Green X 18[™]

User manual

Model: PHT-75CHS

Version: 1.01

English



Full version



Notice

Thank you for purchasing the **Green X 18 (Model: PHT-75CHS)** extra-oral imaging system.

Green X 18 (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 18 (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 18 (Model: PHT-75CHS)** system. It is recommended that you thoroughly familiarize yourself with this manual to make the most effective use of this equipment.

Observe all cautions, safety messages, and warnings 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 18 (Model: PHT-75CHS) is referred to as "equipment" in this manual.

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Table of Contents

Notice			V
Table o	of Contents	•	vi
1.	Introduction		9
	1.1	Overview	. 9
	1.2	Indications for Use	. 9
	1.3	Intended Purposes1	ΙO
	1.4	Intended User Profiles1	L 1
2.	General Info	mation 1	3
	2.1	Manufacturer's Liability1	13
	2.2	Owner and Operator's Obligations	L3
	2.3	Conventions in this Manual	L 4
	2.4	Marks and Symbols 1	L5
3.	Warnings and	d Precautions 1	9
	3.1	General Safety Guidelines1	19
	3.2	Electricity-related Safety Precautions2	23
	3.3	Radiation Safety2	25
	3.4	Warnings2	26
4.	Imaging Syst	em Overview 2	9
	4.1	System Components2	29
	4.2	Features2	29
	4.3	Imaging System Options	30
	4.4	Standards and Regulations	31
	4.5	Operating Principles	32
	4.6	Imaging System Configuration	33
	4.7	Equipment Overview	34
5.	Imaging Soft	ware Overview 4	1
	5.1	PC Specifications (Recommended)4	11
	5.2	EzDent-i4	12
	5.3	Console Software4	13

Table of Contents

6.	Getting S	Started	49
	6.1	Turning on the Equipment	49
	6.2	Running the Image Viewer (EzDent-i)	50
	6.3	Initiating the Console Software	53
7.	Acquirin	g PANO Images	55
	7.1	PANO Imaging Program Overview	55
	7.2	Configuring Exposure Parameters	61
	7.3	Patient Positioning	67
	7.4	X-ray Exposure	83
	7.5	Finishing the Scan	84
	7.6	Checking the Captured Images	84
8.	Acquirin	g CEPH Images (Optional)	85
	8.1	CEPH Imaging Program Overview	85
	8.2	Configuring Exposure Parameters	87
	8.3	Patient Positioning	91
	8.4	X-ray Exposure	105
	8.5	Finishing the Scan	106
	8.6	Checking the Captured Images	106
9.	Acquirin	g CBCT Images	107
	9.1	CBCT Imaging Program Overview	107
	9.2	Configuring Exposure Parameters	111
	9.3	Obtaining Double Scan Image (optional)	116
	9.4	Patient Positioning	120
	9.5	X-ray Exposure	130
	9.6	Finishing the Scan	131
	9.7	Checking the Captured Images	131
10.	Acquirin	g 3D MODEL Scan Images	133
	10.1	3D MODEL Scan Imaging Program Overview	133
	10.2	Configuring Exposure Parameters	134
	10.3	MODEL Positioning	137
	10.4	X-ray Exposure	138
	10.5	Checking the Captured Images	139

11.	Troubleshoo	ting 141
	11.1	Troubleshooting141
	11.2	Error Codes142
12.	Cleaning and	d Disinfection 165
	12.1	Cleaning166
	12.2	Disinfection167
13.	Maintenance	169
	13.1	Regular Maintenance169
	13.2	Maintenance Task Checklist170
	13.3	QA Test171
	13.4	Phantom Kit Contents171
	13.5	QA Test Procedure173
15.	Technical Sp	ecifications 185
	15.1	Mechanical Specifications185
	15.2	Technical Specifications
	15.3	Environmental Specifications195
16.	Appendices	197
	16.1	Recommended X-ray Exposure Tables197
	16.2	X-ray Dose Data208
	16.3	Electromagnetic Compatibility (EMC) Information227
	16.4	Positioning the Pediatric Dental Patients229
	16.5	Acquiring Images for Pediatric Dental Patients237
	16.6	Abbreviations240

1. Introduction

1.1 Overview

Green X 18 (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 18 (Model: PHT-75CHS), a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography, **Green X 18 (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 18 (Model: PHT-75CHS) can also acquire 2D diagnostic image data in conventional panoramic and cephalometric modes.

1.2 Indications for Use

Green X 18 (Model: PHT-75CHS) is intended to produce panoramic, cephalometric, or 3D digital x-ray images. It provides diagnostic details of the dento-maxillofacial, ENT, sinus, and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. This device is to be operated by healthcare professionals.



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 facial bones, mandible, condylar neck, orbital floor, and fractures of teeth where plain film imaging is equivocal
- Planning any craniofacial surgery where 3D models of the jaw/facial skeleton/skull are required
- Diagnosis of most malformations and dysplasia, traumatic lesions, and thin osseous labyrinthine wall erosion or dehiscence through CBCT inner ear imaging
- Visualization of eustachian tube obstruction
- 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
- Instant 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 3D analysis of the jaw is required
- Storing Plaster Casts in 3D data

1.4 Intended User Profiles

Considerations	Requirement Description
Education	 Licensed dentists or dental hygienists, radiologists, and graduates of relevant bachelor's degree (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, operating conditions
Language understanding	 Understanding how to use manuals (English/Korean) or Understanding other language 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	Qualified personnel should use X-ray CBCT (dentists, dental hygienists, or radiologists only).
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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 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.

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.

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

<u>^</u>WARNING	WARNING	Indicates information that should be followed with the utmost care. Failure to comply with a warning may severely damage the operator and patient's equipment or physical injury.
△CAUTION	CAUTION	Indicates a situation that demands prompt and careful action, a specific remedy, or emergency attention.
IMPORTANT	IMPORTANT	Indicates a situation or action that could potentially cause problems to the equipment and its operation.
NOTICE	NOTICE	Emphasizes essential information or provides useful tips and hints.
	RADIATION	Indicates a possible danger from radiation exposure.
2	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.

2.4 Marks and Symbols

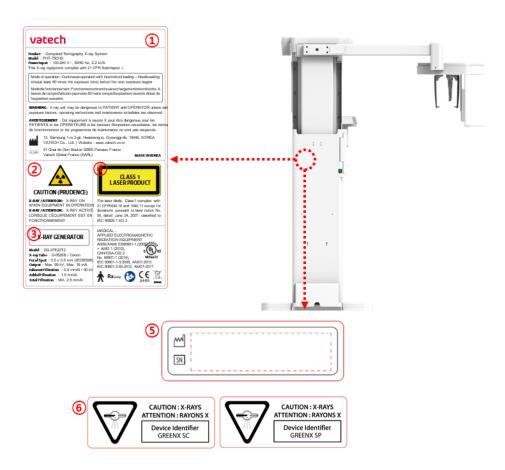
Symbols	Description	Location
4	Dangerous voltage	Powerboard /Inverter board /Monoblock
	Protective earth (Ground)	Column
0	Off (power: disconnected to the Main Power Switch)	Main Power Switch
	On (power: connected to the Main Power Switch)	Main Power Switch
\sim	Alternate current	Label
†	Type B Applied Equipment (IEC 60601-1: Degree of protection against leakage current and electric shock: Class 1 equipment)	Label
	Radiation hazard	Label
EC REP	Indicates the authorized representative in the European Community.	Label
C € 2460	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Label
C UL US E476672	UL mark No. E476672	Label
Rx Only	Caution: Federal law restricts this device to sale by or on a licensed healthcare practitioner's order.	Label
	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

2. General Information

Symbols	Description	Location
	Warns ESD hazard.	MCU board /Board package
CLASS 1 LASER PRODUCT	Indicates that this equipment is classified as a CLASS 1 LASER PRODUCT by IEC 60825-1 ED. 2 regulations.	Label
(is	Indicates that the user needs to refer to the User Manual.	Label
	Indicates the date of manufacture.	Label
SN	Indicates the manufacturer's serial number so that the specific equipment can be identified.	Label

2.4.1 Label Locations

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





The labels' design and contents may be different in some countries based on local regulations and standards.

2. General Information

No.	ltem
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) For Canada, the Model is distinguished by Green X 18 RC and Green X 18 SP. Green X 18 RC: CEPH included Green X 18 SP: CEPH not included

3. Warnings and Precautions



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



This x-ray unit may be dangerous to patients and operators unless safe exposure factors, operating instructions, and maintenance schedules are observed.

3.1 General Safety Guidelines

Operator qualifications

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

- To operate this equipment, the operator must:
 - Read and understood the **User Manual**.
 - Be familiar with the fundamental structure and functions of this equipment.
 - Be able to recognize the intermittent operation of this equipment and implement appropriate measures to remedy such irregularities.

General safety precautions

- Follow the instructions specified in this manual to ensure the safety of both the patient and the operator.
- The operator must 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 conduct inspection and maintenance of this equipment.
- Do not place any heavy objects on this equipment at any time.
- Do not place any objects within this equipment's field of operation. It may cause property damage.
- 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 until the equipment arm has stopped moving and the reset motion is completed.
- Observe all local fire regulations. Always keep a fire extinguisher near the equipment.
- The operator of this equipment must be familiar with this equipment's emergency protocols.

3. Warnings and Precautions

- Ensure that this equipment is kept away from water, moisture, or foreign substances always.
- If this product is exposed to water, moisture, or a foreign substance, immediately turn off the equipment's main power and contact your VATECH technical support representative.
- If there are signs of oil leakage, immediately cease all this equipment's operations 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).
- 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.

Ventilation

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

Hygiene



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

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 the equipment, as this could cause a fire.

- All movable patient support components (the Bite, the Chinrest, the Temple Supports, and the Ear Rods) can be cleaned using alcohol-based cleaning solutions.
- Clean the Support Handles by using alcohol-based cleaning solutions before taking photos of the next patient.
- Other surfaces of the equipment, including the Control Panel, can be cleaned using a soft cloth dampened with a mild cleaning solution.

 New hygiene cover must be provided for each new patient to prevent the transmission of communicable diseases.





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

Condensation

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

Cooling

- Allow the proper amount of cooling downtime (for the X-ray tube to cool down) before acquiring the next image.
 - Mode of operation: Continuous operation with intermittent loading Needs waiting time (at least 60 times the exposure time) before the next exposure begins
 - Column operation time: Max. 2 min. On/18 min. Off (Ratio 1:9)
- If the tube head's temperature reaches 60 °C (140 °F), X-ray exposure will cease, and an error message will be displayed. Normal X-ray capabilities will resume after the generator reaches 58 °C (136.4 °F).
- If the fan (optional) is installed, it automatically operates when the tube head's temperature reaches the pre-defined level: 40 °C (104 °F). The setpoint temperature is configurable.

Turning the equipment on/Adjusting the height of the equipment

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

Emergency stop

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

3. Warnings and Precautions

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 thirdparty accessories expressly approved by VATECH.

3.2 Electricity-related Safety Precautions



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

- Check the status of the power source, PC, and cables before operating the equipment.
- Ensure that Main Power Switch is set off when the equipment is not in use.
- Always disconnect the power supply before cleaning the equipment.
- Always keep electrical cords away from hot appliances or radiators.
- Do not place the PC or peripheral equipment connected to the PC near the patient.
- The equipment and PC should be connected to a common protective earth.
- Never overload the equipment's circuit by sharing it with too many appliances.
- 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 systems, radio link systems, or MRI systems are located within 5 m of the unit, please observe the installation requirements' specifications.
- Portable Radio Frequency (RF) communications equipment may interfere with medical electrical equipment. Therefore, the use of mobile wireless phones in medical offices or hospital environments must be prohibited.
- For more details, refer to 16.3 Electromagnetic Compatibility (EMC) Information.
- Please also observe the Electro-Static Discharge (ESD) protective measures described.

Static Discharge

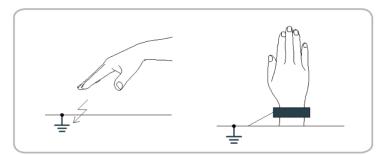
 Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without observing ESD protective measures.



Electro-static discharge (ESD)

ESD protective measures include

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



3.3 Radiation Safety



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 outside the shielded area.
- The operator should continuously check the status of the patient and the equipment during imaging.
- The operator should be at least 2 m (6 feet) away from the equipment during imaging.
- The operator must immediately stop imaging if the equipment malfunctions.
- The patient must wear a lead apron with neck and thyroid protection during X-ray exposure.
- Children and pregnant women must consult with a doctor before X-ray exposure.





As a radiology equipment manufacturer that conforms to stringent protection standards worldwide, we guarantee maximum protection against our equipment's radiation hazards.

3.4 Warnings

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

 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 carefully read this User Manual and abide by all warnings and cautions stated. The 3D image should not be used for screening examinations. Each exam must be justified by demonstrating that the benefits outweigh the risk. 		i e e e e e e e e e e e e e e e e e e e
examinations. Each exam must be justified by	<u>^</u>WARNING	operator if proper exposure safety measures and operating instructions are not observed. It is essential to carefully read this User Manual and
 The evaluation of soft tissues will likely be required as part of the patient's radiological assessment, and conventional medical CT or MR should be used instead of dental cone beam imaging. 	<u></u> <u> </u> <u> </u> <u> </u>	examinations. Each exam must be justified by demonstrating that the benefits outweigh the risk. The evaluation of soft tissues will likely be required as part of the patient's radiological assessment, and conventional medical CT or MR should be used instead
 Green X 18 (Model: PHT-75CHS) system, like other medical equipment, uses high-frequency electrical signals to 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 18 (Model: PHT-75CHS) system is designed to withstand the effects of defibrillation. However, when 	<u>^</u>WARNING	medical equipment, uses high-frequency electrical signals to 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 18 (Model: PHT-75CHS) system is designed to
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.		possible, disconnect the Dental X-ray system during defibrillation since a malfunction of the safety controls
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.	△CAUTION	a dentist or with the descriptive designation of any other practitioner licensed by the law of the State in which he

Lasers

- The system incorporates Class 1 laser products. The light localizers used in this
 product are intended for correct patient positioning and must not be used for any
 other purpose.
- For maximum safety, advise the patient not to look directly at the laser beam.
- While adjusting the patient, ensure that the laser beam is not directed at the patient's eyes.
- Wavelength: 650 nm, Radiant power: Max. 039 mW



Risk of eye injury!

Do not use this equipment with any other laser sources, and do not change 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 medical electrical 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 increase EMISSIONS or decrease IMMUNITY OF EQUIPMENT or SYSTEM.

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.
- Equipment should only be installed by an authorized technician, complying with proper installation procedures.



For further details on installation, refer to the **Green X 18** (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 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.

4. Imaging System Overview

4.1 System Components

- Green X 18 (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(18×24), 18x15, 16x11, 12x9, 8x8, 8x5, 5x5, Endo(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: 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 the 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

4. Imaging System Overview

4.3 Imaging System Options

Configuration	Item	Sensor	
SP	PANO +CBCT	PANO/CBCT	Xmaru1524CF Master Plus OP
RC	PANO +CBCT +CEPH	PANO/CBCT	Xmaru1524CF Master Plus OP
		СЕРН	Xmaru2602CF

4.4 Standards and Regulations

Standards

Green X 18 (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

C € 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.
CULUS 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

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



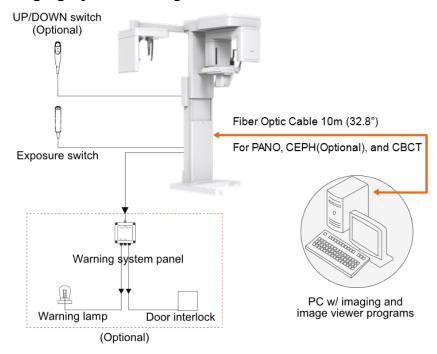
4.5 Operating Principles

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

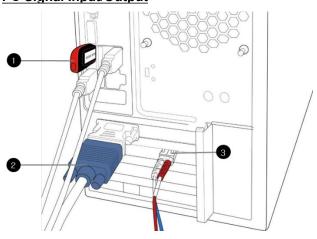
They hit anode to produce an X-ray. The machine acquires images by emitting X-ray continuously and rotates on the human tooth at different angles.

