Panorama X-ray Unit

Veraview IC5 HD

INSTRUCTIONS FOR USE

Thinking ahead. Focused on life.

2024-04-21
Pub. No.: X251-93001-503 (en)

Thank you for purchasing the Veraview IC5.

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

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 Operator's 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 Operator's Manual.

SAFETY INSTRUCTIONS AND RECORDING INFORMATION

When the Veraview IC5 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:

⚠WARNING This warns the user of danger of death, serious bodily injury or total equipment damage and failure or fire.

⚠CAUTION This alerts the user to the risk of light to medium injury or equipment damage.

Usage Note This alerts the user of important points concerning operation.

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 low 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

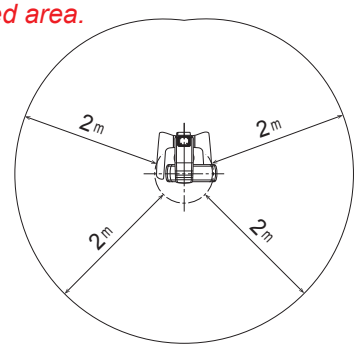
• The useful life of the Veraview IC5 is 10 years from the date of installation provided it is regularly and properly inspected and maintained.

• 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.

Warnings and Cautions for Safe Operation

⚠WARNING

- *This X-ray unit may be dangerous to PATIENT and OPERATOR unless safe exposure factors and operating instructions are observed.*
- *Only dentists and other legally qualified and authorized personnel are allowed to operate this equipment.*
- *Do not use this equipment for patients when it is being maintained or serviced.*
- *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.*
- *To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth*
- *To avoid the risk of electric shock, do not replace the power supply cord.*
- *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.*
- *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
  URL: https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm489704.htm
- *Judgement and caution should be used in regards to radiographs of pregnant women. The decision should be based on "clinical need of diagnostic information".*
- *Do not use this unit for fluoroscopic examinations.*
- *Do not use the wireless transmission devices listed below in the examination area; electromagnetic interference from these devices could cause the Veraview IC5 to operate in a random, unexpected and dangerous manner.*
  1. *Cell phone terminals*
  2. *Wireless transmitting devices such as ham radios, walkie-talkies, and transceivers*
  3. *Cell phones*
  4. *Routers for intra-building paging systems, wireless LAN cordless, analogue telephones, and other electric wireless devices*
- *Interference from the Veraview IC5, devices listed below might malfunction or operate in a random, unexpected and dangerous manner.*
  1. *Electric medical devices for examination, diagnosis and treatment.*
  2. *Personal computers*
- *The Unit 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 unit 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.*

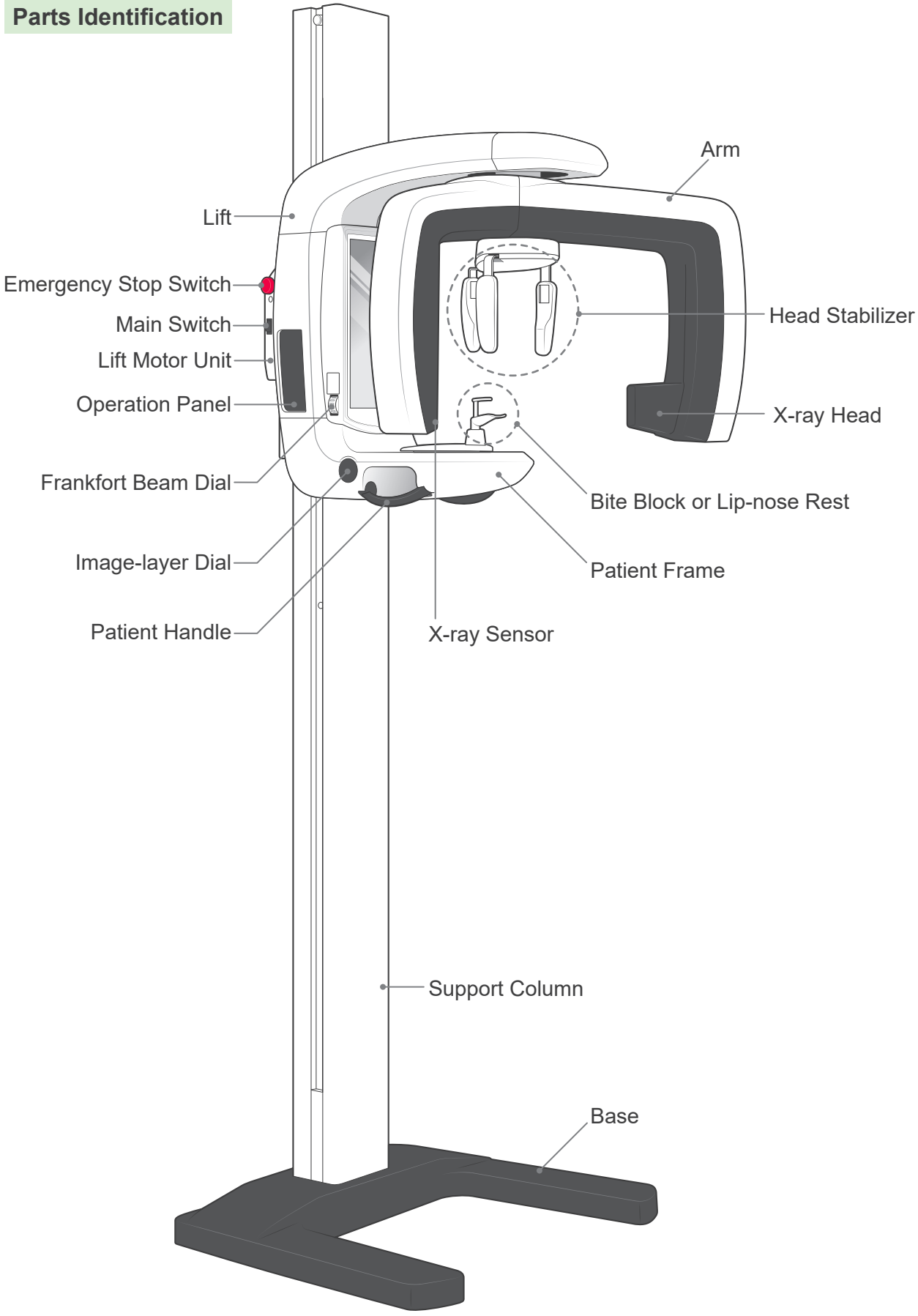
- *The patient and operator must be provided with appropriate X-ray protection gear such as lead-impregnated clothing that conforms to local regulations.*
- *The operator must be able to see the exposure emissions lights and hear the audible signal during operation of the equipment.*
- *The operator 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.*
- *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.*
- *Proper infection control procedures must be established and maintained for each patient.*
- *Do not leave anything within the movement area of the arm, lift and patient frame.*
- *Do not touch simultaneously the patient and the conductive parts, such as the connector terminals.*

⚠CAUTION

- *Be careful not to trip over the LAN cable. It may damage the LAN connectors, communication circuit and/or the PC.*

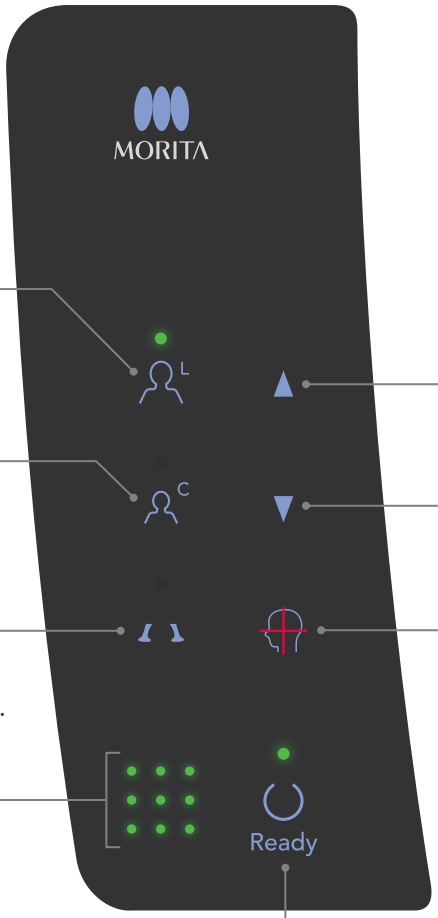
Parts Identification

Parts Identification



Operation Panel and Control Box Descriptions

Operation Panel



Panorama Key

Press this to make a standard panorama. The green LED will light up.

Pedodontic Panorama Key

Press this to make a pedodontic panorama. The green LED will light up.

TMJ Key

Press this to make a quadruple TMJ exposure. The green LED will light up.

Data Transmission Indicator

- Transmission Test: Green, blinking
- Ready for Exposure: Green, stays on
- Transmitting Data: Orange, blinking
- Transmission Failure: Red, blinking

Up Key

Hold this down to raise the lift.

Down Key

Hold this down to lower the lift.

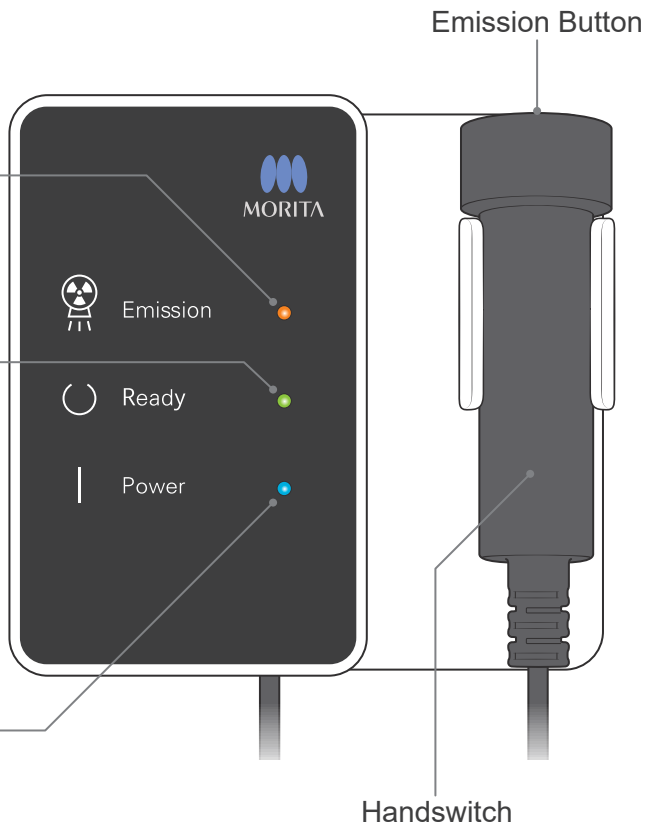
Beams On and Off Key

Press this key to turn the beams on if they are off or turn them off when they are on. The beams turn themselves off automatically after 1 minute.

Ready Key

Press this when the green LED is blinking. The arm will go to its Start position and the unit will be ready to make an exposure; then the green LED stops blinking and stays on.

Control Box



Emission Light

Yellow.
Light up during x ray emission.

Ready Light

- Green.
  Blinks when unit is turned on.
  Stays on after Ready Key on the arm is pressed, arm moves to its Start position, and the unit is ready to make and exposure.
- Orange.
  Blinks during data transmission.

Power Light

- Blue.
  Lights up when main power is turned on.

Operation

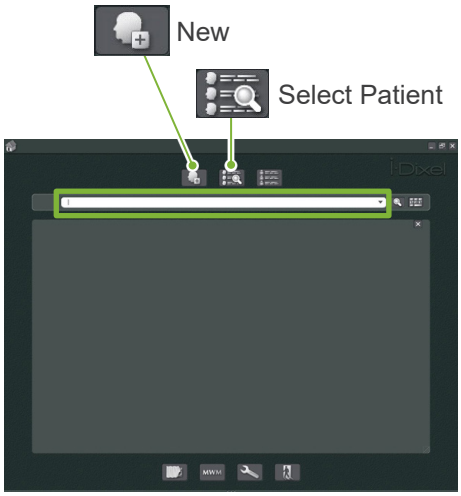
* If an accident occurs, the equipment must not be used until repairs have been completed by a qualified and trained technician provided by the manufacturer.

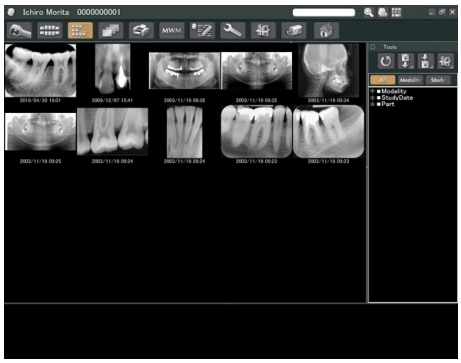
* Have patients remove glasses, necklaces, earrings and other accessories which could interfere with diagnosis.

* If the unit has not been used for some time, make sure it operates normally and safely before actually using it.

⚠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.





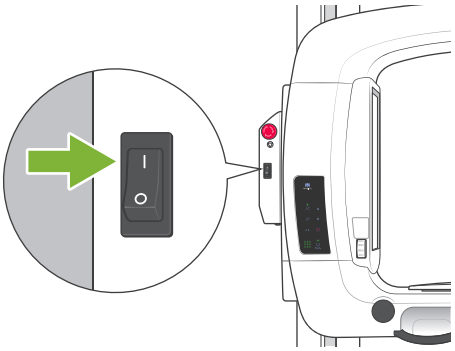
Patient Page

Getting Ready

* PC Set Up (Refer to the user's manual for i-Dixel or other application.)
  For the i-Dixel application, 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.

