



Veraview FX800

INSTRUCTIONS FOR USE

ENT



Instructions for Use in Electronic Format (eIFU)



The electronic data (PDF document) of the Instructions for Use is available. Scan the following QR code and visit our website.



In order to view PDF documents, you will need the free Adobe Acrobat Reader distributed by Adobe Inc. Download the latest version via the Adobe website. PDF documents may not be displayed correctly using previous versions.

Thank you for purchasing the Veraview FX800.

For optimum safety and performance, read this manual thoroughly before using the unit and pay close attention to warnings and notes.

Keep this manual in a readily accessible place for quick and easy reference.

The Veraview FX800 is only available in the U.S.A.

Trademarks and Registered Trademarks:

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1 Prevent Accidents

1.1 Attention Customers

Do not fail to receive clear instructions concerning the various ways to use this equipment as described in this accompanying Instructions for Use.

Fill out and sign the warranty and give the dealer from whom you purchased the equipment a copy.

1.2 Attention Dealers

Do not fail to give clear instructions concerning the various ways to use this equipment as described in this accompanying Instructions for Use.

After instructing the customer in the operation of the equipment, have him fill out and sign the warranty.

Then fill in your own section of the warranty and give the customer his copy. Do not fail to send the manufacturer's copy to J. MORITA MFG. CORP.

1.3 Safety Instructions and Recording Information

When the Veraview FX800 is installed, the installer or other responsible party must explain the precautions and usages in the Instructions for Use to the user and the person responsible for maintenance and management.

In accordance with the laws of the relevant country or region, information such as the installation date, explained contents, the name of operator and healthcare facility's maintenance representative, and the name of the installer or other responsible party, may need to be recorded.

1.4 Prevent Accidents


Most operation and maintenance problems result from insufficient attention being paid to basic safety precautions and not being able to foresee the possibilities of accidents.


Problems and accidents are best avoided by foreseeing the possibility of danger and operating the unit in accordance with the manufacturer's recommendations.

First thoroughly read all precautions and instructions pertaining to safety and accident prevention; then, operate the equipment with the utmost caution to prevent either damaging the equipment itself or causing bodily injury.

The following symbols and expressions indicate the degree of danger and harm that could result from ignoring the instructions they accompany:

 **WARNING** A hazard with a medium risk of injury or death if not avoided.

 **CAUTION** A hazard with a low risk of minor or moderate injury if not avoided.

 **(Usage Note)** This informs the user of important points concerning operation or the risk of equipment damage.

The user (i.e., healthcare facility, clinic, hospital etc.) is responsible for the management, maintenance and use of medical device.

Disregarding the information on safety is considered ABNORMAL USE.

This equipment must only be used by medical doctors, dentists, and other legally licensed professionals.

Do not use this equipment for anything other than its specified medical and dental X-ray exposure purpose.

1.5 Disclaimer

J. MORITA MFG. CORP. will not be responsible for accidents, equipment damage, or bodily injury resulting from:

1. Repairs made by personnel not authorized by J. MORITA MFG. CORP.
2. Any changes, modifications, or alterations of its products.
3. The use of products or equipment made by other manufacturers, except for those procured by J. MORITA MFG. CORP.
4. Maintenance or repairs using parts or components other than those specified by J. MORITA MFG. CORP. and other than in their original condition.
5. Operating the equipment in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being observed.
6. Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
7. Fires, earthquakes, floods, lightning, natural disasters, or acts of God.

The useful life of the Veraview FX800 is 10 years from the date of installation provided it is regularly and properly inspected and maintained.

J. MORITA MFG. CORP. will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued. For the duration of this period, we will supply replacement parts and be able to repair the product.

1.6 In Case of Accident

If an accident occurs, the Veraview FX800 must not be used until repairs have been completed by a qualified and trained technician provided by the manufacturer.

Report any serious incident related to the device to the manufacturer and the authority having jurisdiction in their locale.

1.7 User Qualifications

Intended Operator Profile

a) Qualification:

Legally qualified person such as a medical doctor, dentist and radiologic technologist (radiologic technician) for X-ray device operation (it may differ among countries).

b) Education and Knowledge:

It is assumed that the user understands the risks of X-rays and the protective steps required. It is also assumed that the user is thoroughly familiar with X-ray diagnosis, anatomy, and hygiene including the prevention of cross contamination.

c) Language Understanding:

English (Intended for professional use as described above)

d) Experience:

Experienced person with operating cone beam computed tomography or panoramic X-ray device.

No special training is required except in cases where this is required by legal regulations of the relevant country or region.

2 Precautions

WARNING

- To avoid the risk of electric shock, this equipment must only be connected to the supply mains with protective earth.
- Do not modify this equipment without authorization of J. MORITA MFG. CORP.
- When an examination requires X-ray irradiation to implantable or wearable electronic medical device, the operator must take proper care after referring to the instructions for use (and related safety information) for such implantable or wearable electronic medical devices because if a diagnostic X-ray device directly irradiates an implantable or wearable electronic medical device, it can cause sufficient electronic interference to affect the function and operation of the medical device.
 - * For reference, U.S.A. FDA published about interference with cardiac implantable electronic devices (pacemakers and implantable cardioverter defibrillators), insulin pumps, and neurostimulators on the following web site. (Accessed July 2018)
Title: Interference between CT and Electronic Medical Devices
URL: <https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm489704.htm>
- The patient and operator must be provided with appropriate X-ray protection gear such as lead-impregnated clothing that conforms to local regulations.

● Infection Control

- Proper infection control procedures must be established and maintained for each patient.
- Disposable covers for the chinrest must never be re-used. A new one must be used for each patient.
- The chinrest must be disinfected by wiping with ethanol (70 vol% to 80 vol%) after each use, and disposable covers put on the chinrest.
- The patient handle must be disinfected by wiping it with ethanol (70 vol% to 80 vol%) after each patient. If the patient has an open or bleeding wound on his hand, the patient handle should be covered to prevent cross contamination before the patient grips it.

IMPORTANT PRECAUTIONS

These caution remarks are especially critical for safe operation and use.

- This unit must be used in a X-ray controlled area. Local regulation for radiation protection must be observed.
- Control box and emission switch must install and in radiation protected area.
- Special attention must be paid to the strength of the floor and wall materials, refer to the installation instructions.
- Steps must be taken to limit entry to the X-ray room during X-ray emission.
- User must restrict access to the equipment in accordance with local regulations for radiation protection.
- This equipment has an optional function so that it can be connected to external electrical devices such as a door switch that will stop X-ray emission or prevent X-ray emission. In this case we recommend that the management of the facility post a visible notice to inform people of the use of the external electrical devices.
- No unauthorized personnel be in the immediate area when the equipment is in use.
- If, for some reason, a person other than the patient must be within the X-ray controlled area during X-ray emission, he must take adequate X-ray protection measures.
- Proper radiation safety precautions must be established in accordance with local, state and governmental regulations in regards to operator and patient protection. The ultimate responsibility lies with the owner/operator to ensure that the protection requirements of national and local codes are met.
- Do not use this unit for fluoroscopic examinations.

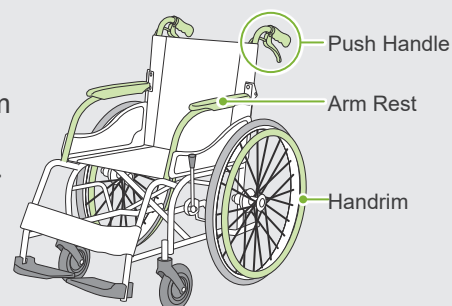
- Do not use the wireless transmission devices listed below in the examination area:
 - (1) Mobile phones and smart devices.
 - (2) Wireless transmitting devices such as ham radios, walkie-talkies, and transceivers.
 - (3) Personal Handy-phone System (PHS).
 - (4) Routers for intra-building paging systems, wireless LAN, cordless analogue telephones, and other electric wireless devices.
- Interference from the Veraview FX800, devices listed below might malfunction or operate in a random, unexpected and dangerous manner.
 - (1) Electric medical devices for examination, diagnosis and treatment.
 - (2) Personal computers.
- Responsible organization in medical institution need for providing means for audio and visual communication between the operator and the patient.
- The operator must be able to see the exposure emissions lights and hear the audible signal during operation of the equipment.
- The operator must be able to see and hear the patient during the operation of the equipment.
- Watch the area around the moving parts to avoid collision against the body parts or other objects which may result in injury.
- Make sufficient space around the power distribution panel so that it is easily to breaker open in case of emergency.
- Do not open or remove any of the unit's enclosures. No user serviceable parts inside.
- The operator shall not touch the LAN connector when touching the patient.
- Do not use this equipment for patients when it is being maintained or serviced.
- CT images cannot be used for diagnosis of soft tissue.
- For optimum radiation protection, refer to the recommendations and advice issued by the ICRP (International Commission on Radiological Protection) and EADMFR (European Academy of Dentomaxillofacial Radiology).
 - * As Low As Reasonably Achievable (ALARA): All exposure to radiation should be kept at the lowest level as is reasonably possible taking into consideration social and economic factors. (ICRP, 1977)
 - * Basic Principles on the use of Cone Beam CT (EADMFR)
- This equipment does not provide CT Numbers (required in 21 CFR 1020.33 and IEC 60601-2-44) or any equivalent values calculated from the absolute X-ray absorption of the target material.
- The inspection examination protocols must be created by your facility. The examination protocols are not preloaded on the device.

● Pregnant Women, Women in Labor, Nursing Mothers, and Infants

- Careful and prudent judgment must be exercised before exposing pregnant women, women who might be pregnant, women in labor, nursing mothers, infants etc. to X-ray examination, the X-ray dosage should be reduced as much as possible and the examinee must be provided with adequate X-ray protection.
- Judgment and caution should be used in regards to radiographs of pregnant women. The decision should be based on “clinical need of diagnostic information”.

● Patient in a Wheelchair or Sitting in a Chair

- This unit has an electric lift mechanism. Whenever the lift is lowered, make sure none of its parts (control panel support, arm, arm support) hit or contact the patient.
- Make sure the push handles, arm rests, handrims etc. of a wheelchair do not make contact with the X-ray unit.
- Before making an exposure, run a test with no X-ray mode to make sure that the patient or the wheelchair does not make contact with the arm.

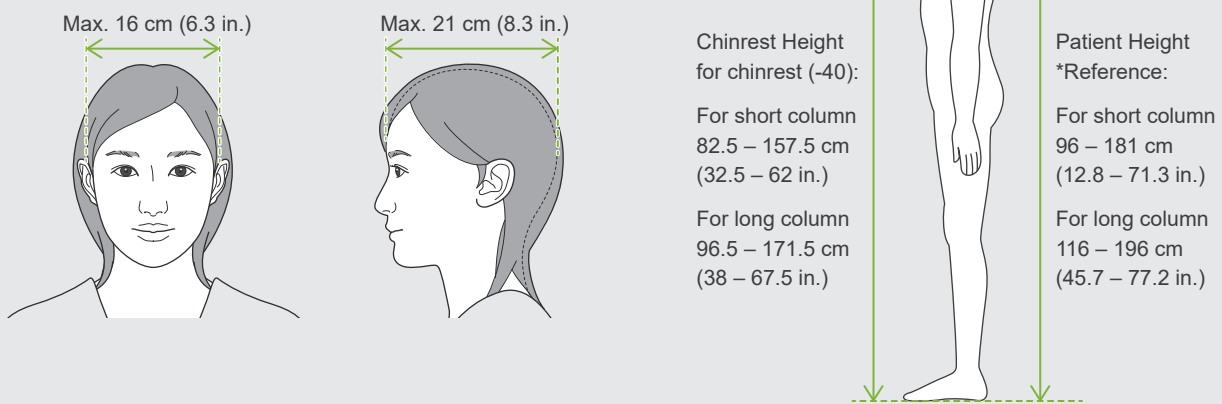


● Patient Size and Positioning

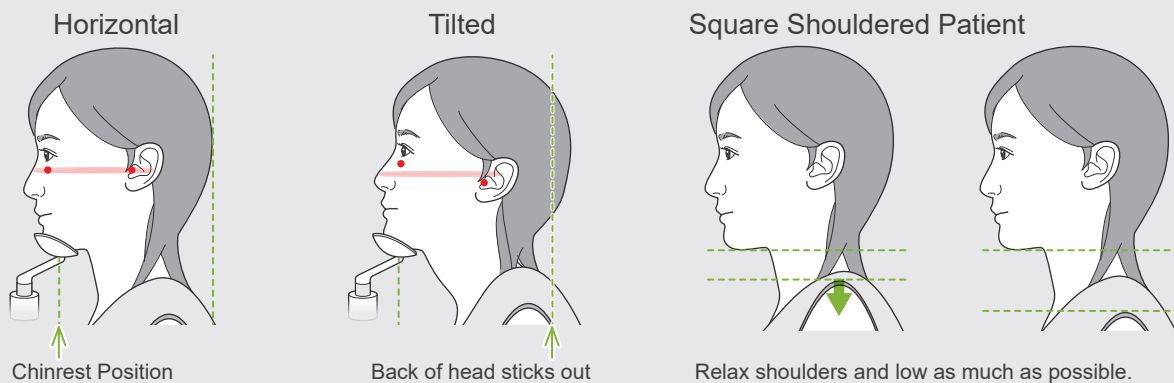
- The X-ray detector, X-ray head and arm rotate around the patient during emission. Depending on the patient's head size, positioning and shoulder location, the arm might make contact with the patient. To avoid this, the operator must carefully consider the patient's size and positioning.
- If the patient might be larger than permitted, run a test with no X-ray mode to make sure that the arm does not make contact with the patient.
- For a CT exposure of a large or larger than permitted patient, use 180° exposure mode to keep the arm from contacting the patient.

Assumed Patient Size

* Positioning with horizontal line from the orbitale to ear orifice.



- If the line from the orbitale to the ear orifice is not horizontal, the back of the head might stick out and make contact with the arm. If this is the case, run a test with no X-ray mode to make sure the arm does not contact the patient.
- For patients who have square shoulders or short necks, the arm might contact the shoulder. In this case, have the patient lower his shoulders as much as possible and then run a test with no X-ray mode to make sure the arm does not contact the patient.



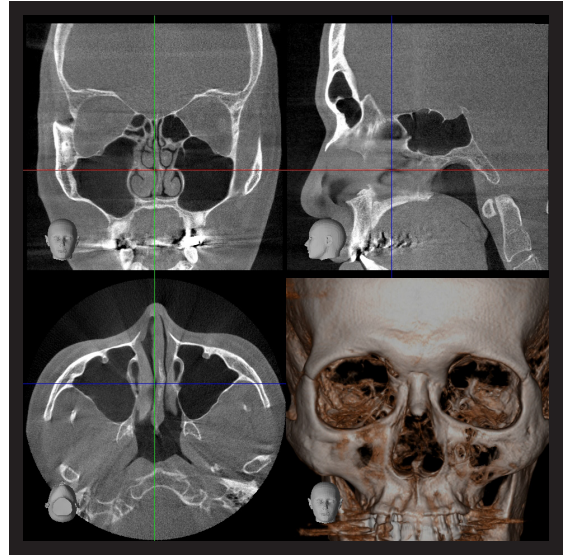
3 Production Information

3.1 Capabilities

The Veraview FX800 is a diagnostic X-ray device intended to perform cone beam computed tomography (hereafter “CT”).

● CT Exposures

- Partial Sinus
- Unilateral Temporal Bone



3.2 Related Documents

To use this unit, read the documents listed below and follow all cautionary notes and usage methods.

- Instructions for Use
- Quality Test Procedure

3.3 Acronyms

FOV: Field of View, mainly for CT exposure regions.

ROI: Region of Interest (exposure areas)

3.4 Environmental Considerations

Disposal of this unit, its accessories and replacement parts must conform to all local and international regulations.

Materials used in this unit:

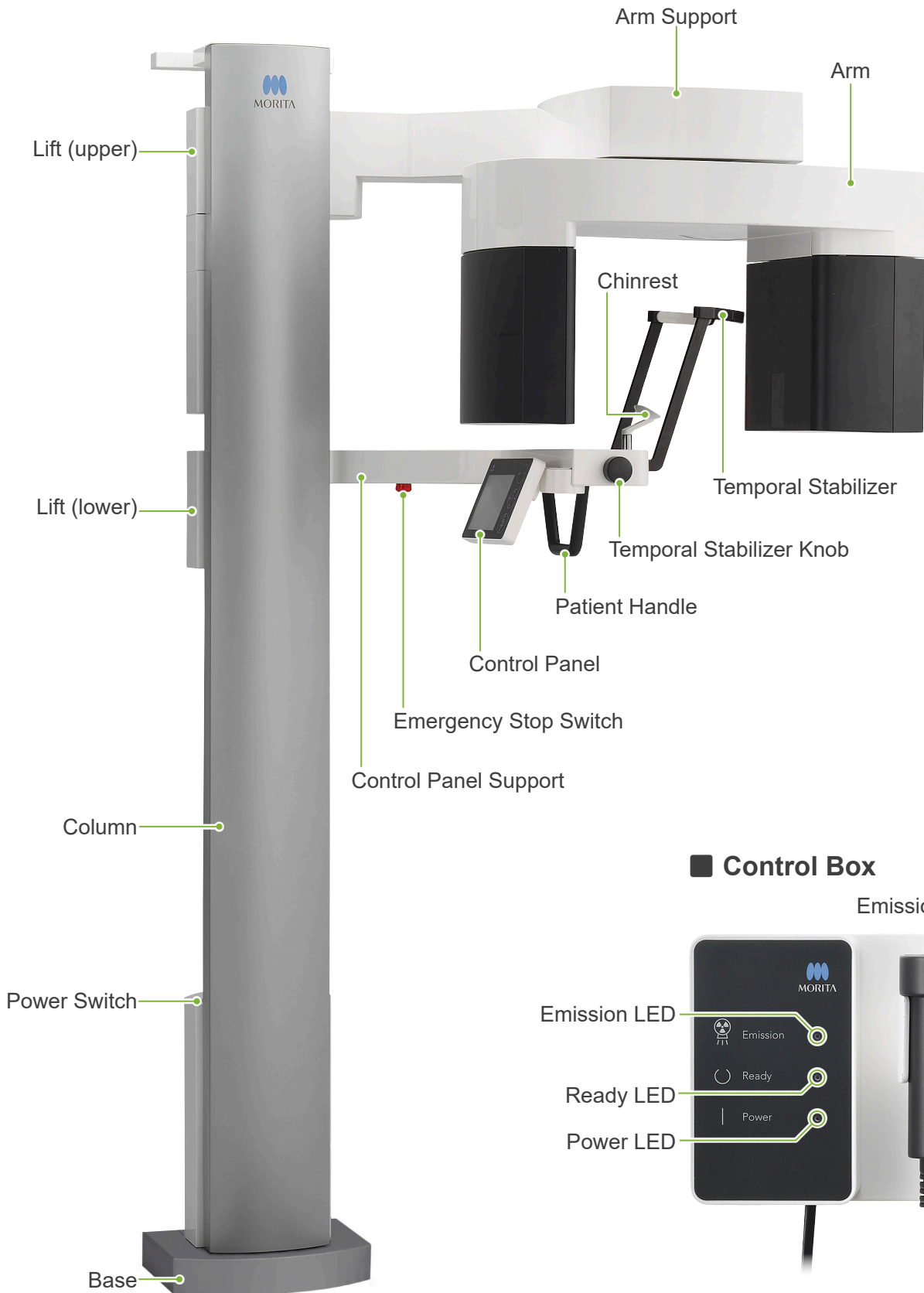
- X-ray Head: Lead, High voltage insulation oil
- X-ray Detector: Lead
- Collimator: Lead

! The FX800 contains metallic lead inside.

Lead is listed as a SVHC (substance of very high concern) under the European REACH Regulation (REGULATION (EC) No 1907/2006), but as long as the product is used in accordance with this manual, it will not come into contact with lead, nor will lead dust, fumes, or vapors be generated, so it can be used safely.

4 Parts Identification

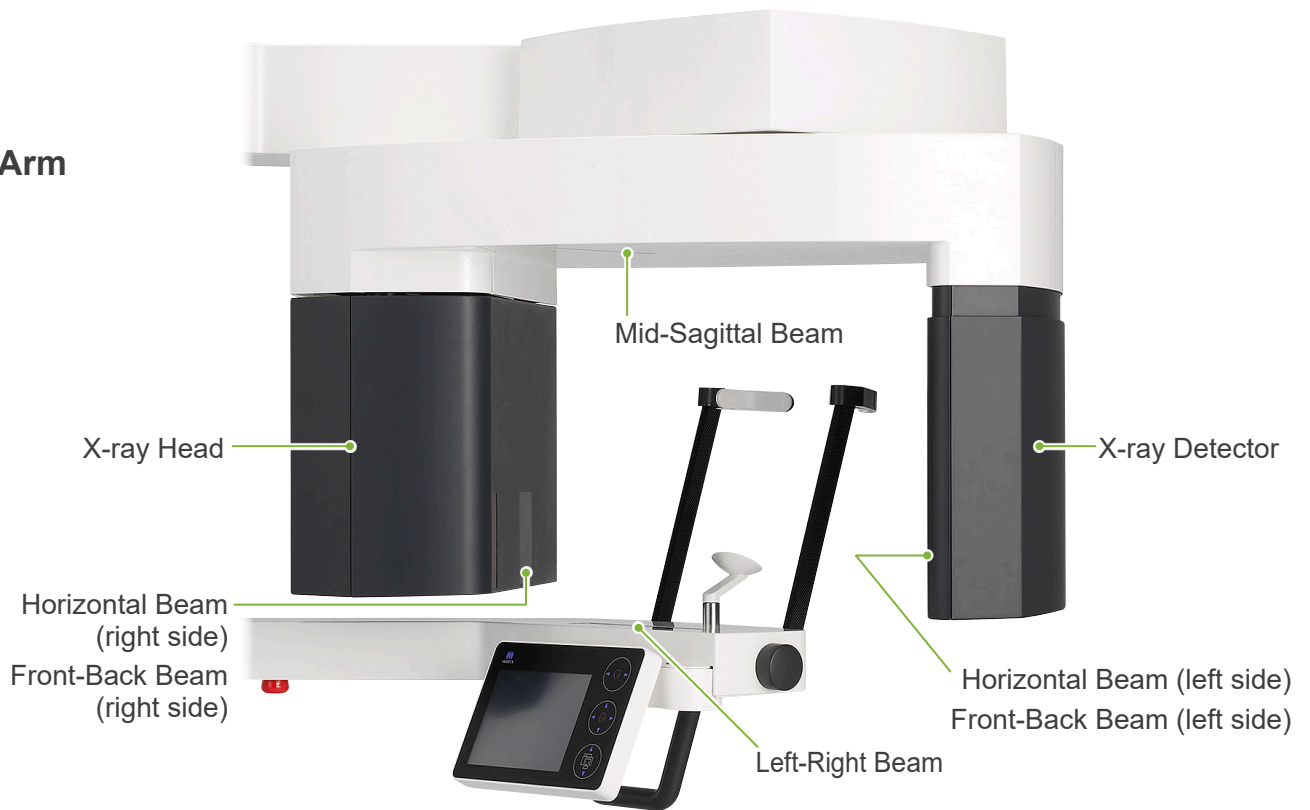
■ Main Unit



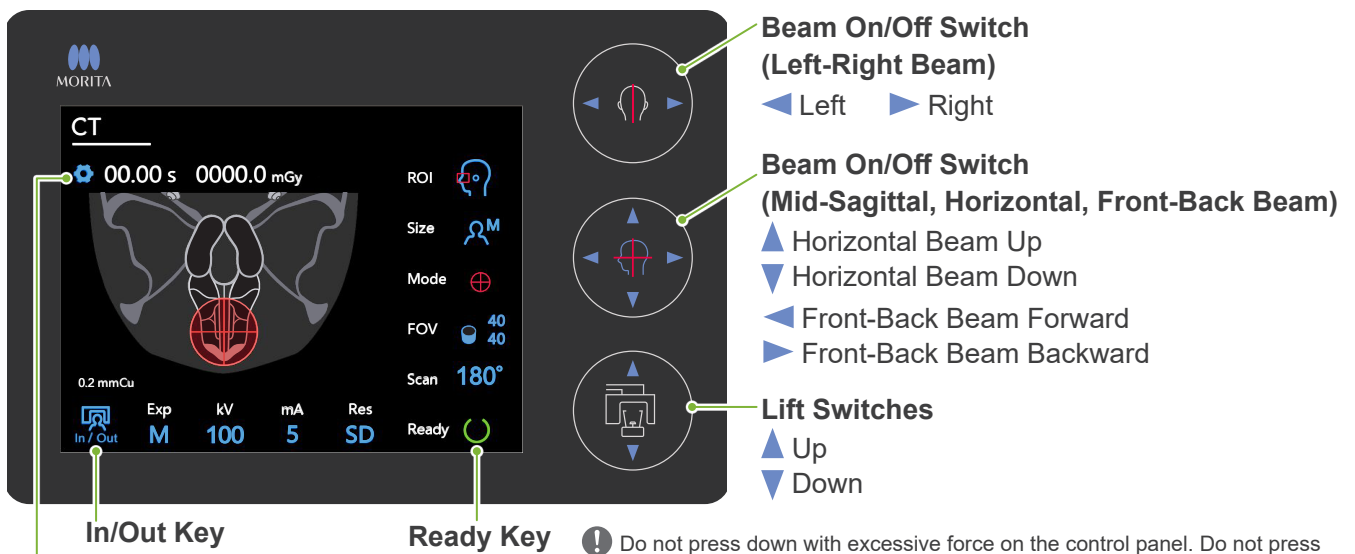
■ Control Box



■ Arm



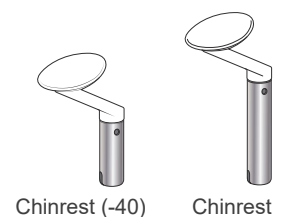
■ Control Panel Blue icons and the Ready key are activated by touch.



- ! Do not press down with excessive force on the control panel. Do not press on the panels with any sharp objects like ballpoint pens or fingernails etc.
- ! Do not use the Beam On/Off or Lift Up/Down switches while touching some other part of the panel.

Patient Positioning Tools and Consumable Parts

- Chinrest (-40) (1)
- Chinrest (1)
- Chinrest Disposable Cover (1 box of 100 pcs.)



5 Before and After Use

5.1 Operation Conditions

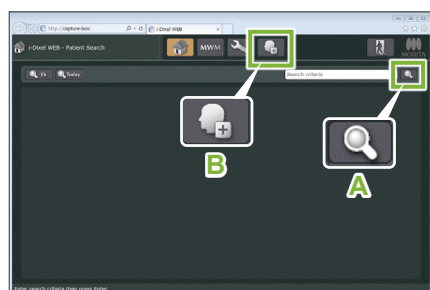
● Use Veraview FX800 Under Following Conditions:

The Veraview FX800 must be operated under specific conditions (ambient temperature range, humidity, and atmospheric pressure range). Follow the descriptions in the “**Operating Conditions**” (p. 80) of “**12.1 Technical Specifications**”.

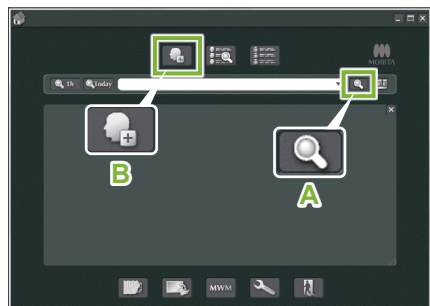
- * If an accident occurs, the equipment must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.
- * Have patients remove glasses, earrings and any other accessories that might interfere with the exposure.
- * Before use make a start-up inspection to make sure the unit will operate properly and safely.

5.2 Set Up

5.2.1 Start i-Dixel WEB



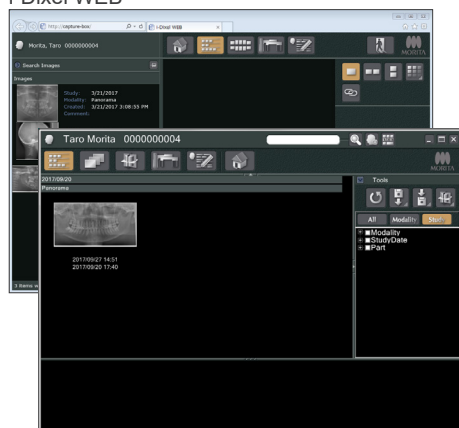
i-Dixel WEB



i-Dixel

Patient ID	Name	Sex	Birth Date	Age	Regi Date	Update	Image S	X
000000001	Morita Haruo	O	2017/04/05	0	2017/04/12	2017/09/27	0/0	103
000000002	Morita Haruko	O			2017/08/17	2017/09/27	4/62	839.5
000000004	Morita Taro	O	2017/08/25	0	2017/09/27		1	4.2

i-Dixel WEB



i-Dixel

1. Start i-Dixel or i-Dixel WEB

Start the i-Dixel or i-Dixel WEB software (hereinafter referred to as “i-Dixel WEB”).

