



Clear rainbow™ CT User Manual

I031-01MU-03 rev.11 (2023.05)

Dentium
For Dentists By Dentists

CE 0068

Dentium
For Dentists By Dentists

1 Over view	6
1.1 Production Information and Purpose	6
1.1.1 rainbow™CT Product Information	6
1.1.2 Intended Purpose	6
1.2 Characteristics of rainbow™CT	6
2 Safety Information	7
2.1 Symbols	7
2.2 Precautions	8
2.3 Caution for Use	8
2.4 Electrical Precaution	9
2.5 Radiation Protection Policy	9
2.6 Policy on Manufacturer Liability	10
2.7 Safety Function	10
2.7.1 System Safety	10
2.7.2 Indication/Warning System	10
2.7.3 Examinee Protection Device	10
2.8 Product Labeling and Symbol	11
2.8.1 Product Labeling	11
2.8.2 X-ray Generator Label	12
3 Equipment Structure and Function	14
3.1 Structure (Name)	14
3.2 Accessory	16
3.3 Exposure Switch	17
3.4 UP/DOWN Switch	17
3.5 Emergency Switch	18
3.6 Power Switch	18
3.7 Control Switch	19
3.8 Status Indicator	19
4 How to Use	20
4.1 Scan Menu	20
4.1.1 Panoramic Scan Mode	20
4.1.2 CT Scan Mode	20
4.1.3 Cephalometric Scan Mode	21
4.2 Scan Program Details	21
4.2.1 Main Screen (Pano/CT/Ceph)	21
4.2.2 Basic Panoramic Scan Screen	21
4.2.3 Basic CT Scan Screen	22
4.2.4 Cephalometric Scan Screen	22
4.2.5 Common Menu	22
4.2.6 Panoramic Setting Menu	23
4.2.7 CT Setting Menu	24
4.2.8 Cephalometric Setting Menu	24
4.3 Scan Preparation	25
4.3.1 Image management program	26
4.3.2 Panoramic Scan	30
4.3.3 Examinee Posture Alignment	32
4.3.4 TMJ Scan (Temporomandibular joint) Open/Close Mode	34
4.3.5 SINUS Scan Mode (Detained explanation will be added)	36
4.3.6 Scanned Image Check	38
4.3.7 Finish Scanning	38

4.4 CT Scan	39
4.4.1 Opening the examinee prior to CT scanning	39
4.4.2 Starting CT Scan Program	40
4.4.3 Examinee Alignment and Scan	42
4.4.4 Examinee Alignment and Scan	42
4.5 Cephalometric Image Scan	46
4.5.1 Starting Cephalometric Scan Program	46
4.5.2 Setting Scan Environment	47
4.5.3 Examinee Alignment and Scan	47
4.5.4 Viewing Scanned Image	53
5 Maintenance	54
5.1 Routine Maintenance and Checklist	54
5.2 Daily Checklist	54
5.3 General Maintenance	54
5.4 Warranty and Service	54
5.4.1 Warranty Period	54
5.4.2 Cases Excluded from Warranty	54
5.5 Troubleshooting	55
5.5.1 When the equipment does not operate	55
5.5.2 Impossible to align the examinee (When the laser beam is off)	55
5.5.3 Equipment Initialization Problem	55
5.5.4 Radiation Switch Operation Problem	55
5.5.5 Lift Column Operation Problem	56
5.5.6 Patient align error	57
6 Technical Information	62
6.1 General Specification	62
6.2 CT FOV Size	62
6.3 Cephalometric FOV Size	62
6.4 Scan Time	63
6.5 Electrical Specification and Environment	63
6.6 X-ray Tube Specification	64
6.7 X-ray Detector Specification	65
6.7.1 CT & Pano Detector Specification (X-ray imaging detector)	65
6.7.2 Cephalometric Detector Specification	65
6.8 Recommended PC Specification	65
7 Applied Standard	66
8 Electronic Compatibility	66
8.1 Major Component	66
8.2 Electromagnetic Emission	66
8.3 Electronic Interference Resistance	67
8.4 Protective Distance	69
9 Installation Cautions	70
9.1 Recommendations for Installation Place	70
9.2 Gantry Power Cable Connection	71
9.3 Peripheral Equipment Connection	73
9.3.1 Peripherals and Accessories	73
10 Cautions for System Disposal	74

Manual Information

This manual explains the functions and scanning methods of rainbow™ CT in detail, the digital image scanning equipment for dentist.

For the smooth use of equipment, please read this manual carefully before use

This manual is subject to change without prior notice according to the product quality upgrade, the change of specification, etc.

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1 Over view

1.1 Production Information and Purpose

1.1.1 rainbow™CT Product Information

- As an X-ray computed topography equipment for dentist to obtain the image of the image of patient's tooth, nasal cavity and temporomandibular joint, this is a medical diagnostic equipment designed to obtain the topographic image by arranging X-ray and the image display unit facing each other and by rotating it around the patient as a central axis and to analyze the topographic image of the interested area from the patient displaying it on the screen through the calculation of computer. In addition, this product includes the functions of reconstructing displaying, correcting, saving the image, etc. as the image manipulation function.
- The system is composed of X-ray generator, X-ray detector, X-ray collimator, main frame, rotation unit, PC and Monitor, etc. as standard.

1.1.2 Intended Purpose

- As an equipment to obtained the topographic image of the tooth, jaw, etc. by converting X-ray signal to digital using the semiconductor, etc for the purpose of diagnosis, it is designed to scan the panoramic image of the tooth, jaw and oral structure.

1.2. Characteristics of rainbow™CT

- It integrates the CBCT, panorama and cephalometric (scan, One-shot) functions in one equipment providing 3-in-1 functions and is the comprehensive diagnostic and analytical digital image equipment for dentist
- When CT or panoramic scanning, it is changed to auto mode without changing the sensor or rotation.
- Enable to select the local, standard and stitching mode as required when CT scanning.
- In case of infant, scanning with minimum exposure dose is possible.
- Minimize the user's inconvenience by equipping self-diagnosis function
- Applied the intuitive interface for the user's convenience in operation.
- Reduced the exposure dose considerably compared to general medical CT scanners
- Complied with DICOM 3.0 (Digital Imaging Communication in Medicine), which is international medical imaging standard.

2 Safety Information

2.1 Symbols Used in Manual

- In this manual, for the efficient product use, following symbols are used. Please understand comply with the contents referred by symbol thoroughly
- To prevent the body injure and the damage to the property, please observe the safety precautions specified in this document. The precautions are shown as listed in symbol.

Symbol	Name of Symbol	Meaning
	NOTE	It shows the information and precautions required to use the product.
	X-ray	It shows the precautions on the risk of radiation and warnings
	CAUTION	It is the important instruction required to use the product. Violating it may cause critical damage to the equipment and the body
	WARNING HAZARD VOLTAGE	Do not touch. If not, it may cause the injury by the electric shock
	LASER	Do not look directly with eyes. It may cause critical damage to eyes
	ELECTRIC SHOCK	There is potential risk of electric shock
	If X-ray is not used correctly, X-ray may be dangerous or harmful to the body. User should observe the instruction and warnings contained in this manual without fail. This equipment should be installed in the X-ray shielding room. The room where the equipment is installed should comply with all the regulation regarding the safety protection from X-ray	

2.2 Precautions Before Use

- This product is the radiological medical instrument and should be operated by the qualified personnel only
- In any circumstance, do not only the equipment cover. When the product may be failed or problem may occur, please contact with the distributor near to you or manufacturer. The equipment operator should be able to communicate by voice or visually with the examinee before starting scan to completion
- When the equipment is not in use, Turn off the power switch
- When using the equipment, always use it after checking up the condition of power, PC, cable, etc
- When the equipment error may occur by the water or any foreign material during the use, Turn of the power immediately and contact with the distributor nearby or manufacturer
- When relocating or installing the computer, please avoid closed space. It may cause the product failure (computer vent is needed)
- Install the equipment in a place free from hazard material, flooded or water leak, etc.
- Do not place or hang any heavy object on the equipment. It may cause the equipment failure
- For the stable operation of equipment, use it at the room temperature at 20-25°C
- The component required the sterilization should be sterilized before use

 CAUTION	To prevent the risk of electric shock, connect the equipment earth to the ground
 CAUTION	warning: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth The software installed on this equipment PC is optimized for X-ray diagnosis. Do not install software other than the built-in software as it may not be able to shoot normally when installing vaccines and other virus programs

2.3 Precaution in Use

- Perform the scan after the examinee wears the protective clothing and the thyroid guard before scanning. Particularly for the child/infant, pregnant, etc. perform after consulting with physician
- The used components, etc. for hygiene should be sterilized whenever it is used
- When adjusting the height of equipment, do not allow the examinee to approach close to the equipment
- Guide the examinee to stand still in position until the equipment stops completely
- When the oil leak is suspected in the X-ray unit, turn off the power immediately and contact with the distributor nearby or manufacturer
- When the product may be disassembled or modified, the product shall not be eligible for warranty
- When the X-ray equipment may not comply with the exposure safety regulation and the operational guidelines, it may pose the hazard to both operator and examinee. Please comply with safety regulation
- X-ray scan should be performed in the place equipped with safety protection facilities and the operator should pay attention to the examinee's safety and the equipment operation
- Perform the scan in the condition that verbal or visual communication with the examinee is possible
- Explain how to operate the emergency stop switch to the examinee so that he/she can get away from the danger quickly when incident occurs during the X-ray scanning

2.4 Electrical Precaution

- Use in-put voltage of 220V
- Do install the equipment when disconnecting the power plug is not easy
- When the in-put power should be changed, please contact with the distributor nearby or manufacturer.
- Do not place any object within the area of installation defined in this manual
- Perform the scan after educating the examinee's action before/after the X-ray scan
- If the height is needed to be adjusted when aligning the examinee, adjust the height paying attention to the safety
- Do not pull off the power plug by force

	To prevent the risk of electric shock, connect the equipment earth to the ground
---	--

- Do not use laser beam other than the examinee alignment,
- When aligning the examinee, the space between the laser-beam should be maintained more than 10 cm (4") and pay attention in order not to look at it directly
- Do not pour or spray the liquid such as water on the product. It may cause the electric shock or damage or fire, etc. of the equipment.
- If the exposure safety regulation and the operational guidelines are not complied, it may pose the danger to both examinee and operator.
- Do not place any object within the radius of equipment operation. When scanning, it may cause the danger to the equipment and the examinee
- Do not keep the inflammables around the equipment. It may cause the fire
- During the scanning, do not manipulate the switch of the equipment or PC. It may cause the malfunction of the equipment
- When any problem may occur, stop the operation of equipment immediately by releasing the irradiation switch or pressing the emergency switch located below the equipment handle frame
- When the electrical fire may occur, use the fire extinguisher marked with corresponding purpose only. Using water or liquid for electrical fire may cause serious damage to the body and the equipment. Before the extinguishing the fire, prevent the danger of electric shock by disconnecting the power plug
- Do not sterilize with the spray. There is danger for sprayed sterilizer or disinfectant to be ignited

2.5 Radiation Protection Policy

	This is the important instruction required to use the product. Violating it may cause critical damage to the equipment and the body This equipment should be used only in a shielded location
---	---

- If the equipment may be operated abnormally during the scan, stop the equipment immediately by pressing emergency button.
- When scanning, operator should be away at least more than 2m from the equipment
- Scanning for children or pregnant should be performed after consulting with the physician in charge
- When scanning, the operator is obliged to provide the means of protection such as lead apron, etc
- The operator should check up the condition of examinee and equipment continuously for the emergency during the scan
- X-ray equipments should be located inside of the shielding facilities and the operator should scan watching inside of shielding facilities through the window at outside of it.

2.6 Policy on Manufacturer Liability

 NOTE	Manufacturer is entitled to revise the manual of this equipment without prior notice
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Limited to following cases, the manufacturer has the responsibility for the safety and normal operation of X-ray products

- In case that the equipment damage and accident is not caused by the arbitrary negligence of the customer
- In case that the equipment is used normally according to the user's manual
- In case that the genuine product approved by manufacturer is used
- In case that the maintenance is made by the distributor qualified by the manufacturer
- In case that the product is installed by the distributor qualified by the manufacturer
- In case that the equipment is installed complying with the installation conditions and the precautions specified by the manufacturer

2.7 Safety Function

2.7.1 System Safety

- When the power is down by the power failure or the manipulation of emergency switch.
- The auto scan down time (cooling time) is varied according to the grade of kV/mAs and actual radiation emission time.
The down time is set automatically between 8 - 600 seconds according to the tube loading

2.7.2 Indication/Warning System

- When the error occurs in the equipment, the red lamp is lit.
- During the irradiation of X-ray, the orange lamp is lit and the music is transmitted.

2.7.3 Examinee Protection Device

- When pressing the emergency switch during the abnormal operation of equipment, the equipment operation is stopped to protect the examinee
- In case of children, the tube voltage and tube current are set automatically through the registered information minimizing the radiation dose.

2.8 Product Labeling and Symbol

- Prevent the accident by attaching the label on the part of the product that can cause the dangerous situation.

2.8.1 Product Labeling

- As shown in Fig. , attach the label contained the product name, purpose, rated voltage, etc.(to be changed)

rainbow™ CT		Dentium Digital Dentistry System		Dentium For Dentists By Dentists	
REF ICT-R01	MADE IN Korea				
LOT	Dental Extra-oral X-ray System				
	Input Power: 100-240V~, 50/60Hz 2.6 - 2.3kVA Mode of operation Irradiation duration max: 19s/Rest duration: min 10min Column operation duration: Max1min/ Rest period: min 5min Permanent filtration: 0.8mm Al Added filter: 2.0mm Al				       
Dentium Co.,Ltd. (ICT Branch) (16229) 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea T+82-70-7098-4027, 6909 F+82-31-281-5561		"This product is a medical device" I031-01LA-02 rev.07			
Emurgo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands "This equipment should be used only in a shielded location."					

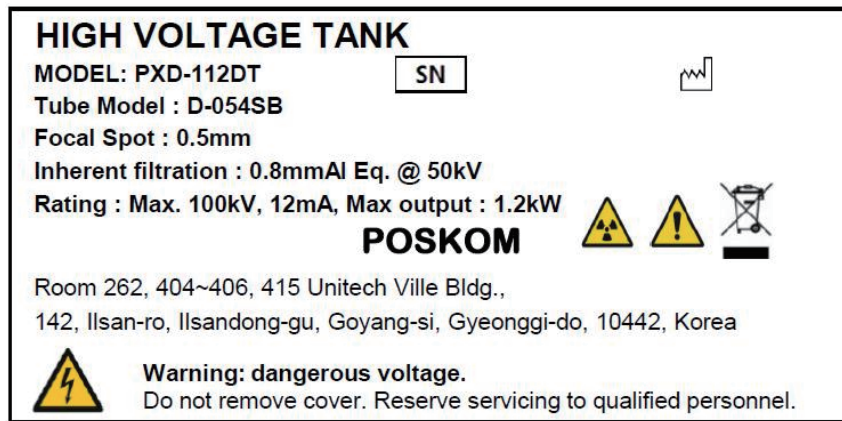
rainbow™ CT		Dentium Digital Dentistry System		Dentium For Dentists By Dentists	
REF ICT-R01-L	MADE IN Korea				
LOT	Dental Extra-oral X-ray System				
	Input Power: 100-240V~, 50/60Hz 2.6 - 2.3kVA Mode of operation Irradiation duration max: 19s/Rest duration: min 10min Column operation duration: Max1min/ Rest period: min 5min Permanent filtration: 0.8mm Al Added filter: 2.0mm Al				       
Dentium Co.,Ltd. (ICT Branch) (16229) 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea T+82-70-7098-4027, 6909 F+82-31-281-5561		"This product is a medical device" I031-01LA-03 rev.07			
Emurgo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands "This equipment should be used only in a shielded location."					

rainbow™ CT		Dentium Digital Dentistry System		Dentium For Dentists By Dentists	
REF ICT-R01-O	MADE IN Korea				
LOT	Dental Extra-oral X-ray System				
	Input Power: 100-240V~, 50/60Hz 2.6 - 2.3kVA Mode of operation Irradiation duration max: 19s/Rest duration: min 10min Column operation duration: Max1min/ Rest period: min 5min Permanent filtration: 0.8mm Al Added filter: 2.0mm Al				       
Dentium Co.,Ltd. (ICT Branch) (16229) 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea T+82-70-7098-4027, 6909 F+82-31-281-5561		"This product is a medical device" I031-01LA-02 rev.07			
Emurgo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands "This equipment should be used only in a shielded location."					

- rainbow CT Indonesia Only Label (ICT-R01, ICT-R01-L, ICT-R01-O)

Dentium For Dentists By Dentists		rainbow™ CT		MADE IN Korea	
				Dental Extra-oral X-ray System	
REF ICT-R01	Input Power: 110-240V~, 50/60Hz 2.2 - 2.0kVA Mode of operation Irradiation duration max: 19s/Rest duration: min 10min Column operation duration: Max1min/Rest period: min 5min Permanent filtration: 0.8mmAl Added filter: 1mm Al				
SN					
	     				
Dentium Co., Ltd. #201,#401,150, Eondong-ro, Giheung-gu, Yongin-si, Gyeonggi-do,Korea T+82-2-501-8560 F+82-31-281-5561		Distributor : PT.ICT Worldwide Indonesia OFFICE 88 Floor 25 Unit H, Kota Kasablanka, JL Kasablanka, No. 88, Jakarta Selatan, Indonesia Tel. +62 21 2208 3970, Fax. 62 21 2208 3972			
					
		I031-01LA-10 rev.02			

2.8.2 X-ray Generator Label



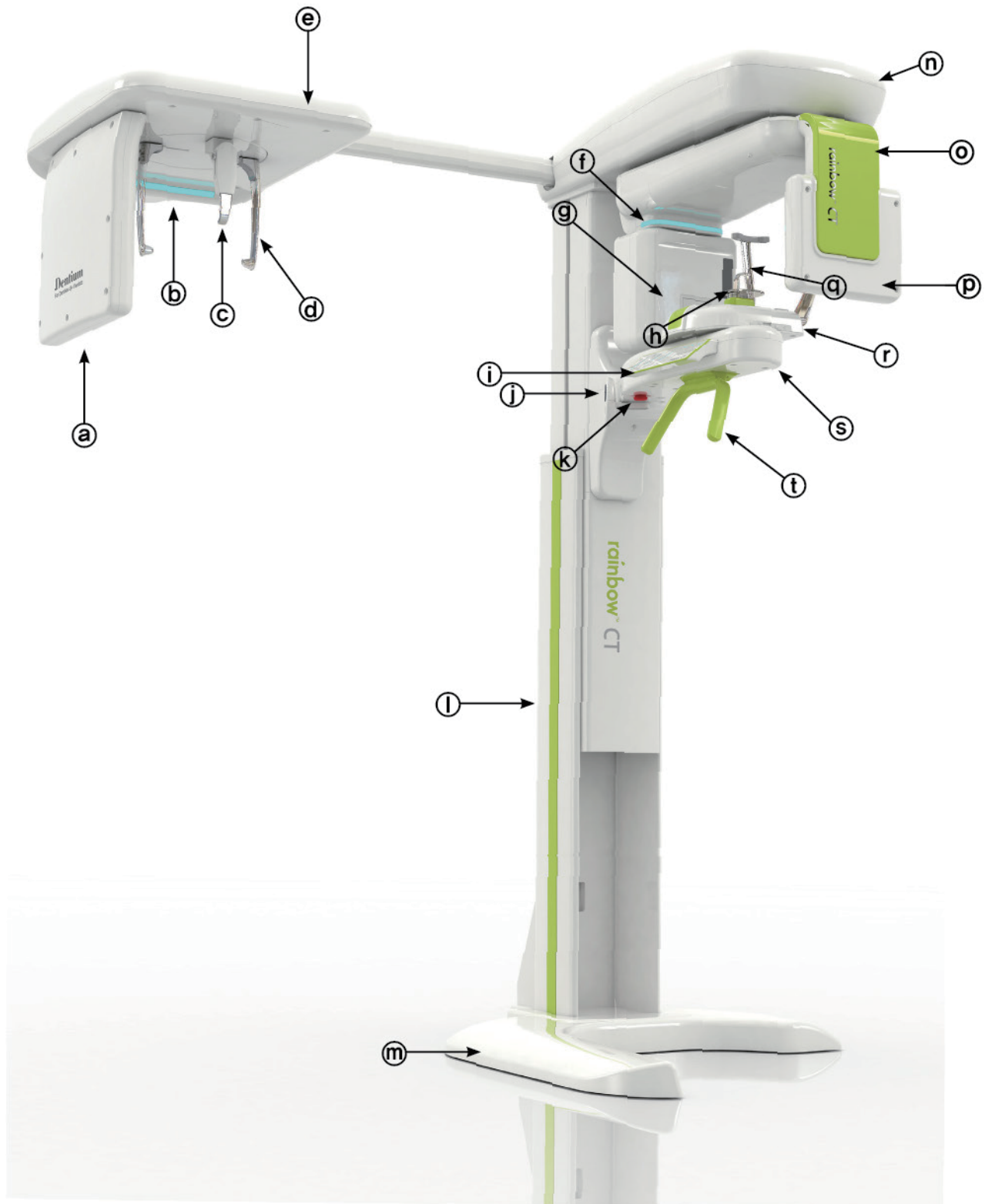
■ Mark and Symbol

Symbol	Symbol Name	Meaning
	Caution	Important instruction required to use the product
	High Voltage Hazard	Caution of electric shock by high equipment voltage
	Radiation	Danger of radiation exposure
	Laser Beam	Caution of laser beam
	Emergency Switch	Indication of emergency switch
	Protective Earth	Indicate the protective earth for entire equipment
	Type B equipment	Non-patient contacting equipment
	AC Power	Equipment using AC power
	ON	Turn power on
	OFF	Turn power off

