User Manual for Master3DS (Release Version 1.1.0 / Dated October 15th, 2008)

Master3DS

3-D Dental Imaging

New revolution for oral & Maxillofacial Specialist

- **User** Manual for Master3DS Dental Imaging

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 Introduction

This Chapter describes the overall features and components of the products, as well as various precautions, in detail.

1. Introduction

Master3DS is the diagnostic equipment of Computed Tomography X-ray System with Cone Beam Technology. It's a system based on digital and computed tomography. Especially, its advanced digital imaging process allows for a considerably efficient diagnosis, all kind of management information, and real-time sharing of image information on the network. It's equipped with the-state-of-the-art CT sensor to capture 3-D Computed Tomogram X-ray Scanned Image.
This manual includes information for the user of Master3DS. So you have to read this manual carefully before using.

Movement Technology	Multi-motor with digital trajectory control / Motorized carriage movement
Patient Positioning	Triple [Mid-Sagittal / Vertical / Horizontal] laser beam positioning system
Patient Positioning Aid	Chin rest, head rest, mirror, LCD for instruction Occlusion correction
Voice Instruction	Typical – English
Chair Up/Down Movement	Smooth up/down movement with two stage speed by step motor

1.1. Product Features

- Master3DS provides high quality digital image.
- Master3DS helps the patients to understand the diagnosis by viewing the invisible part with a 3-D viewer program, EzImplant.
- The FOV (Field Of View) is optimized for Implant surgery.
- Its image can be sliced to a minimum thickness of 0.1 mm (or thicker).
- Master3DS is equipped with a headrest for CT examination program mode, so the position of the patients should be fixed correctly.
- Master3DS has a minimal X-ray dose for the safety of the patients, as compared with other Dental CT systems.
- You can set and control the Examination Program Mode with a console PC.

- Master3DS supports the DICOM Format.

- Master3DS supports publishing of an image via CD.

1.1.1. Models

- Master3DS Standard FOV Model
  Extended FOV Model

1.1.2. Capture modes of CT System

- Shooting Mode:

Extended FOV Model		Standard FOV Model	
20x19:	Head Full Scan	20x15:	Head Full Scan
16x10:	Arch/ TMJ	16x10:	Arch/ TMJ
16x07:	Mandible/Occlusion /Maxillary/TMJ	16x07:	Mandible/Occlusion /Maxillary/TMJ

- Shooting Range: 90 kVp / 3.0 mA ~ 4.5 mA
- Basic Display View: Longitudinal/Cross Sectional/Sagittal
- 3D Image: Mandatory

1.1.3. Exposure Time

[CT]

Scan Time (All Model)

Normal Quality Mode	15 sec
High Quality Mode	24 sec

1.1.4. Anatomic Programs

- Patient Type: 2 choices: adult, senior-weak-children

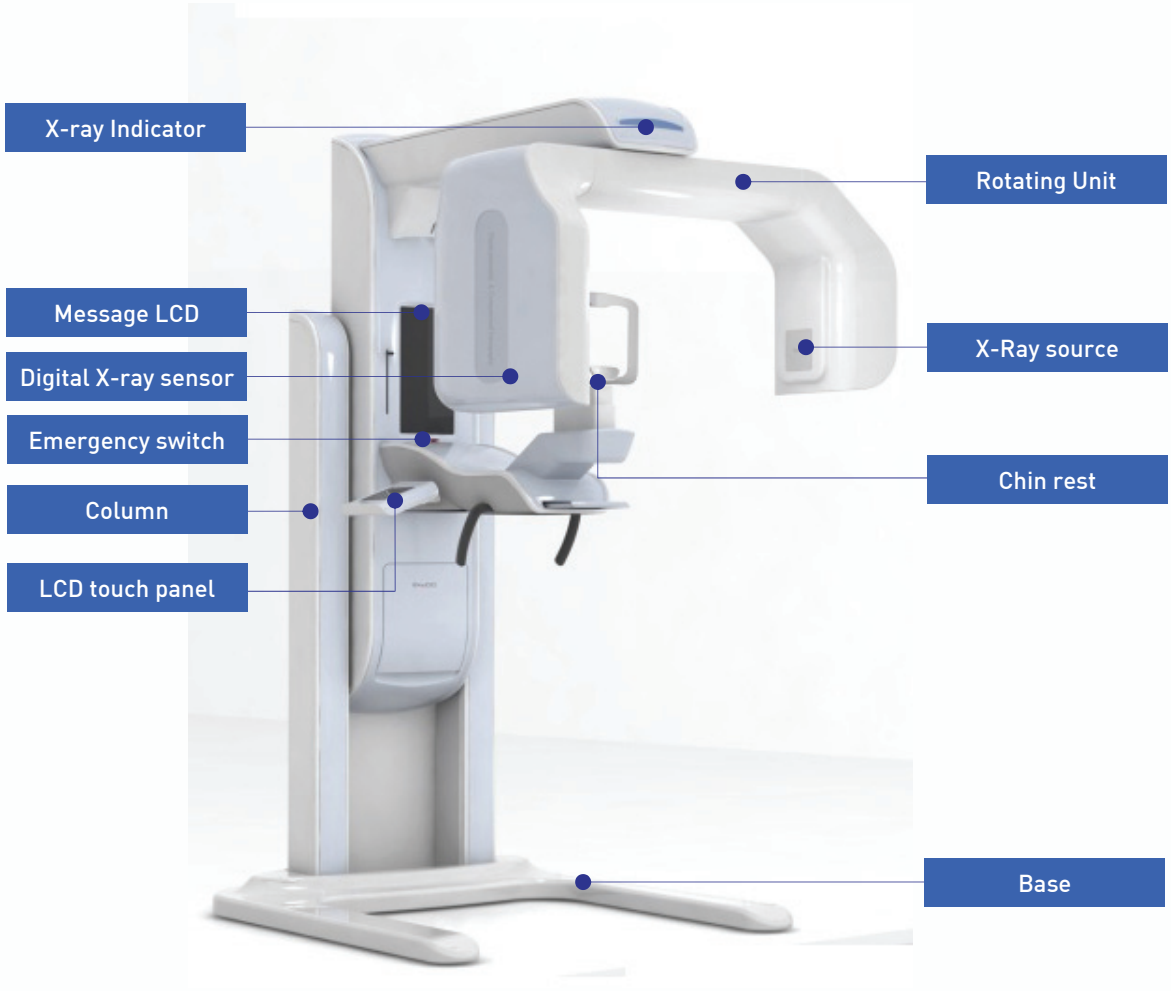
1.1.5. Image Magnification

- Digital CT Magnification (DICOM Image) 1:1

1.1.6. User Interface

- All operating functions are easily controlled from the PC (kVp, mA, Image Capture Mode etc.)
- Voice instruction in English
- X-ray exposure switch with extensible cable

1.2. Structure & Part



- **X-ray indicator :** Lamp for X-ray irradiating
- **Message LCD :** Displays the operation status of the equipment as text in LCD
- **Digital X-ray sensor :** Digital X-ray Image Sensor
- **Emergency switch :** Switch for stopping Up & Down movement in case of emergency
- **Column :** Unit that moves the system up & down for patient positioning
- **LCD touch panel :** Unit with functional control board
- **Rotating Unit :** Unit which turns around the patient's head during image capture
- **X-ray source :** Part for X-ray radiation exposure

- **Chin rest :** Unit for supporting patient's chin

- **Base :** Unit for supporting the system

NOTE

The above information may vary according to the model.

1.3. Cautions

WARNING

Make sure to observe the following.

- Follow the specified process of operation for the safety of the users and patients.
- Check the conditions 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 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 image.
- Place this product away from water, moisture, or foreign substance since this product is a precision medical electronic device.
- Turn off the power, immediately, if the product is exposed to water or foreign substance during use, resulting in abnormal operation. Contact the agent for technical support.

1.4. Warning

WARNING

Make sure to observe the following.

- Master3DS is a precision electro-mechanical system. Therefore, please read this manual carefully before operation. E-WOO is not responsible for damages caused by improper installation and maintenance procedures and wrong operations.

1.5. Radiation Protection Policy

NOTE

User should comply with rules and regulations of your country on radiation safety and protection 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 the 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.

WARNING

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

1.6. 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:

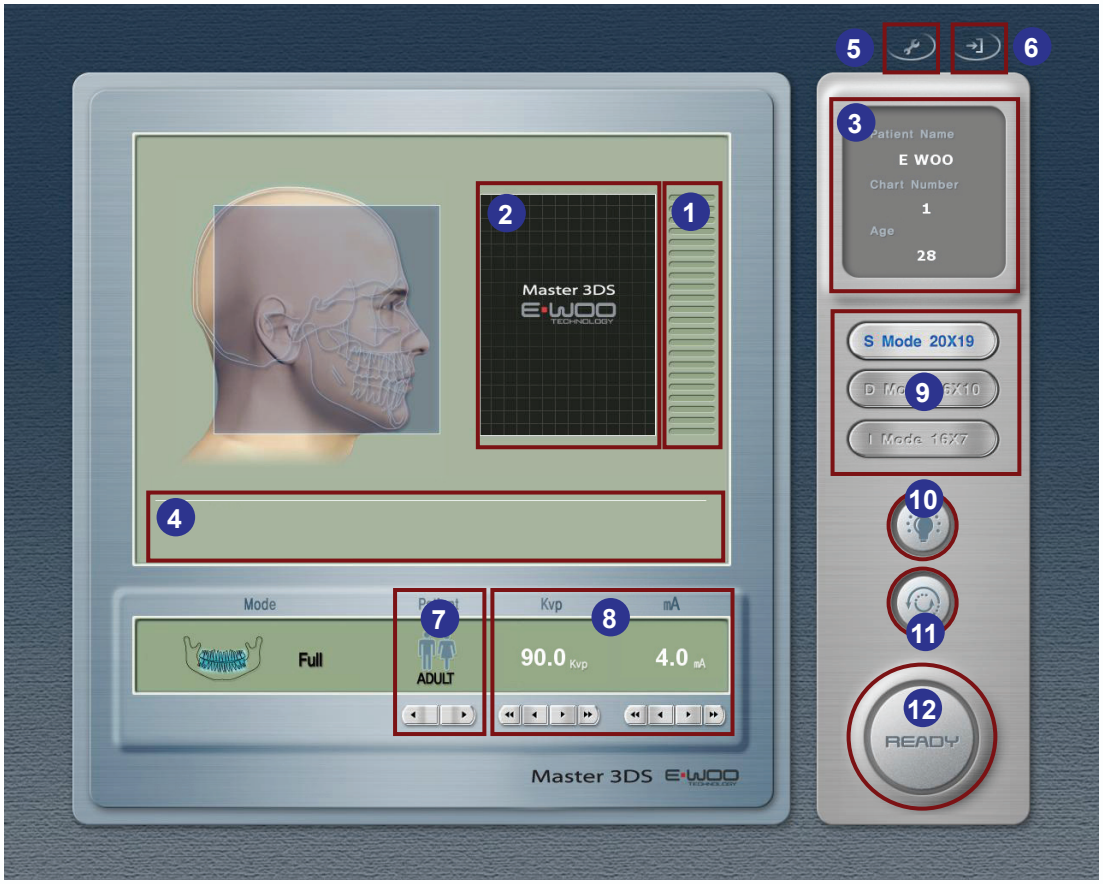
- If the product is installed by our authorized agent.
- If the product is installed in accordance with cautions and conditions for installation.
- If a genuine product is used, as approved by our company.
- If maintenance / repair service is performed by our authorized agent.
- If the product is normally 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 software architecture of the product, in detail.