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

4.6 Imaging System Configuration

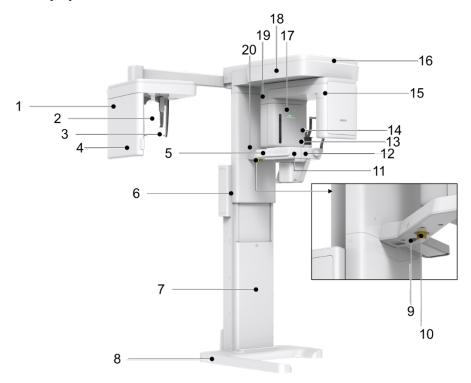


PC Signal Input/Output

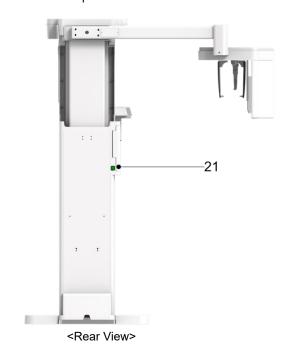


No.	Item
1	3D viewer License Key
2	Video output
3	Fiber optic cable (Data in/out)

4.7 Equipment Overview



< Perspective View>

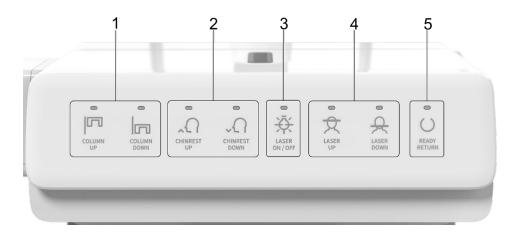


No.	Item	Description	
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor	
		Positions the patient during CEPH imaging.	
2	Nasal Positioner	The ruler used for reference in an acquired image that is different from the actual size	
3	Ear Rods	Secure the patient's head during CEPH imaging.	
4	Column UP/DOWN button (CEPH Part)	Adjust column height to adjust the height of the vertical frame.	
5	Control Panel	Adjust column height to change the vertical frame's height, up or down the Chinrests, prepares for operation when the READY/RETURN button is pressed, and operate the Horizontal Laser Beam. (For the details, refer to 4.7.1 Control Panel .)	
6	Column UP/DOWN Switch (optional)	Adjust column height to adjust the height of the vertical frame.	
7	Stationary Column	Supports the whole part of the equipment.	
8	Base (Optional)	Balances the equipment and maintains its safety.	
9	D-Sub Connector	The input signal port for Column UP/DOWN Switch	
10	Emergency Stop Switch	Immediately stops the moving parts and cuts off all power to the equipment's electrical components.	
11	Canine beam guide adjuster	Adjust the canine beam guide back and forth.	
12	Temple Supports OPEN/CLOSE Knob	Adjusts the Temple Supports for patient positioning.	
13	Chinrest	The place to rest the chin.	
14	Temple Supports	Supports the patient's head by holding the temples. It is used in PANO and CBCT modes.	
15	X-ray Detector for PANO/CBCT	Xmaru1524CF Master Plus OP for PANO/CBCT imaging sensor	
16	LED Lamp	Displays the status of X-ray exposure. Green: Standby Yellow: In operation (X-ray on)	
17	X-ray Generator	The X-ray tube where the X-ray is produced.	
	•	Holds the Rotating Unit.	
18	Vertical Frame	It can be controlled with the Column UP/DOWN switch.	

4. Imaging System Overview

No.	Item	Description	
19	Rotating Unit	Rotates around the patient's head while the image is being acquired.	
		(Its movement is different according to the scan mode.)	
20	Enclosed Component Storage	, , , , , , , , , , , , , , , , , , , ,	
21	Main Power Switch	r Switch Turns on/off the main power of the equipment.	

4.7.1 Control Panel



No.	Buttons	Description	
1	COLUMN UP/DOWN Button	Moves the Vertical Frame up or down. (For adjusting the height of the Chinrest)	
2	CHINREST UP/DOWN Button	Adjusts the Chinrests for patient positioning.	
3	LASER ON/OFF Button	Turn the laser beam on or off for patient positioning.	
4	LASER UP/DOWN Button	Aligns the Horizontal Beam in PANO mode.	
5	READY/RETURN Button	Indicates that imaging is ready for X-ray after paramete settings, and the patient positioning is complete. Initializes the positioning of the Rotating Unit.	

4.7.2 Emergency Stop Switch

During operation, the following emergencies may occur:

- X-ray emission even after the Exposure Switch has been released
- Physical injury to the patient or damage to the equipment
- Other emergencies

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

The **Emergency Stop Switch** is located under the bottom of the Handle Frame.



4.7.3 Exposure Switch

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

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

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

IMPORTANT

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

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

4.7.4 Enclosed Components

The enclosed components can be disassembled and cleaned. All enclosed components used to support the patient (the Bite, the Chinrest, the Ear Rods, and the Temple Supports) should be cleaned with ethanol and wiped with clean towels.

Components	Name and Function	Materials
19	Normal Bite - For PANO and CBCT normal patients	PC (Polycarbonate)
J.	Special Bite A - For PANO TMJ and Sinus modes - For CBCT TMJ patients	PC (Polycarbonate)
Q-	Special Bite B - For PANO edentulous patients	PC (Polycarbonate)
9	Normal Chinrest - For Normal Bite	ABS (Acrylonitrile butadiene styrene) copolymer
	Temple Supports (1 set)	PC (Polycarbonate)
	Ear Rods (1 set)	Silicone
(B)	Nasal Positioner Cover - For CEPH	Silicone
	Carpus Plate	PC (Polycarbonate)
Pancerana Course 30 pc	Sanitary Vinyl Covers (disposable) for the Bite	PP+PE
	Protractor (1 set) - For positioning the patient's body in CEPH mode.	PC (Polycarbonate)

Components	Name and Function	Materials
<u>0</u>	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)



- The PC system plays a vital role in image processing and verification. Configure the PC environment to meet the following specifications. If the PC specifications are not met, the image quality can be lower.
- Do not place patients 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)		
	2 PCI Express Gen3 x 16 slot		
	1 PCI Express Gen3 x 8 Slot		
Slots	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		

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.
	Security Capabilities
NOTICE	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 used 3 rd party security tools and application systems.
NOTICE	 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.

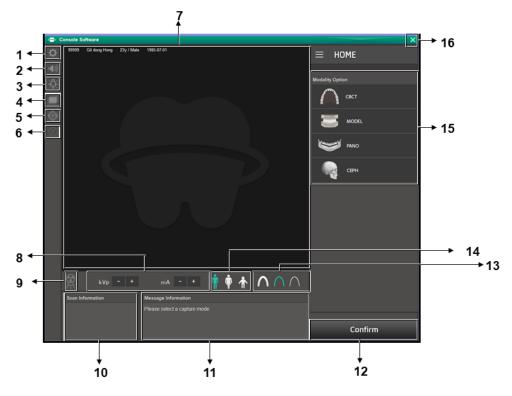
5.3 Console Software

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



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

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



No.	. Item Description	
1	Settings button	Displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, etc.
2	Volume button	Adjusts the sound of audio from the equipment. Click the button and move the volume control bar to change the audio's volume. Ensure to save the change after selects the new volume.

5. Imaging Software Overview

No.	Item	Description		
3	Laser Beam ON/OFF button	Turns the Laser Beam on or off for patient positioning. The button is enabled when the CONFIRM button is clicked after the imaging conditions are configured.		
4	Manual Reconstruction button	Reconstructs the image manually when automatic image reconstruction fails: 1. Select a Modality after clicking this button. 2. Click the Search button. 3. Select an image to reconstruct. 4. Click the Reconstruction button.		
5	Phantom button	Image acquisition using the Phantom Jig: 1. Click the Phantom button. 2. Select the Modality and click the Capture button. 3. Check the parameters displayed in the main GUI window, align the Phantom Jig, and then click the READY button. 4. Press and hold down the Exposure Switch.		
6	Test Rotation button	Switches to the Test mode to check if any part of the patient's body is reached the equipment's surface before the actual exposure. NOTICE To change to the test mode, 1. Align the patient to the equipment. (For the details, refer to the "Positioning the Patient" section of each modality chapter.) 2. Select a modality. 3. Click the CONFIRM button. 4. Click the Test Rotation button. Then, ON at the Test Rotation button is changed to OFF.		

No.	Item	Description
		 To initiate test rotation, press the BEAM ON/OFF button on the Control Panel. To finish the test mode, click the Test Rotation button or READY button.
		NOTICE This functions to PANO and CBCT modalities only.
		Displays information on the selected patient.
7	Patient Information window	NOTICE The user can freely control the mouse in the guide area and specify the exposure range.
0	Tube Voltage	If the patient is selected in EzDent-i , the default kVp/mA, according to the patient's information (gender/age), is displayed. This tool adjusts the kVp and mA values and controls the X-ray's power to improve image quality. If necessary, adjust the kVp and mA values manually using the arrows.
8	and Current Adjustment	The tube voltage and its correspondence with the selected patient, refer to 16.1 Recommended X-ray Exposure Tables.
9	X-ray indicator	The radiation mark turns yellow, and the lamp image changes to colored.
10	Scan Information window	Displays estimated DAP (Dose Area Product), scan time, and exposure time after exposure parameter settings are completed.
11	Guide Message window	Displays various text instructions for the operator.
12	CONFIRM /READY button	Confirm Applies the selected settings and moves to the next step.

5. Imaging Software Overview

No.	Item		D	escriptio	on	
		(Exposure parameter setting and patient positioning > Ready for exposure)				
		When you click the CONFIRM button, estimated DAP (Dose Area Product), scan time, and exposure time would be displayed DAP, Scan Time, and Exposure Time Display window.				
		Ready It is activated when you click the CONFIRM butto the patient positioning is completed. Click the but when all aspects of preparation are completed fo acquisition.				
						button
		Selects X-ray				
		ray intensity	may be cla			ent's head, X- mal, or Soft:
13	X-ray intensity	Soft ≤ Norma	al ≤ Hard			
10	A-lay illelisity	Age Group	Average Circumfere		Range (cm)	X-ray Intensity
			hild 53±3		>53±3	Hard
		Child		:3	53±3	Normal
				<53±3	Soft	
			Adult 56±3	_	>56±3	Hard
		Adult		:3	56±3	Normal
		-			<56±3	Soft
	Patient's gender/age group	Displays the centered in Ezlinecessary, the selected.	Dent-i 's pa	tient info	rmation field	ds. If
14		Gender / Age Group		VATECH's Standard		
		Child	d	2 ~ 12	2 ~ 12 years of age	
		A -1 -11	Man			
		Adult	Woman	> 12 y	ears of age	

No.	Item	Description
	Modality	Selects the imaging parameters for each mode: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan
15	Selection button	NOTICE
		Selecting Modality changes the Modality Selection screen to the Imaging Parameters Configuration panel.
16	EXIT button	Exits the console software.



After completing the X-Ray survey, a pop-up message shows the image acquisition progress and displays a preview of the acquired image.

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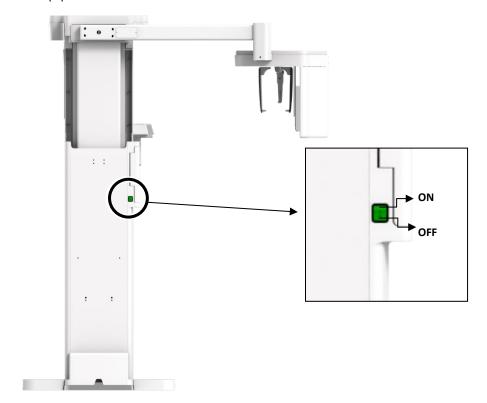
48

6. Getting Started

6.1 Turning on the Equipment



- Do not place the patient close to the equipment when it is being turned on. Doing so may cause physical injury to the patient and damage to the equipment.
- Do not operate the PC while the equipment is in operation. Doing so may cause an error in the equipment.
- Press the Main Power Switch located under the middle of the Column to turn on the equipment.



NOTICE

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

2. Make sure that the green LED light at the top of the equipment is on.

6.2 Running the Image Viewer (EzDent-i)

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

NOTICE	For further details on this subject, refer to the EzDent-i User Manual .		
NOTICE	 Security Capabilities 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 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 18 (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 keep patient information.		

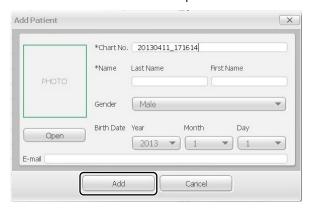
6.2.1 Creating a New Patient Record

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

1. Click the PATIENT tab and click the Add Patient icon from the main GUI window.



- Enter the required patient information. Chart Number, E-Mail address, First Name, and Last Name are required fields that must be filled in. (The Chart Number is filled in automatically.)
- 3. Click the Add button to save the patient record.



6.2.2 Retrieving Patient Records

You can search through the patient database using a patient's Chart Number, First Name, or Last Name.

 Enter the Name or Chart Number of the patient to be searched on the Patient Search panel, and then click the Search button. The information on the patient that fits the search condition appears.





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



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



6.3 Initiating the Console Software



For a new patient, the patient information needs to be registered first.

I. Search and select the patient to be captured.



Click the ACQUISITION tab and select the imaging mode (CT, Panorama, or Cephalo).



3. The Main Screen for the selected mode appears. From the Main Screen, you can configure the imaging parameter settings before acquiring an image.



Refer to the following **chapters** (7~10) for more information on image acquisition.

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7.1 PANO Imaging Program Overview

Result Images

It provides conventional 2D panoramic images.

■ Image Acquisition Method

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

■ Examination Programs

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

Examination Type	Arch Selection	ROI	Example
	Narrow Normal Wide Orthogonal	Right	- Amarian
		Front	
PANO Examination		Left	
Examination		Standard	
	Child	Front	· Allu
	Cillia		
PANO Examination	Child	Left	· Antimities

Examination Type	Arch Selection	ROI	Example
		Standard	
		Right	
		Front	
	Orthogonal	Left	· Illing
		Bitewing Right*	- American
		Standard	
		Bitewing Left*	- American Hilliams
		Bitewing*	
PANO Examination	Orthogonal	Bitewing Incisor* (Optional)	· Samuel Transport
PANO Examination (Insight PAN**)	Normal	-	

Examination Type	Arch Selection	ROI	Example
	Child	-	
	N/A	TMJ LAT Open	7
		TMJ LAT Close	
SPECIAL Examination			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.

 $^{^{\}star\star}$ When InsightPAN is selected, the user can freely change the exposure areas (FOV) with mouse control and drag.

■ Main Imaging Programs

Examination Type	Arch Selection	ROI	Description & Sample Image
PANO Examin ation	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 teeth' overlapped region from X-ray exposure, which is beamed perpendicularly between teeth.

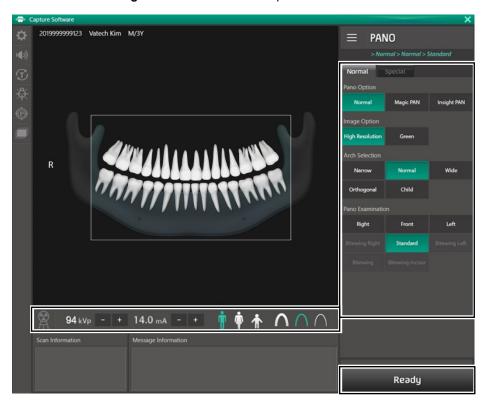
Examination Type	Arch Selection	ROI	Description & Sample Image		
			A panoramic imaging mode to acquire an image only for the region of interest through the orthogonal trajectory. (Pros: less X-ray exposure than the		
		Bitewing** (Bitewing Incisor mode is Optional)	Normal mode. /Cons: TMJ and some parts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

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

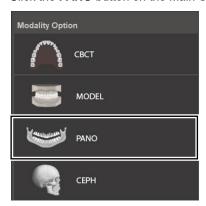
^{**} Bitewing imaging mode is activated only when Orthogonal is selected in Arch Selection.

7.2 Configuring Exposure Parameters

To acquire PANO Images, **6. Getting Started** must be completed first. If not, you must return to the **6. Getting Started** and finish the step first.



1. Click the PANO button on the Main Screen.





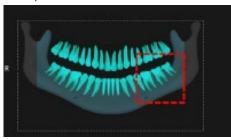
The CEPH button exists only when the CEPH imaging program is included in the equipment.

2. Select a Pano Option.



Mode	Description	
Normal	Provides a normal panoramic image.	
Magic PAN	Provides a single optimal panoramic image having multiple focal images combined.	
(Optional)	Minimizes the difference in the quality of images defined by the patient's positioning and arch shape.	
Insight PAN (Optional)	Provides multiple panoramic images having different focal planes along with a typical panoramic image together. Enables detailed verification of images in-depth direction.	
NOTICE	When "Insight PAN" is selected, Image Options are disabled.	
NOTICE	When Insight PAN is selected, the user can freely set the exposure area (FOV) with mouse control and drag. (Multi FOV available)	
NOTICE	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.	

When Insight PAN is selected, the user can freely set the exposure area (FOV) with mouse control and drag. (Multi FOV available)



<Selected the exposure area in Console Software>



<Exposure area in real image>

NOTICE

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

(The minimum selectable area: about 50 x 50 mm².) 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 EzDent-i (Insight NAVI) viewer.



