RAYSCAN α

RAYSCAN α- Expert3D

User Manual

RUG-310-EN

Rev. 3.2

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This document contains information for the appropriate use of RAYSCAN α.

The operator must read this manual carefully before using the product.

The operator must follow instructions and safety regulations described in the user manual to prevent any injury to the operator and the patient or damage to the product.

User manual provided with device can be modified without notice when devices are upgraded or specifications are changed. This Document was originally written in English.

Caution (US only): This product should be sold only to or by the order of a physician, a dentist or a licensed professional by the Federal law.

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This manual is subject to change without prior notice.

For further inquiries, contact your sales representative or customer service of manufacturer.

Ray Co., Ltd.

332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 18380, Korea

Phone: +82-31-605-1000 Fax: +82-2-6280-5534 www.raymedical.com

Ray America

725 River Road, Suite 118 Edgewater, NJ 07020, USA

Phone: +1-800-976-4586

CE 1639

Table of Contents

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User Manual Introduction

1

1 USER MANUAL INTRODUCTION

1.1 System Introduction

RAYSCAN α(RAYSCAN α-3D, SM3D, M3DL, M3DS) provides 3D computed tomography for scanning hard tissues such as bone and teeth. By rotating the C-arm, which houses a high-voltage generator, a X-ray tube and a detector on each end, CBCT images of dental maxillofacial structures are obtained by recombining data scanned from the same level at different angles. Functionalities include panoramic image option and cephalometric option.

1.1.1 Intended Use

The RAYSCAN α–3D, SM3D, M3DL, M3DS panoramic X-ray imaging system with Cephalostat is an extra-oral source X-ray system, intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry. The device is also capable, using the CBVT technique, of generating dental maxillofacial 3D images. The device employs a cone-shaped X-ray beam projected onto a flat panel detector, and the examined volume image is reconstructed as a 3D image. 2D images are obtained using the standard narrow beam technique.

1.1.2 General information about the RAYSCAN α

- Type of protection against electric shock: Class I Equipment
- Degree of protection against electric shock: Type B Applied Part
- Degree of protection against the ingress of water: IPX0
- Equipment not suitable for use in the presence of a flammable anesthetic mixture using air, oxygen or nitrous oxide.

- Class 1 laser equipment: IEC 60825-1

Warning

3D imaging should not be used for routine examinations.

3D imaging examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.

1.2 User Manual Reference Symbols

1.2.1 User Manual Reference Symbols

The following symbols introduce cautionary measures for the safe operation of the RAYSCAN α.

Symbol	Name	Description
 Warning	Warning	Non-observance of contents described herein may result in casualties or severe injuries.
 Caution	Caution	Non-observance of contents described herein may result in physical injuries or loss of property.
Note	Note	Provision of additional information for assisting users.

1.2.2 User Requirements


Caution

Operation of the system described herein shall be performed only by dentists and those having received professional training, for example, radiologists. Users must be familiar with the operating method and safety guidelines stated in the user manual prior to using equipment. Inadequate knowledge of the operating method and safety guidelines could result in physical injuries to patients or users.

We hold no responsibility for any damage to the device or accidents caused by an operator. Operators must fully understand the procedures and cautions described in this document. This document may not fully describe all versions of the products due to differences in specifications.

This equipment has been tested and found to comply with the limits for medical devices in IEC/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation.

This equipment can generate, use and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the separation between this system and other devices.
- Connect the system into an outlet on a circuit different from that to which other devices are connected.
- Consult the distributor or an experienced technician for help.

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Safety Management and Regulations

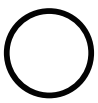
2

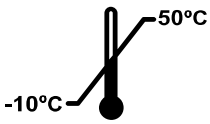
2 SAFETY MANAGEMENT AND REGULATIONS

This chapter is intended to provide safety information that users should familiarize themselves with prior to operating the equipment. The contents of this chapter are intended to preserve user safety and prevent property damage, and should be thoroughly studied in preparation for operation. When subsequent training is required, please contact the local representative.

2.1 System Symbols

The following table lists symbols closely related to patient and user safety.

Symbol	Description
	This symbol indicates the date of manufacture.
	This symbol indicates manufacturer.
	This symbol indicates Authorized Representative in the European Community.
	Indicates hazards arising from dangerous voltages.
	Indicates the absolute necessity of referencing the operating guidelines to ensure safe operation.
	Identifies a Type B applied part complying with IEC 60601-1.
	Indicates exposure or imminent exposure to X-rays.
	Indicates (on the rating plate) that the equipment is suitable for alternating current only.
	Indicates the “ON” condition.
	Indicates the “OFF” condition.

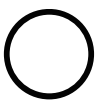
	Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
	Indicates the danger of hands, long hair or loose clothing becoming caught or jammed.
	Indicates the necessity for compliance to guidelines appearing in this manual for safe operation of the equipment.
	General warning sign
	General mandatory action sign
	General prohibition sign
	Identifies the switch or button which suspends operation of the equipment in an emergency situation.
	Caution: Equipment is emitting a laser beam.
	Caution sign
	Caution: ionizing radiation.
	Do not open when box is broken or damaged.
	In-use or in-storage temperature sign.
	In-use or in-storage humidity sign.

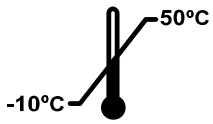
2 Administration de sécurité et Statuts

Ce chapitre offre l'information de sécurité obligée d'être bien informé par l'utilisateur avant d'utiliser ce produit. Ainsi qu'il est un contenu en vue de respecter la sécurité de l'utilisateur et prévenir un dommage des biens, il faut utiliser convenablement après la lecture sans défaut. En cas d'éducation supplémentaire, contactez l'agence de chaque région.

2.1 Singes pour usage du système

Les signes concernant la sécurité du patient ou l'utilisateur parmi les signes utilisant dans ce système sont identiques au tableau suivant.

Signes	Explication
	Il désigne la date de production.
	Il désigne le fabricant.
	Ce symbole indique le Représentant Autorisé dans la Communauté Européenne(EC).
	Il désigne un danger permettant de se produire par une haute tension etc.
	Il désigne une nécessité de suivre les instructions de fonctionnement pour assurer une fonction en sécurité.
	Il désigne un contentement pour type B qui suit les statuts d'IEC 60601-1.
	Il désigne une situation dans laquelle le rayon X est juste avant d'examiner ou en train d'examiner.
	Il désigne une convenance unique de l'appareil pour l'alternateur.
	Il désigne une marche de l'appareil.
	Il désigne un arrêt de l'appareil.

	Il désigne tous les teminaux qui se lient au conducteur extérieur afin de protéger l’appareil contre un choc électrique.
	Il désigne un danger permettant dêtre inséré ou écrasé pour les mains.
	Il désigne une nécessité de respecter les instructions du manuel pour faire marcher l’appareil en sécurité.
	Il désigne un avertissement ordinaire.
	Il désigne les obligations.
	Il désigne les interdits.
	C’est un signe d’anonncer le bouton de fonctionnement qui arrête l’apparel en cas d’urgence.
	C’est un signe de remarque pour rayon laser de l’appareil.
	Il désigne une remarque ordinaire.
	Il désigne un avertissement du danger de radiation pour ionisation.
	Il désigne un interdit d’ouvrir le produit en cas de casse ou dommage de la boîte.
	Il désigne une température d’usage ou de conservation.
	Il désigne une humidité d’usage ou de conservation.

2.2 General Safety

Warning

- The system described herein emits X-rays. Therefore, installation and operation of the equipment must be in compliance with international regulations.
- This system is considered dangerous to patients and users if exposure safety standards, operating guidelines and maintenance schedules are not properly followed. Additionally, the X-ray equipment described herein should be operated only by qualified users, such as dentists and radiologists.
- Only authorized users are permitted to touch any part of the system other than the Patient Handle.
- Device operation must be terminated immediately if any electrical and/or mechanical failure occurs. System failures can be verified through the display panel or by the warning alarm.
- When connecting parts to this system from an alternate machine, consult a professionally trained specialist. Use only the connectable accessories certified in compliance with IEC standards (IEC 60950-1 or IEC 60601-1). In addition, always comply with the relevant articles in IEC 60601-1 when connecting additional devices to the input/output signal elements.
- The system described herein requires regularly scheduled maintenance. For further details, refer to the section in this manual on Maintenance, Cleaning and Disposal.
- The system may not be usable if an error message appears during operation. Contact a service representative if an error message appears.
- Ray Co., Ltd. is not liable in the following circumstances.
  - Defects or physical injuries resulting from incorrect user-performed maintenance procedures.
  - Physical injuries as a result of user carelessness.
  - Defects, damages or physical injuries caused or initiated by supplemental equipment provided by anyone other than Ray Co., Ltd.

- Range of application
  - Conservative dentistry
  - Endodontics
  - Periodontology / Prosthodontics
  - Functional diagnosis and therapy of craniomandibular dysfunctions
  - Surgical dentistry
  - Implantology
  - Oral and maxillofacial surgery
  - Orthodontics

- Contraindications
  - Caries diagnoses, especially of proximal lesions
  - Display of cartilaginous structures
  - Display of soft tissues

- No modification of this equipment is allowed
- Do not modify this equipment without authorization of the manufacture
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment

2.2 Administration de sécurité générale

Warning

- Ainsi que ce système produit le rayon X il faut installer ou utiliser l'appareil selon la méthode de l'appareil médical lors d'un usage.
- Lorsqu'on ne sait pas parfaitement l'élément d'une exposition de la sécurité, les instructions de fonctionnement et le programme d'entretien etc, un danger peut se causer pour le patient ou l'utilisateur. De plus, cet appareil de rayon X ne doit s'utiliser que par les utilisateurs permis tels que les dentistes, le radiopraphe etc.
- Il faut faire attention pour ne pas saisir d'autres parties de ce système sauf la poignée qui est partie d'installation du patient.
- En cas de production d'un défaut életrique ou mécanique, il faut arrêter immédiatement son usage. Le défaut peut s'informer par affichage ou alerte.
- En cas de connexion d'un composant d'autres appareils à ce système, il faut consulter un spécialiste du fabricant relatif. Utilisez certainement le produit certifié selon la norme d'IEC(IEC 60950-1 ou IEC 60601-1) pour l'appareillage en connexion. Et en cas de connexion d'un appareil additionnel aux input et output du signal il faut respecter l'article d'IEC 60601-1.
- Pour ce système on doit exécuter régulièrement un entretien et une gestion. Le détail peut se consulter dans l'entretien, le nettoyage et le rejet.
- En cas d'arrivée d'un message en erreur lors d'un usage de ce système, l'appareil peut ne pas fonctionner. En cas d'apparition d'un message en erreur, contactez le responsable de service de notre entreprise.
- (S.A.)Ray décline toute reponsabilité sur les points suivants.
  - un défaut ou un dommage produit lors d'un entretien de l'appareil par une méthode inconvenable de l'utilisateur.
  - un dommage causé par une faute inattentive de l'utilisateur.
  - un défaut ou un dommage produit par l'appareil secondaire qui n'est pas offert par (S.A.)Ray.

- Champ d'usage
  - Dentisterie conservatrice
  - Endodontiques
  - Périodontologie
  - Prosthodontiques
  - Diagnose fonctionnelle et Thérapie des dysfonctionnements craniomandibulaires
  - Dentisterie chirurgicale
  - Implantologie
  - Chirurgie orale et maxillofaciale
  - Orghdontiques

- Usage interdit
  - Diagnose d'une carie, surtout des régions proximales
  - Affichage des structures castilagineuses
  - Affichage du tissu dur utilisant le raypon X

- Aucune modification de cet appareil n'est permise.
- Ne pas modifier l'appareil sans autorisation du fabricant.
- Si l'appreil est modifié, l'inspection et l'essai appropriés doivent être conduit pour assurer un usage sûr durable de l'appareil.

2.3 Electrical Safety

- The medical equipment described herein complies with Safety Class I, Type B in accordance with IEC 60601-1.
- The system must be operated in an environment fulfilling the IEC safety regulation requirements.

Warning

- Do not remove the system cover, beneath which there are no user-serviceable parts. Removing the cover exposes the user to the risk of electrocution from high-voltage current.

Warning

- Do not permit liquids to penetrate the system.
- If an unintended system operation places patients or users in danger, the equipment may be forced to turn off by pressing the Emergency Stop Switch.

Caution

- An unstable power supply may cause irregular system operation or suspension which could result in physical injuries to patients and users. Stable power supply must be taken into consideration at the time of installation.
- Emergency Stop Switch
  If the system poses a danger to patients or users, it can be shut down by pressing the Emergency Stop Switch. The Emergency Stop Switch is located on the front side of the Main Power Switch.

Caution

- If there is a malfunction or a dangerous situation, you can forcibly turn off the power by pressing the Mains Switch.

Caution

- If the Emergency Stop Switch is pressed while an X-ray is being emitted, X-ray emission is immediately suspended.
- Use the Emergency Stop Switch only in case of emergency. Turning the system OFF with the Emergency Stop Switch can result in the loss of patient information.
- Emergency Stop Switch Release
  To release the Emergency Stop Switch, rotate the switch to the right.

2.3 Administration de sécurité électrique

- Cet appareil médical respecter la classe de sécurité I, le type B selon la norme d'IEC 60601-1.
- Ce système doit s'utiliser dans l'ambiance satisfaite aux conditions exigées de la norme de sécurité d'IEC.

Warning

- Il ne faut pas enlever la couverture de ce système sans raison. En cas d'enlèvement de la couverture, on peut recevoir une commotion électrique par le courant à haute tension dans le produit.

Warning

- Ce système doit se lier à l'alimenteur électrique ayant un conducteur de terre en sécurité afin d'éviter un danger de la commotion.
- Il faut faire attention pour ne pas laisser l'eau pénétrer dans ce système.

Caution

- En cas de danger d'endommager le patient ou l'utilisateur par fonctionnement indésirable du système, on peut couper le courant de l'appareil de force en appuyant sur le bouton d'arrêt en urgence.
- En cas d'insécurité de l'alimentation électrique le système peut endommager le patient ou l'utilisateur par anomalie fonctionnelle ou arrêt. Alors, il faut certainement installer en alimentation stable.
- Bouton d'arrêt en urgence
  En cas de danger d'endommager le patient ou l'utilisateur par le système, on peut l'arrêter en appuyant sur le bouton d'arrêt en urgence. Celui-ci est au devant du commutateur.

Caution

- On peut couper le courant par force en appuyant sur le commutateur lors d'une anomalie ou un danger.

Caution

- Faites attention à l'arrêt immédiate de l'examen de rayon X si l'on appuie sur le bouton d'arrêt en urgence pendant l''examen du patient par rayon X.
- Comme l'information du patient en rayon X peut être perdue en cas de coupe du courant avec le bouton d'arrêt en urgence, il ne faut s'utiliser certainement que dans la situation d'urgence.
- Annulation du bouton d'arrêt en urgence
  Si l'on veut annuler le bouton d'arrêt en urgence il faut le tourner à droite.

2.4 Mechanical Safety

Warning

- Do not remove system cover and cable unless directed by a professionally trained specialist.
- Audible and visual contact between patient and equipment operator must be maintained at all times during examination.
- Prevent body parts or clothing from being caught or jammed in the machinery. A warning sign is affixed to sections of the equipment which pose a risk of jamming and/or collision during use.

2.4 Administration de sécurité mécanique

Warning

- Ne pas enlever la couverture et le câble du système sans raison à moins qu le spécialiste enseigné profesionnellement n'ordonne pas.
- Il faut que le patient et l'utilisateur de l'appareil puissent se communiquer toujours acoustiquement et visuellement en roue occasion pendant la période d'examen par ce système.
- Il faut faire attention pour que le corps ou le vêtement ne s''insère pas lors d'un fonctionnement du système. Un signe d'avertissement est collé sur la partie permettant de laisser le patient ou l'utilisateur insérer ou heurter dans l'appareil lors d'un usage de celui-ci.

2.5 Fire Safety

Warning

- Do not operate this system in locations exposed to fire hazards.
- In the event of a fire, end equipment operation immediately and turn the power off Extinguish the fire using a CO2 fire extinguisher. Do not use water or other liquids.

2.5 Administration de sécurité contre l'incendie

Warning

- Il ne faut pas faire marcher ce système au lieu où il y a un danger d'incendie.
- En cas d'incendie, il faut couper le courant immédiatement de l'alimentateur électrique après l'arrêt de l appareil total. Après, on mate une incendie avec l'extincteur de dioxide de carbone. Il ne faut jamais utiliser l'eau ou d'autres liquides.

2.6 Explosion Safety

Warning

- Do not operate this system in locations which present the risk of explosion. This system is not designed for use in locations with explosion hazards and does not comply with AP/AGP standards.

2.6 Administration de sécurité contre l’explosion

Warning

- Il ne faut pas faire marcher ce système au lieu où il y a un danger d’explosion. Ce système n’est pas prograqmmé pour s’utiliser au lieu où il y a un danger d’explosion sans satisfaire la norme d’AP/AGP.

2.7 Electromagnetic Compatibility

Warning

- Use of mobile phones and similar wireless devices in the vicinity of this system is prohibited. Use of devices non-compliant with EMC standards in close proximity can lead to unintended consequences due to electromagnetic interference.
- If the system is intended for use on patients having an “Implantable Cardiac Pacemaker” or “Implantable Defibrillator”, the user is obligated to inform patients that X-rays exposure may cause malfunction of these devices. When using this machine, avoid direct X-ray exposure of the “Implantable Cardiac Pacemaker” or “Implantable Defibrillator” and emit X-rays for the shortest duration possible.
- Protect the equipment from external electromagnetic waves.
- This device is only for use in an X-ray shielded room providing over 20dB attenuation. The increased limits (beyond 20dB) were taken into account during the manufacturer’s radiated emission tests.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The RAYSCAN α is intended for use in the electromagnetic environment specified below.
The customer or the user of the RAYSCAN α should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The RAYSCAN α uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The RAYSCAN α is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the RAYSCAN α or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The RAYSCAN α is intended for use in the electromagnetic environment specified below. The customer or the user of the RAYSCAN α should assure that is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line ±2 kV line(s) to earth	±1kV ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Functions Interruption Functions Interruption Functions Interruption Functions Interruption	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RAYSCAN α requires continued operation during power main interruptions, it is recommended that the RAYSCAN α be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">The RAYSCAN α is intended for use in the electromagnetic environment specified below. The customer or the user of the RAYSCAN α should assure that is used in such an environment.</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>0.15~80 MHZ
3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the RAYSCAN α, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = [\frac{3,5}{V1}]\sqrt{p}$
$d = [\frac{3,5}{E1}]\sqrt{p}$ 80 MHz to 800 MHz
$d = [\frac{7}{E1}]\sqrt{p}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).

Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following.

Radiated RF symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3V/m
80 MHz to 2.5 GHz</td><td>10 V/m
80 MHz to 2.5 GHz</td></tr>
</table>

TABLE: Recommended separation distances between portable and mobile RF communications equipment and the equipment

The RAYSCAN α is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RAYSCAN α can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the RAYSCAN α as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = $1.2\sqrt{P}$	80 MHz to 800 MHz d = $1.2\sqrt{P}$	800 MHz to 2.5 GHz d = $2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.387	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note1	At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.
Note2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.7 Compatibilité électromangétique

Warning

- Il ne faut pas utiliser le portable ou l'appareil san fil semblable à celui-ci dans les environs de ce système. En cas d'utilisation au lieu proche malgré l'appareil confrome à la norme d'EMC il peut se causer une anomalie par interférence électromagnétique.
- En cas d'utilisation de ce système pour le patient installant "le pacemaker cardiaque implantable" ou "le défibrilateur implantable", l'utilisateur doit annoncer une anomalie de l'appareil au patient lors d'un examen de rayon X en série de type d'impulsion sur la partie d'implantation de "le pacemaker cardiaque implantable" ou "le défibrilateur implantable. Au moment d'utiliser cet appareil il faut éviter d'examiner directement le rayon X sur "le pacemaker cardiaque implantable" ou "le defibrilateur implantable" si possible avec l'examen de rayon X pour un temps court autant que possible.
- Il faut protéger l'appareil contre l'onde électronique extérieure.
- Cet appareil doit s'utiliser dans la chambre confinée en décroissance plus de 20db. Alors cet appareil était appliqué en augmentant en 20db la norme de limitation de l'examen de radiation.

<table>
<tr><th colspan="3">Obstacle électromagnétique</th></tr>
<tr><td colspan="3">RAYSCAN α se sert à l'ambiance électrimagnétique désignée ci-dessous. Le client et l'utilisateur de RAYSCAN α doivent confirmer d'utiliser RAYSCAN α dans telle ambiance.</td></tr>
<tr><th>Examen de radiation</th><th>Compatibilité</th><th>Ambiance électromagnétique-Direction</th></tr>
<tr><td>RF émissions CISPR 11 - Groupe 1</td><td>Group 1</td><td>RAYSCAN α n'utilise l'énergie de RF que pour la fonction interne. Alors la radiation de RF est très basse avec une basse possiblité qui entrave l'appareil électrique d'alentour.</td></tr>
<tr><td>RF émissions CISPR 11 – Classe A</td><td>Class A</td><td rowspan="3">RCT s'utilise convenablement dans toute installation sauf les appareils ménagers, sous la condition d'avetir comme ci-dessous, il est convenable d'utiliser aux installations directement liant au réseau électrique public de basse tension qui s'offre à l'installation ménagère et au bâtiment en usage ménager.
Avertissement: ce RAYSCAN α est réservé au spécialiste médical en permettant de causer un obstacle de radio ou empêcher l';appareil proche de fonctionner. Les mesures d'atténuation ainsi que la défense ou le changement de la position de RAYSCAN α ou bien le blocage du lieu etc peuvent être nécessaires.</td></tr>
<tr><td>Émissions Harmonique IEC 61000-3-2 – Classe A</td><td>Class A</td></tr>
<tr><td>Fluctuations du Voltage/ Émissions du Scintillateur IEC 61000-3-3 - Conformes</td><td>Complies</td></tr>
</table>

Résistance électromagnétique			
RAYSCAN α se sert à l'ambiance électromagnétique désignée comme ci-dessous. Le client et l'utilisateur de RAYSCAN α doit confirmer d'utiliser dans telle ambiance.			
Résistance Examen	**Condition d'examen d'IEC 60601**	**Niveau de compatibilité**	**Ambiance électromagnétique-Direction**
Décharge électrostatique(ESD) IEC 61000-4-2	±6 kV contact ±8 kV aérien	±6 kV contact ±8 kV aérien	Le plancher se fait en bois, béton ou catelle. En cas de couverture du plancher par le composite, l'humidité relative doit être plus de 30%.
Transitoire rapide électrique / explosion IEC 61000-4-4	±2 kV pour les lignes d'alimentation ±1 kV pour les lignes d'entrée/sortie	±2 kV ±1 kV	La qualité électrique du secteur doit être identique à celle de l'ambiance commerciale ou hospitalière typique.
Serge IEC 61000-4-5	Espace ±1 kV Ligne-terre ±2 kV	±1kV ±2kV	La qualité électrique du secteur doit être identique à celle de l'ambiance commerciale ou hospitalière typique.
Chutes du voltage, les interruptions courtes et les variations du voltage sur les lignes d'input en alimentation	<5% UT (diminution >95% d'UT) pour la pendant le cycle de 0,5 40% UT (diminution 60% d'UT) pour la pendant le cycle de 5 70% UT (diminution 30% d'UT) pour la pendant le cycle de 25 <5% UT (diminution >95% d'UT) pour la pendant le sec de 5	Fonctions en interruption Fonctions en interruption Fonctions en interruption Fonctions en interruption	La qualité électrique du secteur doit être identique à celle de l'ambiance commerciale ou hospitalière typique. En cas de nécessité d 'un usage par l'utilisateur de RAYSCAN α pendant la panne de courant il est recommandé de s'approvisionner pour l'énergie de RAYSCAN α dans le système ou la batterie d'alimentation sans interruption.
IEC 61000-4-11	3 A/m	Conformes	Le champ magnétique en fréquence du secteur doit avoir un niveau du lieu représentant dans l'ambiance commerciale ou hospitalière typique.

