YOSHIDA

Operation Manual

X-ERA SMART

This “Operation Manual” describes information on how to operate “X-era Smart”, a digital panoramic tomographic X-ray diagnostic apparatus for dental use, arm-type X-ray CT diagnostic equipment and precautions for use.

- To avoid any unexpected accident, failure, or damage to the system, read this “Operation Manual” prior to system installation.
- Be sure to keep this manual after having read through it.

Introduction

Although the equipment has undergone strict quality control and inspections before shipment, please contact your dealer if you find any failure or defect of the device.

- A symbol ⚠ used in this manual alerts the user to possible dangers to the human body or possible damage to the equipment. To avoid these unexpected accidents, read carefully and adhere to the instructions following the symbol.
- Be sure to read through the manual prior to use to take full advantage of the equipment and use it effectively for many years to come. To avoid any unexpected accident, failure, or damage, once you have read the manual, keep it in a prominent place near the equipment.
- If you have any question or opinion about the manual, feel free to contact your dealer. Should any nonconsecutive numbering or page missing is found, the defective manual will be replaced with a new one.
- Reproduction or reprint of part or all of the manual without prior written permission is strictly prohibited.
- Modifications may be made to the manual at any time without prior notice.

Disclaimer

We will not be liable for any failure, damage, and condition occurring in X-era Smart attributable to:

- Installation, relocation, maintenance, and/or repair by us any other subcontractor than those we nominated.
- Any other product than those we delivered.
- Maintenance and/or repair using any other repair parts than those we designated.
- Negligence of precautions/instructions and the correct operating procedure described in the manual.
- Ambient environment departing from the operating conditions (power supply, installation environment, etc.) for the equipment defined in the manual.
- Natural disasters such as fire, earthquake, flood, and lighting.

Table of Contents

Safety Precautions

Meaning of symbols

A symbol ⚠ and its variations used in the manual and attached to the equipment have the meanings described below. To avoid any possible danger, be sure to adhere to the instructions following these symbols.

⚠ : Informs the user of any general caution, warning, or danger.

⚠ **Danger** : Alerts the user to a direct danger, which may lead to fire, serious damage to the equipment and its surrounding proprietary (e.g.totally lost machine), serious personal injury or death.

⚠ **Warning** : This is used to indicate an indirect danger that could cause fire severe porperty damage (e.g.complete failute of the equipment), serious personal injury or death.
Following is an example of indirect danger.
Example: Ignoring a warning label and opening a cover and touching a high-voltage terminal could result in death.

⚠ **Caution** : Alerts the user to a risk of any accident, which may lead to loss of computer data, partially destroyed equipment or mild to moderate injuries.

Precautions for Use

⚠ Warning

CARELESS OR IMPROPER USE OF X-RAY EQUIPMENT CAN BE EXTREMELY HAZARDOUS.

1. This product is only to be used in the radiaton control area.
2. During image acquisition or positioning, the rotation arm unit will rotate around the patient. To avoid the accident, look out for patient's safety at all time. In case of any dangerous situation occurs, immediately stop the operation.
3. During image acquisition or positioning, the rotating arm unit will rotate around the patient. To avoid the accident, ask the patient to refrain from moving until rotating arm unit stops the movement.
4. Ensure that the power switch is OFF (O) if you do not intend to operate the equipment for a long period.
5. Modification of the device is prohibited. Do not remove any covers or cables on system.
6. Electromagnetic wave

   This medical device could malfunction due to electromagnetic waves. Instruct persons in your fascility to turn off the power of electronic devices such as mobile phones, transceivers, radio control transmitters, etc.
7. Be sure to plug a medical ground cable into a ground outlet prior to use of X-era Smart. Do not plug the cable into any other kind of outlet than that for exclusive use.
8. Do not connect any devices other than the specified for this equipment. Also, do not install software other than the specified to the PC connected to the system.
9. Do not install the film processor in the same room as the equipment. The gas generated by the film processor may corrode the equipment and cause serious damage.
10. Do not look directly into the positioning beam. The power output (Class 2) is at the level which adverse effect on the eyes can be avoided by blinking. However caution should be taken for maximum safety.
11. Do not apply any heavy load or shock on the equipment, e.g. suspending from the chin rest or sliding mechanism, otherwise the equipment may be damaged.
12. Be sure to keep the infants and small children away from the equipment unless required for radiographic purpose.
13. Do not give high impact or excessive external load to this product. It may cause malfunction.

⚠ Warning

14. Do not hang down from or apply force on the Cephalometric unit (including the Cephalometric-arm). The equipment may fall or be damaged.
15. Also, do not allow children to hang on or lean on to the Cephalometric unit (including the Cephalometric-arm).
16. User or operator of the device is responsible to follow the relevant local law, regulation and standards regarding the usage, the installation and the maintenance.

⚠ Caution

1. Only trained and qualified personnel should take radiographic photos. The use of this equipment by unqualified personnel is prohibited by law.
2. Usually, turning the power switch on moves the arm unit automatically to the patient positioning point. To avoid damage to surrounding physical assets, do not place anything within a movable range of the arm unit.
3. Be sure to press the correct switches, such as the Up and Down switches, during positioning, otherwise the patient may be injured.
4. Be sure to carefully open or close the head support by gripping its base without applying excessive force, otherwise the patient may be injured.
5. Do not wipe off the plastic or coated surfaces of the equipment with cloth dampened with any solution containing chemicals, e.g. paint thinner, benzene, and alcohol. It may cause discloration, malfunction or accident.
6. Carefully read "Safety Precautions in Using Medical Electric Equipment".
7. Ask the patient to wear an X-ray protective apron and the child patient to wear both the X-ray protective apron and a thyroid shields.
8. Avoid taking X-ray of pregnant patient or patient with possibility of pregnancy.
9. Do not use any other accessories other than designated by YOSHIDA.
10. Keep the patient away from the equipment until the arm unit of the equipment has returned to its start position. Patient may get caught by the arm unit and cause injury.
11. Be careful not to direct the positioning laser beam into patient’s eyes. And also, advise the patient not to look directly into the beam.
12. To ensure proper function of the equipment, operate the equipment only under the specified condition defined in "11.1 Specification".
13. Take great care when turning on the heater in the X-ray room. A sudden temparature rise in the cold X-ray room may cause dew condensation, leading to malfuction of the equipment.

⚠ Caution

14. To minimize the X-ray dose irradiated on the patient, be sure to position the patient correctly prior to image acquisition.
15. To prevent the patient from infection, always use a new bite block for each patient and wipe it with alcohol-dempened cotton prior to use.
16. Correctly connect the PC protective earth terminal to ground.
17. Do not rotate the arm unit manually, as the patient body may be caught by the arm unit or a failure may occur in the equipment.
18. Once the arm unit is positioned, be sure to return the positioning mirror to its original position.
19. Be careful not to get your fingers caught in the equipment during the operation, such as rotating, opening and closing, moving back and forth, of the ear rod and nose support of the Cephalometric unit.
20. Do not touch the Sensor unit and the Second Slit unit while the Cephalometric Sensor is operating. It is dangerous as your fingers or hands may get caught and cause injured.
21. Do not apply force to the Sensor unit. It may cause failure in the equipment.
22. Be sure to open or close the ear rod of the Cephalometric unit by its knob without applying excessive force. Otherwise the patient may be injured.
23. Be sure to connect the additional protective earth conductor of the equipment.
24. Beware not to touch the equipment while the movable 3D sensor is in motion. The finger or hand might get caught and injured.
25. Look out for the safety of the patient when moving the nose support of the Cephalometric unit up, down, back or forth.
26. Advise the patient to stay still while an image is being acquired. If the patient moves, it causes image blurring and degrades the image quality.Especially for 3D oral image acquisition, advise the patient to stay still until the whole process of the acquisition is completed.
27. Set up the monitor where is not affected by the reflection of light used inside or outside the room and ensure you get the most suitable viewing condition and quality of the image.
28. Do not operate this equipment in case of earthquake occurrence. After an earthquake, check to see if the equipment operates properly to ensure the safety of the patient.
29. Do not place any objects inside the X-ray field of the equipment.
30. When attaching and detaching the sensor, firmly hold it by the knob and make sure you do not drop it. Dropping the sensor may cause failure of the equipment.
31. The sensor unit is equipped with a shock sensor. The shock sensor records any excessive impact incurred, such as when the equipment falls down, and the equipment will not qualify as being warrantable. Exercise caution in handling the equipment.

Required Maintenance and Inspection

Maintenance and inspection are needed to ensure safe use of the equipment.

Durable Period

The usable life is 10 years from the date of manufacture as long as the equipment is properly maintained and inspected. * Based on Company data.

Guaranteed Supply of Replacement Perfomance Parts

Supply of the replacement performance parts for this product (parts required to maintain the function of the product) is guaranteed by the Company for 10 years from the date of manufacture.

Actions to be taken in case of an Accident

1. In the event an accident occurs, immediately stop the equipment by pressing the emergency button and ensure the safety of the persons involved in the accident.
2. Provide appropriate first aid as required by the accident conditions.
3. If necessary, turn off the power of the computer and then turn off the equipment's scanner switch and system main switch.
4. Immediately contact the dealer where the equipment was purchased.
5. Use the contact information provided at the end of this manual.

⚠ Warning

- Never use the equipment until the measure for preventing from possible dangers have be taken and it has been confirmed that safety is ensured in the dental office.

Signage used in the Manual

The following signage is used throughout the manual.

NOTE : Provides general information on operations independent of safety precautions.

Suppl. : Provides supplementary information on operations and functions independent of safety precautions.

See also :Indicates the title to be quoted or page.

EMC Conformity Symbol

- Complied Standard Number and Publication Year: IEC 60601-1-2:2001, A1:2004
- Compliance Statement: This product complies with EMC Standard IEC 60601-1-2: 2001, A1: 2004
- Classification: CISPR11 Group 1 Class A

Electromagnetic Compatibility

TABLE:Guidance and manufacturer's declaration - electromagnetic emissions		
The X-era Smart is intended for use in the electromagnetic environment specified below. The customer or the user of the X-era Smart should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The X-era Smart uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The X-era Smart is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the X-era Smart or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

TABLE: Guidance and manufacturer's declaration - electromagnetic immunity			
The X-era Smart is intended for use in the electromagnetic environment specified below. The customer or the user of the X-era Smart should assure that is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Functions Interruption Functions Interruption Functions Interruption Functions Interruption	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X-era Smart requires continued operation during power main interruptions, it is recommended that the X-era Smart be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

TABLE: Guidance and manufacturer's declaration - electromagnetic immunity			
The X-era Smart is intended for use in the electromagnetic environment specified below. The customer or the user of the X-era Smart should assure that is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the X-era Smart, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the X-era Smart is used exceeds the applicable RF compliance level above, the X-era Smart should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the X-era Smart

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE: Recommended separation distances between portable and mobile RF communications equipment and the equipment

The X-era Smart is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X-era Smart can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the X-era Smart as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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
100	12	12	23

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠ Warning

Use of accessories, transducers, and cables other than those specified may result in degraded electromagnetic compatibility performance of this device!

Storage and Usage Environment Precautions

Do not operate or store the equipment in the environment as described below. If you must operate or store it in such an environment, contact YOSHIDA or your dealer prior to use or storage.

1. In areas with a temperature range that exceeds the values stated in the specifications.
2. Areas where the air pressure is less than 700 hPa or over 1060 hPa.
3. Areas subject to harmful gases.
4. Areas with excessive relative humidity (30 to 75%, no condensation).
5. Areas subject to steam.
6. Areas subject to water drops.
7. Areas with much dust or sand.
8. Areas with much oil vapor.
9. Areas subject to salty air.
10. Areas containing explosive gases or dust.
11. Areas subject to excessive vibration or shock.
12. Areas with a noticeable slope.
13. Areas where the power voltage fluctuates abnormally.
14. Areas where the power voltage drops excessively when a load is applied.
15. Areas subject to direct sunlight.
16. Areas where chemical products are stored.
17. Areas where developer units are installed.
18. Areas exposed to intense noise.

⚠ Caution

- Be sure to use the equipment at ambient temperatures of 10 - 40 degree C.
  If used at other range of temperature, it may not work properly.

See also : For information regarding Storage and Usage Environment Precautions of the computer, refer to the Product Information Guide included with the computer at delivery.

Precautions for Installation and Relocation

1. Installation Areas
   (1) Install in the X-ray room.
   (2) The size of the installation area should be at least 1,350 mm (W) × 1,350 mm (D) × 2,400 mm (H) or 54" (W) × 54" (D) × 95" (H) (* in case of Cephalometric -attached model, 2,300 mm (W) × 1,500 mm (D) × 2,400 mm (H) or 92" (W) × 60" (D) × 95" (H)), to allow the patients to be put in and taken out, the equipment to be operated, the equipment to be used correctly such as allowing for daily inspections, and to perform work to maintain equipment performance.
   If installed alongside other pieces of equipment, be sure not to place them within the range of the arm unit's movement.
   The installation area size differs depending on the room shape, door locations, etc. For details contact the dealer where the equipment was purchased.
   (3) Rapidly warming a cool X-ray room results in condensation inside the equipment that causes problems. When heating a room, do so slowly.
   The environmental range for using this equipment in good condition is as follows.
   Temperature: 10 to 40ºC (50 to 95°F)
   Relative humidity: 30 to 75% (no condensation)
   Air pressure: 700 to 1060 hPa
   (4) Install in the area equipped with light fixture to ensure the product's operability, X-ray image quality and its viewability. Set the monitor to the area where is unaffected by the light reflection from indoors and outdoors.

2. Power
   (1) Prepare a hospital grade outlet (grounding is required) of your area's power voltage and dedicate it for X-era Smart
   100V: More than AC 100V, 15.0A
   110V: More than AC 110V, 18.1A
   120V: More than AC 120V, 16.6A
   220V: More than AC 220V, 9.09A
   230V: More than AC 230V, 8.69A
   240V: More than AC 240V, 8.33A
   (2) Never use an extension cord or plug multiple cords into one outlet.
   (3) Wipe off dust that has accumulated on the power plug and outlet. Leaving the dust on them could allow a minute electrical current to flow due to humidity, etc., and result in overheating or a fire.
   (4) Do not impair, damage, or modify the power cord. In addition, do not place heavy objects on it, pull on it, or bend it excessively as these could damage the power cord and cause a fire or electrical shock.
   (5) Be sure to connect the additional protective groundings of the main unit and the computer.

3. Grounding
   This product is grounded by plugging the medical grade plug into a medical grade outlet.

4. Movement and Transport
   To move or transport this equipment, contact the dealer where the equipment was purchased.

⚠ Caution

Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.(for USA)

1 Before Using this Product

⚠ Caution

- To ensure safe use of this product, be sure to read this "Safety Precautions" P.7 Information before thoroughly using this product.
- Do not use this product for other than its intended use.
- Perform only the operations described in this manual.
- Always follow the instructions in the labels affixed to this product.

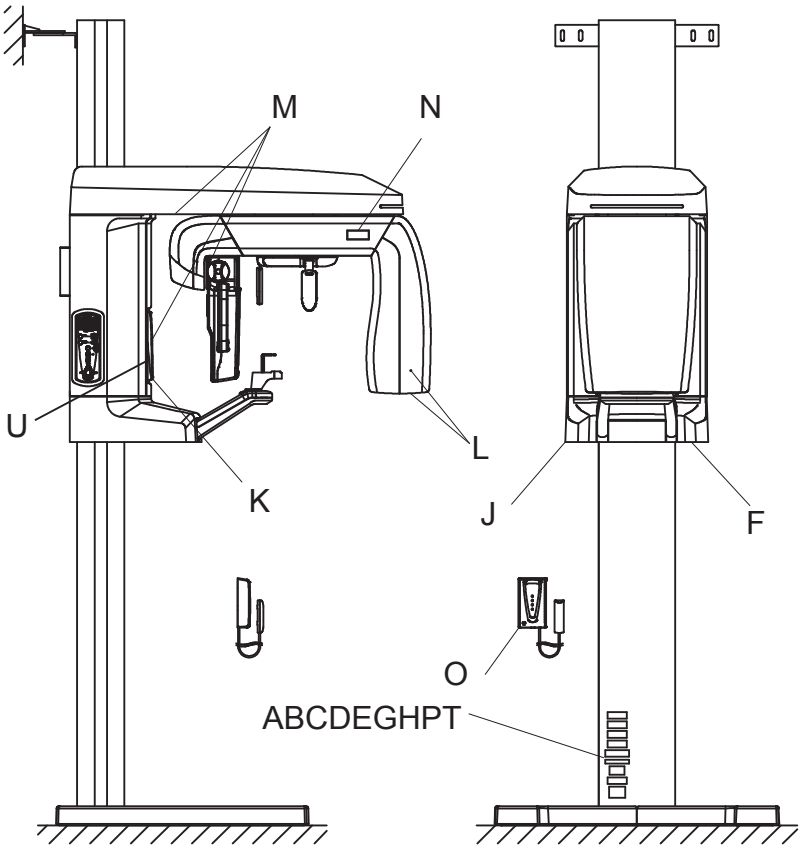
1.1 Intended Use

The X-era Smart dental panoramic, cephalometric (*) and 3D(**) image acquisition device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray projection images. The device must only be operated and used by dentists and other legally qualified professionals.

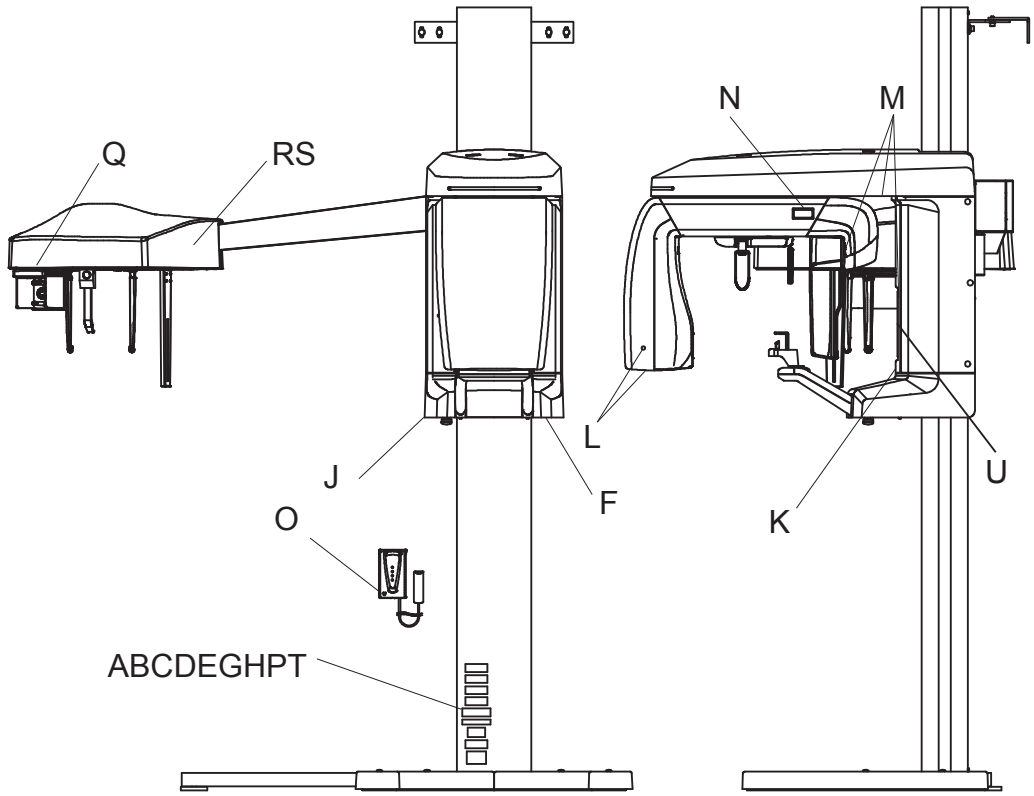
* For equipment with Cephalometric

** For equipment with 3D function

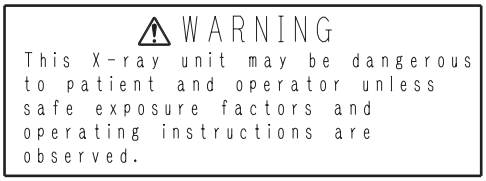
1.2 Main Label



* Equipment with Cephalometric

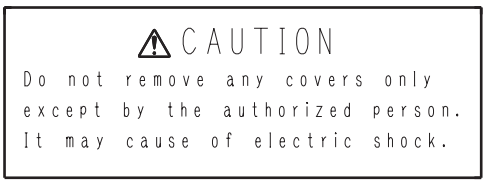


A : X-ray radiation warining label

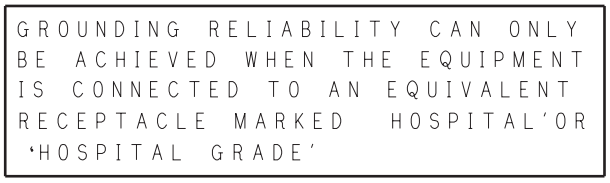


B : Safety device warning label

C : Electric shock caution label

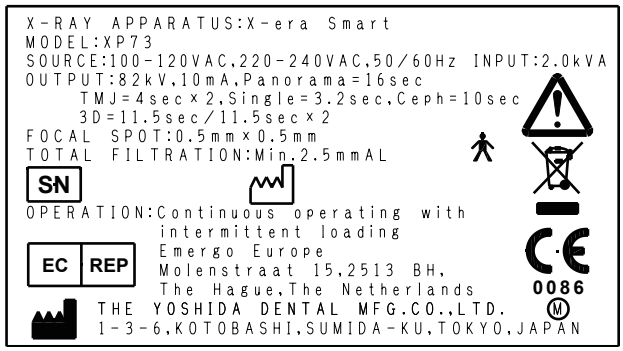


D : Protective earth reliability label

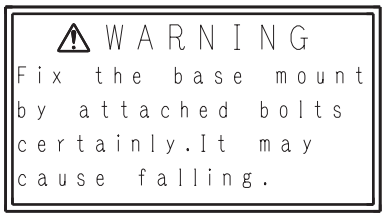


E : Read instructions caution label

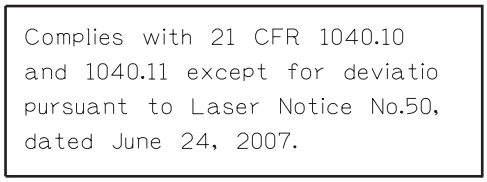
F : Product label



G : Column fixing warning label

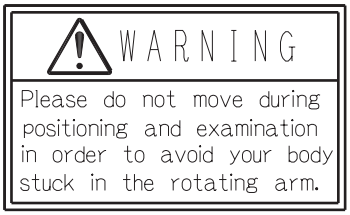


H : Laser notice label



J : Emergency stop label

K : Shooting warning label

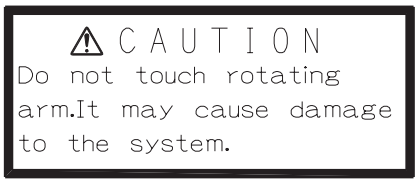


L : Focus label

○

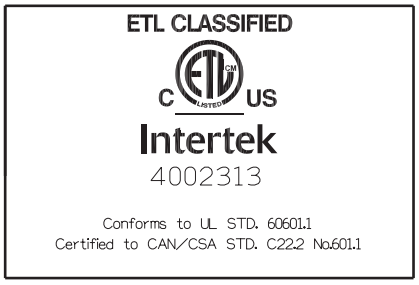
M : Laser marker label

N : Rotation warning label

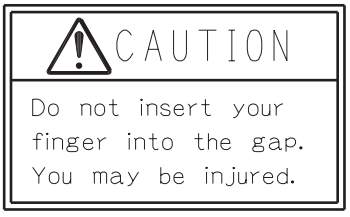


O :Ionizing radiation mark

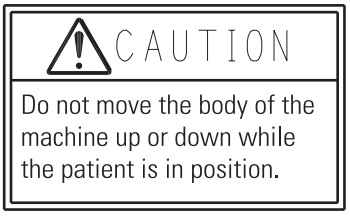
P :ETL mark label



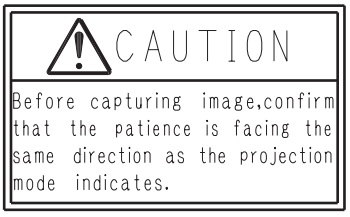
Q :Finger scissors attention label



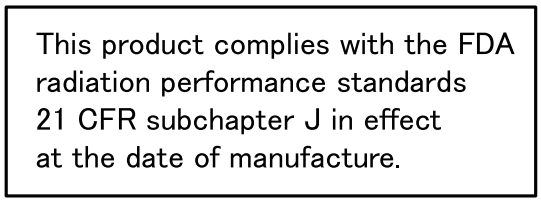
R :Up/down caution label



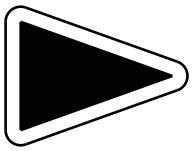
S :The projection mode caution label



T: Certification Statement Label



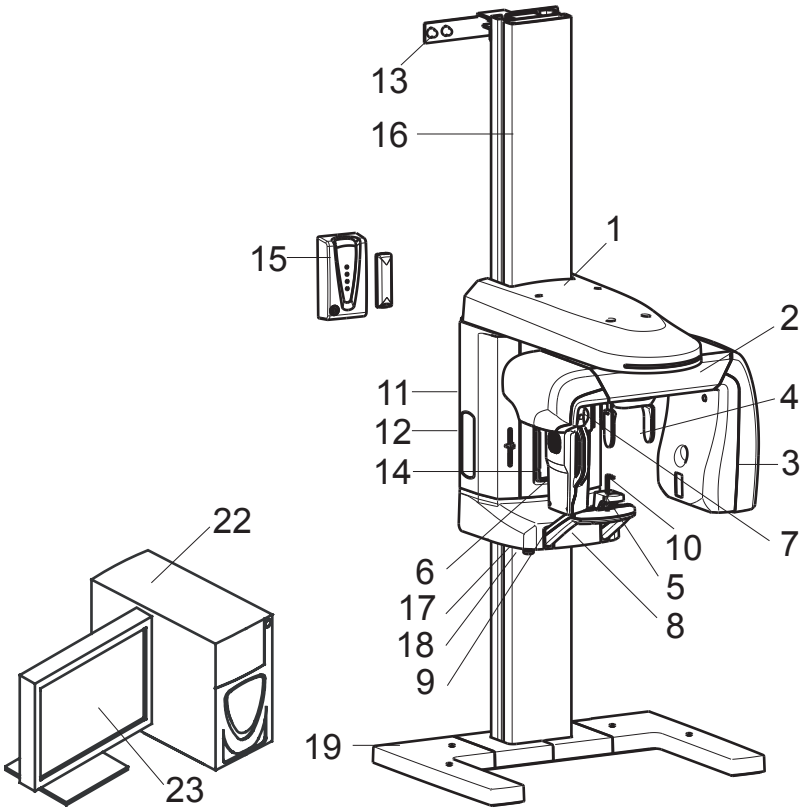
U:FOV Label (**)



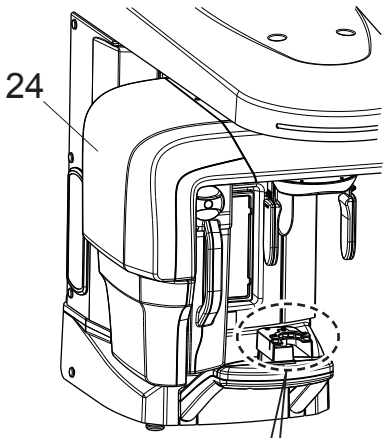
** For equipment with 3D function

1.3 Names and Functions of Units and Their Parts

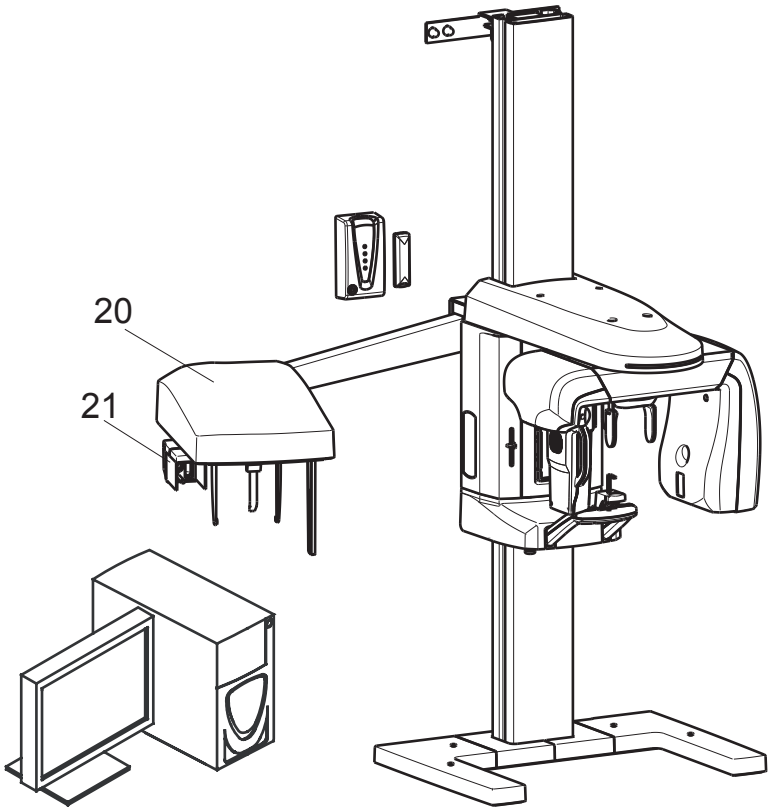
1.3.1 Main body

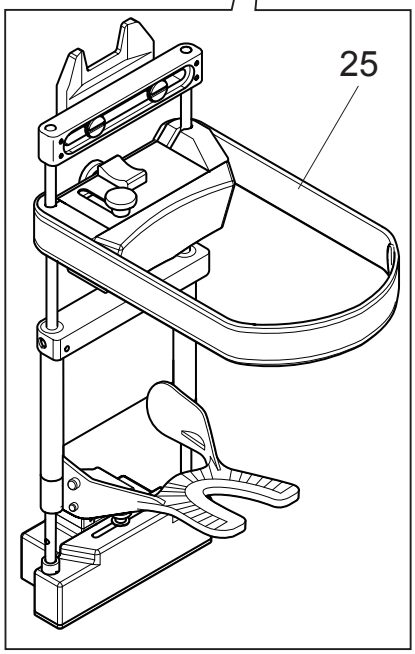


**** For equipment with 3D function**



*** Equipment with Cephalometric**





For 3D

	Name	Function
1	Driving unit	Contains the driving mechanism of the arm unit.
2	Arm unit	Supports the X-ray head and the sensor and is rotated by the internal driving mechanism.
3	Head unit	Contains the X-ray generator and slits to generate the X-ray beam necessary for image acquisition. * For equipment with Cephalometric, internal drive switches the inner slits according to the image acquisition mode selected.
4	Head support unit	Supports and makes the patients head immobile during X-ray acquisition.
5	Chin rest base	The chin rest block and bite block are attached in the Panoramic modes and the TMJ adaptor is attached in the TMJ *1 mode.
6	Sensor unit (Detachable)	Converts X-ray absorption data into electronic data in response to the signals from the controller during image acquisition to output to the PC. It also has a movable structure. For panoramic image acquisition, attach the sensor unit to the docking station unit (Panoramic). NOTE : There are two types of sensors (for Panoramic, or for Panoramic / Cephalometric). A sensor for Panoramic cannot be used to Cephalometric and Carpus radiography. (See "21 Docking station unit (Cephalometric)" below)
7	Docking station unit (Panoramic)	For panoramic image acquisition, attach the Panoramic/Cephalometric -combined sensor here.
8	Chin rest unit	Supports the chin rest base. Equipped with an emergency stop switch at its bottom.
9	Handle	Grasped by the patients to keep posture safety during image acquisition.
10	Patient positioning part	This part is used for patient positioning. The part consists of Chin rest block, Adaptor for edentulous jaw, TMJ adaptor (Panorama), TMJ adaptor (CHILD) and Bite block (disposable) (accessory).
11	Sliding body	Supports the driving unit mounting the arm and the chin rest unit and moves up or down when the Up or Down switches are pressed. Equipped with a positioning mirror on the front a cover and the power switch at the bottom.
12	Control panel	Enables the operator to set the Exposure modes, emit the positioning beams, up/down the sliding body part, reset or move back/forth the position of the arm unit.
13	Wall fixing bracket	Fixes the equipment on the wall by means of coach screws.
14	Positioning mirror	Enables the operator to check the patients face for any inclination.
15	Hand switch box	Fixed on the wall outside of the X-ray room and equipped with the Exposure switch. Pressing the Exposure switch irradiates X-ray and the arm rotates for image acquisition.
16	Column unit	The sliding mechanism being moved up and down to align to the patient's target level by means of an electric actuator.
17	Power switch	Supplies power to X-era Smart (ON: power supplied, OFF: no power supplied.)
18	Emergency stop switch	When pressed in case of emergency, X-era Smart stops.
19	Base unit (optional)	May be used depending on the strength of the floor, on which the equipment is installed.
20	Cephalometric unit (*)	Equipped with a head-positioning device (patient-positioning unit) necessary for Cephalometric radiography. This unit converts the X-ray absorbed data into electronic data by the signal from the control device and exports the image to the computer unit.
21	Docking station unit (Cephalometric) (*)	For Cephalometric image acquisition, attach the Panoramic/Cephalometric -combined sensor here. Moves during image acquisition.
22	PC (*2)	Enables image information management and processing via the keyboard and mouse.
23	Monitor (*2)	Displays Panoramic images and others acquired to use for radiogram interpretation.

	Name	Function
24	Sensor unit (movable) (**)	Converts X-ray absorption data into electronic data in response to the signals from the controller during image acquisition to output to the PC. Depending on each image acquisition mode, the internal driving mechanism slides the sensor unit.
25	Head fixator for 3D image acquisition (**)	This part is attached to chin rest base for accurate patient positioning while 3D image acquisition.

* For equipment with Cephalometric

** For equipment with 3D function

*1 TMJ (Temporomandibular Joint) mode: mandibular images

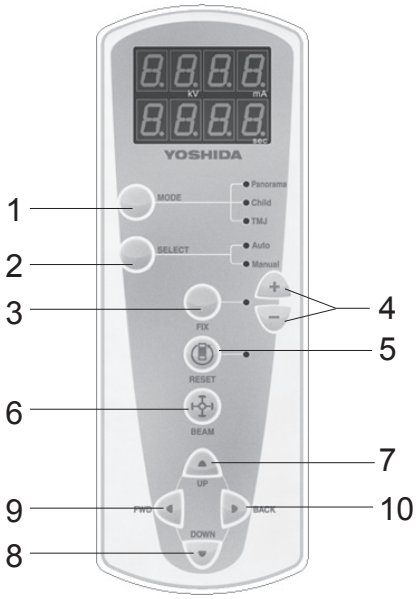
*2 PC and Monitor are not contained to this product. Please prepare them, which fulfill the required specification described in the "11.1 Specification" prior to using the equipment.

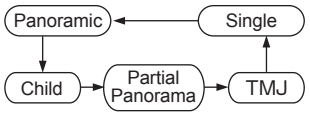
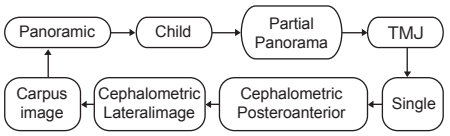
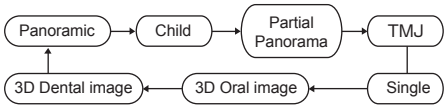
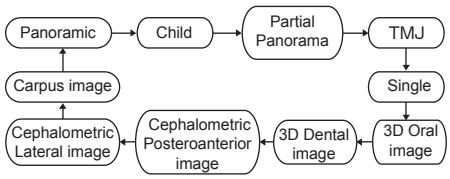
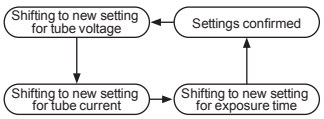
Suppl. : Slide elevation mechanism

The elevation mechanism of the equipment is driven by an electric motor to achieve 800 mm of stroke. For this reason, driving motor may generate slighly large noise, however it is not the result of failure of the equipment.

1.3.2 Names and functions of control panel switches and indicators (1)

Each of the control panel switches executes its own function, moves the sliding mechanism up or down, moves the arm unit forward or backward, specifies radiography settings, irradiates the positioning beam, etc. A buzzer will go off intermittently during X-ray exposure.



	Name	Function	
1	Mode switch	When pressed, switches between "Panoramic", "Child","Partial Panorama", "TMJ", and Single to select any of these exposure modes. The LED associated with selected mode will go on.	
		* For equipment with Cephalometric, it switched between "Panoramic", "Child", "Partial Panorama", "TMJ", "Single", "Cephalometric Posteroanterior image", "Cephalometric Lateral image" and "Carpus image". **See also** :"1.3.3 Names and functions of control panel switches and indicators (2)" P.29	
		*** For equipment with 3D function, it switches between "Panoramic", "Child", "Partial Panorama", "TMJ", "Single", "3D Oral image" and "3D Dental image". **See also** :"1.3.3 Names and functions of control panel switches and indicators (2)" P.29	
		*** For equipment with 3D function and Cephalometric, it switches between "Panoramic", "Child", "Partial Panorama", "TMJ", "Single", "3D Oral image", "3D Dental image" "Cephalometric Posteroanterior image", "Cephalometric Lateral image" and "Carpus image". **See also** :"1.3.3 Names and functions of control panel switches and indicators (2)" P.29	
2	Select switch	Switches between "AUTO" and "MANUAL". In the MANUAL status, values for "Tube voltage", "Tube current", and "Exposure time" may be specified.	
3	Fix switch	Used in the Manual Mode. When this switch is pressed after "Tube Voltage", "Tube Current" or "Exposure Time" is entered, the value will be set. When "Exposure Time" is confirmed, various settings will also be confirmed.	

* For equipment with Cephalometric

** For equipment with 3D function

*** For equipment with 3D function and Cephalometric

	Name	Function
4	"+" and "-" switch	Used to specify any value for "Tube voltage", "Tube current", and "Exposure time". "+" increases the current value by one level and "-" decreases by one level. For more information on the allowable ranges of tube voltage, tube current, and exposure time, see "Parameter settings table" P.28 .
5	Reset switch	Rotates the arm up to the start point for each exposure mode. Also used to release the error message. Pressing this switch for 3 seconds rotates the arm to the sensor detachable position.
6	Positioning beam switch	Positions the patient using positioning beams. When pressed, moves the arm unit to the positioning point and turn on the positioning beams associated with "Midsagittal line", "Frankfurt line", and "Canine position". The beam will be turned off automatically after 60 seconds. When pressed again while the beam is on, the beam will be turned off.
7	Up switch	When pressed and held down, moves the sliding mechanism up to adjust the chin rest level. When released, stops sliding movement.
8	Down switch	When pressed and held down, moves the sliding mechanism down to adjust the chin rest level. When released, stops sliding movement.
9	Forward switch (*1)	When pressed and held down, moves the arm unit forward (toward the column) to adjust the patient position for acquiring topographic images of front teeth. When released, stops sliding movement.
10	Back switch (*1)	When pressed and held down, moves the arm unit backward (toward the opposite side of the column) to adjust the patient position for acquiring topographic images of front teeth. When released, stops sliding movement.

*1 Pressing the positioning beam switch causes the positioning beam to remain activated for 60 seconds.

Parameter settings table

Parameter			Settings						
Tube voltage [kV]			58	60	63	65	68	71	73
			76	79	82				
Tube current [mA]			2.0	2.5	3.2	4.0	5.0	6.3	8.0
			10						
Exposure time [sec]	Panoramic	Panorama	8	14	16				
		Child	6.4	11.2	12.8				
	TMJ		8(*1)						
	Single		0.10	0.12	0.16	0.20	0.25	0.32	0.40
			0.50	0.63	0.80	1.00	1.20	1.60	2.00
			2.50	3.20					
	Cephalometric *	LA	10.0						
		PA	8.0						
		Carpus	8.0						
	3D**	Oral	23*2						
		Dental	11.5						

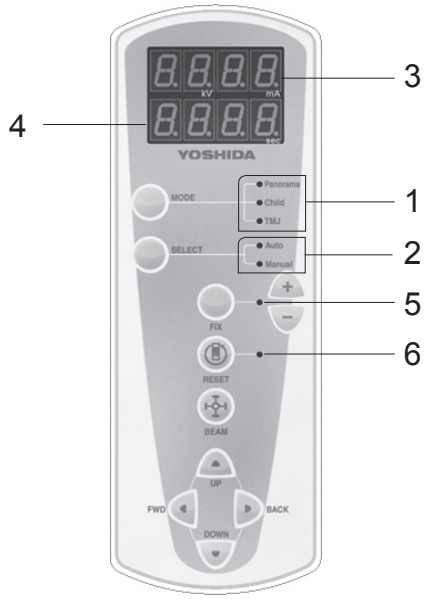
* For equipment with Cephalometric

** For equipment with 3D function

*1 Exposure time for TMJ image acquisition is 4 seconds × 2. When acquiring images of both mouth opening and closing positions, it will be two acquisitions of 4 seconds × 2 each.

*2 Exposure time for 3D Oral image acquisition is 11.5 seconds × 2.

1.3.3 Names and functions of control panel switches and indicators (2)

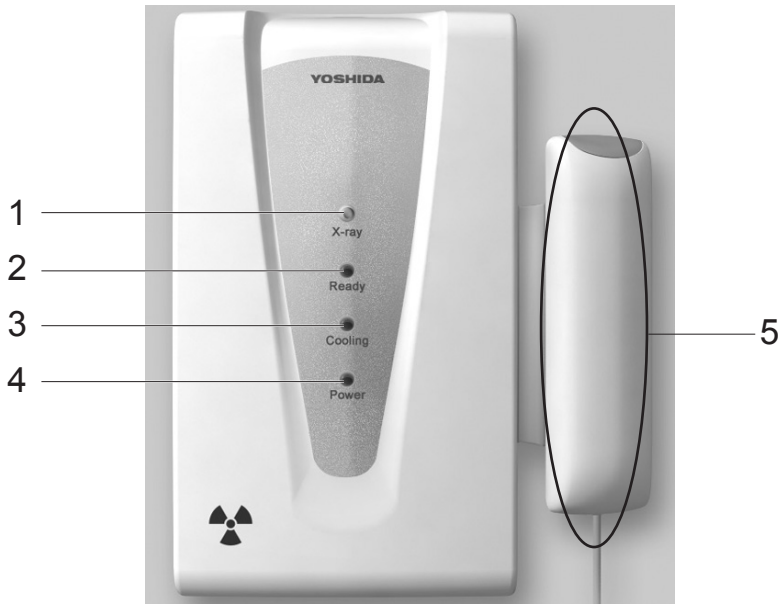


	Name	Function
1	Exposure mode indicator	Panoramic, Partial Panoramic : Panorama LED turns on, if selected. Child panoramic : Child LED turns on, if selected. TMJ : TMJ LED turns on if selected. Single : Panorama LED, Child LED and TMJ LED turns on if selected. Cephalometric : Panorama LED, Child LED and TMJ LED turns on if selected. 3D** : Panorama LED, Child LED and TMJ LED turns on if selected.
2	Exposure status indicator	AUTO : Auto LED turns on, if selected. MANUAL : Manual LED turns on, if selected.
3	Tube voltage indicator	Indicates the current setting for Tube voltage. Single :Displays SnGL on Tube voltage and Tube current indicator. Cephalometric * :Displays CEPH on Tube voltage and Tube current indicator. 3D** : Displays 3d on Tube voltage and Tube current indicator.
	Tube current indicator	Indicates the current setting for Tube current.
4	Exposure time indicator	Indicates the exposure time usually; the remaining time during image acquisition; the remaining waiting time during cooling down. Single : Displays SHot. Cephalometric * : Displays PA/LA/CArP. (PA:Cephalometric Posteroanterior, LA: Lateral, CArP: Carpus) 3D** : Displays orAL : dEnt. (orAL/3D Oral, dEnt: 3D Dental)
5	Fix LED	Flashes during modification to the value for Tube voltage or current. Turns on when pressed to confirm the modification.
6	Reset LED	Flashes while the equipment (e.g. the rotating arm) is operating; turns on when it has returned to its reset point in each exposure mode; turns off when it leaves the reset point. Flashes while the arm is moving to the positioning beam exposure point; turns off when it has reached the point.

* For equipment with Cephalometric

** For equipment with 3D function

1.3.4 Names and functions of hand-switch box indicators and switches

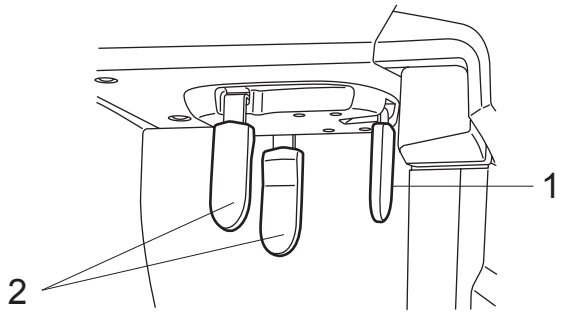


	Name	Function
1	X-ray LED (yellow)	Stays on during X-ray exposure with an intermittent buzzer sound.
2	Ready LED (green)	Flashes while the equipment (e.g. the rotating arm) is operating; turns on when it has returned to its reset position in each exposure mode; turns off when it leaves the reset position. Flashes while the arm is moving to the positioning beam Exposure point; turns off when it has reached the point.
3	Cooling LED (green)	Stays on during cooling time after X-ray exposure; turns off when the cooling time has expired.
4	Power LED (green)	Stays on while power is being supplied.
5	X-ray Exposure switch	Pressed and held down in the Ready for exposure state (Ready LED on) to irradiate X-ray for a specified time period.

* In case of an error, X-ray LED, Ready LED and Cooling LED flashes. When the problem is fixed, The LED turns off.

1.3.5 Head support unit

The head support unit supports and makes the patient's head immovable at the give position during radiographic image acquisition.



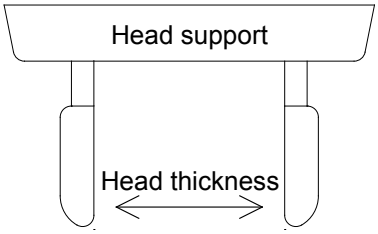
	Name	Function
1	Forehead support (*2)	Supports the patient's forehead to avoid back and forth movement of the patient's head. For equipment with 3D function, it is detachable.
2	Lateral head support (*2)	Supports and makes the patient's head immovable. When image acquisition status is set to "AUTO", it automatically sets the appropriate exposure condition by measuring the head thickness of the patient.(*1) (For automatic setting of exposure condition, see "Exposure condition for image acquisition set to AUTO" P.31.) For equipment with 3D function, it is detachable.

*1 For equipment with Cephalometric, when image acquisition status is set to "AUTO", it will be set to the default exposure condition of each image acquisition mode.

*2 When acquiring 3D image, remove the forehead support and the Lateral head support.

Exposure condition for image acquisition set to AUTO

Image acquisition mode	Head thickness	Exposure condition	
		Tube voltage	Tube current
Panoramic	Less than 170 mm	73 kV	6.3 mA
Child panoramic Partial Panorama	170 mm and above	79 kV	6.3 mA
TMJ	Less than 170 mm	73 kV	10 mA
	170 mm and above	79 kV	10 mA
PA		82 kV	10 mA
LA		82 kV	10 mA
Carpus		63 kV	5.0 mA
3D Oral 3D Dental		82kV (*3)	4.0 mA(*3)



*3 This can be changed from User Program Mode No.22 setting. See "5 User Program Mode" P.119 .

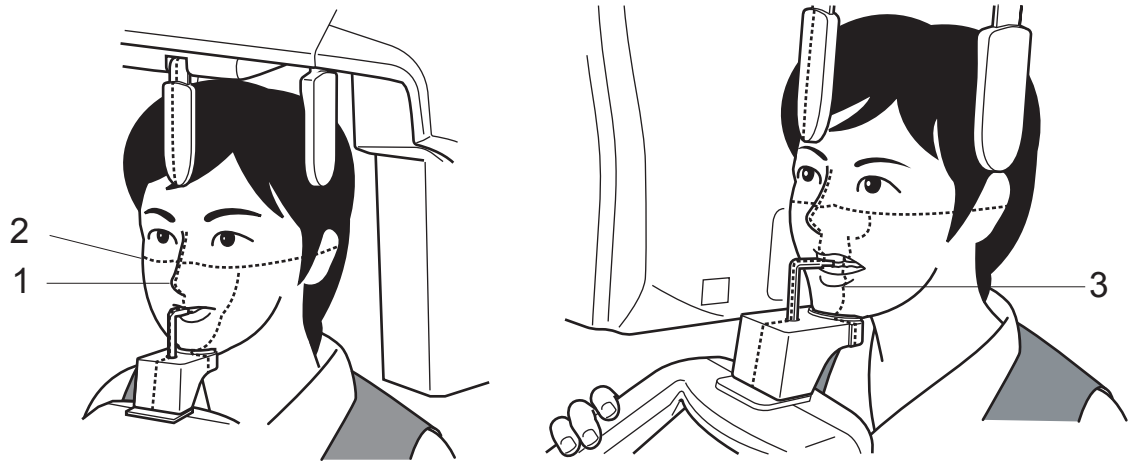
⚠ Caution

- Do not open or close the head support by forcedly without gripping its base, otherwise the patient may be injured.

1.3.6 Positioning beams

Positioning for Panoramic Image Acquisition

Pressing any of the positioning beam switches activates its associated positioning beam (at the same time, the arm unit moves to the positioning point). These positioning beams can be used to make the patient's head immovable at the position appropriate for image acquisition.



	Name	Function
1	Midsagittal vertical beam	Used to adjust any horizontally inclined patient's face by aligning to the patient's midsagittal.
2	Frankfurt horizontal beam	Used to adjust any anteroposteriorly inclined patient's face by aligning to the patient's reference face plane (Frankfurt or Camper plane).
3	The canine beam	Used to adjust the patient's anterior tooth row and the X-ray exposure point by aligning the beam to the tops of anterior tooth roots (around the center of the mandibular third tooth).

⚠ Warning

- Do not look directly into the positioning beam. The power output (Class 2) is at the level which adverse effect on the eyes can be avoided by blinking. However, caution should be taken for maximum safety.

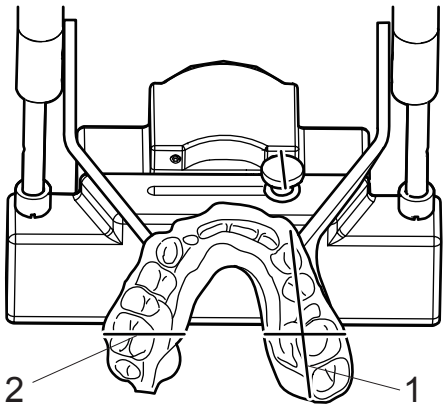
⚠ Caution

- Be careful not to direct the positioning laser beam into patient's eyes. And also, advise the patient not to look directly into the beam.

Suppl. : The positioning beams automatically turns off approximately 60 seconds after activation. If the positioning beams have turned off before positioning is successfully finished, retry pressing the beam switches to turn the positioning beams on.

Positioning for 3D image acquisition

Press the positioning beam switch on the control panel to turn on the positioning beam (the arm unit moves to the positioning point). Adjust the intersection of the Midsaggital vertical beam and the Canine beam to the center of 3D.



	Name	Function
1	Midsaggital vertical beam	Intersection of the Midsaggital vertical beam and the Canine beam shows the center of 3D image acquisition.
2	Canine beam	

⚠ Warning

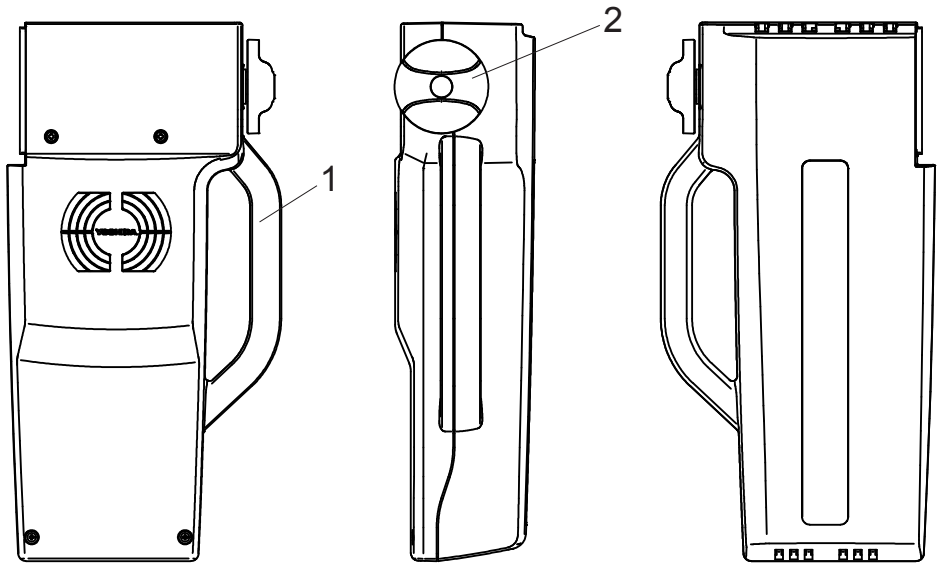
Do not look directly into the positioning beam although the power output (Class 2) is at the level in which adverse effect on the eyes can be avoided by blinking.

⚠ Caution

Positioning beam is a laser beam. Be careful not to direct the positioning laser beam into patient's eyes. Also, advise the patient not to look directly into the beam.

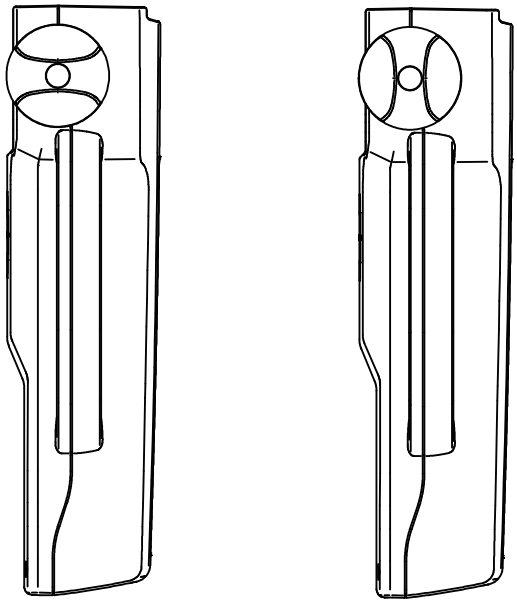
Suppl. : The positioning beam automatically turns off approximately 60 seconds after activation. If the positioning beam has turned off before positioning is successfully finished, press the beam switch again to turn on the positioning beam.

1.3.7 Sensor unit (detachable)



	Name	Function
1	Handle	When docking station the sensor, hold the handle to retain it.
2	Knob for detaching	Rotate the knob to fix the sensor to the docking station.

Locking/unlocking position of the knob for detaching

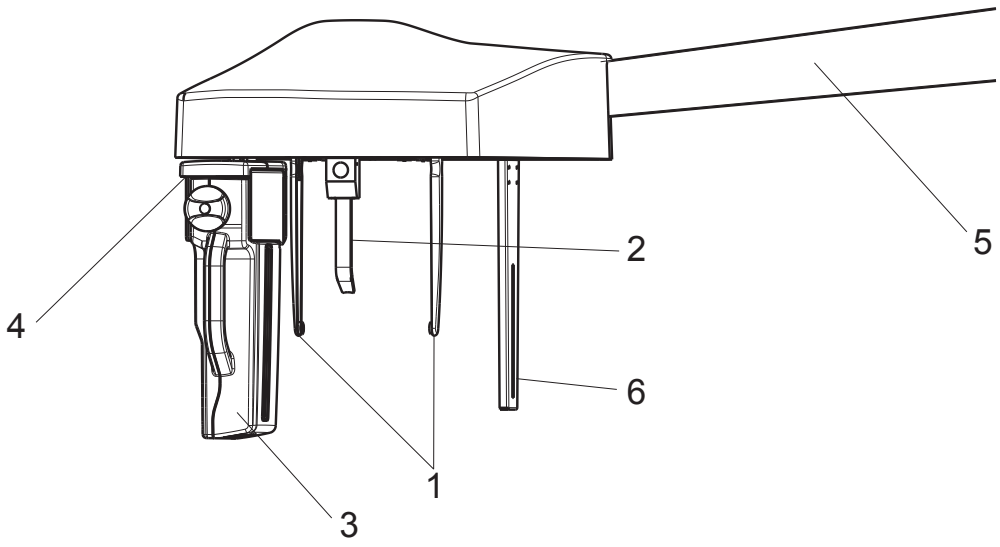


When locking When unlocking

⚠ Caution

- Be sure to hold the handle when detaching the sensor. The sensor may drop if you hold other parts. Dropping the sensor may cause failure.
- The sensor unit is equipped with a shock sensor. The shock sensor records any excessive impact incurred, such as when the equipment falls down, and the equipment will not qualify as being warrantable.

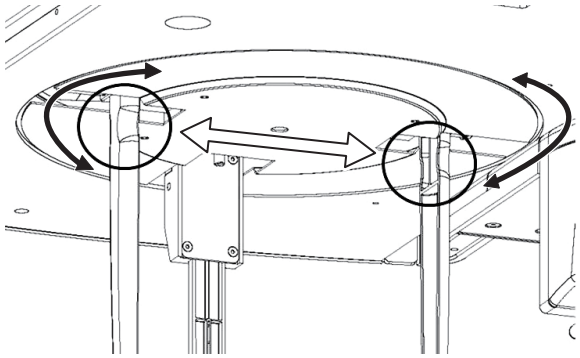
1.3.8 Cephalometric unit (*)



	Name	Function
1	Ear rod	Adjusts to the patient's porus acusticus and fixes the head.
2	Nose support	Adjusts to the center of patient's eyebrows and fixes the head.
3	Cephalometric sensor (Panoramic/Cephalometric-combined sensor)	This unit converts the X-ray absorption data into electronic data by the signal from the control device and exports the image to the computer unit. This sensor can be used as Panoramic sensor.
4	Docking station (Cephalometric)	For Cephalometric image acquisition, attach the Panoramic/ Cephalometric-combined sensor here. Moves during image acquisition.
5	Cephalometric arm	Supports Cephalometric sensor.
6	Second slit	Reduces the radiation exposure for the patient.

* For equipment with Cephalometric

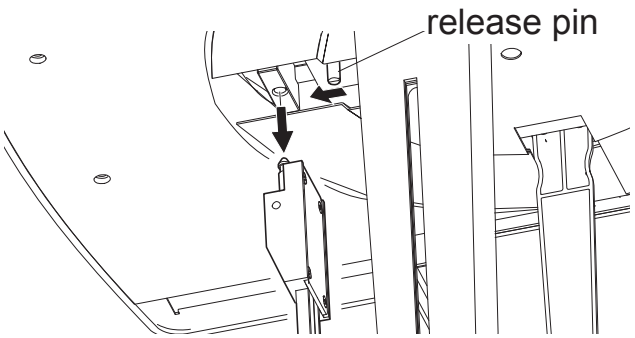
Methods of Rotating, Opening and Closing of Nose Support and Ear Rods



Hold the indentations pictured left and rotate the nose support and ear rods.

Hold the same indentations when opening and closing ear rods.

Detaching nose support

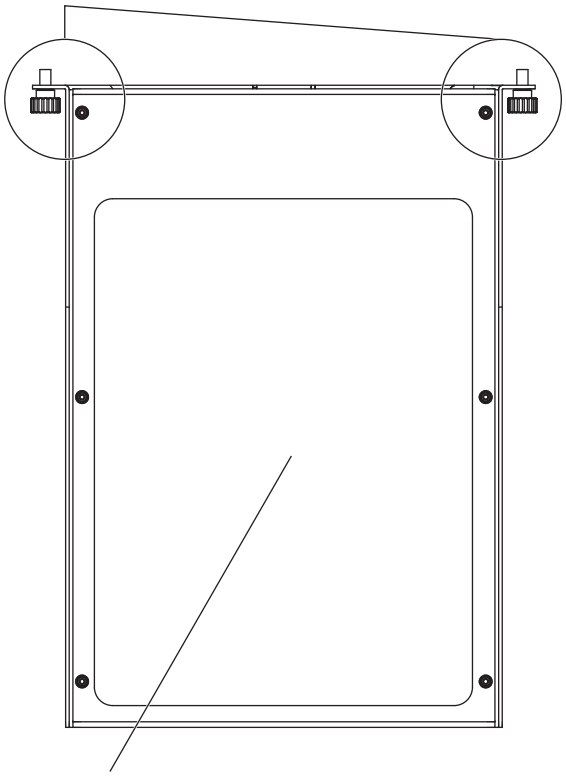


As shown on the picture on the left, pull the release pin of the nose support for detachment.

Carpus support

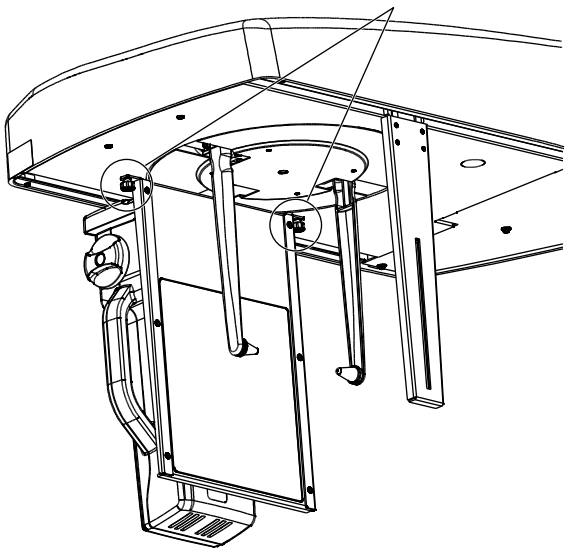
When acquiring carpus images, attach the carpus support to the cephalometric main unit.
Attach the carpus support by fastening the screws into the screw holes on the cephalometric main unit.