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

3. Select an Image Option.



Mode	Description	
High Resolution	High-Resolution image	
Green	Normal-Resolution image	
	The default is the High Resolution . And the Green is	



optional.

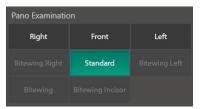
When the Pano Option is selected to the **Normal**, Image Option is selectable between the **High Resolution** and the **Green**. When the **Magic Pan** or the **Insight PAN** option is selected, the Image Options section is invisible.

4. Make an Arch Selection.



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

Select an Examination Program in the Pano Examination or Special Examination panel.



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





- When a Special Examination option is clicked, the PANO Examination panel is disabled. If you want to select a PANO Examination option, please conduct Arch selection again.
- For more information about the Examination Program, refer to the 7.1 PANO Imaging Program Overview.
- **6.** The Gender/Age group of the patient is selected automatically based on the patient information. If necessary, you can select the option manually.





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

7. Select X-ray intensity.



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

Soft ≤ Normal ≤ Hard



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

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

Scan Time : 14.1 sec Exposure Time : 13.5 sec

Confirm

When you click the CONFIRM button,

- The Rotating Unit will move to its initial scanning position.
- The Vertical Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Scan Information



Scan Information

DAP

: 109.704666 mGy x cm^2

10. Guide the patient to the equipment.

7.3 **Patient Positioning**

<u>^</u>WARNING	 Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation. Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss. 	
IMPORTANT	 Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition. Metal implants or bridges may reduce the quality of the images. Be sure to adjust the laser beam correctly. Otherwise, the images' quality can be lower due to ghost images or expansion/reduction of the images. 	
NOTICE	There is a horizontal beam laser for the guide that points the patient's shoulder in the rotator section. This laser allows you to proactively identify the possibility of moving the rotator and touching the patient's shoulder. If the laser is pointing at the patient's shoulder, it can be lowered further to prevent the rotator from touching the patient's shoulder.	

Getting prepared

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



<Control Panel>



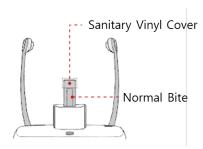


<Column UP/DOWN switch>

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

Normal Patient Positioning

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



The Sanitary Vinyl Cover is for sole use only. It should be replaced for each patient. Be sure to use the approved vinyl cover.



- Clean the Chinrest and the Bite with ethanol and wipe with a dry towel before the next patient.
- 2. Guide the patient to the inside of the equipment.
- 3. Use the **Column UP/DOWN** button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.



<Control Panel>



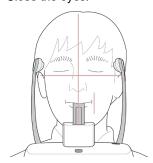


<Column UP/DOWN switch>

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

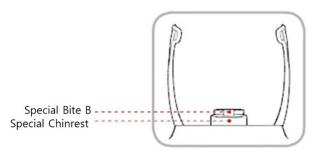


- 5. Let the patient maintain the posture as follows:
 - Close the mouth.
 - Place the tongue to the roof of the mouth.
 - · Close the eyes.



Edentulous Patient Positioning

- Remove the Normal Chinrest and insert the Special Chinrest into the equipment.
- 2. Insert the Special Bite B into the Special Chinrest.





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

- 3. Guide the patient to the equipment.
- **4.** Use the **Column UP/DOWN** button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.



<Control Panel>





<Column UP/DOWN switch>

- **5.** Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
- **6.** Let the patient maintain the posture as follows:
 - Close the mouth.
 - Place the tongue to the roof of the mouth.
 - Close the eyes.



Laser Beam Aligning

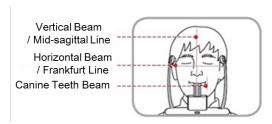


Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.

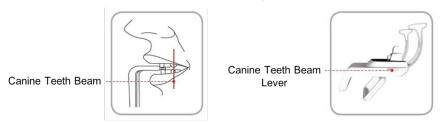


If the laser beam is not correctly positioned, distortion may cause the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the laser beam properly.

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



3. Direct the patient to smile and align the Canine Teeth Beam to the center of the canines. Use the Canine Teeth Beam Lever to adjust the position of the beam.



Finishing Patient Positioning

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



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

7.3.2 SPECIAL Examination Mode (TMJ/Sinus)

<TMJ Open Mode (LAT/PA)>

The TMJ Close image can be acquired after the TMJ Open image is acquired.

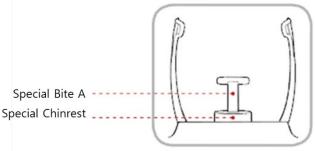


Steps for TMJ Mode

Patient positioning for TMJ Open > Laser Beam Aligning > X-ray Exposure > Patient positioning for TMJ Close > Laser Beam Aligning > X-ray Exposure

Patient Positioning

- Remove the Normal Chinrest and insert the Special Chinrest into the equipment.
- 2. Insert the Special Bite A into the Special Chinrest





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

3. Guide the patient to the equipment.

Use the Column UP/DOWN button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.



<Control Panel>





<CEPH part>

<Column UP/DOWN switch>

- Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
- Guide the patient to press the nose's base (acanthion point) against the Chinrest and tilt the head forward about 5°. At this point, make sure the patient's jaw does not touch the equipment.



- If the jaw touches the equipment, it is difficult to maintain the proper position to get good images.
- Be careful; the patient does not touch the equipment with his/her jaw.

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





- The integrated Chinrest's support unit should touch the patient's acanthion point, as shown in the picture.
- Ask the patient to maintain his/her position until the operation is completed.

Laser Beam Aligning

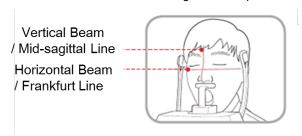


Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.



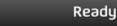
If the laser beam is not correctly positioned, distortion may cause the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the laser beam properly.

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



Finishing Patient Positioning

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



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

<TMJ Close Mode (LAT/PA)>

The TMJ Close image can be acquired after the TMJ Open image is acquired.



Steps for TMJ Mode

Patient positioning for TMJ Open > Laser Beam Aligning > Xray Exposure > Patient positioning for TMJ Close > Laser Beam Aligning > X-ray Exposure

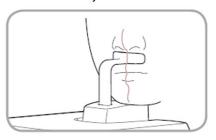
Patient Positioning

 "Do you want to capture a TMJ Close image?" message will appear when the TMJ Open mode is completed. Press/Click the **OK** button to begin TMJ Close mode.



<Console Software>

- **2.** Guide the patient to the equipment.
- 3. Guide the patient to place the base of his/her nose (acanthion point) against the Chinrest and bend the head forward about 5°.
- **4.** Let the patient maintain the posture as follows:
 - Close the mouth.
 - Place the tongue to the roof of the mouth.
 - Close the eyes.





- The integrated Chinrest's support unit should touch the patient's acanthion point, as shown in the picture.
- Let the patient maintain his/her position until the operation is completed.

Green X 18 (Model: PHT-75CHS) User Manual

Laser Beam Aligning

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

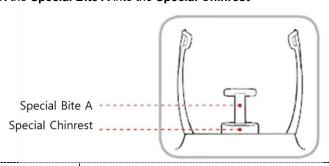
Finishing Patient Positioning

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

<Sinus Mode (LAT/PA)>

Patient Positioning

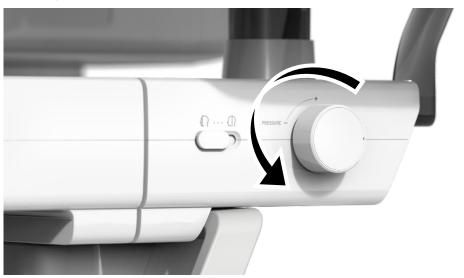
- Remove the Normal Chinrest and insert the Special Chinrest into the equipment.
- 2. Insert the Special Bite A into the Special Chinrest





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

 Use the Temple Supports OPEN/CLOSE wheel on the handle frame to widen the Temple Supports. (Turn the wheel counterclockwise to open Temple Supports.)



4. Guide the patient to the equipment.

Use the Column UP/DOWN button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.



<Control Panel>





<CEPH part>

<Column UP/DOWN switch>

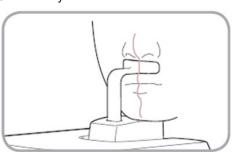
- Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
- Guide the patient to press the nose's base (acanthion point) against the Chinrest and tilt the head forward about 5°. At this point, make sure the patient's jaw does not touch the equipment.

IMPORTANT

- If the jaw touches the equipment, it is difficult to maintain the proper position to get good images.
- Be careful; the patient does not touch the equipment with his/her jaw.

Let the patient maintain the posture as follows:

- Close the mouth.
- Place the tongue to the roof of the mouth.
- Close the eyes.





- The integrated Chinrest's support unit should touch the patient's acanthion point, as shown in the picture.
- Ask the patient to maintain his/her position until the operation is completed.

Laser Beam Aligning



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

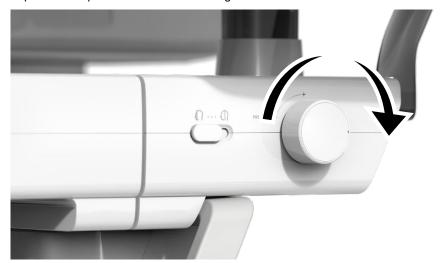


If the laser beam is not correctly positioned, distortion may cause the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the Laser Beam properly.

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

Finishing Patient Positioning

 After checking the patient's positions and the Laser Beam, Turn the wheel clockwise; the **Temple Supports the OPEN/CLOSE** wheel on the handle frame to prevent the patient's head from moving.





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

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



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

7.4 X-ray Exposure



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



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

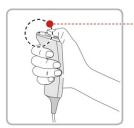
IMPORTANT

- Let the patient close the eyes during the operation.
 - To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.
- 1. Get out of the X-ray room and close the door.

IMPORTANT

The operator must always keep vocal/visual contact with the patient during image acquisition.

2. Press and hold down the Exposure Switch until image acquisition is completed.



Yellow: X-ray On

NOTICE

The image appears on the screen.

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

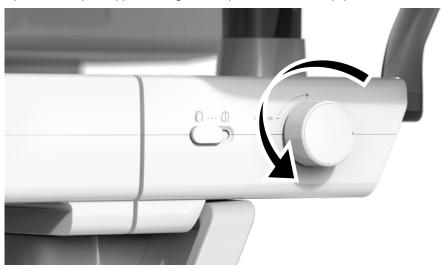
- The LED light of the **Exposure Switch** turns yellow.
- The LED light on the top of the equipment turns yellow.
- An alert sound comes out to indicate that X-ray emission is currently underway.
 - On Console Software, the radiation mark turns green.



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

7.5 Finishing the Scan

1. Open the Temple Supports and guide the patient out of the equipment.



- 2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.
- 3. Press the **READY** button to bring the Rotating Unit back to its initial position.



7.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

The exported images can be confirmed in EzDent-i.



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

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

8.1 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 detector's linear movement and reconstructs them to a single 2D image through computer calculations.

■ Examination Programs

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

Examination Area	Description	Position
Lateral/ Full Lateral (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 connecting the cranial measurement points to assess the facial region's growth further. It's widely used in Orthodontics and Oral and Maxillofacial Surgery. 	<lateral> <full 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 maxillary sinus's sidewall, the frontal sinus, and antrum ethmoidal, olfactory pits, and optic disc pits. Measures the angles formed by connecting the cranial measurement points to assess the facial region's 	<pa></pa>

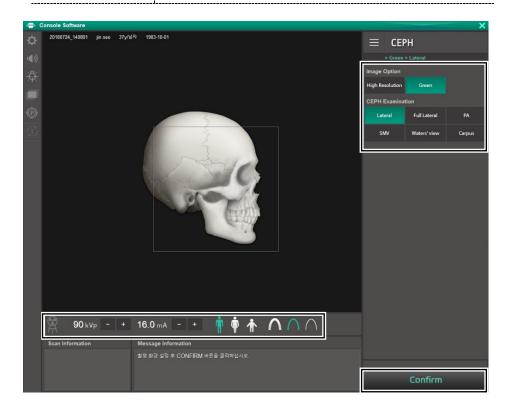
Examination Area	Description	Position
	growth further. It is widely used in Orthodontics and Oral and Maxillofacial Surgery.	
SMV	Used to study the skull's base, horizontal angulation of the mandibular condylar axis, the sphenoid sinus, the curvature of the lower jaw, the sidewall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull.	<smv></smv>
Waters' view	 Used to study the frontal sinus, the antrum ethmoidal, the optic disc pit, the frontozygomatic suture, the nasal cavity, the coronoid process between the upper jaw and the zygomatic arch. 	<waters' view=""></waters'>
Carpus	 Used to assess hand bone age to compare the changes in the skull. 	<carpus></carpus>

8.2 Configuring Exposure Parameters

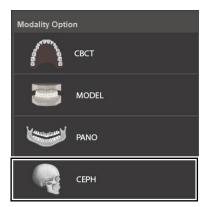
To acquire CEPH images, 6. Getting Started must be completed first.



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



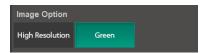
1. Click the CEPH button on the Main Screen.





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

2. Select an Image Option.



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



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





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

5. Select X-ray intensity.



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

Soft ≤ Normal ≤ Hard



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

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

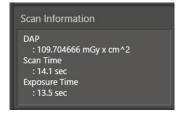
7. Click the **CONFIRM** button when the exposure parameter setting is completed.



When you click the **CONFIRM** button,

 The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Scan Information window.





8. Guide the patient to the equipment.

8.3 Patient Positioning



 Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.

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

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

IMPORTANT

CAUTION

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

Getting prepared

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



<Control Panel>





<Column UP/DOWN switch>

8.3.1 Lateral/Full Lateral (Optional) Mode



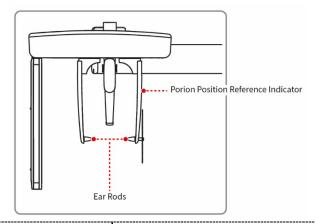
Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.

Patient Positioning

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



2. Leave enough space between the Ear Rods.





Use the Porion Position Reference Indicator that appears in the acquired image to confirm Porion's location.

- 3. Guide the patient to the CEPH unit.
- 4. Direct the patient to relax his/her neck and shoulders and stand upright.

5. Use the **Column UP/DOWN** button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.



<Touch panel>



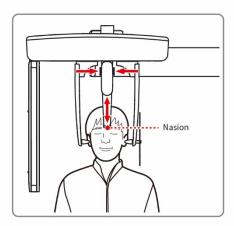


<Column UP/DOWN switch>

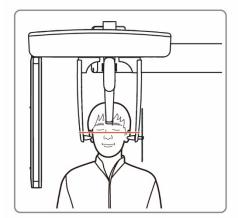
MARNING

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

6. Align the Ear Rods into the patient's ears properly so that the head does not move during the operation. Moreover, aligning the Nasal Positioner with the patient's nasion by adjusting its height.



7. Align horizontally, so the patient's Frankfurt Line is parallel with the floor.



- **8.** Direct the patient to swallow first before closing the mouth and to remain in his/her current position until image acquisition is completed.
- **9.** Click the **READY** button. The x-ray exposure has not started yet.

Ready

10. Now go to 8.4 X-ray Exposure to start the exposure.

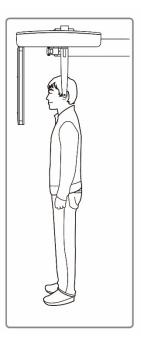
8.3.2 PA Mode

Patient Positioning

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

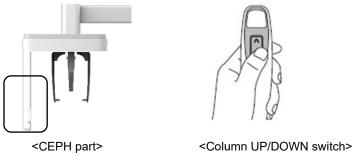


- 2. Fold the Nasal Positioner up. The Nasal Positioner is not used in PA mode.
- 3. Guide the patient to the CEPH unit.
- **4.** Ask the patient to stand upright facing the sensor. Make sure that the patient's shoulders are level and that his/her neck is relaxed.



 Use the Column UP/DOWN button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.

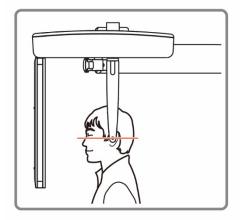






After adjusting the height of the column, align the Ear Rods to the patient.

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



8. Direct the patient to swallow first before closing his/her mouth and to remain in his/her current position until image acquisition is completed.

9. Click the **READY** button. The x-ray exposure has not started yet.

Ready

10. Now go to 8.4 X-ray Exposure to start the exposure.

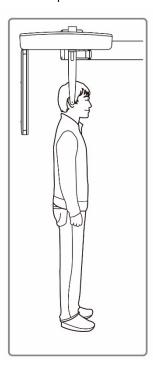
8.3.3 SMV Mode

Patient Positioning

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



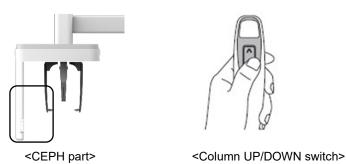
- 2. Fold the Nasal Positioner up. The Nasal Positioner is not used in SMV mode.
- 3. Guide the patient to the CEPH unit.
- 4. Guide the patient to face the X-ray tube and stand upright.