<table>
<tr><th colspan="4">Résistance électromagnétique</th></tr>
<tr><td colspan="4">RAYSCAN α se sert à l’ambiance électromagnétique désignée comme ci-dessous. Le client et l’utilisateur de RAYSCAN α doit confirmer d’utiliser dans telle ambiance.</td></tr>
<tr><td>Conduite de RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>0.15~80 MHZ
3 V</td><td rowspan="2">Le portable ou l’appareil transportable ne doit pas s’utiliser plus proche que la distance d’écart calculée par équation appliquée à la fréquence du transmetteur sur n’importe quelle partie de RAYSCAN α comprenant le câble.
Distance d’écart recommandée
$d = [\frac{3,5}{V1}]\sqrt{p}$
$d = [\frac{3,5}{E1}]\sqrt{p}$ 80 MHz to 800 MHz
$d = [\frac{7}{E1}]\sqrt{p}$ 800 MHz to 2.5 GHz
Ici p est la puissance maximum en régime(unité W) désignée par le fabricant et d est une distance d’écart recommandée(unité m).
L’intensité électromagnétique du transmetteur de RF fixe déterminée par examen du banc d’essai électromagnétique doit ètre plus basse que le niveau de compatibilité de chaque champ de fréquence.
Il peut arriver un obstacle dans les environs de l’appareil médical désigné par signe ci-dessous.
  </td></tr>
<tr><td>Radiation de RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>10 V/m
80 MHz to 2.5 GHz</td></tr>
</table>

Distance d'écart recommandée entre le portable, l'appareil de télécommunication de RF transportable et RAYSCAN α.

On veut utiliser RAYSCAN α dans l'ambiance électromagnétique contrôlée de l'obstacle de RF électromagnétique. L'achateur ou l'utilisateur de RAYSCAN α peut prévenir une interférence électromagnétique en maintenant la distance minimum recommandée ci-dessous entre le portable, l'appareil de télécommunication de RF transportable(transmetteur) et RAYSCAN α.

Puissance maximum en régime du transmetteur (W)	Distance d'écart conforme à la fréquence du transmetteur (m)		
	150 kHz to 80 MHz d = $1.2\sqrt{P}$	80 MHz to 800 MHz d = $1.2\sqrt{P}$	800 MHz to 2.5 GHz d = $2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.387	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

La distance d'écart recommandée sur le transmetteur ayant comme régime la puissance maximum non pas mentionnée ci-dessus, d(m) peut être déterminé en utilisant la formule appliquable à la fréquence du transmetteur correspondant mais là, p veut dire une valeur en régime de la puissance maximum du transmetteur désigné en W, éclairé par le fabricant.

Note 1 On applique un champ de fréquence un peu plus haute entre 80 MHz 와 800 MHz.

Note 2 On ne peut pas appliquer ce principe dans toutes les situations puisque la transamission életromagnétique peut subir l'influence par absorption et réflexion de la construction, l'objet ou l'homme etc.

2.8 Radiation Protection

Warning

- The X-ray equipment described herein is in compliance with the radiation protection standard IEC 60601-1-3.
- Use available protective gear on patients during X-ray exposure to protect critical anatomy. (Neck area, especially around thyroid gland, reproductive organs, etc.)
- Excessive X-ray exposure can and must be avoided. Accurate scanning will reduce the number of rescans.
- X-ray scanning should be conducted in an examination room when possible.
- In the event that anyone other than the patient must be in the X-ray room when X-rays are emitted, protective gear and a film badge or TLD badge must be worn.

2.8 Administration de sécurité contre le rayon radioactif

Warning

- Cet appareil de rayon X respecte la prescription d'IEC 60601-1-3 pour protection contre le rayon raidioactif.
- Lors d'un examen en rayon X on protège la région essentiel avec une protection possible.
- Il faut éviter l'examen en rayon X excessif en réduisant la radiographie supplémentaire avec celle exacte.
- La radiographie s'exècute dans la chambre confinée du rayon X
- Lors d'un examen en rayon X dans la salle radiographique l'utilisateur doit mettre certainement une protection et vérifier la quantité irradiée de soi-même en mettant la bande en pellicule ou celle de TLD etc.

2.9 Maintenance, Cleaning, and Disposal

- Maintenance

  - Perform regularly scheduled equipment inspections for safety of patients and users.

Maintenance Tasks	Period
Check power plug for secure connection to the dedicated power supply.	Daily
Check software for proper functioning after turning on the PC.	Daily
Check the connection between the device and the Workstation. (Confirm indication in User Interface.)	Daily
Make sure that Patient Information (Name, ID, etc.) appears correctly.	Daily
Check for correct appearance of scanned images on Workstation and Touch Monitors.	Daily
Check to make sure that scanned images are saved.	Daily
Turn the device off and confirm that all bolts are tightened.	Monthly

- Cleaning

  - Turn off all equipment power prior to cleaning.
  - Do not inject liquids while system cover is open.
  - Use a soft cloth to clean the Touch Monitor user interface and LCD monitor. When using spray detergents made for LCDs, do not spray directly on the LCD. Instead, spray appropriate amount of detergent onto cloth, then wipe.
  - Patient-contacting components such as Chinrest, Bite Block, Patient Handles and Temple supports can be cleaned with alcohol-based solutions. Other unit surfaces, including the Control Panel display, can be cleaned using a soft cloth slightly dampened with mild cleaning solution.

Note Do not use cleaning agents in aerosol or spray form directly on unit surfaces.

- Sterilization
  - Parts coming in direct or indirect contact with patients must be sterilized periodically.
  - Follow hospital or clinic's sanitary regulations.

- Disposal

  - Because the system includes industrial waste materials in its composition, inappropriate disposal can cause environmental pollution. Do not dispose along with common industrial or household waste. When disposing of the system in whole or in part, observe all local, state, and federal biohazard handling regulations.
  - For waste disposal related matters, contact Ray Co., Ltd. or a local authorized agent.

2.9 Entretien, Nettoyage et Rejet

- Entretien

  - Il faut examiner régulièrement l'appareil pour la sécurité du patient ou l'utilisateur.

Travaux d'entretien	Période
Vérifiez si la ligne électrique se lie convenablement à l'alimentateur exclusif.	Tous les jours
Allumez l'ordinateur et vérifiez si le logiciel s'exècute bien.	Tous les jours
Vérifiez la connexion entre l'appareil et la station de travail. (vérifiez le signe de la connexion pour l'appareil d'UI)	Tous les jours
Vérifiez si l'information du patient(nom. ID etc) s'indique clairement.	Tous les jours
Vérifiez si l'image radiographiée se présente bien sur l'écran de touche et la station de travail.	Tous les jours
Vérifiez si l'image radiographiée est conservée.	Tous les jours
Vérifiez si tous les boulons de l'appareil sont serrés bien lors d'un arrêt de l'appareil.	Tous les mois

- Nettoyage

  - Il faut couper le courant de l'appareil sans faute avant le nettoyage ou la stérilisation.
  - Il ne faut pas mettre le liquide en ouvrant la couverture du système.
  - L'écran du moniteur de touche peut être nettoyé avec un tissu doux trempé dans la solution de nettoyage tiède. When using spray detergents made for LCDs, do not spray directly on the LCD. Instead, spray appropriate amount of detergent onto cloth, then wipe.
  - Patient-contacting components such as Chinrest, Bite Block, Patient Handles and Temple supports can be cleaned with alcohol-based solutions. Other unit surfaces, including the Control Panel display, can be cleaned using a soft cloth slightly dampened with mild cleaning solution.

Note	Ne pas appliquer directement les solution de nettoyage sur la surface de l'appareil.

- Stérilisation

  - En cas de composants en contact direct ou indirect avec les patients comme suivant, on recommande de stériliser périodiquement.
  - Suivre les règles d'hygiène de l'hôpital ou de la clinique.

- Reject

  - Ainsi que ce système comprend les déchets industriels le rejet inconvenable peut causer une pollution environnementale. Alors, il ne faut jamais rejeter avec les déchets industriels ordinaires ou ceux ménagers. Lors d'une disposition du système en total ou partie, observez touutes les règles sur le traitement en dager biologique du gouvernement local, national et fédéral.
  - Pour le rejet contactez nécessairement (S.A.)Ray ou l'agence de chaque région.

Precautions

3

3 PRECAUTIONS

The following includes information related to user safety in regard to possible incidents caused by fire or electricity, and should be understood fully before using the product.

3.1 General Precautions

1. The device should not be used by anyone other than trained users.

2. Installation pre-checks and precautions.

    - Install in a location where water damage is unlikely to occur.
    - Install in a location not subject to variations in air pressure, temperature, humidity, ventilation, direct sunlight, excessive dust, salinity, ion levels, etc.
    - Maintain safe working conditions by not subjecting the system to tilt, vibration, or shock.
    - Do not install in a location where chemical substances are stored or where gas is generated.
    - Pay attention to the voltage input, power frequency and acceptable tube current (or consumed power).
    - Check that the power is grounded.
    - Device not suitable for use in the presence of a flammable anesthetic mixture, especially in the presence of high oxygen or nitrous oxide levels.

3. Precautions prior to use

    - Inspect the switch operation. Verify that the device operates properly.
    - Make sure that the device ground is firmly connected.
    - Check all cables for firm and proper connection.
    - Do not use while other nearby devices are in operation, as problems may occur in obtaining accurate diagnoses.
    - Check for proper grounding.

4. Precautions during use

    - Continually monitor the device and patient behavior for irregularities.
    - When an irregularity is detected, stop the device, move the patient to a safe location, then pursue appropriate actions.

5. When malfunctions occur, do not touch the device under any circumstances. Immediately contact the manufacturer and distributor.

6. This device shall not be modified without permission.

7. Maintenance and inspection

    - Consult the manufacturer or an authorized service technician for assistance.
    - Device and components should be regularly inspected.
    - When the device is used after a long period of non-use, it should be tested for normal operation.
    - Clean using a neutralizing agent. Exercise caution to ensure that external substances do not enter the internal machinery.
    - Sterilize by using sterilizing liquids such as ethyl alcohol.
    - Do not use corrosive cleaning or sterilizing agents.

8. Other requirements

    - See User Manual for device handling and maintenance.

3 Remarques lors d’un emploi du produit

Ce chapitre comprend l’information concernant la sécurité de l’utilisateur sur l’accident par incendie ou électricité. Faites attention en lisant nécessairement avant d’utiliser le produit.

3.1 Remqraues ordinaires

1. Ce produit ne peut pas s’utiliser par d’autres personnes que les utilisateus bien enseignés.

2. Inspection prélalable et Remarques pour installation.

    - on installe au lieu hors d’atteinte de l’eau.
    - on installe au lieu sans lnfluence de l’air ainsi que la pression, la température, l’humidité, la ventilation, le rayon direct, la poussière, la salure, la densité d’ion etc.
    - il faut maintenir l’état stable pour ne pas que le produit penche, tremble ou subisse un choc.
    - il ne faut pas installer au lieu où se conserve la substance chimique ou que se produit le gaz.
    - il faut vérifier l’input électrique, la fréquence électrique, le courant de tube permis(ou l’électricité consommée).
    - il faut vérifier que l’électricité se met à la terre.
    - il ne faut pas utiliser au lieu ayant l’oxygène, l’oxyde azoteux ou un mélange combustible.

3. Remarques avant l’usage du produit.

    - on vérifie le fonctionnement du bouton, la polarité et si le produit marche bien.
    - on vérifie si le produit se met à la terre bien.
    - on vérifie si tous les câbles sont bien connectés.
    - il ne faut pas utiliser un autre appareil en même temps puisqu’il peut se produire un problème pour diagnostic exact.
    - on vérifie si l’électricité principale s’approvisionne bien.

4. Remarques lors d'un usage du produit.

    - on vérifie sans cesse si l'appareil marche anormalement ou le patient se met en position ou situation inconvenable.
    - en cas d'anomalie on arrête l'appareil et déplace le patient en lieu sûr pour prendre des mesures efficaces.

5. Lors d'une anomalie de l'appareil, il faut contacter immédiatement le fabricant ou l'agence pour la réparation sans toucher en aucun cas.

6. Cet appareil ne peut pas être modifié ou transformé sans permission.

7. Entretien et Contrôle.

    - il faut consulter le fabricant ou l'ingénieur de service pour se faire aider.
    - il faut examiner régulièrement l'appareil et son composant.
    - lors d'un nouvel emploi de l'appareil hors de service longtemps, il faut examiner si l'appareil marche normalement et parfaitement.
    - au moment de nettoyer la surface de l'appareil il faut essuyer avec attention pour défendre la pénétration dans l'appareil avec un tissu doux mis de l'eau tiède ou du savon.
    - en cas de nécessité d'une stérilisation, profitez de la stérilisation avec l'éthylalcool etc.
    - lors d'un nettoyage ou une stérilisation il ne faut pas utiliser la solution corrodant.

8. Remarques supplémentaires.

    - il faut consulter le manuel pour utlisateur afin de traiter l'appareil ou entretenir celui-ci.

3.2 Device-Related Precautions

1. When scanning, user should be positioned outside the X-ray shielded room, operating the device through the use of an extension cable.
2. The user should be positioned to the rear of the X-ray scanner, rather than in front of it.
3. During installation, verify that the power cord is properly connected to the ground relay set.
4. Check the power ground. Connect the device to an outlet on a circuit to which no other device is connected.
5. Turn off the power when inspecting the device's internal components.
6. Continued maintenance and regular testing of the device is required.
7. X-ray Generation

    - This device generates X-rays and may cause harm to patient and user if used inappropriately.
    - This device may not be repaired by unauthorized personnel.
    - User is responsible for regular inspection of the device. Inspection routines are explained in hospital regulations and/or during installation and user training.

8. Warnings and Cautions

    - Pay attention to any warning signs evident on the equipment.
    - Application of the device based on the patient's age, gender and medical condition shall follow the physician's professional judgment.
    - This device generates X-rays and may cause serious harm or injury to patient and user. The device should be used only after proper user training, including thorough familiarization with this User Manual.
    - Pregnant women, or patients taking prescriptions, should consult with their physician prior to X-ray exposure.
    - Only authorized personnel should be allowed to enter the examination room.
    - Ensure an adequate supply of input power.

- Device operator should stay alert while using the equipment to monitor for possible side-effects and reduce the risk of accidents caused by carelessness.
- Because the device generates X-rays it should be installed and used according to the relevant international regulations.
- Adjust Lift column height slowly to prevent equipment from dropping onto or colliding with the patient's head.
- Since various components rotate during the X-ray scan, advise the patient not to move while the scan is being performed.

9. Hygiene and disinfection

- Disinfect any parts of the system where the patient and the operator contact after each patient.
- Use hygienic cover for each patient to prevent cross contamination.
- Hygienic cover should be used once.

3.2 Remarques concernant l'appareil

1. Lors d'une radiographie, il faut examiner le rayon X hors de la chambre confinée.
2. Lors d'une rotation de l'appareil, il faut rester au derrière non pas au devant de l'appareil.
3. Lors d'une installation, on vérifie si la fiche électrique se connecte à la prise mise à la terre.
4. On vérifie un raccord à la terre. Il faut connecter à un autre lieu non pas celui connecté par un autre appareil.
5. Il faut couper le courant au moment d'examiner l'intérieur de l'appareil.
6. Il faut examiner régulièrement et entretenir durablement l'appareil.
7. Production du rayon X.

- cet appareil produit le rayon X, en cas d'usage inconvenable, il peut endommager le patient ou l'utilisateur.
- Cet appareil ne peut pas être réparé par le responsable non pas permis.
- l'utilisateur est en charge d'une maintenance périodique de l'appareil. Ceci s'explique dans la prescription hospitalière ou l'installation de l'appareil ou bien le programme d'enseignement de l'utilisateur.

8. Avertissement et Attention

- l'utilisateur doit savoir parfaitement un signe d'avertissement.
- l'usage de l'appareil doit suivre la décision du médecin sur l'âge, le sexe, l'état de santé etc du patient.
- puisque cet appareil produit le rayonX, et qu'il peut endommager gravement ou produire un accident pour le patient ou l'utilisateur il faut traiter en état bien enseigné avec une éducation convenable en lisant parfaitement le manuel pour utilisateur sans faute.
- la femme enceinte ou le patient nécessaire à la prescription du spécialiste doivent suivre l'ordonnance ou la prescription du médecin avant l'usage.
- uniquement l'homme permis peut entrer dans la salle de radiographie.
- l'input électrique doit s'approvisonner suffisamment.
- l'utilisateur doit faire attention au danger d'un accident causé par l'effet secondaire ou l'usage inattentif qui peut se produire toujours.
- puisque cet appareil produit le rayon X on doit installer ou utiliser selon la norme internationale concernée.
- il faut contrôler doucement afin de prévenir la chute ou un choc de la tête du patient lors d'un ajustage de l'hauteur de Lift Column(la colonne de l'ascenseur).
- puisque les composants divers se tournent lors d'une radiographie, il faut que le patient ne bouge pas en faisant une remarque.

9. Hygiène et Stérilisation

- il faut stériliser tous les endroits de l'appareil touchés par le patient ou l'utilisateur.
- il faut utiliser en couvrant la couverture d'hygiène au multiplet avant l'usage en vue de prévenir la réinfection ou l'infection alterne.
- la couverture d'hygiène doit s'utiliser certainement pour une seule fois.

System Overview

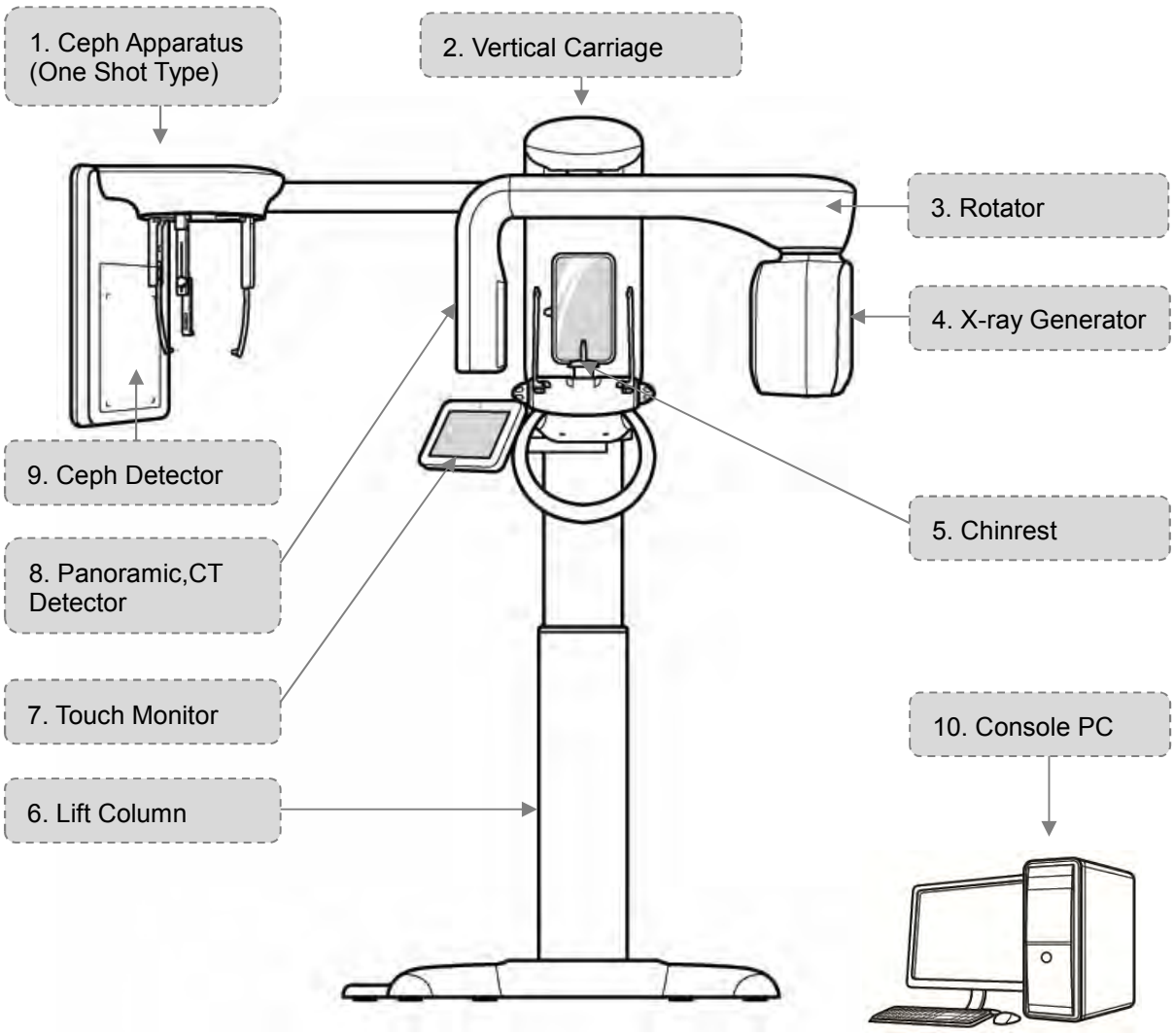
4

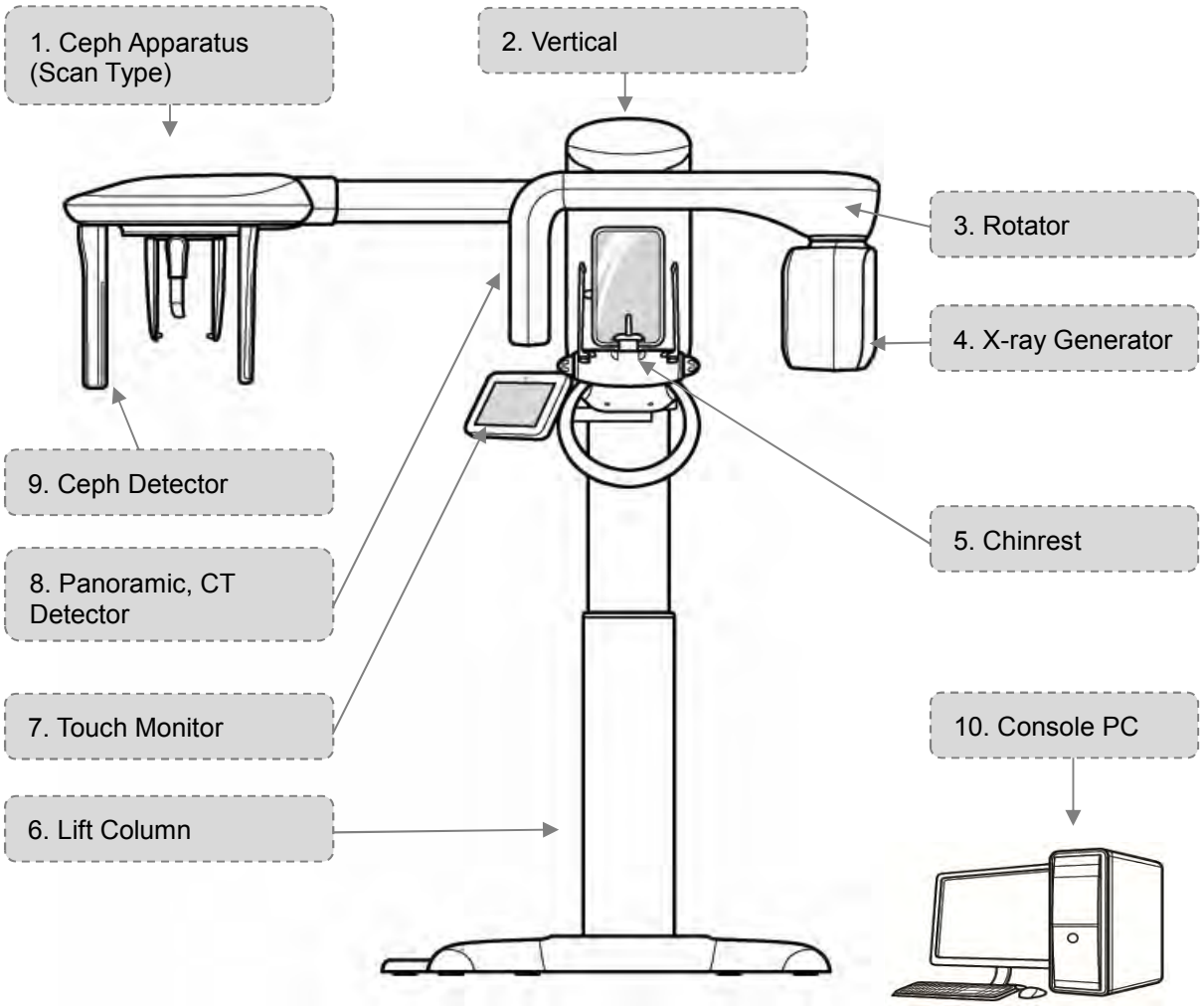
4 SYSTEM OVERVIEW

4.1 System Purpose

RAYSCAN α(RAYSCAN α-3D, SM3D, M3DL and M3DS) are 3D computed tomography devices for scanning hard tissues such as bone and teeth. By rotating the C-arm, which houses a high-voltage generator, detectors (one at each end), and an all-in-one X-ray tube, complete images of anatomical structures may be obtained by recombining data acquired by scanning tissue levels from different angles. Included are panoramic image scanning functions for obtaining images of whole teeth, and a cephalometric scanning option for obtaining cephalic images.

