



Panorama, Cephalo and CT Capabilities

INSTRUCTIONS FOR USE





Thinking ahead. Focused on life.

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This manual covers a fully equipped model; refer to the sections covering the instruments and functions of your own unit.

Thank you for purchasing the Veraviewepocs 2D.

For optimum performance and safety, read this manual thoroughly before using the equipment. Pay special attention to the cautionary warnings and safety statements. Keep this manual in a handy place for ready reference.

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Prevent Accidents

ATTENTION CUSTOMERS

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

To access the warranty information for this product, scan the following QR code and visit our website.



ATTENTION DEALERS

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

SAFETY INSTRUCTIONS AND RECORDING INFORMATION

When the Veraviewepocs 2D 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.

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.

Note the meaning of the following symbols and expressions:



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

Disregarding the information on safety is considered ABNORMAL USE.

Do not use this equipment for anything other than its specified dental treatment purpose.

Caution: Federal law restricts this device to sale by or on the order of a dentist (Valid only for U.S.A.)

INTENDED OPERATOR PROFILE

a) Qualification:

Legally qualified person such as radiologic technician and dentists 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 X-ray devices

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

RELATED DOCUMENTS

· Installation Instructions

THE USEFUL LIFE

- The useful life of the Veraviewepocs 2D 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.

WARNING

- Do not use the wireless transmission devices listed below in the examination area:
 - 1. Mobile terminals 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 Veraviewepocs 2D, devices listed below might malfunction or operate in a random, unexpected and dangerous manner.
 - 1. Electrical diagnostic, examination or treatment devices.
 - 2. Personal computers
- The Veraviewepocs must be installed in an X-ray shield location. Local regulation for radiation protection must be observed.
- The control box and emission button must be installed in a radiation protected area.
- If the Veraviewepocs is not enclosed by an X-ray booth or other protective barrier, everyone except the patient must stay outside the area shown in the illustration during X-ray emission.

The X-ray protection area should consist of a wall, floor and ceiling with a minimum of 1.5 mm lead shielding or its equivalent and should have glass windows with a minimum of 1.5 mm lead shielding or its equivalent, through which the operator can observe the patient. A sign should clearly identify the area as an X-ray protection area, and a caution sign should light up during X-ray emission. Observe local regulations.



- The user must restrict access to the equipment in accordance with local regulations for radiation protection.
- The patient and operator must be provided with appropriate X-ray protection gear such as lead-impregnated clothing that conforms to local regulations.
- Proper infection control procedures must be established and maintained for each patient.
- It is strongly suggested that no unauthorized personnel be in the immediate area when the equipment is in use.
- This unit is not designed for and must not be used for "fluoroscopic examinations".
- 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.
- When an examination requires X-ray irradiation to implantable or wearable electronic medical device, the operator must take proper care after referring to the operation manual (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
 - Title: Interference between CT and Electronic Medical Devices
 - URL: <u>https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm489704.htm</u>
- Judgement and caution should be used in regards to radiographs of pregnant women. The decision should be based on "clinical need of diagnostic information".
- 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.
- Responsible organization in medical institution needs for providing means for audio and visual communication between the operator and the patient.

WARNING

- Watch the area around the moving parts to avoid collision against the body parts or other objects which may result in injury.
- The EQUIPMENT should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the EQUIPMENT should be observed to verify normal operation in the configuration in which it will be used.
- Do not fail to turn the unit off after use; this will eliminate the risk of electrical leakage and accidents.
- The main switch should be turned off during standard maintenance procedures. It is also recommended that the main breaker or fuse on the main electrical distribution panel be turned off as some electricity reaches the main power terminal inside the unit even when the main switch is off.
- Do not use this equipment for patients when it is being maintained or serviced.
- Use special care to explain to the patient proper instructions as to when they can move as there are "multiple movements" with certain exposures.
- Do not press the panel too hard not to damage the panel.
- Make sufficient space around the Main Switch so that it is easily accessible in case of emergency.
- Make sufficient space around the power plug so that it is easily unplugged in case of emergency. (For EX-1)
- Make sufficient space around the power distribution panel so that it is easily to open the breaker in case of emergency. (For EX-2)
- To avoid the risk of electric shock, this equipment must only be connected to the supply mains with protective earth.
- Do not use multiple portable socket outlet nor extension cord for the system power supply.
- Do not touch simultaneously the patient and the conductive parts, such as the connector terminals.

Always try to maintain contact with the patient visually and auditorily to ensure safe operation of the unit.

Parts Identification

(I) Parts Identification

Main Unit



Control box



Patient Frame



Temple Stabilizer Knob

Cephalo Unit (Option)



(II) Patient Frame and Arm Operation Panels

Patient Frame Operation Panel



1. Ready Key

Before the Ready key is pressed, the green LED for it will be blinking on and off. Press the Ready key in order to complete patient positioning. The arm will rotate slightly and the positioning beams will light up. Pressing the Ready key also enables X-ray emission. During image data transmission the LED will go out.

2. Lift Up Key

Hold down to raise the lift.

3. Lift Down Key

Hold down to lower the lift.

4. Image Layer Beam Forward Key

Hold down when unit is in Ready mode to move the beam forward. For panorama, line this beam up with the distal side of the upper, left canine.

5. Image Layer Beam Backward Key

Hold down when unit is in Ready mode to move the beam backward. For panorama, line this beam up with the distal side of the upper, left canine.

6. Beam On/Off Keys

Positioning beams automatically go off after 3 minutes. Press either one of these keys to turn them back on. Or press one of them to turn the beams off.

7. Incisal Occlusion Key

This key is used to make a panorama exposure for a patient with standard occlusion biting on a mouthpiece. After adjusting the height of the positioning (AF) sensor, press this key to automatically move the arm backwards or forwards to the optimum position.

8. Natural Occlusion Key

This key is used to make a panorama exposure for a patient with standard occlusion without using a mouthpiece. After adjusting the height of the positioning (AF) sensor, press this key to automatically move the arm backwards or forwards to the optimum position.

9. Protruding Maxillary Occlusion Key

This key is used to make a panorama exposure for a patient with protruding maxillary without using a mouthpiece. After adjusting the height of the positioning (AF) sensor, press this key to automatically move the arm to the optimum position.

10. Protruding Mandibular Occlusion Key

This key is used to make a panorama exposure for a patient with protruding mandible without using a mouthpiece. After adjusting the height of the positioning (AF) sensor, press this key to automatically move the arm to the optimum position.

11. Frame Liquid Crystal Display (LCD)

Display various information including Ready mode, Image layer beam position, exposure mode, exposure conditions, patient positioning guide etc.

12. Frankfort Plane Beam Up/Down Knob

Turn the knob to the right to lower the beam or to the left to raise the beam. For panorama exposures, lines up with the patient's Frankfort plane.

13. Auto Positioning (AF) Sensor Beam Up/Down Knob

Turn the knob to the right to lower the beam or to the left to raise the beam. Adjust the beam so it strikes the center of the mouthpiece in the patient's mouth.

Arm Operation Panel

Usage Note

• Do not press down with excessive force on any of the operation panels. Do not press on the panels with any sharp objects like ballpoint pens or fingernails etc.



1. Panorama Exposure Keys

Use these keys to make various settings for panorama exposures. The LED for each key lights up when it is selected.

•	- 212-	• • •	ROI	—— Region Keys	:	Dental Arch, Maxillary Sinus, and TMJ
	• <u>R</u>	ૈસ્	Size	—— Size	:	Adult and Child
	×1.3	×1.6	Mag	—— Magnification	:	1.3× and 1.6×
* SD	* A	TA ot	Mode	—— Projections	:	Standard, Shadow Reduction, and Orthoradial

2. Cephalo Exposure Keys

Use these keys to select the type of cephalo exposure, either LA (lateral) or PA (posteroanterior) . Press the auto density compensation key to turn it on and off. The LED for each key lights up when it is selected.



Auto density compensation key, LA (lateral), and PA (posteroanterior)

3. X-ray Emission Keys

Use the X-ray Emission keys (Auto Level, kV, and mA key) and Up/Down keys to set X-ray emission conditions.



4. Auto and Manual Emission Keys

For auto exposures, press Auto Level key and confirm that the corresponding LED lights up. For manual exposures, press kV key or mA key and confirm that the corresponding LED lights up.

5. Up/Down Keys

Press the Up/Down keys to change the value displayed for the kV or mA, whichever is selected. (When the Down key is held down continuously, all displayed values disappear, and the unit is set for the No X-ray mode.)

6. X-ray Emission Display

Shows the Auto Level or the tube voltage (kV) and tube current (mA).

7. Memory Key

Use this key to save the X-ray emission conditions currently set.

8. Exposure Time Display

Shows the expected exposure time before the exposure and the actual time after the exposure.

9. Ready key

Press this key to return the arm its start position. This also enables X-ray emission.

10. Ready LED

When the power switch is turned on, this LED blinks. When the Ready key is pressed, it stops blinking and remains lit continuously.

Cephalo Operation Panel (Only for models with the cephalo unit.)



(III) Parts of Device

• Panorama & Cephalo (PAN/CEPH) Cassette (1) (Only for models with the cephalo unit, or cephalo upgradable models.)

(IV) Patient Positioning Tools and Consumable Parts

- Chin Rest (1)
- Lip-nose Rest (1)
- Mouthpieces (1 Box of 50)
- Bite Block (1)*1
- Bite Block Covers (1 Box of 300)*1
- Hand X-ray Plate (1)^{*2}
- Ear Rods (2)*2
- *1 EX-1 type only.
- *² Only for models with the cephalo unit.



Operation

- * 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, necklaces, earrings and other accessories which could interfere with diagnosis.
- * If the unit has not been used for some time, make sure it operates normally and safely before use.

WARNING

In case of lightning, avoid the risk of electrical shock: Stop using the equipment immediately and have the patient move away from it. Do not touch the equipment or the main power cord.



(I) Preliminary Procedures

Turn the computer on and start the application software to receive the image data read-in.

<For the i-Dixel application>

The i-Dixel application will start up automatically.

Select and display the Patient Page and then make the exposure. (For new patients, first register the patient and then display the new Patient Page.) The exposure will be automatically transmitted to the i-Dixel application.

* For details refer to the user manual for the i-Dixel application.

Turn Main Switch On

Press the top (|) of the main switch. The blue main LED will light up to show that the unit is on.

Do not turn the main switch on if the patient is standing near the unit. The arm will move and it could hit the patient.

Check Resolution

Move the mouse cursor to the resolution icon (2010) on the task tray at the lower right to display the presently selected resolution.

Change Resolution

Click the resolution icon () on the task tray at the lower right to select the resolution.

(Either High resolution or Super high resolution will be marked with a check. To change the resolution, click the one without a check mark.)

- * Fine high-speed mode: High resolution mode
- * Superfine mode: Super high resolution mode











Check Panorama Operation

Insert the PAN/CEPH cassette into the cassette holder and press the Dental Arch key.* Press the Ready key to enable X-ray emission. Hold down the emission button and check that the arm rotates, X-rays are emitted, the X-ray emission LED lights up, and the audible signal sounds. Also check that after the emission time has elapsed, X-ray emission stops and the arm stops rotating.

Press the emission button again to return the arm to its patient entry position.

* Cassette insertion is not required for panorama models.

Check Cephalo Operation

Insert the PAN/CEPH cassette into the cephalo cassette holder and press the LA key on the operation panel.

Completely close the temple stabilizers for panorama exposures by turning the adjustment knob.

Press the Ready key to move the X-ray head and the arm into their Cephalo positions. Check that the Ready LED on the Arm Operation Panel or the control box is on. Hold down the emission button and check that X-rays are emitted, the X-ray emission LED lights up, and the audible signal sounds. Also check that after the emission time has elapsed, X-ray emission stops, the emission LED goes out and the audible emission signal stops.



Usage Note

 The unit cannot be turned on if the Emergency Stop switch has been accidentally pressed during cleaning etc. Turn the switch in the direction indicated by the arrow to release it.

(II) Operation Procedures

Safety Check

For safety, keep fingers away from moving parts when they are moved.

Keep fingers away from gaps and openings for moving parts such as the cassette and its holder and the temple stabilizers as well as the holes on the support column for threaded bolts.









Panorama Exposures

(1) Turn Main Switch On

Make sure that the i-Dixel application is running. Press the top (|) of the main switch. The blue main LED will light up to show that the unit is on.



