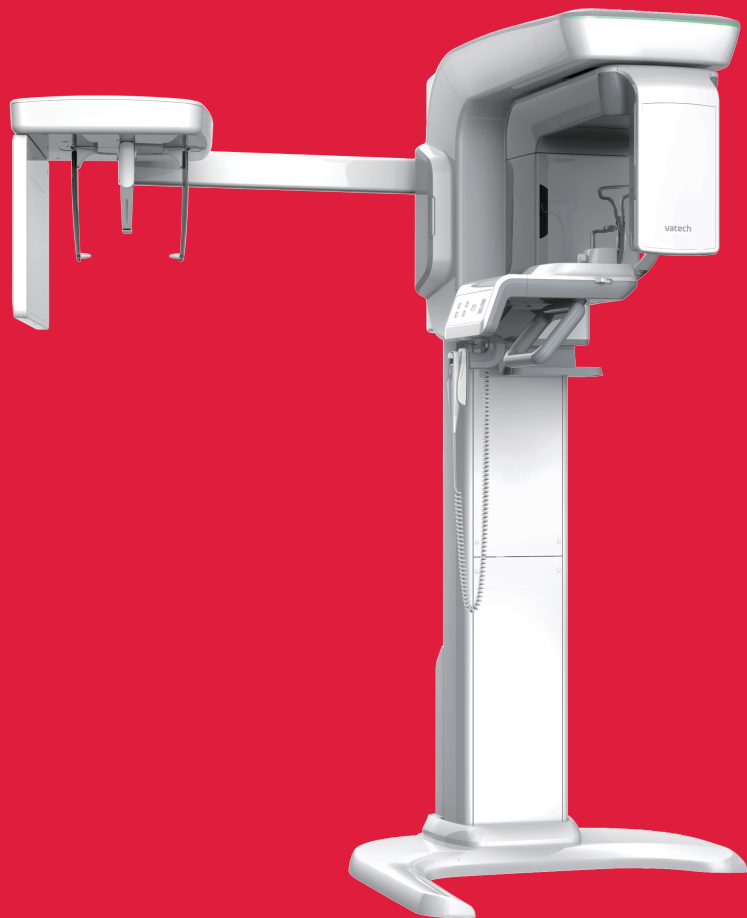


Smart PlusTM

User manual

Model : PHT-35LHS
Version : 1.31

- English



Full version

vatech

Notice

Thank you for purchasing the **Smart Plus (PHT-35LHS)** extra-oral imaging system.

Smart Plus is an advanced digital diagnostic system that incorporates PANO, CEPH (Optional), CBCT, and 3D MODEL Scan imaging capabilities into a single system.

Module	Option details
Smart Plus SP	CBCT + PANO
Smart Plus SC	CBCT + PANO + CEPH

This manual describes how to operate the **Smart Plus** system. It is recommended that you thoroughly familiarize yourself with this manual to make the most effective use of this equipment.

Observe all cautions, safety messages, and warnings that appear 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.

Phone: +82-1588-9510

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This document is originally written in English.

The **Smart Plus** is referred to as “equipment” in this manual.

Manual Name: Smart Plus (PHT-35LHS) User Manual

Document number: VDH-UM-069

Version: 1.31

Publication Date: 2021-06

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1. Introduction

1.1 Overview

Smart Plus (PHT-35LHS) is an advanced 4-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), CBCT, and 3D MODEL Scan imaging capabilities into a single system.

Smart Plus, a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography, **Smart Plus** is a complete digital X-ray system equipped with imaging viewers, an X-ray generator, and a dedicated SSXI detector.

The digital CBCT system is based on a CMOS digital X-ray detector. The CMOS CT detector is used to capture 3D radiographic images of the head, neck, oral surgery, implant, and orthodontic treatment. With Auto Pano function, it also reconstructs the 3D CT data and produces 2D panoramic images without an additional scan.

Smart Plus can also acquire 2D diagnostic image data in conventional panoramic and cephalometric modes.

1.2 Indications for Use

Smart Plus (PHT-35LHS) is intended to produce panoramic, cephalometric, or 3D digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, and TMJ 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 Intended Purposes

- Determination of the extent of lesions, tumors, cysts, etc., which cannot be fully visualized on plain films
- Diagnosis of foreign bodies or displaced roots involving the maxillary sinus
- Diagnosis of bone diseases, cysts, etc., affecting the temporomandibular joints
- Identifying the relationship of the inferior dental canal to a tooth/lesion that is to be removed
- Assessment of fractures on maxilla, mandible, condylar neck, orbital floor, and fractures of teeth where plain film imaging is equivocal
- Visualization of the 3D anatomy of the alveolar clefts
- Diagnosis of un-erupted teeth impacted teeth and odontomas
- Diagnosis of root resorption of teeth
- Assessment of cleft palate
- Planning any surgery where 3D analysis of the jaw is required
- Storing Plaster Casts in 3D data
- Detailed verification of images in-depth direction

1.4 Contraindications

There are no known contraindications to the use of this equipment.

1.5 Intended User Profiles

Considerations	Requirement Description
Education	<ul style="list-style-type: none"> Licensed dentists or dental hygienists, radiologists, and graduates of relevant bachelor's degree (national qualifications)
Knowledge	<ul style="list-style-type: none"> Understanding the treatment and diagnosis of dental disease Understanding the terms and guidance of hardware and software of a diagnostic medical radiation device and recognizing device connection, installation, operating conditions
Language understanding	<ul style="list-style-type: none"> Understanding how to use manuals (English/Korean) Or Understanding other language provided
Experience	<ul style="list-style-type: none"> 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

The dental X-ray CT should be used by qualified personnel (dentists, dental hygienists, or radiologists) only.

2. General Information

2.1 Manufacturer's Liability

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

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

2.2 Owner and Operator's Obligations








- The owner of this equipment shall perform constancy tests at regular intervals to ensure patient and operator safety. These tests must be performed by local X-ray safety regulations.
- The owner of this equipment shall perform regular inspection and maintenance of the mechanical and electrical components in this equipment to ensure safe and consistent operation (IEC 60601-1).

The owner of this equipment shall ensure inspection and cleaning work is performed by the maintenance schedule outlined in **Chapter 12 Cleaning and Maintenance**.













2.3 Conventions in this Manual

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







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

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

2.4 Marks and Symbols

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

2. General Information

Symbols	Description	Location
	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.2 regulations.	Label
	Indicates that the user needs to refer to the Instruction Manual .	Label
	Indicates the date when the equipment was manufactured.	Label
	Indicates the manufacturer's serial number so that specific equipment can be identified.	Label

2.4.1 Label Locations

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

①

Product : Computed Tomography X-ray System
 Model: PHT-35LHS
 Power Input : 100-240V~, 50/60 Hz, 2.0 kVA
 This X-ray equipment complies with 21 CFR Subchapter J

Mode of operation : Continuous operation with intermittent loading – Needs waiting time(at least 60 times the exposure time) before the next exposure begins
 Mode de fonctionnement : Fonctionnement continu avec chargement intermittent - A besoin de temps d'attente (au moins 60 fois le temps d'exposition) avant le début de l'exposition suivante

WARNING: X-ray unit may be dangerous to PATIENT and OPERATOR unless safe exposure factors, operating instructions and maintenance schedules are observed.
AVERTISSEMENT: Cet équipement à rayons X peut être dangereux pour les PATIENTS et les OPERATEURS si les facteurs d'exposition sécuritaires, les instructions de fonctionnement et les programmes de maintenance ne sont pas respectés.

13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, KOREA
 VATECH Co., Ltd. | Website: www.vatech.co.kr

51 Quai de Dion Bouton 92800 Puteaux France
 Vatech Global France (SARL) MADE IN KOREA

②

CAUTION (PRUDENCE)

X-RAY / ATTENTION : X-RAY ON WHEN EQUIPMENT IN OPERATION
 X-RAY / ATTENTION : X-RAY ACTIVE LORSQUE L'EQUIPEMENT EST EN FONCTIONNEMENT

CLASS 1 LASER PRODUCT

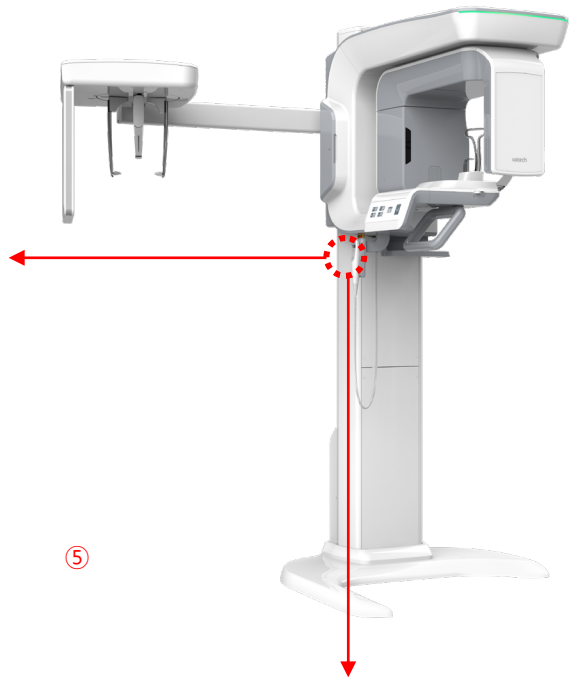
The laser diode, Class 1 complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser notice No. 50, dated June 24, 2007, classified to IFC 60825-1 ED-2 ④

③

X-RAY GENERATOR

Model : DG-07E22T2
 X-ray Tube : D-0525B / Canon
 Focal Spot : 0.5 x 0.5 mm (IEC 60336)
 Output : Max. 99 kV / Max. 16 mA
 Inherent Filtration : 0.8 mmAl / 50 kV
 Added Filtration : 1.5 mmAl
 Total Filtration : Min. 2.5 mmAl

MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT
 ANSI/AAMI E560601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 E476672
 No. 60601-1 (2014), IEC 60601-1-3 (2008), IEC 60601-2-63 (2012)



SN

REF

Weight(kg): L

⑥ For Canada only (with CEPH)

CAUTION : X-RAYS
ATTENTION : RAYONS X

Device Identifier
 SMART PLUS SC

⑥ For Canada only (without CEPH)

CAUTION : X-RAYS
ATTENTION : RAYONS X



Device Identifier
 SMART PLUS SP

NOTICE

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

No.	Item
①	Smart Plus (PHT-35LHS) Main Label
②	CAUTION Label - X-ray/Attention: X-ray on when equipment in operation.
③	X-RAY GENERATOR Label : 1.6 kW Generator
④	CLASS 1 LASER PRODUCT Label
⑤	Manufacturer Label - The date of manufacture/Serial Number/Weight of the equipment
⑥	Device Identifier Label (For Canada only) For Canada, the Model is distinguished by Smart Plus SC and Smart Plus SP. <ul style="list-style-type: none"> ● Smart Plus SC: CEPH included ● Smart Plus SP: CEPH not included

3. Warnings and Precautions

 WARNING	Be sure to observe all warnings and safety instructions included in this manual.
 WARNING	This x-ray unit may be dangerous to patients and operators unless safe exposure factors, operating instructions, and maintenance schedules are observed.

3.1 General Safety Guidelines

3.1.1 Operator qualifications

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

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

3.1.2 General safety precautions

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

3. Warnings and Precautions

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

3.1.3 Ventilation

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

3.1.4 Hygiene



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

Do not expose this equipment to liquids, mists, or sprays. Exposing this equipment to liquids may cause an electric shock or otherwise damage the system.

Do not use spray cleaners on the equipment, as this could cause a fire.

- All removable patient support components (the Bite, the Chinrest, the Temple Supports, and the Ear Rods) can be cleaned using non-alcohol-based cleaning solutions.
- Clean the Support Handles by using non-alcohol-based cleaning solutions before taking photos of the next patient.

- Other surfaces of the equipment can be cleaned using a soft cloth dampened with a mild cleaning solution.
- New hygiene cover must be provided for each new patient to prevent the transmission of communicable diseases.



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

3.1.5 Condensation

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

3.1.6 Cooling

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

3.1.7 Turning the equipment on/Adjusting the height of the equipment

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

3.1.8 Emergency stop

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

3.1.9 Trouble-free operation

- Do not use this equipment in an environment that is susceptible to explosion.
- Always operate the equipment within a temperature range of 10 °C to 35 °C (50 °F to 95 °F) for the safe operation. Image quality may deteriorate if the equipment is operated outside of this range.
- Always allow the equipment enough time to warm up (while switched on) if it has been exposed to temperatures below 10 °C (50 °F).
- Only perform X-rays of patients if the system is in full working order.
- Always ensure that equipment movement is not obstructed by the patient's clothing, a medical device (such as a wheelchair), or the patient.
- Do not leave the patient unattended around the equipment.
- Remove all radio-controlled devices, mobile phones, et cetera. from the X-ray room before image acquisition as these objects may cause the equipment to malfunction.

3.1.10 Modifying the equipment

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

3.2 Electricity-related Safety Precautions



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

- Check the status of the power source, PC, and cables before operating the equipment.
- Ensure that Main Power Switch is set off when the equipment is not in use.
- Always disconnect the power supply before cleaning the equipment.
- Always keep electrical cords away from hot appliances or radiators.
- Do not place the PC or peripheral equipment connected to the PC near the patient.
- The equipment and PC should be connected to a common protective earth.
- Do not overload the equipment's circuit by sharing it with too many appliances.
- Use the same power circuit for the PC and the equipment.

3.2.1 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 that is not provided with the equipment.

3.2.2 Electromagnetic compatibility

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

3.2.3 Static Discharge

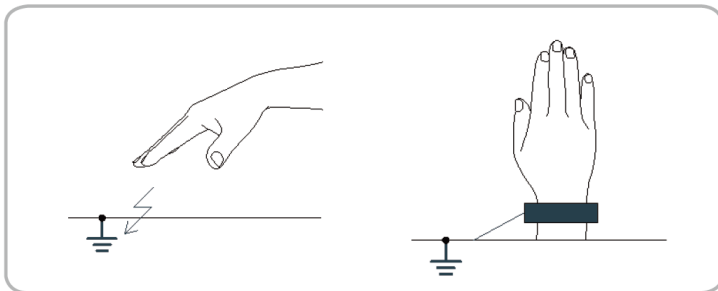
- Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without observing ESD protective measures.



Electrostatic discharge (ESD)

3.2.4 ESD protective measures include

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



3.3 Radiation Safety



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





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



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

3.4 Warnings

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

	<ul style="list-style-type: none"> ▪ X-ray equipment is hazardous to the patient and the operator if proper exposure safety measures and/or operating instructions are not observed. ▪ It is important to read this User Manual carefully and abide by all warnings and cautions stated within it.
	<ul style="list-style-type: none"> ▪ The 3D image should not be used for screening examinations. Each exam must be justified by demonstrating that the benefits outweigh the risk. ▪ Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, conventional medical CT or MR should be used instead of dental cone beam imaging.
	<ul style="list-style-type: none"> ▪ Smart Plus system, like other medical equipment, uses high-frequency electrical signals that can interfere with implantable devices such as pacemakers and Implantable Cardioverter Defibrillators (ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately power off the Dental X-ray system. ▪ Smart Plus system is designed to withstand the effects of defibrillation. However, when possible, disconnect the Dental X-ray system during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.
	<p>Federal law restricts this device to sale by or about a dentist or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices using or order the use of the device.</p>

3.4.1 Lasers

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



Risk of eye injury!

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

3.4.2 Cleaning

- Do not expose this equipment to liquids, mists, or sprays. Exposing this equipment to liquids may cause an electric shock or otherwise damage the system.
- Do not use spray cleaners on this equipment, as this could cause a fire.

3.4.3 During the Operation

- Do not use this equipment in an environment that is susceptible to explosion.
- Do not place flammable materials near this equipment.
- Do not operate the PC while the equipment is operating. Failure to comply with this instruction may result in system malfunction.
- Immediately stop imaging if the equipment malfunctions in any way.
- If a problem occurs during imaging, press the red Emergency Stop Switch to immediately stop all moving parts and cut off all power to the equipment's electrical components.
- Do not touch the patient while he or she is touching the SIP/SOP connectors.
- The medical electrical equipment or medical electrical system should not be used adjacent to or stacked with other equipment and that 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 of EQUIPMENT or SYSTEM.

3.4.4 In case of an electrical fire

- Use only fire extinguishers designed for electrical fires to extinguish fires on this equipment.

Liquid extinguishers, such as those which use water, could damage the equipment, and/or cause physical injury.
- Unplug the equipment's power cable before extinguishing any fire.

3.4.5 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/or personal injury may occur.
- Do not push or pull the equipment.
- Equipment should only be installed by an authorized technician, complying with proper installation procedures.

NOTICE

For further details on installation, refer to the **Smart Plus (PHT-35LHS) Installation Manual**.

3.4.6 Security Capabilities

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

3.4.7 Side effects

- There are no known side effects from the use of this equipment.

4. Imaging System Overview

4.1 System Components

- **Smart Plus (PHT-35LHS)** X-ray equipment
- PC system
- Console Software (v1.1): PANO, CEPH (Optional), CBCT, and 3D MODEL Scan
- EzDent-i/EasyDent: 2D viewer and patient management software
- Ez3D-i/Ez3D Plus: 3D viewer and image analysis software

4.2 Features

- Multi-FOV support: Selectable FOV - 10x8.5, 10x7 and 5x5 (cm)
- The multi-imaging solution for Accurate Diagnostics
- Conventional 2D (PANO and CEPH) image acquisition
- 3D and 2D (*Auto Pano) image acquisition by a single scan
- 3D scanning for Plaster Cast with FOV 10x8.5 (cm)
- DICOM (Digital Imaging Communication in Medicine) format supported

NOTICE

*Auto Pano

Auto Pano is a feature used to acquire reconstructed 2D images during 3D CT scans without additional X-ray exposure. It has the same region that conventional panoramic images offer. (It provides images for the Standard mode in DICOM or BMP format.)

Auto Pano option is available when FOV 10x8.5 or 10x7 is selected.



When the Auto Pano option is selected, the Auto Pano image is automatically acquired and can be seen on the **EzDent-i/EasyDent** Viewer.

4.3 Standards and Regulations

4.3.1 Standards

Smart Plus is designed and developed to comply with the following international standards and regulations:

- MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012),
CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-1-3 (2008), IEC 60601-2-63 (2012)
- 21 CFR 1020.30, 31, 33
- NEMA Standard publication PS 3.1-3.18

	<p>This is Class IIb equipment and obtained CE marking in April 2007 for regulations compliance in accordance with the revised European Union's MDD (Medical Devices Directive) 93/42 EEC.</p>
	<p>This equipment received the UL certification mark in accordance with ANSI/AAMI, CAN/CSA-C22.2 No. 60601-1 regulations.</p>

4.3.2 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: Temple Supports, Chinrests, and Bites.



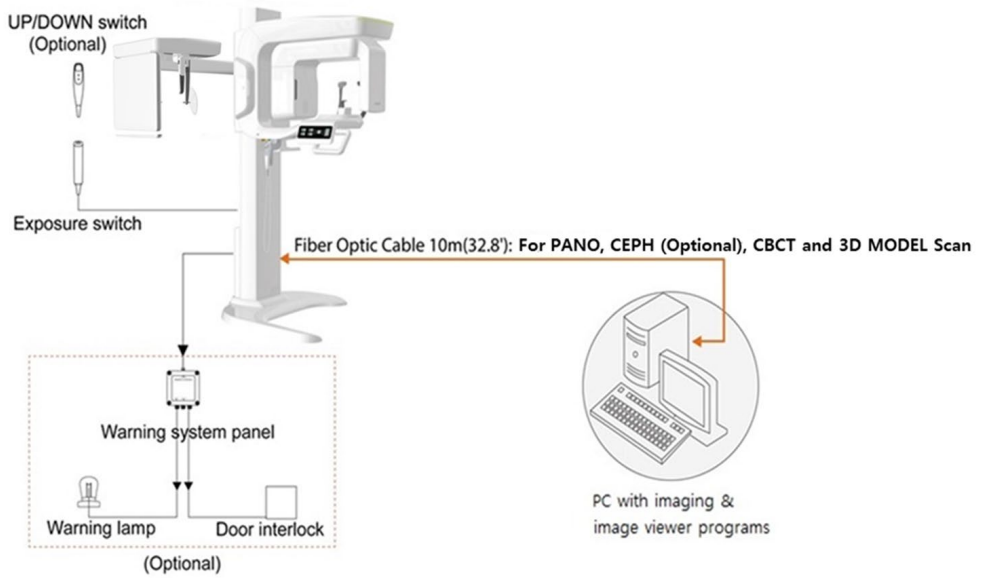
4.4 Operating Principles

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

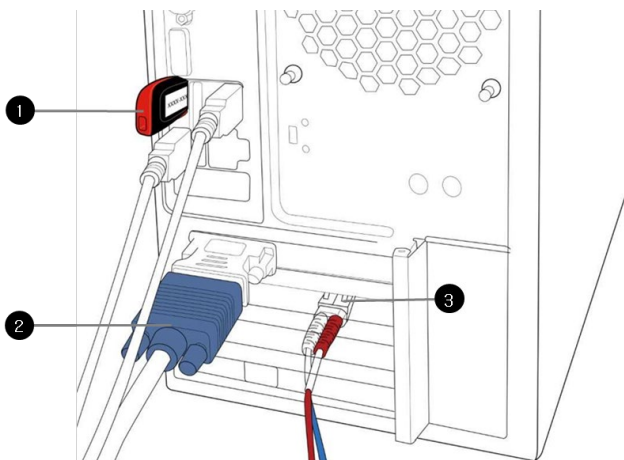
They hit anode to produce an X-ray. The machine acquires images by emitting X-ray continuously and rotates on the human tooth at different angles.

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

4.5 Imaging System Configuration

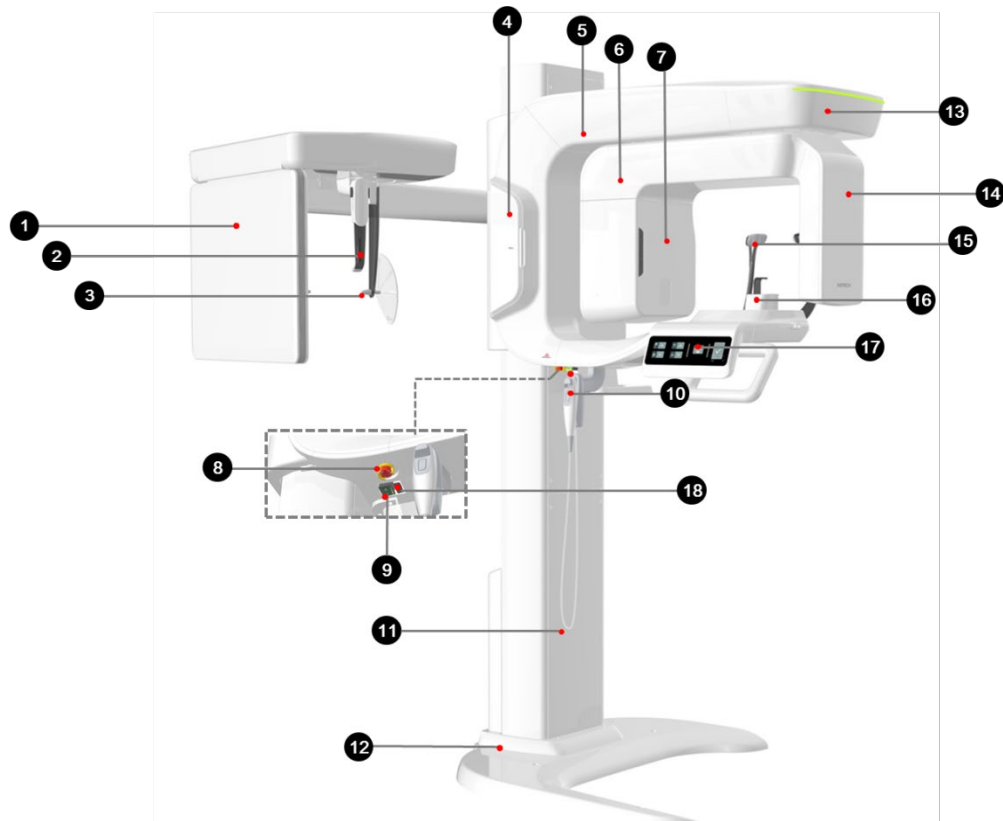


4.5.1 PC Signal Input/Output

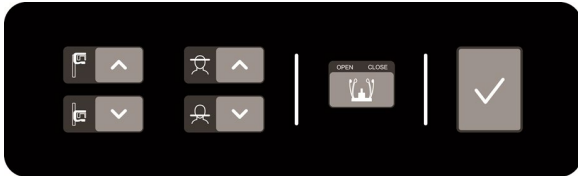


No.	Item
1	3D viewer License Key
2	Video output
3	Fiber optic cable (Data in/out)

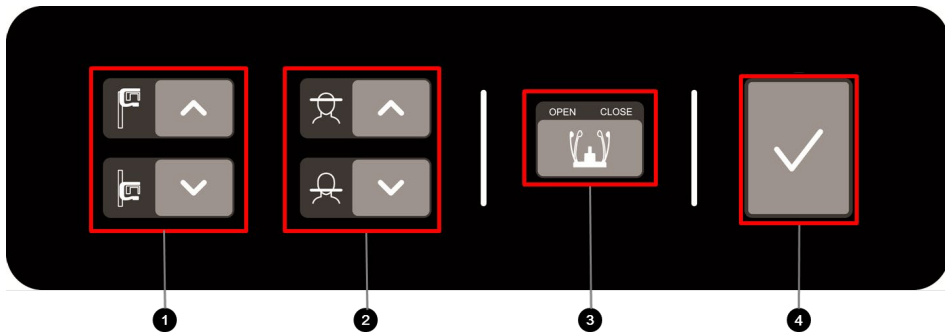
4.6 Equipment Overview



No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor
2	Nasal Positioner	<ul style="list-style-type: none"> – Positions the patient during CEPH imaging. – The ruler used for reference in an acquired image that is different from the actual size
3	Ear Rods	Secure the patient's head during CEPH imaging.
4	Enclosed Component Storage	The place where Bites, Chinrest Assay, and the other components can be stored.
5	Vertical Frame	Holds the Rotating Unit. It can be controlled by the Column UP/DOWN switch.
6	Rotating Unit	Rotates around the patient's head while the image is being acquired. (Its movement is different according to the scan mode.)

No.	Item	Description
7	X-ray Generator	The vacuum tube where the X-ray is produced.
8	Emergency Stop Switch	Immediately stops the moving parts and cuts off all power to the equipment's electrical components.
9	Main Power Switch	Turns on/off the main power of the equipment.
10	Column UP/DOWN Switch (optional)	Adjusts the height of the Vertical Frame.
11	Stationary Column	Supports the whole part of the equipment.
12	Base (Optional)	Balances the equipment and maintains its safety.
13	LED Lamp	Displays the status of X-ray exposure. - Green: Standby - Yellow: In operation
14	X-ray Detector for PANO/CBCT	Xmaru1404CF-Plus for PANO/CBCT imaging sensor
15	Temple Supports	Supports the patient's head by holding the temples. Used in PANO and CBCT modes.
16	Chinrest	The place to rest the chin.
17	Control Panel	<p>Operates the Horizontal Beam, opens/closes Temple Supports, adjusts the height of the Vertical Frame, and prepares for operation when the READY button is pressed. (For the details, refer to 4.6.1 Control Panel.)</p>  <p>* The Membrane type control panel below is the default.</p>
18	D-Sub Connector	The input signal port for Column UP/DOWN Switch

4.6.1 Control Panel



No.	Item	Description
1	Column UP/DOWN button	Moves the Vertical Frame up or down. (For adjusting the height of the Chinrest)
2	Horizontal Beam UP/DOWN button	Aligns the Horizontal Beam in PANO mode.
3	Temple Supports OPEN/CLOSE button	Adjusts the Temple Supports for patient positioning.
4	READY/RETURN button	It indicates that imaging is ready after parameter settings and the patient positioning is complete. Initializes the positioning of the Rotating Unit.

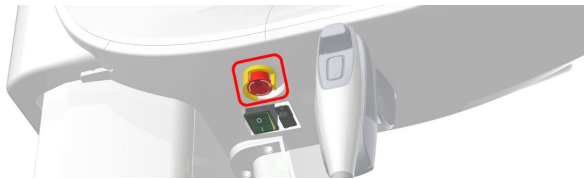
4.6.2 Emergency Stop Switch

During operation, the following emergencies may occur:

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

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

The **Emergency Stop Switch** is located at the bottom of the Vertical Frame.

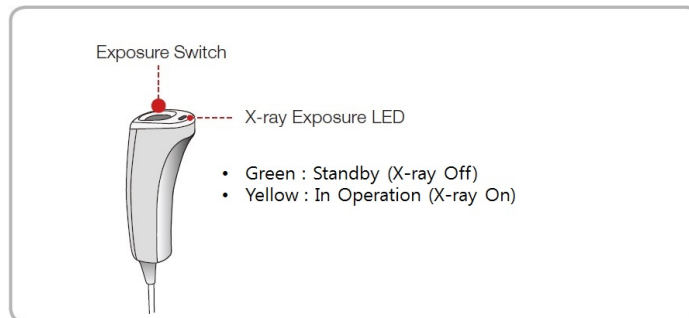


4.6.4 Exposure Switch

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

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

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










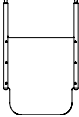






IMPORTANT

- The **Exposure Switch** is detachable. Ensure the **Exposure Switch** cable is not detached from the unit accidentally during the operation.
- Keep vocal/visual contact with the patient during exposure. If any problem occurs during exposure, release the **Exposure Switch** immediately.

4.6.5 Enclosed Components

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

Components	Name and Function	Materials
	Normal Bite : For PANO and CBCT normal patients	PC (Polycarbonate)
	Deep Bite Block*	PC (Polycarbonate)
	Special Bite A : For PANO TMJ and Sinus modes : For CBCT TMJ patients	PC (Polycarbonate)
	Special Bite B : For PANO edentulous patients	PC (Polycarbonate)
	Normal Chinrest : For Normal Bite	ABS (Acrylonitrile butadiene styrene) copolymer
	Special Chinrest : For Special Bite A and Special Bite B	ABS (Acrylonitrile butadiene styrene) copolymer
	Temple Supports (1 set)	PC (Polycarbonate)
	Ear Rods (1 set)	Silicone
	Nasal Positioner Cover : For CEPH	Silicone
	Carpus Plate	PC (Polycarbonate)
	Sanitary Vinyl Covers (disposable) for the Bite 	LDPE (Low-density polyethylene)
	Protractor (1 set) : For positioning the patient's body in CEPH mode.	PC (Polycarbonate)

Components	Name and Function	Materials
	Model Scan Jig	ABS (Acrylonitrile butadiene styrene) copolymer

*. Deep Bite Block is only available in some Asian countries.

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5. Imaging Software Overview

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

- **EzDent-i/EasyDent:** 2D viewer and patient management software
- **Ez3D-i/Ez3D Plus:** 3D viewer software
- **Console software (v1.1):** PANO, CEPH (Optional), CBCT, and 3D MODEL Scan

5.1 PC Specifications (Recommended)

NOTICE

- The PC system plays a significant role in image processing and verification. Configure the PC environment to meet the following specifications. If the PC specifications are not met, the image quality can be lower.
- Do not place patients near the equipment and PC.

Item	Specifications (HP)
CPU	Intel Xeon W-2223 3.6 GHz 4 Core Processor
Chipset	Intel® C612
RAM	2x8GB DDR4-2400 Registered RAM
HDD	1TB SATA 7200 rpm
Graphics board	NVIDIA GeForce GTX1060 6GB
Ethernet Interface	Integrated Intel I218LM PCIe GbE Controller Intel Ethernet I210-T1 PCIe NIC (Option)
Serial Port (RS232)	HP Serial Port Adapter Kit (Option)
Power Supply	≥ 700 Watts (90% efficient)
Slots	2 PCI Express Gen3 x16 slot 1 PCI Express Gen3 x 8 Slot 1 PCI Express Gen2 x 4 Slot 1 PCI Express Gen2 x 1 Slot 1 PCI 32bit/33MHz
CD/DVD drive	DVD Writer 5.25"
Operating System	Windows 7 Professional 64-bit (available through downgrade rights from Windows 10 Pro)
Recommended System	HP Z440

5.2 EzDent-i/EasyDent

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

NOTICE

Please refer to **6.2.1 Creating a New Patient Record** and **6.2.2 Retrieving Patient Records** and **EzDent-i/EasyDent User Manual** for more information.

NOTICE

Security Capabilities

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

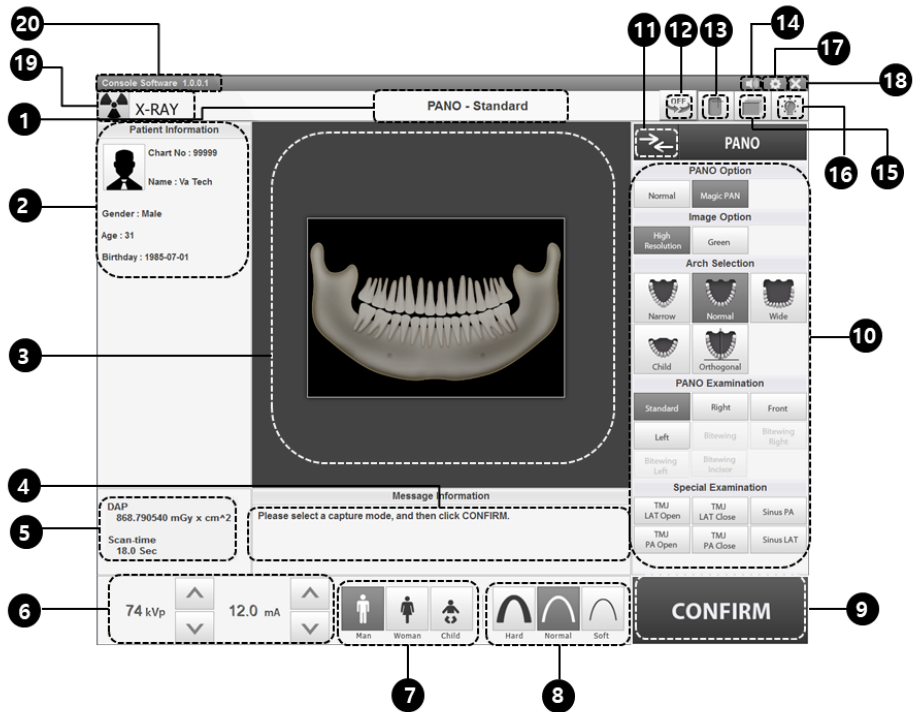
5.3 Console Software

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

NOTICE


- You can set the imaging parameters on Console Software running on the PC.
- To improve program functions, the Console Software may change without notice


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



No.	Item	Description
1	Imaging Mode Display	Displays the current imaging mode.
2	Scanning Status and Image Preview window	Show image acquisition progression and display a preview of the images acquired.
3	Patient Information window	Displays information on the selected patient.

No.	Item	Description																				
4	Guide Message window	Displays various text instructions for the operator.																				
5	DAP, Scan Time, and Exposure Time Display window	Displays estimated DAP (Dose Area Product), scan time, and exposure time after exposure parameter settings are completed.																				
6	Tube Voltage and Current Adjustment	<p>If the patient is selected in EzDent-i/EasyDent, the default kVp/mA according to the patient's information (gender/age) is displayed. This tool adjusts the kVp and mA values and controls the power of the X-ray to improve image quality. If necessary, adjust the kVp and mA values manually using the arrows.</p> <hr/> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 5px; margin-right: 10px;">NOTICE</div> <div> <p>For the tube voltage and its correspondence with the selected patient, refer to 16.1 Recommended X-ray Exposure Table.</p> </div> </div> <hr/>																				
7	Patient's gender/age group	<p>Displays the current patient's gender/age group as entered in EzDent-i/EasyDent's patient information fields. If necessary, the gender/ age group can be manually selected.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Gender / Age Group</th> <th style="text-align: left;">VATECH's Standard</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Child</td> <td>2 ~ 12 years of age</td> </tr> <tr> <td style="text-align: center;">Adult</td> <td style="text-align: center;">> 12 years of age</td> </tr> <tr> <td style="text-align: center;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Man</td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">Woman</td> <td></td> </tr> </table> </td> <td></td> </tr> </tbody> </table>	Gender / Age Group	VATECH's Standard	Child	2 ~ 12 years of age	Adult	> 12 years of age	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Man</td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">Woman</td> <td></td> </tr> </table>	Man		Woman										
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Man																						
Woman																						
8	X-ray intensity	<p>Selects X-ray intensity.</p> <hr/> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 5px; margin-right: 10px;">NOTICE</div> <div> <p>Depending on the circumference of the patient's head, X-ray intensity may be classified as Hard, Normal, or Soft:</p> <p>Soft ≤ Normal ≤ Hard</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Age Group</th> <th>Average Head Circumference (cm)</th> <th>Range (cm)</th> <th>X-ray Intensity</th> </tr> </thead> <tbody> <tr> <td rowspan="3" style="text-align: center;">Child</td> <td rowspan="3" style="text-align: center;">53±3</td> <td style="text-align: center;">>53±3</td> <td style="text-align: center;">Hard</td> </tr> <tr> <td style="text-align: center;">53±3</td> <td style="text-align: center;">Normal</td> </tr> <tr> <td style="text-align: center;"><53±3</td> <td style="text-align: center;">Soft</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Adult</td> <td rowspan="3" style="text-align: center;">56±3</td> <td style="text-align: center;">>56±3</td> <td style="text-align: center;">Hard</td> </tr> <tr> <td style="text-align: center;">56±3</td> <td style="text-align: center;">Normal</td> </tr> <tr> <td style="text-align: center;"><56±3</td> <td style="text-align: center;">Soft</td> </tr> </tbody> </table> </div> </div> <hr/>	Age Group	Average Head Circumference (cm)	Range (cm)	X-ray Intensity	Child	53±3	>53±3	Hard	53±3	Normal	<53±3	Soft	Adult	56±3	>56±3	Hard	56±3	Normal	<56±3	Soft
Age Group	Average Head Circumference (cm)	Range (cm)	X-ray Intensity																			
Child	53±3	>53±3	Hard																			
		53±3	Normal																			
		<53±3	Soft																			
Adult	56±3	>56±3	Hard																			
		56±3	Normal																			
		<56±3	Soft																			

No.	Item	Description
9	CONFIRM/READY button	<p>CONFIRM</p> <p>Applies the selected settings and moves to the next step. (Exposure parameter setting and patient positioning > Ready for exposure)</p> <hr/> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 5px; margin-right: 10px;">NOTICE</div> <div> <p>When you click the CONFIRM button, estimated DAP (Dose Area Product), scan time and exposure time would be displayed DAP, Scan Time, and Exposure Time Display window.</p> </div> </div> <hr/> <p>READY</p> <p>Activated when you click the CONFIRM button after the patient positioning is completed. Click the button when all aspects of preparation are completed for image acquisition.</p>
10	Imaging parameters configuration panel	Selects the imaging parameters for each mode: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan
11	Modality Selection button	Returns to Modality Selection (PANO, CEPH (Optional), CBCT, and MODEL) screen.
12	Rotation Test button	<p>Switches to the Rotation Test mode to check if any part of the patient's body reaches the surface of the equipment before the actual exposure.</p> <p>To change to the Rotation test mode,</p> <ol style="list-style-type: none"> 1. Align the patient to the equipment. (For the details, refer to the "Positioning the Patient" section of each modality chapter.) 2. Select a modality. 3. Click the CONFIRM button. 4. Click the Rotation Test button. Then, the button is changed to the OFF state and icon. <div style="text-align: center; margin: 10px 0;">  </div> <ul style="list-style-type: none"> ● To start the rotation test, press the BEAM ON/OFF button on the Control Panel. ● To finish the test mode, click the Rotation Test button or READY button. <hr/> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 5px; margin-right: 10px;">NOTICE</div> <div> <p>This function is applied to PANO and CBCT modalities only.</p> </div> </div>

No.	Item	Description
13	Phantom button	<p>This function is used to acquire Phantom images.</p> <div style="border: 1px dashed black; padding: 5px;"> <div style="display: flex; align-items: center;"> <div style="border: 2px solid blue; padding: 2px 10px; margin-right: 10px;">NOTICE</div> <div> <p>Image acquisition using the Phantom Jig:</p> <ol style="list-style-type: none"> 1. Click the Phantom button. 2. Select the Modality and click the Capture button. 3. Check the parameters displayed in the main GUI window and align the Phantom Jig, and then click the READY button. 4. Press and hold down the Exposure Switch. </div> </div> </div>
14	speaker volume button	<p>This button is used to adjust the speaker volume. Clicking on the speaker icon brings up the volume control bar, and you can adjust the volume by clicking and moving the volume control bar with your mouse. After moving the bar, release the mouse to play the current volume and save the current volume.</p>
15	Manual Reconstruction button	<p>Reconstructs the image manually when automatic image reconstruction fails: Select a Modality after clicking this button. > Click the Search button. > Select an image to reconstruct. > Click the Reconstruction button.</p>
16	Laser Beam ON/OFF button	<p>Turns the Laser Beam on or off for patient positioning. Enabled when the CONFIRM button is clicked after the imaging conditions are configured.</p>
17	Settings button	<p>Displays and sets various equipment-related parameters, including language, automatic save, DAP display unit, et cetera.</p>
18	EXIT button	<p>Exits the console software.</p>
19	X-ray indicator	<p>The radiation mark turns yellow and “X-RAY” changes to “X-RAY ON.”</p> <div style="display: flex; align-items: center;">  <div style="background-color: #f0f0f0; padding: 5px; border: 1px solid #ccc;"> X-RAY ON </div> </div>
20	Version Information	<p>Displays the Console Software version.</p>

6. Getting Started

6.1 Turning on the Equipment



- Do not place the patient close to the equipment when it is being turned on. Doing so may cause physical injury to the patient and damage to the equipment.
- Do not operate the PC while the equipment is in operation. Doing so may cause an error in the equipment.



- The extreme fluctuation of temperature may cause condensation inside the equipment. Do not switch on the equipment until it has reached normal room temperature.
- Rebooting the equipment: After turning it off, wait for approx. 20 seconds before turning it on again.
- Warm-up the equipment for at least 5 minutes before the operation. For the best image quality, it is recommended to have a warm-up phase for more than 30 minutes.

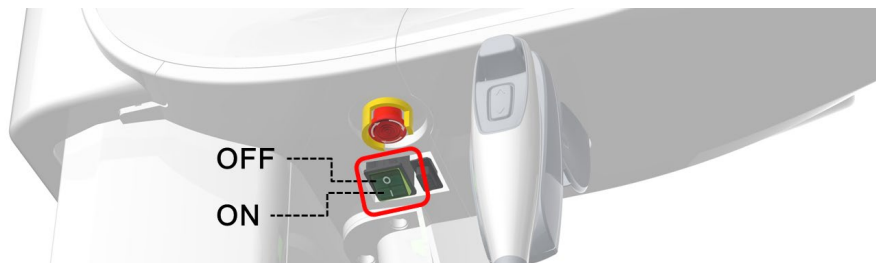
IMPORTANT

If the equipment has not been used for a long time, please let it have enough time to be warmed up. It extends the life of the X-ray tube.

The imaging system consists of the imaging equipment and the PC.

Before turning on the equipment, please confirm that the equipment and PC have been installed correctly.

- Turn on the PC.
- Press the **Main Power Switch** that is located at the bottom of the Vertical Frame to turn on the equipment.



NOTICE

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

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

6.2 Running the Image Viewer (EzDent-i/EasyDent)

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

NOTICE

For further details on this subject, refer to the **EzDent-i/EasyDent User Manual**.

NOTICE

Security Capabilities

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

NOTICE

For the **Smart Plus** dental computed tomography X-ray system, both 3D viewer (**Ez3D-i/Ez3D Plus**) and Console Software are being accessed through 2D viewer (**EzDent-i/EasyDent**) SW. 3D viewer and Console Software do not have an image storage capacity of their own, and both programs will not be able to keep patient information.

6.2.1 Creating a New Patient Record

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

EzDent-i

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

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

EasyDent

1. Click the Patient icon in the upper left corner of EasyDent's main GUI window.



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

3. Click the **Add** button to save the patient record.

6.2.2 Retrieving Patient Records

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

EzDent-i

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

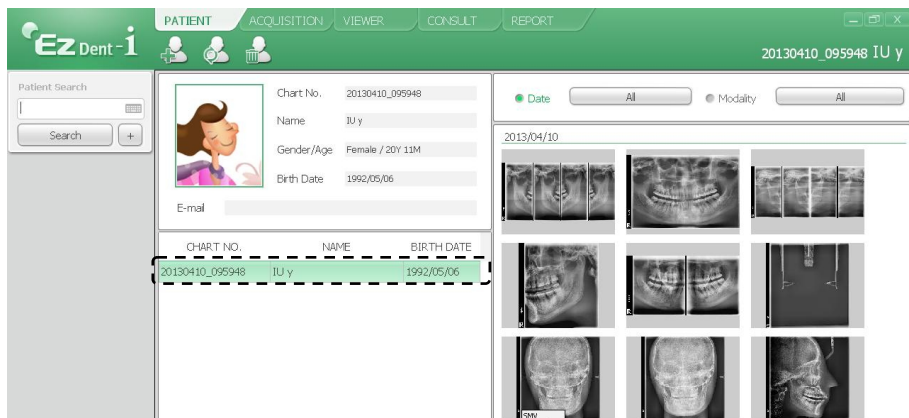


NOTE

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



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

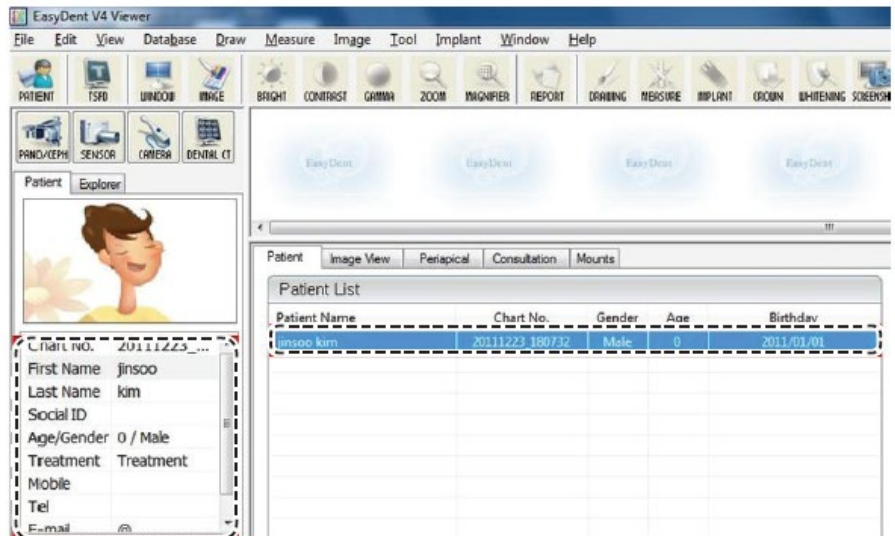


EasyDent

1. On the **Patient Information** pane, double-click the Chart No., First name, or Last name of the patient, and the virtual keyboard will pop up.