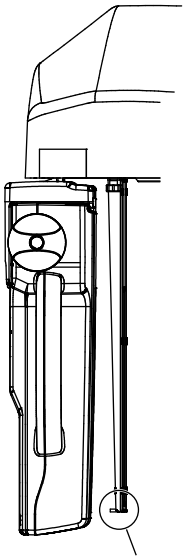
Carpus Support Attaching Screws



Carpus Support

Carpus Support Attaching Screw Holes





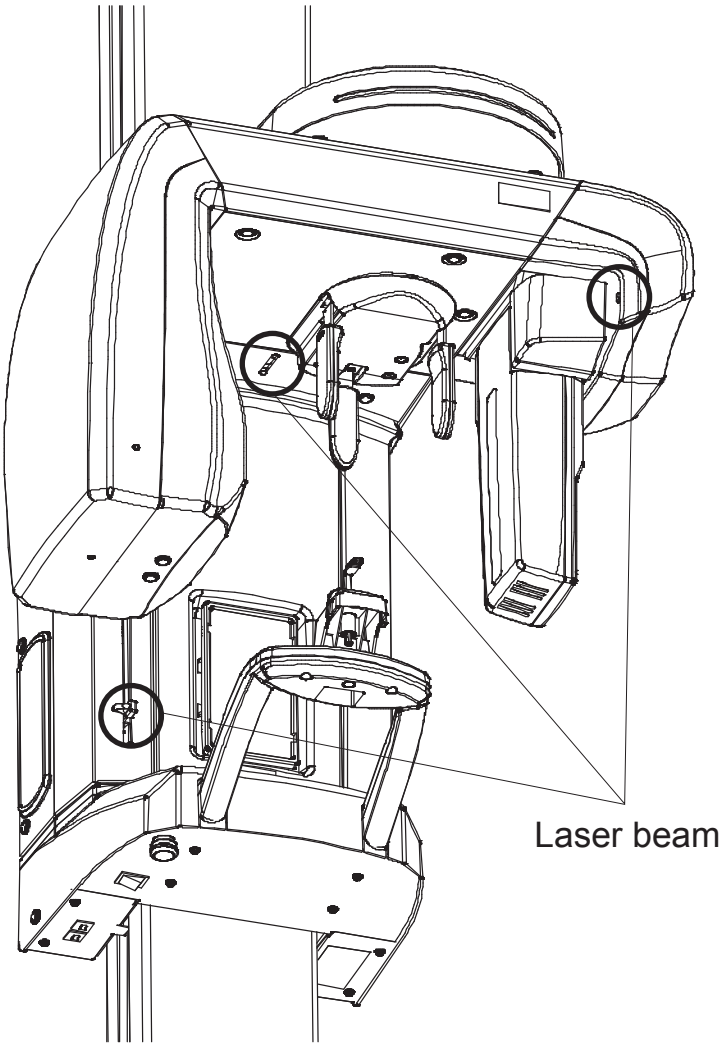
Carpus Support edge

⚠ Caution

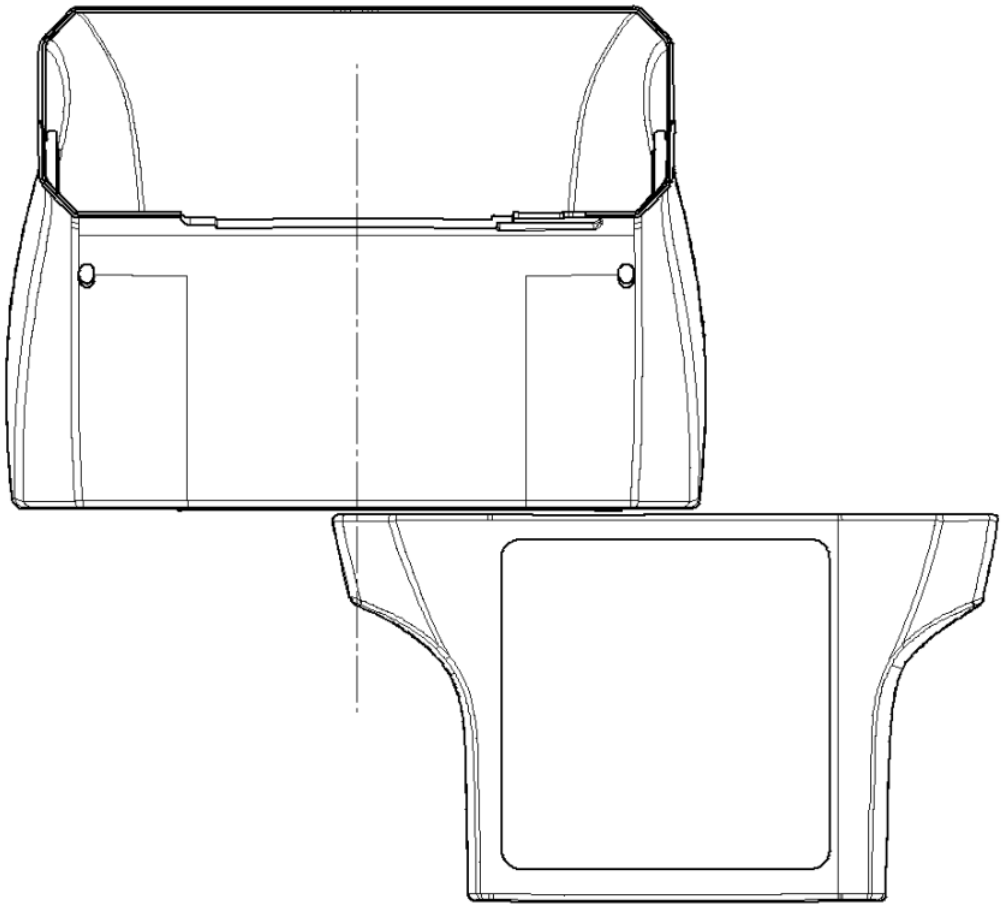
- Make sure that the edge of the Carpus support is facing the sensor when attaching (as shown in the picture above). If faces the other way, patient may get injured by the edge.
- When acquiring images, ask the patient not to apply load to the carpus support.

1.3.9 Positioning beam allocation

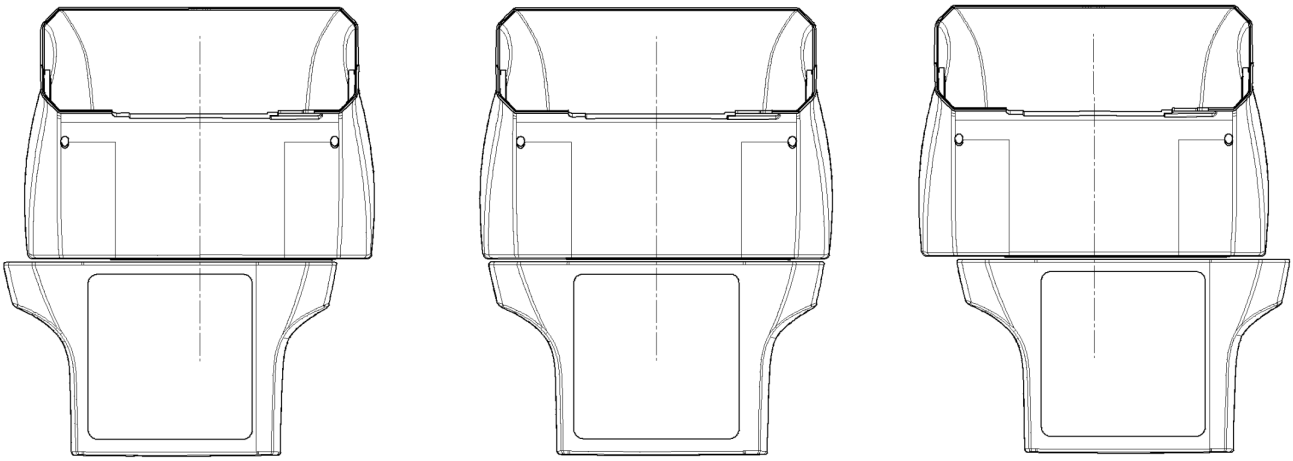
X-era Smart equips with a laser beam as patient positioning beam allocated in the position shown below.



1.3.10 Sensor unit (movable) (**)



Sensor position for Panoramic and Cephalometric (image looking from head unit)



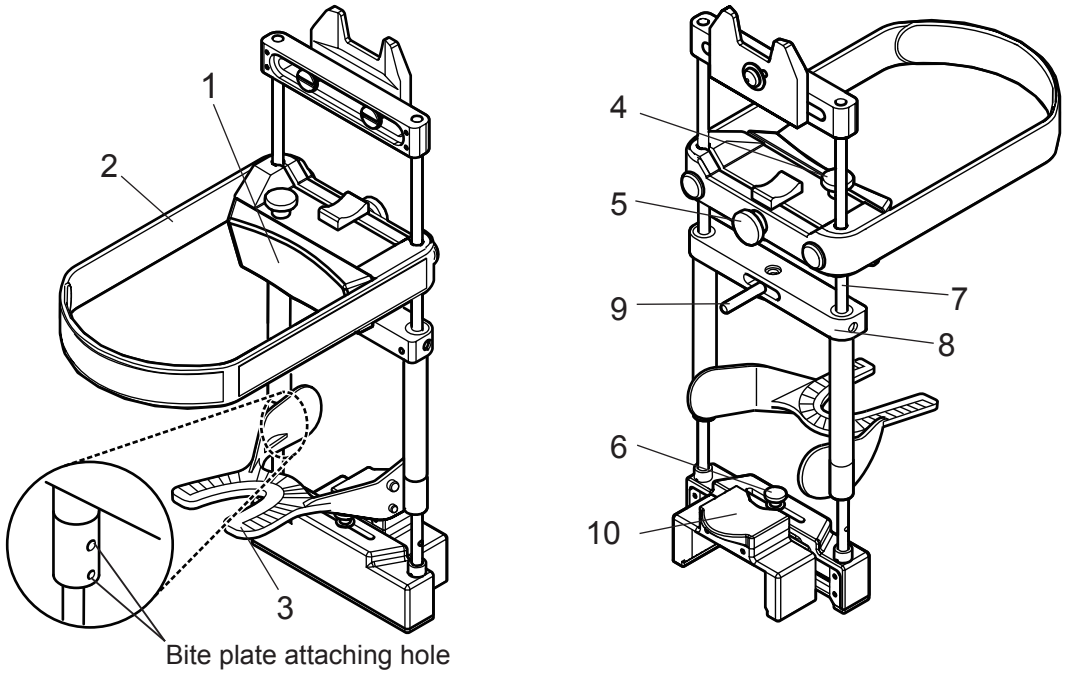
3D left position | 3D center position | 3D right position

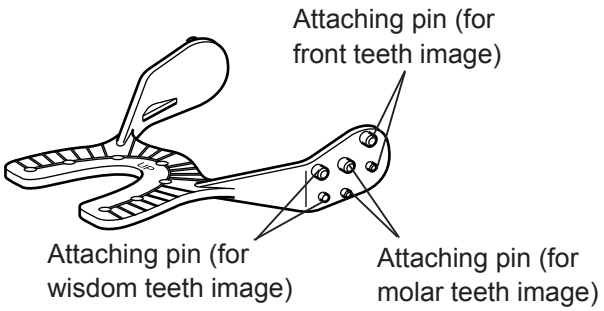
Sensor position for 3D (image looking from head unit)

** For equipment with 3D function

1.3.11 Head fixator for 3D image acquisition(**)

This part is attached to chin rest base for patient positioning while 3D image acquisition.





Bite plate

	Name	Function
1	Forehead support	Holds patient's forehead to support patient's head. Place on the patient's forehead. Adjust the position using the front-back slide adjustment knob.
2	Head band	Fixes the patient's head.
3	Bite plate	Place in the patient's mouth for biting to fix position.Attaching pins are placed on both sides which correspond to image acquiring position. Front row pins x 2 for wisdom teeth image, center row pins x 2 for molar teeth image and rear row pins x 2 for front teeth image (three position type). Each of the upper pin is thicker.
4	Front-back slide fixing knob	Fixes the front-back sliding. Loosen to adjust the front-back position of the forehead support.
5	Up-down slide fixing knob	Fixes the up-down sliding. Loosen to adjust the up-down position of the forehead support.

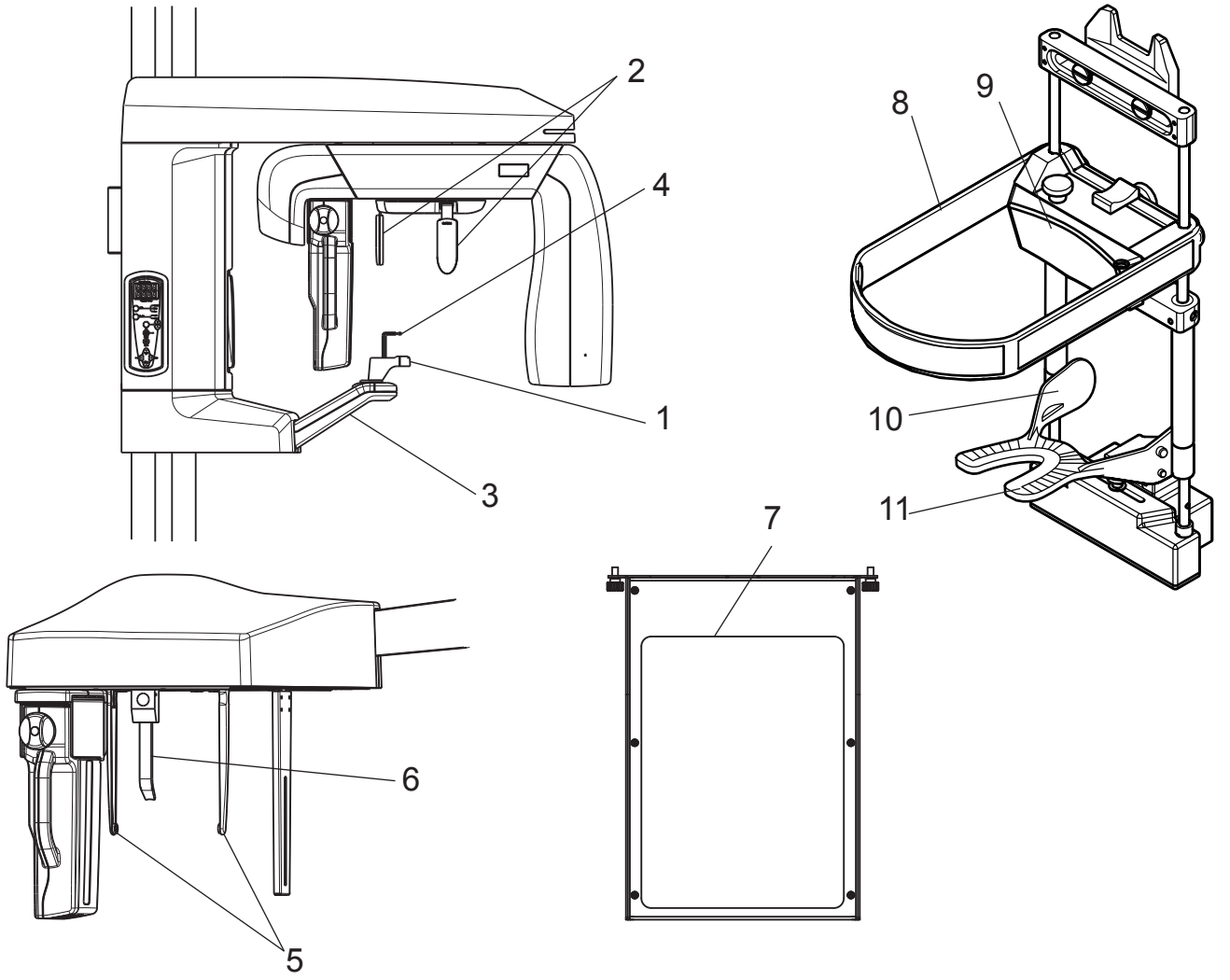
6	Left-right slide fixing knob	Fixes the left-right sliding. Loosen to adjust the left-right position of the forehead support.
7	Shaft	Holds up the forehead support. There are two marks on both sides which indicate FOV height. Upper mark shows the upper end of FOV and the lower mark shows the lower end of FOV.
8	Up-down positioning unit	Adjusts the attachment and height of bite plate.
9	Up-down lock lever	Fixes the up-down positioning unit at the arbitrary height. Fixes by clicking in the left-right position and cancels in the center position.
10	Head fixator lever	Head fixator lever fix the head fixator for 3D image acquisition to the chin rest.

NOTE : Attach the head fixator for 3D image acquisition when acquiring 3D image. An error occurs for the following cases.

Description	How to solve
X-ray Exposure switch is pressed without attaching the head fixator for 3D image acquisition in the 3D image acquisition mode.	Warning messages (FL06) is displayed. Cancel the error using the reset switch from the control panel. Attach the head fixator for 3D image acquisition.
The head fixator for 3D image acquisition is attached other than in 3D image acquisition mode.	Warning messages (FL05) is displayed. Cancel the error using the reset switch from the control panel. Remove the head fixator for 3D image acquisition.

1.4 Materials of Applied Parts

The applied parts coming in contact with the patient have been made of the materials described below.



	Name	Function
1	Chin rest block	ABS resin, PC resin (adaptor for edentulous jaw)
2	Head support	ABS resin
3	Handle	ABS resin
4	Bite block	ABS resin
5	Ear rod *	PC resin
6	Nose support *	PC resin
7	Carpus Support *	PC resin
8	Head band**	Vinyl resin
9	Forehead support**	Silicone resin
10	Bite plate**	PC resin
11	Dental impression material ** (*1)	Silicone, or alginate

* For equipment with Cephalometric
** For equipment with 3D function

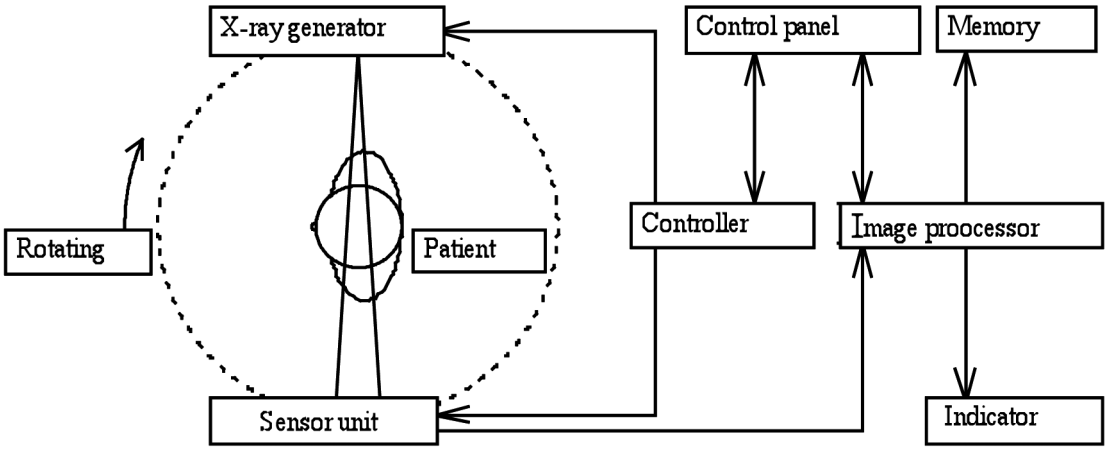
*1 Coated on a bite plate.

1.5 Principle of Operation

1.5.1 X-ray generating mechanism

An X-ray beam is generated using part of the kinetic energy converted when electrons rapidly spinning decelerate in the material. To accelerate the thermoelectrons of the X-ray beam emitted by an X-ray tube, several tens kilo voltages of high DC voltage is required. To this requirement, an internal high-voltage transformer increases the voltage by several hundreds voltage. The quality of the X-ray beam varies with the level of the voltage applied to the X-ray tube (X-ray tube voltage). With higher X-ray tube voltage applied, a higher transmission power of X-ray beam is generated. The X-ray dose depends on the magnitude of a current flowing through the X-ray tube (X-ray tube current).

1.5.2 Operating principle



This equipment features several devices: an X-ray generator, a Sensor unit , Arm unit, which is attached to a sliding body unit on a Column unit. While rotating around the patient's teeth and jaw, the equipment irradiates X-ray and detects X-ray absorbed data at the Sensor unit multiple times. Detected multiple pictures are transferred to an image processing unit and the data is superimposed with appropriate shift value according to the X-ray moving speed by the arm rotation to acquire panoramic image or the image of jaw joint.
To acquire Cephalometric image and Carpus image, attach the Panoramic/Cephalometric -combined CMOS sensor to the Cephalometric unit and the equipment irradiates X-ray to head, teeth, jaw and hand, and detect X-ray absorbed data at the Sensor unit. (*) Sync the data transferring speed of 3D sensor and the X-ray moving speed by the arm rotation to acquire 3D image in the image processing unit from the multiple data detected by 3D sensor.(**)
Images will be displayed on the Indicator and image data will be recorded in the memory of magnetic disk and so on.

* For equipment with Cephalometric

** For equipment with 3D function

1.5.3 Principle of Radiographic

Panoramic modes

Keep pressing the X-ray Exposure switch to rotate the arm unit. The X-ray tube assembly that irradiates a narrow beam is suspended to the arm unit. The arm unit rotates at a specified speed around the stationary patient. During the arm unit rotation, data will be acquired by the Sensor unit multiple times. In the image processing unit, data acquired in the Sensor unit are superimposed with the shift value according to the desired tomographic area to acquire tomographic view.

TMJ mode

In the same manner as that in the panoramic mode, the patient can be positioned within the field of radiographic to acquire only the images of left and right joint areas necessary for diagnosis.

Cephalometric radiography (*)

A plain radiographic image with stable magnification percentage of the properly positioned patient's head, between the narrow beam irradiating X-ray generator and the Cephalometric sensor which is the optical receiver, can be acquired.

Carpus radiography (*)

A plain radiographic image with stable magnification percentage of the properly positioned patient's hand, between the narrow beam irradiating X-ray generator and the Cephalometric sensor which is the optical receiver, can be acquired.

3D image acquisition (**)

Keep pressing the X-ray Exposure switch. Irradiate from the X-ray generator which rotates around the stationary patient. The X-ray which passes through the patient is detected by the 3D sensor. Reconfigure the image by computer using the X-ray absorbed data detected to acquire tomographic view.

⚠ Caution

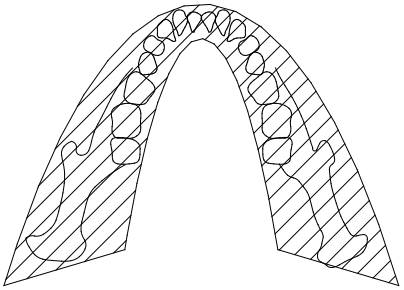
- Errors may be observed when measurement is made on 2D images acquired in the panoramic mode.

* For equipment with Cephalometric
** For equipment with 3D function

1.6 Radiographic Functions

1.6.1 Functions of exposure modes

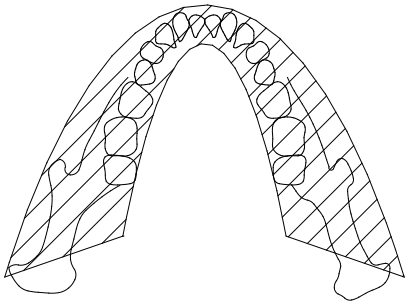
Panoramic



Standard panoramic mode trajectory

Panoramic images of the patient's dental arch may be acquired in a normal exposure time (approximately 14 seconds).

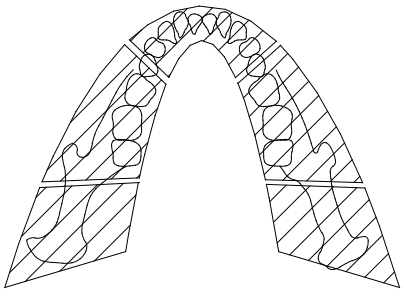
Child panoramic



Child panoramic-mode trajectory

For child and small female patients, the child panoramic mode can be used to acquire images in a shorter exposure time (normal: approximately 11.2 seconds).

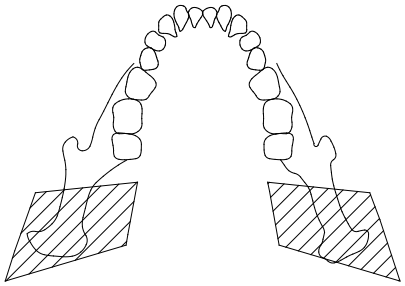
Partial Panoramic



Partial Panoramic image acquisition track

Partial Panoramic function can be selected to reduce the exposed dose of the patient. From the selection area divided into five parts, only necessary part of dental panoramic image can be acquired.

TMJ mode

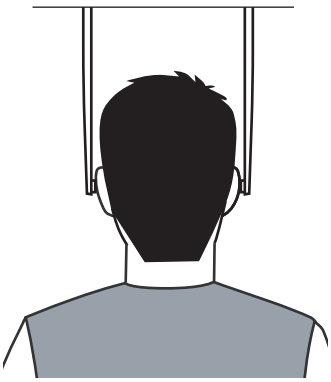


TMJ-mode trajectory

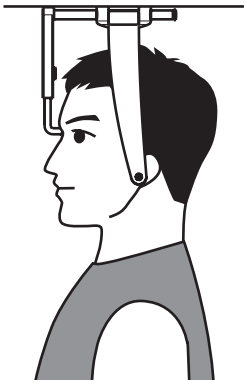
Split images of the patient's temporomandibular joint can be acquired in an exposure time of 4 seconds/stage.

Cephalometric radiography (*)

Choose between posteroanterior image (PA) and lateral image (LA). Image acquisition time for a posteroanterior and a lateral image is 8 seconds and 10 seconds respectively.

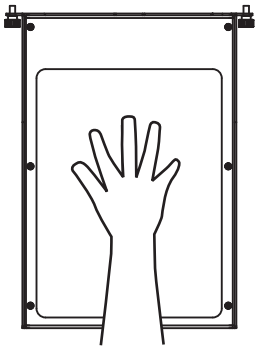


PA



LA

Carpus radiography (*)



Carpus

Image acquisition time for a carpus image is 8 seconds.

Single image radiography

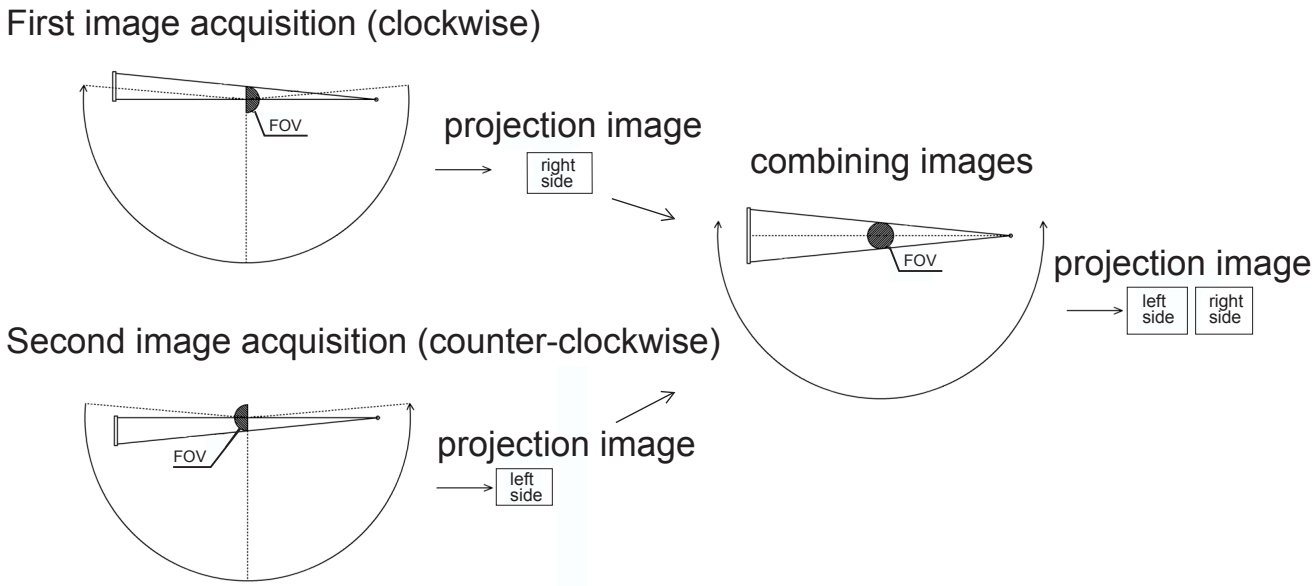
This image acquisition mode is used for maintenance purposes only. In this mode, the sensor's response to X-ray can be checked.

NOTE : Do not conduct image acquisition on the patient using this mode.

* For equipment with Cephalometric

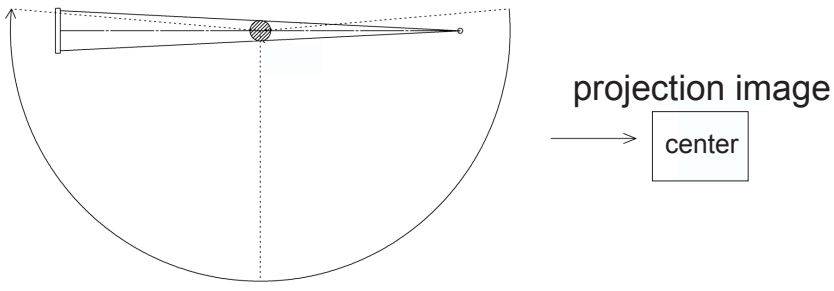
3D Oral image radiography (**)

Images acquired from clockwise image acquisition (irradiation time 11.5 seconds) and counter-clockwise image acquisition (irradiation time 11.5 seconds) are combined. Reconfigure the combined images to acquire a large FOV 3D image.
(FOV: Diameter 77mm, height 54mm)



3D Dental image acquisition (**)

Reconfigure the acquired image from the clockwise image acquisition (irradiation time 11.5 seconds). 3D image can be acquired.
(FOV: Diameter 40mm, height 57mm)



* For equipment with Cephalometric
** For equipment with 3D function

1.6.2 Selecting Exposure status

You may select either exposure status of AUTO or MANUAL.

Exposure status

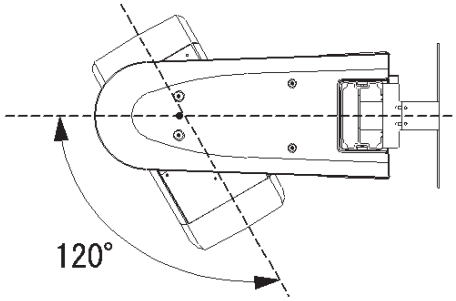
AUTO : The tube voltage, tube current, and exposure time are automatically set appropriately for the size of the patient's dental arch.
In case of Cephalometric radiography and Carpus radiography, tube voltage, tube current and exposure time are set to default of each image acquisition mode.(*)
For 3D image acquisition, default tube voltage, tube current, and exposure time are set. (**)

MANUAL : The tube voltage, tube current, and exposure time may be arbitrarily modified.

* For equipment with Cephalometric
** For equipment with 3D function

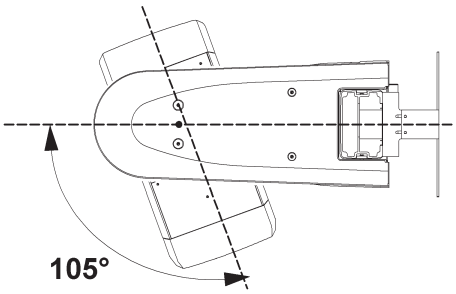
1.6.3 Names of arm unit positions

Start / Reset position

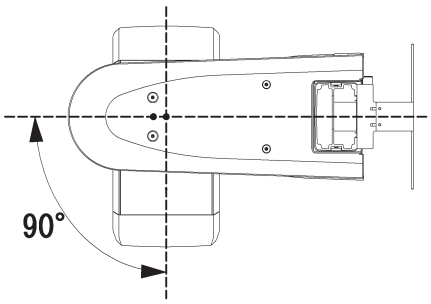


For 3D image acquisition, start position moves 60mm backward than the Panoramic start position (**).

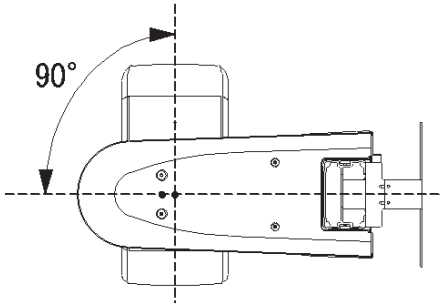
Patient positioning position



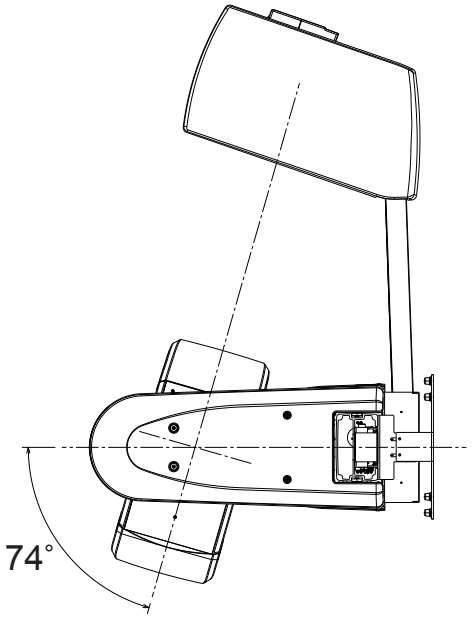
Patient entry position



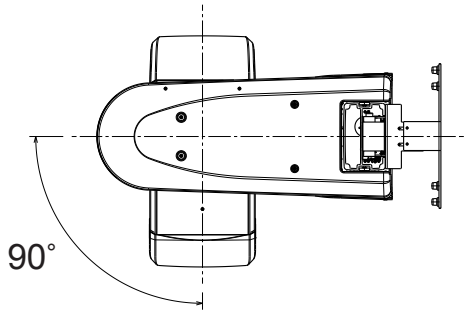
Patient exit position



Cephalometric and Carpus radiography position (*)



Sensor detachment position



* For equipment with Cephalometric

** For equipment with 3D function

1.7 Cooling Time

The equipment has incorporated a variable-cooling time function. X-ray radiographic may be repeated consecutively three or four times after it has not been used for a long time; however, the X-ray tube head, once reaching a given temperature, should be cooled for a given time depending on the radiographic conditions as shown in the following table.
The cooling time of the equipment are as described in the following table.

Panoramic mode

	Tube Voltage [kV]	Tube Current [mA]	Exposure Time [sec]	Cool. Time [sec]	Max. exposure/hr [No. of times]
Con.1	73	6.3	16	352	10
Con.2	73	6.3	14	308	12
Con.3	79	6.3	16	383	10
Con.4	79	6.3	14	335	11

TMJ mode

	Tube Voltage [kV]	Tube Current [mA]	Exposure Time [sec]	Cool. Time [sec]	Max. exposure/hr [No. of times]
Con.1	73	10	8	232	15
Con.2	79	10	8	256	13

Cephalometric and Carpus radiography (*)

	Tube Voltage [kV]	Tube Current [mA]	Exposure Time [sec]	Cool. Time [sec]	Max. exposure/hr [No. of times]
Con.1	82	10	8	320	12
Con.2	82	10	10	400	9

3D X-ray image acquisition cycle (**)

	Tube Voltage [kV]	Tube Current [mA]	Exposure Time [sec]	Cool. Time [sec]	Max. exposure/hr [No. of times]
Con.1	82	4.0	11.5	178	19
Con.2	82	4.0	23	355	9

* For equipment with Cephalometric
** For equipment with 3D function

1.8 Software

X-era Smart ControlManager

Confirmation of the following features: exposure Condition, projection Mode, projection Status and Main Unit Circuit Board Program Version, User Program Mode Settings and Communication port Settings can be configured.

Image Creator

Projection Mode settings, Acquisition of images, Formulation of Panoramic images, Adjustment of the Tomographic plane of Panoramic images, and Transfer of the images to a Viewer software can be configured.

2 Directions for Use

⚠ Caution

- To assure the operator’s and patient’s safety, be sure to read through this section prior to use of the equipment.

2.1 Pre/post-operational Procedures

Pre-operational procedure

Plug the power cable of the equipment into the medical ground outlet.
Check the surrounding area of the equipment 'to make sure' there is no object that interferes with the X-ray radiography.
Be sure to check the equipment in reference to "7.2 Periodical Checks" P.128 and "Periodical check list" P.128 prior to use.

Post-operational procedure

After use, turn off (O) the power switch of the equipment and then unplug the power cable from the medical ground outlet.

⚠ Caution

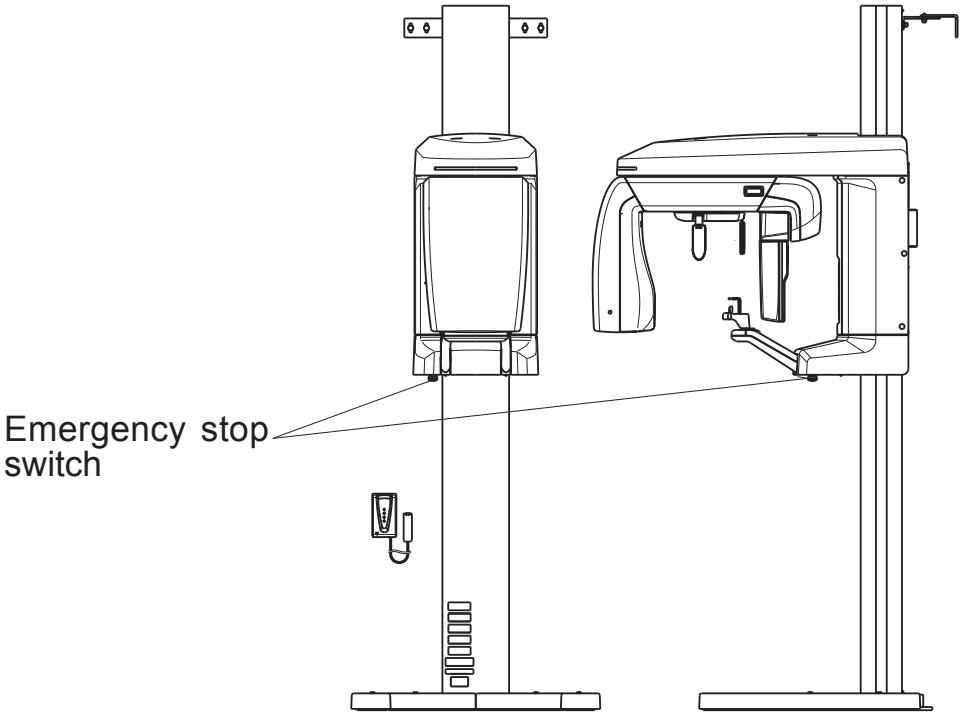
- Do not place any object within the movable field of the arm unit, otherwise the equipment or its surrounding physical proprietaries may be damaged.

NOTE : Be sure to clean up the equipment.

See also : "7.1 Cleaning" P.127

2.2 Emergency Stop

In case of an emergency, one of two steps described below should be followed to immediately stop the equipment.



1 By releasing the X-ray exposure switch during image acquisition, X-ray irradiation and image acquisition will stop immediately and Er08 will be displayed on the control panel.

See also : "6.1.2 Troubles associated error messages displayed on the screen" P.125

2 Pressing the Emergency Stop switch shuts off power supply to the main body, causing X-ray exposure and image acquisition to stop.

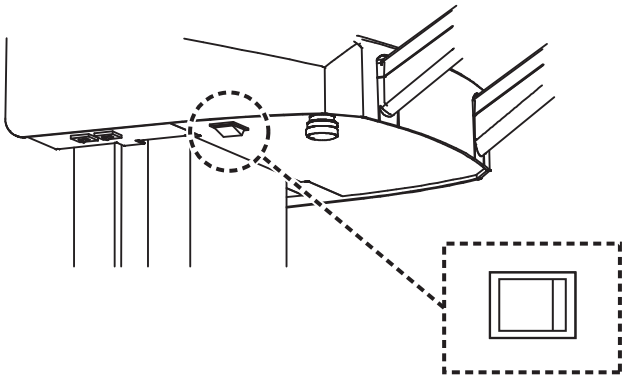
All the functions will stop because of power shutdown. After emergency stop, be sure to evacuate the patient to safe area. Then, turn off the power switch or unplug the power cable from the power outlet.
Finally, eliminate the trouble caused the emergency stop. To reactivate the equipment, turn the Emergency Stop switch clockwise to deactivate.

2.3 Procedure of Panoramic and TMJ Radiography

2.3.1 Turning the power switch on

1 Turn the computer's power switch on.

2 Turn the power switch on (|) on the equipment to check that the power LED (green) has been turned on (also, check that the Emergency Stop switch has been disabled).



When power is turned on, the arm unit will move automatically to the patient entry point (The settings for automatic motion may be modified in the program mode. See "Descriptions of User Program Mode" of the section "5 User Program Mode").

⚠ Caution

- When the unit has been activated, usually the arm unit will move automatically to the patient entry point. Do not place any object within the movable field of the arm unit. Its surrounding physical proprietaries may be damaged.
- Instruct the patient to keep away from the equipment until the arm unit returns to its reset position.
- If the equipment is not used for a long time, ensure that the power switch (O) is off.
- Properly ground the computer.
- Before initiating the image acquisition, make sure that the sensor unit (detachable) is firmly attached and locked to the docking station unit (panoramic).
- The detachable sensor unit is equipped with a shock sensor. The shock sensor records any excessive impact incurred, such as when the equipment falls down, and the equipment will not qualify as being warrantable. Exercise caution in handling the equipment.
- When attaching or detaching the detachable sensor unit, exercise caution not to drop the unit. If dropped, the detachable sensor unit might be damaged and may lead to a failure of the image acquisition.
- Beware not to touch the equipment while the movable 3D sensor is in motion. The finger or hand might get caught and injured.
- Warning message (FL05) is displayed on the control panel if the power switch is turned on with the head fixator for 3D image acquisition attached. Remove the head fixator before turning on the power switch.

3 Wait for a while until the link between the internal sensor and the computer has been established.

NOTE : If the link between the sensor and the computer is not established for more than one minute, turn off the equipment and turn it on once again.

2.3.2 Flow of Image Acquisition

When acquiring images by activating Image Creator using TWAIN function of the viewer:

- Start up the viewer.
- Set “Yoshida” in equipment setting.
- Start TWAIN function.
- The main screen of Image Creator is displayed.
- Set the exposure conditions.
- Seat and position the patient.
- X-ray exposure begins.
- Preview image is displayed in Image Creator while X-ray is irradiated.
- The patient exits.
- Image construction, tomographic adjustment, and display adjustment.
- Press “OK” on Image Creator and transfer the image to the Viewer.
- The Viewer displays the image acquired.

When acquiring images using the “Drag & Drop” function of Image Creator:

- Start up the viewer.
- Start up Image Creator.
- Set the exposure conditions.
- Seat and position the patient.
- X-ray exposure begins.
- Preview image is displayed in Image Creator while X-ray is irradiated.
- The patient exits.
- Image construction, tomographic adjustment, and display adjustment.
- Drag the “Drag & Drop” button on Image Creator to the Viewer and drop it on the display window of the Viewer.
- The Viewer displays the image acquired.

⚠ Caution

- Use a Viewer compatible with TWAIN Version 2.1.

See also : For detailed operation of the Viewer and TWAIN, refer to the instruction manual of the Viewer in use.
For detailed operation of Image Creator, refer to "4 Directions for Use of Image Creator" P.110.

2.3.3 Setting the Exposure mode

From the control panel:

To set the Exposure mode:

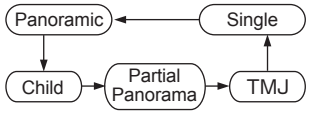
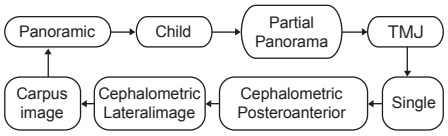
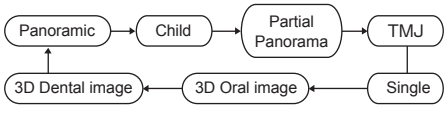
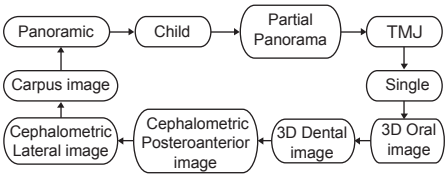
1 Keep on pressing the Mode switch until the mode you desire is selected from "Panoramic", "Child","Partial Panorama", "TMJ" and "Single". The LED associated with the selected mode will illuminate. (*1)

* For equipment with Cephalometric, selection of the modes would be from "Panoramic", "Child", "Partial Panorama", "TMJ", "Single", "Cephalometric Posteroanterior image", "Cephalometric Lateral image" and "Carpus image".
The LED of the selected image acquisition mode turns on.

** For equipment with 3D function, it switches between "Panoramic", "Child", "Partial Panorama", "TMJ", "Single", "3D Oral image" and "3D Dental image".

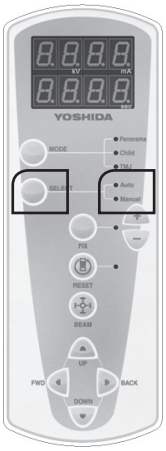
*** For equipment with 3D function and Cephalometric, it switches between "Panoramic", "Child", "Partial Panorama", "TMJ", "Single", "3D Oral image", "3D Dental image" "Cephalometric Posteroanterior image", "Cephalometric Lateral image" and "Carpus image".

*1 Three LED lamps illuminate in Cephalometric and 3D image acquisition modes.

<table>
<tr><th>Exposure Mode</th><th>Function</th><th>To which the mode is switched when Mode switch is pressed</th></tr>
<tr><td>Panoramic</td><td>Acquires panoramic images of the patient's dental arch in exposure time, normally 14 sec.</td><td rowspan="5"> 
</td></tr>
<tr><td>Child Panoramic</td><td>Acquires panoramic images of the child patient's dental arch in exposure time, normally 11.2 sec.</td></tr>
<tr><td>Partial Panorama</td><td>Standard exposure time lasts for 14 seconds. From the selection area divided into five parts, only necessary part of dental panoramic image can be acquired.
NOTE : Desired area for Partial Panorama cannot be selected from the control panel. To select the desired area for image acquisition, go to the Image Acquisition Condition Setting screen from the Image Creator.</td></tr>
<tr><td>TMJ</td><td>Acquires two-or four-view of patient's mandibular joint in exposure time, 4 sec./ stage.</td></tr>
<tr><td>Single</td><td>Acquires an image of the size of the panoramic sensor without moving the arm.
NOTE : This mode is for maintenance purpose only. Do not conduct image acquisition on the patient using this mode.</td></tr>
<tr><td>Cephalometric *</td><td>Acquires “Posteroanterior image (PA)”, “Lateral image (LA)”, and “Carpus image (CarP)”.</td><td> 
</td></tr>
<tr><td rowspan="2">3D **</td><td rowspan="2">Acquires "3D Oral (orAL)" and "3D Dental (dEnt)".</td><td> 
</td></tr>
<tr><td> 
</td></tr>
</table>

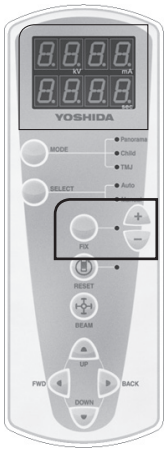
* For equipment with Cephalometric

** For equipment with 3D function



2 Press the Select switch to select “Auto” or “Manual” switches. The LED associated with the selected mode will turn on.

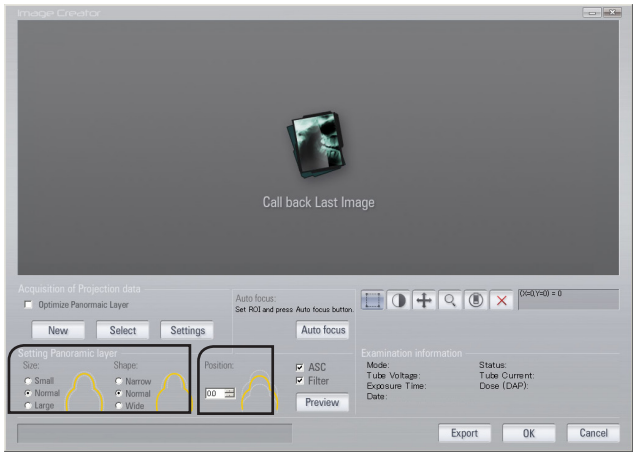
Exposure status	Function	To which mode is switched when Select switch is pressed
AUTO	Specifies automatically the values for Tube voltage and Exposure time appropriate for the patient's dental arch size.	Auto ⇄ Manual
MANUAL	Allows the operator to modify arbitrarily the value for Tube voltage, Tube current, or Exposure time.	



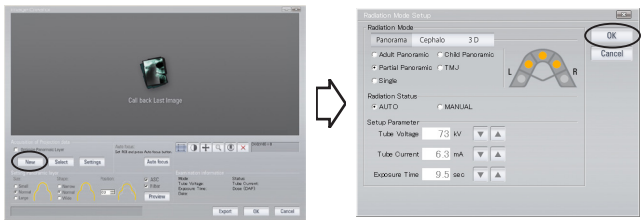
3 In the Manual status, press the Fix switch, select “Tube voltage”, “Tube current”, and “exposure time”, and use the “+” and “-” switches to modify the settings.

To which mode is switched when Fix switch is pressed
Shifting to new setting for tube voltage ⇄ Settings confirmed Shifting to new setting for tube current → Shifting to new setting for exposure time

See also : "Parameter settings table" P.28



4 In the main screen of Image Creator, set up the dental arch size and dental arch shape according to the patient. Set the tomographic position at 0.

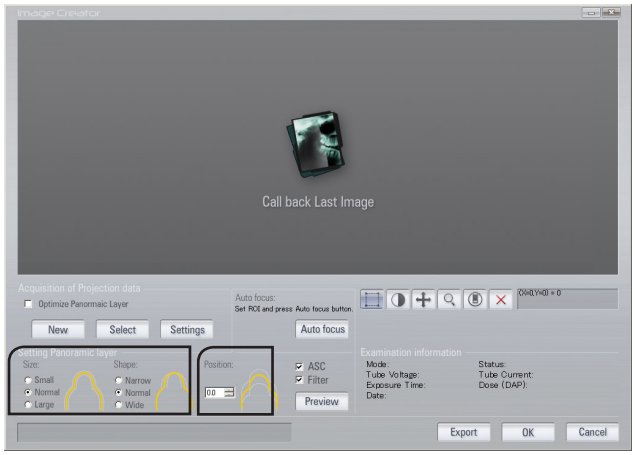


5 Click “New” in the main screen of Image Creator and Image Acquisition Condition Setting screen is displayed.

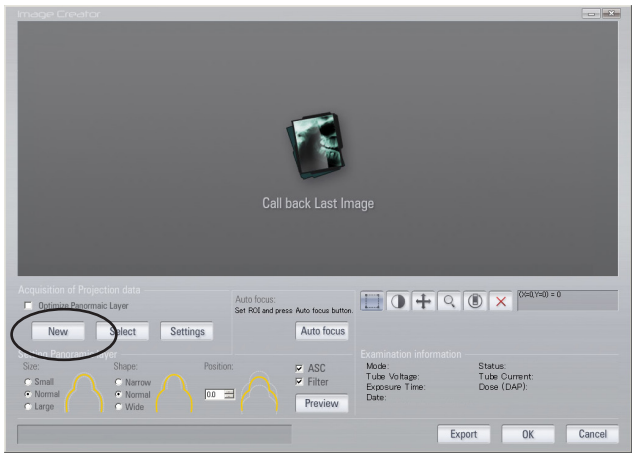
Make sure that the settings in the screen match with the settings made on the Control Panel, and press “OK”.

From the Image Creator :

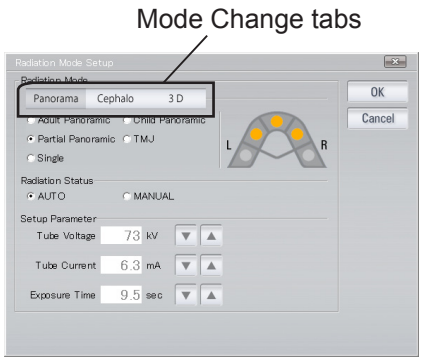
Set up the image acquisition mode using the Image Creator on the computer.



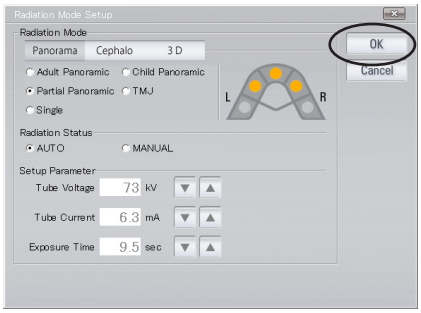
1 In the main screen of Image Creator, set up the dental arch size and dental arch shape according to the patient. Also, set the tomographic position at 0.



2 Click “New” in the main screen of Image Creator, and Image Acquisition Condition Setting screen is displayed.



3 In order to switch between Panoramic Radiation Mode, Cephalometric Radiation Mode and 3D Acquisition Mode, press the Mode Change tab.



4 In the “Image Acquisition Condition Setting” screen, select mode, status and parameters (tube voltage, tube current, Exposure time) of the image acquisition, and press “OK”. The setting information is transferred to the main equipment.

Suppl. : Once having confirmed the modification by clicking on “Set”, you can no longer restore the previous setting (s) even by clicking “Cancel”.

: The value set on either of the control panel and the PC is reflected.

Checking the chin rest block

Check that the chin rest block appropriate for the selected exposure mode has been selected.

Panoramic mode

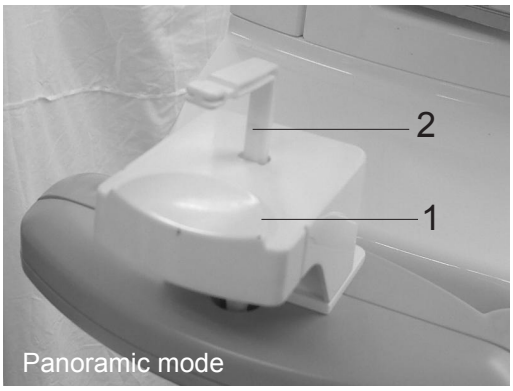
TMJ mode

⚠ Caution

- Use the chin rest block appropriate for the selected exposure mode. Otherwise, no correct image can be obtained.

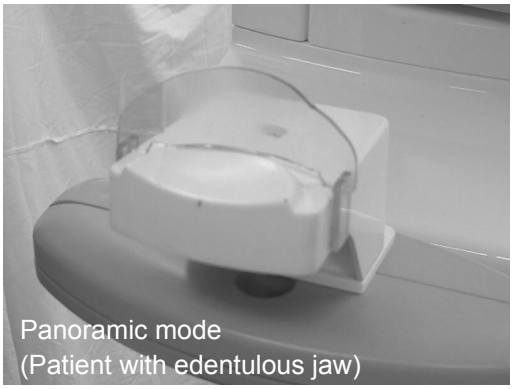
Preparation for using an adaptor

Insert an adaptor appropriate for the selected exposure mode into the chin rest block.



Panoramic mode

1 Insert a bite block (2) into the chin rest block (1).


Panoramic mode
(Patient with edentulous jaw)

2 To acquire the images of the patient with edentulous jaw or with no front teeth, insert the adaptor for edentulous jaw into the chin rest block.


TMJ mode

3 Remove the chin rest and attach the TMJ adaptor to the chin rest block base.

Use the TMJ adaptor (CHILD) for the child patient to acquire the highest quality of images of the temporomandibular joint.

⚠ Caution

- Be sure to use the adaptor appropriate for the Exposure conditions. If not, high quality of images cannot be acquired.
- Use a new bite block for each patient to prevent infectious diseases. Wipe off the bite block with alcohol-dampened cloth.
- Always clean the chin rest block, adaptor for the patient with endentulous jaw, and TMJ adaptor after each patient.

2.3.4 Seating the patient inside the equipment

⚠ Caution

- Be sure to ask the patient to wear an X-ray protective apron and child patients to wear both the X-ray protective apron and a thyroid shield prior to X-ray exposure.
- Ask the patient to remove eye glasses and accessories prior to X-ray exposure, otherwise they may be reflected on the images.
- Ensure that the patient's hair, especially when hair is tied up, does not come in contact with the equipment. It may cause injury of the patient.
- Ask the patient to keep away from the equipment until the arm unit of the equipment has been reset. Otherwise, the patient may be caught by the arm unit and be injured.
- Do not rotate the arm unit manually, the patient may be caught by the arm unit, and be injured or a failure may occur in the equipment.

Adjusting the chin rest height

Before seating the patient inside the equipment, adjust the chin rest close to the patient's height. Press the Up/Down switch on the control panel to move the sliding body up and down.

Panoramic mode

TMJ mode

Panoramic mode (child) : Panoramic mode chin rest block adjusted close to the patient's jaw height

TMJ mode : TMJ adaptor adjusted close to the patient's subnasal point.

⚠ Caution

- Ask the patient to keep away from the equipment until the height of the equipment has been successfully adjusted. If not, the patient may be hit by the equipment, becoming injured.

Seating the patient inside the equipment

(Panoramic)

Spread the head support open by holding the base portion and seat the patient inside the equipment. Instruct the patient to sit straight up, bite on to the block and grip the handles.

⚠ Warning

- Do not apply heavy load or shock on to the equipment, e.g. suspending from the chin rest or handle. Failure to follow this instruction may cause damage to the equipment.

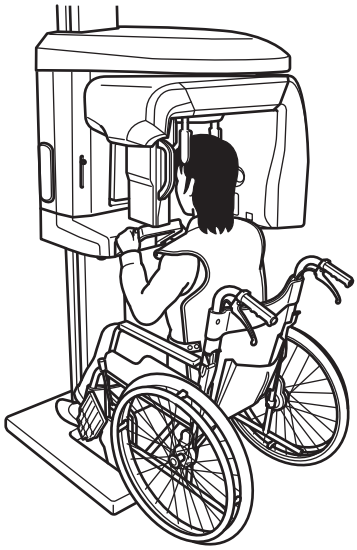
(Panoramic)

If the sensor comes in contact with the patient's shoulder, ask the patient to grip the handles by crossing their arms across their chest.

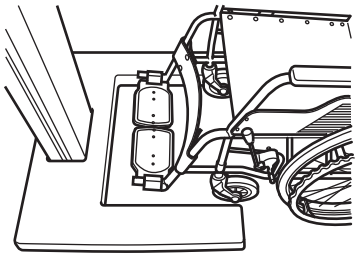
⚠ Caution

- If the proper posture with straighten back is not achieved, the white shadow of the cervical vertebra may hide the front teeth, resulting in invalid images.
- Do not open or close the head support forcedly without gripping its base, otherwise the patient may be injured.
- Be sure to press the correct switches, e.g. the Up or Down switch, for positioning, otherwise, the patient may be injured.

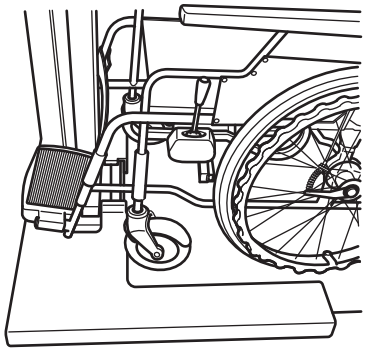
Suppl. : Patient on a wheelchair



Position the patient in a wheelchair all the way to the column so that the patient is able to have their back straight and sit upright.



When an optional normal-sized base is used, position the wheelchair so that the front wheels sit nicely between the base and rear wheels are free from hitting the base.



When an optional wide base is used, fold up the foot rests of the wheelchair if necessary in order to position the wheelchair all the way to the column.

⚠ Caution

- The Image acquisition of the patient on a standard wheel chair is possible. However, the wheelchair with a longer backrest or custom-made wheelchair may interfere with the movement of the equipment. Under such circumstance, ensure before the acquisition that the wheel chair does not interfere with the movement of the equipment.
- Be careful not to hit the patient’s legs against the column while positioning the patient on a wheelchair especially with folded foot rests, all the way to the column.
- With the patient on a wheelchair, the patient's shoulder may come in to contact with the equipment due to the difficulty with keeping the upright posture. To avoid this problem, ask the patitient to straighten his/her spine during positioning and then acquire images.

2.3.5 Patient Positioning in Panoramic mode

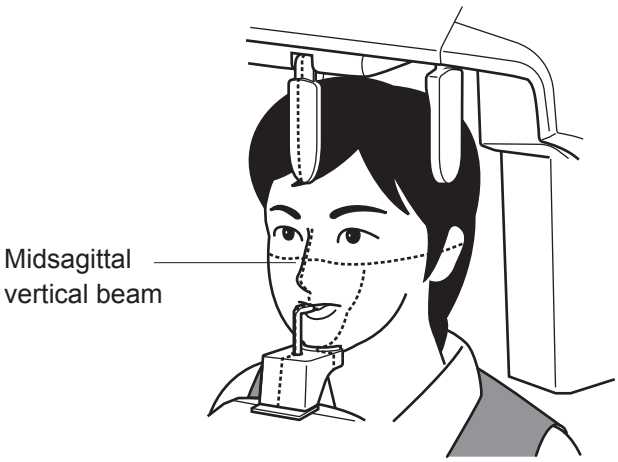
⚠ Warning

- Do not look directly into the positioning beam. The power output (Class 2) is at the level which adverse effect on the eyes can be avoided by blinking. However caution should be taken for maximum safety.

⚠ Caution

- Be sure not to direct the positioning laser beam into patient's eyes. And also, advise patient not to look directly into the beam.
- To minimize patient dose, be sure to position the patient correctly.
- If the rotating arm is deviated from its correct position, e.g. when the patient shoulder hits against it, positioning may not be appropriately performed. To avoid this problem, be sure to return the arm to its reset position and then retry.

Aligning the midsagittal vertical beam



Once the patient has been positioned inside the equipment, press the Positioning beam switch. The rotating arm unit will move to the positioning point and the beam will be emitted. Then, align the midsagittal vertical beam to the patient's midsagittal line. Check in the positioning mirror that the beam is right on the patient's midsagittal line. (The correct line runs through the middle point between the left and right incisors and the nose ridge.)