Do not turn the main switch on if the patient is standing near the unit. The arm will move and it could hit the patient.





Emergency Stop Switch

In case of an emergency, press the Emergency Stop Switch. This will stop the arm's rotation, lift movement and X-ray emission. Do not use this switch for anything. If the Emergency Stop Switch is pressed, the lift will stop within 10 mm and the arm rotation within 15 degrees.

After Pressing the Emergency Switch

Guide the patient away from the unit and turn the main switch off. This will return the unit to a safe condition.

Turn the switch in the direction indicated by the arrow and restart the computer. Then turn the main unit back on and check that it is set for Panorama Exposure. If the unit cannot be returned to a safe condition or will not operate, contact your local dealer or J. MORITA OFFICE.

The image will be lost if the Emergency Stop Switch is pressed during its transmission or if the main switch is turned off.

(2) Cassette Insertion

Insert the PAN/CEPH cassette.

- * This procedure is not required for panorama models since the builtin X-ray detector is used with those models.
- 1. Hold the cassette with handle towards the front. Use the other hand to support the bottom of the cassette and gently slide the cassette into the holder.

2. When the cassette stops, press the button and slide the cassette in slightly more, then release the button.

LED

∱ Holder

Handle

Button



3. Slide the cassette all the way in until the rod goes into its hole inside the holder. The rod will make and audible click and the button will pop out.

A beep will also sound. After a few seconds the green LED on the cassette will start to blink on and off.

Depending on the LAN set up, it may take longer for the LED to start blinking.

Check the following points after inserting the cassette.

- The button on the cassette is popped out and the red ring is visible around the bottom of the button.
- Without pressing the button, give a light tug on the cassette and make sure it does not come out.



Storage Conditions

Temperature: -10°C~50°C Humidity: less than 85% (without condensation) Avoid direct sunlight.

WARNING

- Do not bump, jiggle, vibrate or use excessive force.
- Use both hands to put the cassette in and take it out. The cassette weights about 2 kg, and it could injure your foot if you dropped it. The sensor would also be damaged.
- Do not swing the cassette around. The vibrations could disturb the sensor's adjustment.

• Do not store under conditions of high temperature and humidity.

Storage Temperature; -10°C to +50°C (+14°F to +122°F) Storage humidity: 5% to 85% relative humidity with no condensation.

No frequent or continuous exposure to direct sunlight.

- Do not get water, detergents or chemical solutions on the cassette. These could seep inside and damage it.
- Put the cassette in and take it out with great care. Using excessive force could damage the connection components.
- Clean by wiping with a soft, dry cloth. Do not touch the connection components directly with bare fingers etc. Static electricity could damage the sensor.
- Do not allow dust or other debris to collect on the connection components; this could cause poor contact.
- Slide the cassette all the way into the holder and make sure it is locked into place.
 Otherwise images could be distorted, transmission could be interrupted, or equipment could be damaged.

Turn Main Switch On

Green:

Normal.

Amber On:

For X-ray emission and image transmission.

Red Bllinking:

Abnormal. Transmission malfunction. Cannot make exposure.

Off:

Power is off or cassette is not properly inserted.

Slide the cassette all the way into the holder and make sure it is locked into place.

Otherwise images could be distorted, transmission could be interrupted, or equipment could be damaged.

* Never rotate the arm manually.

Rotating the arm by hand too fast can cause the arm motor to generate an electric current, and this could activate the protection circuit for the motor switching power. This, in turn, would cause the motors to stop working.

If the protective circuit has been activated, turn the unit off. Wait about 1 minute and then turn it back on again. This will deactivate the protective circuit.



4

sec

V



(3) Panorama Settings

When the unit is turned on, the operation panel is set to the factory defaults shown in the photo to the left.

(3)-1. Auto Exposure (Digital Direct Auto Exposure)

For auto exposure, the X-ray dosage is monitored and adjusted in real time depending on the patient's anatomy and the selected exposure region.

Press the Auto Level key to use auto exposure.

Image: Sec

Image: Sec
</tr

()

Chart 1

Auto Level	X-ray Output Ratio			
+4	286 %			
+3	220 %			
+2	169%			
+ 1	130 %			
0	100 %			
- 1	77 %			
-2	59%			
-3	46 %			
-4	35 %			

The current auto level value is shown on the left side of the Auto Level key. This value can be changed. Up and Down keys will also appear to the right; use these to change the settings. Auto level can be adjusted from +4 to -4 in increments of 1.

* The factory setting for the Auto Level is 0.

Chart 1 shows the relative X-ray output for each auto level.

Panorama Exposures

(3)-2. Manual Exposure

Press the kV or mA key to switch to manual exposure.

mΑ

()

7. 3 sec

88



Press the kV key to display the tube voltage value. This value can be changed. Use the Up and Down keys to increase or decrease the value.

Press the mA key to display the tube current value. This value can be changed. Use the Up and Down keys to increase or decrease the value.

kV can be set from 60 to 80 kV in increments of 1 kV, and mA from 1 to 10 mA in increments of 1 mA.

* The factory settings are 65 kV and 5 mA.

(3)-3. No X-ray Setting

Use this to rotate the arm to make sure it will not hit the patient or for other tests which do not require X-ray emission.

To activate No X-ray mode, hold down the Down key until the Auto Level, kV and mA displays go out.

To restore normal operation, hold down the Up key.

WARNING

To use the No X-ray mode, make sure the Auto Level, kV and mA displays are blank.









Selected regions are turned black and will not be exposed.



(3)-4. Partial Panorama

Partial panorama function divides a panoramic image into five areas and only selected areas will be exposed to reduce the X-ray dose.

Right-click the resolution icon in the task tray.

Select "Show DixelD dialog" from the shortcut menu.

* If "Show DixeID dialog" selection is grayed out:



The DixelD Dialog window is already open. It may be covered by another window (i.e., i-Dixel). Minimize other windows to show the DixelD Dialog window.

The DixelD Dialog window appears.

Select areas that you do not want to include in the X-ray. Click the area again to cancel the selection.

* Note that the partial panorama setting is not sent to the unit yet. Be sure to perform the following:

Click OK. A two-toned beep will sound from the unit.

Usage Note

 The setting for the partial panorama function will reset after the exposure. You need to choose the setting from the DixelD Dialog window every time when using this function.





(4) Patient Positioning

Press the Ready key. The arm will automatically move into position for patient positioning.

The green Ready LED will stop blinking and stay on. The Frankfort plane, Mid-sagittal, Image layer and AF beams will light up.

Usage Note

• Before pressing the Ready key, make sure the temple stabilizers are closed all the way.

WARNING

CLASS 2 LASER PRODUCT: A class 2 laser is used for the positioning beams. The laser beams could damage the eyes. Do not stare into the positioning beams. Warn the patient not to look at the positioning beams.

The beams go off automatically after 3 minutes. Press either one of the beam on and off keys to turn them back on again.

* The Image layer beam will not light up if the Ready key has not been pressed.

- Have patients remove glasses, earrings and any other accessories that might interfer with making a good exposure.
- Keep fingers away from gaps and openings for moving parts such as the cassette and its holder and the temple stabilizers as well as the holes on the support column for threaded bolts.
- Do not let patients touch the switches on the Frame Operation Panel.
- Take care that the patient's does not get caught in the cassette or other moving parts.



Chin Rest Positioning

1. <Initial Patient Positioning>

Put an X-ray protection apron on the patient. Have the patient perform the incisal occlusion while biting on an unused mouthpiece. Line up the center of the mouthpiece with the center of the upper and lower incisors.

Have the patient stand in front of the chin rest. Look at him from the side, and have him pull in his chin and straighten his back. Then look from behind and make sure his shoulders and back are straight.

WARNING

A new, uncontaminated mouthpiece must be used for each patient to prevent from cross-contamination.

Do not use anything other than the special mouthpieces provided.

* Keep mouthpieces in a clean, uncontaminated area.



2. Use the Lift Up or Down Key to raise or lower the chin rest and line it up with the patient's chin. Release the key when the chin rest is at the right height.

The Lift has a Slow Start and Slow Stop. It will stop automatically if there is an excessive load on it.

Usage Note

- Always use the Up and Down Keys to move the Lift. Never try to force it; this would damage it.
- The over current protection circuit could be activated after 3 seconds for reasons such as an excessive load or the failure to insert the cassette. The lift will stop and an audible signal will sound. The unit will stop working and one of the following messages will appear in the display on the frame:

LIFT OVERLOAD! PROTECTOR ACTIVE LIFT OVERTIME! PROTECTOR ACTIVE To restore normal working order, press any one of the occlusal type keys underneath the display on the patient frame.

WARNING

Take care that the temple stabilizers do not strike the patient in the eye.

- Do not use excessive force to close the temple stabilizers.
 - This could be uncomfortable for the patient or damage the stabilizers.
- Forcing the patient in or out could also damage the stabilizers.
- 3. Use the knob to open the temple stabilizers. Have the patient move forward without slouching or otherwise changing his posture. Then have him put his chin on the chin rest and lightly grip the patient handles. Make sure his shoulders are lowered.



Chin Rest



4. Close the temple stabilizers until they lightly touch the patient's temples.

 Make sure the patient's face is straight and then line up the Frankfort plane beam with the patient's frankfort plane using the beam Up or Down key.

WARNING

CLASS 2 LASER PRODUCT: A class 2 laser is used for the positioning beams. The laser beams could damage the eyes. Do not stare into the positioning beams. Warn the patient not to look at the positioning beams.





6. Move the patient's head to the left or right until the Mid-sagittal beam lines up with the patient's mid-sagittal plane. Then tighten up the temple stabilizer so that the patient's face will not move.

Line up with center of mouthpiece



AF Sensor Beam Up/ Down Knob

7.

7-1. <Auto Positioning>

Use the Auto Positioning (AF) Sensor Beam Up/Down knob to raise or lower the beam so that it strikes the center of the patient's mouthpiece.

Usage Note

- Make sure the mouthpiece is perpendicular and the beam strikes the center of it. If the beam is off center, the image layer will not be properly detected and the image could be spoiled.
- Condensation on the lens for the AF sensor beam could prevent proper detection of the image layer. Use a soft cloth to wipe condensation off the lens.

Panorama Exposures

R



I Keys other than Incisal Occlusion Press the Incisal Occlusion Key, which is used for auto positioning with the mouthpiece.

The arm (and the Image layer beam) will move to line the image layer up with the patient, and the value of the image layer will be displayed. Check that the Image layer beam is lined up with the distal side of the upper left canine.

There are three types of auto positioning that do not use the mouthpiece.

For these, the AF sensor beam is lined up with the center of the upper incisors.

- * For natural occlusion, press the Natural Occlusion Key
- * For a protruding maxillary, press the Protruding Maxillary Key
- * For a protruding mandible, press the Protruding Mandible Key

In each case, the arm will move to match the image layer with the patient's dentition and the image layer value will be displayed.

Usage Note

- If the mouthpiece is not used, the AF sensor beam may not detect the correct image layer position for edentulous patients, patients with twisted upper incisors, or patients with lustrous crowns or full orthodontic bands. In these cases, use Manual Positioning.
- * If a patient is not standing in place or is out of the range for the arm's back and forth movement (+20 mm to -20 mm), a continuous beeping will indicate an error when a patient type key is pressed.



Image Layer Beam Forward / Backward Key



Mid-sagittal Beam



Frankfort Plane Beam



7-2. < Manual Positioning>

WARNING

CLASS 2 LASER PRODUCT: A class 2 laser is used for the positioning beams. The laser beams could damage the eyes. Do not stare into the positioning beams. Warn the patient not to look at the positioning beams.

 Depending on the shape of the patient's face, the Image layer beam may not directly strike the distal side of the upper left canine. In this case, position the beam so that an imaginary extension of it is lined up properly.

The beam's movement range is normally from +20 mm to -20 mm, but it is less for some types of exposures.

Make sure the Frankfort plane, Mid-sagittal and Image layer beams are lined up properly.



Warn the patient not to move during the X-ray exposure (while the melody is playing). If the patient moves, he could be hit by the arm or the exposure could be a failure.

The base is shaped to accommodate a wheel chair as shown in the illustration to the right.

* However, wheel chairs with a width greater than 480 mm will not fit.



