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Green X™

User manual

Model : PHT-75CHS
Version : 1.15

- English



Full version

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Notice

Thank you for purchasing the **Green X™ (Model: PHT-75CHS)** extra-oral imaging system.

Green X™ (Model: PHT-75CHS) is one of the manufacturer's Green CT product series for aiding dental professionals in providing excellent care in a safe environment that promotes healing.

Green X™ (Model: PHT-75CHS) is an advanced digital diagnostic system that incorporates PANO, CEPH (Optional), CBCT, and 3D MODEL Scan imaging capabilities into a single system.

This manual describes how to operate the **Green X™ (Model: PHT-75CHS)** system. It is recommended that you thoroughly familiarize yourself with this manual to effectively use this equipment.

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

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

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This document is originally written in English.

Green X™ (Model: PHT-75CHS) is referred to as "equipment" in this manual.

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Table of Contents

Notice v

Table of Contents vi

1. Introduction 10

1.1 Overview 10
1.2 Indications for Use 10
1.3 Intended Purposes 11
1.4 Intended User Profiles 12
1.5 Contraindications 12

2. General Information 14

2.1 Manufacturer's Liability 14
2.2 Owner and Operator's Obligations 14
2.3 Conventions in this Manual 15
2.4 Marks and Symbols 16

3. Warnings and Precautions 20

3.1 General Safety Guidelines 20
3.2 Electricity-related Safety Precautions 24
3.3 Radiation Safety 26
3.4 Warnings 27

4. Imaging System Overview 30

4.1 System Components 30
4.2 Features 30
4.3 Imaging System Options 31
4.4 Standards and Regulations 31
4.5 Operating Principles 32
4.6 Imaging System Configuration 33
4.7 Equipment Overview 35

5. Imaging Software Overview 43

5.1 PC Specifications (Recommended) 43
5.2 EzDent-i 44
5.3 Console Software 45

6. Getting Started 49

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stomdevice

6.1 Turning on the Equipment 49
6.2 Running the Image Viewer (EzDent-i) 50

7. How to Acquire PANO Images 55

7.1 PANO Imaging Program Overview 55
7.2 Configuring Exposure Settings 61
7.3 Patient Positioning 70
7.4 Taking an X-ray Exposure 81
7.5 After an X-ray exposure 82
7.6 Checking Images 82

8. How to Acquire CEPH Images (Optional) 84

8.1 CEPH Imaging Program Overview 84
8.2 Configuring Exposure Settings 86
8.3 Patient Positioning 89
8.4 Taking an X-ray Exposure 99
8.5 After an X-ray Exposure 100
8.6 Checking Images 100

9. How to Acquire CBCT Images 101

9.1 CBCT Imaging Program Overview 101
9.2 Configuring Exposure Settings 106
9.3 Acquiring a Double Scan Image (Optional) 111
9.4 Taking a Scout Image (Optional) 116
9.5 Patient Positioning 120
9.6 Taking an X-ray Exposure 128
9.7 After an X-ray Exposure 129
9.8 Checking Images 129

10. How to Acquire 3D Model Scan Images 131

10.1 3D Model Scan Imaging Program Overview 131
10.2 Configuring Exposure Settings 132
10.3 MODEL Positioning 134
10.4 Taking an X-ray Exposure 135
10.5 Checking the Captured Images 136

11. Troubleshooting 138

11.1 Troubleshooting 138
11.2 Error Codes 139

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stomdevice

12. Cleaning and Disinfection 144

12.1 Cleaning 145

12.2 Disinfection 146

13. Maintenance 148

13.1 Regular Maintenance 148

13.2 Maintenance Task Checklist 149

13.3 QA Test 150

13.4 Phantom Kit Contents 150

13.5 QA Test Procedure 152

14. Disposing of the Equipment 163

15. Technical Specifications 165

15.1 Mechanical Specifications 165

15.2 Technical Specifications 168

15.3 Electrical Specifications 174

15.4 Environmental Specifications 175

16. Appendices 177

16.1 Recommended X-ray Exposure Tables 177

16.2 X-ray Dose Data 188

16.3 Electromagnetic Compatibility (EMC) Information 206

16.4 Acquiring Images for Pediatric Dental Patients 208

16.5 Abbreviations 219

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1. Introduction

1.1 Overview

Green X™ (Model: PHT-75CHS) is an advanced 4-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), CBCT, and 3D MODEL Scan imaging capabilities into a single system.

Green X™ (Model: PHT-75CHS), a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography, **Green X™ (Model: PHT-75CHS)** is a complete digital X-ray system equipped with imaging viewers, an X-ray generator, and a dedicated SSXI detector.

The digital CBCT system is based on a CMOS digital X-ray detector. The CMOS CT detector is used to capture 3D radiographic images of the head, neck, oral surgery, implant, and orthodontic treatment.

Green X™(Model: PHT-75CHS) can also acquire 2D diagnostic image data in conventional panoramic and cephalometric modes.

1.2 Indications for Use

Green X™ (Model: PHT-75CHS) is intended to produce panoramic, cephalometric, or 3D digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, TMJ, and ENT for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.



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1.3 Intended Purposes

- Determination of the extent of lesions, tumors, cysts, etc., which cannot be adequately visualized on plain films
- Diagnosis of foreign bodies or displaced roots involving the maxillary sinus
- Diagnosis of bone diseases, cysts, etc., affecting the temporomandibular joints
- Identifying the relationship of the inferior dental canal to a tooth/lesion that is to be removed
- Assessment of fractures on maxilla, mandible, condylar neck, and fractures of teeth where plain film imaging is equivocal
- Visualization of the 3D anatomy of the alveolar clefts
- Diagnosis of un-erupted teeth impacted teeth and odontomas
- Diagnosis of root resorption of teeth
- Assessment of cleft palate
- Diagnosis of CRS (chronic rhinosinusitis)
- Assessment of complex root canal anatomy
- Diagnosis of periapical pathology
- Diagnosis of vertical root fracture
- Examinations of the airways for measuring the volume and dimensions of air passages
- Planning any surgery where a 3D analysis of the jaw is required
- Storing Plaster Casts in 3D data

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1.4 Intended User Profiles

Considerations	Requirement Description
Education	▪ Licensed dentists or dental hygienists, radiologists, and graduates of relevant bachelor's degrees (national qualifications)
Knowledge	▪ Understanding the treatment and diagnosis of dental disease ▪ Understanding the terms and guidance of hardware and software of a diagnostic medical radiation device and recognizing device connection, installation, and operating conditions
Language understanding	▪ Understanding how to use manuals (English/Korean) or ▪ Understanding other languages provided
Experience	▪ Understanding the objectives and effects of the diagnosis and treatment of dental disease using diagnostic medical radiation devices ▪ Understanding of the normal operation of diagnostic medical radiation equipment ▪ Understanding the contents of the **User Manual**

IMPORTANT	Only qualified personnel must use X-ray CBCT (dentists, dental hygienists, or radiologists).

1.5 Contraindications

DO NOT use this device other than the intended purpose.
There are no other contraindications to it since the technology is at a controllable level in accordance with global standards.

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2. General Information

2.1 Manufacturer's Liability

The manufacturers and retailers of this X-ray equipment assume responsibility for the safe and healthy operation of this product only when:

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

2.2 Owner and Operator's Obligations

- The owner of this equipment shall perform constancy tests at regular intervals to ensure patient and operator safety. Local X-ray safety regulations must perform these tests.
- The owner of this equipment shall perform regular inspection and maintenance of the mechanical and electrical components in this equipment to ensure safe and consistent operation (IEC 60601-1).
- The owner of this equipment shall ensure inspection and cleaning work is performed by the maintenance schedule outlined in **Chapter 12: Cleaning and Disinfection**.

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2.3 Conventions in this Manual

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

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

	**WARNING**	Indicates information that should be followed with the utmost care. Failure to comply with a warning may result in severe damage to the equipment or physical injury to the operator and patient.
	**CAUTION**	Indicates a situation that demands prompt and careful action, a specific remedy, or emergency attention.
	**IMPORTANT**	Indicates a situation or action that could potentially cause problems to the equipment and its operation.
	**NOTICE**	Emphasizes essential information or provides useful tips and hints.
	**RADIATION**	Indicates a possible danger from radiation exposure.
	**SINGLE USE**	Indicates a component that must be replaced for each new patient.
	**ESD susceptibility**	Indicates that an item is susceptible to damage from electrostatic discharges.

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2.4 Marks and Symbols

Symbols	Description	Location
	Dangerous voltage	Powerboard /Inverter board /Monoblock
	Protective earth (Ground)	Column
	Off (power: disconnected to the **Main Power Switch**)	Main Power Switch
	On (power: connected to the **Main Power Switch**)	Main Power Switch
	Alternate current	Label
	Type B Applied Equipment (IEC 60601-1: Degree of protection against leakage current and electric shock: Class 1 equipment)	Label
	Radiation hazard	Label
	Indicates the authorized representative in the European Community.	Label
	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Label
	UL mark No. E476672	Label
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Label

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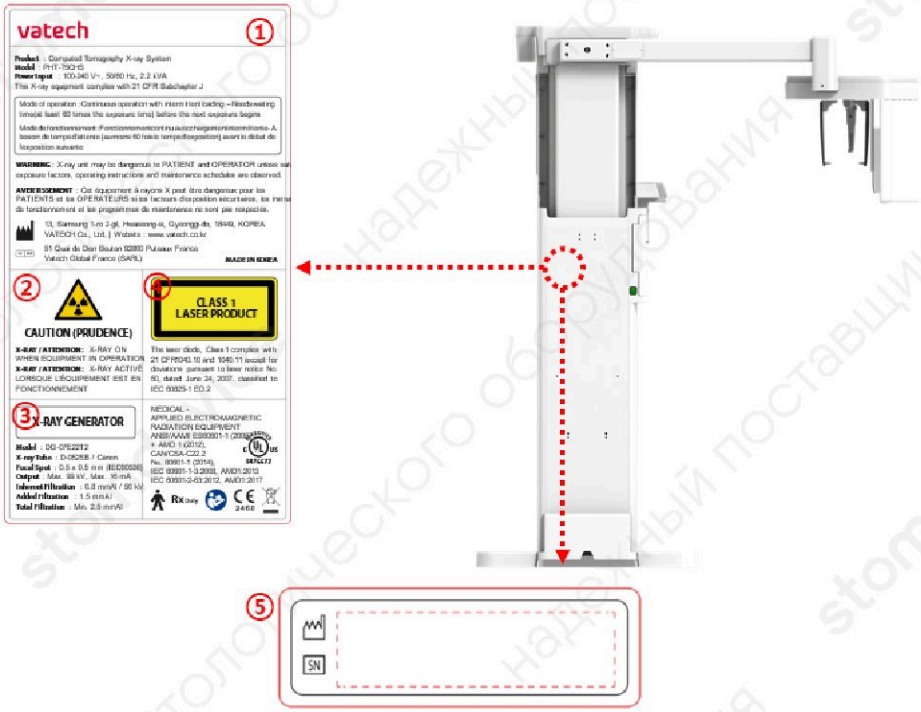
Symbols	Description	Location
	Addresses where the equipment was manufactured.	Label
	Indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Label
	Warns ESD hazard.	MCU board /Board package
	Indicates that this equipment is classified as a CLASS 1 LASER PRODUCT by IEC 60825-1 ED. 3 regulations.	Label
	Indicates that the user needs to refer to the **User Manual**.	Label
	Indicates the date of manufacture.	Label
	Indicates the manufacturer's serial number to identify the specific equipment.	Label

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2.4.1 Label Locations

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





NOTICE The design and contents of the labels may be different in some countries based on local regulations and standards

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No.	Item
1	**Main Label**
2	**CAUTION Label** - X-ray / Attention: X-ray on when equipment in operation.
3	**X-RAY GENERATOR Label** : 1.6 kW Generator
4	**CLASS 1 LASER PRODUCT Label**
5	**Manufacturer Label** : The date of manufacture / Serial Number
6	**Device Identifier Label** (For Canada only) In Canada, the Model is distinguished by Green X RC And Green X SP. • Green X RC: CEPH included • Green X SP: CEPH not included

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3. Warnings and Precautions

⚠WARNING	Follow all warnings and safety instructions in this manual to assure a safe operation.
⚠WARNING	Follow precautions and conduct regular inspections to work safely around the X-ray equipment. Ignoring the precautions may endanger both patients and operators.

3.1 General Safety Guidelines

Operator Qualifications

This equipment must be operated by a qualified person trained for the operation procedure. To operate the equipment, the operator must:

- Read and understand the **User Manual**.
- Have full knowledge of the structure and functions of the equipment.
- Recognize problems in the equipment and implement appropriate solutions to resolve the issues.

General Safety Precautions

- Follow the instructions specified in this manual to ensure the safety of both the patient and the operator.
- The operator must always maintain vocal/visual contact with the patient during imaging.
- Do not open or remove the cover panels on this equipment. Always have a trained and authorized service technician to inspect and maintain this equipment.
- Do not place any heavy objects on this equipment at any time.
- Do not place any objects within this equipment's field of operation. It may cause property damage.
- Do not push or pull the equipment. Overbalances of the equipment may cause the risk of physical injuries or property damage.
- The operator must instruct the patient to remain still until the equipment arm has stopped moving and the reset motion is completed.
- Observe all local fire regulations. Always keep a fire extinguisher near the equipment.
- The operator of this equipment must be familiar with this equipment's emergency protocols.

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- Ensure that this equipment is always kept away from water, moisture, or foreign substances.
- If this product is exposed to water, moisture, or a foreign substance, immediately turn off the main power of the equipment and contact your **VATECH** technical support representative.
- If there are signs of oil leakage, immediately cease all operations of this equipment and contact your **VATECH** technical support representative.
- External equipment intended for connection to signal input, signal output, or other connectors, shall comply with relevant IEC Standard (e.g., IEC 60950 for IT equipment and IEC 60601-1 series for medical electrical equipment).
- Also, all such combination-system-shall comply with the standard IEC 60601-1, and IEC 60601-1-1 harmonized national standard or the combination. If in doubt, contact a qualified technician or your local representative.
- Any person or organization that installs an external door interlock switch is responsible for ensuring that it has a radiation indicator or equivalent alarm system to show the state of the current.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Ventilation

- Do not block the equipment's ventilation slot. Blocking the slot may lead to overheating and equipment malfunction.
- Do not spray a cleaning product into the ventilation slot. The air-sprayed liquid may damage the electrical and mechanical components inside. Use a soft cloth to disinfect the ventilation slot.
- Leave enough space around the PC system to avoid overheating.

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Hygiene

⚠ CAUTION	Turn off the equipment before you start cleaning.
⚠ CAUTION	Do not use a spray-type cleaner on the equipment. Spraying liquids may cause a fire and bring other damage to the equipment.

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



Condensation

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

Cooling

- Allow the X-ray tube to cool down before starting the next X-ray exposure. The continuous operation without a cooling time may cause an overload.
  - **Mode of operation**: non-continuous operation (NFPA 70: long time operation) - needs waiting time (at least 60 times the exposure time) before the next exposure begins
  - **Column operation time**: Max. 2 min. On / 18 min. Off (Ratio 1:9)
- The X-ray exposure stops, and an error message is displayed on the control panel when the tube head temperature rises to 60 °C (140 °F). The equipment starts working again when the tube head temperature drops to 58 °C (136.4 °F).
- The fan (optional) is automatically turned on when the tube head reaches the pre-defined temperature level: 40 °C (104 °F). You can change the temperature setting for the fan.

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Turning the Equipment On / Adjusting Equipment's Height

- Ensure that the patient does not stand near the equipment when the staff is turning on the system or adjusting the equipment's height to avoid injuries from the rotating unit or vertical frame's movement.

Conducting Emergency Stop

- Press the **emergency stop switch** when you detect a problem with the equipment during the operation. The equipment will stop as you press the switch. The emergency stop switch is located under the handle frame. If the problem is resolved, turn the switch in the direction of the arrow to reboot the system.

Trouble-Free Operation

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

Modifying the Equipment

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

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3.2 Electricity-related Safety Precautions

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

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

Combining this equipment with other devices

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

Electromagnetic compatibility

- This X-ray equipment complies with IEC standard 60601-1-2.
- Medical electrical equipment is subject to special Electromagnetic Compatibility (EMC) preventive measures. It must be installed and operated as specified in EMC information.
- If high-voltage, radio link, or MRI systems are located within 5 m of the unit, please observe the specifications stated in the installation requirements.
- Portable Radio Frequency (RF) communications equipment may interfere with medical electrical equipment. Therefore, mobile wireless phones in medical offices or hospital environments must be prohibited.
- For more details, refer to **16.3 Electromagnetic Compatibility (EMC) Information**.
- Please also observe the Electro-Static Discharge (ESD) protective measures described.

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Static Discharge

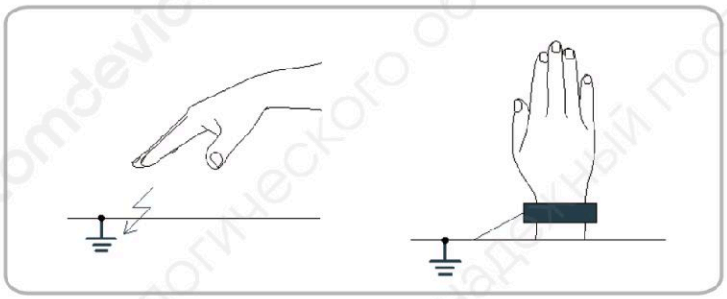
- Without observing ESD protective measures, connector pins or sockets bearing ESD warning labels must not be touched or interconnected.



Electrostatic discharge (ESD)

ESD protective measures include

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



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3.3 Radiation Safety

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

- This equipment must be housed inside an X-ray shielded room.
- The operator must remain outside a shielded room during X-ray exposure to protect himself/herself from radiation.
- During imaging, the operator must maintain vocal/visual contact with the patient from outside the shielded area.
- The operator should continuously check the status of the patient and the equipment during imaging.
- During imaging, the operator should be at least 2 m (6 feet) away from the equipment.
- The operator must immediately stop imaging if the equipment malfunctions.
- During X-ray exposure, the patient must wear a lead apron with neck and thyroid protection.
- Children and pregnant women must consult with a doctor before X-ray exposure.



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

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3.4 Warnings

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

⚠WARNING	▪ X-ray equipment is hazardous to the patient and the operator if proper exposure safety measures and operating instructions are not observed. ▪ It is essential to read this **User Manual** carefully and abide by all warnings and cautions stated.
⚠WARNING	▪ The 3D image should not be used for screening examinations. Each exam must be justified by demonstrating that the benefits outweigh the risk. ▪ Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, conventional medical CT or MR should be used instead of dental cone beam imaging.
⚠WARNING	▪ **Green X (Model: PHT-75CHS)** 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. ▪ **Green X (Model: PHT-75CHS)** system is designed to withstand the effects of defibrillation. However, when possible, disconnect the Dental X-ray system during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.
ⓘ CAUTION	Federal law restricts this device to sale by or on the order of a dentist or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices using or order the use of the device.

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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.
- Advise the patient not to look directly at the laser beam for maximum safety.
- While adjusting the patient, ensure that the laser beam is not directed at the patient's eyes.
- Wavelength: 650 nm, Radiant power: Max. 039 mW

⚠ CAUTION	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 described in these operating instructions.

Cleaning

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

During the Operation

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

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In case of an 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 cause physical injury.

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

Installation

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

NOTICE	For further details on installation, refer to the **Green X™ (Model: PHT-75CHS) Installation Manual**.

Security Capabilities

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

3.4.1 Side Effects

- X-ray imaging exam should be performed only after careful consideration of the patient's health needs. The operator must understand the well-known risks which can occur during the X-ray exposure and minimize them by preventing unnecessary radiation exposure for patients.

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4. Imaging System Overview

4.1 System Components

- **Green X (Model: PHT-75CHS)** X-ray equipment
- PC system
- Console Software: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan
- **EzDent-i**: 2D viewer and patient management software
- **Ez3D-i**: 3D viewer software

4.2 Features

- Multi-FOV support: Selectable FOV among Double Scan(16x15), 16x9, 12x9, 8x8, 8x5. 5x5, and 4x4 (cm)
- **Endo Mode:** the option that provides high-resolution 3D images essential for root canal treatment, including nerves, pulp structure, and blood vessels inside the tooth.
- **Double Scan:** Algorithm to reconstruct large FOV CT images by stitching upper and lower FOV CT images
- **Insight PAN is** a multi-image acquisition option that reconstructs the panoramic image into multiple focal images in depth regions. Its main purpose is to diagnose depth regions, which cannot be confirmed with ordinary panoramic. The option also provides images of user-specified areas in Console software.
- The multi-imaging solution for Accurate Diagnostics
- Conventional 2D (PANO and CEPH) image acquisition
- 3D scanning for Plaster Cast with FOV 8x8 (cm)
- Control Panel implemented for easy use
- DICOM (Digital Imaging Communication in Medicine) format supported
- Differentiated Console Software Interface
- MAR(Metal Artifact Reduction) supported

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4.3 Imaging System Options

Configuration	Item	Sensor	
SP	PANO +CBCT	PANO/CBCT	Xmaru1314CF
RC	PANO +CBCT +CEPH	PANO/CBCT	Xmaru1314CF
		CEPH	Xmaru2602CF

4.4 Standards and Regulations

Standards

Green X (Model: PHT-75CHS) is designed and developed to comply with the following international standards and regulations:

- MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT

  AS TO ELECTRICAL SHOCK, FIRE, AND MECHANICAL

  HAZARDS ONLY IN ACCORDANCE WITH

  ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014),

  IEC 60601-1-3:2008, AMD1:2013, IEC 60601-2-63:2012, AMD1:2017
- 21 CFR 1020.30, 31, 33
- NEMA Standard publication PS 3.1-3.18

CE 2460	This is Class IIb equipment and obtained CE marking in April 2007 for regulations compliance in accordance with the revised European Union's MDD (Medical Devices Directive) 93/42 EEC.
CLASSIFIED c UL us E476672	MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-1-3:2008, AMD1:2013, IEC 60601-2-63:2012, AMD1:2017

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Classifications (IEC 60601-1 6.1)

- The degree of protection against water ingress: Ordinary Equipment: IPX0
- The degree of protection against electric shock: Class 1 equipment, Type B applied parts (chinrest, bite and cover, nasal positioner and cover, ear rod and cap, carpus plate).



4.5 Operating Principles

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

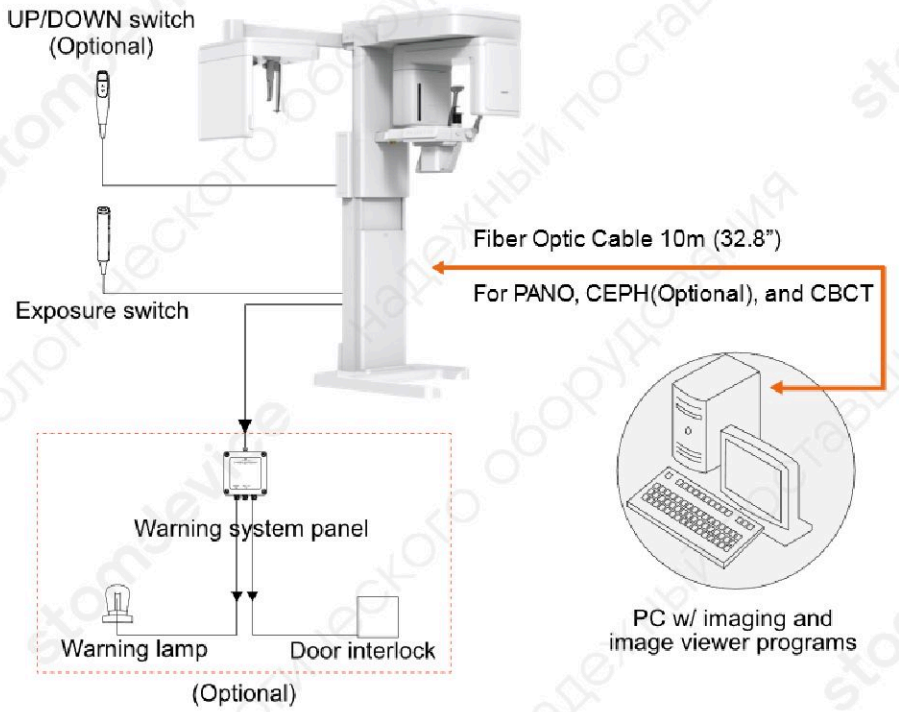
They hit anode to produce an X-ray. The machine acquires images by emitting X-rays continuously and rotates on the human tooth at different angles.

Images are acquired, computed, and recompiled to reproduce 2D or 3D images.