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



6.3 Initiating the Console Software

NOTICE

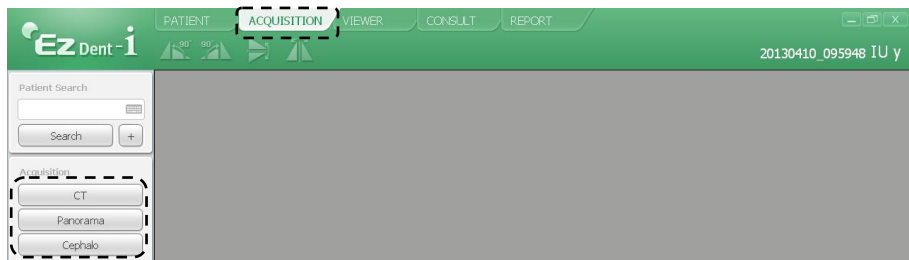
For a new patient, the patient information needs to be registered first.

EzDent-i

1. Search and select the patient to be captured.



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



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

NOTICE

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

EasyDent

1. First, click the patient information in the **Patient List**, and click an imaging modality button to select on the upper left corner.



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

NOTICE

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

7. Acquiring PANO Images

7.1 PANO Imaging Program Overview

- **Result Images**

It provides conventional 2D panoramic images.

- **Image Acquisition_Method**




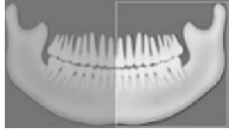
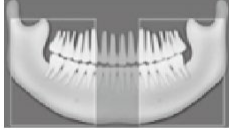
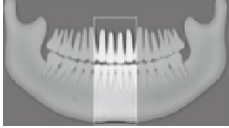
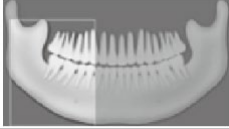



It reconstructs U-shaped arch data to a single 2D image utilizing multiple images taken with the X-ray beam scanning specific oral & maxillofacial regions at different angles.





- **Available PANO Options**

Mode	Description
Normal	Provides a normal panoramic image.
Magic PAN (Optional)	Provides a single optimal panoramic image having multiple focal images combined. Minimizes the difference in the quality of images which vary according to the patient's positioning and the arch shape.
Insight PAN	Multi-image acquisition option that reconstructs the panoramic image into multiple focal images in depth regions. Its main purpose is to diagnose depth regions, which cannot be confirmed with ordinary panoramic images.

■ Examination Programs

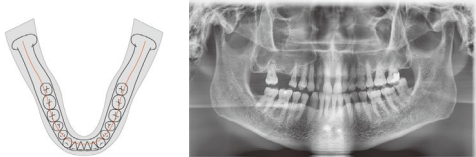

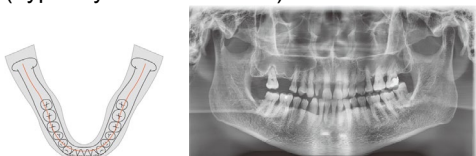
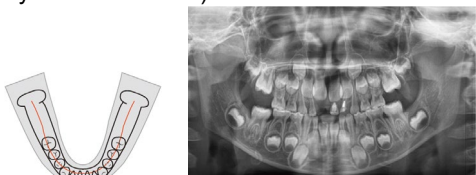

It is classified as below based on the ROI (Region of Interest).

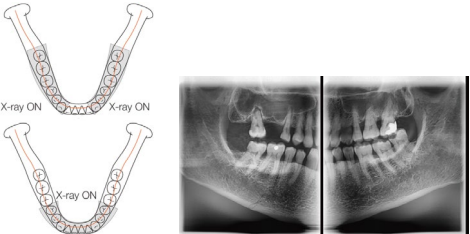
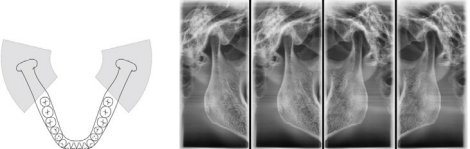


Examination Type	Arch Selection	ROI	Sample Image	
PANO Examination	Narrow Normal Wide Child Orthogonal	Standard		
		Right		
		Front		
		Left		
	Orthogonal	Bitewing*		
		Bitewing Incisor* (Optional)		
		Bitewing Right*		
		Bitewing Left*		
	SPECIAL Examination	N/A	TMJ LAT Open	
			TMJ LAT Close	

Examination Type	Arch Selection	ROI	Sample Image
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	



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

■ Main Imaging Programs

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

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

7. Acquiring PANO Images

Examination Type	Arch Selection	ROI	Description & Sample Image
		Sinus PA	<p data-bbox="740 328 1207 415">A special imaging mode to acquire a Sinus image, in which an X-ray beam is directed on the frontal region of the maxillary sinus.</p>  

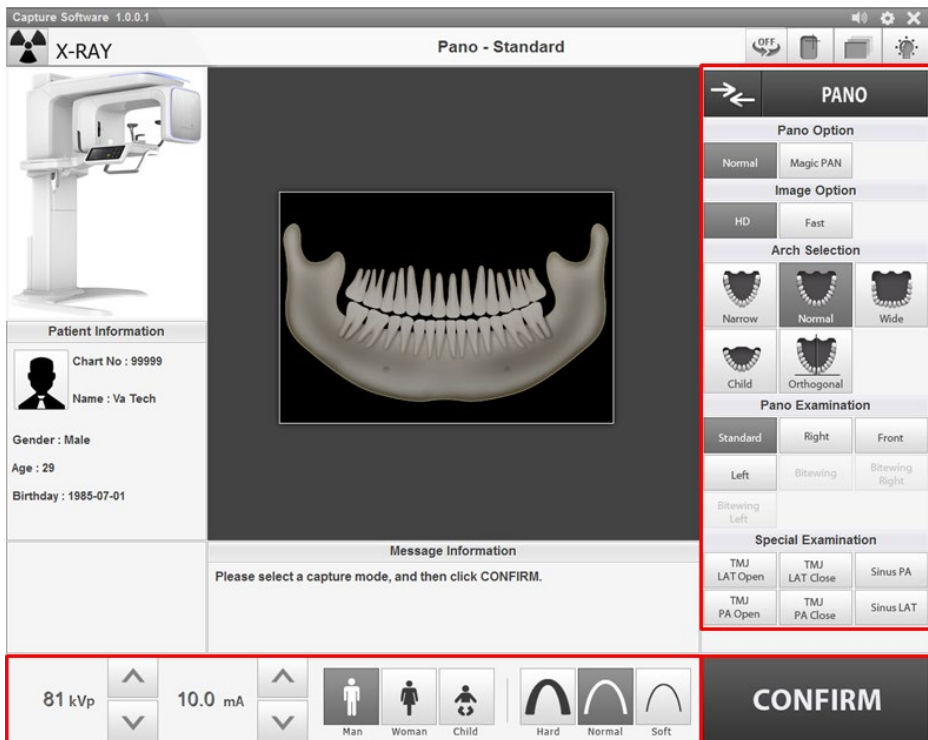
** Bitewing imaging mode is activated only when Orthogonal is selected in Arch Selection.

7.2 Configuring Exposure Parameters

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

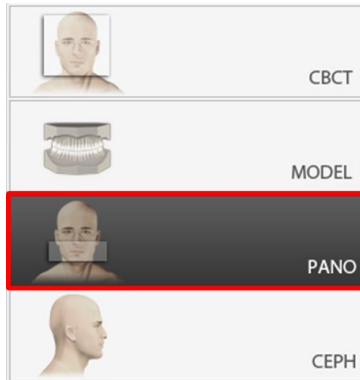
NOTICE

You can set the imaging parameters on Console Software running on the PC.



7. Acquiring PANO Images

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



NOTICE

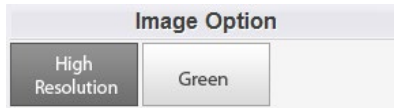
The **CEPH** button exists only when the CEPH imaging program is included in the equipment.

2. Select a Pano Option.



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

3. Select an Image Option.

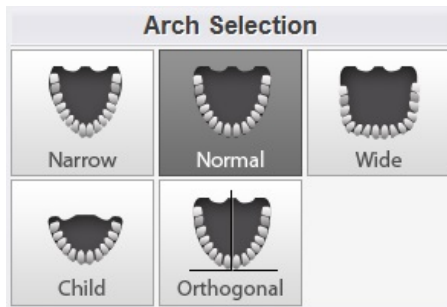


Mode	Description
High Resolution	High-Resolution image
Green	Normal quality image

NOTICE

The default is "High Resolution." "Green" is optional. When "Green" is enabled, the Image Option becomes selectable between "High Resolution" and "Green." When "Green" is disabled, the Image Options section is invisible. When "Insight PAN" is selected among Pano Options, Image Options are disabled.

4. Make an Arch Selection.



Arch Selection	Description
Narrow	Panoramic image of V-shaped palatal arches (a small number of adult females)
Normal	Panoramic image of normal adult palatal arches
Wide	Panoramic image of square-shaped palatal arches (some number of adult males)
Child	Panoramic image of child palatal arches, more than 40% less X-ray dose than in Normal mode.
Orthogonal	<p>A panoramic image where the x-ray angle enters vertically in between the teeth, so overlapping images is minimized.</p> <div style="border: 1px dashed black; padding: 5px;"> <p>NOTICE</p> <p>If Orthogonal Arch is selected, Bitewing examinations (Bitewing, Bitewing Incisor (Optional), Bitewing Right, Bitewing Left) are activated.</p> </div>

7. Acquiring PANO Images

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

PANO Examination		
Standard	Right	Front
Left	Bitewing	Bitewing Right
Bitewing Left	Bitewing Incisor	
Special Examination		
TMJ LAT Open	TMJ LAT Close	Sinus PA
TMJ PA Open	TMJ PA Close	Sinus LAT

NOTICE

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



- When a Special Examination option is clicked, the "PANO Examination" panel is disabled. If you want to select a PANO Examination option, please conduct Arch selection again.
- For more information about the Examination Program, refer to the **7.1 PANO Imaging Program Overview**.

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



NOTICE

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

7. Select X-ray intensity.



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

Soft ≤ Normal ≤ Hard

NOTICE

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

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



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

CONFIRM

When you click **CONFIRM** button:

NOTICE

When you click **CONFIRM** button,

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

DAP
127.334307 mGy x cm²

Scan-time
13.5 Sec

Exposure-time
13.5 Sec

- Guide the patient to the equipment.

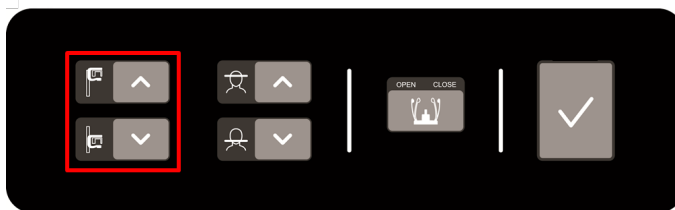
7.3 Patient Positioning



- Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
 - Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
-
- Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.
 - Metal implants or bridges may reduce the quality of the images.
 - Be sure to adjust the laser beam correctly. Otherwise, the quality of images can be lower due to ghost images or expansion/reduction of the images.

7.3.1 Getting prepared

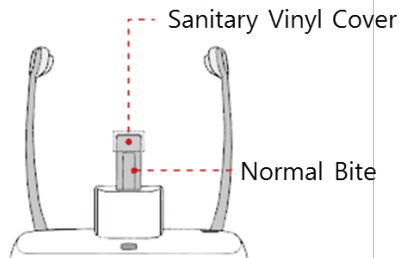
1. Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button or switch option to adjust the equipment to match the height of the patient.
4. Press the **Rotation test** button in the Console program and check that the equipment touches a part of the patient while the equipment is running.



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

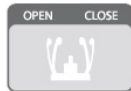
7.3.2.1 Normal Patient Positioning

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



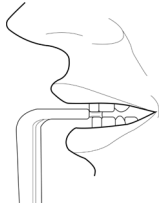
- The Sanitary Vinyl Cover is for individual use only. It should be replaced for each patient. Be sure to use the approved vinyl cover.
- Clean the Chinrest and the Bite with ethanol and wipe with a dry towel before the next patient.

2. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.

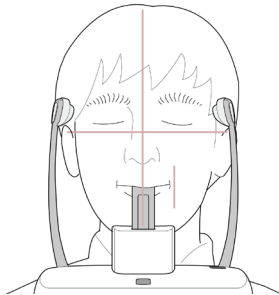


3. Guide the patient to the inside of the equipment.
4. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.

6. Let the patient bite the Bite along its grooves with his/her front teeth.

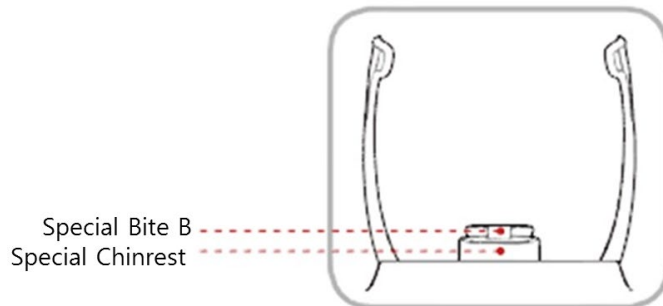


7. Let the patient maintain the posture as follows:
 - Close the mouth.
 - Place the tongue on the roof of the mouth.
 - Close the eyes.



7.3.2.2 Edentulous Patient Positioning

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



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

7. Acquiring PANO Images

3. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.



4. Guide the patient to the equipment.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and standstill.
7. Let the patient maintain the posture as follows:
 - Close the mouth.
 - Place the tongue on the roof of the mouth.
 - Close the eyes.



7.3.2.3 Laser Beam Aligning

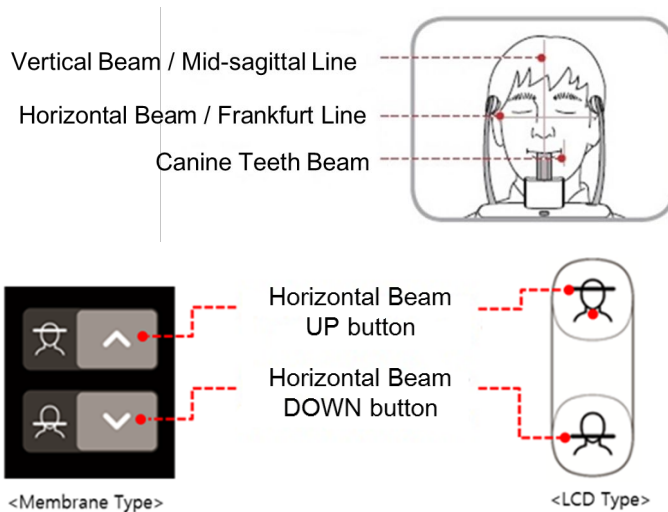


Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.

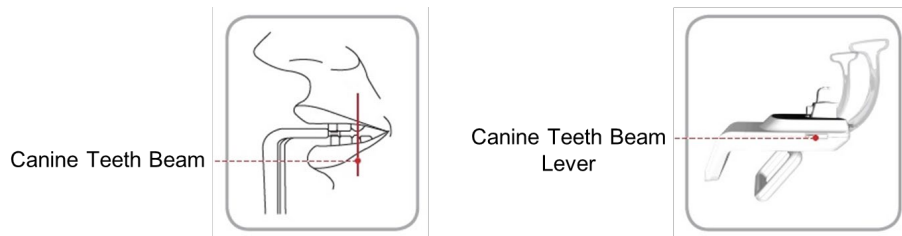


If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the laser beam properly.

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



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



7.3.2.4 Finishing Patient Positioning

1. After checking the positions of the patient and the laser beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.



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

2. Click the **READY** button. X-ray exposure has not started yet.
 3. Now go to **7.4 X-ray Exposure** to start the exposure.
-

7.3.3 SPECIAL Examination Mode (TMJ/Sinus)

7.3.3.1 TMJ Open Mode (LAT/PA)>

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

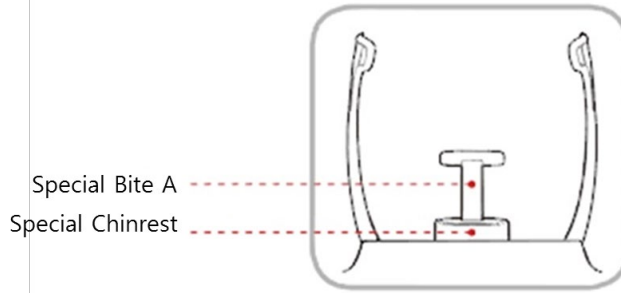
NOTICE

Steps for TMJ Mode

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

7.3.3.1.1 Patient Positioning

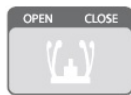
1. Remove the **Normal Chinrest** and insert the **Special Chinrest** into the equipment.
2. Insert the **Special Bite A** into the **Special Chinrest**



CAUTION

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

3. Use the **Temple Supports Open/Close** button on the control panel to widen the Temple Supports.



4. Guide the patient to the equipment.
5. Use the **Vertical Frame UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and standstill.

7. Acquiring PANO Images

7. Guide the patient to press the base of the nose (acanthion point) against the Chinrest and tilt the head forward about 5°. At this point, make sure the patient's jaw does not touch the equipment.

IMPORTANT

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

8. Let the patient maintain the posture as follows:

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



NOTICE

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

7.3.3.1.2 Laser Beam Aligning

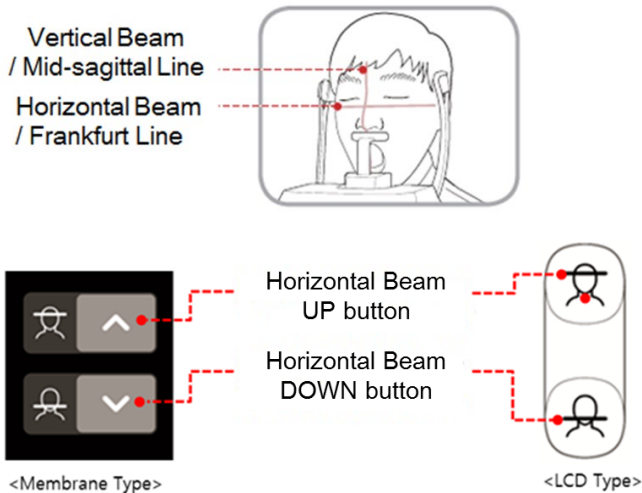
**WARNING**

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

**CAUTION**

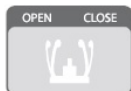
If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the laser beam properly.

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



7.3.3.1.3 Finishing Patient Positioning

1. After checking the positions of the patient and the laser beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.

**CAUTION**

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

2. Click the **READY** button. X-ray exposure has not started yet.
3. Now go to **7.4 X-ray Exposure** to start the exposure.

7.3.3.2 TMJ Close Mode (LAT/PA)

The TMJ Close image can be acquired after the TMJ Open image has been acquired.

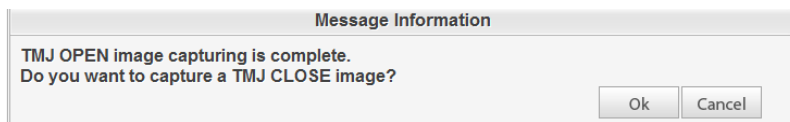
NOTICE

Steps for TMJ Mode

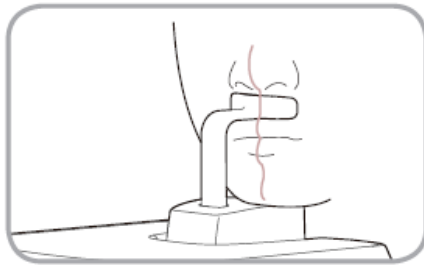
Patient positioning for TMJ Open > Laser Beam Aligning > X-ray Exposure > Patient positioning for TMJ Close > Laser Beam Aligning > X-ray Exposure

7.3.3.2.1 Patient Positioning

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



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



NOTICE

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

7.3.3.2.2 Laser Beam Aligning

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

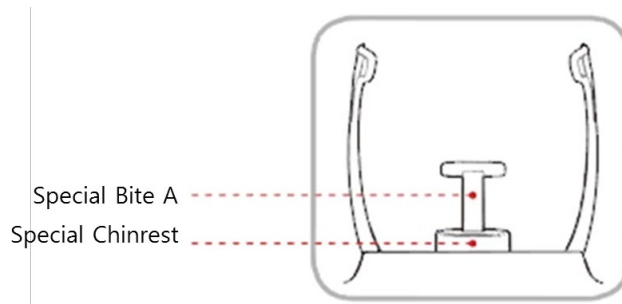
7.3.3.2.3 Finishing Patient Positioning

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

7.3.3.3 Sinus Mode (LAT/PA)

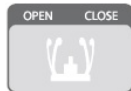
7.3.3.3.1 Patient Positioning

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



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

3. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.



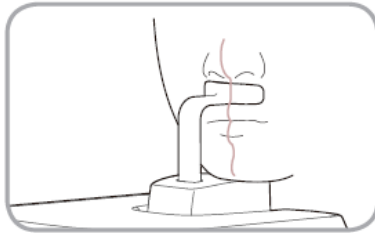
4. Guide the patient to the equipment.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and standstill.
7. Guide the patient to press the base of the nose (acanthion point) against the Chinrest and tilt the head forward about 5°. At this point, make sure the patient's jaw does not touch the equipment.

IMPORTANT

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

7. Acquiring PANO Images

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



NOTICE

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

7.3.3.2 Laser Beam Aligning



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

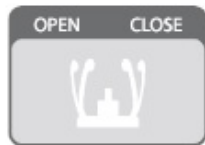


If the laser beam is not correctly positioned, there may be distortion, causing the image to be enlarged or reduced, or ghost shadows may occur and lower the image quality. Be sure to align the Laser Beam properly.

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

7.3.3.3 Finishing Patient Positioning

1. After checking the positions of the patient and the Laser Beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.



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

2. Click the **READY** button. X-ray exposure has not started yet.
3. Now go to **7.4 X-ray Exposure** to start the exposure.

7.4 X-ray Exposure



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



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

IMPORTANT

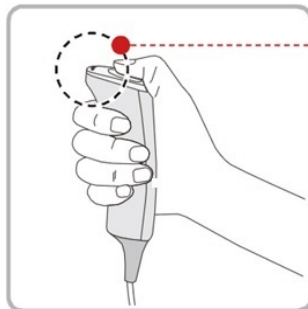
- Instruct the patient to close his or her eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.

1. Get out of the X-ray room and close the door.

IMPORTANT

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

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



• Yellow : X-ray On

NOTICE

The image appears on the screen.

NOTICE

- During X-ray exposure, the status appears as follows.
- The LED light of the **Exposure Switch** turns yellow.
 - The LED light on the top of the equipment turns yellow.
 - An alert sound comes out to indicate that X-ray emission is currently underway.
 - On Console Software, the radiation mark turns yellow, and "X-RAY" changes to "X-RAY ON."



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

7.5 Finishing the Scan

1. Open the Temple Supports and guide the patient out of the equipment.
2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.
3. Press the **READY** button to bring the Rotating Unit back to its initial position.

7.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

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

NOTICE

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

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

Left blank intentionally

8. Acquiring CEPH Images (Optional)

8.1 CEPH Imaging Program Overview

■ Result Images




It provides conventional 2D cephalometric images.

■ Image Acquisition Method


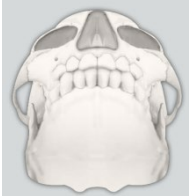

It acquires multiple images by scanning the specific oral & maxillofacial regions with the linear movement of the narrow detector and reconstructs them to a single 2D image through computer calculations.

■ Examination Programs

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

Examination Area	Description	Position
Lateral/ Full Lateral (Optional)	<ul style="list-style-type: none"> Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate. Measures the angles formed by the connecting lines between the cranial measurement points to further assess the growth of the facial region. It's widely used in Orthodontics and Oral and Maxillofacial Surgery. 	 <Lateral>  <Full Lateral>
PA	<ul style="list-style-type: none"> The radiation is directed from the posterior of the skull to the anterior. Used to examine cranial diseases, trauma, and congenital malformations. Used to assess the growth of the lateral side of the face. It is also used to examine the ramus mandibulae, the posterior region of the third-largest molar in the lower jaw, the sidewall of the maxillary sinus, the frontal sinus, antrum ethmoidal, olfactory pits, and optic disc pits. Measures the angles formed by the connecting lines between the cranial measurement points to further assess the growth of the facial region. It is widely used in Orthodontics and Oral and Maxillofacial Surgery. 	 <PA>

8. Acquiring CEPH Images (Optional)

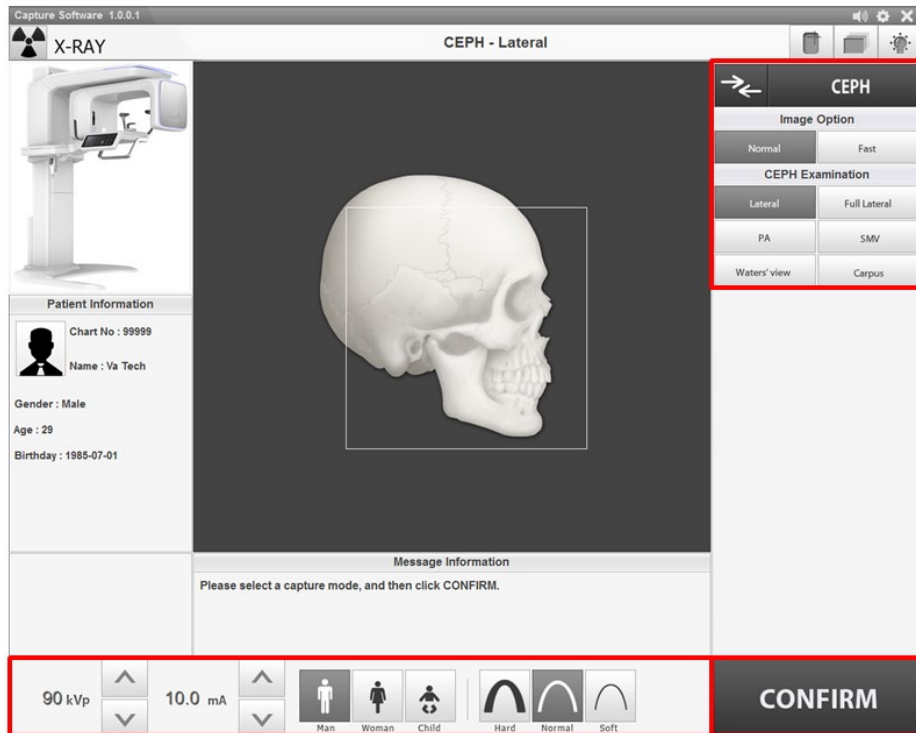
Examination Area	Description	Position
SMV	<ul style="list-style-type: none">Used to study the base of the skull, horizontal angulation of the mandibular condylar axis, the sphenoid sinus, the curvature of the lower jaw, the sidewall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull.	 <p data-bbox="1026 510 1104 533"><SMV></p>
Waters' view	<ul style="list-style-type: none">Used to study the frontal sinus, the antrum ethmoidal, the optic disc pit, the frontozygomatic suture, the nasal cavity, the coronoid process between the upper jaw and the zygomatic arch.	 <p data-bbox="989 765 1141 788"><Waters' view></p>
Carpus	<ul style="list-style-type: none">Used to assess hand bone age to compare the changes in the skull.	 <p data-bbox="1016 993 1114 1016"><Carpus></p>

8.2 Configuring Exposure Parameters

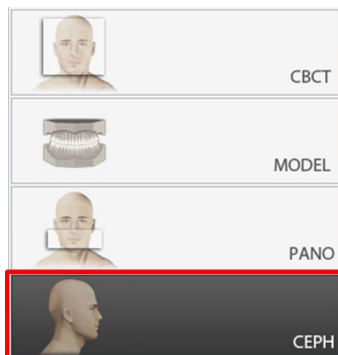
To acquire CEPH images, **6. Getting Started** must be completed first.

NOTICE

You can set the imaging parameters on Console Software running on the PC.



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

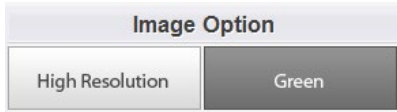


NOTICE

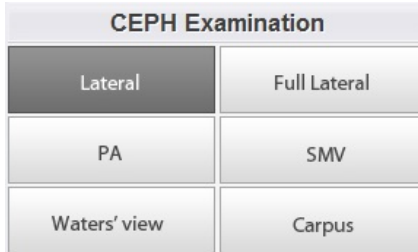
The **CEPH** button exists only when the CEPH imaging program is included in the equipment.

8. Acquiring CEPH Images (Optional)

2. Select an Image Option.



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



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



NOTICE

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

5. Select X-ray intensity.



Hard

Normal

Soft

NOTICE

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

Soft \leq Normal \leq Hard

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

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



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

CONFIRM**NOTICE**

When you click **CONFIRM** button,

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




DAP
127.334307 mGy x cm²

Scan-time
13.5 Sec

Exposure-time
13.5 Sec

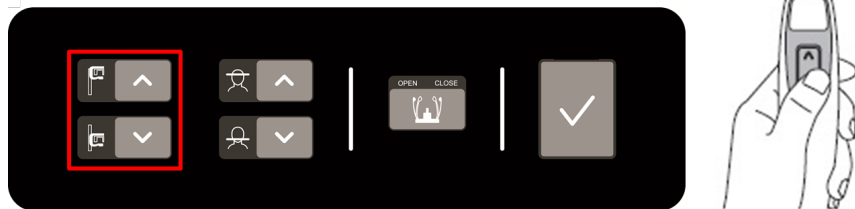
8. Guide the patient to the equipment.

8.3 Patient Positioning

	<ul style="list-style-type: none">▪ Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.▪ Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.
	<p>Ensure that the Nasal Positioner is left unfolded, before adjusting the Ear Rods in the proper direction.</p>
	<ul style="list-style-type: none">▪ Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.▪ Metal implants or bridges may reduce the quality of the images.

8.3.1 Getting prepared

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



< Control Panel – Membrane type >

8.3.2 Lateral/Full Lateral (Optional) Mode

NOTICE

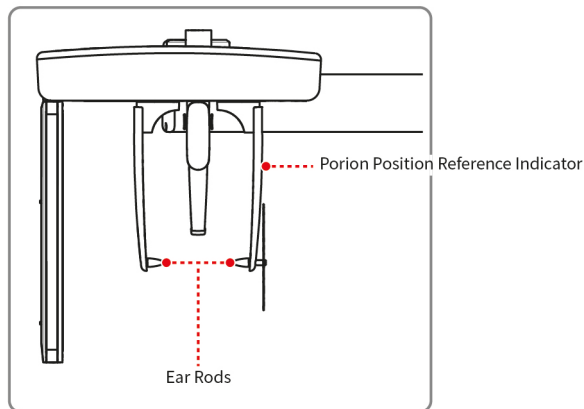
Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.

8.3.2.1 Patient Positioning

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



2. Leave enough space between the Ear Rods.



NOTICE

Use the Porion Position Reference Indicator that appears in the acquired image to easily confirm the location of Porion.

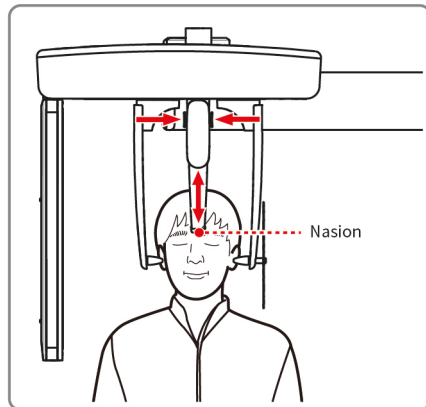
3. Guide the patient to the CEPH unit.
4. Direct the patient to relax his/her neck and shoulders and stand upright.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to match the height of the patient.

WARNING

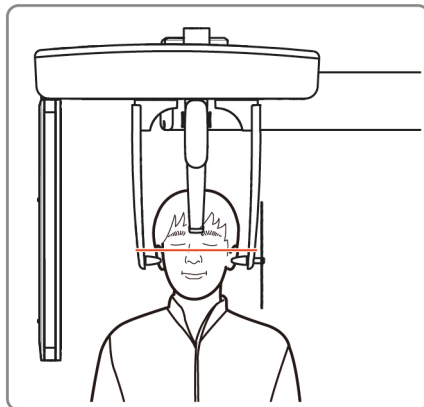
After adjusting the height of the column, align the Ear Rods and Nasal Positioner to the patient.

8. Acquiring CEPH Images (Optional)

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



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



8. Direct the patient to swallow first before closing the mouth and to remain in his/her current position until image acquisition is completed.
 9. Click the **READY** button. The x-ray exposure has not started yet.
 10. Now go to **8.4 X-ray Exposure** to start the exposure.
-

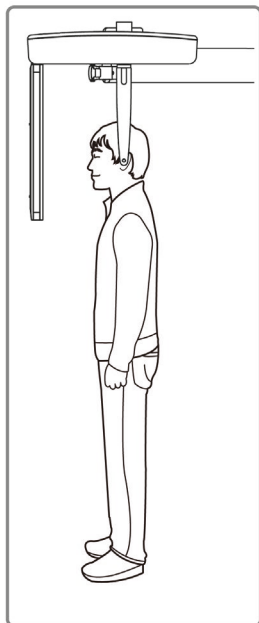
8.3.3 PA Mode

8.3.3.1 Patient Positioning

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



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



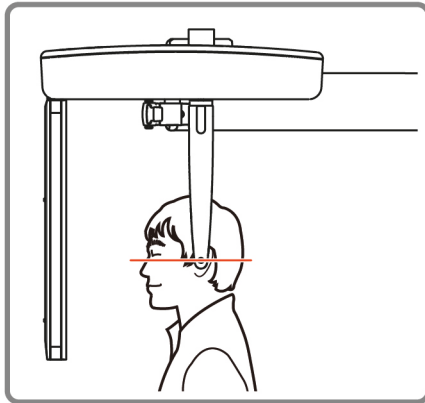
8. Acquiring CEPH Images (Optional)

5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to match the height of the patient.



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

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



8. Direct the patient to swallow first before closing his/her mouth and to remain in his/her current position until image acquisition is completed.
9. Click the **READY** button. The x-ray exposure has not started yet.
10. Now go to **8.4 X-ray Exposure** to start the exposure.

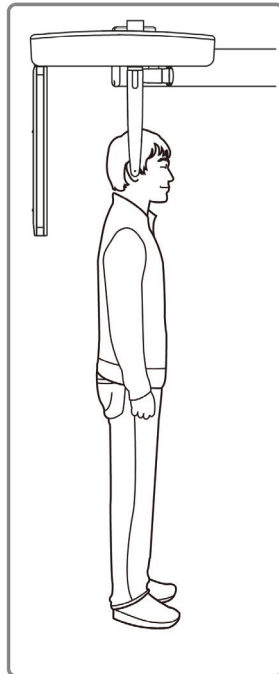
8.3.4 SMV Mode

8.3.4.1 Patient Positioning

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



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



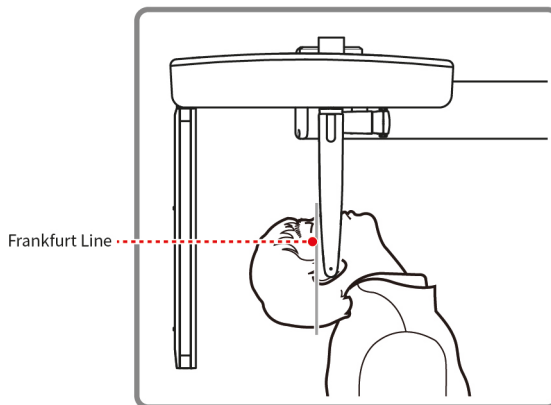
8. Acquiring CEPH Images (Optional)

5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to match the height of the patient.



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

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



9. Click the **READY** button. The x-ray exposure has not started yet.
10. Now go to **8.4 X-ray Exposure** to start the exposure.

8.3.5 Waters' view Mode

8.3.5.1 Patient Positioning

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

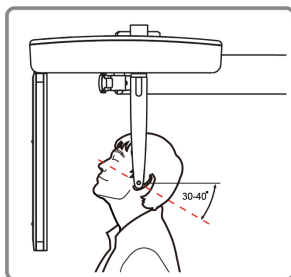


2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Waters' view mode.
3. Guide the patient to the CEPH unit.
4. Ask the patient to stand upright facing the sensor. Make sure that the patient's shoulders are level and that his/her neck is relaxed.
5. Use the **Column UP/DOWN** button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



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

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



8. Click the **READY** button. The x-ray exposure has not started yet.
9. Now go to **8.4 X-ray Exposure** to start the exposure.

8.3.6 Carpus Mode

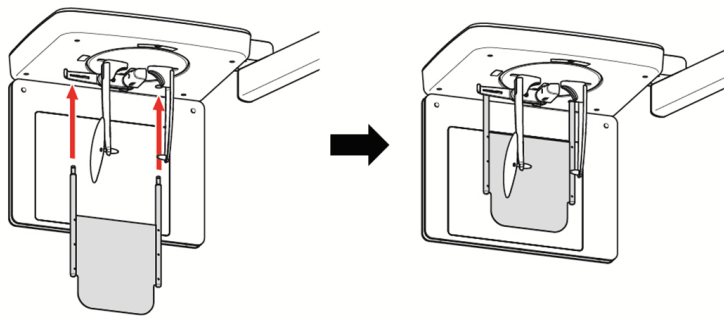
For Carpus Mode, install the Carpus Plate first before positioning the patient.

8.3.6.1 Installing the Carpus Plate

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



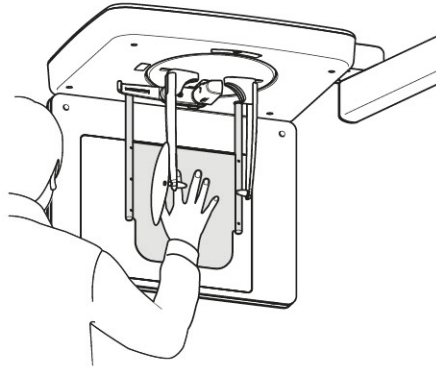
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Carpus mode.
3. Fit the two ends of the Carpus Plate into the two holes of the CEPH unit as below.



4. Confirm that the Carpus Plate is safely mounted.




8.3.6.2 Patient Positioning

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

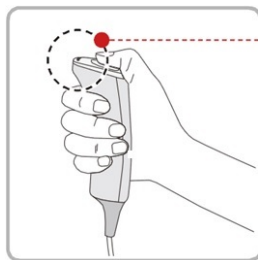


2. Ask the patient to close his/her eyes and stand still until the image acquisition is completed.
3. Click the **READY** button. The x-ray exposure has not started yet.
4. Now go to **8.4 X-ray Exposure** to start the exposure.

8.4 X-ray Exposure

	<ul style="list-style-type: none"> ▪ If an emergency occurs during image acquisition, release the Exposure Switch to cease X-ray emission. ▪ The operator shall always observe the X-ray safety regulations applicable to his/her area during the operation of this equipment.
	<ul style="list-style-type: none"> ▪ The operator must always keep vocal/visual contact with the patient during the image acquisition process. ▪ Do not operate the PC during the exposure. Doing so may cause the system to malfunction.
	<ul style="list-style-type: none"> ▪ Instruct the patient to close his or her eyes during the operation. ▪ To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.

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



• Yellow : X-ray On

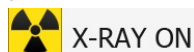
NOTICE

The image appears on the screen.

NOTICE

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

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



3. Release the **Exposure Switch** when “Image capturing is completed” message appears on the screen.

8.5 Finishing the Scan

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

8.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

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

NOTICE

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

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

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9. Acquiring CBCT Images

9.1 CBCT Imaging Program Overview

■ Result Images

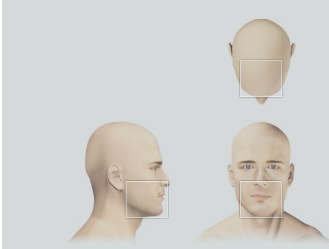
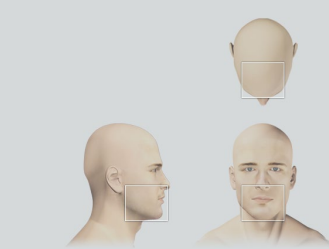
It provides conventional 3D CT sliced images.

■ Image Acquisition Method

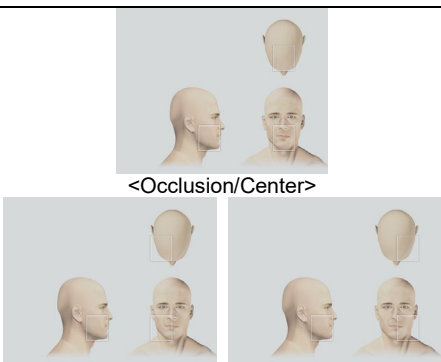
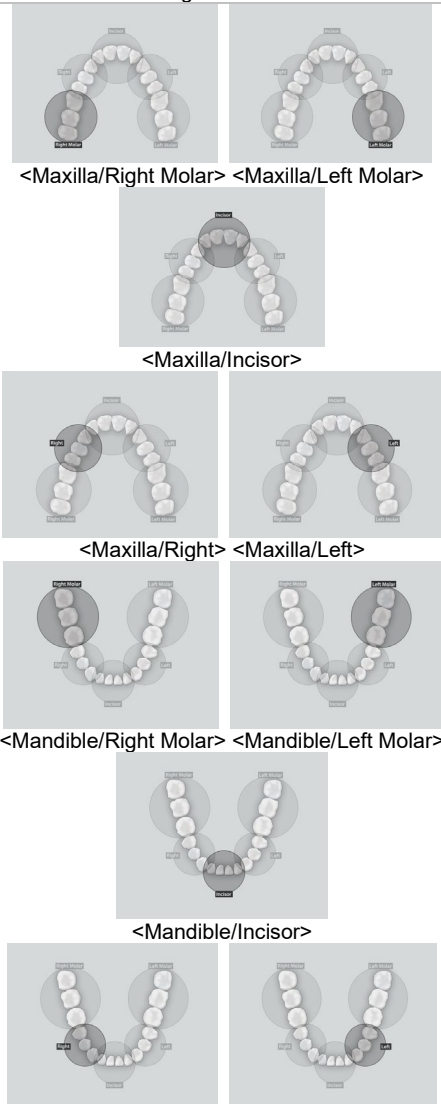
It acquires images with the X-ray beam scanning specific oral & maxillofacial regions and reconstructs them to 3D sliced images.

■ Examination Programs

It is classified as below based on the FOV.

Available FOVs (cm)	ROI	Description
10x8.5	 <p data-bbox="554 1112 743 1136"><Occlusion/Center></p>	<ul style="list-style-type: none"> <li data-bbox="937 846 1157 1006">▪ Covers both maxillary and mandibular structures including the 3rd molar region. <li data-bbox="937 1020 1157 1151">▪ Suitable for most oral surgery cases as well as multiple implant surgery.
10x7	 <p data-bbox="554 1483 743 1506"><Occlusion/Center></p>	<ul style="list-style-type: none"> <li data-bbox="937 1174 1157 1251">▪ For children aged between 0 and 13. <li data-bbox="937 1265 1157 1425">▪ Covers both maxillary and mandibular structures including the 3rd molar region. <li data-bbox="937 1439 1157 1570">▪ Suitable for most oral surgery cases as well as multiple implant surgery.

9. Acquiring CBCT Images

<p>8x8</p>	 <p><Occlusion/Center></p> <p><Occlusion/Right> <Occlusion/Left></p>	<ul style="list-style-type: none"> ▪ Selectable FOV for region (left/center/right).
<p>5x5</p>	 <p><Maxilla/Right Molar> <Maxilla/Left Molar></p> <p><Maxilla/Incisor></p> <p><Mandible/Right Molar> <Mandible/Left Molar></p> <p><Mandible/Incisor></p> <p><Mandible/Right> <Mandible/Left></p>	<ul style="list-style-type: none"> ▪ Covers 3 ~ 4 areas through capturing ROIs. ▪ Can acquire 3 ~ 4 teeth at once. ▪ Endo mode (Voxel Size: 0.08) applied.

■ Special Option

Auto Pano

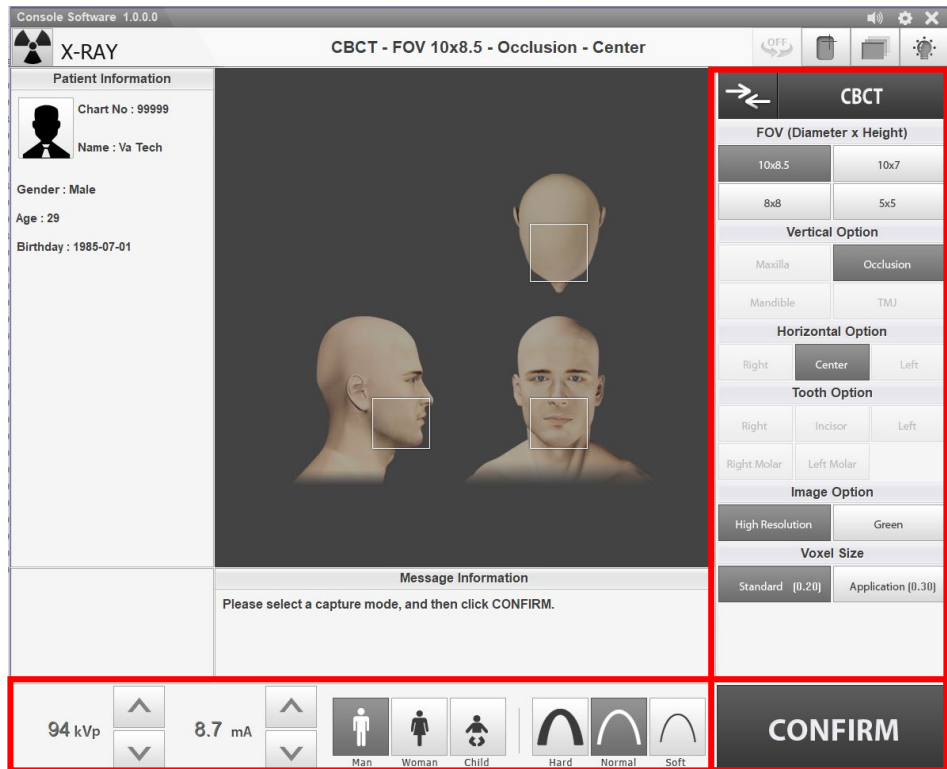
: 2D images of conventional panoramic views are available with the specific FOVs. For more details on Auto Pano, please refer to **9.2 Configuring Exposure Parameters**.

