

Green X 21TM

User Manual
Model | PHT-90CHO
Version | 1.13

English

Green X 21TM User Manual English

vatech



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Notice

Thank you for purchasing the **Green X 21™ (Model: PHT-90CHO)** extraoral imaging system.

Green X 21™ (Model: PHT-90CHO) is one of the manufacturers' Green CT product series for aiding dental professionals in providing excellent care in a safe environment that promotes healing.

Green X 21™ (Model: PHT-90CHO) is an advanced digital diagnostic system that incorporates PANO, CEPH (Optional), DENTAL CT, ENT CT, MODEL, and FACE SCAN imaging capabilities into a single system.

This manual describes how to operate the **Green X 21™ (Model: PHT-90CHO)** system. It is recommended that you thoroughly familiarize yourself with this manual to effectively use this equipment.

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

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

VATECH Co., Ltd.

E-mail: gcs@vatech.co.kr

This document is originally written in English.

Green X 21™ (Model: PHT-90CHO) is referred to as "equipment" in this manual.

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1. Introduction

1.1 Overview

Green X 21™ (Model: PHT-90CHO) is an advanced 6-in-1 digital X-ray system specifically designed for 2D and 3D dental radiography. This system features six imaging modalities: PANO, CEPH (optional), DENTAL CT, ENT CT, MODEL, and FACE SCAN, all integrated into a single unit.

Green X 21's imaging system is based on digital TFT detectors, accompanied by imaging viewers and an X-ray generator.

1.2 Indication For Use

It enables:

- 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.
- 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 the cleft palate
- Diagnosis of CRS (chronic rhinosinusitis)
- Assessment of complex root canal anatomy
- Diagnosis of Periapical Pathology
- Diagnosis of vertical root fracture
- Examinations of the airways for measuring the volume and dimensions of air passages
- Planning any surgery where 3D analysis of the jaw is required.
- Storing Plaster Casts in 3D data
- 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
- Assisting the patient consultation with 3D photo scan data.

1.3 Intended Purpose

1.3.1 For the EU Market

Green X 21 (Model: PHT-90CHO) is intended to produce panoramic, cephalometric, or 3D digital X-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, TMJ, and ENT for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.

1.3.2 For the U.S Market

Green X 21 (Model: PHT-90CHO) is intended to produce panoramic, cephalometric, or 3D digital X-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, TMJ, and ENT for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.



1.4 Intended User Profiles

Considerations	Requirement Description
Qualification	A legally qualified person such as a dentist and healthcare professional for X-ray device operation
Knowledge	- Understanding the treatment and diagnosis of dental disease - Understanding the terms and guidance of hardware and software of a diagnostic medical radiation device and recognizing device connection, installation, and operating conditions
Language understanding	- Understanding how to use manuals (English/Korean) or - Understanding other languages provided
Experience	- Understanding the objectives and effects of the diagnosis and treatment of dental disease using diagnostic medical radiation devices - Understanding of the normal operation of diagnostic medical radiation equipment - Understanding the contents of the user manual

IMPORTANT

Only qualified personnel such as dentists, dental hygienists, or radiologists can use X-ray devices.

1.5 Contraindications

Do not use this device other than the intended purpose.

There are no other contraindications to it since the technology is at a controllable level in accordance with global standards. It can be used on adult and pediatric patients, but infants (1 month to 2 years) are excluded.

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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 installed and uninstalled the equipment.
- The equipment was installed following all the procedures and conditions required for installation.
- **VATECH**-approved equipment and components are used.
- A **VATECH**-authorized agent performed all maintenance and repairs.
- The equipment was used following the instructions in the **user manual**.
- The owner or the operator did not cause damage to the equipment.

2.2 Owner and Operator's Obligations

- The owner of this equipment shall perform constancy tests at regular intervals to ensure patient and operator's 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 **14 Cleaning and Disinfection**.

2.3 Conventions in this Manual

This manual uses the following conventions to inform users. Please familiarize yourself with each convention and follow the accompanying instructions.

 WARNING	WARNING	Failure to comply with the information with this convention may result in severe injuries to the people or damage to the equipment.
 CAUTION	CAUTION	Requires the user's immediate attention or action due to the possibility of safety issues.
 IMPORTANT	IMPORTANT	Requires the user's attention because the stated action and environment may cause trouble.
 NOTICE	NOTICE	Indicates useful information for users.
	RADIATION	Indicates a possible danger from radiation exposure.
	SINGLE-USE	Indicates a component that must be replaced for each new patient.
	ESD susceptibility	Indicates that an item is susceptible to damage from electrostatic discharges.

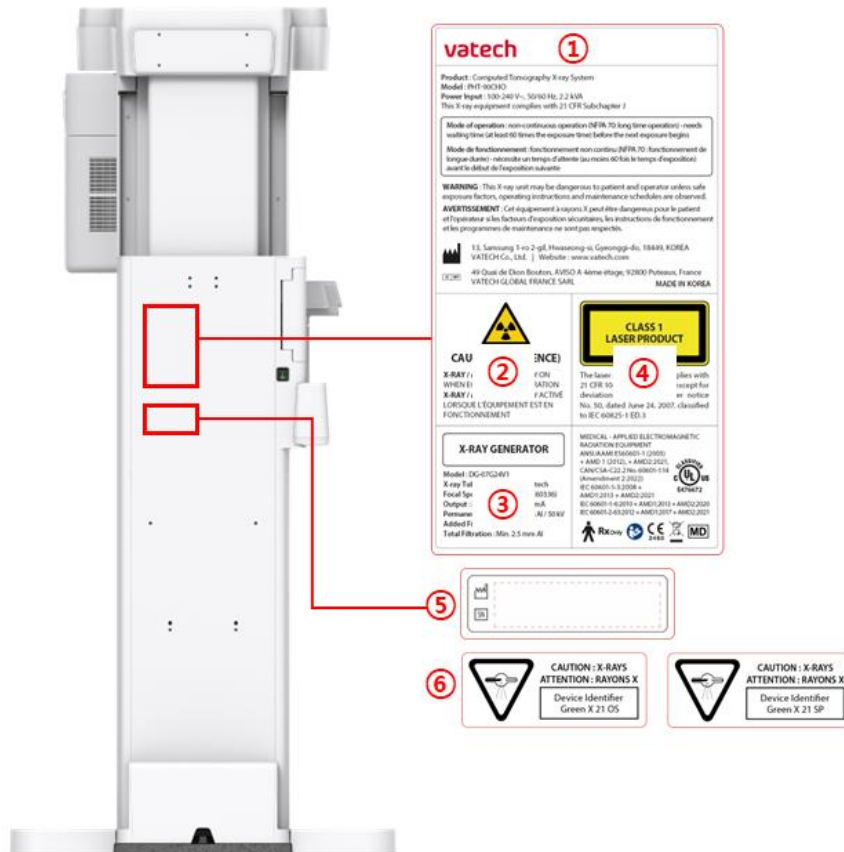
2.4 Marks and Symbols

Symbols	Description	Location
	Dangerous voltage	Power board /Inverter board /Monoblock
	Protective earth (Ground)	Column
	Off (power: disconnected to the Main Power Switch)	Main Power Switch
	On (power: connected to the Main Power Switch)	Main Power Switch
	Alternate Current	Label
	Type B Applied Equipment (IEC 60601-1: Degree of protection against leakage current and electric shock: Class 1 equipment)	Label
	Radiation hazard	Label
	Indicates the authorized representative in the European Community.	Label
	The CE symbol indicates that this product complies with the European Regulation for Medical Devices Regulation 2017/745 as a class IIb device.	Label
	UL mark No. E476672	Label
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Label

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

2.4.1 Label Location

The following labels are attached to the equipment as illustrated below.



NOTICE

The design and contents of the labels may vary by country based on local regulations and standards.

2. General Information

No.	Item
1	Main Label
2	CAUTION Label - X-ray / Attention: X-ray is on when equipment is 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 • Green X 21 SP: CEPH unit excluded. • Green X 21 OS: CEPH unit included

3. Warnings and Precautions

3.1 General Safety Guidelines

Operator Qualifications

This equipment must be operated by a qualified person who is trained in proper operating procedures. To operate the equipment, the operator must meet the following standards:

- Read and understand the **user manual**.
- Understand this equipment's structure and function.
- Recognize problems with the equipment and implement appropriate solutions.

General Safety Precautions

- Follow the instructions in this manual to ensure the safety of both the patient and the operator.
- The operator must maintain vocal or visual communication with the patient while acquiring an image.
- Do not open or remove this equipment's cover. Only VATECH-approved technicians can inspect and repair this equipment.
- Do not place any heavy objects on this equipment under any condition.
- Do not place any objects within this equipment's field of operation. This may cause property damage.
- Install equipment with a wall bracket or other connecting parts. Both operators and patients can receive injuries from the equipment tip-over if it is not securely mounted to the wall or the floor.
- Instruct the patient to remain still until the equipment stops moving after the image acquisition.
- Observe all local fire regulations. Always keep a fire extinguisher near the equipment.
- The operator must be familiar with this equipment's emergency protocols.
- Keep the equipment away from water, moisture, or foreign substances. This equipment is an IPX0 device and is not intended to be used near liquids.
- Ensure that no liquid enters the equipment while acquiring an image of the patient under the following conditions:
 - Patients who have implants or underwent oral anesthesia or other procedures that can cause drooling during the image acquisition.

3. Warnings and Precautions

- When this equipment is exposed to water, moisture, or a foreign substance, turn off the equipment immediately and contact your **VATECH** technical support representative.
- When there is a sign of oil leakage, stop the equipment immediately and contact your **VATECH** technical support representative.
- The external parts connected to the outside of equipment such as cables must comply with relevant IEC Standards. (e.g., IEC 60950 for IT equipment and IEC 60601-1 series for medical electrical equipment).
- Likewise, these parts must comply with IEC 60601-1, IEC 60601-1-1, and the national regulations of the country where the equipment is installed. Please contact **VATECH** or its area representative if you have questions.
- Any person or organization that installs an external door interlock switch is responsible for ensuring that the switch has a radiation indicator or equivalent alarm system to show the state of the current.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Ventilation

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



Follow all warnings and safety instructions in this manual to guarantee a safe operation.



To work safely around the X-ray equipment, follow precautions and conduct regular inspections. Ignoring the precautions may endanger both patients and operators.

Hygiene

Turn off the equipment before you start cleaning.



Do not use a cleaner spray on the equipment. Spraying liquid directly over the equipment can cause a fire or damage the electrical parts inside the equipment.

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



- If you use sanitary vinyl covers for a 3rd party, ensure that the product conforms to one of the following standards:
 - ISO 10993-1 (Biological Evaluation of Medical Devices)
 - FDA
 - CE
 - Local regulations in your area

Condensation

- Condensation can occur inside the equipment when the temperature difference is great between the outside and inside of the X-ray shielding room, where the equipment is installed. To avoid condensation, refer to the operating condition table in **17.4 Environmental Specifications**.

Cooling

- Give an intermission between each X-ray exposure to allow the X-ray tube to cool down. The continuous operation without a cooling time may cause an overload.
 - **Mode of operation:** non-continuous operation (NFPA 70: long time operation) - needs waiting time (at least 60 times the exposure time) before the next exposure begins.
 - **Column operation time:** Max. 2 min. On / 18 min. Off (Ratio 1:9)
- When the tube temperature rises to 60 °C (140 °F), the X-ray exposure is halted, and the error message appears on the console software window. To restart the X-ray exposure, the tube head temperature must be dropped to 58 °C (136.4 °F) or below.
- When the tube temperature rises to 40 °C (104 °F), the cooling fan is activated and starts working to cool down the tube.

Turning the Equipment On / Adjusting the Equipment's Height

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

Stopping the Equipment in Emergency

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

Trouble-Free Operation

- Never use this equipment in an environment that is susceptible to explosion.
- Always operate the equipment within a temperature range of 10 °C to 35 °C (50 °F to 95 °F) for safe operation. Image quality may deteriorate when the equipment operates outside of this temperature range.
- Always allow the equipment enough time to warm up (while switched on) if exposed to temperatures below 10 °C (50 °F).
- Acquire an image of the patient only when the system is in a proper condition.
- Ensure that no person or object, such as the patient's clothing stands in the way of the equipment.
- Do not leave the patient unattended around the equipment.
- Remove all radio-controlled devices and mobile phones from the X-ray room before image acquisition because these objects may cause trouble for the equipment.

Modifying the Equipment

- Modifying the equipment in any way which may affect the safety of the people is prohibited by law.
- Operators cannot replace or repair any parts of this equipment. Only a VATECH-approved technician has the right to inspect and repair this equipment.
- Always use accessories and parts for this equipment provided either by **VATECH** or a VATECH-approved 3rd party.

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 the **main power switch** is turned 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.
- PC must be used outside the patient environment such as the X-ray room.

Combining This Equipment with Other Devices

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

Electromagnetic Compatibility

- This X-ray equipment complies with IEC standard 60601-1-2.
- Medical electrical equipment is subject to special Electromagnetic Compatibility (EMC) preventive measures. It must be installed and operated as specified in EMC information.
- If high-voltage, radio link, or MRI systems are located within 5 m of the unit, please observe the specifications stated in the installation requirements.
- Portable Radio Frequency (RF) communications equipment may interfere with medical electrical equipment. Therefore, mobile wireless phones in medical offices or hospital environments must be prohibited.
- For more details, refer to **18.5 Electromagnetic Compatibility (EMC) Information**.
- Please also observe the Electro-Static Discharge (ESD) protective measures described.

Static Discharge

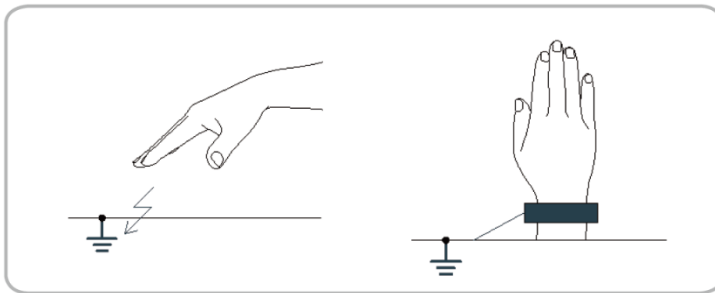
- Without observing ESD protective measures, connector pins or sockets bearing ESD warning labels must not be touched or interconnected.



Electrostatic discharge (ESD)

ESD Protective Measures

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



3.3 Radiation Safety

- Ensure to install this equipment inside an X-ray room.
- The operator must stay outside of the X-ray room while acquiring an X-ray image to protect himself or herself from radiation exposure.
- The operator must be able to communicate with his or her patient either visually or verbally while the equipment is in operation.
- Check the status of the patient and the equipment until the image acquisition is completed.
- Stay at least 2 m (7 ft) away from the equipment during image acquisition.
- Stop the equipment immediately when a problem occurs during the image acquisition.
- Guide the patient to wear a lead apron with a neck collar to protect thyroid gland prior to imaging. Wearing lead glasses is also recommended. Note, however, that the lead glasses may cause an image artifact in the acquired image.
- Children and pregnant women must consult their doctors before X-ray scanning.
- Check if your patients have an electrical medical device implanted in their body or are currently under radioactive iodine seed treatment. Patients who meet one of these conditions must be informed before X-ray scanning about the danger associated with radiation exposure.
- Guide the following patients to consult their doctor before taking an X-ray:
 - 1) the patients with the implanted medical device.
 - 2) the patients under the radioactive iodine seed treatment.
- The implanted medical devices that require a doctor's consultation before X-ray scanning are insulin pumps, cardiac implantable electronic devices (pacemaker and implantable cardioverter defibrillators), and neurostimulators.



As a manufacturer of radiology equipment, **VATECH** guarantees the maximum degree of protection against radiation hazards for its product.



Because the radiation safety regulations differ across countries, both equipment owners and users are responsible for following radiation safety regulations and protective measures in their areas.

3.4 Warnings

Follow the warnings below to ensure your safety. Failure to follow these warnings can cause injuries or damage to the equipment.

 WARNING	▪ X-ray equipment is hazardous to the patient and the operator if proper exposure safety measures and operating instructions are not observed. ▪ Read this user manual and follow all warnings and cautions in the manual.
 WARNING	▪ Taking an X-ray is justified only when its benefits outweigh its risks. ▪ Use the medical CT or MRI to examine the patient's soft tissue, instead of the dental CT.
 WARNING	▪ Green X 21 (Model: PHT-90CHO) uses high-frequency electrical signals like other medical devices, so it may interfere with implanted medical devices such as pacemakers or implantable cardioverter-defibrillators (ICDs). If a patient is using such an implanted medical device, please be aware of this and immediately turn off the device if interference occurs. ▪ If there is a concern about electromagnetic interference (EMI) with a patient's implanted medical device, please guide them to consult with the physician in charge of the implanted medical device.
 CAUTION	Federal law restricts the sale of this device to dentists, or the personnel licensed by the law of the state where he or she uses or orders the use of the device.

Lasers

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



Risk of Eye Injury!

- Do not use this equipment with any other laser sources.
- Do not make a change to the settings or process written in this manual.

Cleaning

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

During 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 **emergency stop switch** to immediately stop all moving parts and cut off all power to the equipment's electrical components.
- Never touch the patient while he or she is touching the SIP/SOP connectors.
- The medical electrical equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the medical electrical equipment or medical electrical system should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories and cables other than those specified, except cables sold by **VATECH** of the medical electrical equipment or medical electrical system as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY EQUIPMENT or SYSTEM.

In case of an electrical fire

- Ensure to use the fire extinguisher for electrical fire only. Using a fire extinguisher that uses water, foam, or other wet chemicals can damage the equipment and cause electrical shock or burns.

Installation

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

NOTICE

For more information about installing the equipment, read the **Green X 21** 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 protected by Windows built-in firewall and anti-spyware tools.
- Using the latest version of Windows built-in firewall and anti-spyware tools are recommended.
- The software can be updated by the manufacturer only. Unauthorized software update through a third party, not the manufacturer, is prohibited. Please contact the manufacturer for cybersecurity issues related to the software and medical devices. (E-mail: gcs@vatech.co.kr)

3.4.1 Side Effects

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

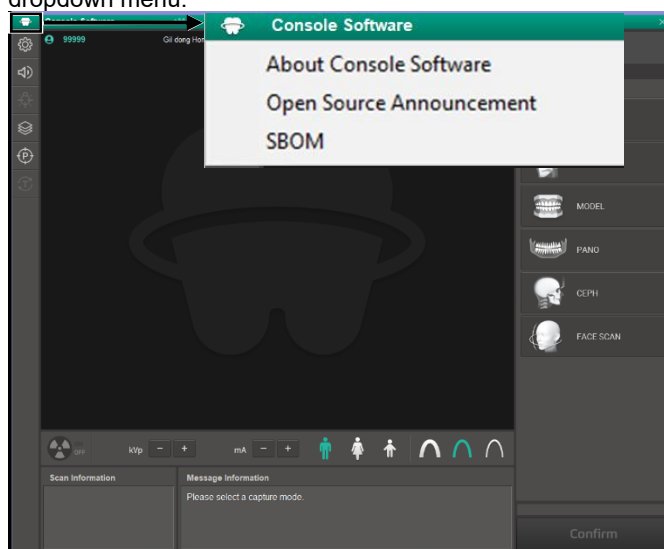
3.5 Cybersecurity

3.5.1 SBOM in a Machine-Readable Format

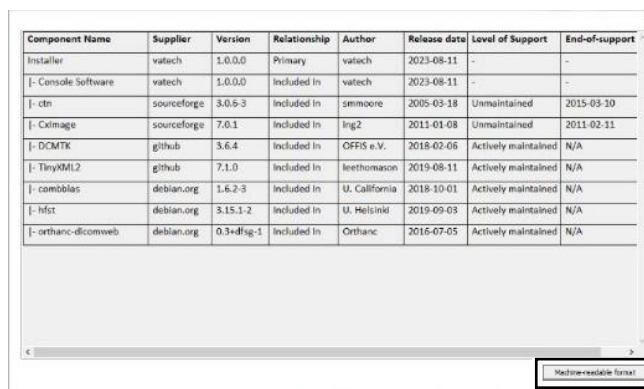
Vatech monitors SBOM vulnerabilities to maintain the cybersecurity of this device and will take appropriate action in accordance with the company's cyber security policy in the case of an event that could compromise the safety and effectiveness of the device.

Follow the steps below to find the SBOM for this device.

1. Launch the console software.
2. Click  in the console software window and select the SBOM option from the dropdown menu.



3. Click the **Machine-readable** format button.



Component Name	Supplier	Version	Relationship	Author	Release date	Level of Support	End-of-support
Installer	vatech	1.0.0.0	Primary	vatech	2023-08-11	--	--
I- Console Software	vatech	1.0.0.0	Included In	vatech	2023-08-11	--	--
I- ctn	sourceforge	3.0.6-3	Included In	smmoore	2005-03-18	Unmaintained	2015-03-10
I- Cximage	sourceforge	7.0.1	Included In	ing2	2011-01-08	Unmaintained	2011-02-11
I- DCMtk	github	3.6.4	Included In	OFFIS e.V.	2018-02-06	Actively maintained	N/A
I- TinyXML2	github	7.1.0	Included In	leethomason	2019-08-11	Actively maintained	N/A
I- combblas	debian.org	1.6.2-3	Included In	U. California	2018-10-01	Actively maintained	N/A
I- libst	debian.org	3.15.1-2	Included In	U. Helsinki	2019-09-03	Actively maintained	N/A
I- orthanc-dicomweb	debian.org	0.34-dfsg-1	Included In	Orthanc	2016-07-05	Actively maintained	N/A

At the bottom right of the table, there is a button labeled 'Machine-readable format' which is highlighted with a red box.

4. After clicking the button, the SBOM list opens in a web browser.


```

"xeFormat": "DyCloneDX",
"xeVersion": "1.4",
"serialNumber": "aa7e3194-b489-556a-b228-f5db039edfce",
"revision": 1,
"dependencies": [
  {
    "type": "library",
    "bom-ref": "pkg:etc/MicrosoftX20CorporationX3kadvapi32.dll@10.0.22621.3810",
    "name": "Microsoft Corporation:advapi32.dll",
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  }
]

```

In addition, users can contact Vatech at the email address given if they have any questions about SBOM or any cybersecurity issue.

Email: gcs@vatech.co.kr

3.5.2 Cybersecurity Information

This section outlines the essential cybersecurity practices that equipment users must follow. To maintain the cybersecurity of the system, please adhere strictly to the following guidelines.

NOTICE

EzServer is a server that stores patient data and imaging information collected via EzDent-i and Clever One. It is provided together with the installation package for EzDent-i and Clever One.

1. Enforce Password Policy Compliance for Confidentiality

Before using X-ray system manufactured by VATECH, user ID and password for EzDent-i or Clever One must be created via EzServer.

EzServer is a required database/server software for operating EzDent-i or Clever One and is included in their installation packages.

Access to VATECH's imaging software is only possible through EzDent-i or Clever One, and only authorized users with registered accounts on EzServer can use these applications.

Measures to Limit the User Access to the Authorized Personnels Only

1) Access Rights for Authorized EzDent-i or Clever one user only

User accounts must be created and assigned appropriate grades via the Account menu in the EzServer Web Console.

NOTICE

For detailed instructions on account creation and permission settings, refer to the separate EzServer manual.

2) Password safety was considered.

If the password entered does not meet EzServer's password policy, account creation will fail, and a warning message will be displayed.

Passwords for EzDent-i or Clever One must meet the following criteria:

- Must include at least two types from the following: lowercase letters, uppercase letters, numbers, special characters
- Must be at least 8 characters long
- Passwords composed of a single repeated character or number (e.g., 1111111111) are not allowed

- 3) Only authorized users can access and handle patients' medical information.

Assign one of the following four grades based on the user's responsibilities within the clinics: Master Admin, Admin, Dentist, or Staff.

Access to patient and imaging data will vary depending on the assigned grade. For more details on account creation and role assignment, refer to the EzServer manual

NOTICE

For detailed instructions on account creation and permission settings, refer to the separate EzServer manual.

- 4) To enhance security, the system is configured to automatically log out users after a period of inactivity.

2. When updating the firmware and the console software linked to the device, follow the precautions below:

- DO NOT remove or open the security cover installed on the back of the equipment. Only a VATECH-authorized engineer can remove or open this cover.
- Only VATECH-authorized engineers can perform console software and firmware updates related to the device.

3. DO NOT Leave the Information Unprotected.

Users are encouraged to lock the computer screens when they don't use the computer. Leaving screens unlocked increases the risk of someone viewing or accessing sensitive data.

4. DO NOT disable built-in protection.

Users are encouraged to keep firewalls enabled. Firewalls are put in place to block certain types of network traffic which keeps the computer system safe from external threats. Disabling the firewall opens the organization to malicious attacks that rely on open network ports.

Finally, as an additional layer of protection, users should always enable antivirus. Antivirus software offers real-time protection by scanning new files and will immediately alert the user if it detects any threats.

5. Using USB drives is not recommended.

Do not use USB drives. USBs are not only small and easy to lose, but they're usually not encrypted. This means that the USB could transfer a virus into the user's computer if the user used it on the equipment after using the same USB on a personal or public computer that is not secure.

6. Beware of suspicious emails and texts.

Users are encouraged to pay close attention to suspicious-looking emails. Users should be trained in security awareness such as phishing campaigns and what to look out for when it comes to suspicious emails.

7. If a malfunction occurs, please contact us.

This device does not require complex resiliency/recovery solutions for software malfunctions. In case of an issue, please check the error code and either contact us or try restarting the software. There is no need for separate user backup/restore. Vatech provide solutions to resolve any problems, so please reach out to us for assistance.

8. Contact VATECH for support regarding the device issue including cybersecurity risks even after the end of service support

This device may no longer receive ongoing support regarding known or anticipated cybersecurity information after the end of support with the user. Even after the end of support, 'cybersecurity risks' may still exist.

Consequently, users must take additional cybersecurity management measures to address potential cybersecurity threats, such as utilizing external cybersecurity solutions, including third-party cybersecurity software, to maintain the device's security.

Furthermore, it may be necessary to consider transitioning to a newer model in preparation for the end of device support.

Newer models provide continuous cybersecurity solutions, which can help minimize cybersecurity risks.

After the end of support, customers can still contact the manufacturer through the associated sales point to inquire about device-related issues, including cybersecurity issues, and they can receive appropriate actions in accordance with our cybersecurity policies.

9. How to notify and response security event

This device is designed to detect typical anomalous conditions. Possible security events include changes in the physical connection between the device and the PC, or unauthorized configuration changes during the device operation.

These changes are monitored at the time of device operation, and if any anomalies are detected, relevant alarms will be displayed to the user via the console software.

The user can refer to the 'Error Code' section in **Chapter 13 ("Troubleshooting")** of the manual to contact Vatech and receive appropriate support.

10. How to use log for security events

Users can access the log records for each event in the specified sub-folder where the Console SW is installed.

(i.e. C:\VCaptureSW\subfolder")

If an issue occurs, users can provide the error code and details about the problem to us. We provide solutions based on the log records and error information. Please contact us if any issues arise.

11. How to securely decommission the device

To securely decommission the device, it is recommended to delete or reset log files, configuration data, and other information stored on the PC where the Console SW is installed.

Additionally, to maintain physical security, key components such as X-ray monoblock, X-ray detector, and main MCU board should be safely disconnected and disposed of.

After these actions, it is necessary to check that the device's software and configuration data have been securely deleted.

The obligation to carry out the necessary actions related to the decommission of the device, as indicated above, does not lie with the user, and it is required to be installed or disassembled by a VATECH-approved engineer only.

4. Imaging System Overview

4.1 System Components

- Green X 21 (Model: PHT-90CHO) X-ray equipment
- PC system
- Console Software
- Image Viewer

4.2 Features

- Supports various FOV (Field of View) and ROI (Region of Interest) for dental diagnosis. (**The supported FOV: 21x19, 18x15, 12x9, 12x5, 8x8, 8x5, 5x5, 4x4** (unit: cm))
- Supports various FOV (Field of View) and ROI (Region of Interest) for ENT (Ear, Nose, and Throat) diagnosis. (**The supported FOV: 21x19, 18x15, 12x9, 8x8** (unit: cm))
- 2D panoramic and cephalometric imaging capabilities.
- Offers 2D and 3D dental capture modes that allow the user to acquire an image for a single tooth or selected area only.
- **Insight PAN:** the 2D capture mode that scans specifically the chosen area only. It produces multiple 2D images with various focal points in a single scan, allowing the users to examine the regions difficult to access by conventional 2D panorama images.
- **Endo:** the 3D capture mode that scans a single tooth and delivers a 4x4 high-resolution image of the scanned tooth, revealing intricate details such as blood vessels and nerves.
- **Smart Focus:** the 3D capture mode that delivers 4x4 high-resolution images of the user-selected areas and optionally provides a 2D panorama and 3D 12x9 images in a single scan.
- **Green Plus:** A low-dose capture mode optimized for orthodontic applications that provides a full cranial image using a 21x19 FOV.
- **Magic PAN:** a 2D image reconstruction algorithm designed to minimize differences between the actual arch shape and the reconstructed image.
- **Face Scan:** an imaging mode that provides a 3D photograph of the patient's face. The face scan data can be acquired either independently or concurrently with the 21x19, 18x15, and 12x9 CT scan.

**The face scan mode is provided for patient consultation purposes only. This mode is not intended for clinical diagnosis.

- **Full Arch:** a selectable feature in the smart focus mode that delivers a 3D 12x9 image of the patient's entire arch.
- **Auto Pano:** a selectable feature that creates a 2D panorama image from 3D CT scan data. (supported for FOV 21x19, 18x15, 12x9, and Smart Focus mode)
- **Auto Ceph:** a selectable feature that creates a 2D cephalometric image from 3D CT scan data (supported only for FOV 21x19).
- **Scout View:** an optional capture program provided with the FOV 12x5, 8x5, 5x5, or ENDO that allows the users to confirm the imaging area before actual image acquisition.
- MAR (Metal Artifact Reduction)
- DICOM (Digital Imaging and Communications in Medicine) Format
- Easy-to-use and intuitive console software.

4.3 Operating Principles

X-rays are emitted when a high voltage is supplied to the X-ray tube assembly, which frees electrons from the cathode. They hit an anode to produce an X-ray. The machine acquires images by emitting X-rays continuously and rotates on the human tooth at different angles. Images are acquired, computed, and recompiled to reproduce 2D or 3D images.

4.4 Imaging System Options

Model Name	Brand Name	Device Identifier	System Configuration (X-ray Detector)	
PHT-90CHO	Green X 21	Green X 21 SP	PANO / DENTAL CT / ENT CT	Jupi1012X
		Green X 21 OS	PANO / DENTAL CT / ENT CT	Jupi1012X
			CEPH	Venu1012VD

4.5 Standards and Regulations

Standards

Green X 21 (Model: PHT-90CHO) 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 ES 60601-1:2005 + AMD1:2012 + AMD2:2021,
CAN/CSA-C22.2 No. 60601-1:14 (Amendment 2:2022)
IEC 60601-1-3:2008 + AMD1:2013 + AMD2:2021
IEC 60601-1-6:2010 + AMD1:2013 + AMD2:2020
IEC 60601-2-63:2012 + AMD1:2017 + AMD2:2021

- 21 CFR 1020.30, 31, 33
- NEMA Standard publication PS 3.1-3.18



This is class IIb equipment and obtained CE marking in May 2017 for regulation compliance by the enacted European Union's MDR (Medical Device Regulation)

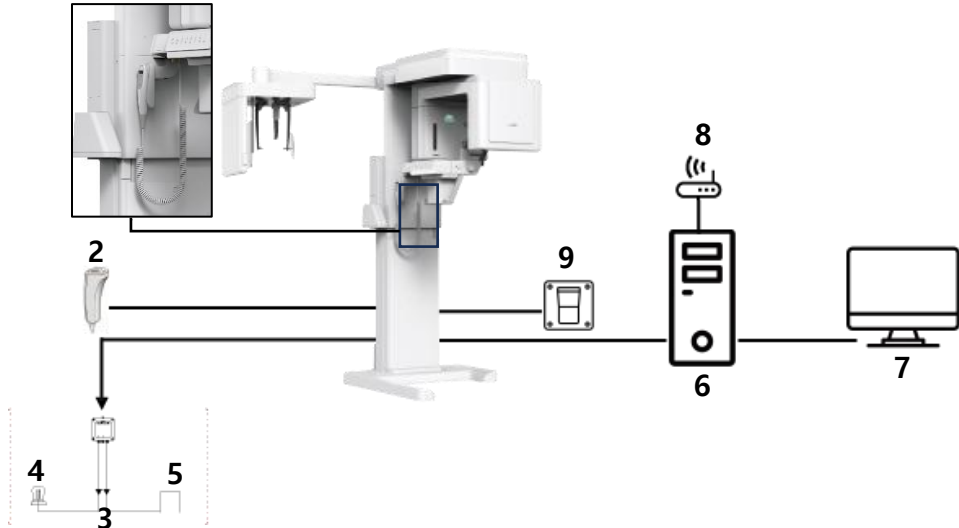
Classifications (IEC 60601-1 6.1)

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



4.6 Imaging System Configuration

4.6.1 X-ray Unit Connection Diagram



No	Item
1	Up / Down Switch (Optional)
2	Exposure Switch
3	Warning System Panel (Optional)
4	Warning Lamp (Optional)
5	Door Interlock (Optional)
6	1) RS232 cable 2) Ethernet cable 1 (PANO / CT X-ray detector) 3) Ethernet cable 2 (CEPH X-ray detector)
7	Graphic card cable (connected to the PC monitor)
8	Router (for face scanner)
9	Emergency stop switch (only in Russia, optional)

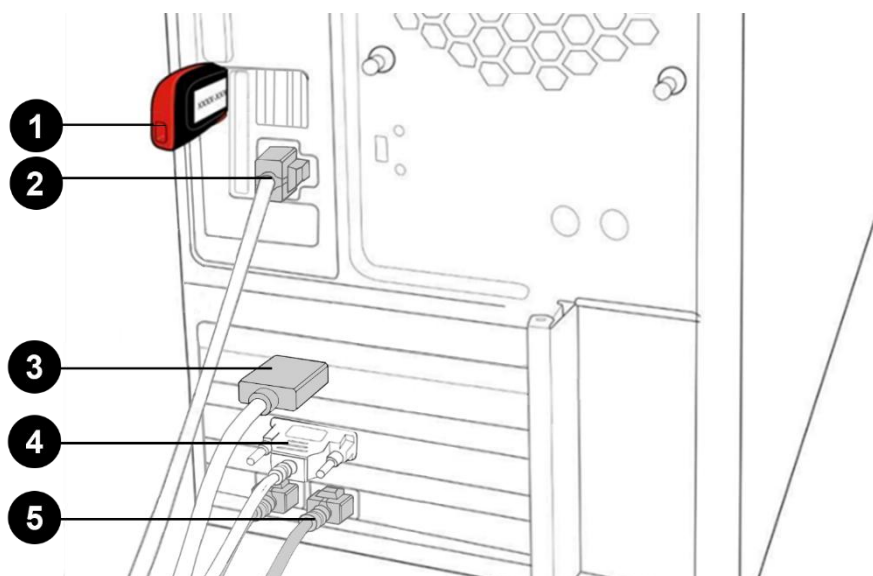
IMPORTANT

Ensure to use the PC outside of the patient environment such as X-ray (Radiology room).

NOTICE

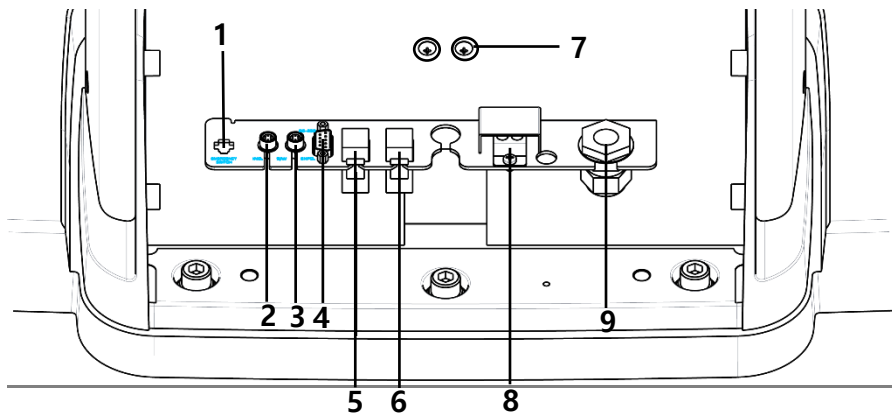
Interlock tools within the red dot lines are provided as options to prevent an X-ray emission in the event of forced opening of the X-ray room required by the national regulations for medical facilities in each country.

4.6.2 PC Signal Input / Output

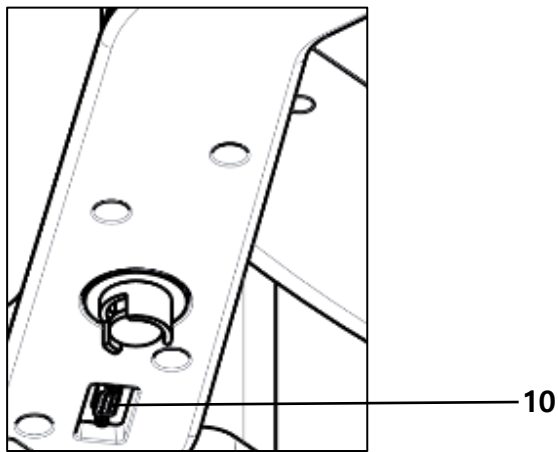


No.	Item
1	3D viewer License Key
2	Router cable port (for face scanner)
3	Graphic card cable port (connected to the PC monitor)
4	RS232 cable port
5	Ethernet cable 1 port (PANO/ CT X-ray detector) Ethernet cable 2 port (CEPH X-ray detector)

4.6.3 Ports and Cable Connections



<Behind the Column>

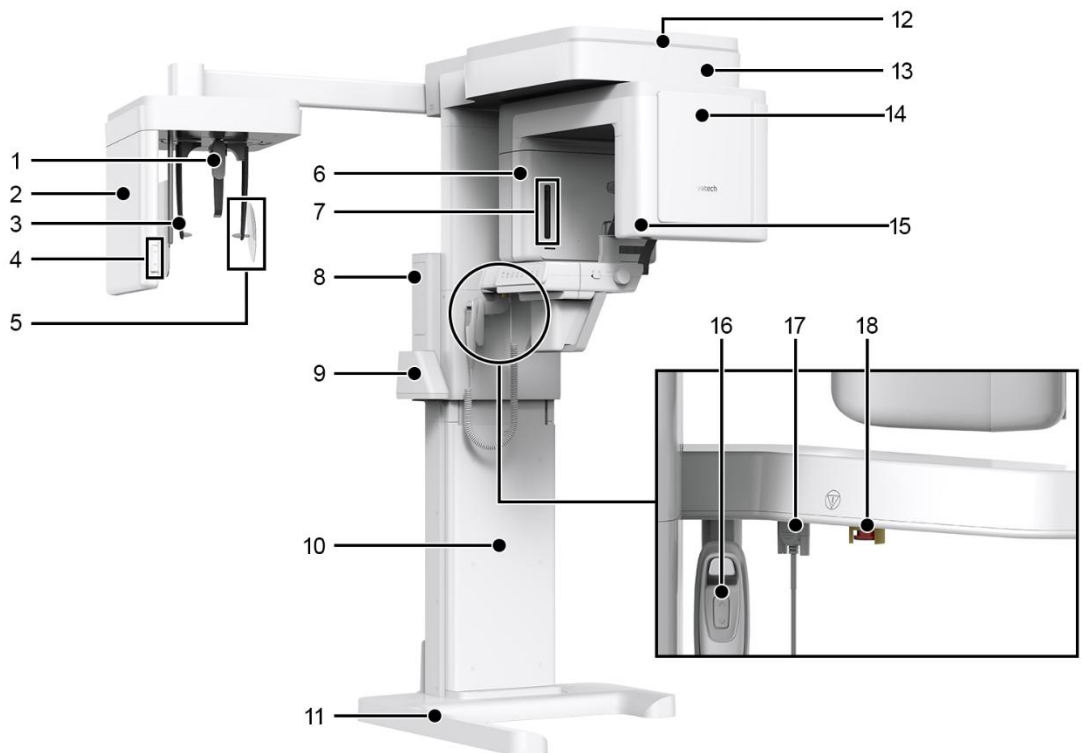


<Underneath the handle frame>

No.	Item	Description
1	Hole or Emergency Stop Switch Port *	Connects the emergency stop switch to the equipment. *Only for the product sold in Russia, the port is installed.
2	Warning System Panel Port (Optional)	Connects the door lock cable to the equipment when installing a door lock.
3	Exposure Switch Port	Connects the exposure switch to the equipment.
4	RS232 Cable Port	Connects the Main MCU with the PC.
5	Ethernet Cable 1 Port (PANO / CT X-ray detector)	Connects the PANO and CT X-ray detectors with PC.
6	Ethernet Cable 2 Port (CEPH X-ray detector)	Connects the CEPH X-ray detectors with PC. .
7	Frame Ground	Connects the external FG with the internal FG.
8	Terminal Block	Connects the external power cable with the internal power cable.
9	Cord Bushing	Used to secure the power cable (cord anchorage).
10	Up/down switch port (optional)	Connects the up/down switch.