Bite Block Positioning (Option)

- Some part of the bite block will appear in the image.
- 1. Replace the chin rest with the bite block. Put a cover on the bite block.
- Have the patient put on an X-ray protection apron.
 Open the temple stabilizers and have the patient step up to the unit.

WARNING

- A new, uncontaminated bite block cover must be used for each patient to prevent from cross-contamination.
- Take care that the temple stabilizers do not hit the patient in the eye.

Usage Note

- Keep bite block covers in a clean, uncontaminated area.
- 3. Use the Up and Down keys to match the lift with the height of the patient.

Keep fingers away from gaps for moving parts such as the cassette and the temple stabilizers as well as the holes on the support column.

Usage Note

- Always use the Up and Down Keys to move the Lift. Never try to force it; this would damage it.
- The over current protection circuit could be activated after 3 seconds for reasons such as an excessive load or the failure to insert the cassette. The lift will stop and an audible signal will sound. The unit will stop working and one of the following messages will appear in the display on the frame:

LIFT OVERLOAD! PROTECTOR ACTIVE LIFT OVERTIME! PROTECTOR ACTIVE To restore normal working order, press any one of the occlusal type keys underneath the display on the patient frame.



Lift Down key





Frankfort Plane Beam





4. Have the patient stand straight, move forward and lightly take the bite block in his mouth and then set his chin on it. Have him grip the handles and lower his shoulders.

Close the temple stabilizers until they lightly contact the patient's head.

Use the laser beams as described on page 27 and then close the temple stabilizers firmly.

- Do not use excessive force to close the temple stabilizers.
 - This could be uncomfortable for the patient or damage the stabilizers.
- Forcing the patient in or out could also damage the stabilizers.

5. Make sure the patient's face is straight and then line up the Frankfort plane beam with the patient's frankfort plane using the beam Up or Down key.

WARNING

The laser beam could cause eye damage. Do not look directly into it or let it strike you or the patient in the eye.

6. Move the patient's head to the left or right until the Mid-sagittal beam lines up with the patient's mid-sagittal plane. Then tighten up the temple stabilizer so that the patient's face will not move.


7. Use the Backward and Forward keys to line the Image layer beam up with the distal side of the patient's upper, left canine.

WARNING

The laser beam could cause eye damage. Do not look directly into it or let it strike you or the patient in the eye.

Depending on the shape of the patient's face, the Image layer beam may not directly strike the distal side of the upper left canine.
In this case, position the beam so that an imaginary extension of it is lined up properly.

The beam's movement range is normally from +20 mm to -20 mm, but it is less for some types of exposures.

- 8. Make sure the Frankfort plane, Mid-sagittal and Image layer beams are lined up properly.

Warn the patient not to move during the X-ray exposure (while the melody is playing). If the patient moves, he could be hit by the arm or the exposure could be a failure.

Usage Note

- If the patient is not properly positioned the image may not be useful for diagnosis. Refer to the examples below to better understand proper patient positioning.
- 7-3. <Examples of Patient Positioning and Image Results>

Correct Positioning





Patient Looking Down





Patient Looking Up





Patient Looking to the right





Patient Looking to the left









Image-layer Beam too far back







- * The "Double-Ready*1 Function" reduces the length of time that the emission button needs to be held down. Press the Ready key a second time after completing patient positioning in Ready mode; a two-toned beep will sound and the arm will move to its exposure start position. The Ready LED will light up again and the Image layer beam will go out.
- * In Double-Ready^{*1} mode, X-ray emission starts as soon as the emission button is pressed.
- In Double-Ready^{*1} mode, other operation keys and switches are disabled except for the Ready key and Lift keys.
- * In Double-Ready*1 mode, press the Ready key again to return to the patient positioning Ready mode.

Usage Note

- ♦ If the patient moves out of position after the unit is set for Double-Ready^{*1}, press the Ready key again to return the unit to its normal Ready setting and re-position the patient.
 - *1 The Double-Ready function is not enabled by default. To enable the Double-Ready function, contact your local dealer or J. MORITA OFFICE.

(5) Panorama Exposures



1. Make sure the green Ready LED is on; check the arm, patient frame or control box.





2. Pick up the handswitch and hold down the emission button. The arm will start to rotate and X-rays will be emitted.

During X-ray emission, the yellow Emission LED on the control box will light up and an audible signal will sound.

* During X-ray emission, the LED on the cassette will be amber.

Usage Note

 Error number 18 (Err. 18) appears if the computer is not ready.

If this happens, turn off the main switch. When the computer is ready, turn the main switch back on. If the cassette is not in the panorama cassette holder, insert it and press the Ready key on the arm operation panel again.

3. Keep holding the emission button down. X-ray emission and arm rotation will stop, the Emission LED will go out, and the audible signal will stop. Then the arm will go to its patient egress position. This completes the exposure procedure.

Now release the emission button.

The Ready LED will blink and be amber to show that the image is being transmitted. After transmission is completed, the Ready LEDs on the arm and control box will change to green and blink on and off.



MWARNING

- Always leave the X-ray booth, and press the emission button outside of it.
- In case of an emergency, release the emission button; this will completely stop the unit.

- 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.
- Hold the emission button down until the exposure is completed. If you let go of the button during the exposure, the arm will stop and the exposure will be aborted. To make another exposure, first carefully guide the patient away from the X-ray unit and then return the apparatus to its patient entry position. If the X-ray head or the detector is in back of the patient, turn the unit off and then carefully rotate the arm manually before guiding the patient away from the unit. If you perform the Ready procedure before guiding the patient away from the unit, the arm could hit the patient and cause an injury.
- If an error occurs during emission, the arm will stop and the exposure will be aborted. Carefully guide the patient away from the unit. If the X-ray head or the detector is in back of the patient, turn the unit off and then carefully rotate the arm manually before guiding the patient away from the unit. If you perform the Ready procedure before guiding the patient away from the unit, the arm could hit the patient and cause an injury.
- To perform a positioning method other than the Frankfurt plane method, the arm could hit the patient during the exposure if his head has been moved back a little. Pay attention to this point when performing a positioning method. If the patient has a large head, set the unit for "No X-ray", and do a dry run to visually check that there is no chance of the arm hitting the patient.



4. Hang the handswitch back in its holder.



(6) Patient Egress and Image Transmission

1. <Patient Egress>

After the exposure, the arm will automatically go to the patient egress position, 90 degrees.

Open the temple stabilizers all the way up and guide the patient away from the unit. Then close the stabilizers all the way.

WARNING

- Never use excessive force to move the patient away; this could injure the patient or damage the stabilizers.
- Take care that the stabilizers do not strike the patient in the eye.

Take the mouthpiece from the patient and throw it away.



2. Press the Ready key on the arm operation panel or the patient frame to automatically move the arm to the patient entry position. The Ready LEDs on the operation panel and the control box will light up green to show that the unit is ready to make another panorama exposure.

WARNING

- Make sure the patient is clear of the unit before returning the arm to the patient entry position; otherwise it could hit the patient.
- In case of an emergency when the arm is returning to the patient entry position, press the emission button, the Ready key on the operation panel, or the emergency switch to stop it.

If the arm return operation is performed without closing the temple stabilizers or without guiding the patient away from the unit after the exposure, the arm operation panel will display "Err. 42."

If you go ahead and press the Ready key without closing the temple stabilizers or without guiding the patient away from the unit, the arm will rotate to its start position. This can cause the arm to strike the temple stabilizers or the patient. 3. During image transmission, a message will appear in the computer monitor screen.



Then a progress bar will appear while the panorama image is being reconstructed.



The image will appear after a few seconds.



Usage Note

- After image transmission, a two-toned beep will sound and the LED will change to green and start blinking. However, another exposure cannot be made until the image appears in the computer's display.
- During image transmission, pressing the emission button will result in a series of beeps, but X-rays cannot be emitted.



- * Software density compensation is applied to create the optimum image. However, if some areas of the image are exceptionally dark, the density compensation will tend to make the entire image whiter than usual.
- * For an enlarged digital image, there is a junction line that is not visible when the image is displayed initially. However, if the image is magnified, it appears as a fine, horizontal line through the center of the image. This line is where the two CCD sensors come together.



ROI ROI ROI x1.3 x1.6 Mag

Mode

Pan



Pedodontic Panorama



2. Press either the adult or the child key.

For a Pedodontic panorama, the arm's angle of rotation and exposure range are reduced; the X-ray dosage is also reduced by from 10% to 15%.

* The pedodontic panorama is for people who have a small jaw bone. If the jaw bone is too large, the TMJ may not appear in the image.

For the entire jaw to appear in the image, the length of a horizontal line from the center of the incisors to the outer ear orifice should be less than 70 mm.

3. Press either 1.3 or 1.6.

If you select 1.6 × magnification, the image will have about 20 % more information for the dental arch than 1.3 × magnification. However, the TMJ may be cut off.



Enlarged Panorama



4. Select one of the three projections (X-ray beam angles).

Panorama Exposures



Standard Panorama Projection





Shadow Reduction Projection





Orthoradial Projection



a. Standard Panorama Projection

Very good for making measurements for implants etc.

Press the Standard Projection Key.

b. Shadow Reduction Projection

Reduces shadows obscuring the mandibular ramus.

Press the Shadow Reduction Key.

c. Orthoradial Projection

Reduces overlapping of teeth because X-ray beam is at a right angle to the dental arch.

Press the Orthoradial Projection Key.

(7)-2. Maxillary Sinus (posterior) (Mag.: 1.5×, throughout)

[To examine the posterior maxillary sinus or facial injuries.]

Press the Maxillary sinus key.





Maxillary Sinus Panorama





Chin Rest Position

Put the chin rest in the lowest position to make a maxillary sinus exposure.

* If, for children or short people, the AF sensor beam does not strike the mouthpiece even when it is at its lowest setting, set the chinrest at its Medium position.

Low (for maxillary sinus)

Line up the Low Groove (see illustration) with the back of the chin rest holder.

<u>Medium (maxillary sinus for children and short people)</u> Line up the Medium Groove (see illustration) with the back of the chin rest holder.



High (standard panorama)

Line up the High Groove (see illustration) with the back of the chin rest holder.

Usage Note

• Be careful when replacing the chin rest with the lipnose rest; it could break if it is dropped.





(7)-3. TMJ Quadruple (Mag.: 1.3×, throughout)

Press the TMJ key.

Press either the Adult key or the Child key.

Estimated Distance between Joints

Adult	:	100 mm
Child	:	90 mm
Thickness	:	10.5mm
Length	:	54 mm

Select the size best for the patient.



Mag.: 1.3 ×

Four images will appear in the computer display: one each for the mouth open and closed on both sides. The X-ray beam angle is optimum for the average distance between the joints and the average length.

The arm rotates twice to make a complete set of images.



1. Replace the chin rest with the lip-nose rest set at medium height.

Patient Positioning

2. Put an X-ray protection apron on the patient and stand in front of the lip-nose rest. Look at him from the side, and have him pull in his chin and straighten his back. Then look from behind and make sure his shoulders and back are straight.



3. Open the temple stabilizers and use the Up or Down Lift key to raise or lower the lip-nose rest to the right height for the patient. Release the key when the rest is at the right height.

Keep your fingers away from moving parts, gaps between the cassette and its holder and for head stabilization components, and holes in the support column.

Usage Note

- Always use the Up and Down Keys to move the Lift. Never try to force it; this would damage it.
- The over current protection circuit could be activated after 3 seconds for reasons such as an excessive load or the failure to insert the cassette. The lift will stop and an audible signal will sound. The unit will stop working and one of the following messages will appear in the display on the frame:

LIFT OVERLOAD! PROTECTOR ACTIVE LIFT OVERTIME! PROTECTOR ACTIVE To restore normal working order, press any one of the occlusal type keys underneath the display on the patient frame.



Frankfort Plane Beam



Frankfort Plane Beam Up/Down Knob



Image Layer Beam Forward / Backward Keys

4. Use the knob to open the temple stabilizers. Have the patient move forward without slouching or otherwise changing his posture. Then have him put his upper lip on the lip-nose rest and lightly grip the patient handles. Make sure his shoulders are lowered.

MWARNING

Take care that the temple stabilizers do not strike the patient in the eye.

5. Keep the patient's Frankfort plane horizontal and align the beam with the patient's external auditory orifices by turning the Frankfort plane beam Up/Down knob. Then hold his head in place by lightly closing the temple stabilizers.