Suppl. : The positioning beam be automatically turned off in approximately 60 seconds after activation. If the beam has been turned off before positioning is successfully finished, press the Beam switch to activate the positioning beam.

Suppl. : Improper midsagittal vertical beam alignment may affect the images as described below.

1. Inclined patient's face

Problems

- Prominent difference between the tops of left and right temporomandibular joints.
- Distorted image with a difference in size between left and right mandibular angles.

Possible causes

- Inclined patient's face toward either of the left and right sides.

Corrective measure

- Align the reference median line (vertical line) to the patient's midsagittal line.

2. One half of the patient' face enlarged and the other reduced

Problems

- One half of the patient's face is enlarged and the other reduced.
- A difference in size between the tops of left and right temporomandibular joints.

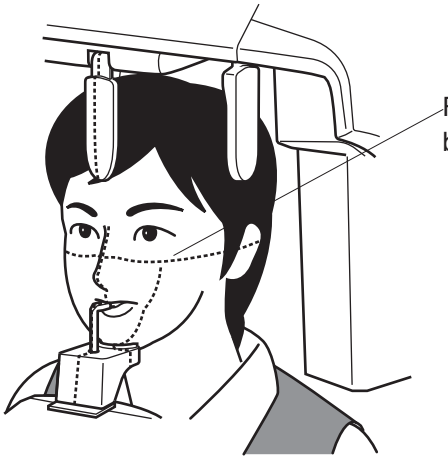
Possible causes

- The patient does not face front, tilting toward either of the left and right sides.
- Inclined patient's face toward either of the left and right sides.

Corrective measure

- Align the reference median line (vertical line) to the patient's midsagittal line.

Aligning the Frankfurt horizontal beam



Move the sliding mechanism up or down so that the Frankfurt horizontal beam may be positioned parallel to the patient's Frankfurt plane.

⚠ Warning

- Do not apply heavy load or shock on to the equipment, e.g. suspending from the chin rest or handle. Failure to follow this instruction may cause damage to the equipment.

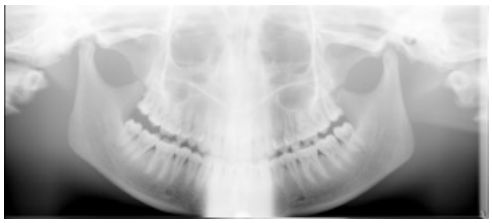
⚠ Caution

- Be sure to press the correct switches, e.g. the Up or Down switch, for positioning, otherwise, the patient may be injured.

Suppl. : The positioning beam automatically turns off in 60 seconds from the activation. If the positioning beam has turned off before positioning has been successfully finished, press the Beam switch to activate the beam.

: Improper lateral positioning may affect the images as described below.

1. The patient's face inclined downward



Problems

- Blurred root apexes of mandibular teeth.
- Patient's hyoid bone overlapped on the mandibular front teeth.

Possible causes

- The patient's face inclined downward.
- The patient's forehead inclined anteriorly.

Corrective measure

- Align the reference facial plane to the horizontal reference line (horizontal line).

2. The patient's face inclined upward

Problems

- Blurred maxillary front teeth.
- Patient's hard palate overlapped on the root apexes on the maxillary tooth row.

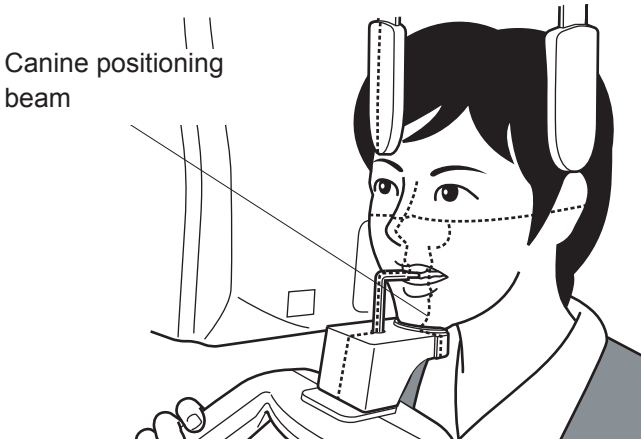
Possible causes

- The patient's face inclined upward.
- The patient's mandible inclined anteriorly.

Corrective measure

- Align the reference facial plane to the horizontal reference line (horizontal line)

Aligning canine positioning beam



Move the arm unit forward or backward using the Forward or Backward switch on the control panel to align the tomographic canine positioning beam to the root apexes of the anterior teeth the center of the mandibular third tooth.

At the end of positioning, check that all the beams are right on their correct points.

* The positioning switch, once pressed, turns on with its associated beam activated for 60 seconds.
When the positioning beam turns off, press the Positioning switch to activate.

Suppl. : To align the beam to the middle point of the mandibular third tooth, ask the patient to: Pronounce “E”. Open the mouth so that the canine teeth are exposed.

⚠ Caution

- Be sure to press the correct switches, e.g. the Up or Down switch, for positioning, otherwise, the patient may be injured.

Suppl. : The positioning beam automatically turns off in 60 seconds from the activation. If the beam has turned off before positioning is successfully finished, press the Beam switch to activate the beam.

Suppl. : Improper beam positioning on the mandibular third tooth may have the following complications;

1. The patient's face inclined downward

Problems
- Blurred root apexes of mandibular front teeth.
- Patient's hyoid bone overlapped on the mandibular front teeth.

Possible causes
- The patient's face inclined downward.
- The patient's forehead inclined anteriorly.

Corrective measure
- Align the reference facial plane to the horizontal reference line (horizontal line).

2. The patient's face inclined upward

Problems
- Blurred maxillary front teeth.
- Patient's hard palate overlapped on the root apexes on the maxillary tooth row.

Possible causes
- The patient's face inclined upward.
- The patient's mandible inclined anteriorly.

Corrective measure
- Align the reference facial plane to the horizontal reference line (horizontal line)

Adjusting the head support

Slide the head support toward the patient’s forehead by gripping its base to stabilize as well as immobilize the patient's head.

⚠ Caution

- Do not open or close the head support forcedly without gripping its base. Otherwise, the patient may be injured.

Adjusting the head support

Slide the head support in contact with the patient's head while gripping its base and then close it. With the Auto setting, the tube voltage appropriate for the patient will be automatically set.
At the end of adjustment, try to turn on the positioning beams to check that they focus on their correct positions.

⚠ Caution

- Do not open or close the head forcedly without gripping its base. Otherwise, the patient may be injured.

Turning off the positioning beams

Press the Beam switch to turn off the positioning beam. Return the positioning mirror to its original position.

⚠ Caution

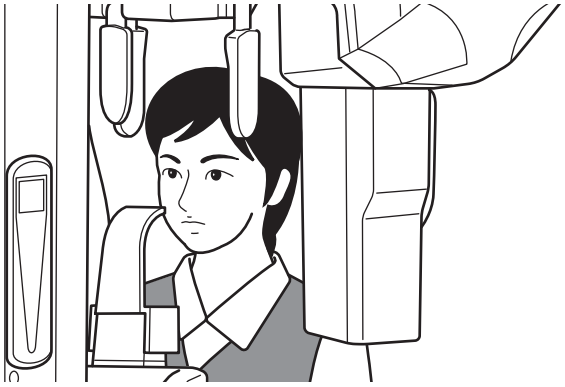
- Once positioning has been successfully finished, be sure to return the positioning mirror to its original position.

2.3.6 Patient Positioning in TMJ mode

⚠ Caution

- If the rotating arm unit deviates from its correct position, e.g. when it hits against the patient's shoulder, positioning may not be correctly performed. To avoid this problem, be sure to return the arm unit to its reset position and then retry.

Adjusting the chin rest height



Set the chin rest at the height of the patient's jaw. Position the patient inside the equipment and moves the sliding mechanism up or down on the control panel so that the TMJ adaptor is positioned at the patient subnasal point with the back straighten up. Then, press the Beam switch to activate the positioning beam.

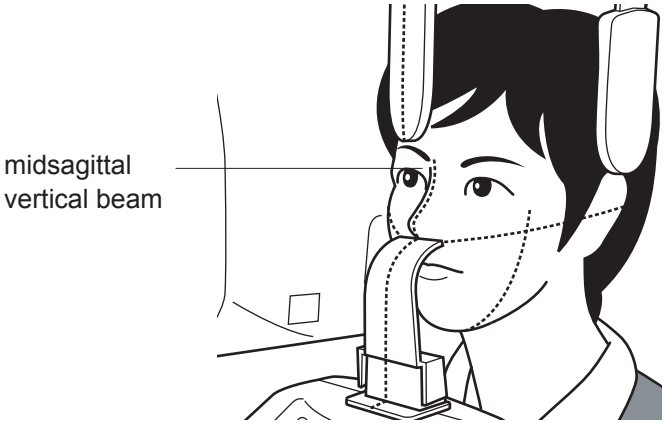
⚠ Warning

- Do not apply heavy load or shock on to the equipment, e.g. suspending from the chin rest or handle. Failure to follow this instruction may cause damage to the equipment.

⚠ Caution

- Be sure to press the correct switches, e.g. the Up or Down switch, for positioning, otherwise, the patient may be injured.

Aligning the midsagittal vertical beam



After Position the patient inside the equipment, press the Beam switch. The rotating arm unit moves to the positioning point and the positioning beam activates.
Next, align the midsagittal vertical beam to the patient's midsagittal line. Monitor the patient in the positioning mirror to check that the beam is right on the patient's center line. (The correct line runs through the middle between the left and right incisors and the nose ridge.)

⚠ Caution

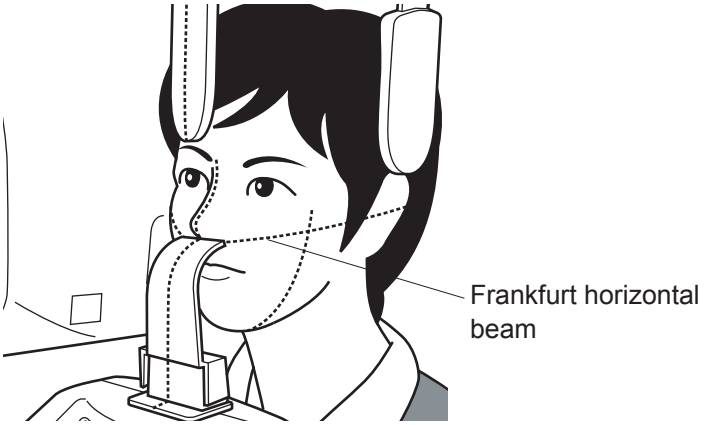
- Ask the patient not to look directly into the positioning laser beams.

⚠ Warning

- Do not look directly into the positioning beam. The power output (Class 2) is at the level which adverse effect on the eyes can be avoided by blinking. However caution should be taken for maximum safety.

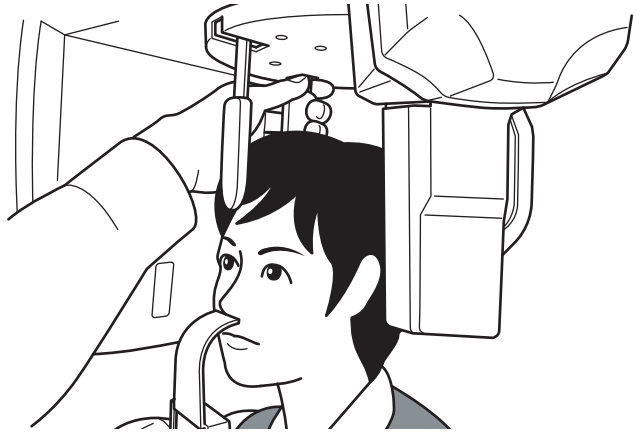
Suppl. : The positioning beam turns off in approximately 60 seconds automatically after activation. If the beam has turned off before positioning is successfully finished, press the Beam switch to activate the beam.

Aligning Frankfurt horizontal beam



Align the horizontal line of the head support parallel to the camper plane on patient's head. Moves the sliding mechanism up or down to adjust the chin rest height so that the TMJ adaptor may be positioned at the subnasal point. Then, make a fine-adjustment to align the Frankfurt horizontal beam to the camper plane on the patient's head.

Adjusting the head support

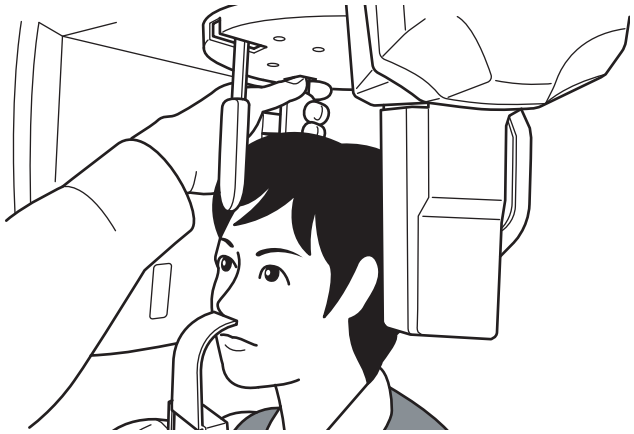


Slide the head support toward the patient's forehead, by gripping its base, to stabilized as well as immobilize the patient's head.

⚠ Caution

- Do not open or close the head support forcedly without gripping its base. Otherwise, the patient may be injured.

Adjusting the forehead support



Slide the forehead support in contact with the patient's head by gripping its base and then close it. With the Auto setting, the tube voltage appropriate for the patient is automatically set.
At the end of adjustment, turn on the positioning beam again to confirm that the beam is right on the proper point.

⚠ Caution

- Do not open or close the head support forcedly without gripping its base. Otherwise, the patient may be injured.

Turning off positioning beam

Press the Beam switch to turn off the positioning beam. Return the positioning mirror to its original position.

⚠ Caution

- Once positioning has been successfully finished, be sure to return the positioning mirror to its original position.

⚠ Caution

- After the positioning is completed, be sure to return the positioning mirror to its original position.

2.3.7 X-ray Exposure

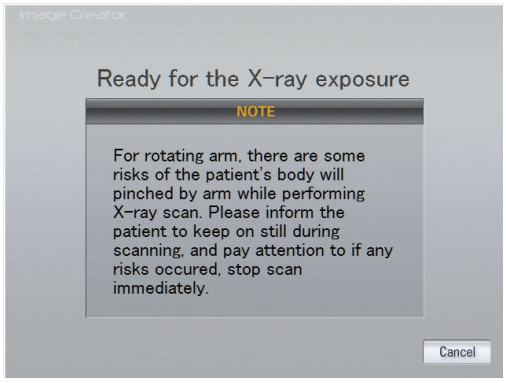
⚠ Warning

- Ask the patient not to move during image acquisition, otherwise the patient may be caught by the rotating arm. Monitor the patient throughout image acquisition and in case of an emergency, immediately stop the equipment.

⚠ Caution

- Only trained and qualified person should take radiographic photos. The use of this equipment by unqualified person is prohibited by law.
- To minimize patient dose, be sure to position the patient correctly.
- In some cases, image of the anterior teeth may be unclear due to the cervical adjustment levels (User Program Mode: Prog No. 05). Check the cervical adjustment level before image acquisition.

Starting X-ray Exposure



1 After the operations described in "From the control panel:", make sure that Image Creator is under Acquisition standby status.

2 Make sure that the Ready LED (green) is turned on and the equipment is ready for image acquisition.Press the X-ray exposure switch to begin the X-ray radiography. By holding the X-ray exposure switch down, X-ray is irradiated according to the acquisition time specified. While X-ray is being irradiated, the X-ray LED (yellow) on the hand-switch box is lit and buzzer on the Control Panel goes off continuously.

The equipment employs a dead man's switch *. If the finger is removed from the X-ray exposure switch, the X-ray exposure and image acquisition operation stop.

* Dead man's switch: A system which operates only when the operator applies force to the equipment.

⚠ Caution

- If the X-ray exposure switch is released during an exposure, X-ray exposure and image acquisition will be stopped and an exposure error will occur, requiring a retake and consequently increases the patient dose. Unless it is necessary to stop for emergency, do not release the X-ray exposure switch.
- Leave the controlled area during X-ray exposure.

Exposure in TMJ mode

⚠ Caution

- To minimize patient dose, be sure to position the patient correctly.

● Radiography at mouth closed position

Ask the patient to close their mouth. Check that the patient has closed their mouth and then press and hold down the X-ray Exposure switch until image acquisition is successfully finished. To scan images of left and right temporomandibular joints, total of 8-second X-ray exposure is executed on both joints, 4 seconds each. After X-ray exposure, release your finger from the X-ray Exposure switch.

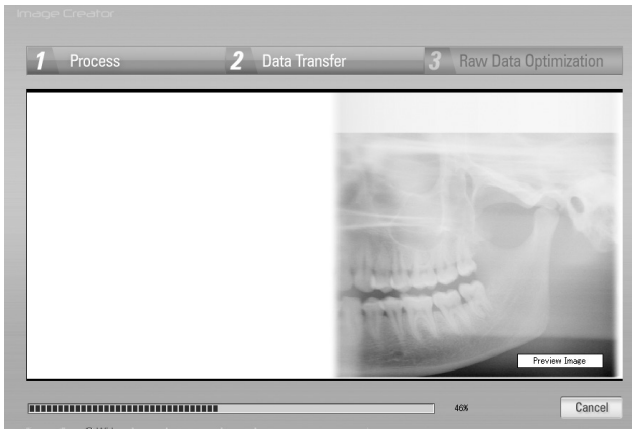
● Radiography at mouth opened position

Ask the patient to open the mouth with the TMJ adaptor attached to the subnasal point.
Check that the patient has opened the mouth and then press and hold down the X-ray Exposure switch until image acquisition is successfully finished.
To scan images of left and right temporomandibular joints, total of 8-second X-ray exposure is executed on both joints, 4 seconds each. After X-ray exposure, release your finger from the X-ray Exposure switch.

⚠ Caution

- During data acquisition in the TMJ mode, X-ray Exposure stops with X-ray Exposure LED off and an audible alarm silenced in any other area than temporomandibular joints. Note that the X-ray Exposure switch must be pressed and held down until the arm unit stops.
- If the X-ray exposure switch is released during an exposure, X-ray exposure and image acquisition will be stopped and become an exposure error, requiring the retake and consequently increases the patient dose. Unless it is necessary to stop for emergency, do not release the X-ray exposure switch.
- Leave the controlled area during X-ray exposure.

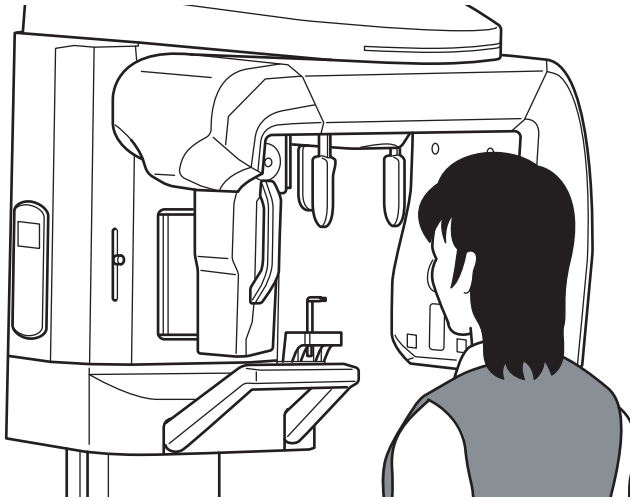
Image Acquisition Preview



*Panoramic mode

Once an X-ray image acquisition commences, Image Creator display will change from "standby" screen to the "acquisition" screen. In the acquisition screen, image construction is displayed simultaneously with the acquisition progress.

2.3.8 Patient's Exit

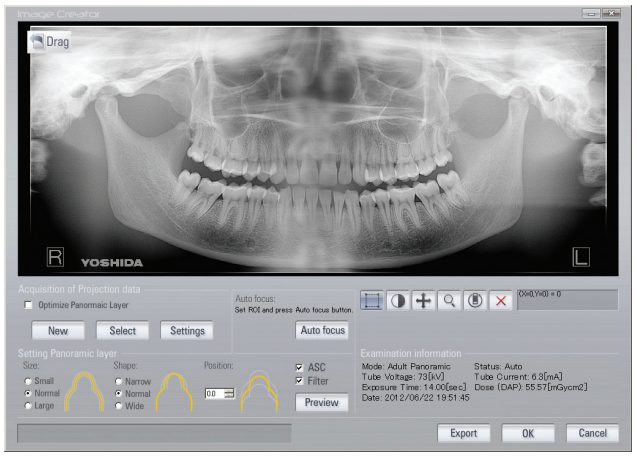


Open the head support. Ask the patient to move backward carefully.

⚠ Caution

- When the patient makes his/her exit, make sure to escort and lead the way. Since the patient needs to move backward when removing him/herself from the equipment, the patient might trip over or cause similar accidents.

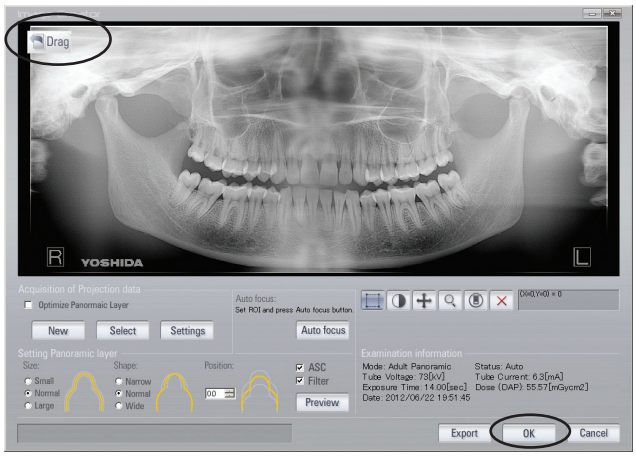
2.3.9 Image Transfer



*Panoramic mode

1 When X-ray exposure is initiated, the equipment starts transferring the image data to the computer (Image Creator). Once the transfer is complete, Image Creator starts formulating and displaying the image. When Optimize Panoramic Layer is checked, the software automatically adjusts the Panorama tomographic position and constructs Panoramic images after the image acquisition is completed.

Note : Optimize Panoramic Layer function may fail in Panorama tomographic position adjustment depending on the patient. After the panoramic image is displayed, set "Position" to 0, the "Preview" button to display the panoramic image again.



*Panoramic mode

2 Click "OK" to transfer the image using the TWAIN function. To transfer the image using the "Drag & Drop" function, drag the "Drag" button from the upper left on the screen and drop it on the display window of the Viewer.

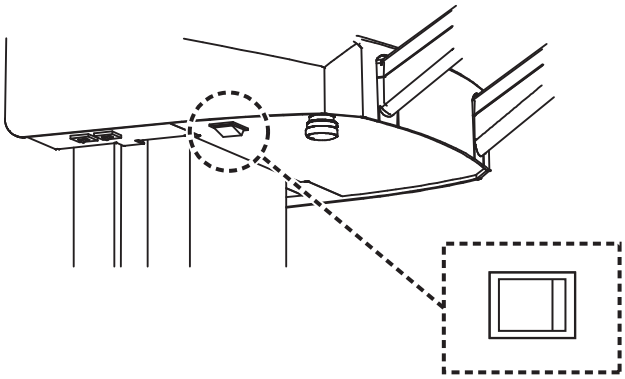
NOTE : Since a panoramic image has been converted into a two-dimensional image, some errors may be observed when a measurement is taken on the acquired image.

See also : For detailed operations of the viewer, refer to the operation manual of the viewer in use.

⚠ Caution

- Malfunctions or erroneous operations, such as unintended formatting of the hard disk drive, might render important data or programs inoperative. Use a backup program to copy the contents of the hard disk drive into an auxiliary storage device. Please note that we are not liable for the loss of data because of a malfunction or erroneous operation.

2.3.10 Turning Off the Equipment



Turn the power switch off (O) and make sure the power indicator (green) is unlit.

2.4 Procedures of Cephalometric and Carpus Radiography

2.4.1 Turning the power switch on

See also : "2.3.1 Turning the power switch on"

2.4.2 Flow of Image Acquisition

See also : "2.3.2 Flow of Image Acquisition"

2.4.3 Setting the Exposure Mode

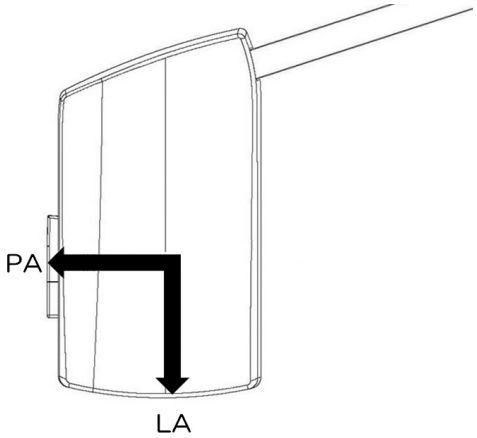
Setting the Exposure mode using the control panel

See also :"From the control panel:" in "2.3.3 Setting the Exposure mode".

Setting the Exposure mode using Image Creator

See also : "From the Image Creator :" in "2.3.3 Setting the Exposure mode"

Setting of the Cephalometric Unit



Turn the ear rod and nose support of the Cephalometric Unit to the appropriate position according to the desired image acquisition mode, namely “Posteroanterior Image (PA)” or “Lateral Image (LA)”. (The arrow indicates the direction of which the patient should face.)

* When performing a carpus image acquisition, the PA (posteroanterior) positions are used.

⚠ Caution

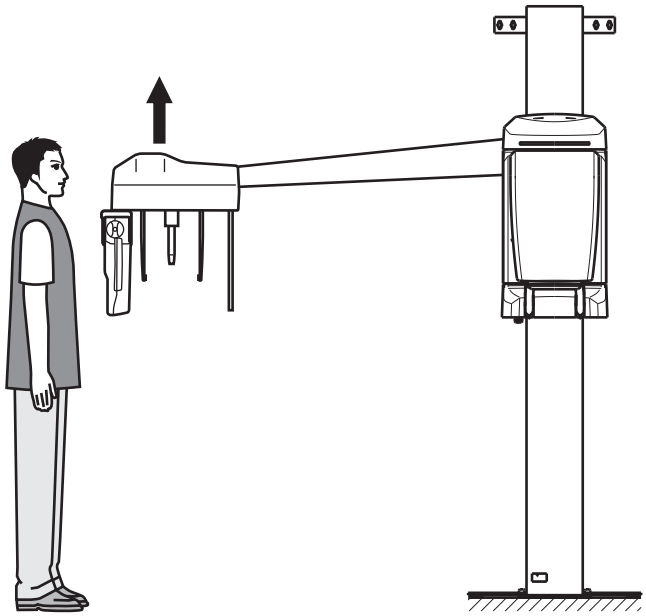
- Before initiating the image acquisition, make sure that the sensor unit (detachable) is firmly attached and locked to the docking station unit (Cephalometric).
- The detachable sensor unit is equipped with a shock sensor. The shock sensor records any excessive impact incurred, such as when the equipment falls down, and the equipment will not qualify as being warrantable. Exercise caution in handling the equipment.
- When attaching or detaching the detachable sensor unit, exercise caution not to drop the unit. If dropped, the detachable sensor unit might be damaged and may lead to a failure of the image acquisition.
- Clean the ear rod and nose support after each patient.
- Before positioning the patient, make sure that the image acquisition mode and the rotation points of the ear rod and nose support match with each other.
- Beware not to have your finger or other objects caught when rotating, opening, closing, or moving back and forth the ear rod or nose support on the Cephalometric unit.

2.4.4 Patient's entry and Positioning

⚠ Caution

- Be sure to ask the patient to wear an X-ray protective apron and the child patient to wear both the X-ray protective apron and a thyroid shield prior to X-ray exposure.
- Ask the patient to remove eye glasses and accessories prior to X-ray exposure, otherwise they may be reflected on the images.
- Ensure that the patient's hair, especially when hair is tied up, does not come in contact with the equipment. It may cause injury of the patient.
- Ask the patient to keep away from the equipment until the arm unit of the equipment has been reset. Otherwise, the patient may be caught by the arm unit, and be injured.
- Do not rotate the arm unit manually, the patient may be caught by the arm unit, and be injured or a failure may occur in the equipment.

Preparation for the Patient's entry and Positioning



Press the Reset Switch on the Control Panel. The arm unit and sensor unit automatically move to the Cephalometric image acquisition position, and the slits in the head unit automatically switch.

Before inviting the patient in, move the ear rod to an approximate position of his/her height. Press the Up/Down switch on the Control Panel to move the equipment upward or downward.

⚠ Caution

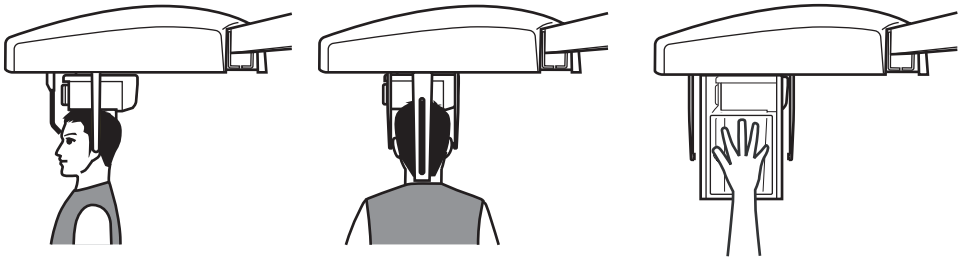
- Ask the patient to keep off the equipment until the height of the equipment has been successfully adjusted. Otherwise, the patient may be hit by the equipment, being injured.
- If an object is placed within the field of the arm unit’s movement or underneath the Cephalometric unit, it might cause damage to the object or malfunction to the equipment.
- If the patient contacts with the ear rod at the time of entry and exit from the equipment, the patient might get injured or the ear rod might be dislocated. Guide the patient in such a way that he/she would come into contact with the ear rod.
- Beware not to touch the equipment while the movable 3D sensor is in motion. The finger or hand might get caught and injured.
- If the reset switch is turned on with the head fixator for 3D image acquisition attached, Cephalometric image acquisition position does not move. Warning message (FL05) is displayed on the control panel. Remove the head fixator before the reset operation.

Seating and Positioning the Patient

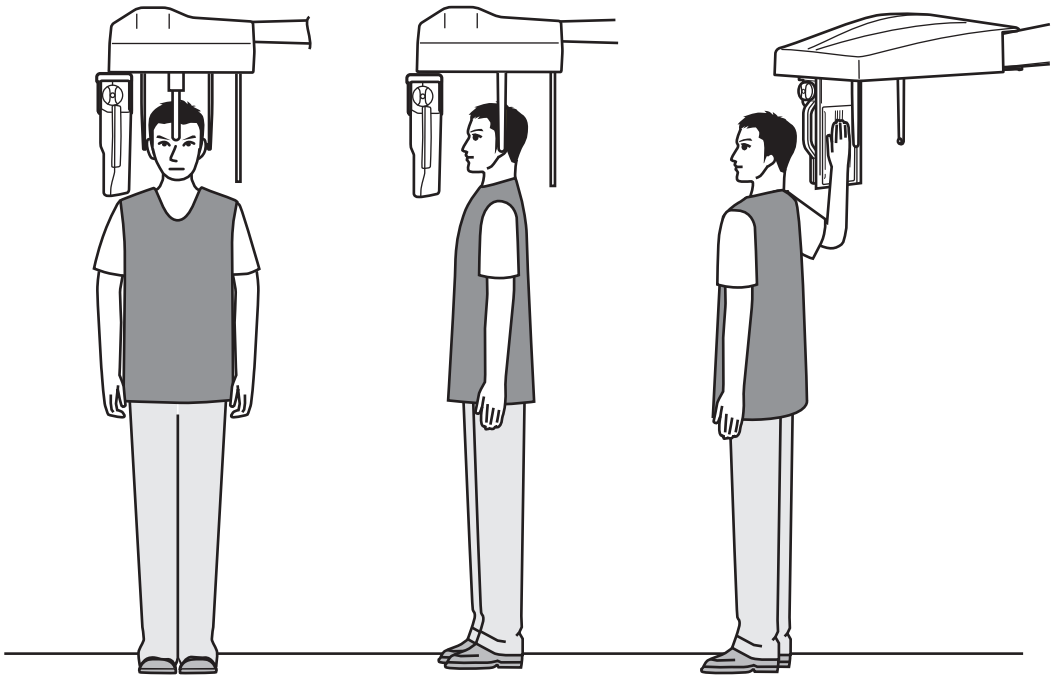
After seating the patient, move the ear rods upward or downward to match the heights of patient's porus acusticus. Insert the ear rod into the porus acusticus on one side and close the ear rod. Then gently insert the ear rod on the other side. When inserting the ear rod, make sure that the patient's Frankfurt plane is positioned horizontally.

When acquiring a lateral (LA) image, adjust the height of the nose support at the center between the patient's eyebrows, and gently place it to fix. (Remove the nose support when acquiring an posteroanterior (PA) image or a carpus image.) Instruct the patient to close his/her mouth with some appropriate tension.

Slide the ear rods by gripping their upper portion (closer to the head) to widen or narrow. For carpus image, widen the ear rods to the maximum.



LA PA Carpus



LA PA Carpus

When acquiring a carpus image, instruct the patient to stand next to the equipment and place the wide-spread palm on the carpus support, stand the patient at the side of the equipment. Instruct the patient to open his/her hands completely and place them in front of the carpus

support.

⚠ Caution

- In order to minimize the patient dose, make sure that the image acquisition is done with a correct positioning.
- Slide the ear rods by gripping their upper portion (closer to the head) to widen or narrow. The patient might get injured if excessive force is applied to move the ear rods.
- Be cautious not to hit the patient's face or other body parts when moving the nose support up/down or forward/backward.
- Be sure to press the correct switches, e.g. the Up or Down switch, for positioning, otherwise, the patient may be injured.
- Do not move the equipment up/down or forward/backward while the ear rods are in the patient's porus acusticus. The patient might get injured.

2.4.5 X-Ray Exposure

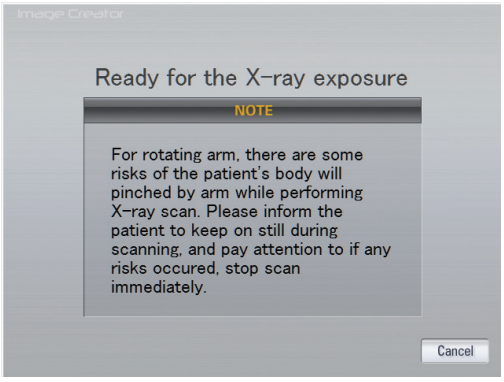
⚠ Warning

- If the patient moves during the image acquisition, the patient's body might get caught between the sensor and the second slit. Ask the patient to refrain from moving. Look out for patient's safety at all times. In case any dangerous situation occurs, immediately stop the operation.

⚠ Caution

- Be sure to press the correct switches, e.g. the Up or Down switch, for positioning, otherwise the patient may be injured.
- To minimize patient dose, be sure to position the patient correctly.

Initiating X-Ray Exposure



1 After the operation described in "2.4.3 Setting the Exposure Mode", make sure that Image Creator is displaying the "Image Acquisition Standby" Screen.

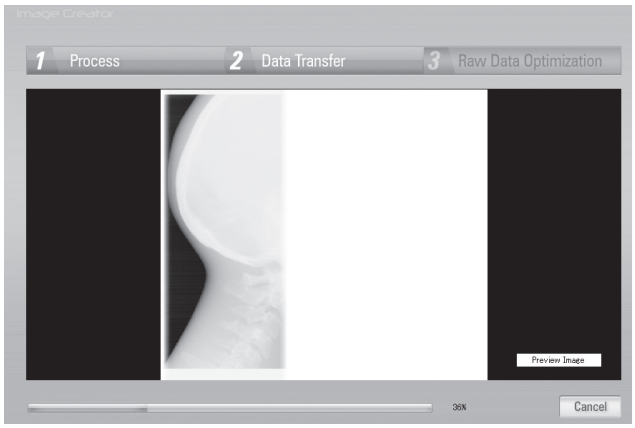
2 Make sure that the Ready LED (green) is turned on and the equipment is ready for image acquisition.Press the X-ray exposure switch to begin X-ray radiography. By holding the X-ray exposure switch down, X-ray is irradiated according to the acquisition time specified. While X-ray is being irradiated, the X-ray LED (yellow) on the hand-switch box is lit and a buzzer sounds continuously. It also sounds from the Control Panel.

The equipment employs a Dead Man's switch *. If the finger is removed from the X-ray exposure switch, the X-ray exposure and image acquisition operation stop.

* Dead man's switch: A system which operates only when the operator applies force to the equipment.

⚠ Caution

- If the X-ray exposure switch is released during an exposure, X-ray exposure and image acquisition will be stopped and become an exposure error, requiring the retake and consequently increases the patient dose. Unless it is necessary to stop for emergency, do not release the X-ray exposure switch.
- Beware not to touch the equipment while the docking station unit (Cephalometric) or sensor unit is in motion. The finger or hand might get caught and injured.
- If the X-ray Exposure switch is pressed while the head fixator for 3D image acquisition is attached, X-ray exposure the image acquisition operation will not be performed. Warning message (FL05) is displayed on the control panel. Remove the head fixator before X-ray exposure and image acquisition.
- Leave the controlled area after X-ray exposure.



Once an X-ray acquisition commences, the display will change from "standby" screen to the "acquisition" screen. In the acquisition screen, image construction is displayed simultaneously with the acquisition progress.

NOTE : To make it easier to handle by cephalo analysis tools and other features, when cephalo LA image is acquired, it is set as factory default setting to display the image with head facing its right. (For Image Creator Version 2.06 and above)

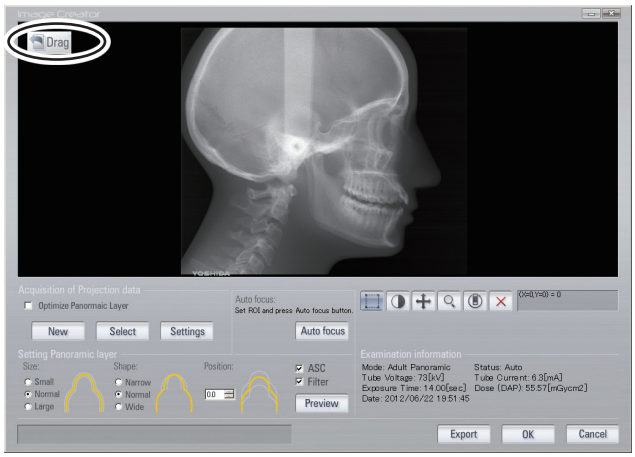
2.4.6 Patient's Exit

Open the ear rods and instruct the patient to move away from the equipment.

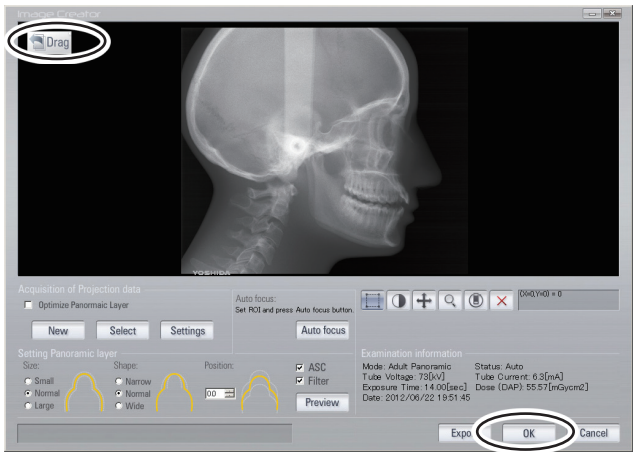
⚠ Caution

- When the patient makes his/her exit, make sure to escort and lead the way. Since the patient needs to move backward when removing him/herself from the equipment, the patient might trip over or cause similar accidents.

2.4.7 Image Transfer



1 When X-ray irradiation is initiated, the equipment starts transferring the image data to the computer (Image Creator). Once the transfer is complete, Image Creator starts formulating and displaying the cephalometric image.



2 Click "OK" to transfer the image using the TWAIN function. To transfer the image using the "Drag & Drop" function, drag the "Drag" button from the upper left on the screen and drop it on the display window of the Viewer.

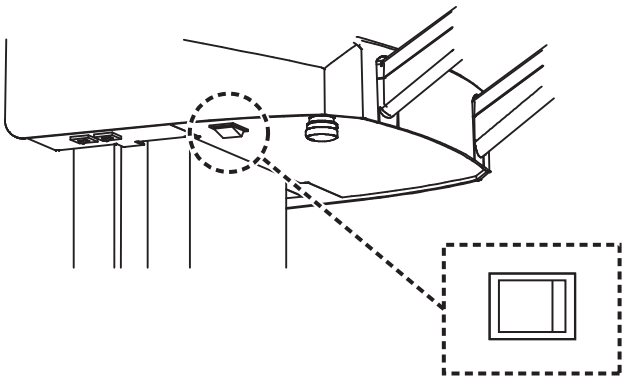
NOTE : Since a Cephalometric image has been converted into a two-dimensional image, some errors may be observed when a measurement is taken on the acquired image.

See also :For detailed operations of the viewer, refer to the operation manual of the Viewer in use.

⚠ Caution

- Malfunctions or erroneous operations such as unintended formatting on the hard disk drive might render important data or programs inoperative. Use a backup program etc. to copy the contents of the hard disk drive into an auxiliary storage device. Please note that we are not liable for the loss of data because of a malfunction or erroneous operation.

2.4.8 Turning Off the Equipment



Turn the power switch off (O) and make sure the power indicator (green) is unlit.

2.5 Procedure of 3D Radiography

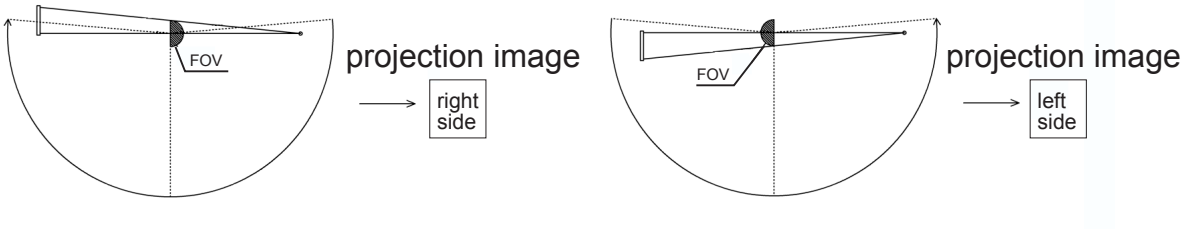
2.5.1 About 3D image acquisition

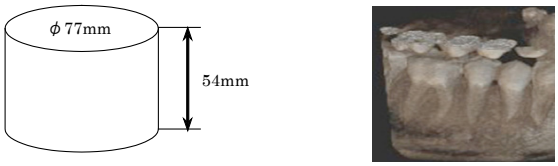
(a) 3D Acquisition mode

3D Acquisition mode has "3D Oral Image" and "3D Dental Image".

1. 3D Oral image

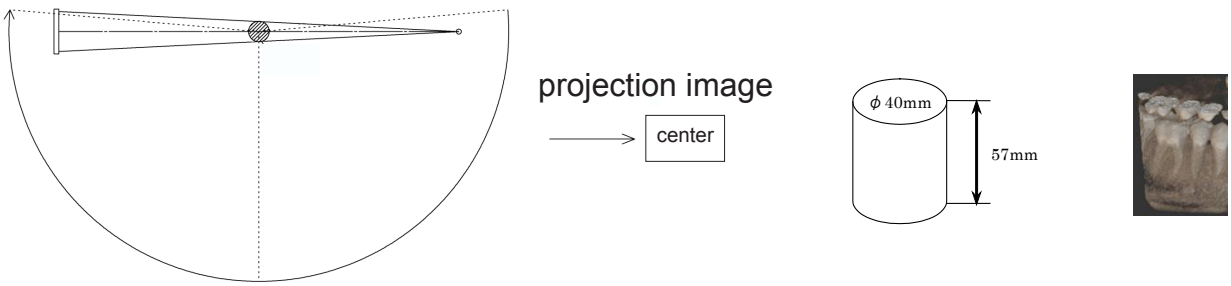
Move the 3D sensor position to the right. Images acquired from clockwise image acquisition (irradiation time 11.5 seconds) and counter-clockwise image acquisition (irradiation time 11.5 seconds) are combined and reconfigured to acquire a large FOV 3D image.
(FOV: Diameter 77mm, height 54mm)





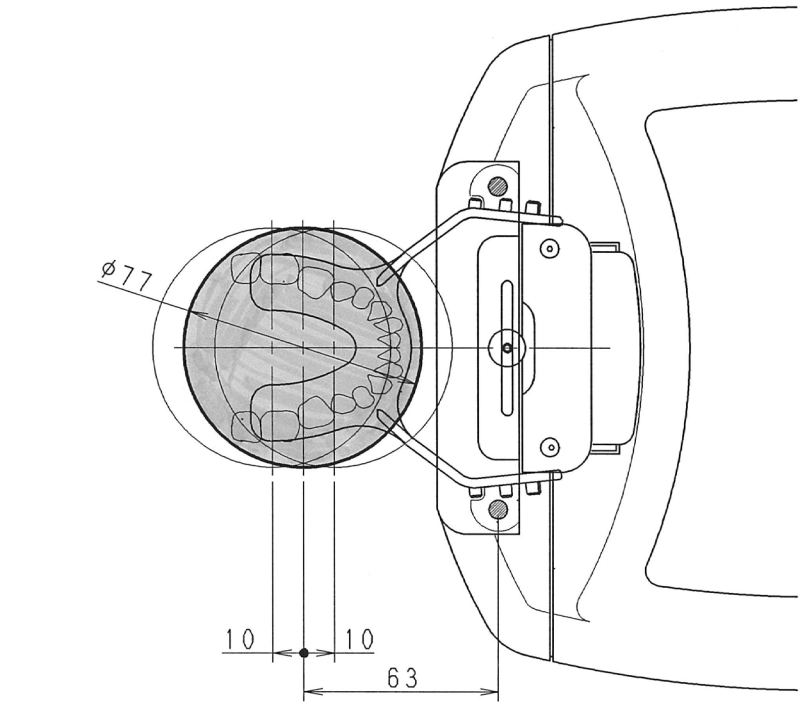
2. 3D Dental image

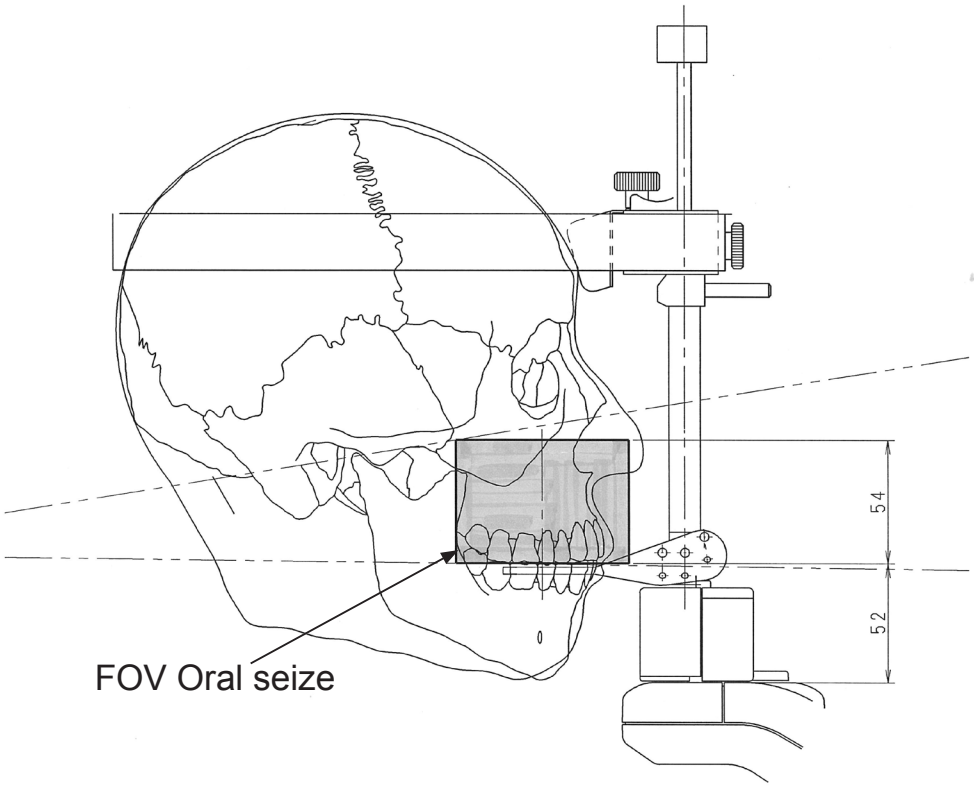
Move the 3D sensor position to the center. Reconfigure the acquired image from the clockwise image acquisition (irradiation time 11.5 seconds). 3D image can be acquired.
(FOV: Diameter 40mm, height 57mm)



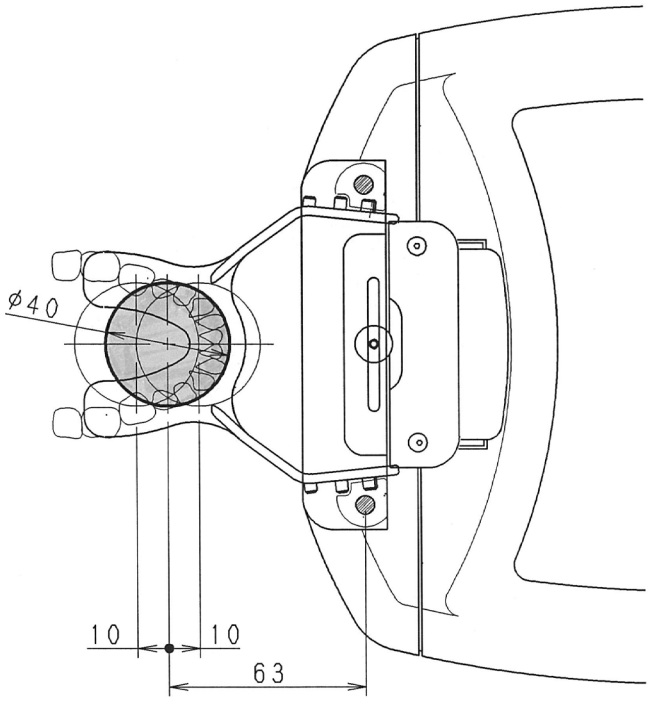
(b) FOV position

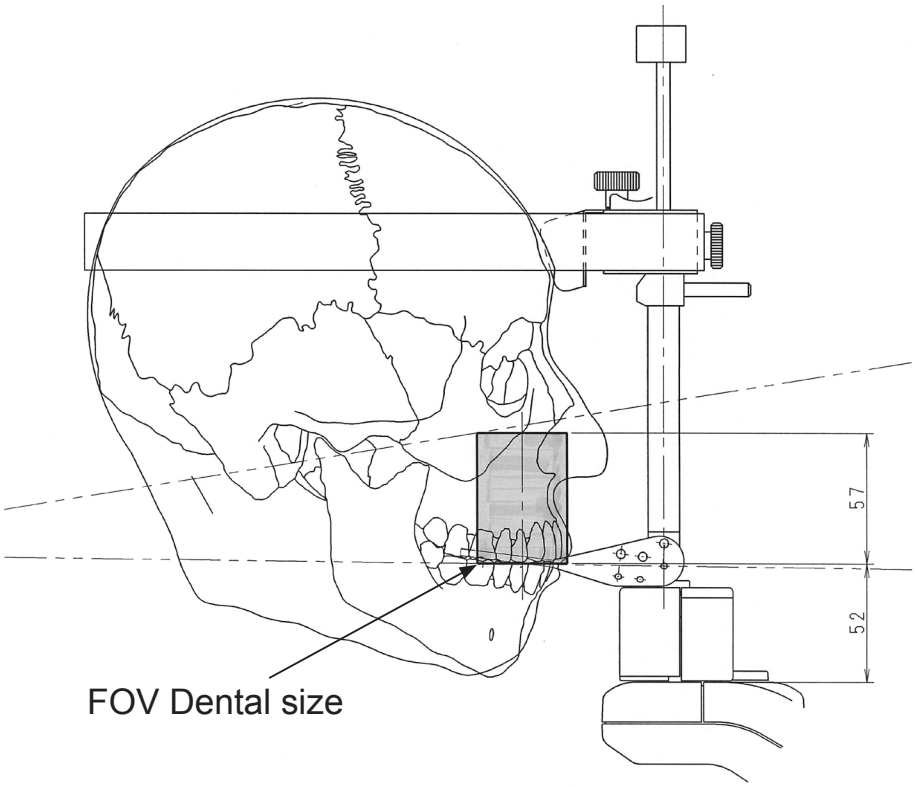
1. FOV of 3D Oral image





2. FOV of 3D Dental image





2.5.2 Turning the power switch on

See also : "2.3.1 Turning the power switch on" P.54

2.5.3 Openingng the image formulating window of Image Creator

See also : "4 Directions for Use of Image Creator" P.110

2.5.4 Setting the Exposure Mode

Setting the Exposure mode using the control panel

See also : "From the control panel:" P.56

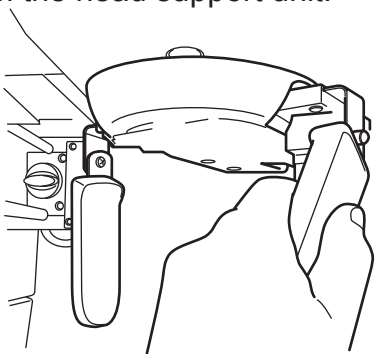
Setting the Exposure mode using the image formulating window of Image Creator

See also : "From the Image Creator :" P.59

2.5.5 Seating and positioning the patient

2.5.5.1 Removing the head support

Removing the forehead support and Lateral head support from the head support unit.



How to remove and attach the head support

1. How to remove

Rotate the forehead support and the Lateral head support to the removing position. Refer to the figure for the rotation direction.

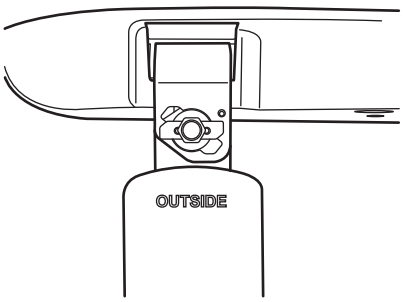
Forehead support: Rotate to the right and pull to the inner side.

- Right Lateral head support: Rotate to the front and pull to the inner side.
- Left Lateral head support: Rotate to the back and pull to the inner side.

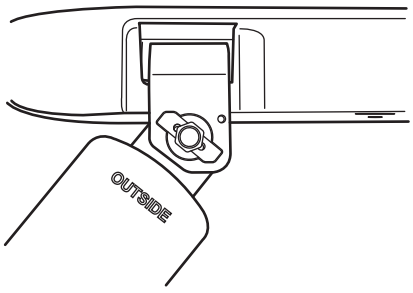
2. How to attach

To attach, simply reverse the removal procedure.

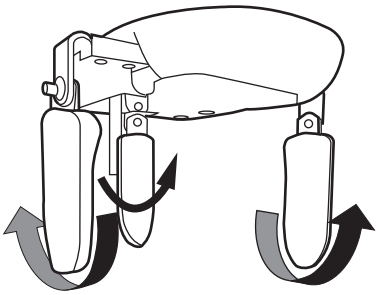
Tilt forehead support and lateral head support toward the removing position. Insert them into the holes from inside and rotate them to the fixing position.



fixed positioning



removing position



removing direction

2.5.5.2 Move to 3D image starting position

Press the reset switch from the control panel. Arm unit and movable sensor move to 3D image position automatically. The movable sensor moves to the selected 3D image mode position automatically.

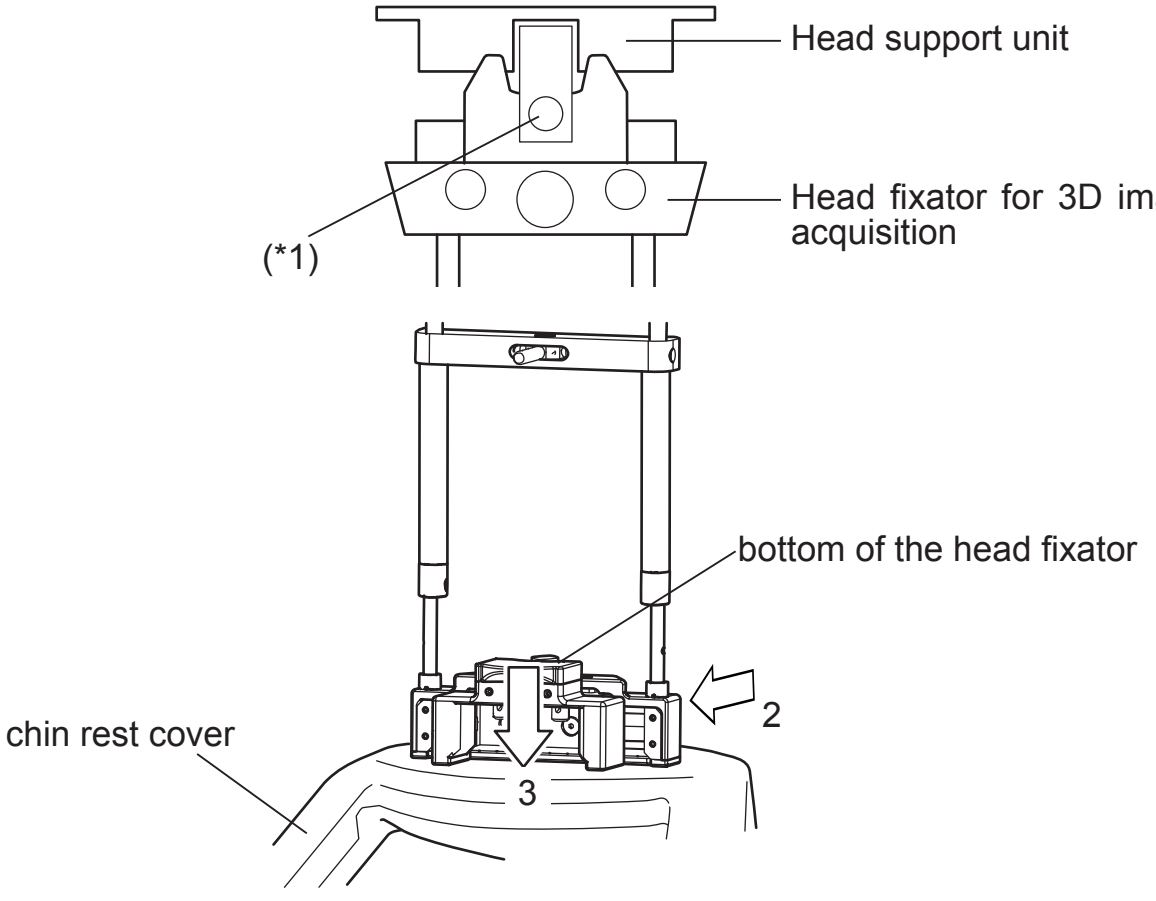
> **⚠ Caution**
> • Remove the head support before pressing the reset switch from the control panel. Pressing the reset switch with the head support attached may cause damage to the equipment or injury to the patient.

2.5.5.3 Attaching the head fixator for 3D image acquisition

1 Move the forehead support detachable mechanism of the head support unit forward. Hold the head fixatorfor for 3D image acquisition with both hands. Insert (*1) part into the forehead support mounting hole in a direction toward the column.

2 Mount the head fixator for 3D image acquisition to the chin rest base in a direction toward the column.

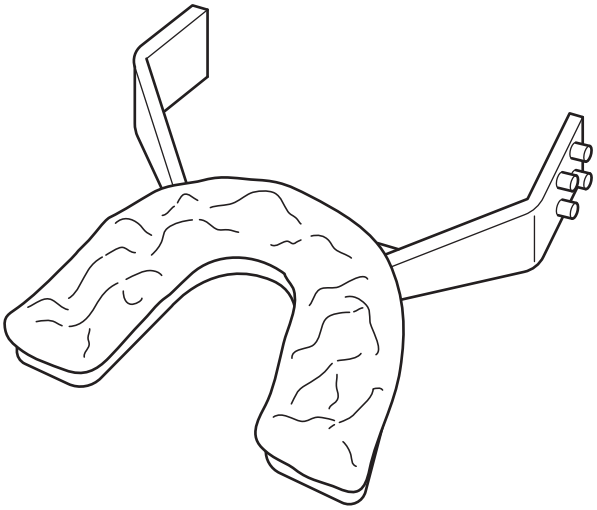
3 Lower the head fixator for fixture lever of the head fixator for 3D image acquisition to fix it. Make sure the bottom of the head fixator for 3D image acquisition touches the chin rest cover.

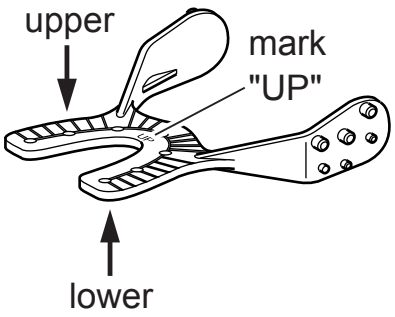


2.5.5.4 Preparing the bite plate and the impression material

⚠ Caution

- To prevent the patient from infection, always use new bite plate and impressing material for each patient. Wipe off the bite plate with alcohol-dampened cloth prior to use to maintain cleanliness.
- Clean the head fixator for 3D image acquisition for each patient prior to use.
- Use general commercial products, "dental alginate impression materials" and "Dental Silicone impression materials" for 3D image acquisition. Using other kinds of impression material may cause degradation of 3D image quality.

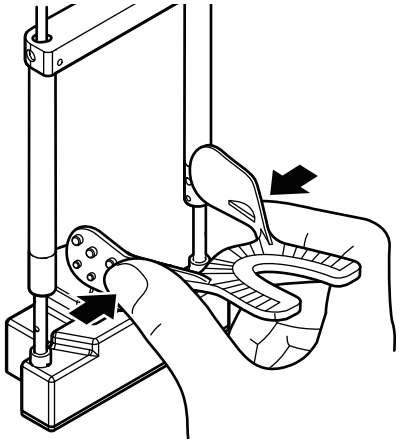




Coat the bite plate with dental impression material (Use general commercial products, "dental alginate impression materials", "Dental Silicone impression materials", etc). Advise the patient to bite on the bite plate coated with dental impression material. Wait until the impression material hardens.