5. Use the **Column UP/DOWN** button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.



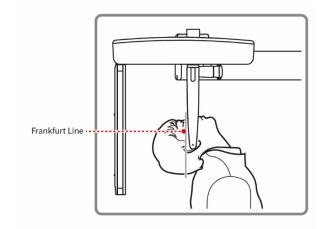
<Control Panel>





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

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



9. Click the **READY** button. The x-ray exposure has not started yet.

Ready

10. Now go to 8.4 X-ray Exposure to start the exposure.

8.3.4 Waters' view Mode

Patient Positioning

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



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



<Control Panel>





<Column UP/DOWN switch>



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

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



8. Click the **READY** button. The x-ray exposure has not started yet.

Ready

9. Now go to 8.4 X-ray Exposure to start the exposure.

8.3.5 Carpus Mode

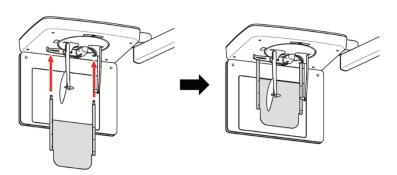
For Carpus Mode, install the Carpus Plate first before positioning the patient.

Installing the Carpus Plate

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



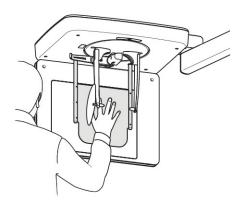
- 2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Carpus mode.
- 3. Fit the two ends of the Carpus Plate into the two holes of the CEPH unit as below.



4. Confirm that the Carpus Plate is safely mounted.

Patient Positioning

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



- Ask the patient to close his/her eyes and stand still until the image acquisition is completed.
- 3. Click the **READY** button. The x-ray exposure has not started yet.

Ready

4. Now go to 8.4 X-ray Exposure to start the exposure.

8.4 X-ray Exposure

<u></u>MARNING

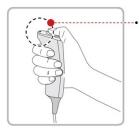
- If an emergency occurs during image acquisition, release the Exposure Switch to cease X-ray emission.
- The operator shall always observe the X-ray safety regulations applicable to his/her area during this equipment's operation.



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

IMPORTANT

- Let the patient close the eyes during the operation.
 - To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.
- 1. Get out of the X-ray room and close the door.
- 2. Press and hold down the Exposure Switch until image acquisition is completed.



Yellow: X-ray On

NOTICE

The image appears on the screen.

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



- 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.
- On Console Software, the radiation mark turns Green.



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

8.5 Finishing the Scan

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

8.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

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



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

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

9. Acquiring 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 to 3D sliced images.

■ Examination Programs

It is classified as below based on the FOV.

Available FOVs (cm)	ROI	Description
Double Scan (18×24; Optional)	1. <mandible center=""> 2. <maxilla center=""> NOTICE After taking 2 consecutive exposures in the order of "1 → 2", it is automatically synthesized and displayed as one full image.</maxilla></mandible>	- Full arch, sinus, left and right TMJ area can be checked - Suitable for most intra-oral surgery, including multiple implant placement
18x15	<occlusion center=""></occlusion>	- Covers full arch region, sinus, and left/right TMJ Suitable for most oral surgery cases as well as multiple implant surgery.

9. Acquiring CBCT Images

Available FOVs (cm)	ROI	Description
16x11	<occlusion center=""></occlusion>	 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=""></airway></tmj></tmj></occlusion>	- Covers both maxillary and mandibular structures, including the 3 rd molar region TMJ Right/Left and Airway mode are available.
8x8	<occlusion center=""></occlusion>	- Selectable FOV for region (left/center/right) Covers both maxillary and mandibular areas and left/right TMJ.

Available FOVs (cm)	ROI	Description
	<tmj left=""> <tmj right=""></tmj></tmj>	
	<tmj left=""> <tmj right=""> <occlusion left=""> <occlusion right=""></occlusion></occlusion></tmj></tmj>	
	<mandible center=""></mandible>	
8x5	<pre><mandible left=""></mandible></pre>	- Selectable FOV for region (left/center/right) Covers both maxillary and mandibular areas.
	<maxilla center=""></maxilla>	

9. Acquiring CBCT Images

Available FOVs (cm)	ROI	Description
	< Maxilla/Left> < Maxilla/Right>	
5x5	R	- Covers 3~4 areas through capturing ROI Can acquire 3~4 teeth at once Voxel Size: 0.08/0.12 applied.
Endo (4x4)	R CONTRACTOR OF THE PARTY OF TH	- Covers 3~4 areas through capturing ROI Can acquire 3~4 teeth at once Voxel Size: 0.05 applied.



The Endo mode FOV size is 40 x 40 mm², an area including 2-3 teeth. Before exposure, check the presence or absence of wisdom teeth and select the tooth's location to be exposed. It provides a scout function for accurate exposure.

9.2 Configuring Exposure Parameters

To acquire CBCT Images, 6. Getting Started must be completed first.

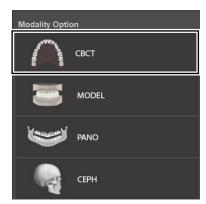


You can set the imaging parameters on the Console Software running on the PC. They are synchronized and display the same environmental settings.



9. Acquiring CBCT Images

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





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

2. Select FOV Size (with Vertical Option, Horizon Option, Tooth Option.)



The 5x5 and the Endo mode guide areas show both maxilla and mandible, allowing the user to select the teeth to exposure directly.





The teeth consist of 16 maxillary/16 mandibles, a total of 32 teeth, including 3rd molar.

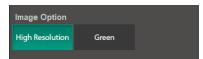
Before exposure, the presence or absence of the 3rd molar should be checked, and a guide should be provided so that there is no misdiagnosis when selecting FOV.

Available options for each FOV are as below.

Available FOV (cm)	Vertical option	Horizontal option
18x15	Occlusion	Center
16x11	Occlusion	Center
	Occlusion	Center
12x9	TMJ	Right
1289	TIVIO	Left
	Airway	Center
		Right
	Occlusion	Center
8x8		Left
	TMJ	Right
		Left
	Maxilla	Right
		Center
8x5		Left
0.0	Mandible	Right
		Center
		Left
5x5	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)
Endo (4x4)	Maxilla/Mandible	Selectable FOV by Teeth (Total: 32)
Double Scan (18×24 stitching) (Optional)	Mandible (First Scan) Maxilla (Second Scan)	Center

9. Acquiring CBCT Images

3. Select an Image Option.



Select a Voxel Size.



MAR (Metal Artifact Reduction) function is applied automatically if there are metal objects in the image. MAR may increase image reconstruction time.



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





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

6. Select X-ray intensity.



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





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

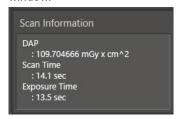
7. The tube voltage and current values are configured automatically according to the patient's gender/age group and X-ray intensity. Click the **UP/DOWN** arrow to adjust kVp and mA. The dose is adjustable by ±1 kVp and ± 0.1 mA, respectively.

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

Confirm

When you click the CONFIRM button,

- The Rotating Unit will move to its initial scanning position.
- The Vertical Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Scan Information window.



9. Guide the patient to the equipment.



9.3 Obtaining Double Scan Image (optional)

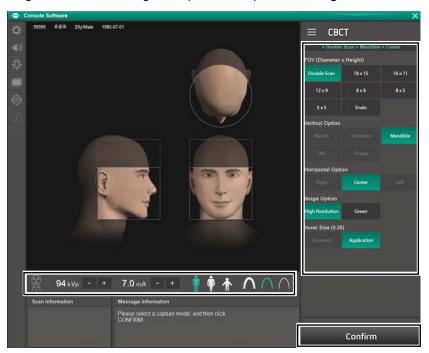
FOV 18X15 images can be acquired by upper/lower double scans and stitched to acquire full FOV 18x24 CBCT images.

IMPORTANT

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

9.3.1 First Scan Step of Double Scan

To get a double scan image, Complete the steps in 6. Getting Started first.



1. Click the **Double Scan** button on the CBCT main screen.



2. Select the Image Option.



3. The patient's gender/age group is automatically selected based on patient information. You can choose manually if necessary.



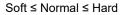


Gender / Age Group		VATECH's Standard
Child		2 ~ 12 years of age
Adult	Man	> 12 years of and
	Woman	> 12 years of age

4. Select the X-ray intensity.



X-ray intensity can be classified as Hard, Soft, Normal according to the patient's head circumference.





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

- **5.** The tube voltage and tube current values are automatically set according to the patient's performance and X-ray intensity. If you click the arrow button, you can make fine adjustments in \pm 1 kVp, \pm 0.1 mA increments.
- **6.** After setting the Exposure conditions, click the **CONFIR**M button.





When you click the CONFIRM button

- The rotating unit moves to the initial position.
- The vertical beam is activated.

9. Acquiring CBCT Images

 Below the Scan Information window, DAP (Dose Area Product), Scan Time, Exposure Time values are displayed.



- Guide the patient to the equipment and align the patient's posture. For more information on patient posture alignment, see section <u>9.4 Patient Positioning</u>
- **8.** Press the **READY** button. At this time, X-rays are not irradiated.

Ready

- 9. Go to 9.5 X-ray Exposure and proceed with X-ray exposure.
- 10. Guide the patient out of the shielded room with equipment.

9.3.2 Second Scan Steps of Double Scan

1. Select the Maxilla as the Vertical Option. It is automatically selected.



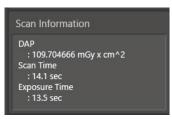
- 2. The tube voltage and tube current values are automatically set according to the patient's performance and X-ray intensity. If you click the arrow button, you can make fine adjustments in \pm 1 kVp, \pm 0.1 mA increments
- 3. Click the CONFIRM button



When you click the **CONFIRM** button

- The rotating unit moves to the initial position.
- The vertical beam is activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Scan Information window.



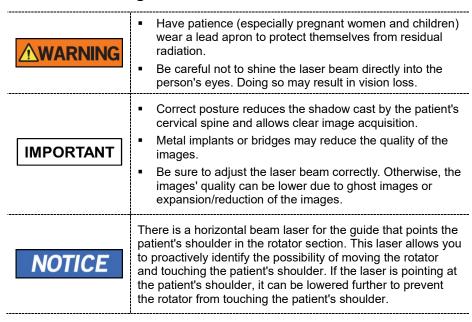


- **4.** Guide the patient to the equipment and align the patient's posture. For more information on patient posture alignment, see section **9.4 Patient Positioning.**
- **5.** Press the **READY** button. At this time, X-rays are not irradiated.



- **6.** Go to **9.5 X-ray Exposure** and proceed with X-ray exposure.
- 7. Guide the patient out of the shielded room with equipment.
- 8. Move to the <u>9.6 Finishing the Scan</u> to finish shooting and check the image.

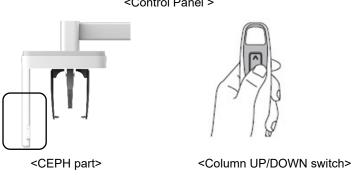
9.4 Patient Positioning



Getting prepared

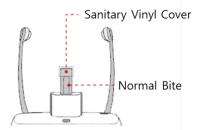
- Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
- 2. Have the patient wear a lead apron to protect themselves from residual radiation.
- 3. Use the **Column UP/DOWN** button in the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





Normal Patient Positioning

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

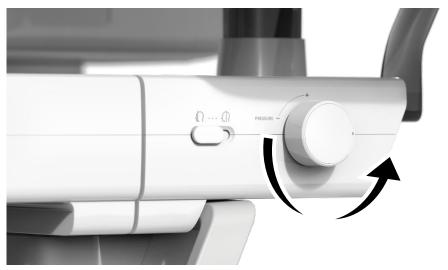




 The Sanitary Vinyl Cover is for sole use only. It should be replaced for each patient. Be sure to use the approved vinyl cover.



- Clean the Chinrest and the Bite with ethanol and wipe with a dry towel before the next patient.
- 2. Use the **Temple Supports OPEN/CLOSE** wheel on the handle frame to widen the Temple Supports.



3. Guide the patient to the equipment.

Use the Column UP/DOWN button in the Control Panel and CEPH part or use the switch option to adjust the equipment to match the patient's height.



< Control Panel >





<CEPH part>

<Column UP/DOWN switch>

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



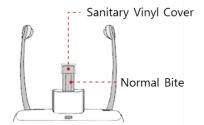
- Let the patient maintain the posture as follows:
 - Close the mouth.
 - Place the tongue to the roof of the mouth.
 - Close the eyes.



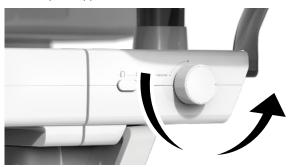
Double Scan (Mandible) Patient Positioning



- When doing double scan Patient positioning, keep the patient's posture the same for the first (lower) and second (upper) exposures.
- Provides a function to save each image when matching fails due to patient movement between the first (lower) and second (upper) images.
- Insert the Normal Bite into the Normal Chinrest and cover it with a Sanitary Vinyl Cover.



2. Use the **Temple Supports OPEN/CLOSE** wheel on the handle frame to widen the Temple Supports.

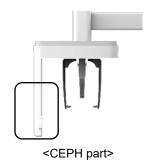


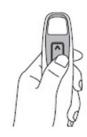
3. Guide the patient to the equipment.

 Use the Column UP/DOWN button in the Control Panel and CEPH part or use the switch option to adjust the equipment's height so that the patient's chin reaches the Chinrest.



< Control Panel >



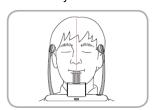


<Column UP/DOWN switch>

- **5.** Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
- 6. Let the patient maintain the posture as follows:
 - Close the eyes.



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





 Ask the patient to maintain his/her position until the operation is completed.

Double Scan (Maxilla) Patient Positioning



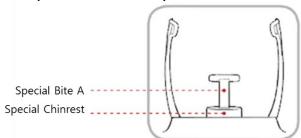
 Before exposure to the Maxilla, the chin should be moved down.



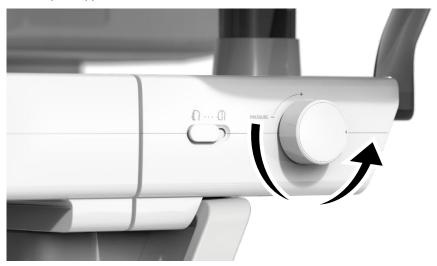
 Double Scan (Maxilla) Patient Positioning is the same as Double Scan (Mandible) Patient Positioning.

TMJ Patient Positioning

- 1. Remove the **Normal Chinrest** and insert the **Special Chinrest** into the equipment.
- 2. Insert the Special Bite A into the Special Chinrest



3. Use the **Temple Supports OPEN/CLOSE** wheel on the handle frame to widen the Temple Supports.

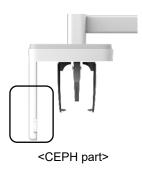


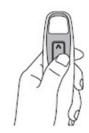
4. Guide the patient to the equipment.

Use the Column UP/DOWN button in the Control Panel and CEPH part or use the switch option to adjust the equipment's height so that the patient's chin reaches the Chinrest.

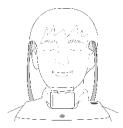


< Control Panel >





<Column UP/DOWN switch>





- **6.** Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
- 7. Let the patient maintain the posture as follows:
 - Close the eyes.



Ask the patient to maintain his/her position until the operation is completed.

Laser Beam Aligning

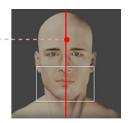


Be careful not to shine the Laser Beam directly into the person's eyes. Doing so may result in vision loss.



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

Vertical Beam / Mid-sagittal Line



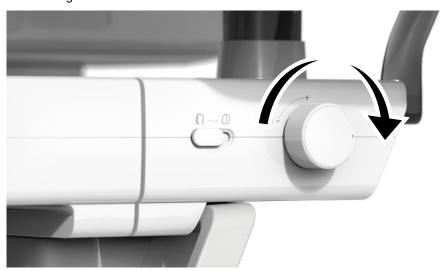
NOTICE

This is a sample illustration for reference only. Actual FOV may vary from the image, as shown above.

 Align the Vertical Beam with the center of the face (Mid-sagittal Line). (It is to prevent the horizontal expansion of the image)

Finishing Patient Positioning

 After checking the patient and the Laser Beam's positions, use the Temple Supports OPEN/CLOSE wheel on the handle frame to prevent the patient's head from moving.



△CAUTION

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

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



3. Now go to 9.5 X-ray Exposure to start the exposure.

9.5 X-ray Exposure

<u>∧</u>WARNING

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

△CAUTION

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

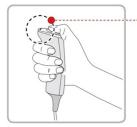
IMPORTANT

- Let the patient close the eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.
- 1. Get out of the X-ray room and close the door.