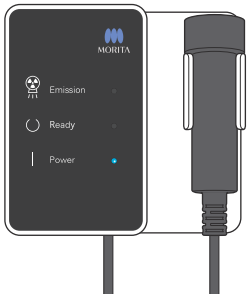
Turn the PC and HUB on and start the application software. Then turn on the Veraview IC5.

The Veraview IC5 checks the PC connection through the application software when it starts. An error will be reported if the application software is not open for capturing images when the Veraview IC5 is turned on. Restart the Veraview IC5 after starting the application software if a communication error occurs when it is turned on.



Turn the Main Switch On

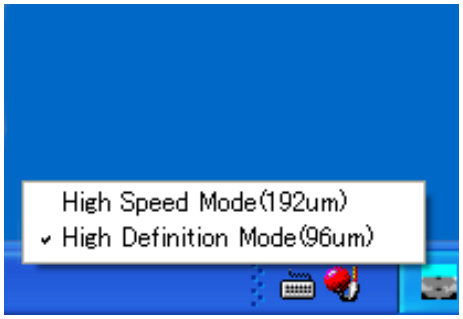
Press the top of the main switch (|) on the support column to turn the Veraview IC5 on.



The blue Power light on the control box will light up.

* If the unit is not used for 30 minutes, it will automatically go into power-save mode.

* Press the Ready key to go back to normal operation mode.



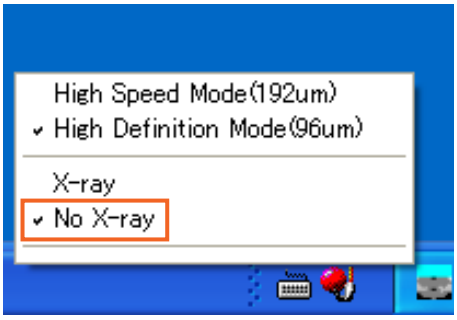
Check Resolution

Place the mouse cursor on the resolution icon on the task bar and see what it is set for.

High Speed Mode (192 um)

High Definition Mode (96 um)

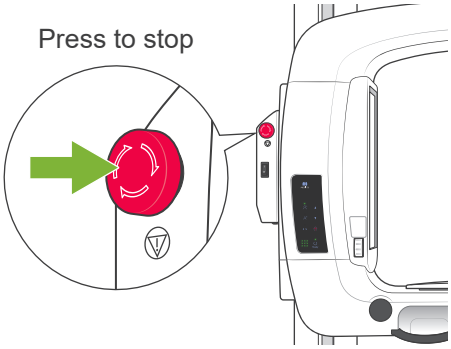
To change the resolution, click the resolution icon.



Operation Check

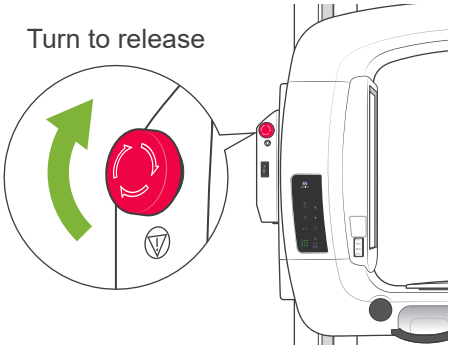
Press the Ready key; the arm will move to its Start position. Check that the green Ready light lights up. Then hold the emission button down. Check that the arm starts to rotate, X-rays are emitted, the yellow emission lamp lights up and the audible signals sounds. Check that X-ray emission and arm rotation stop after the irradiation time is up.

*To test the arm rotation without emitting any X-rays, right-click the resolution icon in the task bar and set the unit for “No X-ray”.



Emergency Stop Switch

In an emergency, press the Emergency Stop Switch to stop the arm's rotation and the emission of X-rays. Do not use this switch for any other reason.



In Case the Emergency Switch Has Been Pressed

Turn the main switch off. Then turn the emergency switch in the direction indicated by the arrow to put the unit back into its normal and safe operating mode. Restart the computer. Turn the X-ray unit back on and check that it operates normally in panorama mode. If it does not, contact your local dealer or J. MORITA MFG. CORP.

⚠CAUTION

If the emergency stop switch was pressed during the transmission of data, wait until the transmission is completed before turning off the main switch. However, if the transmission is not completed after 3 minutes, go ahead and turn off the main switch anyway.

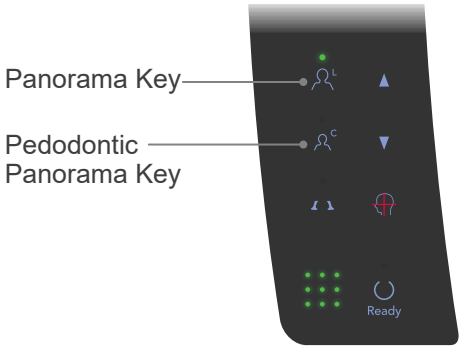
Usage Note

- *If the emergency switch has been accidentally pressed during cleaning or for some other reason, the arm will not rotate and X-rays will not be emitted. In this case, turn the emergency switch in the direction indicated by the arrow to restore normal operation.*

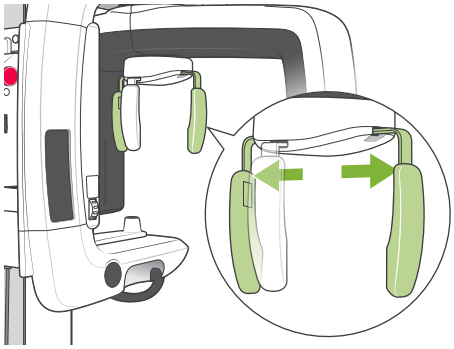
Exposure Procedures

Standard and Pedodontic Panorama Exposures

[Patient Positioning and Exposure Procedure]

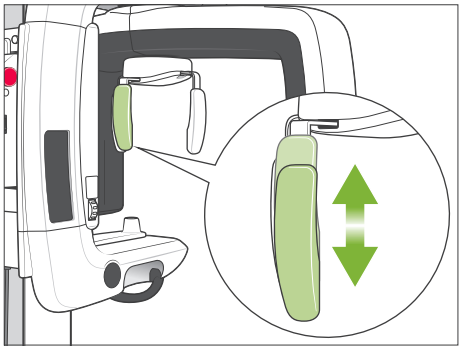


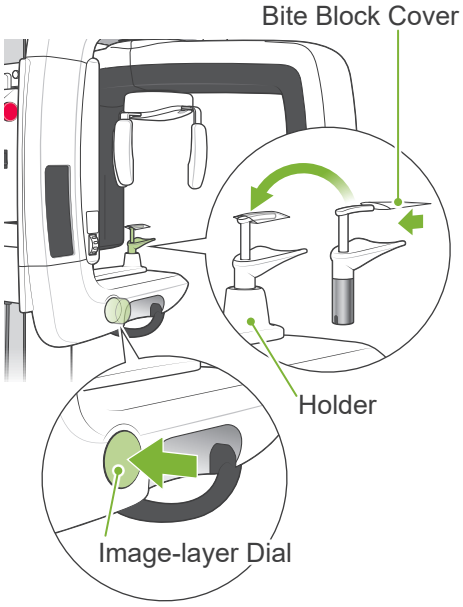
1. Press the Panorama or Pedodontic key.



2. Grip the base of the plates for the head stabilizer and spread them out as far as they will go.

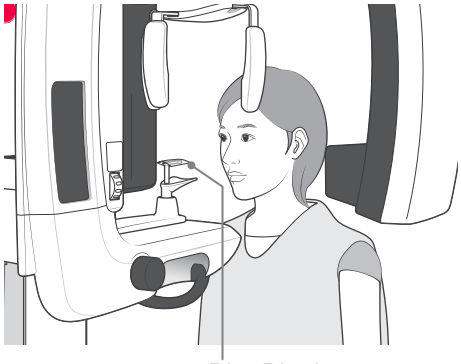
   * The plate for the forehead slides up and down.





3. Put a cover on the bite block and then put it in its holder. Press the Image-layer Dial to free it.

   * If the bite block cannot be used in the case of edentulous patients or for some other reason, use the chin rest instead.



4. Have the patient wear an X-ray protection apron and stand in front of the bite block.

⚠WARNING

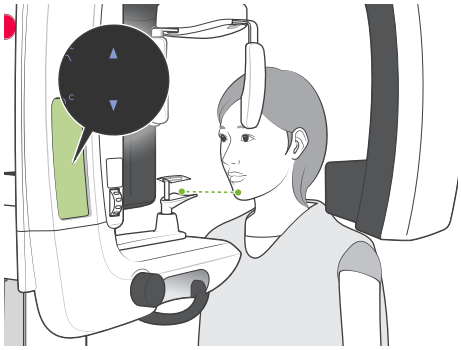
A new, uncontaminated bite block cover must be used for each patient to prevent from cross-contamination.

⚠CAUTION

Have patients remove glasses, earrings and any other accessories that might interfere with making a good exposure.

Usage Note

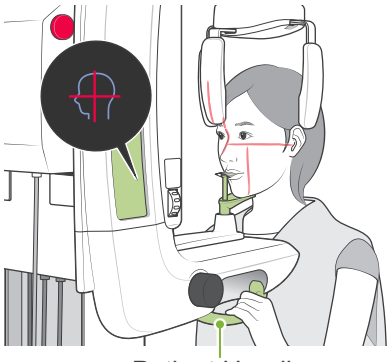
- *Store the covers for the Bite Block in a clean, uncontaminated area.*

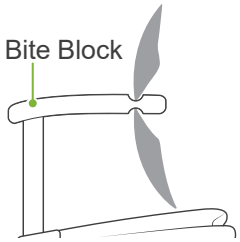


5. Use the Up and Down keys to adjust the height of the patient frame to the patient's height.
Have the patient pull his chin in and stand as straight as possible. Observe the patient from the rear to make sure he is standing straight and not leaning to the side.

Usage Note

- *Always use the Up and Down keys to adjust the height of the patient frame; manual adjustment could damage the lift mechanism.*





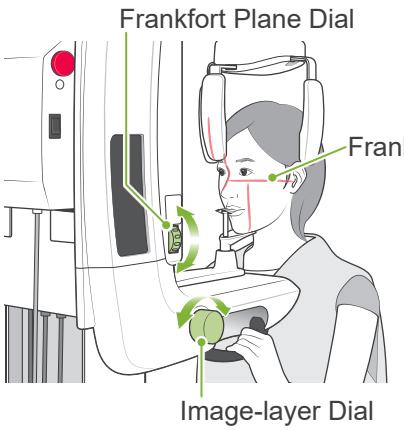
6. Making sure the patient keeps a good posture, press the Beams On and Off key to turn the beams on.
Have the patient lightly bite down on the bite block, rest his chin lightly on the plate below it, and grip the patient handles.

⚠WARNING

The beams are lasers that could injure the eyes; never look directly into them or allow them to strike anyone in the eye.

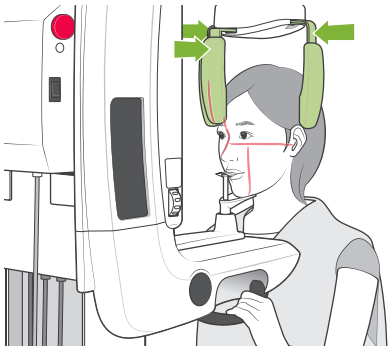
⚠CAUTION

The beams turn off automatically after 60 seconds except during an exposure. After an exposure, the beams go out after the arm rotates to the patient egress position and stops.



7. Line up the patient's sagittal plane with the sagittal beam. Make sure the patient's frankfort plane is level, and then use the frankfort plane dial to line up the beam with the frankfort plane.

Move the Bite Block with the Image-layer Dial so that the image-layer beam is lined up with the distal side of the patient's upper, left canine (tooth 23). Then press the dial to lock it in place.



Close the head stabilizer to immobilize the patient's head.

