



English



Notice

**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 CT 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:

VATECH Co., Ltd.

Phone: +82-1588-9510

E-mail: gcs@vatech.co.kr

This document is originally written in English.

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

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05

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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.

<b>A</b>	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.
<u> </u>	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.
<b>✓</b>	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.
2	SINGLE USE	Indicates a component which must be replaced for each new patient.

# **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.

#### 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.

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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 CT 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	-	
		СТ	Xmaru1215CF MP	100 X 80, 80 X 80, 50 X 50	
			Xmaru1524CF MP	160 X 100, 120 X 90, 80 X 80, 50 X 50	
		PANO	Xmaru1501CF	-	
		СТ	Xmaru1215CF MP	100 X 80, 80 X 80, 50 X 50	
sc	PANO+CBCT +CEPH		Xmaru1524CF MP	160 X 100, 120 X 90, 80 X 80, 50 X 50	
	102111	СЕРН	Xmaru2301CF	Scan Type	
			Xmaru3001CF	Scan Type	
	PANO+CBCT +CEPH	PANO	Xmaru1501CF	-	
os		СТ	Xmaru1215CF MP	100 X 80, 80 X 80, 50 X 50	
08			Xmaru1524CF MP	160 X 100, 120 X 90, 80 X 80, 50 X 50	
		CEPH	910SGA	One shot Type (inches): 9 X 10, 8 X 8	
	PANO+CBCT +CEPH	PANO	Xmaru1501CF	-	
OP		СТ	Xmaru1215CF MP	100 X 80, 80 X 80, 50 X 50	
			Xmaru1524CF MP	160 X 100, 120 X 90, 80 X 80, 50 X 50	
		CEPH	1210SGA	One shot Type (inches): 12 X 10, 9 X 10, 8 X 8	

#### 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.



UL symbol grants this equipment compliance with the UL 60601-1 / CAN/ CSA C22.2 No.601.1

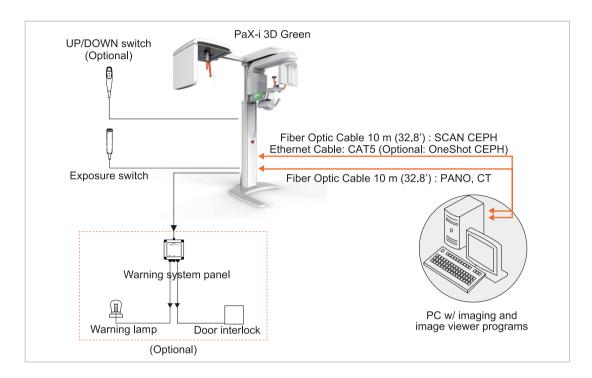
#### Classifications (IEC60601-1 6.1):



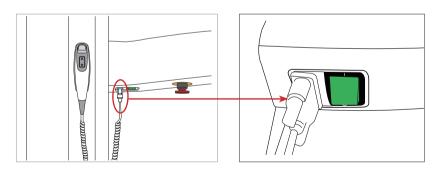
Protection against the ingress of water: Ordinary Equipment: IPX0

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)





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

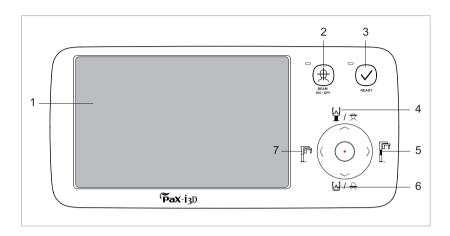


No.	Item	Details
1	X-RAY SENSOR (CEPH)	CEPH imaging sensor (optional) 1-1. One shot Type - 1-2. Scan Type
2	NASAL POSITIONER	<ul> <li>Positions the patient during CEPH imaging.</li> <li>The ruler for use to compensate the acquired image that is different from actual size.</li> </ul>
3	EAR RODS	Secure 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 / CT)	Sensors: used for CT and PANO imaging.  This module consists of two different sensors that perform different functions (CT and PANO). When you select a scanning mode, the sensor will be switched automatically (CT ↔ 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.



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 <b>3.3.2 Touch Screen</b> .		
2	Laser Beam ON / OFF	Turns ON or OFF the laser beams.		
3	READY	Indicates that parameter settings and the patient alignment are finished and imaging is ready.		
4	Chinrest UP	Moves the chinrest up Functions only in the CT imaging mode.		
4	Frankfurt plane laser beam UP	Moves Frankfurt plane laser beam up Functions only in the PANO imaging mode.		
5	Column UP	Moves the column up.		
•	Chinrest DOWN	Lowers the chinrest Functions only in the CT imaging mode.		
6	Frankfurt plane laser beam DOWN	Moves Frankfurt plane laser beam down Functions only in the PANO imaging mode.		
7	Column DOWN	Lowers the column.		

#### 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.

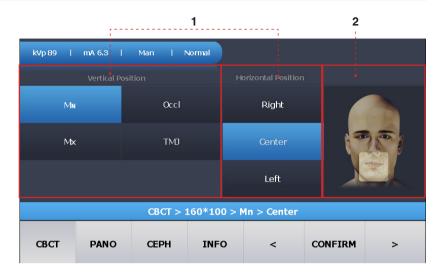


Never use pointed objects, such as a ballpoint pen or pencil, to manipulate the LCD screen as they could scratch or damage the LCD screen.

#### **CBCT**



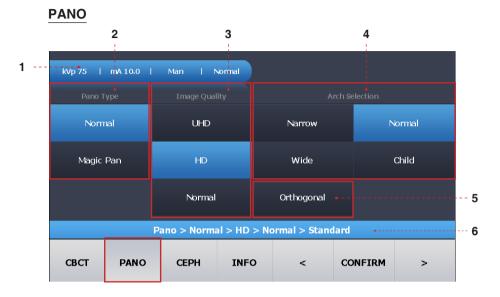
No.	Function	Description
1	Imaging parameter settings information	Displays currently set information such as patient type and X-Ray setting values.
2	FOV selection	Shows the CT sensor model mounted.
3	Selection settings	Displays the current selections in sequential order.
4	Imaging mode selection	Select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



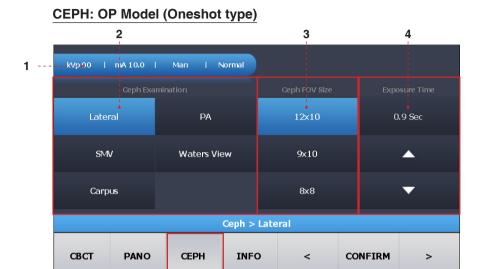
No.	Function	Description
1	Examination area selection	Selects the tooth position
2	Guidance Image	_



No.	Function	
1	Tube voltage UP / DOWN	
2	Tube current UP / DOWN	
3	Patient's gender selection	
4	Patient's bone density selection	
5	Displays the parameter settings	
6	Temple support adjustment	



No.	Function	Description	
1	Imaging parameter settings information	-	-
2	Pano Type	Magic Pan	Optional
3	Image Quality	UHD	Optional
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: SC Model (Scan Type)**

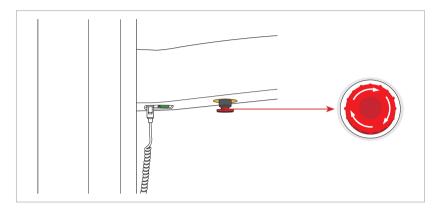


No.	Function	Description		
1	Imaging parameter settings information		_	
2	CEPH Examination		_	
3	CEPH FOV Size (inches)		_	
4	Exposure Time adjustment	OS/OP	Enable the user to adjust the exposure time	
4		models	with the UP and DOWN buttons.	
5	Image Quality	HD	_	
		FAST	(Optional)	



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

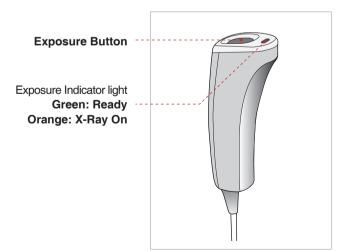


During operation, the following emergency situations may occur:

- 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 orange 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	A	Silicon cover: Nasal Positioner	
Chin Support: TMJ, Sinus, Edentulous		Protractor: CEPH	
Silicon cover: Chin Support		Carpus plate	
Silicon cover: Chinrest		Hygiene cover :	Panorama Cover
Temple Supports (1 set)	TT	bite block (single use)	2