2. Software Functions

2.1. Menu on CT



① Imaging, Image Processing Status Bar (Progress bar)

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

② Imaging Status and Image Display Window

Shows imaging progress status for capturing image and shows the image captured after imaging (shows image captured in real time at the time of actual imaging).

③ Patient Information Window

Shows information of the patient such as name, age and chart number.

④ Imaging Instruction Window

Shows various kinds of text instruction messages for imaging.

⑤ Setting Control Button

Set a configuration of the system (do not operate this, unless you are a certified engineer).

⑥ Exit Button

Exit the imaging program.

⑦ Patient Button

Select the patient (adult, senior-weak-child (under 10 years old))

⑧ X-ray Setting

Adjust KVp, tube voltage value; and mA, tube current value.

⑨ Imaging Mode Buttons

Select the imaging mode of S mode 20*19, D mode 16*10 and I mode 16*7. (In case of Standard FOV Model)

⑩ Lamp Button

Turn position lamp On/Off to assist in the correct alignment of the patient's head.

⑪ Return Button

Cancel the current settings of patient.

⑫ Ready / Cancel button

Confirm the imaging of patient or cancel imaging.

NOTE

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

2.2. LCD Panel

2.2.1. Main Screen

2.2.2. Lamp Screen

- **LAMP:** alignment lamp to place the patient in position

2.2.3. Return Screen

- **RETURN :** Return rotating unit to initial position

2.2.4. Arch Screen

- **ARCH :** Moves the chin rest up & down for patient positioning

3 Preparation for image Capture

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. Preparation for image capture

3.1. Preparation before capturing Image

Make sure to check the following before capturing image:

- **Check whether the equipment is turned on.**
- **Make sure to check whether two lock keys are installed at the PC, and then turn on the PC.**

NOTE

You can not capture and see Master3DS images without the two lock keys.

3.2. How to register new patients

3.2.1. How to register new patients

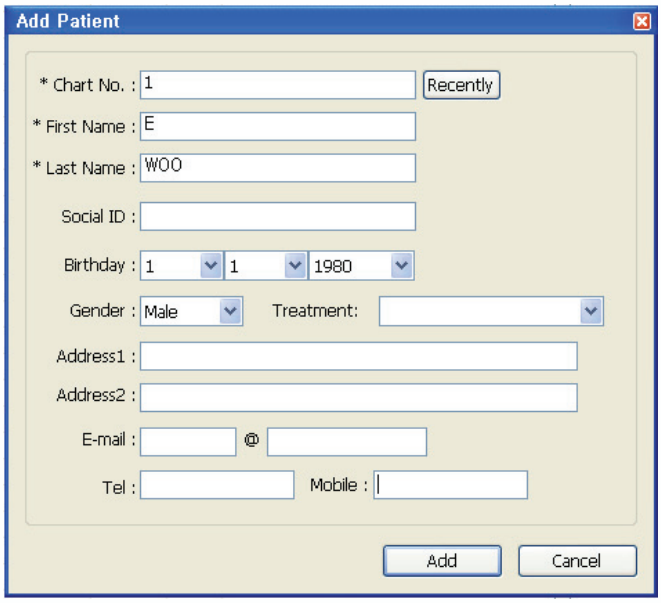
Follow the steps shown below to register a new patient:

① Turn on the product and the computer.

② Execute EasyDent V4 and click ‘Patient (

)’ icon to register new patient.

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



④ Click 'Add' to close the dialog box if you are done filling it.

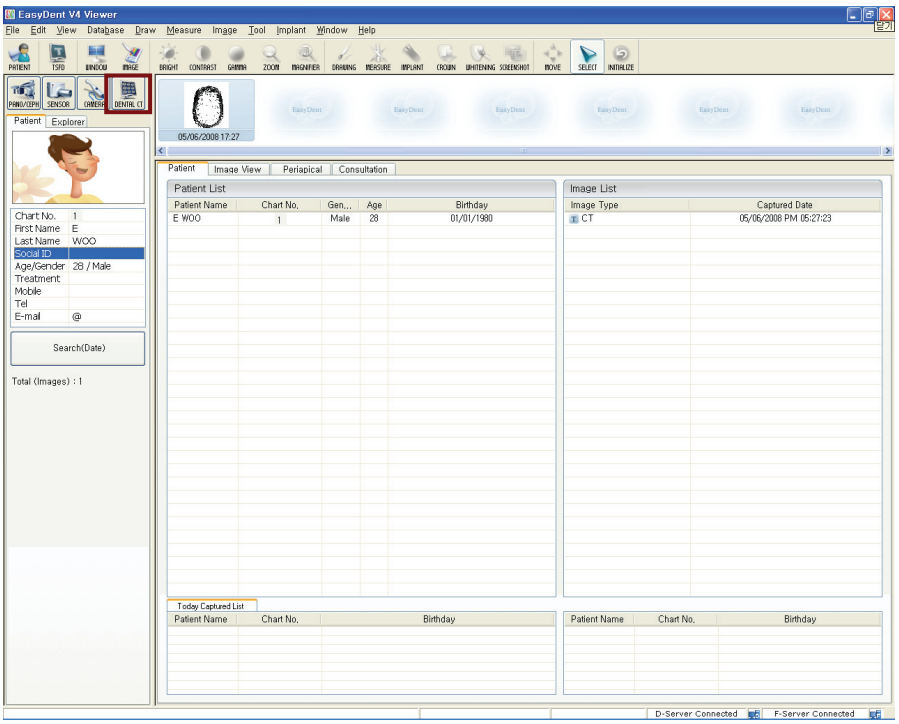
3.2.2. CT Imaging Procedure

In order to get CT images, perform the imaging in the order specified:

① Switch on the power of the equipment.

② Execute EasyDent V4 program in the PC.

③ The program will be displayed as shown in the figure below. Search and select the patient for imaging.



[EasyDent V4 Program Screen]

④ Click 'Dental CT(

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

NOTE

For unregistered patient, register him / her first before capturing image. Refer to EasyDent V4 program user's manual prepared separately.

NOTE

Sensor module check may encounter error due to wrong installation of the sensor. In this case, reinstall the sensor and try again.

CT Procedures 4

This Chapter gives instructions on how to position the patient and capture CT image.

4. CT Procedures

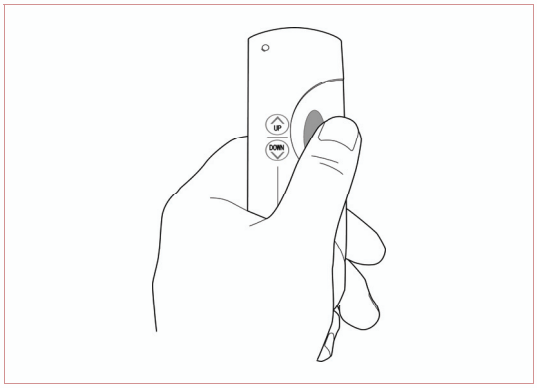
4.1. Patient positioning for CT unit

① Insert the head rest and chin rest with hygienic covers.

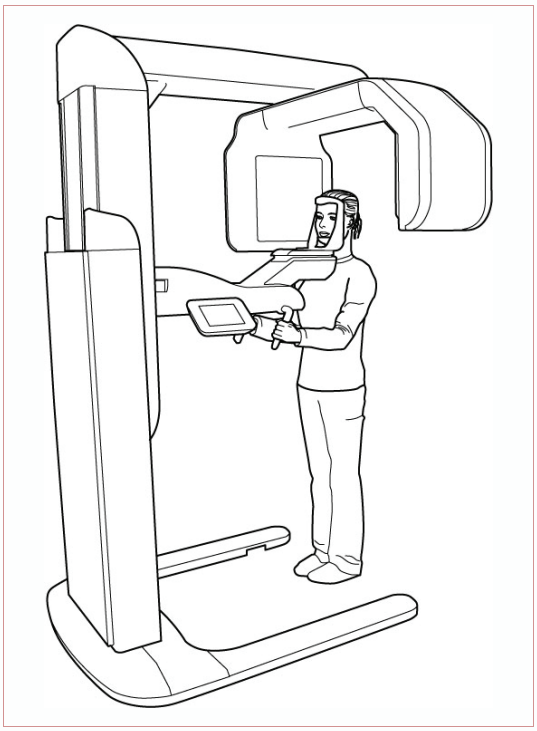
② Ask the patient to remove any metal objects; such as eyeglasses, dentures, hearing aids, hairpins, earrings, necklace, etc., from the head and neck area. Shadows caused by these opacities may obscure diagnosis.

③ It is strongly recommended that the patient wear lead apron for radiation protection.

④ Guide the patient to the unit facing the chin rest.



⑤ Adjust the height of the unit to fit the patient. By pressing the up & down button on the Column up-down switch, adjust the carriage height so the chin rest is on the level of the patient's chin. The carriage column moves slowly at first, and then faster.