⚠WARNING

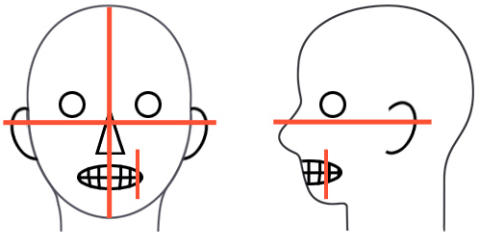
- *Be extremely careful when moving the lift after the patient is in position; this could put stress on the patient's teeth or cause his shoulder to contact the X-ray arm*
- *Do not accidentally hit the patient's eye with the head stabilizer.*

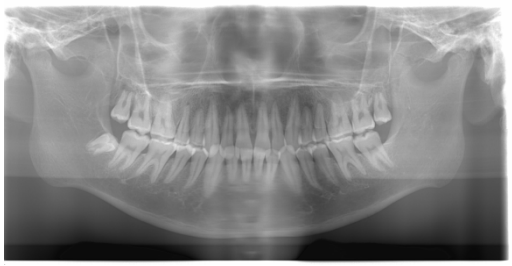
Usage Note

- *If the patient is resting his chin on the bite block, pressing the dial may not release it. In this case, push the bite block a little towards the patient.*
- *If the image-layer dial is pressed when the bite block is positioned all the way at the front or the end of the patient frame, the positioning mechanism might jam and the position cannot be adjusted after releasing the image-layer dial. To avoid this, move the bite block position slightly towards the center of the patient frame before pressing the image-layer dial.*
- *Poor patient positioning may make it hard to make a correct diagnosis. Refer to "Examples of Correct and Poor Patient Positioning" on the next page.*

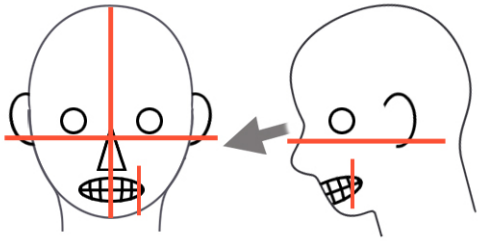
Examples of Correct and Poor Patient Positioning

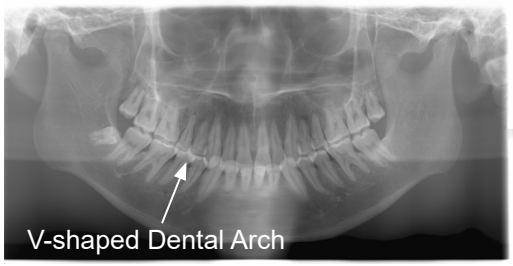
Correct Positioning



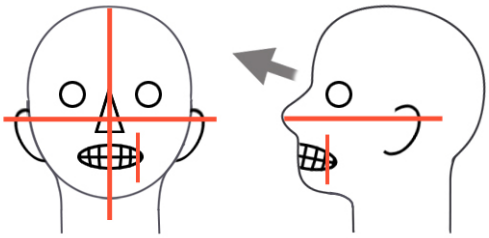


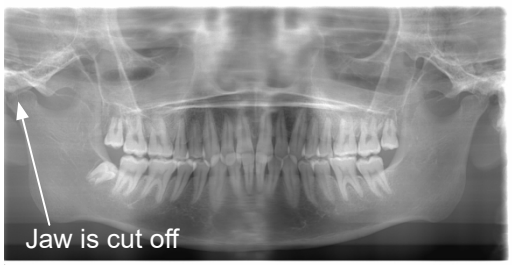
Patient Looking Down



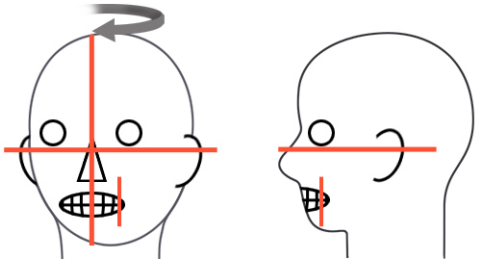


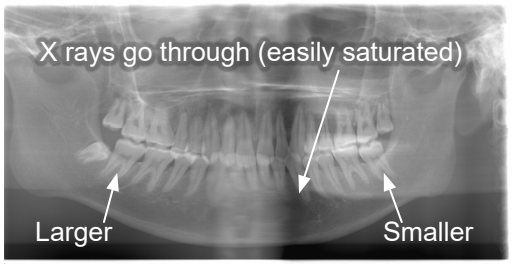
Patient Looking Up



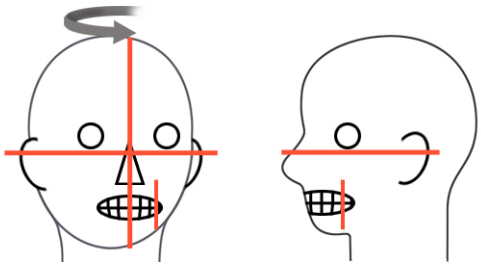


Patient Looking to the right





Patient Looking to the left



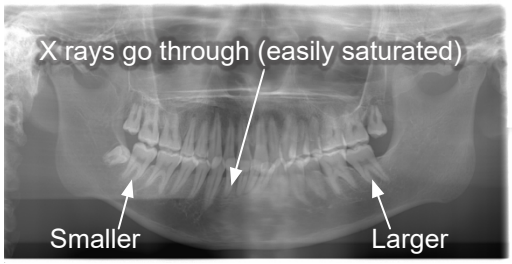
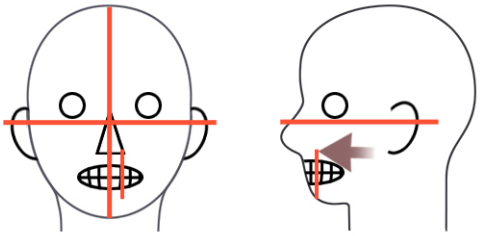


Image-layer Beam too far forward



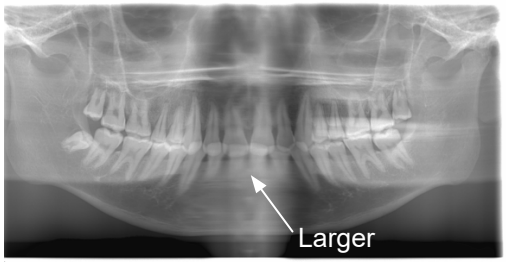
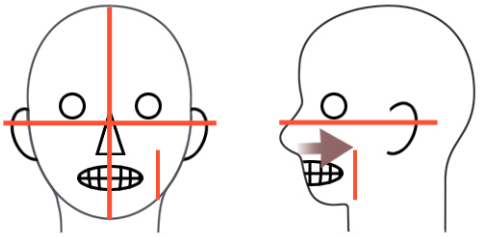
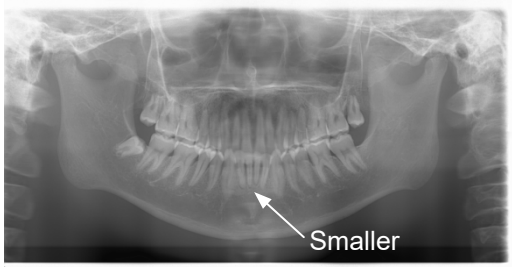


Image-layer Beam too far back

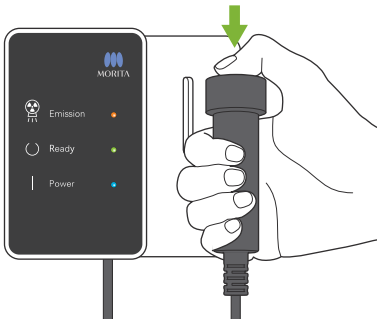




8. Press the Ready key. The arm will move to its Start position. The green LED will light up to show that the unit is ready to make an exposure.

⚠WARNING

Make sure the X-ray arm does not hit the patient's shoulder after you press the Ready key, and it starts moving.



9. Make sure the green Ready light on the control box is on (not blinking).
Pick up the handswitch and hold down the emission button.
During X-ray emission, the yellow Emission light on the control box lights up and an audible signal sounds.

⚠WARNING

- *Leave the X-ray booth to hold down the emission button.*
- *In an emergency release the emission button to stop the arm and X-ray emission or press the emergency switch.*

⚠CAUTION

- *Tell the patient not to move during X-ray emission and while the audible signal is sounding; otherwise, the arm might strike the patient or the exposure might be ruined.*
- *Continue to hold the emission button down until the exposure is finished; releasing it will terminate X-ray emission.*

* If the exposure is interrupted, press the Ready key to return the arm to its start position and then repeat the exposure.

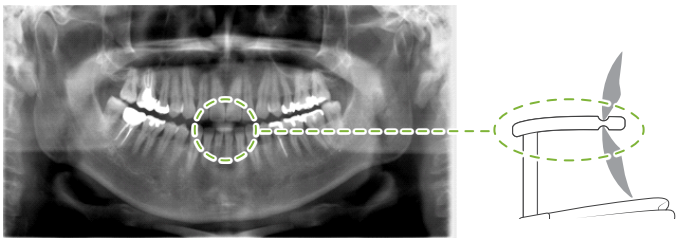
10. When the exposure is completed, the Ready light will change to orange and blink on and off, the Emission light will go out, and the audible signal will stop.
The arm will then go to the patient egress position. Release the Emission button and hang the handswitch up on the control box.

⚠CAUTION

Never turn off the main switch while data is being transmitted. This will cause the image to be lost and the computer to freeze. During data transmission, the Data Transmission Indicator on the operation panel and the Ready light on the control panel will change to orange and blink on and off.

⚠CAUTION

A portion of the Bite-Block will be visible in the image as it lies within the X-ray field.



* Do not try to make another exposure before the image is displayed on the computer monitor.
* After the exposure is completed, the X-ray image will be display on the computer's monitor.
* Density compensation is automatically applied to digital images, but in cases where a part of the image is unusually dark, the image including the dark area may become somewhat whitish or milky.
* The seam in the center of the image where the two CCD sensors are joined may be visible in an enlarged image although it will not be visible when the image is displayed right after transmission. This is normal, not a flaw or malfunction.
* If the image transfer stops before the image is shown on the PC display, leave the Veraview IC5 unit on and check the LAN connection. The last image is possibly retrieved if the LAN connection can be re-established properly before turning off the unit.

Patient Egress

Release the head stabilizer and carefully guide the patient away from the X-ray unit.

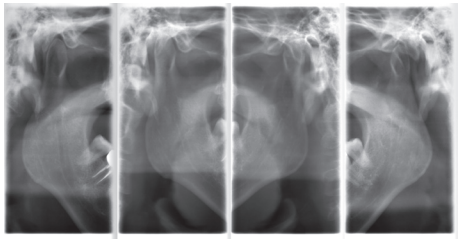
* Dispose of the used cover for the bite block.

⚠WARNING

- *Make sure the head stabilizer is all the way open and be very careful when guiding the patient away from the X-ray unit. Otherwise, the patient could be injured, or the head stabilizer might be broken.*
- *Do not accidentally hit the patient's eye with the head stabilizer.*
- *To stop the arm in an emergency when it is returning to its start position, press the Ready key on the operation panel, the emission button or the emergency switch.*

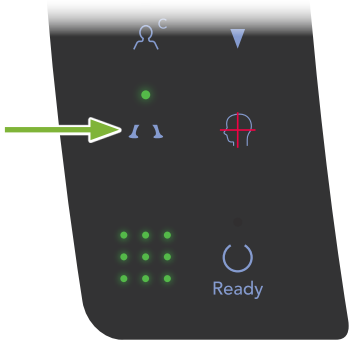
TMJ Quadruple Exposure

[Patient Positioning and Exposure Procedure]

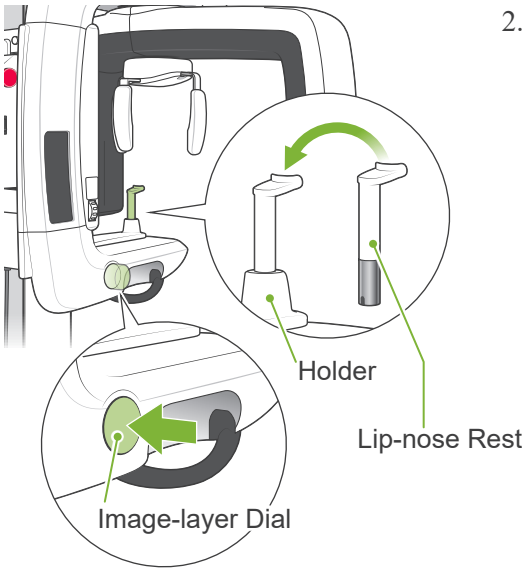


This procedure will produce four images of the TMJ: one each when the mouth is opened and closed for both the left and right sides.

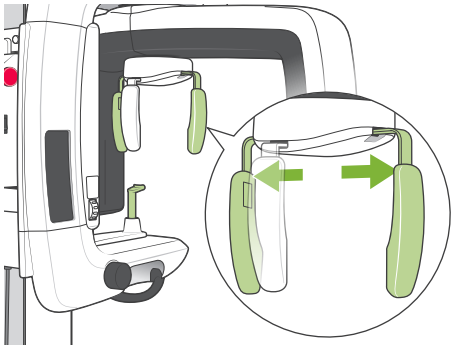
This requires the arm to make two rotation cycles.
Do not fail to perform both cycles.



1. Press the TMJ key.

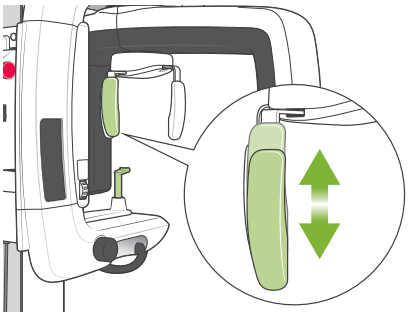


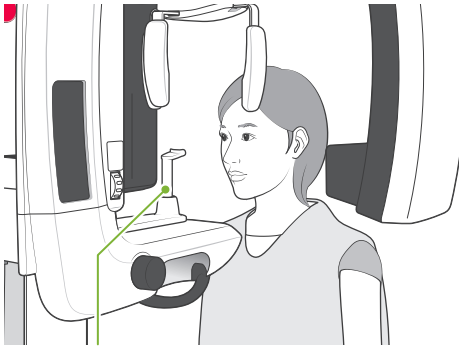
2. Take the bite block out of the holder and replace it with the lip-nose rest.
   Press the Image-layer Dial to free it.



3. Grip the base of the plates for the head stabilizer and spread them out as far as they will go.

   * The plate for the forehead slides up and down.