IMPORTANT

The operator must always keep vocal/visual contact with the patient during image acquisition.

2. Press and hold down the Exposure Switch until image acquisition is completed.



--• Yellow : X-ray On

NOTICE

The image appears on the screen.

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

- The LED light of the **Exposure Switch** turns yellow.
- The LED light on the top of the equipment turns yellow.



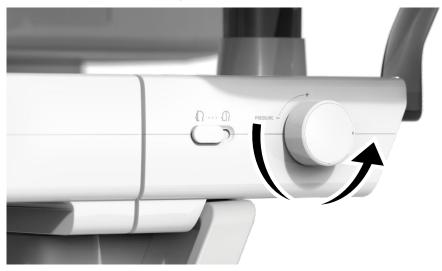
- An alert sound comes out to indicate that X-ray emission is currently underway.
- On Console Software, the radiation mark turns Green.



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

9.6 Finishing the Scan

1. Open the Temple Supports and guide the patient out of the equipment.



- 2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.
- 3. Press the **READY** button to bring the Rotating Unit back to its initial position.



9.7 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

The exported images can be confirmed in EzDent-i.



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

- 1. The images are transferred to **EzDent-i** automatically.
- The images are automatically saved if the automatic save option is configured as default. If it is not configured as default, click the Save button to save the images.
- 3. To check the image, double-click the one on the Patient List.
- **4.** Then, **Ez3D-I** automatically starts a 3D viewing of the saved image.

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10. Acquiring 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, 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.

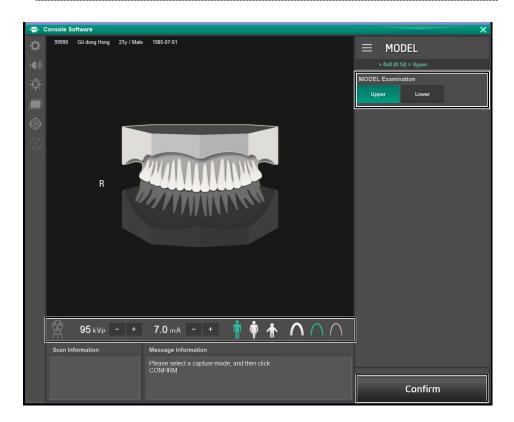
Applied FOV (cm)	Vertical Option	ROI	Description
949	Upper (Maxilla)		Captures a whole maxillary Plaster Cast.
8x8	Lower (Mandible)		Captures a whole mandibular Plaster Cast.

10.2 Configuring Exposure Parameters

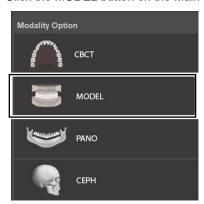
To acquire 3D MODEL Scan Images, **6. Getting Started** must be completed first.



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



Click the MODEL button on the Main Screen.





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

1. Select Model Examination type.



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





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

10. Acquiring 3D MODEL Scan Images

3. Select X-ray intensity.



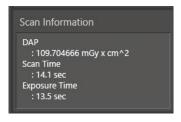
- 4. The tube voltage and current values are configured automatically according to the patient's gender/age group and X-ray intensity. Click the UP/DOWN arrow to adjust kVp and mA. The dose is adjustable by ±1 kVp and ± 0.1 mA, respectively.
- 5. Click the **CONFIRM** button when the exposure parameter setting is completed.



When you click the CONFIRM button,

- The Rotating Unit will move to its initial scanning position.
- The Vertical Beam will be activated to make patient positioning easier.
- The DAP (Dose Area Product), Scan Time, and Exposure Time will be displayed below the Scan Information window.



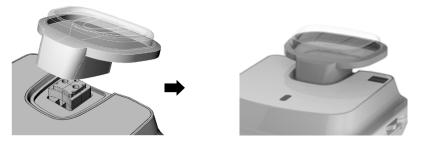


6. Bring the Plaster Cast to the equipment.

10.3 MODEL Positioning

MODEL Scan Jig Installation

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



Laser Beam Aligning

 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** button. X-ray exposure has not started yet.



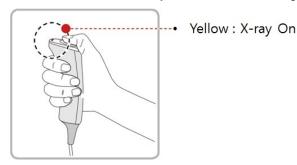
4. Now go to 10.4 X-ray Exposure to start the exposure.

10.4 X-ray Exposure

ACAUTION

Do not operate the PC during exposure. Doing so may cause the system to malfunction.

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



NOTICE

The image appears on the screen.

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

- The LED light of the Exposure 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.
- On Console Software, the radiation mark turns Green.



- Release the Exposure Switch when the "Image capturing is completed" message appears on the screen.
- 4. Remove the Plaster Cast out of the equipment.

10.5 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM or STL (Stereo Lithography) format.



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

- 1. The images are transferred to **EzDent-i** automatically.
- 2. The images are automatically saved if the automatic save option is configured as default. If it is not configured as default, click the **Save** button to save the images.
- 3. To check the image, double-click the one on the Patient List.
- **4.** 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 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.

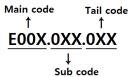
11.2 Error Codes

In abnormal operation instances, 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.

Error messages will be displayed in the format written below.

[Code: E00X.0XX.0XX]

The code consists of three parts: Main code, sub-code, 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	Solution		
	Check the CAN communication response by sending the following command to the inverter board, sensor, and the collimator to check the CAN communication operation of the Main MCU. Inverter board: [SPM_IVER]			
	Appears when 001 the tube is not ready for use			Sensor: [SPM_FISS_0001]
001		 Collimator: [SPM_CVER] If the inverter board, sensor, and collimator do not respond, replace the Main MCU. 		
		3. If only the inverter board does not respond, check the connection status of H001909A (Pin 1, 3) and H001922A (Pin 7, 8) cable to check CAN communication between the Main MCU and inverter board.		

Tail code	Description	Solution
		Connection status refers to reconnection, disconnection, pin status, etc. 3.1. If the cable is normal, check that 24V is normally applied to pins 1, 2 of CN13 to check the inverter board's input voltage. 3.2. When 24V is normally applied to the inverter board, replace the generator. 3.3. If 24V is not confirmed, check the power cables H001909A (Pin 21, 22) and H001922A (Pin 1, 2) from the Main MCU to the inverter board. 3.4. If the cable is normal, see if DC 24V is normally applied to pins 4, 5 of CN1600 to check the main MCU's input power. 3.5. If 24V is applied, replace the Main MCU. 3.6. If 24V is not applied, replace the power board.
002	Appears when the cable between the tube tank and Inverter board are disconnected	1. Check the connection of the high voltage cable between the inverter board and the tube tank. 2. If the same problem occurs after cable replacement, replace tegenerator. NOTICE The generator includes a tube tank and an inverter board. Generator inverter high voltage cable: H001907A
003	Appears when a current of the inverter board exceeds the maximum allowable level during X-ray irradiation	1. Send out the following command to the motor, inverter board, sensor, and the collimator to check the operation status and IC board component status. (Advance remote check required) Motor: [SPM_TEST] Inverter board: [SPM_IVER] Sensor: [SPM_FISS_0001]

Tail code	Description	Solution
		Collimator: [SPM_CVER]
		NOTICE
		If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator.
		If there is no problem, replace the generator.
		 Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%.
		3. When the X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more)
		NOTICE If any problem occurs in stage 2 or 3, replace the power board.
		For equipment manufactured before 2014/04/19, apply the brass bar solution.
004	Appears when there is ±10kV or more voltage difference in tube voltage compared to a reference value	Follow the instructions described in the tail code 003.
005	Appears when there is ±0.5mA or more current difference in tube current compared to a reference value	Follow the instructions described in the tail code 003.
006	Appears when there is ±20kV or more voltage difference in	Follow the instructions described in the tail code 003.

Tail code	Description	Solution
	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	Follow the instructions described in the tail code 003.
008	Appears when the temperature of the mono tank is above the setting temperature	Check that the mono-tank temperature is 55°C or higher through the log message of the capture program.
		NOTICE
		The temperature is automatically checked every 10 seconds in the terminal program.
		2. If the temperature is higher than 55°C, the problem has occurred from continuous shooting using the capture program. It is necessary to notify and educate the staff members that enough cooling time is required during shooting.
		NOTICE
		The cooling time Vatech suggests is 1:60. (60 seconds pause at the time of 1-second irradiation)
		If the same problem occurs after the measurements stated above, replace the generator.
009	Appears when the inverter output current is higher than 1A during X-ray irradiation	Follow the instructions described in the tail code 003.
	(In EP, IP condition)	

Tail code	Description	Solution
010	Appears when the inverter board falsely recognizes the exposure switch signal as OFF after the irradiation On command	Check if 24V is typically applied to the inverter board.
		If there is any problem with the power, check if 24V is typically outputted from H001922A (Main MCU), pins 1, 2 of CN13 (inverter board), and pins 4, 5 of CN3 (power board).
		Check the multiple cables. Check the connection status of H001913A of the exposure switch from the Main MCU and the inverter board.
		Connection status refers to reconnection, disconnection, pin status, etc. 3. If the problem is not resolved, replace the generator.
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	 Make sure that the staff member correctly presses the exposure switch during irradiation. Replace the exposure switch and check if the same error occurs. Check the connection status of the H001909A (pin 1, 3) and H001922A (pin 7, 8) from the Main MCU to the inverter board.
		Connection status refers to reconnection, disconnection, pin status, etc. 3.1. If the problem is not resolved, replace the multiple cables. 4. Check if 24V is applied to the Main MCU and the
		inverter board. 4.1. Check if the input voltage of pins 5, 6 of CN600 of the Main MCU is 24V. If not 24V, replace the power board.
		4.2. Check if the input voltage of pin 1, 2 of CN13 of the inverter board is 24V.

Tail code	Description	Solution
		If not 24V, replace the Main MCU.
		If 24V is applied regularly, replace the generator.
012	Appears when kV feedback is over -20kV compared to the setting value during X-ray irradiation	Follow the instructions described in the tail code 003.
013	Appears when kV feedback is over +20kV compared to the setting value during X-ray irradiation.	Follow the instructions described in the tail code 003.
014	Appears when the mA feedback value is less than 50% compared to setting conditions during X-ray irradiation.	Follow the instructions described in the tail code 003.
015	Appears when the mA feedback value is higher than 150% compared to setting conditions during X-ray irradiation.	Follow the instructions described in the tail code 003.

11.2.1.2 Subcode - Motor related error (002)

Tail code	Description	Solution
020	Appears during p-axis motor	Check the operation status due to mechanical load.

11. Troubleshooting

Tail code	Description	Solution
	origin movement	NOTICE Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		2. Check if the photosensor LED of the p. axis motor and the XORG LED of the Main MCU lights up. Also, check if 24V is outputted from pins 4, 5 of CN1701.
		 If there is a problem, replace the photosensor. 3. If p-axis motor usually operates, increase the torque value of the p-axis motor.
		NOTICE Back up the torque value by [SPM_XMRT] and apply the torque value as 2000 higher than the current value.
		Check the cable connection of the p-axis motor.
		NOTICE Connection status refers to reconnection, disconnection, pin status, etc.
		Check the p-axis motor for defects and replace the motor if a problem occurs.
		5.1. Make sure the resistance between pins 1, 3, and pins 2, 4 of CN1701 is 1.1~1.3 Ω.
		5.2. Check if there is a short between pins 1, 4, and pins 2, 3 of CN1701.
		6. If the problem is not resolved, replace the Main MCU.
	Appears during rotator-axis	Check the operation status due to mechanical load.
021	motor origin movement	NOTICE

Tail code	Description	Solution
		Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		 Check if the rotator-axis motor's photosensor LED and the RORG LED of the Main MCU lights up. Also, check if 24V is outputted from pins 1, 2 of CN2708 (rotator)/CN1600 (Main MCU).
		 If there is a problem, replace the photosensor.
		If rotator-axis motor usually operates, increase the torque value of the rotator-axis motor.
		Back up the torque value by [SPM_RMRT] and apply the torque value as 2000 higher than the current value.
		Check the cable connection of the rotator-axis motor.
		NOTICE Connection status refers to reconnection, disconnection, pin status, etc.
		Check the rotator-axis motor for defects and replace the motor if a problem occurs.
		5.1. Make sure the resistance between pins 1, 3, and pins 2, 4 is 1.1~1.3 Ω.
		5.2. Check if there is a short between pins 1, 4, and pins 2, 3.
		If the problem is not resolved, replace the Main MCU.
007	Appears during Cephalo sensor	Check the operation status due to mechanical load.
027	motor origin movement	NOTICE

Tail code	Description	Solution
		Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		 If there is a problem, replace the photosensor.
		 Check if the LED of the cephalo sensor motor lights up. Also, check if 24V is outputted from pins 1, 3 of CN302.
		 If there is a problem, replace the photosensor.
		 Increase the torque value of the cephalo sensor motor.
		NOTICE
		Back up the torque value by [SPM_HMRT] and apply the torque value as 2000 higher than the current value.
		Check the cable connection of the cephalo sensor axis motor.
		NOTICE
		Connection status refers to reconnection, disconnection, pin status, etc.
		Check the cephalo sensor axis motor for defects and replace the motor if a problem occurs.
		5.1. Make sure that the resistance between pins 1, 3, and pins 2, 4 is 4.5~6 Ω .
		5.2. Check if there is a short between pins 1, 4, and pins 2, 3.
		If the problem is not resolved, replace the main MCU.
	Appears during	Check if the collimator MCU FW is the latest version.
030	quadruple axis collimator Left origin movement	NOTICE When upgrading, the firmware upgrade cable is required.

Tail code	Description	Solution
		If the problem is not resolved, check the operation status due to mechanical load.
		Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		 If any foreign substance is found, remove the substance, and lubricate the component. Apply the torque value as 100~200 higher than the current value.
		Check and back up the current torque value by [SPM_TQB?]. Adjust the torque value by [SPM_TOQB_xxxx].
		 If the problem is not resolved, replace the collimator assembly. If the problem is not resolved after replacing the collimator assembly, replace the Main MCU.
		Check if the collimator MCU FW is the latest version.
031	Appears during quadruple axis collimator Right origin movement	When upgrading, the firmware upgrade cable is required.
		If the problem is not resolved, check the operation status due to mechanical load. NOTICE Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		 If any foreign substance is found, remove the substance, and lubricate the component.

Tail code	Description	Solution
		3. Apply the torque value as 100~200 higher than the current value.
		NOTICE
		Check and back up the current torque value by [SPM_TQA?]. Adjust the torque value by [SPM_TOQA_xxxx].
		If the problem is not resolved, replace the collimator assembly.
		If the problem is not resolved after replacing the collimator assembly, replace the Main MCU.
		Check if the collimator MCU FW is the latest version.
		NOTICE
	Appears during quadruple axis collimator Up origin movement	When upgrading, the firmware upgrade cable is required.
		If the problem is not resolved, check the operation status due to mechanical load.
		NOTICE
032		Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		 If any foreign substance is found, remove the substance, and lubricate the component.
		3. Apply the torque value as 100~200 higher than the current value.
		NOTICE
		Check and back up the current torque value by [SPM_TQD?]. Adjust the torque value by [SPM_TOQD_xxxx].
		If the problem is not resolved, replace the collimator assembly.
		5. If the problem is not resolved after replacing the

Tail code	Description	Solution
		collimator assembly, replace the Main MCU.
		Check if the collimator MCU FW is the latest version.
		NOTICE When upgrading, the firmware upgrade cable is required.
		If the problem is not resolved, check the operation status due to mechanical load.
		NOTICE
200	Appears during quadruple axis collimator down origin movement	Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
033		 If any foreign substance is found, remove the substance, and lubricate the component.
		3. Apply the torque value as 100~200 higher than the current value.
		NOTICE
		Check and back up the current torque value by [SPM_TQC?]. Adjust the torque value by [SPM_TOQC_xxxx].
		If the problem is not resolved, replace the collimator assembly.
		If the problem is not resolved after replacing the collimator assembly, replace the Main MCU.
037	Appears during generator tilting	Make sure the product is a Ceph model. If it is not a Ceph model, check whether [SPM_CISC], [SPM_TITY], is activated.
		If the output is standard, check the operation status due to mechanical load.
		NOTICE

Tail code	Description	Solution
		Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		After sending the [SPM_TICE] command, check if the generator is tilting in Ceph mode, and the limit switch is detected. After confirmation, send [SPM_TIFR] to stop the motor drive.
		 After sending the [SPM_TIPA] command, check whether the generator is tilting in the PANO/CT mode, and the limit switch is detected. After confirmation, send [SPM_TIFR] to stop the motor drive.
		If the limit switch is not recognized usually, replace the Main MCU.
		If the tilting motor does not operate normally, check the tilting motor for defects.
		4.1. If the tiling motor is standard, please replace the Main MCU.
	Appears during temple support the motor operation	If there is any noise during operation, replace the ass'y.
		Check the limit switch of the temple support.
		NOTICE
		Check whether the TSO1 and TSO2 LED light up.
		3. Check the ORG cable of the temple support.
		Check the alignment of the motor and the bearing block. (critical*)
038		Adjust the torque value and see if the problem is resolved.
		NOTICE
		Check the current torque value by [SPM_TQK?]. Adjust the torque value by [SPM_TOQK_xxxx].
		6. If the same problem occurs, replace the Main MCU.
		7. If the problem is not resolved, replace the temple support ass'y.

