User Manual for Picasso - Duo (Release Version 1.0.0 / Published 2009-01)

Picasso - Duo

3-D Dental Imaging System

Compact & Standard Dental CT for Dental Clinics

• **User** Manual for Picasso - Duo 3-D Dental Imaging System

CE 0499

ISO 13485:2003

E-WOO Technology Company Limited

Attention

For improvement of product performance, supplementation, or follow-up of information; the contents of this manual are subject to change without separate prior notice.

Please note that our company has neither responsibility for any accidents nor obligation to do free repair service for any damage of the equipment due to user's mistake, which resulted from failure to follow the contents in this manual. Make sure to be familiar with the safety precautions and usage procedures. Also note that the product may slightly differ from the contents of this manual depending on specification.

The following marks are used for the effective use of the product in this manual.

Indicates useful information and tips to use the system and about the system.

Indicates important instructions. If not observed, malfunction or damage to the system or other property may occur.

Indicates warnings and instructions for SAFETY. If not respected, serious risks and injury may be caused to the patient and user.

Contents

1

Product Overview

This chapter describes the overall features and components of the products, as well as various detailed cautions.

1. Product Overview

Picasso-Duo is a diagnostic equipment that incorporates Digital Dental Panoramic Imaging System & Computed Tomography System with Cone Beam Technology. This equipment is based on Digital and Computed Tomography. Specifically, its advanced digital imaging process allows for a considerably efficient diagnosis, well-rounded management information, and a real-time sharing of image information in a network. It is equipped with the state-of-the-art CT sensor to capture 3D X-ray Computed Tomogram Scanned Images. This manual provides information for the users of Picasso - Duo. So users must read this manual carefully before using the product.

1.1. Product Features

- Picasso-Duo, a dental CT with digital panoramic system, provides high quality digital images.
- Picasso-Duo has a Sensor Auto-Switching function, thus providing user convenience because there is no longer any need to attach or detach sensors alternately for panoramic or CT imaging.
- Picasso-Duo helps the patients to understand diagnostic results through its 3D viewer program 'EzImplant', which allows the patients to see areas of their teeth that are invisible to the naked eye.
- Its wide FOV size enables the user to capture the Maxillary, Mandible, and whole arch.
- Picasso-Duo is a 2-in-1 system; therefore, there is no longer any need to purchase separate CT and panoramic systems.
- Viewing its 3D CT images is helpful to dentists for proper planning and treatment.

- It occupies a disk space for installation that is no bigger than that of a general panoramic system.
- It provides a clear tomography image up to a minimum of 0.1mm at any direction.
- It has a drastically reduced X-ray expose dose, as compared to a medical CT, in consideration to patient's safety.
- The user can set and control the examination program mode with a console PC.
- It support more accurate diagnostic imaging through LCD, as well as voice announcement function for patients and staffs.
- Picasso-Duo supports DICOM Format.
- Picasso-Duo supports CD publishing of images.

1.2. Technical Specification

X-ray Beam: Cone Beam
Data Bit: 12bit
Slice Thickness (mm): 0~10mm
Rotating Unit Scan Angle (degree): 360deg
Number of Views: 720 frames
Number of Sliced Images: 384 slice
Voxel Size : 0.2 mm
Patient Position: standing
Patient Alignment: Normal standard Arch Alignment
FOV: 8x8, 13x8 (Cm)
Reconstruction Time : 8X8 : Less than 1 minute, 13X8: Less than 1 minute
Exposure Time:

Standard Panoramic Adult/Child	
Standard scan	13 sec
High scan	9 sec
Hemi-Panoramic (Left and Right)	6.5 sec
Frontal Dentition	10 sec
TMJ Open/Close mouth	2.8x4 sec
Maxillary Sinus	10 sec
Incisor clear	5 sec

Canal clear	3.8 sec
Maxillary Molar clear	3.8 sec

Scan Time: [CT] (8X8) Scan Time	Normal Mode	:	15 sec
	High Mode	:	24 sec
[CT] (13X8) Scan Time	Normal Mode	:	15 sec
	High Mode	:	24 sec

Anatomic Programs

- Patient Type: 3 choices (adult man, adult woman, child)
- Patient Size: 3 choices (hard, normal, soft)
- Patient Jaw Size: 4 choices (Normal, Narrow, Wide, child)

Panorama X-ray detector

- Technology: TDI type (Time Delay Integration)
- Active Area: 147.456x6.144 mm
- Image Acquisition Area: 146x6 mm
- Pixel Resolution: 5.2 lp/mm
- Gray Level: 12 bit

X-ray Tube

- Focal Spot Size : 0.35x0.5 mm
- Tube Voltage : 40~90 kVp
- Tube Current : 2-10 mA

Environmental Characteristics

• Operating temperature	10 ~ 40℃
• Operating relative humidity	30 ~ 75%
• Operating atmospheric pressure	700 ~ 1060 hPa
• Transport and storage temperature	-20 ~ 70℃
• Transport and storage relative humidity	< 90% non-condensing
• Transport and storage atmospheric pressure	500 ~ 1060 hPa

Source to image distance [Focal spot to Sensor]	**CT:**	692 mm
	Pano:	601 mm
Vertical column movement:	**Max:**	700 mm

Weight	185 kg
Length * Width * Height:	(L)1490*(W)1057*(H)2346 mm

Generator

• Ripple	< 4%
• Inverter frequency	36 kHz push-pull
• Tube type	D-051, stationary anode type
• Nominal power	Below 1.3 KW
• Tube voltage	
CT Mode	50 - 90 kV (adjustable by 1kV)
Panorama Mode	40 - 90 kV (adjustable by 1kV)
• Tube current	
CT Mode	2.0 - 10.0 mA (adjustable by 0.1 mA)
Panorama Mode	2 - 10 mA (adjustable by 1 mA)
• High voltage	DC

1.3. Product Components

< Hardware Components>

- Equipment main frame
- User's manual
- Installation CD
- Accessories including Lock-Keys (Reconstruction Key and 3D Viewer Key)

NOTE

For improvement of product performance, the Components and specification of this product may be subjected to changes without any notice.

< Software Components>

- Viewer program : EasyDent4 V4 program, EzImplant(3D Viewer program)
- Imaging program : EasyDent4 V4

NOTE

For improvement of product performance, the Components and specification of this product may be subjected to changes without any notice.

1.4. Marks & Graphic Symbols

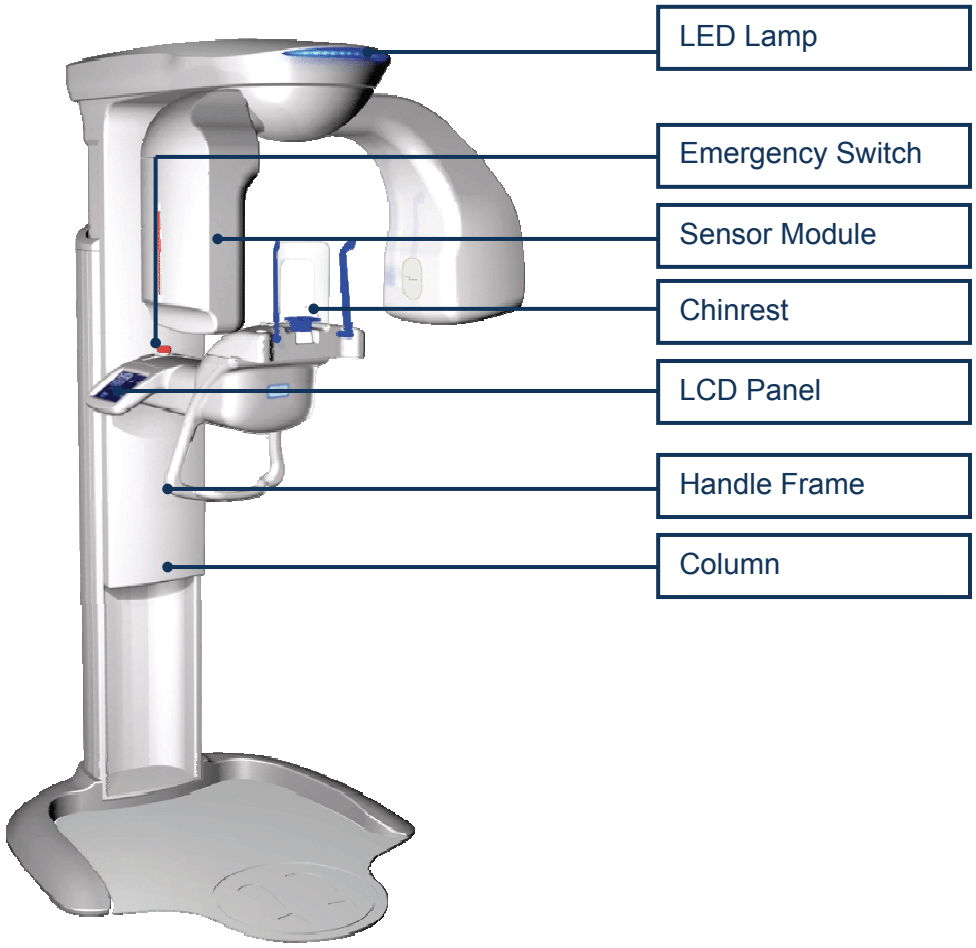
TYPE B Equipment

Radiation hazard

CE 0499

This CE symbol grants the product compliance to the European Directive for Medical Devices 93/42 as a class IIB device, as authorized by Grand-Duche De Luxemburg.

1.5. Structure & Parts



- **LED Lamp:** LED for checking X-ray irradiation
- **Emergency switch:** Switch to stop the movement of Picasso-Duo when it shows abnormal movement.
- **Sensor Module:** Digital X-ray image sensor module for (Panoramic and Dental CT). It is not necessary to attach and detach the panoramic sensor due to Auto-Switching systems.
- **Chinrest:** A part for fixing the patient head during panoramic imaging
- **LCD panel:** For operate the equipment through LCD panel
- **Handle frame:** A part to help the patient be set in a proper position.
- **Column:** For adjusting the column carriage height according to the height of patient.

NOTE

This equipment configuration may differ depending on the specification of your product.

1.6. Tooth bites

VATECH Co.,Ltd provides 4 kinds of tooth bites (supports). The use of each bite depends on the image to be taken.

① Normal bite

② Toothless support

③ TMJ support

④ Sinus support

1.7. Cautions

Make sure to observe the following.

- Follow the specified process of operation for the safety of the users and patients.
- Check the condition of each component of the product such as power, PC, and cable before using.
- Perform operation only when the product has stopped moving (initializing). Failure to follow this instruction may cause product malfunction.
- When capturing an image, make sure to let Cooling Time (a process of cooling down the X-ray tube) pass before proceeding to the next imaging status, in accordance with a voice announcement from the device after capturing the image.
- Place this product away from water, moisture, or foreign substances since this product is a precision medical electronic device.
- Off the power, immediately, if the product is exposed to water or foreign substances during use, resulting in abnormal operation. Contact the agent for technical support.

1.8. Warning

Make sure to observe the following.

- Picasso-Duo is a precision electro-mechanical system. Therefore, please read this manual carefully before operating the product. VATECH is not responsible for damages caused by improper installation and maintenance procedures, and wrong operations.

1.9. Radiation Protection Policy

Rules and regulations on radiation safety and protection of the country where the product is installed should be observed by the user since they differ among countries.

- User should wear lead apron or use protection wall to protect himself / herself from radiation during the imaging process.
- User should provide protection devices such as lead apron to patient during the imaging process.
- Children or pregnant women should consult with the doctor in charge before imaging.
- User should be at least 2 m (6 feet) away from the equipment during imaging.
- Equipment should be located inside an X-ray shield facility. During imaging; the worker should watch inside carefully, through the window, from outside the shield facility.
- User should continuously check the patient and the equipment status during imaging.
- User should immediately stop imaging if equipment malfunctions.

Do not use this product in an environment with risk of explosion. Be careful from such risk.

1.10. Manufacturer Liability Policy

The manufacturers / sellers of X-ray equipments, such as this product, only assume responsibility for a safe and normal operation of the product in the following cases:

- If the product is installed by our authorized agent.
- If the product is installed in accordance with cautions and conditions for installation.
- If a genuine product is used, as approved by our company.
- If maintenance and repair services are performed by our authorized agent.
- If the product has been normally used in accordance with the user's manual.
- If equipment damage or accident is not attributable to a mistake of the customer.

2

Software Functions

This chapter describes hardware components and software architecture of the product in details.

2. Software Architecture

2.1. Menu for Panoramic Imaging Unit

① Imaging Status and Image Display Window

Shows the image capturing progress status and the final captured image, on real time.

② Patient Information Window

Shows information such as name, age, gender, and chart no. of the patient, whose image is to be taken.

③ Imaging Instruction Window

Shows text instruction messages throughout the imaging process.

④ X-ray Setting Control Buttons

Shows the up and down arrow buttons for kVp, tube voltage value**;** and mA, tube current value adjustments.

⑤ Patient Select Buttons

For selecting the patient specifications such as gender (Man, Woman, Child) and bone density (Hard, Normal, Soft).

⑥ Panoramic Property Button

Selection: Standard or Special Mode.

(Select various types of imaging modes depending on the selected panoramic property.)

⑦ Panoramic Imaging Mode Buttons

- Standard modes selection:

Panoramic, Left, Front, Right, TMJ open, TMJ Close, Sinus

- Special modes selection:

Maxillary clear, Canal clear, Incisor clear, Orthogonal

⑧ Arch Select Buttons

Selections: Normal, Wide, Narrow, Child

⑨ Lamp Button

Turn the lamp On/Off for patient beam alignment

⑩ Imaging Mode Buttons

Select one of the following imaging modes; Panorama or Dental CT.

⑪ Confirm Button

Confirm the current setting (press the Confirm Button after making all the necessary settings).

⑫ Ready Button

Perform imaging according to the instruction message after clicking the 'Ready' button.

⑬ Image Processing Status Bar (Progress bar)

Shows the imaging and image processing progress status with a graph.

⑭ Exit Button

Exit the imaging program

NOTE

This software architecture may differ depending on the specification of your product and may be subjected to changes without notice for the improvement of product performance.

2.2. Menu on Dental CT

- FOV : 8X8

- FOV : 13X8

① Imaging Target area, Imaging Status, and Image Display Window

Shows the target teeth position to be captured and the imaging progress status, as well as the final captured image (shown on real time).

② Patient Information Window

Shows information of the patient such as name, age, and chart no.

③ Imaging Instruction Window

Shows text instruction messages during the imaging process.

④ X-ray Setting Control Buttons

Shows the up and down arrow buttons for kVp, tube voltage value; and mA, tube current value adjustments.

⑤ Patient Select Buttons

Shows the selection of patient type (Adult or Weak).

⑥ Dental CT Imaging Mode Selection Buttons

- For FOV 8X8

Mandible (Right, Front, Left), Maxillary (Right, Front, Left), Occlusion (Right, Front, Left), TMJ (Right, Left)

- For FOV 13X8

Mandible, Maxillary, Occlusion, TMJ (Right, Left)

⑦ Arch Select Buttons

Selections: Normal, Wide, Narrow, Child

⑧ Lamp Button

Turn the lamp On/Off for patient beam alignment.

⑨ Imaging Mode Buttons

Select Panorama or Dental CT imaging mode.

⑩ Confirm Button

Confirm the current setting (press the 'Confirm' button after making all the necessary settings).

⑪ Ready Button

Perform imaging according to the instruction message after clicking the 'Ready' button.

⑫ Image Processing Status Bar (Progress bar)

Shows the imaging and image processing progress status with a graph.

⑬ Exit Button

Exit the imaging program.

NOTE

This software architecture may differ depending on the specification of your product and may be subjected to changes without notice for the improvement of product performance.

3

Imaging Preparations

This Chapter describes product preparation before imaging, as well as explanations of the important functions for easy understanding and use of the product by the users. Refer to this Chapter for an effective use of the product.

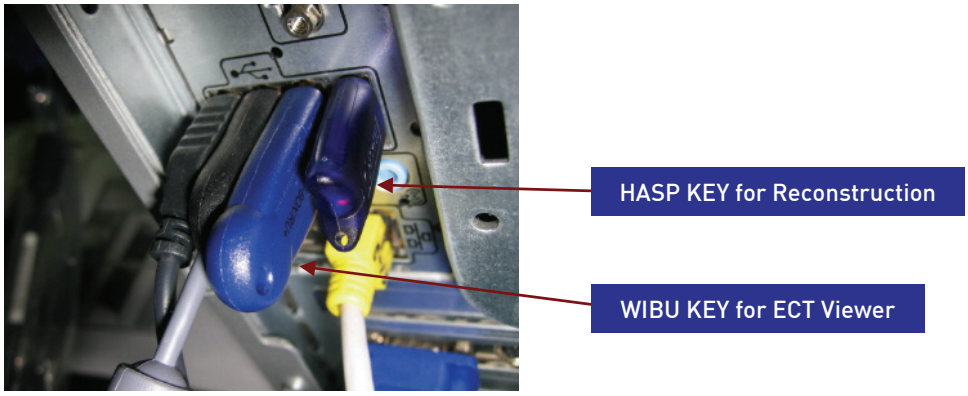
3. Imaging Preparations

3.1. Preparation before capturing an image

Make sure to check the following before capturing an image:

- **Check whether the imaging equipment is turned on.**

- **Check that the PC has two (2) lock keys, which are properly inserted. Then, switch on the PC.**



NOTE

You cannot capture and view Picasso-Duo images without the two lock keys.

3.2. New patient registration and imaging preparation procedures

3.2.1. How to register a new patient

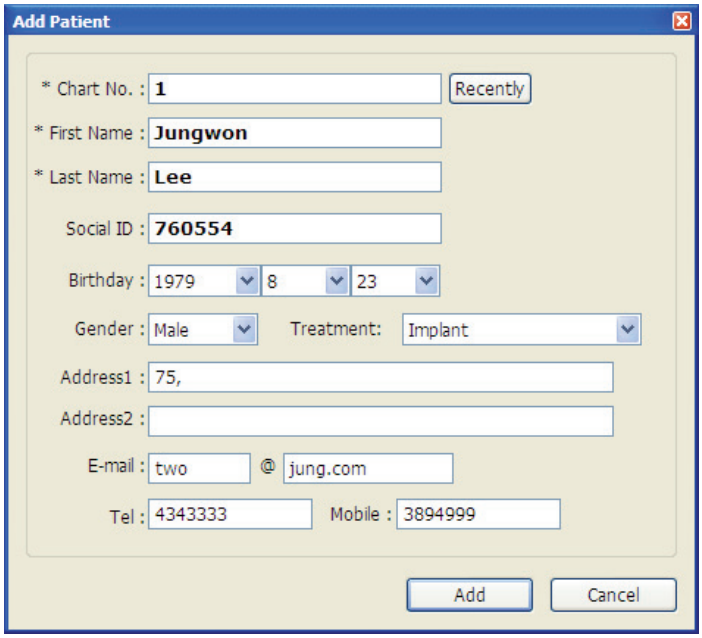
Follow the steps shown below to register a new patient:

① Turn on the Picasso-Duo equipment and the computer.