2. Retrieve a registered patient

Enter the patient ID in the search field and click the search icon (A). To use the patient list, select a patient and then double-click it.

● Register a New Patient

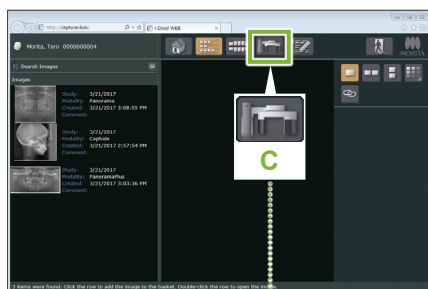
To begin, register a patient. Click the icon B to register a new patient. Fill out the form that appears and then click the Register button.

* Patient ID, Name and Sex are required items.

The screenshot shows the patient registration form. It includes fields for ID (000000005), Name (First, Middle, Last), Name (Kanji), Name (Kana), Sex (Male, Female, Other), Birth Date, Zip/Postal, Address1, Address2, Phone No. (1, 2), E-Mail, Attendant Dr., Operator, and Comments. A 'Register' button is highlighted with a green box.

An image list will appear.

* In CT exposure mode, the resolution is set automatically and cannot be changed.



3. Open Veraview FX800 Exposure window

Click the Veraview FX800 Exposure Window icon (C).
When the window opens, an exposure can be made.

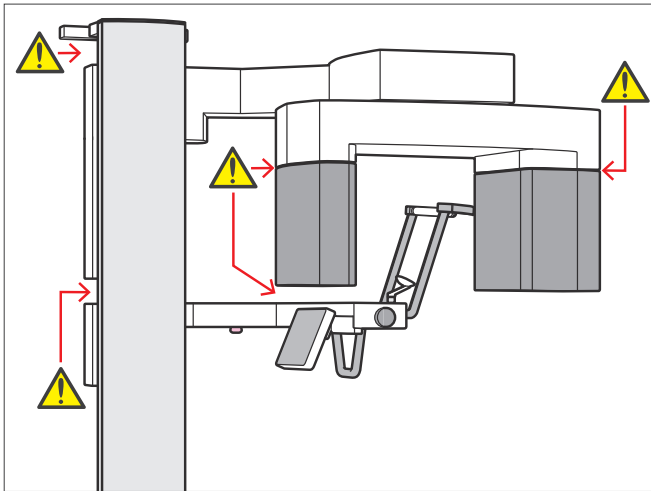
⚠ CAUTION

- When a patient is selected with i-Dixel WEB, the patient name appears on the title bar for the Veraview FX800 Exposure Window. Before making the exposure, make sure the name on the title bar is the name of the patient subject to the exposure. If it is not the right name, close the window, and then click the icon (C) to reopen the window. Check that the right name appears on the title bar, and then make the exposure. If the wrong name is on the title bar, the exposure data will be saved for the wrong patient.
- If multiple tabs or windows are open for i-Dixel WEB, processing can become unstable and this could lead to saving data in the wrong patient file or not being able to make the exposure. Do not fail to close all tabs and windows before clicking the icon (C) for the Veraview FX800 Exposure Window.

* Do not fail to open the Veraview FX800 Exposure Window before making an exposure.

* For details refer to the Instructions for Use for i-Dixel WEB.

5.2.2 Safety Check for Moving Parts

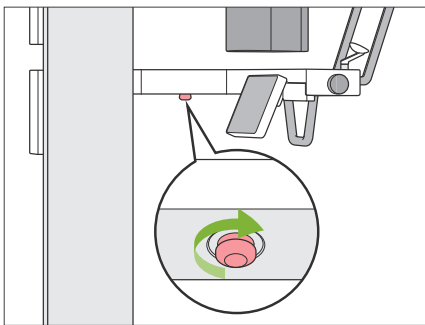


For safety, make sure that fingers will not be pinched before moving any parts.

⚠ CAUTION

- Keep fingers away from gaps and openings of moving parts as well as the holes on the support column.

■ Emergency Stop Switch



● In Case of Emergency

Press the Emergency Stop switch. This will stop the arm rotation and X-ray emission.

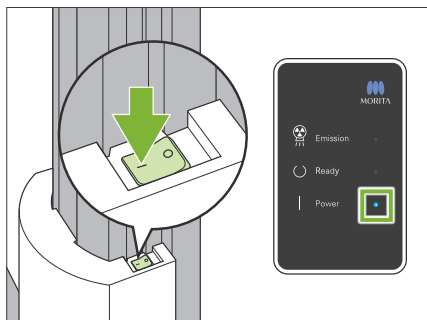
* Never use this switch except in the case of an emergency.

● After Pressing Emergency Stop switch.

1. Guide the patient away from the unit and turn off the Power switch.
2. Restore the unit to a safe condition.
3. Turn the Emergency Stop switch in the direction shown by the arrow in the illustration until it clicks to release it.
4. Restart the computer.
5. Turn on the Power switch.
6. Check the CT exposure operation.

If the unit cannot be returned to a safe condition or will not operate, contact your local dealer or J. MORITA OFFICE.

5.2.3 Start Main Unit



Press the side of the Power switch on the lower part of the column that is marked with a line (|).

The unit will turn on and the blue Power LED on the control box will light up.

⚠ CAUTION

- Do not press the Power switch if the patient is near or inside the equipment. Otherwise, the arm will rotate and the control panel support will move and could injure the patient.

- ! If the Emergency Stop switch has been inadvertently pressed while the unit was being cleaned etc., the unit cannot be turned on. Release the Emergency Stop switch, and then turn on the unit.
- ! When starting up the Veraview FX800 right after turning it off (e.g., rebooting the equipment), wait at least 5 seconds to turn it on again. Failure to do so could result in malfunction or damage to the equipment.

PC and cassette communication check

Please wait while communication between the digital cassette and PC is verified.

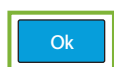
The “PC and cassette communication check” dialogue box will appear.

⚠ CAUTION

- If the temporal stabilizers are open, a message will appear warning to check them. The arm might hit them so turn the knob and close them.

Initialization

The unit will move to its initial position. The arm will move in multiple directions so ensure the immediate area is clear of obstructions before proceeding. If a patient is positioned in the unit, have them exit the unit before proceeding.



Then the “Initialization” dialogue box will appear.

If the patient is already in position, have him step away from the equipment.

Check the area and then click the “Ok” button.

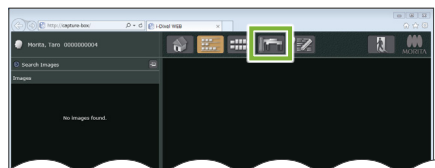
The arm will move to the patient entry position.

⚠ CAUTION

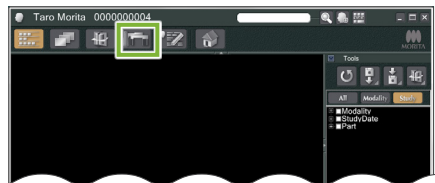
- Do not fail to move the patient away from the equipment and check the area for safety before initializing the equipment. Otherwise, the arm might move and it could hit the patient.

5.3 Start-up Inspection

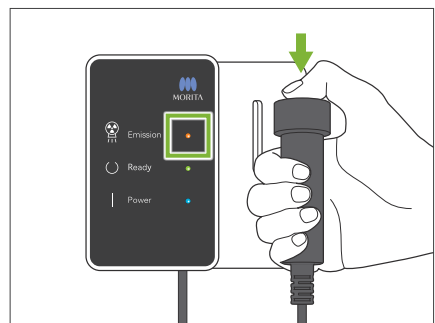
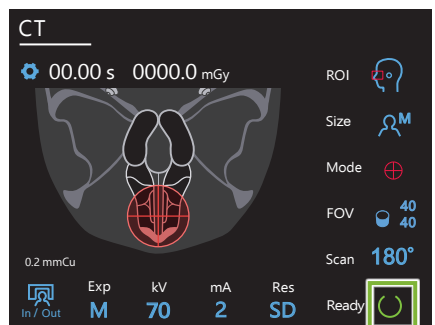
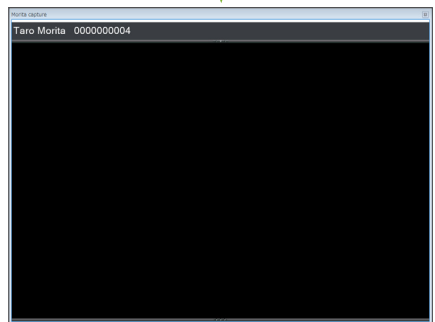
Before use make a start-up inspection to make sure the unit will operate properly and safely.



i-Dixel WEB



i-Dixel



1. Open the image list for the start-up inspection

Select the test patient used for the start-up inspection from the i-Dixel WEB patient list and display the image list for it.

● First Time Only

To begin, the test patient must be registered in i-Dixel WEB.

Click the Patient Registration Window icon to display the registration window, fill out the form and then click the Register button.

2. Open Veraview FX800 Exposure window

Click the Veraview FX800 Exposure Window icon to open it.

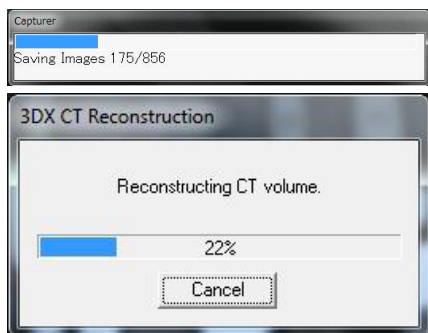
3. Check operation for CT exposure

Set the exposure conditions as shown below.

- Exposure Setting (Exp): "M" (manual)
- Tube Voltage (kV): 70 kV
- Tube Current (mA): 2 mA

Touch the Ready key to light it up.

- Hold down** the Emission switch and check the following items:
- Arm moves and X-rays are being emitted.
 - The Emission LED is on and the melody is playing.
 - X-rays emission and the arm rotation stop when the exposure is completed.
 - The Emission LED turns off and the melody stops.
- Release the Emission switch and hang it in its holder on the control box.



6. CT image display

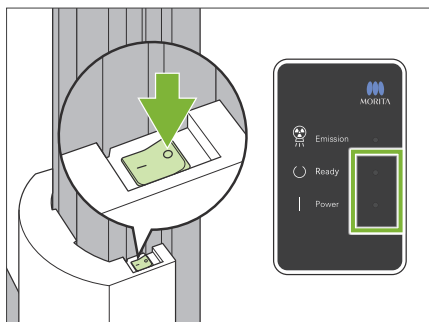
The inspection image will appear after about 5 minutes.

7. Delete the inspection data

Delete the data acquired during the inspection exposure.

5.4 After Use

5.4.1 Turn Off the Unit



Press the side of the Power switch marked with a circle (○).
The unit will turn off. The Ready and Power LEDs will turn off.

CAUTION

- Do not fail to turn off the Power switch. This prevents the risk of current leakage, inadvertent operation, etc.
- ⚠ When starting up the Veraview FX800 right after turning it off (e.g., rebooting the equipment), wait at least 5 seconds to turn it on again. Failure to do so could result in malfunction or damage to the equipment.

6 CT Exposure

6.1 Exposure Types and Functions

6.1.1 FOV (Field of View)

■ Ø40

For small regions such as a part of sinuses or middle ear. X-ray dosage is very low because exposure is localized.

■ Ø80

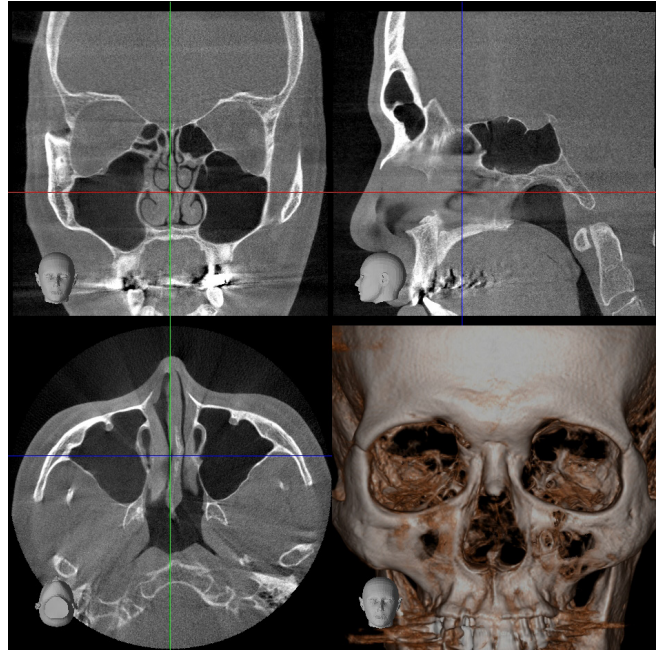
For one side of maxillary sinuses, ethmoid or sphenoid sinuses.

■ Ø150

For most of maxillofacial area including paranasal sinuses.

* The arm rotates 360°, but the data is equivalent to a 180° rotation.

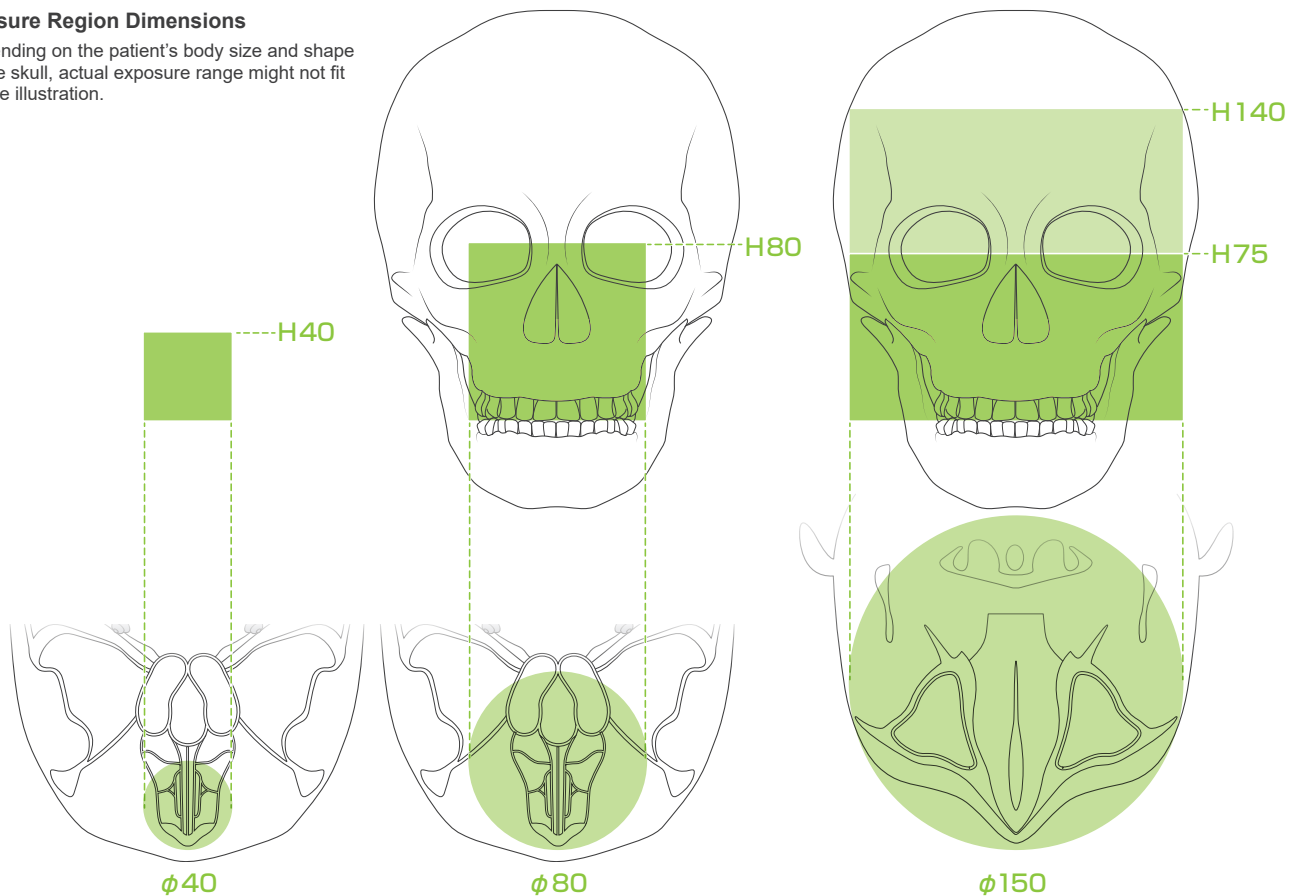
* For an H140 exposure, the lower part is made first and then the upper part.



Ø150 × H140

Exposure Region Dimensions

* Depending on the patient's body size and shape of the skull, actual exposure range might not fit as the illustration.



Exposure Functions Chart

Field of View (FOV)	Scan (Scan)		Resolution (Res)	
	180°	360°	HR (high resolution)	SD (standard)
Ø40 × H40	○	○	○	○
Ø80 × H80	○	○	–	○
Ø150 × H75 Ø150 × H140	○	–	–	○

6.1.2 180° & 360° Exposure Modes

Data for image reconstruction can be obtained with either 180° or 360° scans.

■ 180°

Use this for patients who find it hard to stand still or to reduce X-ray dosage.

■ 360°

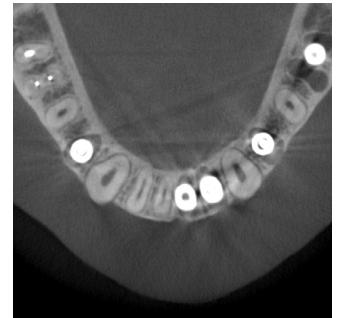
Since the data obtained has a higher density, there are fewer artifacts in the image.

- * For a CT exposure of a large or larger than permitted patient, use 180° exposure mode to keep the arm from contacting the patient.
- * For the Ø150, the arm rotates 360°, but the data is equivalent to a 180° rotation.

180° Exposure



360° Exposure



* Images of the dental arch show the difference between 180° and 360° exposure modes.

6.1.3 Resolution (Res)

■ High Resolution (HR)

High resolution images are ideal for treatment of Temporal bone etc. Voxel size is 80 μm .

Patient Size	2.5 lp/mm MTF (%)
C (Children), S, M	10
L	7

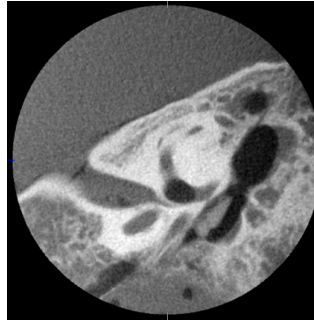
* MTF (Modulation Transfer Function) can be affected by the installation environment. For the recommended installation environment, refer to the Installation Instructions.

* If the equipment receives vibrations during exposure, the values may be lower.

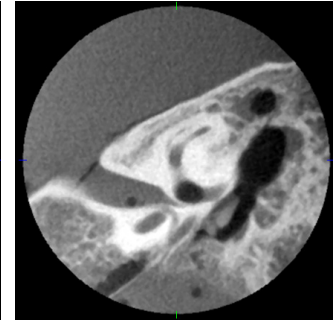
* Even slight patient movement can greatly affect the image quality. Consider doing the following things to make sure the patient stays as still as possible.

- Tell the patient to close his eyes during the exposure.
- For greater stability, it is better to have the patient sit on a chair.
- Using the 180° exposure is recommended if it is hard for the patient to stay still for a long time.

HR Exposure



SD Exposure



● i-Dixel WEB Operation and Resolution

Zoom Reconstruction Function

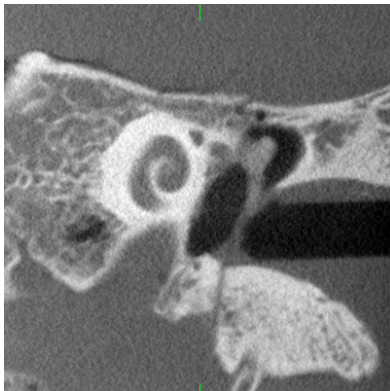
A higher resolution image (80 μm pixels) can be made without repeating the exposure by specifying a region of a completed CT image and having that area reconstructed again.

Slice Thickness Adjustment

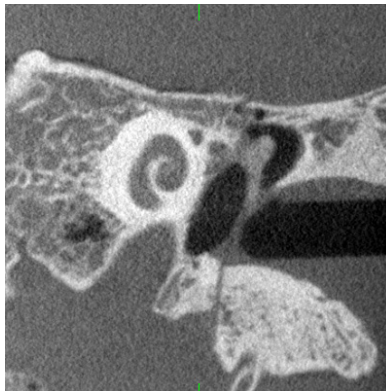
After making a CT exposure, the slice thickness can be adjusted with i-Dixel WEB. Adjusting the slice thickness has the following effects:

- Thicker slices have lower resolution but make smoother images.
- Thinner slices have higher resolution but are grainier.

0.96 mm Slice (standard setting)



Slice Thickness: 0.48 mm



Since the pixel size for high resolution (HR) is 0.2 pt 80 μm , a 0.48 mm slice should produce better resolution than the standard resolution (SD). Adjust the slice thickness to suit your purposes such as observing delicate features of hard tissue.

* For details refer to the Instructions for Use for i-Dixel WEB.

6.2 Operation and General Settings

6.2.1 CT Exposure

A

CT
00.00 s 0000.0 mGy

ROI [Icon] 1

Size [Icon] M 2

Mode [Icon] 3

FOV 40 40 4

Scan 180° 5

0.2 mmCu

In/Out [Icon] B

Exp M 6

kV 100 7

mA 5 8

Res SD 9

Ready [Icon] C

Numbers 1 to 9 show the current settings. Touch any one of the icons to show other selections.

Pan Ceph CT

ROI [Icon]

Size [Icon] M

Mode [Icon]

FOV 40 40

Scan 180°

Exp M kW 100 mA 5 Res SD Ready [Icon]

Exposure Time
00.00 s 0000.0 mGy

X-ray Dosage

A. Settings Key

Hold down this key to save the current settings for each patient size. The Veraview FX800 will load these settings as the default values from the next start-up.

B. In/Out Key

Touch for patient entry and egress. The arm moves to 90° to the lift for easy patient entry and egress.

C. Ready Key

Shows that the unit is in the ready state.

This key blinks when the Power switch is turned on.

Touch it after guiding the patient into position: it will light up. The arm will move to its patient position and the mid-sagittal, horizontal, and front-back (left-right) beams will light up. The unit is ready to begin X-ray exposure whenever the Emission switch is pressed.

6.2.2 Positioning Beams

Mid-Sagittal Beam
This beam lines up with the patient's mid-sagittal plane. Press the Beam On/Off switch to turn it on.

Horizontal Beam ▲▼
Indicates the height center of the FOV.











Front-Back Beam ◀▶
Indicates the center in the front-back direction of the FOV.

Left-Right Beam ◀▶
Indicates the center in the horizontal direction of the FOV.

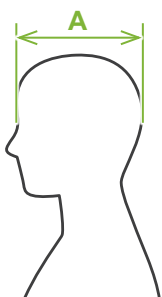
Beam On/Off Switch (Mid-sagittal, Horizontal, Front-Back)

Beam On/Off Switch (Left-Right)

6.2.3 Settings

1. Exposure Area (ROI)	2. Patient Size (Size)	3. Positioning Modes (Mode)	4. Exposure Region (FOV)		5. Scanning (Scan)	6. Exposure Setting (Exp)	7. Tube Voltage (kV)	8. Tube Current (mA)	9. Resolution (Res)	Positioning Tool
			∅	H						
Partial Sinus 	 	Two-Direction Scout 	40	40	180° (Half Scan)	M (Manual)	100	2 – 8	HR (High Resolution) SD (Standard)	Chinrest (-40)
			80	80						
Unilateral Temporal Bone 		Beam Positioning 	40	40	360° (Full Scan)	Off (No X-ray Emission)	85	2 – 9	HR (High Resolution) SD (Standard)	
Sinus 		Beam Positioning 	150	75						
				140		70				

■ Patient Size and Tube Voltage / Current



Tube voltage and current are adjusted according to patient size.

The set values for patient size is the sagittal length of the skull (**A**).

The upper limit for the lift cannot accommodate patients taller than 191 cm (75.2 in.) (176 cm (69.3 in.) for optional short column models). We recommend seating patients who are too tall.

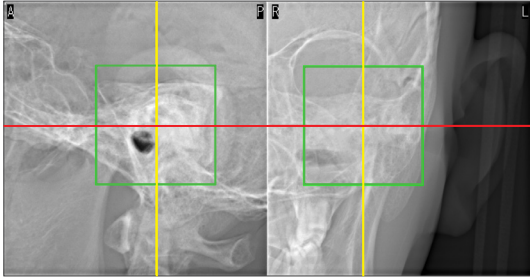
	C (Child)	S (Small)	M (Middle)	L (Large)
Sagittal Length (A)	Max. 17 cm (6.7 in.)	Max. 17 cm (6.7 in.)	Max. 19cm (7.5 in.)	Max. 21cm (8.3 in.)
Tube Voltage	100 kV	100 kV	100 kV	100 kV
Tube Current	3 mA	3 mA	5 mA	7 mA

* The above values are estimates only. The medical doctor or dentist should judge this by the patient's body shape, skeletal structure etc.

* The above values are the factory default settings only. You can save your desired values with the Setting key (p. 22).

■ Positioning Modes

There are two ways to perform positioning to make a CT exposure: the two-direction scout, and beam positioning.

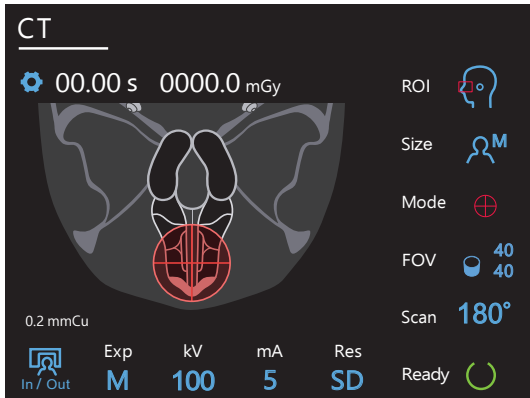


Two-Direction Scout

Determine the exposure area using two images, one lateral and the other posterior-anterior.

Intended ROI: Partial Sinus, Unilateral Temporal Bone

Intended FOV: Ø40, Ø80



Beam Positioning

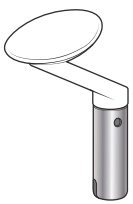
Determine the exposure area by lining up the beams with the patient without the aid of i-Dixel WEB.

* For edentulous patients, it is hard for scout positioning to be reproduced for a CT scan, and beam positioning should be used instead.

Intended ROI: All

Intended FOV: All

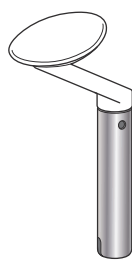
■ Positioning Tool



● Chinrest (-40)

Short Shaft Type:

Use this chinrest for general purposes.



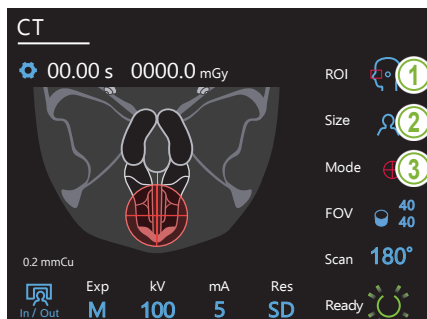
● Chinrest

Long Shaft Type:

Use this chinrest when making exposures for regions lower than chinrest (-40).

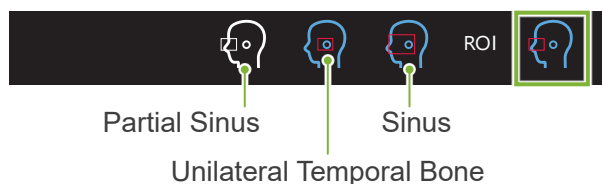
6.3 CT Exposure

6.3.1 Preparation



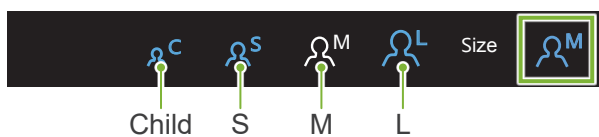
1. Set exposure area

Touch the icon to the right of "ROI" to select the region of interest.



2. Select patient size

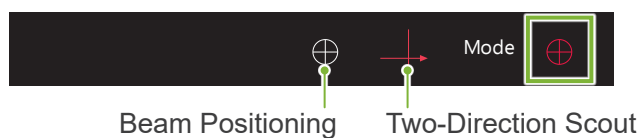
Touch the icon to the right of "Size" to select the patient size.

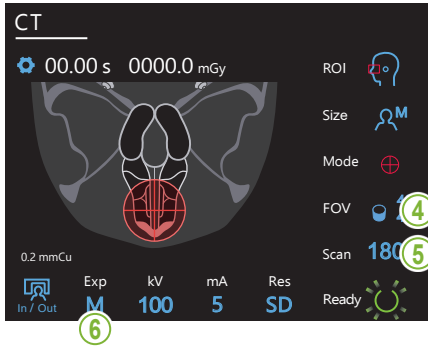


3. Check positioning mode

Make sure the "Mode" is set for "Beam Positioning".