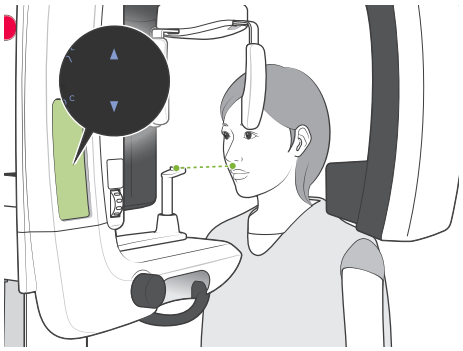




Lip-nose Rest

4. Have the patient wear an X-ray protection apron and stand in front of the lip-nose rest.

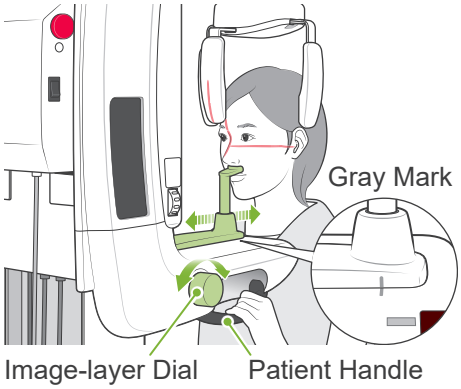
⚠CAUTION
Have the patient remove glasses, earrings or other objects that could spoil the X-ray.



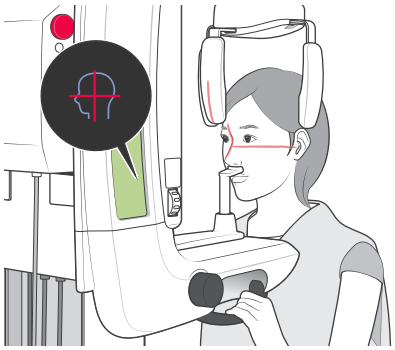
5. Use the Up and Down keys to adjust the height of the patient frame to the patient's height.
   Have the patient pull his chin in and stand as straight as possible.
   Observe the patient from the rear to make sure he is standing straight and not leaning to the side.

Usage Note

- *Always use the Up and Down keys to adjust the height of the patient frame; manual adjustment could damage the lift mechanism.*



6. Use the Image-layer Dial to move the lip-nose rest and line it up with the gray mark; then lock it in place. Making sure the patient keeps a good posture, have him move forward and put his nose on the lip-nose rest and also lightly grip the patient handles.



Press the Beams On and Off key to turn the beams on.

* The image-layer beam will not light up.

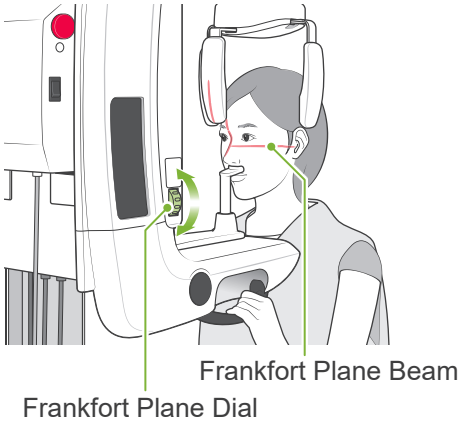
⚠WARNING

The beams are lasers that could injure the eyes; never look directly into them or allow them to strike anyone in the eye.

7. Press the Ready key. The arm will move to its Start position. The green LED will light up to show that the unit is ready to make an exposure.

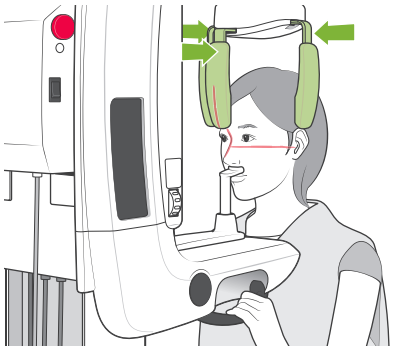
⚠WARNING

Make sure the X-ray arm does not hit the patient's shoulder after you press the Ready key, and it starts moving.



8. Have the patient close his mouth and line him up with the sagittal beam.

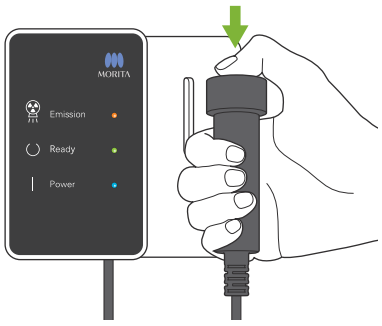
   Make sure the patient's frankfort plane is level, and then use the frankfort plane dial to line up the beam with the frankfort plane.



Close the head stabilizer to immobilize the patient's head.

⚠WARNING

Do not accidentally hit the patient's eye with the head stabilizer.



9. Make sure the green Ready light on the control box is on (not blinking).
   Pick up the handswitch and hold down the emission button. The arm will start moving and make exposures of the left and right joints. X-rays will be emitted twice before the arm stops.
   During X-ray emission, the yellow Emission light on the control box lights up and an audible signal sounds.

⚠WARNING

- *Leave the X-ray booth to hold down the emission button.*
- *In an emergency release the emission button to stop the arm and X-ray emission or press the emergency switch.*

⚠CAUTION

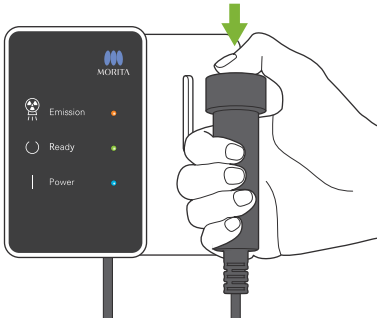
- *Tell the patient not to move during X-ray emission and while the audible signal is sounding; otherwise, the arm might strike the patient or the exposure might be ruined.*
- *Continue to hold the emission button down until the exposure is finished; releasing it will terminate X-ray emission.*

10. Release the emission button when the arm stops moving.

11. Press the Ready key to return the arm to its Start position. Have the patient open his mouth.

⚠WARNING

Make sure the X-ray arm does not hit the patient's shoulder after you press the Ready key, and it starts moving.



12. Make sure the green Ready light on the control box is on (not blinking).
Pick up the handswitch and hold down the emission button. The arm will start moving and make exposures of the left and right joints. X-rays will be emitted twice before the arm stops.
During X-ray emission, the yellow Emission light on the control box lights up and an audible signal sounds.

⚠WARNING

- *Leave the X-ray booth to hold down the emission button.*
- *In an emergency release the emission button to stop the arm and X-ray emission or press the emergency switch.*

⚠CAUTION

- *Tell the patient not to move during X-ray emission and while the audible signal is sounding; otherwise, the arm might strike the patient or the exposure might be ruined.*
- *Continue to hold the emission button down until the exposure is finished; releasing it will terminate X-ray emission.*

13. When the exposure is completed, the Ready light will change to orange and blink on and off, the Emission light will go out, and the audible signal will stop.
The arm will then go to the patient egress position. Release the Emission button and hang the handswitch up on the control box.

⚠CAUTION

Never turn off the main switch while data is being transmitted. This will cause the image to be lost and the computer to freeze.

During data transmission, the Data Transmission Indicator on the operation panel and the Ready light on the control panel will change to orange and blink on and off.

* Do not try to make another exposure before the image is displayed on the computer monitor.

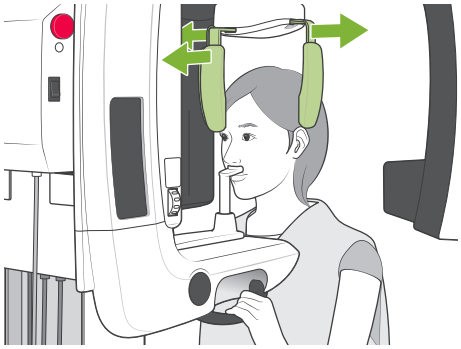
* After the exposure is completed, the X-ray image will be display on the computer's monitor.

* It will take longer if the image window is open while the data is being transmitted.

* Density compensation is automatically applied to digital images, but in cases where a part of the image is unusually dark, the image including the dark area may become somewhat whitish or milky.

* The seam in the center of the image where the two CCD sensors are joined may be visible in an enlarged image although it will not be visible when the image is displayed right after transmission. This is normal, not a flaw or malfunction.

* If the image transfer stops before the image is shown on the PC display, leave the Veraview IC5 unit on and check the LAN connection. The last image is possibly retrieved if the LAN connection can be re-established properly before turning off the unit.



Patient Egress

Release the head stabilizer and carefully guide the patient away from the X-ray unit.

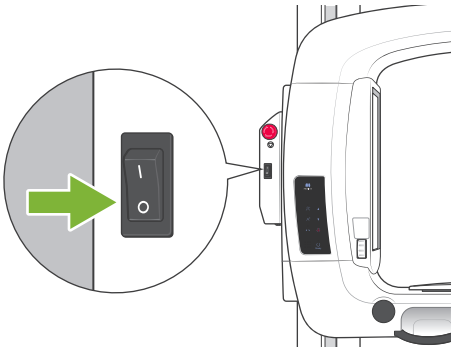
Remove the lip-nose rest and replace it with the bite block.

⚠WARNING

- *Make sure the head stabilizer is all the way open and be very careful when guiding the patient away from the X-ray unit. Otherwise, the patient could be injured, or the head stabilizer might be broken.*
- *Do not accidentally hit the patient's eye with the head stabilizer.*
- *To stop the arm in an emergency when it is returning to its start position, press the Ready key on the operation panel, the emission button or the emergency switch.*

After Use

Turn the main switch off.



Press the bottom of the main switch on the support column (the side marked with a circle). The Power Light on the control box will go out.

⚠WARNING

Do not fail to turn the unit off after use; this will avoid the risk of electrical leakage or unintended operation.

Maintenance, Parts Replacements, and Storage

Maintenance

Cleaning

- After each use (patient), disinfect the head stabilizer, bite block, lip-nose rest, chin rest, and patient handles 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 the operation panel with ethanol (70 vol% to 80 vol%).
- Every 6 months, put some of the grease provided on the wire cables for the lift.

⚠WARNING

Do not fail to turn the main switch off.
This will avoid the risk of electric shocks, burns, or accidentally pressing a switch.

Usage Note

- *Use only ethanol (70 vol% to 80 vol%) or a neutral detergent to clean outer surfaces. Alkali or acidic solutions, cresol liquid soap, and other chemicals can cause discoloration and surface damage.*
- *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.*
- *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.*
- *When cleaning, never pull on any cables or cords.*

Verification of Automatic Exposure Control

- Read the section titled "Veraview IC5 DDAE Verification Procedure" (p. 36) for the verification method of the automatic exposure control.

Replacement Parts

- Replace the parts as necessary depending on degree of wear and length of use.
  For details, see page 29 "Service Life, Consumables, and Replacement Parts".
- Order replacement parts from your local dealer or J. MORITA OFFICE.

Storage

- No frequent or continuous exposure to direct sunlight.
- Store the bite block covers in an aseptic environment.
- 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 accredited 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 every 6 months.
- 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 further preventive inspection and maintenance during the life of the device.

*For repair or other types of service contact 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 nominal Voltage ± 10%
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 wirings inside the enclosures may only be done by the accredited service personnel.
6. 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
   Make an X-ray exposure of a standard test piece and compare the density of the resulting image with a standard image.
2. X-ray Slit
   Make sure the X-ray beam goes through the slit for the digital cassette.
3. Arm Rotation
   Hold down the emission switch and rotate the arm. Make sure it does not make an abnormal noise or slip and that it stops at the specified point. Repeat three times.
4. Arm Emergency Stop
   Make sure the arms stops when the emission button is released.
5. Bite Block Movement
   Turn the Bite Block Dial back and forth and make sure the Bite Block moves accordingly.

6. Head Stabilizer, Bite Block, and Lip-nose Rest
   Make sure the head stabilizer opens and closes properly.
   Make sure Bite Block and Lip-nose rest are properly secured.
7. Positioning Beam Keys
   Make sure the Sagittal, Frankfort plane, and Image-layer Beams light up properly and turn off automatically after 1 minute.
8. Operation Panel and Control Box
   Make sure all switches and lights on the operation panel and the control box work properly.

Lift

1. Movement
   Press the up and down keys. Make sure the lift moves smoothly and stops properly. Repeat this 3 times.
2. 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.

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.

Component Service Life List

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

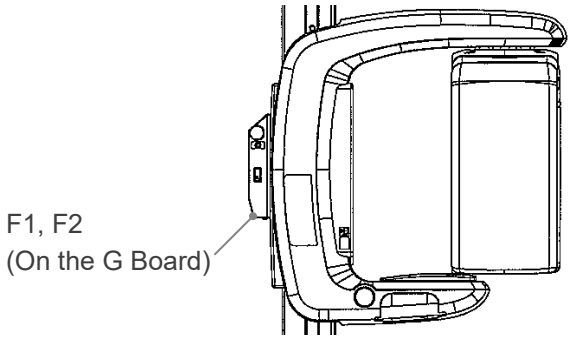
*1 The service life of the X-ray tube depends on the number and length of exposures it is used for as well as the output (tube voltage and current) and the time between exposures. Of these factors, the most critical is the number of exposures which degrades the anode. As the anode gradually degrades,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

*2 The service life of the 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
Bite-Block Covers	6211120	Single use	Yes	For infection control.
Bite-Block (RAL)	6351404	1 year or whenever scratched or damaged.	N/A	
Bite-Block Assembly (RAL)	6351403	1 year or whenever scratched or damaged.	N/A	
Chin Rest (RAL)	6351401	1 year or whenever scratched or damaged.	N/A	
Lip-nose Rest (RAL)	6351402	1 year or whenever scratched or damaged.	N/A	
IC5 3-piece Copper Filter (RAL)	6351001	Whenever scratched or damaged.	N/A	

Replacement Parts



Code No.	Description	Rating	Type	Qu.
6350040	F1, F2 (Main fuse for EX-1)	F15 A, 250 V	Fast-acting, High Breaking Capacity Size: 0.25 × 1.25 inches	1
3810984	F1, F2 (Main fuse for EX-2)	F6.3 A, 250 V	Time Lag, High Breaking Capacity Size: 5 × 20 mm	1

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

⚠CAUTION

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 Veraview IC5 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 MFG. CORP. to repair those parts.

