GENORAY

Diagnostic computed tomography limited view field X-ray system

GT300 & GT300-C

User Manual

UM-C01 FDA

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Preface

This manual provides the operational information of **GT300 & GT300-C (hereafter, "the equipment"),** including the introduction, screen configuration, menu, etc. and is applicable to equipment with standard features. Some of the contents may differ from the actual equipment depending on the model and specification. Subject to changes to improve the equipment without any notification.

In case you have any questions about the equipment and/or this manual, please refer to the information on the manufacturer or the vendor at the end of this manual for contact details.

Federal law restricts this device to sale by or on the order of a Dentists and Radiologists.

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Reporting Serious Incidents

If the device has caused to user and/or patient that any serious incident, you should report to the manufacturer and the competent authority of the Member state in which the user and/or patient is established.

How to Report

The responsible personnel for reporting the incident may use the following:

- Notify the competent authority of the member state where the user is located,
- Contacts to the vendor or the service team of the manufacturer, or
- genoray@genoray.com E-mail

Necessary Information for the Report

The following information should be reported along with the incident:

- Product name,
- Serial number and the date of production,
- Date of the incident,
- Statement of the incident including its effect/injury caused to the operator or the patient,
- Address and location of installation, name and title of the responsible personnel, and contact number.

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1. Overview

Provides general information regarding the manual and the equipment.

1.1) General Information of the Manual

This section provides information regarding the definition of the manual, notations, warnings, signs, and the contents of the manual.

1.1.1) Definition of the Manual

- The user of the equipment should operate it only after reading this manual carefully and understand it thoroughly. Also, this manual should be stored at which the user can easily access and look it up whenever needed.
- This manual is provided along with the equipment from shipping.

Important Notes

- This manual is not allowed to be replicated without the consent of the manufacturer.
- This manual is created based on the shipping date of the equipment. However, it is subject to modification due to design changes and/or adding features, and this manual may lack such changes yet.
- If any content in this manual does not correspond with the actual equipment, contact the service center.

1.1.2) Notation in the Manual

"Notations" refers to special symbols or rules used in a user's manual.

This manual uses the following notations to allow the user to easily understand the contents of this manual.

Item	Description
▪ ABC ▪ ABC ▪ ABC	Used to classify or organize equivalent items based on specific conditions.
1 ABC 2 ABC 3 ABC	Used to arrange the steps of a task procedure in order.
❶ ❷ ❸	Used to describe the names or details of components in an image.
① ② ③	Used to describe the order of actions in an image.

1.1.3) Signs in the Manual

NOTICE

The user should check the following signs to guarantee safe use of the equipment:

Feature	Description	Location
	AC	-
	Grounding	Boards
	"ON" (Power)	Equipment (Circuit breaker)
	"OFF" (Power)	Equipment (Circuit breaker)
	High voltage generator, X-ray exposure	Label
	Warning: High voltage	Generator
	Warning: Laser	Equipment
	B type mounting unit	Label
	WEEE Mark	Label
	Manufacturer name and address	Label
	Date of production	Label
SN	Product Serial No.	Label
	Refer to the user manual.	Label
MD	Mark for medical device	Label
UDI	Unique device identifier	Label/Manual
CC	Country of production	Label

1.1.4) Warnings in the Manual

This equipment is potentially dangerous regarding the X-ray during operation. The user should thoroughly understand the safety issues, measures for emergency, and proper ways of operating the equipment. In this manual, the warning signs are defined so that the users can easily understand them.

The user of the equipment should thoroughly understand potential injury or equipment damage during the operation of the equipment by recognizing the following signs:

	When the instruction with this sign is not followed, it may cause severe accident and the user also may be injured gravely. The user should follow the instruction with the Danger sign strictly.
	When the instruction with this sign is not followed, it may cause loss or damage to the internal program or data in the equipment and the user also may be injured. The user should follow the instruction with the Warning sign strictly.
	This sign indicates instructions that must be checked by the user. The user should check the instructions and observe it.
	This sign indicates instructions that must be noted by the user.

1.1.5) Contents of the Manual

This manual is composed of 9 chapters and an Appendix. A brief description of each chapter is shown below.

- Chapter 1. Overview

  Provides general information regarding the manual and the equipment.

- Chapter 2. Safety Instructions

  Provides information regarding the precautions the user must take for safe use of the equipment, the types of safety devices inside the equipment, the operation of the safety devices, and how to check the equipment condition.

- Chapter 3. Equipment Structure

  Provides information regarding the components of the equipment, including the name of each unit and the OP screen, etc.

- Chapter 4. OP (Operation panel)

  Provides information regarding the components of the Operation Panel (OP) of the equipment.

- Chapter 5. Turning On/Off the Equipment

  Provides information regarding how to turn on the equipment and how to turn it off depending on different situations.

- Chapter 6. Image acquisition

  Provides information regarding registration of the patients and acquisition of images in each mode.

- Chapter 7. Maintenance

  Provides information regarding maintenance, including storage, care, movement of the components, maintenance cycle, and the process of hygiene management, such as cleaning and disinfection of the equipment.

- Chapter 8. Error solution

  Provides instructions to solve problems during the use of the equipment and information regarding the warning and error message codes, which stop the equipment.

- Chapter 9. Specifications

  Provides information regarding the specifications of the equipment and devices, such as the dimensions, weights, and environmental requirements.

- Chapter 10. Security and Protection of Privacy

  This section provides information on the security and privacy protection required for the operation of the equipment.

- Appendix

  Provides references for operation, including disposal of wastes, table of X-ray exposure conditions, etc.

1.1.6) Language for the Manual

This manual is written in Korean and available for use in Korean and English, basically.

Any problem caused by incorrect use of the equipment due to mistranslation of the manual into any other language other than Korean and English is not the liability of the company.

This manual should be translated by a translator who is familiar with medical contents.

1.2) General Information of the Equipment

This section provides brief information about the equipment, including its purpose of use, categories of the intended users, information security, labels, etc.

1.2.1) Introduction of the Equipment

The X-ray image acquisition systems for dental diagnosis, GT300 and GT300-C acquire images of dental and oral structure, as well as cranial images in Panoramic, Cephalo (Option), and Computed Tomography (CT) modes. The equipment is designed to realize images with high resolution and reduce unnecessary exposure to the X-ray. Its panoramic multi-imaging technology and advanced motor rising required only a small amount of X-ray dose, while the equipment still provides the images with accurate image ratio in magnification.

The equipment is categorized as GT300, the standard type available for Panoramic image and CT image, and GT300-C, the other version available for Panoramic image, CT image, and Cephalo image.

This equipment is a medical diagnostic equipment, which is used to diagnose the patient by acquiring X-ray images. This equipment must be operated only by doctors or radiologists who are legally qualified.

1.2.1.1) Characteristics of the Equipment

- Selection of the dental arches of various patients
- Selection of acquisition speed and image quality
- Selection of X-ray exposure conditions that are optimally tailored to each patient
- Minimum level of exposure of the X-ray to the patient through adjustment of the X-ray per section
- Various image acquisition modes allowing accurate analysis of TMJ
- Various acquisition modes for CT images suitable for the purpose

1.2.1.2) Expected service life time

- 10 Years

1.2.1.3) Indication

Dental diagnostics such as dental implant planning, orthodontic surgery planning and impacted tooth removal, cyst and tumor evaluation.

1.2.1.4) Contraindications

- Absolute contraindications:

  No absolute contraindications.

- Relative contraindications:

  Children, pregnant women, lactating women, and those with mental disorders that make it difficult to cooperate with radiography should follow the judgment of the doctor in charge.

1.2.1.5) Adverse events

During CBCT scans, panoramic and cephalometric, exposure is carefully controlled and limited to specific areas of interest. In addition, the scan time is relatively short, which reduces the duration of radiation exposure and thus minimizes potential risks.

1.2.1.6) Information for Residual Risk

This manual contains the warnings and precautions for use applicable to the equipment.

Every individual risk level per hazard and the overall residual safety risk is acceptable using the criteria defined in the Risk Management Plan and in the applicable internal procedures.

1.2.2) Indication for Use

It is intended to produce 2D (panoramic, cephalometric) or 3D (Cone Beam Computed Tomography) images. It provides diagnostic details of the dental-maxillofacial, TMJ and SINUS for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment.

This equipment should not be used for other purposes.

1.2.2.1) Intended User

Dentists, Radiologists and other professionals who are licensed to perform X-rays by the law of the region in which it is being used.

1.2.3) User Information

1.2.3.1) Categorization of the User Type

Depending on the scope of operation and use of the equipment, the Company categorizes the users as follows:

Category	Scope
Operator	Users who operate the equipment to acquire the images. ▪ Specialists of acquisition and check of the images. Dentists, Radiologists and other professionals who are licensed to perform X-rays by the law of the region in which it is being used.
Maintenance staff	Users who manage the equipment in software and hardware, such as in system operation, regular check-ups, maintenance, etc. ▪ Medical experts and image engineers with relevant knowledge conducting tests on the equipment for quality assurance.
Service manager	Users who belong to the Company and perform services on the equipment, including diagnosis of failure, repair of modules, and replacement of components. ▪ Service managers, who take charge of the maintenance including installation, configuration, and calibration of the equipment.

NOTICE

Do not perform any task which is prohibited for the category to which you belong.

1.2.3.2) User Requirement

To operate or maintain the equipment, the users in each category need an understanding and/or qualification regarding the following items:

Item	Requirement
Education	Doctor's license, radiologist's license, or equivalent license (national license) or degree in the field.
Knowledge	▪ Understanding of the diagnosis and treatment ▪ Understanding of the terminology and instructions regarding the diagnostic medical X-ray equipment. ▪ Understanding of the installation, operation, and configuration of the equipment. ▪ Capability to diagnose using the diagnostic medical X-ray equipment. ▪ Understanding of the purpose and the effect of the treatment.
Language	Capability to read and understand the manual written in Korean, English, or other language.

1.2.3.3) Training Program

GENORAY Co., Ltd. takes no responsibility for any damage or accidents caused due to inappropriate operation of the equipment.

All the users should finish the training to use the equipment before actually operating it. The user should contact the manufacturer or the vendor for more information regarding usage training.

1.2.3.4) Equipment Installation Qualifications

The installation of this equipment must be performed only by service personnel who have received professional training from our company, Ltd. or an official service center. For any inquiries related to equipment installation, please contact us through our official website or service center.

- For more information regarding the installation of the equipment, refer to the **"INSTALLATION MANUAL"**
- Service center
  - Operating hours: Monday to Saturday (KST +09:00 ~ 18:00)
  - Phone: 1660-4048
  - Website: http://www.genoray.com/cs/contact_us/

1.2.4) Class and Compliance of the Medical Equipment

This section provides information regarding the class of the equipment and the standard of compliance.

1.2.4.1) Class of Medical Equipment

Item	Description
Product	Diagnostic X-ray system
Product name	Diagnostic computed tomography limited view field X-ray system
Protection against electric shock	Class I medical equipment
Degree of external protection for water resistance	Equipment: IPX0
Protection against electric shock	▪ Class I medical equipment ▪ Type B applied part • Patient Support
Protection against laser	Class 1

NOTE

- This equipment does not have protection against liquid intrusion for the main body of the equipment. Please be careful to prevent liquids, such as water or soap, from penetrating inside the main body.
- If liquids such as water or soap penetrate inside the main body, it can cause equipment failure and render the equipment unusable, so please be cautious.

1.2.4.2) Standard and Regulation

This equipment is designed and developed in compliance with international standards and regulations.

The user is responsible for monitoring that the equipment is used in compliance with all the following standards and regulations all the time. Regarding specific requirement(s) and/or standard(s) that should be applied to using medical electronic equipment, ask relevant international institutions and regional/federal institutions in each country.

Standard	No.
IEC / EN	IEC / EN 60601-1
	IEC / EN 60601-1-2
	IEC / EN 60601-1-3
	IEC / EN 60601-1-6
	IEC / EN 60601-2-63

NOTE

The parameters of this equipment are expressed in SI units in accordance with ISO 80000-1.

1.2.4.3) Essential Features

This equipment provides essential features as the following to meet the international standards and regulations:

- Accuracy for the X-ray exposure condition which has less than ±10% of error range;
- Coefficient of variation which is less than 0.05 in measured Air Kerma value;
- Air Kerma Linearity which is less than 0.2;

Radiation Dose Structured Report (RDSR) according to IEC/PAS 61910-1:2014 is provided.

1.2.5) Liability of the Manufacturer and Obligations of the User

Liability of the Manufacturer

- The manufacturer guarantees the performance of the equipment in normal condition and the quality of the features regarding the X-ray. However, the company is liable for the defect(s) only in circumstances where all the following conditions are fulfilled:
  - The procedures for maintenance are performed normally;
  - The genuine components approved by the company are used;
  - The equipment is used normally in conformity with the manual;
  - The defect or damage is not caused by negligence or mistake of the user; and
  - The defect persists even after being serviced by the company or the vendor that was authorized by the company.
- The company does not take any responsibility for injury and/or damage to the equipment caused by incorrect operation.
- Also, the company does not take any responsibility for the incorrect diagnostic condition and the diagnostic result.

Obligation of the User

- The user is responsible for monitoring user qualification, constant compliance with regulations applicable to the equipment, and specifications for operation.
- All the instructions and ways for operation in the manual should be referred to and observed.

1.2.6) Unauthorized Modification

Any unauthorized change or modification of the equipment affects its compliance with international regulations and standards. Also, it may lead to an accident regarding equipment safety.

The international standard applicable to X-ray equipment should be observed.

Unless our company. has approved, no change or modification of the equipment is allowed.

2. Safety Instructions

Provides instructions to what the user should understand thoroughly regarding the equipment to assure the safe operation.

2.1) General Safety

2.1.1) Precaution during Operation

Medical equipment using X-rays and electricity always comes with potential risks.

Make sure to understand the following safety instructions thoroughly:

- If any defect is detected during the operation, stop the operation immediately and contact the service center.
- Do not use the equipment with malfunction or defect. Contact the service center immediately and stop operating the equipment until the service engineer gives the instruction.

Do NOT modify the equipment. Unauthorized modification of the equipment is prohibited.

- This equipment must be operated only by doctors or radiologists who are legally qualified.
- The user of this equipment should be familiar with the way to operate it before actually using it. Call the service center to get training about the usage of the equipment.
- Other than the components provided for the equipment, no other part is allowed to be installed on the equipment.
- Make sure to understand the safety instructions in the manual thoroughly, including the proper usage, measures in case of an emergency, etc.
- Check the specifications and settings of the equipment and its main components before operation all the time.
- The user should be capable of recognizing the situations that may lead to potential danger and take preemptive actions in proper ways to prevent such danger.
- This equipment may induce injury or equipment damage when it fails to follow the usage instructions in the manual correctly.
- This equipment may induce danger to the user and the patient when it fails to be operated correctly with proper X-ray exposure condition.
- The PC used with the equipment should be used only for image acquisition, not for other purposes.
- If leakage occurs from the X-ray generator, please have it repaired immediately by the manufacturer or a designated service provider.

The maintenance staff is responsible for validation of constant accuracy in X-ray exposed dose, leakage radiation, the center of the effective beam, and accuracy in voltage (kV) and tube current (mAs).

2.1.2) Malfunction of the Equipment

2.1.2.1) Situations Possibly Causing Malfunction

The equipment can malfunction under the following situations. Be careful.

- Unintended power cut-off to the equipment;
- RF Interference by other medical device or non-medical device; or
- Connection of unauthorized component or external device to the equipment.

2.1.2.2) Countermeasure against Malfunction

Upon a malfunction of the equipment, take the following procedure:

1. Push the emergency switch and push the power button to turn off the equipment.
2. Disconnect the power cable of the equipment.
3. Contact the service center and inform the situation.
4. Check the equipment status and take proper actions according to the instruction of the service engineer.
5. When the malfunction is identified too grave for the user to take care of, follow the following procedure:
   a. Mark **Do Not Use** on the equipment and keep it away from use by other users.
   b. When the abnormality of the equipment is properly taken care of, reboot the equipment.
   c. After the equipment is completely rebooted, try to acquire an X-ray image to see if the equipment operates normally.

If a circuit breaker is activated at the facility, cutting off the power to the equipment, contact the service center immediately and do not resume operation until the checkup for the equipment is finished.

Make sure to be familiar with the proper measures to ensure the safety of the patient and the user in the case of malfunction.

Make sure to place the power cable in a position where it can be easily disconnected in case of a problem.

2.1.3) Incorrect Connection to Other Device

Only the devices and the parts approved by the manufacturer can be used with the equipment.

Make sure to connect external devices and parts correctly to the equipment, all the time. Incorrect connection with such devices or parts may cause electrical problems, damaging to the equipment.

2.1.4) External Device

To assure the safety of the patient, this equipment should be connected to other external devices that are approved for use.

- All the external devices working in the patient environment should abide by IEC 60601-1.
- Connection of unauthorized device to the equipment may cause injury to the user and/or the patient and damage to the equipment.
- When it is necessary to use any external device beyond the patient environment, all the applicable international standards should be fulfilled.

2.1.5) Laser Safety

To prevent any dangerous situation related to laser during the use of the equipment, make sure to understand the following safety instructions thoroughly:

CAUTION

- Direct exposure of the radiation to the eye of the patient or the user may cause eye damage. Be careful.
- While the laser is turned on, do not stare at the laser directly.

NOTICE

You can activate the function using the laser button on the equipment's control panel. The laser will automatically turn off after a certain period or when the imaging process begins.

Laser button on the Main control panel

NOTE

This equipment is certified as a Class 1 laser product, compliant with IEC/EN requirements.

2.1.6) Cooling Efficiency

This equipment adopts natural cooling. For more efficient cooling, make sure to understand the following notes:

Covering some parts of the equipment with cloth or other cover can interrupt air flow and reduce the cooling efficiency. So, the equipment needs to be covered only when it is exposed to excessive volume of liquid or not used for a long time.

2.1.7) Permeation of Liquid

To prevent any dangerous situation related to permeation, make sure to understand the following safety instructions thoroughly:

NOTICE

- When excessive volume of liquid, such as disinfectant or any fluid, permeates to the equipment, it may cause damage to the interior part.
- Do not use cleaning solution excessively during cleaning the equipment.

NOTE

This equipment is not protected from liquids. If liquid permeated to the equipment, disconnect the power cable and contact the service center.

2.1.8) Contact Burn

The intended temperature of the surface that may contact with the patient does not exceed 41℃ even if it has been used for a long time. There is no risk regarding contact burn to the patient, however, potential side effects may occur during the operation of the equipment. Get enough advice from dentists, radiologists, and experts of local laws and regulations before using the equipment.

2.1.9) Precautions regarding Data Loss

In the following situations, the equipment automatically turns itself off, along with the PC and the OP. When these happen, the data inside the equipment, such as personal and/or medical information of the patients, can be lost. Be careful.

- Sudden blackout during equipment operation.
- PC damage due to unintended use.
- If a magnet or magnetic object is placed near the equipment or PC

Do not turn off the equipment when it is being used for scanning or other reason.

- The PC provided for image acquisition and diagnosis should not be used for any other purpose.
- Do not put any magnet or magnetic object near the equipment.

- When a blackout shuts down the equipment, it may lead to data loss. To prevent it from happening, it is recommended to install a UPS.
- When installing UPS, be familiar with how to use it in advance.

2.1.10) Storage Capacity

Check the storage capacity of the PC and make sure to secure enough space for the acquired images.

When the storage capacity is not enough, an error message is displayed. Make sure that the PC has enough capacity to keep the images in order to prevent re-acquisition of the image.

2.2) Electrical Safety

To prevent any dangerous situation related to electricity, make sure to understand the following safety instructions thoroughly:

- Do not remove the cover from the equipment arbitrarily.
- Check the shielding, connection, and voltage of the power cable before supplying the power to the equipment.
- Do not disconnect the power cable while the equipment is still turned on.
- Do not use any power strip or extended plug to supply power to the equipment.
- Check the power and connect the power cable of the equipment to the power socket.
- For all the other external devices (Signal I/O including the devices), check the same when supplying power to them.
- The maintenance staff should check if the specific power is being supplied properly to the installation site before connecting the equipment to the power source.
- It is recommended to use AC power to prevent conflict among requirements for other equipment(s).
- Do not push or pull the equipment.

- Do not share the power source of this equipment with other external devices.
- This equipment should be installed independently to the panel board.

- This equipment is not protected from liquids. If liquid permeated to the equipment, disconnect the power cable and contact the service center.
- As an X-ray equipment, this equipment complies with national standards, such as IEC 60601-1, and applicable regulations in all matters regarding the signal I/O and other connected items to the connector.
- The protection type and level for the ratings used in this equipment is Class I.

2.2.1) Protective grounding

This equipment must be connected only to a power system with a dedicated protective grounding.

To prevent electric shock, the equipment should be connected only to a power supply or a power outlet equipped with protective grounding. Use of the equipment without grounding can cause malfunction or damage to the equipment due to a short circuit or noise.

This equipment should be installed independently to the panel board.

2.2.2) Disconnecting the Power

To disconnect electricity from the equipment, disconnect the power cable.

In the cases where an emergency occurs during the equipment operation and requires to stop the equipment or turn the power off, push the emergency switch.

The disconnecting process should be performed when the equipment is not used.

2.2.3) Electric Shock

To prevent any dangerous situation related to electric shock, make sure to understand the following safety instructions thoroughly:

- Before and after the operation, check the ground connection and power connection to prevent electric shock.
- To prevent electric shock, the equipment should be connected only to a power supply or a power outlet equipped with protective grounding. Use of the equipment without grounding can cause malfunction or damage to the equipment due to a short circuit or noise.
- The voltage used for the electrical circuits in this equipment is extremely high, enough to cause severe injury or even death by electric shock. To prevent the risk about it, the user should not remove any cover from the equipment.

2.2.4) Outage of the Equipment

2.2.4.1) Preparation for Power Recovery

Blackouts and other power problems can cut off the power to the equipment, making it unavailable for operation. Installing an Uninterrupted Power Supply (UPS) system is recommended to prevent the acquired images and minimize the risk of exposure to the X-ray due to re-examination. The instructions for the use of UPS should also be followed.

- Uninterruptible Power Supply (UPS)
- Other emergency power source

Emergency power supply systems, such as UPS, should be installed in the space where the equipment is operated and the usage of such systems should be well instructed.

2.2.4.2) Recovery Procedure for the Equipment

1. Check the issue with the power supply.
2. Turn the equipment's power switch to [OFF] then disconnect the main power supply.
3. Disconnect the power cable of the equipment.
4. Connect the power cable to UPS.
5. Turn the equipment's power switch to [ON], then connect the main power supply.
6. Once the equipment is fully booted, try to acquire an X-ray image to see if the equipment operates normally.

2.3) Overheat on X-Ray Generator

Overheat on the X-ray generator triggers the following warnings:

Temperature	Displayed Color	Description
Below 10℃	 (Blue)	X-ray exposure unavailable (X-ray generator warm-up required)
10 ℃ to less than 45 ℃	 (Green)	X-ray exposure available
45 ℃ to less than 55 ℃	 (Yellow)	X-ray exposure available (Warning for overheat on X-ray generator)
55 ℃ or above	 (Red)	X-ray exposure unavailable (Overheat on X-Ray Generator)

NOTICE

- If an error message appears due to equipment overheating, turn off the power and refrain from using the equipment for about 2–3 hours.
- If the equipment is naturally cooled after being left unused, the error message disappears when it is turned on again and the equipment becomes available for use.
- Since continued exposure without cooling the equipment may damage the X-ray tube, the cooling time should be observed after each X-ray exposure.
- For more information regarding the cooling time, refer to the Cooling time in "**9.3) X-ray Generator**"
- Since continued exposure without cooling the equipment may overheat the X-ray generator, do not touch the cover of the X-ray generator while the equipment is in operation.

2.4) Radiation Safety

2.4.1) Precautions regarding Radiation

The user of the equipment should always comply with the laws and regulations regarding the safety and protection against radiation in the country or the region where the equipment is used.

This equipment should be operated in a designated area like a shielded room for safe operation.

- The equipment has an emergency switch to abort the X-ray in emergency.
- Repetitive exposure to the X-ray or exposure for a long time may cause severe skin damage. Therefore, the equipment should be used very carefully using the optimal settings for the X-ray exposure condition.
- Pregnant patients should discuss X-ray exposure with the doctor before the image acquisition.

The user should be careful to check the alarming lamp and sound activated while the X-ray is being exposed.

2.4.2) Radiation Protection

This equipment should be operated in a designated area like a shielded room for safe operation.

If not necessary, do not give any instruction to the patient during the X-ray exposure.

Make sure to acquire the image accurately to prevent additional acquisition, so that the patient is not excessively exposed to radiation.

- This equipment should be used in a shielded room.
- Position the irrelevant body parts of the patient as far as the X-ray tube so that the patient can absorb minimal dose.

2.4.3) Radiation level

The basis of determining whether the radiation level of this equipment is a necessary level for the deterministic effect of radiation or the accompanying tissue reactions thereof has been decided by referring to **Publication 60, ICRP, 1991b**. (Refer to Section A 56 in Appendix A.)

The deterministic effect (hazardous tissue reaction) is mostly due to extinction/dysfunction of cells caused by irradiation of high doses of radiation.

The radiation level was determined based on biological and clinical data, the mechanism of cells or tissues which forms basis of tissue reaction, and the ICRP's determination about the threshold dose that applies to the vital organs and tissues. It is determined that dysfunction that is clinically meaningful to tissues does not occur in a radiation absorbed dose range of up to about 100 mGy.

This level is considerably lower compared to the aforesaid radiation level which is the deterministic effect, which shows that this equipment does not belong to equipment that has deterministic radiation levels.

2.4.4) Coverage and Type of Radiation Generated by Equipment

The coverage and type of radiation generated by this equipment are categorized as follows:

2.4.4.1) X-ray beam field

The X-ray beam field, which is primary radiation, is launched from the collimator area of the X-ray tube and covers the detector's effective imaging area. The effective image area is fully covered. Exams that are outside the effective imaging area can be checked from the QAP (Quality Assurance Program).

2.4.4.2) Scatter (Indirect) X-ray radiation

Nevertheless, the scatter radiation in X-ray from the collimator, the target, or the detector is low level during image acquisition, refraining from being exposed to the Scatter X-ray. Radiation scattered in the significant zone of occupancy is the same as the exposure to natural radiation. The user should wear personal protection equipment against radiation, if necessary.

2.4.4.3) Leakage radiation

It refers to a dose of exposure in an unintended direction, radiation emitted in other direction than the X-ray outlet port of the tube, and radiation that penetrates the X-ray detector and leaks via the detector rear.

- Regulations on leakage radiation (1 mGy/h at a distance of 1 meter from the tube)

2.4.5) Patient Population

The patient population can be the possible person who can be taken X-ray diagnostic radiation exposure.

There is no restriction for ethnic group, Gender, weight, health, or condition.

We recommend X-ray diagnostic radiation exposure to be over 5 years old.

2.4.6) Pediatric Subpopulation

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 years old according to FDA guidance "Pediatric Information for X-ray Imaging Device Premarket Notifications.

a. 5-year-old [~21 kg, 113 cm standing height]: Child

b. 12-year-old [~52 kg, 156 cm standing height]: Overlap small size adults- Small

c. 21-year-old [~80kg, 170 cm height]: Adult- Middle

d. Adult [more than 80 kg, 180 cm standing height]: Large Adult- Big

Radiation exposure is a concern in both adults and children. However, Children are more sensitive to radiation than adults and have a longer life expectancy. Radiation risk is higher in young patients, as they have more rapidly dividing cells than adults. The younger the patient, the more sensitive they are. Using the same exposure parameters on a child as used on an adult may result in larger doses for the child. There is no need for these larger doses for children, and X-ray settings can be adjusted to reduce dose significantly while maintaining diagnostic image quality.

Use special care when imaging patients outside the typical adult size range.

Please refer to the web pages regarding additional pediatric information.

- FDA's Pediatric X-ray Imaging webpage:

  https://www.fda.gov/radiation-emitting-products/medical-imaging/pediatric-x-ray-imaging

- The Image Gently During Dental Procedures

  https://www.imagegently.org/Procedures/Dental

2.5) EMC (Electro-Magnetic Compatibility)

This equipment generates Radio Frequency (RF) energy and wireless communication with other medical or non-medical devices can cause frequency interference that results in malfunction of the equipment. If the equipment affects or is affected by such frequency interference, turn off the equipment and follow the following instructions:

1. Adjust the distance between the equipment and others as well as its direction or position.
2. Use another power outlet to connect the equipment.
3. Otherwise, contact the service center.

- Keep distance from the power generator, other X-ray equipment, and broadcast station to avoid electrical interference before the operation of the equipment. If the equipment shares one power source with another electric/electronic device, abnormal images can be acquired.
- Do not place any electromagnetic wave generator such as a mobile phone, a radio, a remote controller, etc. with the device together in a room, because such items generate electromagnetic waves that can cause malfunction to the equipment.
- Portable or RF communication devices can affect the equipment.
- Even if the other device complies with CISPR requirements, the equipment can be affected.
- Use of any cable and/or part which was not supplied by the manufacturer may cause increase of electromagnetic emission or reduction in electromagnetic immunity and result in malfunction of the equipment.
- The manufacturer is not responsible for any malfunction due to use of unauthorized part.

- This equipment is provided with the standard of radiation applicable to Group 1, Class A type medical devices and the immunity level that complies with IEC 60601-1-2 for protection against frequency interference.
- Protection against frequency interference is not assured all the time, thus make sure to refer to the EMC guidance before the operation of the equipment.

2.5.1) EMC Guidance

Declaration of Manufacturer and Instruction - Electromagnetic Emission

This equipment is available for use under the electromagnetic environment as follows: The user or the maintenance staff should check the use environment of the equipment.

<table>
<tr><th>Emission Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>This equipment uses RF energy only for its internal functions. Therefore, its RF emissions are very low and it does not cause interference with nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class A
(The Equipment in combination with the shield location)</td><td rowspan="2">This equipment is suitable for use in all areas other than residential and such areas and, if warnings as follows are observed, it is possible to use in the facility that is directly connected to a public low-voltage power grid which supplies power to residential facilities and buildings with residential purpose.
Warning: This equipment should be used by medical experts. This equipment can cause RF interference and/or interrupt operation of other nearby equipment. Sometimes mitigative actions may be required such as redirection, relocation, shielding, etc.</td></tr>
<tr><td>Voltage fluctuations/
Flicker
Emissions
IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">It is important to ensure that the RF shielding effect and the filter attenuation of the shielded position actually reach or exceed the minimum value of the designated limit.</td></tr>
</table>

Declaration of Manufacturer and Instruction - Electromagnetic Immunity

This equipment is available for use under the electromagnetic environment as follows: The user or the maintenance staff should check the use environment of the equipment.

Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2, ±4, ±8, ±15 kV Air	±8 kV Contact ±2, ±4, ±8, ±15 kV Air	Floors should be wood, concrete, or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be sustained at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for input a.c power ports ±1 kV for signal input/output ports	±2 kV for input a.c power ports ±1 kV for signal input/output ports	The main power quality should comply with the requirements of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	The main power quality should comply with the requirements of a typical commercial or hospital environment.
Voltage dips and interruptions IEC 61000-4-11	Voltage Dips: 0% U_T for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T for 1 cycles at 0° 70% U_T for 25 / 30 cycles at 0° Voltage Interruptions: 0% U_T for 250 / 300 cycles	Voltage Dips: 0% $U_T$for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T for 1 cycles at 0° 70% U_T for 25 / 30 cycles at 0° Voltage Interruptions: 0% U_T for 250 / 300 cycles	The main power quality should comply with the requirements of a typical commercial or hospital environment. If the user needs to operate the equipment continuously during a power outage, an uninterruptible power supply supplies the power to the equipment.

Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the main voltage before applying the AC test level.

Declaration of Manufacturer and Instruction– Electromagnetic Immunity

This equipment is available for use under the electromagnetic environment as follows: The user or the maintenance staff should check the use environment of the equipment.

Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in the ISM Band 3 V/m 80 MHz to 2700 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in the ISM Band 3 V/m 80 MHz to 2700 MHz	Warning: All the portable RF communication devices, including external devices such as antenna cable and external antenna, should not be farther than 30 cm (12 in) from all the parts of the equipment, including the cable that the manufacturer designated. Otherwise, the performance of the equipment can be degraded.
There can be an exception for the instruction to be applied. The RF is affected by structures, objects, and absorption to and reflection by human body. a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment from fixed RF transmitters, an electromagnetic site survey should be considered. If the electric intensity that was measured at a location where the equipment is used exceeds the applicable RF compliance level above, the equipment should be monitored to check normal operation. If abnormal performance is observed, additional actions may be required such as redirection and/or relocation of the equipment.			

2.6) Storage

- Check the environment for use and decide a proper spot.
- Ensure that the equipment is completely turned off.
- Cover the equipment with cloth such as a dust cover.
- For the information regarding the precise temperature for storage, refer to **"9.2) Environment"**

2.6.1) Condensation

The temperature change due to the environment for storage and/or use of the equipment may cause condensation on its surface. To guarantee safe use of the equipment, all the operators of the equipment should understand and observe the following precautions:

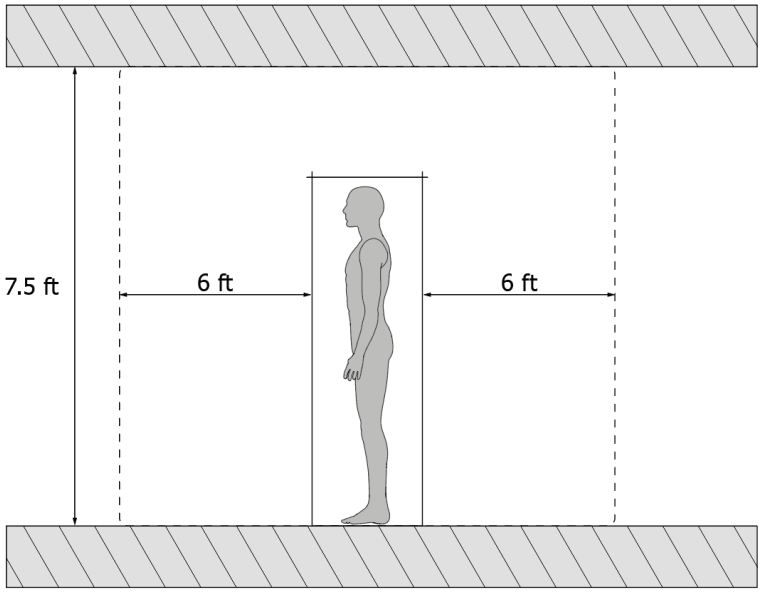
- Do not try to operate the equipment until it gets as warm as the range from 15°C to 35°C, where it can be used safely without the risk of condensation.
- Always try to keep the equipment from undergoing drastic temperature changes during its storage and use.

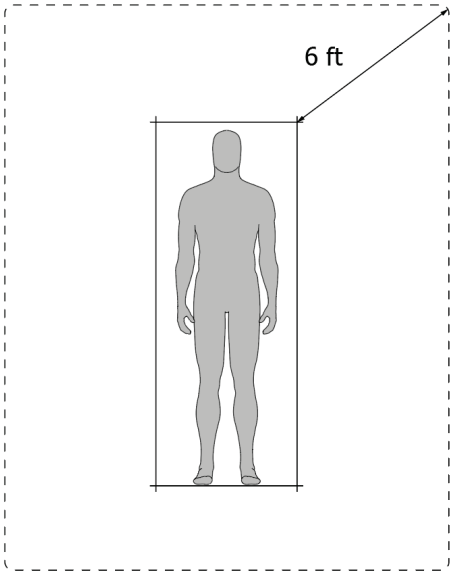
2.7) Patient Environment

The patient environment means the space that encloses all the surfaces touched by the patient or any other person who directly contacts the patient within a medically used room.

2.7.1) Patient Environment (USA)

The patient environment refers to the area within an inner boundary extending 6 feet (approximately 1.83 m) around the examination table, operating table, treatment booth, or similar equipment in a designated space. This area also extends vertically up to 7.5 feet (approximately 2.29 m) from the floor within an indoor setting.



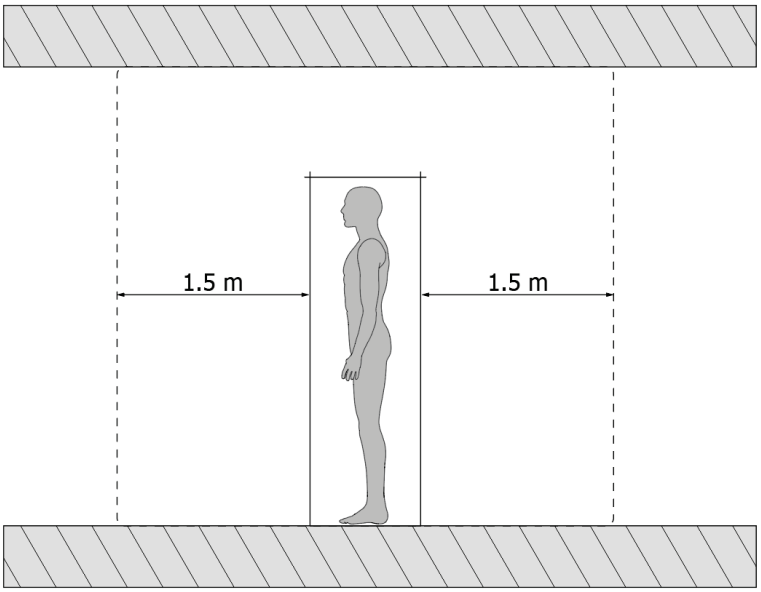


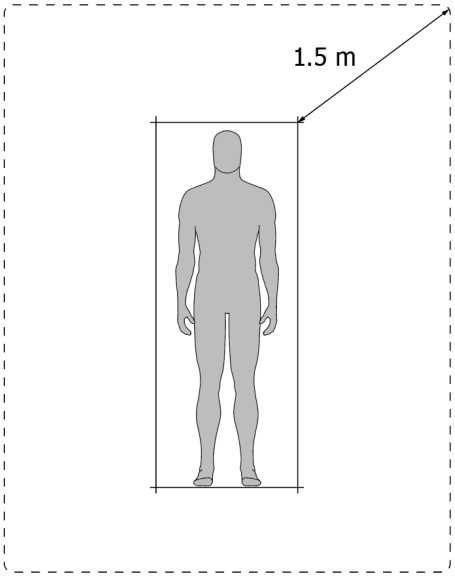
NOTE

The patient environment for this equipment in the United States complies with the requirements of NFPA 99.

2.7.2) Patient Environment (International Standard)

The patient environment refers to the area within an inner boundary extending 1.5 m around the examination table, operating table, treatment booth, or similar equipment in a designated space.





NOTE

The patient environment for this equipment complies with the requirements of the international standard, IEC/EN 60601-1.

2.8) Safety devices

This equipment uses the following devices to ensure safe use of the equipment.

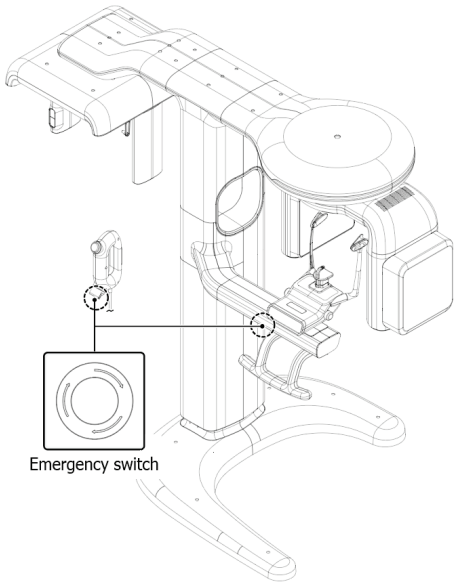
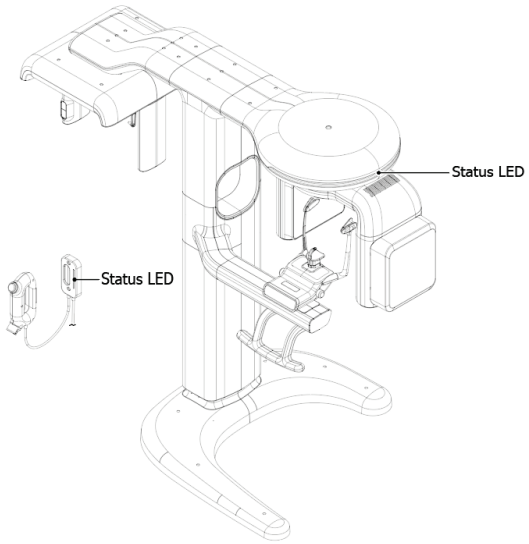
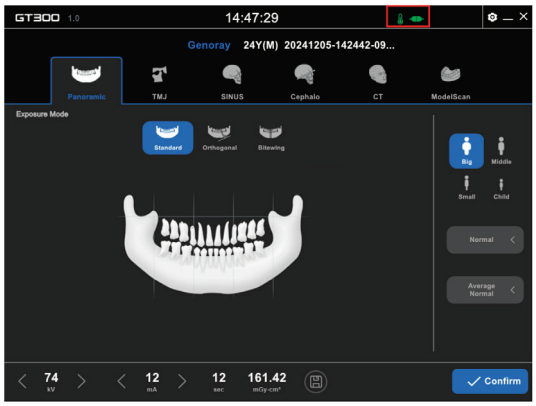
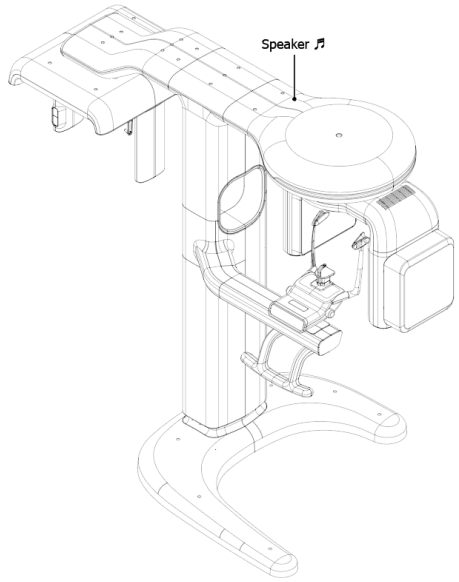
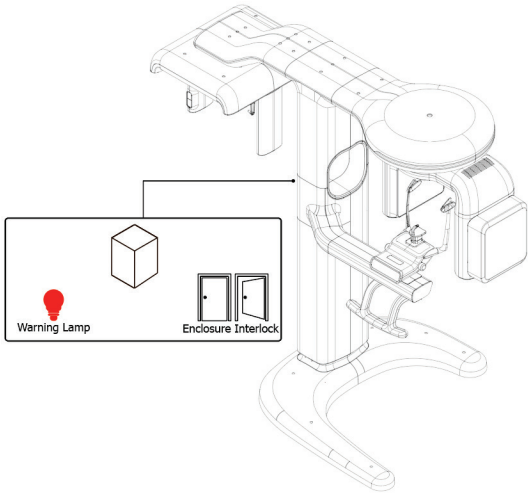
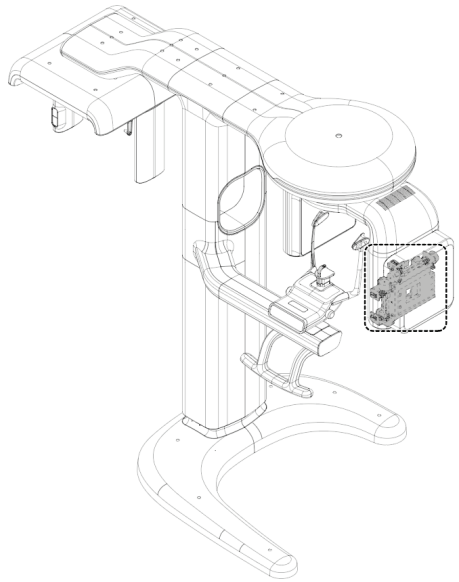
Image	Item	Description
	Emergency stop switch	Press an emergency stop switch to stop the equipment operation when an emergency situation occurs.
	Status Indicator	▪ Status indicator LED The LED lamp lights up in different colors, depending on the equipment status.
		▪ Status indicator of the Operation Panel (OP) Indicates the current status of the equipment.

