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PaX-i3D™

User Manual

Model : PHT-6500
Version : 1.44

- ENGLISH



Full Version

vatech

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General Information

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1 General Information

1.1 Notice

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

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

The user manual is a part of the product. This manual describes how to operate the PaX-i3D 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, this 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.

Manual Name: PaX-i3D (Model: PHT-6500) User Manual

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1.2 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.

1.3 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**.

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1.4 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.

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

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

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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.

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- 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 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.

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- The user should apply single use disposable barrier membranes to the bite block and all other patient contacting surfaces, and these barriers must be removed and replaced with unused barriers for each patient.



- 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. 24 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 be cease and an error message will be displayed. Normal X-Ray capabilities will resume after the generator reaches 58 °C (136.4 °F).

Turning the equipment on / adjusting the height of the equipment

- Do not position the patient 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 switch to immediately stop all moving parts and cut off all power to the equipment.

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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.

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- 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.
- In normal condition, the enclosure leakage current from or between parts of the system within the patient environment shall not exceed 0.1 mmA. If the value exceeds the limit, it should be provided common protective earth.

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-i3D 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.

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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.

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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.



- **PaX-i3D system, like other medical equipment, uses high-frequency electrical signals that can interfere with implantable devices such as pacemakers and implantable cardioverter-defibrillators(ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately power off the Dental X-ray system.**
- **PaX-i3D system is designed to withstand the effects of defibrillation. However, when possible, disconnect the Dental X-ray systems during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.**

Lasers

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



Risk of eye injury!

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

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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 while the equipment is performing an operation. Failure to comply with this instruction may result in system malfunction.
- Immediately stop imaging if the equipment malfunctions in any way.
- If a problem occurs during imaging, press the red emergency stop switch located on top of the handle frame 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 Imaging System Overview

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3 PaX-i3D Imaging System Overview

3.1 Introduction

The PaX-i3D 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 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, for planning and diagnostics.

The PaX-i3D 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 (The PaX-i3D may be used for ENT (Ear, Nose and Throat) examination in countries requiring the CE marking).

3.1.1 System Components

- PaX-i3D digital X-Ray equipment
- PC
- EasyDent: 2D viewer and patient management software
- Imaging software
- Ez3D plus: 3D viewer

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:** 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.
- Multi-FOV (Field Of View): FOV is selected according based on the most suitable ROI.

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- Provides an auto-switching between 2 sensors for the PANO and CBCT imaging, without the intervention of the operator.
- CAN (Controlled Area Network) is employed to provide reliability and dependability.
- 3D Viewer **Ez3D plus**: 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 Options

The following options are all based on the **PaX-i3D**.

Item	Description		Remark
PaX-i3D	PANO + CBCT		2 in 1
PaX-i3D SC	PANO + CBCT + CEPH (scan type)		3 in 1
PaX-i3D OP	PANO + CBCT + CEPH (one shot type)	Premium	3 in 1

Item	Description	FOV	Sensor
120 x 90 M	PANO and CBCT	Multi FOV (mm) 120 x 90, 80 x 80, 80 x 50, 50 x 50	Xmaru1215CF-Plus
80 X 80 M	PANO and CBCT	Multi FOV (mm) 80 x 80, 80 x 50, 50 x 50	Xmaru0712CF

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3.1.4 Standards and Regulations

Standards:

The PaX-i3D 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 [HDG-07B10T2] IEC 60601-2-28 (1993)

CE 2460

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.

C SA US 266436

This equipment received the CSA certification mark in accordance with CAN/CSA C22.2 No.601.1 regulations.

Classifications (IEC60601-1 6.1):

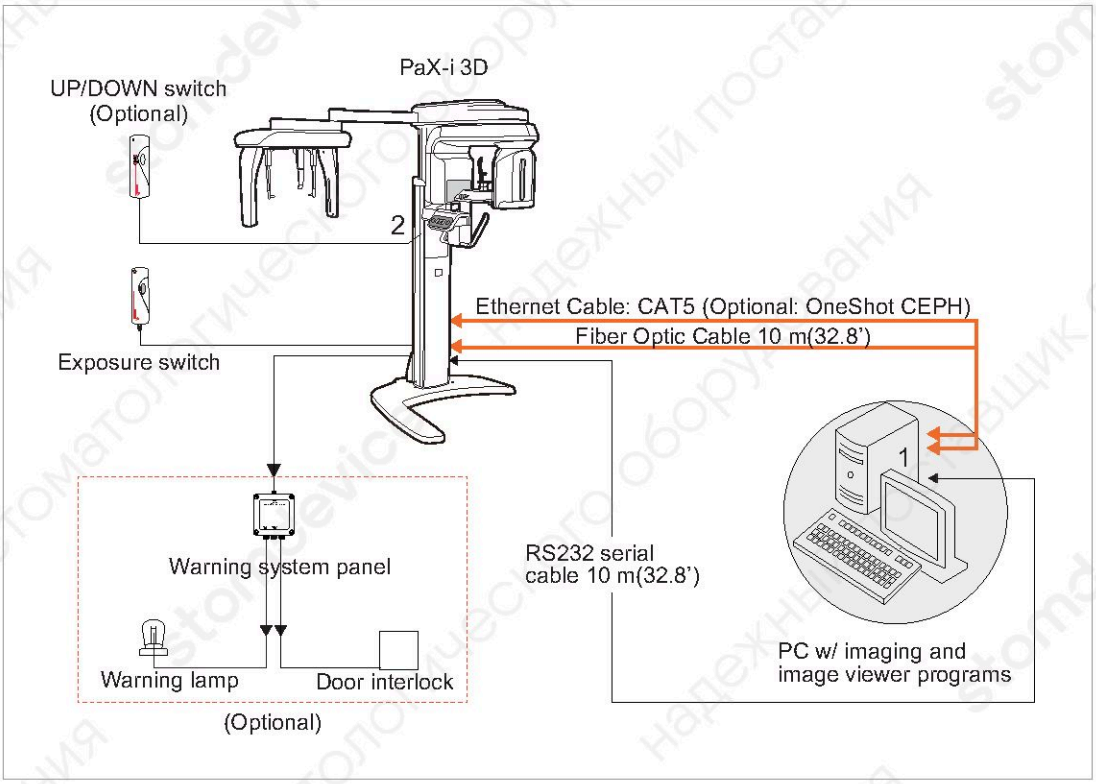
Protection against the ingress of water: Ordinary Equipment: IPX0

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

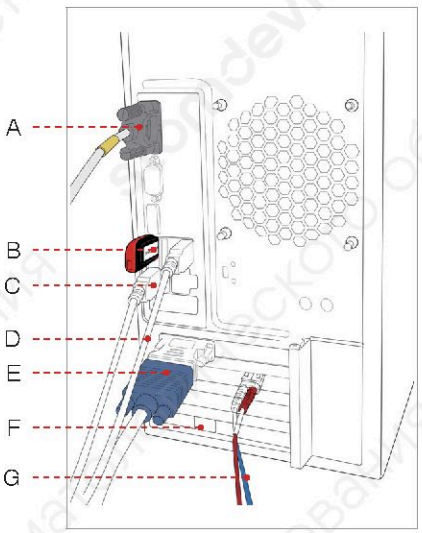
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3.2 Imaging System Structure



1. Signal input / output on PC

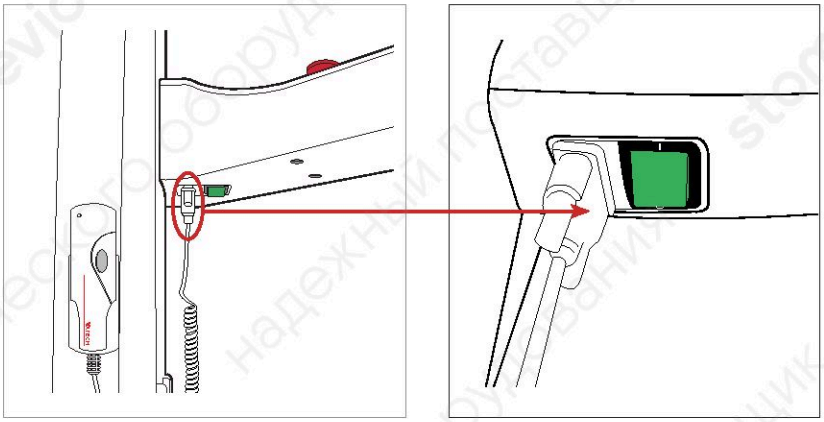


A. RS-232 in / out
B. Ez3D plus Licence Key
C. Keyboard input
D. Mouse input
E. Video out
F. Ethernet cable: CAT5 (OneShot CEPH)
G. Fiber optic cable in / out
(PANO / CT / Scan CEPH)

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



NOTE

External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC60601-1series for medical electrical equipment).

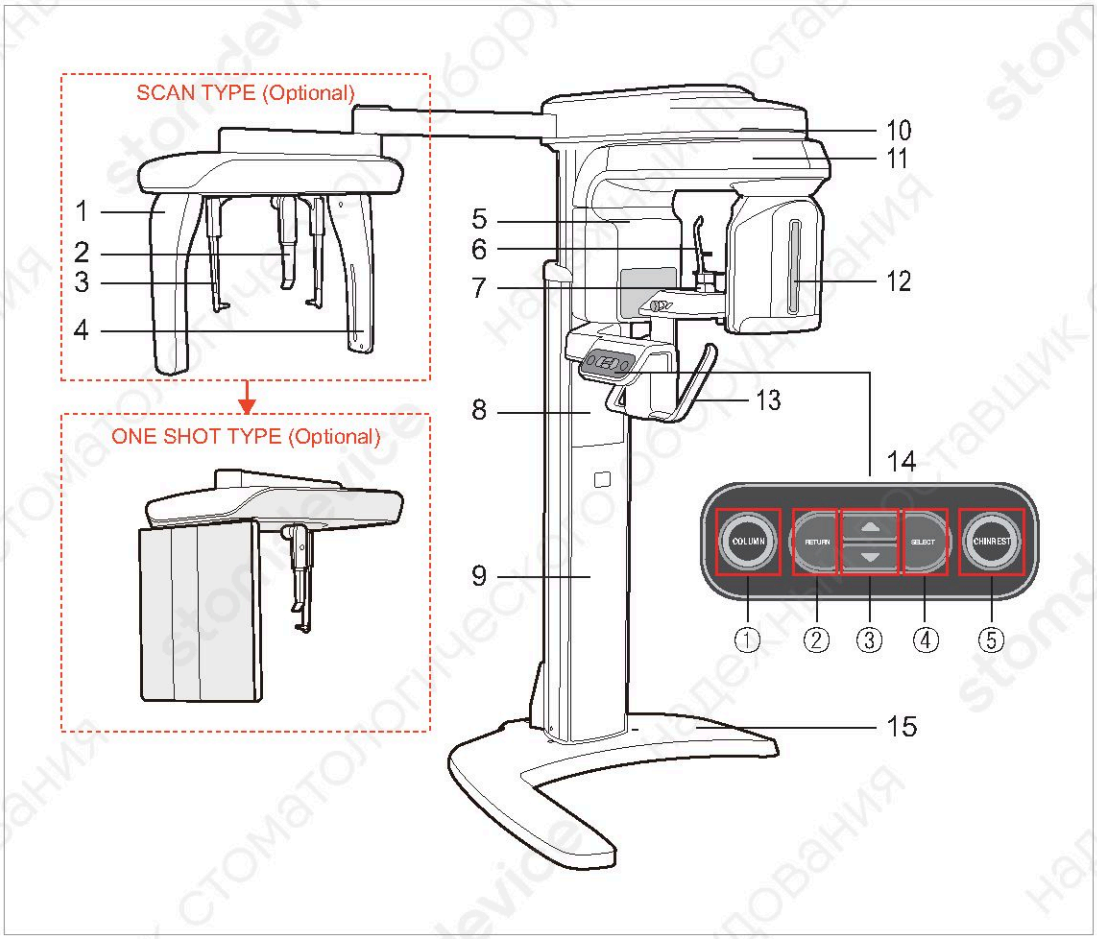
In addition, all such combination-system-shall comply with the standard IEC60601-1 and/or IEC60601-1-1 harmonized national standard or the combination.

If in doubt, contact a qualified technician or your local VATECH representative.

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3.3 General View of the PaX-i3D



Item		Details
1	X-RAY SENSOR (CEPH)	CEPH imaging sensor (optional). - Scan Type - One shot Type
2	NASAL POSITIONER	- Positions the patient during CEPH imaging. - The ruler for use to compensate the acquired image that is different from actual size.
3	EAR RODS	Secures the patient's head during CEPH imaging.
4	SECONDARY COLLIMATOR	Limits the X-Ray irradiation field for CEPH scanning.

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Item		Details
5	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).
6	TEMPLE SUPPORT	Supports the patient's temples during PANO scan.
7	CHINREST	Supports the patient's chin during imaging.
8	TELESCOPIC COLUMN	Moves the column up or down for patient positioning.
9	STATIONARY COLUMN	The portion of the column fixed to the base.
10	LED LAMP	Indicates current exposure activity. Green: Ready Orange: X-Ray On
11	ROTATING UNIT	Rotates around the patient's head during exposure (depending on the imaging mode).
12	X-RAY TUBE	The source of X-Ray emission.
13	HANDLE FRAME	Held firmly by the patient during imaging to stabilize his / her position.
14	① COLUMN	When COLUMN selected, the LED light is on.
	② RETURN	Enables the rotating unit to return to an initial position for the next exposure.
	③ UP / DOWN	Moves the Column / Chinrest up / down.
	④ SELECT	Mode selection: COLUMN, CHINREST w/ LED on. - Works only for the CT mode. When touched, the LED is ON on the CHINREST. - Disabled in PANO and CEPH modes.
	⑤ CHINREST	When CHINREST selected, the LED light is on - Fine adjustment in the CT mode.
15	BASE	Used to balance and stabilize the equipment.

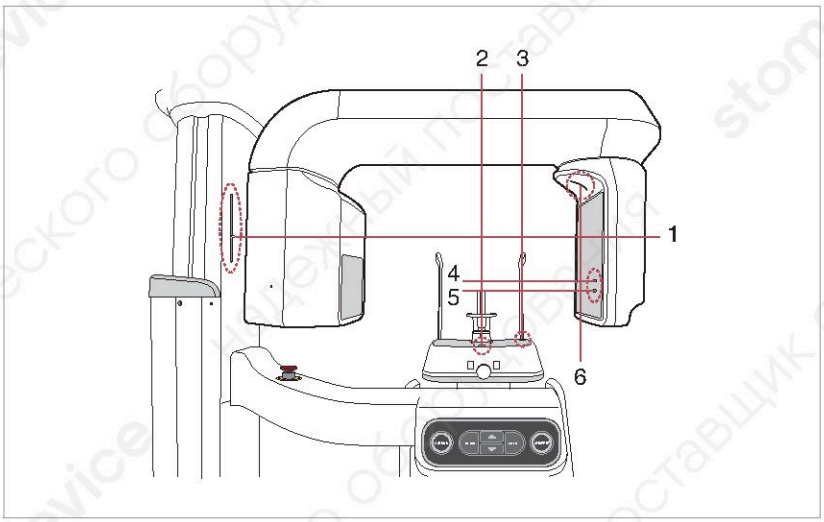
NOTE

The structural overview of the PaX-i3D may differ depending on the model. For more information, refer to section 3.1.3 The PaX-i3D Options.

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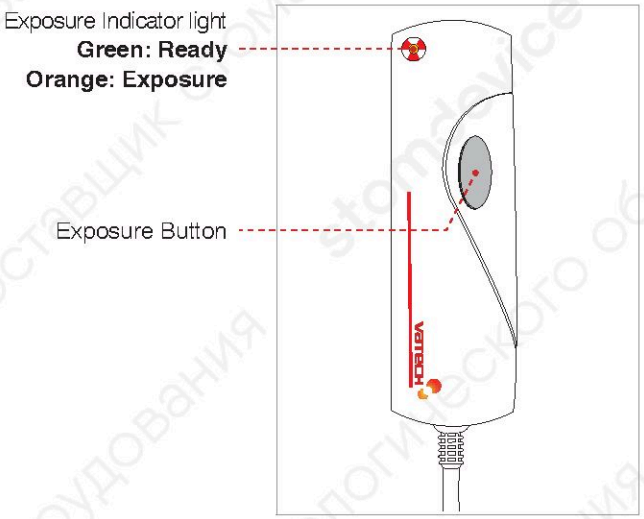
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3.3.1 Laser Beams



1. Frankfurt laser beam (Front): PANO
2. Mid-sagittal plane laser beam (Front): PANO / CT
3. Canine laser beam (Lateral): PANO
4. CT horizontal laser beam (Lateral: Upper): Large FOV
5. CT horizontal laser beam (Lateral: Lower): Small FOV
6. CT vertical laser beam (Lateral)

3.3.2 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.

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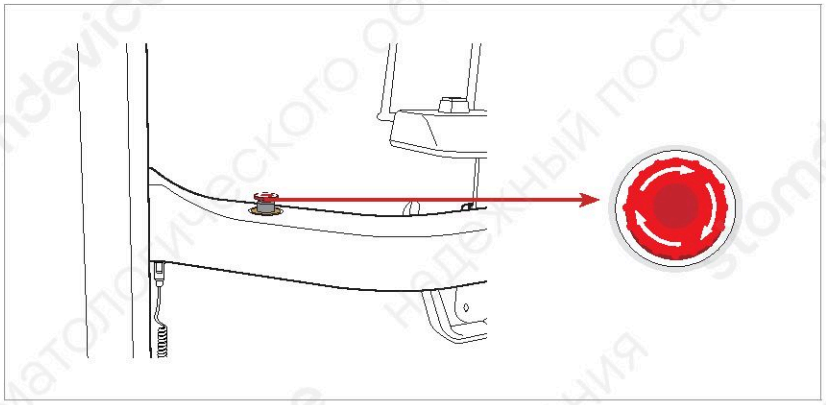
3.3.3 Emergency Stop Switch

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.

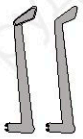


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3.3.4 Components and Positioning Accessories

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, chin support or temple supports, using an alcohol-based solution and allow them to dry before use.

Accessories		Order No.
Chin support w/ bite block: Normal		M0400419 / M0400145
Chin support: Edentulous		M0400421
Chin support: TMJ		M0400422
Chin support: Sinus		M0400420
Temple supports		M0400835 : L M0400836 : R
Carpus plate		M0100074
Hygiene cover for bite block (single use)		

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3.4 Examination Programs and Exposure Time

The PaX-i3D has been designed to carry out the following radiological examinations:

- PANO
- CBCT
- CEPH

3.4.1 PANO Mode

PANO Type:

Version	Mode	Option
Basic	PANO examination / Special examination	
Magic PAN	PANO examination: Standard	optional

NOTE

Magic PAN: A 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.