* Even for a two-direction scout exposure, patient positioning is performed by the beam positioning mode.

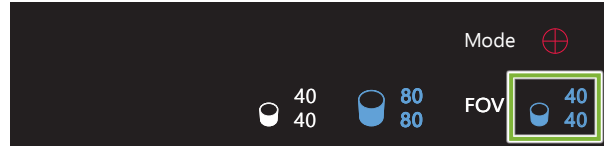




4. Select exposure area (FOV)

Touch the icon to the right of "FOV" to select exposure area.

Partial Sinus CT



Unilateral Temporal Bone CT



Sinus CT



5. Select scan mode

* Ø40 and Ø80 only.

Touch the number to the right of "Scan" to select scan mode.

180°: The arm rotates for half the circumference around the head (half-scan). This reduces X-ray dosage.

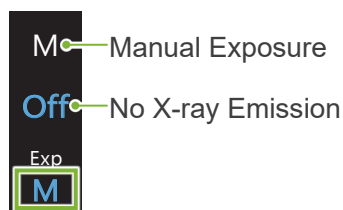
360°: This is a full scan where the arm rotates all the way around the head. This provides better image quality and reduces artifacts.

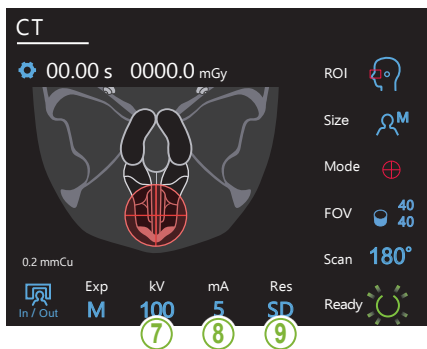


* For a CT exposure of a large or larger than permitted patient, use 180° exposure mode to keep the arm from contacting the patient.

6. Set exposure mode

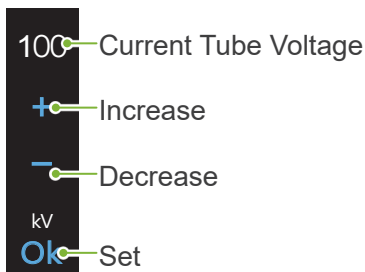
Touch the letter under "Exp" to set the exposure mode.





7. Set tube voltage (kV)

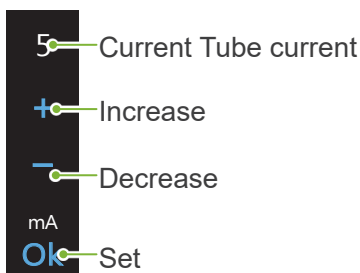
Touch the number under “kV” to set the voltage. It can be set from 70 – 100 kV in 5 kV increments.



		Patient Size			
		C	S	M	L
Estimated Tube Voltage (kV)	CT Exposure	100	100	100	100
	Two-Direction Scout Exposure	90	90	90	90

8. Set tube current

Touch the number under “mA” to set the tube current. It can be set from 2 – 10 mA in 1 mA increments.



		Patient Size			
		C	S	M	L
Estimated Tube Current (mA)	CT Exposure	3	3	5	7
	Two-Direction Scout Exposure	2	2	2	2

⚠ CAUTION

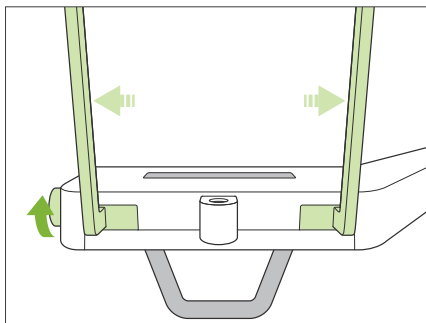
- Strong X-ray emission can saturate the photo diodes on the sensor for areas having high X-ray transparency. In the resulting image, this might falsely appear to be a complete absence of tissue. Watch the rotating image produced during X-ray emission to see if this happens and take this into consideration when making a diagnosis.

9. Select resolution

* Ø40 × H40 only.

Touch the letters under “Res” to set the resolution.



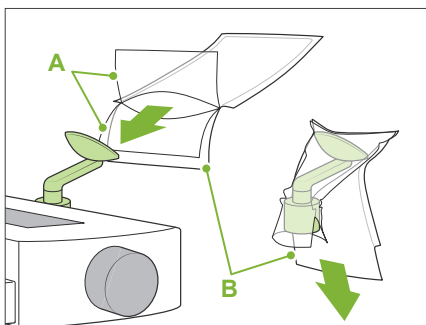


10. Set chinrest (-40)

Turn the temporal stabilizer knob and open the stabilizers.

Wipe the chinrest (-40) with ethanol (70 vol% to 80 vol%) and put it in the chinrest holder.

* Before use, make sure the component is not scratched or damaged in any way.



Open a chinrest disposable cover (A) and put it on the chinrest. Pull down the paper (B) and peel it.

⚠ WARNING

- The chinrest must be disinfected by wiping with ethanol (70 vol% to 80 vol%) after each use, and before putting on a disposable cover.
- Disposable covers must never be re-used. A new one must be used for each patient.
- The patient handle must be disinfected by wiping it with ethanol (70 vol% to 80 vol%) after each patient. If the patient has an open or bleeding wound on his hand, the patient handle should be covered to prevent cross contamination before the patient grips it.

⚠ CAUTION

- The chinrest can withstand a load of 20 kg. These parts could be broken or the patient injured if the patient rests too much body weight on them.

❗ Store disposable covers in a clean, hygienic place.

6.3.2.1 Patient Entry and Positioning (Partial Sinus/Sinus)

! Since there is an upper limit for the Sinus CT exposure, it may be necessary to have very tall patients sit down or lower their posture.

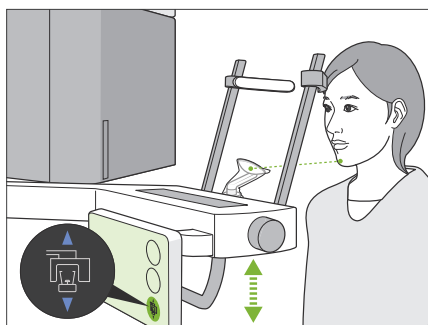
For patient positioning, refer to the **2 Precautions, “Patient Size and Positioning” (p. 8)**.

1. Prepare patient

Have the patient wear an X-ray protection apron.

⚠ CAUTION

- Patient must remove glasses and all accessories like necklaces etc. Otherwise the exposure could fail.
- Make sure the patient’s hair cannot get caught in moving parts. If the patient’s hair is tied in the back like a pony tail etc., have the patient undo it. Otherwise, the arm might hit the patient.



2. Adjust unit height

Adjust the height of the unit so that the chinrest is even with the patient’s chin.

Press and hold the Lift Up/Down switches to raise or lower the unit; release the switch to stop the unit.

⚠ CAUTION

- Take care that the temporal stabilizers do not strike the patient in the eye.
- Take care that the patient is not hit or pinched by any part of the lift assembly (control panes support, arm, and arm support).

! Always use the Lift Up/Down switches to adjust the unit’s height. Never try to force it; this would damage the unit.

! If the lift reaches its upper limit, a series of beeps will sound. If at this point the Ready key is touched, a message will appear saying that this is the limit for a CT exposure. If you make a CT at this point, the sinus region may not be fully exposed. In this case, have the patient sit down or lower his position in some other way.

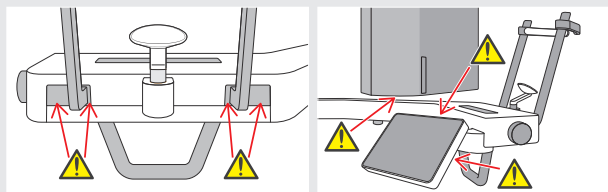


3. Patient entry

Have the patient step forward and put his chin on the chinrest. Have the patient lightly hook his thumbs on the patient handle.

⚠ CAUTION

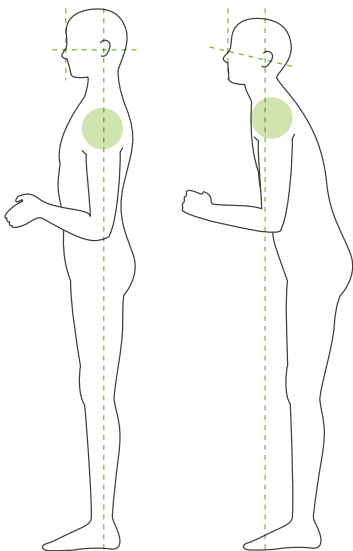
- Do not exert force to have the patient enter or leave; this could damage the temporal stabilizers.
- Never let the patient touch any of the control panel keys and switches.
- The chinrest can withstand a load of 20 kg, the patient handle, control panel support, and each temporal stabilizer can withstand a load of 5 kg. These parts could be broken or the patient injured if the patient rests too much body weight on them.
- Keep fingers away from gaps and openings of moving parts as well as the holes on the support column.



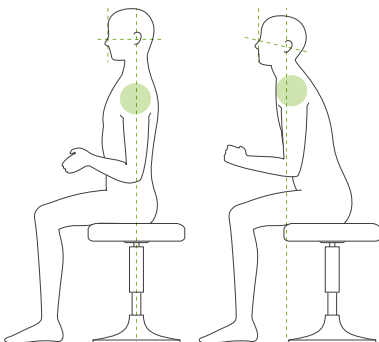
Positioning Point 1

Correct Posture

Correct Incorrect



Correct Incorrect



Patient stands straight and neck is as perpendicular as possible.

If the patient stands (or sits) too far back, the upper torso will lean forward and the neck will be slanted. Have the patient move forward in this case.

Pull jaw in and make the line from the orbitale to the ear orifice horizontal.

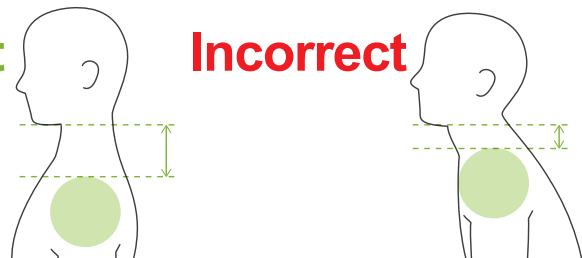
To get correct posture, it helps to tell the patient to move his forehead forwards while keeping his neck stretched while the lift is being lowered.

Relax and lower shoulders.

If the shoulders are too close to the jaw, the arm might hit them. For patients with square shoulders or a short neck, have them relax and lower their shoulders as much as possible.

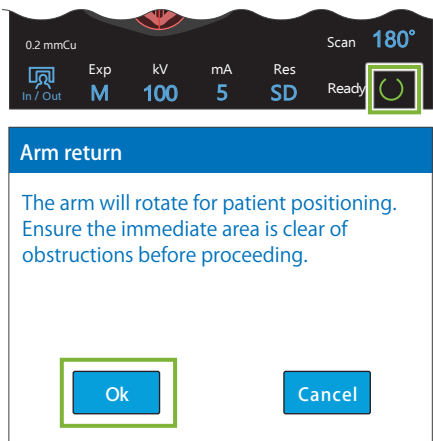
If the neck is slanted, have the patient straighten it and pull in his jaw. If the shoulders are too tension, the patient may be gripping the handle too tightly. Have patients lightly hook their thumbs on the handle instead.

Correct Incorrect



⚠ CAUTION

- For patients who have square shoulders or short necks, the arm might contact the shoulder. In this case, have the patient lower his shoulders as much as possible and then run a test with no X-ray mode to make sure the arm does not contact the patient.



4. Touch Ready key

Touch the Ready key.

The “Arm return” dialogue will appear. Make sure the area is safe, and then touch the “Ok” button.

! If a dialogue box asking to check the temporal stabilizers appears, touch the “Ok” button.

The arm will move to its patient position and the mid-sagittal, horizontal and front-back beams will light up.

⚠ WARNING

- The laser beam could damage a person’s eyesight; never look directly into the beam and let it strike anyone’s eyes.

Positioning Point 2

Align Positioning Beams

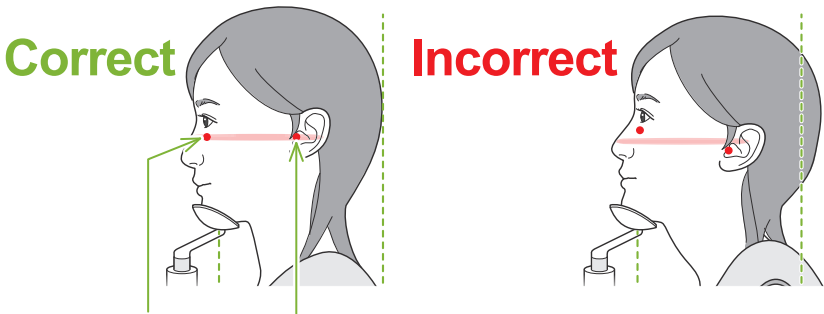
5. Line up beams

A: Mid-sagittal beam lines up with mid-sagittal plane.

Move the patient’s head to line it up with the beam.

B: Horizontal beam lines up with the line from orbitale to ear orifice.

Have the patient keep a posture with the line from orbitale to ear orifice horizontal and then touch the Beam Up/Down switches to line the beam up with it.



Beam passes through these two points.

Horizontal Beam
 ▲ Up ▼ Down

Front-Back Beam
 ◀ Forward ▶ Backward

⚠ CAUTION

- If the line from the orbitale to the ear orifice is not horizontal, the back of the head might stick out and make contact with the arm during an exposure or ready move. For a patient who has a large head, run a test with no X-ray emission mode to make sure the arm does not contact the patient.

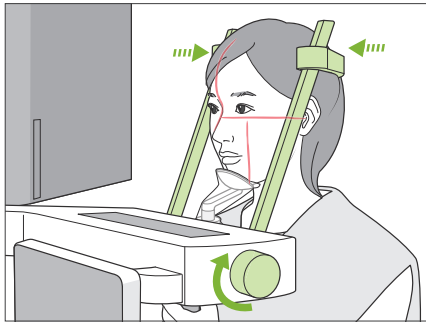
C: Front-back beam lines up with the distal side of the left canine teeth.

First line the patient up so that the beam is roughly in the right position. Then press the Beam Forward/Backward switches to move the beam so that it is properly lined up.

* If the beam cannot be line up with the distal side of the left canine teeth for edentulous patients or some other reason, line it up about 10 mm (0.4 in.) in back of the corner to the mouth.

* The front-back beam can be moved from -20 mm (0.8 in.) to +15 mm (0.6 in.) (less in some exposure modes).

! Make sure to use the two-direction scout or positioning beams for patient positioning. The FOV circle in the control panel is a reference. The patient’s head geometry varies between individuals and precise patient positioning cannot be made with the FOV circle. Note that it also does not indicate vertical position.

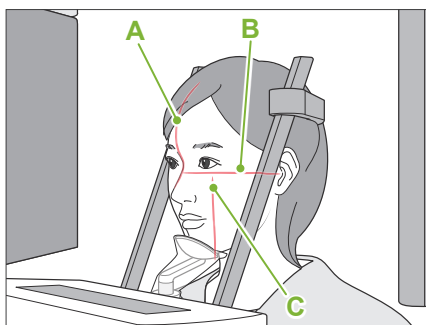


6. Close temporal stabilizers

Adjust the height of the temporal stabilizers.
Turn the temporal stabilizer knob and close the stabilizers firmly.

⚠ CAUTION

- Do not use excessive force to close the temporal stabilizers. This could be uncomfortable for the patient or damage the stabilizers.



7. Check beams

Check the positioning of the all beams.
Mid-sagittal beam (A) lines up with mid-sagittal plane.
Horizontal beam (B) lines up with the line from orbitale to ear orifice.
Front-back beam (C) lines up with the distal side of the left canine teeth.

Tell the patient not to move his head during X-ray emission (or while the melody is playing) and then leave the X-ray room.

⚠ CAUTION

- Warn the patient not to move during emission (while the melody is sounding). If the patient moves, he could be hit by the arm or the image might be ruined.

❗ If the patient watches the arm go around, he may move his head. It is a good idea to tell the patient to close his eyes.

■ Min. Scan Move Function
(If this function is turned on.)

Before leaving the X-ray room, the arm can be moved to the position which will require the shortest exposure time (least time needed to hold down the Emission switch).

8. Touch Ready key

Make sure the patient has his hands on the patient handle. With the unit already in the ready state, press the Ready key again. The arm will move to its Min. Scan Move position and then a two-toned beep will sound.

Min. Scan Move:

- X-ray emission will begin as soon as the Emission switch is pressed.
- Only the Ready key will work.
- * Touch the Ready key again the arm will move back to its original patient positioning position.

❗ If after the arm moves to the Min. Scan Move position, one of the beams is not properly line up, touch the Ready key again to move the arm back to its original patient positioning position and re-position the patient.

After the arm moves, re-check the patient's positioning and hand position on the patient handle and then leave the X-ray booth.

6.3.2.2 Patient Entry and Positioning (Unilateral Temporal Bone)

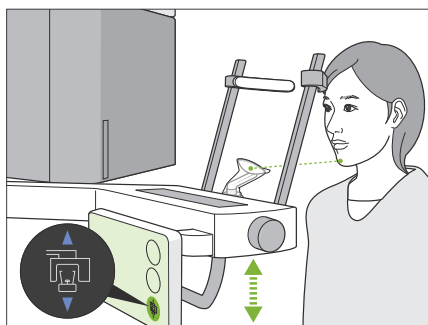
For patient positioning, refer to **2 Precautions, “Patient Size and Positioning” (p. 8)**.

1. Prepare patient

Have the patient wear an X-ray protection apron.

⚠ CAUTION

- Patient must remove glasses and all accessories like necklaces etc. Otherwise the exposure could fail.
- Make sure the patient's hair cannot get caught in moving parts. If the patient's hair is tied in the back like a pony tail etc., have the patient undo it. Otherwise, the arm might hit the patient.



2. Adjust unit height

Adjust the height of the unit so that the chinrest is even with the patient's chin.

Press and hold the Up and Down switches to raise or lower the unit; release the switch to stop the unit.

⚠ CAUTION

- Take care that the temporal stabilizers do not strike the patient in the eye.
- Take care that the patient is not hit or pinched by any part of the lift assembly (control panes support, arm, arm support).

- ❗ Always use the Up and Down switches to adjust the unit's height. Never try to force it; this would damage the unit.
- ❗ If the lift reaches its upper limit, a series of beeps will sound. If at this point the Ready key is pressed, a message will appear saying that this is the limit for a CT exposure. If you make a CT at this point, the maxillary region may not be fully exposed. In this case, have the patient sit down or lower his position in some other way.



3. Patient entry

Have the patient move forward and put his chin on the chinrest. Have the patient lightly hook his thumbs on the patient handle.

⚠ CAUTION

- Do not exert force to have the patient enter or leave; this could damage the temporal stabilizers.
- Never let the patient touch any of the control panel keys and switches.
- The chinrest can withstand a load of 20 kg, the patient handle, control panel support, and each temporal stabilizer can withstand a load of 5 kg. These parts could be broken or the patient injured if the patient rests too much body weight on them.
- Keep fingers away from gaps and openings of moving parts as well as the holes on the support column.

Positioning Point 1

Correct Posture

Correct Incorrect

Correct Incorrect

Patient stands straight and neck is as perpendicular as possible.

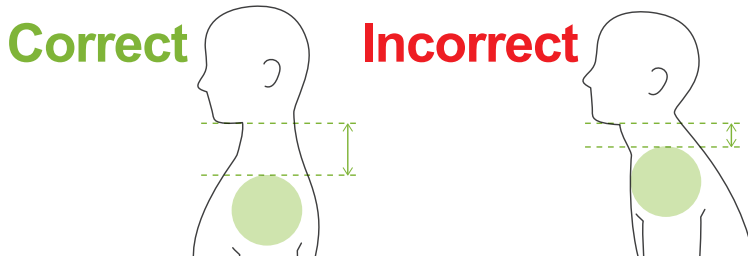
If the patient stands (or sits) too far back, the upper torso will lean forward and the neck will be slanted. Have the patient move forward in this case.

Pull jaw in and make the line from the orbitale to the ear orifice horizontal.

To get correct posture, it helps to tell the patient to move his forehead forwards while keeping his neck stretched while the lift is being lowered.

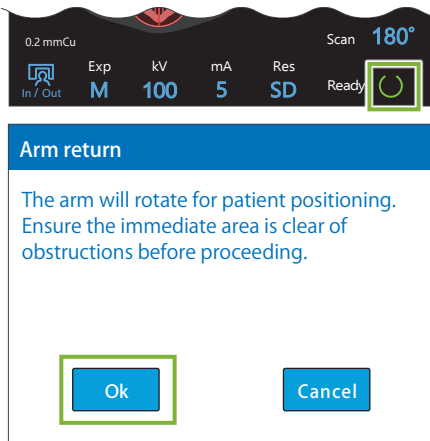
Relax and lower shoulders.

If the shoulders are too close to the jaw, the arm might hit them. For patients with square shoulders or a short neck, have them relax and lower their shoulders as much as possible. If the neck is slanted, have the patient straighten it and pull in his jaw. If the shoulders are too tension, the patient may be gripping the patient handle too tightly. Have patients lightly hook their thumbs on the handle instead.



⚠ CAUTION

- For patients who have square shoulders or short necks, the arm might contact the shoulder. In this case, have the patient lower his shoulders as much as possible and then run a test with no X-ray mode to make sure the arm does not contact the patient.



4. Touch Ready key

Touch the Ready key.

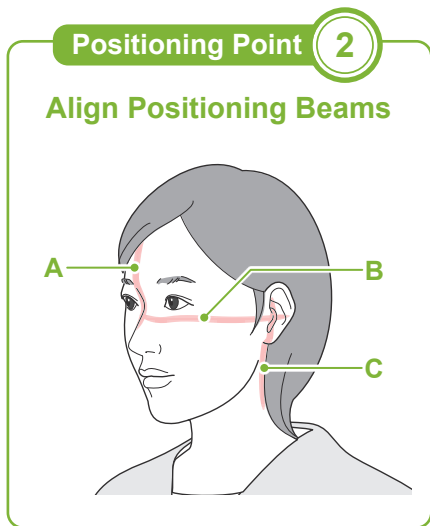
The “Arm return” dialogue will appear. Make sure the area is safe, and then touch the “Ok” button.

! If a dialogue box asking to check the temporal stabilizers appears, touch the “Ok” button.

The arm will move to its patient position and the mid-sagittal, horizontal and front-back beams will light up.

! WARNING

- The laser beam could damage a person’s eyesight; never look directly into the beam and let it strike anyone’s eyes.



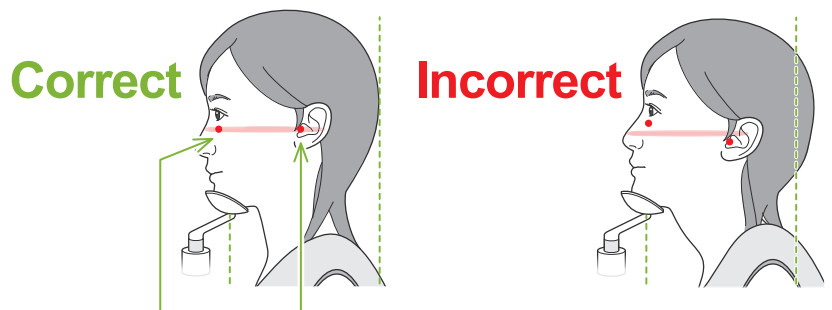
5. Line up beams

A: Mid-sagittal beam lines up with mid-sagittal plane.

Move the patient’s head to line it up with the beam.

B: Horizontal beam lines up with the line from orbitale to ear orifice.

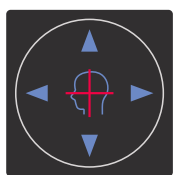
Have the patient keep a posture with the line from orbitale to ear orifice horizontal and then press the Up or Down switches to line the beam up with it.



Beam passes through these two points.

! CAUTION

- If the line from the orbitale to the ear orifice is not horizontal, the back of the head might stick out and make contact with the arm during an exposure or ready move. For a patient who has a large head, run a test with no X-ray emission mode to make sure the arm does not contact the patient.



Horizontal Beam Switches

▲ Up ▼ Down

Front-Back Beam Switches

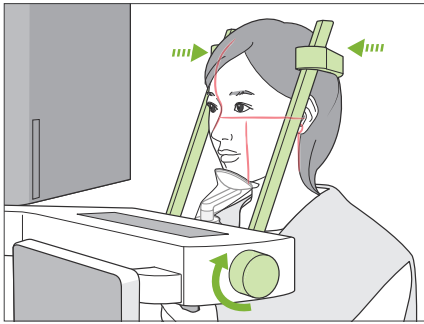
◀ Forward ▶ Backward

- ! Make sure to use the two-direction scout or positioning beams for patient positioning. The FOV circle in the control panel is a reference. The patient’s head geometry varies between individuals and precise patient positioning cannot be made with the FOV circle. Note that it also does not indicate vertical position.

C: Front-back beam lines up with the outer ear orifice.

Press the Forward or Backward switches to move the beam so it is properly lined up.

* The image layer is about 12 mm (0.5 in.) in front of the front-back beam.

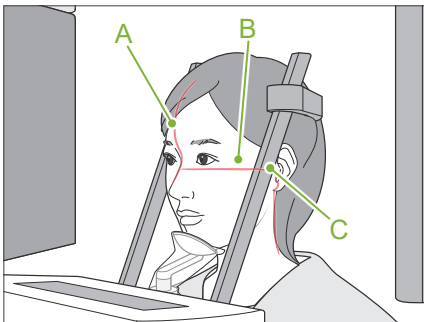


6. Close temporal stabilizers

Adjust the height of the temporal stabilizers.
Turn the temporal stabilizer knob and close the stabilizers firmly.
Have the patient close his mouth.

⚠ CAUTION

- Do not use excessive force to close the temporal stabilizers. This could be uncomfortable for the patient or damage the stabilizers.



7. Check beams

Check the positioning of the all beams.
Mid-sagittal beam (A) lines up with mid-sagittal plane.
Horizontal beam (B) lines up with the line from orbitale to ear orifice.
Front-back beam (C) lines up with the outer ear orifice.

Tell the patient not to move his head during X-ray emission (or while the melody is playing) and then leave the X-ray room.

⚠ CAUTION

- Warn the patient not to move during emission (while the melody is sounding). If the patient moves, he could be hit by the arm or the image might be ruined.

- ❗ If the patient watches the arm go around, he may move his head. It is a good idea to tell the patient to close his eyes.

■ Min. Scan Move Function

(If this function is turned on.)

Before leaving the X-ray room, the arm can be moved to the position which will require the shortest exposure time (least time needed to hold down the Emission switch).

8. Touch Ready key

Make sure the patient has his hands on the patient handle. With the unit already in the ready state, press the Ready key again. The arm will move to its Min. Scan Move position and then a two-toned beep will sound.

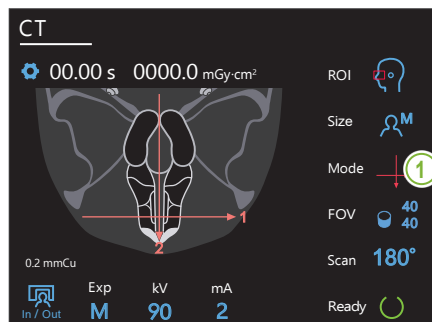
Min. Scan Move:

- X-ray emission will begin as soon as the Emission Switch is pressed.
- Only the Ready key will work.
- * Touch the Ready key again the arm will move back to its original patient positioning position.

! If after the arm moves to the Min. Scan Move position, one of the beams is not properly line up, touch the Ready key again to move the arm back to its original patient positioning position and re-position the patient.

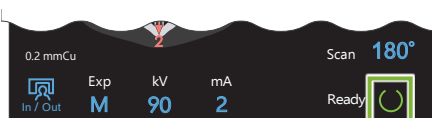
After the arm moves, re-check the patient's positioning and hand position on the patient handle and then leave the X-ray booth.

6.3.3.1 Set FOV Position with Two-Direction Scout (for Partial Sinus and Unilateral Temporal Bone ROIs)



1. Select two-direction scout

Touch the icon to the right of "Mode" to select "Two-Direction Scout". The positioning beams will turn off.



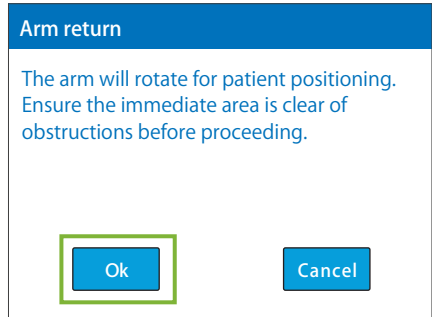
2. Touch Ready key

Touch the Ready key.