Image	Item	Description
	Voice Guide	The equipment is available for voice guides regarding the operation status of the equipment, instructions for image acquisition, EMO switch operation status, etc., using the internal speaker.
	Interlock	To prevent unexpected X-ray exposure, make sure to close the shielded room first and then expose the X-ray, all the time you use the equipment. With the door of the shielded room opened, the OP of the equipment displays an error message, making it impossible to use the equipment.
	Beam-limiting device	The beam-limiting device of this equipment is a collimator that restricts the X-ray exposure area to protect the user from unnecessary radiation exposure.

2.8.1) Emergency Stop Switch

If you press an emergency stop switch, all functions of the equipment are paused.

The positions of the emergency stop switches are shown below:

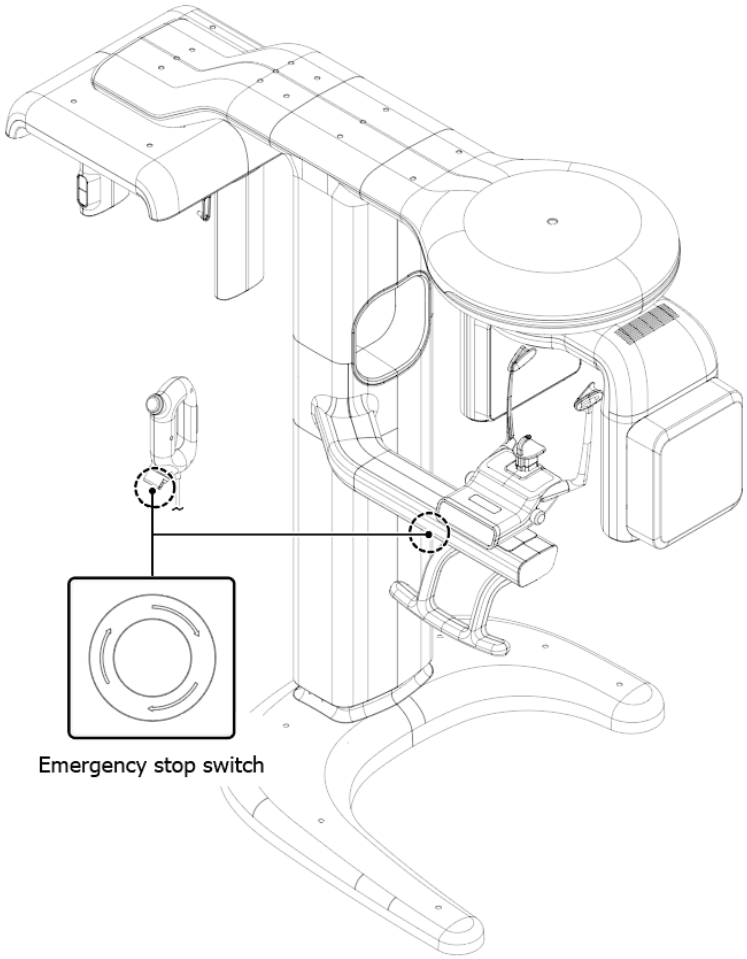


Fig. 2-1 Position of the emergency stop switches

The operator should be familiarized with the location and the operational instruction of the emergency stop switch before operating the equipment.

Using the emergency stop switches

The following shows how to activate an emergency stop switch and recover from emergency stop.

Activate the Emergency Stop Switch whenever emergency stop is required due to any defect during the use of the equipment. If an emergency stop switch is pressed, the status indicator LED on the equipment lights up red and the equipment stops operation.

1. If an emergency situation occurs, immediately press an emergency stop switch.
2. Once an emergency stop switch is pressed, the switch is kept held down.

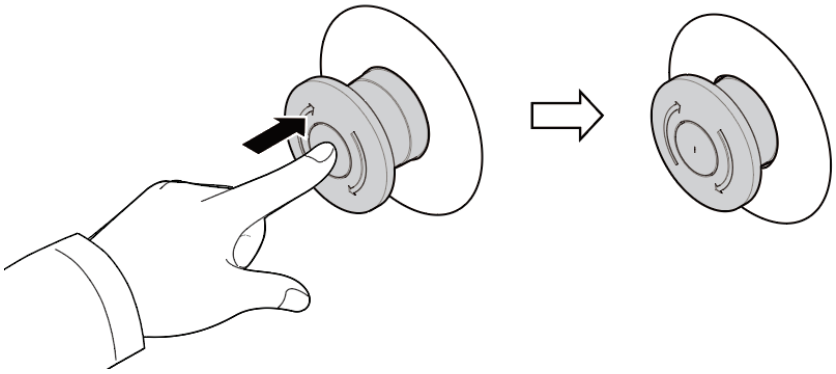


Fig. 2-2 Using an emergency stop switch

NOTICE

The equipment cannot be operated until the pressed emergency stop switch is released.

Releasing an emergency stop switch

After an emergency condition is cleared, turn the pressed emergency stop switch to the right to recover from the emergency stop.

1. Remove the cause of the emergency situation.
2. Turn the emergency stop switch to the right.

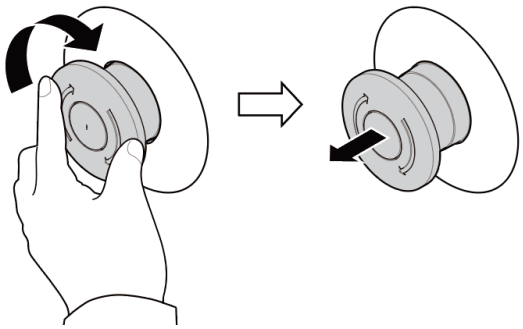


Fig. 2-3 Releasing an emergency stop switch

2.8.2) Status Indicator

2.8.2.1) Status indicator LED

Indicates various statuses of the equipment using different colors of the LED light.

Specific position of the status indicator LED is like the following:

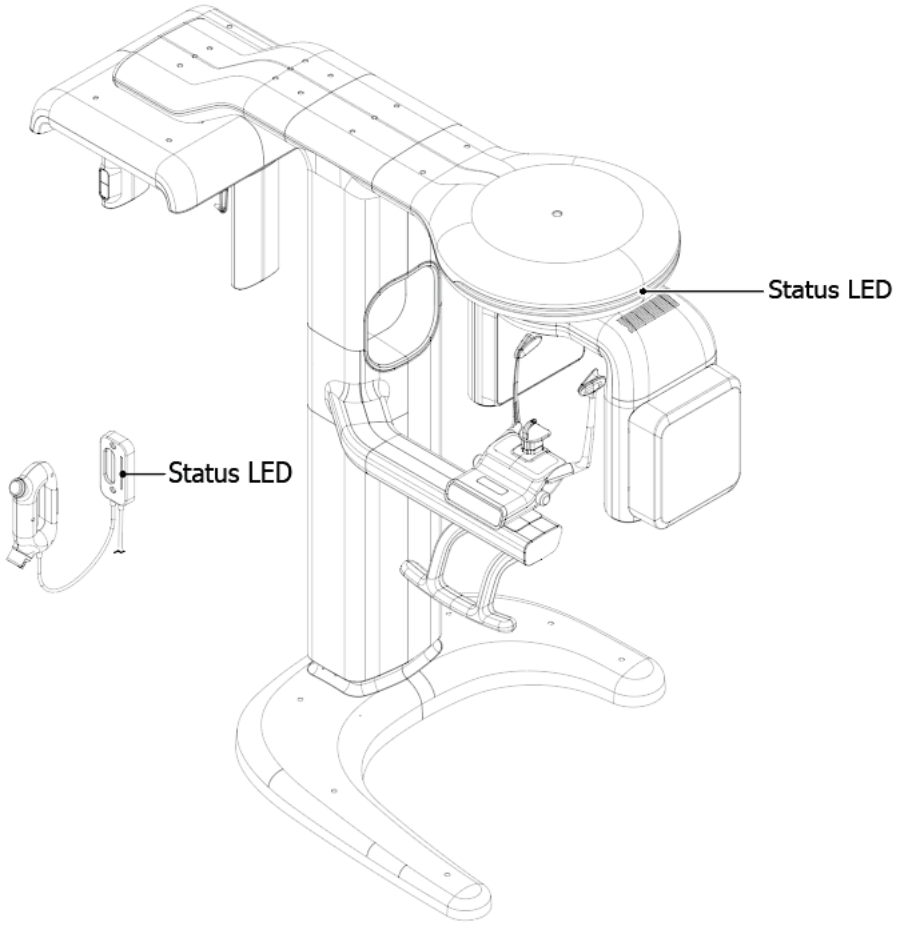
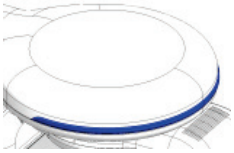
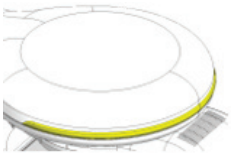
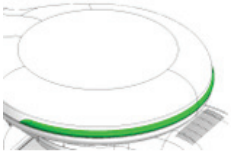
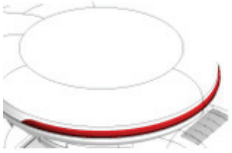


Fig. 2-4 Positions of the status indicator LED lamps

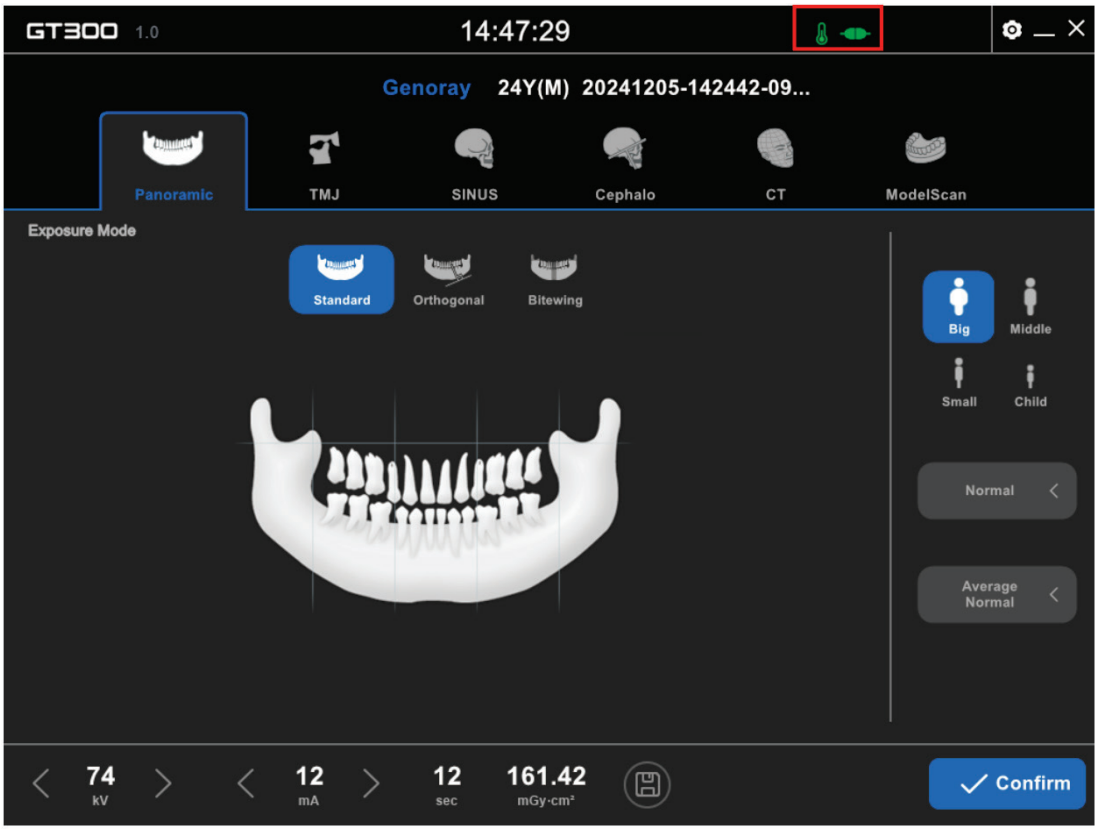
LED lamp color		Description
	Blue	The equipment is moving and rotating
	Yellow	X-ray exposure is in progress
	Green	X-ray exposure is ready
	Red	An error occurs, scanning is stopped, and an emergency stop switch is pressed.

NOTICE

- Before acquisition, make sure to check if the equipment is ready for image acquisition all the time by checking the status indicator LED.
- The user should pay attention to the colors of the status indicator LED lamps.

2.8.2.2) Status indicator of the operation panel (OP)

The status indicator indicates the current status of the equipment. The details of the unit are as follows:



No.	Indication	Status	Description
1		X-ray exposure available	10 ℃ to less than 55 ℃ (Normal operation) ▪ Green ▪ Yellow
			
		X-ray exposure unavailable	55 ℃ or above (High voltage generator overheat) ▪ Red
			Below 5 ℃ (High voltage generator requires warm-up) ▪ Blue
2		Equipment connection to PC	Not connected ▪ Gray
			Connected ▪ Green

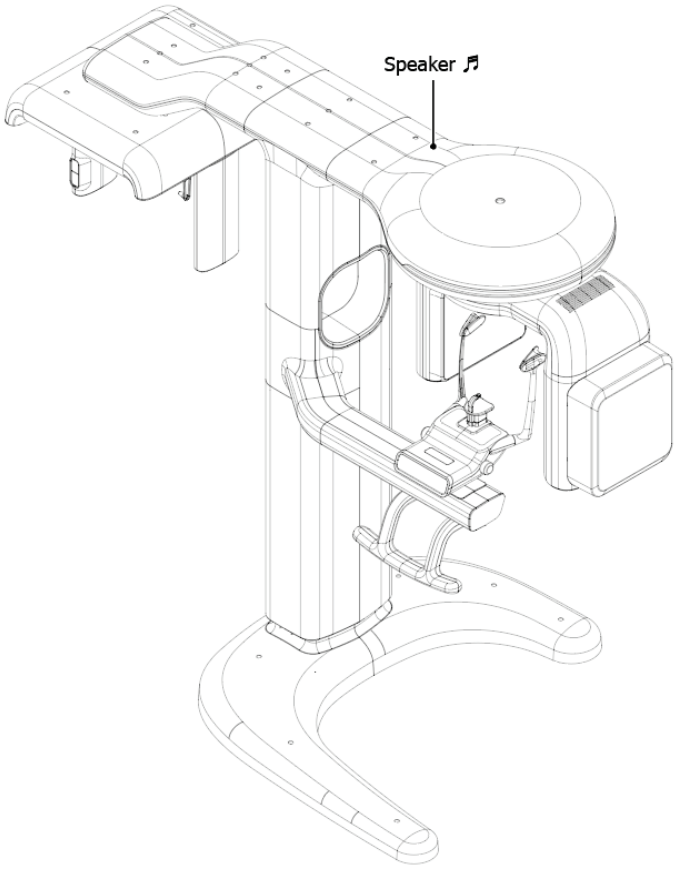
NOTICE

- Before acquisition, make sure to check if the equipment is ready for image acquisition all the time by checking the status indicator LED.
- The user should pay attention to the colors of the status indicator LED lamps.

2.8.3) Voice Guide

The equipment is available for voice guides regarding the operation status of the equipment, instructions for image acquisition, EMO switch operation status, etc., using the internal speaker.

The location of the speaker is shown in the figure below.



NOTICE

The user must maintain visual and auditory contact with the patient during equipment operation.

NOTE

- Language Setting

  The setting is available at **[OP > Option Setting > General > Language]**.

  - Trying to set up an unavailable language triggers a voice guide in English.
  - The available languages above can be changed or added without any prior notice.
- Volume Setting

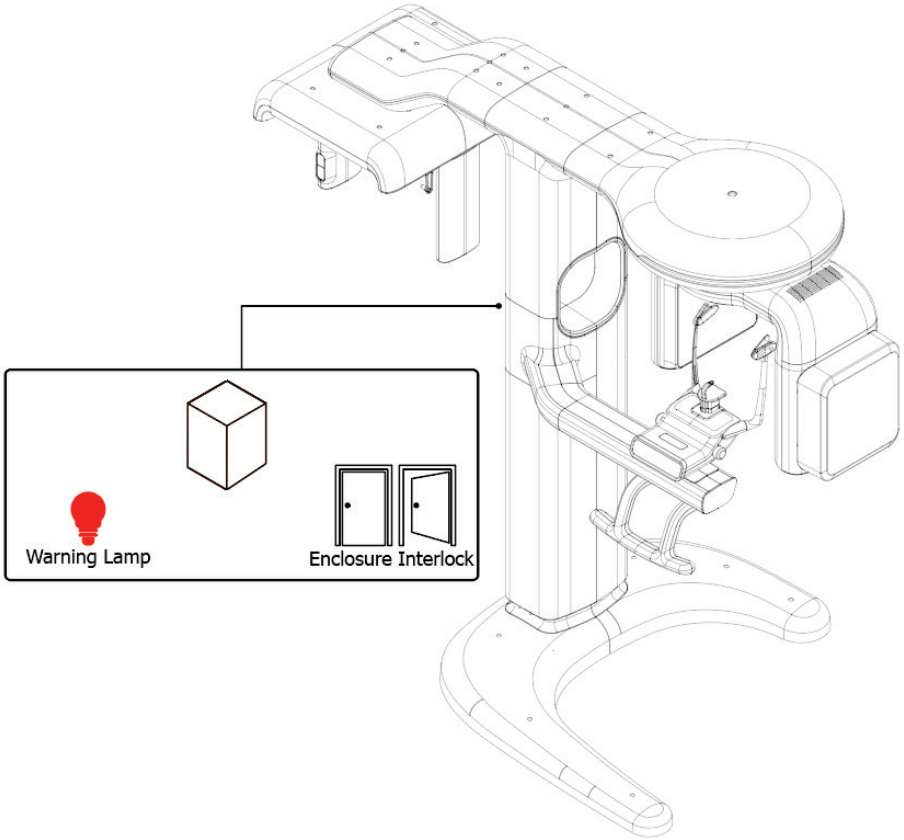
  You can adjust the sound volume at **[OP > Option Setting > General > Volume Setting]**.

2.8.4) Interlock

To prevent unexpected X-ray exposure, make sure to close the shielded room first and then expose the X-ray, all the time you use the equipment.

With the door of the shielded room opened, the OP of the equipment displays an error message like the following, making it impossible to use the equipment.

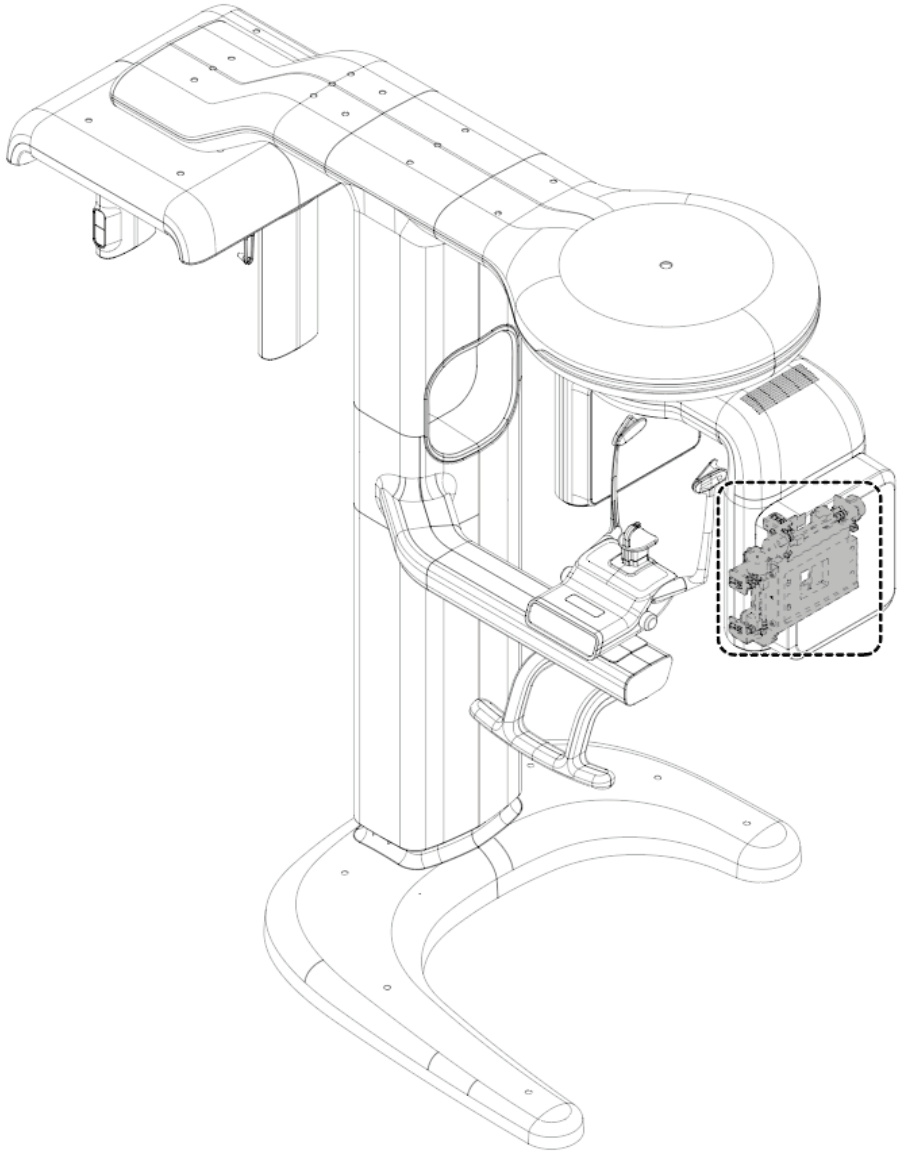
- CODE-W01-004



2.8.5) Beam-limiting device

The beam-limiting device of this equipment is a collimator that restricts the X-ray exposure area to protect the user from unnecessary radiation exposure.

The location of the collimator is as follows.



CAUTION	The collimator is automatically set to the optimal value according to the imaging mode and examination conditions, so no separate user settings are required. Before imaging, be sure to verify that the selected imaging mode is appropriate for the patient's examination area to prevent unnecessary radiation exposure to the patient.

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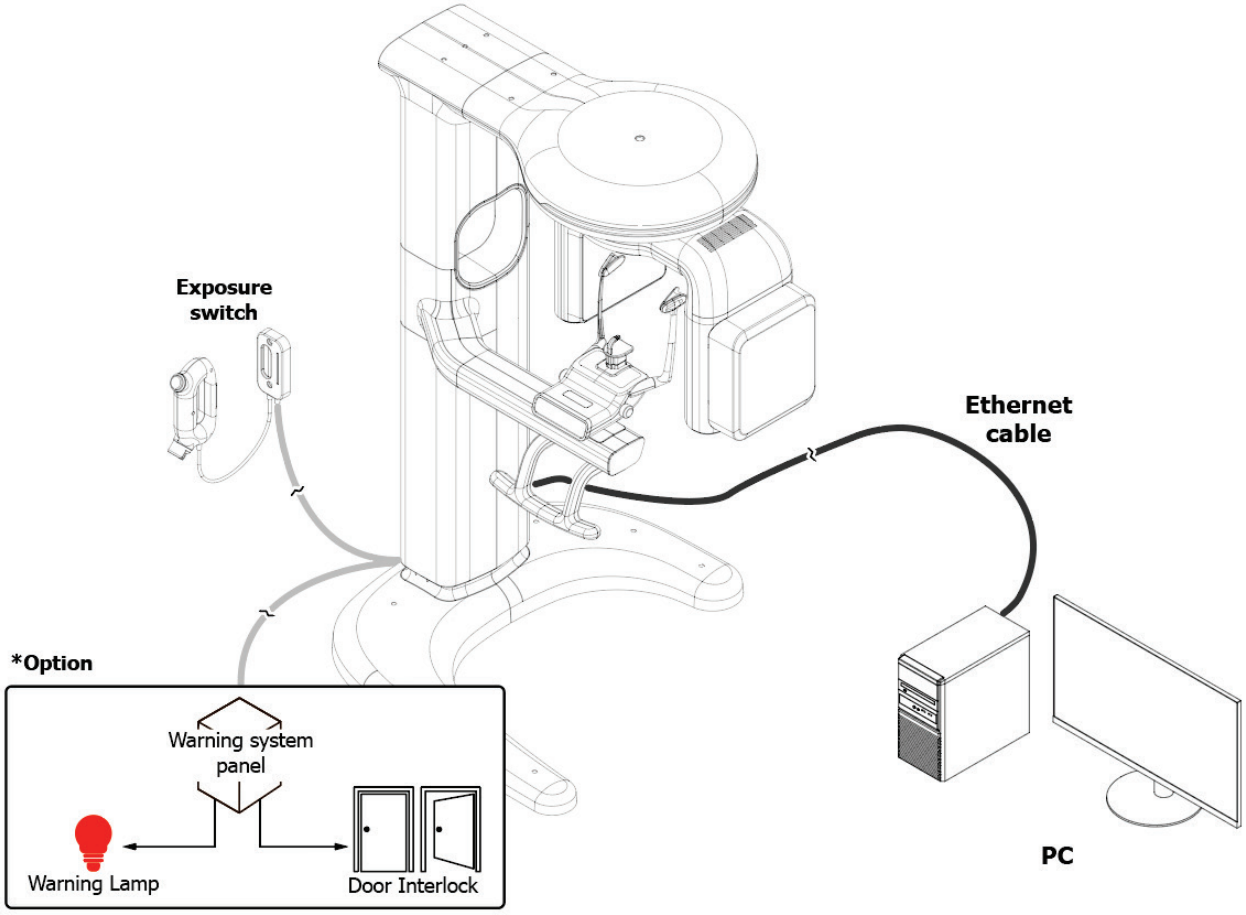
3. Equipment Structure

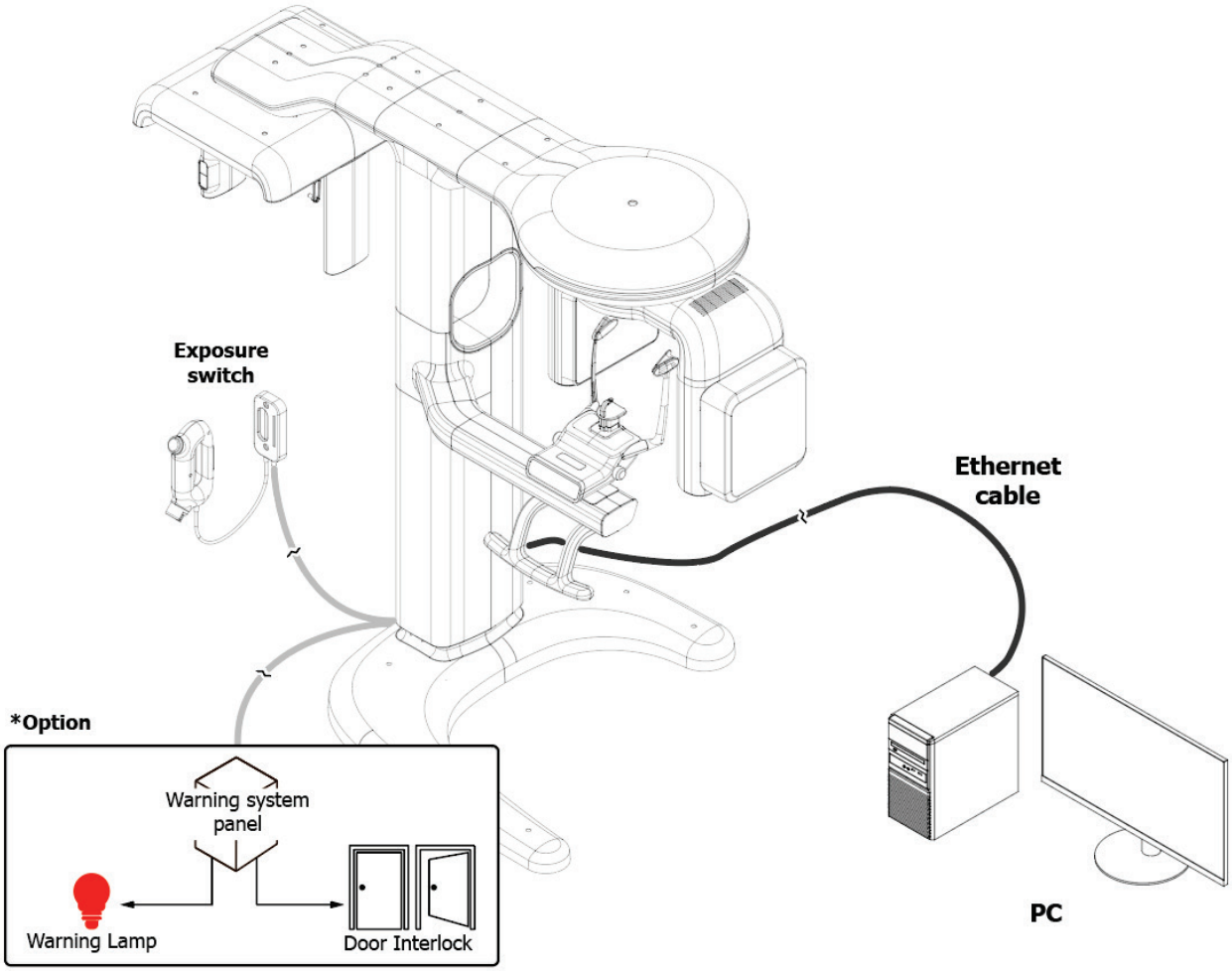
Provides information regarding the components of the equipment, including the name of each unit and the OP screen, etc.

3.1) System Configuration

GT300

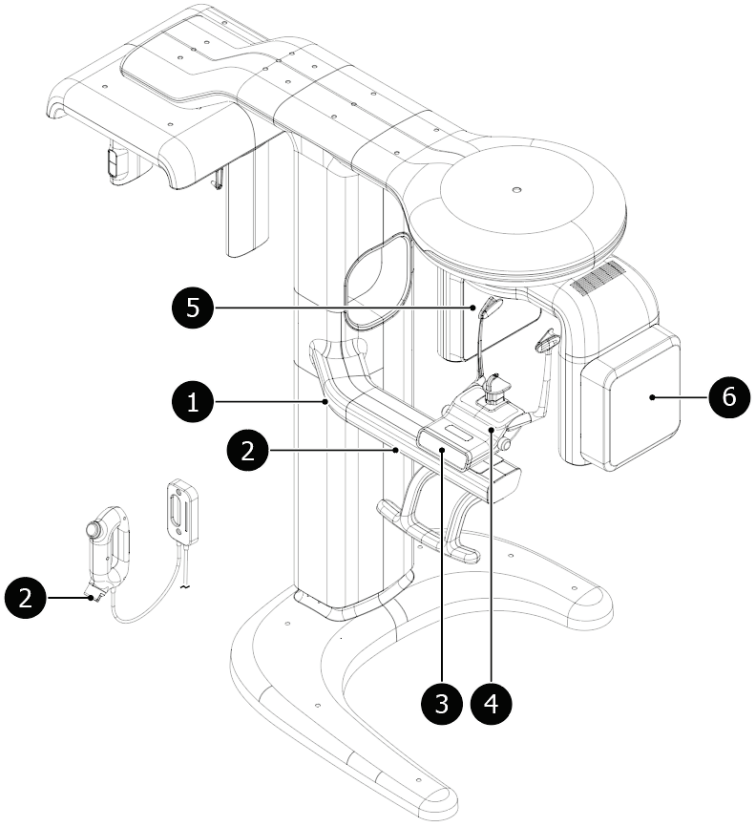


GT300-C

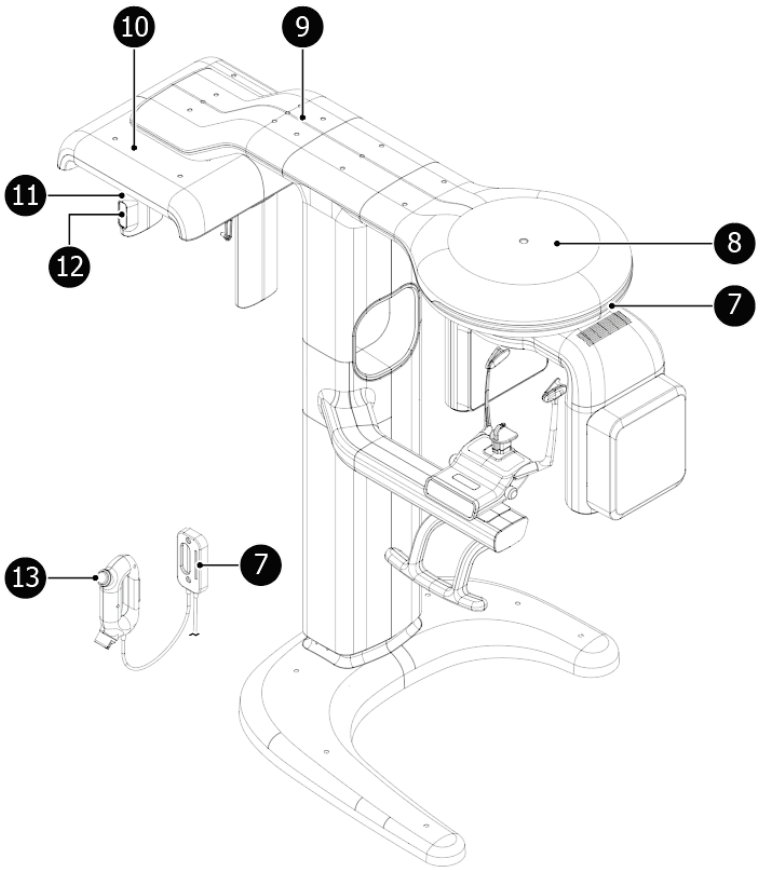

Exposure switch
Ethernet cable
*Option
Warning system panel
Warning Lamp
Door Interlock
PC

3.2) Names and functions of the components

The components and their functions of the equipment are as follows:



No.	Name
1	Power ON/OFF switch
2	Emergence stop switch
3	Main control panel
4	Patient Support
5	Detector (Panoramic, CT)
6	X-ray generator

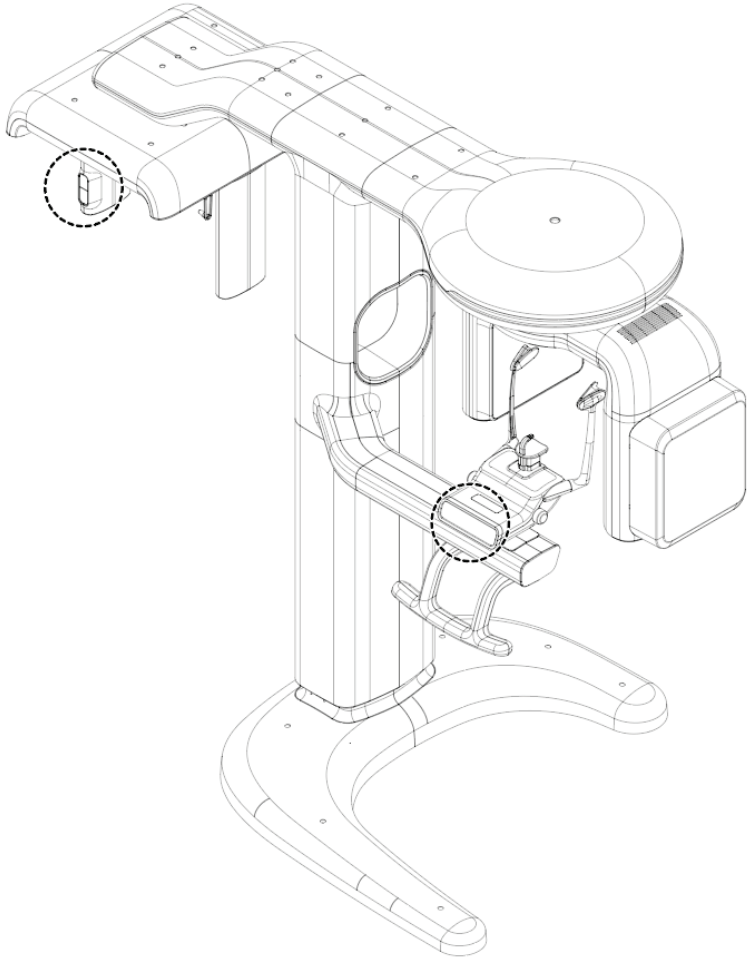


No.	명칭
7	Status indicator LED
8	Driving Unit
9	Cephalo supporting arm (Option)
10	Cephalo Unit (Option)
11	Detector (Cephalo) (Option)
12	Main control panel for Cephalo unit (Option)
13	Exposure switch

3.2.1) Equipment control panel

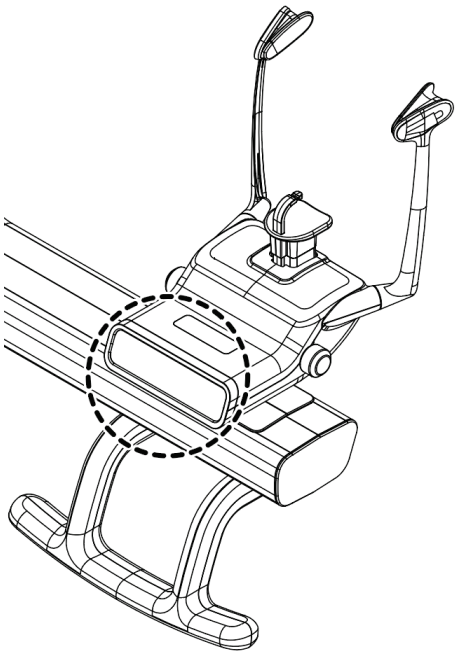
The location of the equipment control panel is as follows.

- Main control panel
- 2nd control panel (Option)



3.2.1.1) Main control panel

Controls the movement of the equipment and the laser using the buttons.



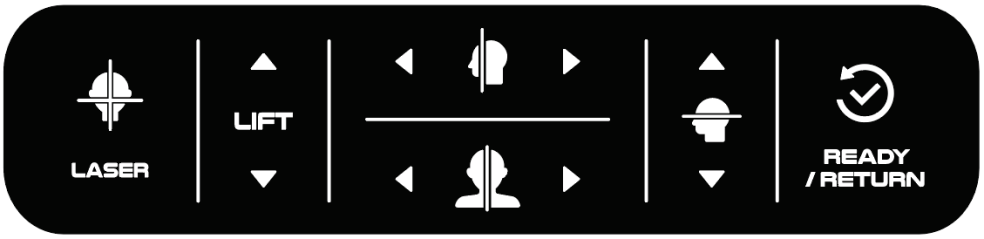


Image	Name	Description
	Laser ON/OFF Button	Turns on/off the laser. Once the button is pushed, the laser is turned on. Pushing the button one more time will turn off the laser. After a certain amount of time, the laser is turned off by itself.
	Lift Up Button	Raises and lowers the equipment. ▪ (∧): Raises the equipment. ▪ (∨): Lowers the equipment.
	Lift Down Button	

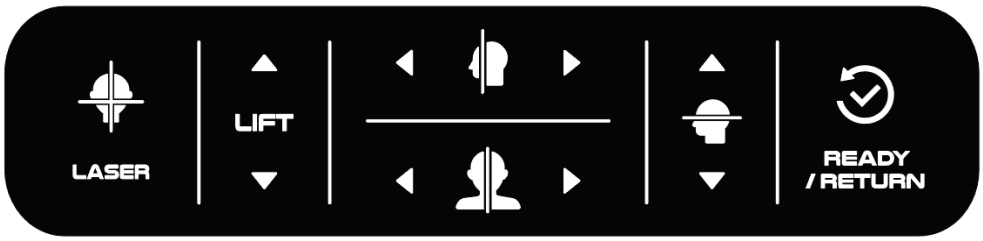


Image	Name		Description
	Gantry Forward Button	Gantry Backward Button	Moves the gantry unit of the equipment forward and backward. Decides the patient's position for image acquisition. Use the canine laser for the Panoramic mode and the FOV center laser for the CT mode. ▪ Forward: Moves the gantry unit approach the operator. ▪ Backward: Moves the gantry unit away from the operator.
	Chinrest Left Button	Chinrest Right Button	Moves the patient support of the equipment left and right. Usually used to find the best position for image acquisition of the patient with the laser projection. ▪ LEFT: Moves the patient support to the left from the operator. ▪ RIGHT: Moves the patient support to the right from the operator.
	Frankfort Laser Up Button		Moves the Frankfort laser up and down. Used to find the best position for each acquisition mode with the laser projection. ▪ UP: The Frankfort laser moves up from the operator. ▪ DOWN: The Frankfort laser moves down from the operator.
	Frankfort Laser Down Button		
	Ready / Return Button		▪ hen ready for imaging: Move to the starting position. ▪ After imaging: Return to the standby position.

NOTE

Do not project the laser directly to the eyes of the patient.

3.2.1.2) Laser control

Adjusts the vertical position of the laser guiding the Frankfort Horizontal plane (hereafter, Frankfort) of the patient, depending on the position of the patient.

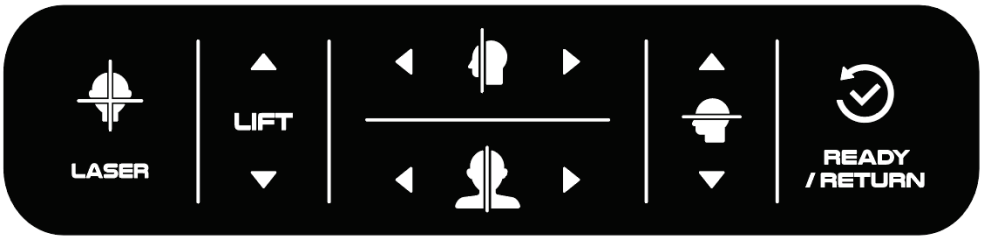


Image	Name		Description
	Laser ON/OFF Button		Turns on/off the laser. Once the button is pushed, the laser is turned on. Pushing the button one more time will turn off the laser. After a certain amount of time, the laser is turned off by itself.

