

# Smart Plus<sup>TM</sup>

## User manual

Model : PHT-35LHS

Version : 1.32

- 
- 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:

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This document is originally written in English.

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

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# Table of Contents

<b>Notice</b>	<b>v</b>
---------------	----------

<b>Table of Contents</b>	<b>vii</b>
--------------------------	------------

<b>1.</b>	<b>Introduction</b>	<b>1</b>
-----------	---------------------	----------

1.1	Overview .....	1
1.2	Indications for Use .....	1
1.3	Intended Purposes .....	1
1.4	Contraindications .....	2
1.5	Intended User Profiles .....	2

<b>2.</b>	<b>General Information</b>	<b>3</b>
-----------	----------------------------	----------

2.1	Manufacturer's Liability .....	3
2.2	Owner and Operator's Obligations .....	3
2.3	Conventions in this Manual .....	4
2.4	Marks and Symbols .....	5

<b>3.</b>	<b>Warnings and Precautions</b>	<b>9</b>
-----------	---------------------------------	----------

3.1	General Safety Guidelines .....	9
3.2	Electricity-related Safety Precautions .....	13
3.3	Radiation Safety .....	15
3.4	Warnings .....	16

<b>4.</b>	<b>Imaging System Overview</b>	<b>19</b>
-----------	--------------------------------	-----------

4.1	System Components .....	19
4.2	Features .....	19
4.3	Standards and Regulations .....	20
4.4	Operating Principles .....	20
4.5	Imaging System Configuration .....	21
4.6	Equipment Overview .....	22

<b>5.</b>	<b>Imaging Software Overview</b>	<b>29</b>
-----------	----------------------------------	-----------

5.1	PC Specifications (Recommended) .....	29
5.2	EzDent-i .....	30

5.3	Console Software .....	31
<b>6.</b>	<b>Getting Started</b>	<b>34</b>
6.1	Turning on the Equipment.....	34
6.2	Running the Image Viewer (EzDent-i).....	35
<b>7.</b>	<b>Acquiring PANO Images</b>	<b>39</b>
7.1	PANO Imaging Program Overview .....	39
7.2	Configuring Exposure Parameters .....	45
7.3	Patient Positioning .....	50
7.4	Laser Beam Aligning.....	62
7.5	X-ray Exposure.....	64
7.6	Finishing the Scan .....	65
7.7	Checking the Captured Images .....	65
<b>8.</b>	<b>Acquiring CEPH Images (Optional)</b>	<b>67</b>
8.1	CEPH Imaging Program Overview.....	67
8.2	Configuring Exposure Parameters .....	69
8.3	Patient Positioning .....	72
8.4	X-ray Exposure.....	83
8.5	Finishing the Scan .....	84
8.6	Checking the Captured Images .....	84
<b>9.</b>	<b>Acquiring CBCT Images</b>	<b>86</b>
9.1	CBCT Imaging Program Overview .....	86
9.2	Configuring Exposure Parameters .....	89
9.3	Patient Positioning .....	93
9.4	X-ray Exposure.....	98
9.5	Finishing the Scan .....	99
9.6	Checking the Captured Images .....	99
<b>10.</b>	<b>Acquiring 3D MODEL Scan Images</b>	<b>100</b>
10.1	3D MODEL Scan Imaging Program.....	100
10.2	Configuring Exposure Parameters .....	101
10.3	MODEL Positioning .....	104

	10.4	X-ray Exposure.....	105
	10.5	Checking the Captured Images .....	106
<b>11.</b>		<b>Troubleshooting</b>	<b>108</b>
	11.1	Troubleshooting .....	108
	11.2	Error Codes.....	109
<b>12.</b>		<b>Cleaning and Disinfection</b>	<b>114</b>
	12.1	Preparation .....	114
	12.2	Cleaning .....	115
	12.3	Disinfection .....	116
<b>13.</b>		<b>Maintenance</b>	<b>118</b>
	13.1	Regular Maintenance .....	118
	13.2	Maintenance Task Checklist .....	119
<b>14.</b>		<b>Disposing of the Equipment</b>	<b>120</b>
<b>15.</b>		<b>Technical Specifications</b>	<b>122</b>
	15.1	Mechanical Specifications .....	122
	15.2	Technical Specifications .....	125
	15.3	Electrical Specifications .....	130
	15.4	Environmental Specifications .....	131
<b>16.</b>		<b>Appendices</b>	<b>132</b>
	16.1	Recommended X-ray Exposure Tables .....	132
	16.2	X-ray Dose Data .....	142
	16.3	Electromagnetic Compatibility (EMC) Information .....	154
	16.4	Hand-wrist Image Evaluation References.....	157
	16.5	Acquiring Images for Pediatric Dental Patients .....	161
	16.6	Abbreviations .....	172
<b>17.</b>		<b>Image Evaluation Manual</b>	<b>175</b>
	17.1	PANO .....	175
	17.2	CEPH.....	187
	17.3	CBCT .....	194

<b>18.</b>	<b>Image Test Manual</b>	<b>218</b>
18.1	PANO .....	218
18.2	CEPH.....	228
18.3	CBCT .....	238

# 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"> <li>Licensed dentists or dental hygienists, radiologists, and graduates of relevant bachelor's degree (national qualifications)</li> </ul>
Knowledge	<ul style="list-style-type: none"> <li>Understanding the treatment and diagnosis of dental disease</li> <li>Understanding the terms and guidance of hardware and software of a diagnostic medical radiation device and recognizing device connection, installation, operating conditions</li> </ul>
Language understanding	<ul style="list-style-type: none"> <li>Understanding how to use manuals (English/Korean) Or</li> <li>Understanding other language provided</li> </ul>
Experience	<ul style="list-style-type: none"> <li>Understanding the objectives and effects of the diagnosis and treatment of dental disease using diagnostic medical radiation devices</li> <li>Understanding of the normal operation of diagnostic medical radiation equipment</li> <li>Understanding the contents of the <b>user manual</b></li> </ul>

### 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 Disinfection** and **Chapter 13. Maintenance**.













## 2.3 Conventions in this Manual








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

 <b>WARNING</b>	<b>WARNING</b>	Failure to comply with the given information may result in severe injuries to the people or damages to the equipment.
 <b>CAUTION</b>	<b>CAUTION</b>	Requires the user's immediate attention or action due to the possibility of safety issues.
<b>IMPORTANT</b>	<b>IMPORTANT</b>	Requires the user's attention because the stated action and environment may cause trouble.
<b>NOTICE</b>	<b>NOTICE</b>	Indicates useful information for users.
	<b>RADIATION</b>	Indicates a possible danger from radiation exposure.
	<b>SINGLE USE</b>	Indicates a component that must be replaced for each new patient.
	<b>ESD susceptibility</b>	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 <b>Main Power Switch</b> )	Main Power Switch
	On (power: connected to the <b>Main Power Switch</b> )	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

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.3 regulations.	Label
	Indicates that the user needs to refer to the <b>Instruction Manual</b> .	Label
	Indicates the date when the equipment was manufactured.	Label
	Indicates the manufacturer's serial number so that specific equipment can be identified.	Label
	Indicates compliance with the MDR guidance	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.


**vatech** ①

Product : Computed Tomography X-ray System  
 Model : PHT-35LH5  
 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.

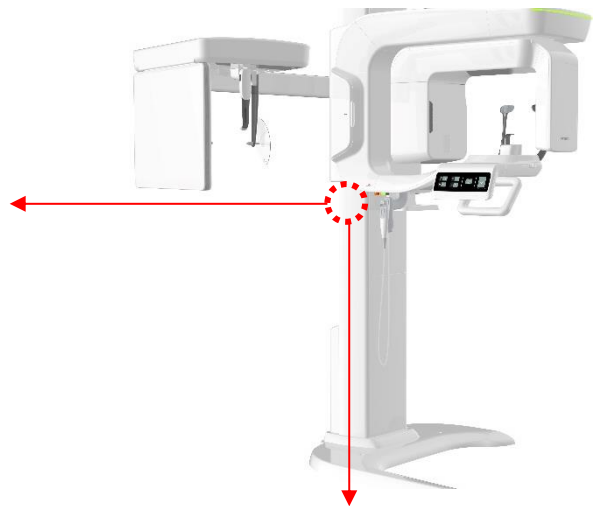
13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, KOREA  
 VATECH Co., Ltd. | Website : www.vatech.co.kr  
 51 Quai de Dion Bouton 92800 Puteaux France  
 Vatech Global France (SARL) MADE IN KOREA

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

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

④ 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 IEC 60825-1 ED.2

MEDICAL - APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT  
 ANSI/AAMI ES60601-1 (2005)  
 + AMD 1 (2012), CAN/CSA-C22.2  
 No. 60601-1 (2014), IEC 60601-1-3 (2008), IEC 60601-3-63 (2012)  
  
  
  




#### 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	<b>Smart Plus (PHT-35LHS) Main Label</b>
②	<b>CAUTION Label</b> - X-ray/Attention: X-ray on when equipment in operation.
③	<b>X-RAY GENERATOR Label</b> : 1.6 kW Generator
④	<b>CLASS 1 LASER PRODUCT Label</b>
⑤	<b>Manufacturer Label</b> - The date of manufacture / Serial Number
⑥	<b>Device Identifier Label</b> (For Canada only) For Canada, the Model is distinguished by Smart Plus SC and Smart Plus SP. <ul style="list-style-type: none"> <li>• Smart Plus SC: CEPH included.</li> <li>• Smart Plus SP: CEPH not included.</li> </ul>

## 3. Warnings and Precautions



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



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

### 3.1 General Safety Guidelines

#### 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.

- 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, mist, 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:** non-continuous operation (NFPA 70: long time operation) - needs waiting time (at least 60 times the exposure time) before the next exposure begins.
  - Column operation time: Max. 2 min. On/18 min. Off (Ratio 1:9)
- 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 the 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

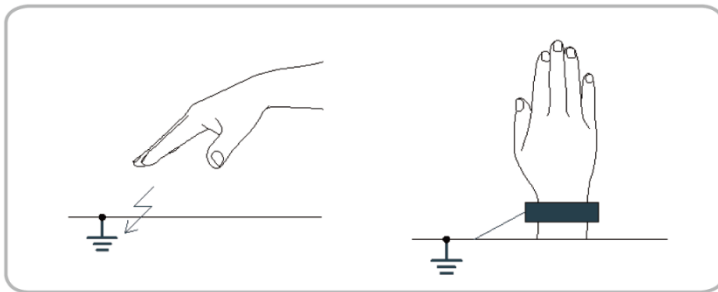
- Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without observing ESD protective measures.



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.

 <b>WARNING</b>	<ul style="list-style-type: none"> <li>▪ X-ray equipment is hazardous to the patient and the operator if proper exposure safety measures and/or operating instructions are not observed.</li> <li>▪ It is important to read this <b>User Manual</b> carefully and abide by all warnings and cautions stated within it.</li> </ul>
 <b>WARNING</b>	<ul style="list-style-type: none"> <li>▪ The 3D image should not be used for screening examinations. Each exam must be justified by demonstrating that the benefits outweigh the risk.</li> <li>▪ 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.</li> </ul>
 <b>WARNING</b>	<ul style="list-style-type: none"> <li>▪ <b>Smart Plus</b> 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.</li> <li>▪ <b>Smart Plus</b> 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.</li> </ul>
 <b>WARNING</b>	<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** 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 antispymware tools, and other commonly used 3<sup>rd</sup> 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: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan
- EzDent-i: 2D viewer and patient management software
- Ez3D-i: 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 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

 2460	This is Class IIb equipment and obtained CE marking in April 2007 for regulations compliance in accordance with the revised European Union's MDD (Medical Devices Directive) 93/42 EEC.
 E476672	This equipment received the UL certification mark in accordance with ANSI/AAMI, CAN/CSA-C22.2 No. 60601-1 regulations.

### 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

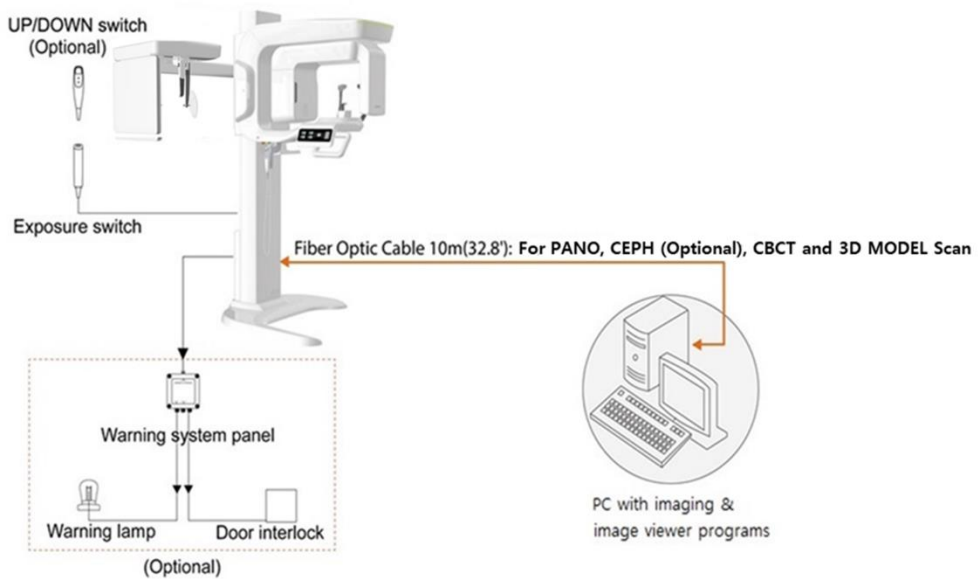
X-ray is emitted when a high voltage is supplied to the X-ray tube assembly which frees electrons from the cathode.

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.

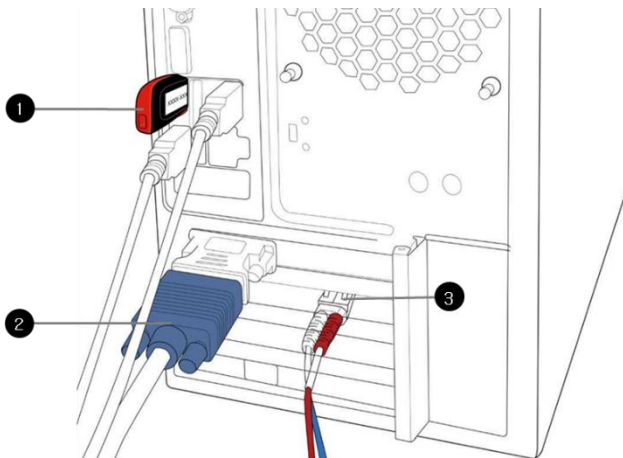
Images are acquired, computed, and recompiled to reproduce 2D or 3D images.



## 4.5 Imaging System Configuration

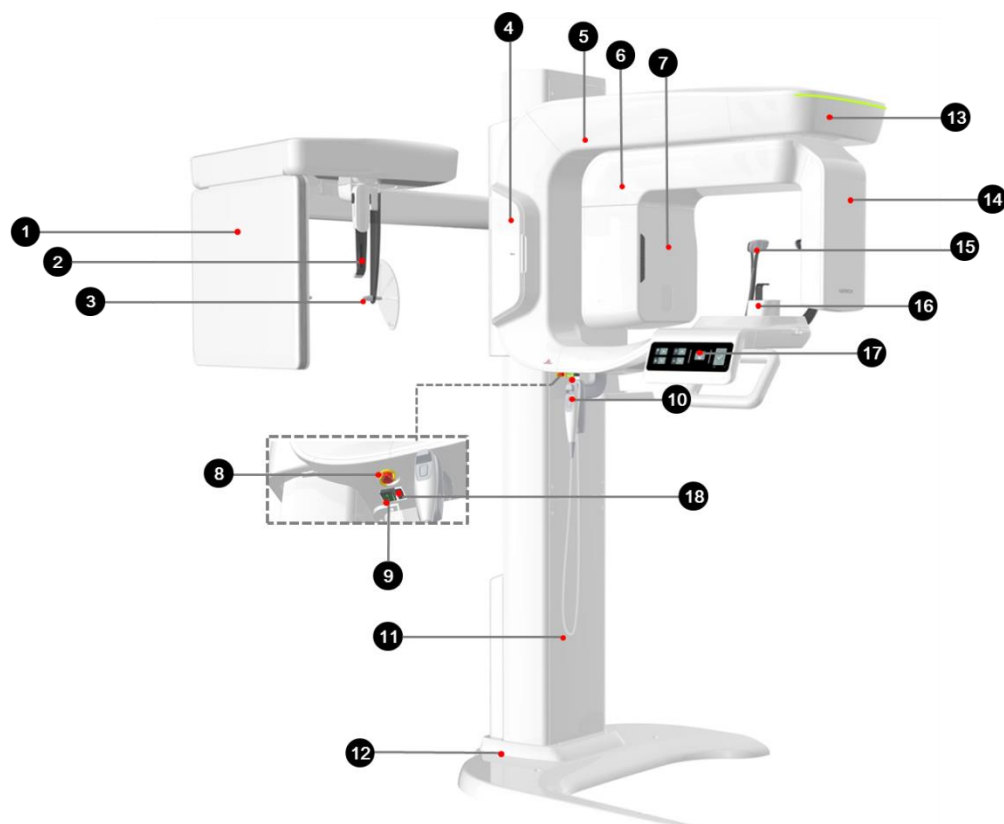


### 4.5.1 PC Signal Input/Output




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

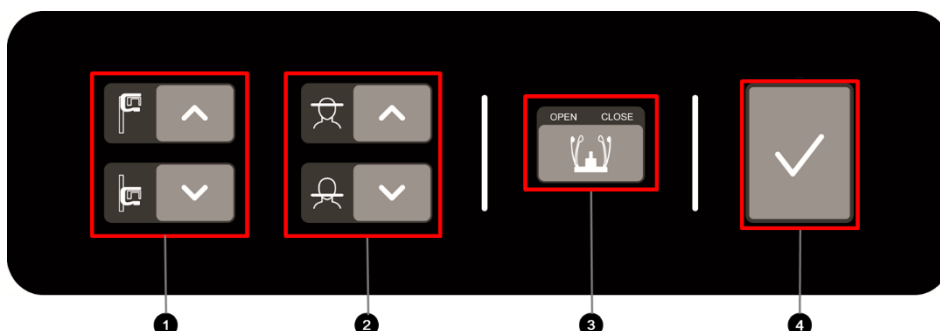
## 4.6 Equipment Overview



No.	Item	Description
1	X-ray Detector for CEPH (Optional)	Xmaru2602CF for CEPH imaging sensor
2	Nasal Positioner	<ul style="list-style-type: none"> <li>Positions the patient during CEPH imaging.</li> <li>The ruler used for reference in an acquired image that is different from the actual size</li> </ul>
3	Ear Rods	Secure the patient's head during CEPH imaging.
4	Enclosed Component Storage	The place where Bites, Chinrest Assy, and the other components can be stored.
5	Vertical Frame	Holds the Rotating Unit. It can be controlled by the <b>Column UP/DOWN</b> 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 <b>READY</b> button is pressed. (For the details, refer to <b>4.6.1 Control Panel</b>.)</p>  <p>* The Membrane type control panel below is the default.</p>
18	D-Sub Connector	The input signal port for <b>Column UP/DOWN</b> 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.

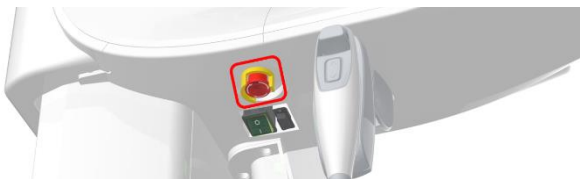
### 4.6.2 Emergency Stop Switch

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.

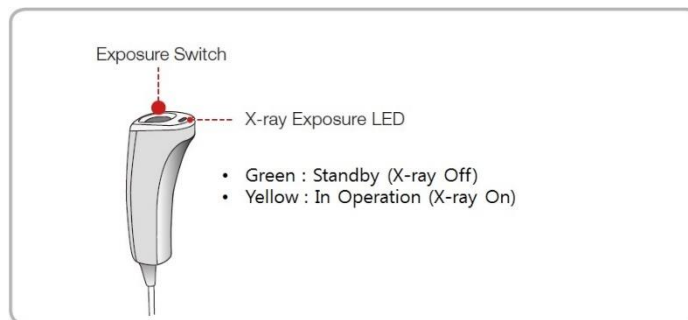


### 4.6.4 Exposure Switch

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.












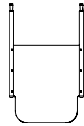

#### IMPORTANT



- 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 are used to support the patient positioning and must be cleaned before each patient.

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

Components	Name and Function	Materials
	<b>Normal Bite</b> <ul style="list-style-type: none"> <li>- For normal patients</li> <li>- For normal Pano and CT modes</li> </ul>	PC (Polycarbonate)
	<b>Deep Bite</b> <ul style="list-style-type: none"> <li>- For normal patients</li> <li>- For normal Pano and CT modes</li> </ul>	PC (Polycarbonate)
	<b>Special Bite A</b> <ul style="list-style-type: none"> <li>- For normal and edentulous patients</li> <li>- For TMJ and SINUS mode</li> </ul>	PC (Polycarbonate)
	<b>Special Bite B</b> <ul style="list-style-type: none"> <li>- For edentulous patients</li> <li>- For normal PANO and CT modes</li> </ul>	PC (Polycarbonate)
	<b>Normal Chinrest</b> <ul style="list-style-type: none"> <li>- For normal PANO and CT modes</li> </ul>	ABS (Acrylonitrile butadiene styrene) copolymer
	<b>Special Chinrest</b> <ul style="list-style-type: none"> <li>- For TMJ and Sinus mode</li> </ul>	ABS (Acrylonitrile butadiene styrene) copolymer
	<b>Temple Supports (1 set)</b>	PC (Polycarbonate)
	<b>Ear Rods (1 set)</b>	Silicone
	<b>Nasal Positioner Cover</b> <ul style="list-style-type: none"> <li>- For CEPH mode</li> </ul>	Silicone
	<b>Carpus Plate</b>	PC (Polycarbonate)
	<b>Sanitary Vinyl Covers (disposable)</b>	PP+PE (Low-density polyethylene)

Components	Name and Function	Materials
	Protractor (1 set) - For positioning patient for CEPH mode	PC (Polycarbonate)
	Model Scan Jig	ABS (Acrylonitrile butadiene styrene) copolymer

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## 5. Imaging Software Overview

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

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

### 5.1 PC Specifications (Recommended)

#### IMPORTANT

If your PC does not meet the recommended specifications provided below, it may result in degraded image quality.



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

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 10
Recommended System	HP Z440

## 5.2 EzDent-i

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

### NOTICE

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

### NOTICE

#### Security Capabilities

- It is recommended to install and operate **EzDent-i** SW within a secure operating environment that allows only authorized users to access, and a system network equipped with Windows built-in firewall, Windows Defender antispymware tools, and other commonly used 3<sup>rd</sup> 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 updates by a third party are prohibited. For cybersecurity issues related to the software and medical devices, please contact the manufacturer.

### 5.3 Console Software

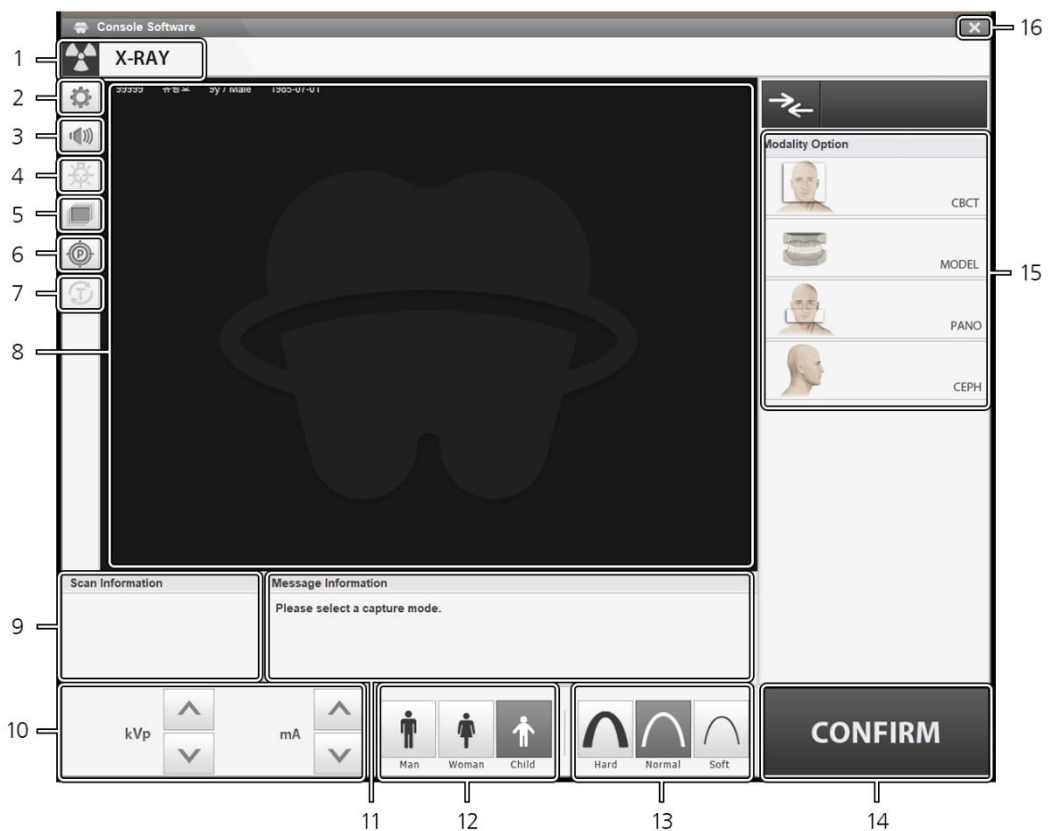
You can set exposure settings for the capture mode you selected and capture an image on the console software. The main window for Smart Plus console software is shown below:


#### NOTICE

The **Modality Option** may look different depending on the options of the equipment you purchased.

#### NOTICE

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



No.	Item	Description
1	X-ray Indicator	<p>Indicates X-ray exposure status by changing the indicator's color and message.</p> <ul style="list-style-type: none"> <li>▪ <b>Grey and “X-RAY”:</b> X-ray is turned off</li> <li>▪ <b>Yellow and “X-RAY ON”:</b> X-ray is turned on</li> </ul> 
2	<b>Settings</b> Button	<p>Sets various equipment-related parameters, including:</p> <ul style="list-style-type: none"> <li>▪ <b>Language</b></li> <li>▪ <b>Automatic Save on/off</b></li> <li>▪ <b>DAP display unit</b></li> </ul>
3	<b>Volume</b> Button	<p>Changes the volume of the audio message. Ensure to save your change each time you reset the volume.</p>
4	<b>Laser Beam ON/OFF</b> Button	<p>Turns the laser beam on or off for patient positioning. This button appears after you click the CONFIRM button.</p>
5	<b>Manual Reconstruction</b> Button	<p>Reconstructs the captured image manually when the system fails to run automatic image reconstruction. Follow the instructions below for manual reconstruction:</p> <ol style="list-style-type: none"> <li>(1) <b>Click a manual reconstruction.</b></li> <li>(2) <b>Select a modality.</b></li> <li>(3) <b>Click Search.</b></li> <li>(4) <b>Select an image for reconstruction.</b></li> <li>(5) <b>Click Reconstruction.</b></li> </ol>
6	<b>Phantom</b> Button	<p>Switches the system for the phantom image acquisition using a phantom jig.</p>
7	<b>Test Rotation</b> Button	<p>Sets the system for a rotation test, which checks if the rotating unit hits the patient's body before actual imaging. To run a rotation test, follow the procedure below:</p> <ol style="list-style-type: none"> <li>(1) <b>Ask the patient to position the equipment.</b></li> <li>(2) <b>Select a modality.</b></li> <li>(3) <b>Click the Confirm button.</b></li> <li>(4) <b>Click the Test Rotation Button. Then “ON” on the button is changed into “OFF.”</b></li> <li>(5) <b>Press the Laser Beam ON/OFF button on the control panel.</b></li> <li>(6) <b>To finish the test mode, click the Test Rotation button or the READY button.</b></li> </ol>

8	Patient Information Window	Displays the information of a selected patient.										
9	Scan Information Window	Displays estimated DAP (Dose Area Product), scan time, and exposure time after you set up X-ray exposure parameters.										
10	Tube Voltage and Current Buttons	Changes tube voltage (kVp) and current (mA) values. Click arrows to modify the voltage and current originally set by the system.										
11	Guide Message Window	Displays text instructions during the operation.										
12	Patient's Gender/Age Group	<p>Displays the current patient's gender/age group as entered in EzDent-i's patient information fields. If necessary, the gender/age group can be selected manually.</p> <table border="1"> <thead> <tr> <th colspan="2">Gender / Age Group</th><th>VATECH's Standard</th></tr> </thead> <tbody> <tr> <td colspan="2">Child</td><td>2 ~ 12 years of age</td></tr> <tr> <td rowspan="2">Adult</td><td>Man</td><td rowspan="2">&gt; 12 years of age</td></tr> <tr> <td>Woman</td></tr> </tbody> </table>	Gender / Age Group		VATECH's Standard	Child		2 ~ 12 years of age	Adult	Man	> 12 years of age	Woman
Gender / Age Group		VATECH's Standard										
Child		2 ~ 12 years of age										
Adult	Man	> 12 years of age										
	Woman											
13	X-ray Intensity	Selects X-ray intensity.										
14	<b>CONFIRM / Ready</b> Button	<div>CONFIRM</div> <p>Applies selected options and turns into the Ready button.</p> <div>Ready</div> <p>The Ready button appears after you click CONFIRM button. When you click the button, the system becomes ready for image acquisition.</p>										
15	<b>Modality Selection</b> Button	Selects the imaging parameters for each mode: PANO, CEPH (Optional), CBCT, and 3D MODEL Scan.										
16	<b>Exit Button</b>	Leaves the console software.										

## 6. Getting Started

### 6.1 Turning on the Equipment



**WARNING**

- 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.



**CAUTION**

- 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.



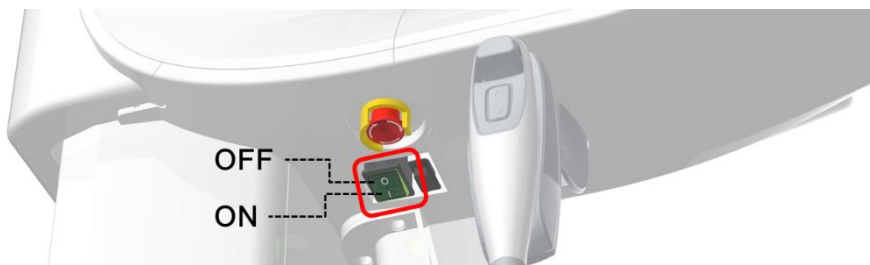
**IMPORTANT**

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)

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

### NOTICE

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

### NOTICE

#### Security Capabilities

- It is recommended to install and operate **EzDent-i** SW within a secure operating environment that allows only authorized users to access, and a system network equipped with Windows built-in firewall, Windows Defender antispyware tools, and other commonly used 3<sup>rd</sup> 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 updates 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**) and Console Software are being accessed through 2D viewer (**EzDent-i**) SW. 3D viewer and Console Software do not have an image storage capacity of their own, and both programs will not be able to keep patient information.

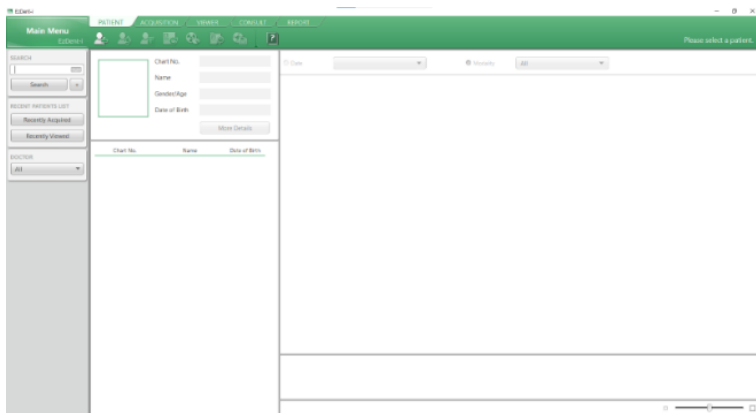
### 6.2.1 Creating a New Patient Information


If you want to create a new patient information on the EzDent-i, Follow the steps below.


#### NOTICE

For further details that are not included in this manual, please read the EzDent-i user manual that is supplied separately.

4. Double-click the **EzDent-i** icon on your computer.
5. The EzDent-i's main menu window will pop up after you click the icon.



6. Click  and enter the information in the **ADD PATIENT** window. The chart number and name are required fields. Ensure to enter both to move to the next step.

7. Click  to save the new patient record.



## 6.2.2 Retrieving Existing Patient Information

If you want to view existing patient information, follow the steps below.

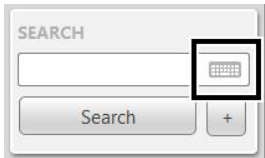
1. Select the Patient tab. and Go to the search box.

Chart No.	Name	Date of Birth
20221031_102015	DiResta Jonathan	01/08/2022
20221031_102059	Wapelhorst Lloyd	01/01/2022
20221031_102144	Foster Megannnnnnnnn...	01/01/2022

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

NOTICE

If necessary, click the keyboard icon next to the search field to use the virtual keyboard.



