X-ray setting values.
2	FOV selection	Shows the CBCT sensor model mounted.
3	Selection settings	Displays the current selections in sequential order.
4	Imaging mode selection	Select the imaging mode.
5	INFO	Enables the user to set a patient's gender and X-ray intensity and controls kVp / mA.
6	Back	Moves to the previous level
7	Forward	Moves to the next level
8	CONFIRM	Click this button when the parameter settings are finished.



No.	Function	Description
1	Examination area selection	Selects the tooth position
2	Guidance Image	—

INFO



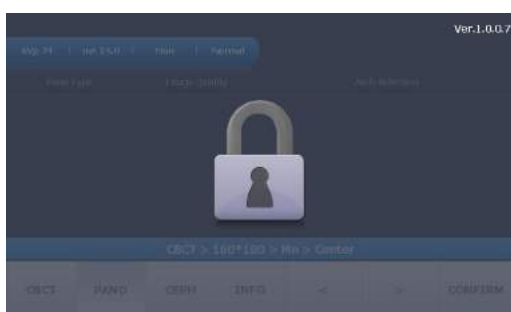
No.	Function
1	Tube voltage UP / DOWN
2	Tube current UP / DOWN
3	Patient's gender selection
4	Patient's X-ray intensity selection
5	Displays the parameter settings

Temple Support Adjustment Button



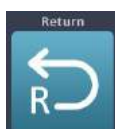
Touch Screen LOCK

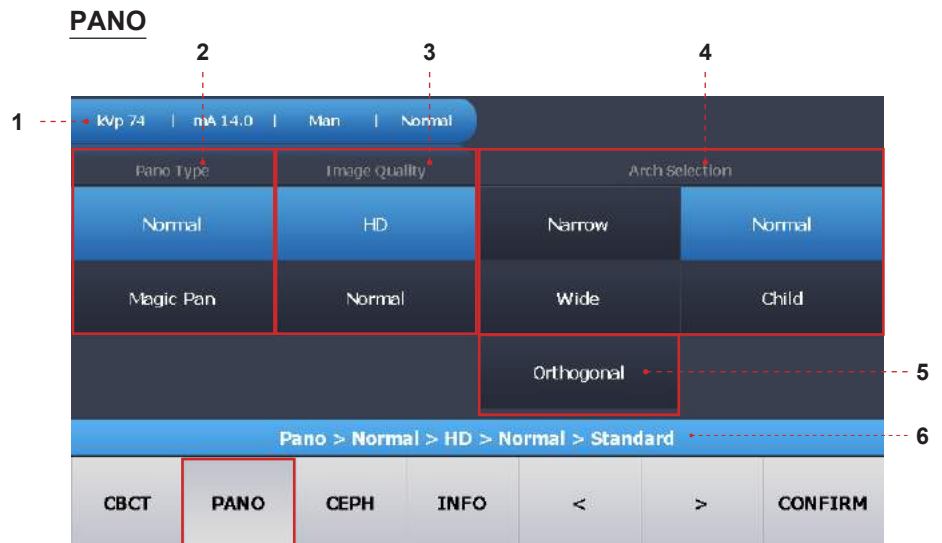
Touch Screen is automatically locked while exposure.



RETURN

Returns the Rotating Unit back to its initial position.





No.	Function	Description
1	Imaging parameter settings information	—
2	Pano Type	Normal, Magic Pan(Optional)
3	Image Quality	HD, Normal
4	Arch Selection	Selects the type of patient's dental arch
5	Orthogonal Mode	Minimizes overlapping in the image
6	Selection Settings	Displays the current selections in sequential order.

CEPH: OP Model (Oneshot type)**CEPH: SC Model (Scan Type)**

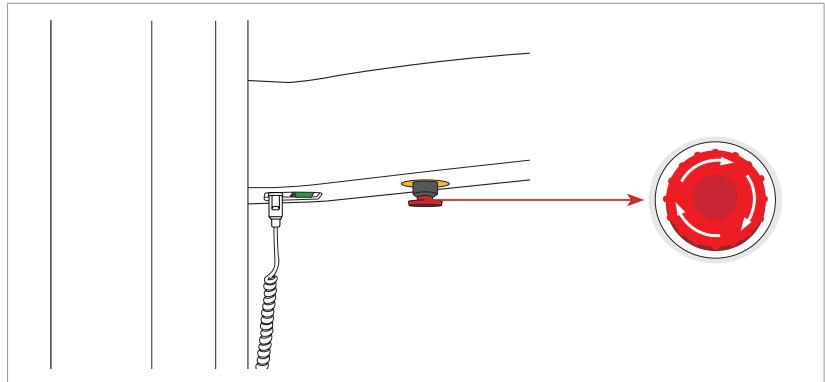
No.	Function	Description	
1	Imaging parameter settings information	—	
2	CEPH Examination	—	
3	CEPH FOV Size (inches)	—	
4	Exposure Time Adjustment	Oneshot type	Enable the user to adjust the exposure time with the UP and DOWN buttons.
5	Image Quality	Fast	Fast Scan



NOTE

Exposure time can be adjusted by resolution of 0.1 s in the range of 0.5 s to 1.2 s (One shot type only).

3.3.3 Emergency Stop Switch

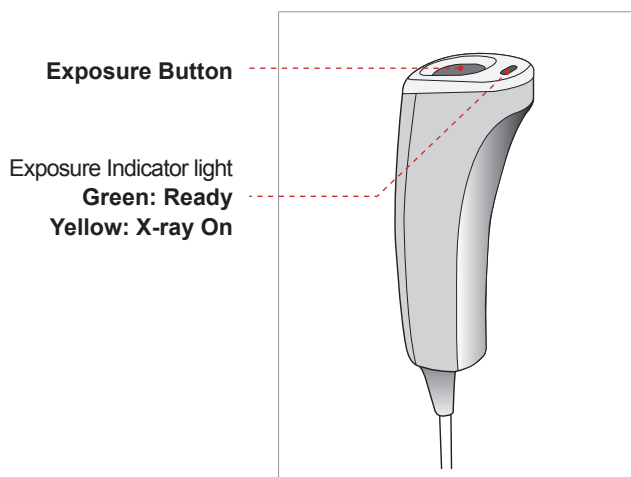


During operation, the following emergency situations may occur:

- X-ray emission continues after the exposure switch has been released
- Injury to the patient or damage to the equipment
- Other emergency situations

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

3.3.4 The Exposure Switch



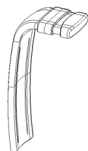
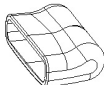
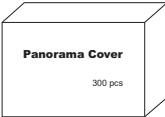
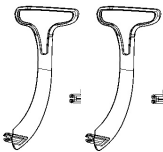
The exposure switch allows the operator to control image acquisition from outside of the X-ray room. Press and hold the exposure switch down until acquisition is complete. Premature release of the exposure switch will abort image acquisition.

Pressing the exposure switch activates the Yellow indicator light to indicate that the X-ray is being emitted.

3.3.5 Components and Positioning Accessories

The following accessories can be disinfected after they have been separated from the equipment.

Disinfect all accessories which come into direct contact with the patient, such as the bite block, Chinrest or temple supports, using an alcohol-based solution and allow them to dry before use.

Accessories			
Bite block: Normal		Ear Rod cover (1 set)	
Silicon cover: bite block		Silicon cover: Nasal Positioner	
Chin Support: TMJ, Sinus		Protractor: CEPH	
Silicon cover: Chin Support		Carpus plate	
Silicon cover: Chinrest		Hygiene cover : bite block (single use)	 
Temple Supports (1 set)			

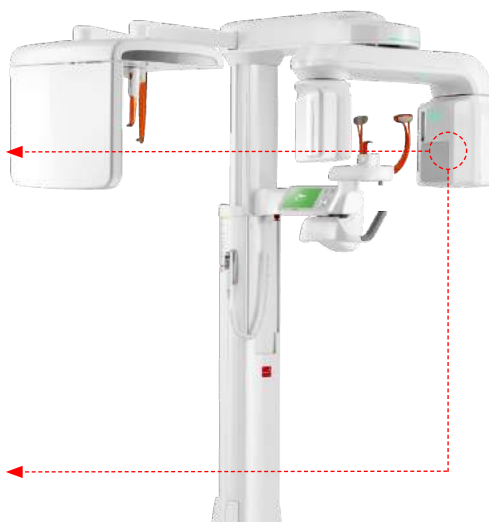
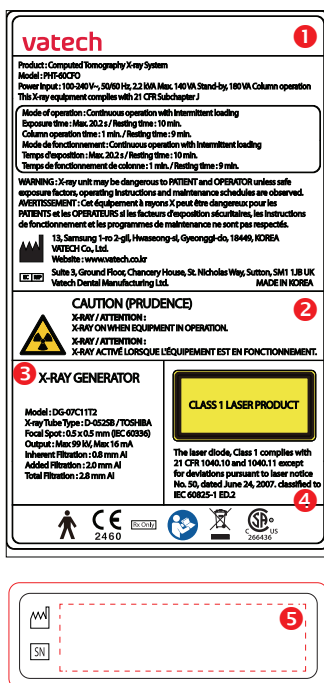
3.4 Marks and Symbols

Symbols	Description	Location
	Alternate current	-
	Attention: consult accompanying documents	Label
	Dangerous voltage	Power board
	Protective earth (Ground)	Power board
	Off (power: disconnect from the main switch)	Main switch
	On (power: connect to the main switch)	Main switch
	TYPE B Equipment	Label
	Radiation hazard	Label
	EC representative	Label
	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Label
	This equipment received the CSA certification mark in accordance with CAN/CSA C22.2 No.601.1 regulations.	Label
	Address where the equipment was manufactured	Label
	This symbol indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Label
	This symbol warns ESD hazard.	MCU board/ Board package
	This symbol indicates that this equipment is classified as a CLASS 1 LASER PRODUCT in accordance with IEC 60825-1 ED.1 regulations.	Label
	Date of manufacture	Label
	Refer to Instruction manual	Label

Symbols	Description	Location
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Label
	Indicates the manufacturer's serial number so that the specific equipment can be identified.	Label

3.4.1 Label Locations

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



No.	Item
1	Main Label
2	CAUTION Label - X-ray / Attention: X-ray on when equipment in operation.
3	X-RAY GENERATOR Label
4	CLASS 1 LASER PRODUCT Label
5	Manufacturer Label - The date of manufacture / Serial Number

4

Software Overview

4.1	PC System Requirements (Recommended)	44
4.2	EasyDent / EzDent-i	45
4.3	Imaging Software Overview.....	46
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4.3.2	CEPH	56
4.3.3	CBCT	58

4 Software Overview

Three programs come with this equipment to acquire, process, and view the image:

- **EasyDent / EzDent-i:** 2D viewer, analysis, and patient management
- **Ez3D plus / Ez3D-i:** 3D Viewer and analysis
- Imaging software: **PANO / CEPH / CBCT**

4.1 PC System Requirements (Recommended)



NOTE

- Image quality may be diminished if the PC specifications are not met, please adhere to the requirements specified in the following table.
- **DO NOT** place the PC or peripheral equipment connected to the PC in the immediate vicinity of the patient

Item	HP
CPU	E5-1607v4 4C 3.1GHz 2133 10MB
RAM	2x8GB DDR4-2400 Registered RAM
Hard disk drive	1TB SATA 7200 rpm
Graphic board	NVIDIA Quadro K2200 4GB * For America: NVIDIA Geforce GTX1060 6GB
Ethernet interface	Integrated Intel I218LM PCIe GbE Controller Intel Ethernet I210-T1 PCIe NIC (Option)
Serial Port (RS232)	HP Serial Port Adapter Kit (Option)
Power supply	≥ 700 Watts (90% efficient)
Slots	2 PCI Express Gen3 x 16 slots 1 PCI Express Gen3 x 8 slot 1 PCI Express Gen2 x 4 slot 1 PCI Express Gen2 x 1 slot 1 PCI 32bit/33MHz
CD/DVD drive	DVD Writer 5.25"
Operating system	Windows 7 Professional 64-bit (available through downgrade rights from Windows 10 Pro)
Recommended system	Z440

4.2 EasyDent / EzDent-i

As the basic imaging platform for all VATECH dental X-ray equipment, **EasyDent / EzDent-i** is designed to be easy to use. The Imaging Program is interfaced with **EasyDent / EzDent-i**. Images acquired by the Imaging Program are imported directly into **EasyDent / EzDent-i**, where analysis and diagnosis can be performed quickly and easily.

The screenshot below is of **EasyDent / EzDent-i's** initial GUI window.



NOTE

For more details about patient search, refer to sections “5.2.1 Creating a New Patient Record” and “5.2.2 Retrieving Patient Records”.

4.3 Imaging Software Overview



NOTE

You can set the imaging parameters on either the touch screen or the imaging program running on the PC. They are synched in real time and display the same environmental settings. For more details on the Touch Screen, refer to “3.3.2 Touch Screen”.

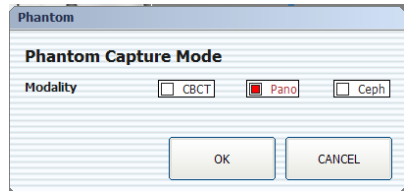
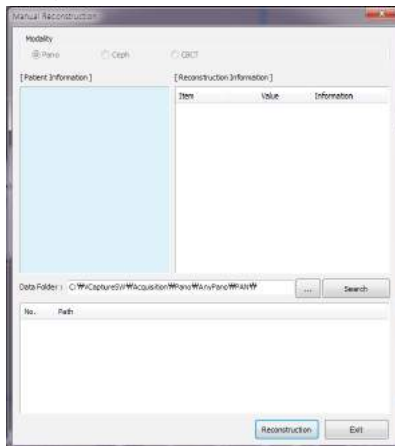
Imaging parameters can be set using the imaging program. The following screenshot shows the main interface in PANO mode. For details concerning PANO, CEPH and CBCT imaging, refer to sections 4.3.1 - 4.3.3.

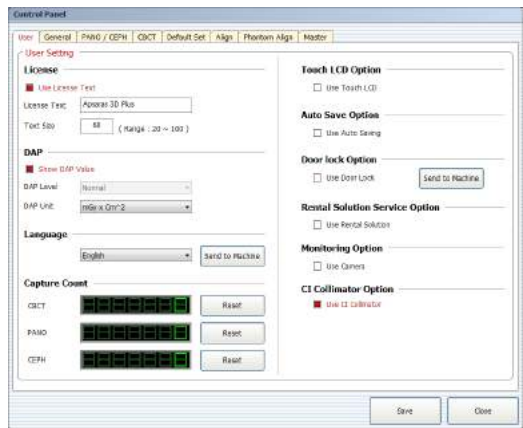


No.	Item	Description
A	Imaging Mode Display	Displays the current imaging mode.  - Indicates that the Magic PAN is supported in the PAN imaging modality. - Displayed only for the Standard mode, with the Magic PAN enabled NOTE
B	Scanning Status and Image Preview window	Shows image acquisition progression and displays preview of the images acquired.
C	Patient Information window	Displays information on the selected patient.

No.	Item	Description																				
D	DAP, Scan Time and Exposure Time Display window	Displays estimated DAP (Dose Area Product), scan time and exposure time after exposure parameter settings are completed.																				
E	Guide Message window	Displays various text instructions for the operator.																				
F	Tube Voltage and Current Adjustment	If the patient is selected in EasyDent / EzDent i, the default kVp / mA according to the patient's information (gender / age) is displayed. This tool adjusts the kVp and mA values and controls the power of the X-ray in order to improve image quality. If necessary, adjust the kVp and mA values manually using the arrows.  NOTE * Adjustable Resolution - Tube Voltage: ± 1 kVp - Tube Current: ± 1 mA (PANO, CEPH), ± 0.1 mA (CBCT) * For the tube voltage and its correspondence with the selected patient, refer to Appendices > 1 Recommended X-ray Exposure Table.																				
G	Patient's gender / age group	Displays the current patient's gender / age group as entered in patient information fields of EasyDent / EzDent i. If necessary, gender/ age group can be manually selected. <table><thead><tr><th colspan="2">Gender / Age Group</th><th>VATECH's Standard</th></tr></thead><tbody><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></tbody></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																					
H	X-ray intensity	Selects X-ray intensity.  NOTE Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft: Soft ≤ Normal ≤ Hard <table><thead><tr><th>Age Group</th><th>Average Head Circumference (cm)</th><th>Range (cm)</th><th>X-ray Intensity</th></tr></thead><tbody><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></tbody></table>	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																			

No.	Item	Description
I	CONFIRM button	Applies the selected settings and moves to the next step. (Exposure parameter setting and patient positioning > Ready for exposure)  NOTE When you click CONFIRM button, estimated DAP (Dose Area Product), scan time and exposure time will be displayed DAP, Scan Time and Exposure Time Display window.
J	READY button	Activated when you click CONFIRM button after the patient positioning is completed. Click the button when all aspects of preparation are completed for image acquisition.
K	Modality Selection and Imaging parameters configuration panel	Selects the Modality Selection (PANO / CEPH (Optional) / CBCT) and imaging parameters for each modality. Refer to section 4.3.1 ~ 4.3.3 for the details regarding PANO, CEPH and CBCT imaging modes.
L	X-ray indicator	The radiation mark turns yellow when the X-ray is on. 
M	Test Rotation button	Switches to the Test mode to check if any part of the patient's body is reached to the surface of the equipment before the actual exposure. This function is applied to PANO and CBCT modalities only. In order to change to the test mode, 1. Align the patient to the equipment. (For the details, refer to the "Positioning the Patient" section of each modality chapter.) 2. Select a modality. 3. Click CONFIRM button. 4. Click Test Rotation button. Then, "ON" on the Test Rotation button is changed to "OFF."  To initiate test rotation, press BEAM ON/OFF button on the Control Panel. To finish the test mode, click Test Rotation button or READY button.

No.	Item	Description
O	Phantom button	This function is used to acquire Phantom images. Image acquisition using the Phantom Jig:  NOTE 1. Click Phantom button. 2. Select the Modality and click OK button. 3. Check the parameters displayed in the main GUI window. If correct, click CONFIRM button. 4. Align the Phantom Jig, and then click READY button. 5. Press and hold down the Exposure Switch.
P	Manual Reconstruction button	Reconstructs the image manually when automatic image reconstruction fails:  Select a Modality. > Click Search button. > Select an image to reconstruct. > Click Reconstruction button.
Q	Laser Beam ON/OFF button	Turns the Laser Beam on or off for patient positioning. Enabled when CONFIRM button is clicked after the imaging conditions are configured.

No.	Item	Description
R	Settings button	Settings button Displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, etc. 
S	EXIT button	Exits the console software.

4.3.1 PANO

PANO Type

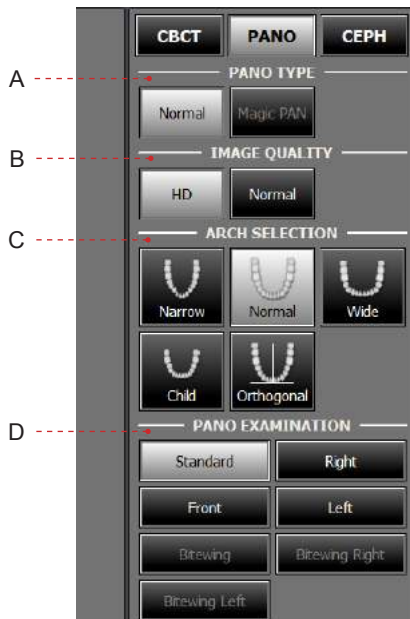
The PaX-i3D Green conditionally offers 2 levels of panoramic imaging system.

Level	Mode	Option	
Normal	Pano examination / Special examination	-	-
Magic PAN	Pano examination (Standard mode)	Magic PAN	optional



NOTE

Magic PAN: an high quality image reconstructed from the optimal auto-focused images throughout the panoramic region to correct the improper patient positioning and rotating unit's trajectory.



A. PANO Type: One of two modes (Magic PAN or Normal) can be selected for PANO imaging.

Magic PAN (optional): a feature to acquire the sharper image. When enabled, the symbol  appears on the upper right for the imaging modes which incorporate this feature.

B. Image Quality

One of two modes (HD or Normal) can be selected for PANO imaging.

- **HD:** Image with higher resolution than **Normal** Mode
- **Normal:** Normal image



NOTE

Setting the default mode in the PANO: The most frequently used mode among the HD and Normal can be configured as the default, which requires the authority.

To change the default mode,

1. Ask the engineer in your region for the mode change.
2. Re-run the imaging program after setting up the related parameters.



CAUTION

The default mode, if any, specified in a specific country can't be changed for the user's intent.

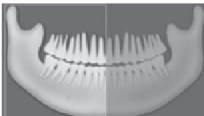
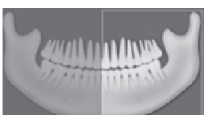
C. Arch Selection

Select the patient's arch type: Narrow, Normal, Wide, Child, and Orthogonal.

Orthogonal: Enables the image to be acquired with overlapping regions of the teeth minimized.