Have the patient move his head left or right until the Mid-sagittal beam lines up with his mid-sagittal plane. Then tight up the temple stabilizer so that the patient's face will not move.

- 6. Use the Backward and Forward keys to line the Image layer beam up with the patient's ear orifice. (Arm moves from +20 mm to -16 mm.)
- * The image layer is about 12 mm in front of the Image layer beam. Have the patient close his mouth.

WARNING

CLASS 2 LASER PRODUCT: A class 2 laser is used for the positioning beams. The laser beams could damage the eyes. Do not stare into the positioning beams. Warn the patient

not to look at the positioning beams.

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.

- * The "Double-Ready*1 Function" reduces the length of time that the emission button needs to be held down.
- * Press the Ready key a second time after completing patient positioning in Ready mode; a two-toned beep will sound and the arm will move to its exposure start position. The Ready LED will light up again and the Image layer beam will go out.
- * In Double-Ready^{*1} mode, X-ray emission starts as soon as the emission button is pressed.
- * In Double-Ready^{*1} mode, other operation keys and switches are disabled except for the Ready key and Lift keys.
- * In Double-Ready^{*1} mode, press the Ready key again to return to the patient positioning Ready mode.

Usage Note

- If the patient moves out of position after the unit is set for Double-Ready^{*1}, press the Ready key again to return the unit to its normal Ready setting and re-position the patient.
 - *1 The Double-Ready function is not enabled by default. To enable the Double-Ready function, contact your local dealer or J. MORITA OFFICE.

Open and Closed Mouth Exposures

Check that the Ready LED (green) on the patient frame, operation panel, or control box is on.





Open Mouth Exposure (Second Exposure)

- 1. Have the patient open their mouth.
- 2. Pick up the handswitch and hold down the emission button. The arm will start to rotate and exposures will be made of the left and right sides. Release the emission button when the arm stops rotating.

The Ready LED on the control box will go out to show that the exposure procedure has been completed.

WARNING

- Always leave the X-ray booth, and press the emission button outside of it.
- In case of an emergency, release the emission button; this will completely stop the unit.
- 3. Open the temple stabilizers all the way up and guide the patient away from the unit.

Press the Ready key on the patient frame or the arm operation panel.

The arm will go back to the patient entry position.



4. Remove the lip-nose rest and replace it with the chin rest.



Hole Hole and the bottom of the cassette holder.

MWARNING

- Do not bump, jiggle, vibrate or use excessive force.
- Use both hands to put the cassette in and take it out. The cassette weighs about 2 kg, and it could injure your foot if you dropped it. The sensor would also be damaged.
- Do not swing the cassette around. The vibrations could disturb the sensor's adjustment.

- Do not store under conditions of high temperature and humidity.
 - Storage Conditions:Temperature: -10°C to +50°C (+14°F to +122°F).

Relative Humidity: 5% to 85% (without condensation). No frequent or continuous exposure to direct sunlight.

- Do not get water, detergents or chemical solutions on the cassette. These could seep inside and damage it.
- Put the cassette in and take it out with great care. Using excessive force could damage the connection components.
- Clean by wiping with a soft, dry cloth. Do not touch the connection components directly with bare fingers etc. Static electricity could damage the sensor.
- Do not allow dust or other debris to collect on the connection components; this could cause poor contact.





(8) Removing the Digital Cassette

- ^r This procedure is not required for panorama models since the builtin X-ray detector is used with those models.
- * Make sure the green LED on the cassette is either blinking or out.
- 1. Support the cassette holder with one hand and press the release button. Pull the cassette out a little and then release the button.

Usage Note

 Make sure you press the button down far enough; otherwise, the attachment rod may not come all the way out of its hole, and the cassette will not come out.







Cephalo Exposures (option)

(1) Turn Main switch On

1. Press the top (|) of the main switch. The blue main LED will light up to show that the unit is on.

- 2. Press either the LA (Lateral) or PA (posteroanterior) key to set the unit for cephalo exposure.
- 3. Before pressing the Ready key, make sure the temple stabilizers for panorama exposures are completely closed.
- Press the Ready key. The X-ray head will turn to its cephalo direction, and the arm will rotate.

The arm and head automatically go into and lock in their cephalo positions.

Usage Note

 If the temple stabilizers are not closed or the patient has not exited after the exposure, the LCD on the patient frame will display "Err. 42."

Make sure a patient is no longer near the unit, before pressing the Ready key; otherwise he could be hit by the arm.

5. The green Ready LED will light up.

Usage Note

• Do not move the arm manually.

The arm may not be set in the proper cephalo position if it is suddenly moved by hand. This is also true if the arm hits the operator's shoulder or something while it is moving. If the arm is accidentally turned by hand or is touched during movement, press the Dental Arch key. Then press either the LA or PA key once again. After this press the Ready key.

Emergency Stop Switch

In case of an emergency, press the Emergency Stop Switch. This will stop the arm's rotation, lift movement and X-ray emission. Do not use this switch for anything. If the Emergency Stop Switch is pressed, the lift will stop within 10 mm and the arm rotation within 15 degrees.

After Pressing the Emergency Switch

Guide the patient away from the unit and turn the main switch off. This will return the unit to a safe condition.

Turn the switch in the direction indicated by the arrow and restart the computer. Then turn the main unit back on and check that it is set for Panorama Exposure. If the unit cannot be returned to a safe condition or will not operate, contact your local dealer or J. MORITA OFFICE.

The image will be lost if the Emergency Stop Switch is pressed during its transmission or if the main switch is turned off.



(2) Cassette Insertion

- * Insert the PAN/CEPH cassette, used for both panorama and cephalo exposures.
- 1. Press the Cephalo Start Position Key. Both the cassette holder and the secondary slit plate will move forward.





2. Hold the cassette with handle towards the front. Use the other hand to support the bottom of the cassette and gently slide the cassette into the holder.



3. When the cassette stops, press the button and slide the cassette in slightly more, then release the button.





4. Slide the cassette all the way in until the rod goes into its hole inside the holder. The rod will make and audible click and the button will pop out. A beep will also sound. After a few seconds the green LED on the cassette will start to blink on and off.

Check the following points after inserting the cassette.

- The button on the cassette is popped out and the red ring is visible around the bottom of the button.
- Without pressing the button, give a light tug on the cassette and make sure it does not come out.

WARNING

- Do not bump, jiggle, vibrate or use excessive force.
- Use both hands to put the cassette in and take it out. The cassette weighs about 2 kg, and it could injure your foot if you dropped it. The sensor would also be damaged.
- Do not swing the cassette around. The vibrations could disturb the sensor's adjustment.

• Do not store under conditions of high temperature and humidity.

No frequent or continuous exposure to direct sunlight.

- Do not get water, detergents or chemical solutions on the cassette. These could seep inside and damage it.
- Put the cassette in and take it out with great care. Using excessive force could damage the connection components.
- Clean by wiping with a soft, dry cloth. Do not touch the connection components directly with bare fingers etc. Static electricity could damage the sensor.
- Do not allow dust or other debris to collect on the connection components; this could cause poor contact.
- Slide the cassette all the way into the holder and make sure it is locked into place.
 Otherwise images could be distorted, transmission could be interrupted, or equipment could be damaged.

Usage Note

- Never slide the cassette in with excessive force. This could break the lock rod or damage the electrical connection components.
- 5. Press the Patient Entry and Egress Key to move the cassette holder and secondary lit plate all the way back.

Usage Note

 Do not move the cassette holder or the secondary slit plate manually. Suddenly moving these components by hand could cause damage or a malfunction.

Cephalo Exposures





1. Press the LA key.



- Turn the Dens Comp key on to select both the required soft and hard tissues for making cephalo measurements. (Dens Comp: automatic density compensation)
- * When the Dens Comp key is turned on, the arm operation panel will display "90 kV."
- * For children, it may be better to set the tube voltage for 80 kV.
- * Cephalo exposures cannot be made with Auto Exposure.
- * In Cephalo mode, the No X-ray function can be used to check the movement of the cassette holder and the secondary slit plate without emitting X-rays.



(4) Patient Positioning

1. Use the Up or Down key to raise or lower the craniostat match the patient's height. Release the key to stop the craniostat moving.

Usage Note

- The craniostat Up and Down keys will not work if the unit is not set for cephalo and the Ready key has not been pressed to turn the X-ray head in the cephalo direction.
- The over current protection circuit could be activated after 3 seconds for reasons such as an excessive load or the failure to insert the cassette. The craniostat will stop and an audible warning signal will sound. The unit will stop working and one of the following messages will appear in the display on the frame:

LIFT OVERLOAD! PROTECTOR ACTIVE LIFT OVERTIME! PROTECTOR ACTIVE To restore normal working order, press any one of the occlusal type keys underneath the display on the patient frame.

 Always use the Up and Down Keys to move the craniostat. Never try to force it; this would damage it.

Keep your fingers away from moving parts, gaps between the cassette and its holder and craniostat components, and holes in the support column.

Craniostat



Nasion Plate

2. Grip the base of the ear rod plates and rotate the craniostat to its Lateral position.

The nasion plate must be at the front; a proper exposure cannot be made if it is reversed.

Usage Note

- Rotate the craniostat with the nasion plate is down and inside.
 - *Turning the craniostat roughly could cause it to hit the cassette holder and damage it.*
- To move the nasion plate, grip the base of its arm. Otherwise this could be damaged.



3. Grip the ear rod plates with both hands and open them up all the way.



4. Make it easy for the patient to take his place by raising the nasion plate and moving it out.

5. Put the ear rods on their studs.



- 6. Have the patient put on an X-ray protection apron and stand directly underneath the craniostat.



7. With the Up or Down key, raise or lower the craniostat until the ear rods line up with the patient's outer ear orifice and then release the key.



8. Grip the ear rod plates with both hands and carefully close them until the ear rods go into the patient's ears.

MWARNING

Be extremely careful when inserting the ear rods and do not move the craniostat after they have been inserted. This could seriously injure the patient.

Nasion Plate

Frankfort Plane Beam

9. Use the key for the Frankfort Plane Beam to line it up with the patient's Frankfort Plane and make sure that it is perpendicular to the patient's mid-sagittal plane.

Adjust the length of the nasion plate and put it against the patient's nasion.

WARNING

CLASS 2 LASER PRODUCT: A class 2 laser is used for the positioning beams. The laser beams could damage the eyes. Do not stare into the positioning beams. Warn the patient not to look at the positioning beams.



10. After making sure the mid-sagittal and Frankfort plane beams are lined up and the ear rods are in place, press the Start Position Key.



11. The cassette holder and secondary slit plate will move into their starting positions.

- 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.
- Make the cassette holder or the secondary slit plate will not hit the patient's shoulder.



(5) X-ray emission

- 8.8. sec 9.8 ۲ $\langle \rangle$ • () Ready Ready LED





2. Pick up the handswitch and hold down the emission button. After a few seconds the secondary slit and cassette holder will start to move and X-rays will be emitted.

1. Check the arm operation panel, patient frame or control box, and

make sure the green Ready LED is on.

During X-ray emission, the yellow Emission LED on the control box will light up and an audible signal will sound.

* During X-ray emission the LED on the cassette will light up and be amber.



3. Keep holding the emission button down. When the exposure is finished, the cassette holder and secondary slit plate will stop moving and X-ray emission will also stop. The Emission LED will go out, and the audible signal will stop.

Now release the emission button.

The Ready LED will blink and be amber to show that the image is being transmitted. After transmission is completed, the Ready LEDs on the arm and control box will change to green and blink on and off.

WARNING

- Always leave the X-ray booth, and press the emission button outside of it.
- In case of an emergency, release the emission button; this will completely stop the unit.

- 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.
- Hold the emission button down until the entire procedure is completed; releasing the button will terminate the exposure procedure.
- If an exposure has been terminated before completion, guide the patient away from the unit. Check that the LED on the cassette is green and blinking, Then press the Ready key to move the arm into the patient entry position. Repeat the patient positioning and then make the exposure.
- 4. Hang the handswitch back in its holder.
- * Hanging a mirror on the wall where the patient can see it helps to keep the patient from moving during X-ray emission.