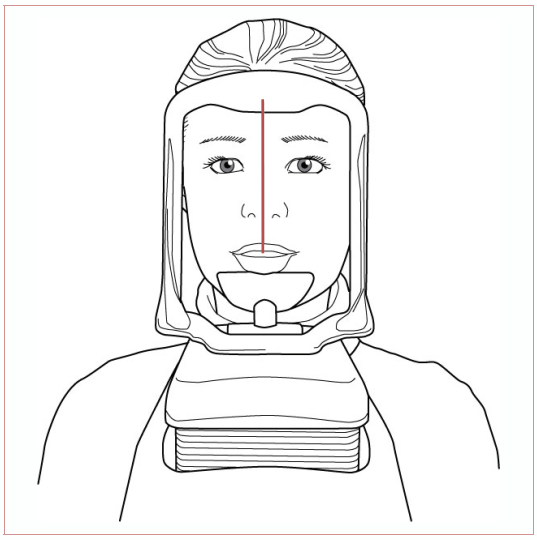


⑥ Ask the patient to step forward and to hold the patient handles firmly.

⑦ Make sure that the chin rest and head rest are covered with hygienic covers, then, ask the patient to put chin at the chin rest comfortably.

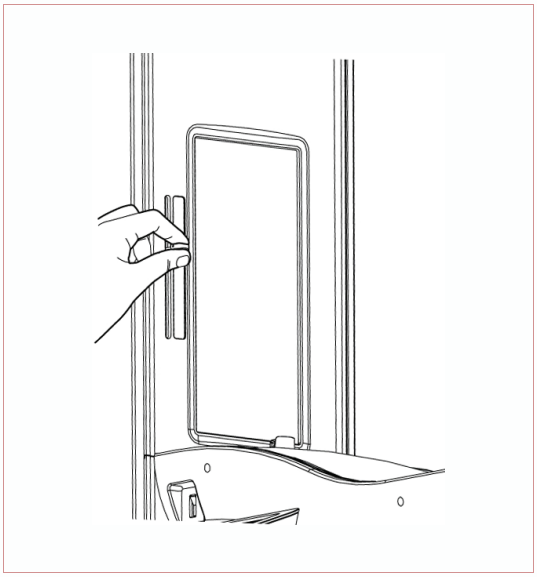
⑧ Make sure that the patient's shoulders are level and the neck is relaxed. Backbone should be straight and upright.

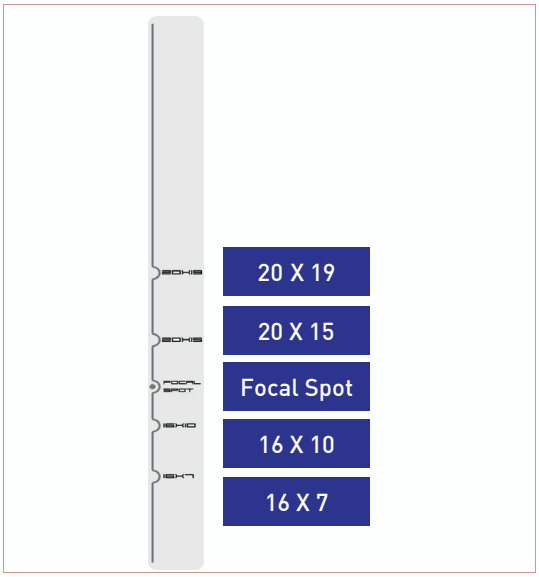
◈ Laser beam alignment



⑨ Position the head of the patient so that the midsagittal plane will coincide with the vertical beam.

⑩ Adjust the horizontal beam to position the FOV size you want.

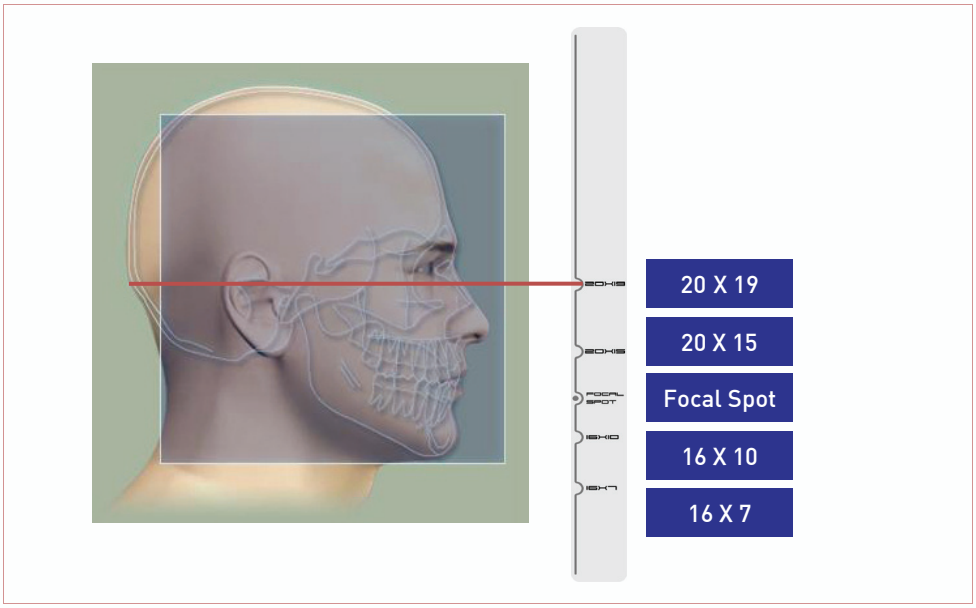




NOTE

The beam position the half of each FOV.

Adjust the horizontal beam in accordance with each of the FOV mode.



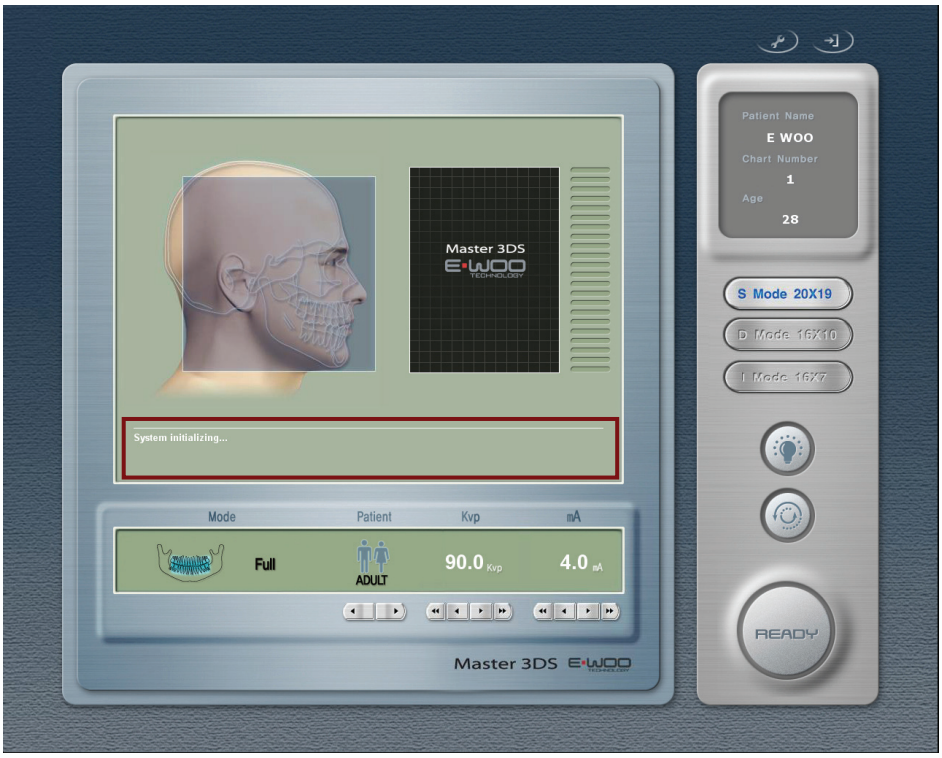
For instance, if you want to take 20*19 FOV size, the horizontal beam positions at the center of FOV size (9.5cm)

⑪ Make sure that the patient's eyes are closed.

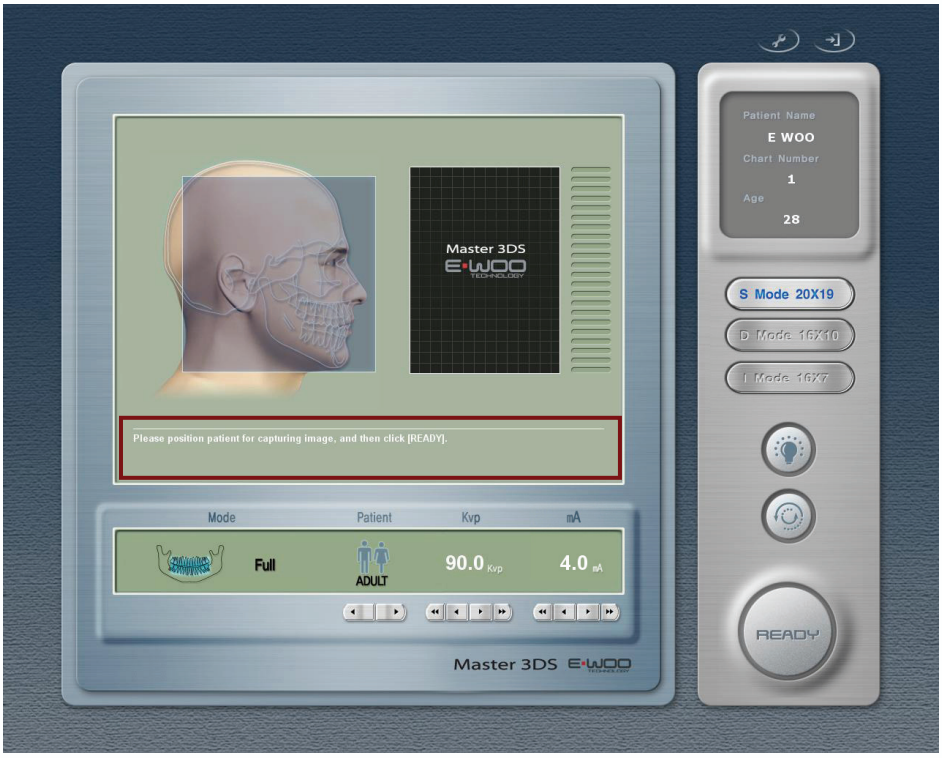
⑫ Tell the patient to stand still, to not make any movements until capturing image is finished, and to be ready for exposure.