Troubleshooting

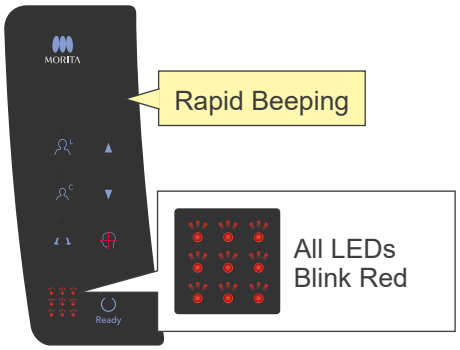
If the equipment operation does not seem to be normal, check or adjust the following before requesting a repair service.

- 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.
- Contact your local dealer or J. MORITA OFFICE. for repairs if the apparatus does not work normally even after performing the steps recommended below.

Problem	Response
• No power when main switch is turned on.	Make sure the unit is plugged in.
• Switches don't work. • LEDs or indicators do not work • Arm does not go to Start position	Turn the unit off, wait one minute and then turn it back on again.
• Image is too light or washed out • Lines in image • White margins are too large • Part of image is cut off • Switches don't work • Beeps or other audible signals do not sound right	Possible electrical noise interference. Turn the main switch off and guide the patient safely away from the unit Then turn the unit back on again and see if it works properly. Make sure the unit is connected to a devoted circuit with the specified voltage and current. See page 45 for the power requirements for various countries and regions. Do not use any equipment or devices that might produce electrical noise nearby while the unit is in use.
• Lines in image • Strobe effect • Image is too light or washed out • Image is completely black • Suddenly returns to same conditions as when it was first turned on. • Switches don't work	Possible temporary power outage. Turn the main switch off and guide the patient safely away from the unit Then turn the unit back on again and see if it works properly. Make sure the unit is connected to a devoted circuit with the specified voltage and current. See page 45 for the power requirements for various countries and regions.
• Errors occur • Suddenly returns to same conditions as when it was first turned on • Switches don't work	Possible build up of static electrical charge Turn the main switch off and guide the patient safely away from the unit Then turn the unit back on again and see if it works properly. Make sure the ground is properly connected. Make sure the room is not too dry.

Problem	Response
• Errors occur • Suddenly returns to same conditions as when it was first turned on • Switches don't work	Turn the main switch off and guide the patient safely away from the unit Then turn the unit back on again and see if it works properly.
• Image density is erratic or uneven	Possible poor patient positioning. Position patient correctly. Check and correct patient positioning. Use i-Dixel software to improve image quality.
• Up and Down keys for lift do not work	Patient may be gripping the patient frame or leaning on it. Have the patient relax and instruct him to not lean on the frame.
• Lift went up but will not come down. • Left went down but will not come up. (Error signal sounds when Up or Down key is pressed.)	Restore normal working condition by holding down the Standard Panorama key and then pressing either the Up or the Down key. Never try to force the lift to move when the power is turned off; this could damage the lift mechanism.
• Cannot release the image-layer dial. (It does not pop up even when the dial is properly pushed.)	When the patient is resting their chin on the bite block, pressing the dial may not release it. Slightly push the bite block to the back (direction towards the patient). If it still does not move, carefully guide the patient away from the X-ray unit. Then pinch the dial and pull it out. (Do not push the dial forcibly.) * If it is difficult to release the dial, contact your local dealer or J. MORITA OFFICE.

Operation Panel Error Signals



System Errors

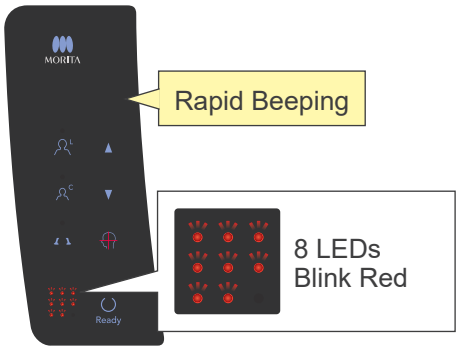
Rapid beeping and all LEDs blinking indicate a system error.

(Possible Causes)

- Malfunction during transmission to computer.
- Problem with X-ray unit's transmission circuitry

(Response)

Turn the X-ray unit off and restart the i-Dixel application. Then check the connections between the unit and the computer. Turn the X-ray unit back on. If this does not solve the problem, contact your local dealer or J. MORITA OFFICE.



Error C3

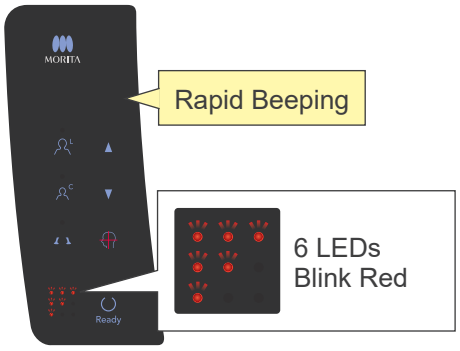
Rapid beeping and 8 LEDs blinking in the pattern shown to the left indicate error C3.

(Possible Causes)

- Disconnected LAN cable between X-ray unit and HUB
- HUB is not turned on.

(Response)

- Check cable connection between X-ray unit and HUB
- Make sure HUB is turned on.



Error C4

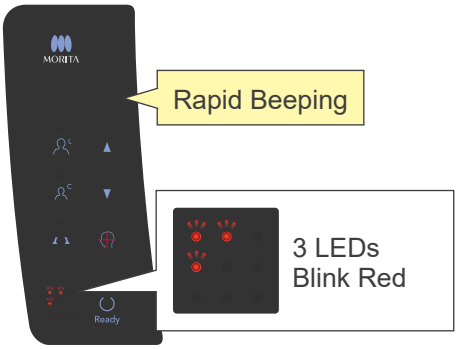
Rapid beeping and 6 LEDs blinking in the pattern shown to the left indicate error C4.

(Possible Causes)

- Disconnected LAN cable between computer and HUB
- Computer is not turned on.

(Response)

- Check cable connection between computer and HUB
- Make sure computer is turned on



Error C6

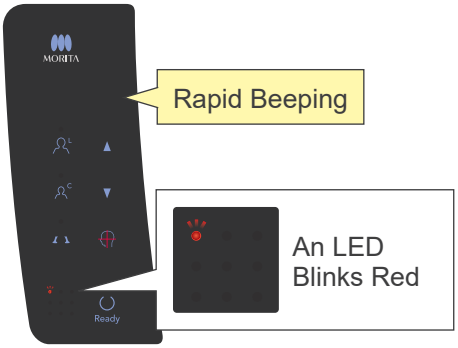
Rapid beeping and 3 LEDs blinking in the pattern shown to the left indicate error C6.

(Possible Causes)

• Application (i-Dixel) is not running

(Response)

• Make sure application is running



Error C0

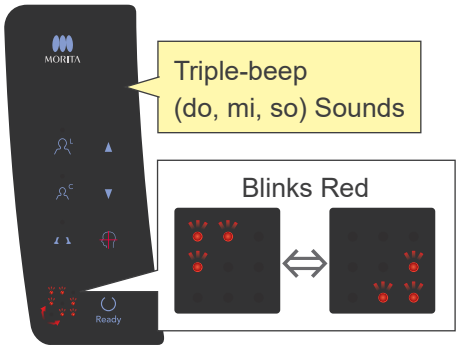
Rapid beeping and the LED shown to the left blinking indicate error C0.

(Possible Causes)

• Application (i-Dixel) is not ready for an exposure.

(Response)

• Restart application.

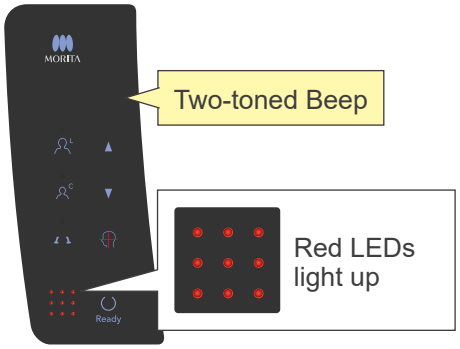


Lift Error

The photo at the left shows what happens when there is a lift error.

(Response)

• While the lift is not moving, press the Up or Down key



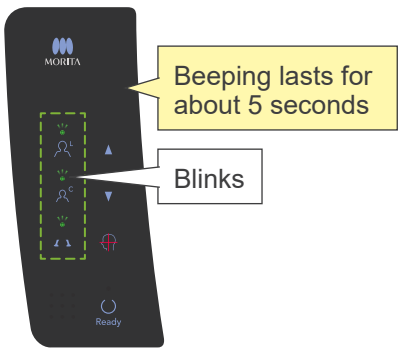
Emergency Stop Error

The photo at the left shows what happens when there is an emergency stop error.

(Response)

• If emergency switch was pressed, restore the emergency switch to its normal setting and then turn the unit off. Wait 10 seconds and then turn the unit back on again.

• If the emergency switch has not been pressed, turn the unit off immediately and contact your dealer or J. MORITA OFFICE.



Arm Error

The photo at the right shows what happens when there is an arm error.

(Response)

• Check to see if something is blocking the arm. Then press the standard panorama, pedodontic panorama or TMJ key.

• The X ray head may be overheated due to excessive use.
Turn the unit off, wait about 30 minutes, and then turn it back on again.

Veraview IC5 DDAE Verification Procedure

Content

For V3.00 First Edition

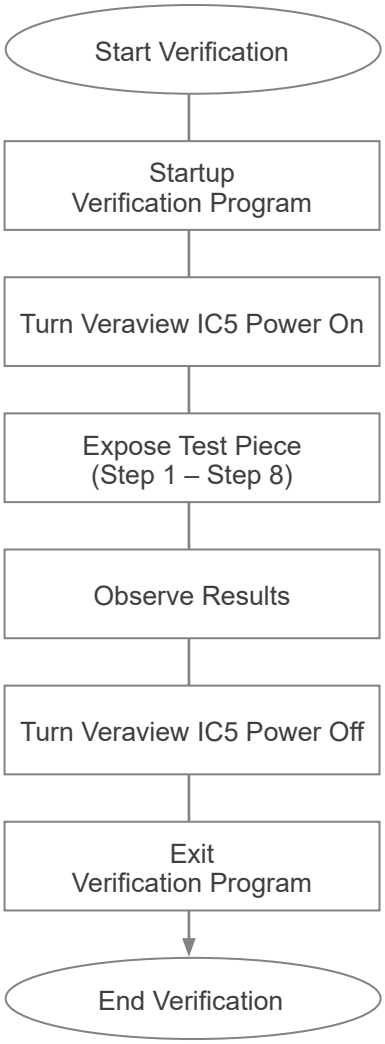
1. Introduction

1-1. DDAE Verification

This procedure tests the effectiveness of the auto exposure (DDAE) function, which regulates X-ray emission depending on the transparency or opacity of the X-ray subject.

1-2. DDAE Verification Flowchart

Perform the DDAE verification according to the following procedure:



1-3. Warnings and Caution

* If any errors occur during the verification procedure, turn off Veraview IC5 immediately and exit the verification program.
  Repeat the procedure from “Start Verification”.

2. Setup

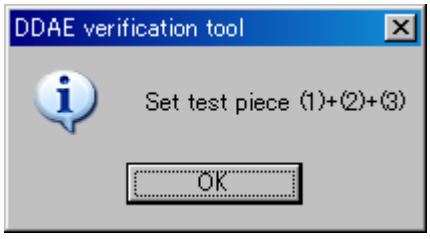
2-1. Equipment Checklist

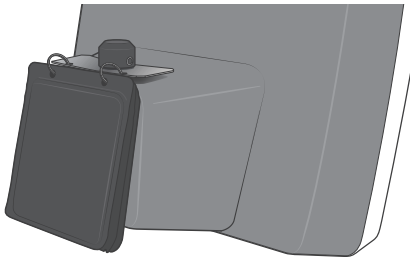
- CDROM that includes the Verification Program
- Test Piece which is used for the verification test (option)

2-2. Set Test Piece

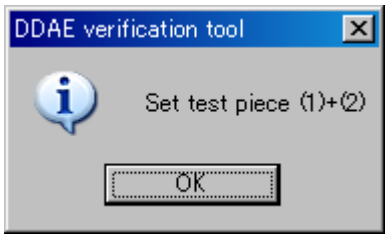
Set the test piece as follows when asked by the verification program.
The test piece consists of three copper plates: (1), (2), (3).