## 3.4 Marks and Symbols

Symbols	Description	Location
$\sim$	Alternate current	-
À	Attention: consult accompanying documents	Label
4	Dangerous voltage	Power board
	Protective earth (Ground)	Power board
0	Off (power: disconnect from the main switch)	Main switch
	On (power: connect to the main switch)	Main switch
<b>*</b>	TYPE B Equipment	Label
A	Radiation hazard	Label
EC REP	EC representative	Label
<b>C €</b> 0120	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
C UL US	UL mark: UL 60601-1 / CAN/CSA C22.2 No.601.1 3ZY1	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.	
	This symbol warns ESD hazard.	MCU board/ Board package
CLASS 1 LASER PRODUCT	This symbol indicates that this equipment is classified as a CLASS 1 LASER PRODUCT in accordance with IEC 60825-1 ED.1 regulations.	Label

# **Software Overview**

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## 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)



- 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	LENOVO
CPU	Intel Xeon E5-1607 3GHz 1600 4C or Faster	Intel XeonE5-1620 3.60GHz 4C or Faster
RAM	8GB DDR3-1600 MHz ECC RAM	8GB DDR3 1333MHz UDIMM-Non ECC
Hard disk drive	1TB SATA 7200 RPM 1st HDD	1TB SATA 7200 RPM 1st HDD
Graphic board	GTX660 TI 2.0GB	GTX660 TI 2.0GB
Ethernet interface	Broadcom 5761 Gigabit	Intel 82579 Gigabit
Serial Port (RS232)	HP Serial Port Adapter Kit	1
Power supply	≥ 600 Watts (90 % Efficiency)	≥ 610 Watts (85 % Efficiency)
Slots	1 PCI Express Gen3 x 8 Slot 2 PCI Express Gen3 x 16 slot 1 PCI Express Gen2 x 8 Slot 1 PCI Express Gen2 x 4 Slot 1 PCI Slot	1 PCI Express Gen3 x 16 Slot 1 PCI Express Gen2 x 4 Slot 2PCI Slots
CD/DVD drive	16XSuperMulti DVD Drive	SATA DVD-ROM/DVD Recordable
Monitor	19"1280 x 1024 screen resolution	19"1280 x 1024 screen resolution
Operating system	Windows 7 Professional 64-Bit	Windows 7 Professional 64-Bit
Recommended system	Z420	S30

## 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.



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



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**.



This displays the current imaging mode.





- Indicates that the Magic PAN is supported in the PANO imaging modality.
- Is displayed only for the Standard mode, with the Magic PAN enabled.

#### **B. Scanning Status and Image Preview Window**

This shows image acquisition progression in real-time.

#### C. Patient Information

This displays information about the selected patient.

#### D. Imaging Guide Window

This displays various text instructions for the operator to follow.

#### E. Scan Time and DAP Display Window

Upon clicking **Confirm**, the scan time and estimated DAP value is displayed in this window.

#### 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 to accommodate the circumference of the patient's head or control the power of the X-Ray in order to improve image quality. If necessary, adjust the kVp and mA values manually using the arrows.



For the tube voltage and its correspondence with the current patient, refer to "Appendix 1. Recommended X-Ray Exposure Table".

#### G. Patient Gender

This displays the current patient's gender as entered in EasyDent / EzDent-i's patient information. If necessary, gender can be manually selected.

Age Group / Gender		VATECH's Standard
	Child	≤12
A duit	Man	≥13
Adult	Woman	≥13

#### H. Bone Density

This tool selects the patient's bone density.



Depending on the circumference of the patient's head, bone density may be classified as Hard, Normal, or Soft :  $Soft \leq Normal \leq Hard$ 



#### I. Phantom Capture



This function is used when the Phantom Jig is being used to acquire images.

Image acquisition using the Phantom Jig:

1. Click Phantom Capture Icon.



- 2. Select the Modality, followed by OK.
- 3. Check the parameters displayed in the main GUI window. If correct, click the 'Confirm' button.
- 4. Align the Phantom Jig, and click the 'Ready' button.
- 5. Press and hold down the exposure switch.



#### J. Manual Image Reconstruction



If automatic reconstruction of the image fails, use this function to reconstruct the image manually. Select **Modality** and click **Search** → **Reconstruction**.



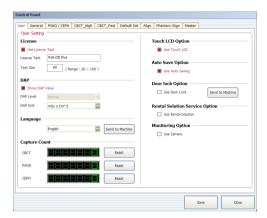
#### K. Laser Beam On / Off Button

Use this icon to turn the laser beam on or off for patient positioning. This button is enabled when the **CONFIRM** button is clicked after the imaging environmental parameters are configured.



#### L. Settings

This Control Panel displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, etc.





#### M. Exit

This button exits the capturing program.

#### N. Imaging Mode

This selects an imaging mode – PANO, CEPH or CBCT. Refer to section **4.3.1** ~ **4.3.3** for the details regarding **PANO**, **CEPH and CBCT** imaging modes.

#### O. Confirm

After confirming all settings required for scanning, press **CONFIRM** to apply the settings.



#### Scan Time: 0.0 DAP: 0.00 uGy x m^2

When you click CONFIRM, the scan time and estimated DAP (Dose Area Product) value will be shown on the main display for the exposure you are going to take.

#### P. Ready

This button is used when all aspects of preparation have done for image acquisition (including parameter settings and patient positioning)

#### 4.3.1 PANO

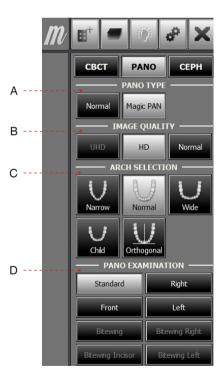
#### **PANO Type**

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

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



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 papears 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



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.



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	
	Right	Imaging lateral right	Supported by
	Front	Imaging frontal area	any arch type selection
	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			of Interest: hogonal	Remark
	Standard	Imaging PANO Standard image		
	Right	Imaging PANO lateral right		Supported by any
	Front	Imaging P	ANO frontal area	arch type selection
	Left	Imaging PANO lateral left		
	Bitewing		Left/Right	
	Bitewing Incisor	Bitewing	Incisor region	Supported by any
	Bitewing Right	imaging	Right region	arch type selection
	Bitewing Left		Left region	

## **Special Examination**



Mode		Details	
7	TMJ LAT Open	Takes a side view image of the TMJ with the mouth open.	
7	TMJ LAT Close	Takes a side view image of the TMJ with the mouth closed.	
7	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
Marie San Control	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)

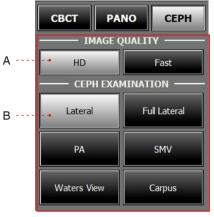
			Scan Time (s)		
Examination	Arch Selection	Examination Mode	HD	Normal	
		Standard         13.5         10.1           Front         11.1         8.4           Right         6.7         5.1           Left         6.7         5.1           Standard         13.5         10.1           Front         11.1         8.4           Right         6.7         5.1           Left         6.7         5.1           Standard         13.5         10.1           Front         11.1         8.4           Right         6.7         5.1           Left         6.7         5.1           Standard         11.5         8.6           Front         9.2         6.9           Right         5.7         4.3           Left         5.7         4.3           Standard         13.5         10.1           Front         11.1         8.4           Right         6.7         5.1           Left         5.7         4.3           Left         6.7         5.1           Bitewing         9.6         7.2           Bitewing lncisor         2.5         1.9           Bitewing Left         4.8         3.6			
	Name	Front	11.1	8.4	
	Narrow	Right	6.7	5.1	
		Left	6.7	5.1	
		Standard	13.5	10.1	
	Normal	Front	11.1	8.4	
	Nomai	Right	6.7	5.1	
		Left	6.7	5.1	
		Standard	13.5	10.1	
	Wide	Front	11.1 8.4 6.7 5.1 6.7 5.1 11.5 8.6	8.4	
	vvide	Right	6.7	5.1	
PANO		Left	5.1		
Examination		Standard	11.5	8.6	
	Child	Front	9.2	6.9	
	Crilia	Right	6.7     5.1       6.7     5.1       13.5     10.1       11.1     8.4       6.7     5.1       6.7     5.1       11.5     8.6       9.2     6.9       5.7     4.3       5.7     4.3       13.5     10.1       11.1     8.4       6.7     5.1       9.6     7.2		
		Left	5.7	4.3	
		Standard	13.5	10.1	
		Front	11.1	8.4	
		Right	6.7	5.1	
	Orthogonal	Left	6.7	5.1	
	Orthogonal	Bitewing			
		Bitewing Incisor	2.5	1.9	
		Bitewing Right	4.8	3.6	
		Bitewing Left	4.8	3.6	
		TMJ LAT Open	6.1	15	
		TMJ LAT Close	0.1	4.5	
Special		TMJ PA Open	7.0	5.3	
Examination		TMJ PA Close	7.0	5.3	
		Sinus LAT	6.0	4.5	
		Sinus PA	10.3	7.7	



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

#### 4.3.2 CEPH

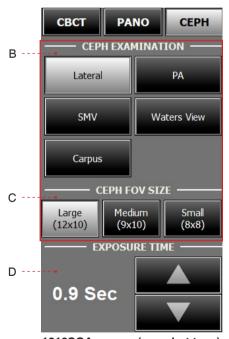
Depending on the sensor type employed, one of the three kinds of imaging program comes with the equipment for the CEPH mode examination.