(6) Patient Egress and Image Transmission

1. Use both hands to carefully open the ear rod plates and get the ear rods out of the patient's ears.

MWARNING

Open the ear rod plates very carefully and make sure the ear rods are well clear of the patient's ears; otherwise the patient could be injured.

2. Pull the nasion plate out and then raise it up, the guide the patient away from the unit.





 During image transmission the LED on the cassette will light up amber. After transmission is completed, it will change to green and start blinking.

("Transferring image!" will appear in the computer display, and after about 30 seconds the image will appear.)

During image transmission the LED on the cassette will light up amber. After transmission is completed, it will change to green and start blinking.

Do not do any of the following things until this LED has changed to green and starts blinking:

- 1. Do not turn off the main switch
- 2. Do not take the cassette out of its holder

Any of the above actions will cause the image to be lost and the computer to freeze.

Usage Note

- After image transmission, a two-toned beep will sound and the LED will change to green and start blinking. However, another exposure cannot be made until the image appears in the computer's display.
- During image transmission, pressing the emission button will result in a series of beeps, but X-rays cannot be emitted.



- * Software density compensation is applied to create the optimum image. However, if some areas of the image are exceptionally dark, the density compensation will tend to make the entire image whiter than usual.
- * For an enlarged digital image, there are junction lines that are not visible when the image is displayed initially. However, if the image is magnified, they appear as fine, horizontal lines dividing the image in thirds. These lines are where the three CCD sensors come together.



 * There are seven, one-millimeter steel balls lined up in the center of the nasion plate at intervals of five millimeters.
These balls can be used to estimate lengths when, for instance, using analysis software.

(7) PA (posteroanterior) Exposure

1. Press the PA key.

- Dens Comp
- Dens Comp
- 2. Turn the Dens Comp key on to select both the required soft and hard tissues for making cephalo measurements.(Dens Comp: automatic density compensation)(Soft tissues will not be selected if the Dens Comp key is turned off.)
- * When the Dens Comp key is turned on, the arm operation panel will display "90 kV."
- * Cephalo exposures cannot be made with Auto Exposure.

Patient Positioning

Turn the craniostat into the PA exposure position.

 Otherwise, positioning, X-ray emission, patient egress are all the same as for the LA exposure.
However, the nasion plate should be raised up.





45 Degree Slant Exposure

Set the craniostat at a 45 degree angle to either the right or left. Set the unit for a PA Exposure.

Hand Exposure

1. Select PA Exposure.



 $\left\{ \right\}$

Mode

Ceph

2. Turn the Density Compensation off.





- * 90 kV and 1 mA are rough estimates for a child, but mA can be adjusted depending on the patient's size.
- * Cephalo exposures cannot be made with Auto Exposure.



 Set the craniostat in the PA Exposure position. Raise the nasion plate up.
Open the ear rod plates all the way.





6. Have the patient place his hand inside the rectangle on the Hand X-ray Plate.

ACAUTION

- Make sure nothing other than the patient's hand is inside the rectangle on the Hand X-ray Plate.
- Do not fail to take the Hand X-ray Plate off after completing the exposure. Otherwise, the next cephalo exposure made could be ruined.
- * The X-ray emission procedure is the same as that for cephalo exposures.
- * Remove the Hand X-ray Plate after completing the exposure.





- * Make sure the green LED on the cassette is either blinking or out.
- 1. Support the cassette holder with one hand and press the release button. Pull the cassette out a little and then release the button.

Usage Note

 Make sure you press the button down far enough; otherwise, the attachment rod may not come all the way out of its hole, and the cassette will not come out.



2. Hold the cassette with both hands and carefully slide it out along the rail on the bottom of the cassette holder.

WARNING

- Do not bump, jiggle, vibrate or use excessive force.
- Use both hands to put the cassette in and take it out. The cassette weighs about 2 kg, and it could injure your foot if you dropped it. The sensor would also be damaged.
- Do not swing the cassette around. The vibrations could disturb the sensor's adjustment.

• Do not store under conditions of high temperature and humidity.

Storage Conditions: Temperature: -10°C to +50°C (+14°F to +122°F).

Relative Humidity: 5% to 85% (without condensation). No frequent or continuous exposure to direct sunlight.

- Do not get water, detergents or chemical solutions on the cassette. These could seep inside and damage it.
- Put the cassette in and take it out with great care. Using excessive force could damage the connection components.
- Clean by wiping with a soft, dry cloth. Do not touch the connection components directly with bare fingers etc. Static electricity could damage the sensor.
- Do not allow dust or other debris to collect on the connection components; this could cause poor contact.
Calibrating Digital Cephalo Data for Software Analysis

Digital cephalo data must be calibrated for whatever analysis software you are using.

Measurements will not be correct if the data is not calibrated.

- * Cephalo image data has a resolution of 176 dpi.
- * Refer to the user's manual for your analysis software for instruction on how to calibrate the data.

Calibration Data

* A CD disk with the calibration data is provided. It is titled "Chart(176 dpi).jpg"

How to Use the Calibration Data

- Import the data into your analysis software.
- Refer to the user's guide for your analysis software to perform the calibration.
 - * The distance from the center of one cross to the next in the data image is 27.5 mm. Therefore, the total distance of 4 crosses is 110 mm.
- Based on the above distances, select calibration points and check the distance between them.
 For example, calibrate the software so that the distance from one cross to the fourth cross away from it is 110 mm.
 - * Keep the calibration data in a handy, safe place. We recommend that you copy the data onto your hard drive in a folder named "C:\Program Files\3dxcom"



CD Provided



Chart(176 dpi).jpg



(III) After Use

Turn Main switch Off

Press the bottom (\circ) of the main switch to turn it off. The main LED will go out.



Do not fail to turn the unit off after use; this will eliminate the risk of electrical leakage and accidents.



Maintenance, Parts Replacements, and Storage

(I) Regular Maintenance

• Disinfect the Temple Stabilizers, Ear Rods, the Chin Rest, the Bite Block, the Nasion Plate, the Hand X-ray Plate, the Lip-nose Rest and the Patient Handles after each patient by wiping them with ethanol (70 vol% to 80 vol%).

If it is not possible to obtain ethanol (70 vol% to 80 vol%), 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 quick disinfectant
- DÜRR DENTAL's FD 360 imitation leather cleaning and care
- DÜRR DENTAL's FD 366 sensitive Rapid disinfection
- Wipe cassettes carefully with a soft dry cloth. (Do not directly touch the connection area or components.)
- Wipe the operation panel with ethanol (70 vol% to 80 vol%).
- Every 6 months, inspect and grease the wire cables for the lift.

WARNING

Always turn the main switch off before performing maintenance. This will eliminate the risk of shocks, burns, and accidental switch operation which could result in an injury.

Usage Note

- Use only ethanol (70 vol% to 80 vol%) or a neutral detergent to clean outer surfaces. Never use alkaline or acidic solutions, cresol soap, or other chemical solutions; this could cause discoloration or degrade the materials.
- Dampen a soft cloth with ethanol (70 vol% to 80 vol%) or a neutral detergent, and wring it out thoroughly. Make sure no liquid seeps inside; this could cause mechanical or other malfunctions.
- Do not directly apply neutral detergent or other chemical solutions, or put adhesive tape on the base cover; this could cause discoloration or degrade the materials.
- Use ethanol (70 vol% to 80 vol%) to immediately wipe off any water, detergent or other chemicals that get on the outer surfaces.
- Do not directly spray ethanol (70 vol% to 80 vol%), neutral detergent or water on the unit. Make sure no liquid seeps inside; this could cause mechanical or other malfunctions.
- Do not use ozone water to clean the unit. Ozone water could damage to the unit.
- Do not disinfect the clinic with ozone gas or ultraviolet light. This could damage plastic and rubber components.
- Do not get the main unit or any of the cassettes wet; this could damage them.
- When cleaning, never pull on any cables or cords.

(II) Replacement Parts

- Replace the parts listed in the Regular Inspection List as necessary depending on degree of wear and length of use. For details, see page 75 "Service Life, Consumables, and Replacement Parts".
- Order replacement parts from your local dealer or J. MORITA OFFICE.

(III) Storage

- · No frequent or continuous exposure to direct sunlight.
- Keep the mouthpieces and the bite block covers in a clean, uncontaminated area.
- Store the cassettes where they will not get wet and where no chemicals will be spilled on them.
- If the unit has not been used for some time, make sure it works properly before using it again.

Regular Inspection

- Maintenance and inspection are generally consider to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out these duties, they may be performed by the accedited service personnel. Contact your local dealer or J. MORITA OFFICE for details.
- This unit should be inspected for all the items in the following list once a year.
- At the start and end of each business day, make sure that switching the main switch to ON and OFF turns the equipment on or off without fail.
- The inspection items marked * may only be performed by the service personnel for furether preventive inspection and maintenance during the life of the device.
- For repair or other types of service contanct your local dealer or J. MORITA OFFICE.

Regular Inspection List

Power Supply and Physical Stability

- 1. Power Supply Voltage
 - * Use a digital or analog tester to measure the unit's power supply. The result must be 120 V AC \pm 10 % for EX-1, and 220/230/240 V AC \pm 10 % for EX-2.
- 2. Ground connection

Visually inspection the ground connection to make sure it is securely and properly connected.

3. Floor and base securing bolts

Visually inspect the floor and base securing bolts. Check that the floor is level and make sure the base bolts have not loosened up.

4. Bolt and screw tightness

Inspect all the bolts and screws on the unit. Make sure that all bolts are in place and properly secured.

5. Electrical circuitry

Make sure all wiring and connections are intact. * Inspection of the wiring inside the enclosures may only be done by the accredited service personnel.

6. LAN cables

Make sure no cables are bent or pinched and that they are all securely connected

7. Outer appearance and labels

Make sure outer covers and panels etc are not damaged, cracked, loose or dirty. Make sure labels for rating, tube, and lasers are all properly in place and securely attached.

8. Main switch

Turn the main switch on and off and make sure the main LED on the control box lights up.

9. Emergency Stop Switch

Turn on the main switch and then press the emergency stop switch. Check that the power goes off. (Main LED on the control box goes out.)

10. Patient Auto Positioning (AF)

Put a test object in place. Press the patient type keys and make sure the arm moves forward or backward. Repeat this test 3 times with the test object in a different position each time. Make sure auto positioning sensor moves up and down smoothly.

11. Light Beams

Make sure the Mid-sagittal, Frankfort plane and Image layer beams light up and can be turned on and off. Also make sure that the Mid-sagittal, Frankfort plane and Image layer beams move smoothly.

12. Patient Handles

Make sure handles are tight and properly secured.

13. Temple stabilizers and chinrest

Turn the temple stabilizer knob to make sure the stabilizers open and close properly. Make sure the chinrest and lipnose rest are secure in both their upper and lower positions.

14. Lift Mechanism

Press the up and down keys.

Make sure the lift moves smoothly and stops properly. Repeat this 3 times.

15. Wire Cables

Check the wire cables for broken strands. Make sure the ends are properly secured. Grease the cables with the grease provided by the manufacturer.

16. Operation panel and display

Press all the keys on the operation panel and display and make sure they work. Press all the keys on the patient frame and make sure they work. Make sure the LED on the control box lights up when the Ready key is pressed.

17. X-ray Emission and Display

Make sure the Emission LED (yellow) on the control box lights up during X-ray emission and that the audible signal sounds.

18. Digital Cassette

Press the lock button and make sure the lock pin moves smoothly. Repeat 3 times.

19. Digital Cassette

Visually inspect connector. Make sure it is not cracked and that the pins are not bent.

20. Oil Leak

Check for the oil leak, if the insulation oil filled in the tube head assembly in X-ray Head from the outside of the enclosure. * Oil leak check from the tube head assembly inside the enclosure may only be done by the accredited service personnel.

Panorama Exposures

1. X-ray emission and image read-in

Make an X-ray exposure of a test piece and check the resulting image in the computer monitor.

2. Arm Rotation

Hold down the emission button to rotate the arm. Make sure it does not make an abnormal noise or slip and that it stops at the specified point.

3. Arm Emergency Stop

Make sure the arms stops when the emission button is released and when the emergency stop switch is pressed.

4. DDAE Verification

Cephalo Exposure

1. X-ray Head changeover

Close the panorama temple stabilizers. Press either LA or PA cephalo and then the Ready key. Make sure the X-ray head turns around and that it and the arm automatically go into their cephalo positions. Make the above operation is not performed when the panorama temple stabilizers are open even if the cephalo and Ready keys are pressed. Repeat each procedure 3 times.