② On the computer, execute Easydent4 V4 and then click the 'Patient (

)' icon to register a new patient.

③ Enter the patient information when the following dialog box appears.



④ After filling out, click 'Add' to register and to close the dialog box.

NOTE

An unregistered patient should be registered first before capturing an image. For more information, please refer to Easydent V4 program user's manual, which is prepared separately.

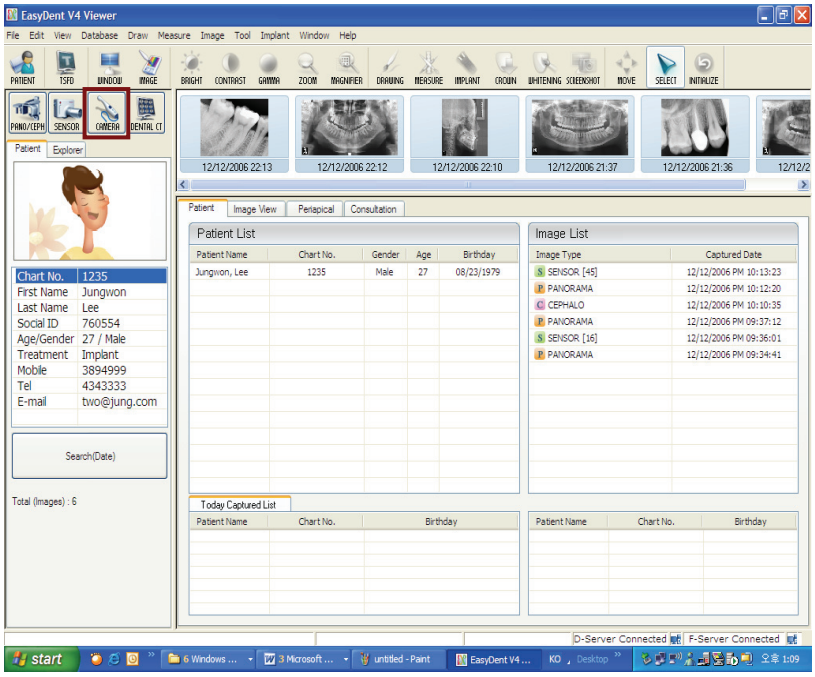
3.2.2. Panoramic Imaging Preparation Procedure

In order to capture an effective panoramic image, follow the imaging procedure in the order as specified:

① Check that the power switch of Picasso-Duo has been turned on.

② Execute the EasyDent V4 program on the PC.

③ The program will be displayed, as in the following figure below. Search and select the patient, whose image is to be taken.



[Main Screen of EasyDent V4 Program]

④ Click the 'Dental CT(

)' icon on the left upper part of the main screen to execute the imaging program.

⑤ The capture program will be run automatically and the Picasso-Duo system will be initialized.

4

Panoramic Imaging Procedures

This chapter gives instructions on how to position the patient and how to capture image on the panoramic imaging unit.

4. Panoramic Imaging Procedures

4.1. Preparation Before Imaging

Make sure that you conform to the following before starting:

- Start the imaging program on the PC only after switching on the power of the equipment.
- Check whether the equipment has been turned on.
- Do not perform any operation at the PC while the product is initializing.
- Check whether there is any problem in operation of the PC.

NOTE

Make sure that two (2) lock keys (Reconstruction key and EzImplant Key) are installed at the PC. You cannot capture and view the captured images without the two lock keys.

4.2. How to position the Patient on the Panoramic Unit

1) To capture a panoramic image, click the 'Panorama' button. Subsequently, the sensor will move to panoramic imaging initial position.

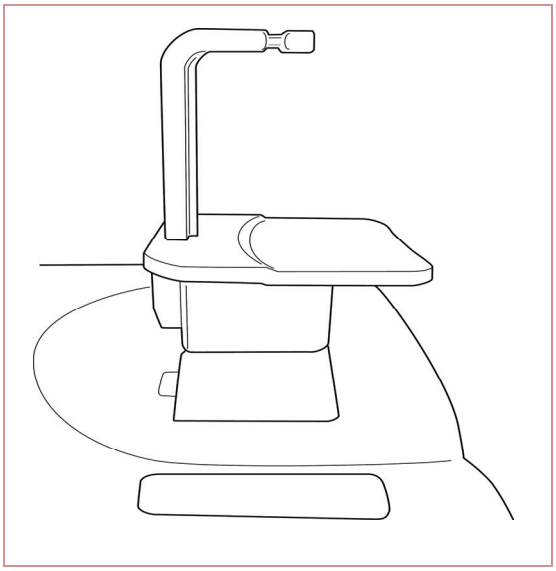
CAUTION

Do not operate the system and the capture program while the PC is initializing its communication with the sensor. Otherwise, failure of the system to function will occur.

2) After the initialization of communication between the PC and the sensor, set the configuration for image capturing. And then, click the 'Confirm' button.

3) Ask the patient to remove any metal objects; such as eyeglasses, dentures, hearing aids, hairpins, earrings, necklace, etc., from the head and neck area. Shadows caused by these opacities may obscure diagnosis.

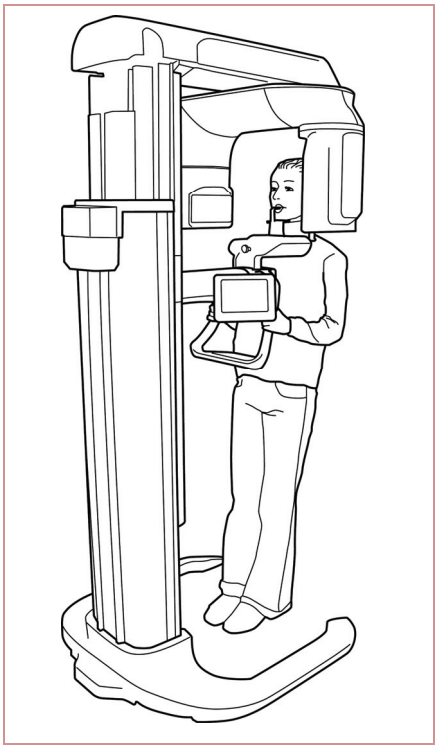
4) Insert the chin support and bite fork rod in hygienic cover on the chinrest.



5) Guide the patient to the radiation room to set position.

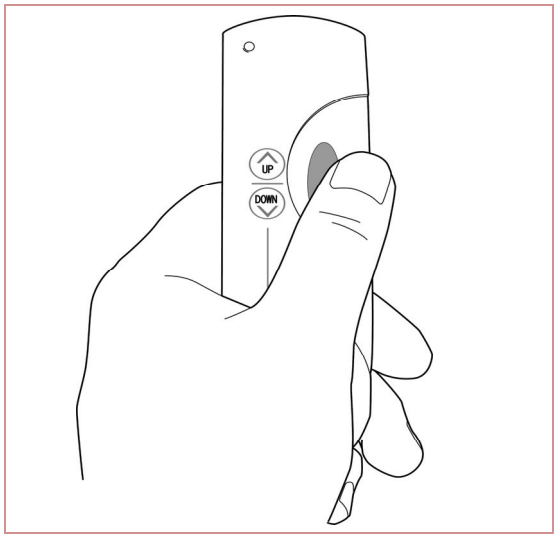
6) Have the patient wear protective clothing. It is recommended that the patient wear protective clothing, like lead apron, for protection against radiation.

7) Guide the patient to stand at the center of the system at upright position. It is better if the patient comes closer to the system as much as possible. Ask the patient to step forward and to hold the patient handles firmly.

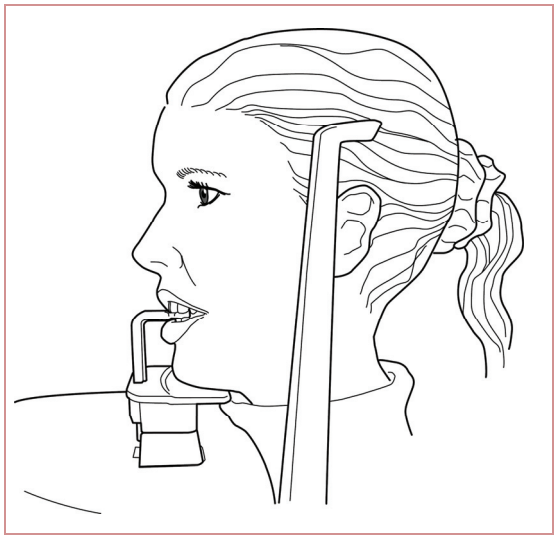


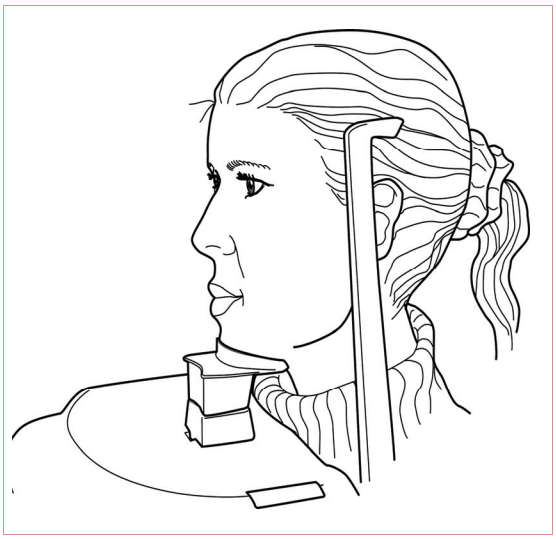
8) Press the 'Position' button on the LCD panel at the system. Subsequently, 3 light beams will appear as guides for proper patient positioning. Also, the camera will be turned on automatically and the patient's face will be displayed on the LCD panel to guide the operator in properly aligning the light beams at the landmarks on the patient's face.

9) Adjust the height of system to fit to patient using column up / down switch until the chin rest is on the level of the patient's chin. Stretch and straighten the patient's neck.



10) Make sure that the bite fork is covered with hygienic cover, then, ask the patient to bite the bite fork. The incisor edges of the maxillary and mandibular teeth must be along the groove of the bite fork.





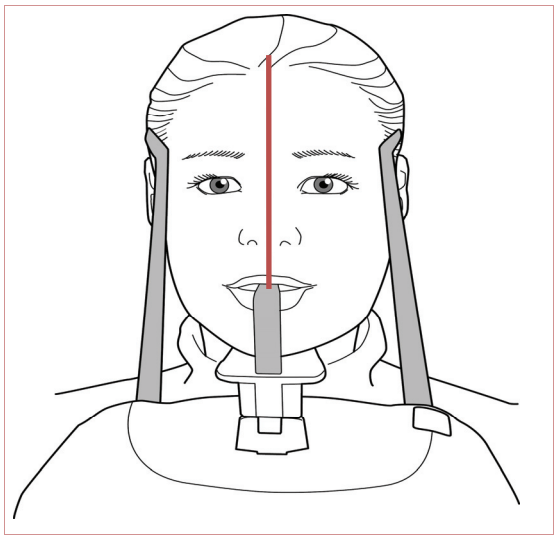
NOTE

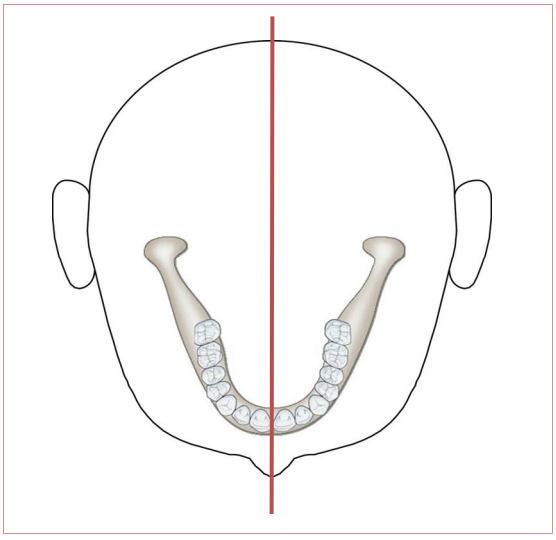
For a Patient with no teeth, the vertical beam should be positioned within the midsagittal line while the horizontal beam should be aligned along the Frankfort plane on the patient's face. The canine beam should be aligned within the fold at the side of the nose. The Patient's mouth should be closed.

11) Adjust the temples support to fit snugly on the patient's temples by turning the temple support wheel button at the rare of the patient support table.

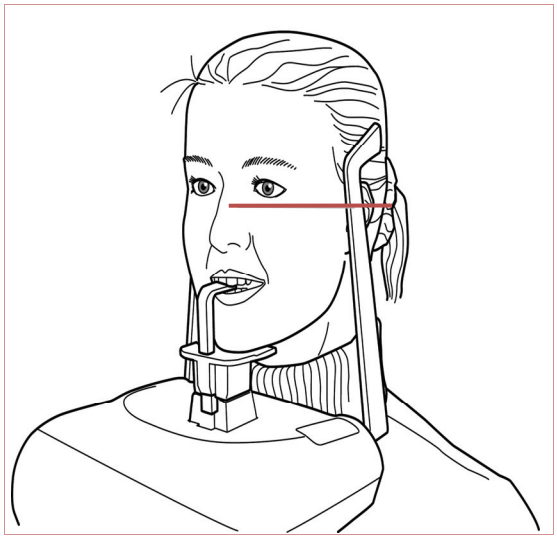
12) Make sure that the patient's shoulders are level and the neck is relaxed. The cervical spine should be straight and upright. If the vertical beam does not get through the center of the occipital bone, the panorama image would appear to have different magnifications on the right and on the left sides, or an unexpected ghost image would appear.

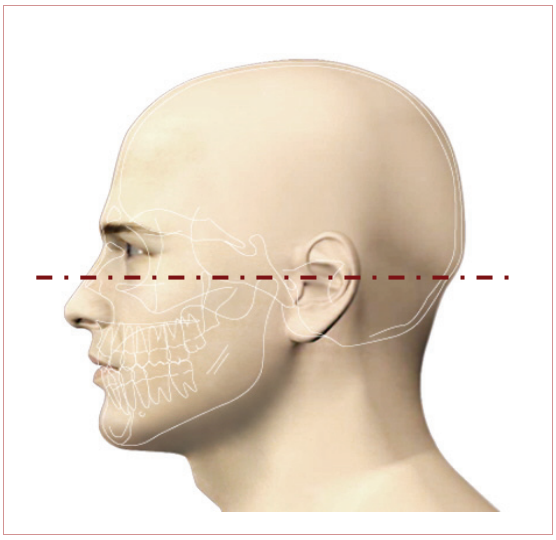
13) Position the head of the patient in a manner where the midsagittal plane will coincide with the vertical beam.



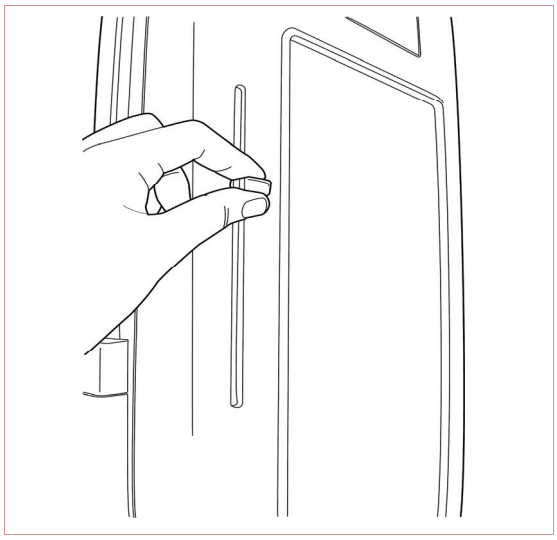


14) Position the head of the patient so that the Frankfort line will coincide with the horizontal beam. For proper positioning, adjust the tilt of the patient's head by adjusting the unit slightly upward or downward. Frankfort plane is the line from the infra-orbital point to the superior edge of the external auditory meatus.

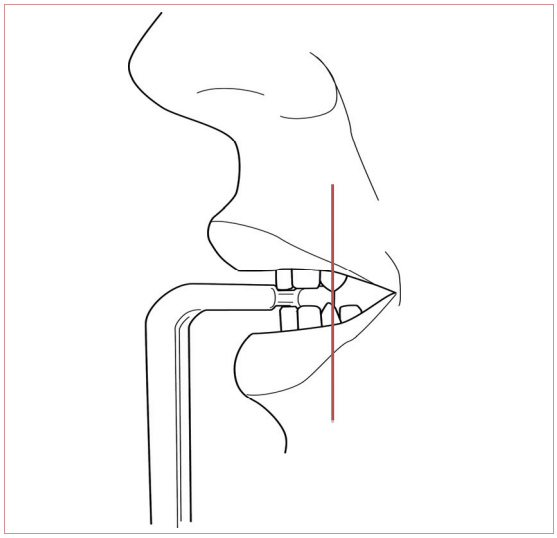


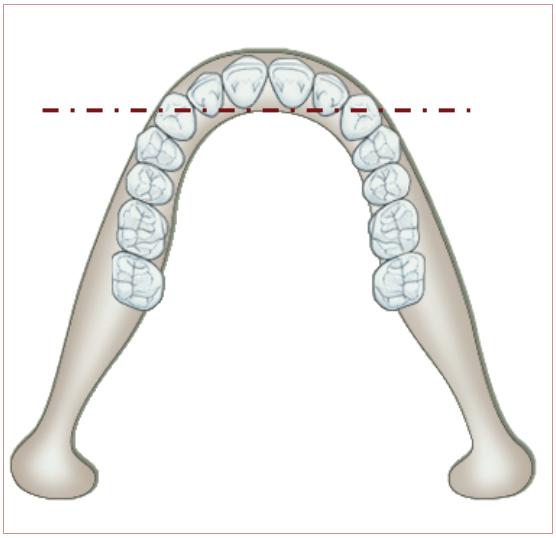


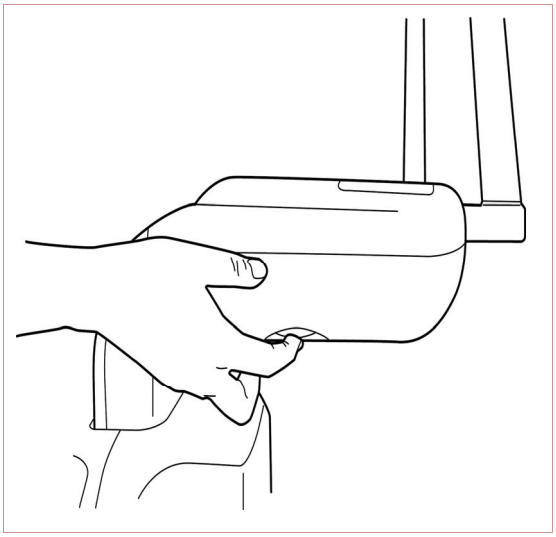
15) The horizontal laser beam which is located at the side of the column, can be moved up or down to accommodate different head sizes. This is done by moving the horizontal laser beam lever upward or downward manually.