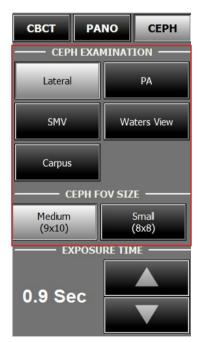
Xmaru2301CF / Xmaru3001CF sensor (scan type)

#### A. Image Quality

-Fast (optional): scans faster with lower
 X-Ray dose than the Normal mode.



1210SGA sensor (one shot type)



0910SGA sensor (one shot type)

#### **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
The state of the s	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	Model
12 x 10	Full size	OP
9 x 10	Region of the no interest of the rear part of the head is eliminated to minimize the X-Ray exposure area.	OP/OS
8 x 8	Child	OP/OS

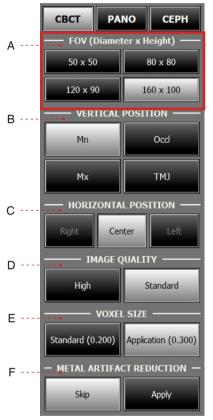
#### D. Exposure Time

Sensor Type	Examination Modes	Scan Time (s) - Default	
	Full Lateral	16.9	-
Scan	Lateral	12.9	Fast Scan: 3.9 s (optional)
	PA / SMV / Waters View / Carpus	12.9	Fast Scan: 4.9 s (optional)
Oneshot	Lateral		0.7
Uneshot	PA / SMV / Waters View / Carpus		0.9



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







Xmaru1215CF Master Plus

#### A. FOV Size

This selects the FOV (Field Of View) size.



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

#### **B. Vertical Position**

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

#### C. Horizontal Position

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

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

#### 4. Image Quality

Mode	Scan Time
High	5.9 s
Standard	5.9 s



- High: Higher quality image acquisition than "Standard"
- Standard: Fast scan with low X-Ray dose.

#### E. Voxel Size

FOV (mm)	Mode	Voxel Size (mm)
50 x 50	Standard	0.120
50 X 50	Application	0.200
80 x 80	Standard	0.200
00 X 00	Application	0.300
100 x 80	Standard	0.200
100 X 60	Application	0.300
120 x 90	Standard	0.200
120 X 90	Application	0.300
160 x 100	Standard	0.200
100 X 100	Application	0.300

#### 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.



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.



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

**FOV & Examination Positioning** 

FOV 6: ()	Vautiaal	Daaitian	Hori	zontal Pos	ition
FOV Size (mm)	Vertical Position		Right	Center	Left
	Mx.	0			
50 X 50	Occl.	X	A		aatabla
50 X 50	Mn.	0	A specific tooth selectable		
	TMJ	X			
	N	lx.	0 0 0		0
80 X 80	Occl.		0	0	0
100 x 80	Mn.		0	0	0
	TMJ		0	0	0
	Mx.		Χ	0	Χ
120 X 90	Occl.		Χ	0	Χ
120 X 90	Mn.		Χ	0	Χ
	TMJ		Х	X	Χ
	Mx.		Χ	0	Χ
160 X 100	Od	ccl.	Χ	0	Χ
100 X 100	N	ln.	Х	0	Х
	TMJ		Х	0	Х

## **Image Reconstruction Time**

#### Xmaru1215CF Master Plus

		Reconstruction Time (s)				
FOV (mm) Voxel Size		Standard (Scan Time: 5.9 s)		High (Scan Time: : 5.9 s)		File Size (MB)
		Skip	Apply	Skip	Apply	
E0 v E0	0.120	20	38	20	38	137
50 x 50	0.200	14	26	14	26	29.4
80 x 80	0.200	24	48	24	48	122
00 X 00	0.300	18	40	18	40	35.4
100 x 80	0.200	32	70	32	70	188
100 x 60	0.300	22	53	22	53	54.5

#### The test condition:

- PC system: HP Z420: Windows7 Professional 64-Bit, Intel Xeon E5-1607 @ 3.0 GHz CPU, 8 GB RAM, Geforce GTX 660 T1 / 2.0 GB

- Object: Skull

#### Xmaru1524CF Master Plus

	Reconstruction Time (s)					
FOV (mm)	Voxel Size			Standard Hig Scan Time: 5.9 s) (Scan Tim		File Size (MB)
		Skip	Apply	Skip	Apply	
50 x 50	0.120	20	34	20	34	137
50 X 50	0.200	13	24	13	24	29.4
80 x 80	0.200	27	50	27	50	122
60 X 60	0.300	20	40	20	40	35.4
120 x 90	0.200	36	78	36	78	308
120 X 90	0.300	26	56	26	56	90.7
160 x 100	0.200	60	142	60	142	606
100 X 100	0.300	35	77	35	77	174

#### The test condition:

- PC system: Lenovo S30: Windows7 Professional 64-Bit, Intel Xeon E5-1620 @ 3.6 GHz CPU, 8 GB RAM, Geforce GTX660 T1 VGA Card
- Object: Skull



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

# **Getting Started**

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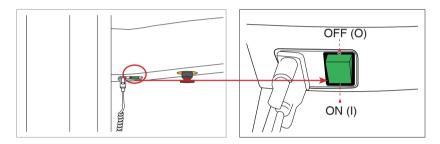
## 5 Getting Started

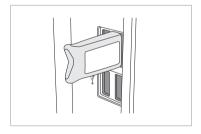
## 5.1 Turning on the PaX-i3D Green

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.



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.



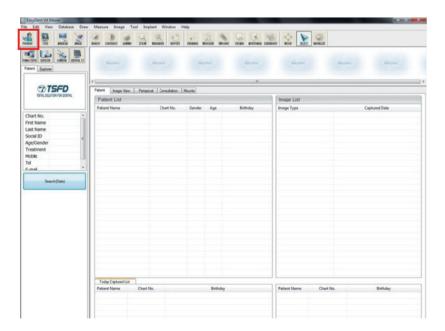
For further details on this subject, refer to the EasyDent / EzDent-i user manual.

## 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.

Cancel

Add

D. Click Add to save the patient record.

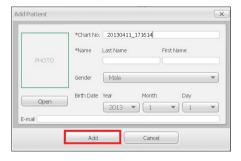
#### EzDent-i

Doctor :

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

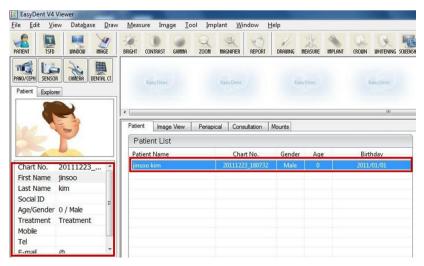
#### **EasyDent**

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.

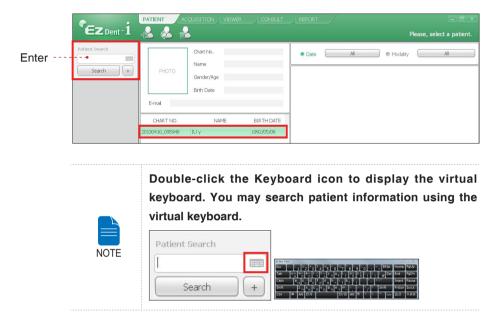


- B. Enter **the Chart No.**, **First name**, **or Last name** of the patient by clicking the mouse on the virtual key board and click the **Enter** (The physical keyboard can be used to do the same job).
- C. Patient information can be displayed on the **Patient information pane** and **Patient List**.

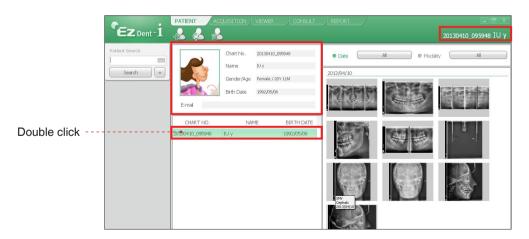


#### EzDent-i

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.