3. Click .
4. Double-click the patient information you want to retrieve.

Chart No.	Name	Date of Birth
20221031_102015	DiResta Jonathan	01/08/2022
20221031_102059	Wapelhorst Lloyd	01/01/2022
20221031_102144	Foster Megannnnnnnnn...	01/01/2022

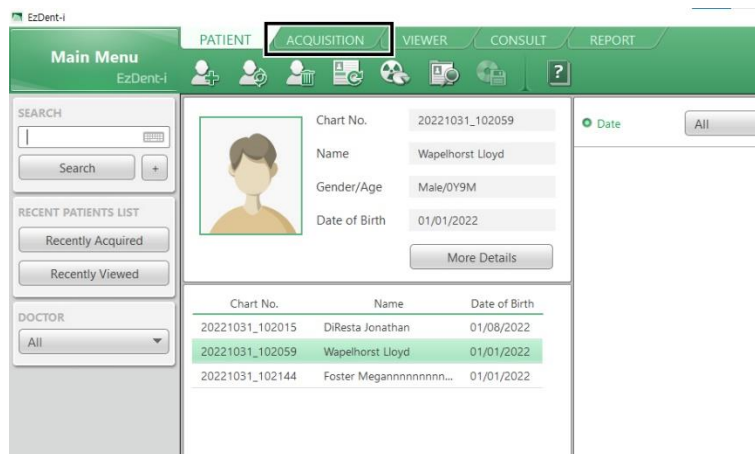
### 6.2.3 Starting Console Software

Follow the steps below to start the console software after retrieving (creating) the patient record.

#### IMPORTANT

Before starting the console software, ensure to create or retrieve the patient record.

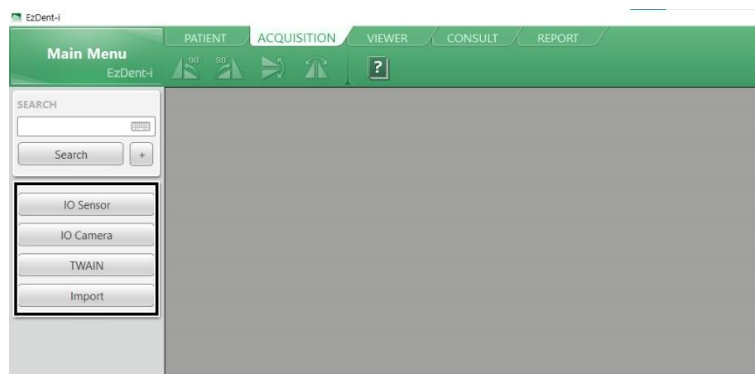
1. Select the **ACQUISITION** tab.



2. The capture mode menu appears below the search box. Select the capture mode you want to take an image with.

#### NOTICE

The menus on the window can be different according to the option that your equipment has.



## 7. Acquiring PANO Images

### 7.1 PANO Imaging Program Overview

#### ■ Result Images

It provides conventional 2D panoramic images.

#### ■ Image Acquisition Method


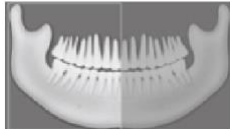

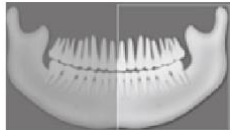

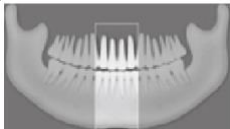

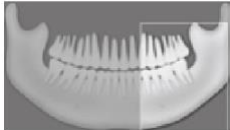

It reconstructs U-shaped arch data to a single 2D image utilizing multiple images taken with the X-ray beam scanning specific oral & maxillofacial regions at different angles.






#### ■ 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).

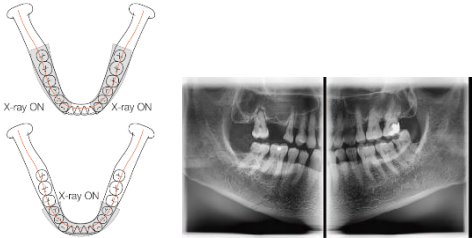
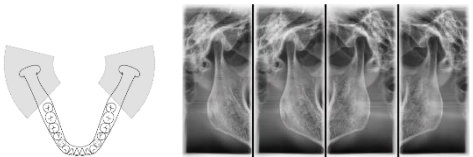
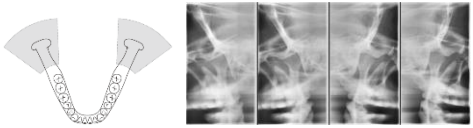

Examination Type	Arch Selection	ROI	Sample Image
PANO Examination	Narrow Normal Wide Child Orthogonal	Standard	
		Right	
		Front	
		Left	
	Orthogonal	Bitewing*	
		Bitewing Incisor* (Optional)	
		Bitewing Right*	
		Bitewing Left*	
SPECIAL Examination	N/A	TMJ LAT Open	

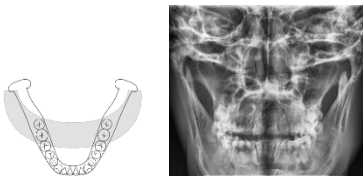
Examination Type	Arch Selection	ROI	Sample Image
		TMJ LAT Close	
		TMJ PA Open (Optional)	
		TMJ PA Close (Optional)	
		Sinus LAT (Optional)	
		Sinus PA	

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

### ■ 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
		Bitewing** (Bitewing Incisor mode is Optional)	<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> 
SPECIAL Examination	N/A	TMJ LAT Open/Close	<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> 
		TMJ PA Open/Close (Optional)	<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> 
		Sinus LAT (Optional)	<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> 

Examination Type	Arch Selection	ROI	Description & Sample Image
		Sinus PA	<p>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.

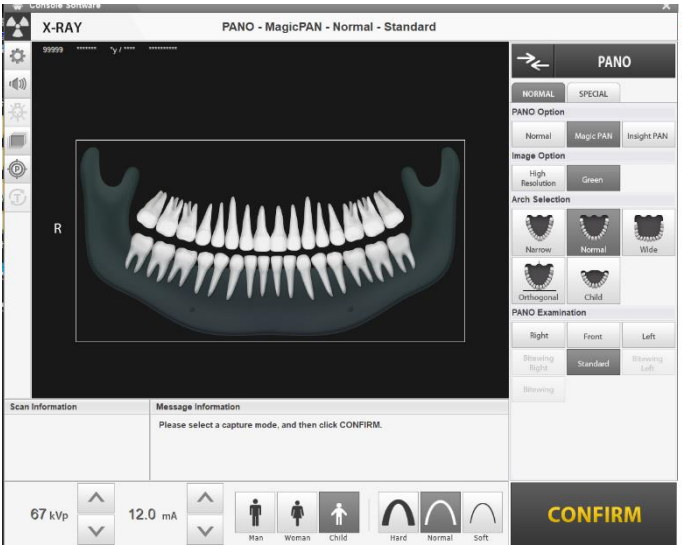


7.2 Configuring Exposure Parameters

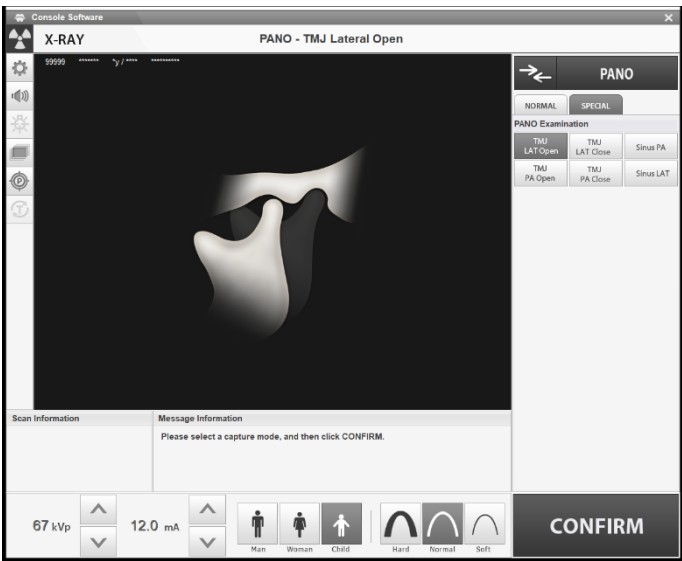
Follow the steps on the next page to select exposure settings for the PANO mode. For the PANO mode, you can select a normal or special tab accordingly to the image option that you want to acquire an image with.

NOTICE

Before selecting exposure settings, ensure that you completed all steps from 6.Getting Started.



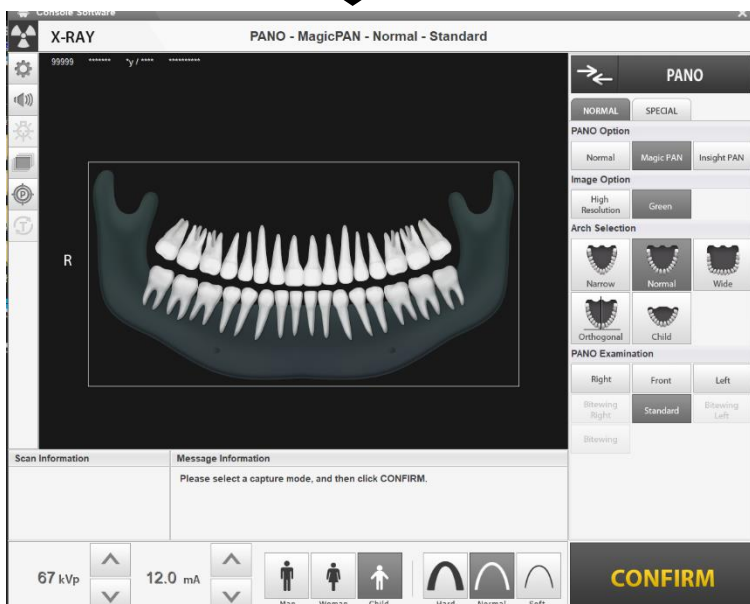
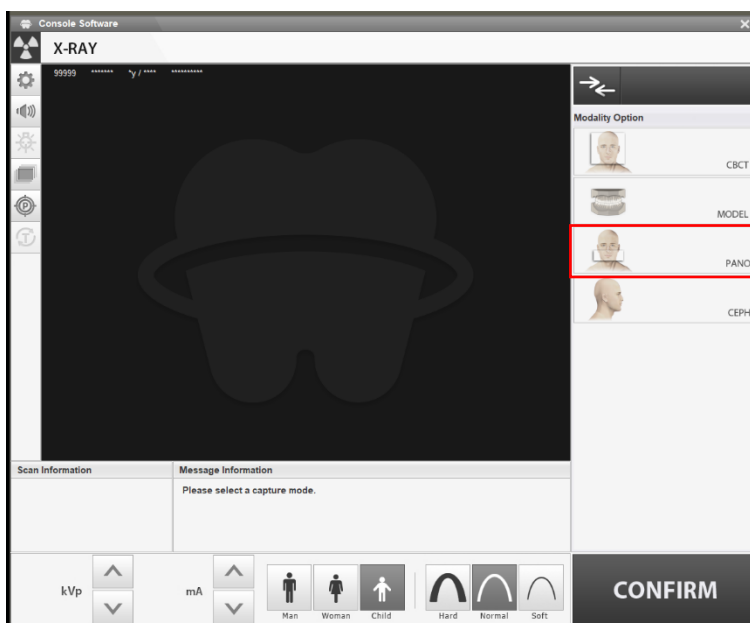
<Normal Tab Window>



<Special Tab Window>

## 7. Acquiring PANO Images

1. Click the **PANO** on the main console window. The window will turn to the PANO main window after you click the button.



2. Select the Normal tab.



### NOTICE

To acquire a TMJ or Sinus image, select the Special tab.

3. Select a PANO option.



4. **[Optional]** Select an image option.

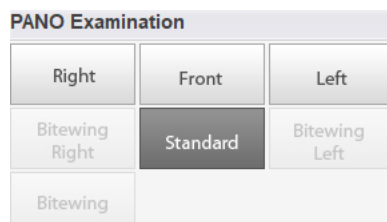
### NOTICE

To access the image option menu, first enable the 'Green' option on the console software setting page. If the option is not enabled, system will automatically select 'High Resolution' as the default image option.

5. Select an Arch type.



6. Select one of the PANO examination options.



### NOTICE

To access, the 'Bitewing' options such as 'Bitewing Left', first select 'Orthogonal' from the Arch Selection menu.

7. Select a patient type.



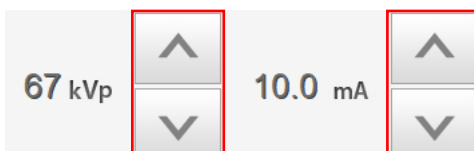
Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females under the age of 12

8. Select an X-ray intensity level. The system will automatically set exposure condition accordingly to your choice.



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

9. If you want to change the selected condition, click the plus-minus button next to the voltage and current symbols. Each time you click the button, the voltage value will change by  $\pm 1.0$  kVp and the current value will change by  $\pm 1.0$  kVp.



10. Click Confirm. The system will operate as the below after you click the button:



**CONFIRM**

- The rotating unit moves.
- The laser beams are turned on.
- The Scan information window shows DAP(Dose Area Product), scan time and exposure time.

11. Guide the patient to the equipment.



Do not guide the patient to the equipment until it stops moving.

### 7.3 Patient Positioning



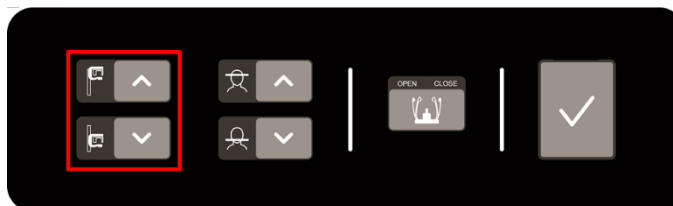
- Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.



- 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

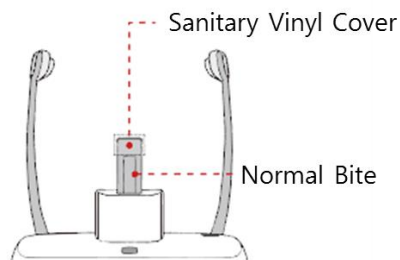
1. Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button or switch 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**.
2. Cover the **normal bite** with a **sanitary vinyl cover**.



Do not reuse the sanitary vinyl cover after taking an X-ray and ensure to use the approved vinyl cover only.

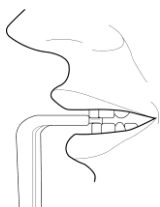


3. Use the **Temple Support OPEN/CLOSE** button on the control panel to widen the Temple Supports.



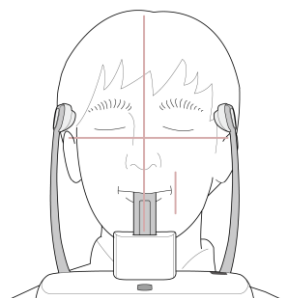
4. Guide the patient to the inside of the equipment.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined 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 stand still.

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



8. 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 bite from the normal chinrest and insert the **special bite B**.



Clean the chinrest and the bite after X-ray imaging and dry them with a soft towel.

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



### 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.

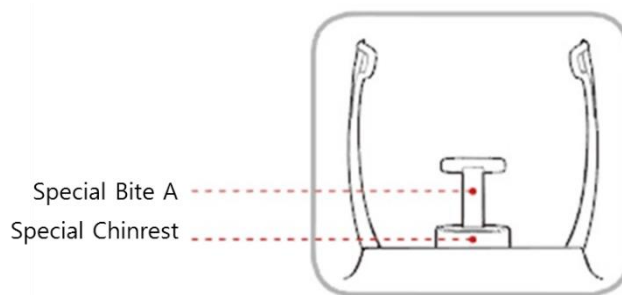
#### NOTICE

##### 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 (Normal and Edentulous Patient)

1. Remove the normal chinrest and insert the **special chinrest**.
2. Insert the **special bite A** into the special chinrest.



#### CAUTION

Clean the chinrest and the bite after X-ray imaging and dry them with a soft towel.

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. 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**

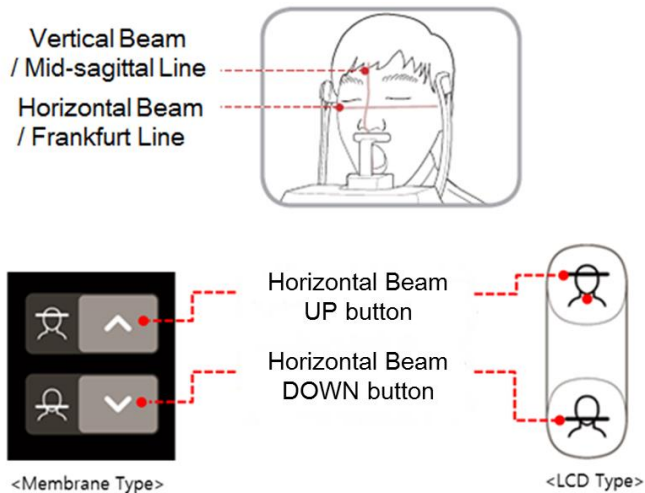
Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.



**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.



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.

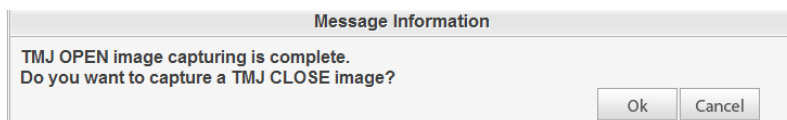


#### Steps for TMJ Mode

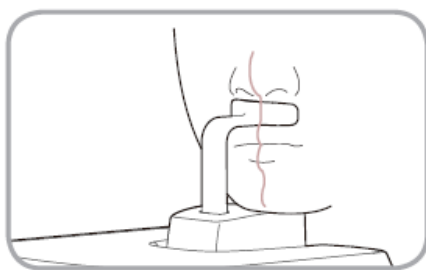
Patient positioning for TMJ Open > Laser Beam Aligning > X-ray Exposure > Patient positioning for TMJ Close > Laser Beam Aligning > X-ray Exposure

#### 7.3.3.2.1 Patient Positioning (Normal and Edentulous Patient)

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°.
  - 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.

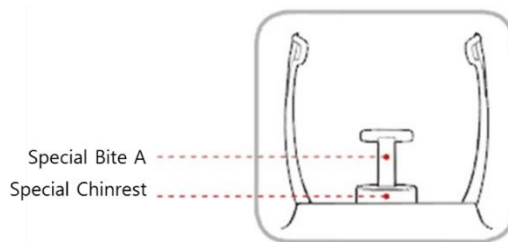
#### **7.3.3.2.3 Finishing Patient Positioning**

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

### 7.3.3.3 Sinus Mode (LAT/PA)

Follow the steps below to take a sinus mode for normal and edentulous patients.

1. Remove the normal chinrest and insert the **special chinrest**.
2. Insert the **special bite A** into the special chinrest.



Clean the chinrest and the bite block after X-ray imaging and dry them with a soft towel.

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



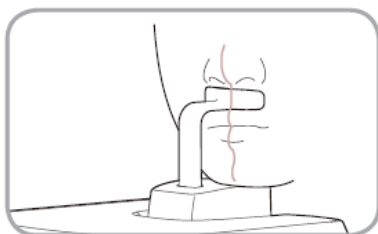
4. Guide the patient to the equipment.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
6. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
  - 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.



- 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:

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



### 7.3.3.3.1 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 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.

### 7.3.3.3.2 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 **7.4 X-ray Exposure** to start the exposure.

## 7.4 Laser Beam Aligning



**WARNING**

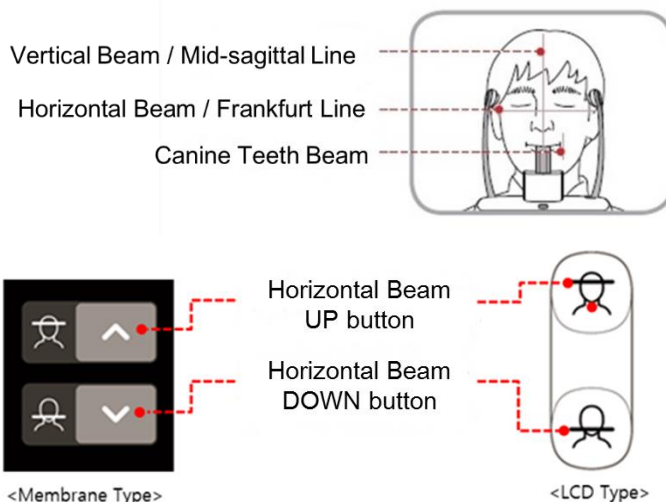
Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.



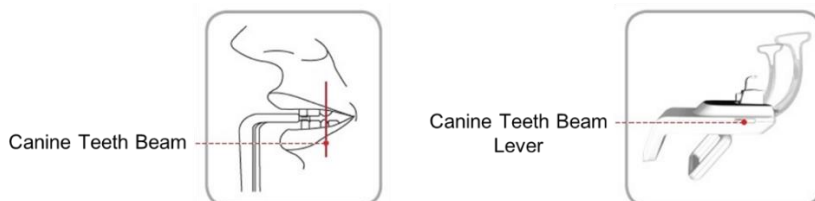
**CAUTION**

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.



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.



### 7.4.1.1 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.

## 7.5 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

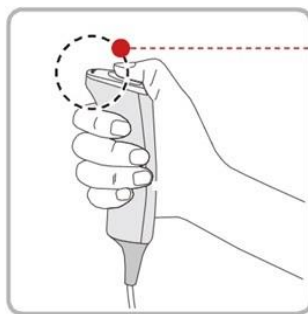
- Instruct the patient to close his or her eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.

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."



X-RAY ON

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

## 7.6 Finishing the Scan

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

## 7.7 Checking the Captured Images

Acquired images can be reconstructed and converted to DICOM format. The exported images can be confirmed in **EzDent-i**

### NOTICE

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

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

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## 8. Acquiring CEPH Images (Optional)

### 8.1 CEPH Imaging Program Overview

#### ■ Result Images



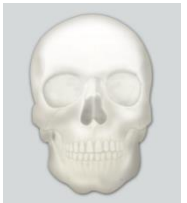
It provides conventional 2D cephalometric images.




#### ■ 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"> <li>Used to study craniofacial disease, trauma, and congenital malformation and examine the soft tissue in the otorhinolaryngological area, the sinus, and the hard palate.</li> <li>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.</li> </ul>	 <Lateral>  <Full Lateral>
PA	<ul style="list-style-type: none"> <li>The radiation is directed from the posterior of the skull to the anterior.</li> <li>Used to examine cranial diseases, trauma, and congenital malformations.</li> <li>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.</li> <li>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.</li> </ul>	 <PA>

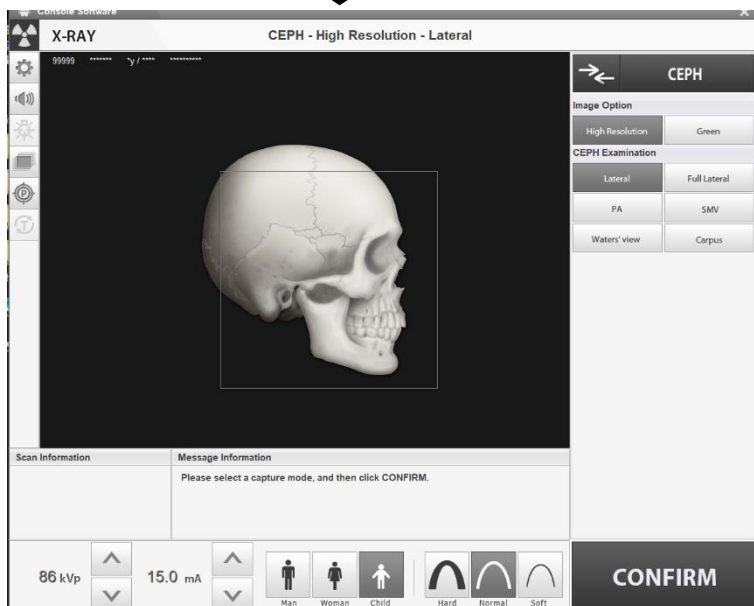
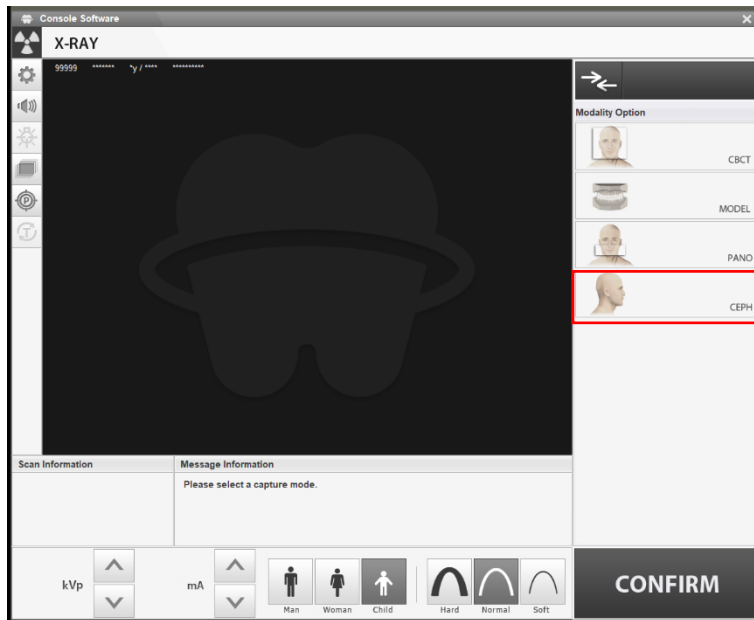
Examination Area	Description	Position
SMV	<ul style="list-style-type: none"> <li>Used to study the base of the skull, horizontal angulation of the mandibular condylar axis, the sphenoid sinus, the curvature of the lower jaw, the sidewall of the maxillary sinus, and zygomatic arch fractures. Also used to study the inner and outer alar plates and holes at the base of the skull.</li> </ul>	 <SMV>
Waters' view	<ul style="list-style-type: none"> <li>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.</li> </ul>	 <Waters' view>
Carpus	<ul style="list-style-type: none"> <li>Used to assess hand bone age to compare the changes in the skull.</li> </ul>	 <Carpus>



## 8.2 Configuring Exposure Parameters

Follow the steps on the next page to select exposure settings for the CEPH mode.

1. Click the **CEPH** on the main console window. The window will turn to the CEPH main window after you click the button.

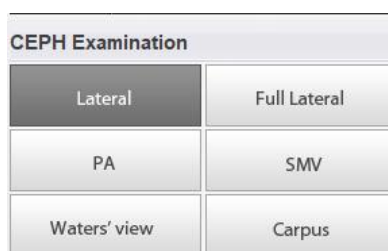


## 8. Acquiring CEPH Images (Optional)

2. Select an Image Option.



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



4. Select a patient type.



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

5. Select X-ray intensity.



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

6. If you want to change the selected condition, click the plus-minus button next to the voltage and current symbols. Each time you click the button, the voltage value will change by  $\pm 1.0$  kVp and the current value will change by  $\pm 1.0$  kVp.





7. Click the **Confirm**. The scan information window will show DAP (Dose Area Product).



8. Guide the patient to the equipment.

### 8.3 Patient Positioning

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

#### 8.3.1 Getting prepared

- Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
- Have the patient wear a lead apron to protect themselves from residual radiation.
- 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

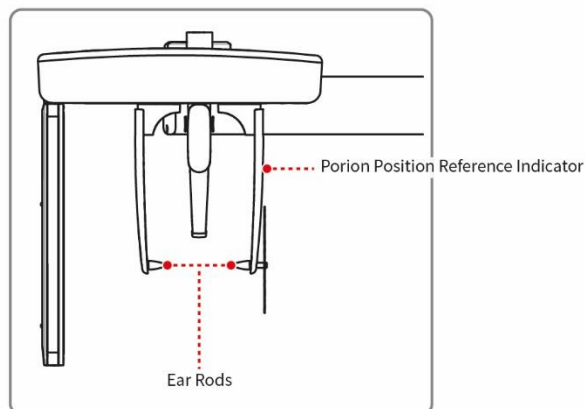
Correct posture reduces the shadow cast by the patient's cervical spine and allows clear image acquisition.

#### 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.

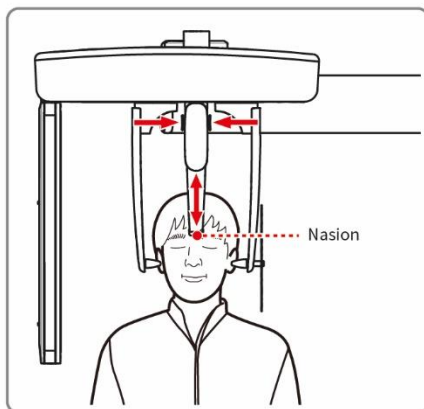
3. Guide the patient to the CEPH unit.
4. Direct the patient to relax his/her neck and shoulders and stand upright.
5. Use the **Column UP/DOWN** button or switch option to adjust the height of the CEPH unit to match the height of the patient.

#### WARNING

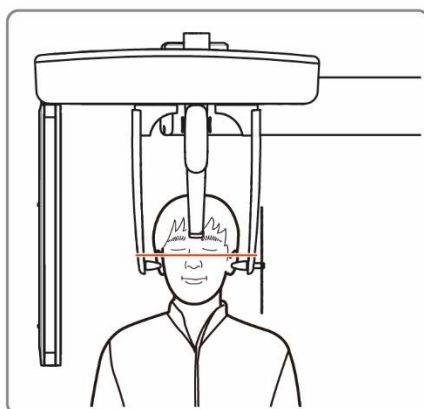
After adjusting the height of the column, align the Ear Rods and Nasal Positioner to the patient.

## 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.

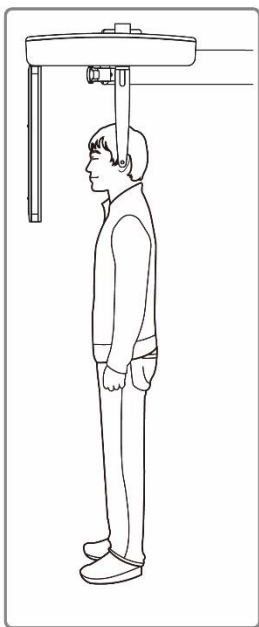
### 8.3.3 PA Mode

#### 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.



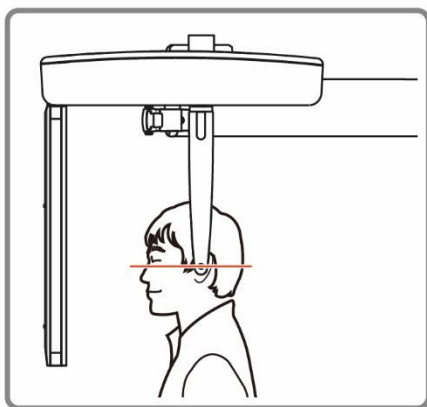
## 8. Acquiring CEPH Images (Optional)

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.



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.



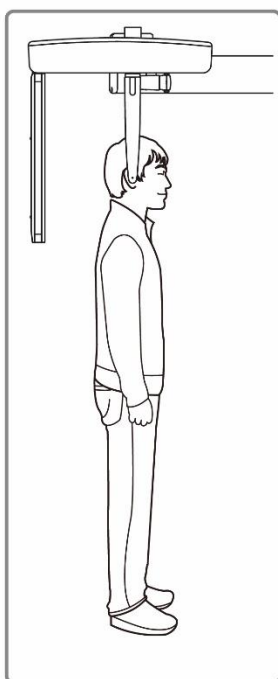
### 8.3.4 SMV Mode

#### 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.



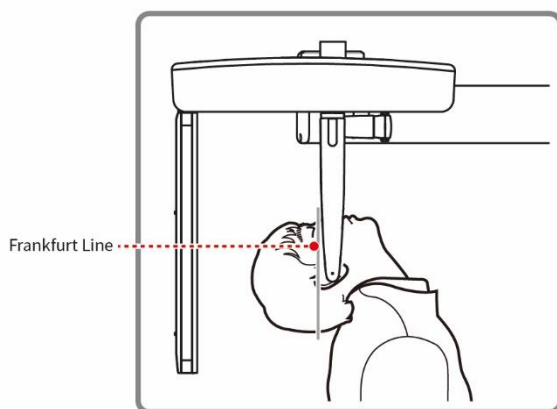
## 8. Acquiring CEPH Images (Optional)

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.

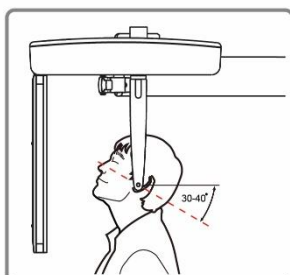


After adjusting the height of the column, align the Ear Rods to the patient.

6. During the operation, properly align the Ear Rods to the patient's ears, so his/her head does not move.

## 8. Acquiring CEPH Images (Optional)

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

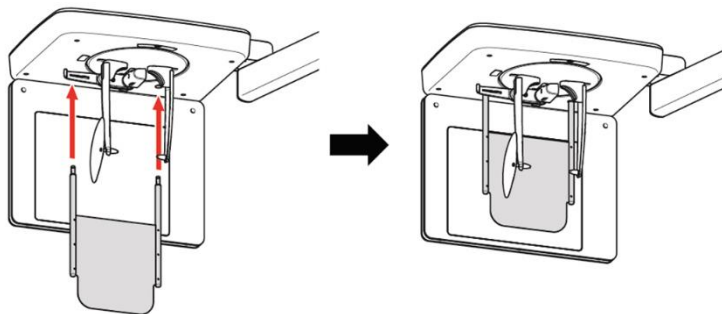
For Carpus Mode, install the Carpus Plate first before positioning the patient.