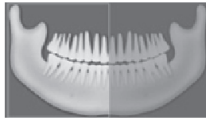
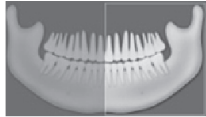
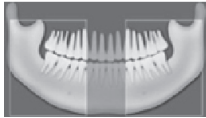
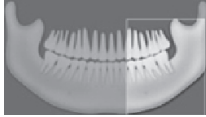
D. PANO Examination

Acquire the image for a specific ROI in panoramic mode.

Mode		Region of Interest: PANO Image	Remark
	Standard	Imaging standard images	Supported by any arch type selection
	Right	Imaging lateral right	
	Front	Imaging frontal area	
	Left	Imaging lateral left	

The following table summarizes the sub-modes for orthogonal imaging.

***Orthogonal mode:** Acquires an image that minimizes overlapping regions of teeth.

Sub-mode		Region of Interest: Orthogonal		Remark
	Standard	Imaging PANO Standard image		Supported by any arch type selection
	Right	Imaging PANO lateral right		
	Front	Imaging PANO frontal area		
	Left	Imaging PANO lateral left		
	Bitewing	Bitewing imaging	Left/Right	Supported by any arch type selection
	Bitewing Right		Right region	
	Bitewing Left		Left region	

Special Examination



Mode		Details	
	TMJ LAT Open	Takes a side view image of the TMJ with the mouth open.	
	TMJ LAT Close	Takes a side view image of the TMJ with the mouth closed.	
	TMJ PA Open	Takes a posterior/anterior image of the TMJ with the mouth open.	optional
	TMJ PA Close	Takes a posterior/anterior image of the TMJ with the mouth closed.	optional
	Sinus LAT	Takes a side view image of the sinus.	optional
	Sinus PA	Takes a posterior-anterior image of the sinus.	

Exposure Time (Max. 20.2 s)

Examination	Arch Selection	Examination Mode	Scan Time (s)	
			HD	Normal
PANO Examination	Narrow	Standard	13.5	10.1
		Front	11.1	8.4
		Right	6.7	5.1
		Left	6.7	5.1
	Normal	Standard	13.5	10.1
		Front	11.1	8.4
		Right	6.7	5.1
		Left	6.7	5.1
	Wide	Standard	13.5	10.1
		Front	11.1	8.4
		Right	6.7	5.1
		Left	6.7	5.1
	Child	Standard	11.5	8.6
		Front	9.2	6.9
		Right	5.7	4.3
		Left	5.7	4.3
	Orthogonal	Standard	13.5	10.1
		Front	11.1	8.4
		Right	6.7	5.1
		Left	6.7	5.1
		Bitewing	9.6	7.2
		Bitewing Incisor	2.5	1.9
		Bitewing Right	4.8	3.6
		Bitewing Left	4.8	3.6
Special Examination		TMJ LAT Open	6.1	4.6
		TMJ LAT Close		
		TMJ PA Open	7.0	5.3
		TMJ PA Close		
		Sinus LAT	6.0	4.5
		Sinus PA	10.3	7.7

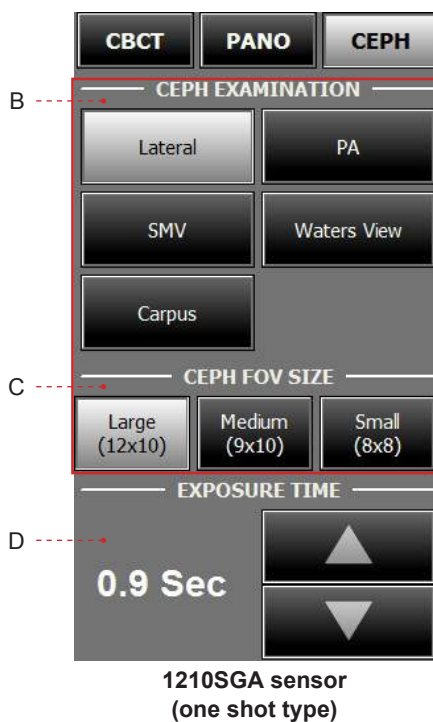
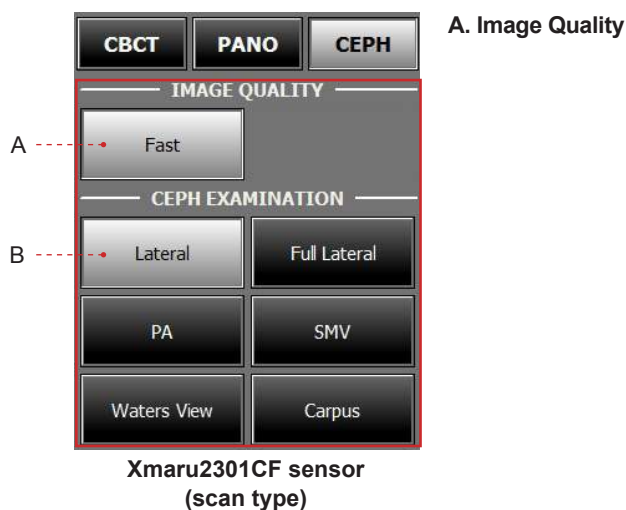


NOTE

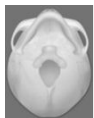
- : Indicates that the examination supports Magic PAN.
- Maximum exposure time deviation: $\pm 10\%$ (IEC 60601-2-7)

4.3.2 CEPH

Depending on the sensor type employed, one of the three kinds of imaging program comes with the equipment for the CEPH mode examination.



B. CEPH Examination

	Mode	Details
	Lateral	Takes a lateral view image partially
	Full Lateral (Scan CEPH)	Takes a lateral view image fully
	PA	Takes a posterior-anterior image
	SMV	Takes a SMV(Sub-Mento Vertical) image
	Waters View	Takes a Waters View image
	CARPUS	Takes a CARPUS image

C. FOV Selection

The Multi FOV is supported for the equipment with the OS (one shot) CEPH sensor (optional).

[With one shot type sensor]

FOV	Details
12 x 10 (inches) 30.48 x 25.40 (cm)	Full size
9 x 10 (inches) 22.86 x 25.40 (cm)	Region of the no interest of the rear part of the head is eliminated to minimize the X-ray exposure area.
8 x 8 (inches) 20.32 x 20.32 (cm)	Child

D. Exposure Time

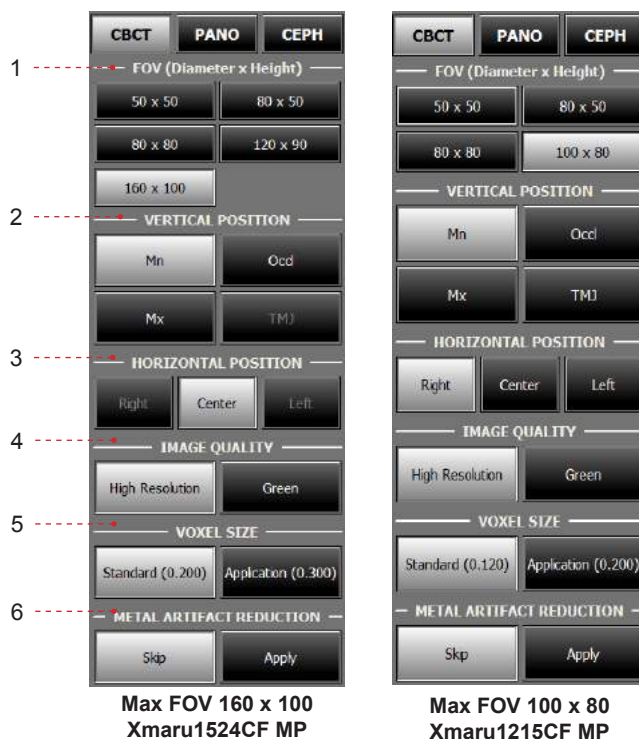
Sensor Type	Examination Modes	Scan Time (s) - Default
Scan	Full Lateral	5.4
	Lateral	4.0
	PA / SMV / Waters View / Carpus	4.9
Oneshot	Lateral	0.7
	PA / SMV / Waters View / Carpus	0.9



NOTE

Exposure time can be adjusted by resolution of 0.1 s in the range of 0.5 s to 1.2 s (One shot type only).

4.3.3 CBCT



CBCT	PANO	CEPH
FOV (Diameter x Height)		
50 x 50	80 x 50	
80 x 80	120 x 90	
150 x 150		
VERTICAL POSITION		
Mn	Ocd	
Mx	TMJ	
HORIZONTAL POSITION		
Right	Center	Left
IMAGE QUALITY		
High Resolution	Green	
VOXEL SIZE		
Standard (0.200)	Application (0.300)	
METAL ARTIFACT REDUCTION		
Skip	Apply	

Max FOV 150 x 150
Xmaru1524CF MP

Max FOV 170 x 150
Xmaru1524CF MP

A. FOV Size

This selects the FOV (Field Of View) size.



NOTE

The FOV size is decided by the attached CBCT sensor (optional).

B. Vertical Position

This selects the vertical imaging region: **Mandible, Occlusion, Maxillary or TMJ.**¹

C. Horizontal Position

This selects the horizontal imaging region: **Right, Center, or Left.**

Guidance Image	FOV (mm)	ROI
	170 X 150	Mn - Center
	160 X 100	Mn - Center
	150 X 150	Mn - Center
	120 X 90	Mn - Center
	100 X 80	Mn - Center
	80 X 80	Mn - Center
	80 X 50	Mn - Center
	50 X 50	Mn / Left Central Incisor

4. Image Quality

Model	Mode	Scan Time
MaX FOV 100 x 80	High Resolution/Green	9.0/5.9 s
MaX FOV 160 x 100	High Resolution/Green	9.0/5.9 s
MaX FOV 150 x 150	High Resolution/Green	15.0/9.0 s
MaX FOV 170 x 150	High Resolution/Green	15.0/9.0 s

E. Voxel Size

FOV (mm)	Mode	Voxel Size (mm)
50 x 50	Standard	0.08
	Application	0.12
80 x 50	Standard	0.12
	Application	0.20
80 x 80	Standard	0.12
	Application	0.20
100 x 80	Standard	0.12
	Application	0.20
120 x 90	Standard	0.20
	Application	0.30
150 x 150	Standard	0.20
	Application	0.30
160 x 100	Standard	0.20
	Application	0.30
170 x 150	Standard	0.20
	Application	0.30

F. Metal Artifact Reduction

This function is used to reduce the artificial effect generated by patients with metallic materials in their dental region and improve image quality. When Metal Artifact Reduction is selected, the time required to reconstruct an image is doubled.



NOTE

Setting the default mode in the CBCT: The most frequently used mode under the Image Quality, Voxel Size, Metal Artifact Reduction can be configured as the default, which requires the authority to change.

To change the default mode,

- 1. Ask the engineer in your region for the mode change.**
- 2. Re-run the imaging program after setting up the related parameters.**



CAUTION

The default mode, if any, specified in a specific country can't be changed for the user's intent.

FOV & Examination Positioning

FOV Size (mm)	Vertical Position		Horizontal Position		
			Right	Center	Left
50 X 50	Mx.	O	A specific tooth selectable		
	Occl.	X			
	Mn.	O			
	TMJ	X			
80 X 50 80 X 80 100 x 80	Mx.		O	O	O
	Occl.		O	O	O
	Mn.		O	O	O
	TMJ		O	X	O
120 X 90 150 X 150 160 X 100 170 X 150	Mx.		X	O	X
	Occl.		X	O	X
	Mn.		X	O	X
	TMJ		X	X	X

Image Reconstruction Time**Xmaru1215CF Master Plus**

FOV (mm)	Voxel Size	Reconstruction Time (s)				File Size (MB)
		High Resolution Mode (Scan Time: 9.0 s)		Green Mode (Scan Time: 5.9 s)		
		MAR Skip	MAR Apply	MAR Skip	MAR Apply	
50 x 50	0.08	48	102	41	84	482
	0.12	24	53	21	41	137
80 x 50	0.12	39	100	33	77	358
	0.20	19	47	15	36	77
80 x 80	0.12	63	145	53	118	579
	0.20	30	63	24	49	122
100 x 80	0.12	87	206	74	167	922
	0.20	32	74	26	56	191

Xmaru1524CF Master Plus (Max FOV 160 x 100)

FOV (mm)	Voxel Size	Reconstruction Time (s)				File Size (MB)
		High Resolution Mode (Scan Time: 9.0 s)		Green Mode (Scan Time: 5.9 s)		
		MAR Skip	MAR Apply	MAR Skip	MAR Apply	
50 x 50	0.08	48	102	41	84	482
	0.12	24	53	21	41	137
80 x 50	0.12	39	100	33	77	358
	0.20	19	47	15	36	77
80 x 80	0.12	63	145	53	118	579
	0.20	30	63	24	49	122
120 x 90	0.20	47	120	40	92	313
	0.30	30	74	24	54	92
160 x 100	0.20	91	212	70	165	622
	0.30	48	128	35	86	184

The test condition:

- PC system: HP Z440, Windows7 pro 64bit OS: Intel® Xeon® E5-1607v3 4C 3.1GHz 1866 10MB cache CPU, 8GB RAM, NVIDIA Quadro K2.200 4GB VGA Card.

- Object: Skull



NOTE

- Image reconstruction time varies depending on computer specifications and/or working conditions.

- The Xmaru series stand for the individual sensor.

- MAR: Metal Artifact Reduction

Xmaru1524CF Master Plus (Max FOV 150 x 150)

FOV (mm)	Voxel Size	Reconstruction Time (s)				File Size (MB)
		High Resolution Mode (Scan Time: 9.0 s)		Green Mode (Scan Time: 5.9 s)		
		MAR Skip	MAR Apply	MAR Skip	MAR Apply	
50 x 50	0.08	54	114	45	90	482
	0.12	19	45	16	35	137
80 x 50	0.12	43	98	35	76	358
	0.20	17	44	13	32	77
80 x 80	0.12	68	153	57	120	579
	0.20	25	60	19	44	122
120 x 90	0.20	45	107	35	80	313
	0.30	27	68	19	46	92
150 x 150	0.20	98	173	84	135	812
	0.30	43	105	33	73	239

The test condition:

- PC system: HP Z440, Windows7 pro 64bit OS: Intel® Xeon® E5-1607v3 4C 3.1GHz 1866 10MB cache CPU, 8GB RAM, NVIDIA Quadro K2200 4GB VGA Card.
- Object: Skull



NOTE

- Image reconstruction time varies depending on computer specifications and/or working conditions.
- The Xmaru series stand for the individual sensor.
- MAR: Metal Artifact Reduction

5

Getting Started

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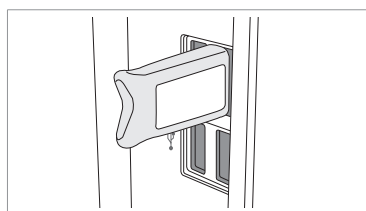
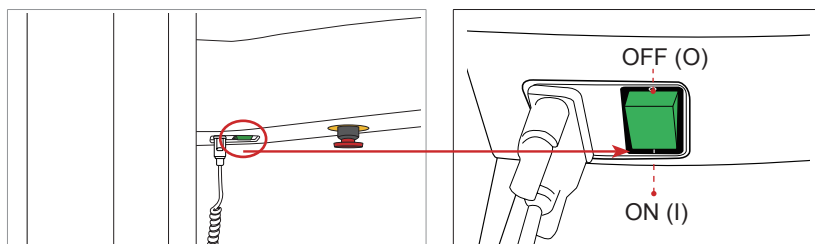
5 Getting Started

5.1 Turning on the PaX-i3D Green

To turn on the system, follow the steps below:

A. Before turning the equipment on, check whether the system is correctly connected and installed (check the connection status between the equipment and the PC).

B. Turn the **ON / OFF** switch underneath the handle frame to the ON position.



C. Insert the license key for **Ez3D plus** into the USB port on the back of PC. The license key for **Ez3D plus** must be attached to view or analyze the 3D images.



- If it has not been used for a long time, allow at least an hour before the first exposure since turning on the equipment.



- Condensation could form inside the equipment if it is a different temperature than the surrounding room. Only turn on the equipment once it has reached room temperature.
- Wait at least 20 seconds after the equipment has been turned off to turn it back on.
- Allow the equipment to warm up for at least 5 minutes before acquiring images or preferably more than 30 minutes for image quality.



Do not position the patient in the unit while it is initiating. The patient could be injured if the equipment malfunctions.

5.2 Running the Image Viewer

EasyDent / EzDent-i is a basic imaging platform for all VATECH's dental X-ray equipments. The Imaging Program is interfaced with **EasyDent / EzDent-i**. On your desktop, double-click **EasyDent / EzDent-i** icon. The **EasyDent / EzDent-i** main window will be displayed.



NOTE

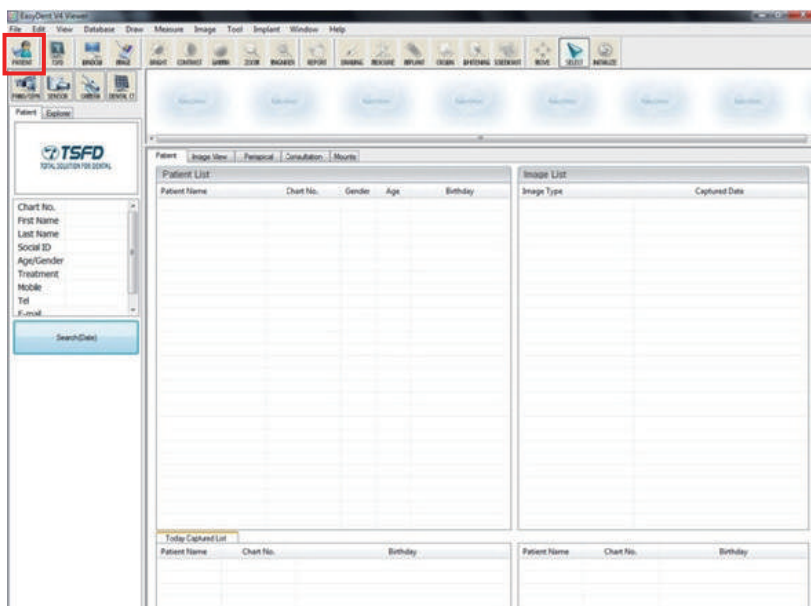
For further details on this subject, refer to the **EasyDent / EzDent-i** user manual.

5.2.1 Creating a New Patient Record

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

EasyDent

A. Click the **Patient** icon on the upper left corner of the EasyDent's main GUI window.



B. The following dialog box will open.

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

D. Click **Add** to save the patient record.

EzDent-i

A. Click the **Add Patient** icon from main GUI window.

B. Enter the required patient information. The **Chart Number, E-Mail address, First Name, and Last Name** are required fields which must be filled in. (The chart number fills in automatically.)

C. Click **Add** to save the patient record.

5.2.2 Retrieving Patient Records

EasyDent

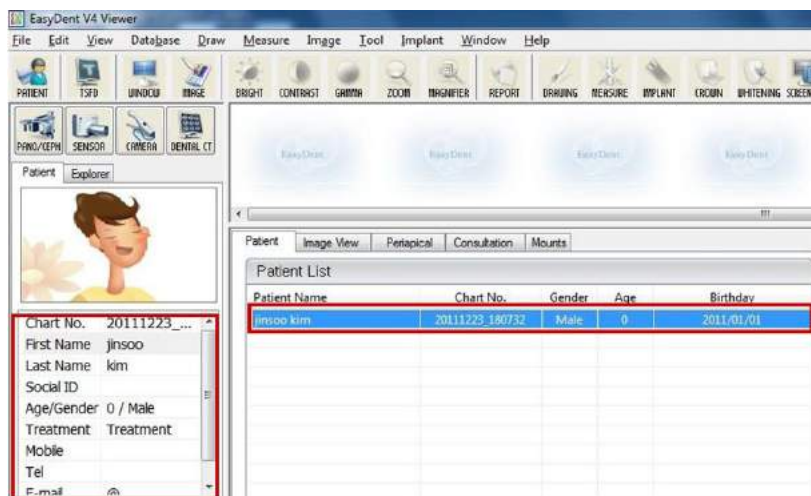
You can search through the patient database using a patient's chart number, their first name, or their last name.

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



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

C. Patient information can be displayed on the **Patient information pane** and **Patient List**.



EzDent-i

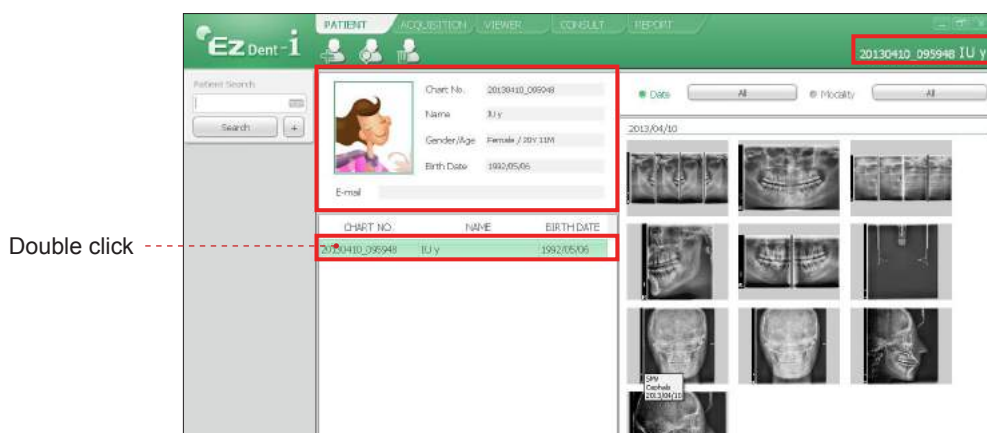
A. Enter the name or chart number of the patient to be searched on the **Search** pane and then click the **Search** button. The information on the patient that fits the search condition appears.