16) With the mouth opened, position the Canine beam so that its light would be directly at the center of the canine teeth. To adjust and properly align the canine beam, rotate the thumb wheel, which is located under the patient's support table, forward or backward.







17) Tell the patient to relax his mouth and to roll his tongue upwards (this prevents the tongue from creating a ghost image). Make sure that the patient's eyes are closed. The patient should not make any movements until the end of the capturing of image.

18) After properly positioning the patient, click the ‘Ready’ button.

19) Press and hold the exposure switch to capture image. When X-ray is being exposed, the progress bar will be changed from blue to orange. Press and hold the exposure switch until the progress bar shows that the acquisition of image has been completed.

NOTE

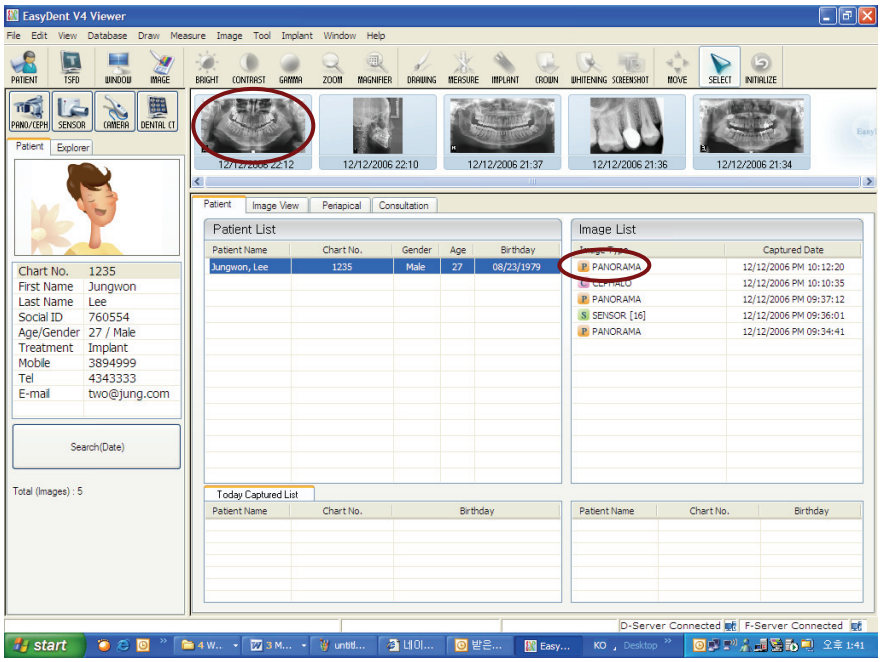
You should hold the exposure switch until the system finishes the acquisition of image.

20) After capturing, click 'OK' to save the image. If you want to cancel the captured image, click 'Cancel'.

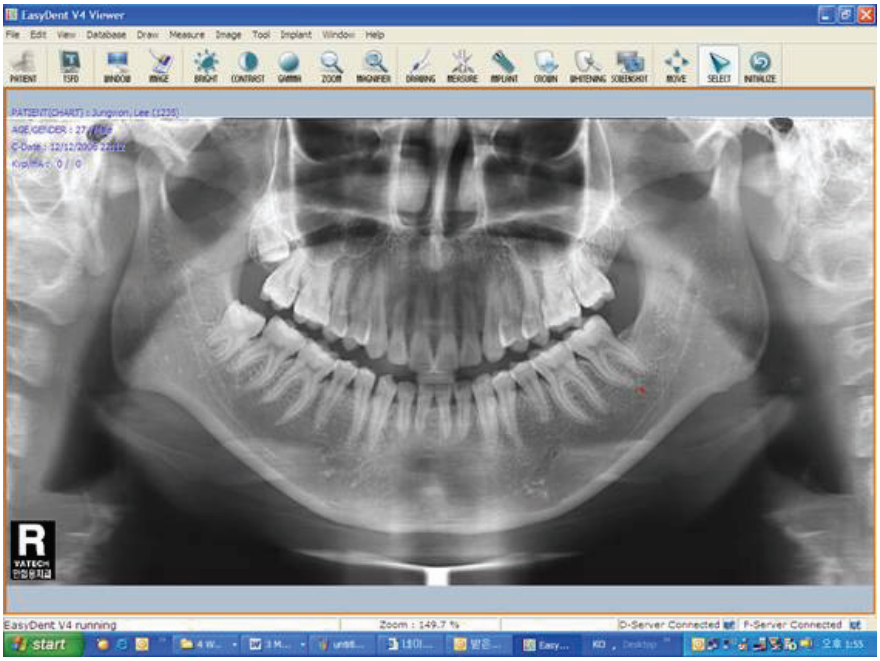
NOTE

If you want to capture an image of the same patient again, click 'Ok'.

21) After imaging, when you click the name of the patient on the patient list of EasyDent V4, the image list will be reconfigured. Thumbnail view of a recently captured image will appear on the left, as shown in the figure below. Double-click on it to check the image in detail.



※ Sample final panoramic image checked through Easydent V4.



5

TMJ Imaging Procedures

This chapter gives instructions on how to position the patient and capture TMJ images on the panoramic imaging unit.

5. TMJ Procedures

5.1. Preparation Before Imaging

Make sure that you conform to the following before starting:

- Start the imaging program on the PC only after switching on the power of the equipment.
- Check whether the equipment has been turned on.
- Do not perform any operation at the PC while the product is initializing.
- Check whether there is any problem in operation of the PC.

NOTE

Make sure that two (2) lock keys (Reconstruction key and EzImplant Key) are installed at the PC. You cannot capture and view the captured images without the two lock keys.

5.2. How to position the Patient for TMJ imaging

1) To capture TMJ images, click the 'Panorama' button. Subsequently, the sensor will move to panoramic imaging initial position.

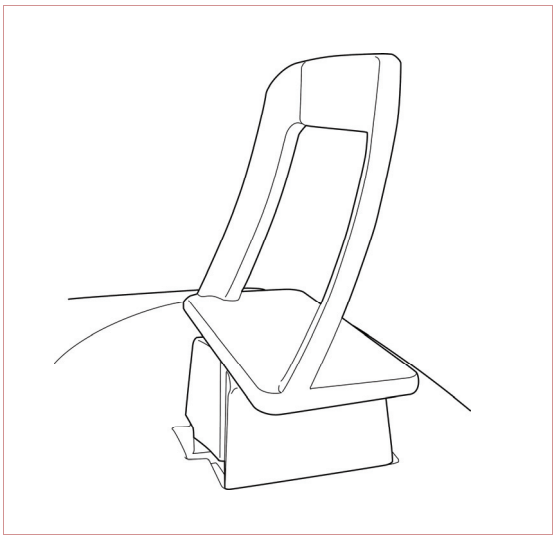
CAUTION

Do not operate the system and the capture program while the PC is initializing its communication with the sensor. Otherwise, failure of the system to function will occur.

2) After the initialization of communication between the PC and the sensor, set the configuration for image capturing. And then, click the 'Confirm' button.

3) Ask the patient to remove any metal objects; such as eyeglasses, dentures, hearing aids, hairpins, earrings, necklace, etc., from the head and neck area. Shadows caused by these opacities may obscure diagnosis.

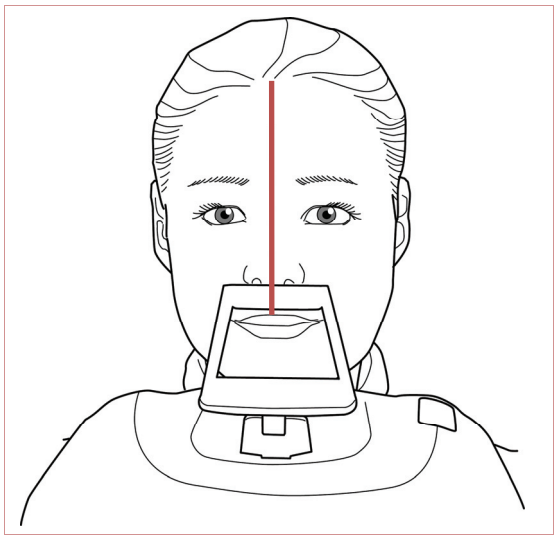
4) Insert the TMJ chin support into of the holes in the chin rest.

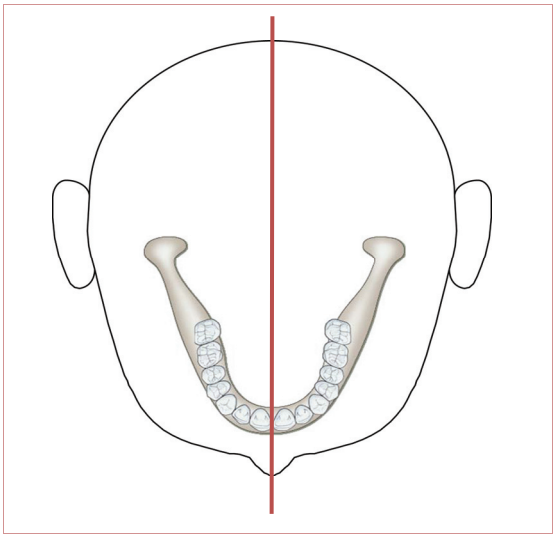


5) Adjust the temples support to fit snugly on the patient's temples by turning the temple support wheel button at the rear of the patient support table.

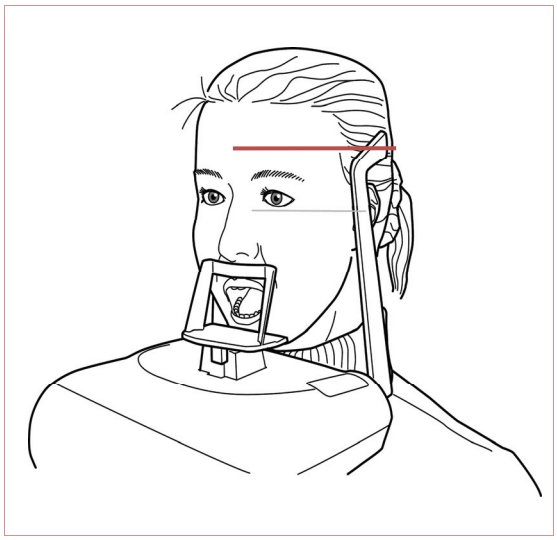
6) Make sure that the patient's shoulders are level and the neck is relaxed. The cervical spine should be straight and upright. If the vertical beam does not get through the center of the occipital bone, the panorama image would appear to have different magnifications on the right and on the left sides, or an unexpected ghost image would appear.

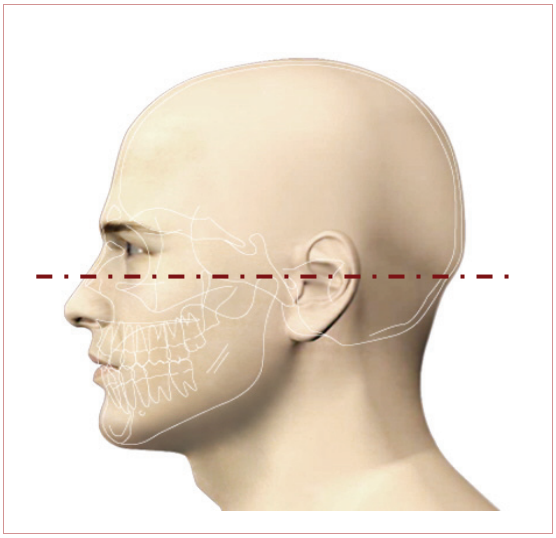
7) Position the head of the patient in a manner where the midsagittal plane will coincide with the vertical beam.



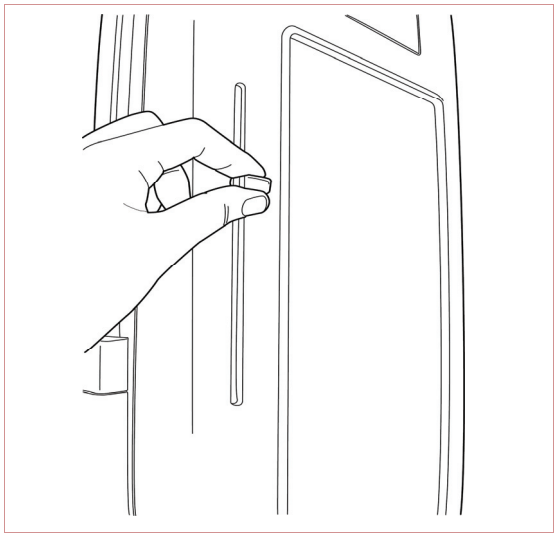


8) Position the head of the patient so that the Frankfort line will coincide with the horizontal beam. For proper positioning, adjust the tilt of the patient's head by adjusting the unit slightly upward or downward. Frankfort plane is the line from the infra-orbital point to the superior edge of the external auditory meatus.

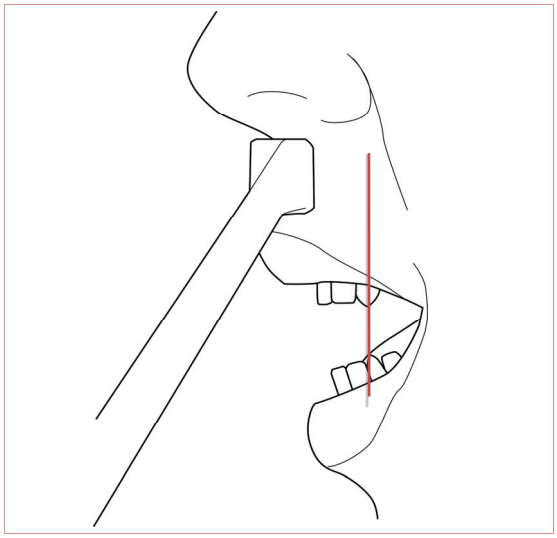


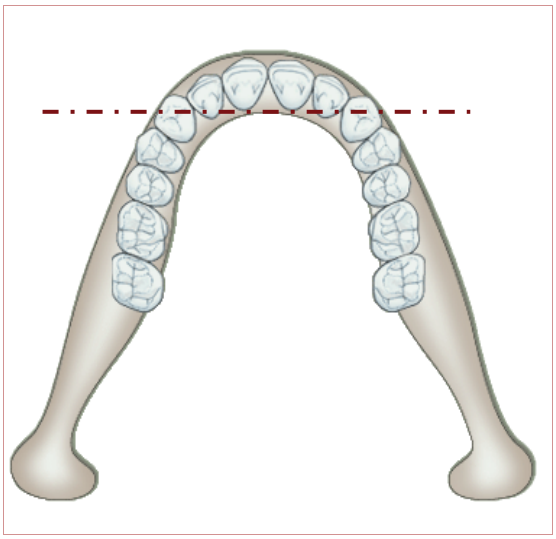


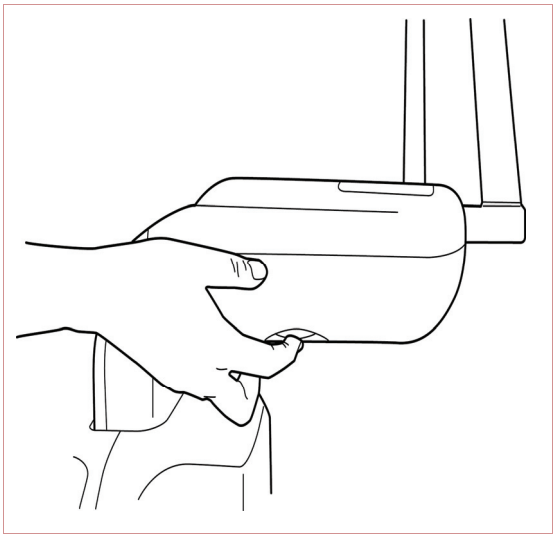
9) The horizontal laser beam which is located on the side of the column, can be moved up or down to accommodate different head sizes. This is done by moving the horizontal laser beam lever upward or downward manually.



10) With the mouth opened for TMJ open imaging, position the Canine beam so that its light would be directly at the center of the canine teeth. To adjust and properly align the canine beam, rotate the thumb wheel, which is located under the patient's support table, forward or backward.







11) Tell the patient to relax his mouth and to roll his tongue upwards (this prevents the tongue from creating a ghost). Make sure that the patient's eyes are closed. The patient should not make any movements until the end of the capturing of image.

12) After properly positioning the patient, click the ‘Ready’ button.

13) Press and hold the exposure switch to capture image. When X-ray is being exposed, the progress bar will be changed from blue to red. Press and hold the exposure switch until the progress bar shows that the acquisition of image has been completed.

NOTE

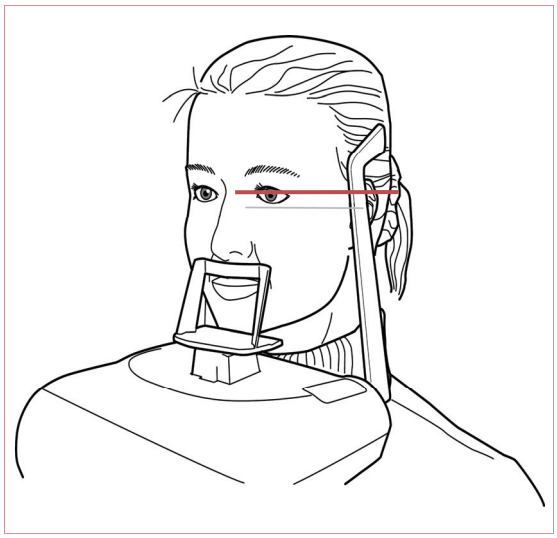
You should hold the exposure switch until the system finishes the acquisition of image.