#### 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.



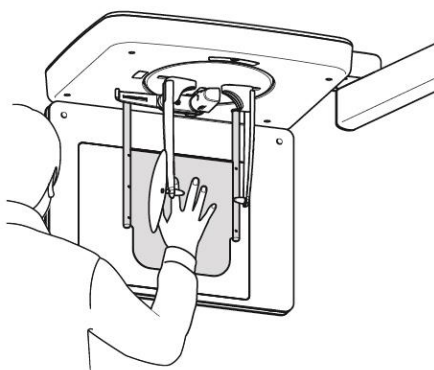
2. Fold the Nasal Positioner up. The Nasal Positioner is not used in Carpus mode.
3. Fit the two ends of the Carpus Plate into the two holes of the CEPH unit as below.



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

### **WARNING**

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

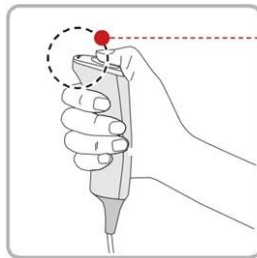
### **CAUTION**

- 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 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."



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**

#### **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**.



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## 9. Acquiring CBCT Images

### 9.1 CBCT Imaging Program Overview

#### ■ Result Images

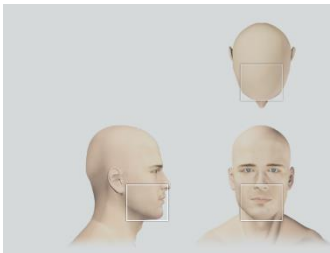
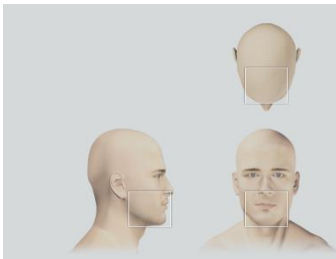
It provides conventional 3D CT sliced images.

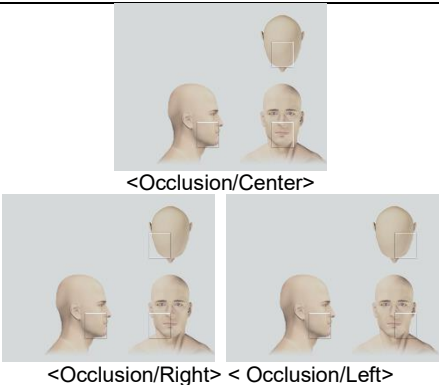
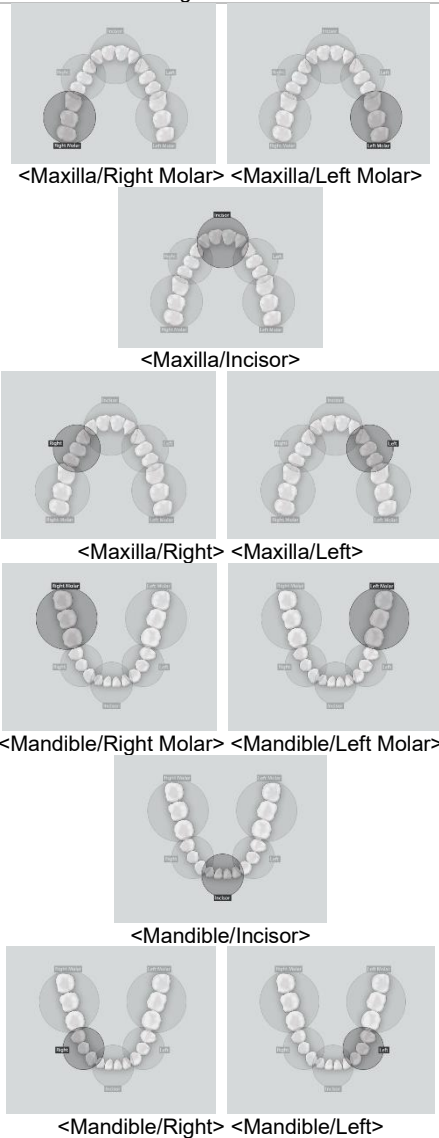
#### ■ Image Acquisition Method

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>&lt;Occlusion/Center&gt;</p>	<ul style="list-style-type: none"> <li>Covers both maxillary and mandibular structures including the 3<sup>rd</sup> molar region.</li> <li>Suitable for most oral surgery cases as well as multiple implant surgery.</li> </ul>
10x7	 <p>&lt;Occlusion/Center&gt;</p>	<ul style="list-style-type: none"> <li>For children aged between 0 and 13.</li> <li>Covers both maxillary and mandibular structures including the 3<sup>rd</sup> molar region.</li> <li>Suitable for most oral surgery cases as well as multiple implant surgery.</li> </ul>

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

### ■ Special Option

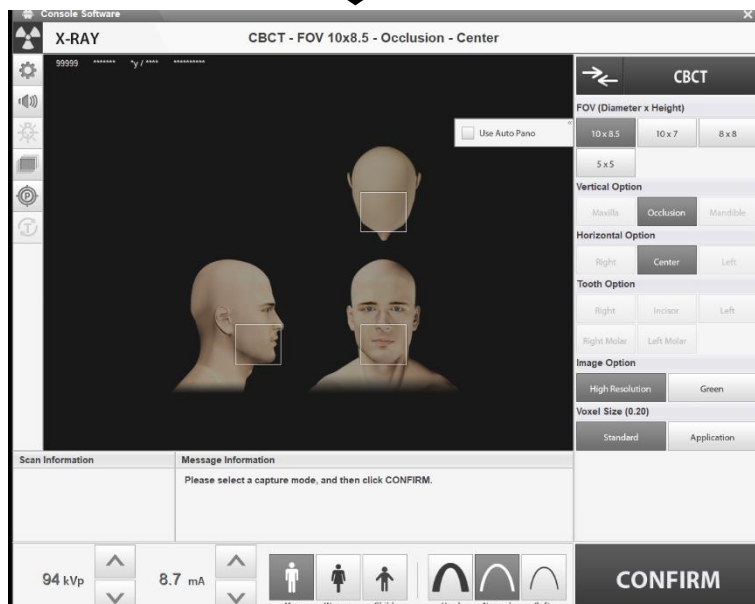
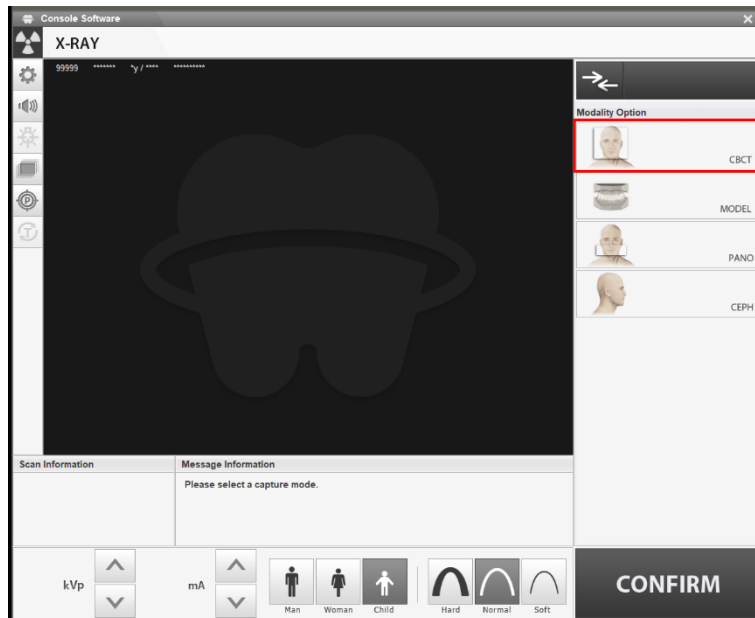
#### Auto Pano

: 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

Follow the steps below to select exposure settings for the CBCT mode.

1. Click CBCT on the main console window. The window will turn to the CBCT main window after you click the button.



- Select an FOV size. For some FOV, you can access to additional option that are not available in others.

**FOV (Diameter x Height)**

10 x 8.5	10 x 7	8 x 8
5 x 5		

- When you select **10x8.5** or **10x7**, you can choose the **Auto Pano** option.

☒ Use Auto Pano << 10 x 8.5

- When you select **5x5**, you can access the **tooth options**.
- For **10x8.5**, **10x7**, and **8x8**, the system will automatically select the vertical and horizontal options as shown in the table below:

Available FOV (cm)	Vertical option	Horizontal option
10x8.5	Occlusion	Center
10x7	Occlusion	Center
8x8	Occlusion	Right
		Center
		Left

### NOTICE

If you did not select 5x5 for FOV size, skip the step 3 through 5.

- [Optional]** Select a vertical option.

**Vertical Option**

Maxilla	Occlusion	Mandible
---------	-----------	----------

- [Optional]** Select a horizontal option.

**Horizontal Option**

Right	Center	Left
-------	--------	------

5. **[Optional]** Select a tooth option.

**Tooth Option**

Right	Incisor	Left
Right Molar	Left Molar	

6. Select an image option.

**Image Option**

High Resolution	Green
-----------------	-------

7. Select a voxel size.

**Voxel Size (0.20)**

Standard	Application
----------	-------------

8. Select a patient type.

		
Man	Woman	Child

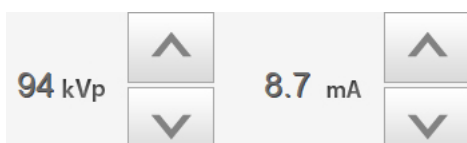
Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females under the age of 12

9. Select an X-ray intensity level. The system will automatically set exposure condition accordingly to your choice.

		
Hard	Normal	Soft

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

10. If you want to change the selected condition, click the **arrows** next to the voltage and current symbols. Each time you click the button, the voltage value will change by **± 1.0 kVp** and the current value will change by **± 0.1 kVp**.



11. Click **Confirm**. The system will operate as the below after you click the button:



- The rotating unit moves.
  - The laser beams are turned on.
  - The Scan information window shows DAP(Dose Area Product), scan time and exposure time.
12. Guide the patient to the equipment.



Do not guide the patient to the equipment until it stops moving.



### 9.3 Patient Positioning



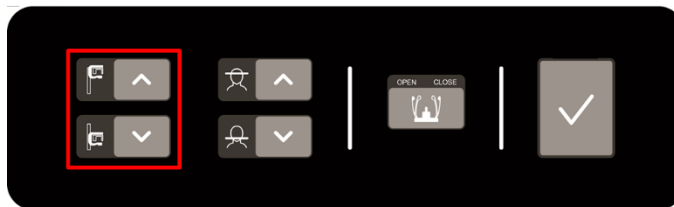
- Have patience (especially pregnant women and children) wear a lead apron to protect themselves from residual radiation.
- Be careful not to shine the laser beam directly into the person's eyes. Doing so may result in vision loss.



- 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

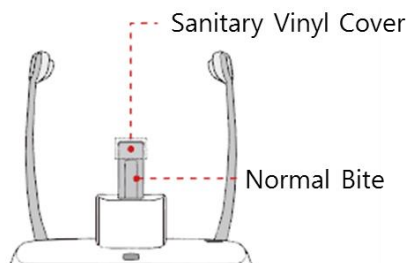
1. Let the patient remove all the metal objects (glasses, earrings, hairpins, braces, false teeth, etc.). Metal objects may induce ghost images and lower image quality.
2. Have the patient wear a lead apron to protect themselves from residual radiation.
3. Use the **Column UP/DOWN** button or switch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

#### 9.3.2.1 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.

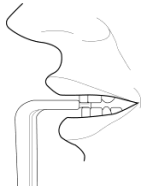


2. Use the **Temple Supports OPEN/CLOSE** button on the control panel to widen the Temple Supports.



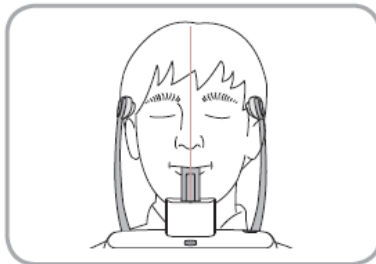
3. Guide the patient to the equipment.
4. Use the **Column UP/DOWN** button or switch option to adjust the height of the equipment so that the patient's chin reaches the Chinrest.
5. Guide the patient to stand in the center of the equipment and direct them to remain in the position outlined below.
  - 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.



7. Let the patient maintain the posture as follows:

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



### 9.3.2.2 Edentulous Patient Positioning

1. Remove the normal bite from the normal chinrest and insert the **special bite B**.



Clean the chinrest and the bite after X-ray imaging and dry them with a soft towel.

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



9.3.2.3 Laser Beam Aligning



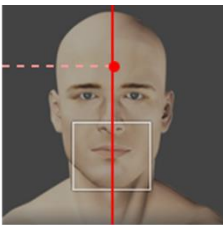
Be careful not to shine the Laser Beam directly into the person's eyes. Doing so may result in vision loss.



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 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.)

Vertical Beam / Mid-sagittal Line



FOV 10x8.5 (cm)



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

9.3.2.4 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 **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

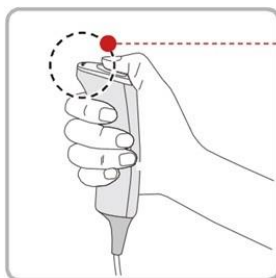
- Instruct the patient to close his/her eyes during the operation.
- To acquire optimized images, instruct the patient to hold his/her breath and not to swallow. Also, do not let the patient move until the Temple Supports are open.

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."



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**.

### 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. Then, **Ez3D-i** will run automatically for 3D viewing.

## 10. Acquiring 3D MODEL Scan Images

### 10.1 3D MODEL Scan Imaging Program

#### ■ Result Images


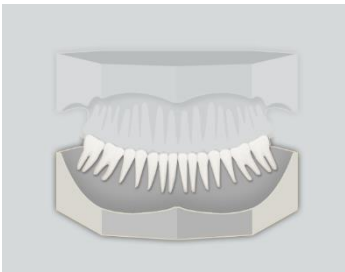
It provides 3D modeling surface data of the Plaster Cast. (STL file)

#### ■ 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.

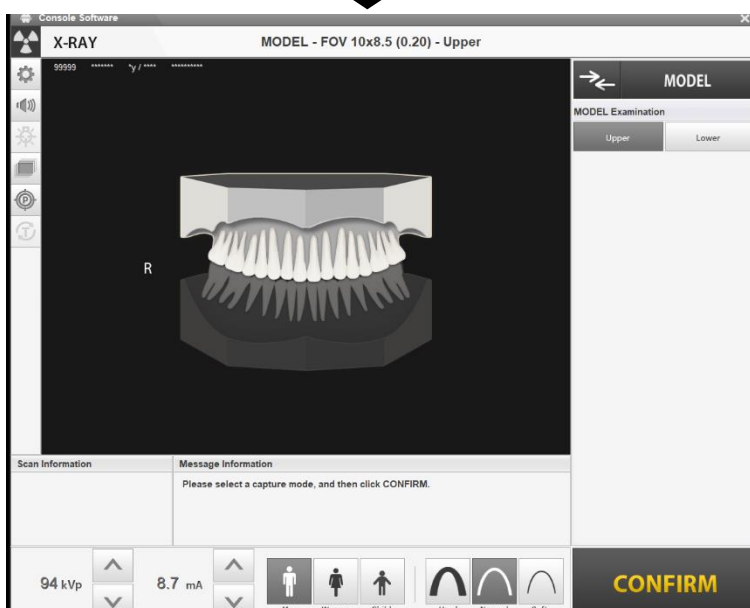
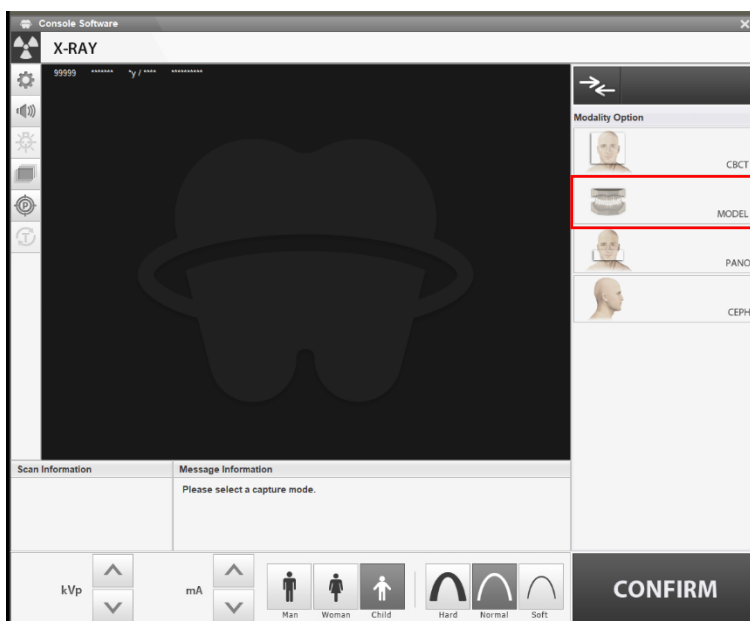
Applied FOV (cm)	Vertical Option	ROI	Description
10x8.5	Upper (Maxilla)		Captures a whole maxillary Plaster Cast.
	Lower (Mandible)		Captures a whole mandibular Plaster Cast.



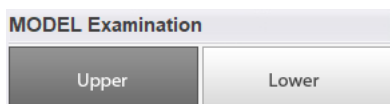
## 10.2 Configuring Exposure Parameters

Follow the steps below to select exposure settings for the Model mode.

1. Click **MODEL** on the main console window. The window will turn to the Model main window after you click the button.



- Select an option for the Model examination.



- Select a patient type.



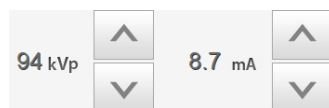
Patient	VATECH standard
Man	Males over the age of 12
Woman	Females over the age of 12
Child	Males or Females under the age of 12

- Select X-ray intensity level.



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

- If you want to change the selected condition, click the **arrows** next to the voltage and current symbols. Each time you click the button, the voltage value will change by **± 1.0 kVp** and the current value will change by **± 0.1 kVp**.



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



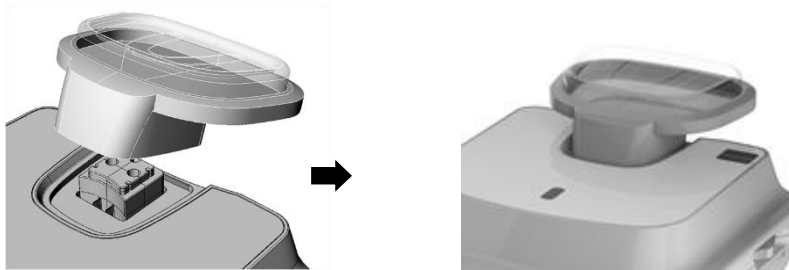
**CONFIRM**

- The rotating unit moves.
  - The laser beams are turned on.
  - The Scan information window shows DAP(Dose Area Product), scan time and exposure time.
7. Follow **10.3 Model Positioning** to place a plaster cast.

## 10.3 MODEL Positioning

### MODEL Scan Jig Installation

1. Remove the Temple Supports and the Chinrest
2. Insert the model scan jig.

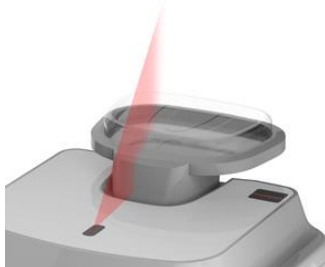


### Laser Beam Aligning

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)



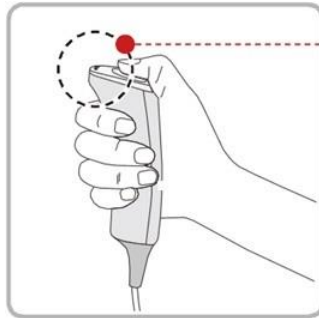
3. Click the **READY** button. X-ray exposure has not started yet.
4. Now go to **10.4 X-ray Exposure** to start the exposure.

## 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 3<sup>rd</sup> 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.

Main code      Tail code  
 ↑                    ↑  
**E00X.0XX.0XX**  
                          ↓  
                          Sub code

- **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 two parts: Tail code and description.

Tail Code	Description

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

**11.2.1.1.2 Sub code - Motor related error (002)**

Tail Code	Description
020	Appears during p-axis motor origin movement
021	Appears during rotator-axis motor origin movement
024	Appears during CT horizontal laser up/down axis motor origin movement
027	Appears during Cephalo sensor motor origin movement
030	Appears during quadruple axis collimator Left origin movement
031	Appears during quadruple axis collimator Right origin movement
032	Appears during quadruple axis collimator Up origin movement
033	Appears during quadruple axis collimator down origin movement
037	Appears during generator tilting
038	Appears during temple support the motor operation
039	Appears during X-axis motor origin movement
040	Appears during Y-axis motor origin movement

**11.2.1.1.3 Subcode – Exposure switch related error (003)**

Tail Code	Description
060	Appears if the exposure switch is pressed when turning on the equipment.

**11.2.1.1.4 Subcode – Other error (004)**

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

## 11.2.2 Software

### 11.2.2.1 Main code (002)

#### 11.2.2.1.1 Subcode – Sequence related error (001)

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

#### 11.2.2.1.2 Sub code – PC Resolution related error (010)

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

#### 11.2.2.1.3 Sub code – PC Network related error (024)

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

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

#### 11.2.3.1.2 Sub code – Capture Failure related error (020)

Tail Code	Description
000	Appears when there is a capture error

**11.2.3.1.3 Sub code – Reconstruction Failure related error (030)**

Tail Code	Description
001	Appears when bugs exist in VXM-file or there is insufficient memory

**11.2.3.1.4 Subcode – Hardware related error (061)**

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

## 12. Cleaning and Disinfection

### 12.1 Preparation

Before cleaning or disinfecting the equipment, you must:

- Turn off the equipment.
- Wear safety gloves.
- Select the product that satisfies the following conditions:
  - Chlorine-Dioxide based
  - Non-alcoholic
  - Contains none of the following chemicals: silicone, acetone, phenol, acetic acid, peroxide, sodium hypochlorite, isopropyl alcohol (2-propanol, isopropanol), iodine-splitting agents, and oxygen-splitting agents.
  - Not an oil or gas type.
  - Approved by FDA and local regulations for chemical products.



Do not clean the equipment while the power is still on. This can cause electrical shock, burns, and other injuries to you or other people near the equipment.



Oil or gas-type cleaning agents can cause corrosion and deterioration.

## 12.2 Cleaning

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

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

Accessory /Part	Procedure
Bite (Normal / Special A / Special B)	1) Remove visible soil with a paper wipe or disposable cloth.
Temple Supports	2) Use a soft cloth dampened with a cleaning agent. And gently wipe the target area with the cloth.
Chinrest	3) Dry the cleaned parts and accessories with a dry cloth until no liquid is left.
PC and its peripherals	Clean each part following the manufacturer's instructions
Outer covers	Wipe the outer covers with a dry cloth once a day.

### NOTICE

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

### WARNING

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

### IMPORTANT

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

### 12.3 Disinfection

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

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



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## 13. Maintenance

### 13.1 Regular Maintenance

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

## 13.2 Maintenance Task Checklist

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



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



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



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

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## 15. Technical Specifications

### 15.1 Mechanical Specifications

#### 15.1.1 Dimensions (unit = mm)

	With CEPH unit	Without CEPH unit
Top view		
Side view		

#### (Wall bracket dimensions)

Front view	Side view

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)
Rotating Unit Vertical Movement		1905.9 (L) x 1557.5 (W) x 2337.5 (H) (mm, with Base)
Installation Type		75.1 (L) x 61.4 (W) x 92.1 (H) (inch, with Base)
Packing Box Organization		Base Stand/Wall Mount (Default: Wall Mount type)
		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

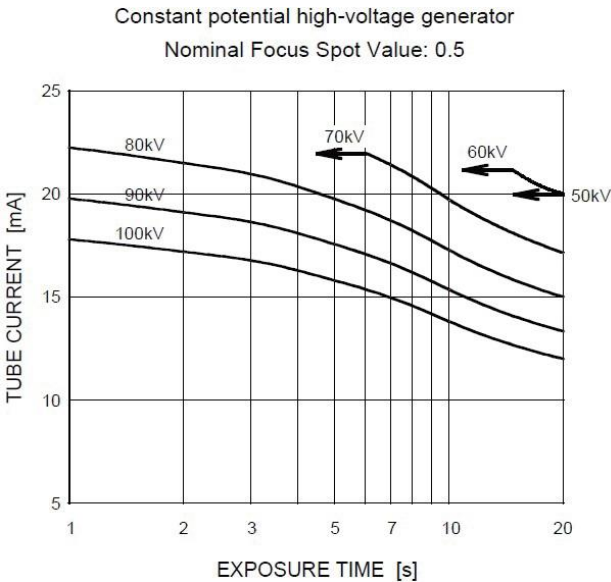
#### 15.2.1.1 Specifications

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
	Permanent filtration	Min. 1.0 mm Al
Tube	Added filter	1.5 mm Al (Fixed)/PANO and CEPH mode 1.5 mm Al (Fixed) + 3.0 mm Al (Automatically added)/CBCT mode
	Manufacturer	Canon
	Model	D-052SB (Stationary Anode type)
	Focal spot size	0.5 mm (IEC 60336)
	Target Angle	5 degrees
	Permanent Filtration	At least 0.8 mm Al equivalent at 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)

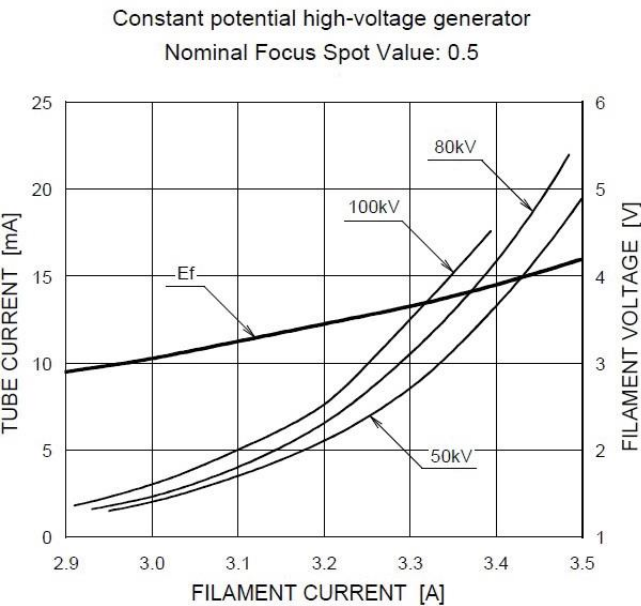
## 15.2.1.2 Test Condition

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
	60 ~ 90	4 ~ 14	1.4
CEPH	60 ~ 99	4 ~ 16	1.9
	60 ~ 99	4 ~ 15	2.4
	60 ~ 99	4 ~ 15	3.9
	60 ~ 99	4 ~ 14	4.9
	60 ~ 99	4 ~ 14	5.4
CBCT	60 ~ 99	4 ~ 12	16.4
	60 ~ 99	4 ~ 12	11.0

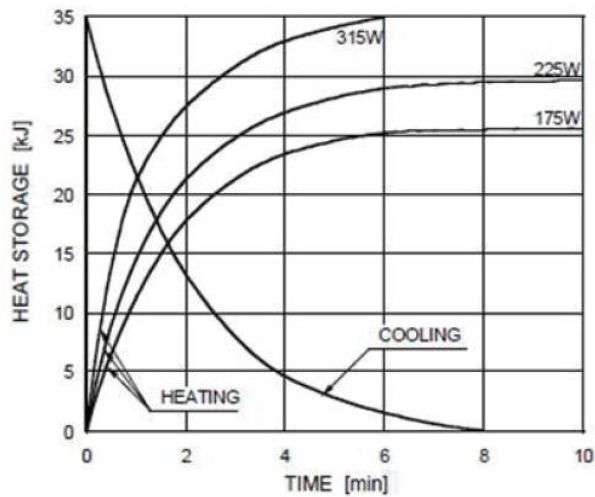
15.2.1.3 Maximum Rating Charts



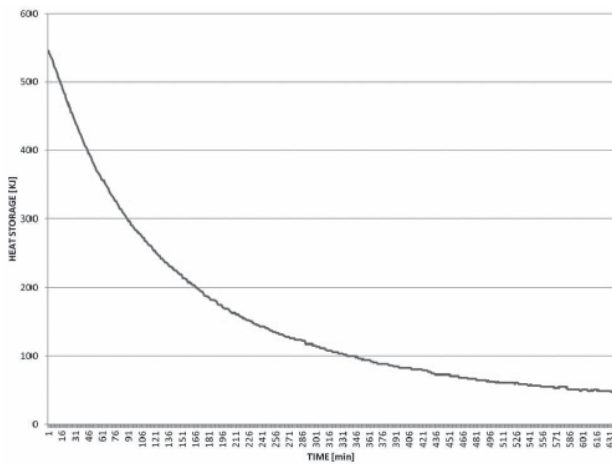
15.2.1.4 Emission & Filament Characteristics



### 15.2.1.5 Anode Thermal Characteristics



### 15.2.1.6 X-ray Housing Assembly Tube Characteristics



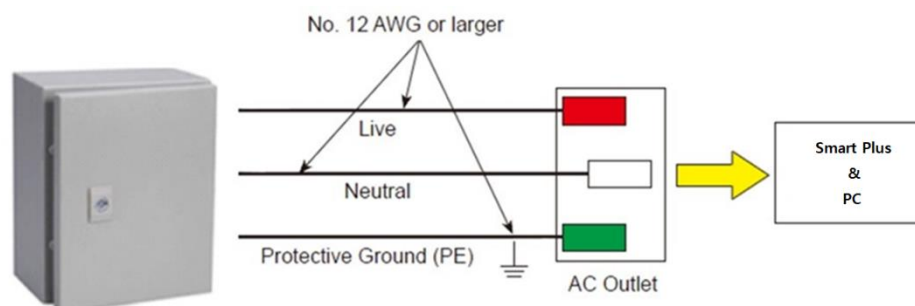
### 15.2.2 Detector Specifications

Item	Description	
	PANO & CBCT	CEPH
Model	Xmaru1404CF-Plus	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 $\mu\text{m}$ @ 4X4 binning (49.5 $\mu\text{m}$ @ no binning)	200 $\mu\text{m}$ @ 2x2 binning
Active area	CBCT - 36.4 mm X 135.8 mm PANO - 5.9 mm X 135.8 mm	259.20 x 15.60 (mm)
Frame Rate	~ 308 fps @ 4X4 binning	~ 320 fps @ 2x2 binning
Analogue-Digital Conversion	14 Bit	
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	<1.0 kg
Converter	CsI:Ti	
Energy Range	50 ~ 120 kVp	40~120 kVp
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 40 % @ 1 lp/mm > 8 % @ 2.5 lp/mm	$\geq 2$ % @ 2.5 lp/mm
Dynamic Range	> 80 dB	$\geq 68$ dB

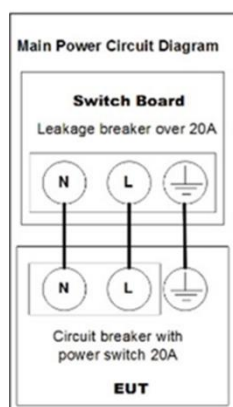
## 15.3 Electrical Specifications

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) $\pm (5\% + 50\text{ ms})$

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



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



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 &gt; 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

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)	<b>PANO:</b> $\leq 93 \text{ mGy} \cdot \text{cm}^2$ (Adult)/ $67 \text{ mGy} \cdot \text{cm}^2$ (Child) <b>CEPH:</b> $\leq 40 \text{ mGy} \cdot \text{cm}^2$ (Adult, Lateral)/ $25 \text{ mGy} \cdot \text{cm}^2$ (Child, Lateral) <b>CBCT:</b> $\leq 250 \text{ mGy} \cdot \text{cm}^2$ (Basis of the single implant)
AERB (IND)	Dose	All dose values must be within $\pm 20 \%$ of the SPECIFIED values

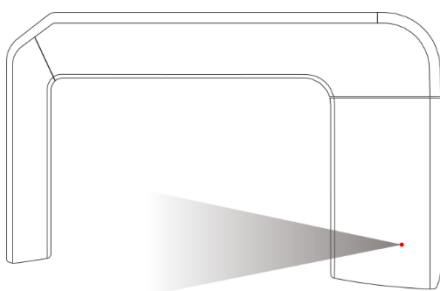
### 16.2.1.2 DAP (Dose Area Product) Calculation

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

#### 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 <sup>2</sup> ]
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

Mode	Exposure Condition	DAP [mGy·cm <sup>2</sup> ]
CBCT FOV 10x8.5 Adult Man (Green)	79 kVp/5.0 mA/16.4 s	256
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