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Exposure Time (Max. 20.2 s)

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

NOTE

- **: Indicates that the examination supports Magic PAN .**

- **Maximum exposure time deviation: ± 10 % (IEC 60601-2-7)**

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3.4.2 CEPH Mode

Scan Type Sensor (optional)

Examination Modes	Scan Time (s) - Default
Lateral / PA / SMV / Waters View / Carpus	12.9
Full Lateral	16.9

One shot Type Sensor (optional)

Examination Modes	Scan Time (s) - Default
Lateral	0.9
PA / SMV / Waters View / Carpus	1.2

NOTE

Exposure time can be adjusted by resolution of 0.1 s in the range of 0.7 s to 1.2 s (One shot type only).

3.4.3 CBCT Mode

FOV & Examination Positioning

FOV Size (mm)	Vertical Position		Horizontal Position		
			Right	Center	Left
50 x 50	Mx.	O	specific tooth selection		
	Occl.	X			
	Mn.	O			
	TMJ	X			
80 x 50 / 80 x 80	Mx.		O	O	O
	Occl.		O	O	O
	Mn.		O	O	O
	TMJ		O	X	O
120 x 90	Mx.		X	O	X
	Occl.		X	O	X
	Mn.		X	O	X
	TMJ		X	X	X

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Image Reconstruction

Image reconstruction time varies depending on computer specifications and / or working conditions. The Xmaru series stand for the individual sensor.

* **MAR**: Metal Artifact Reduction

[Xmaru1215CF- plus sensor]

FOV (mm)	Voxel Size	Reconstruction Time (s)				File Size (MB)
		STANDARD (Scan Time: 15 s)		HIGH (Scan Time: 24 s)		
		*MAR Skip	*MAR Apply	*MAR Skip	*MAR Apply	
50 x 50	0.120	22	67	39	98	138
	0.200	19	52	32	78	30
80 x 50	0.200	24	68	37	105	76.5
	0.300	19	61	32	92	21.8
80 x 80	0.200	32	110	54	168	122
	0.300	27	96	43	148	35
120 x 90	0.200	44	169	71	274	310
	0.300	34	125	57	182	91.5

The test condition: LENOVO Workstation E30: Intel Xeon E3-1230 3.20Ghz CPU, 4GB RAM, NVIDIA Quadro 600 VGA Card.

[Xmaru0712CF sensor]

FOV (mm)	Voxel Size	Reconstruction Time (s)				File Size (MB)
		STANDARD (Scan Time: 15 s)		HIGH (Scan Time: 24 s)		
		*MAR Skip	*MAR Apply	*MAR Skip	*MAR Apply	
50 x 50	0.120	31	72	44	102	137
	0.200	23	55	39	84	29
80 x 50	0.200	30	66	46	110	75.6
	0.300	23	56	38	89	21.2
80 x 80	0.200	40	103	55	132	122
	0.300	31	80	48	126	35

The test condition: HP Workstation Z400: Intel Xeon w3550 @ 3.07 GHz CPU, 3 GB RAM, NVIDIA Quadro 600 VGA Card.

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3.5 Marks and Symbols

Symbols	Description	Location
	Alternate current	
	Attention: consult accompanying documents	Label
	Dangerous voltage	Power board
	Protective earth (Ground)	Power board
	Off (power: disconnect from the main switch)	Main switch
	On (power: connect to the main switch)	Main switch
	TYPE B Equipment	Label
	Radiation hazard	Label
	EC representative	Label
	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Label
	CSA mark No.266436	Label
	Address where the equipment was manufactured	Label
	This symbol indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Label
	This symbol warns ESD hazard.	MCU board/ Board package
	This symbol indicates that this equipment is classified as a CLASS 1 LASER PRODUCT in accordance with IEC 60825-1 ED.1 regulations.	Label

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Symbols	Description	Location
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Label
	Indicates that the user needs to refer to the Instruction Manual.	Label
	Indicates the date of manufacture.	Label
SN	Indicates the manufacturer's serial number so that the specific equipment can be identified.	Label

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3.5.1 Label Locations

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



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

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4

Software Overview

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4 Software Overview

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

- EasyDent: 2D viewer, analysis, and patient management
- Imaging software: **PANO / CEPH / CBCT**

4.1 PC System Requirements (Recommended)

NOTE

- **The PC system plays a large role in processing and viewing quality images. Image quality may be diminished if the PC specifications are not met. Please adhere to the requirements specified in the following table.**
- **If necessary, upgrade your PC's system configuration to meet the following specifications.**
- **DO NOT place the PC or peripheral equipment connected to the PC in the immediate vicinity of the patient.**

Item	Specifications
CPU	E5-1607v4 4C 3.1GHz 2133 10MB
Chipset	Intel® C612
RAM	1x4GB DDR4-2400 Registered RAM
HDD	500GB SATA 7200 rpm
Graphics board	NVIDIA Quadro K620 2GB
Ethernet Interface	Integrated Intel I218LM PCIe GbE Controller Intel Ethernet I210-T1 PCIe NIC (Option)
Serial Port (RS232)	HP Serial Port Adapter Kit (Option)
Power Supply	≥ 700 Watts (90% efficient)
Slots	2 PCI Express Gen3 x16 slot 1 PCI Express Gen3 x 8 Slot 1 PCI Express Gen2 x 4 Slot 1 PCI Express Gen2 x 1 Slot
	1 PCI 32bit/33MHz
CD/DVD drive	DVD Writer 5.25"
Operating System	Windows 7 Professional 64-bit (available through downgrade rights from Windows 10 Pro)
Recommended System	HP Z440

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Item	HP	LENOVO
Slots	1 PCI Express Gen3 x8 Slot 2 PCI Express Gen3 x16 slot 1 PCI Express Gen2 x8 Slot 1 PCI Express Gen2 x4 Slot	1 PCI Express Gen3 x16 Slot 1 PCI Express Gen2 x16 Slot 1 PCI Express Gen2 x1 Slot
	1 PCI Slot	1 PCI Slot
CD/DVD drive	DVD-ROM, DVD+/-RW, Blu-Ray	DVD-ROM DVD R/W, Blu-Ray R/W
Monitor	19" 1280 x 1024 screen resolution	19" 1280 x 1024 screen resolution
Operating system	Windows 7 Professional 64-Bit OS	Windows 7 Professional 64-Bit OS
Recommended system	Z420	P300

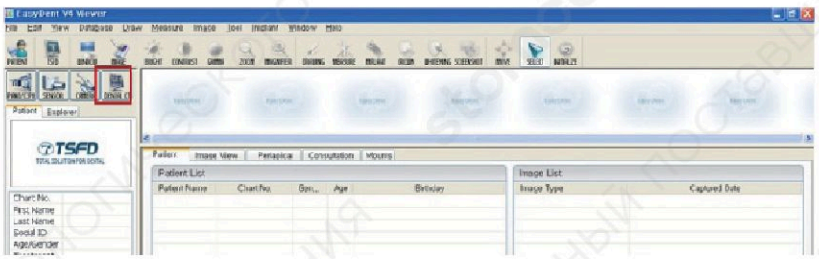
4.2 EasyDent

As the basic imaging platform for all VATECH dental X-Ray equipment, **EasyDent** is designed to be easy to use. Both the **Imaging Program** and the **3D Viewer** are interfaced with **EasyDent**. Images acquired by the **Imaging Program** are imported directly into **EasyDent**, where analysis and diagnosis can be performed quickly and easily.

EasyDent has the following key features:

- 2D viewer, image analysis and patient information management
- Extra oral/intraoral image management
- 3D image management

The screenshot below is of **EasyDent's** initial GUI window.



For details about patient search, refer to sections **5.2.1 Creating a new patient record** and **5.2.2 Retrieving patient records**.

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4.3 Imaging Software Overview

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**.



A. Imaging Mode Display

This displays the current imaging mode.

NOTE

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

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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

This tool adjusts the kVp and mA values 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.

NOTE

Adjustable resolution:

- **Tube voltage: ± 1 kVp**
- **Tube current: ± 1 mA(PANO, CEPH), ± 0.1 mA(CT)**

NOTE

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's patient information. If necessary, gender can be manually selected.

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

H. X-ray intensity

This tool select X-ray intensity.

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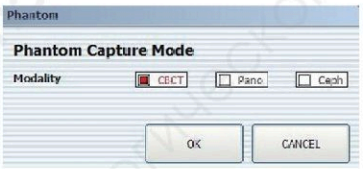
NOTE

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

Soft ≤ Normal ≤ Hard

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

I. Phantom Capture



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

NOTE

Image acquisition using the Phantom Jig:

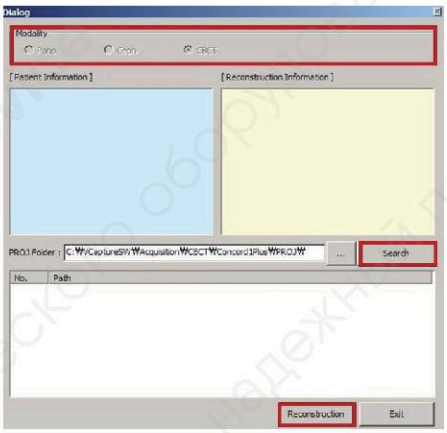
1. **Click Phantom Capture Icon.**
2. **Select the Modality, followed by OK.**
3. **Check the parameters displayed in the main GUI window. If correct, click the 'Confirm' button.**
4. **Align the Phantom Jig, and click the 'Ready' button.**
5. **Press and hold down the exposure switch.**

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**.

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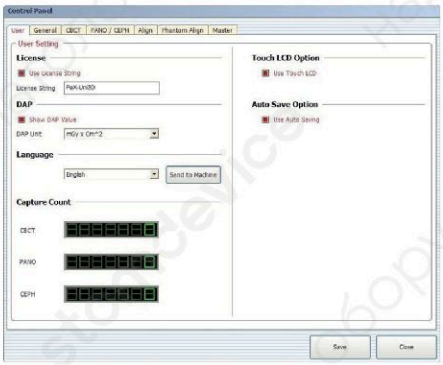
K. Laser Beam On / Off Button

Use this icon to turn the laser beam on or off for patient positioning.



L. Setting

This Control Panel displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, etc. Settings are classified into two groups: operator and installer.



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M. Exit

This button exits the capturing program.

N. Imaging Mode

This toggles the imaging mode.

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.



NOTE

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.



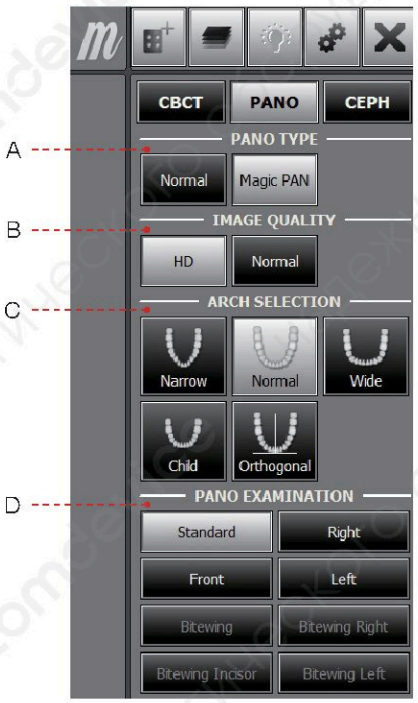
P. Ready

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

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4.3.1 PANO Mode



A. PANO TYPE

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

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

B. Image Quality

One of three modes (UHD, HD or Normal) can be selected for PANO imaging.

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

NOTE

Setting the default mode in the PANO:

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

To change the default mode,

1. Ask the engineer in your region for the mode change.

2. Re-run the imaging program after setting up the related parameters.

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CAUTION

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

C. Arch Selection

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

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

D. PANO Examination

Acquire the image for a specific ROI in panoramic mode.

Mode		Region of Interest: PANO Image
	Standard	Imaging standard images
	Right	Imaging lateral right
	Front	Imaging frontal area
	Left	Imaging lateral left

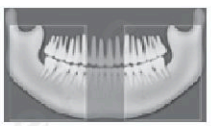
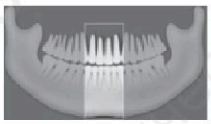
The following table summarizes the sub-modes for orthogonal imaging.

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

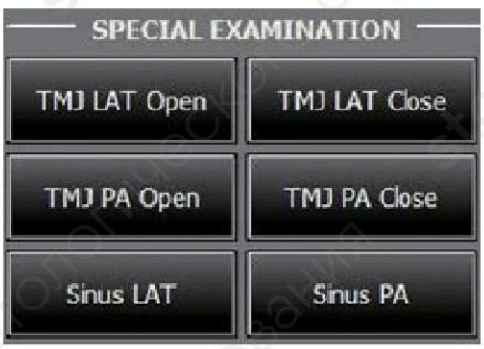
Sub-mode		Region of Interest: Orthogonal
	Standard	Imaging PANO Standard image

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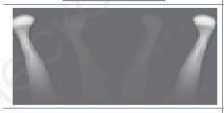
Sub-mode		Region of Interest: Orthogonal	
	Right	Imaging PANO lateral right	
	Front	Imaging PANO frontal area	
	Left	Imaging PANO lateral left	
	Bitewing	Bitewing imaging	Left / Right
	Bitewing Incisor		Incisor region
	Bitewing Right		Right region
	Bitewing Left		Left region

Special Examination



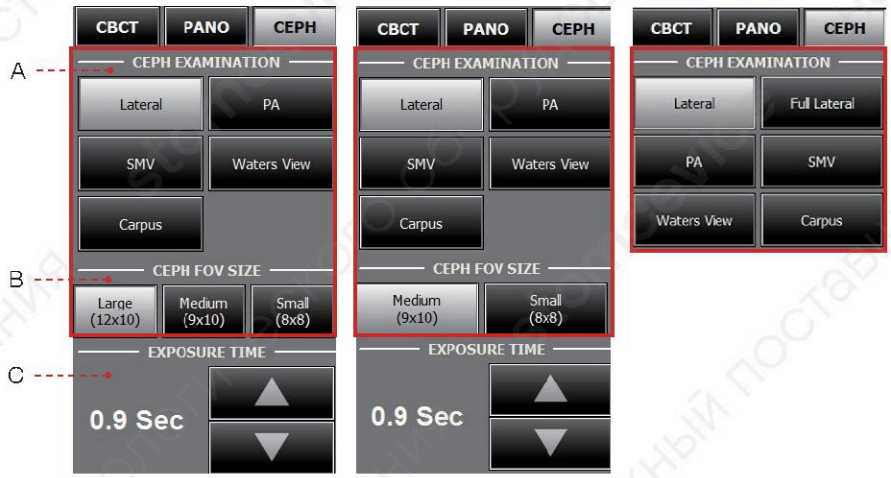
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Mode		Details	
	TMJ LAT Open	Takes a side view image of the TMJ with the mouth open.	
	TMJ LAT Close	Takes a side view image of the TMJ with the mouth closed.	
	TMJ PA Open	Takes a posterior/anterior image of the TMJ with the mouth open.	optional
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

4.3.2 CEPH Mode

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



1210SGA sensor (one shot type) | **0910SGA sensor (one shot type)** | **Xmaru2301CF sensor (scan type)**

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A. CEPH Examination

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

B. FOV Selection

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

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

C. Exposure Time

One shot Type Sensor (optional)

Examination Modes	Scan Time (s) - Default
Lateral	0.9
PA / SMV / Waters View / Carpus	1.2

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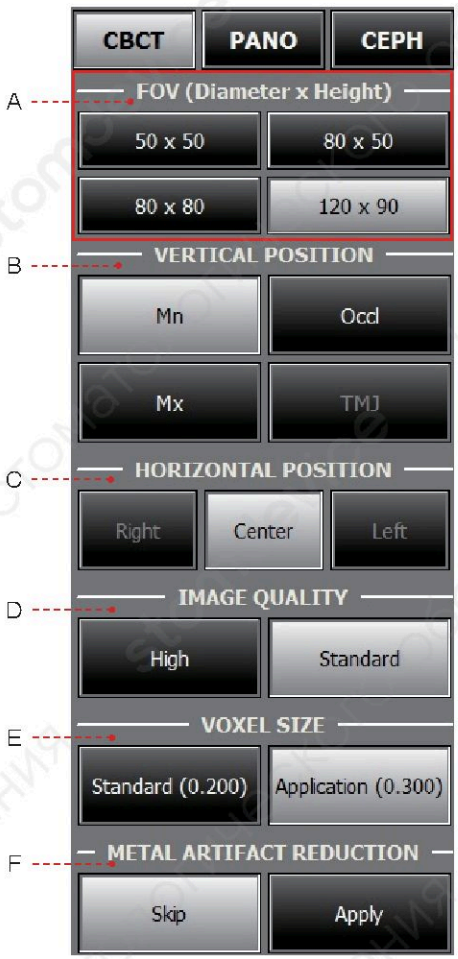
NOTE

Exposure time can be adjusted by resolution of 0.1 s in the range of 0.7 s to 1.2 s (One shot type only).

Scan Type Sensor (optional)

Examination Modes	Scan Time (s) - Default
Lateral / PA / SMV / Waters View / Carpus	12.9
Full Lateral	16.9

4.3.3 CBCT Mode



Xmaru1215CF Plus sensor



Xmaru0712CF Sensor

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A. FOV Size

This selects the FOV (Field Of View) size.

NOTE

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**.

D. Image Quality

This selects the image acquisition speed: **High (24 s)** or **Standard (15 s)**.

NOTE

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

E. Voxel Size

High / Standard

FOV (mm)	Mode	Voxel Size (mm)
120 x 90 80 x 80 80 x 50	Standard	0.200
	Application	0.300
50 x 50	Standard	0.120
	Application	0.200

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.

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NOTE

Setting the default mode in the CBCT:

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

To change the default mode,

1. Ask the engineer in your region for the mode change.

2. Re-run the imaging program after setting up the related parameters.



CAUTION

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

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5

Getting Started

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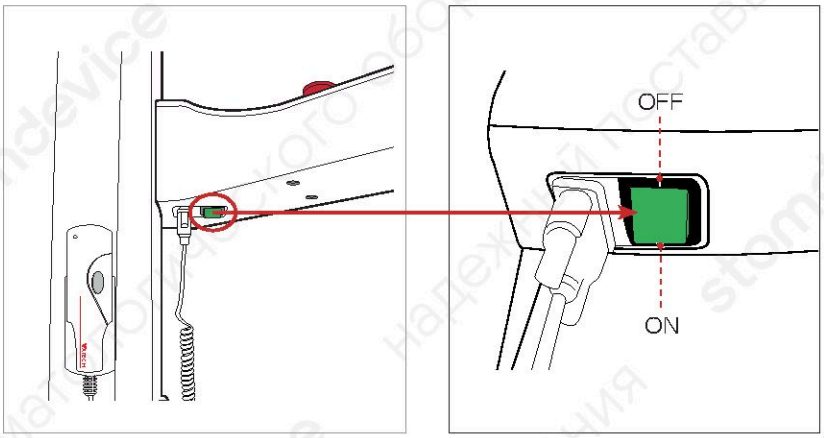
5 Getting Started

5.1 Turning on the PaX-i3D

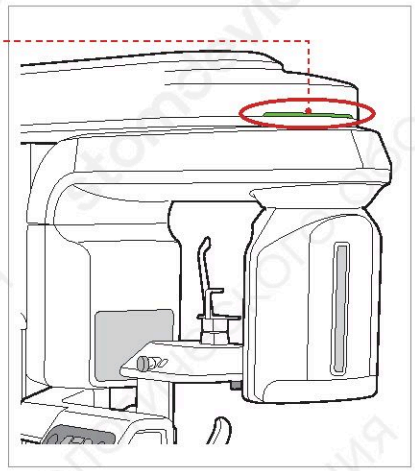
To turn on the system, follow the steps below:

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.