Tail code	Description	Solution
	Appears during X-axis motor origin movement	Check the operation status due to mechanical load.
		NOTICE Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc.
		2. Check if the LED of the x-axis motor and the XORG LED of the Main MCU lights up. If there is a problem, replace the
		photosensor. 3. If the x-axis motor usually operates, increase the torque value of the x-axis motor.
039		NOTICE Back up the [SPM_XMRT] value and apply 1 increment of torque.
		Check the cable connection of the x-axis motor.
		NOTICE
		Connection status refers to reconnection, disconnection, pin status, etc.
		Check the x-axis motor for defects and replace the motor if a problem occurs.
		5.1. Make sure the resistance between pins 1, 3, and pins 2, 4 is 1.1~1.3Ω.
		5.2. Check if there is a short between pins 1, 4, and pins 2, 3.
		If the problem is not resolved, replace the Main MCU.

11. Troubleshooting

Tail code	Description	Solution
	Appears during Y-axis motor origin movement	 Check the operation status due to mechanical load. NOTICE Operation status includes motor operation, a foreign substance in the axis, the mechanical load, timing belt, etc. Check if the LED of the y-axis motor and the YORG LED of the Main MCU lights up. If there is a problem, replace the photosensor. If the y-axis motor usually operates, increase the torque value of the Y-axis motor. NOTICE Back up the [SPM_YMRT] value and apply 1 increment of torque. Check the cable connection of the Y-axis motor. NOTICE Connection status refers to reconnection, disconnection, pin status, etc. Check the y-axis motor for defects and replace the motor if a problem occurs. Make sure that the resistance between pins 1, 3, and pins 2, 4 is 1.1~1.3Ω. Check if there is a short between pins 1, 4, and pins 2, 3.
		If the problem is not resolved, replace the Main MCU.

11.2.1.3 Subcode - Exposure switch related error (003)

Tail code	Description	Solution
060	It appears if the	To check whether the exposure switch usually

Tail code	Description	Solution
	exposure switch is pressed when	operates or not, conduct the following measurement.
	turning on the equipment.	1.1. Remove the exposure switch and see if the same problem occurs.
		Replace the current exposure switch with an extra switch provided
		 Replace the exposure switch if the problem occurs after conducting the measurements mentioned above.
		Check the status of the extension cable.
		NOTICE
		Connection status refers to short-circuited, disconnection, etc.
		3. If there is no problem in stages 1 and 2, replace the Main MCU.

11.2.1.4 Subcode - Other error (004)

Tail code	Description	Solution
102	Appears when there is no response during CAN communication.	1. Replace the Main MCU and the collimator manufactured before 2019.01.17, S/N: 069-002730, when H102 error occurs intermittently. NOTICE If an error occurs all the time or after replacing the Main MCU and the collimator, follow the instructions written below. 2. Check the CAN communication response by sending the following command to the inverter board and the sensor to check the CAN communication operation of the Main MCU.
		Inverter board: [SPM_IVER]Sensor: [SPM_FISS_0001]
		3. If both the inverter board and sensor do not respond, replace the Main MCU.

 If only the inverter board does not respond, check the connection status of CN13 (H001922A cable of the inverter. To check CAN communication between the Main MCU and the inverter board.

NOTICE

Connection status refers to reconnection, disconnection, pin status, etc.

- 4.1. If the cable is normal, check that 24V is normally applied to pins 1, 2 of CN13 to check the inverter board's input voltage.
- 4.2. When the 24V power supply is normal, replace the inverter board.
- 4.3. If 24V is not confirmed, check the H001904A cable from the Main MCU to the inverter board.
- 4.4. If the cable is normal, check if 24V is applied to pins 1, 2 of CN13 to check the main MCU's input power.
- 4.5. If 24V is applied, replace the Main MCU.
- 4.6. If 24V is not applied, replace the power board.
- If only the sensor does not respond, check the connection status of H001909A, H001918A, and H001925A cable to check CAN provide communication between the main MCU and the sensor.

NOTICE

Connection status refers to reconnection, disconnection, pin status, etc.

- 5.1. If the cable is normal, check that 8V is normally applied to the sensor.
- 5.2. When the 8V power supply is normal, replace the sensor.
- If 8V power is not confirmed, check if 24V is normally applied to pins 6, 8 of CN2801 (DC04 board).
- 5.4. If the 8V is applied, replace the DC04 board.

- 5.5. If the 8V is not confirmed, check if 24V is normally applied to pins 21, 22 of CN2704 (SUB046 board).
- 5.6. If the 24V is applied, replace the SUB046 board.
- 5.7. If the 24V is not confirmed, check if 24V is normally applied to pins 5, 6 of CN1600 (Main MCU board).
- 5.8. If 24V is applied, replace the Main MCU.
- 5.9. If 24V is not confirmed, replace the power board.
- If only the collimator does not respond, check the H001909A and H001915A cable's connection status to check CAN communication between the Main MCU and the collimator.

NOTICE

Connection status refers to reconnection, disconnection, pin status, etc.

- 6.1. If the cable is normal, check if 24V is normally applied to pins 1, 4 of CN500.
- 6.2. If 24V is applied, replace the collimator ass'y.
- 6.3. If 24V is not confirmed, check if 24V is normally applied to pins 21, 22 of CN2704 (SUB046 board).
- 6.4. If 24V is applied, replace the SUB046 board.
- 6.5. If 24V is not confirmed, check if 24V is applied to pins 5 and 6 of CN1600 (Main MCU board).
- 6.6. If 24V is applied, replace the Main MCU.
- 6.7. If 24V is not confirmed, replace the power board.

11.2.2 Main code – Software (002)

11.2.2.1 Subcode – Sequence related error (001)

Tail code	Description	Solution
001	Appears when the packing mode is	Check whether the packing mode is enabled.

11. Troubleshooting

Tail code	Description	Solution
	enabled	
002	Appears when the door is open	 Check whether the door is open. Check if the DoorLock function is activated when capturing SW and the firmware of the main MCU. Check the [SPM_DROP_000x] value by sending [SPM_ISDR] through serial communication. (0: Deactivated, 1: Activated) Check the door sensor. If the problem is not resolved, contact the customer service team for further information.
003	Appears when the exposure switch is pressed	 To check whether the exposure switch usually operates or not, conduct the following measurement. Remove the exposure switch and see if the same problem occurs. Replace the current exposure switch with an extra switch provided Replace the exposure switch if the problem occurs after conducting the measurements mentioned above. Check the status of the extension cable. NOTICE Connection status refers to short-circuited, disconnection, etc. 4. If there is no problem in stages 1 and 2, replace the Main MCU.

11.2.2.2 Subcode – PC Resolution related error (010)

Tail code	Description	Solution
001	Appears when the resolution is less than	Check whether the resolution setting is 1280x1024 or higher than 1280x1024.
	1280x1024	Check whether the magnification of the resolution is 100%.
002	Appears when the resolution is less than	Check whether the resolution setting is 1200x960 or higher than 1200x1024.

Tail code	Description	Solution
	1200x960	Check whether the magnification of the resolution is 100%.

11.2.2.3 Subcode – PC Network related error (024)

Tail code	Description	Solution
	Appears when the port is invalid	Check whether the power of the equipment is on when the capture SW is running.
		Check the communication port setting. (Default COM4)
002		Check the communication cable connection status
		NOTICE Connection status refers to reconnection, bending, contamination, etc.
003	Appears when the time is out	Check whether the power of the equipment is on when the capture SW is running.
		Check the optic cable of each section from the PC to the Main MCU using the extra optic cable.
		3. If the cable is regular, replace the Main MCU.

11.2.3 Main code - Acquisition Module (003)

11.2.3.1 Subcode – Initialization Failure related error (010)

Tail code	Description	Solution
	Appears when the COM port cannot be opened	Check whether the driver of the grabber and virtual comport is recognized in the device manager. (Advance remote check is required.)
000		Reinstall the driver to the latest version. (Advance remote check is required.)
		Move the grabber to another PC slot and check if there is a problem.
		If the problem is not resolved, replace the grabber.
		5. 5. If the same problem occurs after replacing

11. Troubleshooting

Tail code	Description	Solution
		the grabber, replace the PC.
	Appears when the frame grabber interface cannot be initialized or memory for acquisition cannot be reserved	Check whether the driver of the grabber is recognized in the device manager. (Advance remote check is required.)
		Reinstall the driver to the latest version. (Advance remote check is required.)
001		Check the PC specification and the Windows & Bios setting. (Advance remote check is required.)
		Move the grabber to another PC slot and check if the problem occurs.
		If the problem is not resolved, replace the grabber.
		If the same problem occurs after replacing the grabber, replace the PC.
002	Appears when the MCU is not communicable, or the modem ring signal is in an improper state	Check whether the communication is available with the Main MCU.
		If there is a problem, replace or reconnect the optic cable.
		3. Replace the Main MCU.

11.2.3.2 Subcode – Capture Failure related error (020)

Tail code	Description	Solution
	Appears when there is a capture error	Check the Windows & Bios setting. (Advance remote check is required.)
		Check the grabber card. (Advance remote check is required.)
000		NOTICE Check whether the device manager and grabber driver are recognizable. Check the FPGA version and conduct the pattern test.
		Check whether the Dark is secured. (Advance remote check is required.)
		4. If there is no problem, check whether 5V is

applied to the sensor.

- 5. Connect the sensor and the PC Grabber with an optic cable to confirm whether the image data can be acquired.
- 5.1. If the equipment usually operates, check the optic cable and optic hub board for each section.



Section: from the sensor to the optic hub, from optic hub to the column, from column to PC

6. If the problem is not resolved, replace the sensor.

11.2.3.3

Subcode - Reconstruction Failure related error (030)

Tail code	Description	Solution
001	Appears when bugs exist in VXM-file or there is insufficient memory	 Check whether the graphics card is installed. Check whether the capturing PC satisfies the required PC specification (CPU, RAM, GPU). If the PC specification is usual, upgrade the graphics card driver to the latest version. If the problem is not resolved, replace the graphics card.

11.2.3.4 Subcode – Hardware related error (061)

Tail code	Description	Solution
HW Error No	Appears when the error occurs during acquisition module operation	Follow the instructions stated in the hardware error code section according to the code number.

Left blank intentionally

12. Cleaning and Disinfection

The liquid can cause damage to the equipment. When cleaning or disinfecting, liquids may enter the equipment or the release button via the ventilation slots.

- Do not spray the equipment with Cleaners or disinfectant agents. Apply the Cleaners or disinfectant agents to a clean cloth and wipe it.
- Make sure that no liquids run along the surface into the ventilation slots or release button.
- Remove any soiling with a soft, wet, lint-free cloth.
- Please follow the Cleaners or disinfectant agents' instructions for use.
- When cleaning or disinfect the surfaces, always disconnect the equipment from the main power.
- Do not use spray cleaner or disinfectant directly onto the equipment, as this could cause a fire.
- Cleaners or disinfectant agents may contain powerful ingredients. Unsuitable cleaning and disinfectant agents are detrimental to health and attack the surface of the equipment.
- Do not use cleaners or disinfectant agents containing Phenol, acetic acid, peroxide, other oxygen splitting agents, sodium hypochlorite, and isopropyl alcohol (2-propanol, isopropanol), or iodine-splitting agents.
- Comply with the specifications contained in the operating instructions of the Cleaners or disinfectant agents.
- Wear safety gloves.



12.1 Cleaning



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

- Thoroughly clean the equipment areas that come in direct contact with the patient, such as the Chinrest and the Bite.
- Do not use spray cleaners or solvents that could flow into the equipment and damage the electrical components or cause a fire.
- Do not use abrasive liquids such as acetone, gas, or oil, which may cause corrosion on the equipment's surface.
- Do not use any cleaning products which contain silicon. They could potentially damage the equipment's electrical components.
- The equipment surfaces can be cleaned with a soft cloth damped in a nonalcohol-based, non-corrosive cleaning solution. Do not use sponges or, in any case, any material that can be reused.

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

Components	Cleaning Process		
Bite			
(Normal Bite, Special Bite A, and Special Bite B, Double Scan Support)	Clean with a non-alcohol-based, non-corrosive cleaning solution, and gently wipe with a dry towel before the next patient.		
Temple Supports			
Chinrest			
Computer and peripherals	Follow the manufacturers' instructions found in the accompanying manuals.		
Outer covers of equipment	Wipe the unit with a dry cloth at the end of each day.		
·			
INVEGRIANT	not use cleaning agents in aerosol or spray form directly he surface of the equipment.		

12.2 Disinfection

- Use only disinfectants that comply with the respective national regulatory body's valid requirements or whose bactericidal, fungicidal, and virucidal properties have been verifiably tested and approved accordingly.
- Sterilization and disinfection should be performed thoroughly for items that have been in frequent contact with patients and operators.
- Do not use UV systems to disinfect the equipment, as exposed parts of the device can turn yellow or discolor.
- The use of unsuitable Cleaners or disinfectant agents and methods can damage the equipment and accessories. Only use the Cleaners or disinfectant agents specified or approved by VATECH
- The following Cleaners or disinfectant agents have been evaluated for safe use on the surfaces.
- Never combine products or liquids other than the products listed above.
- Damages to surfaces and materials due to different products cannot be excluded even if they are not included in the exceptions mentioned above.
- Use a non-alcoholic chlorine dioxide-based disinfectant.

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13. Maintenance



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



- 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.



- 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.

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.		
After using the equipment, make sure that the Main Power Switch has been turned off.		
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.		
Confirm that activating the Emergency Stop Switch ceases the unit's operation. Pressing the Emergency Stop Switch should stop all movement of the equipment and X-ray emission.		
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	

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 using the PHANTOM KIT effectively. 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

VATECH's phantom kit consists of:

- 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

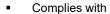
- Manufacturer
 - VATECH Co., Ltd.
- Intended Use
 - CT Image Homogeneity Inspection
 - CT Image Noise Inspection
- Complies with
 - IEC 61223-2-6
 - IEC 61223-3-5





S&C Check Phantom

- Manufacturer
 - VATECH Co., Ltd.
- Intended Use
 - Low Contrast Resolution Inspection
 - High Contrast Resolution Inspection



- IEC 61223-2-6
- IEC 61223-3-5

Phantom Jig Assembly

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



13.5 QA Test Procedure

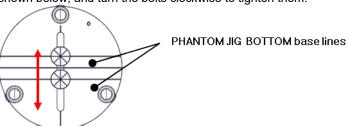
- Each facility shall establish a committee of individuals responsible for the Radiation Safety/Quality Assurance program. For a non-hospital facility, this committee might be composed of a dentist, an X-ray technician, an office manager, and a certified service representative to perform radiological 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.
- 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

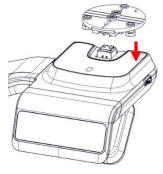
Follow the CT Number Test procedure below to produce correct images and analyze the User Phantom. Test results must be documented and maintained for at least one year. The CT number for water should be recorded and compared each day to the established specifications.

13.5.1.1 Setting up CT Number Phantom

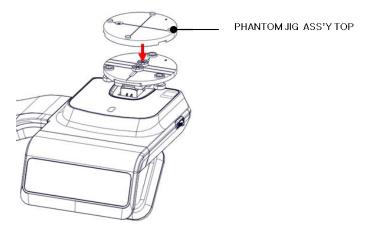
- 1. Remove Bite and Temple Supports from the Unit.
- 2. Align the PHANTOM FIXING BOLTs to the PHANTOM JIG BOTTOM baseline, as shown below, and turn the bolts clockwise to tighten them.



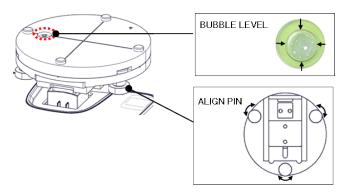
3. Insert the PHANTOM JIG BOTTOM into the Chinrest and then put the PHANTOM JIG TOP on the PHANTOM JIG BOTTOM.



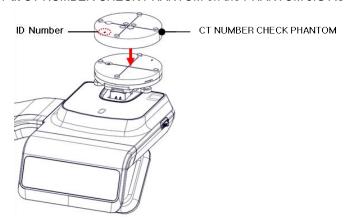
4. Put the PHANTOM JIG ASS'Y TOP on the PHANTOM JIG ASS'Y BOTTOM as shown below.