Symbol	Symbol Name	Meaning
	WEEE Separate Disposal	Indicate separate disposal
	Recycling	Indicate recycling
	Neutral point (IEC 60445)	neutral point of an electrical supply system
	Temperature limit	This symbol indicates the category temperature range.
	Humidity limitation	This symbol indicates the operating humidity range.
	Note	It shows the information and precautions required to use the product
	Note	It shows the information and precautions required to use the product
	Caution	Consult instructions for use

3 Equipment Structure and Function

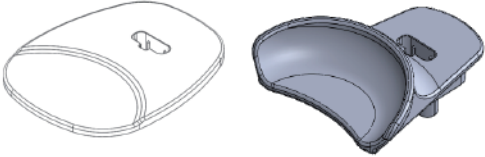
3.1 Structure (Name)



■ Detailed Explanation

㉑	Cephalo Sensor	Device that detects, digitalizes and transmits the subject scan signal
㉒	Status Indicator	This is the lamp to check up the X-ray irradiation status and is changed from green to orange when starting the scan
㉓	Forehead Ruler	This is used to align the examinee's posture when cephalo scanning
㉔	Ear Rod	This is used to align the examinee's posture when cephalo scanning
㉕	Cephalo Unit	This is the cephalo scanning module
㉖	Status Indicator	This the lamp to check up the X-ray irradiation status and is changed from yellow to orange when starting the scan
㉗	X-ray Tube	This is the device to generate the X-ray
㉘	Chin Rest	This is used to align the examinee's posture to take X-ray
㉙	Switch Module	The switch to adjust the equipment height for examinee alignment and to control the laser operation, etc.
㉚	UP/DOWN Switch	Switch to adjust the equipment height
㉛	Emergency Switch	As the switch to protect the examinee under the emergency during the scanning by stopping the equipment quickly (When the switch is operated, the power is turned off)
㉜	Lift Column	Function to adjust the equipment height
㉝	Base Support	Module to fix and balance the equipment
㉞	Top Frame	Module to support the scanning module
㉟	Rotating Unit	When selecting the scan mode, it moves to the scan position automatically and the scan is performed by rotating around the head of examinee when performing the scan
㊱	CT/PANO Sensor	Device to digitalize and transmit the image come out through the subject (CT, Panoramic)
㊲	Ear Rod	This is used to align the examinee's posture when scanning
㊳	Temple Support Module	This is used to align the examinee's position when scanning
㊴	Chin Rest Arm	Support fixture to fix the examinee position alignment module
㊵	Handle	Handle that examinees can grab stably when aligning the examinees

3.2 Accessory

Explanation	Picture of Accessory
Standard / Edentulous Jaw Chin Rest	
Edentulous bite	
TMJ bite	
Tooth Bite	
Temple Support	
Manual - rainbow™ CT User Manual - rainbow™Ceph manual - rainbow™ 3D viewer manual - rainbow™ImageViewer manual	

3.3 Exposure Switch

- After completing the scan preparation, the image is scanned when pressing Exposure Switch outside of shielding Room. This switch should be pressed until the scan is completed. If this switch is released during the scan, the scan is stopped



Exposure Switch



X-ray irradiation switch be sure to work on defensive zone

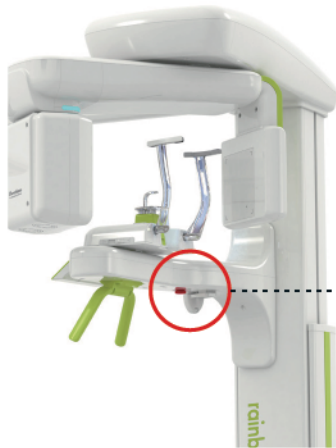
3.4 UP/DOWN Switch

- This is the switch to move the main column up/down and if the Up button is pressed, the main column goes up and if the Down button is pressed, it goes down



UP/DOWN Switch

3.5 Emergency Switch



Location of Emergency Switch



Appearance of Emergency Switch

- Emergency Switch is located below Handle Frame. If the emergency may occur when using the equipment, stop the equipment operation immediately by pressing Emergency Switch
- When the examinee may be bumped with the equipment during the scanning
- When X-ray scanning is made or other error may occur by the malfunction of equipment
- When the scan is made without pressing Irradiation Switch
- When the scan is performed when releasing Irradiation Switch
- If Emergency Switch is turned to the direction of arrow mark, the emergency mode is released

3.6 Power Switch

- The equipment power can be turned on/off using the Power Switch at the back of the product

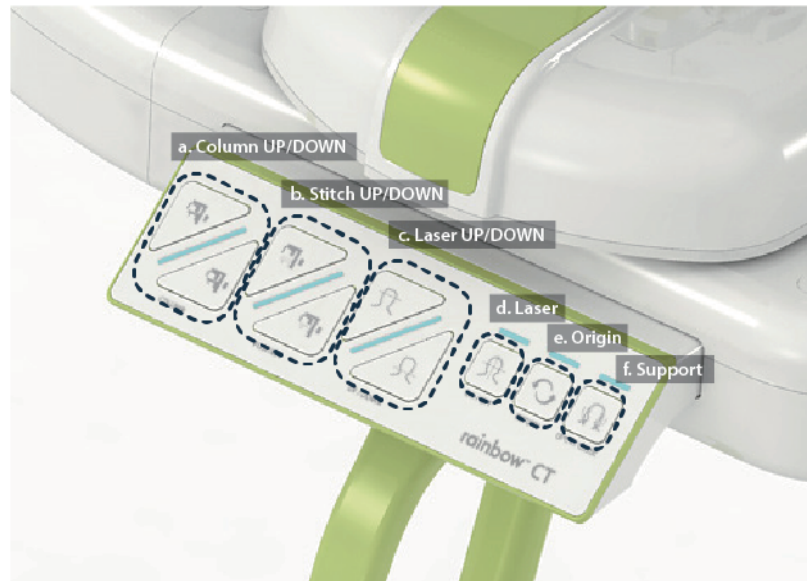


[Power Turned On]



[Power Turned Off]

3.7 Control Switch



- ① **Column up/down** : Lift Column goes up or down according to the switch pressed (700mm)
- ② **Stitch up/down** : Stitching Module is moved up to 80mm according to the switch pressed
- ③ **LASER up/down** : The laser beam position goes up or down according to the switch pressed
- ④ **LASER** : When pressing the switch, it is turned on and when pressing again, it is turned off
- ⑤ **Origin** : Press this switch when the examinee comes out after the scanning. The equipment moves to the standby position
- ⑥ **SUPPORT** : When pressing this switch after determining the examinee's position for scan, the temple support fix the both sides of examinee's forehead stably

3.8 Status Indicator



- When the power is supplied, Status Indicator will be lit in green
- When X-ray is emitted after starting the scan, it is lit in orange
- When error occurs, Status Indicator is lit in red

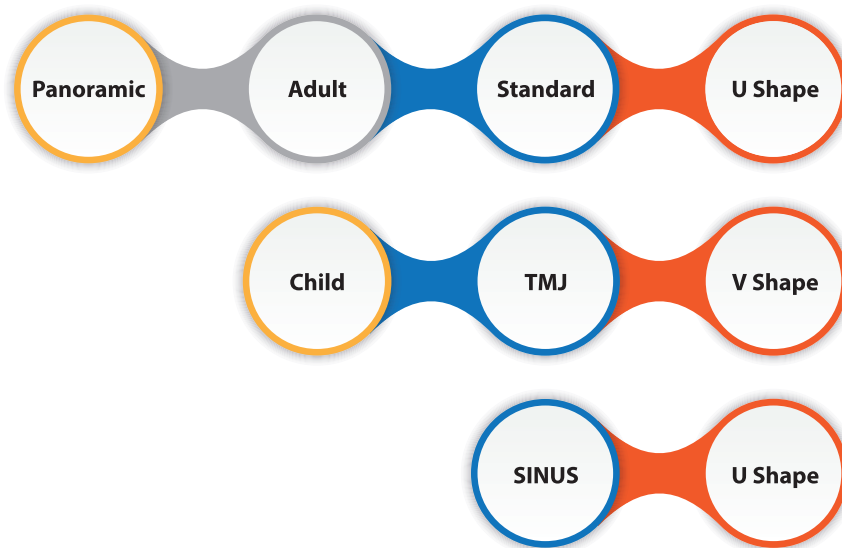


4 How to Use

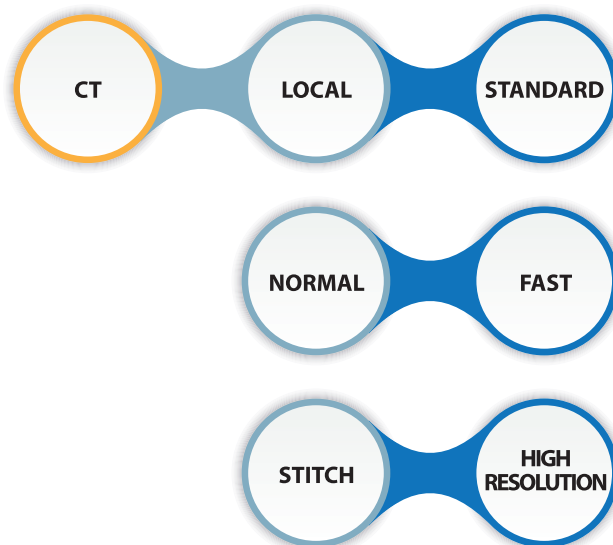
4.1 Scan Menu

- * There are 3 scan mode and the details are as follows
- Panoramic Scan Mode
- CT Scan Mode
- Cephalometric Scan Mode (Line, One-shot Cephalography)

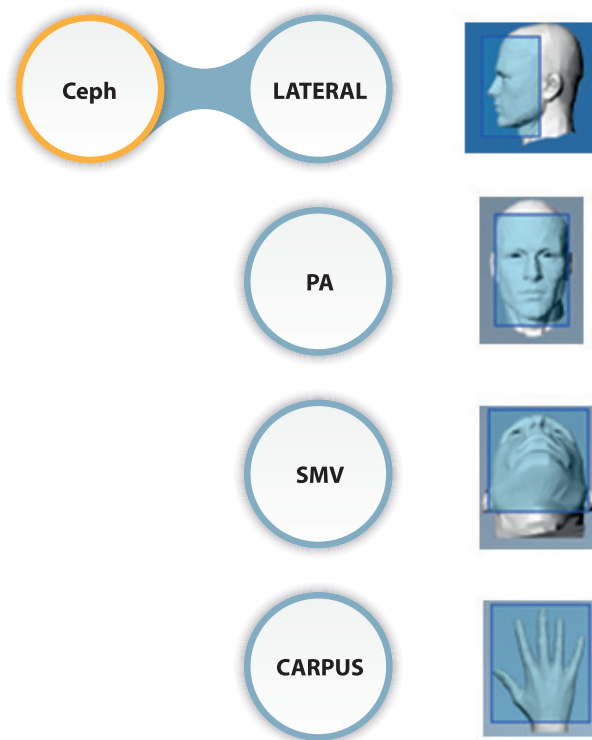
4.1.1 Panoramic Scan Mode



4.1.2 CT Scan Mode



4.1.3 Cephalometric Scan Mode



4.2 Detailed Explanation of Scan Program

4.2.1 Main Screen (Pano/CT/Ceph)

- When starting Scan Mode, Main Screen appears as follows
- Select the desired mode to scan (Pano, CT, Ceph)

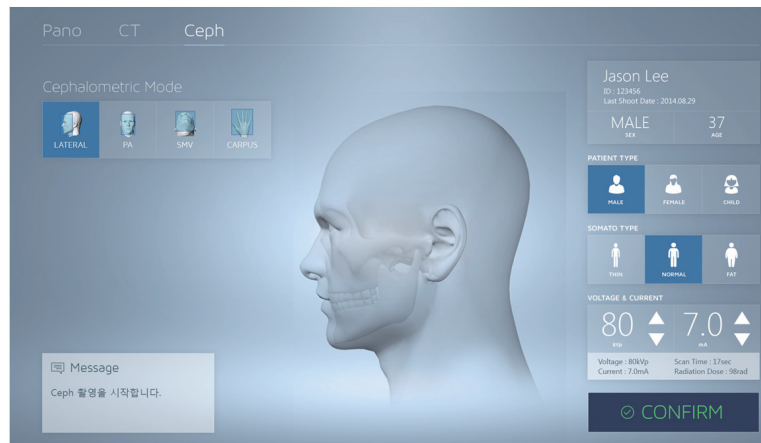
4.2.2 Basic Panoramic Scan Screen



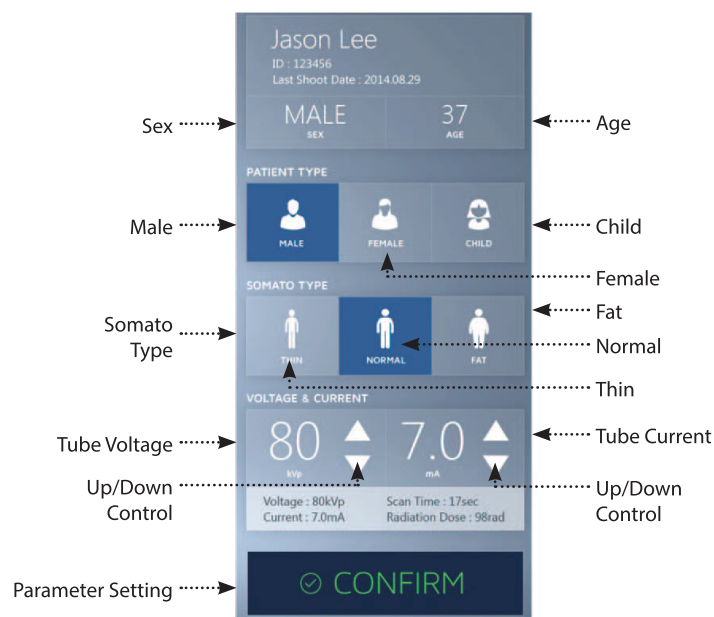
4.2.3 Basic CT Scan Screen



4.2.4 Cephalometric Scan Screen

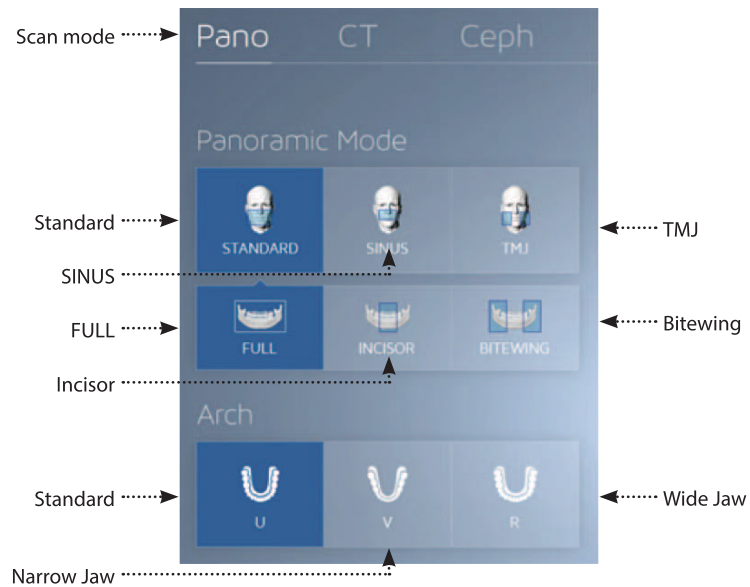


4.2.5 Common Menu



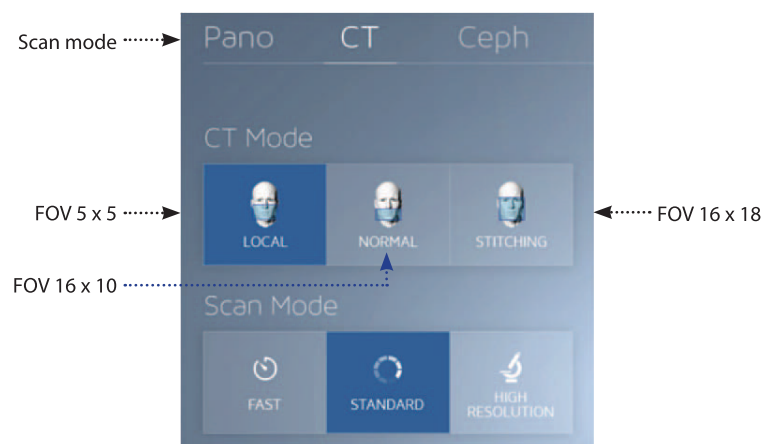
- Sex : Select according to male, female and child
- Somatotype Setting : Select according to the somatotype of examinee
- Tube voltage/ Tube current : More precise image can be obtained through the adjustment
- CONFIRM : Make scan-ready mode by pressing the button when the parameter setting is completed.