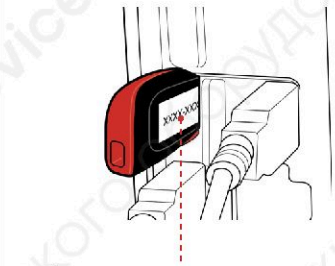
Green: ON



C. Check whether the LED lamp on top of the equipment is illuminated. If it is illuminated, the equipment is ready for image acquisition.

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License key for Ez3D plus

D. 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.

IMPORTANT

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

CAUTION

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

WARNING

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

EasyDent is a basic imaging platform for all VATECH's dental X-Ray equipments. Both the **Imaging Program** and **3D Viewer** are interfaced with **EasyDent**.

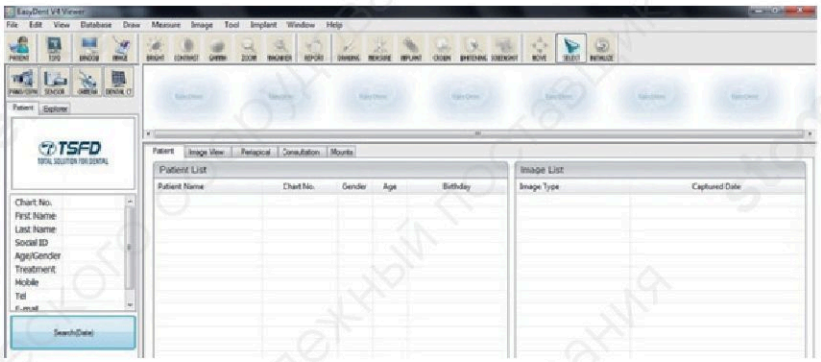
On your desktop, double-click **EasyDent** or click **Start→All Programs→EasyDent**.

The **EasyDent** main window will be displayed.

Go to the section **5.2.1 ~5.2.2** to create or open an existing patient record.

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NOTE

For detailed guide to using this software, please refer to the EasyDent user manual.

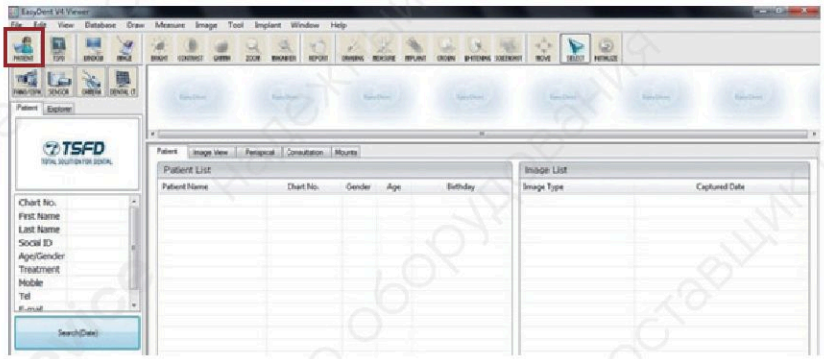
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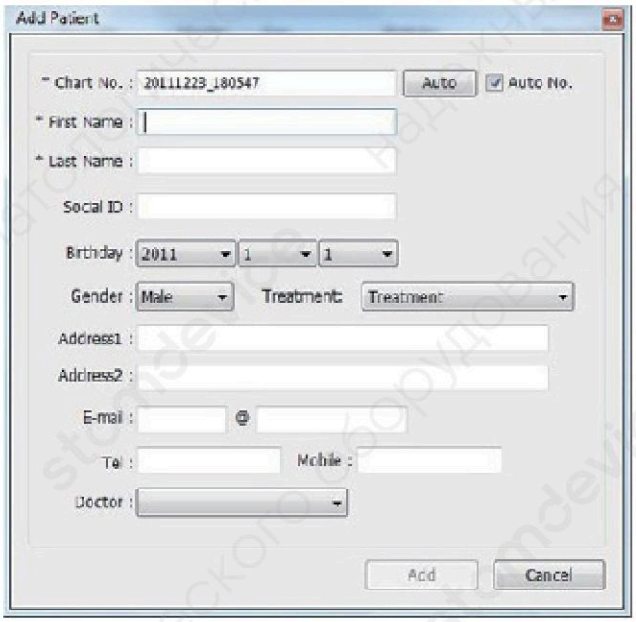
5.2.1 Creating a New Patient Record

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

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



B. The following dialog box will open.



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

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

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5.2.2 Retrieving Patient Records

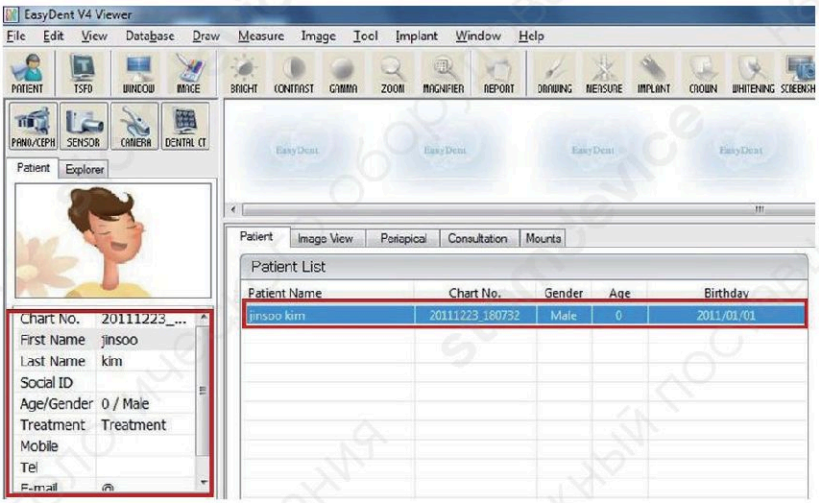
You can search through the patient database using a patient's chart number, their first name, or their last name.

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**.

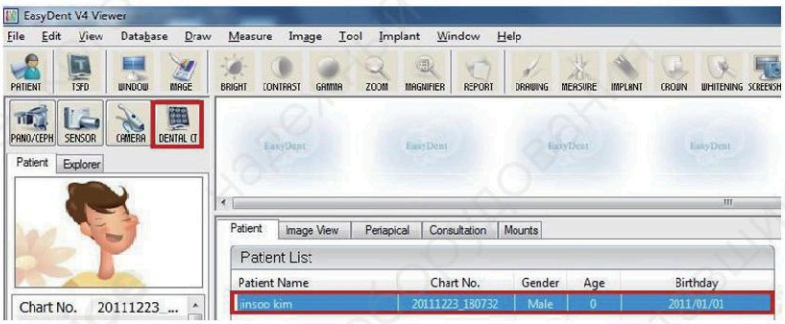


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5.3 Initiating the Imaging Program

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



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



Please proceed to the next chapter.

NOTE

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

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6

Acquiring PANO Images

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6 Acquiring PANO Images

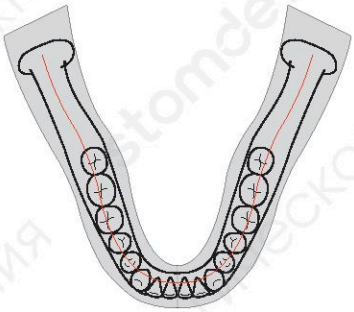
This chapter requires the preparatory steps in **Chapter 5** to have already been completed. If you have not completed these steps, please return to **Chapter 5** and complete the process outlined there before proceeding with this chapter.

6.1 PANO Imaging Program

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

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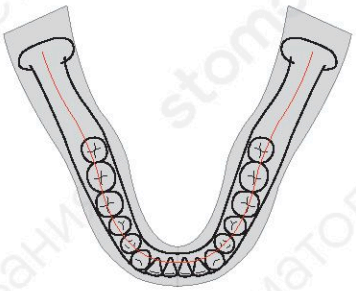
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① Narrow_Standard

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

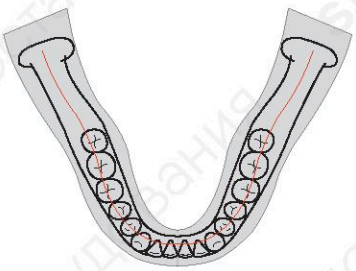




② Normal_Standard

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





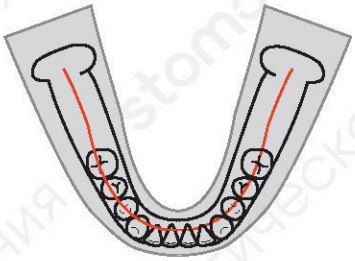
③ Wide_Standard

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



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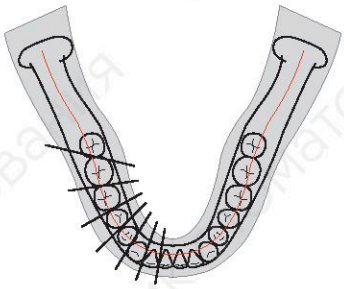
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④ Child_Standard

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





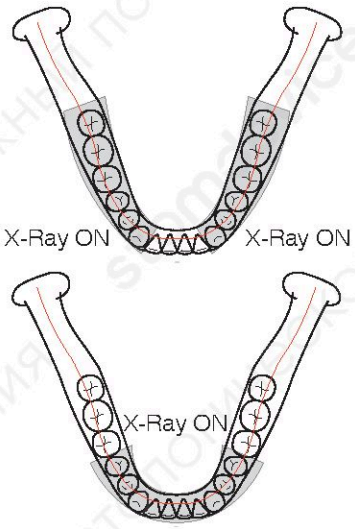
⑤ Orthogonal_Standard

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



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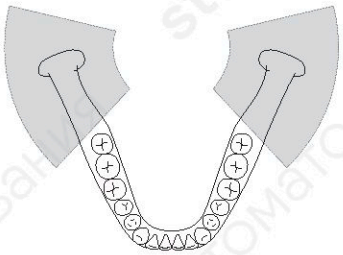
⑥ Orthogonal_Bitewing

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 Normal mode. **Cons**: TMJ and parts of an image of the maxillary sinus are not acquired.



⑦ TMJ LAT Open / Close

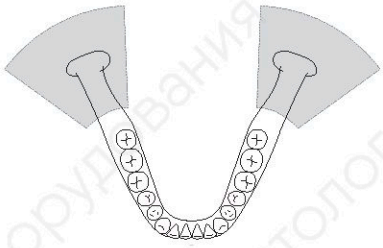
An imaging mode to acquire a lateral image of the TMJ, in which the X-Ray beam is directed on the lateral TMJ region: TMJ (Open and Close).





⑧ TMJ PA Open / Close

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).



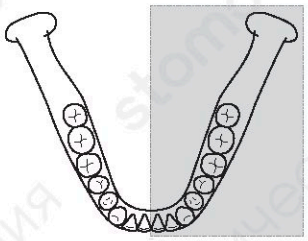


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⑨ Sinus LAT

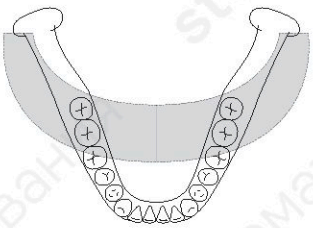
A special imaging mode to acquire a Sinus image, in which X-Ray beam is directed on the lateral region of the maxillary sinus.

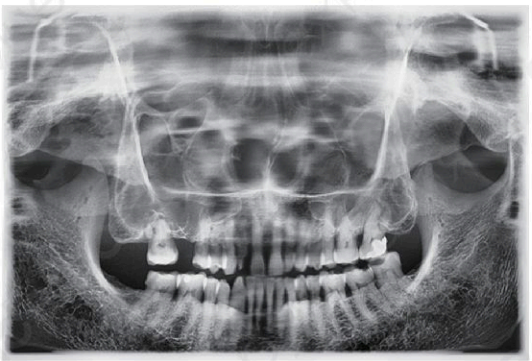




⑩ Sinus PA

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



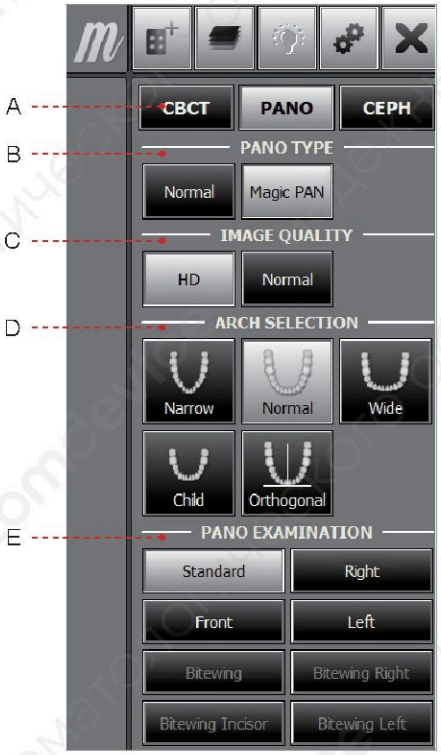


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6.2 Setting Exposure Parameters

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 Mode**.



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

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

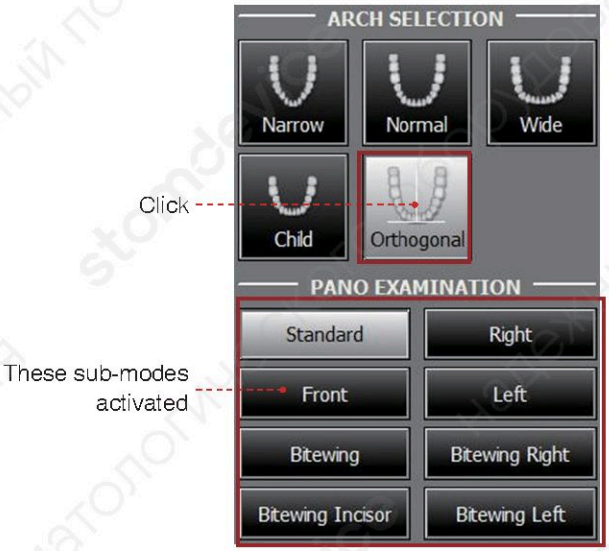
Mode	Details	
Normal	Normal image.	
Magic PAN	Image with ultra-high resolution	optional

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	

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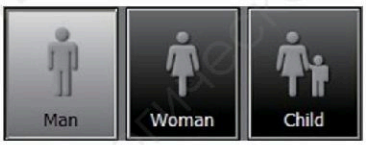
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D. Select the patient's arch type under **Arch Selection**. By default, **Normal** is selected.

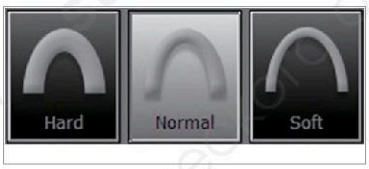
Orthogonal: This mode enables overlapping regions of teeth to be minimized when acquiring images in the ROI. If **orthogonal** arch is selected, its sub-modes are activated.

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. Nevertheless, ensure that this information is correct.

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



G. Select X-ray intensity.

NOTE

X-ray intensity (Hard, Normal, Soft) is according to the operator's decision.

Soft≤Normal≤Hard

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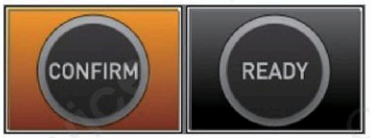
H. A default value for the tube voltage (kVp) and current (mA) will be displayed based on the gender and X-ray intensity.

If necessary, further adjustments can be made using the arrows to the right of each number.

NOTE

Adjustable resolution:

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



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

NOTE

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

When you click the **Confirm** button,

- The **Ready** button will begin blinking to show that it has been activated.
- The rotating unit will move to its initial scanning position.
- The chin support will adjust itself according to the mode selected.
- 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.

NOTE

The laser beam On / Off button ( ) is located in the upper right side of the window.



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

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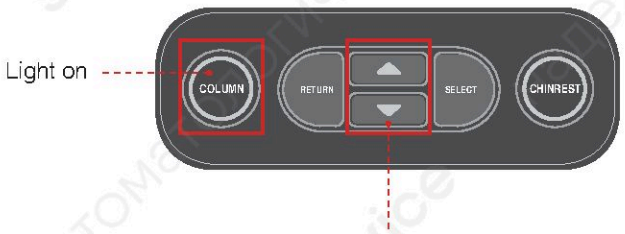
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J. Guide the patient to the equipment. Position the patient within the equipment. For further information about patient positioning, refer to section **6.3 Positioning the Patient**.

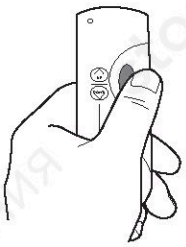
6.3 Positioning the Patient

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 (optional).



Up / Down buttons



Column Up / Down switch (optional)

NOTE

The SELECT button is disabled in PANO and CEPH modes.

NOTE

In general, imaging is performed with the patient in an upright position.

However, a stool may be used for imaging patients with special circumstances. If a stool is used, ensure that the beams and movement of unit are not obstructed by the stool

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NOTE

Correct positioning is an important factor in capturing the best possible image. Proper positioning will reduce the appearance of the cervical spine in the image.

WARNING

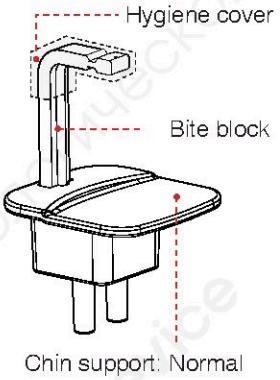
Be careful not to project the laser beams directly into the patient's eyes as this could severely damage the patient's vision.

6.3.1 PANO Standard

Positioning the patient

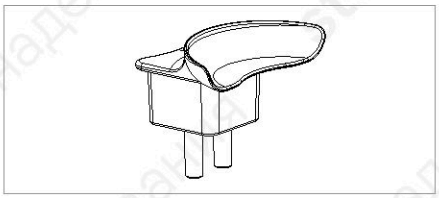
PANO Standard_ENG

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



A. Insert the normal chin support and bite block into the chin support receptacle on the equipment.

B. Place a hygienic cover over the bite block.



* For patients who lack teeth, use the edentulous chin support. Refer to section **3.3.3 Components and Positioning Accessories**.