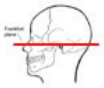
	Gantry Forward Button	Gantry Backward Button	▪ Canine laser is used when moving forward and backward.
			  ▪ Forward: The gantry unit moves toward the user.
			  ▪ Backward: The gantry unit moves away from the user.
			▪ The Canine laser is categorized based on the shooting mode as follows:
			  ▪ Panoramic mode: Canine laser
			  ▪ CT mode: F.O.V. center laser

	Chinrest Left Button	Chinrest Right Button	Moves the patient support of the equipment left and right. Usually used to find the best position for image acquisition of the patient with the laser projection. ▪ LEFT: Moves the patient support to the left from the operator. ▪ RIGHT: Moves the patient support to the right from the operator.

Image	Name	Description
	Frankfort Laser Up Button	Moves the Frankfort laser up and down. Used to find the best position for each acquisition mode with the laser projection. ▪ UP: The Frankfort laser moves up from the operator. ▪ DOWN: The Frankfort laser moves down from the operator.
	Frankfort Laser Down Button	

NOTE

The Frankfort laser is projected marking the line section between a spot over the earhole (supramental opening) to another spot beneath the eyeball of the patient.



CAUTION

Do not project the laser directly to the eyes of the patient.

3.2.1.3) 2nd control button (Option)

The 2nd control button is placed on the Cephalo Unit and moves up and down the unit.

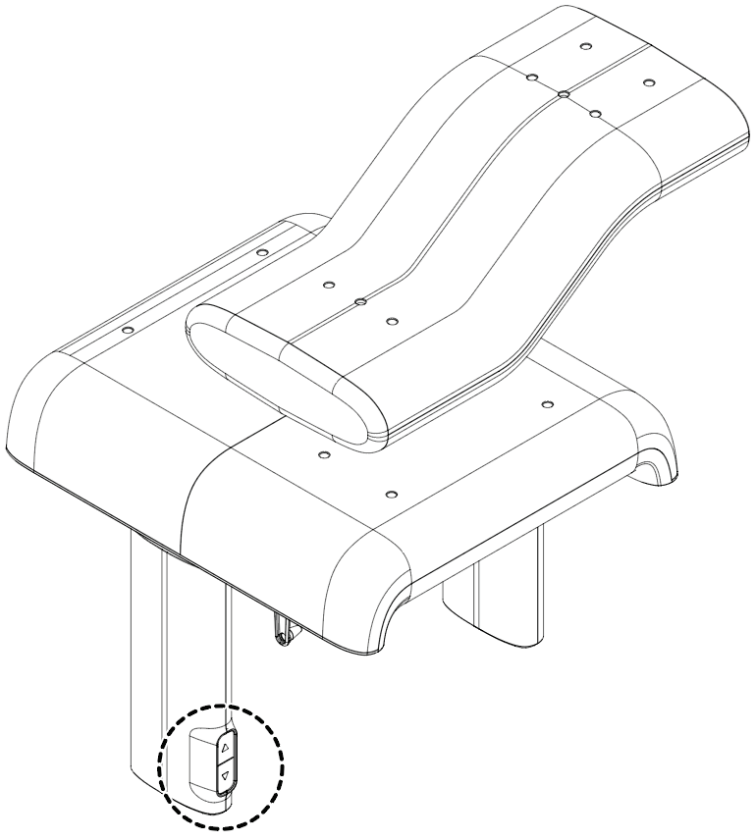


Image	Description
△ ▽	Raises and lowers the equipment. ▪ (∧): Raises the equipment. ▪ (∨): Lowers the equipment.

3.2.1.4) Control buttons available for each mode

The control buttons available for each mode are as follows:

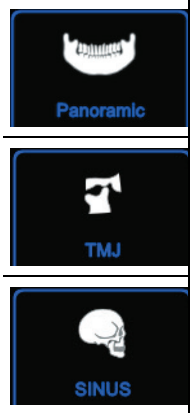
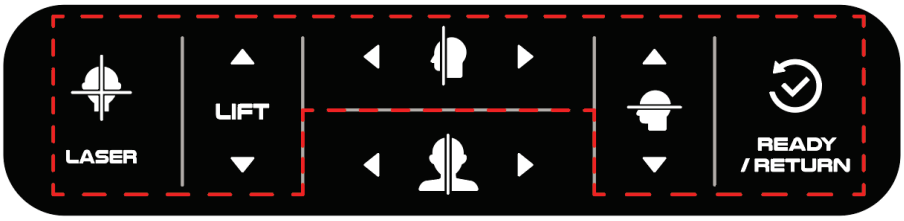
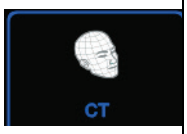
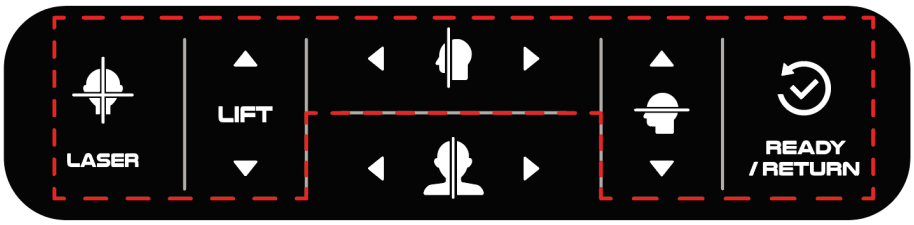
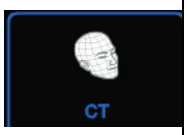
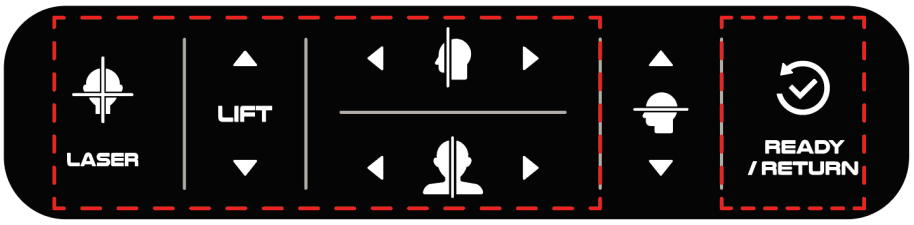
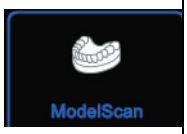
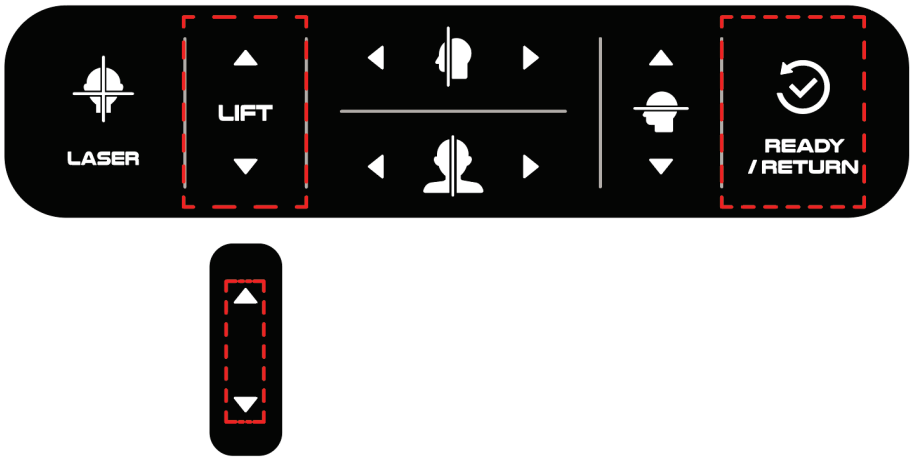
Image	Description
	
 ▪ Endo ▪ Tooth	
 ▪ Teeth ▪ Jaw1 ▪ Jaw2	
 Option	

Image	Description
 Option	

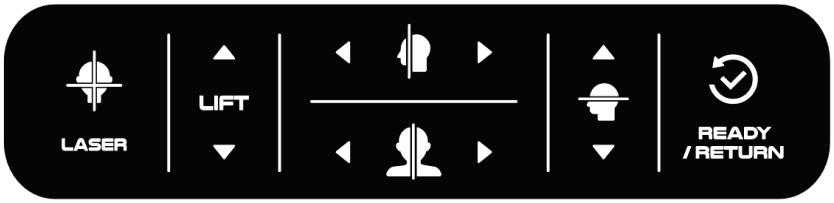
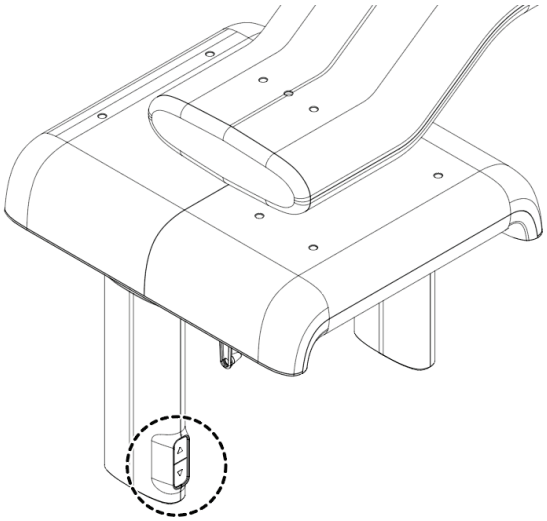
NOTICE

Prior to using the equipment, users should verify which control buttons are available for each exposure mode.

3.2.1.5) Locking/Unlocking the Control Panels

Locking the Control Panels

The control panels get locked, and the LED is turned off if the equipment is not in use for about 30 seconds.

Name	Image
Main Control Panel	
Secondary Control Panel (Option)	

The preset time before locking each control panel may vary.

The following are two different locking conditions for the control panels.

- After using any button on the main control panel
  - The main control panel is locked after 30 seconds from the last time you used any button.
  - The secondary control panel is locked after 30 seconds from idling the equipment regardless of whether the button is used.
- After using any button on the secondary control panel
  - The main control panel is locked after 30 seconds from idling the equipment regardless of whether the button is used.
  - The secondary control panel is locked after 30 seconds from the last time you used any button.

Unlocking the Control Panels

To unlock the control panels, follow the instructions.

NOTE

Before using the equipment, check if the control panels are locked.

- Unlocking Each Control Panel

  Unlock the selected control panel respectively with the following:

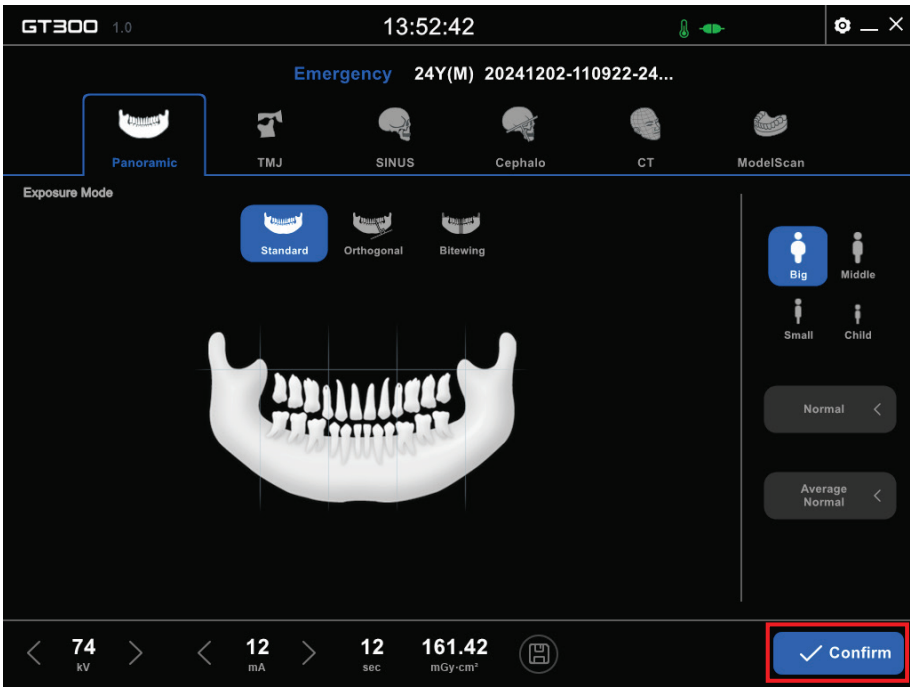
  - Main Control Panel

    Push 4 or more buttons at once and hold for longer than 0.2 seconds.

  - Secondary Control Panel

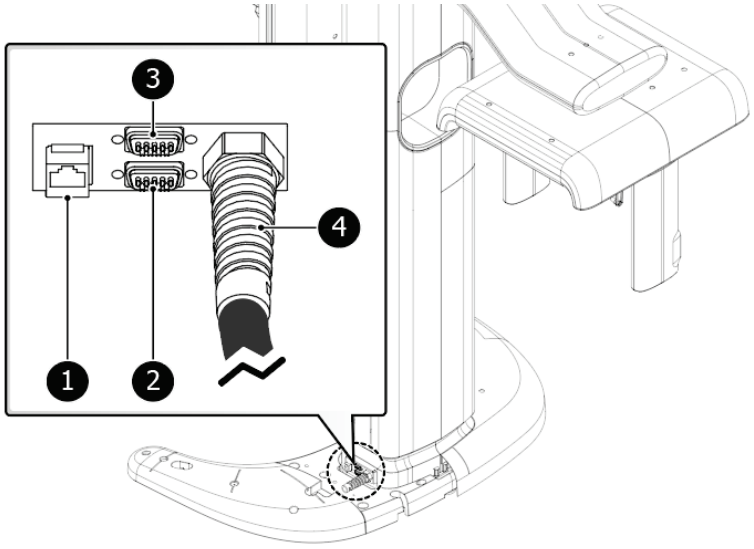
    Push 2 or more buttons at once and hold for longer than 0.2 seconds.

- Both Control Panels
  - From the OP screen, push the [Confirm] button.



3.2.2) Connection to Power

The I/O port for external device is inside the base cover on the rear of the equipment, and each of the ports is as follows:



No.	Item	Description
1	Ethernet network port	Connects the equipment to the PC via an Ethernet network.
2	Warning & interlock port	Connects the cable linked to the shielded room.
3	Exposure switch port	Connects the exposure switch.
4	Power cable	Connects the power cable to the power source.

NOTE

No other external I/O connection is allowed other than the purpose explained above.

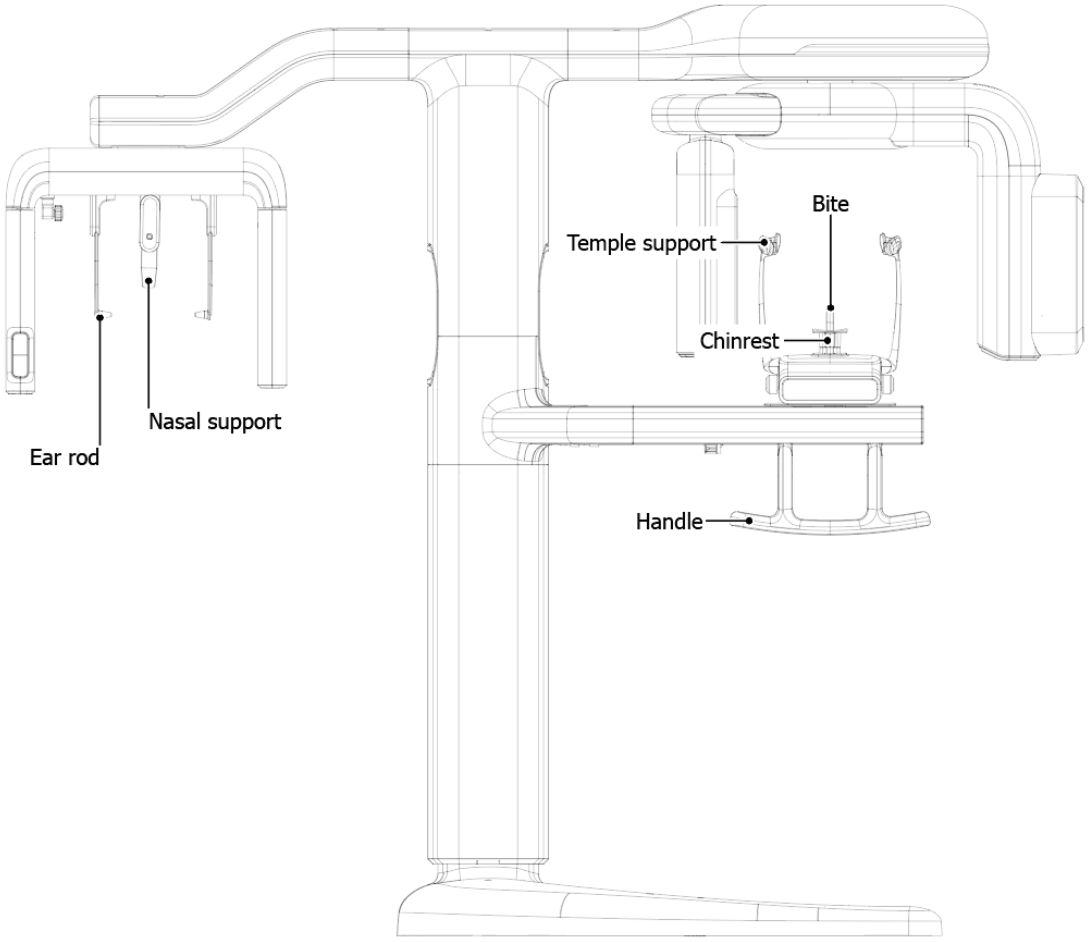
NOTE

If the following occurs when the external I/O port is connected to a device, call the service center for servicing:

- When the alarming LED turns red, or
- When an error message is displayed and the equipment becomes uncontrollable

3.2.3) Patient Support

The patient support components of the equipment are listed below.



CAUTION

Every time after image acquisition, make sure to disinfect the patient support. Sweep it gently with alcohol swap or gauze.

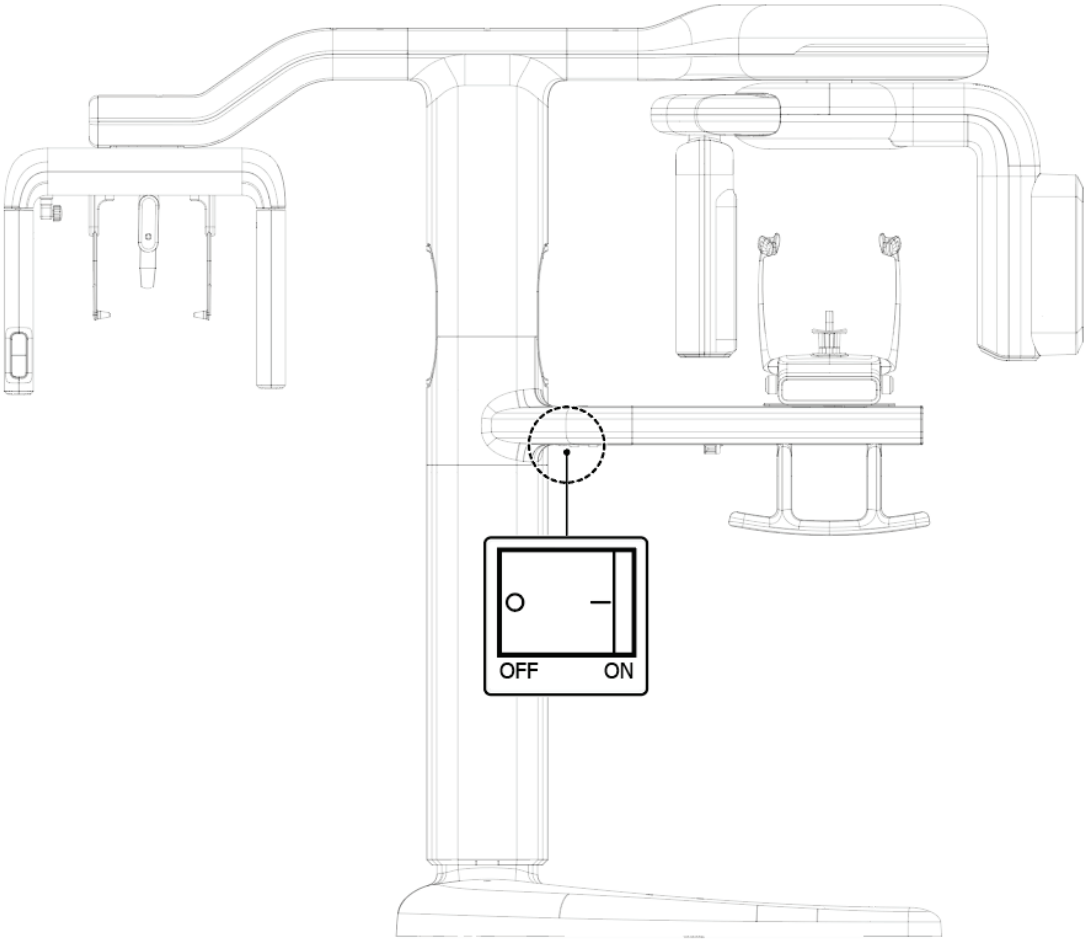
NOTE

To guide the patient on a wheelchair or a seat to the position for image acquisition, get him/her to move under the equipment.

3.2.4) Power On/off switch

The Power on/off switch is placed on the bottom of the side of the equipment.

Turning on the switch makes the status indicator LED blink, starting up for operation. When the equipment is ready, the status indicator LED lights in green.



NOTICE

- The user must check the location of the power switch before operating the equipment.
- For any abnormality in the indicator LED or the main screen, ask the manufacturer or the service center immediately for it may be a sign that the equipment can harm the operator or the patient.

NOTE

To use the equipment, it should take seconds to warm up.

3.3) Accessory

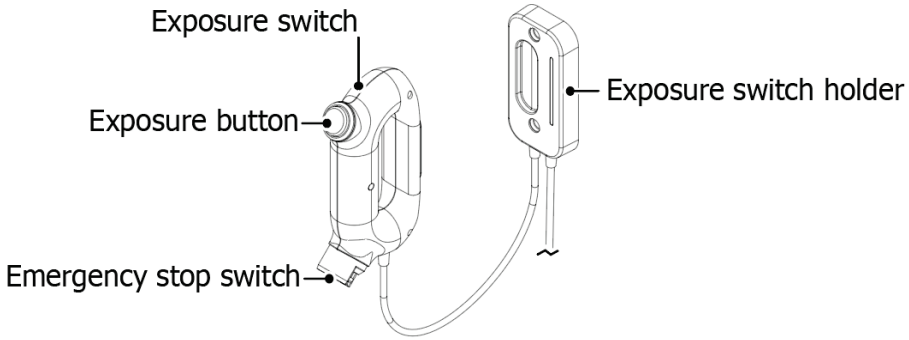
NOTE

- The accessory components differ, depending on the type of the purchased equipment.
- The shape and/or specification of the equipment is subject to change or add for improvement of the performance.

3.3.1) Exposure switch

Stick the mount on the wall and mount the switch on the mount.

Other than the Exposure switch, it also has the Emergency Stop Switch to stop the equipment in the case of an emergency.



Item	Description
Exposure switch	This refers to the entire exposure switch unit.
Exposure Button	Pressing the exposure button initiates or terminates the X-ray exposure.
Emergency Stop Switch	Pressing the emergency stop switch temporarily halts all functions of the equipment.
Exposure switch holder	This is a device that can hold the exposure switch.

CAUTION

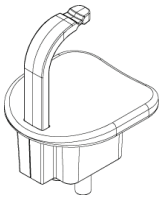
When the X-ray exposure switch is not in use, always place it on the holder to prevent accidental X-ray exposure.

NOTICE

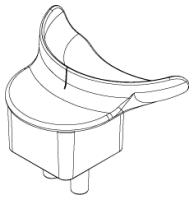
The exposure switch should be pushed and held as long as the image acquisition process is going on. Releasing the switch during the image acquisition will stop the equipment immediately and the OP displays a help message.

3.3.2) Chinrest

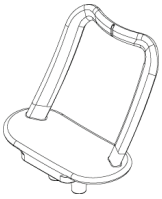
The chinrest can be changed depending on the status of the patient or the image acquisition mode.



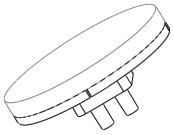
For normal patients



For edentulous patients



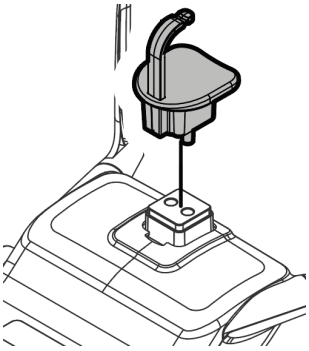
For SINUS and TMJ modes



Model Scan

Changing the chinrest

Select a proper chinrest type for the desired acquisition mode and clip it to the hole on the lower portion of the patient support.



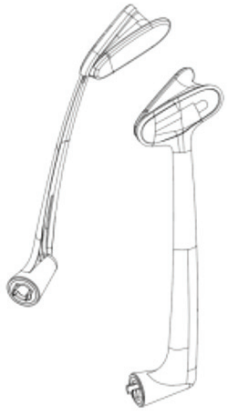
CAUTION

Make sure to use the part provided by the manufacturer.

For any damage to the equipment or accident due to use of the parts that were not provided by the manufacturer, the manufacturer has no liability.

3.3.3) Temple support

The shape of the temple support and how to replace it are as follows:

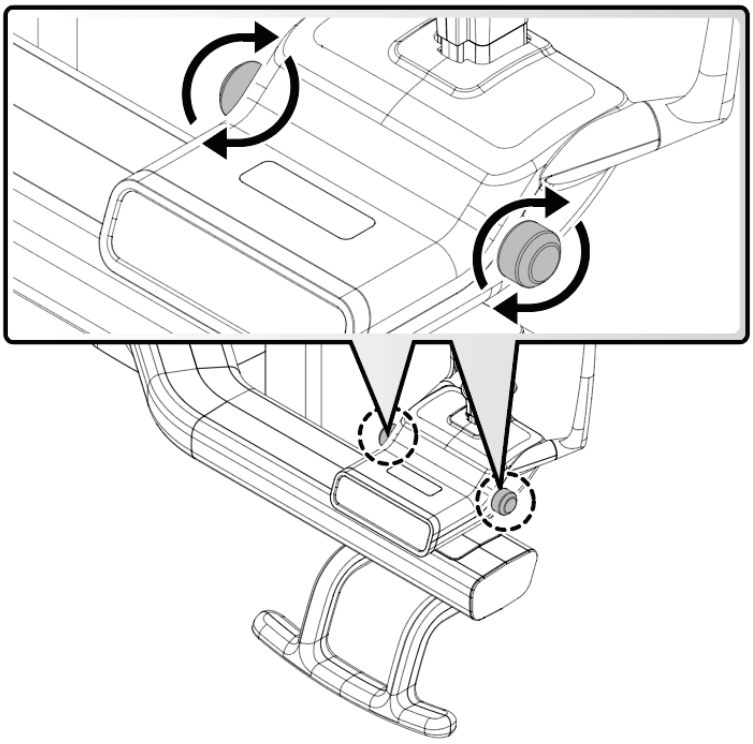


Temple support

Operation of the Temple Support

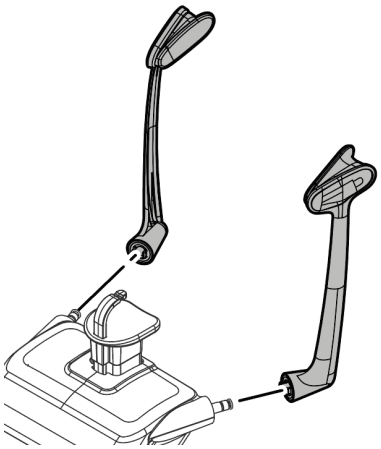
Turn the fixation lever of the temple support to or against the operator so that the support fixes or releases the patient.

- Turning the lever toward the operator: Fixes the support.
- Turning the lever against the operator: Releases the support.



Replace of the Temple Support

The temple support cannot only be removed by grasping the assembly joint and pulling it, but also it can be assembled using the hole at the patient support.



CAUTION

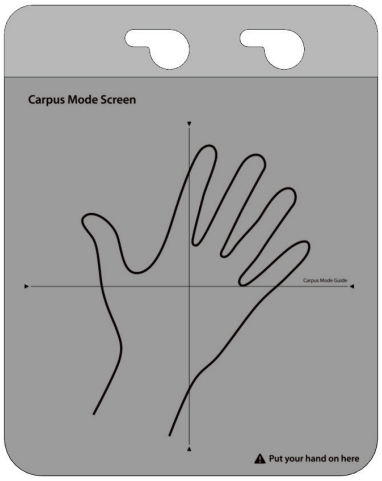
Make sure to use the part provided by the manufacturer.

For any damage to the equipment or accident due to use of the parts that were not provided by the manufacturer, the manufacturer has no liability.

3.3.4) Carpus Plate (Option)

This is the wrist supporting place for the Carpus mode, one of the acquisition program under Cephalo mode.

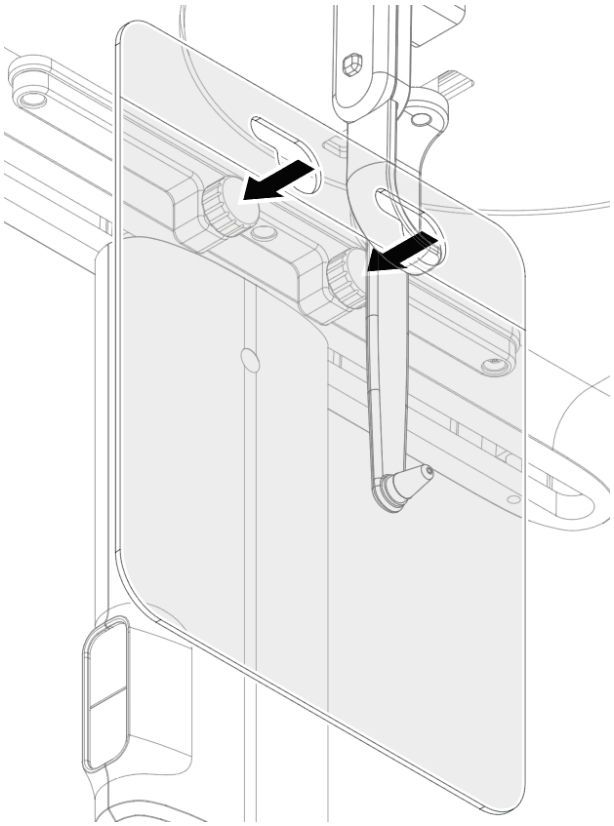
The shape of the support and how to replace it are as follows:



Carpus Plate

Installation of Carpus Place

1. Referring to the following figure, assemble the carpus plate to the fixing levers.



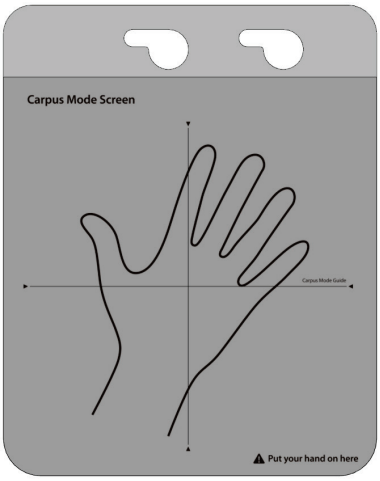
CAUTION

Make sure to use the part provided by the manufacturer.

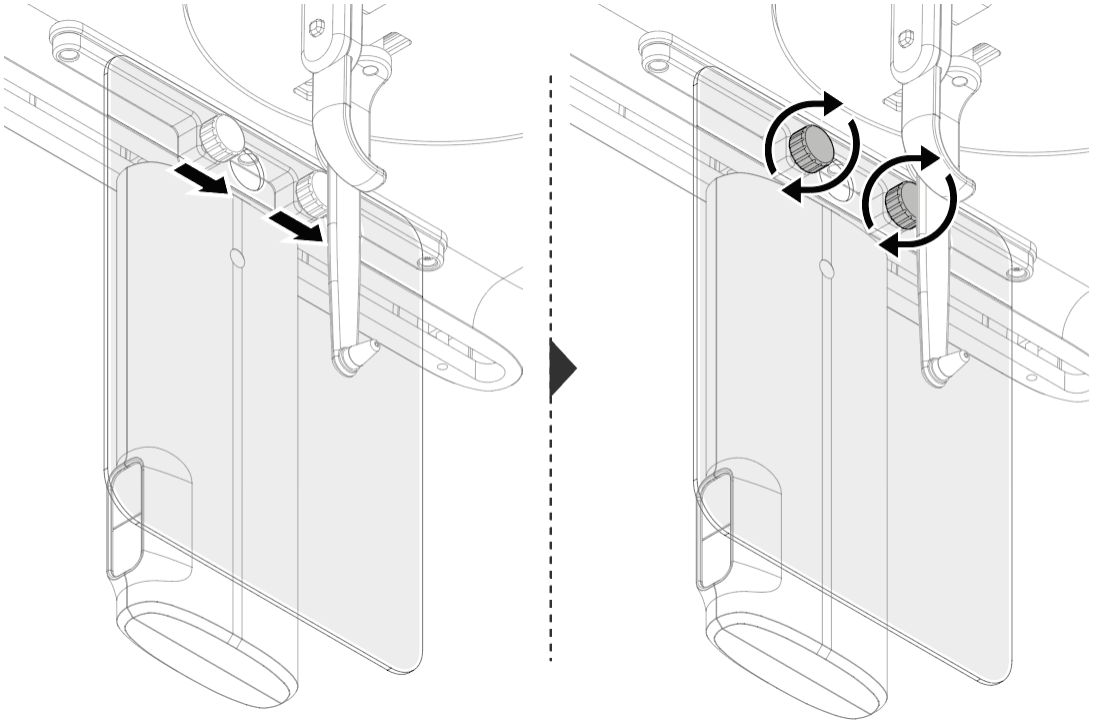
For any damage to the equipment or accident due to use of the parts that were not provided by the manufacturer, the manufacturer has no liability.

NOTICE

When attaching the carpus wrist support plate, be careful to ensure that the hand shape drawn on the support plate is not reversed, and pay attention to the correct attachment direction.



2. Referring to the following figure, slide the carpus plate to the right and then turn the fixing levers to fix the plate.
   - Turning the lever toward the operator: Fixes the support.
   - Turning the lever against the operator: Releases the support.



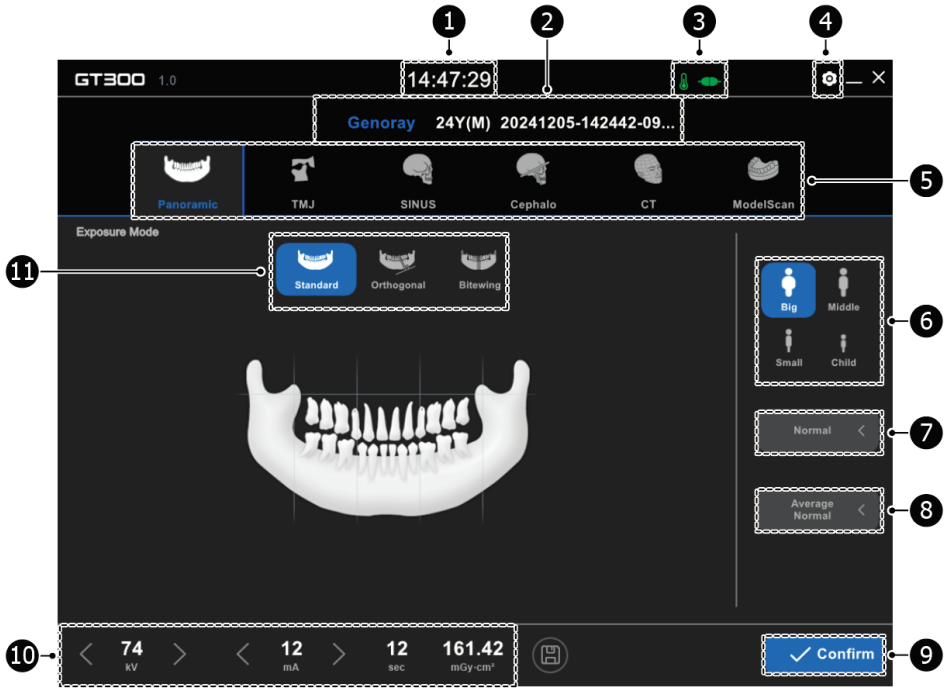
NOTE

When removing the Carpus wrist support plate, follow the reverse order of the attachment procedure.

4. OP (Operation panel)

Provides information regarding the components of the Operation Panel (OP) of the equipment.

4.1) OP screen configuration

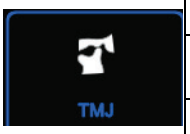


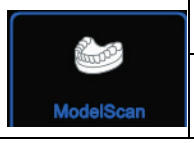
No.	Name	Description
1	Date and time display	Current time
2	Patient information	Information of the patient waiting for image acquisition ▪ ID age (gender) name
3	Equipment status display	Current status of the equipment
4	Options	Options for use environment
5	Acquisition mode selection buttons	Selects the image acquisition mode from the equipment.
6	Patient size selection buttons	Selects the size that was preset according to the actual size of the patient.
7	Image quality selection buttons	Selects the image quality.
8	Jaw type selection	Selects the size and shape of the jaw of the patient.
9	Operational buttons	Sets the condition for image acquisition and makes the equipment ready.
10	Acquisition condition display and setting	Manually adjusts the condition for image acquisition.
11	Acquisition program selection buttons	Selects the proper program for each image acquisition mode.

4.2) Acquisition mode configuration

This equipment supports various types of acquisition programs depending on the purpose of diagnosis.

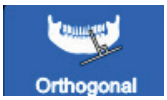
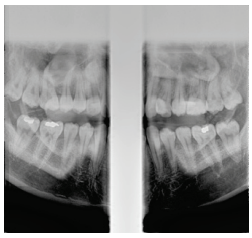
To select an acquisition program, click the acquisition mode selection button from the OP main screen.

<table>
<tr><th colspan="3">Acquisition Mode</th><th colspan="2">Acquisition program</th><th colspan="2">X-Ray Exposure</th></tr>
<tr><td rowspan="9">Panoramic</td><td rowspan="3">Panoramic</td><td rowspan="3"> 
</td><td colspan="2">Standard</td><td colspan="2" rowspan="9">Continuous</td></tr>
<tr><td colspan="2">Orthogonal</td></tr>
<tr><td colspan="2">Bitewing</td></tr>
<tr><td rowspan="3">TMJ</td><td rowspan="3"> 
</td><td colspan="2">Lateral</td></tr>
<tr><td colspan="2">PA</td></tr>
<tr><td colspan="2">LAT-PA</td></tr>
<tr><td rowspan="3">SINUS</td><td rowspan="3"> 
</td><td colspan="2">Midsagittal</td></tr>
<tr><td colspan="2">Lateral</td></tr>
<tr><td colspan="2">Lateral Mid</td></tr>
<tr><td colspan="3" rowspan="10">CT</td><td rowspan="10"> 
</td><td colspan="2">Endo</td><td colspan="2" rowspan="2">Continuous</td></tr>
<tr><td colspan="2">Tooth</td></tr>
<tr><td rowspan="2">Teeth</td><td>High Def</td><td rowspan="6">Pulse</td><td>▪ Pulse width: 23.1 ms
▪ Pulse period: 36 ms</td></tr>
<tr><td>Normal</td><td>▪ Pulse width: 7.1 ms
▪ Pulse period: 20 ms</td></tr>
<tr><td rowspan="2">Jaw1 (16x11)</td><td>Normal</td><td>▪ Pulse width: 27.1 ms
▪ Pulse period: 40 ms</td></tr>
<tr><td>Low dose</td><td>▪ Pulse width: 19.1 ms
▪ Pulse period:32 ms</td></tr>
<tr><td rowspan="2">Jaw2 (20x11)</td><td>Normal</td><td>▪ Pulse width: 27.1 ms
▪ Pulse period:40 ms</td></tr>
<tr><td>Low dose</td><td>▪ Pulse width: 19.1 ms
▪ Pulse period:32 ms</td></tr>
</table>

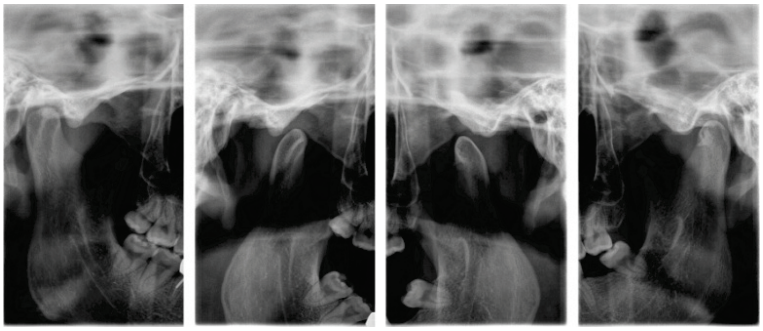
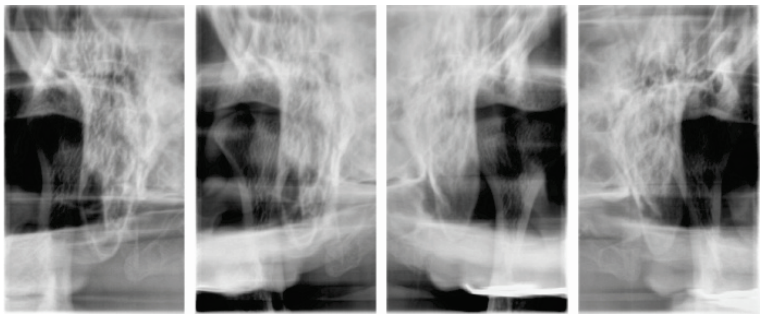
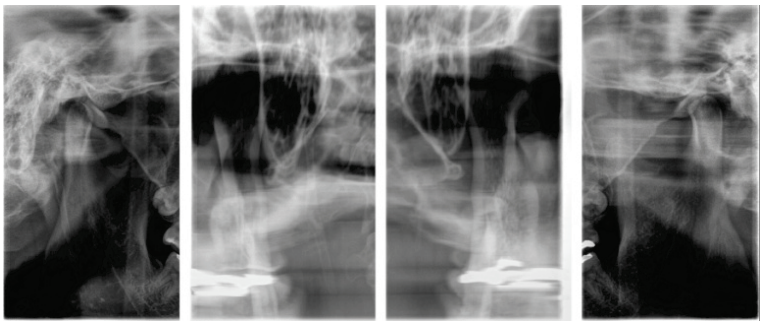
Acquisition Mode		Acquisition program	X-Ray Exposure	
Cephalo		Lateral	Continuous	
		AP		
		PA		
		Water's view		
		SMV (Submentovertex)		
		Carpus		
ModelScan		Stone	Pulse	▪ Pulse width: 23.1 ms ▪ Pulse period: 36 ms
		Impression		

4.2.1) Panoramic Acquisition mode

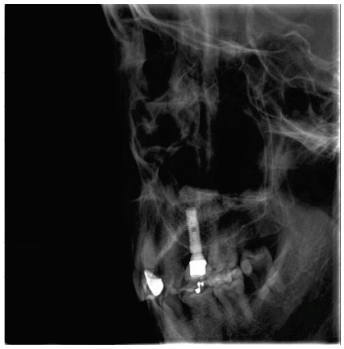
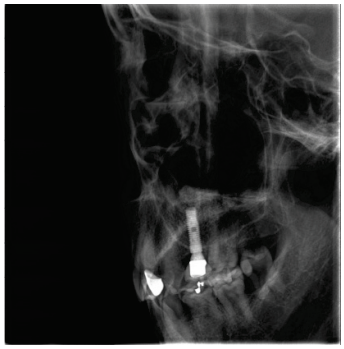
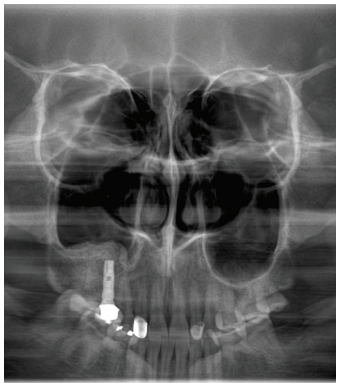
Panoramic

Item	Description
	▪ Standard The Standard program acquires the patient images using the trajectory of normal panoramic image. 
	▪ Orthogonal On the Orthogonal program, the incident angle of the X-ray comes to the patient's jaw more vertically, compared with the Standard program. Overlapping of the teeth in the Standard image is reduced, while the shade made out of the jaw and the teeth on the opposite side of the target area increases. 
	▪ Bitewing The Bitewing program only uses the trajectory for acquiring images of Bitewing areas in the Panoramic image. Basically, the Bitewing program and the Orthogonal program share the same incident angle for image acquisition. 