NOTE : Bite plate has the distinction between upper surface and lower surface. Upper surface has thicker attaching pin. Upper surface also has the engraved mark "UP". When coating the bite plate with impression material and advising the patient to bite on the bite plate, make sure which side is upper and which side is lower.

2.5.5.5 Attaching the bite plate

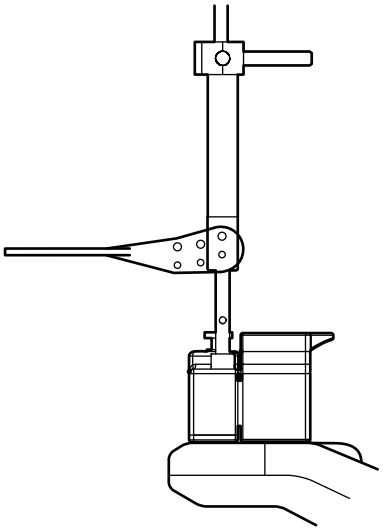


As shown in the figure, hold the bite plate coated with the hardened impression material. Creep the attaching unit and insert the pin into the attaching hole of the up-down positioning unit of the head fixator for 3D image acquisition.

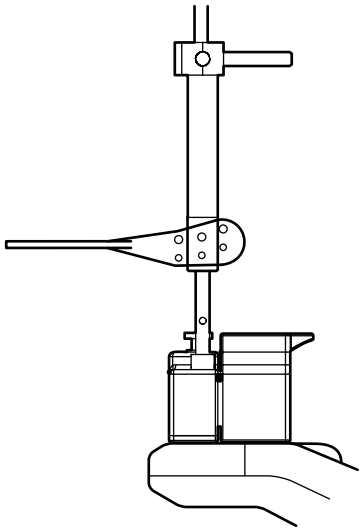
NOTE : If the bite plate is crept too much, it may cause damage.

2.5.5.6 Attaching position of the bite plate

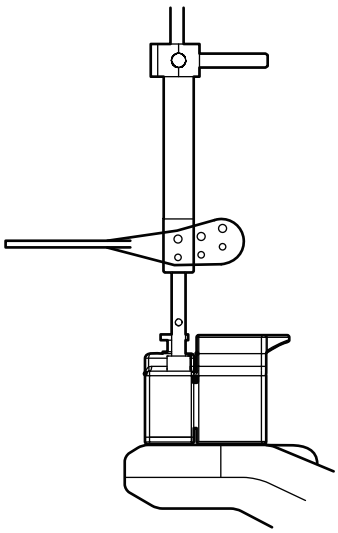
Adjust the bite plate to the image acquiring position and attach it to the shaft unit of the head fixator for 3D image acquisition.



1 For front teeth image acquisition, insert the rear row pins of the bite plate to attach.



2 For molar teeth image acquisition or front teeth 3D Oral image acquisition, insert the center row pins of the bite plate to attach.



3 For wisdom teeth image acquisition, insert the front row pins of the bite plate to attach.

Suppl. : Oral mode is recommended for wisdom teeth image acquisition.

2.5.5.7 Positioning of 3D image acquisition

⚠ Warning

- Do not look directly into the positioning beam although the power output (Class 2) is at the level in which adverse effect on the eyes can be avoided by blinking.

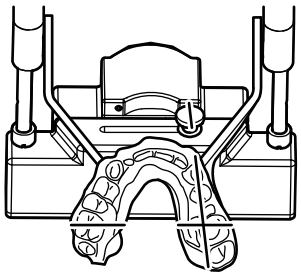
⚠ Caution

- Positioning beam is a laser beam. Be careful not to direct the positioning laser beam into patient's eyes. Also, advise the patient not to look directly into the beam.
- To minimize X-ray exposure, properly position the patient.
- If the rotating arm is deviated from its correct position, it may cause complications during the procedure. Be sure to return the arm to its reset position and then retry.

1. Aligning the positioning beam

Align the horizontal position of the image acquiring area.

Fix the forehead support to the top and the up-down positioning unit to the bottom.

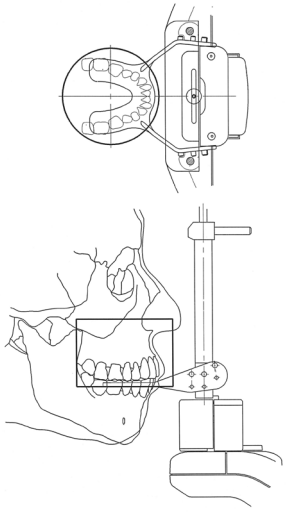


3D Oral image : Diameter 77mm
3D Dental image : Diameter 40mm

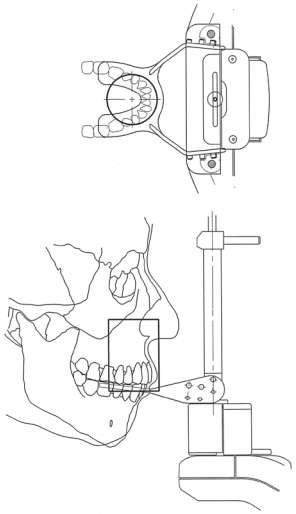
Press the positioning beam switch. The rotating arm unit will move to the positioning point and the beam will be emitted. The intersection point of the emitted median beam and the medsagittal vertical beam will be the center of FOV. Move the rotating arm and the head fixator for 3D image acquisition so that the desired area for image acquisition comes into the image acquisition area.

Suppl. : Take into account the diameter of the FOV and adjust the beam slightly inside the row of teeth.

Example of 3D Oral and upper anterior tooth image acquisition



Example of 3D Dental and upper anterior tooth image acquisition

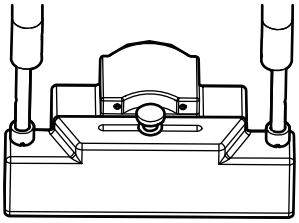


2. How to adjust the center of FOV

Position adjustment of front-back direction

Press forward switch or back switch of the control panel to adjust the front-back direction of the center of FOV. It moves ±10mm in front-back direction towards the column unit.

Position adjustment of left-right direction



Loosen the left-right slide fixing knob of the head fixator for 3D image acquisition to adjust the left-right direction of the center of FOV. After adjustment, tighten the slide fixing knob. It moves ±20mm in left-right direction towards the column unit.

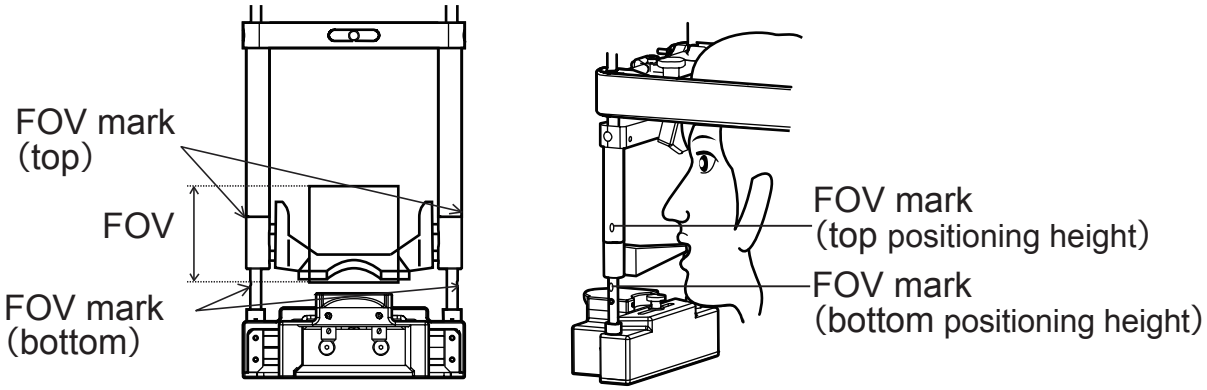
Suppl. : The positioning beam automatically turns off approximately 60 seconds after activation. If the positioning beam has turned off before positioning is successfully finished, press the beam switch again to turn on the positioning beam.

Suppl. : As the rotating arm approaches the front teeth (column unit), it becomes hard for the positioning beam to intersect. Estimate the intersection point for positioning.

Note. : Fix the forehead support of the head fixator for 3D image acquisition to the top and the up-down positioning unit to the bottom in a way that the positioning beam will not be blocked.

3. Aligning the up-down positioning height

Align the vertical position of the image acquiring area. Adjust the Frankfurt horizontal beam slider to the FOV mark (Top/Bottom) to show the top and bottom position of FOV. Fix the up-down positioning unit so the desired area of image acquisition fits in this range.



Note : Do not align the up-down positioning height while the lock lever is in locked condition. This may cause failure.

Note : Make sure to do up-down positioning before seating the patient.

Note : Set the up-down positioning unit above the top of FOV so the top of patient's head easily fits the head support. Make sure before the image acquisition.

2.5.5.8 Turning off the positioning beam

Press the beam switch to turn off the positioning beam.

⚠ Caution

- After the positioning is completed, be sure to return the positioning mirror to its regular position.

2.5.5.9 Adjusting the chin rest height

⚠ Caution

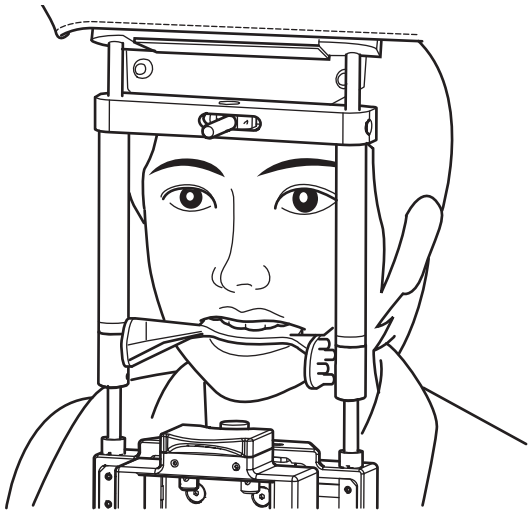
- Be sure to ask the patient to wear an X-ray protective apron and the child patient to wear both X-ray protective apron and a thyroid shield.
- Ask the patient to remove eye glasses and accessories prior to X-ray exposure. Otherwise, they may be reflected on the images.
- Ensure that the patient's hair, especially when hair is tied up, does not come in contact with the equipment. It may cause injury of the patient.
- Ask the patient to keep away from the equipment until the arm unit of the equipment has been reset. Otherwise, the patient may be caught by the arm unit and be injured.
- Do not rotate the arm unit manually. Otherwise, the patient may be caught by the arm unit and be injured. Failure may occur in the equipment as well.

Seat the patient and move the chin rest unit up and down to adjust the bite plate to the height of patient's mouth. Press the Up/ Down switch on the control panel to move the chin rest unit up and down.

⚠ Caution

- Ask the patient to keep away from the equipment until the height of the equipment has been successfully adjusted. If not, the patient may be hit by the equipment, being injured.

2.5.5.10 Biting the bite plate attached to the head fixator for 3D image acquisition.

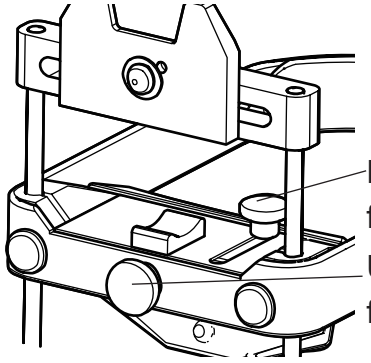


Ask the patient to bite the bite plate along with the impression material.

2.5.5.11 Adjusting forehead support

Adjust the vertical and horizontal position of the forehead support of the head fixator for 3D image acquisition so that it fits the patient's forehead.

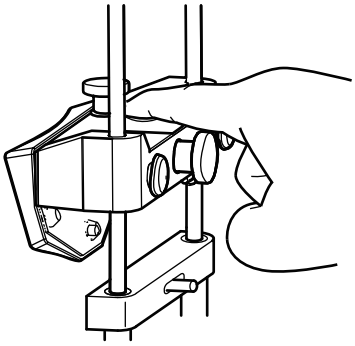
Adjusting vertical position

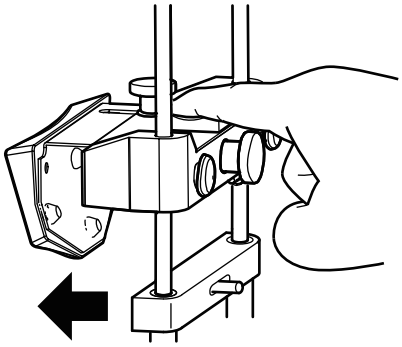


The forehead support can slide vertically if the up-down slide fixing knob is loosened. Position the forehead support at the height of the patient's head, and tighten the up-down slide fixing knob.

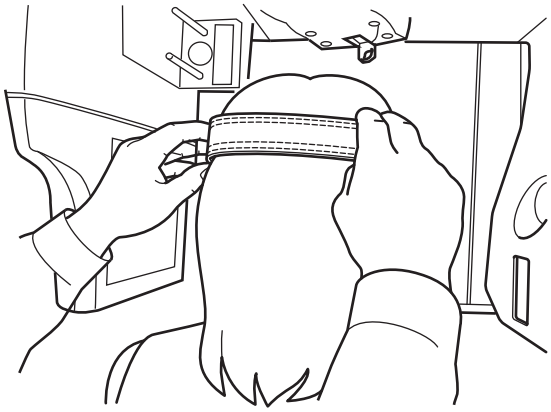
Adjusting horizontal position

The forehead support can slide horizontally (front-back) if the up-down slide fixing knob is loosened. Position the forehead support to suit the patient's forehead, and tighten the front-back slide fixing knob.





2.5.5.12 Fixing the patient's head



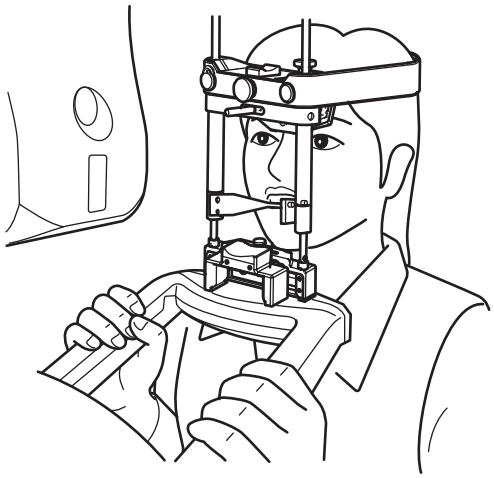
Position the patient's forehead at the forehead support, and stabilize the patient's head by using the head band. At that time, ask the patient not to lean on the head fixator for 3D image acquisition.

Note : In 3D image acquisition, the distance between the patient's occipital and sensor part are narrower than in panoramic image acquisition. When fixing the patient's head, position the patient so that his/her occipital does not interfere with the sensor part.

⚠ Caution

- When excessive load is applied on the head fixator for 3D image acquisition, the bite plate may get dislocated and the subject part may move out of the acquisition range.

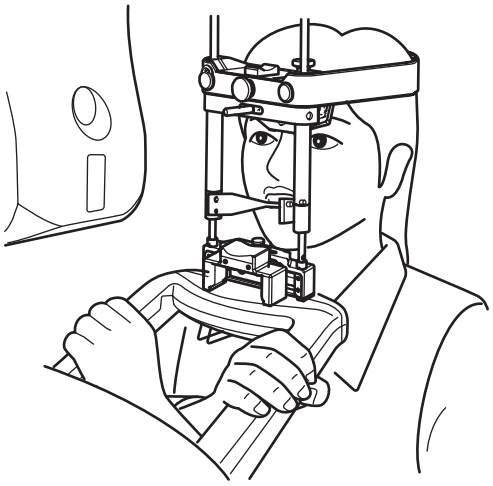
2.5.5.13 Gripping on the handles



Ask the patient to stretch his/her back and grab the handles.

⚠ Warning

- Do not apply heavy load or shock on to the equipment, e.g. suspending from the chinrest or handle. Failure to follow this instruction may cause damage to the equipment.

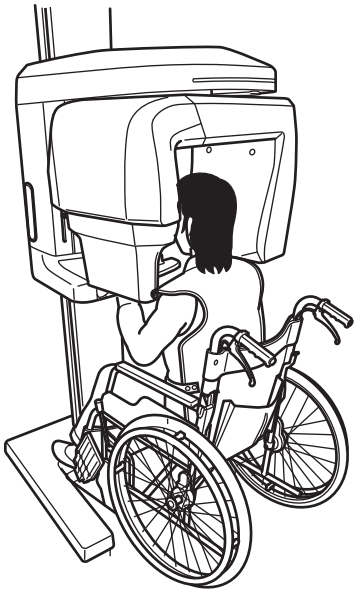


If the sensor comes in contact with the patient's shoulder, ask the patient to grip the handles by crossing the arms on their chest.

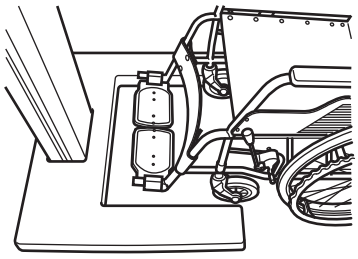
⚠ Caution

- Do not move the equipment upward/downward when the patient is fixed or is biting the bite plate. Otherwise, the patient may be injured.
- If the up/down switch is wrongly pressed when positioning, the patient may be injured. Be extra cautious when operating the switches.

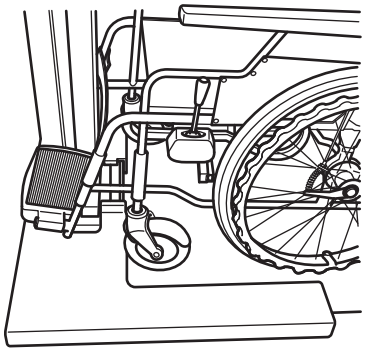
Suppl. : Patient on a wheelchair



Position the patient on a wheelchair all the way to the column so that the patient is able to have the back straighten and sit upright.



When an optional normal-sized base is used, position the wheelchair so that the front wheels sit nicely between the base and rear wheels are free from hitting the base.



When an optional wide base is used, fold up the foot rests of the wheelchair if necessary in order to position the wheelchair all the way to the column.

⚠ Caution

- Image acquisition for patients in wheel chairs is possible. However, wheelchairs with a longer backrest or custom-made wheelchairs may interfere with the movement of the equipment. Under such circumstance, ensure before the acquisition that the wheel chair does not interfere with the movement of the equipment.
- Be careful not to hit the patient’s legs against the column while positioning the patient on a wheelchair especially with folded foot rests, all the way to the column.
- With the patient on a wheelchair, the patient's shoulder may come in to contact with the equipment due to the difficulty with keeping the upright posture. Straighten his/her spine during positioning and then acquire images.

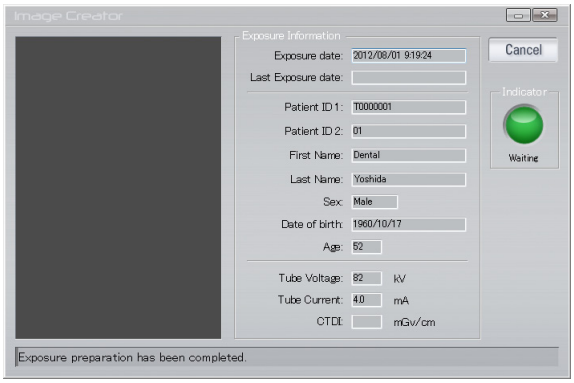
2.5.6 X-ray Exposure

⚠ Caution

- Only trained and qualified person should take radiographic photos. X-ray exposure (or image acquisition) by unqualified person is prohibited by law.
- To minimize the X-ray exposure, properly position the patient.
- Instruct the patient not to move during the image acquisition. When the patient moves during the image acquisition, the image may get blurred and the quality low. Especially for 3D oral image acquisition, advise the patient to stay still until the whole process of the acquisition is completed.
- Before 3D image acquisition, make sure that the panoramic sensor is detached from the sensor part (detachable). If image acquisition is proceeded with the panoramic sensor attached, 3D image cannot be acquired properly, and the patient may get accidentally injured due to the interference with the equipment.
- Before 3D image acquisition, make sure that the head part and movable sensor part are not interfering with the patient's head.

Starting X-ray Exposure

After the operations described in "From the control panel:" P.56 or , "From the Image Creator :" P.59 make sure that the Image Creator's Image Construction Screen is under Acquisition standby status.



Make sure that the Ready LED (green) is turned on and the equipment is ready for image acquisition. Press the X-ray Exposure switch to start image acquisition. Holding down the switch activates X-ray Exposure during the specified Exposure time. While X-ray is irradiated, the X-ray indicator (yellow) on the hand-switch box turns on, and the buzzer continually buzzes. An audible alarm also sounds at the control panel.

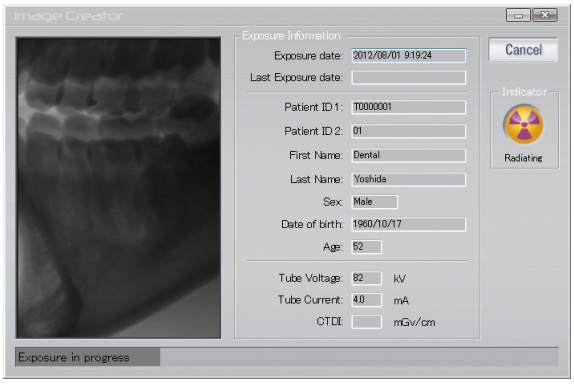
To stop X-ray Exposure and image acquisition by the equipment during the process, simply release your finger from the X-ray Exposure switch because it is the deadman type switch.
* Deadman type switch: A system which operates only when the operator applies force to the equipment.

Note : In 3D oral image acquisition, the image is acquired clockwise first, then counter-clockwise. Keep pressing the X-ray Exposure switch until the counter-clockwise (return) image acquisition is complete. If the X-ray exposure switch is released during an exposure, X-ray exposure and image acquisition will be stopped and become an exposure error.

⚠ Caution

- If the X-ray exposure switch is released during an exposure, X-ray exposure and image acquisition will be stopped and cause an exposure error, resulting in a retake and consequently increasing the patient dose. Unless it is necessary to stop for emergency, do not release the X-ray exposure switch.
- Leave the controlled area during X-ray exposure.

Image Acquisition Preview



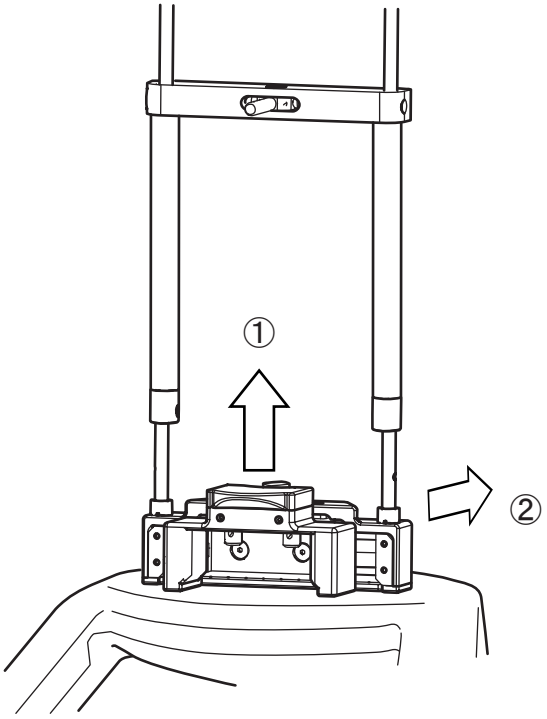
Once an X-ray image acquisition commences, Image Creator display will change from "3D Image Acquisition Standby" screen to the "acquisition" screen. In the acquisition screen, image construction is displayed simultaneously with the acquisition progress.

2.5.7 Patient's Exit

Remove the head band on the head fixator for 3D image acquisition, and instruct the patient to step straight back.

> **⚠ Caution**
>
> • When the patient makes his/her exit, make sure to escort and lead the way. Since the patient needs to move backward when removing him/herself from the equipment, the patient might trip over or cause similar accidents.

2.5.8 Detaching the head fixator for 3D image acquisition



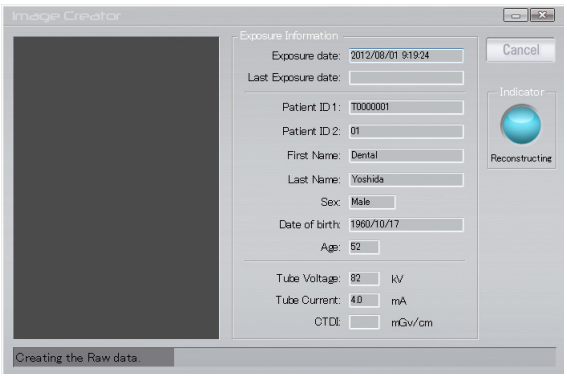
When you have finished 3D image acquisition, dismount the head fixator for 3D image acquisition in the following steps.

1 Raise the head fixator fixture lever of the head fixator for 3D image acquisition.

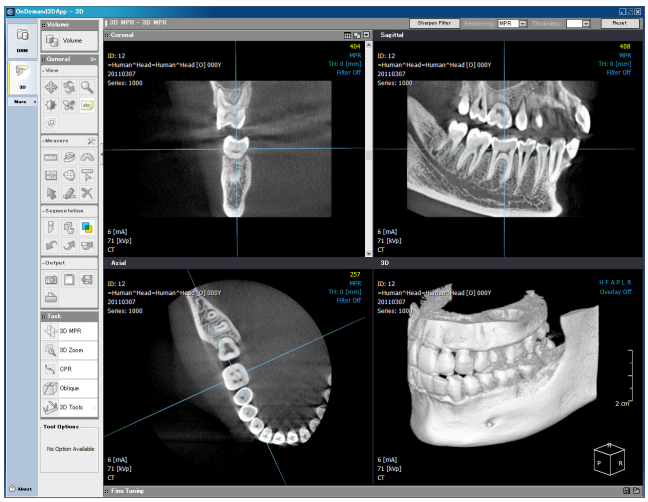
2 Hold the shaft of the head fixator for 3D image acquisition with both hands. Detach it from the chin rest base in the opposite direction from the column.

2.5.9 Image Transfer

Once X-ray irradiation is complete, reconstruction of acquired image automatically starts.



1 Image Creator's Image Construction screen changes from "acquisition" to "3D Image Reconstructing", and data is reconstructed to be transferred to 3D viewer.

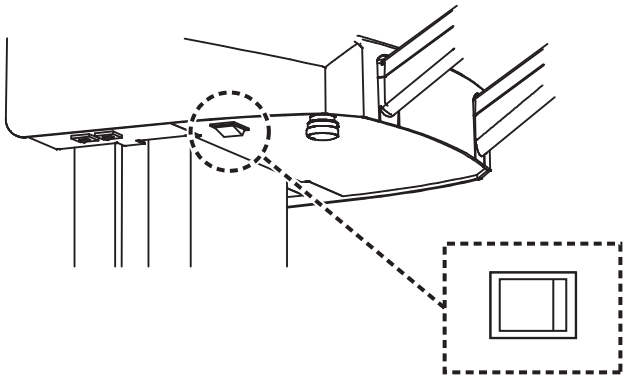


2 Image Creator's Image Construction screen activates the 3D viewer software, and transfers the 3D image. The 3D image transferred into the 3D viewer software is displayed.

⚠ Caution

- Malfunctions or erroneous operations such as unintended formatting on the hard disk drive might render important data or programs inoperative. Use a backup program etc. to copy the contents of the hard disk drive into an auxiliary storage device. Please note that we are not liable for the loss of data because of a malfunction or erroneous operation.

2.5.10 Turning Off the Equipment



Turn the power switch off (O) and make sure the power indicator (green) is unlit.

3 Directions for Use of X-era Smart Control-Manager

In ControlManager, Confirmation of the exposure Condition, the exposure Mode, the exposure status, the User Program Mode Settings, Confirmation of the Main Unit Circuit Board Program Version and Communication Port Settings can be configured.

NOTE : When the software needs to be reinstalled due to replacement of computers, etc., the installation procedure needs to be done by a professional service personnel only.

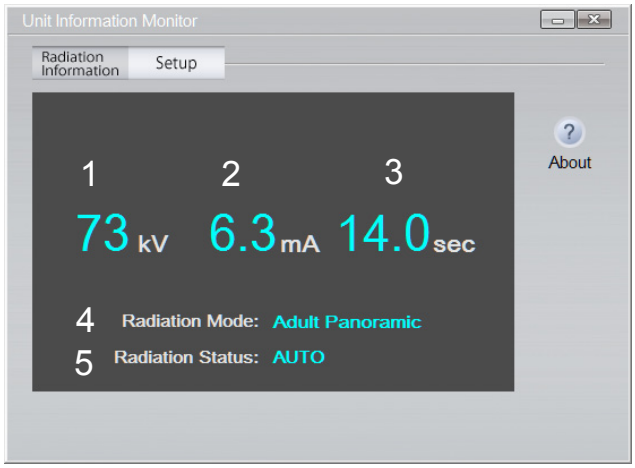
⚠ Caution

- The contents of this software are subject to change for improvement at any time in the future and without notice.
- Use of this software is solely licensed to the user of our corresponding product.
- Do not install any software on the computer outside the specifications.
- Do not connect the computer to the Internet.
- Responsibly manage the computer so that it does not get infected with viruses. In case of viral infection, there are possibilities of serious failures including Exposure due to malfunctions during image acquisitions. Anti-virus software or virus detecting software cannot be installed on the computer.
- The performance of the Image Creator software can be lowered when it is run concurrently with other pieces of software on the computer.

3.1 Starting up X-era Smart ControlManager

At the computer's boot-up, ControlManager automatically starts on the background. While ControlManager is active,  is displayed on the task tray.

3.2 Descriptions of Unit Information Monitor

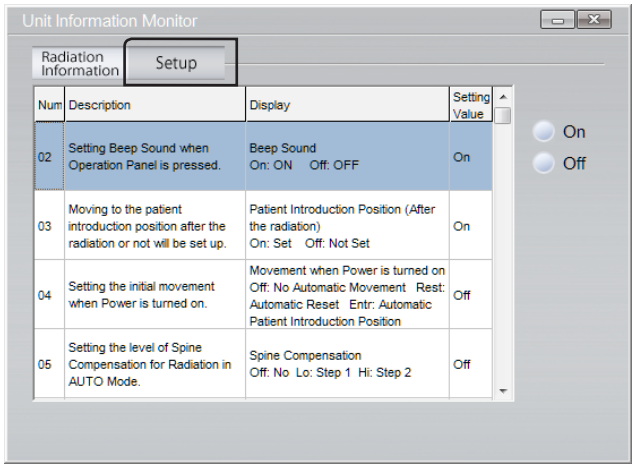


Clicking "Radaition Information" brings up "Unit Information Monitor"on the PC screen. On the "Unit Information Monitor" screen, these data will be indicated.

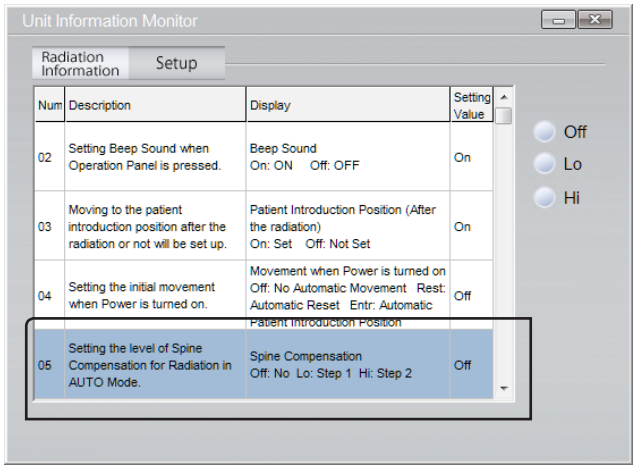
1 Tube voltage
2 Tube current
3 Exposure time
4 Exposure mode
5 Exposure status

3.3 Descriptions of "Setup" Screen

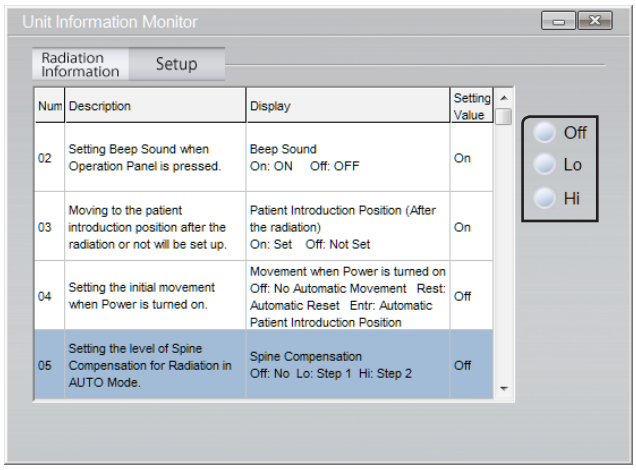
Software "X-era Smart ControlManager" can be used to configure User Program Mode on the PC. For more information on program numbers and their descriptions, refer to "5 User Program Mode" P.119.



1 Click "Setup".



2 Click the program number of the program to be modified to select.

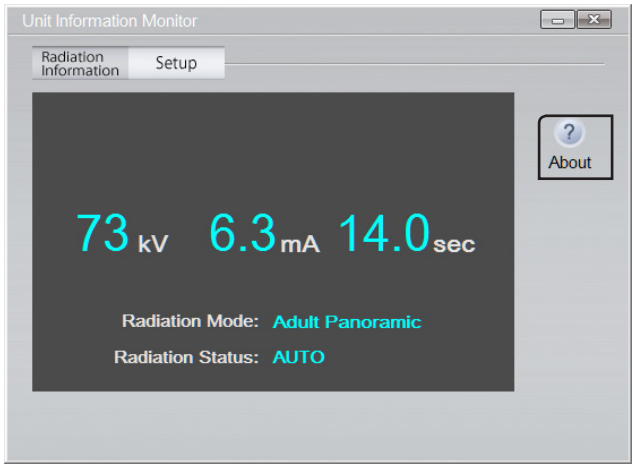


3 Click the button associated with the setting to be modified.

4 The left-hand dialog will open. To confirm the modification, click “OK”.

Suppl. : In the User Program Mode, any operation from the exposure switch or the control panel is not activated.

3.4 Confirming Program Versions



1 Click “About” in “Main Menu”.

2 The “Program Version Confirmation” screen will open.

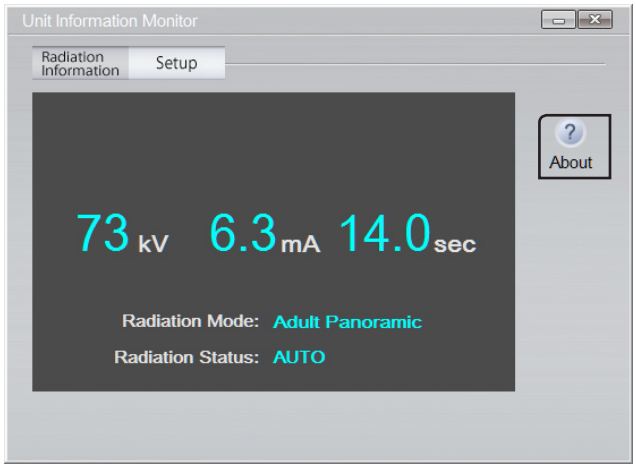
3 Program versions are listed as shown in the following screen.

1. Main program version
2. Control panel program version
3. Hand Switch Box program version
4. Cephalometric control relay board program version (*)
5. X-era Smart ControlManager version

* For equipment with Cephalometric

Suppl. : The version numbers in the above figure are for reference only. The actual numbers may vary.

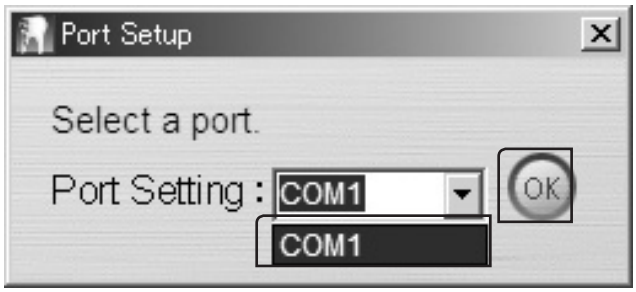
3.5 Configuring a Communication Port (s)



1 Click “About” in “Main Menu”.

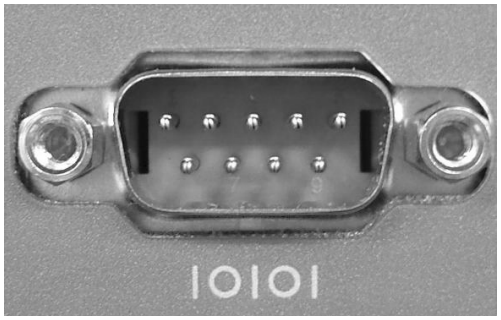
2 The “Version Confirmation” screen will open.
Click “Port Setting”.

3 The “Port Setup” dialog will open.



4 From the pulldown menu, select your desired port (s) and then click “OK”. You will return to the “System Setup” screen.

Suppl. : About “communication ports”



1 The equipment has incorporated “serial type” of communication ports.

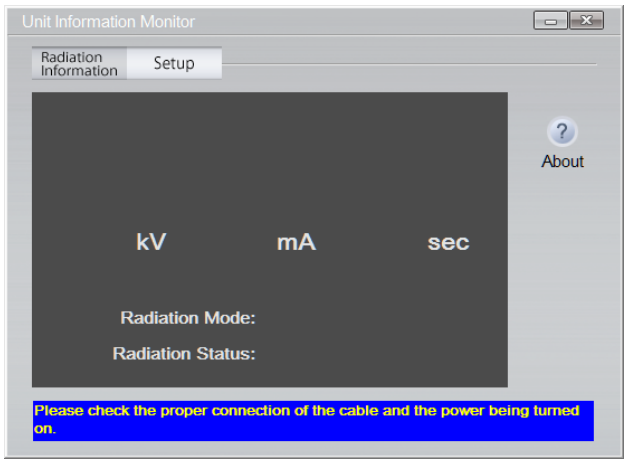
A set of serial ports are arranged as shown in the left-hand photograph. The rear panel of the PC has one or more receptacles labeled “IOIOI” as shown in the photograph.

2 Each of these serial ports (hereafter, called ports) has a designation assigned on the PC.

e.g.: COM3 COM6
(The assigned numbers are not always serial numbers.)

3 With more than one port incorporated in the equipment, you need to indicate (configure) which port is connected to the PC via cabling.

X-era Smart ControlManager can be used to select your desired port (s) from a port list for easy configuration.



4 Selecting any wrong port will bring up an error message; “Please check the proper connection of the cable and the power being turned on”. In response to this message, select a correct port (s).

4 Directions for Use of Image Creator

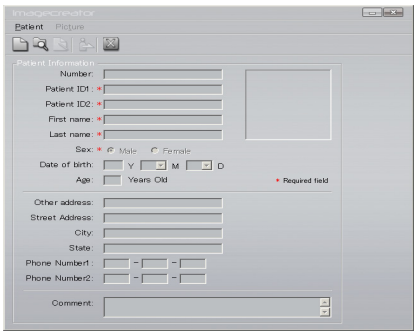
Using Image Creator in order to set up the image acquisition mode, acquire images, formulate panoramic images, adjust the tomographic setting of panoramic images, and transfer images to the Viewer.

NOTE : If the software needs to be reinstalled due to replacement of computers, etc., the installation procedure needs to be done by professional service personnel only.

⚠ Caution

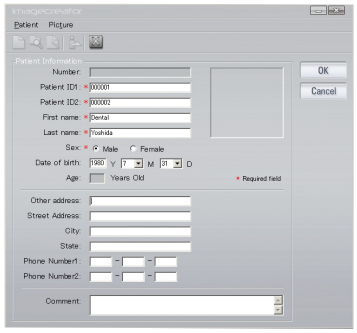
- The contents of this software product are subject to change for improvement at any time in the future and without notice.
- Use of this software product is solely licensed to the user of our corresponding product.
- Do not install any software products on the computer outside the specifications.
- Do not connect the computer to the Internet.
- Responsibly manage the computer so that it does not get infected with viruses. In case of viral infection, there are possibilities of serious failures including radiation exposure due to malfunctions during image acquisitions. Anti-virus software or virus detecting software cannot be installed on the computer.
- The performance of the Image Creator software can be lowered when it is run concurrently with other pieces of software on the computer.

4.1 About the Patient Selection Screen



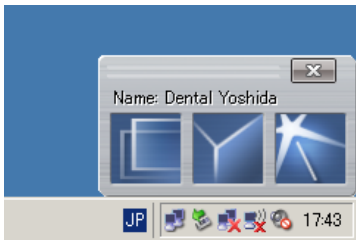
When Image Creator is activated, at first the patient selection screen appears. In the patient selection screen, narrow search and registrations of patients can be conducted. Select a patient and the launcher screen will display.

4.2 About the Patient Registration Screen



Press the "Patient Registration" button, and the patient registration screen appears. Register a Patient ID. Select the patient's name, date of birth, and sex. Press the "Register" button, and the new patient is registered

4.3 About the Launcher Screen



Select a patient in the patient selection screen, and the launcher screen appears. The image construction screen, 2D image viewer, and 3D image viewer can be activated from the launcher window.

4.4 How to use the Image Construction Screen

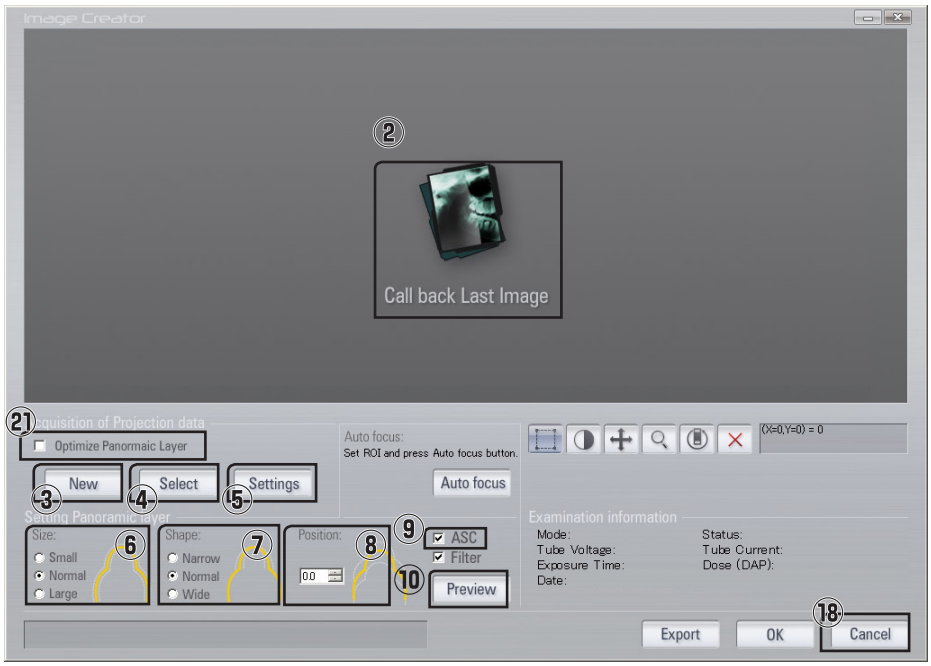


Image Creator main image (without panorama pictures)

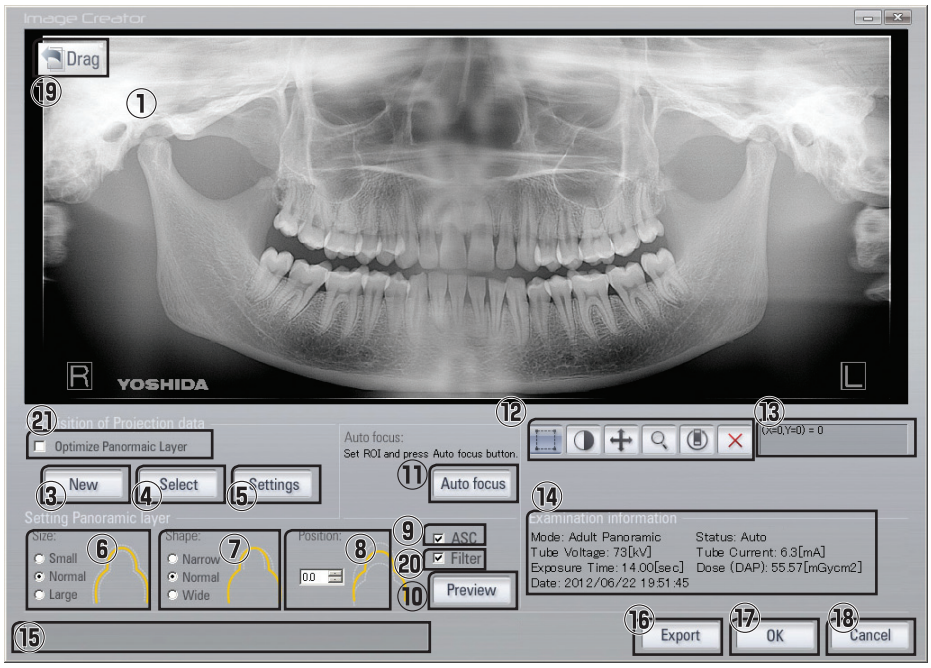


Image Creator main image (with panorama pictures)

	Name	Function
1	Image Display Area	Displays acquired image.
2	“Call Back Last Image” Button	Loads the RAW data, the last image acquired. Such operations can be done on the loaded RAW data as reformulation and readjustment of tomographic setting on the panoramic or Cephalometric radiographic images.
3	“New” Button	Acquires a new image from the patient. Such operations can be done on the loaded RAW data as reformulation and readjustment of tomographic setting on the panoramic or Cephalometric radiographic image.
4	“Select” Button	Loads a previously acquired RAW data. Such operations can be done on the loaded RAW data as reformulation and readjustment of tomographic setting on the panoramic or Cephalometric radiographic image.
5	“Settings” Button	Displays the Settings screen of the User Program Mode. In the User Program Mode, the main equipment can be set up. For details, refer to "4 Directions for Use of Image Creator" P.110 .
6	Dental arch Size Group	When acquiring a new image, the size of tomographic trajectory is selected for the panoramic image displayed in the preview and the panoramic image to be newly created. After the image acquisition, the size of tomographic trajectory is selected for the panoramic image to be reformulated when the “Preview” Button is pressed. Select one from Small / Normal / Large. * With Cephalometric image, dental arch can not be adjusted.
7	Dental arch Shape Group	When acquiring a new image, the shape of tomographic trajectory is selected for the panoramic image displayed in the preview and the panoramic image to be newly created. After the image acquisition, the shape of tomographic trajectory is selected for the panoramic image to be reformulated when the “Preview” Button is pressed. Select one from Narrow / Normal / Wide. * With Cephalometric image, dental shape can not be adjusted.
8	Tomographic Position Group	When acquiring a new image, the position of tomographic trajectory is selected for the panoramic image displayed in the preview and the panoramic image to be newly created. After the image acquisition, the position of tomographic trajectory is selected for the panoramic image to be reformulated when the “Preview” Button is pressed. Select a position within the range between -10.0 mm and +10.0 mm. * With Cephalometric image, tomographic position can not be adjusted.
9	“ASC” Check box	When this box is checked, the cervical spine adjustment function is activated when formulating the panoramic image. After image acquisition, cervical spine adjustment (or lack thereof) is applied to the panoramic image reconstructed by pressing Preview Button. This function can be used for previously acquired images as well. * With Cephalometric image, changes in cervical spine adjustment can not be applied.
10	“Preview” Button	Using a previously acquired image, reformulates the panoramic image using the settings in the items 6-9 above.
11	“Auto-Focus” Button	Automatically focuses on the rectangular domain specified at the Image Display Area.
12	Display Adjustment Buttons	Adjusts the image display of the Image Display Area. The left-drag function of the mouse changes according to the button pressed.
13	Coordinates Display	When the mouse cursor is on the Image Display area, the coordinates and values of the pixel pointed at by the cursor are displayed. When a rectangular domain is set, the starting and ending coordinates and the mean pixel value of the selected area are displayed.
14	Image Acquisition Information Display	Displays the information of the image at the Image Display area.

	Name	Function
15	Progress Display	When a time-consuming process, such as reformulation of panoramic or Cephalometric radiographic image is in progress, the processing progress is displayed.
16	“Export” Button	Exports the image newly acquired or formulated by tomographic adjustment as a file in the TIFF format. Names and exports the loaded data (RAW data).
17	“OK” Button	Transfers the image newly acquired or formulated by tomographic adjustment to the Viewer and closes the screen of Image Creator.
18	“Cancel” Button	Closes the screen of Image Creator without transferring the image to the Viewer.
19	“Drag & Drop” Button	The image formulated by a new acquisition or tomographic adjustment is transferred to the viewer by the mouse’s drag and drop. By right-clicking the mouse, the format of file to be transferred can be chosen from Tiff 8-bit, Tiff 16-bit, DICOM 16-bit, and Trophy Windows Format 16-bit.
20	“Filter” check box	When checked, the image processing filter is applied when panoramic image is constructed, and the soft tissue filter is applied when cephalometric image is constructed. After image acquisition, the presence or lack thereof is reflected on the panoramic image reconstructed by pressing the Preview button. This function can also be applied to images acquired in the past.
21	"Optimize Panoramic Layer" check box	When checked, the front tomographic position is optimized before panoramic image construction, and the calculated information on the tomographic position is used in constructing the panoramic image. This function can also be applied to images acquired in the past.

NOTE : When the "Filter" is applied, surroundings of parts which do not readily allow X-ray penetration may appear dark due to the image processing. When the surrounding area appears dark, it may appear like a secondary caries. In such a case, check the image without the "Filter" applied.

4.5 Image Data

There are two kinds of acquired data: RAW data consisting of multiple strip-shaped frame images, and image data (panoramic image and cephalometric image) constructed from RAW data . Tomographic position can be changed on RAW data, but its file size is large (approx. 900MB). As for image data constructed from RAW data, the file size is small (approx. 10MB), but the tomographic position cannot be changed.

4.6 Saving and Loading of Acquired Data (RAW Data)

Call back Last Image

Image Creator automatically saves the data one acquired image only after its acquisition. That image can be easily recalled using the Call back Last Image" function.

NOTE :When the computer is turned off or rebooted after image acquisition, the acquired image is loaded from the file and it takes time to load the data.

: If another data is loaded after the data is acquired, it takes some time for the data to be called back as the acquired data is loaded from the file.

Select and Export

Press the Export button and the acquired data can be named and saved. The saved data can be selected and loaded using "Select" button to specify the file.

NOTE : The file size of acquired data is approximately 900 MB. Please check the capacity of destination disk when saving the file using Export. Since the file size of acquire data is approximately 900MB, loading acquired data using Select takes time.

4.7 Tomographic Adjustment

Manual Adjustment

When “Preview” is pressed after the Dental Arch Size, Dental Arch Shape, and Tomographic Position are set, the panoramic image is reformulated according to the parameters set.

Dental Arch Size

Name	Small	Normal	Large
Image			

Dental Arch Shape

Name	Narrow	Normal	Wide
Image			

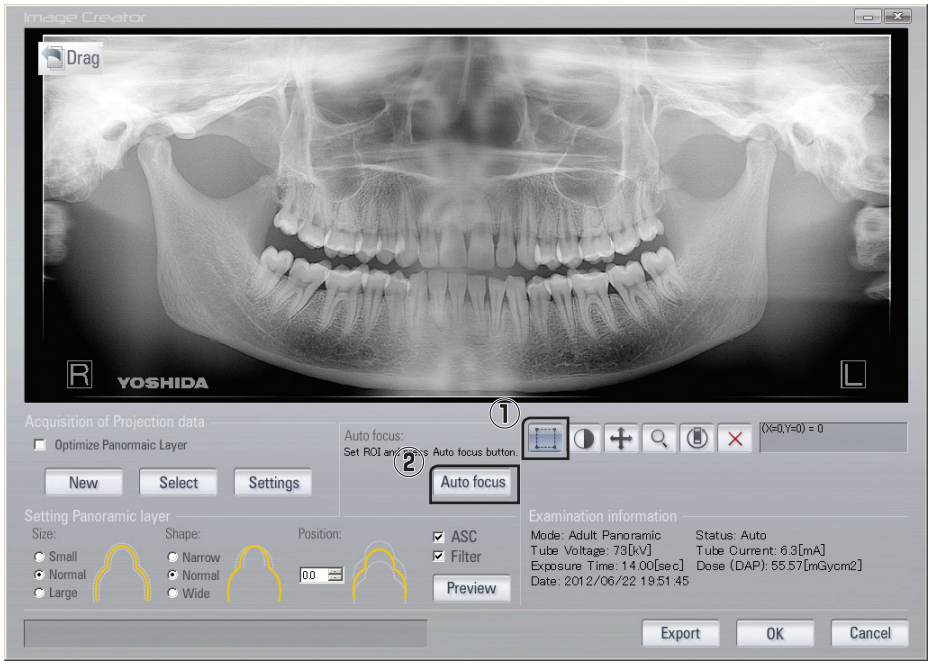
Tomographic Image

Position	-10 mm	…	+10 mm
Image			

Auto-Focus

Click on the Domain button (1) to set the rectangular domain on the panoramic image, By selecting a rectangular domain on the panoramic image and pressing “Auto-Focus(2)”, the panoramic image is reformulated by the selected domain being focused and the tomographic domain being automatically readjusted.

By selecting a rectangular domain on the panoramic image and pressing “Auto-Focus”, the panoramic image is reformulated by the selected domain being focused and the tomographic domain being automatically readjusted.



NOTE : When a tomographic domain is adjusted using Auto-Focus, the tomographic domain of upper and lower selected rectangular domain are also relocated.

NOTE : When the length measurement function is used in the viewer, the result of the measurement may differ because magnification of the image is changed by the use of tomographic adjustment feature.

Suppl. : By selecting Auto focus, the specified domain will be in focus automatically. However, in some cases with unclear images due to the certain factors such as containing opacity objects (prosthetic material, root-canal filling material, and implants), patient’s individual characteristics, or incorrect positioning, auto-focus function may not bring proper tomographic position into focus.

4.8 Display Adjustment

By operating the Display Adjustment Buttons, the left-drag function of the mouse for the Image Display area can be chosen.

Domain Button

Domain Button is used when defining a rectangular domain on the image shown at the Image Display area. A rectangular domain is defined by the mouse's left-dragging from the starting coordinates to the ending coordinates. Only one rectangular domain can be set for the displayed image.

Window Level Button

Window Level Button is used when adjusting the window level of the image shown at the Image Display area. Click and drag with the left mouse button to adjust.

Horizontal Movement Button

Horizontal Movement Button is used when moving the image shown at the Image Display area horizontally. Click and drag with the left mouse button to adjust.

Zoom Button

Zoom Button is used when enlarging or reducing the image shown at the Image Display area. Click and drag with the left mouse button to enlarge/reduce.

Reset Button

If pressed when Domain Button is selected, the domain defined becomes unselected.
If pressed when Window Level Button is selected, the window level returns to the default value.
If pressed when either Horizontal Movement Button or Zoom Button is selected, the image fits into the Image Display area.

Delete button

When pressed while a panoramic image is displayed, the "Call back Last Image" screen is displayed.

Display adjustments can also be done with mouse movements only without using these buttons.

Window Level Adjustment	:	Dragging the mouse while both right and left buttons pressed.
Horizontal Movement	:	Mouse's right-drag
Zoom	:	Wheel movements
Window Level Reset	:	Mouse's left double-click
Position and Zoom Reset	:	Mouse's right double-click

4.9 Image Export

The image shown at the Image Display area can be transferred to the viewer or exported as a file in TIFF format.

Transfer to the viewer

- Transfer Using TWAIN

  When Image Creator is activated from the viewer using TWAIN, press “OK” to transfer the image shown at the Image Display area to the viewer.

  For viewers capable of handling 16 bpp* grayscale images, the formulated image is transferred as it is.

  For viewers only capable of handling 8 bpp* grayscale images, the image is transferred after the subtractive color process according to the Window Level shown at the Image Display area.

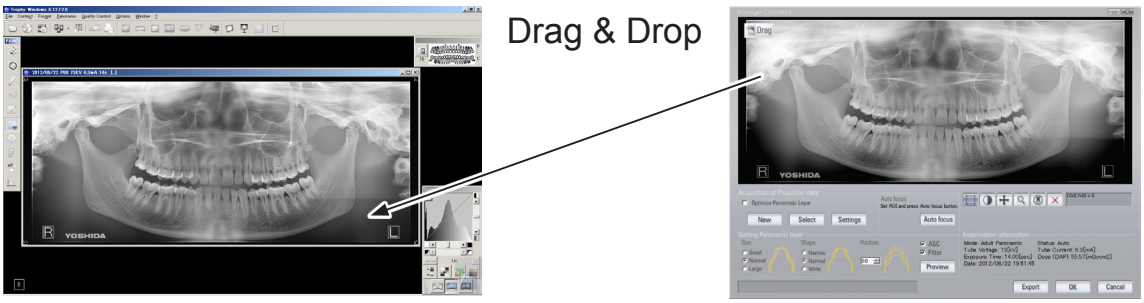
  * bpp (Bit Par Pixel) indicates how many bits exist in one pixel. 8 bpp denotes 256-step gray scale whereas 16 bpp denotes 65536-step grayscale.

- Transfer by Drag and Drop

  When the image acquired is displayed at the Image Display of Image Creator, left-click the “Drag & Drop” Button and drag it to the Viewer Screen and drop it there, and the image is transferred to the viewer. By right-clicking the “Drag & Drop” Button, a pop-up menu is displayed and the transferring file format can be chosen.

  <File Format Options>

  - Tiff (16-bit)
  - Tiff (8-bit)
  - DICOM (16-bit)
  - Trophy Windows Format (16-bit)



Suppl. :There are some viewers that do not accept drag and drop actions. In such a case, use TWAIN to transfer the image or output the file using the Tiff format.

Exporting a file in the TIFF format

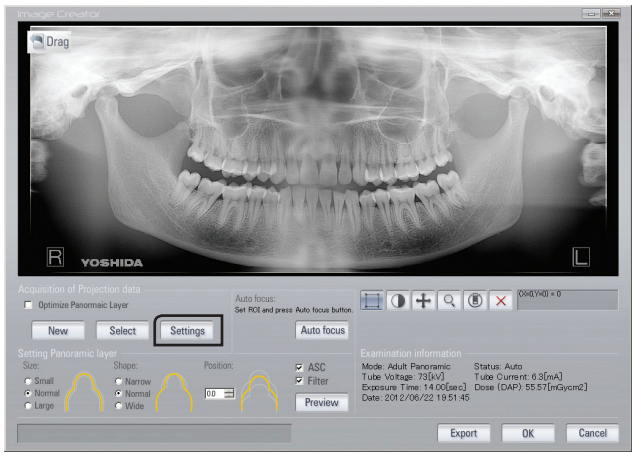
When Export Button is pressed while an image is shown at the Image Display area, the image is named and exported into a file. The file can be exported either in the TIFF 8 bpp* grayscale format or in the TIFF 16 bpp* grayscale format.

* bpp (Bit Per Pixel) indicates how many bits exist in one pixel. 8 bpp denotes 256-step gray scale whereas 16 bpp denotes 65536-step grayscale.

5 User Program Mode

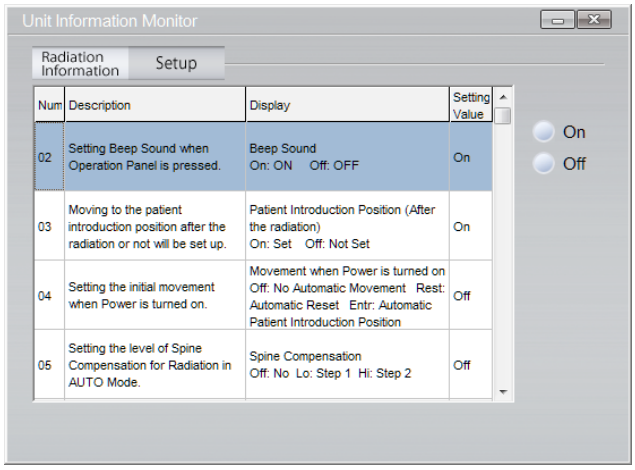
In the User Program Mode, various settings can be made so that this equipment can be operated more easily. The settings can be made in “Image Creator” or “X-era Smart Control-Manager” software installed on the computer. Refer to Descriptions of User Program Mode in the end of this section for the program number and display contents.

Operation through Image Creator

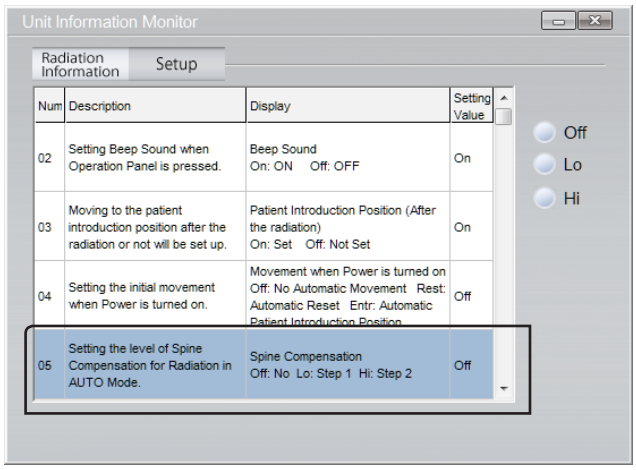


Activate “User Program Mode” by pressing the Setting Button in Image Creator.