WARNING

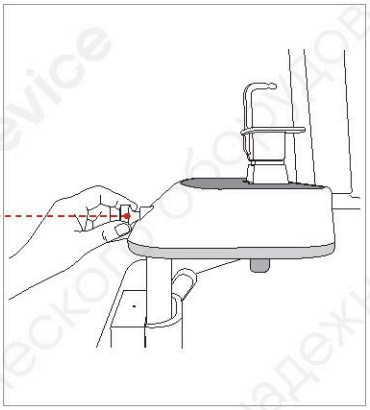
The hygiene cover for the bite block is intended for single use only. Always replace the hygiene cover for each new patient.

CAUTION

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

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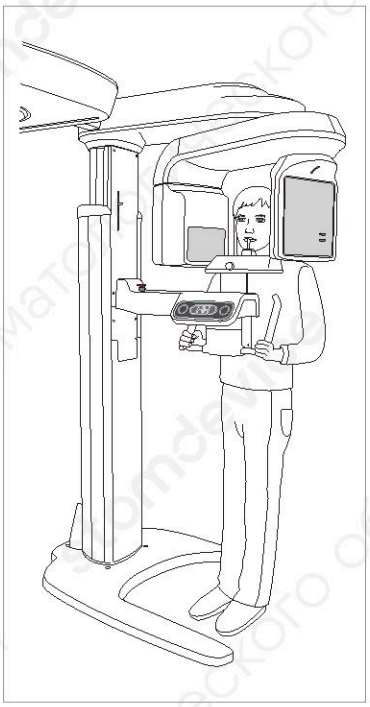
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C. Loosen the Temple Supports by turning the Temple Support Wheel.

D. Guide the patient — facing the chin support — to the equipment.

E. Adjust the height of the column using the column up / down button until the patient's chin rests comfortably on the chin support.



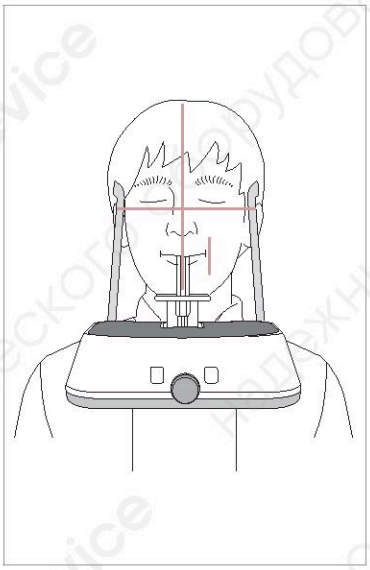
F. Ask the patient to:

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

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

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H. Have the patient bite the bite block along its grooves using his/her upper and lower incisors (for edentulous patients, use the edentulous chin support).

I. Have the patient

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

Ask the patient to remain still until scanning is completed.

CAUTION

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

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

Aligning the Laser Beams

NOTE

Clicking on the Confirm button after setting the parameters for imaging will activate the three laser beams (Mid-sagittal plane, Frankfurt plane and Canine) to facilitate patient alignment. The beams will disappear after 20 minutes or if the 'Ready' button is clicked.

To turn the laser beams On or Off, click the icon on the imaging GUI.

WARNING

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

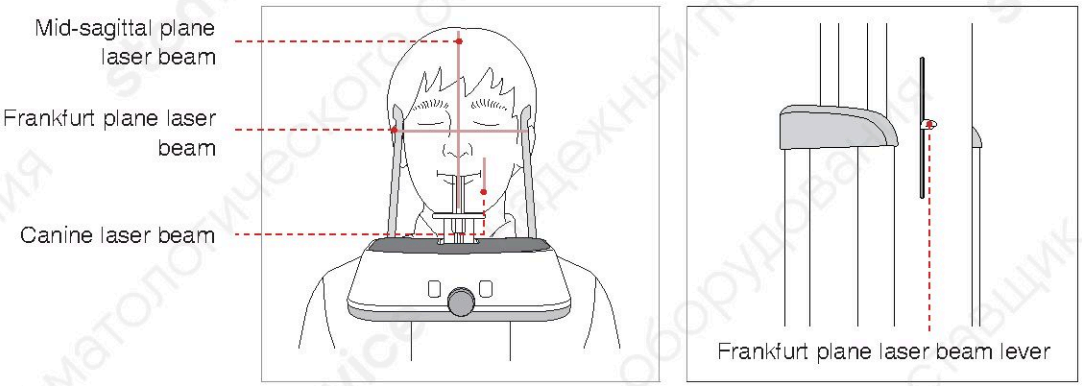
A. **Mid-sagittal plane laser beam**: Position the Mid-sagittal plane laser beam on the center of the patient's face to prevent magnifications of the left or right side in the final image.

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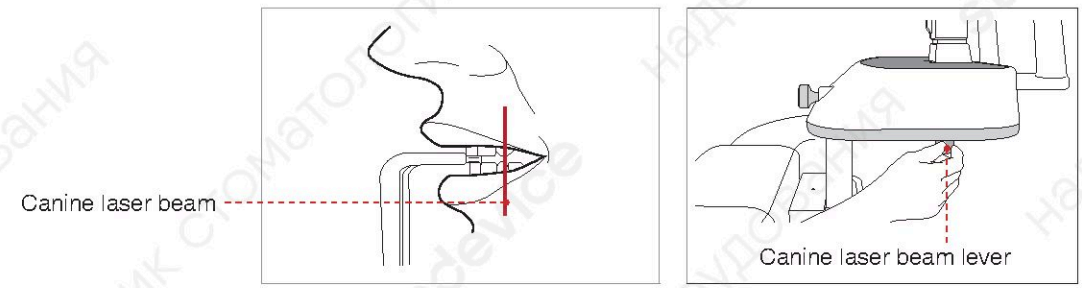
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B. **Frankfurt plane laser beam**: Position the patient's head so that the Frankfurt plane is aligned with the Frankfurt plane laser beam.

** 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. Rotate the thumb wheel, located under the patient support rest, forward or backward to properly align the beam.



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 wheel. The temple support wheel is located at the front of the patient support rest.



B. Click the **Ready** button on the GUI after the patient has been properly positioned. No X-Ray will be emitted at this point. The rotating unit will then move into position for imaging.

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

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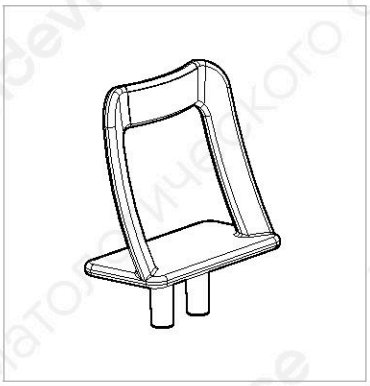
6.3.2 TMJ Open

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

IMPORTANT

- **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.**

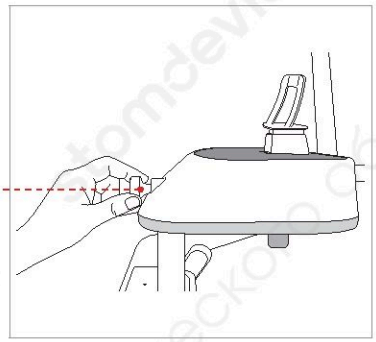
Positioning the patient



A. Insert the TMJ chin support.

CAUTION

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



B. Loosen the **Temple Supports** by turning the **Temple Support Wheel** at the rare of the patient support table.

C. Guide the patient —facing the chin support — to the equipment.

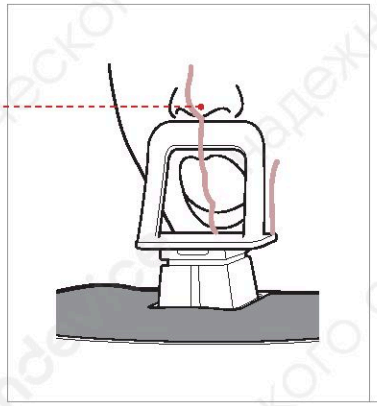
D. Adjust the height of the equipment using the column up/down button until the patient's chin is resting on the chin support. Ensure that the chin is in contact with the chin support.

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E. Ask the patient to:

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



F. 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.

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

The top of the TMJ support and the patient's acanthion point must remain in contact at all times during exposure.

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. Ask the patient to remain still until scanning is complete.

CAUTION

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

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

Aligning the Laser Beams

NOTE

Clicking on the Confirm button after setting the parameters for imaging will activate the three laser beams (Mid-sagittal plane, Frankfurt plane and Canine) to facilitate patient alignment. The beams will disappear after 20 minutes or if the 'Ready' button is clicked.

To turn the laser beams On or Off, click the icon on the imaging GUI.

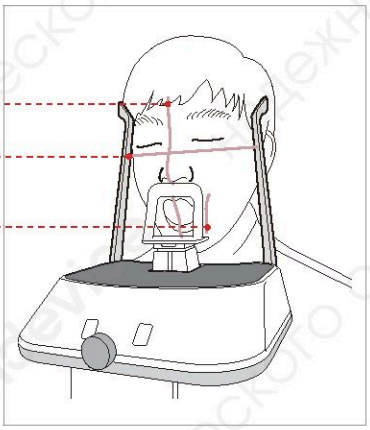
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WARNING

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.

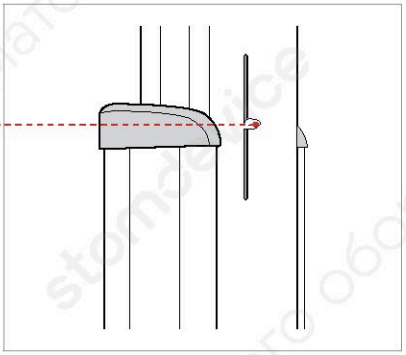


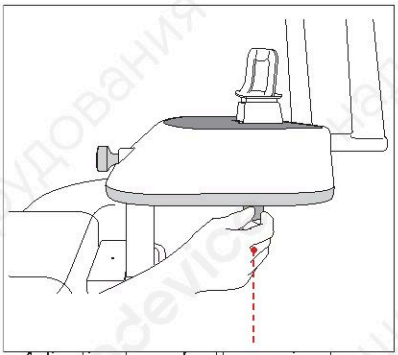
B. **Frankfurt plane laser beam**: Position the patient's head so that the Frankfurt plane is aligned with the Frankfurt plane laser beam.

For proper positioning, adjust the way in which the patient's head is tilted by adjusting the height of the column using the column up / down switch.

** 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**: Position the canine laser beam to the left corner of the patient's lips. Rotate the thumb wheel, located under the patient support rest, forward or backward to properly align the laser.




Adjusting lever for the canine laser

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 wheel. The temple support wheel is located at the front of the patient support rest.

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B. Click the **Ready** button on the GUI after the patient has been properly positioned. No X-Ray will be emitted at this point. The rotating unit will then move into position for imaging.

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

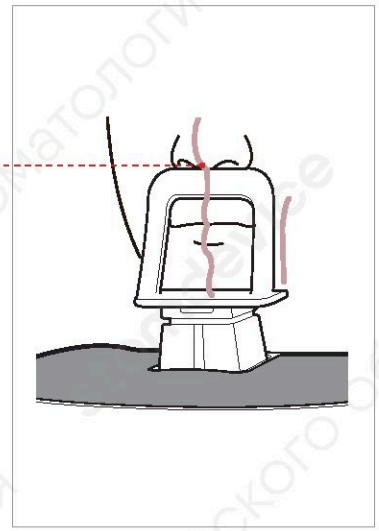
6.3.3 TMJ Close

NOTE

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

The positions are the same for both modes, except for the position of the lips.

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



B. 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 TMJ support must remain in contact with the patient's acanthion point during exposure.

Ask the patient to remain still until scanning is complete.

C. The laser beams should be aligned in the same way as for **TMJ Open** imaging.

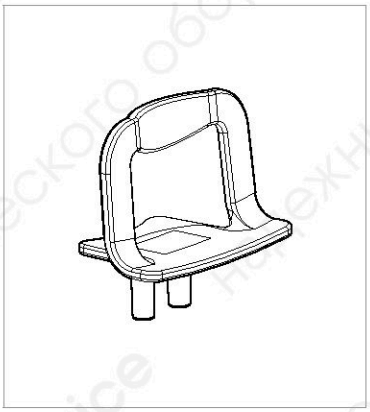
D. Proceed to section **6.4 Initiating X-Ray Exposure**.

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6.3.4 Sinus

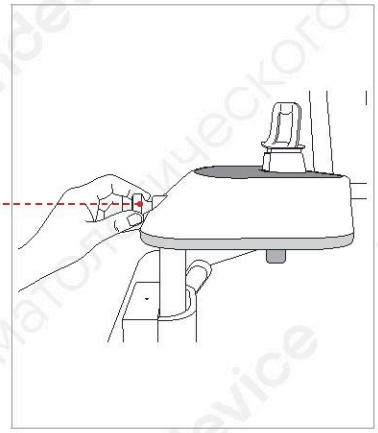
Positioning the Patient



A. Insert the chin support (Sinus) into the receptacle on the equipment.

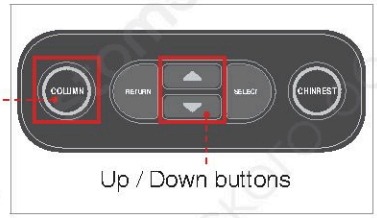
CAUTION

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



B. Loosen the **Temple Supports** by turning the **Temple Support Wheel** at the rear of the patient support table.

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



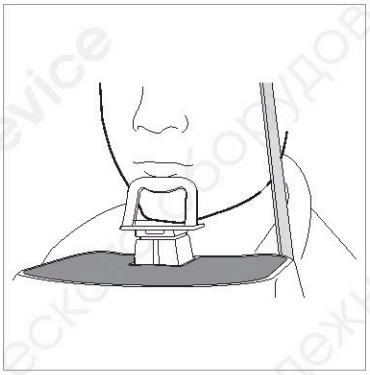
D. Adjust the height of the equipment using the column up / down button until the patient's chin rests comfortably on the chin support.

E. Ask the patient to:

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

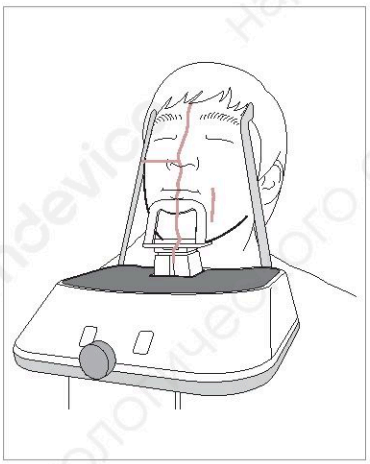
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F. Ask the patient to press his/her lips against the chin support.

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



H. Have the patient:

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

Ask the patient to remain still until scanning is completed.

CAUTION

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

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

Aligning the Laser Beams

NOTE

Clicking on the Confirm button after setting the parameters for imaging will activate the three laser beams (Mid-sagittal plane, Frankfurt plane and Canine) to facilitate patient alignment.

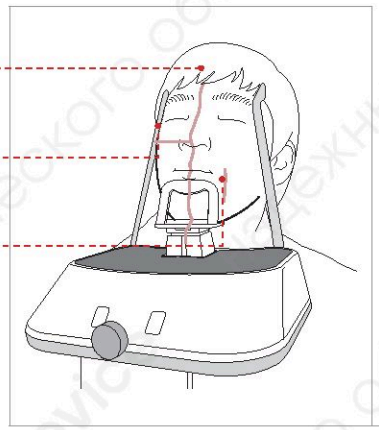
The beams will disappear after 20 minutes or if the Ready button is clicked. To turn the laser beams On or Off, click the icon on the imaging GUI.

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WARNING

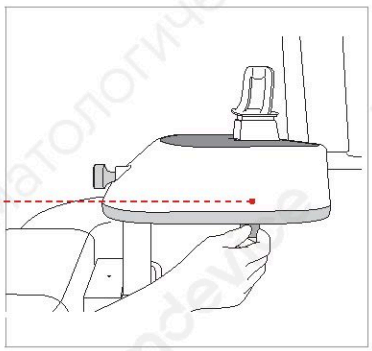
Be careful not to project the laser beams directly into the patient's eyes as this could severely damage the patient's vision.



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

B. **Frankfurt plane laser beam**: The Frankfurt plane laser beam should go from the top of the ear to the tip of the nose when the patient's head is tilted back 10 – 15 °.

You may adjust the Frankfurt plane laser beam by manually adjusting the Frankfurt plane laser beam lever.



C. **Canine laser beam**: Have the patient smile to properly position the canine laser beam on the center of the patient's canine tooth.

Rotate the thumb wheel, located under the patient support rest, forward or backward to properly align the beam.

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 wheel. The temple support wheel is located at the front of the patient support rest.



B. Click the **Ready** button on the PC after the patient has been properly positioned. At this point, X-Ray will not be emitted. The rotating unit will move to position for imaging.

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

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6.4 Initiating X-Ray Exposure

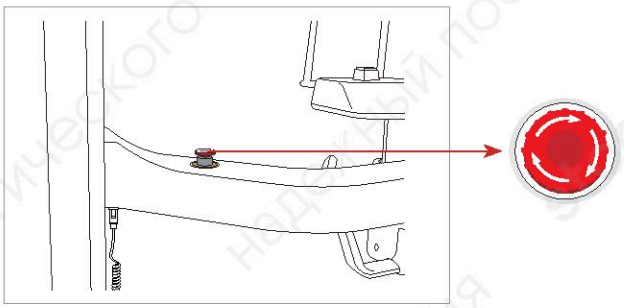
The X-Ray exposure method and its sequences are the same for PANO Standard and PANO Special modes. The example used in this manual is the PANO Standard mode.

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

WARNING

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

To reset this switch, turn it clockwise until it pops up.



WARNING

- **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.**

CAUTION

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

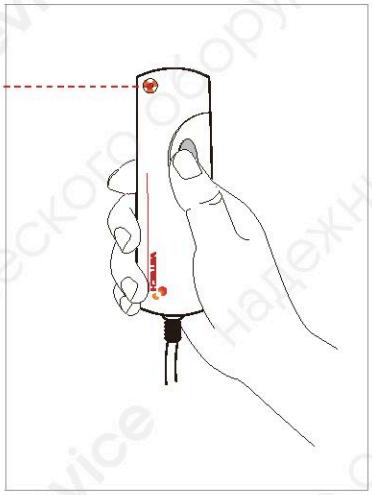
A. Leave the X-Ray room and close the door. The operator must visually monitor the patient at all times during image acquisition.