4.2 System Configuration





1) Ceph Apparatus

- Composed of an arm which connects to the Lift Column, a head-positioning assembly for patient placement, and a Ceph Detector. (One Shot Type/Scan Type)

2) Vertical

- This part is equipped with Rotator part.

3) Rotator

- Rotates during X-ray examination.

4) X-ray Generator

- High Frequency Generator and X-ray Tube integrated.
- High Frequency Generator: Supplies power to the X-ray Tube.
- X-ray Tube: Accelerates thermionic electrons emitted from a heated filament. Accelerated thermions collide with the Anode to generate X-rays.

5) Chinrest

- Attaches and detaches chinrest accessories and guides.
- Installed Headrest and patient handle.

6) Lift Column

- Height adjustable
- Mirror for patient positioning
- Touch Monitor for scanning, condition, control, etc.
- Remote control for height adjustment, etc. (The remote control is not provided in Canada.)
- Switch for X-ray exposure (Exposure Switch)
- Base installed for floor support
- Primary power installation

7) Touch Monitor

- Displays touch-activated control buttons.
- Preview function for scanned images is available. (For detailed description, refer to paragraph 6.5.3.6: Confirm Image View.)

8) Panoramic, CT Detector

- Receives X-rays which have penetrated the human body and converts them into an electrical signal for transmission to a visual display device.

9) Ceph Detector

- Receives X-rays which have penetrated the human body and converts them into an electrical signal for transmission to a visual display device.

10) Console PC

- Console PC Set (PC, Monitor, Keyboard, Mouse)

System Hardware Operation

5

5 SYSTEM HARDWARE OPERATION

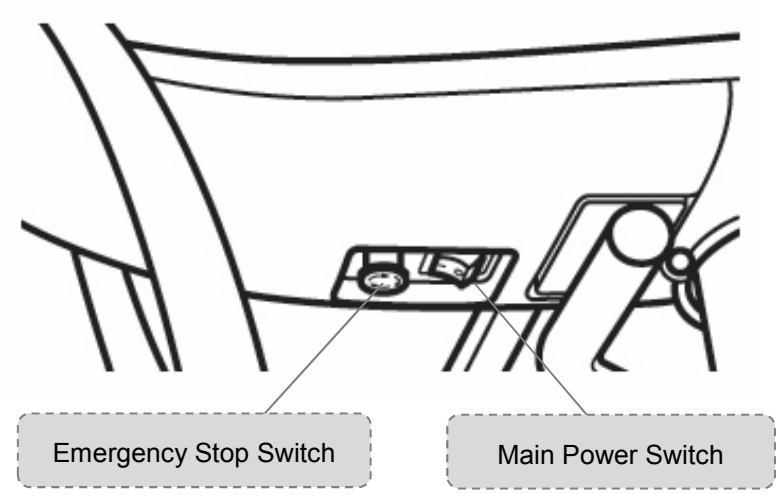
Prior to use of the device:

Warning

- Check the Main Power Switch and make sure the device is operating normally.
- Check ground for firm connection.
- Check all cables for firm and accurate connection.
- The simultaneous use of other devices may cause problems with accurate diagnosis.
- Check the power ground.

5.1 Power ON/OFF

5.1.1 System Power ON Sequence



1	To turn on the RAYSCAN α, press the Main Power Switch located on the front of the equipment handle to the “ON” position.
2	Turn on the Console PC power.
3	RAYSCAN is automatically loaded.

5.1.2 System Power OFF Sequence

1	Close the RAYSCAN.
2	To turn off the RAYSCAN α, press the Main Power Switch located on the front of the equipment handle to the “OFF” position.

Note	When rebooting after turning the equipment off, wait approximately 5-10 seconds, then press the Main Power Switch to the “ON” position.

5.2 System Emergency Stop

In order to stop the equipment immediately in case of an emergency, press the Emergency Stop Switch located at the front of the equipment’s Main Power Switch. This will automatically halt device operation and suspend X-ray exposure.

To restart the equipment, turn the Emergency Stop Switch in a clockwise direction. This will release the switch from the “OFF” position and allow for system restart.

Warning

The Emergency Stop Switch must only be used when physical injury to users or patients is imminent or ongoing, or when operating conditions become dangerous to the system, users or patients, or the immediate environment. Additionally, the Emergency Stop Switch may be used in dangerous situations caused by irregular scanning, natural disasters, or equipment malfunction.

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Software Operation

6

6 SOFTWARE OPERATION

6.1 RAYSCAN composition

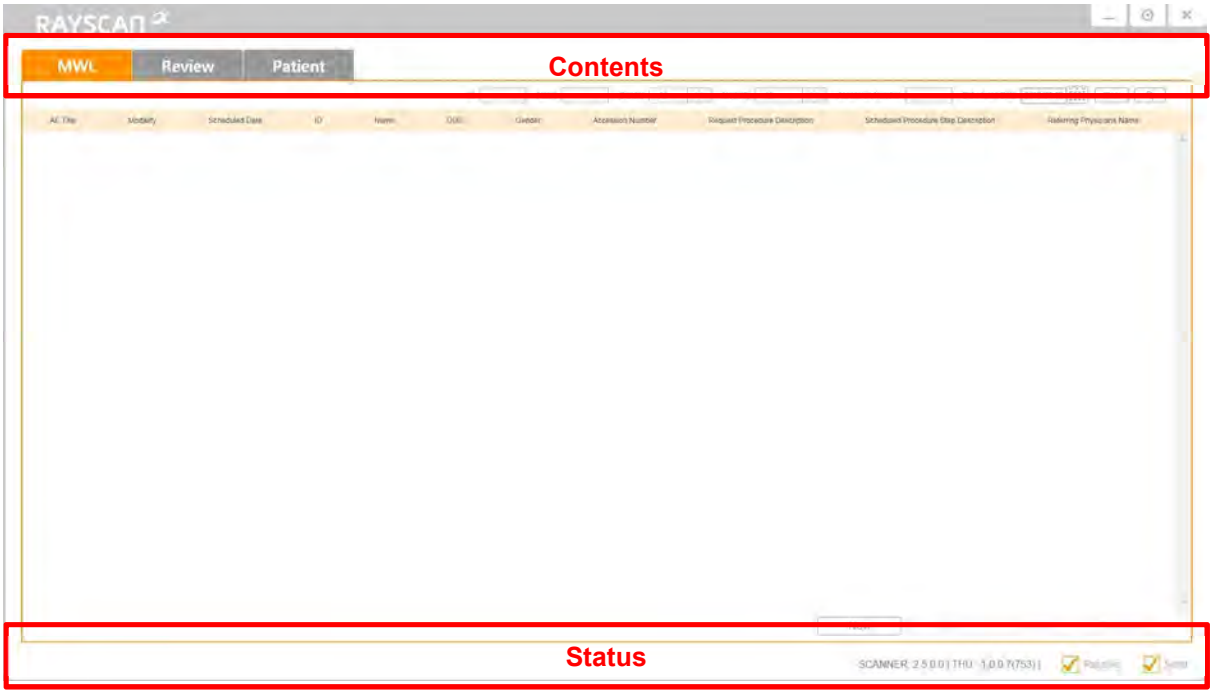


Fig 1 RAYSCAN composition

Contents

Item	Description
MWL	Displays the modality worklist (MWL). MWL may be prepared, modified, deleted, and selected for scanning. Search MWL using ID, Name, etc. For detailed description, refer to paragraph 6.2 MWL (Modality worklist).
Review	Shows the scanning-completed MWL. Send scanning-completed MWL to an alternate server; Export; DICOM print; completed image confirm and transmit to DICOM server. Search scanning completed MWL using ID, Name, etc. For detailed description, refer to paragraph 6.3 Review.
Patient	Displays patient information in thumbnail or list. Patient information may be added, modified or deleted. Search patient information using ID, Name, etc. For detailed description, refer to paragraph 6.4 Patient Management.

Status

Scanning enabled only when both Receive and Send categories are checked.

Item	Description
Version	Shows the SCANNER and THU version. Displays the version when connected the system.
Receive	Checked when the RAYSCAN is ready to receive data from the system. Cannot be user-designated.
Send	Checked when the RAYSCAN is ready to send data to the system. Cannot be user-designated.

6.2 MWL (Modality worklist)

6.2.1 MWL

This tab provides MWL(order list of image acquisition) management function such as new, modify, delete and delete all.

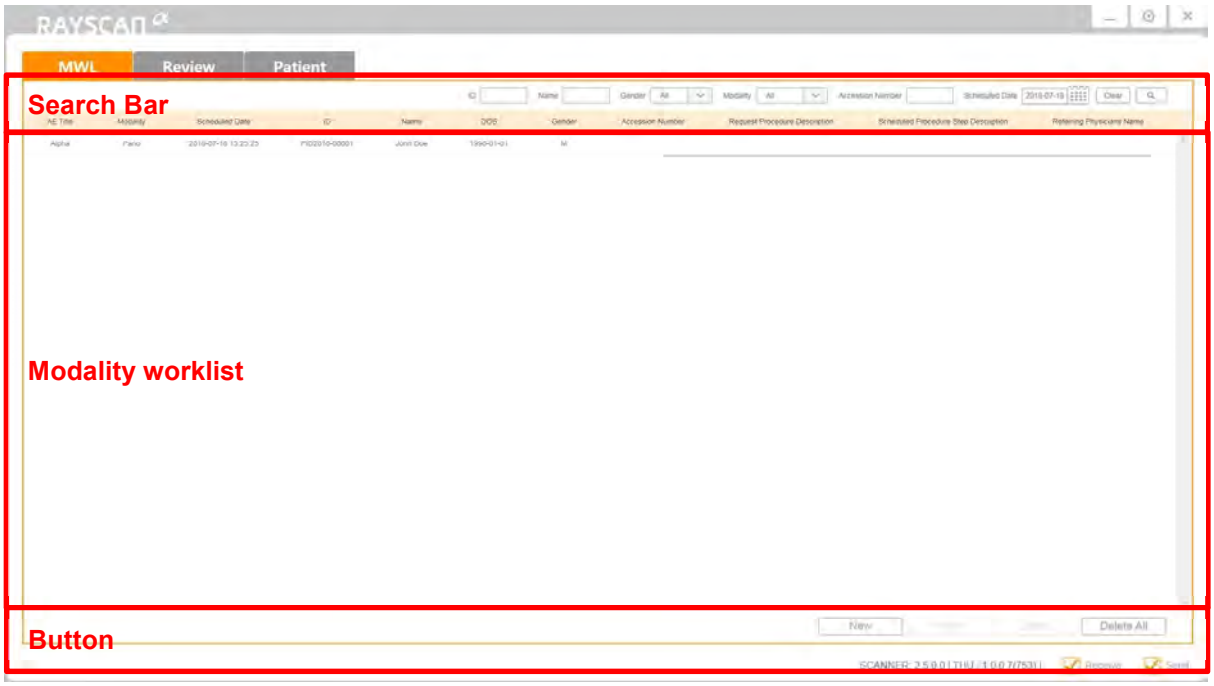


Fig 2 MWL

Search Bar

Item	Description
ID	Input Criteria: Fewer than 20 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period) are available for input. Insert the first letter and click the ”Search” button to see a list of words that begin with the selected letter.
Name	Input Criteria: Fewer than 50 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), “,” (comma), blank characters are available for input. Enter the name(or first name, middle name, last name) of patient.
Gender	Type: All (Default), Male, Female, Other (example: Emergency)
Modality	In this category, the type of scanning differs depending on the type of device. Through use of the Config Editor Tool, it is possible to mark and use a category. Type: All(Default), CT, Pano, Ceph, Intraoral

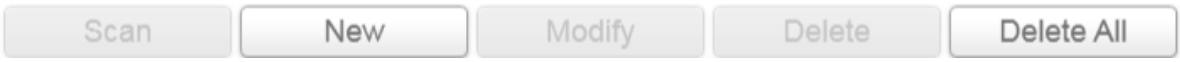
Accession Number	Input Criteria: Fewer than 20 characters, English·Numeric·Chinese Characters·Japanese/Special Characters "-" (hyphen), "." (period) are available for input. When using insurance claim numbers, insert the relevant claim number in the DICOM scanning information. Searching by accession number will be available in the future.
Scheduled Date	Scanning date (Default: Today's Date)
[Calendar]	Click to display calendar for date selection. When date is selected, calendar automatically disappears and selected date is shown in the text box.
[Clear]	Deletes the designated criteria and returns to initial condition.
[Search]	Searches MWL based on the designated search criteria.

Modality worklist

Item	Description
AE Title	This separator is for checking where the image was acquired.
Modality	Type: CT, Pano, Ceph, Intraoral
Scheduled Date	Scanning date. (Default: Today's date)
ID	Patient ID.
Name	Patient name
Birth Date	Patient birth date
Gender	Type: M (Male), F (Female), O (Other)
Accession Number	When using insurance claim numbers, insert the relevant claim number in DICOM scanning information.
Request Procedure Description	Requested procedure ID. If saved format for specific scanning method exists, insert relevant ID.
Scheduled Procedure Step Description	Shows name of requesting physician.
Referring Physician Name	Referring physician's name. Name of the doctor who requested the scan.

Button

[Default]



[At MWL selection – buttons are activated as shown below.]

Item	Description
[Scan]	Select modality worklist and click [Scan] button to start image acquisition or double click the MWL (RAYSCAN will go to Acquisition screen). For detailed description, refer to paragraph 6.2.2 Acquisition.
[New]	Create new MWL for preparing acquisition. For detailed description, refer to paragraph 6.2.3 Create Modality Worklist.
[Modify]	Modify MWL information for proper acquisition. For detailed description, refer to paragraph 6.2.4 MWL Modify.
[Delete]	Delete the selected MWL. For detailed description, refer to paragraph 6.2.5 MWL Delete.
[Delete All]	Delete all requested MWL. For detailed description, refer to paragraph 6.2.6 MWL Delete All.

6.2.2 Acquisition

Acquisition occurs when the [Scan] button is clicked in the MWL screen.

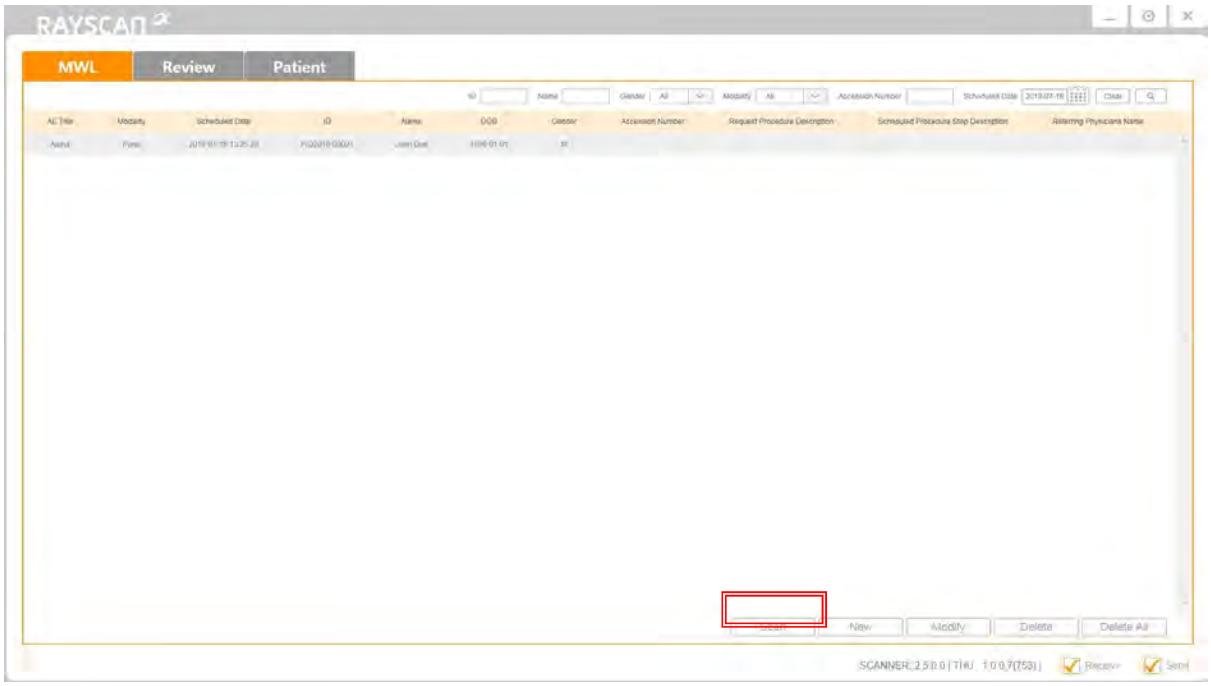


Fig 3 MWL Scan

6.2.2.1 Patient Information

Confirm the patient information for correct image acquisition.

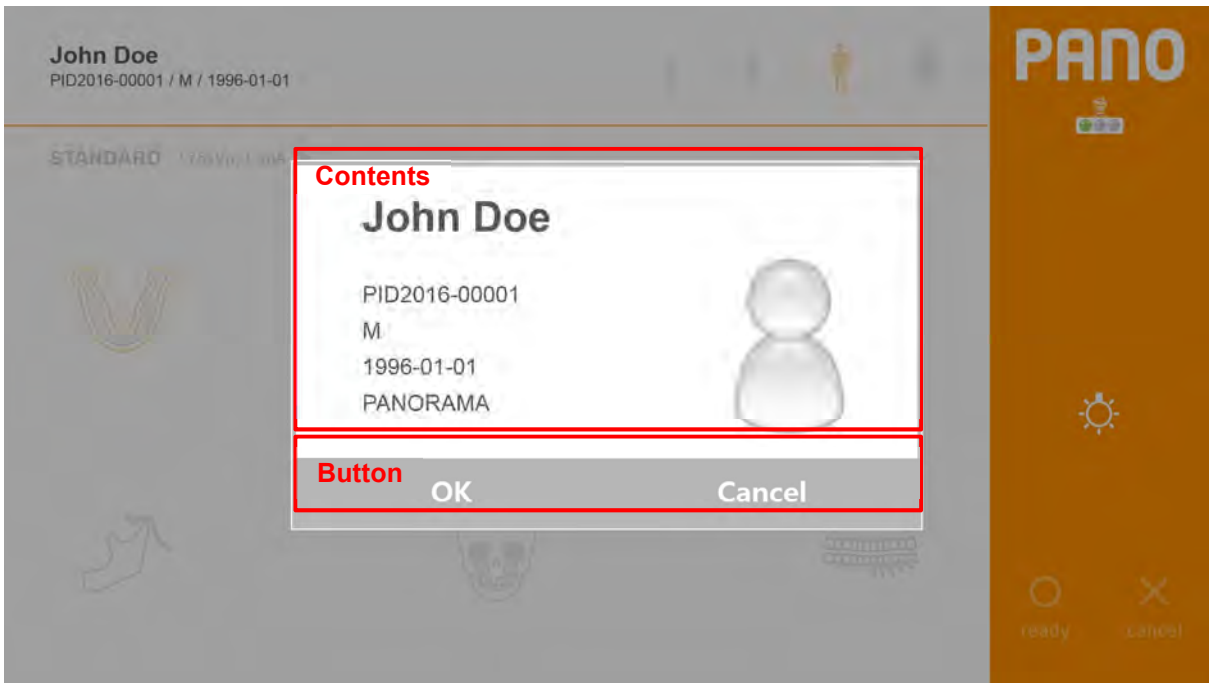


Fig 4 Patient Information

Contents

Item	Description
Portrait	Shows the patient photo when a patient photo is registered. When the photo is not registered, displays default image.
ID	Patient ID.
Name	Patient name
Gender	Type: M (Male), F (Female), O (Other)
Birth Date	Patient birth date
Modality	Type: CT, Pano, Ceph, Intraoral

Button

Item	Description
[OK]	Verify patient information. If correct, click to close Patient Information screen and go to Scanning screen.
[Cancel]	Click when patient information is incorrect or scanning is cancelled. Click to cancel scanning. Close Patient Information screen and Scanning screen in that order and return to MWL screen.