2. X-ray emission and image read-in

Make an X-ray exposure of a test piece and check the resulting image in the computer monitor.

3. Craniostat Movement

Move the craniostat up and down with the up and down keys. Make sure it moves smoothly and stops accurately. Repeat 3 times.

4. Cassette Holder and Secondary Slit

Press the Start Position key and the patient Entrance and Egress key and make sure the cassette holder and secondary slit move smoothly and stop accurately. Repeat 3 times.

5. Craniostat

Grip the ear rod plates at their base with both hands and make sure they open and close smoothly and go securely into position.

Grip the nasion retainer at the base and make sure it moves to the left and right and up and down smoothly and goes securely into position.

6. Light Beam

Make sure the Frankfort plane cephalo light beam can be turned on and off with its switch.

7. Cephalo Emergency Stop

Release the emission button while the cassette holder and secondary slit are moving and make sure they stop.

Service Life, Consumables, and Replacement Parts

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 refer 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 service life. However, if a maintenance contract has been agreed to, this will depend on the contents of that contract. For details concerning regular inspection and parts replacements, contact your local dealer or J. MORITA OFFICE.

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 *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	
Patient Handles	6 years	Yes	
Temple Stabilizers	3 years	N/A	
Ear Rod Plates	3 years	N/A	
Nasion Plate	3 years	N/A	

Component Service Life List

*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 X-ray detector 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 regular inspections, but partial sensitivity degradation cannot always be corrected.

Consumable Parts

Components	Code No.	Exchange Frequency	Critical Safety Component	Remarks
Mouth Pieces (100)	6270750	Single use	Yes	For infection control
Bite Block Cover	6211120	Single use	Yes	For infection control
Chin Rest (RAL)	6213900	1 year or whenever scratched or damaged.	N/A	
Lip-nose Rest (RAL)	6213901	1 year or whenever scratched or damaged.	N/A	
Bite Block (RAL)	6213903	1 year or whenever scratched or damaged.	N/A	
Bite Block Assembly (RAL)	6213902	1 year or whenever scratched or damaged.	N/A	
Ear Rod	6290325	1 year or whenever scratched or damaged.	N/A	
Hand X-ray Plate (RAL)	6292400	1 year or whenever scratched or damaged.	N/A	
X550 2D/3D 3-piece Copper Filter (RAL)	6331001	Whenever scratched or damaged.	N/A	

Replacement Parts

Туре	Code No.	Description	Rating	Туре	Qu.
EX-1	6112442	Main Fuse	F25A 250V	Fast-acting, High Breaking Capacity Size: 0.25 × 1.25 inches	1
EX-2	6112473	Main Fuse	F12.5A 250F	Fast-acting, High Breaking Capacity Size: 5 × 20 mm	1

Fuse shall be replaced by qualified person. The user should never replace the fuse himself.

Some portion remains "live" even if the main switch is turned off. Be sure to turn off the circuit breaker for EX-2 or unplug the power supply cord for EX-1 before servicing to avoid electrical shock.

Service

The Veraviewepocs 2D may be repaired and serviced by:

- The technicians of J. MORITA's subsidiaries all over the world.
- 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.

Trouble shooting

If the equipment operation does not seem to be normal, check or adjust the following before requesting a repair service.

- If the equipment does not operate properly after the inspection, adjustment, or parts replacement or if you cannot perform the inspection yourself, 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 conducting the inspection or adjustment, confirm that the Main LED (blue) on the control box is lit.
- Contact your local dealer or J. MORITA OFFICE for repairs if the apparatus does not work normally even after performing the steps recommended below.

Main Unit			
Problem	Possible Cause	Remedy	
	No power supply	Check the breaker on the distribution panel.	
No power when main switch is turned on.	Emergency Switch has been pressed.	Release emergency switch and turn on main switch.	
	Some function or process is in progress	Wait a while. If normal operation is not restored, turned the unit off, wait 1 minute, and then turn it on again.	
Switches don't work Arm doesn't go to starting		* In the Double-Ready*1 mode, other operation keys are disabled except for the Ready key. Press the Ready key.	
		*1 The Double-Ready function is not enabled by default. To enable the Double-Ready function, contact your local dealer or J. MORITA OFFICE.	

Computer Screen and Arm Display			
Problem	Possible Cause	Remedy	
Warning Messages	LAN cable transmission problem		
In computer screen for CT images	* LAN cable is not properly connected.	Reconnect and confirm LAN cable connection. Restart i-Dixel application.	
Video capture failed.			
(for CT exposure)			
In X-ray unit Arm Display The computer is not receiving the image. X-ray is terminated.			
If either of the following error messages appear in the i-Dixel computer screen DixelD X Could not allocate memory. Restart the application software and the X-ray equipment.	This happens when the computer runs out of memory due to repeated exposures and image reconstruction.	Restart i-Dixel application	
Reconstructor Unable to proceed with calculation due to lack of memory resources. Please restart the application. CMemoryException' occured in FilteredBackprojection. OK			
 * If the above error messages appear the following message may appear in the Arm Display: Computer is not ready to capture images. 			

Computer Screen and Arm Display			
Problem	Possible Cause	Remedy	
Warning Messages In computer screen I-VIEW Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is not selected. Image: The capturing is stopped because a patient is	Exposure was initiated without selecting a patient page.	 Close the message in the computer monitor and select a patient page. Press the Ready key and then repeat the Ready procedure (press Ready key or emission button) Make the exposure 	
Warning Messages In computer screen In Computer screen Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capturing is stopped because the application is in operation. Image: State of the capture of the	Initiated exposure when software was not capable of processing a new exposure * i-Dixel message	 Close the message in the computer monitor Press the Ready key and then repeat the Ready procedure (press Ready key or emission button) Make the exposure 	

Exposures and Main Unit			
Problem	Possible Cause	Remedy	
 Panorama & Cephalo Image too light Line in image Large white border Partial image Completely black 	 * Noise Interference * Short, temporary power 	Turn unit off. Make sure of patient and user safety. Turn unit back on and see if it works normally. Make sure that the power supply is AC 108 to 132 V (Including line voltage regulation) with at least 20 A capacity for EX-1, AC 220/230/240 V, 16 A for EX-2 and that the unit is properly grounded. Do not use devices which might produce noise during an exposure.	
 Unit spontaneously goes back to same condition as when it was turned on at first. Or switches will not work at all 	cut	Turn unit off. Make sure of patient and user safety. Turn unit back on and see if it works normally. Make sure that the power supply is AC 108 to 132 V (Including line voltage regulation) with at least 20 A capacity for EX-1, AC 220/230/240 V, 16 A for EX-2 and that the unit is properly grounded.	
Panorama & Cephalo Image has strobe effect	Metal prosthetics can cause excessive feedback in the Auto Exposure system and produce a strobe effect. (AE Strobe)	Check by making exposure without using AE	
Incisor area is blurred	Poor patient positioning	Review patient positioning procedures. Patient may have moved after auto positioning was completed.	
center of panorama image is white and left side is contracted.		lined up with the upper left canine	
Inconsistent density	Application setting	Configure application with tool bar	
Uneven image density	i-Dixel application setting	Adjust density with i-Dixel tool bar settings	
Extremely dark areas or entire image is too white	Poor exposure condition settings	Adjust Auto Level or manual kV and mA settings	

Exposures and Main Unit			
Problem	Possible Cause	Remedy	
 LCD goes out. Weird characters in LCD Error message in LCD LCD color is abnormal Unit spontaneously goes back to same condition as when it was turned on at first. Switches will not work at all 	Build up of static electricity	Turn unit off. Make sure of patient and user safety. Turn unit back on and see if it works normally. Make sure ground is properly connected. Maintain room temperature.	
Message in arm display LIFT OVERLOAD	Patient is leaning or pulling on frame	Have patient relax and not lean or pull on the frame.	

Message Numbers

Messages appear in the Arm Display when anomalies are detected. Respond according to the error message number as explained in the following chart. If this does not solve the problem, contact your local dealer or J. MORITA OFFICE. Make a note of the error number and report it when requesting help for the company.

Message No.	Possible Cause	Remedy
00	Overcurrent protection for the low-voltage circuit is activated.	Turn off, wait 1 minute, turn back on
01	Short pin is not installed on DCN12 of the CPU1board.	Contact your local dealer or J. MORITA OFFICE.
02	X-ray head overheat! Leave the unit at least 30 minutes to cool down.	Wait at least 30 minutes for the unit to cool down. Overheating is due to excessively frequent X-ray emission. This will eventually degrade the tube performance and should be avoided.
03	X Axis of the Arm did not return to its original position in specified time.	Press Ready key and put unit into Ready mode
04	Y Axis of the Arm did not return to its original position in specified time.	Press Ready key and put unit into Ready mode
05	Arm did not return to its original position in specified time.	Press Ready key and put unit into Ready mode
07	AF Beam did not return to its original positioning specified time.	Press Ready key and put unit into Ready mode
08	Horizontal slit did not return to its original position in specified time.	Turn off, wait 1 minute, turn back on
09	X-ray Head did not return to its original angle in specified time.	Turn off, wait 5 seconds, turn back on
C1	No communication with the host computer.	Error C1 occurs when there is no response from the application software. Make sure that the computer and the HUB are turned on and that the application is running. Then turn the X-ray unit off and back on again.
C2	Transmission speed of the HUB doesn't match.	Remove the cassette, press Ready key to reset the error, and then reinsert the cassette. Check connections between HUB and main X-ray unit.
C3	No response from HUB.	Check connections between HUB and main X-ray unit.

Message No.	Possible Cause	Remedy
C4	No response from PC.	Check connections between HUB and computer. Make sure computer is turned on.
C6	Application software is not running.	Make sure application software is running.
C7	The network interface card in the computer does not support jumbo frames.	Change the setting of the network interface card to support jumbo frames.
C0	No response from the application software.	Restart application software.
10	The Cephalo mechanism is not moving.	Do exposure over again
11	The positioning is not correct for the selected imaging mode.	Check exposure mode and patient direction, LA or PA
15	 AF function is not available in the Double-Ready*1 mode or during another operation. *1 The Double-Ready function is not enabled by default. To enable the Double-Ready function, contact your local dealer or J. MORITA OFFICE. 	Adjust the AF only when the unit is in Ready condition and not moving.
16	No response from the patient positioning unit and cephalo-unit. Patient positioning is not available but image capture may be possible.	Turn the unit off, wait about one minute and then turn it back on.
18	Computer is not ready to capture images.	Make sure application is running. Check for error messages. Check LAN cable connections.
19	Error in the patient positioning unit and cephalo-unit. Patient positioning operation is suspended for safety.	Guide the patient away from the unit. Turn the unit off, wait about one minute and then turn it back on.
22	No analog power given to the imaging module.	Contact your local dealer or J. MORITA OFFICE.
23	HOLIZONTAL BEAM did not return to its original	Press Ready key again to put unit into Ready mode
26	Right & left beam did not return to its original position in specified time.	Press Ready key again to put unit into Ready mode
27	Cephalo slit did not return to its original position in specified time.	Press Ready key again to put unit into Ready mode
29	Cephalo imaging module did not return to its original position in specified time.	Press Ready key again to put unit into Ready mode
30	Cannot establish communication with the driver software. The application software may not be ready, or busy in processing data.	Start the application software if it is not already running. Wait for the computer to finish if it is busy reconstructing an image or some other processing procedure.

Message No.	Possible Cause	Remedy
32	Vertical slit did not return to its original position in specified time.	Press Ready key again to put unit into Ready mode
33	Hardware backup timer has been activated.	Turn off, wait 1 minute, turn back on
35	The computer is not receiving the image. X-ray is terminated.	Make sure the application is running properly. Restart it if you are not sure. Check for computer errors. Check LAN cable connections. If the above does not solve the problem, restart the computer.
36	No response from the touch panel module.	Turn off, wait 1 minute, turn back on
37	The touch panel is not connected with its controller.	Turn off, wait 1 minute, turn back on
39	High-voltage circuit is not working. X-ray is terminated.	Turn off, wait 1 minute, turn back on
42	Before pressing the READY key, have the patient exit the unit and close the Temple Stabilizer completely. Failure to do so may result in the arm striking the patient or Temple Stabilizer during rotation."	When the exposure is over, guide the patient away from the unit and close the temple stabilizer completely before pressing the Ready key (or emission button).
43	Exceeded the operational range of the unit. Adjust the image layer beam (front back beam) backward to be in the operational range."	Move coronal beam back
44	Exceeded the operational range of the unit. Adjust the image layer beam (front back beam) forward to be in the operational range."	Move coronal beam forward
45	Unclear LAN error.	Turn off, wait 1 minute, turn back on. Restart the application software. Check if there are any computer errors. Make sure LAN cables are properly connected. If above actions do not solve the problem, restart the computer.
46	Unable to establish connection with the PC. System will not be able to receive images properly. Do not continue to use the unit in this state. Contact your J.MORITA Service Center/Distributor to restore the setting."	Contact your local dealer or J. MORITA OFFICE.