4.2.6 Panoramic Setting Menu



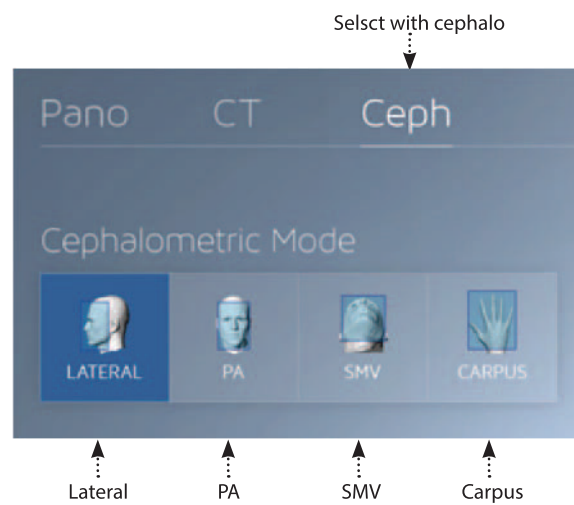
- STANDARD : As standard panoramic scan mode, scan entire dental arch
- SINUS : Mode to scan sinus domain
- TMJ : Mode to scan temporomandibular joint
- Dental Arch Selection : More precise image can be obtained if this is selected according to the examinee's dental arch shape

4.2.7 CT Setting Menu



- LOCAL : FOV 5X5 domain can be scanned
- NORMAL : FOV 16X10 can be scanned / maxillary and mandible can be scanned
- STITCHING : FOV 16X18 domain can be scanned

4.2.8 Cephalometric Setting Menu



- LATERAL : Scan the lateral side of the examinee's head
- PA : Scan the frontal area of examinee's head
- SMV: Scan the perpendicular plane of examinee's head
- CARPUS : Scan the examinee's hand or wrist and determine the information on the examinee's growth

Panoramic Scan Method and Procedure

 CAUTION	During the scan preparation, the equipment move to initial position to prepare the scan. After the scan preparation is completed, allow the examinee to advance to the equipment
--	---

Note for Examinee

 NOTE	The examinee's posture alignment has great influence on the image quality. To obtain good image, please read following procedure and guidelines.
 CAUTION	Scan the examinee after removing the metallic accessories (hairpin, glasses, earring, oral hygiene instrument, etc). The metallic material degrade the image quality by generating the artifact.
 CAUTION	The examinee should be scanned after wearing the protective clothing and thyroid guard, and particularly, scan the child or pregnant after consulting with physician

4.3 Scan Preparation

- Before turn on the equipment power, check if the cable between rainbow™ CT and PC is connected correctly
- Apply the power by pressing the power switch located at the back column of equipment to "I"



- When the product is not in use, turn the power off safely by pressing the switch to "O"

 NOTE	If the equipment has not been used for long time, preheat the equipment more than 5 minute before use to extend the X-ray tube life.
 CAUTION	When the equipment is operating, do not manipulate PC and control switch. It may cause malfunction

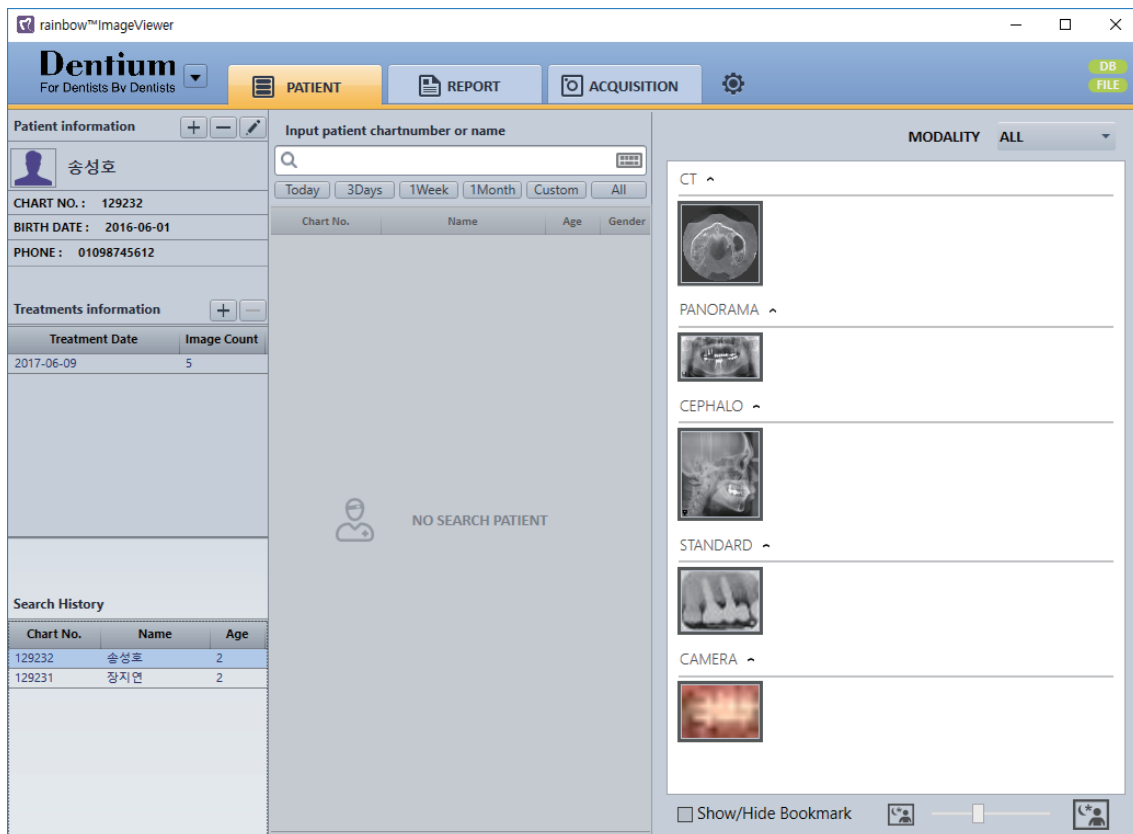
4.3.1 Image management program

■ summary

- rainbow™ImageViewer is an image management program for dental program that allows you to manage and analyze the fast and accurate diagnosis, imaging

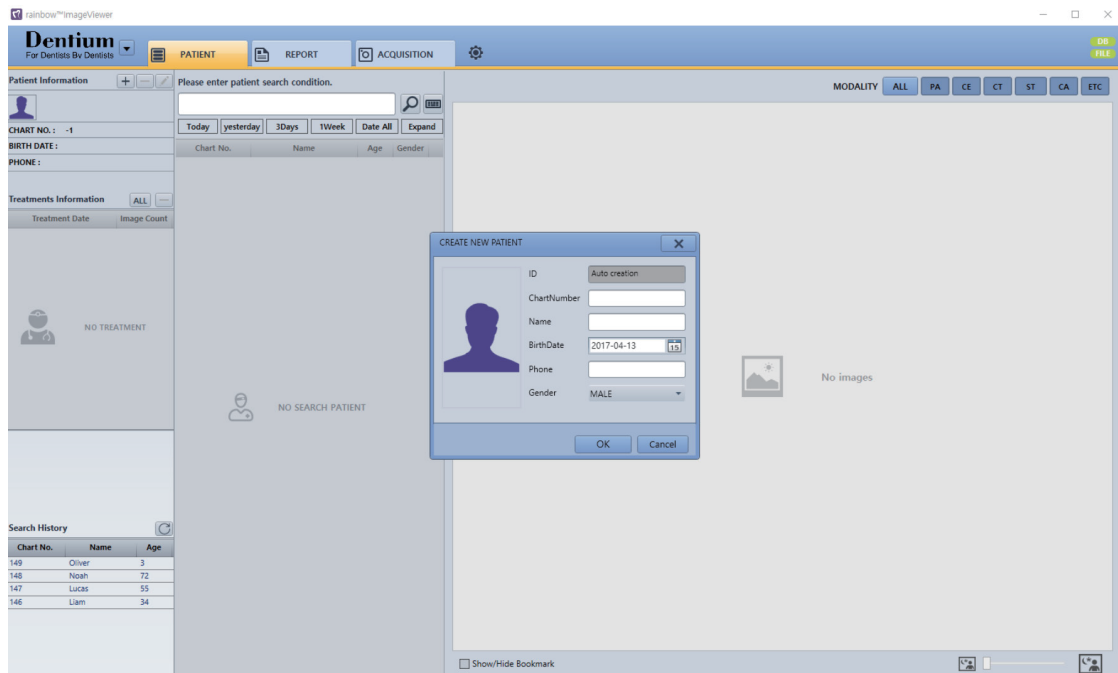
■ The start of the program

- Double-click an image management program "Easy view" icon on the desktop to run the program
- The "rainbow™ImageViewer" or retrieve information on existing patient can register a new patient



■ Registration of new patients

- Register a new patient in the following order
- rainbow™ImageViewer icons are created when you run the main window, as shown above New patient registration



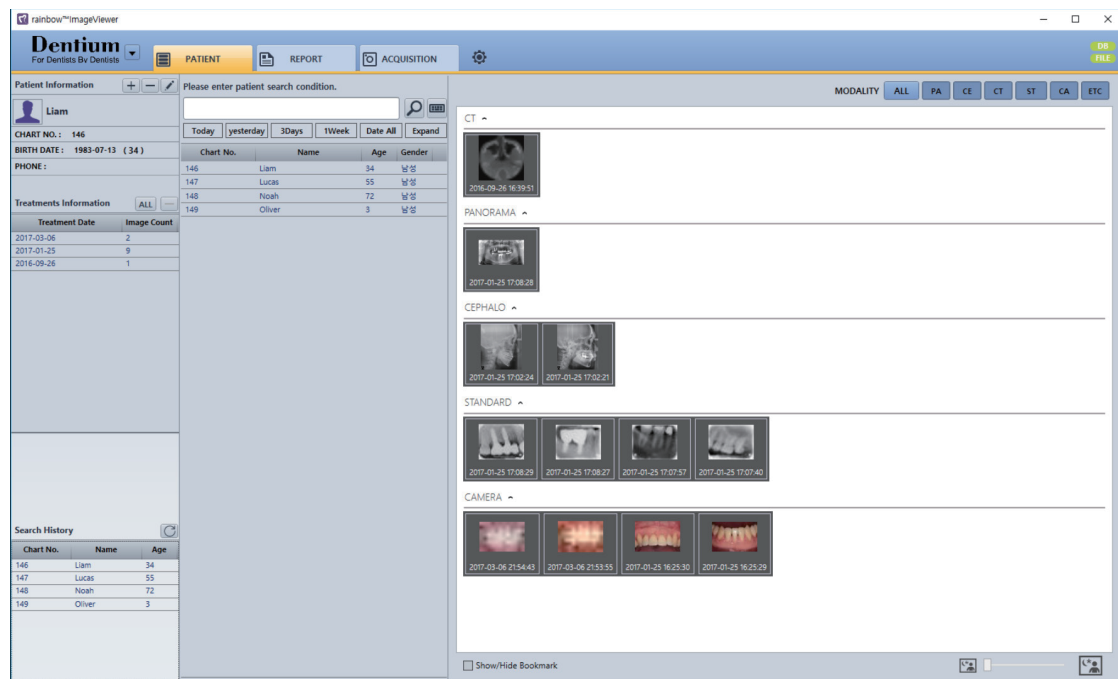
- New Patient ID, Name, Age and then press the OK button to enter the patient registration



To learn more, please refer to the User's Manual "rainbow™ImageViewer"

■ Import Patient Information

- Enter the name of the registered patients, age, date, ID, you can retrieve patient list Search patient information, you can check the details in the upper left "rainbow™ImageViewer"
- The examinee whose image was registered on corresponding date can be searched in the list by pressing buttons of Today, yesterday, 3day, 1Week, 1Month, Date All at the bottom of Search Window.



If you search a patient's chart number search is to enter the entire number,
If you find just by typing the first letter in the name is related to all patients will
be searched

- Patient information is displayed as shown below, and you can check the patient information and medical images

rainbow™imageViewer

Dentium
For Dentists By Dentists

PATIENT REPORT ACQUISITION

MODALITY ALL PA CE CT ST CA ETC

Patient Information

Please enter patient search condition.

Today yesterday 3Days 1Week Date All Expand

Chart No. Name Age Gender

146	Liam	34	남성
147	Lucas	55	남성
148	Noah	72	남성
149	Oliver	3	남성

Treatments Information

ALL

Treatment Date	Image Count
2017-03-06	2
2017-01-25	9
2016-09-26	1

Search History

Chart No.	Name	Age
146	Liam	34
147	Lucas	55
148	Noah	72
149	Oliver	3

CT

2016-09-26 16:39:51

PANORAMA

2017-01-25 17:08:28

CEPHALO

2017-01-25 17:02:24 2017-01-25 17:02:21

STANDARD

2017-01-25 17:08:29 2017-01-25 17:07:57 2017-01-25 17:07:40

CAMERA

2017-03-06 21:54:43 2017-03-06 21:53:55 2017-01-25 16:25:30 2017-01-25 16:25:29

Show/Hide Bookmark

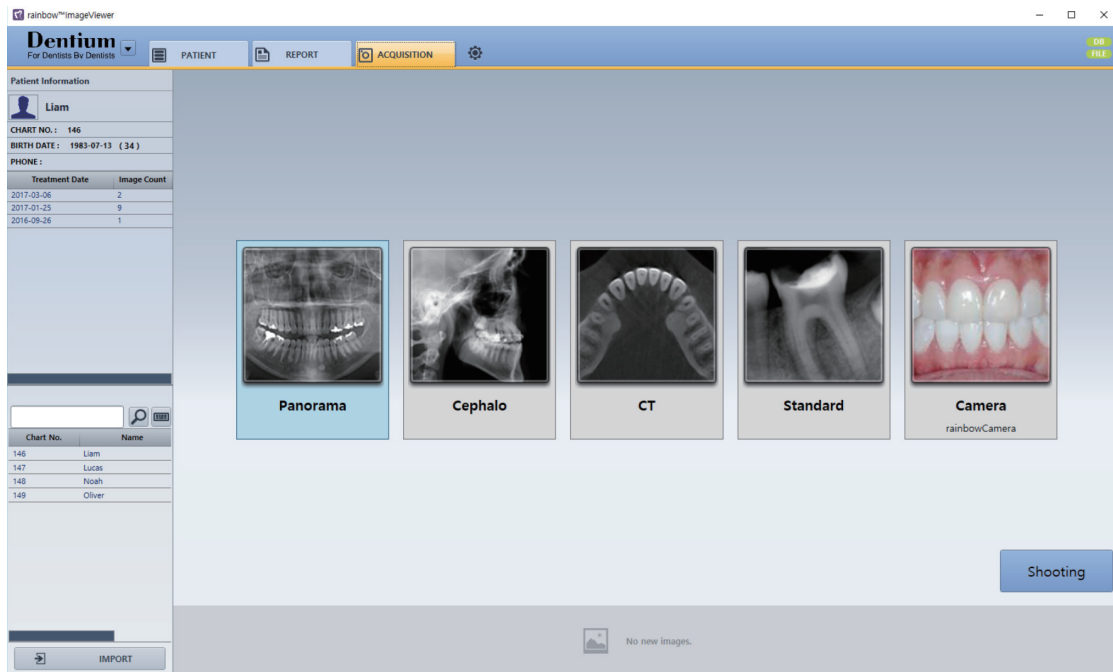
Please enter patient search condition.

Today yesterday 3Days 1Week Date All Expand

Chart No.	Name	Age	Gender
146	Liam	34	남성
147	Lucas	55	남성
148	Noah	72	남성
149	Oliver	3	남성

■ Image Scan

- Import or newly registered patient information Enter patient information
- Please refer to the below rainbow™ImageViewer



- If ACQUISITION tab is clicked, the screen for x-ray scan appears.
- The patient's shooting date is automatically selected as the current date
- Please see details below each shooting mode

4.3.2 Panoramic Scan

- Activate the image management program shown in the screen by clicking it (ACQUISITION Tap)
- Click the examinee to be scanned by searching in the program or register as new patient
- Select the panoramic scan mode in the image management program



NOTE

Updating the operating system (OS) in the computer is not recommended.

- Following panoramic scan main screen appears



 NOTE	Check if the examinee information displayed at the top of the examinee information window is coincided with the name of examinee to be scanned.
---	--

- Set the parameters of the right center of the scan program
- Set them according to condition of Adult/Female/Child
- Select the type of bone density according to the somatotype of examinee
- Tube voltage and tube current is set to default values and the more precise image can be obtained by changing according to the resulting image

 NOTE	If the tube voltage and tube current may need to be adjusted according to the image quality, do it fit to the characteristics of the examinee with fine-tuning.
 CAUTION	The tube voltage / tube current value, it may affect the dose increased, and the image of the patient during adjustment, please use to fine-tune

4.3.3 Examinee Posture Alignment

 NOTE	The examinee's posture alignment has great influence on the image quality. Therefore, to obtain good image, please read following procedure and guidelines.
 CAUTION	Scan the examinee after removing the metallic accessories (hairpin, glasses, earring, oral hygiene instrument, etc). The metallic material degrade the image quality by generating the artifact.
 CAUTION	The examinee should be scanned after wearing the protective clothing and thyroid guard, and particularly, scan the child or pregnant after consulting with physician.

■ Examinee Alignment

- Guide the examinee to relax in order for shoulder to be parallel and to maintain upright.
- The cervical vertebra (neck bone) should be straightened upright
- Remove all the metallic material of the examinee such as glasses, earring, hairpin, oral hygiene device, etc.
The metallic material degrade the image quality by generating artifact
- Fix the general chin rest and tooth Bite bloc in the chin rest hole and cover the hygiene cover over the Bite bloc
(common use for edentulous jaw)

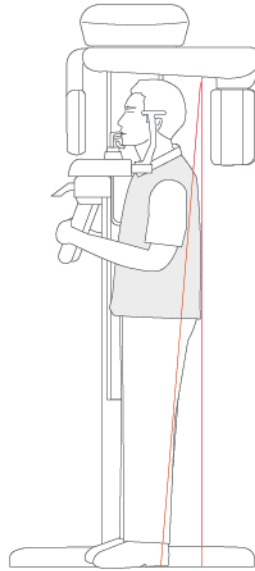


(Tooth Bite Block)

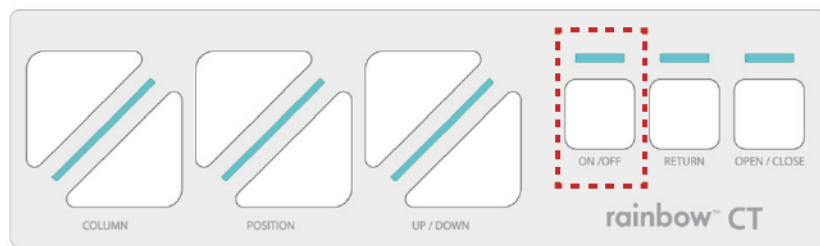
 CAUTION	Replace the hygiene cover with new one for the next examinee. It may cause the infection
--	---

- Make the examinee stand upright on the equipment in order to match the chin with chin rest and grab the handle below the equipment. (Place the feet slightly inside of the straight line)
- Adjust the height of equipment so that the chin of examinee can reach on the chin rest using Up/Down switch of the column.