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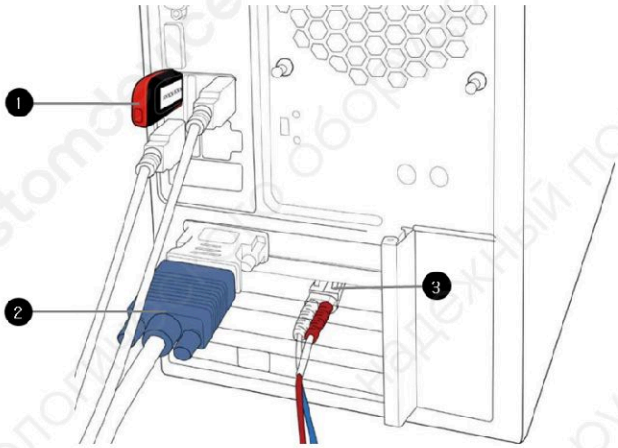
4.6 Imaging System Configuration



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PC Signal Input/Output

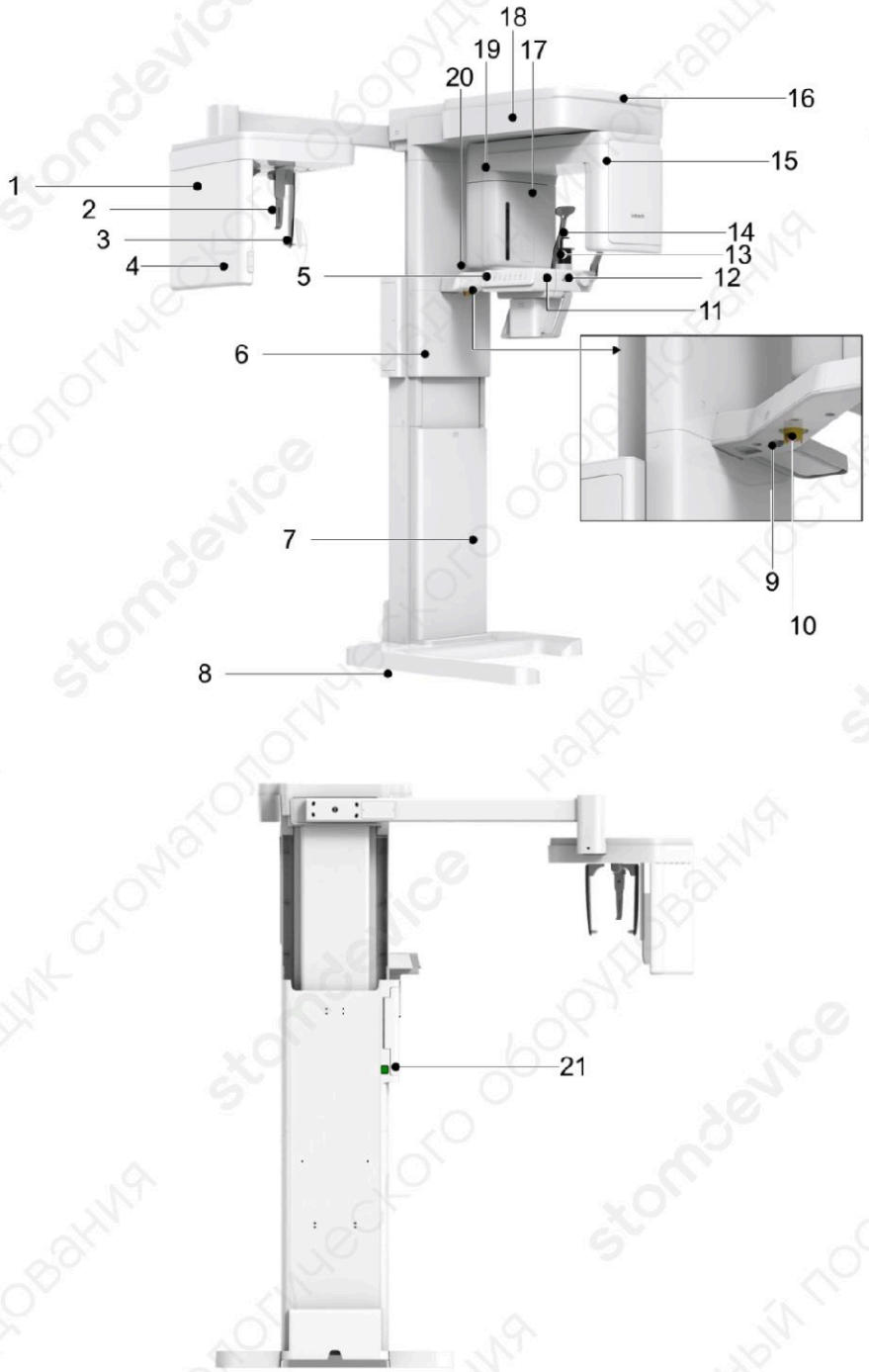


No.	Item
1	3D viewer License Key
2	Video output
3	Fiber optic cable (Data in/out)

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4.7 Equipment Overview



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No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor.
2	Nasal Positioner	Corrects the patient's position for the CEPH imaging procedure.
3	Ear Rods	Secures the patient's head during CEPH imaging.
4	Column UP/DOWN button (CEPH Part)	Adjusts the column's height
5	Control Panel	Controls the laser beam, rotating unit, and column's height. For more information, go to **4.7.1 Control Panel**.
6	Column UP/DOWN Switch (optional)	Adjusts the column's height
7	Column	Supports the whole part of the equipment.
8	Base (Optional)	Balances the equipment and maintains its safety.
9	D-Sub Connector	Serves as the input signal port for the **column up/down** switch.
10	Emergency Stop Switch	Stops the equipment in an emergency. For more information, go to **4.7.2 Emergency Stop Switch**.
11	Canine Teeth Beam Lever	Changes the canine beam's location to align the beam with the patient's Frankfurt line(plane).
12	Temple Supports OPEN/CLOSE Knob	Opens or closes the temple supports.
13	Chinrest	Places the patient's chin for the imaging procedure.
14	Temple Supports	Holds the patient's head in position for PANO and CBCT imaging.
15	X-ray Detector for PANO/CBCT	Xmaru1314CF for PANO and CBCT imaging sensor.
16	LED Lamp	Indicates the X-ray exposure status. ▪ **Green**: X-ray is on standby ▪ **Yellow**: X-ray is on
17	X-ray Generator	The X-ray tube where the X-ray is produced.
18	Vertical Frame	Holds the rotating units
19	Rotating Unit	Rotates around the patient's head to acquire an X-ray image.
20	Enclosed Component Storage	Stores bites, chinrest, and other accessories.
21	Main Power Switch	Turns on or off the equipment.

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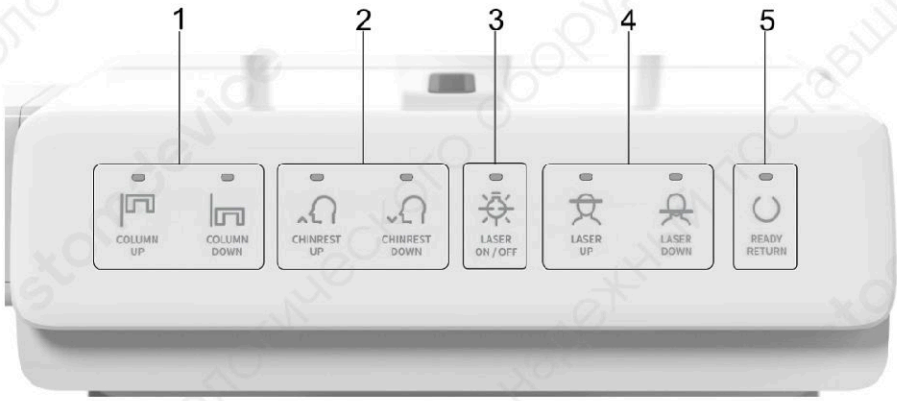
4.7.1 Control Panel

On the control panel, you can set or changes the options for:

- The column's height
- Chinrest's height (for CBCT mode only)
- Laser Beam on/off
- Horizontal beam's location (for Panoramic mode only)
- The Rotating unit's position

The control panel also indicates:

- The X-ray exposure status



No.	Buttons	Description
1	Column UP/DOWN Button	Adjusts the column's height by moving the moving column up and down.
2	Chinrest UP/DOWN Button	Adjusts the chinrest's height for the CBCT imaging.
3	Laser ON/OFF Button	Turns on or off the laser beams for patient positioning.
4	Laser UP/DOWN Button	Adjusts the horizontal beam's location for the panoramic imaging.
5	Ready/Return Button	Indicates that the X-ray is ready for exposure with the LED. Moves the rotating unit's position to its initial place.

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4.7.2 Emergency Stop Switch

Press the **emergency stop switch** to stop the equipment in an emergency. The switch is located under the handle frame. As you press the switch, the equipment will stop.

To restart the system after the problem is resolved, turn the switch until it pops up.

An emergency may include the following situations but is not limited to:

- Continuing X-ray emission (when the exposure switch is not pressed)
- Physical injuries of the patient
- Damages to the equipment and other properties.



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4.7.3 Exposure Switch

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

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

Pressing the exposure switch activates the LED indicator to turn yellow. This color indicates that the X-ray is being emitted.

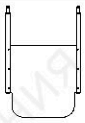
IMPORTANT	Ensure the **exposure switch** cable is not detached from the equipment during the operation.
IMPORTANT	Keep vocal/visual contact with the patient during exposure. In an emergency, release the **exposure switch** immediately.

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4.7.4 Accessories

The following accessories are used to position the patient and support the equipment. The accessories that have contact with the patient must be disinfected between each patient. For more information about cleaning accessories, go to **Chapter 12. Cleaning and Disinfection**.

Accessory	Descriptions	Materials
	Normal Bite - For PANO and CBCT normal patients	PC (Polycarbonate)
	Special Bite A - For PANO TMJ and Sinus modes - For CBCT TMJ patients	PC (Polycarbonate)
	Special Bite B - For PANO edentulous patients	PC (Polycarbonate)
	Normal Chinrest - For Normal Bite - For CBCT Double scan mode((Mandible).	ABS (Acrylonitrile butadiene styrene) copolymer
	Temple Supports (1 set)	Temple Supports: PA(Polyamide) Temple Support Pad: Silicone
	Ear Rods (1 set)	Silicone
	Nasal Positioner Cover - For CEPH	Silicone
	Carpus Plate	PC (Polycarbonate)
	Sanitary Vinyl Covers (disposable) for the Bite	PP+PE

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Accessory	Descriptions	Materials
	Protractor (1 set) - For positioning the patient's body in CEPH mode.	PC (Polycarbonate)
	Model Scan Jig	ABS (Acrylonitrile butadiene styrene) copolymer
	Up/Down Switch and Holder	ABS (Acrylonitrile butadiene styrene) copolymer
	Wall Bracket	SPCC

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5. Imaging Software Overview

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

- **EzDent-i** 2D viewer and patient management software
- **Ez3D-i** 3D viewer software
- Console software: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan

5.1 PC Specifications (Recommended)

NOTICE

- The PC system plays a vital role in image processing and verification. Set up the PC environment to meet the following specifications. An unsatisfactory PC environment can lower the image quality.
- Ensure that patients do not stand near the equipment and PC.

Item	Specifications
CPU	Intel Xeon W-2223 3.6 GHz 4 Core Processor
RAM	16 GB DDR4 2666 ECC Registered RAM or larger
HDD	1 TB SATA
Graphics board	ZOTAC GAMING GTX1660Ti 6GB or greater
Ethernet Interface	Integrated Intel I218LM PCIe GbE
Serial Port (RS232)	NEXT-SL601 PCI-E
Power Supply	≥ 700 Watts (90% efficient)
Slots	2 PCI Express Gen3 x 16 Slots 1 PCI Express Gen3 x 8 Slot 1 PCI Express Gen2 x 4 Slot 1 PCI Express Gen2 x 1 Slot
	1 PCI Slot
CD/DVD drive	DVD-ROM, DVD+/-RW, Blu-Ray
Monitor	19" 1280x1024 screen resolution
Operating System	Windows 10
Recommended System	HP Z4G4

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5.2 EzDent-i

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

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

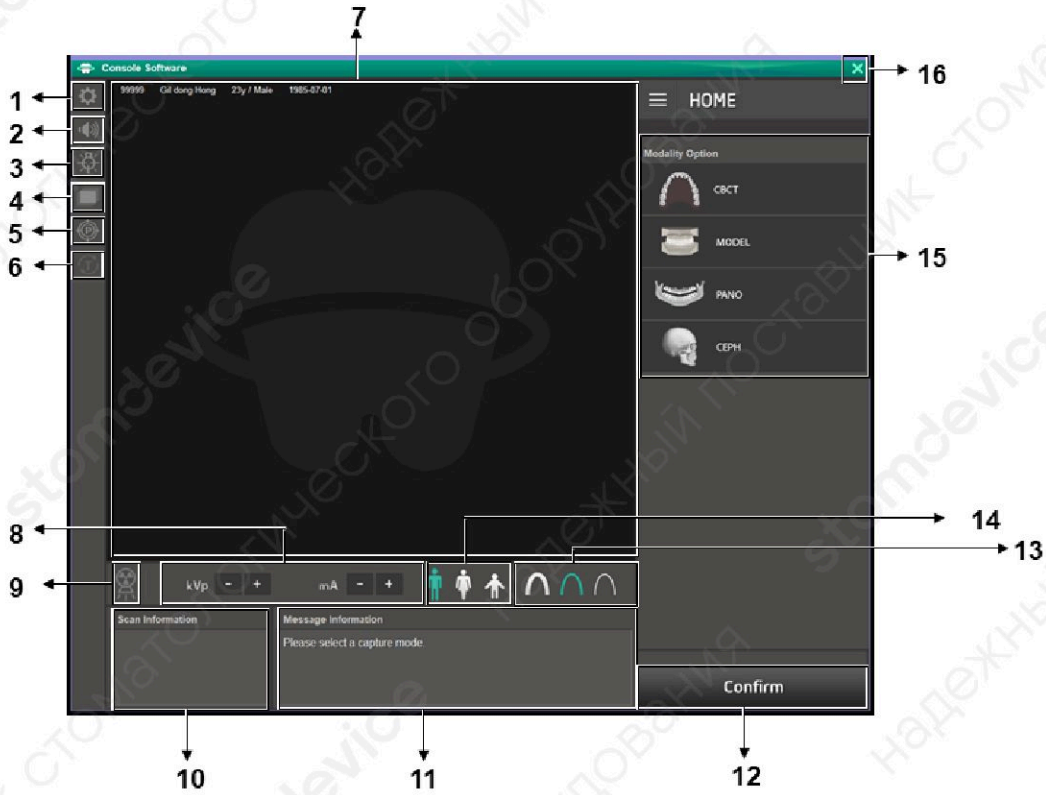
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5.3 Console Software

Using the console software, you can set and change exposure parameters.

NOTICE	The console software's UI and features can be updated without notice due to product enhancement.



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No.	Item	Description
1	**Settings** button	Sets X-ray exposure parameters and user environments such as language and auto-save option.
2	**Volume** button	Adjusts the guide message's volumes and deep sound during the X-ray exposure.
3	**Laser Beam ON/OFF** button	Turns on or off the laser beams. The button is enabled after clicking the **confirm** button.
4	**Manual Reconstruction** button	Performs a manual image reconstruction after automatic reconstruction fails. To perform a manual reconstruction: 1) Click the **manual reconstruction button**. 2) Select a modality. 3) Click **Search**. 4) Select an image for reconstruction. 5) Click the **manual reconstruction button** again.
5	**Phantom** button	Captures a phantom image. To capture a phantom image: 1) Click the **phantom button**. 2) Select a modality and click **Capture**. 3) Set exposure parameters and place a phantom jig. 4) Click **Ready**. 5) Press the **exposure switch**.
6	**Test Rotation** button	Performs a test rotation to check if the equipment touches the patient's body before an X-ray exposure. 1) To start a test rotation: 2) Ask the patient to enter the unit. 3) Select a modality. 4) Click Confirm. 5) Click the test rotation button. After clicking, the button turns green.  6) Click the laser beam On/Off button.

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<table>
<tr><th>No.</th><th>Item</th><th colspan="2">Description</th></tr>
<tr><td>7</td><td>Patient Information window</td><td colspan="2">Displays the selected patient information.</td></tr>
<tr><td>8</td><td>Tube Voltage and Current Adjustment</td><td colspan="2">Adjusts a tube voltage and current.</td></tr>
<tr><td>9</td><td>X-ray indicator</td><td colspan="2">Indicates whether the X-ray is on.
▪ Gray: X-ray is off
▪ Orange: X-ray is on</td></tr>
<tr><td>10</td><td>Scan Information window</td><td colspan="2">Displays estimated DAP (Dose Area Product), scan time, and exposure time after configuring exposure settings.</td></tr>
<tr><td>11</td><td>Guide Message window</td><td colspan="2">Displays text instructions for the user.</td></tr>
<tr><td rowspan="2">12</td><td rowspan="2">Confirm /Ready button</td><td>
</td><td>Confirms the exposure settings you selected.</td></tr>
<tr><td>
</td><td>Prepares the system ready for X-ray exposure. This button appears after clicking the confirm button.</td></tr>
<tr><td rowspan="4">13</td><td rowspan="4">X-ray intensity</td><td colspan="2">Sets the level of X-ray intensity according to the patient's age and head circumference. See the table below for an X-ray intensity selection guide:
<table>
<tr><th>Age Group</th><th>Average Head Circumference (cm)</th><th>Range (cm)</th><th>X-ray Intensity</th></tr>
<tr><td rowspan="3">Child</td><td rowspan="3">53±3</td><td>>53±3</td><td>Hard</td></tr>
<tr><td>53±3</td><td>Normal</td></tr>
<tr><td><53±3</td><td>Soft</td></tr>
<tr><td rowspan="3">Adult</td><td rowspan="3">56±3</td><td>>56±3</td><td>Hard</td></tr>
<tr><td>56±3</td><td>Normal</td></tr>
<tr><td><56±3</td><td>Soft</td></tr>
</table></td></tr>
<tr><td></td><td>Hard</td></tr>
<tr><td></td><td>Normal</td></tr>
<tr><td></td><td>Soft</td></tr>
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<table>
<tr><th>No.</th><th>Item</th><th>Description</th></tr>
<tr><td rowspan="4">14</td><td rowspan="4">Patient type</td><td>Selects a patient type according to the person's age and gender. See the table below for the patient selection guide:
<table>
<tr><th colspan="2">Gender / Age Group</th><th>VATECH's Standard</th></tr>
<tr><td colspan="2">Child</td><td>2 ~ 12 years of age</td></tr>
<tr><td rowspan="2">Adult</td><td>Man</td><td rowspan="2">> 12 years of age</td></tr>
<tr><td>Woman</td></tr>
</table></td></tr>
<tr><td></td><td>Man (Adult)</td></tr>
<tr><td></td><td>Woman (Adult)</td></tr>
<tr><td></td><td>Child (Under Age 12)</td></tr>
<tr><td>15</td><td>Modality Selection button</td><td>Selects an imaging option: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan.</td></tr>
<tr><td>16</td><td>EXIT button</td><td>Leaves the console software.</td></tr>
</table>

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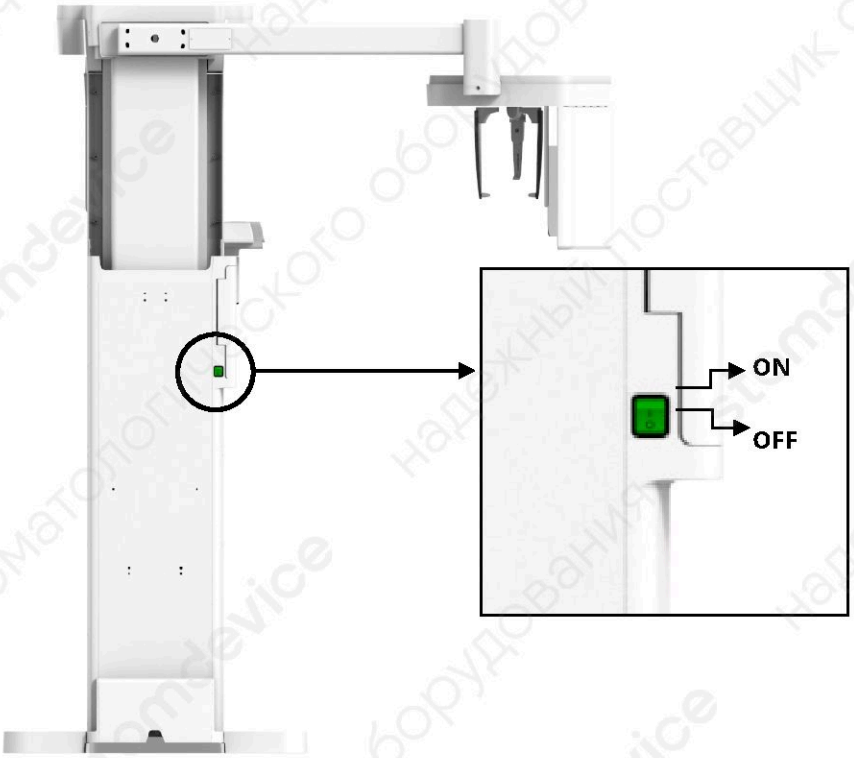
6. Getting Started

6.1 Turning on the Equipment

⚠WARNING	Ensure that the patient does not stand near the equipment when you are turning the system on. The patient can get injured by moving the rotating unit.

To turn on the equipment:

1. Press the main power switch located behind the column.



2. Check if the green light comes on the LED light in front of the rotating unit.

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6.2 Running the Image Viewer (EzDent-i)

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

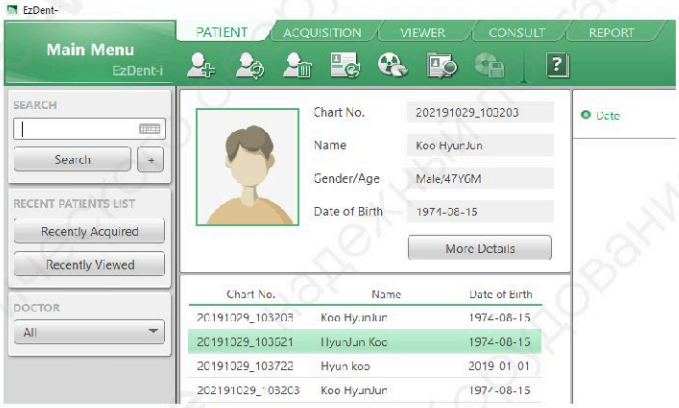
NOTICE	For further details on this subject, refer to the **EzDent-i User Manual**.
NOTICE	**Security Capabilities** ▪ It is recommended to install and operate **EzDent-i** SW within a secure operating environment that allows only authorized users to access a system network equipped with Windows built-in firewall, Windows Defender antispyware tools, and other commonly used 3rd party security tools and application systems. ▪ The latest updates for anti-virus software and a firewall are recommended. ▪ The software can be updated by the manufacturer only. Unauthorized software update through a third party, not the manufacturer, is prohibited. For cybersecurity issues related to the software and medical devices, please contact the manufacturer.
NOTICE	For **Green X (Model: PHT-75CHS)** dental computed tomography X-ray system, both 3D viewer (**Ez3D-i**) and Console Software are being accessed through 2D viewer (**EzDent-i**) SW. 3D viewer and Console Software do not have an image storage capacity of their own, and both programs will not be able to keep patient information.

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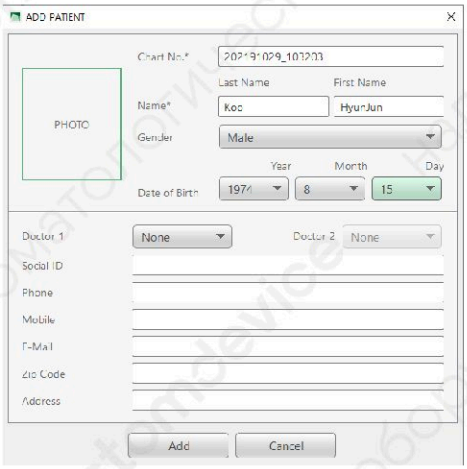
6.2.1 Creating a New Patient Record

To create a new patient record with **EzDent-i**:



EzDent-i Main Window

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



2. In the dialog box, fill out **Chart No**. and **Name**. If necessary, fill out other areas such as social ID and mobile.

3. Click  to save the new patient record.

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

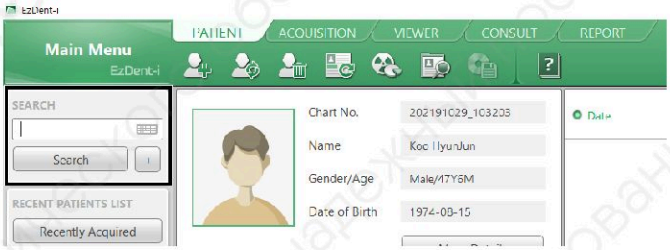
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6.2.2 Retrieving Patient Record

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

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



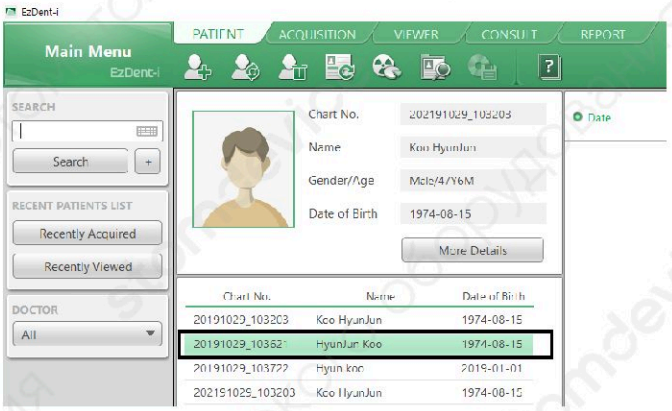
NOTICE

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



2. Click Search.

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



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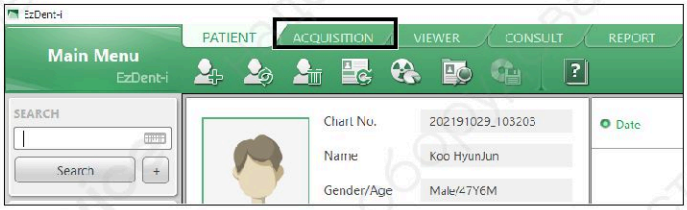
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6.2.3 Initiating the Console Software

To initiate the console software:

NOTICE	Before starting the console software, you must create new patient information. Go to **6.2.1 Creating a New Patient Information** for more information.

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



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



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7. How to Acquire PANO Images

7.1 PANO Imaging Program Overview

■ Result Images

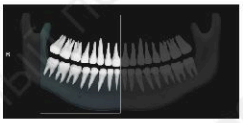
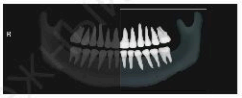
It provides 2D panoramic images.

■ Image Acquisition Method

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

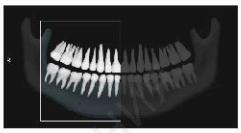
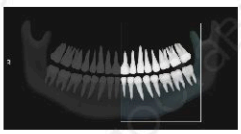
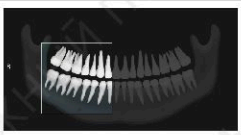
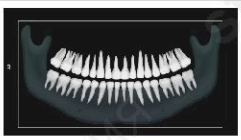
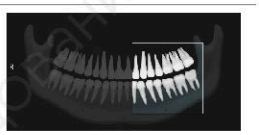
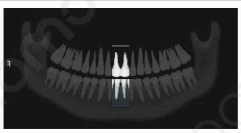
■ Examination Programs

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

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

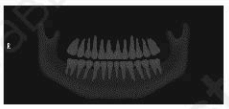
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Examination Type	Arch Selection	ROI	Example
		Standard	
	Orthogonal	Right	
		Front	
		Left	
		Bitewing Right*	
		Standard	
		Bitewing Left*	
		Bitewing*	
PANO Examination	Orthogonal	Bitewing Incisor* (Optional)	
PANO Examination (Insight PAN**)	Normal	-	

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Examination Type	Arch Selection	ROI	Example
	Child	-	
SPECIAL Examination	N/A	TMJ LAT Open	
		TMJ LAT Close	
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

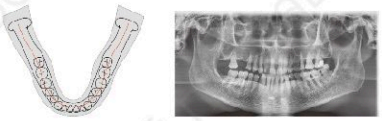
* Bitewing imaging mode is activated only when Orthogonal is selected in Arch Selection.

** When InsightPAN is selected, the user can freely change the exposure areas (FOV) with mouse control and drag.

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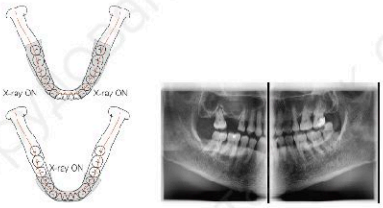
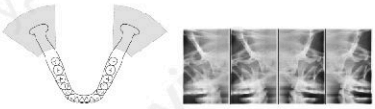
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■ Main Imaging Programs

Examination Type	Arch Selection	ROI	Description & Sample Image
PANO Examination	Narrow	Standard	A panoramic imaging mode for patients with a V-shaped arch trajectory. (Typically for some females) 
	Normal	Standard	A panoramic imaging mode for adult patients with a typical arch trajectory. 
	Wide	Standard	A panoramic imaging mode for the patients with a square-shaped arch trajectory. (Typically for some males) 
	Child	Standard	A panoramic imaging mode for child trajectory. (Less X-ray exposure than the Normal mode by more than 40%) 
	Orthogonal	Standard	A panoramic imaging mode to minimize the overlapped region of the teeth from the X-ray exposure, which is beamed perpendicularly between teeth. 

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Examination Type	Arch Selection	ROI	Description & Sample Image
		Bitewing** (Bitewing Incisor mode is Optional)	A panoramic imaging mode to acquire an image only for the region of interest through the orthogonal trajectory. (Pros: less X-ray exposure than the Normal mode. /Cons: TMJ and some parts of the maxillary sinus cannot be acquired.) 
SPECIAL Examination	N/A	TMJ LAT Open/Close	An imaging mode to acquire a lateral image of the TMJ, in which the X-ray beam is directed on the lateral TMJ region. (TMJ Open and Close) 
		TMJ PA Open/Close (Optional)	An imaging mode to acquire a TMJ image, in which the X-ray beam is directed on the frontal TMJ, with the patient's mouth open fully and closed. 
		Sinus LAT (Optional)	A special imaging mode to acquire a Sinus image, in which an X-ray beam is directed on the lateral region of the maxillary sinus. 