Message No.	Possible Cause	Remedy
54	Arm motor is not moving	Contact your local dealer of J. MORITA OFFICE. to have the unit inspected and repaired.
99	The error occurred between equipment and application software. Please reboot equipment and application software.	Turn off, wait 1 minute, turn back on

<Cable Routing Diagram>

Cable connections and routing may differ depending on the model.



DDAE Verification Procedure

1. DDAE Verification

DDAE (Digital Direct Auto Exposure) is verified by this procedure.

1) DDAE Verification Flowchart



2) Warning and Caution

If any errors occur during the verification procedure, turn off Veraviewepocs immediately. After checking the conditions, restart the procedure from "Start".

2. Setup

1) Test Piece (Option)

DDAE verification uses copper plates attached to Veraviewepocs. Test copper piece consists of three copper plates (1), (2), (3)

2) Set the Test Pieces

2)-1 Remove the chin rest and close the temple stabilizers.



2)-2 Set the Test Piece as shown below.



3) Setup i-Dixel

- 3)-1 Startup i-Dixel
- 3)-2 To add "Additional Information" in the Tool Panel if it is not shown, go to "Home Menu" and open "Settings Window" by clicking the screw wrench button at the bottom.

	×
×	
Settings Window	

3)-3 Open Tool Panel tab and select "Additional information" Available buttons box on the left. Then, click "Add >>".



3)-4 Click OK, and restart i-Dixel so that the change is reflected.

- 3. Make exposure
 - 1) Startup
 - 1)-1 Open a patient for the test.
 - 1)-2 Turn on the Veraviewepocs.
 - 2) Make a panorama exposure
 - 2)-1 Set the copper plate (1) + (2). Two plates are to be in the X-ray field.
 - 2)-2 Make a Panorama exposure with Auto Exposure Level "0".
 - 2)-3 Check DAP Value

After the exposure, check the Additional information. Additional information is shown at the bottom in the right pane. Scroll down the window to find the DAP value.



- 2)-4 Memorize the DAP value.
- 3) Make another scan
 - 3)-1 Remove copper plate (2). Use only 1 plate in the X-ray field.
 - 3)-2 Make a Panorama scan with Auto Exposure Level "0".
 - 3)-3 Check the DAP value in the same way.

4. Verification Procedure

- Compare the DAP values from the previous two scans; scan with the copper plate (1) and with the copper plate (1) + (2).
- 2) Check if the value with the copper plate (1) + (2) is greater than the one with the copper plate (1).
- 3) Use the following flowchart to verify the DDAE.



- 4) Results
 - PASS : DDAE operates correctly.
 - FAIL : Try the same procedure carefully again. If still not improved, please contact your local sales representative.

Technical Specifications

(I) Specifications

Product Name	Veraviewepocs
Model	X550
Туре	EX-1 / EX-2

Classification

Protection against electric shock	Class I, Type B
Type B applied parts	Temple Stabilizers, Ear Rods, Chin Rest, Bite Block, Bite Plate, Nasion Plate, Hand X-ray Plate, Lip-nose Rest, Patient Handles (non-conductive connection to patient)
Protection against ingress of liquids	IPX0
Operating altitude	3000 m (max)
Pollution degree	2
Overvoltage category	II
Mode of operation	Non-continuous operation
Disinfection methods:	

- Every patient, disinfect the Type B applied parts by wiping them with ethanol (70 vol% to 80 vol%). If it is not possible to obtain ethanol (70 vol% to 80 vol%), 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 quick disinfectant
- DÜRR DENTAL's FD 360 imitation leather cleaning and care
- DÜRR DENTAL's FD 366 sensitive Rapid disinfection
- Once a day, wipe the operation panel with ethanol (70 vol% to 80 vol%) and wipe the LCD with a dry cloth.
- Single use item; mouth piece and bite block cover.

Product Description

Dental Panoramic X-ray unit with a high frequency switching mode X-ray generator. In addition to panoramic exposure, the unit can also take TMJ Quadruple. Also cephalometric device is available that uses the panoramic X-ray source.

Intended Use

X 550 is used for diagnostics in dentistry by exposing X-ray image receptor and for the use by authorised persons in the practice of dentistry or medicine, and/or associated procedures.

X 550 is intended for dental radiographic examination and diagnosis over the whole Dent-maxillofacial area such as teeth, periodontal tissues or chin-bone etc.

X-ray Tube Head Assembly with High Voltage Generator

Tubo	D 051
Focal Spot	0.5
Target Angle	5°
Target Material	Tungsten
Filtration	Inherent filtration minimum 2.5 mm Al, 75 kV/HVL 3.5 mm AL (X-ray tube filtration: 0.8 mm Al, Al filter: 1.7 mm)
Beam Quality	HVL minimum 2.9 mm AI at 80 kV
	HVL minimum 3.2 mm AI at 90 kV
Maximum Output Power	0.8 kW nominal at 80 kV, 10 mA
·	0.9 kW nominal at 90 kV, 10 mA (Only for Cephalometric
	radiography)
Rectification	Direct Current
Filament	Preheated
Duty Cycle	1:59, 90 kV / 10 mA
	For example, maximum 20.3 sec of irradiation with 1198
	sec (20 min) of interval.
Outer Shell Temperature	45 ⁰C maximum
Cooling	Oil Cooling
Maximum Heat Unit of X-ray Tube Head Assembly	194.45 kJ (1 HU=1.35 Joule)
Maximum Heat Dissipation of X-ray Tube Head Assembly	2 kJ/min.
Primary Protective Shielding	Minimum 1.5 mm Pb or equivalent
Leakage Radiation	Max. 0.88 mGy/h at 1 m
Weight of X-ray Head	13.8 kg (with collimators)

Control

Operating Tube Potential

60 to 80 kV (±1 kV, 21 steps) Digital Display 60 to 90 kV (±1 kV, 31 steps) Digital Display (Only for Cephalometric radiography) Accuracy of displayed values: ±10 % 1 to 10 mA Accuracy of displayed values: ±10 %

Operating Tube Current

Exposure Time

Dental arch panoramic:

Patient size	Magnification	Tomographic orbit	High resolution Mode	Super High resolution Mode
		Standard	7.4s	14.9s
	1.3	Shadowless	7.9s	15.8s
Adult		Orthoradial	8.1s	16.2s
Adult		Standard	8.1s	16.2s
	1.6	Shadowless	8.3s	16.5s
		Orthoradial	8.1s	16.2s
Pedodontic	1.3	Standard	6.5s	13.0s
		Shadowless	6.5s	13.0s
		Orthoradial	6.5s	13.0s
	1.6	Standard	6.0s	12.0s
		Shadowless	6.0s	12.0s
		Orthoradial	6.0s	12.0s

Maxillary Sinus Panoramic:

Patient size	High resolution Mode	Super High resolution Mode
-	10.1s	20.3s

TMJ Quadruple (2/4 images):

Patient size	High resolution Mode	Super High resolution Mode
Adult / Pedodontic	4.3s	8.6s

Cephalometric:

Direction	Lateral	PA
Dens Comp. ON	4.9 s	4.1 s
Dens Comp. OFF	3.5 s	5.0 s

Accuracy of displayed values: ± (5 % + 50 ms) (* Registered value for FDA is ± 10 %)

Test instruction of X-ray tube voltage, current, and exposure time Reproducibility of air karma Minimum mAs Constant (manual) exposure mode Coefficient of variation max. 0.05 Dental Arch Panoramic: 6.0 mAs Cephalometric: 3.5 mAs Dead Man Type

Emission Button

Auto Exposure (Not applied for Cephalometric)

Setting parameters Maximum possible excursion

Reproducibility of air karma Minimum exposure time Verification method +4 to -4 (9 steps) Digital Display 60 to 80 kV 1 to 10 mA Coefficient of variation max. 0.05 4.3 seconds (Exposure time is fixed value, not auto exposure factor.) by test piece

Power Requirements

	EX-1	EX-2
Input Voltage	AC120 V 60 Hz single phase	AC 220/230/240 V 50-60 Hz single phase
Line Voltage regulation*1	Max. 8 %	Max. 8 %
Range of line voltage	108 to 132 V (Including Line voltage regulation)	AC 220/230/240 V ± 10 % (Including Line voltage regulation)
Line current (Operation) Panoramic, Upgradable Cephalometric: With Cephalometric: (Stand by)	Max. 19 A Max. 21.3 A Max. 1.2 A	10.4/ 10/ 9.5 A 10.4/ 10/ 9.5 A 1.0 A
Technique factor for the Maximum line current Panoramic, Upgradable Cephalometric: With Cephalometric:	80 kV, 10 mA 90 kV, 10 mA	80 kV, 10 mA 90 kV, 10 mA
Power Consumption Panoramic, Upgradable Cephalometric: With Cephalometric: Stand by	Max. 2.0 kVA Max. 2.3 kVA 0.3 kVA	2.3 kVA 2.3 kVA 0.3 kVA
Fuse at the distribution panel	 20 A, 120 V, slow * The maximum current rating of this X-ray unit is momentary. The recommended ampacity of supply circuit conductor and the current rating of over current protection device are based on the National Electrical Code 2017, Article 517, Part V, X-ray Installation 	16 A, 220/230/240 V, slow
Power line resistance	Max. 0.5 Ohm	Max. 1 Ohm

Means isolation from supply mains

EX-1: Mains plug, EX-2: Main switch

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

*1 Line-voltage regulation = 100 (Vn – Vi) / Vi

Vn = No-load line voltage, Vi = Load line voltage

Mechanical Parameters

Panoramic	SID 518.5 mm (± 20 mm)
Cephalometric	SID 1,650 mm (± 20 mm)
Magnification	Standard Panoramic: 1.3×, 1.6×
	Maxillary Sinus Panoramic: 1.5×
	Pedodontic Panoramic: 1.3×, 1.6×
	Shadow Reduction Panoramic: 1.3×, 1.6×
	Orthoradial Panoramic: 1.3×, 1.6×
	TMJ Quadruple: 1.3×,
	Cephalometric: 1.1×
X-ray Field	Panoramic: W6 × H143 mm
	(W: +1mm or less on each side, H: inside image reception area) Cephalometric: W6 × H220 mm
	(W: +1mm or less on each side, H: inside image reception area)
Weight	Panoramic: Approximately 184 kg Boxed
-	Cephalometric: Approximately 268 kg Boxed
Outer Dimensions	
Main Unit	W 1,020 × D 1,330 × H 2,355 mm (H 2,185 mm Option) (Panoramic, Upgradable Cephalometric)
	W 2,000 × D 1,330 × H 2,355 mm (H 2,185 mm Option) (with Cephalometric)
Control box	W 70 × D 40 × H 115 mm

Vertical Height of Focal Spot	1,055 to 1,775 mm (Panoramic)		
	970 to 1,605 mm	n (Option)	
	1,125 to 1,775 m	nm (with Cephalometric, Upgradable Cephalometric)	
	1,040 to 1,605 m	nm (Option)	
Patient Positioning	Auto focus using light sensor for distance measurement and electrically operated posi- tioning system		
Patient Positioning Beam	Class 2 Laser. Accordance with 21CFR Part1040.10 and IEC60825-1.		
	Wavelength: typical 655 nm		
	Beam divergence: 120 mm ±10% in length, 0.8±0.2 mm in width @250 mm		
	Pulse duration a	nd repetition rate: Continuous	
	Maximum energ	y output: 1 mW	
Attenuation equivalent of Patient	head stabilizer		
	Panoramic	less than 1.7 mmAl	
	Cephalometric	less than 1.7 mmAl	

Leakage Technique Factors

80 kV, 600 mAs/h (80 kV, 10 mA, duty cycle 1:59, for example 7.4 s exposure per 7 minutes 17 seconds cool-down period) 90 kV, 600 mAs/h (90 kV, 10 mA, duty cycle 1:59, for example 4.9 s exposure per 4 minutes 49 seconds cool-down period)

Measurement Bases

Tube voltage:Actual X-ray radiation is monitored by Non Invasive Evaluator of Radiation Output.Tube current:The mA is measured by monitoring current in the HT return line, which equals the tube current.Exposure time:Exposure time is measured the open time of gate circuit which distributes high voltage to X-ray tube head assembly, by counter (TP8 – TP GND on CPU1 PWB)

Collimator

Panoramic slit and Cephalo slit,

Imaging Device

Panoramic (without Cephalometric):	Built-in	
With Cephalometric :	Model CDCP70	0, PAN/CEPH cassette
Sensor:	CCD	
Detail recognition:	0.096 mm pixel 0.144 mm pixel	size for Superfine mode size for Fine high-Speed mode and Digital Cephalometric mode
Image size:	Panoramic:	max. 3,000 × 1,536 pixel (Superfine mode) max. 2,000 × 1,024 pixel (Fine high-Speed mode)
	Cephalometric:	max. 1,750 × 1,537 pixel

Image Quality

Panoramic:	
Line pair resolution	2.5 LP/mm
Low contrast resolution	diameter 2.0mm
Cephalometric:	
Line pair resolution	2.5 LP/mm
Low contrast resolution	diameter 2.5mm

X-ray Dose Information

The following image information is recorded for each exposure.