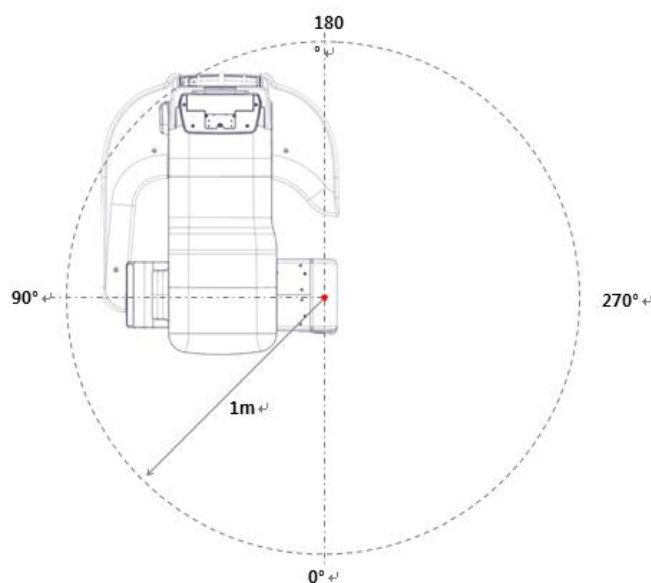
## 16.2.2 Leakage Dose

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

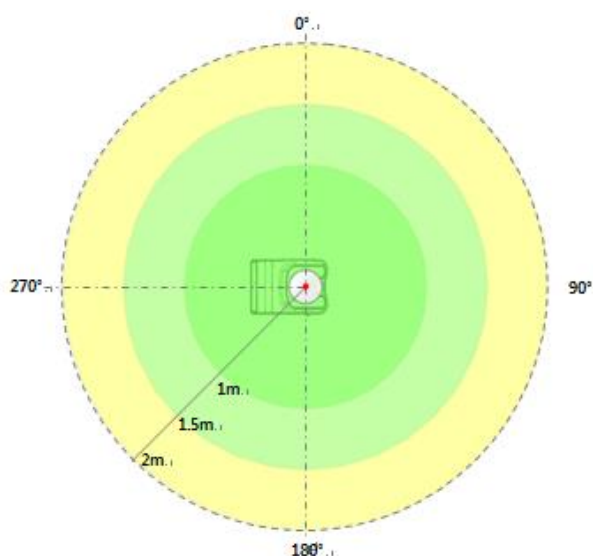
#### 16.2.2.5.2 Results

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

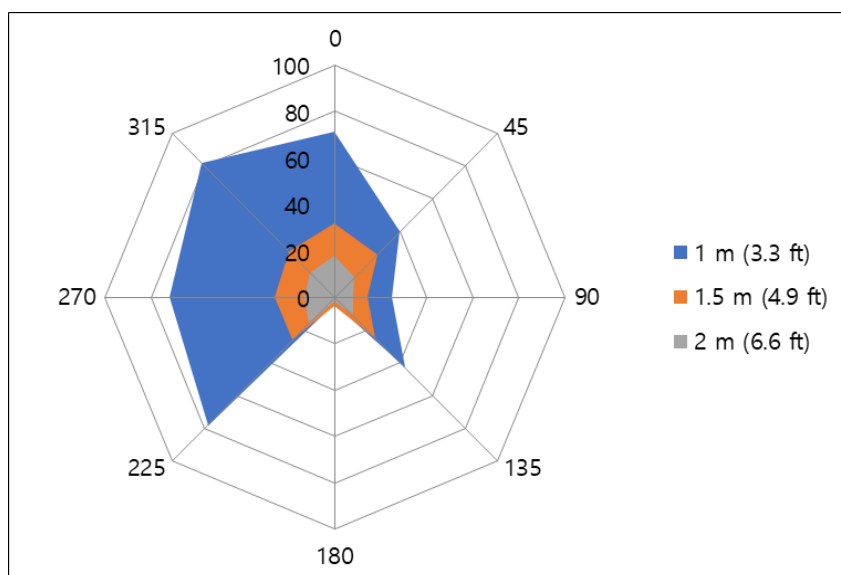
#### 16.2.3.2.1 PANO Option: Normal

##### 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



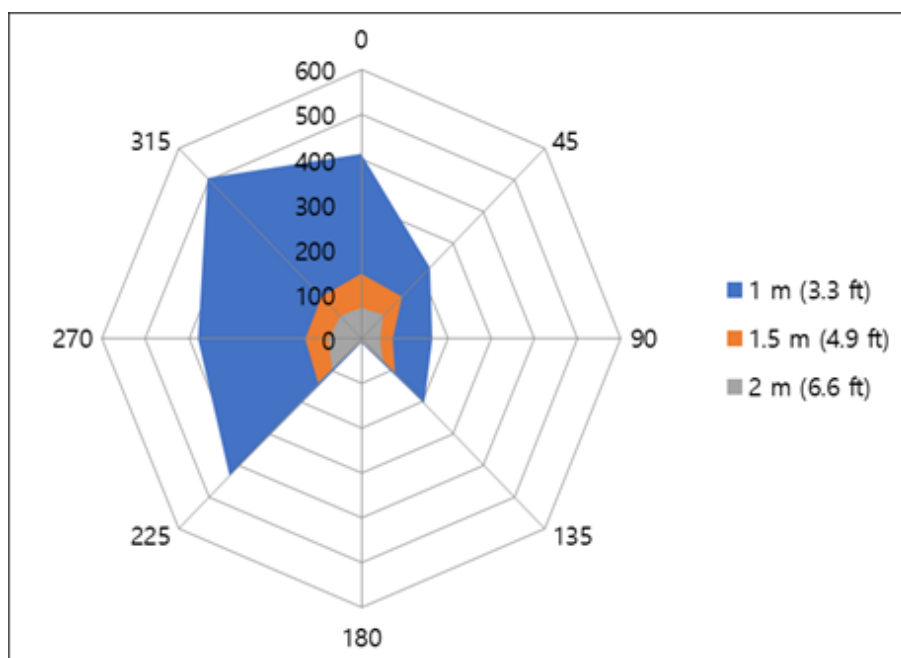
## 16.2.3.2.2 PANO Option: Insight PAN

## 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



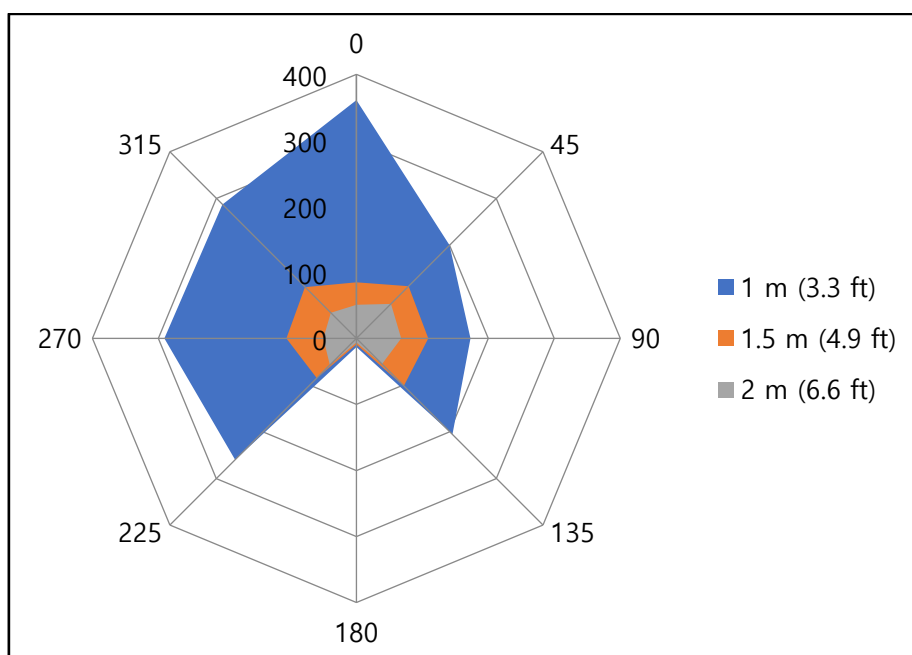
### 16.2.3.3 CBCT Mode

#### 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

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: $\pm 2$ kV Signal: $\pm 1$ 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 $\pm 0.5$ kV, $\pm 1$ kV  Line to Ground $\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ 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



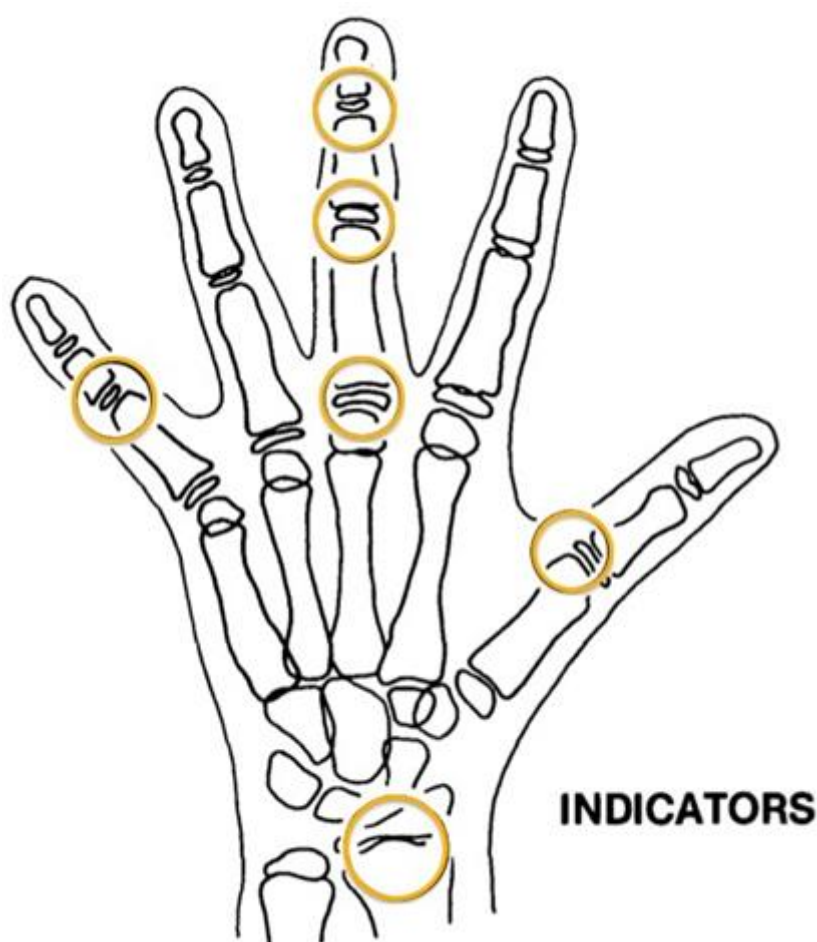
## 16.4 Hand-wrist Image Evaluation References

**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.

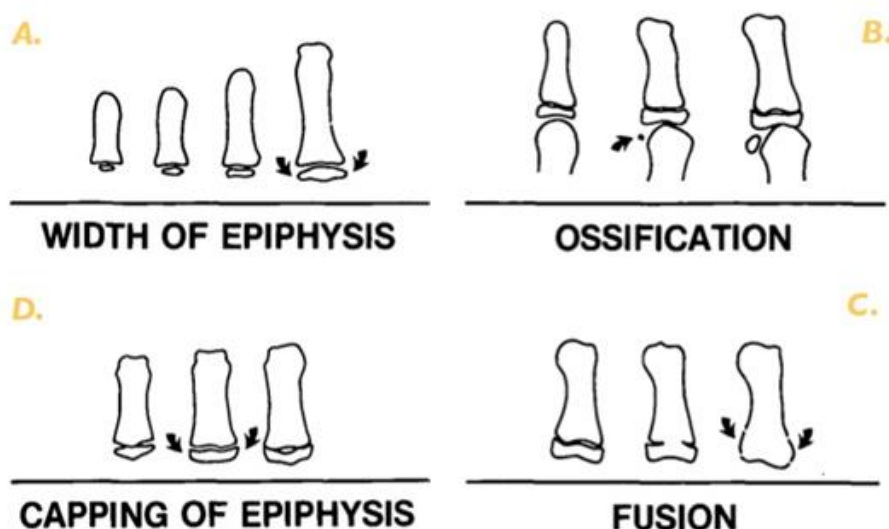


Fig. 2 Radiographic identification of skeletal maturity indicators.  
 A. Epiphysis equal in width to diaphysis.  
 B. Appearance of adductor sesamoid of the thumb.  
 C. Capping of epiphysis.  
 D. Fusion of epiphysis.

[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**

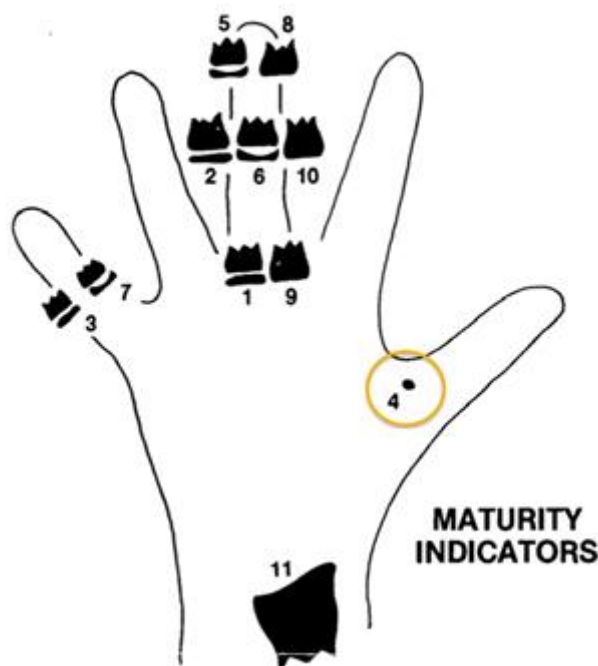
1. Third finger –distal phalanx
2. Third finger –middle phalanx
3. Fifth finger – middle phalanx

### D. Fusion

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

### ◆ Eleven Skeletal maturity indicators (SMIs)

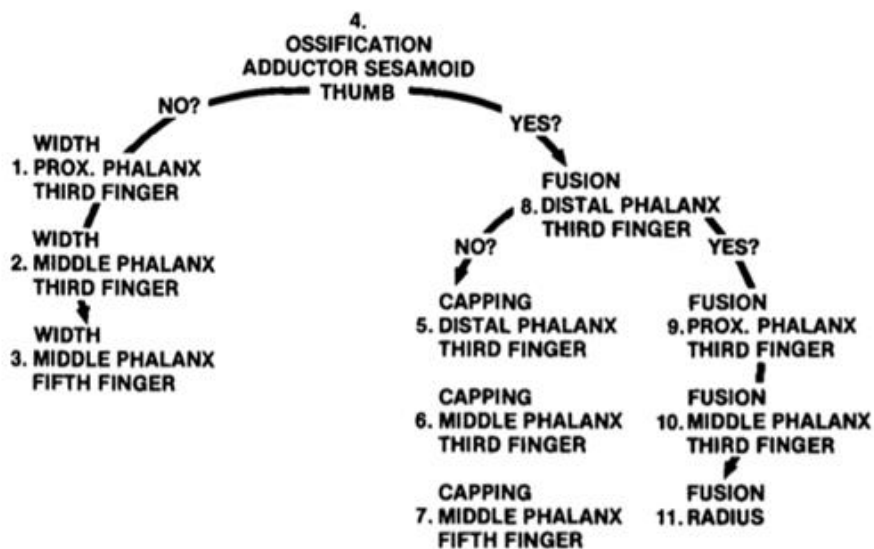
The System uses only four stages of bone maturation, all found at six anatomical sites located on the thumb, third finger, fifth finger, and radius, as seen in Fig 1. Eleven discrete adolescent skeletal maturational indicators (SMI's), covering the entire period of adolescent development, are found on 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.dimensionsofdentistry.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.<sup>1-3</sup> While the panoramic technique seems relatively straightforward, producing a diagnostic quality image of the pediatric patient requires a mastery of technical skills.<sup>4</sup> Modern panoramic x-ray equipment is designed for ease of use, yet studies continue to demonstrate a high incidence of errors.<sup>5-7</sup> Positioning errors may occur at an even higher rate in pediatric panoramic radiographs.<sup>7</sup> 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.<sup>8,9</sup> 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.<sup>4,10</sup> 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.

FEBRUARY 2009

Dimensions OF DENTAL HYGIENE

### Anterior-Posterior Positioning Error

When the arches are positioned incorrectly in the anterior-posterior direction, distortion or ghosting of the anterior anatomy occurs. Unerupted teeth in the anterior region may not be imaged on the radiograph if positioned outside of the focal trough. It is important to note that an error of only 3 mm to 4 mm in either direction will result in a significantly compromised image.<sup>11</sup> 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.

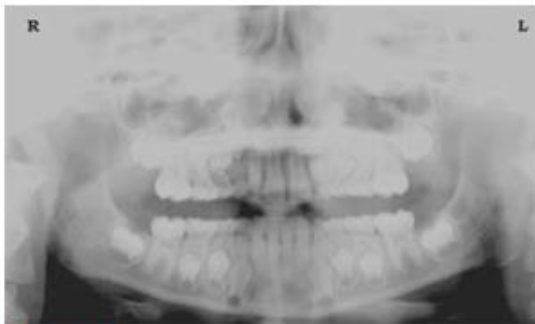
To avoid imaging errors that result from incorrect lateral positioning, the midsagittal plane must be positioned perpendicular to the floor. Most panoramic x-ray machines have a head positioner and/or laser light beam guide, along with a mirror, to assist in determining the correct lateral head position. 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.<sup>9</sup>

### 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.<sup>11</sup>

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.<sup>7</sup> 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.<sup>7</sup>

## 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.<sup>6</sup> 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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*Elsevier Mosby; 2000:71-72.*

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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

<b>AC</b>	Alternating Current
<b>AF</b>	Auto-Focusing
<b>AMPT</b>	Adaptive layer Mode Panoramic Tomography
<b>CAN</b>	Controlled Area Network
<b>CBCT</b>	Cone-Beam Computed Tomography
<b>CMOS</b>	Complementary Metal-Oxide -Semiconductor
<b>CT</b>	Computed Tomography
<b>DAP</b>	Dose Area Product
<b>DC</b>	Direct Current
<b>DICOM</b>	Digital Imaging and Communications in Medicine
<b>EMC</b>	Electromagnetic Compatibility
<b>ENT</b>	Ear, Nose, and Throat
<b>ESD</b>	Electrostatic Discharge
<b>EUT</b>	Equipment Under Test
<b>FDD</b>	A focal spot to Detector Distance
<b>FOD</b>	A focal spot to Object Distance
<b>FOV</b>	Field of View
<b>FPD</b>	Flat Panel Detector
<b>IEC</b>	International Electrotechnical Commission
<b>ISO</b>	International Standards Organization
<b>LED</b>	Light-Emitting Diode
<b>MAR</b>	Metal Artifact Reduction
<b>MPSO</b>	Multiple Portable Socket-Outlet



<b>ODD</b>	Object to Detector Distance
<b>PA</b>	Posterior/Anterior
<b>RF</b>	Radio Frequency
<b>ROI</b>	Region of Interest
<b>SID</b>	Source to Image Receptor Distance
<b>SIP</b>	Signal Input Part
<b>SOP</b>	Signal Output Part
<b>SMV</b>	Submento-Vertical
<b>STL</b>	Stereo Lithography
	Temporomandibular Joint
<b>UHD</b>	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.

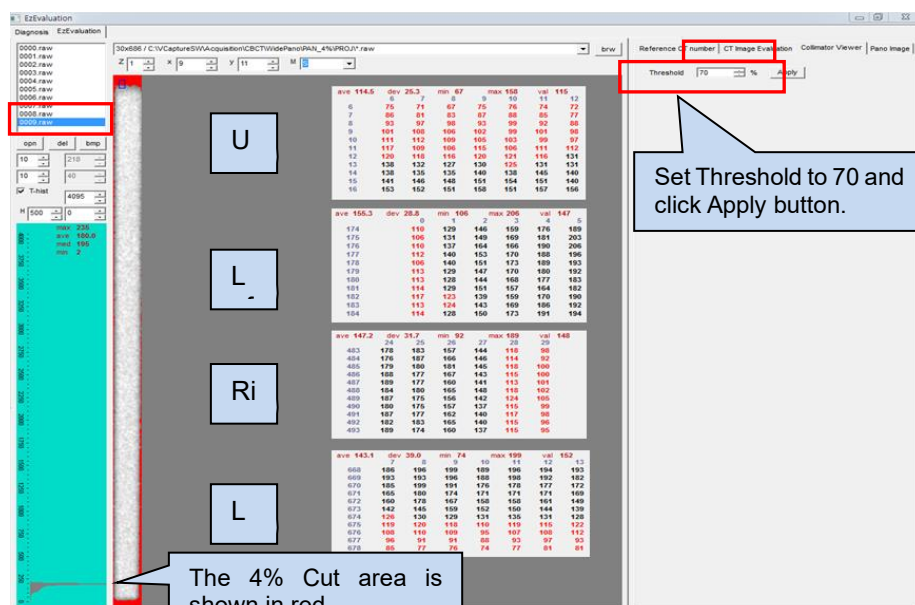
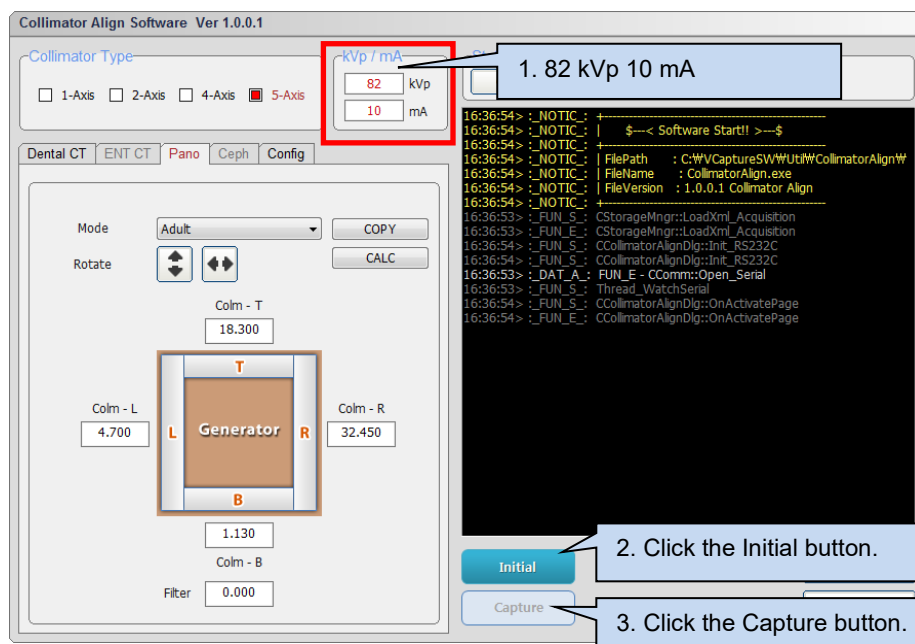
##### 17.1.1.2 Image Evaluation Phantom Configuration

- 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

1. Run C:\VCaptureSW\Util\CollimatorAlign\CollimatorAlign.exe.



2. Run EzEval.exe and select **EzEvaluation** from the top left tap menu.

3. 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:\VCaptureSW\Acquisition\X-Ray Image folder.

**FOV 100x85 4% Cut Standard Value**

<b>Collimator</b>	<b>Min</b>	<b>Max</b>
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**

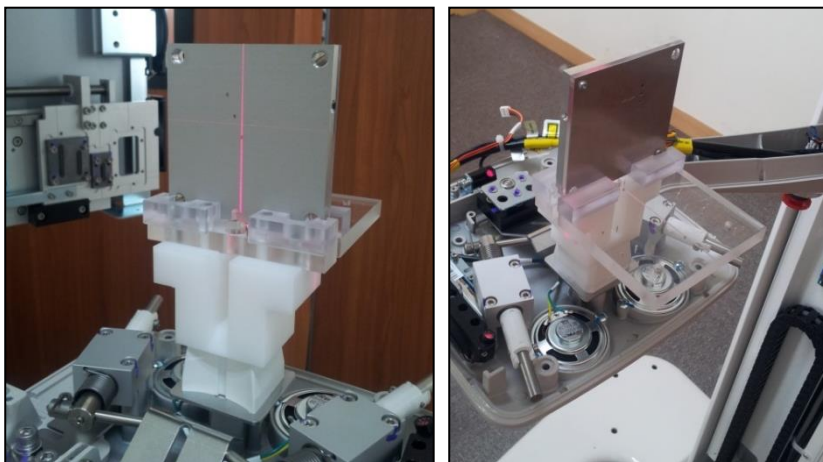
It is recommended to check X-ray Alignment by X-ray exposure when Generator Tube temperature is 25 ~ 30 °C."

**17.1.2.2 Geometry Phantom**

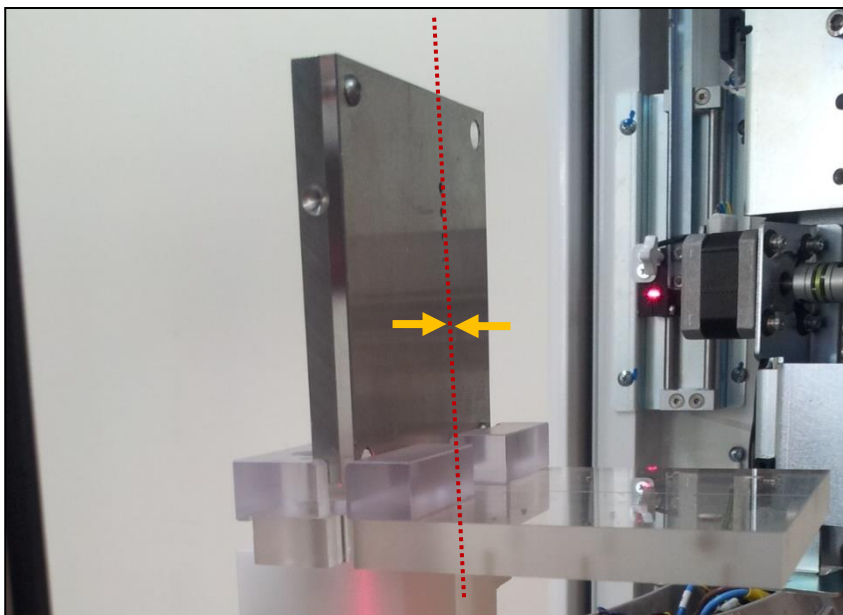
Acquiring an image for image evaluation, the procedure of the Image Inspection manual should be completed.

#### 17.1.2.2.1 Phantom alignment

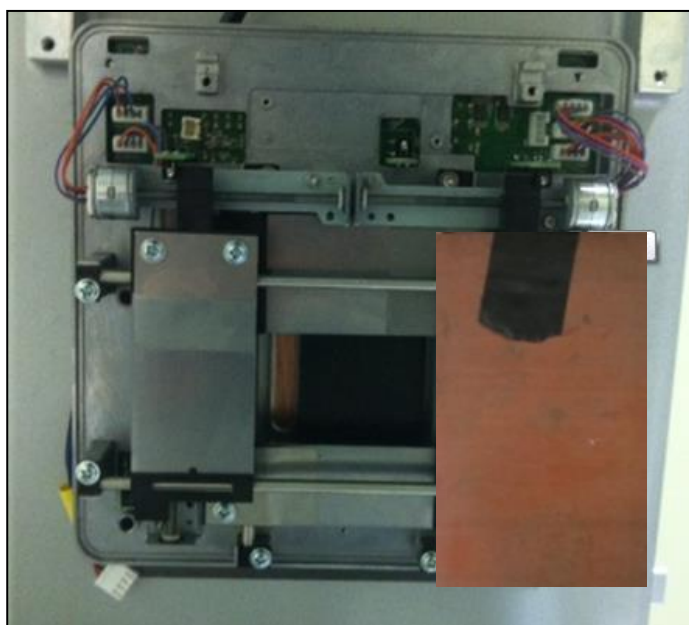
1. When the machine moves to Position mode, mount Ball Phantom and Quart Phantom on Chinrest as shown in the picture.



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

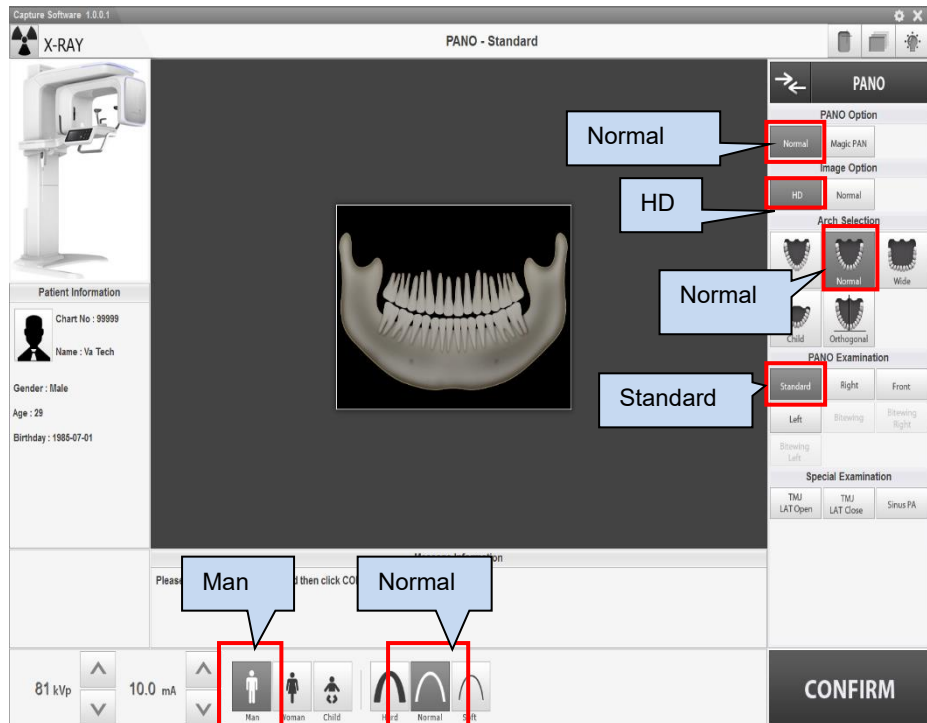


3. Attach a 1.8T copper filter in front of the collimator.

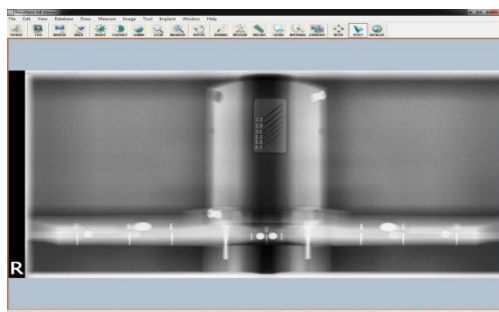


### 17.1.2.2.2 Capture S/W

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

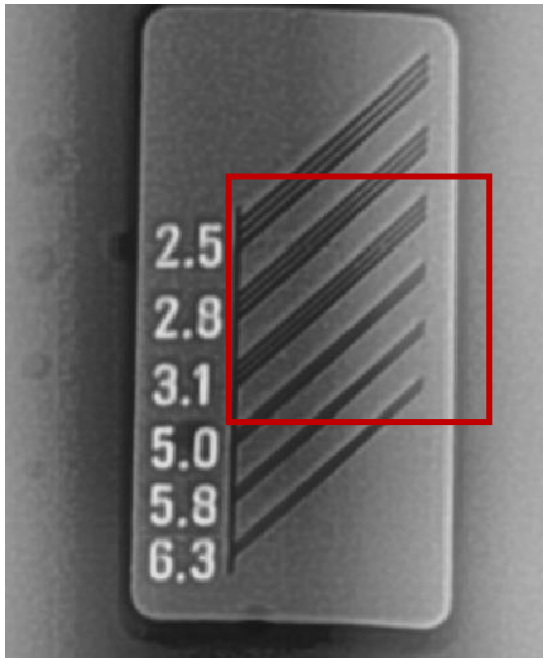




### 17.1.3 Pano image Evaluation

#### 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.

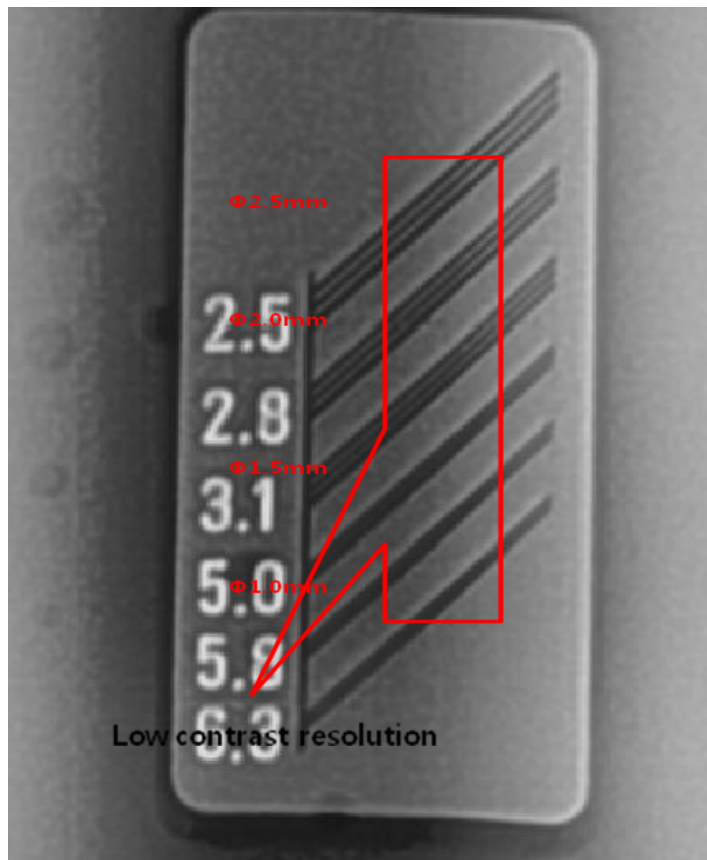


	VATECH Standard	Remarks
Line Pair	3.1 lp/mm	

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.