The "Arm return" dialogue will appear. Make sure the area is safe, and then touch the "Ok" button.

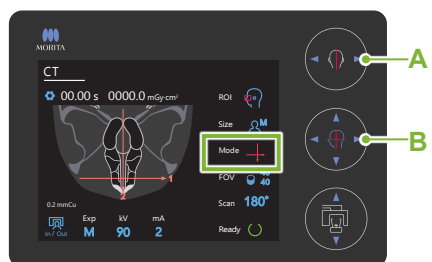
! If a dialogue box asking to check the temporal stabilizers appears, touch the "Ok" button.

The X-ray head will move and the positioning beams (horizontal, front-back, and left-right) will light up. The unit is now in the ready state. The horizontal beam moves to the scout position.



! WARNING

- The laser beam could damage a person's eyesight; never look directly into the beam and let it strike anyone's eyes.



3. Line up beams

Make sure the FOV positioning: "Mode" is set for two-direction scout. Line up the front-back and left-right beams with the center of the target area.

* The exposure range for the two-direction scout is W80 × H80. If these beams are too far off the target, it may not be contained within the two-direction scout image.

A Left-Right Beam Switches

- Left
- Right

B Front-Back Beam Switches

- Forward
- Backward

● Reference Point for Exposure Position

Partial Sinus

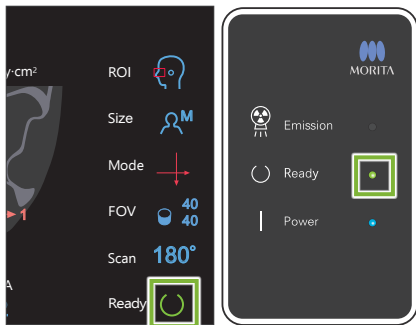
Front-Back Beam: first molar

Unilateral Temporal Bone

Front-Back Beam: ear orifice

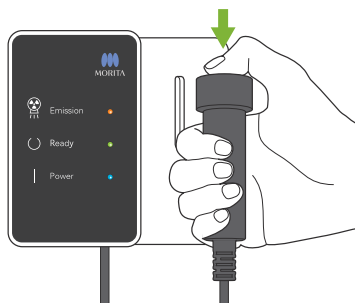
Left-Right Beam: seen head-on, patient's Ear position

! For a Unilateral Temporal Bone exposure, make sure the "ROI" is set for "Unilateral Temporal Bone". The scout and CT exposure ranges for the Partial Sinus and the Unilateral Temporal Bone are not the same.



4. Check ready state

Check that the Ready key on the control panel and the Ready LED (green) on the control box are on.



5. Execute two-direction scout exposure

Hold down the Emission switch. The arm will rotate and X-ray emission will start. The Emission LED (yellow) on the control box will light up and the melody will sound.

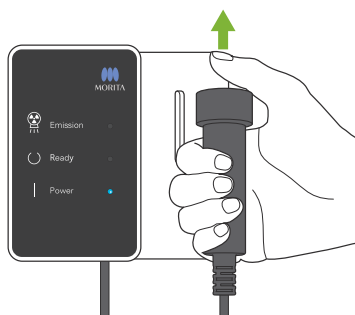
! As much as 15 seconds could elapse from the time the Emission switch is pressed until X-ray emission actually starts. This is not abnormal. It takes some time for the unit to verify the computer settings.

! WARNING

- If an emergency occurs, release the Emission switch. Or press the Emergency Stop switch. This will stop the arm rotation and X-ray emission.

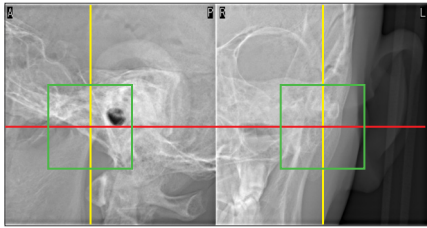
! CAUTION

- Go outside the X-ray room to press the Emission switch.
- If the operator must stay in the X-ray room for some reason, he should wear an X-ray protection apron and stay at least 2 meters away from the X-ray emission focal point. Also he should stay outside the area exposed to X-ray emission.
- If the Emission switch is released before completing the entire scout exposure process, the exposure will be immediately terminated. In this case guide the patient away from the unit. If the X-ray head or the detector is directly in back of the patient, turn off the unit and slowly rotate the arm so the patient can leave. If you perform the ready procedures without having the patient move away from the unit, the arm could hit and possibly injure the patient.
- For the two-direction scout, hold the Emission switch down until both exposures are completed. Releasing it after only one has been made will result in losing the first exposure and not getting any image at all.



The melody stops when the exposure has been completed.

Release the Emission switch and hang it in its holder on the control box.



6. Scout image display (i-Dixel WEB)

The two-direction scout image will be displayed in the capture window.

The intersection of the red and yellow lines shows the center of the exposure area and the green frame shows the size of the FOV.

The size of the frame reflects the size of the selected FOV.

⚠ CAUTION

- Do not close the scout image until the CT exposure has been completed. If the scout image is closed, positioning will no longer be possible.

● Changing the FOV on i-Dixel WEB

The FOV can be changed with i-Dixel WEB.

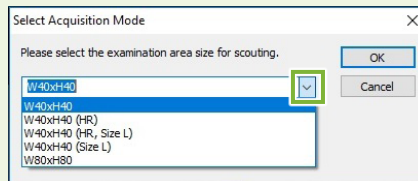
Click the Set CT Area icon

Click the Set CT Area icon (A) on the scout panel to display a exposure mode selection dialogue box.



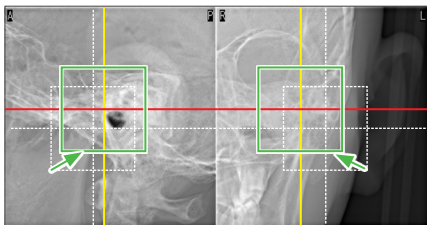
Select area size

Select an area size from the pull-down menu and then click the "OK" button.



The area size will change

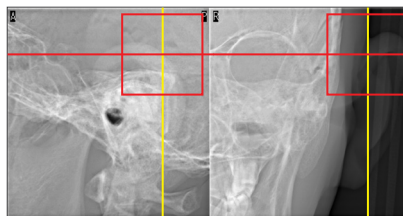
A beep will sound and the area size will change to the one selected.

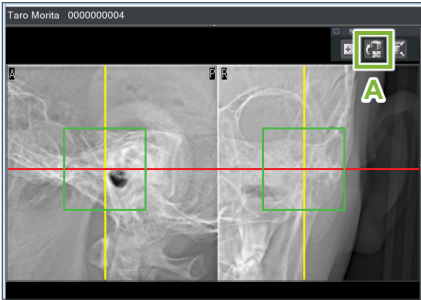


7. Specify FOV position (i-Dixel WEB)

Drag the frame to determine the center of the FOV.

- ⚠ Repeated clicking or dragging for a long time can slow down the computer's reaction or even freeze it.
- ⚠ Do not touch any operation keys on the X-ray unit while the exposure area frame is being displayed in i-Dixel WEB. This could cause the X-ray unit to stop working.
- ⚠ If the frame goes out of the possible range of CT exposure, it will turn red, and it will not be possible to specify the center of the FOV.





8. Send FOV position (i-Dixel WEB)

Click the Send CT Scout Position icon (A) on the scout tool panel. A cross mark “+” will appear at the center of the exposure area in the image.



! Do not fail to click the Send CT Scout Position icon after positioning the frame. Otherwise, the newly selected area will not be recognized by the Veraview FX800.

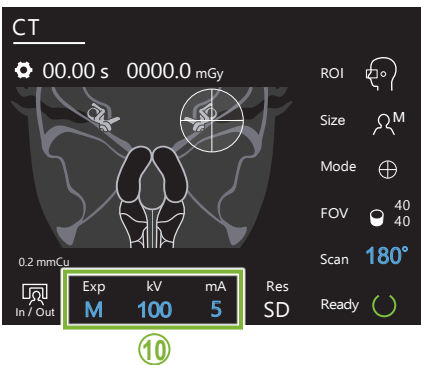
Scout position check

Press OK to move the unit to the scouted position. The arm will move in multiple directions so ensure the immediate area is clear.
 Press Cancel to start the scout operation from the beginning.

Ok

Cancel

If the selected position is OK, a two-toned beep will sound and the message shown to the left will appear in the control panel.
 Touch the “Ok” button to confirm the positioning.
 Touch the Cancel button to cancel it.



9. Register FOV position

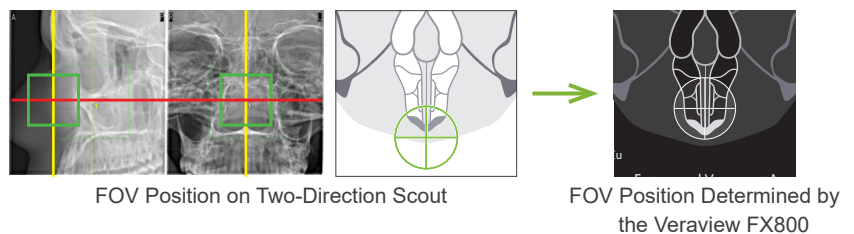
Touch the “Ok” button, then the arm will move into position correspond to the registered FOV position.
 The exposure area specified by the two-direction scout will appear as an FOV circle in the control panel.

! The FOV circle determines a reference range, but its accuracy cannot be guaranteed.

● Incisal Positioning

When the scout indicates the incisal region, the FOV circle in the control panel may appear slightly back. This is because the unit has adjusted the position so that the FOV is within the exposure range of the unit. The incisal region will not be exactly in the center of the FOV, but it will be included in the exposure range. Continue with the procedure.

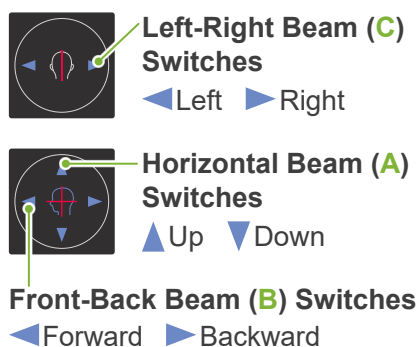
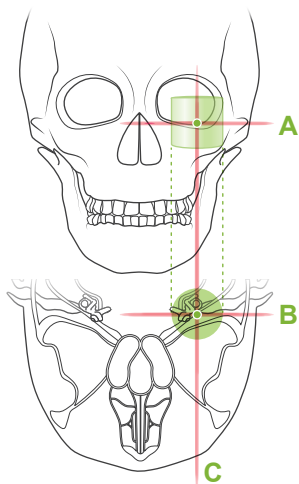
* Note that the FOV position specified on the scout image differs from the position displaying on the control panel.



10. Set exposure mode

Set the exposure (Exp), tube voltage (kV), and current (mA) settings for the CT exposure.

For details, refer to **6.3.1 Preparation “6. Set exposure mode” – “8. Set tube current”** (pp. 26–27).

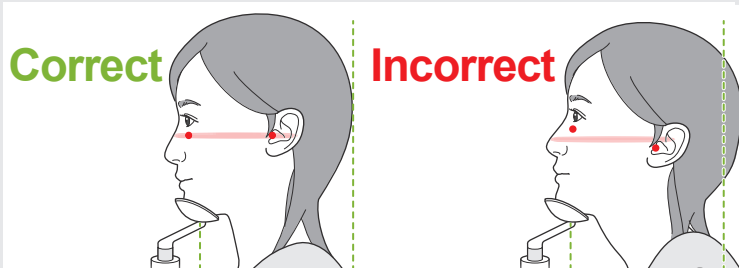


11. Check exposure position

The horizontal (A), front-back (B), and left-right (C) beams will intersect at the center of the exposure area.
 Check that the beams are on target.

⚠ CAUTION

- If the line from the orbitale to the ear orifice is not horizontal, the back of the head might stick out and make contact with the arm during an exposure or ready move. For a patient who has a large head, run a test with no X-ray emission mode to make sure the arm does not contact the patient.



Tell the patient not to move his head during X-ray emission (or while the melody is playing) and then leave the X-ray room.

⚠ CAUTION

- Warn the patient not to move during emission (while the melody is sounding). If the patient moves, he could be hit by the arm or the image might be ruined.

- ❗ If the patient watches the arm go around, he may move his head. It is a good idea to tell the patient to close his eyes.

■ Min. Scan Move Function

(If this function is turned on.)

12. Touch Ready key

Make sure the patient has his hands on the patient handle.
 With the unit already in the ready state, press the Ready key again.
 The arm will move to its Min. Scan Move position and then a two-toned beep will sound.

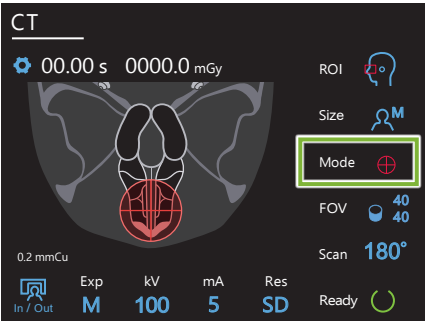
After the arm moves, re-check the patient's positioning and hand position on the patient handle and then leave the X-ray room.

To continue go to "6.3.4 CT Exposure" (p. 45).

● Relationship between CT and Two-Direction Scout Images

The CT and two-direction scout images are linked. If you double-click the green cross mark "+" in the two-direction scout image, the CT image for that place will be automatically displayed.
 If the CT exposure has not been made, the cross mark "+" will be yellow. In this case, there is no linkage with anything.

6.3.3.3 Set FOV Position with Beam Positioning



When beam positioning is selected as the FOV positioning: "Mode", the FOV circle appears on the control panel. This shows the horizontal plane for the sinus and is the approximate location of the exposure area. The front-back and left-right beams are linked to the FOV circle, and it will move accordingly when the beams are moved.

! The FOV circle determines a reference range, but its accuracy cannot be guaranteed.



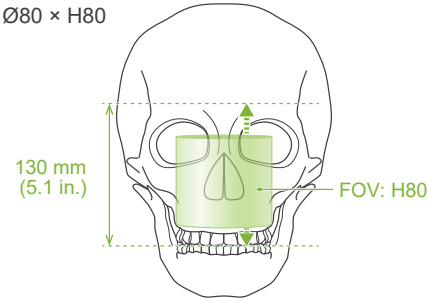
1. Line up horizontal beam

Move the horizontal beam up or down to set the vertical position. This beam indicates the height center of the FOV.

● FOV Range

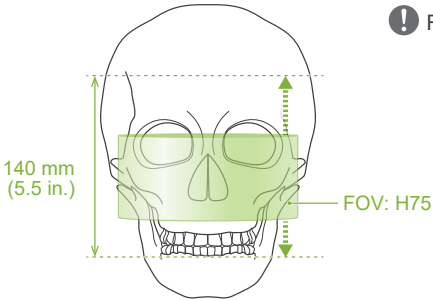
For Ø40 and Ø80:

The FOV has a vertical range of 130 mm (5.1 in.). (It can be moved 50 mm (2 in.) up from its lowest position for an H80, and 90 mm (3.5 in.) an H40.)



For Ø150:

The FOV has a vertical range of 140 mm (5.5 in.). (It can be moved 65 mm (2.6 in.) up from its lowest position for an H75, and 90 mm (3.5 in.) an H50.)



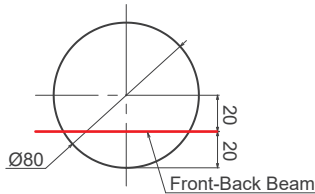
! For H140, two exposures are made.

2. Line up front-back and left-right beams

Consider following points when positioning the beams.

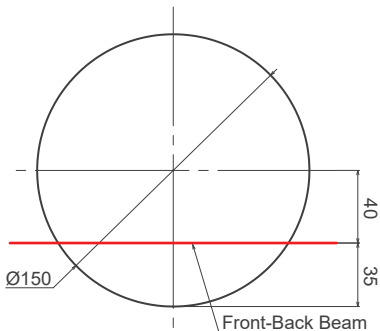
● **Ø80**

The FOV encompasses 20 mm in front of the front-back beam. The FOV center is located 20 mm backward of the beam.



● **Ø150**

The FOV encompasses 35 mm in front of the front-back beam. The FOV center is located 40 mm backward of the beam.



● **Ø40**

The horizontal (A), front-back (B), and left-right (C) beams will intersect at the center of the FOV.

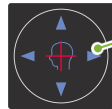
Move the front-back and horizontal beams to set FOV position.

Check that the beams are on target.



Left-Right Beam (C) Switches

◀ Left ▶ Right



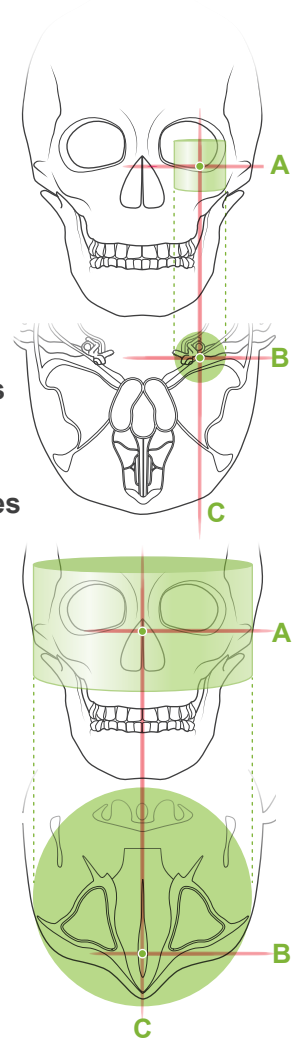
Front-Back Beam (B) Switches

◀ Forward ▶ Backward

● **Ø80 and Ø150**

The horizontal (A), and left-right (C) beams will intersect at the center of the FOV. The front-back beam (B) is left lined up with the distal side of the left canine teeth and does not need to be adjusted.

Check that the beams are on target.



* The FOV circle in the control panel is approximate. Check the beams for the exact position.

Tell the patient not to move his head during X-ray emission (or while the melody is playing) and then leave the X-ray room.

⚠ CAUTION

- Warn the patient not to move during emission (while the melody is sounding). If the patient moves, he could be hit by the arm or the image might be ruined.

- ! If the patient watches the arm go around, he may move his head. It is a good idea to tell the patient to close his eyes.

■ Min. Scan Move Function

(If this function is turned on.)

3. Press Ready switch

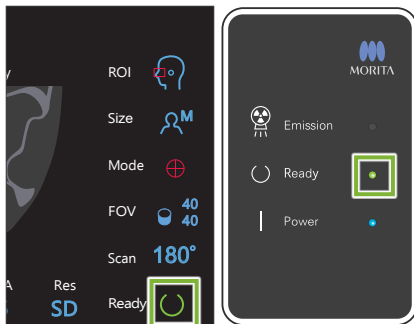
Make sure the patient has his hands on the patient handle.

With the unit already in the ready state, press the Ready key again.

The arm will move to its Min. Scan Move position and then a two-toned beep will sound.

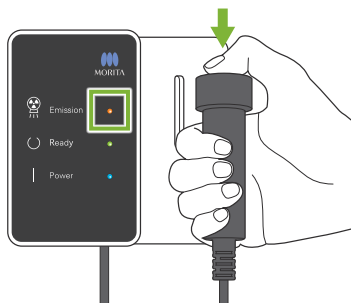
After the arm moves, re-check the patient's positioning and hand position on the patient handle and then leave the X-ray room.

6.3.4 CT Exposure



1. Check ready state

Check that the Ready key on the control panel and the Ready LED (green) on the control box are on.



2. X-ray emission

Hold down the Emission switch.

The arm will rotate and X-ray emission will start.

The Emission LED (yellow) on the control box will light up and the melody will sound.

* For the $\text{Ø}150 \times \text{H}140$ exposure, two exposures are made one after the other. Continue to hold down the Emission switch after the first exposure is made. The arm will go up and return to its Ready position. Then the second exposure will be made. If you release the Emission switch before both exposures are completed, a complete image will not be made.

! As much as 15 seconds could elapse from the time the emission switch is pressed until X-ray emission actually starts. This is not abnormal. It takes some time for the unit to verify the computer settings.

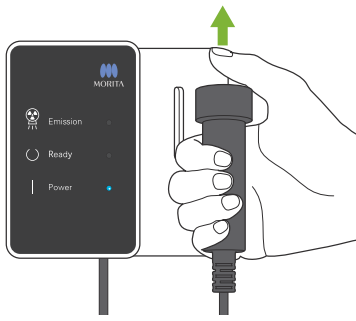
⚠ WARNING

- If an emergency occurs, release the Emission switch. Or press the Emergency Stop switch. This will stop the arm rotation and X-ray emission.

⚠ CAUTION

- Go outside the X-ray room to press the Emission switch.
- If the operator must stay in the X-ray room for some reason, he should wear an X-ray protection apron and stay at least 2 meters away from the X-ray emission focal point. Also he should stay outside the area exposed to X-ray emission.
- Releasing the Emission switch during X-ray emission will stop the arm's rotation and terminate the exposure. In this case guide the patient away from the unit. If the X-ray head or the detector is directly in back of the patient, turn off the unit and slowly rotate the arm so the patient can leave. If you perform the ready procedures without having the patient move away from the unit, the arm could hit and possibly injure the patient.
- If an error occurs during an exposure, the arm will stop and the exposure will be terminated. In this case guide the patient away from the unit. If the X-ray head or the detector is directly in back of the patient, turn off the unit and slowly rotate the arm so the patient can leave. If you perform the ready procedures without having the patient move away from the unit, the arm could hit and possibly injure the patient.

* If X-ray emission does not start when you press the Emission switch, check to see if the computer is busy reconstructing and image or asking for instructions.



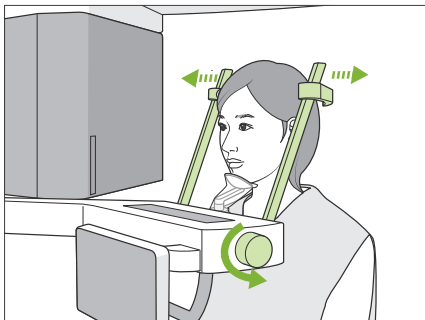
3. Exposure completed

The melody stops when the exposure has been completed.

The arm will automatically move to the patient egress position and stop.

Release the Emission switch and hang it in its holder on the control box.

6.3.5 Patient Egress



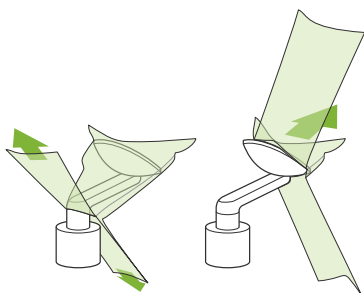
1. Guide patient away from the unit

Turn the temporal stabilizer knob and open the stabilizers completely.

Guide the patient away from the unit.

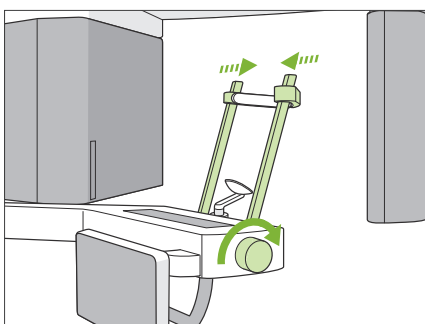
⚠ CAUTION

- Take care that the temporal stabilizers do not strike the patient in the eye.
- Be careful of the stabilizers when the patient leaves the unit.



2. Throw away disposable covers etc.

Throw away the chinrest cover. If the chinrest cover is removed by splitting its seams and turning it inside out, the outer surface will not touch anything.



3. Close temporal stabilizer

Turn the temporal stabilizer knob and close the stabilizers completely.

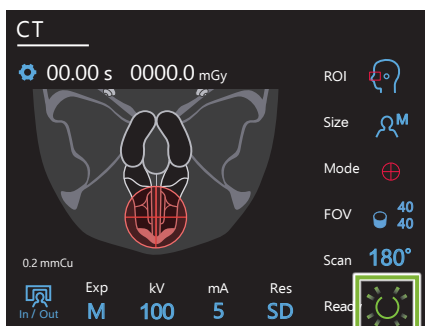
4. Touch Ready key

Touch the Ready key.

The "Arm return" dialogue will appear. Make sure the area is safe, and then touch the "Ok" button.

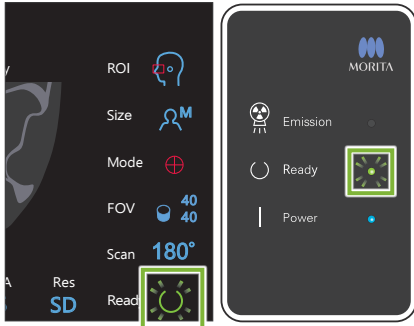
The arm will move back to its original patient positioning position.

* If another exposure will be made right away, touch the In/Out key to move the arm to its patient entry position.



6.3.6 Image Transmission

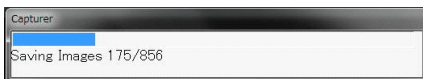
1. Image transmission



After the exposure is completed, the image is sent to i-Dixel WEB. During transmission, the Ready LED on the control box is orange and blinks on and off.

After transmission has been completed, the Ready LED on the control box and the Ready key in the control panel will turn green and blink on and off.

! A two-toned beep sound when transmission has been completed and the LED turns green and blinks, but another exposure cannot be made until the image appears in the computer screen.



2. Image reconstruction

CT reconstruction will be performed.

* Image reconstruction takes about 5 minutes.

- ! If all the CT tasks are save, the hard disk will fill up rather quickly. CT tasks should be moved or deleted periodically.
- ! During image acquisition, vertical or horizontal lines may appear. These are due to disparities in pixel sensitivity and does not indicate any sensor defect.
- ! For details on the software, refer to the user manual for i-Dixel WEB.

6.4 Cautionary Remarks on Imaging

6.4.1 Artifacts Due to Sensitivity Discrepancies of Flat Panel Detector

The flat-panel detector (FPD) is an extremely dense and precise array of photo diodes (pixels). By compensating for the discrepancy in pixel sensitivity, the image can show greater detail than ordinary fluoroscopy. However, this discrepancy cannot be completely eliminated when a CT image is reconstructed.

To make a CT image, the X-ray beam rotates around the object and produces a fluoroscopic image. Points away from the center of the imaging area move on the imaging surface depending on the angle of their projection. This tends to even out the fluctuations in sensitivity, but it does not completely eliminate them. (See Fig. 1.) Therefore, artifacts can appear near the center of the imaging area as shown in Fig. 2. The appearance of these artifacts depends somewhat on the exposure conditions and the X-ray transparency of the object. To make a detailed analysis and precise diagnosis, the radiologist must carefully take into consideration the possibility and nature of artifacts.