Make the PHANTOM JIG ASS'Y level by using BUBBLE LEVEL and three ALIGN PINs.



6. Put CT NUMBER CHECK PHANTOM on the PHANTOM JIG ASS'Y.



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

13.5.1.2 Imaging CT Number Phantom

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

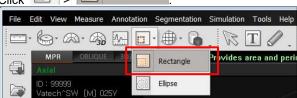


- 3. Click the CT check box and click Capture.
- 4. Click the **NEXT** button at the bottom of the Capture Software screen.
- 5. Click the **READY** button when enabled.
- **6.** Capture the PHANTOM image according to capture software instructions.
- 7. When image capturing is completed, save the image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

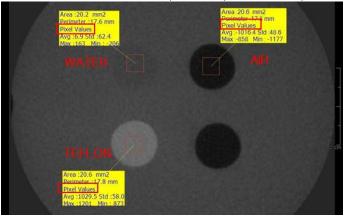
13.5.1.3 Analyzing CT Number Phantom

- 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.





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





Try to make each box as close to 20.0 mm² in the area as possible.

13. Maintenance

5. Compare the CT NUMBER average values from the WATER, TEFLON, 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	

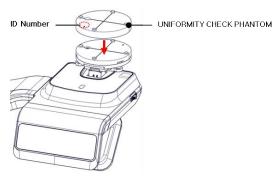
- 6. Record the mean CT Number value of each material.
- 7. Click | Full screen... and save the captured screen in EzDent-i.
- 8. Remove User Phantom from the PHANTOM JIG ASS'Y.

13.5.2 QA CT Uniformity Test

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

13.5.2.1 Imaging 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.



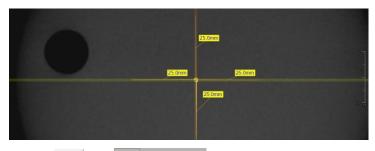
- 7. Click the CT check box and click Capture.
- 8. Click the NEXT button at the bottom of the Capture Software screen.
- 9. Click the READY button when enabled.
- **10.** Capture the PHANTOM image according to capture software instructions.
- 11. When image capturing is completed, save the image in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

13.5.2.2 Analyzing CT Uniformity Check Phantom

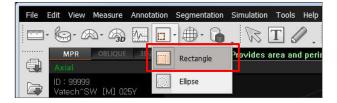
- 1. Double-click the saved PHANTOM image in EzDent-i to run Ez3D-i.
- 2. In the Axial pane, click in the upper-right corner to maximize the Axial view.



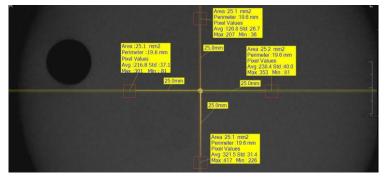
Make 25mm lines from the center to UP/DOWN/LEFT/RIGHT directions, as shown below.



5. • Click Property > Rectangle



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



Try to make each box as close to 25.0 mm2 in the area as possible.

Put the 4 ROIs at the end of each 25mm line.

 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	EVALUATION	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 > Full screen... and save the captured screen in **EzDent-i**.
- 10. When finished, exit EzDent-i.

13.5.3 High Contrast and Low Contrast Resolution Tests

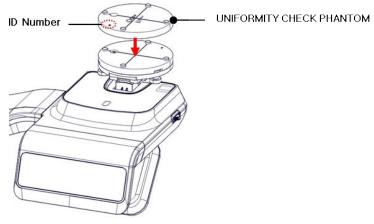
Test Frequency

- HIGH CONTRAST RESOLUTION: Initially and Yearly
- LOW CONTRAST RESOLUTION: Initially and Yearly

Follow the High and Low Contrast Resolution Test procedure below to image and analyze the S&C Check Phantom correctly. Test results must be documented and maintained for at least one year.

13.5.3.1 Imaging S&C Check Phantom

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



- 5. Click to run Capture Software in 2D viewer.
- 6. Click to enter Phantom Capture mode.



- 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.

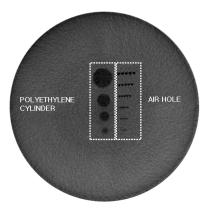
13.5.3.2 Analyzing S&C Check Phantom

- 1. Remove Bite and Temple Supports 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 I for full-screen mode.
- 4. Adjust the brightness and contrast of the image by clicking

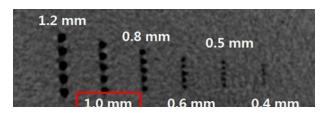


and dragging left/right (contrast) or up/down (brightness).

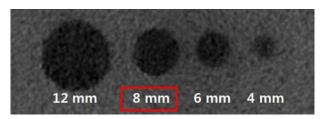
Make sure that you can see the minimum size of the Airhole and the PE (Polyethylene) cylinder at a distance of 50 cm (20 inches) from the monitor.



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>

14. Disposing of the Equipment

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

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

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

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



Clean/Disinfect/Sterilize the equipment before disassembling it and disposing of its parts.



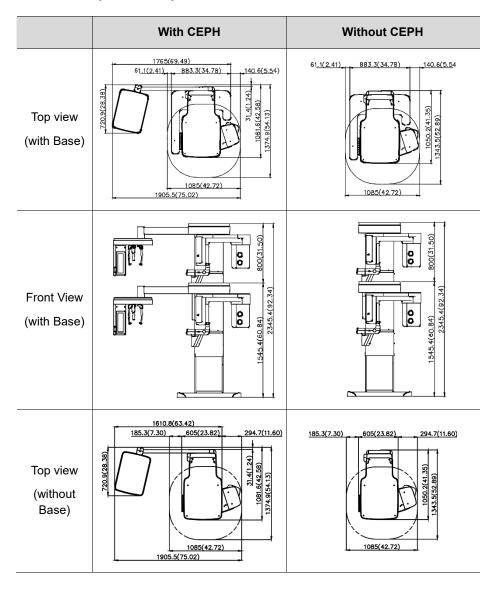
Observe all regulations relevant to the disposal of waste in your country.

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15. Technical Specifications

15.1 Mechanical Specifications

15.1.1 Dimensions (unit = mm)



15. Technical Specifications

	With CEPH	Without CEPH
Front View (without Base)	000(31.50)	1515.4(39.66) 800(31.50) 2315.4(91.16)

Item		Description	
Weight	Without	165.9 kg (365.74 lbs without Base)	
	CEPH unit	220.9 kg (487.00 lbs. – with Base)	
weignt	With	190.9 kg (420.86 lbs without Base)	
	CEPH unit	245.9 kg (542.11 lbs with Base)	
Total Height	Without Base	Max. 2315.4 mm (91.16")	
rotai Height	With Base	Max. 2345.4 mm (92.34")	
	Without	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)	
Dimensions	CEPH unit	with Base:	
during operation (Length x Width		1085.0(L) x 1343.5(W) x 2345.4(H) (mm)	
x Height)		42.72(L) x 52.89 (W) x 92.34(H) (inch)	
		without Base:	
	With CEPH unit	1905.5(L) x 1374.9 (W) x 2315.4(H) (mm)	
	CEI II GIII	75.02(L) x 54.13 (W) x 91.16(H) (inch)	

Item		Description
		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)

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
СВСТ	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

15.2 Technical Specifications

15.2.1 X-ray Generator Specifications

Specifications

ltem			Description
	Model		DG-07E22T2
	Rated output power		1.6 kW
	Inverter model name		INV-22
	Туре		Inverter
		kVp	60 kV~99 kV (1 kV increment)
Generator	Normal/ Pulse	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
	Manufacturer		Canon Electron Tubes & Devices
	Model		D-052SB (Stationary Anode type)
	Focal spot size		0.5 mm (IEC 60336)
	Target /	Angle	5 degree
Tube	Inherent F	iltration	At least 0.8 mm Al equivalent at 50 kV
	X-ray Co	verage	75 mm x 380 mm at SID 550 mm
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time: Interval time)

Test Condition

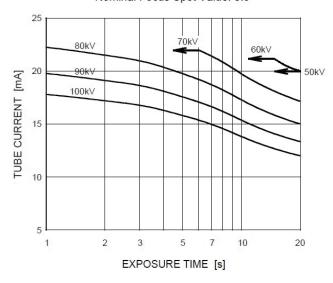
Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
,	60~90	4~14	13.5
	60~90	4~14	11.5
	60~90	4~14	11.2
	60~90	4~14	9.2
	60~90	4~14	9.0
	60~90	4~14	8.0
	60~90	4~14	6.8
	60~90	4~14	6.7
	60~90	4~14	6.7
	60~90	4~14	6.2
PANO	60~90	4~14	5.7
	60~90	4~14	5.5
	60~90	4~14	4.5
	60~90	4~14	3.9
	60~90	4~14	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

15. Technical Specifications

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
	60~90	4~14	0.8
	60~99	4~16	1.9
	60~99	4~15	2.4
CEPH	60~99	4~15	3.9
	60~99	4~14	4.9
	60~99	4~14	5.4
	60~99	4~12	9.0
CBCT	60~99	4~16	2.9
	60~99	4~12	18.0

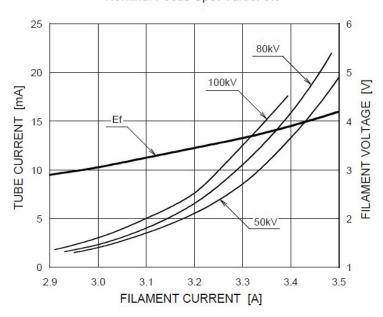
■ ■ Maximum Rating Charts

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

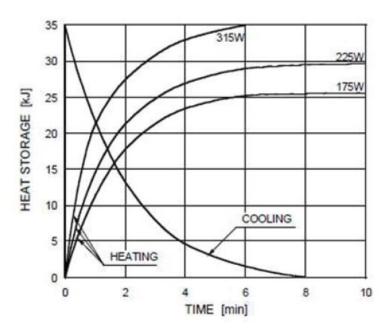


■ ■ Emission & Filament Characteristics

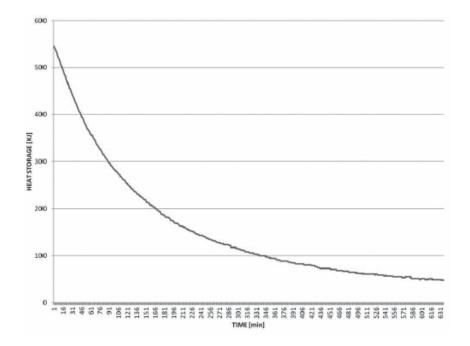
Constant potential high-voltage generator Nominal Focus Spot Value: 0.5



■ ■ Anode Thermal Characteristics



■ I X-ray Housing Assembly Tube Characteristics



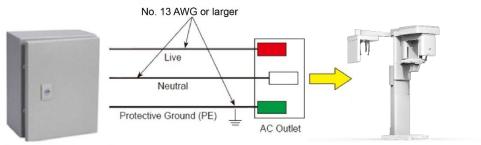
15.2.2 Detector Specifications

	Description			
Item	PANO & CBCT	СЕРН		
Model	Xmaru1524CF Master Plus OP	Xmaru2602CF		
Detector Type	CMOS photo	odiode 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: 233.04 x 145.73(mm) PANO: 5.9 X135.8(mm)	15.60 mm x 259.00 mm		
Frame Rate	~ 94 fps @ 4x4 binning ~ 30 fps @ 2x2 binning	~ 330 fps @ 2x2 binning		
Analogue-Digital Conversion	14 bits			
Operating condition	10~35 °C (Temperature) 10~75 % (Humidity)			
Storage condition	-10~60 °C (Temperature)			
	10~75 % (Humidity)			
Sensor size	198.7 (L) x 326.9 (W) x 32.5 (H) (mm)	110 (L) x 279 (W) x 20 (H) (mm)		
Sensor weight	2800 g	1050 g		
Converter	Csl	: Ti		
Energy Range	40~12	20 kVp		
Readout	Charge amplifier array			
Video Output	Optic			
MTF	> 50 % @ 1.0 lp/mm (2x2 binning) > 40 % @ 1.0 lp/mm (4x4 binning)	> 40% @ 1.0 lp/mm > 8 % @ 2.5 lp/mm		
DQE	> 50 % @~0 lp/mm	> 70 % @~0 lp/mm		
Dynamic Range	> 79 dB	> 70 dB		

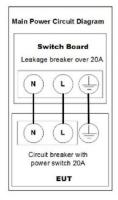
Electrical Specifications

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: Continuous operation with intermittent loading 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)



Central distribution panel w/a circuit breaker





- A separate 3-core grounded power cable connected directly to the central distribution panel with an overcurrent circuit breaker rated for 20A must be used to assure line voltage quality.
- Maximally allowed deviation of the tube voltage/tube current/exposure time:

Tube Voltage (kVp) \pm 10 %/Tube Current (mA) \pm 20 %/Exposure Time (s) \pm (5 % + 50 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.

15.3 Environmental Specifications

	Item	Description
During Operation	Temperature	10~35 ℃
	Relative humidity	30~75 %
	Atmospheric pressure	860~1060 hPa
D : T .	Temperature	-10~60 °C
During Transport and Storage	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/A ge group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
			Hard	75	10
		Man	Normal	74	10
			Soft	73	10
			Hard	74	10
	High Resolution	Woman	Normal	73	10
	resolution		Soft	72	10
			Hard	70	8
		Child	Normal	69	8
PANO			Soft	68	8
Examination			Hard	85	14
		Man	Normal	84	14
	Green (Optional)		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	High	Man & Woman	Normal	70	6
(Insight PAN; Optional)	Resolution	Child	Normal	67	6
			Hard	75	10
		Man	Normal	74	10
			Soft	73	10
CDECIAL			Hard	74	10
SPECIAL Examination	N/A	Woman	Normal	73	10
			Soft	72	10
			Hard	70	10
		Child	Normal	69	10
			Soft	68	10

Scan Time/Exposure Time

Examinatio n Mode	Arch Type	Examinatio n Mode	High	High Resolution		(Optional)
n Mode		п моде	Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
		Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
	Narrow	Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
		Standard	14.1	13.5	4.0	3.9
		Right	14.1	6.7	4.0	2.0
	Normal	Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
		Standard	14.1	13.5	4.0	3.9
) A (* 1	Right	14.1	6.7	4.0	2.0
	Wide	Front	14.1	11.2	4.0	3.2
		Left	14.1	6.7	4.0	2.0
PANO		Standard	12.0	11.5	7.0	6.8
Examination	Child	Right	12.0	5.7	7.0	3.3
	Child	Front	12.0	9.2	7.0	5.5
		Left	12.0	5.7	7.0	3.3
		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
	Orthogonal	Bitewing Incisor (Optional)	14.1	2.8	4.0	0.8
		Bitewing Right	14.1	4.5	4.0	1.5
		Bitewing Left	14.1	4.5	4.0	1.5
		TMJ LAT Open TMJ LAT Close	14.1	6.7	n/a	n/a
SPECIAL Examination	-	TMJ PA Open (Optional) TMJ PA Close (Optional)	10.0	6.1	n/a	n/a
		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.

16.1.2 **CEPH Mode**

Exposure Condition

Examination Program	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
			Hard	92	15.0
		Man	Normal	90	15.0
			Soft	88	15.0
			Hard	90	15.0
	High Resolution	Woman	Normal	88	15.0
			Soft	86	15.0
			Hard	88	15.0
		Child	Normal	86	15.0
Lateral			Soft	84	15.0
Lateral	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
			Hard	92	14.0
		Man	Normal	90	14.0
			Soft	88	14.0
= "	High		Hard	90	14.0
Full Lateral (Optional)	Resolution/	Woman	Normal	88	14.0
(-1/	Green		Soft	86	14.0
			Hard	88	14.0
		Child	Normal	86	14.0
			Soft	84	14.0

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

Scan Time/Exposure Time

Examination	High R	Resolution	Green		
Program	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.