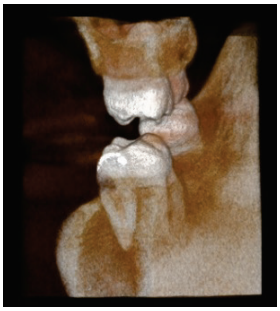
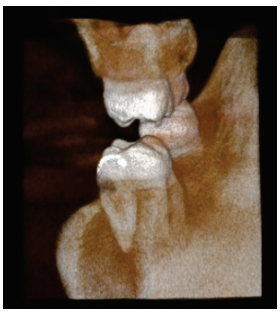
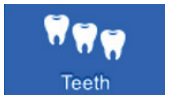
TMJ

Item	Description
	▪ Lateral The Lateral program acquires the side image of the temporomandibular joint (TMJ). Acquires images of both TMJs and compares each other or acquires the TMJ images with the patient's mouth open and closed. 
	▪ PA The PA (Posterior Anterior) program acquires the TMJ images into the PA trajectory. Acquires images of both TMJs and compares each other or acquires the TMJ images with the patient's mouth open and closed. 
	▪ LAT- PA The LAT (Lateral)– PA (Posterior Anterior) program takes turns to acquire images of the Lateral mode and the PA (Posterior Anterior) mode. It is available for acquiring images for maximally 4 times: LAT shot, PA shot, Open shot, and Closed shot. 

Sinus

Item	Description
	▪ Lateral The Lateral program acquires lateral images of the maxillary sinus, just like the Lateral Mid (middle). In doing so, the focal plane goes to the right or the left beyond the mid-sagittal plane. 
	▪ Lateral Mid The Lateral Mid (middle) program acquires lateral images of the maxillary sinus. The focal plane of the image is on the mid-sagittal plane. 
	▪ PA The PA (Posterior Anterior) program acquires the images of the maxillary sinus into the PA trajectory. 

4.2.2) CT Acquisition mode

Item	Description
	▪ Endo This program provides high resolution 3D images of nerves, pulp structure, veins in the target tooth (teeth) for endodontic treatment. • F.O.V.: Φ50-H50 
	▪ Tooth This program provides detailed images of a tooth or two teeth. This mode acquires the most detailed images so that the examiner can see the dental nerve. • F.O.V.: Φ50-H50 
	▪ Teeth This program provides detailed images of multiple teeth. This mode acquires the second most detailed images after the Tooth mode. • F.O.V.: Φ110-H110 

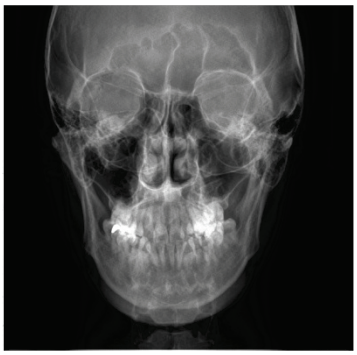
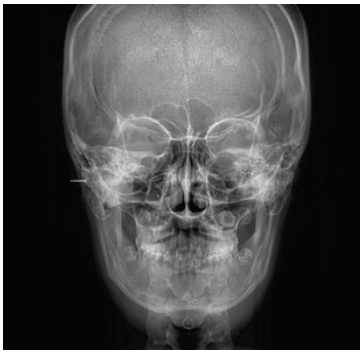
Item	Description
	▪ Jaw 1 This program provides images or the entire jaw of the patient. • F.O.V.: Φ160-H110 
	▪ Jaw 2 This program provides images or the entire jaw of the patient. • F.O.V.: Φ200-H110 

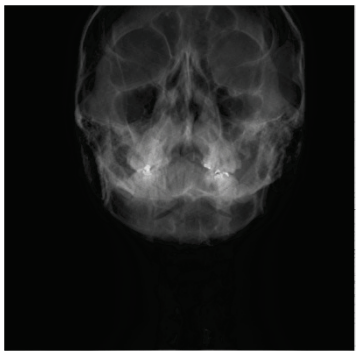
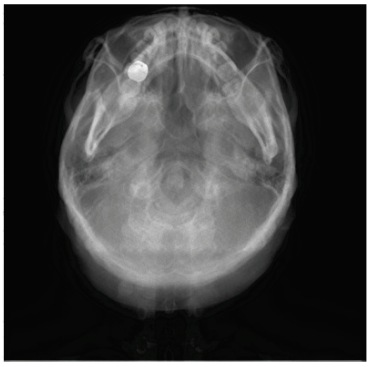
The F.O.V. varies depending on the CT imaging mode.

Size of voxel

Item		Description
CT Mode	Endo	65 μm
	Tooth	100 μm
	Teeth	140, 180 μm
	Jaw	180, 300 μm

4.2.3) Cephalo mode (Option)

Item	Description
	▪ Lateral The Lateral program acquires images of the patient's cranial bone following the incidental trajectory of the X-ray that is projected toward his/her right and left side. 
	▪ AP The AP (Anterior Posterior) program acquires images of the patient's cranial bone following the incidental trajectory of the X-ray that is projected along the AP (Anterior Posterior) direction. 
	▪ PA The PA (Posterior Anterior) program acquires images of the patient's cranial bone following the incidental trajectory of the X-ray that is projected along the PA (Posterior Anterior) direction. 

Item	Description
	▪ Water's The Water's view acquires images of the patient's cranial bone while the patient is tilting his/her Frankfort line for about 45 degrees against the detector plane. 
	▪ SMV The SMV (Submentovertex) acquires the patient's images while the patient is positioning his/her Frankfort line parallel to the detector plane. 
	▪ Carpus To acquire images on the Carpus mode, the wrist support for the Carpus mode (Option) should be set onto the equipment first. 

4.2.4) ModelScan mode (Option)

Item	Description
	▪ Stone This is the imaging program of the dental stone model for the STL data extraction. • F.O.V.: Φ110-H110 
	▪ Impression This is the imaging program of the dental impression model for the STL data extraction. • F.O.V.: Φ110-H110 

NOTE

The F.O.V. varies depending on the CT imaging mode.

Size of voxel

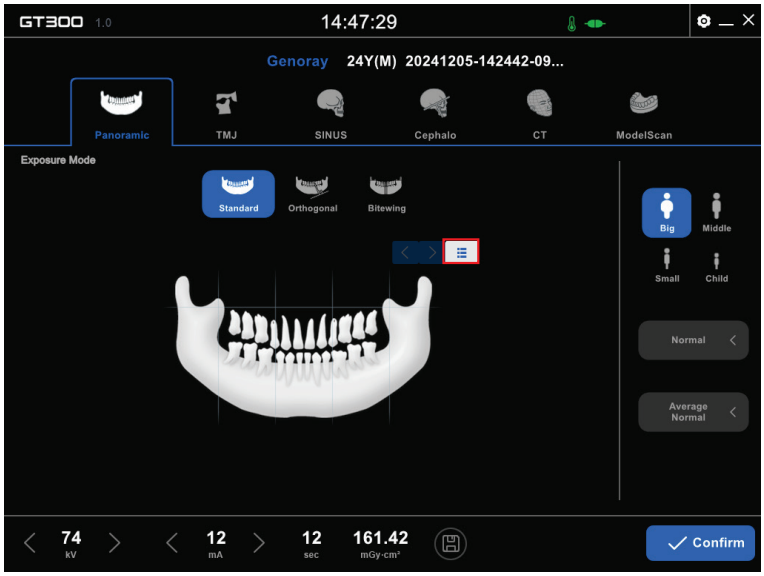
Item		Description
Modelscan Mode	Stone	140 μm
	Impression	140 μm

4.3) Auto positioning

For patients with scanning history, the program, the scanning condition, and the equipment position are automatically set as the previous scanning. The patient does not need to adjust his/her position for image acquisition and the equipment still can get the best images.

1. The OP screen for the auto positioning appears.

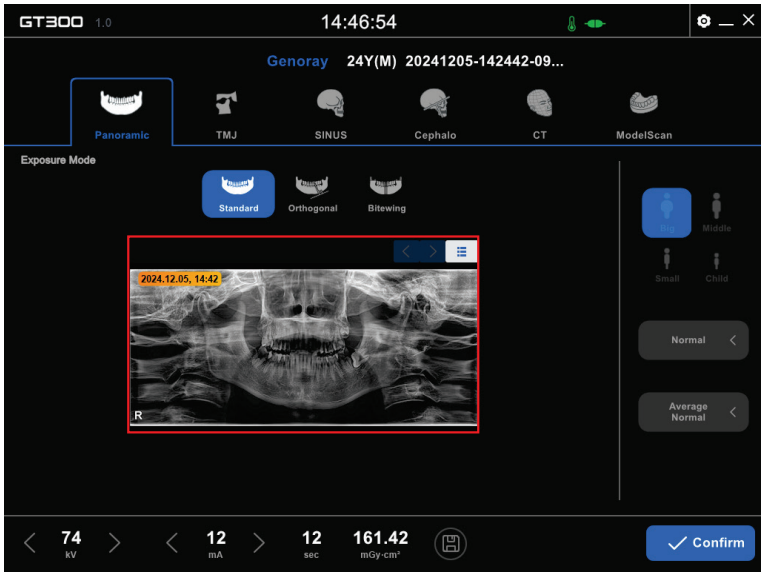
On the right to the OP, the list icon for the feature appears.



NOTICE

It only appears when there is a scanning program with history.

2. Clicking the left mouse button on the list icon displays the previous images.



No.	Image	Description
1		When clicked, it changes to previous image.
2		When clicked, it changes to next image.
3		When clicked, it shows previous image(s).

3. Clicking the Confirm button resets the equipment position and scanning condition as the previous setting.

NOTE

Clicking the left mouse button on the list icon sets back to the default scanning condition.

4.4) Select Patient (Preset) Size

On each program, selecting one of the patient size buttons adjusts the setting according to the actual body size of the patient.

There are four options for the body size and selecting one of them arranges proper trajectory and exposure condition of the X-ray accordingly on each program.

Each program has its own setting for the X-ray exposure.

4.5) Imaging speed and quality selection

Panoramic, TMJ, SINUS, and Cephalo mode

On the Panoramic, the TMJ, the SINUS, and the Cephalo acquisition modes, the image quality option is provided as follows:

There are three options: Normal, Fast, and HD (high definition), and specifically for the Cephalo mode, the Ultra Fast is also available.

- Fast

  Lower image quality than Normal. Suitable for fast scanning.

- HD

  Takes longer for image acquisition than Normal. Suitable for taking more accurate images.

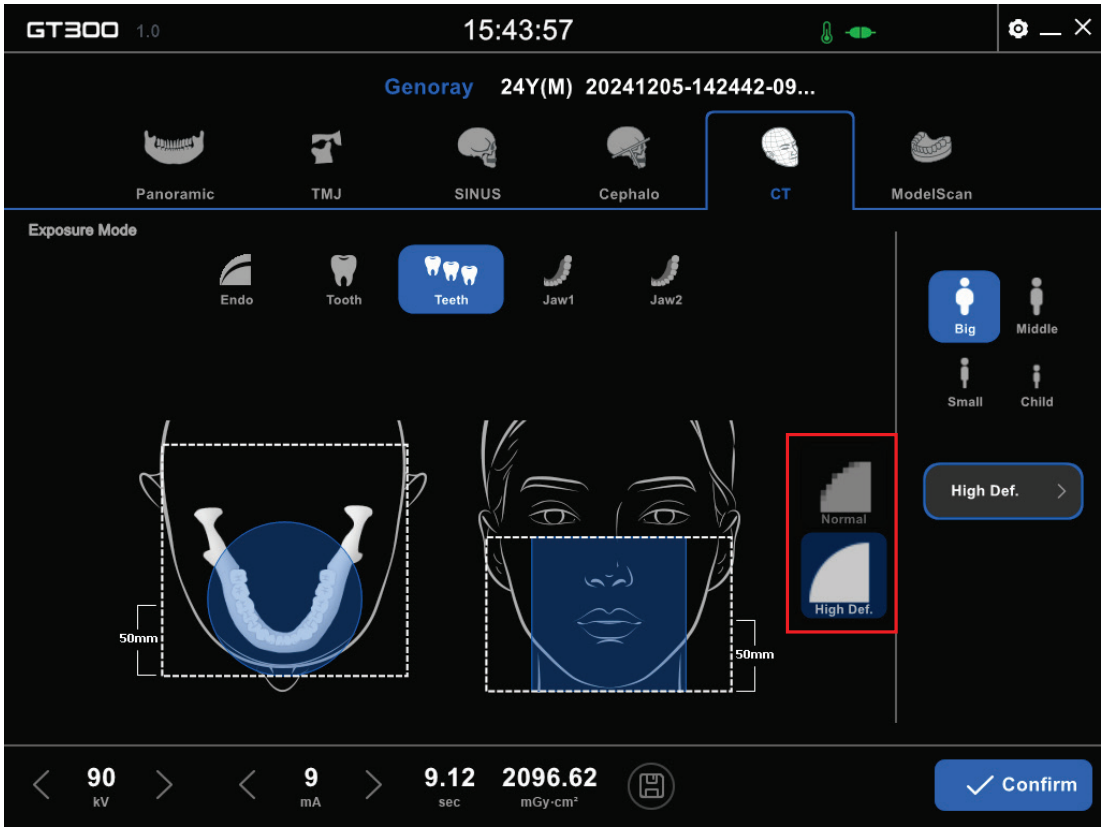
- Ultra Fast

  Suitable for even faster scanning than Fast by scanning the patient quickly for 2 seconds to acquire an image.

CT Acquisition mode

There are a total of 5 image quality levels available on the CT mode.

The options for the image quality are: Low Dose, Normal, High Def (High Definition), High Res (High Resolution), and Endodontic. For each acquisition program, up to two image qualities are available.



NOTE

Endodontic quality level is available to select only for the Endo program.

4.6) Setting of the X-ray exposure

To adjust the settings of the X-ray exposure, you can click the lift and right arrows on the kV setting and mA setting from the X-ray setting display.

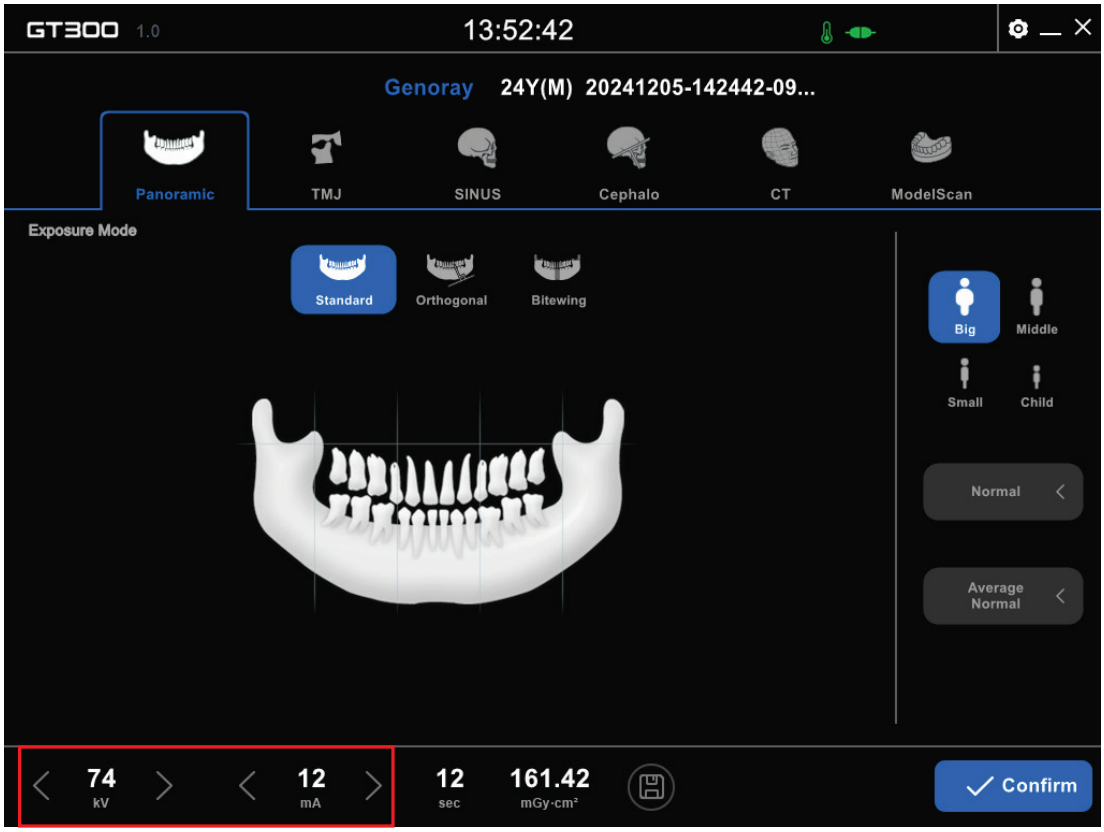
- kV

  ±1 kV per click

- mA

  ±0.5 mA per click

Clicking the save icon saves the changed settings for exposure.



NOTICE

Selecting the patient size and the scanning program automatically adjusts the proper setting. If necessary, adjust the setting manually.

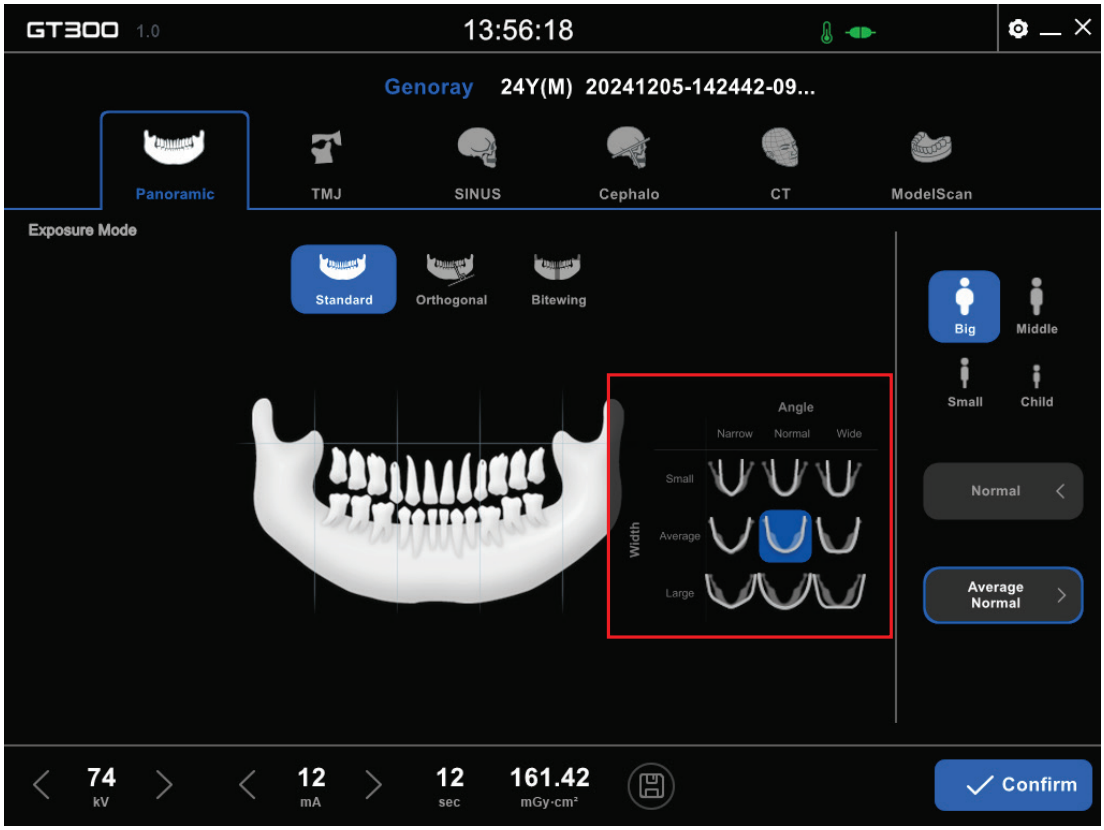
NOTE

The time for exposure is not subject to change.

4.7) Jaw type selection

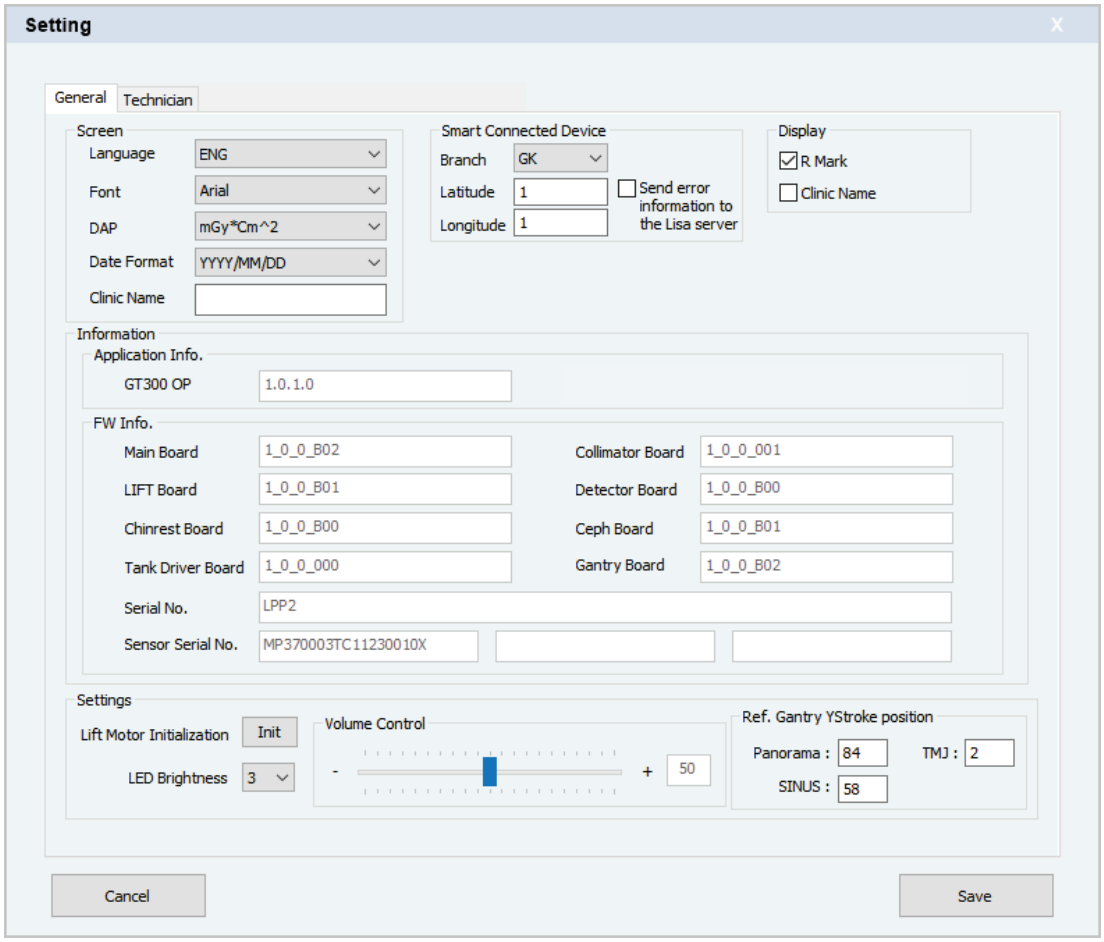
In Panoramic exposure mode, the user can make an appropriate selection based on the size and shape of the patient's jaw.

Total nine options are available by combining the jaw shape (triangular, standard, rectangular) and the jaw size (large, normal, small).



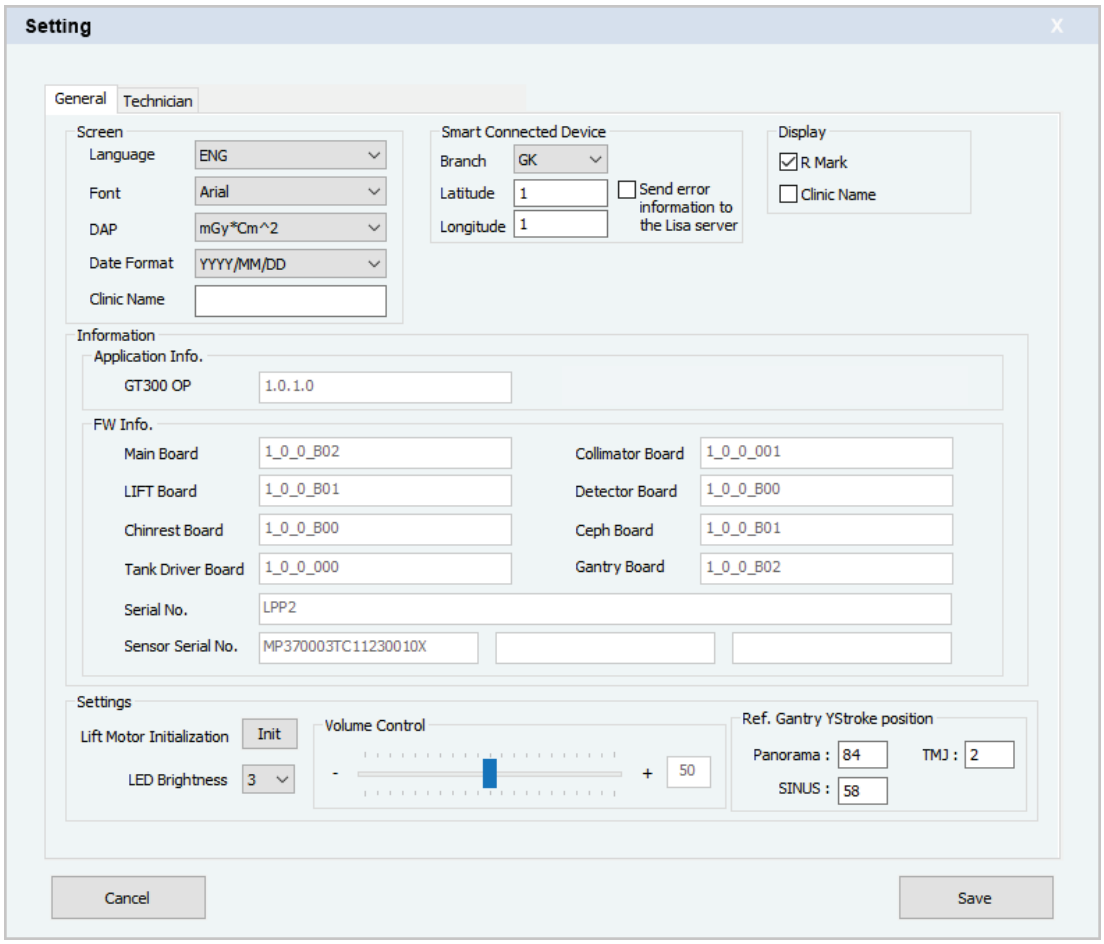
4.8) Options

This section provides explanation regarding the option setting of the use environment for GT300 OP, tab by tab.



No.	Item	Description	Notation
1	General	Screen configuration, equipment, program version.	
2	Technician	Engineer mode	

4.8.1) General



No.	Item		Description
1	Language		Language setting
2	Font		Font setting
3	DAP		DAP output unit setting
4	Date format		Date format setting
5	Clinic name		Clinic name setting
6	Branch		Designated service center setting
7	Latitude		Set up coordinate for latitude
8	Longitude		Set up coordinate for longitude
9	Send error information to the Lisa server		Checks the transfer error to the LISA server. When an error occurs, related error information and its log file are automatically sent to the LISA server.
10	Display	R-mark	Decides whether to print the position R mark and the clinic name on the image.
		Clinic Name	
11	GT300 OP		OP version

No.	Item	Description
12	GT300 REC	REC program version
13	Main Board	Main board version
14	LIFT Board	Lift version
15	Chinrest Board	Patient support board version
16	Tank Driver Board	Generator driver board version
17	Collimator Board	Collimator board version
18	Detector Board	Detector board version
19	Ceph Board	Ceph board version
20	Gantry Board	Gantry board version
21	Serial num	Serial numbers of the equipment
22	Sensor Serial	Serial numbers of the sensor
23	LED Brightness	LED Brightness setting
24	Volume control	Setting for volume level of the equipment
25	YStroke position	The Canine laser position setting when positioning the patient

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5. Turning On/Off the Equipment

This chapter provides information regarding connection of the equipment power supply and details on how to turn on or off the equipment.

5.1) Connection to Power

5.1.1) Checklist before Connecting the Power

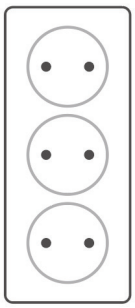
CAUTION

This equipment is designed for the shielded room which is equipped with the power supply system.

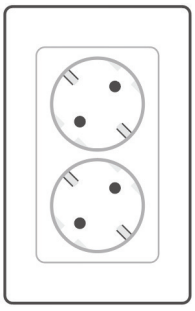
NOTICE

This equipment is not designed to use in domestic establishments and it should be avoided connecting the equipment directly to the main power supply that is shared within the building.

1. Check if there is a grounding pin for the outlet.



No pin is installed



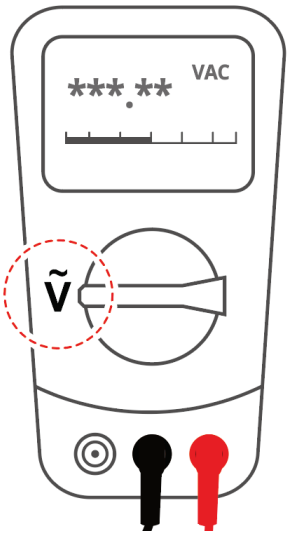
A pin is installed

NOTE

- Although there is a grounding pin, there is still a chance that it is not connected to the power supply. So be sure to check the power supply is grounded.
- When using a power strip inevitably, make sure to use one that is equipped with a grounding pin and whose rated current exceeds 16 A, along with no other equipment connected to the power strip.

2. Using multi tester, check if there are any problems with the voltage.

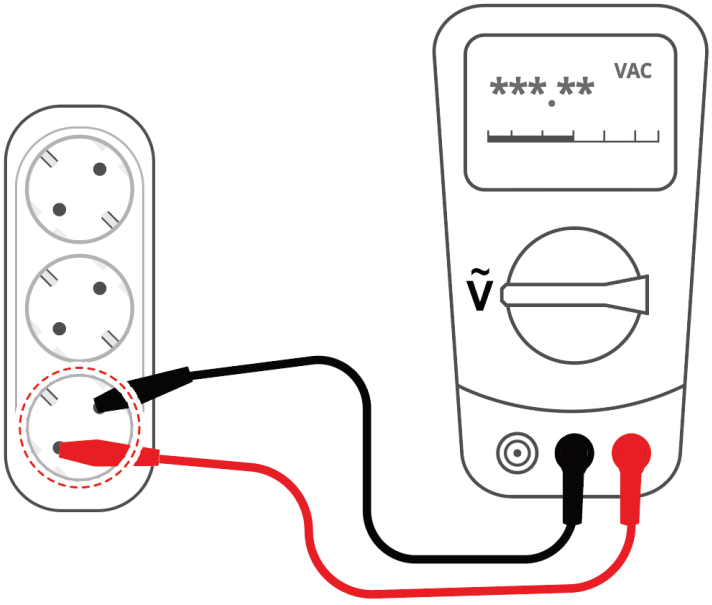
   a. Set the multi tester mode to measure for the AC voltage.



NOTE

- The multi tester is not included with the equipment.
- Depending on the multi tester, the shape and mode selection of the User Interface can vary.

   b. Put the two probe pins into the holes of the outlet, one into each hole, and check for the voltage.

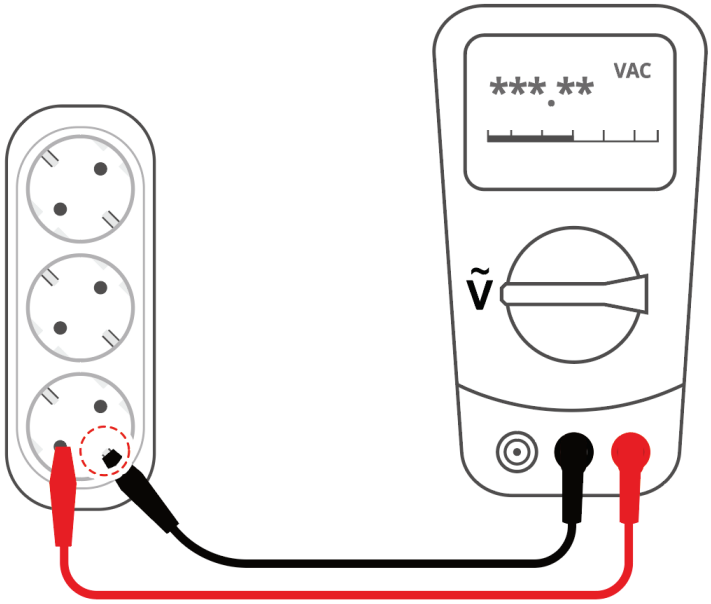


NOTE

The voltage can vary depending on the voltage at the installation.

- For example: 100 V and higher, 110-120 V and higher, 200-240 V and higher, etc.

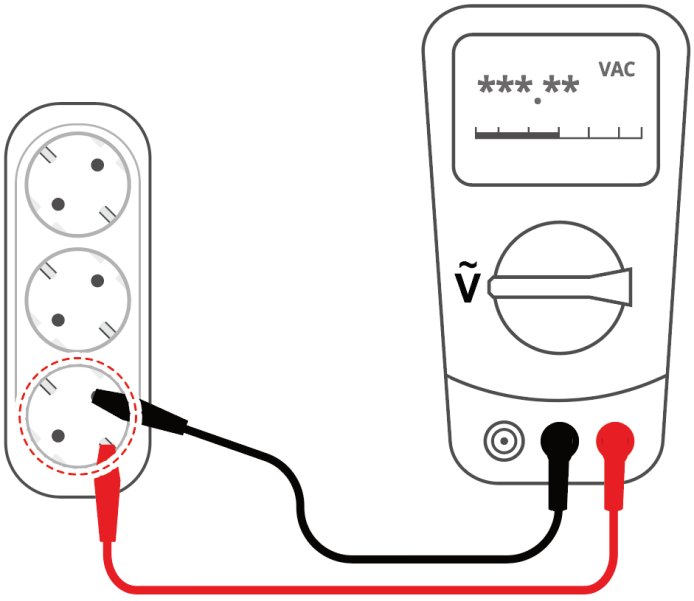
c. Retrieve a probe pin and connect it to the grounding pin of the power outlet.



NOTE

If the measured voltage is similar to step (b), the hole of the outlet for the red probe pin is **"Line"** and the other hole is **"Neutral."**

d. Check the voltage of the **"Neutral"** hole and the grounding pin of the outlet.

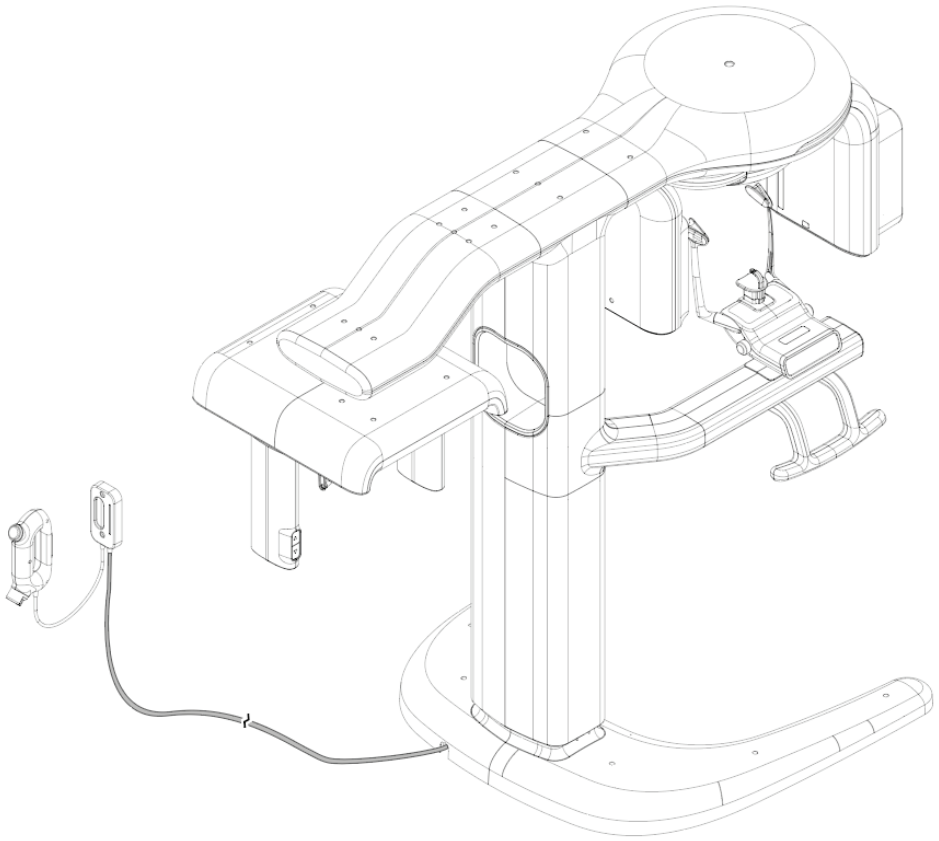


NOTE

- If the voltage value reads 0-5 V, the grounding is properly connected.
- If the voltage reads 60-80 V, 110V, or higher at the **"Neutral"** hole and the grounding pin, it means there is a problem with the grounding. In this case, you should ask an expert for help to check the power supply, then check the voltage at the same spot one more time.

5.1.2) Connecting the equipment

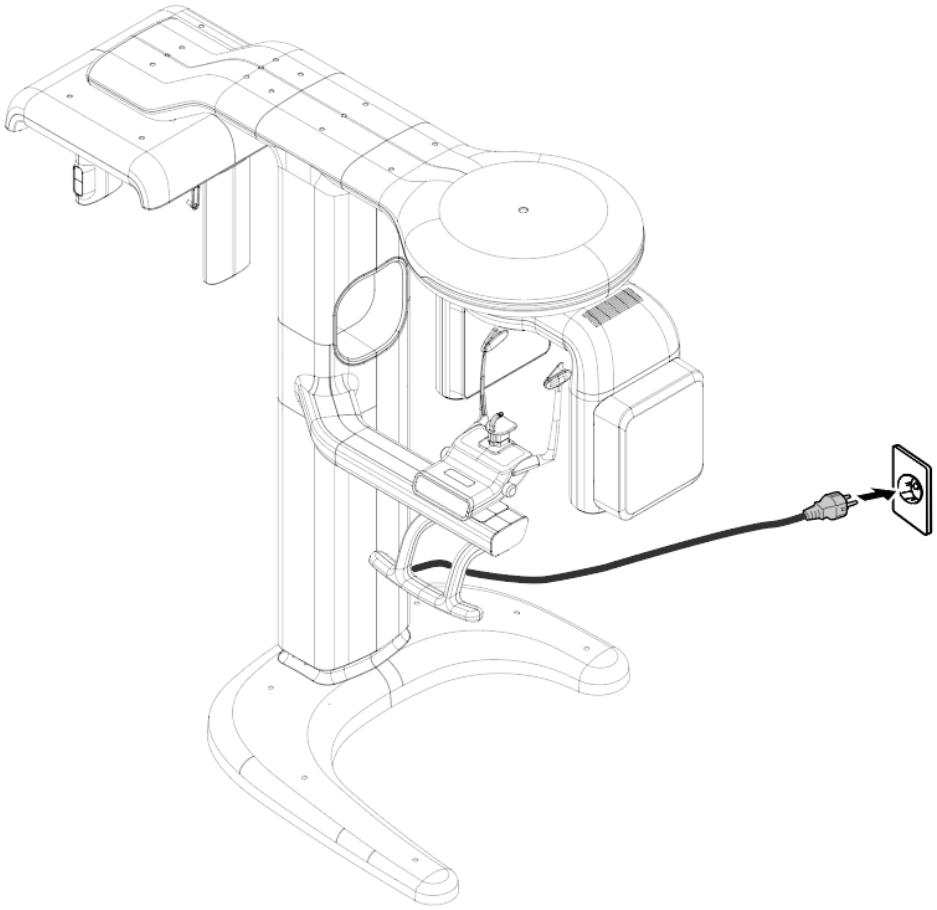
1. Connect the exposure switch to the equipment.



NOTICE

Make sure to connect the ports only with the parts provided by the manufacturer.