9.2 Configuring Exposure Parameters

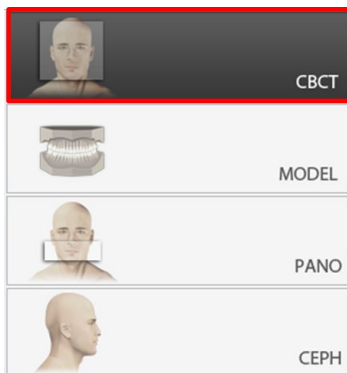
To acquire CBCT Images, **6. Getting Started** must be completed first.

NOTICE

You can set the imaging parameters on Console Software running on the PC.



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



NOTICE

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

2. Select FOV Size.

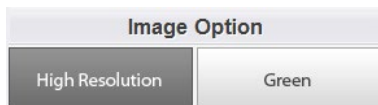
- You can configure **Auto Pano** options when **10x8.5** or **10x7** is selected.



- For both 10x8.5, 10x7, and 8x8 FOVs, the Vertical option and Horizontal option are set as below by default.
- For FOV 5x5, the Vertical option and the Tooth option are available.

Available FOV (cm)	Vertical option	Horizontal option	Tooth option
10x8.5	Occlusion	Center	N/A
10x7	Occlusion	Center	N/A
8x8	Occlusion	Right	N/A
		Center	N/A
		Left	N/A
5x5	Maxilla/Mandible	N/A	Right Molar
			Right
			Incisor
			Left
			Left Molar

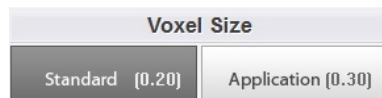
3. Select an Image Option.



4. Select a Voxel Size.

NOTICE

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



9. Acquiring CBCT Images

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



NOTICE

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

6. Select X-ray intensity.



NOTICE

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

Soft ≤ Normal ≤ Hard

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

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



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

CONFIRM

NOTICE

When you click **CONFIRM** button,

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

DAP
127.334307 mGy x cm²

Scan-time
13.5 Sec

Exposure-time
13.5 Sec

9. Guide the patient to the equipment.

9.3 Patient Positioning



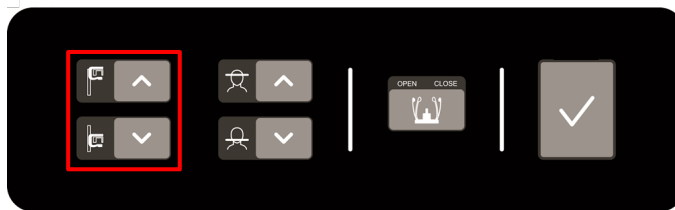
- Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.

IMPORTANT

- Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.
- Metal implants or bridges may reduce the quality of the images.
- Be sure to adjust the laser beam correctly. Otherwise, the quality of images can be lower due to ghost images or expansion/reduction of the images.

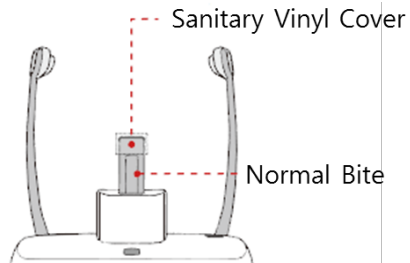
9.3.1 Getting prepared

1. Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button or switch option to adjust the equipment to match the height of the patient.
4. Press the **Rotation test** button in the Console program and check that the equipment touches a part of the patient while the equipment is running.



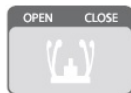
9.3.2 Normal Patient Positioning

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

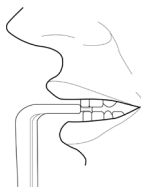


- The Sanitary Vinyl Cover is for individual use only. It should be replaced for each patient. Be sure to use the approved vinyl cover.
- Clean the Chinrest and the Bite with ethanol and wipe with a dry towel before the next patient.

2. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.

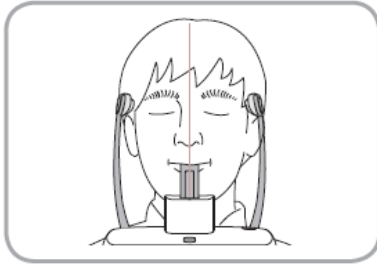


3. Guide the patient to the equipment.
4. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
6. Let the patient bite the Bite along its grooves with his/her front teeth.



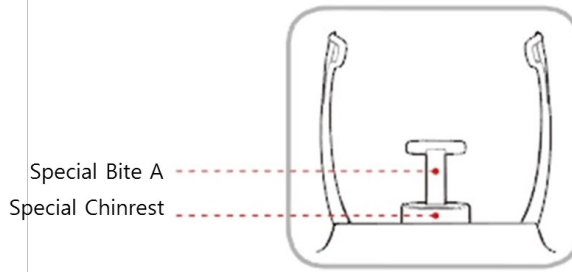
9. Acquiring CBCT Images

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

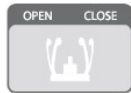


9.3.3 TMJ Patient Positioning

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



3. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.



4. Guide the patient to the equipment.
5. Use the **Vertical Frame Up/Down** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
 - Hold the handles tightly.
 - Press the chest against the equipment.
 - Keep both feet close to the inside of the base.
 - Keep both shoulders parallel.
 - Straighten the Cervical Spine and stand still.
7. Let the patient maintain the posture as follows:
 - Close the eyes.

NOTICE

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

9.3.3.1 Laser Beam Aligning



WARNING

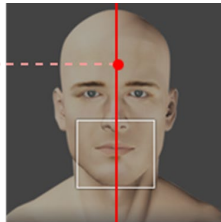
Be careful not to shine the Laser Beam directly into the person's eyes. Doing so may result in vision loss.



CAUTION

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

Vertical Beam / Mid-sagittal Line



FOV 10x8.5 (cm)

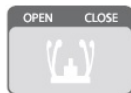
NOTICE

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

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

9.3.3.2 Finishing Patient Positioning

1. After checking the positions of the patient and the Laser Beam, click the **Temple Supports OPEN/CLOSE** button on the control panel to prevent the patient's head from moving.



CAUTION

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

2. Click the **READY** button. X-ray exposure has not started yet.
3. Now go to **9.4 X-ray Exposure** to start the exposure.

9.4 X-ray Exposure



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



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

IMPORTANT

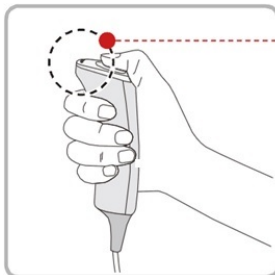
- Instruct the patient to close his/her eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.

1. Get out of the X-ray room and close the door.

IMPORTANT

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

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



• Yellow : X-ray On

NOTICE

The image appears on the screen.

NOTICE

- During X-ray exposure, the status appears as follows.
- The LED light of the **Exposure Switch** turns yellow.
 - The LED light on the top of the equipment turns yellow.
 - An alert sound comes out to indicate that X-ray emission is currently underway.
 - On Console Software, the radiation mark turns yellow, and "X-RAY" changes to "X-RAY ON."



X-RAY ON

3. Release the **Exposure Switch** when “Image capturing is completed” message appears on the screen.

9.5 Finishing the Scan

1. Open the Temple Supports and guide the patient out of the equipment.
2. For Normal Bite, remove the Sanitary Vinyl Cover from the Bite.
3. Press the **READY** button to bring the Rotating Unit back to its initial position.

9.6 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format.

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

NOTICE

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

1. The images are transferred to **EzDent-i/EasyDent** automatically.
 2. The images are automatically saved if the automatic save option is configured as default. If it is not configured as default, click the **Save** button to save the images.
 3. To check the image, double-click the one on the **Patient List**.
 4. Then, **Ez3D-i/Ez3D Plus** will run automatically for 3D viewing.
-

10. Acquiring 3D MODEL Scan Images

10.1 3D MODEL Scan Imaging Program

- **Result Images**

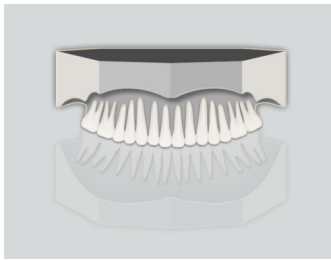
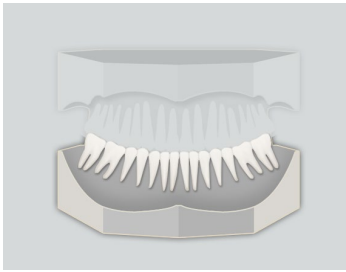
It provides 3D modeling surface data of the Plaster Cast. (STL file)

- **Image Acquisition Method**

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

- **Examination Programs**

It is classified as below based on the MODEL type.

Applied FOV (cm)	Vertical Option	ROI	Description
10x8.5	Upper (Maxilla)		Captures a whole maxillary Plaster Cast.
	Lower (Mandible)		Captures a whole mandibular Plaster Cast.

NOTICE

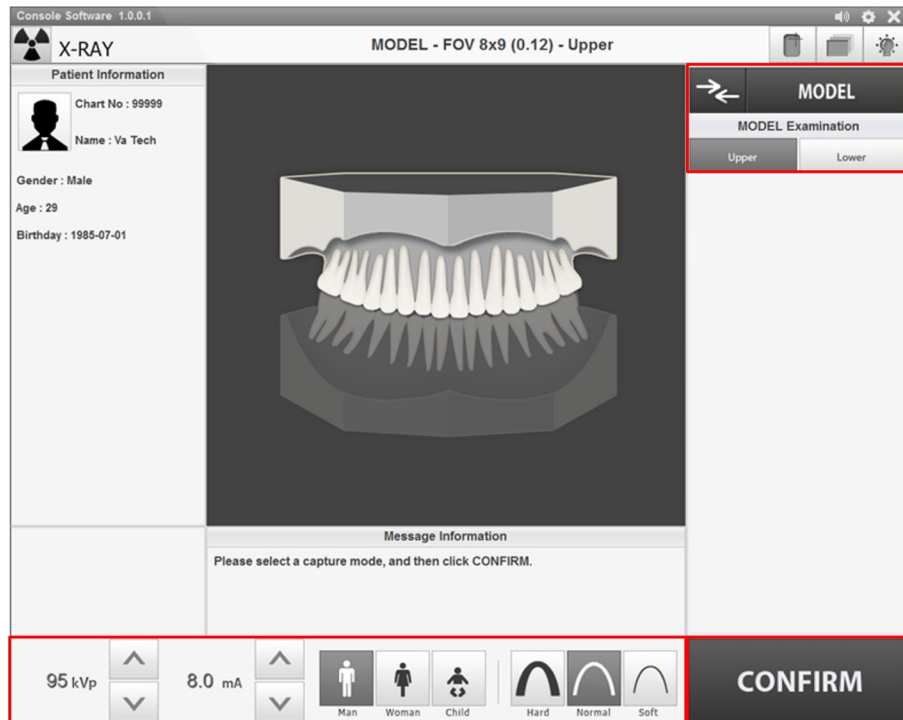
The 3D MODEL Scan modality is not available for EasyDent/Ez3D Plus users.

10.2 Configuring Exposure Parameters

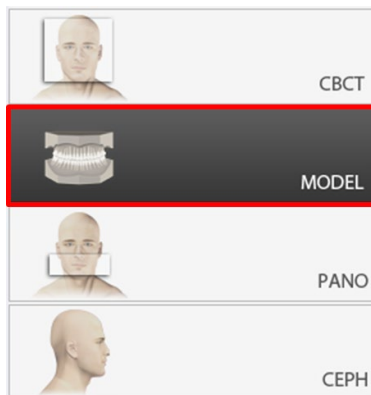
To acquire 3D MODEL Scan Images, **6. Getting Started** must be completed first.

NOTICE

You can set the imaging parameters on Console Software running on the PC.



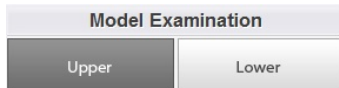
1. Click the **MODEL** button on the Main Screen.



NOTICE

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

2. Select Model Examination type.



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

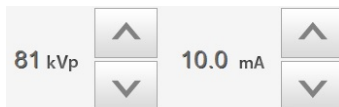
**NOTICE**

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

4. Select X-ray intensity.



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



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

CONFIRM

NOTICE

When you click **CONFIRM** button,

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

DAP
127.334307 mGy x cm²

Scan-time
13.5 Sec

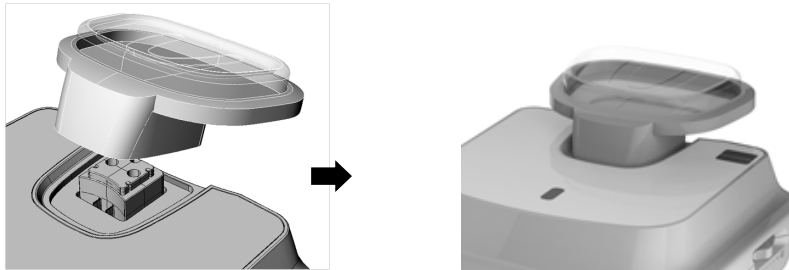
Exposure-time
13.5 Sec

- Bring the Plaster Cast to the equipment.

10.3 MODEL Positioning

MODEL Scan Jig Installation

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

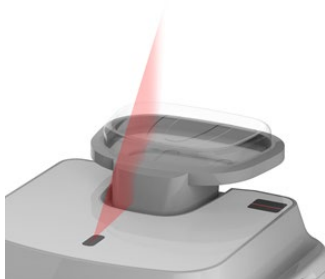


Laser Beam Aligning

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



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



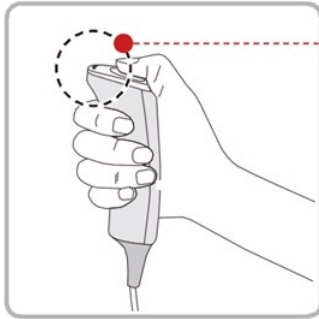
3. Click the **READY** button. X-ray exposure has not started yet.
4. Now go to **10.4 X-ray Exposure** to start the exposure.

10.4 X-ray Exposure



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

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



• Yellow : X-ray On

NOTICE

The image appears on the screen.

NOTICE

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

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



X-RAY ON

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

10.5 Checking the Captured Images

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

NOTICE

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

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

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11. Troubleshooting

11.1 Troubleshooting

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

If the equipment is not working

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

If the Exposure Switch is not functioning

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

If imaging cannot be performed

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

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

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

11.2 Error Codes

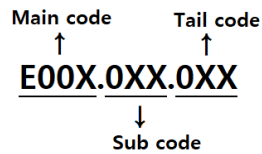
In instances of abnormal operation, error messages will be displayed with error codes on the Console Software and Control Panel. If a problem persists, please request assistance from the customer support information services.

IMPORTANT

Error messages will be displayed in the format written below.

[Code: **E00X.0XX.0XX**]

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



The main code indicates the source of error codes. The source is categorized as hardware, software, acquisition module, et cetera.

Subcode describes the specific area where an error has occurred according to the main code.

Tail Code explains the detailed symptoms and causes of the errors mentioned in the subcode.

IMPORTANT

The tables of the following chapter consist of four parts: Tail Code, Description, Solution, CS Part List.

Tail Code	Description	Solution

- **Tail Code** explains the detailed symptoms and causes of the errors mentioned in the subcode.
- **The description** provides a brief cause of the problems according to each error code.
- **The solution** provides instructions to solve the problem according to each error code.

It is categorized into three parts: Essential, Recommended, and Optional.

11.2.1 Hardware

11.2.1.1 Main code (001)

11.2.1.1.1 Subcode – Generator related error (001)

Tail Code	Description	Solution
001	Appears when the tube is not ready for use	<ol style="list-style-type: none"> 1. Check the CAN communication response by sending the following command to the inverter board, sensor, and the collimator to check the CAN communication operation of the Main MCU. <ul style="list-style-type: none"> ▪ Inverter board: [SPM_IVER] ▪ Sensor: [SPM_FISS_0001] ▪ Collimator: [SPM_CVER] 2. If the inverter board, sensor, and collimator do not respond, replace the Main MCU. 3. If only the inverter board does not respond, check the connection status of H001909A (Pin 1, 3) and H001922A (Pin 7, 8) cable to check CAN communication between the Main MCU and inverter board. <ul style="list-style-type: none"> ※ Connection status refers to reconnection, disconnection, pin status, et cetera. 3-1. If the cable is normal, check that 24V is normally applied to pins 1, 2 of CN11 to check the input voltage of the inverter board. 3-2. When 24V is normally applied to the inverter board, replace the generator. 3-3. If 24V is not confirmed, check the power cable H001909A (Pin 21, 22) and H001922A (Pin 1, 2) from the Main MCU to the inverter board. 3-4. If the cable is normal, see if DC 24V is normally applied to pins 5, 6 of CN1600 to check the input power of the Main MCU. 3-5. If 24V is applied, replace the Main MCU. 3-6. If 24V is not applied, replace the power board.

11. Troubleshooting

002	Appears when the cable between the tube tank and Inverter board are disconnected	<ol style="list-style-type: none"> 1. Check the connection of the high voltage cable between the inverter board and the tube tank. 2. If the same problem occurs after cable replacement, replace the generator. <p>※ The generator includes a tube tank and an inverter board.</p>
003	Appears when a current of the inverter board exceeds the maximum allowable level during X-ray irradiation	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
004	Appears when there is ±10kV or more voltage difference in tube voltage compared to the reference value	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator.

		<ol style="list-style-type: none"> 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
005	Appears when there is ±0.5mA or more current difference in tube current compared to the reference value	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
006	Appears when there is ±20kV or more voltage difference in tube voltage feedback compared to the normal value	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required)

11. Troubleshooting

		<ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. <ol style="list-style-type: none"> 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
007	Appears when there is ±1mA or more current difference in tube current feedback compared to the normal value	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.

008	Appears when the temperature of the mono tank is above the setting temperature	<ol style="list-style-type: none"> 1. Check that the temperature of the mono-tank is 55°C or higher through the log message of the capture program. <ul style="list-style-type: none"> ※ The temperature is automatically checked every 10 seconds in the terminal program. 2. If the temperature is higher than 55°C, the problem has occurred from continuous shooting using the capture program. It is necessary to notify and educate the staff members that enough cooling time is required during shooting. <ul style="list-style-type: none"> ※ The cooling time Vatech suggests is 1:60. (60 seconds pause at the time of 1-second irradiation) 3. If the same problem occurs after the measurements stated above, replace the generator.
009	Appears when the inverter output current is higher than 1A during X-ray irradiation (In EP, IP condition)	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
010	Appears when the	<ol style="list-style-type: none"> 1. Replace the exposure switch and check if

	<p>inverter board falsely recognizes the exposure switch signal as OFF after the irradiation On command</p>	<p>the same problem occurs.</p> <ol style="list-style-type: none"> 2. Check if 24V is normally outputted from pins 5, 6 of CN3 of the power board. 2-1. If 24V is not applied, replace the power board. 2-2. If 24V is applied, see if 24V is outputted from pins 21, 22 of CN1716 to check the input power of the Main MCU. 2-3. If 24V is not applied, replace the Main MCU. 2-4. If 24V is applied, check the multipole cable. Check the connection status of the exposure switch cable H001909A (Pin 5) and H002705A (Pin 3) connected from the Main MCU board to the inverter board. 3. If the problem is not resolved, replace the generator.
<p>011</p>	<p>Appears when the X-ray OFF command is not sent to the inverter board in 0.5 seconds after turning off the exposure switch</p>	<ol style="list-style-type: none"> 1. Make sure that the staff member properly presses the exposure switch during irradiation. 2. Replace the exposure switch and check if the same error occurs. 3. Check the connection status of the H001909A (pin 1, 3) and H001922A (pin 7, 8) from the Main MCU to the inverter board. ※ Connection status refers to reconnection, disconnection, pin status, et cetera. 3-1. If the problem is not resolved, replace the multipole cable. 4. Check if 24V is applied to the Main MCU and the inverter board. 4-1. Check if the input voltage of pins 5, 6 of CN600 of the Main MCU is 24V. <ul style="list-style-type: none"> - If not 24V, replace the power board. 4-2. Check if the input voltage of pin 1, 2 of CN13 of the inverter board is 24V. <ul style="list-style-type: none"> - If not 24V, replace the Main MCU. - If 24V is applied normally, replace the generator.

012	Appears when kV feedback is over -20kV compared to the setting value during X-ray irradiation	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
013	Appears when kV feedback is over +20kV compared to the setting value during X-ray irradiation.	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more)

11. Troubleshooting

		<ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. <ol style="list-style-type: none"> 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
014	Appears when the mA feedback value is less than 50% compared to setting conditions during X-ray irradiation.	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IIVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%. 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
015	Appears when the mA feedback value is higher than 150% compared to setting conditions during X-ray irradiation.	<ol style="list-style-type: none"> 1. Send out the code [SPM_TEST], [SPM_IIVER], [SPM_CVER], and [SPM_FISS_0001] through the terminal to check the operation status and IC board component status. (Advance remote check required) <ul style="list-style-type: none"> - If there is a problem during operation or communication, replace the corresponding component (motor, board) and generator. - If there is no problem, replace the generator. 2. Check the high voltage input power (power board output voltage) of the inverter board CN11 pin 1, 2 is DC 380V±10%.

		<ol style="list-style-type: none"> 3. When X-ray is irradiated, check whether the high voltage input power of the inverter board CN11 pin 1, 2 is 340V or more. (Normal if 340V or more) <ul style="list-style-type: none"> - If any problem occurs in stage 2 or 3, replace the power board. 4. For equipment manufactured before 2014/04/19, apply the brass bar solution.
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11.2.1.1.2 Sub code - Motor related error (002)

Tail Code	Description	Solution
020	Appears during p-axis motor origin movement	<ol style="list-style-type: none"> 1. Check the operation status due to mechanical load. <ul style="list-style-type: none"> ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera. 2. Check if the photosensor LED of the p-axis motor and the XORG LED of the Main MCU lights up. <ul style="list-style-type: none"> - If there is a problem, replace the photosensor. 3. If the p-axis motor operates normally, increase the torque value of the p-axis motor. <ul style="list-style-type: none"> ※ Back up the [SPM_XMRT] value and apply 1 increment of torque. 4. Check the cable connection of the p-axis motor. <ul style="list-style-type: none"> Connection status refers to re-connection, disconnection, pin status, et cetera. 5. Check the p-axis motor for defects and replace the motor if a problem occurs. 5-1. Make sure the resistance between pins 1, 3, and pins 2, 4 is 1.1~1.3 Ω. 5-2. Check if there is a short between pins 1, 4, and pins 2, 3. 6. If the problem is not resolved, replace the Main MCU.
021	Appears during rotator-axis motor origin movement	<ol style="list-style-type: none"> 1. Check the operation status due to mechanical load. <ul style="list-style-type: none"> ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing

Tail Code	Description	Solution
		<p>belt, et cetera.</p> <ol style="list-style-type: none"> 2. Check if the photosensor LED of the rotator-axis motor and the RORG LED of the Main MCU lights up. <ul style="list-style-type: none"> - If there is a problem, replace the photosensor. 3. If the rotator-axis motor operates normally, increase the torque value of the rotator-axis motor. ※ Back up the [SPM_RMRT] value and apply 1 increment of torque. 4. Check the cable connection of the rotator-axis motor. <ul style="list-style-type: none"> ※ Connection status refers to re-connection, disconnection, pin status, et cetera. 5. Check the rotator-axis motor for defects and replace the motor if a problem occurs. 5-1. Make sure the resistance between pins 1, 3, and pins 2, 4 is 1.1~1.3 Ω. 5-2. Check if there is a short between pins 1, 4, and pins 2, 3. 6. If the problem is not resolved, replace the Main MCU.
024	Appears during CT horizontal laser up/down axis motor origin movement	<ol style="list-style-type: none"> 1. Check the operation status due to mechanical load. <ul style="list-style-type: none"> ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera. 2. Check if the LED of the CT horizontal laser up/down axis motor and the LORG LED of the Main MCU lights up. <ul style="list-style-type: none"> - If there is a problem, replace the photosensor. 3. If the photosensor operates normally, replace the CT horizontal beam assembly. 4. If the problem is not resolved, replace the Main MCU.
027	Appears during Cephalo sensor motor origin movement	<ol style="list-style-type: none"> 1. Check the operation status due to mechanical load. <ul style="list-style-type: none"> ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing

Tail Code	Description	Solution
		<p>belt, et cetera.</p> <ul style="list-style-type: none"> - If there is a problem, replace the photosensor. <p>2. Check if the LED of the cephalo sensor motor and the CSOR LED of the Main MCU lights up.</p> <ul style="list-style-type: none"> - If there is a problem, replace the photosensor. <p>3. Increase the torque value of the cephalo sensor motor.</p> <p>※ Back up the [SPM_HMRT] value and apply 1 increment of torque.</p> <p>4. Check the cable connection of the cephalo sensor axis motor.</p> <p>※ Connection status refers to re-connection, disconnection, pin status, et cetera.</p> <p>5. Check the cephalo sensor axis motor for defects and replace the motor if a problem occurs.</p> <p>5-1. Make sure that the resistance between pins 1, 3 and pins 2, 4 is 4.5Ω.</p> <p>5-2. Check if there is a short between pins 1, 4, and pins 2, 3.</p> <p>6. If the problem is not resolved, replace the main MCU.</p>
030	Appears during quadruple axis collimator Left origin movement	<p>1. Check if the collimator MCU FW is the latest version.</p> <p>※ When upgrading, the firmware upgrade cable is required.</p> <p>2. If the problem is not resolved, check the operation status due to mechanical load.</p> <p>※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera.</p> <ul style="list-style-type: none"> - If any foreign substance is found, remove the substance, and lubricate the component. <p>3. Apply the torque value as 100~200 higher than the current value.</p> <p>※ Check and back up the current torque value by [SPM_TQB?]. Adjust the torque value by [SPM_TOQB_xxxx].</p> <p>4. If the problem is not resolved, replace the</p>

Tail Code	Description	Solution
031	Appears during quadruple axis collimator Right origin movement	<p>collimator assembly.</p> <ol style="list-style-type: none"> 1. Check if the collimator MCU FW is the latest version. <ul style="list-style-type: none"> ※ When upgrading, the firmware upgrade cable is required. 2. If the problem is not resolved, check the operation status due to mechanical load. <ul style="list-style-type: none"> ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera. <ul style="list-style-type: none"> - If any foreign substance is found, remove the substance, and lubricate the component. 3. Apply the torque value as 100~200 higher than the current value. <ul style="list-style-type: none"> ※ Check and back up the current torque value by [SPM_TQA?]. Adjust the torque value by [SPM_TOQA_xxxx]. 4. If the problem is not resolved, replace the collimator assembly.
032	Appears during quadruple axis collimator Up origin movement	<ol style="list-style-type: none"> 1. Check if the collimator MCU FW is the latest version. <ul style="list-style-type: none"> ※ When upgrading, the firmware upgrade cable is required. 2. If the problem is not resolved, check the operation status due to mechanical load. <ul style="list-style-type: none"> ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera. <ul style="list-style-type: none"> - If any foreign substance is found, remove the substance, and lubricate the component. 3. Apply the torque value as 100~200 higher than the current value. <ul style="list-style-type: none"> ※ Check and back up the current torque value by [SPM_TQD?]. Adjust the torque value by [SPM_TOQD_xxxx]. 4. If the problem is not resolved, replace the

Tail Code	Description	Solution
		collimator assembly.
033	Appears during quadruple axis collimator down origin movement	<ol style="list-style-type: none"> 1. Check if the collimator MCU FW is the latest version. ※ When upgrading, the firmware upgrade cable is required. 2. If the problem is not resolved, check the operation status due to mechanical load. ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera. <ul style="list-style-type: none"> - If any foreign substance is found, remove the substance, and lubricate the component. 3. Apply the torque value as 100~200 higher than the current value. ※ Check and back up the current torque value by [SPM_TQC?]. Adjust the torque value by [SPM_TOQC_xxxx]. 4. If the problem is not resolved, replace the collimator assembly.
037	Appears during generator tilting	<ol style="list-style-type: none"> 1. Make sure the product is a Ceph model. If it is not a Ceph model, check whether [SPM_CISC], [SPM_TITY] is activated. 2. If the output is normal, check the operation status due to mechanical load. ※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera. <ul style="list-style-type: none"> - After sending the [SPM_TICE] command, check if the generator is tilting in Ceph mode and the limit switch is detected. After confirmation, send [SPM_TIFR] to stop the motor drive. - After sending the [SPM_TIPA] command, check whether the generator is tilting in the PANO/CT mode and the limit switch is detected. After confirmation, send [SPM_TIFR] to stop the motor drive. 3. If the limit switch is not recognized

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Tail Code	Description	Solution
		<p>normally, replace the Main MCU.</p> <p>4. If the tilting motor does not operate normally, check the tilting motor for defects.</p> <p>4-1. If the tiling motor is normal, please replace the Main MCU.</p>
038	Appears during temple support the motor operation	<p>1. If there is any noise during operation, replace the assembly.</p> <p>2. Check the limit switch of the temple support. Check whether the TSO1 and TSO2 LED light up.</p> <p>3. Check the ORG cable of the temple support.</p> <p>4. Check the alignment of the motor and the bearing block. (critical*)</p> <p>5. Adjust the torque value and see if the problem is resolved.</p> <p>※ Check the current torque value by [SPM_TQK?]. Adjust the torque value by [SPM_TOQK_xxxx].</p> <p>6. If the same problem occurs, replace the Main MCU.</p> <p>7. If the problem is not resolved, replace the temple support assembly.</p>
039	Appears during X-axis motor origin movement	<p>1. Check the operation status due to mechanical load.</p> <p>※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera.</p> <p>2. Check if the LED of the x-axis motor and the XORG LED of the Main MCU lights up. - If there is a problem, replace the photosensor.</p> <p>3. If the x-axis motor operates normally, increase the torque value of the x-axis motor.</p> <p>※ Back up the [SPM_XMRT] value and apply 1 increment of torque.</p> <p>4. Check the cable connection of the x-axis motor.</p> <p>※ Connection status refers to re-connection,</p>

Tail Code	Description	Solution
		<p>disconnection, pin status, et cetera.</p> <p>5. Check the x-axis motor for defects and replace the motor if a problem occurs.</p> <p>5-1. Make sure the resistance between pins 1, 3, and pins 2, 4 is 1.1~1.3Ω.</p> <p>5-2. Check if there is a short between pins 1, 4, and pins 2, 3.</p> <p>6. If the problem is not resolved, replace the Main MCU.</p>
040	Appears during Y-axis motor origin movement	<p>1. Check the operation status due to mechanical load.</p> <p>※ Operation status includes motor operation, a foreign substance in the axis, the existence of the mechanical load, timing belt, et cetera.</p> <p>2. Check if the LED of the y-axis motor and the YORG LED of the Main MCU lights up.</p> <p>- If there is a problem, replace the photosensor.</p> <p>3. If the y-axis motor operates normally, increase the torque value of the Y-axis motor. Back up the [SPM_YMRT] value and apply 1 increment of torque.</p> <p>4. Check the cable connection of the Y-axis motor.</p> <p>※ Connection status refers to re-connection, disconnection, pin status, et cetera.</p> <p>5. Check the y-axis motor for defects and replace the motor if a problem occurs.</p> <p>5-1. Make sure that the resistance between pins 1, 3, and pins 2, 4 is 1.1~1.3Ω.</p> <p>5-2. Check if there is a short between pins 1, 4, and pins 2, 3.</p> <p>6. If the problem is not resolved, replace the Main MCU.</p>

11.2.1.1.3 Subcode – Exposure switch related error (003)

Tail Code	Description	Solution
060	Appears if the exposure switch is pressed when turning on the	<p>1. To check whether the exposure switch operates normally or not, conduct the</p>

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Tail Code	Description	Solution
	equipment.	<p>following measurement.</p> <ol style="list-style-type: none"> 1-1. Remove the exposure switch and see if the same problem occurs. 1-2. Replace the current exposure switch with the extra switch provided <ul style="list-style-type: none"> - Replace the exposure switch if the problem occurs after conducting the measurements mentioned above. 2. Check the status of the extension cable. <p>※ Connection status refers to short-circuited, disconnection, et cetera.</p> <ol style="list-style-type: none"> 3. If there is no problem in stages 1 and 2, replace the Main MCU.

11.2.1.1.4 Subcode – Other error (004)

Tail Code	Description	Solution
102	Appears when there is no response during CAN communication.	<ol style="list-style-type: none"> 1. Replace the Main MCU and the collimator for the equipment manufactured before 2019.01.17, S/N: 069-002730 when H102 error occurs intermittently. <p>If an error occurs all the time or after replacing the Main MCU and the collimator, follow the instructions written below.</p> 2. Check the CAN communication response by sending the following command to the inverter board and the sensor to check the CAN communication operation of the Main MCU. <ul style="list-style-type: none"> - Inverter board: [SPM_IVER] - Sensor: [SPM_FISS_0001] - Collimator: [SPM_CVER] 3. If both the inverter board and sensor do not respond, replace the Main MCU. 4. If only the inverter board does not respond, check the connection status of the H001909A and H001922A cable to check CAN communication between the Main MCU and the inverter board. <p>※ Connection status refers to reconnection, disconnection, pin status, et cetera.</p>

Tail Code	Description	Solution
		<p>4-1. If the cable is normal, check that 24V is normally applied to pins 1 and 2 of CN13 to check the input voltage of the inverter board.</p> <p>4-2. When the 24V power supply is normal, replace the inverter board.</p> <p>4-3. If 24V power is not confirmed, check if 24V is applied to pins 1 and 2 of CN13 to check the input power of the Main MCU.</p> <p>4-4. If 24V is applied, replace the Main MCU.</p> <p>4-5. If 24V is not applied, replace the power board.</p> <p>5. If only the sensor does not respond, check the connection status of H001909A, H001918A, and H001925A cables to check CAN communication between the main MCU and the sensor.</p> <p>※ Connection status refers to reconnection, disconnection, pin status, et cetera.</p> <p>5-1. If the cable is normal, check that 8V is normally applied to the sensor.</p> <p>5-2. When the 8V power supply is normal, replace the sensor.</p> <p>5-3. If 8V power is not confirmed, check if 24V is normally applied to pins 6 and 8 of CN2801 (DC04 board).</p> <p>5-4. If the 8V is applied, replace the DC04 board.</p> <p>5-5. If the 8V is not confirmed, check if 24V is normally applied to pins 21 and 22 of CN2704 (SUB046 board).</p> <p>5-6. If the 24V is applied, replace the SUB046 board.</p> <p>5-7. If the 24V is not confirmed, check if 24V is normally applied to pins 5 and 6 of CN1600 (Main MCU board).</p> <p>5-8. If 24V is applied, replace the Main MCU.</p> <p>5-9. If 24V is not confirmed, replace the power board.</p> <p>6. If only the collimator does not respond, check the connection status of the H001909A and H001915A cables to check CAN communication between the Main</p>

Tail Code	Description	Solution
		<p>MCU and the collimator.</p> <p>※ Connection status refers to reconnection, disconnection, pin status, et cetera.</p> <p>6-1. If the cable is normal, check if 24V is normally applied to pins 1 and 4 of CN500.</p> <p>6-2. If 24V is applied, replace the collimator assembly.</p> <p>6-3. If 24V is not confirmed, check if 24V is normally applied to pins 21 and 22 of CN2704 (SUB046 board).</p> <p>6-4. If 24V is applied, replace the SUB046 board.</p> <p>6-5. If 24V is not confirmed, check if 24V is applied to pins 5 and 6 of CN1600 (Main MCU board).</p> <p>6-6. If 24V is applied, replace the Main MCU.</p> <p>6-7. If 24V is not confirmed, replace the power board.</p>

11.2.2 Software

11.2.2.1 Main code (002)

11.2.2.1.1 Subcode – Sequence related error (001)

Tail Code	Description	Solution
001	Appears when the packing mode is enabled	Check whether the packing mode is enabled.
002	Appears when the door is open	<ol style="list-style-type: none"> 1. Check whether the door is open. 2. Check if the activation of the DoorLock function in the capturing SW and the firmware of the main MCU. 3. Check the [SPM_DROP_000x] value by sending [SPM_ISDR] through serial communication. (0: Deactivated, 1: Activated) 4. Check the door sensor. 5. If the problem is not resolved, contact the customer service team for further

Tail Code	Description	Solution
		information.
003	Appears when the exposure switch is pressed	<ol style="list-style-type: none"> 1. To check whether the exposure switch operates normally or not, conduct the following measurement. <ol style="list-style-type: none"> 1-1. Remove the exposure switch and see if the same problem occurs. 1-2. Replace the current exposure switch with the extra switch provided <ul style="list-style-type: none"> - Replace the exposure switch if the problem occurs after conducting the measurements mentioned above. 2. Check the status of the extension cable. <p>※ Connection status refers to short-circuited, disconnection, et cetera.</p> <ol style="list-style-type: none"> 3. If there is no problem in stages 1 and 2, replace the Main MCU.

11.2.2.1.2 Sub code – PC Resolution related error (010)

Tail Code	Description	Solution
001	Appears when the resolution is less than 1280x1024	<ol style="list-style-type: none"> 1. Check whether the resolution setting is 1280x1024 or higher than 1280x1024. 2. Check whether the magnification of the resolution is 100%.
002	Appears when the resolution is less than 1200x960	<ol style="list-style-type: none"> 1. Check whether the resolution setting is 1200x960 or higher than 1200x1024. 2. Check whether the magnification of the resolution is 100%.

11.2.2.1.3 Sub code – PC Network related error (024)

Tail Code	Description	Solution
002	Appears when the port is invalid	<ol style="list-style-type: none"> 1. Check whether the power of the equipment is on when the capture SW is running. 2. Check the communication port setting. (Default COM4) 3. Check the communication cable connection status. <p>※ Connection status refers to reconnection, bending, contamination, et cetera.</p>
003	Appears when the time is out	<ol style="list-style-type: none"> 1. Check whether the power of the equipment is on when the capture SW is

Tail Code	Description	Solution
		running. 2. Check the optic cable of each section from PC to the Main MCU by using the extra optic cable provided. 3. If the cable is normal, replace the Main MCU.

11.2.3 Acquisition Module

11.2.3.1 Main code (003)

11.2.3.1.1 Sub code – Initialization Failure related error (010)

Tail Code	Description	Solution
000	Appears when the COM port cannot be opened	1. Check whether the driver of the grabber and virtual comport is recognized in the device manager. (Advance remote check is required.) 2. Reinstall the driver to the latest version. (Advance remote check is required.) 3. Check the PC specification and the Windows & Bios setting. 4. Move the grabber to another PC slot and check if there is a problem. 5. If the problem is not resolved, replace the grabber. 6. If the same problem occurs after replacing the grabber, replace the PC.
001	Appears when the frame grabber interface cannot be initialized or memory for acquisition cannot be reserved	1. Check whether the driver of the grabber is recognized in the device manager. (Advance remote check is required.) 2. Reinstall the driver to the latest version. (Advance remote check is required.) 3. Check the PC specification and the Windows & Bios setting. (Advance remote check is required.) 4. Move the grabber to another PC slot and check if the problem occurs. 5. If the problem is not resolved, replace the grabber. 6. If the same problem occurs after replacing the grabber, replace the PC.
002	Appears when the MCU is not communicable or the modem ring signal is in	1. Check whether the communication is available with the Main MCU. 2. If there is a problem, replace or reconnect the optic cable.

Tail Code	Description	Solution
	an improper state	3. Replace the Main MCU.

11.2.3.1.2 Sub code – Capture Failure related error (020)

Tail Code	Description	Solution
000	Appears when there is a capture error	<ol style="list-style-type: none"> 1. Check the Windows & Bios setting. (Advance remote check is required.) 2. Check the grabber card. (Advance remote check is required.) ※ Check whether the device manager and grabber driver are recognizable. Check the FPGA version and conduct the pattern test. 3. Check whether the Dark is secured. (Advance remote check is required.) 4. If there is no problem, check whether 5V is applied to the sensor. 5. Connect the sensor and the PC Grabber with an optic cable to confirm whether the image data can be acquired. 5-1. If the equipment operates normally, check the optic cable and optic hub board for each section. ※ section: from the sensor to the optic hub, from the optic hub to the column, from the column to the PC 6. If the problem is not resolved, replace the sensor.

11.2.3.1.3 Sub code – Reconstruction Failure related error (030)

Tail Code	Description	Solution
001	Appears when bugs exist in VXM-file or there is insufficient memory	<ol style="list-style-type: none"> 1. Check whether the graphics card is installed. 2. Check whether the capturing PC satisfies the required PC specification (CPU, RAM, GPU). 3. If the PC specification is normal, upgrade the graphics card driver to the latest version. 4. If the problem is not resolved, replace the graphics card.

11.2.3.1.4 Subcode – Hardware related error (061)

Tail Code	Description	Solution
HW Error	Appears when the error	Follow the instructions stated in the hardware

11. Troubleshooting

Tail Code	Description	Solution
No	occurs during acquisition module operation	error code section according to the code number.

12. Cleaning and Disinfection



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

- Do not spray the equipment with Cleaners or disinfectant agents. Apply the Cleaners or disinfectant agents to a clean cloth and wipe it.
- Make sure that no liquids run along the surface into the ventilation slots or release button.
- Remove any soiling with a soft, wet, lint-free cloth.
- Please follow the Cleaners or disinfectant agents' instructions for use.
- When cleaning or disinfect the surfaces, always disconnect the equipment from the mains.
- Do not use spray cleaner or disinfectant directly onto the equipment, as this could cause a fire.

IMPORTANT

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

NOTICE

The equipment has to be installed and maintained on a flat surface.

- Cleaners or disinfectant agents may contain powerful ingredients. Unsuitable cleaning and disinfectant agents are detrimental to health and attack the surface of the equipment.
- Do not use cleaners or disinfectant agents containing Phenol, acetic acid, peroxide, other oxygen splitting agents, sodium hypochlorite, and isopropyl alcohol (2-propanol, isopropanol) or iodine-splitting agents.
- Comply with the specifications contained in the operating instructions of the Cleaners or disinfectant agents.
- Wear safety gloves.
-

12.1 Cleaning



WARNING

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

- Thoroughly clean the areas of the equipment that come in direct contact with the patient, such as the Chinrest and the Bite.
- Do not use spray cleaners or solvents as they could flow into the equipment and damage the electrical components or cause a fire.
- Do not use abrasive liquids such as acetone, gas, or oil, which may cause corrosion on the surface of the equipment.
- Do not use any cleaning products which contain silicon. They could potentially damage the equipment's electrical components.

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

Components	Cleaning Process
Bite (Normal Bite, Special Bite A, and Special Bite B)	Clean with ethanol and gently wipe with a dry towel before the next patient.
Temple Supports	Clean with ethanol and gently wipe with a dry towel before the next patient.
Chinrest	Clean with ethanol and gently wipe with a dry towel before the next patient.
Computer and peripherals	Follow the manufacturers' instructions found in the accompanying manuals.
Outer covers of equipment	Wipe the unit with a dry cloth at the end of each day.

IMPORTANT

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

12.2 Disinfection

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

Sample



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13. Maintenance

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

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

13.1 Regular Maintenance



- Always turn off the equipment before performing any maintenance.
- Do not remove equipment covers. There are no repairable parts inside.
- The only parts that can be replaced by the user are the input fuses, which must comply with the manufacturer's specifications.
- As a precaution against fire, the replacement should be one in the same type and range.

IMPORTANT

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

- Do not unplug cables by force.
- Do not expose the equipment or components in an area that is susceptible to water or humidity.
- Do not expose the equipment in an area of extreme fluctuation in temperature, poor ventilation, direct sunlight, dust, salt, et cetera.
- Keep all detachable components well organized and clean.
- Make sure that the equipment is well-grounded.
- Do not try to modify this equipment, including the wires or cables. Doing so may damage it beyond repair.

13.2 Maintenance Task Checklist

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

14. Disposing of the Equipment

To reduce environmental contamination, this equipment is designed to be as safe as possible to use and dispose of. Most components of this equipment are environmentally friendly and recyclable except for the same as X-ray tubes.