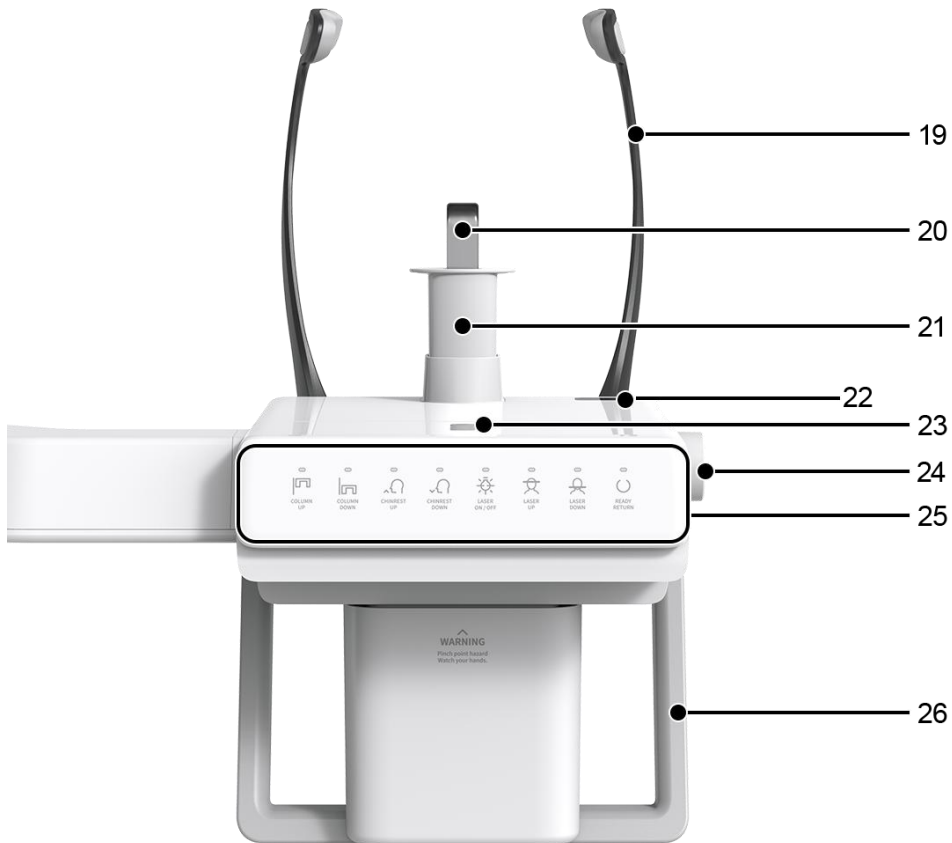
*Emergency stop switch port is used in Russia only.

4.7 Equipment Overview

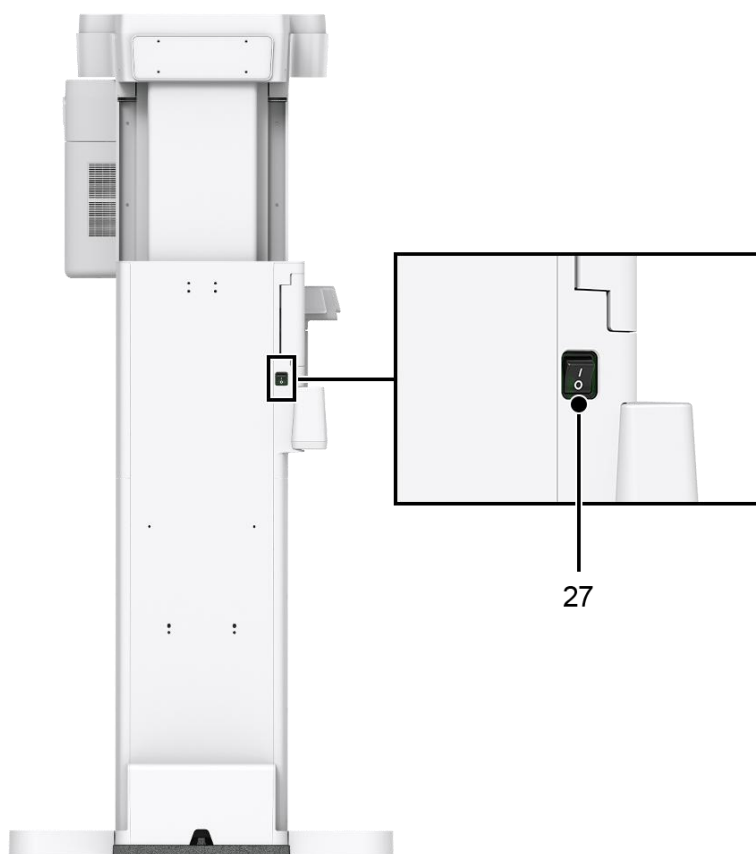


4. Imaging System Overview

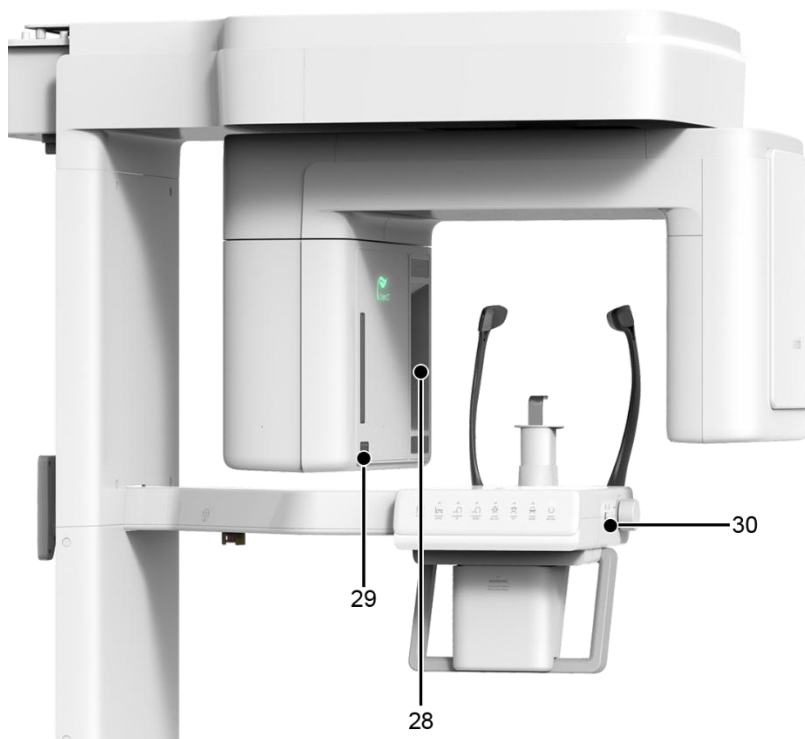
No.	Item	Description
1	Nasal Positioner	Secures the patient's forehead position.
2	CEPH Sensor (Optional)	Venu1012VD for CEPH image acquisition.
3	Ear Rods	Supports the patient's head for CEPH image acquisition
4	Column Up/Down Button.	Adjusts the column height for the patient.
5	Protractor	Supports the patient's position alignment.
6	X-ray Generator	Generates X-ray source.
7	Horizontal Beam	Marks the patient's Frankfurt plane.
8	Accessory Storage	Stores accessories and toolkits.
9	Puddle Lamp	Marks the patient's standing place.
10	Column	Supports X-ray unit's weight and balance.
11	Base (Optional)	Supports X-ray unit's balance.
12	LED Lamp	Displays the equipment and the X-ray exposure statuses. • White: the equipment is in an idle state. • Green: the X-ray exposure is ready. (X-ray OFF) • Yellow: the X-ray is in operation. (X-ray ON)
13	Vertical Frame	Moves the rotating unit for image acquisition.
14	Rotating Unit	Rotates around the patient's head while the image is being acquired. (Its movement is different according to the scan mode.)
15	PANO / DENTAL CT / ENT CT Sensor	Jupi1012X for PANO, DENTAL CT, and ENT CT image acquisitions.
16	Column Up/Down Switch	Adjusts the column height for the patient.
17	D-Sub Connector	Serves as an input signal port for the column up/down switch.
18	Emergency Stop Switch	Halts the X-ray unit's operation in case of an emergency.



No.	Item	Description
19	Temple Support	Fixes the patient's head during the PANO, DENTAL CT, and ENT CT image acquisition.
20	Bite Block	Positions the patient's teeth for the PANO, DENTAL CT, and ENT CT image acquisition.
21	Chinrest	Places the patient's chin for image acquisition.
22	Canine Beam	Marks the patient's canine tooth location.
23	Vertical Beam	Marks the center line on the patient's face.
24	Temple Support Knob	Opens or closes the left and right temple supports.
25	Control Panel	Controls the column, chinrest, laser, and sensor's movements.
26	Handle	Allows the patient to stand securely during the PANO, DENTAL CT, ENT CT, and FACE SCAN image acquisition.

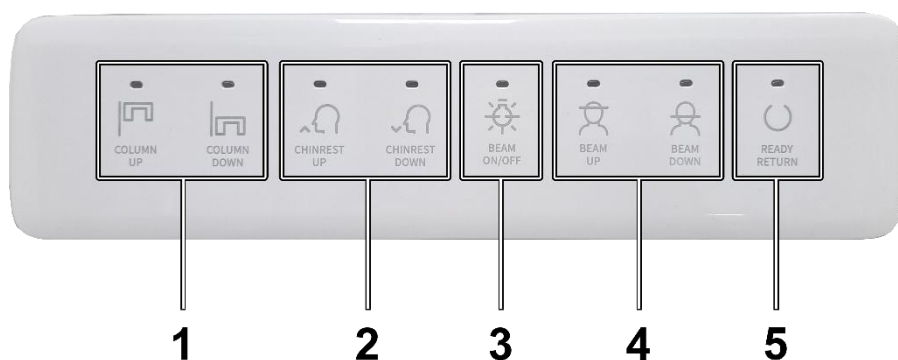


No.	Item	Description
27	Power switch	Turns on or off the power of the X-ray unit.



No	Item	Description
28	Face Scanner	Acquires face scan data of the patient.
29	Shoulder Beam	Indicates whether the rotating unit hits the patient's shoulder.
30	Canine Beam Slider	Adjusts the canine beam location.

4.7.1 Control Panel.



No.	Item	Description
1	Colum up/down	Moves the column up or down.
2	Chinrest up/down	Moves the chinrest up or down.
3	Laser on/off	Turns the laser beams on or off.
4	Laser up/down	Moves the horizontal laser beam up or down.
5	Ready / Return	This button function as both the “Ready” and “Return” buttons. Ready: prepares the X-ray system for image acquisition. Return: moves the rotating unit back to its initial position

4.7.2 Emergency Stop Switch

The emergency stop switch is located underneath the handle frame. In case of an emergency, press the switch to stop the equipment. The emergency may include the following situations but may not be limited to:

- When the X-ray emission continues even after releasing the exposure switch
- When the equipment hits the patient
- Mechanical failures.

Once the switch is pressed, the equipment will immediately stop operation. To restart the equipment, turn the emergency stop switch until it pops up again.



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

Ensure the **exposure switch** cable is not detached from the equipment during the operation.

IMPORTANT

Keep vocal/visual contact with the patient during exposure. In an emergency, release the **exposure switch** immediately.

4.7.4 Accessories

Some of the accessories listed in the table below may require disinfection between each patient. For more information, go to **14. Cleaning and Disinfection**.

The following accessories are classified as class I under Rule 1 of Annex VIII of MDR 2017/745. (The following accessory is classified as Class I and therefore is not included in the assessment scope of the Notified Body.)

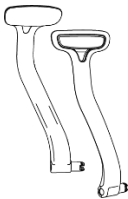
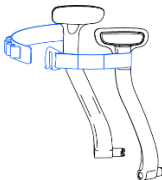
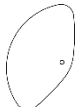
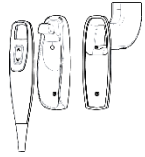
Image / Name	Function	Materials
 Normal Bite	For standard panorama, Dental CT, and ENT image acquisition of dentate patients	PC (Polycarbonate)
 Special Bite A	For PANO TMJ and SINUS image acquisition of dentate and edentulous patient	PC (Polycarbonate)
 Special Bite B	For standard panorama, dental CT, and ENT image acquisition of edentulous patients	PC (Polycarbonate)
 Chinrest	For resting the patient's chin	ABS (Acrylonitrile butadiene styrene) copolymer
 Temple Supports (1 set)	For securing the patient's head during the image acquisition.	- Temple Supports :PA (Polyamide) - Temple Support Pad :Silicone
 Temple Supports for face scan (1 set)	For securing the patient's head during the face scan.	- Temple Supports :PA (Polyamide) - Temple Support Pad :Silicone - Straps: PVC

Image / Name	Function	Materials
 Ear Rod Caps (1 set)	For covering ear rods to protect patient's ears.	Silicone
 Nasal Positioner Cover	For covering nasal positioner to prevent contamination	Silicone
 Carpus Plate	For placing the patient's hand to acquire a carpus image.	PC (Polycarbonate)
 Sanitary Vinyl Cover (single-use, disposable)	For covering the normal bite to prevent contamination	PP+PE
 Protractor	To assist with a correct patient position.	PC (Polycarbonate)
 MODEL Jig	To store the model scan jig used for MODEL mode	ABS (Acrylonitrile butadiene styrene) copolymer
 Up/Down Switch and Holder	To adjust the column height	ABS (Acrylonitrile butadiene styrene) copolymer
 X-ray exposure switch	To start X-ray emission	ABS (Acrylonitrile butadiene styrene) copolymer

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5. Imaging Software Overview

To acquire and view image data, the following software applications are required:

- **Console software** – acquires images based on the user-selected exposure conditions for PANO, CEPH, Dental CT, ENT CT, Model, and Face scan.
- **Image viewer** – allows access to the 2D and 3D scan images acquired by the console software.

5.1 PC Specifications (Recommended)

The PC operating the image software applications must meet or exceed the specifications below to ensure image quality.

Item	Specifications
CPU	Intel Core i7-14700 vPro Enterprise 5.40G
RAM	64GB (4x16GB) DDR5 4800 UDIMM NECC Memory
HDD	HP 512GB M.2 / HP 2TB 7200RPM SATA 3.5in
Graphics board	NVIDIA RTX 4070 Super 12 GB GDDR6X Graphics
Ethernet Interface	Integrated Intel® I219LM PCIe GbE Controller PCI Express 4port 2.5Gbps LAN card
Serial Port (RS232)	HP Z2 2nd serial port
Power Supply	700 W EPA92 Power Supply
Slots	Slot 1: PCIe Gen5 x16 Slot 2: PCIe Gen3 x1 - with x4 open end Connector Slot 3: PCIe Gen3 x4 - with x16 Connector Slot 4: PCIe Gen3 x4 with open end connector
CD/DVD drive	9.5mm SuperMulti DVDRW
Monitor	19" 1280x1024 screen resolution
Operating System	Windows 11 Professional 64-bit OS
Recommended System	HP Z2 Series

IMPORTANT

Using the PC below the minimum standards may lower the image quality and slow down the image acquisition process.



Prior to using the PC, ensure that Windows Defender Firewall is enabled to protect your PC and data from network security threats.

5.2 Imaging Viewer Software

Both Clever One and EzDent-i are image viewer applications provided by Vatech. They allow users to access acquired 2D and 3D scan data and offer patient information management tools.

NOTICE

EzDent-i and Clever One are third-party software programs that separate European medical device certifications.

For more information about Clever One or EzDent-i, refer to their respective user manuals which are provided separately from this manual.

IMPORTANT

Security Capabilities

- Install and operate EzDent-i or Clever One in a secure environment where only authorized users can access the system network protected by Windows built-in firewall and anti-spyware tools.
- Contact VATECH for inquiries regarding cyber security issues with its device and software.
- The system network for EzDent-i or Clever One must be protected by Windows firewall and anti-spyware tools.
- Regularly update Windows built-in firewall and anti-spyware tools to the latest versions.
- The security cover is installed on the back of the equipment. Do not remove or open this cover unless you are a VATECH-authorized engineer.
- All software provided by VATECH must be updated by VATECH.

5.3 Console Software

The **Green X 21** console software window consists of various menus and shortcut buttons as illustrated below.

NOTICE

Due to ongoing product enhancements, the console software GUI (Graphical User Interface) is subject to change without notice.

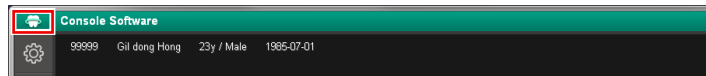


No.	Item	Description
1	Patient information	Displays the selected patient's information.
2	Setting button	Sets user environments for the console software and capture modes such as auto-save option or language.
3	Volume button	Changes audio message's volume level.
4	Laser on/off button	Turns on or off the laser beams.
5	Manual reconstruction button	Reconstructs the captured image after the system fails automatic reconstruction.
6	Phantom Button	Captures a phantom image.
7	Test Rotation Button	Perform a test rotation to check before scanning if the equipment hits the patient.
8	X-ray exposure indicator	Indicates the X-ray exposure status. ▪ Gray: X-ray is off ▪ Yellow: X-ray is on
9	Exposure condition menu	Select exposure conditions (tube current and voltage).
10	Patient selection menu	Selects or changes a patient type.
11	X-ray level selection menu	Selects or changes an X-ray level intensity.
12	Scan information window	Displays the estimated DAP (Dose Area Product), scan, and exposure times for the exposure settings you selected.
13	Message information window	Displays text guides for the user at each stage of operation.
14	Confirm (Ready) button	This button performs a dual role. ▪ Confirm: Confirm the selected imaging options and exposure condition. ▪ Ready: Set the system ready for an X-ray exposure.
15	Modality Option	Select a modality for image acquisition: PANO, CEPH (Optional), DENTAL CT, ENT CT, MODEL, and FACE SCAN.
16	Exit button	Leaves the console window.

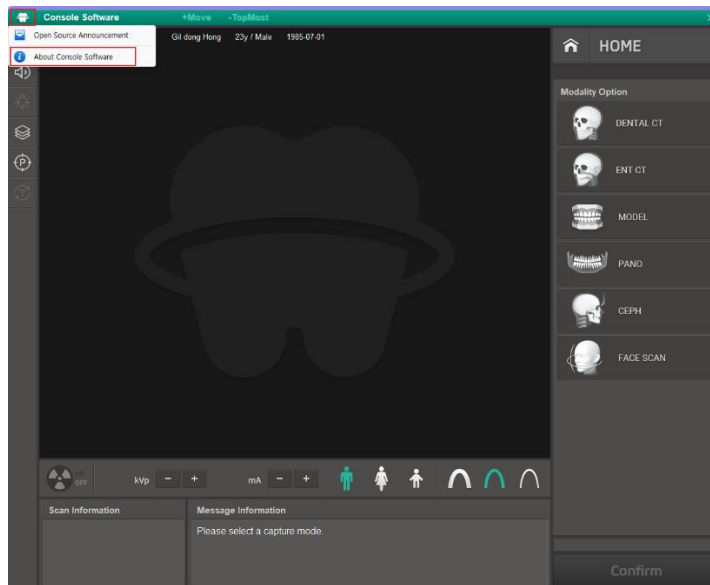
5.3.1 How to Check the Console Software Version

To Check your console software version, follow the steps below.

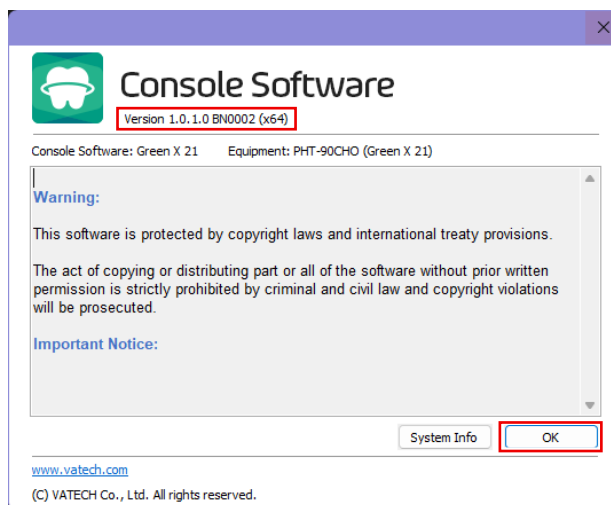
1. Click the tooth icon on the top of the console software window.



2. In the drop-down menu, select **"About Console Software"**



3. Review the console software version and click the **OK** button to close the window.



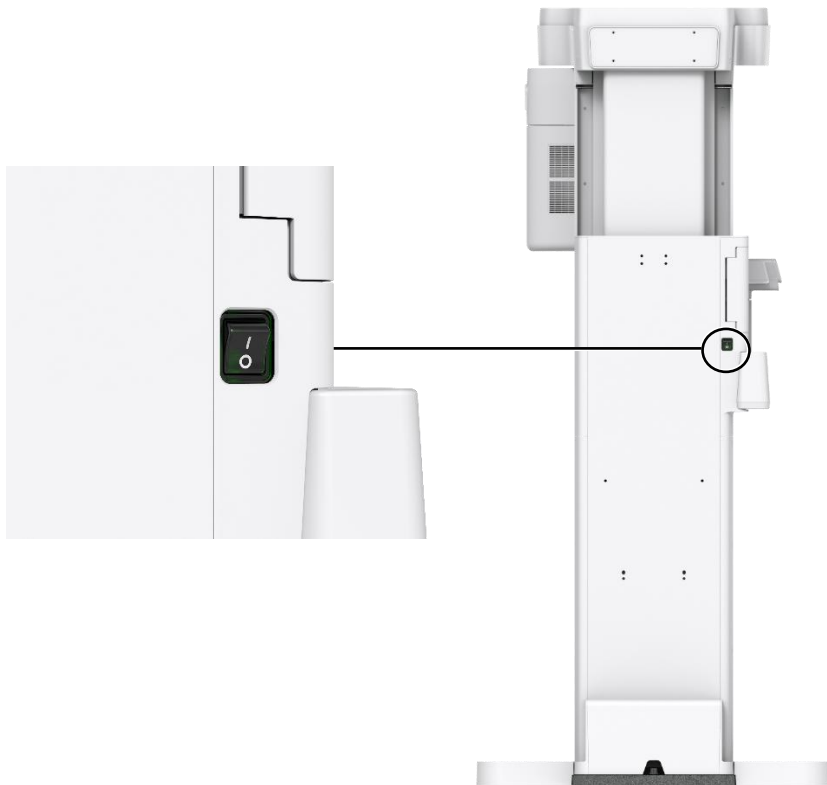
6. Getting Started

6.1 Turning on the Equipment

To turn on the equipment, press down the main power switch located behind the column to the “Power On” symbol.



Do not turn on the equipment while people are standing near the equipment.



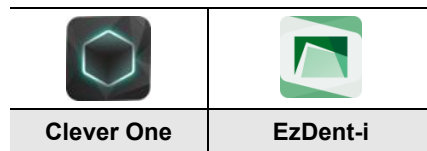
6.2 Launching the Console software

Before launching the console software via the image viewer to acquire an image, you must either enter new patient information or retrieve it from the existing patient database.

6.2.1 Registering New Patient Information

Follow the steps below to register new patient information:

1. Double-click on your PC Clever One or EzDent-i icon.



2. In the main menu, click the "Add Patient" button.

Clever One ▼



EzDent-i ▼



3. Click the added button after filling out all required fields (*)

The image shows the 'ADD PATIENT' window in the EzDent-i software. It is a light grey window with various input fields. The 'Chart No.*' field is highlighted with a red box and contains the value '202191029_103203'. The 'Name*' field is also highlighted with a red box and contains 'Koo' for the last name and 'Hyunjun' for the first name. The 'Gender' field is set to 'Male'. The 'Date of Birth' field is set to '1974-8-15'. The 'Add' button at the bottom is highlighted with a red box.

▲ EzDent-i Window

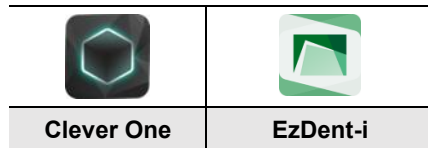
The image shows the 'ADD PATIENT' window in the Clever One software. It is a dark grey window with various input fields. The 'Chart No.' field is highlighted with a red box and contains the value '20210214_101402'. The 'Name' field is also highlighted with a red box and contains 'Koo' for the last name and 'Hyunjun' for the first name. The 'Gender' field is set to 'Male'. The 'Date of Birth' field is set to '2000-01-01'. The 'Add' button at the bottom is highlighted with a red box.

▲ Clever One Window

6.2.2 Retrieving the Saved Patient Information.

Follow the steps below to retrieve a patient's information saved in the server.

1. Double-click on your PC Clever One or EzDent-i icon.

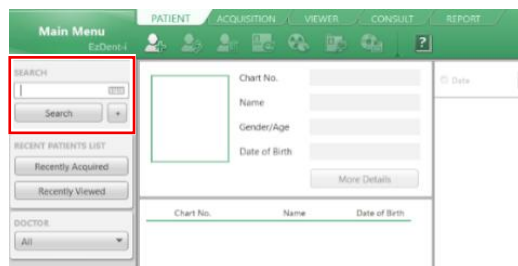


2. Enter a patient's name or chart number in the search box.

Clever One ▼

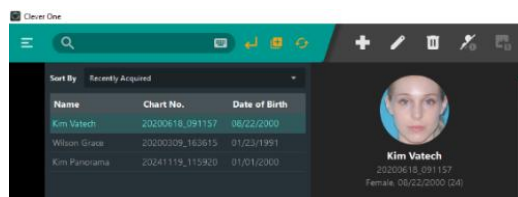


EzDent-i ▼



3. Select the patient information that you want to retrieve.

Clever One ▼



EzDent-i ▼



6.2.3 Launching the Console Window

Follow the steps below to select an image modality and open the linked console window.

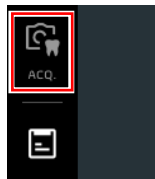
NOTICE

Before following the instructions on this page, ensure that the console software is linked to the image viewer.

1. In the main window, select the **ACQUISITION** tab (For Clever One, click the ACQ icon.)

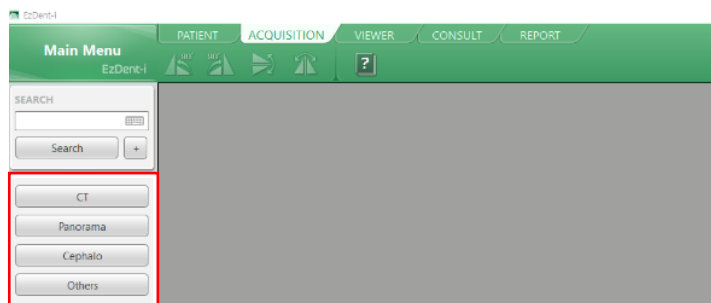


▲ EzDent-i (See the upper menu)

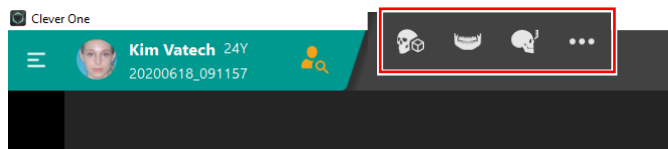


▲ Clever One (see the lower left menu)

2. Select the imaging menu you wish to use to acquire an image. When you click the button, the console window for the selected menu will open.



▲ EzDent-i



▲ Clever One

NOTICE

The configuration of the imaging menu may vary depending on the equipment options.

6.3 Preparing for the Patient

Before image acquisition, instruct the patient to remove any metallic items such as jewelry, hearing aids, or glasses. Wearing metallic objects during image acquisition may degrade image quality by causing shadows or artifacts.

For face scan imaging, provide the following additional instructions:

- Neatly arrange the bangs so that the forehead is visible.
- Tuck the hair behind the ears to ensure both ears are visible.

7. PANO Image Acquisition

7.1 Program Overview

- **Role**

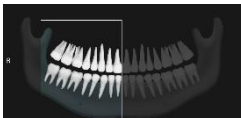
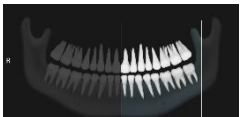
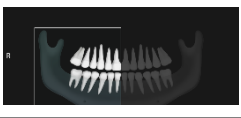
Provides 2D panoramic images of the patient's arch.

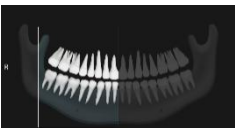
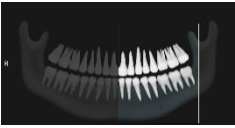
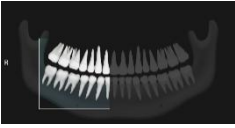
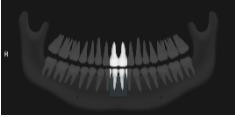
- **Image Acquisition Method**

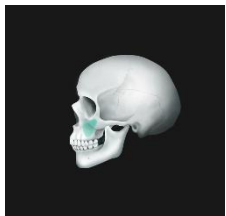
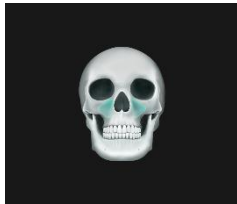
When the user selects the arch and examination option, the system scans the patient's arch with the X-ray beam and reconstructs the acquired U-shaped arch data into a single 2D image based on the selected oral and maxillofacial regions.

- **Examination Programs**

PANO mode provides the following examination and arch options.

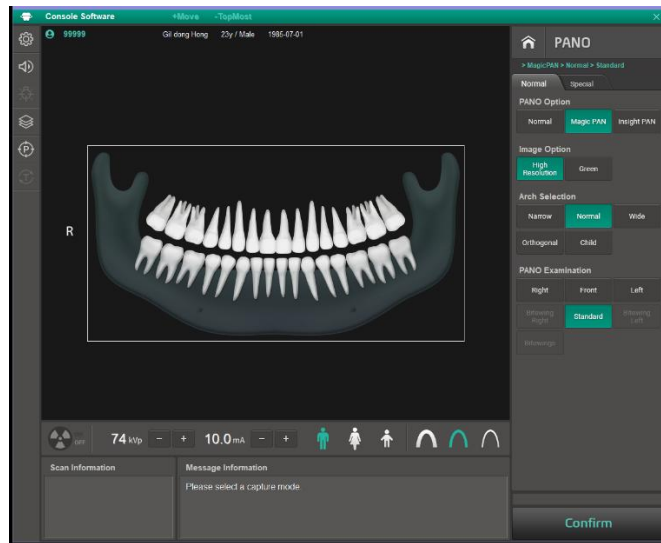
PANO Option	Arch Selection	ROI	Example
Normal Magic PAN	Narrow Normal Wide Orthogonal	Right	
		Front	
		Left	
		Standard	
	Child	Right	
		Front	
	Child	Left	
Normal	Child	Left	

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

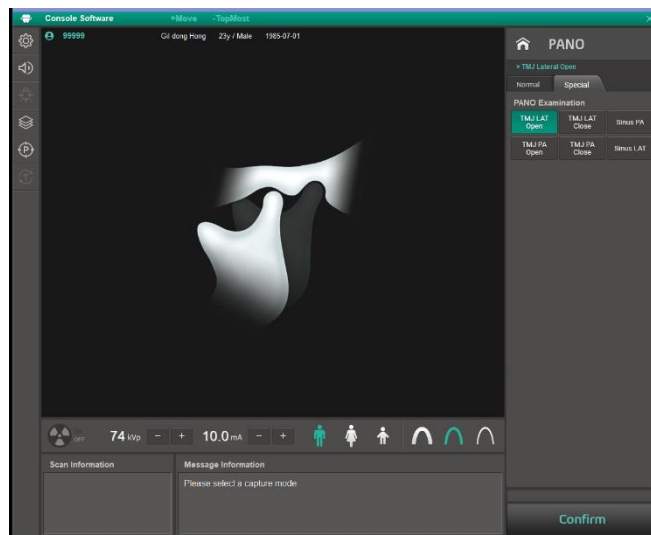
PANO Option	Arch Selection	ROI	Example
	Child	-	
Special	N/A	TMJ LAT Open	
		TMJ LAT Close	
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

7.2 Selecting Exposure Settings

The PANO console window provides two tabs based on the imaging mode. Choose the appropriate tab for the desired mode.



▲ Normal Tab Window (PANO, Magic PAN and Insight PAN)

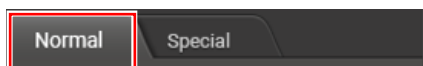


▲ Special Tab Window (TMJ and Sinus)

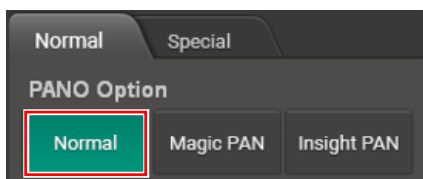
7.2.1 Normal / Magic PAN

Follow the steps below to select exposure settings:

1. Select the **Normal** tab.



2. Select the PANO option.



3. Select the image option.

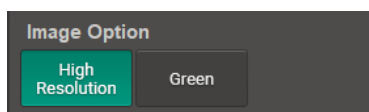
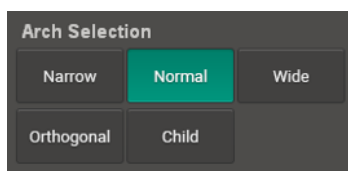


Image Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

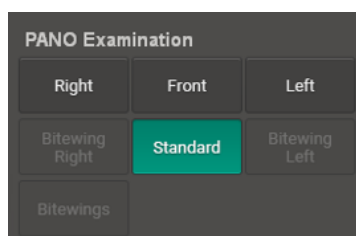
4. Select the arch option. To enable bitewing options, select **Orthogonal**.



NOTICE

Bitewing options: Bitewing Left, Bitewing Right, Bitewings.

5. Select the PANO examination option.



NOTICE

Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

6. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Man Woman Child

Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females at the age of 12 or under

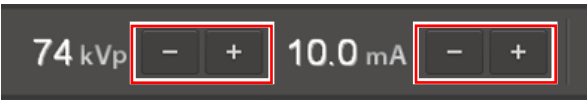
7. Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.



Hard Normal Soft

Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

8. Check the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts ± 1.0 kVp and the tube current by ± 1.0 mA.



Mode / Option	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
PANO / Normal Magic PAN	60	4	90	14

9. Click the **Confirm** button.



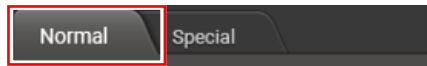
When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

10. After the equipment finishes moving, guide the patient to the X-ray room.

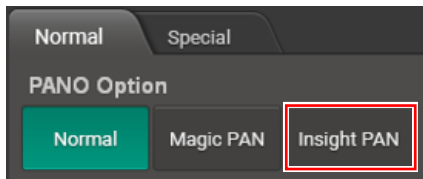
7.2.2 Insight PAN

Follow the steps below to select exposure settings:

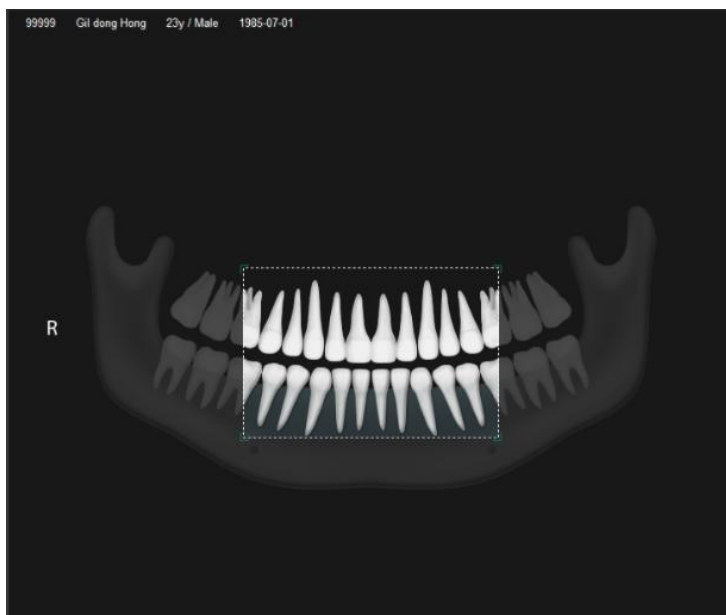
1. Select the **Normal** tab.



2. Select **Insight PAN**.



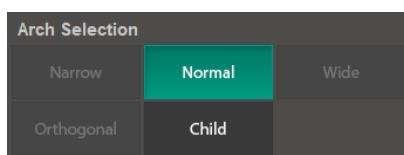
3. Select the image acquisition area by confirming the size and location of the crop box in the window. When capturing a single tooth, ensure that the crop box includes both the target and its adjacent teeth.



NOTICE

The minimum size of the image acquisition area is **50x50 mm²**

4. Select the arch option. In Insight PAN mode, only 'Normal' and 'Child' are available in the Arch Selection menu.



NOTICE

Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

5. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Man Woman Child

Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females at the age of 12 or under

6. Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.

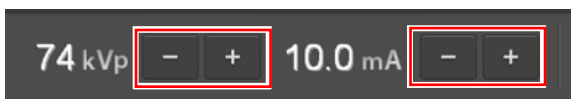


Hard Normal Soft

Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

7. PANO Image Acquisition

- Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 1.0 mA.



Mode/option	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
PANO / Insight PAN	60	4	90	14

- Click the **Confirm** button.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

- After the equipment finishes moving, guide the patient to the X-ray room.

7.2.3 TMJ / SINUS

Follow the steps below to select exposure settings:

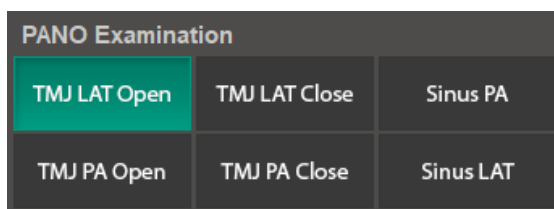
1. Select the **Special** tab.



2. Select the PANO examination option.

NOTICE

To capture a TMJ LAT Close or TMJ PA Close image. Select 'TMJ LAT Open' or 'TMJ PA Open' option.



NOTICE

Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

3. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Man Woman Child

Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females at the age of 12 or under

7. PANO Image Acquisition

- Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

- Check the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts ±1.0 kVp and the tube current by ±1.0 mA.



Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
PANO / TMJ. SINUS	60	4	90	14

- Click the '**Confirm**' button. After the button is clicked, the equipment moves to image capturing location.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

- After the equipment finishes moving, guide the patient to the X-ray room.

7.3 Positioning the Patient

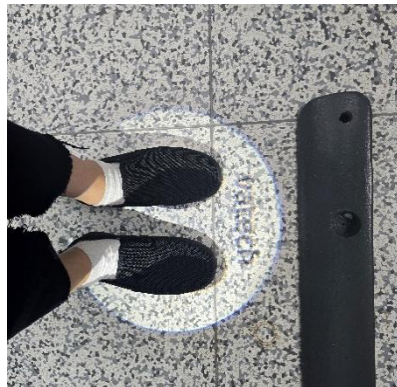
Follow the steps below to position the patient.

1. Press the column up/down button on the control panel to adjust the column height for the patient's height.



Ensure that the patient does not move during the column height adjustment.

2. Ask the patient to stand on the puddle lamp light.



3. Ask the patient to grab the handles on both sides.



If you use the sanitary vinyl covers provided by the 3rd party, ensure that the product conforms to one of the following standards:

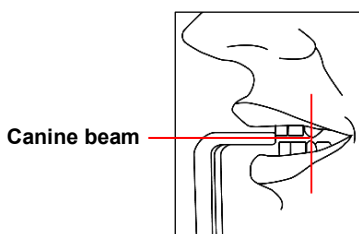
- ISO 10993-1 (Biological Evaluation of Medical Devices)
- FDA
- CE
- Local regulations in your area

- Instruct the patient to gently bite or press the bite block and to close their eyes.

Bite type instruction according to the patient type

Normal patient	Edentulous patient	All patient type
Standard Panorama	Standard Panorama	TMJ and Sinus
Gently bite the groove of the normal bite block with front teeth.	Press the head of the special B bite block with chin.	Press the head of the special A bite block with Philtrum.
		

- Check the laser beam's location. If necessary, adjust the patient position for alignment.
 - The **vertical beam** should come at the center of the patient's face.
 - The **horizontal beam** should be aligned with the patient's Frankfurt plane.
 - The **shoulder beam** should not touch the patient's shoulder.
 - (Normal and Magic PAN modes only)** the **canine beam** should mark the patient's left canine tooth (Tooth No.3). If the beam is out of place, use the canine beam lever to relocate the beam.



CAUTION

Be careful not to have the patient stare into the laser beam.

NOTICE

To adjust the canine beam position, use the canine beam lever located on the side of the control panel.



6. Use the temple support knob to close the left and right temple support.



7. Leave the X-ray room and follow the instructions **7.4 Acquiring the Image**.

7.4 Acquiring the Image

Follow the steps below to acquire an X-ray image.

IMPORTANT

Refrain from using the PC during the X-ray exposure.

IMPORTANT

The staff should be able to communicate with patients either verbally or visually during the image acquisition.

1. Click the **Ready** button either on the console window or control panel.



NOTICE

Once the system is ready for image acquisition, the **Confirm** button on the console window changes to the **Ready** button.

2. Press the X-ray exposure switch when the message information window instructs you to press the switch.

WARNING

In case of an emergency, release the exposure switch immediately and press the **emergency stop switch** located under the handle frame.



3. Release the X-ray exposure switch when the system announces the end of the image capture.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, image capture is canceled.

4. Wait until the equipment returns to its starting location. Then turn the temple support knob to open the left and right supports and guide the patient out of the equipment.

**WARNING**

Do not approach the equipment until the equipment finishes moving.

7.5 Viewing the Acquired Images

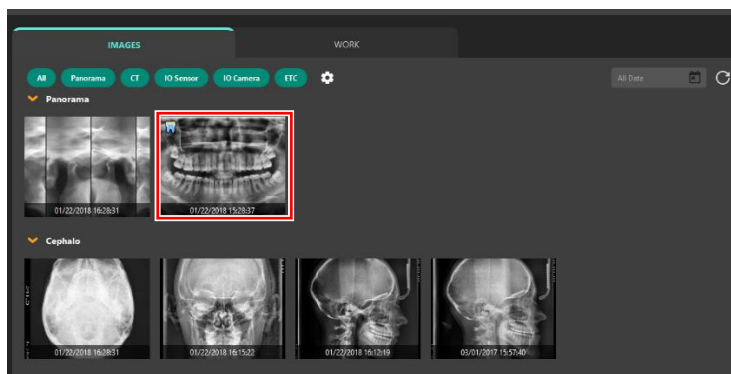
Follow the steps below to view the acquired images.

1. Click the **Save** button when the console window prompts you to save the captured image. Once you click the button, the console window will close, and the image viewer will launch automatically.