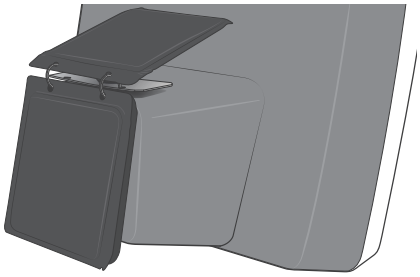
- If the following dialog is displayed, set test pieces (1), (2), (3).



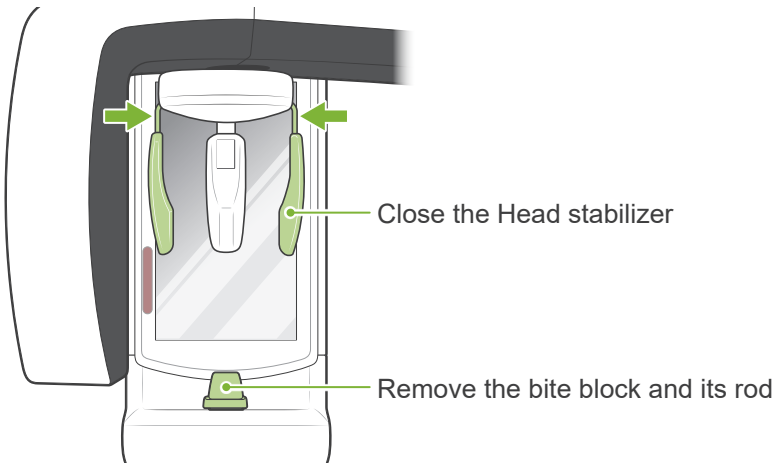


- If the following message is displayed, set test pieces (1) and (2).





*Notice

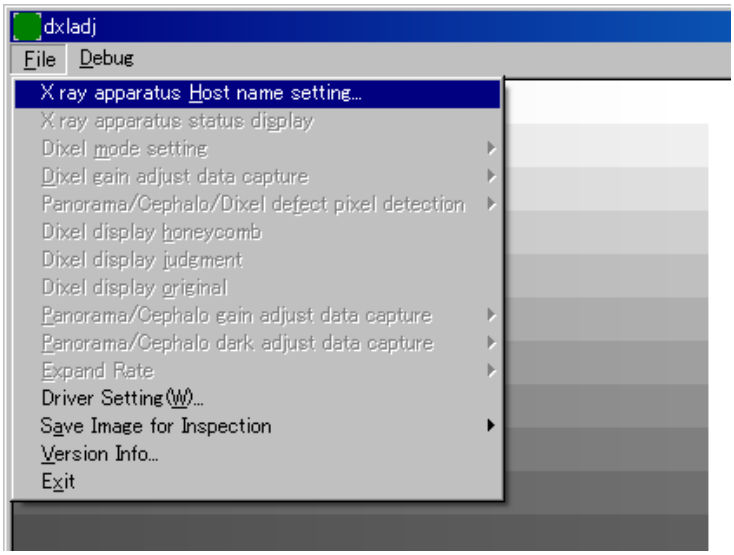


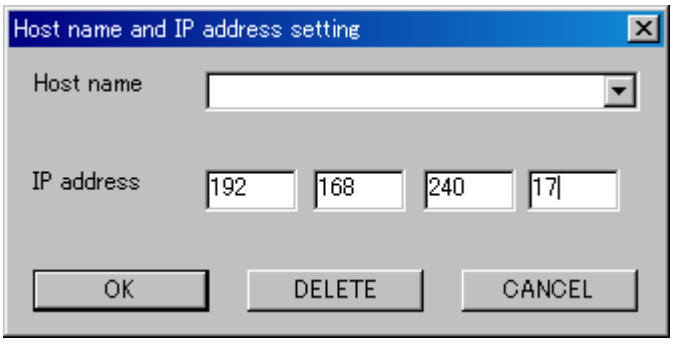
2-3. Explanation of the Test Program

2-3-1. Dxladj

2-3-1-1. Startup

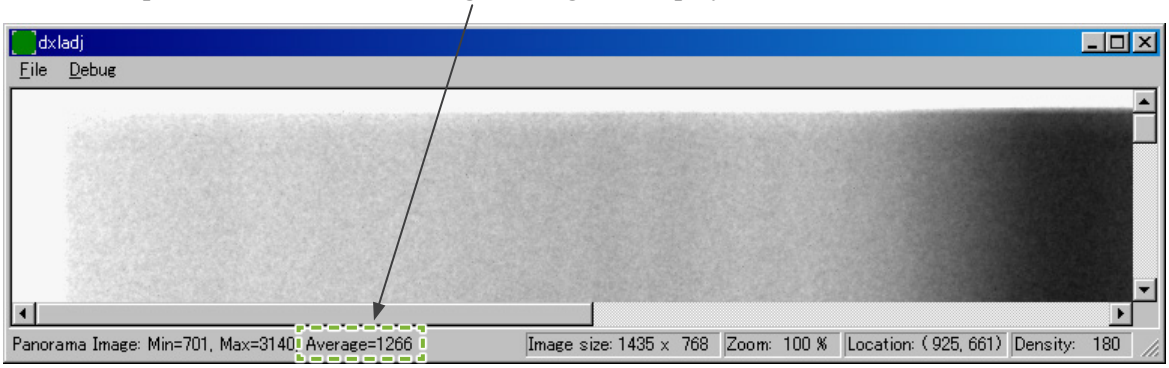
1. Exit the data base application and startup Dxladj.exe.
2. File-->Click the host name setting of the connected X-ray device.
   Change the IP address to 192.168.240.17.





2-3-1-2. Acquire Panorama Image Average

After the exposure, the “Panorama Image Average” is displayed in the status bar.

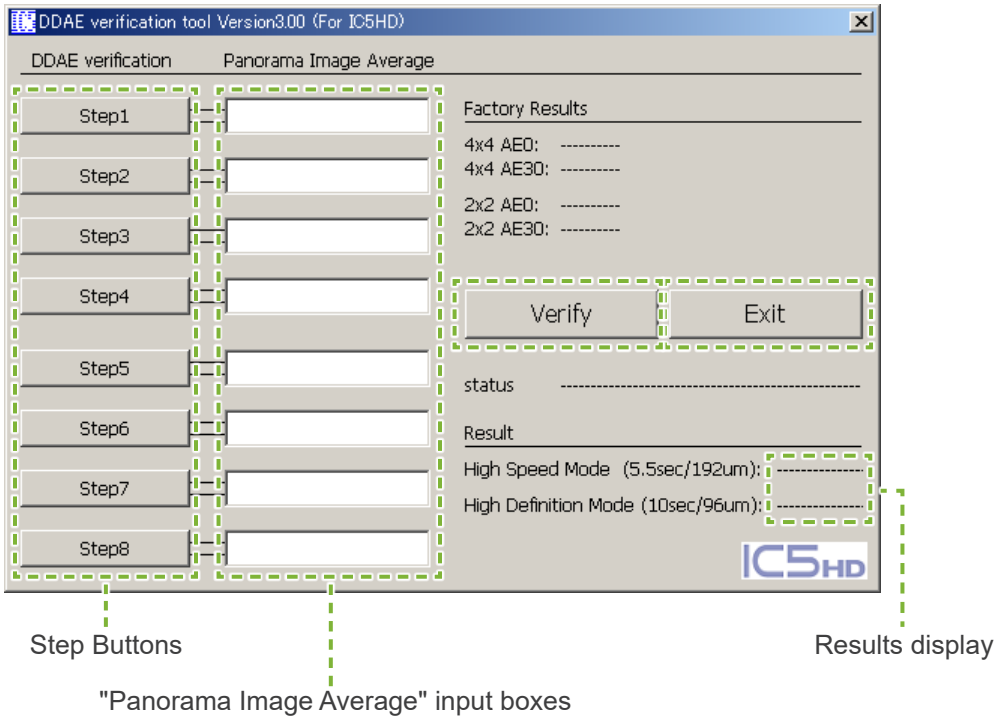


2-3-2. DDAE_Verification_tool

2-3-2-1. Startup

Double-click the “DDAE_Verification_tool.exe” file on the CDROM.

2-3-2-2. Window Explanation



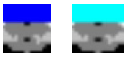
- Step Buttons
  Set the device modes according to the selected step.
- “Panorama Image Average” input boxes
  After the exposure, input the acquired “Panorama Image Average” for the step performed.
- Verify Button
  Performs DDAE verification based on the input parameters.
- Application exit button
  Closes the application.
- Results display.
  Display the results of the DDAE verification.

3. Verification Procedure

(1) Exit the database application then run the Dxladj program and set the host name.

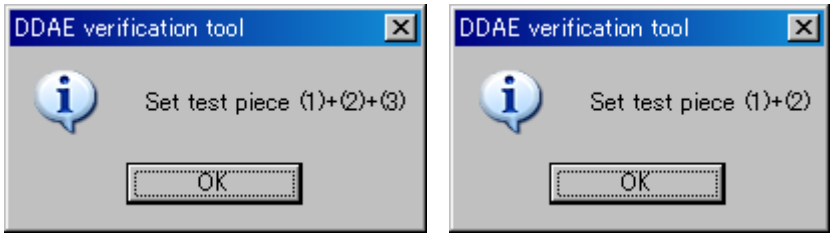
(2) Start the DDAE Verification Tool.

(3) Turn on Veraview IC5.

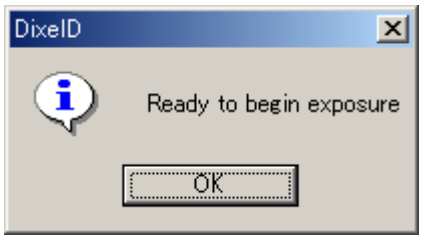
(4) When the resolution icon is displayed on the task bar, set the test piece then expose it by performing steps 1 through 8 in order. * Resolution icon: 

1. Press the “Step 1” Button.

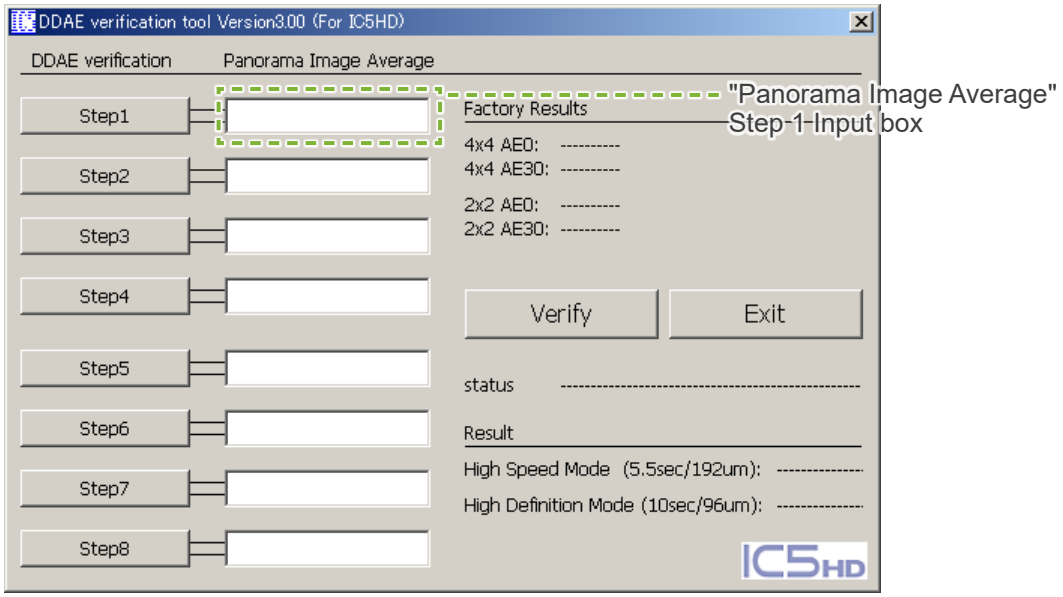
2. Set the test pieces listed in the message box and click “OK”.



3. When the exposure mode is set correctly, the following message is displayed with a confirmation sound. Click “OK” to start the exposure.



After the image transfer, enter the “Panorama Image Average” which is displayed in the Dxladj status bar into the Step 1 input box.



4. Do Steps 2 through 8 the same way as Step 1, each time recording the resulting Panorama Image Average.

5. Verify the results of steps 1 through 8.

   Click the “Verify” button to view the results of steps 1 through 8.

   Display the result of each exposure mode:
   High Speed Mode (192 um), and High Definition Mode (96 um).

   OK: DDAE verification succeeded.

   Failed: DDAE verification failed.

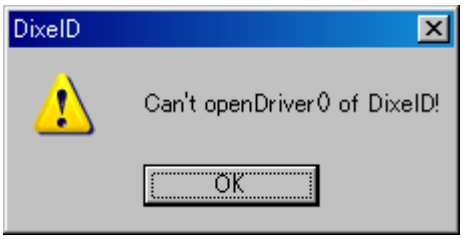
6. Turn off Veraview IC5.

7. Exit the DDAE Verification tool.

8. Exit Dxladj.

4. Troubleshooting

1. [Problem]
   The following error message from Dxladj is displayed:



   [Cause]
   The database application and Dxladj are running at the same time.

   [Solution]
   Shutdown the database application then restart Dxladj.

2. [Problem]
   The following error message from the DDAE Verification tool is displayed:

   [Cause]
   The required communication acknowledgement signal was not received from Veraview IC5.

   [Solution]
   Turn off Veraview IC5 and close Dxladj and the DDAE Verification tool.
   Restart the procedures from Step 1.