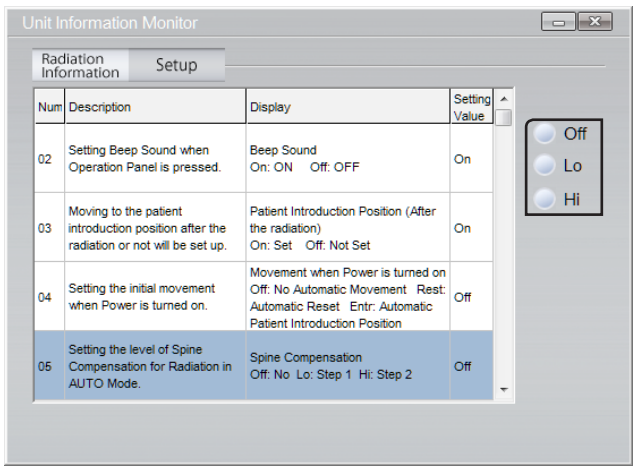
Operation through X-era Smart ControlManager



1 Activate “User Program Mode” by pressing “Setting” Tab on X-era Smart ControlManager.



2 Click and select the User Program Number that needs adjustment.



3 Press the button of the setting value needing adjustment.

4 A dialog box as in the figure on the left is displayed and the setting is completed.

Descriptions of User Program Mode

Program No.	Description	Setting			Default
Prog No.02	Specifies whether an audible alarm sounds when any button is pressed on the touch panel.	Audible alarm			On
		On: an alarm sounds	Off: no alarm sounds		
Prog No.03	Specifies whether the arm automatically moves to the patient positioning point after image acquisition.	Patient positioning point (after acquisition)			On
		On: specified	Off: not specified		
Prog No.04	Specifies power-on behavior	Power-on behavior			Entr
		Off: no auto behavior	Entr: patient positioning point	Rest: auto reset point	
Prog No.05	Specifies the correction level of cervical spine for image acquisition	Cervical spine correction			Lo
		Off: no correction	Hi: step 2	Lo: step 1	
Prog No.06	Specifies whether a service maintenance message appears once 2,000 th exposure has finished.	Service maintenance message			No
		Yes: no message appears	No: message appears		
Prog No.07	Resets the settings in memory to their defaults.	User program settings			No
		Yes: resets to defaults	No: existing settings retained		
Prog No.09	Stores the initial state in memory at power-on.	Initialization at power-on			No
		Yes: Initialization at power-on	No: not stored in memory		
Prog No.11	Specifies whether an audible alarm sounds when an error occurs.	Audible alarm sound			On
		On: an alarm sounds	Off: no alarm sounds		
Prog No.22*	Sets the irradiation conditions of the AUTO mode in 3D image acquisition.	Irradiation conditions in 3D exposure.			2
		1 : 82kV , 2.0mA	2 : 82kV , 4.0mA	3 : 82kV , 6.3mA	

*** For equipment with 3D function**

Suppl. : During setting the mode in the User Program Mode, any operation from the exposure switch or control panel is inactivated.

6 Trouble Shooting

6.1 Troubles and Their Corrective Measures

6.1.1 Troubles with image acquisition

These troubles should be appropriately addressed according to the corrective measures described in "Corrective measures for troubles with image acquisition".

Corrective measures for troubles with image acquisition

Symptom	Possible cause	Action
Enlarged and blurred anterior tooth area	Images are enlarged and blurred. The anterior tooth area has been shifted at the back of the anterior tooth tomographic area and the distance between the sensor and the patient is too long.	Adjust the tomographic position using Image Creator. Shift the sensor several millimeters backward using the Back switch in positioning.
Reduced and blurred anterior tooth area	Images are reduced and blurred. The anterior tooth area has been shifted at the anterior of the anterior tooth tomographic area and the distance between the sensor and the patient is too short.	Adjust the tomographic position using Image Creator. Shift the sensor several millimeters forward using the Forward switch in positioning.
Blurred left or right molar tooth	The center of the chin rest block does not agree the patient's midsagittal line.	Align the center of the chin rest block with the patient's midsagittal line.
	The head does not face front.	Ask the patient to face front.
Whitish and blurred anterior tooth area	With the oblique cervical spine, X-ray is absorbed leading to a shadow formed on the anterior tooth area.	Check the “ASC” box in Image Creator and formulate the image. Modify the level of “Prog No. 05” in User Program Mode. Ask the patient to hold up his/her head.
Image is unclear due to the white horizontal line appears on the apexes of the maxillary tooth roots.	The image of the plate bone overlaps with the image of tooth roots.	Ask the patient to incline slightly the face forward until the frankfurt plane is positioned horizontally.
Several fine lines appear on the image.	Insufficient dose	Increase the dose to acquire correct images.
	The X-ray beam deviates from the given path.	Contact your dealer.
No image has been acquired	Image Creator is not in Acquisition standby status.	Switch Image Creator to Acquisition standby status.
	The data cable has not been correctly connected to the PC.	Connect the cable correctly to the PC.
	The sensor is not responding to the X-ray.	Check the image by Single image radiography for maintenance purpose.
	The sensor does not respond to the X-ray	X-ray response can be checked by using single acquisition for maintenance.
	Failed unit	Contact your dealer.
No operation activated	No power is supplied to the unit.	Plug in the power cable into the outlet.
	The circuit breaker has tripped.	Reset the breaker.
	The power switch has been turned off (O).	Turn the power switch on (|).
	Failed unit	Contact your dealer.

Symptom	Possible cause	Action
With the power switch on (|), X-ray cannot be exposure.	Failed unit	Contact your dealer.
	The emergency stop switch has been pressed.	Turn the emergency stop switch clockwise to release the switch.
Abnormal noise sounds during X-ray exposure.	The X-ray tube has been shorted out or a gas has been generated in it.	Contact your dealer.
	The high-voltage transformer coil has been shorted out.	
No reaction to operation from the PC	The mouse keyboard has not been correctly connected to the PC.	Connect the mouse keyboard connector to the PC.
No power is supplied to the PC.	The power cable has not been connected to the PC.	Plug in the power cable firmly into both the PC and the outlet.
None appears on the monitor screen.	The cable has not been correctly connected between the monitor and the PC.	Connect correctly the cable to the PC.
	The power cable has not been connected to the monitor.	Plug in the power cable firmly into both the monitor the outlet.
	The PC has been activated but the power switch of the monitor has not been turned on.	Check that the power button of the monitor has been pressed and power is supplied (ON).
"Please check the proper connection of the cable and the power being turned on." message has appeared.	The PC connection cable has not been correctly connected to the PC.	Connect correctly the cable to the PC.
	The PC communication port has not been configured.	Configure the communication port (see "5 User Program Mode" P.119).
	No power is supplied to the unit.	Turn the main switch on (|).
	Failed unit	Contact your dealer.

(For equipment with Cephalometric)

Symptom	Possible cause	Action
The equipment does not switch to Cephalometric image acquisition mode.	Arm does not move to the Cephalometric image acquisition position.	Contact your dealer if this happens frequently.
	Sensor unit does not move to Cephalometric image acquisition position,	
Some parts of the Cephalometric image is missing (exposure field is off).	Slit position or Cephalometric sensor position is not adjusted properly.	Contact your dealer.
Cephalometric image is blurred.	Patient may have moved during the image acquisition.	Fix the patient properly and advise him not to move during image acquisition.
Right and left ear rods position for the Cephalometric lateral image (LA) is off from the original position.	Something may have hit the ear rod.	Contact your dealer.

(For equipment with 3D function only)

Symptom	Possible cause	Action
Reconstruction of 3D image is not completed.	3D image was acquired while a panoramic image was open.	Acquire a 3D image after closing all images.
	3D images on multiple parts of the same patient were consecutively acquired.	When acquiring 3D images on multiple parts, proceed with the next image acquisition only after checking that the previously acquired image has been reconstructed.
The reconstructed 3D image acquired is distorted.	The 3D sensor is dislocated.	Contact the dealer.
The 3D image acquired is blurred.	The patient may have moved while the image acquisition was in progress.	Fasten the patient's head using the head band on the head fixator for 3D image acquisition, and instruct the patient not to move while image acquisition is in progress.
The 3D image acquired is out of the normal domain.	Excessive load may have been applied to the head fixator for 3D image acquisition, and the bite plate may be dislocated.	Instruct the patient not to lean on the head fixator for 3D image acquisition.

6.1.2 Troubles associated error messages displayed on the screen

If an error message appears on the control panel, follow the corrective measures described in "Error message code list" to fix.

Error message code list

Error code	Description	Action
Er08	The X-ray exposure switch has been released during image acquisition.	Press the Reset switch on the control panel to recover from the error. Retry.
Er09	The rotating arm has rotated faster than the given speed.	If this error persists, contact your dealer.
Er10	The rotating arm has rotated slower than the given speed.	
Er27	FLASH memory writing error	
Er28	X-ray cannot be irradiated at the specified strength	Immediately contact your dealer.
Er29	X-ray cannot be irradiated at the specified dose.	
Er30	X-ray tube head temperature has exceeded the given value.	If this error persists, contact your dealer.
Er31	Failure in the X-ray tube head	Immediately contact your dealer.
Er34	Failure in arm sensor AR	
Er39	Failure in arm sensor AL	
Er44	Two or more arm driving sensors including the arm sensor have been activated at the same time.	
Er46	Communication error between CPU circuit board and touch panel	If this error persists, contact your dealer.
Er50	When the unit has been activated, the X-ray exposure switch has been pressed in the hand switch box.	Press the Reset switch on the control panel to recover from the error. If this error persists, contact your dealer.
Er54	The arm unit movement does not finish within the given time period.	
Er56	The back-and-forth driving motor movement does not finish within the given time period.	
Er57	Failure in back-and-force driving sensor. A wrong combinations of arm driving sensors have been activated at the same time.	Immediately contact your dealer.
Er59	Motor control error. Image acquisition control has abnormally terminated.	If this error persists, contact dealer.
Er60	Arm unit driving control error. Arm unit driving motor control has abnormally terminated.	
Er62	Back-and-forth driving motor error. Back-and-forth driving motor control has abnormally terminated.	
Er67	A major difference has observed between the arm unit driving pulse and the value detected by the arm position detector.	Press the Reset switch on the control panel to recover from the error. If this error persists, contact your dealer.
Er68	The value detected by the arm position detector has exceeded the normal range of operation due to running idle.	
Er69	The timing between the back-and-forth driving motor pulse and the toggling of back-and-forth driving sensor ON and OFF has exceeded the normal range.	
Er71	X-ray tube head control error	
Er73	Communication error between CPU circuit board and hand switch box	Press the Reset switch on the control panel to recover from the error. If this error persists, contact your dealer.

Error code	Description	Action
Er75 (*)	Cephalometric relay board communication error	Press the Reset switch on the control panel to recover from the error. If this error persists, contact your dealer.
Er79 (**)	3D sensor slide position error	
Er80 (*)	Collimator switching limit sensor error	
Er81 (*)(**)	Collimator switching position error	
Er82	Sensor (detachable) is not attached to Docking Station (Panorama) when acquiring panoramic image.	
	The sensor unit (detachable) is not detached to the docking station unit (Panoramic) when acquiring a 3D image.(**)	
Er83 (*)	Sensor (detachable) is not attached to Docking Station (Cephalo) when acquiring cephalometric image.	
Er84 (*)	Motor movement of the Cephalometric unit did not complete properly.	

* For equipment with Cephalometric
** For equipment with 3D function

Warning message code list

Warning Code	Description	Action
FL01	Notice of service maintenance services. Total No. of Exposure has exceeded 2,000.	It is recommended that you will perform regular checks. Contact your dealer.
FL02	The exposure switch has been pressed during selecting Exposure conditions.	It will be cancelled by the reset switch on the Control panel. Contact your dealer if it happens frequently.
FL03	The exposure switch has been pressed during X-ray cooling time period.	
FL05(**)	The head fixator for 3D image acquisition is attached other than in 3D image acquisition mode.	Pressing the reset switch on the control panel releases the error. Remove the head fixator for 3D image acquisition.
FL06(**)	The head fixator for 3D image acquisition is not attached in 3D image acquisition mode.	Pressing the reset switch on the control panel releases the error. Attach the head fixator for 3D image acquisition.

** For equipment with 3D function

6.2 Contact Procedures at the Time of Failure

If any problem persists even though the appropriate corrective measure described above has been taken, contact your dealer and provide information on:

1. Product name (X-era Smart) and its serial number (**-****).
2. Operation, which might cause the failure (as detailed as possible).
3. Current condition
   e.g.: An error message ○○ is displayed. The arm unit or sliding mechanism has stopped with .....
4. See the contacts described at the end of the manual.

7 Maintenance Services

X-era Smart has been designed so that the user may take full use of it reliably and satisfactorily over many years. To assure the operator's and the patient's safety in using the equipment, the user is responsible for performing preventive maintenance services.
To perform the preventive maintenance services, follow the instructions in Section "7.2 Periodical Checks" and "7.3 Periodical Check Services". If you desire to outsource the regular checks, feel free to contact your dealer. It should be noted that if you outsource these check services, they are not always performed just as described in the regular check list.

⚠ Caution

- To assure the operator's and the patient's safety in using the equipment, be sure to read through this section.

7.1 Cleaning

1. Cleaning coated surfaces
   Wipe out dirt on the coated surfaces of the equipment with a water-dampened soft cloth and then wipe away remaining moisture with a dry cloth.
2. Cleaning plated surfaces
   Wipe out dirt on the plated surfaces of the equipment with a water-dampened soft cloth and then wipe away remaining moisture with a dry cloth.
3. Cleaning exterior cover surfaces
   Wipe out dirt on the cover surfaces with a mild detergent-dampened, well-wrung soft cloth, and then wipe away remaining moisture with a dry cloth.
4. Cleaning the chin rest block and adaptor
   Wipe out dirt on the chin rest and adaptors for edentulous jaw and TMJ with a mild detergent-dampened, well-wrung soft cloth, and then wipe away remaining moisture with a dry cloth.
5. Cleaning the head support
   Remove the head and temporal head supports by pulling directly downward from the head support unit. Wipe off dirt (e.g. hair dressing) on the head and temporal head support with a mild detergent-dampened, well-wrung soft cloth, and then wipe away remaining moisture with a dry cloth.
6. Cleaning the PC
   Refer to the Instruction Manual provided with your PC to follow the appropriate cleaning procedure.

7. Cleaning the ear rod, nose support and carpus support (*)
   Dampen a soft cloth with mild detergent, wring well and wipe out dirt from the ear rod, nose support and carpus support. Wipe away moisture with a dry cloth.
8. Cleaning the X-ray irradiator (Head unit) and the image reception area (Sensor unit)
   Dampen a soft cloth with mild detergent, wring well and wipe out dirt. Wipe away moisture with a dry cloth. Make sure that there is no dust remained after cleaning.
9. Cleaning the head fixator for 3D image acquisition (**)
   Wring a soft cloth with neutral detergent absorbed, and thoroughly clean the forehead support and head band. Wipe off the water with a dry cloth.

* For equipment with Cephalometric
** For equipment with 3D function

⚠ Caution

- Wiping the plastic and painted surface with chemicals such as thinner, benzene and alcohol may cause change or discoloration and/or equipment failure. Use a soft cloth dampened with water to clean the equipment.

7.2 Periodical Checks

Periodical check list

No.	Check that:	Timing	Remarks
1	The power cable has been firmly inserted in the outlet.	pre-operation	
2	No cracks or scratches are found on the power cable.	pre-operation	
3	The unit has sit on the floor stably with no rattle. (For more information, see Step 1 of "7.4 Performing Regular Check Services")	pre-operation	
4	"The unit moves up and down properly with no abnormal noise. (For more information, see Step 2 of "7.4 Performing Regular Check Services")	pre-operation	
5	The power plug has not generated excessive heat.	as needed	
6	There is no object around the unit that may interrupt the image acquisition.	each time	
7	The power switch has been turned off after image acquisition.	each time	
8	The head support moves properly. (For more information, see Step 3 of "7.4 Performing Regular Check Services")	each time	
9	The unit acquires images properly. (For more information, see Step 4 of "7.4 Performing Regular Check Services")	each time	
10	The power cable has been unplugged from the outlet after image acquisition.	post-operation	

No.	Check that:	Timing	Remarks
11	X-ray irradiator (Head unit) and the image reception area (Sensor unit) are clean with no dent, dirt or dust.	pre-operation	

The user is responsible for performing the regular checks listed above.
For more information on how to perform regular checks, see "7.4 Performing Regular Check Services".

7.3 Periodical Check Services

The periodical checks listed below are required on the equipment.

Periodical check list

No.	Check that:	Timing	Remarks
1	Supply power (input power: 90-132V or 198-264 V) is supplied.	every 6 months	
2	The protective earth line is correctly connected to ground.	every 6 months	
3	QA (Quality Assurance)	every 6 months	

The user is responsible for performing the periodical checks listed above.
The periodical checks can be outsourced to a subcontractor. In such case, the checking items are differ from the above. Please see 7.3.1.
For more information on how to perform above periodical checks, see "7.4 Performing Regular Check Services".

7.3.1 Outsourcing the Periodical check services

The periodical check services can be outsourced to a subcontractor. The main check services are listed below. The details are described in the “maintenance and inspection list” kept by your dealer. Please ask the dealer for further information.

List of Periodical check by subcontractor

No.	Check that:	Timing	Remarks
1	Supply power (input power: 90-132V or 198-264 V) is supplied.	every 6 months	
2	The protective earth line has been connected to ground.	every 6 months	
3	X-ray output is normal.	every 6 months	
4	Operational safety, e.g., in arm rotating, is assured.	every 6 months	
5	All the sensors operate properly.	every 12 months	
6	Electrical safety is assured.	every 12 months	

7.3.2 Archiving records on Periodical check

To ensure the reliability and safety of X-era Smart, be sure to archive the result records on regular check and scheduled check services.

7.4 Performing Regular Check Services

1. Installation: The equipment is properly fixed to the floor.
   Check that the equipment has been stably installed with no rattle.
2. Column's up and down movement:
   Move the column up and down to check that it moves up and down properly with no abnormal noise.
3. Head support movement:
   (1) Open and close the head support while gripping its base.
   (2) Check that the head support opens and closes properly without any trouble or abnormal noise.

   For equipment with Cephalometric

   (3) Slide the ear rod knob to perform open and close movement, back and forth/up and down movement of nose support, and rotating movement of ear rod and nose support.
   (4) Check if there is no major trouble such as difficulty in the above movements or abnormal noise.
4. Image acquisition:
   (1) Acquire images in the Panoramic mode in the empty X-ray room for 16 seconds.
   (2) Check that the images have been imported in the PC.
   Observe the machine during image acquisition to check that the equipment operates properly as described below.
   1. The arm unit rotates smoothly.
   2. The arm rotates properly with no abnormal noise.

   For equipment with Cephalometric

   (3) Perform Cephalometric lateral image acquisition (LA) in a completely desolated X-ray room.
   (4) Check that the images have been imported to the PC.

   For equipment with 3D function

   (5) Unman the X-ray room and acquire 3D images (both oral and dental modes).
   (6) Check that image has been taken into the computer.
5. Power supply voltage (input power source):
   Use a Multimeter to check that the equipment has been correctly connected to an appropriate power outlet as described below.
   (1) Voltage range
   AC 90 ~ AC 132 V (with load* [1])
   AC 198 ~ AC 264 V (with load *[1])
   (2) Accuracy of a voltmeter (tester)
   AC Voltage ± (0.7% 2 digits) or its equivalents
   (3) Multimeter type
   True RMS type

(4) Procedure

1. Set the measurement range of the Multimeter to AC (measurable range 0 ~300 V).
2. Connect the Multimeter probe between both the polarities (L (line) - N (neutral) of the power outlet.

*1: “with load” indicates such a condition that the elevating motor or rotating arm is activated and/or X-ray is being irradiated.

6. Ground Protective earth

Check that the equipment has been connected to the correctly-grounded power outlet.

(1) Accuracy of a voltmeter (tester)
AC Voltage± (0.7% + 2 digits) or its equivalents

(2) Multimeter type
True RMS type

(3) Recommended Multimeters

1. Fluke 87 V (Fluke)
2. PC510 (SANWA)
3. 3802 (HIOKI)

or their equivalents

(4) Procedure

1. Set the measurement range of the Multimeter to AC (measurable range 0 ~ 300 V).
2. Connect the Multimeter probe to L (line) or N (neutral) of the power outlet.
3. Check that the results described below have been obtained.

(i) L-G (ground) voltage: AC 90 ~ AC 132 V or AC 198 ~ AC 264 V

7. QA (Quality Assurance)

Check the panoramic image of this equipment.

For equipment with 3D function, check the 3D image acquired as well.

See also: "12 QA (Quality Assurance)" P.187

⚠ Caution

- To avoid electrical shock, be sure to read the instruction manual supplied with the Multimeter carefully prior to use.

8 Disposal

This product cannot be disposed of as regular industrial waste. The customer is responsible for the proper disposal of this product with following the each countries'/local governments' regulation/code. For more information, please contact to your dealer.

Proper Disposal of Electronic Equipment

NOTE : The following information is valid in the European Union. If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

This symbol on the products and/or accompanying documents means that used electrical and electronic products should not be mixed with general household waste.

For proper treatment, recovery, and recycling, please take these products to designated collection points where they will be accepted on a free-of-charge basis. Alternatively, in some countries, you may be able to return your products to your local retailer upon the purchase of an equivalent new product.

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

Please contact your local authority for further details of your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste in accordance with national legislation.

NOTE : For Business users in the European Union
If you wish to discard electrical and electronic equipment, please contact your dealer or supplier for further information.

- Tubehead(Pb)
- Collimator(Pb)
- All electronic circuits
- Sensor covers(EMC painted)
- 3D Sensor covers(Pb)

9 Patient Positioning Part

Patient positioning part list

Item Name	Quantity
Chin rest block	1
Adaptor for edentulous jaw	1
TMJ adaptor (Panorama)	1
TMJ adaptor (CHILD)	1
Bite block (consumable) (accessory)	1
Head fixator for 3D image acquisition (**)	1
Bite plate (consumable) (**)	5

** For equipment with 3D function

⚠ Caution

- Do not use any part other than those listed in the above table.

10 List of Periodical Replacement Parts and Consumable Replacement Parts

10.1 Periodical Replacement Parts

The equipment contains no component.

10.2 Consumable Replacement Parts

The equipment contains consumable stores listed in the following table.
If you need to acquire any one of these consumable replacement parts, contact your dealer described at the end of this manual to provide information on your order (product name, part No. , and quantity).

Consumable store list

No.	Item Name	Remarks
1	Bite block	1
2	Bite plate	1

11 Main Specification

11.1 Specification

Item	Specifications			
Equipment type	Digital panoramic, tomographic X-ray diagnostic equipment, arm-type X-ray CT diagnostic equipment for dental use.			
Product name (Model name)	X-era Smart			
Type number	XP73			
Operating mode	Continuous operation with intermittent loading			
High-voltage generator	DC rectification			
X-ray tube focal spot size	0.5 mm × 0.5 mm			
X-ray tube cooling method	Oil cooling			
Nominal maximum electric power (combination of X-ray tube voltage and tube current at maximum output)	0.82 kW (82 kV, 10 mA)			
Tube voltage	58, 60, 63, 65, 68, 71, 73, 76, 79, 82 kV (±5%)			
Tube current	2.0, 2.5, 3.2, 4.0, 5.0, 6.3, 8.0, 10 mA (±15%)			
Exposure time	Panoramic	Panorama	8, 14, 16 sec	±(10% + 1ms)
		Child	6.4, 11.2, 12.8 sec	
	TMJ		4 sec × 2	
	Single		0.10, 0.12, 0.16, 0.20, 0.25, 0.32, 0.40, 0.50, 0.63, 0.80, 1.00, 1.20, 1.60, 2.00, 2.50, 3.20 sec	
	Cephalometric / Carpus image acquisition (*)		8, 10 sec	
	3D Oral image radiography (**)		11.5 seconds x 2	
	3D Dental image acquisition (**)		11.5 seconds	
Photographing direction	Panorama, TMJ and 3D Oral: clockwise/counterclockwise, 3D Dental: clockwise rotation			
Image magnification factor	Panoramic image acquisition, TMJ image acquisition		1.2 - 1.29	
	Cephalometric / Carpus image acquisition (*)		1.1	
Filter type	Add Filter 1.5 mmAl			
	Exposure orifice plate 0.17 mmAl Criteria: Tube Voltage / Current = 85 kV / 12 mA			
Total filtration	2.5 mmAl equivalent or over (at Tube voltage: 82 kV)			
Leakage dose	0.88 mGy/h or less			
Leakage dose calculation standards	Tube voltage 82 kV, tube current 10 mA, Duty cycle 1:40			
Duty cycle	1:40			

Item	Specifications	
Radiation dose ($CTDI_{100}$) (*2)	Standard image acquisition : 3D oral 58 kV, 2.0 mA: 2.0 mGy (center value), 2.0 mGy (surrounding value)	
	Other image acquisition conditions (when the standard image acquisition is set as 1) 3D Oral 71 kV, 6.3mA: 5.7 (center value), 5.7 (surrounding value) 82 kV, 10.0mA: 13 (center value), 12 (surrounding value) 3D Dental 58 kV, 2.0mA: 0.58 (center value), 0.56 (surrounding value) 71 kV, 6.3mA: 3.3 (center value), 3.1 (surrounding value) 82 kV, 10.0mA: 7.8 (center value), 6.6 (surrounding value)	
Linearity of X-ray output	±5%	
Pixel	100 μm isotropic/pixel	
	Matrix 64 × 1510 (Panoramic) 64 × 2266 (Cephalometric) 672 × 992(3D)	
Dimensions of the Exposure field of the image reception area	6.4 mm × 151 mm (Panoramic), 6.4 mm × 226.6 mm (Cephalometric)	
SID/SOD (Panoramic)	485 mm / 350 mm	(19.1 inch / 13.8 inch)
SID/SOD (Cephalometric) (*)	1650 mm / 1500 mm	(65.0 inch / 59.1 inch)
SID/SOD(3D) (**)	570mm/350mm	(22.4inch/13.8inch)
FOV (**)	3D Oral image radiography	Diameter 77mm, height 54mm
	3D Dental image acquisition	Diameter 40mm, height 57mm
Emergency stop method	Deadman-type / emergency stop switch	
Rated power	Number of phases Single phase	
	Frequency: 50 Hz/60 Hz	
	Power supply voltage: AC 100V-120V±10 / AC220V-240V±10	
	Input: 2.0 kVA	
	Apparent Resistance Of Supply Mains R ≤0.3Ω	
Wiring circuit breaker (fuse) type and capacity	AC 100V-120V	20A over-current release
	AC 220V-240V	10A over-current release
Classification	Class I, Type B	
Durable period	10 years (when prescribed maintenance and inspections are performed)	
Up-and-down stroke	800 mm (short type: 400 mm)	
Weight	Standing position wall-mount: Panoramic type: 130 kg	
	Standing position wall-mount short type: Panoramic type: 125 kg	
	Standing position wall-mount long type: Panoramic type: 135 kg	
	Standing position base-mount (with an optional base(*3)): Panoramic type: 155 kg	
	Standing position base-mount short type (with an optional base(*3)): Panoramic type: 150 kg	
	Standing position base-mount long type (with an optional base(*3)): Panoramic type: 160 kg	
	Standing position wall-mount: Cephalometic type: 170 kg	

Item	Specifications	
Weight	Standing position wall-mount short type: Cephalometic type: 165 kg	
	Standing position wall-mount long type: Cephalometic type: 175 kg	
	Standing position base-mount (with an optional base(*3)): Cephalometic type: 195 kg	
	Standing position base-mount short type (with an optional base(*3)): Cephalometic type: 190 kg	
	Standing position base-mount long type (with an optional base(*3)): Cephalometic type: 200 kg	
	Standing position wall-mount: 3D type 140 kg	
	Standing position wall-mount short type: 3D type 135kg	
	Standing position wall-mount long type: 3D type 145kg	
	Standing position base-mount (with an optional base (*3)): 3D type 165kg	
	Standing position base-mount short type (with an optional base (*3)): 3D type 160kg	
	Standing position base-mount long type (with an optional base (*3)): 3D type 170kg	
	Standing position wall-mount: 3D & Cephalometric type 180kg	
	Standing position wall-mount short type: 3D & Cephalometric type 175kg	
	Standing position wall-mount long type: 3D & Cephalometric type 185kg	
	Standing position base-mount (with an optional base (*3)): 3D & Cephalometric type 205kg	
	Standing position base-mount short type (with an optional base (*3)): 3D type & Cephalometric type 200kg	
	Standing position base-mount long type (with an optional base (*3)): 3D type & Cephalometric type 210kg	
Operating condition	Temperature	10 to 40°C (50 to 104°F)
	Relative humidity	30 to 75% (no condensation)
	Atmospheric pressure	700 to 1060 hPa
Required storing and shipping condition	Temperature	5 to 45°C (41 to 113°F)
	Humidity	30 to 75% (no condensation)
	Atmospheric pressure	700 to 1060 hPa
Recommended PC Performance, specifications	(1) CPU: Intel Core2 Duo 3.0 GHz or faster	
	(2) RAM: DDR3 2GB or larger (4GB or larger(**))	
	(3) HDD: 80GB or larger	
	(4) Resolution of monitor: True Color (24bit RGB), SXGA (1280 × 1024) or higher	
	(5) Network: Dedicated Gigabit Intel / 3Com / Marvel chipset	
	(6) OS: Microsoft Windows® XP SP3 Microsoft Windows® 7 SP1 (Microsoft Windows® Vista is not supported.)	
	(7) PC and monitor must have CE marking	

Item	Specifications
Recommended PC	HP Z400 Workstation (Microsoft Windows® 7 32bit)
Recommended Viewer	Trophy Windows (V6.12.12.0), MEDIA DENT (V6), DBS Win (ver.5.2.0) Apteryx Imageing (ver.3.12), SIDEXIS XG (ver.2.52)

* For equipment with Cephalometric

** For equipment with 3D function

*1 This product is automatically stopped when the thermal circuit breaker attached to the X-ray tube head senses the temperature of 60 ±5℃ (140 ±41°F)

*2 The position of the phantom when CTDI100 is measured is where the rotating center of the arm and the central axis of the phantom are matched, and the central point of the length of the probe in the phantom at the direction of the axis and the height of focal point of the Z-ray bulb are matched.

*3 Add 5kg in case of optional wide base.

*4 Peak tube potential (Tube voltage) and Tube current are calculated from a reference-voltage signal (feedback signal) measured at the control PCB by using a digital multimeter. The waveform of the signals will become stable within 0.1 sec from the beginning of exposure, however response of multimeter needs few seconds therefore the exposure time during the measurement is set to a time, which is enough to measure a sufficiently stable reference-voltage signals.

*5 This product employs a laser and was evaluated to CDRH 21 CFR Parts 1010 and 1040 using additional allowance of Laser Notice 50 and determined to be a Class 2 Laser Product with Class 2 Laser radiation.

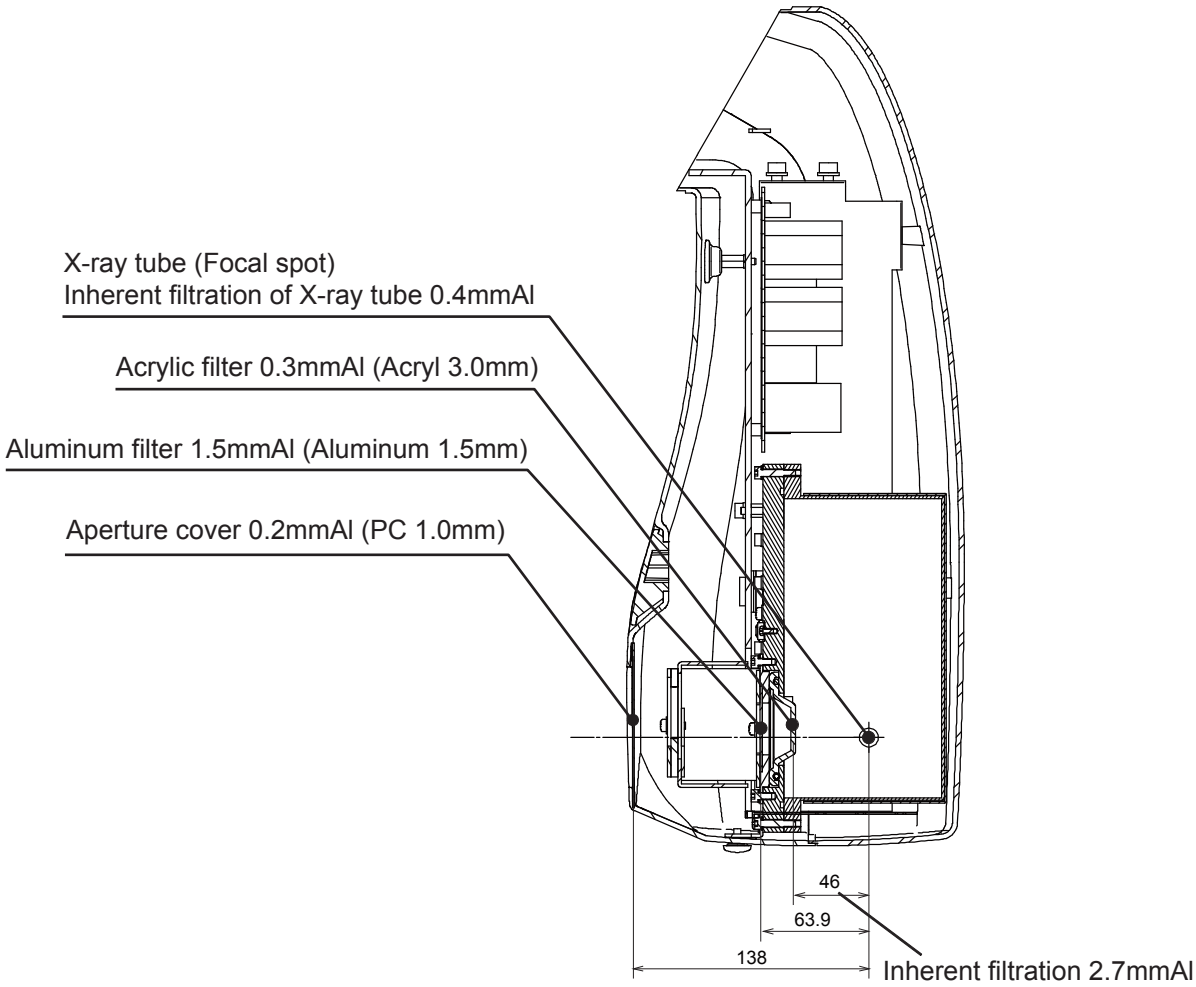
This product complies with the following EMC standards.

IEC 60601-1: 1988/A1: 1991/A2: 1995
IEC 60601-1-2: 2001/A1: 2004
IEC 60601-1-3: 1994
IEC 60601-1-4: 1996/A1: 1999
IEC 60601-1-6: 2004
IEC 60601-1-8: 2006
IEC 60601-2-7: 1998
IEC 60601-2-28: 1993
IEC 60601-2-32: 1994
IEC 60601-2-44: 2001/A1: 2002
IEC 60336: 2005
IEC 61223-3-4: 2000
IEC 61223-3-5: 2004
IEC 60825-1: 2007
IEC 62304: 2006
IEC 62366: 2007
UL 60601-1: 2003
CAN/CSA -C22.2 No. 601-1-M90

This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture.
X-era Smart is in conformity with the provisions of Council Directive 93/42/EEC as amended by the Directive 2007/47/EC concerning medical devices.
Performance Standards and European Union Directive 93/42/EEC (Medical Devices Directive).

CE
0086

11.2 Filter Specifications

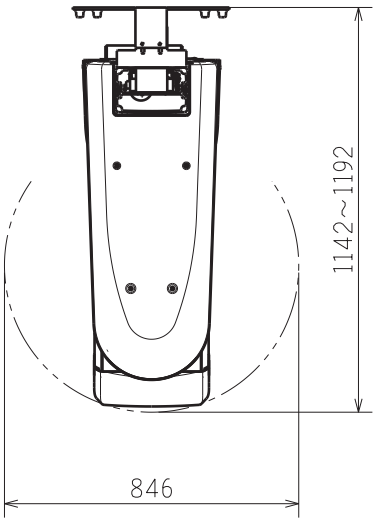


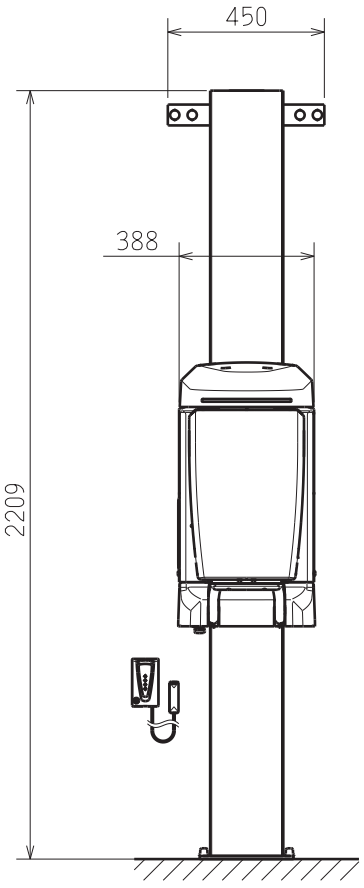
Total filtration : more than 2.5mmAl / 82k

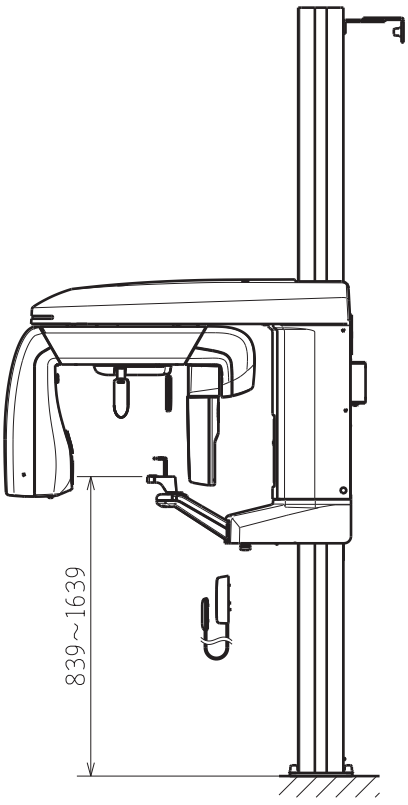
11.3 Dimensional Drawing

11.3.1 Standing position wall-mount: Panoramic type

Unit: mm

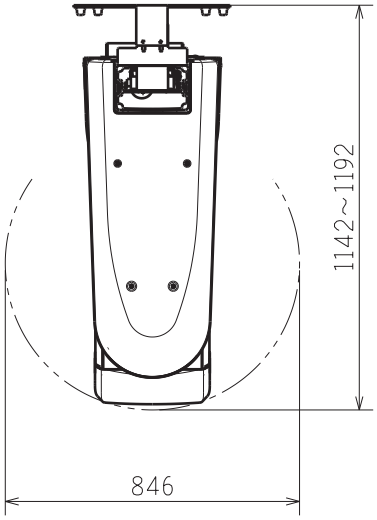


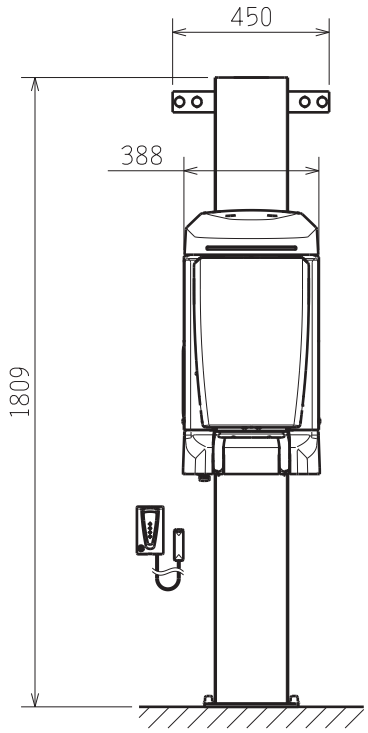


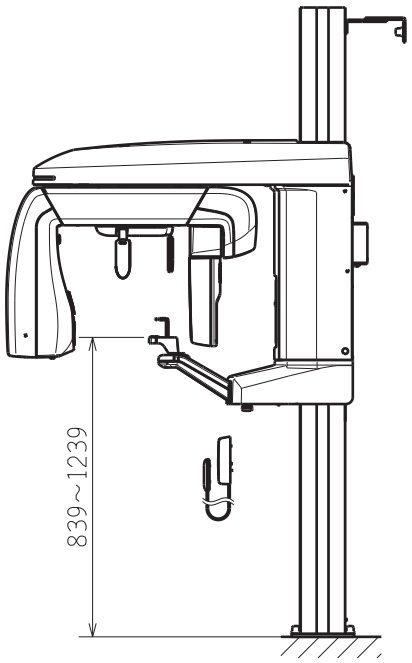


11.3.2 Standing position wall-mount short type: Panoramic type

Unit: mm

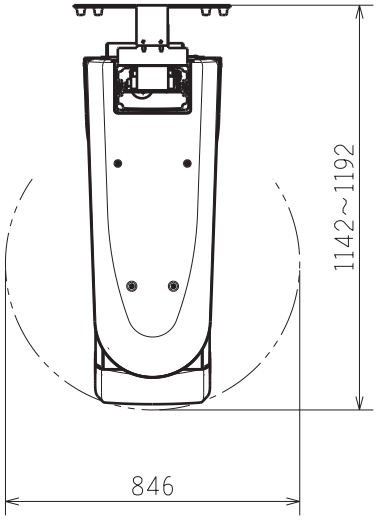


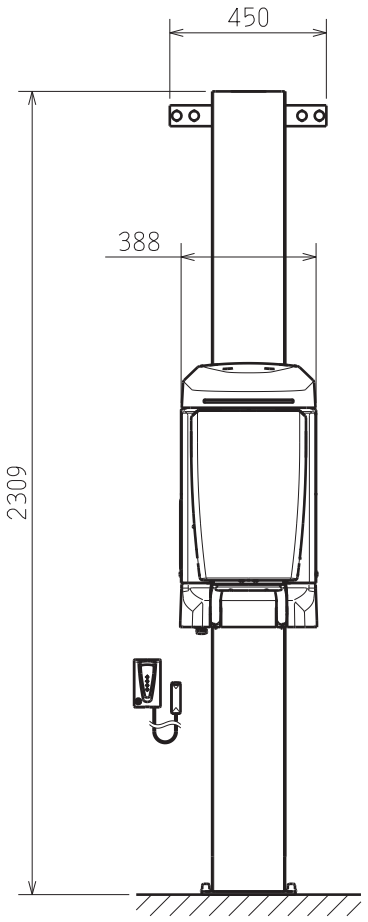


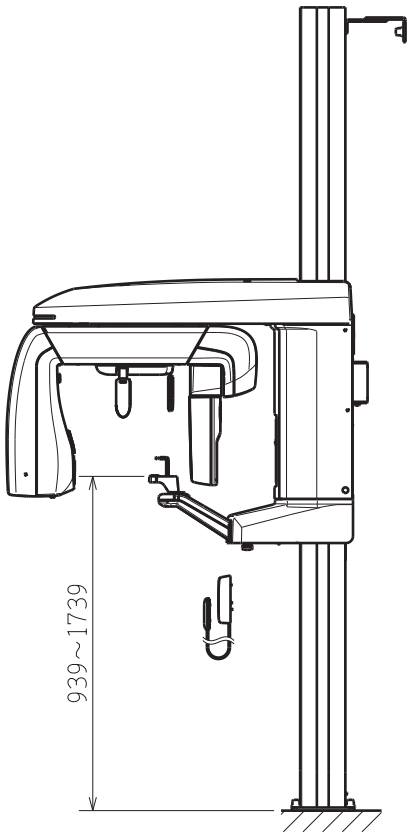


11.3.3 Standing position wall-mount long type: Panoramic type

Unit: mm

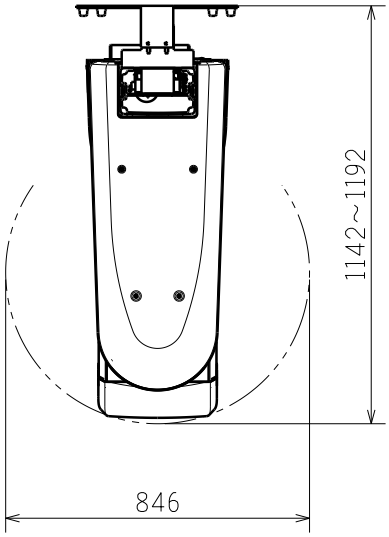


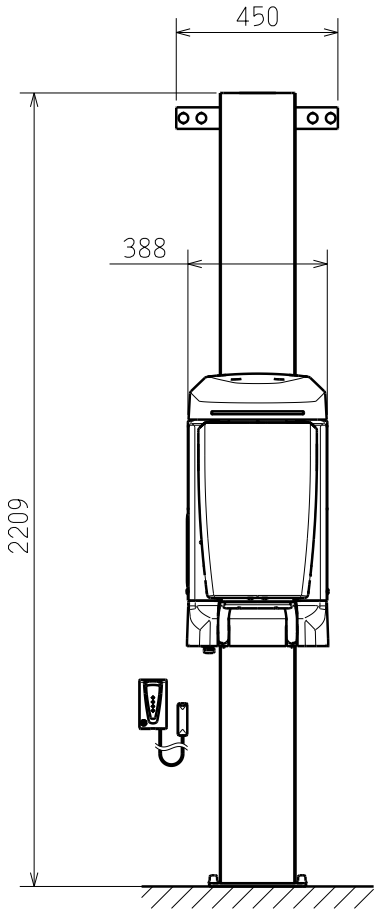


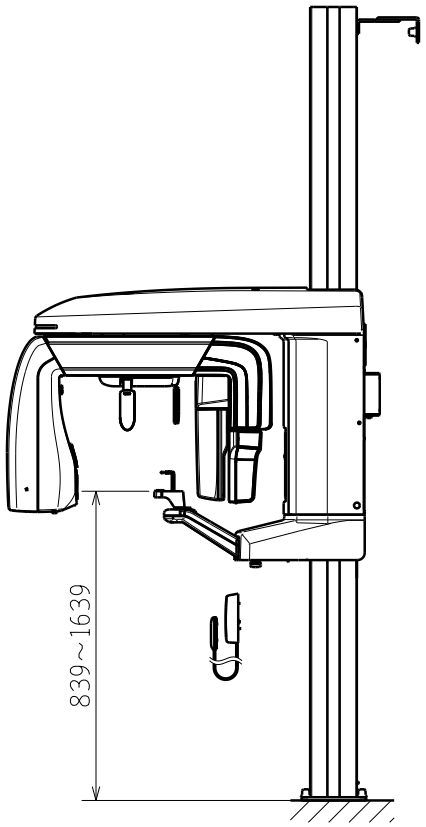


11.3.4 Standing position wall-mount: 3D type

Unit: mm

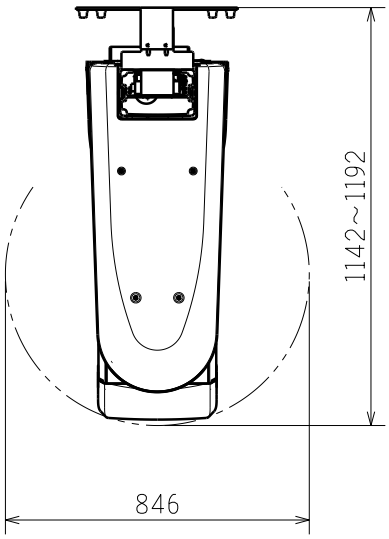


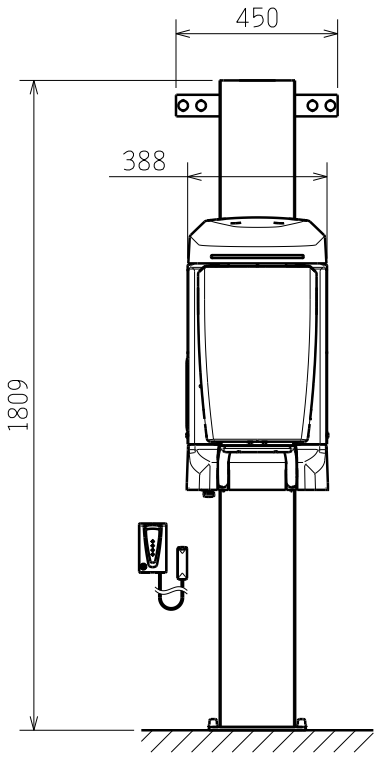


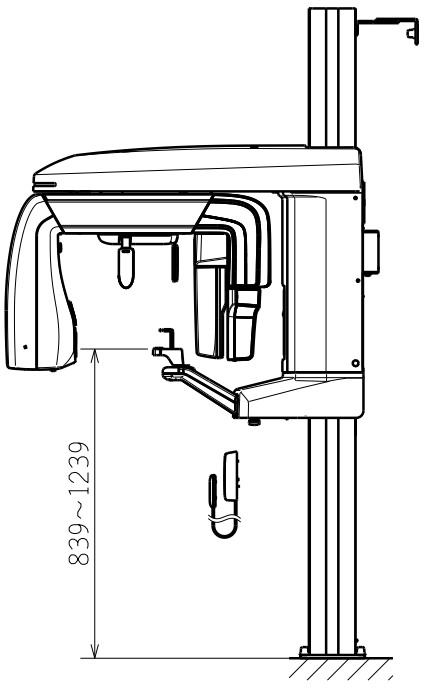


11.3.5 Standing position wall-mount short type: 3D type

Unit: mm

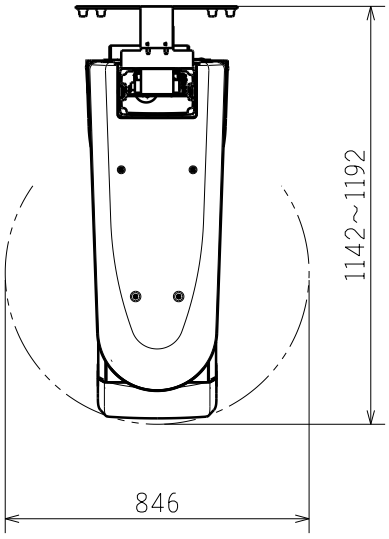


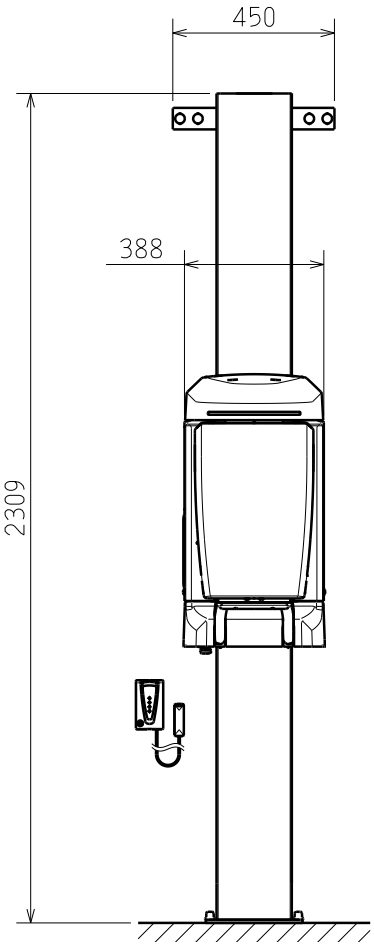


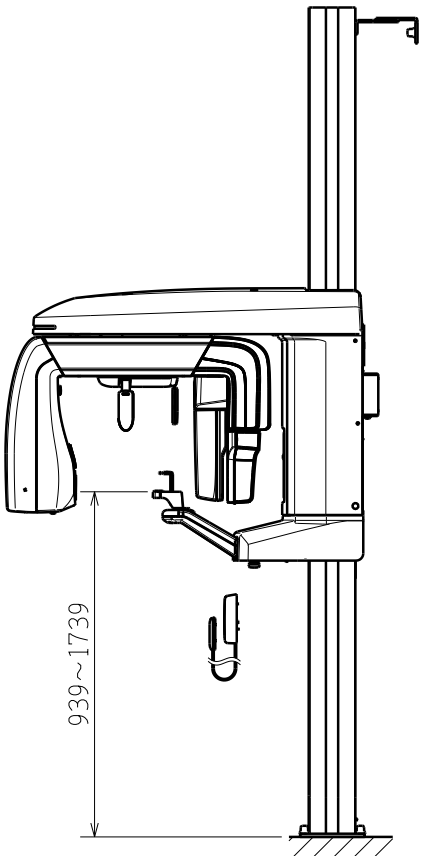


11.3.6 Standing position wall-mount long type: 3D type

Unit: mm

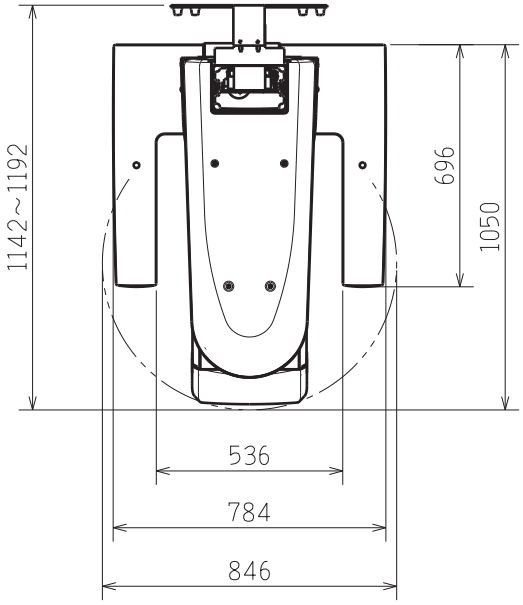


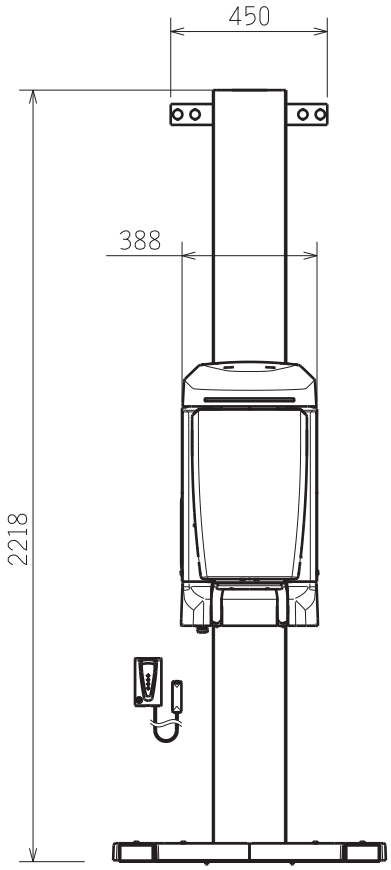


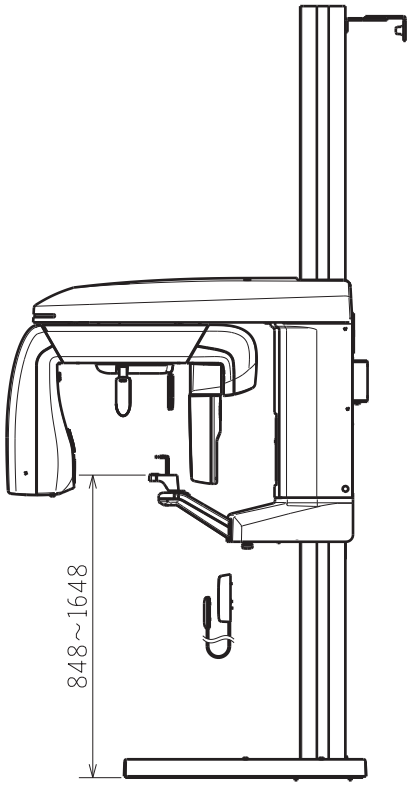


11.3.7 Standing position base-mount (with an optional base): Panoramic type

Unit: mm

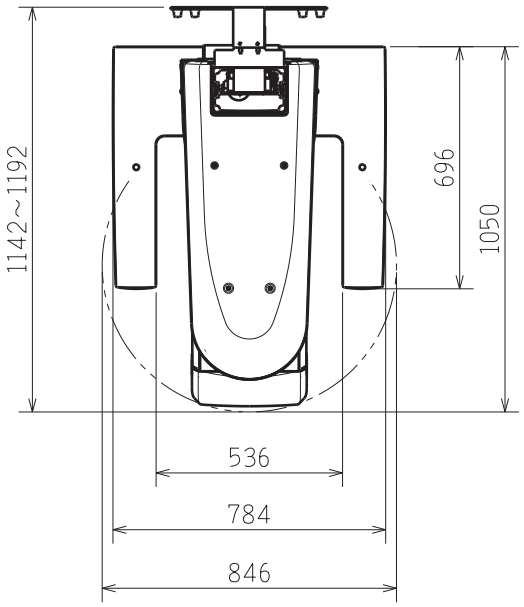


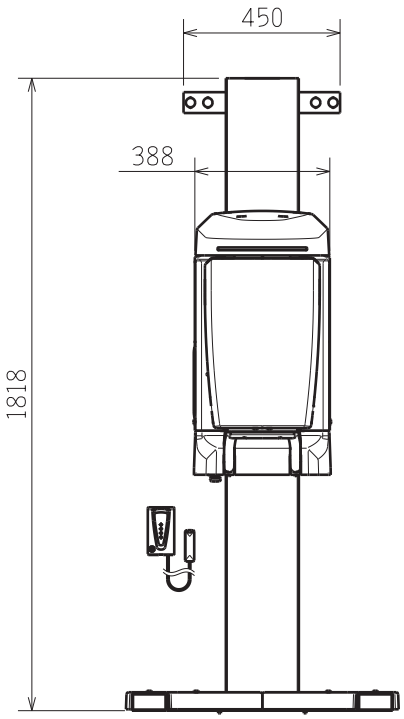


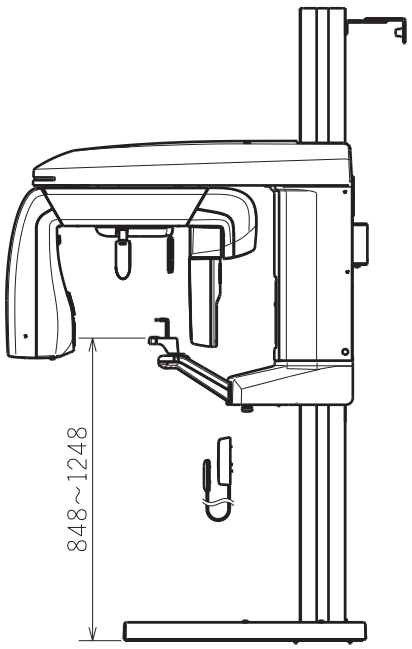


11.3.8 Standing position base-mount short type (with an optional base): Panoramic type

Unit: mm

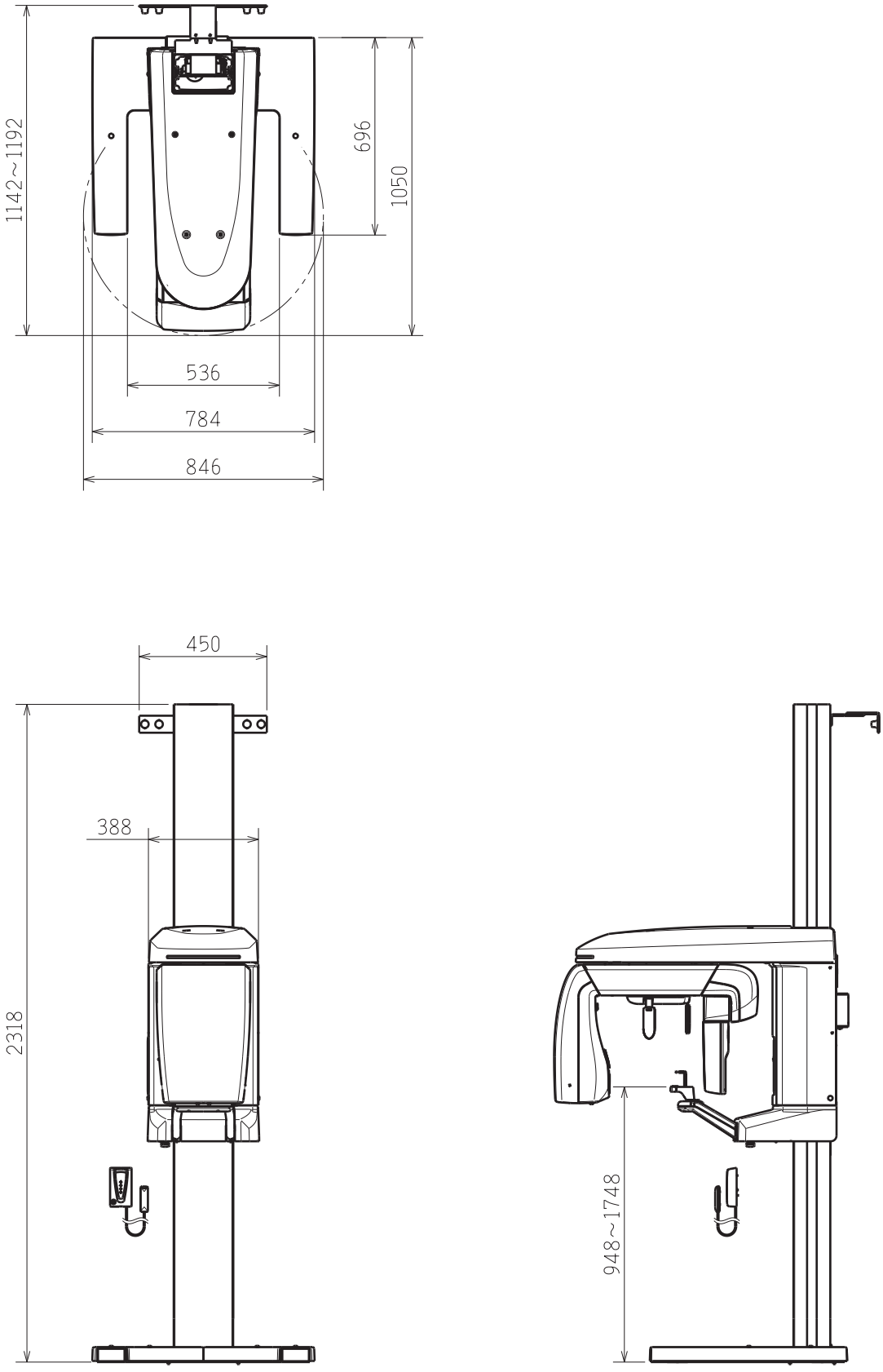






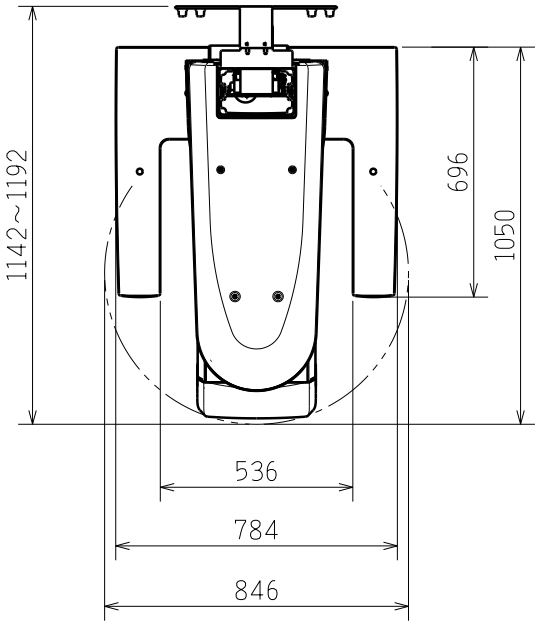
11.3.9 Standing position base-mount long type (with an optional base): Panoramic type