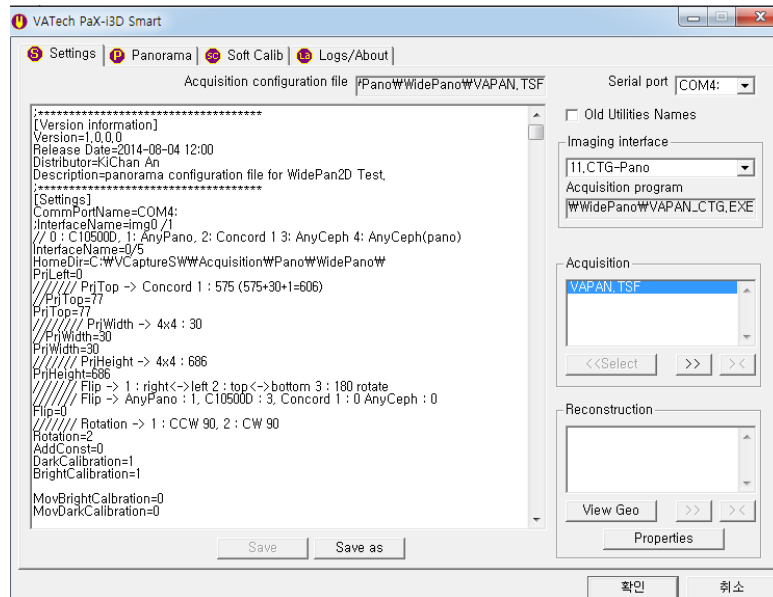


	VATECH Standard	Remarks
Line Pair	0.5 mm or less	

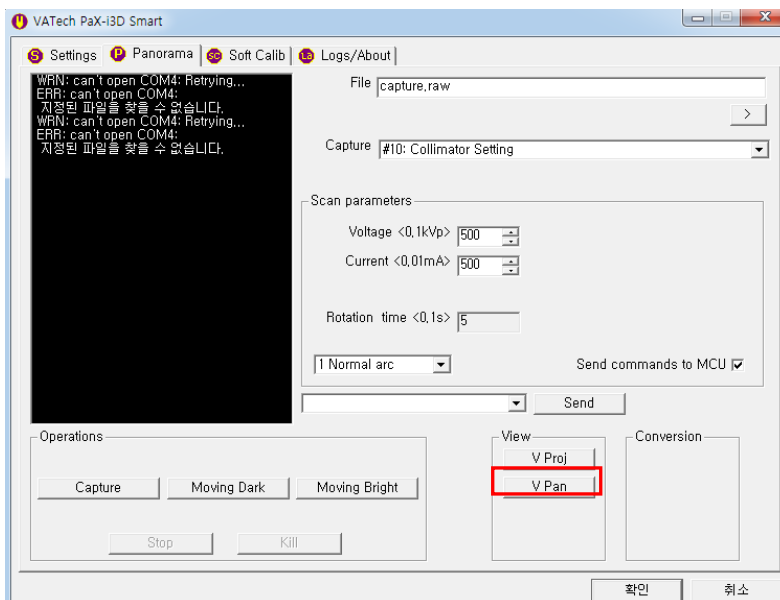
3. Check if the left hole is 1.5 mm.

### 17.1.3.3 Pano Image Noise (Dev) and Homogeneity Methods

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

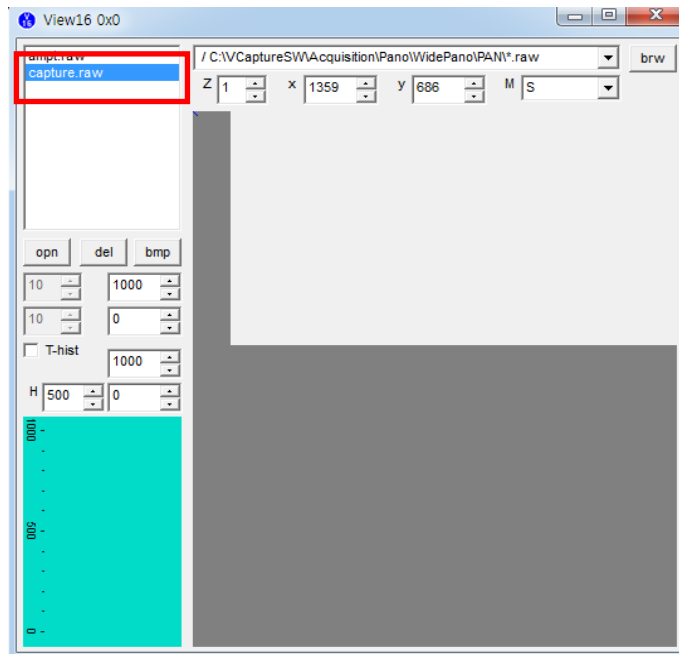


2. Select the Panorama Tab.
3. Click the V Pan button to call the View16 Program.

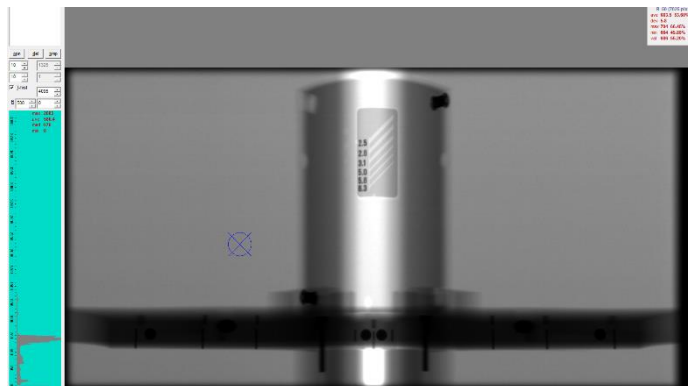


4. Select the Capture. raw file to load the captured image.

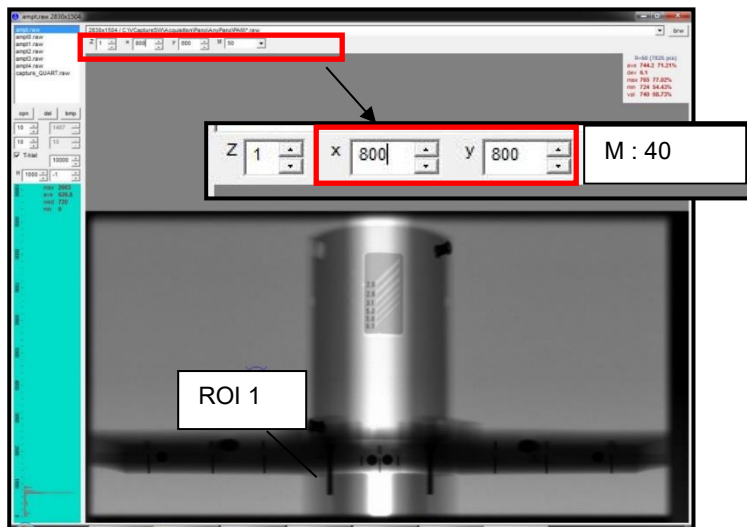
5. Panorama image size: 2719 (variable) x 1372 (constant)



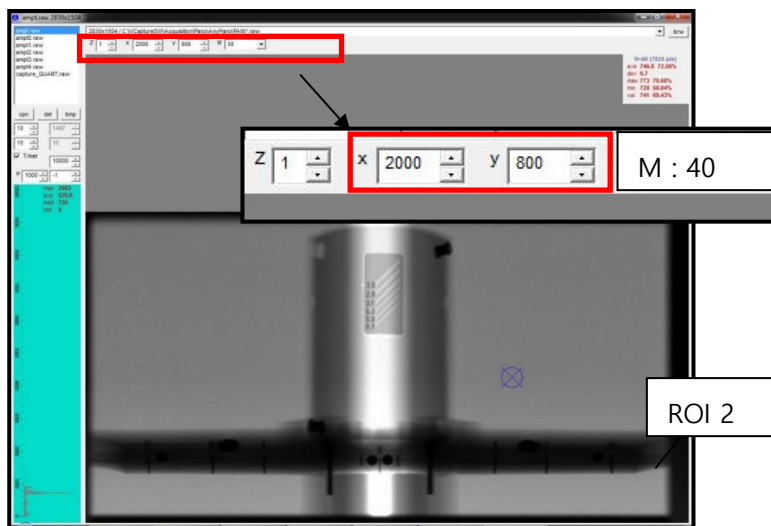
6. Enter Capture. raw and Image Size to display the following image.



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

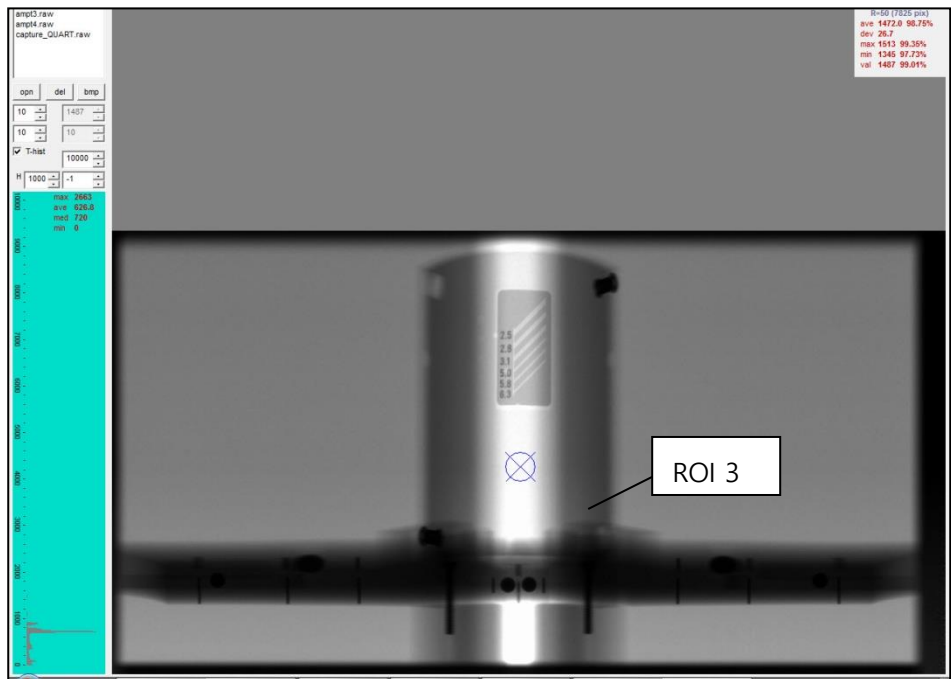


8. As shown in the above figure, check if the noise (dev) and homogeneity (avg) of the ROI1 part meet the Reference value.
9. Enter “2000” in the “x” coordinates and “800” in the “y” coordinates.



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

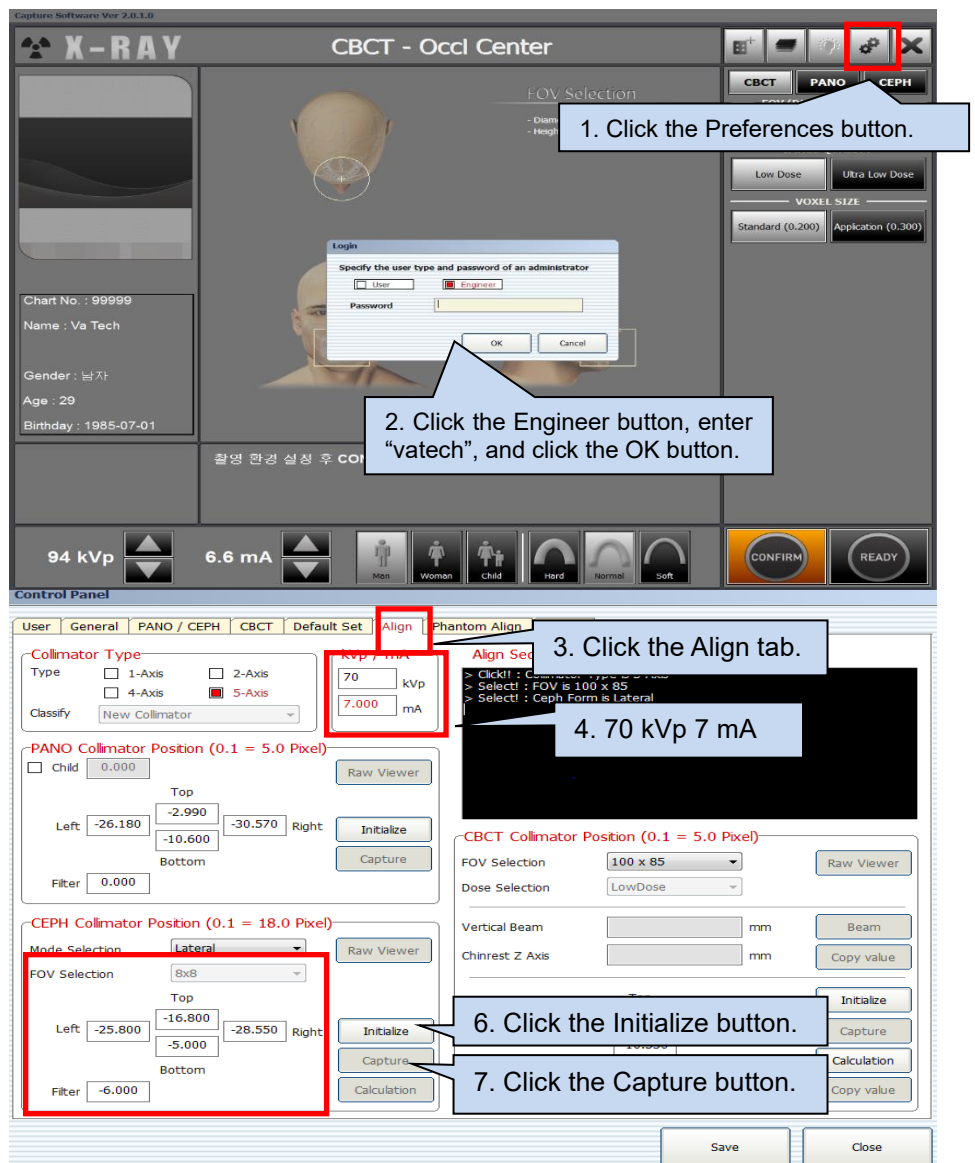
- X-ray alignment: evaluates the accuracy of symmetry in the "X-ray on" area.
- Geometry phantom: evaluation for the "Geometry accuracy"
- Line pair resolution: More than 2.5 Lp/mm
- Low contrast resolution: evaluates the "Noise (Dev)" and "Homogeneity."

## 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.





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.

	<b>Align Criteria</b> (T-hist “75” setting)	<b>Pixel Criteria</b>	<b>Remarks</b>
1 <sup>st</sup> Collimator	Upper/Lower X-ray off area	20~50 pixel	
2 <sup>nd</sup> 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.

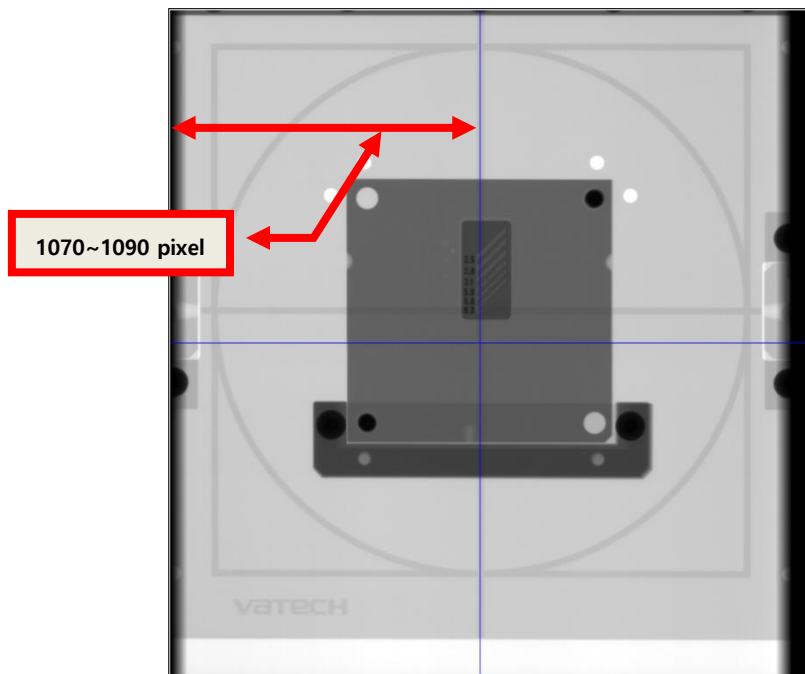


4. The exposure conditions of the frontal mode Phantom are as follows.
  - Exposure conditions: 60 kVp, 5 mA
  - Mode: PA mode



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.

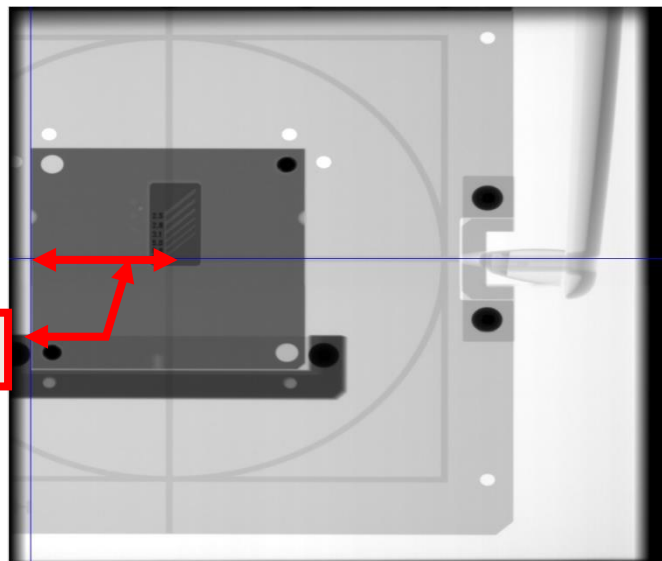
**Default: [spm\_xfta\_0100]**

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
- Filter: Mount the 1T Cu Filter.



- 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]**

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

### 17.2.3 Evaluate the Quart Phantom

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)

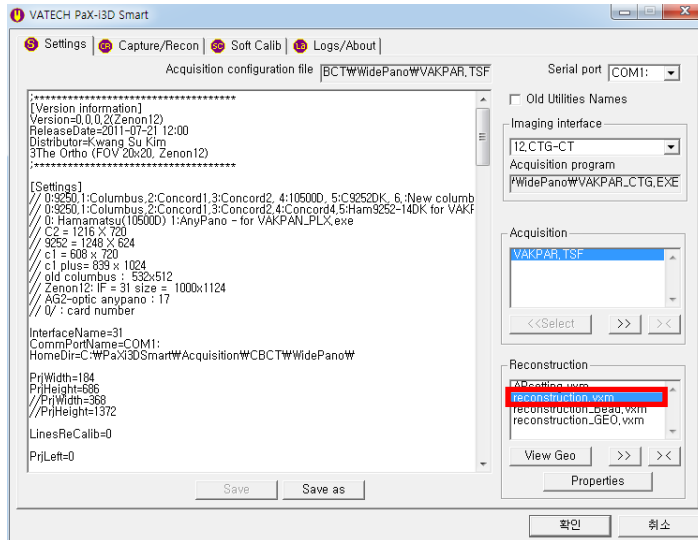
#### **17.3.1.3 Image Evaluation Phantom Configuration**

- 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

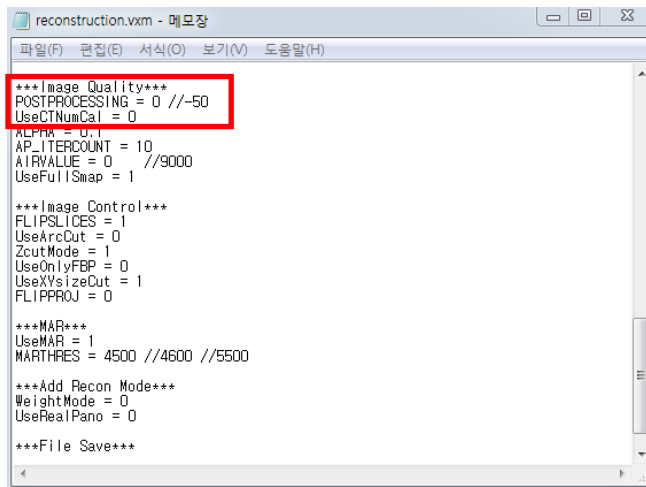
1. VAKCAP.exe in all folders and double-click on the Reconstruction. vxm file.



2. When evaluating with Phantom, change UseArcCut = 0, and when all evaluations are complete, change UseArcCut = 1.

- Each Phantom is labeled DICOM, SLICE.

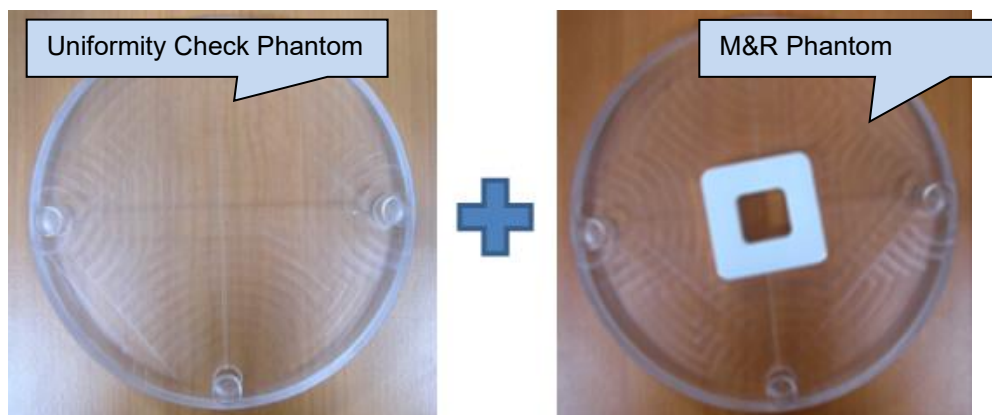
- ① DICOM: POSTPROCESSING = -50, UseCTNumCal = 1
- ② SLICE: POSTPROCESSING = 0, UseCTNumCal = 0



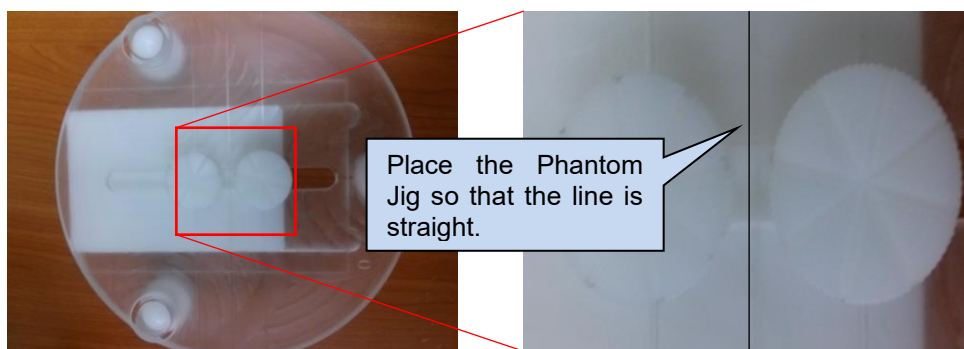
### 17.3.2.2 Acquire M&R, Uniformity Phantom Image (DICOM, SLICE)

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

#### 17.3.2.2.1 Phantom alignment

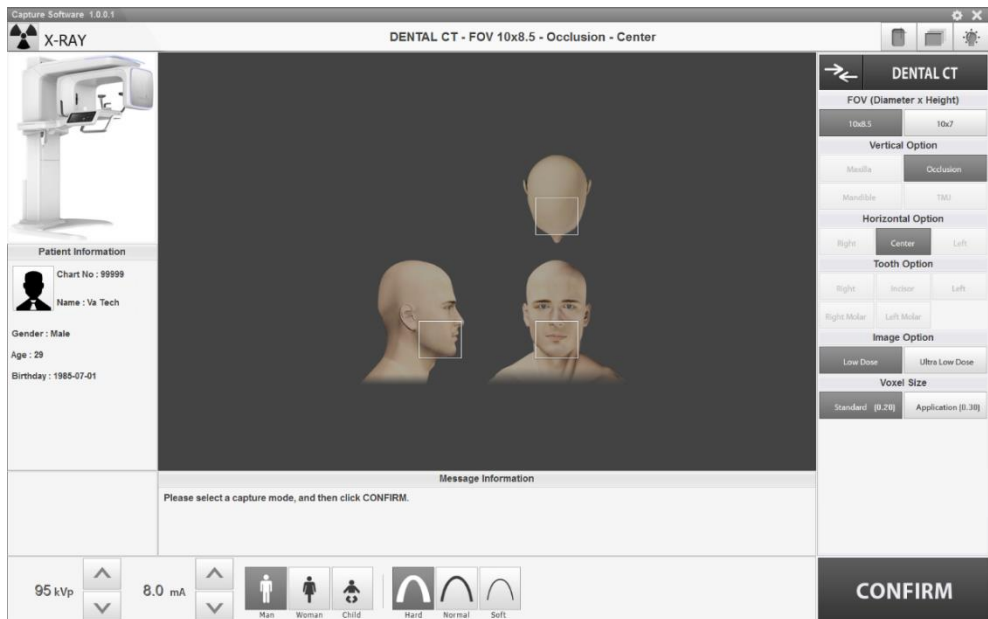


Tighten the Phantom jig in the order of Uniformity Check (bottom) and M & R Phantom (top).





## 17.3.2.2.2 Acquire Image

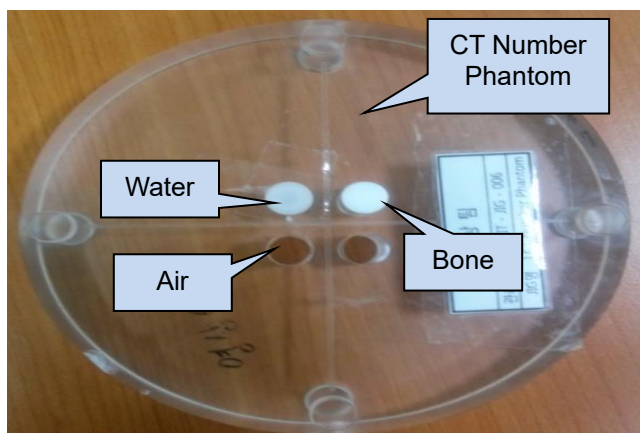


1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Exposure with M&R and Uniformity Phantom on Phantom Jig.
3. When the reconstruction is completed, change the Slice image folder name and C:\VCaptureSW\ImageOutput\CT in C:\VCaptureSW\Acquisition\CBCT\WidePano\SLICE folder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

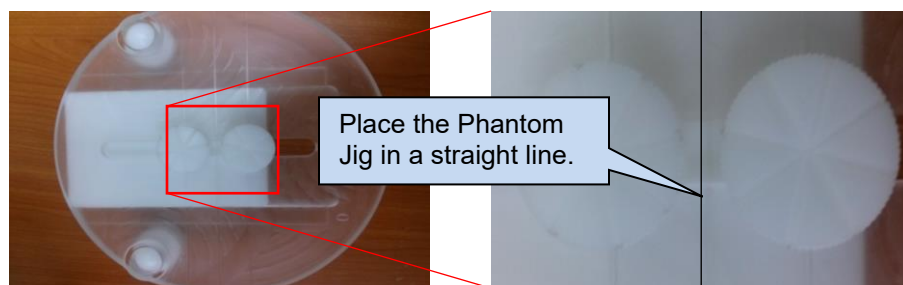
#### 17.3.2.3.1 Phantom alignment



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

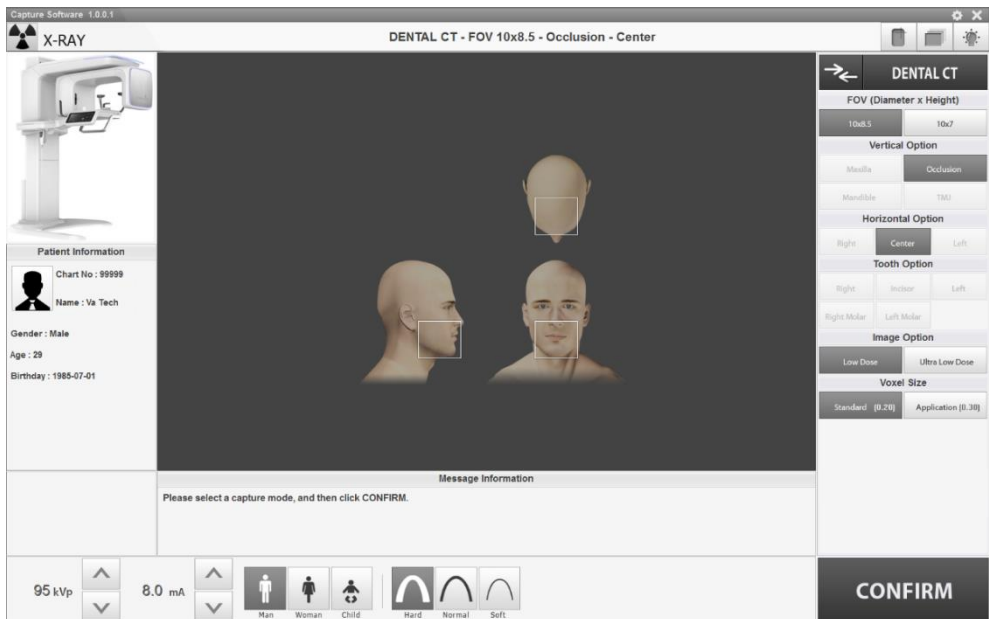
**NOTICE**

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



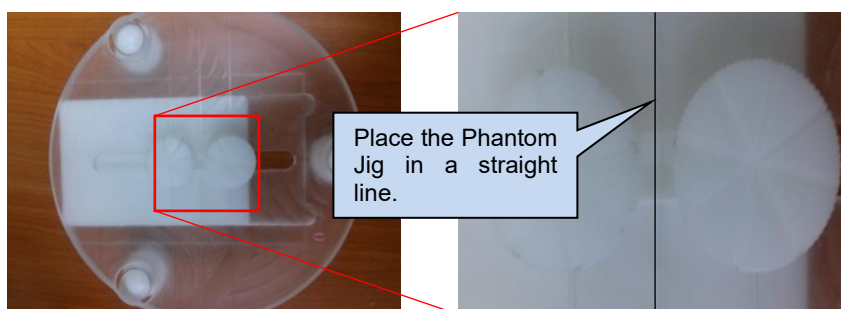
1. Put the S&C Phantom on the Phantom Jig.

---

**NOTICE**

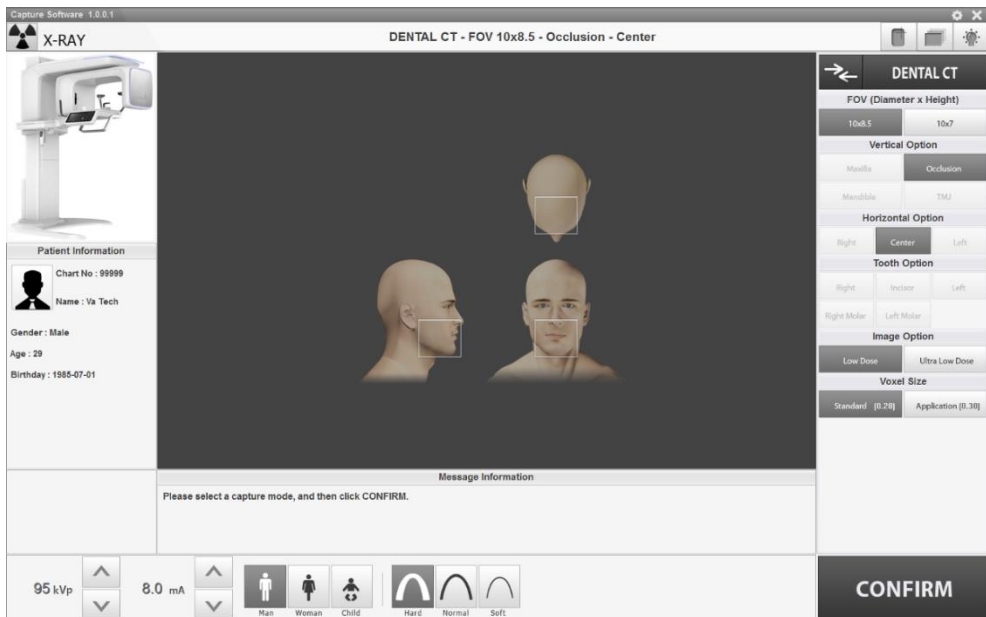
Use Phantom Jig for only PHT-30LFO.

---



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

## 17.3.2.4.2 Acquire Image

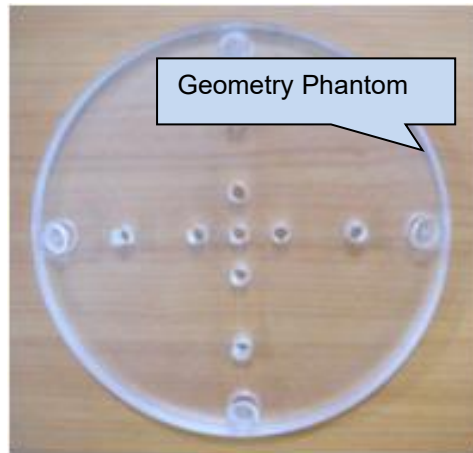


1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Place the S&C Phantom on the Phantom Jig and exposure.
3. When the reconstruction is completed, change the CT folder name of C:\VCaptureSW\ImageOutput\CT folder to CT\_S&C Phantom and save it.