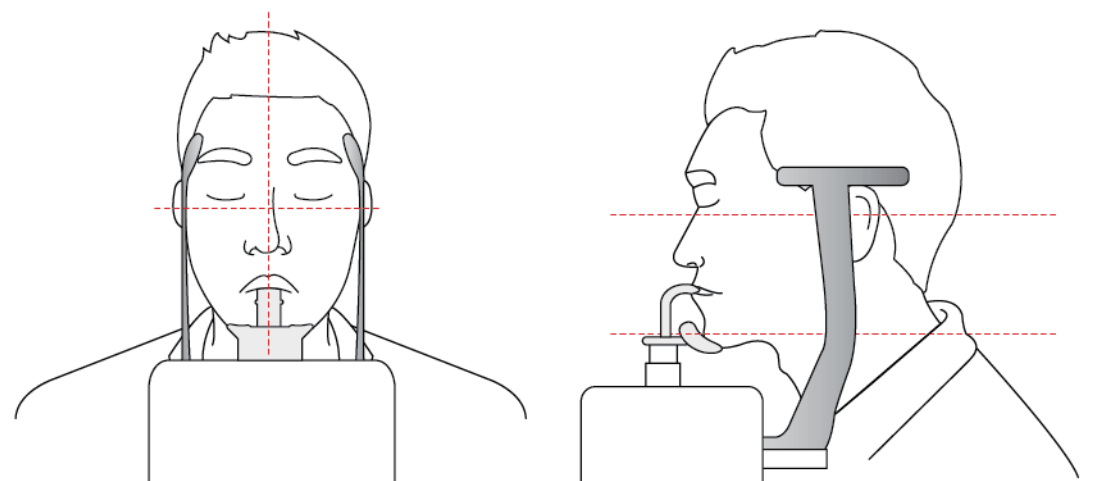
- Make the examinee stand upright on the equipment in order to match the chin with chin rest and grab the handle below the equipment. (Place the feet slightly inside of the straight line)



- Adjust the height of equipment so that the chin of examinee can reach on the chin rest using Up/Down switch of the column



- Laser beam will be turned on when pressing ON/OFF button. Please proceed as following explanation
- Vertical beam is fixed. Position the examinee so that the vertical beam is located at the center of face



- Horizontal Beam: Adjust the horizontal beam so that the Frankfurt line of the examinee's face are matched with it. Frankfurt line refers to the line connected from below the eye to the top edge of the external auditory meatus as shown in the figure
- The lower horizontal beam is fixed and the upper beam can be adjusted using the control switch



- Position the canine beam at the center of examinee's canine tooth
- The control switch of canine beam is located at right side of Temple Support Module

 CAUTION	Be careful not to direct the laser beam on the examinee's eyes. It may cause critical damage to the sight.
 NOTE	Laser beam is turned off automatically when start scanning

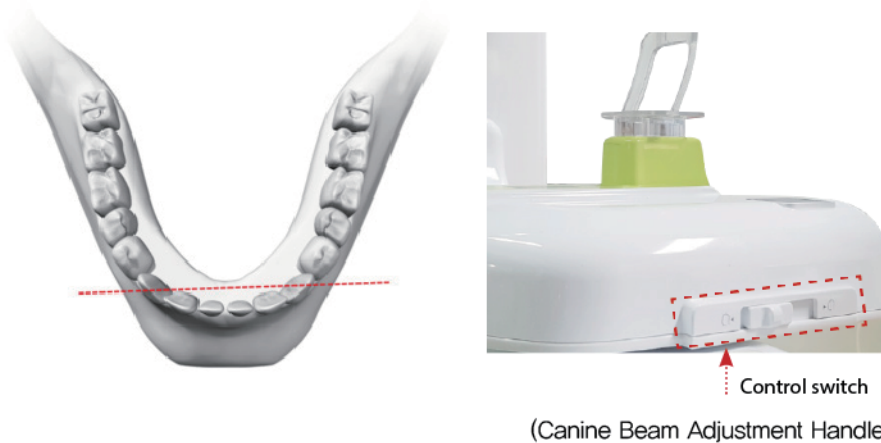
- When the examinee positions on the chin rest, fix the both sides of the examinee's head comfortably by pressing ON/OFF button in the control switch
- Guide the examinee so that during the scanning, he/she close the mouth and put the tongue on the palate
- Check if the examinee is closing the eyes. Guide the examinee to maintain the posture without moving until the scan is completed
- If the CONFIRM button located at the right bottom of the Scan screen, the equipment moves to the scanning position. When the movement is completed, the Scan switch is blinking. This shows that the x-ray irradiation is ready
- Scan the examinee under the condition that the verbal or visual communication with the examinee is possible
- The lamp will be changed to orange during the X-ray scan and when the scan is completed, it will be changed in green
- After scan is completed, guide the examinee outside of the shielding room

4.3.4 TMJ Scan (Temporomandibular joint) Open/Close Mode

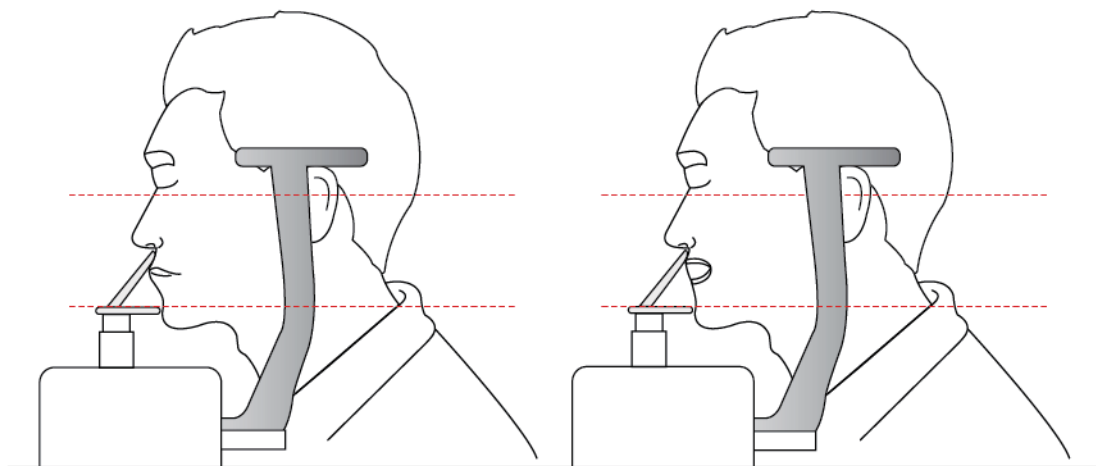
- TMJ mode has two modes; Open and Close modes. The TMJ Close image can be scanned in the same posture after TMJ Open scanning. Align the examinee according to following sequence
- Remove all the metallic materials worn by the examinee such as earring, glasses, necklace, hairpin, etc. The metallic material degrade the image quality by generating artifact



- Install existing chin rest on the temple support module
- Guide the examinee to stand upright in the center of the equipment so that the chin of examinee can be matched with the chin rest and grab the handle under the temple support. Guide the examinee to place the foot inside of the equipment
- Adjust the lift column to the height that the examinee do not feel uncomfortable in order for the examinee's chin to reach on the chin rest using the Up/Down switch. Place the examinee's chin on the chin rest
- Place the TMJ scan modul to Temple Support Module
- Make the examinee stand upright on the equipment in order to match the chin with chin rest and grab the handle below the equipment. (Place the feet slightly inside of the straight line)
- Adjust the life column to comfortable height by adjusting Up/Down switch so that the philtrum of examinee is contact with the top of the chin rest
- Vertical Beam: Vertical beam is fixed. Adjust the face so that it is located at the center of the beam
- Horizontal Beam: Adjust the horizontal beam so that the Frankfurt line of the examinee's face are matched with it
Frankfurt line refers to the line connected from below the eye to the top edge of the external auditory meatus as shown in the figure



- Match the canine beam to the oral angle of the examinee or the center between the canine and premolar of the examinee by adjusting the Canine Beam Adjustment Handle (match it by moving left to right)



- For the vertical/ horizontal laser beam alignment, see Panoramic Scanning Method
- TMJ Open : Make the examinee to open the mouth widely after swallowing the saliva. Induce to breath with nose placing the tongue on the back of palate
- After completing the alignment of examinee, press the Open/Close button of Control Switch in order to fix both sides of examinee's head
- Guide the examinee to close eyes and not to move until the scan is completed

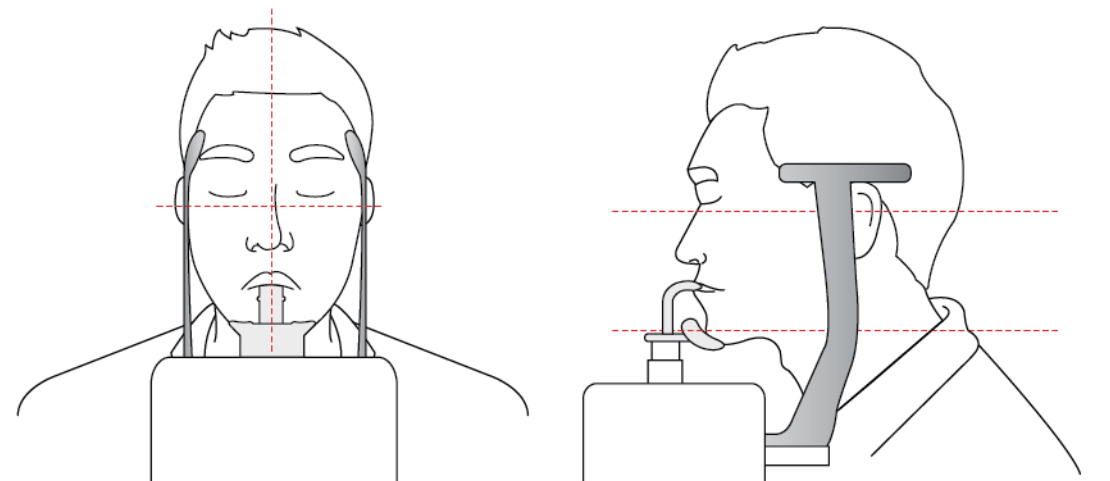
- Scan while maintaining this posture
- If the CONFIRM button located at the right bottom of the Scan screen, the equipment moves to the scanning position. When the movement is completed, the Scan switch is blinking. This shows that the x-ray irradiation is ready
- Press Scan button until the scan is completed. If Scan button is released, the scanning is stopped
- Scan the examinee under the condition that the verbal or visual communication with the examinee is possible
- During the X-ray scanning, the lamp is changed to orange and when the scan is completed, it is changed to green
- Guide the examinee to outside of shielding room after the scan is completed
- TMJ Close image can be scanned closing the mouth in the same posture after TMJ Open scanning. When the TMJ Open image is saved, the message asking if the TMJ Close image will be scanned continuously appears. Perform TMJ Close scanning by pressing OK button. To cancel it, press Cancel button

4.3.5 SINUS Scan Mode (Detained explanation will be added)

- Remove all the metallic materials worn by the examinee such as earring, glasses, necklace, hairpin, etc. The metallic material degrade the image quality by generating artifact
- Install the sinus chin rest on the equipment

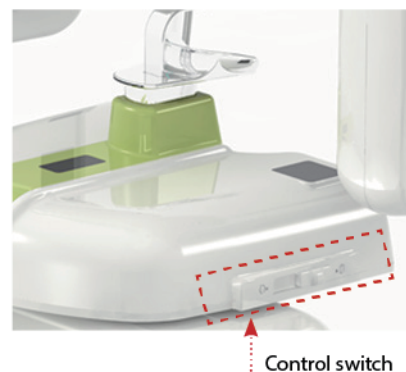


- Guide the examinee to stand in the center of the equipment so that the chin of examinee can be matched with the chin rest and grab the handle under the temple support. And align in order for examinee to place the foot inside of the equipment
- Adjust the lift column to the height that the examinees do not feel uncomfortable in order for the examinee's chin to reach on the chin rest using the Up/Down switch. Place the examinee's chin on the chin rest
- Make the examinee to relax for the shoulders to be parallel and maintain the upright posture
- The cervical vertebra (neck bone) should be extended straight



 CAUTION	Be careful not to direct the laser beam on the examinee's eyes. It may cause critical damage to the sight
 NOTE	Laser beam will be turned on about 3 minutes when it is turned on and when the time elapses, it will be turned off automatically. To turn it on again, press On/Off button

- The vertical beam is fixed. Align the posture so that the vertical mean is positioned in the center of the examinee's face



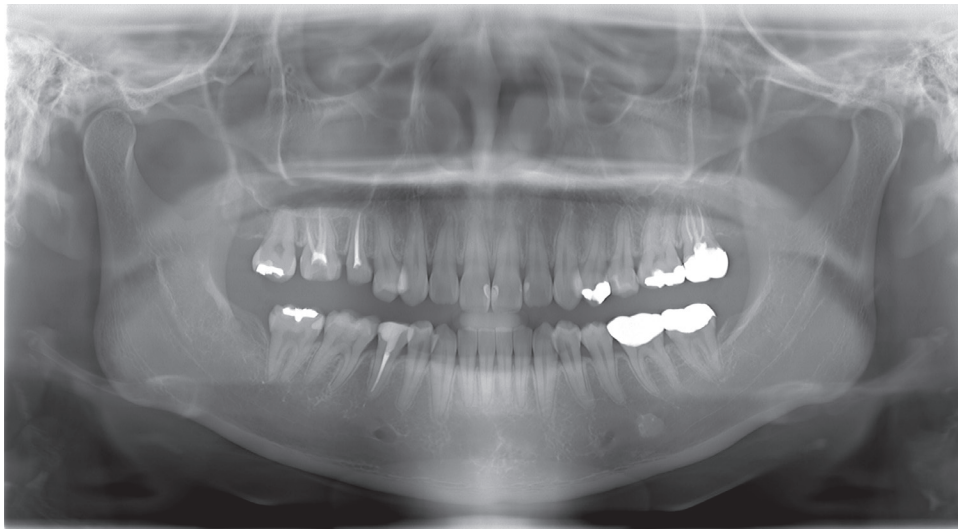
(Canine Beam Adjustment Handle)

- Match the canine beam to the corner of mouth or to the center of examinee's premolar with canine beam adjustment handle (Match it moving right to left)
 - If the alignment of 3 laser lines is completed, fix the examinee's forehead by pressing Temple Support button
 - Guide the examinee to close eyes
 - Make the equipment to be in ready mode by pressing Confirm button located at the right bottom of PC Monitor Scan Program after completing the alignment of examinee's posture
 - When pressing Confirm button, Scan switch located outside of shielding room blinks informing that X-ray irradiation is ready
- Press Scan button until the scan is completed
- During the X-ray scanning, the lamp will be changed to yellow and when the scan is completed, it will be changed to green
 - After completing the scan, guide the examinee outside of shielding room

 NOTE	Reference of X-ray Scan Sequence - Close the door of shielding room - Start scanning by pressing Scan switch monitoring the examinee from outside of shielding room - Press the button until the scan is completed and after completing the scan, release the button - If the button is released during the scan, the scan is stopped
 CAUTION	- If the problem occurs during the scan, stop the equipment operation immediately by releasing Irradiation switch or pressing Emergency button located below the handle frame - Operator always should monitor the examinee so that respond to the problem immediately during the X-ray scan

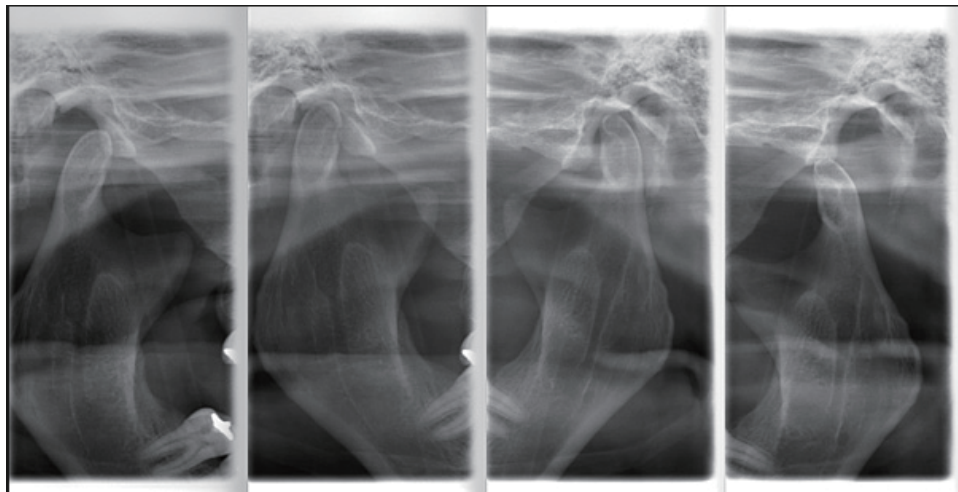
4.3.6 Viewing Scanned Image

- Standard Panoramic Image



- To store scanned image correctly, press Finish button.
- If you want to store the image with bright image or dark image, please refer below
- Brightness adjustment function If you place the cursor in the panoramic image, and drag to left while pressing the left mouse button, the image becomes darker and if you drag the mouse from left to right, the image becomes brighter. After adjusting the image, save it

- TMJ Image



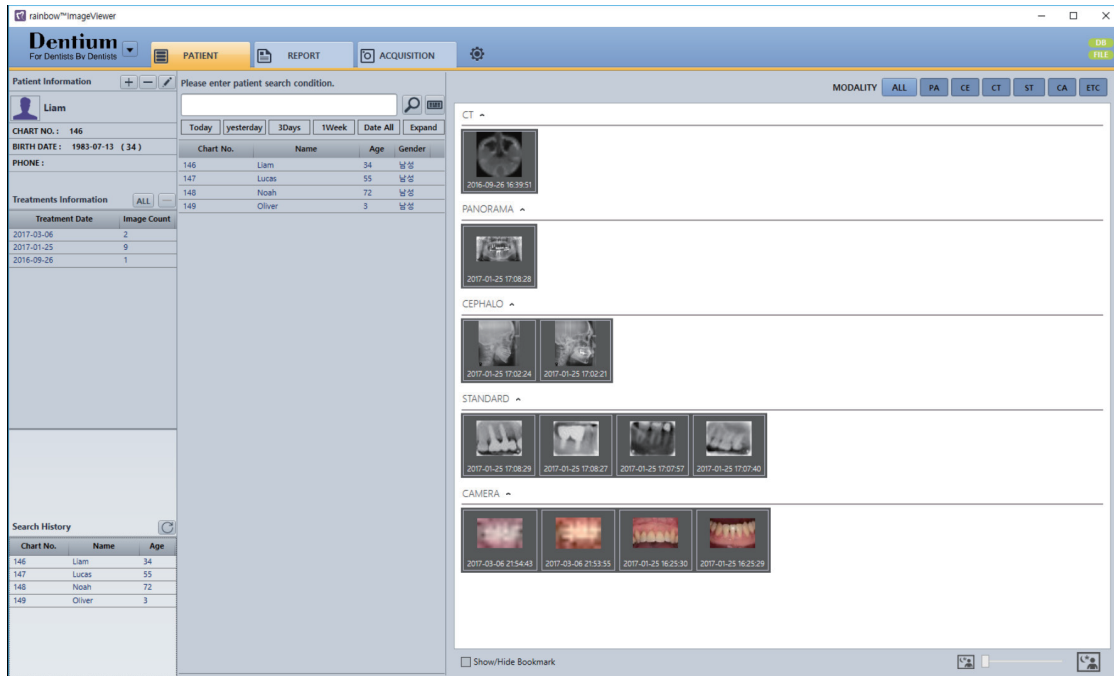
4.3.7 Finish Scanning

- Verify if the image is obtained correctly
- Open Temple Support and guide the examinee to outside
- Remove the hygiene vinyl cover of Bite bloc
- Position the rotating unit to initial position for next scan

4.4 CT Scan

4.4.1 Opening the examinee prior to CT scanning

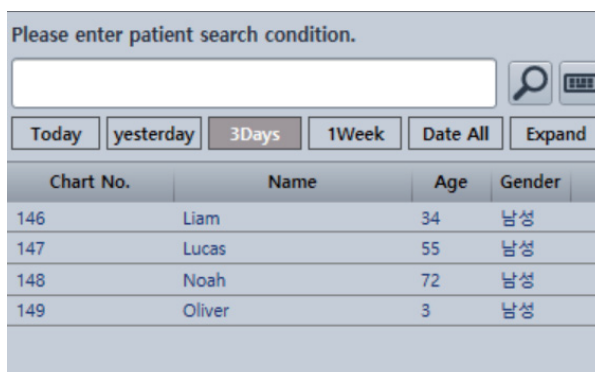
- Enter the name of the registered patients, age, date, ID, you can retrieve patient list Search patient information, you can check the details in the upper left "rainbow™ImageViewer"
- The examinee whose image was registered on corresponding date can be searched in the list by pressing buttons of Today, yesterday, 1day, 1Week, 1Month, Custom and All at the bottom of Search Window.



NOTE

Updating the operating system (OS) in the computer is not recommended

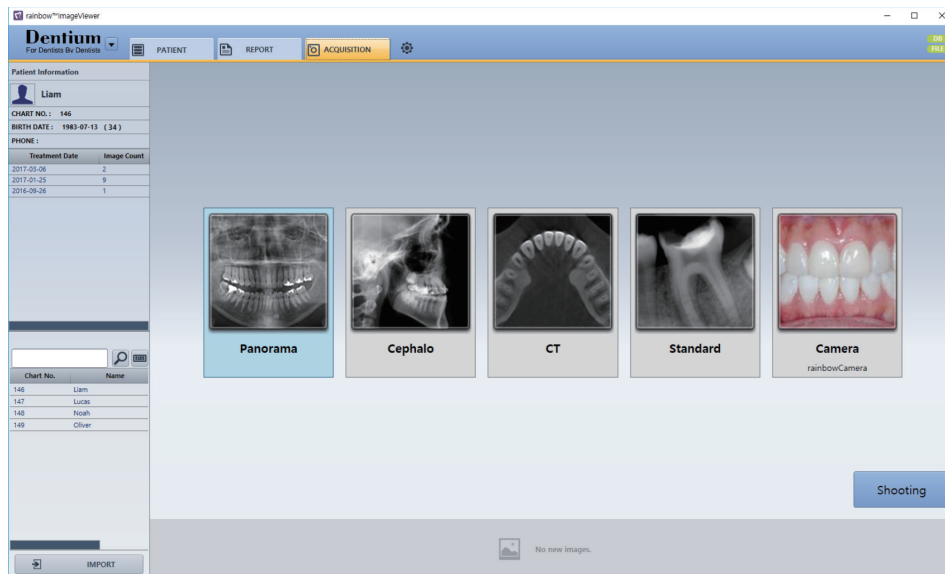
- The information of the searched examinee are displayed as shown below and the examinee information, scanned date and scanned image can be verified.