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



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



5.3 Initiating the Imaging Program



NOTE

For a new patient, first register the patient information.

EasyDent

A. First, click the patient information in the patient list, and click the **Dental CT** icon () in the upper left corner of the EasyDent's main window to open the imaging program.



B. The following imaging program window opens. The sole purpose of this window is to control equipment settings and acquire images.

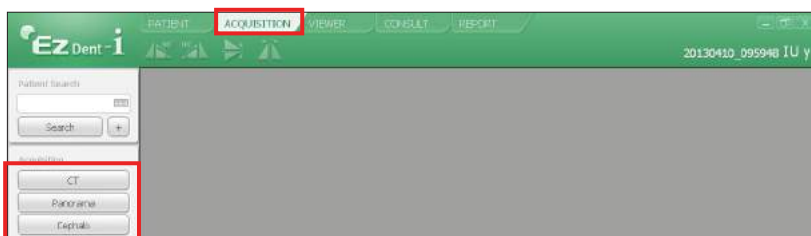


EzDent-i

A. Search and select the patient to be captured.



B. Click **Acquisition** and the imaging mode (CT, Panorama, or Cephalo).



C. The main screen for the selected mode appears. (See **4.3 Imaging Software Overview**). From the main screen, you can configure the imaging parameter settings prior to acquiring an image.

Please proceed to the next chapter.



NOTE

Refer to chapters 6 - 8 for information regarding image acquisition.

6

Acquiring PANO Images

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6 Acquiring PANO Images

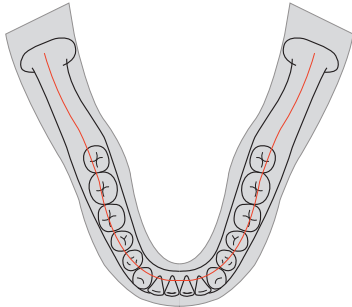
This chapter requires the preparatory steps in **Chapter 5** to have already been completed. If you have not completed these steps, please return to **Chapter 5** and complete the process outlined there before proceeding with this chapter.

6.1 PANO Imaging Program

EXAMINATION	ARCH SELECTION	EXAMINATION PROGRAM	
PANO EXAMINATION	Narrow	Standard	①
		Right	
		Front	
		Left	
	Normal	Standard	②
		Right	
		Front	
		Left	
	Wide	Standard	③
		Right	
		Front	
		Left	
	Child	Standard	④
		Right	
		Front	
		Left	
	Orthogonal	Standard	⑤
		Right	
		Front	
		Left	
		Bitewing	⑥
		Bitewing Right	
		Bitewing Left	
SPECIAL EXAMINATION	-	TMJ LAT Open	⑦
		TMJ LAT Close	
		TMJ PA Open	⑧
		TMJ PA Close	
		Sinus LAT	⑨
		Sinus PA	⑩

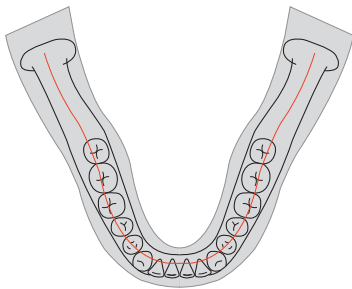
① Narrow_Standard

A panoramic imaging mode for the patients with the V-shaped arch trajectory (typically for some females).



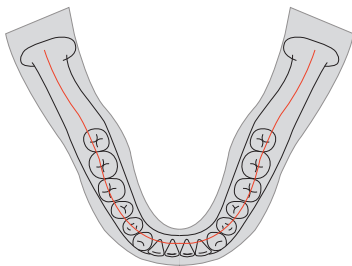
② Normal_Standard

A panoramic imaging mode for the adult patients with the normal arch trajectories.



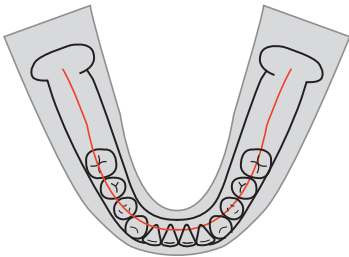
③ Wide_Standard

A panoramic imaging mode for the patients with the square-shaped arch trajectory (typically for some males).



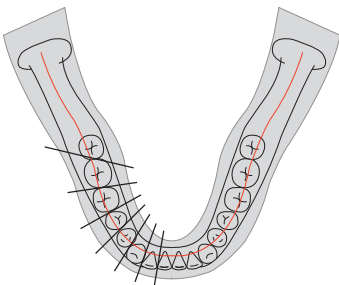
④ Child_Standard

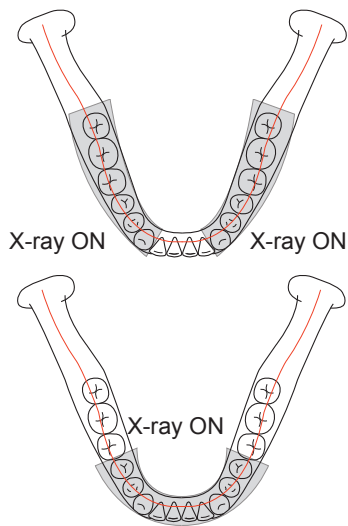
A panoramic imaging mode for the child arch trajectory, in which case the X-ray exposure is 40% less than that in **Normal** mode.



⑤ Orthogonal_Standard

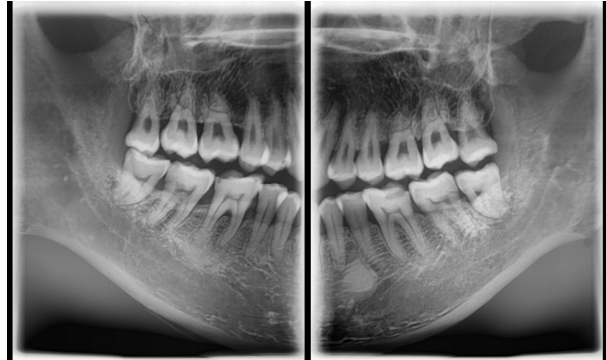
A panoramic imaging mode to minimize the overlapped region of the teeth from the X-ray exposure which is beamed perpendicularly between teeth.





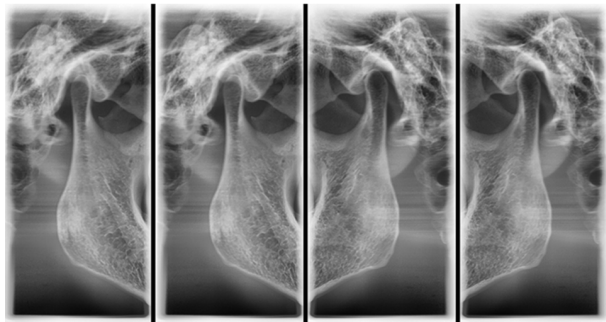
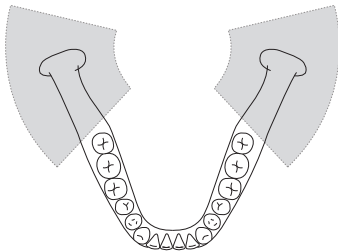
⑥ Orthogonal_Bitewing

A panoramic imaging mode to acquire an image only for the region of interest through the orthogonal trajectory: **Pros:** less X-ray exposure than the Standard mode. **Cons:** TMJ and parts of an image of the maxillary sinus are not acquired.



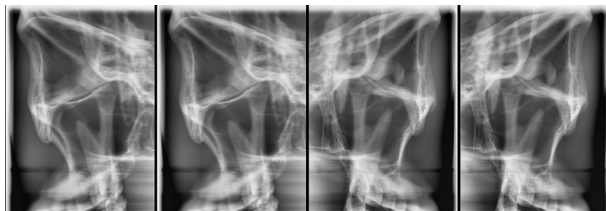
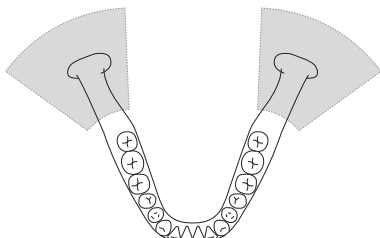
⑦ TMJ LAT Open / Close

An imaging mode to acquire a lateral image of the TMJ, in which the X-ray beam is directed on the lateral TMJ region: TMJ (Open and Close).



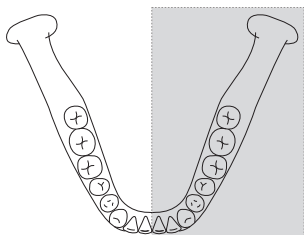
⑧ TMJ PA Open / Close (Optional)

An imaging mode to acquire a TMJ image, in which the X-ray beam is directed on the frontal TMJ, with the patient's mouth open fully and close (Open and Close).



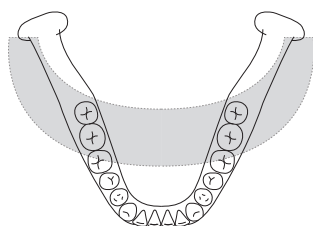
⑨ Sinus LAT (Optional)

A special imaging mode to acquire a Sinus image, in which X-ray beam is directed on the lateral region of the maxillary sinus.



⑩ Sinus PA

A special imaging mode to acquire a Sinus image, in which X-ray beam is directed on the frontal region of the maxillary sinus.



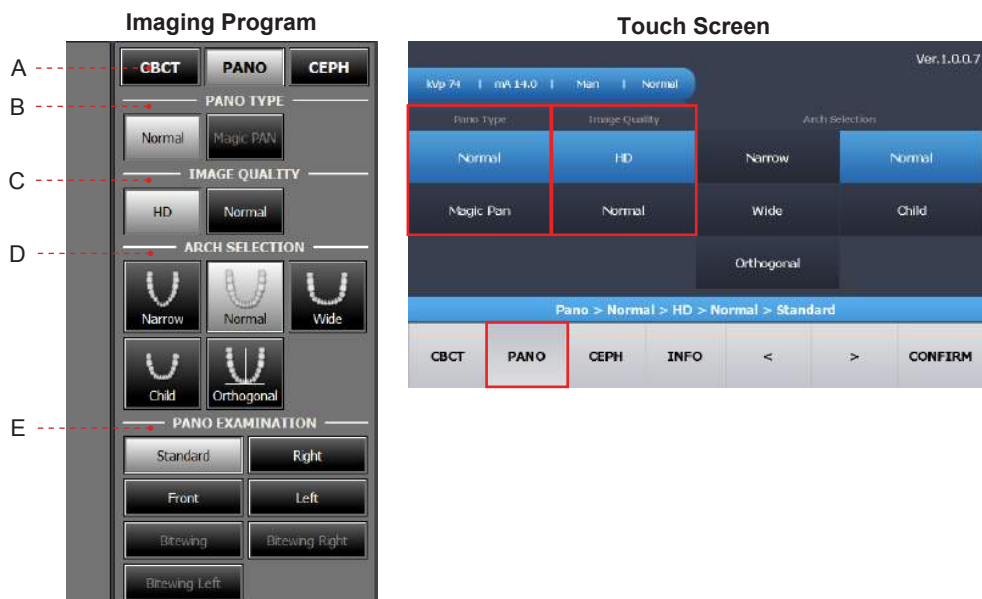
6.2 Setting Exposure Parameters

Perform the following procedures to select the capture parameters for the specific patient and capture mode. For more details, refer to **4.3.1 PANO**.



NOTE

You can set the imaging parameters on either the touch screen or the imaging program running on the PC. They are synched in real time and display the same environmental settings.



A. Choose an imaging mode under **Imaging Mode**.

B. Select the mode under PANO Type: **Normal or Magic PAN**.

Mode	Details	
Normal	Normal image.	
Magic PAN	Image with ultra-high resolution	optional

C. Select the image quality for the image.

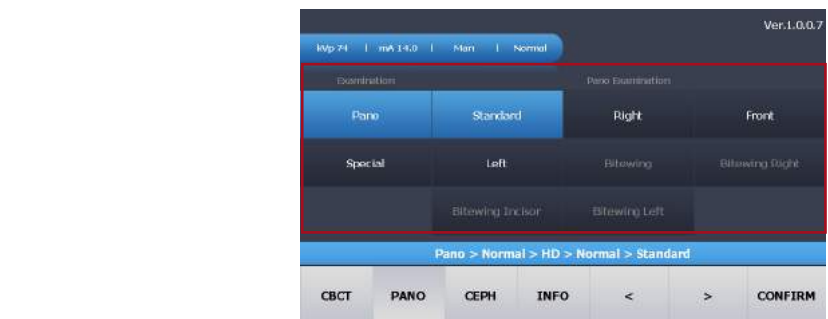
Mode	Details
HD	Image with higher resolution than Normal. Takes longer scan time than the Normal.
Normal	Normal image

D. Select the patient's arch type under **Arch Selection**. By default, **Normal** is selected.



Orthogonal: This mode enables overlapping regions of teeth to be minimized when acquiring images in the ROI. If orthogonal arch is selected, its sub-modes are activated.

E. Select the ROI for panoramic image acquisition under **PANO Examination**.



F. The patient's gender will be automatically selected according to the patient information registered in EasyDent / EzDent-i. Nevertheless, ensure that this information is correct.

G. Select X-ray intensity.



NOTE

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

Soft ≤ Normal ≤ Hard

Age Group	Average head circumference	Range (cm)	classification of head circumference
Child	53±3 cm	> 53±3	Hard
		53±3	Normal
		53±3 <	Soft
Adult	56±3 cm	> 56±3	Hard
		56±3	Normal
		56±3 <	Soft

H. A default value for the tube voltage (kVp) and current (mA) will be displayed based on the gender and X-ray intensity. If necessary, further adjustments can be made using the arrows to the right of each number.



NOTE

Adjustable resolution:

- Tube voltage: ± 1 kVp
- Tube current: ± 1 mA

I. Click the **CONFIRM** button for these parameters to take effect.



NOTE

Please wait for a moment, while the rotating unit moves to its initial scanning position.

When you click the **CONFIRM** button,

- The **READY** button will begin blinking to show that it has been activated.
- The rotating unit will move to its initial scanning position.
- Three Laser Beams, **Mid-sagittal plane**, **Frankfurt plane** and **Canine**, will be activated to facilitate patient positioning. These beams will disappear after 20 minutes or if the **READY** button is clicked.

Scan Time	Exposure Time
14.1 Sec	13.5 Sec
DAP	
96.236111 mGy x Cm^2	



Laser beam On / Off buttons:



: Imaging Program



: Control Panel

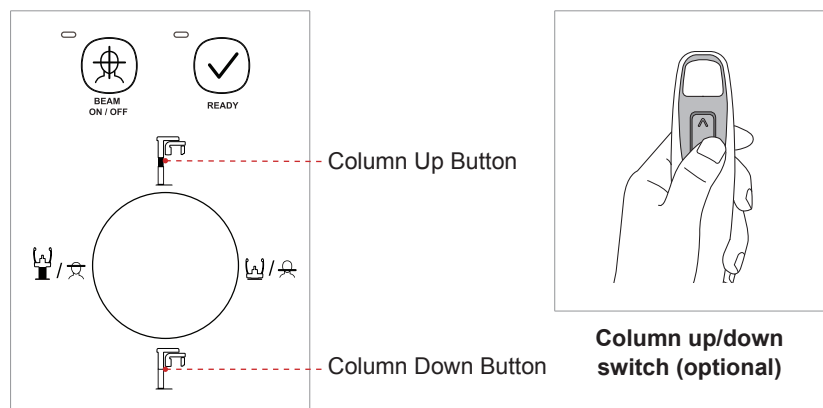
- The scan time, exposure time and DAP (Dose Area Product) values will be shown on the main display for the selected exposure.

J. Guide the patient to the equipment. Position the patient within the equipment. For further information about patient positioning, refer to section **6.3 Positioning the Patient**.

6.3 Positioning the Patient

Before Positioning the Patient

- Ask the patient to remove all jewelry and metallic objects, such as earrings, hair pins, spectacles, dentures, and orthodontic appliances. These items may cause shadow images which could obscure diagnosis.
- It is strongly recommended that the patient wear a lead apron for protection against any possible scatter radiation.
- Adjust the column height to the patient's height using the up/down button or switch.



NOTE

- 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 unit are not obstructed by the stool.
- Correct positioning is an important factor in capturing the best possible image. Proper positioning will reduce the appearance of the cervical spine in the image.



CAUTION

If you don't adjust the Laser Beams for patient alignment (Vertical, Horizontal, and Canine beams), part of the image may be zoomed in or out or a ghost may appear in the image.



WARNING

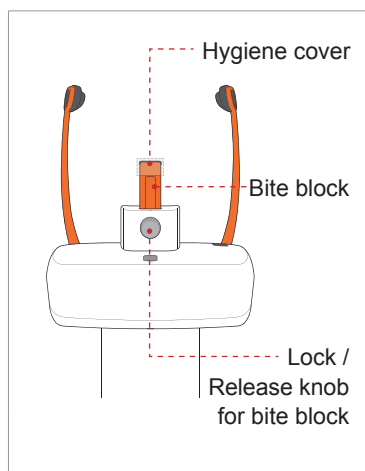
Be careful not to project the Laser Beams directly into the patient's eyes as this could severely damage the patient's vision.

6.3.1 PANO Standard and Bitewing mode

Positioning the patient



*To link to the video manual: scan the QR code with smart phone or pad.



A. Insert the bite block into the Chinrest receptacle on the equipment.

B. Place a hygienic cover over the bite block.



The hygiene cover for the bite block and chin support is intended for single use only. Always replace the hygiene cover for each new patient.



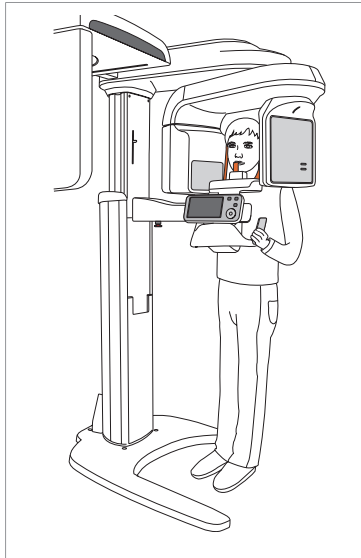
Disinfect the Chinrest, Chin support and bite block using an alcohol-based cleaning solution and wipe away all residue with dry cloth.



C. Open the temple supports by clicking the temple support adjustment button.

D. Guide the patient —facing the Chinrest — to the equipment.

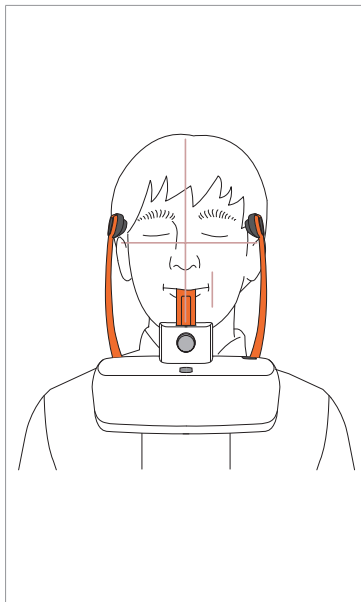
E. Adjust the height of the column using the column up/down button or switch (optional) until the patient's chin rests comfortably on the Chinrest.



F. Ask the patient to:

- Stand upright
- Firmly grip the handle
- Lean his/her chest lightly against the equipment
- Position his/her feet slightly forward and open stance

G. Ensure that the patient's shoulders remain level and that his/her neck is relaxed. The cervical spine should be straight and upright.



H. Have the patient bite the bite block along its grooves using his/her upper and lower incisors

I. Secure the bite block firmly by turning the locking knob to the right.

J. Have the patient

- Close his/her lips around the bite block
- Keep his/her tongue pressed against his/her palate
- Close his/her eyes

Ask the patient to remain still until scanning is completed.

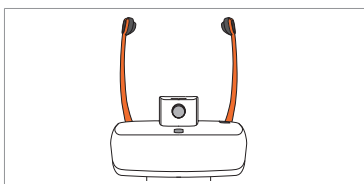


CAUTION

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

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

Positioning the edentulous patient



A. Remove the bite block from the Chinrest receptacle on the equipment.



B. Open the temple supports by clicking the temple support adjustment button.

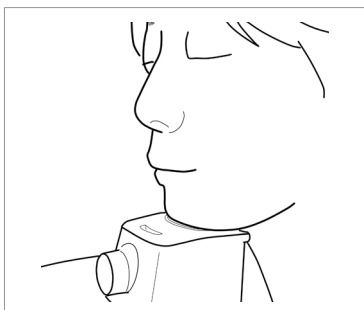
C. Guide the patient —facing the Chinrest — to the equipment.



D. Adjust the height of the column using the column up/down button or switch (optional) until the patient's chin rests comfortably on the Chinrest.