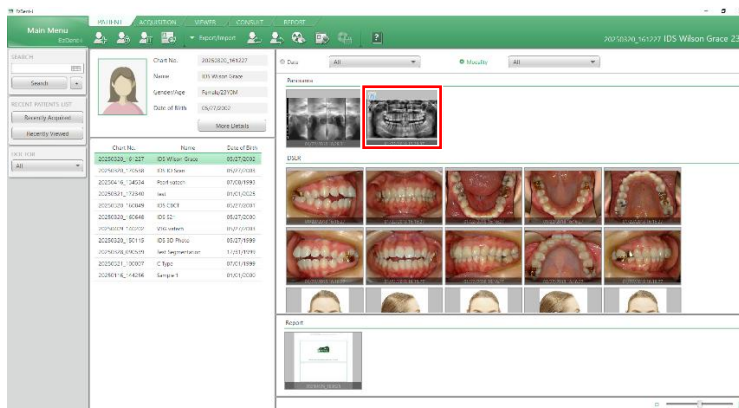
NOTICE

If you have selected the **Auto Save** option before image acquisition, the captured image will be saved automatically without prompting.

2. Double-click the thumbnail of the image you wish to view.



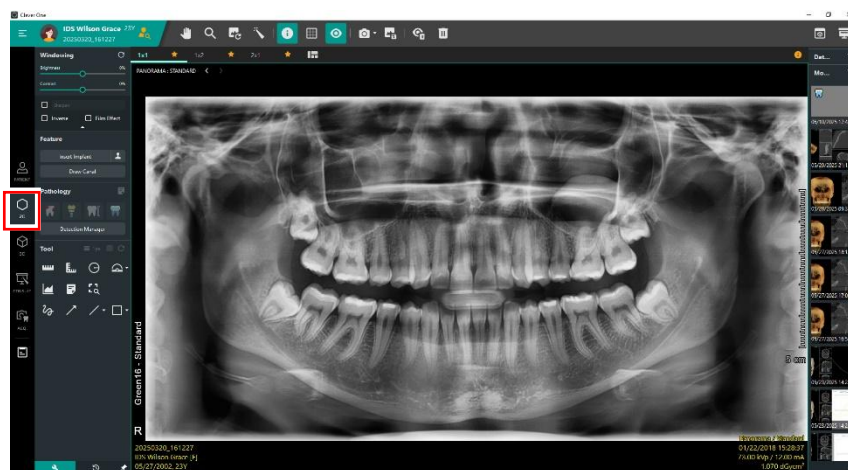
▲ Clever One



▲ EzDent-i

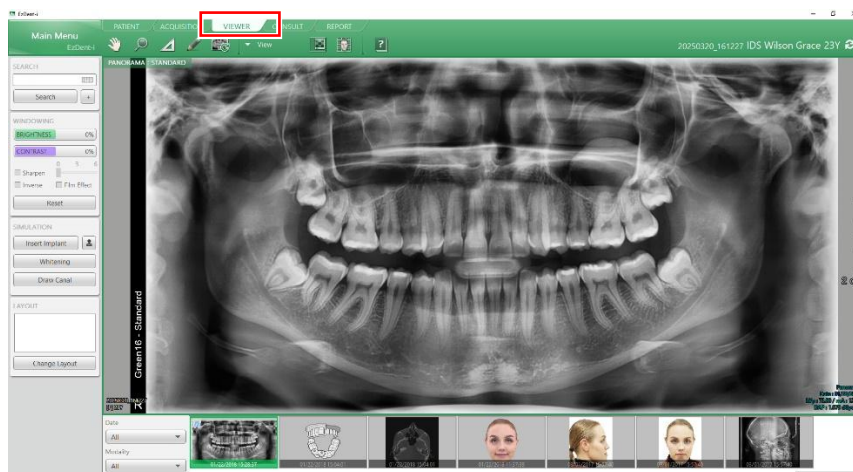
3. Depending on the viewer you are using, the selected image will open as follows:

- In **Clever One**, the image opens in the **2D** module.



▲ Clever One

- In **EzDent-i**, the image will open in the **Viewer** tab.



▲ EzDent-i

8. CEPH Image Acquisition

8.1 Program Overview

- **Role**

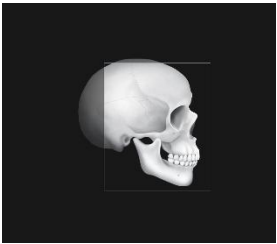
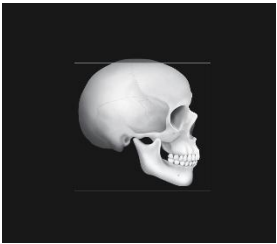
Provides conventional 2D cephalometric images.

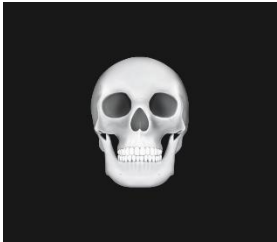
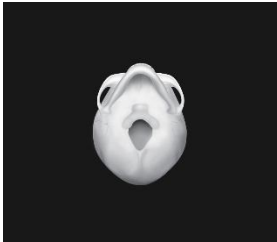
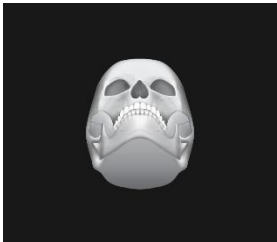
- **Image Acquisition Method**

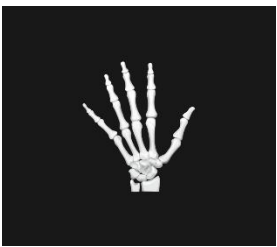
Once the user selects a specific oral or maxillofacial region, the system acquires image data in a single shot by moving the collimator while keeping the sensor in the same location. The acquired data is reconstructed into a 2D image through computer calculations.

- **Examination Programs**

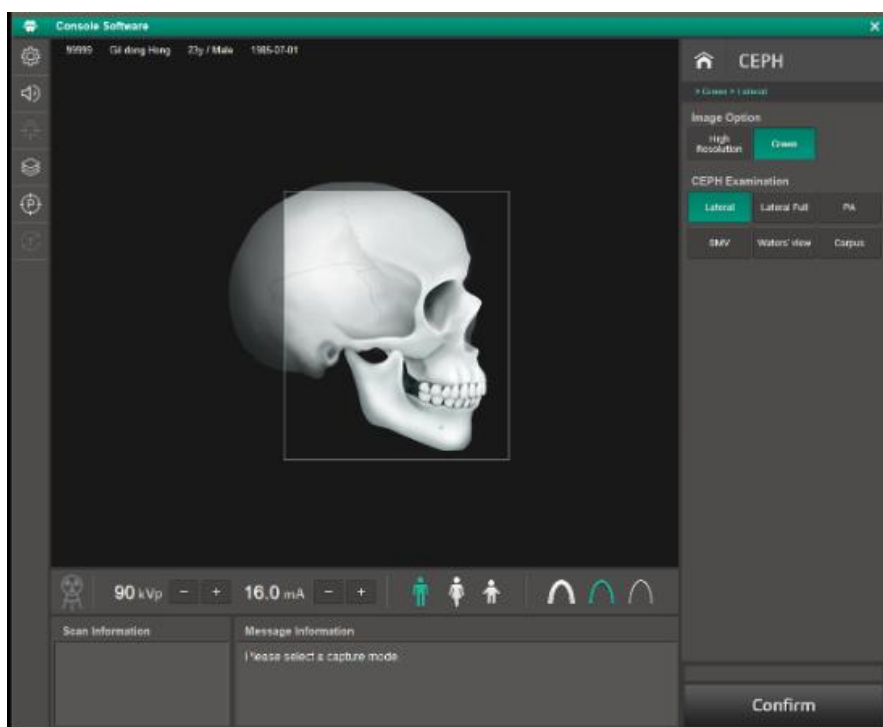
CEPH mode provides the following options and FOV.

CEPH Examination	ROI (Region of Interest)	Description
Lateral / Full Lateral (Optional)	 <Lateral>	- Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate. - Measures the angles formed by the connecting lines between the cranial measurement points to assess the growth of the facial region further. It's widely used in Orthodontics and Oral and Maxillofacial Surgery.
	 <Full Lateral>	

CEPH Examination	ROI (Region of Interest)	Description
PA		- The radiation is directed from the posterior of the skull to the anterior. - It is used to examine cranial diseases, trauma, and congenital malformations. - It is used to assess the growth of the lateral side of the face. It is also used to examine the ramus mandibulae, the posterior region of the third-largest molar in the lower jaw, the sidewall of the maxillary sinus, and the frontal sinus, antrum ethmoidal olfactory pits, and optic disc pits. - Measures the angles formed by the connecting lines between the cranial measurement points to assess the growth of the facial region further. It is widely used in Orthodontics and Oral and Maxillofacial Surgery.
SMV		- Used to study the base of the skull, horizontal angulation of the mandibular condylar axis, the sphenoid sinus, the curvature of the lower jaw, the sidewall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull.
Waters' View		- Used to study the frontal sinus, the antrum ethmoidal, the optic disc pit, the frontozygomatic suture, the nasal cavity, and the coronoid process between the upper jaw and the zygomatic arch.

CEPH Examination	ROI (Region of Interest)	Description
Carpus		- Used to assess hand bone age to compare the changes in the skull.

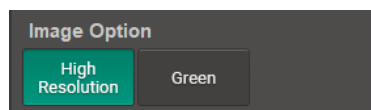
8.2 Selecting Exposure Settings



▲ CEPH Console Window

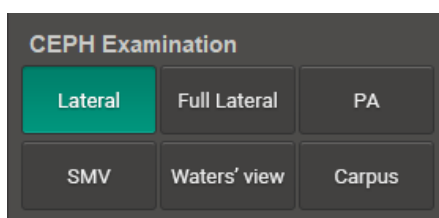
8. CEPH Image Acquisition

1. Select the image option.



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

2. Select the CEPH examination option.



NOTICE

Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

3. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females at the age of 12 or under

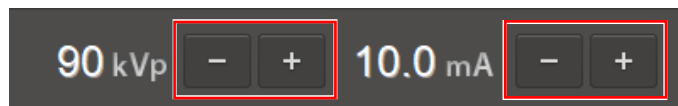
4. Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.



Hard Normal Soft

Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

5. Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 1.0 mA.



Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
CEPH	60	4	99	15

6. Click the **Confirm** button.



7. Guide the patient to the X-ray room.

8.3 Positioning the Patient

8.3.1 Lateral / Full Lateral

Follow the steps below to position the patient for the lateral or full lateral mode.

1. Rotate the nasal positioner to the '**Lateral**' mark.
2. Push the left and right ear rods outward to provide enough space for the patient's head.
3. Ask the patient to stand next to the CEPH unit and then use the column up/down switch or button to adjust the column height until the ear rods come at the patient's ears.



4. Ask the patient to stand between the left and right ear rods. If necessary, the column height again.
5. Slid the ear rods and gently insert each tip into the patient's ear canals to ensure proper placement and avoid discomfort.
6. From the side, check if the patient's Frankfurt plane is parallel to the floor. If necessary, gently tilt the patient's head.
7. Unfold the nasal positioner down and set it on the root of the nose between the eyes.
8. Ask the patient to stand still and keep the eyes closed until the end of the image acquisition.
9. Leave the X-ray room and follow the instructions in **8.4 Acquiring the Image**.

8.3.2 PA

Follow the steps below to position the patient for the PA mode.

1. Rotate the nasal positioner to the '**PA /Water's View / Carpus**' mark.
2. Push the left and right ear rods outward to provide enough space for the patient's head.
3. Ask the patient to stand next to the CEPH unit and then use the column up/down switch or button to adjust the column height until the ear rods come at the patient's ears.



4. Ask the patient to stand between the left and right ear rods and adjust the column height again if necessary.
5. Slid the ear rods and gently insert each tip into the patient's ear canals to ensure proper placement and avoid discomfort.
6. From the side, check if the patient's Frankfurt plane is parallel to the floor. Gently tilt the patient's head if necessary.
7. Ask the patient to close their eyes and stand still until the end of the image acquisition.
8. Leave the X-ray room and follow the instructions in **8.4 Acquiring the Image**.

8.3.3 SMV

Follow the steps below to position the patient for the SMV mode.

1. Rotate the nasal positioner to the '**SMV**' mark.
2. Push the left and right ear rods out to provide enough room to place the patient's head.
3. Ask the patient to stand next to the CEPH unit and then use the column up/down switch or button to adjust the column height until ear rods are approximately at the patient's ear.



4. Ask the patient to stand between the left and right ear rods, facing the opposite direction of the CEPH sensor. If necessary, adjust the column height again.
5. Slide the ear rods and gently insert each tip into the patient's ear canals to ensure proper placement and avoid discomfort.
6. Ask the patient to slowly tilt the head back, until the patient Frankfurt plane is approximately perpendicular to the floor.
7. Ask the patient to close their eyes and stand still until the end of the image acquisition.
8. Leave the X-ray room and follow the instructions in **8.4 Acquiring the Image**.

8.3.4 Water's View

Follow the steps below to position the patient for the Water's View mode.

1. Rotate the nasal positioner to the '**PA / Water's View / Carpus**' mark.
2. Push the left and right ear rods outward to provide enough space for the patient's head.
3. Ask the patient to stand next to the CEPH unit and then use the column up/down switch or button to adjust the column height until the ear rods come at the patient's ears.



4. Ask the patient to stand between the left and right ear rods, facing the CEPH sensor.
5. Slid the ear rods and gently insert each tip into the patient's ear canals to ensure proper placement and avoid discomfort.
6. Ask the patient to slightly tilt his or her head back, for an approximate angle of **30 to 40 degrees**.
7. Ask the patient to close their eyes and stand still until the end of the image acquisition.
8. Leave the X-ray room and follow the instructions in **8.4 Acquiring the Image**.

8.3.5 Carpus

Follow the steps below to position the patient for the carpus mode.

1. Fold the nasal positioner up and install the carpus plate.
2. Ask the patient to spread the right hand and locate the hand on the carpus plate. Ensure that your patient does not bend fingers.
3. Ask the patient to place his or her right hand on the carpus plate with all five fingers fully stretched out.
4. Ask the patient to keep the same position until the end of the image acquisition.
5. Leave the X-ray room and follow the instructions in **8.4 Acquiring the Image**.

8.4 Acquiring the Image

Follow the steps below to acquire an X-ray image.

IMPORTANT

Refrain from using the PC during the X-ray exposure.

IMPORTANT

The staff should be able to communicate with patients either verbally or visually during the image acquisition.

1. Click the **Ready** button either on the console window or control panel.



NOTICE

Once the system is ready for image acquisition, the **Confirm** button on the console window changes to the **Ready** button.

2. Press the X-ray exposure switch when the message information window instructs you to press the switch.



WARNING

In case of an emergency, release the exposure switch immediately and press the **emergency stop switch** located under the handle frame.



3. Release the X-ray exposure switch when the system announces the end of the image capture.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, image capture is canceled.

4. Wait until the equipment returns to its starting location and guide the patient out of the equipment.



Do not approach the equipment until the equipment finishes moving.

8.5 Viewing the Acquired Images

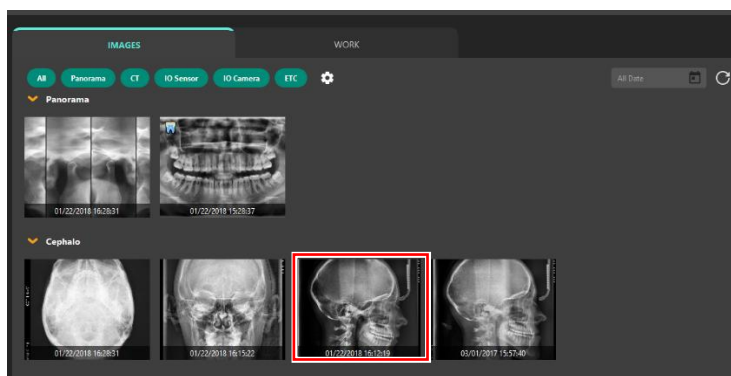
Follow the steps below to view the acquired images

1. Click the **Save** button when the console window prompts you to save the captured image. Once you click the button, the console window will close, and the image viewer will launch automatically.

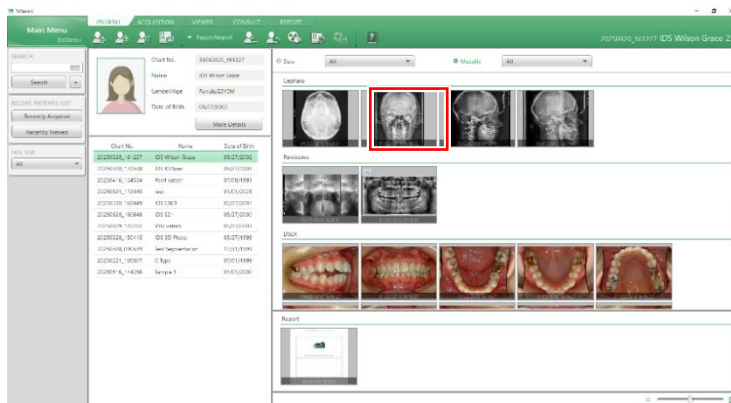
NOTICE

If you have selected the **Auto Save** option before image acquisition, the captured image will be saved automatically without prompting.

2. Double-click the thumbnail of the image you wish to view.



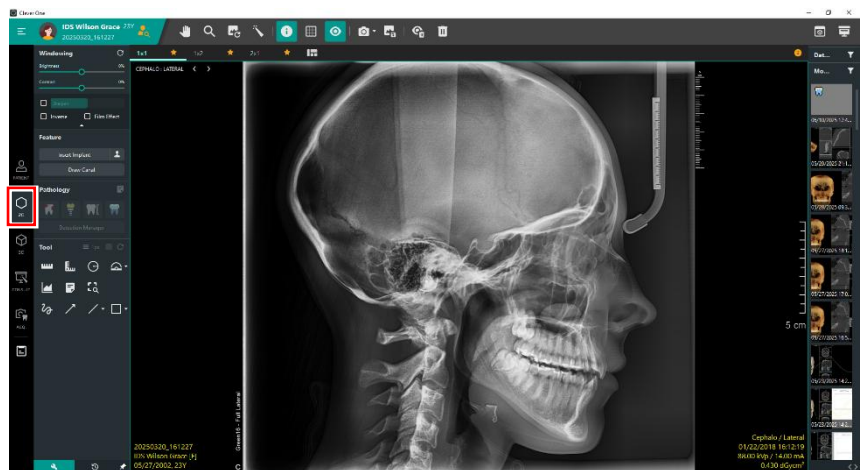
▲ Clever One



▲ EzDent-i

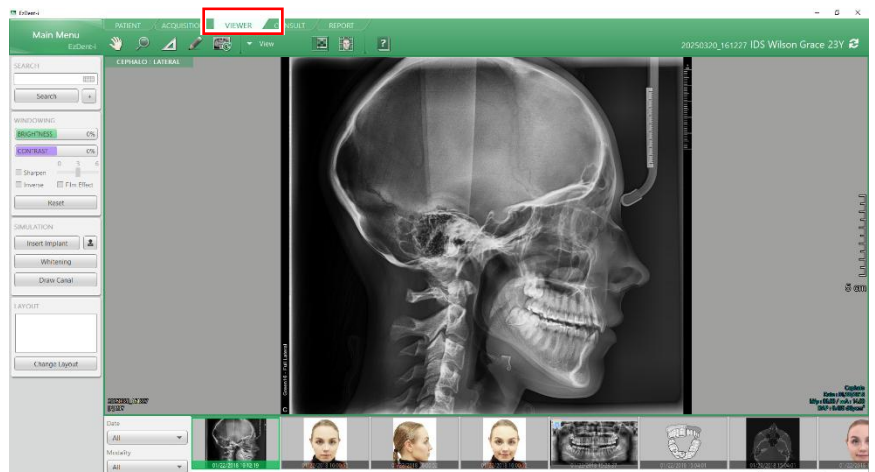
3. Depending on the viewer you are using, the selected image will open as follows:

- In **Clever One**, the image opens in the **2D** module.



▲ Clever One

- In **EzDent-i**, the image will open in the **Viewer** tab.



▲ EzDent-i

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9. DENTAL CT Image Acquisition

9.1 Program Overview

- **Role**

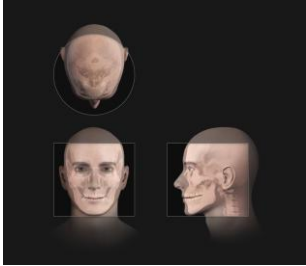
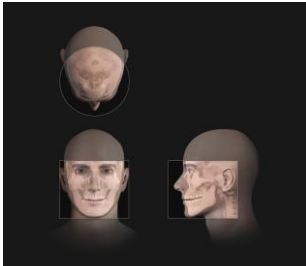
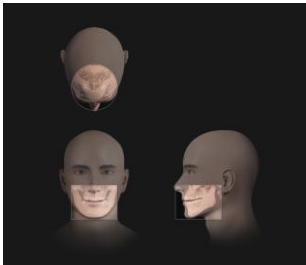
Provides sliced CT images for dental diagnosis.

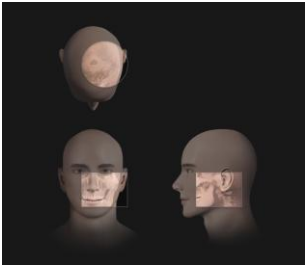
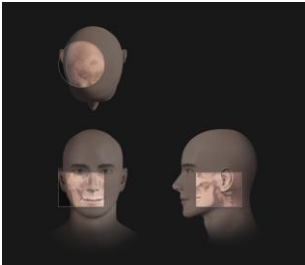
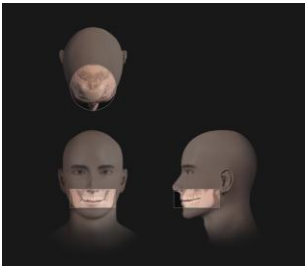
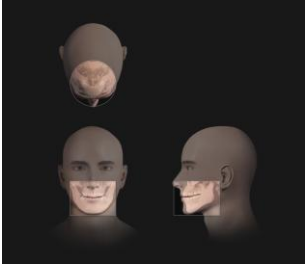
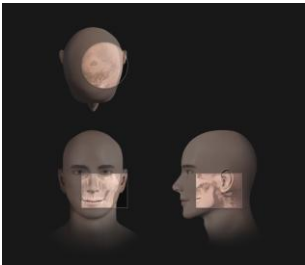
- **Image acquisition method**

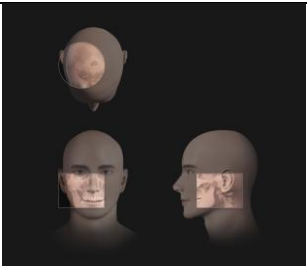
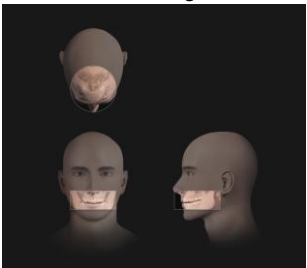
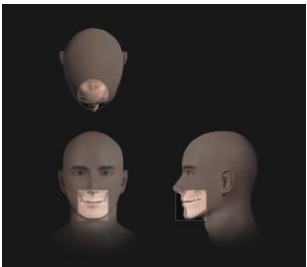
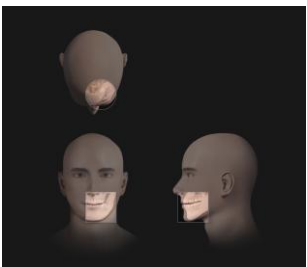
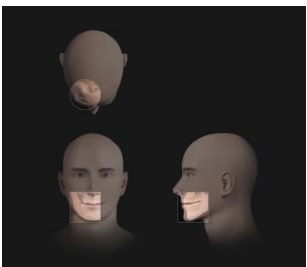
After the user selects a specific area covering the oral or maxillofacial region on the console software, the system scans the selected area with the X-ray beam to acquire image data and reconstructs it into the sliced 3D CT images by computer calculation.

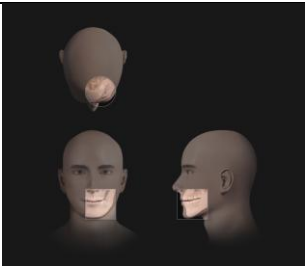
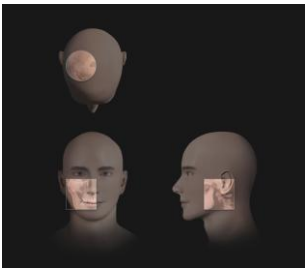
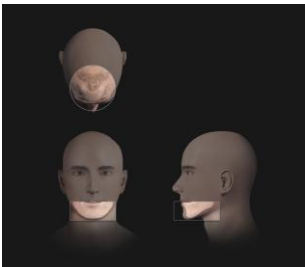
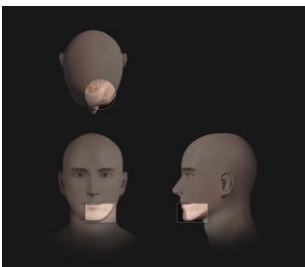
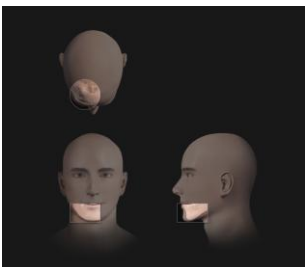
- **Examination programs**

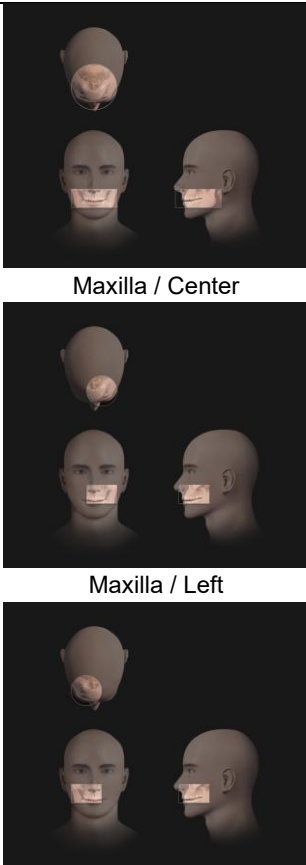
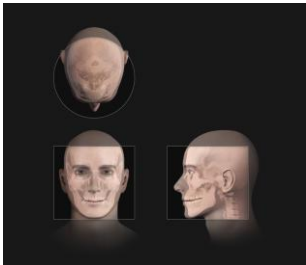
DENTAL CT mode provides the following FOV and ROI options.

FOV	ROI (Region of Interest)	Description
21x19	 Occlusion / Center	- Supports imaging of full arch, sinus, and TMJ (left and right) areas in a one-shot scan. - Provides anatomical analysis to plan intra-oral surgeries including multiple implant placement.
18x15	 Occlusion / Center	- Supports imaging of full arch, sinus, and TMJ (left and right) areas. - Provides anatomical analysis to plan intra-oral surgeries including multiple implant placement.
12x9		- Supports imaging of the maxilla and mandible, including the third molar region. - Provides analysis of TMJ (left and right) and sinus areas

	Occlusion / Center  TMJ / Left  TMJ / Right  Sinus / Center	
12x5	Occlusion / Center  TMJ / Left 	- Supports imaging of the maxilla and mandible, including the third molar region. - Provides analysis of TMJ (left and right) and sinus areas

	 TMJ / Right  Sinus / Center	
8x8	 Occlusion / Center  Occlusion / Left  Occlusion / Right	- Supports imaging of maxillary, mandibular, and TMJ (left and right) areas

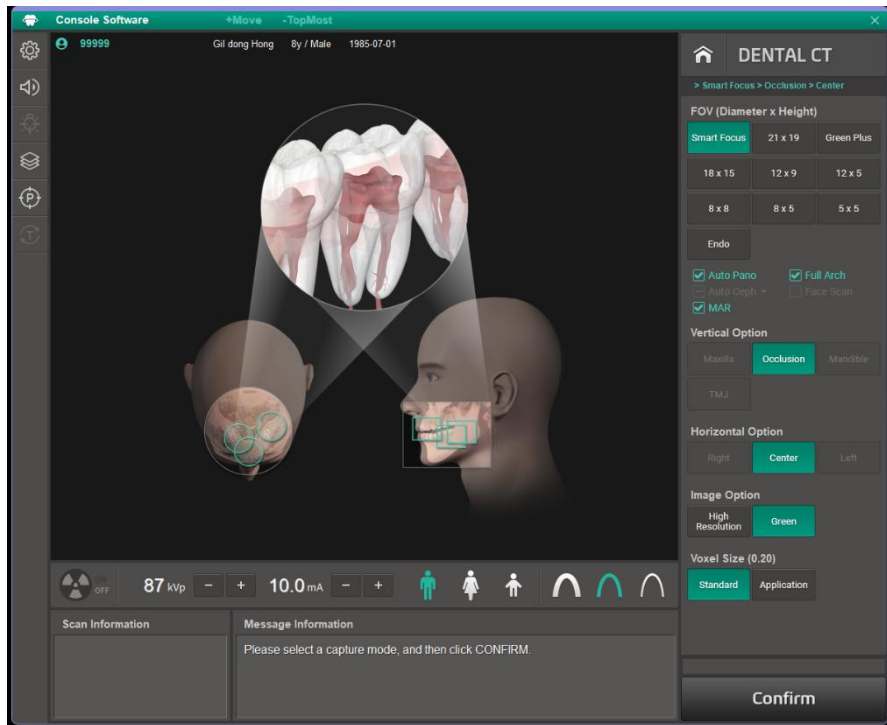
	 TMJ / Left  TMJ / Right	
8x5	 Mandible / Center  Mandible / Left  Mandible / Right	- Supports imaging of the maxillary, mandibular, and TMJ (left and right) areas

	 Maxilla / Center Maxilla / Left Maxilla / Right	
5x5	 Varies by user selection	- Support imaging of user-selected areas consisting of 3~4 teeth.
Green Plus (21x19)	 Occlusion / Center	- Supports imaging of full arch, sinus, and TMJ (left and right) areas in a one-shot scan.

9. DENTAL CT Image Acquisition

Smart focus (12x9)	 Occlusion / Center	- Supports imaging of user-selected areas. - Users can select up to three areas.
Endo (4x4)	 Varies by user selection	- Supports imaging of a single tooth that the user selected.

9.2 Selecting Exposure Settings



▲ DENTALCT Console Window

NOTICE

Please note that Auto Ceph images are not intended for cephalometric tracing.

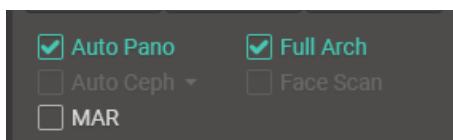
9.2.1 General Dental CT

Follow the steps below to select exposure settings:

1. From the FOV menu, select a desired FOV other than 'Smart Focus' and 'Endo'



If desired, select additional imaging options by checking boxes below the FOV menu.



NOTICE

When **Auto Pano** is selected, a panoramic image reconstructed from 3D data is additionally acquired along with the Smart Focus Image.

NOTICE

The **Auto Ceph** is enabled only when 21×19 is selected from the FOV menu.

2. Select the image option.

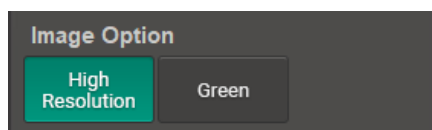
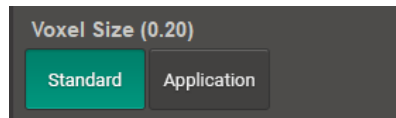


Image Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

3. Select the voxel size.



NOTICE

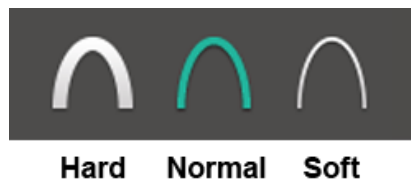
Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

4. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females at the age of 12 or under

5. Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

9. DENTAL CT Image Acquisition

- Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 0.1 mA.



Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
DENTAL CT	60	4	99	12

- Click the **Confirm** button.



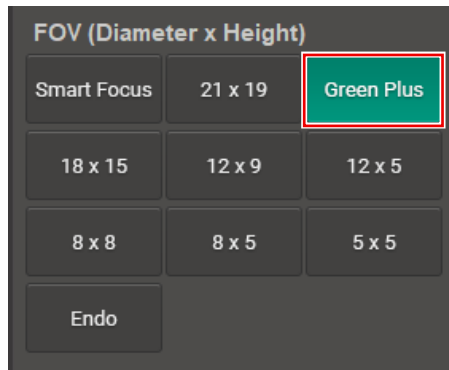
When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

- After the equipment finishes moving, guide the patient to the X-ray room.

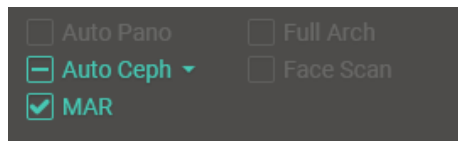
9.2.2 Green Plus (Optional)

Follow the steps below to select exposure settings:

1. Select **Green Plus** from the FOV menu.



If desired, select additional imaging options by checking boxes below the FOV menu.



2. Select the image option.

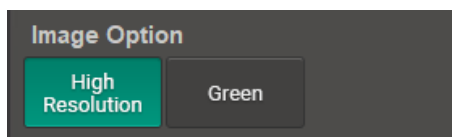
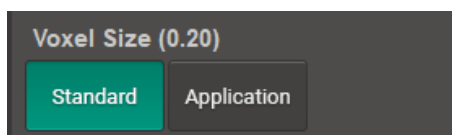


Image Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

3. Select the voxel size.



NOTICE

Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

- Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Man Woman Child

Patient	VATECH standard
Man	Males above the age of 12
Woman	Females above the age of 12
Child	Males or Females below the age of 12

- Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.



Hard Normal Soft

Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

- Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 0.1 mA.



Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
Smart Focus	60	4	99	12

7. Click the **Confirm** button.



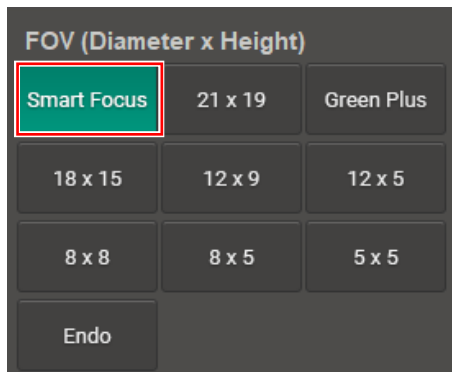
When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

8. After the equipment finishes moving, guide the patient to the X-ray room and follow the instruction in **9.3 Positioning the Patient** to align the patient's posture.
9. Proceed with CT scanning according to the instruction in **9.4 Acquiring the Image**.

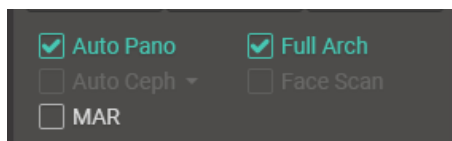
9.2.3 Smart Focus

Follow the steps below to select exposure settings:

1. Select **Smart Focus** from the FOV menu.



If desired, select additional imaging options by checking boxes below the FOV menu.



NOTICE

When **Auto Pano** is selected, a panoramic image reconstructed from 3D data is additionally acquired along with the Smart Focus Image.

NOTICE

When **Full Arch** is selected, a 12x9 CT image is additionally acquired along with the Smart Focus Image.

2. Select the image option.

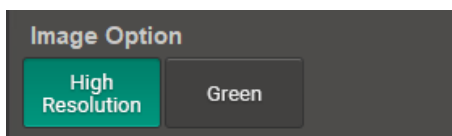
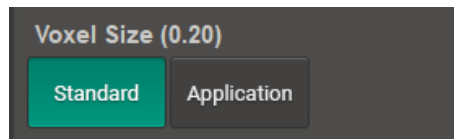


Image Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

3. Select the voxel size.

**NOTICE**

Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

4. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Man Woman Child

Patient	VATECH standard
Man	Males above the age of 12
Woman	Females above the age of 12
Child	Males or Females below the age of 12

5. Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.



Hard Normal Soft

Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

9. DENTAL CT Image Acquisition

- Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 0.1 mA.



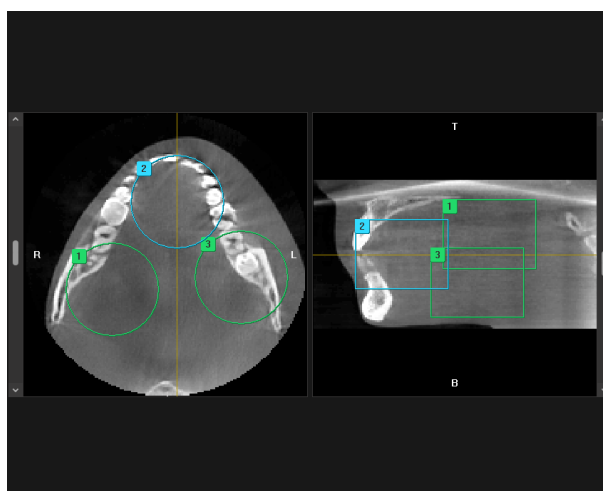
Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
Smart Focus	60	4	99	12

- Click the **Confirm** button.

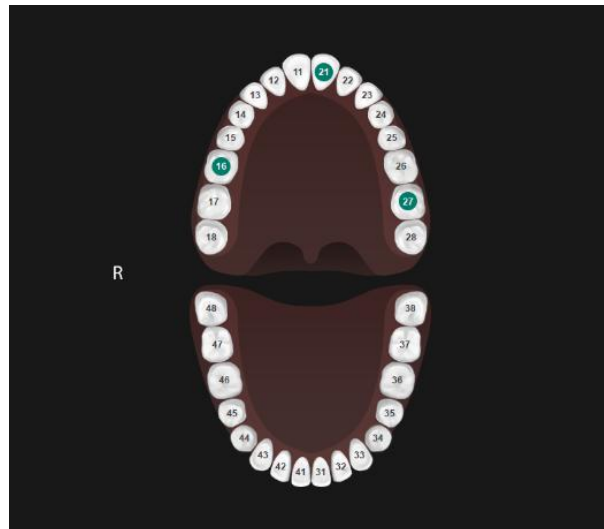


When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

- After the equipment finishes moving, guide the patient to the X-ray room and follow the instruction in **9.3 Positioning the Patient** to align the patient's posture.
- Proceed with CT scanning according to the instruction in **9.4 Acquiring the Image**.
- After scanning, select the reconstruction area. You can select up to three areas.



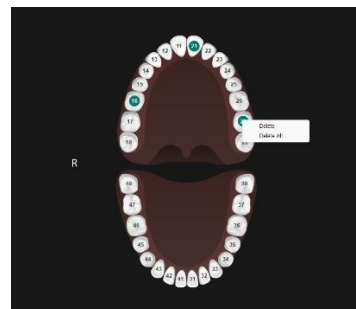
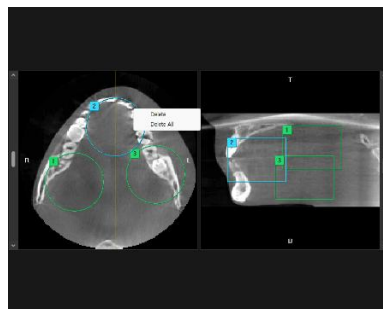
If the Tooth Selection Option was pre-configured in the console settings, the Tooth Selection screen will appear. You can select up to three teeth on this screen.



NOTICE

If the Tooth Selection Option was not configured, the Reconstruction Areas Screen will appear by default.

To cancel a selected area, right-click on the desired reconstruction area or tooth and choose **Delete** or **Delete All** from the menu.



11. Once the desired reconstruction areas or teeth are selected, click the **Complete** button.

Complete

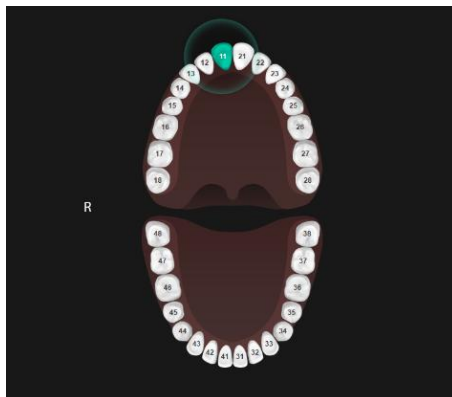
9.2.4 Endo

Follow the steps below to select exposure settings:

1. Select **Endo** from the FOV menu.



2. Select a tooth to capture an image.



3. Select an image option.

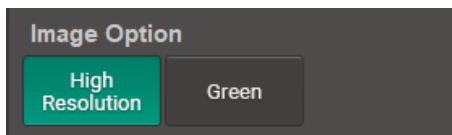


Image Option	Description
High Resolution	High-Resolution image
Green	Normal-Resolution image

NOTICE

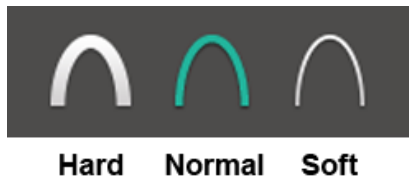
Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

4. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



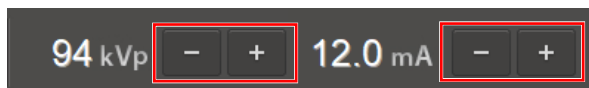
Patient	VATECH standard
Man	Males above the age of 12
Woman	Females above the age of 12
Child	Males or Females below the age of 12

5. Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.



Category	Average head circumference (cm)	Range (cm)	Intensity level
Child (Age 12 or under)	53±3	>53±3	Hard
		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

6. Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 0.1 mA.



Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
Endo	60	4	99	12

- Click the **Confirm** button.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

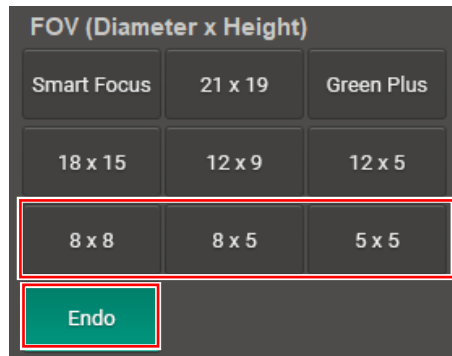
- After the equipment stops moving, guide the patient to the equipment.

9.2.5 Scout View

Scout View, which provides a 2D preview of the target area, is only available when 12x5, 8x5, 5x5, or Endo is selected from the FOV menu.