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7. How to Acquire PANO Images

Examination Type	Arch Selection	ROI	Description & Sample Image
		Sinus PA	A special imaging mode to acquire a Sinus image, in which an X-ray beam is directed at the frontal region of the maxillary sinus.  

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

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7.2 Configuring Exposure Settings

Before configuring the exposure setting, finish the steps in **Chapter 6. Getting Started.**

IMPORTANT	**Patient Motion Detection** is featured in Green X; it is designed to protect patients from the rotating unit's sudden movement during the exposure parameter configuration. When the system detects a patient inside of the equipment during the configuration, it will halt the procedure, and the following audio message will be played: "During the system preparation, a patient has been detected at the imaging location." Guide the patient out of the equipment to a safe location, then restart the image capture program.
IMPORTANT	**Patient motion detection** is **disabled in certain countries, including the United States.** For more information, contact your local Vatech Representative.

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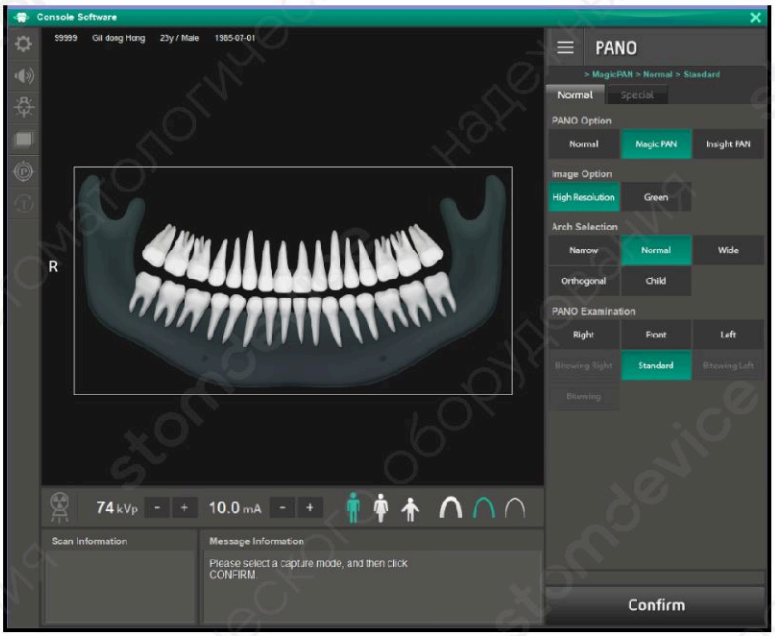
7.2.1 Normal Tab

To set the exposure settings on the Normal tab:

1. Select **PANO** from the **Modality Option**.



After clicking PANO, the main window looks as below



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2. Click the **Normal** tab.



3. Select a **PANO option**.



Mode	Description
Normal	Provides a normal panoramic image.
Magic PAN (Optional)	▪ Provides a single optimal panoramic image having multiple focal images combined. ▪ Minimizes the difference in the quality of images varies according to the patient's positioning and arch shape.
Insight PAN (Optional)	▪ Provides multiple panoramic images that have different focal planes, along with a typical panoramic image. ▪ Provides detailed verification of images in-depth direction.

NOTICE For **Insight PAN**, you can specify the X-ray exposure range.

4. Select an option from the **Image Option**.



Mode	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

NOTICE When you select the **Insight PAN** or **Magic PAN,** the buttons on the Image Option are disabled.

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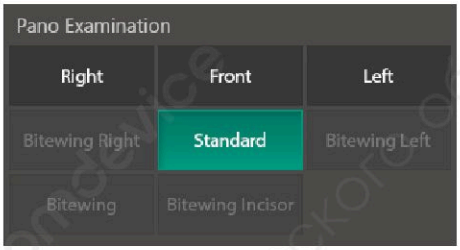
5. Select an option from the **Arch Selection.**



NOTICE

To enable Bitewing options (Bitewing, Bitewing Left, Bitewing Right, Bitewing Incisor), select **Orthogonal** from the arch selection menu.

6. Select an option from the **PANO Examination**.



7. Select a patient type.



8. Select an X-ray intensity.



9. Set tube voltage and current. Each time you click the -/+ button, the voltage increases by ±1 kVp, the current by ±1.0 mA.



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10. Click **Confirm**.



After clicking the button:

- The rotating unit moves to its initial scanning position.
- Laser beams are turned on.
- The scan information window displays DAP (dose area product), scan time, and exposure time.

IMPORTANT	After clicking **Confirm**, you cannot change exposure settings

11. Guide the patient to the equipment.

⚠ CAUTION	Until the rotating unit stops moving, do not allow the patient to enter the equipment.

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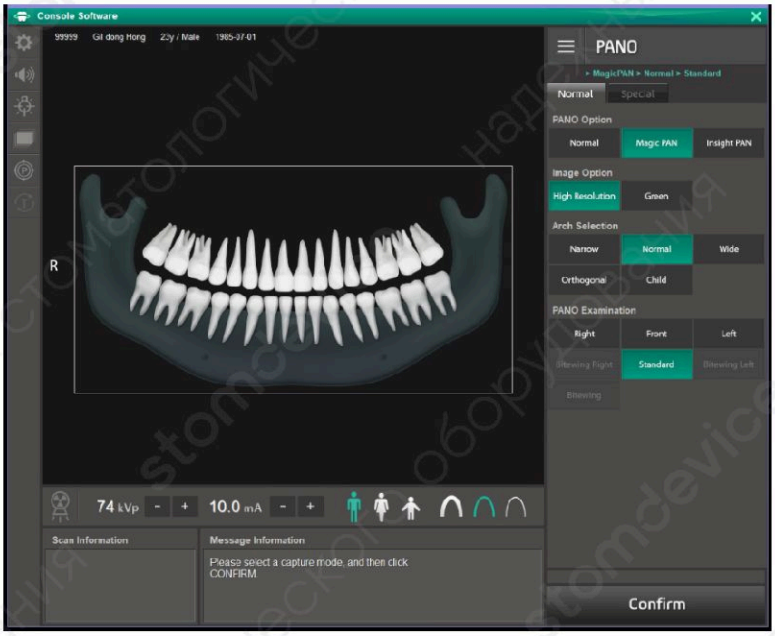
7.2.2 Special Tab

To set the exposure settings on the Special tab:

1. Select **PANO** from the **Modality Option**.



After clicking the **PANO**, the main window looks as the below:



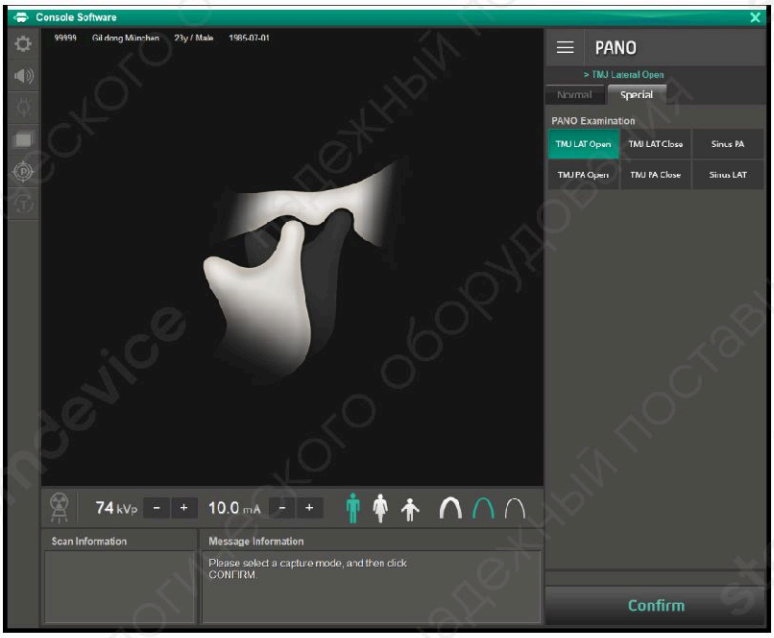
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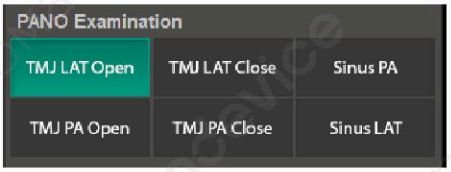
2. Click the **Special** tab.



After clicking the **Special** tab, the main window looks as the below:



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



4. Select a patient type.



5. Select an X-ray intensity.



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6. Set tube voltage and current. Each time you click the -/+ button, the voltage increases by ±1 kVp, the current by ±1.0 mA.



7. Click **Confirm**.



After clicking the button:

- The rotating unit moves to its initial scanning position.
- Laser beams are turned on.
- The scan information window displays DAP (dose area product), scan time, and exposure time.

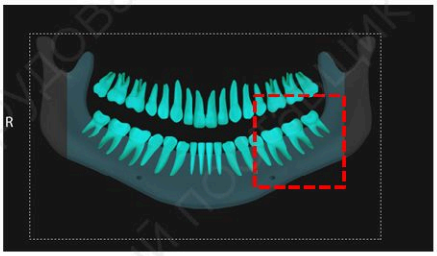
IMPORTANT	After clicking **Confirm**, you cannot change exposure settings

8. Guide the patient to the equipment.

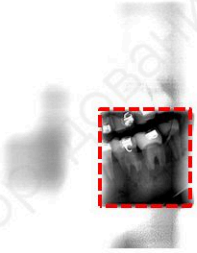
⚠ CAUTION	Until the rotating unit stops moving, do not allow the patient to enter the equipment.

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<Selected the exposure area in Console Software>



<Exposure area in real image>

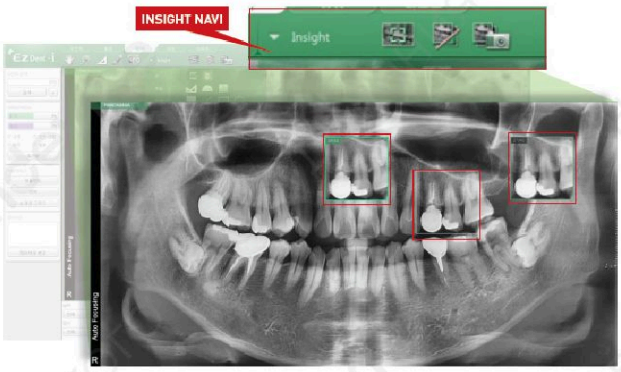
NOTICE

Considering the deviation of the various arches of the patient, if the exposure area is a single tooth, specify a sufficient exposure area, including the left and right teeth.

(The minimum selectable area: is about 50 x 50 mm^2.)

In terms of patient caring, it has the advantage of minimizing the amount of radiation exposure to the patient by adjusting the area of exposure.

The captured Insight PAN image can be viewed in the Insight NAVI of the EzDent-i (Insight NAVI) viewer.



For more information, refer to the EzDent-i (Insight NAVI) viewer's user manual.

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7.3 Patient Positioning

To prepare patients for imaging:

1. Remove metal objects that the patient wears or carries, such as glasses.
2. Cover the patient with a lead apron, blanket, or protective clothing.

⚠WARNING	▪ Cover patients with a lead apron or a blanket to protect their bodies from radiation exposure. ▪ Do not shine the laser beam directly into the person's eyes. This can cause vision loss. ▪ Pregnant women must consult a doctor before taking an X-ray
IMPORTANT	▪ Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition. ▪ Metal implants or bridges may reduce the quality of the images.

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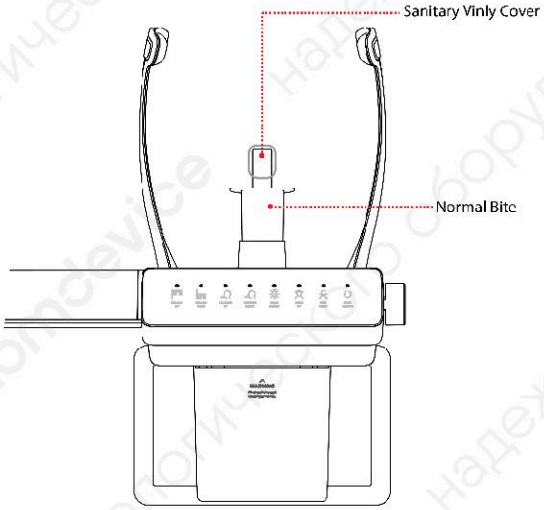
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7.3.1 Normal Mode

To position the patient for a normal panoramic image:

IMPORTANT	If you are positioning edentulous patients, insert **special bite B** into the normal chinrest instead of the normal bite block.

1. Insert a normal bite into the normal chinrest.
2. Cover the **normal bite** with a sanitary vinyl cover.



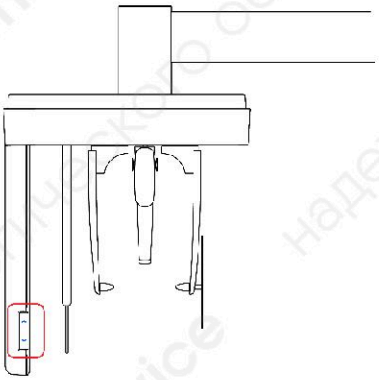
IMPORTANT	Use a new sanitary vinyl cover between each patient. Take off the cover each time the imaging procedure ends.
IMPORTANT	Ensure to cover the bite with FDA-cleared or CE-marked product.
IMPORTANT	Chinrest, bite, and other accessories that had contact with the patient should be cleaned between patients with a chlorine dioxide-based alcohol-free product.

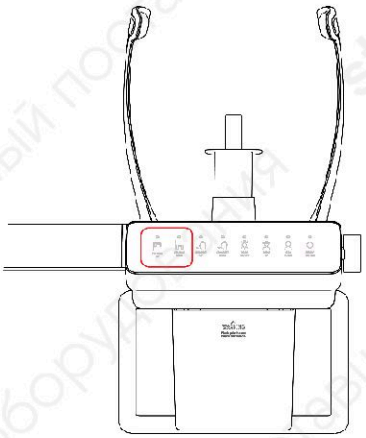
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3. Guide the patient to the equipment.

4. Press the column UP/DOWN button to adjust the column's height. You can find the button on the control panel or the CEPH unit (see below).





5. Ask the patient to:

   - Grab the handles with both hands
   - Put their chin on the chinrest.
   - Stand erect and stretch the neck straight.
   - Have shoulders parallel.
   - Lean forward until the chest press against the equipment.
   - Gently bite the tip of the bite with the front teeth

6. When the patient positioning is complete, ask the patient to:

   - Close their mouth.
   - Close their eyes.
   - Place the tongue on the roof of the mouth.

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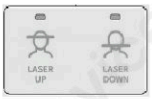
Laser Beam Positioning

After clicking **Confirm** on the console software, the following beams are turned on:

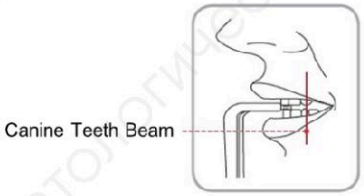
- Horizontal beam
- Vertical beam
- Canine Teeth beam
- Shoulder beam

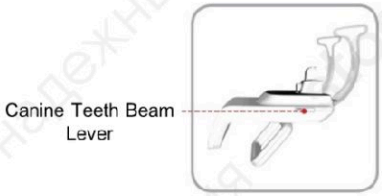
Follow the steps below to position each beam:

1. Check if the **vertical beam** is aligned with the **patient's mid-sagittal line** (plane). Adjusts the patient's head position if necessary.
2. Check if the **horizontal beam** is in line with the patient's Frankfurt line (plane). If necessary, use the **laser up/down button** to adjust the beam's height.



3. Check if the **canine teeth beam** hits the patient's canine. If necessary, use the lever to adjust the beam's location.





4. Check if the **shoulder beam** touches any part of the patient's shoulder. Ask the patient to lower his or her shoulder if necessary.

⚠WARNING	Ensure that the laser beam does not hit the patient's eyes. Direct contact with the laser beam may cause vision loss.
NOTICE	The laser up/down button works only in the panoramic mode. In other modes, you cannot move the horizontal beam.

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Finishing Patient Positioning

After finishing the patient positioning:

1. Click the **Ready** button. X-ray exposure has not started yet.



2. Now go to **7.4 Taking an X-ray Exposure** to start the exposure.

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7.3.2 TMJ Open Mode

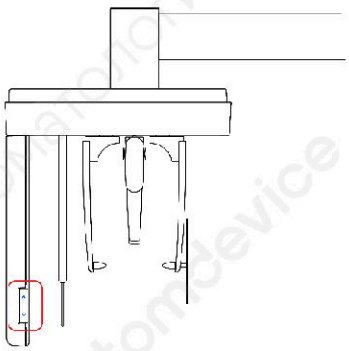
IMPORTANT	**When selecting TMJ mode**, the chinrest automatically goes down by 20 mm. Adjust the column's height after the chinrest finishes going down for accurate patient positioning.

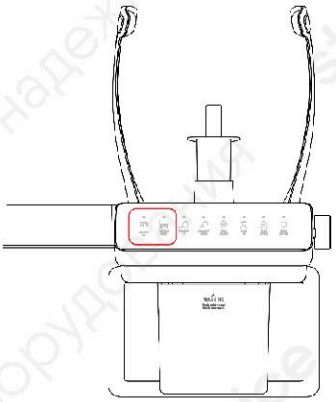
To position patients for TMJ open mode:

1. Insert the **special bite A** into the normal chinrest.

IMPORTANT	Check if the **special bite A** and **chinrest** are clean before using the parts.
IMPORTANT	Chinrest, bite, and other accessories that had contact with the patient should be cleaned between patients with a chlorine dioxide-based alcohol-free product.

2. Turn the temple support Open/Close knob to open the temple supports.
3. Guide the patient to the equipment.
4. Press the column UP/DOWN button to adjust the column's height. You can find the button on the control panel or the CEPH unit (see below).





5. Ask the patient to
   - Stand up straight
   - Grip the handle with both hands
   - Place the chin on the chinrest
   - Relax and balance the shoulder
   - Press the chest to the equipment

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6. Ask the patient to rest the acanthion point on the **special bite A** and tilt the head **forward at 5**°. Ensure that the patient's jaw does not touch the equipment.

7. When the patient positioning is complete, ask the patient to:

   - Open their Mouth
   - Close their eyes
   - Place the tongue on the roof of the mouth

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Laser Beam Positioning

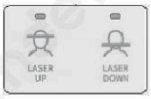
NOTICE	The canine beam is turned off in **TMJ open, close,** and **Sinus mode.**

After clicking **Confirm** on the console software, the following beams are turned on:

- Horizontal beam
- Vertical beam
- Canine Teeth beam
- Shoulder beam

Follow the steps below to position each beam:

1. Check if the **vertical beam** is aligned with the **patient's mid-sagittal line** (plane). Adjusts the patient's head position if necessary.
2. Check if the **horizontal beam** is in line with the patient's Frankfurt line (plane). If necessary, use the **laser up/down button** to adjust the beam's height.



3. Check if the **shoulder beam** touches any part of the patient's shoulder. Ask the patient to lower his or her shoulder if necessary.

⚠WARNING	Ensure that the laser beam does not hit the patient's eyes. Direct contact with the laser beam may cause vision loss.
NOTICE	**The laser up/down button** works only in the panoramic mode. In other modes, you cannot move the horizontal beam.

Finishing Patient Positioning

After finishing the patient positioning.

1. Click the **Ready** button. X-ray exposure has not started yet.



2. Now go to **7.4 Taking an X-ray Exposure** to start the exposure.

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7.3.3 TMJ Close Mode

Acquire a TMJ close image after taking a TMJ open image.

NOTICE To acquire a TMJ close image, you must complete TMJ open imaging procedure.

To position the patient for TMJ close mode:

1. After you finish capturing a TMJ open image, the message "Do you want to capture a TMJ close image" will appear on the console software.

   Click **O.K**. to capture a TMJ close image,



2. Guide the patient to the equipment.
3. Ask the patient to rest the acanthion point on the **special bite A** and tilt the head **forward at 5**°. Ensure that the patient's jaw does not touch the equipment.
4. When the patient positioning is complete, ask the patient to
   - Close the Mouth
   - Close the eyes
   - Place the tongue on the roof of the mouth
   - Swallow
   - Breath with noses

Positioning Laser Beams

This part is the same as the TMJ open mode.

Finishing Patient Positioning

This part is the same as the TMJ open mode.

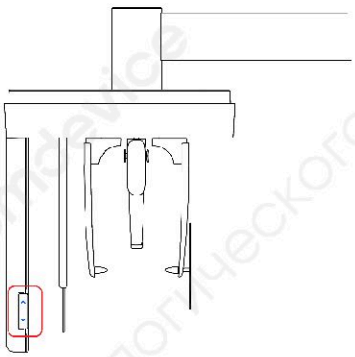
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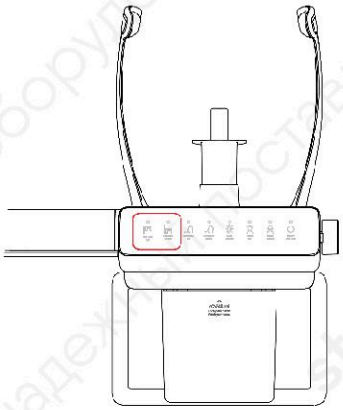
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7.3.4 Sinus Mode (LAT / PA)

To position the patient for sinus mode:

1. Insert the **special bite A** into the normal chinrest.
2. Turn the **temple supports Open/Close knob** clockwise to open Temple Supports.
3. Ask the patient to enter the unit.
4. Press the **column UP/DOWN button** to adjust the Column's height for the patient. You can find the button on the control panel and the CEPH unit (**see below**).





5. Ask the patient to:
   - Stand up straight
   - Grip the handle with both hands
   - Place the chin on the chinrest
   - Relax and balance the shoulder
   - Press the chest to the equipment

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6. Ask the patient to rest the acanthion point (the base of the nose) on Special Bite A and tilt the head forward about 5°. Ensure that the patient's jaw does not touch the equipment. It can be difficult for the patient to stay in the proper posture if his or her jaw touches the equipment.

7. When the patient positioning is complete, ask the patient to:

   - Open their mouth
   - Close their eyes
   - Place the tough on the roof of the mouth

Positioning Laser Beams

This part is the same as the TMJ open mode.

Finishing Patient Positioning

This part is the same as the TMJ open mode.

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7.4 Taking an X-ray Exposure

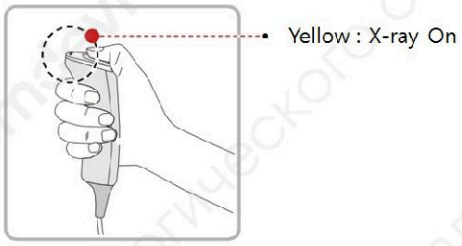
⚠WARNING	In an emergency, release the **exposure switch** to stop X-ray exposure.
ⓘ CAUTION	Do not use the PC during the X-ray exposure.

To take an X-ray exposure:

1. Ask the patient to close their eyes.
2. Leave the X-ray room and close the door.

ⓘ CAUTION	Ensure to keep vocal and visual contact with the patient during the X-ray exposure.

3. Press the **exposure switch**. Hold down the switch until the end of X-ray exposure.



When the X-ray exposure begins:

- The LED light on the **exposure switch** turns yellow.
- The LED light on the top of the rotating unit turns yellow.
- A sound alert is turned on.
- The radiation mark on the console software turns orange.



4. Release the **exposure switch** when you see the "Imaging capturing is completed" message on the screen.

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7.5 After an X-ray exposure

When the X-ray exposure ends,

1. Open the temple supports and guide the patient out of the equipment.
2. Remove the sanitary vinyl cover from the bite block.
3. Press **Ready** to send the rotating unit back to its initial position.



7.6 Checking the Captured Images

Captured images are converted to DICOM format and transferred to EzDent-i. You can view and confirm the images in EzDent-i.

NOTICE	For more information on how to use EzDent-i, go to the EzDent-i user manual.

1. Click **Save** to save the captured image. If you selected the auto-save option as a default setting, the image is saved automatically.
2. Double-click one of the patient information in the patient list.
3. The system starts **Ez3D-i** automatically and a 3D viewing of the saved image.

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8. How to Acquire CEPH Images (Optional)

8.1 CEPH Imaging Program Overview

■ Result Images

It provides conventional 2D cephalometric images.

■ Image Acquisition Method

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

■ Examination Programs

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

Examination Area	Description	Position
Lateral/ Full Lateral (Optional)	▪ Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate. ▪ Measures the angles formed by the connecting lines between the cranial measurement points to further assess the growth of the facial region. It's widely used in Orthodontics and Oral and Maxillofacial Surgery.	 <Lateral>  <Full Lateral>
PA	▪ The radiation is directed from the posterior of the skull to the anterior. ▪ It is used to examine cranial diseases, trauma, and congenital malformations. ▪ It is used to assess the growth of the lateral side of the face. It is also used to examine the ramus mandibulae, the posterior region of the third-largest molar in the lower jaw, the sidewall of the maxillary sinus, the frontal sinus, antrum ethmoidal olfactory pits, and optic disc pits.	 <PA>

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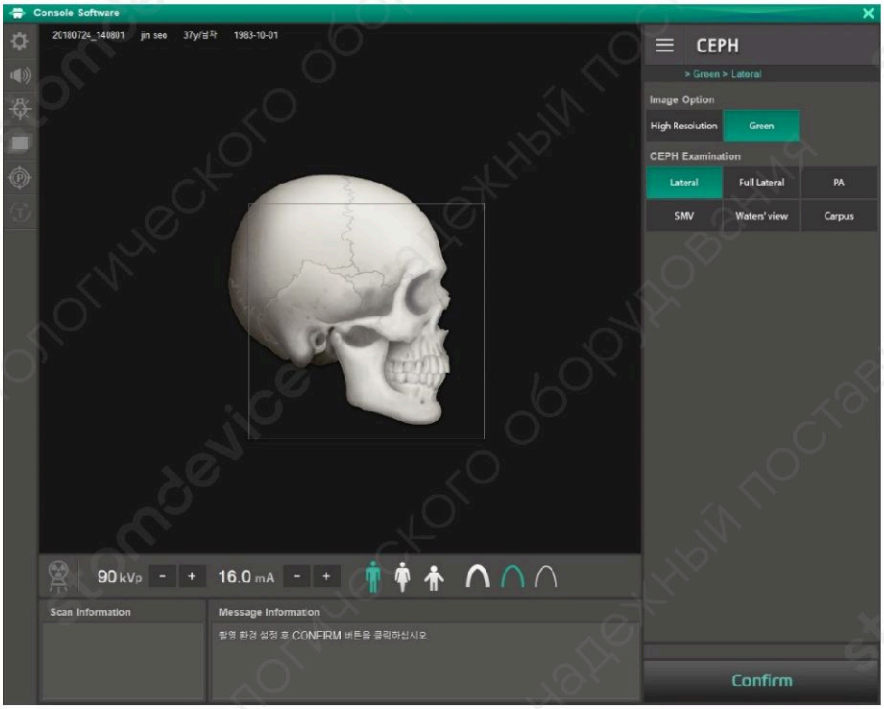
Examination Area	Description	Position
	▪ Measures the angles formed by the connecting lines between the cranial measurement points to further assess the growth of the facial region. It is widely used in Orthodontics and Oral and Maxillofacial Surgery.	
SMV	▪ Used to study the base of the skull, horizontal angulation of the mandibular condylar axis, the sphenoid sinus, the curvature of the lower jaw, the sidewall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull.	 <SMV>
Waters' view	▪ Used to study the frontal sinus, the antrum ethmoidal, the optic disc pit, the frontozygomatic suture, the nasal cavity, and the coronoid process between the upper jaw and the zygomatic arch.	 <Waters' view>
Carpus	▪ Used to assess hand bone age to compare the changes in the skull.	 <Carpus>

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8.2 Configuring Exposure Settings

Before configuring the exposure setting, finish the steps in **Chapter 6. Getting Started.**



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1. Select **CEPH** from the **Modality Option**.