E. Ask the patient to:

- Stand upright
- Firmly grip the handle
- Lean his/her chest lightly against the equipment
- Position his/her feet slightly forward and open stance



F. Have the patient

- Close his/her lips around the bite block
- Keep his/her tongue pressed against his/her palate
- Close his/her eyes

Ask the patient to remain still until scanning is completed.

Aligning the Laser Beams

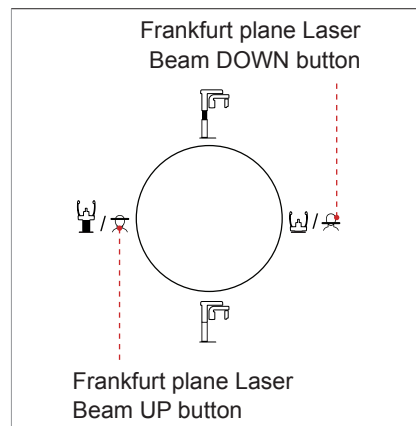
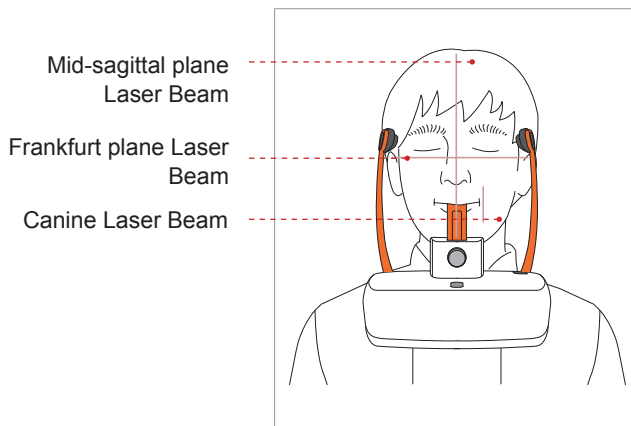


Be careful not to project the Laser Beams directly into the patient's eyes as this could severely damage the patient's vision.

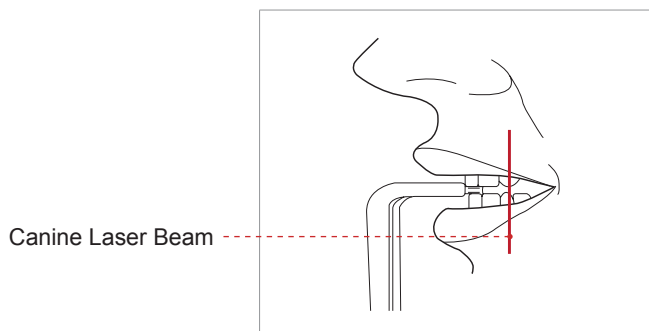
A. Mid-sagittal plane Laser Beam: Position the Mid-sagittal plane Laser Beam on the center of the patient's face to prevent magnifications of the left or right side in the final image.

B. Frankfurt plane Laser Beam: Position the patient's head so that the Frankfurt plane is aligned with the Frankfurt plane Laser Beam.

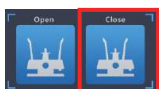
*** The Frankfurt plane is the plane which joins the infra-orbital point to the superior border of the external auditory meatus.**



C. Canine Laser Beam: Have the patient smile to properly position the canine Laser Beam on the center of the patient's canine tooth.



Completing Patient Positioning



A. After confirming patient positioning and beam alignment, adjust the temple supports to fit snugly on both sides of the patient's head by clicking the temple support adjustment button.

B. Click the **READY** button after the patient has been properly positioned. No X-ray will be emitted at this point.

C. Proceed to section **6.4 Initiating X-ray Exposure**.

6.3.2 TMJ Open

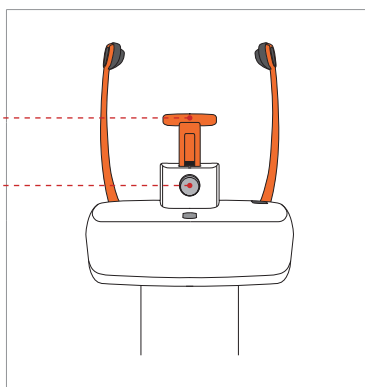
There are two TMJ sub modes: **TMJ Open** and **TMJ Close**. Scan a TMJ Open image first and then scan a TMJ Close image. To prepare and position the patient, follow the process outlined below.



- **Correct positioning is an important factor for image capturing. Proper positioning will reduce the appearance of the cervical spine in the reconstructed image.**
- **For a child with a large head circumference, Man/Woman mode may be selected instead of Child.**

Positioning the patient

Chin support
Lock / release knob
for bite block



A. Insert the Chin support into the Chinrest receptacle on the equipment.



Disinfect the Chinrest using an alcohol-based cleaning solution and wipe away all residues with dry cloth before proceeding any further.



B. Open the **Temple Supports** by clicking the temple support adjustment button.

C. Guide the patient —facing the Chinrest — to the equipment.

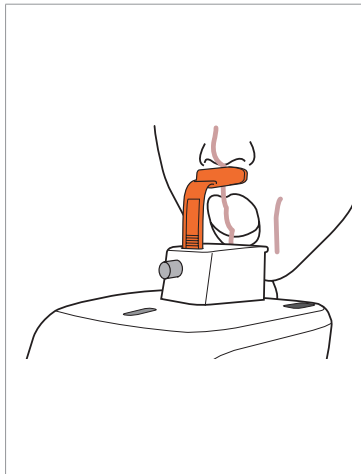
D. Adjust the height of the equipment using the column up/down button or switch (optional) until the patient's chin is resting on the Chinrest. Ensure that the chin is in contact with the Chinrest.

E. Ask the patient to:

- Stand upright
- Firmly grip the handle
- Lean his/her chest lightly against the equipment
- Position his/her feet slightly forward.

F. Adjust the chin support so that it rests snugly on the chin and secure the chin support firmly by turning the locking knob to the right.

G. Have the patient place his / her acanthion point on the chin support and tilt his / her head forward by 5 degree.



H. For **TMJ Open** imaging, have the patient:

- Open his/her mouth as wide as possible
- Keep his/her tongue positioned towards the palate
- Close his/her eyes.

Be careful the chin not to touch any part of the equipment.

I. Ensure that the patient's shoulders remain level and that his/her neck is relaxed. The cervical spine should be straight and upright. Ask the patient to remain still until scanning is complete.



CAUTION

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

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

Aligning the Laser Beams

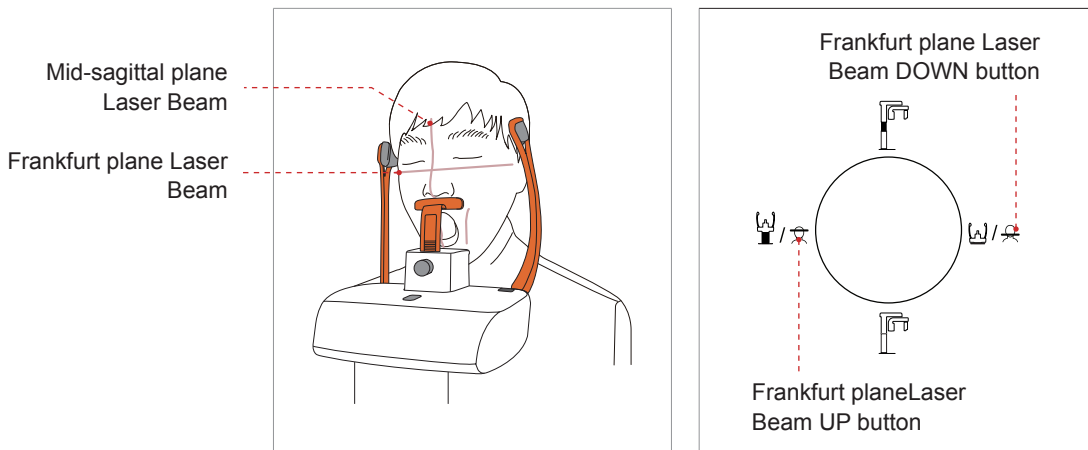


Be careful not to project the Laser Beams directly into the patient's eyes as this could severely damage the patient's vision.

A. Mid-sagittal plane Laser Beam: Position the Mid-sagittal plane Laser Beam at the center of the patient's face to prevent magnifications of the left or right side in the final image.

B. Frankfurt plane Laser Beam: Position the patient's head so that the Frankfurt plane is aligned with the Frankfurt plane Laser Beam.

*** The Frankfurt plane is a plane which joins the lower eye lid to the superior border of the external auditory meatus.**



Completing Patient Positioning



A. After confirming patient positioning and beam alignment, adjust the temple supports to fit snugly on both sides of the patient's head by clicking the temple support adjustment button.

B. Click the **READY** button after the patient has been properly positioned. No X-ray will be emitted at this point.

C. Proceed to section **6.4 Initiating X-ray Exposure**.

6.3.3 TMJ Close

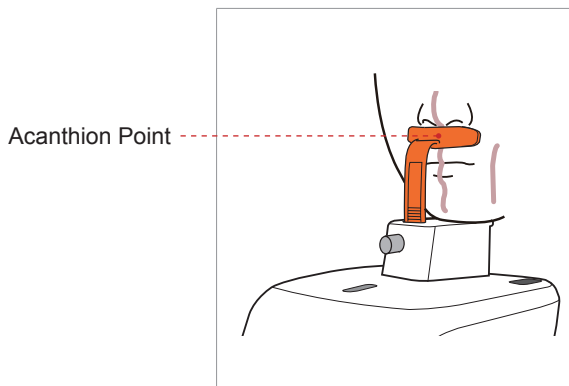


Scan a TMJ Open image first and then scan a TMJ Close image. Guide the patient to close his/her lips for TMJ Close imaging while maintaining the same position used for TMJ Open imaging.

A. Shortly after TMJ Open imaging has been completed, you will receive the following message: "Do you want to take the TMJ Close image continuously?" Press the OK button to capture a TMJ Close image.

B. Adjust the chin support so that it rests snugly on the chin and secure the chin support firmly by turning the locking knob to the right.

C. Have the patient place his / her acanthion point on the chin support and tilt his / her head forward by 5 degree.



D. For TMJ Close imaging, Have the patient:

- Close his/her mouth
- Keep his/her tongue pressed against his/her palate
- Close his/her eyes

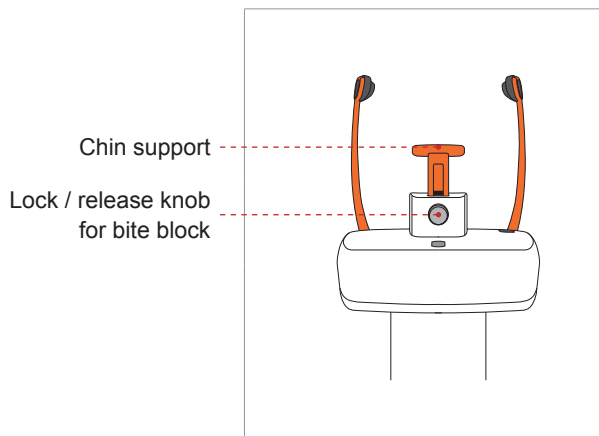
The top of the chin support must remain in contact with the patient's acanthion point during exposure. Ask the patient to remain still until scanning is complete.

E. The Laser Beams should be aligned in the same way as for **TMJ Open** imaging.

F. Proceed to section **6.4 Initiating X-ray Exposure**.

6.3.4 Sinus

Positioning the Patient



A. Insert the Chin support into the Chinrest receptacle on the equipment.



Disinfect the Chinrest using an alcohol-based cleaning solution and wipe away all residues with a dry cloth before proceeding any further.



B. Open the **temple supports** by clicking the **temple support adjustment button**.

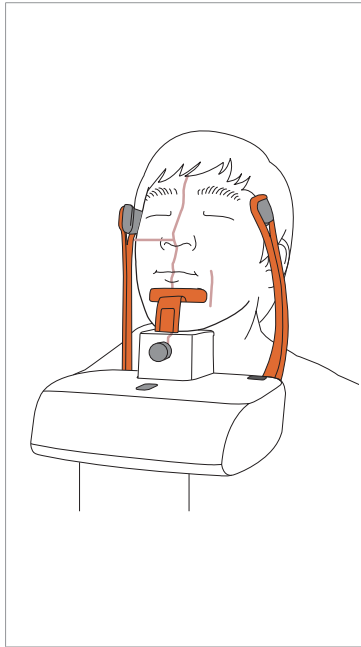
C. Guide the patient —facing the Chinrest — to the equipment. Have the patient stand upright in the center of the equipment.

D. Adjust the height of the equipment using the column up/down button or switch (optional) until the patient's chin rests comfortably on the Chinrest.

E. Ask the patient to:

- Stand upright
- Firmly grip the handle
- Lean his/her chest lightly against the equipment
- Position his/her feet slightly forward.

F. Adjust the chin support so that it rests upon snugly on the chin and secure the chin support firmly by turning the locking knob to the right.



G. Ensure that the patient's shoulders remain level and that his/her neck is relaxed. The cervical spine should be straight and upright.

H. Have the patient:

- Tilt his/her head back by 10-15°
- Close his/her mouth
- Keep his/her tongue pressed against his/her palate
- Close his/her eyes

Ask the patient to remain still until scanning is completed.



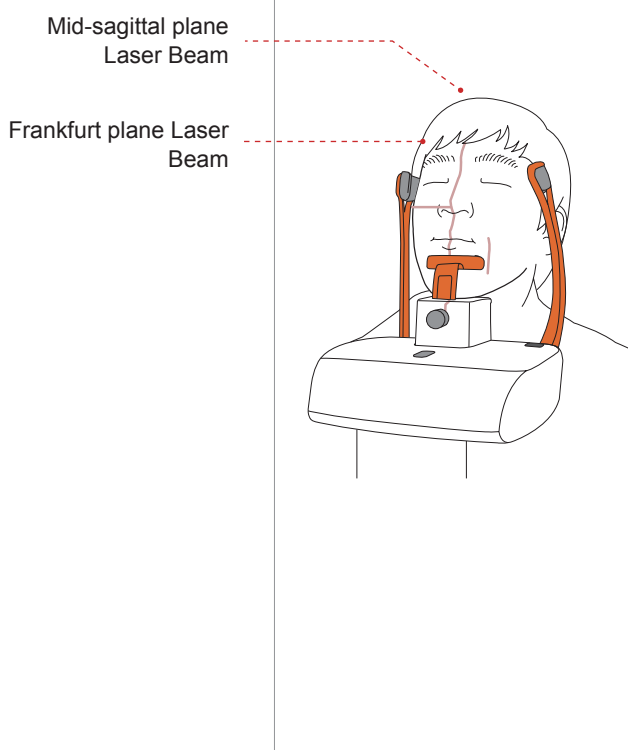
To acquire the best image possible, ask the patient not to:

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

Aligning the Laser Beams



Be careful not to project the Laser Beams directly into the patient's eyes as this could severely damage the patient's vision.

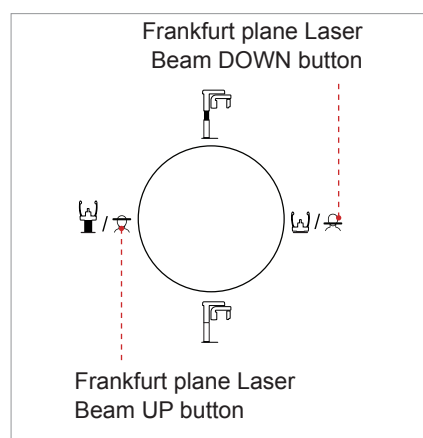


A. Mid-sagittal plane Laser Beam:

Position the Mid-sagittal plane Laser Beam at the center of the patient's face to prevent magnifications of the left or right side in the final image.

B. Frankfurt plane Laser Beam:

The Frankfurt plane Laser Beam should go from the top of the ear to the tip of the nose when the patient's head is tilted back 10 – 15 °.



Completing Patient Positioning

A. After confirming patient positioning and beam alignment, adjust the temple supports to fit snugly on both sides of the patient's head by clicking the temple support adjustment button.

B. Click the **READY** button after the patient has been properly positioned. No X-ray will be emitted at this point.

C. Proceed to section **6.4 Initiating X-ray Exposure**.

6.4 Initiating X-ray Exposure

The X-ray exposure method and its sequences are the same for PANO Standard and PANO Special modes. The example used in this manual is the PANO Standard mode.

To emit the X-ray, perform the following procedure.



- **Do not operate the PC during exposure. Failure to comply with this instruction may cause the system to malfunction.**
- **The operator shall observe the X-ray safety regulations applicable to their area at all times during the operation of this equipment.**

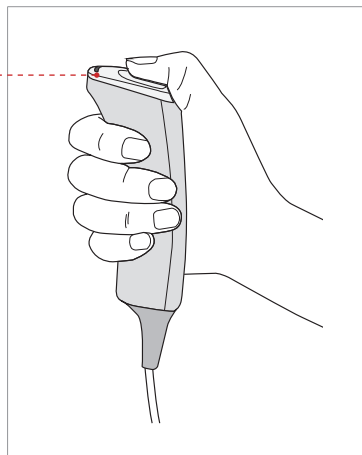


If an emergency occurs during image acquisition, release the exposure switch to cease X-ray emission.

A. Leave the X-ray room and close the door. The operator must visually monitor the patient at all times during image acquisition.

B. Press and hold down the exposure switch until image acquisition is complete.

Exposure indicator
light turns Yellow
Yellow: Exposure

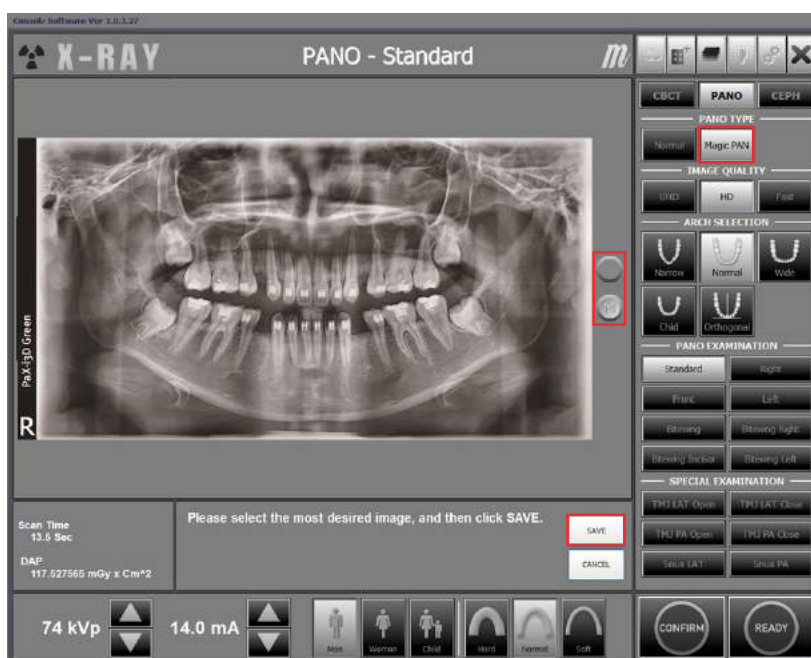


During X-ray irradiation, ensure that

- The LED lamp on top of the equipment turns Yellow to indicate X-ray emission.
- The warning lamp outside the X-ray room turns on.
- The sound (beep or music: optional) goes off.
- The radiation symbol on the upper left corner of GUI turns yellow to indicate X-Rays are being emitted.

C. The image appears in real time on the imaging GUI.

Ex) Magic PAN



Two images are obtained, with each in the **Magic PAN** and **Normal** respectively. You would click either button to compare them with each other.

The buttons:  **Normal**  **Magic PAN**

D. Click the **Save** button to save the image.



NOTE

Magic PAN (Optional): A high quality image reconstructed from the optimal auto-focused images in each segment throughout the panoramic region to correct the improper patient positioning and rotating unit's trajectory.

After Image Acquisition

After acquiring the image, complete the following steps:

- Loosen the temple supports to release the patient.
- Remove the hygiene cover from the bite block (for **standard PANO** mode only).
- Press **Return** to bring the Rotating Unit back to its initial position.



7

Acquiring CEPH Images

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7 Acquiring CEPH Images

This chapter requires all of the preparatory steps outlined in **Chapter 5** to have already been completed. If these steps have not been completed, return to **Chapter 5** and complete the setup processes outlined there before proceeding to the processes outlined in this chapter.