Figure 1: Exposure Principle Diagram

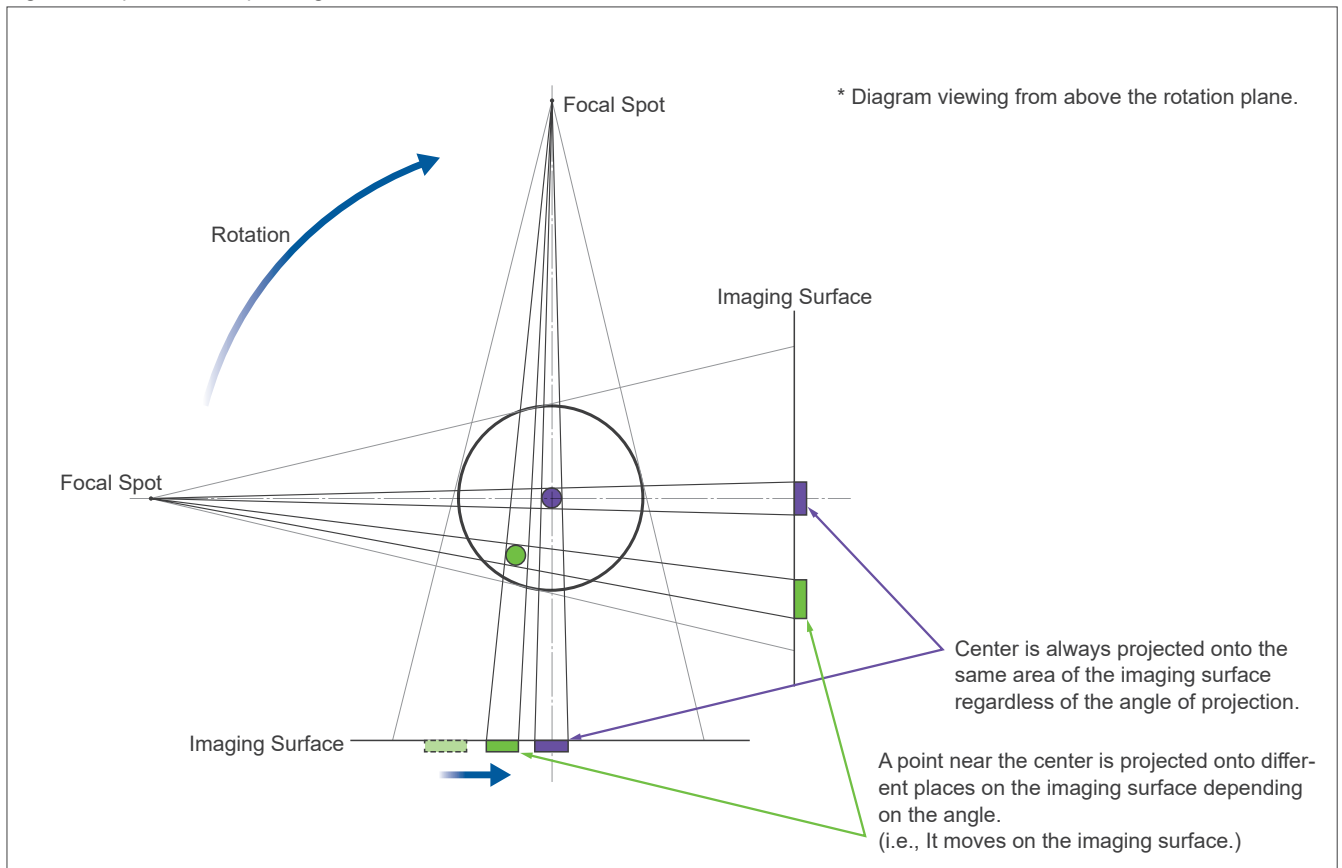
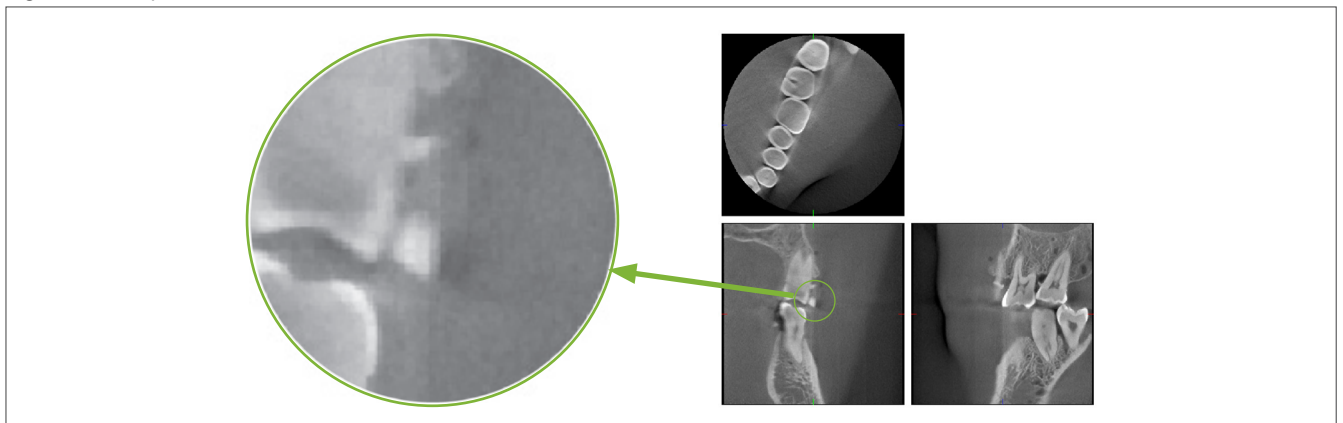


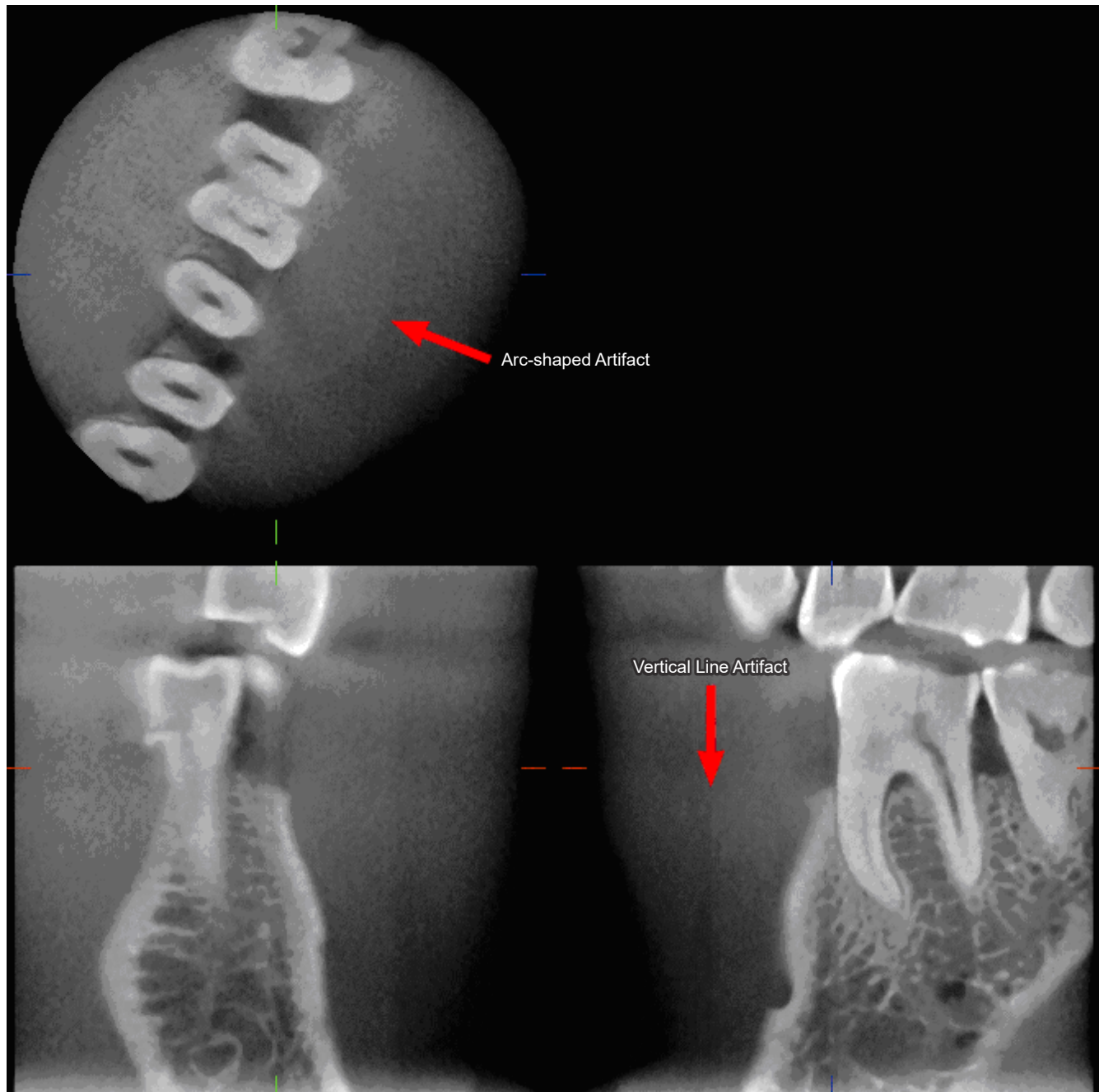
Figure 2: Example of an Artifact



6.4.2 Artifacts Caused by Flat Panel Detector (FPD) Sensitivity Discrepancies

The flat-panel detector (FPD) is an extremely dense and precise array of photo diodes (pixels). Even though the panel is assembled in a clean room, even minutes deposits of dust or other debris can result in uneven discrepancies in the sensitivity of the photo-diodes. The image processing software compensates for these discrepancies and makes them all but invisible. However, logarithmic and filter processing during the reconstruction of the CT image may accentuate sensitivity discrepancies and produce artifacts in the CT image. These discrepancies will have an arc shape in axial (z-plane) images and appear as vertical lines in coronal and sagittal images (x- and y-planes). (Fig. 3 below shows examples of these artifacts.) Artifacts can be identified by comparing the images of all 3 planes. If a vertical line in the coronal and sagittal planes is matched by an arc-shaped line in the axial plane, you may assume that these are artifacts.

Figure 3: Example of Artifacts



6.4.3 Artifacts Due to Angle of X-ray Penetration

Artifacts Characteristic of Cone Beam CT Imaging

Artifacts depend on how far the object is from the plane of the X-ray beam's rotation.

CT images are a kind of tomography; images are reconstructed after collecting the images produced by the passage of X-rays emitted by a rotating beam. (Figure 4.1)

For cone beam CT imaging, artifacts appear above or below the plane of the beam's rotation because of insufficient information. These artifacts appear on a straight line running from the object to the source of the X-ray beam, and they are more conspicuous the farther the object is from the plane of the beam's rotation.

Figure 4: Track of X-ray Source and Detector

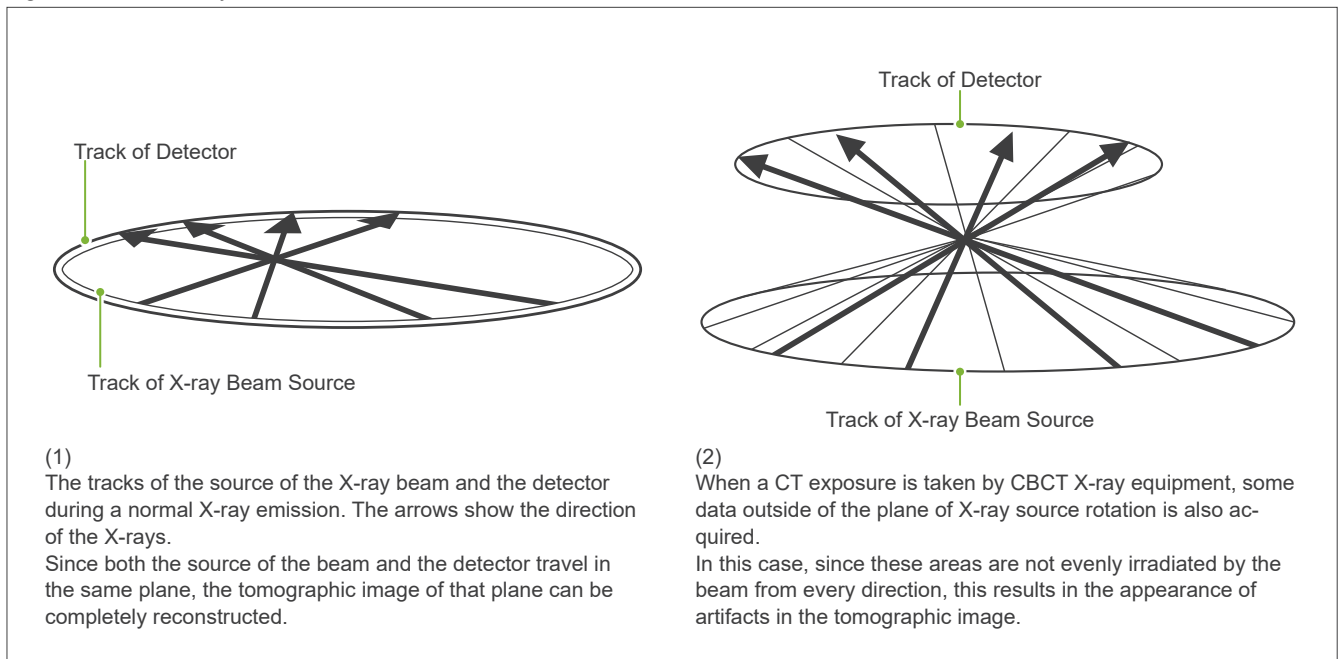


Figure 5 compares the case of 2 images of the same tooth made at different vertical positions. An artifact appears at the tip of the tooth because this area has a high CT value.

In Fig. 5.1, the artifact is nearly horizontal because it is at about the same height as the source of the X-ray beam.

In Fig. 5.2, the artifact is slanted because it is farther away from the plane of rotation for the beam source. It is also wider.

Radiologist must carefully take into consideration the nature of artifacts at the periphery of the area of interest.

Accurate Measurement of Thickness

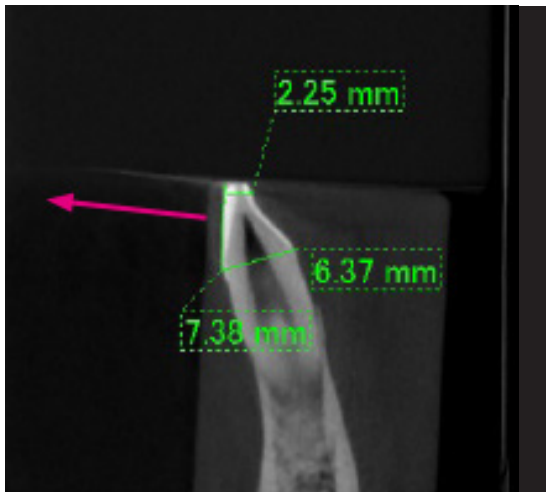
Following the principle stated above, the farther the area is from the plane of the beam's rotation, the less accurate the image is. This is demonstrated by measuring the thickness of a flat object positioned horizontally.

Figure 5.3 shows the images of aluminum disks with a thickness of 1.0 mm (0.04 in.) positioned 20 mm (0.8 in.) apart and parallel to the plane of the beam's rotation. All aluminum disks are arranged horizontally (parallel to the plane of X-ray source rotation). The bottom disk is 10 mm (0.4 in.) up from the bottom edge of the image. Therefore its thickness can be measured accurately. However, the measurement for the middle disk, which is 20 mm (0.8 in.) higher, is less accurate, and the measurement for the top disk is the least accurate of all.

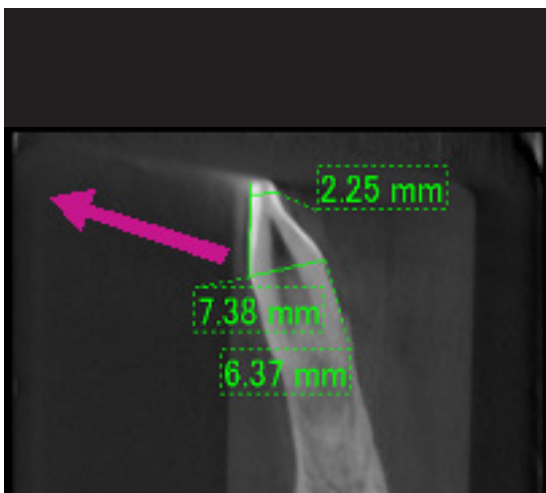
This phenomenon is occurred due to the artifacts, which are extending from each part of the aluminum plates overlapped, and these resulted making the boundary between the aluminum plates and air unclear.

This phenomenon must always be kept in mind for accurate diagnosis and analysis. Whenever an accurate measurement of thickness is required, adjust the bite block to position the area at the same height as the same height as the source of the X-ray beam.

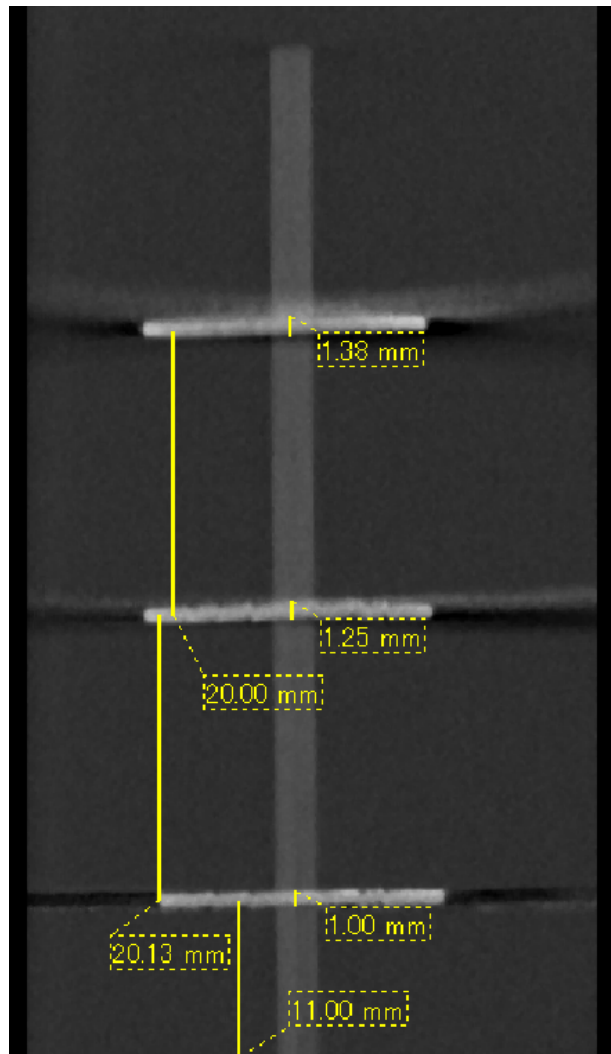
Figure 5: Artifacts



1. The artifact is produced near the plane of the beam's rotation.



2. The area of the artifact is farther away, making it more conspicuous and giving it a different direction. Conspicuousness and direction of artifact are different.



3. CT image of three aluminum disks, each 1.0 mm (0.04 in.) thick, parallel to the plane of beam rotation but at different heights. The lowest one can be accurately measured because it is at the same height as the plane of the beam's rotation. The farther the disks are from the plane of the beam rotation, the thicker they appear in the image.

6.4.4 Artifacts due to Metal Prosthetics

Useful images may not be possible if a patient has metal fillings or prosthetic devices, and it is usually impossible to make a useful image of a crown if it is right next to a metal prosthetic.

Also it is sometimes impossible to make useful images of a root or jaw bone if there is a metal post, crown or other prosthetic right next to it.

Figure 6 through 12 were made of a mandible model with various metal prosthetics, posts and canal fillings to demonstrate what needs to be taken in consideration for accurate diagnosis and analysis.

Figure 6: Model of Full Metal Crown



Top of crown was removed and replaced with a piece of lead.

Figure 7: No Metal Prosthetic

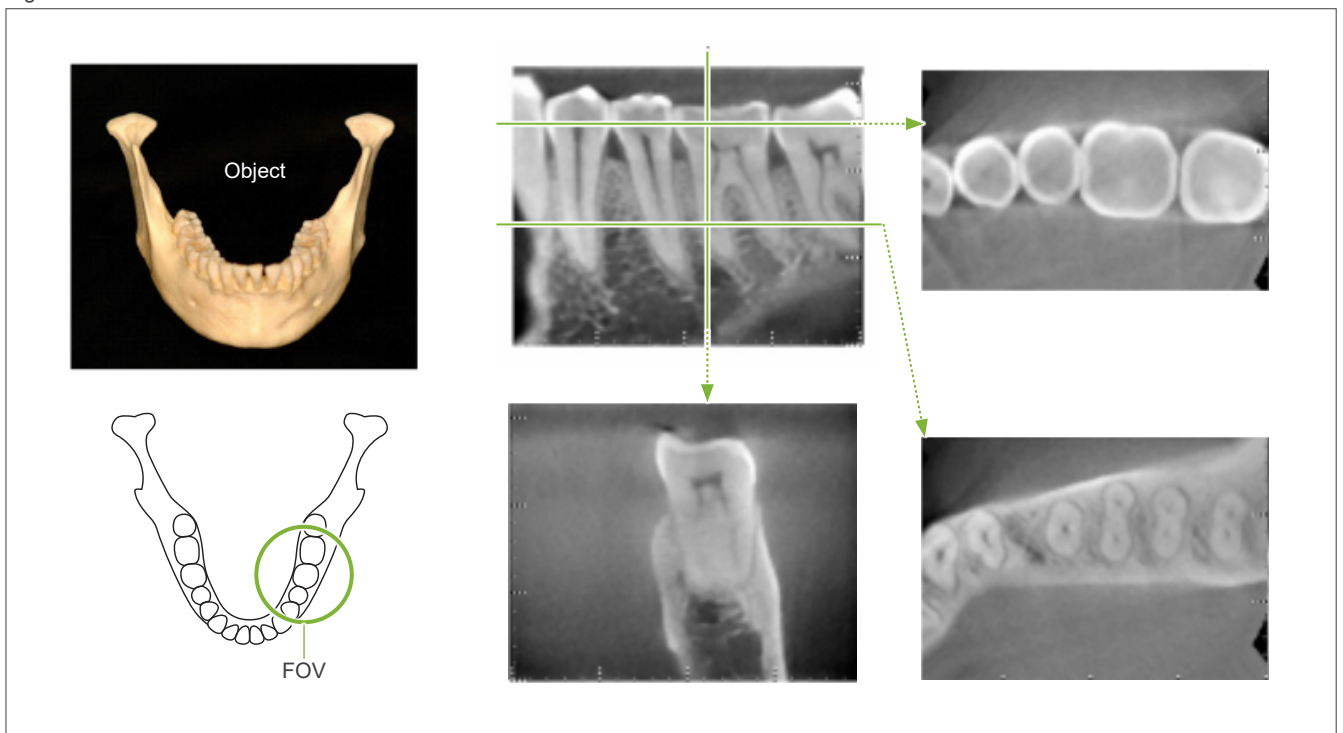


Figure 8: Full Metal Crown is on the Opposite Side of the FOV.

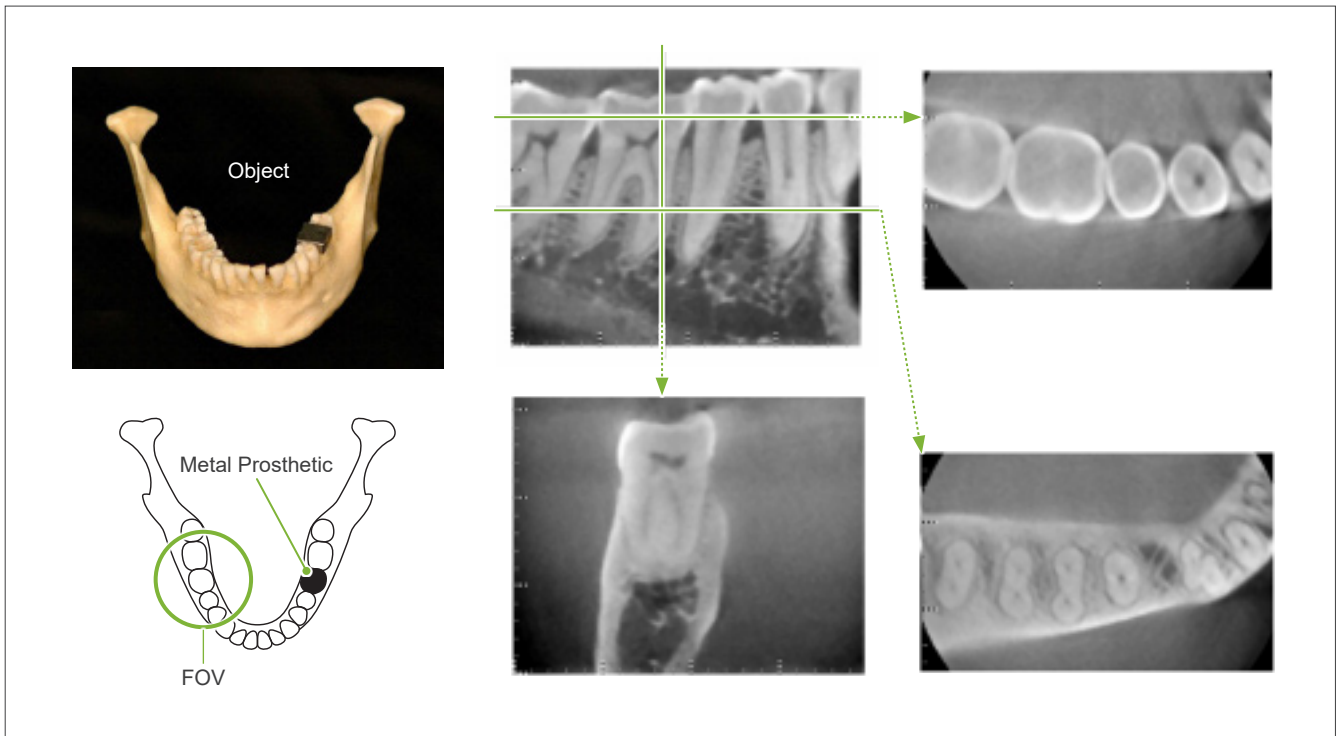


Figure 9: Full Metal Crown is on the Same Side of the FOV.

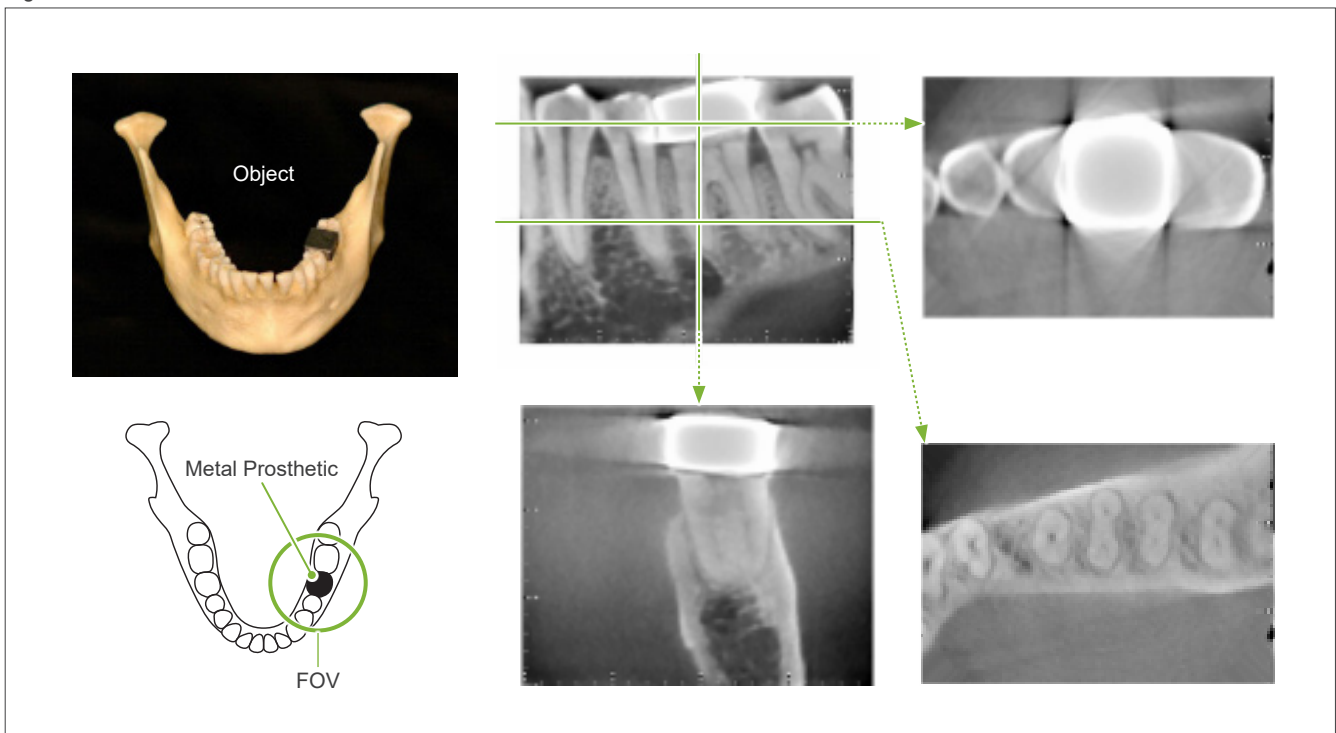


Figure 10 Post Crown



Left: Post and crown made after filling root canal with gutta-percha and point.
 Center: Post and crown attached to tooth.

Figure 11: Post Crown is on the Opposite Side of the Image Area.