- Recent patient list

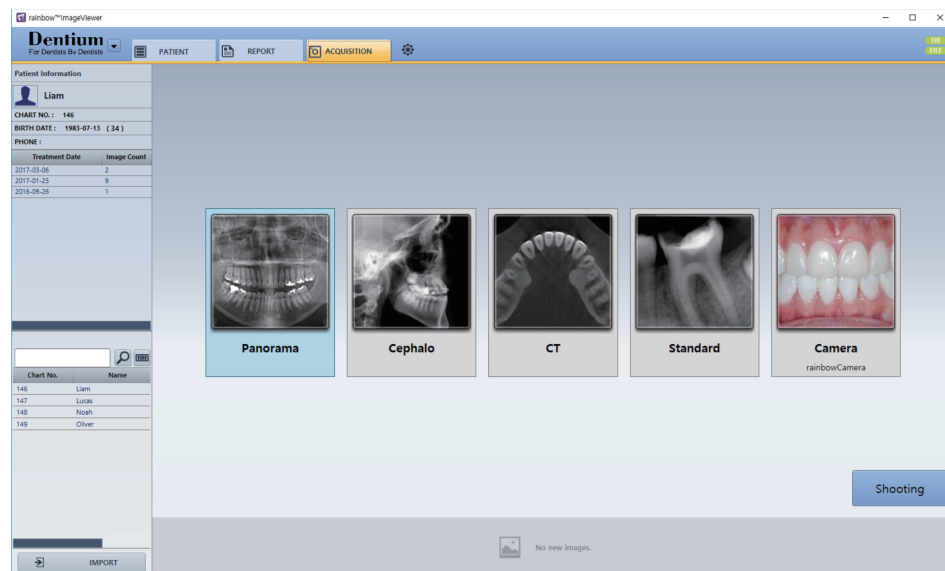
■ CT scan mode

- Open the information of examinee to be scanned or open the information of relevant examinee by registering as new
- Please refer to image management program for scanning



4.4.2 Starting CT scan program

- Activate the image management program shown in the screen by clicking it
- Click the examinee to be scanned by searching in the program or register as new patient
- Select CT Scan mode in the image management program



- The following appears in the main screen, please click on the CT tap
- If the scan mode is selected, the equipment moves to the initial scan position.

 NOTE	Updating the operating system (OS) in the computer is not recommended
 NOTE	Check if the examinee information displayed at the top of the examinee information window is coincided with the name of examinee to be scanned.

- The scan main screen appears as below. Click CT tab
- When the scan mode is selected, the equipment will move to initial scan position



4.4.3 Examinee Alignment and Scan

- Check if the name of examinee to be scanned is coincided with the examinee information
- Set the parameters in the right center of the scan program (Local, Normal, stitching)
- Set them according to condition of Adult/Female/Child
- Select the type of bone density according to the somatotype of examinee
- Tube voltage and tube current is set to default values and the more precise image can be obtained by changing according to the resulting image

 NOTE	If the tube voltage and tube current may need to be adjusted according to the image quality, do it fit to the characteristics of the examinee with fine-tuning.
---	--

- Default values of CT Mode are as shown in left (NORMAL -STANDARD)

■ CT FOV

ITEM	LOCAL	NORMAL	STITCHING
FOV SIZE (cm)	5x5	16x10	16x18

- Standard scan mode is set to Normal mode

■ NORMAL MODE

ITEM	FAST	STANDARD	HIGH RESOLUTION
VOXEL SIZE(μm)	300	300	200

- Scan mode is set to standard. Select Fast or High Resolution mode according to the purpose of use (FAST: low resolution, STANDARD: Normal Resolution, HIGH: High Resolution)

 NOTE	The examinee's posture alignment has great influence on the image quality. Therefore, to obtain good image, please read following procedure and guidelines.
 CAUTION	Scan the examinee after removing the metallic accessories (hairpin, glasses, earring, oral hygiene instrument, etc). The metallic material degrade the image quality by generating the artifact.
 CAUTION	The examinee should be scanned after wearing the protective clothing and thyroid guard, and particularly, scan the child or pregnant after consulting with physician.

- Guide the examinee to relax in order for shoulder to be parallel and to maintain upright.
- The cervical vertebra (neck bone) should be straightened upright
- Remove all the metallic materials from the examinee such as glasses, earring, hairpin, oral hygiene device, etc. The metallic material degrade the image quality by generating artifact
- Cover the hygiene cover over the Bite bloc (common use for edentulous jaw). Bite the bite bloc after fixing the general chin rest and tooth Bite bloc in the chin rest hole

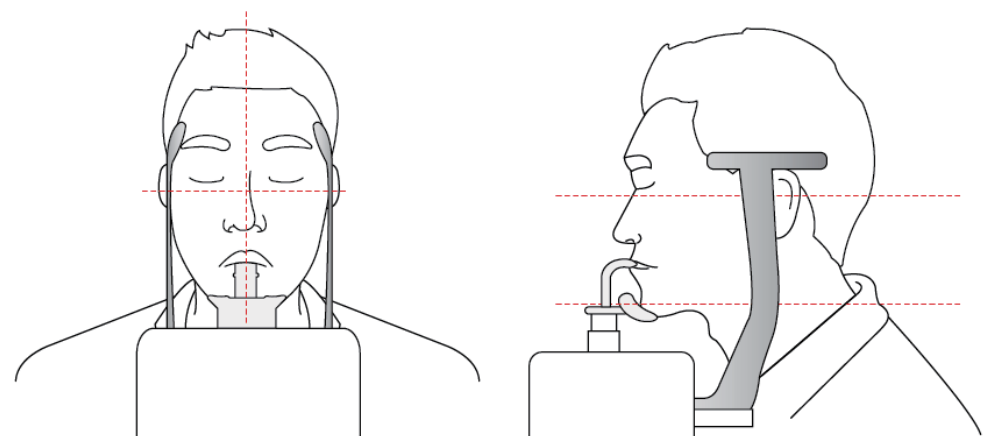
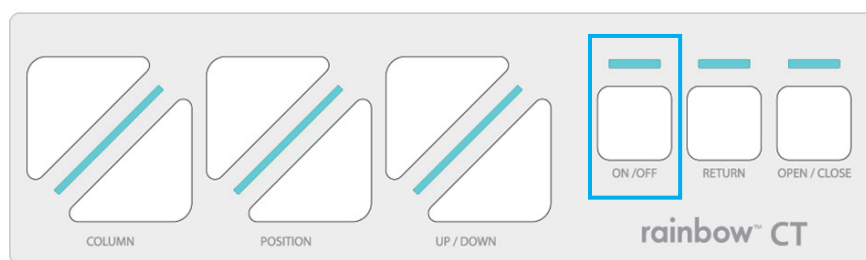


Tooth Bite Bloc



Replace the hygiene cover with new one for the next examinee.
It may cause the infection

- Make the examinee to stand upright on the equipment in order to match the chin with chin rest and to grab the handle below the equipment.
- Adjust the height of equipment so that the chin of examinee can reach on the chin rest using Up/Down switch of the column.
- Make the examinee to bite the front groove of Bite using upper and lower front teeth
- Picture of Switch Module
- Laser beam will be turned on when pressing ON/OFF button. Please proceed as following explanation
- Vertical beam is fixed. Position the examinee so that the vertical beam is located at the center of face.



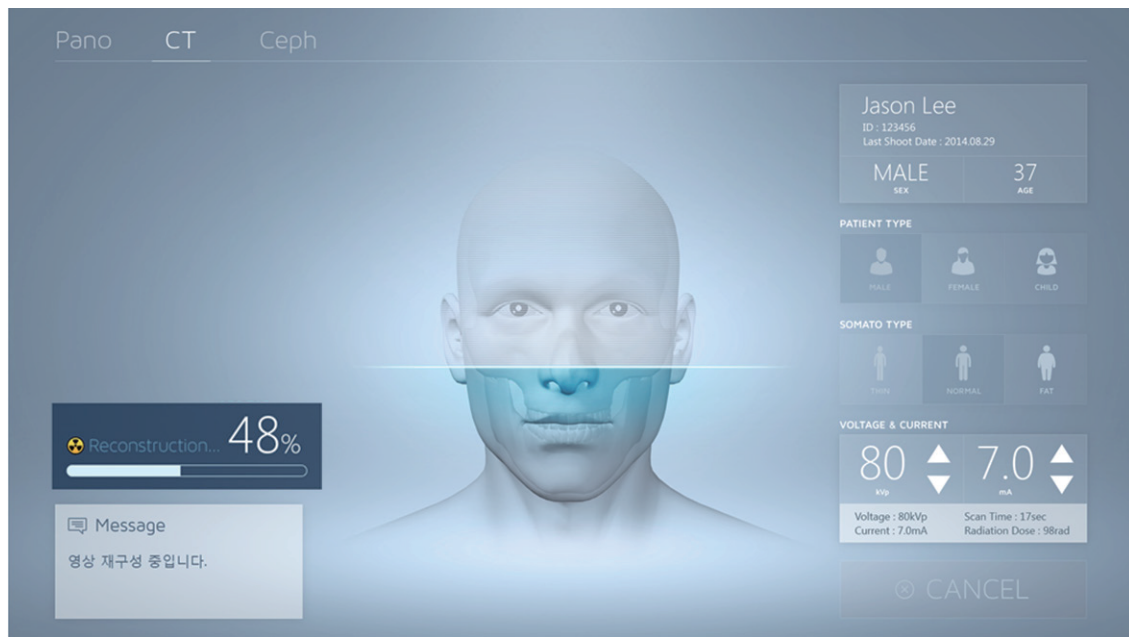
- Adjust the horizontal beam so that it can be perpendicular to the Frankfort line of the examinee's face
- Frankfort line refers to the line connected from the point below the eye to the point of top edge of the external auditory meatus
- The lower horizontal beam is fixed and the upper beam can be adjusted using the control switch



- The lower canine beam is fixed and the upper beam can be adjusted using the Control Up/Down switch.

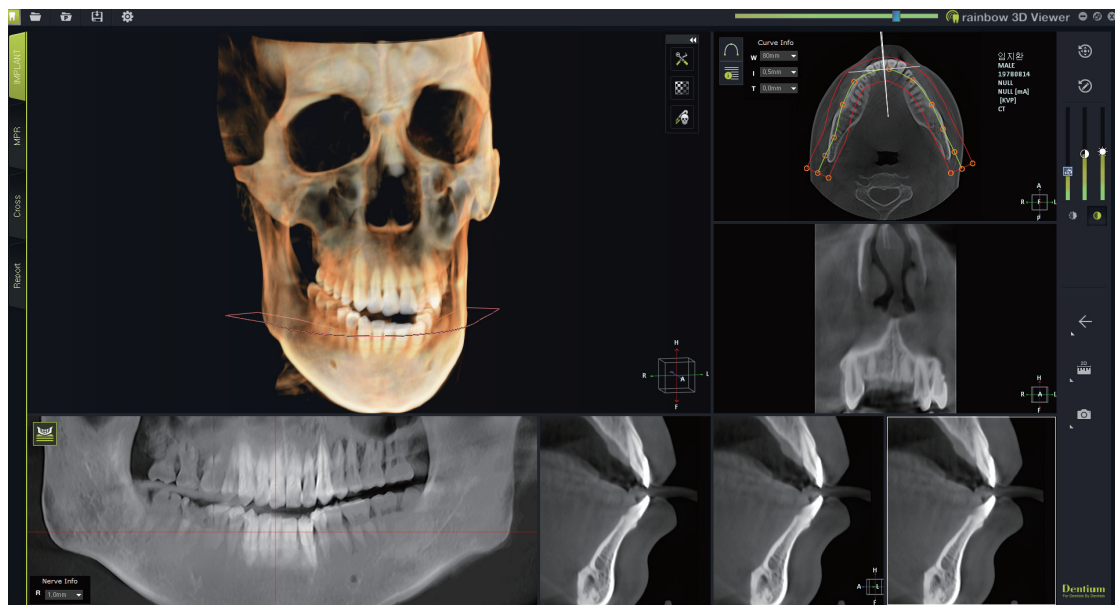
 CAUTION	Be careful not to direct the laser beam on the examinee's eyes. It may cause critical damage to the sight.
--	---

- When the examinee positions on the chin rest, fix the both sides of the examinee's head comfortably by pressing ON/OFF button in the control switch.
- Check if the examinee is closing the eyes. Guide the examinee to maintain the posture without moving until the scan is completed.
- Scan the examinee under the condition that the verbal or visual communication with the examinee is possible
- If Confirm button located at the right bottom of scan screen, the equipment will move to the position for scan. After completing the movement, Scan button will blink indicating that the x-ray irradiation is ready.
- Press the Scan button until the scan is complete. When releasing the button during the scanning, the scan is stopped
- The lamp will be changed to orange during the X-ray scan and when the scan is completed, it will be changed in green
- After scan is completed, guide the examinee outside of the shielding room
- After the scan is completed, following screen will appear to reconstruct the image



- The image scanned recently is converted to DICOM file and stored in the examinee database
- The scanned image can be viewed in the image management program. When selecting the name of examinee in the examinee list, the recently scanned images are listed. If the latest image is selected, it can be viewed by linking with 3D Viewer Program

■ Viewing Scanned Image (rainbow™ 3D Viewer)

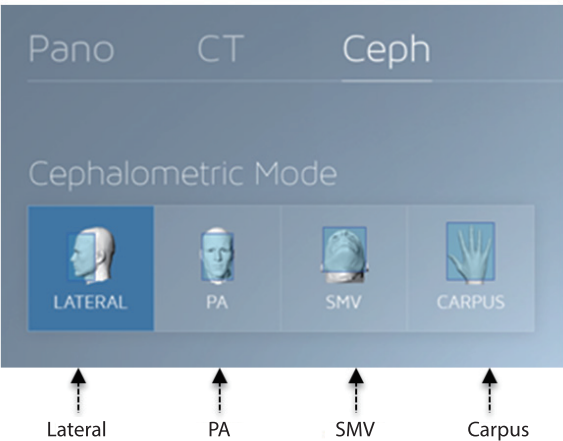


4.5 Cephalometric Image Scan

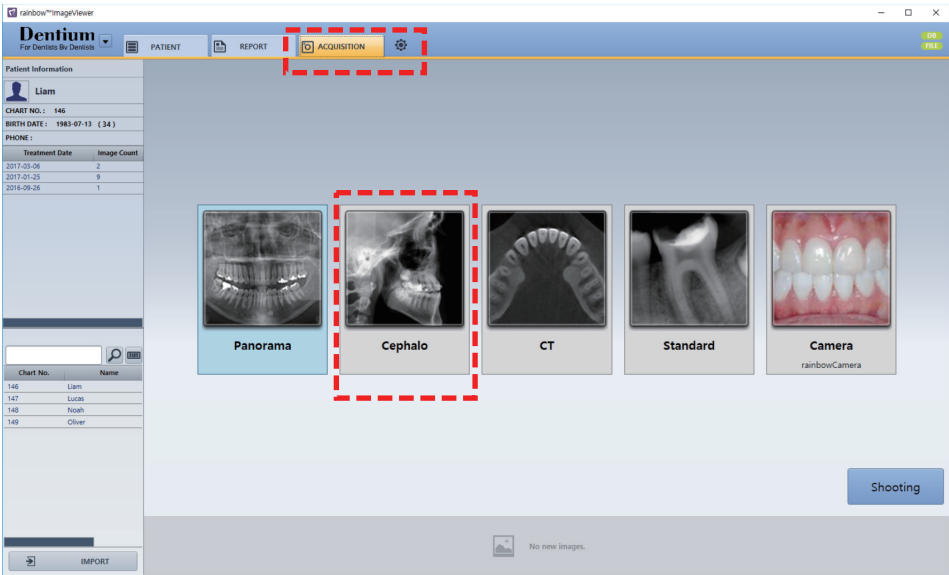
4.5.1 Starting Cephalometric Scan Program

- In Cephalometric Scan mode, scan can be made in total 4 modes

■ Scan Mode



- Activate the rainbow™ImageViewer shown in the screen by clicking it



- Click the examinee to be scanned by searching in the program or register as new patient
- Activate the image management program shown in the screen by clicking it (ACQUISITION Tap)
- Select Cephalometric Scan mode in the image management program

 NOTE	Updating the operating system (OS) in the computer is not recommended.
 NOTE	Check if the examinee information displayed at the top of the examinee information window is coincided with the name of examinee to be scanned.

- The scan main screen appears as below. Click Ceph tab
- When the scan mode is selected, the equipment will move to initial scan position



4.5.2 Setting Scan Environment

- Check if the name of examinee to be scanned is coincided with the examinee information
- Set the parameters in the right center of the scan program
- Set them according to condition of Adult/Female/Child
- Select the type of bone density according to the somatotype of examinee
- Tube voltage and tube current is set to default values and the more precise image can be obtained by changing according to the resulting image

 NOTE	If the tube voltage and tube current may need to be adjusted according to the image quality, do it fit to the characteristics of the examinee with fine-tuning. See Appendix I for proper value by mode
---	--

- When selection is made, start the examinee's posture alignment

4.5.3 Examinee Alignment and Scan

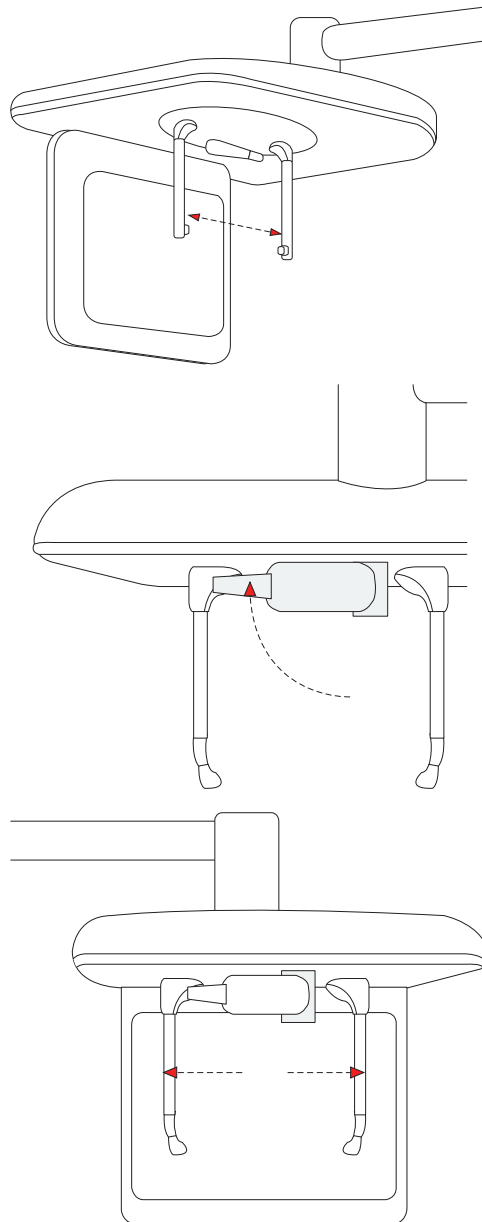
 NOTE	The examinee's posture alignment has great influence on the image quality. Therefore, to obtain good image, please read following procedure and guidelines.
 CAUTION	Scan the examinee after removing the metallic accessories (hairpin, glasses, earring, oral hygiene instrument, etc). The metallic material degrade the image quality by generating the artifact.
 CAUTION	The examinee should be scanned after wearing the protective clothing and thyroid guard, and particularly, scan the child or pregnant after consulting with physician.