2. Connect the power cable of the equipment to the power outlet.



WARNING

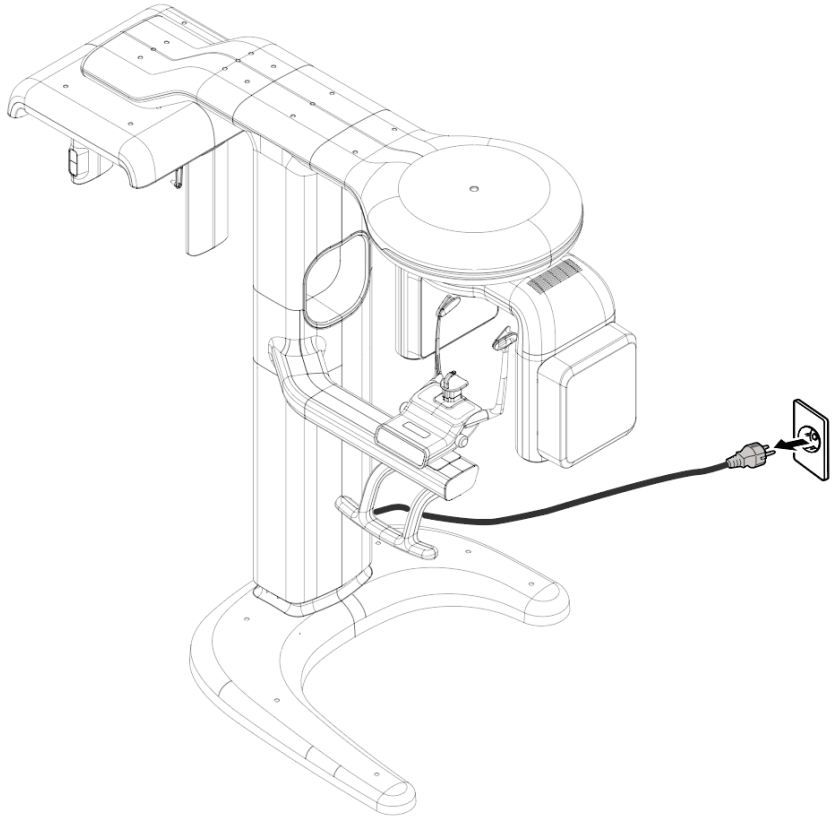
Make sure to connect and fix the power cable in a proper manner.

NOTICE

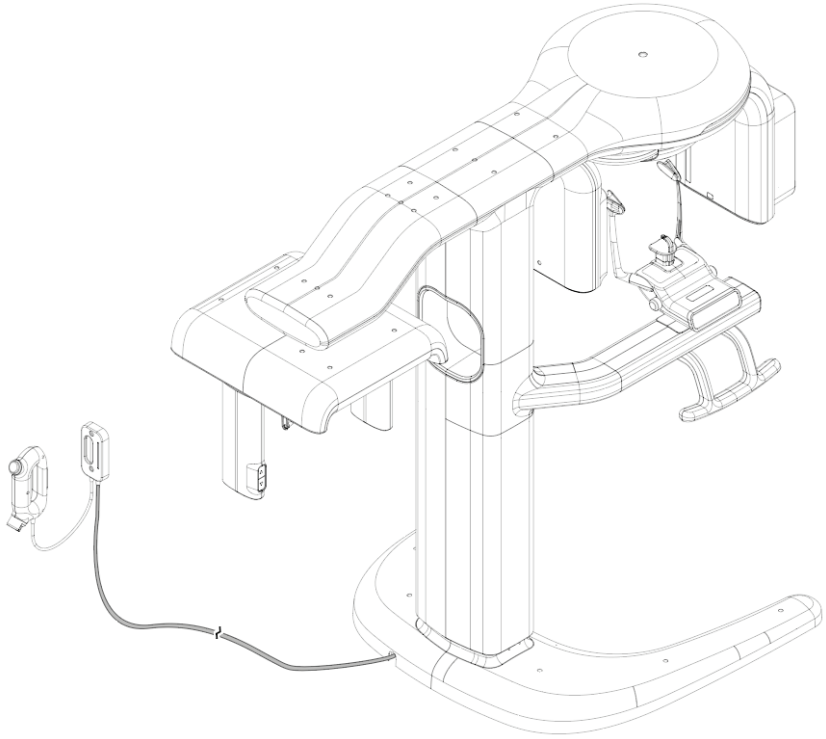
- Do not change anything with the other cables or accessories other than the components provided with the equipment. This can negatively affect the electromagnetic compatibility of the device.
- Make sure to place the power cable in a position where it can be easily disconnected in case of a problem.

5.1.3) Disconnecting the equipment

1. Disconnect the power cable of the equipment from the power outlet.



2. Disconnect the exposure switch from the equipment.



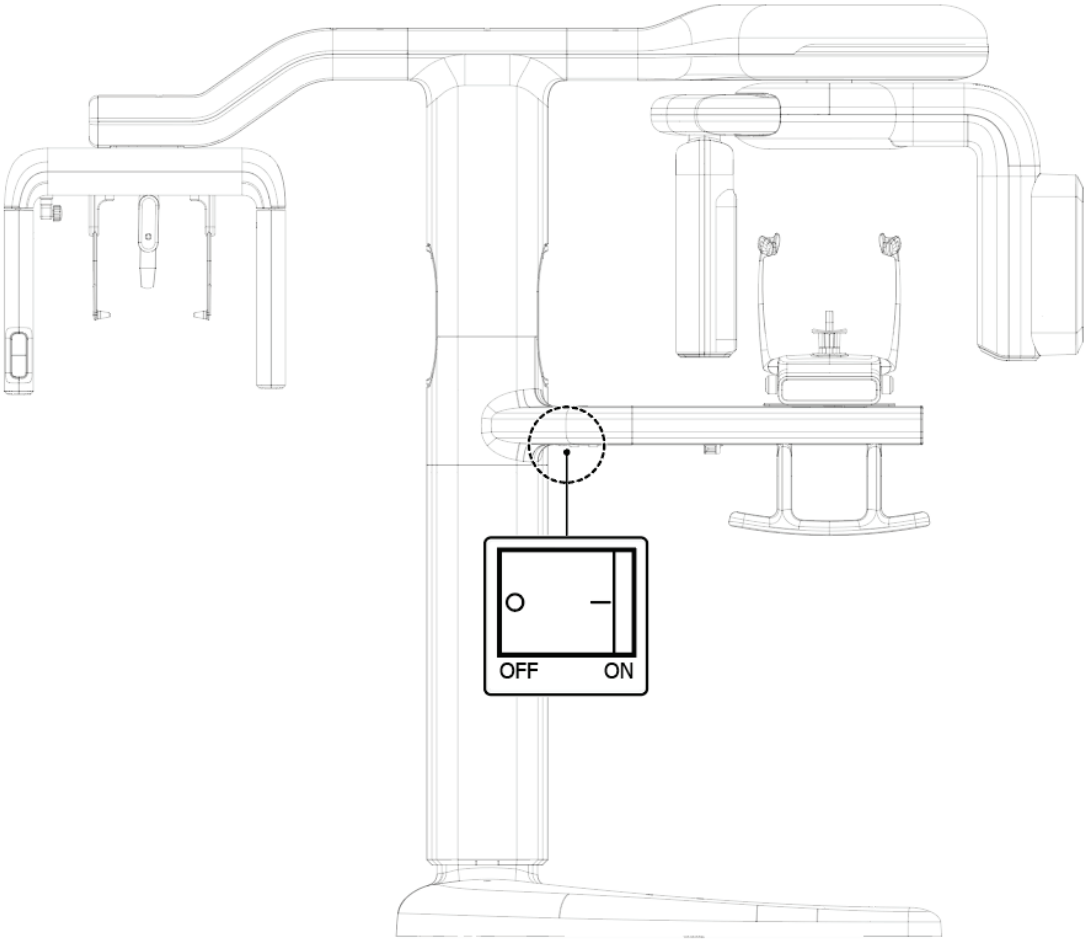
5.2) Turning on/off the equipment

This section describes how to turn on the equipment.

WARNING

Before supplying power, check the power cable connection of the equipment and the voltage of the power source.

1. Following the figure below, turn on the power switch.



2. Check the power supply to the equipment by checking the status indicator LED and the OP screen.

NOTICE

If you hear an abnormal noise after the equipment is turned on or you cannot turn it on, take proper action referring to Chapter **"8 Error solution"**. If the power remains cut off after an action has been taken, contact the service manager.

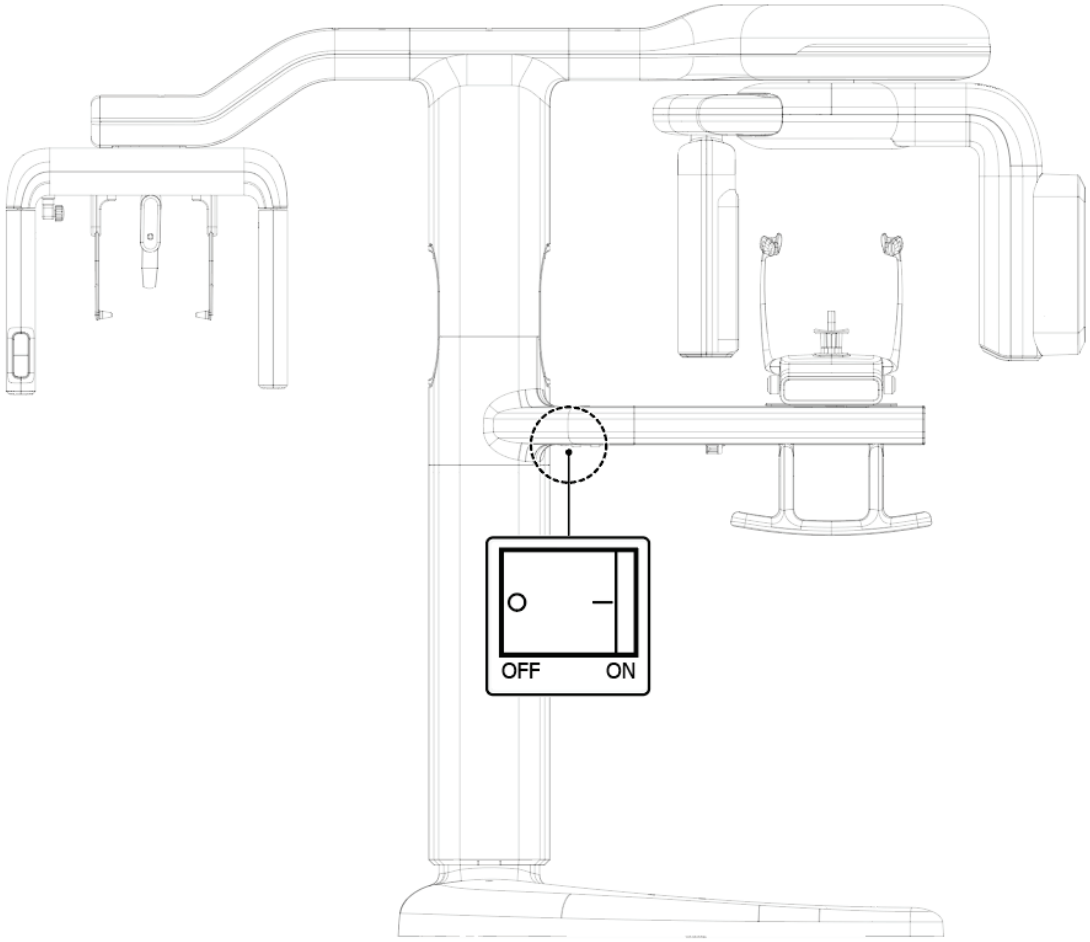
5.3) Turning off the equipment

This section provides instructions for turning the equipment off.

WARNING

Do not disconnect the power cable while the equipment is still turned on.

1. Check the circumstances around the equipment.
2. Following the figure below, turn off the power switch.



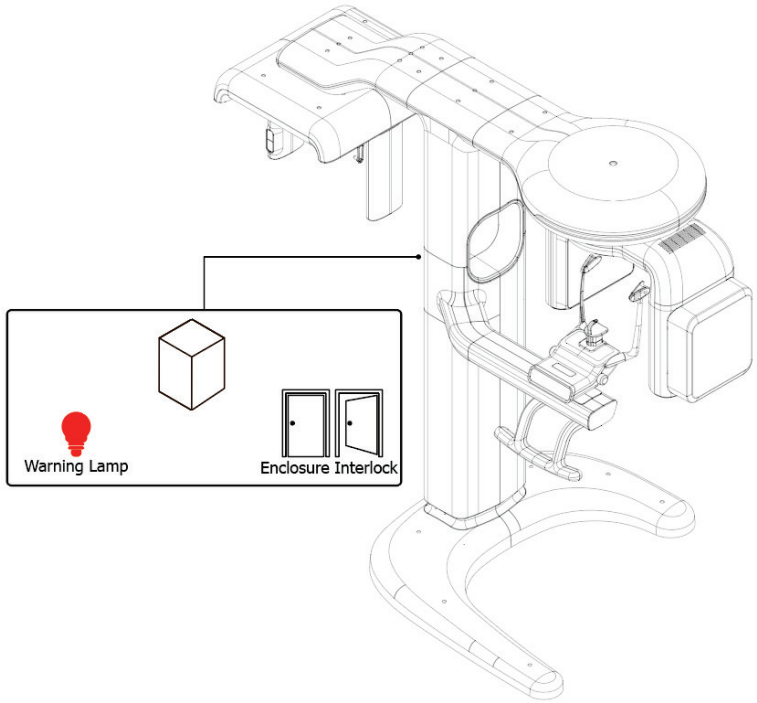
6. Image acquisition

Provides information regarding registration of the patients and acquisition of images in each mode.

NOTE

To prevent unexpected X-ray exposure, make sure to close the shielded room first and then expose the X-ray when you use the equipment.

While the door of the shielded room is open, the OP screen displays an error message, keeping the system unavailable to proceed.



6.1) Launching Theia

1. Turn on the PC that is connected to the equipment.

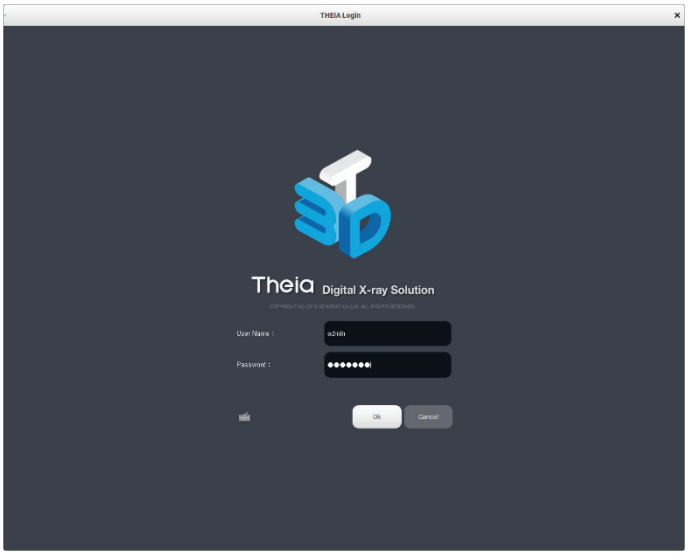
NOTE The PC is not included in the basic package.

2. When the PC is turned on, double click on the Theia program to launch it.

6.2) Theia Log In

The user should log in first to use the program. The specific process of logging in is as follows:

Launch Theia and log in to the program.



NOTICE

To log into it for the first time among all the users, use the following ID and ask the service engineer for the password.

- ID: admin

NOTICE

- After login for the first time, it is recommended to change the password to ensure privacy protection.
- There are two types of common accounts as the following:
  - Admin
  - User

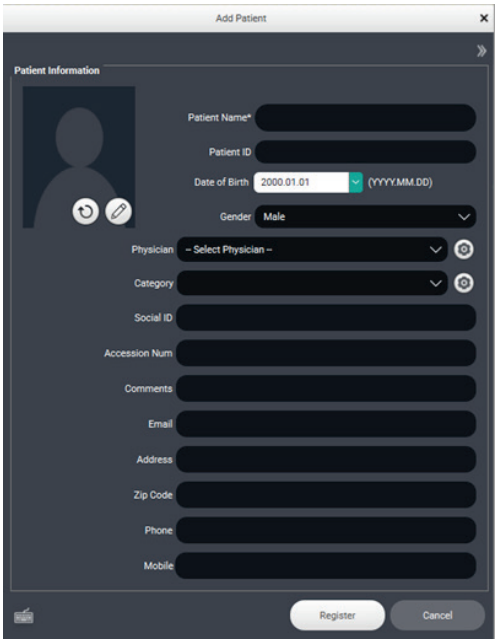
  Each type of account has its own access level. For more information, refer to **"Theia Software Manual"**.

6.3) Patient registration

Launching the Theia software loads the information of the patient for scanning or registers a new patient to create his/her information.

1. Click the registration button.

2. Provide the patient information on the registration window.



3. After writing down the patient information, finish the registration process by clicking the registration button.

NOTICE

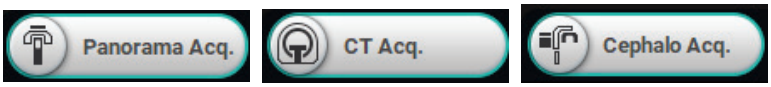
The information regarding registered patients can be searched using the keywords, such as patient name, chart number, registration date, doctor in charge, etc. For more information regarding how to find the patient information and edit it, refer to **"Theia Software Manual"**.

NOTE

- Patient registration on OP

  Automatically sets the patient's name as Emergency and the acquisition mode as the Panoramic Standard.

4. After registration, select the acquisition mode.



NOTE

- The Panoramic mode and the CT mode are available. If the Cephalo mode is available as an option, it can be also selected.
- For more information regarding Theia, refer to the Theia Manual that can be provided in bundle.

5. The OP screen displays the acquisition mode that was selected on Theia, synchronizing Theia to the equipment.

6.4) Image Acquisition on each mode

Equipment Preparation and Patient Registration

1. Refer to "**5.1) Connecting to Power**" to connect the equipment.
2. Refer to "**5.2) Turning on/off the equipment**" to turn on the equipment.
3. Refer to "**6.1) Patient Registration**" to register the patient.
4. Select the exposure mode.

NOTICE

The information regarding registered patients can be searched using the keywords, such as patient name, chart number, registration date, doctor in charge, etc. For more information regarding how to find the patient information and edit it, refer to **"Theia Software Manual"**.

5. Select the acquisition mode.

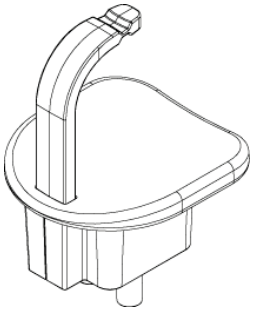
NOTICE

Prior to using the equipment, users should verify which control buttons are available for each exposure mode.

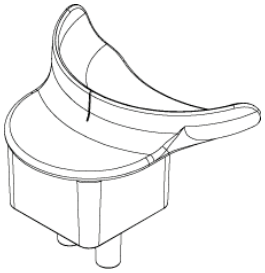
6.4.1) Panoramic mode

Describes the settings and patient positioning for each exposure mode.

1. Attach the chinrest and the bite onto the equipment.



For normal patients



For edentulous patients

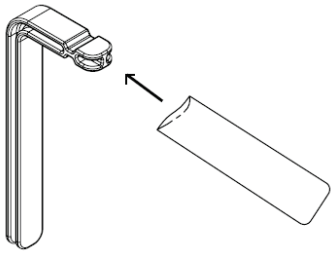
NOTE

For patient who has trouble biting the bite (for he/she has no tooth or is using orthodontic instruments), use the bite for edentulous patients.

NOTE

For how to attach the chinrest, refer to "**3.3.1) Chinrest**".

2. Make sure to cover the bite with the hygienic bag before using the equipment.



NOTICE

This product must be used with a hygienic bag suitable for biocompatibility (ISO 10993-1). Failure to use hygienic bag may result in cross-contamination of diseases or viruses between patients.

NOTE

- The hygienic bag is not a standard component and is not provided by the manufacturer.
- Please use the hygienic bag when using the bite, and do not reuse a cover that has already been used.

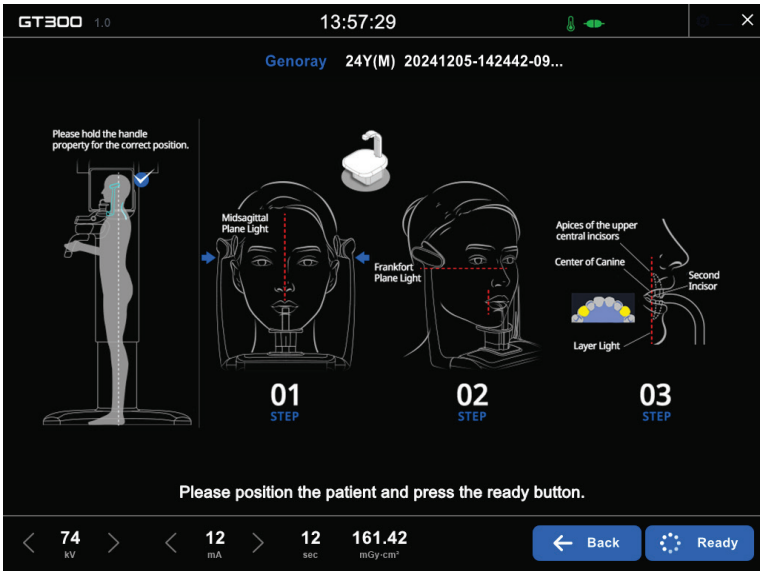
3. Register the patient, select the Panoramic mode, and start the OP.

4. On the OP screen, select the Panoramic mode and scanning condition, and click the [Confirm] button on the lower right corner to show the patient positioning screen.

NOTE

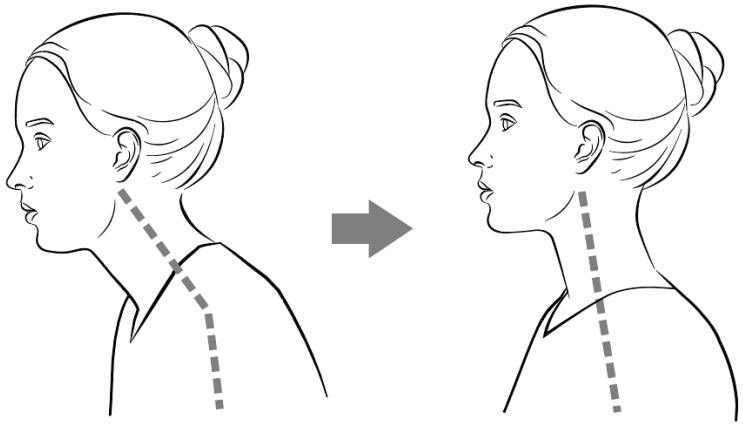
For patients who have scanning history and are going to use the same program again, refer to **"4.3) Auto positioning"**.

5. Guide the patient into the scanning position and adjust the height of the equipment to the patient using the control button.

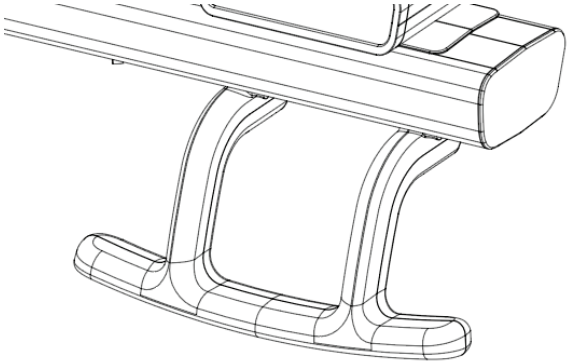


6. Put the patient's chin on the chinrest and help him/her to bite the bite, covered with the hygienic bag as shown in the figure.

7. If the patient's neck is not straightened up, which means the patient's head faces up or down, adjust the height of the equipment with the control button so that the patient can get ready in good position.

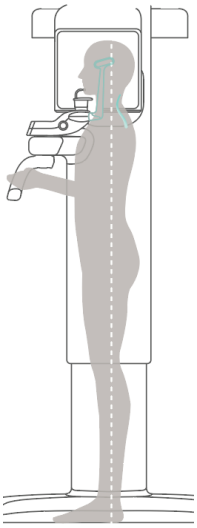


8. When the patient is in good position, help him/her to hold the handle of the patient support.



WARNING The load applied to the handle should be under 20 kg.

9. Check again for the patient's position.



NOTICE

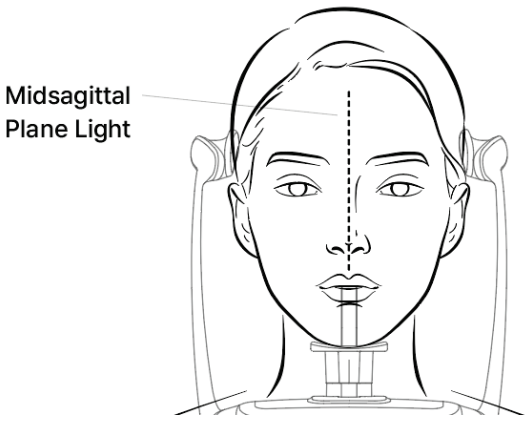
After the patient's alignment has been completed, they should be advised to remain still until the exposure is complete.

10. With the patient biting the bite, push the laser button on the control panel.

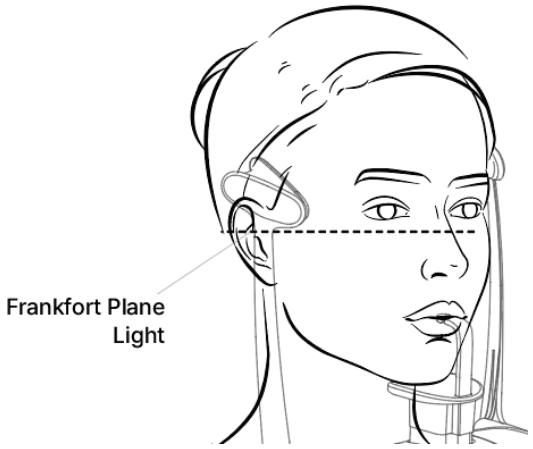
NOTICE

There are three lines of the guide laser and the patient's head should be positioned aligning with each of the three lines, depending on the acquisition mode to acquire images with good quality.

11. Adjust the patient's head so that the patient's mid-sagittal plane (vertical center line of the face) is aligned with the Midsagittal laser line.



12. Adjust the angle of the patient head so that the patient's Frankfort plane is aligned with the Frankfort laser.

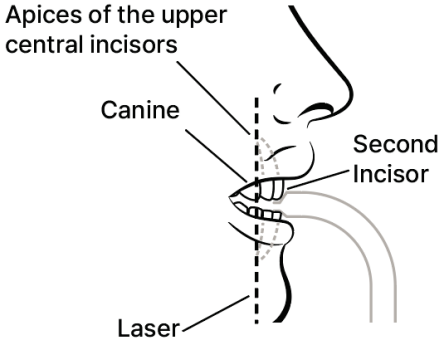


NOTE

The Frankfort laser is projected marking the line section between a spot over the earhole (suprameatal opening) to another spot beneath the eyeball of the patient.

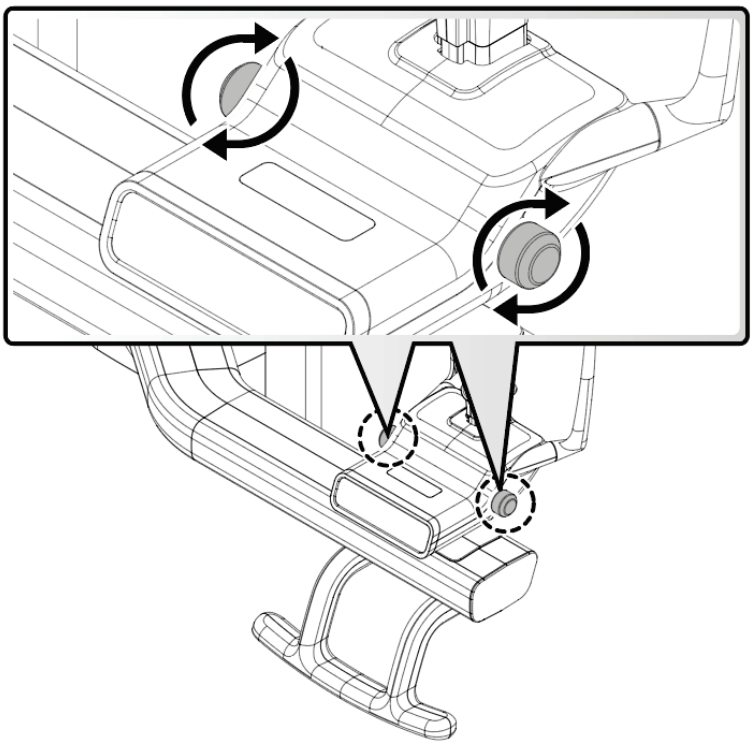
13. Adjust the position of the Canine laser using the control button so that the laser is located on the patient's canine.

- The [Forward] button: Moves the laser toward the operator.
- The [Backward] button: Moves the laser backwards against the operator.



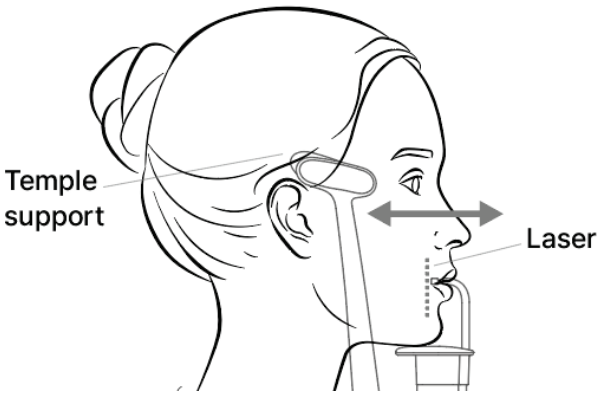
14. Turn the fixation lever of the temple support to or against the operator so that the support fixes or releases the patient.

- Turning the lever toward the operator: Fixes the support.
- Turning the lever against the operator: Releases the support.



15. Fix the position of the patient's face using the temple support and check if any one of the guide laser lines fails the alignment.

If so, reposition the patient aligning with the guide laser.



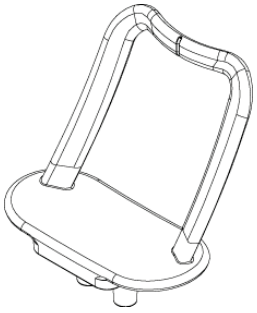
NOTICE

The guide laser is automatically turned off after a certain amount of time or when the image acquisition begins.

6.4.2) TMJ mode

Describes the settings and patient positioning for each exposure mode.

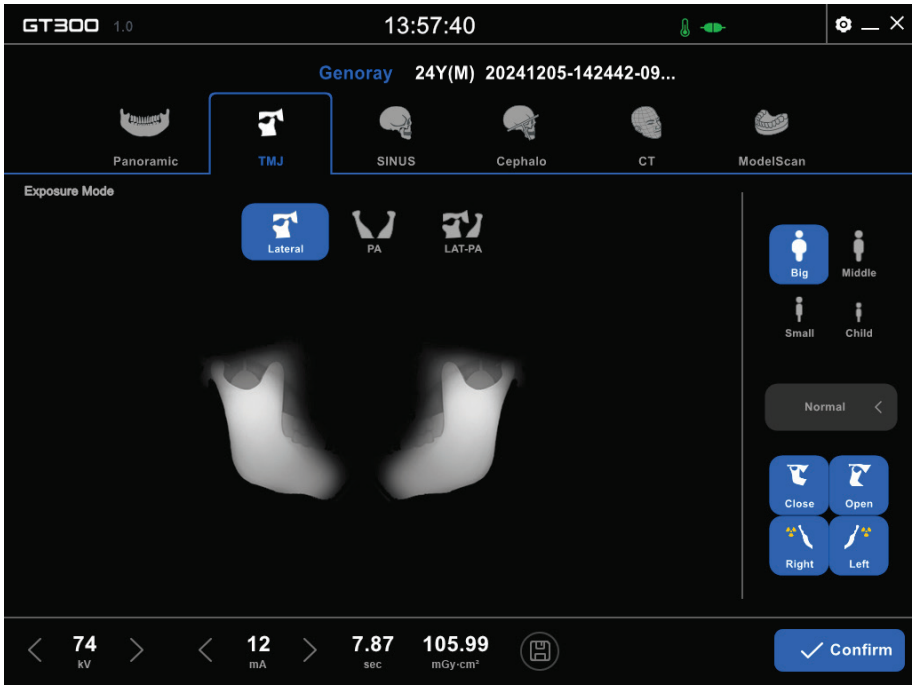
1. Attach the chinrest for the TMJ mode onto the equipment.



For TMJ mode

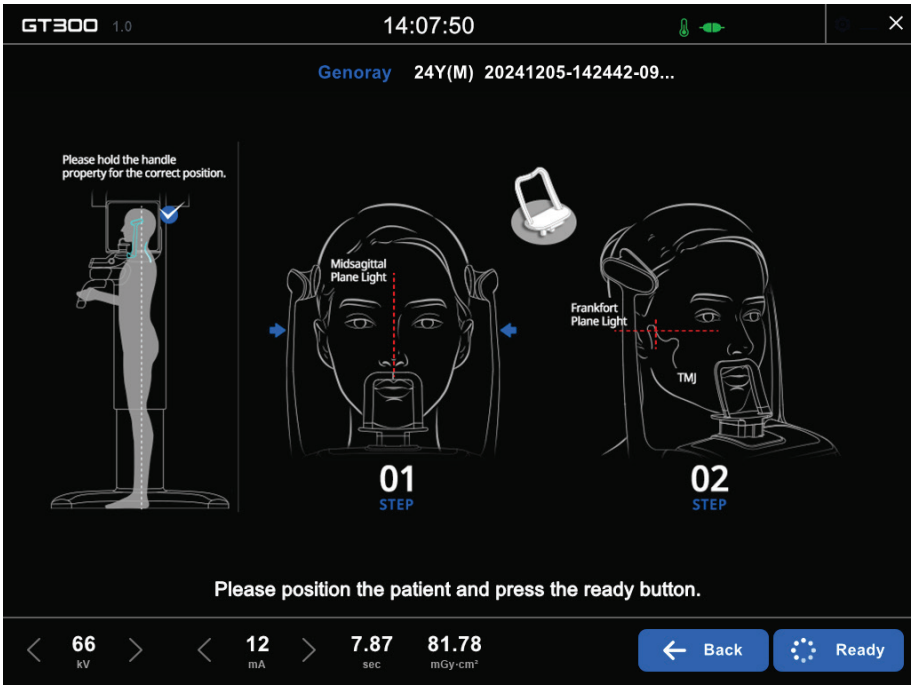
NOTE For how to attach the chinrest, refer to **"3.3.1) Chinrest"**.

2. Register the patient, select the TMJ mode, and start the OP.
3. On the OP screen, select the TMJ mode and scanning condition, and click the [Confirm] button on the lower right corner to show the patient positioning screen.

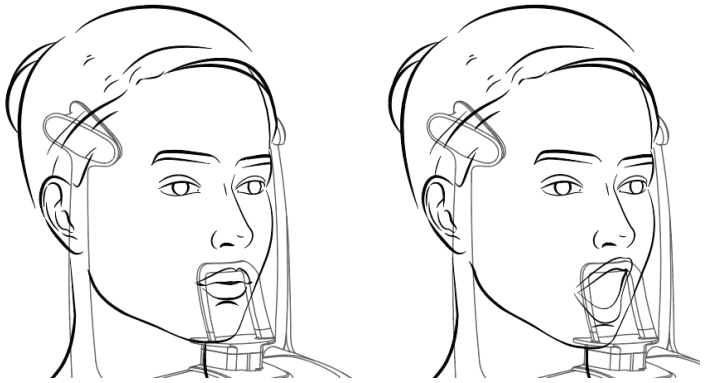


NOTE For patients who have scanning history and are going to use the same program again, refer to **"4.3) Auto positioning"**.

4. Guide the patient into the scanning position and adjust the height of the equipment to the patient using the control button.



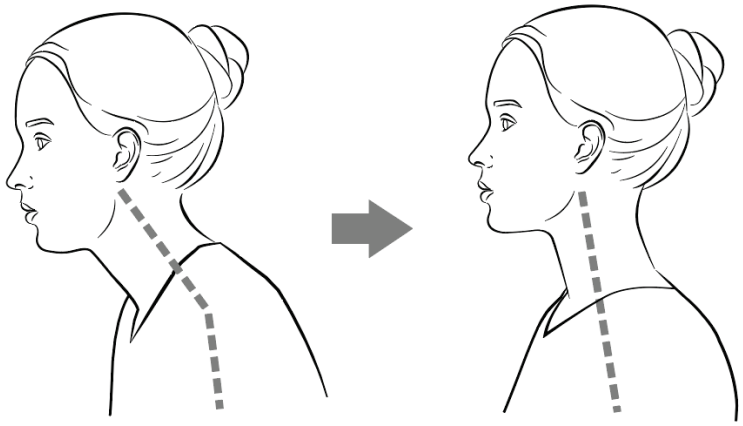
5. Guide the patient to the chinrest as shown in the following figure:



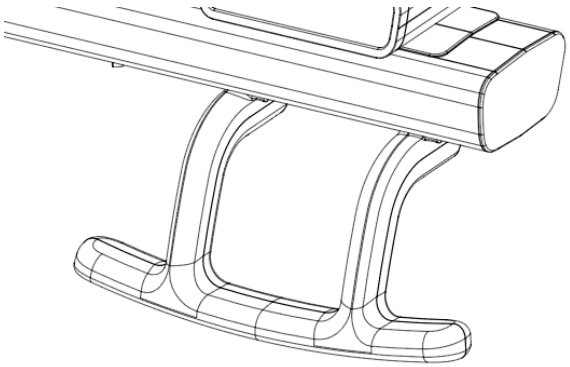
NOTICE

Check the alignment of the guide laser when taking images with the mouth open and closed and if the alignment is not good, reposition the patient.

6. If the patient's neck is not straightened up, which means the patient's head faces up or down, adjust the height of the equipment with the control button so that the patient can get ready in good position.



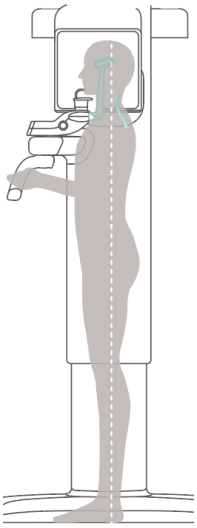
7. When the patient is in good position, help him/her to hold the handle of the patient support.



WARNING

The load applied to the handle should be under 20 kg.

8. Check again for the patient's position.



NOTICE

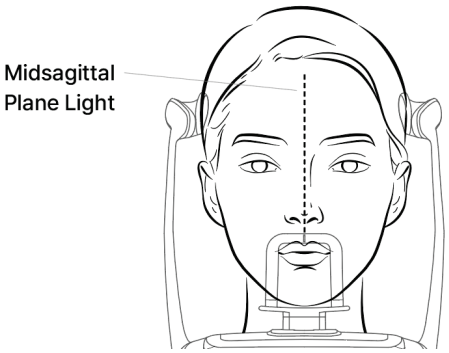
After the patient's alignment has been completed, they should be advised to remain still until the exposure is complete.

9. Guide the patient into the chinrest and push the laser button on the control panel.

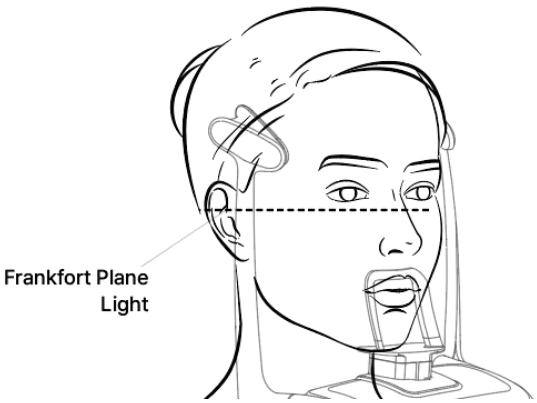
NOTICE

There are three lines of the guide laser and the patient's head should be positioned aligning with each of the three lines, depending on the acquisition mode to acquire images with good quality.

10. Adjust the patient's head so that the patient's mid-sagittal plane (vertical center line of the face) is aligned with the Midsagittal laser line.

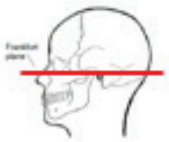


11. Adjust the angle of the patient head so that the patient's Frankfort plane is aligned with the Frankfort laser.



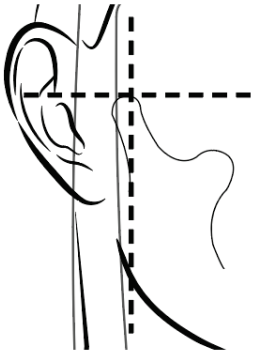
NOTE

The Frankfort laser is projected marking the line section between a spot over the earhole (suprameatal opening) to another spot beneath the eyeball of the patient.



12. Adjust the position of the Canine laser using the control button so that the laser is located on the patient's TMJ.

- The [Forward] button: Moves the laser toward the operator.
- The [Backward] button: Moves the laser backwards against the operator.

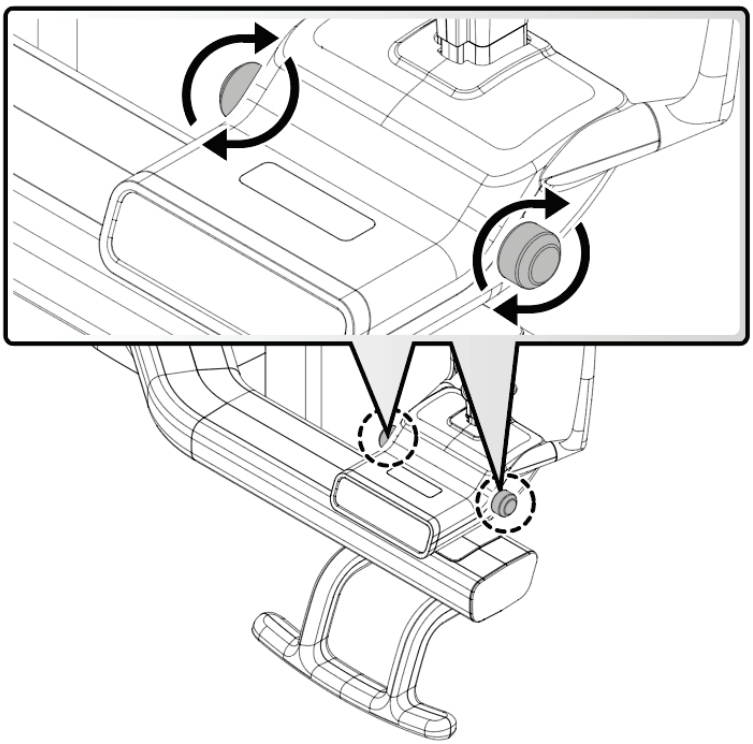


NOTICE

For the TMJ PA scanning, move the Frankfort laser to the TMJ PA mark and adjust the angle of the patient's head so his/her TMJ is aligned with the laser.