4.2. Capturing Program

① PC will check the system (Master3DS) whether it is prepared to capture images or not.



② Set conditions for image-capturing (kVp / mA setting, Adult / Weak select). Then Click ‘Ready’ button when the positioning of patient is finished.

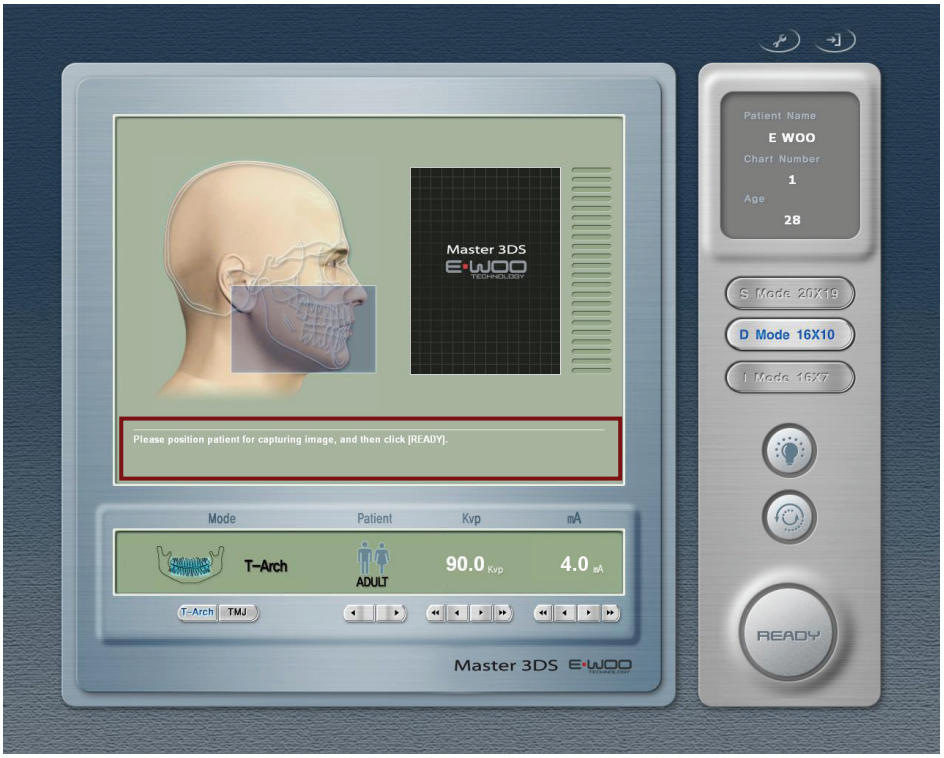


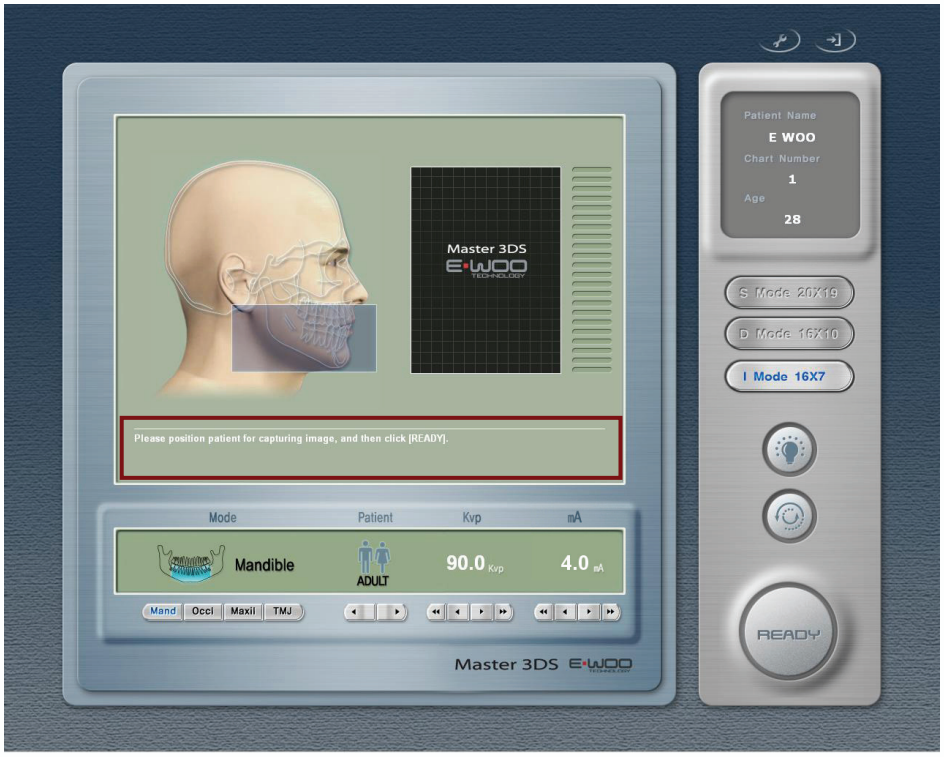
NOTE

This system has three FOV size functions,

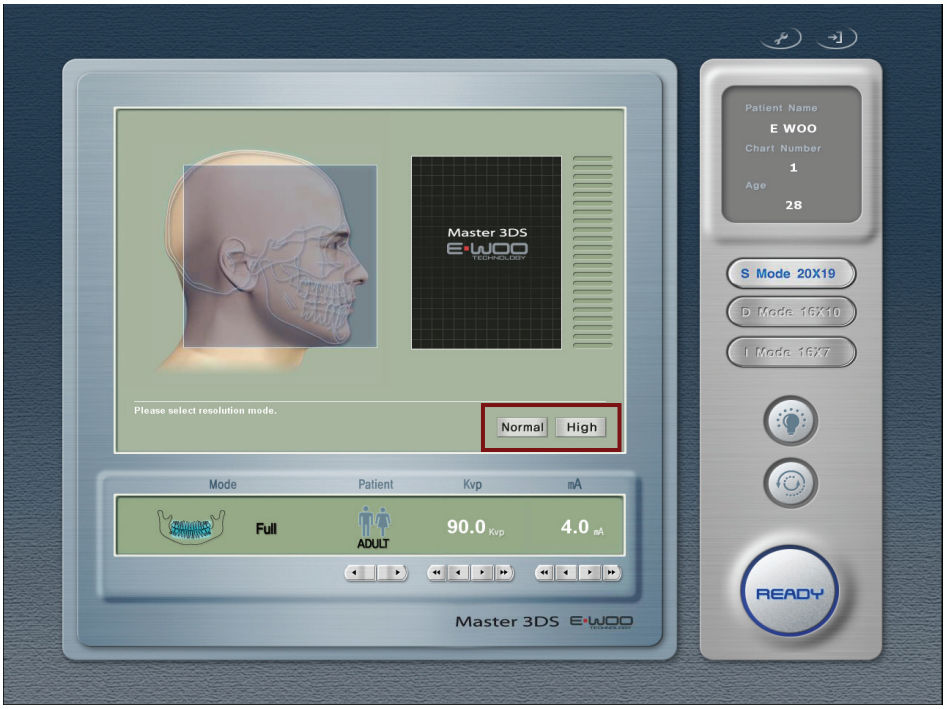
1. Standard FOV mode is 20 x 15, 16 x 10, 16 x 7

2. Extended FOV mode is 20 x 19, 16 x 10, 16 x 7





③ Select ‘Resolution mode’ : An image is captured on Normal mode (resolution) in general



NOTE

High mode (resolution) gives a very clear image. However it takes more time to reconstruct the image on the capturing program and to call the image on the EzImplant program.

NOTE

Reconstruction time according to resolution.

* Standard FOV Model

FOV(Cm)	Voxel Size	Scan Time(sec)	Recon time(sec)
20x15	0.3	High (24)	51
		Normal (15)	32
	0.4	High (24)	42
		Normal (15)	28
16x10	0.3	High (24)	25
		Normal (15)	16
	0.4	High (24)	24
		Normal (15)	15
16x7	0.2	High (24)	24
		Normal (15)	18
	0.3	High (24)	19
		Normal (15)	13

NOTE

* Extended FOV Model

FOV(Cm)	Voxel Size	Scan Time(sec)	Recon time(sec)
20x19	0.3	High (24)	32
		Normal (15)	24
	0.4	High (24)	26
		Normal (15)	18
16x10	0.3	High (24)	14
		Normal (15)	10
	0.4	High (24)	13
		Normal (15)	9
16x7	0.2	High (24)	19
		Normal (15)	14
	0.3	High (24)	14
		Normal (15)	9

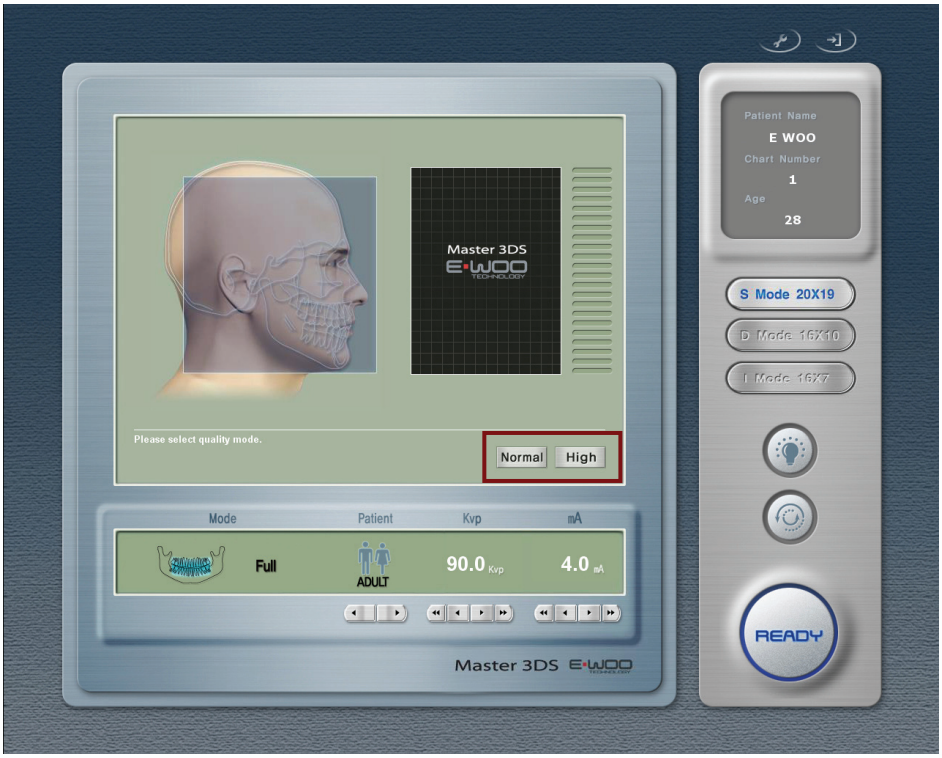
(Remark)

Master 3DS : XW8600, XP SP2ENG, 4GB RAM, GTX280(1GB)RAM

It takes twice the time compared to reconstruction without metal function.