Follow the steps below to set the Scout View conditions:

1. Select **12x5**, **8x5**, **5x5** or **Endo** from the FOV menu.

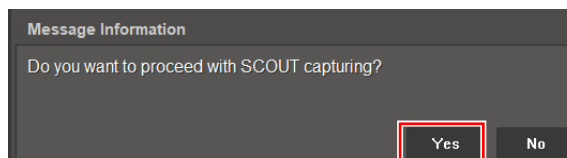


2. Select the rest of the exposure settings as guided in **9.2 Selecting Exposure Settings**, and click the **Confirm** button.



When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

3. When you see the message “**Do you want to proceed with SCOUT capturing**”, click the **Yes** button.



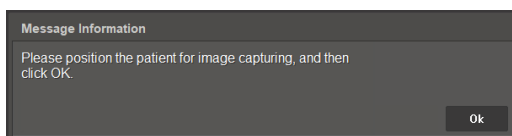
Click the **No** button if you want to skip the Scout View capture.

4. After the chinrest has finished moving, position the patient according to **9.3 Positioning the Patient**.

NOTICE

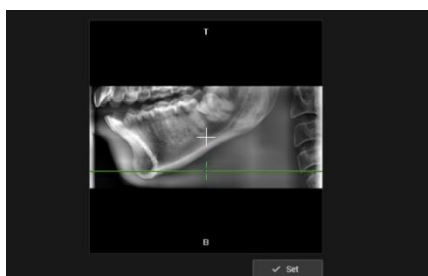
Ensure that the patient does not move until the scout capture ends.

5. Click the **OK** button to start scout image acquisition.

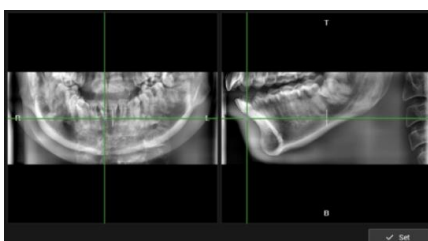


6. After image acquisition, check the preview to ensure the target area is centered on the screen. If it is not centered, adjust the target position by moving the guideline (green line).

- In 12x5 and 8x5 imaging modes, move the horizontal line up or down.



- In 5x5 and Endo imaging modes, move the horizontal and vertical lines in all directions (up, down, left, right).



7. Click the **Set** button to confirm the location of the guideline. the chinrest and rotator will move based on the changed target areas position.



8. Check the patient position according to **9.3 Positioning the Patient** then click the **Ready** button to proceed with the CT image acquisition.

NOTICE

The **Ready** button can be operated only after you click the **Set** button.

9.3 Positioning the Patient

9.3.1 Dental CT only

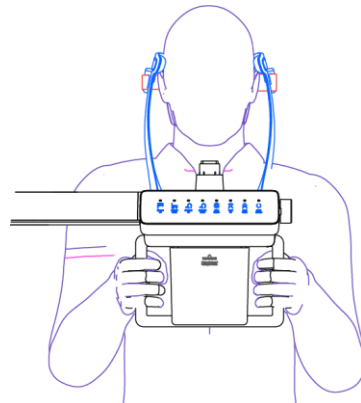
Follow the steps below to position the patient correctly for image acquisition.

1. Press the **Column Up/Down button** on the control panel to set the appropriate height for the patient.



Ensure that the patient does not move while adjusting the column height.

2. Ask the patient to stand on the puddle lamp light and grab the handles on both sides.



If you use the sanitary vinyl covers provided by the 3rd party, ensure that the product conforms to one of the following standards:

- ISO 10993-1 (Biological Evaluation of Medical Devices)
- FDA
- CE
- Local regulations in your area

3. Instruct the patient to gently bite or press the bite block and to close their eyes.

Bite type instruction according to the patient type

Normal patient	Edentulous patient
Gently bite the groove of the normal bite block with front teeth.	Press the head of the special B bite block with chin.
	

4. Check the laser beam's location. If necessary, adjust the patient position for alignment.
 - The **vertical beam** should come at the center of the patient's face.
 - The **shoulder beam** should not touch the patient's shoulder.
5. Use the temple support knob to close the left and right temple supports.



6. Ask the patient to stay in the current position until the image acquisition ends.
7. Leave the X-ray room and follow the instructions in **9.4.1 Dental CT Only**.

9.3.2 Dental CT with a Face Scan

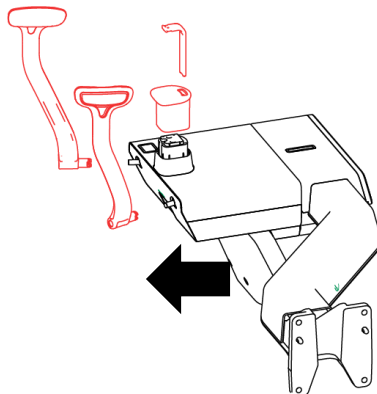
To position the patient for a dental CT with face scanning, follow the steps below.

1. Press the column up/down button on the control panel to adjust the column height for the patient's height.

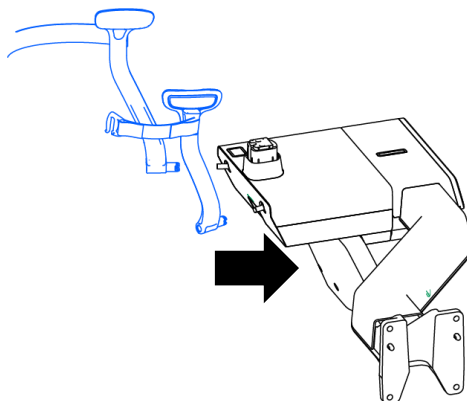


Ensure that the patient does not move while adjusting the column height.

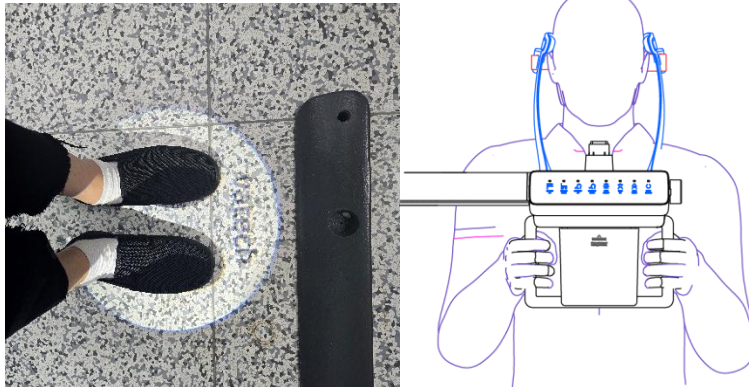
2. Remove the bite block, chinrest, and normal temple supports from the handle frame.



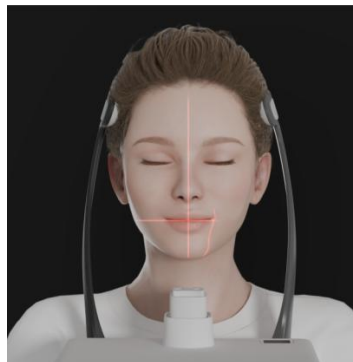
3. Mount the temple supports with strap (for face scan only).



4. Ask the patient to stand on the puddle lamp light and grab the handles on both sides with eyes closed.



5. Check the laser beam's location. If necessary, adjust the patient position for alignment.



- The **vertical beam** should come at the center of the patient's face.
- The **horizontal beam** should pass through the center of the patient's closed lips.
- The **canine beam** should be located at the tip of the patient's lips.
- The **shoulder beam** should not touch the patient's shoulder.



Be careful not to have the patient stare into the laser beam.



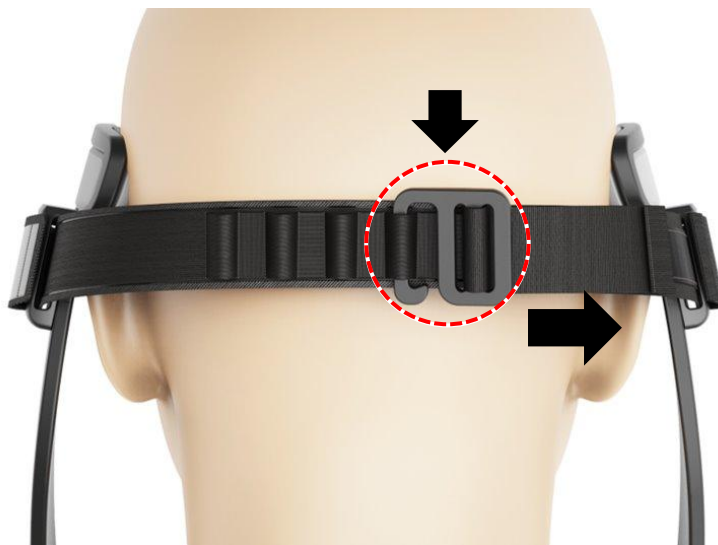
When taking a Face Scan, pull the canine beam lever to the left as shown in the picture below.



6. Use the temple support knob to close the left and right temple supports.



7. Hang the hook on the left strap to the right strap according to the patient's head size. Then pull the left strap to adjust its length.



8. Leave the X-ray room and follow the instructions in **9.4.2 Dental CT with a Face Scan** for image acquisition,

9.4 Acquiring the Image

9.4.1 Dental CT Only

Follow the steps below to acquire an X-ray image.

IMPORTANT

Refrain from using the PC during the X-ray exposure.

IMPORTANT

The staff should be able to communicate with patients either verbally or visually during the image acquisition.

1. Click the **Ready** Button either on the console window or control panel.



NOTICE

Once the system is ready for image acquisition, the **Confirm** button on the console window changes to the **Ready** button.

2. Press the X-ray exposure switch when the message information window instructs you to press the switch.

WARNING

In case of an emergency, release the exposure switch immediately and press the **emergency stop switch** located under the handle frame.



3. Release the X-ray exposure switch when the system announces the end of the image capture.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, image capture is canceled.

4. Wait until the equipment returns to its starting location. Then turn the temple support knob to open the left and right supports and guide the patient out of the equipment.



Do not approach the equipment until the equipment finishes moving.

9.4.2 Dental CT with a Face Scan

Follow the steps below to capture a dental CT with face scanning. The system acquires the face scan first and then moves to acquire a dental CT image.

1. Click the **Ready** Button either on the console window or control panel.



2. To acquire a face scan image, press the X-ray exposure switch when the message information window instructs you to press the switch.

IMPORTANT

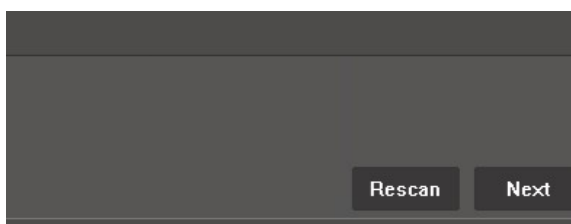
In the Face Scan mode, the X-ray radiation is not emitted while pressing the exposure switch.

3. Release the X-ray exposure switch when the system announces the end of the face scan.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, the face scan is canceled.

4. After image acquisition, the captured face scan image is displayed on the console window. Click the **Rescan** button to rescan or the **Next** button to continue with the CT scan.



5. When patient positioning is completed, click the **Ready** button on the console window.



6. Release the X-ray exposure switch when the system announces the end of the image capture.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, image capture is canceled.

7. Wait until the equipment returns to its starting location. Then turn the temple support knob to open the left and right supports and guide the patient out of the equipment.



Do not approach the equipment until the equipment finishes moving.

9.5 Viewing the Acquired Image

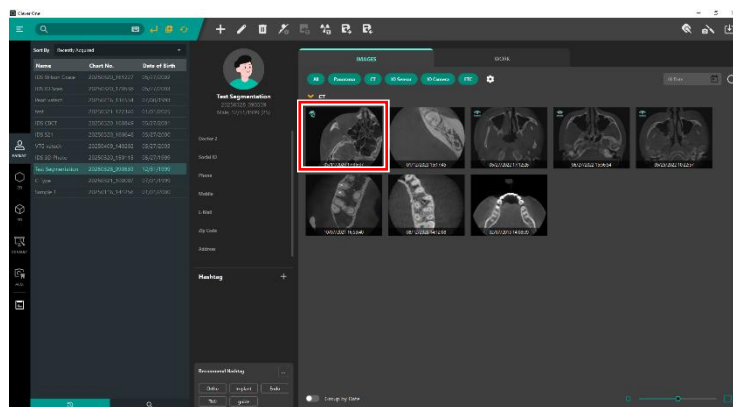
Follow the steps below to view the acquired images.

1. Click the **Save** button when the console window prompts you to save the captured image. Once you click the button, the console window will close, and the image viewer will launch automatically.

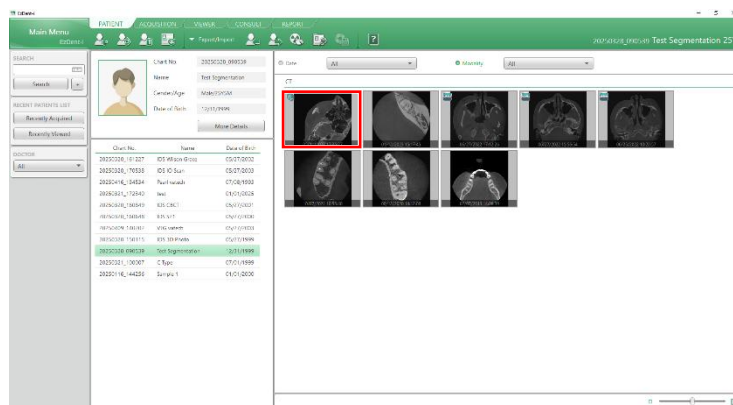
NOTICE

If you have selected the **Auto Save** option before image acquisition, the captured image will be saved automatically without prompting.

2. Double-click the thumbnail of the image you wish to view.



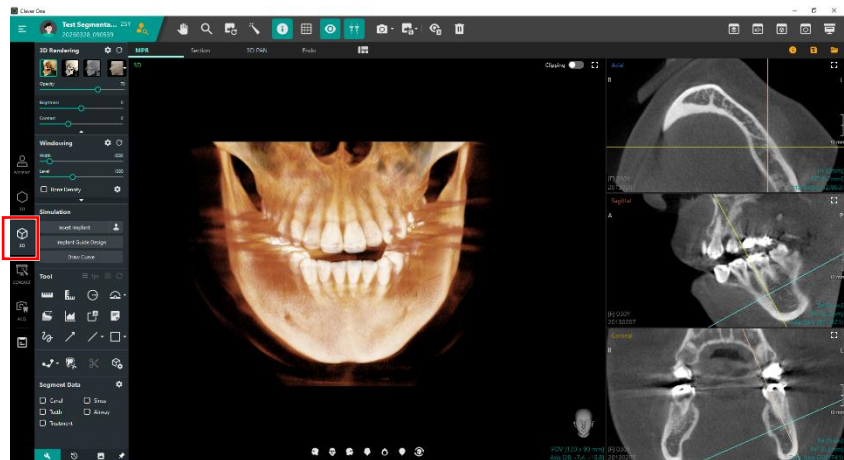
▲ Clever One



▲ EzDent-i

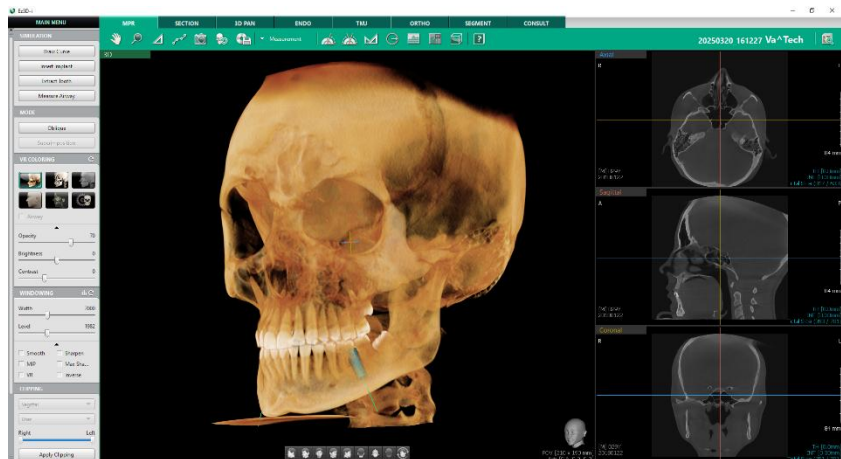
3. Depending on the viewer you are using, the selected image will open as follows:

- In **Clever One**, the image will open in the **3D** module.



▲ Clever One

- In **EzDent-i**, the image will open in the **MPR** tab of the linked **Ez3D-i** viewer.



▲ Ez3D-i

9.5.1 To View the Face Scan Data captured with a CT Image.

Follow the steps below to view the face scan image captured along with the CT scan.

NOTICE

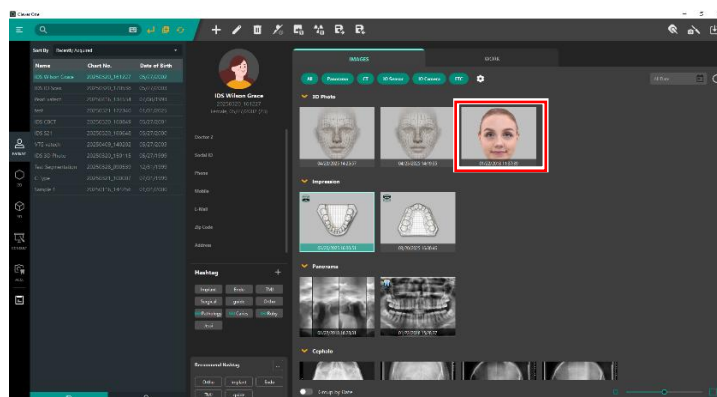
Some steps may vary depending on the version of EzDent-i. Before proceeding, make sure to check the version of EzDent-i you are using.

1. Click the **Save** button when the console window prompts you to save the captured image. Once you click the button, the console window will close, and the image viewer will launch automatically.

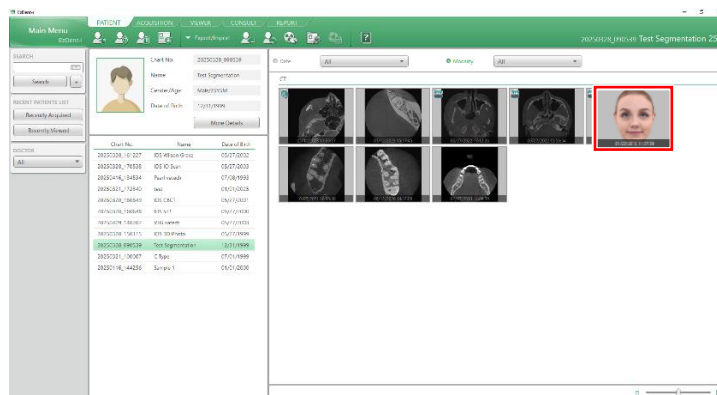
NOTICE

If the **Auto Save** option was enabled before capturing, the image will be saved automatically without showing the message.

2. In the image viewer screen, click the thumbnail of the face scan image.

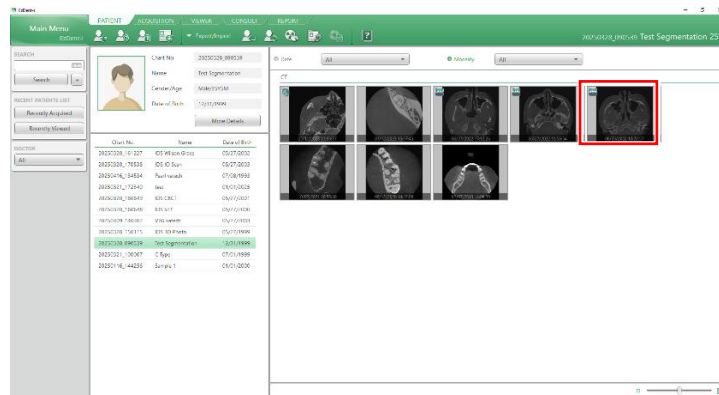


▲ Clever one



▲ EzDent-i (v3.5.15 or later)

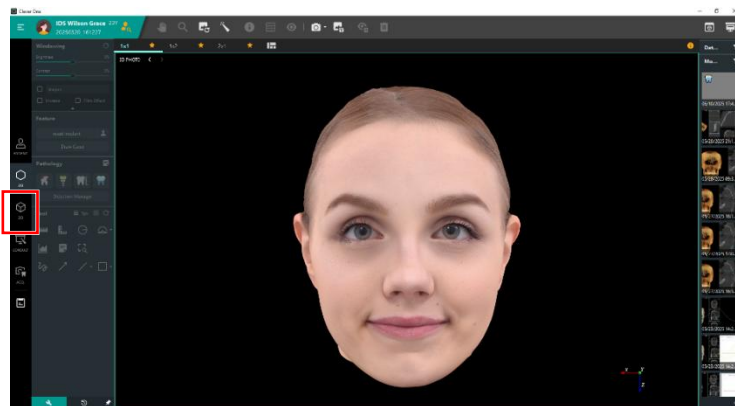
If you are using a version of EzDent-i earlier than v3.5.15, click the patient's CT image thumbnail as shown below.



▲ EzDent-i (version earlier than 3.5.15)

3. Depending on the viewer you are using, the selected image will open as follows:

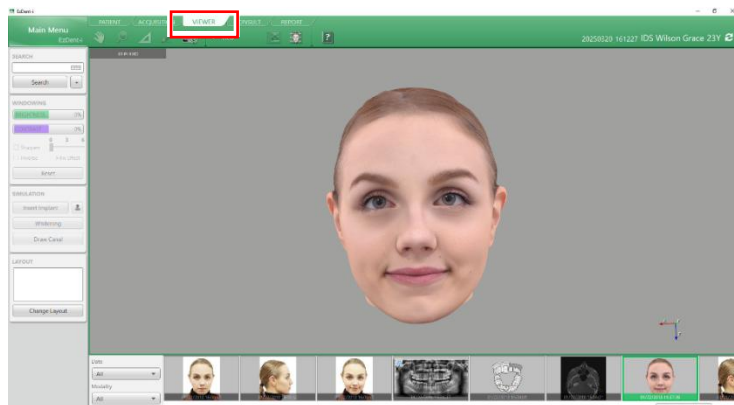
- In Clever One, the image opens in the **2D** module.



▲ Clever One

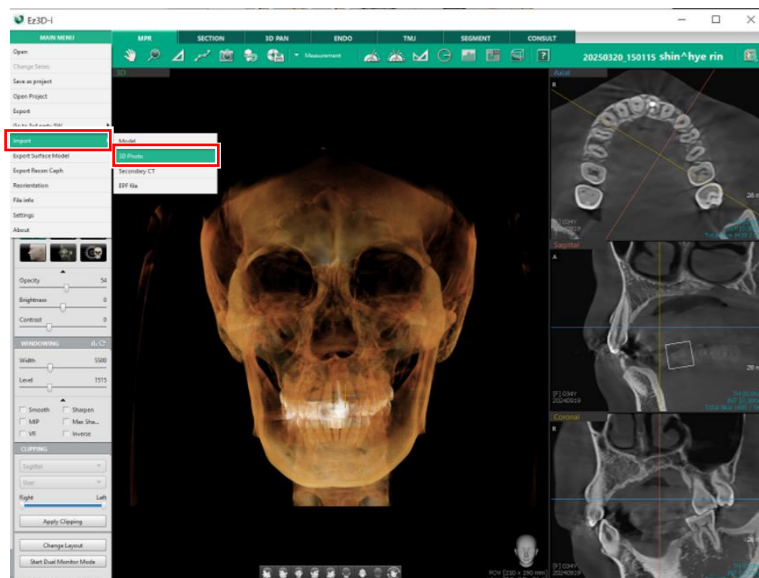
9. DENTAL CT Image Acquisition

- In **EzDent-i version 3.5.15 or later**, the image opens in the **Viewer** tab.

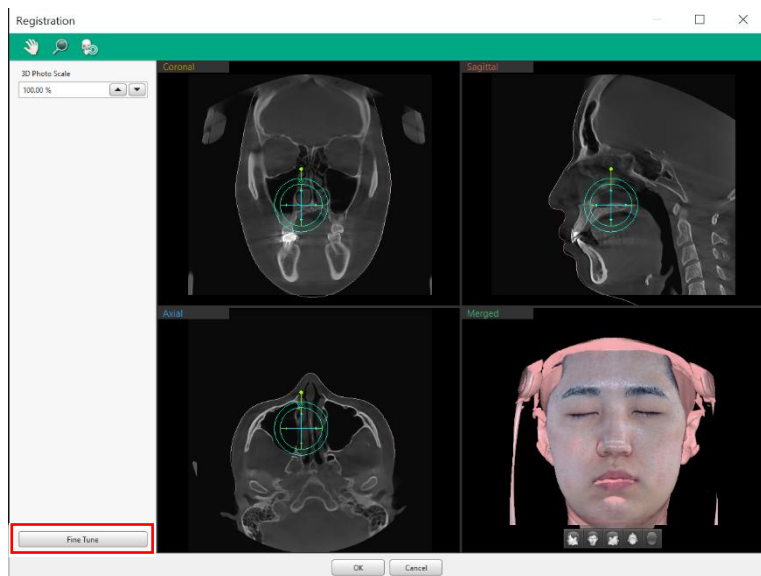


▲ EzDent-i (version 3.5.15 or later)

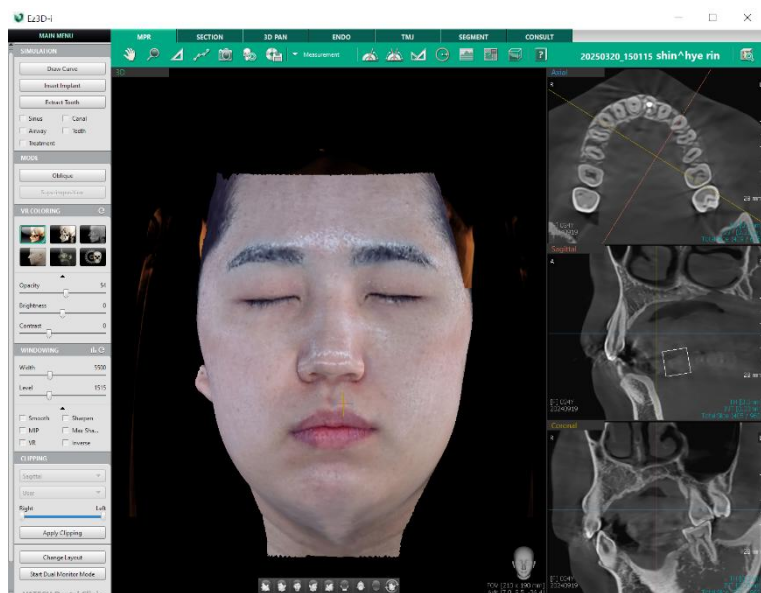
- In **EzDent-i versions earlier than 3.5.15**, follow the steps below to view the image:
 - 1) In the Ez3D-i main menu, select Import > 3D Photo.



- 2) When the alignment window appears, click the Fine Tune button located at the bottom left.



- 3) Check the scan image after the automatic alignment is complete.



10. ENT CT Image Acquisition

10.1 Program Overview

- **Role**

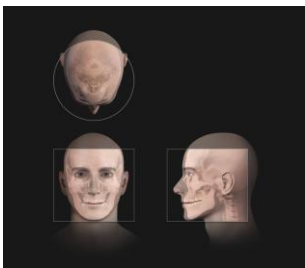
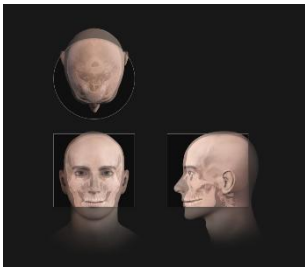
Provides sliced CT images of ENT regions to aid in diagnosis.

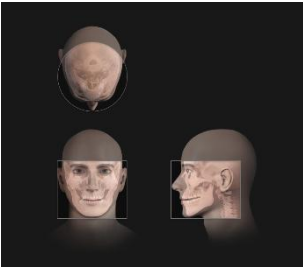
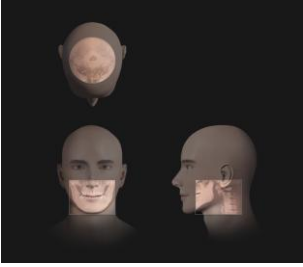
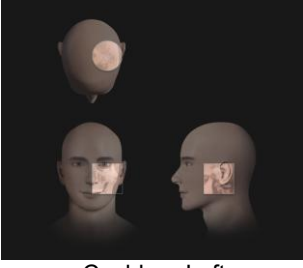
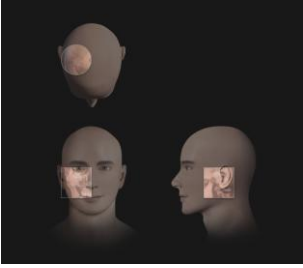
- **Image acquisition method**

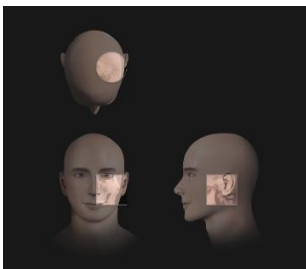
After the user selects an area covering the ENT (Ear, Nose, and Throat) region on the console software, the system scans the selected area with the X-ray beam to acquire image data and reconstructs it into the sliced 3D CT images by computer calculation.

- **Examination programs**

ENT CT mode provides the following FOV and ROI options.

FOV	ROI (Region of Interest)	Description
21x19	 Facial Bone	- Supports imaging of the facial and petrous bones that make up the appearance of the face and protect the vestibular system. - Provides facial and petrous bone analysis to plan treatment for bone injuries.
	 Petrous Bone	

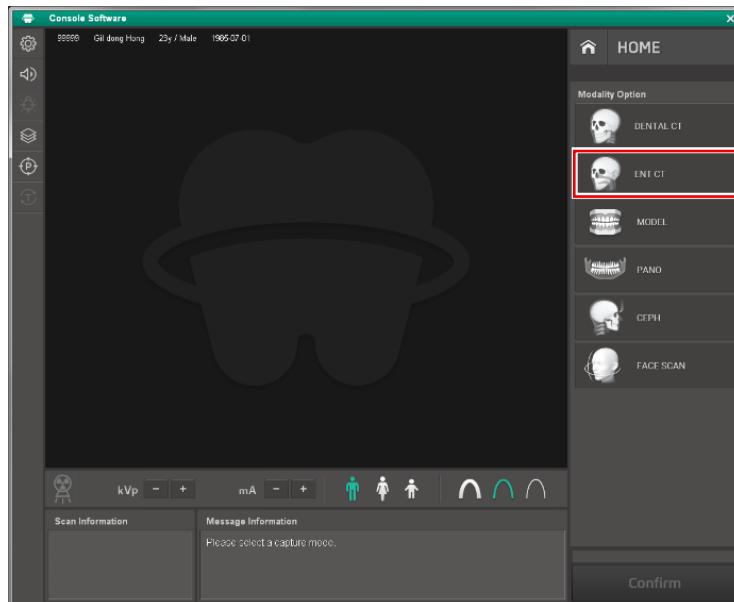
18x15	 Facial Bone	- Supports imaging of the facial bones including the maxilla, and mandible. - Provides facial bone structure and injury analysis for treatment planning.
12x9	 Airway	- Supports airway imaging. - Provides airway structure and injury analysis for treatment planning.
8x8	 Cochlear Left  Cochlear Right	- Supports cochlear and single-ear imaging. - Provides the analysis of cochlear damage for treatment planning. - Provides the analysis of inner ear injuries including bone fractures for treatment planning.

	Single Ear Left  Single Ear Right	
--	--	--

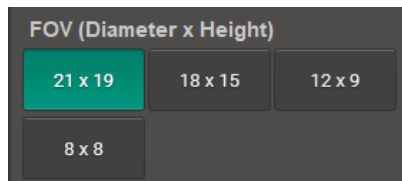
10.2 Selecting Exposure Settings

Follow the steps below to select the exposure settings:

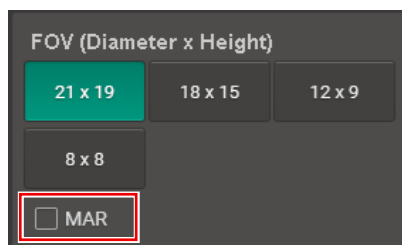
1. Select 'ENT CT' in the HOME console window to open the ENT console.



2. Select a desired FOV from the FOV menu.



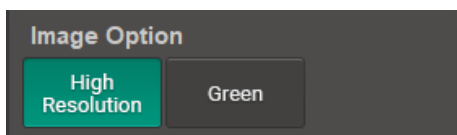
If desired, turn on the MAR option by checking the box below the FOV menu.



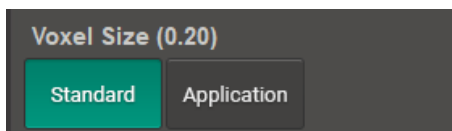
NOTICE

Depending on the selected FOV, certain imaging options or menu items may be disabled.

3. Select the image option.



4. Select the voxel size.



NOTICE

Patient selection, X-ray intensity and exposure conditions are automatically set based on the entered patient information. You can modify these settings if needed.

5. Confirm the patient selection. To make a change, click one of the icons in the menu bar.



Man Woman Child

Patient	VATECH standard
Man	Males above the age of 12
Woman	Females above the age of 12
Child	Males or Females below the age of 12

6. Confirm the X-ray intensity level. To make a change, click one of the icons in the menu bar.

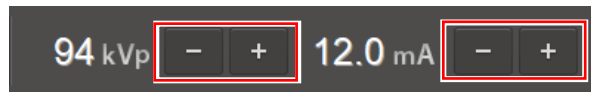


Hard Normal Soft

Category	Average head circumference (cm)	Range (cm)	Intensity level
Child	53±3	>53±3	Hard

(Age 12 or under)		53±3	Normal
		<53±3	Soft
Adult (Above Age 12)	56±3	>56±3	Hard
		56±3	Normal
		<56±3	Soft

7. Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 0.1 mA.



Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
ENT CT	60	4	99	12

8. Click the **Confirm** button.



WARNING

When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

9. After the equipment finishes moving, guide the patient to the X-ray room.

10.3 Positioning the Patient

To position the patient, follow the steps below.

1. Press the column up/down button on the control panel to adjust the column height for the patient's height.



Ensure that the patient does not while adjusting the column height.

2. Ask the patient to stand on the puddle lamp light.



3. Ask the patient to grab the handles on both sides.

4. Instruct the patient to gently bite or press the bite block and to close their eyes.

Bite type instruction according to the patient type

Normal patient	Edentulous patient
Gently bite the groove of the normal bite block with front teeth.	Press the head of the special B bite block with chin.
	

5. Check the laser beam's location. If necessary, adjust the patient position for alignment.
 - The **vertical beam** should come at the center of the patient's face.
 - The **shoulder beam** should not touch the patient's shoulder.
6. Use the temple support knob to close the left and right temple supports.



Be careful not to have the patient stare into the laser beam.

7. Ask the patient to stay in the current position until the image acquisition ends.
8. Leave the X-ray room and follow the instructions in **10.4 Acquiring the Image**.

10.4 Acquiring the Image

Follow the steps below to acquire an X-ray image.

IMPORTANT

Refrain from using the PC during the X-ray exposure.

IMPORTANT

The staff should be able to communicate with patients either verbally or visually during the image acquisition.

1. Click the **Ready** button either on the console window or control panel.



NOTICE

Once the system is ready for image acquisition, the **Confirm** button on the console window changes to the **Ready** button.

2. Press the X-ray exposure switch when the message information window instructs you to press the switch.

WARNING

In case of an emergency, release the exposure switch immediately and press the **emergency stop switch** located under the handle frame.



3. Release the X-ray exposure switch when the system announces the end of the image capture.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, image capture is canceled.

4. Wait until the equipment returns to its starting location. Then turn the temple support knob to open the left and right supports and guide the patient out of the equipment.



Do not approach the equipment until the equipment finishes moving.

10.5 Viewing the Acquired Image

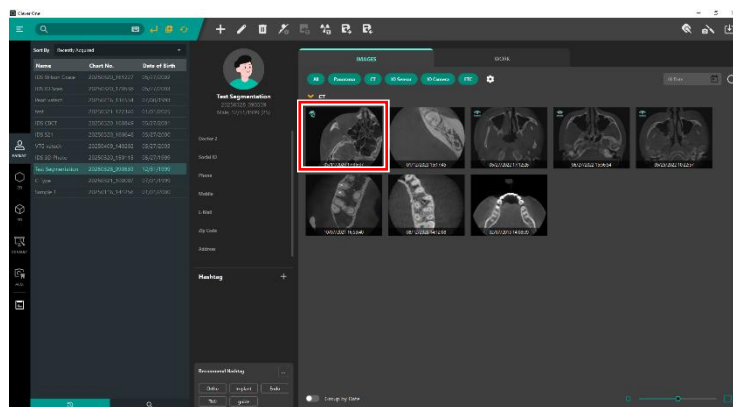
Follow the steps below to view the acquired images.

1. Click the **Save** button when the console window prompts you to save the captured image. Once you click the button, the console window will close, and the image viewer will launch automatically.

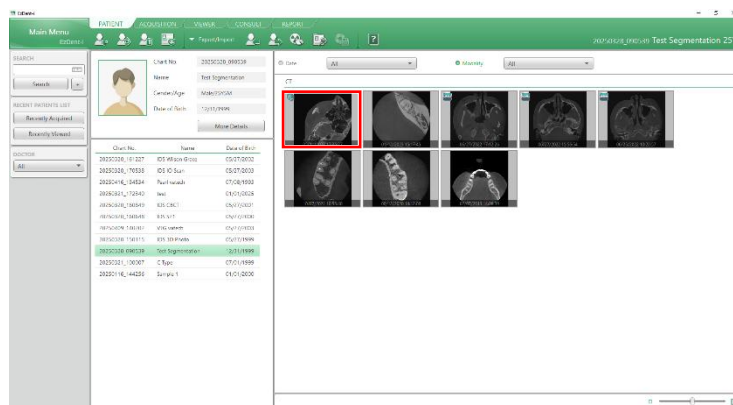
NOTICE

If you have selected the **Auto Save** option before image acquisition, the captured image will be saved automatically without prompting.

2. Double-click the thumbnail of the image you wish to view.



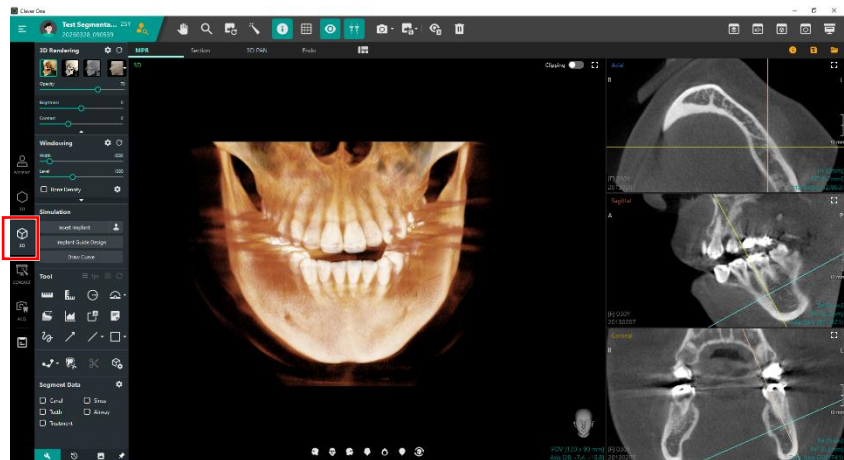
▲ Clever One



▲ EzDent-i

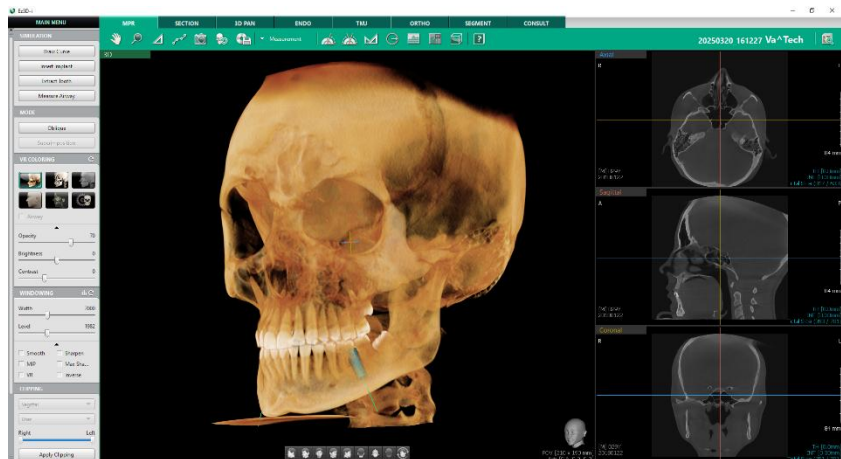
3. Depending on the viewer you are using, the selected image will open as follows:

- In **Clever One**, the image will open in the **3D** module.



▲ Clever One

- In **EzDent-i**, the image will open in the **MPR** tab of the linked **Ez3D-i** viewer.



▲ Ez3D-i

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11. MODEL Image Acquisition

11.1 Program Overview

- **Role**

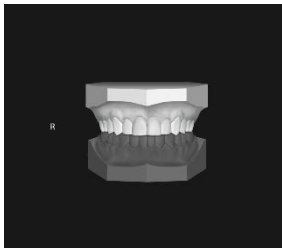
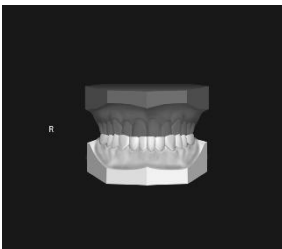
Provides 3D data of plaster cast in STL file.

- **Image Acquisition Method**

Once the user selects a vertical, the system scans the plaster cast with the X-ray beam to acquire image data and reconstructs it into 3D modeling surface data.