7.1 Setting the Exposure Parameters

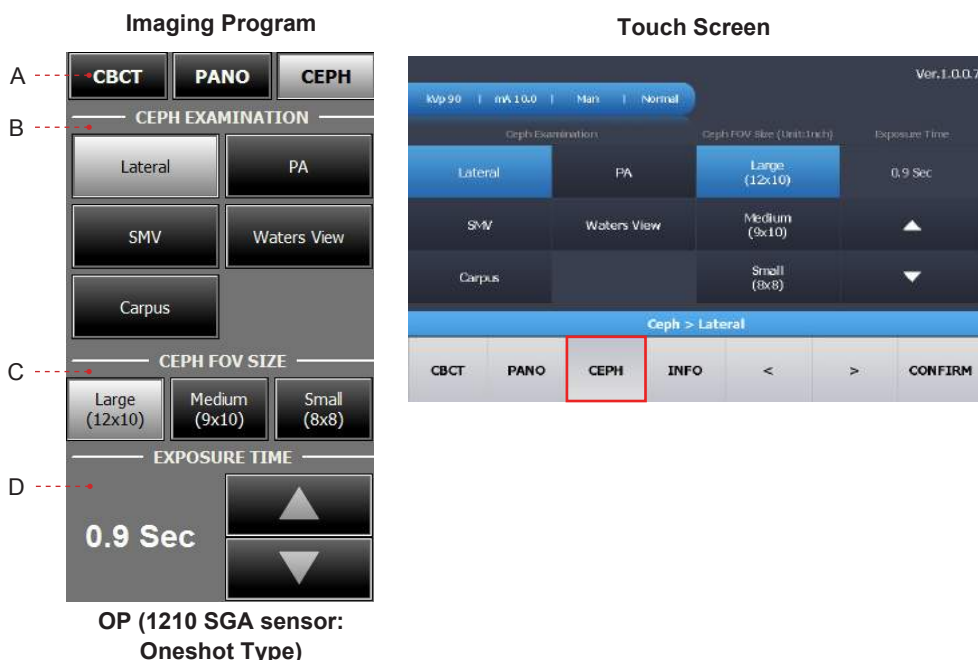


NOTE

You can set the imaging parameters on either the touch screen or the imaging program running on the PC. They are synched in real time and display the same environmental settings.

Perform the following procedures to set the exposure parameters for the specific patient and capture mode (for more details about CEPH imaging, refer to section 4.3.2 CEPH).

Depending on the sensor type employed, one of three kinds of imaging S/W comes with the equipment for the CEPH mode examination.





The Multi FOV is supported for the equipment with the one shot type sensor.

A. Click the **CEPH** button.

B. Select the scanning mode under **CEPH Examination**. – **Lateral, Full Lateral, PA, SMV, Waters View, Carpus**.

C. Select the FOV size for the specific imaging mode.

[With one shot type sensor]

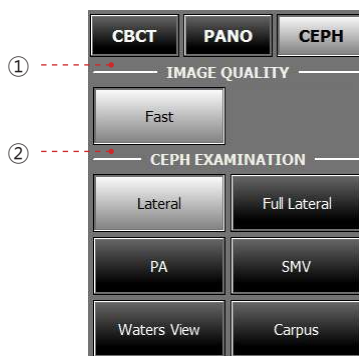
FOV	Details
12 x 10 (inches) 30.48x25.40 (cm)	Full size
9 x 10 (inches) 22.86x25.40 (cm)	Region of the no interest of the rear part of the head is eliminated to minimize the X-ray exposure area.
8 x 8 (inches) 20.32x20.32 (cm)	Child

D. EXPOSURE TIME

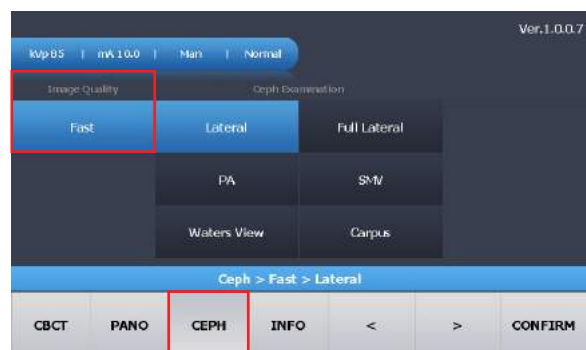


Exposure time can be adjusted by resolution of 0.1 s in the range of 0.5 s to 1.2 s.

For information regarding to the exposure time of each CEPH imaging mode, refer to the section “4.3.2 CEPH”.



SC (Xmaru2301CF Sensor Scan Type)

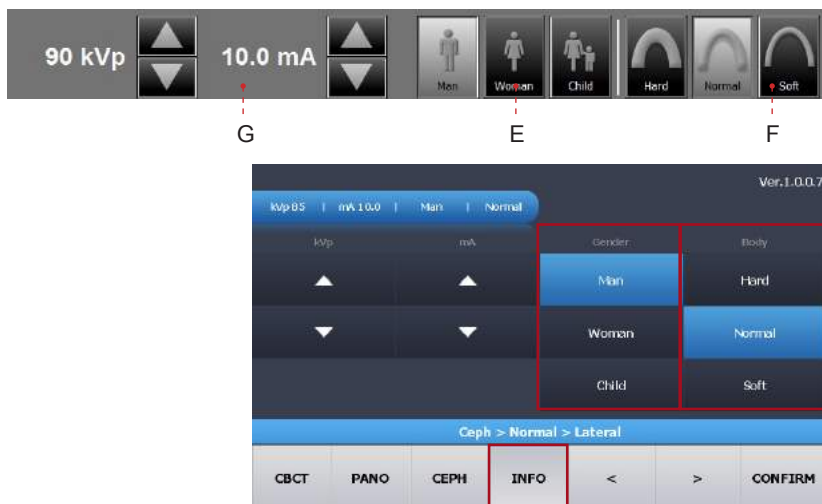


① Image Quality

Fast: Scans faster with lower X-Ray dose than the **Normal** mode.

② CEPH Examination

Full Lateral (Optional): Scan a lateral view image fully.



E. The gender and age of the patient is automatically selected according to EasyDent / EzDent-i's patient information. Nevertheless, ensure that this information is correct.

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



NOTE

A Child is defined as a person who is between 2 and 12 years old. If Child is selected, the image size and exposure dose are automatically reduced.

F. Select X-ray intensity.



NOTE

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

Soft ≤ Normal ≤ Hard

Age Group	Average head circumference	Range (cm)	classification of head circumference
Child	53±3 cm	> 53±3	Hard
		53±3	Normal
		53±3 <	Soft
Adult	56±3 cm	> 56±3	Hard
		56±3	Normal
		56±3 <	Soft

G. Default values for the tube voltage (kVp) and current (mA) will be displayed based on the patient's gender and X-ray intensity. If necessary, you may manually adjust these values using the arrows to the right of each value.

H. Click **CONFIRM** to accept the parameters.



When you click the **CONFIRM** button:

- The **READY** button will begin blinking to show that it is activate.
- The scan time, exposure time and estimated DAP (Dose Area Product) value are shown on the main display for the intended exposure.

Scan Time Exposure Time
14.1 Sec 13.6 Sec

DAP
96.236111 mGy x Cm^2

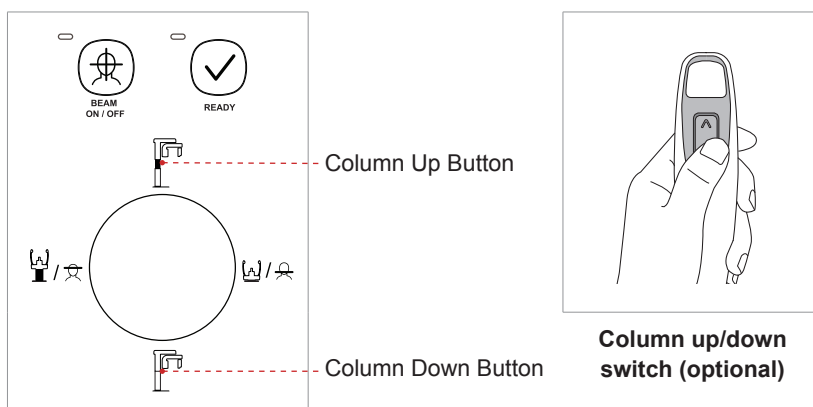
I. Guide the patient to the equipment. Refer to section **7.2 Positioning the Patient**.

7.2 Positioning the Patient

Follow the procedure below to prepare and position the patient for CEPH imaging.

Before Positioning the Patient

- Ask the patient to remove all jewelry and metallic objects, such as earrings, hair pins, spectacles, dentures, and orthodontic appliances. These items may cause shadow images which could obscure diagnosis.
- It is strongly recommended that the patient wear a lead apron for protection against any possible scatter radiation.
- Adjust the column height to the patient's height using the up/down button or switch (optional).



NOTE

Correct positioning is an important factor in capturing the best possible image.



CAUTION

Ensure that the nasal positioner left unfolded, before adjusting the ear rods in the proper direction.



WARNING

Ensure that the patient is clear of all moving parts while adjusting the height of the equipment.



NOTE

Although the illustrations and explanations on patient's posture and device usage are based on the OS / OP models (one shot-type sensor), those for the SC (scan type) model should be the same.

7.2.1 Lateral / Full Lateral



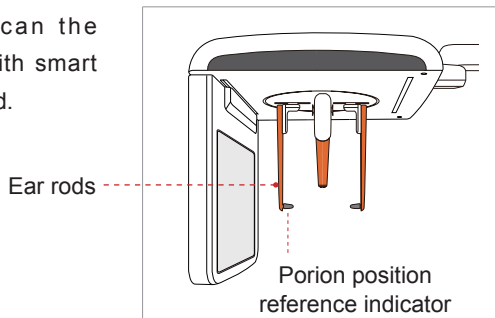
*To link to the video manual: scan the QR code with smart phone or pad.



NOTE

The order and manner to take an image are equivalent for the Lateral and Full Lateral modes, except for the exposure area in which the full lateral covers the patient head 60 mm wider than the Lateral.

Follow the procedure below to position the patient.



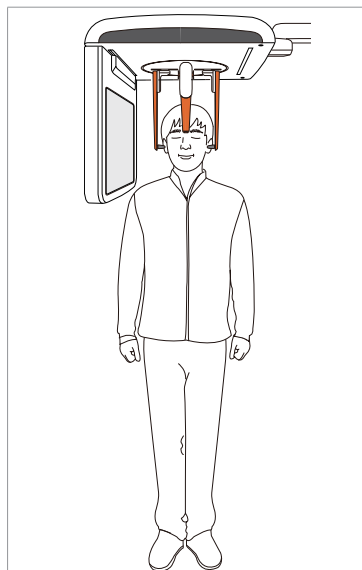
A. Widen the distance between the two ear rods.



NOTE

Porion position reference indicator enables the operator to easily identify the position of the porion on the image.

B. Guide the patient to the CEPH unit.



C. Ask the patient to stand upright.

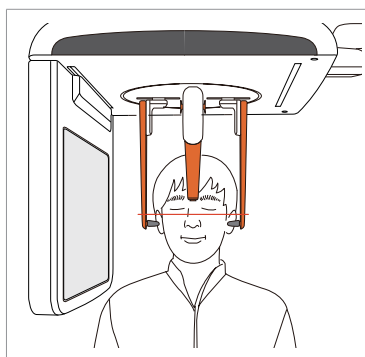
Make sure that the patient's shoulders are level and that their neck is relaxed.

D. Adjust the height of the unit to suit the patient by pressing the column up/down button or switch (optional).



CAUTION

After adjusting the height of the column to suit the patient, fit the ear rods along the patient's ear canals and adjust the nasal positioner.



E. The ear rods should fit properly along the patient's ear canals. The patient's Frankfurt Plane should be parallel to the floor.

F. Position the nasal positioner on the patient's Nasion point. The height of nasal positioner can be adjusted.

G. Ask the patient to swallow any saliva in his/her mouth and remain still until X-ray exposure is complete.

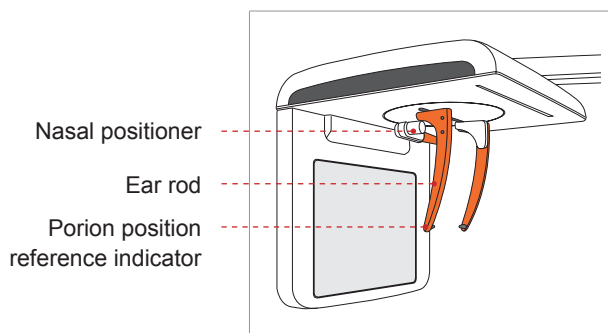


H. Click the **READY** button after the patient has been properly positioned. No X-ray will be emitted at this point.

I. Proceed to section 7.3 Initiating X-ray Exposure.

7.2.2 Frontal (PA)

Follow the procedure below to correctly position the patient.



A. Turn the ear rods 90° clockwise from their initial position.

B. Widen the distance between the two ear rods.

C. The nasal positioner should be flipped to the side and upward to prevent it from obstructing the image acquisition.



Porion position reference indicator enables the operator to easily identify the position of the porion on the image.



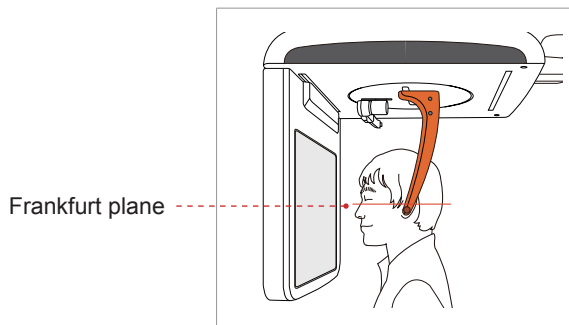
E. Ask the patient to stand upright facing the sensor.

Make sure that the patient's shoulders are level and that his/her neck is relaxed.

F. Adjust the height of the unit to suit the patient by pressing the column up/down button or switch (optional).



After adjusting the column to the patient's height, fit the ear rods along the patient's ear canals.



G. The ear rods should fit properly along the patient's ear canals. The patient's Frankfurt Plane should be parallel to the floor.

H. Ask the patient to swallow any saliva in his/her mouth and remain still with his/her mouth closed until X-ray exposure is complete.

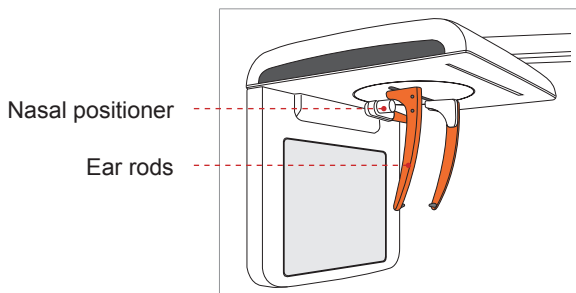


I. Click the **READY** button after the patient has been positioned. No X-ray will be emitted at this point.

J. Proceed to section **7.3 Initiating X-ray Exposure**.

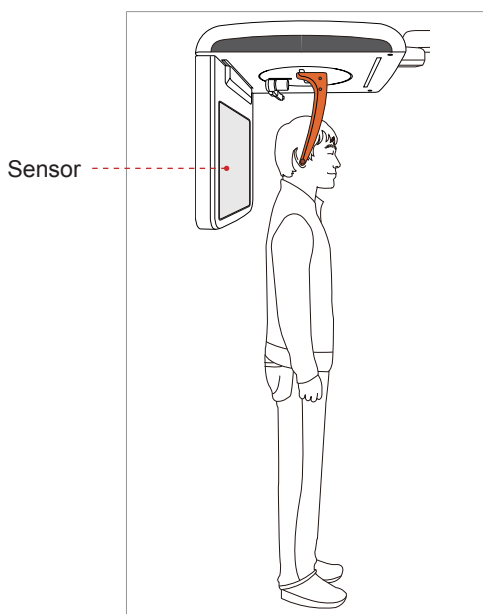
7.2.3 SMV

Follow the procedure below to prepare and position the patient.



A. Widen the distance between the two ear rods.

B. The nasal positioner should be flipped to the side and up to prevent it from obstructing the image acquisition.



C. Guide the patient to the CEPH unit.

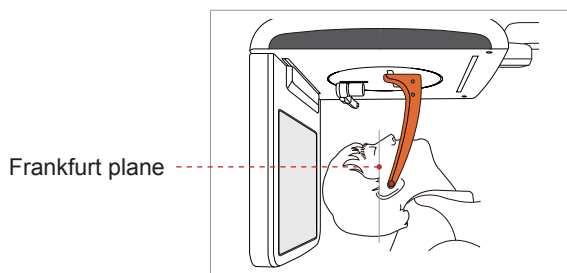
D. Ask the patient to stand upright facing the X-ray tube.

Make sure that the patient's shoulders are level and that his/her neck is relaxed.

E. Adjust the height of the unit to suit the patient by pressing the column up/down button or switch (optional).



After adjusting the column to suit the height of the patient, fit the ear rods along the patient's ear canals.



F. Place the ear rods along the patient's ear canals. Make sure that the ear rods are comfortably, yet firmly in place.

G. Gently tilt the patient's head back until his/her Frankfurt plane is perpendicular to the floor, as shown below.

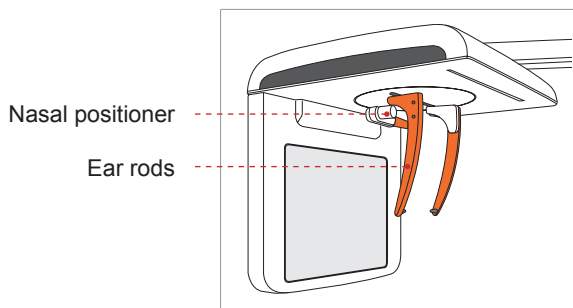


H. Click the **READY** button after the patient has been properly positioned. No X-ray will be emitted at this point.

I. Proceed to section **7.3 Initiating X-ray Exposure**.

7.2.4 Waters View

Follow the procedure below to prepare and position the patient for Waters View mode image acquisition.



A. Widen the distance between the two ear rods.

B. The nasal positioner should be flipped to the side and up to prevent it from obstructing the image acquisition.

C. Guide the patient to the CEPH unit.

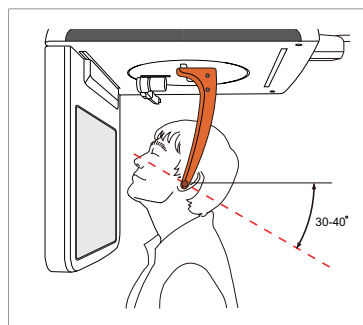
D. Ask the patient to stand upright facing the sensor. Make sure that the patient's shoulders are level and that his/her neck is relaxed.

E. Adjust the height of the unit to suit the patient by pressing the column up/down button or switch (optional).



After adjusting the column to suit the height of the patient, fit the ear rods along the patient's ear canals.

F. Place the ear rods along the patient's ear canals. Make sure that the ear rods are comfortably, yet firmly, in place.



G. Ask the patient to swallow any saliva in his/her mouth and tilt his/her neck back 30° - 40°, with the mouth closed, until X-ray exposure is complete.

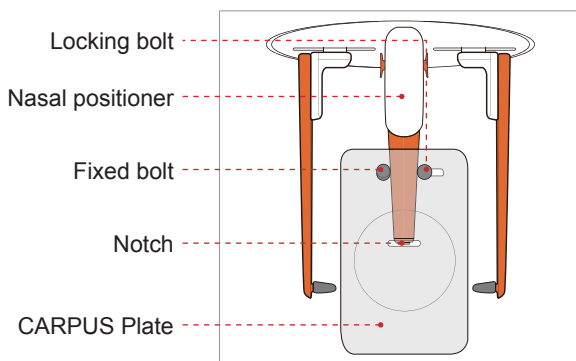


H. Click the **READY** button after the patient has been properly positioned. No X-Ray will be emitted at this point.

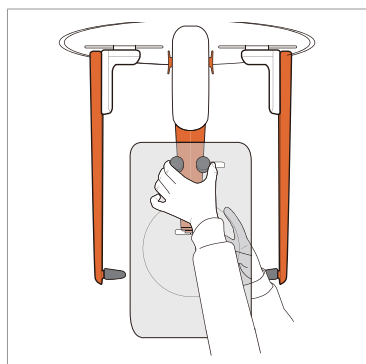
I. Proceed to section **7.3 Initiating X-Ray Exposure**.

7.2.5 CARPUS

Attaching the CARPUS plate



A. Match the notch on the CARPUS plate to the end of nasal positioner.

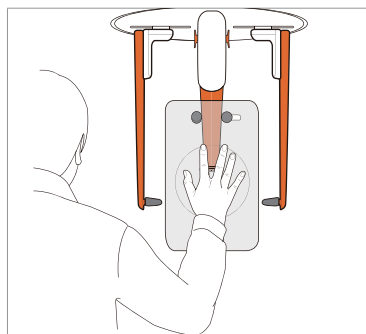


B. Slide the CARPUS plate onto the nasal positioner.

C. Slide the locking bolt on the CARPUS plate towards the nasal positioner and turn it to secure the CARPUS plate in place.

D. Ensure that the CARPUS plate is firmly in place.

Positioning the Patient



A. Ask the patient to put his/her right hand flat on the CARPUS plate. It is important to ensure that the patient does not bend his/her fingers.

B. Have the patient close their eyes and remain still until scanning is complete.



Ask the patient not to block the ruler on the nasal positioner by his / her fingers. It could deteriorate image quality.



C. Click the **READY** button after the patient has been properly positioned. No X-ray will be emitted at this point.

D. Proceed to section **7.3 Initiating X-ray exposure**.

7.3 Initiating X-ray Exposure

The X-ray exposure method and process is the same for all CEPH modes. The example and images below are taken from an X-ray performed in **CEPH Lateral** mode.