Tested time will be subjected to change depenging on user's puerpose & environment.

④ Select 'Quality mode'.

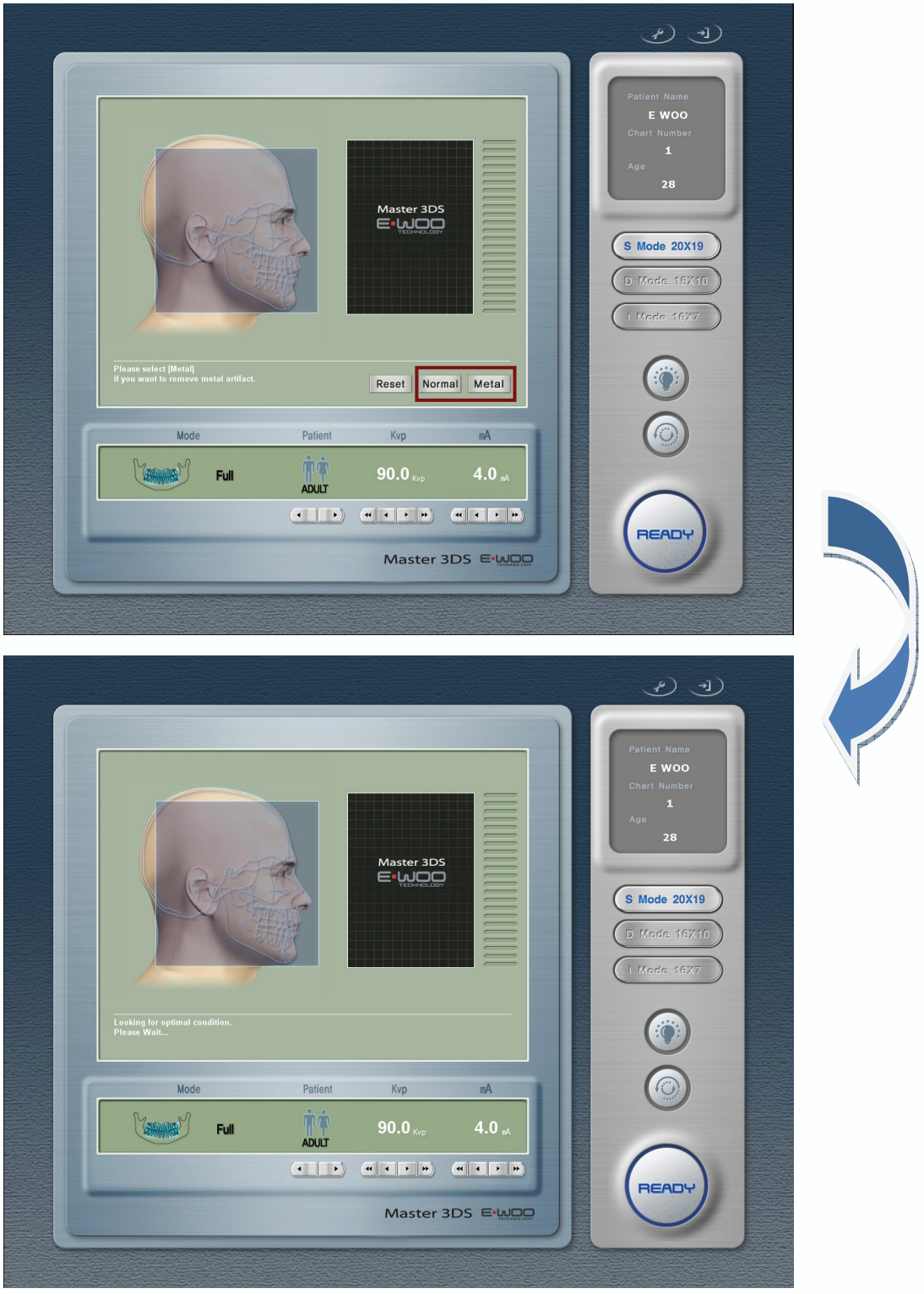


NOTE

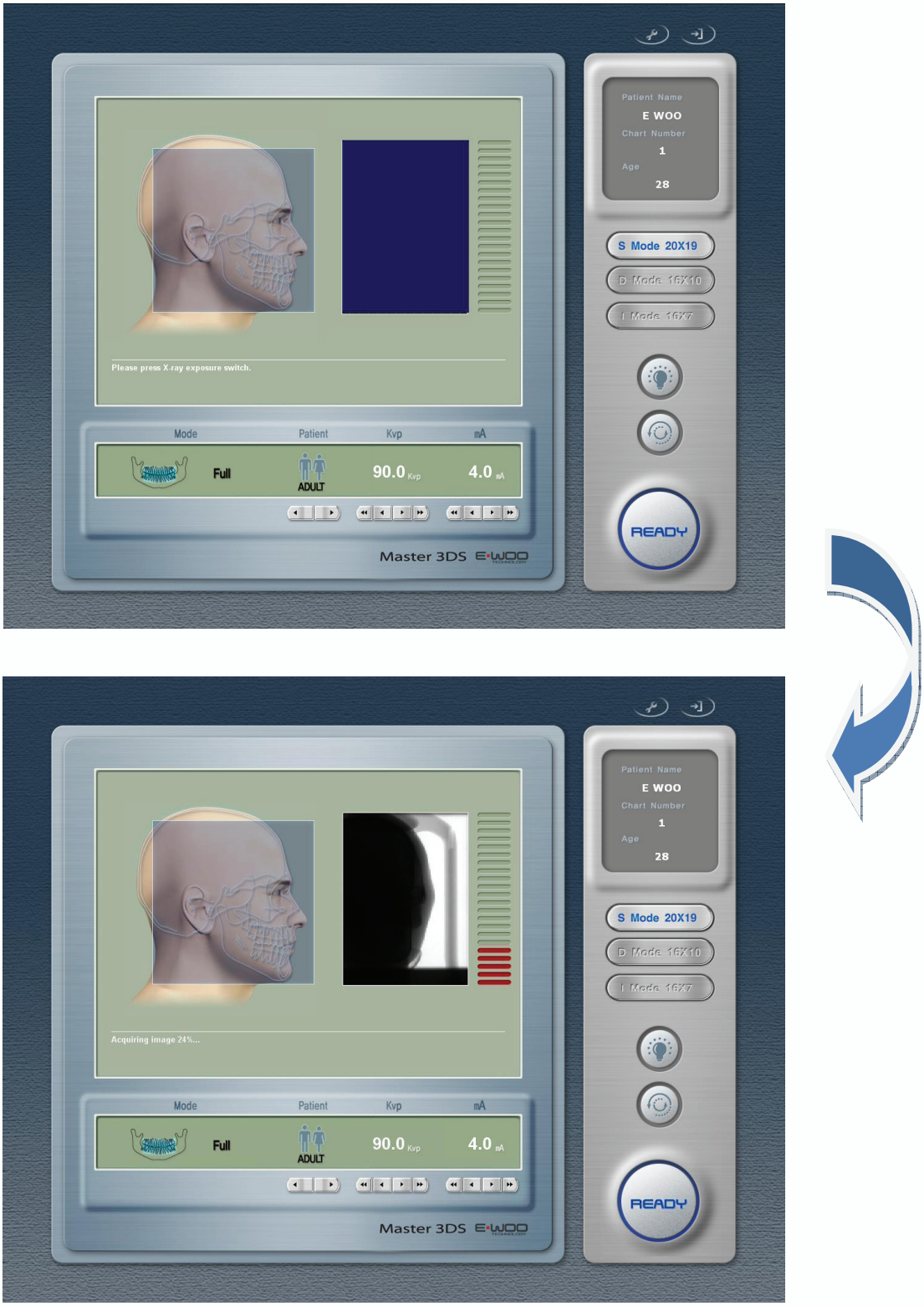
The Quality mode is divided into two according to scan time.

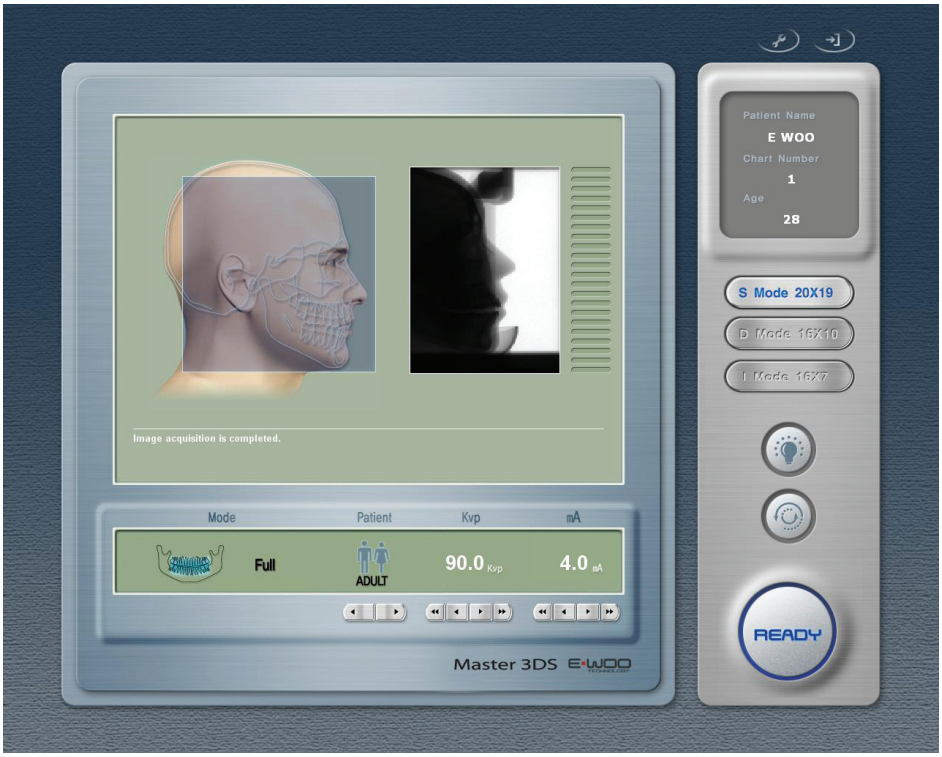
Quality mode	Scan time
Normal	15 sec
High	24 sec