6.2.2.2 Panoramic Acquisition

Panoramic Imaging Setup Screen

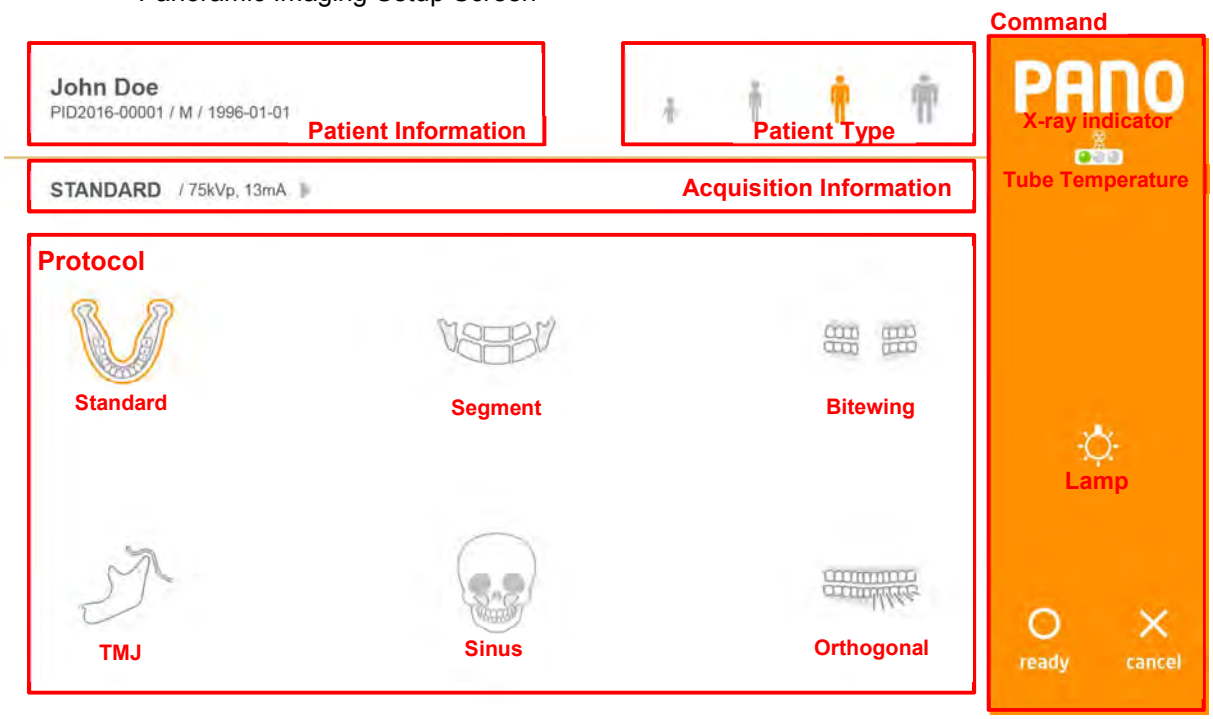


Fig 5 Panoramic Acquisition

Patient Information

Item	Description
ID	Patient ID.
Name	Patient name
Gender	Type: M (Male), F (Female), O (Other)
Birth Date	Patient birth date
Exposure Time	Exposure time varies according to modality and protocol.

Patient Type

Item	Description
[Child]	Child build
[Small adult]	Small adult build
[Adult]	Adult build
[Large adult]	Large adult build

kV (kiloVoltage): Tube Voltage

Item	Description
Tube Voltage (kV)	Displays the preset tube voltage.
[Up]	Increase kV button. The number Increase by 1 kV on click.
[Down]	Decrease kV button. The number Decrease by 1 kV on click.

mA (milliampere): Tube Current

Item	Description
Tube Current(mA)	Displays the preset tube current.
[Up]	Increase mA button. The number Increase by 1 mA on click.
[Down]	Decrease mA button. The number Decrease by 1 mA on click.

Protocol

Item	Description
[Standard]	Select Standard protocol.
[Segment]	Select Segment protocol.
[TMJ]	Select TMJ protocol.
[Sinus]	Select Sinus protocol.
[Bitewing]	Select Bitewing protocol.
[Orthogonal]	Select Orthogonal protocol.

Command

Item	Description
[Lamp]	Alignment Beam ON/OFF Button. Click to turn the alignment beam OFF if turned ON and turn ON if turned OFF. ON  OFF 
[Ready]	Scanning preparation complete button. When clicked, system moves to the start position for scanning.
[Cancel]	Click to cancel scanning, close Pano screen and return to MWL screen. Click after [Ready] button is clicked to cancel the scanning preparation process.
X-ray Indicator	X-ray exposure condition. Yellow light turns on during exposure. ON  OFF 

Temperature

Monitor the X-ray tube temperature. Under normal operating conditions, the green light is on. When the temperature rises, the yellow light turns on. When overheated, the red light turns on. Scanning is possible when the green light is on. When the red or yellow light is on, cooling time is required. (Yellow zone: ~3 minutes, Red zone: ~5 minutes) Remaining cooling time is shown above the [Ready] button.

Fig. 6 shows the cooling time indicator.

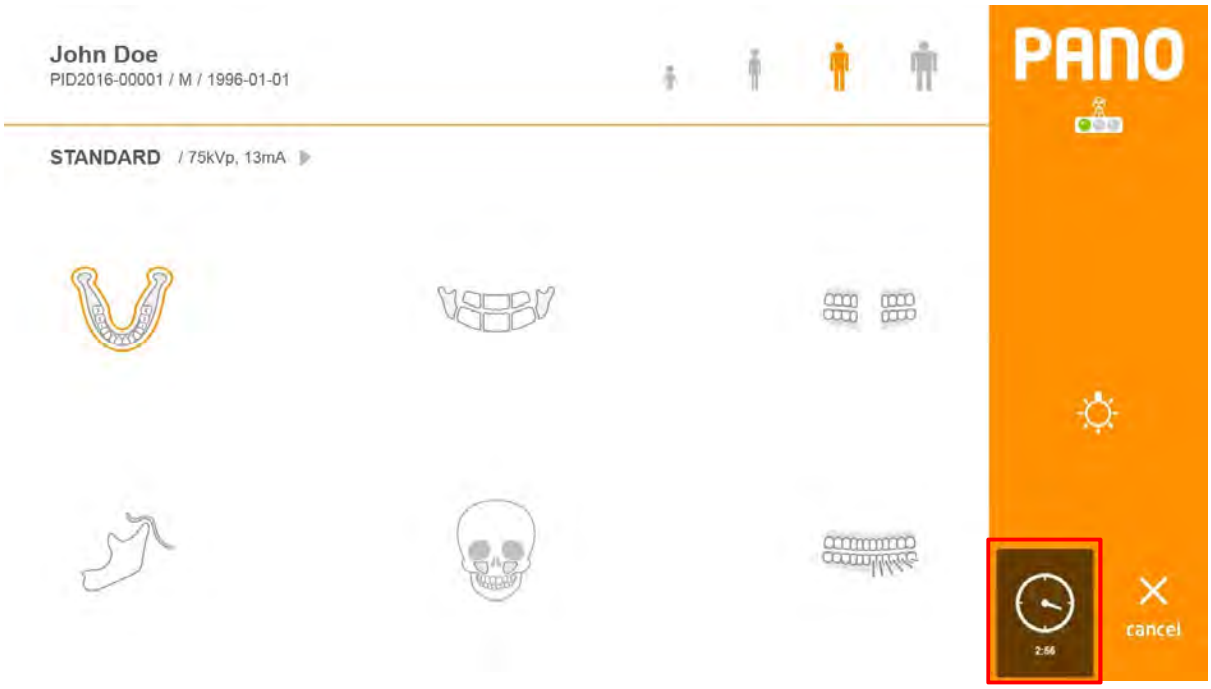


Fig 6 Cooling Time

6.2.2.3 Cephalometric Acquisition (One Shot Type)

One Shot Ceph Imaging Setup Screen

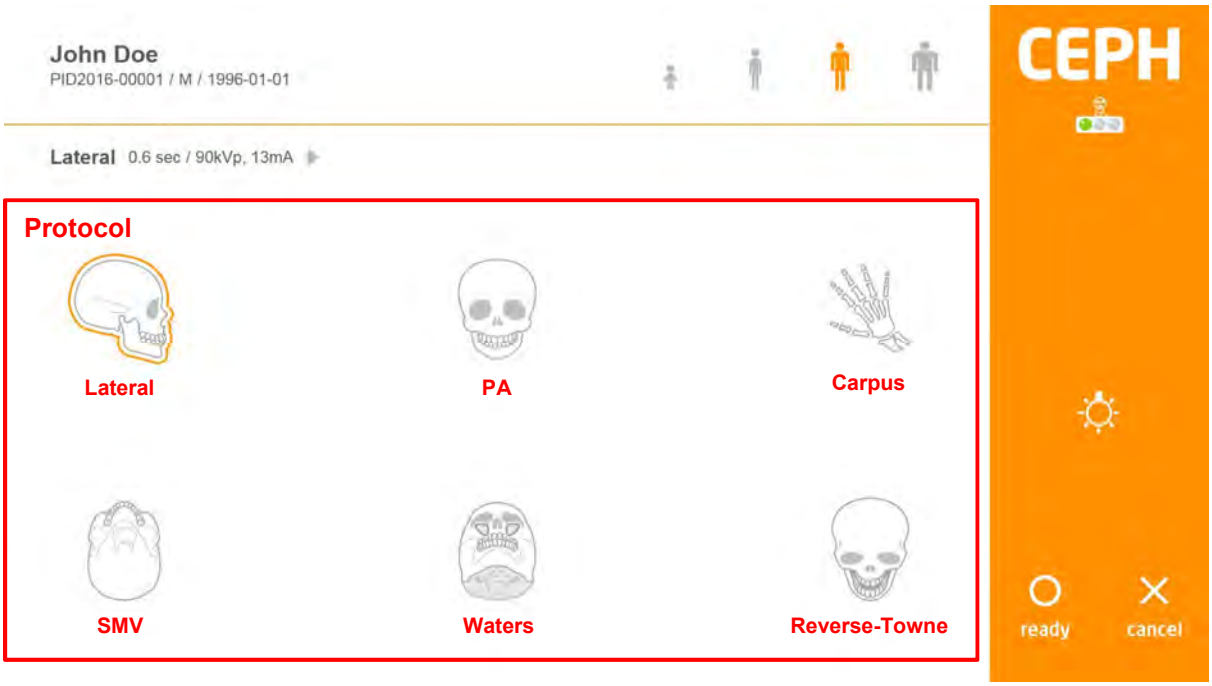


Fig 7 Acquisition: Cephalometric

Protocol

Item	Description
[Lateral]	Select Lateral protocol.
[PA]	Select PA protocol.
[SMV]	Select SMV protocol.
[Carpus]	Select Carpus protocol.
[Waters]	Select Waters protocol.
[Reverse-Towne]	Select Reverse-Towne protocol.

6.2.2.4 Cephalometric Acquisition (Scan Type)

Scan Ceph Imaging Setup Screen

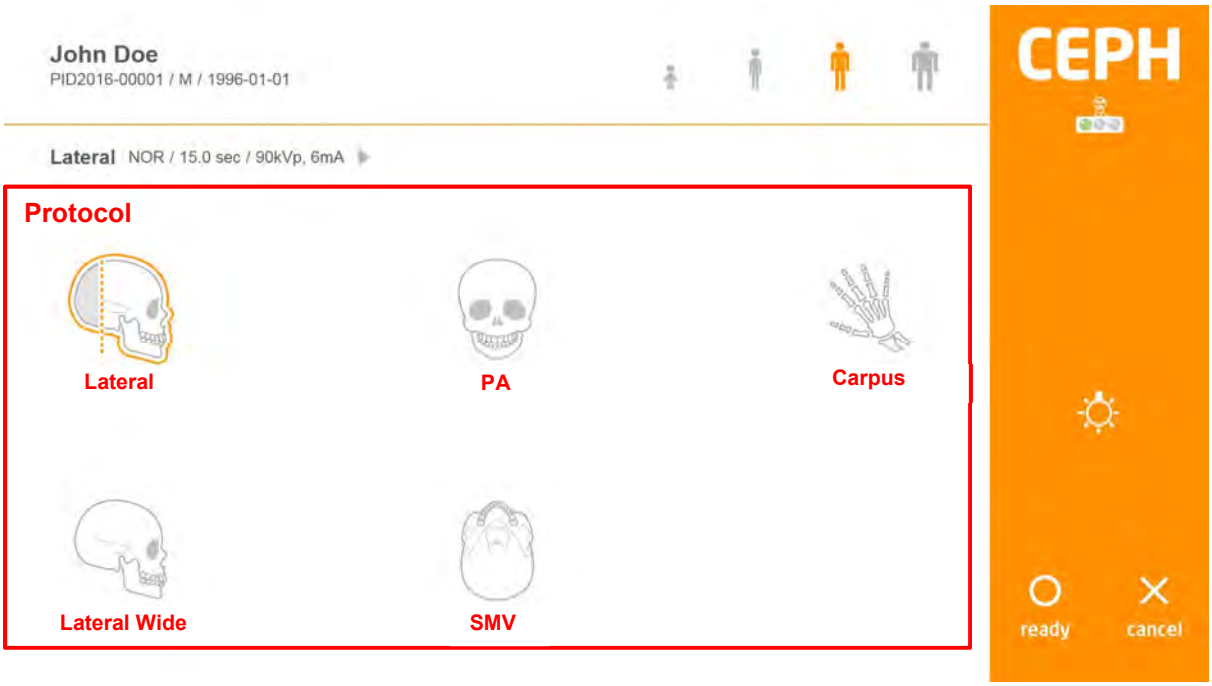


Fig 8 Acquisition: Cephalometric

Protocol

Item	Description
[Lateral]	Select Lateral protocol.
[Lateral Wide]	Select Lateral Wide protocol.
[PA]	Select PA protocol.
[SMV]	Select SMV protocol.
[Carpus]	Select Carpus protocol.

6.2.2.5 CT Acquisition

CT Imaging setup screen.

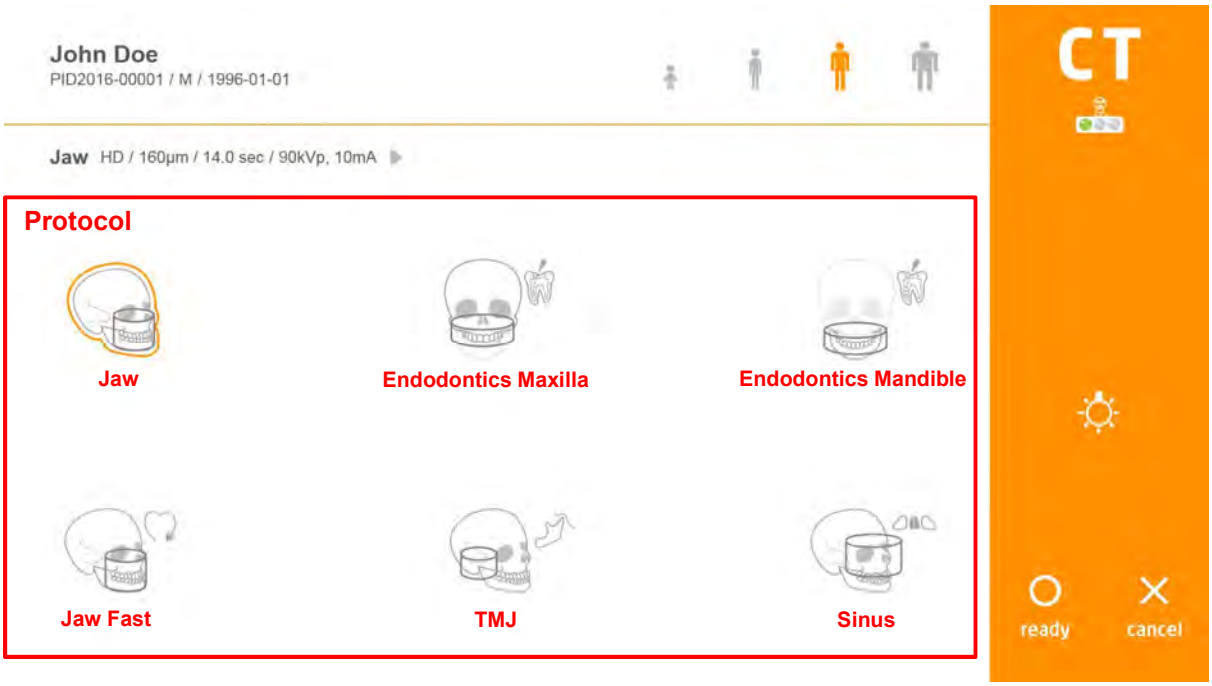


Fig 9 Acquisition: CT

Protocol

Item	Description
[Jaw]	Select Jaw protocol.
[Endodontics Maxilla]	Select Endodontics Maxilla protocol.
[Endodontics Mandible]	Select Endodontics Mandible protocol.
[Jaw Fast]	Select Jaw Fast protocol.
[TMJ]	Select TMJ protocol.
[Sinus]	Select Sinus protocol.

6.2.2.6 Confirm Image View

Image view confirmation screen, displayed after image acquisition has been completed.

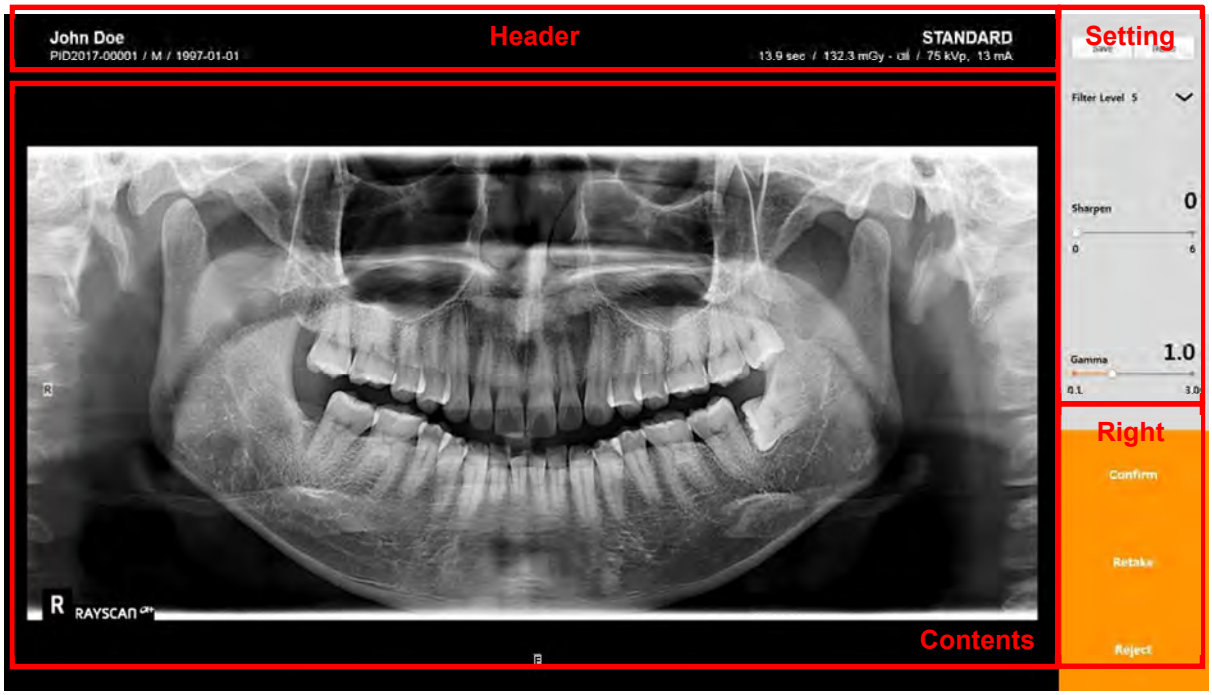


Fig 10 Confirm Image View: Panoramic

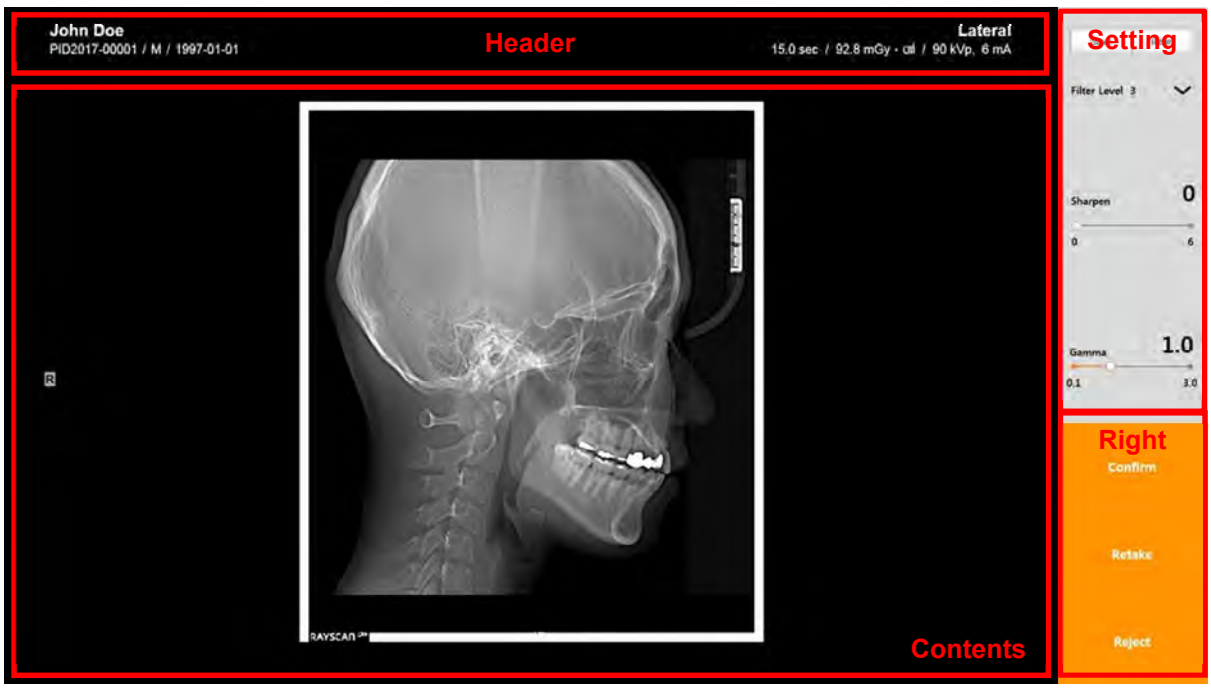


Fig 11 Confirm Image View: Cephalometric

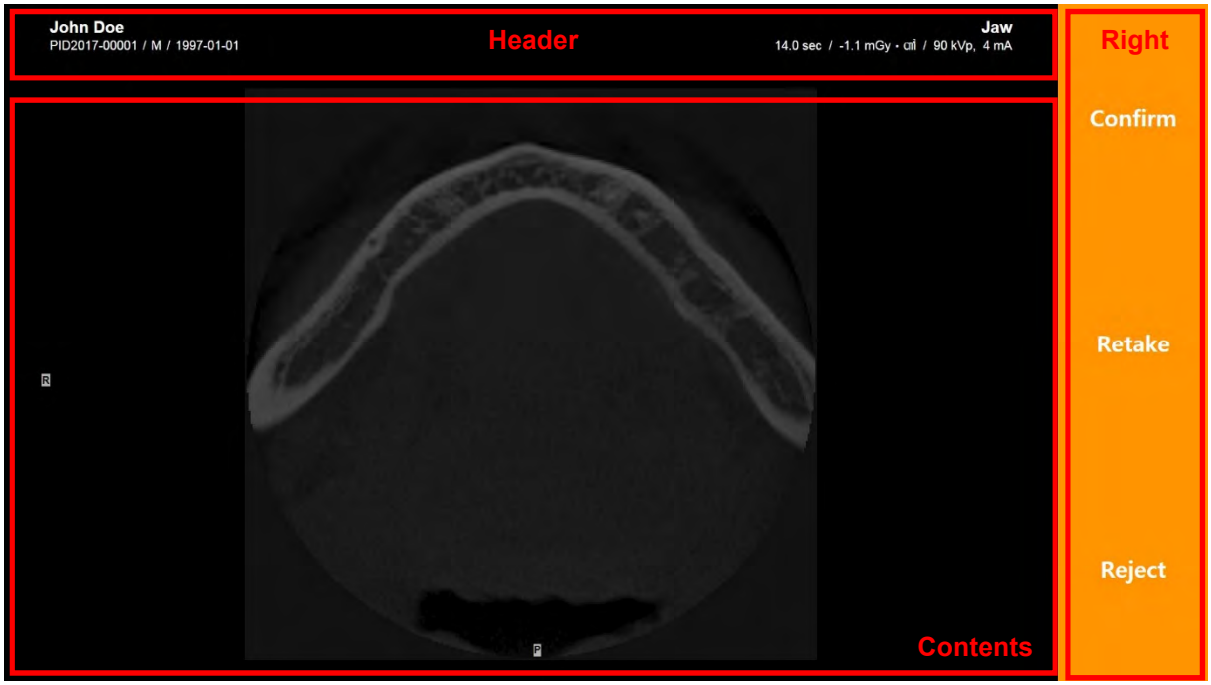


Fig 12 Confirm Image View: CT

Header

Item	Description
ID	Patient ID.
Name	Patient name
Gender	Type: M (Male), F (Female), O (Other)
Birth Date	Patient birth date
Scan Time	Scan time
Dose	X-ray Dose (mGy * cm^2)

Contents

Item	Description
Image	Completed image

Setting

Item	Description
Save	Save the set value.
Reset	Go to the initial value.
Filter Level	Adjust the filter level.
Sharpen	Adjust the sharpness.
Gamma	Adjust the gamma.