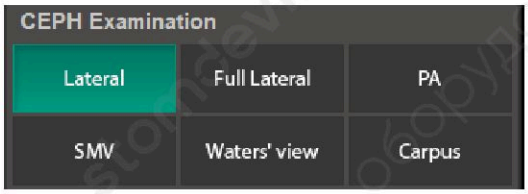


2. Select an option from the **Image Option**.



Mode	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

3. Select an option from the **CEPH Examination**.



4. Select a patient type.



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5. Select an X-ray intensity.



6. Set tube voltage and current. Each time you click the -/+ button, the voltage increases by ±1 kVp, the current by ±1.0 mA.



7. Click **Confirm**.



After clicking the button:

- The rotating unit moves to its initial scanning position.
- The laser beams are turned on.
- Scan information displays DAP (dose area product), scan time, and exposure time.

IMPORTANT	After clicking **Confirm**, you cannot change exposure settings

8. Guide the patient to the equipment.

⚠ CAUTION	Until the rotating unit stops moving, do not allow the patient to enter the equipment.

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8.3 Patient Positioning

To prepare patients for imaging:

1. Remove metal objects that the patient wears or carries, such as glasses.
2. Cover the patient with a lead apron, blanket, or protective clothing.

⚠WARNING	▪ Cover patients with a lead apron or blanket to protect their bodies from radiation exposure. ▪ Do not shine the laser beam directly into the person's eyes. This can cause vision loss. ▪ Pregnant women must consult a doctor before taking an X-ray
IMPORTANT	▪ Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition. ▪ Metal implants or bridges may reduce the quality of the images.

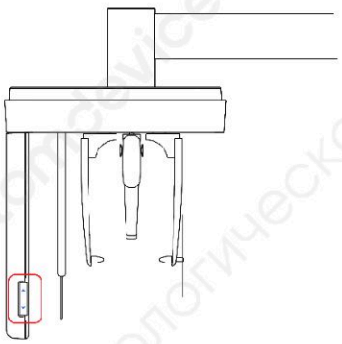
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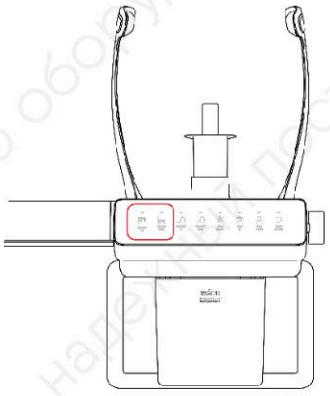
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8.3.1 Lateral / Full Lateral (Optional) Mode

To position the patient for a lateral or full lateral image,

1. Turn the nasal positioner to the **Lateral** mode marker as shown below.
2. Widen the distance between the two ear rods
3. Guide the patient to the CEPH unit
4. Ask the patient to stand erect. The patient's shoulder must be parallel to the floor, and his or her neck must be relaxed.
5. Press the **column UP/DOWN button** on the control panel or CEPH unit to adjust the column's height for the patient. You can also use the column UP/Down switch (optional).





⚠ CAUTION	Ensure to align the ear rods after changing the column's height for the patient.

6. Fit the ear rods along the patient's ear canals to keep the patient's head in position. The patient's Frankfurt line(plane) must be parallel to the floor.
7. Place the nasal positioner on the patient's Nasion point. The height of the nasal positioner can be adjusted.
8. Ask the patient to swallow and remain still until the X-ray exposure is complete.

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



10. Go to **8.4 Taking an X-ray Exposure** and start an X-ray exposure.

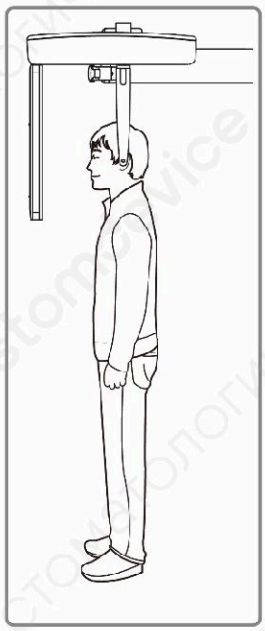
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8.3.2 PA Mode

To position the patient for a PA image:

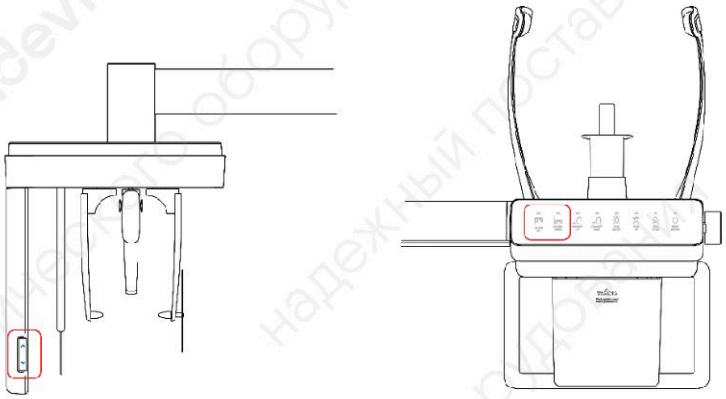
1. Turn the nasal positioner to the PA/Waters' view and Carpus marker, as shown below.
2. Fold the nasal positioner up. The nasal positioner is not used for PA mode.
3. Guide the patient to the CEPH unit.
4. Ask the patient to stand erect, facing the sensor. The patient's shoulder must be parallel to the floor, and his or her neck must be relaxed.



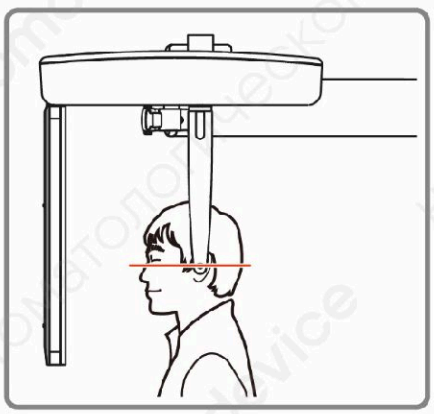
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5. Press the **column UP/DOWN button** on the control panel or CEPH unit to adjust the column's height for the patient. You can also use the column UP/Down switch (optional).



6. Fit the ear rods along the patient's ear canals to keep the patient's head in position. The patient's Frankfurt line(plane) must be parallel to the floor.



7. Ask the patient to swallow saliva and remain still until the X-ray exposure is complete.

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



9. Go to **8.4 Taking an X-ray Exposure** and follow the procedure for the X-ray exposure.

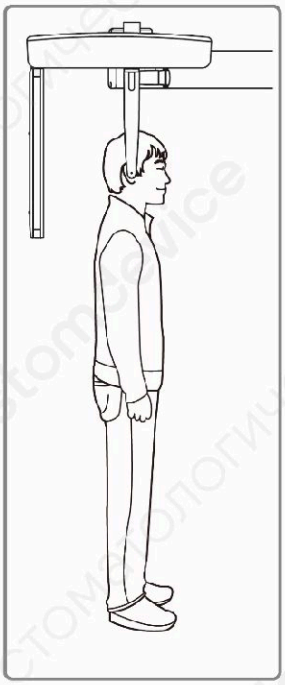
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8.3.3 SMV Mode

To position the patient for an SMV image:

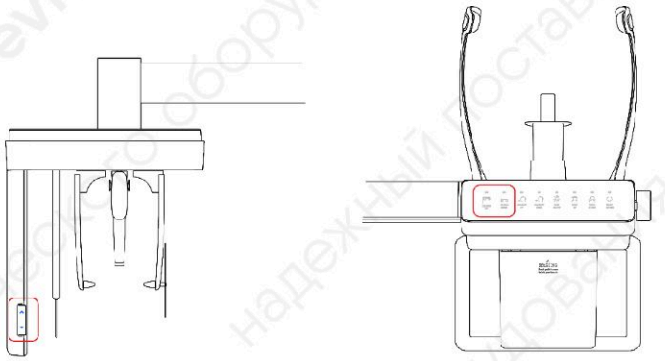
1. Turn the nasal positioner to the **SMV** mode marker, as shown below.
2. Fold the nasal positioner up. The nasal positioner is not used for SMV mode.
3. Guide the patient to the CEPH unit.
4. Ask the patient to stand erect, facing the X-ray tube.



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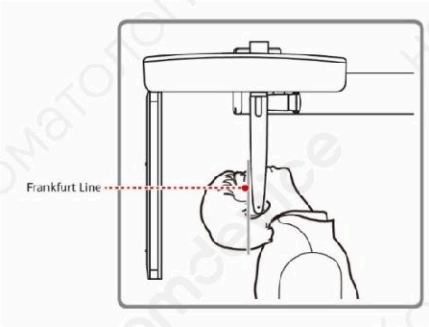
5. Press the **column UP/DOWN button** on the control panel or CEPH unit to adjust the column's height for the patient. You can also use the column UP/Down switch (optional).



CAUTION	Ensure to align the ear rods after changing the column's height for the patient.

6. Fit the ear rods along the patient's ear canals to keep the patient's head in position. The patient's Frankfurt line (plane) must be parallel to the floor.

7. Carefully tilt the patient's head back until his or her Frankfurt line (plane) is vertical to the floor.



8. Ask the patient to swallow and remain still until the X-ray exposure is complete.

9. Click the **Ready**. The X-ray exposure has not started yet.



10. Go **to 8.4 Taking an X-ray Exposure** to start the exposure

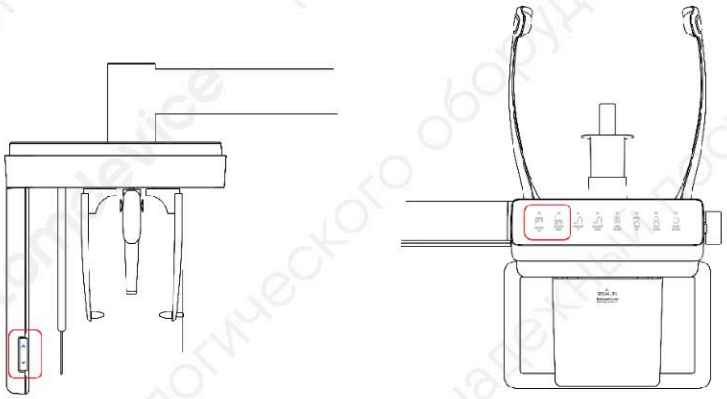
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8.3.4 Waters' View Mode

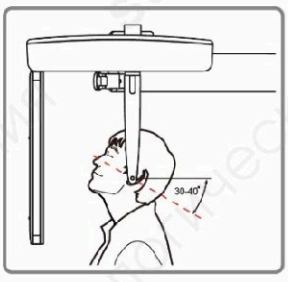
To position the patient for a Water's view image

1. Turn the **nasal positioner** to the Waters' view marker and fold the positioner up. For water's view mode, you don't need the positioner.
2. Guide the patient to the CEPH unit.
3. Ask the patient to stand erect, facing the X-ray sensor. The patient's shoulder must be parallel to the floor, and the neck must be relaxed.
4. Press the **column UP/DOWN button** on the control panel or CEPH unit to adjust the column's height for the patient. You can also use the column UP/Down switch (optional).



⚠ CAUTION	Ensure to align the ear rods after changing the column's height for the patient.

5. Fit the ear rods along the patient's ear canals to keep the patient's head in position. The patient's Frankfurt line (plane) must be parallel to the floor.
6. Ask the patient to tilt his or her neck back to 30˚ - 40˚, as shown in the image below.



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7. Ask the patient to swallow saliva and remain still until the X-ray exposure is complete.

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



9. Go to **8.4 Taking an X-ray Exposure** and follow the procedure for the X-ray exposure.

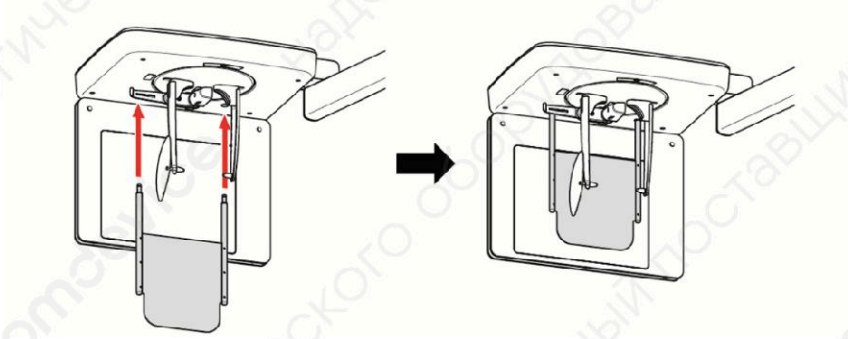
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8.3.5 Carpus Mode

To capture the image on carpus mode, you must install the carpus plate before the imaging process. Follow the procedure below to position the patient for the mode:

1. Turn the nasal positioner to the PA / Waters' view / Carpus mode marker, as shown below.
2. Fold the nasal positioner up. The nasal positioner is not used in Carpus mode.
3. Slide the two ends of the carpus plate into the two holes on the CEPH unit as below. Ensure to check that the carpus plate is fully locked in the position before moving on to the next step.



4. Ask the patient to place his or her right-hand flat on the carpus plate. All fingers must be stretched out and remain in the position until the scanning is complete.
5. Click the **Ready**. The X-ray will not be emitted at this point.



6. Go to **8.4 Taking an X-ray Exposure** and follow the procedure for the X-ray exposure.

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8.4 Taking an X-ray Exposure

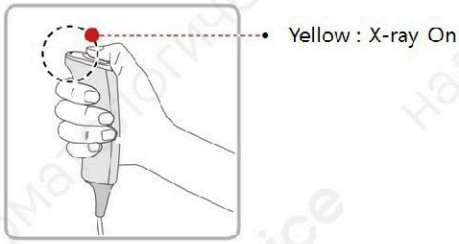
⚠ WARNING	In an emergency, release the **exposure switch**.
ⓘ CAUTION	Do not use the PC during the X-ray exposure.
IMPORTANT	Before starting an X-ray exposure, ask the patient: ▪ To close their eyes. ▪ To hold their breath and stop swallowing. ▪ Stay in their position until the end of X-ray exposure.

To take an X-ray exposure:

1. Ask the patient to close their eyes.
2. Leave the X-ray room and close the door.

ⓘ CAUTION	Ensure to keep vocal and visual contact with the patient during the X-ray exposure.

3. Press the **exposure switch**. Hold down the switch until the end of X-ray exposure.



When the X-ray exposure begins:

- The LED light on the **exposure switch** turns yellow.
- The LED light on the top of the rotating unit turns yellow.
- A sound alert is turned on.
- The radiation mark on the console software turns orange.



4. Release the **exposure switch** when you see the "Imaging capturing is completed" message on the screen.

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8.5 After an X-ray Exposure

When the X-ray exposure ends,

1. Open the temple supports and guide the patient out of the equipment.
2. Remove the sanitary vinyl cover from the bite block.
3. Press **Ready** to send the rotating unit back to its initial position.



8.6 Checking the Captured Images

Captured images are converted to DICOM format and transferred to **EzDent-i.** You can view and confirm the images in **EzDent-i**.

NOTICE	For more information on how to use EzDent-i, go to the EzDent-i user manual.

1. Click **Save** to save the captured image. If you selected the auto-save option as a default setting, the image is saved automatically.
2. Double-click one of the patient information in the patient list.
3. The system starts **Ez3D-i** automatically and a 3D viewing of the saved image.

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9. How to Acquire CBCT Images

9.1 CBCT Imaging Program Overview

■ Result Images

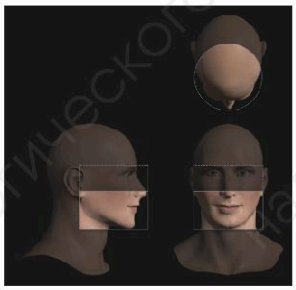
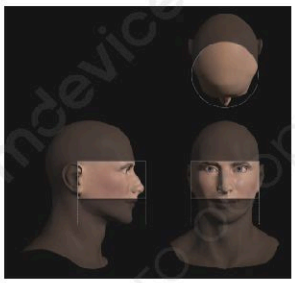
It provides conventional 3D CT sliced images.

■ Image Acquisition Method

It acquires images with the X-ray beam scanning specific oral & maxillofacial regions and reconstructs them into 3D sliced images.

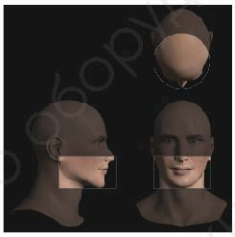
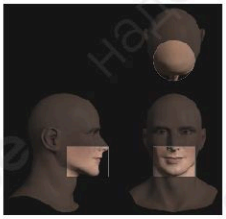
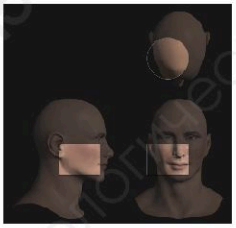
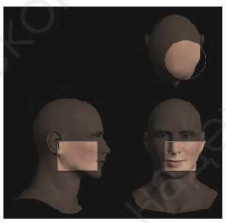
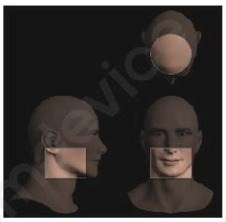
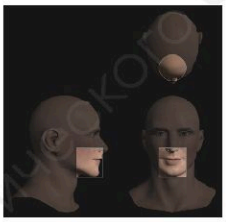
■ Examination Programs

It is classified as below based on the FOV.

Available FOVs (cm)	ROI	Description
Double Scan (Optional)	 <Mandible/Center>  <Maxilla/Center> **NOTICE**: After taking two consecutive exposures in the order of "1 → 2", it is automatically synthesized and displayed as one full image.	- Full arch, sinus, left and right TMJ area can be checked - Suitable for most intra-oral surgery, including multiple implant placement

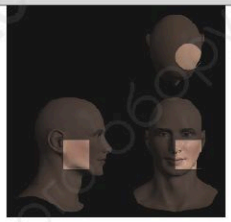
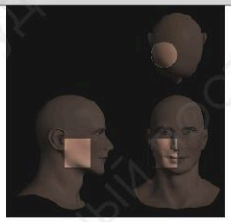
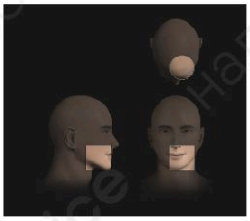
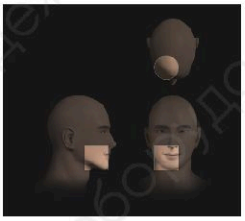
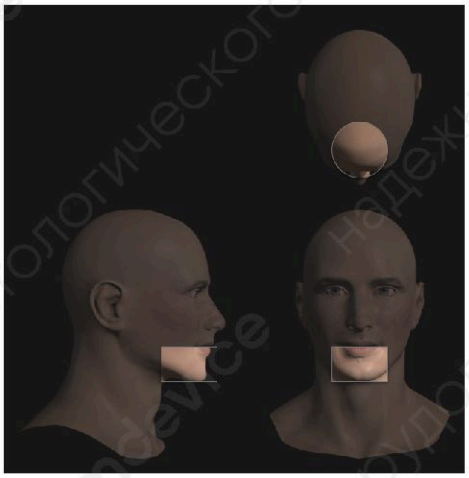
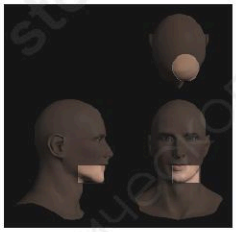
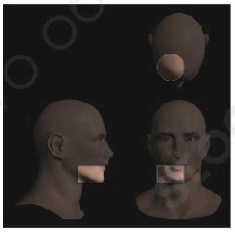
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Available FOVs (cm)	ROI	Description
16x9	 <Occlusion/Center>	- Covers full arch region, sinus, and left/right TMJ. - Suitable for most oral surgery cases as well as multiple implant surgery.
12x9	 <Occlusion/Center>  <TMJ/Right>  <TMJ/Left>  <Airway/Center>	- Covers both maxillary and mandibular structures, including the 3rd molar region. - TMJ Right/Left and Airway mode are available.
8x8	 <Occlusion/Center>	- Selectable FOV for region (left/ center/right). - Covers both maxillary and mandibular areas and left/right TMJ.

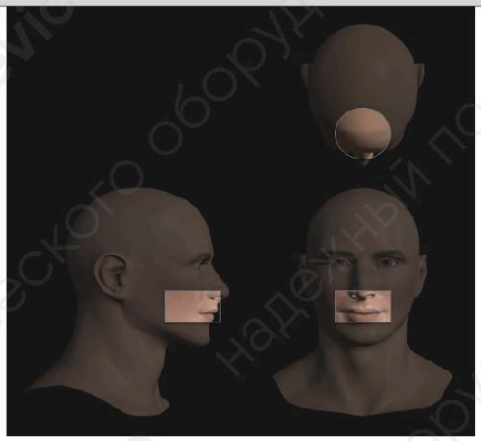
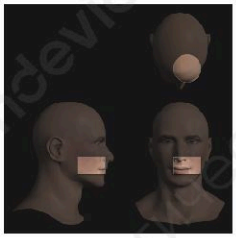
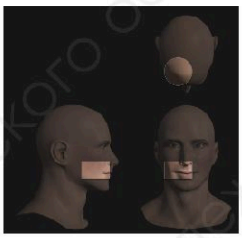
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Available FOVs (cm)	ROI	Description
	 <TMJ/Left>  <TMJ/Right>  <Occlusion/Left>  < Occlusion/Right>	
8x5	 <Mandible/Center>  <Mandible/Left>  <Mandible/Right>	- Selectable FOV for region (left/ center/right). - Covers both maxillary and mandibular areas.

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Available FOVs (cm)	ROI	Description
	 <Maxilla/Center>  < Maxilla/Left>  < Maxilla/Right>	
5x5		- Covers 3~4 areas through capturing ROI. - Can acquire 3~4 teeth at once. - Voxel Size: 0.08/0.12 applied.

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Available FOVs (cm)	ROI	Description
Endo (4x4)		- Covers 3~4 areas through capturing ROI. - Can acquire 3~4 teeth at once. - Voxel Size: 0.05 applied.

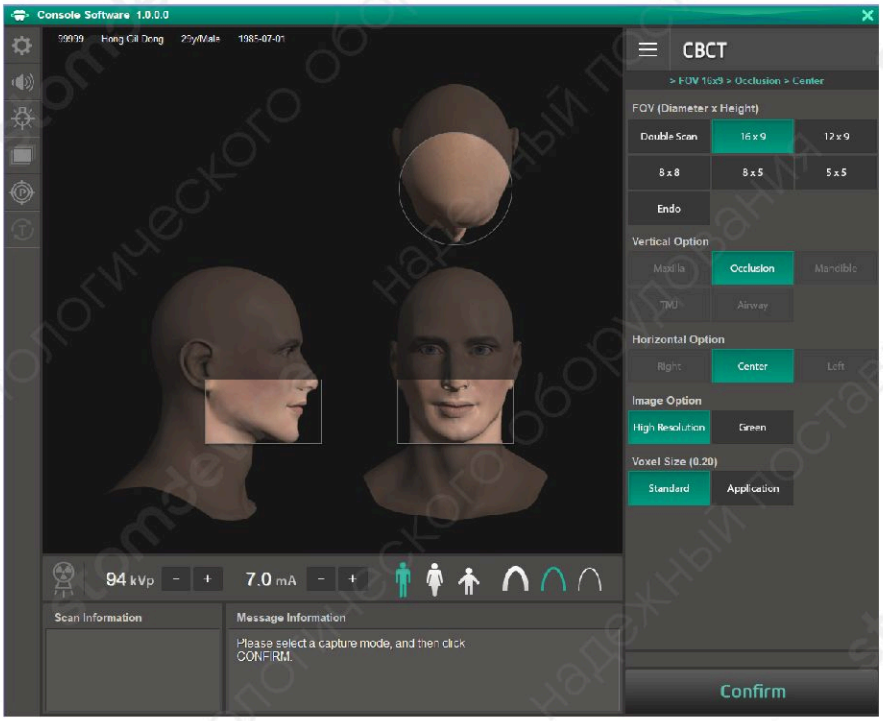
NOTICE	The Endo mode FOV size is 40 x 40 mm^2, which is an area including 2-3 teeth. Before starting the X-ray exposure, check the status of wisdom teeth. Then select the location of the tooth for imaging to provide a scout function for accurate exposure.

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9.2 Configuring Exposure Settings

Complete the steps in **6. Getting Started** before configuring exposure settings in console software.



Console Software Window

IMPORTANT	**Patient Motion Detection** is featured in Green X; it is designed to protect patients from the rotating unit's sudden movement during the exposure parameter configuration. When the system detects a patient inside of the equipment during the configuration, it will halt the procedure, and the following audio message will be played: "During the system preparation, a patient has been detected at the imaging location." Guide the patient out of the equipment to a safe location, then restart the image capture program.
IMPORTANT	**Patient motion detection** is a feature that is **disabled in certain countries, including the United States.** For more information, contact your local Vatech Representative.

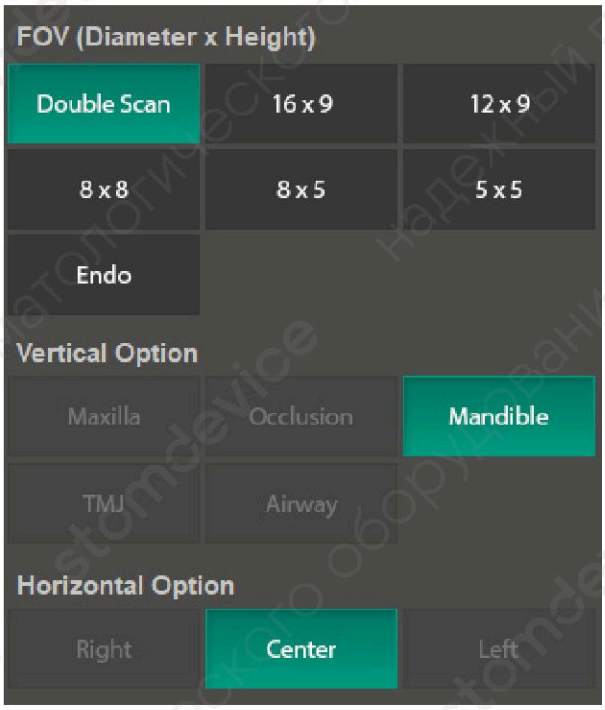
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1. Select **CBCT** from the **Modality Option**.



2. Select a **FOV**. Based on your FOV selection, the system selects a vertical and horizontal option.



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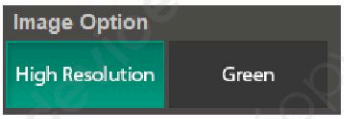
Available options for selected FOV are listed in the table below:

Available FOV (cm)	Vertical option	Horizontal option
16x15 (Double Scan; 16x9 stitching)	Mandible (First Scan) Maxilla (Second Scan)	Center
16x9	Occlusion	Center
12x9	Occlusion	Center
	TMJ	Right
		Left
	Airway	Center
8x8	Occlusion	Right
		Center
		Left
	TMJ	Right
		Left
8x5	Maxilla	Right
		Center
		Left
	Mandible	Right
		Center
		Left
5x5	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)
Endo (4x4)	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)

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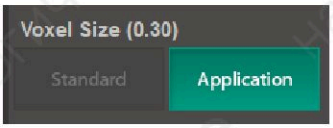
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3. Select an option from the **Image Option**.