- **Do not operate the PC during exposure. Failure to comply with this instruction may cause the system to malfunction.**
- **The operator shall observe the X-ray safety regulations applicable to their area at all times during the operation of this equipment.**

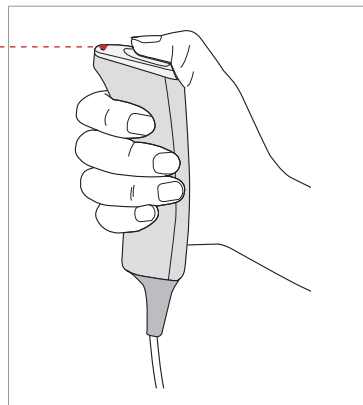


If an emergency occurs during image acquisition, release the exposure switch to cease X-ray emission.

A. Leave the X-ray room and close the door. The operator must visually monitor the patient at all times during image acquisition.

B. Press and hold down the exposure switch until image acquisition is complete.

Exposure indicator
light turns Yellow
Yellow: Exposure



During X-ray irradiation, ensure that

- The LED lamp on top of the equipment turns Yellow to indicate X-ray emission.
- The warning lamp outside the X-ray room turns on.
- The sound (beep or music: optional) goes off.
- The radiation symbol on the upper left corner of GUI turns yellow to indicate X-Rays are being emitted.

The image appears in real time on the imaging GUI.

C. Click the **Save** button to save the acquired image. If automatic save has been selected as a default setting, the image will be saved automatically.

Sample images: with one shot type sensor

PA: Posterior – Anterior

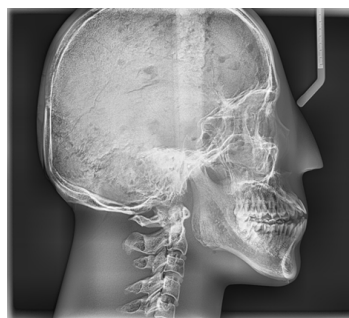


FOV 12 x 10 (inches)
30.48x25.40 (cm)



FOV 9 x 10 (inches)
22.86x25.40 (cm)

Lateral



Full Lateral : FOV 12 x 10 (inches)
30.48x25.40 (cm)



Lateral : FOV 9 x 10 (inches)
22.86x25.40 (cm)



FOV 8 x 8 (inches)
20.32x20.32 (cm)



Carpus

After Image Acquisition

After the image has been acquired, perform the following tasks:

- Fold away the nasal positioner.
- Loosen the ear rod supports and remove them from the patient's ears.
- Release the patient.

8

Acquiring CBCT Images

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8 Acquiring CBCT Images

This chapter requires all preparatory steps outlined in **Chapter 5** to have already been completed.

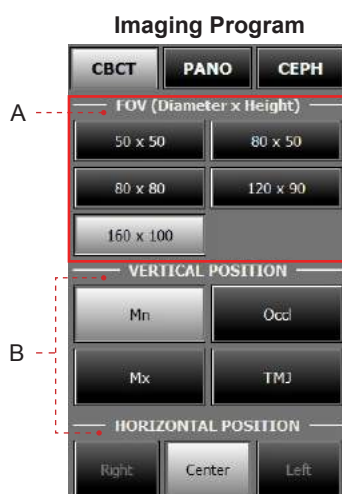
8.1 Setting the Exposure Parameters



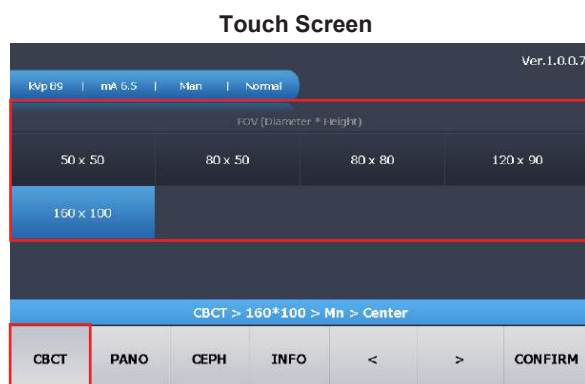
NOTE

You can set the imaging parameters on either the touch screen or the imaging program running on the PC. They are synched in real time and display the same environmental settings.

Perform the following procedures to set capture parameters for the specific patient and capture mode. (For more details, refer to section 4.3.3 CBCT)



Ex: with Xmaru1524CF
Master Plus sensor





NOTE

The FOV size is determined by the CBCT sensor attached on the equipment.

A. Select the FOV size for the CBCT.

B. Select the ROI to be captured under VERTICAL POSITION and HORIZONTAL POSITION. Once you have selected an FOV size and ROI (Region of Interest) to capture, the area of the selected FOV and position of ROI will be viewed on the guidance image. For the FOV 50 X 50, you may select a specific tooth position to be captured on the full arch guidance image.



C. Select the image quality mode

D. Select the voxel resolution

E. If **Metal Artifact Reduction** is necessary, click **Apply** under **Metal Artifact Reduction**. Metal Artifact Reduction reduces the appearance of metal in imaging. This function is most effective when there are fewer than 3 metal artifacts.



NOTE

The MAR (Metal Artifact Reduction) function doubles image reconstruction time.





F. Gender selection will be made automatically according to the patient information registered in EasyDent / EzDent-i. Nevertheless, ensure that this information is correct.

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

G. Select X-ray intensity.



NOTE

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

Soft ≤ Normal ≤ Hard

Age Group	Average head circumference	Range (cm)	classification of head circumference
Child	53±3 cm	> 53±3	Hard
		53±3	Normal
		53±3 <	Soft
Adult	56±3 cm	> 56±3	Hard
		56±3	Normal
		56±3 <	Soft

H. A default tube voltage (kVp) and current (mA) value will be displayed based on the patient's gender and X-ray intensity. If necessary, you can perform manual adjustments by clicking the arrows to the right of each number.

I. Click **CONFIRM** to accept these parameters.



NOTE

Please wait for a moment, while the rotating unit moves to its initial scanning position.

When you click **CONFIRM** button:



- The **CONFIRM** button turns to the **SCOUT** and then the **READY** button is enabled and flashes. This means that the equipment is ready for X-ray exposure.



NOTE

SCOUT capture is featured in FOV size 50 X 50 and 80 X 50. In case of abnormal patient's arch, the chinrest height adjustment through the **SCOUT** feature enables the user to acquire better image. When the **SCOUT** image needs to be acquired, position the patient first, followed by clicking the **SCOUT** button. For details about imaging in the **SCOUT** mode, refer to the section "8.3 Acquiring a Scout image".

- The Rotating unit will move to its initial scanning position.
- The Chinrest will adjust itself according to the mode selected.
- Three Laser Beams (**CBCT Horizontal (X)**, **Mid-sagittal (Y)** and **CT Vertical (Z)**) will activate to facilitate patient alignment. These beams will disappear after 20 minutes or if the **READY** button is clicked.



NOTE

Laser beam On / Off buttons



: Imaging Program



: Control Panel

Scan Time Exposure Time
14.1 Sec 13.5 Sec

DAP
96.236111 mGy x Cm^2

- The scan time, exposure time and DAP (Dose Area Product) value are shown on the main display for the intended exposure.

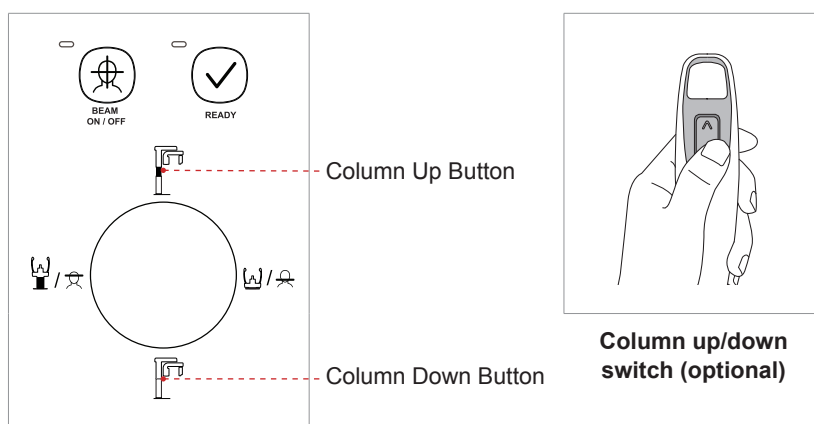
J. Guide the patient to the equipment. Position the patient. Refer to section **8.2 Positioning the Patient**.

8.2 Positioning the Patient

Follow the procedure outlined below to properly position the patient for CBCT scanning.

Before Positioning the Patient

- Ask the patient to remove all jewelry and metallic objects, such as earrings, hair pins, spectacles, dentures, and orthodontic appliances. These items can cause shadow images which could obstruct diagnosis.
- It is strongly recommended that the patient wear a lead apron to protect against scatter radiation.
- Adjust the column height to the patient's height using the up/down button or switch (optional).



NOTE

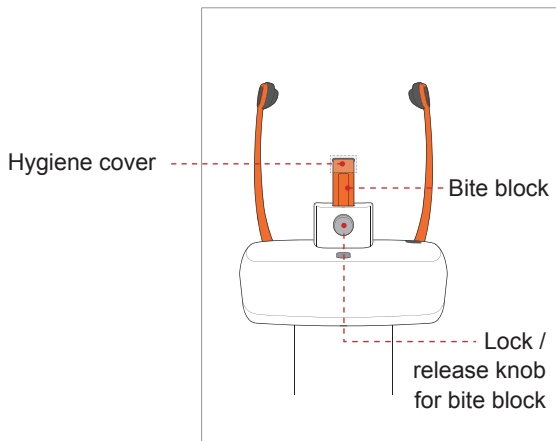
- In general, imaging is performed with the patient in an upright position. However, a stool may be used for imaging patients with special circumstances. If a stool is used, ensure that the beams and movement of unit are not obstructed by the stool
- Correct positioning is an important factor in capturing the best possible image. Proper positioning will reduce the appearance of the cervical spine in the image.



WARNING

Be careful not to project the Laser Beams directly into the patient's eyes as this could severely damage the patient's vision.

Positioning the Patient



A. Insert the bite block into the Chinrest receptacle on the equipment.

B. Place a new hygienic cover over the bite block.



The hygiene cover for the bite block is intended for single use only. Always replace the hygiene cover for each new patient.



Disinfect the Chinrest and bite block using an alcohol-based cleaning solution and wipe away all residue with dry cloth before each new patient.



C. Loosen the temple supports by clicking the Temple Support Wheel Adjustment button.

D. Guide the patient —facing the Chinrest — to the equipment.

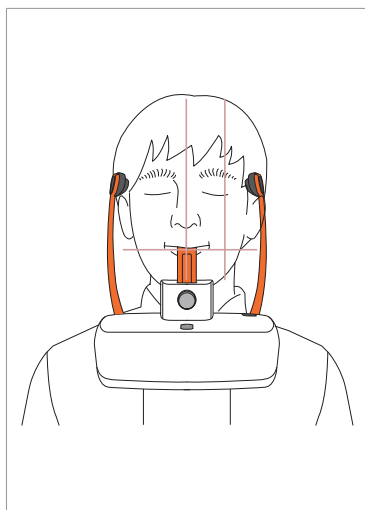
E. Adjust the height of the column using the column up/down button or switch (optional) until the patient's chin rests comfortably on the Chinrest.



F. Ask the patient to:

- Stand upright
- Firmly grip the handles on both sides of the unit
- Lean his/her chest lightly against the equipment
- Position his/her feet slightly forward and open stance

Ensure that the patient's shoulders remain level and that his/her neck is relaxed. The cervical spine should be straight and upright.



G. Have the patient:

- Bite the bite block along its grooves using his/her upper and lower incisors
- Close his/her lips
- Keep his/her tongue pressed against his/her palate
- Close his/her eyes

The patient's occlusion line should be parallel to the floor.

Ask the patient to remain still until scanning is complete.



NOTE

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

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

Aligning the Laser Beams



NOTE

Three Laser Beams - CBCT Horizontal, Mid-sagittal and CBCT Vertical - will be activated to facilitate patient positioning. The beams will disappear after 20 minutes or if the READY button is clicked.

Laser beam On / Off buttons:



: Imaging Program

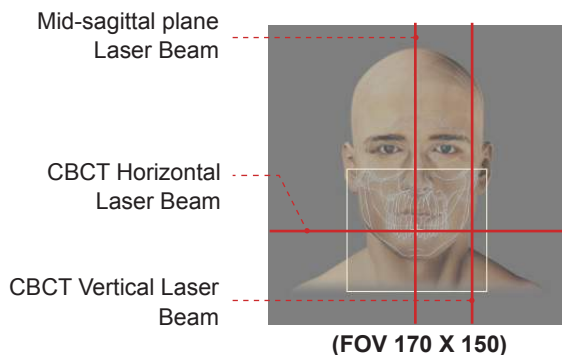


: Control Panel



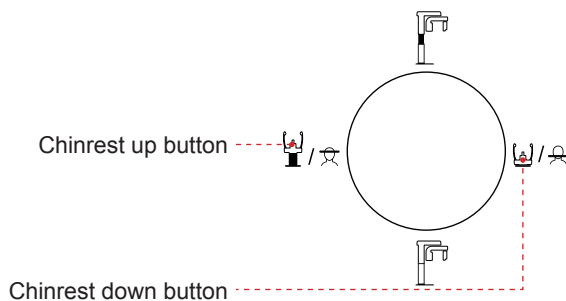
WARNING

Be careful not to project the Laser Beams directly into the patient's eyes as this could severely damage the patient's vision.



The 3D CBCT image centers the FOV on the intersection of the three Laser Beams (CBCT Horizontal, Mid-sagittal and CBCT Vertical).

A. **CBCT Horizontal Laser Beam:** Position the CBCT Horizontal Laser Beam at the center of the FOV area using the chinrest up/down button.



B. **Mid-sagittal plane Laser Beam:** Position the Mid-sagittal plane Laser Beam at the center of the FOV area.

C. **CBCT Vertical Laser Beam:** Position the CBCT Vertical Laser Beam at the center of FOV from the patient's lateral.

Completing Patient Positioning



A. After confirming patient positioning and beam alignment, adjust the temple supports to fit snugly on both sides of the patient's head using the temple support adjustment button.

B. Click the **READY** button after the patient has been properly positioned. No X-ray will be emitted at this point.



If, for the FOV size of 50 x 50 or 80 X 50, the **SCOUT** image is to be acquired, click the **SCOUT** button.



NOTE

SCOUT capture is featured in FOV size 50 X 50 and 80 X 50.

In case of abnormal patient's arch, the chinrest height adjustment through the SCOUT feature enables the user to acquire better image. For details about imaging in the SCOUT mode, refer to the section "8.3 Acquiring a Scout Image".

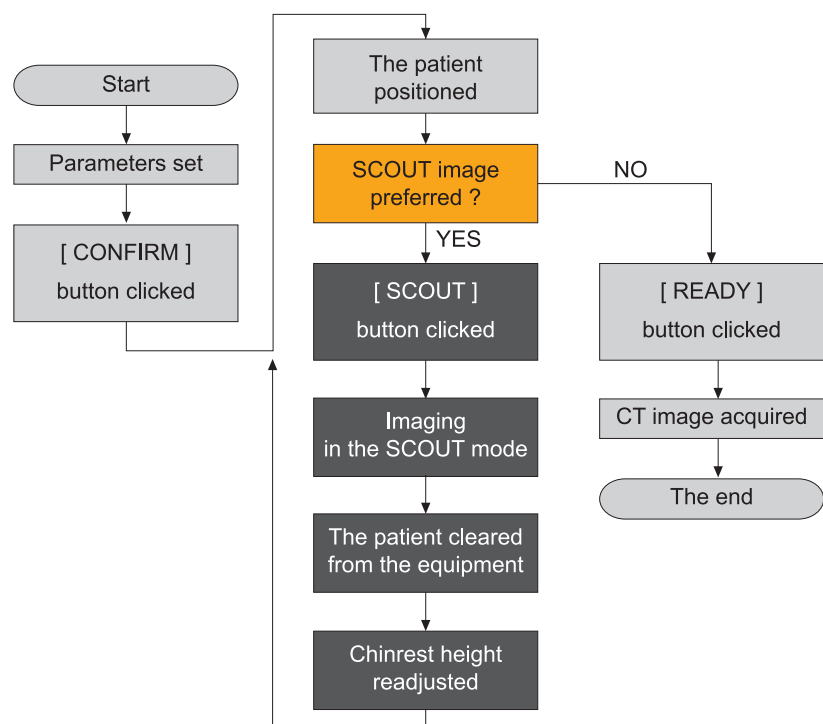
C. Proceed to the section **8.4 Initiating X-ray Exposure**. But if the **SCOUT** feature is selected, continue to the next section **8.3 Acquiring a SCOUT Image**, to the section **8.4 Initiating X-ray Exposure**.

8.3 Acquiring a SCOUT Image

In general, the imaging trajectory is predefined along the normal arch shape. In case of abnormal patient's arch, the chinrest height adjustment through the SCOUT feature enables the user to acquire better image.

8.3.1 Starting imaging with the SCOUT feature

SCOUT Imaging Flow Chart



Imaging and Coordinate compensation

The parameter setting for exposure and patient positioning are the same as those described in the section 8.1 and 8.2. For the SCOUT feature-specific imaging, do take the steps in the following manner.



- A. When the parameter setting and patient position are done, click the **SCOUT** button.
- B. Press and hold down the exposure switch to acquire the **SCOUT** image.

C. Guide the patient out of the equipment.



Always perform the chinrest coordinate adjustment after the patient is cleared from the equipment. Failure to do so could result in the physical injury, due to the vertical movement of chinrest to new position reflected after the 'CONFIRM' button on the SCOUT Viewer is clicked.

D. Once the imaging has been completed, the resulting image with the SCOUT feature appears. The green-colored horizontal line appears on the **SCOUT** image, when the left button of the mouse is clicked at the point which you want to move to the center of the image.

To adjust the image contrast for making the compensating point distinct, you may adjust the black and white level with the Adjust control on the right of image.



For details about the SCOUT Viewer, refer to the section "8.3.2 SCOUT Viewer".

E. Upon clicking the **CONFIRM** button, the **SCOUT** view screen closed, and the chinrest moves to newly compensated position vertically.

F. Guide the patient into the equipment again and position the patient.

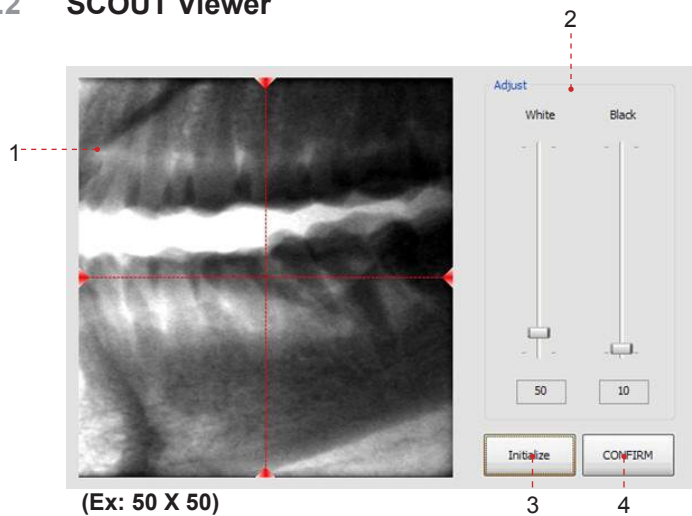
G. Click the **READY** button from the GUI.

H. Press and hold down the exposure switch to acquire the CBCT image: refer to the section **8.4 Initiating X-ray Exposure**.



If the acquired image is unsatisfactory, you may repeat the steps above with a different coordinate.

8.3.2 SCOUT Viewer



1. Raw View Window

- Displays the acquired image and the guideline.
- The green-colored horizontal line appears when the mouse clicked at the point to be moved to on the image.

2. Adjust

- Adjust the current contrast level

White: make the current white level whiter

Black: make the current dark level darker

3. Initialize

- When clicked, returns to the initial state of the completion of the **SCOUT** imaging.

4. CONFIRM

- When clicked, the **SCOUT** view screen closed and the chinrest moves to newly compensated position vertically.

8.4 Initiating X-ray Exposure

Perform the following process to acquire an image in CBCT mode.

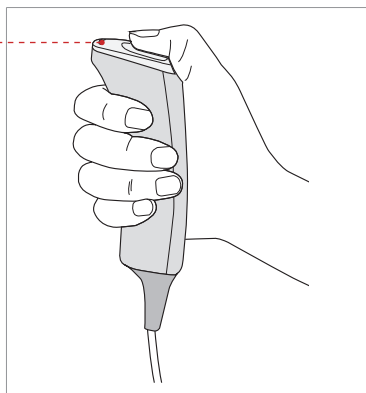


- **Do not operate the PC during exposure. Failure to comply with this instruction may cause the system to malfunction.**
- **The operator shall observe the X-ray safety regulations applicable to their area at all times during the operation of this equipment.**

A. Leave the X-ray room and close the door. The operator must visually monitor the patient at all times during image acquisition.

B. Press and hold down the exposure switch until image acquisition is complete.

Exposure indicator
light turns Yellow
Yellow: Exposure



During X-ray irradiation, ensure that

- The LED lamp on top of the equipment turns Yellow to indicate X-ray emission.
- The warning lamp outside the X-ray room turns on.
- The sound (beep or music: optional) goes off.
- The radiation symbol on the upper left corner of GUI turns yellow to indicate X-Rays are being emitted.