Right

Item	Description
[Confirm]	Save acquired image to the server on confirmation status and go to MWL screen. Scanned image is automatically sent to Auto Routing destination. For detailed description, refer to paragraph 6.3 Review.
[Retake]	Save acquired image to the server on reject status and go to Imaging Setup Screen for acquiring image again.
[Reject]	Save acquired image to the server on reject status and go to MWL screen. Scanned image does not go through Auto Routing procedure. For detailed description, refer to paragraph 6.3 Review. To confirm the rejected image, refer to paragraph 6.3.6 Accept.

Note	Reject image is not displayed on imaging software. You can change reject status to confirmation at Review tab.

6.2.2.7 Panoramic TMJ Acquisition

Use TMJ protocol is for Temporomandibular Joint Disorders and Malocclusion. On 2-View, the operator can select either Open mouth or Close mouth. However, both scanning options can be used on 4-View.

Fig 13 TMJ Open/Close

On 4-View option, scan 2 times continuously and the results are in 1 image view as ‘Fig 15’.

2-View scan: On TMJ Select screen (Fig 13), select either Open or Close to scan and the result image is displayed as ‘Fig 14’.

4-View scan: On TMJ Select screen (Fig 13), select 4-View option and scan Close images first. As soon as the scan is finished, the result image pops-up (Fig 14). Click [Confirm] to scan Open images as following. After all the scans, the finial image is displayed in 1 image view ‘Fig 15’.

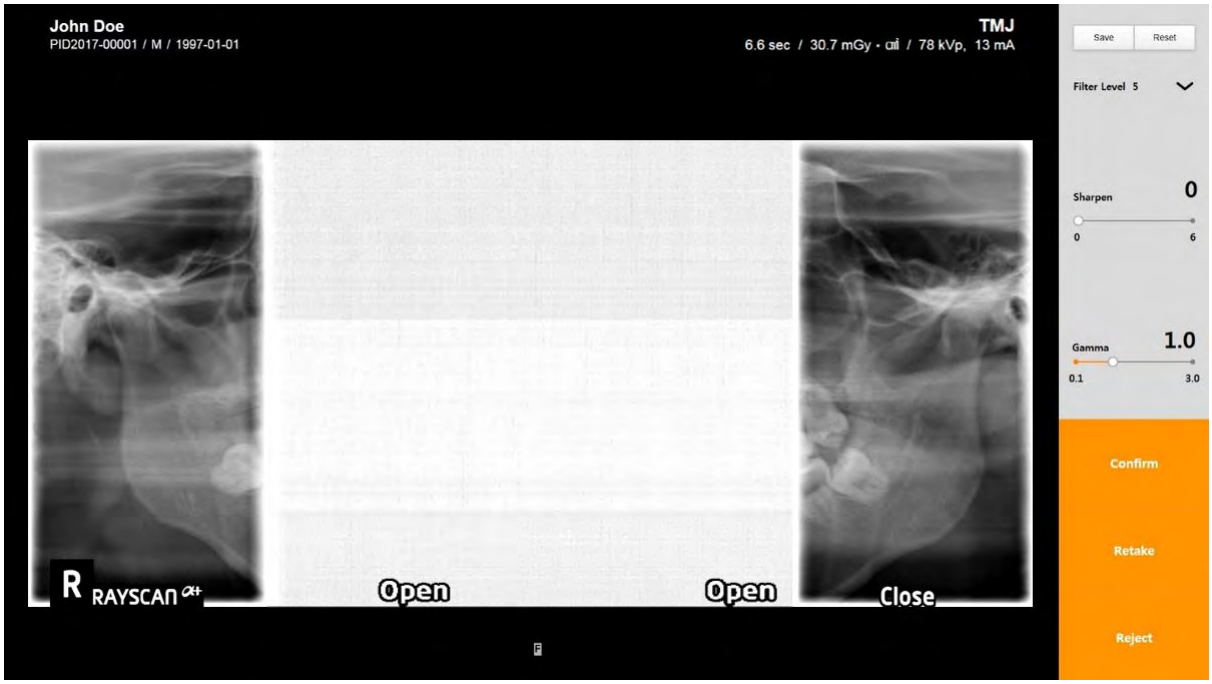


Fig 14 TMJ 2-View

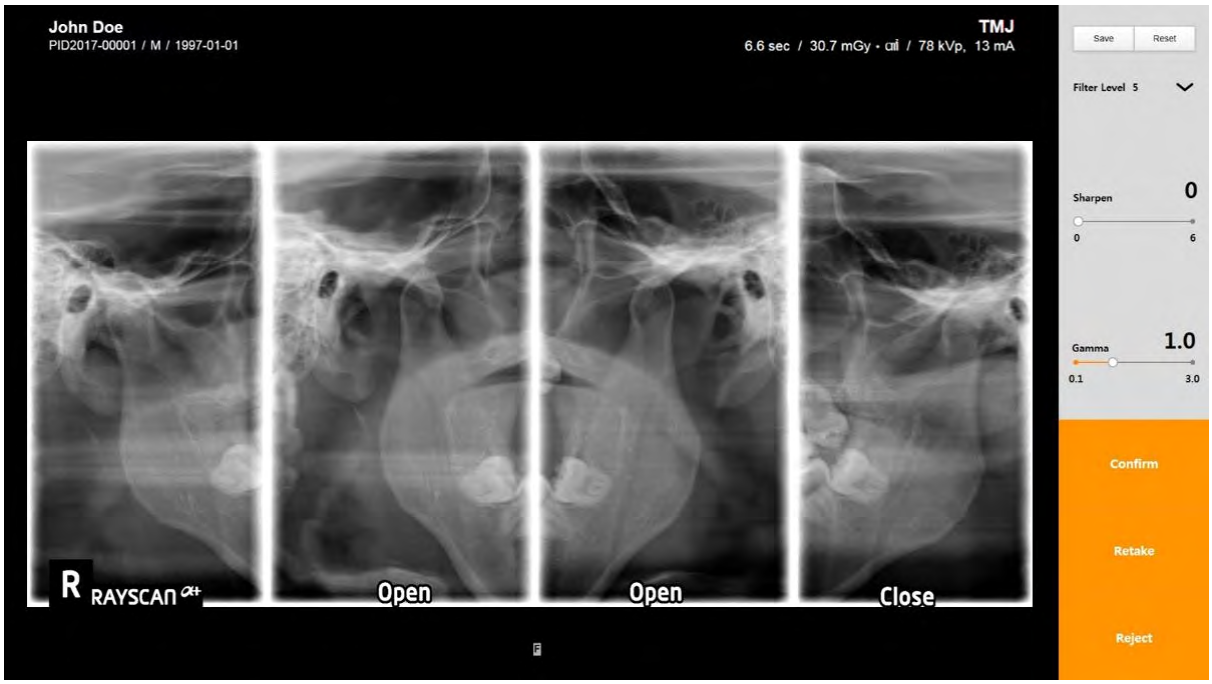


Fig 15 TMJ 4-View

6.2.3 Create Modality Worklist

Click [New] button on MWL tab to make new MWL. Create Modality Worklist window displays as below figure.

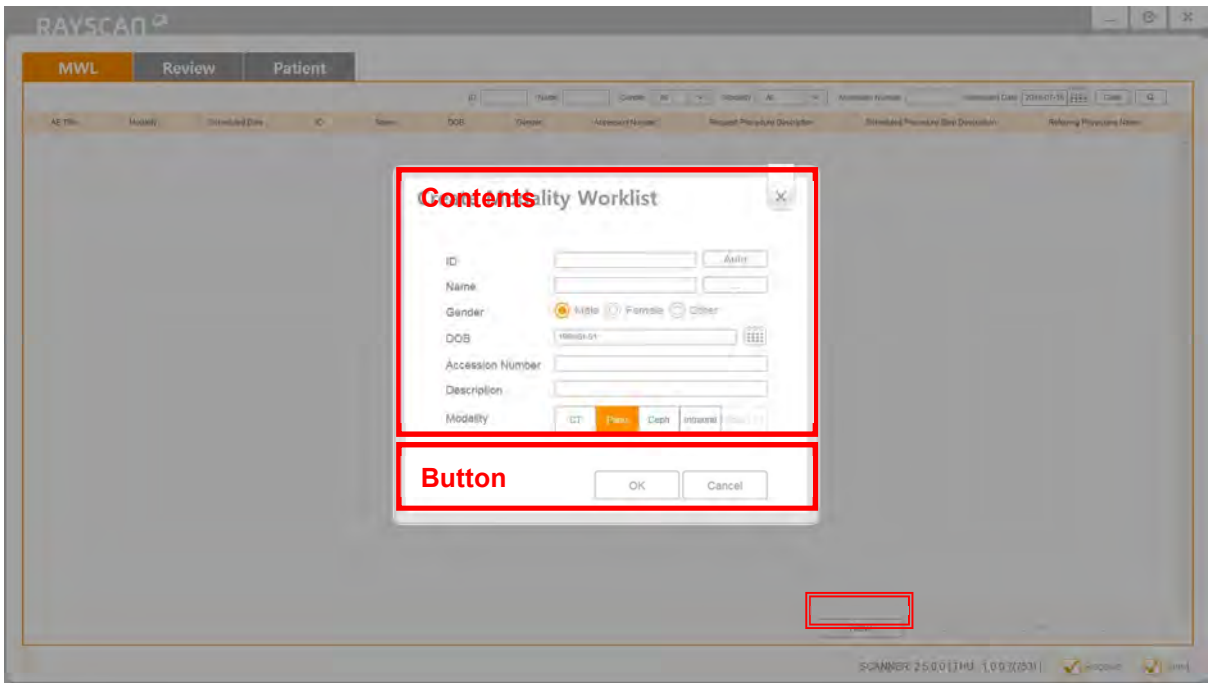
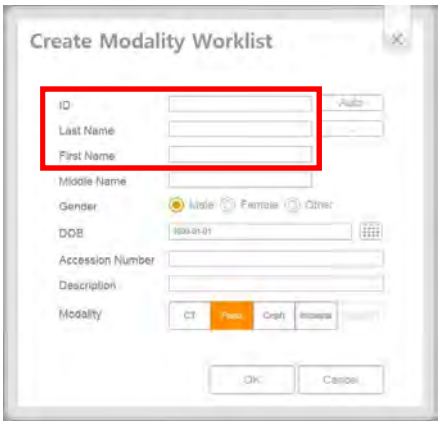
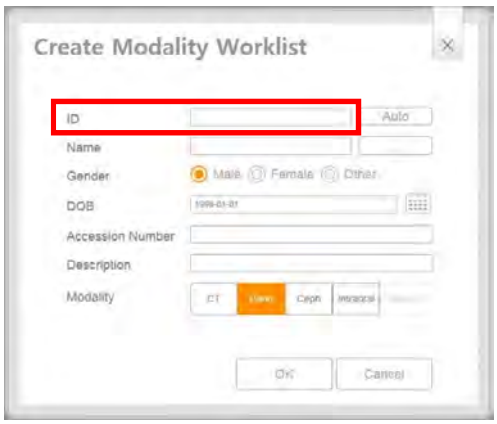


Fig 16 Create Modality Worklist

Patient name displays 2 type, see below figure.





Contents

Item	Description
ID	Input Criteria: Fewer than 20 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period) are available for input.

[Auto]	Patient ID Auto Create Click to create patient ID according to the following auto-create rules. Auto Create Format: PID<Current Year(4 digits)>-<Five Digit Number> (Example: PID2011-00001)
Name	Input Criteria: Fewer than 50 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), “,” (comma), blank characters are available for input. Enter part of the patient’s name and press the [Enter] key, after which the Search Patient pop-up screen will appear.
[…]	Patient name search Select the name of the patient from the Patient name list that appears in the Search Patient pop-up screen. When you select a patient name from the list, the patient's information will be filled in automatically.
Gender	Type: Male (Default), Female, Other (example: Emergency)
Birth Date	Insert correct date of birth. (Patients aged 9 and below are categorized as children.)
[Calendar]	Click to display calendar for date selection. Following date selection calendar disappears automatically and selected date is displayed in the text box.
Accession Number	Input Criteria: Fewer than 16 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period) are available for input.
Study Description	Input Criteria: Fewer than 64 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), blank characters are available for input.
[Modality]	Choose one option only. Selectable choice varies depending on type or device. Type: CT, Pano, Ceph, Intraoral

Button

Item	Description
[OK]	Click to close the pop-up window and create the MWL.
[Cancel]	Click to cancel created MWL process. Close pop-up window and returns to the MWL screen.

6.2.4 MWL Modify

Select MWL and click [Modify] button. Modify Modality Worklist window displays as below figure.

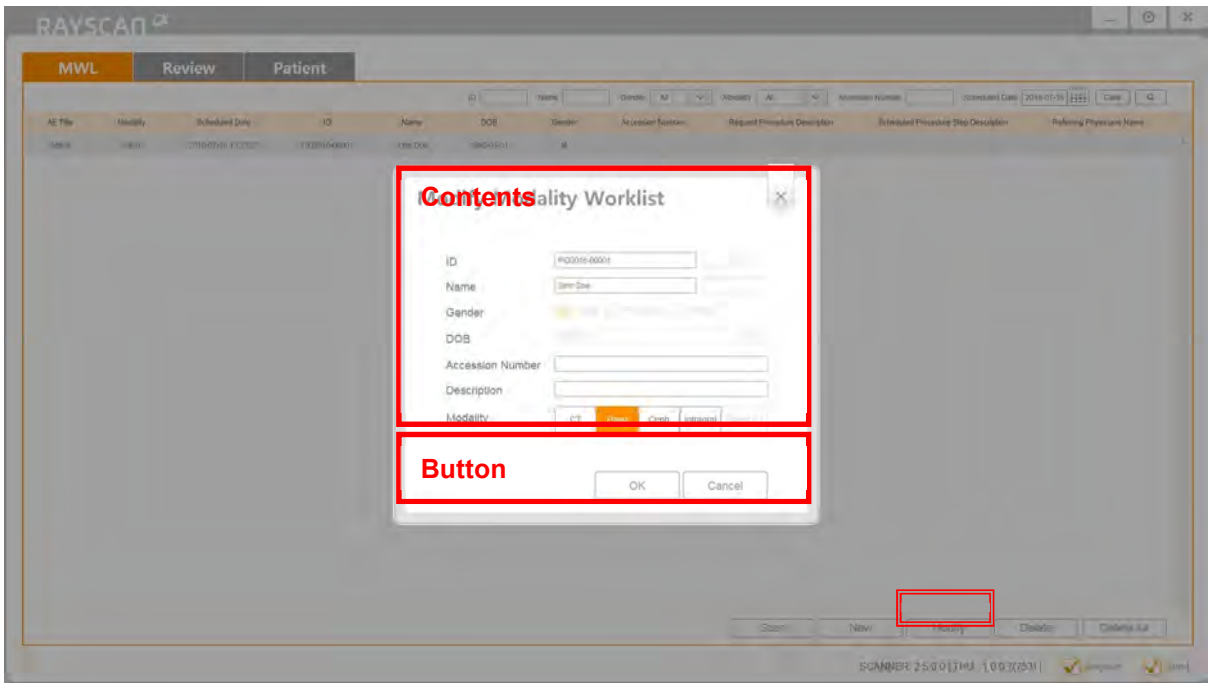
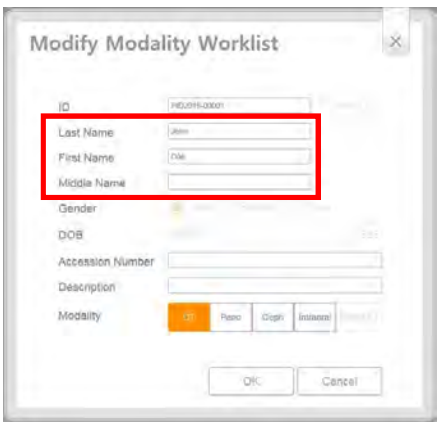
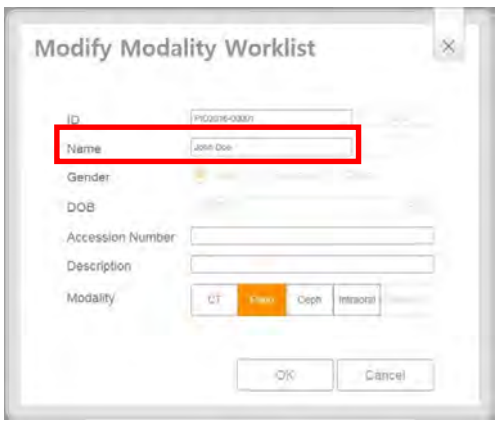


Fig 17 MWL Modify

Patient name displays 2 type, see below figure.





Contents

Item	Description
ID	Modification not permitted.
[Auto]	Patient ID modification is not allowed therefore remains inactive.
Name	Modification not permitted.
Gender	Modification not permitted.
Birth Date	Modification not permitted.
[Calendar]	Remains inactive.
Accession Number	Input Criteria: Fewer than 16 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period) are available for input.
Study Description	Input Criteria: Fewer than 64 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), blank characters are available for input.
[Modality]	Choose one option only. Selectable choice varies depending on type or device. Type: CT, Pano, Ceph, Intraoral

Button

Item	Description
[OK]	Click to modify the selected MWL information. Delete Pop-up window is closed and MWL is updated.
[Cancel]	Click to cancel the MWL modify process. Delete Pop-up window is closed and returns to the MWL screen.

6.2.5 MWL Delete

Select MWL and click [Delete] button. Delete window displays as below figure.

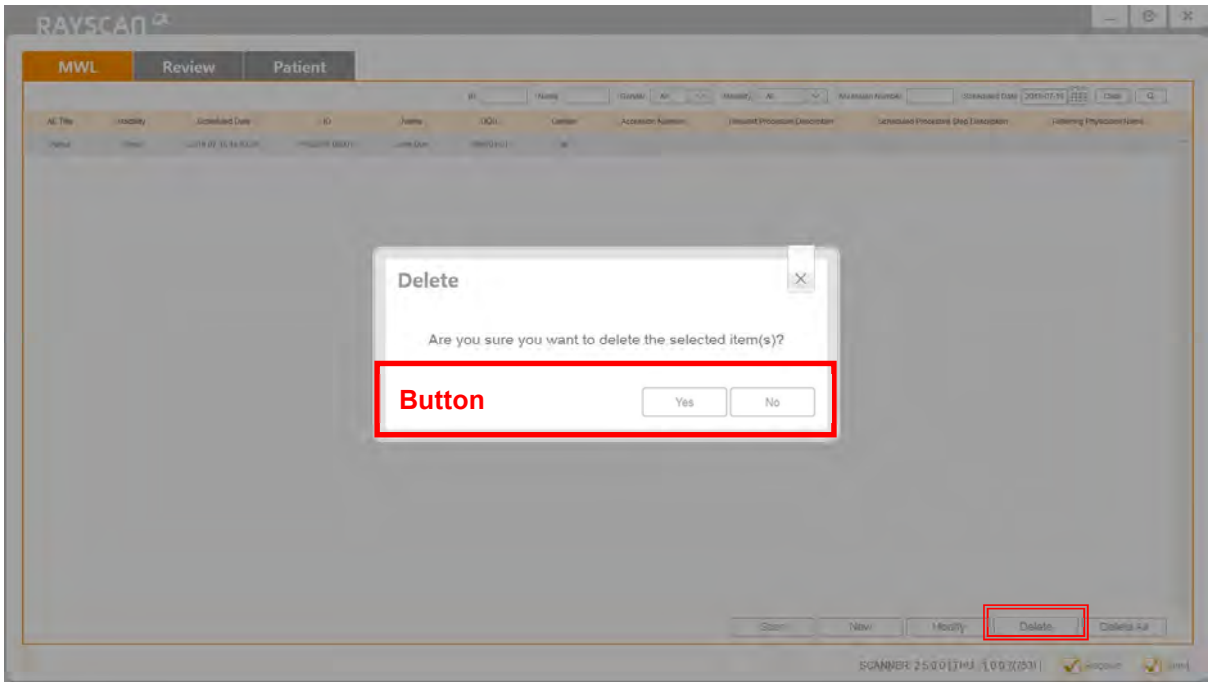


Fig 18 MWL Delete

Button

Item	Description
[Yes]	Click to delete the selected MWL information. Delete pop-up window is closed and MWL is updated.
[No]	Click to cancel the MWL delete process. Delete pop-up window is closed and returns to the MWL screen.

6.2.6 MWL Delete All

Click [Delete All] button. Delete window displays as below figure.