- **Examination Programs**

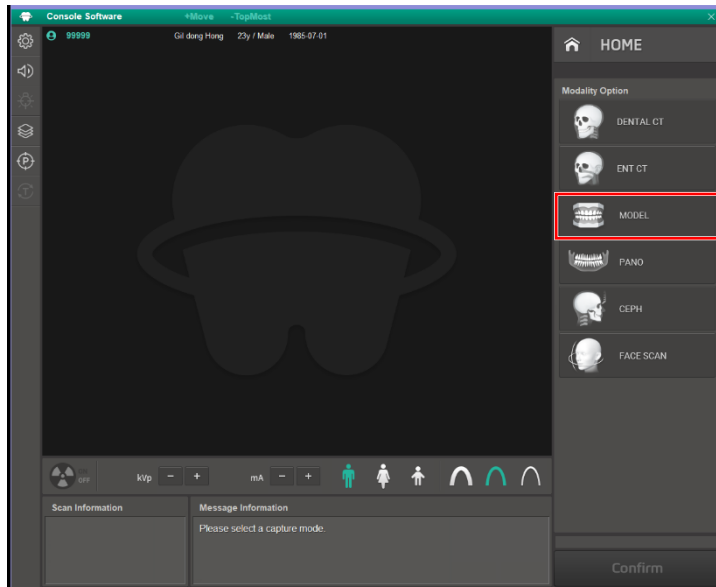
Model mode provides the following options and ROI.

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

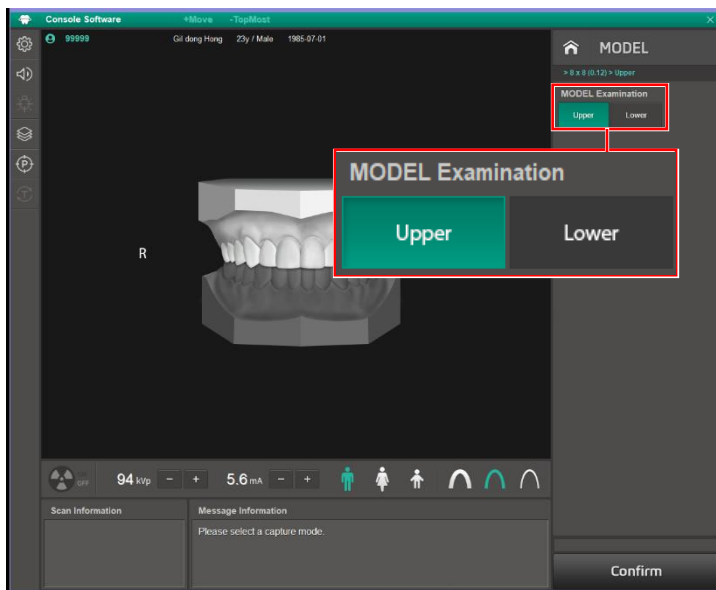
11.2 Selecting Exposure Settings

Follow the steps below to select the exposure settings:

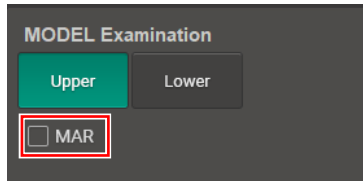
1. Select '**MODEL**' in the HOME console window to open the MODEL console.



2. Select a model examination option.



If desired, turn on the MAR option by checking the box below the FOV menu.



3. Confirm the exposure conditions. To change them, click the plus-minus buttons in the menu bar. Each click adjusts the tube voltage by ± 1.0 kVp and the tube current by ± 0.1 mA.



Mode	Minimum Value		Maximum Value	
	kVp	mA	kVp	mA
MODEL	60	4	99	12

4. Click the **Confirm** button.



When the Confirm button is clicked, the sensor moves to the imaging location. Do not approach the equipment until the movement is finished.

11.3 Positioning the Plaster Cast

After the equipment finishes moving, follow the steps below to position the plaster cast.

1. Insert the model scan jig.



2. Put the plaster cast on the model scan jig. Whether the plaster cast is for the maxilla or mandibular, place it **flat side down**.
3. Check if the center of the plaster cast aligns with the vertical beam. If necessary, adjust the cast's location.

IMPORTANT

If the center of the plaster cast does not align with the vertical beam, the image can be horizontally expanded.

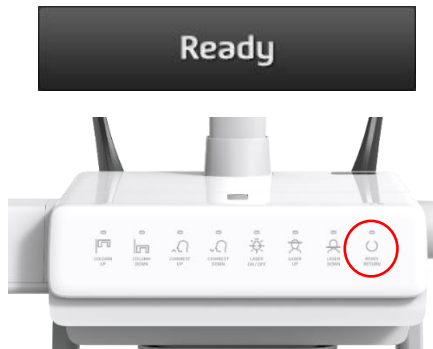
11.4 Acquiring the Image

Follow the steps below to capture an X-ray image.

IMPORTANT

Refrain from using the PC during the X-ray exposure.

1. Click the **Ready** button either on the console window or control panel.



2. Press the X-ray exposure switch when the message information window instructs you to press the switch.



In case of an emergency, release the exposure switch immediately and press the **emergency stop switch** located under the handle frame.



3. Release the X-ray exposure switch when the system announces the end of image capture.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, image capture is canceled.

4. Wait until the equipment returns to its starting location and take out the model scan jig.



Do not approach the equipment until the equipment finishes moving.

11.5 Viewing the Acquired Image

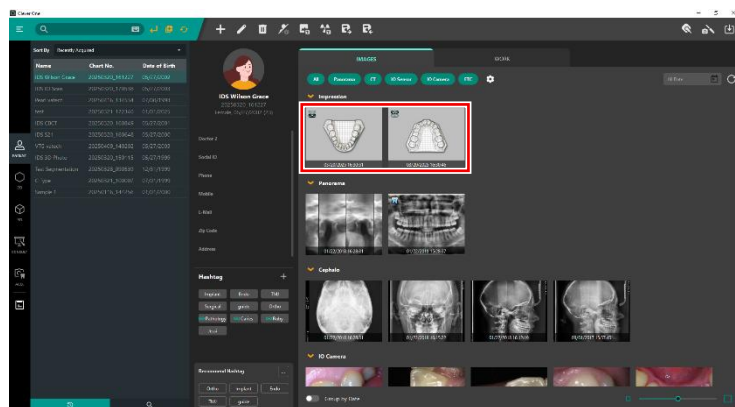
To view and save the acquired image, follow the steps below.

1. Click the **Save** button when the console window prompts you to save the captured image. Once you click the button, the console window will close, and the image viewer will launch automatically.

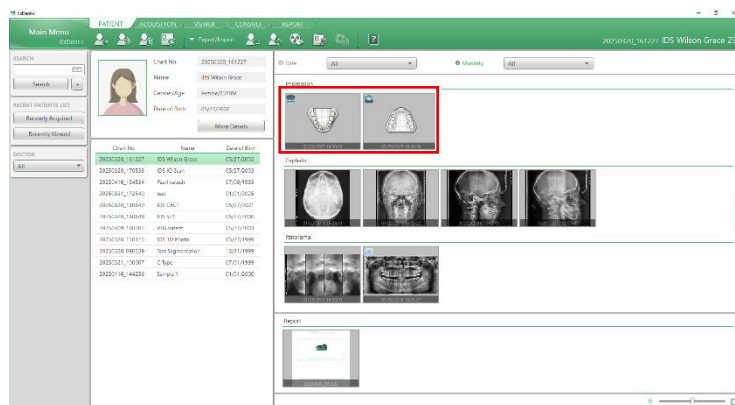
NOTICE

If you have selected the **Auto Save** option before image acquisition, the captured image will be saved automatically without prompting.

2. Double-click the thumbnail of the image you wish to view.



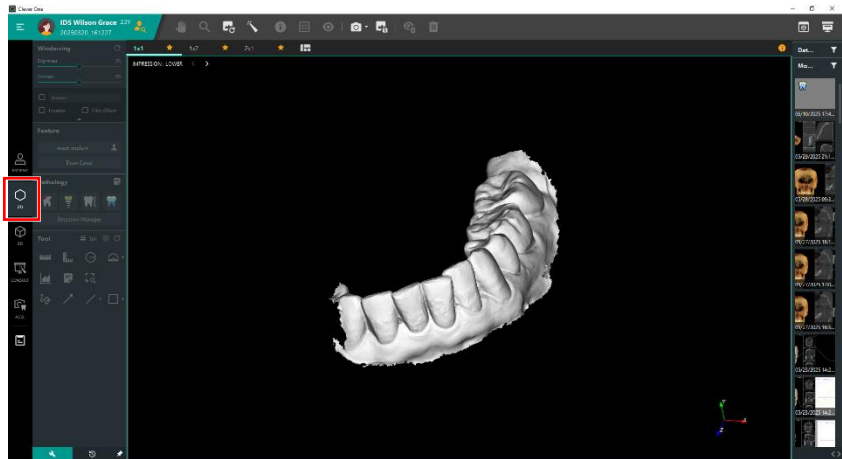
▲ Clever one



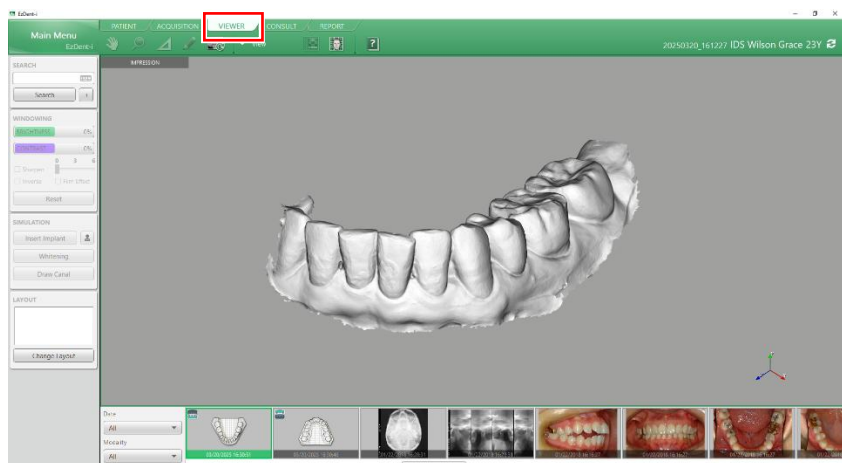
▲ EzDent-i

3. Depending on the viewer you are using, the selected image will open as follows:

- In Clever One, the image opens in the 2D module.
- In EzDent-i version 3.5.15 or later, the image opens in the Viewer tab.
- In EzDent-i versions earlier than 3.5.15, the image opens in the connected the STL viewer.



▲ Clever One



▲ EzDent-i (version 3.5.15 or later)

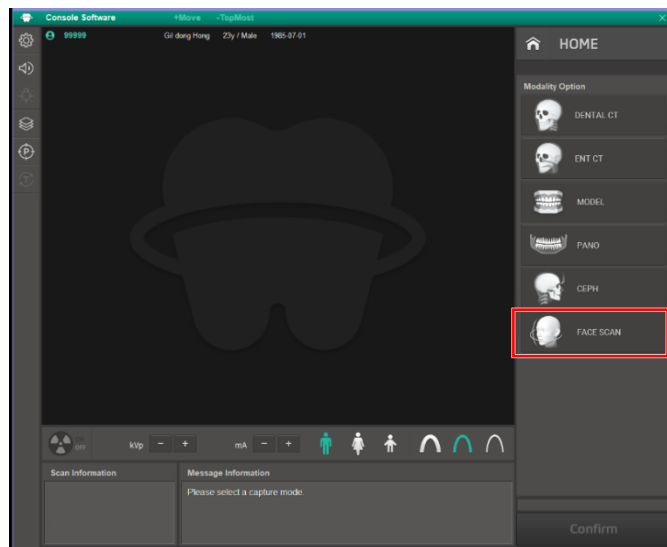
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12. FACE SCAN

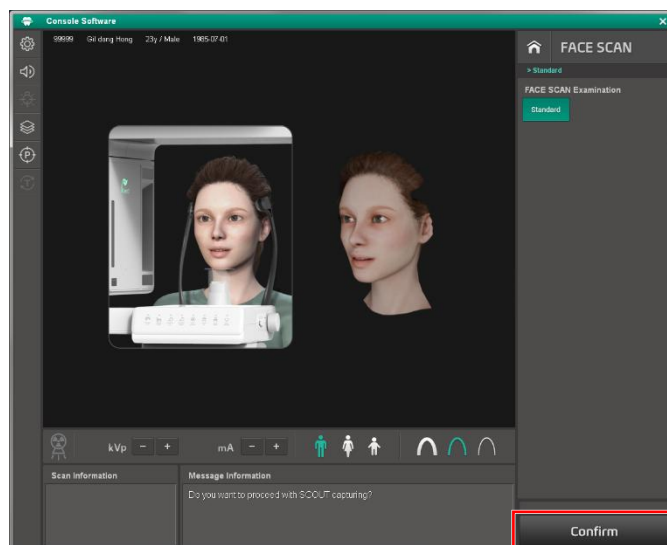
12.1 Selecting Settings

Follow the steps below to select settings for the Face Scan.

1. Select 'FACE SCAN' in the HOME console window to open the FACE SCAN console.



2. Click the **Confirm** button.





When the Confirm button is clicked, the sensor moves to the imaging location. For safety, guide patients enter the X-ray room after the equipment finishes moving.

3. After the equipment finishes moving, guide the patient to the X-ray room.

12.2 Preparing For the Patient

Before acquiring a face scan image, instruct the patient as below:

- Remove all metal items such as jewelry and glasses.
- Trim your bangs neatly so that your forehead is visible.
- Tuck the side hair behind your ears so that both ears are visible.

12.3 Positioning the Patient

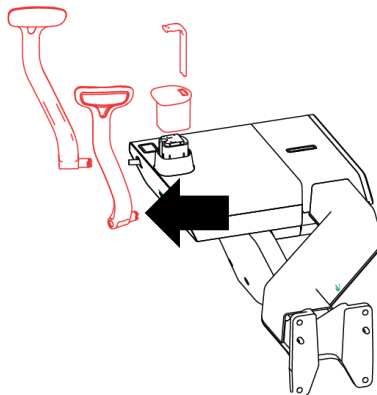
Follow the steps below to position the patient for a face scan.

1. Press the column up/down button on the control panel to adjust the column height for the patient's height.

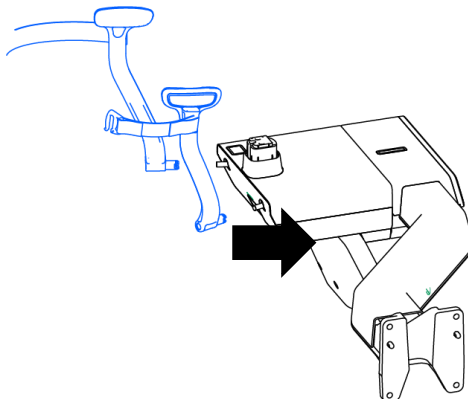


Ensure that the patient does not move during the column height adjustment.

2. Remove the bite block, chinrest, and normal temple supports.

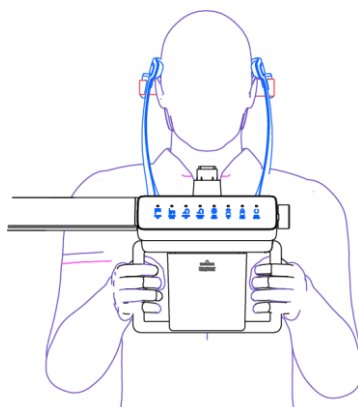
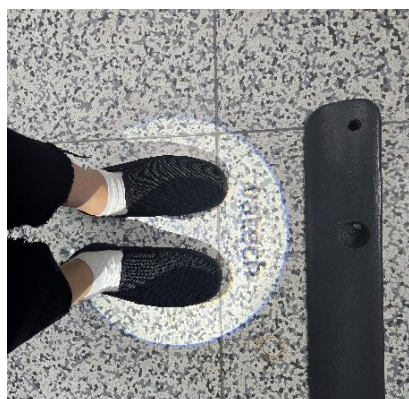


3. Mount the temple supports with strap (for face scan only).

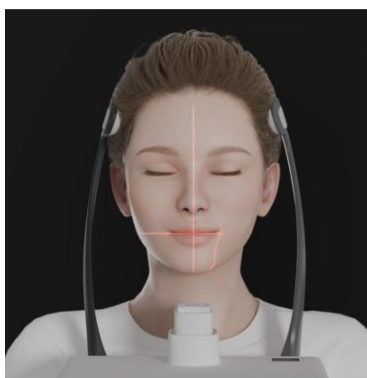


12. FACE SCAN

4. Ask the patient to stand on the puddle lamp light and grab the handles on both sides as illustrated below.



5. Check the laser beam's location. If necessary, adjust the patient position for alignment.



- The **vertical beam** should come at the center of the patient's face.
- The **horizontal beam** should pass through the center of the patient's closed lips.
- The **canine beam** should be positioned at the tip of the patient's lips.
- The **shoulder beam** should not touch the patient's shoulder.

CAUTION

Be careful not to have the patient stare into the laser beam.

NOTICE

When taking a Face Scan, pull the canine beam lever to the left as shown in the picture below.



6. Use the temple support knob to close the left and right temple supports.



7. Hang the hook on the left strap to the right strap according to the patient's head size. Then pull the left strap to adjust its length.



12.4 Acquiring the Scan Data

Follow the steps below to start the face scan.

IMPORTANT

Be careful not to expose the camera to strong light or direct sunlight. Exposure to light may affect scan data quality.

1. Click the **Ready** button either on the console window or control panel.



NOTICE

Once the system is ready for image acquisition, the **Confirm** button on the console window changes to the **Ready** button.

2. Press the X-ray exposure switch when the message information window instructs you to press the switch.



In case of an emergency, release the exposure switch immediately and press the **emergency stop switch** located under the handle frame.



3. Release the X-ray exposure switch when the system announces the end of the face scan.

IMPORTANT

Do not release the exposure switch until you hear the system announcement. Once the switch is released, the face scan is canceled.

4. When the captured image appears in the window, choose whether to save the image, if you want to rescan, click the **Rescan** button.



5. Wait until the equipment returns to its starting location. Then turn the temple support knob to open the left and right supports and guide the patient out of the equipment.



12.5 Viewing the Face Scan Data

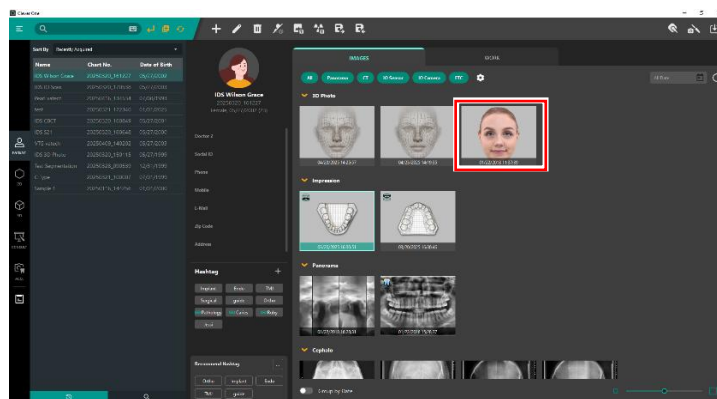
Follow the steps below to view the Face Scan Data.

1. Click the **Save** button when the console window prompts you to save the captured image. Once you click the button, the console window will close, and the image viewer will launch automatically

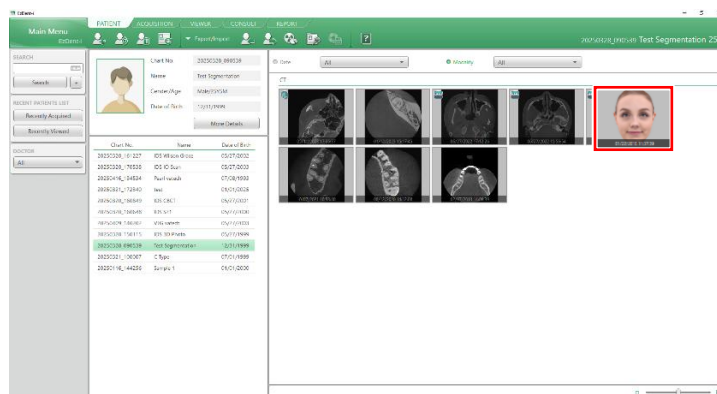
NOTICE

If you have selected the **Auto Save** option before image acquisition, the captured image will be saved automatically without prompting.

2. In the image viewer screen, click the thumbnail of the face scan image.

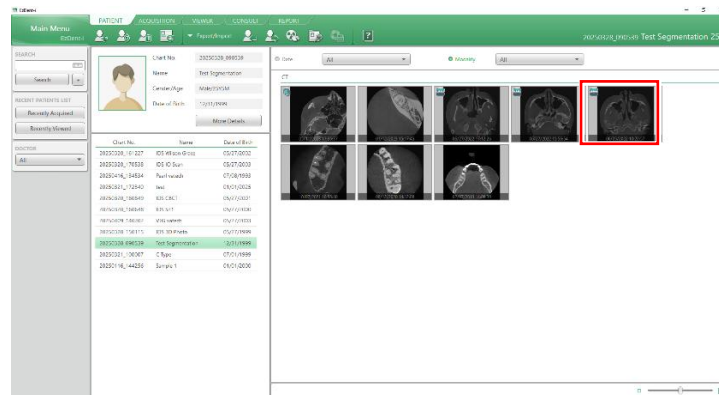


▲ Clever one



▲ EzDent-i (v3.5.15 or later)

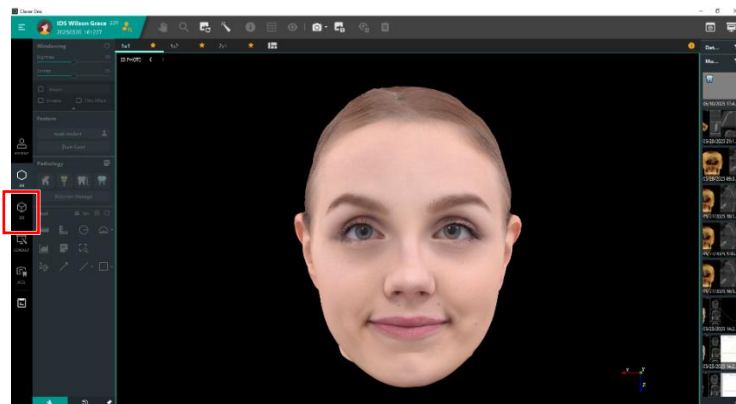
If you are using a version of EzDent-i earlier than v3.5.15, click the patient's CT image thumbnail as shown below.



▲ EzDent-i (version earlier than 3.5.15)

3. Depending on the viewer you are using, the selected image will open as follows:

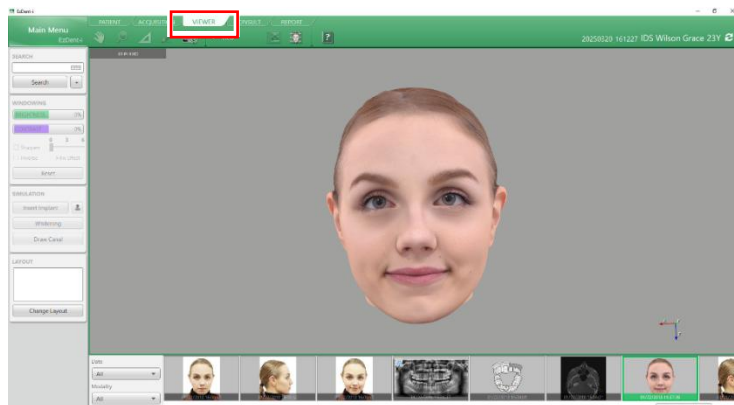
- In Clever One, the image opens in the **2D** module.



▲ Clever One

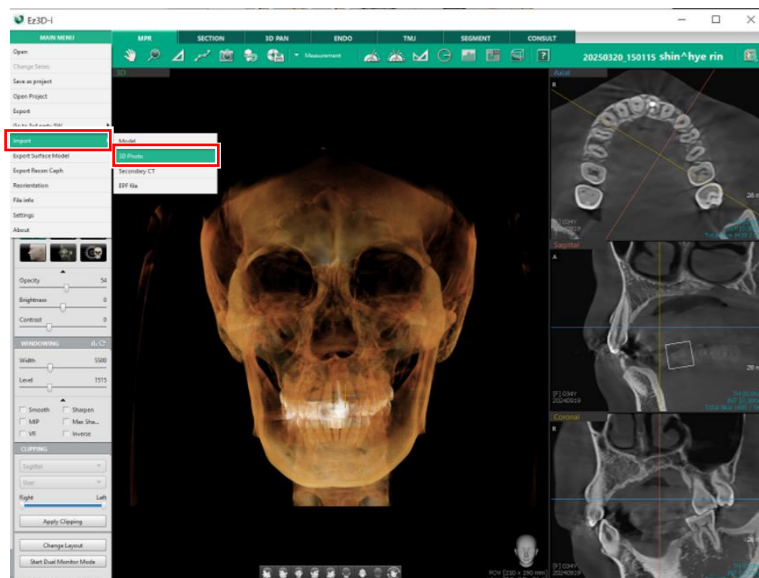
12. FACE SCAN

- In **EzDent-i version 3.5.15 or later**, the image opens in the **Viewer** tab.

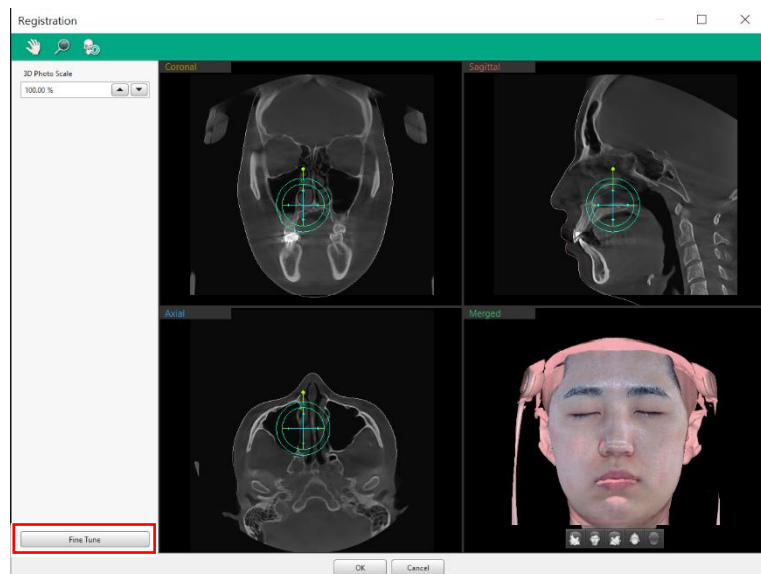


▲ EzDent-i (version 3.5.15 or later)

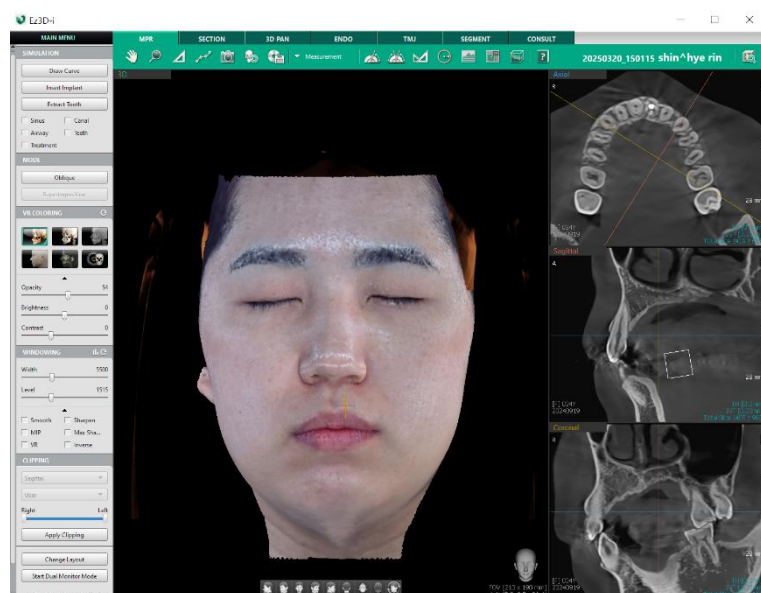
- In **EzDent-i versions earlier than 3.5.15**, follow the steps below to view the image:
 - 1) In the Ez3D-i main menu, select Import > 3D Photo.



- 2) When the alignment window appears, click the Fine Tune button located at the bottom left.



- 3) Check the scan image after the automatic alignment is complete.



13. Troubleshooting

13.1 Troubleshooting

If a problem occurs during the operation, follow the guide on the table below to solve the issue. If the problem persists, contact VATECH customer service.

When the equipment is not working

Description	Action
Failing to turn on	Check the equipment's power connection status.
Failing to initialize	Check the error code on the console window and contact customer service.
Failing to communicate with the PC	Check the communication port (optic) that connects the PC to the equipment.

When the system cannot capture the image

Description	Action
Failing to capture an image	1. Check the exposure switch's connection status. 2. Check if the console software is ready to capture an image.

When the system cannot capture the image after clicking Confirm

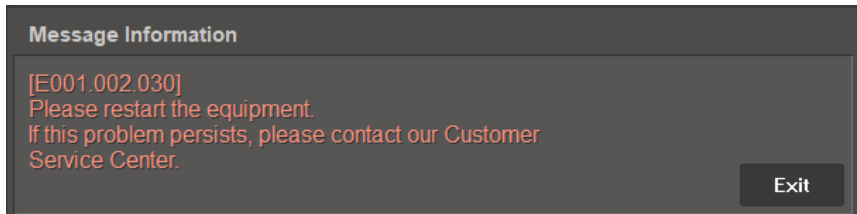
Description	Action
Fail to capture an image	Check the error code on the console window and contact customer service.

When the laser beam is turned off before completing patient positioning

Description	Action
Lasers are turned off	Press the Beam on/off button on the control panel.

13.2 Error Codes

When a problem occurs during the operation, an error message in **red text** with a corresponding code will be displayed in the Message Information window.

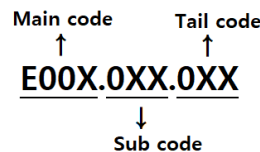


▲ An example of an error message

If the problem persists after following the instructions in the error message, contact the VATECH representative in your area for help.

Error code is written in the following format:

[Code: E00X.0XX.0XX]

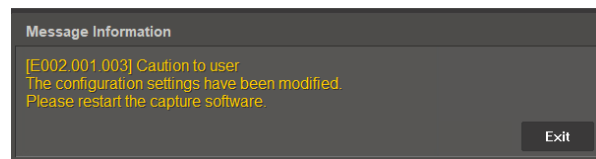


NOTICE

- **The main code** indicates the source of error codes. The source is categorized as hardware, software, an acquisition module, etc.
- **The 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.

For non-error system notifications, the message text will appear in yellow (see below).

NOTICE



13.2.1 Main Code - Hardware (001)

13.2.1.1 Subcode – Generator-Related Error (001)

Tail code	Description
001	Appears when the tube is not ready for use
002	Appears when the cable between the tube tank and Inverter board is disconnected
003	Appears when the inverter board's current exceeds the maximum allowable level during X-ray irradiation
004	Appears when there is $\pm 10\text{kV}$ or more voltage difference in tube voltage compared to a reference value
005	Appears when there is $\pm 0.5\text{mA}$ or more current difference in tube current compared to a reference value
006	Appears when there is $\pm 20\text{kV}$ or more voltage difference in tube voltage feedback compared to the average value
007	Appears when there is $\pm 1\text{mA}$ or more current difference in tube current feedback compared to the average value
008	Appears when the temperature of the mono tank is above the setting temperature
009	Appears when the inverter output current is higher than 1A during X-ray irradiation (In EP, IP conditions)
010	Appears when the inverter board falsely recognizes the exposure switch signal as OFF after the irradiation. On command
011	Appears when the X-ray OFF command is not sent to the inverter board in 0.5 seconds after turning off the exposure switch
012	Appears when kV feedback is over -20kV compared to the setting value during X-ray irradiation
013	Appears when kV feedback is over $+20\text{kV}$ compared to the setting value during X-ray irradiation.
014	Appears when the mA feedback value is less than 50% compared to setting conditions during X-ray irradiation.
015	Appears when the mA feedback value is higher than 150% compared to setting conditions during X-ray irradiation.

13.2.1.2 Subcode - Motor-Related Error (002)

Tail code	Description
021	Appears when rotator-axis motor origin movement fails

Tail code	Description
027	Appears when CEPH sensor motor origin movement fails
030	Appears when quadruple axis collimator left origin movement fails
031	Appears when quadruple axis collimator right origin movement fails
032	Appears when quadruple axis collimator up origin movement fails
033	Appears when quadruple axis collimator down origin movement fails
036	Appears when an error occurs during the collimator filter axis motor initialization
037	Appears when the generator tilting fails
039	Appears when X-axis motor origin movement fails
040	Appears when Y-axis motor origin movement fails
041	Appears when the detector encounters a problem during the location initialization after the user clicks the 'Confirm' button.

13.2.1.3 Subcode – Exposure Switch-Related Error (003)

Tail code	Description
001	Appears when the exposure switch is pressed while turning on the equipment
002	Appears when acquisition process is canceled from the exposure switch by user.

13.2.1.4 Subcode – Other Errors (004)

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

13.2.2 Main Code – Software (002)

13.2.2.1 Subcode – Sequence-Related Error (001)

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

13.2.2.2 Subcode – PC Resolution Related Error (010)

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

13.2.2.3 Subcode – PC Network-Related Error (024)

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

13.2.3 Main Code - Acquisition Module (003)

13.2.3.1 Subcode – Initialization Failure-Related Error (010)

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

13.2.3.2 Subcode – Capture Failure-Related Error (020)

Tail code	Description
000	Appears when there is a capture error

13.2.3.3 Subcode – Reconstruction Failure-Related Error (030)

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

13.2.3.4 Subcode – Hardware-Related Error (061)

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

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14. Cleaning and Disinfection

14.1 Preparation

Before cleaning and disinfecting the equipment, complete the steps below:

- Turn off the equipment.
- Wear safety gloves.

For the cleaning agent, select the product that satisfies the following conditions:

- Non-alcoholic
- Neither oil nor gas type.
- Approved by FDA and local regulations for chemical products.
- Chlorine-Dioxide based.
- Contains none of the listed chemicals: silicone, acetone, phenol, acetic acid, peroxide, sodium hypochlorite, isopropyl alcohol (2-propanol, isopropanol, iodine-splitting agents, and oxygen-splitting agents.

NOTICE	Oil or gas-type cleaning products may cause corrosion and deterioration.
IMPORTANT	The user cannot remove the covers on the equipment. Only VATECH-approved technicians can open them for inspection.
WARNING	Cleaning the equipment while the power is still on may cause electrical shock, burns, and other injuries to you and other people in the vicinity of the equipment.

14.2 Cleaning

Before capturing an image, clean the accessories or parts that have contact with the patient's skin. The list below shows examples of accessories and parts that require cleaning:

(Class I under Rule 1 of Annex VIII of MDR 2017/745)

- Normal / Special A / Special B bite block
- Temple support
- Chinrest
- Nasal positioner
- Ear rods
- Protractor
- Column up/down switch and holder
- Model jig
- Carpus plate

Accessory / Part	Procedure
Bite blocks / Temple supports / Chinrest / Nasal positioner / Carpus plate / Ear rods / Protractor / Model jig/column up / down switch and holder	1) Remove visible soil with a paper wipe or disposable cloth. 2) Gently clean the target area using a soft cloth dampened with a cleaning agent. 3) Dry the cleaned parts and accessories with a dry cloth until no liquid is left.
PC and its peripherals	Clean each part following the manufacturer's instructions.
Outer covers	Wipe the outer covers with a dry cloth once a day.

NOTICE

Contact **VATECH's** customer service for more information on cleaning the equipment.

WARNING

Do not spray or pour the cleaning agent over the equipment. Liquid can damage equipment or cause a fire.

IMPORTANT

Do not use the cloth soaked in the cleaning agent to clean the equipment. Liquids may slip into the equipment. Put a small amount of cleaning agent on the cloth to avoid the incident for use.

14.3 Disinfection

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

- Use the product approved by the safety regulations of the country where the equipment is installed.
- Follow the directions on the product's label.
- Disinfect the accessories and parts that are frequently touched by people including patients.
- Do not use a UV sterilizer to disinfect the equipment. UV light can discolor the equipment's surface.

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15. Maintenance

15.1 Regular Maintenance

- **VATECH** requires periodic constancy tests to assure image quality and safety for its patients and users.
- Only **VATECH**-authorized technicians can inspect and repair the equipment. Contact the service center or your local **VATECH** representative for technical assistance.
- Users cannot inspect or repair the equipment. Contact the service center or your local **VATECH** representative for technical assistance.
- Users cannot remove the equipment's cover. There are no repairable parts inside.
- Users cannot reform or modify the equipment, cables, or wires. Modification can damage the equipment beyond repair.
- Turn off the equipment before inspection or repair.
- Inspect and repair the equipment on a flat surface.
- Do not pull cables by force.
- Ensure that the equipment is well-grounded.
- Ensure that all detachable parts are clean.
- Avoid the following places when storing the equipment or its components:
 - Susceptible to water or humidity
 - Prone to extreme fluctuation in temperature
 - Exposed to direct sunlight, salt, dust, and other pollutants.

15.2 Maintenance Task Checklist

Tasks	Period
Ensure that the equipment is clean and ready for use before the operation.	Daily
Ensure that all parts directly contacting the patients are clean.	Daily
Ensure that the main power switch is turned off after the operation.	Daily
Check for the temperature of the power cords.	Daily
Ensure that the LED indicator turns yellow when you press the exposure switch .	Daily
Ensure that the LED indicator remains yellow during the operation.	Daily
Check for defects on the cables inside and outside the equipment.	Daily
Check the correct operation of the emergency stop switch	Weekly
Ensure that all labels on the equipment are intact and legible.	Weekly
Check the condition of the exposure switch .	Monthly
Check the sound of the audio messages from the equipment.	Monthly

15.3 QA Test

15.3.1 Who Performs a QA Test

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 service representative certified to perform radiological functions by the law in the state where 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 data records.

Test	Recommended Period
CT Number Test	Yearly
CT Uniformity Test	Yearly
High & Low Contrast Test	Initially and yearly

For technical assistance for QA tests, contact your local VATECH service representative.

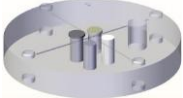
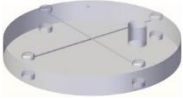
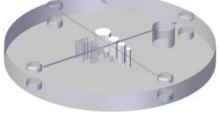
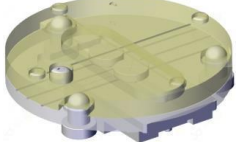
15.3.2 Phantom Kit Information

We strongly recommend regularly performing three tests (CT number, CT uniformity, high & low contrast) explained in this chapter at the interval and time specified by the manufacturer or the state law where the X-ray system is installed.

To conduct tests, you need to use the phantom kit consisting of a user manual and the phantoms as specified in the table below.

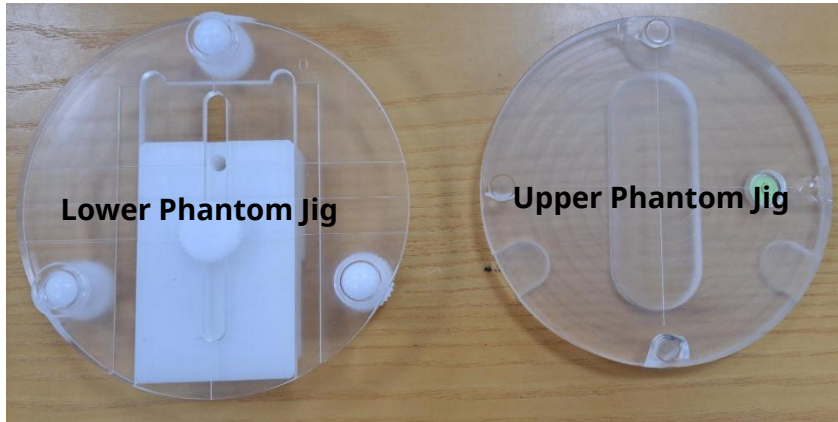
Kit Contents	Qty.
CT number check phantom	1
Uniformity check phantom	1
S&C check phantom	1
Phantom jig	1
Phantom kit user manual	1

The table below shows the specifications for each phantom inside the kit.

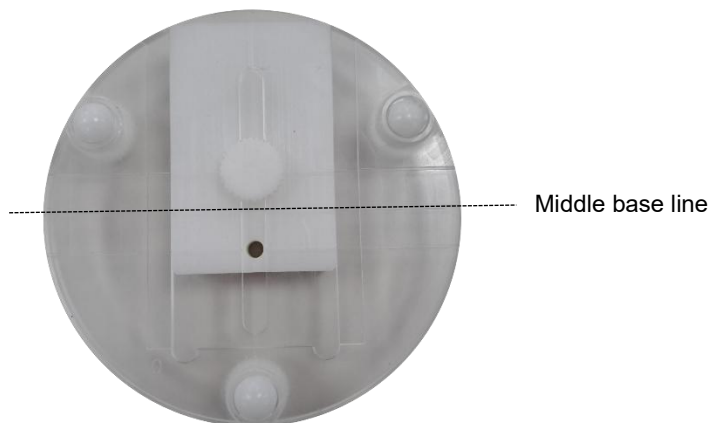
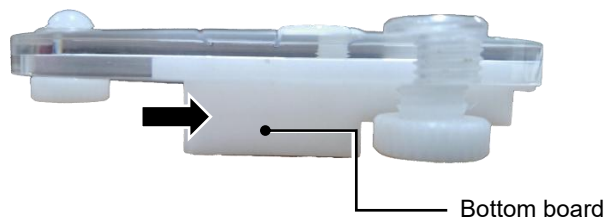
Image	Name	Intended use	Manufacturer
	CT Number Check Phantom	CT number inspection and calibration	VATECH Co., Ltd.
	Uniformity Check Phantom	CT Image Homogeneity and noise inspection	VATECH Co., Ltd.
	S&C Check Phantom	Low and high contrast resolution inspection	VATECH Co., Ltd.
	Phantom Jig	CT image inspection and calibration	VATECH Co., Ltd.

15.3.3 Installing Phantom Jig

Installing the phantom jig is the first key step in a QA test. Follow the steps below to install the phantom jig and calibrate it for the QA test.