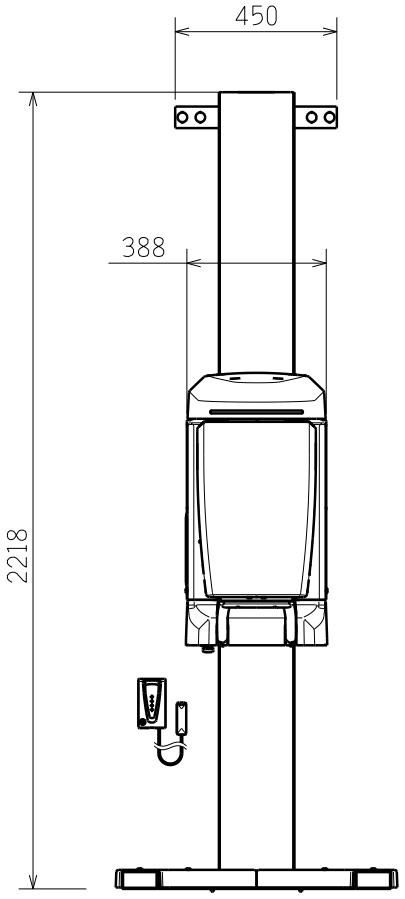
Unit: mm

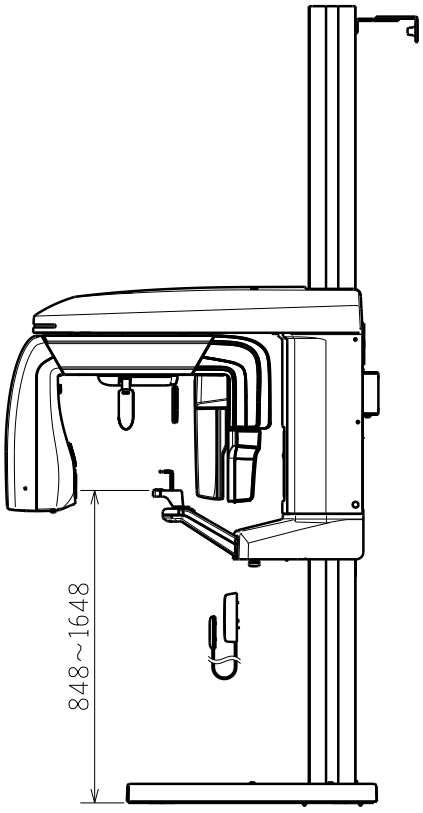


11.3.10 Standing position base-mount (with an optional base):3D type

Unit: mm

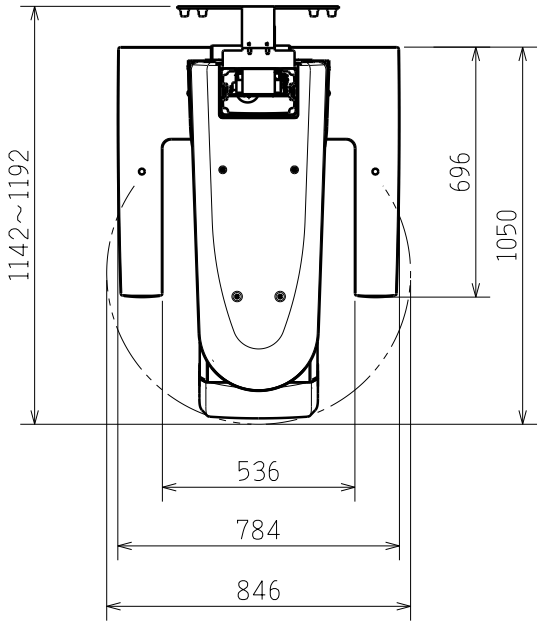


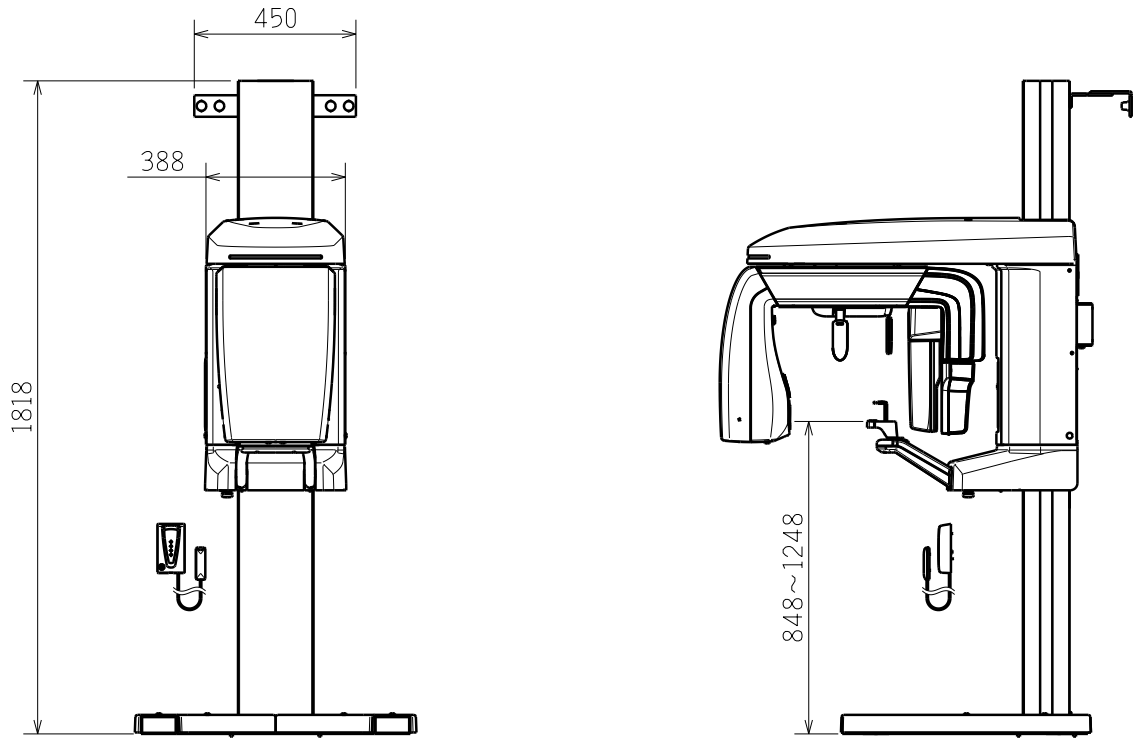




11.3.11 Standing position base-mount short type (with an optional base): 3D type

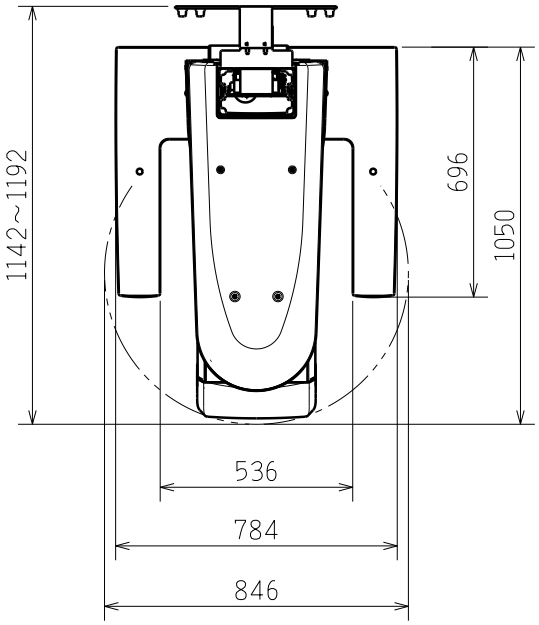
Unit: mm

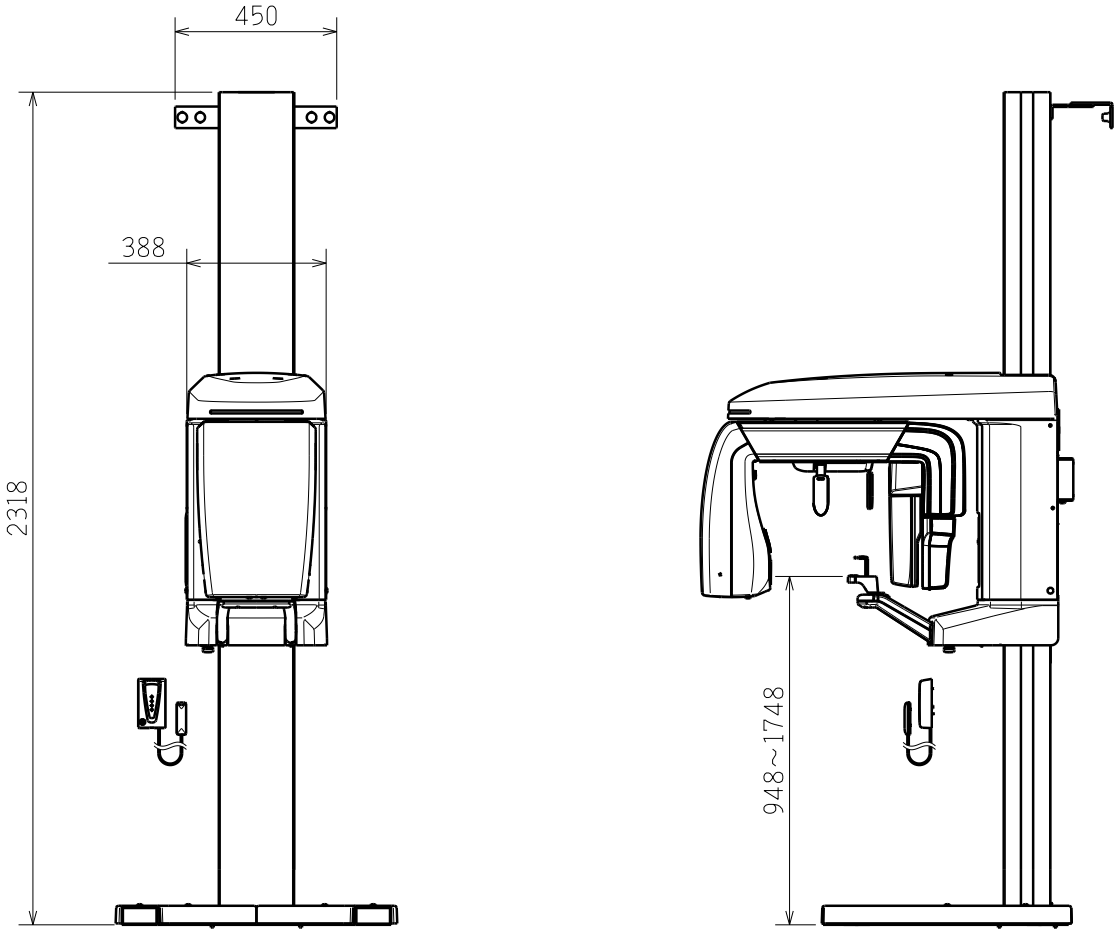




11.3.12 Standing position base-mount long type (with an optional base): 3D type

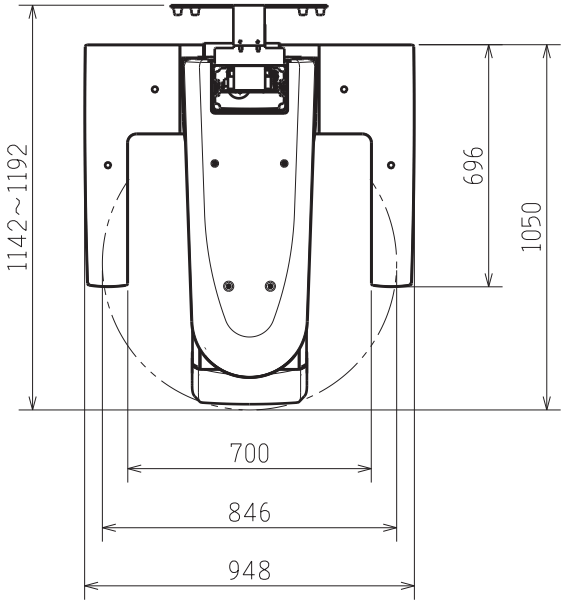
Unit: mm

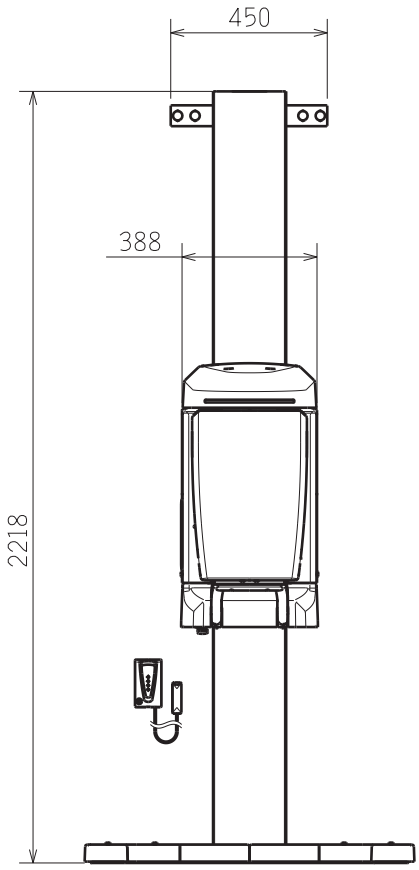


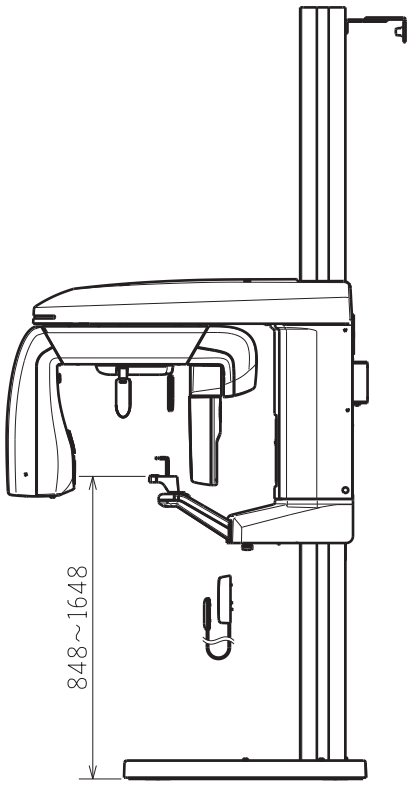


11.3.13 Standing position base-mount (with an optional wide base): Panoramic type

Unit: mm

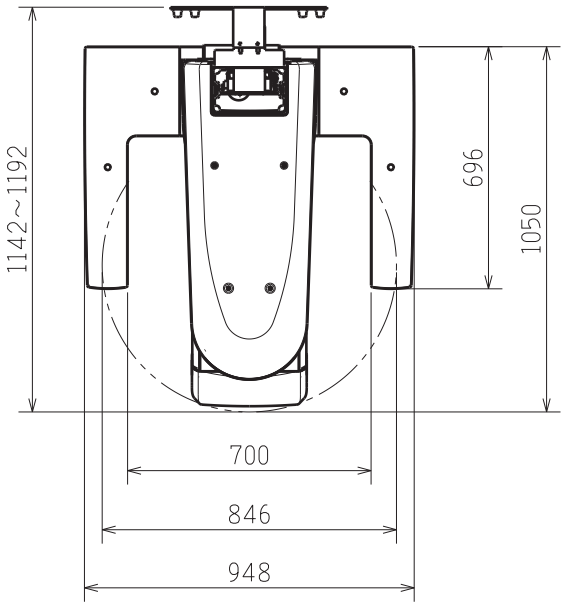


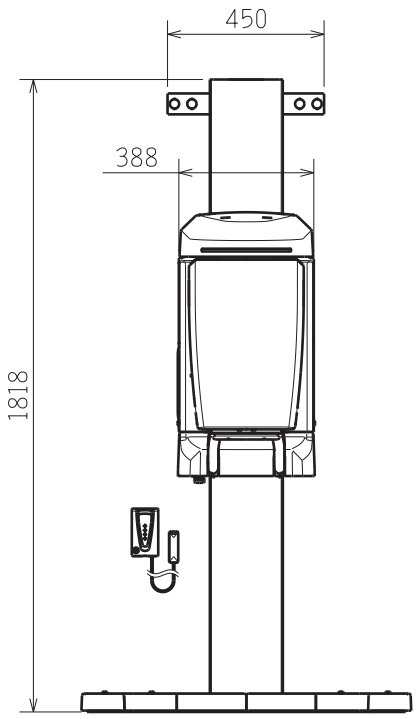


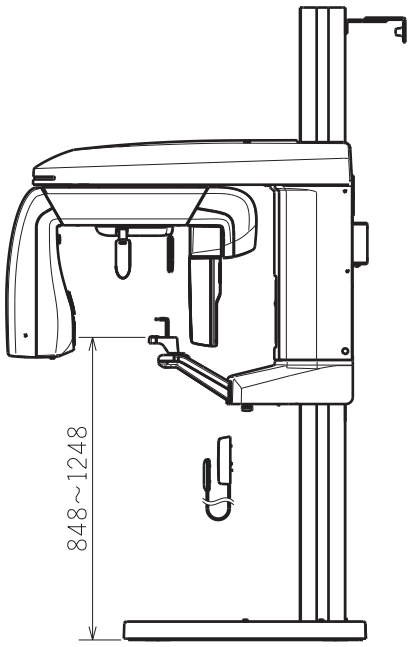


11.3.14 Standing position base-mount short type (with an optional wide base): Panoramic type

Unit: mm

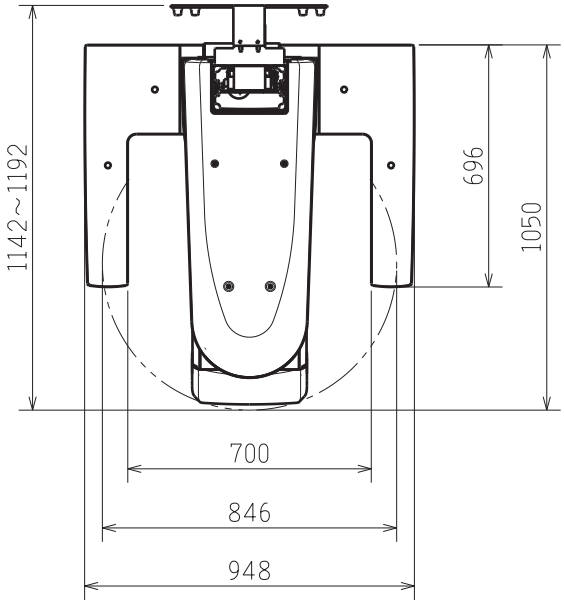


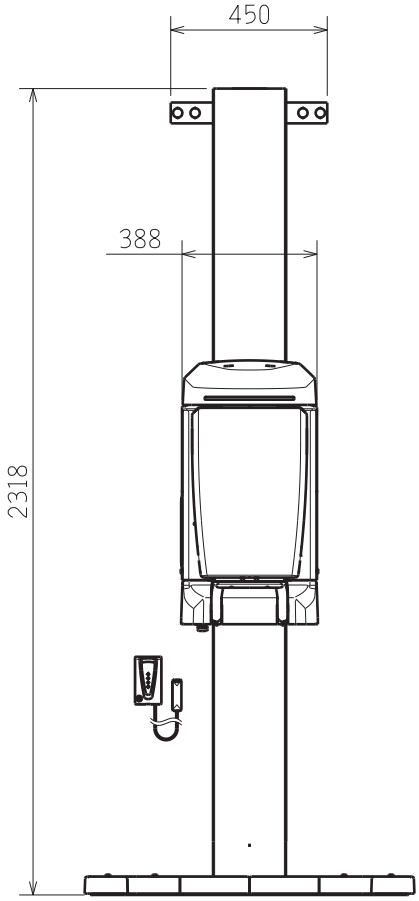


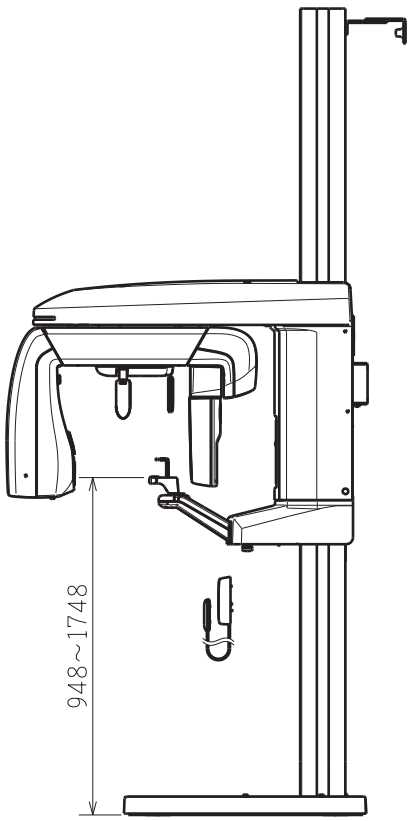


11.3.15 Standing position base-mount long type (with an optional wide base): Panoramic type

Unit: mm

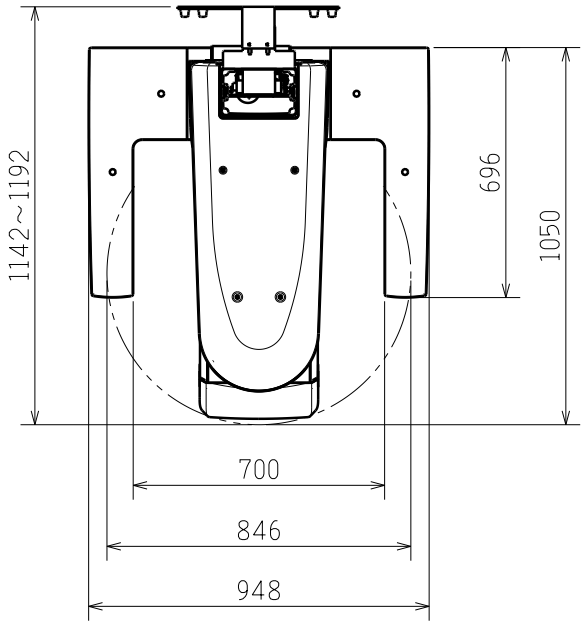


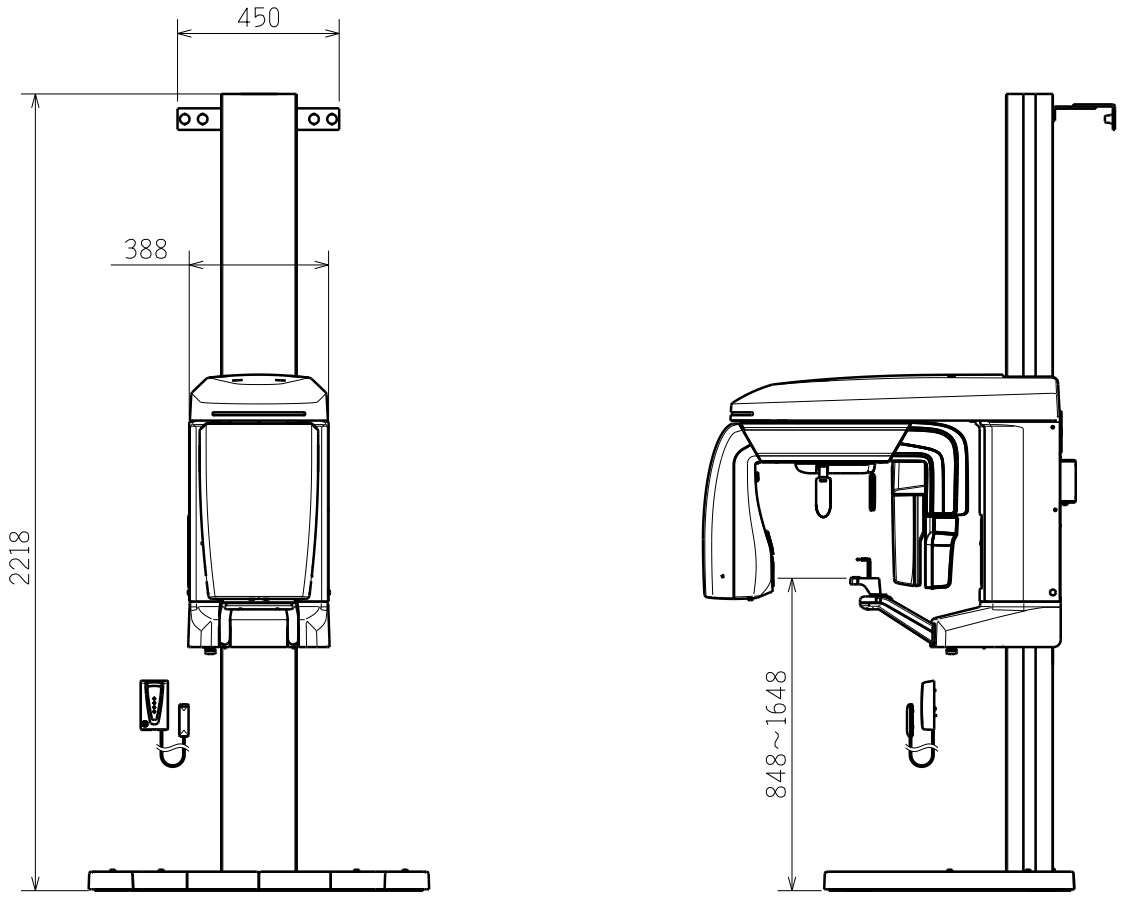




11.3.16 Standing position base-mount (with an optional wide base): 3D type

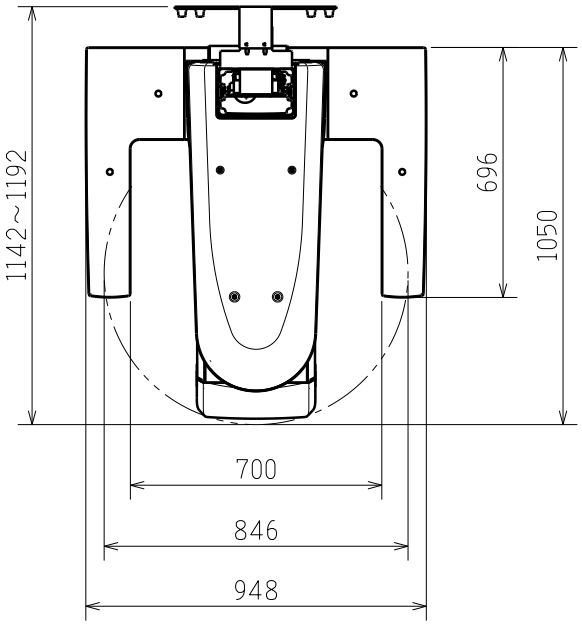
Unit: mm

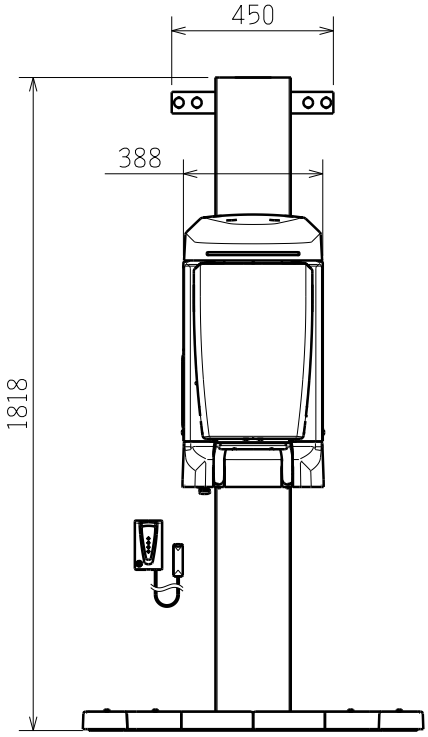


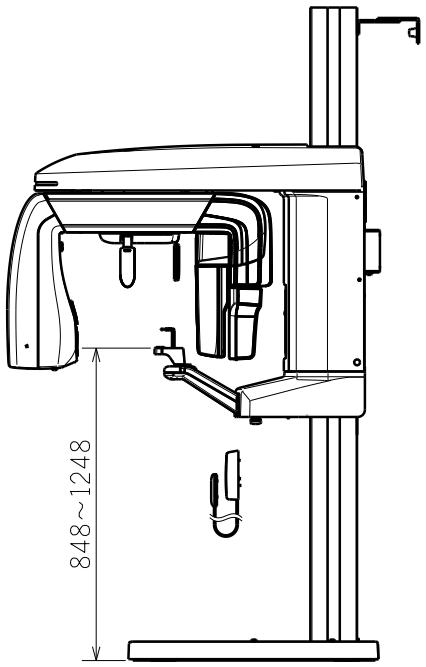


11.3.17 Standing position base-mount short type (with an optional wide base):3D type

Unit: mm

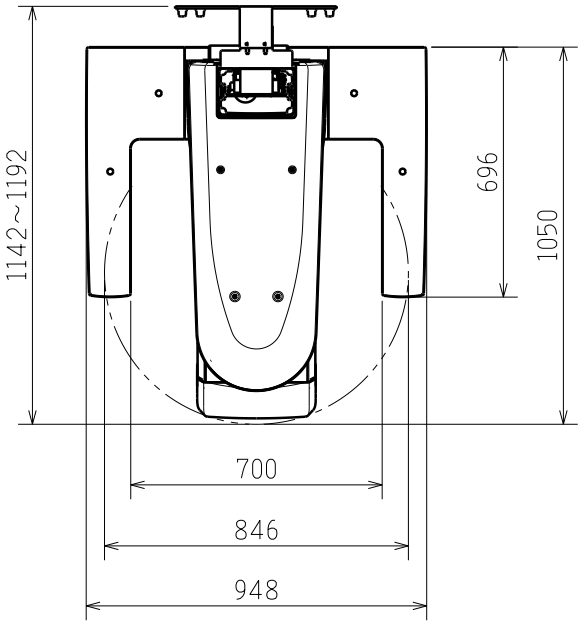


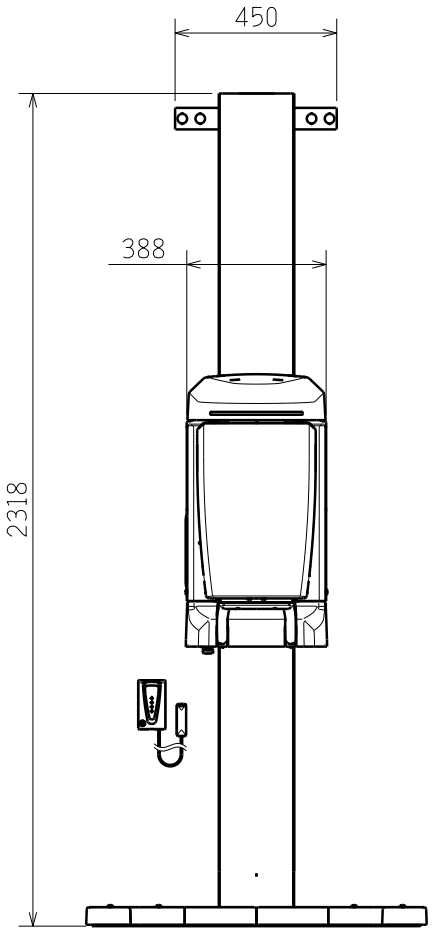


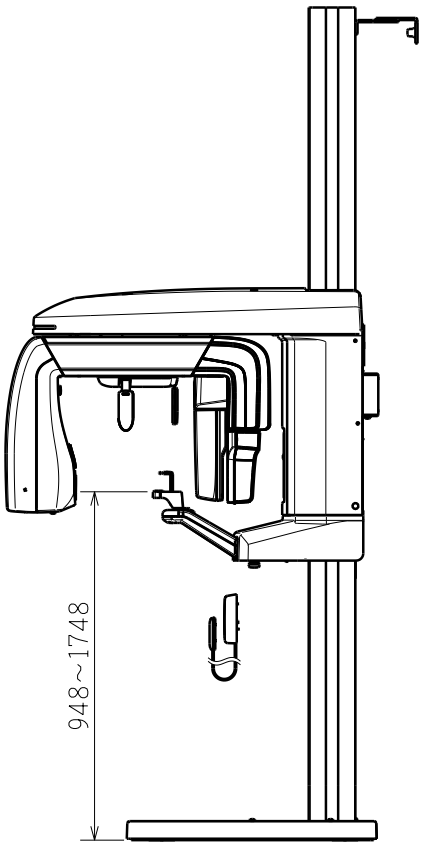


11.3.18 Standing position base-mount long type (with an optional wide base):3D type

Unit: mm

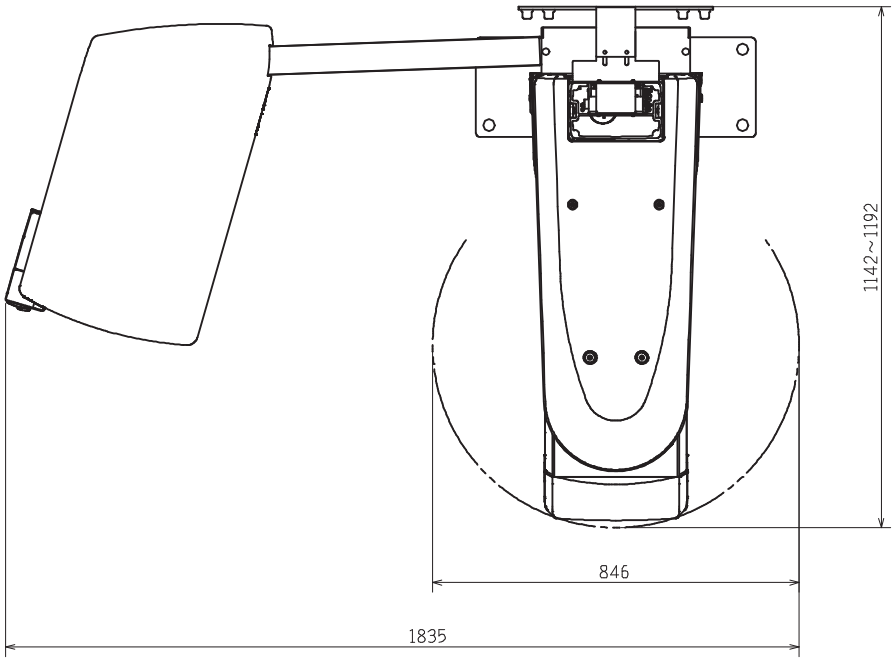


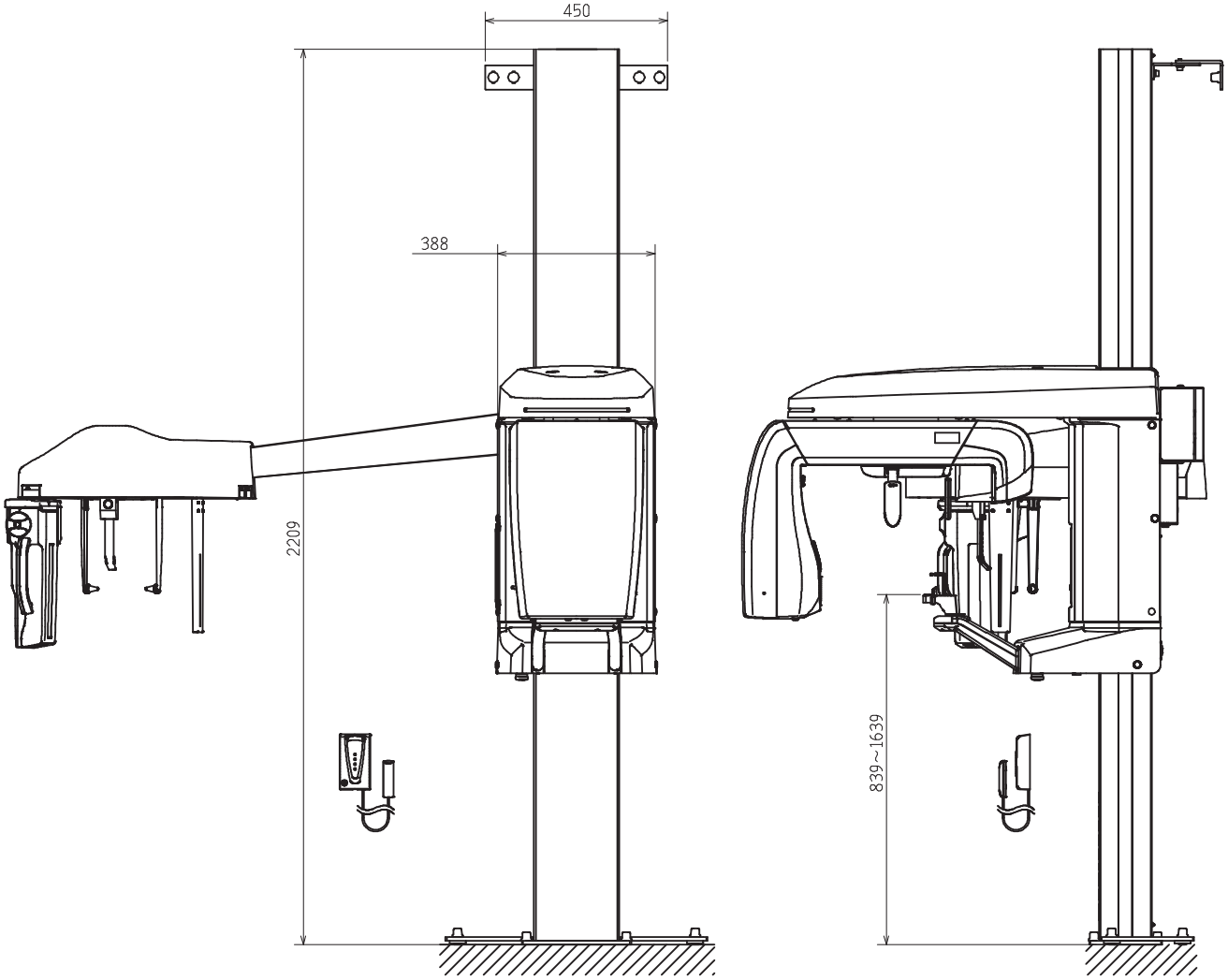




11.3.19 Standing position wall-mount: Cephalometic type

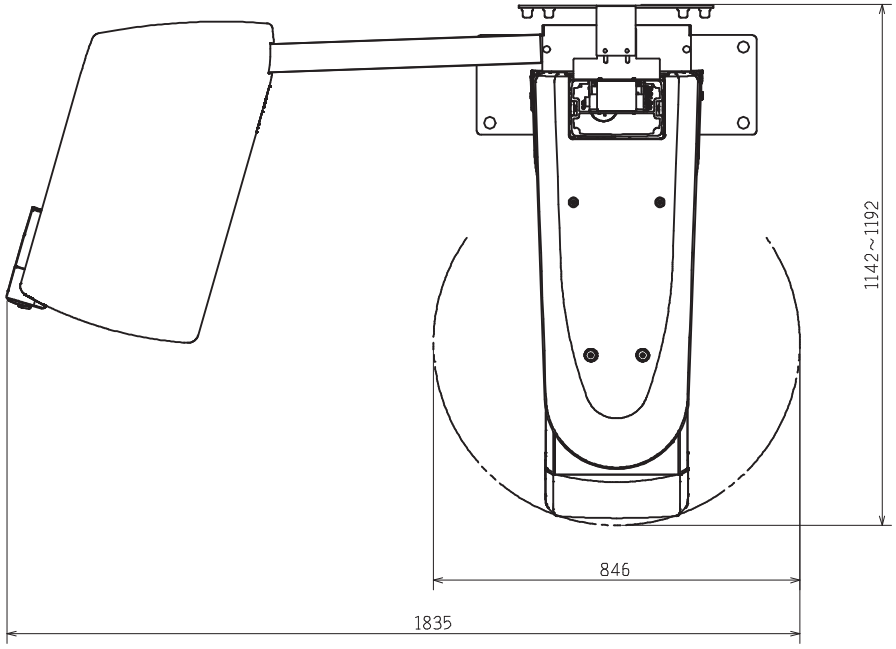
Unit: mm

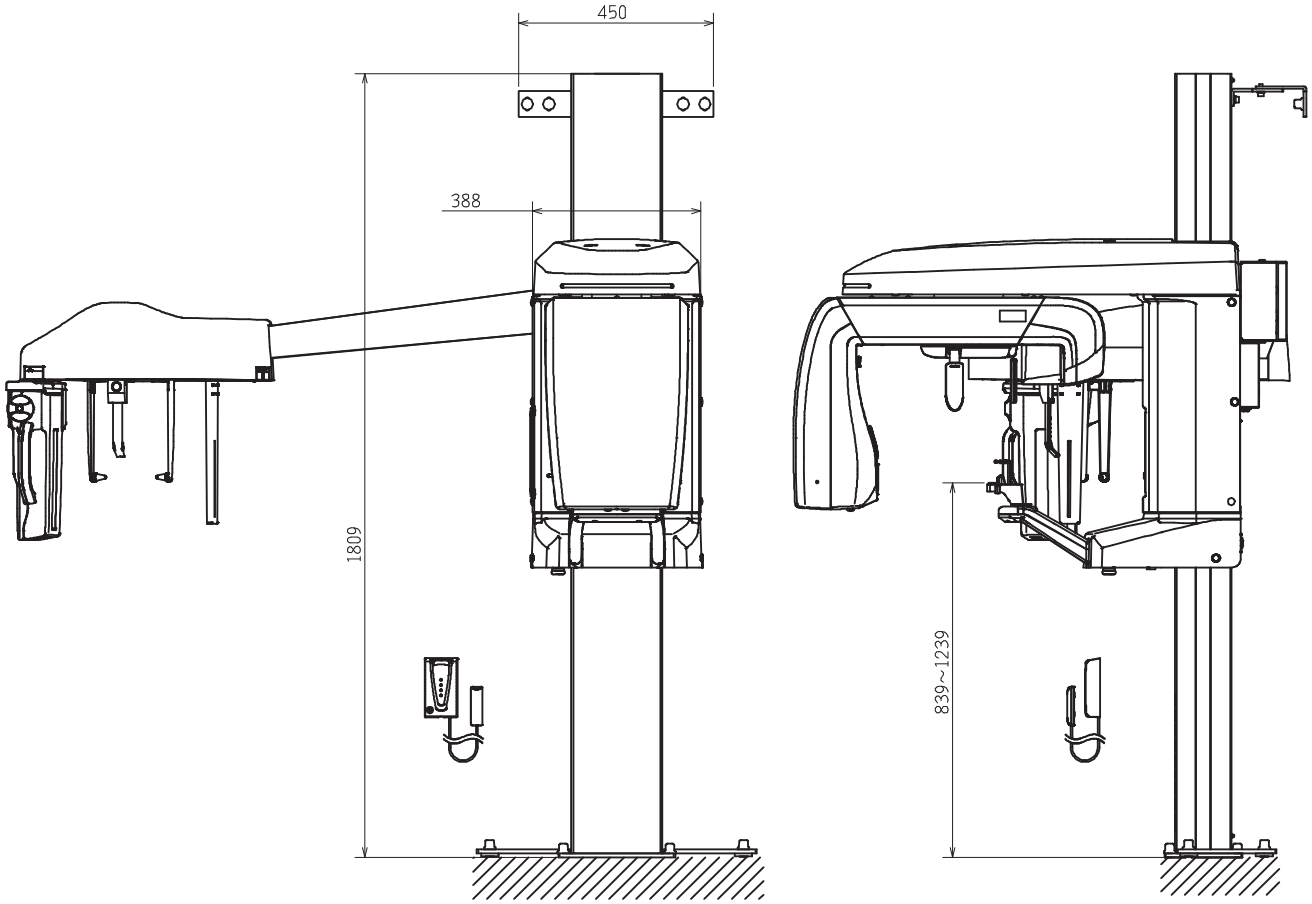




11.3.20 Standing position wall-mount short type: Cephalometic type

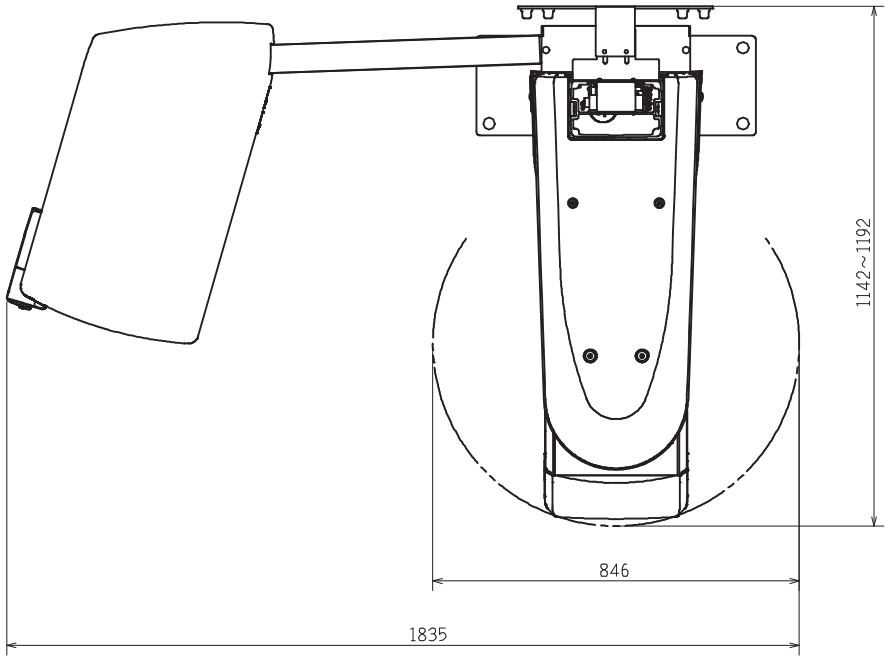
Unit: mm

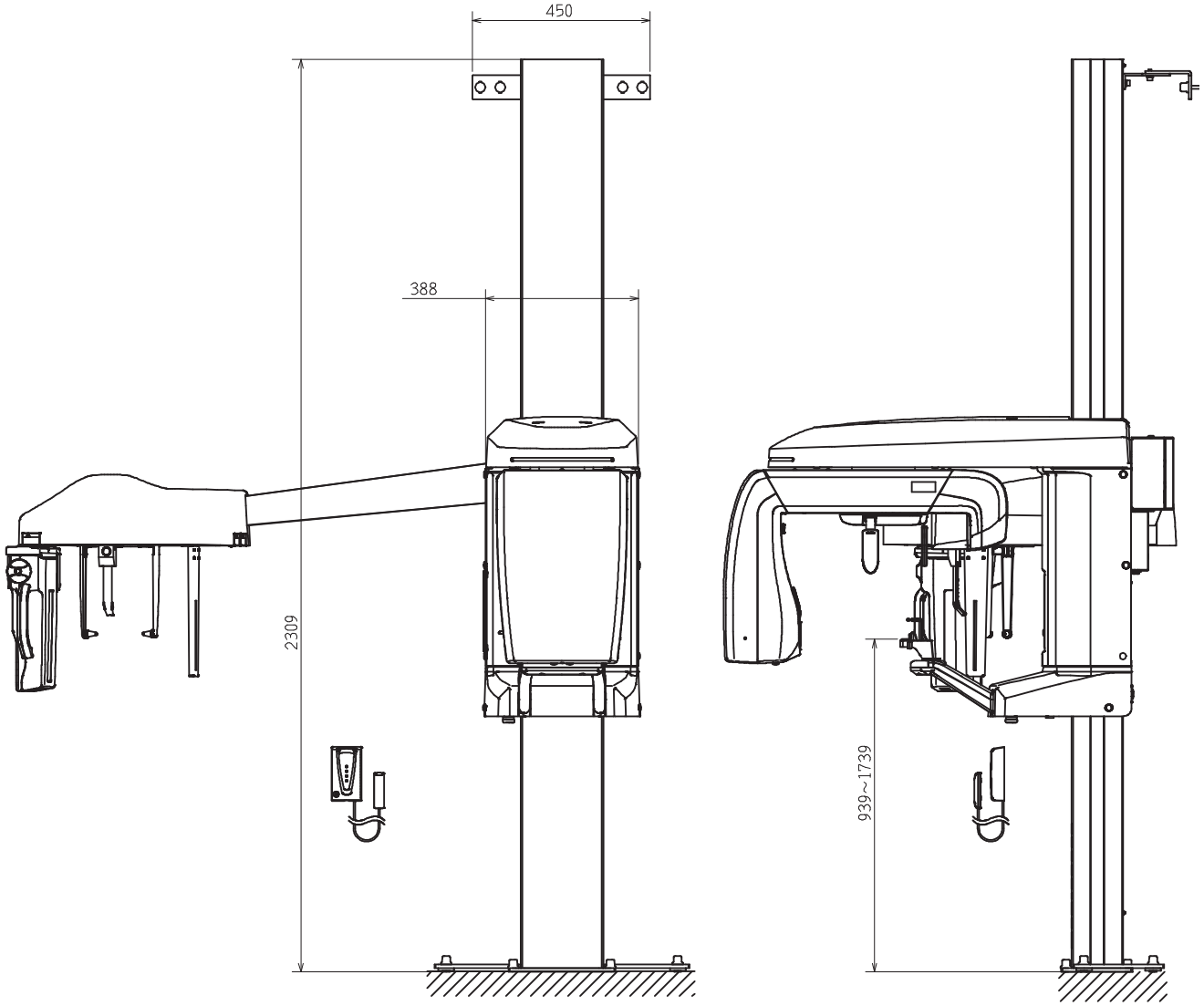




11.3.21 Standing position wall-mount long type: Cephalometic type

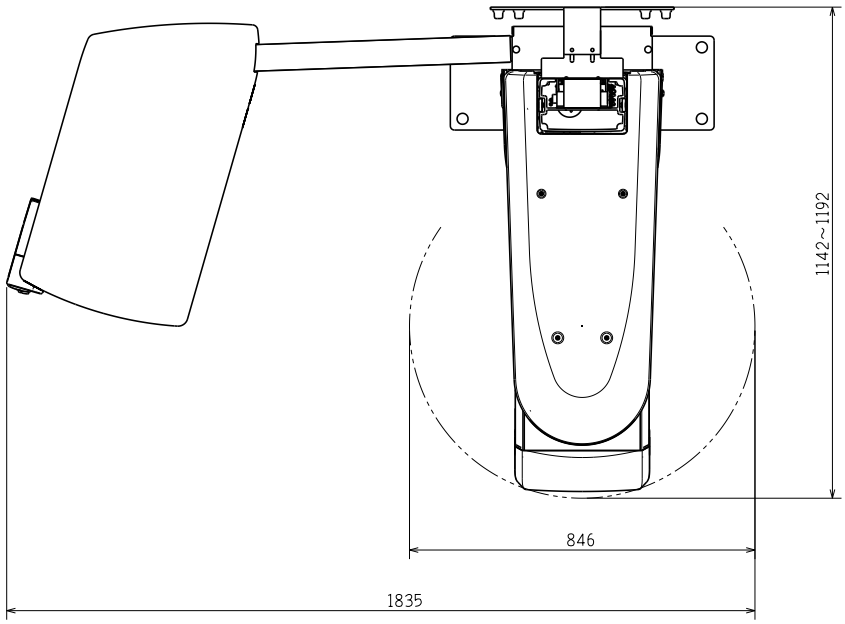
Unit: mm

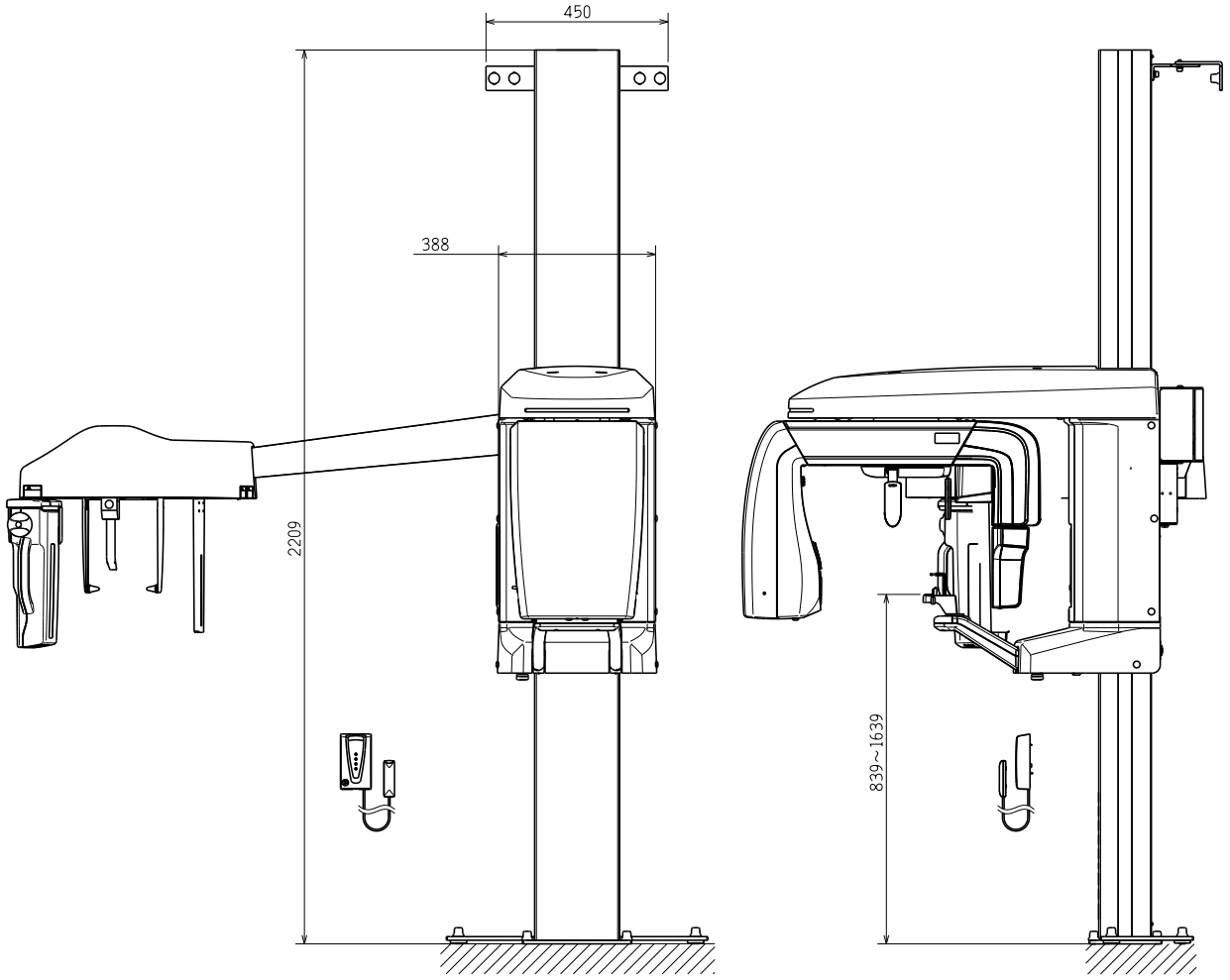




11.3.22 Standing position wall-mount: 3D , Cephalometic type

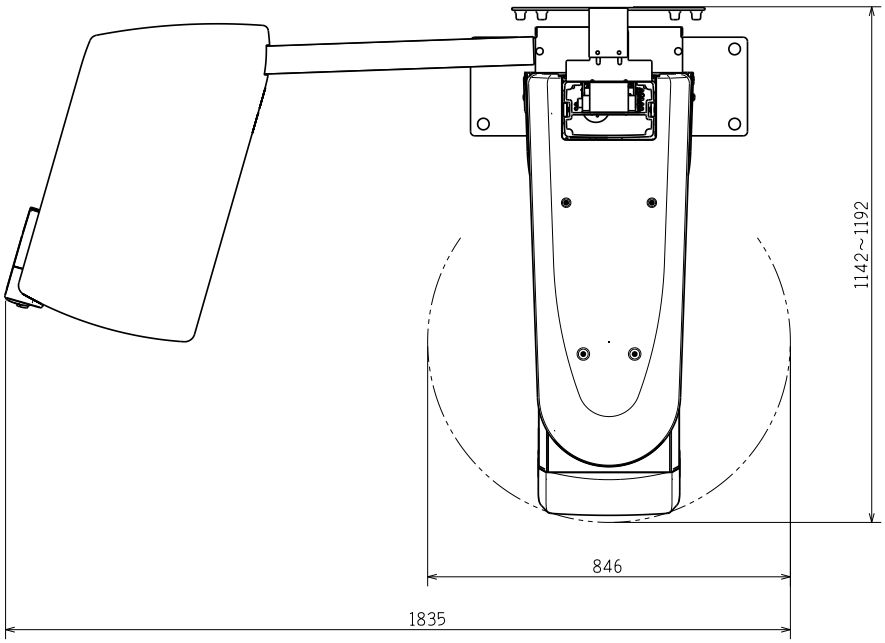
Unit: mm

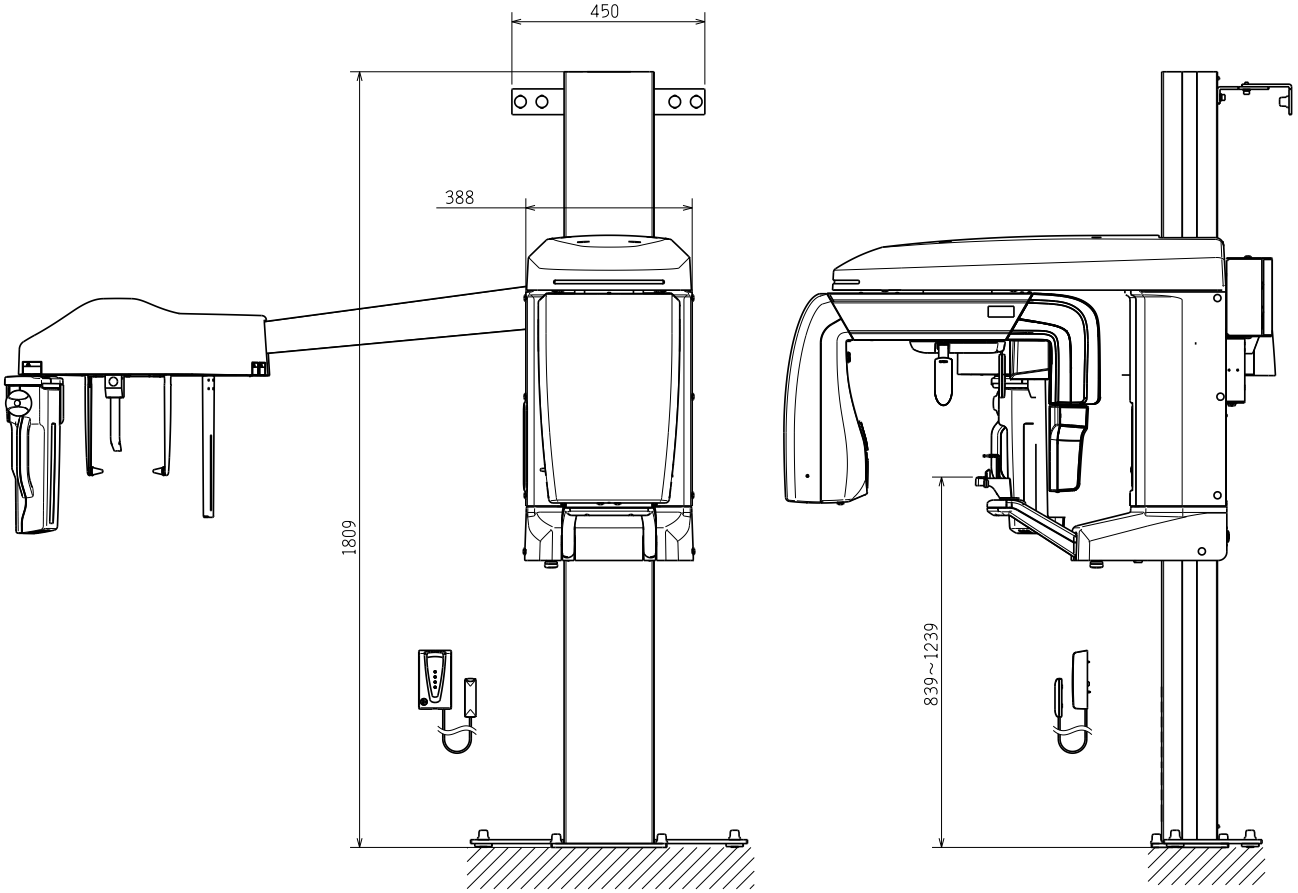




11.3.23 Standing position wall-mount short type: 3D , Cephalometic type

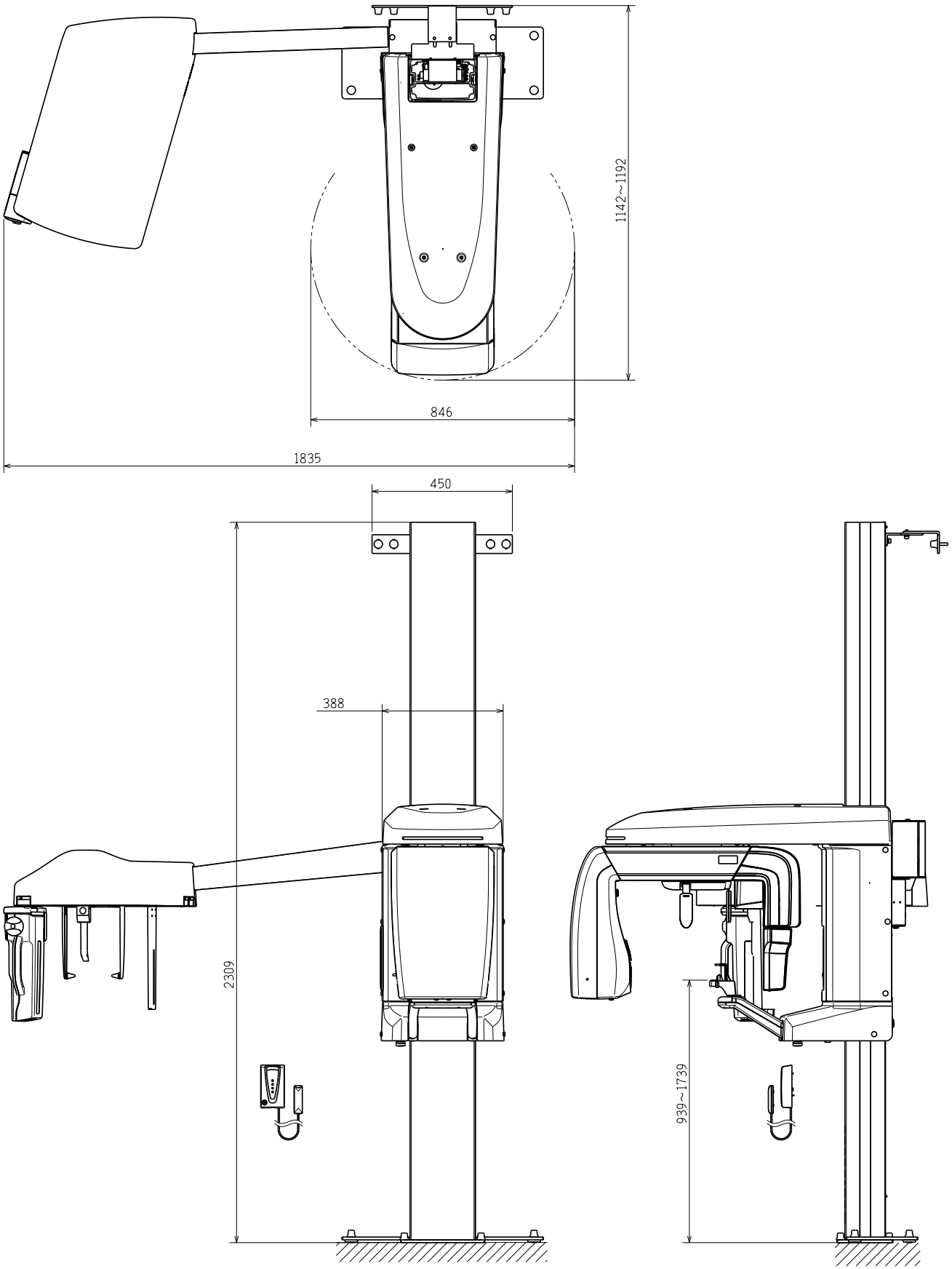
Unit: mm





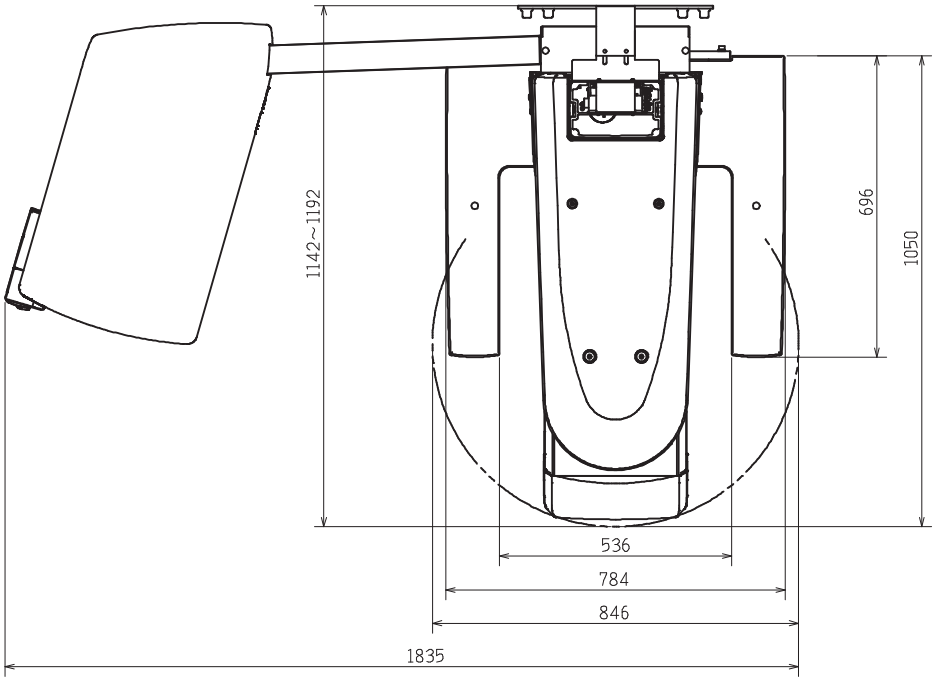
11.3.24 Standing position wall-mount long type: 3D , Cephalometic type