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

Exposure indicator light turns orange
Orange: Exposure



X-Ray ON

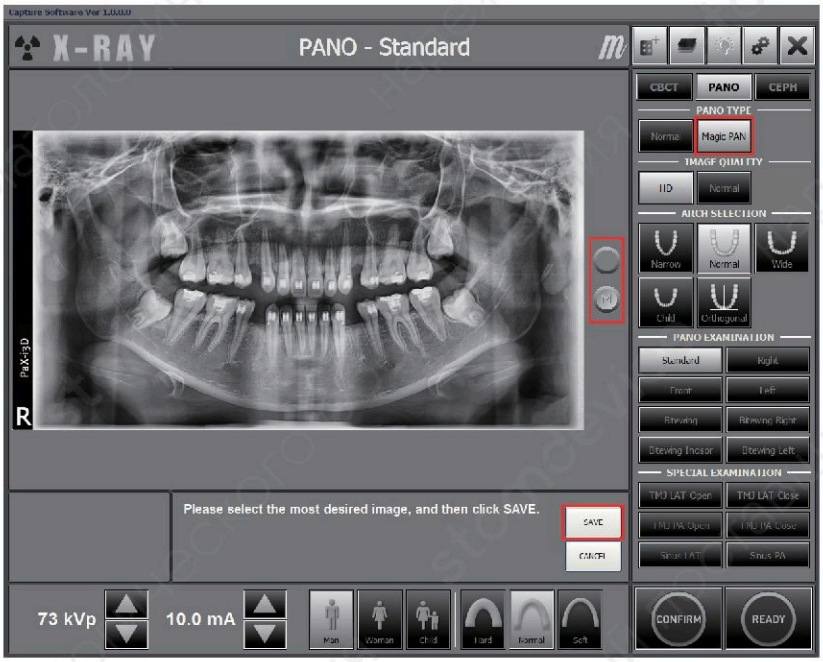


During X-Ray irradiation, ensure that

- 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 announcement mode of either beep or music is initiated, depending on the set-up.
- 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.

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The buttons:

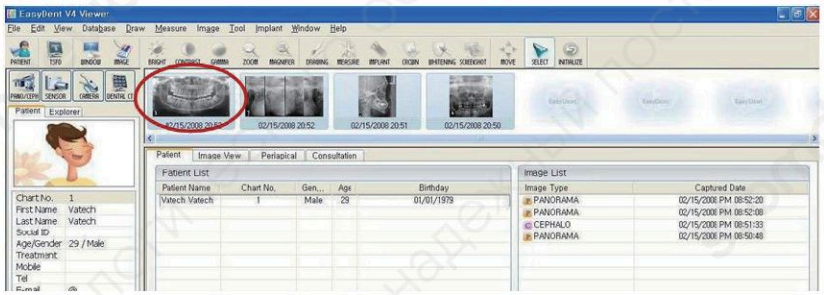

Normal


Magic PAN

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

E. The captured image will be automatically transferred to EasyDent. Clicking the patient's name in the patient list after imaging will refresh the image list for that patient. The patient's most recent image will appear on the far left of the image window, as shown below.

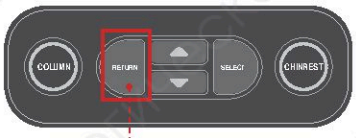
Double-click an image to enlarge it for viewing or to check the quality of the image.



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).
- Press **RETURN** to bring the Rotating Unit back to its initial position.



RETURN button

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Acquiring CEPH Images

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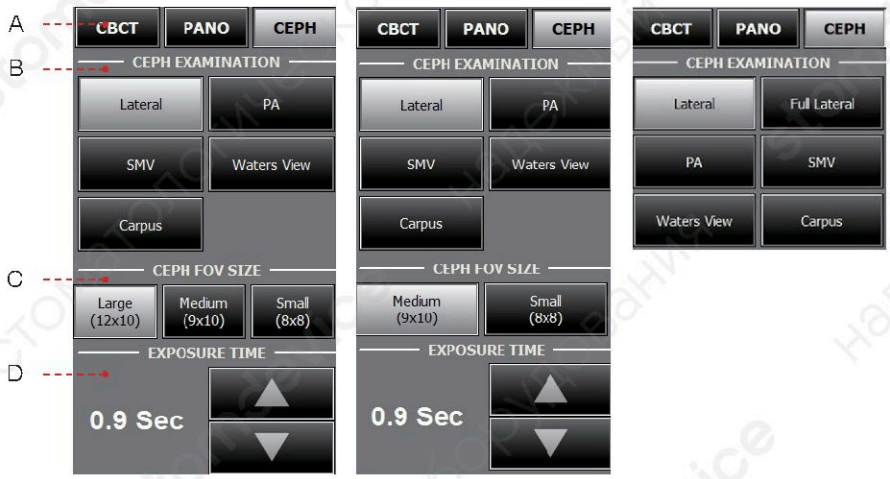
7 Acquiring CEPH Images

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

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 Mode**).

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



1210 SGA (one shot type sensor) | **0910 SGA (one shot type sensor)** | **Xmaru2301CF (scan type sensor)**

NOTE

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

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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.

Model: OP / OS (one shot type sensor)

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

D. **Exposure time**

One shot type sensor (optional)

Examination Modes	Scan Time (s) - Default
Lateral	0.9
PA / SMV / Waters View / Carpus	1.2

NOTE

Exposure time can be adjusted by resolution of 0.1 s in the range of 0.7 s to 1.2 s.

Scan type sensor (optional)

Examination Modes	Scan Time (s) - Default
Lateral / / PA / SMV / Waters View / Carpus	12.9
Full Lateral	16.9

NOTE

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

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

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

NOTE

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 X-ray intensity.

NOTE

X-ray intensity (Hard, Normal, Soft) is according to the operator's decision.

Soft≤Normal≤Hard

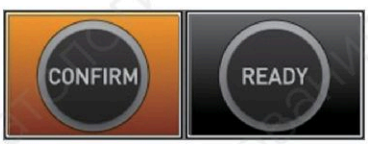


G. Default values for the tube voltage (kVp) and current (mA) will be displayed based on the patient's gender and X-ray intensity. If necessary, you may manually adjust these values using the arrows to the right of each value.

NOTE

Adjustable resolution:

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



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

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When you click **Confirm** button:

- The **Ready** button will begin blinking to show that it is activate. This means that the equipment is ready for X-Ray exposure.
- The CEPH sensor and the 2nd collimator enter positioning mode.



- 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. Position the patient. Refer to section **7.2 Positioning the Patient**.

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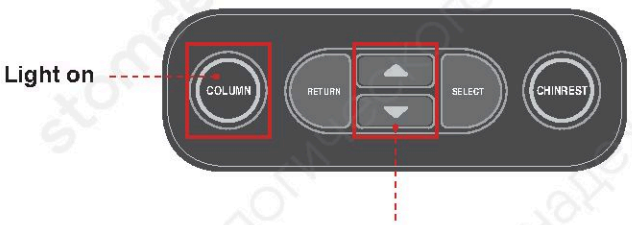
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7.2 Positioning the Patient

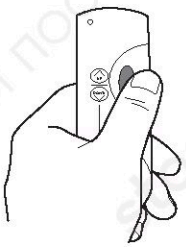
Follow the procedure below to prepare and position the patient for CEPH imaging.

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 that could impede 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).



Up / Down buttons



Column Up / Down switch (optional)

NOTE	**The SELECT button is disabled in PANO and CEPH modes.**
NOTE	**Correct positioning is an important factor in capturing the best possible image.**
CAUTION	**Ensure that the nasal positioner left unfolded, before adjusting the ear rods in the proper direction.**
WARNING	**Ensure that the patient is clear of all moving parts while adjusting the height of the equipment.**

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7.2.1 Lateral (Full Lateral)

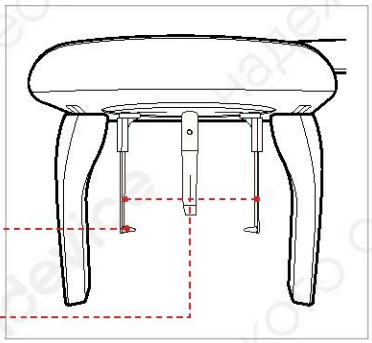
CEPH Lateral_ENG

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

NOTE

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

Follow the procedure below to position the patient.

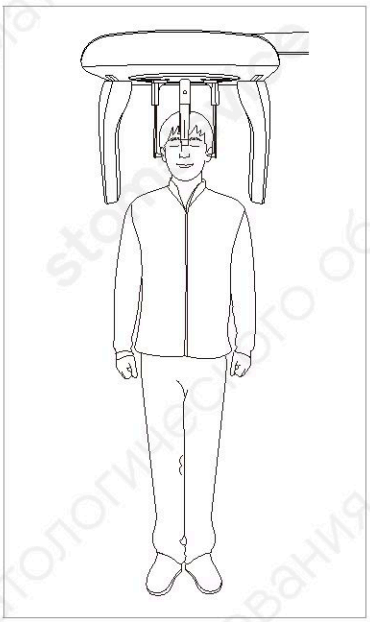


A. Widen the distance between the two ear rods.

NOTE

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

B. Guide the patient to the CEPH unit.



C. Ask the patient to stand upright.

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

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

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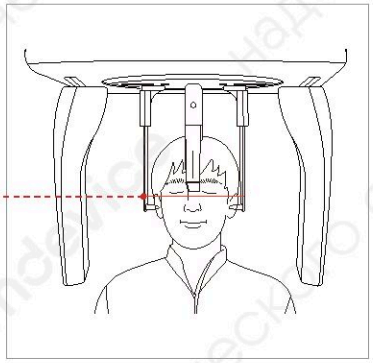
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CAUTION

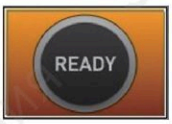
After adjusting the height of the column to suit the patient, fit the ear rods along the patient's ear canals and adjust the nasal positioner.

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

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



G. Ask the patient to swallow saliva 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. The CEPH sensor and the 2nd collimator will enter positioning mode.

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

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7.2.2 Frontal (PA)

Follow the procedure below to correctly position the patient.

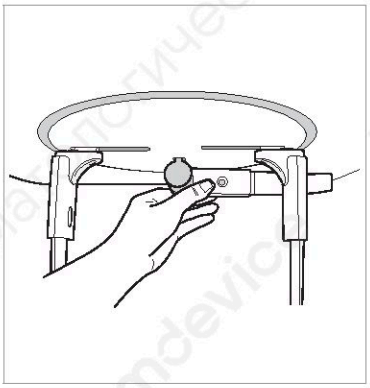


A. Turn the ear rods 90° clockwise from their initial position as shown in the illustration.

B. Widen the distance between the two ear rods.

NOTE

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

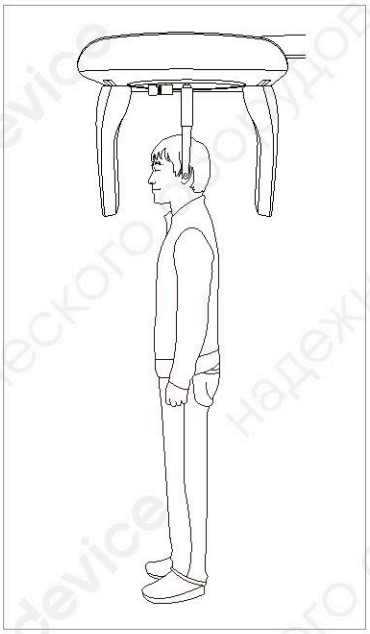


C. The nasal positioner should be flipped to the side and upward to prevent it from obstructing the image acquisition.

D. Guide the patient to the CEPH unit.

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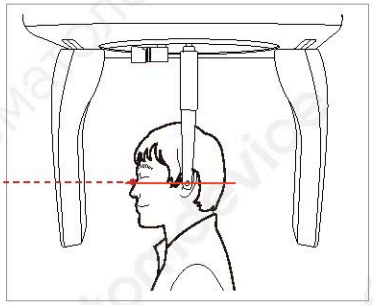
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E. Adjust the height of the unit to suit the patient by pressing the column up / down button or switch (optional).

CAUTION

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



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

G. Ask the patient to swallow saliva and remain still with his/her mouth closed until X-Ray exposure is complete.



H. Click the **Ready** button after the patient has been positioned.

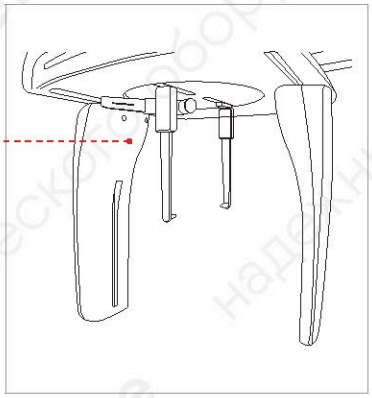
I. Proceed to section **7.3 Initiating X-Ray Exposure**.

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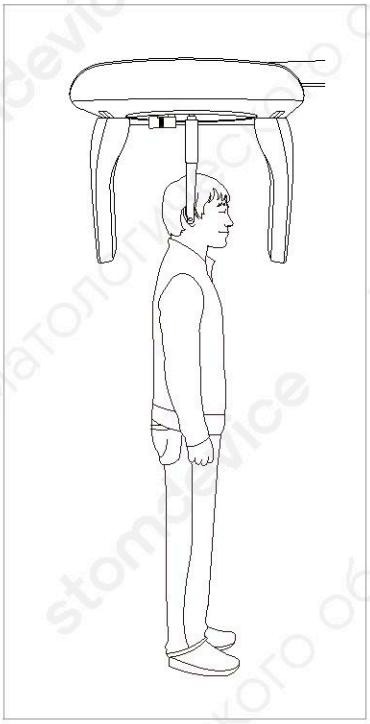
7.2.3 SMV

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

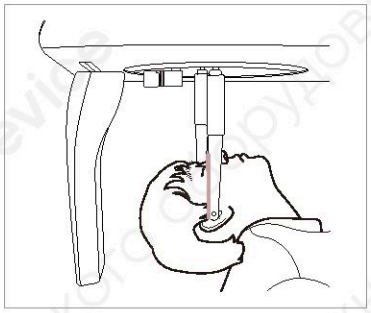
CAUTION

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

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

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

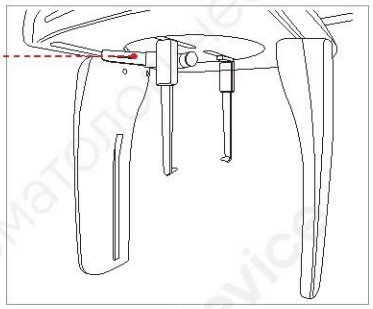


G. Click the **Ready** button after the patient has been properly positioned. No X-Ray will be emitted at this point. The CEPH sensor and the 2nd collimator will enter positioning mode.

H 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).

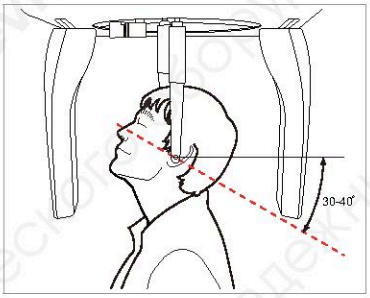
CAUTION

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

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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 saliva and tilt his/her neck back 35° - 40°, with the mouth closed, until X-Ray exposure is complete.

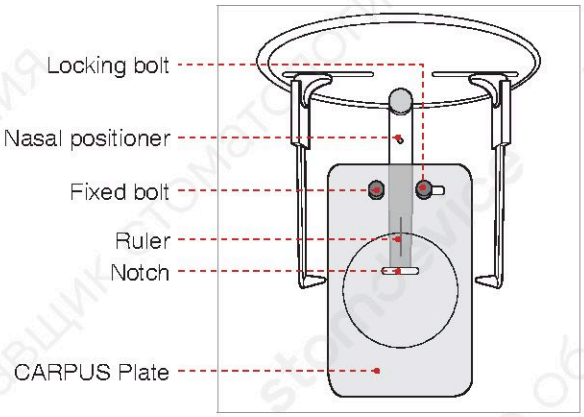


H. Click the **Ready** button after the patient has been properly positioned. No X-Ray will be emitted at this point. The CEPH sensor and the 2nd collimator will enter positioning mode.

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.

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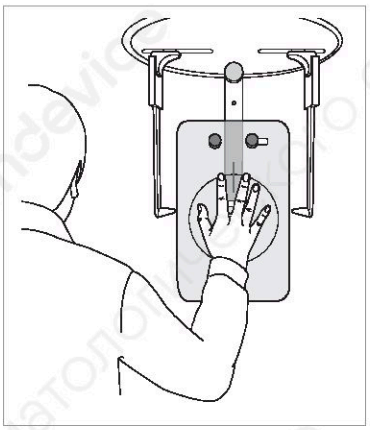


B. Slide the CARPUS plate onto the nasal positioner.

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.

CAUTION

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**.

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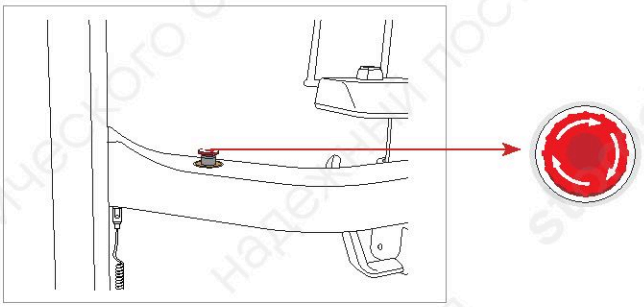
7.3 Initiating X-Ray Exposure

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.

WARNING

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

To reset the emergency switch, turn it clockwise until it pops up.



WARNING

- **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.**

CAUTION

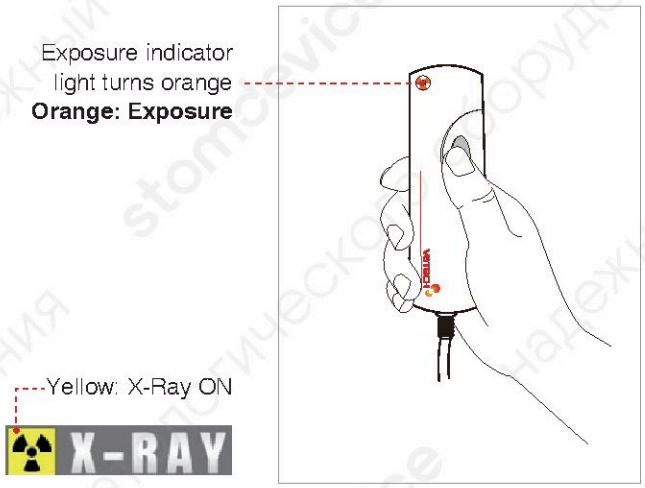
If an emergency occurs during image acquisition, release the exposure switch to cease X-Ray emission.

A. Leave the X-Ray room and close the door. The operator must maintain visual contact with the patient at all times during image acquisition.