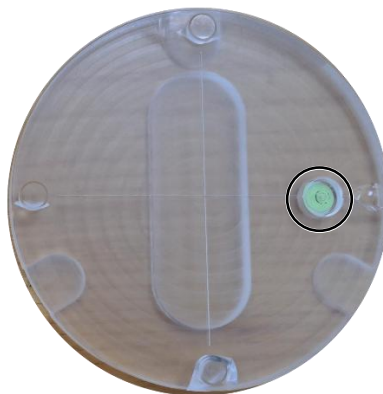
1. Remove the **chinrest**, **bite block**, and **temple supports** from the handle frame.
2. Calibrate the lower phantom jig as illustrated below:
 - 1) Slide the bottom board until the groove on the board is aligned with the middle base line.



- 2) When the alignment is complete, turn the bolt clockwise to fix the bottom board in place.



3. Insert the lower phantom jig on the handle frame where you have removed the chinrest and bite block.
4. Assemble the upper phantom jig on the top of the lower phantom jig.
5. [Leveling the phantom jig] Check the bubble level on the upper phantom jig. If the jig is level, the bubble inside the device should stay at the center.



If it does not, use the align pins of the lower phantom jig to adjust the phantom until the bubble comes to the center.

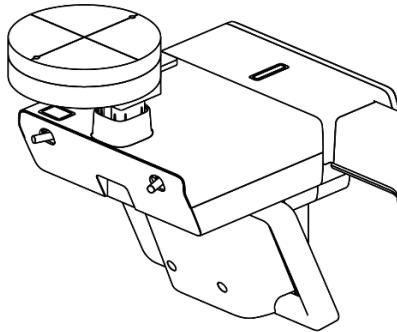
15.3.4 Performing QA Test

NOTICE

Before performing a QA test, ensure that the phantom jig is properly installed.

15.3.4.1 CT Number Test

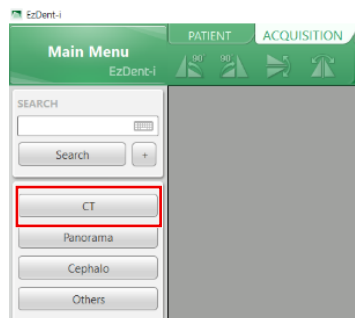
1. Place the **CT number check phantom** on the phantom jig,



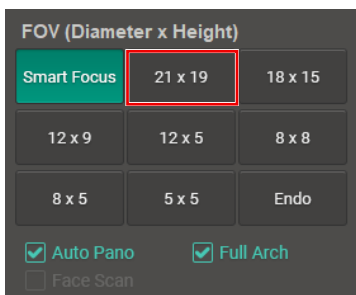
2. Double-click the **EzDent-i** icon on your PC.



3. Go to the **AQUISITION** tab and select 'CT' from the modality menu to open the DENTAL CT console window.



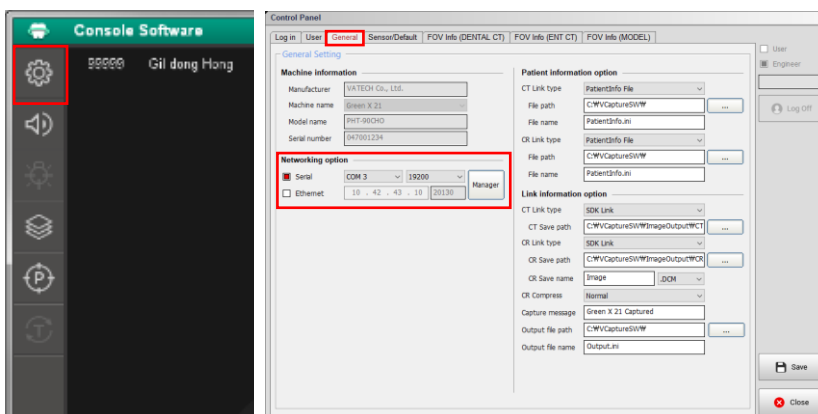
4. In the DENTL CT console window, select '21x19' on the FOV menu.



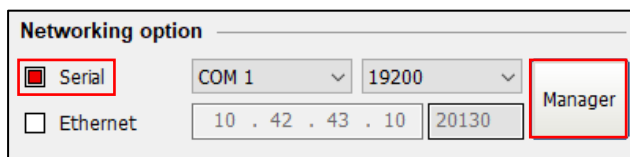
5. Click the **Confirm** button.

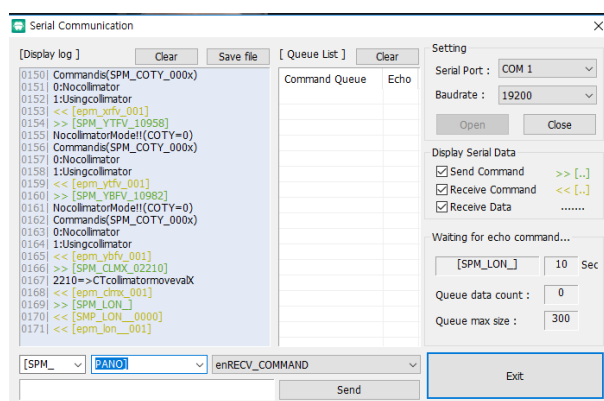


6. Click  on the console software to open the **control panel window**. Then select the **General** tab > **Networking Option** > **Serial**.



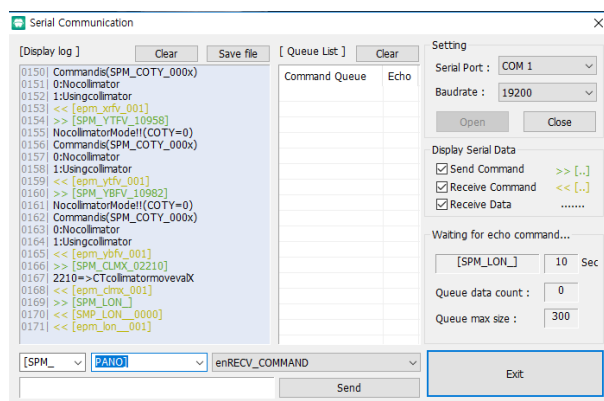
7. Click the **Manager** button to open a **serial communication window**.



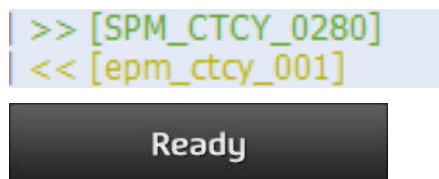


Serial Communication Window

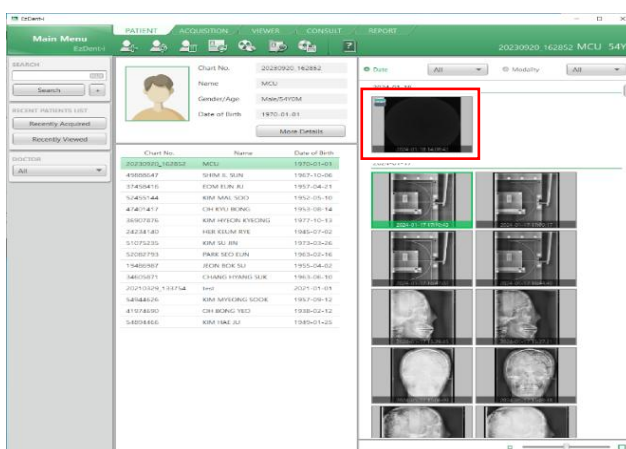
8. In the window, enter "[SPM_CTCY_0282]" to capture the center of the phantom. Click the **Send** button once entering the command.



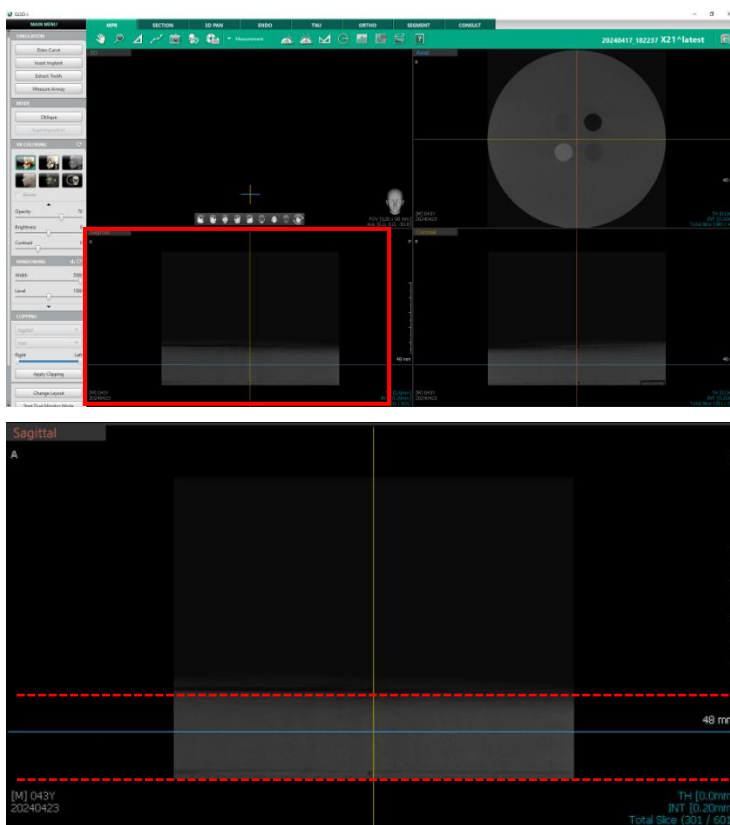
9. When the "[epm_ctcy_001]" appears in the Display log, click the **Ready** button in the console window.



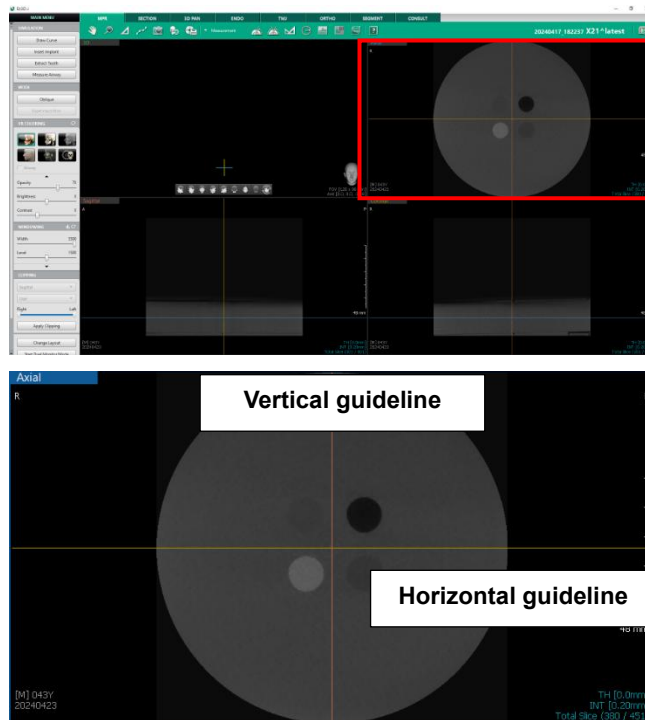
10. Press the X-ray exposure switch according to the instructions in the Message Information window.
11. Return to the Ezdent-i window and click the captured image. Once the image is clicked, Ez3D-i will automatically start.



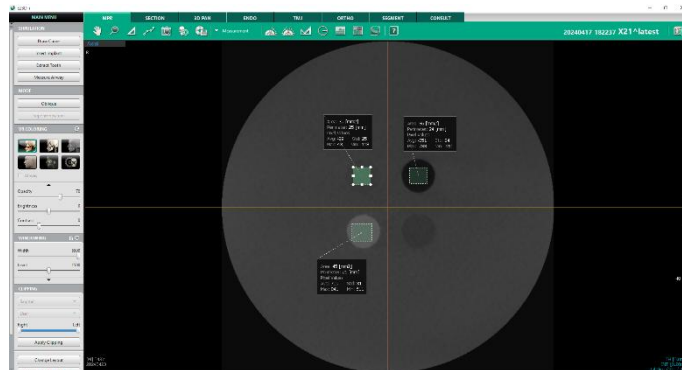
12. In the Ez3D-i window, go to the '**Sagittal**' screen, and drag the guideline down to the middle between the top and bottom of the phantom.



13. Go to the Axial window and check if the vertical and horizontal guidelines are placed as illustrated below. Then double-click the 'Axial' label for the full-screen mode.



14. Select  from the toolbar and click the “Water”, “Air”, and “Teflon” areas as illustrated below. When clicking each area, a pop-up will appear.



15. Check the average (avg) pixel value in the pop-up and compare the value with standards in the table below. The pixel value for each material should fall within the standard range.

Material	Mean	Lower Limit	Upper Limit	Scope
Air	-900 HU	-1030 HU	-990 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	

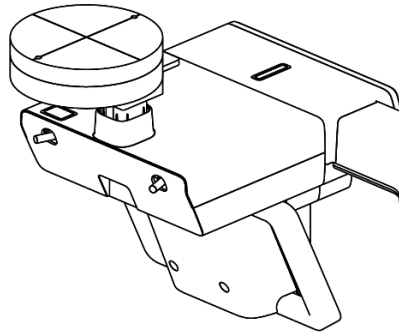


16. Click  to capture and save the Ez3D-i screen with pixel value information.
17. Remove the **CT number check phantom** from the phantom Jig.

15.3.4.2 CT Uniformity Test

Follow the steps below to perform a CT uniformity test.

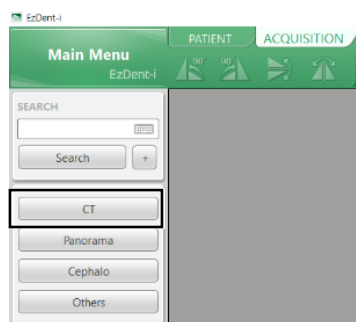
1. Place the **uniformity check phantom** over the phantom jig.



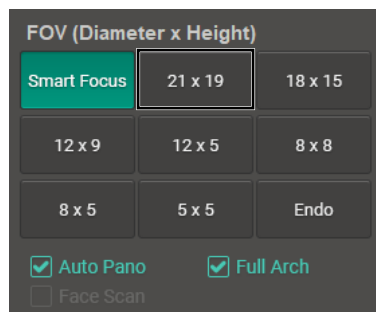
2. Double-click the EzDent-i icon on your PC.



3. Go to the **AQUISITION** tab and select 'CT' from the modality menu to open the DENTAL CT console window.



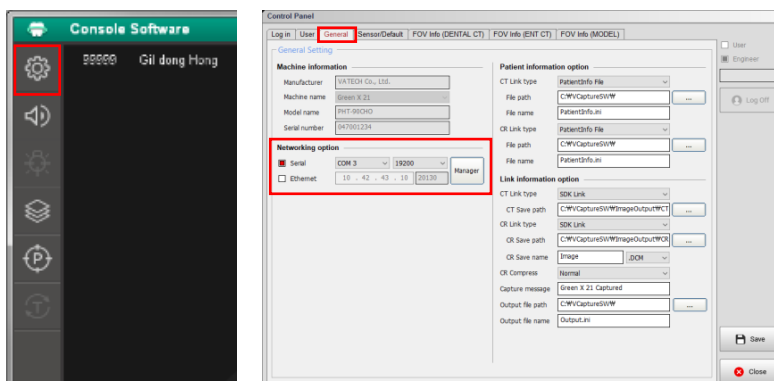
4. In the DENTAL CT console window, select '**21x19**' on the FOV menu.



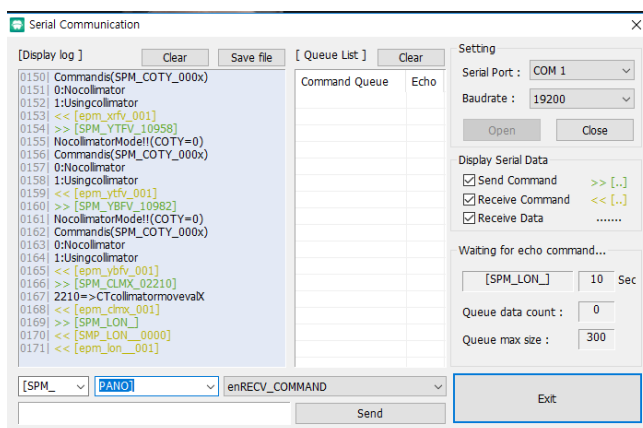
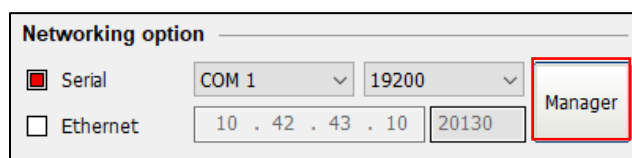
5. Click the **Confirm** button.



6. Click  on the console software to open the **control panel window**. Then select the **General** tab > **Networking Option** > **Serial**.

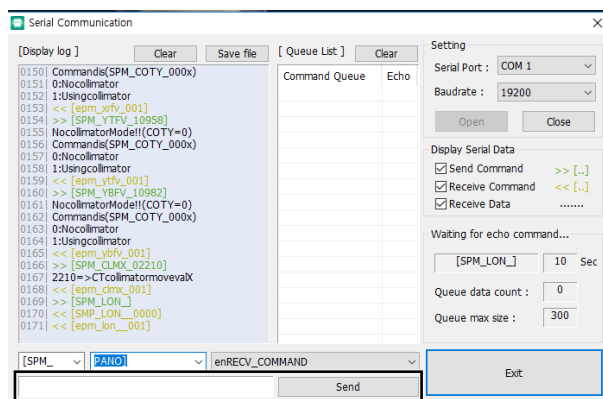


7. Click the **Manager** button to open a **serial communication window**.

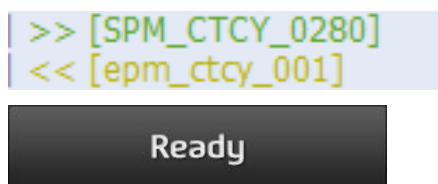


Serial Communication Window

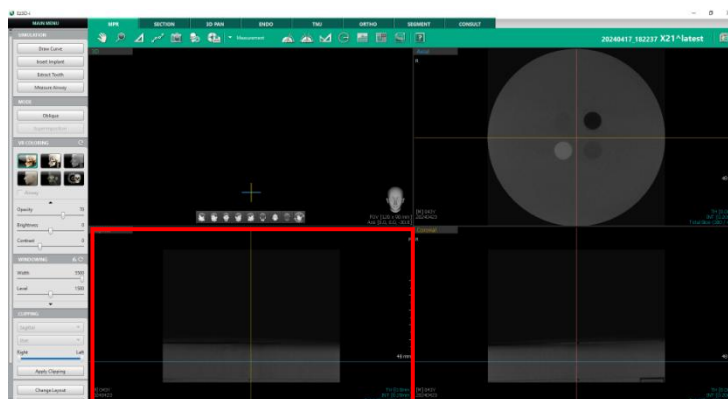
8. In the window, enter "[SPM_CTCY_0282]" to capture the center of the phantom. Click 'Send' after entering the command.

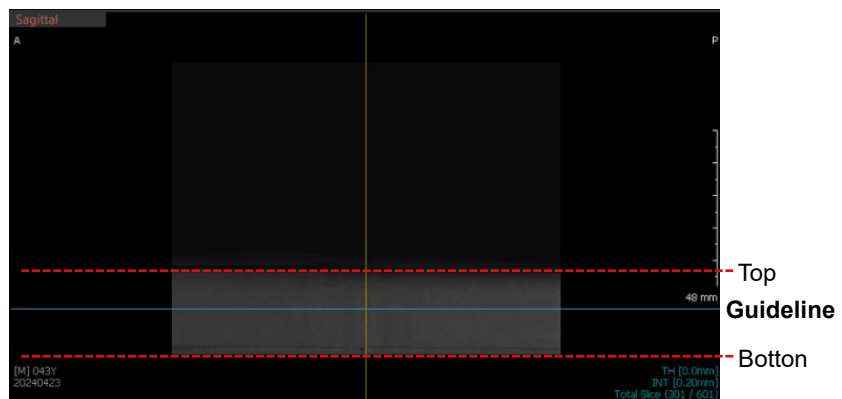


9. When the "[epm_ctcy_001]" appears in the display log, click the **Ready** button in the console window.

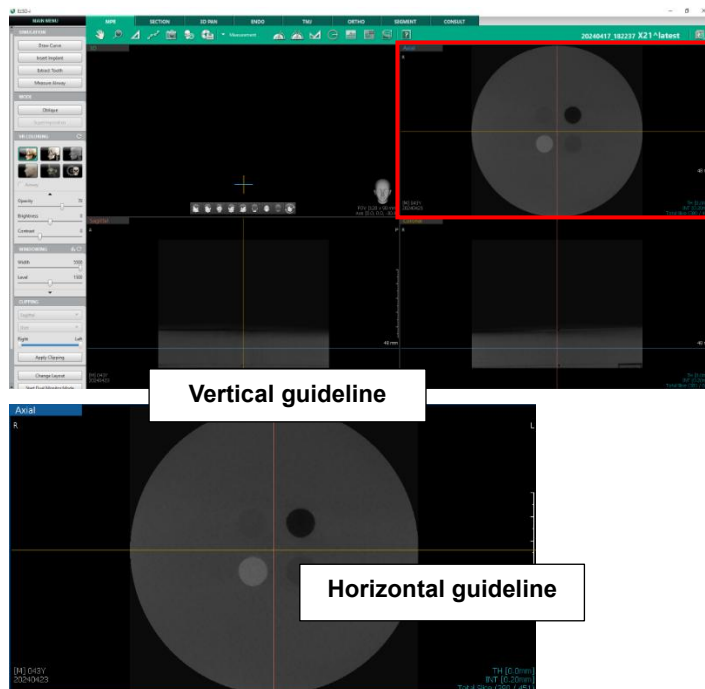


10. Press the X-ray exposure switch according to the instructions in the Message Information window.
11. Return to the Ezdent-i window and select the captured image. The selected image will be opened in the Ez3D-i window.
12. In the Ez3D-i window, go to the 'Sagittal' window, and drag the guideline down to the middle between the top and bottom of the phantom.

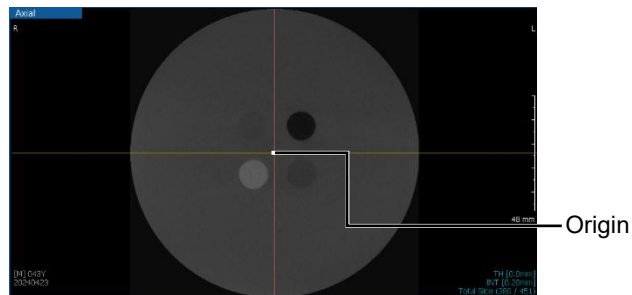




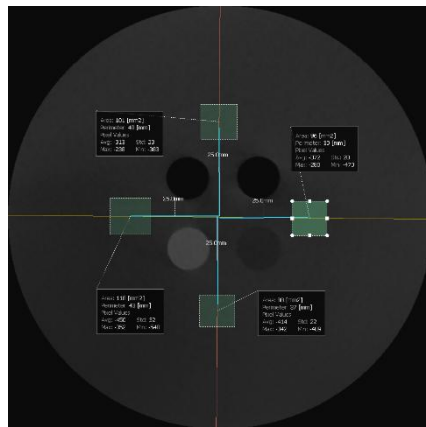
13. Go to the Axial window and check if the vertical and horizontal guidelines are placed as illustrated below. Then double-click the 'Axial' label for the full-screen mode.



14. Click  and draw 25.0 mm lines in four directions from the origin.



15. Click  and select the end of each of the four lines. Once selected, a pop-up will appear as illustrated below.



16. Check the average in the pixel value pop-up and repeat it for all four ROIs.

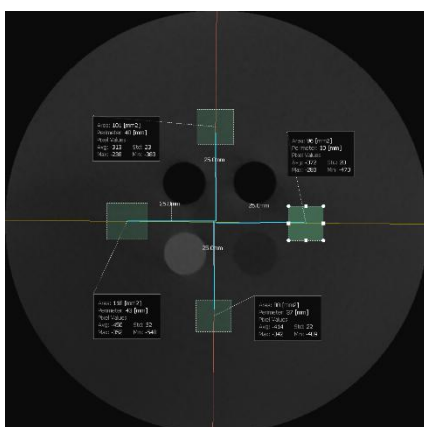


17. **[Measuring Homogeneity]** Among the average values of four ROIS, select the largest and the smallest. Then calculate the difference between two values and compare the result with the standard in the table below.

Calculation	Standard	Scope
Subtract the smallest value from the largest value among the average values of four ROIs	The difference should be less than 400 HU	61223.3.5 INTRODUC TION



18. Click  to capture and save the Ez3D-i screen with pixel value information.

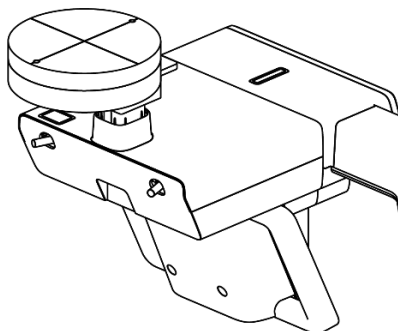


19. Remove the **uniformity check phantom** from the phantom Jig.

15.3.4.3 High and Low Contrast Resolution

Follow the steps below to perform a high and low contrast resolution test.

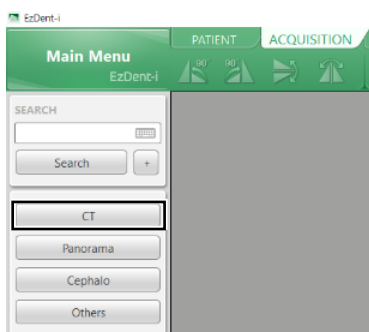
1. Place the **S&C check phantom** on the phantom jig.



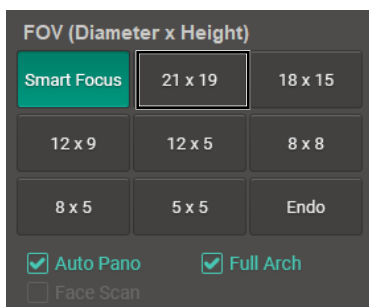
2. Start **EzDent-i** by double-clicking the desktop icon.



3. Go to the **ACQUISITION** tab and select 'CT' from the modality menu to open the DENTAL CT console window.



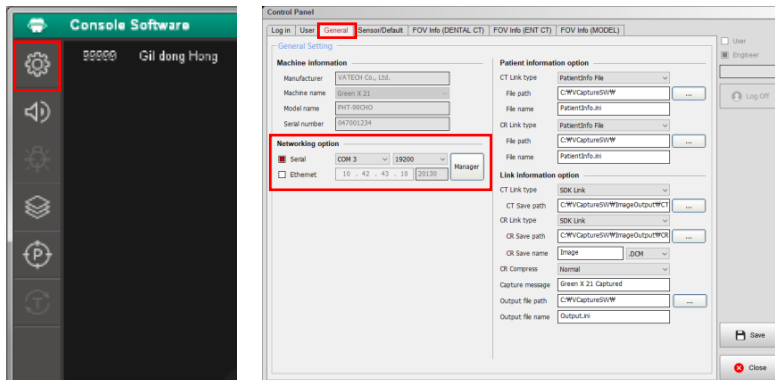
4. In the DENTAL CT console window, select '**21x19**' on the FOV menu.



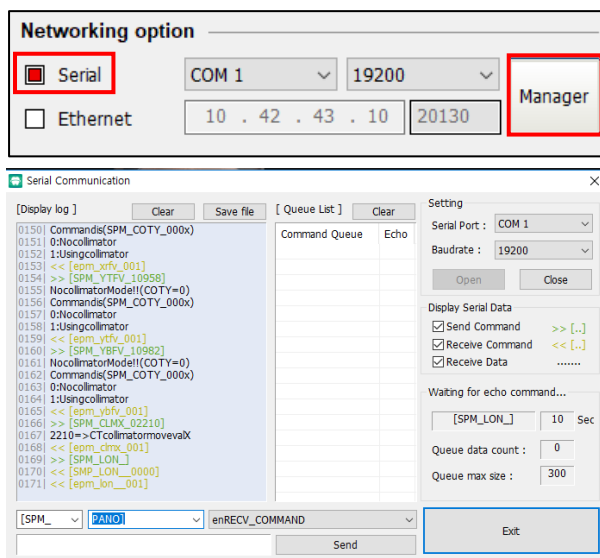
- Click the **Confirm** button.



- Click  on the console software to open the control panel window. Then select the **General** tab > **Networking Option** > **Serial**.

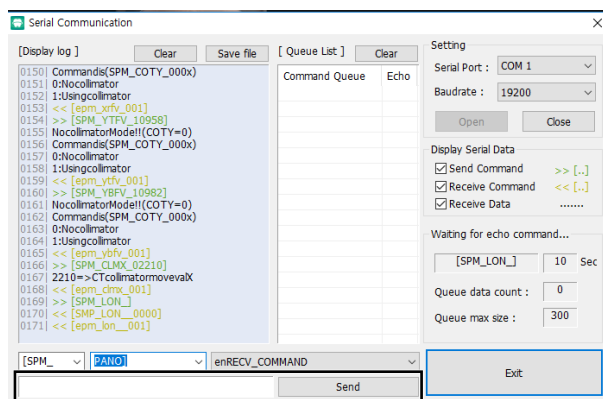


- Click the **Manager** button to open a **serial communication** window.

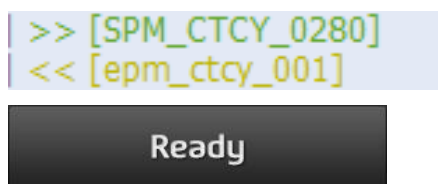


Serial Communication Window

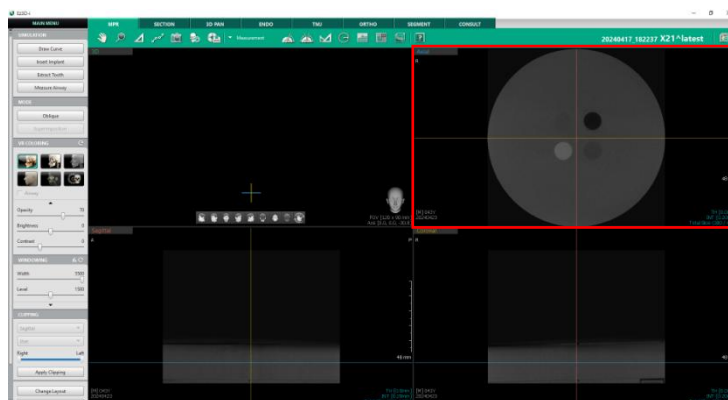
8. In the window, enter "[SPM_CTCY_0282]" to capture the center of the phantom. Click the **Send** button after entering the command.



9. When the "[epm_ctcy_001]" appears in the display log, click the **Ready** button in the console window.

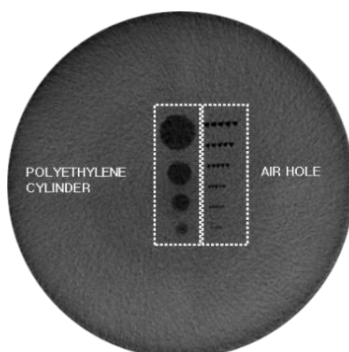


10. Press the X-ray exposure switch according to the instructions in the Message Information window.
11. Return to the Ezdent-i window and click the captured image. Once the image is clicked, Ez3D-i will automatically start.
12. Go to the Axial window and click the 'Axial' label for the full-screen mode.

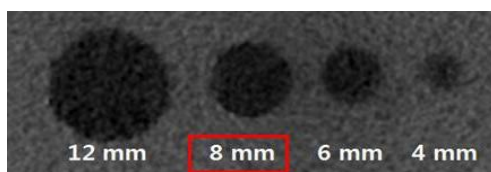




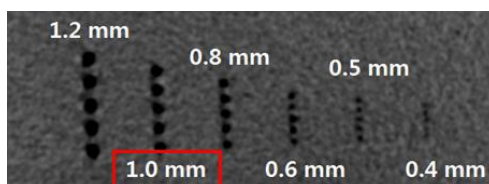
13. **[Checking high & low contrast]** To evaluate the high contrast resolution, check the visibility of the **0.1 mm air hole**. To evaluate the low contrast resolution, check the visibility of the **8.0 mm PE(Polyethylene) cylinder** at 50 cm from the monitor.



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. Click  to capture and save the Ez3D-i screen with pixel value information.
15. Remove the **S&C check phantom** from the phantom Jig.

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16. Disposing of the Equipment

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

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

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



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



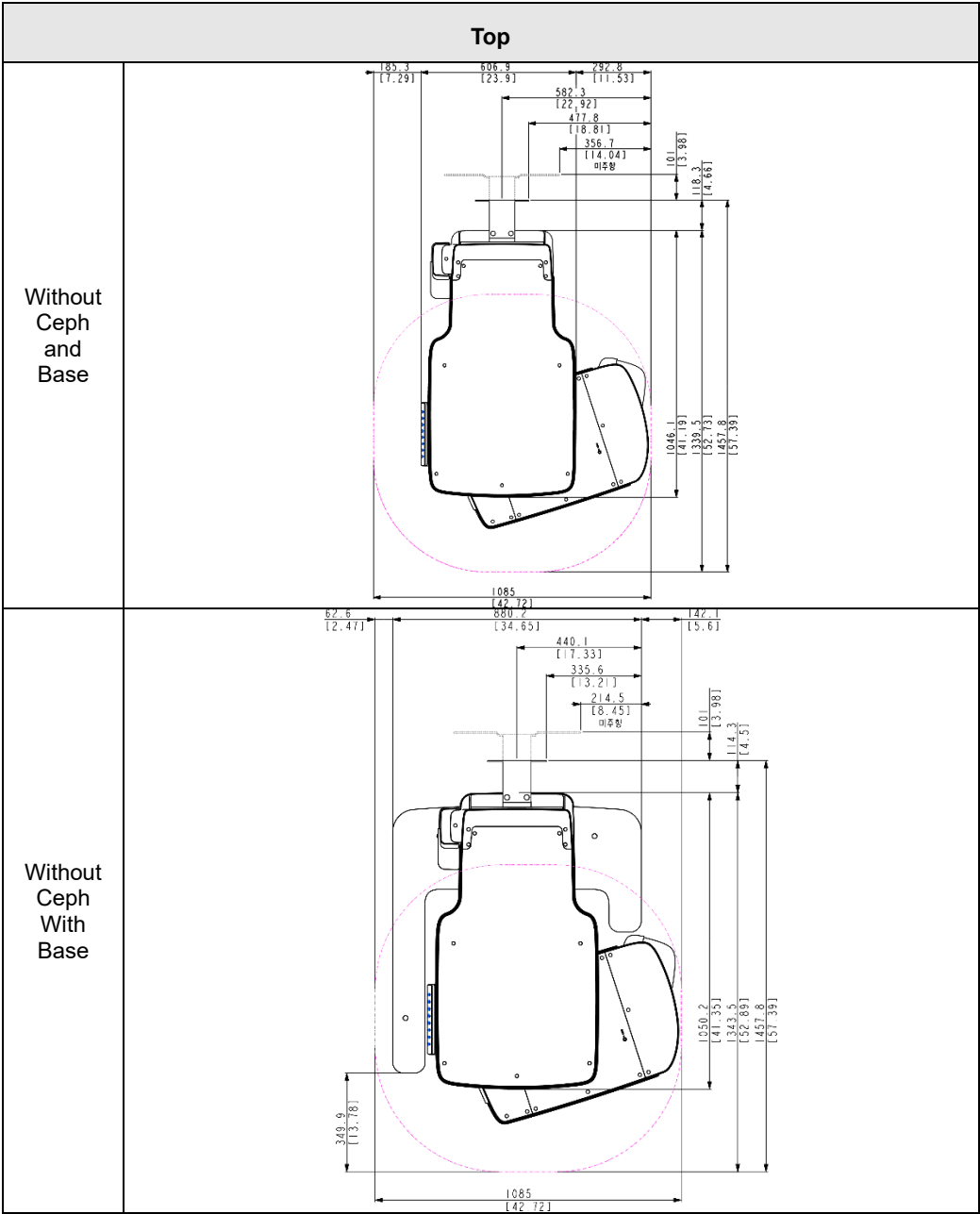
Observe all regulations relevant to the disposal of waste in your country.