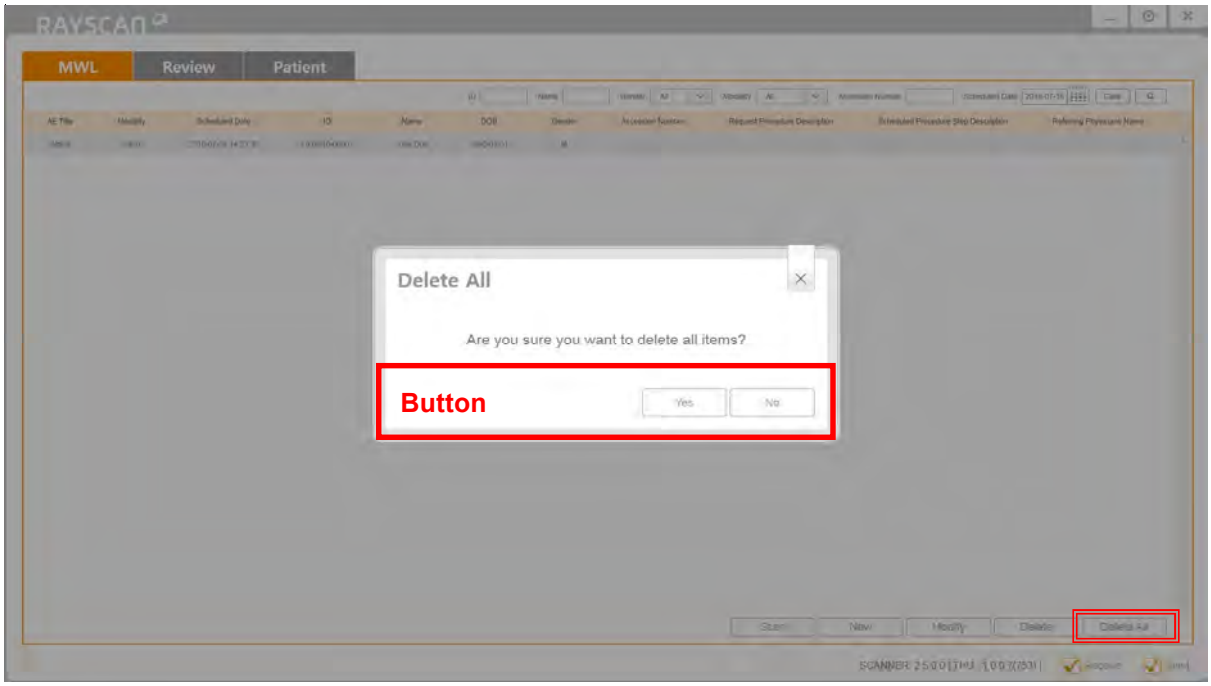


Fig 19 MWL Delete All

Button

Item	Description
[Yes]	Click to delete all the selected MWL information. Delete all pop-up window is closed and delete all requested MWL.
[No]	Click to cancel the MWL delete all process. Delete all pop-up window is closed and returns to the MWL screen.

6.3 Review

6.3.1 Review List

Review tab provides various image management function for completed acquisition. It also supports diverse search option.

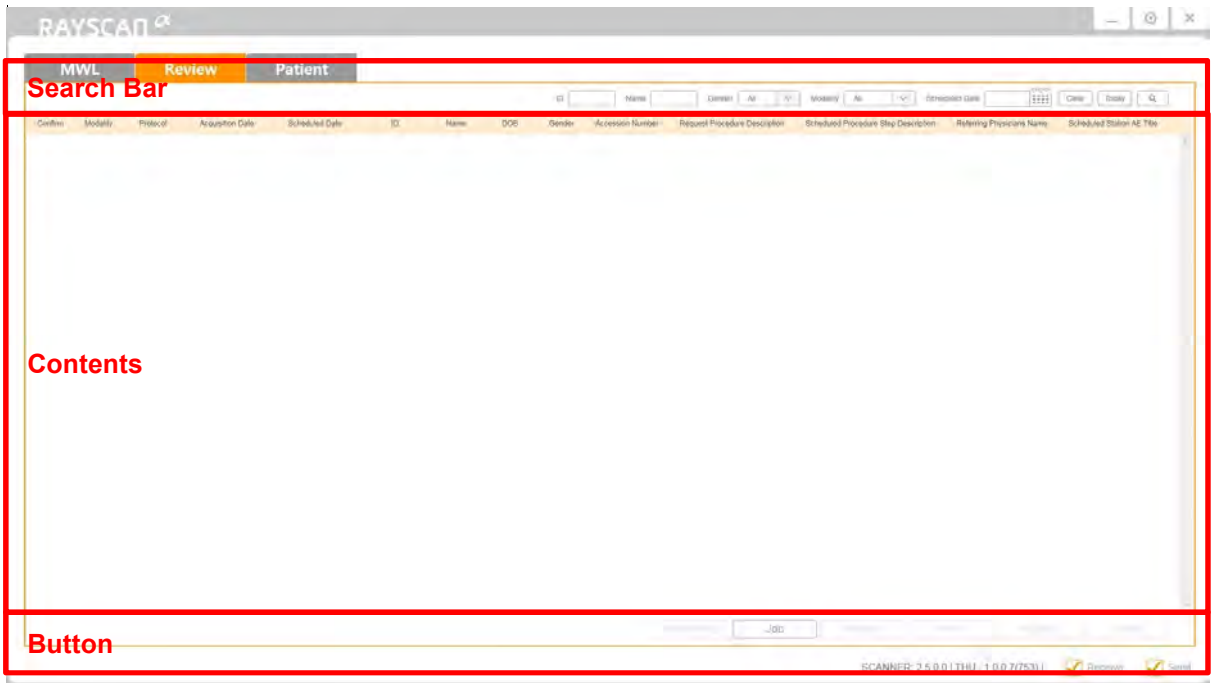


Fig 20 Review List

Search Bar

Item	Description
ID	Input Criteria: Fewer than 20 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period) are available for input.
Name	Input Criteria: Fewer than 50 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), “,” (comma), blank characters are available for input. Insert the first letter and click the “Search” button to see a list of words that begin with the selected letter. Enter the name(or first name, middle name, last name) of patient.
Gender	Type: All (Default), Male, Female, Other (Example: Emergency)
Scheduled Date	Scanning date (Default: Today’s date)
[Calendar]	Click to display calendar for date selection. After date is selected the calendar disappears automatically and date is displayed in the text box.

[Clear]	All specified search conditions and list contents are deleted.
[Today]	Searching for patients who registered today. Search for MWL entries displaying today's registration date. Tip: MWL entries registered in the past must be searched by registration date.
[Search]	Searches the Scanning Completed MWL using the specified search condition.

Contents

Item	Description
Confirm	Image Confirm Status
Modality	Type: CT, Pano, Ceph, Intraoral
Protocol	Pano: Normal, TMJ, Sinus, Bitewing, Orthogonal Ceph: Lateral, PA, SMV, Carpus, Waters, Reverse Towne CT: Jaw, Implant Surgery, Surgical Guide, Endo Treatment, CT Sinus, CT TMJ
Scheduled Date	Scanning date (Default: Today's date)
ID	Patient ID.
Name	Patient name
Birth Date	Patient birth date
Gender	Type: M (Male), F (Female), O (Other)
Accession Number	Accession number
Requested Procedure Description	Requested procedure description
Scheduled Procedure Step Description	Scheduled procedure step description
Referring Physicians Name	Referring physicians name.
Scheduled Station AE Title	Scheduled Station AE Title.

Button

[Default: Buttons are inactive.]

[Click the Review List category to activate buttons.]

Item	Description
[Create MWL]	Click to display Create MWL pop-up screen. For detailed description, refer to paragraph 6.3.2 Create MWL.
[Job]	Click to display SCU pop-up screen. For detailed description, refer to paragraph 6.3.3 Job.
[Export]	Click to display Export Image pop-up screen. For detailed description, refer to paragraph 6.3.4 Export.
[Print]	Click to display Print Image pop-up screen. For detailed description, refer to paragraph 6.3.5 Print.
[Accept]	Remains inactive until scanning is completed and MWL is selected. Click to display Confirm Image pop-up screen. For detailed description, refer to paragraph 6.3.6 Accept.
[Send]	Click to show Send DICOM pop-up screen. For detailed description, refer to paragraph 6.3.7 Send.

6.3.2 Create MWL

Click [Create MWL] button to make new MWL. Create Modality Worklist window is as below figure.

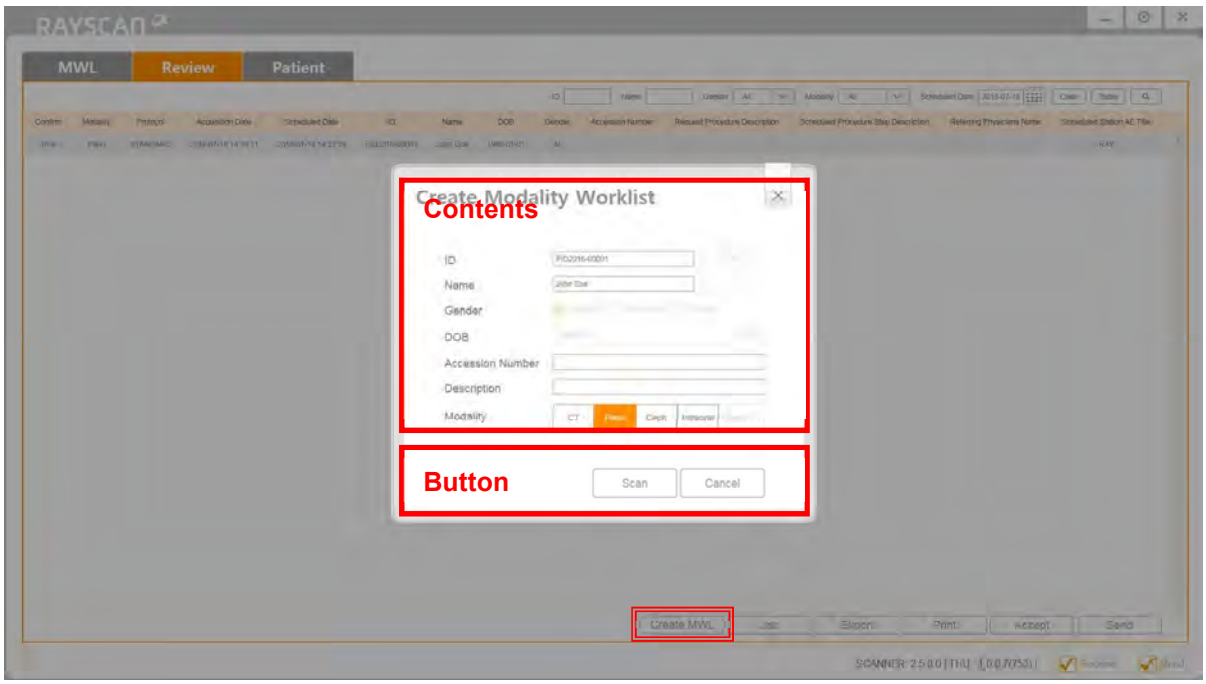
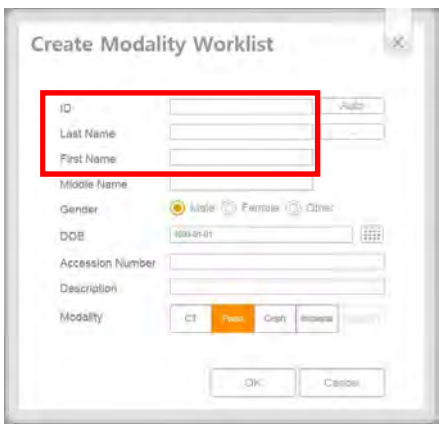
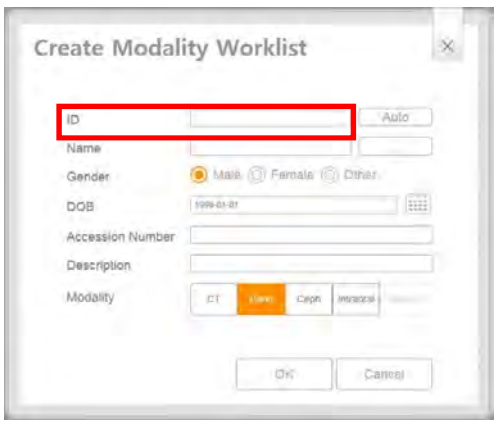


Fig 21 Create MWL

Patient name displays 2 type, see below figure.





Contents

Item	Description
ID	Modification not permitted.
[Auto]	Modification not permitted.
Name	Modification not permitted.
[…]	Patient Name Search Enter the patient's name in the Patient name field. When the patient's name is selected from the search results list, the patient's information will be filled in automatically.
Gender	Modification not permitted.
Birth Date	Modification not permitted.
[Calendar]	Modification not permitted.
Accession Number	Input Criteria: Fewer than 16 characters, English·Numeric·Chinese Characters·Japanese/Special Characters "-" (hyphen), "." (period) are available for input.
Study Description	Input Criteria: Fewer than 20 characters, English·Numeric·Chinese Characters·Japanese/Special Characters "-" (hyphen), "." (period), blank characters are available for input.
[Modality]	Choose one option only. Selectable choice varies depending on type or device. Type: CT, Pano, Ceph, Intraoral

Button

Item	Description
[Scan]	Scanning button remains inactive until MWL is selected. Click to display Acquisition screen.
[Cancel]	Click to create MWL, return to Review List screen.

6.3.3 Job

Job provides Storage SCU status monitoring and resend functions. Select item on Review tab and click [Job] button on the bottom of window, SCU window displays as below figure.

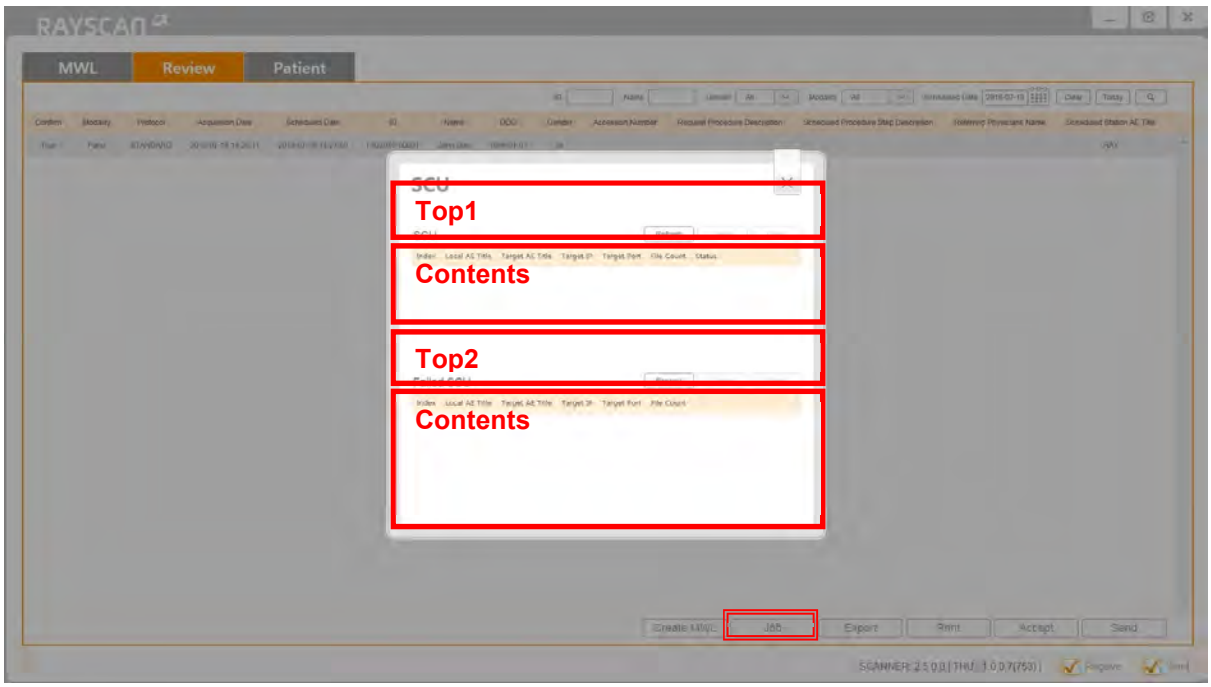


Fig 22 SCU

Top1

Item	Description
[Refresh]	Indicates sending standby status. The list will be deleted after the data is delivered in order.
[Delete]	Delete the selected item.
[Clear]	Delete all items.

Top2

Item	Description
[Resend]	Resend the failed lists.
[Delete]	Delete the selected item.
[Clear]	Delete all items.

Contents

Item	Description
SCU List	Displays the send standby and send in progress List. When relevant items are delivered in order, they are deleted from the list.
[Refresh]	Updates the SCU/Failed SCU List.
Index	Index
Local AE Title	Current RayScan AE title. Default value is set to Alpha.
Target AE Title	AE title of server set as destination.
Target IP	Target IP address
Target Port	Target port number
File Count	Number of files
Status	Send status
Failed SCU List	Displays a list of failed sends.

6.3.4 Export

Select images on Review tab and click [Export] button on the bottom of window. Export Image window displays as below figure.

Publishing supports to export images with image viewer. CD/DVD and USB provide image exporting with various image formats.

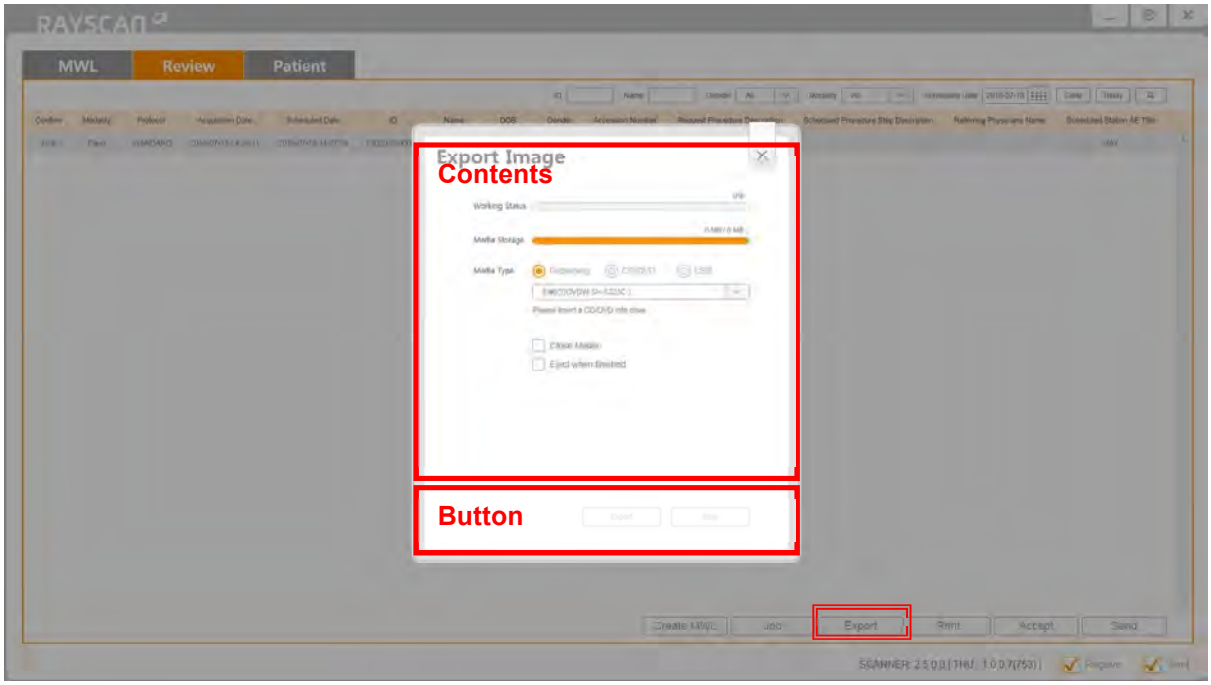


Fig 23 Export to Publishing

Contents

Item	Description
Working Status	Work progress (Unit: %)
Media Storage	Selected media capacity indicator. (Unit: MB or GB)
Media Type	Click Publishing to export images with web viewer. (example: radiology center publishing) It supports CD/DVD and USB.
Addition file(s)	Select a file for adding to the media.
[Close Media]	After the export is complete, the media will check whether or not the write prohibited. (Media Type activates at CD/DVD.)
[Eject when finished]	When Export is finished, ejects the CD automatically. (Media Type activates at CD/DVD.)

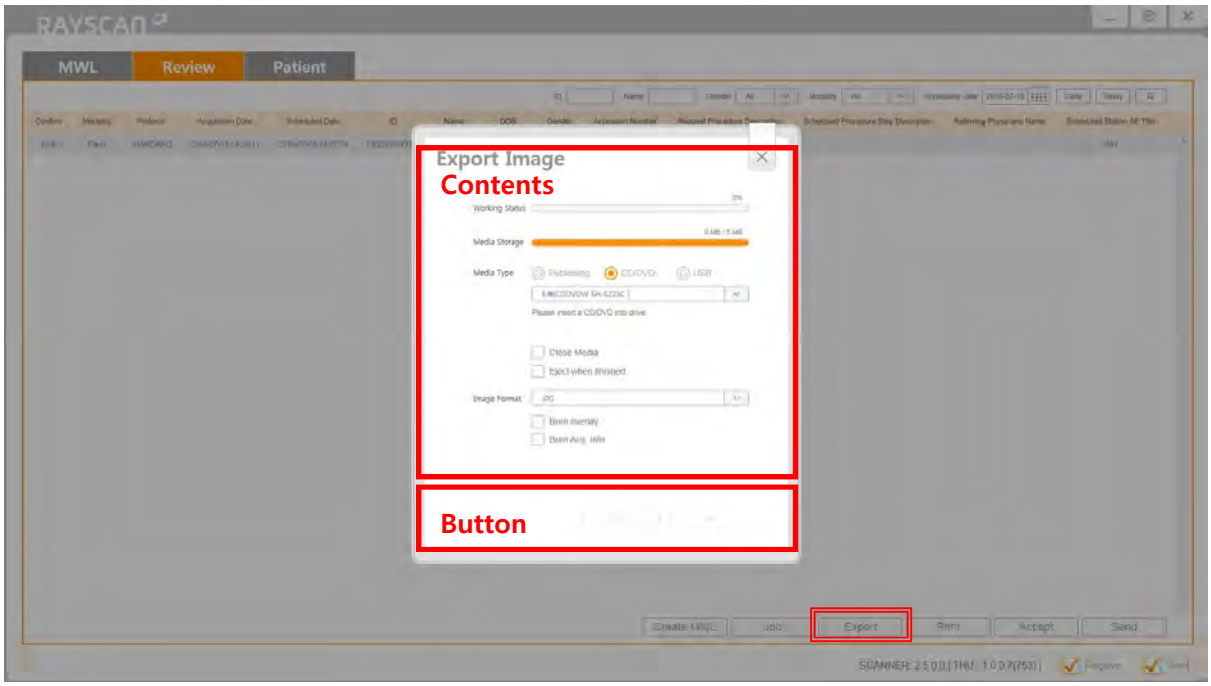


Fig 24 Export to CD/DVD

Contents

Item	Description
Working Status	Work progress (Unit: %)
Media Storage	Selected media capacity indicator. (Unit: MB or GB)
Media Type	Click CD/DVD to export images on CD/DVD. Available media list is display on the below.
Volume Label	When Media Type is CD/DVD, the volume label cannot be used repeatedly in the same media. Standard Setting Format: Ray- <Current Year(4 digits)> <Current Month (2 digits)> <Current Date (2 digits)> (Example: Ray-20110930)
[Close Media]	Following Export completion, close media (writing prohibited) Status (Media Type activates at CD/DVD.)
[Eject when finished]	When Export is finished, ejects CD automatically. (Media Type activates at CD/DVD.)
Image Format	Type: DICOM, RAW, JPG
[Burn overlay]	Image measurements (length, angle, etc.) and annotations are ready for export.
[Burn Acq.info]	Burn patient and scan information in the image then export.