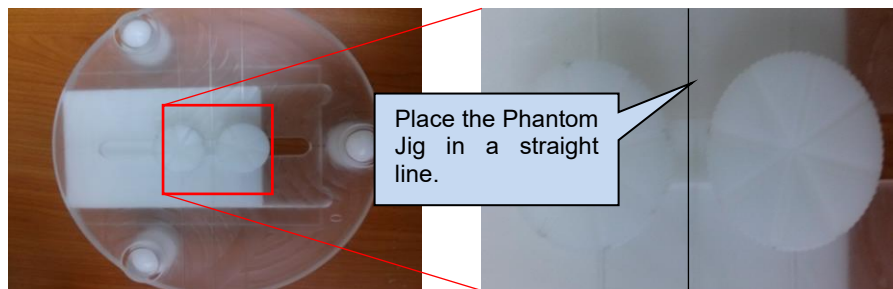
### 17.3.2.5 Acquire Geometry Phantom Image (SLICE)

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

#### 17.3.2.5.1 Phantom alignment

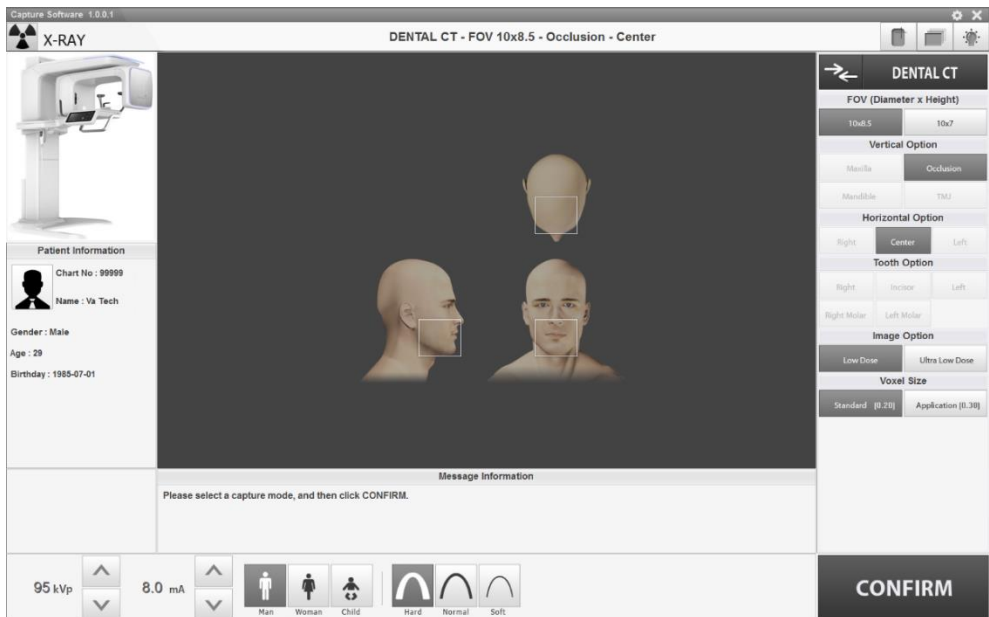


1. Put the Geometry Phantom on the Phantom Jig.



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

## 17.3.2.5.2 Acquire Image

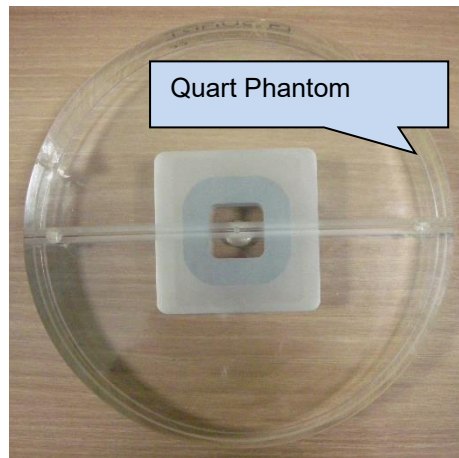


1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Place the Geometry Phantom on the Phantom Jig and exposure.
3. When the reconstruction is completed, change the SLICE folder name in C:\VCaptureSW\Acquisition\CBCT\WidePano\SLICE folder to Slice\_Geometry and save.

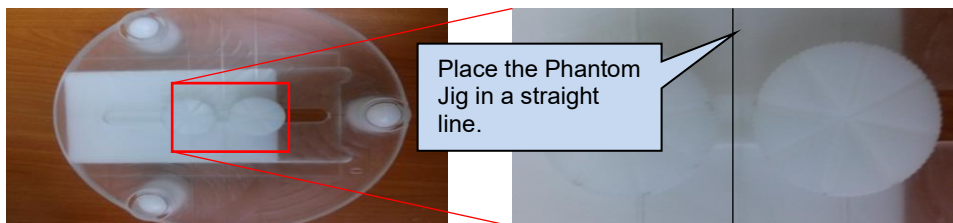
### 17.3.2.6 Acquire Quart Phantom Image (DCM) -After assembling the case

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

#### 17.3.2.6.1 Phantom alignment

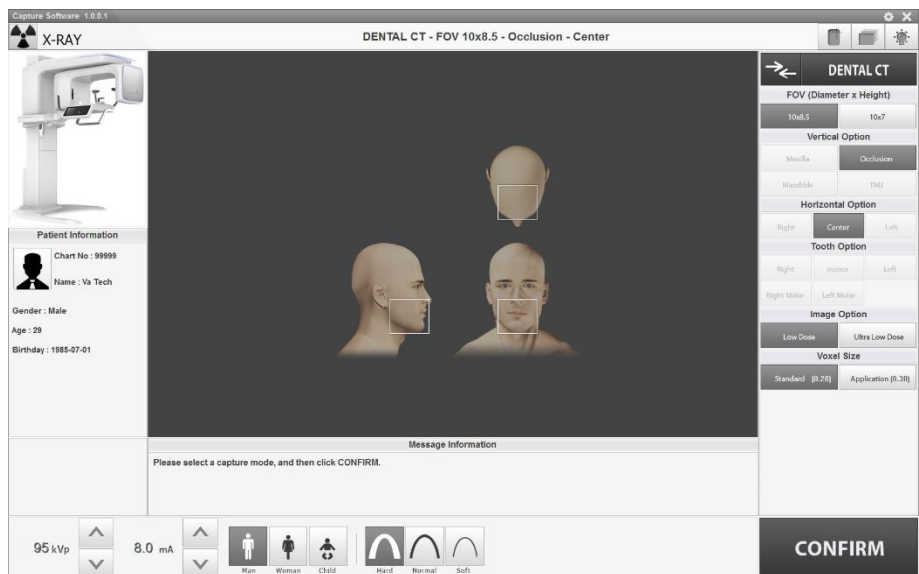


1. Level the tripod and place the Tooth Positioning Phantom on it.



2. Tighten Quart Phantom on CT Number.





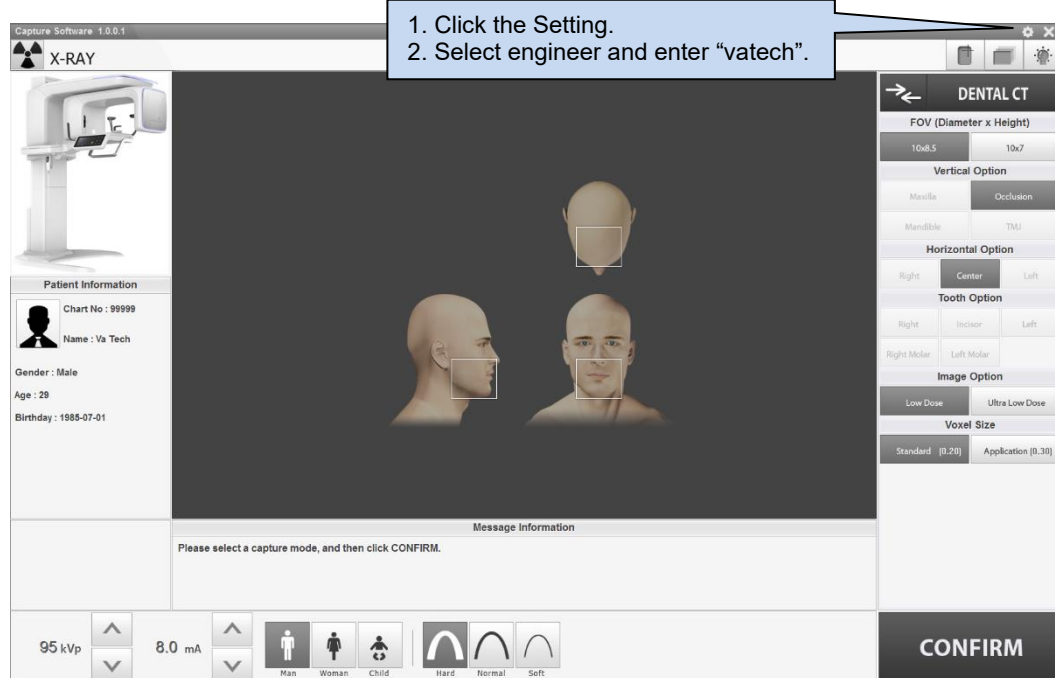
1. Run the capture program and select 10x8.5, Low Dose, Standard, Man, Hard.
2. Place the Quart Phantom on the Phantom Jig and exposure.
3. When the reconstruction is completed, change the Slice folder name of **C:\VCaptureSW\ImageOutput\CT** folder to Quart\_Phantom and save it.

### 17.3.3 CT Image Evaluation

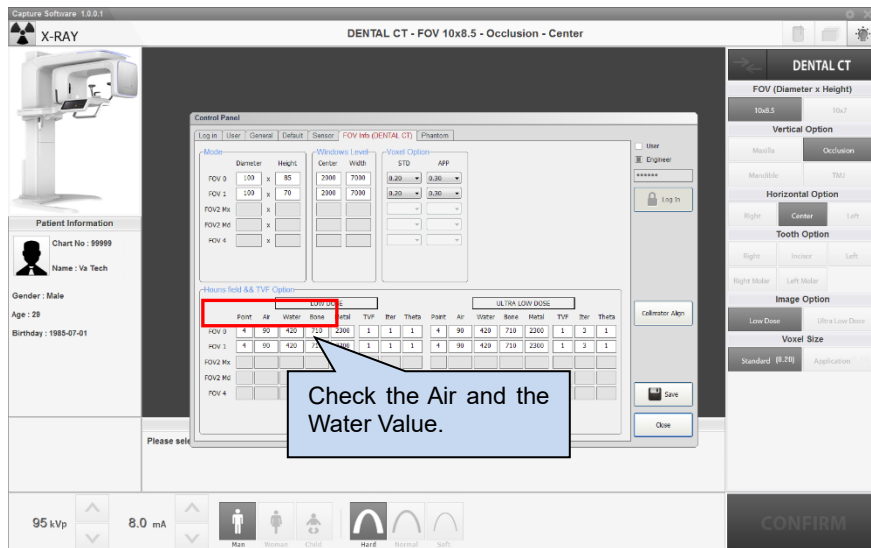
#### 17.3.3.1 Contrast & Noise (Dev) & Homogeneity Evaluation

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

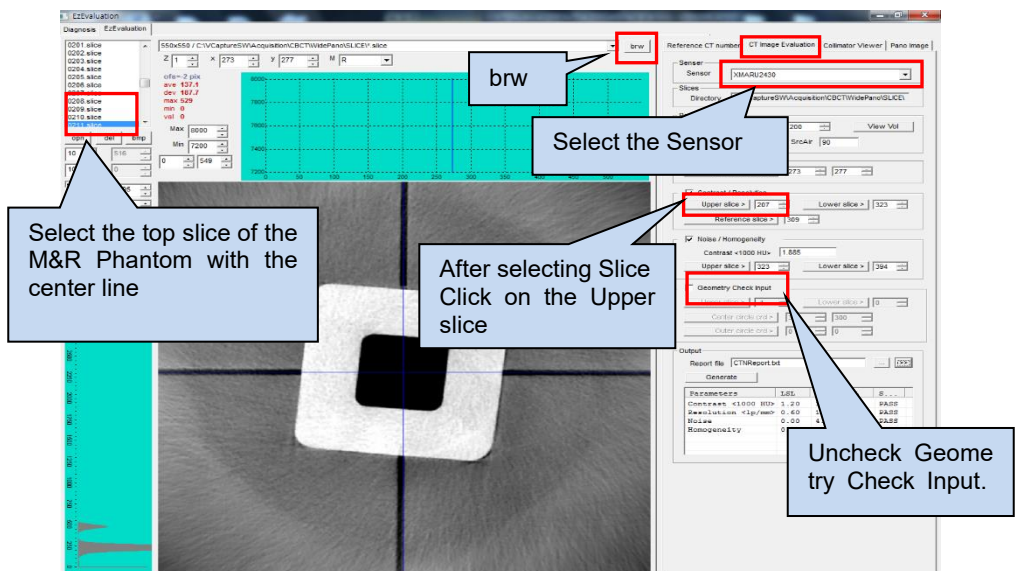
##### 17.3.3.1.1 M&R Phantom Slice



1. 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.

The screenshot shows the EeEvaluation software interface. The main window displays a CT scan image of a phantom. The left panel shows a list of slices, with '0328 slice' selected. The top panel shows the 'Reference data' section with 'Voxel Size <0.001mm>' set to 200. The right panel shows the 'Contrast / Resolution' and 'Noise / Homogeneity' sections, with 'Upper slice' and 'Lower slice' buttons. The bottom panel shows the 'Geometry Check Input' section, which is currently unchecked. Annotations with callouts point to various elements: 'Select the R' points to the 'R' button in the top panel; 'Input the Voxel size 200' and 'Input the Air and the' point to the 'Voxel Size' field; 'Select the Center line's center, And click the button' points to the 'Center circle crd' button; 'After selecting Slice Click on the lower slice' points to the 'Lower slice' button; 'After selecting Slice Click on the Upper slice' points to the 'Upper slice' button; 'Click on the Center' points to the center of the phantom image; 'Uniformity Phantom with center line only Select the upper slice' points to the '0328 slice' in the slice list.

Select the R

Input the Voxel size 200  
Input the Air and the

Select the Center line's center, And click the button

After selecting Slice  
Click on the lower slice

After selecting Slice  
Click on the Upper slice

Click on the Center

Uniformity Phantom with center line only  
Select the upper slice

Reference data

Voxel Size <0.001mm> 200 View Vol

Center circle crd > 275 237

Contrast / Resolution

Upper slice > 226 Lower slice > 332

Reference slice > 332

Noise / Homogeneity

Contrast <1000 HU> 1.800

Upper slice > 332 Lower slice > 413

Geometry Check Input

Upper slice > 1 Lower slice > 0

Center circle crd > 200 200

Outer circle crd > 0 0

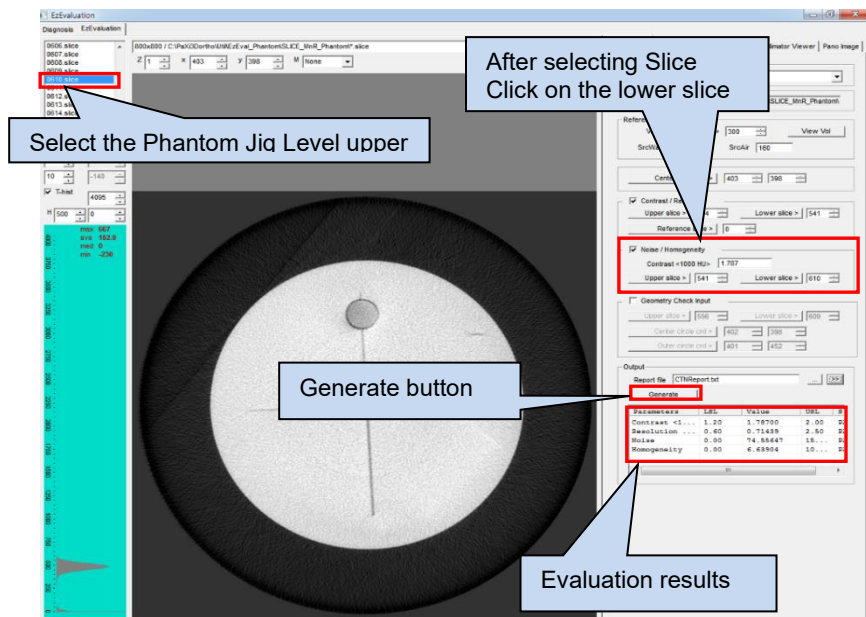
Output

Report file CTRReport.txt

Generate

Parameters	SL	Value	DSL	S...
Contrast <1000 HU>	1.80	1....	3.50	PASS
Resolution <lp/mm>	0.80	2....	2.50	PASS
Noise	0.00	39...	20...	PASS
Homogeneity	0.00	92...	25...	PASS

- Check the Air and Water values in the Control Panel, enter the SrcAir and SrcWater values in the Reference data and set the Voxel size to 200.
- 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.
- Click the Reference slice button.
- Select M as R, click the center of the center line and click the Center circle crd button.



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

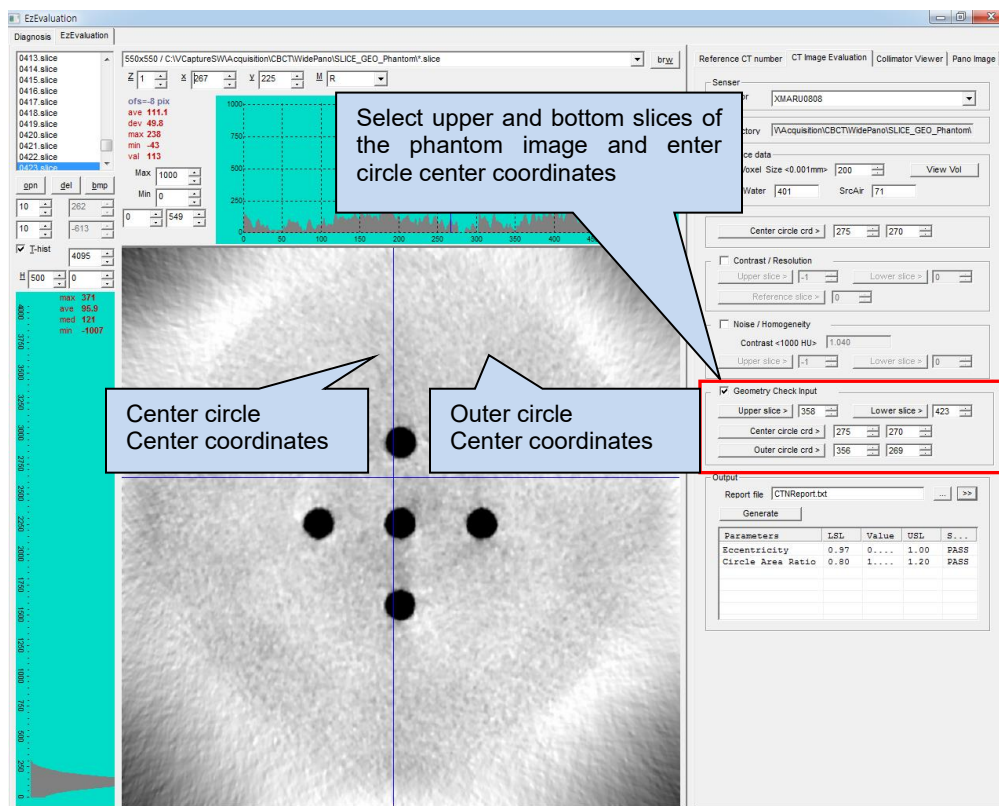
12. As shown in the picture above, select the upper slice of the phantom jig where the hole is located at the end of the centerline, and click the lower slice button of Noise (Dev)/ Homogeneity.
13. When all the settings are completed, click the Generate button to proceed with the evaluation.
14. When the evaluation is completed, the window below shows the minimum reference value, the maximum reference value, and the evaluation result.
15. The evaluation result is saved in the designated folder in the form of CTNReport.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

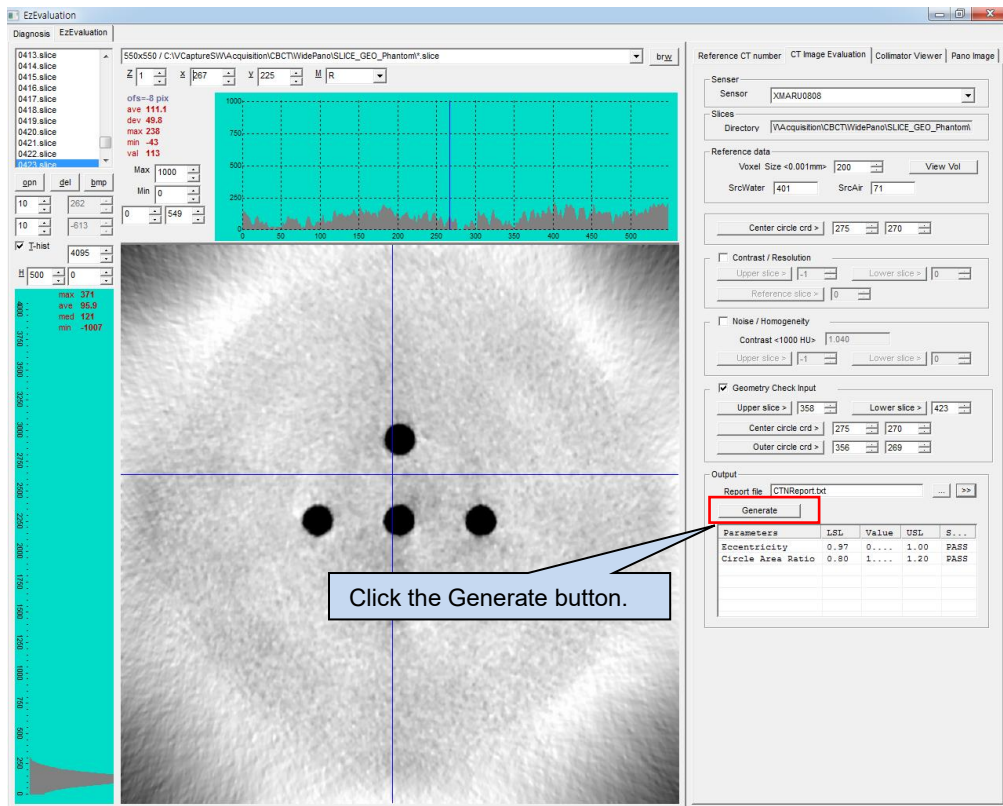
It is a step to evaluate whether the geometry calibration is properly applied by evaluating the eccentricity and blur of the five holes of the Geometry Check phantom.

#### 17.3.3.2.1 Select the Geometry Check Phantom Slice



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.

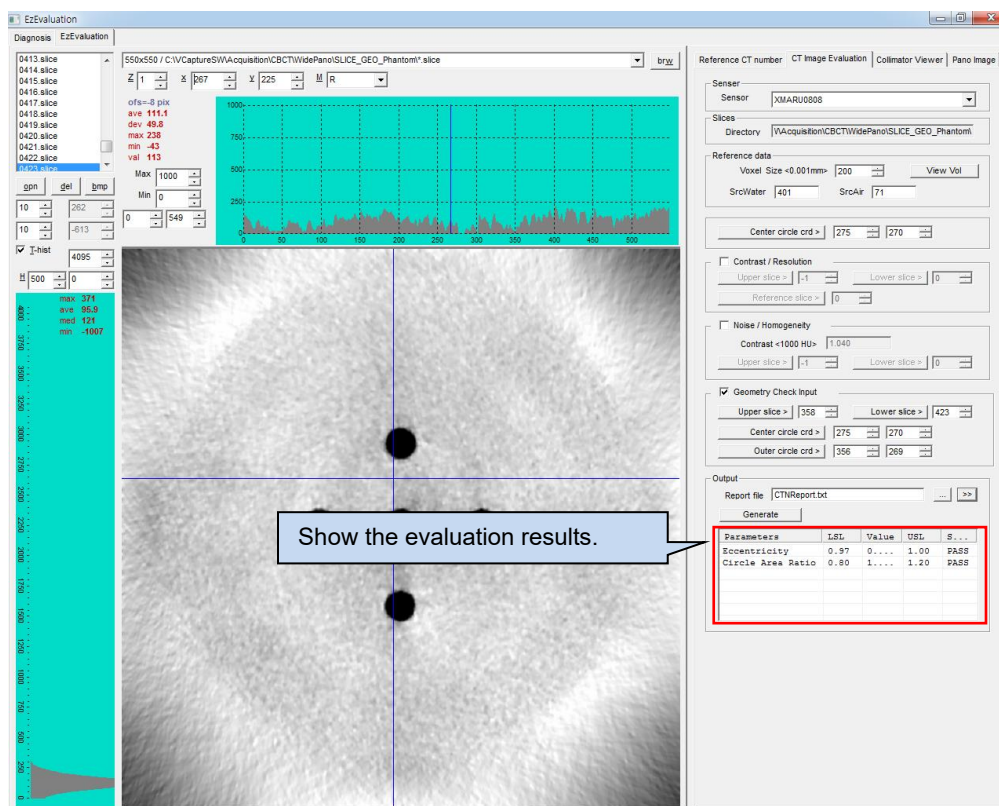
## 17.3.3.2.2 Generate (Evaluation)



1. Uncheck the Contrast / Resolution and Noise (Dev) / Homogeneity checkboxes and check the Geometry Check Input checkbox.
2. Evaluate by clicking the Generate button.



## 17.3.3.2.3 Test Result



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.

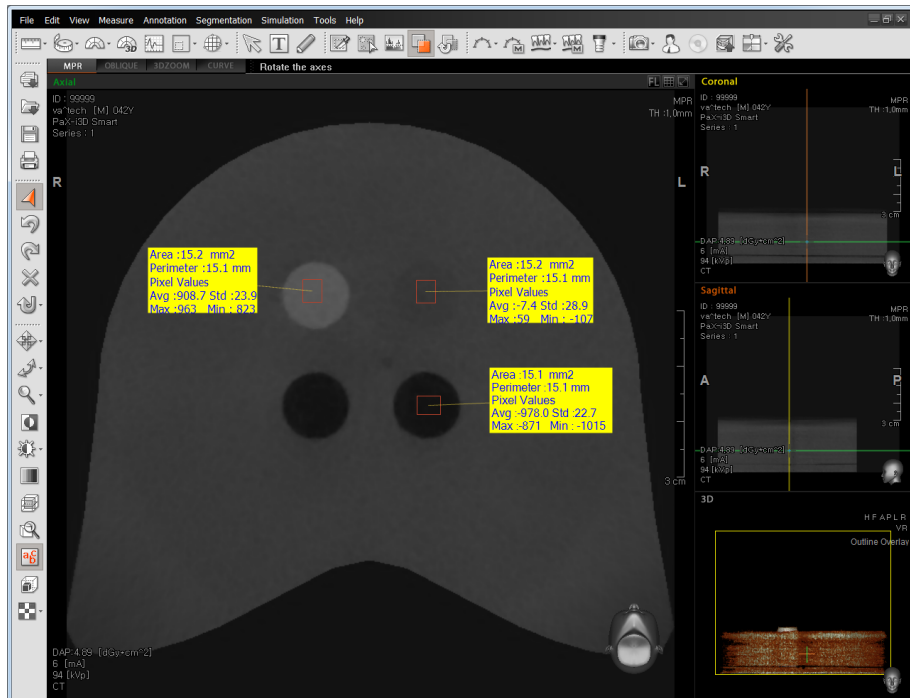
## Standard Value

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.



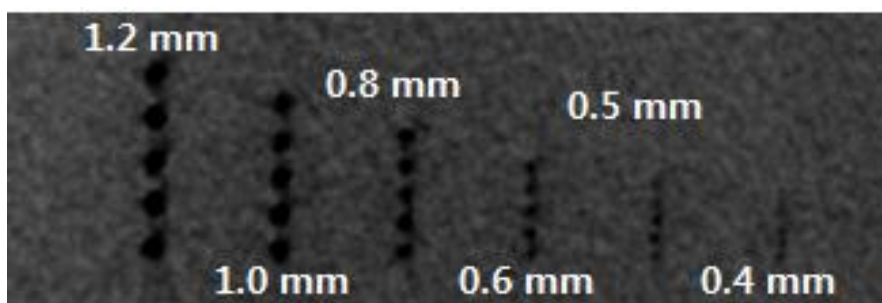
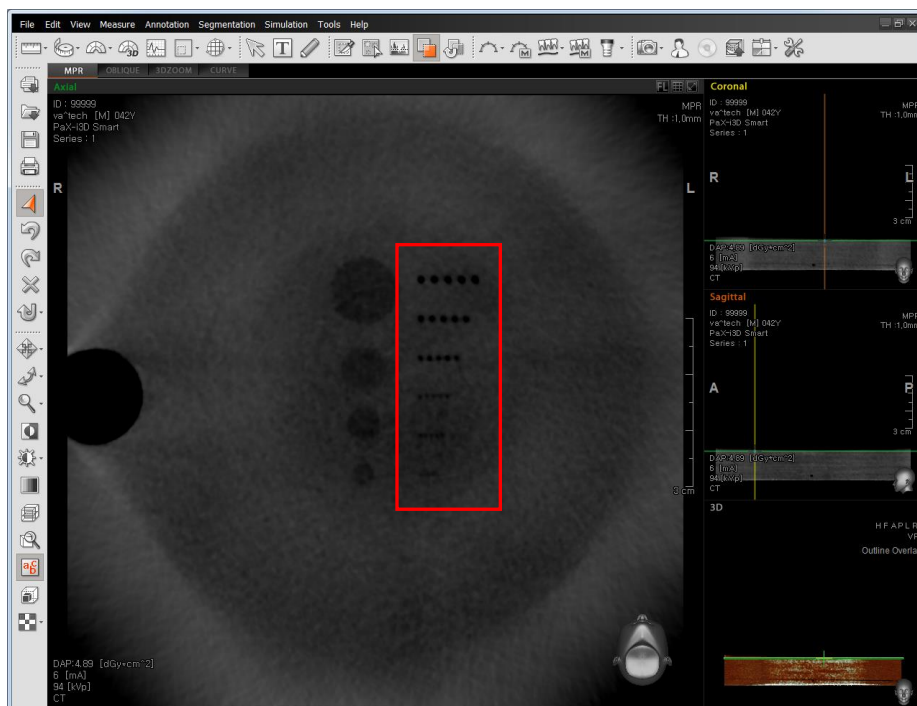
3. Measure the CT Number values of Air and Water in Area  $15 \pm 2 \text{ mm}^2$  in Axial image.
4. Take a screenshot and save it as CT\_Number.jpg in C:\VCaptureSW\Acquisition\CBCT\WidePano\Evaluation folder as shown above.

#### 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.

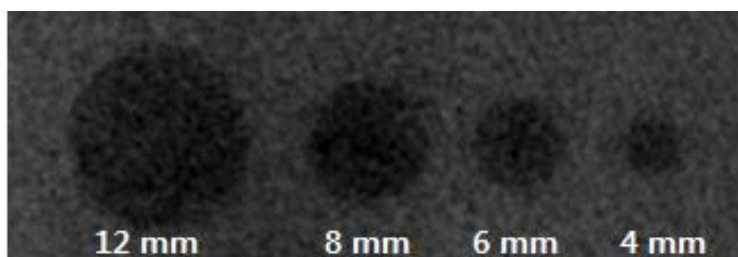
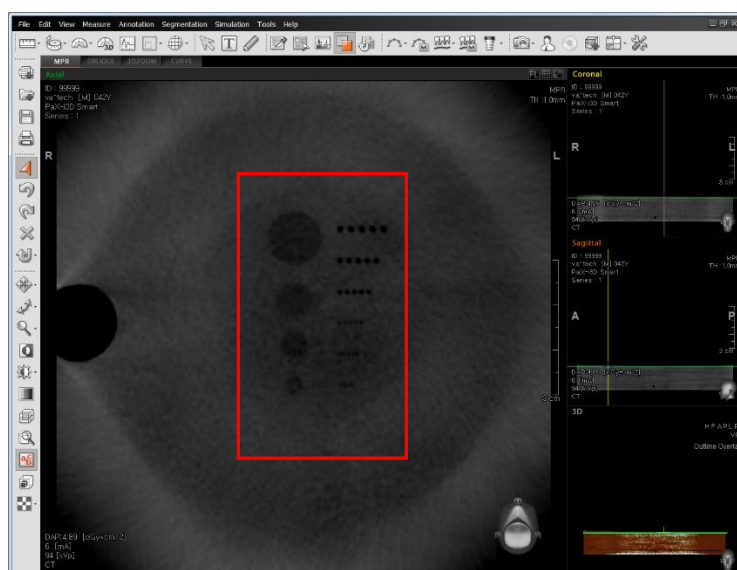


4. Take a screenshot and save it as CT\_High Contrast Resolution.jpg in C:\VCaptureSW\Acquisition\CBCT\WidePano\Evaluation folder.

Standard Value	
Parameters	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.