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

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

CAUTION

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

IMPORTANT

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

NOTICE

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

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15. Technical Specifications

15.1 Mechanical Specifications

15.1.1 Dimensions (unit = mm)

	With CEPH unit	Without CEPH unit
Top view		
Side view		

(Wall bracket dimensions)

Front view	Side view

15. Technical Specifications

Item		Description
Weight	Without CEPH unit	137 kg (302.0 lbs. – without Base)
		190 kg (418.9 lbs. – with Base)
	With CEPH unit	162 kg (357.1 lbs. – without Base)
		215 kg (474.0 lbs. – with Base)
Total Height	Without Base	Max. 2306.0 mm (90.8")
	With Base	Max. 2337.5 mm (92.1")
Dimensions during operation (Length x Width x Height)	Without CEPH unit	1144.3 (L) x 1557.5 (W) x 2306 (H) (mm, without Base)
		45.1 (L) x 61.4 (W) x 90.8 (H) (inch, without Base)
		1144.3 (L) x 1557.5 (W) x 2337.5 (H) (mm, with Base)
		45.1 (L) x 61.4 (W) x 92.1 (H) (inch, without Base)
	With CEPH unit	1905.9 (L) x 1557.5 (W) x 2306 mm (H) (mm, without Base)
		75.1 (L) x 61.4 (W) x 90.8 (H) (inch, without Base)
With CEPH unit	1905.9 (L) x 1557.5 (W) x 2337.5 (H) (mm, with Base)	
	75.1 (L) x 61.4 (W) x 92.1 (H) (inch, with Base)	
Rotating Unit Vertical Movement		Max. 803.7 mm (31.7")
Installation Type		Base Stand/Wall Mount (Default: Wall Mount type)
Packing Box Organization		Main Box, CEPH Box (Optional), Base Box (Optional)

15.1.2 Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	600	477.7	122.3	1 : 1.25
CEPH	1745	1524	221.0	1 : 1.14
CBCT	600	428.6	171.4	1 : 1.40

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

15.2 Technical Specifications

15.2.1 X-ray Generator Specifications

15.2.1.1 Specifications

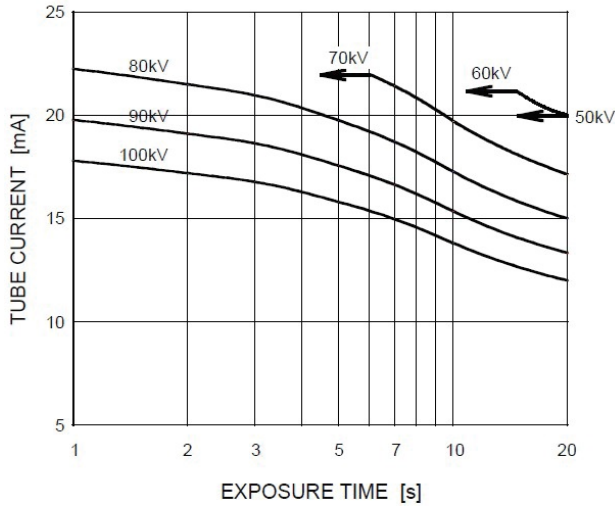
Item		Description	
Generator	Model	DG-07E22T2	
	Rated output power	1.6kW	
	Inverter model name	INV-22	
	Type	Inverter	
	Normal/ Pulse	kVp	60 kV ~ 99 kV (1 kV increment)
		mA	4 mA ~ 16 mA (0.1 mA increment for CBCT, 1 mA increment for PANO and CEPH)
	Cooling	Cooling Protect (Optional fan cooling $\geq 60^{\circ}\text{C}$)	
	Total filtration	Min. 2.5 mm Al	
	Default filtration	1.0 mm Al	
Added filtration	1.5 mm Al (Fixed)/PANO and CEPH mode 1.5 mm Al (Fixed) + 3.0 mm Al (Automatically added)/CBCT mode		
Tube	Manufacturer	CANON ELECTRON TUBES & DEVICES CO., LTD.	
	Model	D-052SB (Stationary Anode type)	
	Focal spot size	0.5 mm (IEC 60336)	
	Target Angle	5 degree	
	Inherent Filtration	At least 0.8 mm Al equivalent at 50 kV	
	X-ray Coverage	95 mm x380 mm at SID 550 mm	
	Anode Heat Content	35 kJ	
Duty Cycle	1:60 or more (Exposure time: Interval time)		

15.2.1.2 Test Condition

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	60 ~ 90	4 ~ 14	13.5
	60 ~ 90	4 ~ 14	11.5
	60 ~ 90	4 ~ 14	11.3
	60 ~ 90	4 ~ 14	11.1
	60 ~ 90	4 ~ 14	9.2
	60 ~ 90	4 ~ 14	7.7
	60 ~ 90	4 ~ 14	7.0
	60 ~ 90	4 ~ 14	6.8
	60 ~ 90	4 ~ 14	6.7
	60 ~ 90	4 ~ 14	6.1
	60 ~ 90	4 ~ 14	5.8
	60 ~ 90	4 ~ 14	5.7
	60 ~ 90	4 ~ 14	5.2
	60 ~ 90	4 ~ 14	5.0
	60 ~ 90	4 ~ 14	3.7
	60 ~ 90	4 ~ 14	3.5
	60 ~ 90	4 ~ 14	3.3
	60 ~ 90	4 ~ 14	2.8
	CEPH	60 ~ 99	4 ~ 16
60 ~ 99		4 ~ 15	2.4
60 ~ 99		4 ~ 15	3.9
60 ~ 99		4 ~ 14	4.9
60 ~ 99		4 ~ 14	5.4
CBCT	60 ~ 99	4 ~ 12	16.4
	60 ~ 99	4 ~ 12	11.0

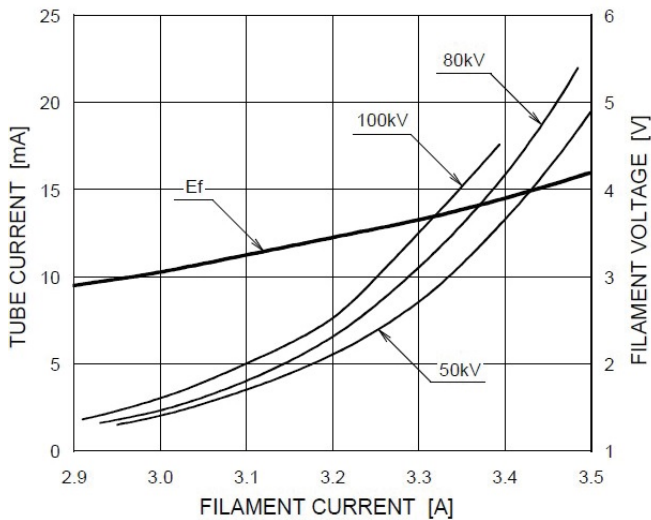
15.2.1.3 Maximum Rating Charts

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

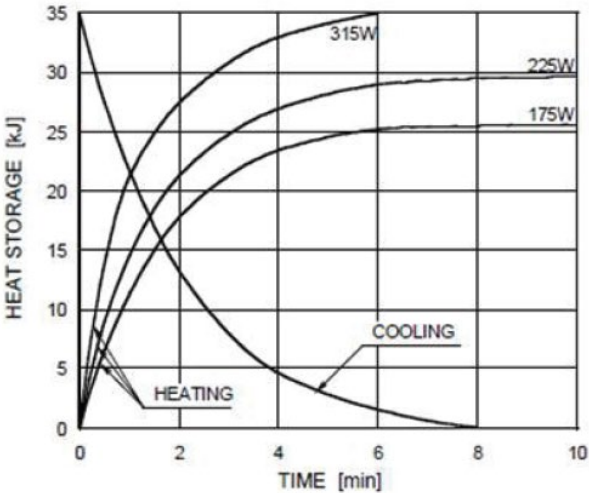


15.2.1.4 Emission & Filament Characteristics

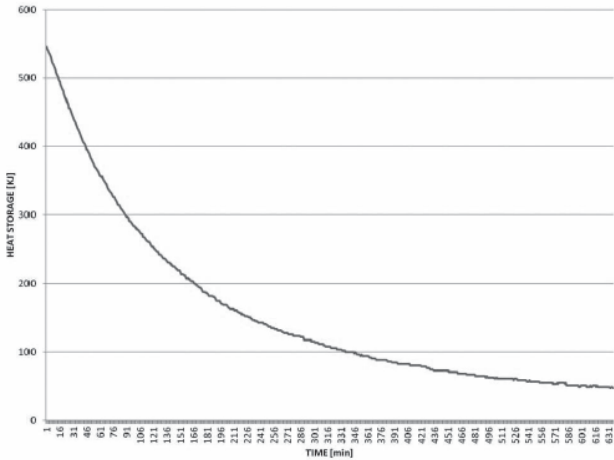
Constant potential high-voltage generator
Nominal Focus Spot Value: 0.5



15.2.1.5 Anode Thermal Characteristics



15.2.1.6 X-ray Housing Assembly Tube Characteristics



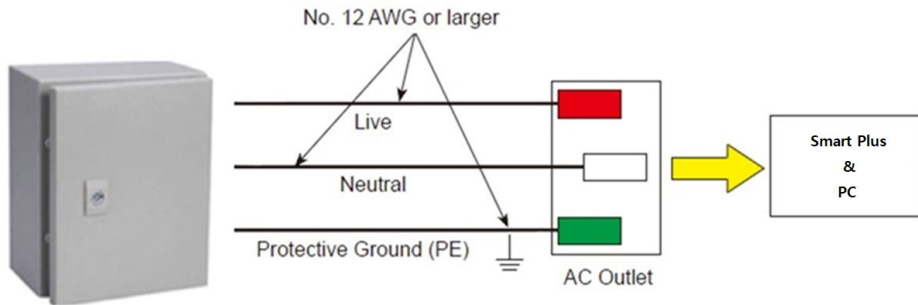
15.2.2 Detector Specifications

Item	Description	
	PANO & CBCT	CEPH
Model	Xmaru1404CF-Plus	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 μm @ 4X4 binning (49.5 μm @ no binning)	200 μm @ 2x2 binning (100 μm @ no binning)
Active area	CBCT - 36.4 mm X 135.8 mm PANO - 5.9 mm X 135.8 mm	15.6 mm x 259 mm
Frame Rate	~ 308 Hz @ 4X4 binning	~ 330 Hz @ 2x2 binning
Analogue-Digital Conversion	14 bits	
Operating condition	10 ~ 35 $^{\circ}\text{C}$ (Temperature) 10 ~ 75 % (Humidity)	
Storage condition	-10 ~ 60 $^{\circ}\text{C}$ (Temperature) 10 ~ 75 % (Humidity)	
Sensor size	160 mm (L) x 230 mm (W) x 26 mm (H)	110 mm (L) x 279 mm (W) x 20 mm (H)
Sensor weight	450 g	1050 g
Converter	CsI:Ti	
Energy Range	50 ~ 120 kVp	
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 40 % @ 1 lp/mm > 8 % @ 2.5 lp/mm	
DQE	> 60 % @ ~ 0 lp/mm	> 60 % @ ~ 0 lp/mm
Dynamic Range	> 80 dB	> 80 dB

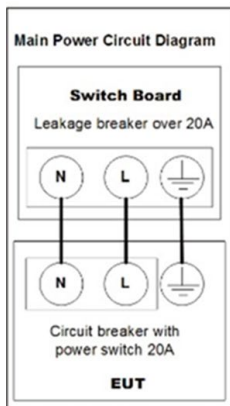
15.3 Electrical Specifications

Item	Description
Power supply voltage	100 - 240 V ~
Frequency	50/60 Hz
Power rating	2.0 kVA
Accuracy	Tube Voltage (kVp) \pm 10 %, Tube Current (mA) \pm 20 %, Exposure Time (s) \pm (5 % + 50 ms)

- The input line voltage depends on the local electrical distribution system.
- Allowable input voltage fluctuation requirement: \pm 10 %.
- Mode of operation: Continuous operation with intermittent loading - Needs waiting time (at least 60 times the exposure time) before the next exposure begins.
- Column operation time: Max. 2 min. On/18 min. Off (Ratio 1:9)



Central distribution panel w/a circuit breaker



NOTICE

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

15.4 Environmental Specifications

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

16. Appendices

16.1 Recommended X-ray Exposure Tables

16.1.1 PANO Mode

16.1.1.1 Exposure Condition

16.1.1.1.1 PANO Option > Normal

Mode	Image Option	Gender /Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	High Resolution	Man	Hard	75	12
			Normal	74	12
			Soft	73	12
		Woman	Hard	74	12
			Normal	73	12
			Soft	72	12
		Child	Hard	68	10
			Normal	67	10
			Soft	66	10
	Green (Optional)	Man	Hard	75	14
			Normal	74	14
			Soft	73	14
		Woman	Hard	74	14
			Normal	73	14
			Soft	72	14
		Child	Hard	68	12
			Normal	67	12
			Soft	66	12

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SPECIAL Examination	N/A	Man	Hard	75	14
			Normal	74	14
			Soft	73	14
		Woman	Hard	74	14
			Normal	73	14
			Soft	72	14
		Child	Hard	68	12
			Normal	67	12
			Soft	66	12

16.1.1.1.2 PANO Option > Insight PAN

Mode	Image Option	Gender/Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination/SPECIAL Examination	N/A	Man	Hard	71	7
			Normal	70	7
			Soft	69	7
		Woman	Hard	71	7
			Normal	70	7
			Soft	69	7
		Child	Hard	68	7
			Normal	67	7
			Soft	66	7

16.1.1.2 Scan Time/Exposure Time

Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
PANO Examination	Narrow	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.8	7.0	3.5
		Front	14.1	11.3	7.0	5.8
		Left	14.1	6.8	7.0	3.5
	Normal	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.8	7.0	3.5
		Front	14.1	11.3	7.0	5.8
		Left	14.1	6.8	7.0	3.5
	Wide	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.8	7.0	3.5
		Front	14.1	11.3	7.0	5.8
		Left	14.1	6.8	7.0	3.5
	Child	Standard	12.0	11.5	6.8	6.7
		Right	12.0	5.7	6.8	3.3
		Front	12.0	9.2	6.8	5.2
		Left	12.0	5.7	6.8	3.3
	Orthogonal	Standard	14.1	13.5	7.0	7.0
		Right	14.1	6.7	7.0	3.5
		Front	14.1	11.1	7.0	5.7
		Left	14.1	6.7	7.0	3.5
		Bitewing	14.1	9.2	7.0	5.0
		Bitewing Incisor (Optional),	14.1	2.8	7.0	1.4
		Bitewing Right	14.1	5.0	7.0	2.8
		Bitewing Left	14.1	5.0	7.0	2.8

Examination Mode	Arch Type	Examination Mode	High Resolution		Green (Optional)	
			Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
SPECIAL Examination	-	TMJ LAT Open	14.1	6.7	14.1	6.7
		TMJ LAT Close				
		TMJ PA Open (Optional),	10.0	6.1	10.0	6.1
		TMJ PA Close (Optional),				
		Sinus LAT (Optional),	4.0	3.7	4.0	3.7
		Sinus PA	8.8	7.7	8.8	7.7

- *For Insight PAN mode, only “High Resolution” is applied to Image Options.*
- *Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.*
- *Exposure Time: The actual time that the patient is exposed to the X-ray emission.*

16.1.2 CEPH Mode

16.1.2.1 Exposure Condition

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

16. Appendices

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

16.1.2.2 Scan Time/Exposure Time

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

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

16.1.3 CBCT Mode

16.1.3.1 Exposure Area

FOV (cm)	Vertical Position	Horizontal Position		
		Right	Center	Left
10x8.5	Occlusion	X	O	X
10x7	Occlusion	X	O	X
8x8	Occlusion	O	O	O
5x5	Maxilla/ Mandible	Right Molar/Right/Incisor/Left/Left Molar		

- 10x8.5 (cm) and FOV 10x7 (cm) capture full arch area. (10x8.5 (cm): Adult mode, FOV 10x7 (cm): Child mode)]

16.1.3.1.1 Exposure Condition (Scan Time: 18.0 s)

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
10x8.5 / 10x7 / 8x8 / 5x5	High Resolution	Man	Hard	95	8.7
			Normal	94	8.7
			Soft	93	8.7
		Woman	Hard	95	8.4
			Normal	94	8.4
			Soft	93	8.4
		Child	Hard	95	8.1
			Normal	94	8.1
			Soft	93	8.1
	Green	Man	Hard	80	5.0
			Normal	79	5.0
			Soft	78	5.0
		Woman	Hard	80	4.7
			Normal	79	4.7
			Soft	78	4.7
Child		Hard	80	4.4	
		Normal	79	4.4	
		Soft	78	4.4	

16.1.3.2 Scan Time/Exposure Time

FOV (cm)	Scan Time (s) (High Resolution/Green)	Exposure Time (s) (High Resolution/Green)
10x8.5	18.0	16.4
10x7	18.0	16.4
8x8	18.0	16.4
5x5	18.0	11.0

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

16.1.3.3 Reconstruction Time/File Size (Measured Object: Skull)

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)	File Size (MB)
10x8.5	0.2	113	260
	0.3	117	77
10x8.5 (with Auto Pano)	0.2	120	267
	0.3	125	84
10x7	0.2	90	202
	0.3	93	60
8x8	0.2	78	181
	0.3	80	52
5x5	0.08	162	466
	0.12	128	139

- *The above data is obtained from a computer system which is based on Intel i7-6700 and NVIDIA GeForce GTX1060 6GB, Graphics Card.*
- *Image reconstruction time varies depending on computer specifications and/or working conditions.*

16.1.4 3D MODEL Scan Mode

16.1.4.1 Exposure Area

FOV (cm)	MODEL Type	Horizontal Position		
		Right	Center	Left
10x8.5	Upper (Maxilla)	X	O	X
	Lower (Mandible)	X	O	X

16.1.4.2 Exposure Condition

FOV (cm)	Gender/Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
10x8.5	Man/Woman/Child	Hard/Normal/Soft	95	8.7

16.1.4.3 Scan Time/Exposure Time

FOV (cm)	Scan Time (s)	Exposure Time (s)
10x8.5	18.0	16.4

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

16.1.4.4 Reconstruction Time/File Size

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)	File Size (MB)
10x8.5	0.2	113	260

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

16.2 X-ray Dose Data

16.2.1 DAP (Dose Area Product)

The X-ray dose data is extracted from the X-ray Dose Test Report for **Smart Plus**.

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

Test Hardware	
Brand Name (Model)	Smart Plus (PHT-35LHS)
Sensor Type	PANO & CBCT: Xmaru1404CF-Plus CEPH: Xmaru2602CF
X-ray Generator	DG-07E22T2
Tube	D-052SB

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

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

16.2.1.1 Standard

National Deviations	Terminology	Permissive Range
PHE (GBR)	DAP (Pano, CEPH and CBCT)	PANO: $\leq 93 \text{ mGy}\cdot\text{cm}^2$ (Adult)/ $67 \text{ mGy}\cdot\text{cm}^2$ (Child) CEPH: $\leq 40 \text{ mGy}\cdot\text{cm}^2$ (Adult, Lateral)/ $25 \text{ mGy}\cdot\text{cm}^2$ (Child, Lateral) CBCT: $\leq 250 \text{ mGy}\cdot\text{cm}^2$ (Basis of the single implant)
AERB (IND)	Dose	All dose values must be within $\pm 20 \%$ of the SPECIFIED values

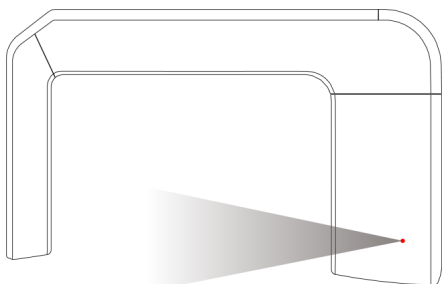
16.2.1.2 DAP (Dose Area Product) Calculation

$$\text{DAP}[\text{mGy} \cdot \text{cm}^2] = \text{Dose}[\text{mGy}] \times \text{Exposed Area}[\text{cm}^2]$$

NOTICE

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

16.2.1.2.1 Measurement Overview



16.2.1.2.2 Results

Mode	Exposure Condition	DAP [mGy·cm ²]
PANO Adult Man Normal (High Resolution)	74 kVp/12.0 mA/13.5 s	110
PANO Child Normal (High Resolution)	67 kVp/10.0 mA/11.5 s	55
PANO Adult Man Normal (Green)	74 kVp/14.0 mA/7.0 s	65
PANO Child Normal (Green)	67 kVp/12.0 mA/6.7 s	35
PANO Adult Man Insight PAN	67 kVp/7.0 mA/11.5 s	403
PANO Child Insight PAN	90 kVp/15.0 mA/3.9 s	295
CEPH Adult Man LAT (High Resolution)	90 kVp/15.0 mA/3.9 s	41
CEPH Child LAT (High Resolution)	86 kVp/10.0 mA/3.9 s	38
CEPH Adult Man LAT (Green)	90 kVp/16.0 mA/1.9 s	25
CEPH Child LAT (Green)	86 kVp/16.0 mA/1.9 s	23
CBCT FOV 10x8.5 Adult Man (High Resolution)	94 kVp/8.7 mA/16.4 s	646
CBCT FOV 10x8.5 Adult Man (Green)	79 kVp/5.0 mA/16.4 s	256

Mode	Exposure Condition	DAP [mGy·cm ²]
CBCT FOV 10x7 Adult Man (High Resolution)	94 kVp/8.7 mA/16.4 s	530
CBCT FOV 10x7 Adult Man (Green)	79 kVp/5.0 mA/16.4 s	210
CBCT FOV 8x8 Adult Man (High Resolution)	94 kVp/8.7 mA/16.4 s	444
CBCT FOV 8x8 Adult Man (Green)	79 kVp/5.0 mA/16.4 s	174
CBCT FOV 5x5 Maxilla Adult Man (High Resolution)	94 kVp/8.7 mA/11.0 s	290
CBCT FOV 5x5 Maxilla Adult Man (Green)	79 kVp/5.0 mA/11.0 s	115
CBCT FOV 5x5 Mandible Adult Man (High Resolution)	94 kVp/8.7 mA/11.0 s	333
CBCT FOV 5x5 Mandible Adult Man (Green)	79 kVp/5.0 mA/11.0 s	132

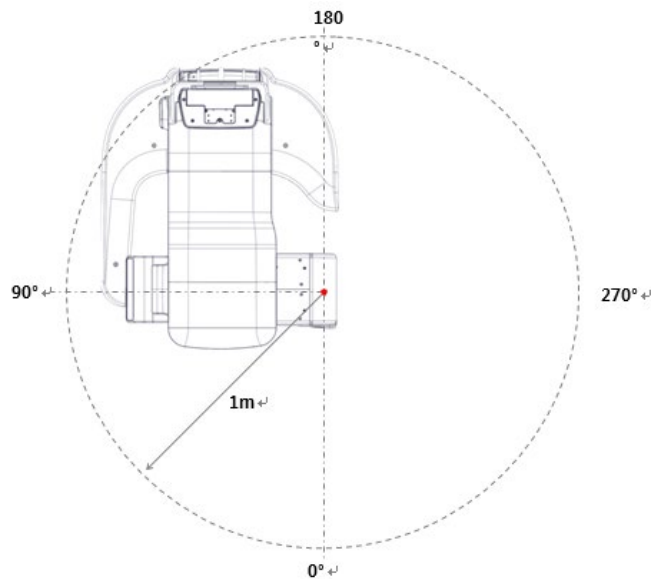
16.2.2 Leakage Dose

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

16.2.2.1 Standard

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

16.2.2.2 Measurement Overview



16.2.2.3 PANO Mode

16.2.2.3.1 PANO Option: Normal

16.2.2.3.1.1. Test Condition

Item	Condition
Tested Mode	PANO (Normal) Adult/Child
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

16.2.2.3.1.2. Results

Direction [°]	Adult		Child	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	9	0.079	8	0.070
22	7	0.061	7	0.061
45	3	0.026	4	0.035
75	2	0.018	3	0.026
90	1	0.009	1	0.009
100	3	0.026	2	0.018
110	3	0.026	3	0.026
120	4	0.035	4	0.035
130	4	0.035	4	0.035
140	5	0.044	5	0.044
150	3	0.026	3	0.026
160	2	0.018	2	0.018
170	9	0.079	9	0.079
180	6	0.053	6	0.053
190	4	0.035	4	0.035
200	9	0.079	8	0.070
210	5	0.044	5	0.044
220	4	0.035	4	0.035
230	3	0.026	2	0.018
240	3	0.026	3	0.026
250	3	0.026	4	0.035
260	3	0.026	3	0.026
270	3	0.026	3	0.026
315	9	0.079	6	0.053
340	7	0.061	5	0.044

16.2.2.3.2 PANO Option: Insight PAN

16.2.2.3.2.1. Test Condition

Item	Condition
Tested Model	PANO (Insight PAN) Adult/Child
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

16.2.2.3.2.2. Results

Direction [°]	Adult		Child	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	11	0.096	10	0.088
22	7	0.061	7	0.061
45	4	0.035	4	0.035
75	7	0.061	7	0.061
90	1	0.009	1	0.009
100	4	0.035	4	0.035
110	4	0.035	4	0.035
120	4	0.035	4	0.035
130	5	0.044	5	0.044
140	2	0.018	2	0.018
150	1	0.009	2	0.018
160	5	0.044	5	0.044
170	12	0.105	12	0.105
180	11	0.096	10	0.088
190	8	0.070	8	0.070
200	7	0.061	7	0.061
210	12	0.105	12	0.105
220	5	0.044	5	0.044
230	4	0.035	4	0.035
240	4	0.035	4	0.035
250	3	0.026	3	0.026
260	3	0.026	3	0.026
270	4	0.035	4	0.035
315	13	0.114	12	0.105
340	9	0.079	9	0.079

16.2.2.4 CEPH Mode

16.2.2.4.1 Test Condition

Item	Condition
Tested Model	CEPH
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

16.2.2.4.2 Results

Direction [°]	[mR/hr]	[mGy/hr]
0	9	0.079
22	7	0.061
45	3	0.026
75	2	0.018
90	1	0.009
100	3	0.026
110	3	0.026
120	4	0.035
130	4	0.035
140	5	0.044
150	3	0.026
160	2	0.018
170	9	0.079
180	6	0.053
190	4	0.035
200	9	0.079
210	5	0.044
220	4	0.035
230	3	0.026
240	3	0.026
250	3	0.026
260	3	0.026
270	3	0.026
315	9	0.079
340	7	0.061

16.2.2.5 CBCT Mode

16.2.2.5.1 Test Condition

Item	Condition
Tested Mode	CBCT (10x8.5/5x5), High Resolution
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12

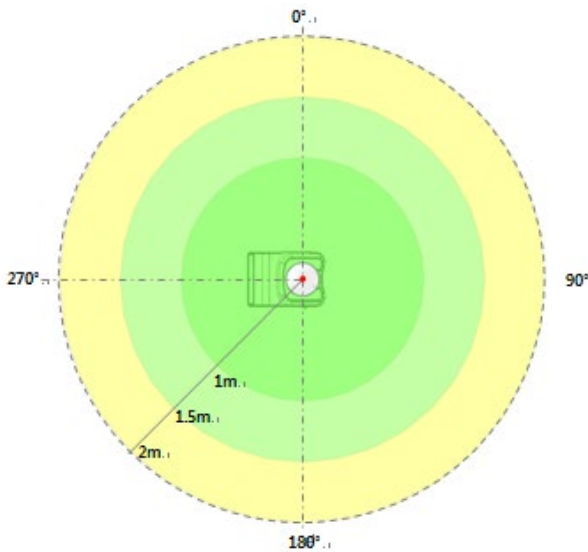
16.2.2.5.2 Results

Direction [°]	FOV 10x8.5		FOV 5x5	
	[mR/hr]	[mGy/hr]	[mR/hr]	[mGy/hr]
0	27	0.237	27	0.237
22	13	0.114	12	0.105
45	8	0.070	8	0.070
75	12	0.105	12	0.105
90	3	0.026	7	0.061
100	6	0.053	6	0.053
110	6	0.053	7	0.061
120	7	0.061	6	0.053
130	5	0.044	5	0.044
140	2	0.018	1	0.009
150	1	0.009	2	0.018
160	6	0.053	6	0.053
170	10	0.088	16	0.140
180	18	0.158	16	0.140
190	11	0.096	12	0.105
200	8	0.070	6	0.053
210	17	0.149	16	0.140
220	7	0.061	7	0.061
230	6	0.053	5	0.044
240	5	0.044	5	0.044
250	4	0.035	4	0.035
260	5	0.044	5	0.044
270	6	0.053	5	0.044
315	21	0.184	21	0.184
340	21	0.184	20	0.175

16.2.3 Scattered Dose

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

16.2.3.1 Measurement Overview



16.2.3.2 PANO Mode

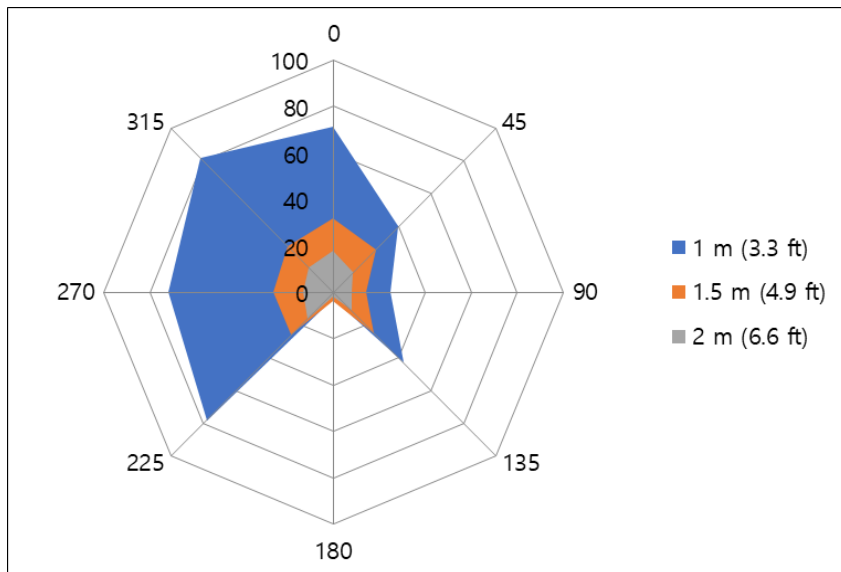
16.2.3.2.1 PANO Option: Normal

16.2.3.2.1.1. Test Condition

Item	Condition
Tested Model	PANO (Normal), High Resolution
Distance from focal point [m]	1 ~ 2
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

16.2.3.2.1.2. Results

Direction [°]	Normal, 13.5 s [mR/hr]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	71	71	71
45	40	40	40
90	25	25	25
135	43	43	43
180	3	3	3
225	78	78	78
270	72	72	72
315	82	82	82



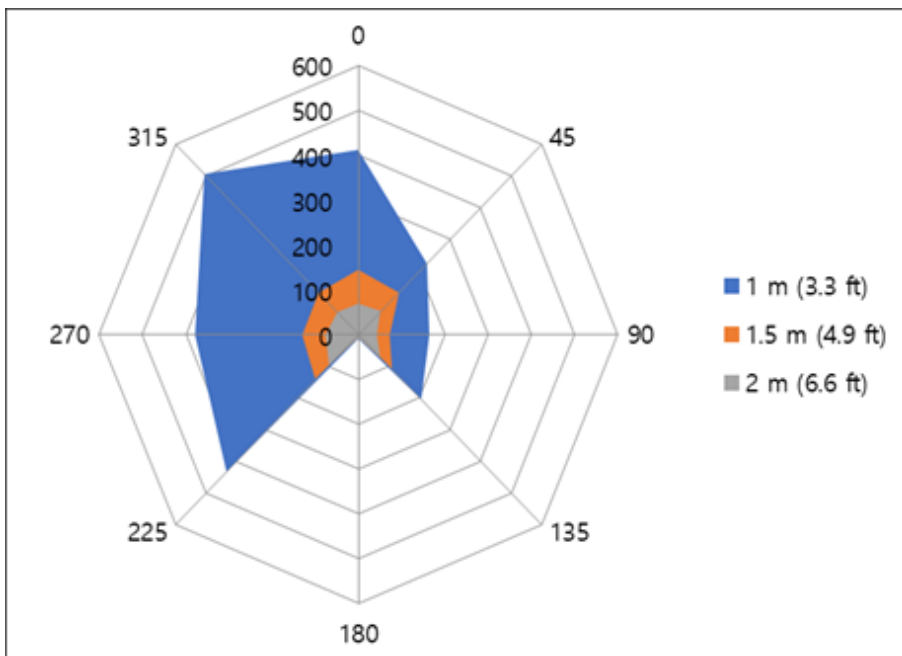
16.2.3.2.2 PANO Option: Insight PAN

16.2.3.2.2.1. Test Condition

Item	Condition
Tested Model	PANO (Insight PAN)
Distance from focal point [m]	1 ~ 2
Applied Tube Voltage Peak [kVp]	90
Applied Tube Current [mA]	14

16.2.3.2.2.2. Results

Direction [°]	Insight PAN, 13.5 s [mR/hr]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	411	145	70
45	224	132	73
90	163	73	42
135	204	110	73
180	10	8	6
225	432	141	96
270	378	130	76
315	506	131	70



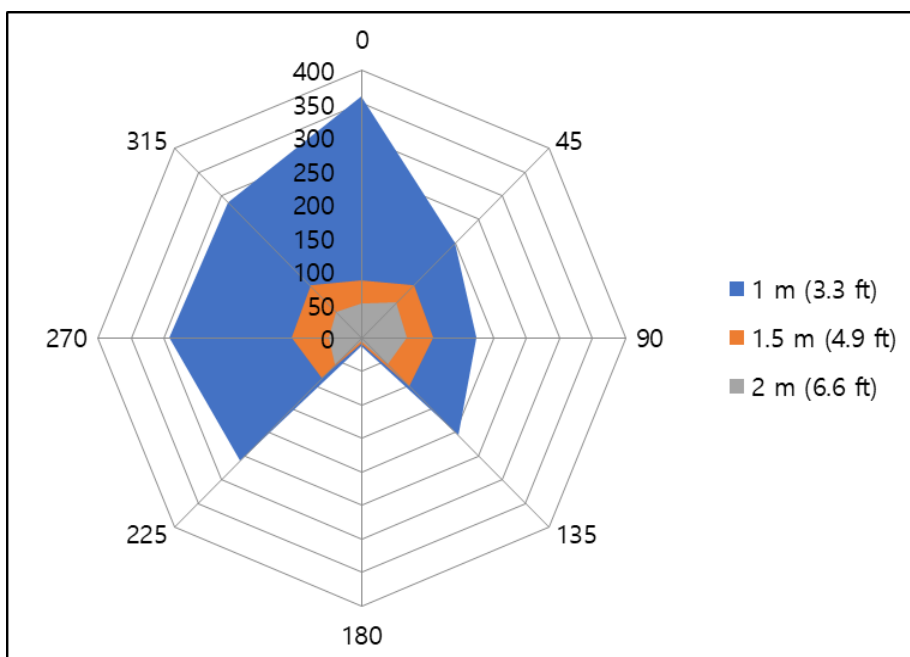
16.2.3.3 CBCT Mode

16.2.3.3.1 Test Condition

Item	Condition
Tested Mode	CBCT (10x8.5), High Resolution
Distance from focal point [m]	1 ~ 2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12

16.2.3.3.2 Results

Direction [°]	FOV 10x8.5, 16.4 s [mR/hr]		
	1 m (3.3 ft)	1.5 m (4.9 ft)	2 m (6.6 ft)
0	361	85	51
45	200	112	74
90	173	109	68
135	206	102	55
180	13	9	6
225	260	85	57
270	291	106	50
315	287	110	55



16.3 Electromagnetic Compatibility (EMC) Information

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Mains terminal disturbance voltage	EN 55011:2009 +A1:2010, CISPR 11:2015	Panoramic/CT/ CEPH scan Lift column moving/Stand by	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Radiated disturbance	EN 55011:2009 +A1:2010, CISPR 11:2015	Panoramic/CT/ CEPH scan Lift column moving/Stand by	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Harmonic Current Emission	EN 61000-3-2:2014, IEC 61000-3-2:2014	Panoramic/CT/ CEPH scan Lift column moving/Stand by	AC Mains	AC 220 V, 60 Hz AC 230 V, 50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	EN 61000-3-3:2013, IEC 61000-3-3:2013	Panoramic/CT/ CEPH scan Lift column moving/Stand by	AC Mains	AC 220 V, 60 Hz AC 230 V, 50 Hz	Pst: 1 Plt: 0.65 Tmax: 0.5 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	EN 61000-4-2:2009, IEC 61000-4-2:2008	Panoramic/CT/ CEPH scan Lift column moving/Stand by	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3:2006 +A2:2010, IEC 61000-4-3:2006 /AMD2:2010	Panoramic/CT/ CEPH scan Lift column moving/Stand by	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	EN 61000-4-3:2006 +A2:2010, IEC 61000-4-3:2006 /AMD2:2010	Panoramic/CT/ CEPH scan Lift column moving/Stand by	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Table 9 in IEC 60601-1-2: 2014

16. Appendices

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012, IEC 61000-4-4:2012	Panoramic/CT/CEPH scan Lift column moving/Stand by	AC Mains Signal lines	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line: ± 2 kV Signal: ± 1 kV 100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2014, IEC 61000-4-5:2014	Panoramic/CT/CEPH scan Lift column moving/Stand by	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Disturbances Induced by RF fields	EN 61000-4-6:2014, IEC 61000-4-6:2013	Panoramic/CT/CEPH scan Lift column moving/Stand by	AC Mains Signal lines	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line & Signal: 3 V, 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	EN 61000-4-8:2010, IEC 61000-4-8:2009	Panoramic/CT/CEPH scan Lift column moving/Stand by	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	30 A/m 50 Hz & 60 Hz
Voltage dips	EN 61000-4-11:2004, IEC 61000-4-11:2004	Panoramic/CT/CEPH scan Lift column moving/Stand by	AC Mains	AC 100 V, 50 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz	0 % U_T : 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
					0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles Single-phase: at 0°
Voltage interruptions	EN 61000-4-11:2004, IEC 61000-4-11:2004	Panoramic/CT/ CEPH scan Lift column moving/Stand by	AC Mains	AC 100 V, 50 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz	0 % U_T ; 250/300 cycle

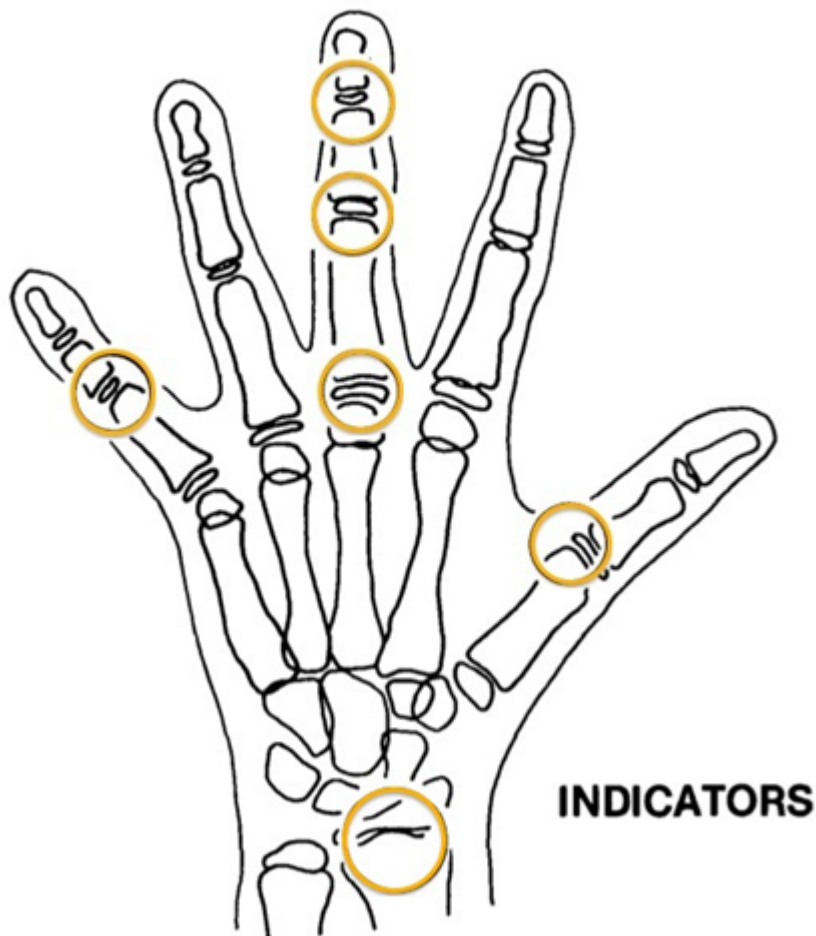
16.4 Hand-wrist Image Evaluation References

Radiographic Evaluation of Skeletal Maturation. A clinically oriented method based on hand wrist films.

Fishman LS. 1982

◆ The system of Skeletal Maturation Assessment (SMA)

The System uses only four stages of bone maturation, all found at six anatomical sites located on the thumb, third finger, fifth finger, and radius, as seen in Fig 1. Eleven discrete adolescent skeletal maturational indicators (SMI's), covering the entire period of adolescent development, are found on these six sites (See orange circles in Fig.1).



[Fig 1. Site of skeletal maturity indicators]

◆ Skeletal Maturity Indicators (SMI)

A system of skeletal maturation assessment based on four stages of bone maturation at six anatomical sites in the hand wrist.

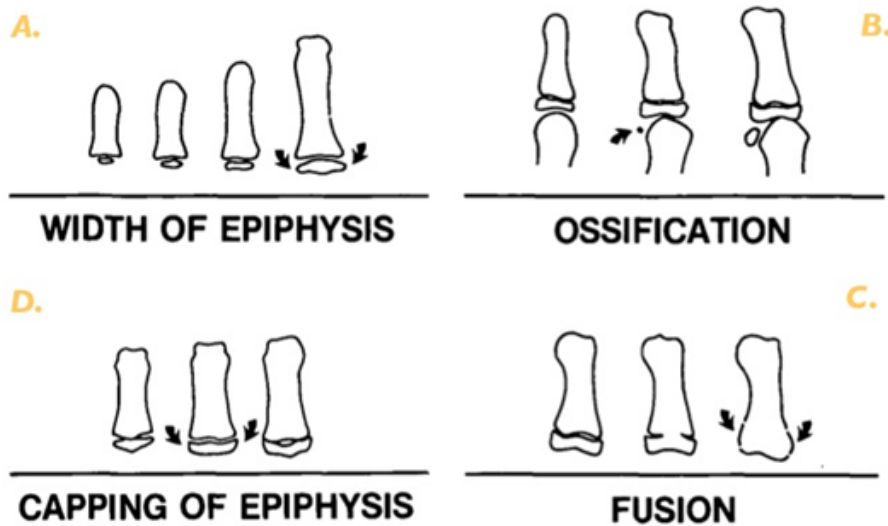


Fig. 2 Radiographic identification of skeletal maturity indicators.
 A. Epiphysis equal in width to diaphysis.
 B. Appearance of adductor sesamoid of the thumb.
 C. Capping of epiphysis.
 D. Fusion of epiphysis.

[Fig 2. Radiographic identification of skeletal maturity indicators]

A. The width of epiphysis as wide as the diaphysis

1. Third finger – Proximal phalanx
2. Third finger – middle phalanx
3. Fifth finger – middle phalanx

B. Ossification

1. Adductor sesamoid of thumb

C. Capping of epiphysis

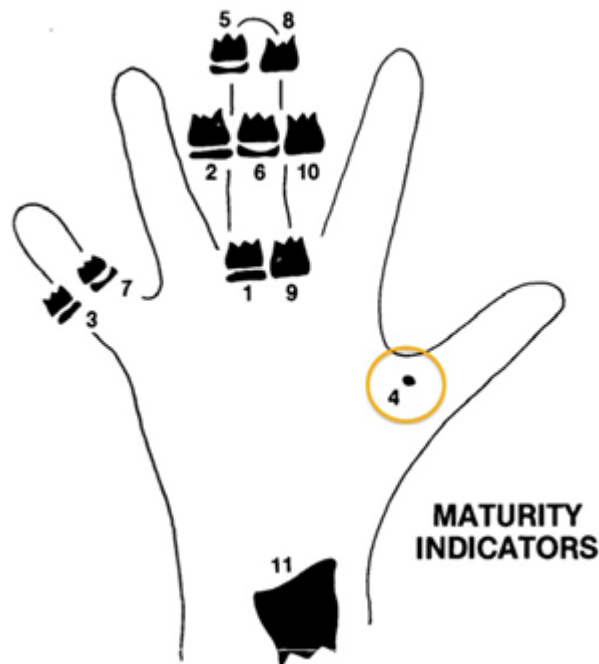
1. Third finger –distal phalanx
2. Third finger –middle phalanx
3. Fifth finger – middle phalanx

D. Fusion

1. Third finger –distal phalanx
2. Third finger – Proximal phalanx
3. Third finger – middle phalanx
4. Radius

◆ Eleven Skeletal maturity indicators (SMIs)

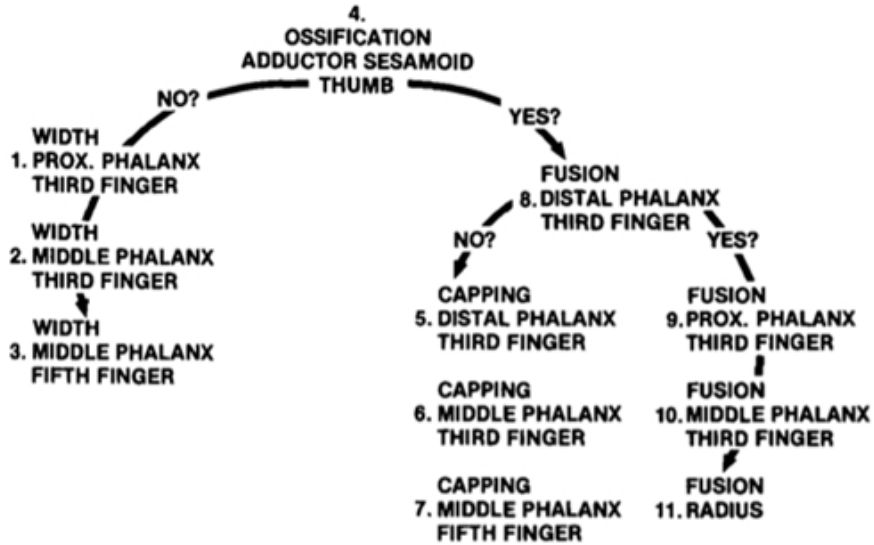
The System uses only four stages of bone maturation, all found at six anatomical sites located on the thumb, third finger, fifth finger, and radius, as seen in Fig 1. Eleven discrete adolescent skeletal maturational indicators (SMI's), covering the entire period of adolescent development, are found on these six sites (Fig 1 orange circles).



[Fig 3. Eleven Skeletal maturity indicators (SMIs)]

A systematic observational scheme such as that shown in the figure above can further facilitate SMI evaluation. With this approach, key stages are checked first, rather than looking for maturity indicators in numerical order. A useful step is to determine if the adductor sesamoid of the thumb can be seen (orange circle). If not, then the applicable SMI will be one of those associated with early epiphyseal widening rather than capping. If the sesamoid is visible, then either the sesamoid or an SMI based on capping or fusion will be applicable.

HAND-WRIST OBSERVATION SCHEME



16.5 Acquiring Images for Pediatric Dental Patients

16.5.1 Age Group: Classification Table

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

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

16.5.2 Positioning the Pediatric Dental Patients

1. Use a laser light beam guide to locate the midsagittal plane. Direct patient focus to mirror 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 patient place chin on 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 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 product error-free radiographic images for the pediatric patient>

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

- By Evelyn M. Thomson, BSDH, MS

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

Producing A Quality Panoramic Image

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

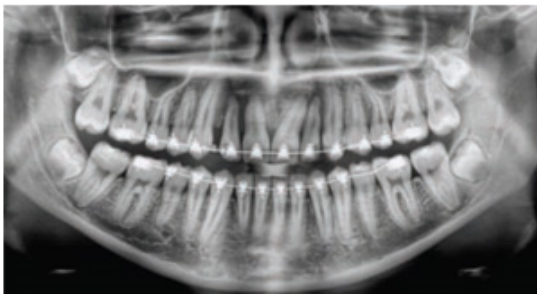


Figure 1: Example of a diagnostically acceptable panoramic radiograph of an adolescent patient undergoing orthodontic intervention. (Courtesy of Jamie Mace and Will Wright of Schick Technologies Inc.)