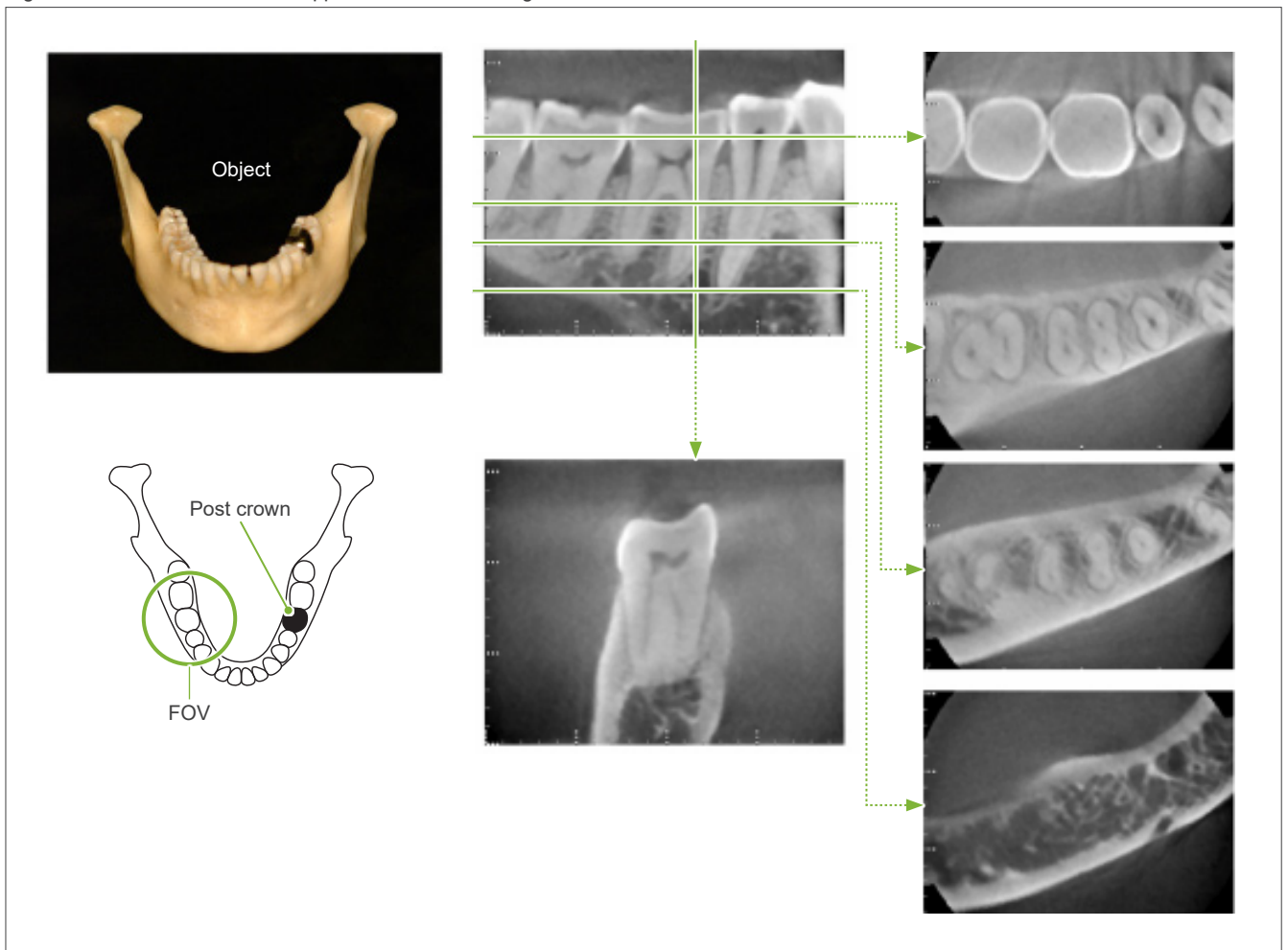
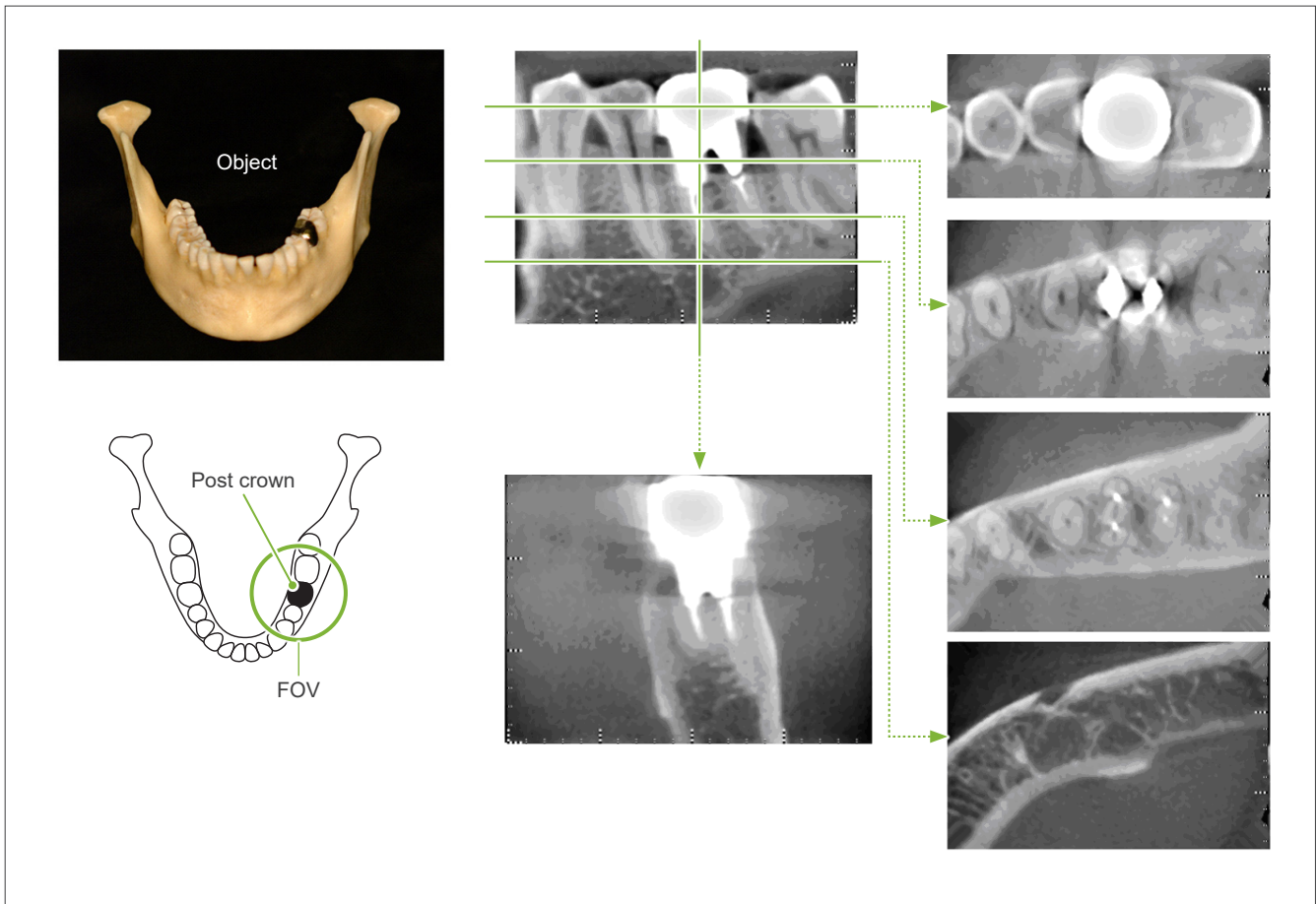
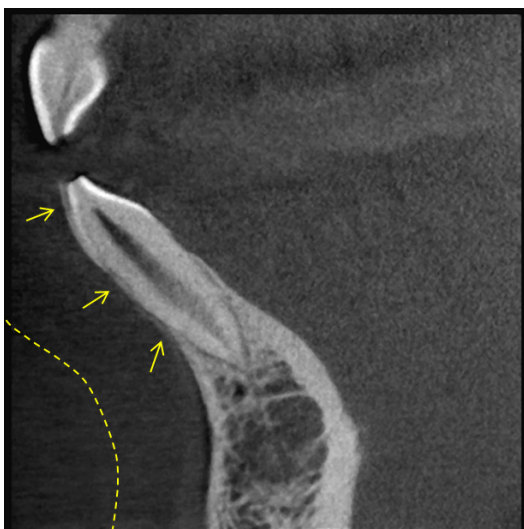


Figure 12: Post Crown is on the Same Side of the Image Area.



6.4.5 Saturation Artifacts

If the X-ray beam is too strong, the flat panel sensor will be saturated, and this will affect the appearance of areas that absorb very little radiation such as soft tissues like lips, cheeks, and gums as well as thin hard tissues such as thin alveolar sockets or teeth. This must be kept in mind when using the image for diagnosis. This is especially a problem if there is a relatively large area of air; the medical doctor or dentist should consider steps such as lowering the X-ray dosage.



6.4.6 Artifacts for 180° Exposures

For 180° exposures, when the X-ray beam passes through the lower plane (a) in Figure 13, the result is the flat shape shown in Figure 14, where the beginning of 180° circuit matches the end of the circuit.

However, when the X-ray beam passes through the upper plane (b) in Figure 13, the result is the conical shape shown in Figure 15, where there is a discontinuity between the beginning and end of the circuit.

Therefore, some slight streaking appears in a 180° exposure that does not appear in a 360° exposure (Figure 16). These streaks run in the direction of the rotation. As a result, some semi-circular artifacts appear in the Z-plane image, and these must be recognized and taken into consideration for accurate diagnosis and analysis.

Figure 13

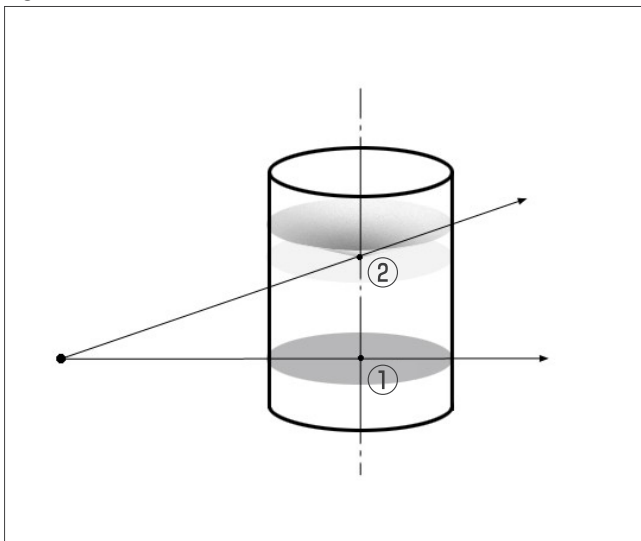


Figure 14

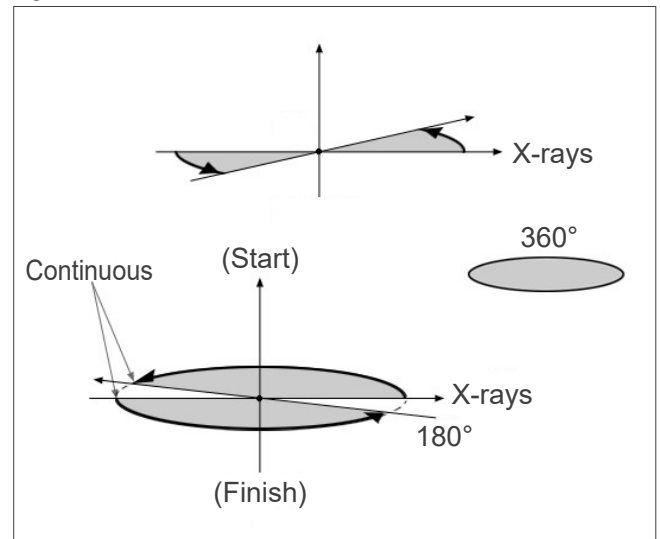


Figure 15

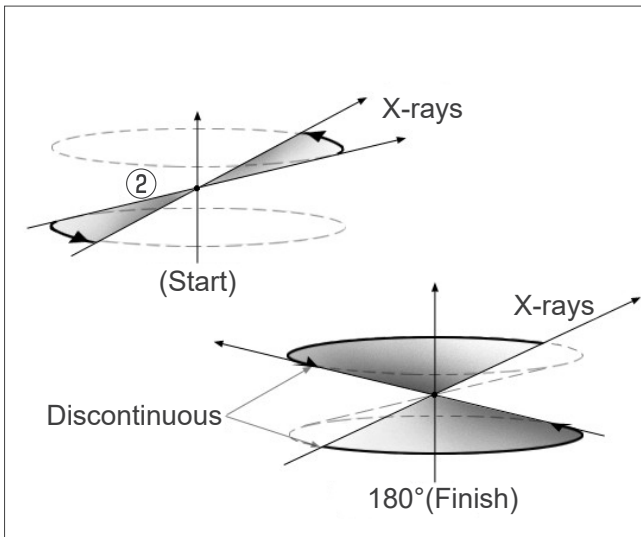
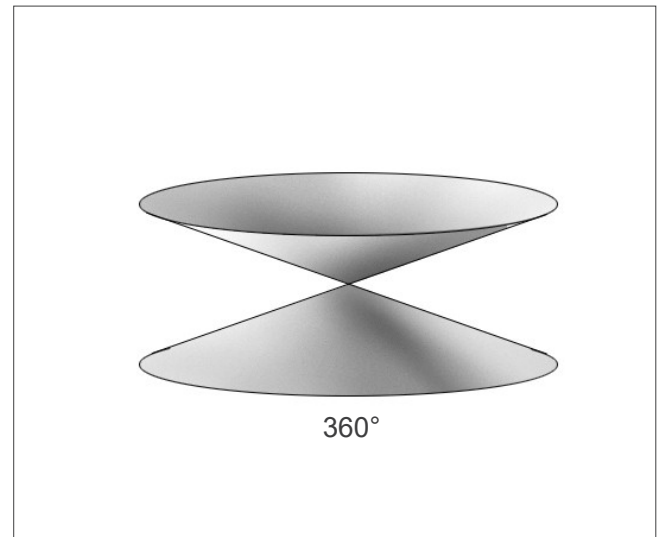


Figure 16



6.4.7 Cautionary Remarks for Ø150 Exposures

Note the following cautionary remarks for Ø150 exposures, and take them into consideration when viewing the images.

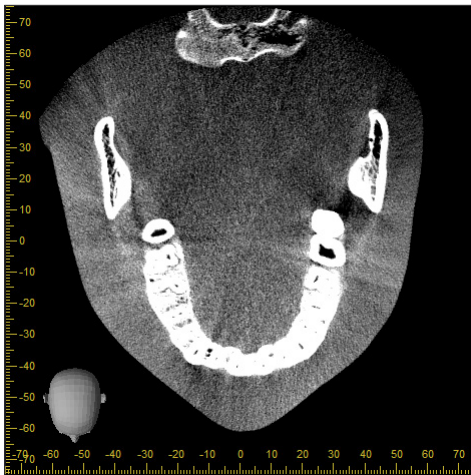
* For clarity of explanations, the artifacts shown in the images below have been highlighted by adjusting the contrast.

■ Ø150 Exposures

● Streak Artifacts

In the axial plane, there may be artifacts that radiate out from the center of the FOV. (Figure 17)

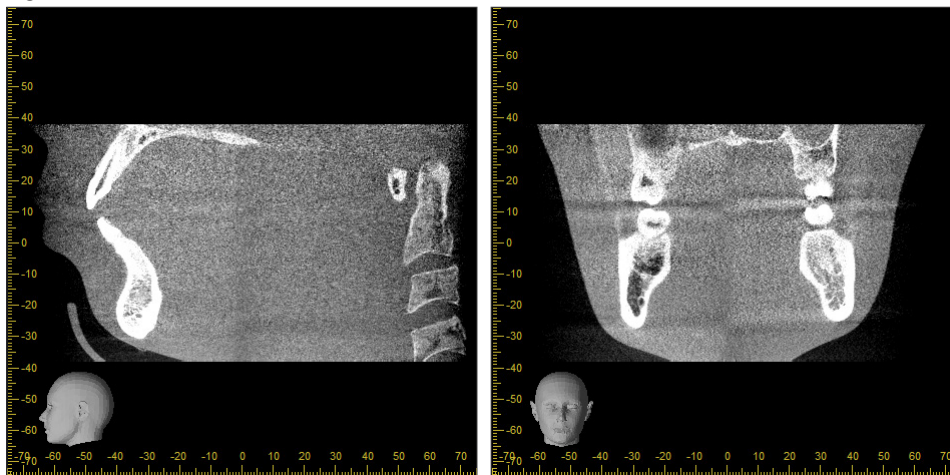
Figure 17



● Artifacts due to Density Disparities

For the X plane (back and forth) and the Y plane (left and right), there may be artifacts due to a slight discrepancy in density. (Figure 18)

Figure 18



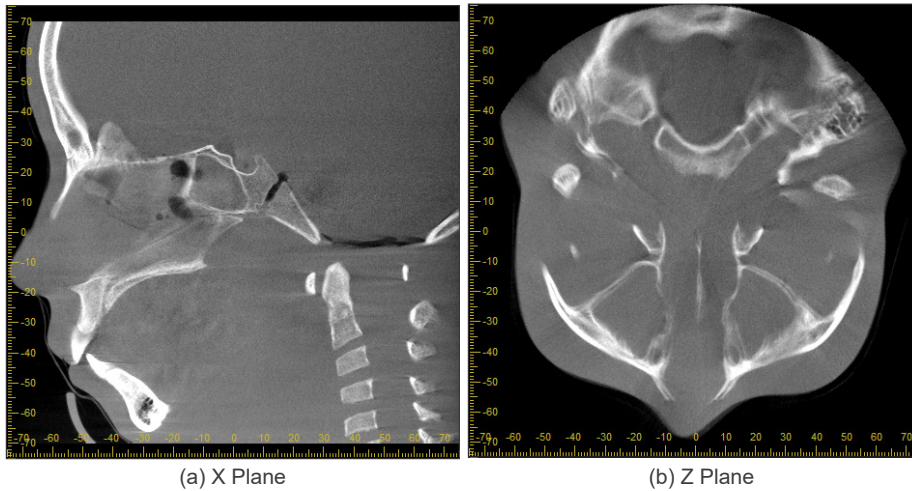
(a) X Plane

(b) Y Plane

■ Ø150 × H140 Exposures

- Due to 2 different exposure data (top and bottom) are used, density might be uneven in the region where are joined.
- The accuracy of the shape of the X-ray target in the region where the 2 exposures are joined is not as good as a conventional CT scan. Therefore, the accuracy of measurements made in this region is also less accurate.
- If the patient moves between the top and bottom exposures, the images cannot be joined properly. (Figures 19 and 20) If the images are not properly joined, the following message will appear in i-Dixel WEB. "Unable to determine the optimum stitching parameters.\r\nDefault values will be used instead. Check the resulting volume carefully when completed."
However, if the patient moves a lot, the message may not appear even though the images are not properly joined.

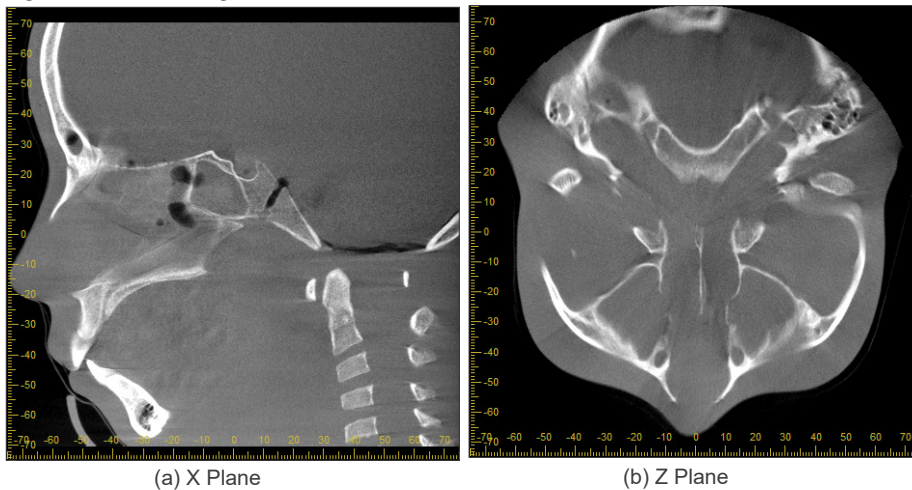
Figure 19: Poor Joining of Images



(a) A jag appears at the end of the nose

(b) Double exposure effect
If this happens only at the plane where the images are joined in the Z direction, the patient probably moved in between the 1st and 2nd exposures. If it happens throughout the volume data, the patient probably moved frequently or constantly during the exposure.

Figure 20: Normal Image



● Corrections for Joint Position and Angle

If the patient moves between the 1st and 2nd exposures, the images will not match up properly when they are joined. Therefore, the position and angle will be automatically corrected based on the overlapped area of the original image. The degree of possible correction is noted below.

- The X, Y, and Z axes can be moved linearly up to 5 mm (0.2 in.).
- The angles for the X, Y, and Z axes can be moved up to 3°.

* These limits may be changed in the future.

Even within the limits noted above, it still may not be possible to join the images properly depending on how they are lined up. Also, it may not be possible to join the images depending on the X-ray target. Furthermore, if the images cannot be joined using the original images, they will be joined by using only the height information for the exposure.

- In order to correct for patient movement in between the 1st and 2nd exposures, the position and angle of the top exposure is automatically adjusted. For this reason a part of the top exposure may be missing as shown in figure 21 below. Figure 22 below shows an example of an image with a missing part.

Figure 21: Why a part is missing.

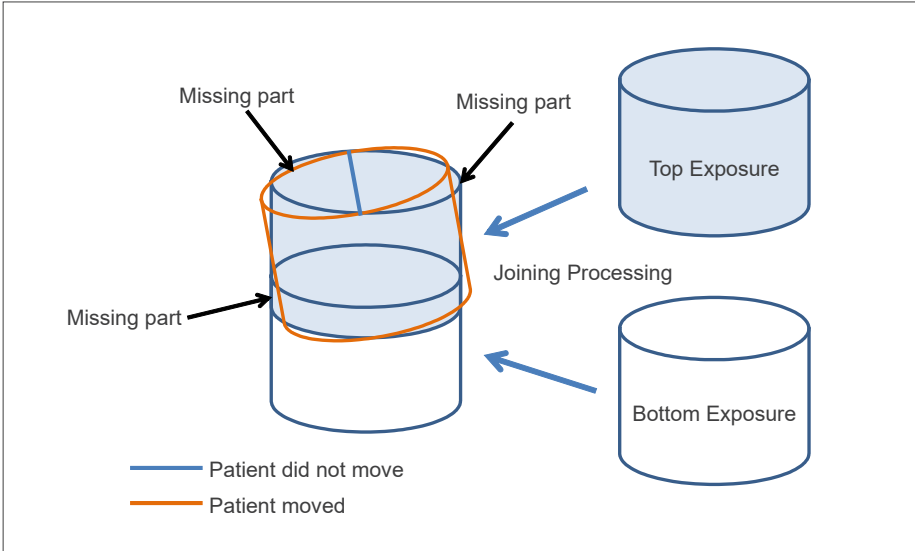
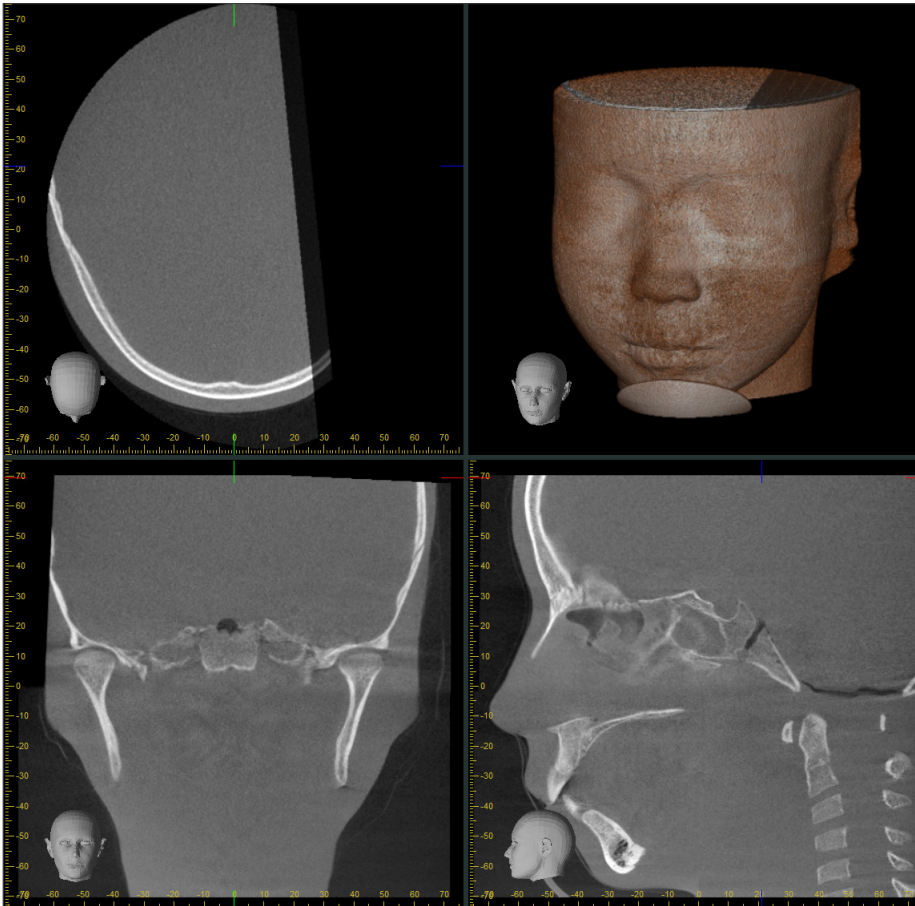


Figure 22: Example of Image with Missing Part

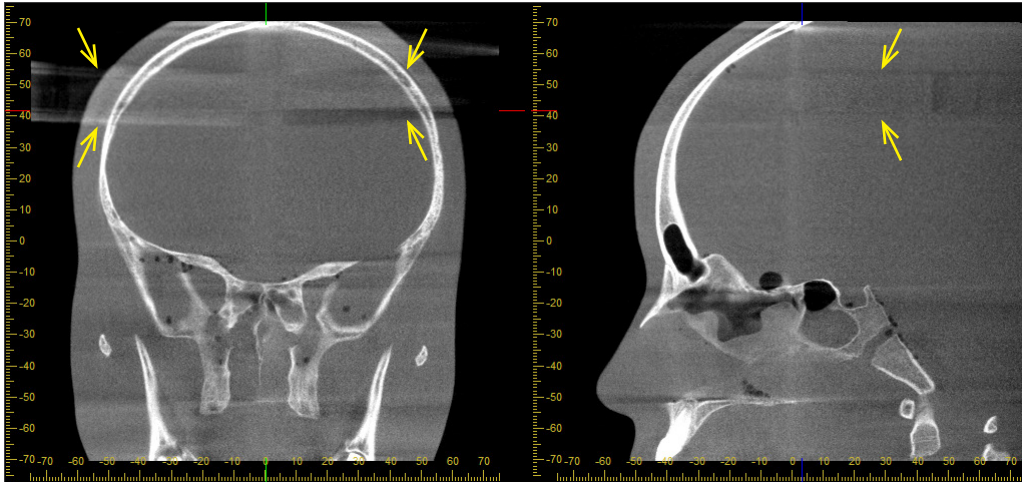


■ Artifacts due to Temporal Stabilizers

When acquiring Sinus images, a strip-shaped horizontal artifact, caused by X-ray absorption of the Temporal Stabilizers, may occur in the upper half of the resulting image. Try positioning the Temporal Stabilizers as high as possible to avoid disturbance to the region of interest such as the frontal sinus.

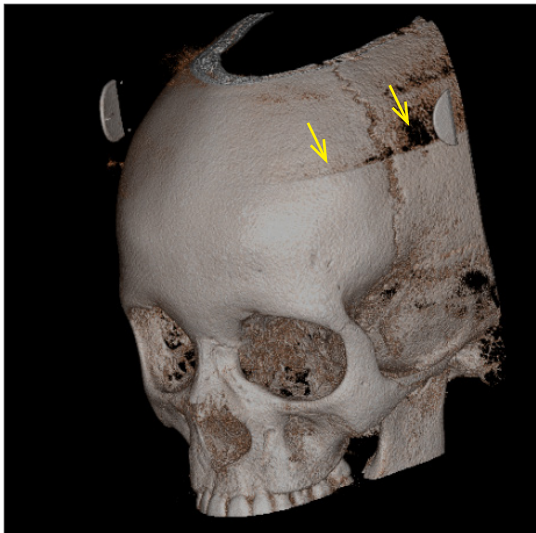
Figure 23 shows the strip-shaped artifacts visible on the coronal and sagittal planes caused by the Temporal Stabilizers positioned on a higher part of the head.

Figure 23: Example of the Strip-shaped Artifact Present in the Coronal and Sagittal Images



The strip-shaped artifact caused by the Temporal Stabilizers may be mistaken for bone loss or other defects, which do not exist in reality. See Figure 24 for an example.