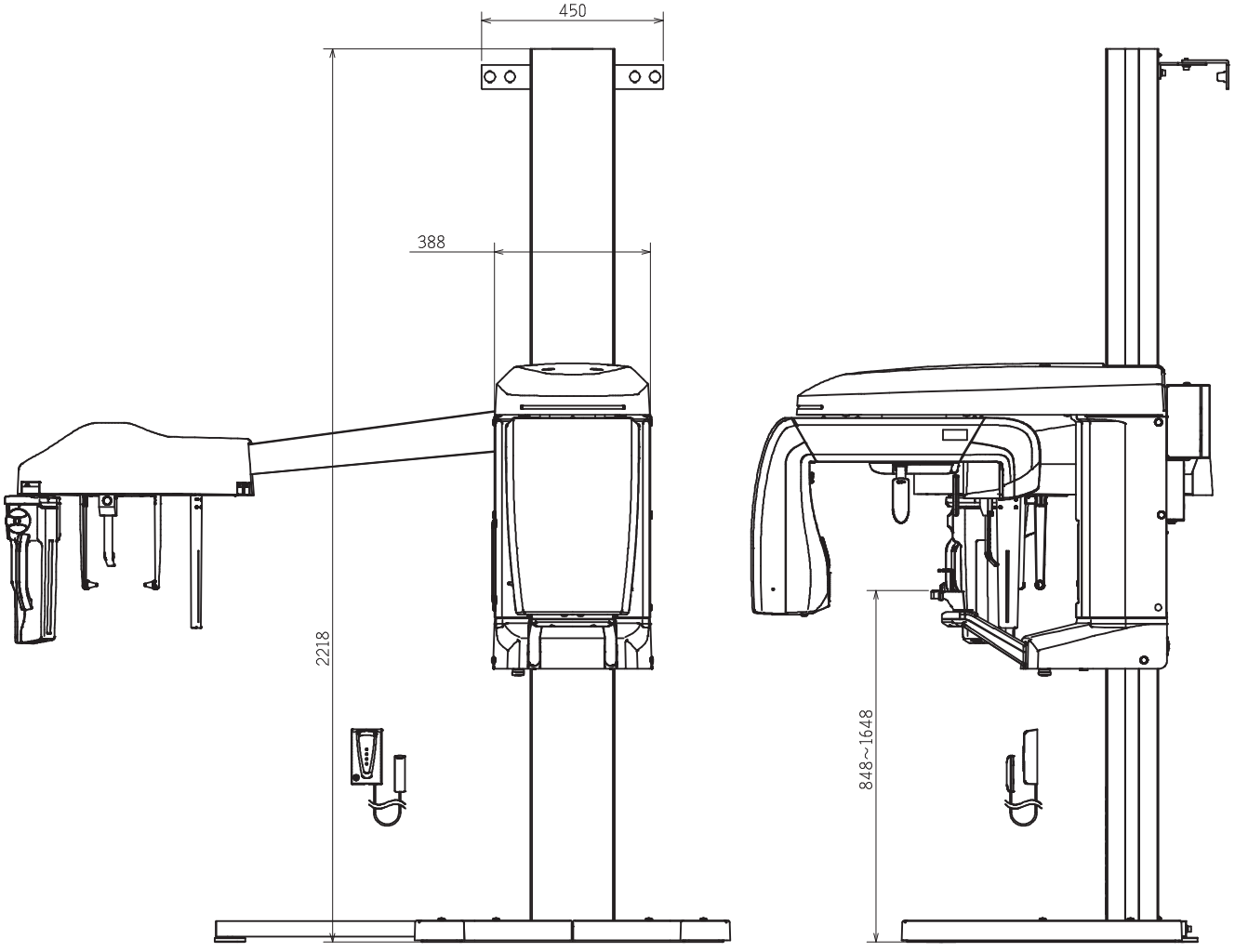
Unit: mm



11.3.25 Standing position base-mount (with an optional base): Cephalometic type

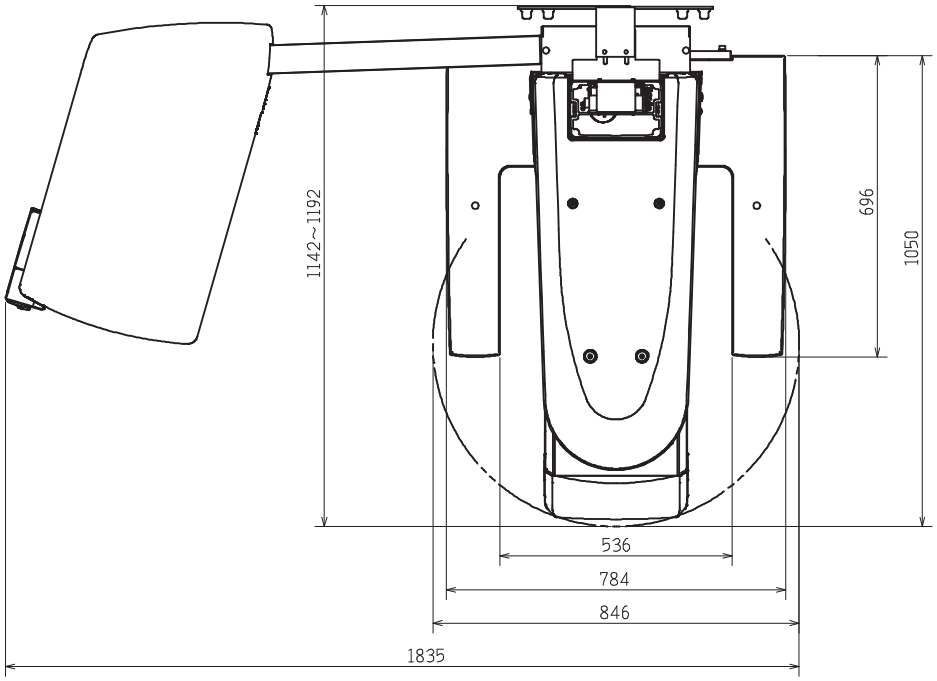
Unit: mm

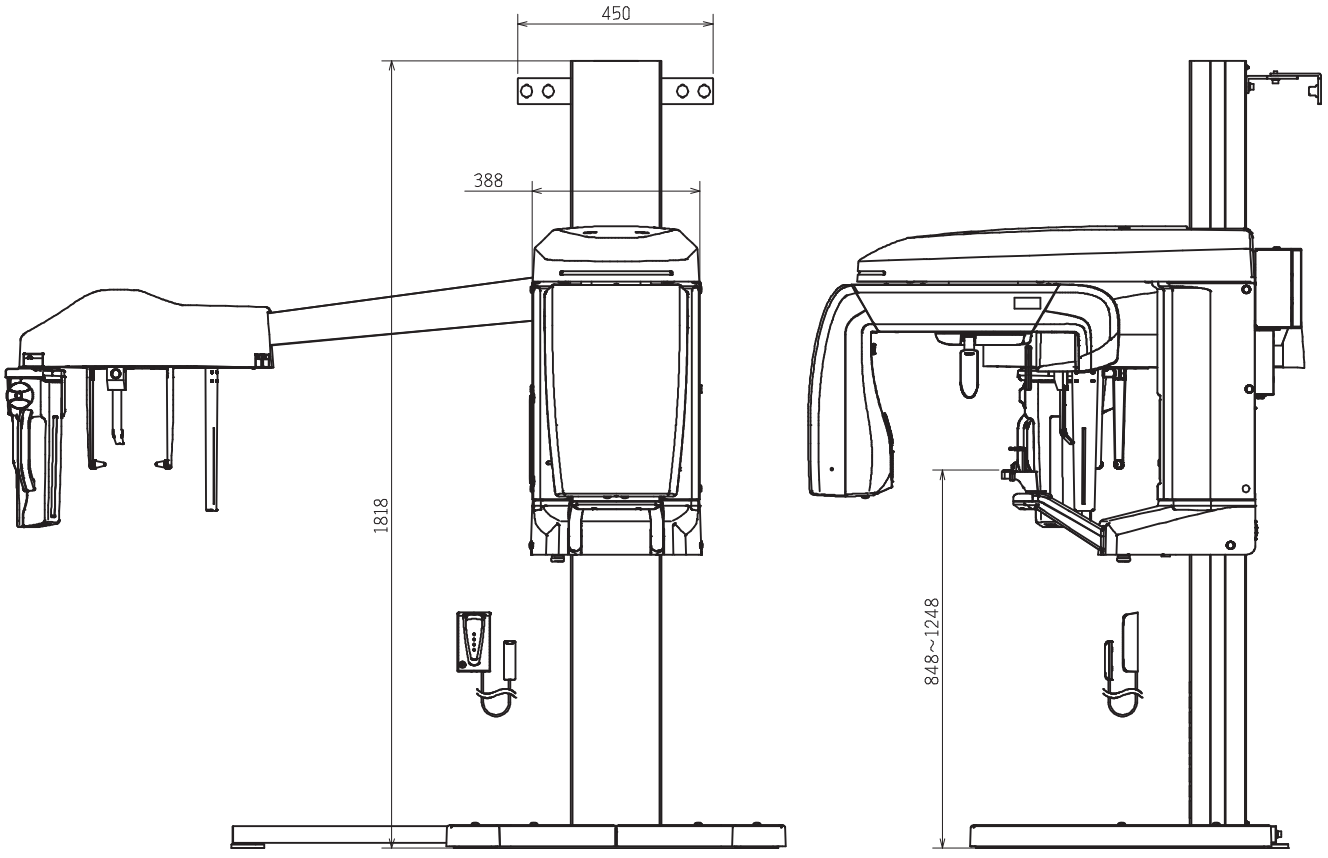




11.3.26 Standing position base-mount short type (with an optional base): Cephalometic type

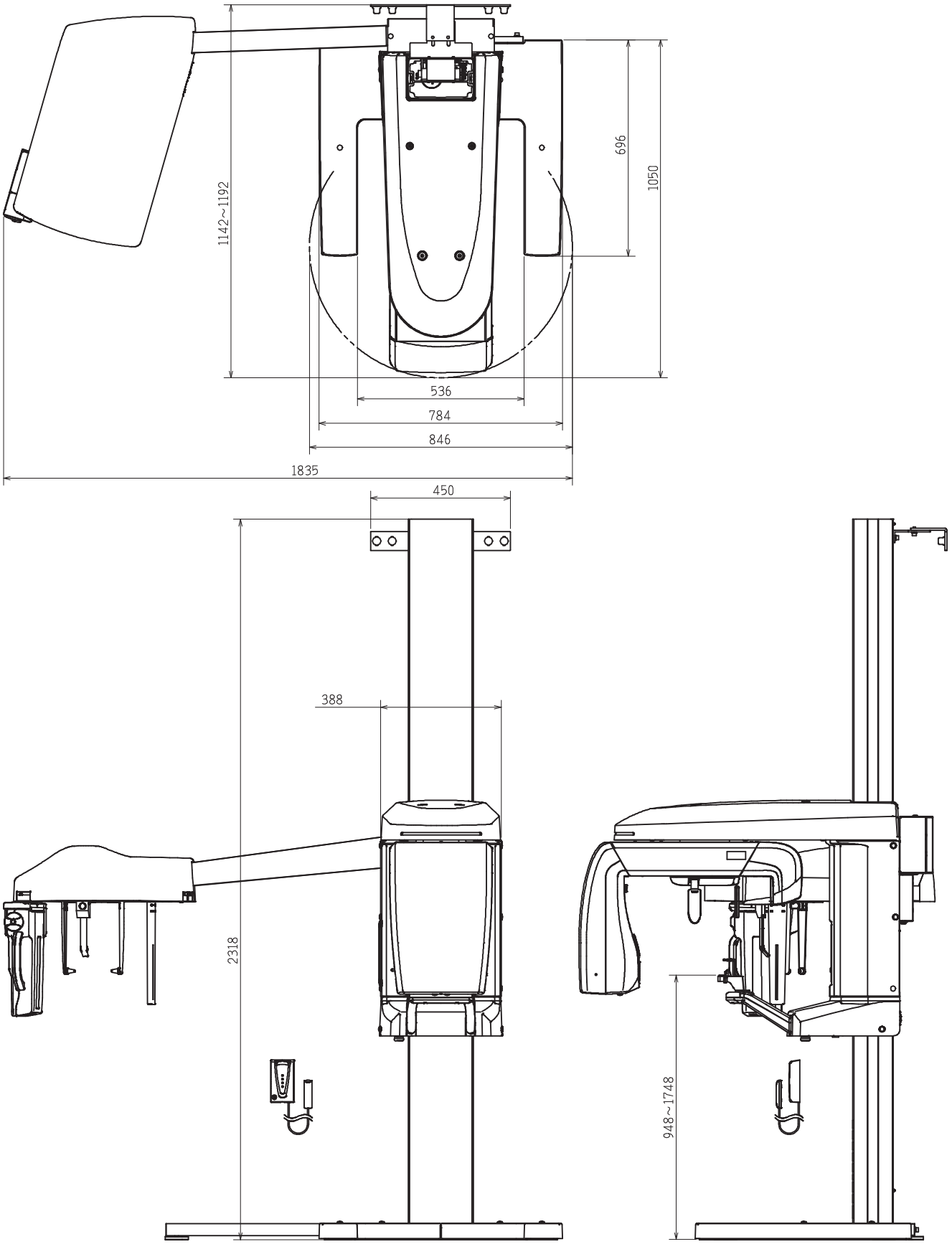
Unit: mm





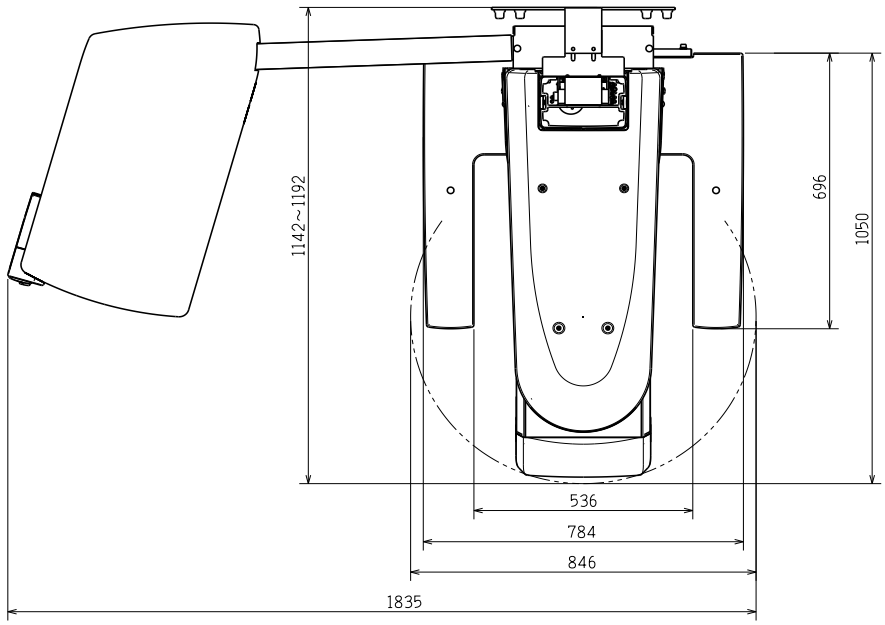
11.3.27 Standing position base-mount long type (with an optional base):Cephalometic type

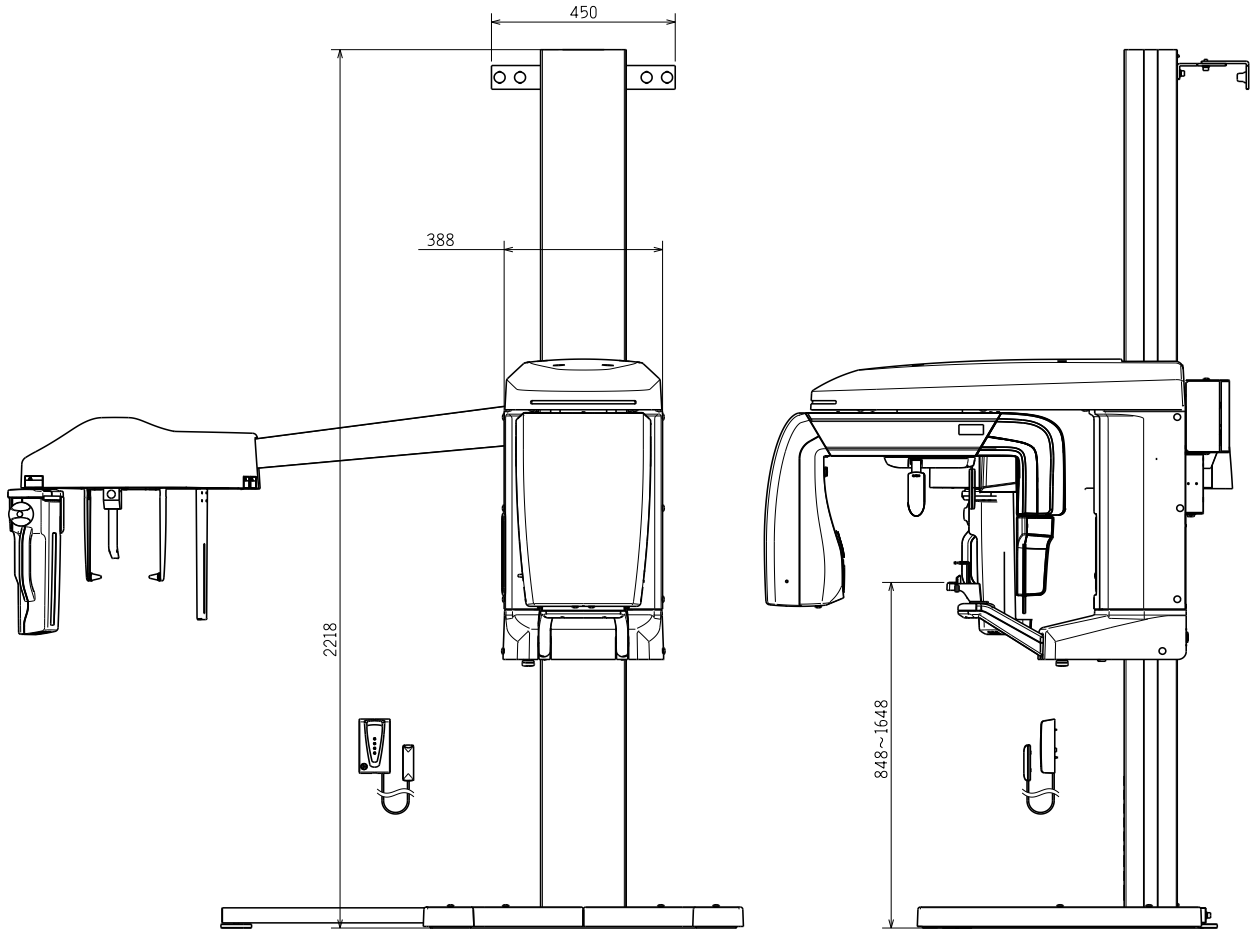
Unit: mm



11.3.28 Standing position base-mount (with an optional base): 3D , Cephalometic type

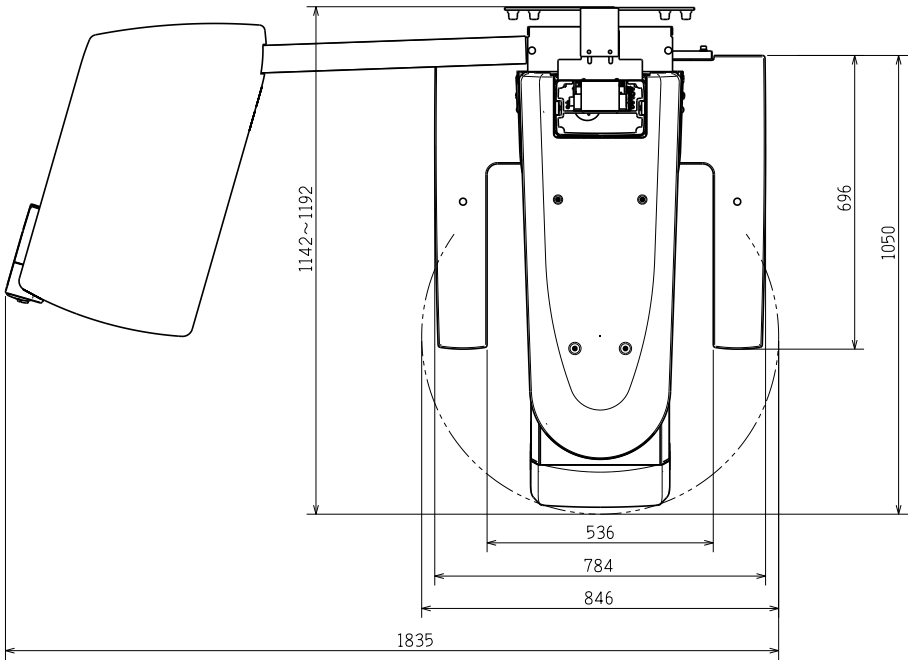
Unit: mm

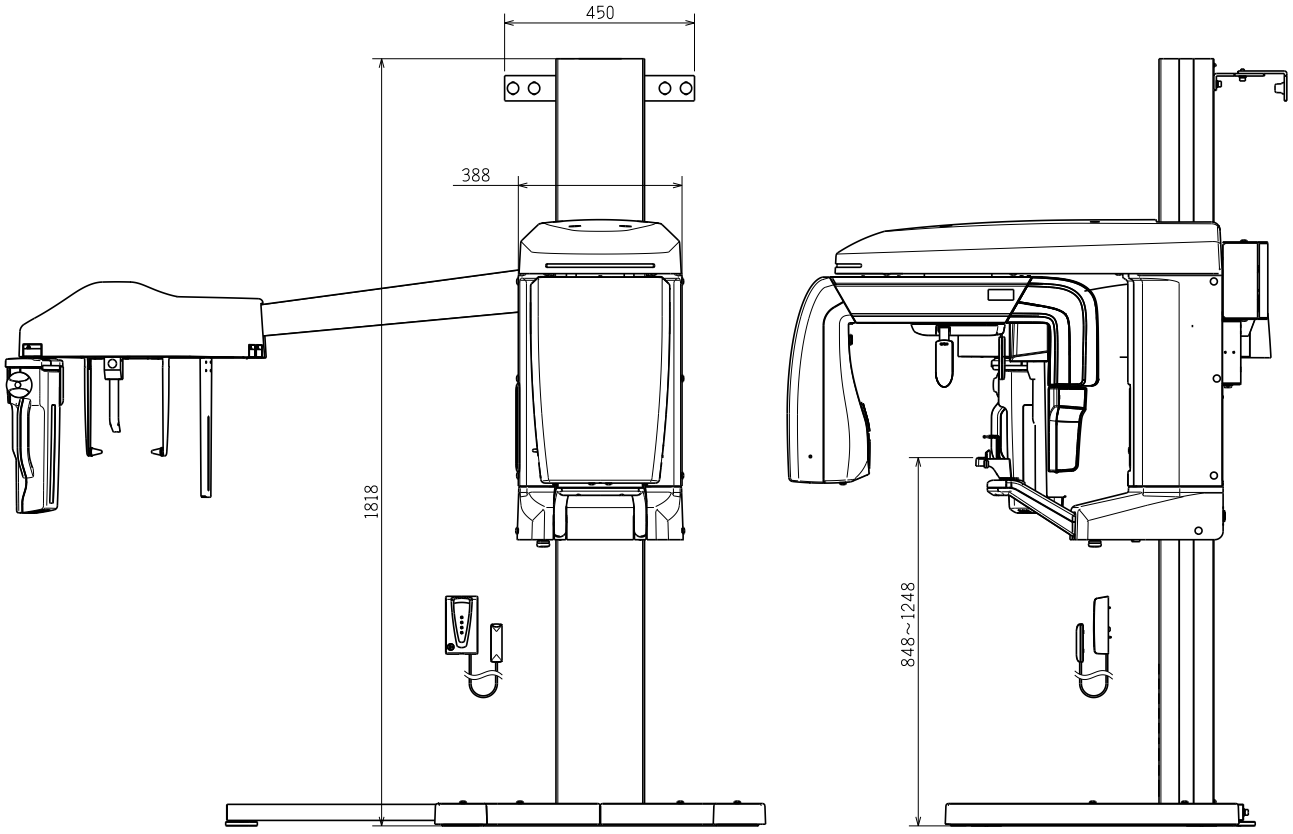




11.3.29 Standing position base-mount short type (with an optionabase): 3D , Cephalometic type

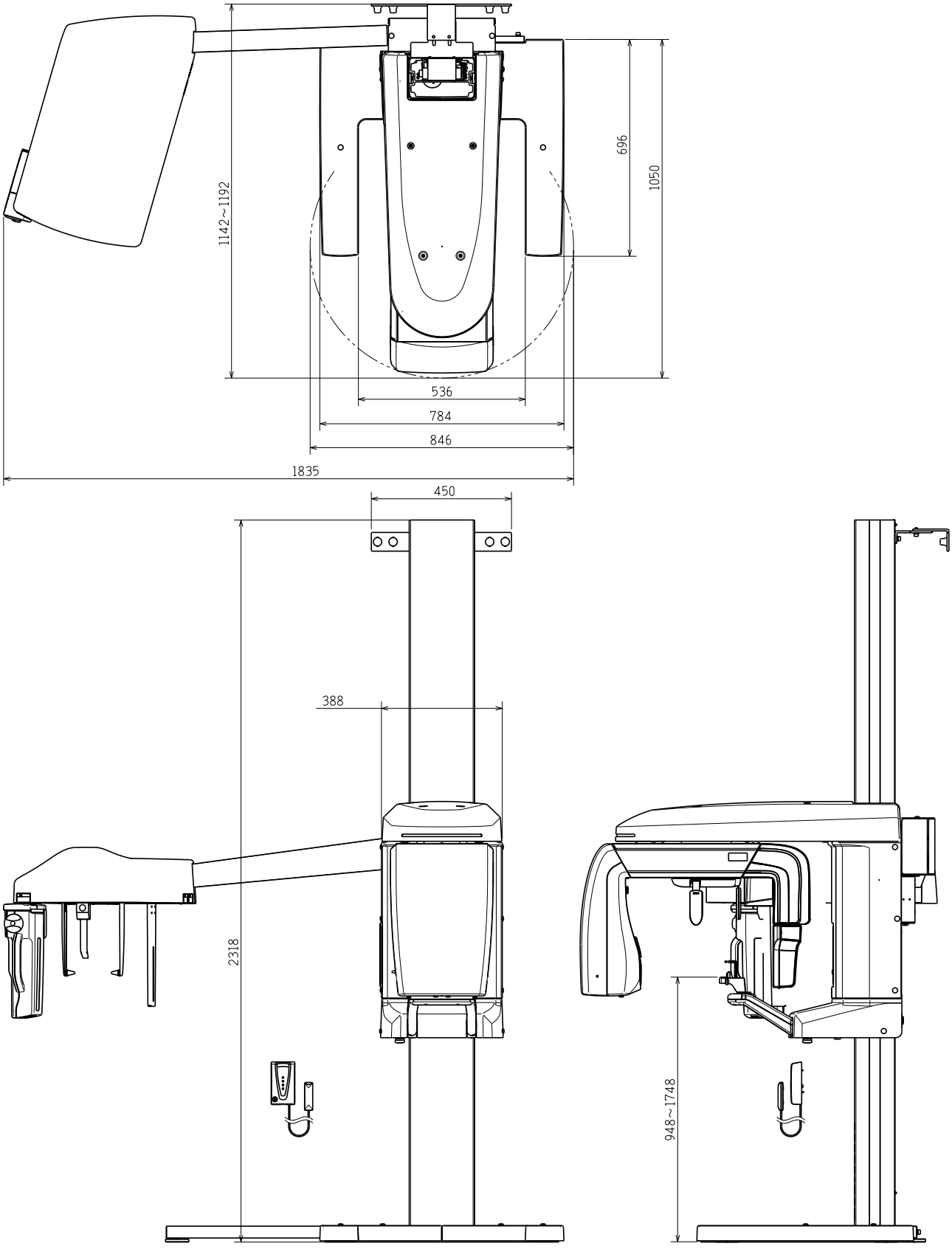
Unit: mm





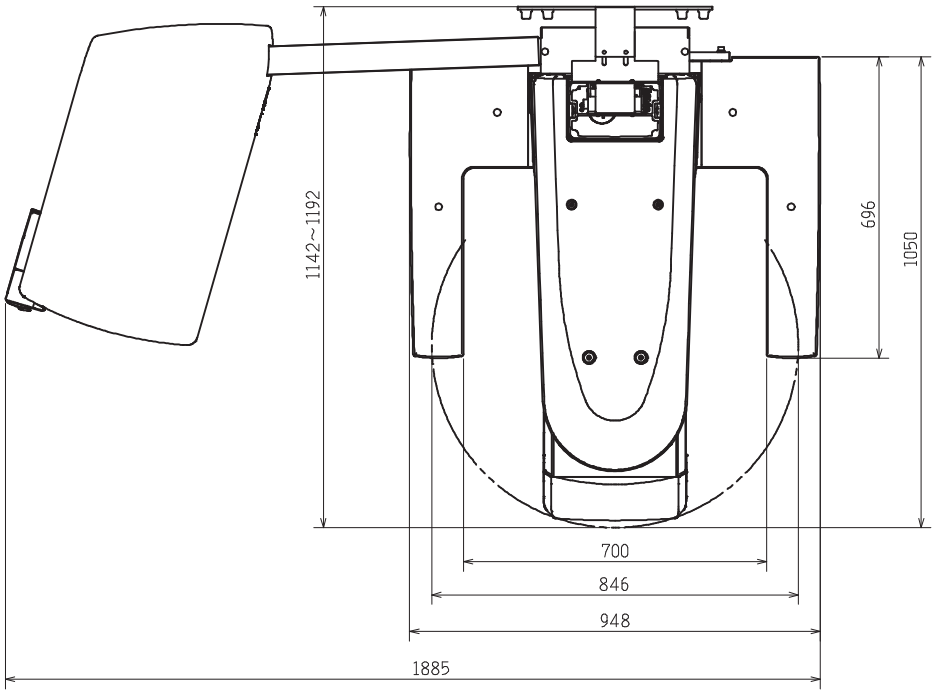
11.3.30 Standing position base-mount long type (with an optional base): 3D , Cephalometic type

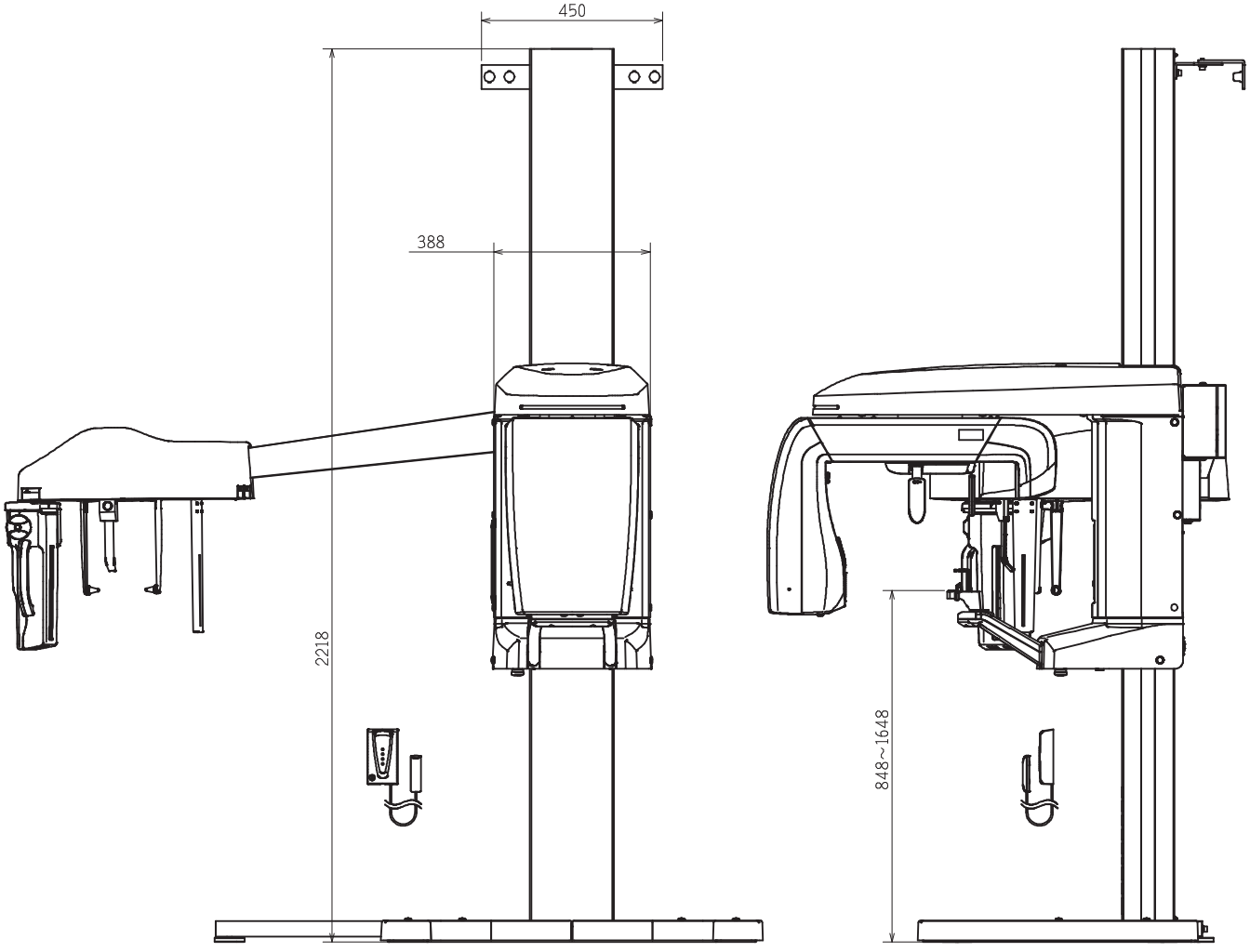
Unit: mm



11.3.31 Standing position base-mount (with an optional wide base): Cephalometic type

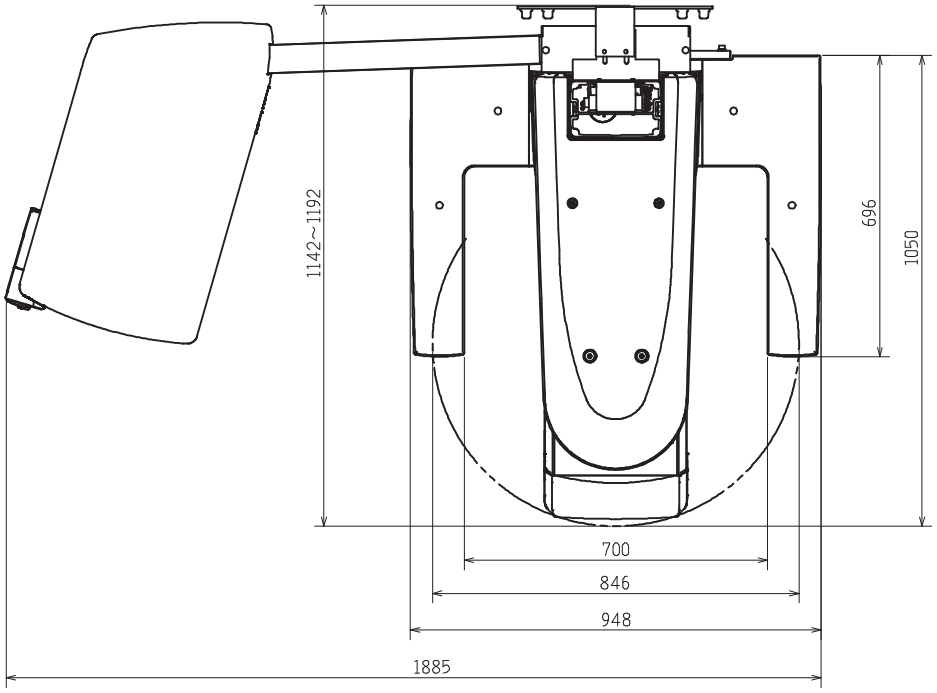
Unit: mm

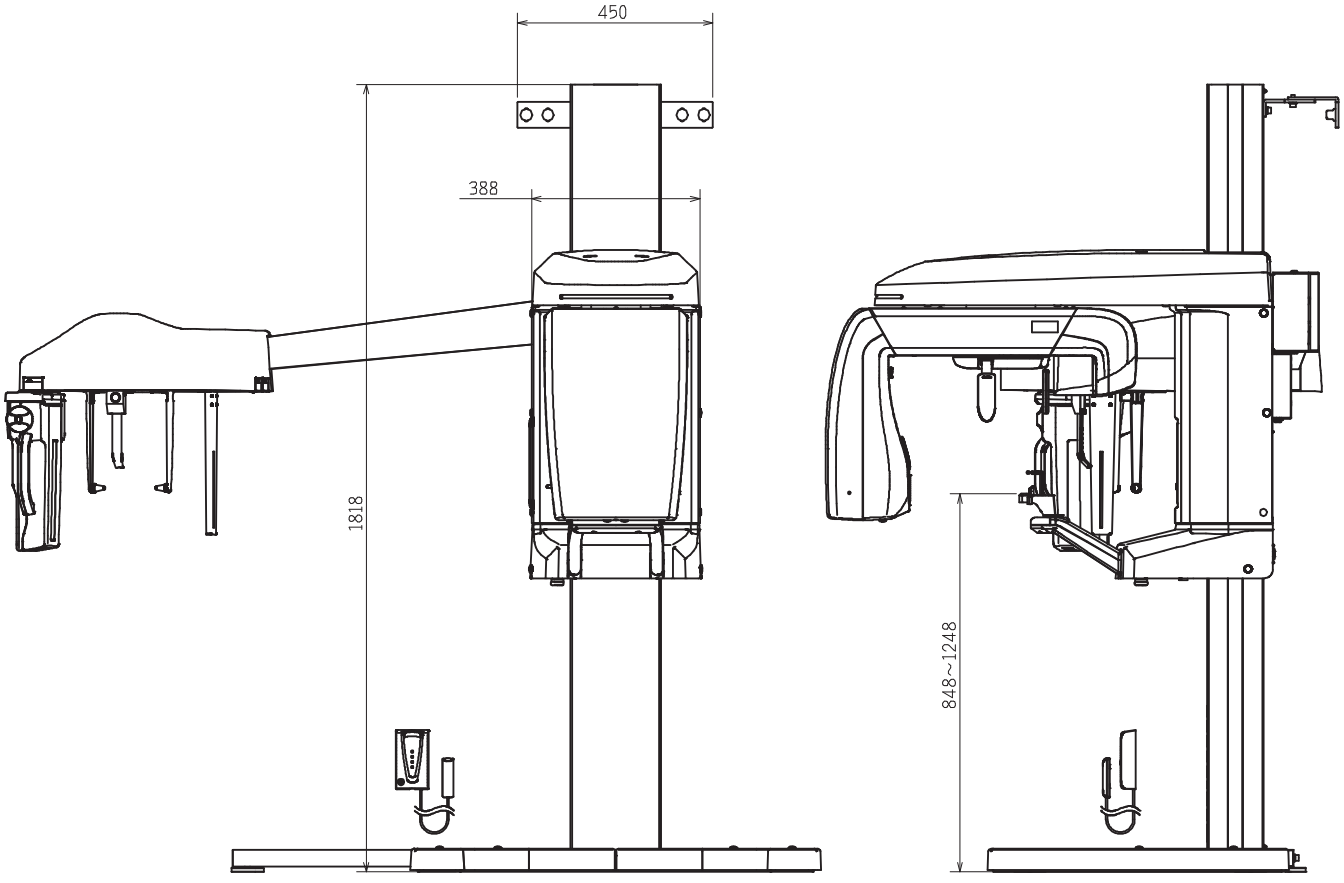




11.3.32 Standing position base-mount short type (with an optional wide base): Cephalometic type

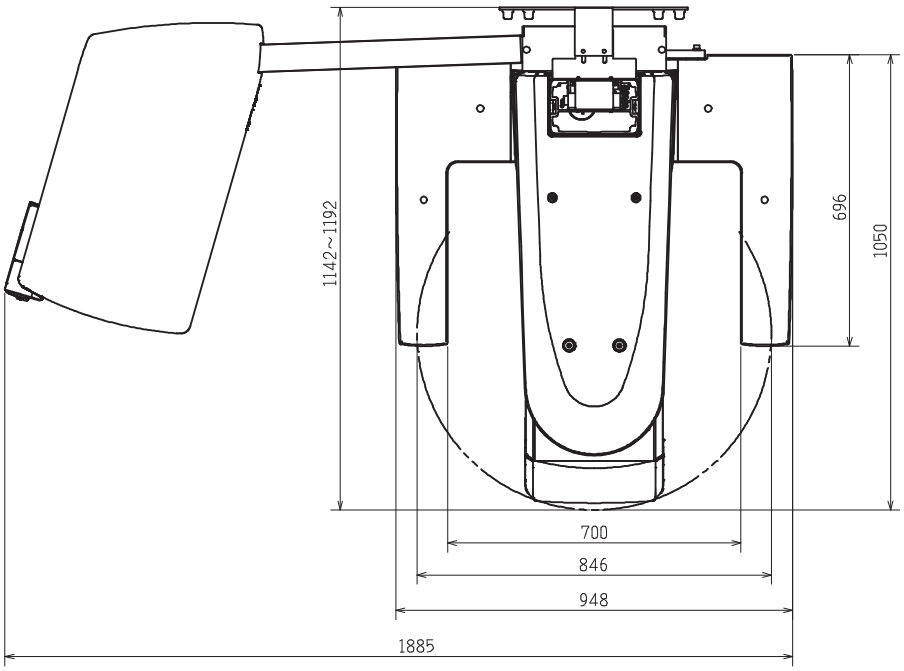
Unit: mm

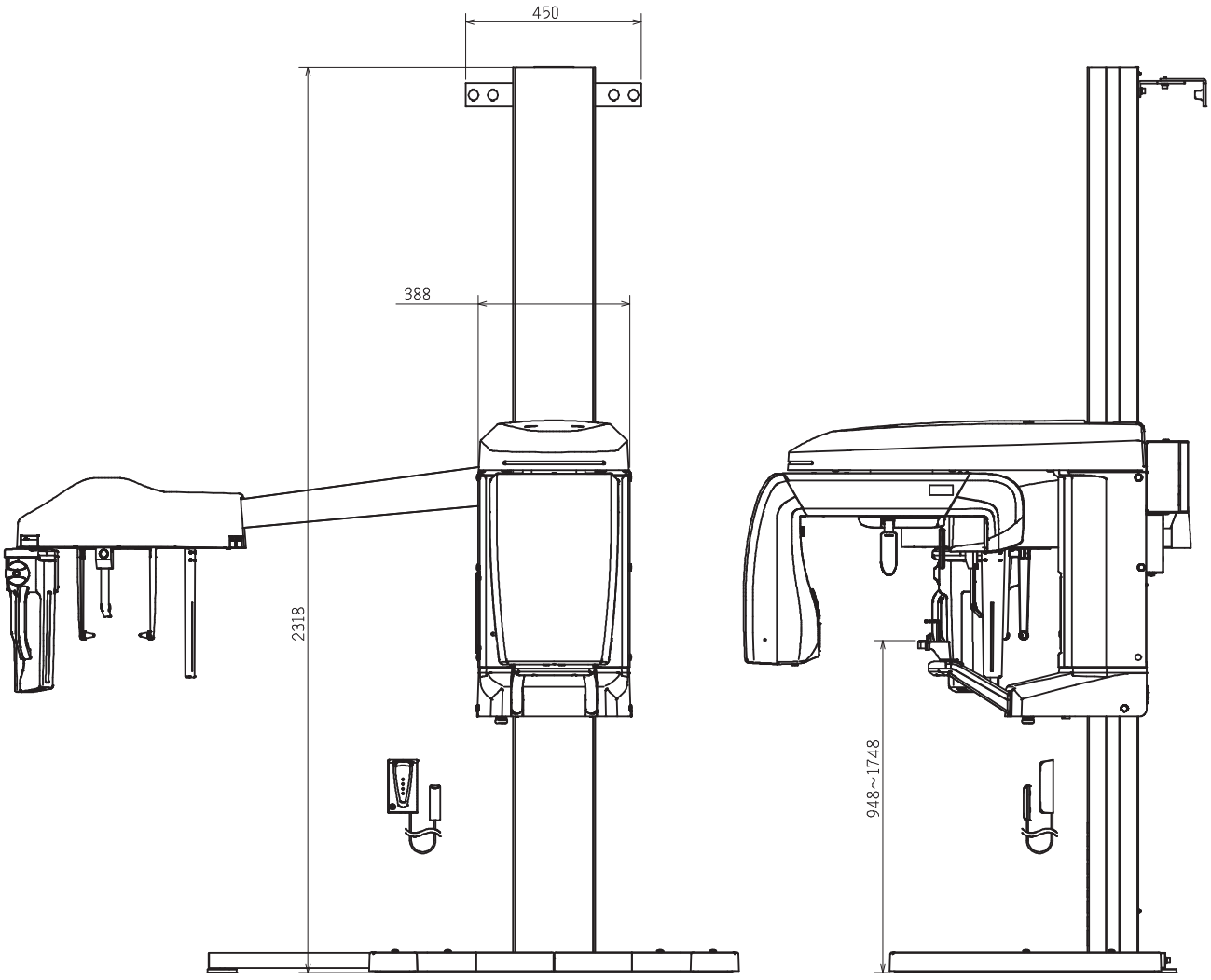




11.3.33 Standing position base-mount long type (with an optional wide base): Cephalometic type

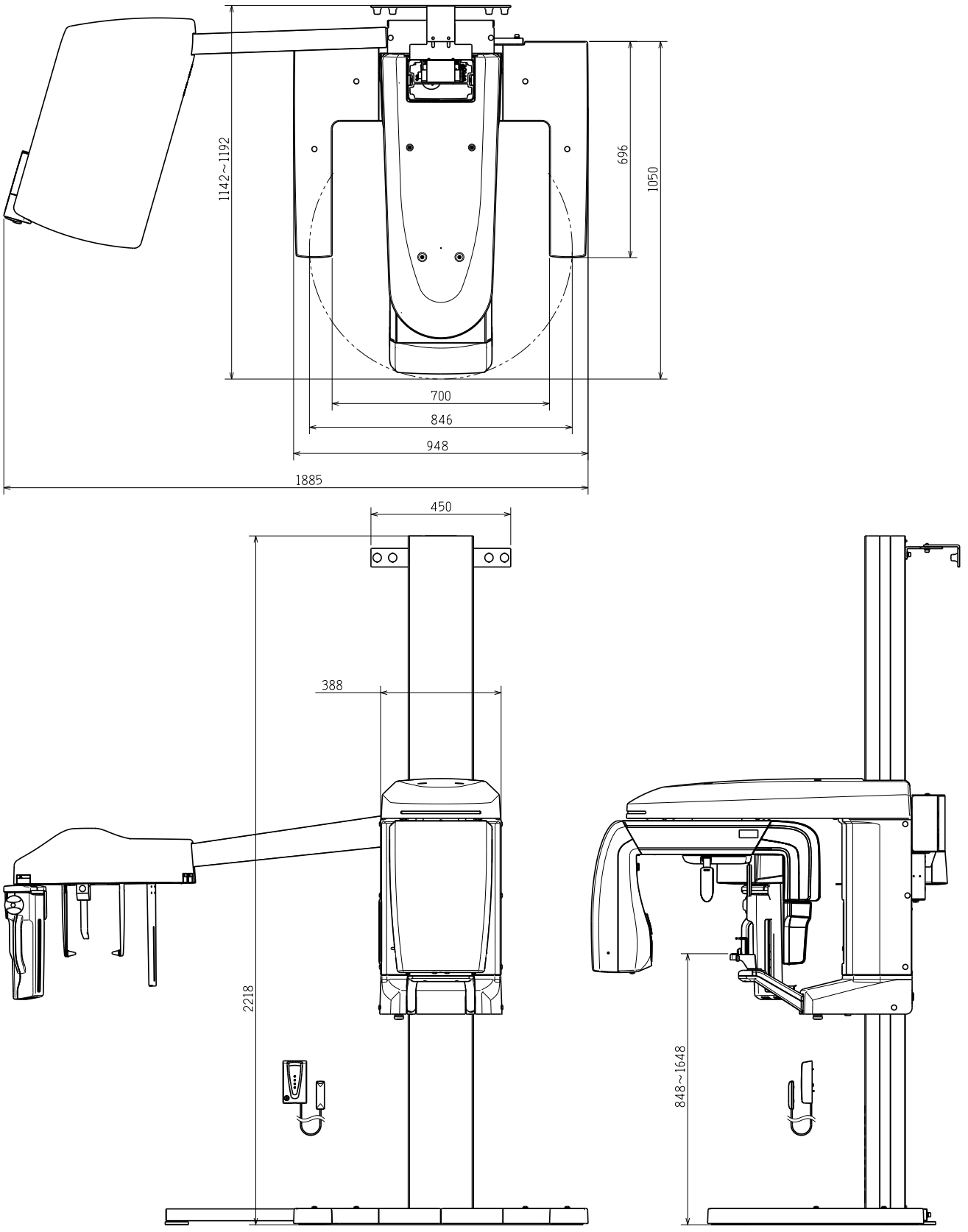
Unit: mm





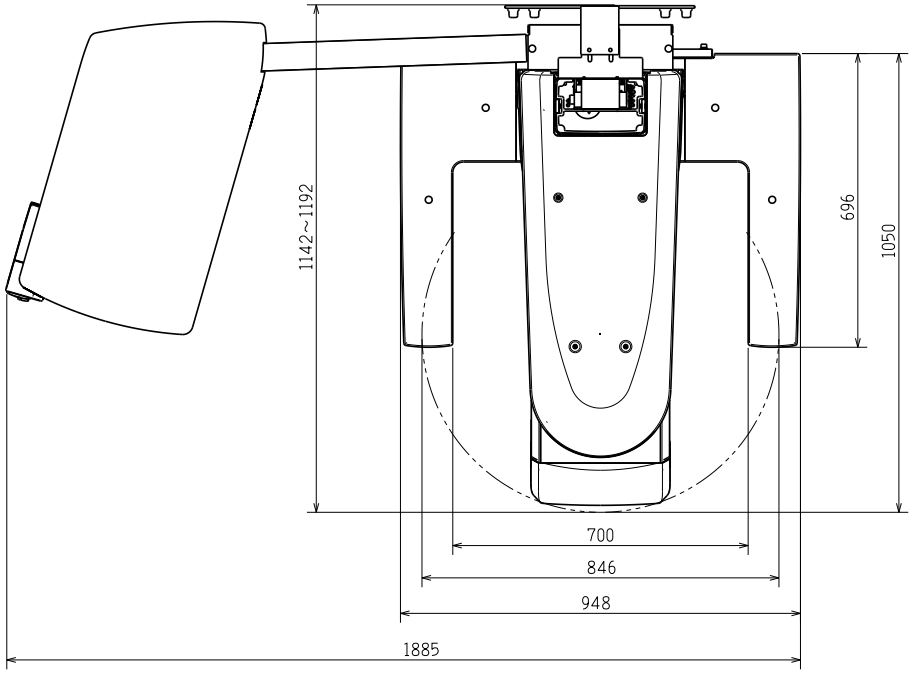
11.3.34 Standing position base-mount (with an optional wide base): 3D , Cephalometic type