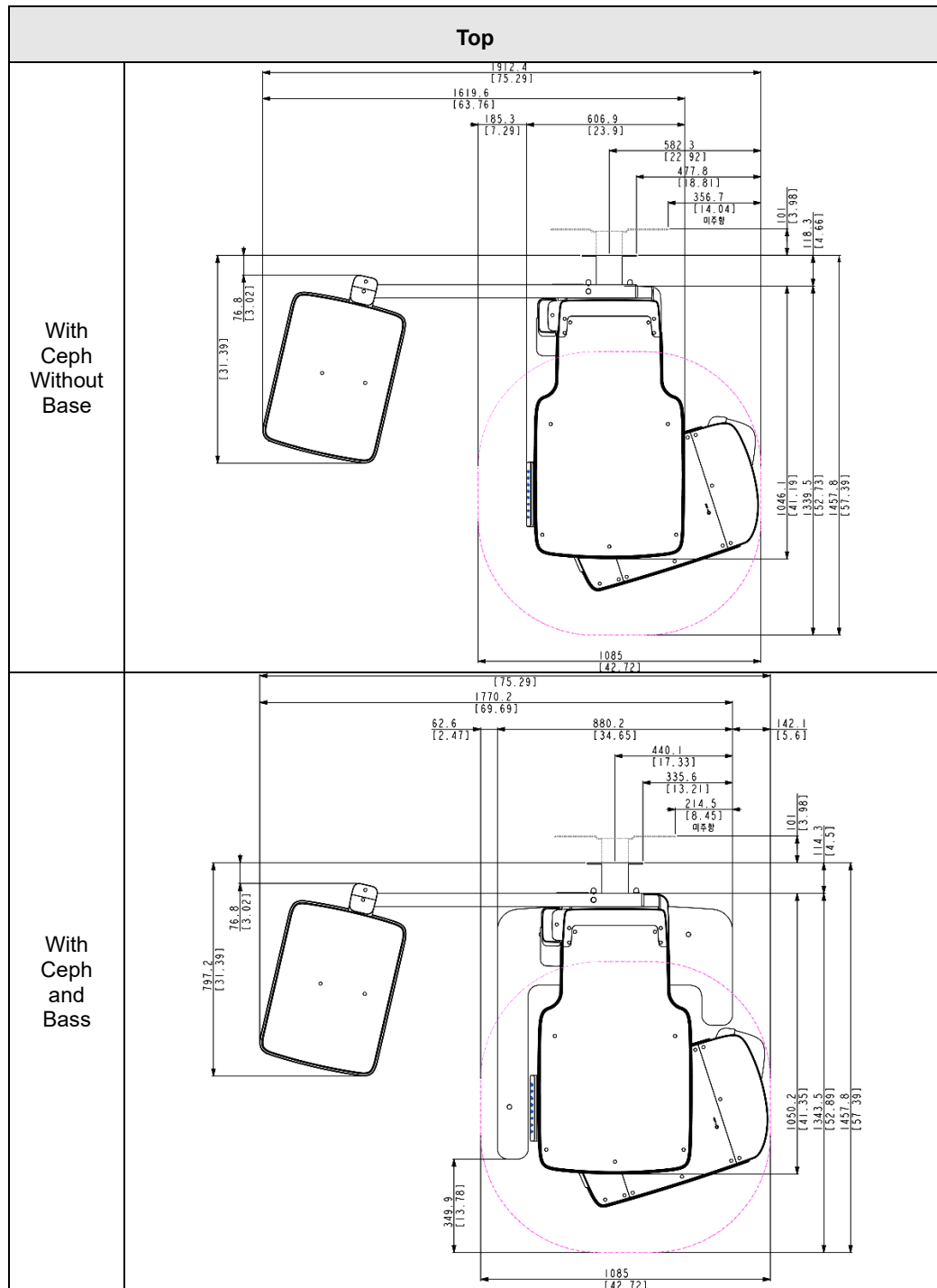
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17. Technical Specifications

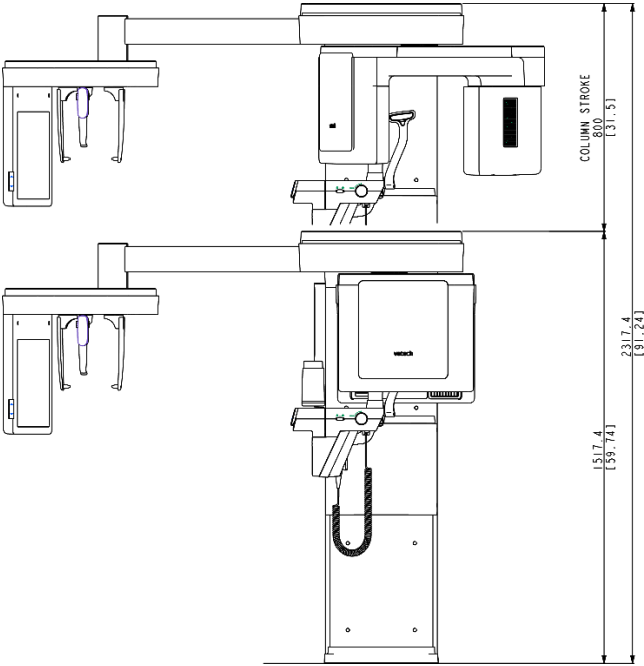
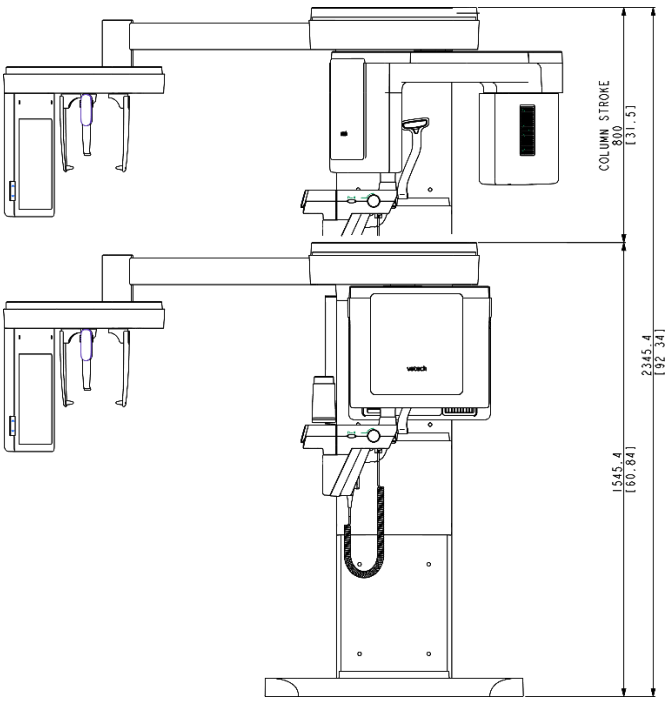
17.1 Mechanical Specifications

17.1.1 Dimensions





Front	
Without Ceph and Base	2317.4 [759.74] COLUMN STROKE 800 [31.5]
Without Ceph With Base	2345.4 [92.34] COLUMN STROKE 800 [31.5]

Front	
With Ceph Without Base	 Column Stroke: 800 [31.5] Overall Height: 1517.4 [59.74] / 2317.4 [91.24]
With Ceph and Base	 Column Stroke: 800 [31.5] Overall Height: 1545.4 [60.84] / 2345.4 [92.34]

Category	Unit Option		Description
	Ceph	Base	
Weight	X	X	165.4 kg (364.64 lbs.)
	X	O	220.7 kg (486.56 lbs.)
	O	X	190.0 kg (418.88 lbs.)
	O	O	245.3 kg (540.79 lbs.)
Total Height	-	X	Max. 2317.4 mm (91.24")
	-	O	Max. 2345.4 mm (92.34")
Dimension (LxWxH)	X	X	1085.0(L) x 1457.8(W) x 2317.4(H) (mm) 42.72(L) x 57.39(W) x 91.24(H) (")
	X	O	1085.0(L) x 1457.8(W) x 2345.4(H) (mm) 42.72(L) x 57.39(W) x 92.34(H) (")
	O	X	1912.4(L) x 1457.8(W) x 2317.4(H) (mm) 75.29(L) x 57.39(W) x 91.24(H) (")
	O	O	1912.4(L) x 1457.8(W) x 2345.4(H) (mm) 75.29(L) x 57.39(W) x 92.34(H) (")
Rotating Unit's Vertical Movement			Max. 800 mm (31.50")
Installation Type			Wall mount (Default) / Base Stand (Optional)
Package Organization			Main box (Default), CEPH box (Optional), Base box (Optional)

17.1.2 Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	560	350	210	1: 1.60
CEPH	1745	1524	211	1: 1.14
CBCT*	560	350	210	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
- **CBCT*** = DENTAL and ENT CT

17.2 Technical Specifications

17.2.1 X-ray Generator

Specifications

Item			Description
Generator	Model		LDG-07E22T2
	Rated output power		1.6 kW (1 sec)
	Inverter model name		INV-22
	Type		Inverter
	Normal/ Pulse	kVp	60 kV~99 kV (1 kV increment)
		mA	4 mA~16 mA Dental / ENT CT: 0.1 mA increment PANO / CEPH: 1.0 mA increment
	Cooling		Thermals protect
	Added Filter		PANO / CEPH: 1.5 mm Al Dental / ENT CT: 1.5 mm Al (fixed) + 3.0 mm Al
	Permanent filtration		Min. 1.0 mm Al
Tube	Total filtration		Min. 2.5 mm Al
	Manufacturer		Canon Electron Tubes & Devices
	Model		D-052SB (Stationary Anode type)
	Focal spot size		0.5 mm (IEC 60336)
	Target Angle		5 degrees
	Permanent filtration		At least 0.8 mm Al equivalent at 50kV
	X-ray Coverage		95 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	Image Option	Arch / FOV	Examination	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	High Resolution	Standard	Standard	60~90	4~14	13.5
			Left	60~90	4~14	6.7
			Right	60~90	4~14	6.7
			Front	60~90	4~14	11.2
		Narrow	Standard	60~90	4~14	13.5
			Left	60~90	4~14	6.7
			Right	60~90	4~14	6.7
			Front	60~90	4~14	11.2
		Wide	Standard	60~90	4~14	13.5
			Left	60~90	4~14	6.7
			Right	60~90	4~14	6.7
			Front	60~90	4~14	11.2
		Orthogonal	Standard	60~90	4~14	13.5
			Left	60~90	4~14	6.7
			Right	60~90	4~14	6.7
			Front	60~90	4~14	11.2
		Bitewing	Standard	60~90	4~14	9.0
			Left	60~90	4~14	4.5
			Right	60~90	4~14	4.5
			Incisor	60~90	4~14	2.8
		Child	Standards	60~90	4~14	11.5
			Left	60~90	4~14	5.7
			Right	60~90	4~14	5.7
			Front	60~90	4~14	9.2
	Green	Standard	Standard	60~90	4~14	7.3
			Left	60~90	4~14	3.7
			Right	60~90	4~14	3.7
			Front	60~90	4~14	5.9
		Narrow	All	60~90	4~14	7.3
			Left	60~90	4~14	3.7
			Right	60~90	4~14	3.7
			Front	60~90	4~14	5.9
		Wide	Standard	60~90	4~14	7.3
			Left	60~90	4~14	3.7
			Right	60~90	4~14	3.7
			Front	60~90	4~14	5.9
		Orthogonal	Standard	60~90	4~14	7.3
			Left	60~90	4~14	3.7
			Right	60~90	4~14	3.7
			Front	60~90	4~14	5.9

Mode	Image Option	Arch / FOV	Examination	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
		Bitewing	Standard	60~90	4~14	5.3
			Incisor	60~90	4~14	1.4
			Left	60~90	4~14	2.6
			Right	60~90	4~14	2.6
			Incisor	60~90	4~14	1.4
		Child	Standard	60~90	4~14	5.6
			Left	60~90	4~14	2.8
			Right	60~90	4~14	2.8
			Front	60~90	4~14	4.5
	-	Sinus LAT	-	60~90	4~14	3.7
		Sinus PA	-	60~90	4~14	8.0
		TMJ LAT	-	60~90	4~14	6.7
		TMJ PA	-	60~90	4~14	6.1
CEPH	High Resolution	Lateral		60~99	4~15	0.9
		PA		60~99	4~15	0.9
		SMV		60~99	4~15	0.9
		Water's View		60~99	4~15	0.9
		Carpus		60~99	4~15	0.9
	Green	Lateral		60~99	4~15	0.9
		PA		60~99	4~15	0.9
		SMV		60~99	4~15	0.9
		Water's View		60~99	4~15	0.9
		Carpus		60~99	4~15	0.9
DENTAL CT	High Resolution	21x19	-	60~99	4~12	15.2
		18x15	-	60~99	4~12	15.2
		12x5	-	60~99	4~12	7.0
		8x8	-	60~99	4~12	7.0
		8x5	-	60~99	4~12	7.0
		5x5	-	60~99	4~12	7.0
		Smart Focus (12X9)	-	60~99	4~12	18.0
		Endo (4x4)	-	60~99	4~12	18.0
	Green	21x19		60~99	4~12	15.2
		18x15		60~99	4~12	15.2
		12x9		60~99	4~12	7.0
		12x5		60~99	4~12	7.0

Mode	Image Option	Arch / FOV	Examination	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
		8x8		60~99	4~12	7.0
		8x5		60~99	4~12	7.0
		5x5		60~99	4~12	7.0
		Smart Focus (12X9)	-	60~99	4~12	18.0
		Endo (4x4)	-	60~99	4~12	18.0
ENT CT	High Resolution	21x19	-	60~99	4~12	15.2
		18x15	-	60~99	4~12	15.2
		12x9	-	60~99	4~12	7.0
		8x8	-	60~99	4~12	7.0
	Green	21x19		60~99	4~12	15.2
		18x15		60~99	4~12	15.2
		12x9		60~99	4~12	7.0
		8x8		60~99	4~12	7.0

17.2.2 X-ray Detector

Item	Description	
	PANO & DENTAL / ENT CT	CEPH
Model	Jupi1012X	Venu1012VD
Detector Type	IGZO TFT	a-Si TFT
Pixel Size	100 μm (1x1 binning) 200 μm (2x2 binning)	125 μm
Active Area	249.6 x 300.8 (mm)	250 x 300 (mm)
Frame Rate	30 fps @ 1x1 binning, 10 GigE. 60 fps @ 2x2 binning, 10 GigE. ≤ 300 fps (Panoramic, 3008x68)	Static detector for one-shot application
Analogue-Digital Conversion	16-bit	16-bit
Operating Condition	10 ~ 40°C (Temperature) 20 ~ 90% (Humidity)	5 ~ 35°C (Temperature) 30 ~ 80% (Humidity)
Storage Condition	-10 ~ 55°C (Temperature) 10 ~ 95% (Humidity)	-10 ~ 55°C (Temperature) 10 ~ 90 % (Humidity)
Sensor Size (L x W x H)	325 x 280 x 37 (mm)	285 x 340 x 15 (mm)
Sensor Weight	≤ 3.5 kg	≤ 2.3 kg (Including detector cable)
Converter	Csl: TI	Csl: TI
Energy Range	40~150 kVp	50~100 kVp
Video Output	10-Gigabit Ethernet	2.5-Gigabit Ethernet
MTF	1.0 @ 0 LP/mm >0.5 @ 1.0 LP/mm >0.3 @ 2.0 LP/mm >0.2 @ 2.5 LP/mm	Typ.71% @ 1.0 LP/mm Typ.41% @ 2.0 LP/mm Typ. 23% @ 3.0 LP/mm Typ. 13% @ 4.0 LP/ mm
Dynamic Range	> 60 dB	≥ 66 dB

17.2.3 Face Scanner

The specifications for the face scanner camera are listed on the table below.

Item	Description
Model	POP 2
Technology	Dual Camera Infrared Structured Light
Output Format	PLY, OBJ, STL
Wi-Fi	Wi-Fi 5

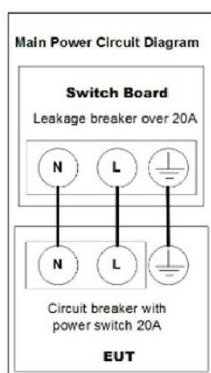
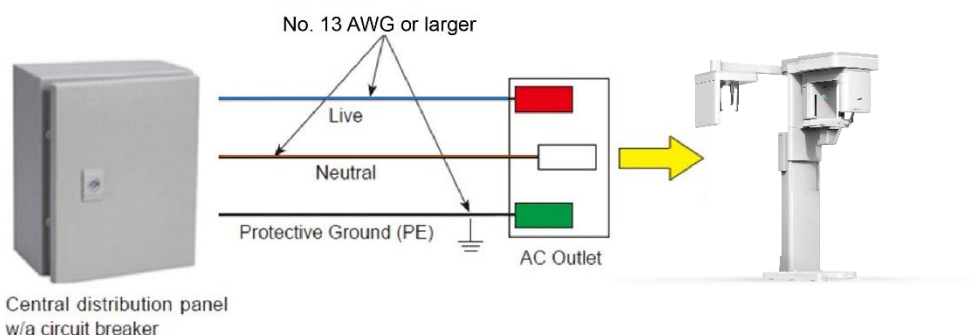
IMPORTANT

For the data transfer between the face scanner and PC, a router should be installed inside the X-ray room.

17.3 Electrical Specifications

Item	Description
Power supply voltage	100-240 V~
Frequency	50 / 60 Hz
Power Rating	2.2 kVA
Accuracy	Tube Voltage (kVp) $\leq \pm 10 \%$, Tube Current (mA) $\leq \pm 20 \%$, Exposure Time (s) $\leq \pm (5 \% + 50 \text{ ms})$

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



NOTICE

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

17.4 Environmental Specifications

	Item	Description
During Operation	Temperature	10~35 °C
	Relative humidity	30~75 %
	Atmospheric pressure	860~1060 hPa
During Transport and Storage	Temperature	-10~55 °C
	Relative humidity	10~75 %
	Atmospheric pressure	860~1060 hPa

17.5 System Performance

Imaging Mode	Performance Standards
PANO	Line Pair Resolution (Min. 3.1 lp/mm)
	Low Contrast (Min. 1.5 mm)
CEPH	Line Pair Resolution (Min. 2.8 lp/mm)
	Low Contrast (Min. 2.0mm)
CBCT	Noise (62.1 / permissive range 10~100)
	Mean CT Number 1) Water (-48/ permissive range -20 ~ 20) 2) Air (-976 / Permissive range -1030 ~ -900) 3) Teflon (975 / Permissive range 900 ~ 1100)
	Uniformity (11 / permissive range 0~150)
	MTF (1.6 / permissive range 1.00~3.50)
	Low Contrast (Min. 6.0 mm / permissive range 8.0~4.0) Note: A lower contrast value indicates better performance.
	High Contrast (Min. 0.4 mm / permissive range 1.0~ 0.4) Note: A lower contrast value indicates better performance.

18. Appendices

18.1 Recommended X-ray Exposure Tables

NOTICE

- **Scan time (ST):** the actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.
- **Exposure time (ET):** the actual time that the patient is exposed to the X-ray emission.

18.1.1 PANO

“Normal” and “Magic Pan” (of the PANO option) use identical exposure conditions.

Tab / PANO Option	Image Option	Arch Selection	PANO Examination	Scan time (s)	Exposure Time (s)
Normal / Normal	High Resolution	Narrow	Standard	14.1	13.5
			Right	14.1	6.7
			Left	14.1	6.7
			Front	14.1	11.2
		Normal	Standard	14.1	13.5
			Right	14.1	6.7
			Left	14.1	6.7
			Front	14.1	11.2
		Wide	Standard	14.1	13.5
			Right	14.1	6.7
			Left	14.1	6.7
			Front	14.1	11.2
		Child	Standard	12.0	11.5
			Right	12.0	5.7
			Left	12.0	5.7
			Front	12.0	9.2
		Orthogonal	Standard	14.1	13.5
			Right	14.1	6.7
			Left	14.1	6.7
			Front	14.1	11.2
			Bitewings	14.1	9.0

Tab / PANO Option	Image Option	Arch Selection	PANO Examination	Scan time (s)	Exposure Time (s)
			Bitewing Left	14.1	4.5
			Bitewing Right	14.1	4.5
			Bitewing Incisor	14.1	2.8
Normal / Normal	Green	Narrow	Standard	7.5	7.3
			Right	7.5	3.7
			Left	7.5	3.7
			Front	7.5	5.9
		Normal	Standard	7.5	7.3
			Right	7.5	3.7
			Left	7.5	3.7
			Front	7.5	5.9
		Wide	Standard	7.5	7.3
			Right	7.5	3.7
			Left	7.5	3.7
			Front	7.5	5.9
		Child	Standard	5.9	5.6
			Right	5.9	2.8
			Left	5.9	2.8
			Front	5.9	4.5
		Orthogonal	Standard	7.5	7.3
			Right	7.5	3.7
			Left	7.5	3.7
			Front	7.5	5.9
			Bitewings	7.5	5.2
			Bitewing Left	7.5	2.6
			Bitewing Right	7.5	2.6
			Bitewing Incisor	7.5	1.4
Normal / Insight PAN	-	Normal	-	14.1	7.5
	-	Child	-	14.1	7.5
Special	-	-	TMJ LAT Open	14.1	6.7

Tab / PANO Option	Image Option	Arch Selection	PANO Examination	Scan time (s)	Exposure Time (s)
	-	-	TMJ LAT Close	14.1	6.7
	-	-	TMJ PA Open	10.0	6.1
	-	-	TMJ PA Close	10.0	6.1
	-	-	Sinus LAT	4.0	3.7
	-	-	Sinus PA	8.8	8.0

*Image option selection (high resolution or green) is not available in the PANO special mode.

Voltage (kVp) / Current (mA)

Tab / PANO Option	Arch Selection	PANO Examination	Image Option	Patient	X-ray Intensity Level	Voltage (kVp)	Current (mA)
Normal / Normal	Narrow Normal Wide Orthogonal	Standard Right Left Front Bitewings Btw. Left Btw. Right Btw. Incisor	High Resolution	Man	Hard	75	10
					Normal	74	10
					Soft	73	10
				Woman	Hard	74	10
					Normal	73	10
					Soft	72	10
				Child	Hard	70	8
					Normal	69	8
					Soft	68	8
			Green	Man	Hard	76	9
					Normal	75	9
					Soft	74	9
				Woman	Hard	75	9
					Normal	74	9
					Soft	73	9
				Child	Hard	71	12
					Normal	70	12
					Soft	69	12
	Child	Standard Right Left Front	High Resolution	Child	Hard	70	8
					Normal	69	8
					Soft	68	8
			Green	Child	Hard	71	12
					Normal	70	12
					Soft	69	12
Normal / Insight PAN	Normal	-	-	Man	Hard	71	6
					Normal	70	6
					Soft	69	6
				Woman	Hard	70	6
					Normal	69	6
					Soft	68	6

Tab / PANO Option	Arch Selection	PANO Examination	Image Option	Patient	X-ray Intensity Level	Voltage (kVp)	Current (mA)
	Child	-		Child	Hard	68	6
					Normal	67	6
					Soft	66	6
				Child	Hard	68	6
					Normal	67	6
					Soft	66	6
Special	TMJ LAT TMJ PA Sinus LAT Sinus PA Open/Close	-	High Resolution	Man	Hard	75	10
					Normal	74	10
					Soft	73	10
				Woman	Hard	74	10
					Normal	73	10
					Soft	72	10
				Child	Hard	70	8
					Normal	69	8
					Soft	68	8
			Green	Man	Hard	75	10
					Normal	74	10
					Soft	73	10
				Woman	Hard	74	10
					Normal	73	10
					Soft	72	10
				Child	Hard	70	8
					Normal	69	8
					Soft	68	8

18.1.2 CEPH

CEPH Examination	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
Full Lateral / Lateral	High Resolution	Man	Hard	91	10	0.9	0.9
			Normal	90	10	0.9	0.9
			Soft	89	10	0.9	0.9
		Woman	Hard	90	10	0.9	0.9
			Normal	89	10	0.9	0.9
			Soft	88	10	0.9	0.9
		Child	Hard	75	10	0.9	0.9
			Normal	74	10	0.9	0.9
			Soft	73	10	0.9	0.9
	Green	Man	Hard	73	5	0.9	0.9
			Normal	72	5	0.9	0.9
			Soft	71	5	0.9	0.9
		Woman	Hard	72	5	0.9	0.9
			Normal	71	5	0.9	0.9
			Soft	70	5	0.9	0.9
		Child	Hard	62	5	0.9	0.9
			Normal	61	5	0.9	0.9
			Soft	60	5	0.9	0.9
PA Water SMV	High Resolution	Man	Hard	91	10	0.9	0.9
			Normal	90	10	0.9	0.9
			Soft	89	10	0.9	0.9
		Woman	Hard	90	10	0.9	0.9
			Normal	89	10	0.9	0.9
			Soft	88	10	0.9	0.9
		Child	Hard	75	10	0.9	0.9
			Normal	74	10	0.9	0.9

CEPH Examination	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
	Green	Man	Soft	73	10	0.9	0.9
			Hard	73	5	0.9	0.9
			Normal	72	5	0.9	0.9
		Woman	Soft	71	5	0.9	0.9
			Hard	72	5	0.9	0.9
			Normal	71	5	0.9	0.9
		Child	Soft	70	5	0.9	0.9
			Hard	62	5	0.9	0.9
			Normal	61	5	0.9	0.9
			Soft	60	5	0.9	0.9
Carpus	High Resolution	Man	Hard	89	10	0.9	0.9
			Normal	88	10	0.9	0.9
			Soft	87	10	0.9	0.9
		Woman	Hard	88	10	0.9	0.9
			Normal	87	10	0.9	0.9
			Soft	86	10	0.9	0.9
		Child	Hard	73	10	0.9	0.9
			Normal	72	10	0.9	0.9
			Soft	71	10	0.9	0.9
	Green	Man	Hard	71	5	0.9	0.9
			Normal	70	5	0.9	0.9
			Soft	69	5	0.9	0.9
		Woman	Hard	70	5	0.9	0.9
			Normal	69	5	0.9	0.9
			Soft	68	5	0.9	0.9
		Child	Hard	62	5	0.9	0.9
			Normal	61	5	0.9	0.9
			Soft	60	5	0.9	0.9

18.1.3 DENTAL CT

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
21x19	High Resolution	Man	Hard	91	5.6	18.3	15.2
			Normal	90	5.6	18.3	15.2
			Soft	89	5.6	18.3	15.2
		Woman	Hard	91	5.3	18.3	15.2
			Normal	90	5.3	18.3	15.2
			Soft	89	5.3	18.3	15.2
		Child	Hard	91	5.0	18.3	15.2
			Normal	90	5.0	18.3	15.2
			Soft	89	5.0	18.3	15.2
	Green	Man	Hard	75	5.6	18.3	15.2
			Normal	74	5.6	18.3	15.2
			Soft	73	5.6	18.3	15.2
		Woman	Hard	75	5.3	18.3	15.2
			Normal	74	5.3	18.3	15.2
			Soft	73	5.3	18.3	15.2
		Child	Hard	75	5.0	18.3	15.2
			Normal	74	5.0	18.3	15.2
			Soft	73	5.0	18.3	15.2
Green Plus	Green	Man	Hard	85	4.0	4.1	4.0
			Normal	84	4.0	4.1	4.0
			Soft	83	4.0	4.1	4.0
		Woman	Hard	82	4.0	4.1	4.0
			Normal	81	4.0	4.1	4.0
			Soft	80	4.0	4.1	4.0
		Child	Hard	75	4.0	4.1	4.0
			Normal	74	4.0	4.1	4.0

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
			Soft	73	4.0	4.1	4.0
Smart Focus	High Resolution	Man	Hard	95	10.0	18.1	18.0
			Normal	94	10.0	18.1	18.0
			Soft	93	10.0	18.1	18.0
		Woman	Hard	95	9.7	18.1	18.0
			Normal	94	9.7	18.1	18.0
			Soft	93	9.7	18.1	18.0
		Child	Hard	95	9.4	18.1	18.0
			Normal	94	9.4	18.1	18.0
			Soft	93	9.4	18.1	18.0
	Green	Man	Hard	88	10.0	18.1	18.0
			Normal	87	10.0	18.1	18.0
			Soft	86	10.0	18.1	18.0
		Woman	Hard	88	9.7	18.1	18.0
			Normal	87	9.7	18.1	18.0
			Soft	86	9.7	18.1	18.0
		Child	Hard	88	9.4	18.1	18.0
			Normal	87	9.4	18.1	18.0
			Soft	86	9.4	18.1	18.0
18x15	Hight Resolution	Man	Hard	91	5.6	18.3	15.2
			Normal	90	5.6	18.3	15.2
			Soft	89	5.6	18.3	15.2
		Woman	Hard	91	5.3	18.3	15.2
			Normal	90	5.3	18.3	15.2
			Soft	89	5.3	18.3	15.2
		Child	Hard	91	5.0	18.3	15.2
			Normal	90	5.0	18.3	15.2

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
	Green	Man	Soft	89	5.0	18.3	15.2
			Hard	75	5.6	18.3	15.2
			Normal	74	5.6	18.3	15.2
		Woman	Soft	73	5.6	18.3	15.2
			Hard	75	5.3	18.3	15.2
			Normal	74	5.6	18.3	15.2
		Child	Soft	73	5.3	18.3	15.2
			Hard	75	5.0	18.3	15.2
			Normal	74	5.0	18.3	15.2
		Child	Soft	73	5.0	18.3	15.2
			Hard	75	5.0	18.3	15.2
			Normal	74	5.0	18.3	15.2
12x9	High Resolution	Man	Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0
			Soft	93	5.6	7.1	7.0
		Woman	Hard	95	5.3	7.1	7.0
			Normal	94	5.3	7.1	7.0
			Soft	93	5.3	7.1	7.0
		Child	Hard	95	5.0	7.1	7.0
			Normal	94	5.0	7.1	7.0
			Soft	93	5.0	7.1	7.0
	Green	Man	Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0
			Soft	73	5.6	7.1	7.0
		Woman	Hard	75	5.3	7.1	7.0
			Normal	74	5.3	7.1	7.0
			Soft	73	5.3	7.1	7.0
		Child	Hard	67	5.0	7.1	7.0
			Normal	66	5.0	7.1	7.0
			Soft	73	5.0	7.1	7.0

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
			Soft	65	5.0	7.1	7.0
12x5	High Resolution	Man	Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0
			Soft	93	5.6	7.1	7.0
		Woman	Hard	95	5.3	7.1	7.0
			Normal	94	5.3	7.1	7.0
			Soft	93	5.3	7.1	7.0
		Child	Hard	95	5.0	7.1	7.0
			Normal	94	5.0	7.1	7.0
			Soft	93	5.0	7.1	7.0
	Green	Man	Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0
			Soft	73	5.6	7.1	7.0
		Woman	Hard	75	5.3	7.1	7.0
			Normal	74	5.3	7.1	7.0
			Soft	73	5.3	7.1	7.0
		Child	Hard	67	5.0	7.1	7.0
			Normal	66	5.0	7.1	7.0
			Soft	65	5.0	7.1	7.0
8x8	High Resolution	Man	Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0
			Soft	93	5.6	7.1	7.0
		Woman	Hard	95	5.3	7.1	7.0
			Normal	94	5.3	7.1	7.0
			Soft	93	5.3	7.1	7.0
		Child	Hard	95	5.0	7.1	7.0
			Normal	94	5.0	7.1	7.0

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
	Green	Man	Soft	93	5.0	7.1	7.0
			Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0
		Woman	Soft	73	5.6	7.1	7.0
			Hard	75	5.3	7.1	7.0
			Normal	74	5.3	7.1	7.0
		Child	Soft	73	5.3	7.1	7.0
			Hard	67	5.0	7.1	7.0
			Normal	66	5.0	7.1	7.0
		Child	Soft	65	5.0	7.1	7.0
			Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0
8x5	High Resolution	Man	Soft	93	5.6	7.1	7.0
			Hard	95	5.3	7.1	7.0
			Normal	94	5.3	7.1	7.0
		Woman	Soft	93	5.3	7.1	7.0
			Hard	95	5.0	7.1	7.0
			Normal	94	5.0	7.1	7.0
		Child	Soft	93	5.0	7.1	7.0
			Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0
		Woman	Soft	73	5.6	7.1	7.0
			Hard	75	5.3	7.1	7.0
			Normal	74	5.3	7.1	7.0
	Green	Man	Soft	73	5.3	7.1	7.0
			Hard	67	5.0	7.1	7.0
			Normal	66	5.0	7.1	7.0
		Woman	Soft	65	5.0	7.1	7.0
			Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
			Soft	65	5.0	7.1	7.0
5x5	High Resolution	Man	Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0
			Soft	93	5.6	7.1	7.0
		Woman	Hard	95	5.3	7.1	7.0
			Normal	94	5.3	7.1	7.0
			Soft	93	5.3	7.1	7.0
		Child	Hard	95	5.0	7.1	7.0
			Normal	94	5.0	7.1	7.0
			Soft	93	5.0	7.1	7.0
	Green	Man	Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0
			Soft	73	5.6	7.1	7.0
		Woman	Hard	75	5.3	7.1	7.0
			Normal	74	5.3	7.1	7.0
			Soft	73	5.3	7.1	7.0
		Child	Hard	75	5.0	7.1	7.0
			Normal	74	5.0	7.1	7.0
			Soft	73	5.0	7.1	7.0
Endo	High Resolution	Man	Hard	95	10.0	18.1	18.0
			Normal	94	10.0	18.1	18.0
			Soft	93	10.0	18.1	18.0
		Woman	Hard	95	9.7	18.1	18.0
			Normal	94	9.7	18.1	18.0
			Soft	93	9.7	18.1	18.0
		Child	Hard	95	9.4	18.1	18.0
			Normal	94	9.4	18.1	18.0

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
	Green	Man	Soft	93	9.4	18.1	18.0
			Hard	88	10.0	18.1	18.0
			Normal	87	10.0	18.1	18.0
		Woman	Soft	86	10.0	18.1	18.0
			Hard	88	9.7	18.1	18.0
			Normal	87	9.7	18.1	18.0
		Child	Soft	86	9.7	18.1	18.0
			Hard	88	9.4	18.1	18.0
			Normal	87	9.4	18.1	18.0
			Soft	86	9.4	18.1	18.0
			Hard	91	6.0	14.5	6.2
			Normal	90	6.0	14.5	6.2
Scout (5x5, Endo)	-	Man	Soft	89	6.0	14.5	6.2
			Hard	91	5.7	14.5	6.2
			Normal	90	5.7	14.5	6.2
		Woman	Soft	89	5.7	14.5	6.2
			Hard	91	5.4	14.5	6.2
			Normal	90	5.4	14.5	6.2
		Child	Soft	89	5.4	14.5	6.2
			Hard	91	5.4	14.5	6.2
			Normal	90	5.4	14.5	6.2
Scout (12x5 8x5)	-	Man	Soft	89	6.0	14.5	3.1
			Hard	91	6.0	14.5	3.1
			Normal	90	6.0	14.5	3.1
		Woman	Soft	89	5.7	14.5	3.1
			Hard	91	5.7	14.5	3.1
			Normal	90	5.7	14.5	3.1
		Child	Soft	89	5.4	14.5	3.1
			Hard	91	5.4	14.5	3.1

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
			Soft	89	5.4	14.5	3.1

- **The full arch** option does not affect the system's scan time and exposure time.
- In **scout mode**, the user can only select the 'high resolution' option.

18.1.4 ENT CT

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
21x19	High Resolution	Man	Hard	91	5.6	18.3	15.2
			Normal	90	5.6	18.3	15.2
			Soft	91	5.6	18.3	15.2
		Woman	Hard	90	5.3	18.3	15.2
			Normal	91	5.3	18.3	15.2
			Soft	90	5.3	18.3	15.2
		Child	Hard	91	5.0	18.3	15.2
			Normal	90	5.0	18.3	15.2
			Soft	91	5.0	18.3	15.2
	Green	Man	Hard	75	5.6	18.3	15.2
			Normal	74	5.6	18.3	15.2
			Soft	73	5.6	18.3	15.2
		Woman	Hard	75	5.3	18.3	15.2
			Normal	74	5.3	18.3	15.2
			Soft	73	5.3	18.3	15.2
		Child	Hard	75	5.0	18.3	15.2
			Normal	74	5.0	18.3	15.2
			Soft	73	5.0	18.3	15.2
18x15	High Resolution	Man	Hard	91	5.6	18.3	15.2
			Normal	90	5.6	18.3	15.2
			Soft	89	5.6	18.3	15.2
		Woman	Hard	91	5.3	18.3	15.2
			Normal	90	5.3	18.3	15.2
			Soft	89	5.3	18.3	15.2
		Child	Hard	91	5.0	18.3	15.2
			Normal	90	5.0	18.3	15.2

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
	Green	Man	Soft	89	5.0	18.3	15.2
			Hard	75	5.6	18.3	15.2
			Normal	74	5.6	18.3	15.2
		Woman	Soft	73	5.6	18.3	15.2
			Hard	75	5.3	18.3	15.2
			Normal	74	5.3	18.3	15.2
		Child	Soft	73	5.3	18.3	15.2
			Hard	75	5.0	18.3	15.2
			Normal	74	5.0	18.3	15.2
			Soft	73	5.0	18.3	15.2
			Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0
12x9	High Resolution	Man	Soft	93	5.6	7.1	7.0
			Hard	95	5.3	7.1	7.0
			Normal	94	5.3	7.1	7.0
		Woman	Soft	93	5.3	7.1	7.0
			Hard	95	5.0	7.1	7.0
			Normal	94	5.0	7.1	7.0
		Child	Soft	93	5.0	7.1	7.0
			Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0
	Green	Man	Soft	73	5.6	7.1	7.0
			Hard	75	5.3	7.1	7.0
			Normal	74	5.3	7.1	7.0
		Woman	Soft	73	5.3	7.1	7.0
			Hard	67	5.0	7.1	7.0
			Normal	66	5.0	7.1	7.0
		Child	Soft	73	5.0	7.1	7.0
			Hard	75	5.0	7.1	7.0
			Normal	74	5.0	7.1	7.0

FOV	Image Option	Patient	X-ray Intensity Level	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
8x8	High Resolution	Man	Soft	65	5.0	7.1	7.0
			Hard	95	5.6	7.1	7.0
			Normal	94	5.6	7.1	7.0
		Woman	Soft	93	5.6	7.1	7.0
			Hard	95	5.3	7.1	7.0
			Normal	94	5.3	7.1	7.0
		Child	Soft	93	5.3	7.1	7.0
			Hard	95	5.0	7.1	7.0
			Normal	94	5.0	7.1	7.0
		Man	Soft	93	5.0	7.1	7.0
			Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0
	Green	Woman	Soft	73	5.6	7.1	7.0
			Hard	75	5.3	7.1	7.0
			Normal	74	5.3	7.1	7.0
		Child	Soft	73	5.3	7.1	7.0
			Hard	67	5.0	7.1	7.0
			Normal	66	5.0	7.1	7.0
		Man	Soft	65	5.0	7.1	7.0
			Hard	75	5.6	7.1	7.0
			Normal	74	5.6	7.1	7.0

18.1.5 MODEL

Modality	Image Option	MODEL Examination	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
MODEL	N/A	Upper	94	5.6	7.1	7.0
		Lower	94	5.6	7.1	7.0

18.1.6 FACE SCAN

Modality	Image Option	FACE SCAN Examination	Tube Voltage (kVp)	Tube Current (mA)	Scan Time (s)	Exposure Time (s)
Face Scan	-	-	-	-	10.0	-

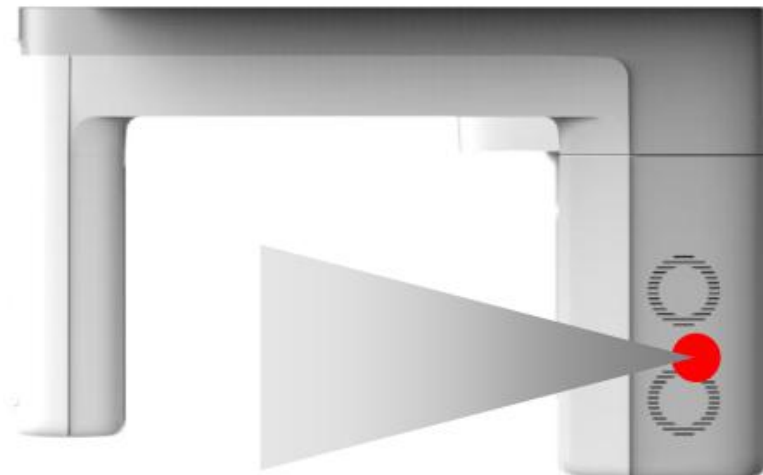
*For Face Scan mode, the system does not use X-ray. For this reason, tube voltage, tube current, and exposure time information are not provided.

18.2 DAP (Dose Area Product)

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 ($\text{mGy} \cdot \text{cm}^2$). Despite the limitation, DAP is the best way to predict effective dose value and is currently the most convenient method for patient dose monitoring.

Test Hardware	
Brand Name (Model)	Green X 21 (PHT-90CHO)
Sensor Type	PANO & DENTAL CT& ENT CT: Jupi1012X CEPH: Venu1012VD
X-ray Generator	LDG-07E22T2
Tube	D-052SB

18.2.1 Measurement Overview



18.2.2 Test Results

18.2.2.1 PANO

Modality	Tab/ PANO Option	Image Option	Patient	X-ray Intensity Level	Exposure Condition (kVp / mA / s)	DAP
PANO	Normal	High Resolution	Man	Normal	74 kVp / 10.0 mA / 13.5 s	110.65
			Child	Normal	69 kVp / 8.0 mA / 11.5 s	54.63
		Green	Man	Normal	75 kVp / 9.0 mA / 7.3 s	55.19
			Child	Normal	70 kVp / 12.0 mA / 5.6 s	40.76
	Insight PAN	High Resolution	Man	Normal	70 kVp / 6.0 mA / 7.5 s	112.42
			Child	Normal	67 kVp / 6.0 mA / 5.0 s	69.32

18.2.2.2 CEPH

Modality	CEPH Examination	Image Option	Patient	X-ray Intensity Level	Exposure Condition (kVp / mA / s)	DAP
CEPH	Lateral	High Resolution	Man	Normal	90 kVp / 10.0 mA / 0.9 s	86.12
			Child	Normal	74 kVp / 10.0 mA / 0.9 s	61.19
		Green	Man	Normal	72 kVp / 5.0 mA / 0.9 s	28.53
			Child	Normal	61 kVp / 5.0 mA / 0.9 s	20.25

18.2.2.3 ENT / Dental CT

Modality	FOV	Image Option	Patient	X-ray Intensity Level	Exposure Condition (kVp / mA / s)	DAP
PANO	Normal	High Resolution	Man	Normal	74 kVp / 10.0 mA / 13.5 s	110.65
			Child	Normal	69 kVp / 8.0 mA / 11.5 s	54.63
		Green	Man	Normal	75 kVp / 9.0 mA / 7.3 s	55.19
			Child	Normal	70 kVp / 12.0 mA / 5.6 s	40.76
	Insight PAN	High Resolution	Man	Normal	70 kVp / 6.0 mA / 7.5 s	112.42
			Child	Normal	67 kVp / 6.0 mA / 5.0 s	69.32
CEPH	Lateral	High Resolution	Man	Normal	90 kVp / 10.0 mA / 0.9 s	86.12
			Child	Normal	74 kVp / 10.0 mA / 0.9 s	61.19
		Green	Man	Normal	72 kVp / 5.0 mA / 0.9 s	28.53

Modality	FOV	Image Option	Patient	X-ray Intensity Level	Exposure Condition (kVp / mA / s)	DAP
ENT / Dental CT			Child	Normal	61 kVp / 5.0 mA / 0.9 s	20.25
			Man	Normal	90 kVp / 5.6 mA / 15.2 s	4719.64
	21x19	High Resolution	Child	Normal	90 kVp / 5.0 mA / 15.2s	4225.74
			Man	Normal	74 kVp / 5.6 mA / 15.2 s	3016.32
		Green	Child	Normal	74 kVp / 5.0 mA / 15.2 s	2700.67
			Man	Normal	84 kVp / 4.0 mA / 4.1s	771.52
	Green Plus	Green	Child	Normal	74kVp / 4.0mA / 4.1s	575.24
			Man	Normal	94 kVp / 10.0 mA / 18.0 s	3426.26
	Smart Focus	High Resolution	Child	Normal	94 kVp / 9.4 mA / 18.0 s	3221.16
			Man	Normal	87 kVp / 10.0 mA / 18.0 s	2714.49
		Green	Child	Normal	87 kVp / 9.4 mA / 18.0 s	2552
			Man	Normal	90 kVp / 5.6 mA / 15.2 s	3416.89
	18x15	High Resolution	Child	Normal	90 kVp / 5.0 mA / 15.2 s	3059.32
			Man	Normal	74 kVp / 5.6 mA / 15.2 s	2183.73
		Green	Child	Normal	74 kVp / 5.0 mA / 15.2 s	1955.21
			Man	Normal	94 kVp / 5.6 mA / 7.0 s	1372.80
	12x9	High Resolution	Child	Normal	94 kVp / 5.0 mA / 7.0 s	1229.27
			Man	Normal	74 kVp / 5.6 mA / 7.0 s	752.41
		Green	Child	Normal	66 kVp / 5.0 mA / 7.0 s	500.95
			Man	Normal	94 kVp / 5.6 mA / 7.0 s	931.29
	12x5	High Resolution	Child	Normal	94 kVp / 5.0 mA / 7.0 s	833.92
			Man	Normal	74 kVp / 5.6 mA / 7.0 s	510.43
		Green	Child	Normal	66 kVp / 5.0 mA / 7.0 s	339.84
			Man	Normal	94 kVp / 5.6 mA / 7.0 s	929.95
	8x8	High Resolution	Child	Normal	94 kVp / 5.0 mA / 7.0 s	832.72
			Man	Normal	74 kVp / 5.6 mA / 7.0 s	509.70
		Green	Child	Normal	66 kVp / 5.0 mA / 7.0 s	339.35
			Man	Normal	94 kVp / 5.6 mA / 7.0 s	603.68
	8x5	High Resolution	Child	Normal	94 kVp / 5.0 mA / 7.0 s	540.56
			Man	Normal	74 kVp / 5.6 mA / 7.0 s	330.87
		Green	Child	Normal	66 kVp / 5.0 mA / 7.0 s	220.29
			Man	Normal	94 kVp / 5.6 mA / 7.0 s	603.68

Modality	FOV	Image Option	Patient	X-ray Intensity Level	Exposure Condition (kVp / mA / s)	DAP
	5x5	High Resolution	Man	Normal	94 kVp / 5.6 mA / 7.0 s	375.13
			Child	Normal	94 kVp / 5.0 mA / 7.0 s	335.91
		Green	Man	Normal	74 kVp / 5.6 mA / 7.0 s	205.60
			Child	Normal	66 kVp / 5.0 mA / 7.0 s	136.89
	Endo	High Resolution	Man	Normal	94 kVp / 10.0 mA / 18.0 s	630
			Child	Normal	94 kVp / 9.4 mA / 18.0 s	592.28
		Green	Man	Normal	87 kVp / 10.0 mA / 18.0 s	499.12
			Child	Normal	87 kVp / 9.4 mA / 18.0 s	469.24
	Scout (5x5 / Endo)	High Resolution	Man	Normal	90 kVp / 6.0 mA / 6.2 s	98.07
			Child	Normal	90 kVp / 5.4 mA / 6.2 s	88.53
	Scout (12x5, 8x5)	High Resolution	Man	Normal	90 kVp / 6.0 mA / 3.1 s	49.04
			Child	Normal	90 kVp / 5.4 mA / 3.1 s	44.26

18.3 Leakage Dose

18.3.1 Standard

National Deviations	Terminology	Permissive Range
International Standard IEC 60601-1-3	Leakage	The leakage dose not exceed 1.0 mGy per hour at 100 cm from the X-ray source.