The most vital 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.

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, maybe 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 completely blurred from the image and the condyles may be cut off from the edges of the film.



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

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

Lateral Left-Right Positioning Error

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

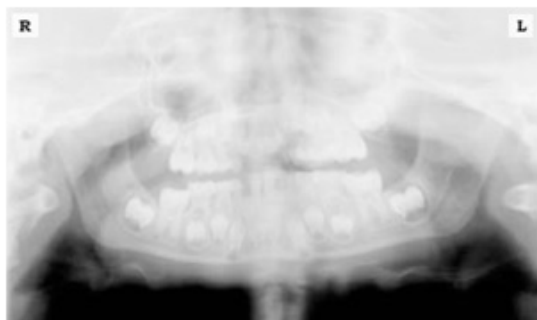


Figure 4: Incorrect lateral position tilted to the right. Note the teeth on the left are wide and poorly defined, while the teeth on the right are narrowed and severely overlapped. The inferior border of the mandible is distorted and the condyles appear asymmetrical.

To avoid imaging errors that result from incorrect lateral positioning, the midsagittal plane must be positioned perpendicular to the floor. Most panoramic x-ray machines have a head positioner and/or 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 difficult 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.

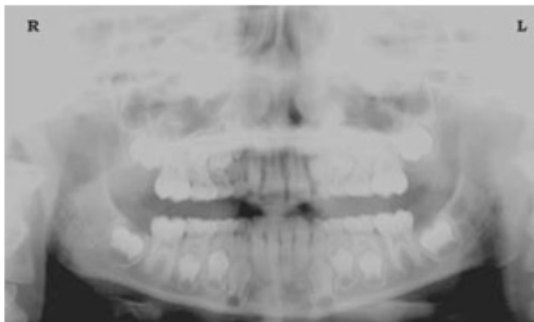


Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

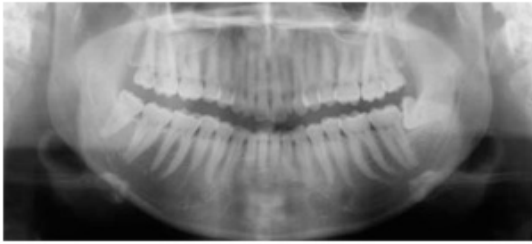


Figure 6: Chin positioned too far down. Note the characteristic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

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

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

Further Recommendations

Before beginning the exposure, the patient should be directed to close the lips around the bite block and to place the tongue against the palate. Leaving the lips open will create a soft tissue shadow across the teeth that can be mistaken for caries.⁷ Leaving the tongue at rest during the exposure allows the radiation to easily penetrate the 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 panoramic equipment operation and pediatric patient management is more likely to produce radiographic images that result in higher diagnostic yields.

References

1. Public Health Service, Food and Drug Administration, American Dental Association Council on Dental Benefits Program, Council on Dental Practice, Council on Scientific Affairs. *The Selection of Patients for Dental Radiographic Examinations*. Washington, DC: United States Department of Health and Human Services; 1987 (revised 2005):1-23.
2. Pinkham PS, Casamassimo, Fields HW, McTigue DJ, Nowak AJ. *Pediatric Dentistry Infancy Through Adolescence*. 4th ed. St. Louis: Elsevier Saunders; 2005:677.
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9. McDonald RE, Avery DR, Dean JA. *Dentistry for the Child and Adolescent*. 8th ed. St. Louis:

Elsevier Mosby; 2000:71-72.

10. Johnson ON, Thomson EM. *Essentials of Dental Radiography for Dental Assistants and Hygienists*. 8th ed. Upper Saddle River, NJ: Prentice-Hall 2007:388-397.

11. Sherman N, Horrell BM, Singer, S. High-quality panoramic radiographs. *Tips and tricks. Dentistry Today*. 2003;22(1):70-73.

16.5.3 Setting Exposure Values to the Age Group

For more information about this topic, refer to the Appendices **16.1 Recommended X-Ray Exposure Table**.

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

1) Literature

◆ 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 high frequency of caries among 5-year-old children, it is recommended to consider dental radiography for each child even without any visible caries or restorations.

Furthermore, radiography should be considered at 8-9 years of age and then at 12-14, which is 1-2 years after the eruption of premolars and second molars. Additional bitewing controls should be based on an overall assessment of the caries activity/risk. The high-risk patient should be examined radiographically annually, while a 2-3-year interval should be considered when caries activity/risk is low. A routine survey by radiographs, except for caries, has not been shown to provide enough information to be justified considering the balance between cost (radiation and resources) and benefit.

- ◆ MICHAEL L. TAYLOR, B.SC. TOMAS KRON, PH.D., AND RICK D. FRANICH, PH.D.:
ASSESSMENT OF OUT-OF-FIELD DOSES IN RADIOTHERAPY OF BRAIN LESIONS IN CHILDREN, *Int. J. Radiation Oncology Biol. Phys.*, Vol. -, No. -, pp. 1–7, 2010 To characterize the out-of-field doses in pediatric radiotherapy and to identify simple methods by which out-of-field dose might be minimized, to reduce the risk of secondary cancers Out-of-field doses to pediatric patients can be minimized by using simple treatment

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

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

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

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

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

brain CT were evaluated for 19 protocols in nine hospitals on various (2–320 detector rows) MDCT scanners.

Results: The maximum value of the mean organ dose in brain CT was 34.3 mGy for the brain. Maximum values of mean doses for the radiosensitive lens and thyroid were 32.7 mGy for a lens in brain CT and 17.2 mGy for thyroid in neck CT. The seventy-fifth percentile of effective dose distribution in brain CT was 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/>
-

16.6 Abbreviations

AC	Alternating Current
AF	Auto-Focusing
AMPT	Adaptive layer Mode Panoramic Tomography
CAN	Controlled Area Network
CBCT	Cone-Beam Computed Tomography
CMOS	Complementary Metal-Oxide -Semiconductor
CT	Computed Tomography
DAP	Dose Area Product
DC	Direct Current
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
ENT	Ear, Nose, and Throat
ESD	Electrostatic Discharge
EUT	Equipment Under Test
FDD	A focal spot to Detector Distance
FOD	A focal spot to Object Distance
FOV	Field of View
FPD	Flat Panel Detector
IEC	International Electrotechnical Commission
ISO	International Standards Organization
LED	Light-Emitting Diode
MAR	Metal Artifact Reduction
MPSO	Multiple Portable Socket-Outlet
ODD	Object to Detector Distance
PA	Posterior/Anterior
RF	Radio Frequency
ROI	Region of Interest
SID	Source to Image Receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SMV	Submento-Vertical
STL	Stereo Lithography
	Temporomandibular Joint
UHD	Ultra-High Definition

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17. Image Evaluation Manual

17.1 PANO

17.1.1 Introduction

17.1.1.1 Purpose

This manual is a document on the evaluation criteria and procedures of the equipment developed by VATECH so that the quality of the images can be evaluated using quantitative values.

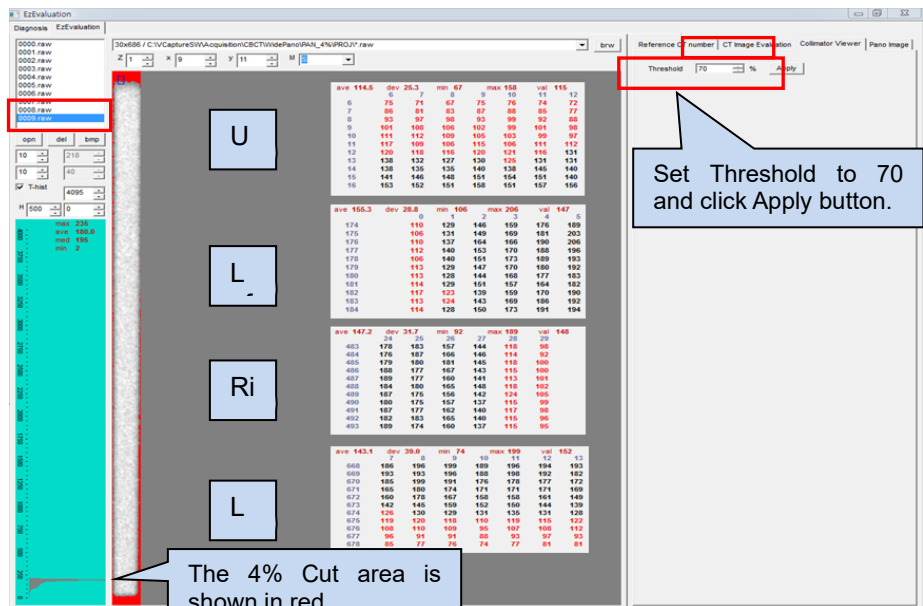
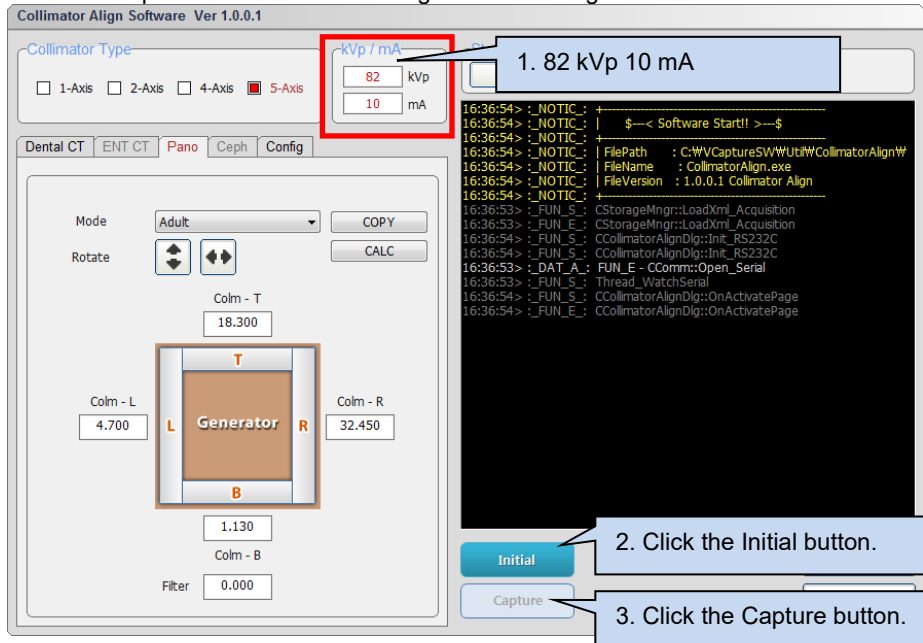
17.1.1.2 Image Evaluation Phantom Configuration

- X-ray Align: Evaluation for the accuracy of X-ray on area symmetry
- Geometry Phantom: Accuracy evaluation for the “Geometry accuracy”
- Line pair Resolution: “Above 2.5 Lp/mm”
- Low contrast Resolution: Evaluation for the “Noise (Dev), Homogeneity”

17.1.2 Acquire Image

17.1.2.1 X-ray alignment

- Run C:\VcaptureSWUtil\CollimatorAlign\CollimatorAlign.exe.



- Run EzEval.exe and select **EzEvaluation** from the top left tap menu.
- Select **Collimator Viewer** from the top right tap menu.

4. Enter 70 in the Threshold and click the **Apply** button to confirm that the 4% Cut Standard Value is met. (Upper/Lower/Left/Right)
5. Evaluate collimator alignment by performing the same evaluation for all FOVs.
6. If it meets the 4% Cut criteria, take a screenshot.
7. Save a screenshot in the C:\VCaptureSWAcquisition\X-Ray Image folder.

FOV 100x85 4% Cut Standard Value

Collimator	Min	Max
A(Left)	1 pixel	3 pixel
B(Right)	1 pixel	3 pixel
C(Upper)	10 pixel	35 pixel
D(Lower)	10 pixel	25 pixel

NOTICE

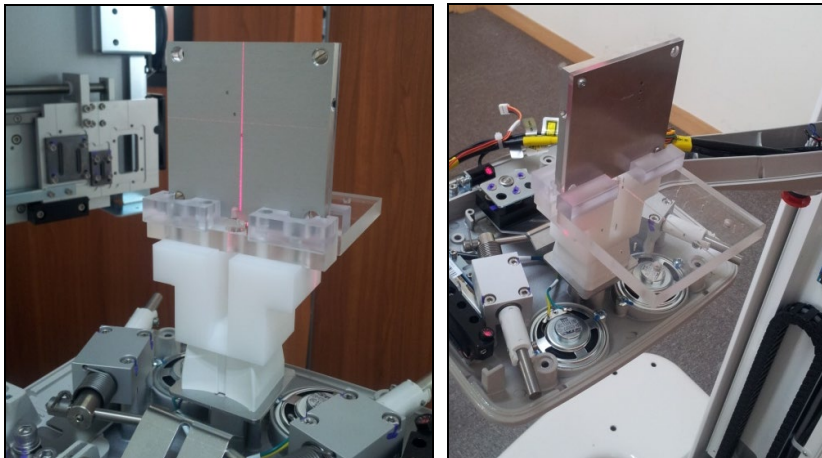
It is recommended to check X-ray Alignment by X-ray exposure when Generator Tube temperature is 25 ~ 30 °C."

17.1.2.2 Geometry Phantom

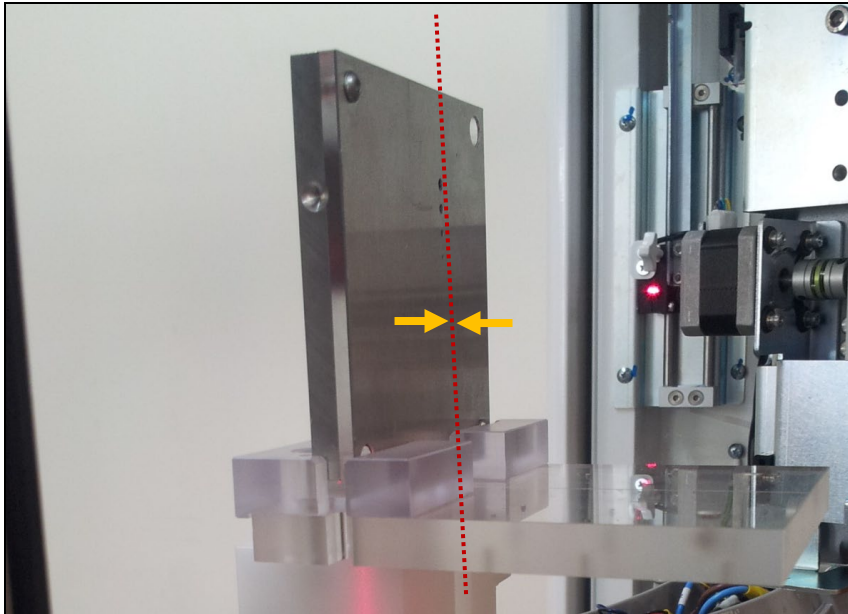
Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.

17.1.2.2.1 Phantom alignment

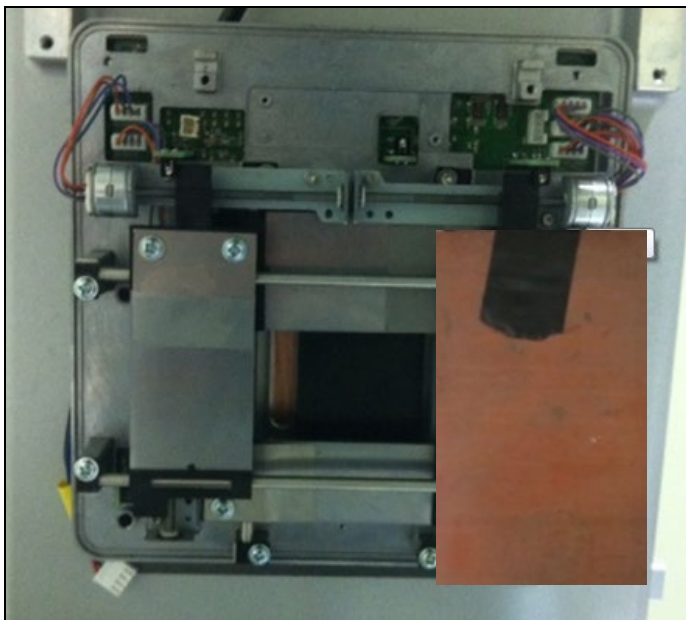
1. When the machine moves to Position mode, mount Ball Phantom and Quart Phantom on Chinrest as shown in the picture.



2. Align the Canine Laser Beam to the Quart Phantom baseline as shown below.

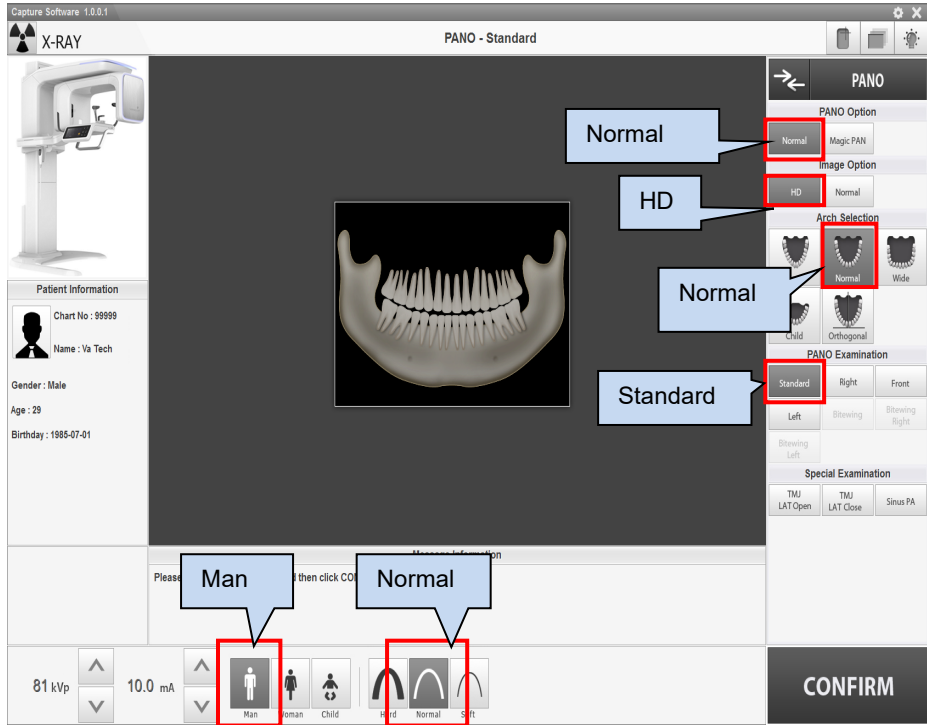


3. Attach a 1.8T copper filter in front of the collimator.

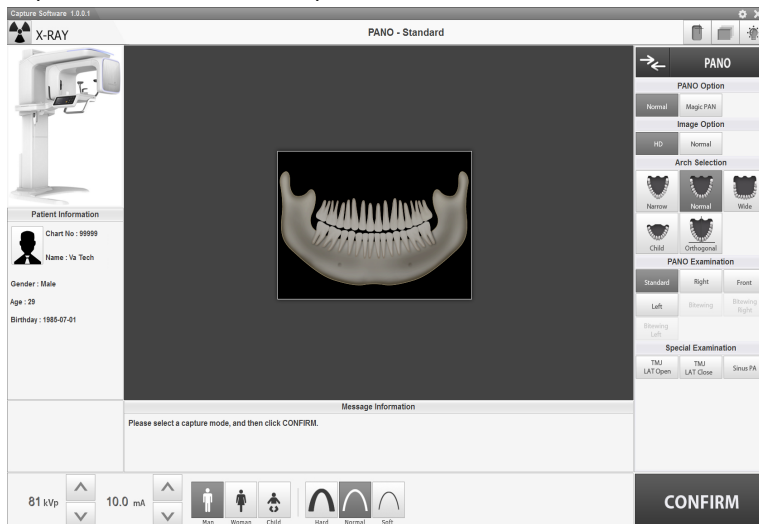


17.1.2.2.2 Capture S/W

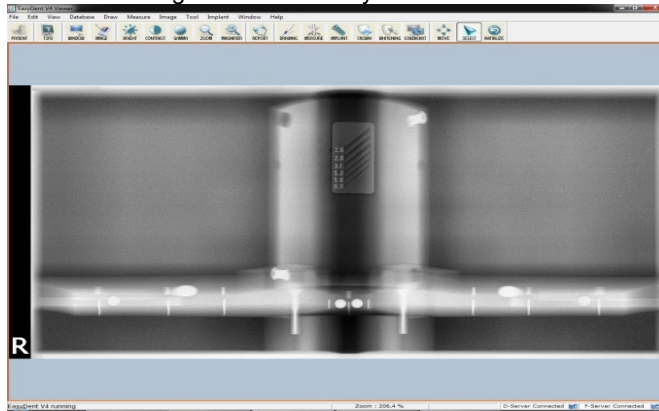
1. Run the C:\VCaptureSWExe\ VCaptureSW.exe file.



2. Follow the instructions for exposure.
3. Default exposure mode and exposure conditions are as follows.
 - Exposure mode: HD mode (13.5s)
 - Patient mode: Man, Normal
 - Exposure conditions: 71 kVp, 10 mA



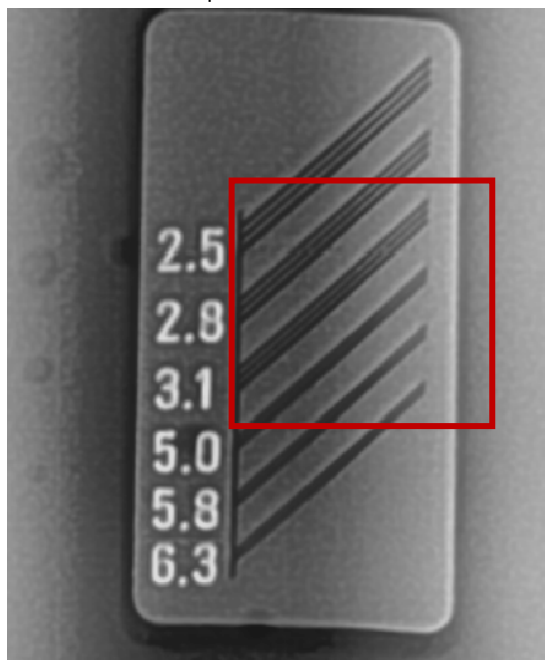
4. Check the image taken on EasyDent V4.



17.1.3 Pano image Evaluation

17.1.3.1 Pano Image-Line Pair Resolution Inspection Method

1. Import Quart Phantom footage from EasyDent V4.
2. Check if the line pair is visible.

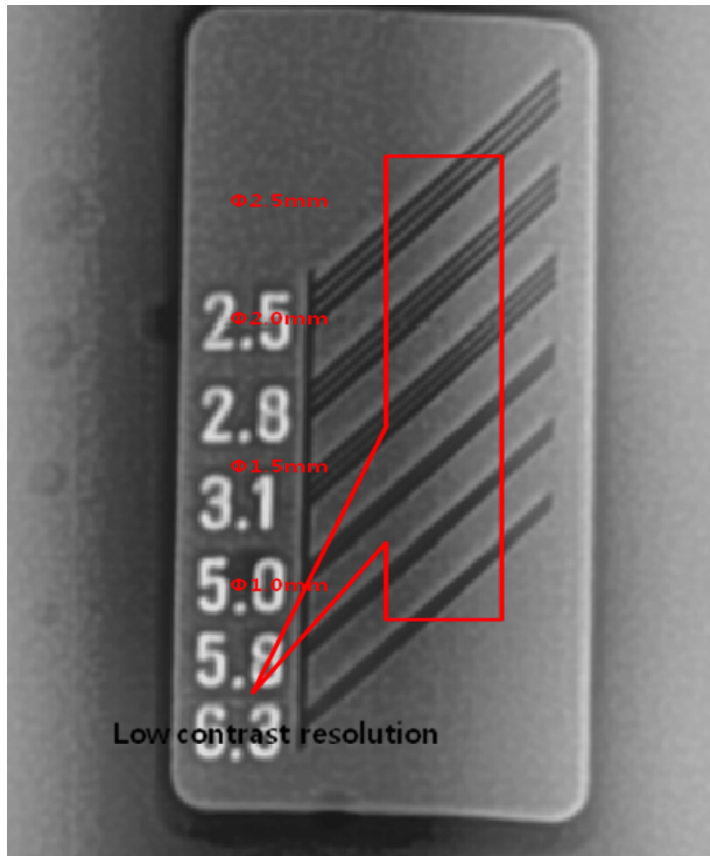


	VATECH Standard	Remarks
Line Pair	3.1 lp/mm	

3. Check 3.1 Lp/mm.
4. Pano Image-Line Pair Resolution criterion.

17.1.3.2 Pano Image Low contrast Resolution Inspection Method

1. Import Quart Phantom footage from EasyDent V4.
2. Check the Low Contrast section.

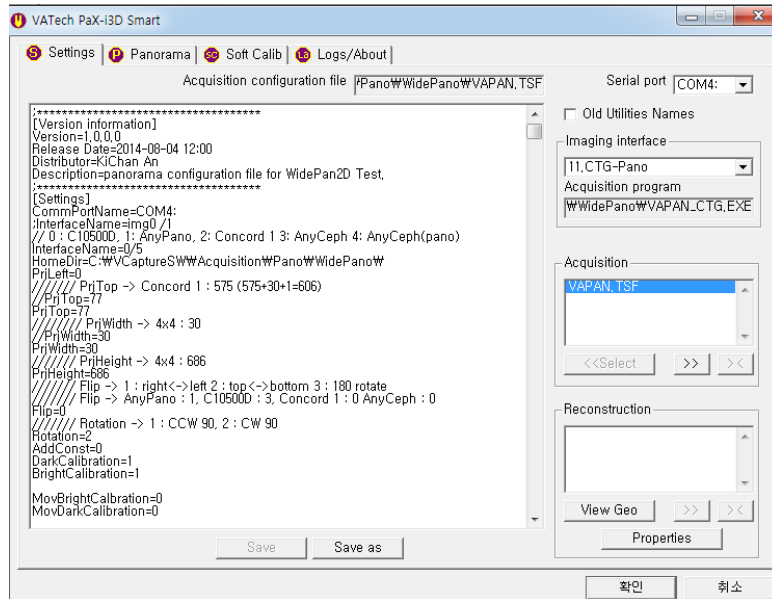


	VATECH Standard	Remarks
Line Pair	0.5 mm or less	

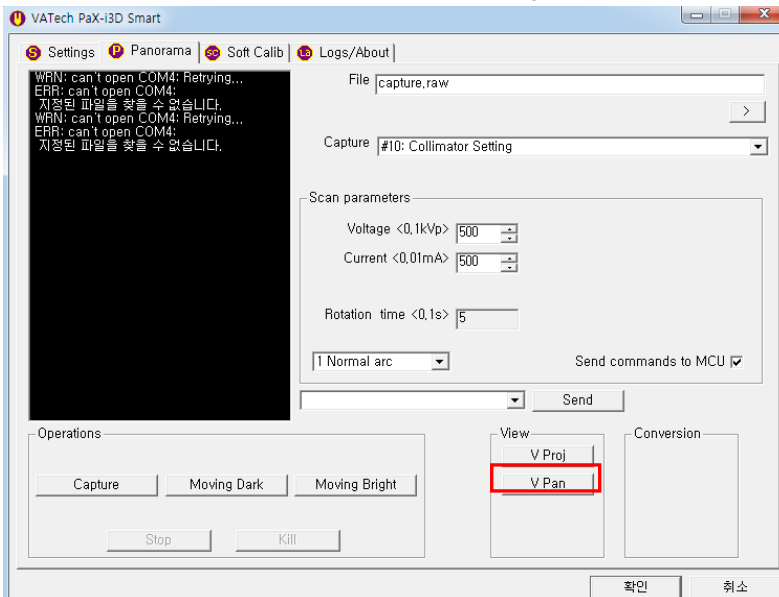
3. Check if the left hole is 1.5 mm.

17.1.3.3 Pano Image Noise (Dev) and Homogeneity Methods

1. Run C:\VCaptureSW\Acquisition\ Pano\WidePano\VAKCAP.exe.

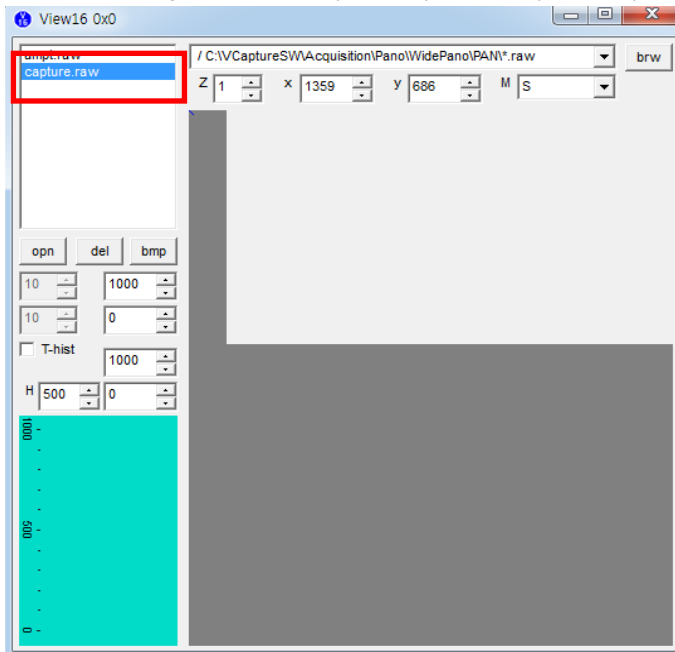


2. Select the Panorama Tab.
3. Click the V Pan button to call the View16 Program.

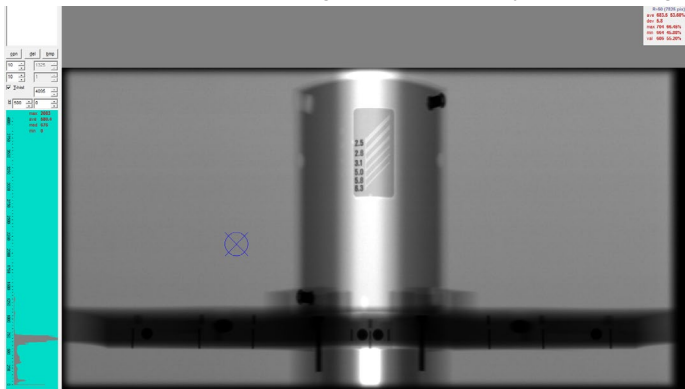


4. Select the Capture. raw file to load the captured image.

5. Panorama image size: 2719 (variable) x 1372 (constant)

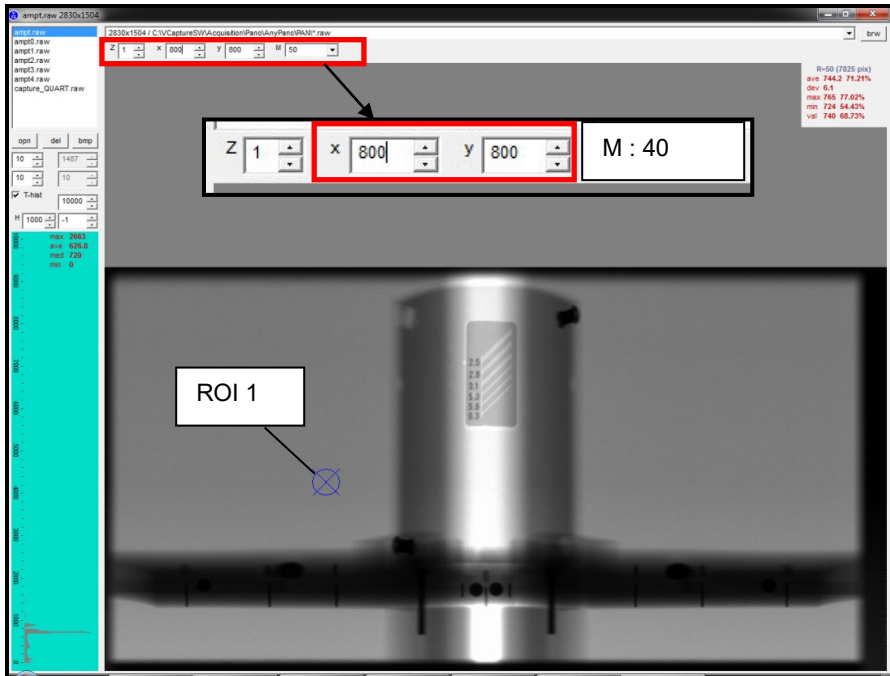


6. Enter Capture. raw and Image Size to display the following image.

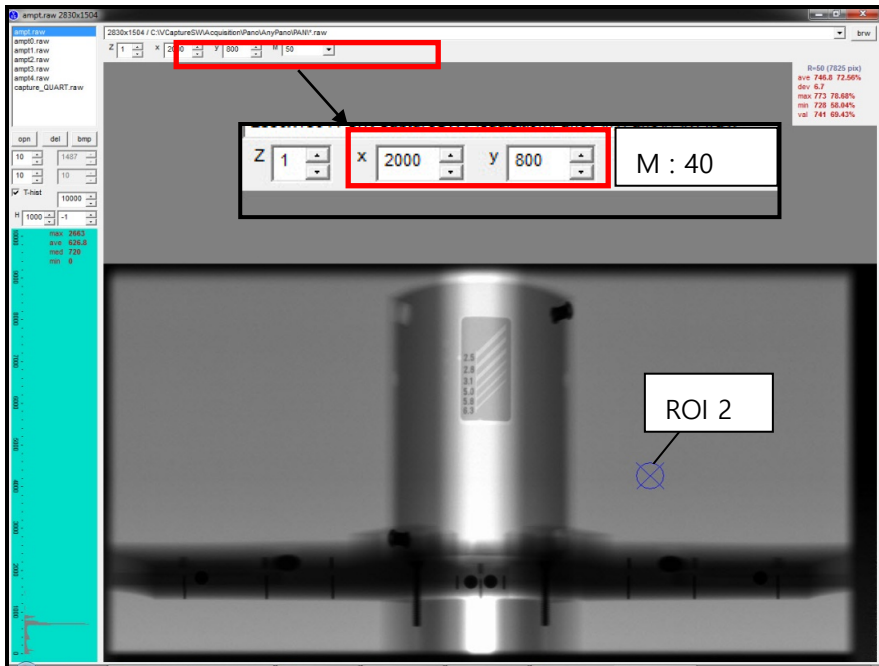


17. Image Evaluation Manual

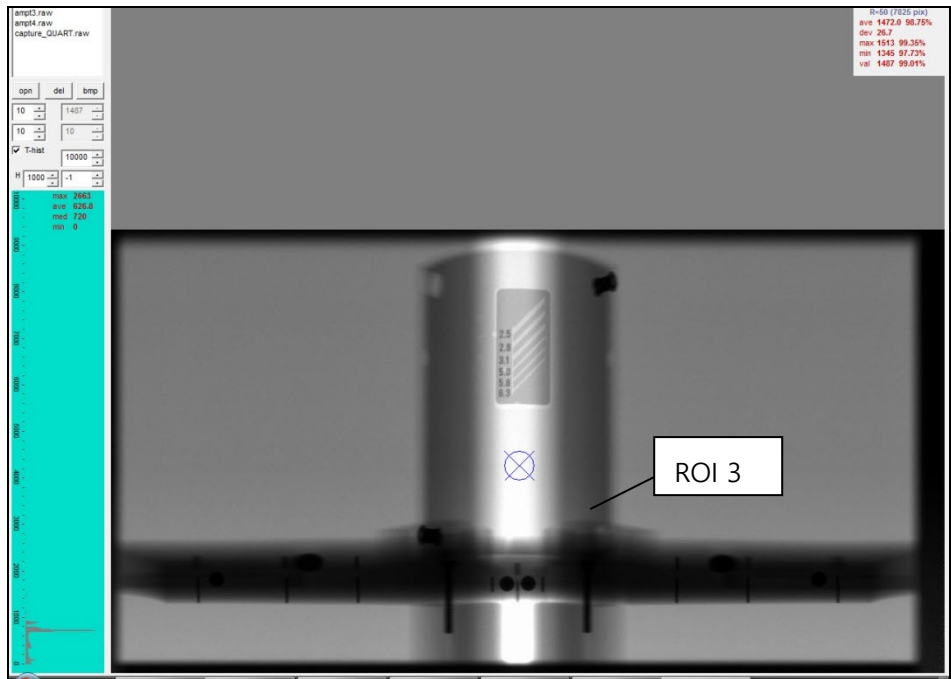
7. Enter the same position value "800" in the "x" and "y" coordinates.



8. As shown in the above figure, check if the noise (dev) and homogeneity (avg) of the ROI1 part meet the Reference value.
9. Enter "2000" in the "x" coordinates and "800" in the "y" coordinates.



10. As shown in the above figure, check if the noise (dev) and homogeneity (avg) of the ROI2 part meet the Reference value.
11. Enter "1330" in the "x" coordinates and "800" in the "y" coordinates.



12. As shown in the above figure, check if the noise (dev) and homogeneity (avg) of the ROI3 part meet the Reference value.

	ROI 1 (800,800)	ROI 2 (2000,800)	ROI 3 (1330,800)	Remarks
Noise (Dev)	8 or less		30 or less	
Homogeneity (avg)	More than 600 (Difference between the two values is less than 10%)		More than 1200	

17.2 CEPH

17.2.1 Introduction

17.2.1.1 Purpose

The "Image Evaluation Manual" is a document on the evaluation criteria and procedures of the equipment developed by VATECH. It is intended to evaluate the image quality using quantitative figures.

17.2.1.2 Image Evaluation Phantom Configuration

- X-ray Align: Evaluate the accuracy of symmetry in the "X-ray on" area
 - Geometry Phantom: Accuracy evaluation for the "Geometry accuracy"
 - Line pair resolution: More than 2.5 Lp/mm
 - Low contrast resolution: evaluation for the "Noise (Dev), Homogeneity"
-

17.2.2 Acquire Image

17.2.2.1 X-ray alignment

17.2.2.1.1 1st Collimator Align

1. Run C:\VCaptureSW\Exe\PaXi3DSmart.exe file.

1. Click the Preferences button.

2. Click the Engineer button, enter "vatech", and click the OK button.

3. Click the Align tab.

4. 70 kVp 7 mA

6. Click the Initialize button.

7. Click the Capture button.

2. After running CollimatorAlign.exe, check the AnyCeph Collimator setting.
 - Checklist before Collimator Setting
 1. Check the Collimator Type. (1-Axis, 4-Axis, 5-Axis)
 2. Check the kip/mA. (70 kVp, 7 mA recommended)
 3. Select the Align Ceph item to proceed with AnyCeph Align.
 4. After running the Raw Viewer, if you set it to "T 70", the X-Ray On / Off area (red) will be displayed as above.
 5. The left and right X-Ray areas should be symmetrical within 2 pixels, and the X-Ray Off areas should be 1 to 3 pixels each. (default value: 01271, move about 15 pixel per value 10)
 6. The top and bottom X-Ray Off zones match the top and bottom off zones equally.
 7. (Fixed slit, so within 20 pixels of error range)
 8. It moves about 18 pixels per 0.1 mm of numerical value with no distinction between top and bottom.
 9. The vertical direction of the X-Ray on the area should not be tilted (mechanical assembly). If the top and bottom tilt difference is more than 3 pixels, reassemble the 2nd Collimator.
- After setting the Align, you must click Save to save the setting.

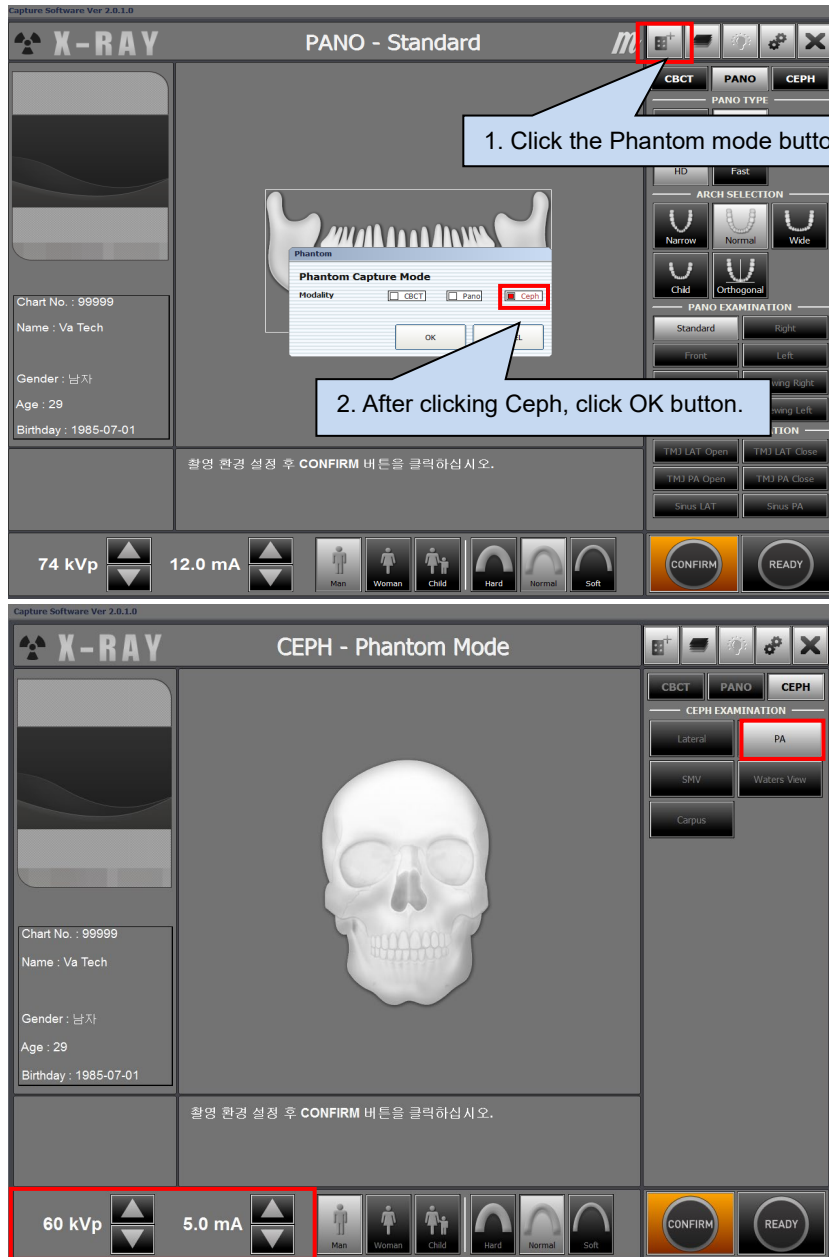
	Align criteria (T-hist "75" setting)	Pixel criteria	Remarks
1 st Collimator	Upper/Lower X-ray off area	20~50 pixel	
2 nd Collimator	Left/Right X-ray off area	1~3 pixel	

10. Align setting value

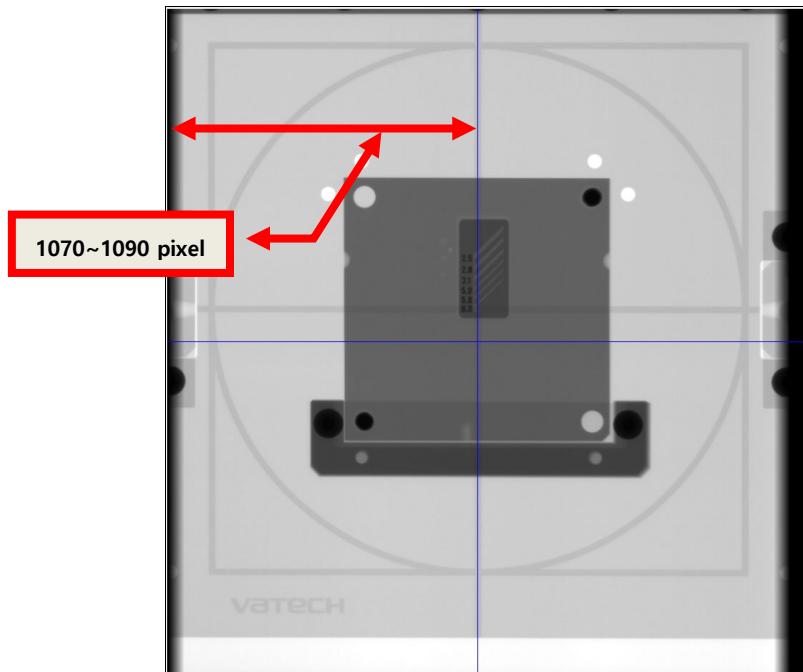
17.2.2.2 Geometry Phantom

17.2.2.2.1 Check the Frontal mode start position

1. Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.
2. A cephalo standard Phantom is attached to the ear rod.
3. Click the C: \ VCaptureSW \ Exe \ PaXi3DSmart.exe file.

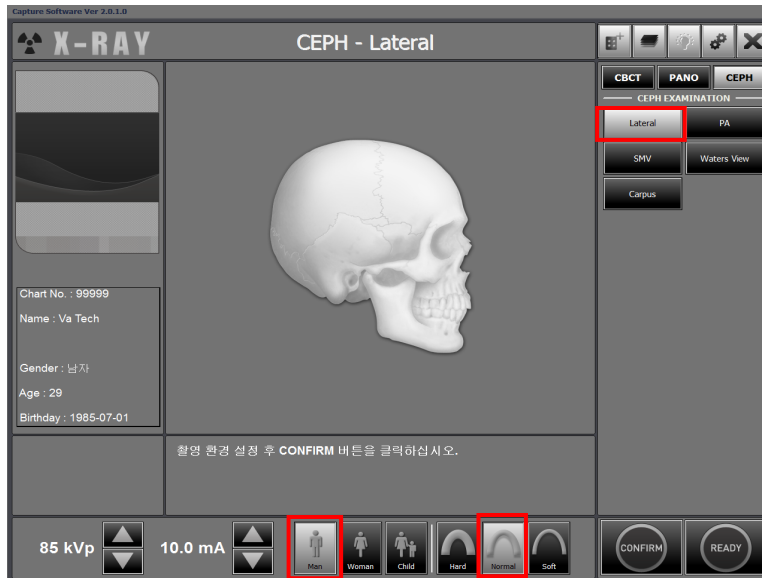


4. The exposure conditions of the frontal mode Phantom are as follows.
 - Exposure conditions: 60 kVp, 5 mA
 - Mode: PA mode
5. If the mode is not phantom, the basic exposure mode setting method is as follows.
 - Exposure conditions: 87 kVp, 10 mA
 - Mode: Frontal mode
 - Filter: Mount the 1T Cu Filter.