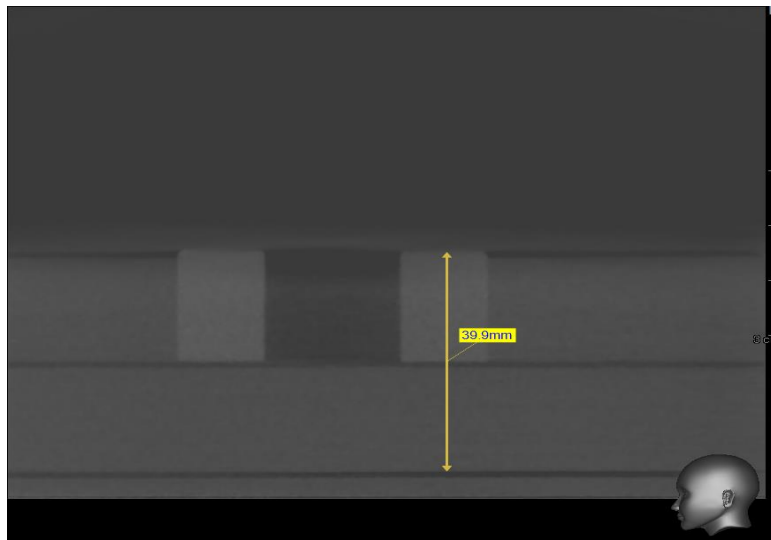
4. Take a screenshot and save it as CT\_Contrast Resolution.jpg in C:\VCaptureSW\Acquisition\CBCT\WidePano\Evaluation folder.

#### 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:\VCaptureSW\Acquisition\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

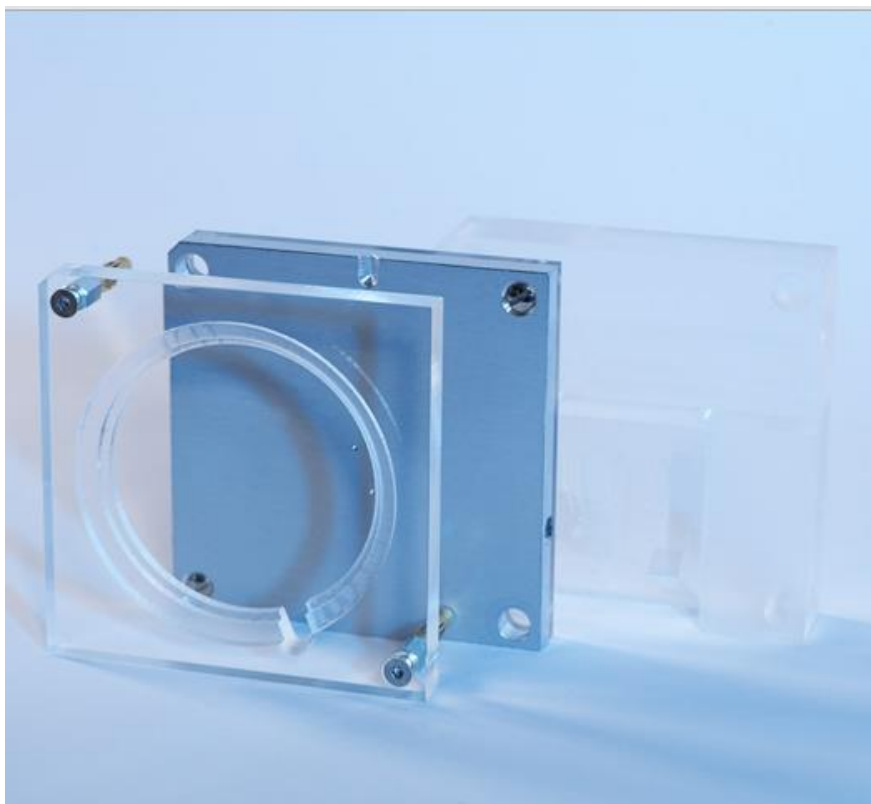
### 18.1 PANO

#### 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	

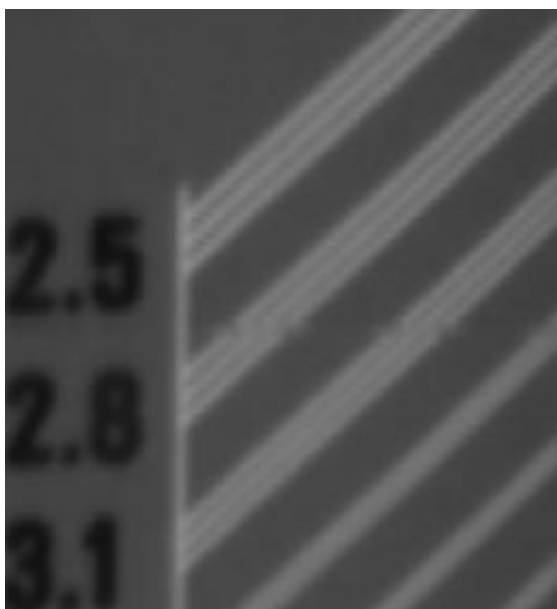
##### 18.1.1.2 Phantom Specification



< 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

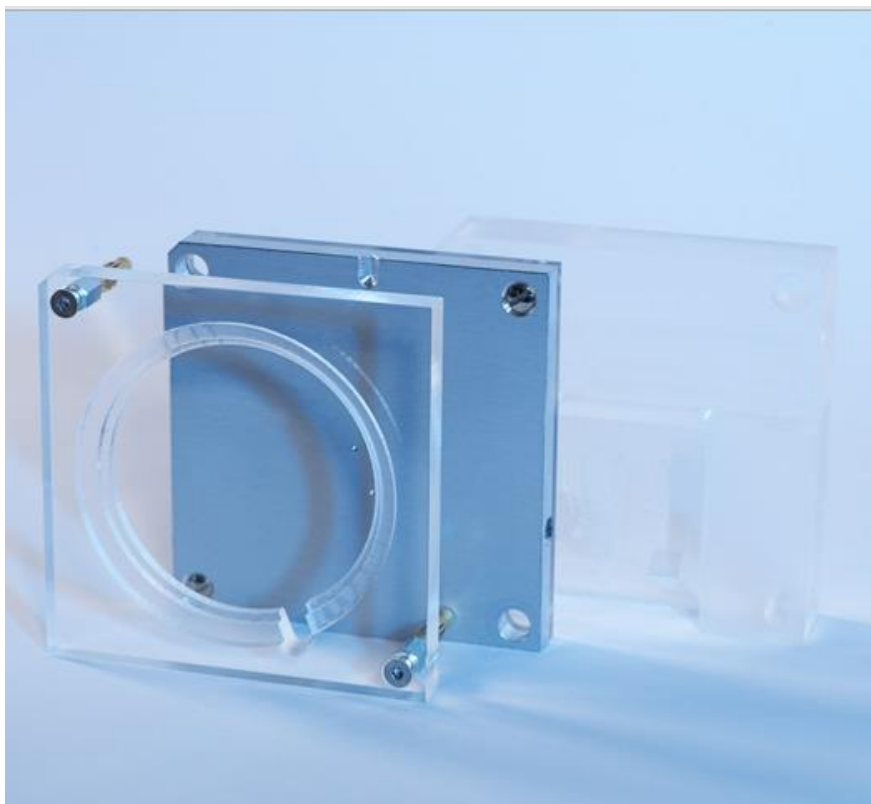
	VATECH Standard	Remarks
Lp/mm (Line Pair)	3.1 Lp/mm	

## 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

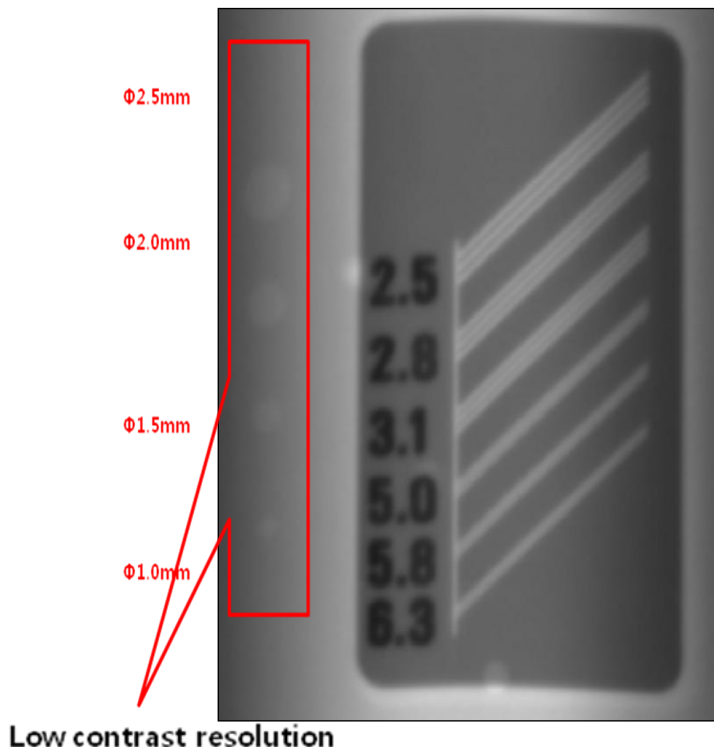


< QUART Phantom >



### 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



### 18.1.2.4 Test Result

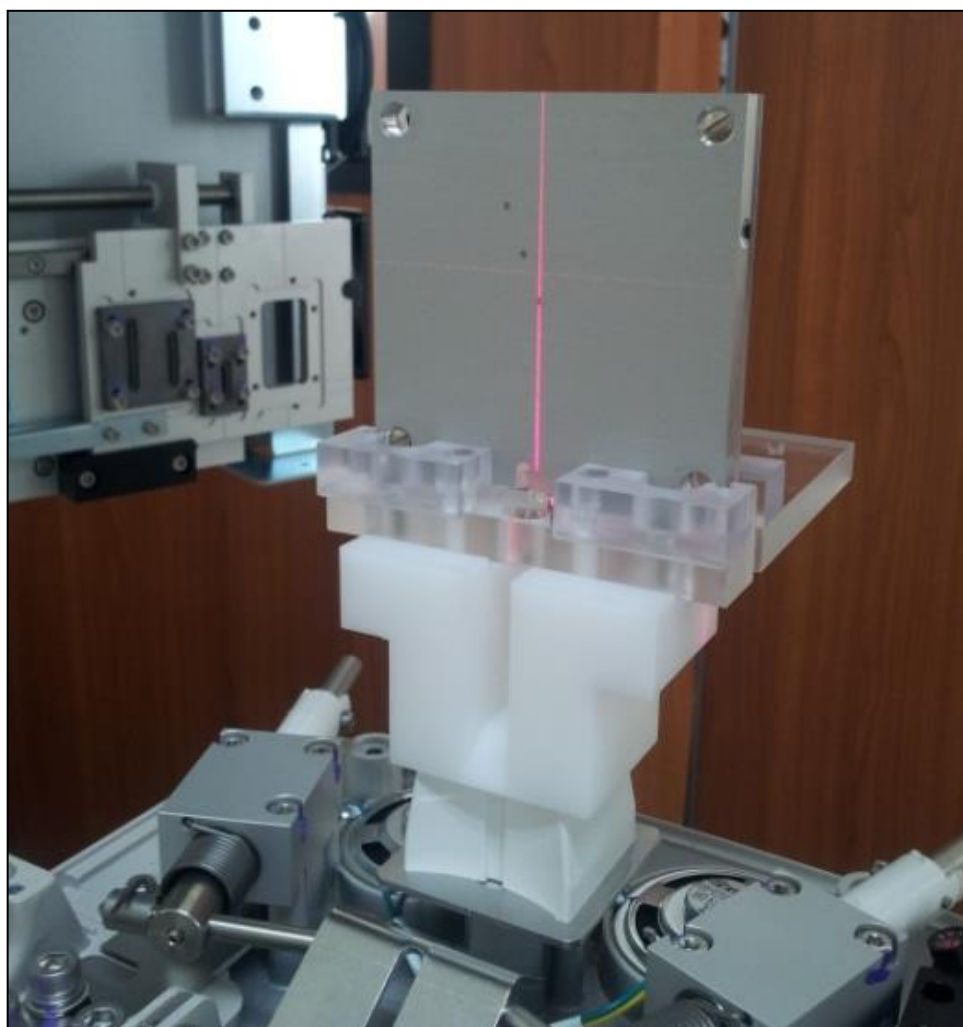
	VATECH Standard	Test results
Hole	1.5 mm or less	Check the 1.0 mm

### 18.1.3 Evaluate the Noise (Dev)

#### 18.1.3.1 Noise (Dev) criterion

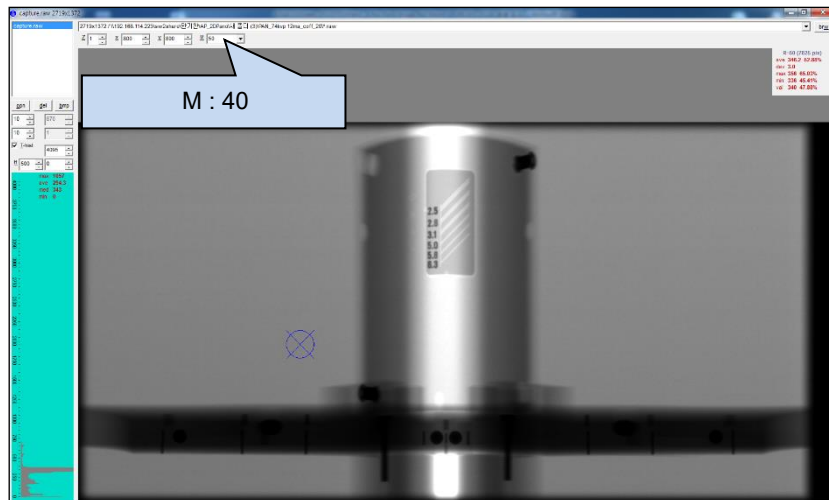
	ROI 1	ROI 2	ROI 3	Remarks
Noise (Dev)	8 or less		30 or less	

#### 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

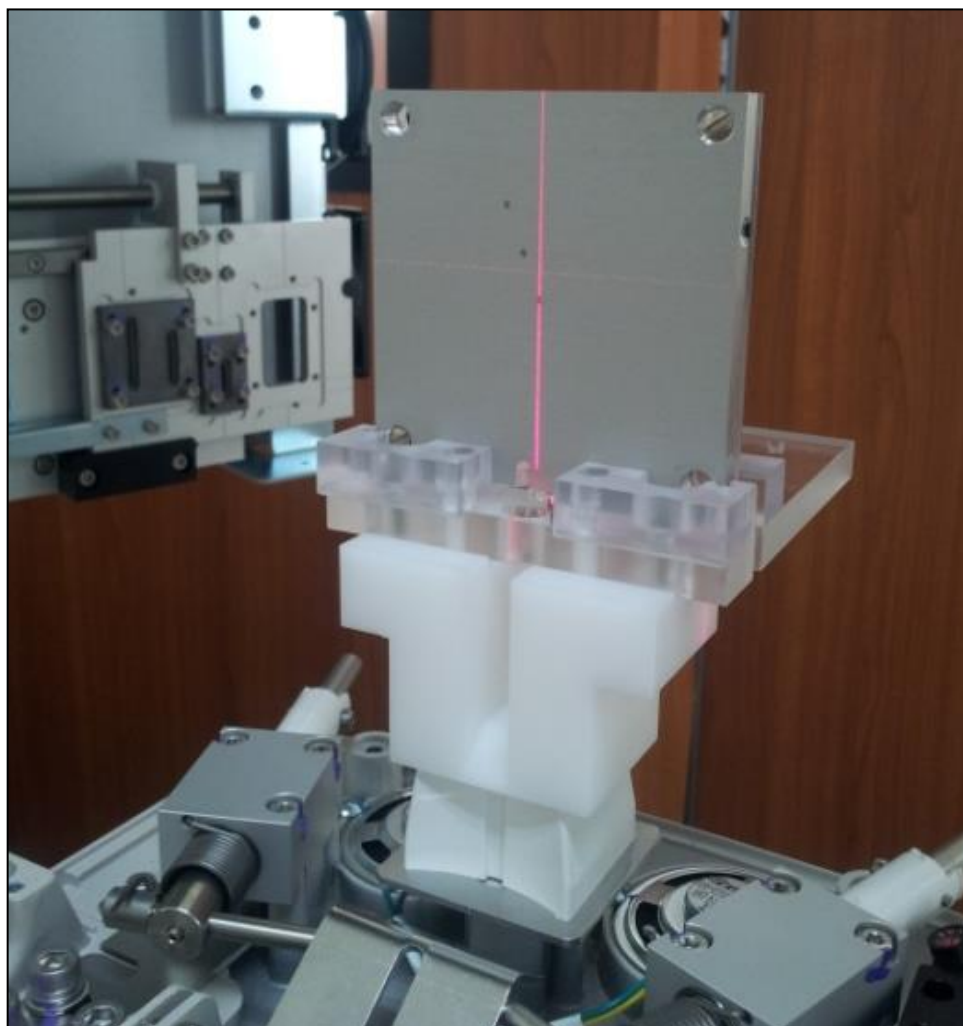
	ROI 1 measurement value (800, 800)	ROI 2 measurement value (2000, 800)	ROI 3 measurement value (1330, 800)
Noise (Dev)	6.2	6.4	11.5

### 18.1.4 Evaluate the Homogeneity

#### 18.1.4.1 Homogeneity criterion

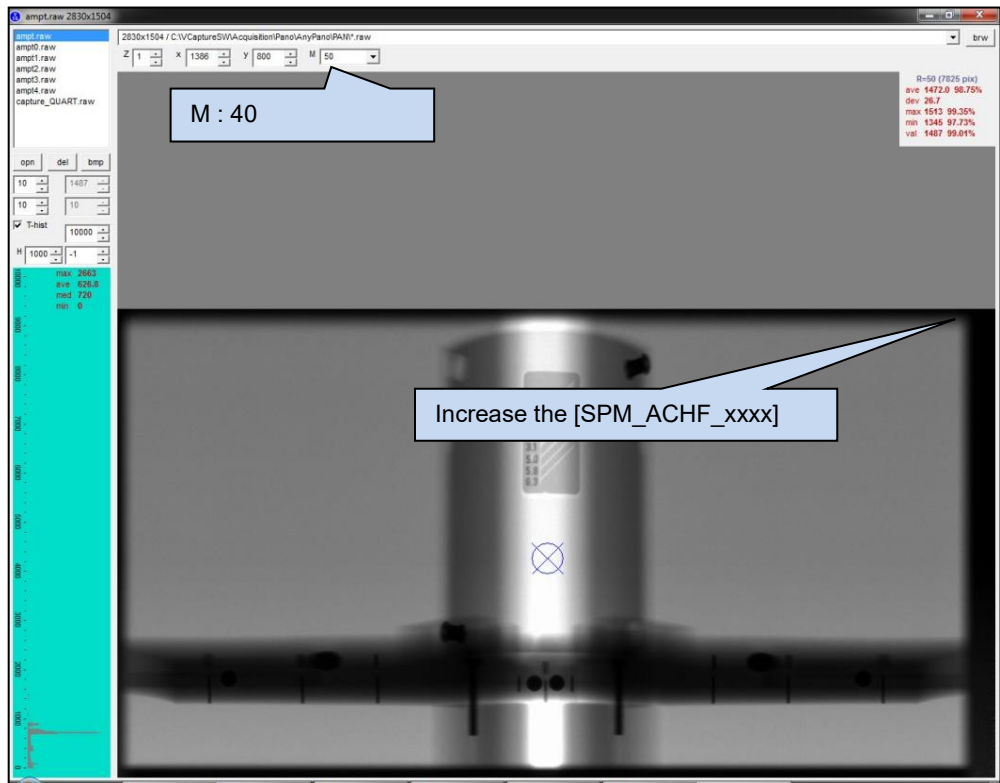
	ROI 1	ROI 2	ROI 3
Noise (Dev)	More than 600 (Difference between the two values is less than 10%)		More than 1200

#### 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

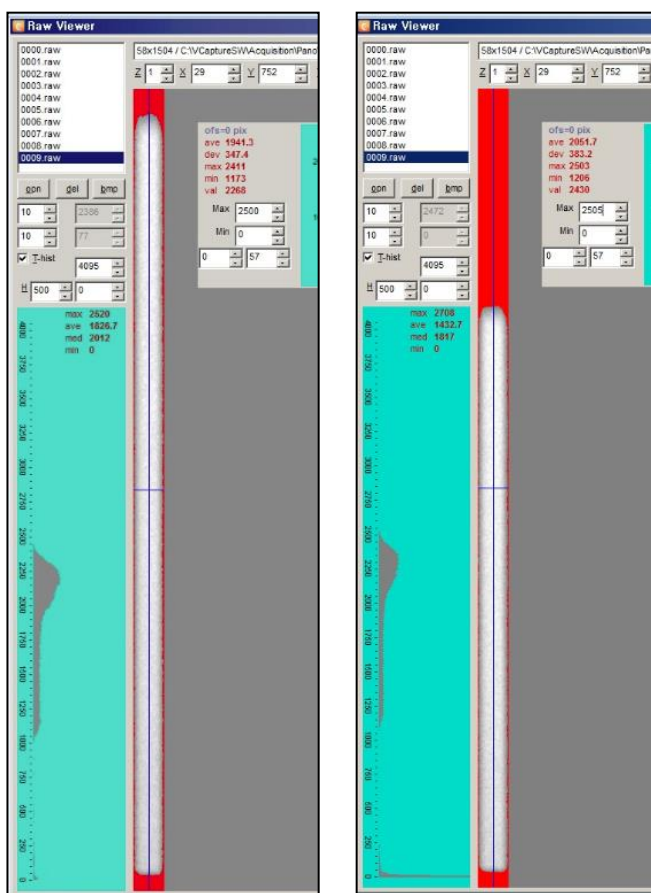
#### 18.1.5.1 Collimator 4% criterion

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 >

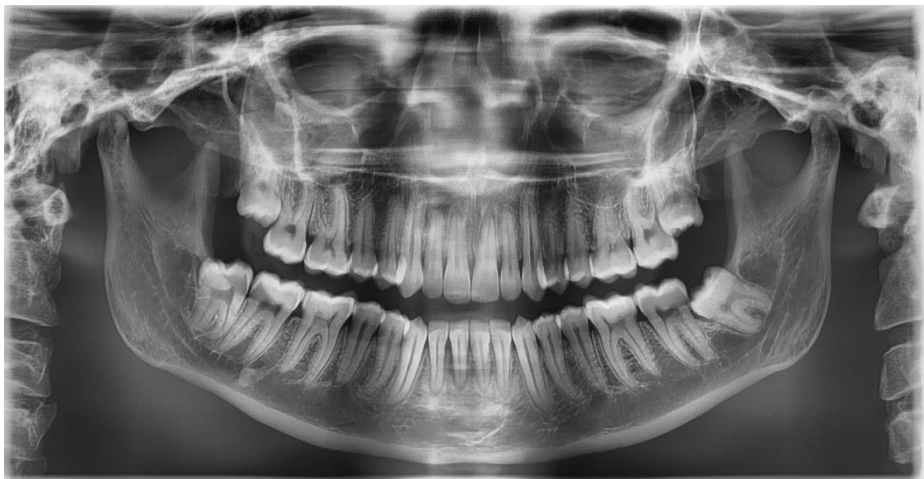
< Child\_Align >

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



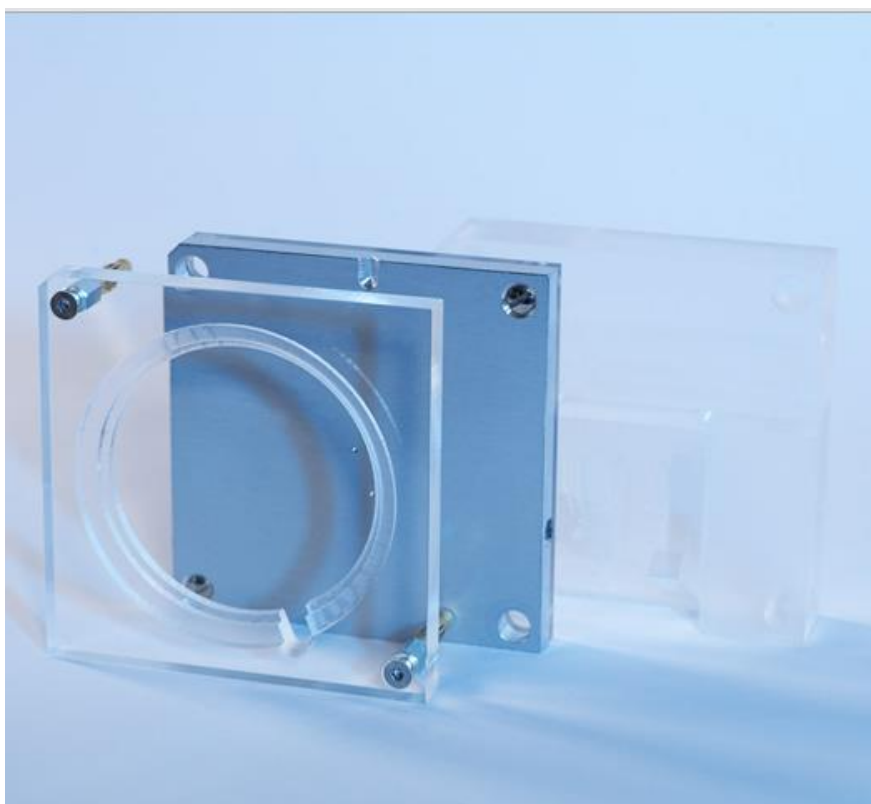
## 18.2 CEPH

### 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

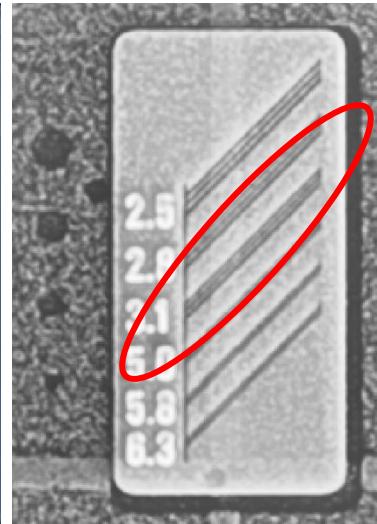
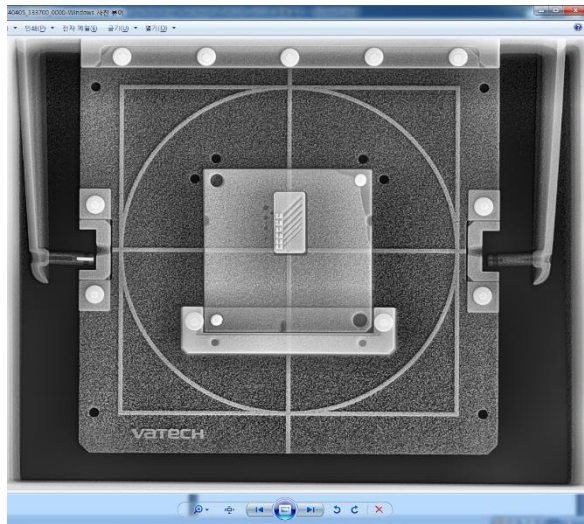


< QUART Phantom >



#### 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

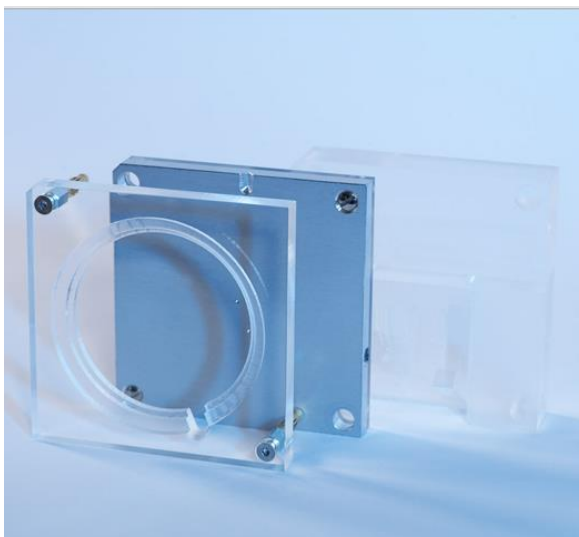
	VATECH Standard	Test results
Lp/mm (Line Pair)	More the 2.5 Lp/mm	3.1 Lp/mm

## 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	

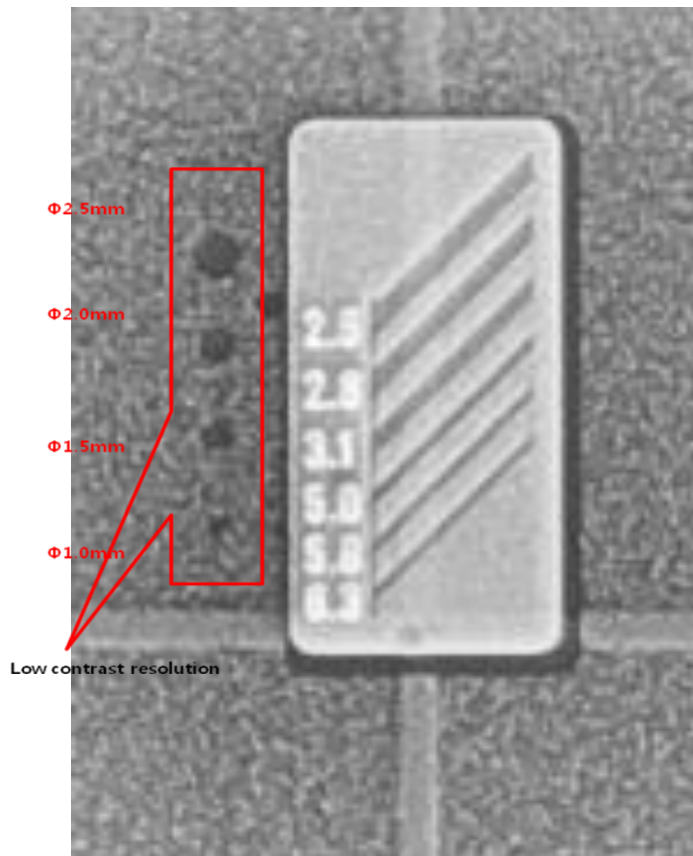
### 18.2.2.2 Phantom Specification



< 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

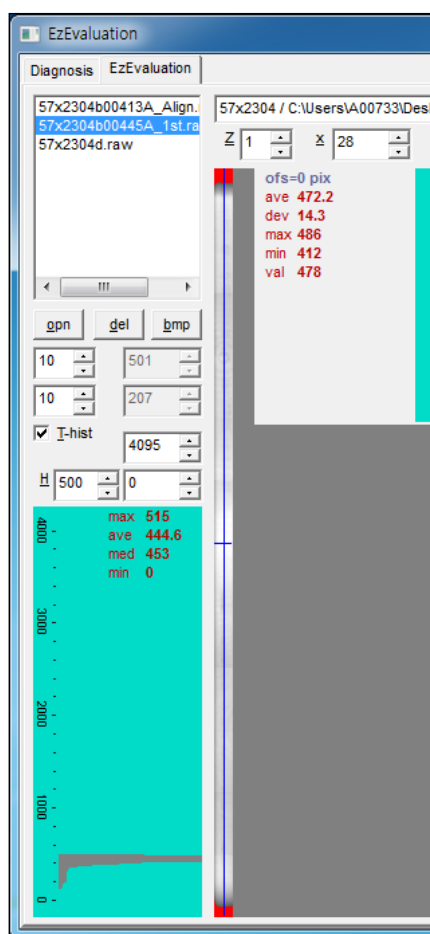
Parameter	Upper/Lower X-ray off area	Left/Right X-ray off area
4% Cut	20~50 pixel	1~3 pixel

#### 18.2.3.2 Phantom Specification

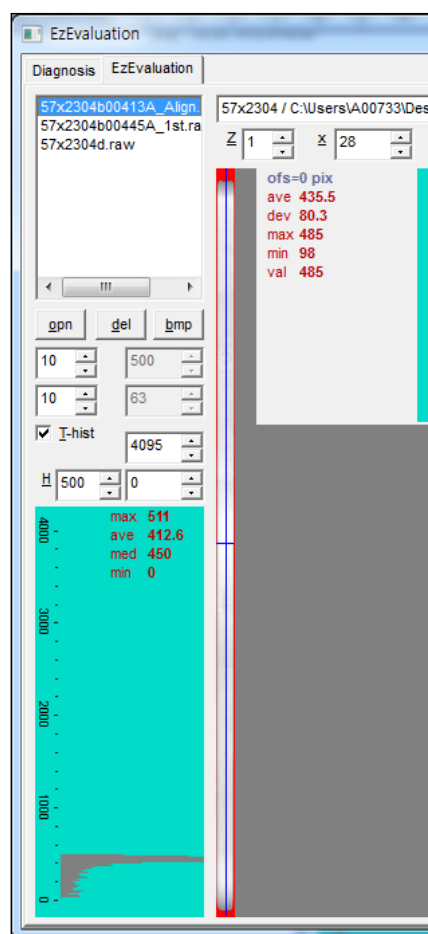
Unused the Phantom

#### 18.2.3.3 Test Method

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



< 1<sup>st</sup>\_Align >



< 2<sup>nd</sup>\_Align >

### 18.2.3.4 Test Result

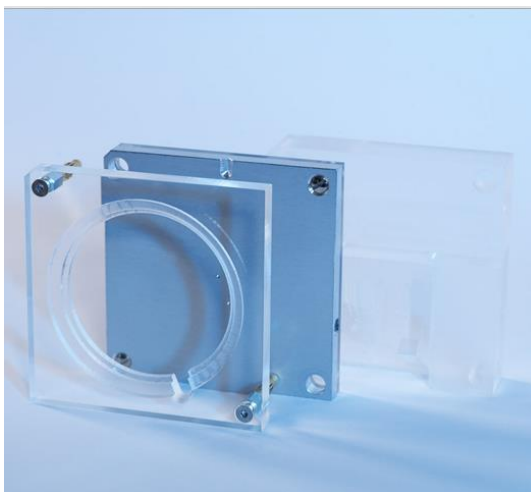
Parameter	LSL	Measurement value	USL	Pass/Fail
High	20 pixel	30 pixel	50 pixel	Pass
Low	20 pixel	30 pixel	50 pixel	Pass
Left	1 pixel	2 pixel	3 pixel	Pass
Right	1 pixel	2 pixel	3 pixel	Pass