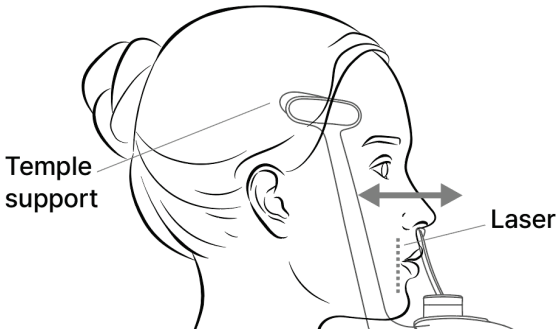
13. Turn the fixation lever of the temple support to or against the operator so that the support fixes or releases the patient.

- Turning the lever toward the operator: Fixes the support.
- Turning the lever against the operator: Releases the support.



14. Fix the position of the patient's face using the temple support and check if any one of the guide laser lines fails the alignment.

If so, reposition the patient aligning with the guide laser.



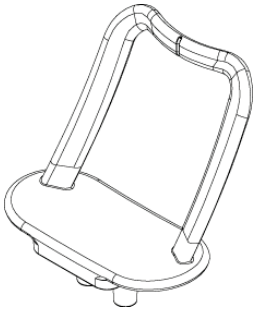
NOTICE

The guide laser is automatically turned off after a certain amount of time or when the image acquisition begins.

6.4.3) Sinus mode

Describes the settings and patient positioning for each exposure mode.

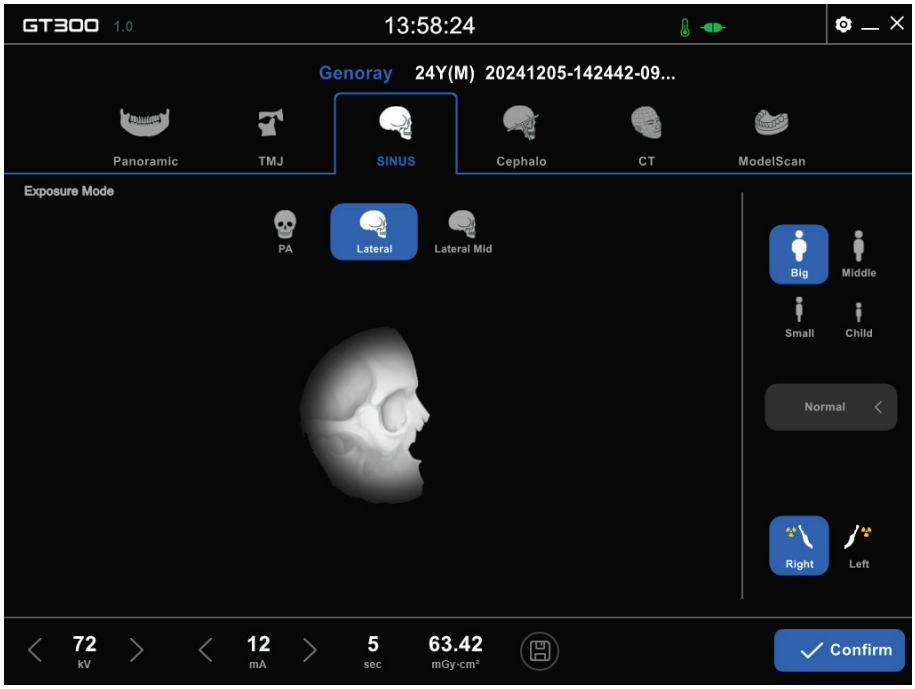
1. Attach the chinrest for the Sinus mode onto the equipment.



For Sinus mode

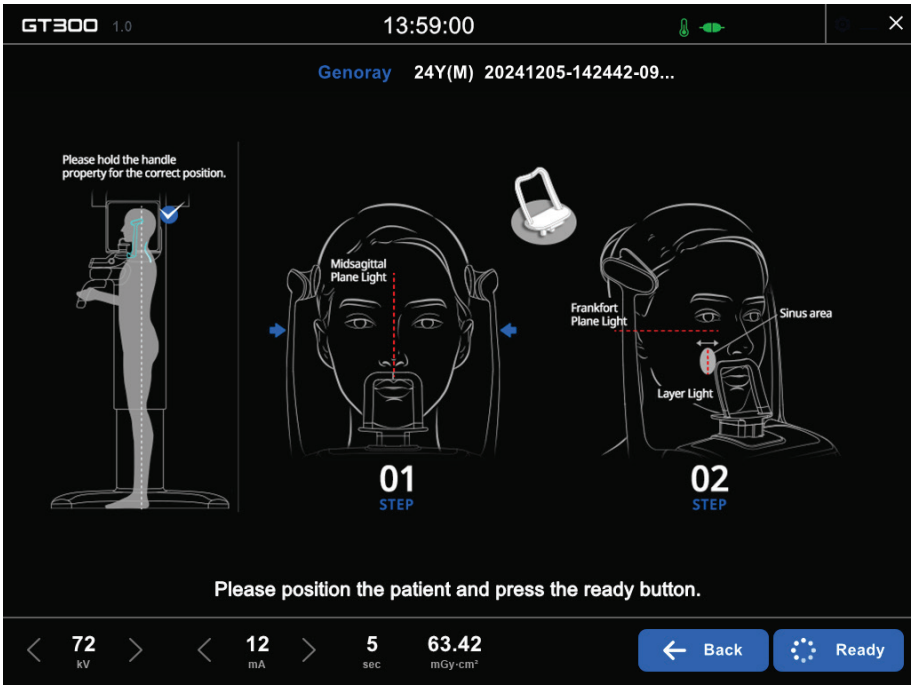
NOTE For how to attach the chinrest, refer to **"3.3.1) Chinrest"**.

2. Register the patient, select the Sinus mode, and start the OP.
3. On the OP screen, select the Sinus mode and scanning condition, and click the [Confirm] button on the lower right corner to show the patient positioning screen.



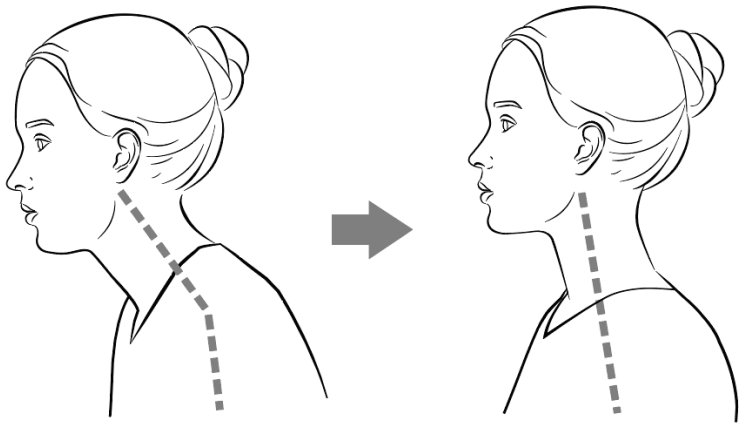
NOTE For patients who have scanning history and are going to use the same program again, refer to **"4.3) Auto positioning"**.

4. Guide the patient into the scanning position and adjust the height of the equipment to the patient using the control button.

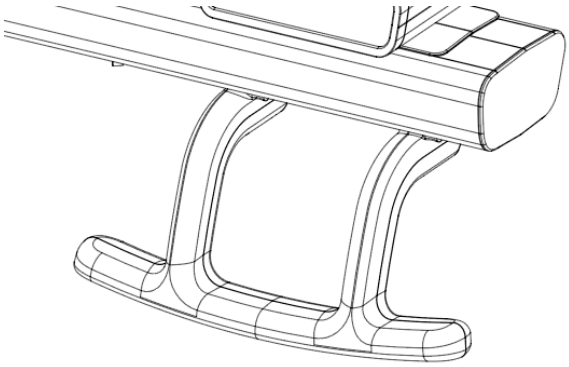


5. Guide the patient to the chinrest as shown in the following figure:

6. If the patient's neck is not straightened up, which means the patient's head faces up or down, adjust the height of the equipment with the control button so that the patient can get ready in good position.

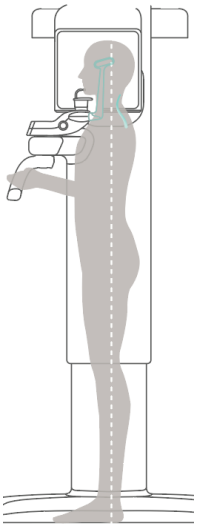


7. When the patient is in good position, help him/her to hold the handle of the patient support.



WARNING The load applied to the handle should be under 20 kg.

8. Check again for the patient's position.



NOTICE

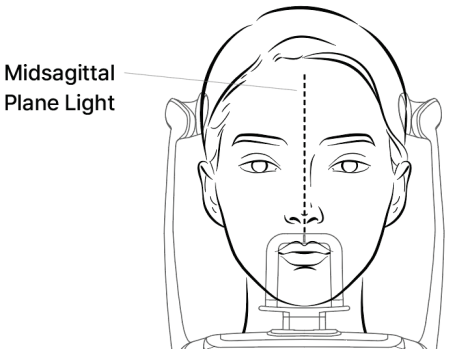
After the patient's alignment has been completed, they should be advised to remain still until the exposure is complete.

9. Guide the patient into the chinrest and push the laser button on the control panel.

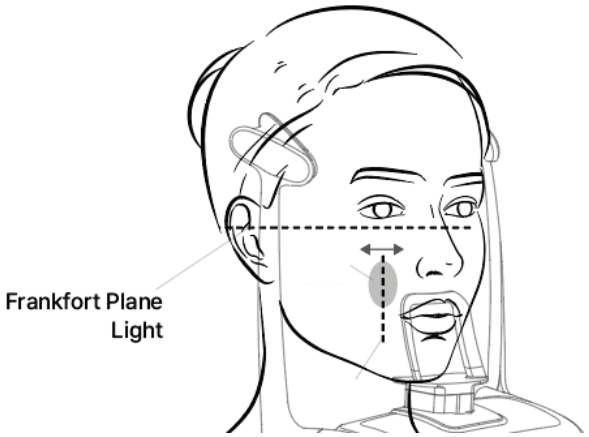
NOTICE

There are three lines of the guide laser and the patient's head should be positioned aligning with each of the three lines, depending on the acquisition mode to acquire images with good quality.

10. Adjust the patient's head so that the patient's mid-sagittal plane (vertical center line of the face) is aligned with the Midsagittal laser line.

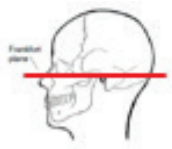


11. Adjust the angle of the patient head so that the patient's Frankfort plane is aligned with the Frankfort laser.



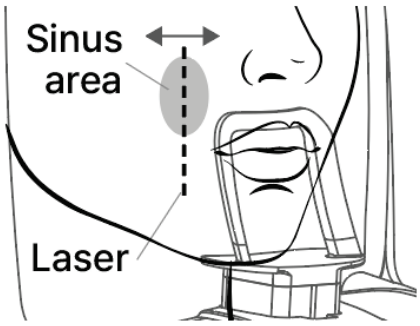
NOTE

The Frankfort laser is projected marking the line section between a spot over the earhole (suprameatal opening) to another spot beneath the eyeball of the patient.



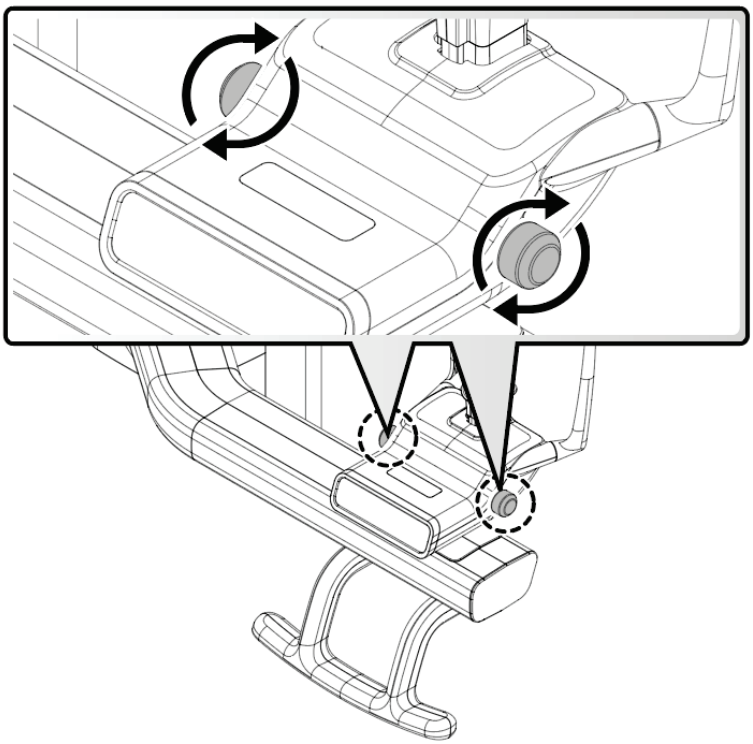
12. Adjust the position of the Canine laser using the control button so that the laser is located on the patient's sinus.

- The [Forward] button: Moves the laser toward the operator.
- The [Backward] button: Moves the laser backwards against the operator.



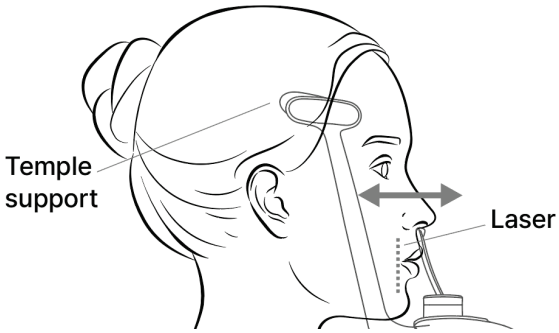
13. Turn the fixation lever of the temple support to or against the operator so that the support fixes or releases the patient.

- Turning the lever toward the operator: Fixes the support.
- Turning the lever against the operator: Releases the support.



14. Fix the position of the patient's face using the temple support and check if any one of the guide laser lines fails the alignment.

If so, reposition the patient aligning with the guide laser.



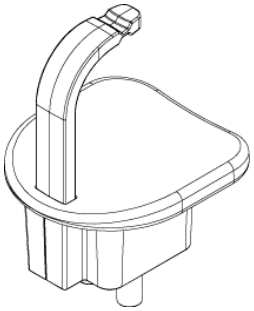
NOTICE

The guide laser is automatically turned off after a certain amount of time or when the image acquisition begins.

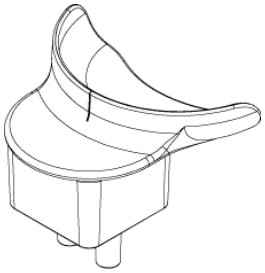
6.4.4) CT mode

Describes the settings and patient positioning for each exposure mode.

1. Attach the chinrest and the bite onto the equipment.



For normal patients



For edentulous patients

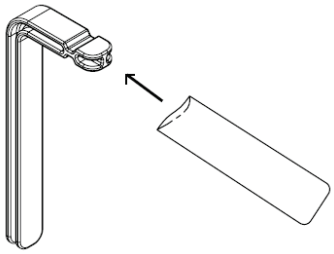
NOTE

For patient who has trouble biting the bite (for he/she has no tooth or is using orthodontic instruments), use the bite for edentulous patients.

NOTE

For how to attach the chinrest, refer to "**3.3.1) Chinrest**".

2. Make sure to cover the bite with the hygienic bag before using the equipment.



NOTICE

This product must be used with a hygienic bag suitable for biocompatibility (ISO 10993-1). Failure to use hygienic bag may result in cross-contamination of diseases or viruses between patients.

NOTE

- The hygienic bag is not a standard component and is not provided by the manufacturer.
- Please use the hygienic bag when using the bite, and do not reuse a cover that has already been used.

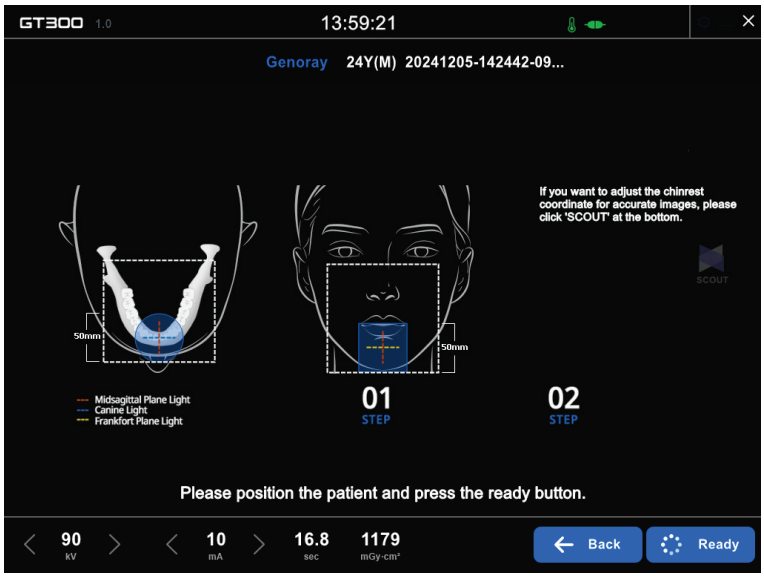
Register the patient, select the CT mode, and start the OP.

3. On the OP, select the CT mode and scanning condition.

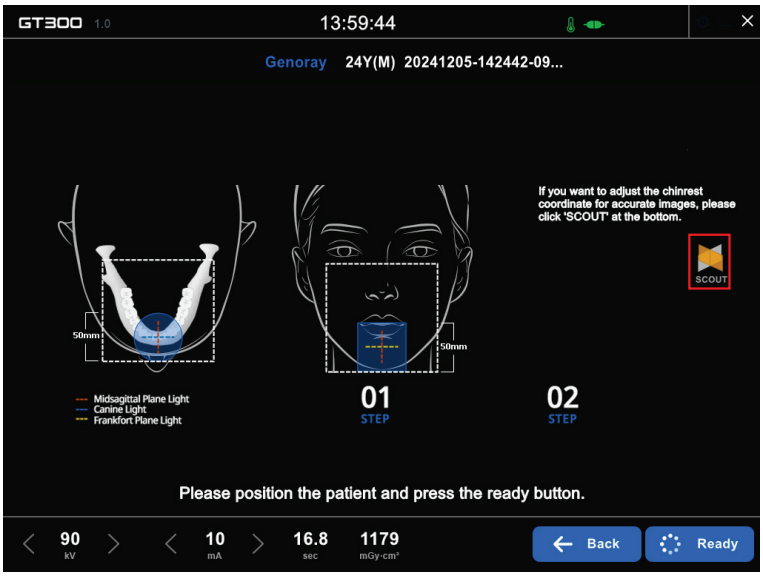
NOTE

For patients who have scanning history and are going to use the same program again, refer to **"4.3) Auto positioning"**.

4. Guide the patient into the scanning position and adjust the height of the equipment to the patient using the control button.



5. To get more accurate images centering the target tooth before the CT scanning, use the Scout scanning.



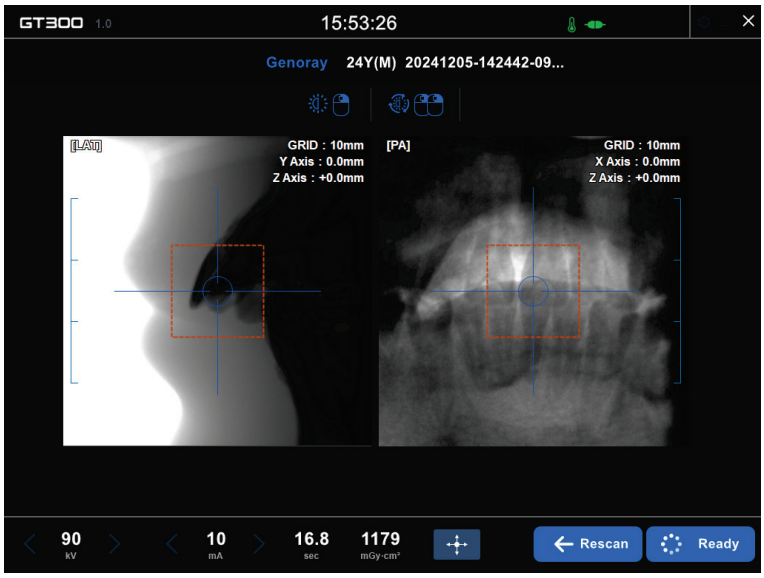
NOTE

The following CT modes support the Scout scanning:

- Endo
- Tooth

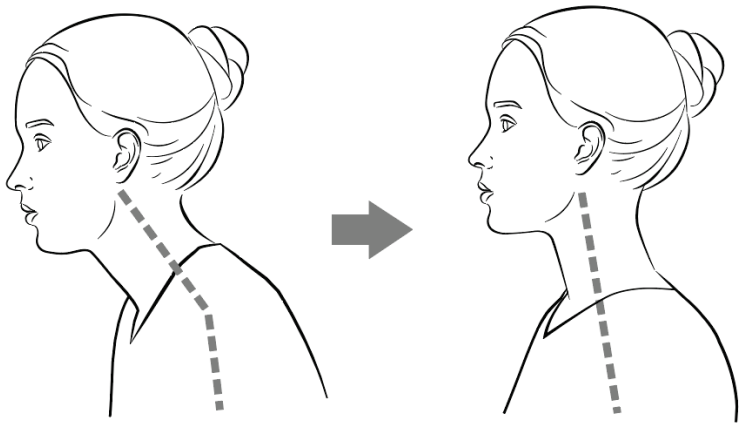
NOTE

In the Scout, you can obtain an accurate image by adjusting the chin rest position after the scan is completed.

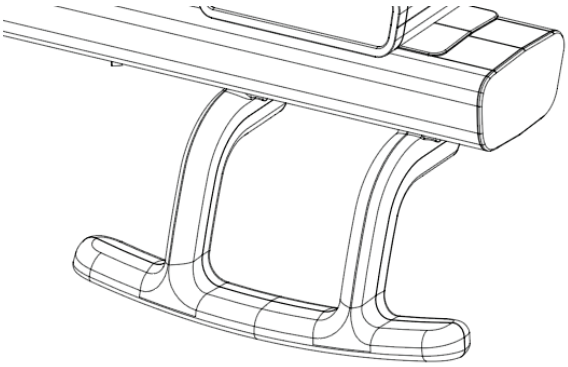


6. Put the patient's chin on the chinrest and help him/her to bite the bite, covered with the hygienic bag as shown in the figure.

7. If the patient's neck is not straightened up, which means the patient's head faces up or down, adjust the height of the equipment with the control button so that the patient can get ready in good position.

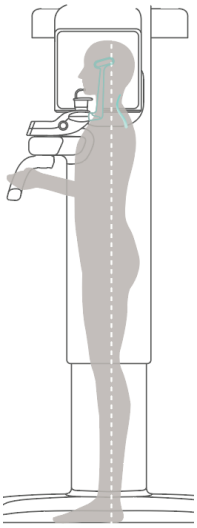


8. When the patient is in good position, help him/her to hold the handle of the patient support.



The load applied to the handle should be under 20 kg.

9. Check again for the patient's position.



NOTICE

After the patient's alignment has been completed, they should be advised to remain still until the exposure is complete.

10. With the patient biting the bite, push the laser button on the control panel.

NOTICE

- There are three lines of the guide laser and the patient's head should be positioned aligning with each of the three lines, depending on the acquisition mode to acquire images with good quality.
- The Frankfort laser automatically marks the center of height of the FOV.

6.4.5) Cephalo mode (Option)

Describes the settings and patient positioning for each exposure mode.

NOTE

Before exposure in Cephalo mode, refer to **"3.3.2) Temple Support and remove the temple support"**.

Lateral, AP, SMV, Water's, PA Program

1. Register the patient, select the Cephalo mode, and start the OP.
2. On the OP, select the Cephalo mode and scanning condition.

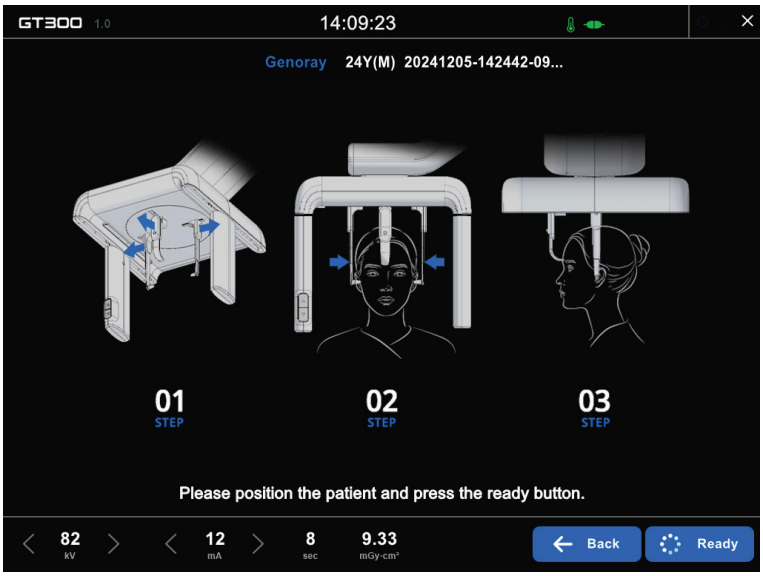
NOTE

For patients who have scanning history and are going to use the same program again, refer to **"4.3) Auto positioning"**.

3. Set the image size and click the [Confirm] button on the lower right corner to show the patient positioning screen.

Item	Image	Description
Resizing image		The image acquisition is carried out with 240 mm in width and part of the lateral image is cut out.
		The image acquisition is carried out with 310 mm in width and the entire lateral image is acquired.

4. Guide the patient into the scanning position and adjust the height of the equipment to the patient using the control button.



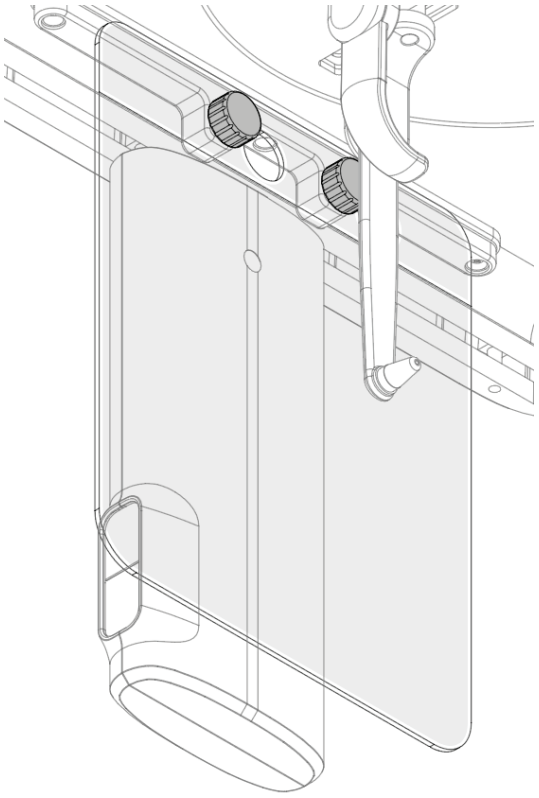
5. Align the ear rod with the earhole of the patient and position the patient for each acquisition program.

NOTICE

After the patient's alignment has been completed, they should be advised to remain still until the exposure is complete.

Carpus program

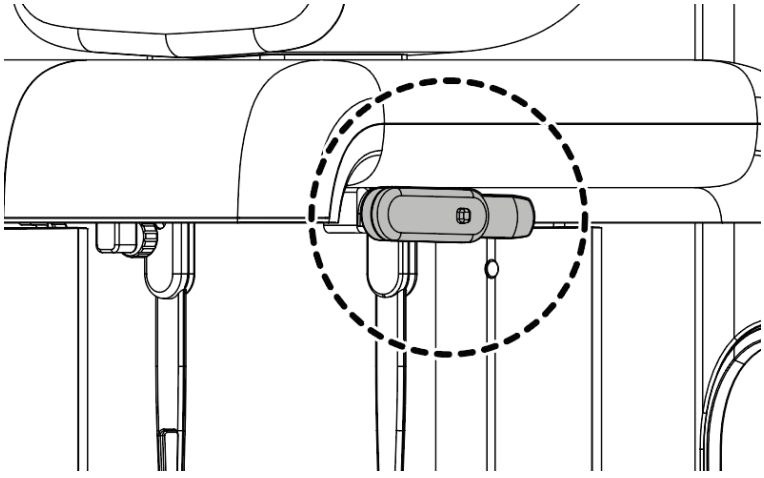
1. Position the Carpus Plate as shown in the illustration, then secure it in place.



NOTE

- For more information regarding the installation of the carpus plate, refer to **"3.3.3) Carpus plate (option)"**.
- The carpus plate should be purchased separately.

2. Place the nasal support as shown in the figure:



3. Register the patient, select the Cephalo mode, and start the OP.
4. On the OP, select the Carpus mode and scanning condition.

NOTE

For patients who have scanning history and are going to use the same program again, refer to **"4.3) Auto positioning"**.

5. Referring to the following figure, put the palm of the patient tightly on the carpus plate.

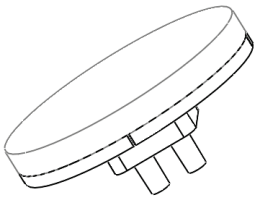
NOTE

Install the Carpus Plate by referring to **"3.3.3) Carpus Plate (Option)"**

6. For the next steps to acquire images, follow the instruction of using the Cephalo mode.

6.4.6) ModelScan mode (Option)

1. Attach the chinrest for the ModelScan shot onto the equipment.



For ModelScan mode

NOTE For how to attach the chinrest, refer to **"3.3.1) Chinrest"**.

2. Register the patient, select the ModelScan mode, and start the OP.
3. On the OP, select ModelScan and scanning condition.

NOTE For patients who have scanning history and are going to use the same program again, refer to **"4.3) Auto positioning"**.

4. Place the stone or the impression model at the center of the tray and adjust the height using the control button.

6.5) Image acquisition and verification

NOTICE

- During the image acquisition, the exposure button on the exposure switch should be pushed and held all the time.

  As soon as the exposure button is released, the job is aborted and the OP displays the message regarding an abnormal stop.
- During the image acquisition process, make sure to watch the patient and the equipment all the time.

  Upon any unexpected event, release the exposure button immediately and push the Emergency Stop Switch.

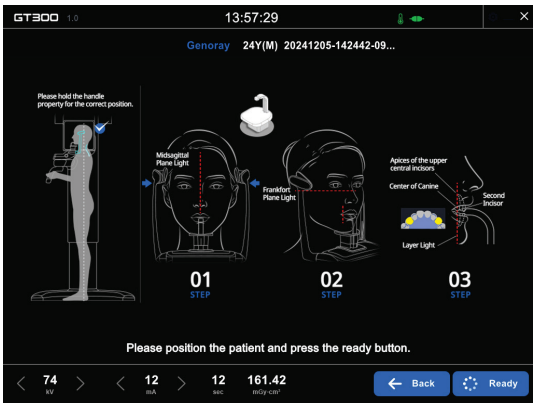
NOTICE

- To ensure accurate image acquisition, the selected exposure mode must be checked before exposure.
- To ensure accurate image acquisition and prevent unnecessary radiation exposure, the selected patient size (preset) must be checked before exposure.
- To ensure accurate image acquisition and prevent unnecessary radiation exposure, the selected exposure options must be checked before exposure.
- To ensure accurate image acquisition and prevent unnecessary radiation exposure, the selected exposure conditions must be checked before exposure.
- To ensure accurate image acquisition, the positions of the ear post and nasal support must be checked according to the selected exposure mode before exposure.
- To ensure accurate image acquisition, the patient's position must be aligned according to the selected exposure mode.
- To ensure accurate scout image acquisition, exposure should be performed only after the motor movement is complete.

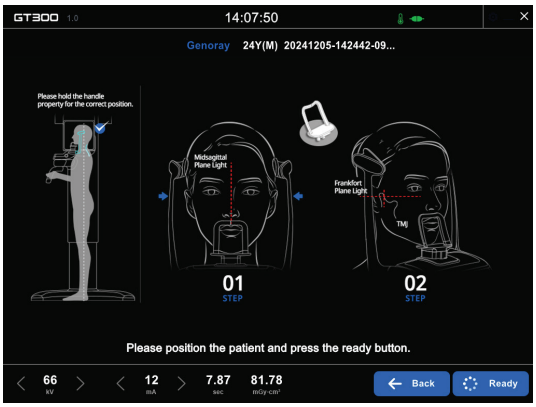
NOTE

The operator should perform the image acquisition at a safe place from the X-ray exposure.

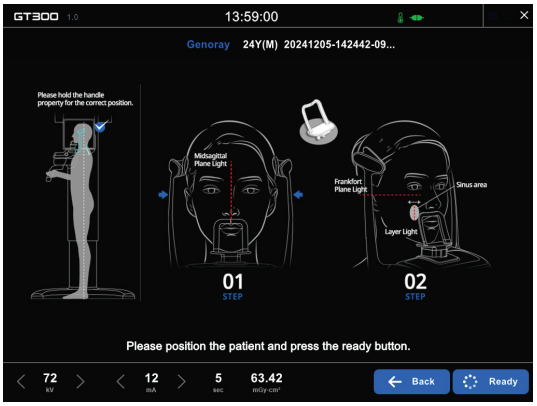
1. Once the patient is in proper position, guide him/her not to move until the image is acquired and then click the [Ready] button on the lower right corner of the OP.



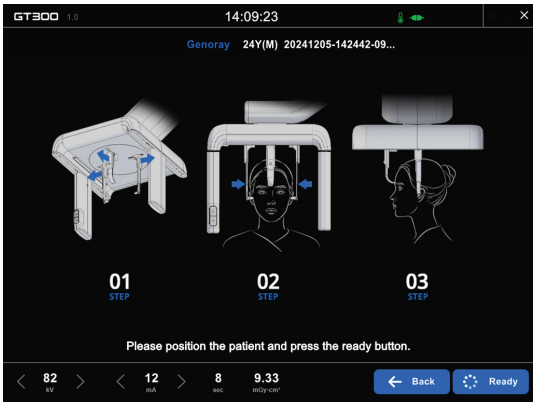
Panoramic



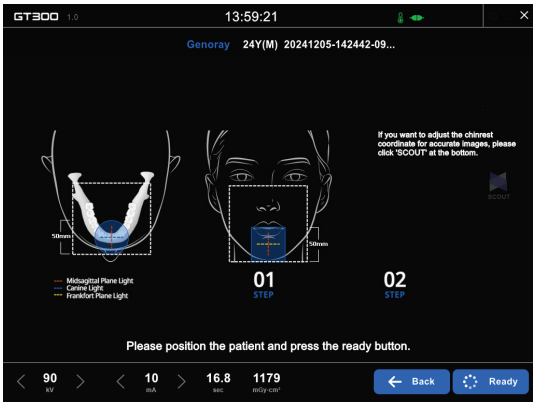
TMJ



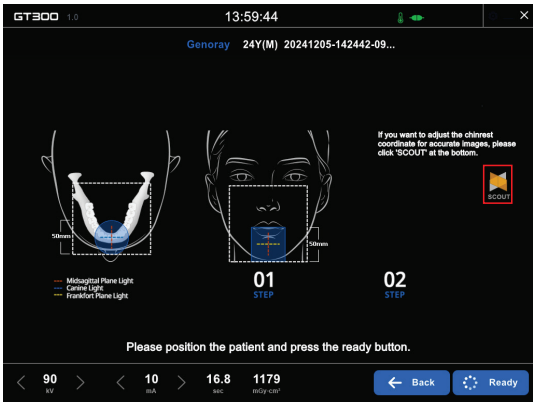
Sinus



Cephalo



CT



CT (Scout)

Model Scan

NOTICE

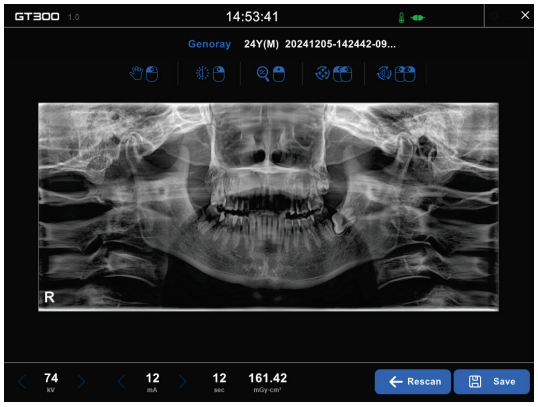
The X-ray exposure will not proceed unless the [Ready] button at the bottom right of the OP is pressed first, even if the exposure button is pressed.

2. When the guide message about the start of the image acquisition appears on the OP, the process begins when the exposure button is pushed.

3. Once the process has begun, the OP displays the warning message about ongoing X-ray exposure along with the image which is being taken. Once the process is all done, the final image is displayed.

OP screen while preparing image acquisition

OP screen during a Panoramic scan

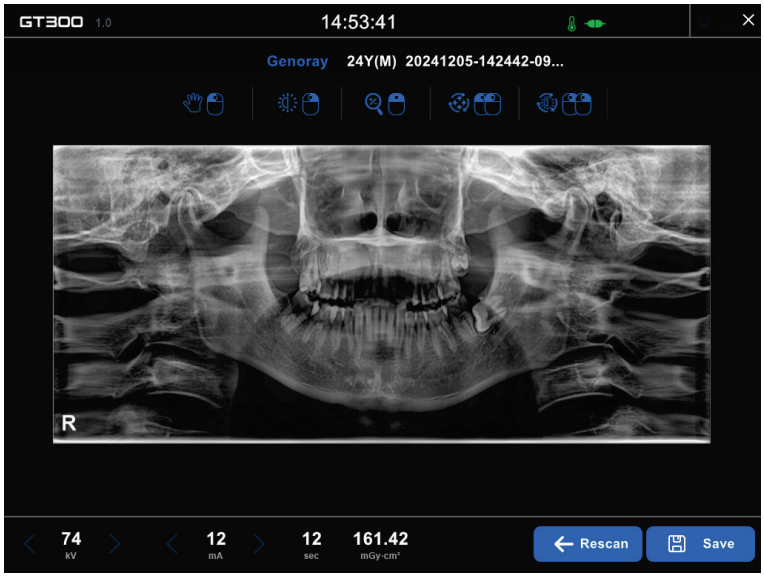


OP screen after a Panoramic scan

NOTICE

If re-exposure is necessary, press the [Rescan] button to perform the re-exposure.

4. Click the [Save] button to save the acquired image.



5. The saved images can be viewed in Theia.

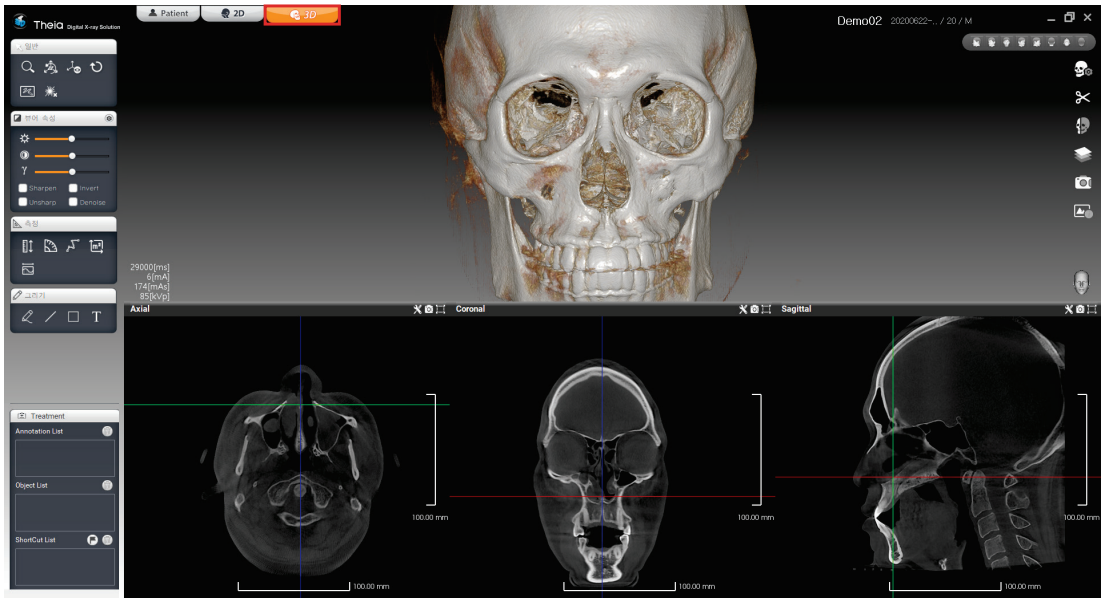


image check via Theia

6.6) Image navigation

When the acquisition process is done and the OP displays the resulted image, you can navigate the image using the mouse.

Common

Image	Input	Description
	Dragging the left mouse button	Moves the image (up/down/right/left).
	Dragging the right mouse button	Brightness selection
	Dragging both mouse buttons	Zooms in/out.
	Double-clicking the left mouse button	Fits the image on screen.
	Double-clicking the right mouse button	Undoes the brightness selection.

TMJ LAT-PA mode

Image	Input	Description
	Dragging the left mouse button	Moves the image (up/down/right/left).
	Dragging the right mouse button	Brightness
	Dragging both mouse buttons	Zooms in/out.
	Double-clicking the left mouse button	Fits the image on screen.
	Double-clicking the right mouse button	Undoes the brightness selection.
	Clicking the mouse wheel	Changes the image focus.

CT mode

Image	Input	Description
	Scrolling the mouse up/down	Shows the previous/next image.
	Dragging the right mouse button	Brightness
	Double-clicking the right mouse button	Undoes the brightness selection.

6.7) Image Quality Management

The following table provides solutions for each type of image quality issue that may occur when the image acquisition was not properly conducted following the manufacturer's instructions. The user can refer to the instructions in this table to ensure the acquisition of the best images all the time.

No.	Item	Items to check	Solution
1	Image too bright	Check if the appropriate patient size has been selected.	Adjust the exposure settings for kV and mA.
2	Image too dark	Check if the appropriate patient size has been selected.	Adjust the exposure settings for kV and mA.
3	Image with too low brightness	Check if the image looks too gray.	Go to the image setting and adjust the contrast.
4	Image with too high brightness	Check if the image looks too monochromatic.	Go to the image setting and adjust the brightness.
5	Image too blurry	Verify that the GCP calibration has been performed correctly.	Perform the GCP calibration again.

6.8) Image Adjustment

Image adjustment for acquired images, such as adjusting brightness, contrast, gamma, etc., are available with Theia, the image adjustment viewer.