■ Examinee Alignment

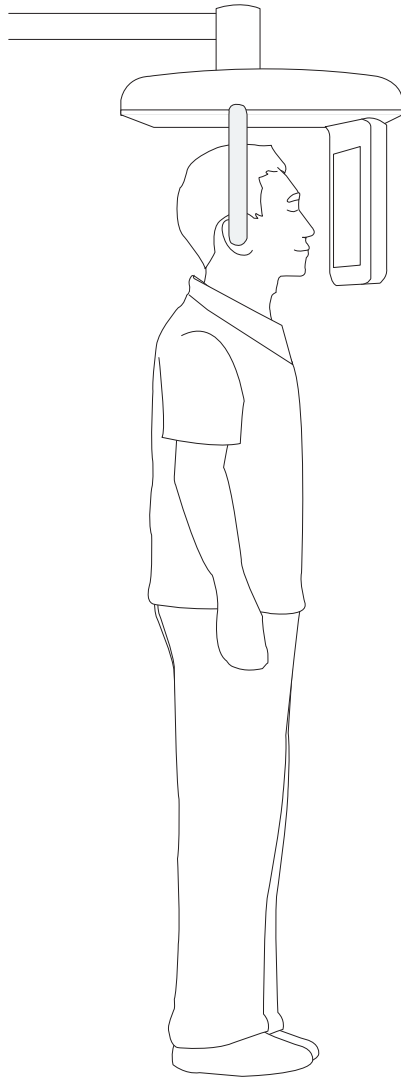
- Guide the examinee to relax in order for shoulder to be parallel and to maintain upright.
- The cervical vertebra (neck bone) should be straightened upright
- Remove all the metallic materials from the examinee such as glasses, earring, hairpin, oral hygiene device, etc.
The metallic material degrade the image quality by generating artifact

■ Frontal Mode

- For the examinee's posture alignment, secure the stable space widening the distance between ear rods by pressing the button as shown in below



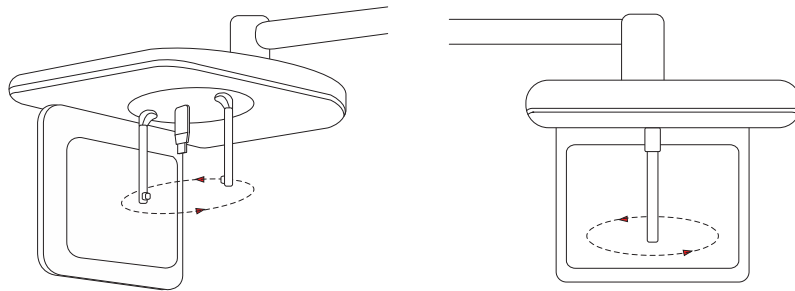
- When scanning in Frontal mode, fold the forehead ruler (image) to upward
- Guide the examinee to Cephalometric scan position
- Guide the examinee to maintain the posture correctly



- Adjust the height of Cephalometric unit fit to the examinee using Up/Down switch of the column.
- After adjusting it, adjust the ear rods fit to the earholes of the examinee
- Press Confirm button
- Get out of the shielding room and start scanning by pressing Irradiation switch observing the examinee
- Scan the examinee under the condition that the verbal or visual communication with the examinee is possible
- The lamp will be changed to orange during the X-ray scan and when the scan is completed, it will be changed in green
- After scan is completed, guide the examinee outside of the shielding room

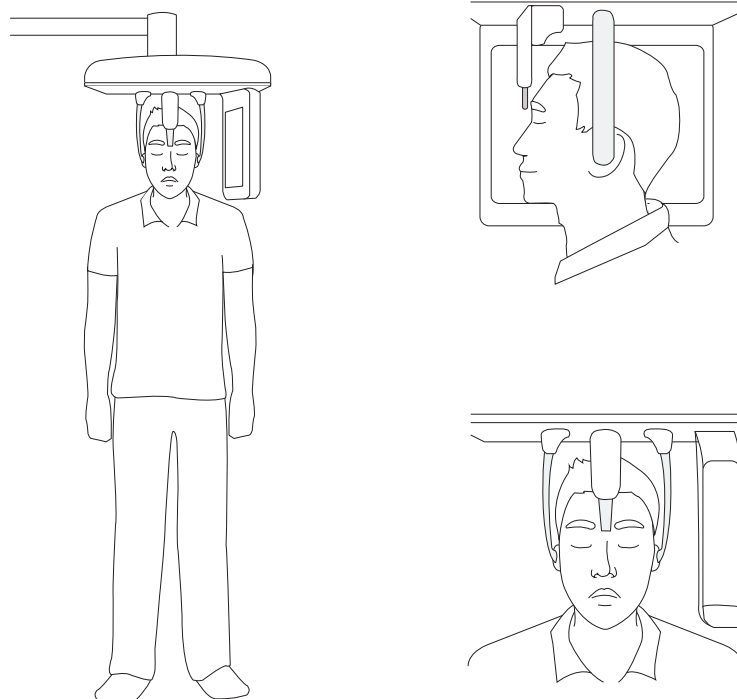
■ Lateral Mode

- For the examinee's posture alignment, secure the stable space widening the distance between ear rods by pressing the button as shown below



 NOTE	The examinee's posture alignment has great influence on the image quality. Therefore, to obtain good image, please read following procedure and guidelines.
 CAUTION	Scan the examinee after removing the metallic accessories (hairpin, glasses, earring, oral hygiene instrument, etc). The metallic material degrade the image quality by generating the artifact.

- Guide the examinee to the Cephalometric scan position
- Guide the examinee to maintain the posture correctly
- Adjust the ear rods fit to the earholes of the examinee

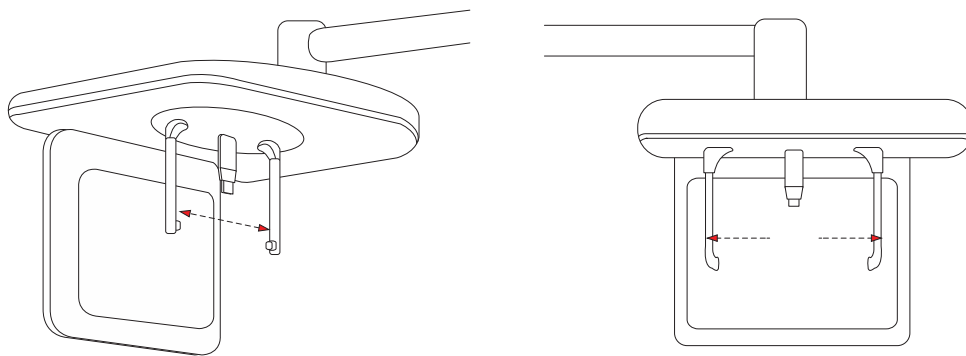


- Adjust the below the eye and top of the area to be parallel to the floor. Match the forehead ruler to the point at examinee's forehead as shown in figure
- Guide the examinee to relax the tension in the neck and shoulder and to stand with correct posture
- Adjust the height of Cephalometric unit fit to the examinee using Lift column Up/Down switch.
- Press Confirm button

- Guide the examinee to close eyes. Guide the examinee to maintain that condition without moving until the scan is complete.
- Get out of the shielding room and start scanning by pressing Irradiation switch observing the examinee
- Scan the examinee under the condition that the verbal or visual communication with the examinee is possible
- The lamp will be changed to orange during the X-ray scan and when the scan is completed, it will be changed in green
- After scan is completed, guide the examinee outside of the shielding room

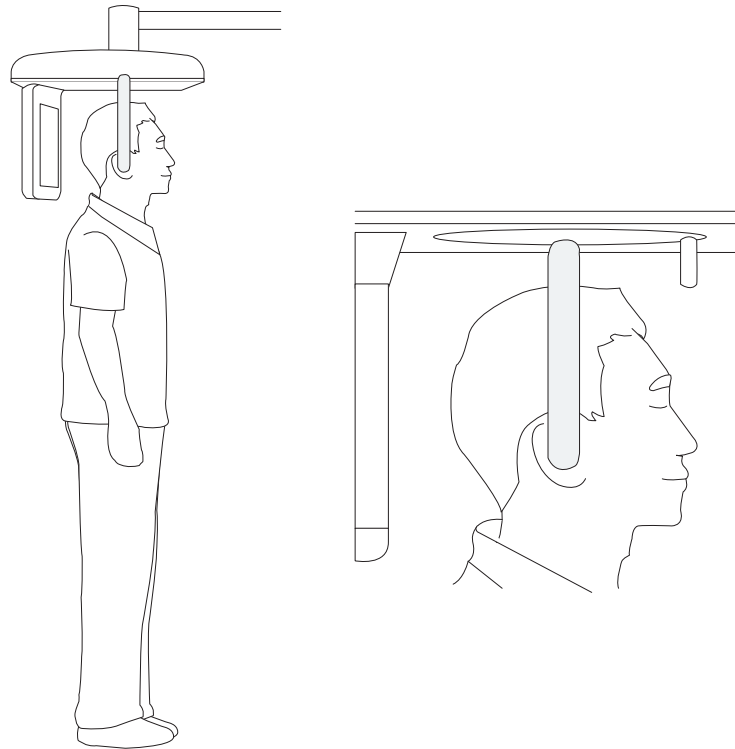
■ SMV(Submental –vertical) Mode

- Align the examinee's posture in follow sequence
- After folding the forehead ruler upward as shown in figure, adjust the distance between ear rods with enough space

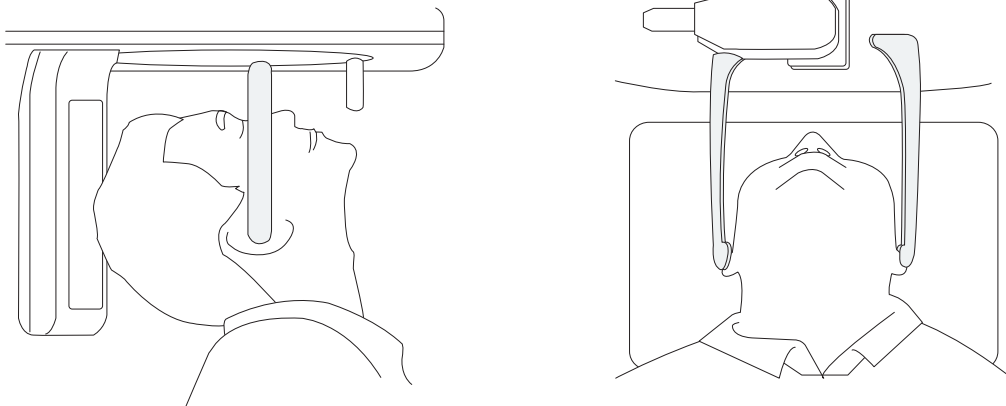


 NOTE	The examinee's posture alignment has great influence on the image quality. Therefore, to obtain good image, please read following procedure and guidelines.
 CAUTION	Scan the examinee after removing the metallic accessories (hairpin, glasses, earring, oral hygiene instrument, etc). The metallic material degrade the image quality by generating the artifact.

- Guide the examinee to the Cephalometric unit and to position correctly seeing toward X-ray tube
- Guide the examinee to maintain the posture correctly



- Adjust the ear rods fit to the earholes of the examinee
- Adjust the height of cephalometric unit fit to the examinee using Lift column Up/Down switch..
- After adjusting the height, adjust the ear rod fit to the earhole of the examinee.
- Adjust the Frankfort plane of the examinee to be perpendicular to the floor in the posture to bending the head backward as shown in below



- If the examinee alignment is completed, press Confirm button located at the right bottom of scan program



If the problem occurs during the scan, stop the equipment operation immediately by releasing Irradiation switch or pressing Emergency button located below the handle frame Operator always should monitor the examinee so that respond to the problem immediately during the X-ray scan

- Guide the examinee to close eyes. Guide the examinee to maintain that condition without moving until the scan is complete.
- Get out of the shielding room and start scanning by pressing Irradiation switch observing the examinee
- Scan the examinee under the condition that the verbal or visual communication with the examinee is possible
- If the CONFIRM button located at the right bottom of the Scan screen, the equipment moves to the scanning position.
- Press the Scan button until the scan is complete. When releasing the button during the scanning, the scan is stopped.
- The lamp will be changed to orange during the X-ray scan and when the scan is completed, it will be changed in green
- After scan is completed, guide the examinee outside of the shielding room

4.5.4 Viewing Scanned Image

- Scanned image is saved in the rainbow™ImageViewer. This moment, the message asking if the relevant image is to be saved and to save the scanned image, press finish button and to cancel it, press Cancel button
- The scanned image is saved in the rainbow™ImageViewer automatically and when clicking the name of examinee, the image list are arranged again. The latest image is located at the left.
- If the latest image is double clicked, it can be viewed with magnified image



<Lateral mode>



<Posterior-Anterior(PA mode)>

- Check the image quality
- For more details, please refer to the user manual rainbow™ CT
- If you want to store the image with bright image or dark image, please refer below.
- Brightness adjustment function If you place the cursor in the scanned image, and drag to left while pressing the left mouse button, the image becomes darker and if you drag the mouse from left to right, the image becomes brighter. After adjusting the image, save it

5 Maintenance

5.1 Routine Maintenance and Checklist

- When cleaning the equipment, rub gently the surface with soft and plane dry cloth
- Avoid the place inclined or having shock
- Do not place the equipment or part where having water or high humidity
- Place the equipment in the place free from influence by temperature, ventilation, light, dust, salt, etc.
- Do not pull off the power plug by force. it may cause the equipment failure and electric shock
- Do not place the equipment close to chemical storage or gas storage
- If lots of water or liquid gets into the equipment, turn off the equipment immediately and get help from an expert

5.2 Daily Checklist

- The equipment and the components should be maintained as basic condition
- If the equipment is used after not using for a long time, check if the equipment is operating without problem
- Only the qualified expert may inspect the equipment
- Check if the equipment uses the designated power consumption and voltage
- Check if the equipment is grounded well with the floor

5.3 General Maintenance

- If any problem may occur during the use, stop the equipment operation immediately and treat the problem after identifying it precisely
- When the equipment malfunctions, please ask help to manufacturer

■ General Cleaning

- Use any component that the user contacts such as chin rest, bite bloc, etc, after cleaning.

■ Cleaning Method

- Clean the equipment with clean cloth sprayed the cleaning solution for the bacteria infection prevention or 80% of ethyl alcohol and do not apply excessive force or do not use sharp object.

■ Cleaning Precaution

- Clean the electronic components after disconnecting the power.
- Do not use compressed air or liquid.
- Do not allow the liquid or foreign material to get inside of equipment.
- Do not apply excessive force. It may cause the equipment failure
- It is prohibited to disassemble the product.

(When the user may disassemble the product arbitrarily, it may excluded from warranty)

5.4 Product Warranty and Service

5.4.1 Warranty Period

- Product warranty shall be 2 years after installation

5.4.2 Cases Excluded from Warranty

- If the user may disassemble, repair, modify, etc. the equipment without authorization
- If the product may be damaged or the accident may occur by the negligence of customer
- Natural disaster (lightning, fire, storm and flood, etc.)
- Cases that product failure occurs by the part or consumable not guaranteed by manufacturer



CAUTION

“WARNING: Do not modify this equipment without authorization of the manufacturer.” Failure to comply may cause serious damage to the human body and equipment

5.5 Troubleshooting

- If the product failure may occur during the use, read followings and take the proper measure.
- If the same problem may persist or not be solved after taking the measure, contact with nearby distributor or customer support center

 CAUTION	If device is showing some mal-function, please refer trouble shooting first. If that symptom is still exist, please contact your service representatives or DENTIUM for getting fixed.
--	--

5.5.1 When the equipment does not operate

Symptom	Troubleshooting
When the equipment does not turn on	Check if the power plug is connected to power outlet well. Check if the power switch is turned on Check if the emergency switch is pressed
When the equipment operates abnormally	Turn off the equipment power and start again Turn off PC power and start again

5.5.2 When it is hard to align the examinee because laser beam is off

Control Switch	Troubleshooting
Laser button in Control Switch Module	Turn the laser on by pressing laser switch and perform examinee alignment
When the equipment does not operate	Use the equipment after rebooting it by turning off the equipment power
If this symptom of laser beam may persist, contact with nearby customer support center	

5.5.3 Equipment Initialization

Symptom	Troubleshooting
Abnormal equipment initialization	Turn on the equipment after turning it off and check if the equipment operates. If the problem may persist, contact with nearby customer support center

5.5.4 Irradiation Switch Operation

Symptom	Troubleshooting
X-ray is not irradiated	Check if the lamp of scan switch blinks If it does not blink, check if Confirm in the scan program is pressed
X-ray is not irradiated	Check if the connecting jack is disconnected
If the problem may persist, contact with nearby customer support center	

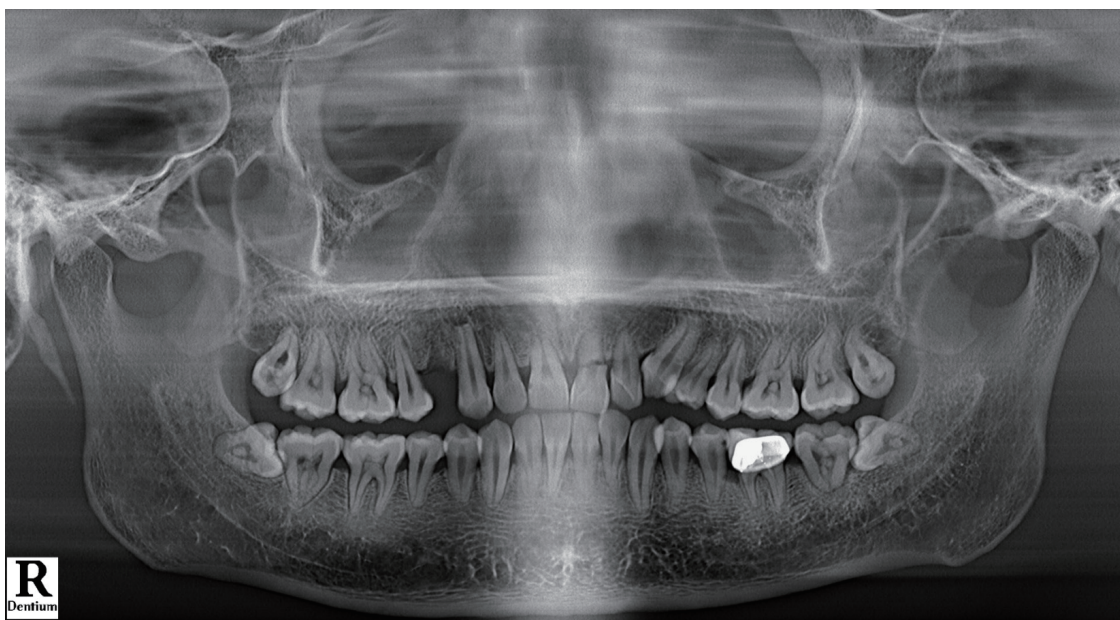
5.5.5 Abnormal Operation of Lift Column

Symptom	Troubleshooting
It operated when the switch is not pressed	Check if the switch is being pressed
It does not operate when pressing the switch	Check if the connector is connected well with the equipment
When lifting, it does not operate with thudding sound	contact with nearby customer support center
If the problem may persist, contact with nearby customer support center	

 CAUTION	Do not change the installed product arbitrarily If the equipment is corrected, proper test should be performed to guarantee the safe use
---	--

5.5.6 Patient align error

- Normal image



- Canine beam adjustment guide



Canine beam normal



Canine beam adjustment error
(front)

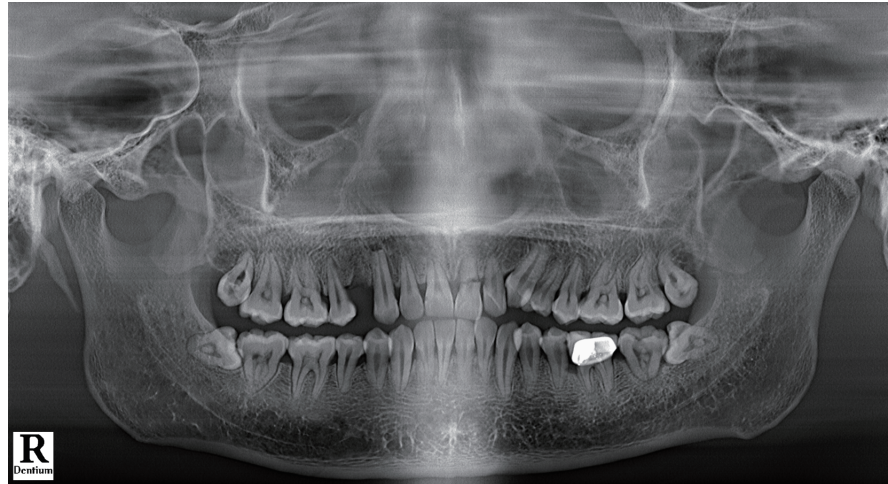


Canine beam adjustment
error (back)