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



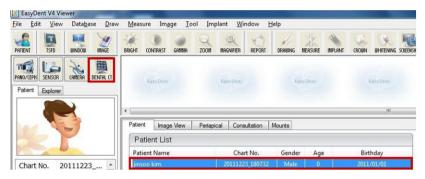
## 5.3 Initiating the Imaging Program



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 ( point of 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.



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

# **Acquiring PANO Images**

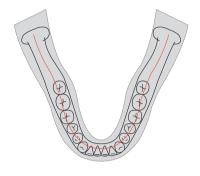
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6.4	Initiating X-Ray Exposure	90

# 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	
		Standard	1
	Narrow	Right	
	INATIOW	Front	
		Left	
		Standard	2
	Normal	Right	
	Normal	Front	
		Left	
		Standard	3
	Wide	Right	
	vvide	Front	
PANO		Left	
EXAMINATION	Child	Standard	(4)
		Right	
		Front	
		Left	
			(5)
		Right	
		Front	
	Orthogonal	Left	
	Onnogonal	Bitewing	6
		Bitewing Incisor	
		Bitewing Right	
		Bitewing Left	
			7
		TMJ LAT Close	
SPECIAL	_	•	
EXAMINATION		TMJ PA Close	
			9
		Sinus PA	10



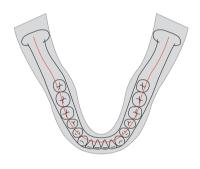
#### ① Narrow\_Standard

A panoramic imaging mode for the patients with the V-shaped arch trajectory (a few women).



#### ② Normal\_Standard

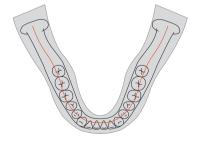
A panoramic imaging mode for the adult patients with the normal arch trajectories.



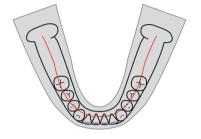


#### 3 Wide\_Standard

A panoramic imaging mode for the patients with the squareshaped arch trajectory (a few adult men).







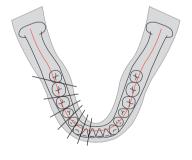
## ④ Child\_Standard

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

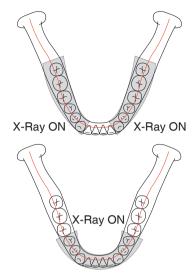


## ⑤ Orthogonal\_Standard

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

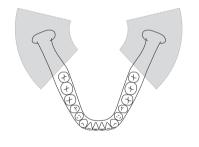
A panoramic imaging mode to acquire an image only for the region of interest through the orthogonal trajectory: **Pros**: less X-Ray exposure than the Standard mode. **Cons**: TMJ and parts of an image of the maxillary sinus are not acquired.





# (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).





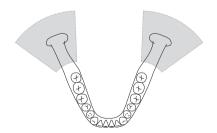






# 8 TMJ PA Open / Close (Optional)

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).

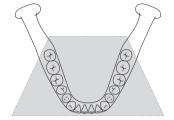












# 9 Sinus LAT (Optional)

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**.



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 --- CBCT PANO CEPH
B --- Normal Magic PAN
C --- IMAGE QUALITY
UHD HD Normal
D --- ARCH SELECTION
Arrow Normal Wide
Chid Orthogonal
PANO EXAMINATION
Standard Right
Front Left
Bitewing Bitewing Right
Bitewing Incisor Bitewing Left



- 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	

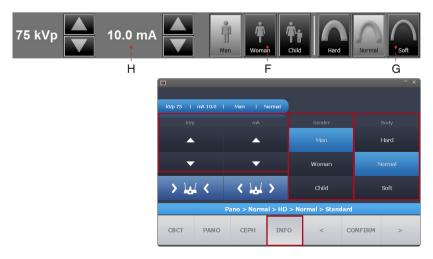
ARCH SELECTION Click Orthogonal Magic Pan PANO EXAMINATION Normal Orthogonal Activated Standard Right Front Left СВСТ INFO CONFIRM Bitewing Bitewing Right Bitewing Incisor Bitewing Left

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 the patient's bone density type under Bone Density Type.



Bone density is determined based on the patient's head size (circumference).

 $Soft \leq Normal \leq Hard$ 

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



### Adjustable resolution:

Tube voltage: ± 1 kVpTube current: ± 0.1 mA

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







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.



### Laser beam On / Off buttons:





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

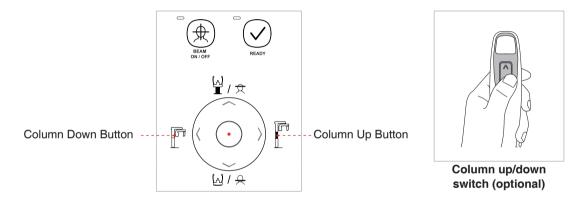
Scan Time : 0.0 DAP : 0.00 uGy x m^2

- The Touch Screen changes to the INFO screen. (Only the Temple Support Adjustment buttons are enabled on the INFO screen.)
- 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.





- 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.



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.



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

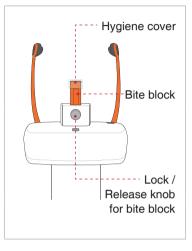
## 6.3.1 PANO Standard

# Positioning the patient



PANO Standard\_ENG

\*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.



\* For the edentulous patients, use the Chin support.





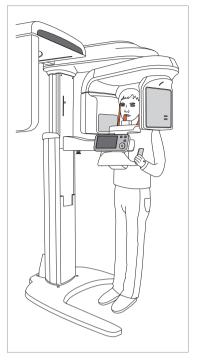
The hygiene cover for the bite block and chin support is intended for single use only. Always replace the hygiene cover for each new patient.



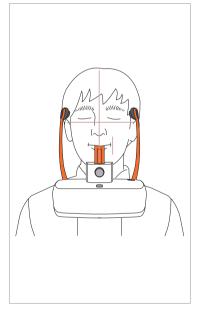
Disinfect the Chinrest, Chin support and bite block using an alcohol-based cleaning solution and wipe away all residue with dry cloth.



- C. Loosen 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
- 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.



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

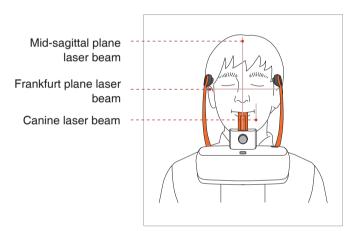
- Breathe or swallow saliva during image acquisition
- Move during image acquisition

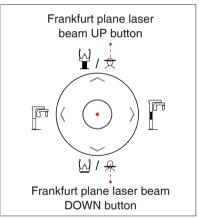
# **Aligning the Laser Beams**



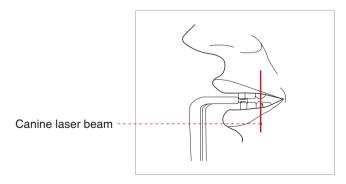
Be careful not to project the laser beams directly into the patient's eyes as this could severely damage the patient's vision.

- A. **Mid-sagittal plane laser beam**: Position the Mid-sagittal plane laser beam 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.**

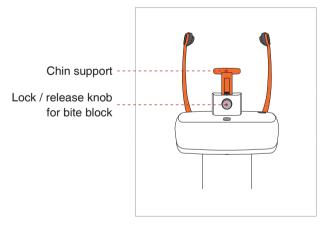
# 6.3.2 TMJ Open

There are two TMJ sub modes: **TMJ Open and TMJ Close**. You may scan a TMJ Close Image subsequent to a TMJ Open 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



- A. Insert the Chin support into the Chinrest receptacle on the equipment.
- B. Place a hygienic cover over the bite block.



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



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



- I. For **TMJ Open** imaging, have the patient:
- Open his/her mouth as wide as possible
- Keep his/her tongue positioned towards the palate
- Breathe through his/her nose
- Close his/her eyes.
- J. 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.