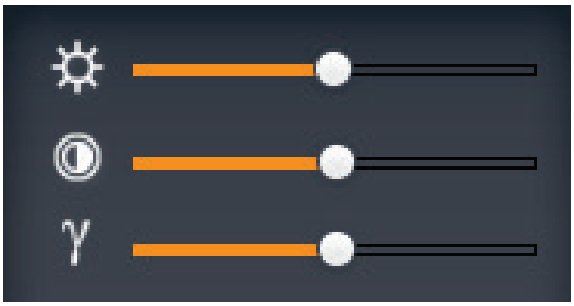
NOTE

For more information regarding image adjustment, refer to **"Theia Software Manual."**

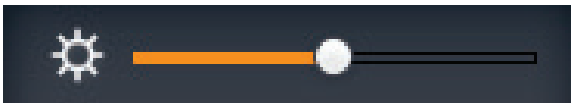
Brightness Adjustment

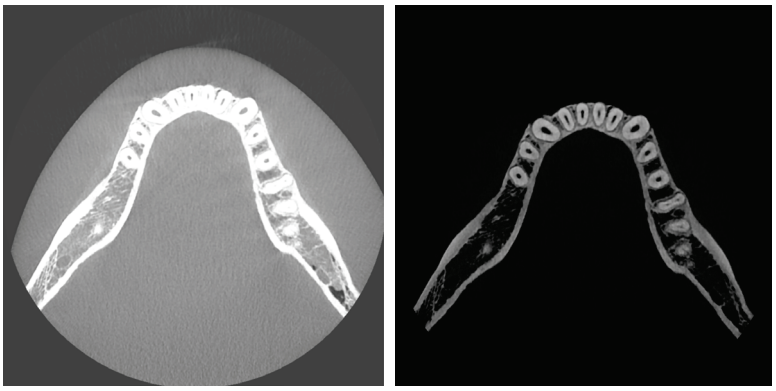
1. From the upper left corner of the main screen, select either 2D tab or 3D tab.

2. Select image edit.



3. Using the Brightness slider, adjust the brightness of the image.
   - To the right: brighter
   - To the left: darker

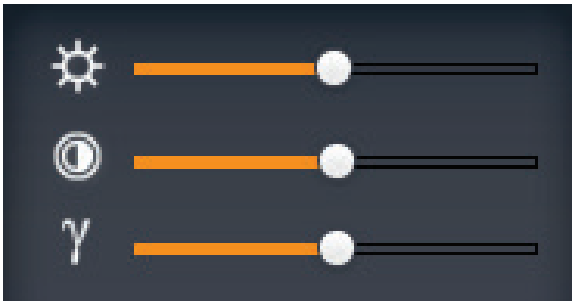




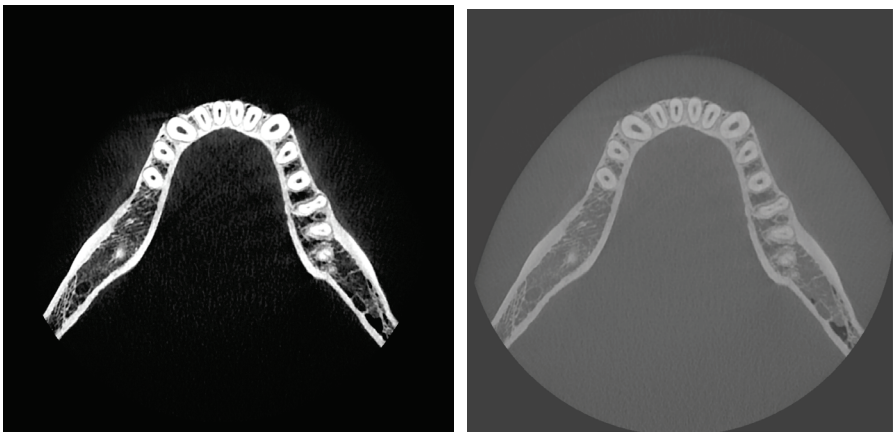
Contrast

1. From the upper left corner of the main screen, select either 2D tab or 3D tab.

2. Select image edit.



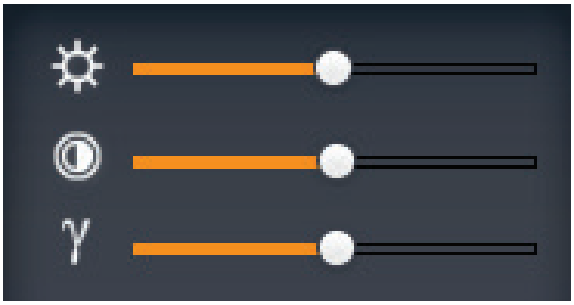
3. Using the Contrast slider, adjust the contrast of the image.
   - To the right: more contrastive
   - To the left: less contrastive



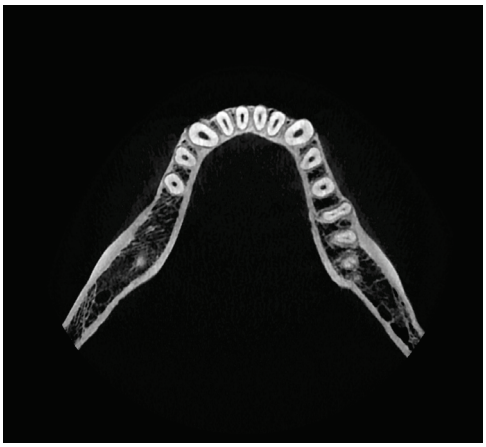
Gamma Adjustment

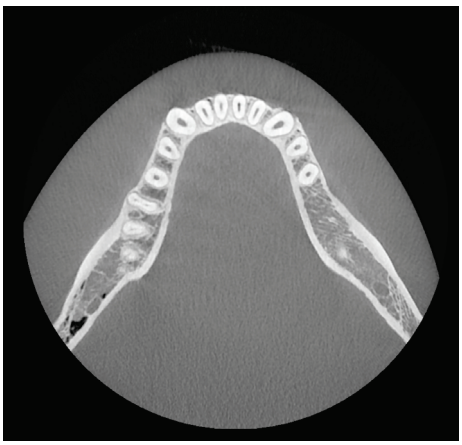
1. From the upper left corner of the main screen, select either 2D tab or 3D tab.

2. Select image edit.



3. Using the Sharpness slider, adjust the sharpness of the image.
   - To the right: more vivid
   - To the left: less vivid





6.9) Importing and Exporting the Image

The image adjustment viewer Theia can import and export acquired images.

For more information, refer to **"Theia Software Manual."**

6.10) Patient Data Management

The image adjustment viewer Theia can manage the patient data, including editing and deleting, etc.

For more information, refer to **"Theia Software Manual."**

6.11) Status messages

No.	Message	Description
1	Ready for next step...	Appears before the next step after image acquisition.
2	Please position the patient and press the ready button.	Appears when the patient is guided into position. Push the ready button and the preparation for X-ray exposure starts.
3	Ready for exposure...	Appears during the preparation of the X-ray exposure from the equipment.
4	Return to initial position.	Appears when the rotation unit of the equipment goes back to the initial position.
5	Press exposure switch	Appears when the X-ray is ready. Pushing the exposure button begins X-ray exposure acquiring images.
6	Scanning...	Appears while the exposure switch is being pushed for image acquisition.
7	Image reconstructing (1/2)...	Appears when the image is being reconstructed after image acquisition.
8	Image correcting (2/2)...	Appears when the image is being corrected after image acquisition.
9	Image Processing (2/2)...	Appears when the image is being processed after image acquisition.
10	Emergency	Appears when the Emergency Stop Switch is pushed.
11	Please wait. The machine is still moving.	Appears while the equipment is moving to the position for image acquisition.
12	Save Raw image...	Appears while the raw image is being saved.
13	Please, position the ear-post like above illustration.	Appears when the ear-post is placed at a wrong position for the selected scanning program on the Cephalo mode. Follow the picture instruction to move it.
14	Position the nasal like above illustration.	Appears when the nasal support is placed at a wrong position for the selected scanning program on the Cephalo mode. Follow the picture instruction to move it.
15	CT reconstructing...	Appears when the image is being reconstructed after image acquisition in the CT mode.
16	Ready for Reconstruction...	Appears when the image is ready for reconstruction after image acquisition.
17	Ready for Image Processing...	Appears when the image is ready for image processing after image reconstruction.

No.	Message	Description
18	Check for Temple support.	Appears while the image acquisition is being performed in the Cephalo mode. Remove the temple support referring to the figure.
19	Please wait. The machine is still moving. Please press and hold the exposure switch.	With the Scout selected on the CT mode, the status message appears when the rotation unit is moving to the position for the PA image acquisition after the Lateral image acquisition is finished. Keep the exposure switch pushed.
20	Please reboot the equipment.	Appears when an error occurred, making it unavailable for image acquisition.

7. Maintenance

Provides information regarding maintenance, including storage, care, movement of the components, maintenance cycle, and the process of hygiene management, such as cleaning and disinfection of the equipment.

The maintenance chapter consists of two parts: regular maintenance and cleaning conducted by the user and maintenance for image quality which should be performed by a qualified service engineer.

NOTICE

For more information regarding the check for image quality and dose performance by the service engineer, refer to **"Technical Manual."**

NOTE

- If the equipment has not been used for a long time, maintenance should be performed preceding the use.
- During the maintenance, make sure to mark "**Do Not Use**" on the top of the equipment to prevent other users from accidentally using it.
- For any performance issue detected during the performance check, the user should stop using the equipment immediately and call the service center.
- To perform maintenance on the equipment, move it to a safe place for the task first and refer to **2.4) Radiation Safety** to comply with radiation safety instruction.

7.1) Table for Maintenance

Performance Check	Items to check	Staff in Charge	Frequency
Mechanical performance	Laser ON/OFF operation	User	Daily
	Lift Up/Down operation		Daily
	GANTRY		Daily
	Forward/Backward operation		Daily
	Chinrest		Daily
	Left/Right operation		Daily
	Frankfort Laser Up/Down operation		Daily
	Ready/Return position movement		Daily
Electrical performance	Exposure switch cables		Daily
	Power cable		Daily
	Power ON/OFF switch		Daily
Performance of Emergency Stop switch	Emergency Stop switch performance		When necessary
Status LED	Check LED display		When necessary
Image quality and dose performance	Image Uniformity Test	The manufacturer	Yearly or when necessary
	Image Resolution Test		Yearly or when necessary
	Image Thickness Test		Yearly or when necessary
	CT Linearity Test		Yearly or when necessary

NOTE

- Make sure to place the table for maintenance around the equipment so that the equipment can be maintained regularly.
- Caution that X-rays are exposed during the test for image quality and dose performance and be careful all the time.

7.1.1) Mechanical Performance Check

1. Click the Laser On/Off button to check if the laser is operational.
2. Click the Lift Up/Down button to check if the height control works without any problem.
3. Click the Gantry Forward/Backward button to check if the forward/backward adjustment of the gantry unit works well.
4. Click the Chinrest Left/Right button to check if the left/right adjustment of the chinrest unit works well.
5. Click the Frankfort Laser Up/Down button to check if the height control of the laser works without any problem.
6. Click the Ready/Return button to check if the units move properly.
   - Select [Confirm] and go to [Ready] from GT300 OP.
   - Selecting the [Return] button after image acquisition moves back to the pre-acquisition position.

7.1.2) Electrical Performance Check

To check the cables, the equipment should be cut off from the power first.

1. Check all the cables for any damage, including cuts, wears, etc.
2. Check if all the cables are properly connected.
3. Refer to "**5 Turning On/Off the Equipment**" and check if the equipment is normally turned on and off.

7.1.3) Emergency Stop Switch Performance Check

1. Push the Lift Up/Down button, and while the equipment is moving vertically, press the Emergency Stop switch.
2. Check if the equipment stops vertical movement.
3. Pushing the exposure switch, check the X-ray exposure is aborted.
4. Push the main power button of the equipment to turn it off.
5. Rotate the emergency switch back and turn on the equipment again.

7.1.4) Image Quality and Dose Performance Check

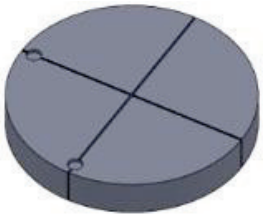
NOTE

The phantom used in this chapter is not a component of the product package.

7.1.4.1) Image Uniformity Test

Checking Tools

CT uniformity phantom

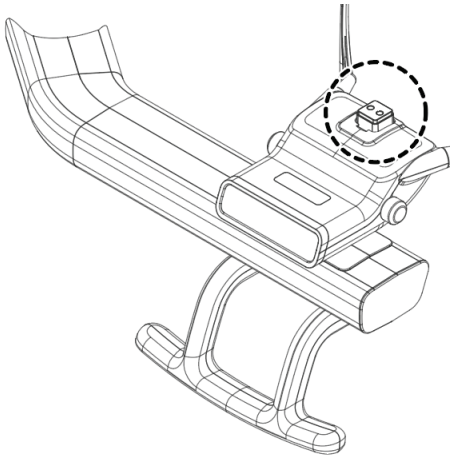


How to Check

1. Make sure all the covers of the equipment are properly attached.

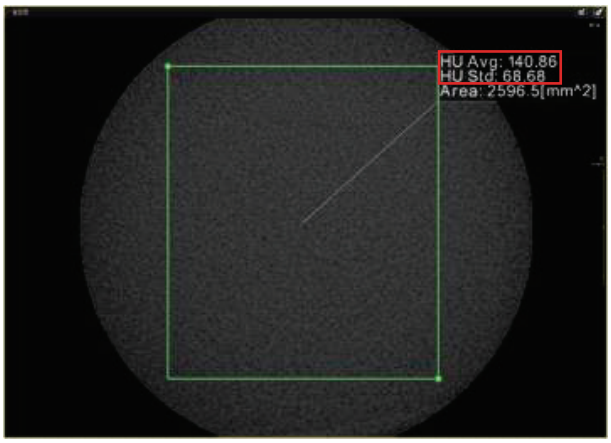
   Check that the key parts of the equipment, such as the X-ray generator, the collimator, the detector, the covers, etc., are all assembled correctly.

2. Place the phantom at the location of the chin rest for image acquisition.



3. Activate the CT mode on Theia.

4. Set up the X-ray exposure condition as 90 kV and 10 mA on the OP and perform image acquisition using the exposure switch.
5. Check the acquired image on the OP and save it if it has no issues.
6. Measure the HU value at the center of the acquired image on Theia.
   - [Tool box > Measurement > Area of the rectangle]



7. Check if the average and standard deviation of the HU value are within the following acceptable range:
   - Avg value: 40 ~ 200 HU
   - Std value: ≤ 100 HU

NOTE

If the resulted values are not within the acceptable range, call the service center for service.

7.1.4.2) Image resolution test

Checking Tools

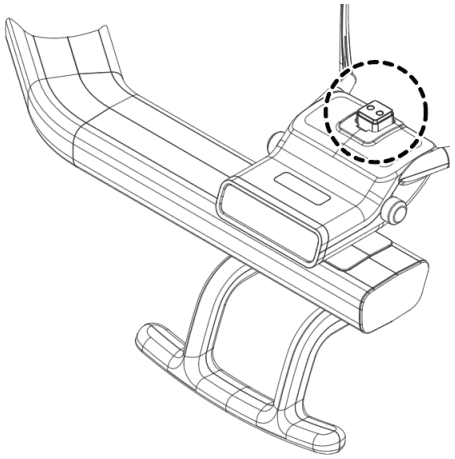
Resolution phantom

How to Check

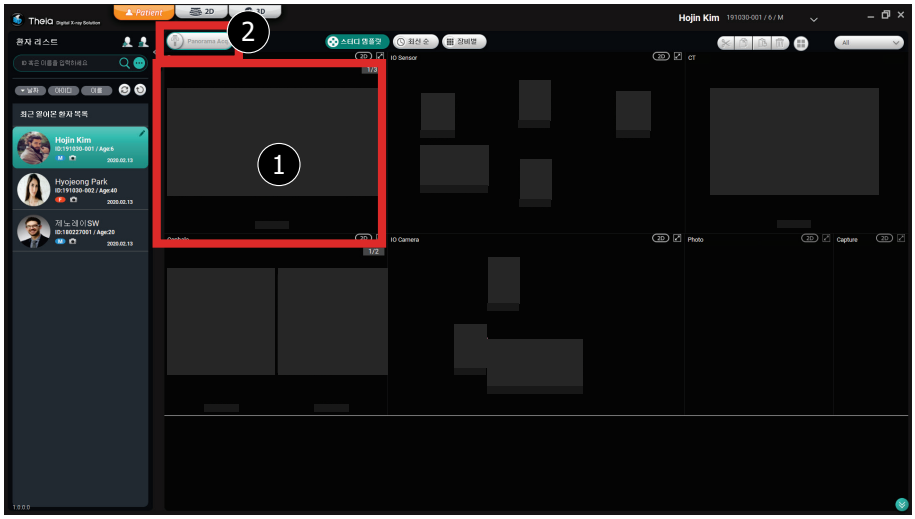
1. Make sure all the covers of the equipment are properly attached.

   Check that the key parts of the equipment, such as the X-ray generator, the collimator, the detector, the covers, etc., are all assembled correctly.

2. Place the phantom at the location of the chin rest for image acquisition.



3. Select an acquisition mode on Theia and activate it.



4. Set up the X-ray exposure condition as the default values on the OP and perform image acquisition using the exposure switch.

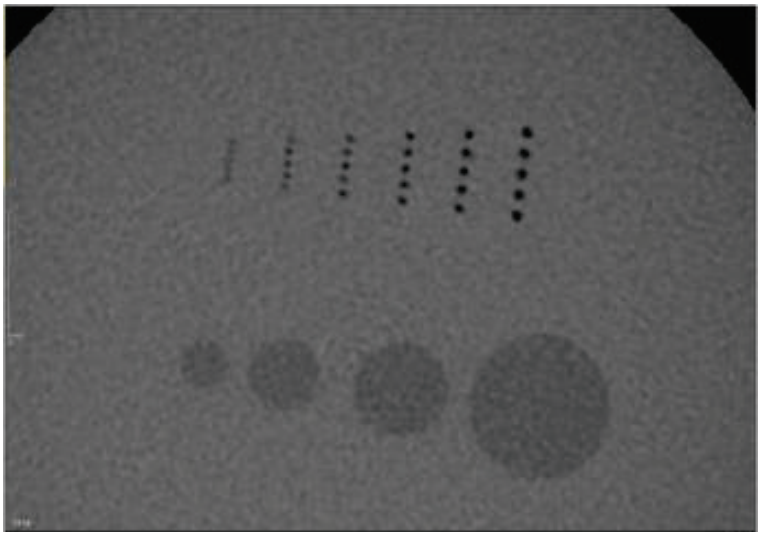
5. Check the acquired image on the OP and save it if it has no issues.

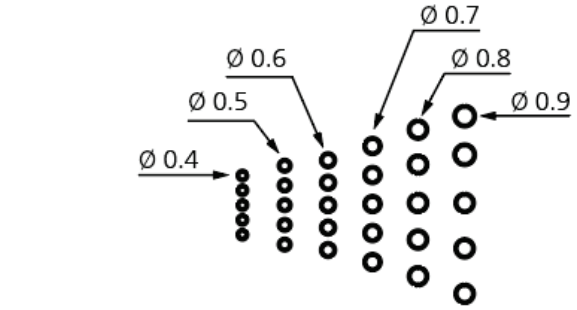
NOTE

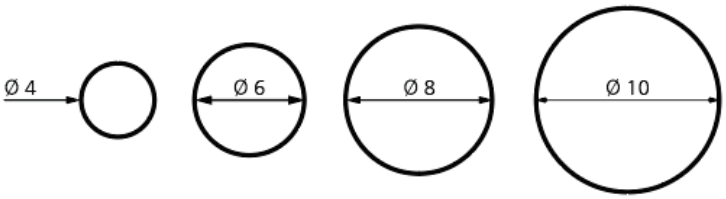
Change the acquisition modes on Theia, perform acquisition under each mode, and save the resulted images so that all of the following acquisition modes can acquire images.

- Panoramic mode
- CT mode
- Cephalo mode (Option)

6. Check if the resolution of the phantom in the acquired images is within the following acceptable range:
   - Spatial resolution: 0.6 mm or less
   - Low contrast resolution: 6 mm or less







NOTE

Check if the resolution of the phantom is within the acceptable range while changing the magnification of the zoom mode to 1.5x and 2.0x.

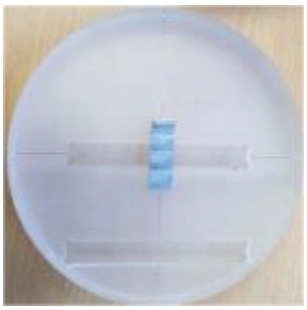
NOTE

If the resulted values are not within the acceptable range, call the service center for service.

7.1.4.3) Image Thickness Test

Checking Tools

Resolution phantom

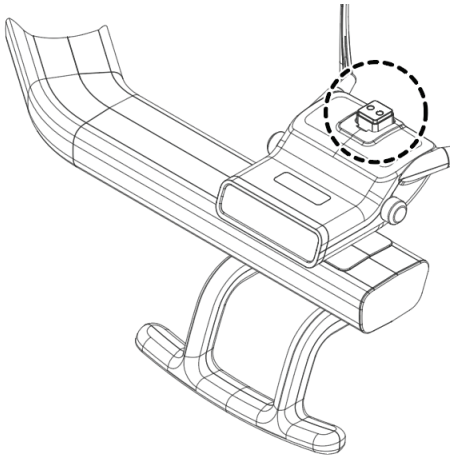


How to Check

1. Make sure all the covers of the equipment are properly attached.

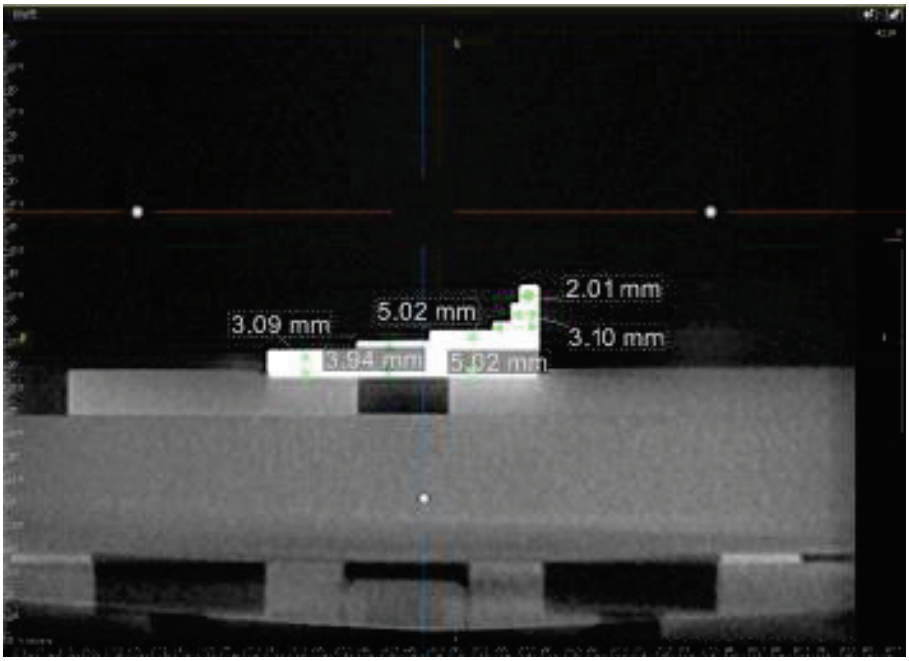
   Check that the key parts of the equipment, such as the X-ray generator, the collimator, the detector, the covers, etc., are all assembled correctly.

2. Place the phantom at the location of the chin rest for image acquisition.

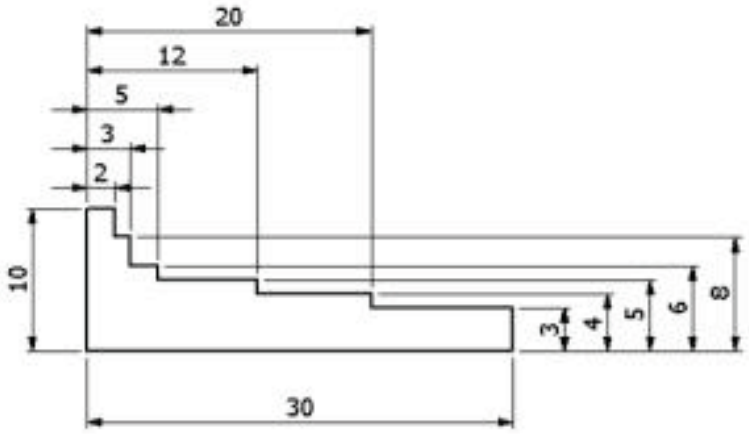


3. Activate the CT mode on Theia.

4. Set up the X-ray exposure condition as 90 kV and 10 mA on the OP and perform image acquisition using the exposure switch.
5. Check the acquired image on the OP and save it if it has no issues.
6. Measure the thickness of the acquired image on Theia.
   - [Tool box > Measurement > Length]



7. Check if the deviation of the length is within the following acceptable range (± 0.5 mm):



NOTE

If the resulted values are not within the acceptable range, call the service center for service.

7.1.4.4) CT Linearity Test

Checking Tools

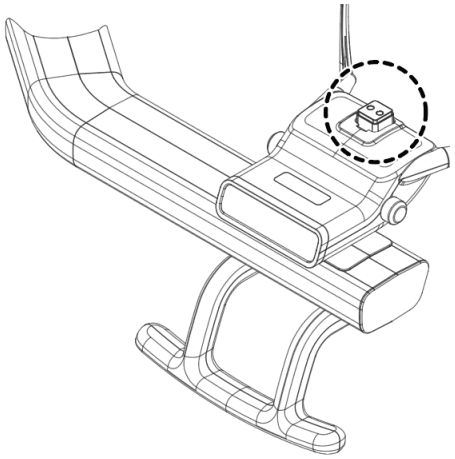
CT linearity phantom

How to Check

1. Make sure all the covers of the equipment are properly attached.

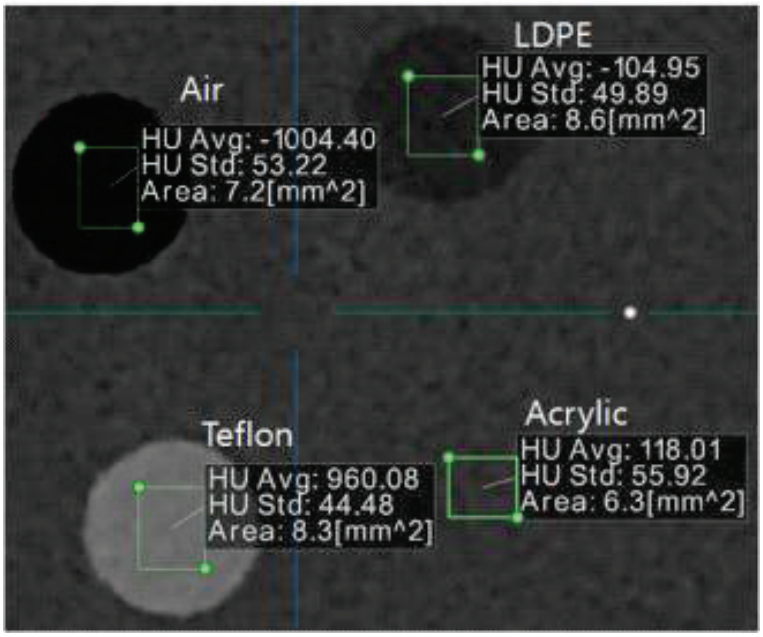
   Check that the key parts of the equipment, such as the X-ray generator, the collimator, the detector, the covers, etc., are all assembled correctly.

2. Place the phantom at the location of the chin rest for image acquisition.



3. Activate the CT mode on Theia.

4. Set up the X-ray exposure condition as 90 kV and 10 mA on the OP and perform image acquisition using the exposure switch.
5. Check the acquired image on the OP and save it if it has no issues.
6. Measure the HU value of each substance in the image acquired by Theia.
   - [Tool box > Measurement > Area of the rectangle]



7. Check if the HU values are within the following acceptable range:
   - Air: -1100 ~ -900
   - LDPE: -180 ~ 20
   - Acrylic: 20 ~ 220
   - Teflon: 900 ~ 1100

NOTE

If the resulted values are not within the acceptable range, call the service center for service.

7.2) Automatic Maintenance Service

Automatic maintenance service is provided for this equipment.

The service includes the following:

- Remote Support Service

  An engineer helps to solve problems with the PC or Theia by remotely sharing the monitor of the equipment.

- Smart Connected Device Service

  For the problems with the equipment, the nature of such errors or defects is checked, analyzed, and then sent to the LISA server, which is the maintenance program. The service engineers in the manufacturer receive the problems, check them, and take proper measures to address them immediately.

For more information including application for the automatic maintenance service, refer to the manufacturer's website:

- Website: http://www.genoray.com/cs/contact_us/

7.3) Cleaning and Disinfection

Turn off the equipment and disconnect the power cable before cleaning and disinfecting the equipment.

Any parts that patients or users may come into contact with must be disinfected after each patient's imaging session to prevent disease transmission.

Using incorrect disinfectants may cause corrosion and damage to the product, so please use the specified disinfectants.

Be careful not to let the solution get into the equipment. This equipment is not waterproof and permeated liquid may cause corrosion or electrical damage.

Cleaning

The following are the parts to clean and related notices:

- The following parts require cleaning:
  - Outer cover of the equipment
  - Accessories
  - Exposure switch
- If the equipment was used near the patient close enough to cause physical contact with the patient, check if it has been contaminated by dust or other foreign substances after use. For any sign of contamination, clean it off from the equipment immediately.
- When cleaning the equipment, refrain from spraying the neutral detergent directly to its surface and use a sponge or wet cloth to remove stains and/or dust.
- To prevent damage to the exterior of the equipment, do not use corrosive solution for cleaning.
- The solution for proper cleaning is as follows:
  - Desired cleaning solution: Water or Water with ethyl alcohol (up to 96%)
- For more detailed instructions, refer to the regulations of the corresponding country or region, or follow the instructions of the disinfection manager of the hospital.

Disinfection

- The following parts require disinfection:
  - Patient Support
  - Other surfaces touched by the patient
- The equipment should be disinfected at the contact points to the patient after use in order to cleanse dust and other foreign substances and prevent infection.
- Conducting disinfection for improperly cleaned equipment may be insufficient for disinfection. Make sure the equipment should be cleaned thoroughly first and proceed with disinfection.
- The solution for proper disinfection is as follows:
  - Desired disinfectant: 70% isopropyl alcohol by volume, not diluted.
  - For more detailed instructions, refer to the regulations of the corresponding country or region, or follow the instructions of the disinfection manager of the hospital.

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8. Error solution

Provides instructions to solve problems during the use of the equipment and information regarding the warning and error message codes, which stop the equipment.

8.1) Solution

This chapter explains some of the issues that may arise with the equipment.

NOTE

- If the problem persists even after troubleshooting with the solutions listed here, contact GENORAY and follow the instructions of the service manager.
- Request service through the service center in the following situations:
  - When a red warning light is displayed
  - When an error/warning message appears and the equipment becomes unusable

When a Defect Occurs

Symptom	Reason	Solution
The equipment does not operate.	Power issue	Check the power of the equipment.
	Emergency stop switch	Check the emergency stop switch.
The equipment does not turn on.	The power switch was not turned on correctly.	Turn off the power switch and then turn it on again.
Exposure unavailable	X-ray exposure switch issue	Contact the manufacturer and follow the instructions of the service team.
	X-ray generator issue	
	Tube deterioration	
Exposure images look too bright or just white	Incorrect exposure angle	Check the exposure angle and retry.
	Not enough x-ray exposure time	Extend the X-ray exposure time.
	Incorrect sensor position	Adjust the sensor position.
Exposure images look too dark.	Incorrect exposure angle	Check the exposure angle and retry.
	Excessive X-ray exposure time.	Shorten the X-ray exposure time.

8.2) Warning message

If an error message appears during use of the equipment, refer to the following description of each error message to resolve the issue:

NOTE

- If the problem persists even after troubleshooting with the solutions listed here, contact GENORAY and follow the instructions of the service manager.
- Request service through the service center in the following situations:
  - When a red warning light is displayed
  - When an error/warning message appears and the equipment becomes unusable

Main

Warning message	CODE-W01-001
Cause	The X-ray exposure button is released earlier during the image acquisition.
Measures	Hold down the X-ray exposure button until scanning is complete.

Warning message	CODE-W01-002
Cause	The X-ray exposure button is pushed earlier before being ready.
Measures	Do not touch the X-ray exposure button until the equipment is ready.

Warning message	CODE-W01-003
Cause	The X-ray exposure switch is not released even after the image acquisition is finished.
Measures	Release the X-ray exposure button after the image acquisition is finished.

Warning message	CODE-W01-004
Cause	The shielded room door is open during the image acquisition
Measures	Close the door first and then go on the process. If the same symptom occurs repeatedly, restart the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W01-005
Cause	The X-ray exposure switch blocked.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W01-006
Cause	Waiting time out
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W01-007
Cause	No SD card inserted.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W01-008
Cause	No sound file.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W01-009
Cause	Exposure time out
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Chinrest

Warning message	CODE-W02-001
Cause	Touch button contacted.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W02-002
Cause	Moving command exceeds the limit of X-axis motor movement.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W02-003
Cause	X-axis response time out
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Collimator

Warning message	CODE-W03-001
Cause	Moving command exceeds the limit of TOP motor movement.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W03-002
Cause	Moving command exceeds the limit of BOTTOM motor movement.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W03-003
Cause	Moving command exceeds the limit of LEFT motor movement.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W03-004
Cause	Moving command exceeds the limit of RIGHT motor movement.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W03-005
Cause	Moving command exceeds the limit of FR Laser motor movement.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W03-006
Cause	Moving command exceeds the limit of Filter motor movement.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W03-007
Cause	TOP motor response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W03-008
Cause	BOTTOM motor response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W03-009
Cause	LEFT motor response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W03-010
Cause	RIGHT motor response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W03-011
Cause	FR Laser motor response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W03-012
Cause	The Calibration button is pushed.
Measures	Release the button. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Lift

Warning message	CODE-W04-001
Cause	EEPROM replacement required.
Measures	Ask for service.

Warning message	CODE-W04-002
Cause	Moving command exceeds the movement limit.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W04-003
Cause	Lift response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W04-004
Cause	Premature moving command before the lift initialization.
Measures	Check the acquisition mode, reboot the equipment, and check the status. If the issue persists, contact for service.

Detector moving

Warning message	CODE-W05-001
Cause	Detector arm response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W05-002
Cause	Rotation for detector response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W05-003
Cause	Moving command exceeds the movement limit of the detector arm.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W05-004
Cause	Moving command exceeds the rotating movement limit of the detector.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Gantry

Warning message	CODE-W06-001
Cause	Moving command exceeds the limit of Y-axis movement.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W06-002
Cause	Moving command exceeds the rotating movement limit.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W06-003
Cause	Y-axis response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W06-004
Cause	Rotator response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W06-005
Cause	Rotating encoder error
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W06-006
Cause	Trajectory reception failure
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W06-007
Cause	Scanning operation failure
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Generator

Warning message	CODE-W07-001
Cause	Too high kV (over 90 kV).
Measures	Ask for service.

Warning message	CODE-W07-002
Cause	Too low kV (under 60 kV).
Measures	Ask for service.

Warning message	CODE-W07-003
Cause	Too high mA (over 12 mA).
Measures	Ask for service.

Warning message	CODE-W07-004
Cause	Too low mA (under 4 mA).
Measures	Ask for service.

Warning message	CODE-W07-005
Cause	Exposure time setting is too long (over 20 seconds).
Measures	Ask for service.

Warning message	CODE-W07-006
Cause	Exposure time setting is too short (under 0.01 second).
Measures	Ask for service.

Cephalo

Warning message	CODE-W08-001
Cause	Detector motor response time out
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W08-002
Cause	2nd Collimator motor response time out.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W08-003
Cause	Moving command exceeds the movement limit of the detector motor.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W08-004
Cause	Moving command exceeds the movement limit of the 2nd Collimator motor.
Measures	Retry the command. If the issue persists, reboot the equipment and check whether the issue is still present. If the issue persists, ask for technical service.

Warning message	CODE-W08-005
Cause	The touch button is pushed.
Measures	Remove all the foreign substances on the button. Reboot the equipment and check the status. If the issue persists, contact for service.

Warning message	CODE-W08-006
Cause	Trajectory reception failure
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

software warning message

Warning message	CODE-W001
Cause	The shielded room door opened.
Measures	Close the door.

Warning message	CODE-W005
Cause	Select the designated branch.
Measures	Check the setting menu. (Normal→SCD)

Warning message	CODE-W006
Cause	The latitude and longitude are required.
Measures	Check the setting menu. (Normal→SCD)

Warning message	CODE-W007
Cause	Tube Cal. No file exists.
Measures	Perform tube calibration.

Warning message	CODE-W008
Cause	Check the network adapter configuration.
Measures	To set up the network adapter, click the 'Network adapter parameter setting (DB server)' button.

8.3) Error Messages

NOTE

- If the problem persists even after troubleshooting with the solutions listed here, contact GENORAY and follow the instructions of the service manager.
- Request service through the service center in the following situations:
  - When a red warning light is displayed
  - When an error/warning message appears and the equipment becomes unusable

Main

Error Messages	CODE-E01-001
Reason	EEPROM error
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-002
Reason	EEPROM replacement required.
Measures	Contact for service.

Error Messages	CODE-E01-003
Reason	System error
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-004
Reason	Chinrest version not compatible.
Measures	Contact for service.

Error Messages	CODE-E01-005
Reason	Collimator version not compatible.
Measures	Contact for service.

Error Messages	CODE-E01-006
Reason	Lift version not compatible.
Measures	Contact for service.

Error Messages	CODE-E01-007
Reason	Detector motor board version not compatible.
Measures	Contact for service.

Error Messages	CODE-E01-008
Reason	Gantry version not compatible.
Measures	Contact for service.

Error Messages	CODE-E01-009
Reason	Generator version not compatible.
Measures	Contact for service.

Error Messages	CODE-E01-010
Reason	Cephalo version not compatible.
Measures	Contact for service.

Error Messages	CODE-E01-011
Reason	Chinrest communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-012
Reason	Collimator communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-013
Reason	Lift communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-014
Reason	Detector motor board communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-015
Reason	Gantry communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-016
Reason	Generator communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E01-017
Reason	Cephalo communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Chinrest

Error Messages	CODE-E02-001
Reason	Chinrest X-axis motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E02-002
Reason	Chinrest axis sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E02-003
Reason	MAIN version not compatible.
Measures	Contact for service.

Error Messages	CODE-E02-004
Reason	Touch panel connection/communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E02-005
Reason	Chinrest system error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Collimator

Error Messages	CODE-E03-001
Reason	TOP motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-002
Reason	BOTTOM motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-003
Reason	LEFT motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-004
Reason	RIGHT motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-005
Reason	FR Laser motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-006
Reason	TOP sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-007
Reason	BOTTOM sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-008
Reason	LEFT sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-009
Reason	RIGHT sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-010
Reason	FR Laser Sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E03-011
Reason	MAIN version not compatible.
Measures	Contact for service.

Error Messages	CODE-E03-012
Reason	Collimator system error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Lift

Error Messages	CODE-E04-001
Reason	Lift system error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-002
Reason	Overload error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-003
Reason	Lift connection/operation error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-004
Reason	Switch Error
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-005
Reason	Encoder connection/operation error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-006
Reason	Lift driver sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-007
Reason	Encoder connection/operation error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-008
Reason	EEPROM error
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-009
Reason	Main board version compatibility error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E04-010
Reason	Motor driver error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Detector moving

Error Messages	CODE-E05-001
Reason	Detector arm motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E05-002
Reason	Rotating motor of detector error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E05-003
Reason	Detector arm sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E05-004
Reason	Rotating sensor of detector error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E05-005
Reason	MAIN version not compatible.
Measures	Contact for service.

Error Messages	CODE-E05-006
Reason	Detector motor board system error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E05-007
Reason	Cephalo board is connected.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Gantry

Error Messages	CODE-E06-001
Reason	Y-axis motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E06-002
Reason	Rotating motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E06-003
Reason	Y-axis motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E06-004
Reason	Rotating sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E06-005
Reason	MAIN version not compatible.
Measures	Contact for service.

Error Messages	CODE-E06-006
Reason	Gantry system error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Generator

Error Messages	CODE-E07-001
Reason	kV Feedback_Over1 (HW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-002
Reason	kV Feedback_Over2 (SW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-003
Reason	Kv(-) feedback Over (SW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-004
Reason	kV Feedback Low
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-005
Reason	kV Feedback malfunction (performance too low)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-006
Reason	kV Feedback malfunction (performance too high)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-007
Reason	mA Feed back_Over (HW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-008
Reason	mA Feed back_Over (SW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-009
Reason	mA Feedback Low
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-010
Reason	Inverter_Current_Over (HW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-011
Reason	Filament_Current_Over (HW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-012
Reason	Filament_Current_Over (SW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-013
Reason	Inverter_InputVoltage_Low (HW)
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-014
Reason	Generator Over Temperature1 (HW)_ temperature switch.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E07-015
Reason	Generator Over Temperature1 (SW)_ temperature sensor.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Cephalo

Error Messages	CODE-E08-001
Reason	Detector motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E08-002
Reason	2nd collimator motor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E08-003
Reason	Detector motor sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E08-004
Reason	2nd collimator motor sensor error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E08-005
Reason	MAIN version not compatible.
Measures	Contact for service.

Error Messages	CODE-E08-006
Reason	Cephalo system error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E08-007
Reason	Detector motor board is connected.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-E08-008
Reason	Touch panel connection/communication error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Software error message

Error Messages	CODE-S001
Reason	Memory unavailable for receiving images
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S002
Reason	Unavailable for detector preparation.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S004
Reason	Reception of acquired images is aborted.
Measures	Check the following: ▪ Windows update, firewall, virus vaccine, or network status (1G) Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S007
Reason	Unavailable for connection to the 'HIVE' service.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S008
Reason	TDI data error.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S009
Reason	Unavailable for creation of the image acquisition information file.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S010
Reason	Image reception error (data missing).
Measures	▪ Unstable network or PC. Check the network connection and if it is fine (1Gbps), reboot the PC. ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S012
Reason	Network unstable.
Measures	Check network connection.

Error Messages	CODE-S013
Reason	Graphic card not supported.
Measures	Check the specifications of the graphic card.