Mode	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

4. Select an option from the **Voxel Size**.



5. Select a patient type.



6. Select an X-ray intensity.



7. Set tube voltage and current. Each time you click the -/+ button, the voltage increases by ±1 kVp, the current by ±0.1 mA.



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8. Click **Confirm**.



After clicking the button:

- The rotating unit moves to its initial scanning position.
- Laser beams are turned on.
- The scan information window displays DAP (dose area product), scan time, and exposure time.

IMPORTANT	You cannot change exposure settings after clicking **Confirm**.

9. Guide the patient to the equipment.

⚠ CAUTION	Until the rotating unit stops moving, do not allow the patient to enter the equipment.

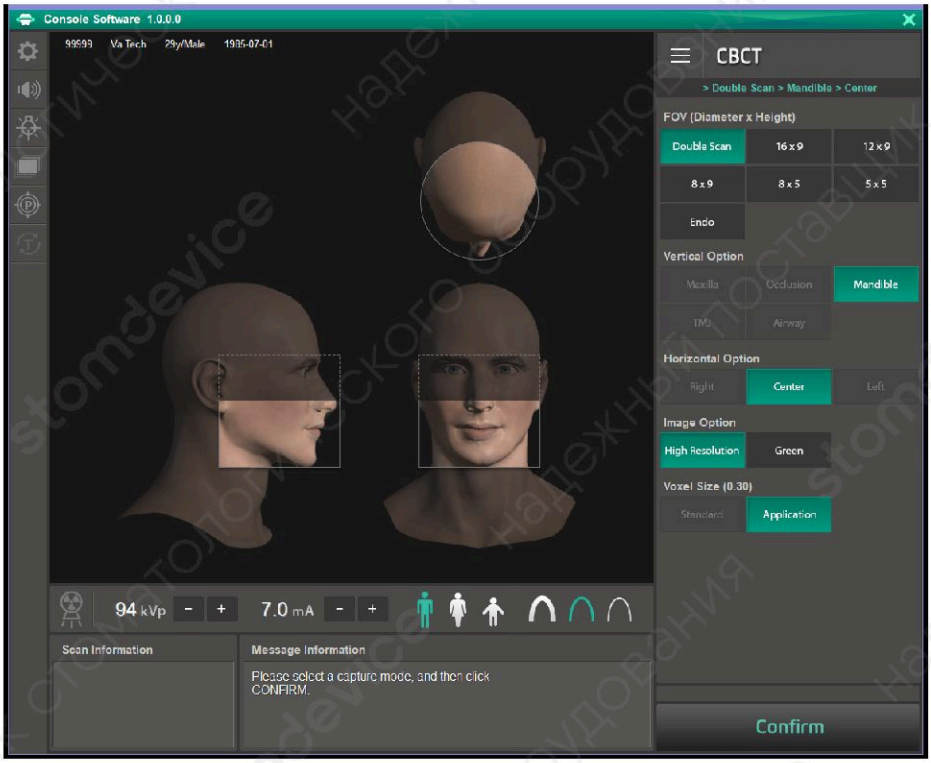
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9.3 Acquiring a Double Scan Image

Double scan mode provides a full radiographic image of the upper and lower jaw. The system runs a rapid scan of upper and lower jaws and stitches two images into one CBCT image.

IMPORTANT	Patient anatomy that is within a central 6 cm tall region of the FOV [comprising 25 % of the total FOV] may receive an increased X-ray dose depending on the FOV setting.



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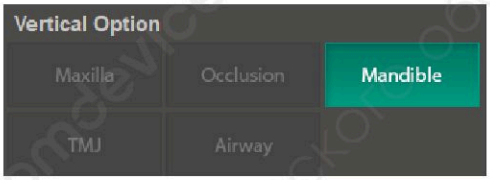
9.3.1 Taking the First Scan

In the Double Scan mode, the system captures a mandible image first. To start the first scan:

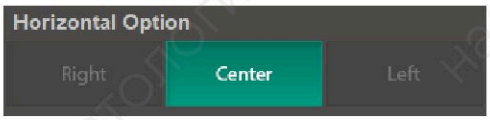
1. Select **Double Scan** from the **FOV**.



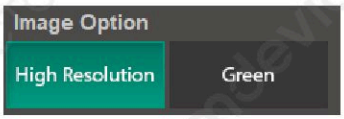
2. Check if **Mandible** is selected for the **Vertical Option**.



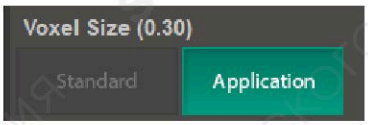
3. Check if **Center** is selected for the **Horizontal Option**.



4. Select an option from the **Image Option.**



5. Check if **Application** is selected for the **Voxel Size**.



IMPORTANT	In double scan mode, Standard is disabled for the Voxel Size.

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6. Select a patient type.



7. Select an X-ray intensity.



8. Set tube voltage and current. Each time you click the -/+ button, the voltage increases by ±1 kVp, the current by ±0.1 mA.



9. Click **Confirm** after setting exposure parameters.



After clicking the **Confirm** button:

- The rotating unit moves to the scanning position.
- The laser beam is turned on.
- The scan information window displays DAP, scan time, and exposure time.

IMPORTANT	After clicking C**onfirm**, you cannot change exposure settings.

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10. Guide the patient to the equipment and position him or her according to **9.5 Patient Positioning.**

⚠ CAUTION	Until the rotating unit stops moving, do not allow the patient to enter the equipment.

11. Click **Ready**.



12. Start an X-ray exposure according to **9.6 Taking an X-ray Exposure**.
13. Guide the patient out of the X-ray room.

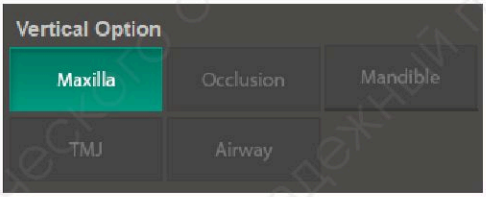
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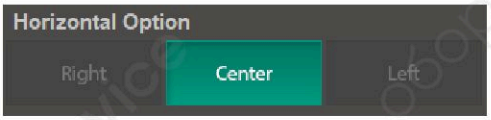
9.3.2 Taking the Second Scan

For the second scan, you don't need to select the following condition again: the patient type, X-ray intensity, tube voltage, and current. To start the second scan:

1. Check if **Maxilla** is selected for the Vertical Option.



2. Check if **Center** is selected for the **Horizontal Option**.



3. Click **Confirm**.



After clicking the **Confirm** button:

- The rotating unit moves to the scanning position.
- The vertical beam is turned on.
- The following information is displayed in the **scan information window**: DAP, scan time, and exposure time.

4. Guide the patient to the equipment and position the patient according to **9.5 Patient Positioning.**

5. Press **Ready**.



6. Starts an X-ray exposure following **9.6 Taking an X-ray Exposure**.

7. Guide the patient out of the X-ray room.

8. Follow the steps in **9.7 After an X-ray exposure** to wrap up the imaging process.

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9.4 Taking a Scout Image

For Endo and 5x5 mode, you can take a scout image before acquiring a CBCT image. To start a scout scan:

1. Select 5x5 or Endo for FOV.



[FOV - 5x5]



[FOV - Endo]

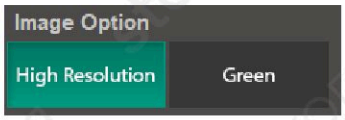
2. Click the tooth that you want to take an image of.



NOTICE

The image guide shows 32 teeth in total (Maxillary: 16 / Mandibles: 16), including the 3rd molar. Ensure to check whether the 3rd molar is displayed before X-ray exposure.

3. Select an option from the **Image Option**.

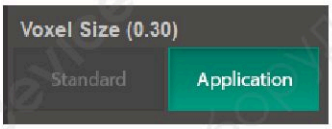


Mode	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

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4. Select an option from the **Voxel Size**.



NOTICE	Under Endo mode, the standard option for voxel size is disabled.

5. Select a patient type.



6. Select an X-ray intensity.



7. Set tube voltage and current. Each time you click the -/+ button, the voltage increases by ±1 kVp, the current by ±0.1 mA.



8. Check if all selections are correct and click **Confirm**.

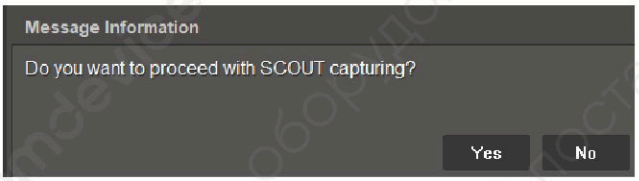


IMPORTANT	After clicking **Confirm**, you cannot change exposure settings.

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9. Click '**Yes**' if you want to take a scout image.



NOTICE If you click '**No,**' the system skips a scout scan and proceeds to the CBCT imaging.

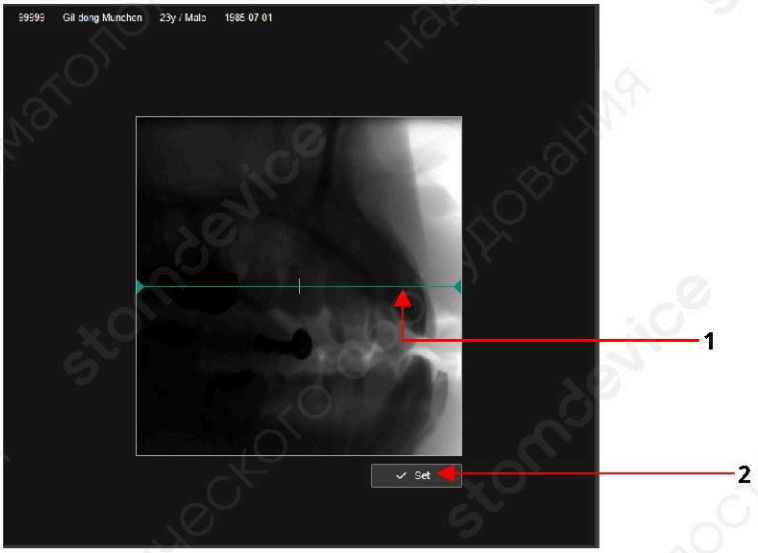
10. [Optional] if you want to change the center of your image:

    1) Click the **green line** and move it up or down to your target area.

    2) Click **Set**. After clicking the button, the chinrest moves up or down based on your selection.

NOTICE You can use the **Set** button only once. After clicking the button disappears from the screen.

    3) Adjust the patient's position for a new chinrest height. If necessary, use the column up/down button to adjust the column's height.



NOTICE If you don't want to change the center of the image, click **Ready**.

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11. Click **Ready**.

IMPORTANT	After clicking the **Ready** button, you cannot adjust the column height.
NOTICE	After clicking the button, CT imaging starts for the image options you selected (5x5 or Endo).

12. Start X-ray exposure following **9.6 Taking an X-ray exposure**.

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9.5 Patient Positioning

To prepare patients for imaging:

1. Remove metal objects that the patient wears or carries, such as glasses.
2. Cover the patient with a lead apron, blanket, or protective clothing.

⚠WARNING	▪ Cover patients with a lead apron or a blanket to protect their bodies from radiation exposure. ▪ Do not shine the laser beam directly into the person's eyes. This can cause vision loss. ▪ Pregnant women must consult a doctor before taking an X-ray
IMPORTANT	▪ Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition. ▪ Metal implants or bridges may reduce the quality of the images.

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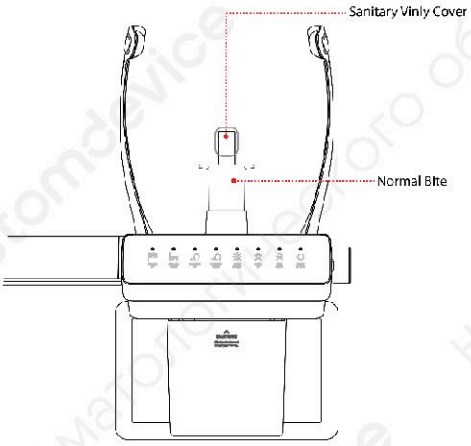
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9.5.1 Normal Mode

IMPORTANT	Use a new sanitary vinyl cover between each patient. Take off the cover each time the imaging procedure ends.
IMPORTANT	Ensure to cover the bite with FDA-cleared or CE-marked product.
IMPORTANT	Chinrest, bite, and other accessories that had contact with the patient must be cleaned between patients with a chlorine dioxide-based alcohol-free product.

To position the patient for a normal CBCT image:

1. Insert the **normal bite** into the **normal chinrest**. Cover the bite with a sanitary vinyl cover.



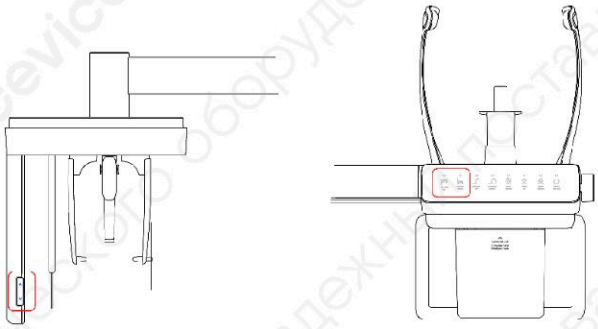
2. Turn the **temple supports open/close knob** clockwise to open Temple Supports.

3. Guide the patient to the equipment.

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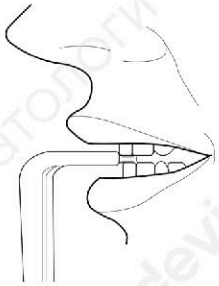
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4. Press the **column UP/DOWN button** to adjust the column's height. You can find the button on the control panel or the CEPH unit (**see below**).



5. Ask the patient to:

   - Grab the handles with both hands
   - Stand erect and stretch the neck straight.
   - Have shoulders parallel.
   - Lean forward until the chest press against the equipment.
   - Put the chin on the chinrest
   - Gently bite the tip of the bite with the front teeth



6. When the patient positioning is complete, ask the patient to:

   - Close their mouth.
   - Close their eyes.
   - Place the tongue on the roof of the mouth.

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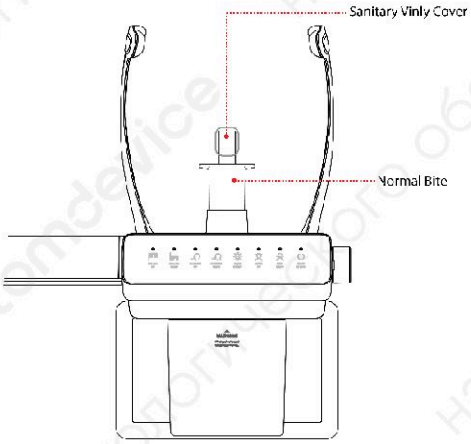
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9.5.2 Double Scan (Mandible) Mode

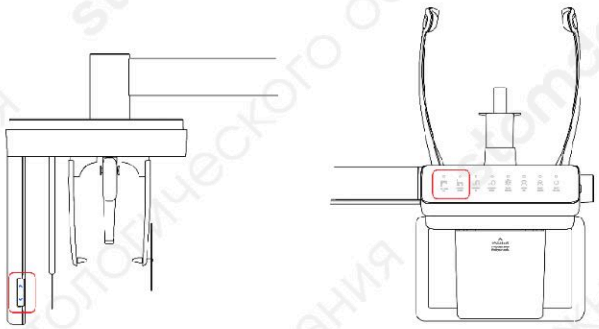
IMPORTANT	▪ The patient must keep the same posture for the first (lower) and the second (upper) exposure when taking an X-ray on the double scan mode. ▪ The equipment provides a function to save each image when matching fails due to patient movement between the first (lower) and second (upper) images.

To position the patient for a double scan (mandible) image:

1. Insert the normal bite into the normal chinrest. Cover the bite with a sanitary vinyl cover.



2. Turn the **Temple Supports OPEN/CLOSE Knob** to open the Temple Supports.
3. Guide the patient to the equipment.
4. Press the column UP/DOWN button to adjust the column's height. You can find the button on the control panel or the CEPH unit (see below).

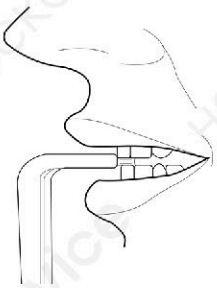


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5. Ask the patient to:

   - Grab the handles with both hands
   - Stand erect and stretch the neck straight.
   - Have shoulders parallel.
   - Lean forward until the chest press against the equipment.
   - Put the chin on the chinrest
   - Gently bite the tip of the bite with the front teeth



6. When the patient positioning is complete, ask the patient to:

   - Close their mouth.
   - Close their eyes.
   - Place the tongue on the roof of the mouth.

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Positioning Laser Beam

After clicking **Confirm** on the console software, the following beams are turned on:

- Horizontal beam
- Vertical beam
- Shoulder beam

Follow the steps below to position each beam:

1. Check if the **vertical beam** is aligned with the **patient's mid-sagittal line** (plane). Adjusts the patient's head position if necessary.
2. Check if the **maxilla or mandible is** in line with **the horizontal beam.** If necessary, adjust the chinrest height with the **chinrest up/down button**.



3. Check if the **shoulder beam** hits any part of the patient's shoulder. If necessary, ask the patient to lower his or her shoulder, if necessary.

⚠WARNING	Ensure that the laser beam does not hit the patient's eyes. Direct contact with the laser beam can cause vision loss.
NOTICE	You can use the **chinrest up/down button** only in the CBCT mode. In other modes, you cannot use the button to change the chinrest height.

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Finalizing the Patient Positioning

⚠ CAUTION	Ensure to close the temple supports before you click the **READY** button.

After laser beam positioning, follow the steps below to finalize the patient positioning.

1. Close the temple support with the temple support open/close knob to hold the patient's head in place.
2. Click the **Ready** button.



3. To proceed with the X-ray exposure, go to **9.5 Taking an X-ray Exposure**

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9.5.3 Double Scan (Maxilla) Mode

NOTICE	Before exposure to the Maxilla, the chin is moved down.
NOTICE	**Double Scan (Maxilla) Patient Positioning** is the same as **Double Scan (Mandible) Patient Positioning**.

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9.6 Taking an X-ray Exposure

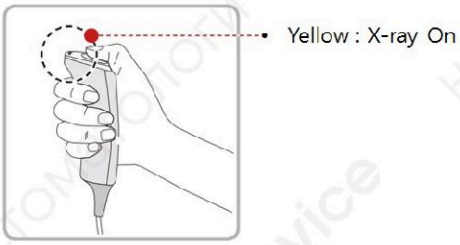
⚠WARNING	In an emergency, release the **exposure switch** to stop X-ray exposure.
ⓘ CAUTION	Do not use the PC during the X-ray exposure.
IMPORTANT	Ask patients to ▪ Close their eyes until the end of X-ray exposure. ▪ Hold their breath and stop shallowing. ▪ Stay in their position until you open the temple supports again.

To take an X-ray exposure:

1. Ask the patient to close their eyes.
2. Leave the X-ray room and close the door.

ⓘ CAUTION	Ensure to keep vocal and visual contact with the patient during the X-ray exposure.

3. Press the **exposure switch**. Hold down the switch until the end of X-ray exposure.



When the X-ray exposure begins:

- The LED light on the **exposure switch** turns yellow.
- The LED light on the top of the rotating unit turns yellow.
- A sound alert is turned on.
- The radiation mark on the console software turns orange.



4. Release the **exposure switch** when you see the "Imaging capturing is completed" message on the screen.

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9.7 After an X-ray Exposure

When the X-ray exposure ends,

1. Open the temple supports and guide the patient out of the equipment.
2. Remove the sanitary vinyl cover from the bite block.
3. Press Ready to send the rotating unit back to its initial position.



9.8 Checking the Captured Images

Captured images are converted to DICOM format and transferred to **EzDent-i.** You can view and confirm the images in **EzDent-i**.

NOTICE	For more information on how to use EzDent-i, go to the EzDent-i user manual.

1. Click **Save** to save the captured image. If you selected the auto-save option as a default setting, the image is saved automatically.
2. Double-click one of the patient information in the patient list.
3. The system starts **Ez3D-i** automatically and a 3D viewing of the saved image.

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10. How to Acquire 3D Model Scan Images

10.1 3D Model Scan Imaging Program Overview

■ Result Images

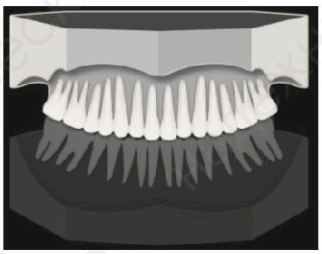
It provides 3D modeling surface data of the Plaster Cast. (STL file)

■ Image Acquisition Method

It acquires images with the X-ray beam scanning the Plaster Cast and reconstructs them to 3D sliced images, and converts the sliced images into 3D modeling surface data.

■ Examination Programs

It is classified as below based on the MODEL type.

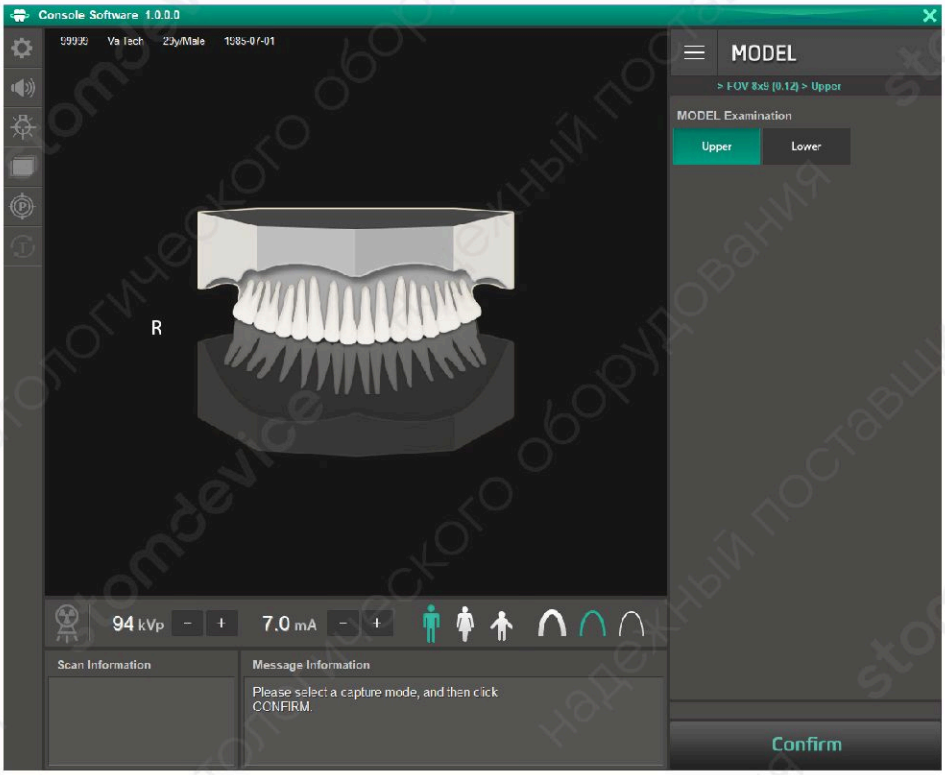
Applied FOV (cm)	Vertical Option	ROI	Description
8x8	Upper (Maxilla)		Captures a whole maxillary Plaster Cast.
	Lower (Mandible)		Captures a whole mandibular Plaster Cast.

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10.2 Configuring Exposure Settings

Before configuring exposure settings, finish the steps in **6. Getting Started**.



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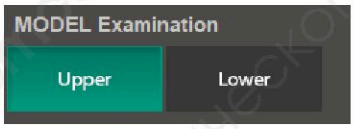
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To configure exposure settings for 3D model scan:

1. Click **MODEL** from the **Modality Option**.



2. Select an option from the **MODEL Examination**.



3. Set tube voltage and current value. Each time you click the +/- button, the tube voltage increases by ±1 kVp, and the current by ± 0.1 mA.



4. Click **Confirm**.



After clicking the **Confirm** button:

- The rotating unit moves to the scanning position.
- The vertical beam is turned on.
- The following information is displayed in the **scan information window**: DAP, scan time, and exposure time.

5. Bring a plaster cast to the equipment.

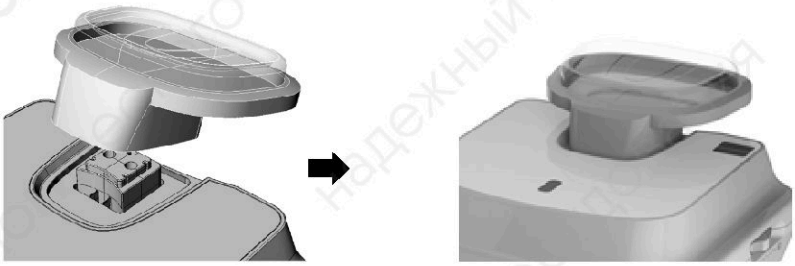
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10.3 MODEL Positioning

MODEL Scan Jig Installation

1. Remove the Temple Supports and the Chinrest
2. Insert the MODEL Scan Jig.



Laser Beam Positioning

1. Put the Plaster Cast on the MODEL Scan Jig. (Whether the Plaster Cast is for Maxilla or Mandibular, place it flat side down.)



2. Align the Mid-sagittal plane Laser Beam to the center of the Plaster Cast. (To prevent the horizontal expansion of the image)



3. Click the **Ready**. X-ray exposure has not started yet.



4. Now go to **10.4 Taking an X-ray Exposure** to start the exposure.

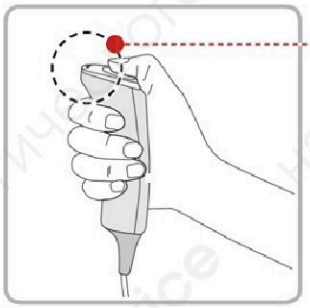
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10.4 Taking an X-ray Exposure

CAUTION	Do not operate the PC during the X-ray exposure. Doing so can cause the system to malfunction.

1. Leave the X-ray room and close the door.
2. Press and hold the **exposure switch** until image acquisition is completed.



NOTICE	During the X-ray exposure, check: ▪ The LED light of the e**xposure switch** turns yellow. ▪ The LED light on the top of the equipment turns yellow. ▪ An alert sound comes out to indicate that X-ray emission is currently underway. ▪ The radiation mark on the console software turns green. 

3. Release the **exposure switch** when the “Image capturing is completed” message appears on the screen.
4. Remove the plaster cast out of the equipment.

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10.5 Checking the Captured Images

The captured images are converted to DICOM or STL format and transferred to **EzDent-i**. Go to the **EzDent-i User Manual** to learn more information about the image conversion process.

To check the captured images:

1. The image is automatically saved when AutoSave has been selected before capturing the image. Click the **Save** Button to store the image. If the AutoSave has not been set up.

2. Double-click to confirm the image in the Patient List.

NOTICE	You can check the captured image with a 3rd party STL viewer.

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11. Troubleshooting

11.1 Troubleshooting

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

If the equipment is not working

Cause	Actions to be taken
Failure of power supply	Check the equipment's power supply.
Initialization status	Wait until the equipment has been initialized, and then try again.
Failure of the Control PC's connection	Check the connection status of the Communication Port (Optic), which connects the PC to the equipment.

If the exposure switch is not functioning

Cause	Actions to be taken
Failure of readiness	Check whether the Console Software is ready for imaging.

If imaging cannot be performed

Cause	Actions to be taken
Failure of initialization	Wait until the equipment is initialized and then try again. If this problem persists, restart the equipment.

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

Cause	Actions to be taken
Expiration of the time allotted for patient positioning	Press the Laser Beam button to turn on the Laser Beam.