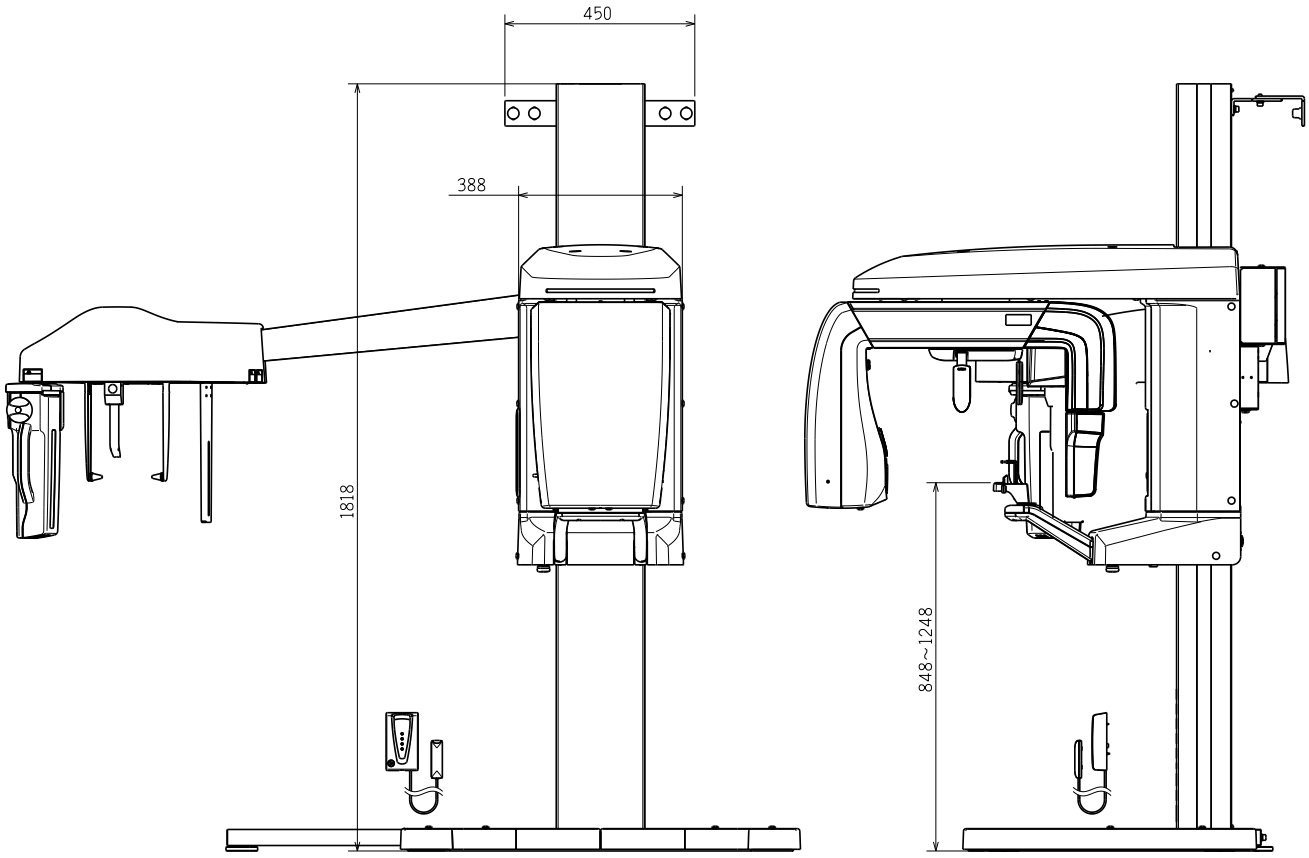
Unit: mm



11.3.35 Standing position base-mount short type (with an optional wide base): 3D , Cephalometic type

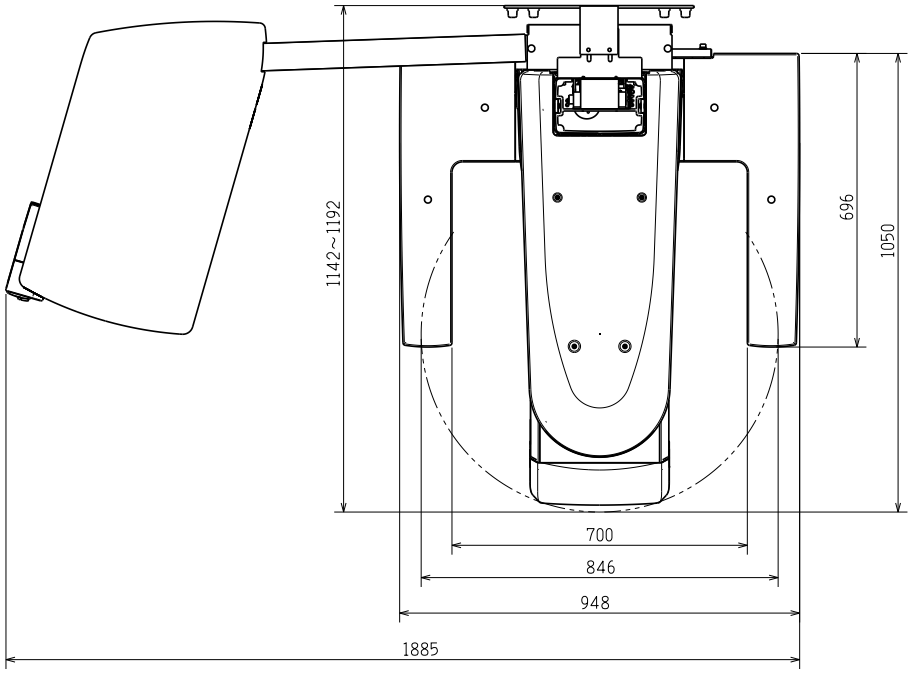
Unit: mm

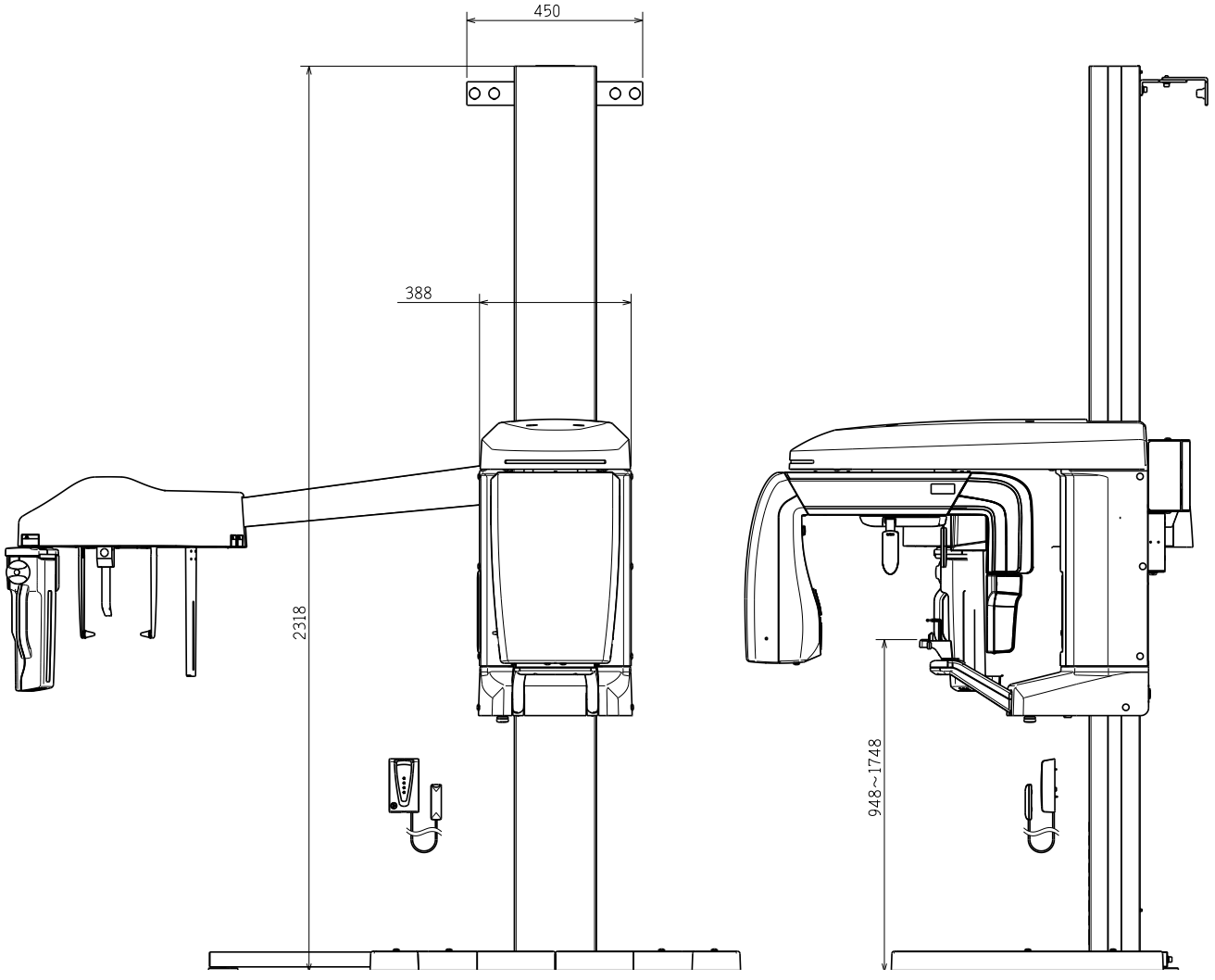




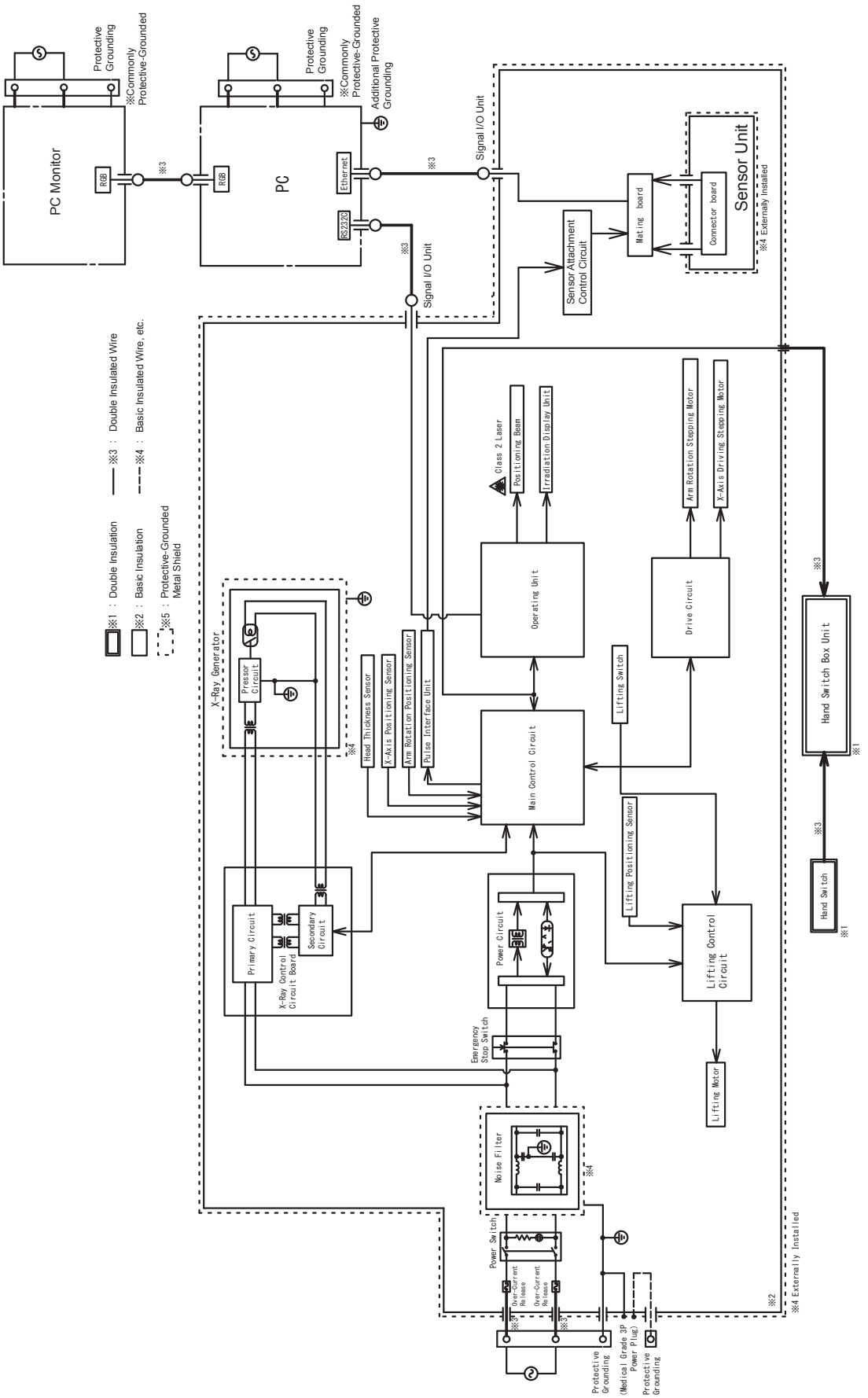
11.3.36 Standing position base-mount long type (with an optional wide base): 3D , Cephalometic type

Unit: mm

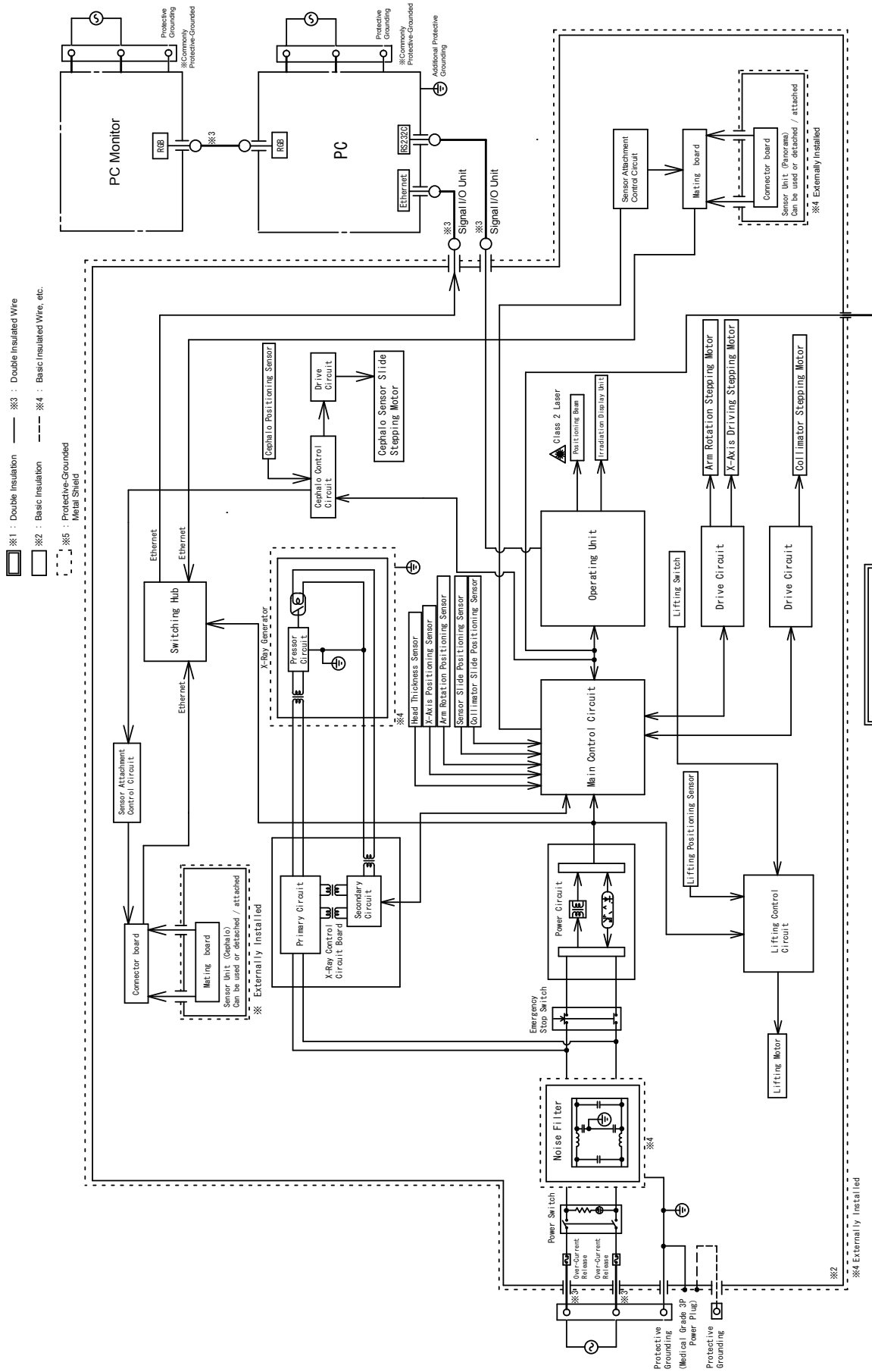




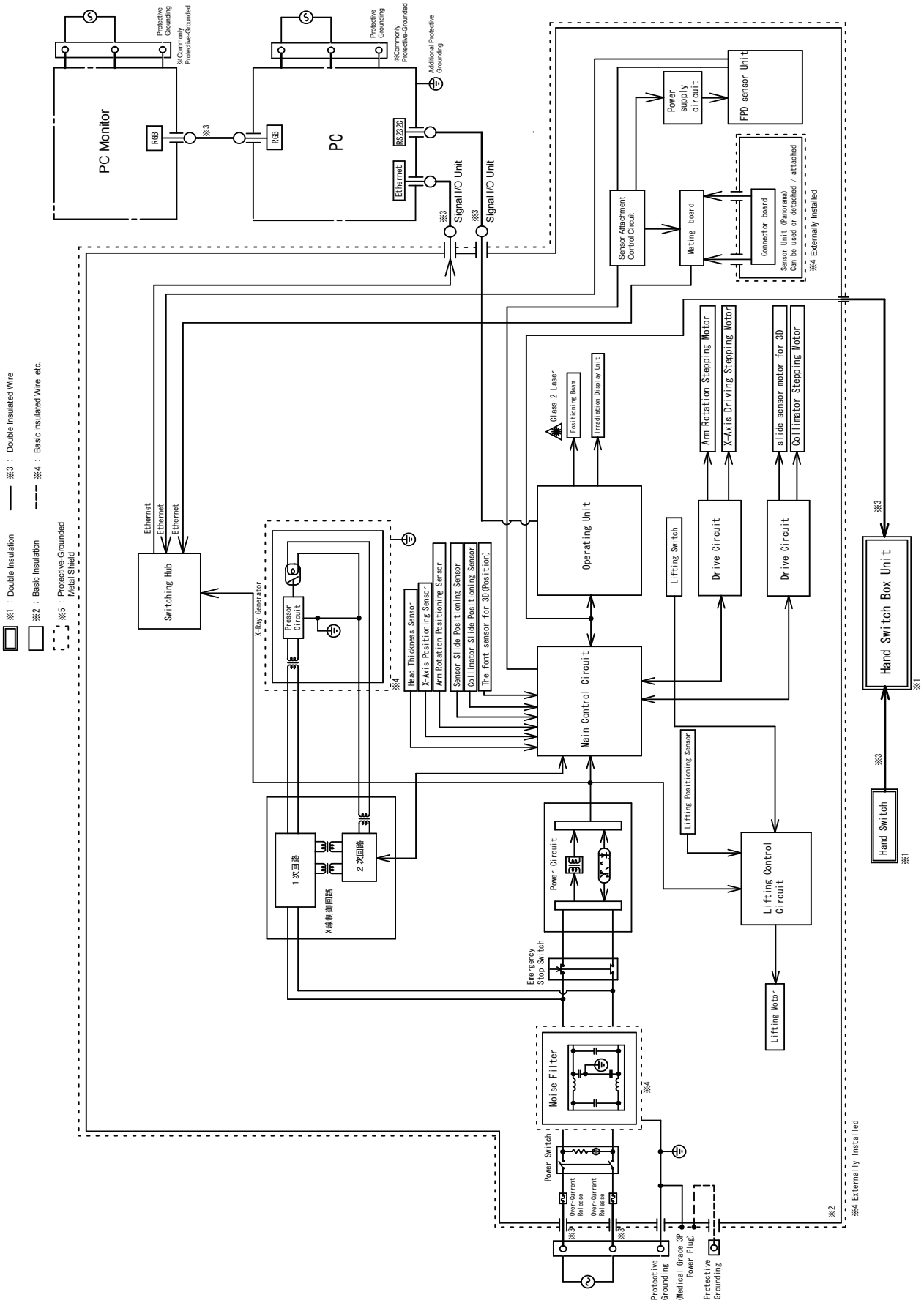
11.4 Circuit Block Diagram



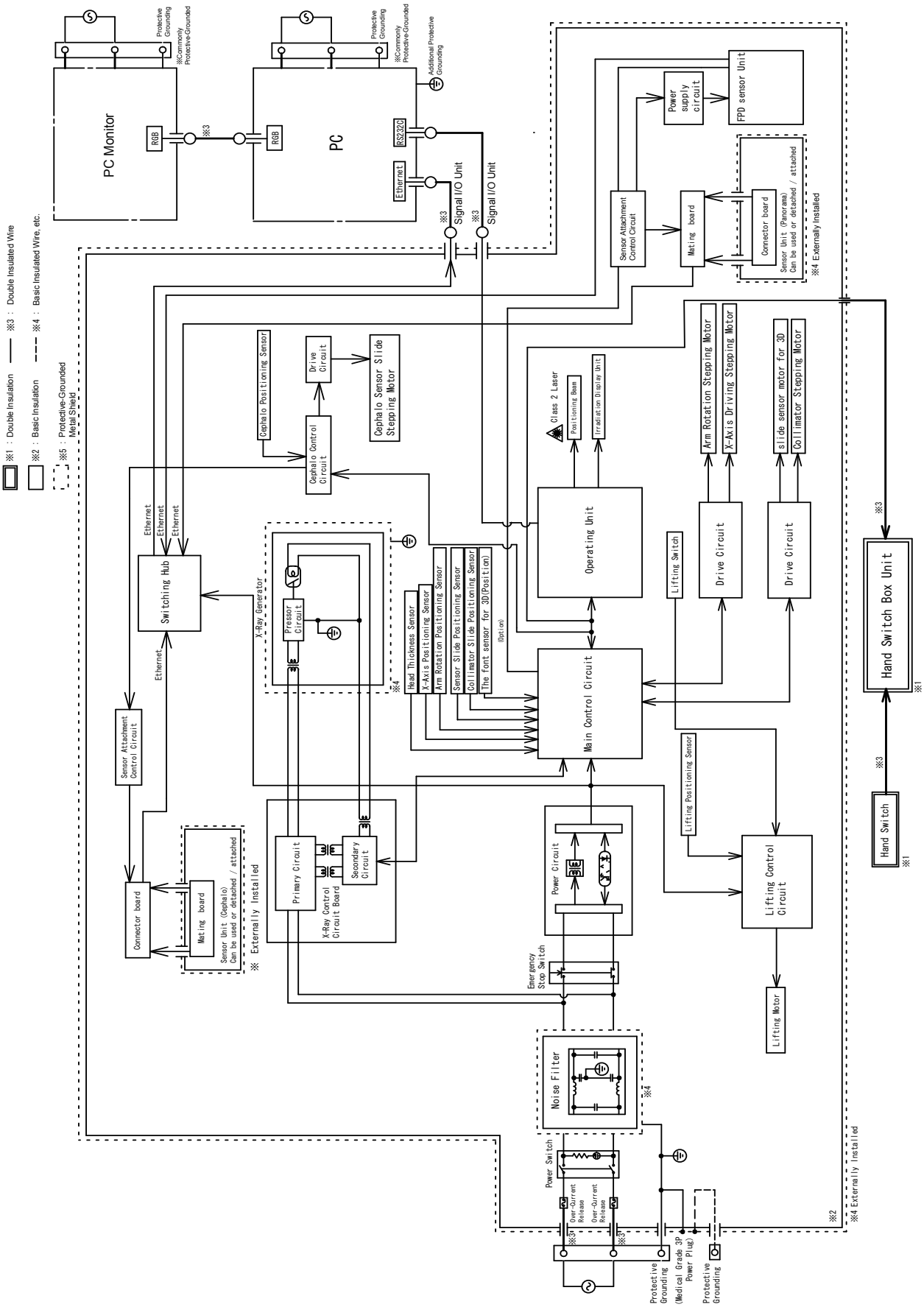
11.5 Circuit Block Diagram (Cephalometic Type)



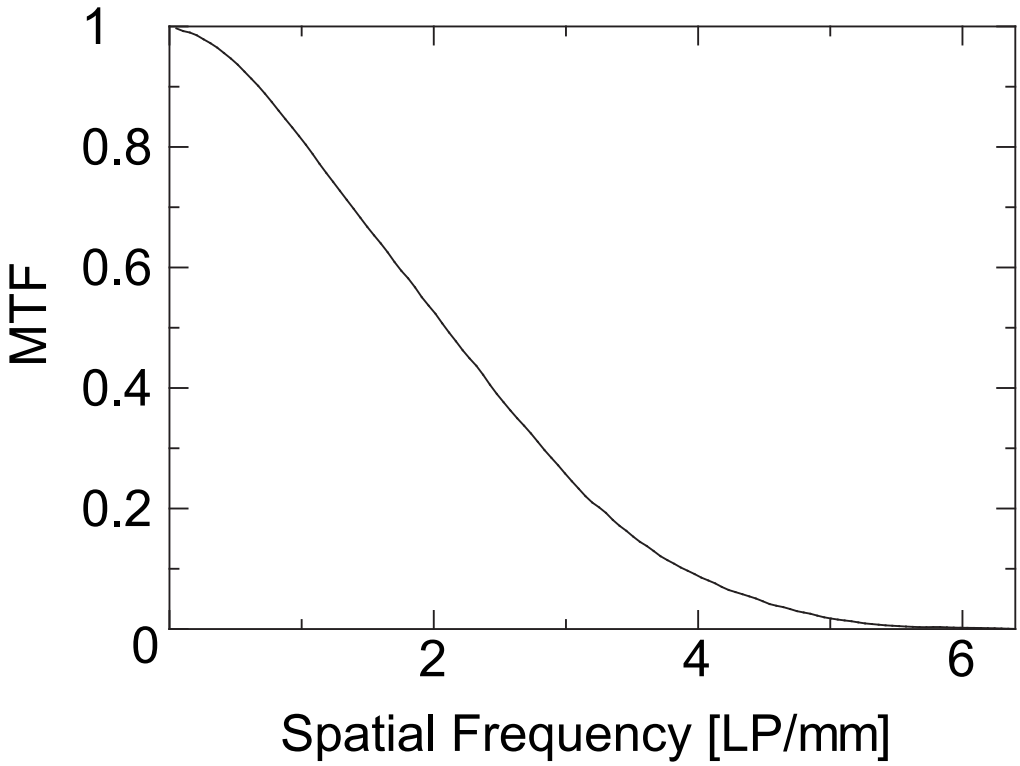
11.6 Circuit Block Diagram (for Equipment with 3D Function)



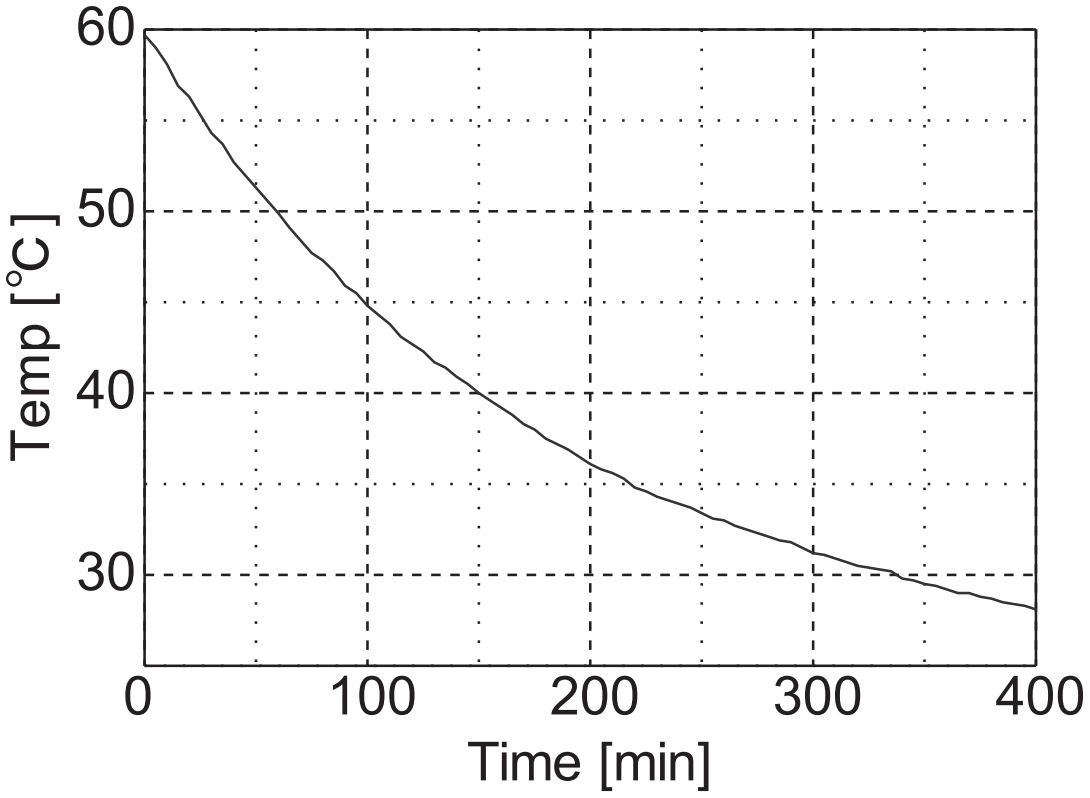
11.7 Circuit Block Diagram (for Equipment with 3D Function and Cephalometric)

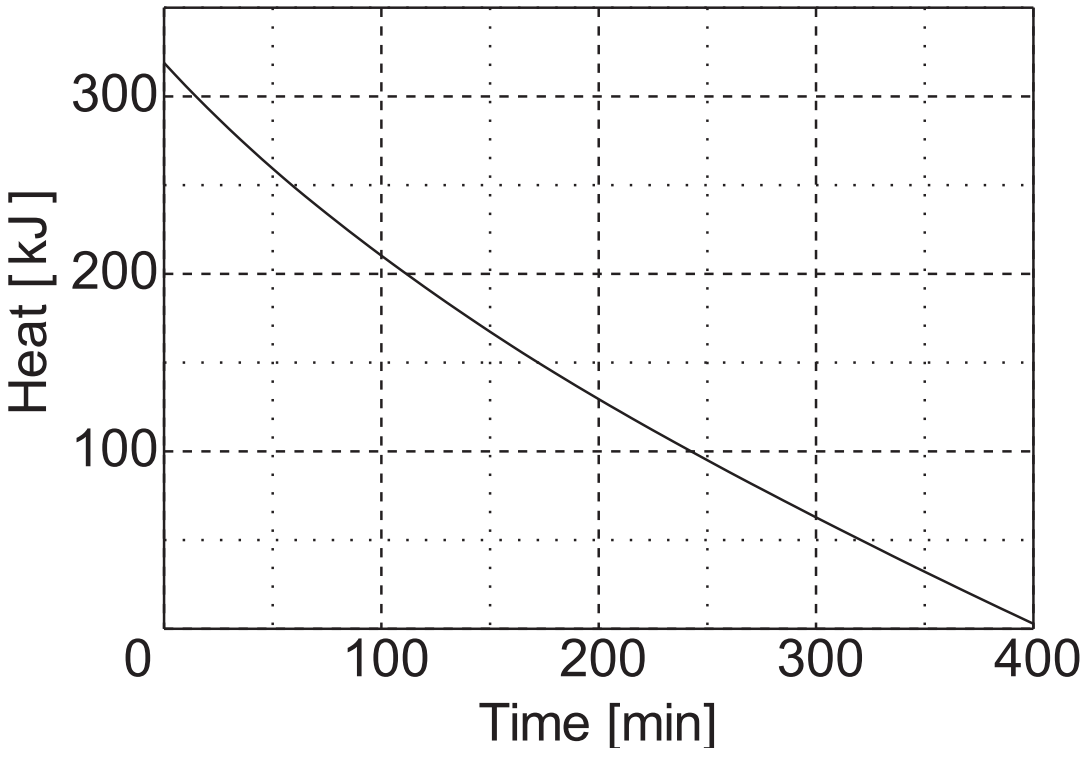


11.8 Spatial Resolution (MTF)



11.9 Anode Cooling Curve and Heat Content of X-ray Tube Head Assembly



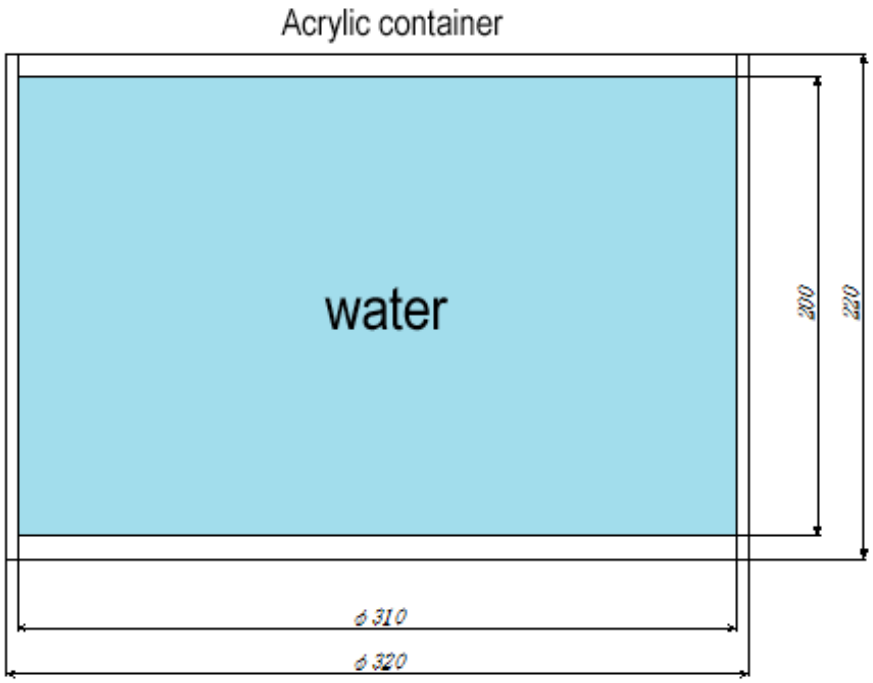


11.10 Stray Radiation Information

Stray radiation dose at the water surface at the height of X-ray focal point.

11.10.1 Dimensions of the phantom used

Unit: mm



11.10.2 How To Test

1 Set measurement points with 500 mm intervals at the front, back, left, and right of the equipment, making the rotation axis as the center.

(Measurement range: (-1.5 [m] to 1.5 [m]) x (-1.5 [m] to 1.5 [m]). (except those measurement points that are in contact with the equipment).

2 Adjust the dosimeter at the same height as the center line (focus height) of X-ray.

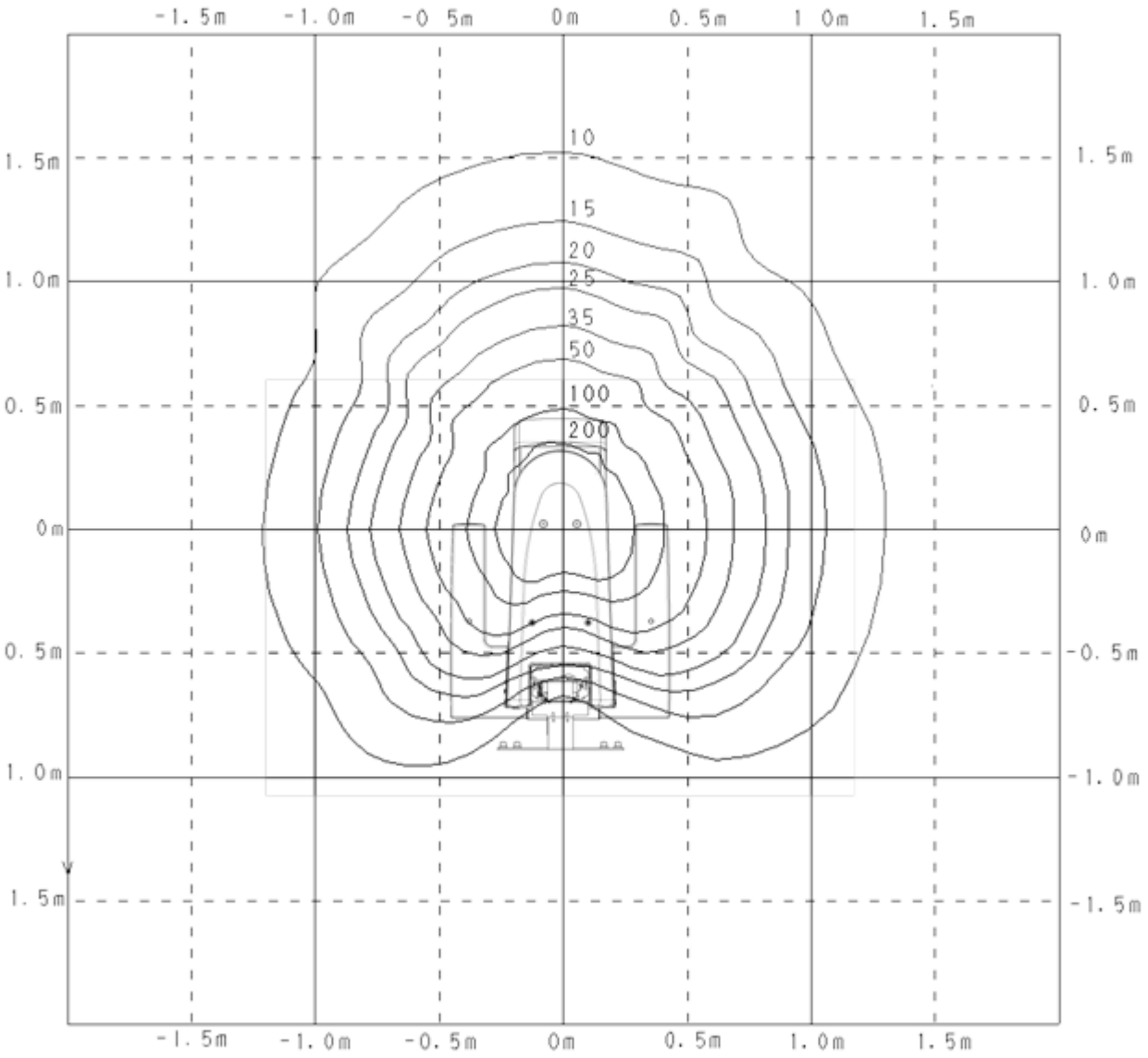
3 Place a cylindrical acrylic water tank (pictured above) at the rotation center as the imaging subject.

4 Place the dosimeter at every measurement point, and measure the dose.

Image Acquisition Conditions	Equipment Configuration	Image Acquisition Mode	Irradiation Conditions		
			Tube Voltage (kV)	Tube Current (mA)	Irradiation Time (sec)
1	with Cephalometric	Dental Mode	82	10.0	11.5
2	with Cephalometric	Oral Mode	82	10.0	23.0
3	without Cephalometric	Dental Mode	82	10.0	11.5
4	without Cephalometric	Oral Mode	82	10.0	23.0

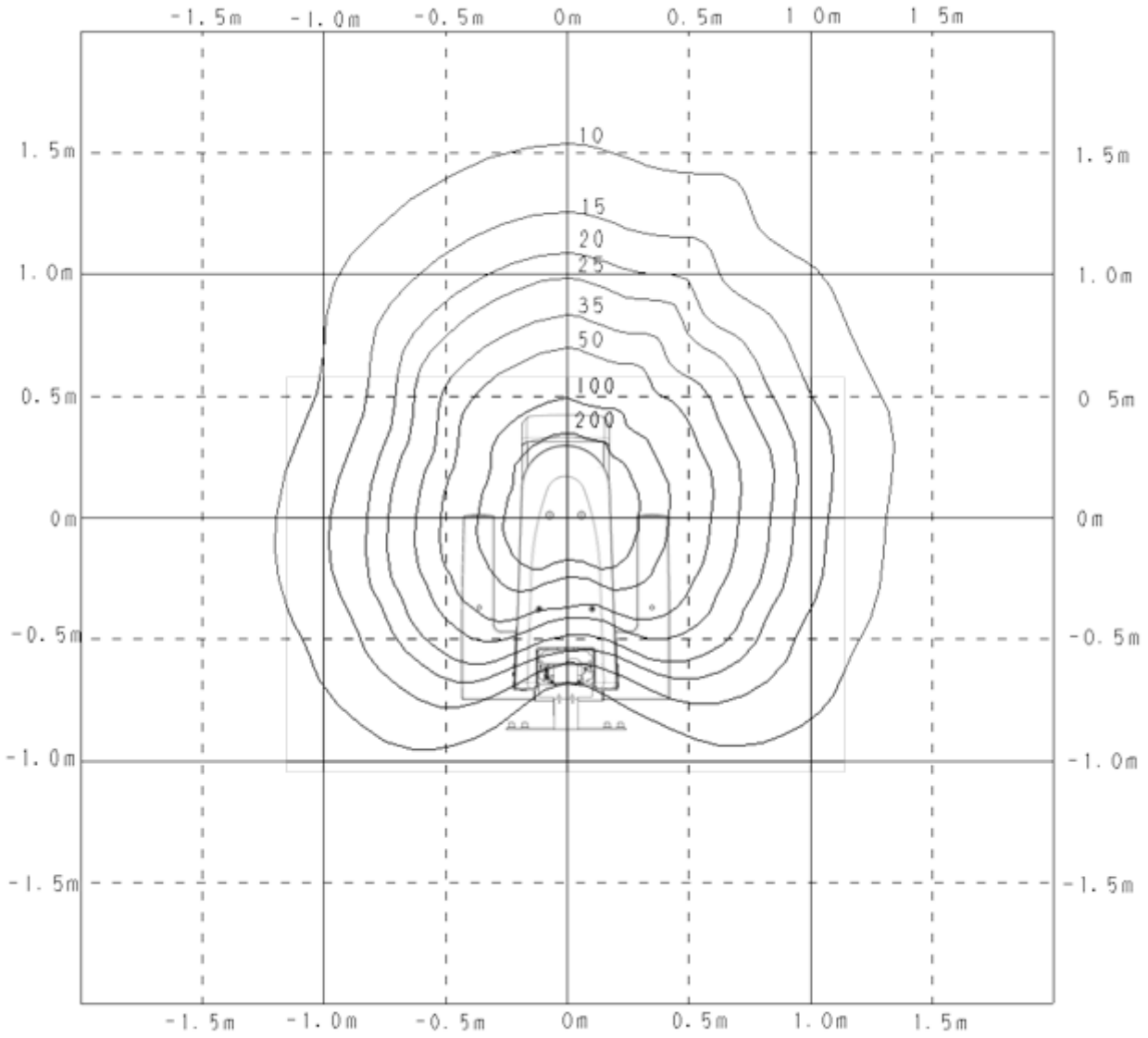
11.10.3 Stray radiation dose of X-era Smart in 3D oral mode

Unit: nGy/mAs



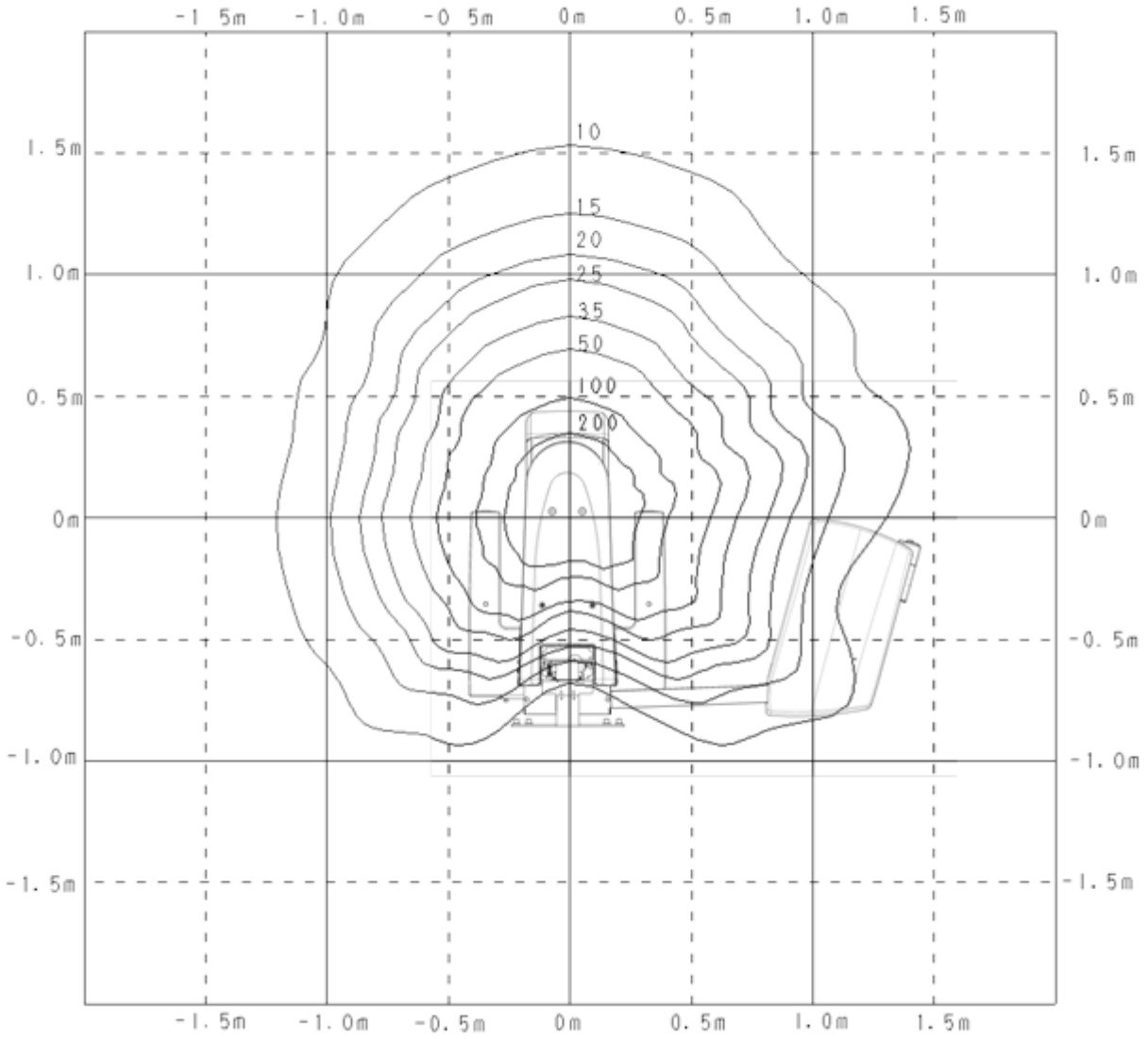
11.10.4 Stray radiation dose of X-era Smart in 3D dental mode

Unit: nGy/mAs



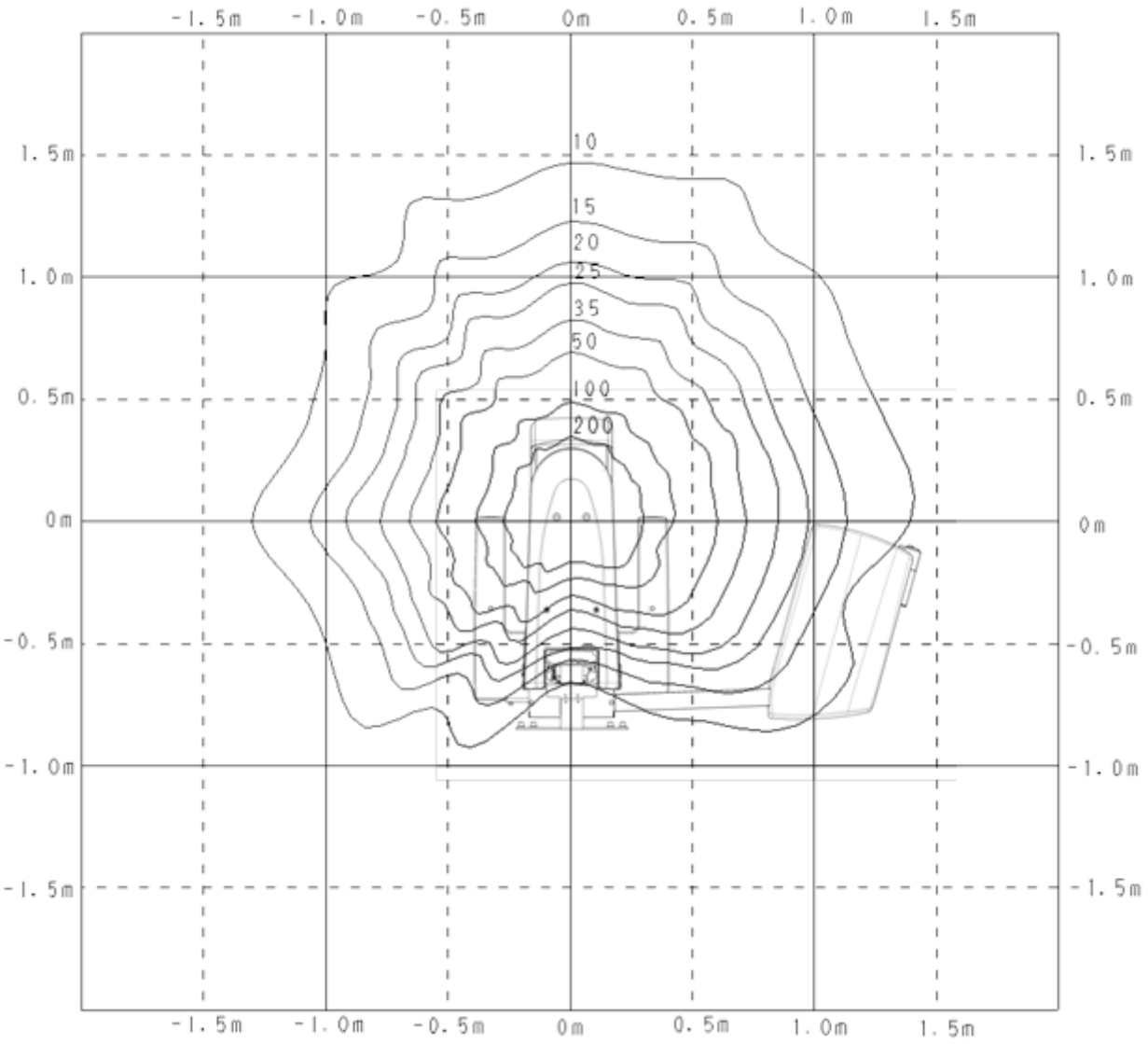
11.10.5 Stray radiation dose of X-era Smart in 3D oral mode with Cephalometric

Unit: nGy/mAs



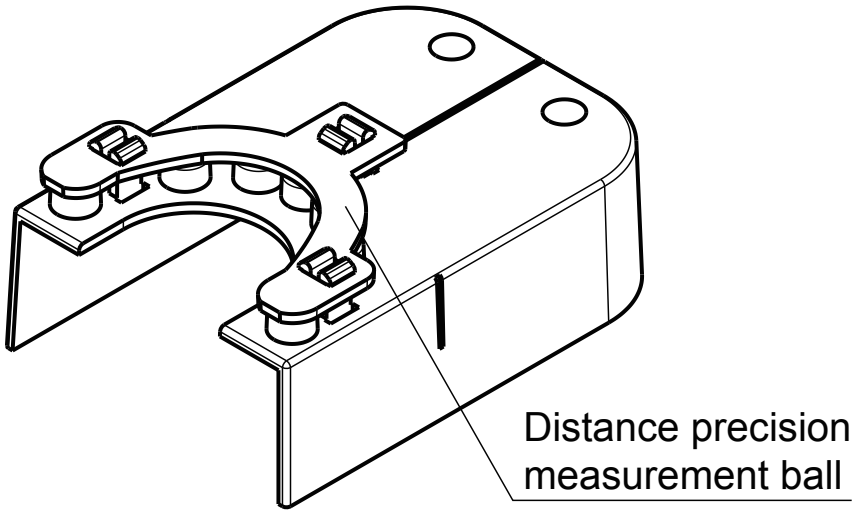
11.10.6 Stray radiation dose of X-era Smart in 3D dental mode with Cephalometric

Unit: nGy/mAs

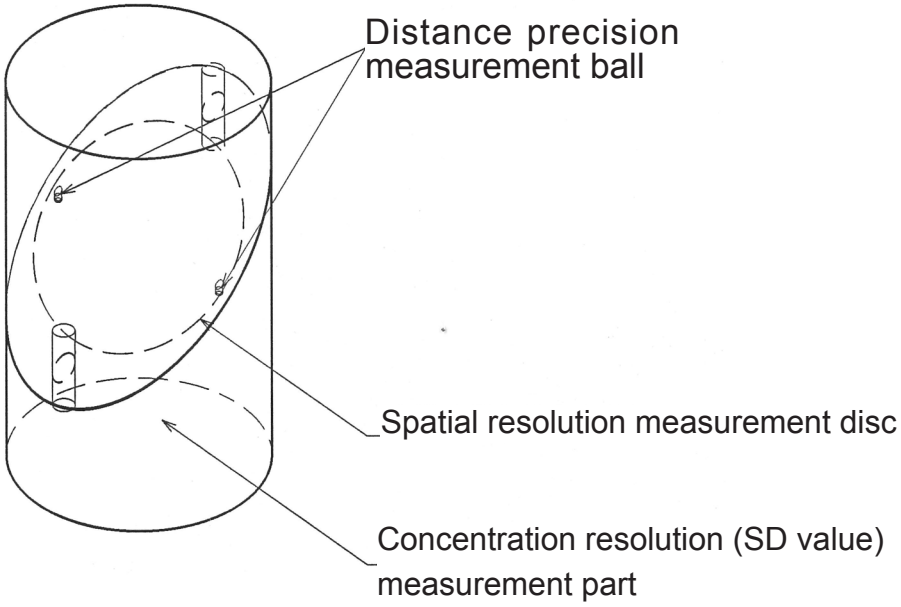


12 QA (Quality Assurance)

12.1 Structure of the Installation Phantom



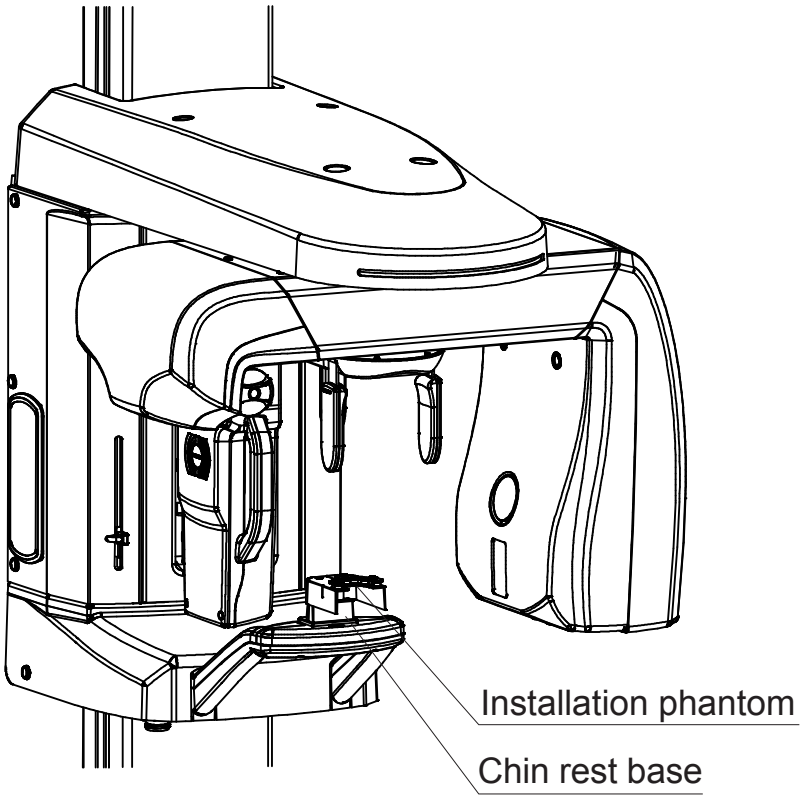
12.2 3D QA Phantom Structure



12.3 QA Procedure (Panorama)

NOTE : Perform an inspection according to the following steps every six months and save the result.

1 Attach the Installation phantom to the chin rest block base.

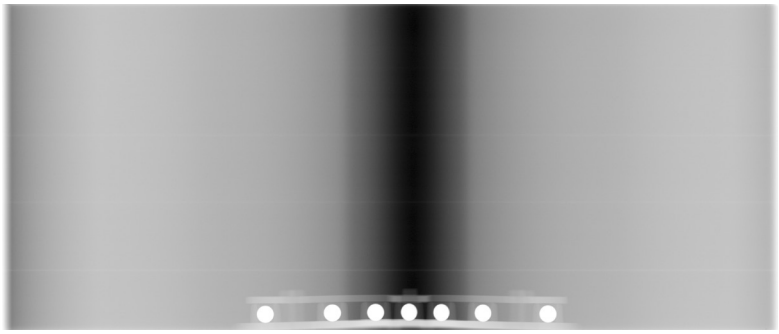


2 Acquire image of the Installation phantom under the following conditions.

	Image acquisition mode	Standard panoramic
Image acquisition mode setting	Image acquisition status	Manual
	Tube voltage	58 kV
	Tube current	2 mA
	Exposure time	16 sec
User program mode setting	Spine compensation	OFF
Image Creator setting	Dental arch size	Normal
	Dental arch shape	Normal
	Tomographic position	0 mm

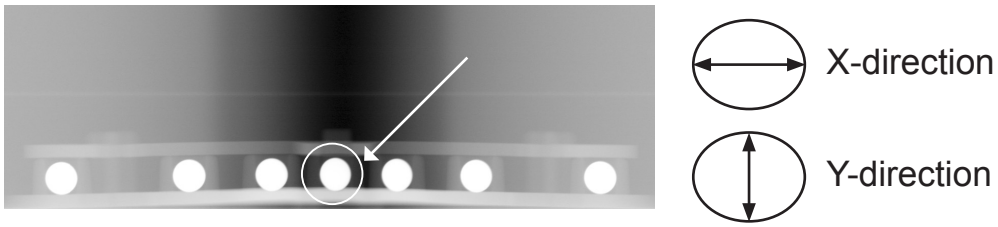
NOTE : For the above image acquisitions, do not move the arm position. If you have moved the arm position using the forward/back switch, press the reset switch to return the arm to the original position before acquiring images.

3 Check the following from the acquired panoramic images.



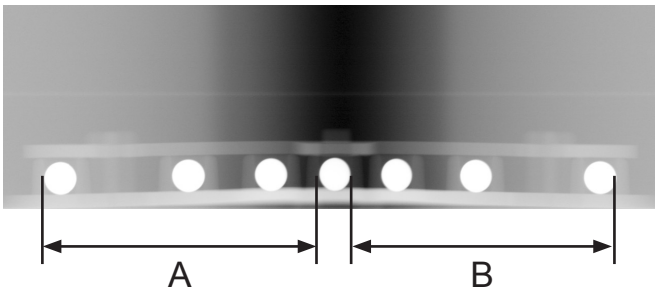
Suppl. : Set the tomographic orbital position to “0.0 “ in Image Creator, and check the acquired image after the adjustment.

1. Check the circularity of the steel ball in the center.
   Radius of the X-direction should be within ±9% of the radius of Y-direction.



   See also : For measurement functions, see the Viewer manual.

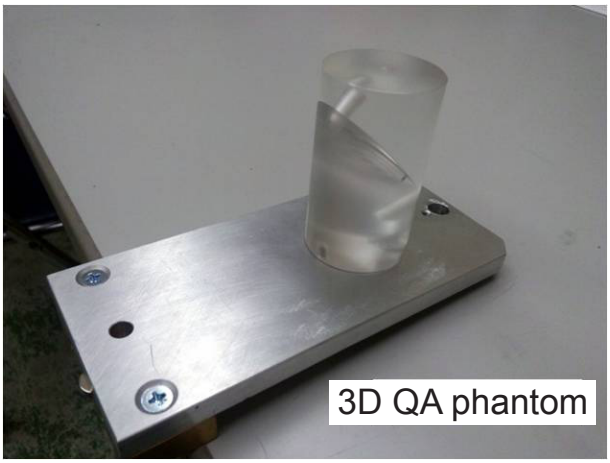
2. Check the distance from the steel ball in the center to the steel balls in the right/left end.
   For the measurement values A and B below, it should be | (A-B)/(A+B) |≦0.035.



   See also : For measurement functions, see the Viewer manual.

12.4 QA Procedure (3D)

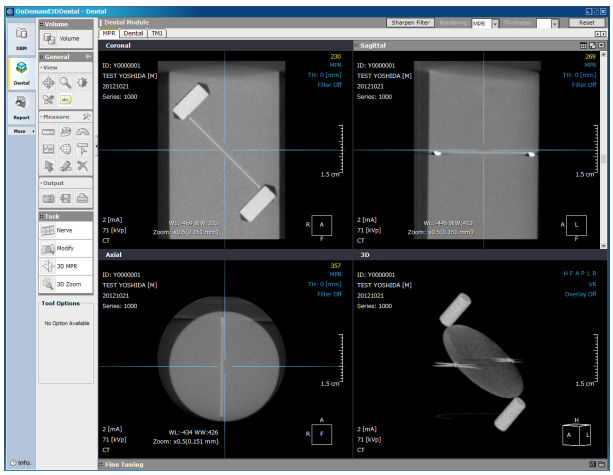
NOTE : Inspect the equipment every six months following steps below, and keep the record.



1 Attach the 3D QA phantom to the chin rest base. Conduct image acquisition in two modes, Dental Mode and Oral Mode.

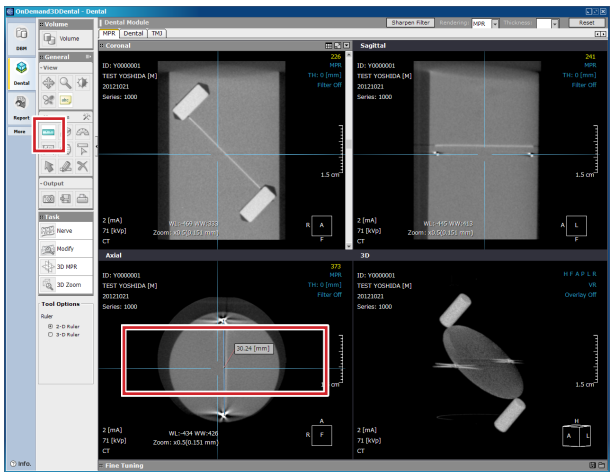
Conditions for image acquisition are as follows: Tube Voltage 71kV, Tube Current 2mA

Note : In this image acquisition, do not move the forward/backward position of the arm. If the arm was moved by pressing forward/backward switch, press the rest switch so that the arm returns to the original position before acquiring images.



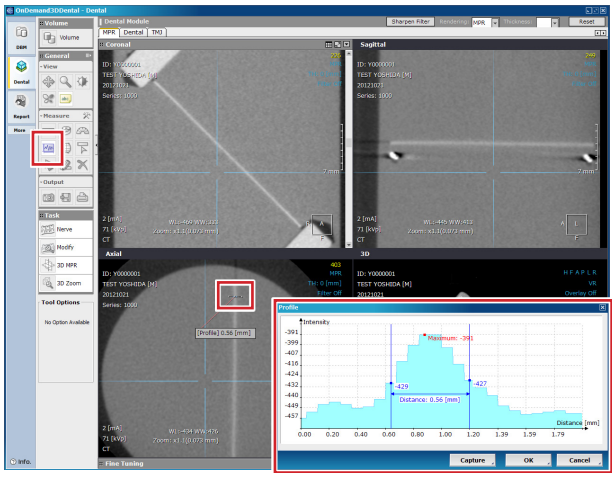
2 Displays the acquired image in OnDemand3D.

Go through steps 3 to 6 and check the images acquired in two modes, Dental Mode and Oral Mode.



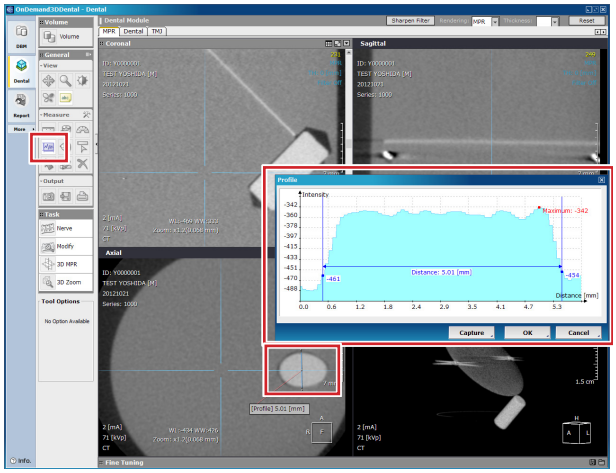
3 Adjust the tilt of the crossbar, and measure the distance between the two steel balls.

Acceptance value 29.6 mm to 30.4 mm (standard value 30.0 mm)



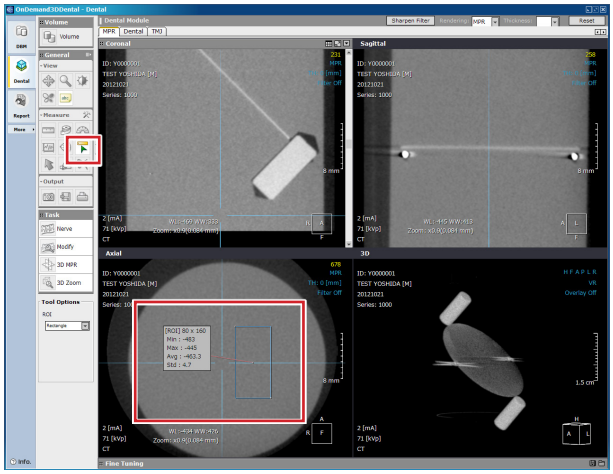
4 Measure aluminum disk thickness from Axial image. However, measure it without adjusting the crossbar tilt.

Where to measure is described in the figure below. Measuring point is above the lower Teflon pin and below the aluminum disk center. Use the profile function to set the profile so it will be perpendicular to the Aluminum disk shown in the Axial image. Measure the width of the graph when the height of the graph is approximately 50%. Acceptance value 0.7 mm or less



5 Measure the short axis diameter of the Teflon pin from Axial image. However, measure it without adjusting the cross-bar tilt.

Where to measure is described in the figure below. Measuring point is around the center of the lower Teflon pin. Use the profile function to set the profile of the short axis diameter of the Teflon pin shown in the Axial image. Measure the width between the initial rising points in the graph. Acceptance value 4.6mm to 5.3mm (standard value 5.0mm)



6 Find out the standard deviation of pixel values of the acrylic part from the Axial image. However, measure it without adjusting the crossbar tilt.

Where to measure is described in the figure below. Measuring point is between the bottom edge of lower Teflon pin and the bottom edge of the image.Use ROI function to read the Std value when acrylic part shown in the Axial image is surrounded by the size of 80 x 160. As shown in the figure below, avoid the center of the Axial image when locating the surrounding area with ROI.

Acceptance value:

For Image Creator Version 2.52 or earlier: 10 or less

For Image Creator Version 2.53 or later: 120 or less

NOTE

Please be sure to fill your information in:

Contact

X-era Smart
Operation Manual
Issue date: February, 2014 (4th version)

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