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



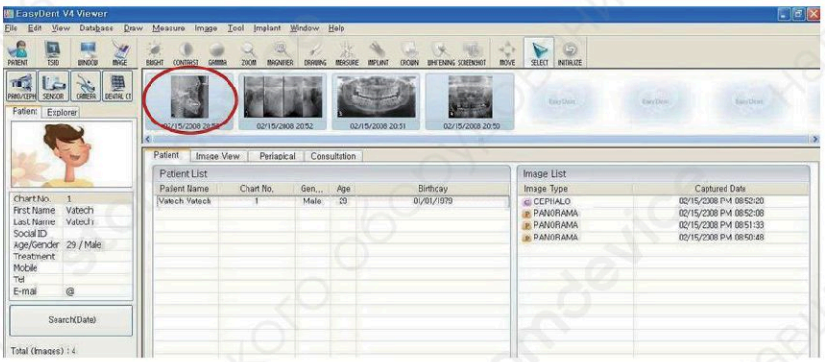
During X-Ray irradiation, ensure that:

- 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 announcement mode of either beep or music is initiated, depending on the set-up.
- 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.

D. The captured image will be automatically transferred to **EasyDent**. Clicking the patient's name in the patient list after imaging will refresh the image list for that patient. The patient's most recent image will appear on the far left of the thumbnail image pane.



E. Double-click on the image to enlarge it for viewing or to check its quality.

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Sample images: with one shot type sensor

PA: Posterior – Anterior



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



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

Lateral



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



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



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



Carpus

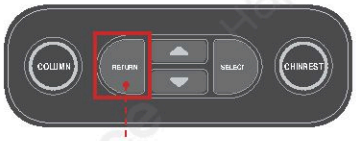
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After Image Acquisition

After acquiring the image, complete the following steps:

- Fold away the nasal positioner.
- Loosen the ear rod supports and remove them from the patient's ears.
- Release the patient.
- Press **RETURN** to bring the Rotating Unit back to its initial position.



RETURN button

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8

Acquiring CT Images

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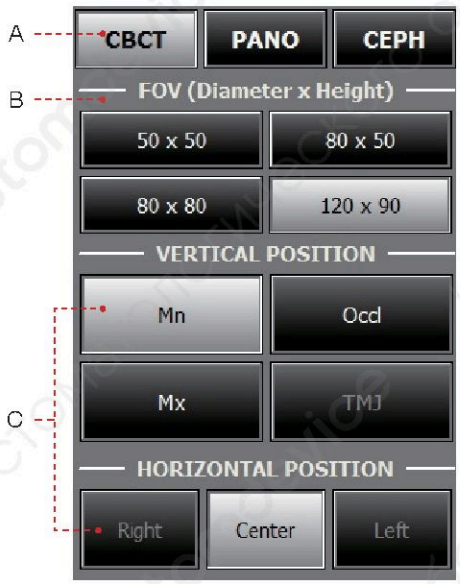
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8 Acquiring CT Images

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

8.1 Setting the Exposure Parameters

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 Mode**).



Xmaru1215CF Plus sensor



Xmaru0712CF sensor

NOTE

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

A. Click the **CBCT** button. The rotating unit will move to position for CT scanning.

B. Select the FOV size for the CT.

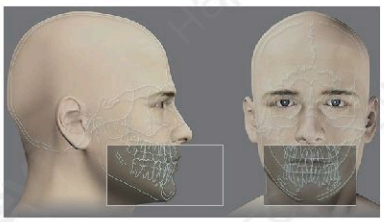
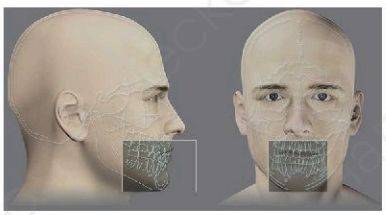
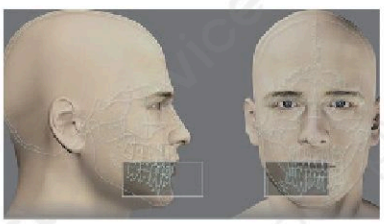
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C. Select the ROI to be captured under VERTICAL POSITION and HORIZONTAL POSITION.

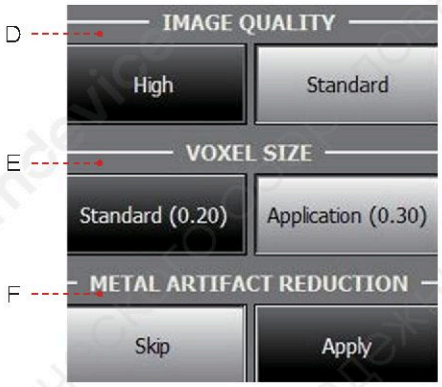
Once you have selected an FOV size and ROI (Region of Interest) to capture, the area of the selected FOV and position of ROI will be viewed on the guidance image as shown below. For the FOV 50 X 50, you may select a specific tooth position to be captured on the full arch guidance image.

The following shows a few examples about guidance image.

Mode	FOV (mm)	ROI
	120 X 90	Mn - Center
	80 X 80	Mn - Center
	80 X 50	Mn - Right
	50 X 50	Mn / Left Central Incisor

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D. Select the image acquisition speed under High (24 s) or Standard (15 s).

NOTE

High: Higher quality image acquisition mode than Standard mode.

E. Select either **Standard** or **Application** mode for the voxel resolution.

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

NOTE

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



G. Gender selection will be made automatically according to the patient information registered in EasyDent. Nevertheless, ensure that this information is correct.

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

H. Select the patient's bone density type.

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NOTE

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

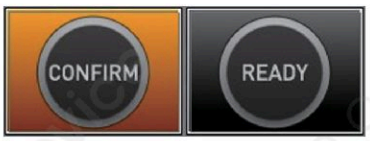
Soft≤Normal≤Hard

I. 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.

NOTE

Adjustable resolution:

- **Tube voltage: ± 1 kVp**
- **Tube current: ± 0.1 mA**

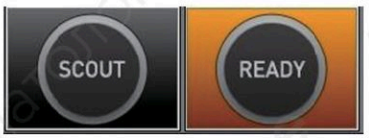


J. Click **Confirm** to accept these parameters.

NOTE

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

When you click **Confirm** button:



- The **Confirm** button turns to the **SCOUT** and then the **Ready** button is enabled and flashes

This means that the equipment is ready for X-Ray exposure.

NOTE

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

In case of abnormal patient's arch, the chinrest height adjustment through the SCOUT feature enables the user to acquire better image. When the SCOUT image needs to be acquired, position the patient first, followed by clicking the SCOUT button.

For details about imaging in the SCOUT mode, refer to the section 8.3 Acquiring a Scout image.

- The Rotating unit will move to its initial scanning position.
- The chin support will adjust itself according to the mode selected.

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- 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.

NOTE

The laser beams On / Off button are on the upper right of the GUI:



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

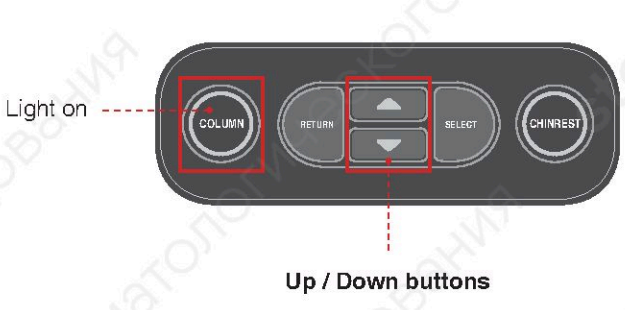
K. Guide the patient to the equipment. Position the patient. Refer to section **8.2 Positioning the Patient**.

8.2 Positioning the Patient

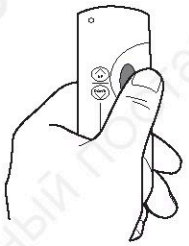
Follow the procedure outlined below to properly position the patient for CT scanning.

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).



Up / Down buttons



Column Up / Down switch (optional)

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NOTE

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

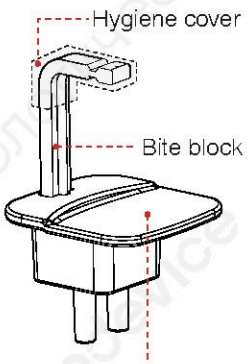
NOTE

Correct positioning is an important factor in capturing the best possible image. Proper positioning will reduce the appearance of the cervical spine in the image.

WARNING

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

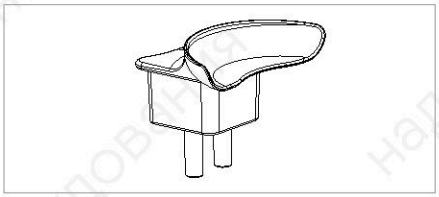
Positioning the Patient



Chin support: Normal

A. Insert the normal chin support and bite block into the chin support receptacle on the equipment.

B. Place a hygienic cover over the bite block.



* For patients who lack teeth, use the edentulous chin support. Refer to section **3.3.3 Components and Positioning Accessories.**

WARNING

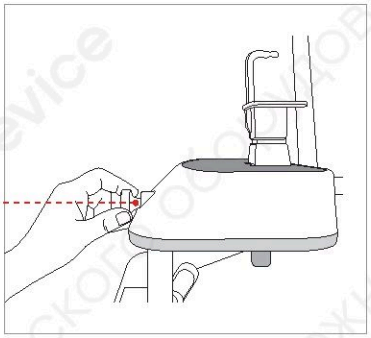
The hygiene cover for the bite block is intended for single use only. Always replace the hygiene cover for each new patient.

CAUTION

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

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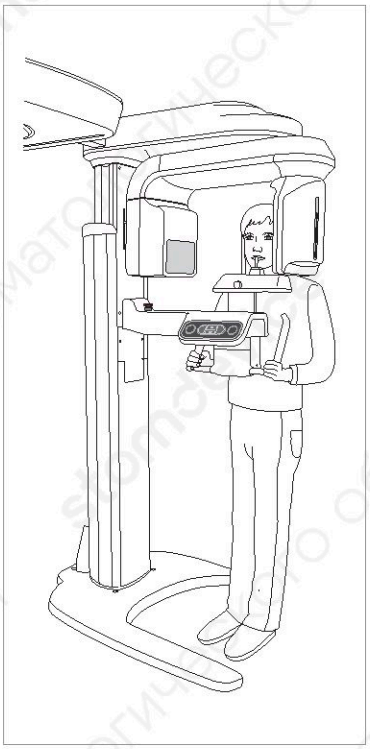
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C. Loosen the temple supports by turning the Temple Support Wheel at the rear of the patient support table.

D. Guide the patient —facing the chin support — 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.



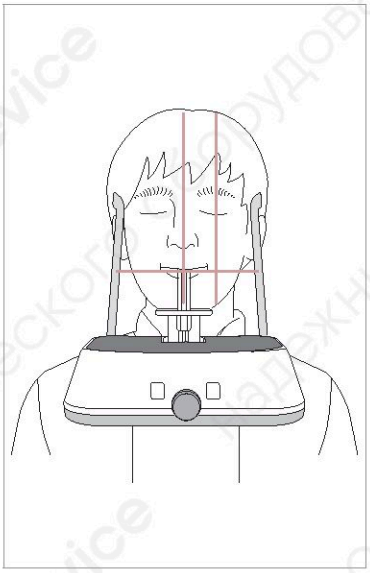
F. Ask the patient to:

- 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.

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G. Have the patient:

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

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

Ask the patient to remain still until scanning is complete.

NOTE

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

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

Aligning the Laser Beams

NOTE

Three laser beams - 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.

To turn the laser beams on or off, click the icon on the imaging GUI.

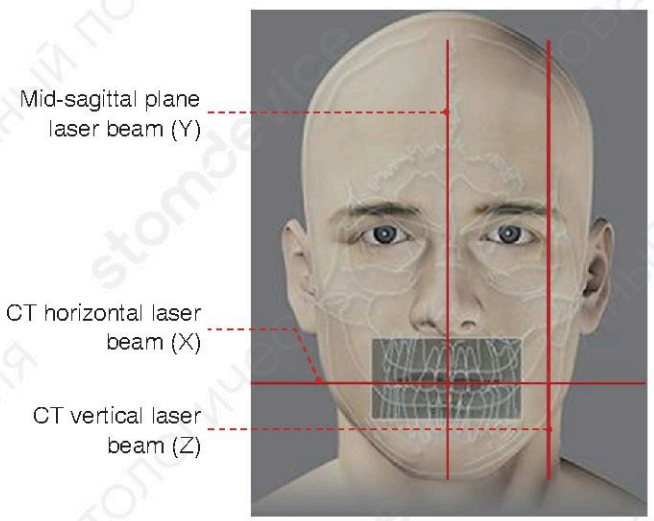
WARNING

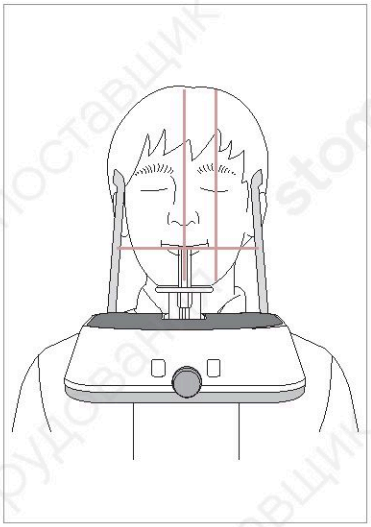
Be careful not to project the laser beams directly into the patient's eyes as this could severely damage the patient's vision.

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

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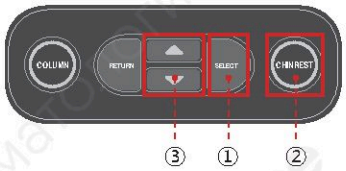
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(FOV 80 X 50)

A. **CT horizontal laser beam (X):** Position the CT horizontal laser beam at the center of the FOV area. If necessary, the CT horizontal laser beam can be manually adjusted by pressing the Chinrest up / down button to make fine adjustments (①→ ②→ ③).



1. Touch the SELECT button to switch the mode (COLUMN → CHINREST).

2. Ensure that the CHINREST LED light is On.

3. Touch the Up / Down buttons.

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

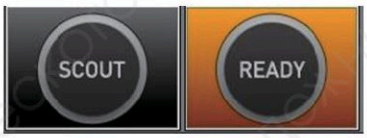
C. **CT vertical laser beam (Z)**: Position the CT vertical laser beam at the center of FOV from the patient's lateral.

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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 wheel. The temple support wheel is located at the front of the patient support rest.



B. Click the **Ready** button on the GUI after the patient has been properly positioned. No X-Ray will be emitted at this point. The rotating unit will then move to position for imaging.

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

NOTE

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

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

C. Proceed to section **8.4 Initiating X-Ray Exposure**.

But if the **SCOUT** feature is selected, move to the following **section 8.3 Acquiring a SCOUT image**, and then 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.

NOTE

The SCOUT feature is incorporated in the CT imaging mode with the FOV 80 x 50 and 50 X 50.

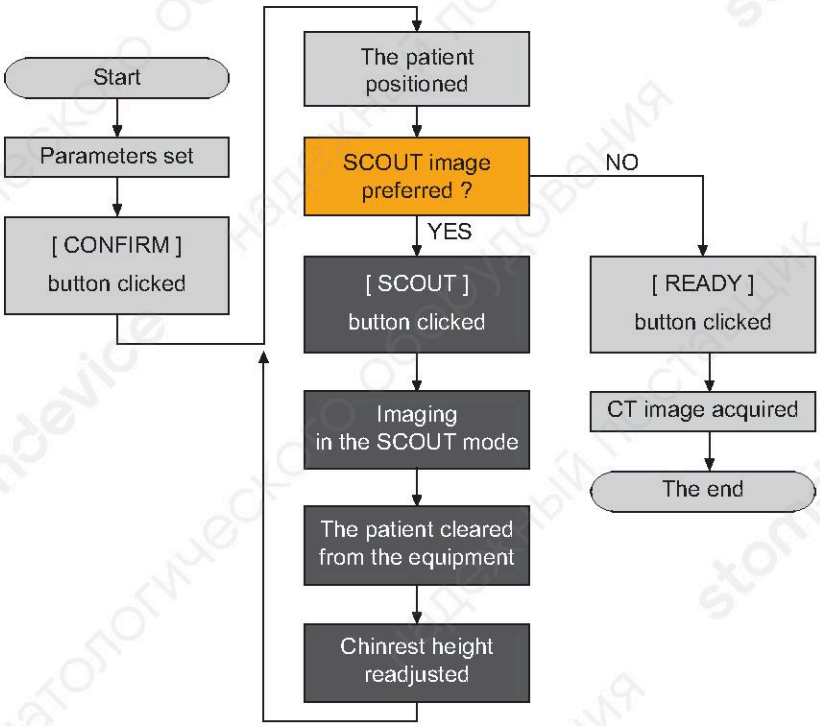
The procedures for the SCOUT image acquisition are the same for both FOVs.

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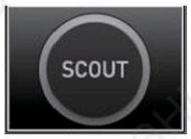
8.3.1 Starting imaging with the SCOUT feature

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.

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WARNING

Always perform the chinrest coordinate adjustment after the patient is cleared from the equipment.

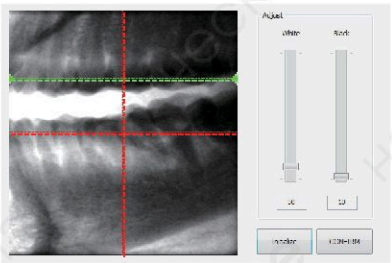
Failure to do so could result in the physical injury, due to the vertical movement of chinrest to new position reflected after the 'CONFIRM' button on the SCOUT Viewer is clicked.

D. Once the imaging has been completed, the resulting image with the SCOUT feature appears.

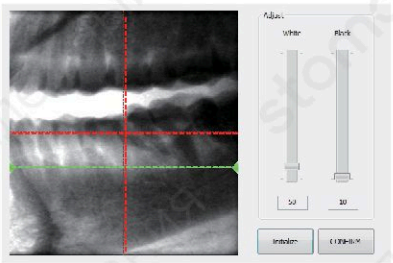
NOTE

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

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 (Ex: 50 x 50).



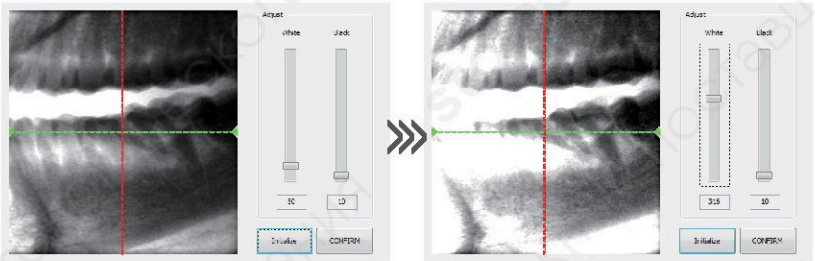
[Maxillary is compensated]



[The teeth root of Mandible is compensated]

NOTE

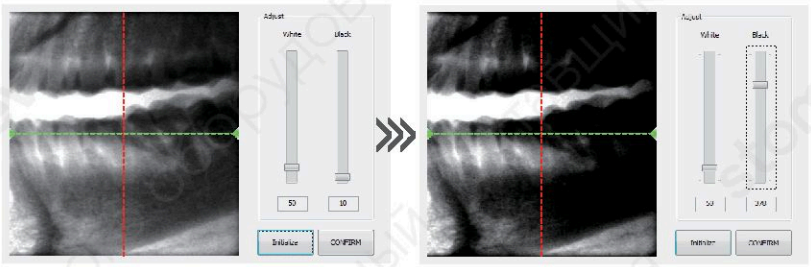
To adjust the image contrast for making the compensating point distinct, you may adjust the black and white level with the Adjust control on the right of image.