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11.2 Error Codes

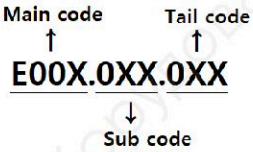
In instances of abnormal operation, error messages appear with error codes on the Console Software and Control Panel. If a problem persists, please request assistance from the customer support information services.

NOTICE

Error messages will be displayed in the format written below.

[Code: E00X.0XX.0XX]

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



- **The main code** indicates the source of error codes. The source is categorized as hardware, software, an acquisition module, etc.
- **Subcode** describes the specific area where the error has occurred according to the main code.
- **The tail code** explains the specific symptoms and causes of the errors mentioned in the subcode.

11.2.1 Main code - Hardware (001)

11.2.1.1 Subcode – Generator-Related Error (001)

Tail code	Description
001	Appears when the tube is not ready for use
002	Appears when the cable between the tube tank and Inverter board is disconnected
003	Appears when a current of the inverter board exceeds the maximum allowable level during X-ray irradiation
004	Appears when there is ±10kV or more voltage difference in tube voltage compared to a reference value
005	Appears when there is ±0.5mA or more current difference in tube current compared to a reference value
006	Appears when there is ±20kV or more voltage difference in tube voltage feedback compared to the average value
007	Appears when there is ±1mA or more current difference in tube current feedback compared to the average value

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Tail code	Description
008	Appears when the temperature of the mono tank is above the setting temperature
009	Appears when the inverter output current is higher than 1A during X-ray irradiation (In EP, IP conditions)
010	Appears when the inverter board falsely recognizes the exposure switch signal as OFF after the irradiation. On command
011	Appears when the X-ray OFF command is not sent to the inverter board in 0.5 seconds after turning off the exposure switch
012	Appears when kV feedback is over -20kV compared to the setting value during X-ray irradiation
013	Appears when kV feedback is over +20kV compared to the setting value during X-ray irradiation.
014	Appears when the mA feedback value is less than 50% compared to setting conditions during X-ray irradiation.
015	Appears when the mA feedback value is higher than 150% compared to setting conditions during X-ray irradiation.

11.2.1.2 Subcode - Motor-Related Error (002)

Tail code	Description
020	Appears during p-axis motor origin movement
021	Appears during rotator-axis motor origin movement
027	Appears during Cephalo sensor motor origin movement
030	Appears during quadruple axis collimator Left origin movement
031	Appears during quadruple axis collimator Right origin movement
032	Appears during quadruple axis collimator Up origin movement
033	Appears during quadruple axis collimator down origin movement
037	Appears during generator tilting
038	Appears during temple support the motor operation

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Tail code	Description
039	Appears during X-axis motor origin movement
040	Appears during Y-axis motor origin movement

11.2.1.3 Subcode – Exposure Switch-Related Error (003)

Tail code	Description
060	It appears that the exposure switch is pressed when turning on the equipment.

11.2.1.4 Subcode – Other Errors (004)

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

11.2.2 Main code – Software (002)

11.2.2.1 Subcode – Sequence-Related Error (001)

Tail code	Description
001	Appears when the packing mode is enabled
002	Appears when the door is open
003	Appears when the exposure switch is pressed

11.2.2.2 Subcode – PC Resolution Related Error (010)

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

11.2.2.3 Subcode – PC Network-Related Error (024)

Tail code	Description
002	Appears when the port is invalid
003	Appears when the time is out

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11.2.3 Main code - Acquisition Module (003)

11.2.3.1 Subcode – Initialization Failure-Related Error (010)

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

11.2.3.2 Subcode – Capture Failure-Related Error (020)

Tail code	Description
000	Appears when there is a capture error

11.2.3.3 Subcode – Reconstruction Failure-Related Error (030)

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

11.2.3.4 Subcode – Hardware-Related Error (061)

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

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12. Cleaning and Disinfection

To prevent product contamination and deformation, clean the equipment and its accessories according to the guidelines in this section.

Before you start cleaning or disinfecting the equipment:

- Turn off the equipment
- Wear safety gloves
- Select the product that does not contain the followings: phenol, acetic acid, peroxide, sodium hypochlorite, isopropyl alcohol (2-propanol, isopropanol), iodine-splitting agents, and oxygen-splitting agents.

When you are cleaning or disinfecting the equipment:

- Read and follow the instructions written on the cleaning agent's label.
- Do not apply liquids to the unit's inside.
- Do not spray liquid over the surface of the equipment
- Wipe thoroughly the areas you cleaned until no liquid is left.

⚠WARNING	Cleaning with the power still on may lead to serious injury for you and other people around the equipment.
⚠WARNING	VATECH does not recommend or endorse a particular cleaning product. It is the responsibility of the user to determine what product is adequate to use for cleaning based on FDA regulations and local codes.
⚠WARNING	Spraying or pouring liquid into the equipment may cause a fire, electric shock, and serious damage to the equipment.

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12.1 Cleaning

The accessories and parts that have contact with the patient's mucous membranes must be cleaned between each patient use, including:

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

When you clean the accessories or the parts, use:

- A soft cloth
- Chlorine dioxide-based and non-alcoholic cleaning products

The following tables describe the proper procedure for each part and accessory:

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

*Deep bite is provided only in Asian countries, including Japan.

IMPORTANT	Do not use abrasive liquids such as acetone, gas, or oil, for they may cause corrosion on the equipment's surface.
IMPORTANT	Do not use a product that contains silicon. Silicone-based products may damage the equipment's electrical component.
IMPORTANT	Always dampen the cloth with the cleaning agent. (Do not soak the cloth into liquids.

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12.2 Disinfection

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

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

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13. Maintenance

NOTICE	The equipment must be installed and maintained on a flat surface.

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

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

13.1 Regular Maintenance

⚠WARNING	▪ Always turn off the equipment before performing any maintenance. ▪ Never remove equipment covers. There are no repairable parts inside. ▪ The only parts that can be replaced by the user are the input fuses, which must comply with the manufacturer's specifications. ▪ As a precaution against fire, the replacement should be one in the same type and range.
IMPORTANT	▪ There are no user-serviceable parts inside this equipment. ▪ If any service is required, please contact the **VATECH** service center or your local **VATECH** representative.

- Do not unplug cables by force.
- Do not expose the equipment or components in an area that is susceptible to water or humidity.
- Do not expose the equipment in an area of extreme fluctuation in temperature, poor ventilation, direct sunlight, dust, salt, etc.
- Keep all detachable components well organized and clean.
- Make sure that the equipment is well-grounded.
- Never try to modify this equipment, including the wires or cables. Doing so may damage it beyond repair.

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13.2 Maintenance Task Checklist

Tasks	Period
Before the operation, ensure that the equipment is clean and ready for use. Make sure that all parts that come in direct contact with the patient have been cleaned thoroughly.	Daily
After using the equipment, make sure that the **main power switch** has been turned off.	Daily
Ensure that the equipment is firmly plugged into a dedicated power source.	Daily
Ensure that the plug and the power cord are not heated abnormally.	Daily
Confirm that the LED indicator turns yellow when **the exposure switch** is pressed. Ensure that the LED indicator remains yellow for the entire duration of the exposure.	Daily
Ensure that the power cable is not kinked, broken, exposed, and free of all other defects.	Daily
Confirm that activating the **emergency stop switch** ceases the unit's operation. Pressing the **emergency stop switch** must stop all movement of the equipment and X-ray emission.	Weekly
Ensure that all visible labels are intact and legible.	Weekly
Check for damages to the **exposure switch** cable.	Monthly
Confirm that the audio message is audible throughout the exposure.	Monthly

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13.3 QA Test

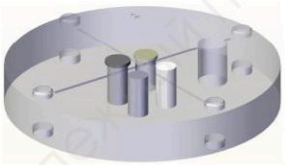
This section is intended to give information about PHT-75CHS PHANTOM KIT for 3D IMAGE QUALITY INSPECTION and CALIBRATION. It is recommended that you thoroughly familiarize yourself with this guide to perform the regular QA test effectively by using the PHANTOM KIT. QA tests should be done annually at the frequency specified by the manufacturer or state regulations in which the X-ray system is being used.

13.4 Phantom Kit Contents

- CT NUMBER CHECK PHANTOM x 1
- UNIFORMITY CHECK PHANTOM x1
- S&C CHECK PHANTOM x1
- PHANTOM JIG A'SSY x 1
- PHANTOM KIT User Manual x 1

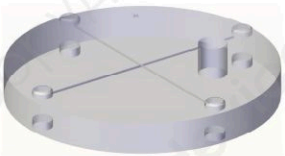
13.4.1 Specifications of Phantom Kit Contents

CT Number Check Phantom



- Manufacturer
  - **VATECH Co., Ltd.**
- Intended Use
  - CT Number Inspection
  - CT Number Calibration
- Complies with
  - IEC 61223-2-6
  - IEC 61223-3-5

Uniformity Check Phantom

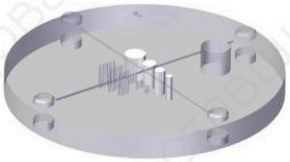


- Manufacturer
  - **VATECH Co., Ltd.**
- Intended Use
  - CT Image Homogeneity Inspection
  - CT Image Noise Inspection
- Complies with
  - IEC 61223-2-6
  - IEC 61223-3-5

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S&C Check Phantom



- Manufacturer
  - **VATECH Co., Ltd.**
- Intended Use
  - Low Contrast Resolution Inspection
  - High Contrast Resolution Inspection
- Complies with
  - IEC 61223-2-6
  - IEC 61223-3-5

Phantom Jig Assembly



- Manufacturer
  - **VATECH Co., Ltd.**
- Intended Use
  - CT Image Inspection
  - CT Image Calibration

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13.5 QA Test Procedure

- Each facility shall establish a committee of individuals to be responsible for the Radiation Safety/Quality Assurance program. For a non-hospital facility, this committee might be composed of a dentist, an X-ray technician, an office manager, and a service representative who is certified to perform radiological functions by the law in the state in which the X-ray system is being used.
- Each facility shall make the radiation safety/quality assurance program, including the following tests, at the frequency specified by the manufacturer or state regulations and maintain records of the data.
- For technical assistance for QA tests, contact your local VATECH service representative.
- If the test criteria are not met, contact your local VATECH service representative.

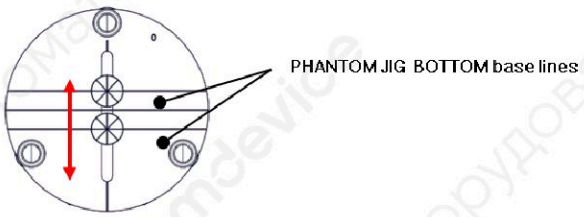
13.5.1 QA CT Number Test

Follow the CT Number Test procedure below to produce correct images and analyze the User Phantom. Test results must be documented and maintained for at least one year. The CT number for water should be recorded and compared each day to the established specifications.

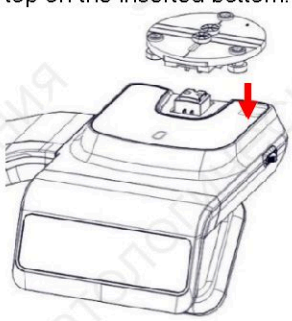
13.5.1.1 Setting up CT Number Phantom

To set a CT number Phantom:

1. Remove the **bite block** and the **temple supports** from the unit.
2. Align the **phantom fixing bolts** to the **phantom jig bottom baseline** as shown below and turn the bolts clockwise to tighten them.



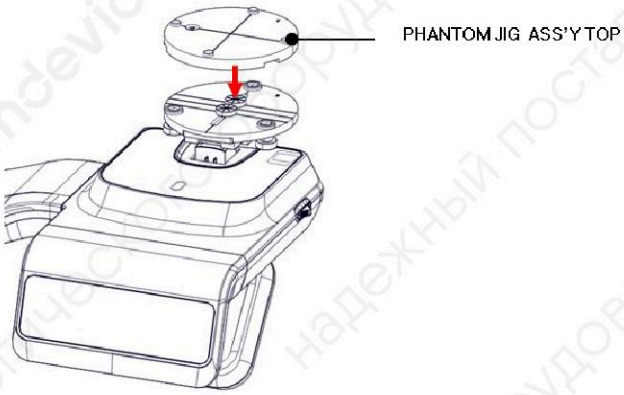
3. Insert the phantom jig bottom into the chinrest and then put the phantom jig top on the inserted bottom.



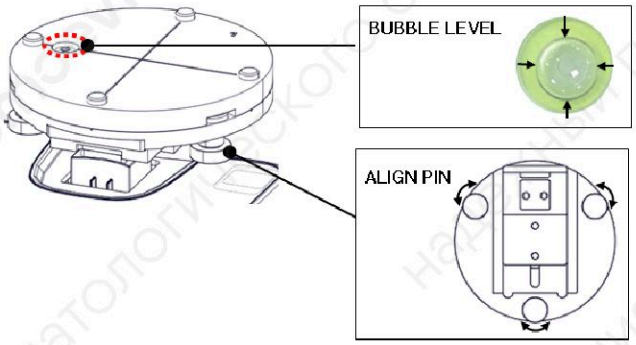
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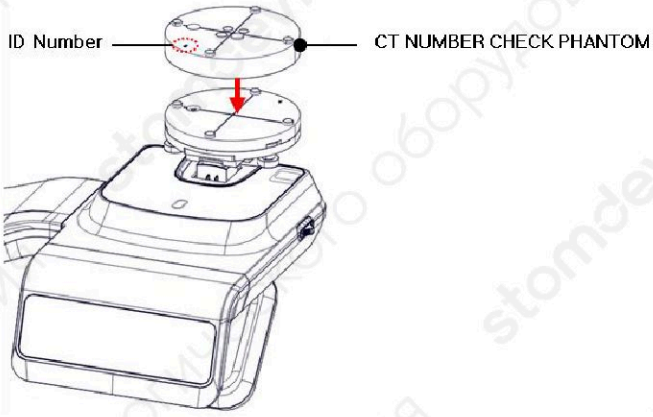
4. Place the phantom jig ass'y top on the phantom jig ass'y bottom as shown below.



5. Make the **phantom jig ass'y** level by using a bubble level and three align pins.



6. Place a CT number check phantom on the phantom jig ass'y.



7. Run the 2D viewer and click to add a patient for the QA test.

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13.5.1.2 Imaging CT Number Phantom

To capture an image with the CT number phantom:

1. Click  to run Capture Software in EzDent-i.
2. Click  to enter Phantom Capture mode.



3. Click the **CT** check box and click **Capture**.
4. Click the **NEXT** button at the bottom of the Capture Software screen.
5. Click the **READY** button when enabled.
6. Capture the PHANTOM image according to capture software instructions.
7. When image capturing is completed, save the image in EzDent-i.

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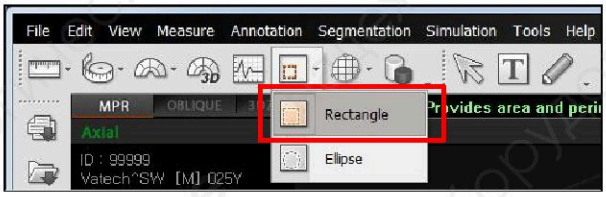
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13.5.1.3 Analyzing CT Number Phantom

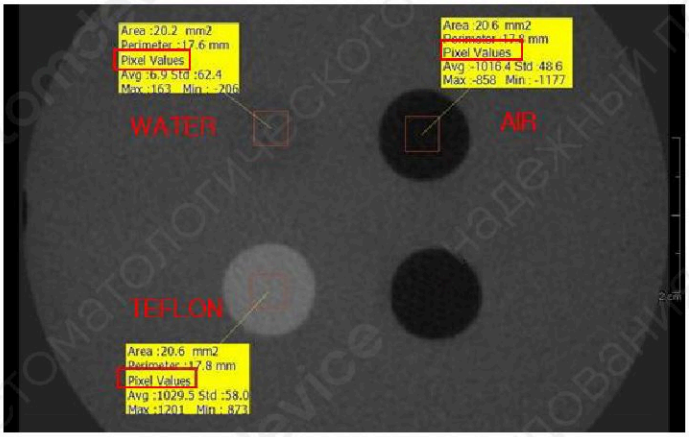
To analyze the test with the CT number phantom:

1. Double-click the saved PHANTOM image in EzDent-i to run Ez3D-I Plus.
2. In the Axial pane, click  in the upper-right corner to maximize the Axial view.
3. Click  > 

.



4. Make the boxes on the WATER, TEFLON, and AIR area as shown below.



NOTICE Try to make each box as close to 20.0 mm^2 in the area as possible.

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5. Compare the CT NUMBER average values from the WATER, TEFLON, and AIR areas with the standard.

MATERIAL	MEAN	LOWER LIMIT	UPPER LIMIT	Scope
AIR	-990 HU	-1030 HU	-900 HU	IEC 61223-2-6: 5.5.4, 5.5.5
WATER	0 HU	-50 HU	50 HU	
TEFLON	980 HU	900 HU	1100 HU	

6. Record the mean CT Number value of each material.
7. Click  > 

and save the captured screen in EzDent-i.
8. Remove User Phantom from the PHANTOM JIG ASS'Y.

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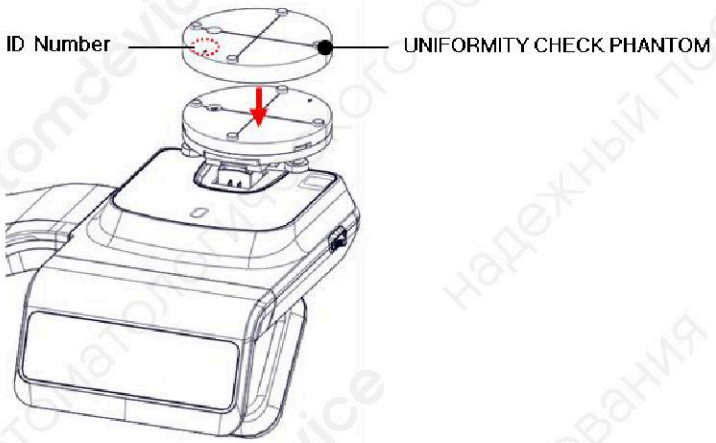
13.5.2 QA CT Uniformity Test

Follow the CT Uniformity Test procedure below to correctly image and analyze the CT Uniformity Check Phantom. Test results must be documented and maintained for at least one year.

13.5.2.1 Imaging CT Uniformity Check Phantom

To capture an image with the CT uniformity, check Phantom:

1. Remove Bite and Temple Supports from the Unit.
2. Insert the PHANTOM JIG BOTTOM into the Chinrest and then put the PHANTOM JIG TOP on the PHANTOM JIG BOTTOM.
3. Make the PHANTOM JIG ASS'Y level by using BUBBLE LEVEL and three ALIGN PINs.
4. Put UNIFORMITY CHECK PHANTOM on the PHANTOM JIG ASS'Y.



5. Click 

to run Capture Software in EzDent-i.
6. Click  to enter Phantom Capture mode.



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7. Click the CT check box and click Capture.
8. Click the NEXT button at the bottom of the Capture Software screen.
9. Click the READY button when enabled.
10. Capture the PHANTOM image according to capture software instructions.
11. When image capturing is completed, save the image in EzDent-i.

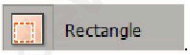
13.5.2.2 Analyzing CT Uniformity Check Phantom

To analyze the test with the CT uniformity check phantom:

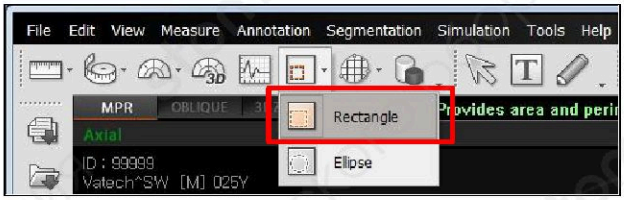
1. Double-click the saved PHANTOM image in **EzDent-i** to run **Ez3D-i**.
2. In the Axial pane, click  in the upper-right corner to maximize the Axial view.
3. Click  > 

.
4. Make 25mm lines from the center to UP/DOWN/LEFT/RIGHT directions as shown below.



5. • Click  > 

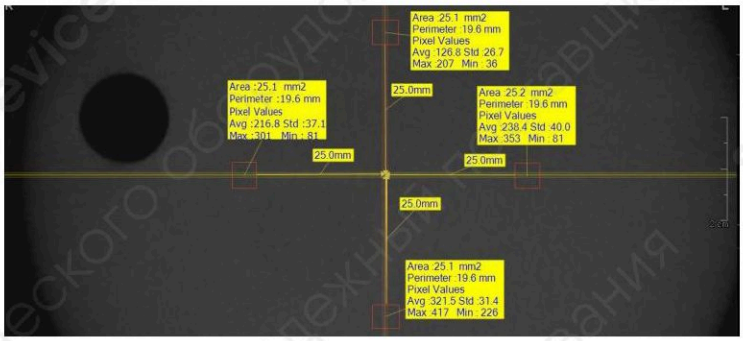
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6. Make the four boxes next to each 25mm line, as shown below.

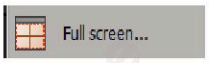


1) Try to make each box as close to 25.0 mm2 in the area as possible.
2) Put the 4 ROIs at the end of each 25mm line

7. Measure the HOMOGENEITY by calculating the difference between Max. average value and min. average value among the 4 ROIs and compare it with its standard.

Calculation	Standard	Scope
Subtract the minimum average value from the Maximum average value among the 4 ROIs	The difference should be less than 400 HU	61223.3.5 INTRODUCTION

8. Record the mean CT Number value of each material.

9. Click  > 

and save the captured screen in **EzDent-i**.

10. When finished, exit **EzDent-i**

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13.5.3 High and Low Contrast Resolution Tests

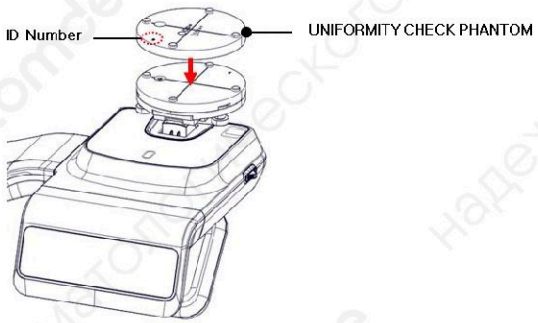
Perform a high/low contrast resolution test at the following interval:

- **High contrast resolution test**: Initially and Yearly
- **Low contrast resolution test**: Initially and Yearly

13.5.3.1 Imaging S&C Check Phantom

To perform a high and low contrast resolution with S&C check phantom:

1. Remove the bite and the temple support from the unit.
2. Insert the PHANTOM JIG BOTOTM into the chinrest
3. Place the PHANTOM JIG TOP over the phantom jig bottom.
4. Make the PHANTOM JIG ASS'Y level by using BUBBLE LEVEL and three ALIGN PINs.
5. Put S&C CHECK PHANTOM on the PHANTOM JIG ASS'Y.



6. Click 

to start Capture Software in 2D viewer.
7. Click  to enter Phantom Capture mode.
8. Click the CT check box and click Capture.
9. Click 'NEXT' at the bottom of the Capture Software screen.
10. Click 'READY' after the bottom is enabled.
11. Follow the capture software's instructions to capture the phantom image.
12. Save the captured image on EzDent-i after taking the image.

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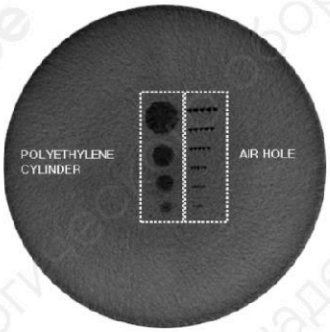
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13.5.3.2 Analyzing S&C Check Phantom

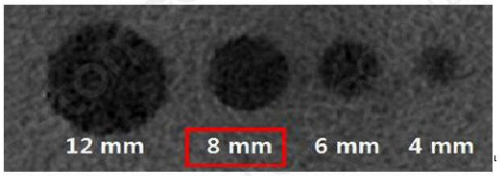
To analyze the test with an S&C check phantom:

1. Remove the bite and temple support from the unit.
2. Double-click the saved phantom image in EzDent-i to run Ez3D-i.
3. Go to the Axial view and click  for full-screen mode.
4. Click  and 

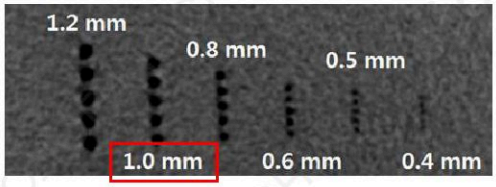
to adjust the brightness and contrast in the saved image. Drag the icon left and right to change the contrast or up and down to adjust the brightness.
5. Make sure that you can see the minimum size of the Airhole and the PE (Polyethylene) cylinder at 50 cm (20 inches) from the monitor.



Parameters	Material	Minimum visible size
High Contrast Resolution	Air Hole	1.0mm
Low Contrast Resolution	PE cylinder	8.0mm



<High Contrast Resolution>



<Low Contrast Resolution>

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14. Disposing of the Equipment

To reduce environmental contamination, this equipment is designed for safe use and disposal. Many components, except for the parts like the X-ray tube, are environmentally friendly and recyclable.

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

Parts	Materials	Recyclable	To the special disposal site	Hazardous waste; Needs Separate Collection
Frame and covers	Aluminum and plastics	•		
Motors		•		
Circuit boards		•		
Cables and transformer	Copper	•		
	Steel	•		
	Oil		•	
Packing	Wood	•		
	Cardboard	•		
	Paper	•		
X-ray tube				•
Sensor head	Return the sensor head to **VATECH**			
Other parts			•	

⚠ CAUTION	This dental equipment shall not be disposed of as domestic garbage materials.
IMPORTANT	Clean/Disinfect/Sterilize the equipment before disassembling it and disposing of its parts.
NOTICE	Observe all regulations relevant to the disposal of waste in your country.