The image appears in real time on the imaging GUI.



If an emergency occurs during image acquisition, release the exposure switch to cease X-ray emission.

C. The captured image is automatically reconstructed and converted into a DICOM file. Click the Save button to store the file in the patient database (If automatic save is selected in the program settings, the image will be saved automatically).

Once acquisition is complete, the image is automatically transferred to **EasyDent / EzDent-i**.



For more details about 2D or 3D viewer, refer to EasyDent / EzDent-i, and Ez3D plus / Ez3D-i user manual.

After Image Acquisition

Perform the following tasks after acquiring a CBCT image:

- Loosen the temple supports and release the patient.
- Remove the hygiene barrier from the bite block.
- Press **Return** to bring the Rotating Unit back to its initial position.



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9

Troubleshooting

9 Troubleshooting

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

- If the device is not moving

Cause	Solution
Power failure	Check the equipment's power supply.
Initialization status	Wait until the equipment has initialized and then try again.
Control PC connection failure	Check the connection status of Serial Port (RS232) which connects the PC to the equipment.

- If the exposure switch is not functioning

Cause	Solution
Ready status	Check whether it is ready for capturing at the imaging program.

- If imaging cannot be performed

Cause	Solution
Initialization status	Wait until the equipment has initialized and then try again. If this problem persists, restart the equipment.

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

Cause	Solution
The time allotted for patient alignment has expired	Press the Laser Beam button to turn on the lasers and then carry out patient alignment.



CAUTION

Do not allow any liquids in the vicinity of the machine as moisture may cause extensive damage to this equipment's electrical components.



WARNING

If a problem occurs during image acquisition, press the red emergency stop switch to immediately stop all moving parts and cut off all power to the equipment's electrical components. You may then safely release the patient from the equipment.

10

Cleaning and Maintenance

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10 Cleaning and Maintenance



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

10.1 Cleaning

- Thoroughly clean areas of the equipment which come into contact with the patient, such as the handle frame, chin support and bite block.
- Do not use spray cleaners or solvents as they could enter the equipment and damage to the electrical components or cause a fire.
- Do not use abrasive liquids such as acetone, gas, or oil, which could corrode the surface of the equipment.
- Do not use cleaning products which contain silicon as they could potentially damage the equipment's electrical components.

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

Accessories	Cleaning Process
Bite block	Clean the bite blocks using an alcohol-based disinfectant and dry thoroughly with a soft dry cloth, before each patient is X-rayed.
Temple support	Clean the temple support using an alcohol-based disinfectant and dry thoroughly with a soft dry cloth before each patient is X-rayed.
Chin support	Clean the chin support using an alcohol-based disinfectant before each patient is X-rayed.
All components that come into contact with the patient or operator	Clean components using an alcohol-based disinfectant before each patient is X-rayed.
Computer and peripherals	Follow the manufacturers' instructions found in the accompanying manuals.
Outer covers of equipment	Wipe the unit with a dry cloth at the end of each day.  Do not use cleaning agents in aerosol or spray form directly on the surface of the equipment.

10.2 Maintenance

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

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

10.2.1 Regular Maintenance



NOTE

There are no user serviceable parts inside this equipment. If servicing is required, please contact the VATECH service center or your local VATECH representative.



WARNING

- **Always turn off the equipment before performing any maintenance.**
- **Never remove equipment covers. There are no repairable parts inside.**
- **The only part that can be replaced by the user is the input fuses, which must comply with the manufacturer's specification.**
- **In order to safeguard against fire, only replace fuses with fuses of the same type and range.**

- Do not use force to unplug cables.
- Do not expose the equipment or components in an area which is susceptible to water or humidity.
- Do not expose the equipment in an area which subject to temperature extremes, poor ventilation, direct sun light, dust, salt, etc.
- Keep all detachable components well organized and clean.
- Make sure that the equipment is well grounded.
- Never try to modify this equipment, including the wires or cables. Modifying this equipment may damage it beyond repair.

10.2.2 Maintenance Task Checklis

Maintenance Tasks	Maintenance period
Before operation, ensure that the equipment is clean and ready for use. Make sure that all parts which come into contact with the patient have been disinfected and cleaned.	Daily
After using the equipment, make sure that the main power switch has been turned off.	Daily
Ensure that the equipment is firmly plugged into a dedicated power source.	Daily
Ensure that the plug and power cord are not hot..	Daily
Confirm that the Yellow (exposure) indicator lamp turns on when the exposure switch is pressed. Ensure that the Yellow (exposure) indicator light remains on for the entire duration of the exposure.	Daily
Ensure that the power cable is not kinked, broken, exposed and that it is free of all other defects.	Weekly
Confirm that activating the emergency stop switch ceases the unit's operation. Pressing the emergency stop switch should stop all equipment movements and X-ray emission.	Weekly
Ensure that all visible labels are intact and legible.	Monthly
Check for possible wear or damage to the exposure switch cable.	Monthly
Confirm that the audio message is audible throughout the duration of the exposure.	Monthly

11

Disposing of the Unit

11 Disposing of the Unit

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

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

Part	Material	Recyclable	Waste 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			●	



NOTE

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



WARNING

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



IMPORTANT

Please clean, disinfect and sterilize the equipment before disassembling it and disposing of its parts.

12

Technical Specifications

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12 Technical Specifications

12.1 Mechanical Specifications

A. Image Magnification

<For 160x100 and 100x80 series>

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	626.8	479.7	147.1	1.31 constant
CEPH	1,745	1,524	221	1.14 constant
CBCT	642.3	449.7	192.6	1.43 constant

<For 170x150 and 150x150 series>

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	585.8	409.7	176.1	1.43 constant
CEPH	1745	1524	221	1.14 constant
CBCT	632.9	409.7	223.2	1.52 constant

FDD : Focal Spot to Detector Distance

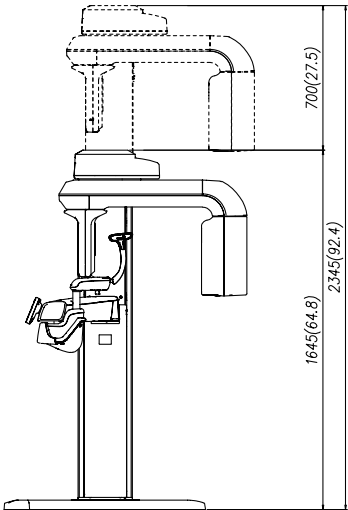
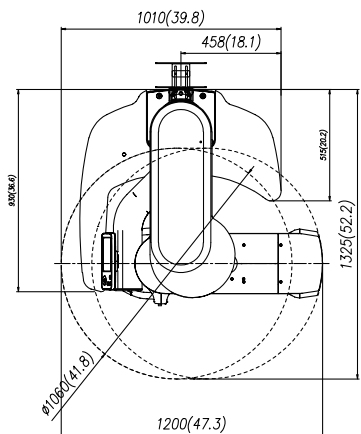
FOD : Focal Spot to Object Distance

ODD: Object to Detector Distance (ODD: FDD - FOD)

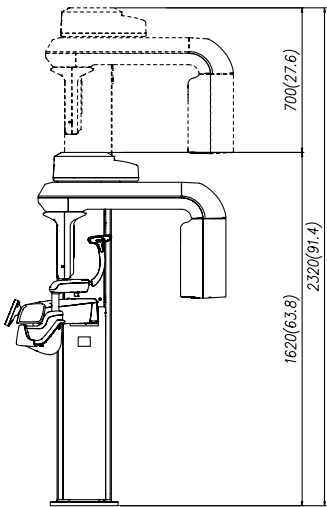
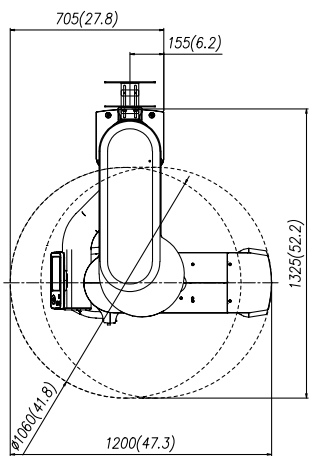
Magnification: FDD / FOD

B. Dimension

Without CEPH Unit & Base type

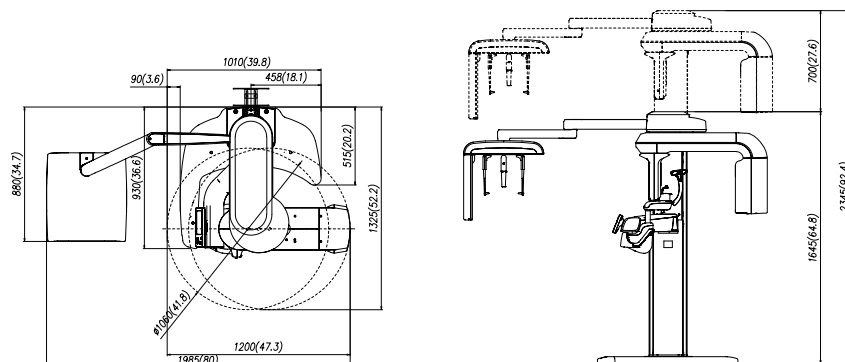


Without CEPH Unit & Non-Base type

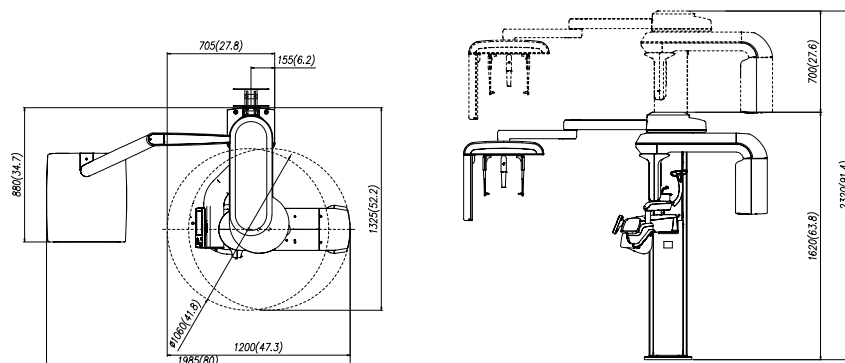


[Unit: mm (Inches)]

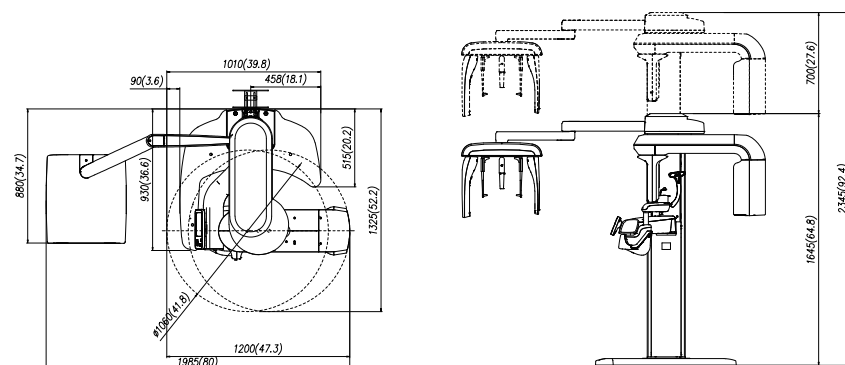
With CEPH(Oneshot type) Unit & Base type



With CEPH(Oneshot type) Unit & Non-Base type

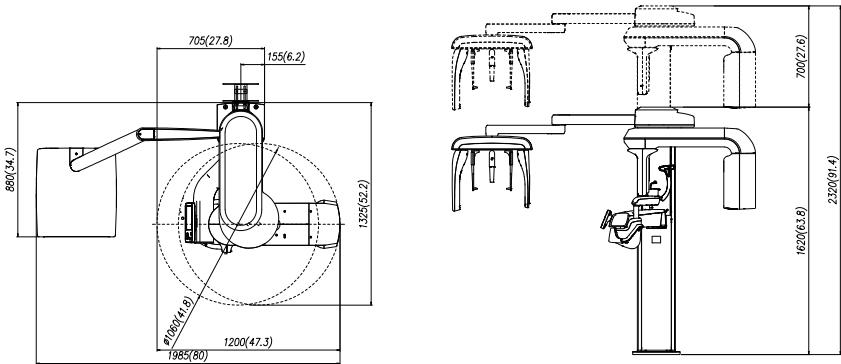


With Cephalometric(Scan type) Unit & Base type

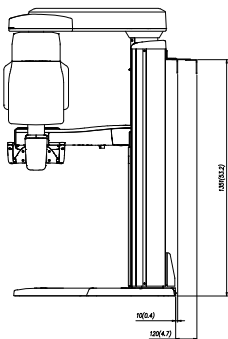


[Unit: mm (Inches)]

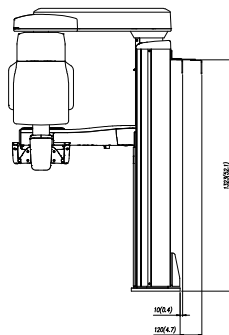
With CEPH(Scan type) Unit & Non-Base type



Common Dimension(Base type)



Common Dimension(Non-Base type)



[Unit: mm (Inches)]



2,345 mm, represents the total height of the equipment with the column extended fully.

Item		Description
Weight (kg)	Without CEPH unit	Without base: 127 (280.0 lbs)
		With base: 182 (401.2 lbs)
	With CEPH unit (Scan Type)	Without base: 157 (346.1 lbs)
		With base: 212 (467.4 lbs)
	With CEPH unit (Oneshot Type)	Without base: 167 (368.2 lbs)
		With base: 222 (489.4 lbs)
Total Height (mm)		Without base: Max. 2,320 mm (91.34 inch)
		With base: Max. 2,345 mm (92.32 inch)
Vertical column movement (mm)		Max. 700 (Max. 27.56 inch.)
Length x Width (mm)	Without CEPH unit	1,200 (L) x 1,325 (W) mm
		47.24 (L) x 52.17 (W) inch
	With CEPH unit (Scan Type)	1,985 (L) x 1,325 (W) mm
		78.15 (L) x 52.17 (W) inch
With CEPH unit (One shot Type)	1,985 (L) x 1,325 (W) mm	
	78.15 (L) x 52.17 (W) inch	
Type of installation		Base Stand / Wall Mount

12.2 Technical Specifications

X-ray Generator

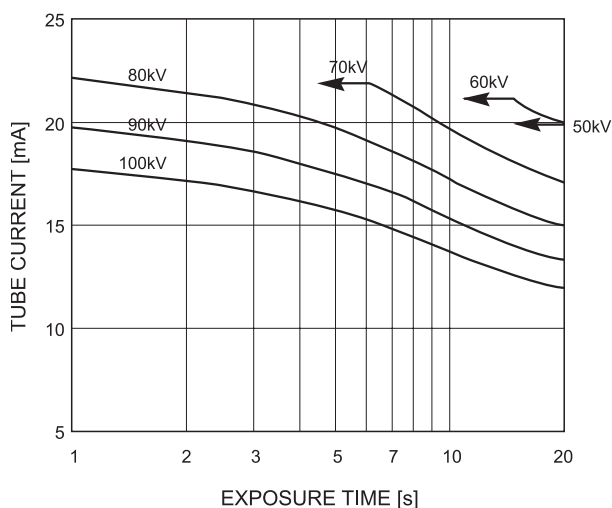
Item			Description
Model			DG-07C11T2 DG-07C11C1
Rated output power			1.6 kW (1 sec)
High voltage generator	Type		Inverter
	Normal/ Pulse	kVp	50 ~ 99 (1 kV step)
		mA	4 ~ 16 (0.1 mA step)
	Cooling		Automatically controlled / Protect $\geq 60^{\circ}\text{C}$ Air Cooling: Optional
	Added Filtration		2.0 mmAl 2.3 mmAl
	Total filtration		2.8 mm Al eq.
X-ray tube	Manufacturer		Toshiba CEI
	Model		D-052SB (Stationary Anode Type) OPX/105
	Tube voltage		Operating 50-100 kV —
	Tube current		Maximum 22 mA —

Item		Description	
X-ray tube	Focal spot size	0.5 mm (IEC60336)	
	Target angle	5 °	
	Heat storage capacity (Maximum heat content)	35 kJ	30 kJ
	Inherent filtration	At least 0.8 mm Al eq.at 50 kV	0.5 mm Al
	X- ray coverage	95 x 380 mm at SID 550 mm	
	Anode heat content	35 kJ	—
	Normal anode input power	1,750 W (at 1.0 s)	2,000 W (at 1.0 s)
	Maximum anode heat dissipation rate	250 W	
	Duty cycle	1:60 or more (Exposure time : interval time)	

D-052SB
Maximum Rating Charts
 DC (Center Grounded)

Constant potential high-voltage generator

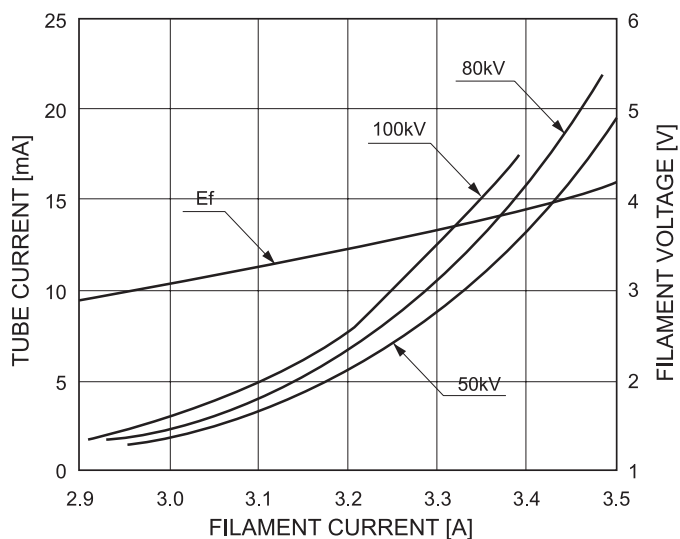
Nominal Focus Spot Value: 0.5



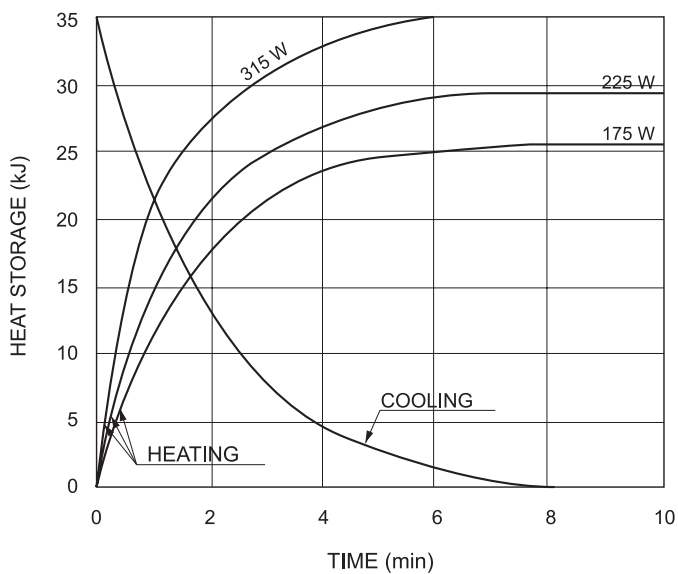
Emission & Filament Characteristics

Constant potential high-voltage generator

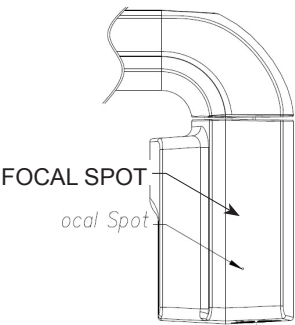
Nominal Focus Spot Value: 0.5



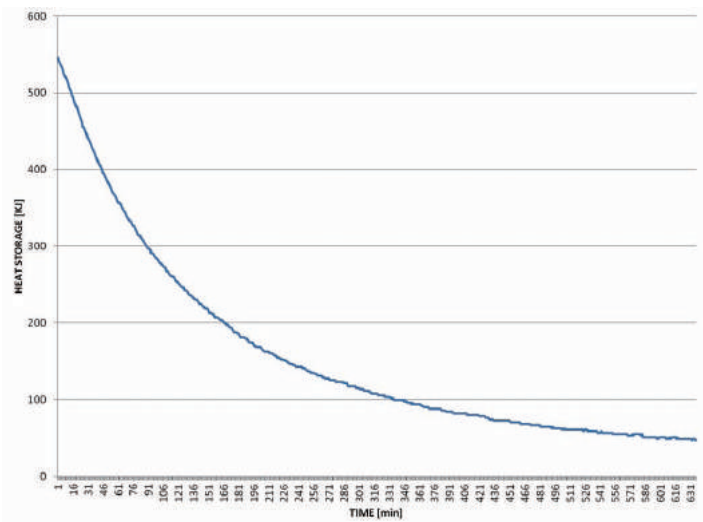
Anode Thermal Characteristics



Indication of focal spot



X-Ray tube Cooling Curve



Detector Specifications

Item	Description		
	PANO	CEPH	
Model	Xmaru1501CF	Xmaru2301CF	1210SGA
Detector type	CMOS photodiode array		Amorphous silicon TFT with scintillator
Pixel size (μm)	100	100	127
Active area (mm)	6 x 150.4	5.9 x 230.4	264 x 325
Frame rate	300 * fps	200 fps	240 ** fph
A/D (bits)	14		
Sensor size L x W x H (mm)	175.4 x 86 x 21.6	251.2 x 69 x 27.1	402 x 364 x 32

* fps: frames per second

** fph: frames per hour

Item	Description	
	CBCT	
Model	Xmaru1215CF Master Plus	Xmaru1524CF Master Plus
Detector type	CMOS photodiode array	
Pixel size (μm)	99 (2 x 2 binning) 198 (4 x 4 binning)	99 (2 x 2 binning) 198 (4 x 4 binning)
Active area (mm)	116.42 x 145.72	145.7 x 232.8
Frame Rate (fps)	2 x 2: 35 fps 4 x 4: 70 fps	2 x 2: 35 fps 4 x 4: 70 fps
A/D Conversion (bits)	14	
Sensor size (mm)	159 x 238.2 x 27	235 x 303 x 30,3

12.3 Electrical Specifications

Item	Description
Power supply voltage	100-240V~
Frequency	50 / 60 Hz (Single)
Power rating	Max. 2.2 kVA

- The input line voltage depends on the local electrical distribution system.
- Allowable input voltage fluctuation requirement: $\pm 10\%$.