14) The captured TMJ open image will be shown on the program after optimization. Click 'OK' if you want to continuously capture TMJ CLOSE image.

NOTE

Click 'OK' if you want to continuously capture TMJ CLOSE image. Otherwise, click 'Cancel'.

15) For capturing TMJ close image; position the patient's Acanthion, which is the point at the base of the anterior nasal spine, along the sinus support.



16) Press and hold the exposure switch to capture image. When X-ray is being exposed, the progress bar will be changed from blue to orange. Press and hold the exposure switch until the progress bar shows that the acquisition of image has been completed.

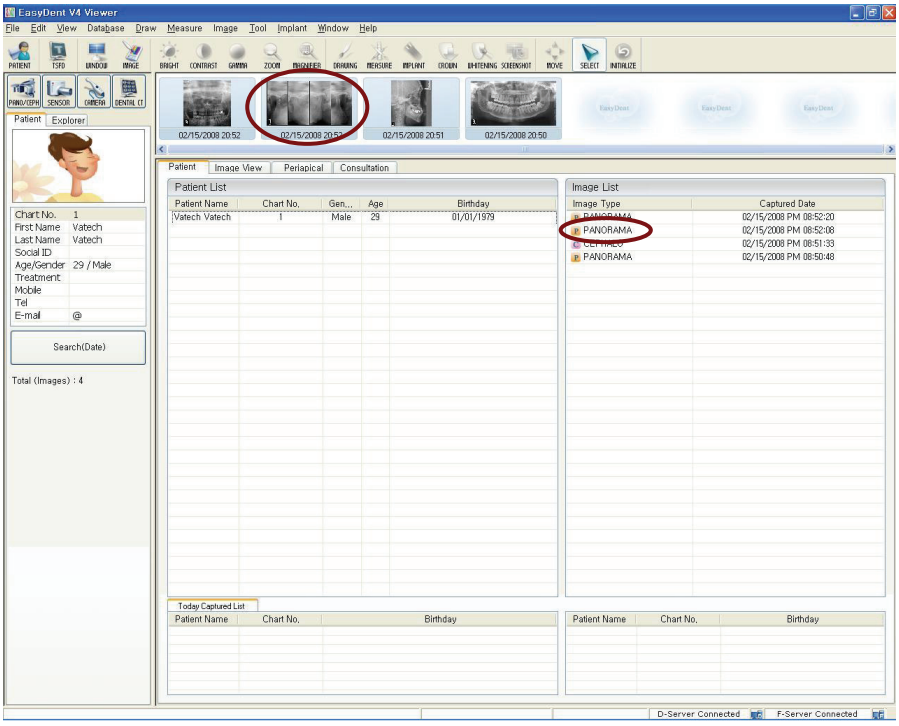
NOTE

You should hold the exposure switch until the system finishes the acquisition of image.

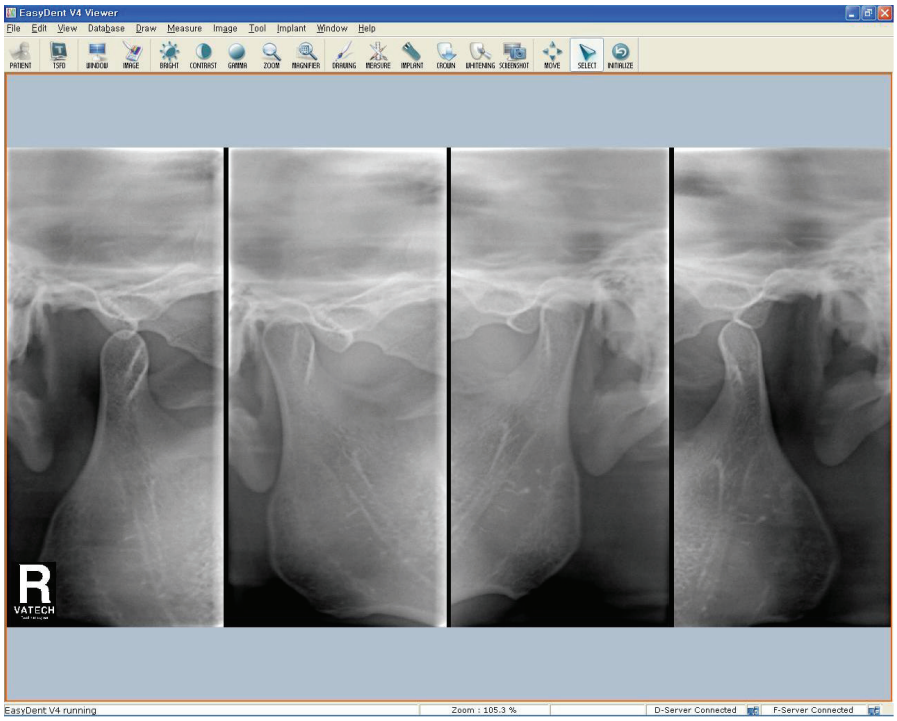
17) If you want to capture the same patient again, click 'OK'.

18) Click 'OK' if you want to save the captured image to DB. Otherwise, click 'Cancel'.

19) After imaging, when you click the name of the patient on the patient list of EasyDent V4, the image list will be reconfigured. Thumbnail view of the recently captured TMJ image will appear on the left as shown in the figure below. Double-click on it to check the image in detail.



※ Sample final TMJ Open & Close images checked through EasyDent



6

SINUS Imaging Procedures

This chapter gives instructions on how to position the patient and capture SINUS image on the panoramic imaging unit.

6. Sinus Imaging Procedures

6.1. Preparation Before Imaging

Make sure that you conform to the following before starting:

- Start the imaging program on the PC only after switching on the power of the equipment.
- Check whether the equipment has been turned on.
- Do not perform any operation at the PC while the product is initializing.
- Check whether there is any problem in operation of the PC.

NOTE

Make sure that two (2) lock keys (Reconstruction key and EzImplant Key) are installed at the PC. You cannot capture and view the captured images without the two lock keys.

6.2. How to position the patient for Sinus imaging

1) To capture sinus image, click the 'Panorama' button. Subsequently, the sensor will move to panoramic imaging initial position.

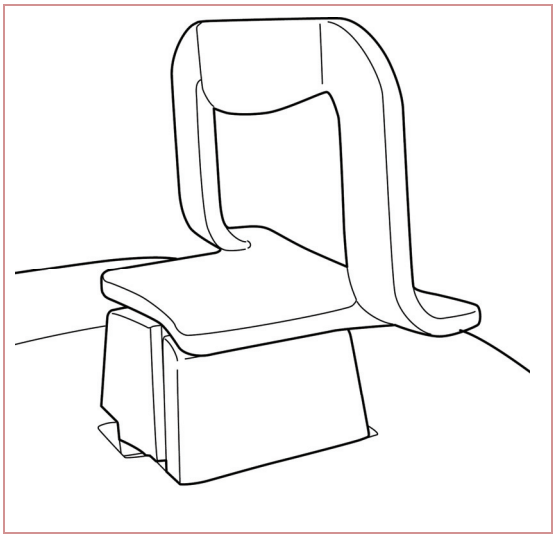
CAUTION

Do not operate the system and the capture program while the PC is initializing its communication with the sensor. Otherwise, failure of the system to function will occur.

2) After the initialization of communication between the PC and the sensor, set the configuration for image capturing. And then click the 'Confirm' button.

3) Ask the patient to remove any metal objects; such as eyeglasses, dentures, hearing aids, hairpins, earrings, necklace, etc., from the head and neck area. Shadows caused by these opacities may obscure diagnosis.

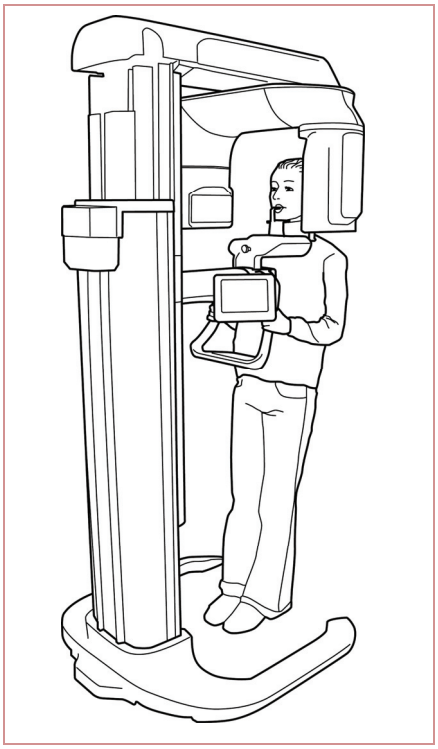
4) Insert the Sinus chin support into the holes of the chin rest.



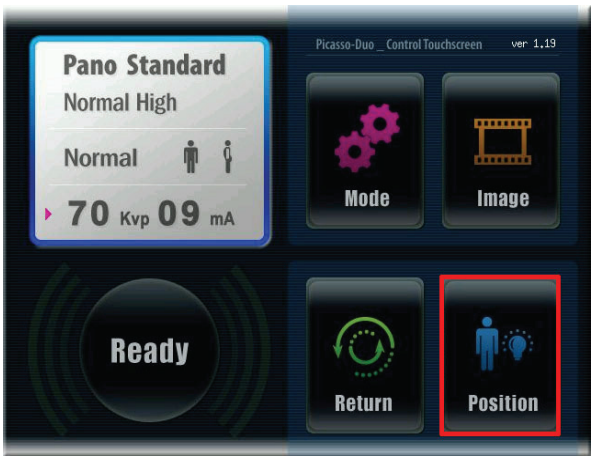
5) Guide the patient into the radiation room to set position.

6) Have the patient wear protective clothing. It is recommended that the patient wear protective clothing, like lead apron, for protection against radiation.

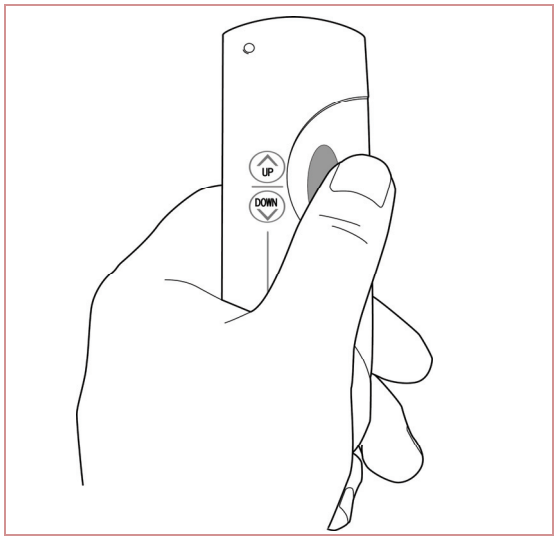
7) Guide the patient to stand at the center of the system at upright position. It is better if the patient comes closer to the system as much as possible. Ask the patient to step forward and to hold the patient handles firmly.



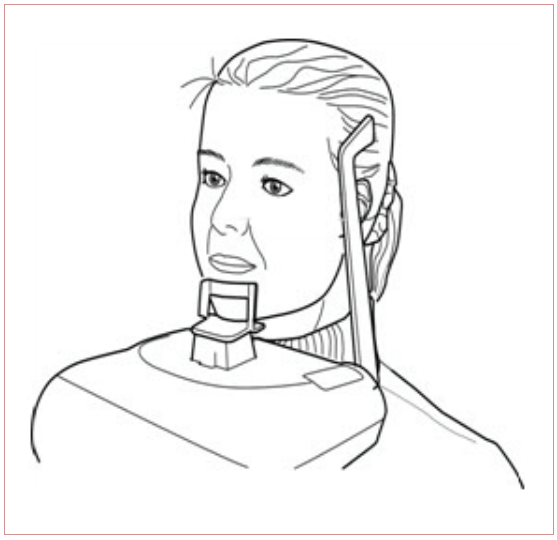
8) Press the 'Position' button on the LCD panel at the system. 3 light beams will appear as guides for proper patient positioning. Also, the camera will be turned on automatically and the patient's face will be displayed on the LCD panel to guide the operator in properly aligning the light beams at the landmarks on the patient's face.



9) Adjust the height of the system to fit the height of the patient using the column up / down switch. Adjust it until the chin rest is properly on the level of the patient's chin. Straighten the patient's neck.



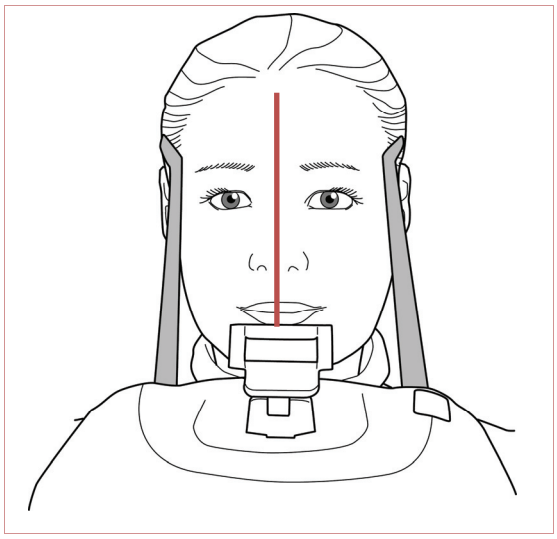
10) Position the patient's chin along the sinus chin support.

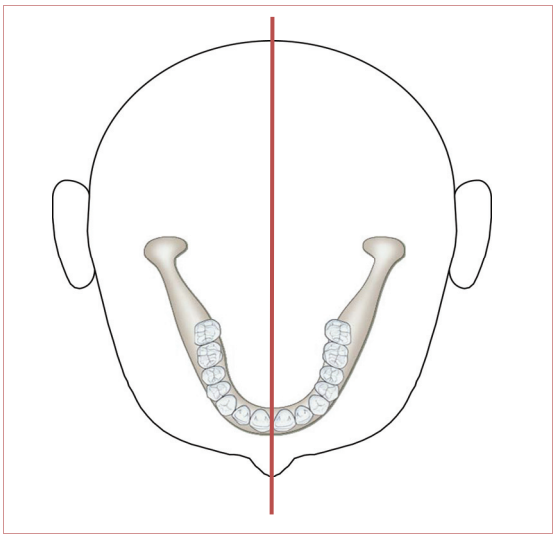


11) Adjust the temples support to fit snugly on the patient's temples by turning the temple support wheel button at the rare of the patient support table.

12) Make sure that the patient's shoulders are level and the neck is relaxed. The cervical spine should be straight and upright. If the vertical beam does not get through the center of the occipital bone, the panorama image would appear to have different magnifications on the right and on the left sides, or an unexpected ghost image would appear.

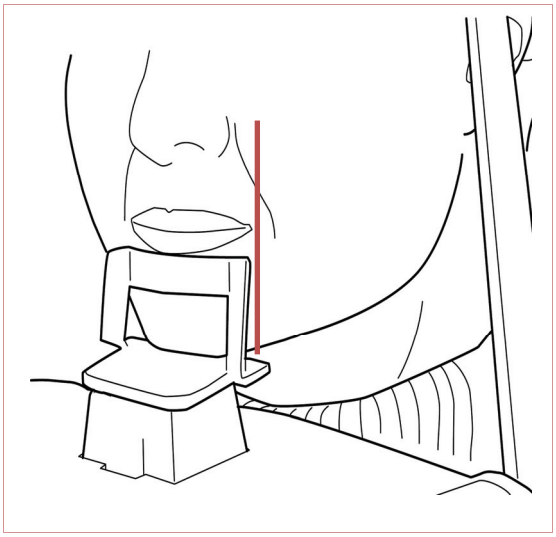
13) Position the head of the patient in a manner where the midsagittal plane will coincide with the vertical beam.

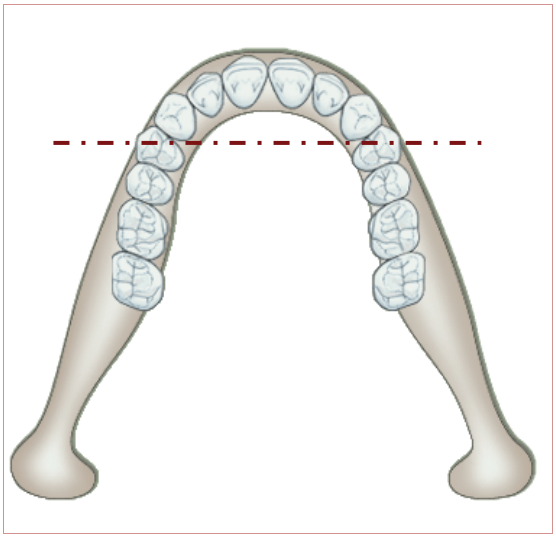




14) Adjust the patient's head by tilting it 10~15 degrees upward.

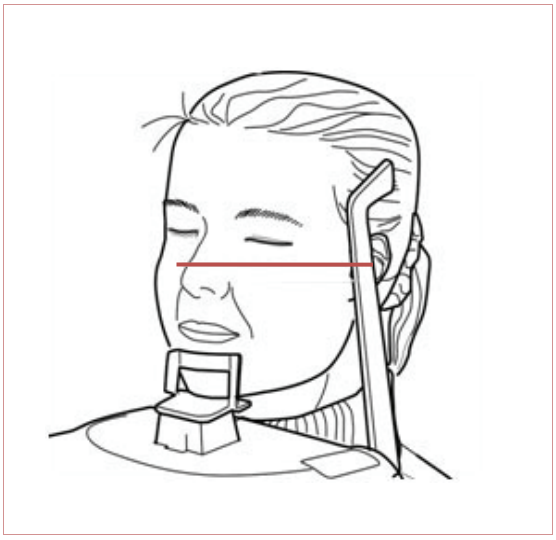
15) With the mouth opened, position the Canine beam so that its light would be directly at the center of the canine teeth. To adjust and properly align the canine beam, rotate the thumb wheel, which is located under the patient's support table, forward or backward.