⑤ Select ‘Metal’ if you want to remove a metal artifact. Otherwise, select ‘Normal’

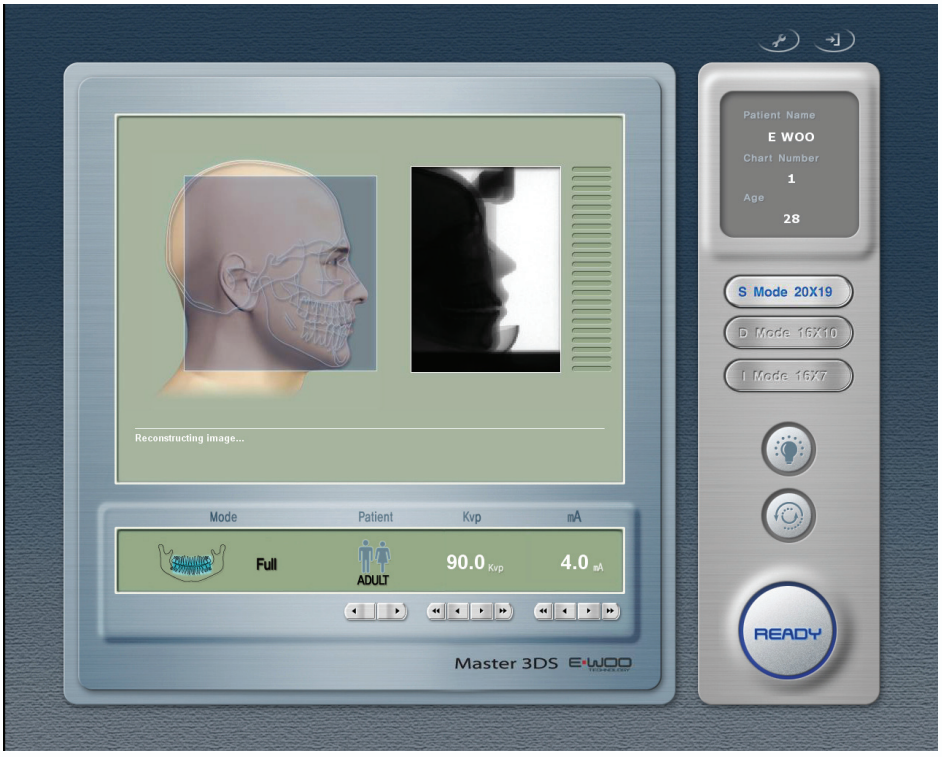


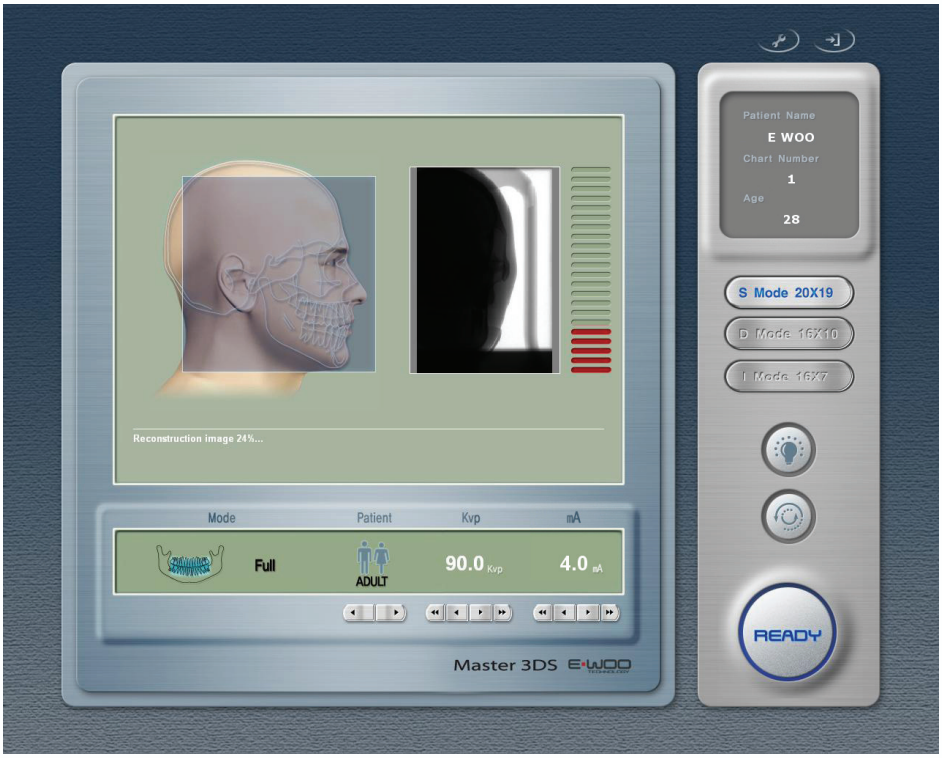
⑥ Push and hold the exposure switch until the image-capturing is finished.





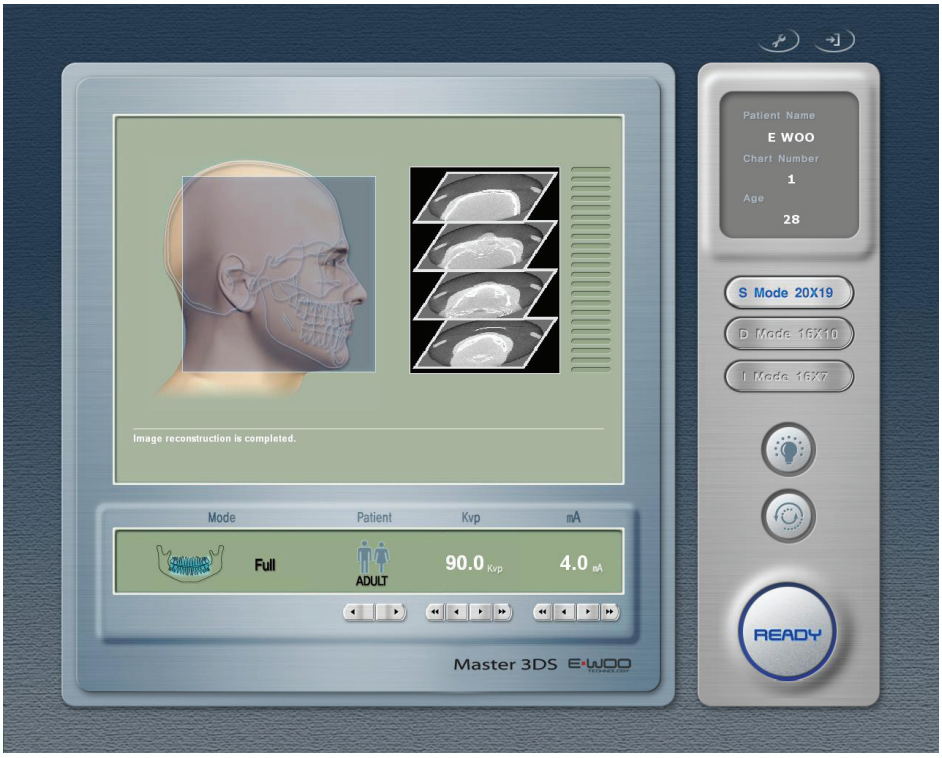
⑦ The captured image will be reconstructed.