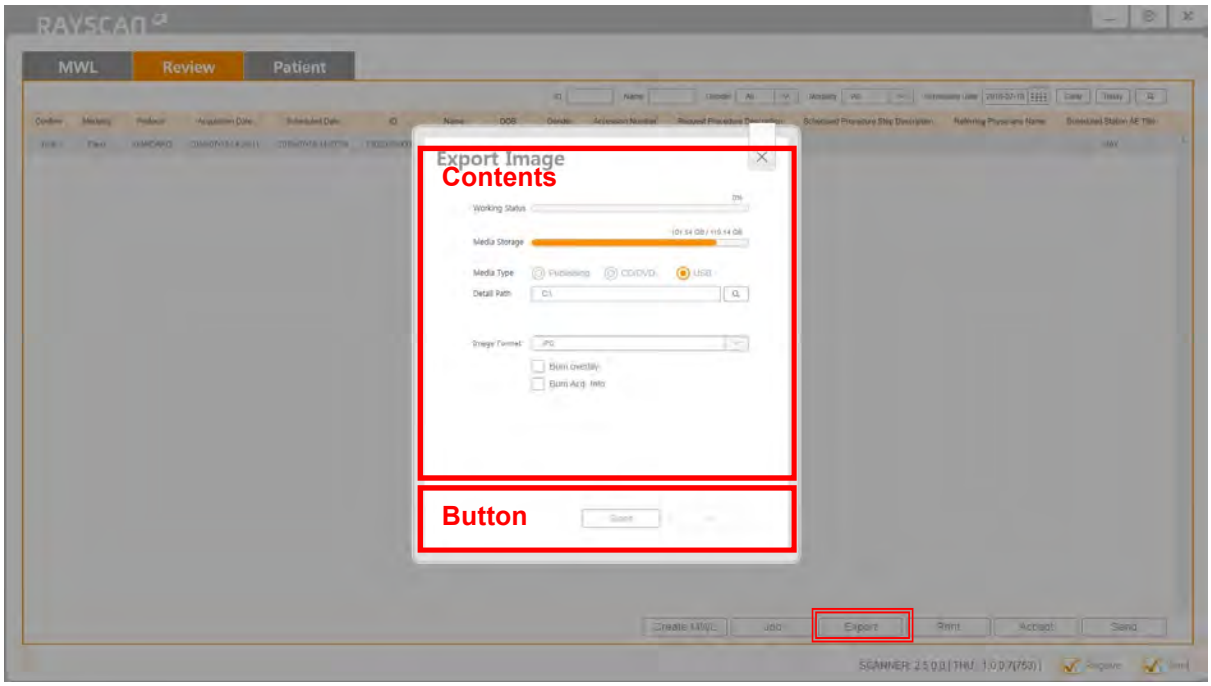


Fig 25 Export to USB

Contents

Item	Description
Working Status	Work progress (Unit: %)
Media Storage	Selected media capacity indicator (Unit: MB or GB)
Media Type	Click USB to export images to USB. It also supports to set detail path.
Detail Path	Select the path
Volume Label	Standard Setting Format: Ray- <Current Year(4 digits)> <Current Month (2 digits)> <Current Date (2 digits)> (Example: Ray-20110930)
Image Format	Type: DICOM, RAW, JPG
[Burn overlay]	Image measurements (length, angle, etc.) and annotations are ready for export.
[Burn Acq.info]	Burn patient and scan information in the image then export.

Button

[Export enabled status] [During Export – Stop enabled status]

Item	Description
[Export]	Click to start export.
[Stop]	Click to stop export process.

6.3.5 Print

6.3.5.1 DICOM Printer

Select image on Review tab and click [Print] button on the bottom of window. In case of DICOM printer, Print Image window displays as below figure.

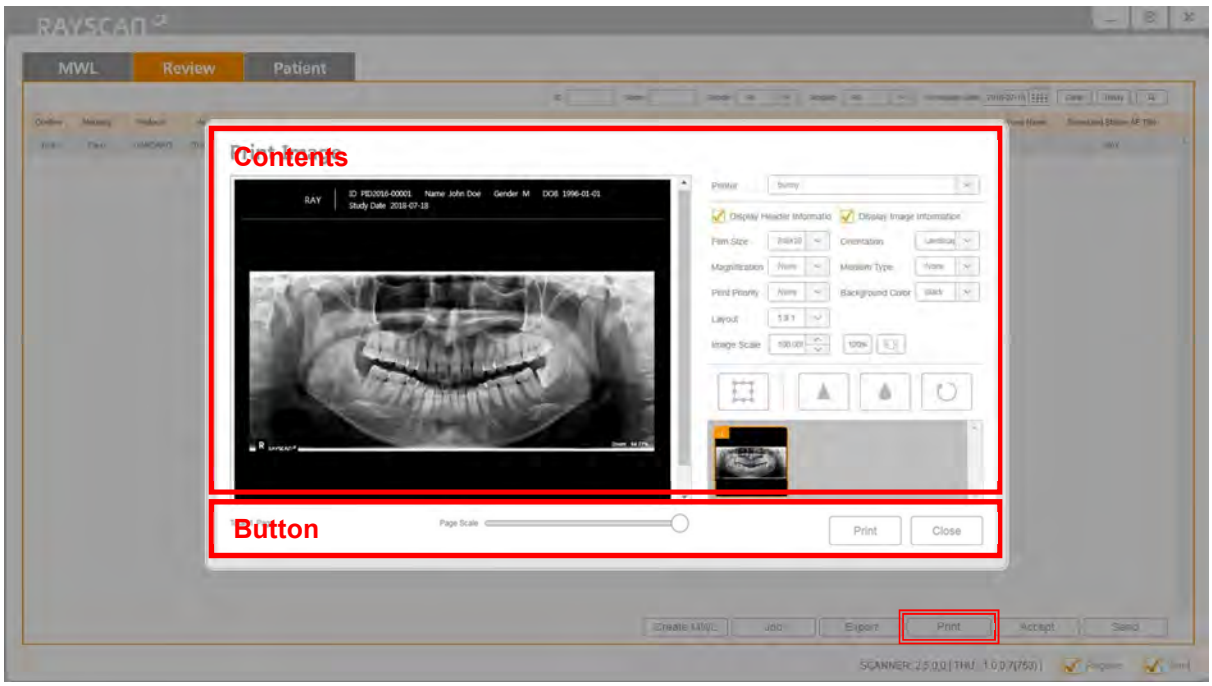


Fig 26 DICOM Print Window

Contents

Item		Description
DICOM Printer		Displays the available DICOM printer list. This item can be modified in the Config Editor.
Film Info.	Film Size	Type: None, IN8x10 , IN8_5x11, IN10x12, IN10x14, IN11x14, IN11x17, IN14x14, IN14x17, CM24x24, CM24x30
	Orientation	Type: Portrait, Landscape
	Magnification	Type: None, Replicate, Bilinear, Cubic
	Medium Type	Type: None, Paper, Clear Film, Blue Film, Mammo Clear Film, Mammo Blue Film
	Print Priority	Type: None, High, Medium, Low
	Background	Type: Black, White
	Image Scale	Fit on, 10-200%
	Layout	Select from minimum 1x1 to maximum 7x7 Default setting: 3x3

Button

Item	Description
[Page Scale] Slide	Page magnification
[Print]	Print start
[Close]	Return to previous window

6.3.5.2 Paper Printer

Select image on Review tab and click [Print] button on the bottom of window. In case of general printer, Print Image window displays as below figure.

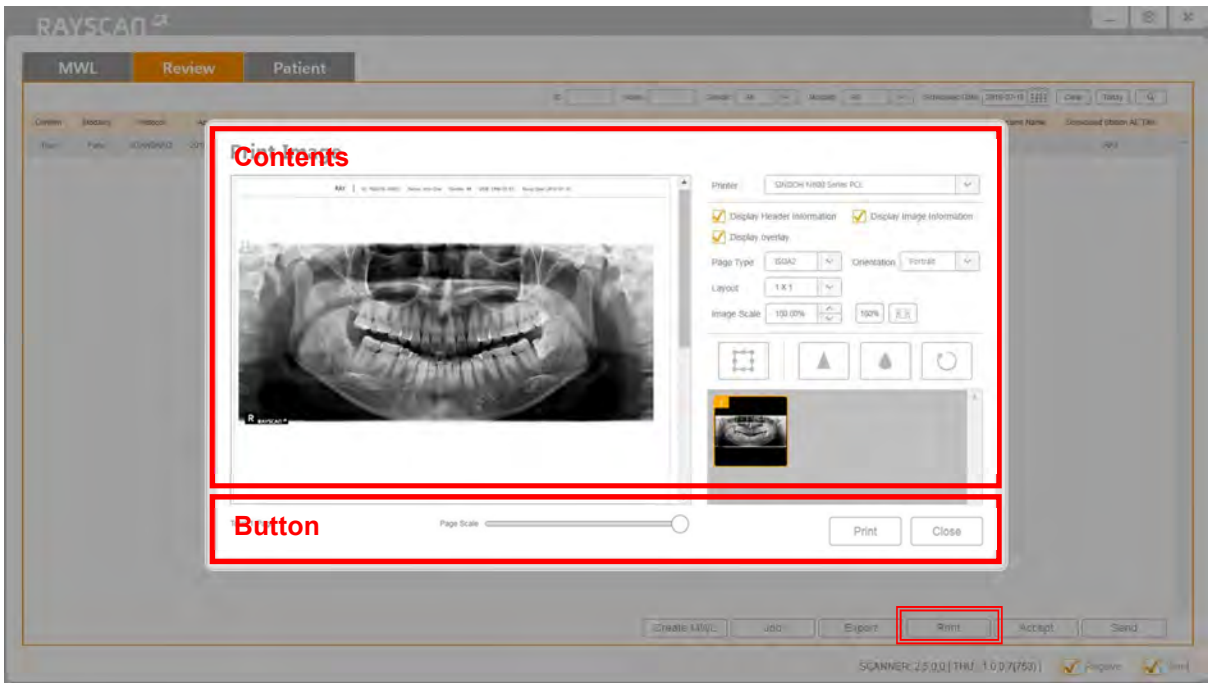


Fig 27 Paper Print Window

Contents

Item		Description
Printer		Displays the available normal printer and DICOM printer list. This item can be modified to Config Editor.
Page Info.	Page Type	Type: ISOA2, ISOA3, ISOA4, ISOA5, ISOA6, JISB4, JISB5, JISB6
	Orientation	Type: Portrait, Landscape
	Image Scale	Fit on, 10-200%
	Layout	Select from minimum 1x1 to maximum 7x7 Default setting: 3x3

Button

Item	Description
[Page Scale] Slide	Page magnification
[Print]	Print start
[Close]	Return to the previous window.

6.3.6 Accept

Select item and click [Accept] button for changing image status to [Confirm] or [Reject] buttons. Confirm Image windows as below figure.

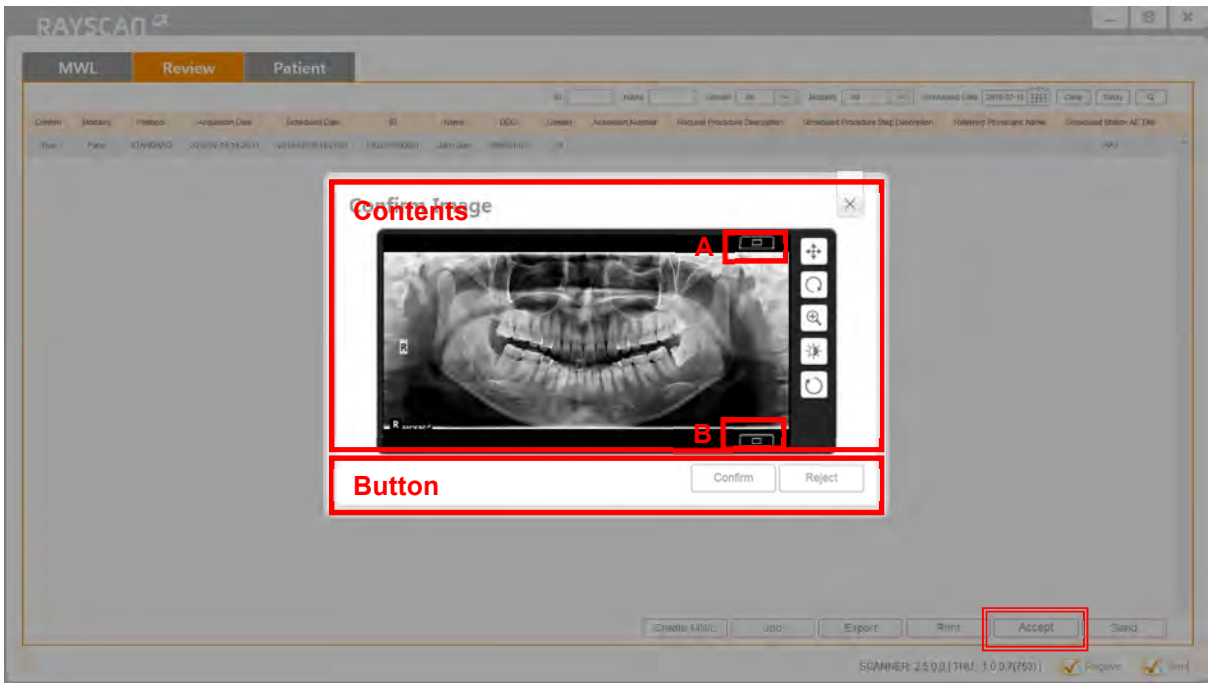


Fig 28 Confirm Image

Contents

Item	Description
A	Click the [A] button to open the ID, Name, Birthday and Scan protocol information.
B	Click the [B] button to open the Radiation exposure, Window center, Window Width, Zoom Ratio and Length Unit information.
[Move] 	Click to select the image for movement. Cursor will change when the mouse pointer is positioned over the image. Image is moved by pressing the left mouse button down and moving the mouse.
[Rotate] 	Click to rotate image. Cursor will change when mouse pointer is positioned over the image. With left mouse button pressed down, move the mouse. Image will rotate in the direction of mouse movement.

[Zoom] 	Click to enlarge/shrink image. Cursor will change when mouse pointer is positioned over the image. With left mouse pressed down, move mouse toward right side of image to shrink, left side to enlarge.
[Windowing] 	Click to adjust image windowing. Cursor will change when mouse pointer is positioned over the image. With left mouse pressed down, move higher to decrease the windowing value and move lower to increase the windowing value.
[Back] 	Ongoing process is cancelled when clicked.

Button

Item	Description
[Confirm]	Confirm patient image.
[Reject]	Reject patient image.

Note	SMARTDent only shows confirmed images.

6.3.7 Send

Select item and click [Send] button when it did not send to PACS server.

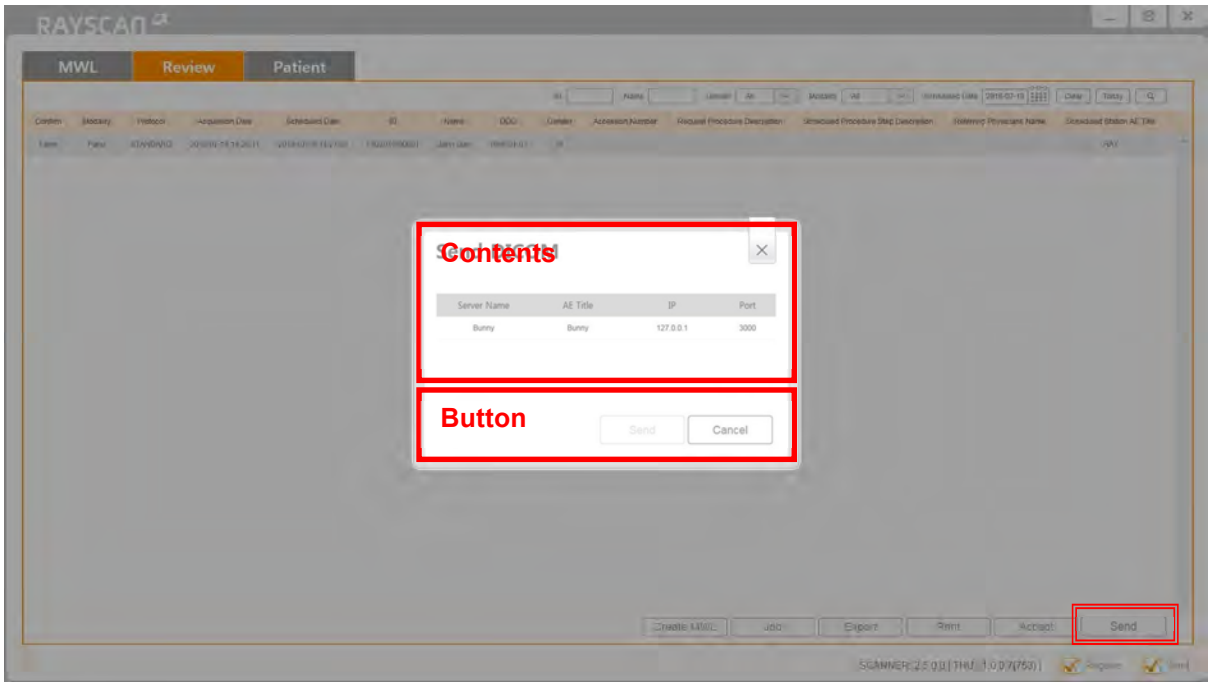


Fig 29 Send DICOM

Contents

Item	Description
Server Name	Name of the server.
AE Title	SCP server to transmit AE Title.
IP	SCP server to transmit IP address.
Port	SCP server to transmit Port number.

Button

[No selected items] [Send abled status]

Item	Description
[Send]	Send image to selected server.
[Cancel]	Cancel image send and close window.

6.4 Patient Management

6.4.1 Patient List

The Patient Information List screen (which appears when the Patient Tab from the Scanner S/W Main is selected), displays both the list of patients not having completed the scanning in MWL Tab and the scanning completed patient list from the Review Tab.

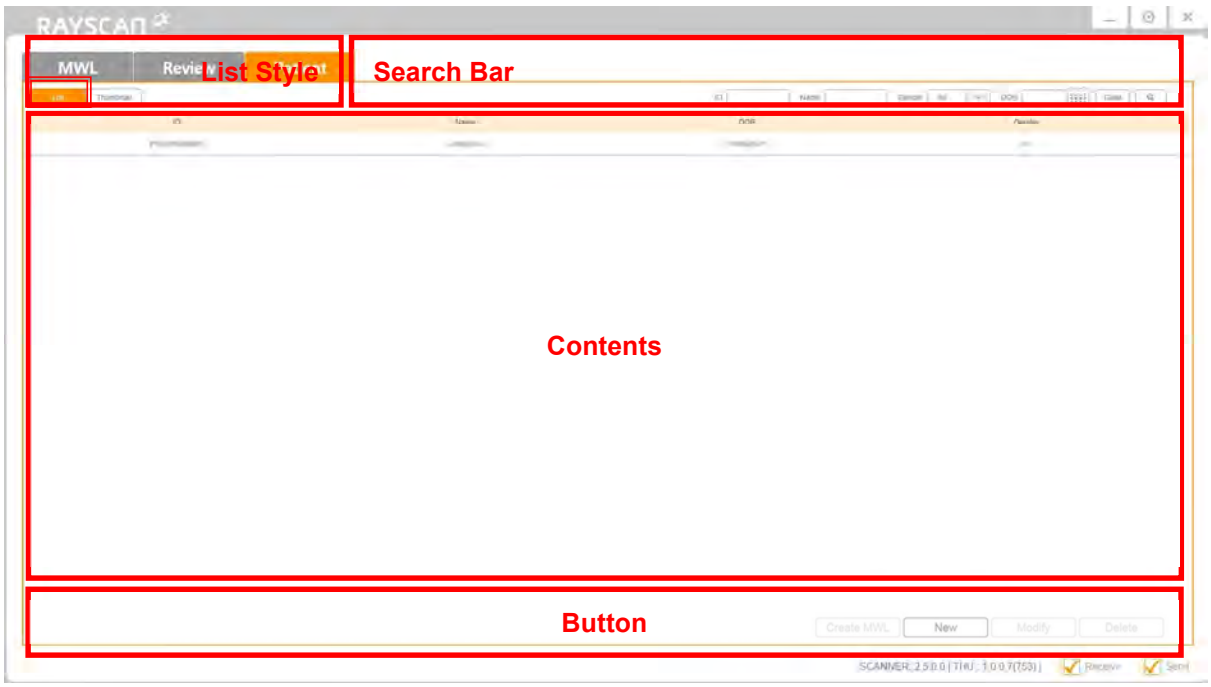


Fig 30 Patient List

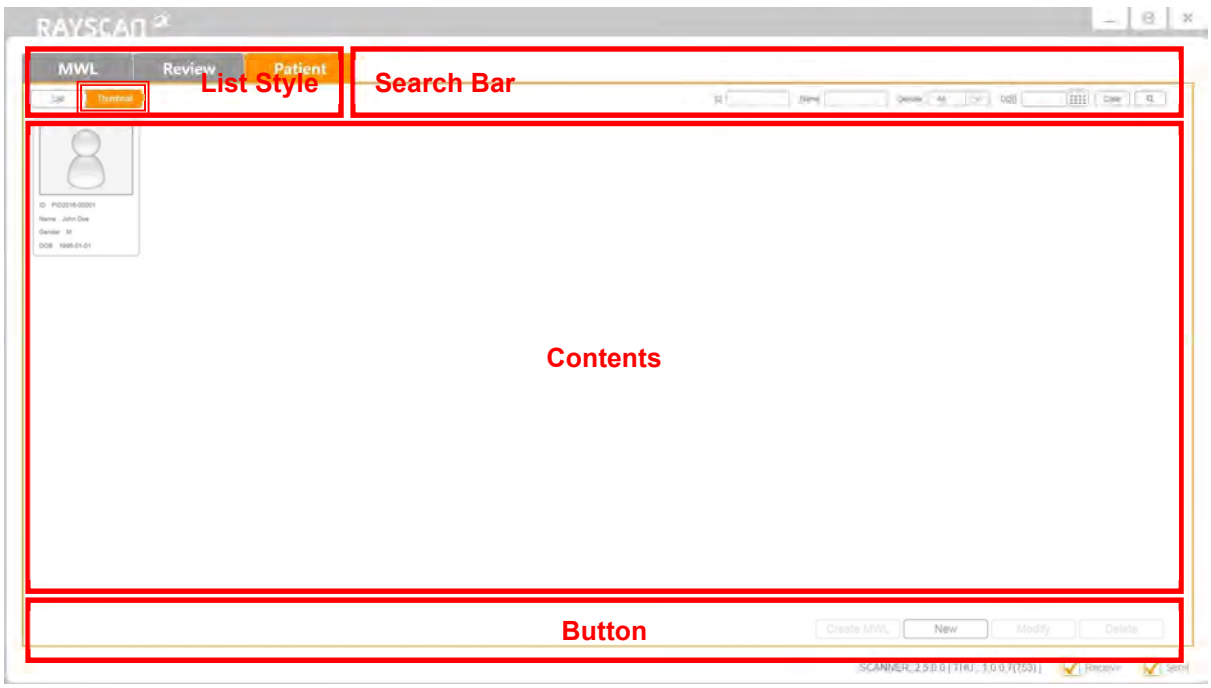


Fig 31 Patient Thumbnail List

List Style

Item	Description
[List]	Displays patient information in list format.
[Thumbnail]	Displays patient information in thumbnail format.