3. [Problem]
   The following error message from the DDAE Verification tool is displayed:

   [Cause]
   Non-integer characters are present in the “Panorama Image Average” input boxes or the box has been left blank.

   [Solution]
   Ensure the correct value has been added to the “Panorama Image Average” box.

Technical Specifications

Specifications

Product Name	Veraview IC5 (The Veraview IC-5 is an identical product to the Veraview IC5.)
Model	XDP1
Type	EX-1, EX-2

Classification

Protection against Electric Shock	Class I, Type B
Type B Applied Parts	Head Stabilizers, Bite Block and Plate, Chin Rest, Lip-nose Rest and Patient handles (No conductive connection to patient.)
Protection against Ingress of Liquids	IPX 0
Operating Altitude	3000 m (max)
Pollution Degree	2
Overvoltage Category	II
Mode of Operation	Non-continuous operation
Duty Cycle	1:29, for example 10 sec. exposure per 5 minutes cool-down period.

Disinfection Methods

- Between patients, type B applied parts disinfect 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%).
- Single use item; bite block cover.

Intended Use

The Veraview IC5 is an extraoral source X-ray unit that is used for dental radiographic examination and diagnosis of teeth, jaw, oral structure and TM-joints by exposing an X-ray image receptor to ionizing radiation.

X-ray Tube

Model	D-055SB
Focal Spot	0.5
Target Angle	12.5º
Target Material	Tungsten
Inherent Filtration	At least 1.0 mmAl
Maximum Input Energy	635 w (1 sec.)
Circuit (Center-Grounded)	Constant Potential (DC)
Maximum Filament Current	3.0 A
Filament Voltage	2.8 - 3.6 V (At max. Filament Current 3.0 A)
Filament Frequency Limits	0 - 20 kHz

Generator / X-Ray Head Assembly

Operating Tube Potential	60 to 70 kV (Automatic control) (accuracy of programmed setting values ± 10 %)
Operating Tube Current	1 mA to 7.5 mA (Automatic control) (accuracy of programmed setting values ± 10 %)
Reproducibility of Air Kerma	Coefficient of variation max. 0.05
Maximum Output Power	525 W (70 kV, 7.5 mA)
Filtration	Inherent filtration minimum 2.5 mm Al, 70 kV/HVL 3 mmAl (X-ray tube filtration: min. 1.0 mm Al, Al filter: 1.5 mm)
Beam Quality	HVL minimum 1.5 mm Al at 70 kV
Primary Protective Shielding	Minimum 0.5 mm Pb or equivalent
Outer Shell Temperature	45ºC maximum
Duty Cycle	1:29
Filament	Preheated
Rectification	Direct Current
Cooling	Oil cooling
Maximum Heat Unit of	116 kJ (1 HU = 1.35 Joule, 1 J = 1 Ws)
Leakage Radiation	Max. 1.0 mGy/h at 1 m
Weight of X-ray Head	Approximately 6 kg
Assembly Minimum mAs	4.8 mAs

Auto Exposure (DDAE)

Tube Voltage	Pedodontic, High Speed Mode 65 kV (Fixed) Other modes 70 kV (Fixed)
Tube Current	Automatically changed based on the X-ray absorption of the object. Maximum possible excursion 1 – 7.5 mA
Reproducibility of Air Kerma	Coefficient of variation max. 0.05

Power Requirements

Rated Nominal Voltage	EX-1 AC 100 – 120 V, 50 – 60 Hz single phase (120 V only for the US and Canada) EX-2 AC 220 – 240 V, 50 – 60 Hz single phase
Fuse at Distribution Panel	EX-1 20 A, slow EX-2 16 A, slow
Power Consumption for EX-2	0.93 kVA 0.2 kVA (stand by)
Power Line Resistance	EX-1 max. 0.5 Ohm EX-2 max. 1 Ohm
Maximum Input Amperes for EX-1	Max. 9.4 – 7.9 A (100 – 120 V with operation) 0.5A (stand by)
Line Voltage Regulation = 100 (Vn – Vi)/Vi Vn = No-load line voltage, Vi = Load line voltage	3%
Technique Factor for Maximum Input Amperes	70 kV 7.5 mA
Means Isolation from Supply Mains	Mains plug

Mechanical Parameters

SID	520 mm (± 20 mm)	
SSD	Min. 150 mm	
Magnification	1.234 to 1.3	
Weight		
Main Unit	Approximately 110 kg	Boxed
Control Box	Approximately 0.33 kg	Boxed
Outer Dimensions		
Main Unit	W 890 × D 970 × H 2,350 mm W 890 × D 970 × H 2,180 mm (Option)	
Control Box	W 120 × D 60 × H 120 mm	
Vertical Height of Focal Spot	1,045 to 1,830 mm ± 20 mm, 960 to 1,660 mm ± 20 mm (Option)	
Positioning Beams	3 provided (Sagittal, Frankfort, Image layer) Class 2 Laser Wavelength: typical 655 nm Beam divergence: 120 mm ± 10 % in length, 0.8 ± 0.2 mm in width @ 250 mm Pulse duration and repetition rate: Continuous Maximum energy output: 1 mW (based on IEC60825 - 1,21 CFR PART 1040.10)	
Attenuation Equivalent of Head Stabilizer, Bite-Block and Chin Rest	Less than 1.7 mm Al	

Exposure Time and Accuracy

High Speed Mode	Panoramic: 5.5 s Pedodontic: 4.8 s TMJ Quadruple: 3.9 s
High Definition Mode	Panoramic: 10.0 s Pedodontic: 8.8 s TMJ Quadruple: 7.1 s
Accuracy	± (5% + 50 ms) (* Registered value for FDA is ±10%)
Emission Switch	Dead Man Type

Leakage Technique Factors

Panoramic	70 kV, 900 mAs/h (70 kV, 7.5 mA, duty cycle 1:29, for example 5.5 s exposure per 2 min 40 s cool-down period)

Measurement Bases

The kV is: Actual X-radiation is monitored by Non Invasive Evaluator of Radiation Output.
The mA is measured by monitoring current in the HT return line, which equals the tube current.
Exposure time: Starting point of exposure is determined at the time when the kV value reaches to 75% of average kV value. Termination of exposure is determined at the time when the kV value decreases to 75% of average kV value.
Test instruction of X-ray tube voltage, current and exposure time: Constant (manual) exposure mode.

Collimator

1 fixed collimator (Panoramic slit)

Digital Radiographic

Sensor	Full flame transfer type 2 dimension CCD image sensor
Resulting Image Format	Max. 288 × 147.5 mm
Detail Recognition (Resolution)	0.192 mm pixel size for High Speed mode 0.096 mm pixel size for High Definition mode
Imaging Method	Time Delay Integration

Image Quality

Line Pair Resolution	2.5 LP/mm
Low Contrast Resolution	Diameter 2.0 mm

X-Ray Dose Data

The Veraview IC5 uses auto exposure to deliver the optimum X-ray dose for the patient.

The following image information is recorded for each exposure.

- Dose-Area-Product (DAP) (mGy * cm^2)
- 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 * cm^2) 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 displayed is the multiplication product of the air kerma end 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.

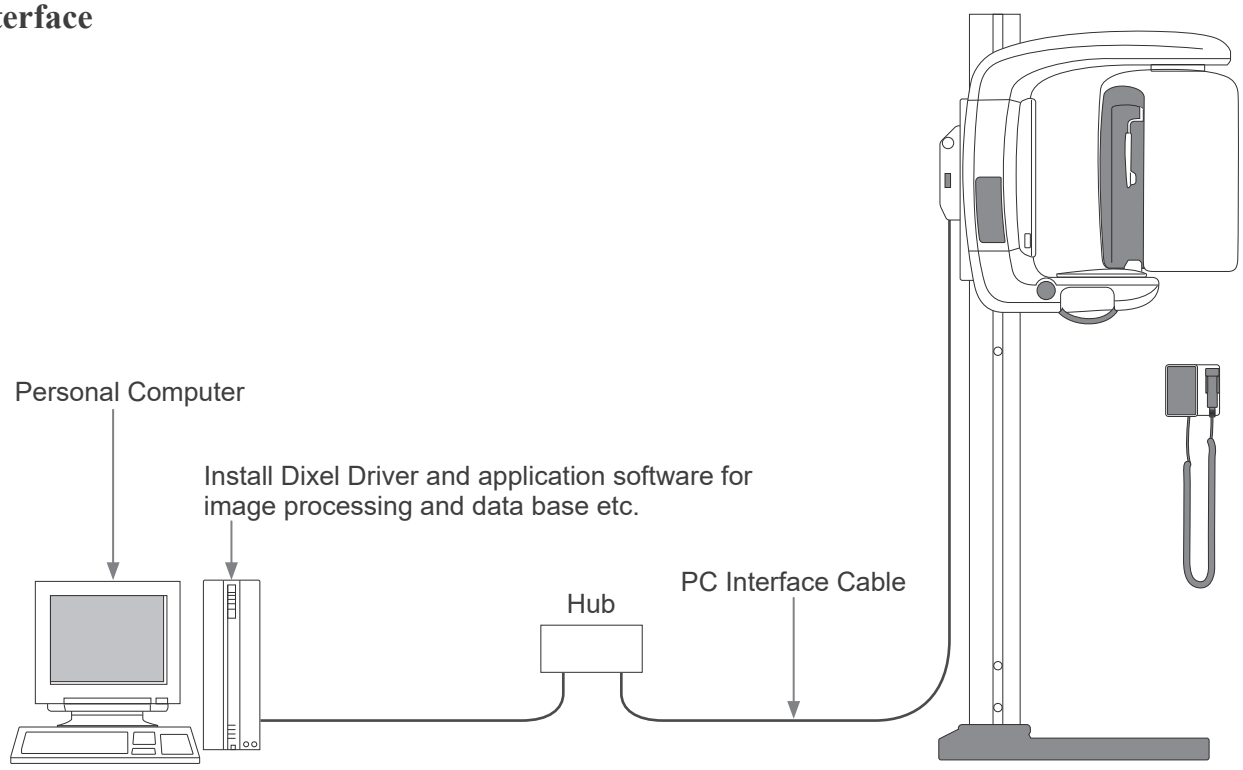
The air kerma is calculated by divided the Dose area product by the X-ray field size of W: 6 mm x H: 143 mm.

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

The dosemeter 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. Be careful it does not fall and that its wiring is properly routed.

Interface



SIP/SOP statement

Cable connection:	Unshielded twisted pair cable with RJ-45 plug connections, max. length 2 m.

Requirements for Computers and Their Peripheral Devices

1. The Veraview IC5 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 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 Veraview IC5. Ask your nearest J. MORITA OFFICE for proper selection of equipment and connections.**

⚠CAUTION

The following devices may not be located in the X-ray protection area (see page 4) or the patient vicinity except the Hub if the Hub is conformed with IEC60950-1 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:	Intel Pentium IV 1.7GHz or higher, or compatible.
Memory:	RAM 512MB
HDD:	HDD 20GB or more are recommended.
Video board:	Video capture board resolution of 1024 × 768 and color depth of 24bit
Network protocol:	TCP/IP with static IP address.
Network interface:	Universal purpose 10BASE-T Ethernet network interface board
Port occupied:	69/udp, 2102/tcp, 2102/tcp
Others:	Network board, CD-ROM drive.
Display:	17 inch TFT LCD 16 million colors 1024 × 768 pixels or better
Standard:	IEC60950-1 or IEC60601-1 EMD regulation Related UL standard (addition to U.S.A.) Related C-UL standard (addition to Canada) Local regulations

Hub

10 Base-T, 100 Base-TX

Standard:	IEC60950-1 if it is used in non-patient vicinity IEC60601-1 or IEC60950-1 with enclosure leakage current is conformed with IEC 60601-1. EMD regulation Related UL standard (addition to U.S.A.) Related C-UL standard (addition to Canada) Local regulations

Recommended Hub, for example

Manufacturer:	Bay Networks
Type:	Bay Stack 350T

Storage Device — Patient data can be saved safely. MO or CD-R disk drive is recommended.

Standard:	IEC60950-1 if it is used in non-patient vicinity EMD regulation Related UL standard (addition to U.S.A.) Related C-UL standard (addition to Canada) Local regulations

Other equipment connected to PC

Standard:	IEC60950-1 if it is used in non-patient vicinity EMD regulation Related UL standard (addition to U.S.A.) Related C-UL standard (addition to Canada) Local regulations

Application Software — Application software for image processing or data base is provided by J. MORITA.
It shall be used with above Windows base computer specifications.
It conforms to 93/42/EEC (in EU), IEC62304 and 21 CFR (in U.S.A.), Medical device regulations (in Canada).
If another application software is used, it must conform to the above regulations and standards, and must match the Dixel driver from J. MORITA MFG. CORP.
Ask your nearest J. MORITA OFFICE for the appropriate interface.

Environmental Data

Operating Conditions

Temperature	+10°C to +35°C (+50°F to 95°F)
Humidity	30% to 75% (without condensation)
Atmospheric Pressure	70 kPa to 106 kPa

Transportation and Storage Conditions

Temperature	-10°C to +50°C (+14°F to +122°F)
Humidity	20% to 80% (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.

Symbols and Markings

* Some symbols may not be used.

WARNING

This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

Explosion hazard: Do not use in presence of flammable anesthetics.