Error Messages	CODE-S014
Reason	Detector is in power saving mode: ON
Measures	▪ Detector not yet ready. Retry the image acquisition. ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S015
Reason	No free space in Z drive.
Measures	▪ Check if Z drive is installed. ▪ Check the free capacity of the Z drive. ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S016
Reason	No GCP file.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE- S017
Reason	Shared folder error
Measures	Check the setting menu. (DB Server->Data Folder Information)

Error Messages	CODE- S018
Reason	Unavailable for creating the DCM file.
Measures	▪ In the log file, check the 'DCM file path.' ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE- S020
Reason	Unable to find the 'Custom preset of CT exposure program' file.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE- S021
Reason	Detector rotation angle not correct.
Measures	▪ Adjust the rotation angle on the Panoramic mode. (Refer to **"Technical manual"**.) ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S023
Reason	Unavailable for initialization of the image acquisition folder.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S024
Reason	Unavailable for connecting detector.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE- S027
Reason	Unavailable for file access.
Measures	▪ In the log file, check the 'tif file path.' ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE- S028
Reason	Incorrect setting for the image acquisition.
Measures	▪ Check the following from the log file: • GEP file path. • Select the detector. (Panoramic/Cephalo) ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE- S029
Reason	'exposure_program.ini' file does not exist.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE- S030
Reason	No data information regarding image acquisition.
Measures	▪ Retry the process. ▪ Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S035
Reason	Incorrect default setting.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

Error Messages	CODE-S036
Reason	Detector IP address not supported.
Measures	Reboot the equipment and check the status. If the issue persists, contact for service.

9. Specifications

Provides information regarding the specifications of the equipment and components, such as the equipment dimensions and weight, and environmental requirements for use.

9.1) Power and Other Specifications

No.	Item	Specifications
1	Rated power	100-240 V~
2	Frequency	50/60 Hz
3	Power consumption	2.4 kVA
4	Over-current release	Fuse 20 A

9.2) Use Environment

The environment that should be avoided during use or storage of the equipment is as follows:

- The equipment can be exposed directly to the sunlight;
- The equipment can be exposed to a dusty environment;
- The equipment can be exposed to a humid environment;
- Ventilation for the equipment is not secured;
- The equipment can be exposed to saline atmosphere; or
- The equipment can be exposed to chemicals or toxic gases.

NOTICE

The use or storage of the equipment should be carried out in an environment where the above conditions are all considered enough.

No.	Item		Specifications
1	In Use	Temperatures	+15 ˚C to +35 ˚C
		Humidity	30 % to 75 %RH (no dew condensation)
		Atmospheric pressure	800 to 1060 hPa
2	In storage	Temperatures	-10 to 55 ˚C
		Humidity	20 % to 90 % RH (no dew condensation)
		Atmospheric pressure	500 to 1060 hPa

9.3) Specifications for Key Components

NOTICE

The specifications for main components should be validated to ensure safe operation of the equipment.

9.3.1) X-ray Generator

No.	Item		Specifications
1	Type		HF Inverter 30-60 kHz
2	Phase		Single
3	Nominal Peak Output Power		1,080 W
4	kV range		60-90 kV
5	mA range	CT mode	4-12 mA
		Panoramic mode	4-12 mA
		Cephalo mode	4-12 mA
6	Exposure time	CT mode	16.8 sec (Max.)
		Panoramic mode	17 sec (Max.)
		Cephalo mode	15.5 sec (Max.)
7	Exposure method		Continuous/Pulsed
8	Cooling time		20 min (between each x-ray exposure)

NOTICE

The user should understand the Maximum X-ray exposure condition thoroughly and choose a proper condition for each patient.

No.	항목		규격 및 사양
9	HVL	Single Focus type	▪ CT mode • 4.65 mm Al@60 kV • 5.42 mm Al@70 kV • 6.18 mm Al@80 kV • 6.76 mm Al@90 kV
			▪ Panoramic mode • 3.35 mm Al@60 kV • 3.94 mm Al@70 kV • 4.56 mm Al@80 kV • 5.13 mm Al@90 kV
			▪ Cephalo mode • 4.13 mm Al@60 kV • 4.86 mm Al@70 kV • 5.61 mm Al@80 kV • 6.27 mm Al@90 kV
10	Housing heat unit		591,192 HU
11	Time Control		0-5 min.

CAUTION

The linearity of the x-ray output is guaranteed by the manufacturer. For further details, Refer to **"7.1.4. Image Quality and Dose Performance Check"**.

NOTE

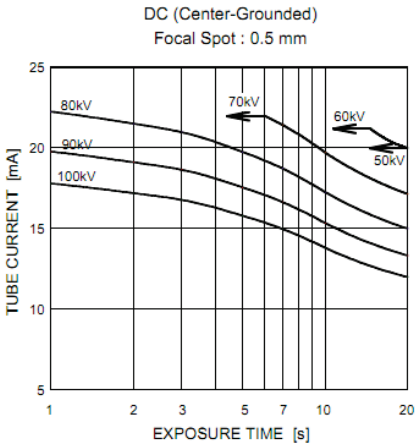
If the HVL measurement value is lower than the value provided during the equipment safety inspection, request repair through the manufacturer or an agency designated by the manufacturer.

9.3.2) X-ray tube

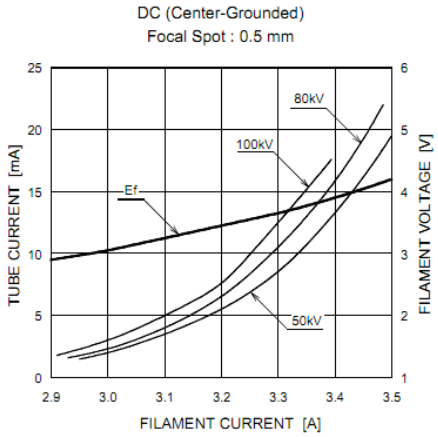
D-054SB

No.	Item		Specifications
1	Electrical Data	Circuit	DC (Center Grounded)
		Focal Spot	0.5 mm
2	Mechanical Data	Tube type	Stationary
		Target angle	5 °
		Anode cooling rate	250 W
		Total filtration ▪ Inherent filtration ▪ Added filtration	2.8 mm Al ▪ 0.8 mm Al ▪ 2.0 mm Al
3	Max. Assessment	Max. Tube voltage	100 kV
		Anode Heat Capacity	35 kJ (49.3 kHU)

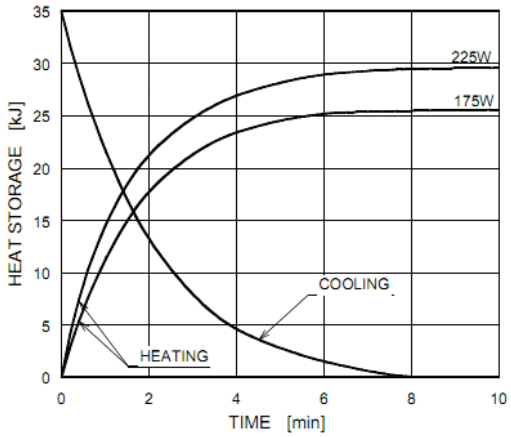
- Maximum Rating Charts (Absolute maximum rating charts)



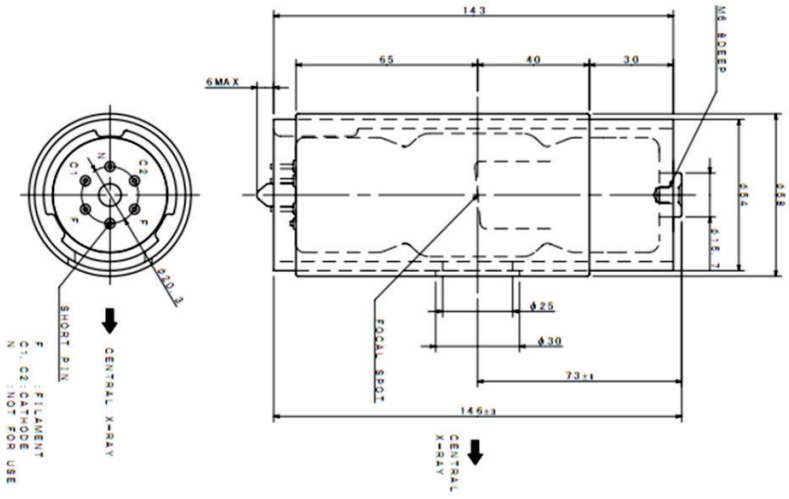
- Emission Characteristics



- Anode Thermal Characteristics



- Dimension (mm)



9.3.3) X-ray Detector

Mercu0707X (Panoramic & CT)

No.	Item	Specifications
1	Sensor Material	a-Si TFT
2	Active area	▪ CT: 179.2 × 179.2 mm ▪ Panoramic: 150.4 x 8 mm
3	Effective pixel	▪ CT: 1792 × 1792 px ▪ Panoramic: 1504 × 80 px
4	Frame rate	▪ CT • 1 x 1 binning (ROI 1792 x 804) 28 fps • 2 x 2 binning (ROI 1792 x 804) 59 fps • 2 x 2 binning (ROI 1792 x 1792) 50 fps ▪ Panoramic: 200 fps
5	A/D Convert	16 bits
6	MTF	▪ 55 % @ 1 lp/mm ▪ 24 % @ 2 lp/mm

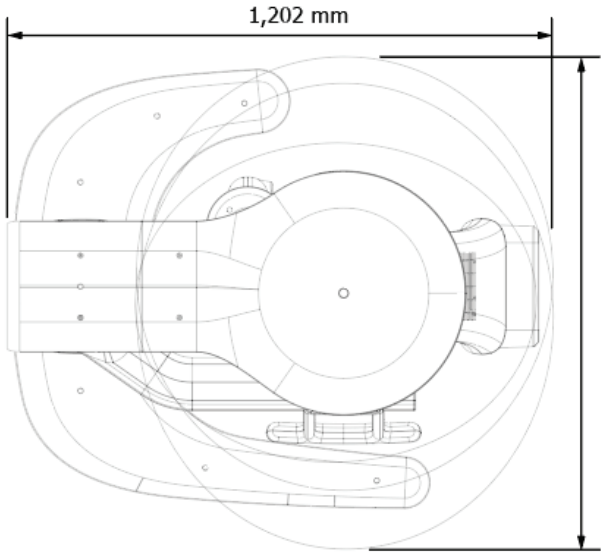
Extor-C (Cephalo)

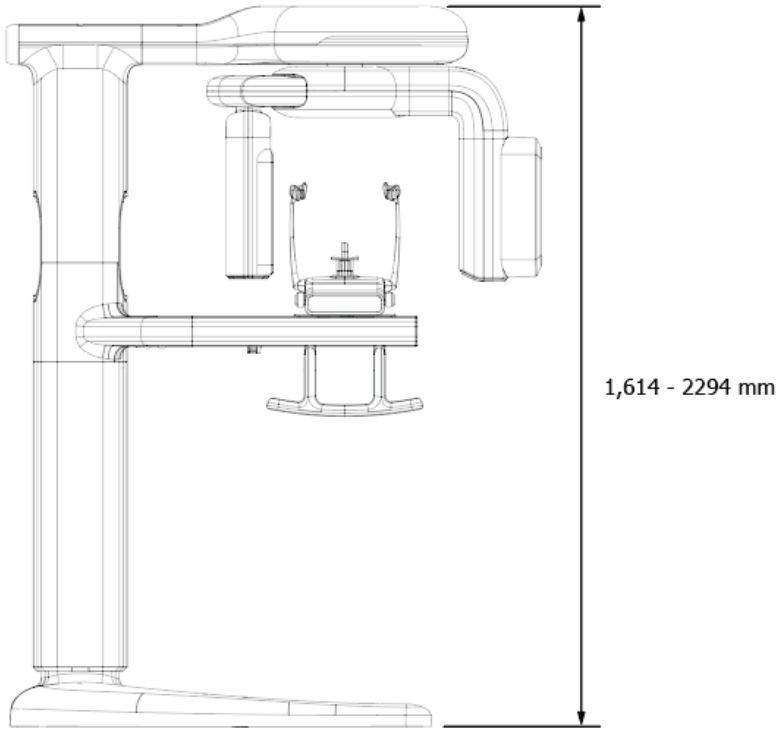
No.	Item	Specifications
1	Sensor Material	CMOS / CsI
2	Active area	227.25 × 6.45 mm
3	Effective pixel	3030 × 86 px
4	Frame rate	200 fps
5	A/D Convert	12 bits
6	MTF	60 % @ 1 lp/mm

9.3.4) Dimension and weight

GT300

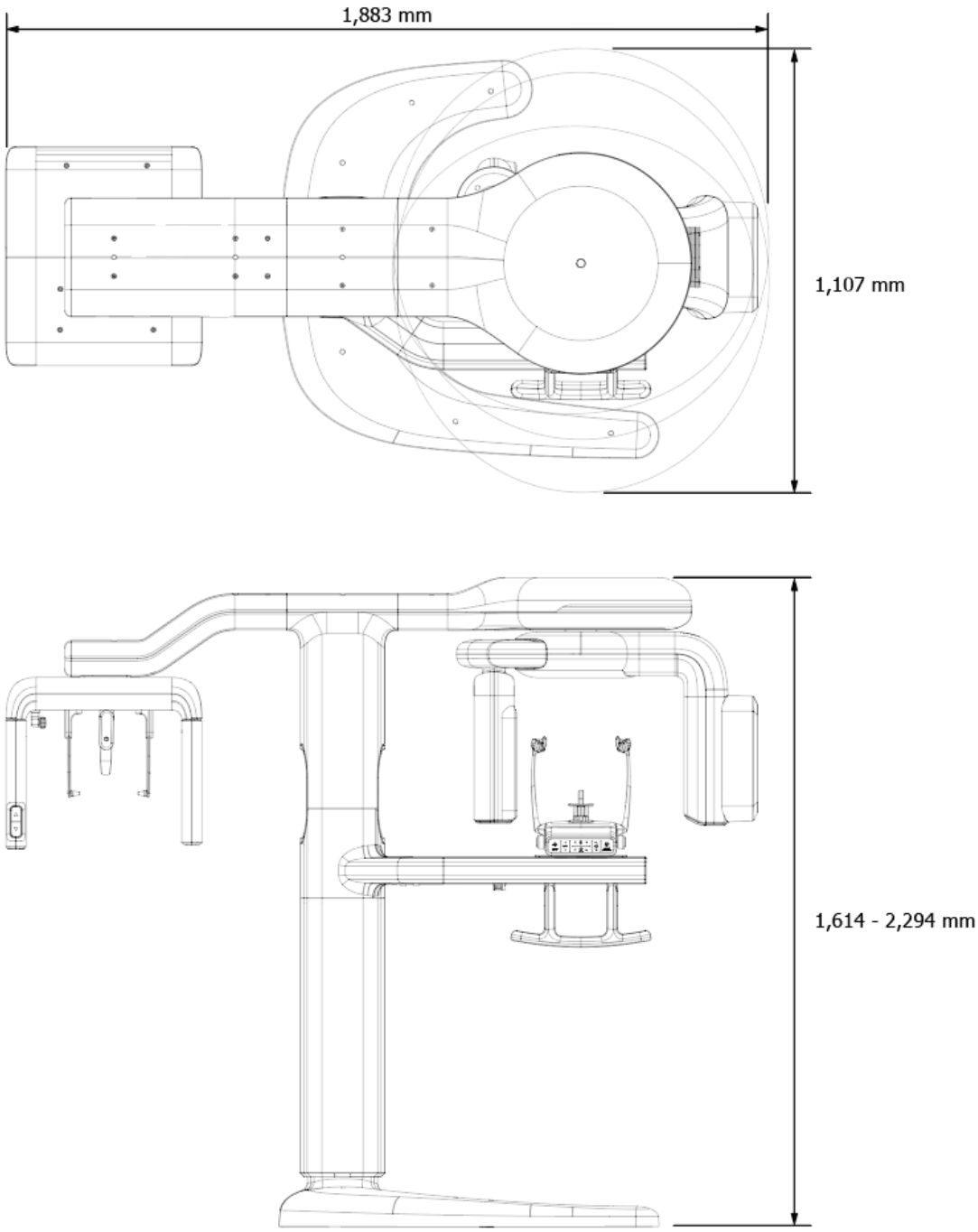
No.	Item		Specifications
1	Dimension (Unit: mm) ±10mm	Width	1202
		Height	1614(Stand)-2294(Max.)
		Depth	1107
2	Weight (Unit: kg) ± 5%		135





GT300-C

No.	Item		Specifications
1	Dimension (Unit: mm) ±10mm	Width	1883
		Height	1614(Stand)-2294(Max.)
		Depth	1107
2	Weight (Unit: kg) ± 5%		151



9.3.5) CBCT Geometry

No.	Item		Specifications
1	SID (Unit: mm) ±10mm	CT mode	588
		Panoramic mode	568
		Cephalo mode	1,758
2	SSD (Unit: mm) ±10mm	CT mode	276
		Panoramic mode	276
		Cephalo mode	1,450
3	Rotation angle (Unit: ˚) ± 10%		410.6

9.3.6) Collimator

No.	Item	Specifications
1	Operation	Remote motor drive
2	Structure	Lead shutter ▪ 4axis Asymmetric Lead Shutter (Square Shutter)
3	Automatic Collimation	Automatically adjust collimation areas

9.3.7) Laser

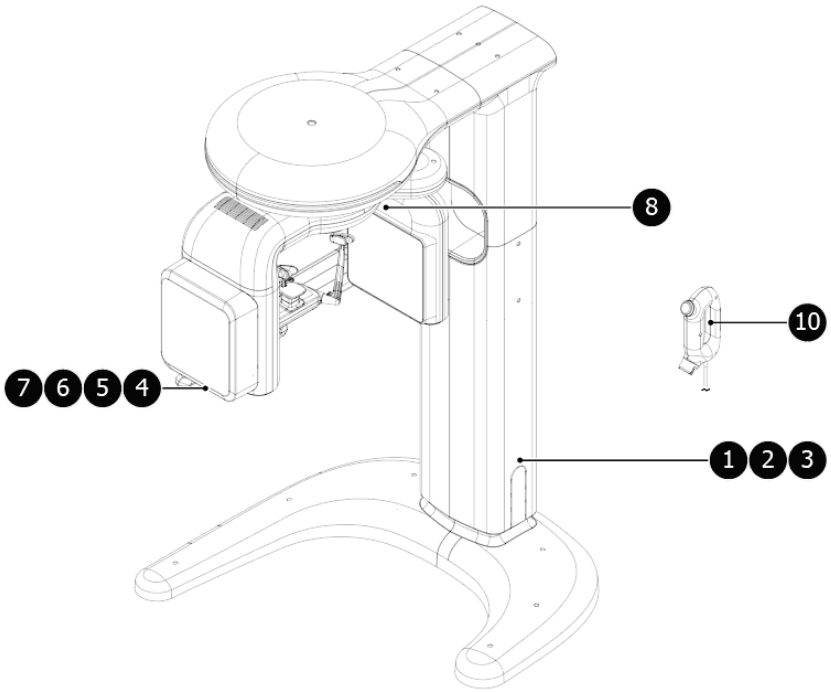
No.	Item	Specifications
1	Type	Line Beam Laser Diodes
2	Level	Class I
3	Wave length	655±5 mm
4	Power	DC 5 V ±5 %
5	Beam type	Line 56 Deg.

9.4) Product Label

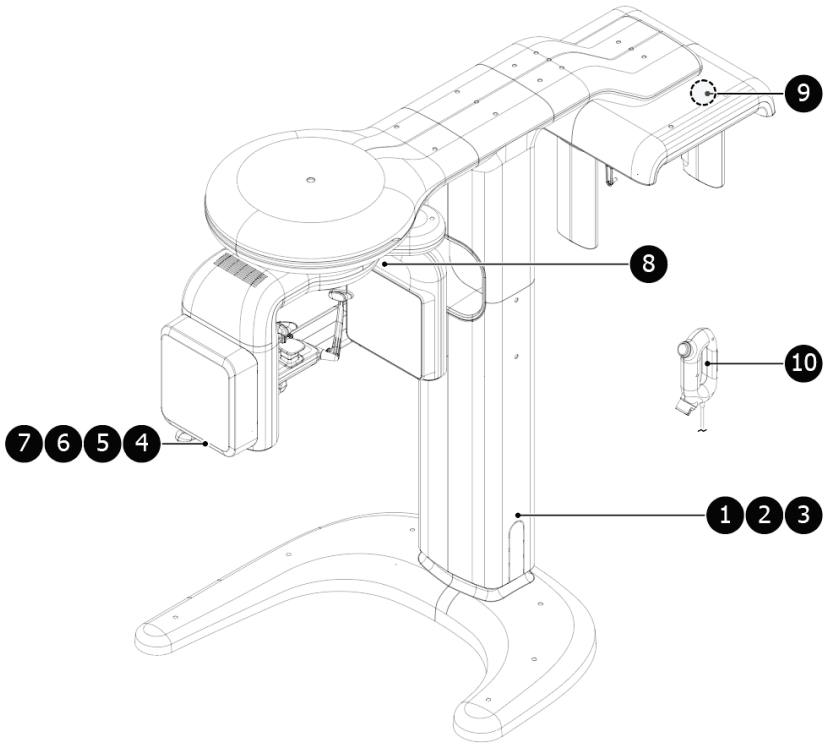
9.4.1) Label attachment location

The visual information of each label and the Shape on the equipment is as follows:

GT300

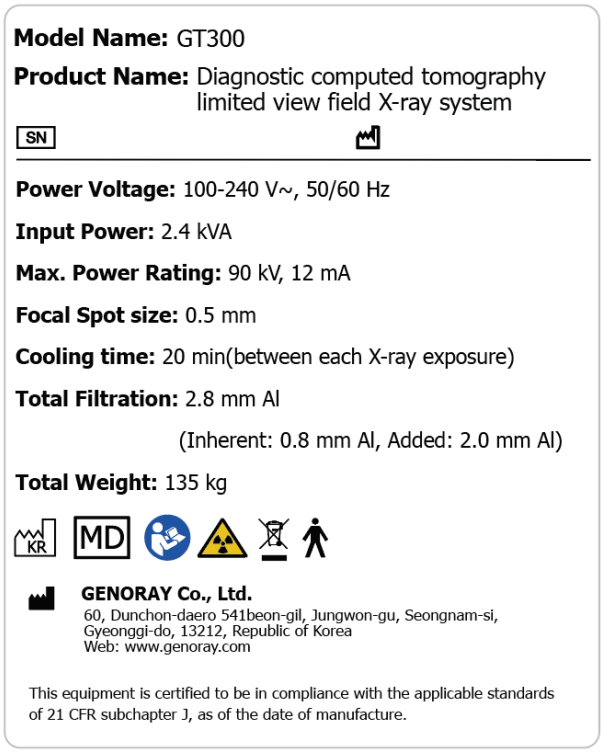


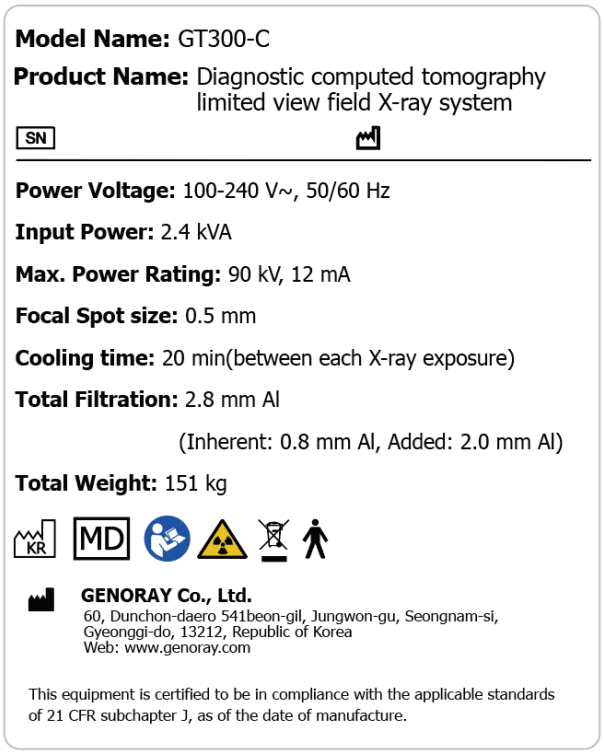
GT300-C



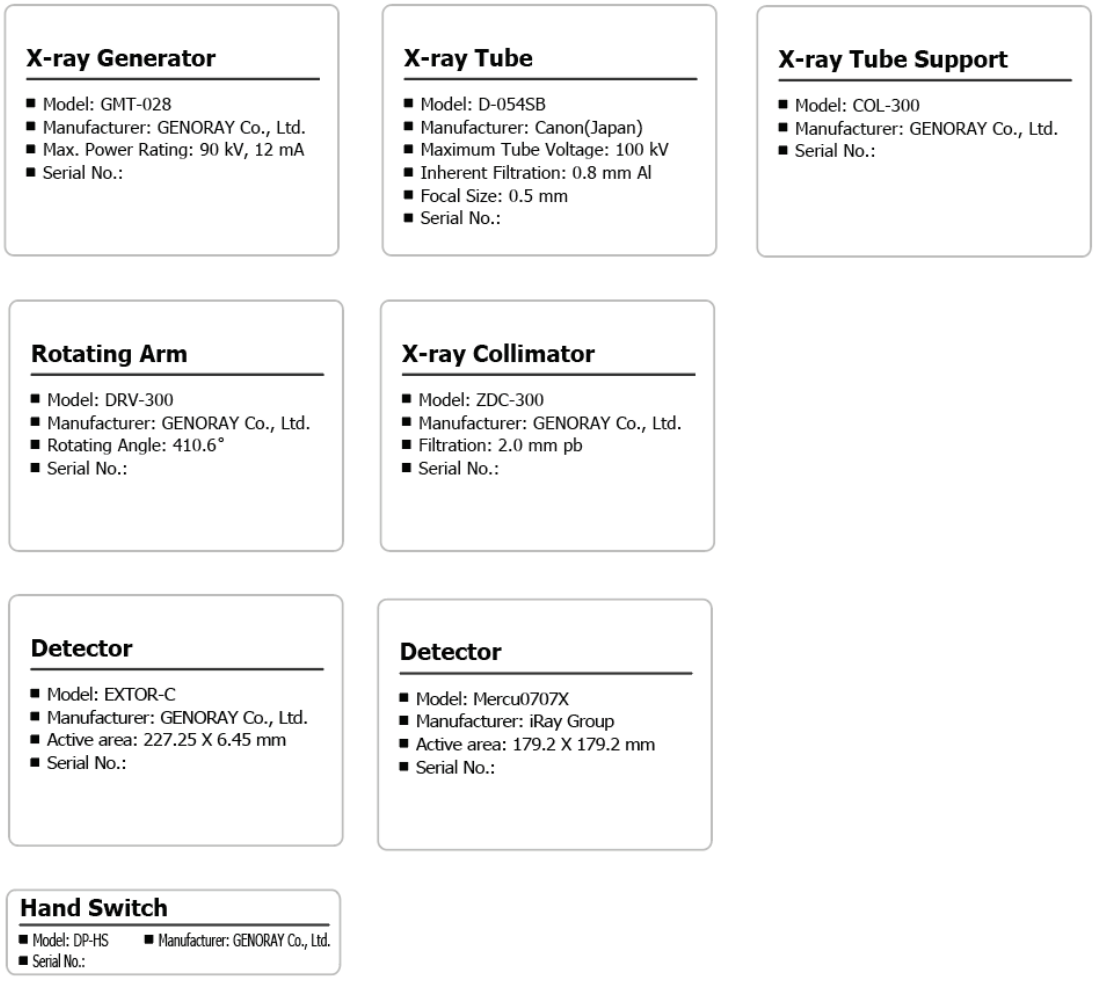
No.	Item	No.	Item
1	Main label	6	Field limiting device label
2	UDI label	7	X-ray operation unit label
3	X-ray tube support label	8	Detector label (Panoramic)
4	High voltage generator label	9	Detector label (Cephalo)
5	X-ray tube label	10	Exposure switch label

9.4.2) Main label



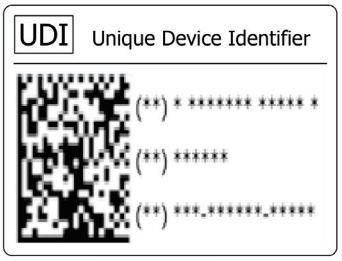


9.4.3) Part label

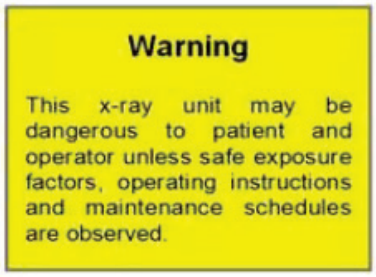


9.4.4) Other Label

UDI (Unique Device Identifier) label



Warning Label



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10. Security and Protection of Privacy

10.1) Security Environment

This equipment has a device where the personal information and the medical information of the patients are stored. The user should understand the following thoroughly to secure privacy and medical information:

- Except for the purpose of examination of the patient, access to and distribution of the patient's privacy are prohibited.
- Regulations regarding personal information protection and data leak can be applied in some countries and regions. The user should check and comply with the regulations applied locally.
- The equipment limits all the other network activity, other than the DICOM service.

  If using another network other than DICOM is necessary, call the service center.
- No one can access the equipment unless he/she is authorized with the proper ID and password.
- If cyber security is breached, call the service center immediately. When a grave danger to the operation of the equipment is recognized, further notice(s) can be sent to the user regarding instructions for security patches.

- It is recommended to use the equipment within a closed network, equipped with physical or virtual firewall.
- The software should be updated only after validation of the service engineer from the manufacturer.
- Service center
  - Operating hours: Monday to Saturday (KST +09:00 ~ 18:00)
  - Phone: 1660-4048
  - Website: http://www.genoray.com/cs/contact_us/

Digital Imaging and Communication in Medicine

- DICOM (Digital Imaging and Communications in Medicine) is a standard for medical image data to do with processing, storing, printing, and transferring medical images and patient information.
- As an applied communication protocol among systems using TCP/IP, DICOM sends and receives medical images and patient data as DICOM formatted files. DICOM includes data files and the network communication protocol, which allows to integrate other companies' scanner, server, workstation, printer, network hardware, etc. into PACS (Picture Archiving and Communication System).

NOTICE

- A joint committee between the ACR (American College of Radiology) and the NEMA (National Electrical Manufacturers Association) developed the system to standardize the medical image data, thus has the copyright.
- DICOM complies with NEMA PS3 and ISO 12052.
- A declaration of electromagnetic compatibility that clarifies the DICOM Class is accompanied with it.

Actions in Case of a Cybersecurity Incident

- If abnormal system behavior is detected (e.g., unexpected restart, performance degradation, or unauthorized network access attempts), immediately disconnect the device from the network.
- In the event of an abnormal symptom, report it to the device administrator and immediately contact the customer support center, providing the time of occurrence and a description of the issue.
- Preserve all incident records, including system logs, and restrict access to the device until an authorized engineer arrives.

Response to Security Vulnerabilities

- In the event that a critical security vulnerability is discovered, we will immediately notify users through our official website and communication channels.
- Security patches or updates will be performed by Genoray's authorized engineers and carried out under the supervision of the medical institution's device administrator.
- All updates will be provided in a format that has passed integrity verification.

10.2) Security Features

This equipment utilizes access control to fortify the information security and decide the access levels for sensitive information, such as patient information.

10.2.1) Access Control

Assigning the Access Level

This equipment is accessible using two different types of accounts for the security setting and each type of account has a different role. These account types are:

- Admin
- User

The access level for each role is shown in the table:

Item	User account	
	Admin	User
Creating new medical information	O	O
Viewing medical information	O	O
Transferring medical information	O	O
Deleting medical information	O	X
Account management	O	X
Log Viewer Access	O	X

User Account Status

- Inactivation of user account

  Once a user creates the user account, the user must change the password when logging in for the first time. Otherwise, the account automatically turns inactive.

  To activate the account, change the password.

- Expiration of user account (password overdue)

  Once a user creates the user account, the user must change the password after 180 days. Otherwise, the account automatically expires

  To undo the expiration, login with the account for Admin and prolong the expiration period or change the password in the [Account] tab.

- Locking user account

  Whenever needed, the user account can be locked to restrict login of its owner.

  To unlock the account, login with the account for Admin and unlock the account in the [Account] tab.

- Deletion of user account

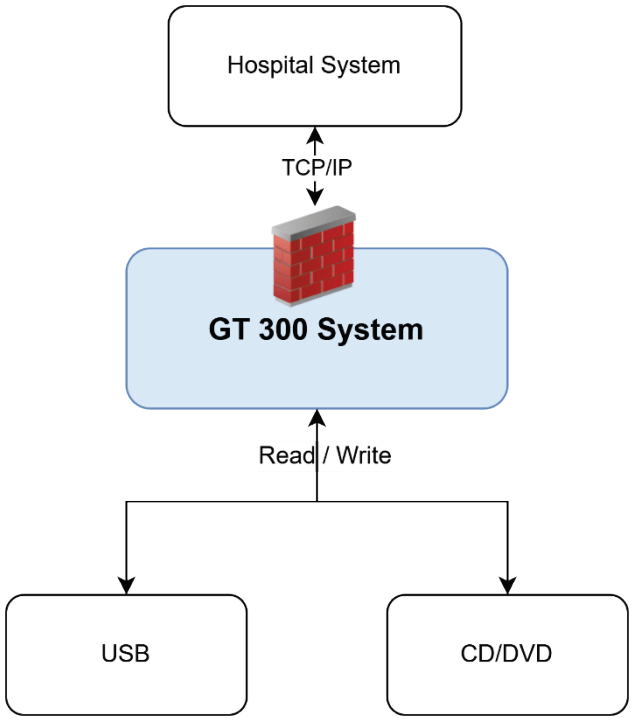
  When an account is deemed unnecessary, the account can be deleted using the account for Admin.

  To delete a user account, login with the account for Admin and delete the user account in the [Account] tab.

- Normal account

  The account is activated and allowed to access all the features.

10.2.2) Recommended Cybersecurity Control Diagram



Prior to system deployment, the appropriate port will be selected in consultation with the hospital and configured on the GT 300 System to align with the hospital's network policies and operational requirements.

10.3) Information Security

This equipment implements the equipment security via supplementation of the information system to eliminate the risk of equipment damage due to the failure of single security device.

10.3.1) Network Security

The equipment requires to set up the network security when the network is connected so that the equipment can stay safe against any unauthorized access.

10.3.1.1) Firewall and Defender

This equipment operates for medical use and utilizes firewall and Windows Defender to protect itself from any unnecessary connection to the Internet network for non-medical purposes.

Category	Full Version	Supplier	Operation Environments
Windows Firewall	Windows 11 Pro 24H2	Microsoft	Windows 11 Pro 24H2
Windows Defender	4.18.25050.5	Microsoft	Windows 11 Pro 24H2

The versions of Windows Defender and Firewall are subject to change to improve the equipment.

The following services and ports are allowed by the firewall configuration:

Service	Port	Purpose	Description
Theia Server	81	Server communication	Handles core requests to the Theia Server
Theia Image Access Sync	83	Concurrent image access management	Controls concurrent access to image files
DB Connection	5306	Database connection	Port for connecting to Theia database

With the firewall activated, all the unused communication ports are deactivated, diminishing the chance of exposure to the attacks from external threats.

10.3.1.2) Antivirus Software

The user should watch the threats of viruses, worms, Trojan horses, DOS, ransom wares, and other malicious softwares (malwares) and defend the system so that they cannot compromise the equipment.

The user should use antivirus software to prevent malware infection.

10.3.2) Mobile Media Security

This equipment supports exportation to mobile media for the main uses as follows:

- Exportation of patient data and image,
- Exportation of equipment backup data.

In the cases mobile media is used, the following precautions should be checked and observed:

- Do not allow to launch any external media.
- Do not allow to auto-launch any external media.
- Do not allow the system to boot from the external media.
- Do not allow to use network booting.

10.3.2.1) USB Storage

Saved data in the USB storage remains there unencrypted. The user can choose whether to allow exportation of the information files during data exportation.

The USB storages should always be used in compliance with applicable regulations and instructions regarding handling personal information (PI) and personal health information (PHI).

10.3.3) Screen Saver

This equipment provides the screen saver. It can be set to appear after a certain time and the screen is secured while it is activated. The screen saver is deactivated automatically whenever a user resumes using the mouse or the keyboard.

10.4) Personal Information Protection

10.4.1) Personal Information Gathered from the Equipment

As a diagnostic and image acquisition device, this equipment collects the following types of personal information. These kinds of information are secured in the equipment and stored until the user deletes the data.

- Personal Information
  - Name, gender, age, phone number, address, etc.
- Personal Health Information
  - Exam record, X-ray image, etc.
- Provider Information
  - Name, address, phone number of the hospital (clinic), etc.

10.4.2) Additional Protection of Personal Information and Precaution

The device must be accessible only to authorized users, and the medical institution is responsible for strict user access management.

The network to which the device is connected must operate in a trusted environment, and the medical institution is responsible for maintaining appropriate network security.

In the cases where the equipment needs to operate around any unauthorized person, the following items should be checked and observed to protect the patient’s personal information:

- This equipment stores the patient information, including the clinical data. The user should delete all the data which is no longer needed.
- Regular data backups of patient information are advised, in compliance with the hospital's data protection policy.
- Key configuration settings of the device should be backed up regularly.
- The system password should be changed on a regular basis to prevent unauthorized access to the patient information. A notice about changing the password appears 180 days after the creation of an account. Change the password following the notice, as a part of account management.
- When not using the equipment, make sure to log out of the system to protect personal information. Also, ask the administrator to lock the account not been used for a long time.

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Appendix1. Disposal of Wastes

The equipment and its components contain several hazardous substances. The equipment should be disposed in environmentally friendly ways in compliance with the applicable regulations and instructions in each country or region to prevent contamination.

Dispose of the equipment by referring to the following table:

Component	Material	Reuse	Special Treatment	Hazardous Substance
Covers	Plastics	•		
Boards			•	
Cable and transformer	Copper	•		
Packaging	Wood	•		
	PVC	•		
	Paper	•		
X-ray tube				•
Others			•	

NOTE

- Abide by the applicable regulations and instructions of the corresponding country or region for disposal. Contact the manufacturer or the vendor for more information.
- Do not dispose of this equipment together with general waste.
- Dispose of the equipment after cleaning/disinfecting it.

Checklist Before Disposing of or Transferring the Equipment

- Erase all stored data (patient, user, network, software) irreversibly.
- Remove and dispose of portable storage media (e.g., USB, DVD) in accordance with hospital security policy.
- Internal disks must be securely wiped or physically destroyed.
- Final confirmation should be conducted by the hospital's IT security officer. Documentation of the deletion process is recommended.

NOTE

- If secure erasure is not feasible, Genoray or a certified engineer should perform the data deletion and device disposal.
- Failure to delete sensitive data may result in legal disputes and financial loss.

Appendix2. X-ray exposure condition

NOTE

- The values in the table of exposure conditions are derived from the averages of what were measured and are subject to change without notification to improve the equipment.
- The values in the following DAP tables are the averages of what were measured and there can be X-ray performance error and measurement error, depending on the individual equipment. The data in the following tables was measured where the tolerance is 50% and the image performance is set as Default Normal mode. If the local regulation specifically requires the data, it should be applied preferentially.

A.2.1) Panoramic mode

Standard

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	74	12	12	161.42
	Middle	70	12	12	142.99
	Small	66	12	12	124.56
	Child	62	10	12	74.66

Orthogonal

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	74	12	12	161.42
	Middle	70	12	12	142.99
	Small	66	12	12	124.56
	Child	62	10	12	74.66

Bitewing

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	74	12	10.5	117.27
	Middle	70	12	10.5	103.88
	Small	66	12	10.5	90.49
	Child	62	10	10.5	64.97

A.2.2) TMJ mode

Lateral

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	74	12	7.87	105.99
	Middle	70	12	7.87	93.98
	Small	66	12	7.87	81.78
	Child	62	10	7.87	49.02

PA

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	74	12	7.53	107.26
	Middle	70	12	7.53	95.57
	Small	66	12	7.53	84
	Child	62	10	7.53	50.36

LAT-PA

NOTE

Perform the Lateral scan first and then the PA scan.

A.2.3) Sinus mode

PA

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	84	10	9	131.74
	Middle	80	10	9	118.71
	Small	76	10	9	106.76
	Child	72	8	9	76.1

Lateral

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	72	12	5	63.42
	Middle	68	12	5	55.74
	Small	64	12	5	48.31
	Child	60	10	5	34.7

Lateral Mid

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	72	12	5	63.42
	Middle	68	12	5	55.74
	Small	64	12	5	48.31
	Child	60	10	5	34.7

A.2.4) Cephalo mode

Lateral

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	90	12	8	11.8
	Middle	86	12	8	10.54
	Small	82	12	8	9.33
	Child	78	12	8	8.16

AP

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	90	12	8	11.8
	Middle	86	12	8	10.54
	Small	82	12	8	9.33
	Child	78	12	8	8.16

Water's

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	90	12	8	11.8
	Middle	86	12	8	10.54
	Small	82	12	8	9.33
	Child	78	12	8	8.16

SMV

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	90	12	8	11.8
	Middle	86	12	8	10.54
	Small	82	12	8	9.33
	Child	78	12	8	8.16

Carpus

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	70	7	8	3.47
	Middle	67	6	8	2.45
	Small	63	5	8	1.4
	Child	60	4	8	0.7

PA

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	90	12	8	11.8
	Middle	86	12	8	10.54
	Small	82	12	8	9.33
	Child	78	12	8	8.16

A.2.5) CT mode

Endo

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Endodontic	Big	90	10	16.8	1179
	Middle	90	9	16.8	1061.1
	Small	90	8	16.8	943.2
	Child	90	6	16.8	707.4

Tooth

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
High resolution	Big	90	12	4.91	413.49
	Middle	90	11	4.91	379.03
	Small	90	10	4.91	344.58
	Child	90	8	4.91	275.66

Teeth

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
High definition	Big	90	9	9.12	2096.6
	Middle	90	8	9.12	1863.7
	Small	90	7	9.12	1630.7
	Child	90	5	9.12	1164.8

Jaw1

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	90	8	13.5	2283.3
	Middle	90	7	13.5	1997.917
	Small	90	6	13.5	1712.5
	Child	90	4	13.5	1141.667

Jaw2

*Resolution	*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
		kVp	mA	Exposure Time (sec)	
Normal	Big	90	8	13.5	2758.72
	Middle	90	7	13.5	2413.88
	Small	90	6	13.5	2069.04
	Child	90	4	13.5	1379.36

Model scan

*Patient type	Recommended X-ray exposure			DAP (mGy*cm²)
	kVp	mA	Exposure Time (sec)	
Stone	90	8	9.12	1863.67
Impression	90	8	9.12	1863.67

GENORAY

MD

GENORAY Co., Ltd. (Legal manufacturer)
60, Dunchon-daero 541beon-gil, Jungwon-gu,
Seongnam-si, Gyeonggi-do, 13212, Republic of Korea
Tel. +82-31-5178-5500
Fax. +82-31-5178-5598
Email. genoray@genoray.com
Web. www.genoray.com