- Dose Area Product (DAP) (mGy × cm2)
- tube voltage average (kV)
- tube current average (mA)

Refer to the application's software manual as the displayed image information differs according to the application software.

The Dose Area Product (DAP) (mGy × cm2) may not be displayed depending on the application software.

The displayed Dose Area Product refers to the tube voltage (kV)/current (mA) for each exposure.

The Dose Area Product is calculated based on typical measurement results.

The Dose Area Product displayed is the multiplication product of the air kerma and the size of the radiation field. These values are typical values and are not the measured Dose Area Products for each X-ray exposure.

The air kerma is calculated by divided the Dose Area Product by the X-ray field size.

The accuracy of the air kerma and the Dose Area Product do not exceed +/- 50%.

The dose meter to check and maintain the accuracy of the Dose Area Product indications shall be calibrated at the appropriate energy.

Method used to estimate dose area product: Measured by DAP (Dosage Area Product) meter. The DAP meter is calibrated according to the instructions in the accompanying user manual. The DAP meter is attached to the front of the X-ray head for the Pan, and in back of the secondary slit for the Cephalo. Be careful it does not fall and that its wiring is properly routed.

SIP/SOP Statement

LAN Interface: Unshielded twisted pair cable with RJ-45 plug connections, Length less than 2 m. Optical Fiber: Multi-mode, Push-lock SC Connectors

Requirements for Computers or other Devices Connected to the Computers

- 1. The Veraviewepocs has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2014 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 vicinity. 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 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 Veraviewepocs. 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 vicinity except the Hub if the Hub is conformed with IEC60601-1, IEC60950-1, or IEC 62368-1 and enclosure leakage current is conformed with IEC 60601-1.

* The patient vicinity is the area where intentional or unintentional contact can occur between a patient or a patient's attendant and the above devices, or between a patient or a patient's attendant and other persons touching the above devices. This area extends 1.83 m beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and vertically 2.29 m above the floor.

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.
- * 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 operation in accordance with the manufacturers' instructions.

Other System Requirements

Hardware

Windows based Personal Computer (Minimum specifications)

		Operating system:	Microsoft Windows 2000 with Service Pack or later.
		CPU: Memory: HDD:	Intel Pentium IV 1.7GHz or higher, or compatible. RAM 512MB HDD 20GB or more are recommended.
		Video board: Network protocol: Network interface:	Video capture board resolution of 1024 × 768 and color depth of 24bit TCP/IP with static IP address. Universal purpose 10BASE-T Ethernet network interface board
		Others: Display:	69/udp, 2102/tcp, 2102/tcp Network board, CD-ROM drive. 17 inch TFT LCD 16 million colors 1024 × 768 pixels or better
		Standard:	IEC60950-1, IEC 62368-1, or IEC60601-1 EMD regulation Related UL standard (addition to USA) Related C-UL standard (addition to Canada) Local regulations
Hub			
		10 Base-1, 100 Base-1X Standard:	IEC60950-1 or IEC 62368-1 if it is used in non-patient vicinity IEC60601-1 or IEC60950-1 or IEC 62368-1 with enclosure leakage current is conformed with IEC 60601-1. EMD regulation Related UL standard (addition to USA) Related C-UL standard (addition to Canada) Local regulations
		Recommended Hub, for Manufacturer: Type:	example Bay Networks Bay Stack 350T
	~		
	Storag	je Device	Patient data can be saved safely. MO or CD-R disk drive is recom- mended.
		Standard:	IEC60950-1 or IEC 62368-1 if it is used in non-patient vicinity EMD regulation Related UL standard (addition to USA) Related C-UL standard (addition to Canada) Local regulations
	Other	equipment connected to F Standard:	PC IEC60950-1 or IEC 62368-1 if it is used in non-patient vicinity EMD regulation Related UL standard (addition to USA) Related C-UL standard (addition to Canada) Local regulations
Application Software		Application software for in It shall be used with above It conforms to 93/42/EEC (in Canada). If another application soft and must match the Dixed Ask your nearest J. MOR	mage processing or data base is provided by J. MORITA OFFICE. ve Windows based computer specifications. C (in EU), IEC62304 and 21 CFR (in USA), Medical device regulations tware is used, it must conform to the above regulations and standards, of driver from J. MORITA MFG. CORP.

Environmental Data

Operating Conditions	
Temperature:	+10°C to +35°C (+50°F to +95°F)
Humidity:	30% to 70% (without condensation)
Atmospheric Pressure:	70 kPa to 106 kPa
Transport and Storage Conditions	
Temperature:	-10°C to +50°C (+14°F to +122°F)
Humidity:	20% to 70% (without condensation)
Atmospheric Pressure:	70 kPa to 106 kPa

Original Language

English

Disposal

The package should be recycled. Metal parts of the equipment are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Material must be disposed according to the relevant national legal regulations. Consult specialized disposal companies for this purpose. Please inquire of the local city/community administrations concerning local disposal companies.



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.

Tube Housing Assembly Heating Curve



Tube Housing Assembly Cooling Curve





Anode Thermal Characteristics



Reference Axis

Panoramic





(II) Symbols and Markings

* Some symbols may not be used.




Package



This way up

Keep away from rain

Humidity limitation



Attention, consult accompany documents



Prescription Device CAUTION: Federal law restricts this device to sale by or on the order of a dentist and a licensed healthcare practitioner. (Valid only for U.S.A.)



Packaging unit



USA

FU

(Examples)

Importer

Manufacturer

GS1 DataMatrix

Union)

Do not reuse

Country or region

Fragile

Temperature limitation

Atmospheric pressure limitation

(Country Names: Conforming to the ISO

Description noted next to the code is an

indication that conforms to the regulations

valid only for the relevant country or region.

3166-1 alpha-3 codes and EU for European



Distributor



Registration number of medical device in Thailand (The 12-digit sample number shown is for demonstration purposes only.)

Rating Label, X-ray Tube Head Assembly Label, and Instructions for Use



USA

EU

(Examples)

REP

EC

Serial number Date of manufacture Medical device Alternating current Country or region (Country Names: Conforming to the ISO 3166-1 alpha-3 codes and EU for European CE Union) 0197 Description noted next to the code is an indication that conforms to the regulations valid only for the relevant country or region. EU authorized representative under the European Directive 93/42/EEC (Valid only for EU) cTUVus certification mark (Valid only for U.S.A. and Canada)

Unique device identifier

Refer to instructions for use

- CE(0197) marking (Valid only for EU) Conforms with the European Directive, 93/42/EEC.
- CE marking (Valid only for EU) Conforms with the European Directive, 2011/65/EU.

Marking of electrical equipment in accordance with the European Directive 2012/19/EU (WEEE) (Valid only for EU)



Consult instructions for use



Authorized representative in Switzerland

Indicated Items on the Rating Label and X-ray Tube Head Assembly Label

- * For details, refer to "Technical Specifications" (p. 92).
- * Some symbols described on the previous page may be included.

Rating Label

Model: Model of X-ray system
Type: Type
Input: Rated input voltage, frequency, and power in operation
Standby: Input power in standby
Duty Cycle: Duty cycle of X-ray system
2D barcode at bottom right: Label code

X-ray Tube Head Assembly Label

MODEL: Model of tube housing assembly HEAD NO.: Serial number of tube housing assembly DATE OF MFG.: Date of manufacture TOTAL FILTRATION: Min. inherent filtration RATING: Rated output of tube housing assembly TUBE MODEL: Model of X-ray tube TUBE ANODE NO.: Serial number of X-ray tube MFD. BY: Manufacturer of X-ray tube EFFECTIVE FOCAL SPOT: Nominal focal spot value

Electromagnetic Disturbances (EMD)

The Veraviewepocs 2D (Model: X550, 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.

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 X550, 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 X550.*

Cable List

No.	Name	Cable Length, Shielding	SIP/SOP & In/Out Port Type
1	LAN Cable	Max. 3 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 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
Radiated 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	
łarmonic current Class A EC 61000-3-2		network that supplies buildings used for domestic purposes.	
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 line	Mains power quality should be that of a typical commercial or hospital environment.		
Surge IEC 61000-4-5	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.		
	Signal input/output ±2 kV line(s) to earth	Signal input/output ^{*1} ±2 kV line(s) to earth			
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	$\begin{array}{c} \underline{\text{dips}} \\ 0\% \ U_{\text{T}}: \ 0.5 \ \text{cycle} \ (\text{at } 0, \ 45, \\ 90, \ 135, \ 180, \ 225, \ 270, \\ 315^\circ) \\ 0\% \ U_{\text{T}}: \ 1 \ \text{cycle} \ (\text{at } 0^\circ) \\ 70\% \ U_{\text{T}}: \ 25/30 \ \text{cycles} \ (\text{at } 0^\circ) \\ 25 \ (50 \ \text{Hz})/30 \ (60 \ \text{Hz}) \\ \hline \underline{\text{short interruptions}} \\ 0\% \ U_{\text{T}}: \ 250/300 \ \text{cycles} \\ 250 \ (50 \ \text{Hz})/300 \ (60 \ \text{Hz}) \end{array}$	$\begin{array}{c} \underline{\text{dips}} \\ 0\% \ U_{\text{T}}: \ 0.5 \ \text{cycle} \ (\text{at } 0, \ 45, \\ 90, \ 135, \ 180, \ 225, \ 270, \\ 315^\circ) \\ 0\% \ U_{\text{T}}: \ 1 \ \text{cycle} \ (\text{at } 0^\circ) \\ 70\% \ U_{\text{T}}: \ 25/30 \ \text{cycles} \ (\text{at } 0^\circ) \\ 25 \ (50 \ \text{Hz})/30 \ (60 \ \text{Hz}) \\ \hline \underline{\text{short interruptions}} \\ 0\% \ U_{\text{T}}: \ 250/300 \ \text{cycles} \\ 250 \ (50 \ \text{Hz})/300 \ (60 \ \text{Hz}) \end{array}$	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 IEC61000-4-39	<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	30 kHz CW, 8 A/m*2 134.2 kHz 2.1 kHz, 65 A/m*3 13.56 MHz 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 2: 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) / amateur radio frequency band: 6 V 150 kHz to 80 MHz	3 V ISM ^(c) / amateur radio 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				
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	3 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	applicable to the frequency of the transmitter. 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 Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, <i>E</i> is the compliance level in V/m and <i>d</i> is the recommended separation distance in meters (m). 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) . Interference may occur in the vicinity of equipment marked with the following symbol: $(((\bullet)))$				
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 ratio (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 of 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 active operation of the emission button.
- X-ray termination with release of the emission button.
- · No unexpected movement of the equipment.

NOTE:

If the essential performance is lost or degraded 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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