<Ex) White level: 50→306>

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<Ex) Black level: 50→306>

NOTE

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.

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.

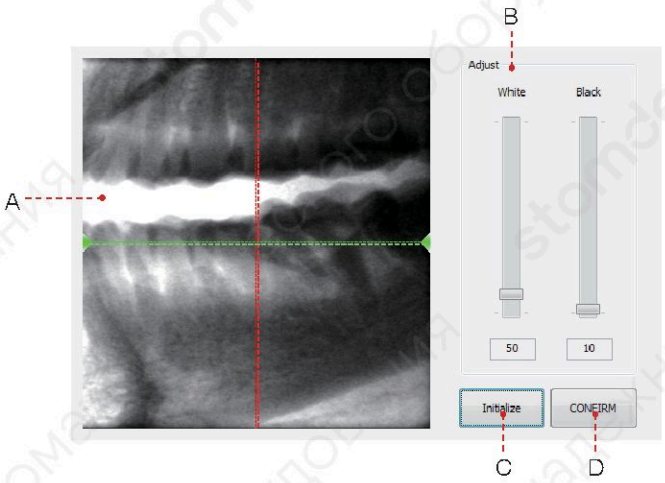
G. Click the **READY** button from the GUI.

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

NOTE

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

8.3.2 SCOUT Viewer



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A. **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.

B. **Adjust**

- White: make the current white level whiter.
- Black: make the current dark level darker.

C. **Initialize** : When clicked, returns to the initial state of the completion of the **SCOUT** imaging.

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

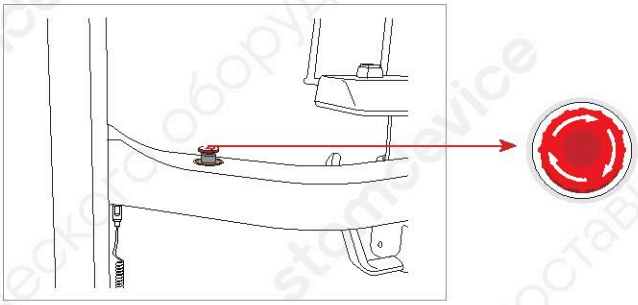
8.4 Initiating X-Ray Exposure

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

WARNING

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

To reset this switch, turn it clockwise until it pops up.



WARNING

Do not operate the PC during exposure. Failure to comply with this instruction may cause the system to malfunction.

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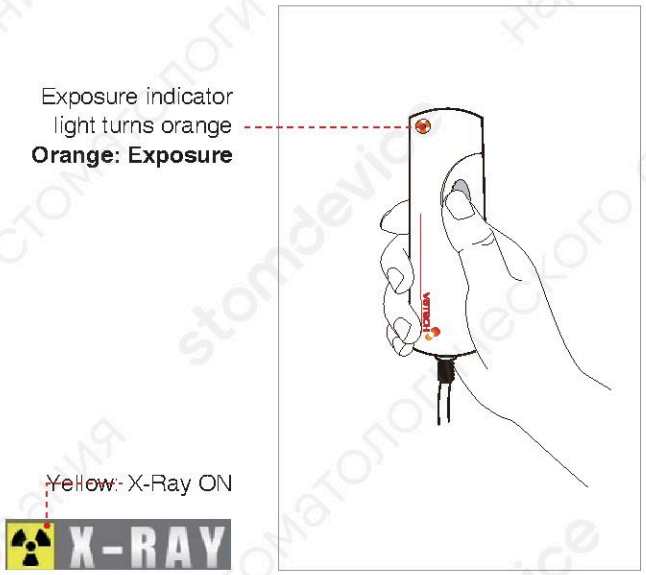
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WARNING

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.



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 announcement mode of either beep or music is initiated, depending on the set-up.
- 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.

CAUTION

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).

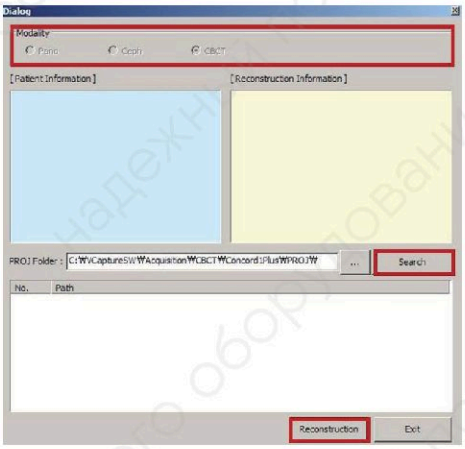
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NOTE

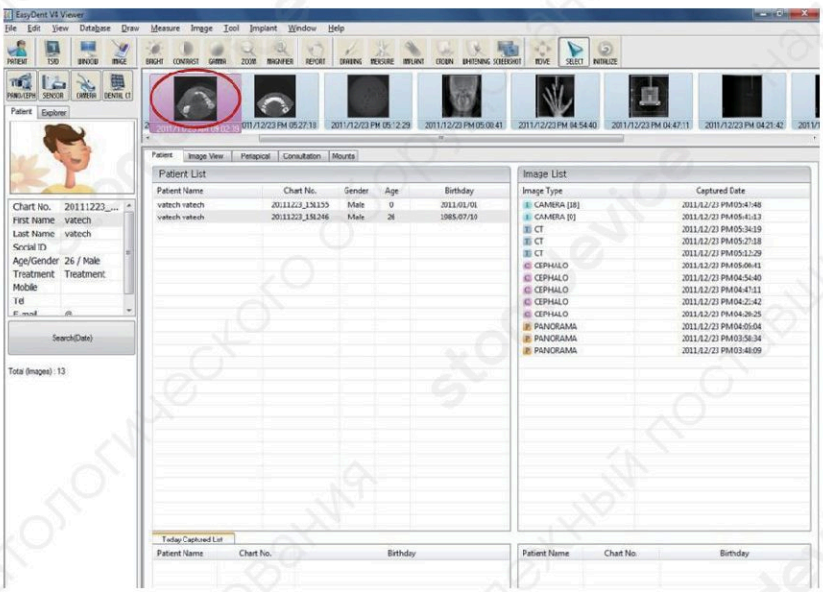
If automatic image reconstruction fails, the image must be reconstructed manually by clicking the reconstruction button ( ) in the upper right corner of the screen.

Select modality and click Search → Reconstruction.



Once acquisition is complete, the image is automatically transferred to **EasyDent**.

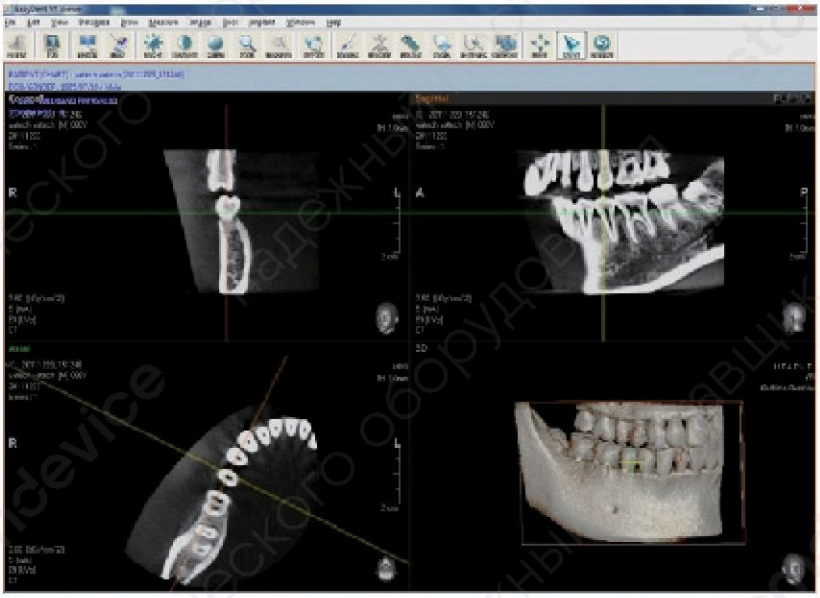
D. Clicking the patient's name in EasyDent's patient list will refresh the image list for that patient. The patient's most recent image will appear on the far left of the thumbnail image pane, as shown below.



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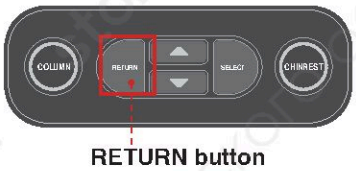
E. Double-click the CT image on the thumbnail to open **Ez3D plus**, the system's 3D viewing program. **Ez3D plus** facilitates prompt analysis and diagnosis of the patient's 3D image.



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.
- Press **RETURN** to bring the rotating unit back to its initial position.



RETURN button

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9

Troubleshooting

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9 Troubleshooting

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

- If the device is not moving

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

- If the exposure switch is not functioning

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

- If imaging cannot be performed

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

- If the laser beam has shut off and patient alignment cannot be performed

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



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 located on the handle frame 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.

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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.

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Accessories	Cleaning Process
Computer and peripherals	Follow the manufacturers' instructions found in the accompanying manuals.
Outer covers of equipment	Wipe the unit with a dry cloth at the end of each day.
	CAUTION **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

NOTE

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

WARNING

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

- Do not use force to unplug cables.
- Do not expose the equipment or components in an area which is susceptible to water or humidity.

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- 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

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11

Disposing of the Unit

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11 Disposing of the Unit

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

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

Part	Material	Recyclable	Waste Disposal Site	Hazardous waste; Needs Separate Collection
Frame and covers	Aluminum and plastics	●		
Motors		●		
Circuit boards		●		
Cables and transformer	Copper	●		
	Steel	●		
	Oil		●	
Packing	Wood	●		
	Cardboard	●		
	Paper	●		
X-Ray tube				●
Sensor head	Return the sensor head to VATECH			
Other parts			●	

NOTE

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

WARNING

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

IMPORTANT

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

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12

Technical Specifications

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12 Technical Specifications

12.1 Mechanical Specifications

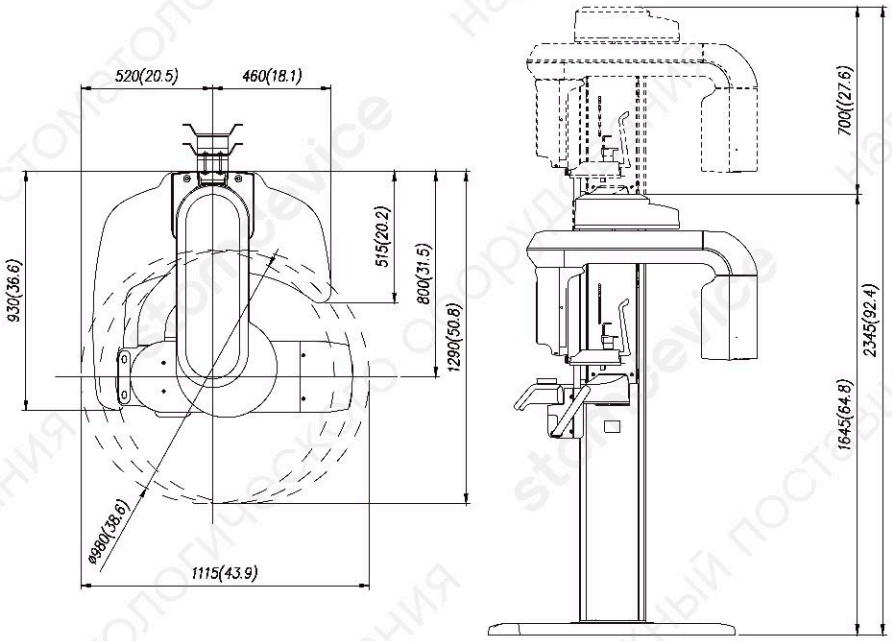
Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	585.9	439.7	146.2	1.33 constant
CEPH	1,745	1,524	221	1.14 constant
CT	642.3	409.7	232.6	1.56 constant

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

Dimension

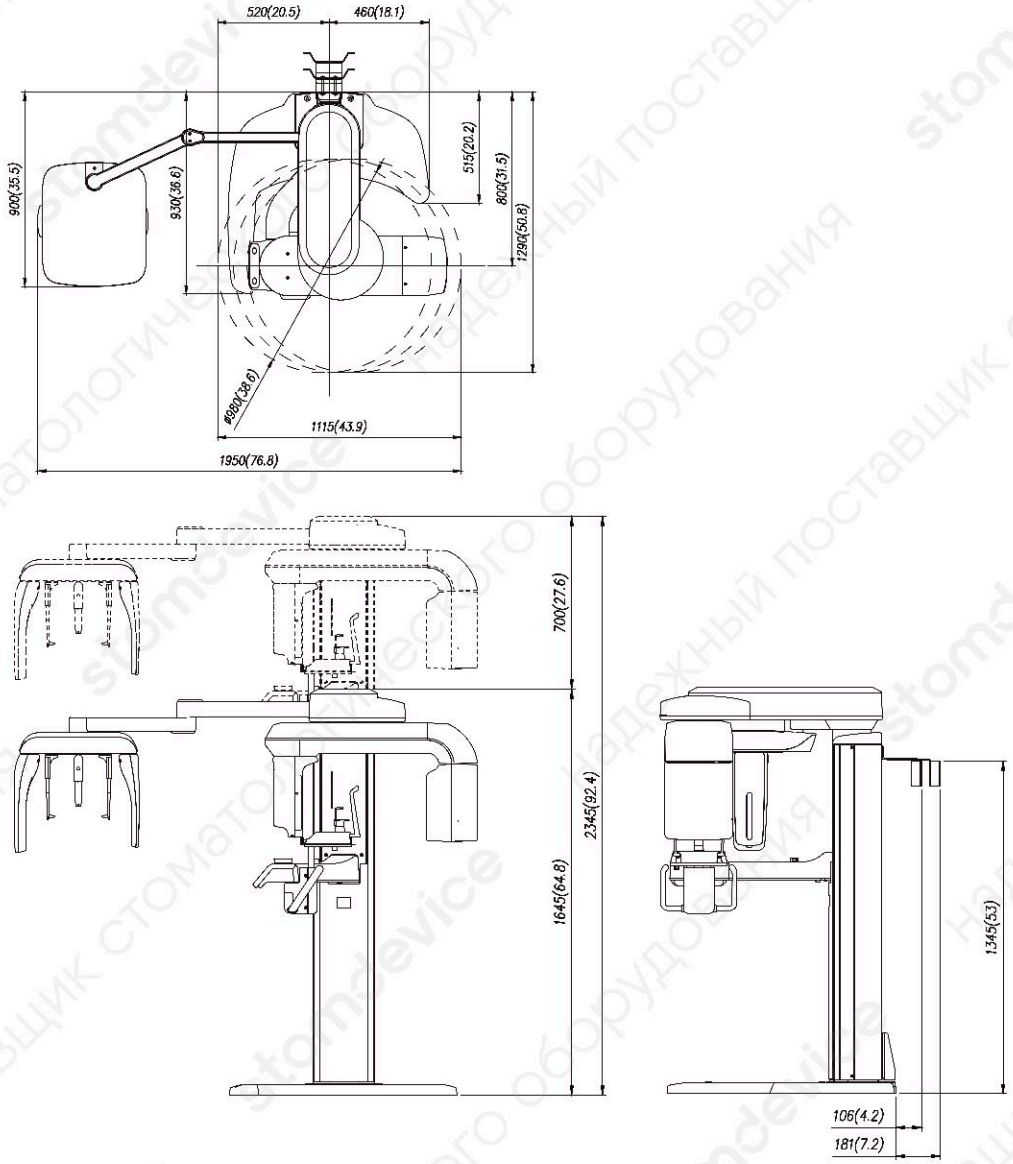
Without Cephalometric Unit [Unit: mm (Inches)]



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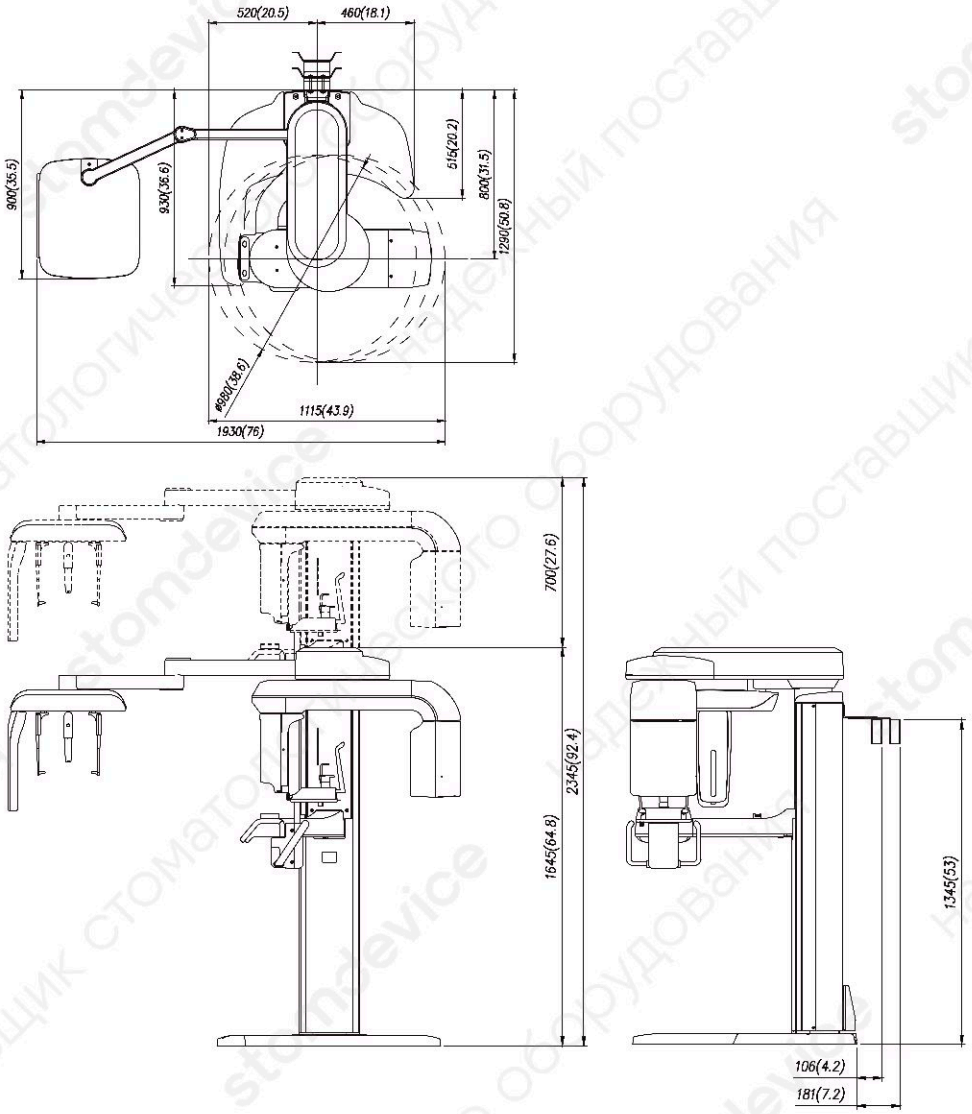
With Cephalometric Unit - Scan Type