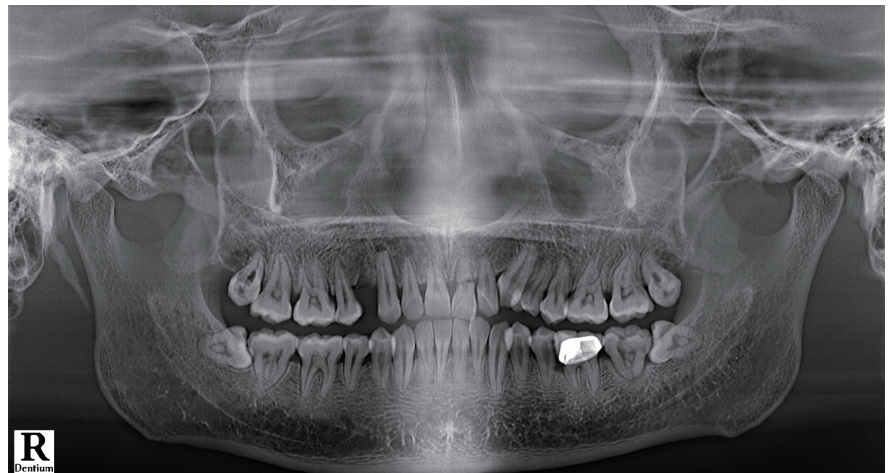


- Canine beam adjustment error (front)
- problem : Image distortion

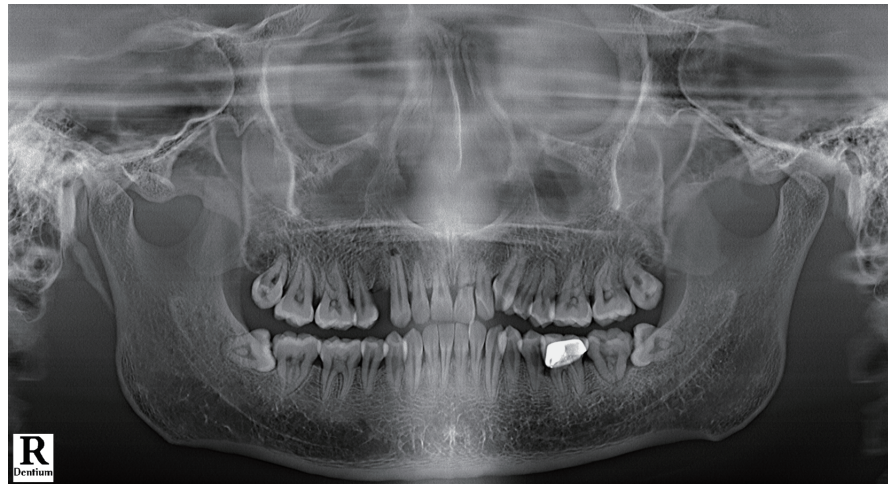
- 3mm



- 6mm



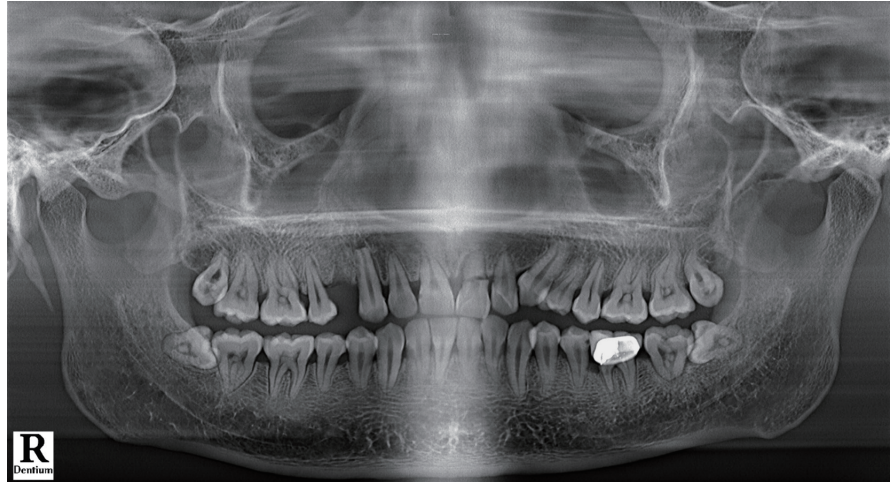
- 12mm



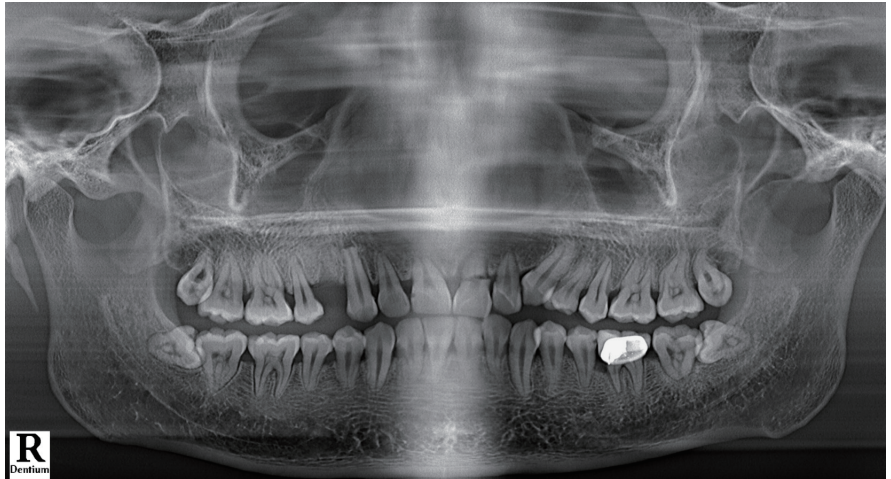


- Canine beam adjustment error (Rear)
- problem : Image distortion

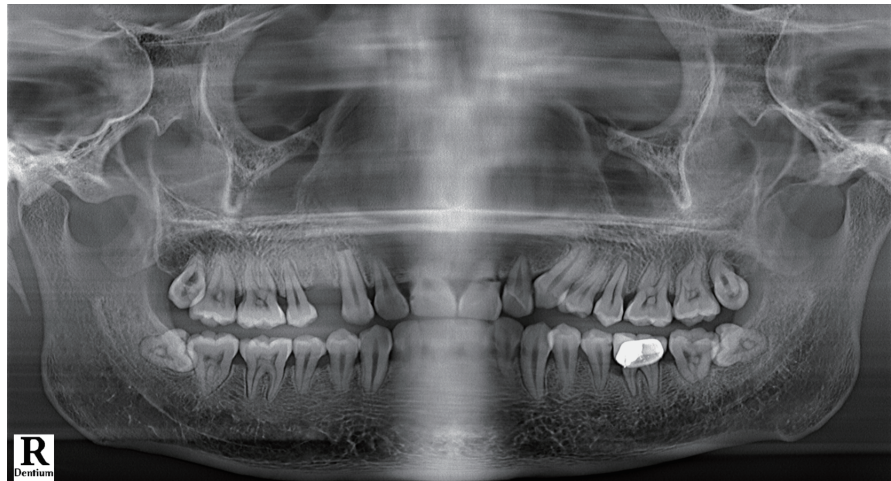
- 3mm

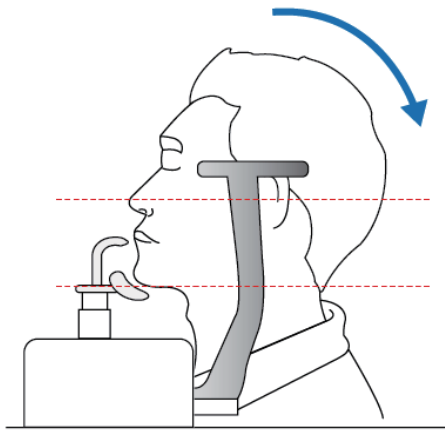


- 6mm

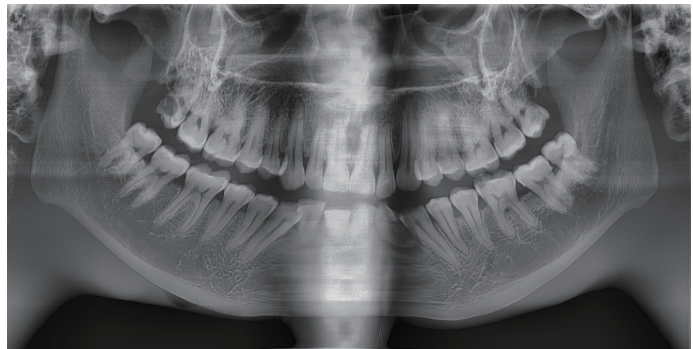
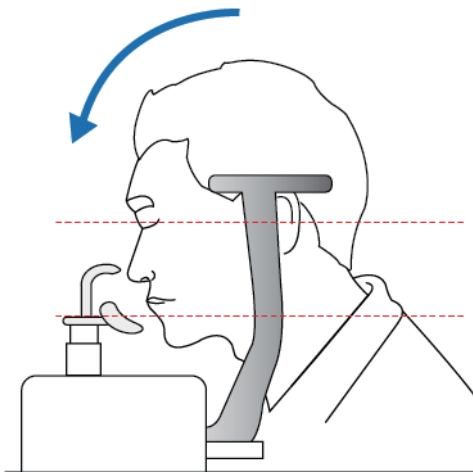


- 12mm





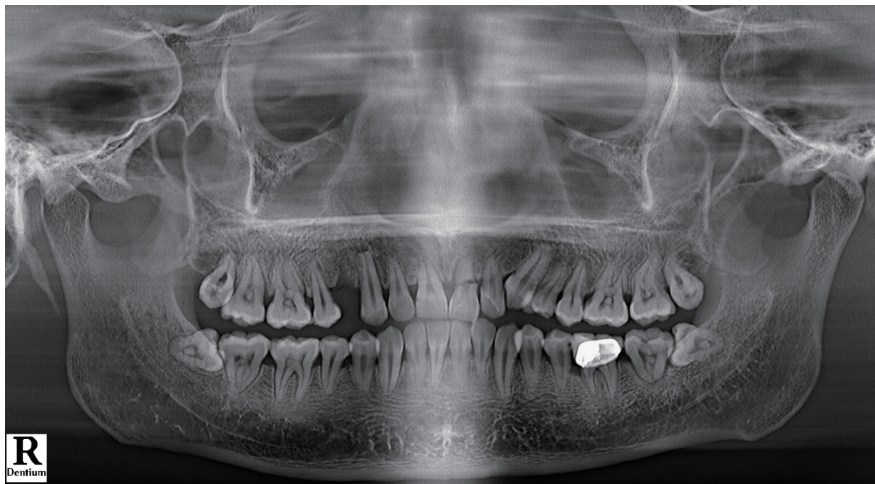
- Patient alignment error 1
- problem : Image distortion



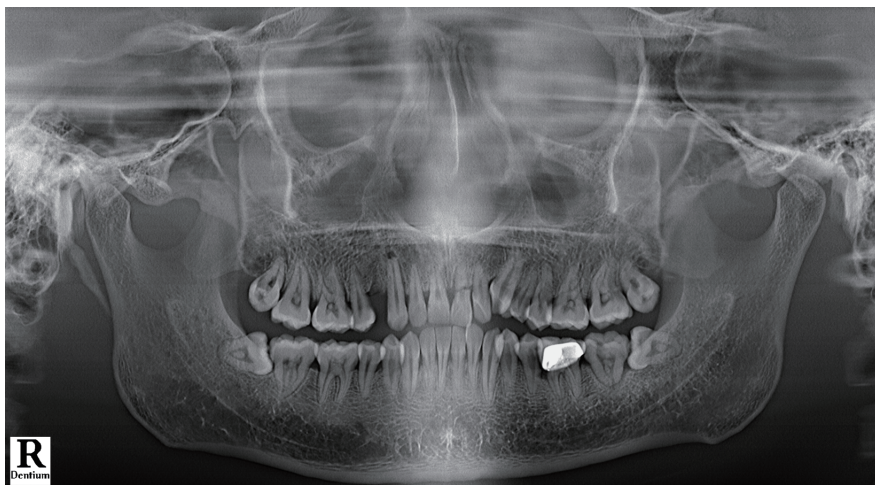
- Patient alignment error 1
- problem : Image distortion

- Image comparison

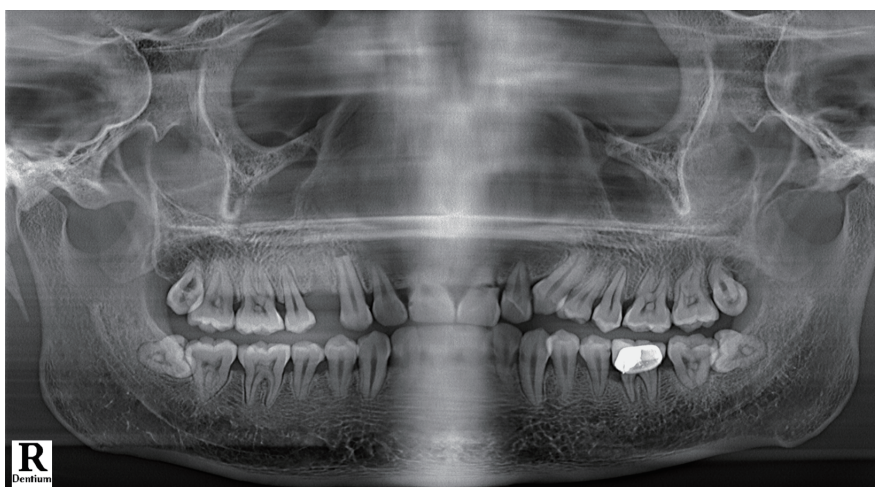
- Normal image



- Canine beam adjustment error (front)



- Canine beam adjustment error (Rear)



6 Technical Information

6.1 General Specification

Item	Detail
Scannable Mode	Panorama, CT, Scan Cephalometric, One-shot Cephalometric
X-ray Beam	Cone Beam
Image Reconstruction Algorithm	Real-time Recon Algorithm
Dynamic Range	14Bit

Item	Detail
Examinee Posture	Stand Straight, Chair
X-ray Irradiation Type	Continuous Mode (PANO+Cephalometric), Pulse Mode (CT)
Rotating Irradiation Angle	360°
Number of Examinee Alignment Laser Beam	4 Beams (Horizontal 2EA, Vertical 1EA, Canine 1EA)
Reconstruction Time	Within 1.5 minutes
Focal Spot Size	0.5 x 0.5(mm)
Data Speed	1Gigabit

6.2 CT FOV Size

Mode	FOV SIZE(cm)
LOCAL	5 x 5(cm)
STANDARD	16 x 10(cm)
STITCHING	16 x 18(cm)

6.3 Cephalometric FOV Size

Mode	FOV SIZE(cm)
One-shot mode	20 x 23(cm)
Line Cephalo mode	28 x 22(cm)

6.4 Irradiation

Mode	FOV SIZE(Sec)
Panoramic (Adult/Child)	17Sec
Cephalometric (One-shot)	0.4Sec
Cephalometric (Scan)	19Sec

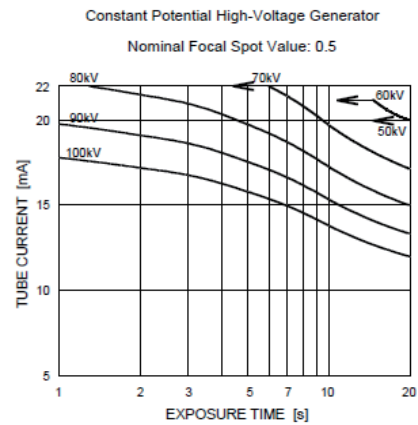
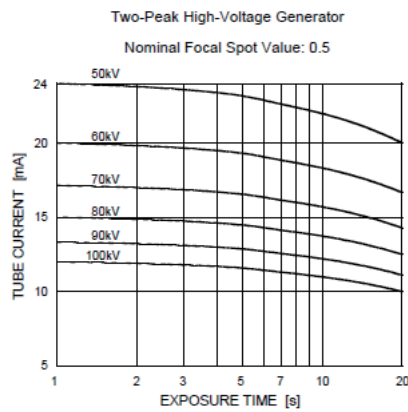
6.5 Electrical Specification and Environment

Item	SPEC	ETC
In-put Voltage	100V-240V	
Power Consumption	2.6-2.3kVA	
Tube Voltage Range	60kV~90kV	
Tube Current Range	4~12mA	
Protective Circuit	Over Current, Over kV	
INV FREQUENCY	40kHz	
Communication Type	ETHERNET Communication	
Environmental Condition	Operational Condition Temperature: +10°C ~ +30°C Humidity: 30% ~ 75%	
	Storage Condition Temperature: -10°C ~ +60°C Humidity: 10% ~ 75%, Non-condensing When storing the equipment, keep it in the plane floor	
FDD (Focal spot to Detector Distance)	CT: 600mm	
	PANO: 600mm	
	Cephalo: 1745mm	
FOD (Focal spot to Object Distance)	CT: 393mm	
	PANO: 443mm	
	Cephalo: 1525mm	
Image magnification	CT: 1.526 : 1	
	PANO : 1.354 : 1	
	Cephalo : 1.14 : 1	
Added filter	2mmAl	

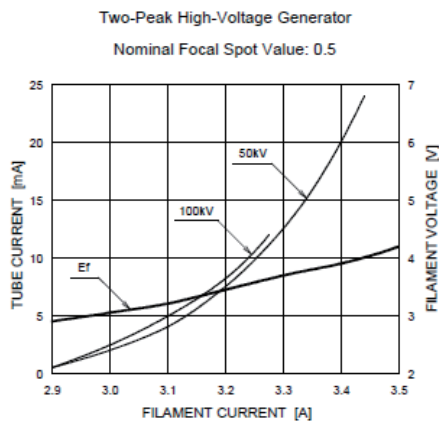
6.6 X-ray Tube Specification

Factors	SPEC	ETC
Maximum tube voltage(kV)	100kV	
Maximum tube Current(mA)	22mA	
Anode heat storage capacity	35kJ	
Maximum Anode Heat Consumption	250W	

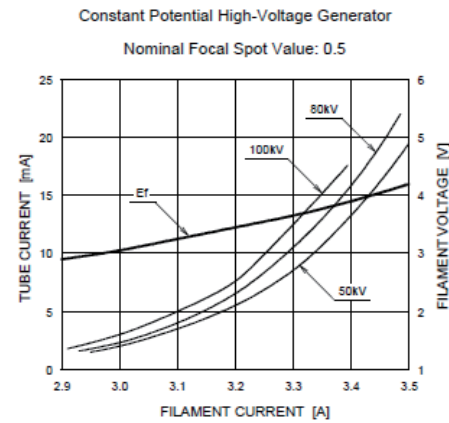
Maximum Rating Charts
(Absolute maximum rating charts)



Emission & Filament Characteristics

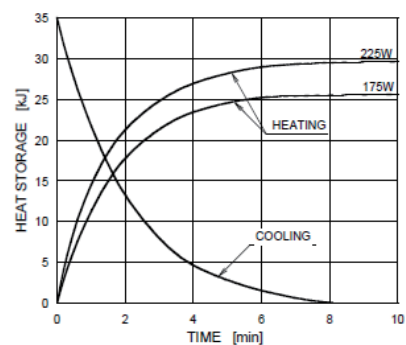


Note: This graph indicates typical characteristics.



Note: This graph indicates typical characteristics.