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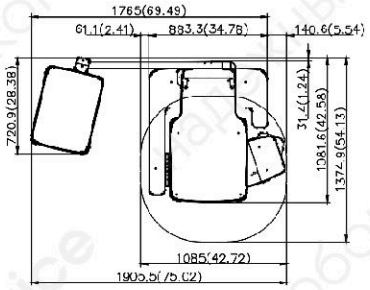
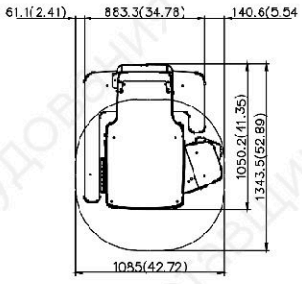
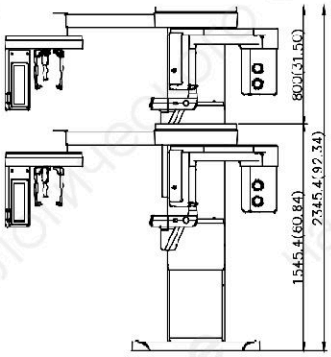
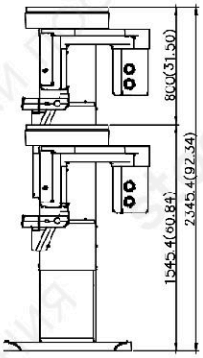
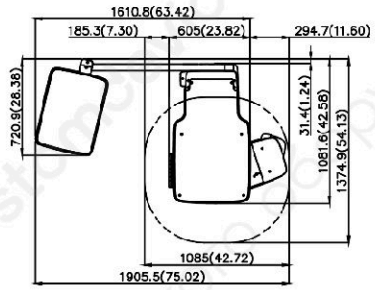
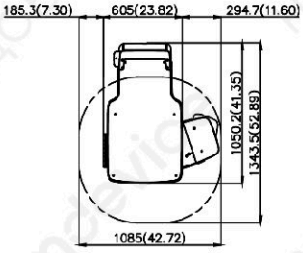
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15. Technical Specifications

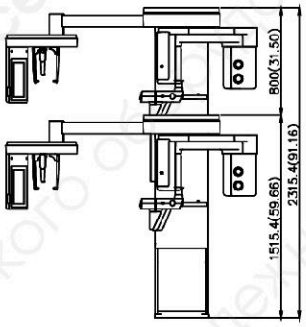
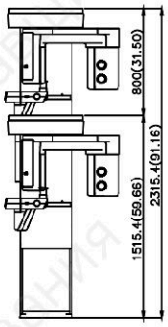
15.1 Mechanical Specifications

15.1.1 Dimensions (unit = mm)

	With CEPH	Without CEPH
Top view (With Base)		
Front View (With Base)		
Top view (Without Base)		

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	With CEPH	Without CEPH
Front View (Without Base)		

Item		Description
Weight	Without CEPH unit	162.9 kg (359.13 lbs. - without Base)
		217.9 kg (480.38 lbs. – with Base)
	With CEPH unit	187.9 kg (414.25 lbs. - without Base)
		242.9 kg (535.50 lbs. - with Base)
Total Height	Without Base	Max. 2305.4 mm (91.16")
	With Base	Max. 2345.4 mm (92.34")
Dimensions during operation (Length x Width x Height)	Without CEPH unit	without Base: 1085.0(L) x 1343.5(W) x 2315.4(H) (mm) 42.72(L) x 52.89 (W) x 91.16(H) (inch)
		with Base: 1085.0(L) x 1343.5(W) x 2345.4(H) (mm) 42.72(L) x 52.89 (W) x 92.34(H) (inch)
	With CEPH unit	without Base: 1905.5(L) x 1374.9 (W) x 2315.4(H) (mm) 75.02(L) x 54.13 (W) x 91.16(H) (inch)
		with Base: 1905.5(L) x 1374.9 (W) x 2345.4 (H) (mm) 75.02(L) x 54.13 (W) x 92.34(H) (inch)
Rotating Unit Vertical Movement		Max. 800 mm (31.50")
Installation type		Base Stand/Wall Mount (Default: Wall Mount type)
Packing Box Organization		Main Box, CEPH Box (Optional), Base Box (Optional)

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15.1.2 Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	560	414.81	145.19	1 : 1.35
CEPH	1745	1524.00	221.00	1 : 1.14
CBCT	560	350.00	210.00	1 : 1.60

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

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15.2 Technical Specifications

15.2.1 X-ray Generator Specifications

Specifications

Item			Description
Generator	Model		DG-07E22T2
	Rated output power		1.6 kW
	Inverter model name		INV-22
	Type		Inverter
	Normal/ Pulse	kVp	60 kV~99 kV (1 kV increment)
		mA	4 mA~16 mA (0.1 mA increment for CBCT, 1 mA increment for PANO and CEPH)
	Cooling		Thermal protect (Optional fan cooling ≥ 40°C)
	Total filtration		Min. 2.5 mm Al
	Default filtration		1.0 mm Al
	Added filtration		1.5 mm Al (Fixed)/PANO and CEPH mode 1.5 mm Al (Fixed) + 3.0 mm Al (Automatically added)/CBCT mode
Tube	Manufacturer		Canon Electron Tubes & Devices
	Model		D-052SB (Stationary Anode type)
	Focal spot size		0.5 mm (IEC 60336)
	Target Angle		5 degree
	Inherent Filtration		At least 0.8 mm Al equivalent at 50 kV
	X-ray Coverage		75 mm x 380 mm at SID 550 mm
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time: Interval time)

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Test Condition

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	60~90	4~14	13.5
	60~90	4~14	11.5
	60~90	4~14	11.2
	60~90	4~14	9.2
	60~90	4~14	9.0
	60~90	4~14	8.0
	60~90	4~14	6.8
	60~90	4~14	6.7
	60~90	4~14	6.7
	60~90	4~14	6.2
	60~90	4~14	5.7
	60~90	4~14	5.5
	60~90	4~14	4.5
	60~90	4~14	3.9
	60~90	4~14	3.7
	60~90	4~14	3.4
	60~90	4~14	3.2
	60~90	4~14	3.0
	60~90	4~14	2.8
	60~90	4~14	2.0
	60~90	4~14	1.5
	60~90	4~14	0.8
CEPH	60~99	4~16	1.9
	60~99	4~15	2.4
	60~99	4~15	3.9
	60~99	4~14	4.9
	60~99	4~14	5.4

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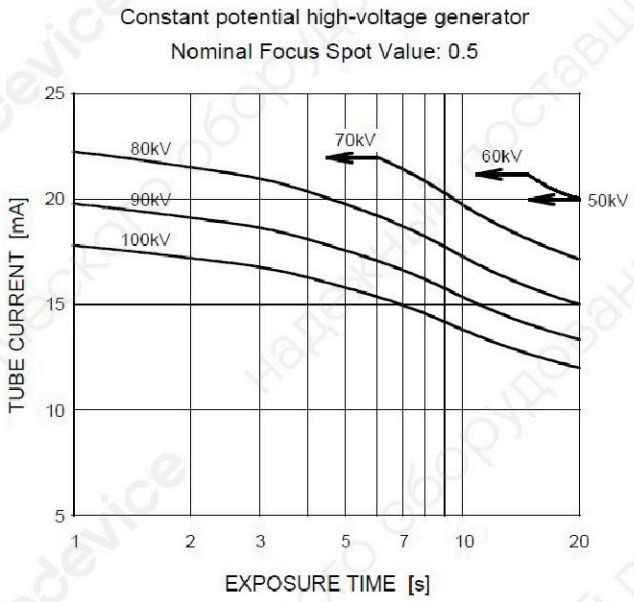
15. Technical Specifications

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
CBCT	60~99	4~12	9.0
	60~99	4~16	2.9
	60~99	4~12	18.0

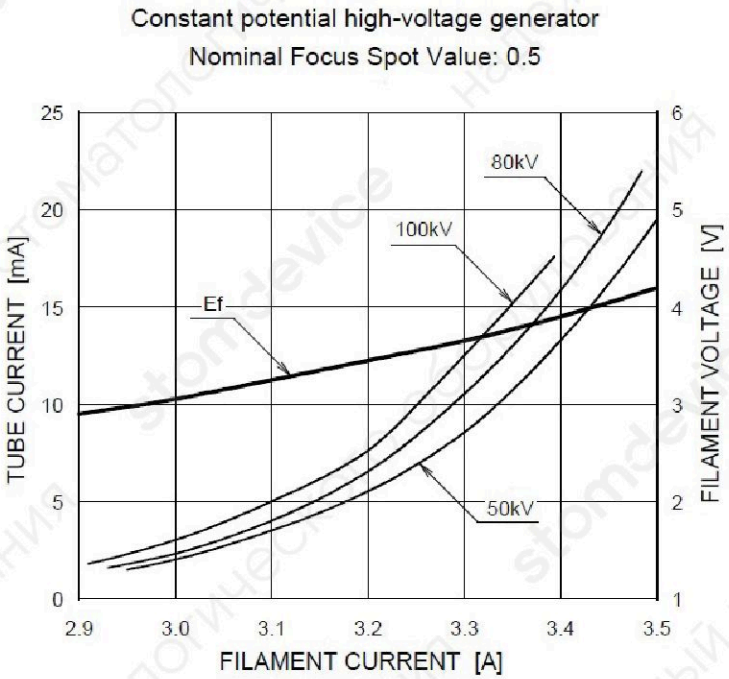
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Maximum Rating Charts



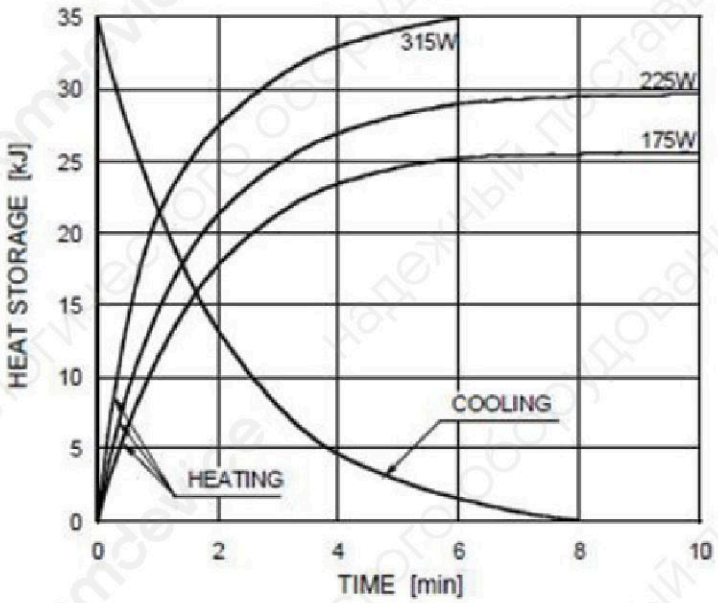
Emission & Filament Characteristics



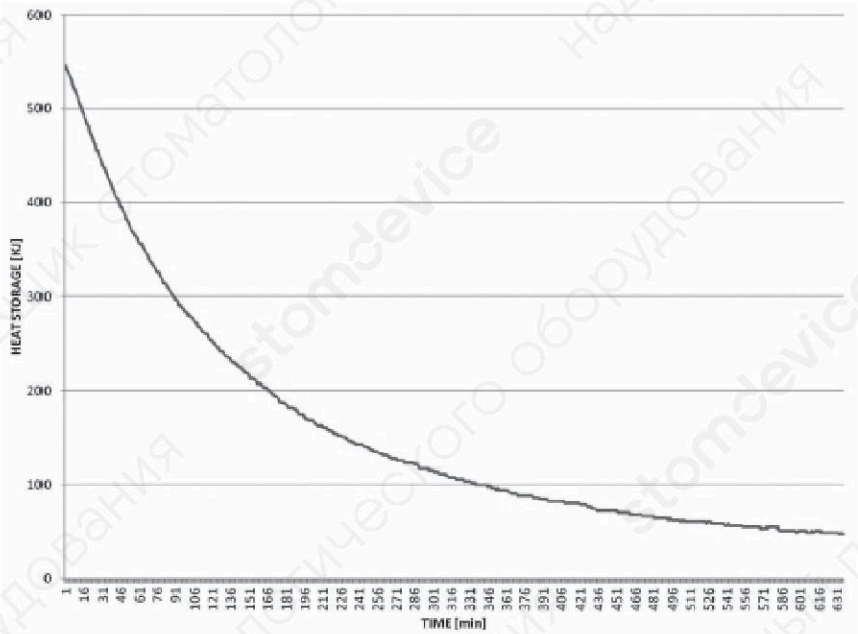
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Anode Thermal Characteristics



X-ray Housing Assembly Tube Characteristics



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15.2.2 Detector Specifications

Item	Description	
	PANO & CBCT	CEPH
Model	Xmaru1314CF	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 μm @ 4x4 binning 99 μm @ 2x2 binning (49.5 μm @ no binning)	200 μm @ 2x2 binning (100 μm @ no binning)
Active area	CBCT - 127.5 x 135.8 (mm) PANO - 5.9 x 135.8 (mm)	15.6 mm x 259 mm
Frame Rate	~ 108 Hz @ 4x4 binning ~ 32 Hz @ 2x2 binning	~ 330 Hz @ 2x2 binning
Analogue-Digital Conversion	14 bits	
Operating condition	10~35 ℃ (Temperature) 10~75 % (Humidity)	
Storage condition	-10~60 ℃ (Temperature) 10~75 % (Humidity)	
Sensor size	165 (L) x 230 (W) x 27 (H) (mm)	110 (L) x 279 (W) x 20 (H) (mm)
Sensor weight	1450 g	1050 g
Converter	CsI : Ti	
Energy Range	50~120 kVp	
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 45 % @ 1.0 lp/mm, > 10 % @ 2.5 lp/mm	> 40 % @ 1.0 lp/mm > 8 % @ 2.5 lp/mm
DQE	> 60 % @~0 lp/mm	> 70 % @~0 lp/mm
Dynamic Range	> 80 dB	> 70 dB

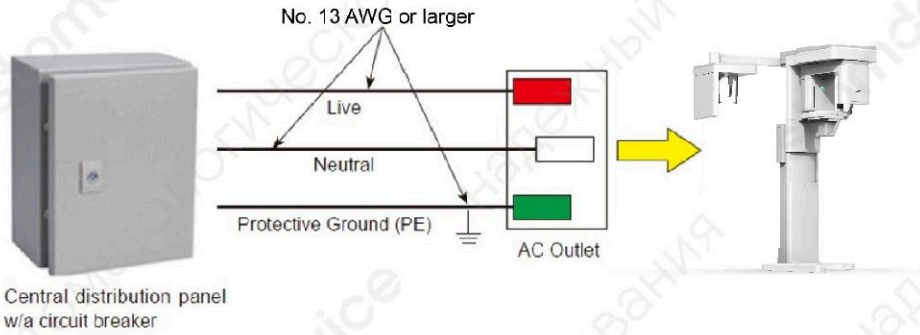
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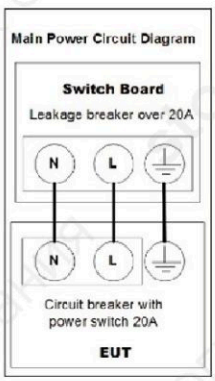
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15.3 Electrical Specifications

Item	Description
Power supply voltage	100-240 V~
Frequency	50/60 Hz
Power rating	2.2 kVA
Accuracy	Tube Voltage (kVp) ± 10 %, Tube Current (mA) ± 20 %, Exposure Time (s) ± (5 % + 50 ms)

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





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NOTICE

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

15.4 Environmental Specifications

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

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16. Appendices

16.1 Recommended X-ray Exposure Tables

16.1.1 PANO Mode

Exposure Condition

Mode	Image Option	Gender/Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	High Resolution	Man	Hard	75	10
			Normal	74	10
			Soft	73	10
		Woman	Hard	74	10
			Normal	73	10
			Soft	72	10
		Child	Hard	70	8
			Normal	69	8
			Soft	68	8
	Green (Optional)	Man	Hard	85	14
			Normal	84	14
			Soft	83	14
		Woman	Hard	84	14
			Normal	83	14
			Soft	82	14
		Child	Hard	70	12
			Normal	69	12
			Soft	68	12
PANO Examination (Insight PAN; Optional)	High Resolution	Man & Woman	Normal	70	6
		Child	Normal	67	6
SPECIAL Examination	N/A	Man	Hard	75	10
			Normal	74	10
			Soft	73	10
		Woman	Hard	74	10
			Normal	73	10
			Soft	72	10

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Mode	Image Option	Gender/Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
		Child	Hard	70	10
			Normal	69	10
			Soft	68	10

Scan Time/Exposure Time

Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
PANO Examination	Narrow	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
	Normal	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
	Wide	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
	Child	Standard	12.0	11.5	7.0	6.8
		Right	12.0	5.7	7.0	3.3
		Front	12.0	9.2	7.0	5.5
		Left	12.0	5.7	7.0	3.3
	Orthogonal	Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
		Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
		Bitewing	14.1	9.0	4.0	3.0
		Bitewing Incisor (Optional)	14.1	2.8	4.0	0.8
		Bitewing Right	14.1	4.5	4.0	1.5

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Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
		Bitewing Left	14.1	4.5	4.0	1.5
SPECIAL Examination	-	TMJ LAT Open	14.1	6.7	n/a	n/a
		TMJ LAT Close				
		TMJ PA Open (Optional)	10.0	6.1	n/a	n/a
		TMJ PA Close (Optional)				
		Sinus LAT (Optional)	4.0	3.7	n/a	n/a
		Sinus PA	8.8	8.0	n/a	n/a

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

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16.1.2 CEPH Mode

Exposure Condition

Examination Program	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
Lateral	High Resolution	Man	Hard	92	15.0
			Normal	90	15.0
			Soft	88	15.0
		Woman	Hard	90	15.0
			Normal	88	15.0
			Soft	86	15.0
		Child	Hard	88	15.0
			Normal	86	15.0
			Soft	84	15.0
	Green	Man	Hard	92	16.0
			Normal	90	16.0
			Soft	88	16.0
		Woman	Hard	90	16.0
			Normal	88	16.0
			Soft	86	16.0
		Child	Hard	88	16.0
			Normal	86	16.0
			Soft	84	16.0
Full Lateral (Optional)	High Resolution/ Green	Man	Hard	92	14.0
			Normal	90	14.0
			Soft	88	14.0
		Woman	Hard	90	14.0
			Normal	88	14.0
			Soft	86	14.0
		Child	Hard	88	14.0
			Normal	86	14.0
			Soft	84	14.0

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Examination Program	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PA SMV Waters' view	High Resolution	Man	Hard	92	14.0
			Normal	90	14.0
			Soft	88	14.0
		Woman	Hard	90	14.0
			Normal	88	14.0
			Soft	86	14.0
		Child	Hard	88	14.0
			Normal	86	14.0
			Soft	84	14.0
	Green	Man	Hard	92	15.0
			Normal	90	15.0
			Soft	88	15.0
		Woman	Hard	90	15.0
			Normal	88	15.0
			Soft	86	15.0
		Child	Hard	88	15.0
			Normal	86	15.0
			Soft	84	15.0
Carpus	High Resolution / Green	Man	Hard	90	6.0
			Normal	88	6.0
			Soft	86	6.0
		Woman	Hard	88	6.0
			Normal	86	6.0
			Soft	84	6.0
		Child	Hard	86	6.0
			Normal	84	6.0
			Soft	82	6.0

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Scan Time/Exposure Time

Examination Program	High Resolution		Green	
	Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
Lateral	3.9	3.9	1.9	1.9
Full Lateral (Optional)	5.4	5.4	3.9	3.9
PA	4.9	4.9	2.4	2.4
SMV	4.9	4.9	2.4	2.4
Waters' view	4.9	4.9	2.4	2.4
Carpus	4.9	4.9	2.4	2.4

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

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16.1.3 CBCT Mode

Exposure Area

FOV (cm)	Vertical Position	Horizontal Position		
		Right	Center	Left
16x9	Occlusion	X	O	X
12x9	Occlusion	X	O	X
	TMJ	O	X	O
	Airway	X	O	X
8x8	Occlusion	O	O	O
	TMJ	O	X	O
8x5	Maxilla/Mandible	O	O	O
5x5	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)		
Endo	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)		
Double scan (Optional)	First Exposure: Mandible Second Exposure: Maxilla	X		

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Exposure Condition

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
16x9 & 12x9 & Double scan (Optional)	High Resolution	Man	Hard	95	7.0
			Normal	94	7.0
			Soft	93	7.0
		Woman	Hard	95	6.7
			Normal	94	6.7
			Soft	93	6.7
		Child	Hard	95	6.4
			Normal	94	6.4
			Soft	93	6.4
	Green	Man	Hard	88	6.1
			Normal	87	6.1
			Soft	86	6.1
		Woman	Hard	88	5.8
			Normal	87	5.8
			Soft	86	5.8
		Child	Hard	88	5.5
			Normal	87	5.5
			Soft	86	5.5
8x8, 8x5, 5x5.	High Resolution	Man	Hard	95	13.0
			Normal	94	13.0
			Soft	93	13.0
		Woman	Hard	95	12.7
			Normal	94	12.7

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FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
			Soft	93	12.7
		Child	Hard	95	12.4
			Normal	94	12.4
			Soft	93	12.4
	Green	Man	Hard	88	9.6
			Normal	87	9.6
			Soft	86	9.6
		Woman	Hard	88	9.3
			Normal	87	9.3
			Soft	86	9.3
		Child	Hard	88	9.0
			Normal	87	9.0
			Soft	86	9.0
Endo	High Resolution	Man	Hard	95	9.5
			Normal	94	9.5
			Soft	93	9.5
		Woman	Hard	95	9.2
			Normal	94	9.2
			Soft	93	9.2
		Child	Hard	95	8.9
			Normal	94	8.9
			Soft	93	8.9

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Scan Time/Exposure Time

FOV (cm)	Scan Time (s) (High Resolution/Green)	Exposure Time (s) (High Resolution/Green)
Double scan (Optional)	18.0	18.0
16x9	9.0	9.0
12x9	9.0	9.0
8x8	2.9	2.9
8x5	2.9	2.9
5x5	2.9	2.9
Endo	18.0	18.0

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

Reconstruction Time/File Size (Measured Object: Skull)

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)		File Size (MB)
		Fast	HD	
Double scan (Optional)	0.3	29	-	282
16x9	0.2	35	149	550
	0.3	15	80	163
12x9	0.2	22	96	309
	0.3	9	61	92
8x8	0.12	36	120	635
	0.2	8	36	138
8x5	0.12	21	72	359
	0.2	4	24	77
5x5	0.08	26	89	466
	0.12	7	32	138
Endo	0.05	61	-	976

- The above data is obtained from a computer system that is based on Intel E5-1607 v3@3.10GHz (16GB of RAM) and NVIDIA GeForce GTX1060 6GB.
- Image reconstruction time varies depending on computer specifications and working conditions.
- When compression is applied, the image file size is reduced to 40% of its original size. The compression is available in all modes.

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16.1.4 3D MODEL Scan Mode

Exposure Area

FOV (cm)	MODEL Type	Horizontal Position		
		Right	Center	Left
8x8	Upper (Maxilla)	X	O	X
	Lower (Mandible)	X	O	X

Exposure Condition

FOV (cm)	Gender/Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
8x8	Man/Woman/Child	Hard/Normal /Soft	95	7.0

Scan Time/Exposure Time

FOV (cm)	Scan Time (s)	Exposure Time (s)
8x8	9.0	9.0

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

Reconstruction Time/File Size

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)	File Size (MB)
8x8	0.12	269	635

- The above data is obtained from a computer system that is based on Intel i7-6700 and NVIDIA GeForce GTX1060 6GB.
- Image reconstruction time varies depending on computer specifications and working conditions.

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16.2 X-ray Dose Data

16.2.1 DAP (Dose Area Product)

The X-ray dose data is extracted from the X-ray Dose Test Report for **Green X (Model: PHT-75CHS)**.

X-ray Dose Test Report for the **Green X (Model: PHT-75CHS)** maintains dosimetric evaluation that the **VATECH** dental diagnostic system meets all requirements specified in the IEC Collateral Standard. To limit unnecessary exposure to the patient, operator, or other staff, **Green X (Model: PHT-75CHS)** is designed to comply with IEC 60601-1-3 Part 1 General Requirements for Safety.

Test Hardware	
Brand Name (Model)	**Green X (Model: PHT-75CHS)**
Sensor Type	PANO & CBCT: Xmaru1314CF CEPH: Xmaru2602CF
X-ray Generator	DG-07E22T2
Tube	D-052SB

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

- *PHE (Public Health England) recommends that any national reference dose that achievable dose (DAP) value of 250 [$mGy \cdot cm^2$] for a clinical protocol for a standard male patient.*

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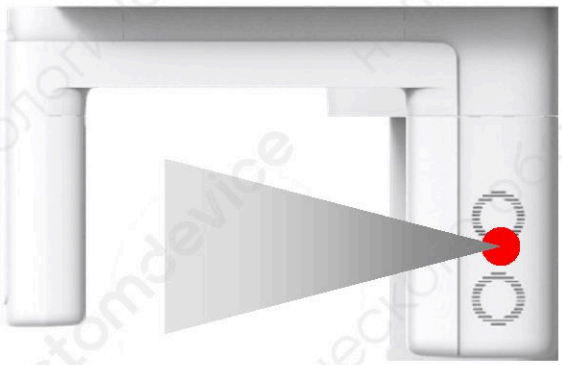
DAP (Dose Area Product) Calculation

DAP[mGy · cm²]=Dose[mGy] x Exposed Area[cm²]

NOTICE

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

Measurement Overview



Results

Mode	Exposure Condition	DAP [mGy·cm²]
PANO Adult Man Normal (High Resolution)	74 kVp/ 10.0 mA /13.5 s	112
PANO Child Normal (High Resolution)	69 kVp / 8.0 mA /11.5 s	54
PANO Adult Man Normal (Green)	84 kVp/ 14.0 mA / 3.9 s	58
PANO Child Normal (Green)	69 kVp / 12.0 mA / 6.8 s	56
CEPH Adult Man LAT (High Resolution)	90 kVp / 15.0 mA / 3.9 s	35
CEPH Child LAT (High Resolution)	86 kVp / 15.0 mA / 3.9 s	32
CEPH Adult Man LAT (Green)	90 kVp / 16.0 mA / 1.9 s	21

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Mode	Exposure Condition	DAP [mGy·cm²]
CEPH Child LAT (Green)	86 kVp/16.0 mA/1.9 s	19
CBCT 16x9 Adult Man (High Resolution)	94 kVp/7.0 mA/9.0 s	1385
CBCT 16x9 Adult Man (Green)	87 kVp/6.1 mA/9.0 s	1004
CBCT 12x9 Adult Man (High Resolution)	94 kVp/7.0 mA/9.0 s	1090
CBCT 12x9 Adult Man (Green)	87 kVp/6.1 mA/9.0 s	790
CBCT 8x8 Adult Man (High Resolution)	94 kVp/13.0 mA/2.9 s	815
CBCT 8x8 Adult Man (Green)	87 kVp/9.6 mA/2.9 s	503
CBCT 8x5 Adult Man (High Resolution)	94 kVp/13.0 mA/2.9 s	525
CBCT 8x5 Adult Man (Green)	87 kVp/9.6 mA/2.9 s	324
CBCT 5x5 Adult Man (High Resolution)	94 kVp/13.0 mA/2.9 s	349
CBCT 5x5 Adult Man (Green)	87 kVp/9.6 mA/2.9 s	215
CBCT Endo Adult Man (High Resolution)	94 kVp/9.5 mA/18.0 s	936
CBCT Double Scan Adult Man (High Resolution) (Optional)	94 kVp/7.0 mA/9.0 s	2770
CBCT Double Scan Adult Man (Green) (Optional)	87 kVp/6.1 mA/9.0 s	2008

- In Double Scan mode, exposure the FOV 16x9 twice, then stitch the acquired images to provide one image.

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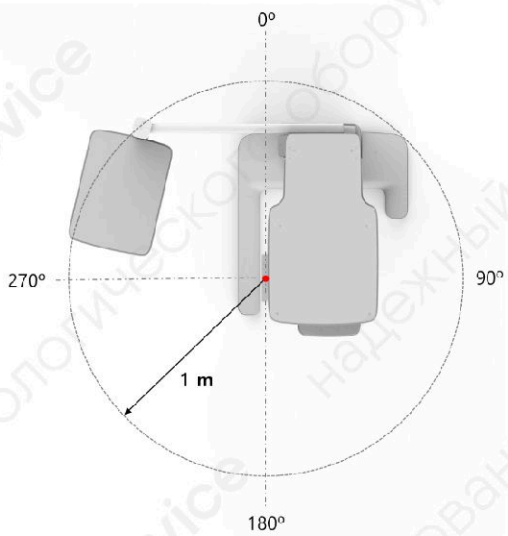
16.2.2 Leakage Dose

X-ray Leakage Dose Test is performed to protect patients against excessive radiation that is not purposed, and this document evaluates the leakage dose amount based on the following standard defined by IEC regulation and has been performed by covering each collimator region in use.