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With Cephalometric Unit- One Shot Type



NOTE

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

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Item		Description
Weight (kg)	Without CEPH unit	120 (264.5 ibs)
		With base: 167 (368.2 ibs)
	With CEPH unit	150 (331 ibs)
		With base: 197 (434.3 ibs)
Total Height (mm)		Max. 2,340 (92.13 in.)
Vertical column movement (mm)		Max. 700 (Max. 27.56 in.)
Length x Width x Height (mm)	Without CEPH unit	1,115 (L) x 1,290(W) x 2,340 (H) mm 43.9 (L) x 50.8 (W) x 92.13(H) inch
	With CEPH unit (Scan Type)	1,930 (L) x 1,290 (W) x 2,340 (H) mm 76 (L) x 50.8 (W) x 92.13(H) inch.
	With CEPH unit (One shot Type)	1,930 (L) x 1,290 (W) x 2,340 (H) mm 76 (L) x 50.8 (W) x 92.13 (H) inch.
Type of installation		Base Stand / Wall Mount

** Column Height Limiting Function: Max. 2,340 - Min. 1,625 (Adjustable in 10 mm)*

12.2 X-Ray Generator

X-Ray Generator

Item			Description
Model			HDG-07B10T2
Rated output power			0.9 kW
High voltage generator	Type		40 kHz Inverter Type
	Normal/ Pulse	kVp	50 - 90 kV
		mA	4 - 10 mA
	Cooling		Automatically controlled / Protect ≥ 60 °C
	Total filtration		2.8 mm Al eq. (IEC60522)
X-Ray tube	Manufacturer		TOSHIBA
	Model		D- 052SB (Stationary Anode type)
	Focal spot size		0.5 mm (IEC60336)
	Target angle		5°

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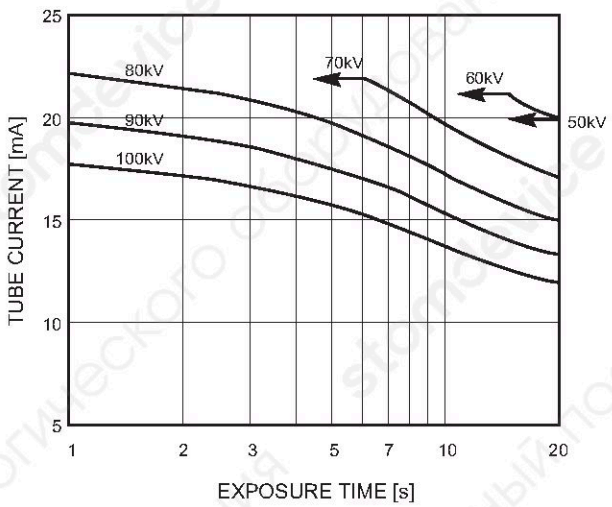
Item		Description
X-Ray Tube	Target material	Tungsten
	Inherent Filtration	At least 0.8 mm Al eq. at 50 kV
	X- ray Coverage	95 x 380 mm at SID 550 mm
	Anode Heat Content	35 kJ
	Duty Cycle	1: 60 or more (Exposure time : interval time)

S/N	XXXX Size (mm)	XXX	XX	XX	XX	XX	XXXX
	Model	Tube	Inverter ver.	F/W ver.	Weekly code	Yearly code	serial

Maximum Rating Charts
DC (Center Grounded)

Constant potential high-voltage generator

Nominal Focus Spot Value: 0.5

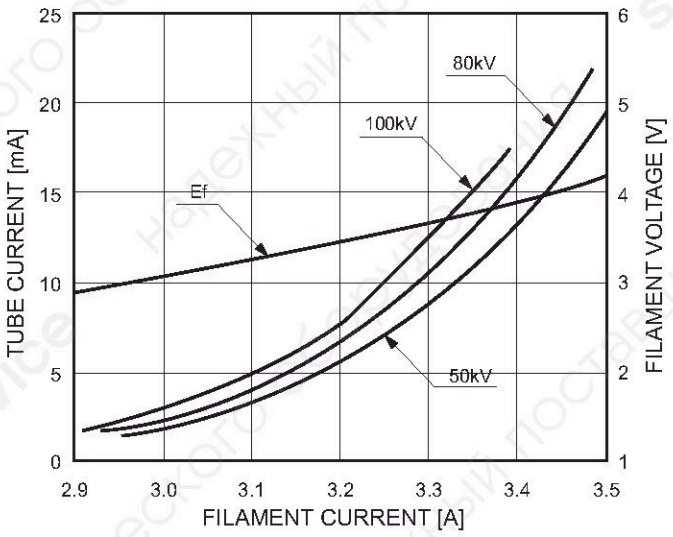


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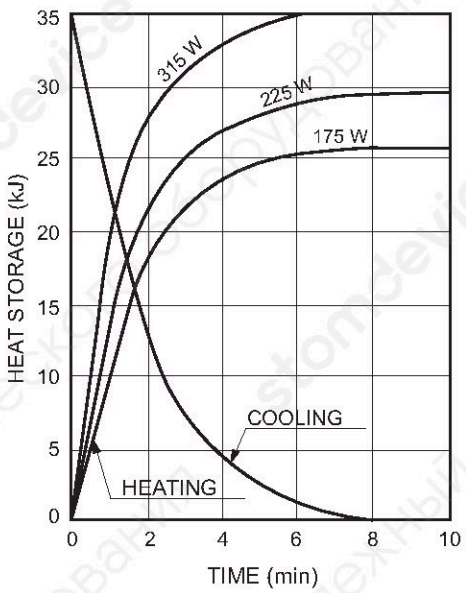
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Emission & Filament Characteristics

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



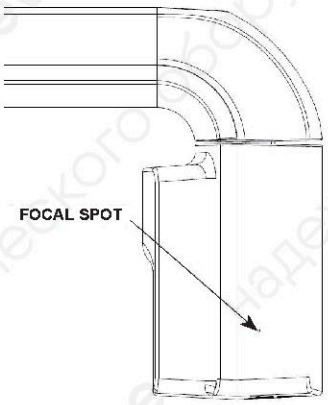
Anode Thermal Characteristics



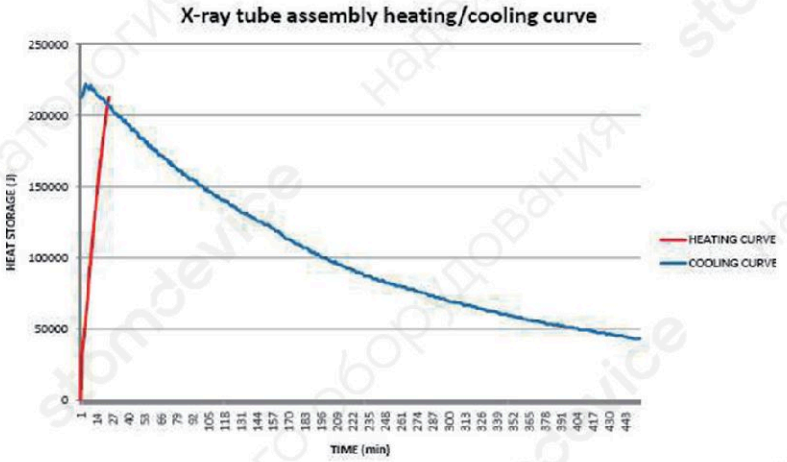
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Indication of focal spot



X-Ray tube assembly heating / cooling curve



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Detector Specifications

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

Item	Description	
	CT (optional)	
Model	Xmaru1215CF Plus	Xmaru0712CF
Detector type	CMOS photodiode array	
Pixel size (μm)	140 (Single operation) 280 (2 x 2 binning)	140
Active area (mm)	143.36 x 117.6	71.68 x 117.46
Frame rate (fps)	30 (Single operation) 50 (2 x 2 binning)	30
A/D (bits)	14	
Sensor size (mm)	212.5 x 150 x 24.7	213.2 x 159 x 24.8

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12.3 Electrical Specifications

Item	Description
Power supply voltage	**AC 100 ~ 120 / 200 ~ 240 V** - AC 100 V (Japan) - AC 110 V (Taiwan) - AC 120 V (USA / Canada) - AC 220 V (China) - AC 110 V / 230 V (European Union or the rest countries) - 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

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

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1 Recommended X-Ray Exposure Table

1.1 PANO

Gender / Figure	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
Man	76 / 10	75 / 10	74 / 10
Woman	75 / 10	74 / 10	73 / 10
Child	68 / 8.0	67 / 8.0	66 / 8.0

1.2 CEPH

Lateral

Gender / Figure	Hard (kVp / mA)		Normal (kVp / mA)		Soft (kVp / mA)	
Sensor Type	One shot	Scan	One shot	Scan	One shot	Scan
Man	90 / 10	86 / 10	90 / 10	85 / 10	89 / 10	84 / 10
Woman	90 / 10	85 / 10	90 / 10	84 / 10	89 / 10	83 / 10
Child	86 / 10	81 / 10	85 / 10	80 / 10	85 / 10	80 / 9

PA / SMV / Waters View

Gender / Figure	Hard (kVp / mA)		Normal (kVp / mA)		Soft (kVp / mA)	
Sensor Type	One shot	Scan	One shot	Scan	One shot	Scan
Man	90 / 10	88 / 10	90 / 10	87 / 10	89 / 10	86 / 10
Woman	90 / 10	87 / 10	90 / 10	86 / 10	89 / 10	85 / 10
Child	86 / 10	83 / 10	85 / 10	82 / 10	84 / 10	81 / 10

Carpus

Gender / Figure	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
Man / Woman / Child	60 / 6.0	60 / 5.0	60 / 4.0

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1.3 CBCT

Xmaru0712CF (optional)

Gender / Figure	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
Man	90 / 5.3	89 / 5.3	88 / 5.3
Woman	90 / 5.0	89 / 5.0	88 / 5.0
Child	86 / 5.0	85 / 5.0	84 / 5.0

Xmaru1215CF plus (optional)

Gender / Figure	Hard (kVp / mA)	Normal (kVp / mA)	Soft (kVp / mA)
Man	90 / 5.5	89 / 5.5	88 / 5.5
Woman	90 / 5.2	89 / 5.2	88 / 5.2
Child	86 / 5.2	85 / 5.2	84 / 5.2

NOTE

- **Maximally allowed tube voltage / current: kVp ± 10 % / mA ± 20 % according to IEC60601-2-7.**
- **Due to image optimization performed prior to shipping, equipment data may differ slightly from those specified in the table.**

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2 X-Ray Dose Data

The X-Ray dose data is extracted from the X-Ray Dose Test Report for the PaX-i3D. X-Ray Dose Test Report for the PaX-i3D 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 is designed to comply with IEC 60601-1-3 Part 1 General Requirements for Safety.

Test Condition	
Brand Name (Model)	PaX-i3D (PHT-6500)
Sensor	PANO: Xmaru1501CF CEPH: Xmaru2301CF CT: Xmaru1215CF Plus
X-Ray generator	HDG-07B10T2

2.1 DAP Table

Test Equipment			
Instrument	Manufacturer	Model	S/N
Dose Meter	Piranha	255	CB2-06090029

Mode Tested: PANO HD / Normal / Standard 13.5 s						
mA	4		6		8	
kVp	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]
60	3.48	25.1	5.00	36.0	6.49	46.7
70	4.48	32.3	6.54	47.1	8.32	59.9
80	5.93	42.7	8.54	61.5	10.61	76.4
90	7.27	52.3	10.46	75.3	13.02	93.7

Mode Tested: CEPH PA, 12.9 s						
mA	4		6		8	
kVp	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]
60	0.27	3.2	0.39	4.7	0.50	6.1
70	0.36	4.4	0.53	6.4	0.71	8.6
80	0.47	5.7	0.69	8.4	0.92	11.1
90	0.59	7.1	0.86	10.4	1.15	13.9

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Mode Tested: CT Adult FOV 120 x 90, 15 s						
mA / kVp	4		6		8	
	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]	[mGy]	[mGy • cm2]
60	1.18	196.7	1.79	296.8	2.42	401.7
70	1.79	297.5	2.75	456.5	3.63	602.3
80	2.49	414.0	3.87	643.2	5.05	838.5
90	3.28	544.6	5.08	844.0	6.64	1102.1

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 120 x 90, 15 s, 90 kVp			
$CTDI_{100}$ [mGy]			
[mA] / Location	4	6	8
Center	292	450	600
0°	268	414	556
90°	240	399	534
180°	316	482	643
270°	272	418	556

Testing Conditions: FOV 80 x 80, 15 s, 90 kVp			
$CTDI_W$ [mGy] DLP [mGy · cm]			
[mA] / Category	4	6	8
$CTDI_W$	2.89	4.49	6.00
DLP	24.53	38.20	51.00

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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
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	10

Mode / Direction [°]	PANO UHD, 20.2 s [mR / hr]		
	1 m (3.3 ft)	**1.5 m (4.9 ft)**	**2 m (6.6 ft)**
0	54.5	28.9	19.8
45	98.7	38.2	20.2
90	97.6	35.2	19.3
135	93.7	35.7	22.8
180	93.7	38.3	21.9
225	81.6	41.2	19.8
270	61.7	27.9	8.2
315	54.2	29.0	19.2

CT Mode

Test Condition	
Tested Mode	FOV 120 x 90, 15 s
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	10

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Mode / Direction [°]	FOV 120 x 90, 15 s [mR/hr]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	38.9	26.6	17.0
45	268	110	72.5
90	204	105	97.4
135	321	137	99.9
180	277	97.9	76.1
225	412	96.6	84.3
270	290	118	102
315	304	176	93.5

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3. Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions.

The model PaX-i3D(PHT-6500) is intended for use in the electromagnetic environment specified below. The customer or the user of the model PaX-i3D(PHT-6500) should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model PaX-i3D(PHT-6500) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A (The model PaX-i3D(PHT-6500) in combination with the shielded location)	The model PaX-i3D(PHT-6500) must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 20 dB from 30 MHz to 230 MHz, 20 dB from 230 MHz to 1 GHz. The model PaX-i3D(PHT-6500) , when installed in such a shielded location, is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

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

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Guidance and manufacturer's declaration - electromagnetic immunity

The model PaX-i3D(PHT-6500) is intended for use in the electromagnetic environment specified below. The customer or the user of the model PaX-i3D(PHT-6500) should assure that it is used in such an environment.

Emissions test	Compliance	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV Contact ±8 kV air	± 6 kV Contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0.5cycle 40 % UT (60 % dip in UT) for 5 cycle, 6 cycle 70 % UT (30 % dip in UT) for 25 cycle, 30 cycle <5 % UT (< 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 0.5cycle 40 % UT (60 % dip in UT) for 5 cycle, 6 cycle 70 % UT (30 % dip in UT) for 25 cycle, 30 cycle <5 % UT (< 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model PaX-i3D(PHT-6500) image intensifier requires continued operation during power mains interruptions, it is recommended that the model PaX-i3D(PHT-6500) be powered from an uninterruptible power supply.

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Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer's declaration - electromagnetic immunity

The model PaX-i3D(PHT-6500) is intended for use in the electromagnetic environment specified below. The customer or the user of the model PaX-i3D(PHT-6500) should assure that it is used in such an electromagnetic environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80MHz 3 V / m 80 MHz to 2.5GHz	3 Vrms 150 kHz to 80 MHz 3 V / m 80 MHz to 2.5 GHz	The model PaX-i3D(PHT-6500) must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 20 dB from 30 MHz to 230 MHz, 20 dB from 230 MHz to 1 GHz. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V / m.a Interference may occur in the vicinity of equipment marked with the following symbol:

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NOTE 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the model PaX-i3D(PHT-6500) is used exceeds 3V/m, the model PaX-i3D(PHT-6500) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the model PaX-i3D(PHT-6500) or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

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4. Acquiring image for the pediatric dental patient

4.1 Age group: classification table

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

Age Group	FDA	VATECH's Standard
Infant	1 month to 2 years	Child
Child/Children	2 ~ 12 years of age	
Adolescent	12 ~16 years of age	Adult
Other	16 ~ 21 years of age	
Adult	> 21 years of age	
The weak		The weak: >60 years of age

4.2 Positioning the pediatric dental patient

Use a cotton roll to fill in missing primary teeth or partially erupted permanent teeth. Adapt adult recommendation for direction of laser light beam guide for use with primary teeth. Observe laser light beam guide on both the right and left sides.

1. Use laser light beam guide to locate mid sagittal plane. Direct patient focus to mirror reflection. Affix decal to mirror to aid patient in maintaining the correct position throughout exposure.

2. Move chinrest into a position that is slightly higher than the patient's chin height before requesting that the patient place chin onto the rest. Direct the patient to assume a position that resembles the erect stance of a soldier.

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3. Direct the patient to stick out the chest while dropping the chin down. While holding the unit handles for stability, direct the patient to take a half step in toward the vertical column of the X-Ray device into a position that feels as if he/she is slightly leaning backward.

4. Direct the patient to the lips closed around the bite block during the exposure.

5. Direct the patient to swallow and note the flat position of the tongue. Request that the patient suck in the cheeks, pushing the tongue into the correct flat position against the palate and maintain this position throughout the exposure.

4.3 Setting exposure values to the age group

For more information about this topic, refer to the Appendices 13.1 Recommended X-Ray Exposure Table.

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

1. I. ESPELID, I. MEJÀRE, K. WEERHEIJM: EAPD guidelines for use of radiographs in children, P40-48. European Journal of Pediatric Dentistry 1/2003

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

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

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

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

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

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

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

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

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

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

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

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5 Abbreviations

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

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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: gcs@vatech.co.kr
Website: www.vatech.co.kr

Headquarters: 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, Korea
Factory: 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, Korea

CE 2460

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

EC REP

EC Representative; Vatech Dental Manufacturing Ltd.
Suite 3, Ground Floor, Chancery House, St. Nicholas Way, Sutton, SM1 1JB UK

Tel: +44-0208-652-1900, +44-0208-643-7109
Fax: +44-0208-652-1909

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PaX-i3D™

Postal Code: 18449
13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, Korea
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