18.3.2 Test Information

Category	Description
Test Model	PHT-90CHO
CBCT (Dental/ENT) Sensor	Jupi1012X
PANO Sensor	Jupi1012X
CEPH Sensor	Venu1012VD
Tube Model	LDG-07E22T2

18.3.3 Test Result

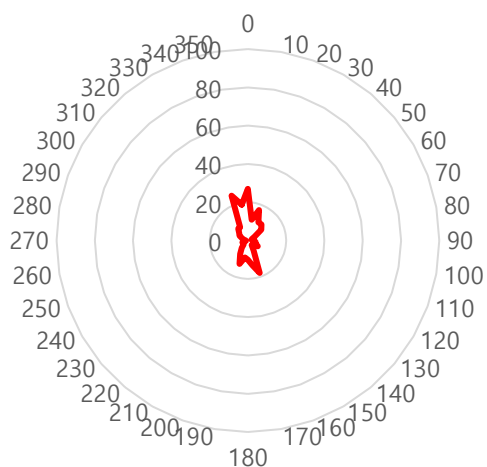
18.3.3.1 PANO (Normal)

Test Condition	
Tested Mode	Test 1 - Modality: PANO - Patient: Man - PANO Option: Normal - Image Option: High resolution - Arch Selection: Normal - PANO Examination: Standard
	Test 2 - Modality: PANO - Patient: Child - PANO Option: Normal - Image Option: High resolution - Arch Selection: Child - PANO Examination: Standard
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	13.5 (Arch: Normal), 11.5 (Arch: Child)

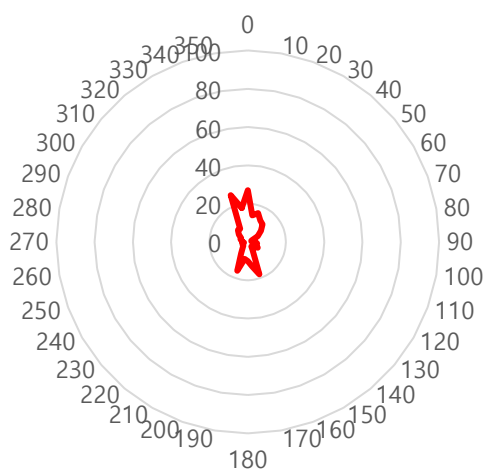
Arch Selection Direction[°]	Normal		Child	
	mR/hr	mGy/hr	mR/hr	mGy/hr
0	27	0.237	27	0.237
10	11	0.096	14	0.123
20	17	0.149	16	0.140
30	11	0.096	13	0.114
40	11	0.096	12	0.105
50	9	0.079	9	0.079
60	4	0.035	6	0.053
70	2	0.018	2	0.018
80	2	0.018	2	0.018

90	3	0.026	4	0.035
100	4	0.035	5	0.044
110	4	0.035	4	0.035
120	6	0.053	6	0.053
130	4	0.035	4	0.035
140	3	0.026	3	0.026
150	6	0.053	5	0.044
160	18	0.158	18	0.158
170	13	0.114	13	0.114
180	10	0.088	10	0.088
190	9	0.079	9	0.079
200	13	0.114	16	0.140
210	8	0.070	7	0.061
220	5	0.044	4	0.035
230	3	0.026	3	0.026
240	3	0.026	3	0.026
250	3	0.026	3	0.026
260	1	0.009	2	0.018
270	1	0.009	3	0.026
280	2	0.018	3	0.026
290	3	0.026	4	0.035
300	5	0.044	4	0.035
310	6	0.053	6	0.053
320	8	0.070	8	0.070
330	8	0.070	8	0.070
340	25	0.219	26	0.228
350	19	0.167	18	0.158

Pano Normal



Pano Child



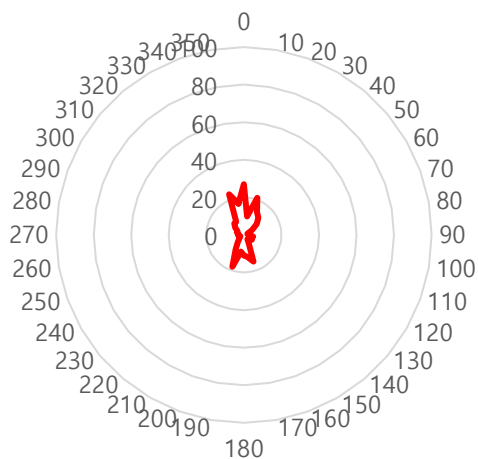
18.3.3.2 PANO (Insight PAN)

Test Condition	
Tested Mode	Test 1 - Modality: PANO - Patient: Man - PANO Option: Insight PAN - Image Option: N/A - Arch Selection: Normal - PANO Examination: N/A
	Test 2 - Modality: PANO - Patient: Child - PANO Option: Insight PAN - Image Option: N/A - Arch Selection: Child - PANO Examination: N/A
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	10.9 (Arch: Normal), 8.2 (Arch: Child)

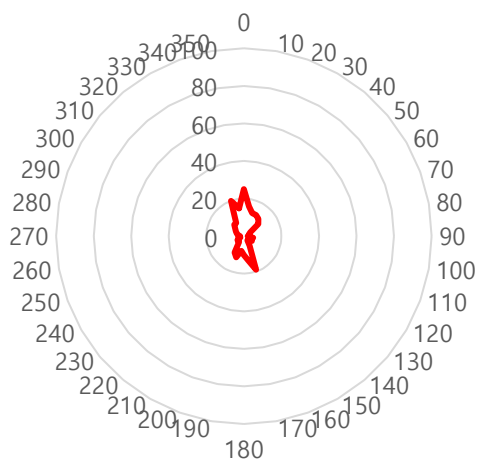
Arch Selection Direction[°]	Normal		Child	
	mR/hr	mGy/hr	mR/hr	mGy/hr
0	27	0.237	25	0.219
10	10	0.088	16	0.140
20	21	0.184	13	0.114
30	14	0.123	13	0.114
40	12	0.105	12	0.105
50	9	0.079	10	0.088
60	5	0.044	4	0.035
70	2	0.018	3	0.026
80	2	0.018	3	0.026
90	3	0.026	2	0.018
100	5	0.044	5	0.044

110	4	0.035	4	0.035
120	5	0.044	5	0.044
130	4	0.035	4	0.035
140	3	0.026	3	0.026
150	5	0.044	6	0.053
160	15	0.132	19	0.167
170	12	0.105	13	0.114
180	11	0.096	10	0.088
190	9	0.079	8	0.070
200	18	0.158	12	0.105
210	9	0.079	10	0.088
220	5	0.044	4	0.035
230	3	0.026	4	0.035
240	3	0.026	4	0.035
250	2	0.018	2	0.018
260	3	0.026	3	0.026
270	3	0.026	2	0.018
280	3	0.026	3	0.026
290	4	0.035	4	0.035
300	4	0.035	5	0.044
310	6	0.053	6	0.053
320	8	0.070	8	0.070
330	8	0.070	8	0.070
340	23	0.202	20	0.175
350	17	0.149	15	0.132

Insight PAN Normal



Insight PAN Child

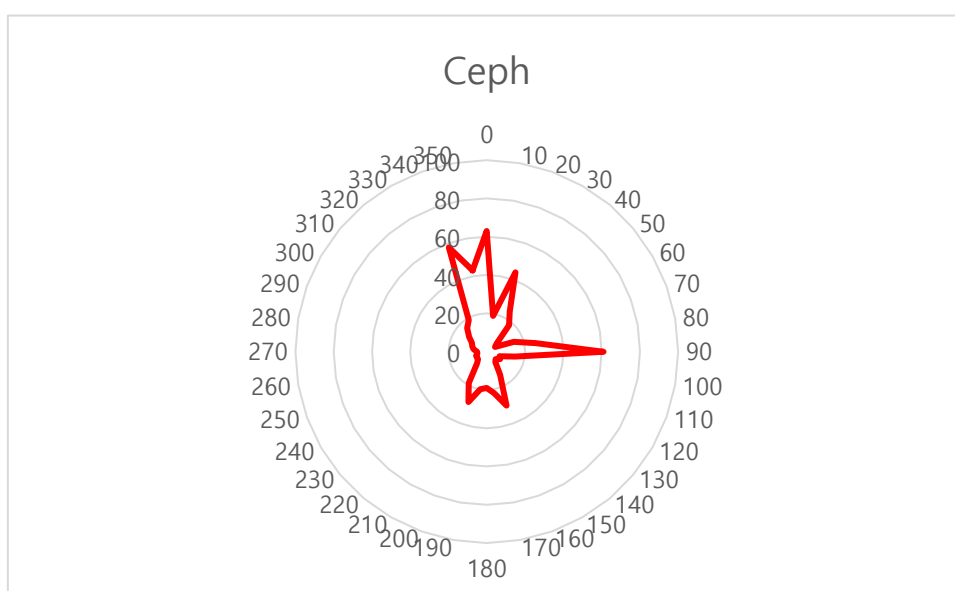


18.3.3.3 CEPH (Lateral)

Test Condition	
Tested Mode	- Modality: CEPH - Patient: Man (Adult) - Image Option: High Resolution - CEPH Examination: Lateral
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	99
Tube Current [mA]	15
Exposure Time [s]	0.9

CEPH Examination Direction[°]	Lateral	
	mR/hr	mGy/hr
0	63	0.553
10	19	0.167
20	44	0.386
30	24	0.211
40	18	0.158
50	7	0.061
60	5	0.044
70	15	0.132
80	26	0.228
90	61	0.535
100	15	0.132
110	7	0.061
120	8	0.070
130	6	0.053
140	7	0.061
150	14	0.123
160	30	0.263
170	22	0.193

180	19	0.167
190	20	0.175
200	28	0.246
210	19	0.167
220	8	0.070
230	6	0.053
240	6	0.053
250	6	0.053
260	5	0.044
270	5	0.044
280	7	0.061
290	8	0.070
300	9	0.079
310	12	0.105
320	16	0.140
330	19	0.167
340	58	0.509
350	43	0.377



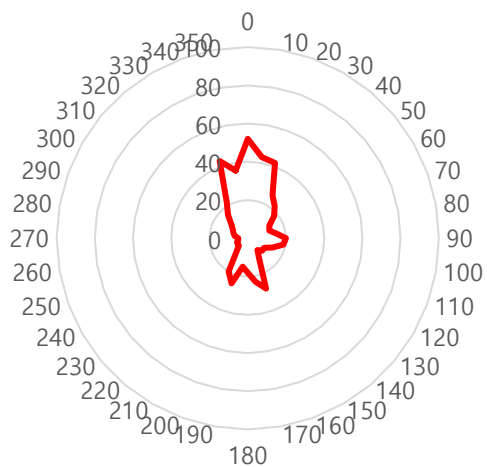
18.3.3.4 DENTAL / ENT CT

Test Condition	
Tested Mode	Test 1 - Modality: Dental CT / ENT CT - Patient: Man - FOV: 21x19 - Vertical Option: Occlusion - Horizontal Option: Center - Image Option: High Revolution - Voxel Size: Application
	Test 2 - Modality: Dental CT - Patient: Man - FOV: Endo (Tooth No. 41) - Vertical Option: N/A - Horizontal Option: N/A - Image Option: High Resolution - Voxel Size: Application
Distance from focal point [m]	1
Tube Voltage Peak [kVp]	99
Tube Current [mA]	12
Exposure Time [s]	15.2 (21x19), 18(Endo)

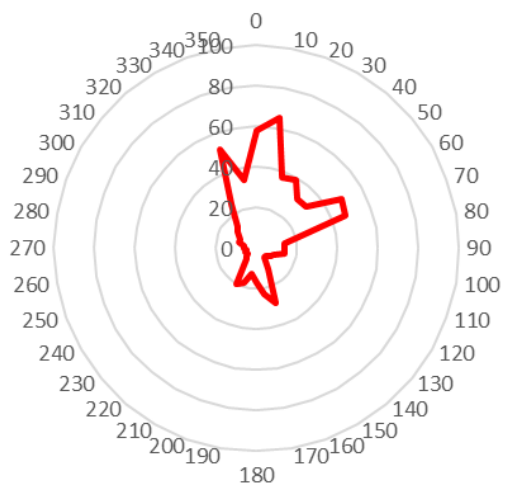
FOV Direction[°]	21x19		Endo (Dental CT only)	
	mR/hr	mGy/hr	mR/hr	mGy/hr
0	52	0.456	50	0.439
10	43	0.377	22	0.193
20	42	0.368	32	0.281
30	26	0.228	22	0.193
40	22	0.193	18	0.158
50	18	0.158	13	0.114
60	13	0.114	7	0.061
70	12	0.105	5	0.044
80	15	0.132	5	0.044

90	20	0.175	10	0.088
100	19	0.167	7	0.061
110	14	0.123	8	0.070
120	10	0.088	12	0.105
130	10	0.088	6	0.053
140	8	0.070	5	0.044
150	12	0.105	8	0.070
160	28	0.246	26	0.228
170	23	0.202	19	0.167
180	18	0.158	15	0.132
190	15	0.132	16	0.140
200	25	0.219	23	0.202
210	20	0.175	13	0.114
220	9	0.079	8	0.070
230	6	0.053	5	0.044
240	6	0.053	5	0.044
250	6	0.053	5	0.044
260	5	0.044	4	0.035
270	5	0.044	5	0.044
280	7	0.061	5	0.044
290	8	0.070	7	0.061
300	9	0.079	7	0.061
310	11	0.096	10	0.088
320	16	0.140	14	0.123
330	22	0.193	16	0.140
340	43	0.377	47	0.412
350	36	0.316	34	0.298

DENTAL/ ENT CT 21x19



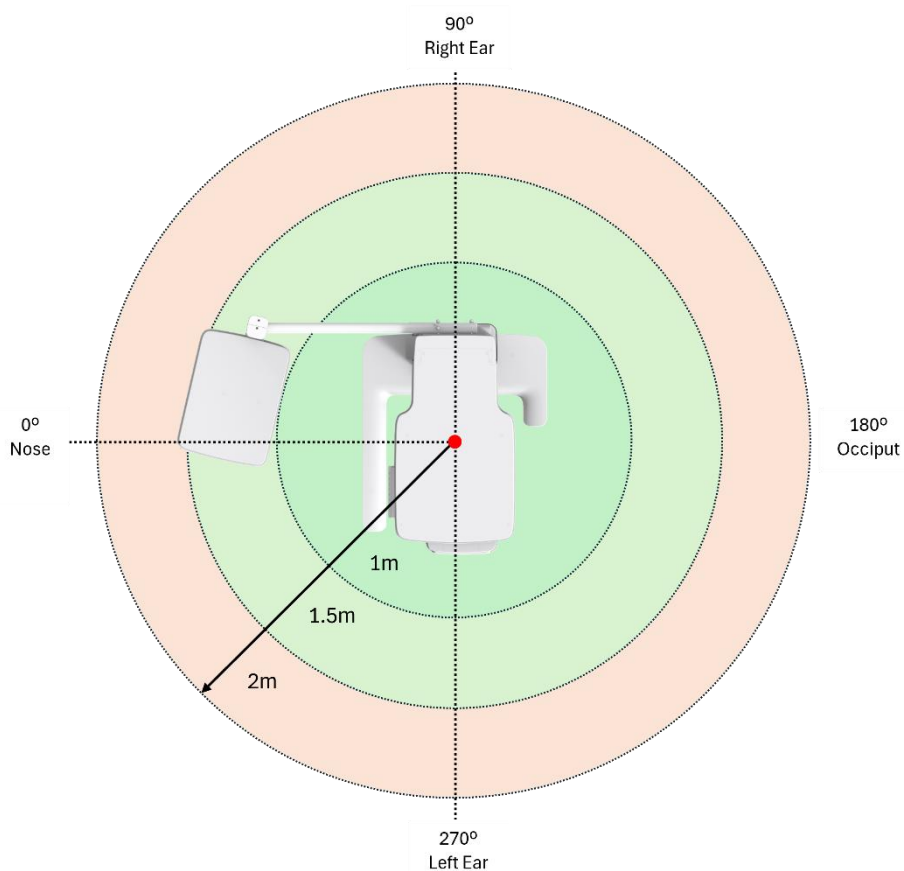
DENTAL CT ENDO



18.4 Scattered Dose

18.4.1 Test Area

The tested plane of radiation areas is defined within a circle of the radius at 1 m, 1.5 m, and 2 m from the phantom as the figure below.



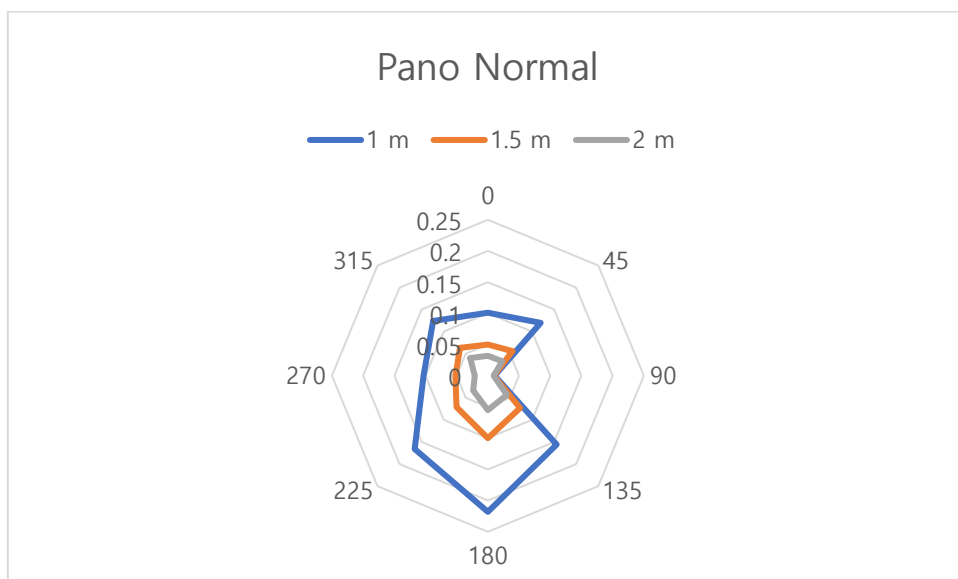
18.4.2 Test Result

18.4.2.1 PANO (Normal / Men)

PANO(Adult)

Test Condition	
Tested Mode	- Modality: PANO - Patient: Man - PANO Option: Normal - Image Option: High Resolution - Arch Selection: Normal - PANO Examination: Standard
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	13.5

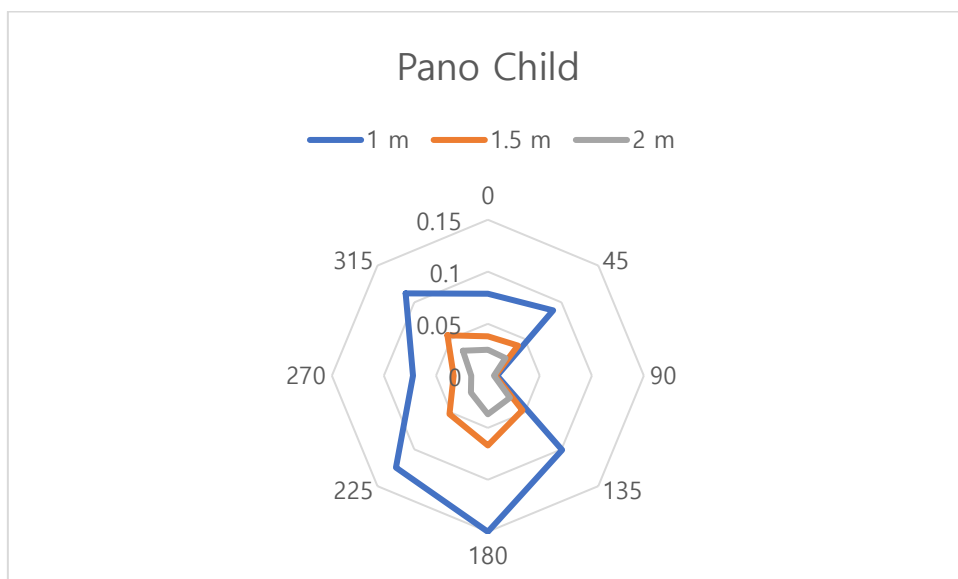
PANO Option / Arch Selection		Normal / Normal [mR]		
		1m (3.3ft)	1.5m (4.9ft)	2m (6.6ft)
0	Nose	0.101	0.050	0.032
45		0.12	0.056	0.033
90	Right Ear	0.011	0.010	0.009
135		0.156	0.073	0.043
180	Occiput	0.218	0.100	0.055
225		0.166	0.071	0.033
270	Left Ear	0.103	0.052	0.021
315		0.124	0.063	0.040



18.4.2.2 PANO (Normal / Child)

Test Condition	
Tested Mode	- Modality: PANO - Patient: Child - PANO Option: Normal - Image Option: High resolution - Arch Selection Child - PANO Examination: Standard
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	11.5

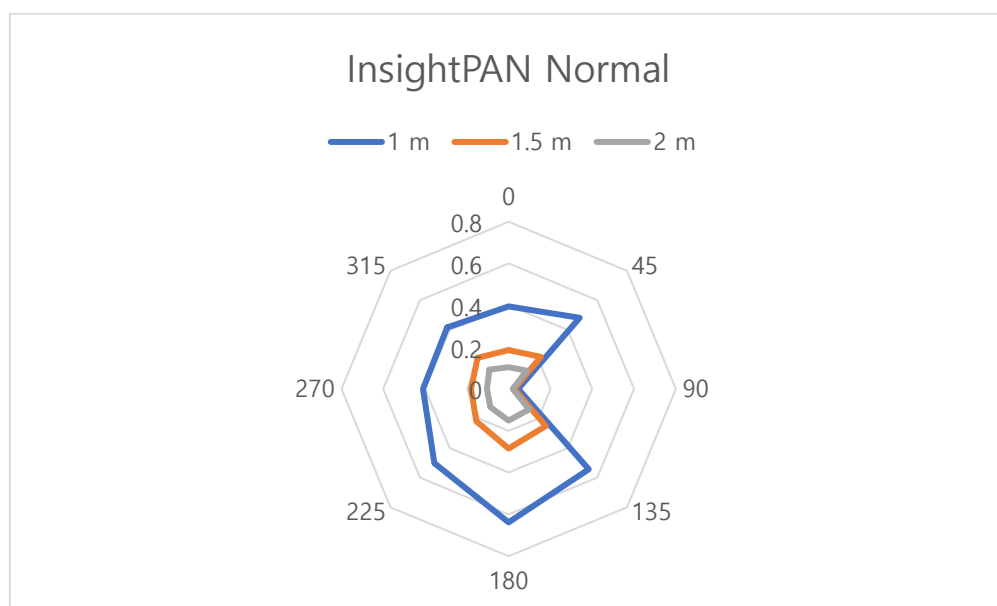
PANO Option / Arch Selection Direction[°]		Normal / Child [mR]		
		1m (3.3ft)	1.5m (4.9ft)	2m (6.6ft)
0	Nose	0.079	0.038	0.025
45		0.089	0.041	0.024
90	Right Ear	0.009	0.007	0.006
135		0.101	0.047	0.030
180	Occiput	0.15	0.067	0.037
225		0.125	0.052	0.023
270	Right Ear	0.072	0.033	0.016
315		0.112	0.055	0.034



18.4.2.3 Insight PAN (Normal)

Test Condition	
Tested Mode	- Modality: PANO - Patient: Man - PANO Option: Insight PAN - Image Option: N/A - Arch selection: Normal - PANO Examination: N/A
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	10.9

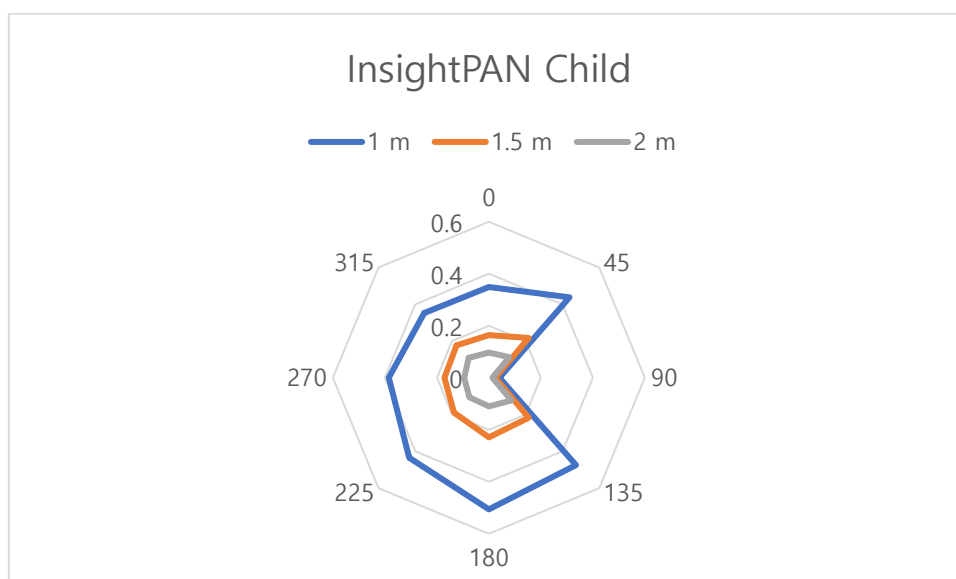
PANO Option/ Arch Selection Direction[°]		Insight PAN / Normal [mR]		
		1m (3.3ft)	1.5m (4.9ft)	2m (6.6ft)
0	Nose	0.395	0.186	0.104
45		0.481	0.218	0.123
90	Right Ear	0.046	0.027	0.020
135		0.542	0.251	0.139
180	Occiput	0.638	0.285	0.151
225		0.502	0.219	0.123
270	Right Ear	0.41	0.180	0.104
315		0.417	0.210	0.131



18.4.2.4 Insight PAN (Child)

Test Condition	
Tested Mode	- Modality: PANO - Patient: Child - PANO Option: Insight PAN - Image Option: N/A - Arch selection: Child - PANO Examination: N/A
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	90
Tube Current [mA]	14
Exposure Time [s]	8.2

PANO Option / Arch Selection		Insight PAN / Child [mR]		
		1m (3.3ft)	1.5m (4.9ft)	2m (6.6ft)
Direction[°]				
0	Nose	0.349	0.164	0.097
45		0.438	0.217	0.111
90	Right Ear	0.041	0.025	0.014
135		0.474	0.217	0.123
180	Occiput	0.506	0.229	0.110
225		0.434	0.189	0.106
270	Right Ear	0.385	0.171	0.095
315		0.352	0.176	0.109



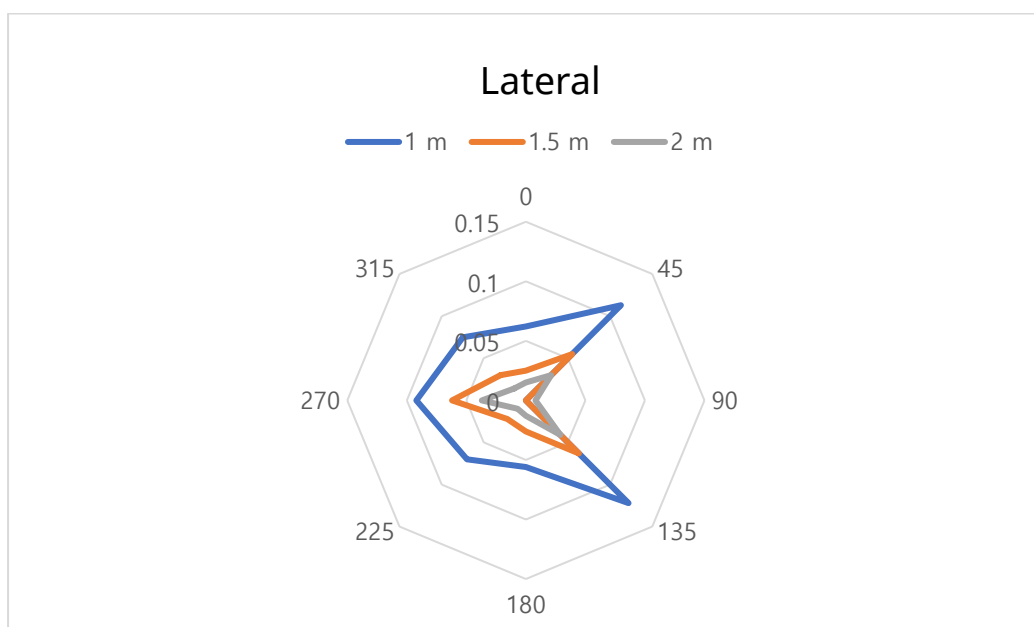
18.4.2.5 CEPH (Lateral)

Test Condition	
Tested Mode	- Modality: CEPH - Patient: Man - Image Option: High Resolution - CEPH Examination: Lateral
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	99
Tube Current [mA]	15
Exposure Time [s]	0.9

CEPH Examination		Lateral [mR]		
Direction[°]		1m (3.3ft)	1.5m (4.9ft)	2m (6.6ft)
0	Nose	0.058	0.027	0.016
45		0.047	0.022	0.013
90	Right Ear	0.046	0.03	0.022
135		0.126	0.043	0.019
180	Occiput	0.066	0.024	0.015
225		0.115	0.049	0.032
270	Left Ear	-	-	0.006
315		0.122	0.066	0.040

NOTICE

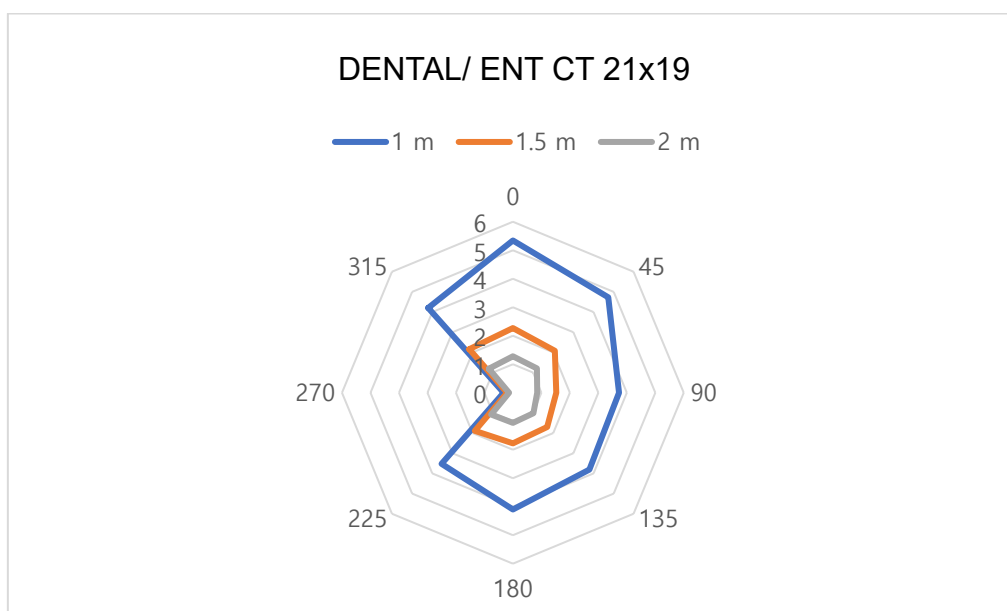
Since the Ion chamber is located between the generator and the object, Data of 1 m and 1.5 m at 270 ° are not measured.



18.4.2.6 DENTAL/ ENT CT (21x19)

Test Condition	
Tested Mode	- Modality: Dental CT / ENT CT - Patient: Man - FOV: 21x19 - Vertical Option: Occlusion - Horizontal Option: Center - Image Option: High Resolution - Voxel Size: Standard
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	99
Tube Current [mA]	12
Exposure Time [s]	15.2

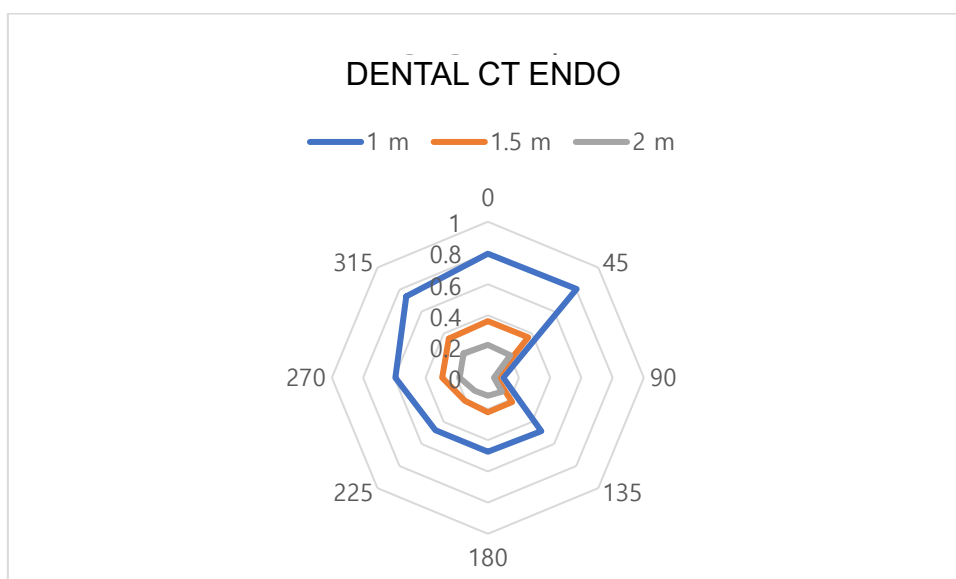
Direction[°] \ FOV		21x19 [mR]		
		1m (3.3ft)	1.5m (4.9ft)	2m (6.6ft)
0	Nose	3.937	1.758	1.005
45		4.215	1.863	1.018
90	Right Ear	0.369	0.183	0.121
135		4.242	1.961	1.124
180	Occiput	4.606	2.127	1.072
225		4.542	2.017	1.147
270	Left Ear	3.222	1.444	0.865
315		3.462	1.623	0.974



18.4.2.7 DENTAL CT (Endo)

Test Condition	
Tested Mode	- Modality: Dental CT - Patient: Man - FOV: Endo (Tooth no. 41) - Vertical Option: N/A - Horizontal Option: N/A - Image option: High Resolution - Voxel Size: Application
Distance from focal point [m]	1~2
Tube Voltage Peak [kVp]	99
Tube Current [mA]	12
Exposure Time [s]	18

FOV Direction[°]		Endo [mR]		
		1m (3.3ft)	1.5m (4.9ft)	2m (6.6ft)
0	Nose	0.795	0.363	0.211
45		0.805	0.366	0.204
90	Right Ear	0.098	0.053	0.039
135		0.485	0.221	0.128
180	Occiput	0.474	0.221	0.115
225		0.476	0.209	0.119
270	Left Ear	0.593	0.293	0.181
315		0.739	0.354	0.221



18.5 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 +A1:2016+A2:2019 EN 55011:2016 /A2:2021	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz	Group1, Class A
Radiated disturbance	CISPR 11:2015 +A1:2016+A2:2019 EN 55011:2016 /A2:2021	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby 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	IEC 61000-3-2:2018 +A1:2020 EN IEC 61000-3-2:2019	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	AC Mains of power supply unit	230 V, 50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	IEC 61000-3-3:2013 +A1:2017 EN 61000-3-3:2013 +A1:2019	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	AC Mains of power supply unit	230 V, 50 Hz	Pst: 1 Plt: 0.65 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	IEC 61000-4-2:2008 EN 61000-4-2:2009	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3:2020 EN IEC 61000-4-3:2020	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3:2020 EN IEC 61000-4-3:2020	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby 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: 2020
Immunity to	IEC 61000-4-39:2017	PANO Mode Dental CT Mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz	Table 11 in

proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz	EN 61000-4-39:2017	ENT CT Mode CEPH Mode Standby Mode		AC 220 V, 60 Hz AC 230 V, 50 Hz	IEC 60601-1-2: 2020
Electrical Fast Transient/Burst Immunity	IEC 61000-4-4:2012 EN 61000-4-4:2012	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby 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
			Exposure S/W, RS-232, CT/PANO and CEPH Ports		
Surge Immunity	IEC 61000-4-5:2014 +A1:2017 EN 61000-4-5:2014 +A1:2017	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6:2013 EN 61000-4-6:2014	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby 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 S/W, RS-232, CT/PANO and CEPH Ports		6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009 EN 61000-4-8:2010	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby 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	IEC 61000-4-11:2020 EN IEC 61000-4-11:2020	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % U_T : 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°

					0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11:2020 EN IEC 61000-4-11:2020	PANO Mode Dental CT Mode ENT CT Mode CEPH Mode Standby Mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % U_T ; 250/300 cycle

18.6 Acquiring Images for Pediatric Dental Patients

18.6.1 Age Group: Classification Table

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

Age Group	FDA's standard	VATECH's Standard
Infant	29 days to less than 2 years	-
Child	2 to less than 12 years	Child
Adolescent	Ages 12 through 21	Adult
Adult	Above 21 years	

18.6.2 Positioning the Pediatric Dental Patients

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

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

- By Evelyn M. Thomson, BSDH, MS

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

Producing A Quality Panoramic Image

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



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

The most critical component in producing a diagnostically acceptable panoramic image is patient positioning. All panoramic X-ray machines have guidelines to assist with positioning the dental arches within the three dimensions of the focal trough, an area where the anatomical structures will be imaged in relative clarity. Most

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



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

Table 1. Common Panoramic Positioning Errors

Error	Cause	Corrective action	Tips for pediatric patients
Anterior teeth narrow Severe posterior overlap Vertebrae superimposed over condyles	Arches positioned too far anterior	Position anterior teeth in appropriate position on bite guide. Locate appropriate position with anterior laser light guide.	Use a cotton roll to fill in missing primary teeth or partially erupted permanent teeth. Adapt adult recommendation for direction of laser light beam guide for use with primary teeth. Observe laser light beam guide on both the right and left sides.
Anterior teeth wide, blurred out of image Condyles not imaged	Arches positioned too far posterior		
Teeth on the right side appear narrowed, severely overlapped Teeth on the left side appear broad, poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the right	Position the midsagittal plane perpendicular to the floor.	Use laser light beam guide to locate midsagittal plane. Direct patient focus to mirror reflection. Affix decal to mirror to aid patient in maintaining the correct position throughout exposure.
Teeth on the left side appear narrowed, severely overlapped Teeth on the right side appear broad and poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the left		
Flat, downward-turned, "frown" appearance to the occlusal plane Palate appears as a widened, thick, dense radiopacity 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 line 5° down toward the floor.	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		
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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Dimensions OF DENTAL HYGIENE

Anterior-Posterior Positioning Error

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



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

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

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

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.

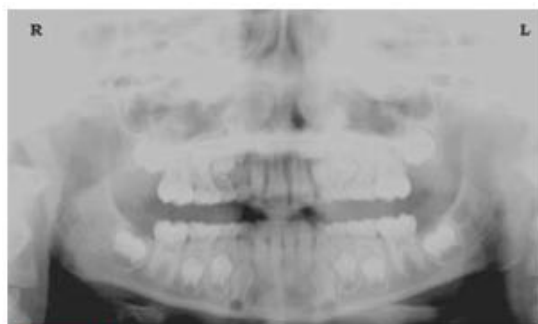


Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

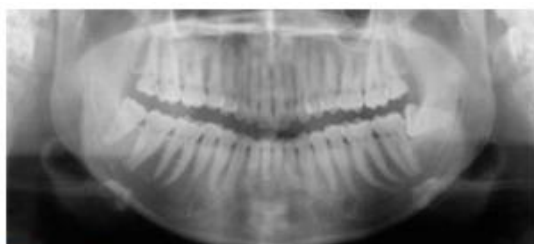


Figure 6: Chin positioned too far down. Note the characteristic “smile” or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

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

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

Further Recommendations

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

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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18.6.3 Setting Exposure Values to the Age Group

For more information about this topic, refer to **18.1 Recommended X-ray Exposure Tables**.

18.6.4 References Pertinent to the Potential Risks for the Pediatric Patients

1) Literature

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

EAPD guidelines for the use of radiographs in children, P40-48. European Journal of Pediatric Dentistry 1/2003 Guidelines in dental radiology are designed to avoid unnecessary exposure to X-radiation and to identify individuals who may benefit from a radiographic examination. Every prescription of radiographs should be based on an evaluation of the individual patient's benefit. Due to the relatively high frequency of caries among 5-year-old children, it is recommended to consider dental radiography for each child even without any visible caries or restorations. Furthermore, radiography should be considered at 8-9 years of age and then at 12-14, which is 1-2 years after the eruption of premolars and second molars. Additional bitewing controls should be based on an overall assessment of the caries activity/risk. The high-risk patient should be examined radiographically annually, while a 2–3-year interval should be considered when caries activity/risk is low. A routine survey by radiographers, 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 doses 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 have 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 have investigated pediatric doses. This study estimates the organ and effective doses for two pediatric tissue-equivalent phantoms using thermoluminescent dosimeters for three dental CBCT units and six imaging protocols. The doses to the thyroid, salivary glands, and brain ranged from 0.068mSv to 1.131mSv, 0.708mSv to 2.009mSv, and 0.031mSv to 1.584mSv respectively. The skin and red bone marrow have received much lower doses than the other three organs. The effective doses ranged from 0.022 mSv to 0.081 mSv. The effective doses calculated in this study were much higher than those 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 performed CT studies in children, raising concerns about radiation dose and their risks to children.

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

Materials and methods: Radiation doses were measured with small-sized silicon photodiode dosimeters that were implanted at various tissue and organ positions within a standard 6-year-old anthropomorphic phantom. Organ and effective

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 thyroids were 32.7 mGy for a lens in brain CT and 17.2 mGy for thyroid in neck CT. The seventy-fifth percentile of effective dose distribution in brain CT was approximately the same as the diagnostic reference level (DRL) in the 2003 UK survey.

2) Website

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

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

18.7 Abbreviations

AC	Alternating Current
AF	Auto Focusing
CAN	Controlled Area Network
CBCT	Cone-Beam Computed Tomography
CEPH	Cephalogram
CRS	Chronic Rhinosinusitis
CT	Computed Tomography
DAP	Dose Area Product
DC	Direct Current
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
ENT	Ear / Nose / Throat
ESD	Electrostatic Discharge
FDD	A focal spot to Detector Distance
FOD	A focal spot to Object Distance
FOV	Field of View
IEC	International Electrotechnical Commission
ISO	International Standards Organization

LED	Light-Emitting Diode
MPSO	Multiple Portable Socket-Outlet
ODD	Object to Detector Distance
PA	Posterior/Anterior
PANO	Panoramic
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

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This is class IIb equipment and obtained CE marking in May 2017 for regulation compliance by the enacted European Union's MDR (Medical Device Regulation)



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