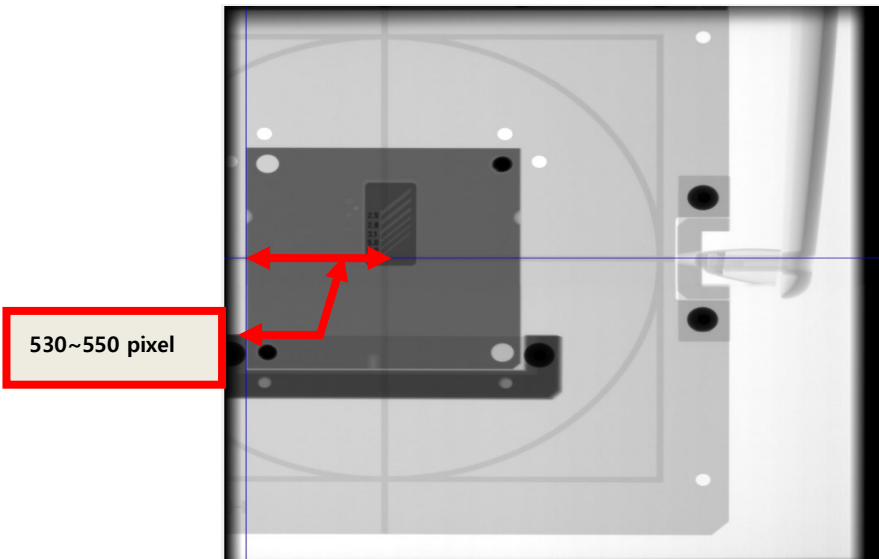


6. As shown in the above image, check whether the earrod Center is the reference coordinate value of the center.
7. Check if it is between 1070 ~ 1090 pixels of center reference coordinate.
8. If it is out of position, adjust the [spm_xfta_xxxx] numerical value to adjust the phantom.
Default: [spm_xfta_0100]
9. As you decrease the value, it moves to the right, about 10 pixels per 1 value.

17.2.2.2 Check the Lateral mode start position



- Exposure conditions: 85 kVp, 10 mA
- Mode: Lateral mode
- Filter: Mount the 1T Cu Filter.



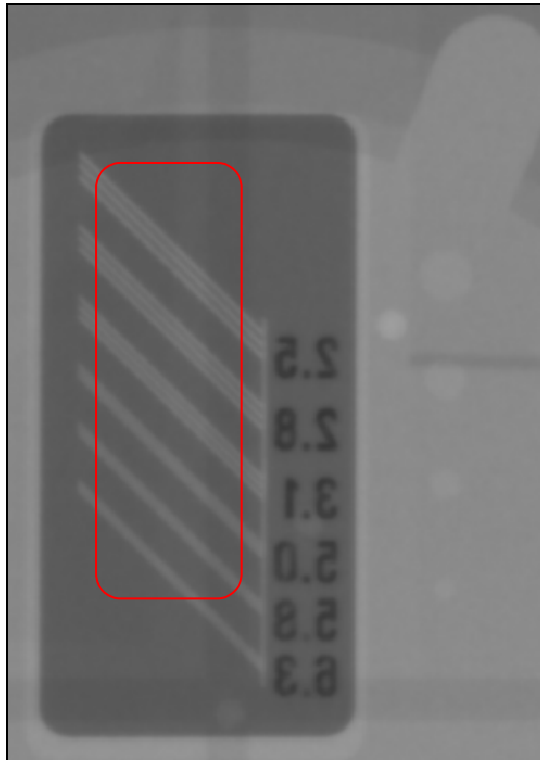
10. As shown in the image below, the Ear Rod Center is set by finely adjusting the [spm_xlta_xxxx] numerical value so that the center coordinate value is 530 ~ 550 pixels.

Default: [spm_xlta_0165]

11. As you decrease the value, it moves to the right, about 10 pixels per 1 value.

17.2.3 Evaluate the Quart Phantom

1. Line pair of Quart Phantom is 2.5 Lp / mm or more, 1 hole or more.



17.3 CBCT

17.3.1 Introduction

17.3.1.1 Purpose

This manual is a document on the CT evaluation criteria and procedures of the equipment developed by VATECH so that the quality of the images can be evaluated using quantitative values.

17.3.1.2 Software configuration

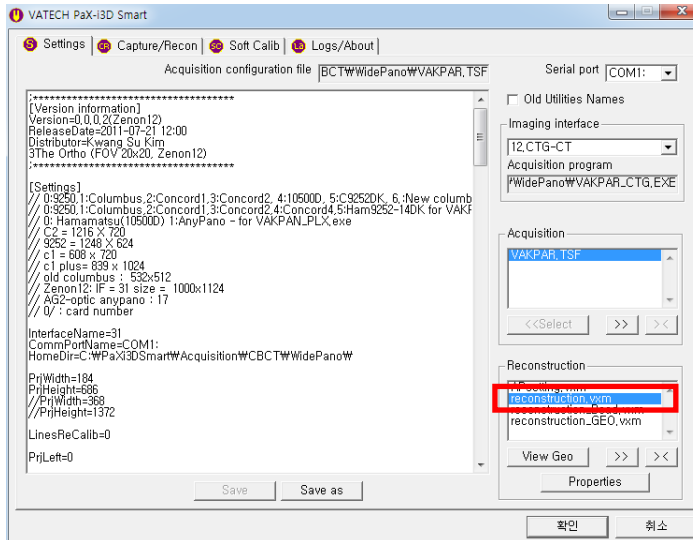
- EzEval.exe: "EzEval" S/W executable file (Ver 0.0.1.2)

17.3.1.3 Image Evaluation Phantom Configuration

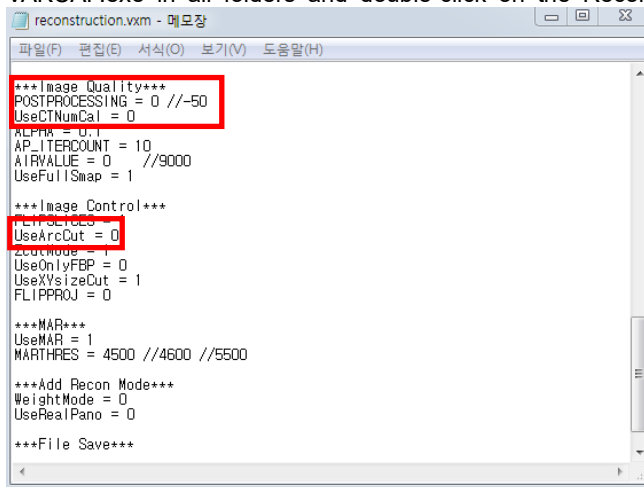
- Geometry Check Phantom: Accuracy evaluation of "Geometry calibration"
- CT Number Phantom: Accuracy evaluation of "CT Number"
- M&R Phantom: Accuracy evaluation of "Contrast"
- Uniformity Check Phantom: Evaluation of "Noise (Dev), Homogeneity"
- S&C Phantom: Evaluation of "High Contrast Resolution, Contrast Resolution"

17.3.2 Acquire Image

17.3.2.1 Change the Reconstruction POSTPROCESSING



1. VAKCAP.exe in all folders and double-click on the Reconstruction. vxm file.

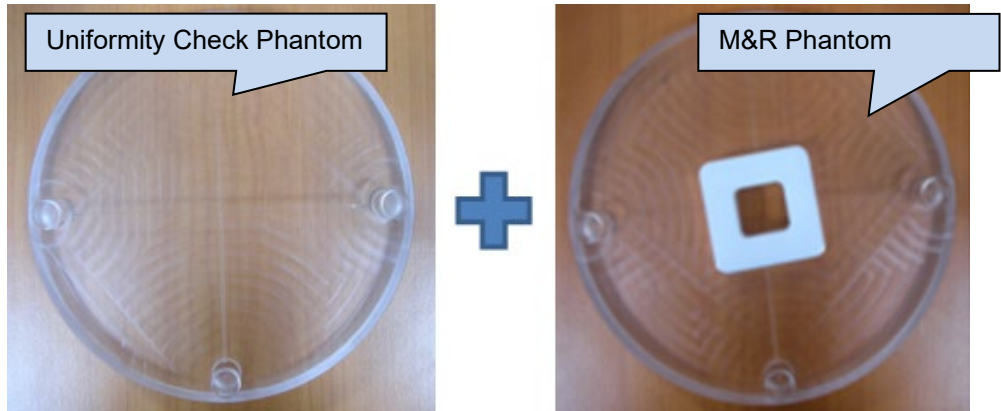


2. When evaluating with Phantom, change UseArcCut = 0, and when all evaluations are complete, change UseArcCut = 1.
3.
 - Each Phantom is labeled DICOM, SLICE.
 - DICOM: POSTPROCESSING = -50, UseCTNumCal = 1
 - SLICE: POSTPROCESSING = 0, UseCTNumCal = 0

17.3.2.2 Acquire M&R, Uniformity Phantom Image (DICOM, SLICE)

Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.

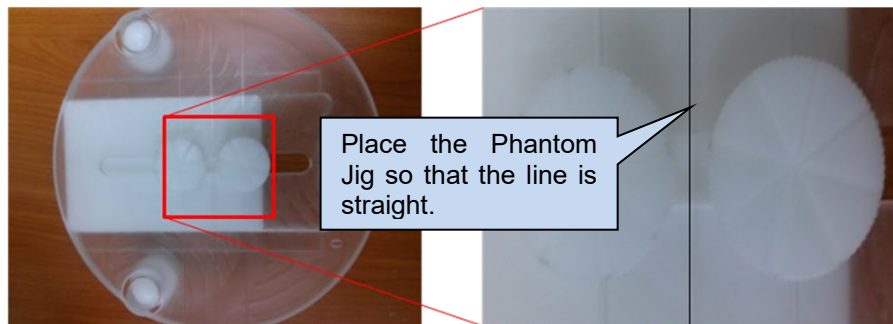
17.3.2.2.1 Phantom alignment



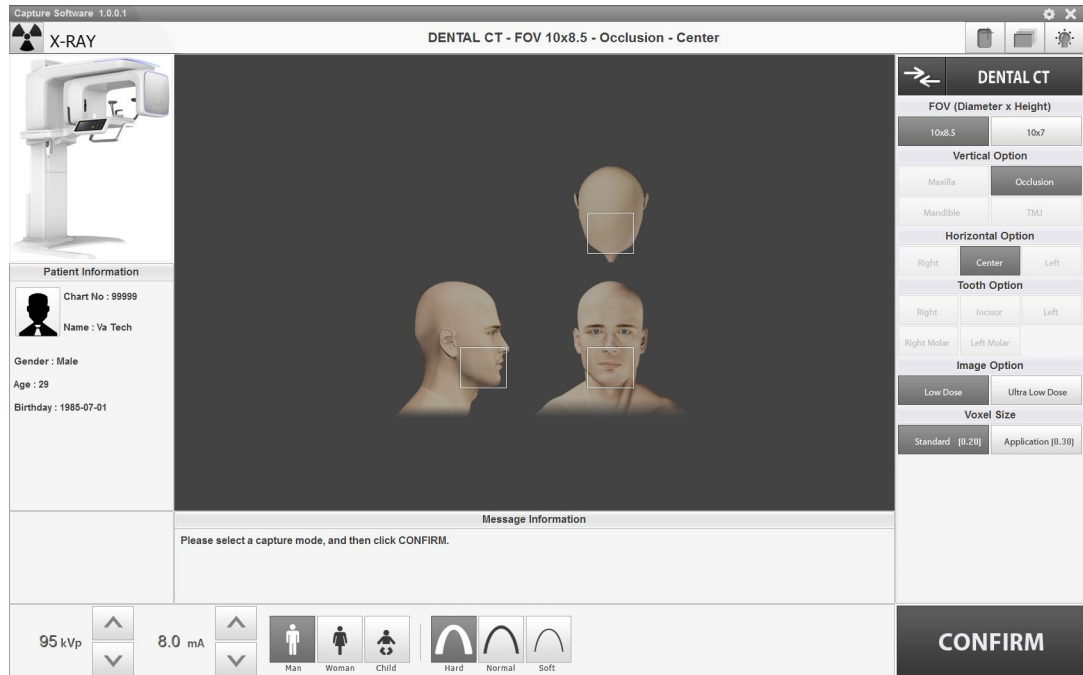
1. Tighten the Phantom jig in the order of Uniformity Check (bottom) and M & R Phantom (top).

NOTICE

Use Phantom Jig for only PHT-30LFO.



17.3.2.2.2 Acquire Image

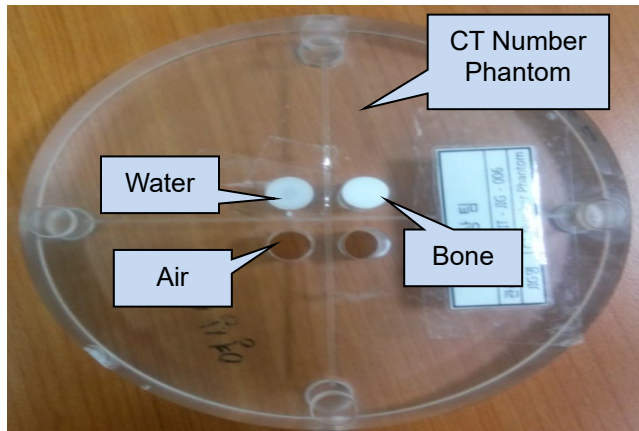


1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Exposure with M&R and Uniformity Phantom on Phantom Jig.
3. When the reconstruction is completed, change the Slice image folder name and C:\VCaptureSW\ImageOutput\CT in C:\VCaptureSW\Acquisition\CBCCT\WidePano\SLICE folder to Slice_M&R Phantom and save.

17.3.2.3 Acquire CT Number Phantom Image (DICOM)

Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.

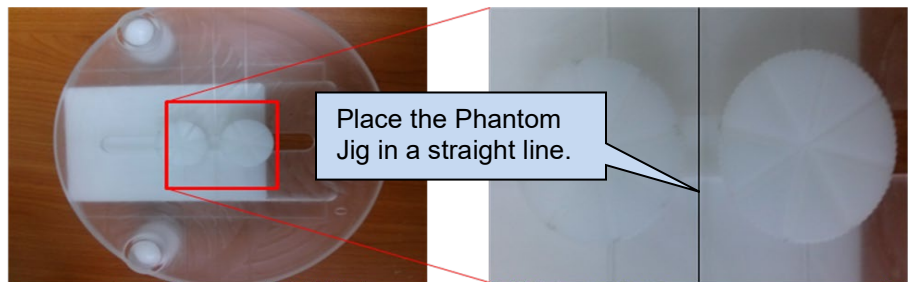
17.3.2.3.1 Phantom alignment



1. Put the CT Number Phantom on the Phantom Jig.

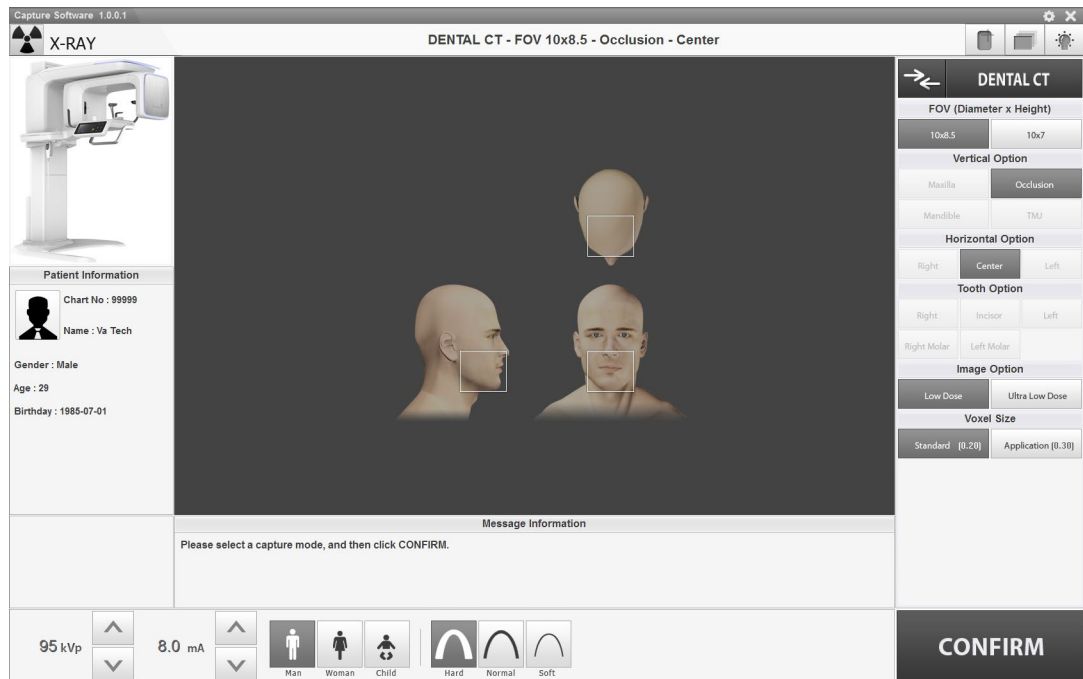
NOTICE

Use Phantom Jig for only PHT-30LFO.



2. Phantom Jig and CT Number Phantom are fastened before exposure.

17.3.2.3.2 Acquire Image

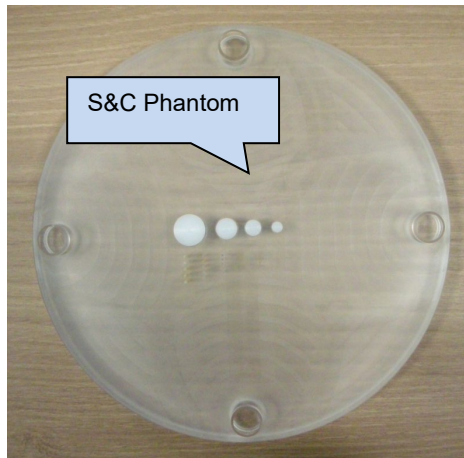


1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Exposure with CT Number on Phantom Jig.
3. When the reconstruction is complete, change C:\VCaptureSW\ImageOutput\CT to Slice_CT_Number Phantom and save.

17.3.2.4 Acquire S&C Phantom Image (DICOM)

Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.

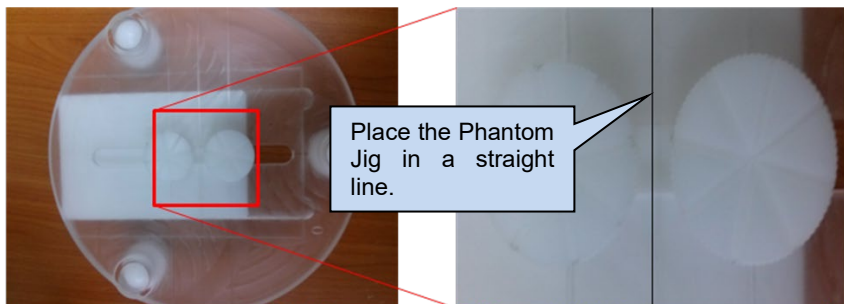
17.3.2.4.1 Phantom alignment



1. Put the S&C Phantom on the Phantom Jig.

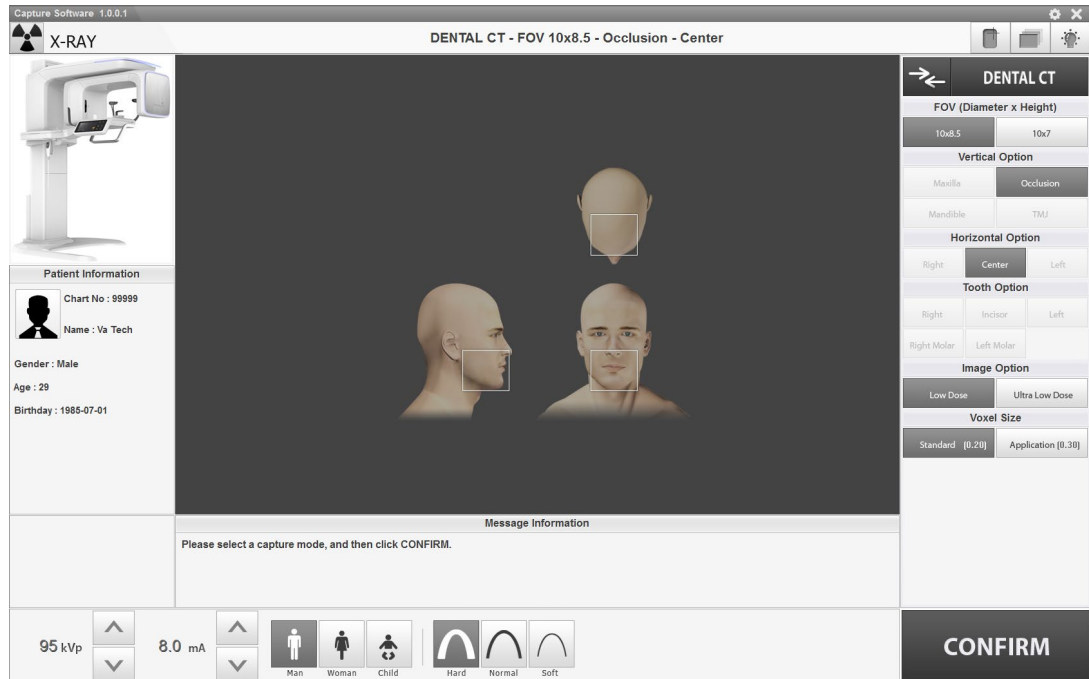
NOTICE

Use Phantom Jig for only PHT-30LFO.



2. Phantom Jig and S&C Phantom are fastened before exposure.

17.3.2.4.2 Acquire Image

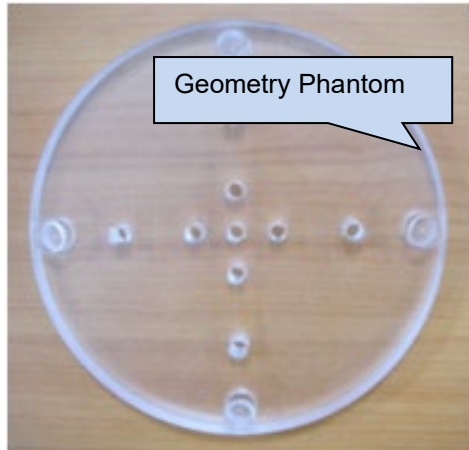


1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Place the S&C Phantom on the Phantom Jig and exposure.
3. When the reconstruction is completed, change the CT folder name of C:\VCapture SW\ImageOutput\CT folder to CT_S&C Phantom and save it.

17.3.2.5 Acquire Geometry Phantom Image (SLICE)

Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.

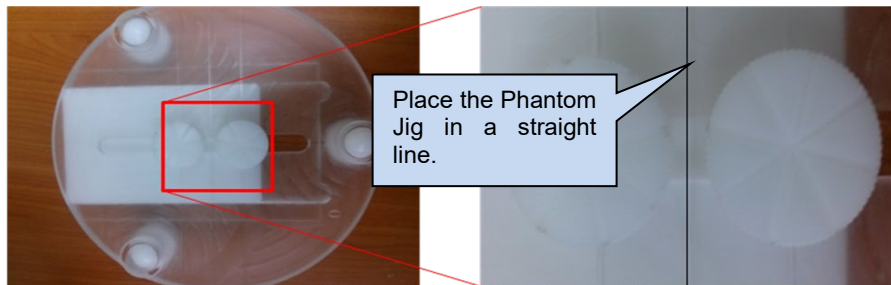
17.3.2.5.1 Phantom alignment



1. Put the Geometry Phantom on the Phantom Jig.

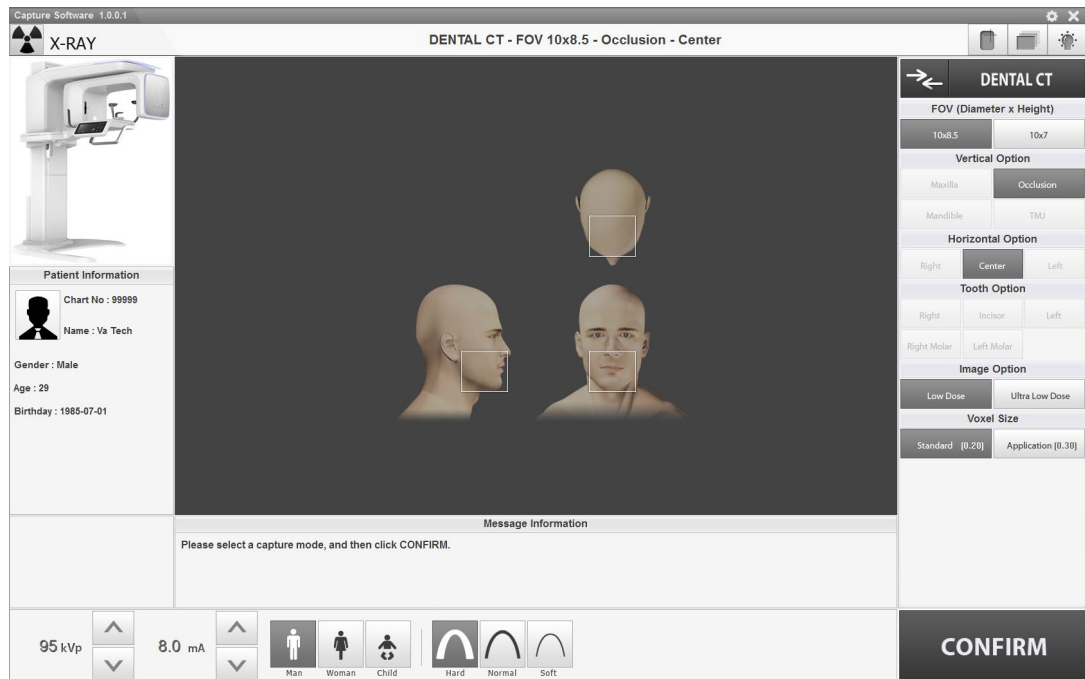
NOTICE

Use Phantom Jig for only PHT-30LFO.



2. Phantom Jig and Geometry Phantom are fastened before exposure.

17.3.2.5.2 Acquire Image

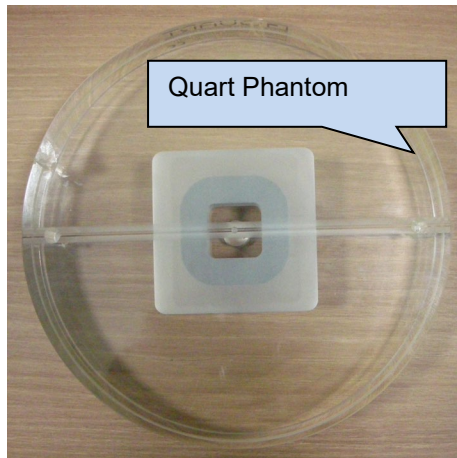


1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Place the Geometry Phantom on the Phantom Jig and exposure.
3. When the reconstruction is completed, change the SLICE folder name in C:\VcaptureSW\Acquisition\CBCTWidePano\SLICE folder to Slice_Geometry and save.

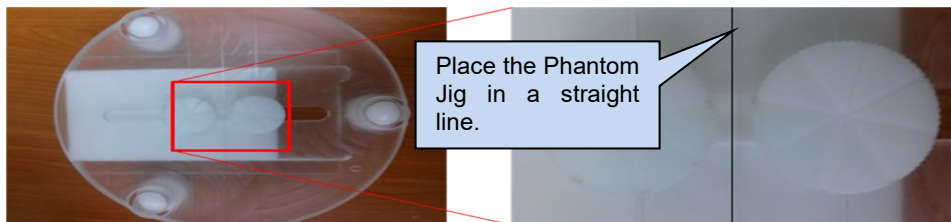
17.3.2.6 Acquire Quart Phantom Image (DCM) -After assembling the case

Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.

17.3.2.6.1 Phantom alignment

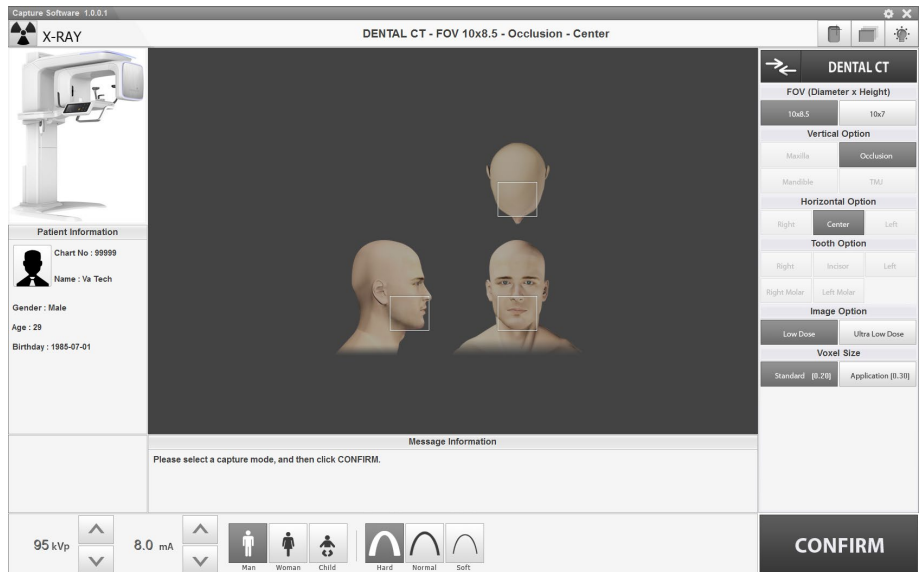


1. Level the tripod and place the Tooth Positioning Phantom on it. Use Phantom Jig for PHT-30LFO.



2. Tighten Quart Phantom on CT Number.

17. Image Evaluation Manual



3. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
4. Place the Quart Phantom on the Phantom Jig and exposure.
5. When the reconstruction is completed, change the Slice folder name of **C:\VCaptu reSW\ImageOutput\CT** folder to Quart_Phantom and save it.

17.3.3 CT Image Evaluation

17.3.3.1 Contrast & Noise (Dev) & Homogeneity Evaluation

Using the obtained Reference CT Number, this step evaluates whether the contrast, Noise (Dev), and homogeneity meet the criteria.

17.3.3.1.1 M&R Phantom Slice

1. Click the Setting.
2. Select engineer and enter "vatech".

Patient Information
 Chart No : 99999
 Name : Va Tech
 Gender : Male
 Age : 29
 Birthday : 1985-07-01

Message Information
 Please select a capture mode, and then click CONFIRM.

95 kVp **8.0 mA**

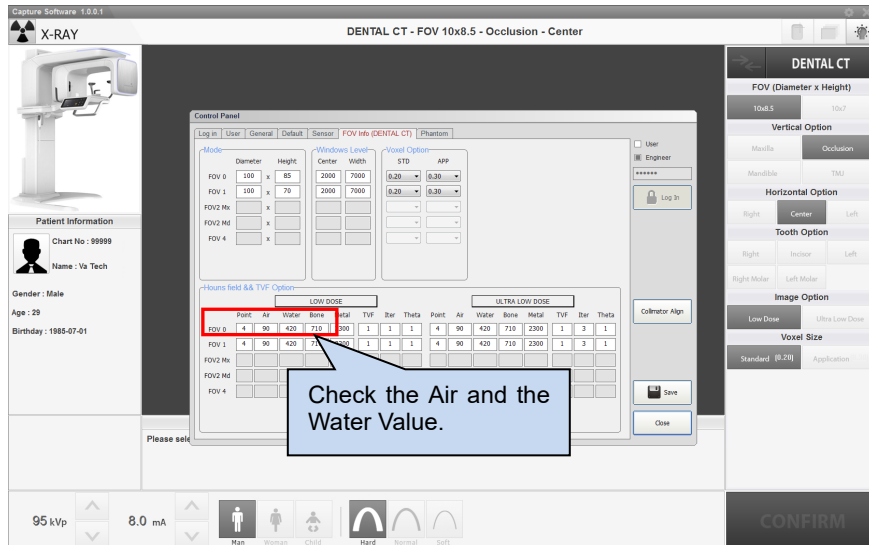
Man Woman Child Hard Normal Soft

DENTAL CT
 FOV (Diameter x Height)
 10x5 10x7
 Vertical Option
 Maxilla Occlusion
 Mandible TMJ
 Horizontal Option
 Right Center Left
 Tooth Option
 Right Incisor Left
 Right Molar Left Molar
 Image Option
 Low Dose Ultra Low Dose
 Voxel Size
 Standard (0.20) Application (0.30)

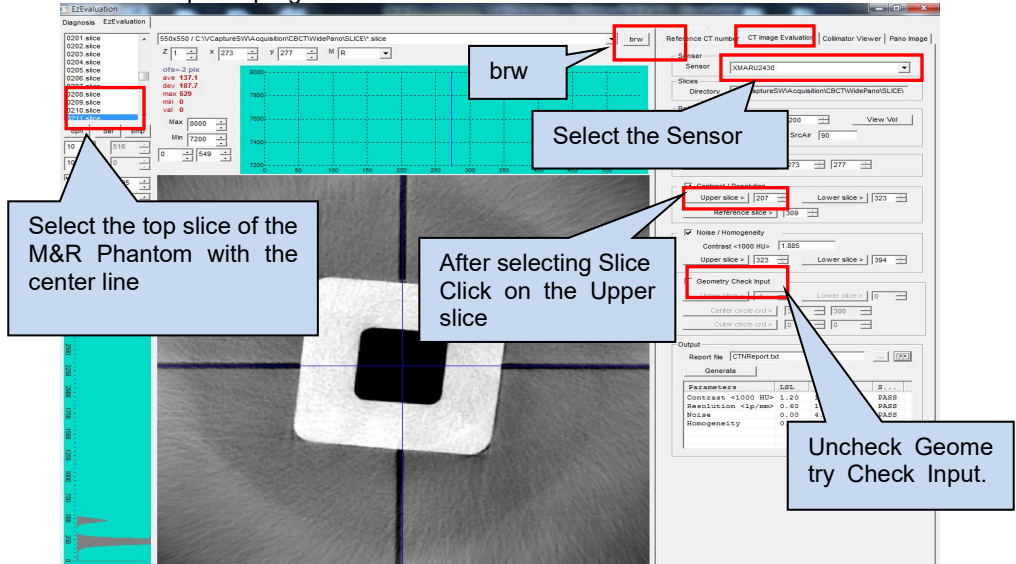
CONFIRM

17. Image Evaluation Manual

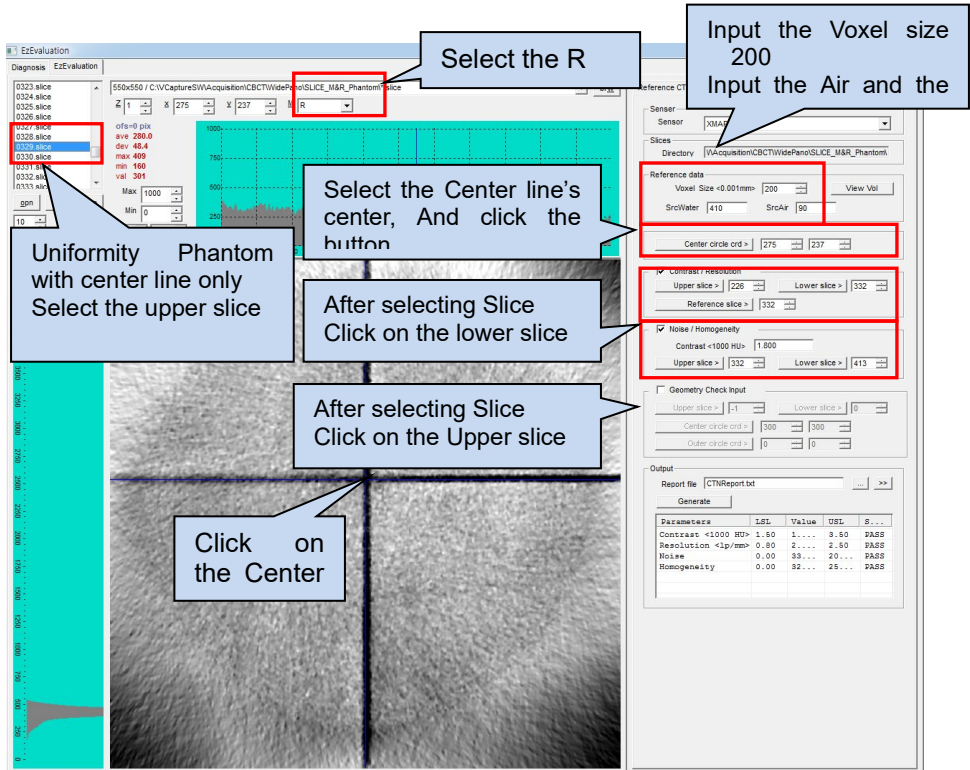
1. Run the C:\VCaptureSW\Exe\VCaptureSW.exe.



2. Run the capture program and check the obtained Reference CT Number value.

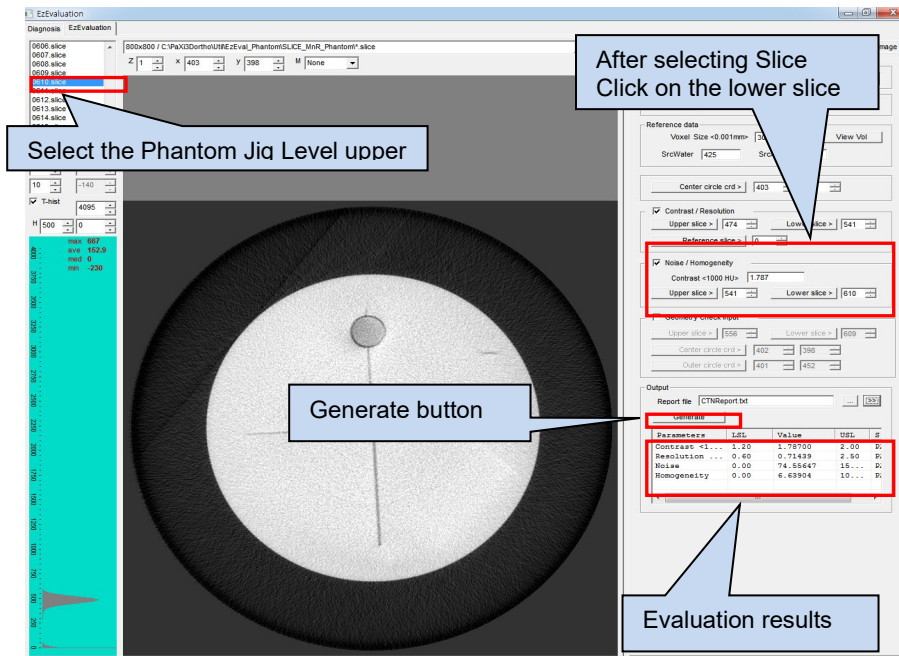


3. Run the EzEval.exe in the C:\VCaptureSW\Util\EzEval_Phantom folder.
4. Click the [brw] button to select Slice_M&R Phantom.
5. Select the CT Image Evaluation tab and select XMARU0808 under Sensor.
6. As shown above, select the top slice of the M&R Phantom with the center line and click the Upper slice button of the Contrast/Resolution.
7. Uncheck Geometry Check Input.



8. Check the Air and Water values in the Control Panel, enter the SrcAir and Src Water values in the Reference data and set the Voxel size to 200.
9. As shown above, select the top slice of the Uniformity Phantom with only the center line and click the Lower slice of Contrast / Resolution and the Upper slice button of Noise (Dev) / Homogeneity.
10. Click the Reference slice button.
11. Select M as R, click the center of the center line and click the Center circle crd button.

17. Image Evaluation Manual



Parameters	LSL	Val	USL	Status
Contrast <1000 HU>	1.50	2.80803	3.50	PASS
Resolution <lp/mm>	0.80	2.26879	2.50	PASS
Noise	0.00	27.21473	200.00	PASS
Homogeneity	0.00	65.45477	250.00	PASS

12. As shown in the picture above, select the upper slice of the phantom jig w here the hole is located at the end of the centerline, and click the lower slice button of Noise (Dev)/ Homogeneity.
13. When all the settings are completed, click the Generate button to proceed with the evaluation.
14. When the evaluation is completed, the window below shows the minimum r eference value, the maximum reference value, and the evaluation result.
15. The evaluation result is saved in the designated folder in the form of CTN Report.txt.
16. When the evaluation result is passed by satisfying the standard value, it is saved as CTNReport_date.txt.
17. You can check the Test Report by clicking >> button.

Parameters	Standard Value	
	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Contrast <1000HU>	1.50	3.50
Noise (Dev)	0.00	150.00
Homogeneity	0.00	50.00

17.3.3.2 Geometry Calibration Evaluation

It is a step to evaluate whether the geometry calibration is properly applied by evaluating the eccentricity and blur of the five holes of the Geometry Check phantom.

17.3.3.2.1 Select the Geometry Check Phantom Slice

Select upper and bottom slices of the phantom image and enter circle center coordinates

Center circle Center coordinates

Outer circle Center coordinates

Geometry Check Input

Upper slice > | 358 | Lower slice > | 423 |

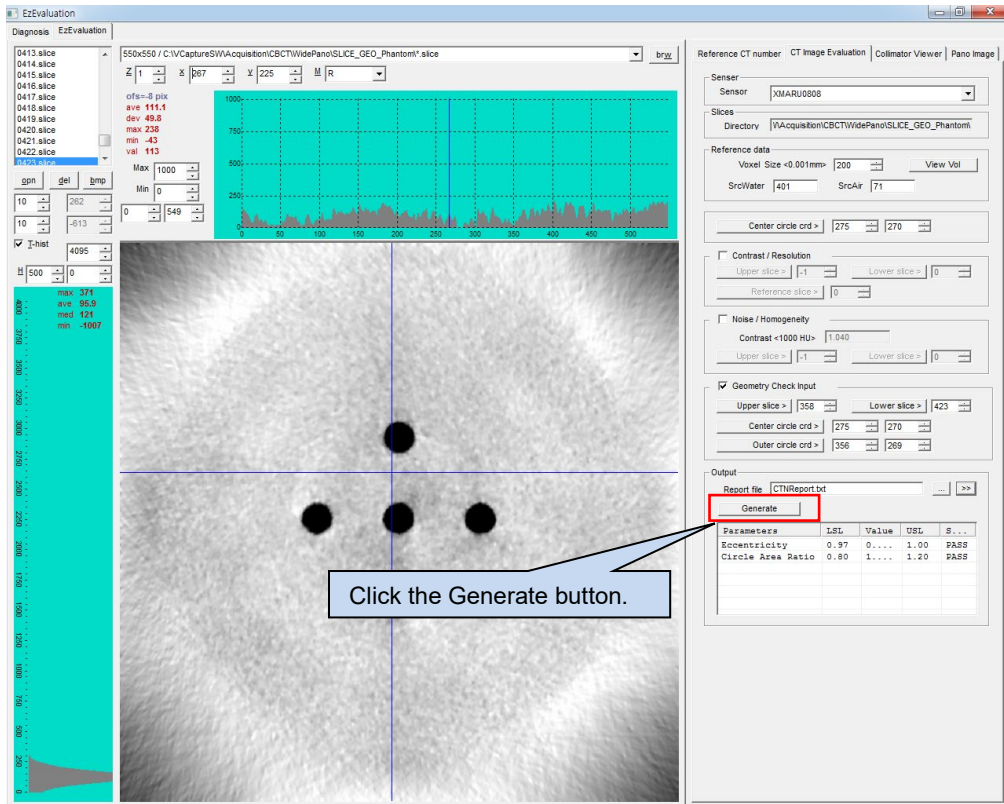
Center circle crd > | 275 | 270 |

Outer circle crd > | 358 | 269 |

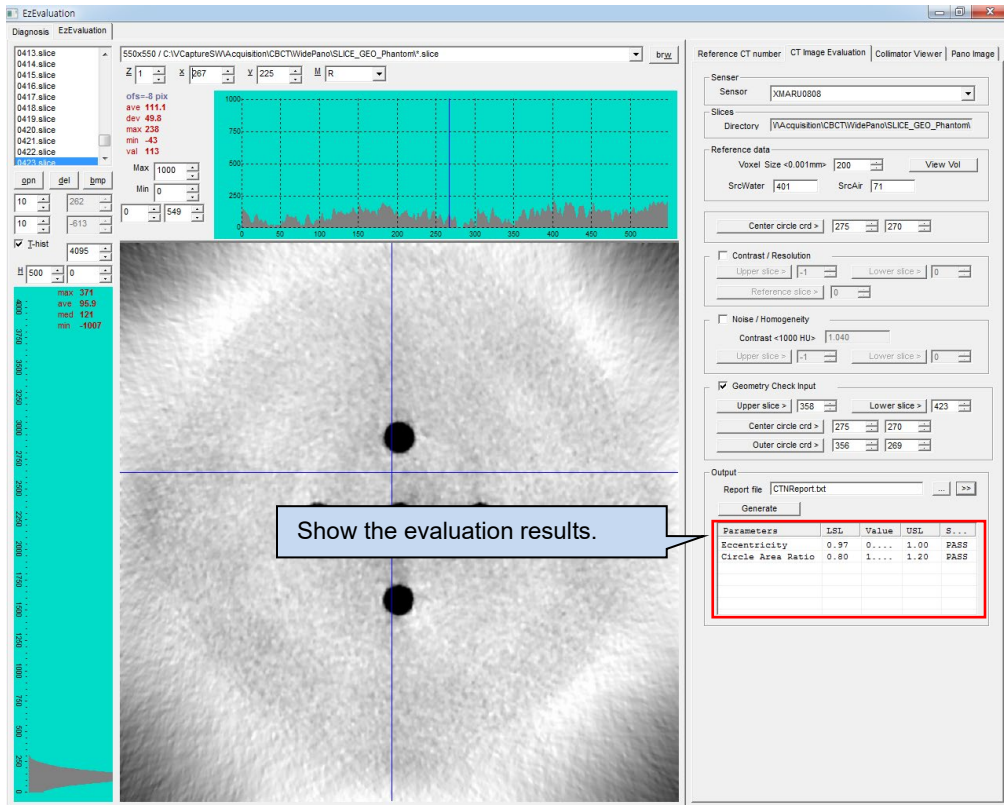
Parameters	LSL	Value	USL	S...
Eccentricity	0.97	0....	1.00	PASS
Circle Area Ratio	0.80	1....	1.20	PASS

1. Click the [brw] button to select the Slice_Geometry Phantom.
2. Click the upper slice button to select the top of the geometry check phantom with the centerline in the View16 Module and click the lower slice button to select the bottom.
3. In the Viw16 Module, click the Center circle crd and Outer circle crd buttons to enter the coordinates.