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

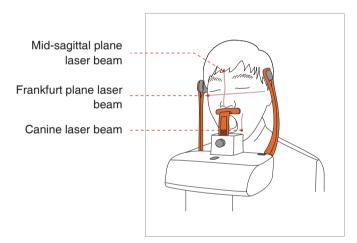
- Breathe or swallow saliva during image acquisition
- Move during image acquisition

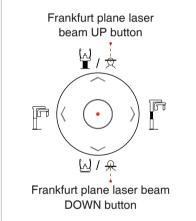
# **Aligning the Laser Beams**

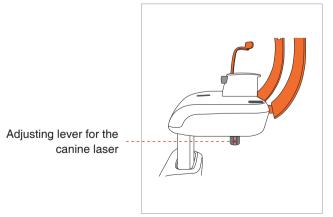


Be careful not to project the laser beams directly into the patient's eyes as this could severely damage the patient's vision.

- 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 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.

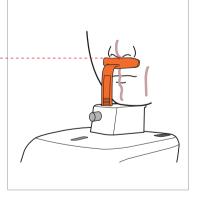
### 6.3.3 TMJ Close



You may scan a TMJ Close image subsequent to a TMJ Open 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.





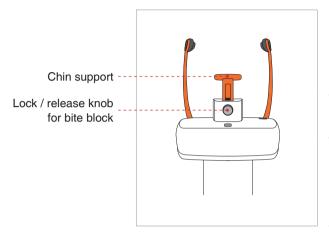
- D. For TMJ Close imaging, Have the patient:
- Close his/her mouth
- Keep his/her tongue pressed against his/her palate
- Close his/her eyes

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**



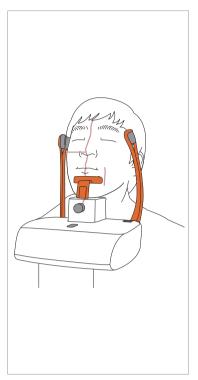
- A. Insert the Chin support into the Chinrest receptacle on the equipment.
- B. Place a hygienic cover over the bite block.



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



- C. Loosen the **temple supports** by clicking the **temple support adjustment button.**
- D. Guide the patient —facing the Chinrest to the equipment. Have the patient stand upright in the center of the equipment.
- E. 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.
- 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.
- 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. Align the patient so that the area right under the lips touches the upper part of the chin support.
- H. Ensure that the patient's shoulders remain level and that his/her neck is relaxed. The cervical spine should be straight and upright.
- I. 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.



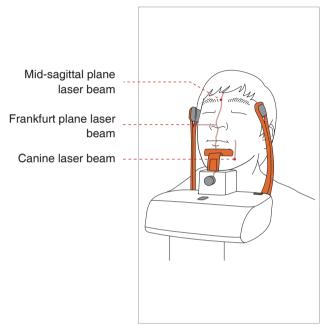
To acquire the best image possible, ask the patient not to:

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

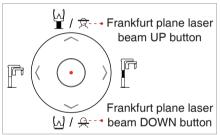
# **Aligning the Laser Beams**

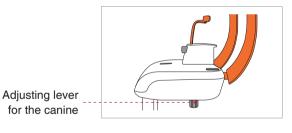


Be careful not to project the laser beams directly into the patient's eyes as this could severely damage the patient's vision.



- 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 cross the tip of patient's nose when the patient's head is tilted back  $10 15^{\circ}$ .





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.

# 6.4 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.

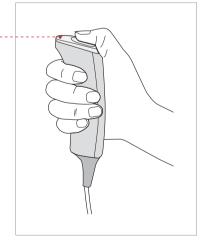


If an emergency occurs during image acquisition, release the exposure switch to cease X-Ray emission.

- 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 orange Orange: Exposure

X-Ray ON



During X-Ray irradiation, ensure that

- The LED lamp on top of the equipment turns orange 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:





D. Click the Save button to save the image.

# **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).

# **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

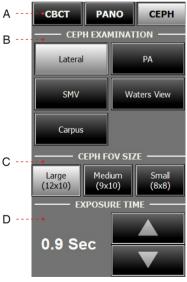


You can set the imaging parameters on either the touch screen or the imaging program running on the PC. They are synched in real time and display the same environmental settings.

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.

## **Imaging Program**



OP(1210 SGA sensor: Oneshot Type)

#### **Touch Screen**





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	Model
12 x 10	Full size	OP
9 x 10	Region of the no interest of the rear part of the head is eliminated to minimize the X-Ray exposure area.	OP/OS
8 x 8	Child	OP/OS

# 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/ Xmaru3001CF Sensor: Scan Type)



## 1 Image Quality

Fast (Optional): scans faster with lower X-Ray dose than the HD 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.

Age Group		VATECH's Standard
	Child	≤ 12
Adult	Man	≥ 13
	Woman	2 13



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

F. Select the patient's bone density type: Hard, Normal, or Soft.



Bone density is determined according to the patient's head size (circumference).

 $Soft \le Normal \le Hard$ 

- G. Default values for the tube voltage (kVp) and current (mA) will be displayed based on the patient's gender and bone density. 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 and estimated DAP (Dose Area Product) value are shown on the main display for the intended exposure.
- I. Guide the patient to the equipment. Refer to section 7.2 Positioning the

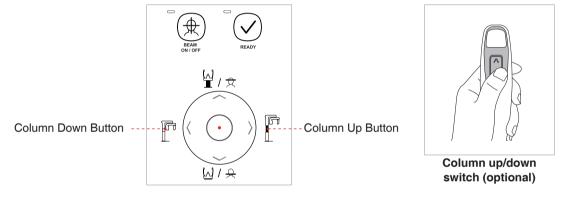
Scan Time: 0.0 DAP: 0.00 uGy x m^2

# 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).





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



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



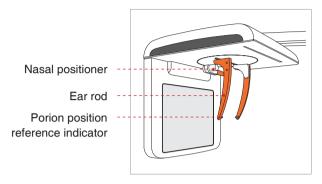
Ensure that the patient is clear of all moving parts while adjusting the height of the equipment.



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** Frontal (PA)

Follow the procedure below to correctly position the patient.

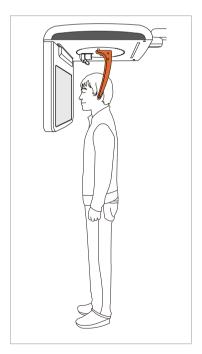


- A. Turn the ear rods 90° clockwise from their initial position.
- B. Widen the distance between the two ear rods.
- C. The nasal positioner should be flipped to the side and upward to prevent it from obstructing the image acquisition.



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

D. Guide the patient to the CEPH unit.



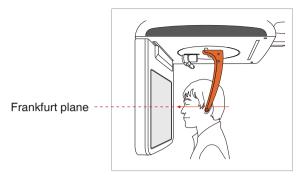
E. Ask the patient to stand upright facing the sensor.

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.

## 7.2.2 Lateral / Full Lateral



CEPH Lateral\_ENG

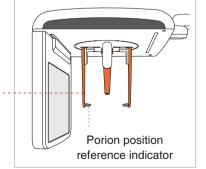
\*To link to the video manual: scan the QR code with smart phone or pad.

Ear rods



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.

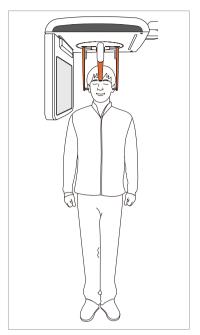


A. Widen the distance between the two ear rods.



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

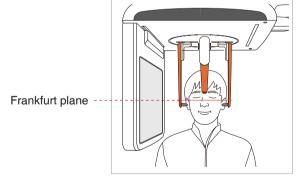




- C. Ask the patient to stand upright.
- Make sure that the patient's shoulders are level and that their neck is relaxed.
- D. Adjust the height of the unit to suit the patient by pressing the column up/down button or switch (optional).



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.

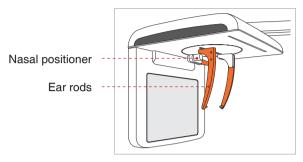




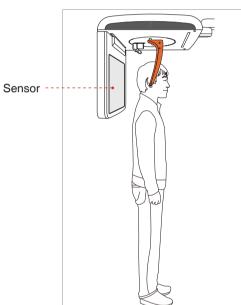
- H. Click the **READY** button after the patient has been properly positioned. No X-Ray will be emitted at this point.
- I. Proceed to section 7.3 Initiating X-Ray Exposure.

### 7.2.3 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.



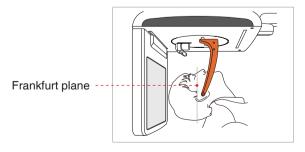
- C. Guide the patient to the CEPH unit.
- D. Ask the patient to stand upright facing the X-Ray tube.

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.