12.4 Environmental Specifications

Item		Description
During operating	Temperature	10 ~ 35 °C
	Relative humidity	30 ~ 75 %
	Atmospheric pressure	860 ~ 1060 hPa
Transport and storage	Temperature	-10 ~ 50 °C
	Relative humidity	10 ~ 75 % non condensing
	Atmospheric pressure	860 ~ 1060 hPa

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1 Recommended X-ray Exposure Table

A. PANO

[Standard / TMJ / Sinus / CARPUS]

Gender / Figure	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
Man	75 / 14	74 / 14	73 / 14
Woman	74 / 14	73 / 14	72 / 14
Child	68 / 10	67 / 10	66 / 10

[Fast Mode]

Gender / Figure	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
Man	75 / 16	74 / 16	73 / 16
Woman	74 / 16	73 / 16	72 / 16
Child	68 / 16	67 / 16	66 / 16

* Tube voltage and current variation range in the PANORAMIC mode: 50 ~ 80 kVp, 4 ~ 16 mA

B. CEPH

[Lateral]

Figure	Hard (kVp / mA)			Normal (kVp / mA)			Soft (kVp / mA)		
Sensor Type Gender	One shot	Scan	Fast Scan	One shot	Scan	Fast Scan	One shot	Scan	Fast Scan
Man	92/14	87/10	97/14	90/14	85/10	95/14	88/14	83/10	93/14
Woman	90/14	85/10	95/14	88/14	83/10	93/14	86/14	81/10	91/14
Child	86/10	82/10	87/12	84/10	80/10	85/12	82/10	78/10	83/12

[PA / SMV / Waters View]

Figure	Hard (kVp / mA)			Normal (kVp / mA)			Soft (kVp / mA)		
Sensor Type Gender	One shot	Scan	Fast Scan	One shot	Scan	Fast Scan	One shot	Scan	Fast Scan
Man	94/14	90/10	99/14	92/14	88/10	97/14	90/14	86/10	95/14
Woman	92/14	88/10	97/14	90/14	86/10	95/14	88/14	84/10	93/14
Child	90/10	85/10	89/12	88/10	83/10	87/12	86/10	80/10	85/12

[CARPUS]

Figure	Hard (kVp / mA)			Normal (kVp / mA)			Soft (kVp / mA)		
Sensor Type Gender	One shot	Scan	Fast Scan	One shot	Scan	Fast Scan	One shot	Scan	Fast Scan
Man	60/6	60/6	60/10	60/5	60/5	60/9	60/4	60/4	60/8
Woman	60/6	60/6	60/10	60/5	60/5	60/9	60/4	60/4	60/8
Child	60/6	60/6	60/10	60/5	60/5	60/9	60/4	60/4	60/8

* Tube voltage and current variation range in the CEPH mode: 60 ~ 100 kVp, 4 ~ 14 mA

C. CBCT**Xmaru1215CF master plus / Xmaru 1524CF master plus**

Mode		High Resolution		Green	
		kVp	mA	kVp	mA
Man	Hard	95	10.0	95	10.0
	Normal	95	9.0	95	9.0
	Soft	95	8.5	95	8.5
Woman	Hard	95	9.5	95	9.5
	Normal	95	8.5	95	8.5
	Soft	95	8.0	95	8.0
Child	Hard	95	9.2	95	9.2
	Normal	95	8.2	95	8.2
	Soft	95	7.7	95	7.7

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

Soft ≤ Normal ≤ Hard



NOTE

Age Group	Average head circumference	Range (cm)	classification of head circumference
Child	53±3 cm	> 53±3	Hard
		53±3	Normal
		53±3 <	Soft
Adult	56±3 cm	> 56±3	Hard
		56±3	Normal
		56±3 <	Soft



NOTE

- Maximally allowed tube voltage / current: kVp ± 10 % / mA ± 20 % according to IEC60601-2-7.

- Due to image optimization performed prior to shipping, equipment data may differ slightly from those specified in the table.

2 X-ray Dose Data

The X-ray dose data is extracted from the X-ray Dose Test Report for the PaX-i3D Green.

X-ray Dose Test Report for the PaX-i3D Green maintains dosimetric evaluation of VATECH dental diagnostic system meets all requirements specified in the IEC Collateral Standard. To limit unnecessary exposure to the patient, operator or other staff, the PaX-i3D Green is designed to comply with IEC 60601-1-3 Part 1 General Requirements for Safety.

Test Condition	
Brand Name (Model)	PaX-i3D Green (PHT-60CF0)
Sensor type	PANO: Xmaru1501CF CEPH: 1210SGA (One shot Type) CBCT: Xmaru1215CF Master Plus Xmaru1524CF Master Plus
X-ray generator	DG-07C11T2

2.1 DAP Table

Test Equipment			
Instrument	Manufacturer	Model	S/N
Dose Meter	Piranha	205	CB2-06090029

Mode Tested: PANO HD Normal Adult Standard 13.5s						
mA	6		8		10	
kVp	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]
60	5.1	36.5	6.7	48.4	8.2	59.2
70	6.6	47.3	8.7	62.7	10.7	76.7
80	8.5	61.4	11.3	81.4	13.8	99.6
90	10.5	75.5	13.9	100.0	17.0	122.3

Mode Tested: CEPH PA (12 x 10), 0.9 s						
mA kVp	6		8		10	
	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]
60	0.05	34.7	0.06	46.1	0.08	57.5
70	0.06	47.5	0.09	62.9	0.11	78.4
80	0.08	61.9	0.11	82.1	0.14	101.9
90	0.10	76.7	0.14	104.3	0.16	120.9

Mode Tested: CEPH LAT (12 x 10), 0.7 s						
mA kVp	6		8		10	
	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]
60	0.04	27.0	0.05	35.9	0.06	44.7
70	0.05	36.9	0.07	48.9	0.09	61.0
80	0.06	48.1	0.09	63.9	0.11	79.3
90	0.08	59.7	0.11	81.1	0.12	94.0

Mode Tested: CBCT (FOV 100x80), High Resolution 9.0s						
mA kVp	6		8		10	
	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]
60	1.30	149.1	1.68	215.0	2.05	277.0
70	2.00	228.0	2.59	329.3	3.18	426.6
80	2.88	327.8	3.72	474.9	4.56	613.7
90	3.89	441.9	5.02	642.6	6.14	828.1

Mode Tested: CBCT (FOV 100x80), Green 5.9 s						
mA kVp	6		8		10	
	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]
60	0.85	97.6	1.10	140.8	1.35	181.4
70	1.31	149.4	1.69	215.7	2.08	279.4
80	1.89	214.7	2.44	311.0	2.99	401.9
90	2.55	289.4	3.29	420.9	4.02	542.4

Mode Tested: CBCT (FOV 170x150), High Resolution 15.0 s

[mA]	6		8		10	
[kV]	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]
60	1.44	478.30	1.89	627.55	2.34	776.81
70	2.41	800.73	3.16	1050.60	3.92	1300.46
80	3.62	1201.09	4.75	1575.90	5.88	1950.70
90	5.27	1748.53	6.91	2294.16	8.55	2839.79

Mode Tested: CBCT (FOV 170x150), High Resolution 15.0 s

[mA]	6		8		10	
[kV]	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]
60	0.86	286.39	1.13	375.96	1.40	465.52
70	1.45	479.84	1.90	629.90	2.35	779.95
80	2.17	719.76	2.85	944.85	3.52	1169.93
90	3.16	1047.62	4.14	1375.22	5.13	1702.83

2.2 X-ray Leakage Dose

Test Equipment

Instrument	Manufacturer	Model	S/N
Radiation Monitor Controller	Radcal	9015	91-1470/19069

Test Condition

Test mode	Detector	kVP	mA	sec
PANO/ Adult	Xmaru 1501CF	80	16	13.5
CEPH/ 12x10(in.)	1210SGA	99	14	0.7
CBCT/ 160x100(mm)	Xmaru 1524CF Master Plus	99	14	9.0
CBCT/ 150x150(mm)	Xmaru 1524CF Master Plus	99	14	15.0
CBCT/ 170x150(mm)	Xmaru 1524CF Master Plus	99	14	15.0

Mode Direction [°]	PANO / Adult	CEPH / 12x10 (in.)	CBCT / 160x100 (mm)	CBCT / 150x150 (mm)	CBCT / 170x150 (mm)
	[mR/hr]				
0	1.1	5.1	5.2	4.8	8.0
45	3.5	14.2	14.6	4.3	23.0
90	5.8	18.2	17.0	12.0 -	17.0
100	7.3	14.3	16.0	7.8	10.0
110	4.7	15.2	11.7	8.0	12.0
120	3.9	22.4	20.3	12.3	10.0
130	12.7	51.2	45.1	35.1	9.0
140	20.7	45.1	48.7	36.8	7.0
150	24.5	57.4	58.1	17.4	6.0
160	22.4	51.1	52.8	41.0	3.0
170	15.1	33.7	33.5	16.4	3.0
180	10.5	33	23.8	16.0	2.0
190	5.9	21.4	18.2	5.5	2.0
200	3.2	12.9	14.2	14.0	13.0
210	2.8	4.3	9.0	3.3	19.0
220	3.2	2.7	7.4	5.6	21.0
230	3.6	5.5	8.5	2.6	2.6
240	4.2	8.2	8.3	4.1	23.0
250	6.8	29.7	23.2	21.7	38.0
260	4.9	33.3	33.3	18.7	52.0
270	19.8	42.1	50.7	25.7	43.0
315	3.4	9.4	12.4	11.2	23.0

2.3 X-ray Scatter Dose

Test Equipment Information			
Instrument	Manufacturer	Model	S / N
Dose Meter	Radcal	9015	91-1431/9913,4

PANO Mode (Xmaru1501CF)

Test Condition	
Mode Tested	PANO HD / Adult
Applied Tube Voltage Peak [kVp]	80
Applied Tube Current [mA]	16

Mode Direction [°]	PANO HD 13.5 s [mR/hr]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	0.070	0.053	0.041
45	0.074	0.055	0.039
90	0.066	0.055	0.045
135	0.325	0.170	0.089
180	0.374	0.162	0.071
225	0.251	0.171	0.117
270	0.193	0.106	0.058
315	0.085	0.072	0.060

Mode Direction [°]	PANO HD 13.5 s [mR/hr]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	0.070	0.053	0.041
45	0.074	0.055	0.039
90	0.066	0.055	0.045
135	0.325	0.170	0.089
180	0.374	0.162	0.071
225	0.251	0.171	0.117
270	0.193	0.106	0.058
315	0.085	0.072	0.060

CBCT Mode (Xmaru1524CF Master Plus)

Test Condition	
Tested Mode	CBCT FOV 160 x 100 High Resolution Mode 9.0s
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	14

Direction [°] \ Mode	FOV 160 x 100 9.0 s [mR]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	1.727	0.971	0.482
45	1.817	0.952	0.499
90	0.656	0.170	0.044
135	2.392	1.121	0.525
180	2.541	1.104	0.480
225	2.399	1.095	0.500
270	2.415	1.185	0.581
315	1.874	0.936	0.467

Test Condition	
Tested Mode	CT FOV 150 x 150 High Resolution Mode 15.0 s
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	14

Direction [°] \ Mode	FOV 150 x 150 15.0 s [mR]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	0.042	0.018	0.004
45	0.843	0.370	0.159
90	1.013	0.411	0.183
135	1.151	0.437	0.145
180	0.946	0.391	0.215
225	1.156	0.479	0.240
270	1.062	0.467	0.211
315	0.541	0.239	0.103

Test Condition	
Tested Mode	CT FOV 170 x 150 High Resolution Mode 15.0 s
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	14

Mode Direction [°]	FOV 170 x150 15.0 s [mR]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	2.046	1.025	0.675
45	2.500	0.725	0.458
90	0.258	0.142	0.046
135	3.688	0.800	0.479
180	4.400	1.129	0.533
225	4.717	1.863	0.546
270	4.138	1.554	0.896
315	3.671	0.988	0.771

3 Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions.

The PaX-i3D Green (Model: PHT-60CFO) is intended for use in the electromagnetic environment specified below. The customer or the user of the PaX-i3D Green (Model: PHT-60CFO) should assure that it is used in such an environment.

Immunity Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The PaX-i3D Green (Model: PHT-60CFO) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A (The PaX-i3D Green (Model: PHT-60CFO) in combination with the shield location)	The PaX-i3D Green (Model: PHT-60CFO) is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/ system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the PaX-i3D Green (Model: PHT-60CFO) or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

NOTE) It is essential that the actual RF shielding effectiveness and filter attenuation of the shielded location be verified to ensure that they meet or exceed the specified minimum values.

Guidance and manufacturer's declaration - electromagnetic immunity

The PaX-i3D Green (Model: PHT-60CFO) is intended for use in the electromagnetic environment specified below.

The customer or the user of the PaX-i3D Green (Model: PHT-60CFO) should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV air	±6kV Contact ±8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2kV for power Supply lines ± 1kV for input/ output lines	±2kV for power Supply lines ± 1kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (<95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (<95% dip in UT) for 5 s	Main Main power quality should be that of a typical commercial or hospital environment. If the user of the PaX-i3D Green (Model: PHT-60CFO) image intensifier requires continued operation during main power interruptions, it is recommended that the PaX-i3D Green (Model: PHT-60CFO) image intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. main voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The PaX-i3D Green (Model: PHT-60CFO) is intended for use in the electromagnetic environment specified below.

The customer or the user of the PaX-i3D Green (Model: PHT-60CFO) should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	V1=3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the PaX-i3D Green (Model: PHT-60CFO), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	E1=3V/m	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80 MHz to 800MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2,5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of the equipment marked with the following symbol : 

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

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the PaX-i3D Green (Model: PHT-60CFO) is used exceeds the applicable RF compliance level above, the PaX-i3D Green (Model: PHT-60CFO) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PaX-i3D Green (Model: PHT-60CFO)

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

Recommended separation distances between portable and mobile RF communications equipment and the PaX-i3D Green (Model: PHT-60CFO)

This is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PaX-i3D Green (Model: PHT-60CFO) can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PaX-i3D Green (Model: PHT-60CFO) as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter [m]

IEC 60601-1-2

Frequency of Transmitter	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
Equation	$d = [\frac{3,5}{V_1}] \sqrt{P}$	$d = [\frac{3,5}{E_1}] \sqrt{P}$	$d = [\frac{7}{E_1}] \sqrt{P}$
Rated maximum output power of transmitter [W]	V ₁ =3Vrms	E ₁ =3V/m	E ₁ =3V/m
	Separation Distance (meters)	Separation Distance (meters)	Separation Distance (meters)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

a. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PaX-i3D Green (Model: PHT-60CFO) is used exceeds the applicable RF compliance level above, the PaX-i3D Green (Model: PHT-60CFO) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PaX-i3D Green (Model: PHT-60CFO)

b. Over the frequency range 150kHz to 80MHz, field strengths should be less than [V1] V/m.

Immunity and Compliance Level

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

4 Acquiring image for the pediatric dental patient

4.1 Age group: classification table

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

Age Group	FDA	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	

4.2 Positioning the pediatric dental patient

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.

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

4.3 Setting exposure values to the age group

For more information about this topic, refer to the Appendices 1 Recommended X-Ray Exposure Table.

4.4 The references pertinent to the potential risks for the pediatric patients

1. 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 are designed to avoid unnecessary exposure to X-radiation and to identify individuals who may benefit from a radiographic examination. Every prescription of radiographs should be based on an evaluation of the individual patient benefit. Due to the relatively high frequency of caries among 5 year old children it is recommended to consider dental radiography for each child even without any visible caries or restorations. Furthermore, radiography should be considered at 8-9 years of age and then at 12-14, that is 1-2 years after eruption of premolars and second molars. Additional bitewing controls should be based on an overall assessment of the caries activity/risk. The high-risk patient should be examined radiographically annually, while a 2-3 years interval should be considered when caries activity/risk is low. Routine survey by radiographs, except for caries, has not been shown to provide sufficient information to be justified considering the balance between cost (radiation and resources) and benefit.

2. MICHAEL L. TAYLOR, B.SC. TOMAS KRON, PH.D., AND RICK D. FRANICH, PH.D.: ASSESSMENT OF OUT-OF-FIELD DOSES IN RADIOTHERAPY OF BRAIN LESIONS IN CHILDREN, Int. J. Radiation Oncology Biol. Phys., Vol. -, No. -, pp. 1-7, 2010

To characterize the out-of-field doses in pediatric radiotherapy and to identify simple methods by which out-of-field dose might be minimized, with a view to reducing the risk of secondary cancers

Out-of-field doses to pediatric patients can be minimized by using simple treatment options, such as using the single-energy mode linear accelerator rather than the multimode, orienting the couch and collimator such that the patient lies along the x-plane and avoiding fields directed along the trunk of the body

3. C. THEODORAKOU, K. HORNER, K. HOWARD, A. WALKER: Pediatric organ and effective doses in dental cone beam computed tomography

Dental CBCT has been associated with higher radiation risk to the patients compared to conventional dental X-Ray imaging. Several studies have investigated the radiation doses involved in dental CBCT for adults but none has looked into pediatric doses. This study estimates the organ and effective doses to two pediatric tissue-equivalent phantoms using thermo luminescent dosimeters for three dental CBCT units and six imaging protocols. The doses to the thyroid, salivary glands and brain ranged from 0.068mSv to 1.131mSv, 0.708mSv to 2.009mSv and 0.031mSv to 1.584mSv respectively. The skin and red bone marrow have received much lower doses than the other three organs. The effective doses ranged from 0.022 mSv to 0.081 mSv. The effective doses calculated in this study were much higher than these of panoramic X-Ray imaging but lower than conventional CT

4. CHIYO YAMAUCHI-KAWAURA & KEISUKE FUJII & TAKAHIKO AOYAMA & SHUJI KOYAMA & MASATO YAMAUCHI: Radiation dose evaluation in head and neck MDCT examinations with a 6-year-old child anthropomorphic phantom, *Pediatr Radiol* (2010) 40:1206–1214 DOI 10.1007/s00247-009-1495-z

Background: CT examinations of the head and neck are the most commonly performed CT studies in children, raising concern about radiation dose and their risks to children.

Objective: The purpose of this study was to clarify radiation dose levels for children of 6 years of age undergoing head and neck multi-detector CT (MDCT) examinations.

Materials and methods: Radiation doses were measured with small-sized silicon-photodiode dosimeters that were implanted at various tissue and organ positions within a standard 6-year-old anthropomorphic phantom. Organ and effective doses of brain CT were evaluated for 19 protocols in nine hospitals on various (2–320 detector rows) MDCT scanners.

Results: The maximum value of mean organ dose in brain CT was 34.3 mGy for brain. Maximum values of mean doses for the radiosensitive lens and thyroid were 32.7 mGy for lens in brain CT and 17.2 mGy for thyroid in neck CT. seventy-fifth percentile of effective dose distribution in brain CT was approximately the same as the diagnostic reference level (DRL) in the 2003 UK survey.

5 Abbreviations

AC	Alternating Current
AF	Auto-Focusing
AMPT	Adaptive layer Mode Panoramic Tomography
CAN	Controlled Area Network
CBCT	Cone-Beam Computed Tomography
CMOS	Complementary Metal-Oxide-Semiconductor
CT	Computed Tomography
DAP	Dose Area Product
DC	Direct Current
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
ENT	Ear, Nose and Throat
ESD	ElectroStatic Discharge
EUT	Equipment Under Test
FDD	Focal spot to Detector Distance
FOD	Focal spot to Object distance
FOV	Field of View
FPD	Flat Panel Detector
IEC	International Electro technical Commission
ISO	International Standards Organization
LCD	Liquid Crystal Display
LED	Light-Emitting Diode
MAR	Metal Artifact Reduction
MPSO	Multiple Portable Socket-Outlet
ODD	Object to detector distance
PA	Posterior / Anterior
RF	Radio Frequency
ROI	Region of Interest

SID	Source to Image receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SMV	Submento-Vertical
TMJ	Temporomandibular Joint
UHD	Ultra High Definition

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