17.3.3.2.2 Generate (Evaluation)



17.3.3.2.3 Test Result



Show the evaluation results.

Parameters	LSL	Val	USL	Status
Eccentricity	0.97	0.97921	1.00	PASS
Circle Area Ratio	0.80	1.01293	1.20	PASS

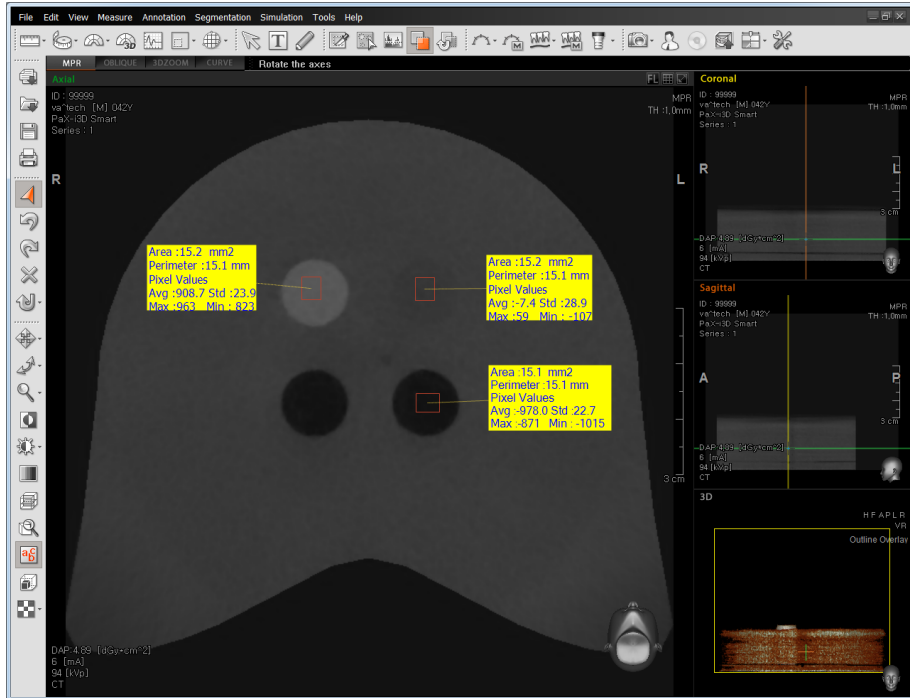
1. When the evaluation is completed, the window below shows the minimum reference value, the maximum reference value, and the evaluation result.
2. The evaluation result is saved in the designated folder in the form of CTNReport.txt.
3. When the evaluation result is passed by satisfying the standard value, it is saved as GEO_CTNReport_date.txt.
4. You can check the Test Report by clicking >> button.

Standard Value

Parameters	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Eccentricity	0.97	1.00
Circle Area Ratio	0.80	1.20

17.3.3.3 CT Number Accuracy Evaluation

1. Run Ez3D 2009 (or Ez3D-i) and open the Dcm file in the CT_ CT Number folder.
2. Specify the center of the air or water column in the sagittal or coronal image.



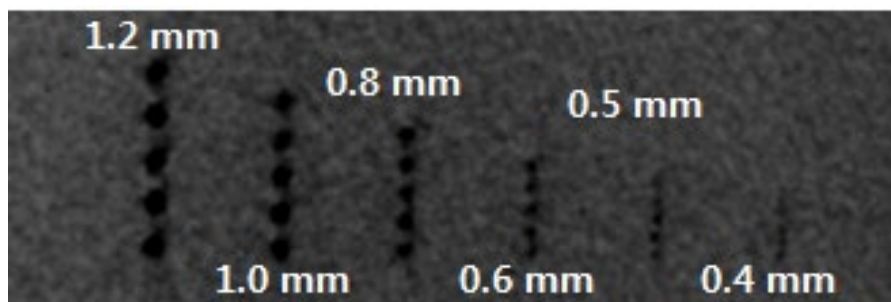
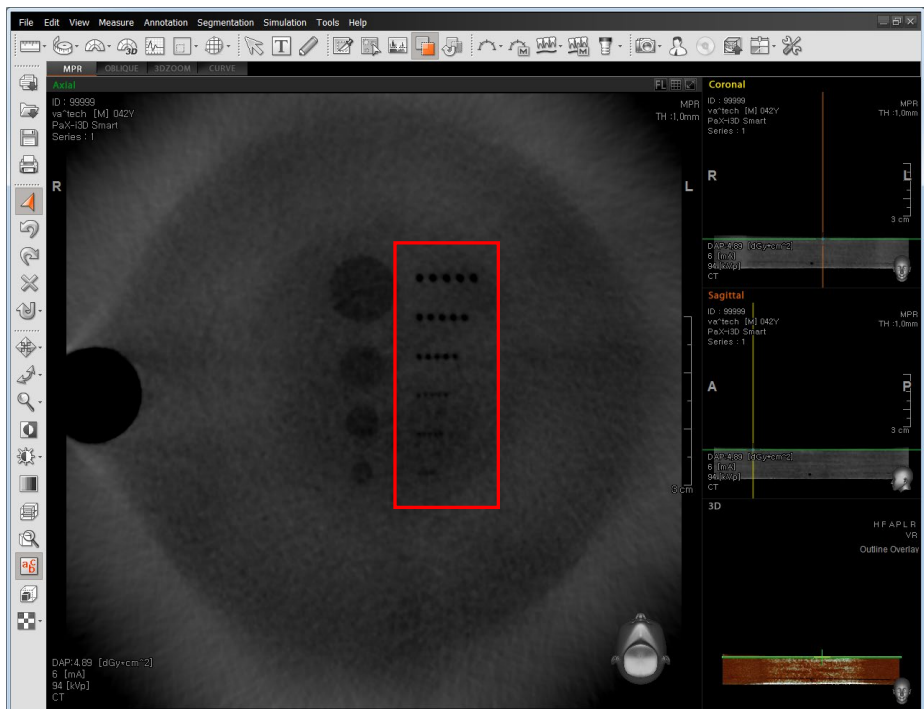
3. Measure the CT Number values of Air and Water in Area $15 \pm 2 \text{ mm}^2$ in Axial image.
4. Take a screenshot and save it as CT_Number.jpg in C:\VCaptureSWAcquisition \CBCTWidePano\Evaluation folder as shown above.

Standard Value

Parameters	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Air CT Number	-1030	-900
Water CT Number	-20	20
Teflon CT Number	900	1100

17.3.3.4 High Contrast Resolution Evaluation

1. Run Ez3D 2009 (or Ez3D-i) and open the Dcm file in the CT_S&C Phantom folder
2. Select the position of Air Hole in Sagittal and check the Air Hole in the Axial image.
3. L: Change the windowing setting to -100 ~ -300, W1000 ~ 1500 by default, and check the size of the air hole that can be visually distinguished at 50 cm from the monitor.

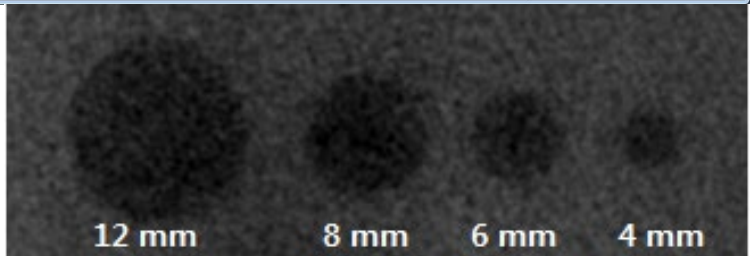
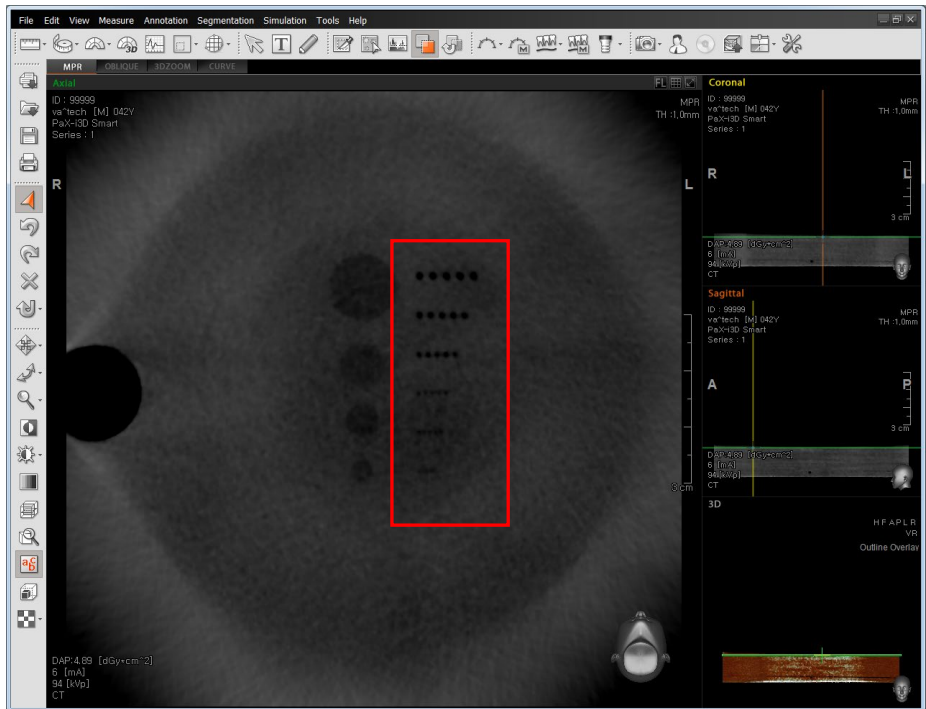


4. Take a screenshot and save it as CT_High Contrast Resolution.jpg in C:\VCaptureSW\Acquisition\CBCTWidePano\Evaluation folder.

Parameters	Standard Value
	USL (Upper Specification Limit)
High Contrast Resolution	1.0 mm

17.3.3.5 Contrast Resolution Evaluation

1. Run Ez3D 2009 (or Ez3D-i) and open the Dcm file in the CT_S&C Phantom folder
2. Select the position of PE (Polyethylene) in Sagittal and check PE in the Axial image.
3. L: Change the windowing setting to -100 ~ -300, W1000 ~ 1500 by default, and check the size of the PE that can be visually distinguished at 50 cm from the monitor.



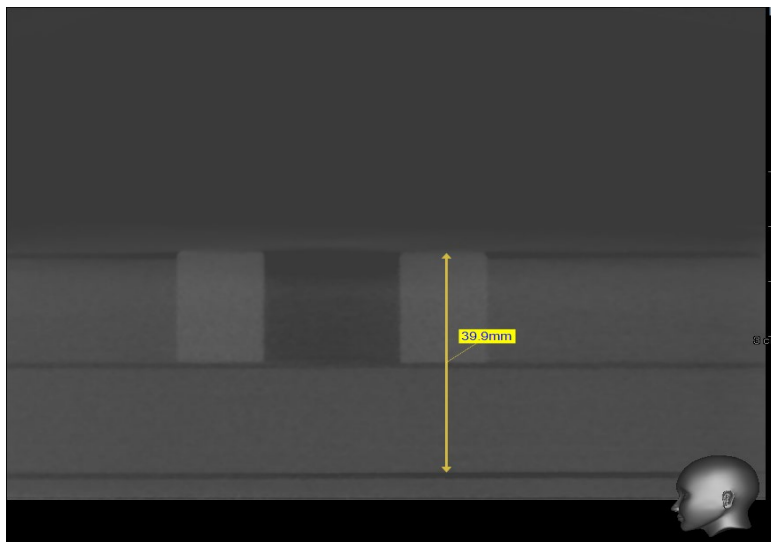
4. Take a screenshot and save it as CT_Contrast Resolution.jpg in C:\VCaptureSW\Acquisition\CBCT\WidePano\Evaluation folder.

Standard Value

Parameters	USL (Upper Specification Limit)
Contrast Resolution	8.0 mm

17.3.3.6 Slice Thickness Evaluation

1. Run Ez3D2009 (or Ez3D-i) and open the Dcm file in the CT_M & R Phantom size folder.
2. Measure the length from the Uniformity Check Phantom to the M & R Check Phantom in Sagittal or Coronal image.



3. Take a screenshot and save it as CT_Slice Thickness.jpg in C:\VCaptureSWAcquisition\CBCT\WidePano\Evaluation folder.

Standard Value

Parameters	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Slice Thickness	38.0 mm	42.0 mm

4. When all evaluations are complete, the parameters in the Reconstruction.vxm file should be changed to UseArcCut = 1, POSTPROCESSING = -50 and UseCTNumCal = 1.

18. Image Test Manual

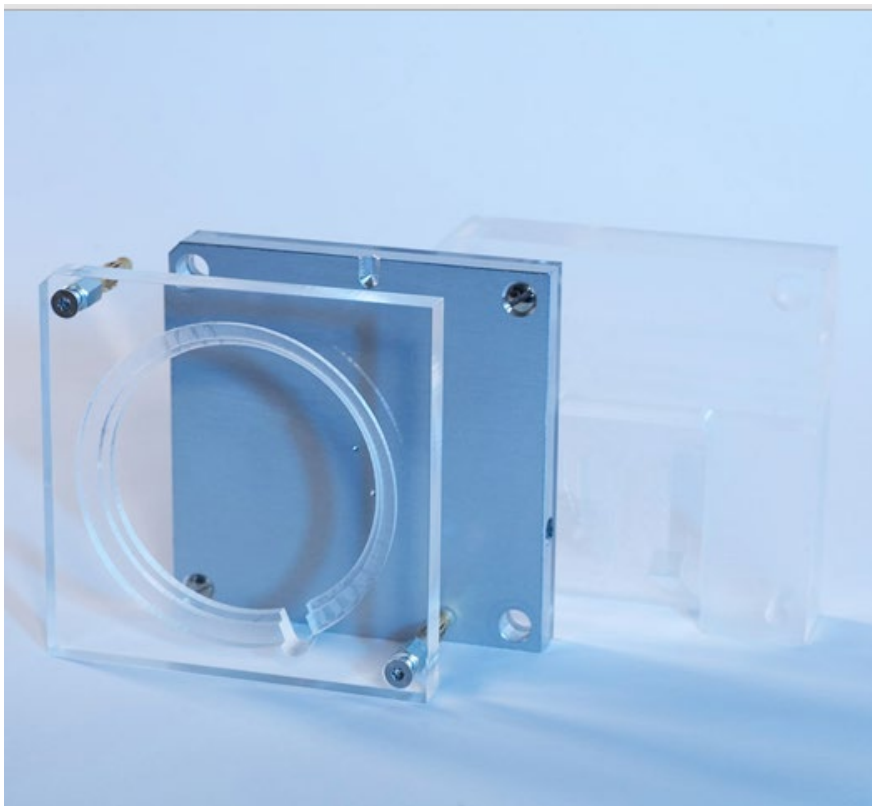
18.1 PANO

18.1.1 Evaluate the Lp/mm (Line Pair)

18.1.1.1 Resolution measurement criterion

Parameter	VATECH Standard	Remarks
Lp/mm	3.1 lp/mm	

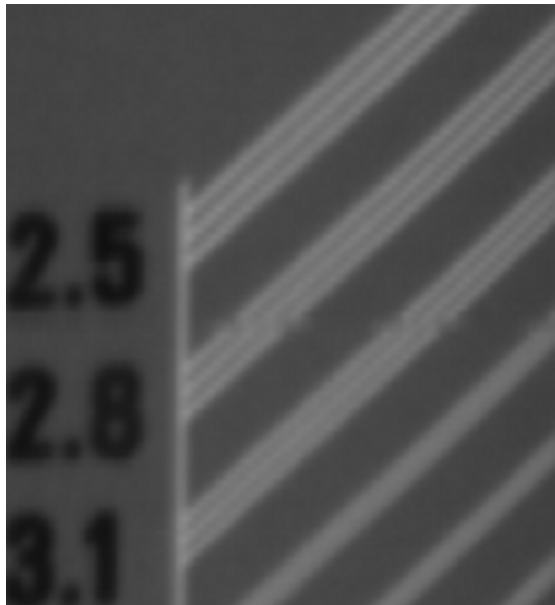
18.1.1.2 Phantom Specification



< QUART Phantom >

18.1.1.3 Test Method

1. Align the QUART Phantom and acquire the image.
2. Default exposure mode and exposure conditions are as follows.
 - Exposure mode: HD mode (13.5s)
 - Patient mode: Man, Normal
 - Exposure conditions: 74 kVp, 12 mA



18.1.1.4 Test Result

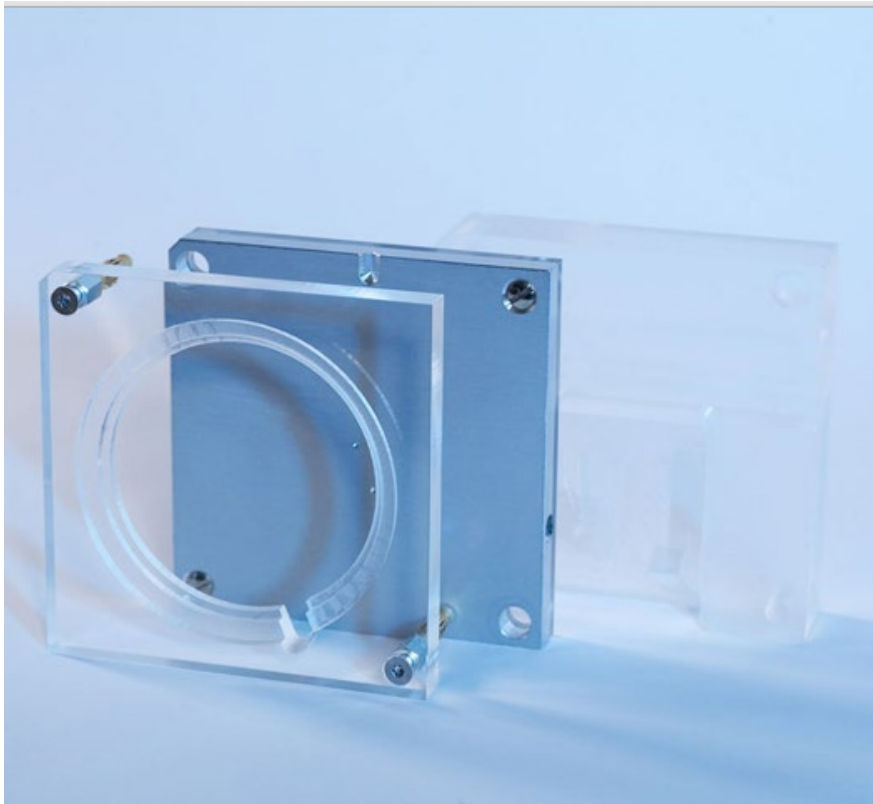
	VATECH Standard	Remarks
Lp/mm (Line Pair)	3.1 Lp/mm	

18.1.2 Evaluate the Low Contrast Resolution

18.1.2.1 High contrast Measure criterion

	VATECH Standard	Remarks
Hole	Less than 1.5 mm	

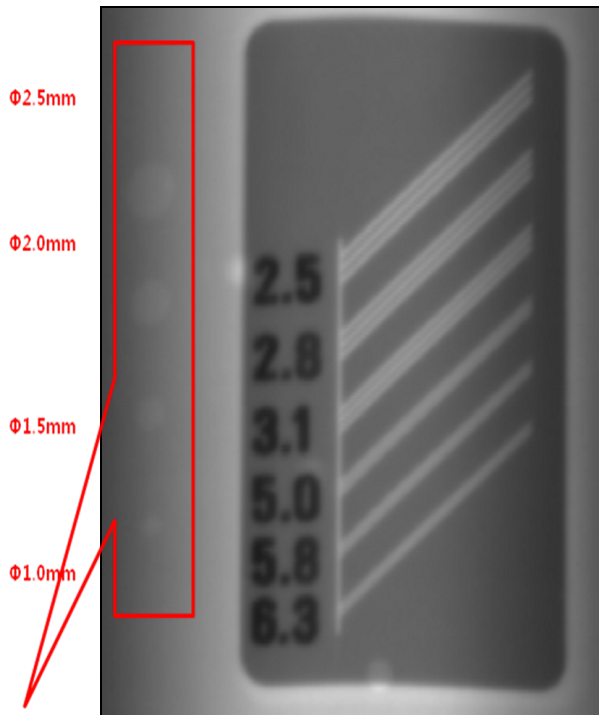
18.1.2.2 Phantom Specification



< QUART Phantom >

18.1.2.3 Test Method

1. Align the QUART Phantom and acquire the image.
2. Default exposure mode and exposure conditions are as follows.
 - Exposure mode: HD mode (13.5s)
 - Patient mode: Man, Normal
 - Exposure conditions: 74 kVp, 14 mA



Low contrast resolution

18.1.2.4 Test Result

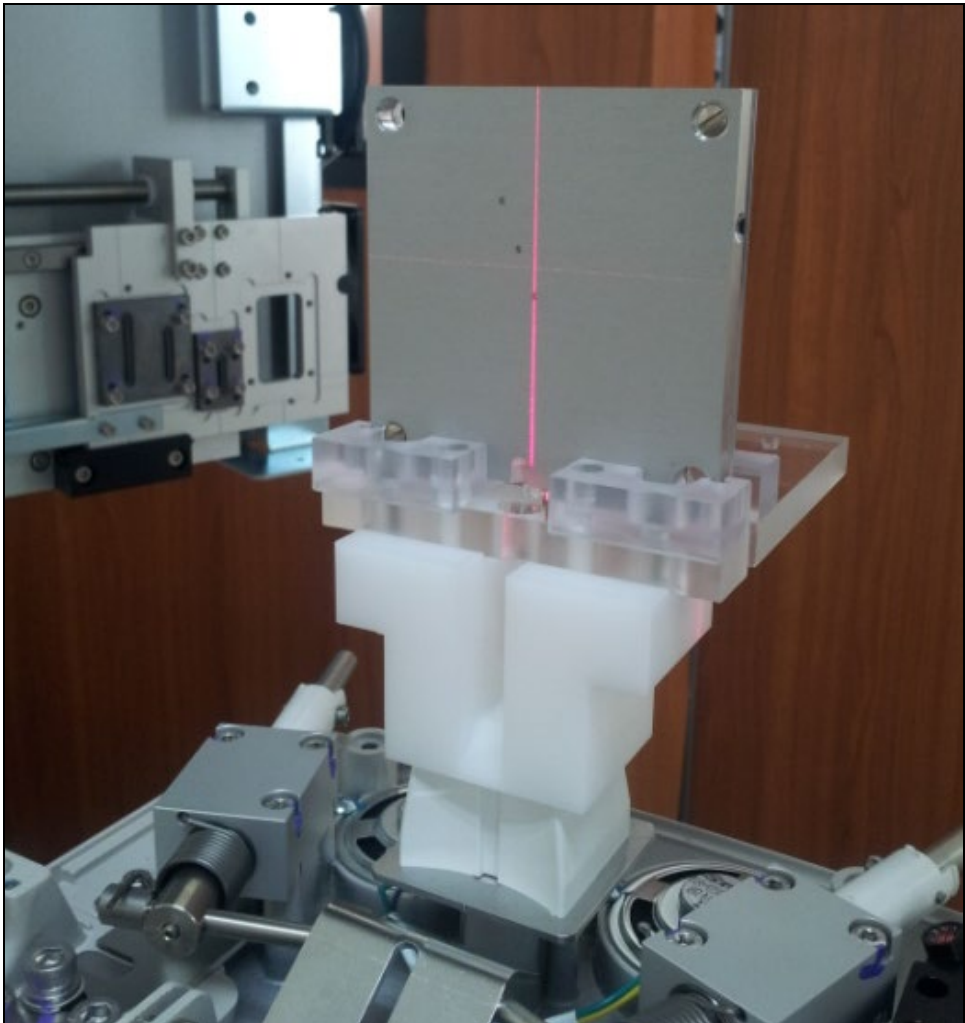
	VATECH Standard	Test results
Hole	1.5 mm or less	Check the 1.0 mm

18.1.3 Evaluate the Noise (Dev)

18.1.3.1 Noise (Dev) criterion

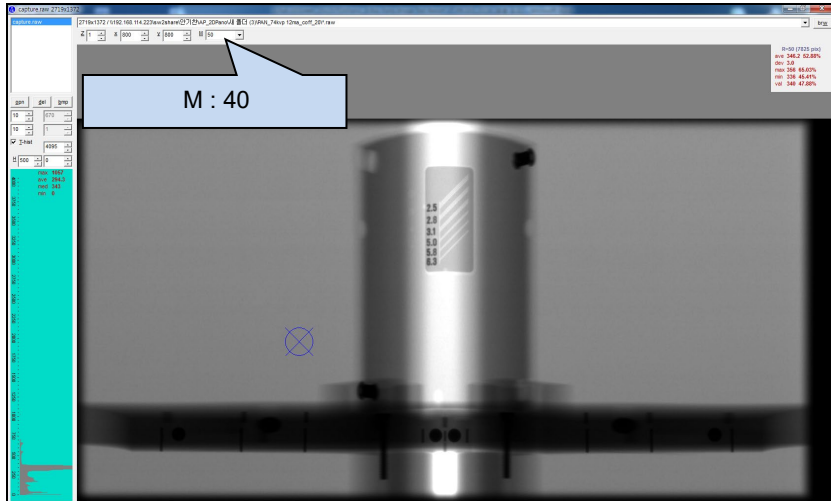
	ROI 1	ROI 2	ROI 3	Remarks
Noise (Dev)	8 or less		30 or less	

18.1.3.2 Noise Phantom Specification



18.1.3.3 Test Method

1. Align Ball Phantom and acquire an image.
2. Select the Panorama Tab.
3. Click the V Pan button to call the view6 Program to evaluate the Noise (Dev).
4. Refer to the Evaluation manual for alignment, image acquisition method, and S/W usage.



18.1.3.4 Test Result

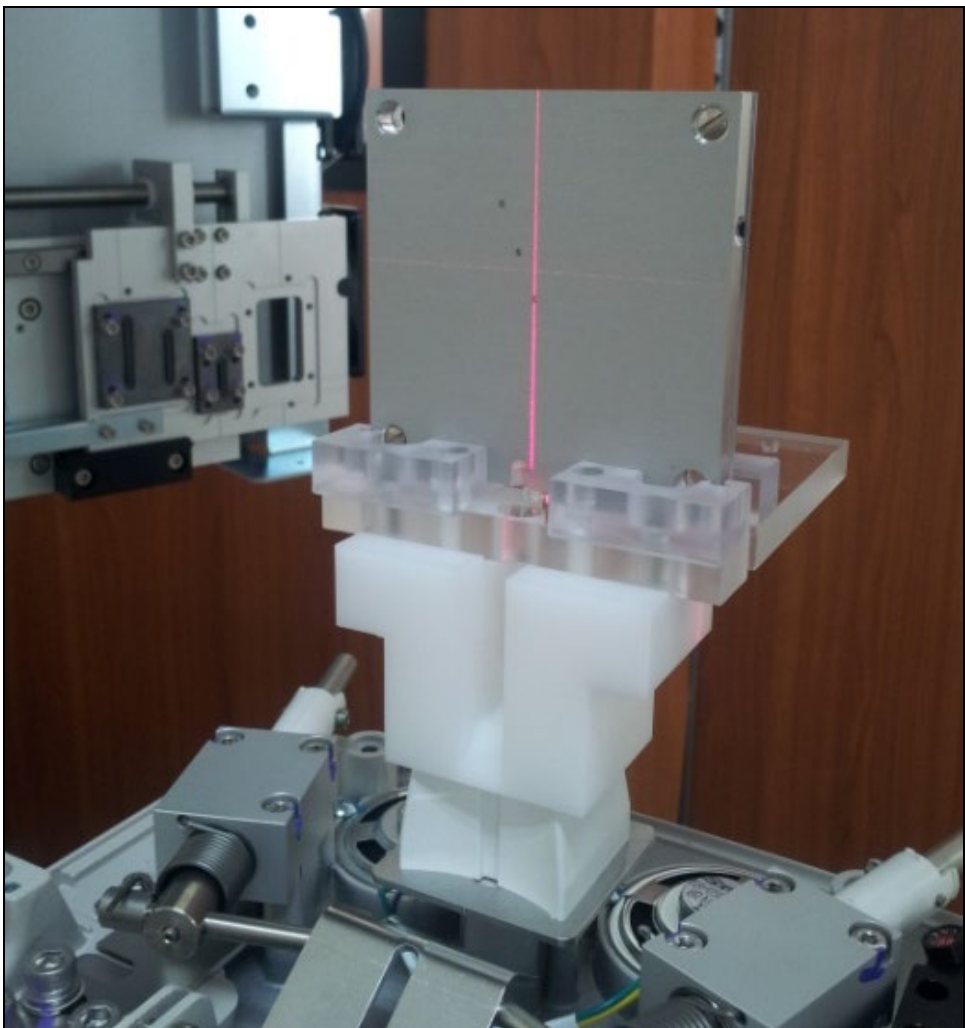
	ROI 1 measurement value (800, 800)	ROI 2 measurement value (2000, 800)	ROI 3 measurement value (1330, 800)
Noise (Dev)	6.2	6.4	11.5

18.1.4 Evaluate the Homogeneity

18.1.4.1 Homogeneity criterion

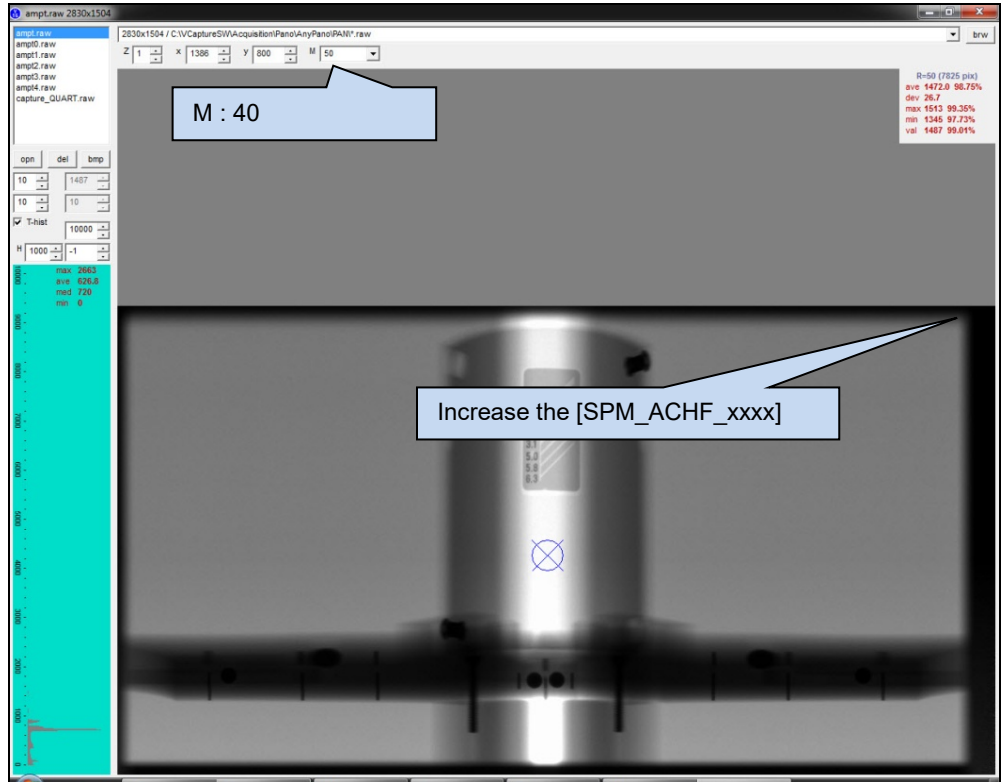
	ROI 1	ROI 2	ROI 3
Noise (Dev)	More than 600 (Difference between the two values is less than 10%)		More than 1200

18.1.4.2 Homogeneity Phantom Specification



18.1.4.3 Test Method

1. Align Ball Phantom and acquire an image.
2. Select the Panorama Tab.
3. Click the V Pan button to call the view6 Program to evaluate the homogeneity.
4. Refer to the Evaluation manual for alignment, image acquisition method, and S/W usage.



18.1.4.4 Test Result

	ROI 1 measurement value (800, 800)	ROI 2 measurement value (2000, 800)	ROI 3 measurement value (1330, 800)
Homogeneity (avg)	927	905	1670

18.1.5 Evaluate the Collimator 4% Cut

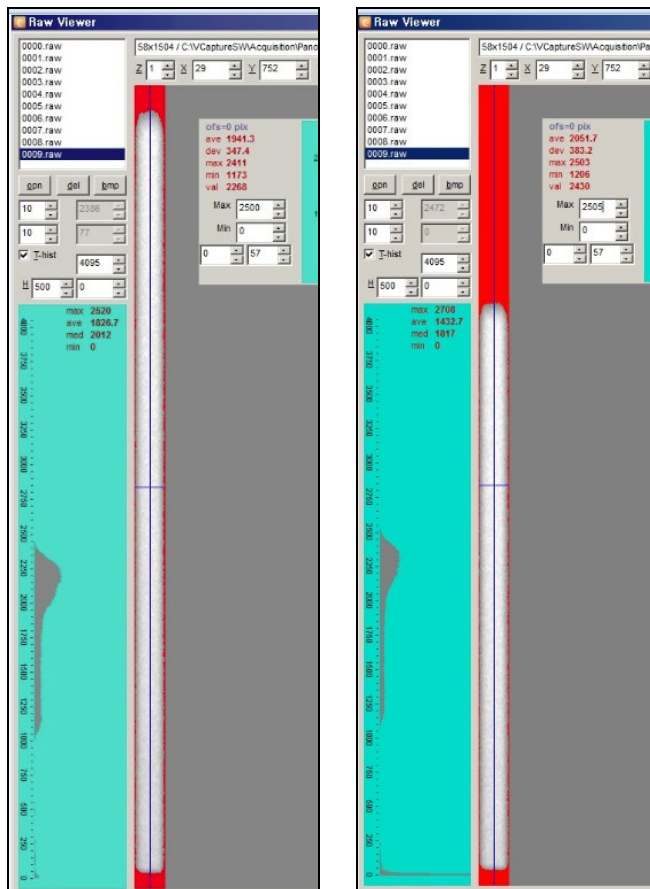
18.1.5.1 Collimator 4% criterion

Parameter	Upper/Lower X-ray off area	Left/Right X-ray off area
4% Cut	High: 10~35 Pixel Low: 10~25 pixel	2~4 pixel

18.1.5.2 Test Method

Complete the Collimator set up and acquire the image at the stop.

18.1.5.3 Test Result



< Adult_Align >

< Child_Align >

Parameter	LSL	Measurement value	USL	Pass/Fail
High	5 pixel	8 pixel	15 pixel	Pass
Low	5 pixel	10 pixel	15 pixel	Pass
Left	1 pixel	2 pixel	3 pixel	Pass
Right	1 pixel	1 pixel	3 pixel	Pass

18.1.6 Skull Sample Image

18.1.6.1 mode: Adult

- Sensor setting: 380 FPS
- Exposure condition: 82 kVp 10 mA
- Scan time: 13.5s



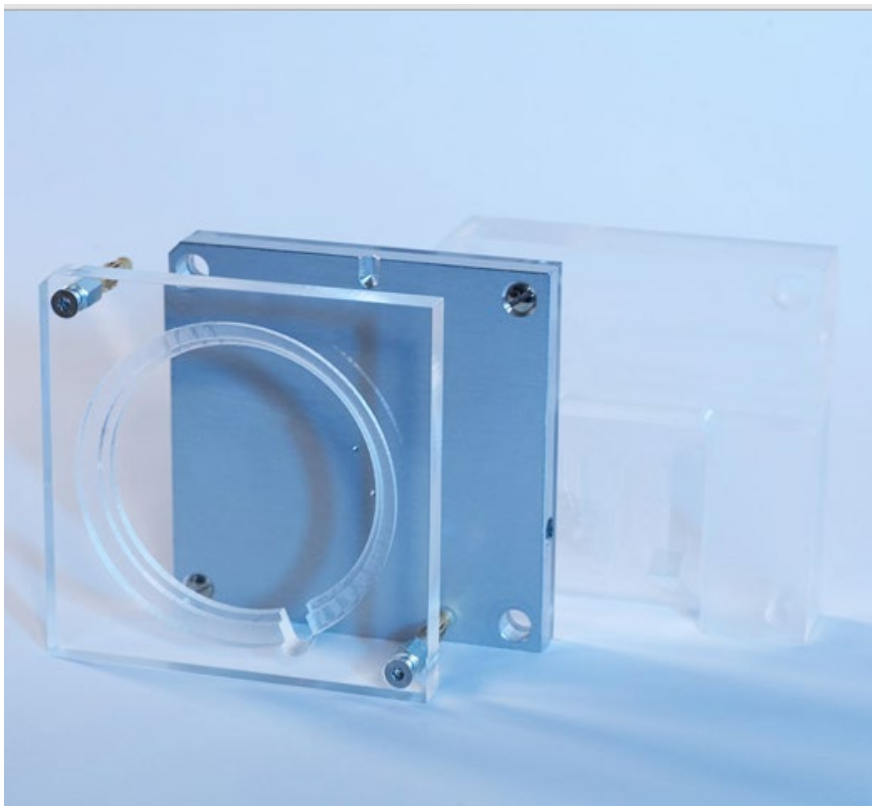
18.2 CEPH

18.2.1.1 Evaluate the Lp / mm (Line Pair)

18.2.1.2 Resolution measurement criterion

Parameter	VATECH Standard	Remarks
Lp/mm	More the 2.5 lp/mm	

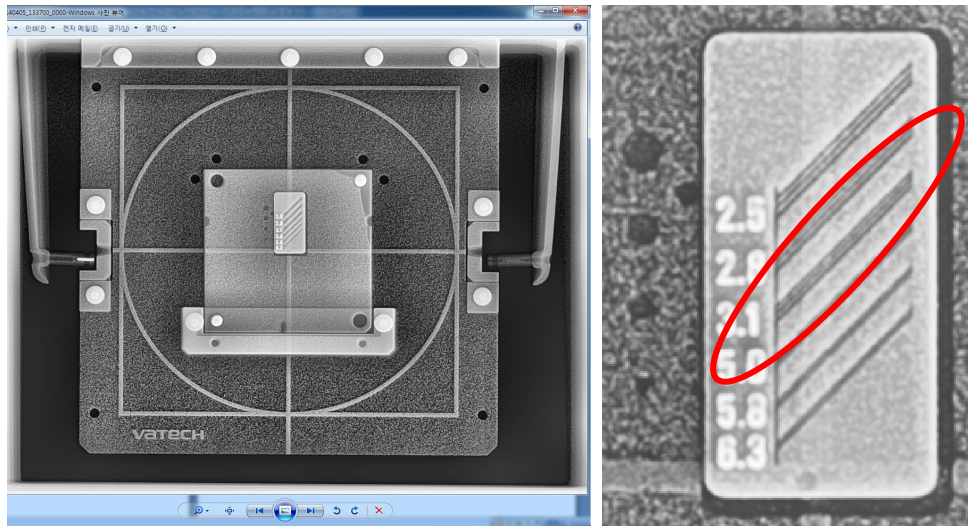
18.2.1.3 Phantom Specification



< QUART Phantom >

18.2.1.4 Test Method

1. Align the QUART Phantom and acquire the image.
2. Default exposure mode and exposure conditions are as follows.
 - Exposure mode: Frontal mode (12.9s)
 - Patient mode: Man, Normal
 - Exposure conditions: 87 kVp, 10 mA



18.2.1.5 Test Result

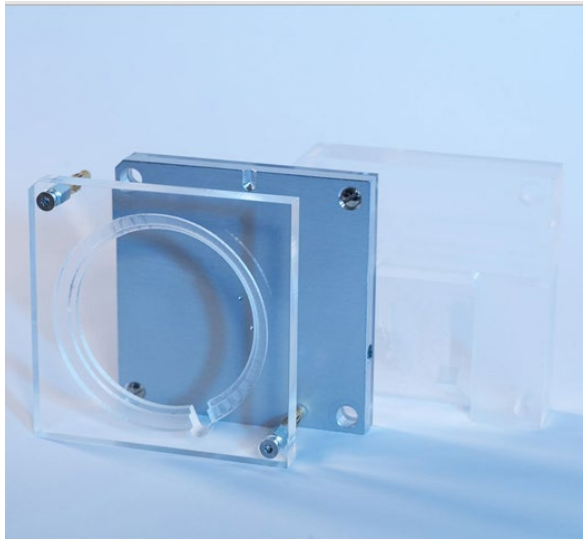
	VATECH Standard	Test results
Lp/mm (Line Pair)	More the 2.5 Lp/mm	3.1 Lp/mm

18.2.2 Evaluate the Low Contrast Resolution

18.2.2.1 High contrast Measure criterion

	VATECH Standard	Remarks
Hole	1.5 mm or less	

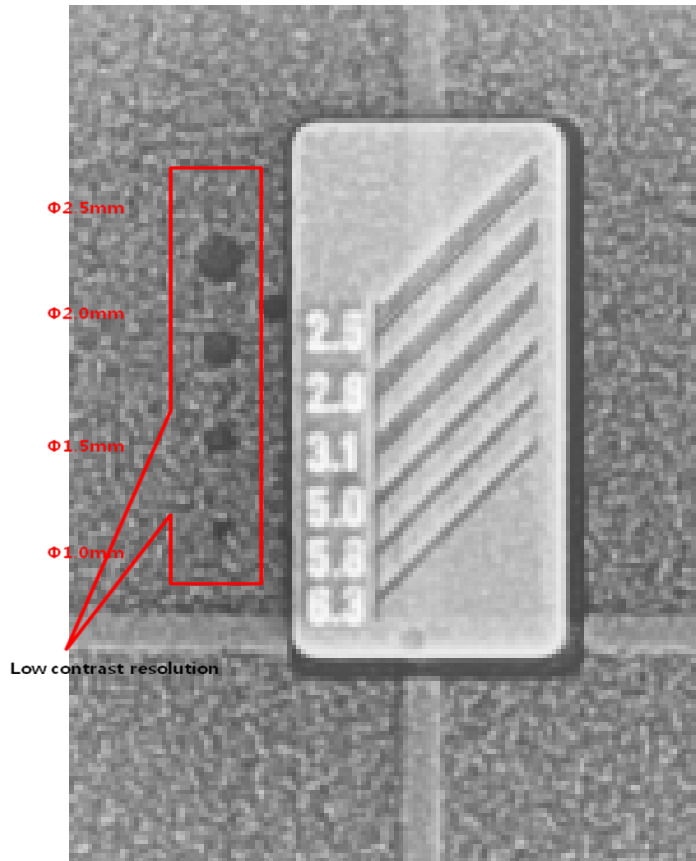
18.2.2.2 Phantom Specification



< QUART Phantom >

18.2.2.3 Test Method

1. Align the QUART Phantom and acquire the image.
2. Default exposure mode and exposure conditions are as follows.
 - Exposure mode: Frontal mode (12.9s)
 - Patient mode: Man, Normal
 - Exposure conditions: 87 kVp, 10 mA



18.2.2.4 Test Result

	VATECH Standard	Remarks
Hole	Check the 1.5 mm	

18.2.3 Evaluate the Collimator 4% Cut

18.2.3.1 Collimator 4% Cut criterion

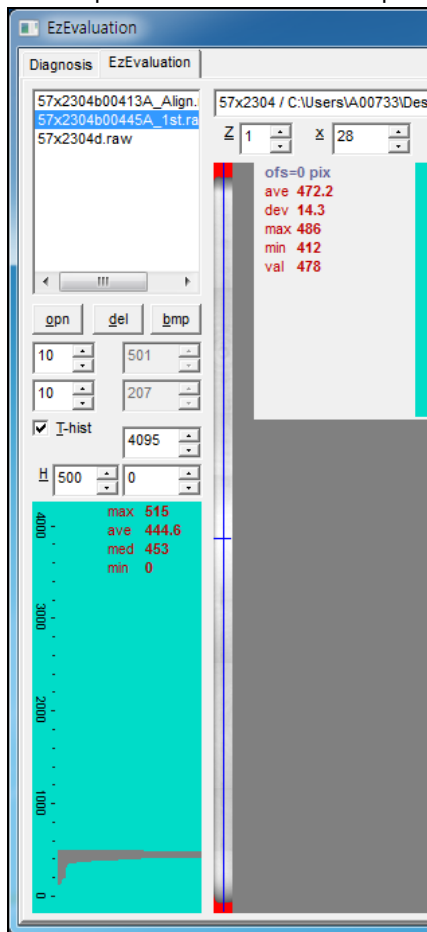
Parameter	Upper/Lower X-ray off area	Left/Right X-ray off area
4% Cut	20~50 pixel	1~3 pixel

18.2.3.2 Phantom Specification

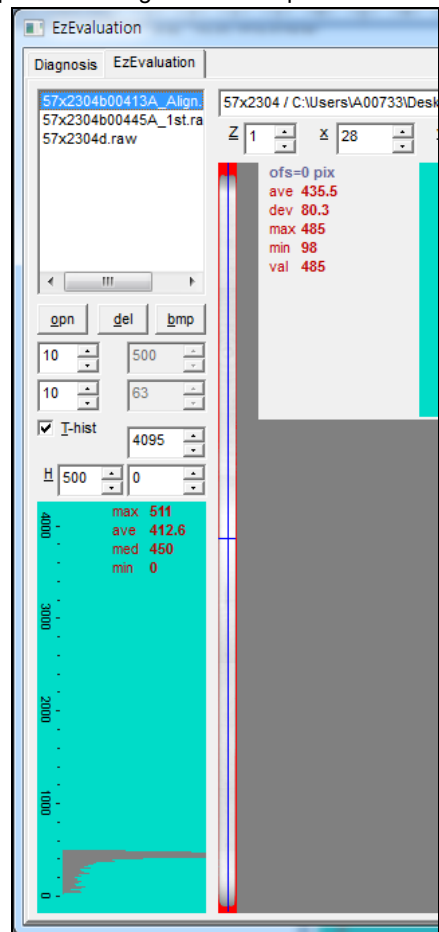
1. Unused the Phantom

18.2.3.3 Test Method

- Complete the Collimator set up and acquire the image at the stop.