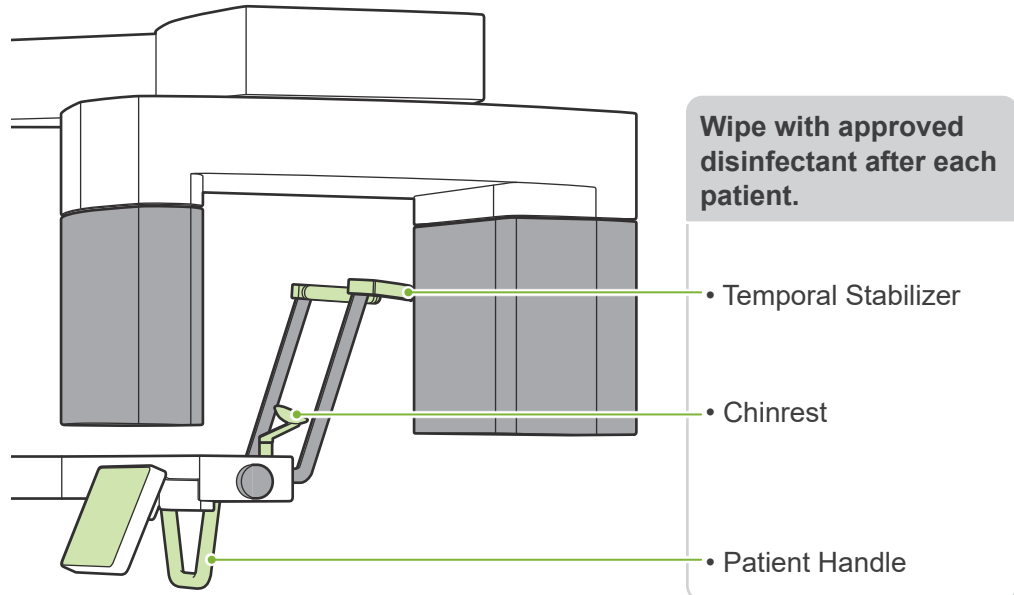
Figure 24: Example of the Strip-shaped Artifact Present in the Volume Rendered Image



7 Maintenance, Parts Replacement, and Storage

7.1 Maintenance (Cleaning and Disinfection)

Always turn off the Power switch before performing regular maintenance.



Parts to be operated for each patient (i.e., Control Panel, Emission Switch, Temporal Stabilizer Knob) wipe with approved disinfectant once a day or when visibly contaminated.

● Disinfection procedure

If visibly contaminated, wipe with approved disinfectant until contamination is removed, then disinfect. The surface to be disinfected must be exposed to disinfectant for a specified period of time to achieve the disinfecting effect. Follow the product information of the disinfectant manufacturer.

Clean other exterior surfaces regularly.

⚠ WARNING

- Do not fail to turn off the Power switch. This will avoid the risk of electric shocks, burns, or accidentally pressing a switch.
- When disinfecting with approved disinfectants, take care that none of it seeps inside the unit. This could damage mechanical parts.

- ⚠ Wear gloves when cleaning and disinfecting.
- ⚠ The disinfectant must be soaked in a wiping cloth before use. The disinfectant never be dropped directly on the surface to be disinfected. A microfiber cloth is recommended for better wiping performance.
- ⚠ Visually check the surface to be disinfected, and if cracks or discoloration occur, change the disinfectant and replace or repair the necessary parts.
- ⚠ Never use alkaline or acidic solutions, cresol soap, or other chemical solutions to clean outer surfaces. These can cause discoloration and material degradation.
Use only ethanol (70 vol% to 80 vol%), neutral detergent, or cleaning detergent supplied with the equipment (if supplied with the equipment).
- ⚠ Use ethanol (70 vol% to 80 vol%) to immediately wipe off any water, detergent or other chemicals that get on the outer surfaces.
- ⚠ The temporal stabilizers, chinrest, and patient handle cannot be autoclaved.

● Approved disinfectants

Ethanol (70 vol% to 80 vol%), if it is not possible to obtain use one of the disinfectants listed below; do not use any other type of disinfectant.

- DÜRR DENTAL's FD 322 quick disinfectant
- DÜRR DENTAL's FD 333 forte quick-action disinfection
- DÜRR DENTAL's FD 366 sensitive disinfection of sensitive surface

7.2 Replacement Parts

- * Replace the parts as necessary depending on degree of wear and length of use. Refer to **“11 Service Life and Consumables” (p.76)**.
- * Order parts from local dealer or J. MORITA OFFICE.

7.3 Storage

The Veraview FX800 must be stored under specific conditions (ambient temperature range, humidity, and atmospheric pressure range). Follow the descriptions in the **“Transport and Storage Conditions” (p. 80)** of **“12.1 Technical Specifications”**.

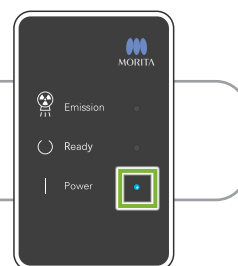
- Do not expose the equipment to direct sunlight for an extended period of time.
- Store disposable covers for the chinrest and chinrest in a clean, hygienic place.
- If the unit has not been used for a long time, make sure it works properly before using.

8 Troubleshooting

8.1 Troubleshooting

If the equipment does not seem to be working properly, the user should first inspect the locations described below.

- * If the user is unable to inspect the equipment himself or if the equipment fails to work properly after being adjusted or after parts are replaced, contact your local dealer or J. MORITA OFFICE.
- * The inside parts of the equipment are charged with high voltage. Do not attempt to perform maintenance or adjustment that is not described in the troubleshooting table.
- * If an accident occurs, the equipment must not be used until repairs have been completed by a qualified and trained technician provided by the manufacturer.



● Before Inspection and Adjustment

Check that the Power LED (blue) on the control box is lit.

8.1.1 Main Unit

Symptoms	Possible Cause	Remedies
No power when the Power switch is turned on.	The Emergency Stop switch has been pressed.	Release the Emergency Stop switch and turn on the Power switch.
<ul style="list-style-type: none"> • Switches don't work. • Control panel display doesn't respond. • The arm doesn't move. 	May still be responding to another key, or some process is in progress.	If normal operation is not restored after waiting a while, turn off the power, wait 1 minute and then turn it on again.
	Set in the Min. Scan Move.	Touch the Ready key to return it to normal ready state.
During usage: <ul style="list-style-type: none"> • Responds the same as when the Power switch is turned on. • Keys don't work. 	<ul style="list-style-type: none"> • Noise • Momentary power interruption 	Turn off the Power switch and have the patient leave the unit. Turn on the Power switch again and see if it operates normally. * Make sure the power supply is on a devoted circuit and is AC 100 V, 20 A, minimum. Also the ground line must be sufficiently grounded.
<ul style="list-style-type: none"> • LCD display goes out. • Display characters are corrupted. • Display color is abnormal (blue etc.) • Responds the same as when the Power switch is turned on. • Keys don't work. 	Build up of static electricity.	Turn off the Power switch and have the patient leave the unit. Turn on the Power switch again and see if it operates normally. Make sure ground is properly connected. Maintain room temperature.

8.1.2 Exposures

Symptoms	Possible Cause	Remedies
Uneven density in image.	i-Dixel WEB setting is not right.	Go to the i-Dixel WEB tool bar and adjust this.
Extremely dark areas or the whole image is too white.	Incorrect exposure conditions.	Adjust the tube voltage "kV" and current "mA".

8.1.3 i-Dixel WEB

Symptoms	Possible Cause	Remedies
If the following error message appears in i-Dixel WEB "Video capture failure."	LAN cable is not properly connected.	Make sure the LAN cable is properly connected and restart the computer.
If either of the following error messages appear in i-Dixel WEB. "Cannot secure sufficient memory. Restart the software and the X-ray unit." "Cannot continue processing due to insufficient memory. Restart the software."	Insufficient computer memory due to repeated CT exposures or reconstructions.	Restart i-Dixel WEB.
If the following error message appears in i-Dixel WEB "Exposure terminated because no patient has been selected."	Exposure initiated without displaying a patient's image list.	Close the error message and then select and display a patient image list. Touch the Ready key to light it up. Then repeat the exposure procedure again.
If the following error message appears in i-Dixel WEB "Exposure terminated because application is busy."	Initiated exposure when i-Dixel WEB was not capable of processing a new exposure.	Close the error message and then select and display a patient image list. Touch the Ready key to light it up. Then repeat the exposure procedure again.

8.2 Error Messages

Error messages will appear in the control panel when some problem or error is detected. If the suggested response does not work, contact your local dealer or J. MORITA OFFICE. Make a note of the error number and report it when requesting help for the company.

Error No.	Messages
C1	The capture computer is not ready.
C2	The communication speed between the device and the HUB is insufficient.
C3	No response from the HUB.
C4	No response from the PC.
C5	The HUB between the device and capture system does not support jumbo frames.
C6	No response from the application software.
C7	The network interface card in the computer does not support jumbo frames.
01	The X-ray generator has overheated and acquisition has been stopped. Leave the power on and wait for approximately 30 minutes for the unit to cool down then try again.
02	Abnormal feedback detected in the voltage line of the X-ray generator. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.
03	A fault was detected in the fan motor of the inverter. Contact your local Morita representative for assistance.
04	Abnormal feedback was detected in the preheat line of the X-ray generator. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.
05	The tube voltage measured in the X-ray generator circuit was less than the specified value. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.
06	The tube voltage measured in the X-ray generator circuit was greater than the specified value. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.
07	The tube current measured in the X-ray generator circuit was less than the specified value. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.
08	An interlock error occurred in the X-ray generator. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.

Error No.	Messages
09	<p>The overvoltage circuit has been activated. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.</p>
0A	<p>The overcurrent circuit has been activated. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.</p>
0B	<p>A PFC error occurred in the X-ray generation circuit. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.</p>
0C	<p>An abnormality was detected in the power supply control of the X-ray generator. Acquisition has been stopped. Press OK to continue using the apparatus. If this message appears frequently, contact your local Morita representative for assistance.</p>
0D	<p>The inverter circuit has overheated. Acquisition has been stopped. Leave the power on and wait for approximately 5 minutes for the unit to cool down then try again.</p>
0E	<p>Communication error between CPU and PCBs. The operation has been stopped.</p>
0F	<p>The arm and FPD control PCBs did not respond. Turn the unit off and on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
10	<p>The X-axis and Y-axis motor control PCB did not respond. Turn the unit off then on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
11	<p>The slit motor control PCB did not respond. Turn the unit off the on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
12	<p>The operation panel control PCB did not respond. Turn the unit off then on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
13	<p>The lift motor control PCB did not respond. Turn the unit off then on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
14	<p>The inverter PCB did not respond. Turn the unit off then on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
15	<p>The Cephalo cassette connector PCB did not respond. Turn the unit off then on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
16	<p>The Cephalo control PCB did not respond. Turn the unit off then on again. If this message appears frequently, contact your local Morita representative for assistance.</p>
17	<p>Abnormality detected during arm rotation and movement has been stopped. Press the Ready button to return to the initial position. If this message appears frequently, the arm rotation mechanism or arm motor PCB may be faulty. Contact your local Morita representative for assistance.</p>

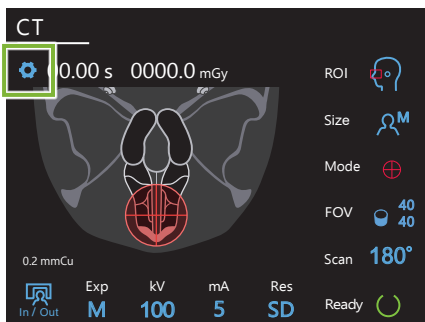
Error No.	Messages
18	<p>Abnormality detected during X-axis operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the X-axis motor or XY motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
19	<p>Abnormality detected during Y-axis operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the Y-axis motor or XY motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
1A	<p>Abnormality detected during operation panel support operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the patient support elevating mechanism or frame motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
1B	<p>Abnormality was detected in left/right beam operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the left/right beam mechanism or frame motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
1C	<p>Abnormality detected in horizontal slit left-side operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the horizontal slit left side or slit motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
1D	<p>Abnormality was detected in horizontal slit right-side operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently the horizontal slit right side or slit motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
1E	<p>Abnormality detected in vertical slit upper-side operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the vertical slit upper side or slit motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
1F	<p>Abnormality detected in vertical slit lower-side operation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the vertical slit lower side or slit motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
20	<p>Abnormality detected during flat panel vertical movement. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the arm rotation mechanism or arm motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
21	<p>Abnormality detected during lift elevation and movement has been stopped. Press the up/down keys on the operation panel to try again.</p> <p>If this message appears frequently, the lift elevating mechanism or Z motor PCB may be faulty. Contact your local Morita representative for assistance.</p>
22	<p>Abnormality detected during X-ray generator rotation and movement has been stopped. Press the Ready button to return to the initial position.</p> <p>If this message appears frequently, the X-ray generator rotation mechanism or slit motor PCB may be faulty. Contact your local Morita representative for assistance.</p>

Error No.	Messages
23	The second scout image was not captured.
24	Capturing the second scout image was interrupted.
25	Emission switch was released during image acquisition. Acquisition has been interrupted.
26	Emergency stop. Emission switch or a key on the operation panel was pressed during acquisition.
27	Returning the unit to its initial position was interrupted. Press the Ready button to return to the initial position.
28	Emergency stop. If a patient is positioned in the unit, have them exit the unit before proceeding. After confirming the unit may be operated safely, release the emergency switch by turning it to the right and pulling down.
29	Image data is not being received by the capture PC. Acquisition has been stopped. If this message appears at the start of the acquisition, this may indicate a timing issue. Please retry and if the error persists, contact your local Morita representative for assistance.
2A	Abnormality detected in Cephalo slit operation and movement has been stopped. Press the Ready button to return to the initial position. If this message appears frequently, the Cephalo slit or Cephalo PCB may be faulty. Contact your local Morita representative for assistance.
2B	Abnormality detected in Cephalo cassette operation and movement has been stopped. Press the Ready button to return to the initial position. If this message appears frequently, the Cephalo cassette or Cephalo PCB may be faulty. Contact your local Morita representative for assistance.
2C	Abnormal communication with 3DXD on the capture PC. The driver may not be running or may otherwise be occupied. Check the software status on the PC then try again.
2D	Abnormal communication with DixelD on the capture PC. The driver may not be running or may otherwise be occupied. Check the software status on the PC then try again.
2E	Abnormal communication with the digital cassette. Turn the unit off then on again and retry the operation.
2F	Scout position has been changed. Please set the scout position again from the capture PC.
30	Abnormality detected in copper filter switching mechanism operation and movement has been stopped. Press the Ready button to return to the initial position. If this message appears frequently, the filter changeover mechanism or slit motor PCB may be faulty. Contact your local Morita representative for assistance.
31	The equipment was moved after acquiring the scout image. The position is no longer valid. Please reacquire the scout image and try again.
32	The short connector of the X-ray generator is not connected.
33	The position is too high for stitched image acquisition. Use the up/down key to lower the arm and try again.

Error No.	Messages
34	The position is too low for stitched image acquisition. Use the up/down key to raise the arm and try again.
35	Abnormality detected in the arm vertical position data. Use the up/down key to lower the arm to the lowest position and reset the position data.
36	Image acquisition cannot be performed as the previous image is still being transferred to the capture PC. When the operation is finished, retry the acquisition.
37	The direction of the Cephalo craniostat does not match the Cephalo acquisition mode. Adjust either the mode or craniostat position then try again.
38	The temple stabilizers are open. Ensure that the temple stabilizers are closed when the arm is rotating to avoid interference.
39	Abnormality detected in the arm vertical position data. Use the up/down key to raise the arm to the highest position and reset the position data.
3A	GUI parameters are incorrect. Turn the unit off then on again.
3B	X-ray is not irradiated. If this message appears many times consecutively, the X-ray generator may be faulty. Contact your local Morita representative for assistance.
3C	Abnormal maximum height detected. Perform lift teaching to resolve. Move the arm to its lowest limit and continue to hold the down key for at least 5 seconds. The lifting teaching screen will appear. Follow the directions in the service manual.
3D	Acquisition has stopped due to an abnormality detected in the backup timer. Contact your local Morita representative for assistance.
3E	An abnormality was detected in the inverter PCB cooling fan. You can continue using the equipment, but take radiographs at intervals of at least 20 minutes. If no interval is provided, the inverter circuit might be overheated. If this message appears frequently, the PCB or the fan may be faulty. Contact your local Morita representative for assistance.
3F	An abnormality was detected in the X-ray head cooling fan. You can continue using the equipment, but take radiographs at intervals of at least 20 minutes. If no interval is provided, the X-ray head might be overheated. If this message appears frequently, the X-ray head or the fan may be faulty. Contact your local Morita representative for assistance.
40	The door to the x-ray room may be open. Please close the door completely before acquisition.
41	Abnormal communication with DixelD on the capture PC. The driver may not be running or may otherwise be occupied. Check the software status on the PC then try again.
42	The capture computer is not ready.

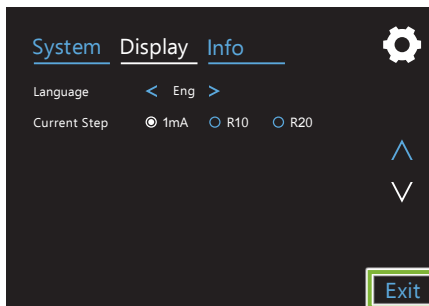
9 Various Settings

● Enter Setting Display

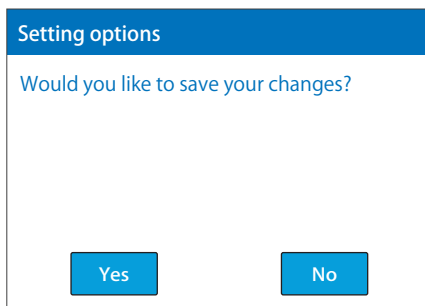


Touch the Settings key in the upper left corner. The display will change to the settings menu.

● Exit Setting Display



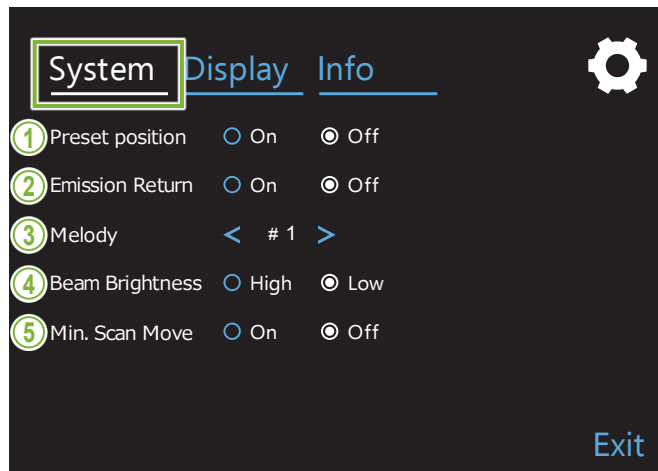
Touch the Exit key in the lower right corner. The “Setting options” dialogue box will appear.




Yes: Touch this button to save the settings.

No: Touch this button to leave the settings as they are and return to the exposure screen. However, these settings will not be saved. The settings will go back to the previous ones when the Power switch is turned off.

9.1 System Settings



Touch the System key to display a menu for various system settings for the unit.

The settings marked with a white circle () are the ones that are currently selected.

1. Preset position

This mode is to safely move the arm and lift to the secure place without making contact with any other device.

On: The arm moves to its specified position when the In/Out key on the control panel is held down.

CAUTION

- Always make sure that the area is clear before doing this operation.

2. Emission Return

Press the Emission Switch once to return the arm after the patient has left the unit.

CAUTION

- Always make sure that the area is clear before doing this operation.

3. Melody

Select the melody to be played during emission.

#1: Electronic beeping

#2: Für Elise (Ludwig van Beethoven)

#3: Minuet (Johann Sebastian Bach)

#4: Symphony No. 9 (Ludwig van Beethoven)

#5: Three Marches Militaires (Franz Schubert)

#6: Hana "Flower" (Rentaro Taki)

#7: Turkish March (Wolfgang Amadeus Mozart)

#0: No melody

(A warning sound is emitted by the control box.)

4. Beam Brightness

Set the brightness for the beams.

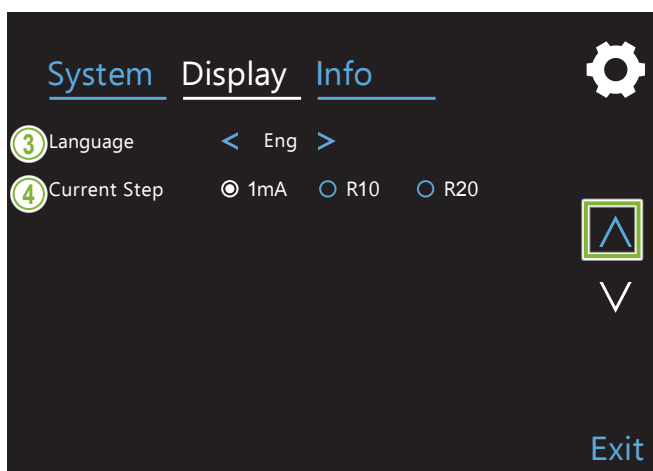
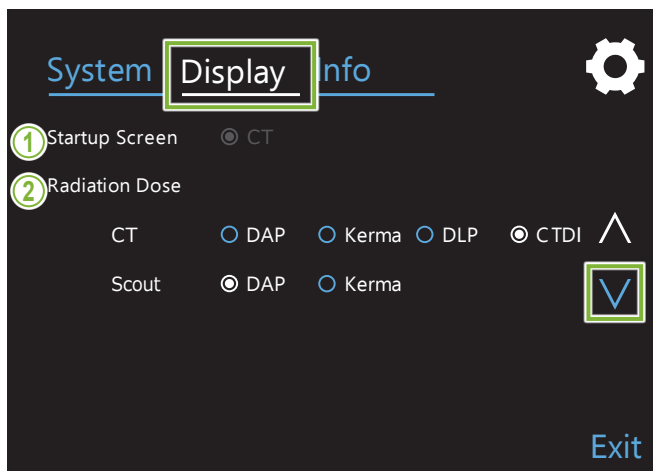
After making the setting, turn off the Power switch to activate it.

High: Bright **Low:** Dim

5. Min. Scan Move

After patient positioning, the arm can be moved to the position which will require the shortest exposure time (least time needed to hold down the Emission Switch) before the operator leaves the X-ray room.

9.2 Display Settings



Touch the Display key to switch the screen menu that shows possible settings for the display.

Use the keys “V” or “^” on the right side to change pages.

1. Startup Screen

Select the screen to be display when the unit is turned on.

2. Radiation Dose

Select the way to display the X-ray dosage.

3. Language

Select the language used for the control panel.

4. Current Step

This sets the increments for increasing or decreasing the “mA” for each time the key “+” or “-” is pressed.

R10 & R20 Settings

R10	R20
2.00	2.00
	2.24
2.50	2.50
	2.80
3.15	3.15
	3.55
4.00	4.00
	4.50
5.00	5.00
	5.60
6.30	6.30
	7.10
8.00	8.00
	9.00
10.00	10.00

9.3 Information

Touch the Info key to display information about the unit.

10 User Periodic Inspection

- * The user (i.e., clinic, hospital, etc.) is responsible for management, maintenance and use of this medical device. Periodic inspections are generally considered to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out these duties, the user may rely on a qualified medical device service technician. Contact your local dealer or J. MORITA OFFICE for details.
- * This device should be inspected every 12 months in accordance with the following user periodic inspection list. However, periodic inspection requirements and frequency may differ among countries, so conduct the inspections in accordance with local regulations.

Name of Institution			
Model		Testing Site	
Serial Number		Temp./Humidity	
Date		Tester	

No.	Category	Test Item	Criteria	Instrument	Results
1	Power Switch and Emergency Stop Switch	Power Switch	The Veraview FX800 can be turned on and off with the device power switch.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		Emergency Stop Switch	While the arm is moving back to its original patient positioning position, pressing the Emergency Stop switch will stop the arm movement immediately, and a message will appear.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
2	Installation Integrity	Floor and Wall Fastenings	The floor must not be sloped. The Veraview FX800 is anchored to the floor or wall. Fastening must not loosen or rattle.	Level & Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		All Component Fastening	Each fixation point of the Veraview FX800 must not be loose and be securely fixed.	Visual & Senses	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
3	Positioning Parts and Beams	Brightness	All beams are sufficiently visible.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
4	Mechanical Movement	Arm Rotation and Moving Parts	No abnormal noise or vibration during any mechanical movements.	Visual & Senses	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		Lift Function	The lift moves smoothly without any abnormal noise when raising and lowering it.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
5	Control Panel Display and Functions	Switches	The touch panel, operation keys/switches, and emission switch are fully functioning and not damaged.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		Display	The LCD display is fully functioning.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
6	X-ray Head	Insulation Oil Leakage	No leakage of the insulation oil from the X-ray head.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
7	Appearance	Patient Positioning Parts	The chinrest, temporal stabilizers, and patient handle are not damaged, loose, or deformed, and are securely fixed and fully functioning.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		Exterior	There are no scratches, dents, or other damage that could harm the patient or user.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

No.	Category	Test Item	Criteria	Instrument	Results
8	Loading Factor	Refer to Veraview FX800 Quality Test Procedure.			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
9	CT Functions				<input type="checkbox"/> Pass <input type="checkbox"/> Fail
10	Computer Functions	Basic Functions	There are no warnings or errors when starting up the computer.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		Storage	There are no disc errors or detection errors. Required free space is available, or other storage means are prepared.	Visual	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

11 Service Life and Consumables

Service life refers to the standard period the unit or individual components can be expected to be usable as long as inspection and maintenance procedures specified by J. MORITA MFG. CORP. are followed.

Component Service Life List refers to components that can be expected to wear out, degrade or break depending on frequency and conditions of usage, which greatly affects how long these components retain their performance standards.

Consumables refers to parts and components that inevitably are degraded and need to be replaced periodically and are not covered by the warranty.

The product warranty is good for 3 years after delivery.

The components on the Component Service Life List that are noted "Yes" are critical for safety. These components must be inspected and replaced or have appropriate maintenance performed as necessary without fail before their standard service life expires.

The user must pay for parts and repairs that are performed after the warranty expires or the part has passed its specified standard service life. However, if a maintenance contract has been agreed to, this will depend on the contents of that contract.

For details concerning periodic inspections and parts replacements, contact your local dealer or J. MORITA OFFICE.

● Component Service Life List

Components	Standard Service Life	Critical Safety Component	Remarks
Moving Parts (for Arm and Lift)	45,000 exposures or 6 years whichever comes first.	Yes	Including cables, bearings, etc.
Motors (for Arm and Lift)	45,000 exposures or 6 years whichever comes first.	N/A	
X-ray Tube *1	15,000 exposures	N/A	
High Voltage Unit	3 years	N/A	
X-ray Detector (FPD) *2	3 years	N/A	
Printed Circuit Boards	6 years	Yes	
LCD Display	6 years	N/A	
Touch Panel, Operation Switches	3 years	N/A	
Temporal Stabilizer	3 years	N/A	
Other Electrical Components	6 years	N/A	

*1 The service life of the X-ray tube depends on the number and length of exposures it is used for as well as the output (tube voltage and current) and the time between exposures. Of these factors, the most critical is the number of exposures which degrades the anode. As the anode gradually degrades, stable output is lost, and the circuit protection system detects errors and terminates X-ray emission.

*2 The service life of the FPD mainly depends on the ambient conditions (temperature and humidity) where it is used and the accumulated amount of X radiation it receives. As the accumulated amount of received X radiation increases, the sensitivity of the detector is gradually degraded. High humidity can also lead to degradation. Semiconductor degradation caused by X radiation and the disparities for individual semiconductor units can cause parts of the detector to lose sensitivity. Loss of sensitivity can be remedied to some degree by performing sensitivity compensation and calibration during periodic inspections, but partial sensitivity degradation cannot always be corrected.

● Consumables

Components	Code No.	Exchange Frequency	Critical Safety Component	Remarks
Chinrest Disposable Cover	6215001	Single use	Yes	For infection control.
Chinrest (-40)	4001146	1 year or whenever scratched or damaged.	Yes	
Chinrest	6215031	1 year or whenever scratched or damaged.	Yes	

● Service

The Veraview FX800 may be repaired and serviced by

- The technicians of J. MORITA's subsidiaries worldwide.
- Technicians employed by authorized J. MORITA dealers and specially trained by J. MORITA.
- Independent technicians specially trained and authorized by J. MORITA.

The circuit diagrams, component parts lists, descriptions, calibration instructions or other information will be available on request, only for the service personnel authorized by J. MORITA to repair those parts.

12 Technical Description

*Specifications may be changed without notice due to improvements.