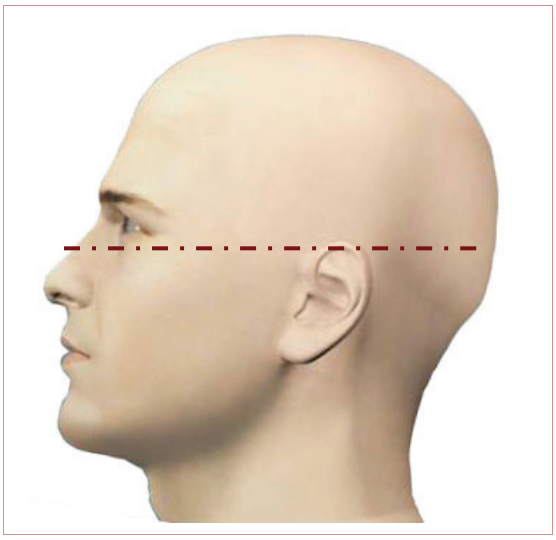




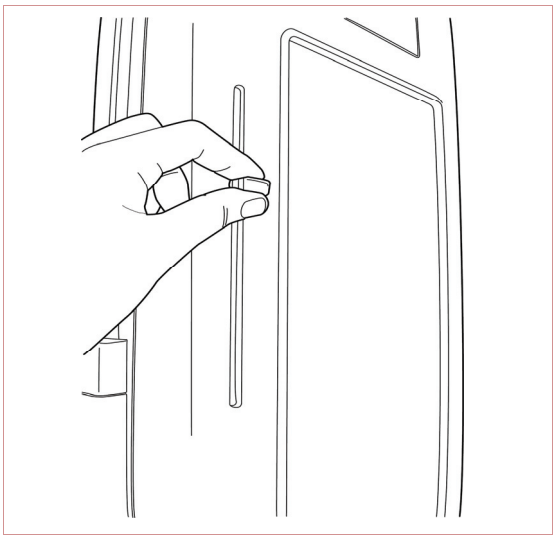
16) Tell the patient to relax his mouth and to roll his tongue upwards (this prevents the tongue from a creating ghost). Make sure that the patient's eyes are closed. The patient should not make any movements until the end of the capturing of image, and to be ready for exposure.

17) Adjust the horizontal laser beam so that it will be aligned with the inferior orbital fissure. For proper positioning, adjust the tilt of the patient's head by adjusting the unit slightly upward or downward.





18) The horizontal laser beam, which is located at the side of the column, can be moved up or down to accommodate different head sizes. This is done by moving the horizontal laser beam lever upward or downward manually.



19) After properly positioning the patient, click the 'Ready' button.

20) Press and hold the exposure switch to capture image. When X-ray is being exposed, the progress bar will be changed from blue to orange. Press and hold the exposure switch until the progress bar shows that the acquisition of image has been completed.

NOTE

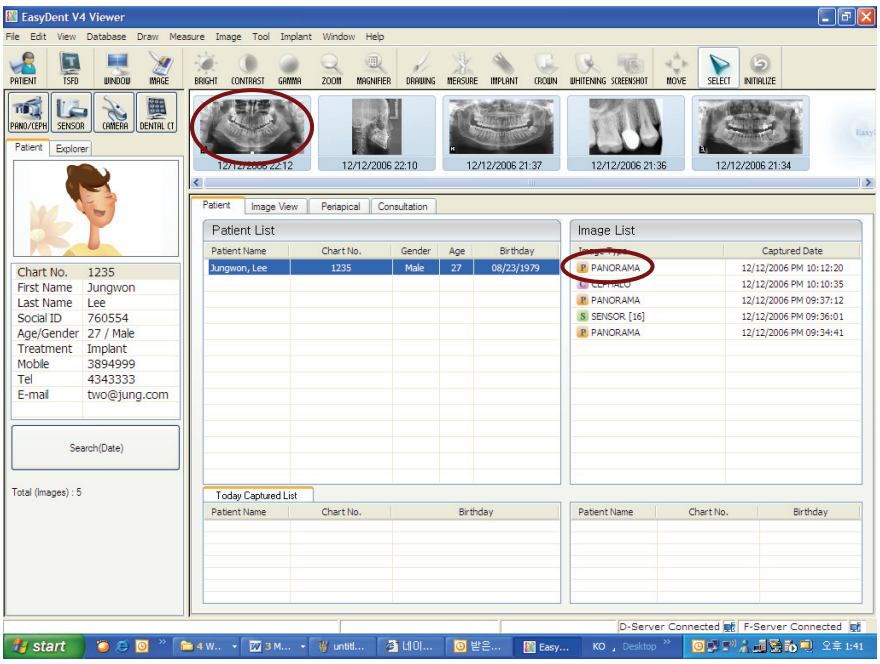
You should hold the exposure switch until the system finishes the acquisition of image.

21) After capturing, click 'OK' to save the image. If you want to cancel the captured image, click 'Cancel'.

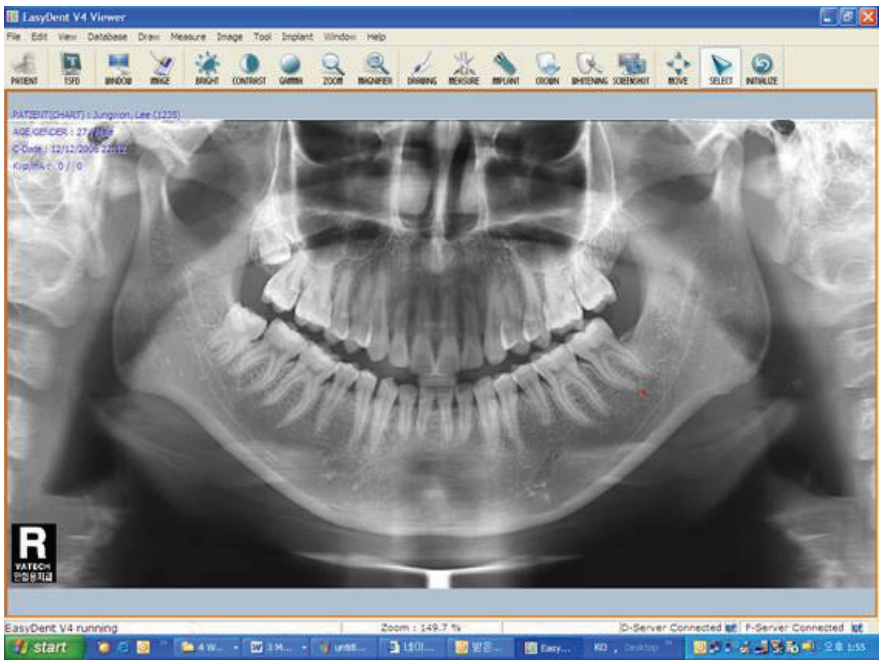
NOTE

If you want to capture the same patient again, click 'Ok'.

22) After imaging, when you click the name of the patient on the patient list of EasyDent V4, the image list will be reconfigured. Thumbnail view of a recently captured image will appear on the left, as shown in the figure below. Double-click on it to check the image in detail.



※ Sample final sinus image checked through EasyDent V4.



7

Panoramic Special Imaging Procedures

This chapter gives instructions on how to position the patient and capture occlusal image on the panoramic imaging unit.

7. Panoramic Special Imaging Procedures

7.1. Preparation Before Imaging

Make sure that you conform to the following before starting:

- Start the imaging program on the PC only after switching on the power of the equipment.
- Check whether the equipment has been turned on.
- Do not perform any operation at the PC while the product is initializing.
- Check whether there is any problem in operation of the PC.

Patient positioning for panoramic special mode is basically same as that of the panoramic standard mode. However, if you want to capture images of a specific area, use the panoramic special imaging mode for a lower X-ray dose and for a fast scan time.

7.2. How to position the patient on the Panoramic Unit

1) To capture a panoramic special image, click the 'Pano Special' button. Subsequently, the sensor will move to panoramic special imaging initial position.

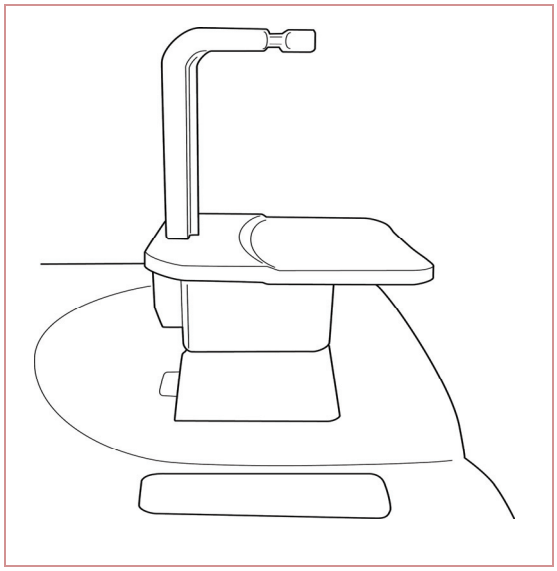
CAUTION

Do not operate the system and the capture program while the PC is initializing its communication with the sensor. Otherwise, failure of the system to function will occur.

2) After the initialization of communication between the PC and the sensor, set the configuration for image capturing. And then, click the 'Confirm' button.

3) Ask the patient to remove any metal objects; such as eyeglasses, dentures, hearing aids, hairpins, earrings, necklace, etc., from the head and neck area. Shadows caused by these opacities may obscure diagnosis.

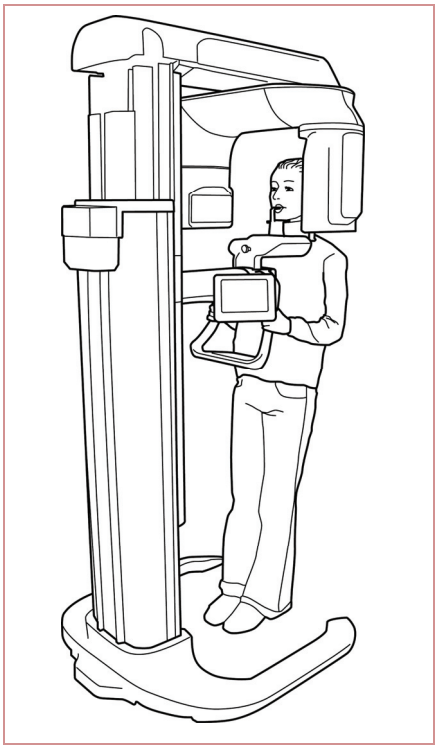
4) Insert the chin support and bite fork rod in hygienic cover on the chinrest.



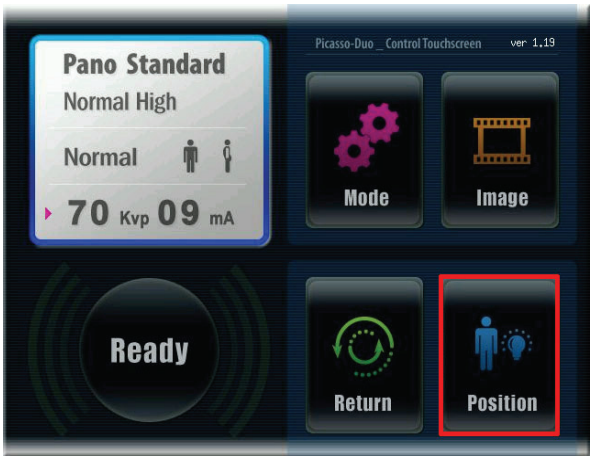
5) Guide the patient to the radiation room to set position.

6) Have the patient wear protective clothing. It is recommended that the patient wear protective clothing, like lead apron, for protection against radiation.

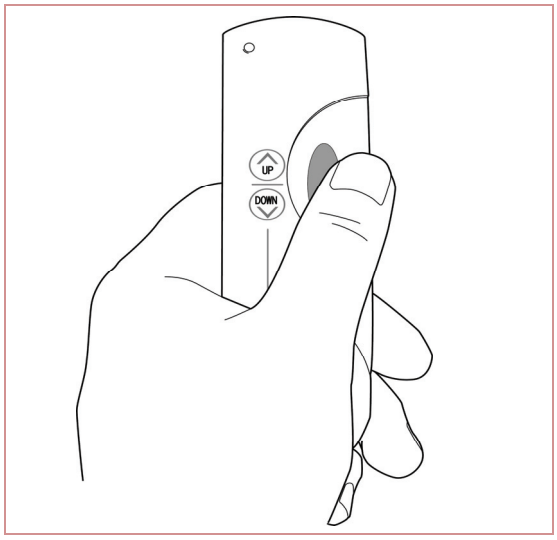
7) Guide patient to stand at the center of the system at upright position. It is better if the patient comes closer to the system as much as possible. Ask the patient to step forward and to hold the patient handles firmly.



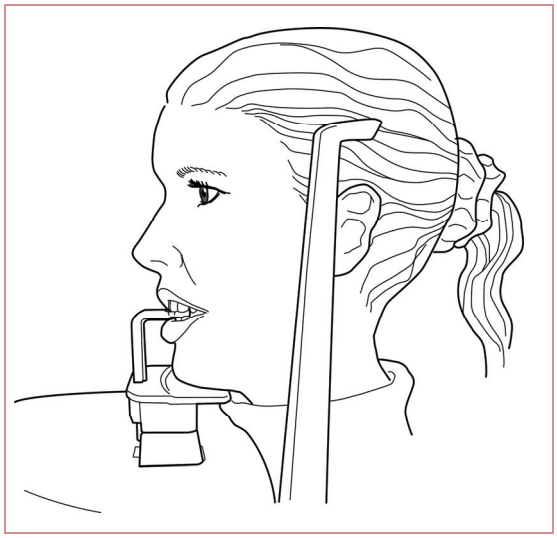
8) Press the 'Position' button on the LCD panel at the system. Subsequently, 3 light beams will appear as guides for proper patient positioning. Also, the camera will be turned on automatically and the patient's face will be displayed on the LCD panel to guide the operator in properly aligning the light beams at the landmarks on the patient's face.

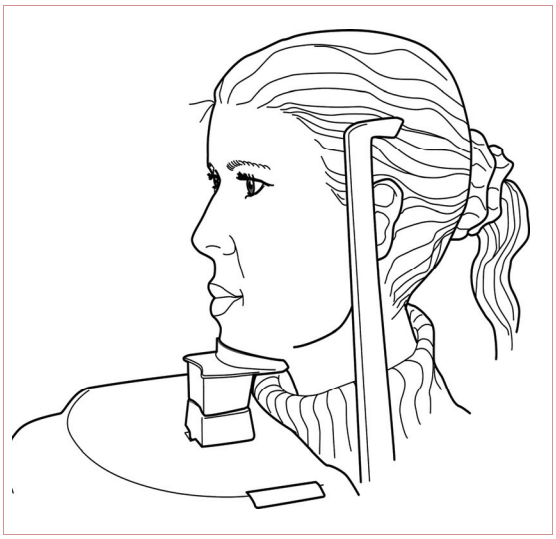


9) Adjust the height of the system to fit the height of the patient using the column up / down switch. Adjust it until the chin rest is properly on the level of the patient's chin. Straighten the patient's neck.



10) Make sure that the bite fork is covered with hygienic cover, then, ask the patient to bite the bite fork. The incisor edges of the maxillary and mandibular teeth must be in the groove of the bite fork.





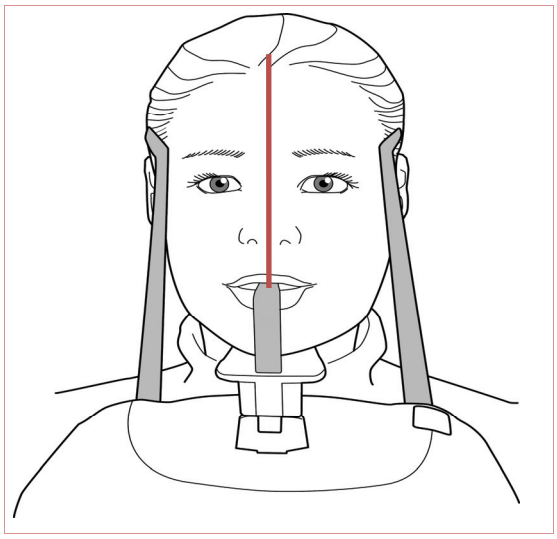
NOTE

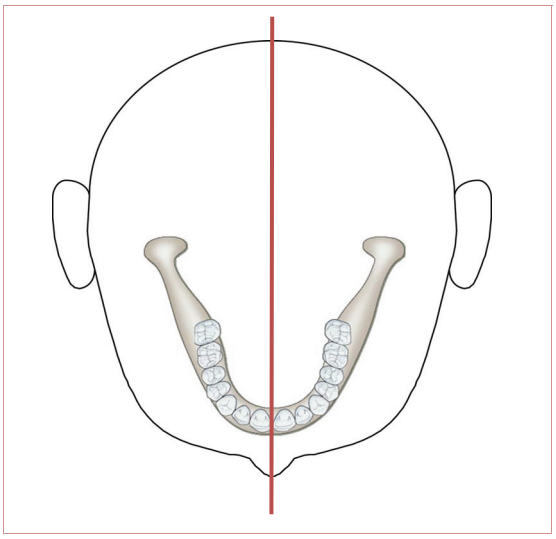
For a Patient with no teeth, the vertical beam should be positioned within the midsagittal line while the horizontal beam should be aligned along the Frankfort plane on the patient's face. The canine beam should be aligned within the fold at the side of the nose. The patient's mouth should be closed.

11) Adjust the temples support to fit snugly on the patient's temples by turning the temple support wheel button at the rare of the patient support table.

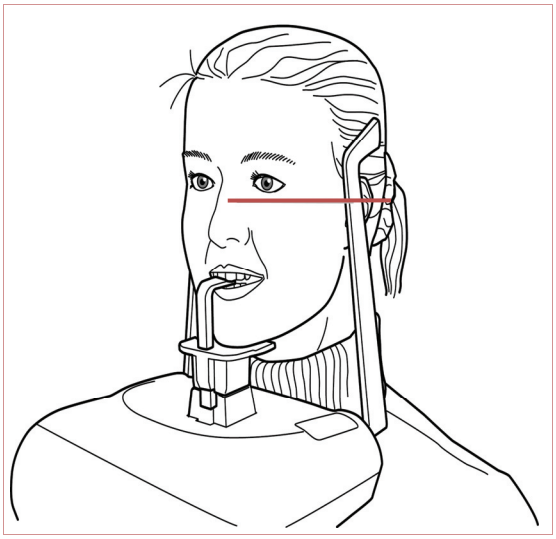
12) Make sure that the patient's shoulders are level and the neck is relaxed. The cervical spine should be straight and upright. If the vertical beam does not get through the center of the occipital bone, the panorama image would appear to have different magnifications on the right and on the left sides; or an unexpected ghost image would appear.