< 1st_Align >



< 2nd_Align >

18.2.3.4 Test Result

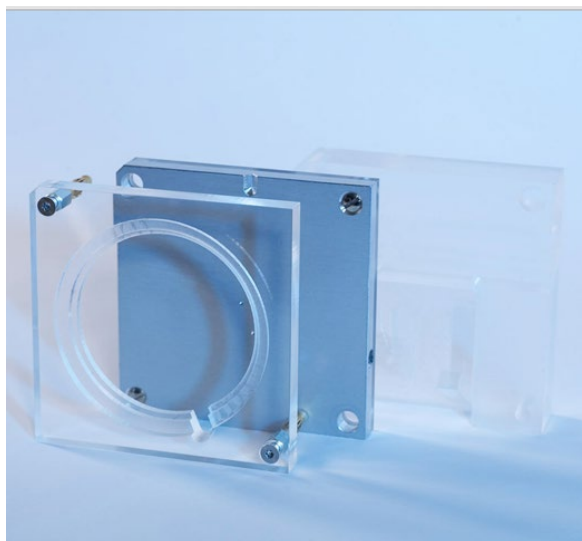
Parameter	LSL	Measurement value	USL	Pass/Fail
High	20 pixel	30 pixel	50 pixel	Pass
Low	20 pixel	30 pixel	50 pixel	Pass
Left	1 pixel	2 pixel	3 pixel	Pass
Right	1 pixel	2 pixel	3 pixel	Pass

18.2.4 Evaluate the Geometry Phantom

18.2.4.1 Geometry Evaluation Criteria

Mode	Company Pixel Criteria	Remarks
Lateral	530 ~ 550 pixel	
Frontal	1070 ~ 1090 pixel	

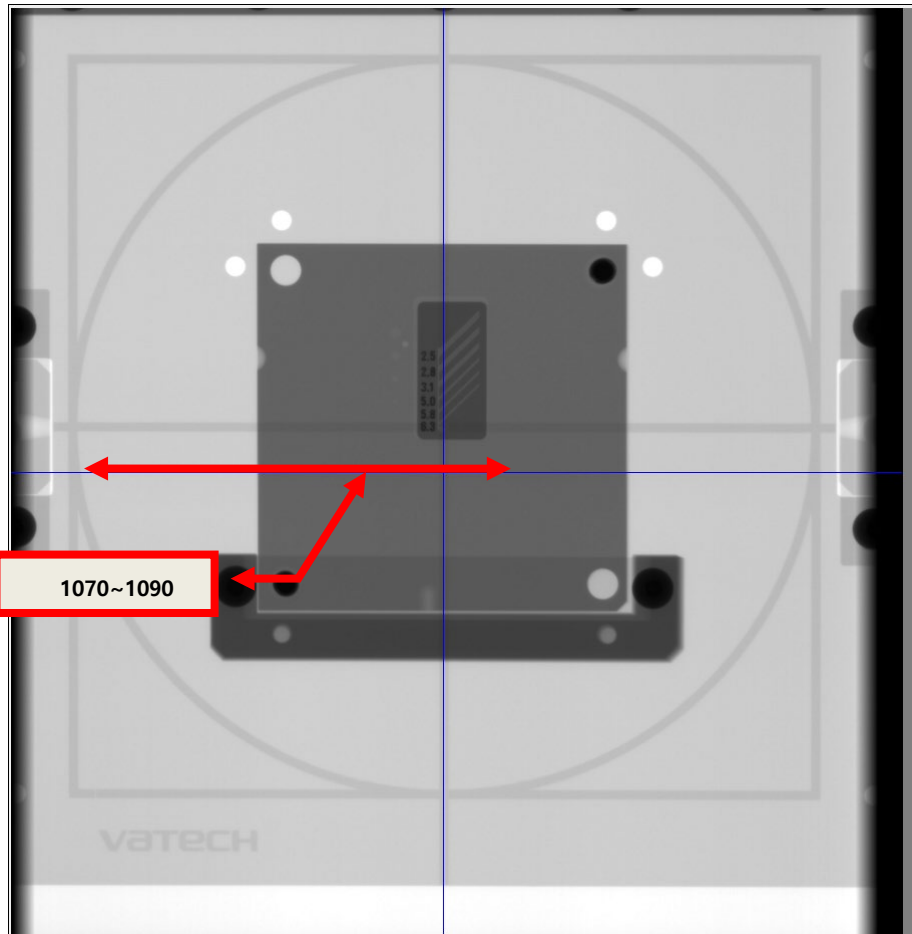
18.2.4.2 Phantom Specification



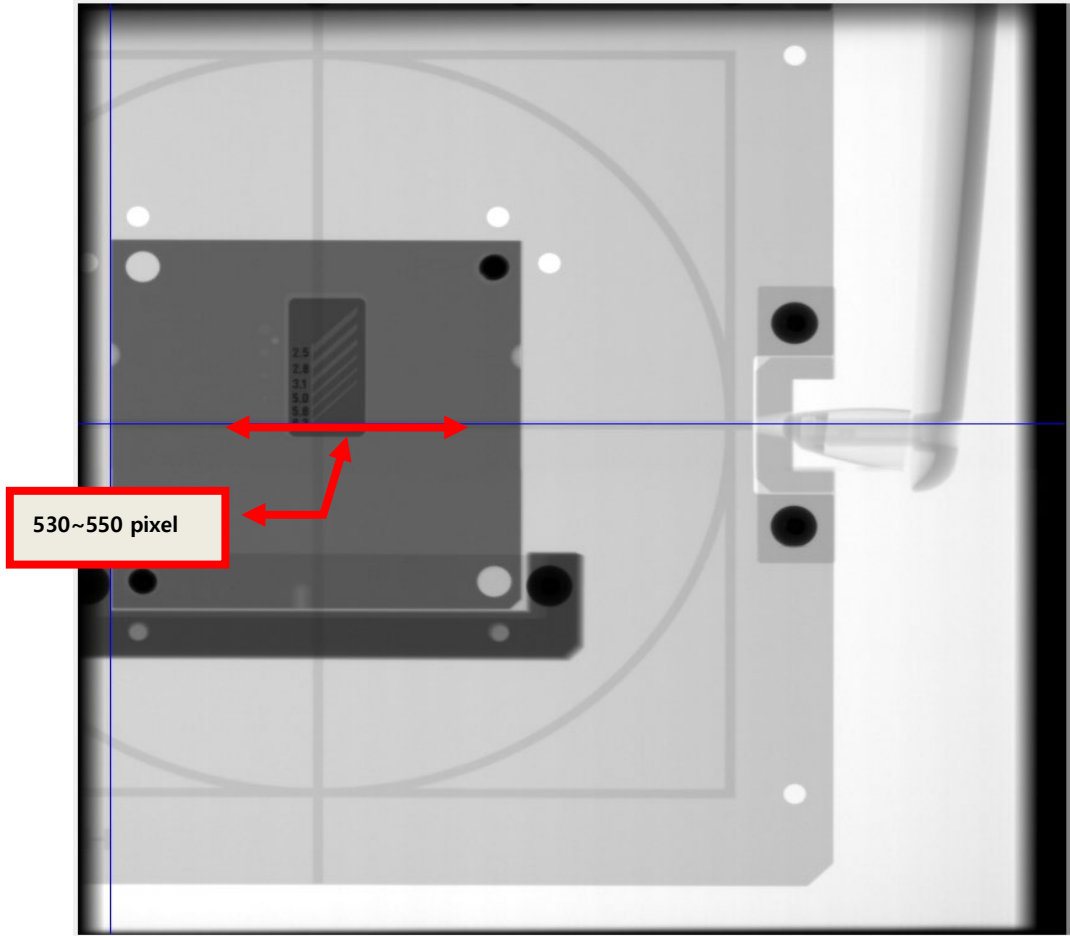
< QUART Phantom >

18.2.4.3 Test Method

1. Align the QUART Phantom and acquire the image.
2. Default exposure mode and exposure conditions are as follows.
 - Exposure mode: Frontal mode (12.9s)
 - Patient mode: Man, Normal
 - Exposure conditions: 87 kVp, 10 mA



3. Align the QUART Phantom and acquire the image.
4. Default exposure mode and exposure conditions are as follows.
 - Exposure mode: Lateral mode (12.9s)
 - Patient mode: Man, Normal
 - Exposure conditions: 85 kVp, 10 mA



18.2.4.4 Test Result

Mode	VATECH Standard	Actual measurement value
Lateral	530 ~ 550 pixel	538 pixel
Frontal	1070 ~ 1090 pixel	1082 pixel

18.2.5 Skull Sample Image

18.2.5.1 Mode: Lateral

- Sensor setting: 160 FPS
- Exposure condition: 85 kVp 10 mA
- Scan time: 12.9 s



18.2.5.2 Mode: Frontal

- Sensor setting: 160 FPS
- Exposure condition: 87 kVp 10 mA
- Scan time: 12.9 s



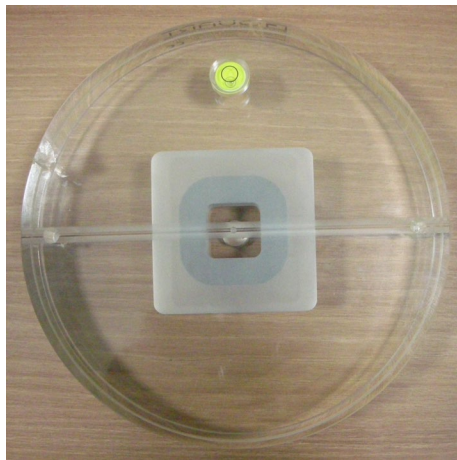
18.3 CBCT

18.3.1 Evaluate the Spatial Resolution (MTF)

18.3.1.1 The Resolution measurement value shall satisfy the following criteria.

Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
MTF 10% <lp/mm>	1.00	3.50

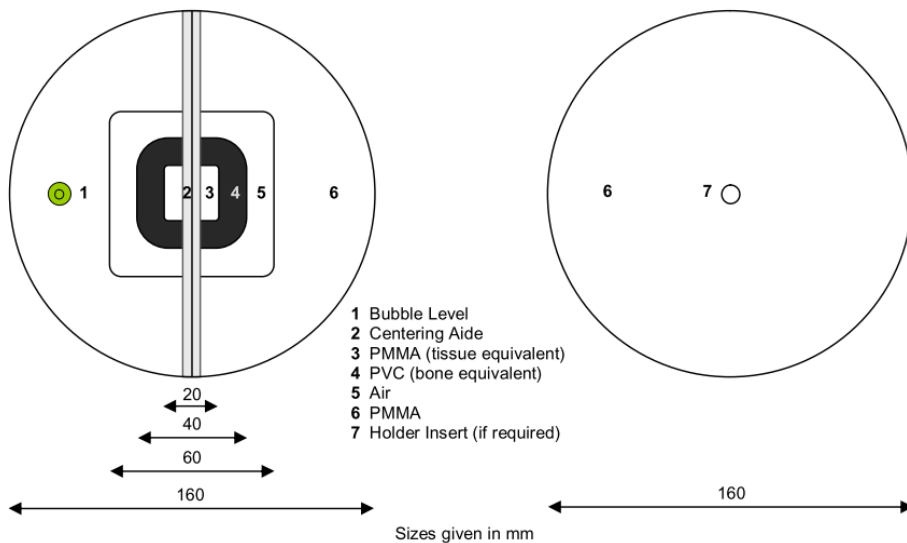
18.3.1.2 Phantom Specification



< QUART Phantom >

Disc 1

Disc 2



18.3.1.3 Test Method

- Align the QUART Phantom and acquire the image.
- Evaluate using DVTpro S/W.

parameter	init. value	tol.	1
Display System	QA complete ?		
Test Person Initials			
Positioning	Phantom adj.?		
Artifacts	No artifacts ?		
PMMA Voxel	1021.2		579.6
PMMA Noise	88.1		34.7
Homogeneity	40.0	>5	31
Contrast	2489.4		977.7
CHR	19.0	30%	34.1
MTF 10%	2.1	>1	2.2
MTF 50%	1.2		1.1
Nyquist Frequency	2.5	5%	2.5

18.3.1.4 Test Result

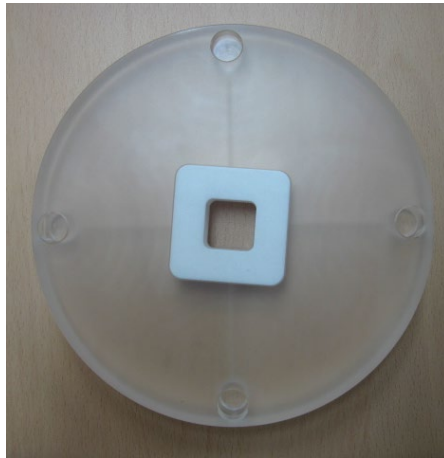
Parameter	LSL	Measurement value	USL	Pass/Fail
MTF 10% <lp/mm>	1.00	2.2	3.50	Pass

18.3.2 Evaluate the Contrast

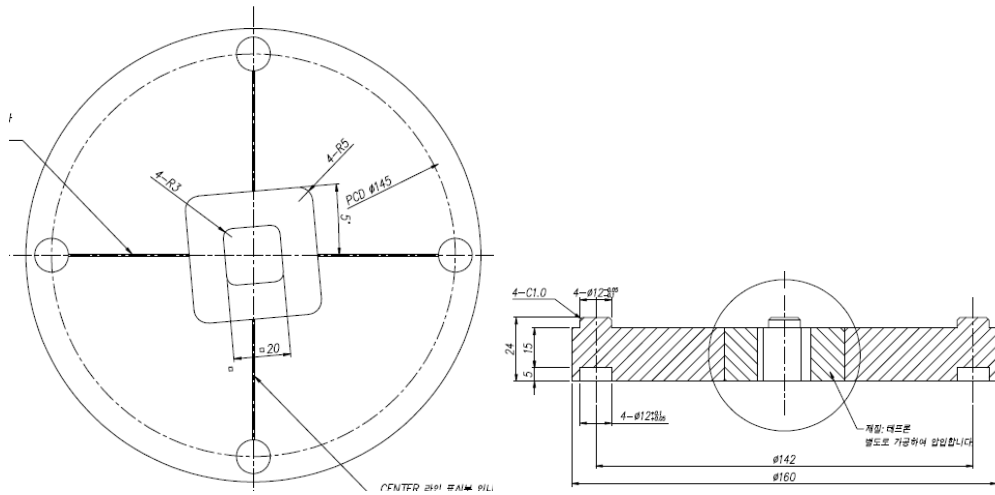
18.3.2.1 The Contrast measurement value shall satisfy the following criteria.

Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Contrast<1000HU>	1.50	3.50

18.3.2.2 Phantom Specification

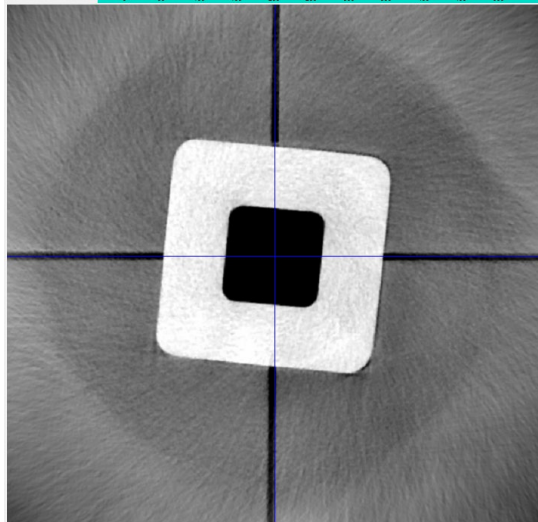


M&R Check Phantom



18.3.2.3 Test Method

- Align the M&R Check Phantom and acquire the image.
- Evaluate using Ezeval.exe which is VATECH's evaluation software.



18.3.2.4 Test Result

Parameter	LSL	Measurement value	USL	Pass/Fail
Contrast<1000HU>	1.50	1.917	3.50	Pass

Parameters	LSL	Val	USL	Status
Contrast <1000 HU>	1.50	1.91795	3.50	PASS
Resolution <lp/mm>	0.80	1.55443	2.50	PASS
Noise	0.00	24.85933	200.00	PASS
Homogeneity	0.00	30.24995	250.00	PASS

18.3.3 Evaluate the Noise (Dev)

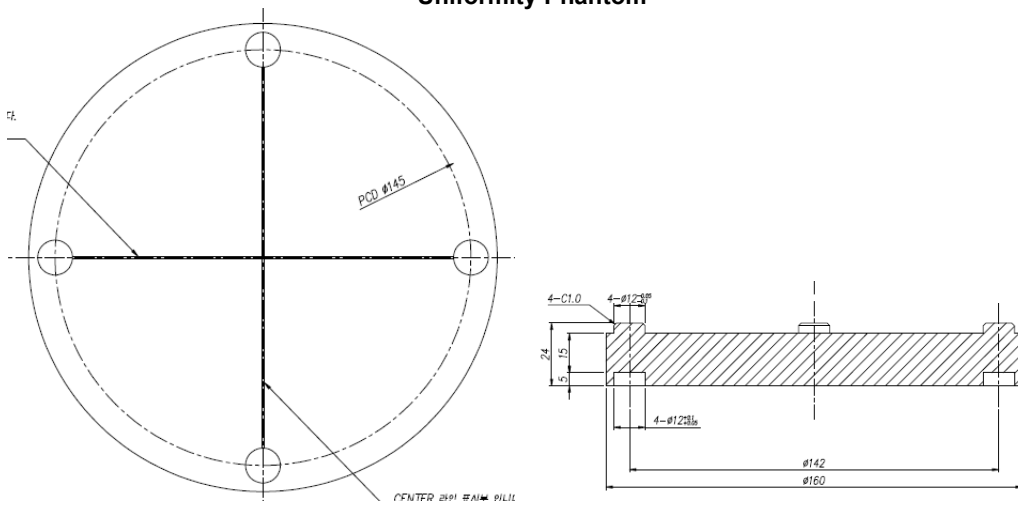
18.3.3.1 The Noise (Dev) measurement value shall satisfy the following criteria.

Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Noise (Dev)	0.00	200.0

18.3.3.2 Phantom Specification

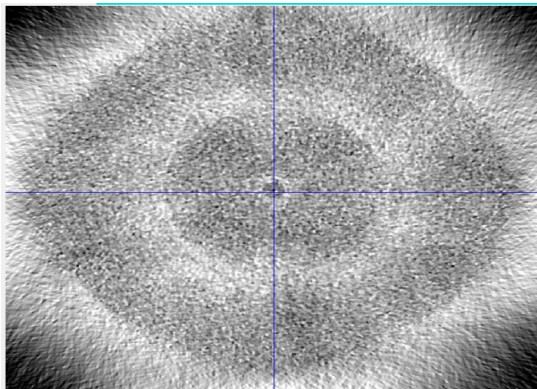


Uniformity Phantom



18.3.3.3 Test Method

- Align uniformity phantom and acquire an image.
- Evaluate using Ezeval.exe which is VATECH's evaluation software.



18.3.3.4 Test Result

Parameter	LSL	Measurement value	USL	Pass/Fail
Noise (Dev)	0.00	24.85	200.0	Pass

Parameters	LSL	Val	USL	Status
Contrast <1000 HU>	1.50	1.91795	3.50	PASS
Resolution <lp/mm>	0.80	1.55443	2.50	PASS
Noise	0.00	24.85933	200.00	PASS
Homogeneity	0.00	30.24995	250.00	PASS

18.3.4 Evaluate the Homogeneity

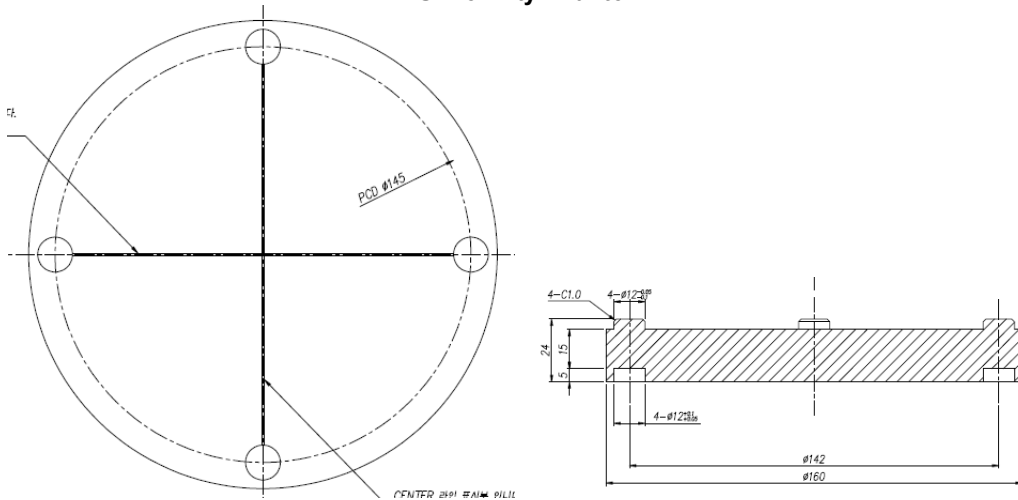
18.3.4.1 The Homogeneity measurement value shall satisfy the following criteria.

Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Homogeneity	0.00	250.0

18.3.4.2 Phantom Specification

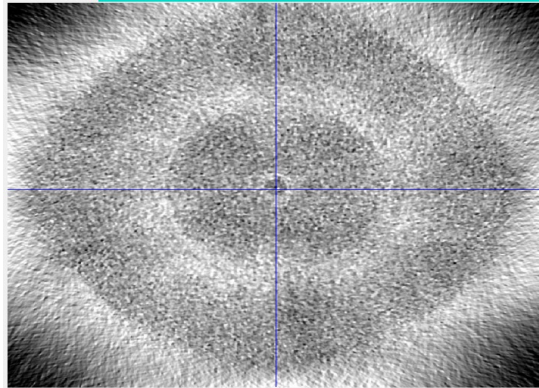


Uniformity Phantom



18.3.4.3 Test Method

- Align the Uniformity Phantom and acquire the image.
- Evaluate using Ezeval.exe which is VATECH's evaluation software.



18.3.4.4 Test Result

Parameter	LSL	Measurement value	USL	Pass/Fail
Homogeneity	0.00	30.24	250.0	Pass

Parameters	LSL	Val	USL	Status
Contrast <1000 HU>	1.50	1.91795	3.50	PASS
Resolution <lp/mm>	0.80	1.55443	2.50	PASS
Noise	0.00	24.85933	200.00	PASS
Homogeneity	0.00	30.24995	250.00	PASS

18.3.5 Evaluate the CT Number Accuracy

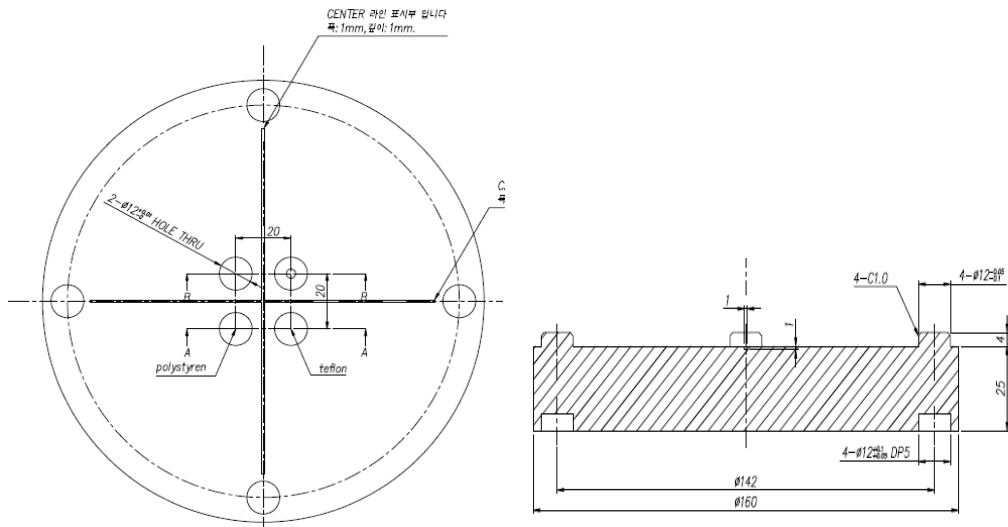
18.3.5.1 CT numbers of air and water shall satisfy the following criteria.

Materials	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Air	-1030	-900
Water	-20	20
Teflon	900	1100

18.3.5.2 Phantom Specification

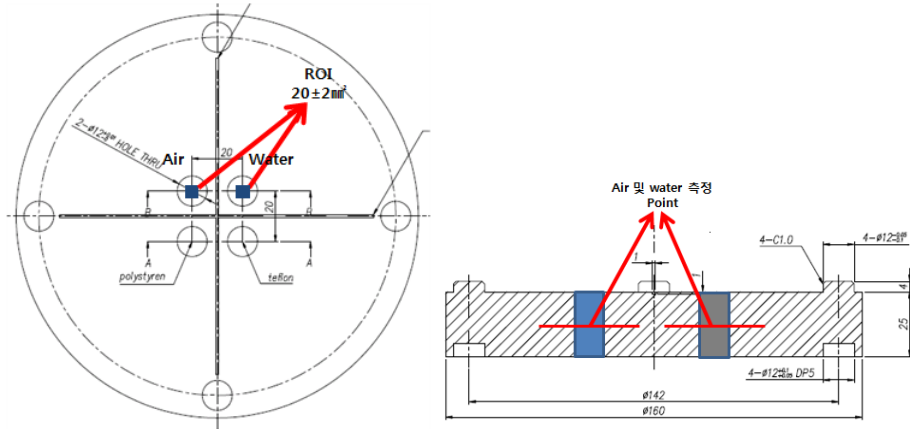


CT Number Phantom

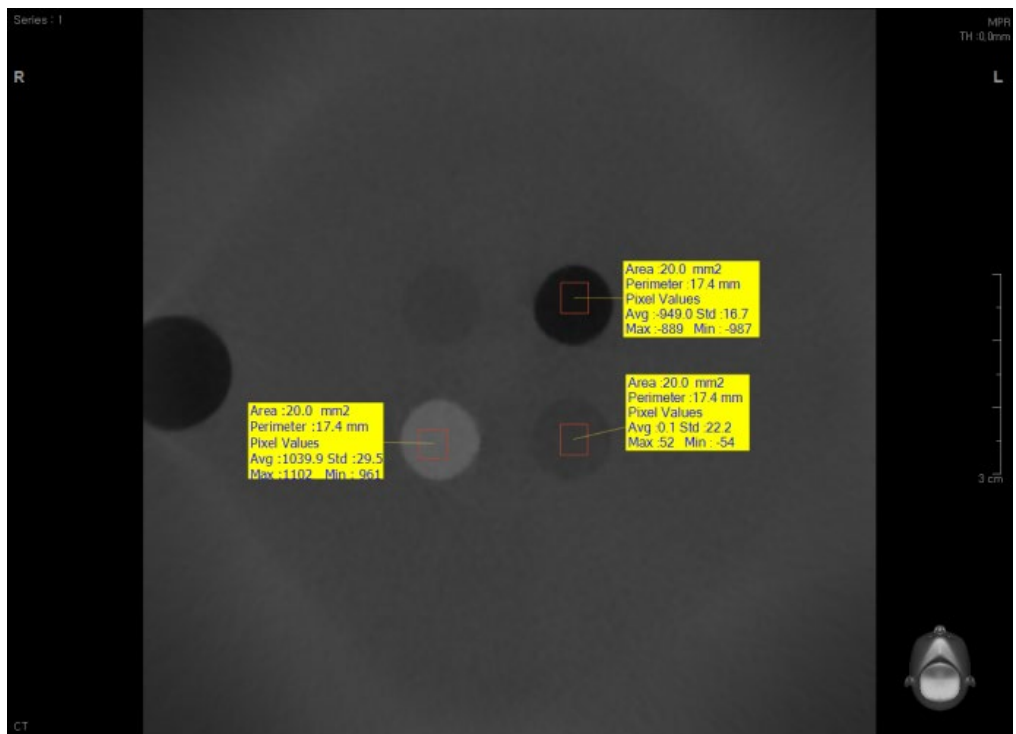


18.3.5.3 Test Method

- Align the CT Number Phantom and acquire the image.
- In the Axial image, set the ROI 15mm^2 at the center of the air column and the water column to measure the CT Number values of air and water.



18.3.5.4 Test Result



Materials	LSL	Measurement value	USL	Pass/Fail
Air	-1030	-949	-900	Pass
Water	-20	0.1	20	Pass
Teflon	900	1039.9	1100	Pass

18.3.6 Evaluate the High Contrast Resolution

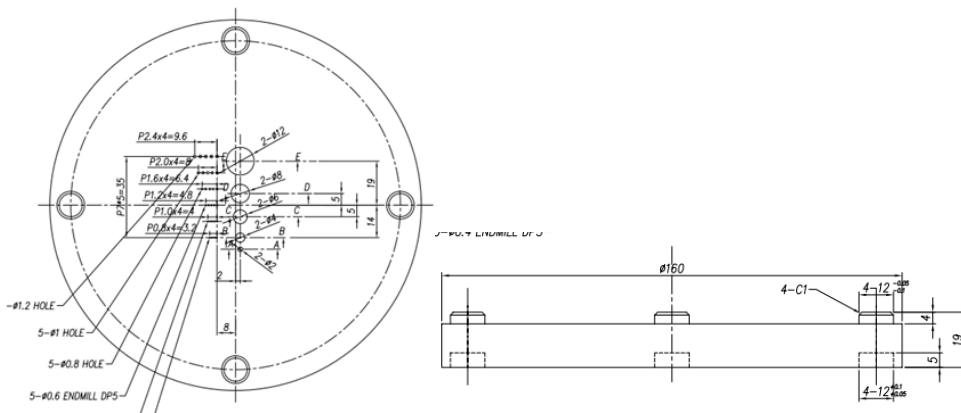
18.3.6.1 The High Contrast measurement value shall satisfy the following criteria.

Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
High Contrast Resolution	-	1.0 mm

18.3.6.2 Phantom Specification



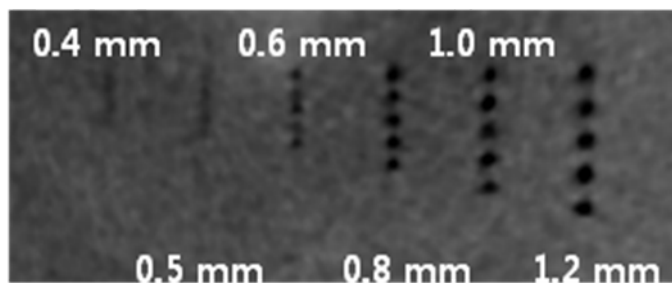
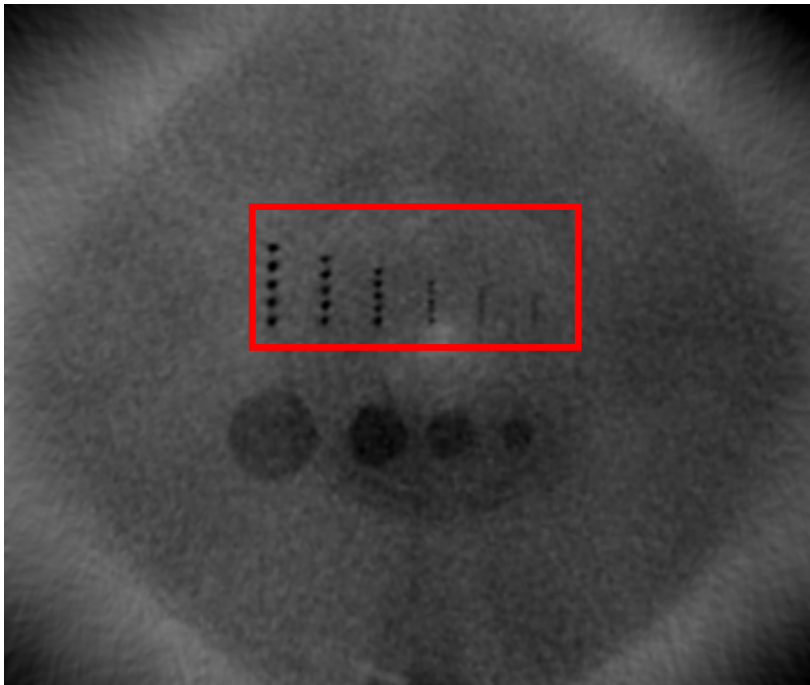
S&C Phantom



18.3.6.3 Test Method

- Align S&C Phantom and acquire an image.
- Change the windowing setting to check the size of the visible air bar at 50 cm from the monitor.

18.3.6.4 Test Result



Parameter	LSL	Measurement value	USL	Pass/Fail
High Contrast Resolution	-	0.8 mm	1.0 mm	Pass

18.3.7 Evaluate the Contrast Resolution

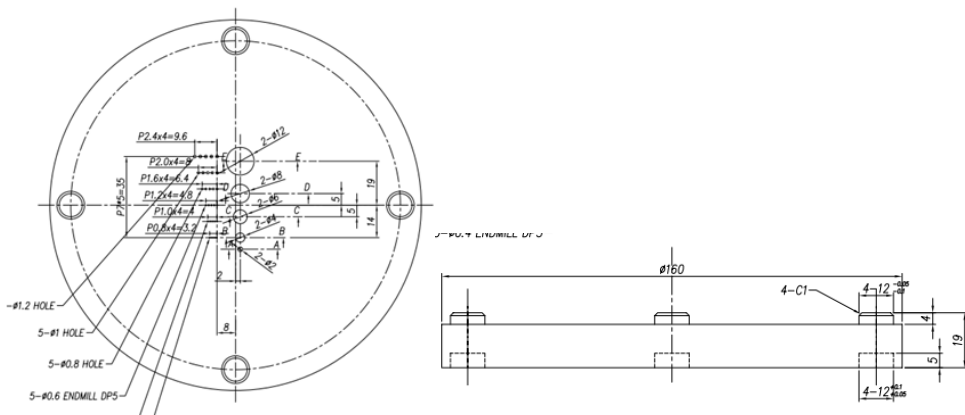
18.3.7.1 The Contrast measurement value shall satisfy the following criteria.

Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Contrast Resolution	-	8.0 mm

18.3.7.2 Phantom Specification



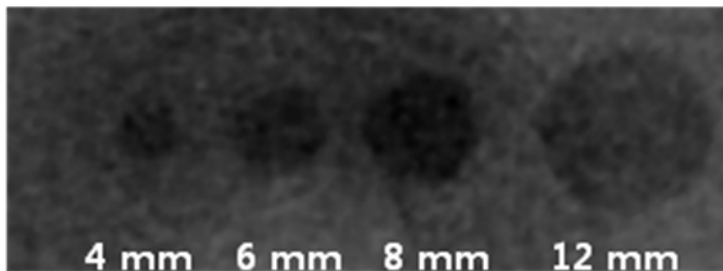
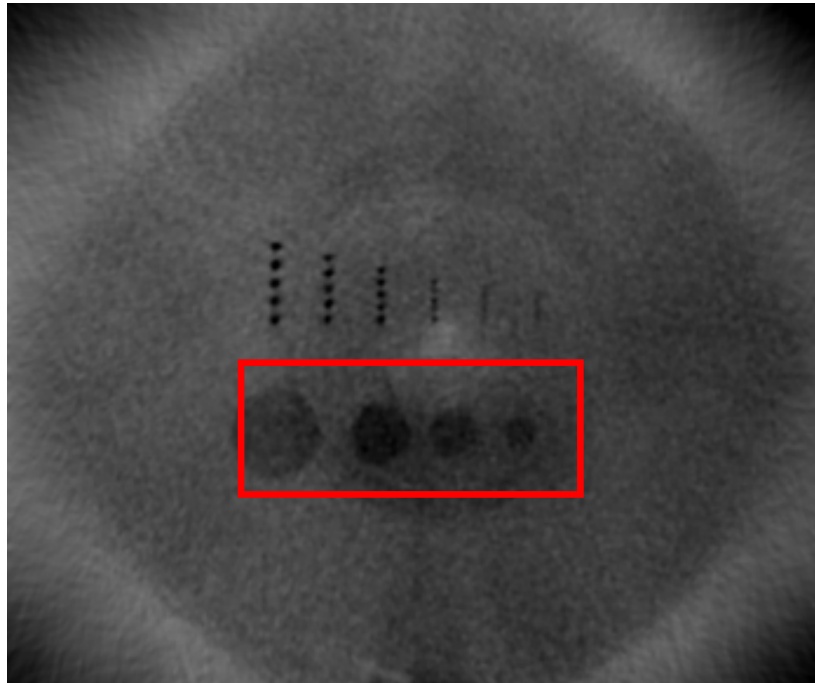
S&C Phantom



18.3.7.3 Test Method

- Align S&C Phantom and acquire an image.
- Change the windowing setting to check the size of the visible air bar at 50 cm from the monitor.

18.3.7.4 Test Result



Parameter	LSL	Measurement value	USL	Pass/Fail
Contrast Resolution	-	6 mm	8 mm	Pass

18.3.8 Evaluate the Slice Thickness

18.3.8.1 The Slice Thickness measurement value shall satisfy the following criteria.

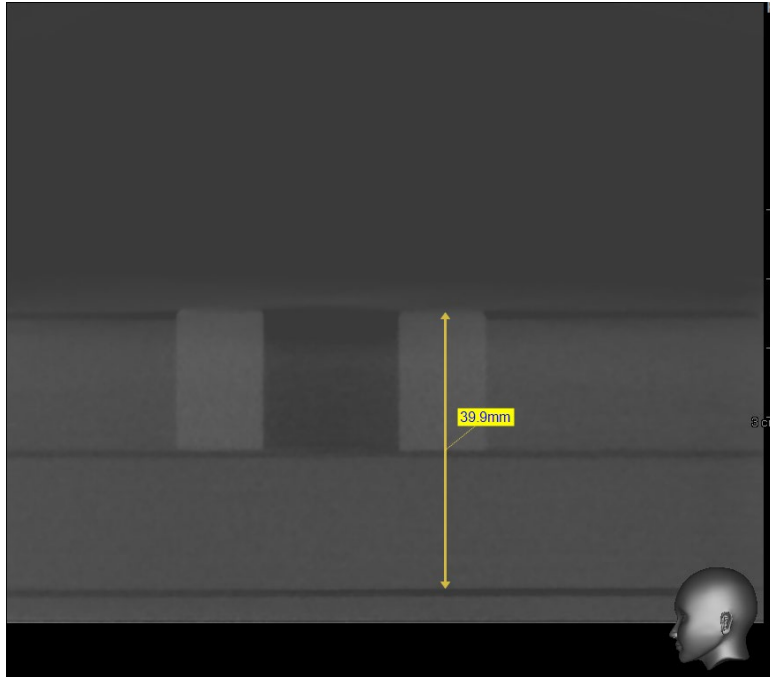
Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
Slice Thickness	38 mm	42 mm

18.3.8.2 Test Method

- It is concluded in the order of M&R Check Phantom and Uniformity Phantom a

nd acquires images.

18.3.8.3 Test Result



Parameter	LSL	Measurement value	USL	Pass/Fail
Slice Thickness	38.0 mm	39.9	42.0 mm	Pass

18.3.9 Evaluate the Collimator 4% Cut

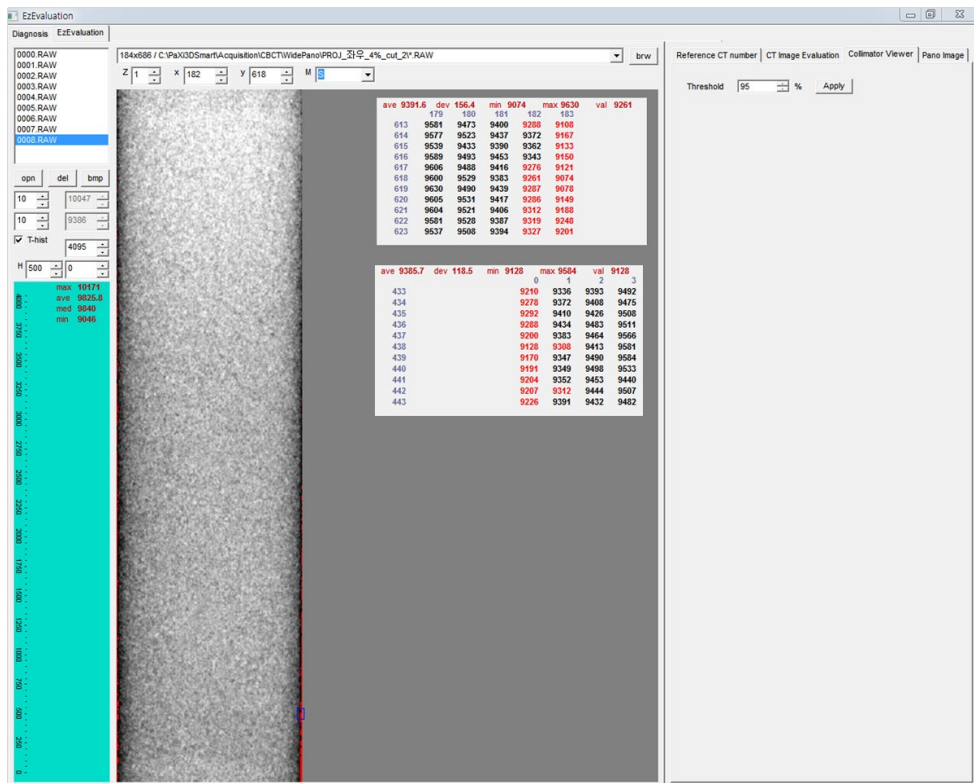
18.3.9.1 The Collimator 4% Cut measurement value shall satisfy the following criteria.

Parameter	LSL (Lower Specification Limit)	USL (Upper Specification Limit)
4% Cut	Upper/Lower 10 Pixel (75%) Left/Right 1 Pixel (95%)	Upper/Lower 15 Pixel (75%) Left/Right 2 Pixel (95%)

18.3.9.2 Test Method

- Complete the Collimator set up and acquire the image at the stop.

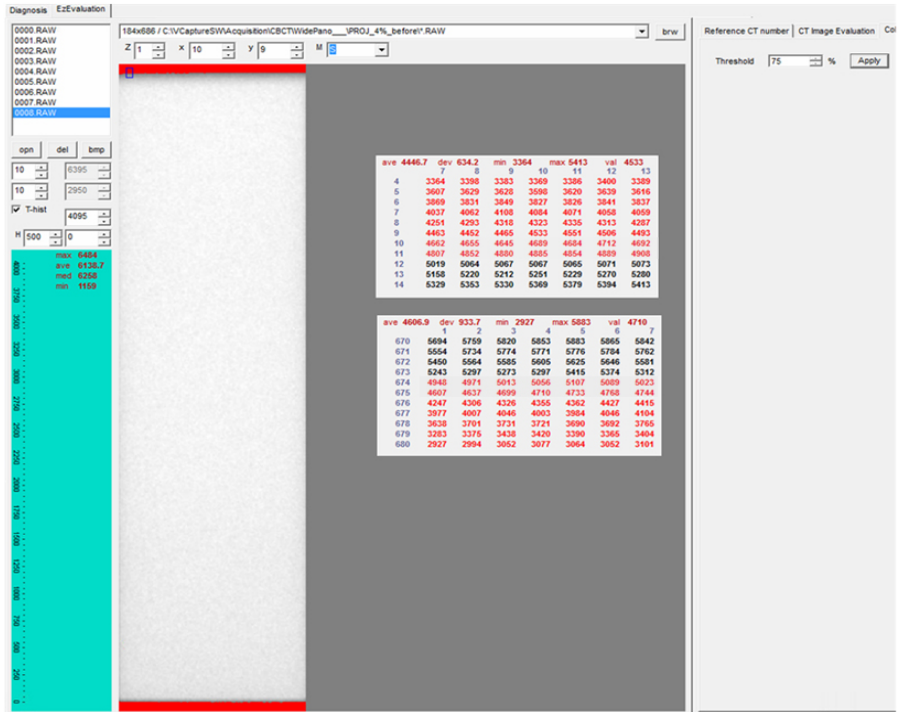
18.3.9.3 Test Result



Left/Right Collimator (Threshold: 95%)

- To check left and right, you must subtract 0.4 from the left and right collimator values.

Ex) Right: -25.9 ---> -26.3
Left: -24.3 ---> -24.7



Upper/Lower Collimator (Threshold: 75%)

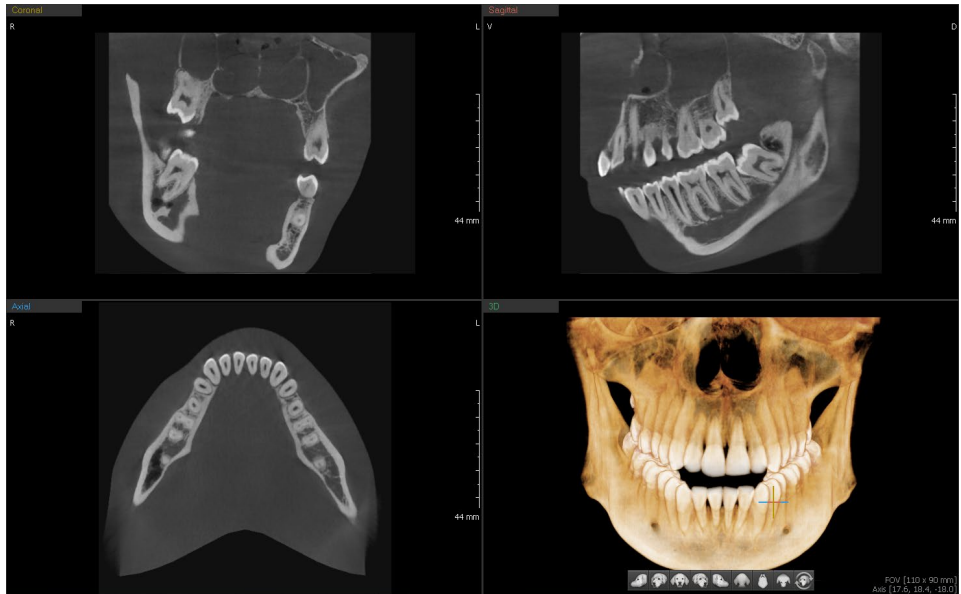
Parameter	LSL	Measurement value	USL	Pass/Fail
Upper	10 pixel	11 pixel	15 pixel	Pass
Lower	10 pixel	11 pixel	15 pixel	Pass
Left	1 pixel	2 pixel	2 pixel	Pass
Right	1 pixel	2 pixel	2 pixel	Pass

18.0

18.3.10 Skull Sample Image

18.3.10.1 mode: Adult

- Sensor setting: 100 FPS
- Exposure condition: 95 kVp 8.7mA
- Scan time: 18.0s



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



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