16.2.2.1 Standard

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

16.2.2.2 Measurement Overview



16.2.2.3 Test Condition

Test mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO Adult Man Normal (High Resolution)	90	14.0	13.5
CEPH Adult Man LAT (High Resolution)	99	16.0	3.9
CBCT 16x9 Adult Man (High Resolution)	99	12.0	9.0

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16.2.2.4 PANO Mode Results

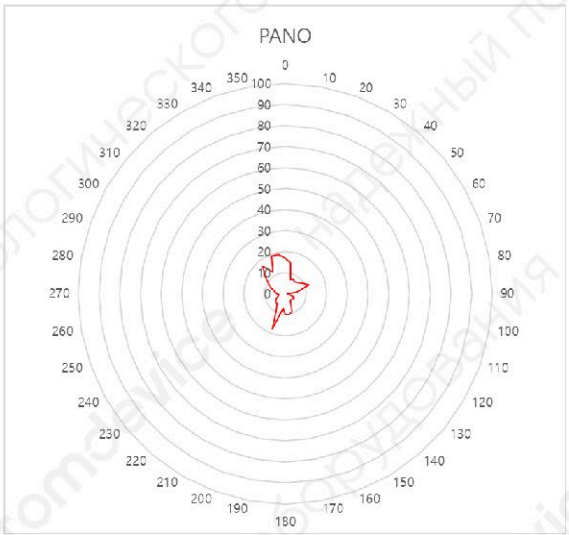
Test Condition	
Tested Mode	PANO
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

Mode / Direction [°]	PANO	
	[mR/hr]	[mGy/hr]
0	17	0.149
10	15	0.132
20	7	0.061
30	8	0.070
40	7	0.061
50	8	0.070
60	10	0.088
70	12	0.105
80	6	0.053
90	1	0.009
100	2	0.018
110	4	0.035
120	5	0.044
130	4	0.035
140	4	0.035
150	5	0.044
160	9	0.079
170	10	0.088
180	10	0.088
190	7	0.061
200	18	0.158
210	9	0.079
220	6	0.053
230	6	0.053
240	5	0.044
250	4	0.035

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Mode / Direction [°]	PANO	
	[mR/hr]	[mGy/hr]
260	3	0.026
270	4	0.035
280	5	0.044
290	7	0.061
300	9	0.079
310	13	0.114
320	17	0.149
330	12	0.105
340	19	0.167
350	19	0.167



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16.2.2.5 PANO Mode Results (Insight PAN)

Test Condition	
Tested Mode	Insight PAN
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

Mode / Direction [°]	Insight PAN	
	[mR/hr]	[mGy/hr]
0	13	0.114
10	12	0.105
20	7	0.061
30	7	0.061
40	6	0.053
50	7	0.061
60	7	0.061
70	11	0.096
80	5	0.044
90	2	0.018
100	2	0.018
110	4	0.035
120	4	0.035
130	4	0.035
140	5	0.044
150	5	0.044
160	10	0.088
170	11	0.096
180	9	0.079
190	7	0.061
200	21	0.184
210	12	0.105

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Mode / Direction [°]	Insight PAN	
	[mR/hr]	[mGy/hr]
220	6	0.053
230	5	0.044
240	4	0.035
250	4	0.035
260	3	0.026
270	3	0.026
280	5	0.044
290	7	0.061
300	9	0.079
310	13	0.114
320	18	0.158
330	11	0.096
340	13	0.114
350	16	0.140



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16.2.2.6 CEPH Mode Results

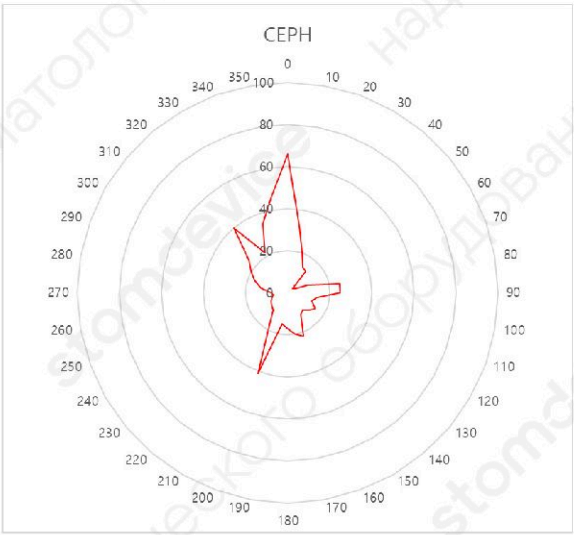
Test Condition	
Tested Mode	CEPH
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	16

Mode / Direction [°]	CEPH	
	[mR/hr]	[mGy/hr]
0	66	0.579
10	32	0.281
20	20	0.175
30	14	0.123
40	13	0.114
50	3	0.026
60	4	0.035
70	10	0.088
80	25	0.219
90	25	0.219
100	14	0.123
110	12	0.105
120	15	0.132
130	13	0.114
140	11	0.096
150	12	0.105
160	22	0.193
170	20	0.175
180	17	0.149
190	15	0.132
200	41	0.360
210	17	0.149

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Mode / Direction [°]	CEPH	
	[mR/hr]	[mGy/hr]
220	11	0.096
230	10	0.088
240	9	0.079
250	8	0.070
260	7	0.061
270	8	0.070
280	13	0.114
290	17	0.149
300	20	0.175
310	24	0.211
320	40	0.351
330	22	0.193
340	35	0.307
350	46	0.404



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16.2.2.7 CBCT Mode Results

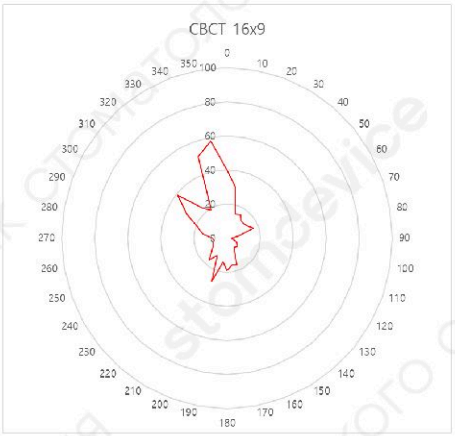
Test Condition	
Tested Mode	CBCT
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12

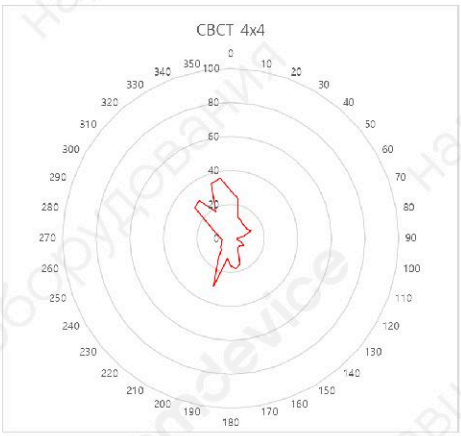
Mode / Direction [°]	16x9 High resolution		Endo 4x4 High resolution	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	40	0.351	28	0.246
10	30	0.263	24	0.211
20	15	0.132	13	0.114
30	16	0.140	12	0.105
40	13	0.114	11	0.096
50	13	0.114	11	0.096
60	14	0.123	11	0.096
70	17	0.149	13	0.114
80	7	0.061	8	0.070
90	3	0.026	4	0.035
100	3	0.026	4	0.035
110	6	0.053	7	0.061
120	7	0.061	9	0.079
130	8	0.070	7	0.061
140	7	0.061	7	0.061
150	9	0.079	9	0.079
160	17	0.149	16	0.140
170	16	0.140	18	0.158
180	19	0.167	16	0.140
190	14	0.123	12	0.105
200	27	0.237	30	0.263
210	12	0.105	15	0.132
220	17	0.149	9	0.079

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Mode / Direction [°]	16x9 High resolution		Endo 4x4 High resolution	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
230	12	0.105	8	0.070
240	10	0.088	6	0.053
250	9	0.079	6	0.053
260	8	0.070	5	0.044
270	9	0.079	6	0.053
280	15	0.132	7	0.061
290	19	0.167	10	0.088
300	28	0.246	14	0.123
310	39	0.342	28	0.246
320	23	0.202	29	0.254
330	19	0.167	18	0.158
340	51	0.447	34	0.298
350	58	0.509	36	0.316





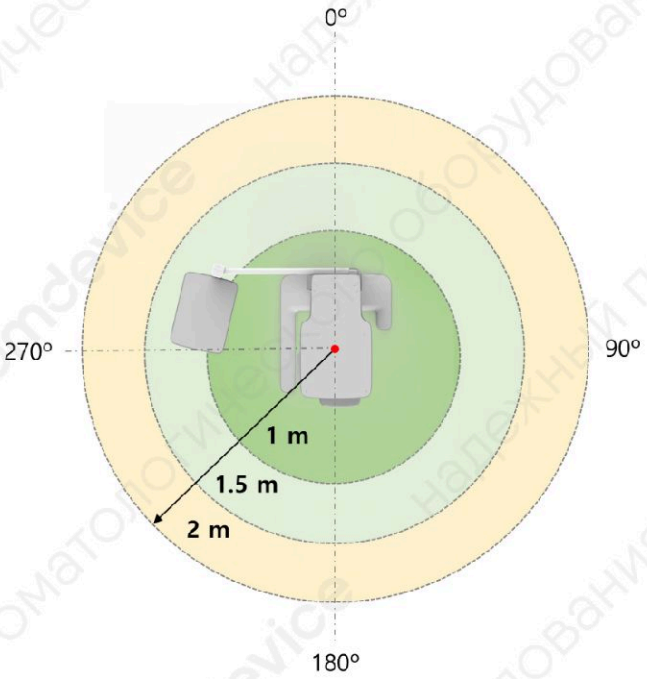
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16.2.3 Scattered Dose

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

16.2.3.1 Measurement Overview



16.2.3.2 Test Condition

Test mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO Adult Man Normal (High Resolution)	90	14.0	13.5
CBCT 16x9 Adult Man (High Resolution)	99	12.0	9.0
CEPH Adult Man LAT (High Resolution)	99	16.0	3.9

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16.2.3.3 CBCT Mode Results

Test Condition	
Tested Mode	CBCT
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12
Applied Exposure time [sec]	9.0

Direction [°] \ Mode		CBCT FOV 16x9 [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Nose	0.985	0.474	0.296
45		1.1	0.525	0.297
90	Right ear	0.127	0.067	0.043
135		1.126	0.528	0.249
180	Occiput	0.906	0.434	0.23
225		1.017	0.541	0.25
270	Left ear	0.958	0.553	0.261
315		1.021	0.497	0.282



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16.2.3.4 CBCT Endo Mode Results

Test Condition	
Tested Mode	CBCT Endo
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12
Applied Exposure time [sec]	18.0

Direction [°] / Mode		CBCT Endo FOV 16x9 [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Nose	0.613	0.282	0.161
45		0.588	0.282	0.164
90	Right ear	0.125	0.055	0.035
135		0.718	0.333	0.159
180	Occiput	0.309	0.154	0.086
225		0.716	0.365	0.16
270	Left ear	0.78	0.402	0.231
315		0.795	0.289	0.169



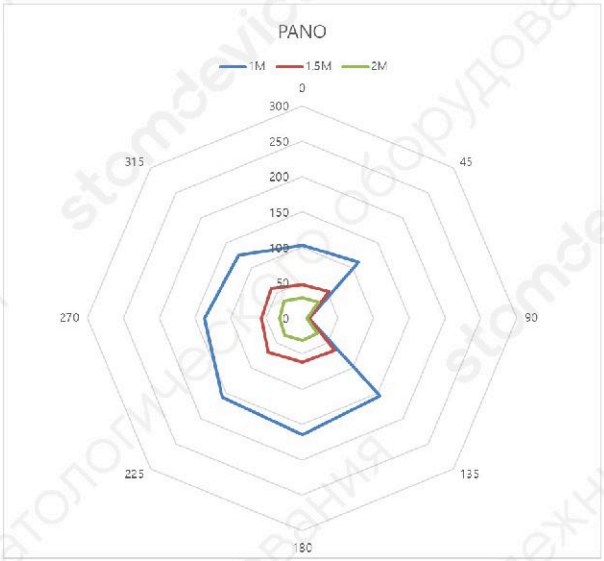
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16.2.3.5 PANO Mode Results

Test Condition	
Tested Mode	PANO
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14
Applied Exposure time [sec]	13.5

Direction [°] \ Mode		PANO FOV 16x9 [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Nose	0.103	0.047	0.028
45		0.111	0.053	0.032
90	Right ear	0.01	0.009	0.006
135		0.154	0.064	0.03
180	Occiput	0.164	0.062	0.03
225		0.157	0.067	0.033
270	Left ear	0.136	0.056	0.031
315		0.125	0.06	0.035



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16.2.3.6 PANO Mode (Insight PAN) Results

Test Condition	
Tested Mode	Insight PAN
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14
Applied Exposure time [sec]	13.5

Direction [°] \ Mode		Insight PAN FOV 16x9 [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Nose	0.543	0.258	0.159
45		0.553	0.303	0.173
90	Right ear	0.058	0.039	0.024
135		0.681	0.308	0.144
180	Occiput	0.574	0.239	0.13
225		0.673	0.315	0.16
270	Left ear	0.752	0.325	0.189
315		0.728	0.327	0.191



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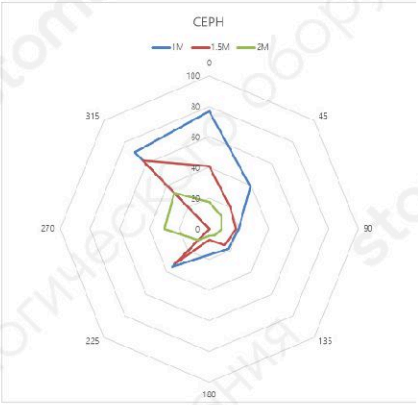
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16.2.3.7 CEPH Mode Results

Test Condition	
Tested Mode	CEPH
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	14
Applied Exposure time [sec]	5.4

Direction [°] \ Mode		CEPH FOV 16x9 [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Nose	0.076	0.041	0.017
45		0.039	0.02	0.012
90	Right ear	0.02	0.018	0.008
135		0.018	0.015	0.006
180	Occiput	0.016	0.007	0.005
225		0.035	0.032	0.01
270	Left ear	-	-	0.03
315		0.07	0.063	0.033

NOTICE Since the Ion chamber is located between the generator and the object, Data of 1 m and 1.5 m at 270 ° are not measured.



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16.3 Electromagnetic Compatibility (EMC) Information

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Mains terminal disturbance voltage	CISPR 11:2015	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Radiated disturbance	CISPR 11:2015	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Harmonic Current Emission	EN 61000-3-2:2014, IEC 61000-3-2:2014	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 220 V, 60 Hz AC 230 V, 50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	EN 61000-3-3:2013, IEC 61000-3-3:2013	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 220 V, 60 Hz AC 230 V, 50 Hz	Pst: 1 Plt: 0.65 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	EN 61000-4-2:2009, IEC 61000-4-2:2008	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3:2006 +A2:2010, IEC 61000-4-3:2010	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	EN 61000-4-3:2006 +A2:2010, IEC 61000-4-3:2010	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Table 9 in IEC 60601-1-2: 2014
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012,	IDLE mode CT mode PANO	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz	AC Line: ± 2 kV Signal: ±1 kV

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Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
	IEC 61000-4-4:2012	mode CEPH mode		AC 220 V, 60 Hz AC 230 V, 50 Hz	100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2014, IEC 61000-4-5:2014	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Disturbances Induced by RF fields	EN 61000-4-6:2014, IEC 61000-4-6:2013	IDLE mode CT mode PANO mode CEPH mode	AC Mains Exposure switch cable	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line & Signal: 3 V, 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	EN 61000-4-8:2010, IEC 61000-4-8:2009	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	30 A/m 50 Hz & 60 Hz
Voltage dips	EN 61000-4-11:2004, IEC 61000-4-11:2004	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single-phase: at 0°
Voltage interruptions	EN 61000-4-11:2004, IEC 61000-4-11:2004	IDLE mode CT mode PANO mode CEPH mode	AC Mains of the power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % U_T; 250/300 cycle

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16.4 Acquiring Images for Pediatric Dental Patients

16.4.1 Age Group: Classification Table

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

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

16.4.2 Positioning the Pediatric Dental Patients

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

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

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

- By Evelyn M. Thomson, BSDH, MS

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

Producing A Quality Panoramic Image

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

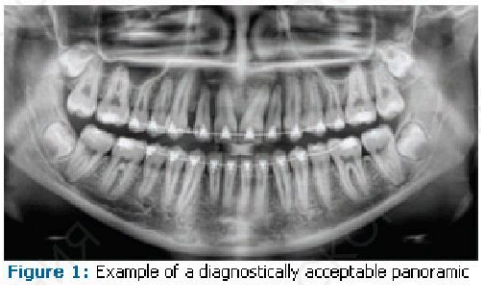


Figure 1: Example of a diagnostically acceptable panoramic radiograph of an adolescent patient undergoing orthodontic intervention. (Courtesy of Jamie Mace and Will Wright of Schick Technologies Inc.)

The most critical component in producing a diagnostically acceptable panoramic image is patient positioning. All panoramic x-ray machines have guidelines to assist with positioning the dental arches within the three dimensions of the focal trough, an

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



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

Table 1. Common Panoramic Positioning Errors

Error	Cause	Corrective action	Tips for pediatric patients
Anterior teeth narrow Severe posterior overlap Vertebrae superimposed over condyles	Arches positioned too far anterior	Position anterior teeth in appropriate position on bite guide. Locate appropriate position with anterior laser light guide.	Use a cotton roll to fill in missing primary teeth or partially erupted permanent teeth. Adapt adult recommendation for direction of laser light beam guide for use with primary teeth. Observe laser light beam guide on both the right and left sides.
Anterior teeth wide, blurred out of image Condyles not imaged	Arches positioned too far posterior		
Teeth on the right side appear narrowed, severely overlapped Teeth on the left side appear broad, poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the right	Position the midsagittal plane perpendicular to the floor.	Use laser light beam guide to locate midsagittal plane. Direct patient focus to mirror reflection. Affix decal to mirror to aid patient in maintaining the correct position throughout exposure.
Teeth on the left side appear narrowed, severely overlapped Teeth on the right side appear broad and poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the left		
Flat, downward-turned, "frown" appearance to the occlusal plane Palate appears as a widened, thick, dense radiopacity Concyles flare out off the edges of the image Anterior teeth appear wide, elongated	Arches positioned too far superior	Position the Frankfort or the canthomeatal plane parallel to the floor, or the ala-tragus line 5° down toward the floor.	More chin rest into a position that is slightly higher than the patient's chin height before requesting that the patient place chin onto the rest. Direct the patient to assume a position that resembles the erect stance of a soldier.
Exaggerated upward curve of the occlusal plane creating a "smile" appearance Hyoid bone superimposed over the mandible Condyles tilt inward Anterior teeth appear narrowed; elongated in the maxilla and foreshortened in the mandible	Arches positioned too far inferior		
Pyramid-shaped radiopacity superimposed over the anterior teeth	Patient in slumped position	Position the back and neck straight.	Direct the patient to stick out the chest while dropping the chin down. While holding the unit handles for stability, direct the patient to take a half step in toward the vertical column of the x-ray machine into a position that feels as if he/she is slightly leaning backward.
Radiolucent shadow of the commissure superimposed over the teeth, mimicking caries	Lips not closed around bite block	Position the lips around the bite block.	Direct the patient to keep the lips closed around the bite block during the exposure.
Radiolucency superimposed over the maxillary teeth apices	Tongue not placed against palate	Position the tongue flat against the roof of the mouth.	Direct the patient to swallow and note the flat position of the tongue. Request that the patient suck in the cheeks, pushing the tongue into the correct flat position against the palate and maintain this position throughout the exposure.

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Anterior-Posterior Positioning Error

When the arches are positioned incorrectly in the anterior-posterior direction, distortion or ghosting of the anterior anatomy occurs. Unerupted teeth in the anterior region may not be imaged on the radiograph if positioned outside of the focal trough. It is important to note that an error of only 3 mm to 4 mm in either direction will result in a significantly compromised image.[11] When the arches are positioned too far anterior, the anterior teeth will appear narrow and diminished in size. The vertebrae of the spinal column may be superimposed over the condyles at the edges of the film and, depending on the size of the child, may be superimposed over the rami of the mandible blocking a clear view of the posterior teeth **(Figure 3)**. When the arches are positioned too far posteriorly, the anterior teeth will appear broad or widened. If the position is excessively posterior, anterior teeth may be blurred entirely from the image, and the condyles may be cut off from the edges of the film.

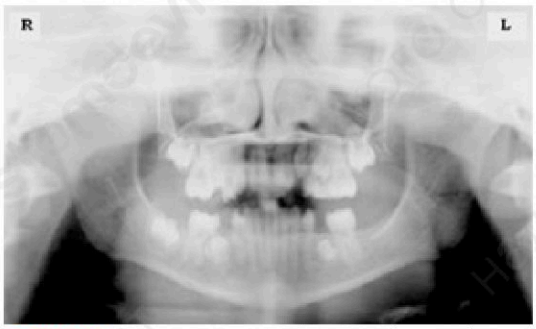


Figure 3: Incorrect position too far anteriorly. Note the narrow anterior teeth and superimposition of the spinal column over the condyles. The radiolucency superior to the maxillary apices indicates that the tongue was not placed against the palate. An open lip line can also be detected.

To avoid these imaging errors, the anterior teeth must occlude edge-to-edge onto the designated area of the bite block. Achieving this position is easily compromised during exfoliation of primary teeth, making precise occlusion difficult when one tooth or multiple teeth are missing or partially erupted. A cotton roll may be attached to the bite block to fill in the space created by the missing tooth or teeth. Additionally, an adjustment may be necessary when using a laser light beam guide. The manufacturer's instructions for directing the laser light beam at a predetermined tooth or interproximal space usually apply to adult patients. These instructions may need to be modified for the pediatric patient with primary or mixed dentition.

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Lateral Left-Right Positioning Error

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



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

To avoid imaging errors that result from incorrect lateral positioning, the midsagittal plane must be positioned perpendicular to the floor. Most panoramic x-ray machines have a head positioner and laser light beam guide, along with a mirror, to assist in determining the correct lateral head position. The pediatric patient may need additional instructions to maintain the correct position throughout the exposure.

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

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Superior-Inferior (Up-Down) Positioning Error

Positioning the dental arches within the superior-inferior (up-down) dimension of the focal trough can be challenging to achieve, especially with children whose smaller size reduces the distance between the shoulders and the inferior border of the chin. When the arches are positioned incorrectly in the superior-inferior direction, the image exhibits multiple distortions, including increased overlap in the premolar regions. When the arches are positioned too far up or down, the teeth will simultaneously move into a position that is too far back or too far forward, respectively, out of the focal trough.[11]

Positioning the arches too far superiorly produces a characteristic "frown" or flat, downward-turned appearance to the occlusal plane **(Figure 5)**. The condyles flare out and off the edges of the image, and the palate appears as a widened, thick, dense radiopacity. This positioning error results in a widened appearance of the palate and obliterates the apical regions of the maxillary teeth, compromising the images of the unerupted developing dentition. As the maxillary arch tips upward, the anterior teeth tilt backward, producing the same widened appearance that results from an incorrect anterior-posterior position. Positioning the arches too far inferior produces a characteristic "smile" appearance or the upward curve of the occlusal plane, with the condyles tilting inward toward the center of the image **(Figure 6)**. Depending on the severity of the downward position, the vertebrae may also curve inward and appear superimposed over the condyles, and the hyoid bone may be superimposed over the mandible blocking a clear view of the erupted and unerupted mandibular teeth.

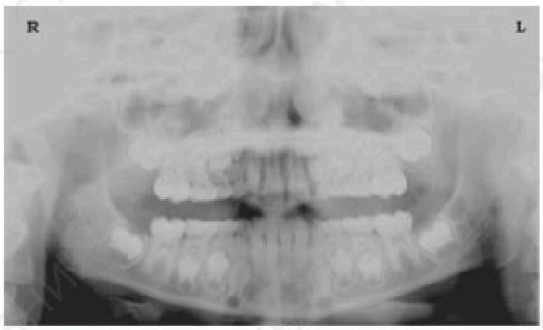


Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

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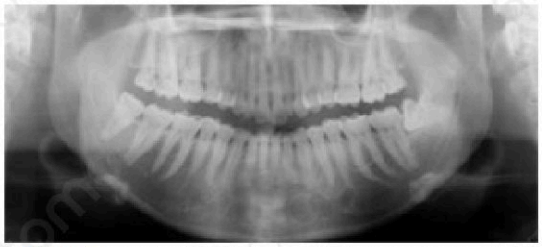


Figure 6: Chin positioned too far down. Note the characteristic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

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

Depending on the manufacturer, panoramic x-ray machines direct the operator to position the Frankfort or the canthomeatal plane parallel to the floor or the ala-tragus line 5° down toward the floor. This is achieved by raising or lowering the chin rest so that the appropriate landmark lines up with indicators on the machine **(Figure 2)**. The patient should be directed to stand in front of the panoramic x-ray machine allowing the operator to place the chin rest in a position that is slightly higher than the patient's chin. The patient is then requested to move into the overhead assembly of the machine and remain standing tall. If further adjustment is needed, it is usually to a lowered chin position. Once the patient's chin is resting on the chin rest, it is easier to move to a lower position than to a higher one. To assist with placing the chin on the chin rest while maintaining an erect posture, the pediatric patient can be directed to stand like a soldier. Most children are familiar with the straight back, chest forward, tucked chin position demonstrated by military persons, and can readily mimic this stance.

Further Recommendations

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

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space of the oral cavity between the dorsal surface of the tongue and the palate, producing a radiolucent shadow that diminishes the diagnostic quality of the radiograph (Figure 3).

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

Conclusion

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

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16.4.3 Setting Exposure Values to the Age Group

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

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

1) Literature

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

EAPD guidelines for the 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's benefit. Due to the relatively high frequency of caries among 5-year-old children, it is recommended to consider dental radiography for each child even without any visible caries or restorations. Furthermore, radiography should be considered at 8-9 years of age and then at 12-14, which is 1-2 years after the eruption of premolars and second molars. Additional bitewing controls should be based on an overall assessment of the caries activity/risk. The high-risk patient should be examined radiographically annually, while a 2-3 year interval should be considered when caries activity/risk is low. A routine survey by radiographs, except for caries, has not been shown to provide enough information to be justified considering the balance between cost (radiation and resources) and benefit.

- MICHAEL L. TAYLOR, B.SC. TOMAS KRON, PH.D., AND RICK D. FRANICH, PH.D.:

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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, to reduce the risk of secondary cancers Out-of-field doses to pediatric patients can be minimized by using simple treatment

- C. THEODORAKOU, K. HORNER, K. HOWARD, A. WALKER:

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

- CHIYO YAMAUCHI-KAWAURA & KEISUKE FUJII & TAKAHIKO AOYAMA & SHUJI KOYAMA & MASATO YAMAUCHI:

Radiation dose evaluation in the 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 concerns about radiation dose and their risks to children.

Objective: The purpose of this study was to clarify radiation dose levels for children 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

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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 the 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 a lens in brain CT and 17.2 mGy for thyroid in neck CT. The seventy-fifth percentile of effective dose distribution in brain CT was approximately the same as the diagnostic reference level (DRL) in the 2003 UK survey.

2) Website

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

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

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16.5 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
ESD	Electrostatic Discharge
EUT	Equipment Under Test
FDD	A focal spot to Detector Distance
FOD	A focal spot to Object Distance
FOV	Field of View
FPD	Flat Panel Detector
IEC	International Electrotechnical Commission
ISO	International Standards Organization
LCD	Liquid Crystal Display
LED	Light-Emitting Diode
MAR	Metal Artifact Reduction

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16. Appendices

AC	Alternating Current
MPSO	Multiple Portable Socket-Outlet
ODD	Object to Detector Distance
PA	Posterior/Anterior
RF	Radio Frequency
ROI	Region of Interest
SID	Source to Image Receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SMV	Submento-Vertical
STL	Stereo Lithography
TMJ	Temporomandibular Joint
UHD	Ultra-High Definition

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