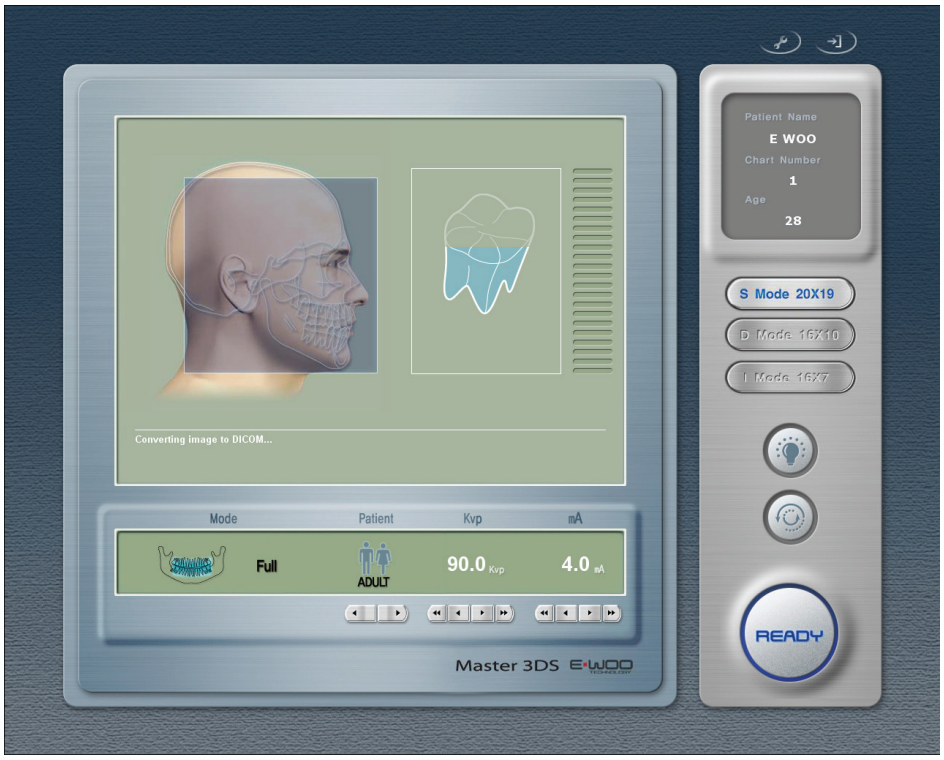


NOTE

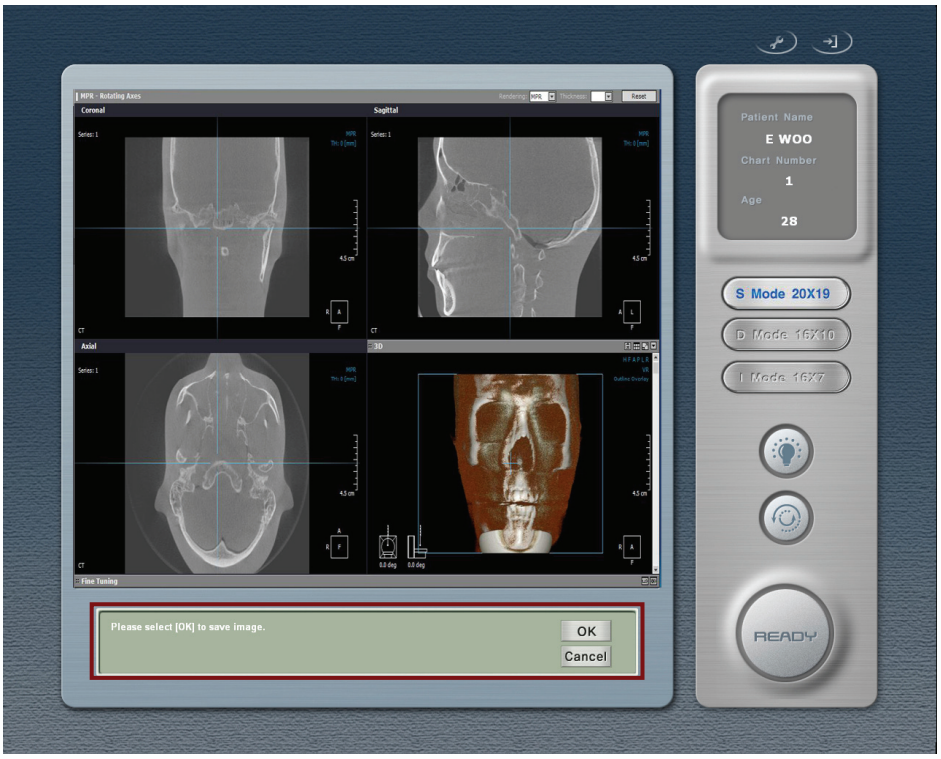
Do not operate the system during the time of initialization of communication between the PC and the sensor, and during the reconstruction of the image. It may cause mis-operation.

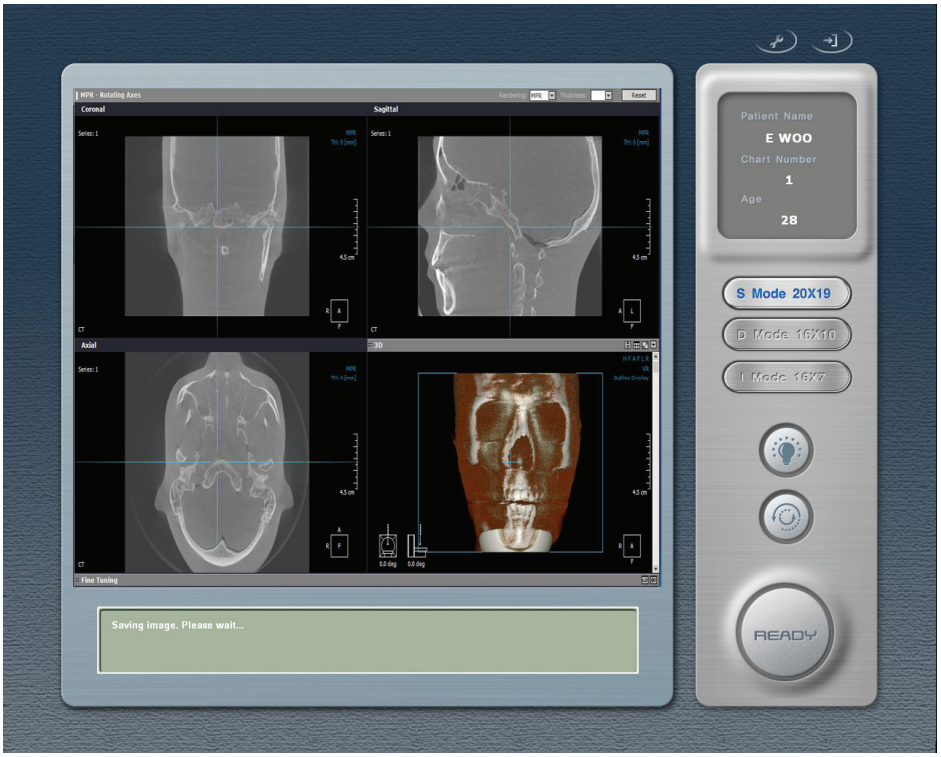


⑧ The image will be converted to DICOM format.

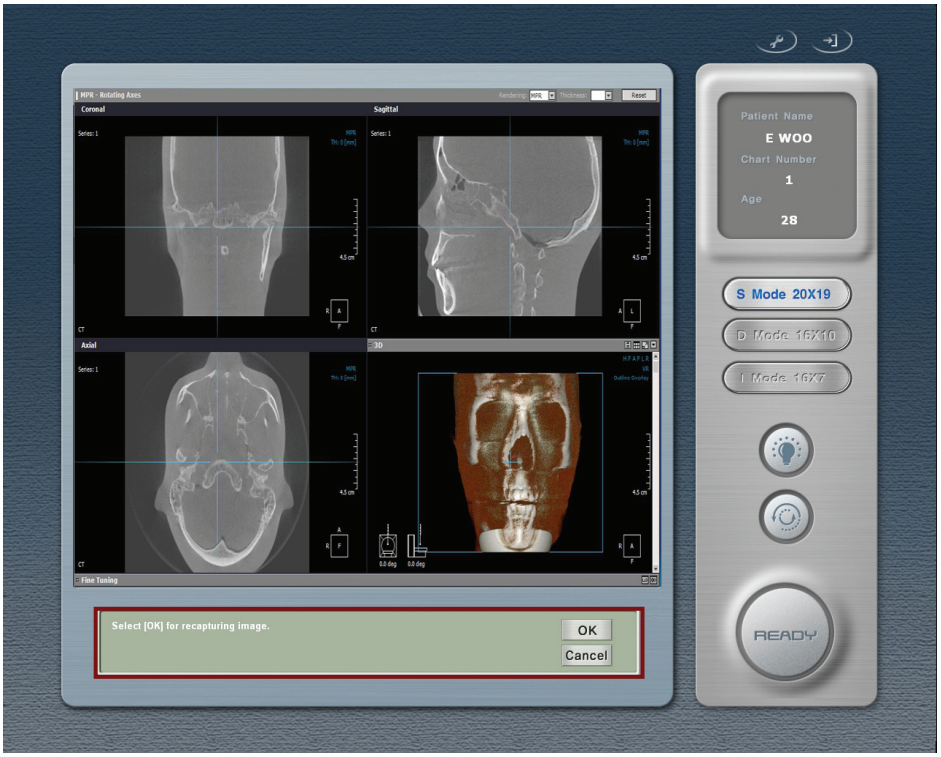


⑨ Click ‘OK’ if you want to save the image to DB.





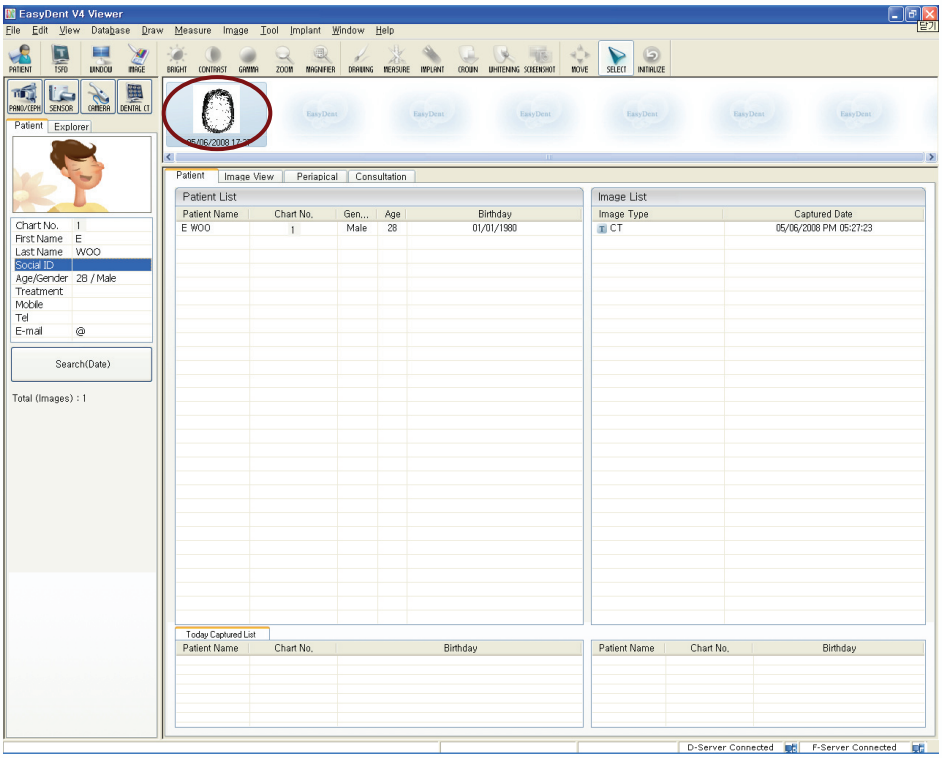
⑩ Click ‘Cancel’ if you do not want to capture the same patient again.