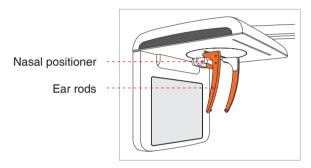




- H. Click the **READY** button after the patient has been properly positioned. No X-Ray will be emitted at this point.
- I. Proceed to section 7.3 Initiating X-Ray Exposure.

### 7.2.4 Waters View

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

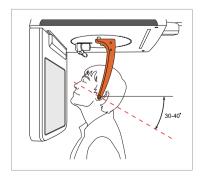


- A. Widen the distance between the two ear rods.
- B. The nasal positioner should be flipped to the side and up to prevent it from obstructing the image acquisition.
- C. Guide the patient to the CEPH unit.
- D. Ask the patient to stand upright facing the sensor. Make sure that the patient's shoulders 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.

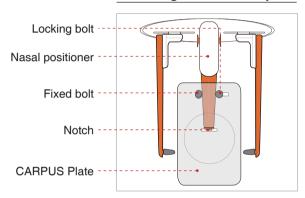




- H. Click the **READY** button after the patient has been properly positioned. No X-Ray will be emitted at this point.
- I. Proceed to section 7.3 Initiating X-Ray Exposure.

### **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.



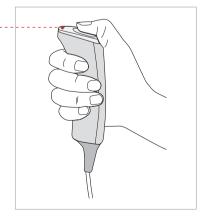
- Do not operate the PC during exposure. Failure to comply with this instruction may cause the system to malfunction.
- The operator shall observe the X-Ray safety regulations applicable to their area at all times during the operation of this equipment.



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 orange Orange: Exposure



During X-Ray irradiation, ensure that

- The LED lamp on top of the equipment turns orange 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 (Unit: inches)



**FOV 12 x 10** 



FOV 9 x 10

# Lateral (Unit: inches)



FOV 12 x 10 (Full Lateral)



FOV 9 x 10



FOV (inches) 8 x 8



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.

# **Acquiring CT Images**

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# 8 Acquiring CT Images

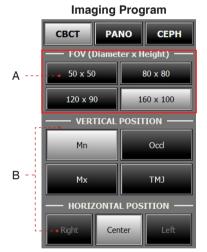
This chapter requires all preparatory steps outlined in **Chapter 5** to have already been completed.

### 8.1 Setting the Exposure Parameters



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



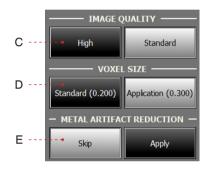


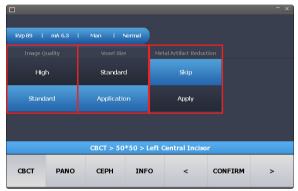


The FOV size is determined by the CT sensor attached on the equipment.

A. Select the FOV size for the CT.

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: High or Standard.
- D. Select the voxel resolution : Standard or Application.
- 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.



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.

Age Group		VATECH's Standard
	Child	≤ 12
اد داد ۸	Man	N 10
Adult	Woman	≥ 13

G. Select the patient's bone density type.



Bone density (Hard, Normal, or Soft) is determined based on the circumference of the patient's head.

**Soft≤Normal≤Hard** 

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



Each patient has a unique bone density that may necessitate manual adjustment of the kVp and mA values in order to obtain a more accurate image.

Adjustable resolution:

Tube voltage: ± 1 kVpTube current: ± 0.1 mA

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







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.



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



#### Laser beam On / Off buttons



: Imaging Program



Scan Time : 0.0 DAP : 0.00 uGy x m^2

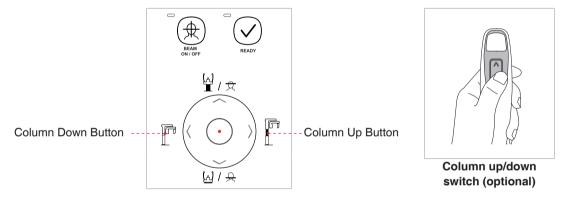
- The scan time and DAP (Dose Area Product) value are shown on the main display for the intended exposure.
- The Touch Screen changes to the INFO screen. (Only the Temple Support Adjustment buttons are enabled on the INFO screen.)
- J. Guide the patient to the equipment. Position the patient. Refer to section 8.2 Positioning the Patient.

### 8.2 Positioning the Patient

Follow the procedure outlined below to properly position the patient for CT 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).



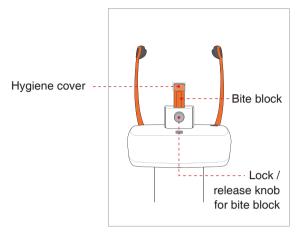


- In general, imaging is performed with the patient in an upright position. However, a stool may be used for imaging patients with special circumstances. If a stool is used, ensure that the beams and movement of unit are not obstructed by the stool
- Correct positioning is an important factor in capturing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



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.





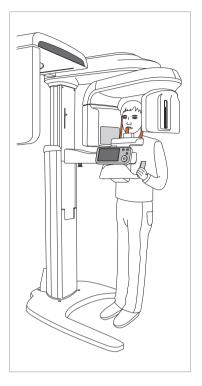
The hygiene cover for the bite block is intended for single use only. Always replace the hygiene cover for each new patient.



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



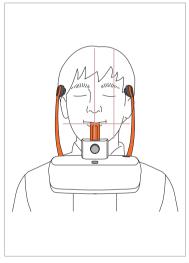
- C. Loosen the temple supports by clicking the Temple Support Wheel Adjustment button.
- D. Guide the patient —facing the Chinrest to the equipment.
- E. Adjust the height of the column using the column up/down button or switch (optional) until the patient's chin rests comfortably on the Chinrest.



#### 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

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.



#### 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**



Three laser beams - CT horizontal (X), Mid-sagittal (Y) and CT vertical (Z) - 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:



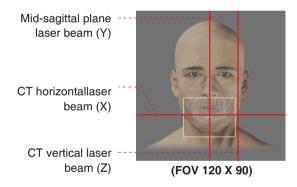
: Imaging Program



: Control Panel

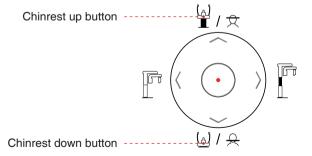


Be careful not to project the laser beams directly into the patient's eyes as this could severely damage the patient's vision.



The 3D CT image centers the FOV on the intersection of the three laser beams (CT horizontal (X), Mid-sagittal (Y) and CT vertical (Z)).

A. CT horizontal laser beam (X): Position the CT horizontal laser beam at the center of the FOV area.



B. **Mid-sagittal plane laser beam (Y)**: Position the Mid-sagittal plane laser beam at the center of the FOV area.

C. CT vertical laser beam (Z): Position the CT 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 80, the **SCOUT** image is to be acquired, click the **SCOUT** button.

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



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".

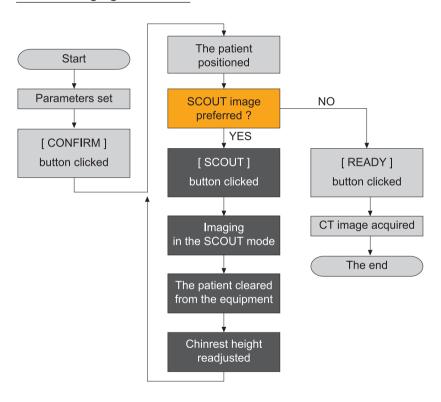
C. Proceed to the section **8.4 Initiating X-Ray Exposure**. But if the **SCOUT** feature is selected, continue to the next section **8.3 Acquiring a SCOUT Image**, to the section **8.4 Initiating X-Ray Exposure**.

## 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.

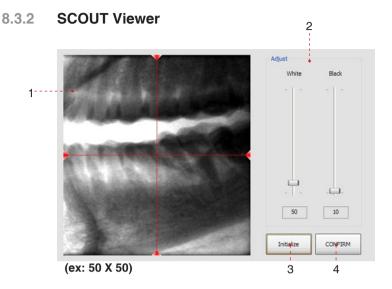


For details about the SCOUT Viewer, refer to the section "8.3.2 SCOUT Viewer".

- 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 CT 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.



#### 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

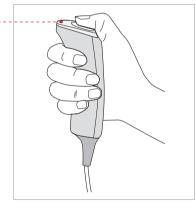
Perform the following process to acquire an image in CT mode.



- 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 orange Orange: Exposure

X-Ray ON



During X-Ray irradiation, ensure that

- The LED lamp on top of the equipment turns orange 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 CT image:

- Loosen the temple supports and release the patient.
- Remove the hygiene barrier from the bite block.