12.1 Technical Specifications


Product Name	Veraview FX800
Model	X800N
Intended Use (Indications for Use)	<p>Veraview FX800 Model X800N is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography.</p> <p>Veraview FX800 Model X800N is an extraoral source X-ray unit that is used for dental and head radiographic examination and diagnosis of teeth, jaw, oral structure, temporomandibular joint, skull including the ENT and dento-maxillofacial areas, and hand for maturity assessment, by exposing an X-ray image receptor to ionizing radiation.</p> <p>The device uses a cone shaped X-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 2D or 3D viewing stations.</p> <p>The device is to be operated and used by medical doctors, dentists, and other legally qualified professionals for pediatric and adult patients.</p>
Electric Shock Protection Classification	Class I
Electric Shock Protection Degree for Applied Part	Type B with applied component with component no conductive connection
Type B Applied Parts	Temporal Stabilizer, Chinrest, Patient Handle
Single Use Item	Disposable covers for the chinrest
Protection Against Ingress of Water	IPX0
Operation Mode	Non-continuous operation, momentary operation for U.S.A.
Operating Altitude	Max. 3,000 m
X-ray Head (including high voltage device)	
X-ray Tube	D-054SB or D-051SB
X-ray Tube Manufacturer	TOSHIBA or Canon
Nominal Focal Spot	0.5
Target Angle	5°
Focal Spot Material	Tungsten
Total Filtration	<p>Inherent Filtration: Min. 2.5 mmAl, 75 kv/HVL 3.5 mmAl</p> <p>Added Filter: 0.2 mmCu (9.6 mmAl, 75 kv/HVL 3.5 mmAl)</p> <p>Indicated Location of Added Filter: Control Panel</p>

Beam Quality(HVL)	Min. 3.6 mmAl at 100 kV Min. 3.2 mmAl at 90 kV Min. 2.9 mmAl at 80 kV Min. 2.5 mmAl at 70 kV Min. 2.2 mmAl at 60 kV
Ignition	Preheated
Rectification	Direct current method
Cooling Method	Oil cooling
Leakage Radiation	Max. 1.0 mGy at 1 m ^{*1}
Reference Loading Conditions	CT Exposure 100 kV, 480 mAs (100 kV, 8 mA with 1:59 duty cycle. e.g. 9.4 sec. emission with 9 min. 15 sec. intermission)
Unit Specifications	
Tube Voltage	60 – 100 kV in 5 kV increments Accuracy: Display value $\pm 10\%$ (Refer to each mode for details.)
Tube Current	2 – 10 mA in 1 mA, R10 or R20 increments Accuracy: Display value $\pm 20\%$ (Refer to each mode for details.)
Exposure Time	Accuracy: Display value $\pm(5\% + 50 \text{ ms})$ (Refer to each mode for details.)
Reproduceability of Air Kerma	Coefficient of Variation: Max. 0.05
Duty Cycle	1:59 (Maximum Irradiation Time: 18.5 sec., Minimum Interval Time: 18 min. 12 sec.)
X-ray Field	Set automatically by select the exposure mode.
Dose Information	User selectable Scout: DAP (Dose Area Product) or Air Kerma CT: DAP (Dose Area Product), Air Kerma, CTDI (volume CT Dose Index), DLP (Dose Length Product) Displayed on control panel Accuracy: Display value $\pm 50\%$ * * Local criteria has priority if required in regulation.
Primary Protective Shielding	2.2 mmPb
Attenuation Equivalent	Exterior Cover in front of Imaging Sensor: Max. 1.2 mmAl
Patient Positioning Method	Laser, Two-Direction scout (Refer to each mode for details.)
Positioning Laser	Class 1 (IEC 60825-1: 2014) Max. 0.39 mW, 655 or 670 nm
Emission Switch	Dead-man type
Main Fuse* * Fuse shall be replaced by qualified person. The user should never replace the fuse himself.	AC 120 V unit (Cord No. 6112442, Qty 1) : 25 A, 250 V Fast-acting, High Breaking Capacity, Size 0.25 × 1.25 inches

⚠ WARNING

- Main fuse is on the Varistor Board located lower right side of the column where remains “live” even if the Power switch is turned off. Be sure to turn off the circuit breaker before servicing to avoid electrical shock.

*1 This value is not a dose rate. Rather, it is a cumulative dose per hour taking into account the duty cycle.

Dimensions	
Main Unit	Long Column: W1,400 × D1,200 × H2,325 mm (W55 × D47 × H92 in.) Short Column: W1,400 × D1,200 × H2,185 mm (W55 × D47 × H86 in.)
Control Box	W120 × D60 × H120 mm (W5 × D2 × H5 in.)
Installation Space and Weight	
Installation Space	1.32 m ²
Weight	Long Column: Approx. 190 kg (419 lbs.) Short Column: Approx. 185 kg (408 lbs.)
Power Requirements	
Rated Input Voltage	AC 120 V
Frequency	50 – 60 Hz single phase
Line Voltage Regulation	Max. 8%
Range of Line Voltage (Including Line Voltage Regulation)	AC 108 – 132 V
Input	Operation: 2.0 kVA
	Standby: 0.2 kVA
Power Supply Apparent Resistance	0.5 Ohm
Over-Current Release at Distribution Panel*2	20 A, Earth leakage current breaker
Connection to Supply Mains	Permanent connection
Maximum Line Current	18.5 A
Technique Factor for the Maximum Line Current	CT Model: 90 kV, 9 mA
 WARNING • To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.	
Environmental Data	
Operating Conditions	
Ambient Temperature Range	+10°C to +35°C (+50°F to +95°F)
Humidity	30% to 75% (without condensation)
Atmospheric Pressure Range	70 kPa to 106 kPa
Transport and Storage Conditions	
Ambient Temperature Range	-10°C to +50°C (+14°F to +122°F)
Humidity	20% to 80% (without condensation)
Atmospheric Pressure Range	50 kPa to 106 kPa

*2 Circuit breaker shall be applied on distribution panel. It is recommended to wire a breaker only for this unit.

CT Exposures	
Tube Current and Voltage	Standard: 2 – 10 mA: 70, 75, and 80 kV 2 – 9 mA: 85 and 90 kV 2 – 8 mA: 95 and 100 kV
Exposure Time	Refer to value in the control panel. Max. 17.9 sec.
Nominal Electric Power	0.8 kW (100 kV, 8 mA, 0.5 sec.)
Field of View (FOV)	Ø40 × H40 mm (Ø1.6 × H1.6 in.), Ø80 × H80 mm (Ø3.1 × H3.1 in.), Ø150 × H75 mm (Ø5.9 × H3.0 in.), Ø150 × H140 mm (Ø5.9 × H5.5 in.)
Focal Spot to Image Receptor Distance	600 mm (23.6 in.)
Image Quality	MTF: Min. 2 LP/mm at SD, Min. 2.5 LP/mm at HR
Geometric Accuracy	Max. ±0.5 mm and ±2 degrees in the X-ray focus plane

12.2 Requirements for Computers or Other Devices Connected to Computers

1. The Veraview FX800 has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2 Edition 4.1 for electromagnetic disturbances.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the environment. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the nearest J. MORITA OFFICE, its representative or its dealer for help.

2. The following equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950-1 or IEC 62368-1 for data processing equipment and IEC 60601-1 for medical equipment).

Everybody who connects additional equipment to the signal input part or signal output part configures a medical electrical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1. If in doubt, consult the nearest J. MORITA OFFICE, its representative or its dealer for help.

* Some of the following devices may cause some technical problems with the Veraview FX800. Ask your nearest J. MORITA OFFICE for proper selection of equipment and connections.

⚠ The following devices may not be located in the X-ray protection area or the patient environment except the Hub. If the Hub is conformed with IEC 60601-1, IEC 60950-1, or IEC 62368-1 and enclosure leakage current is conformed with IEC 60601-1. After installation, check that the IEC 60601-1 leakage current levels are not exceeded.

* If the above is not satisfied the following devices has to be located over 1,5 meters apart from the Veraview FX800.

* The operator shall not touch the LAN connector when touching the patient.

* The Veraview FX800 must be connected to it's own separate power supply. Computers or any other external devices must NOT be connected to the same power supply as the The Veraview FX800.

WARNING

- connect only items that have been specified as part of medical electric system or specified as being compatible with medical electric system.
- Do not use multiple portable socket outlet nor extension cord for the system power supply.

* Computers or any other external devices must be connected in accordance with IEC 60601-1.

* Devices that do not meet the IEC 60950-1 or IEC 62368-1 standard (minimum requirements) must not be connected to the system as they may pose a threat to operational safety.

* Computers or any other external devices must be cleaned in accordance with the manufacturer's instructions.

* Computers or any other external devices must be transport, storage and operate in accordance with the manufacturer's instructions.

■ Other system requirements

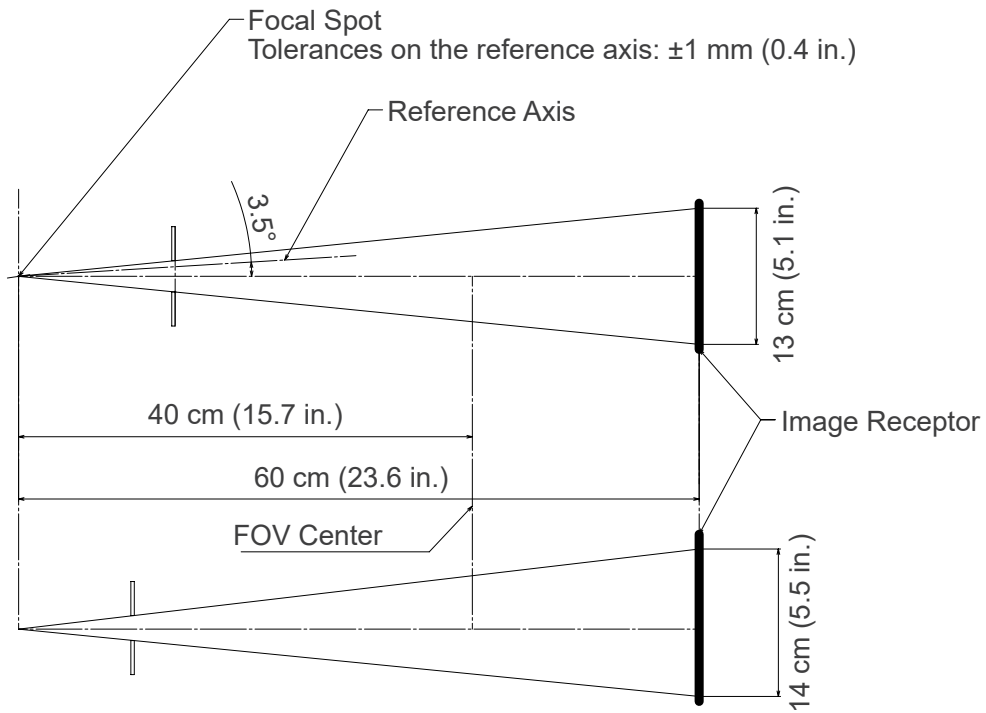
● Hardware

Windows-Based Personal Computer (minimum specifications)	
Operating System	Microsoft Windows 7, 64 bit with Service Pack 2
CPU	Intel® Xeon or higher, or compatible
Memory	RAM minimum 8 GB
HDD	HDD 100 GB or more are recommended
Video Board	Resolution of 1024 × 768 and color depth of 24bit
Network Protocol	TCP/IP with static IP address
Network Interface	Universal 1 G BASE-T Ethernet NIC for internal connection
Others	Network board, DVD drive
Monitor	17 inch TFT LCD 16 Million colors 1024 x 768 pixels or better
Standard	IEC 60950-1, IEC 62368-1, or IEC 60601-1 EMD regulation Related UL standard (addition to U.S.A.) Local regulations
Network Hub	
Specifications	1000BASE-T compatible 5 ports or more Jumbo Frame (Packet) supported
Standard	IEC 60950-1 or IEC 62368-1 if it is used in non patient environment IEC 60601-1 or IEC 60950-1 or IEC 62368-1 with leakage current conformed with IEC 60601-1. EMD regulation Related UL standard (addition to U.S.A.) IEEE802.3x Local regulations
Recommended for example	NETGEAR GS105E
Network Interface Card	
Model	Intel® PRO/1000 GT Desktop Adapter Intel® Gigabit CT Desktop Adapter
Storage Devices	DVD-R disk drive is recommended.
Standard	IEC 60950-1 or IEC 62368-1 if it is used in non patient environment EMD regulation Related UL standard (addition to U.S.A.) Local regulations
Other Equipment Connected to PC	
Standard	IEC 60950-1 or IEC 62368-1 if it is used in non patient environment EMD regulation Related UL standard (addition to U.S.A.) Local regulations
LAN Cable	Unshielded twisted pair cable with RJ-45 plug connections, over Cat. 5e, length less than 2 m.

Application Software: Application software for image processing or database is provided by J. MORITA. MFG. CORP. It shall be used with Windows-based computer specified above.
It conforms to 93/42/EEC (in EU), IEC 62304 and 21 CFR (in U.S.A.).

12.3 Relationship of Focal Spot, X-ray Beam and Image Receptor

■ Ø80 × H80

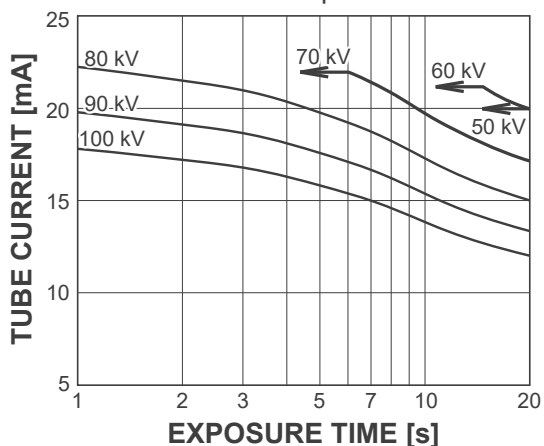


12.4 Tube Rating Chart

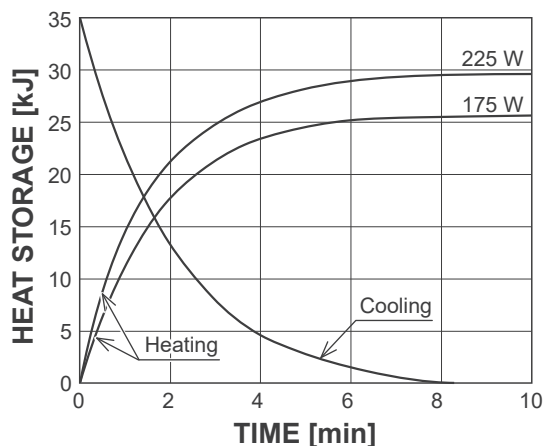
■ D-054SB

● **Maximum Rating Chart**
(absolute maximum rating chart)

Constant Potential High-Voltage Generator
Nominal Focal Spot Value: 0.5



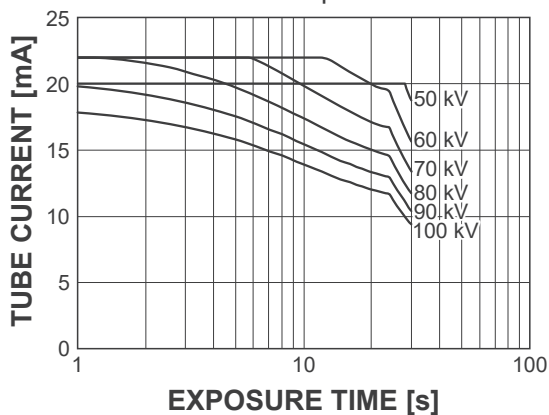
● **Anode Heating / Cooling Curve**



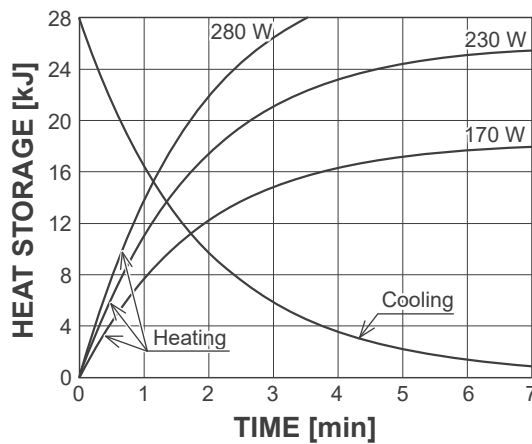
■ D-051SB

● **Maximum Rating Chart**
(absolute maximum rating chart)

Constant Potential High-Voltage Generator
Nominal Focal Spot Value: 0.5

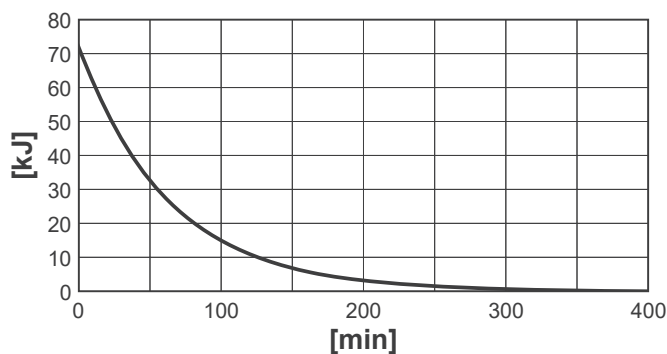


● **Anode Heating / Cooling Curve**



■ Cooling Curve for X-ray Tube Housing

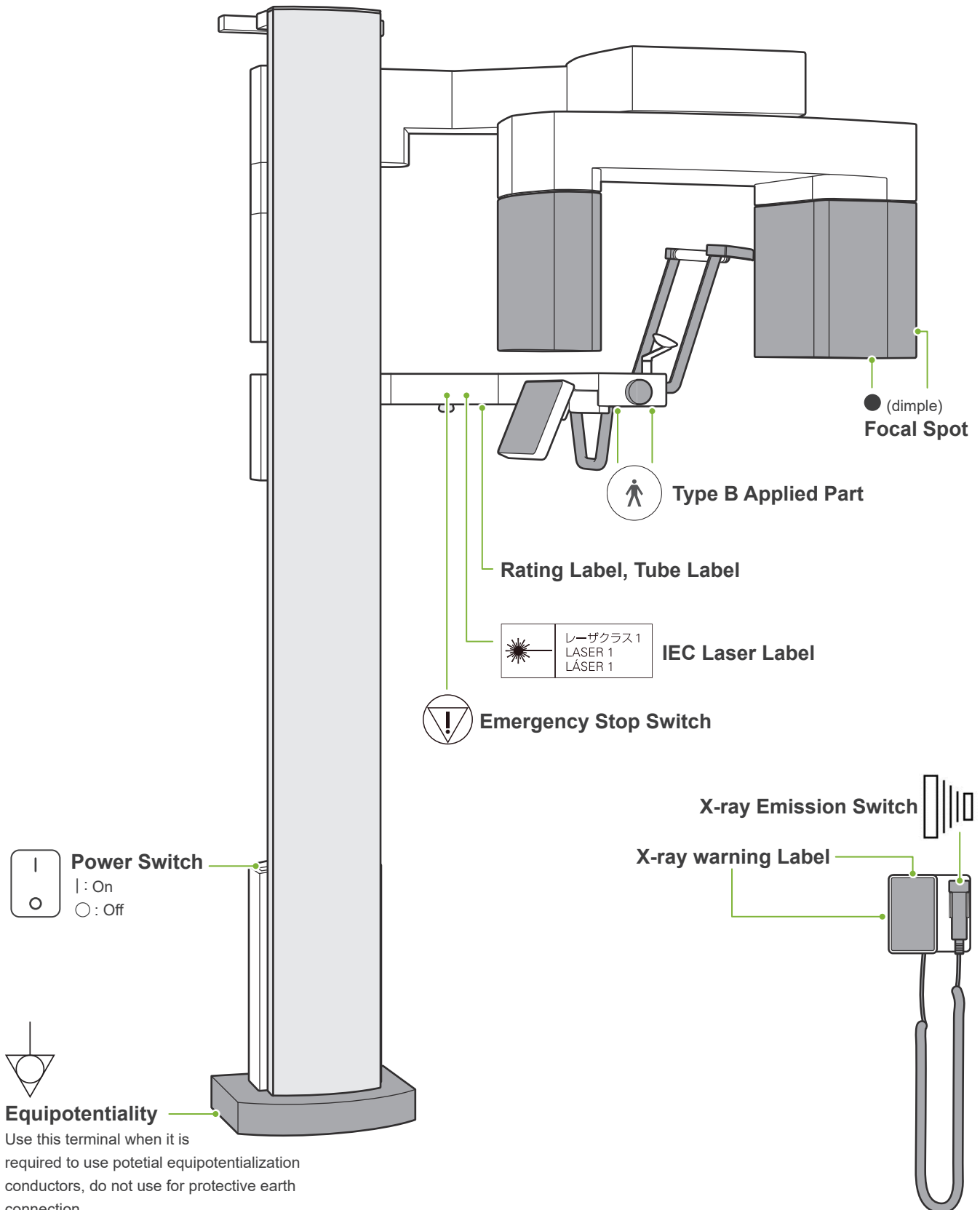
● **Cooling Curve**

















12.5 Symbols and Markings

* Some symbols may not be used.

■ Main Unit and Control Box



Rating Label, Tube Label and Instructions for Use

 Serial number	  (Examples)	Country or region (Country Names: Conforming to the ISO 3166-1 alpha-3 codes)
 Manufacturer	Description noted next to the code is an indication that conforms to the regulations valid only for the relevant country or region.	
 Date of manufactured	 CE(0197) marking (Valid only for EU) Conforms with the European Directive, 93/42/EEC.	
 GS1 DataMatrix	CE marking (Valid only for EU) Conforms with the European Directive, 2011/65/EU.	
 Medical device	 WEEE marking (Valid only for EU) Conforms with the WEEE Directive	
 Unique device identifier	 EU Authorized representative under the European Directive 93/42/EEC (Valid only for EU)	
 Refer to instructions for use	 cTUVus certification mark (Valid only for U.S.A. and Canada)	
 Alternating Current		

Indicated Items on the Rating Label and Tube Labels

* For details, refer to “12.1 Technical Specifications” (p. 78).

Rating Label

X-ray system

Model: Model code

Input: Input voltage, frequency, and power in operation

Duty Cycle: Duty cycle

Tube Voltage: Max. X-ray tube voltage

Tube Current: Max. X-ray tube current

Nom. Focal Spot Value: Nominal focal spot value

Inherent Filtration: Min. inherent filtration

2D barcode at bottom right: Label code

* Some symbols described in this page may be included.

Tube Label

X-ray tube

Model: Model code

Anode : Serial number

: Manufacturer

Tube housing assembly

Model: Model code

: Serial number

: Manufacturer

2D barcode at bottom right: Label code

■ Package



This way up



Keep away from rain



Humidity limit



Fragile



Temperature limit



Atmospheric pressure limit



Do not reuse
(Chinrest Disposable Cover etc.)

Rx Only

Caution: Federal law restricts this device to sale by or the order of a medical doctor, a dentist or a licensed healthcare practitioner. (valid only for U.S.A)

QTY.



Packaging unit



Importer



Distributor



12-3-4-5-6789012

Registration number of medical device in Thailand

(The 12-digit sample number shown is for demonstration purposes only.)

USA

EU

(Exemple)

Country or region

(Country Names: Conforming to the ISO 3166-1 alpha-3 codes and EU for European Union)

Description noted next to the code is an indication that conforms to the regulations valid only for the relevant country or region.

12.6 Standards and Procedures for Disposal of Medical Devices

Any medical devices which could possibly be contaminated must be first decontaminated by the responsible doctor or medical institution and then be disposed of by an agent licensed and qualified to handle standard industrial waste and industrial waste requiring special treatment.



This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact your local dealer or J. MORITA OFFICE for details.

12.7 Description Based on Standards

■ 21 CFR

- **Caution:** Federal law restricts this device to sale by or the order of a medical doctor, a dentist or a licensed healthcare practitioner. (valid only for U.S.A)

■ Collateral and Particular Standards of the IEC 60601-1

- **Test phantoms for dose information:**
Air condition (without any phantoms) for DAP, Air Kerma CTDI phantom, Diameter 160 mm (6.3 in.) in IEC 60601-2-44
- **Dosimeter:** Use the dosimeter calibrated without any phantoms according to the instructions for use of the dosimeter. Some dosimeter may calibrate with phantoms.
- **Specified procedure:** The jaw positioning tools (chinrest etc.) are removed and the temporal stabilizers are closed.
- **Method used to estimate Air Kerma:** A dosimeter (semi-conductor sensor) is put on the front outer cover of the image sensor at the center of the irradiation field. As for the distance conversion, the distance from the dosimeter to the surface of the image receptor must be considered (the distance from the outer cover to the image receptor is 12 mm (0.5 in.)). To measure it with an ionization chamber, the back scatter radiation must be subtracted.
- **Method used to estimate dose area product:** Measured by DAP (Dosage Area Product) meter. The DAP meter is attached to the front of the X-ray head for CBCT. Be careful it does not fall and that its wiring is properly routed.
- **Loading factor affecting to the patient dose:** X-ray tube voltage, X-ray tube current, exposure time, X-ray field (FOV)
- **Loading factor affecting to the radiation quality:** Tube voltage
- **Loading factor affecting to the value of reference air kerma:** Tube voltage, Tube current
- **Highest available air kerma condition:** 100 kV, 10 mA
- **Test instruction of X-ray tube voltage, current and exposure time:** Constant (manual) exposure mode.
- **Test instruction of Current time product:** Multiple X-ray tube current and exposure time.
- **Image processing applied to Original Data:** Raw data send from the equipment is converted to original data for image reconstruction by compensation for dark image offset compensation, sensitivity compensation, saturation compensation, and defective pixel compensation.
- **File transfer format of the images:** The converted original data is saved as a ".tif" file. Also, ancillary information such as dose etc. is save in text format. Reconstruction is performed based on the Original Data and appended information.

13 Electromagnetic Disturbances (EMD)

The Veraview FX800 (Model: FX800, hereafter “this device”) conforms to IEC 60601-1-2 Edition 4.1, the relevant international standard for electromagnetic disturbances (EMD).

Use Environment

The use environment of this device is the Professional healthcare facility environment.

WARNING

- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by us could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the FX800, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- RFID readers and electronic article surveillance (EAS) systems should not be near from any part of the FX800.

Cable List

No.	Name	Cable Length, Shielding	SIP/SOP & In/Out Port Type
1	LAN Cable	2.5 m, Un-shielded	Telecommunication Ports

Compliance for Each EMISSIONS and IMMUNITY Standards


Emissions Test	Compliance	Electromagnetic Environment – Guidance
Conducted disturbance CISPR 11	Group 1 Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radiated disturbance CISPR 11	Group 1 Class B	
Harmonic current IEC 61000-3-2	Class A	
Voltage fluctuations and flicker IEC 61000-3-3	Clause 5	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	<u>AC/DC power</u> ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth <u>Signal input/output</u> ±2 kV line(s) to earth	<u>AC/DC power</u> ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth <u>Signal input/output</u> *1 ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<u>dips</u> 0% U_T : 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T : 1 cycle (at 0°) 70% U_T : 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) <u>short interruptions</u> 0% U_T : 250/300 cycles 250 (50 Hz)/300 (60 Hz)	<u>dips</u> 0% U_T : 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T : 1 cycle (at 0°) 70% U_T : 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) <u>short interruptions</u> 0% U_T : 250/300 cycles 250 (50 Hz)/300 (60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (r.m.s.) 50 Hz or 60 Hz	30 A/m (r.m.s.) 50 Hz or 60 Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	<u>30 kHz</u> CW, 8 A/m <u>134.2 kHz</u> 2.1 kHz, 65 A/m <u>13.56 MHz</u> 50 kHz, 7.5 A/m	<u>30 kHz</u> CW, 8 A/m*2 <u>134.2 kHz</u> 2.1 kHz, 65 A/m*3 <u>13.56 MHz</u> 50 kHz, 7.5 A/m*3	The proximity magnetic field should be at a level characteristic of magnetic fields emitted from RFID, IH (Induction Heating), etc.
NOTE 1: U_T is the a.c. mains voltage prior to application of the test level. NOTE 2: r.m.s.: root mean square			

*1: Not applicable because it does not connect directly to outdoor cable.

*2: This test is not applicable since this device is not intended for use in the HOME HEALTHCARE ENVIRONMENT.

*3: This test is not applicable since this device does not use a circuit that is sensitive to magnetic fields, such as a Hall element or a magnetic resistance element.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 V ISM ^(c) frequency band: 6 V 150 kHz to 80 MHz	3 V ISM ^(c) frequency band: 6 V 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Recommended separation distances $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz $d = \frac{6}{E} \sqrt{P}$ Portable wireless RF communication equipment
	27 V/m 385 MHz	27 V/m 385 MHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the compliance level in V/m and d is the recommended separation distance in meters (m).
	28 V/m 450 MHz	28 V/m 450 MHz	Field strengths from field RF transmitters, as determined by an electromagnetic site survey ^(a) , should be less than the compliance level in each frequency range ^(b) .
	9 V/m 710, 745, 780 MHz	9 V/m 710, 745, 780 MHz	Interference may occur in the vicinity of equipment marked with the following symbol:
	28 V/m 810, 870, 930, MHz	28 V/m 810, 870, 930, MHz	
	28 V/m 1720, 1845, 1970 MHz	28 V/m 1720, 1845, 1970 MHz	
	28 V/m 2450 MHz	28 V/m 2450 MHz	
	9 V/m 5240, 5500, 5785 MHz	9 V/m 5240, 5500, 5785 MHz	
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 predicated 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 this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.			
^(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			
^(c) The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.			

Pass/Fail Criteria on Immunity Test

No X-ray irradiation without an active operation of the Emission switch.

X-ray termination is done by releasing the Emission switch.

No unexpected movement initiated without any active of operation.

NOTE: On fail condition due to electromagnetic disturbance, unexpected movement would be initiated without any active of operation, or X-ray termination would not be done by releasing the Emission switch, or X-ray would be irradiated without an active operation of the Emission switch.



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Diagnostic and Imaging Equipment

Treatment Units

Handpieces and Instruments

Endodontic Systems

Laser Equipment

Laboratory Devices

Educational and Training Systems

Auxiliaries