Anode Heating / Cooling Curve



6.7 X-ray Detector Specification

6.7.1 CBCT & Pano Detector Specification (X-ray imaging detector)

Parameter	CT	Panoramic	unit
Pixel size	240 x 240	120 x 120	um
Active area	161.28 x 158.88	161.28 x 10.8	mm
Pixel of number	664 x 654	328 x 84	EA
Digital Output	15	14	bit

6.7.2 Cephalometric Detector Specification

Parameter	One-shot Cephalometric	Scan Cephalometric	unit
Pixel size	100 x 100	139 x 139	um
Active area	2,268 x 60	1,792 x 2,176	mm
Pixel of number	50~300	36lp/mm	EA
Digital Output	14	16	bit

6.8 Recommended PC Specification

Item	SPEC	unit
CPU	Intel core i5 3.5Ghz	
RAM	4GB x 2 DDR3-1600 RAM	
HDD	1TB 7200RPM	
Graphic card	NVIDIA Geforce GTX750 D5 1GB	
OS	WINDOW 7 64bit or more	
Network	1Gigabit	
Serial Port	RS232 port	Communication between equipment and PC
CD Drive	Yes	Software Installation and Storage
Monitor	22" LED, resolution 1920 x 1080	
Added Filter	2mmAl	

7 Applied Standard

This equipment is design and manufactured complying with follow standards

EN 60601-1, EN 60601-1-3, EN 60601-2-28, EN 60601-2-32

EN 60601-1-2, EN61000-3-2, EN61000-3-3, EN ISO 9001, EN ISO13485

CE 0068 CE Mark is for the class IIB and granted by complying with EU Directive 93/ 42/ EEC on the medical equipments

8 Electronic Compatibility

- Product Name: rainbow™ CT

- Item: Components, Electromagnetic emission, resistance against electronic interference, protection distance

 NOTE	rainbow™ CT meets with the requirements of Electro Magnetic Compatibility according to IEC60601-1-3 2008 rainbow™ CT is referred to as "Equipment" in following sections If the equipment is used according to below sections, the safe operation is guaranteed based on EMC standard
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8.1 Major Component

Control Cable	Supplier
Connecting peripherals with PC	Dentium
EXPOSURE CABLE 15M	Dentium
LAN CABLE 15M	Dentium
RS232 Cable 15M	Dentium

For the normal operation, this equipment should use the components and spare part approved by Dentium. If the component or spare parts not approved may be used, the emission may be increased or the resistance against the electronic interference may be dropped The equipment should not be operated adjacent to other equipment. If it should be operated nearby the other equipment inevitably, the equipment should be observed if the desired operation is made

8.2 Electromagnetic Emission

This equipment is manufactured to operate in the electromagnetic environment described below

The customer or user should verify if this equipment is operated in such environment

HF emission according to CISPR 11	Group 1 Class A	This equipment uses HF energy only for the internal function. Therefore, HF emission is very marginal and nearly no case that other equipment receive interference is found. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. The rainbow™ CT must be used in a shielded location with a minimum RF shielding effectiveness of 20 dB from 30 to 230 MHz.
Emission according to CISPR 11	Group 1 Class A	
Harmonic wave according to IEC61000-3-2	N/A	The rainbow™ CT is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuation/Flicker according to IEC 61000-3-3	Complied	

8.3 Resistance Against Electronic Interference

This equipment is manufactured to operate in the electromagnetic environment described below

The customer or user should verify if this equipment is operated in such environment.

Test of Electronic Interference Resistance	IEC60601-1-2 Test Level	Standard Compliance Level	Electromagnetic Environment Guideline
Electrostatic Discharge (ESD) according to IEC 61000-4-2	Discharge by 8 kV direct contact 15 kV of Air-gap discharge	Discharge by 8 kV direct contact 15 kV of Air-gap discharge	The floor should be wooden or cemented floor or ceramic tile floor. In case that the floor is made of chemical compound materials, the relative humidity should be at least 30%
Radiated RF Electromagnetic Field immunity according to IEC 61000-4-3	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	The rainbow™ CT is suitable to use in professional healthcare environment.
Immunity to Proximity Fields from RF wireless Communications Equipment according to Table 9 in IEC 60601-1-2	28 V/m Max. 385-5785 MHz in according to table 9	28 V/m Max. 385-5785 MHz in according to table 9	RF communication equipment is used on closer than 30 cm to any part of the rainbow™ CT, including cables specified by Dentium.
Transitional quick electrical disturbance/ burst according to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for I/O lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for I/O lines 100 kHz repetition frequency	The quality of supplied power should be suitable for general business site or hospital environment.

Electronic Interference Resistance Test	IEC 60601-1-2 Test Level	Standard Compliance Level	Electromagnetic Environment Guidelines
Induced HF Interference IEC 61000-4-6 Induced HF Interference IEC 61000-4-3	3Veff 150 kHz ~ 80 MHza 3V/m 80MHz ~ 800MHz 3V/m 800MHz ~ 2,5GHza	3Veff 3Veff 3Veff	The portable and mobile wireless device should not be used in the place where the distance to the equipment including cable is closer than the recommended protective distance. Recommended protective distance can be calculated by using the equation appropriate for the transmission frequency. Recommended Distance: $d = [1, 2] P$ $d = [1, 2] P$ In case of 80MHz ~ 800MHz $d = [2, 3] P$ In case of 800MHz ~ 2.5GHz, where P is rated output of the transmitter (unit: W) according to the transmitter manufacturer's data, d is the recommended protective distance (unit: m). Although the strength of the fixed type wireless transmitter's magnetic field is varied according to the site investigation, it should be smaller than the b standard compliance level in all the frequencies. c . In the environment of the device having following symbol, the interference may occur 

■ In case of 80MHz and 800MHz, the higher frequency range is applied.

■ For example, the strength of the fixed type transmitter's magnetic field such as mobile phone, mobile local wireless base station, Ham Radio, AM and FM radio, and television cannot be determined precisely in theory. Therefore, to determine the electromagnetic environment of the fixed type HF transmitter, the site investigation is recommended. If the strength of the magnetic field determined in the location of equipment may exceed the above compliance level, the equipment should be observed if it is operating normally in all the positions. If the different characteristic than normal may appear, the addition measure may be taken, for example, changing the direction of equipment, or change the installation, etc.

■ The strength of magnetic field in the frequency range higher than 150kHz~80MHz, the strength of the magnetic field is smaller than 3V/m.

8.4 Protective Distance

- Recommended protective distance between portable and mobile HF communication device and this equipment
- This equipment is designed to operate in the electromagnetic environment that controls the HF interference radiated.
- The customer or user of this equipment can prevent the electromagnetic disturbance by maintaining the minimum distance between the portable and mobile HF communication device (transmitter) and this equipment according to the output of communication device as follows.

Rated Output of Transmitter (W)	Protective Distance according to Transmitter's Frequency (m)		
	150kHz to 80MHz $d = 1,2\sqrt{P}$	80MHz to 800MHz $d = 1,2\sqrt{P}$	800MHz to 2.5GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

- In case of the transmitter, of which rated output is not specified in above table, the recommended protective distance d (unit: m) can be determined using the equation corresponded to each column. Where, P is the maximum rated output (unit: W) according to the transmitter manufacturer's data.

■ Reference 1

- In case of 80 MHz and 800 MHz, the higher frequency range is applied.

■ Reference 2

- This guideline cannot be used for all cases.
- The electromagnetic wave receives the influence by the absorbance and reflection by the building, surrounding objects and human.

9 Installation Precaution

9.1 Install place

The equipment should be installed in the plane ground having enough extra space

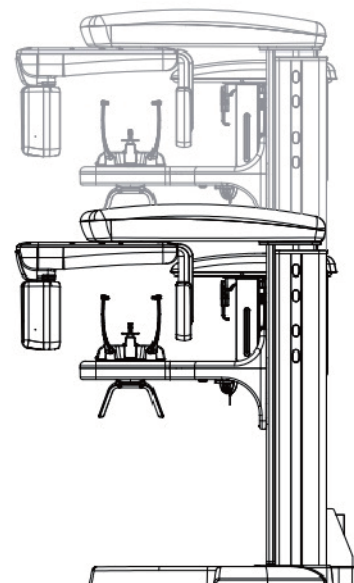
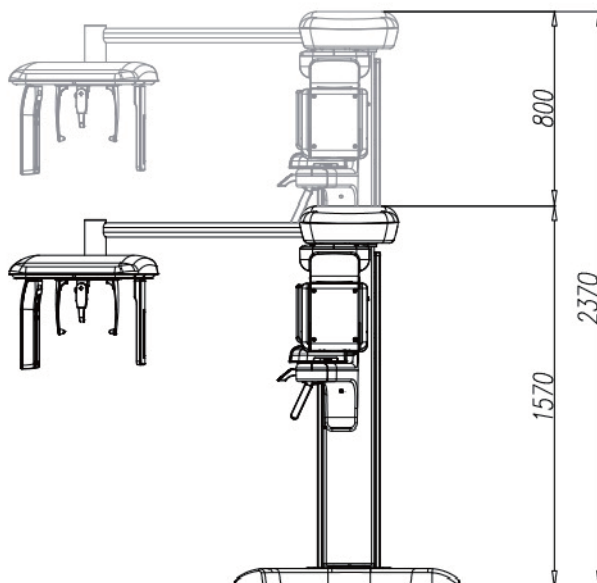
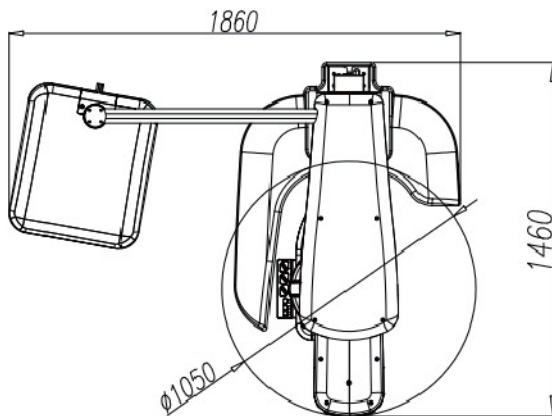


This equipment must be installed by a qualified professional service engineer

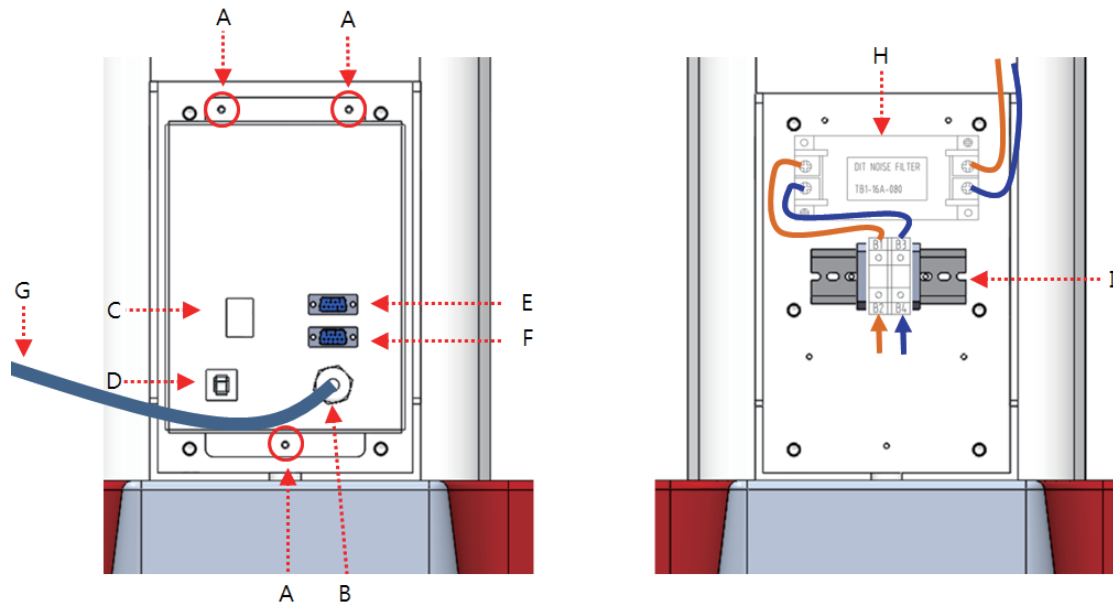
Dimension
(W x D x H mm)

2,000 x 1,460 x 2,370

- Dimension of Equipment Component (Equipment Dimension)



9.2 Gantry Power Cable Connection



- Connect the main power cable.
- Ensure that the breaker is OFF.
- Is separated using the "A" M4 + screw driver in the picture.
- The figure comes out brown, connect the power cable to the left and to the right of the blue color Connect.
- Assemble in reverse order to the three M4 screws that were going on in the left figure if the connection is complete.
- Power on to confirm normal operation

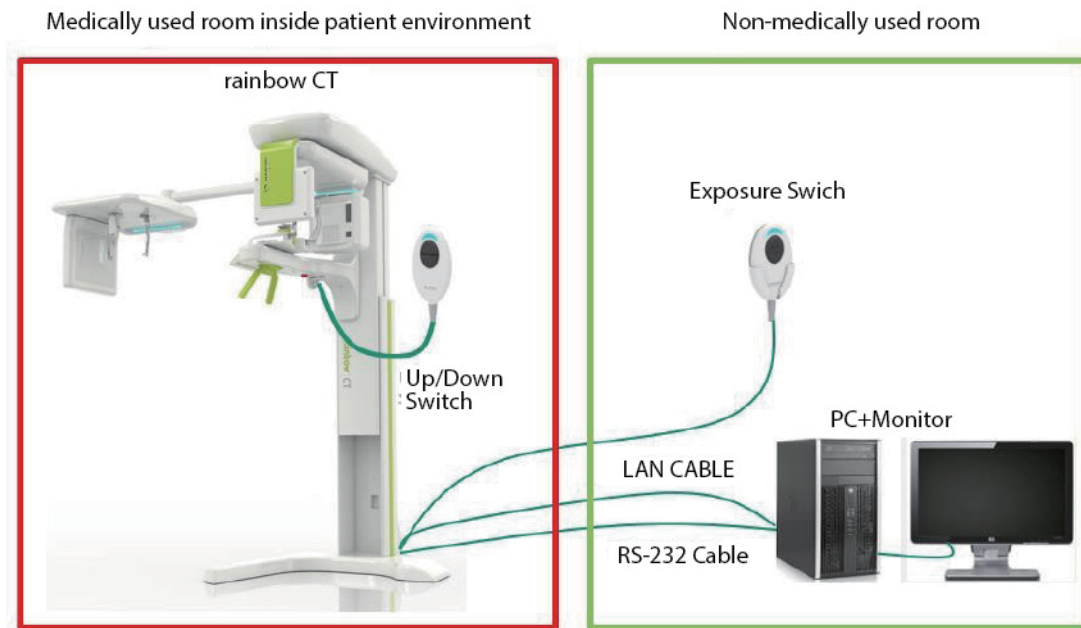
- A : M4 SCREW
- B : Power cable Stopper
- C : LAN Connector
- D : Circuit Breaker
- E : RS232 Connector
- F : Exposure Switch Connector
- G : Power cable (UL1015#14 AWG)
- H : Noise Filter
- I : Main Power Terminal block

The system does not provide the gantry power cable for some countries. If the power cable is not provided, the installed cable must meet the following requirements:

- Only qualified and authorized service personnel should remove covers on the equipment.
- The system requires a 3-wire (14 AWG) single phase AC power mains that contain line conductor, neutral conductor, and protective earth conductor. It is recommended that the unit be installed with a dedicated electrical line connected to a circuit breaker with a minimum 15 amp rating.
- The wiring must provide for a permanently grounded power line configuration.
- The installer must determine the suitability of installing the system with a line cord.
- If a line cord is used, the installer must ensure that the unit is properly grounded and has the required line rating.
- This system must only be used in rooms or areas that comply with all applicable laws and recommendations concerning electrical safety in rooms used for medical purposes, e.g., IEC, US National Electrical code, or VDE standards concerning provisions of an additional protective earth (ground) terminal for power supply connection.
- Max. Line resistance: For normal function of the dental X-ray system the resistance of the power line should not exceed 0.4 Ohm at nominal line voltage.

 CAUTION	This equipment To avoid the risk of electric shock must be connected to the protective earth Note: The operator has no contact with any SIP / SOP (eg USB connectors) on the system.
 CAUTION	All equipment connected to medical electrical equipment (for example, data processing equipment IEC 60950) IEC or ISO standards must comply with.
N	Permanently installed equipment that displays the input supply neutral point
 NOTE	The circuit components of medical electrical equipment service personnel for repairs, parts lists, can be provided by the manufacturer in accordance with the calibration instructions or other information requests
 CAUTION	To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth. Any accessories shall only be replaced when the operator and any part of the machine does not touch the patient. Caution: Operator is not to touch any SIP/SOP (ex. USB connector) on the system.
 CAUTION	Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3 Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above-mentioned requirements. If in doubt, consult your local representative or the technical service department. Equipment connected to the dental x-ray system and in the patient environment must be powered from a medically-isolated power source or must be a medically-isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the dental x-ray system During use of a non-medical grade PC is connected to the dental x-ray system, the dental x-ray system cannot in any way be in contact with a patient. Relevant standards for some non-medical electrical equipment may have limits for enclosure leakage currents higher than required by medical standards. These higher standards are acceptable only outside the patient environment. It is essential to reduce enclosure leakage currents when non-medical electrical equipment is to be used within the patient environment. Measures for reducing leakage current include If a non-medical grade PC is to be used with the dental x-ray system, then you must ensure mitigation is provided to meet all safety requirements. It is the responsibility of the user to ensure that the dental x-ray system in combination with the non-medical grade PC complies with safety requirements. Always use a medically-approved isolation transformer with a non-medical grade PC

9.3 example of a peripheral equipment connection



9.3.1 Peripherals and Accessories

- Dental X-ray system has been verified for overall safety with the following:

- Personal computer
- Manufacturer : HP
- Monitor : HP , LED 22" Monitor

Item	SPEC	etc
CPU	Intel core i5 3.5Ghz	
RAM	4GB X 2 DDR3-1600 RAM	
HDD	1TB 7200RPM	
Graphic card	NVIDIA Geforce GTX750 D5 1GB	
OS	WINDOW 7 64BIT or more	
Network	1Gigabit	
Serial Port	RS232 port	Communication between equipment and PC

Dental X-ray system may also be used safely while connected to devices other than those recommended above. All configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3 Ed. of IEC 60601-1, respectively).



It is the important instruction required to use the product. Violating it may cause critical damage to the equipment and the body

10 Precaution when Disposing System

- When disposing the machine and components, they should be disposed according to the guidelines specified in relevant country. Particularly, collimator and X-ray tube tank contain the hazard substances to body (lead, oil, etc.)
- This symbol means that since the unclassified wastes of the local government should be collected separately, the electric and electronic equipment wastes cannot be disposed.



- Before disposing the product or component, contact with nearby Dentium distributor or manufacturer first and dispose then with safe and appropriate method
- This equipment is basically manufactured in order to be disposed without environment contamination. All the components except the X-ray module can be recycled

Detained Explanation

Component	Raw Material	Recyclable		Hazard Material
Frame	Aluminum + Steel	◆		
Cover	Plastic	◆		
Motor	Steel + Copper	◆		
Control Board	Electronic component +PC	◆		
Cable	Copper +Steel +Oil	◆		
Packing	Wood + cardboard	◆		
X-ray Generator	Oil +Lead			◆
Sensor	Dentium			

Dentium rainbow CT, a Dental Extra-oral X-ray system, is designed in accordance with the medical device regulation, and is made and inspected under a strict quality control system. Dentium Co., Ltd. warrants that this warranty conforms with the international warranty regulation of the consumer protection act.

1) Warranty Information.

- 1) Dentium Co., Ltd warrants to the original purchaser that Dentium iCT and accessories are free from defects in material and workmanship under normal use and service for the period commencing upon the date of purchase and continuing for the specified period of time of 1 year
- 2) This limited warranty is conditional upon the proper use of the product by the purchaser. During the applicable warranty period, Dentium Co., Ltd will repair or replace any defective component part of the product without charge to the purchaser. However, if Dentium Co., Ltd determines that the product is not covered by this limited warranty, then the purchaser must pay all parts, shipping and labor charges for the repair
- 3) Upon your purchase, please fill out the following form and send it to the following fax number +82-31-281-5561
- 4) When you make any claim under this warranty, it is essential that you present the warranty form to the manufacturer

2) This Limited Warranty does not cover, and repair expenses will be billed for

- defects or damage from accident, misuse, abnormal use, abnormal conditions, improper storage
- defects or damage from external causes such as collision with an object, or from fire, flooding, sand, dirt, wind-storm, lightening, earthquake, or exposure to weather conditions
- defects or damage from improper testing, operation, maintenance, installation, service or adjustment not furnished or approved by Dentium Co., Ltd
- defects or damage caused from ignorance of warning indications in this IFU (Instruction For Use)

Product	rainbow CT (ICT-R01, ICT-R01-L , ICT-R01-O)	Customer information (Please fill out the form upon purchase)	
Purchased date		Dentistry	
Manufactured date		Address	
Lot number			
Warranty Period	2 year	Phone number	

Dentium

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