16.1.3 **CBCT Mode**

Exposure Area

	Vertical	Horizontal Position			
FOV (cm)	Position	Right	Center	Left	
18x15	Occlusion	Х	0	Х	
16x11	Occlusion	Х	0	Х	
	Occlusion	Х	0	Х	
12x9	TMJ	0	Х	0	
	Airway	Х	0	X	
8x8	Occlusion	0	0	0	
oxo	TMJ	0	Х	0	
8x5	Maxilla/Mandible	0	0	0	
5x5	Maxilla/Mandible	Selectable	FOV by Teeth (1	Total: 32)	
Endo	Maxilla/Mandible	Selectable	FOV by Teeth (1	Total: 32)	
Double scan (Optional)	First Exposure: Mandible Second Exposure: Maxilla	X			

Exposure Condition

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)		
			Hard	95	7.0		
18x15 &	High Resolution		Man	Man	Normal	94	7.0
16x11 &					Soft	93	7.0
12x9 & Double			Hard	95	6.7		
scan (Optional)		W	Woman	Normal	94	6.7	
(- 1)			Soft	93	6.7		
		Child	Hard	95	6.4		

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
			Normal	94	6.4
			Soft	93	6.4
			Hard	88	6.1
		Man	Normal	87	6.1
			Soft	86	6.1
			Hard	88	5.8
	Green	Woman	Normal	87	5.8
			Soft	86	5.8
			Hard	88	5.5
		Child	Normal	87	5.5
			Soft	86	5.5
	High Resolution	Man	Hard	95	13.0
			Normal	94	13.0
			Soft	93	13.0
		Woman	Hard	95	12.7
			Normal	94	12.7
8x8,			Soft	93	12.7
8x5, 5x5,			Hard	95	12.4
		Child	Normal	94	12.4
			Soft	93	12.4
			Hard	88	9.6
	Green	Man	Normal	87	9.6
	Gieen		Soft	86	9.6
		Woman	Hard	88	9.3

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

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
18x15	9.0	9.0
16x11	9.0	9.0
12x9	9.0	9.0
8x8	4.9	2.9
8x5	4.9	2.9
5x5	4.9	2.9
Endo	18.0	18.0

16. Appendices

- 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)

EOV (om)	Voxel Size (mm)	Reconstruct	Reconstruction Time (s)		
FOV (cm)	voxer Size (IIIII)	Fast	HD	(MB)	
Double scan (Optional)	0.3	108	-	524	
18x15	0.2	163	261	1140	
100.10	0.3	78	245	343	
16x11	0.2	63	165	672	
	0.3	45	161	202	
12x9	0.2	48	145	309	
1239	0.3	25	93	92	
8x8	0.12	120	387	635	
	0.2	36	74	138	
8x5	0.12	68	174	359	
000	0.2	23	54	77	
5x5	0.08	75	149	466	
	0.12	23	55	138	
Endo	0.05	252	<u> </u>	976	

- The above data is obtained from a computer system 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.

16.1.4 3D MODEL Scan Mode

Exposure Area

FOV (cm)	MODEL Type	Horizontal Position			
FOV (CIII)	model type	Right	Center	Left	
8x8	Upper (Maxilla)	Х	0	Х	
	Lower (Mandible)	Х	0	Х	

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 based on Intel i7-6700 and NVIDIA GeForce GTX1060 6GB.
- Image reconstruction time varies depending on computer specifications and working conditions.

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 18** (Model: PHT-75CHS).

X-ray Dose Test Report for the **Green X 18 (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 18 (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 18 (Model: PHT-75CHS)		
Sensor Type	PANO & CBCT: Xmaru1524CF Master Plus OP 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·cm²). Despite the limitation, DAP is the best way to predict effective dose value and 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·cm²] for a clinical protocol for a standard male patient.

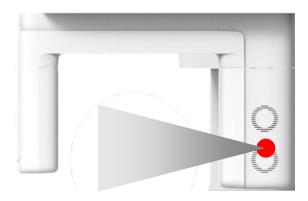
DAP (Dose Area Product) Calculation

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



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
CEPH Child LAT (Green)	86 kVp/16.0 mA/1.9 s	19

Mode	Exposure Condition	DAP [mGy·cm²]
CBCT 18x15 Adult Man (High Resolution)	94 kVp / 7.0 mA / 9.0 s	2702
CBCT 18x15 Adult Man (Green)	87 kVp /6.1 mA / 9.0 s	1959
CBCT 16x11 Adult Man (High Resolution)	94 kVp / 7.0 mA / 9.0 s	1777
CBCT 16x11 Adult Man (Green)	87 kVp / 6.1 mA / 9.0 s	1289
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	5404
CBCT Double Scan Adult Man (Green) (Optional)	87 kVp / 6.1 mA / 9.0 s	3918

[■] In Double Scan mode, image acquisition at FOV 18x15 occurs twice; then stitching transforms obtained images into a single image.

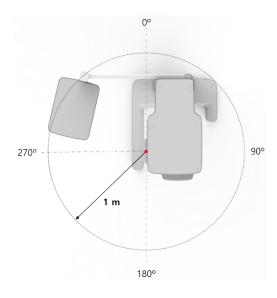
16.2.2 Leakage Dose

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

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

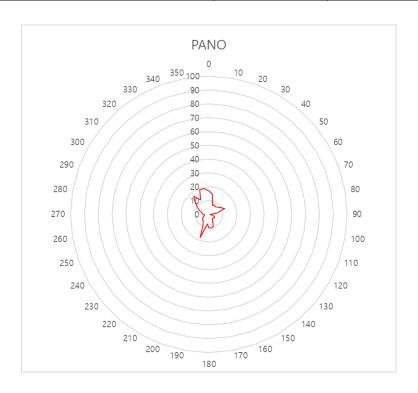


16.2.2.3 PANO Mode Results

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

Mo	ode P/	ANO	
Direction [°]	[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	
260	3	0.026	

Mode	PANO	
Direction [°]	[mR/hr]	[mGy/hr]
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

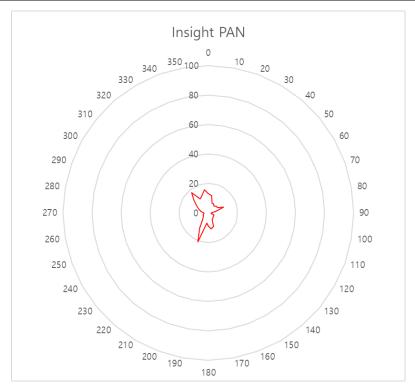


16.2.2.4 PANO Mode Results (Insight PAN)

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

Mode	Insig	ht PAN	
Direction [°]	[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	

Mode	Insigh	Insight PAN	
Direction [°]	[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	

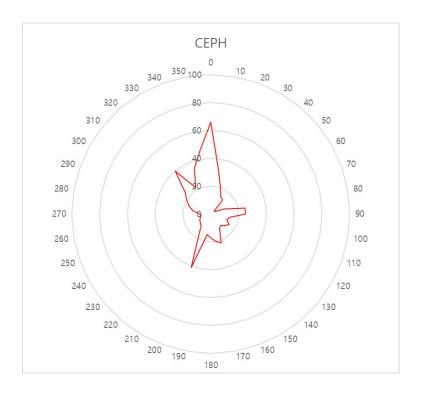


16.2.2.5 CEPH Mode Results

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

M	ode	СЕРН	
Direction [°]	[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	

Mode	СЕРН	
Direction [°]	[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



16.2.2.6 CBCT Mode Results

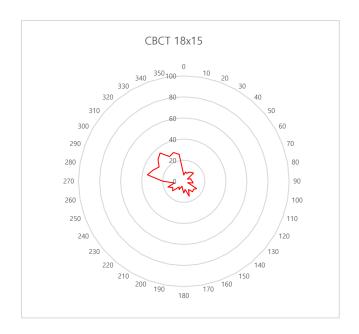
Test Condition			
Tested Mode	СВСТ		
Distance from focal point [m]	1		
Applied Tube Voltage Peak [kVp]	99		
Applied Tube Current [mA]	12		

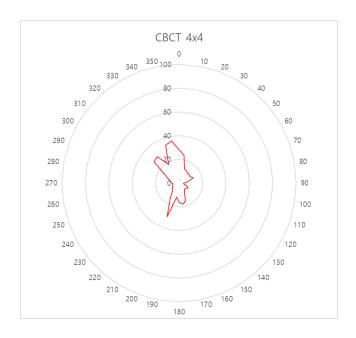
Mode	18x15 High resolution		Endo 4x4 High resolution	
Direction [°]	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	6	0.053	28	0.246
10	9	0.079	24	0.211
20	8	0.070	13	0.114
30	10	0.088	12	0.105
40	11	0.096	11	0.096
50	12	0.105	11	0.096
60	4	0.035	11	0.096
70	7	0.061	13	0.114
80	7	0.061	8	0.070
90	8	0.070	4	0.035
100	9	0.079	4	0.035
110	4	0.035	7	0.061
120	14	0.123	9	0.079
130	12	0.105	7	0.061
140	13	0.114	7	0.061
150	9	0.079	9	0.079
160	15	0.132	16	0.140
170	8	0.070	18	0.158
180	11	0.096	16	0.140
190	7	0.061	12	0.105
200	5	0.044	30	0.263

Mode	18x15 High resolution		Endo 4x4 High resolution	
Direction [°]	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
210	9	0.079	15	0.132
220	7	0.061	9	0.079

Mode	18x15 High resolution		Endo 4x4 Hig	gh resolution
Direction [°]	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
230	14	0.123	8	0.070
240	12	0.105	6	0.053
250	16	0.140	6	0.053
260	9	0.079	5	0.044
270	20	0.175	6	0.053
280	35	0.307	7	0.061
290	31	0.272	10	0.088
300	27	0.237	14	0.123
310	32	0.281	28	0.246
320	35	0.307	29	0.254
330	27	0.237	18	0.158
340	29	0.254	34	0.298
350	26	0.228	36	0.316

• In Double Scan mode, image acquisition at FOV 18x15 occurs twice; then stitching transforms obtained images into a single image.

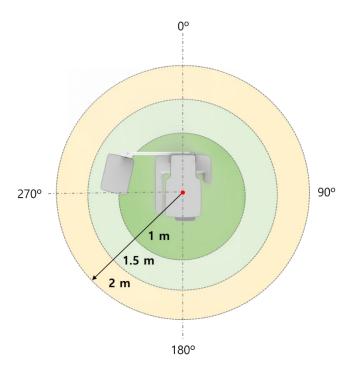




16.2.3 Scattered Dose

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 facilities around the patient's position. This information states the tested phantom's identity and intended position 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.

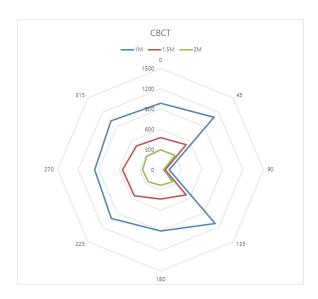
16.2.3.1 Measurement Overview



16.2.3.2 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		

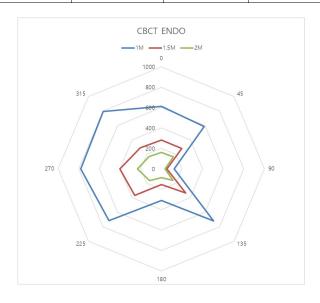
		CBCT FOV 18x15 [mR]		
Direction [°]	Mode	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.985	0.474	0.296
45		1.1	0.525	0.297
90	Right ear	0.127	0.067	0.043
135		1.126	0.528	0.249
180	Occiput	0.906	0.434	0.23
225		1.017	0.541	0.25
270	Left ear	0.958	0.553	0.261
315		1.021	0.497	0.282



16.2.3.3 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	

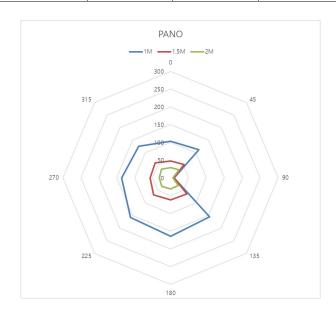
		CBCT FOV Endo [mR]		mR]
Direction [°]	Mode	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.613	0.282	0.161
45		0.588	0.282	0.164
90	Right ear	0.125	0.055	0.035
135		0.718	0.333	0.159
180	Occiput	0.309	0.154	0.086
225		0.716	0.365	0.16
270	Left ear	0.78	0.402	0.231
315		0.795	0.289	0.169



16.2.3.4 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	

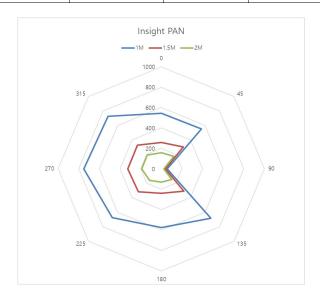
			PANO [mR]	
Direction [°]	Mode	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	Nose	0.103	0.047	0.028
45		0.111	0.053	0.032
90	Right ear	0.01	0.009	0.006
135		0.154	0.064	0.03
180	Occiput	0.164	0.062	0.03
225		0.157	0.067	0.033
270	Left ear	0.136	0.056	0.031
315		0.125	0.06	0.035



16.2.3.5 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	

		PANO	O (Insight PAN)	[mR]
Direction [°]	Mode	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



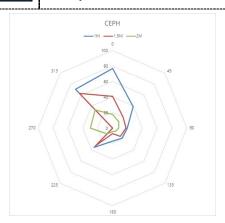
16.2.3.6 CEPH Mode Results

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	

	84 - J -	CEPH Full Lateral [mR]			nR]
Direction [°]	Mode	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.



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 Electromagneti c 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 Communicatio ns 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/Burs t Immunity	EN 61000-4- 4:2012, IEC 61000-4- 4:2012	IDLE mode CT mode PANO mode CEPH mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line: ± 2 kV Signal: ±1 kV 100 kHz repetition frequency
Surge Immunity	EN 61000-4- 5:2014,	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	Line to Line ± 0.5 kV, ± 1 kV

16. Appendices

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
	IEC 61000-4- 5:2014			AC 230 V, 50 Hz	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	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
			Exposure switch cable		6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	EN 61000-4- 8:2010, IEC 61000-4- 8:2009	IDLE mode 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 % <i>U</i> _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 % <i>U</i> _T ; 250/300 cycle

16.4 Positioning the Pediatric Dental Patients

- Use a laser light beam guide to locate the midsagittal plane. Direct patient focusses 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 in toward the vertical column of the X-ray device into a position that feels as if he/she is slightly leaning backward.
- **4.** Direct the patient to close lips around the Bite Block during the exposure.
- **5.** Direct the patient to swallow and note the flat position of the tongue. Request that the patient sucks in the cheeks, pushing the tongue into the correct flat position against the palate and maintain this position throughout the exposure.

<How to 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 pediatric patient's growth and development and for evaluation of developing third molars during adolescence. 1-3 While the panoramic technique seems relatively straightforward, producing a pediatric patient's diagnostic quality image requires technical skill mastery. 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 pediatric patient's assessment while minimizing the occurrence of retakes that result from the 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 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. 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.

Frror	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 posi- tion on bite guide.	Use a cotton roll to fill in missing primary teeth or par tially erupted permanent teeth. Adapt adult recommendation for direction of laser ligl	
Anterior teeth wide, blurred out of image Condyles not imaged	Arches positioned too far posterior	Locate appropriate position with anterior laser light guide.	beam guide for use with primary teeth. Observe laser light beam guide on both the right and left sides.	
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 midsagit- tal plane perpendicu- lar 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		correct position throughout exposure.	
Flat, downward-turned, "frown" appearance to the occlusal plane Palate appears as a widened, thick, dense radiopacity Condyles flare out off the edges of the image Anterior teeth appear wide, elongated	Arches positioned too far superior	Position the Frankfort or the canthomeatal plane parallel to the floor, or the ala-tragus	Move chin rest into a position that is slightly higher than the patient's chin height before requesting that the patient place chin onto the rest. Direct the patient to assume a position that resembles the erect stance of a soldier.	
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	line 5° down toward the floor.		
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. 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.

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.

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

Superior-Inferior (Up-Down) Positioning Error

Positioning the dental arches within the superior-inferior (up-down) dimension of the focal trough can be 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.

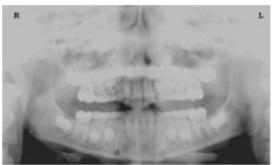


Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

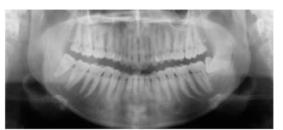


Figure 6: Chin positioned too far down. Note the characteistic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

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

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

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

Conclusion

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

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16.5 Acquiring Images for Pediatric Dental Patients

16.5.1 Age Group: Classification Table

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

Age Group	FDA'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	
Other	16 ~ 21 years of age	Adult
Adult	> 21 years of age	

16.5.2 Setting Exposure Values to the Age Group

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

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

1) Literature

I. ESPELID, I. MEJÄRE, 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 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.:

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 to 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 of 6 years of age undergoing head and neck multi-detector CT (MDCT) examinations.

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

Results: The maximum value of the mean organ dose in brain CT was 34.3 mGy for the 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/radiationemittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm29 8899.htm
- http://www.imagegently.org/

16.6 Abbreviations

AC	Alternating Current				
AF	Auto-Focusing				
AMPT	Adaptive layer Mode Panoramic Tomography				
CAN	Controlled Area Network				
СВСТ	Cone-Beam Computed Tomography				
CMOS	Complementary Metal-Oxide -Semiconductor				
СТ	Computed Tomography				
DAP	Dose Area Product				
DC	Direct Current				
DICOM	Digital Imaging and Communications in Medicine				
EMC	Electromagnetic Compatibility				
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				

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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