# 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	
neauy status	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.		



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



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.		
	Wipe the unit with a dry cloth at the end of each day.		
Outer covers of equipment	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.

#### **Regular Maintenance**



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



- 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.

#### **Maintenance Task Checklist**

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 orange (exposure) indicator lamp turns on when the exposure switch is pressed. Ensure that the orange (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		•		
Oaklasasad	Copper	•		
Cables and transformer	Steel	•		
u ansionne	Oil		•	
	Wood	•		
Packing	Cardboard	•		
	Paper	•		
X-Ray tube				•
Sensor head	Return the sensor head to VATECH			
Other parts			•	



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



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



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

# **Technical Specifications**

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# 12 Technical Specifications

## 12.1 Mechanical Specifications

#### A. Image Magnification

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
CT	642.3	449.7	192.6	1.43 constant

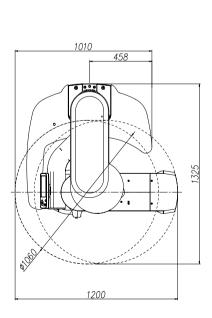
FDD : Focal Spot to Detector Distance FOD : Focal Spot to Object Distance

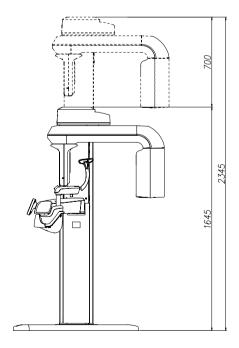
ODD: Object to Detector Distance (ODD: FDD - FOD)

Magnification: FDD / FOD

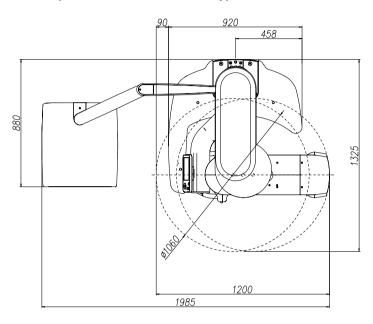
#### **B.** Dimension

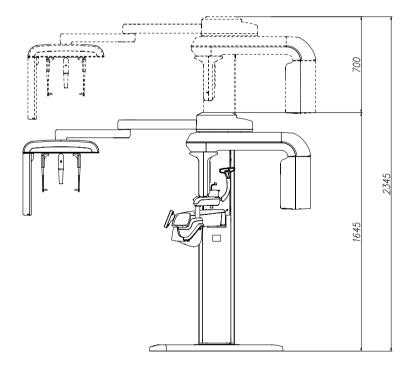
#### Without Cephalometric Unit [Unit: mm (Inches)]



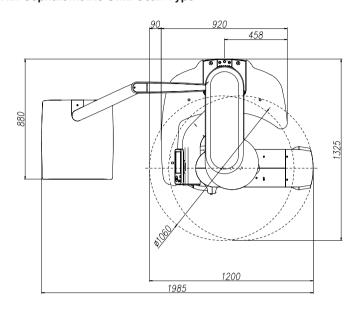


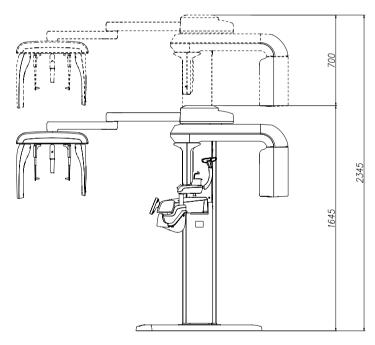
#### With Cephalometric Unit : OneShot Type





#### With Cephalometric Unit: Scan Type





[Unit: mm (Inches)]



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

lí	tem	Description	
	Without CEPH	Without base: 105 (231.5 ibs)	
	unit	With base: 160 (352.7 ibs)	
Moight (kg)	With CEPH unit	Without base: 135 (297.6 ibs)	
Weight (kg)	(Scan Type)	With base: 190 (418.9 ibs)	
	With CEPH unit	Without base: 145 (319.7 ibs)	
	(Oneshot Type)	With base: 200 (440.9 ibs)	
Total Height (m	m)	Max. 2,345 (92.32 inch.)	
Vertical column	movement (mm)	Max. 700 (Max. 27.56 inch.)	
	Without	1,200 (L) x 1,325(W) x 2,340 (H) mm	
	CEPH unit	47.24 (L) x 52.17 (W) x 92.13(H) inch	
Length x Width	With CEPH unit	1,985 (L) x 1,325 (W) x 2,340 (H) mm	
x Height (mm)	(Scan Type)	78.15 (L) x 52.17 (W) x 92.13(H) inch.	
	With CEPH unit	1,985 (L) x 1,325 (W) x 2,340 (H) mm	
	(One shot Type)	78.15 (L) x 52.17 (W) x 92.13(H) inch.	
Type of installat	ion	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)
	Туре		Inverte	r
	Normal/	kVp	50 ~ 100 ( 1 k	V step)
High	Pulse	mA	4 ~ 16 ( 0.1 m	A step)
voltage generator	Cooling		Automatically controlled / Protect $\geq 60^{\circ}$ C Air Cooling: Optional	
	Added Filtration		2.0 mmAl	2.3 mmAl
	Total filtration		2.8 mm Al eq.	
	Manufact	urer	Toshiba	CEI
X-Ray tube	Model		D-052SB (Stationary Anode Type)	IPX/105
	Tube volta	age	Operating 50-100 kV	
	Tube curr	ent	Maximum 22 mA	_

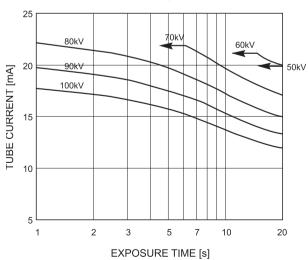
Item			Description						
		Focal spot size				0.5 mm (IEC60336)			
		Targe	t angle			5	0		
			storage c mum hea	apacity	35 kJ		30	kJ	
		Inher	ent filtratio	on	At least Al eq.at	0.8 mm 50 kV	0.5	mm Al	
X-Ra	•	X- ray	/ coverag	е	95 x 38	0 mm at SI	D 550 mn	n	
tube	!	Anod	Anode heat content		35 kJ	35 kJ			
		Normal anode input power			1,750 V	V (at 1.0 s)	'	00 W 1.0 s)	
		Maximum anode heat dissipation rate				250 W			
		Duty	cycle		1:60 or more				
		Daty			(Exposure time : interval time)			e)	
		2007							
S/N	,	XXX Size mm)	XXX	XX	XX	XX	XX	XXXX	
	N	lodel	Tube	Inverter ver.	F/W ver.	Weekly code	Yearly code	serial	

#### **D-052SB**

## **Maximum Rating Charts**

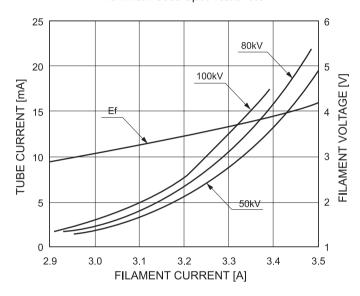
DC (Center Grounded)

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

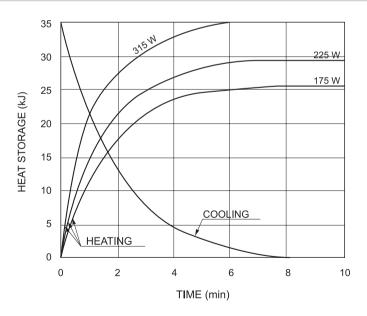


#### **Emission & Filament Characteristics**

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



#### **Anode Thermal Characteristics**



#### Indication of focal spot



#### **Detector Specifications**

Item	Description					
item	PANO		СЕРН			
Model	Xmaru1501CF	Xmaru3001CF	Xmaru2301CF	1210SGA	910SGA	
Detector type	CN	MOS photodiode array  Amorphous silicon TFT  with scintillator				
Pixel size (µm)	100	100	100	127		
Active area (mm)	6 x 150.4	6 x 307.2	5.9 x 230.4	264 x 325	222 x 254	
Frame rate	300 fps	200 fps	200 fps	240 fph		
A/D (bits)	14					
Sensor size	175.4 x 86	322 x 69	251.2 x 69	402 x 364	314 x 279	
(mm)	x 21.6	x 26.5	x 27.1	x 32	x 24	

ltem	Description				
item		ст			
Model	Xmaru1215CF Master Plus	Xmaru1524CF Master Plus			
Detector type	CMOS p	CMOS photodiode array			
	49.5 (full resolution)	49.5 (full resolution)			
Pixel size (µ™)	99 (2 x 2 binning)	99 (2 x 2 binning)			
	198 (4 x 4 binning)	198 (4 x 4 binning)			
Active area (mm)	116.42 x 145.72 143.9 x 232.5				
	Full: 5 fps	Full: 8 fps			
Frame Rate (fps)	2 x 2: 30 fps	2 x 2: 28 fps			
	4 x 4: 100 fps	4 x 4: 90 fps			
A/D (bits)	14				
Sensor size (mm)	159 x 238.2 x 27	235 x 330 x 33			

# 12.3 Electrical Specifications

Item	Description
Power supply voltage	AC 100 - 120 V / 200 - 240 V  - AC 110 V / 230 V (European Union or The rest countries)  - AC 100 V (Japan)  - AC 110 V (Taiwan)  - AC 120 V (USA / Canada)  - AC 220 V (China)  - AC 240 V (Australia)
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: ±10 %.