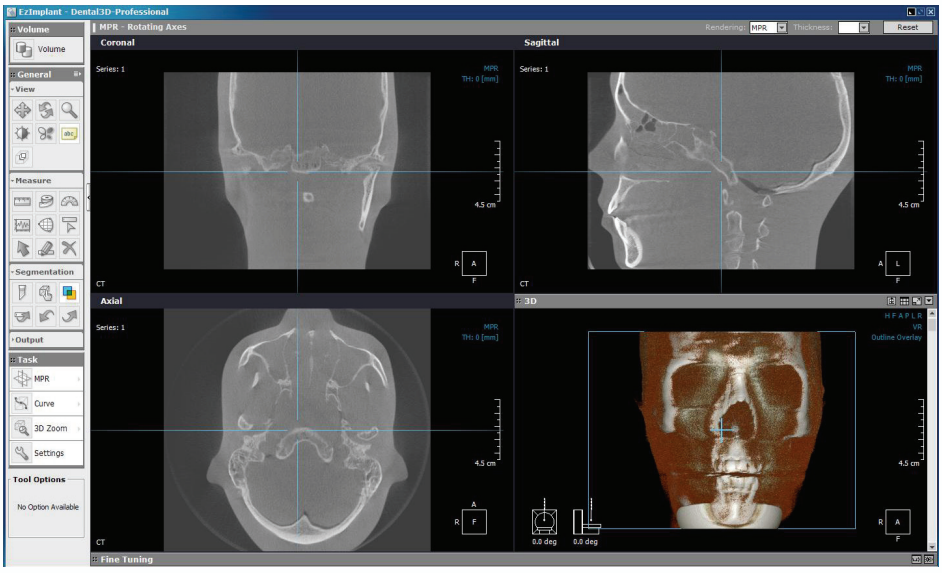


NOTE

If you want to capture the same patient again, click ‘OK’.

⑪ You can see the image on thumbnail of the EasyDent viewer. Double-click on it to see in datail. And then EzImplant will be ran automatically.





NOTE

Refer to the manual of EzImplant for further information about EzImplant software operation procedure.

5 Technical Specification

This Chapter describes technical specification, classification, symbols, and labels of the equipment.

5. Technical Specification

5.1. Specification of Master3DS

- X-ray beam: Cone Beam
- Reconstruction Algorithm: CT Algorithm
- Dynamic Range:
  - Extended FOV Model (20x19) – 14bit
  - Standard FOV Model (20x15) – 14bit
- Slice Thickness (mm): 0 ~ 10 (default: 0.3 mm)
- Scan Time (sec): High Quality Mode - 24sec/ Normal Quality Mode - 15 sec
- Rotating Unit Scan Angle (degree): 360
- Number of View: About 715 Frames (High Quality)/ About 440 frames (Normal Quality)
- Number of Sliced image:
  - Extended FOV Model (20x19): Max 592 (20x19)/ Min 176 (16x7)
  - Standard FOV Model (20x15): Max 496 (20x15)/ Min 176 (16x7)
- Patient Position: Stand
- Patient Alignment: 3 Laser Beams Alignment
- FOV (mm):
  - Extended FOV Model (20x19) – 200x190/ 160x100/ 160x70
  - Standard FOV Model (20x15) – 200x150/ 160x100/ 160x70
- Reconstruction Time:
  - Extended FOV Model (20x19) – Min 9 sec (16x7) / Max 32 sec (20x19)
  - Standard FOV Model (20x15) – Min 13 sec (16x7) /Max 51 sec (20x15)
- kVp Range: 50 ~ 90
- mA Range: 2 ~ 10

5.2. X-ray Generator

- High frequency generator, constant potential, micro processor controlled

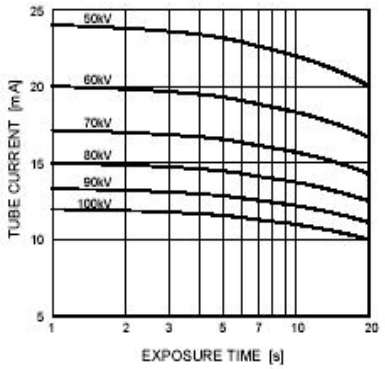
Ripple	< 4%
Inverter frequency	36 kHz push-pull
Tube type	D-051, stationary anode type
Nominal power	Below than 1.3 KW
Tube voltage	40 – 90 kV (adjustable by 1 kV)
Tube current	2 – 10 mA (adjustable by mA)
High voltage	DC
Cooling	by force, one minute for cooling / Protect ≧ 50℃

Maximum Rating Charts

(Absolute maximum rating charts)

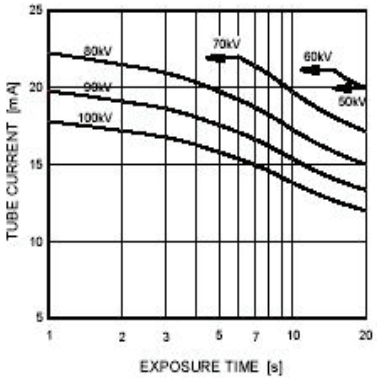
Single-Phase Full-Wave

Focus Spot : 0.5 mm



DC (Center-Grounded)

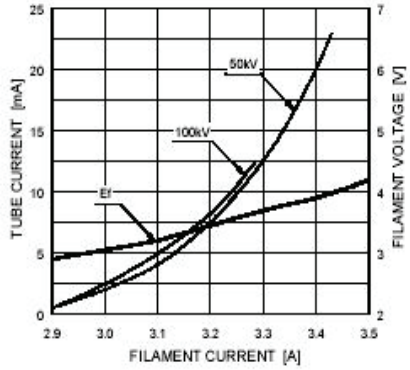
Focus Spot : 0.5 mm



Emission & Filament Characteristics

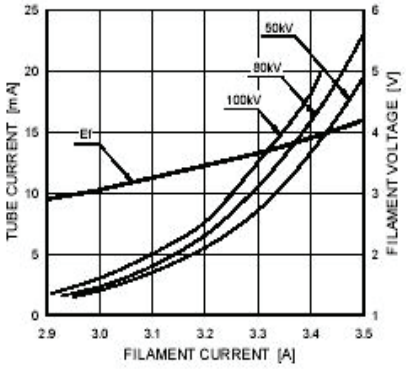
Single-Phase Full-Wave

Focus Spot : 0.5 mm

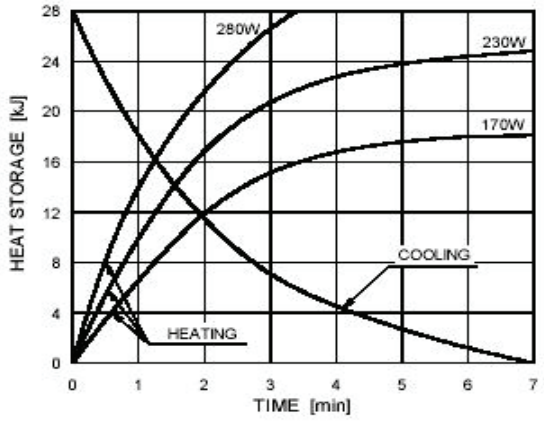


DC (Center-Grounded)

Focus Spot : 0.5 mm



Anode Thermal Characteristics



5.3. X-ray Tube

• Focal spot size	0.35*0.5 mm
• Heat storage capacity	30 kJ (40 Khu)
• Total filtration	2.8 mm Al eq.

5.4. Collimator

• Primary collimator	Changeable by FOV Size

5.5. Electrical Characteristics

• Power supply voltage	AC 110/230V ± 10%
• Frequency	50/60 Hz
• Power rating	1.7KVA

5.6. Environmental Characteristics

• Operating temperature	10 - 30℃
• 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

5.7. System Requirements for the PC

A. Image Capturing

• PC Model	HP workstation XW 8600
• Operating System	Microsoft Window XP Service Pack 2
• CPU	Intel Core 2 Duo 3.4GHz or higher
• Cache Memory	1MB or higher
• HDD	1 TB (prefer bigger capacity)
• Main Memory	3GB DDR2 or higher
• Video Memory	756 MB (Geforce 8800 GTX)
• Network	2 EA of 10/100/1000 Gigabit (Intel Gigabit Ethernet Card)
• Serial	1 EA of RS232 serial port
• DVD+/-RW	
• Monitor	Min, resolution 1024x768

B. Image Viewer

• Operating System	Microsoft XP Home Edition Service Pack 2
• CPU	Intel Core 2 Duo 3.4GHz
• Cache Memory	1MB
• Main Memory	1GB DDR2
• Video Memory	256 MB
• Network	1 EA of 10/100/1000 Gigabit
• DVD+/-RW	
• Monitor	Min, resolution 1024x768

5.8. Classification

• Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529… IPXO Secondary collimator at CEPH to reduce scattered radiation

• According to the mode of operation:

- Continuous operation with intermittent loading

5.9. Marks & Graphic symbols

TYPE B Equipment

Radiation hazard

CE 0499

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

EC Representative ; DentalHolding Sp.Zo.o
ul. Chalubinskiego 8
00-6 Warszawa Poland
Tel: +48-22-313-08-08
Fax: +48-22-313-08-90

Maintenance 6

This Chapter describes the proper maintenance of the system.

6. Maintenance

6.1. Cleaning

The purpose of cleaning and rinsing is to remove all visible adherent stain (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 material.

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 cleaning agents, do not use it.

The following are examples of cleaning agents which are allowed and 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

6.2. 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 system during decontamination.

Do not use any disinfecting sprays since the vapor could ignite which can cause injury.

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

6.3. Sterilization

Do not allow to sterilization of the parts in autoclave since some parts may be transformed during sterilization.

7 Emergency Measures

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

7. Emergency Measure

If a problem occurs while using the product, do not get embarrassed but check the following carefully and take necessary actions or request support through our customer support services.

● If device is not moving	
Cause	**Resolution**
Power status	Check the power of device.
Initialization status	Wait until the device is initialized and then try again.
Control PC connection status	Check the connection status of Serial Port (RS232) connecting PC and device.

● If exposure switch is not working	
Cause	**Resolution**
Ready status	Check whether it is ready for capturing at the imaging program.

● If imaging is not working	
Cause	**Resolution**
Initialization status	Wait until the device is initialized and try again. If it still does not work, turn it off and start again.

● If Laser Beam is turned off and patient alignment cannot be performed	
Cause	**Resolution**
Alignment time over	Press LAMP Button and carry out patient alignment.

Moisture may cause fatal error to an equipment using electricity. Be careful not to allow leakage or penetration of water around the equipment.

Appendix

1. Recommended X-Ray Exposure Table

1.1. Standard/ Extended FOV Mode

Figure / Age	KVp	mA	Back Ground Level
Adult	90 kVp	4 mA	11000 ± 800
Weak	90 kVp	3.5 mA	9200 ± 800

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

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