## 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	

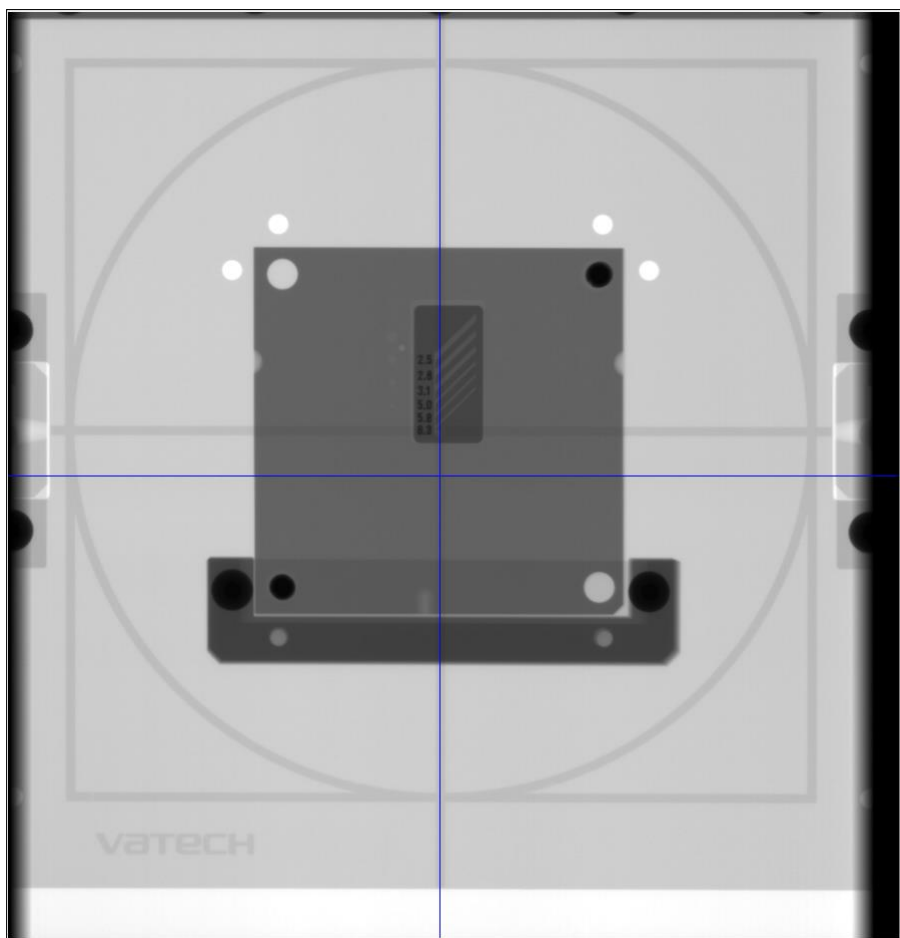
### 18.2.4.2 Phantom Specification



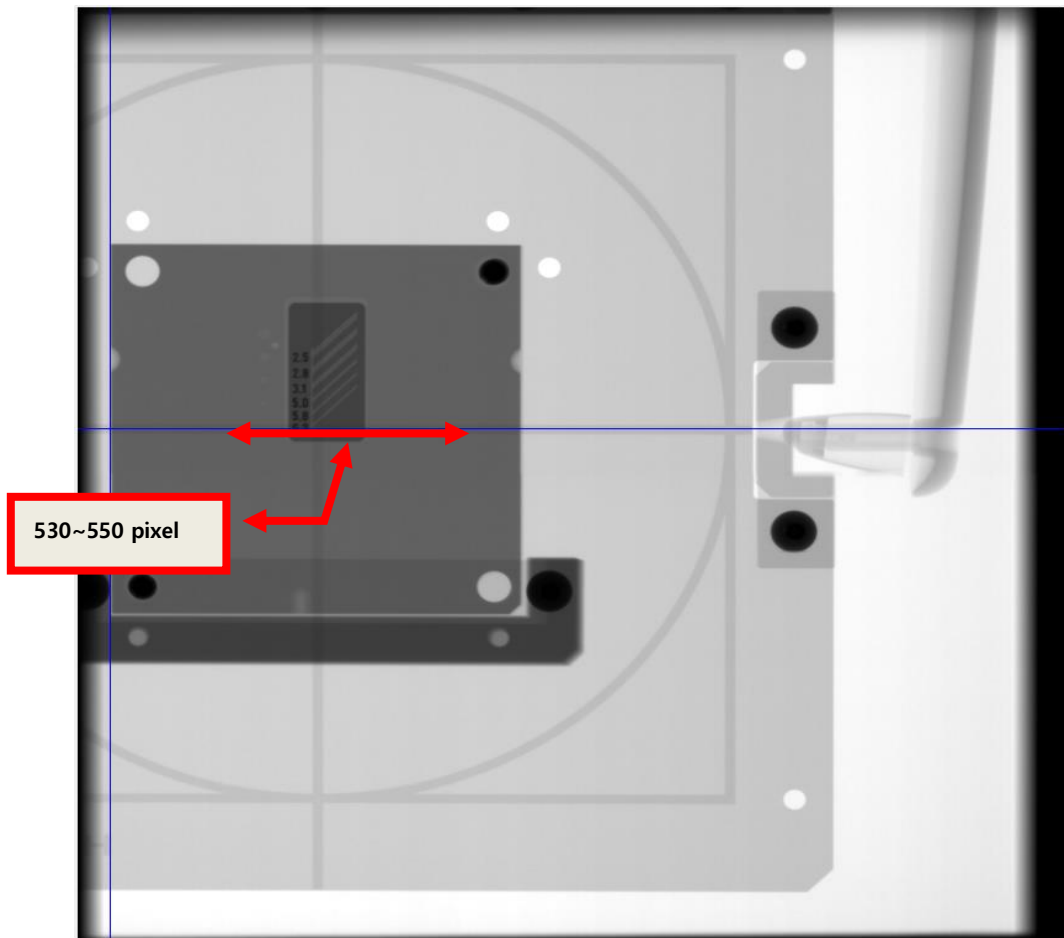
< QUART Phantom >

### 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	<b>538 pixel</b>
Frontal	1070 ~ 1090 pixel	<b>1082 pixel</b>

## 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

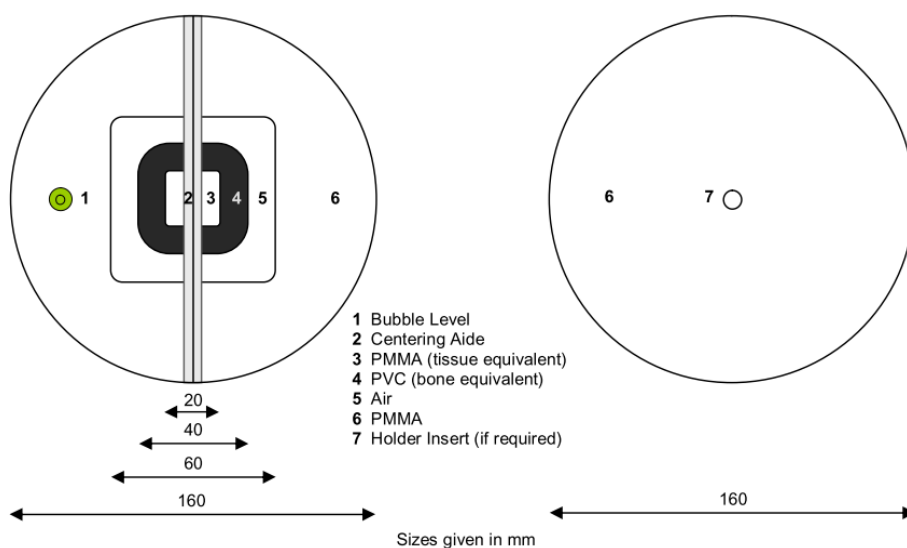
#### 18.3.1.2 Phantom Specification



< 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
CNR	19.6	20%	24.1
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

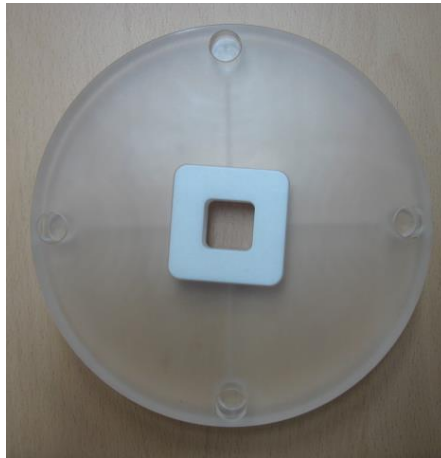
Parameter	LSL	Measurement value	USL	Pass/Fail
MTF 10% <lp/mm>	1.00	2.2	3.50	Pass

### 18.3.2 Evaluate the Contrast

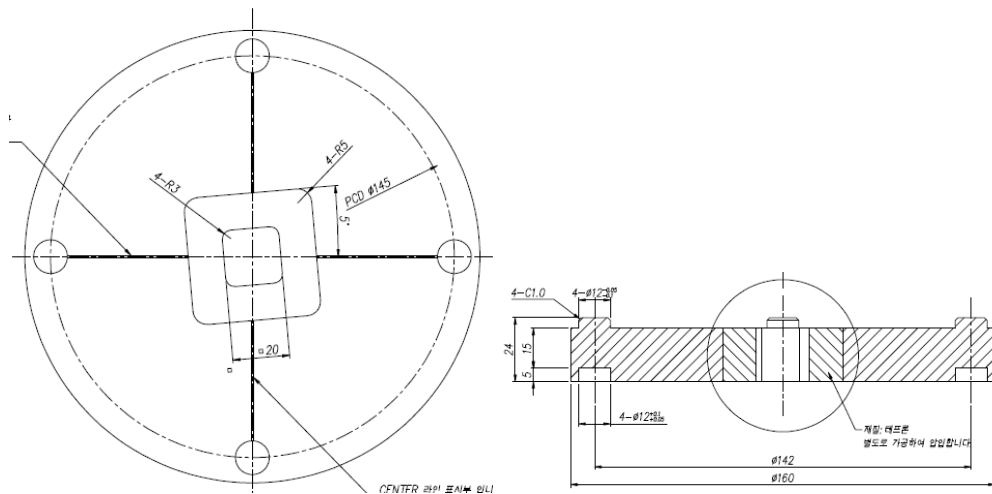
18.3.2.1 The Contrast measurement value shall satisfy the following criteria.

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

#### 18.3.2.2 Phantom Specification

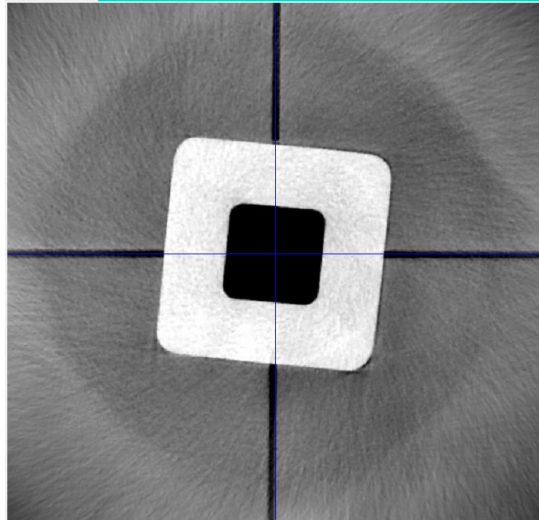


M&R Check Phantom



### 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)

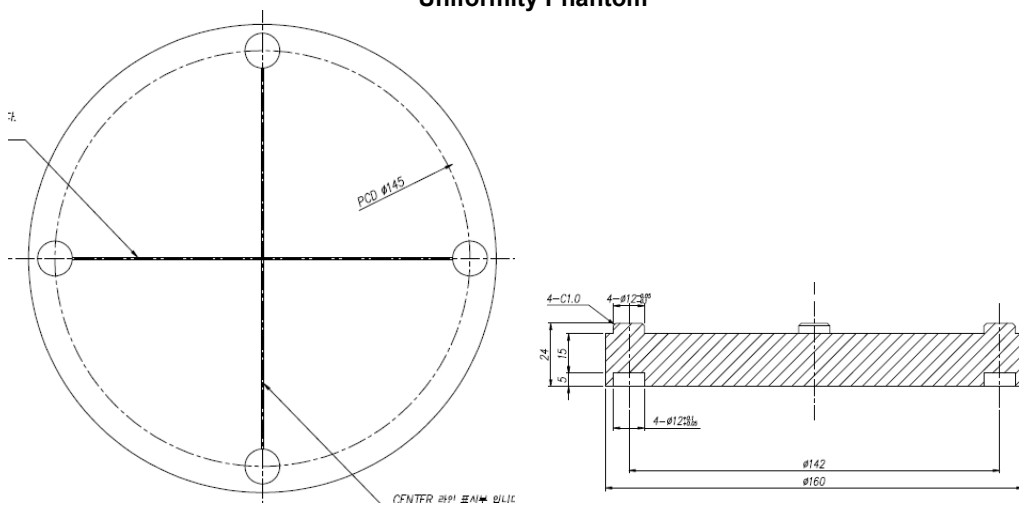
18.3.3.1 The Noise (Dev) measurement value shall satisfy the following criteria.

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

### 18.3.3.2 Phantom Specification

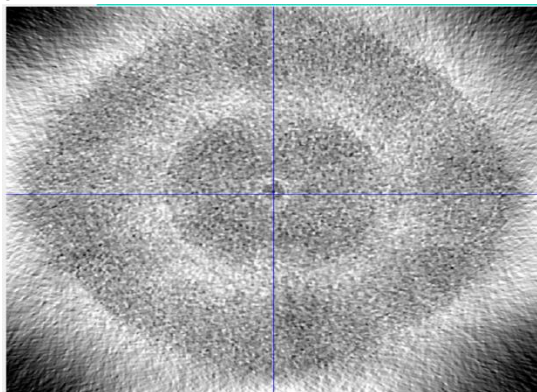


Uniformity Phantom



### 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

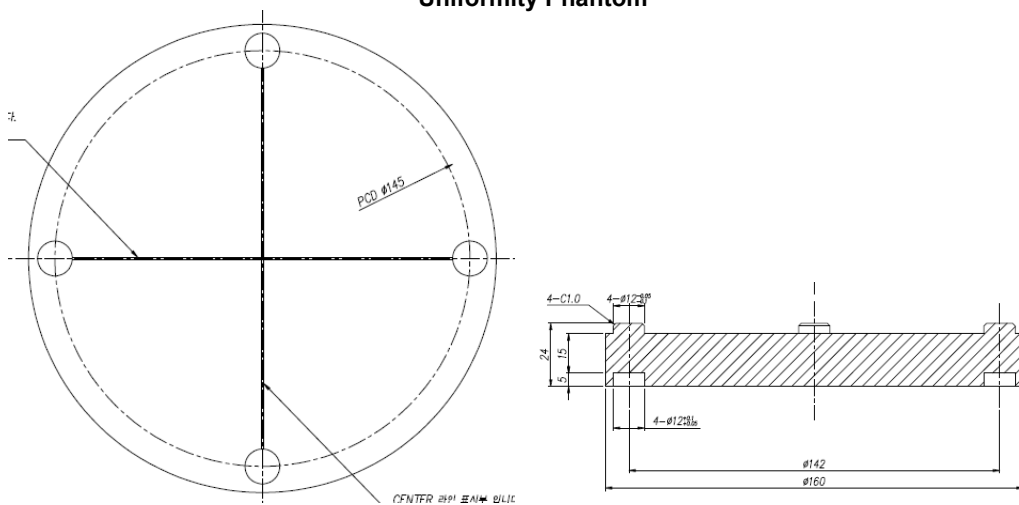
18.3.4.1 The Homogeneity measurement value shall satisfy the following criteria.

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

### 18.3.4.2 Phantom Specification



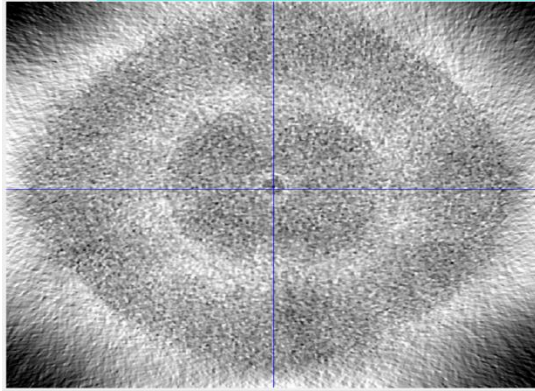
Uniformity Phantom





### 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

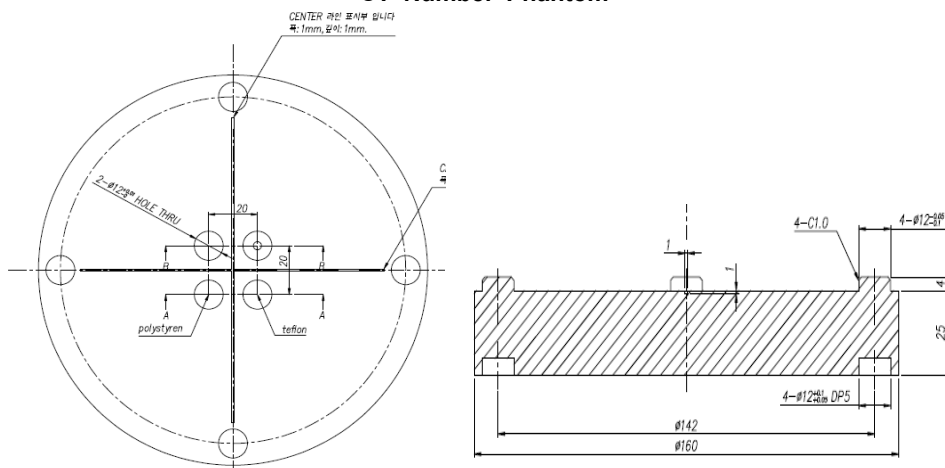
18.3.5.1 CT numbers of air and water shall satisfy the following criteria.

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





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

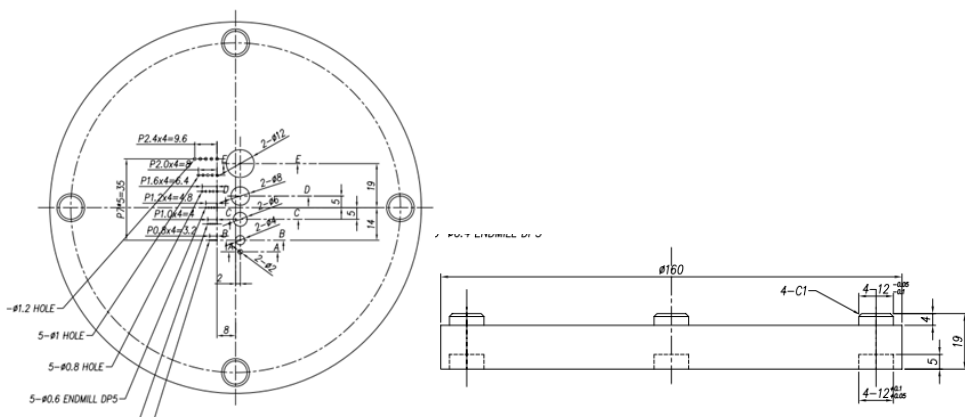
**18.3.6.1 The High Contrast measurement value shall satisfy the following criteria.**

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

### 18.3.6.2 Phantom Specification



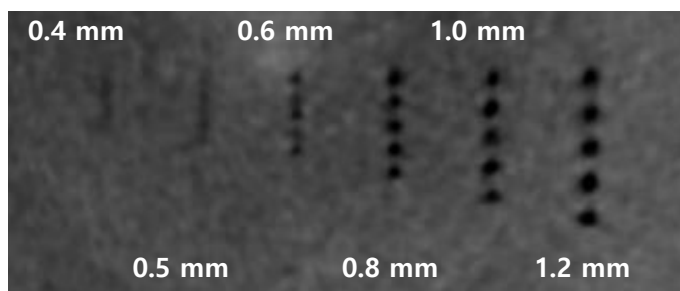
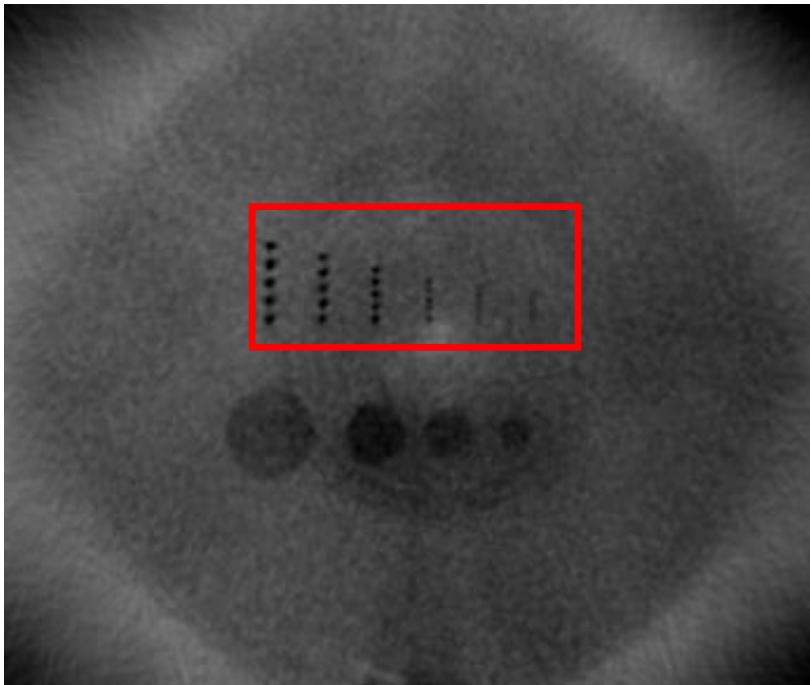
## S&C Phantom



### 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

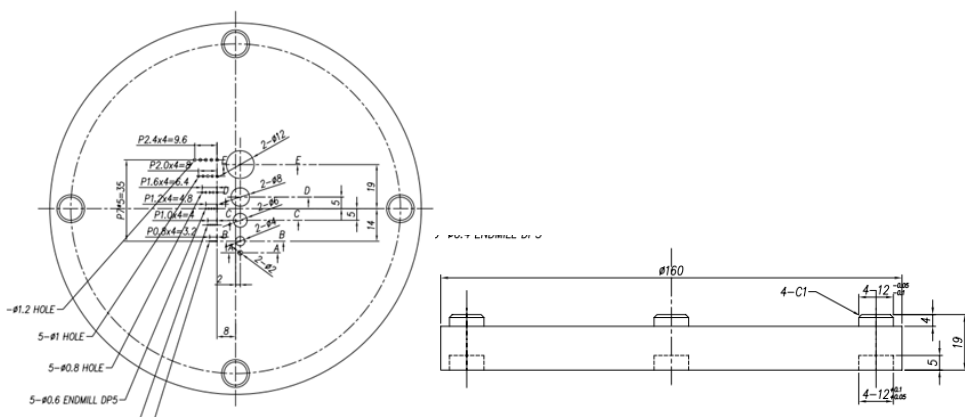
18.3.7.1 The Contrast measurement value shall satisfy the following criteria.

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

#### 18.3.7.2 Phantom Specification



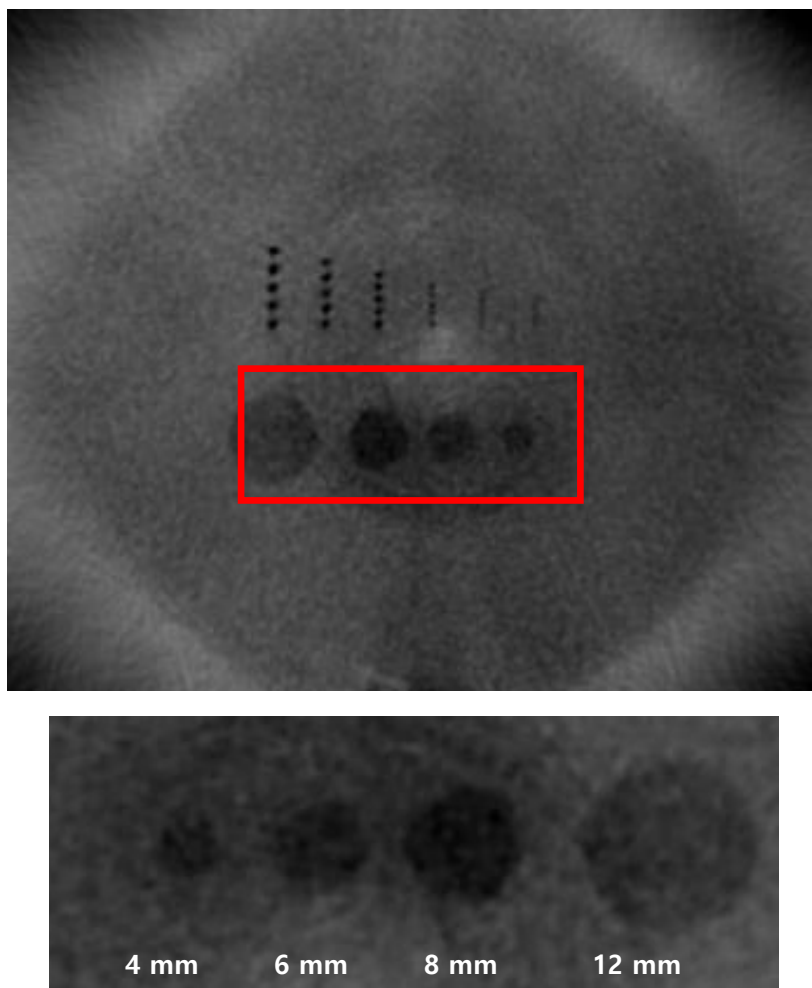
S&C Phantom



#### 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 and 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

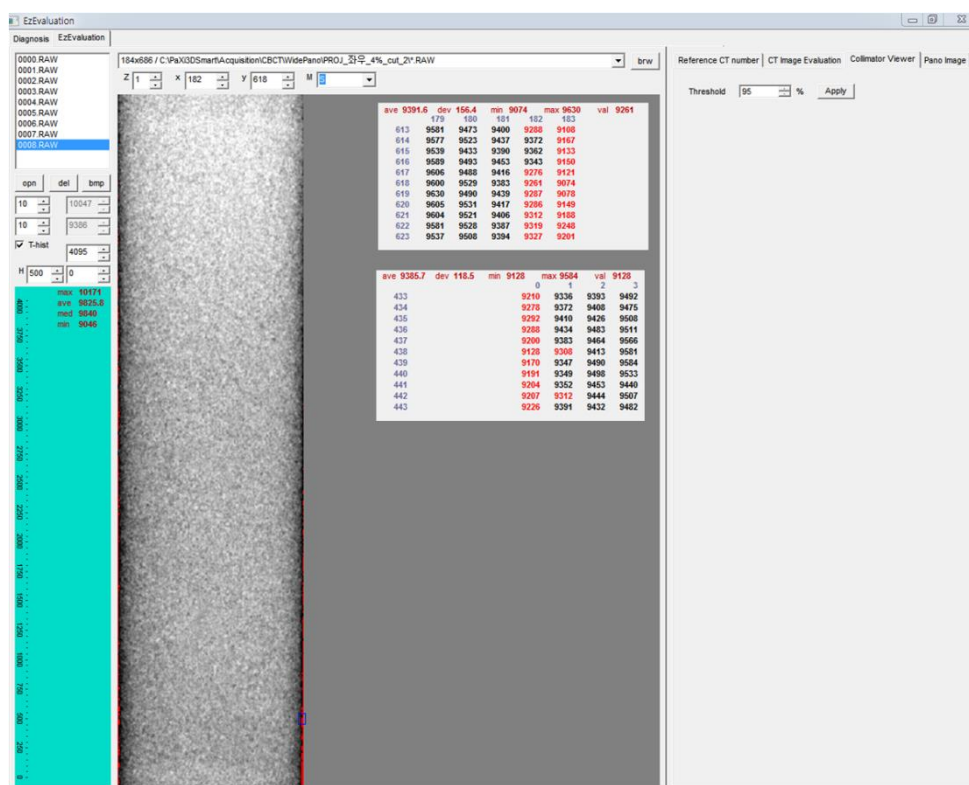
#### 18.3.9.1 The Collimator 4% Cut measurement value shall satisfy the following criteria.

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

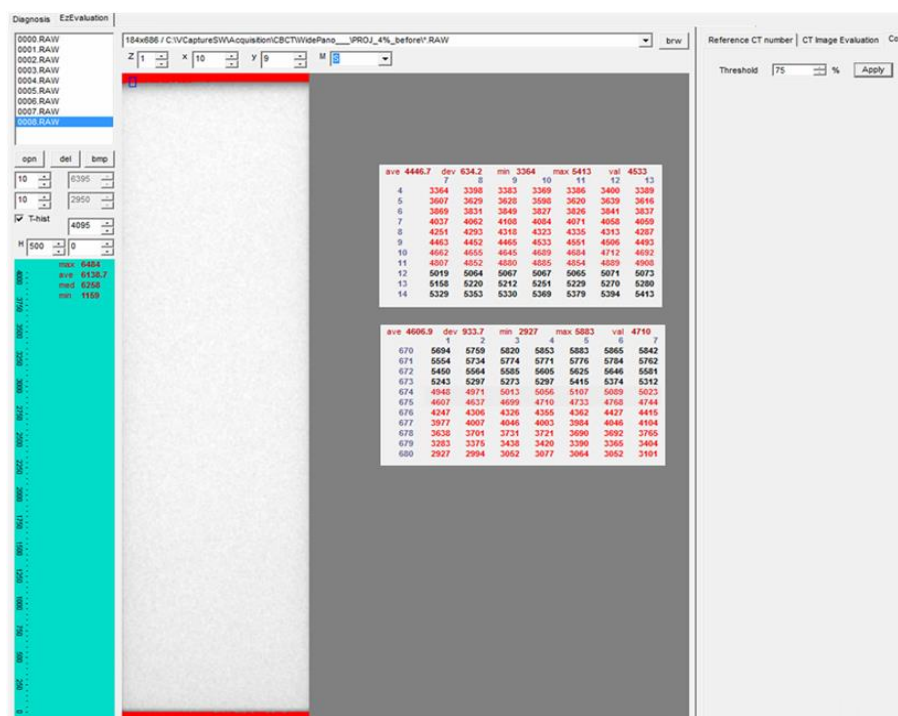


Left/Right Collimator (Threshold: 95%)

- 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

## 18. Image Test Manual



Upper/Lower Collimator (Threshold: 75%)

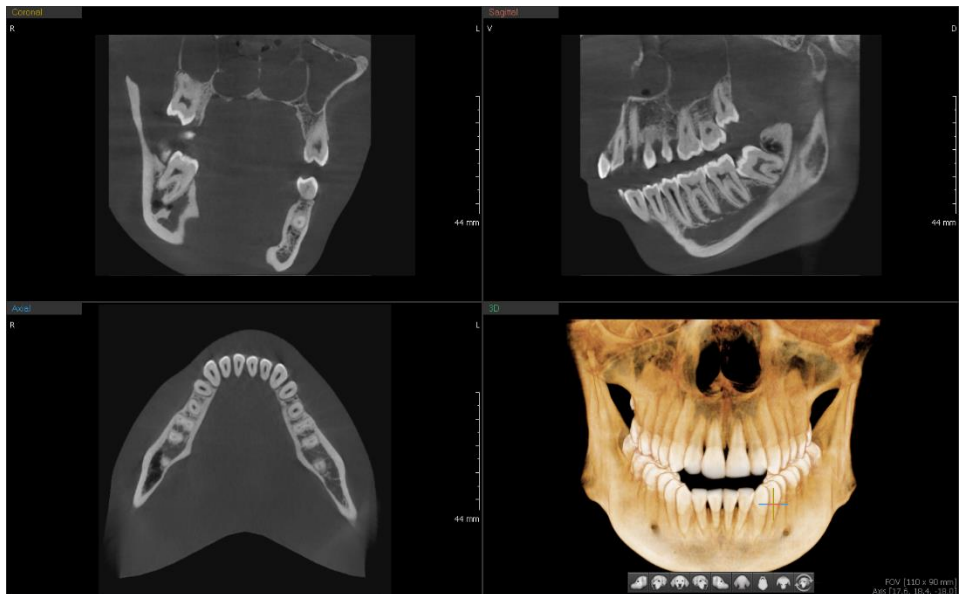
Parameter	LSL	Measurement value	USL	Pass/Fail
Upper	10 pixel	11 pixel	15 pixel	Pass
Lower	10 pixel	11 pixel	15 pixel	Pass
Left	1 pixel	2 pixel	2 pixel	Pass
Right	1 pixel	2 pixel	2 pixel	Pass

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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# Green Smart