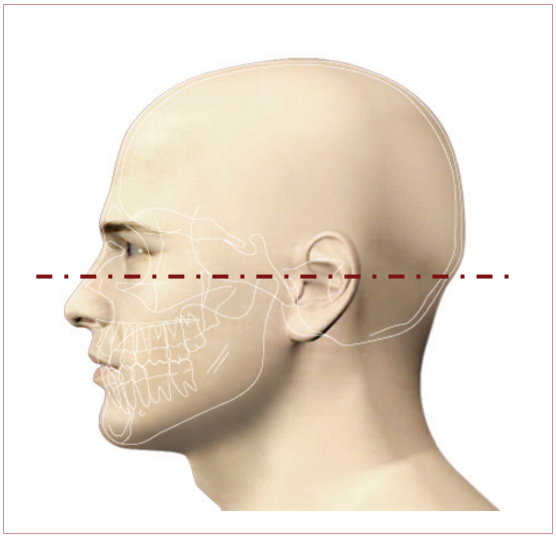
13) Position the head of the patient in a manner where the midsagittal plane will coincide with the vertical beam.



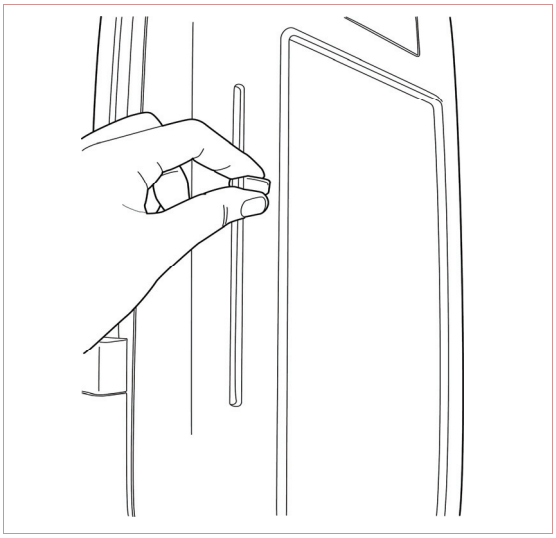


14) Position the head of the patient so that the Frankfort line will coincide with the horizontal beam. For proper positioning, adjust the tilt of the patient's head by adjusting the unit slightly upward or downward. Frankfort plane is the line from the infra-orbital point to the superior edge of the external auditory meatus.

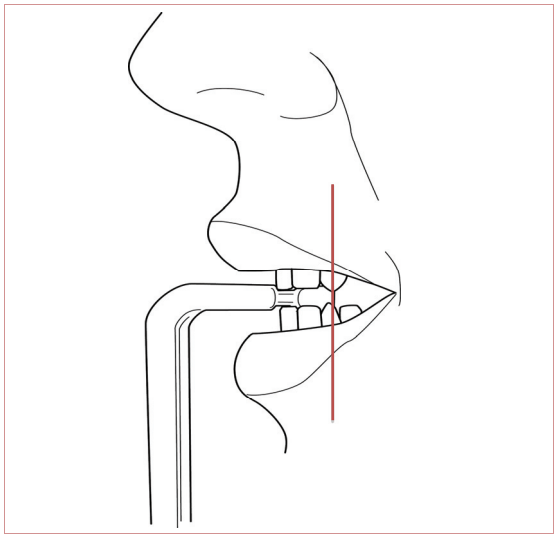


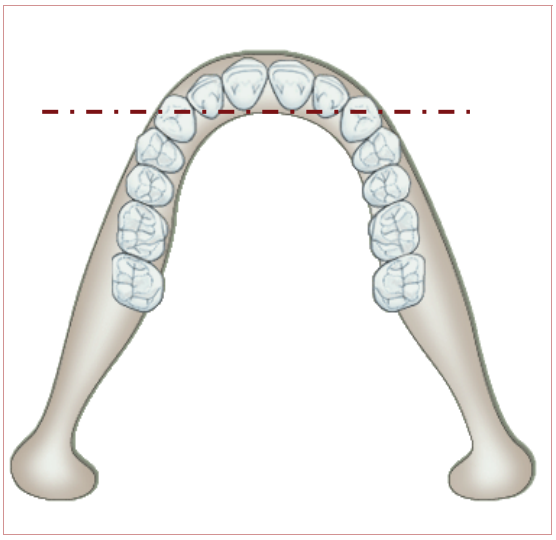


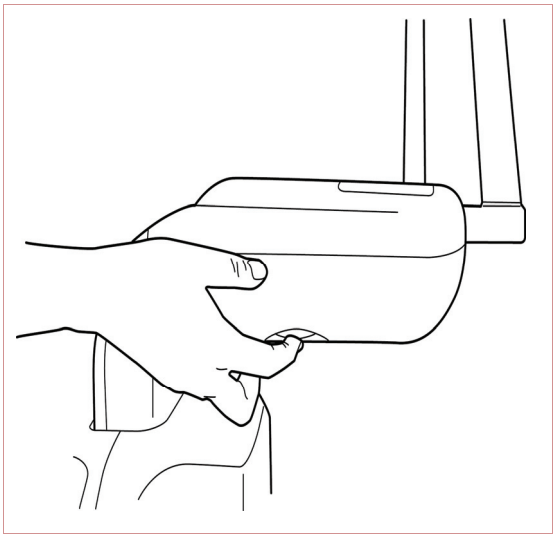
15) The horizontal laser beam which is located at the side of the column, can be moved up or down to accommodate different head sizes. This is done by moving the horizontal laser beam lever upward or downward manually.



16) With the mouth opened, position the Canine beam so that its light would be directly at the center of the canine teeth. To adjust and properly align the canine beam, rotate the thumb wheel, which is located under the patient's support table, forward or backward.







17) Tell the patient to relax his mouth and to roll his tongue upwards (this prevents the tongue from creating a ghost image). Make sure that the patient's eyes are closed. The patient should not make any movements until the end of the capturing of image.

18) After properly positioning the patient, click the 'Ready' button.

19) Press and hold the exposure switch to capture image. When X-ray is being exposed, the progress bar will be changed from blue to orange. Press and hold the exposure switch until the progress bar shows that the acquisition of image has been completed.

NOTE

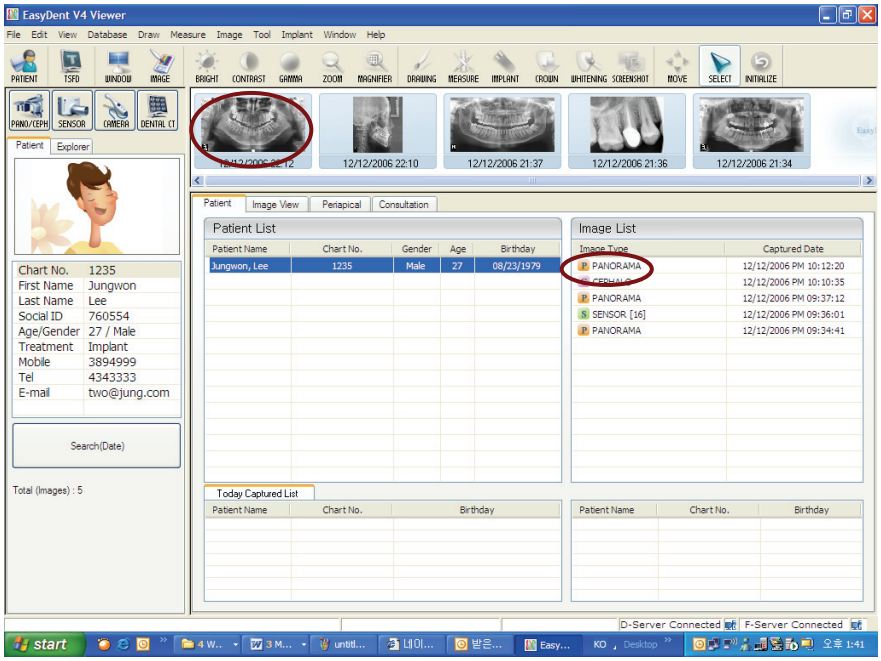
You should hold the exposure switch until the system finishes the acquisition of image.

20) After capturing, click ‘OK’ to save the image. If you want to cancel the captured image, click ‘Cancel’.

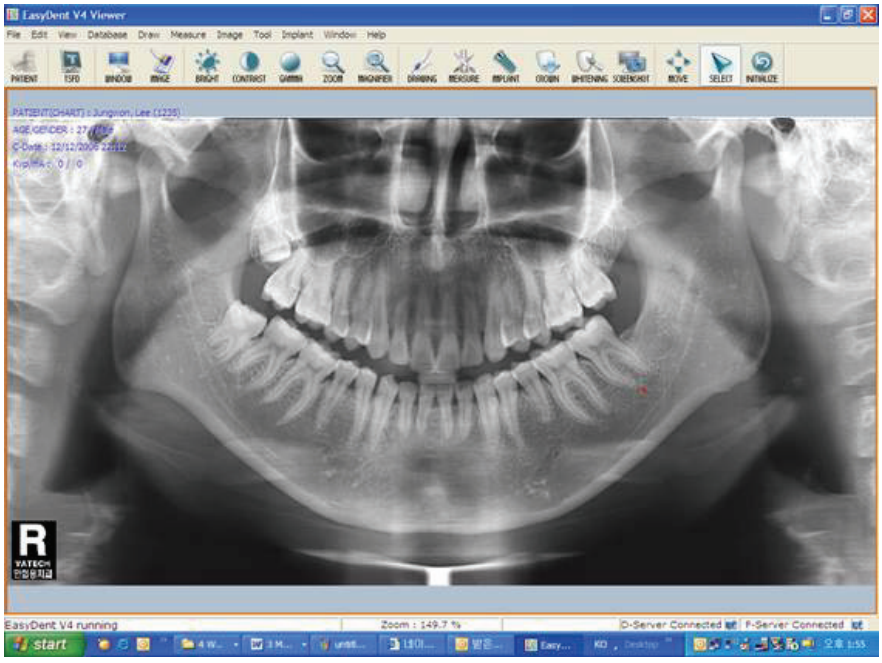
NOTE

If you want to capture an image of the same patient again, click 'Ok'.

21) After imaging, when you click the name of the patient on the patient list of EasyDent V4, the image list will be reconfigured. Thumbnail view of a recently captured image will appear on the left, as shown in the figure below. Double-click on it to check the image in detail.



※ Sample final panoramic image checked through EasyDent V4.



8

CT Procedures

This chapter gives instructions on how to position the patient and how to capture CT images.

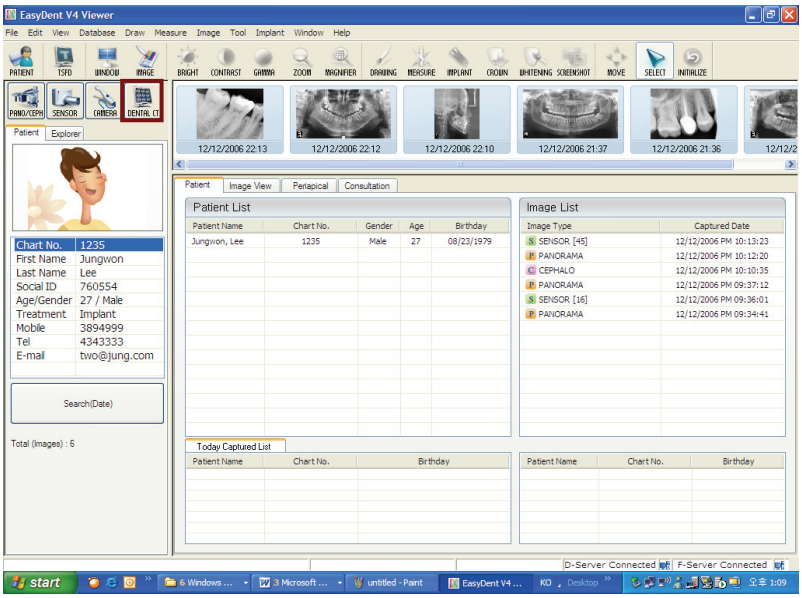
8. CT Procedures

8.1. Dental CT Imaging Procedure

1) Turn on the power of Picasso-Duo.

2) Execute EasyDent V4 program to search for and select the patient for imaging.

3) Click 'Dental CT(DENTAL CT)' icon on the upper left of the main screen to execute the imaging program.



NOTE

An unregistered patient should be registered first before capturing an image. For more information, please refer to Easydent V4 program user's manual, which is prepared separately.

CAUTION

Do not operate the system and the capture program while the PC is initializing its communication with the sensor. Otherwise, failure of the system to function will occur.

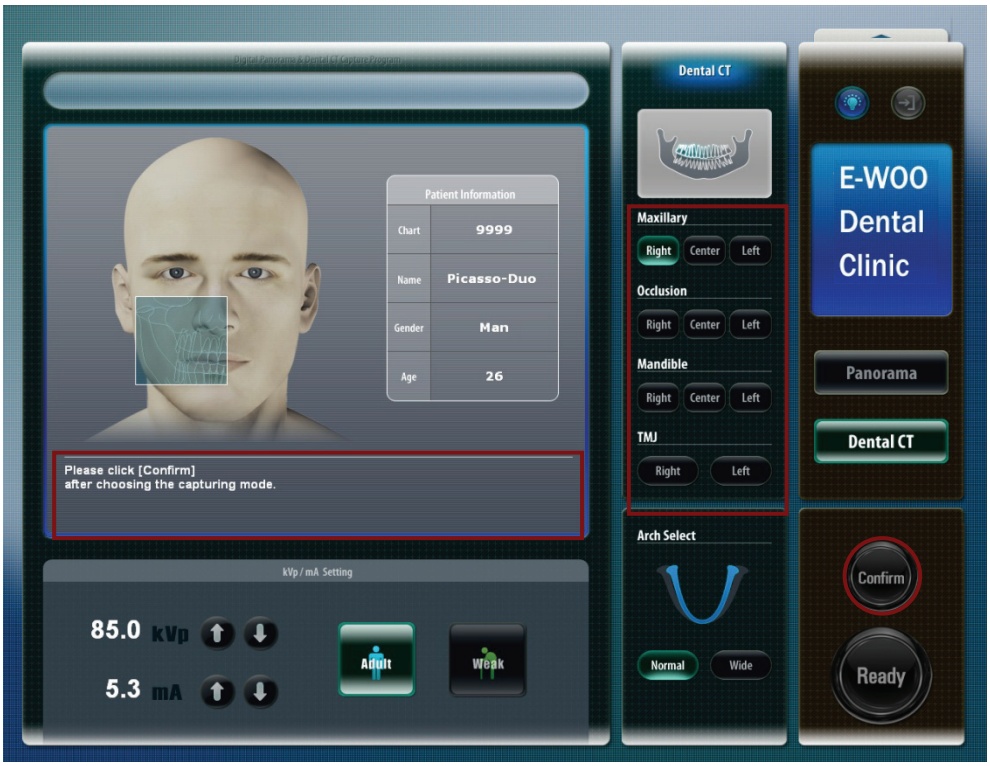
4) Click 'Dental CT', and the sensor will automatically be switched from panoramic sensor to CT sensor.

- FOV : 8X8

- FOV : 13X8

5) Set the image capturing mode configuration, and then click the 'Confirm' button. Subsequently, the chinrest will move to the selected position.

- FOV : 8X8



- FOV : 13X8

- Capture Modes

● FOV 8x8

Mandible (Right, Front, Left) :

Front : Take an image of tooth nos.31~33 & tooth nos. 41~ 43

Left, Right : Take an image of tooth nos. 34~38 of the left mandible or tooth nos. 44~48 of the right mandible.

Maxillary (Right, Front, Left) :

Front : Take an image of tooth nos. 11~13 & tooth nos. 21~23

Left, Right : Take an image of tooth nos. 24~28 of the left maxillary or tooth nos. 14~18 of the right maxillary.

Occlusion(Right, Front, Left) :

Front : Take an image of tooth nos.21~23,31~33 & tooth nos. 11~13,41~ 43

Left, Right : Take an image of tooth nos. 24~28, 34~38 & tooth nos. 14~18, 44~48

TMJ (Left, Right) : Take left or right TMJ open and close images.

- FOV 13x8

Mandible : Take an image of the whole mandible teeth.

Maxillary : Take an image of the whole maxillary teeth.

Occlusion : Take an image of the entire occlusion.

TMJ (Left, Right) : Take a left or a right side image of TMJ.

6) Guide the patient to the x-ray room to set position. Click the 'Ready' button after properly positioning the patient.

- FOV : 8X8

- FOV : 13X8

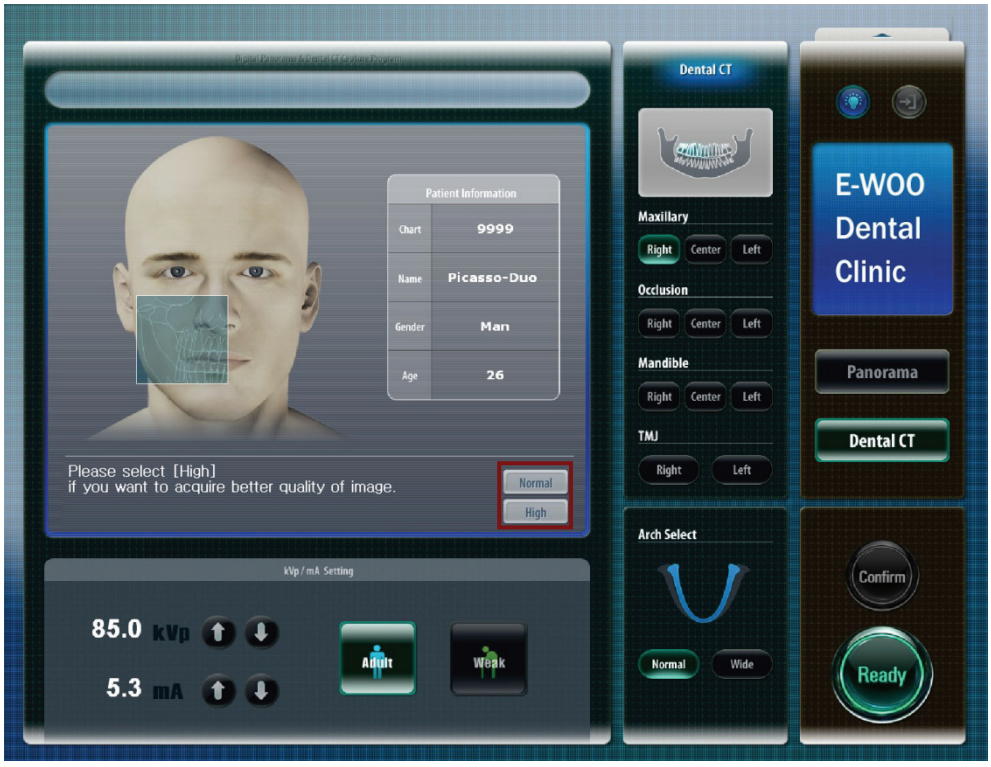
7) Choose ‘Metal’ if you want to remove metal artifact.