MISE EN GARDE

Cet appareil à rayons X peut présenter un danger pour le patient et l'opérateur, si les facteurs d'expositions qui ne présentent pas de danger, les instructions d'emploi et les programmes d'entretien ne sont pas respectés.

Risque d'explosion : ne pas utiliser en présence d'anesthésiants inflammables.

(EX-1)

NOTICE

The audible signal, which is installed in Control Box, is active when X-ray is emitted and is deactivated when X-ray is terminated.

AVIS

Le signal sonore, installé dans la boîte de commande, est activé lorsqu'un rayon X est émis et désactivé lorsque celui-ci est interrompu.

(EX-1)

Tube Voltage

Range: 60 - 70 kV
Accuracy: ±10% of Programmed Setting Value

Tube Current

Range: 1 - 7.5 mA
Accuracy: ±10% of Programmed Setting Value

Exposure Timer

Accuracy: ±10% of Selected Value

	High Definition Mode (sec)	High Speed Mode (sec)
Panorama	10.0	5.5
PEDO	8.8	4.8
TMJ	7.1	3.9

Tube voltage and tube current are controlled by DDAE.

X250-92123-500

(EX-1)

Laser Radiation

Focal Spot (dimple)

Emergency Stop

Main Switch
| : On
O: Off

CAUTION: X-RAYS-
ATTENTION: RAYONS X
WARNING—MISE EN GARDE:
- Any unauthorized use is prohibited.
- Hazardous X-rays are emitted when the equipment is in operation.
- Toute utilisation non autorisée est interdite.
- Lorsque l'équipement est en service, il émet des rayons X dangereux.

- CAUTION LASER, TO AVOID EYE DAMAGE DO NOT LOOK INTO BEAM
- ATTENTION LASER, POUR ÉVITER DES DOMMAGES AUX YEUX NE PAS EGARDER DANS LE FAISCEAU

X710-95082-601

(EX-1)

X-ray Tube Head Assembly Label

Type B Applied Part

Rating Label
Certification / Identification Label

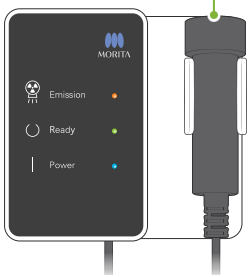
CAUTION
LASER RADIATION
DO NOT STARE INTO BEAM
CW: 600 - 700nm, Max 1mW
CLASS II LASER PRODUCT

(EX-1)

LASER RADIATION
DO NOT STARE INTO BEAM
CLASS2 LASER PRODUCT
レーザ光
ビームをのぞき込まないこと
クラス2レーザ製品
出力 Max.1mW レーザダイオード 655nm
IEC 60825-1: 2007

(EX-2)

X-ray Emission Switch



Equipotentiality

Use this terminal when it is required to use potential equipotentialization conductors, do not use for protective earth connection.

Package


This way up


Keep away from rain


Fragile


Temperature limitation


Humidity limitation


Atmospheric pressure limitation


Attention, consult accompany documents


Do not reuse

Rx Only

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.)

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

Serial number


Manufacturer


Date of manufacture


GS1 DataMatrix

Medical device

Unique device identifier


Alternating current


Refer to instructions for use

Country or region

(Country Names: Conforming to the ISO 3166-1 alpha-3 codes)

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

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.

EU authorized representative under the European Directive 93/42/EEC

(Valid only for EU)


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

(Valid only for EU)

cTUVus certification mark

(Valid only for U.S.A. and Canada)

Authorized representative in Switzerland

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

* For details, refer to “Technical Specifications” (p. 44).
* Some symbols described on the previous page may be included.

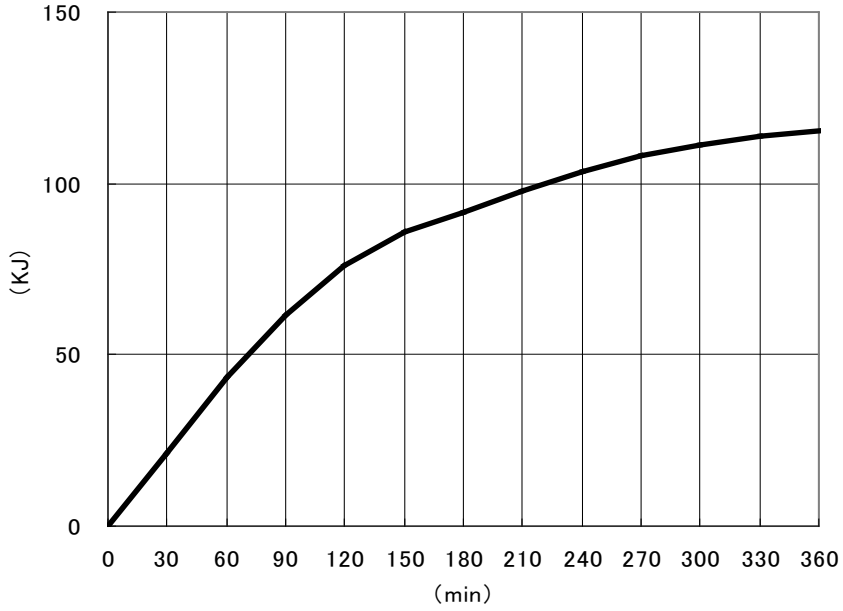
Rating Label

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

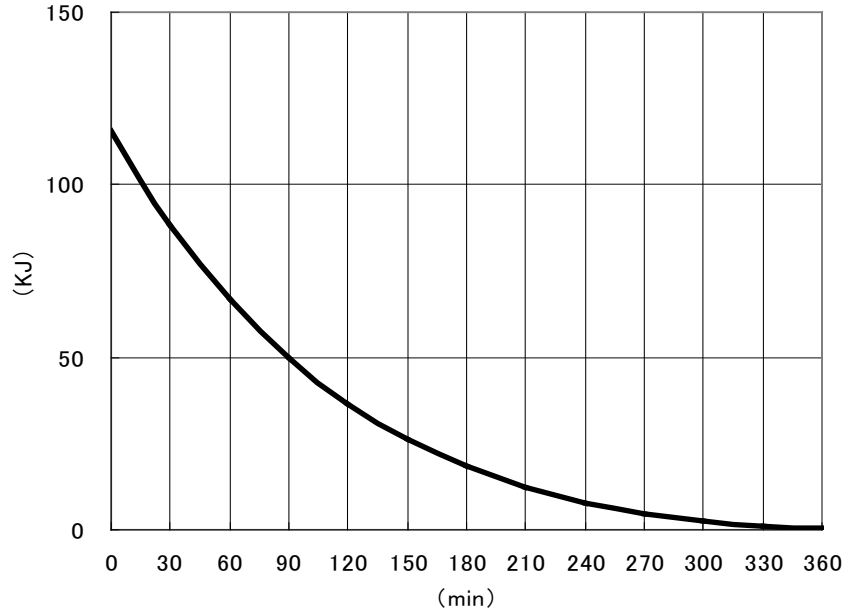
X-ray Tube Head Assembly Label

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

Tube Housing Assembly Heating Curve



Tube Housing Assembly Cooling Curve

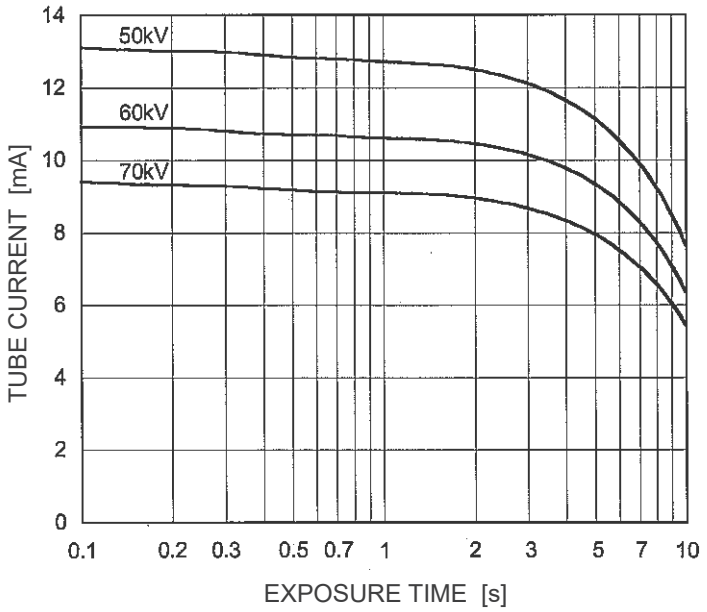


Tube Rating Chart

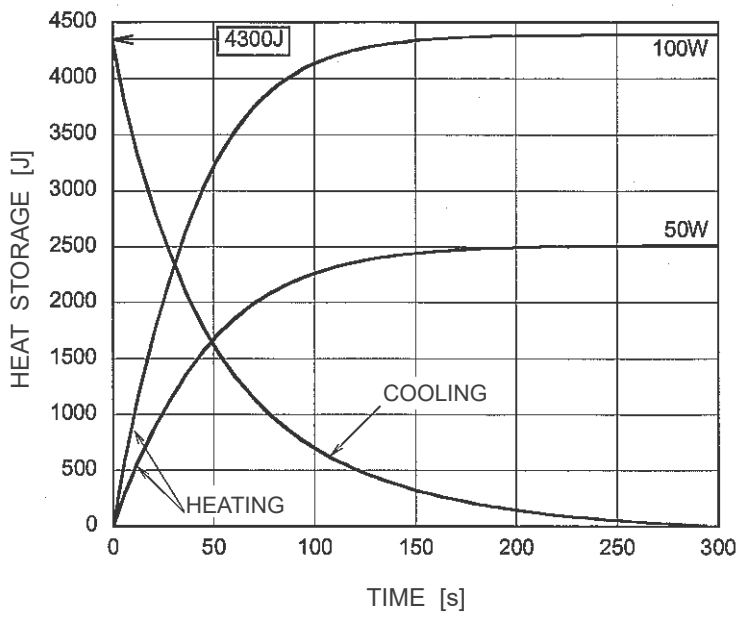
Maximum Rating Charts

(Absolute maximum rating charts)

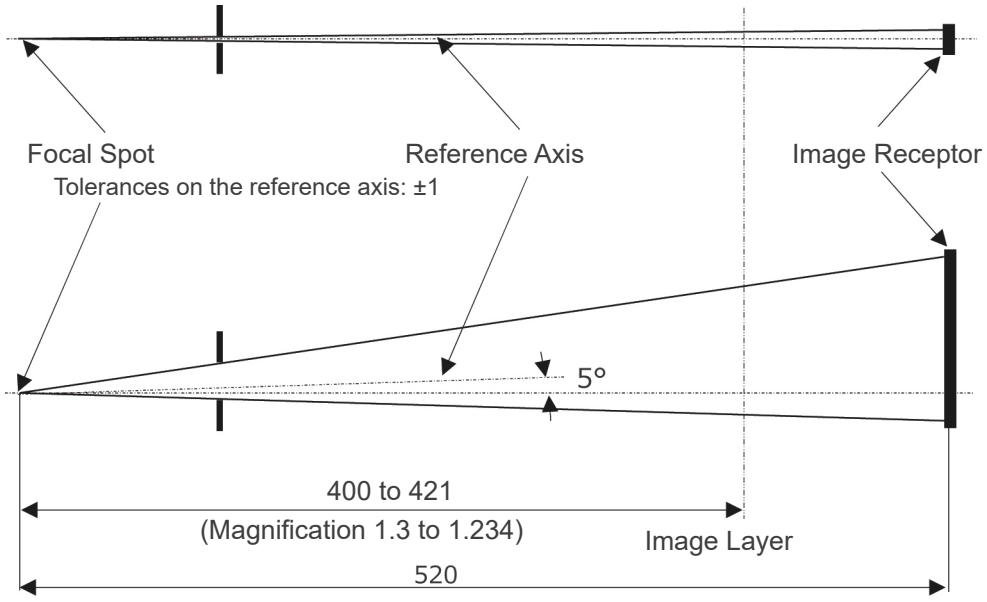
Focus Spot : 0.5 mm



Anode Thermal Characteristics



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



Unit: mm

Electromagnetic Disturbances (EMD)

The Veraview IC5 (Model: XDP1, hereafter “this device”) conforms to IEC 60601-1-2 Edition 4.1, the relevant international standard for electromagnetic disturbances (EMD).

Use Environment

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

⚠WARNING

- *Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.*
- *Use of accessories, transducers and cables other than those specified or provided by us could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.*
- *Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the XDP1, 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 XDP1.*

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 network that supplies buildings used for domestic purposes.
Harmonic current IEC 61000-3-2	Class A	
Voltage fluctuations and flicker IEC 61000-3-3	Clause 5	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/ bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output 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 Signal input/output ±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 Signal input/output*1 ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (r.m.s.) 50 Hz or 60 Hz	30 A/m (r.m.s.) 50 Hz or 60 Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC61000-4-39	30 kHz CW, 8 A/m 134.2 kHz 2.1 kHz, 65 A/m 13.56 MHz 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 1: U_T is the a.c. mains voltage prior to application of the test level. NOTE 2: r.m.s.: root mean square			

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

*2: This test is not applicalble 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 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 *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, *E* is the compliance level in V/m and *d* is the recommended separation distance in meters (m). 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: 
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	

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.

Diagnostic and Imaging Equipment

Treatment Units

Handpieces and Instruments

Endodontic Systems

Laser Equipment

Laboratory Devices

Educational and Training Systems

Auxiliaries

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