# 12.4 Environmental Specifications

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

# **Appendices**

1	Recommended X-Ray Exposure Table 144		
2	X-Ray Dose Data	146	
2.1	DAP Table	146	
2.2	CTDI (CT Dose Index)	147	
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3	Abbreviations	151	

# 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 (7 s)]

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

 $<sup>^{\</sup>star}$  Tube voltage and current variation range in the PANORAMIC mode: 50  $\sim$  80 kVp, 4  $\sim$  16 mA

#### B. CEPH

#### Lateral

Gender / Figure	Hard (kVp / mA)		Normal (kVp / mA)		Soft (kVp / mA)				
	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

Gender / Figure	Hard (kVp / mA)		Normal (kVp / mA)			Soft (kVp / mA)			
	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

Gender / Figure	Hard (kVp / mA)		Norr	Normal (kVp / mA)		Soft (kVp / mA)			
	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

<sup>\*</sup> Tube voltage and current variation range in the CEPHALOMETRIC mode: 60

#### C. CBCT

#### Xmaru1215CF master plus / Xmaru 1524CF master plus

Gender / Figure	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
Man	90 / 7.5	89 / 7.5	88 / 7.5
Woman	90 / 6.5	89 / 6.5	88 / 6.5
Child	86 / 6.5	85 / 6.5	84 / 6.5



Maximally allowed tube voltage / current: kVp  $\pm$  10 % / mA  $\pm$  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.

 $<sup>\</sup>sim$  100 kVp, 4  $\sim$  14 mA

# 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 dosemetric 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)		
	PANO: Xmaru1501CF		
Conserving	CEPH: 910SGA		
Sensor type	(One shot Type)		
	CT: Xmaru1524CF Master Plus		
X-Ray generator type / Inverter type	DG-07C11T2		

#### 2.1 DAP Table

Test Equipment						
Instrument	Instrument Manufacturer Model S/N					
Dose Meter Piranha 205 CB2-07050141						

	Mode Tested: PANO HD / Normal / Standard / Adult / 13.5 s							
mA	6			8	10			
kVp	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]		
60	5.07	36.0	6.72	46.7	8.22	56.5		
70	6.57	47.1	8.71	59.9	10.65	72.3		
80	8.53	61.5	11.31	76.4	13.83	97.7		
90	10.48	75.3	13.89	93.7	16.99	110.1		

Mode Tested: CEPH PA (9 x 10), 0.9 s							
mA		6		8	10		
kVp	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	
60	0.02	17.89	0.04	23.70	0.05	29.57	
70	0.03	24.37	0.06	32.30	0.07	40.30	
80	0.04	31.82	0.08	42.17	0.10	52.61	
90	0.05	40.39	0.10	53.53	0.13	66.79	

Mode Tested: CT Adult FOV 160 x 100, 5.9 s High							
mA	6		8		10		
kVp	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	
60	0.66	225.3	0.87	295.0	1.07	362.4	
70	1.04	352.9	1.37	464.1	1.70	575.3	
80	1.50	509.9	1.96	662.7	2.44	825.8	
90	2.03	689.5	2.64	893.3	3.29	1115.0	

	Mode Tested: CT Adult FOV 160 x 100, 5.9 s Standard							
mA	6		8			10		
kVp	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]	[mGy]	[mGy · cm2]		
60	0.28	93.3	0.33	113.2	0.41	139.7		
70	0.43	147.2	0.56	188.9	0.68	229.4		
80	0.65	221.8	0.82	279.0	1.04	351.2		
90	0.90	304.3	1.14	385.1	1.43	484.4		

# 2.2 CTDI (CT Dose Index)

Testing Equipment						
Instrument	Manufacturer	Model	S/N			
Dose Meter	Unfors	XI Base Unit	163288			
Test Phantom						
PMMA Head Phantom	Radcal	20CT6	16 cm			

Test Condition: FOV 160 x 100, 5.9 s, 99 kVp, Fast						
	CTDI <sub>100</sub> [m	nGy]				
[mA] Location	6	8	10			
Center	2.86	3.68	4.50			
0°	1.34	1.74	2.06			
90°	3.48	4.52	5.45			
180°	6.19	8.10	9.80			
270°	4.33	5.67	6.84			

Testing Conditions: FOV 160 x 100, 5.9 s, 99 kVp, Fast					
CTDI <sub>w</sub> [mGy] DLP [mG·cm]					
[mA] 6 8 10					
CTDI <sub>w</sub>	3.51	4.56	5.52		
DLP	35.10	45.64	55.24		

Test Condition: FOV 160 x 100, 5.9 s, 99 kVp, High					
	CTDI <sub>100</sub> [mGy]				
[mA] 6 8 10					
Center	6.86	8.89	10.76		
0°	3.55	4.28	5.23		
90°	7.85	10.29	12.59		
180°	13.95	18.33	22.48		
270°	9.74	12.80	15.72		

Testing Conditions: FOV 160 x 100, 5.9 s, 99 kVp, High					
CTDI <sub>w</sub> [mGy] DLP [mG·cm]					
[mA] 6 8 10					
CTDI <sub>w</sub>	8.14	10.58	12.93		
DLP	81.38	105.81	129.25		

# 2.3 X-Ray Scatter Dose

Test Equipment Information				
Manufacturer Model S / N				
Dose Meter	Victoreen	660	101114 / 101377	

#### **PANO Mode**

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

Mode	PANO UHD, 20.2 s [mR / hr]		
Direction [°]	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	18.6	14.2	10.8
45	19.7	14.6	10.4
90	17.6	14.6	12.1
135	86.7	45.2	23.6
180	99.7	43.3	18.8
225	66.9	45.6	31.1
270	51.4	28.2	15.5
315	22.6	19.1	16.1

#### **CT Mode**

Test Condition			
Tested Mode FOV 160 x 100, 5.9 s			
Applied Tube Voltage Peak [kVp]	99		
Applied Tube Current [mA]	14		

Mode	Standard, FOV 160 x 100, 5.9 s [mR/hr]		
Direction [°]	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	303	148	72.3
45	322	187	108.6
90	30.6	26.4	22.8
135	468	195	81.3
180	467	185	73.3
225	478	193	77.9
270	476	198	82.4
315	236	124	65.2

Mode	High, FOV 160 x 100, 5.9 s [mR/hr]		
Direction [°]	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	727	409	230.1
45	765	401	210.2
90	276	71.6	18.6
135	1007	472	221.2
180	1070	465	202.2
225	1010	461	210.4
270	1017	499	244.8
315	789	394	196.8

# 3 Abbreviations

AC	Alternating Current
AF	Auto-Focusing
AMPT	Adaptive layer Mode Panoramic Tomography
CAN	Controlled Area Network
СВСТ	Cone-Beam Computed Tomography
CMOS	Complementary Metal-Oxide-Semiconductor
СТ	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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#### Manufactured by VATECH Co., Ltd.

Tel: +82-1588-9510

Email: qcs@vatech.co.kr Website: www.vatech.co.kr

Headquarters: 23-4, Seogu-dong, Hwaseoung-si, Gyeonggi-do, Korea Factory: 23-4, Seogu-dong, Hwaseoung-si, Gyeonggi-do, Korea



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



EC Representative; Vatech Dental Manufacturing Ltd. Axiom House, The Centre, Feltham, Middlesex TW13 4AU UK

Tel: +44-0208-831-1660

Fax: +44-0208-831-1679



445-170 경기도 화성시 석우동 23-4번지 www.vatech.co.kr