- FOV : 8X8

- FOV : 13X8

8) Select an image 'Quality mode' (Normal or High).

- FOV : 8X8



- FOV : 13X8

NOTE

Image reconstruction time:

Metal Mode :

8X8 Reconstruction Time	Normal Mode	:	30 sec
	Metal Mode	:	1 min & 30 sec
13X8 Reconstruction Time	Normal Mode	:	39 sec
	Metal Mode	:	1 min & 57 sec

Quality Mode :

8X8 Reconstruction Time	Normal Mode	:	10 sec
	High Mode	:	19 sec
13X8 Reconstruction Time	Normal Mode	:	15 sec
	High Mode	:	24 sec

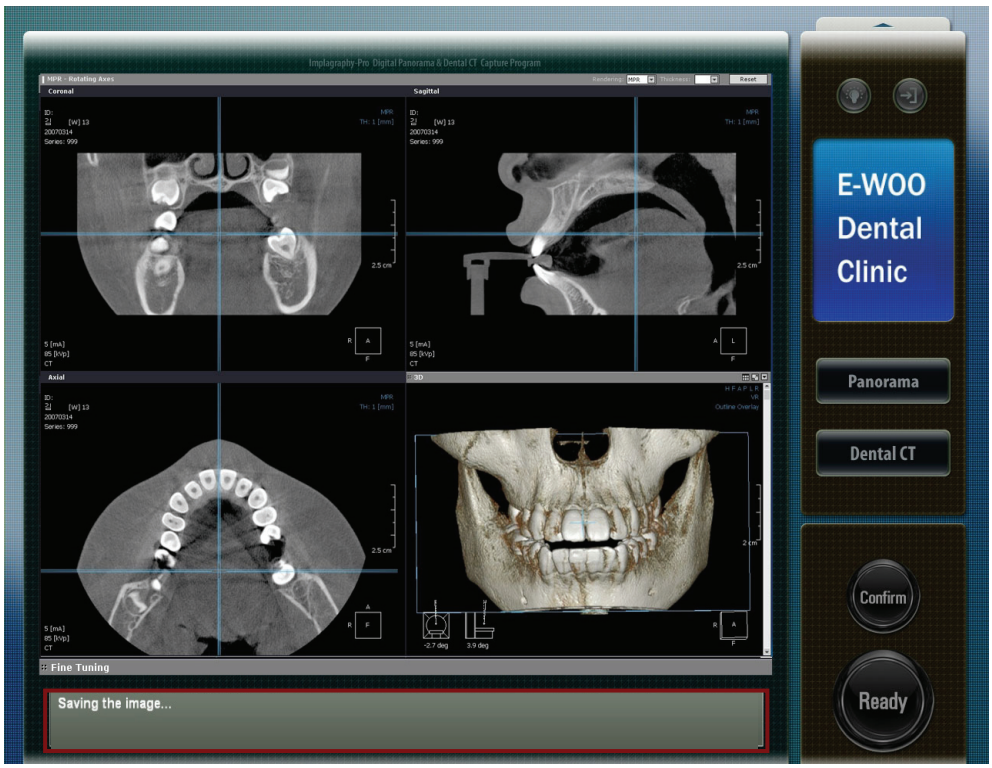
9) Press and hold the exposure switch to start image capturing according to the guidance message.

NOTE

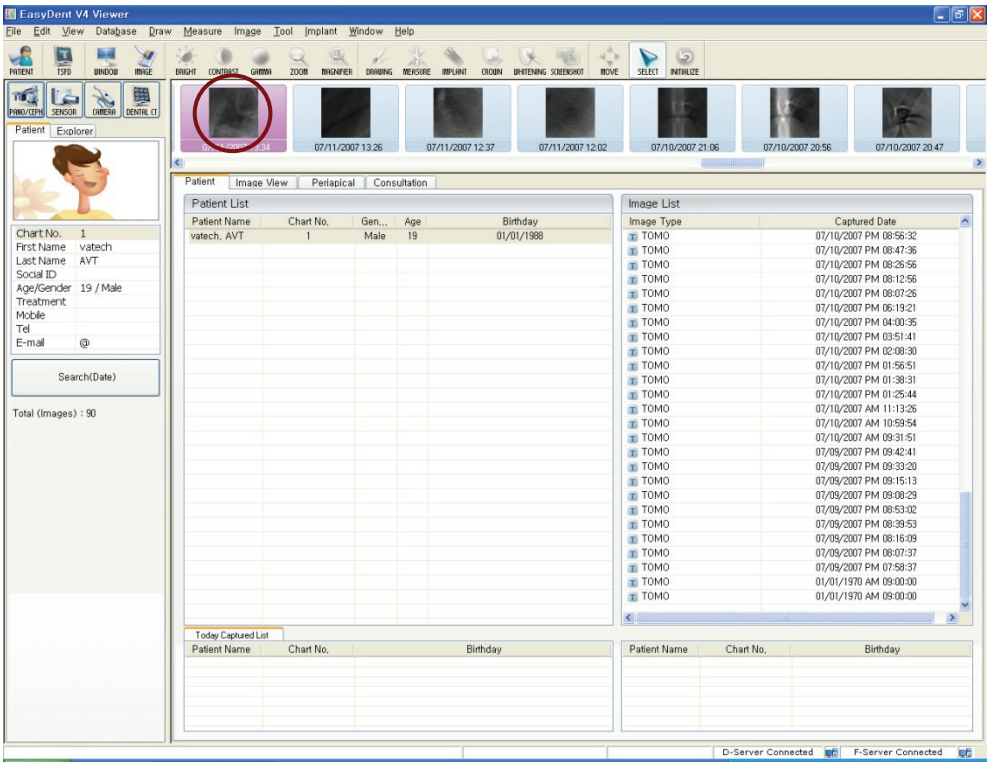
You should hold the exposure switch until the system finishes the acquisition of image.

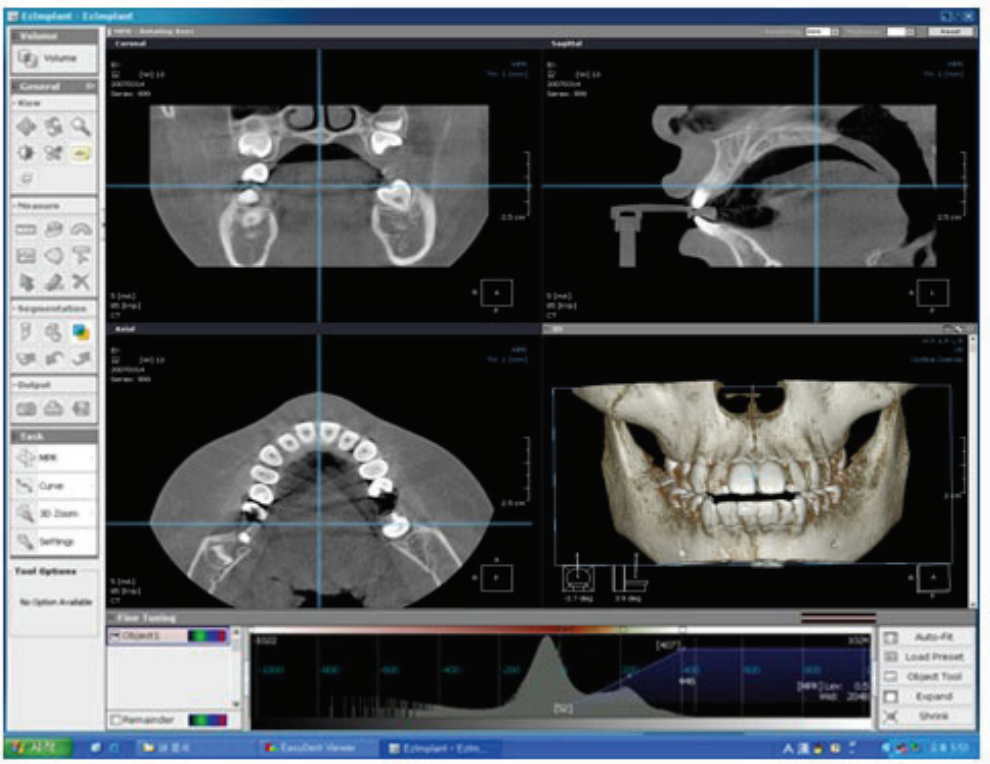
10) The captured image will be reconstructed. Wait until the program completes the image reconstruction.

11) Click ‘OK’ to save the captured image. If you want to cancel the captured image, click ‘Cancel’.



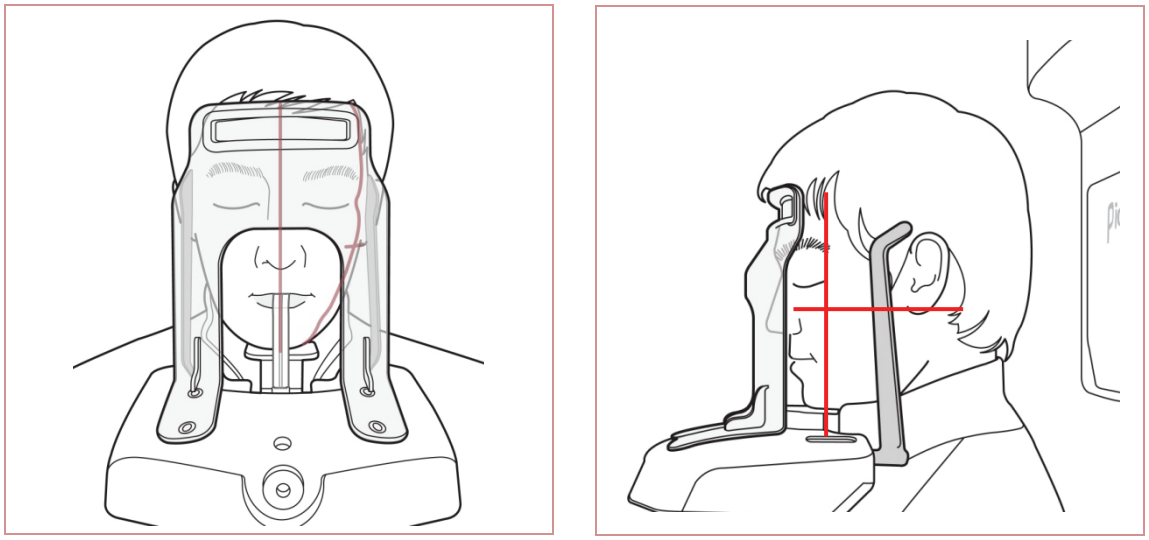
12) After imaging, when you click the name of the patient on the patient list of EasyDent V4, the image list will be reconfigured. Thumbnail view of a recently captured image will appear on the left, as shown in the figure below. To check the image in detail, double-click on it and EzImplant, the CT viewer program will be run automatically.





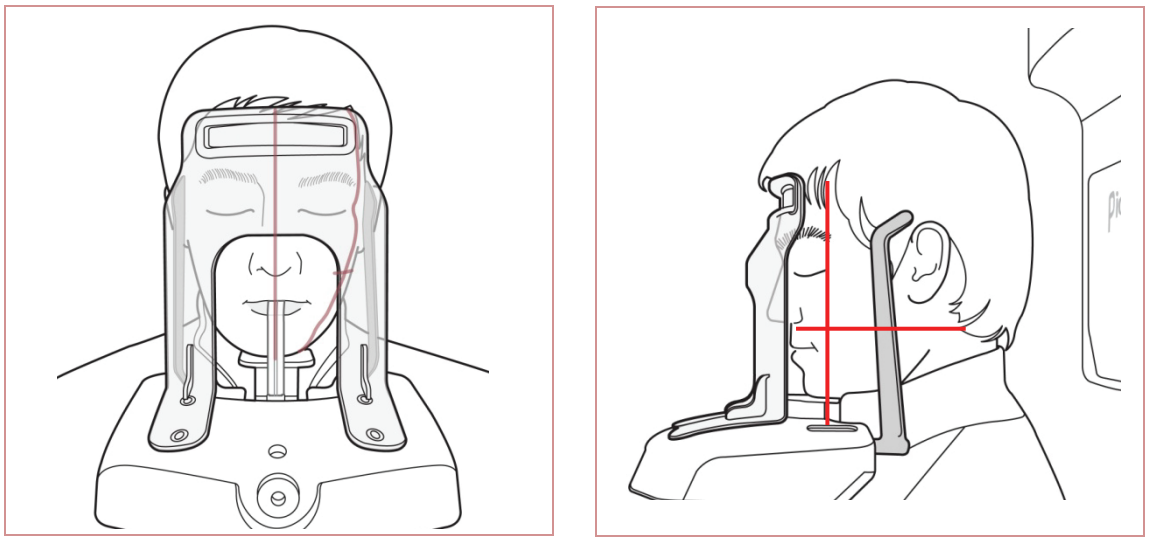
8.2. Patient Positioning for Dental CT

8.2.1. Maxillary (upper jaw) capture mode



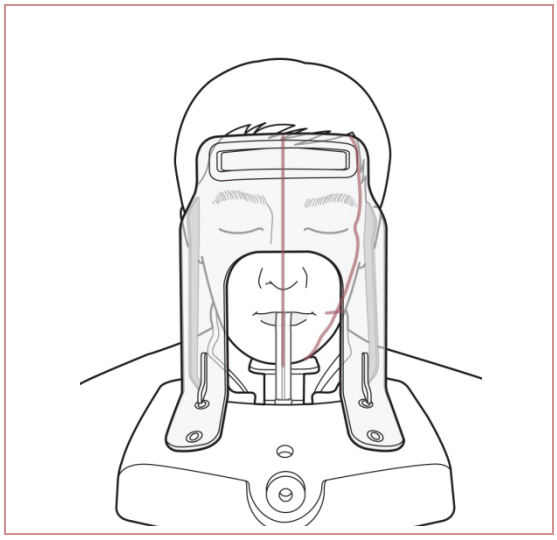
When the Maxillary capture mode is selected, the chinrest will be moved automatically to the proper position.

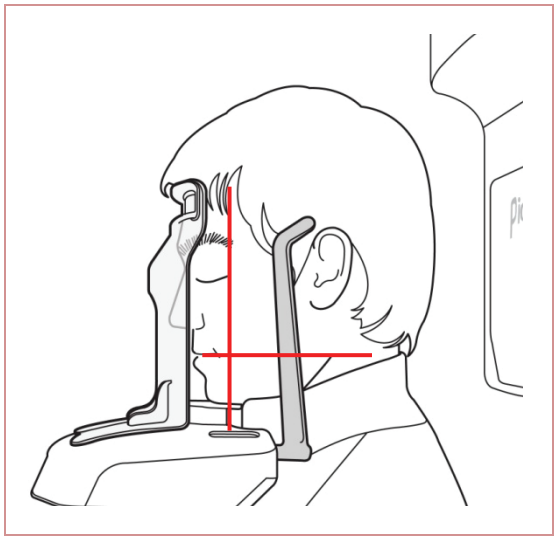
8.2.2. Occlusion (occlusal plane) capture mode



When the Occlusion capture mode is selected, the chinrest will be moved automatically to the proper position.

8.2.3. Mandible (lower jaw) capture mode





When the Mandible capture mode is selected, the chinrest will be moved automatically to the proper position.

CAUTION

To avoid moving artifact, the patient must not move during the capturing process and the head should be secured with the head rest.

8.3. Operation after imaging

Once you are done with all the imaging procedures, check the following:

8.3.1. Cooling time

'Cooling time' is a process for the tube of the system to cool down. After imaging, the 'cooling time' message will be shown on the capture program. After a few seconds, a voice guidance message will be heard telling that the cooling time is finished.

8.3.2. Move the rotator to lamp position

To move the rotator to lamp position, push the return button on the LCD touch screen after the cooling time.

9

Use of LCD

This chapter gives instructions on how to use the LCD panel.

9. How to Use LCD Panel

9.1. Main Screen

① Imaging Display Mode and Patient Setting

Displays the imaging mode, patient type, and X-ray setting values.

② Mode button

Shows the selection of imaging modes (Pano Standard, Pano Special, Dental CT).

③ Image button

Shows an image that is currently saved in the memory (can save up to 10 images).

④ Return button

Return rotating unit to lamp position.

⑤ Position button

To activate the camera and the alignment beams in order to place the patient in position.

⑥ Ready button

Prepare for X-ray imaging according to the mode and conditions set.

9.2. Mode Screen

① Pano Standard

Standard imaging mode selections: Normal, Front, Right, Left, TMJ, or Sinus

② Pano Special

Special imaging mode selections: Orthogonal, Incisor Clear, Maxillary Clear, or Canal Clear

③ Dental CT

Dental CT imaging mode selections: Mandible, Maxillary, Occlusion, TMJ Left, or TMJ Right

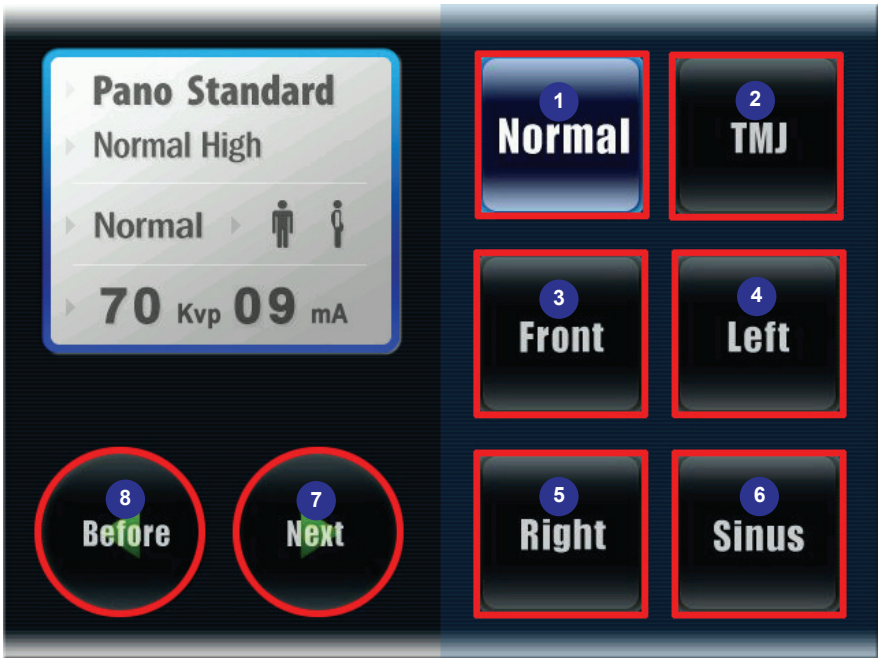
④ Before

Select "Before" to cancel the current setting values and to go back to the previous stage.

⑤ Next

Select "Next" to go to the next stage.

9.3. Pano Standard Screen



① Normal

Press 'Normal' button if you want to take a panoramic image of the patient's whole teeth.

② TMJ

Press 'TMJ' button if you want to take images of the temporomandibular joint (TMJ) of the patient. Images are shown on the PC in one view sheet in the following order: Right Open, Right Close, Left Close, and Left Open. However, LCD panel only displays the Open image during TMJ Open Imaging, and only the Close image during TMJ Close imaging.

③ Front

Press 'Front' for imaging the front teeth of the patient.

④ Left

Press 'Left' to capture an image of the teeth on the left side of the patient's mouth.

⑤ Right

Press 'Right' to capture an image of the teeth on the right side of the patient's mouth.

⑥ Sinus

Press 'Sinus' to capture an image that optimizes the sinus of the patient.

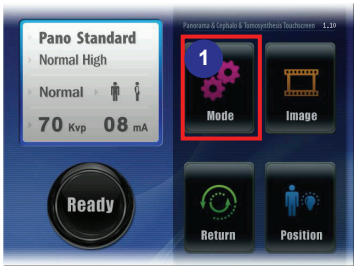
⑦ Next

Select 'Next' to go to the next stage.

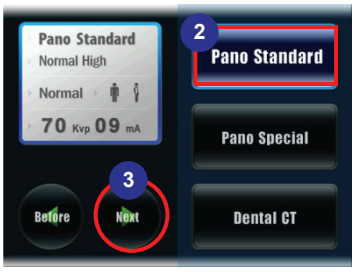
⑧ Before

Select 'Before' to cancel the current setting values and to go back to the previous stage.

9.3.1. Pano Standard (For Normal Imaging)

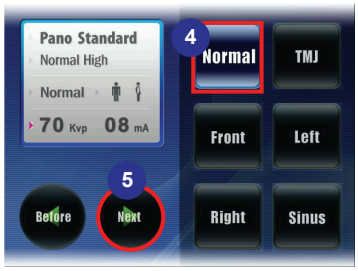


① Mode : Press 'Mode' button to choose the mode for capturing of image.

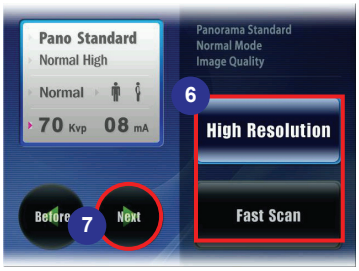


② Pano Standard : Press 'Pano Standard' to capture image on Pano Standard mode.

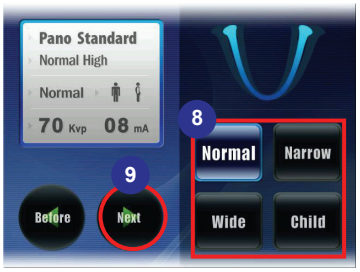
③ Next : Press 'Next' Button to move to the next stage.



④ Normal : Press 'Normal' to capture image on normal panoramic mode (Press the Button of corresponding mode if you want to capture the image on TMJ, Sinus, Right, Front, or Left).
⑤ Next : Press 'next' to move to the next stage.
(Press 'Before' to go back to the previous stage)



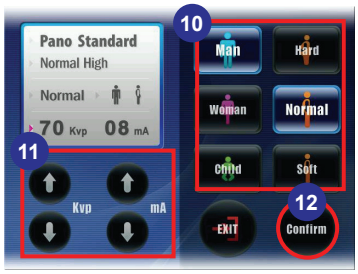
⑥ High Resolution / High Scan : Select the button to capture the image on High Resolution or on High Scan.
⑦ Next : Press to move to the next stage or press 'Before' to go back to the previous stage.



⑧ Arch : Select an arch that is suitable for the patient: Wide, Normal, Narrow, or Child

⑨ Next : Press 'Next' to move to the next stage. Press 'Before' to go back to the previous stage.

.



⑩ Select the X-ray exposure conditions suitable for the features of the patient (sex / bone density).

⑪ kVp / mA : Select the X-ray exposure amount suitable for the patient.

⑫ Confirm : Press to confirm the setting and to move to the main screen.

9.4. Pano Special Screen (CT mode)

① Maxillary clear R

Press 'Maxillary Clear R' for capturing an image that optimizes the maxillary sinus (right side) of the patient.

② Maxillary clear L

Press 'Maxillary Clear L' for capturing an image that optimizes the maxillary sinus (left side) of the patient.

③ Canal clear R

Press 'Canal clear R' for capturing an image that optimizes the canal (right side) of the patient.

④ Canal clear L

Press 'Canal Clear L' for capturing an image that optimizes the canal (left side) of the patient.

⑤ Incisor clear

Press 'Incisor Clear' for capturing an image that optimizes the fore tooth of the patient.

⑥ Orthogonal

Press 'Orthogonal' for capturing an image that minimizes overlapping when the teeth overlap.

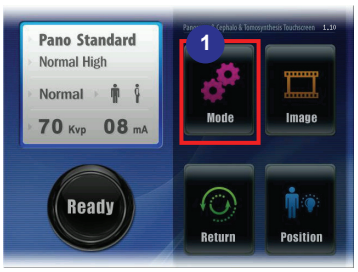
⑦ Next

Select 'Next' to go to the next stage.

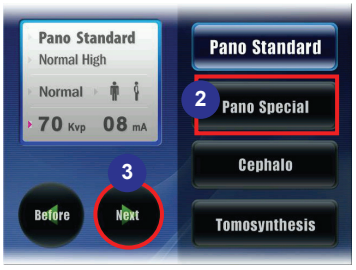
⑧ Before

Select 'Before' to cancel the current setting values and to go back to the previous stage

9.4.1. Pano Special



① Mode : Select the mode for imaging

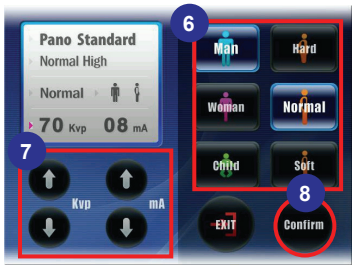


② Pano Special : Select 'Pano Special' to capture an image in Pano Special mode (Press the button of its corresponding mode to capture the image on Pano Standard or Cephalo mode).

③ Next : Move to the next stage.

④ Maxillary Clear R : For capturing the Maxillary Clear – Right image. (Press the other buttons to capture Orthogonal, Incisor Clear, Maxillary Clear–Left, Canal Clear–Right, Canal Clear-Left).

⑤ Next : Move to the next stage.



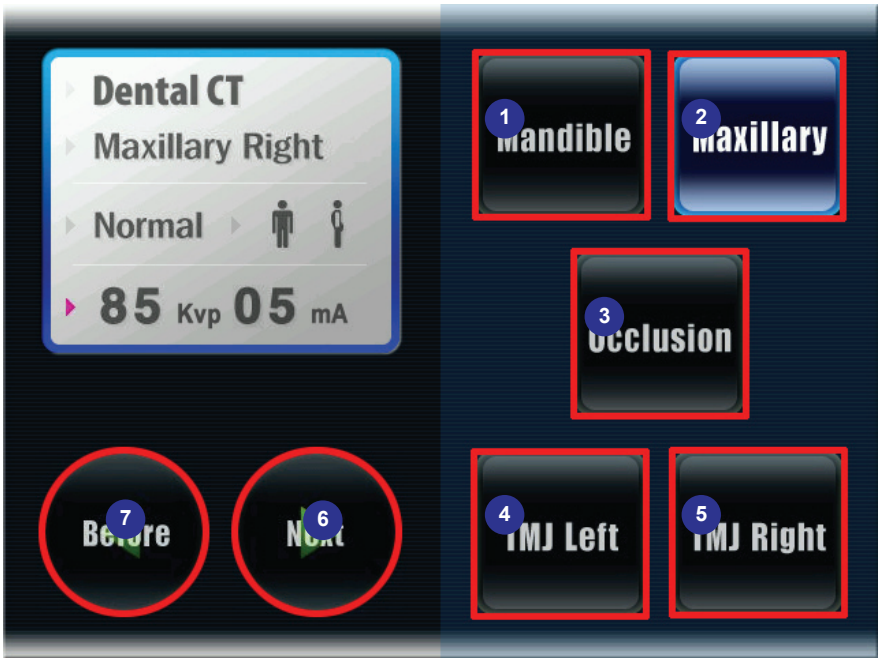
⑥ Select Patient : Select the X-ray exposure conditions suitable for the features of the patient (sex / bone density).

⑦ Select kVp / mA : Select the X-ray exposure amount suitable for the patient.

⑧ Confirm : Press to confirm the current setting.

9.5. Dental CT

- FOV : 8X8



① Mandible

Press 'Mandible' for capturing an image that optimizes the mandible of the patient.

② Maxillary

Press 'Maxillary' for capturing an image that optimizes the maxillary of the patient.

③ Occlusion

Press 'Occlusion' for capturing an image that optimizes the occlusion of the patient.

④ TMJ Left

Press 'TMJ Left' for capturing an image that optimizes the TMJ left of the patient.

⑤ TMJ Right

Press 'TMJ Right' for capturing an image that optimizes the TMJ right of the patient.

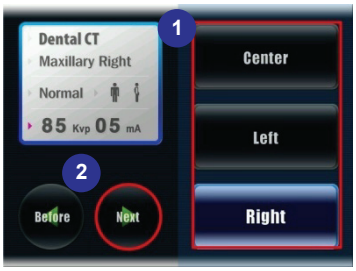
⑦ Next

Select 'Next' to go to the next stage.

⑧ Before

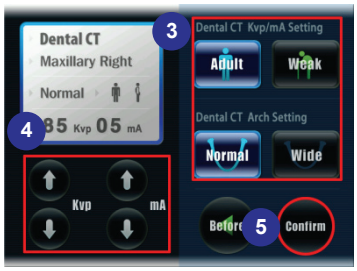
Select 'Before' to cancel the current setting values and to go back to the previous stage.

9.5.1. Dental CT (For Maxillary Mode)



① Select the mode for image capturing.

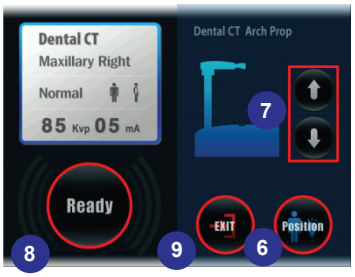
② Next : To move the next stage.



③ Select Patient : Select the X-ray exposure conditions suitable for the features of the patient (sex / bone density).

④ Select kVp / mA : Select the X-ray exposure amount suitable for the patient.

⑤ Confirm : Press to confirm the current setting.



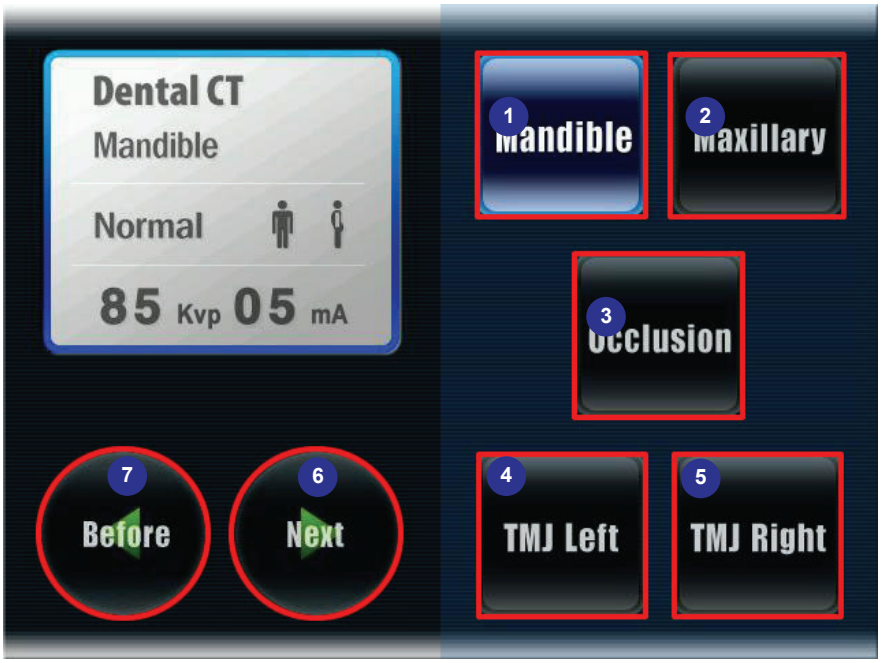
⑥ Position : To activate the camera and alignment lamp in order to place the patient in position.

⑦ Up / Down Arrows: To move the Arch Prop up and down.

⑧ Ready : To prepare for X-ray imaging according to the mode and conditions set.

⑨ Exit : Exit the program.

- FOV : 13X8



① Mandible

Press 'Mandible' for capturing an image that optimizes the mandible of the patient.

② Maxillary

Press 'Maxillary' for capturing an image that optimizes the maxillary of the patient.

③ Occlusion

Press 'Occlusion' for capturing an image that optimizes the occlusion of the patient.

④ TMJ Left

Press 'TMJ Left' for capturing an image that optimizes the TMJ left of the patient.

⑤ TMJ Right

Press 'TMJ Right' for capturing an image that optimizes the TMJ right of the patient.

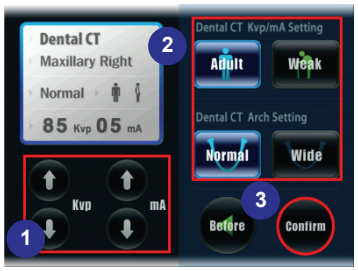
⑦ Next

Select 'Next' to go to the next stage.

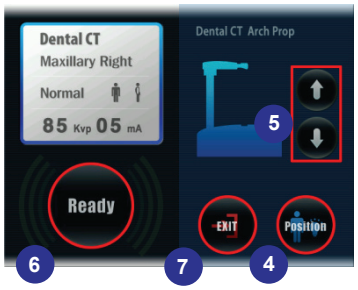
⑧ Before

Select 'Before' to cancel the current setting values and to go back to the previous stage.

9.5.2. Dental CT (For Maxillary Right Mode)



① Select Patient : Select the X-ray exposure conditions suitable for the features of the patient (gender / bone density).
② Select kVp / mA : Select the X-ray exposure amount suitable for the patient.
③ Confirm : Press to confirm the current setting.



④ Position : To activate the camera and alignment lamp in order to place the patient in position.
⑤ Up / Down Arrows: To move the Arch Prop up and down.
⑥ Ready : To prepare for X-ray imaging according to the mode and conditions set.
⑦ Exit : Exit the program.

9.6. X-ray Setting Screen

① X-ray Setting

Select kVp and mA of X-ray setting manually.

② Patient Setting

Select the features (gender and bone density) of the patient.

③ Confirm

Confirm the current setting and go to the next stage.

④ Exit

Cancel the current setting and go back to the previous stage.

10

Maintenance

This chapter describes the proper maintenance of the system.

10. Maintenance

10.1. Cleaning

The purpose of cleaning and rinsing the system is to remove all visible adherent stains (ex. blood, protein substances, and other debris), to reduce the number of particulate and micro-organisms, and to reduce the amount of phylogenic and antigenic materials.

Use a cloth moistened in cool to lukewarm soapy water to clean the unit, and to prevent coagulation and thus facilitate the removal of protein substances. Then wipe with a cloth moistened with clear water.

Mild detergent solution can be used. Never use cleaners or solvents of any kind. If you are uncertain of the nature of the cleaning agent, do not use it.

The following are examples of cleaning agents which are allowed or not allowed for cleaning the unit's panels:
Allowed : Acetylene, Butyl alcohol, Ethanol(ethyl alcohol) 96%, Methanol(ethyl alcohol), Soap.
Not Allowed : Benzene, Chlorine benzene, Acetone, Acetic ether

10.2. Disinfection

For example, use Ethanol 96% for disinfection of the system. Wipe manually with clean cloth moistened in disinfectant solution. Never use corrosive or solvent disinfectants. All items and surfaces should be dried up before the next usage.

Wear gloves and other protection materials during decontamination.

Do not use any disinfecting sprays since the vapor could ignite and may cause injury.

Disinfecting techniques for both the unit and the room must comply with all laws and regulations of the jurisdiction in which the unit is situated.

10.3. Sterilization

Do not use autoclave sterilization of the parts since some parts may get deformed during sterilization. Such parts are Bite block, Chin rest, TMJ chin rest, Sinus chin rest, and so on.

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Emergency Measure

This Chapter describes problems that may occur when using the equipment as well as their solutions.

11. Emergency Measure

If a problem occurs while using the product, check the following carefully and take the necessary actions; or request support through our customer support services.

• **If the device is not moving**	
Causes:	**Solutions:**
Power status	Check the power of the device.
Initialization status	Wait until the device finishes initialization, and then try again.
Control PC connection status	Check the connection status of Serial Port (RS232) that connects the PC and the device.

• **If exposure switch is not working**	
Cause:	**Solution:**
Ready status	Check whether the imaging program is ready for capturing an image.

• **If imaging is not working**	
Cause:	**Solution:**
Initialization status	Wait until the device finishes initialization, and then try again. If it still does not work, turn off the device and start again.

• **If Laser Beam is turned off and patient alignment cannot be performed**	
Cause:	**Solution:**
Alignment time over	Press the 'LAMP' Button again and carry out patient alignment.

Moisture may cause fatal error to this electrical equipment. Be careful not to allow leakage or penetration of water in it.

The information in this document is subject to change without notice and does not represent a commitment on the part of the vendor, who assumes neither liability nor responsibility for any errors that may appear in this manual.

If you do not properly set the device setting, causing it to malfunction or fail, we cannot guarantee any responsibility.

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