Search Bar

Item	Description
ID	Input Criteria: Fewer than 20 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period) are available for input.
Name	Input Criteria: Fewer than 50 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), “,” (comma), blank characters are available for input. Enter the name(or first name, middle name, last name) of patient.
Gender	Type: All (Default), Male, Female, Other
Birth Date	Patient birth date
[Clear]	Clear the selected search condition and refresh the selection.
[Search]	Search the lists with the selected condition.

Contents

Item	Description
ID	Patient ID.
Name	Patient name
Birth Date	Patient birth date
Gender	Type: M (Male), F (Female), O (Other) (example: Emergency)
Portrait	Show the patient’s picture. If patient’s picture is not in the system, standard image will be displayed.

Button

Item	Description
[Create MWL]	Click to display Create MWL pop-up screen. For detailed description, refer to paragraph 6.3.2 Create MWL
[New]	Patient information add button. For detailed description, refer to paragraph 6.4.2 New Patient Registration
[Modify]	Patient information modify button. For detailed description, refer to paragraph 6.4.3 Patient Information Modify
[Delete]	Patient information delete button. For detailed description, refer to paragraph 6.4.5 Patient Delete

6.4.2 New Patient Registration

Click [New] button on Patient tab to create new patient as below figure.

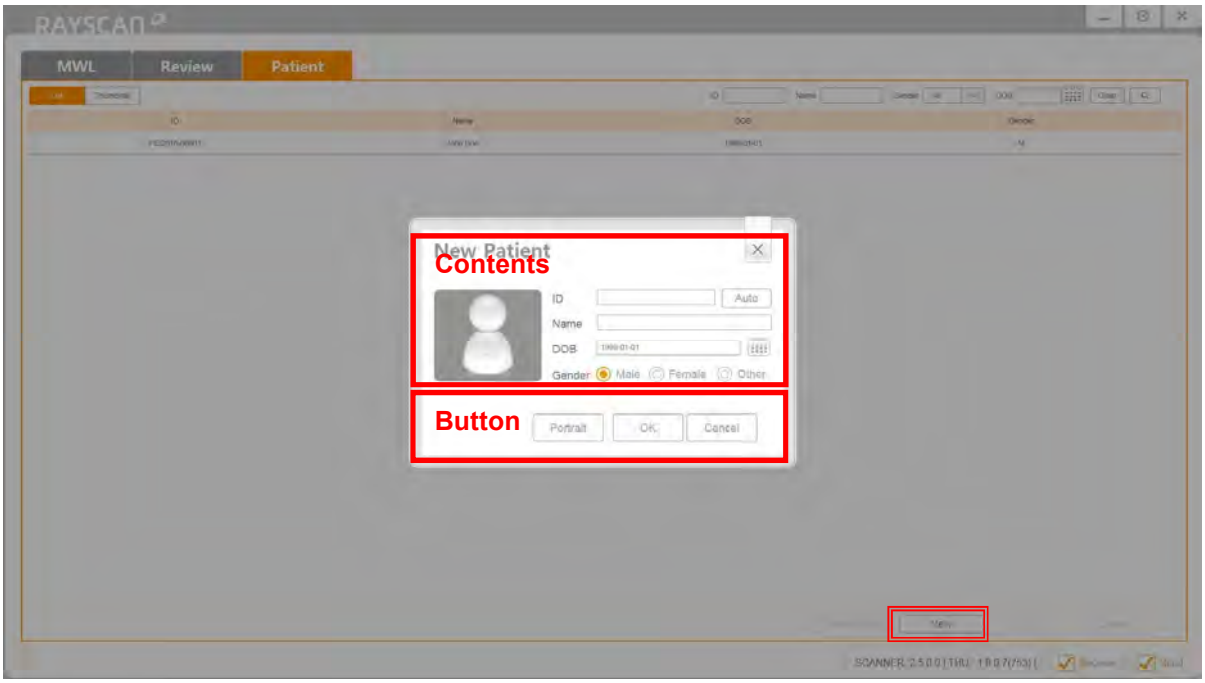


Fig 32 New Patient Registration

Patient name displays 2 type, see below figure.

Contents

Item	Description
ID	Input Criteria: Fewer than 20 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period) are available for input.
[Auto]	Patient ID Auto Create. Click to create patient ID according to the following auto-create rules. Format: PID<Current Year(4 digits)>- <Five Digit Number> (Example: PID2011-00001)

Name	Input Criteria: Fewer than 50 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), “,” (comma), blank characters are available for input.
Gender	Type: Male, Female, Other
Birth Date	Insert correct date of birth. (Patients under the age of 9 are categorized as children.)
[Calendar]	Calendar display button.

Button

Item	Description
[Portrait]	Register a picture of the patient.
[OK]	Save the registered patient information.
[Cancel]	Close the window without saving.

6.4.3 Patient Information Modify

Select patient list and click [Modify] button to change the patient information as below figure.

Note	It takes for a while when images are registered to the patient. Alert message will be displayed as Fig. 34.

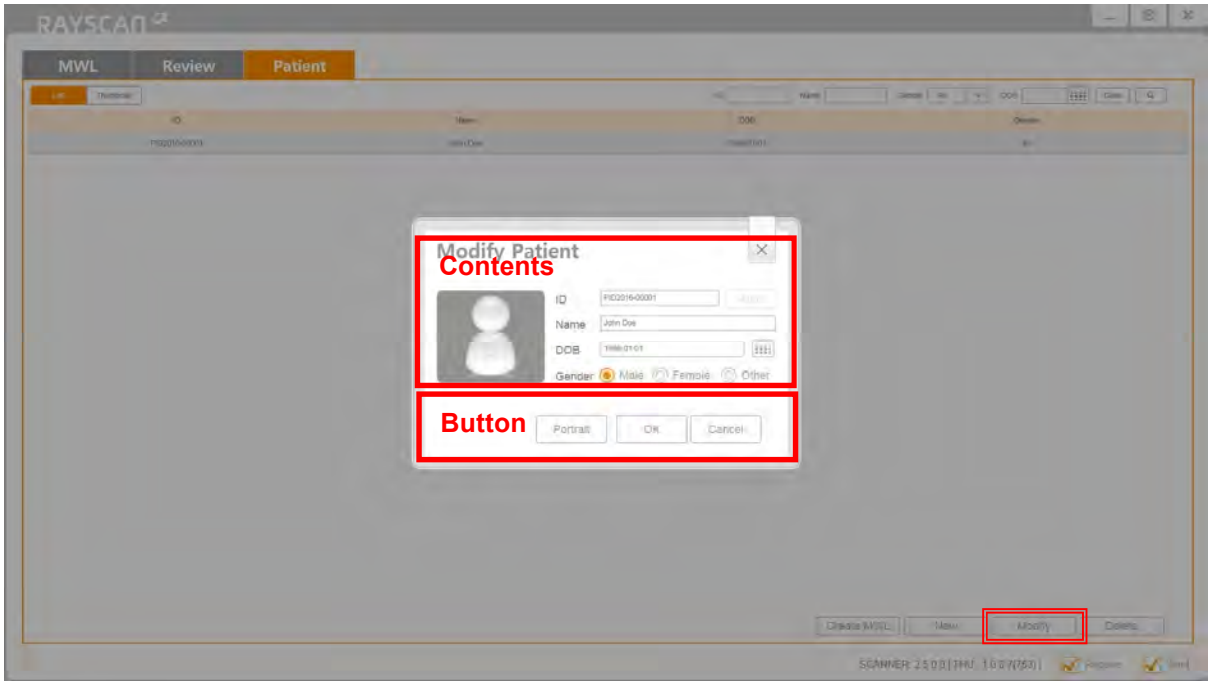
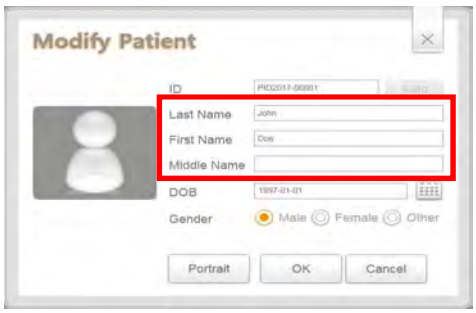


Fig 33 Modify Patient

Fig 34 Modify Alert

Patient name displays 2 type, see below figure.



Contents

Item	Description
ID	Modification not permitted.
[Auto]	Patient ID modification is not permitted. Button remains inactive.
Name	Input Criteria: Fewer than 50 characters, English·Numeric·Chinese Characters·Japanese/Special Characters “-” (hyphen), “.” (period), “,” (comma), blank characters are available for input.
Gender	Type: Male(default), Female, Other (Example: Emergency)
Birth Date	Patient birth date
[Calendar]	Calendar display button

Button

Item	Description
[Portrait]	Properties of patient image.
[OK]	Save the registered patient information.
[Cancel]	Close the window without saving.

6.4.4 Patient Photo Registration

Click [Portrait] button on the Patient Registration or Modification window. Patient Photo Registration Window as below figure.

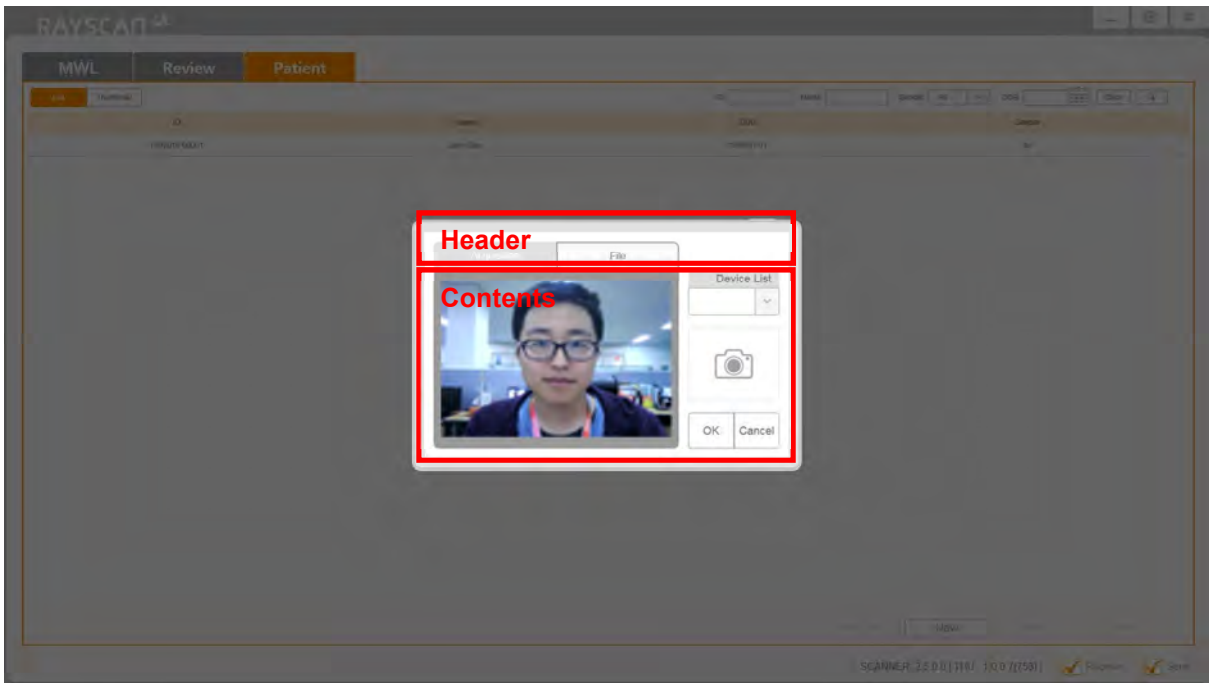


Fig 35 Patient Photo Registration Window

Header

Item	Description
Acquisition	Acquire image using system webcam.
File	Load the photo file on PC.

Contents

Item	Description
[Acquisition]	Take photo with webcam.
[File]	Store the photo file on PC.
Image View	View webcam screen or photo.
Device	Select among webcam devices. (Optional)
[Capture/Open]	Capture current window in acquisition mode. In file mode, recall images using file explorer.
[OK]	Click to close the patient photo registration screen and return to the previous screen.
[Cancel]	Click when registration of patient photo is cancelled and return to the previous screen.

6.4.5 Patient Delete

Screen displayed when [Delete] button is clicked following patient selection in the Patient List screen. From here, patients on the Patient List can be deleted.

Caution

You should be careful to delete patient. Image restore is impossible.

Click to [Delete] button. System will ask for a password.

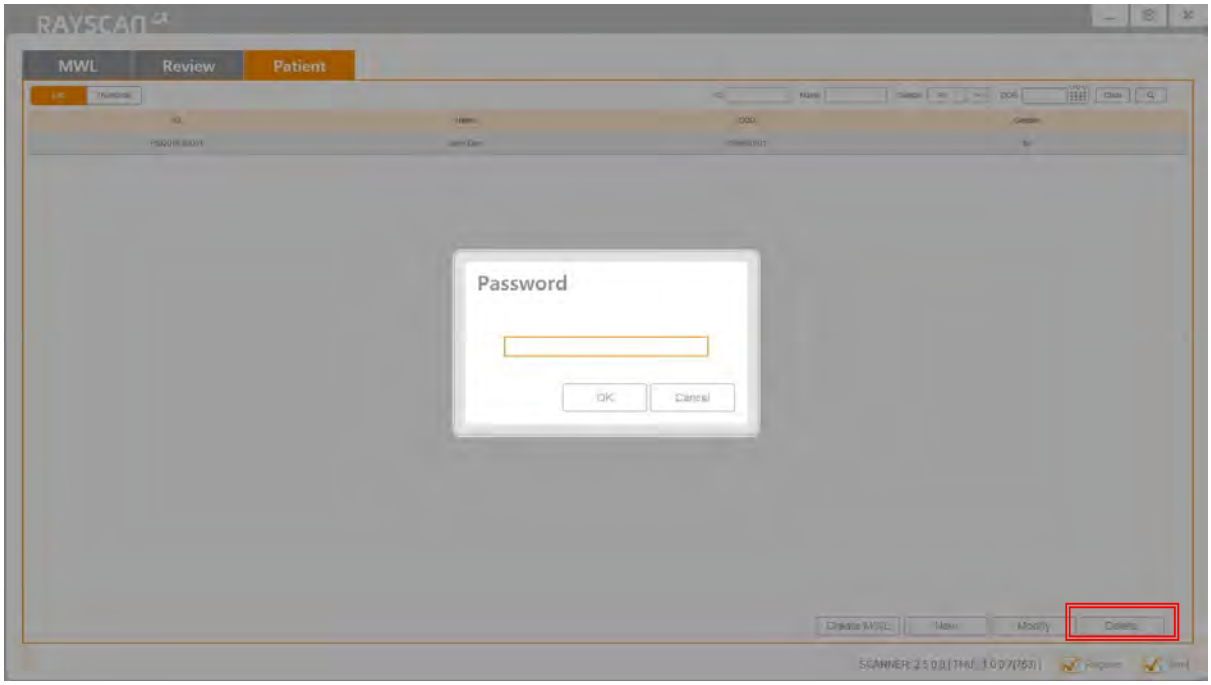


Fig 36 Patient Delete Password

Note	When you forget the password, please contact your representative for the password.

Below is the screen that appears after the correct password is supplied and Patient Information is deleted.

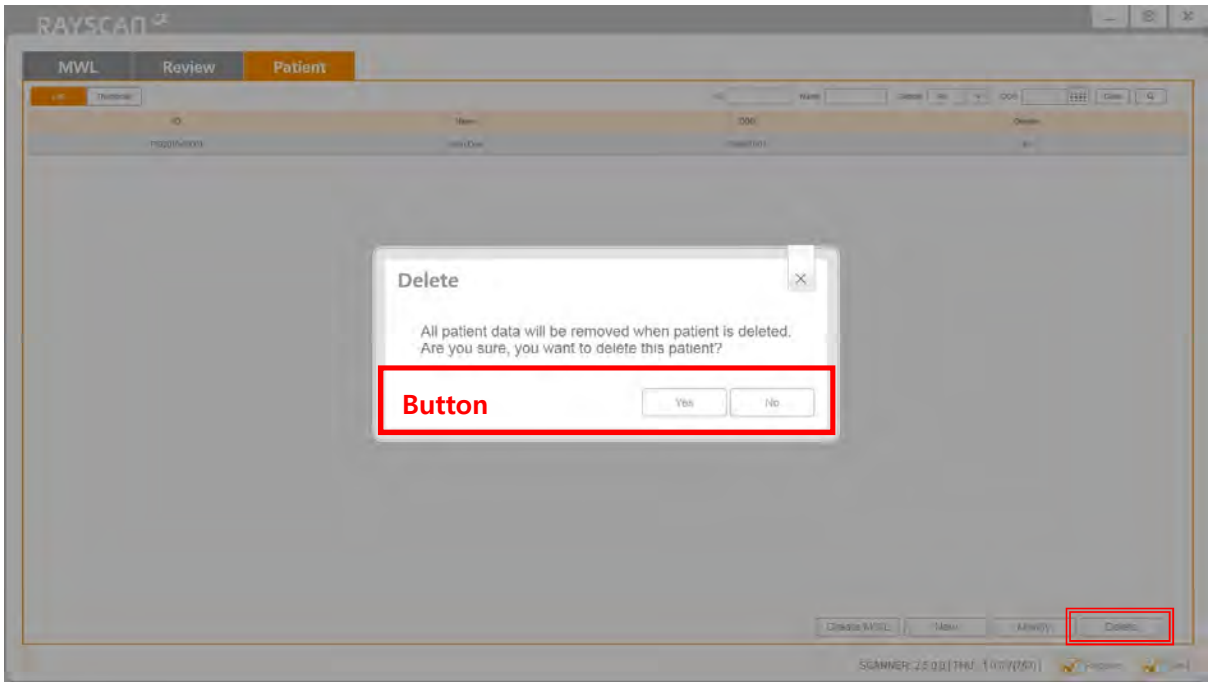


Fig 37 Patient Delete

Button

Item	Description
[Yes]	Delete all patient images and information. After delete, close the window and return to the Patient tab.
[No]	Close the window and return to the Patient tab.

6.5 Touch Monitor

6.5.1 Splash screen

The Splash screen is the touch monitor standby screen that changes to the setup screen when touched by a user. When a scanning sequence is received from the scanner, the Splash screen proceeds to the scanning screen.

Fig 38 Splash screen

6.5.2 System Operation

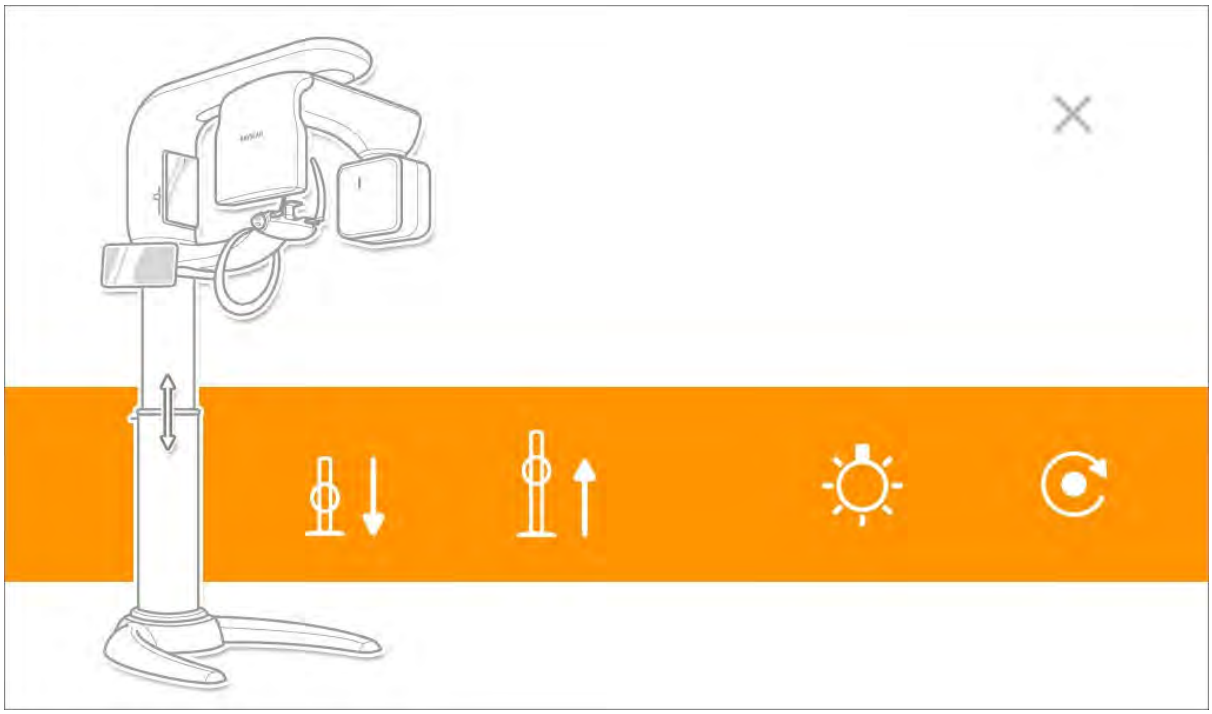


Fig 39 System Operation Setup Screen

Item	Description
[x]	Touch to close Setup screen and return to Splash screen.
[Down] 	Equipment Lift Column lower button Equipment is lowered when user maintains touch on the [Down] button.
[Up] 	Equipment Lift Column raise button Equipment raised when user maintains touch on the [Up] button.
[Lamp]	Alignment Beam ON/OFF button Touch to turn the alignment beam OFF (when turned on) and ON (when turned Off). Turns off automatically after a specified time. ON  OFF 
[Home] 	Equipment initialization button Touch to initialize the equipment.

6.5.3 Acquisition

Screens displayed when [Scan] button is clicked.

6.5.3.1 Patient Information

Before starting image acquisition, Patient Info window appears as below figure.

Please confirm the patient information.

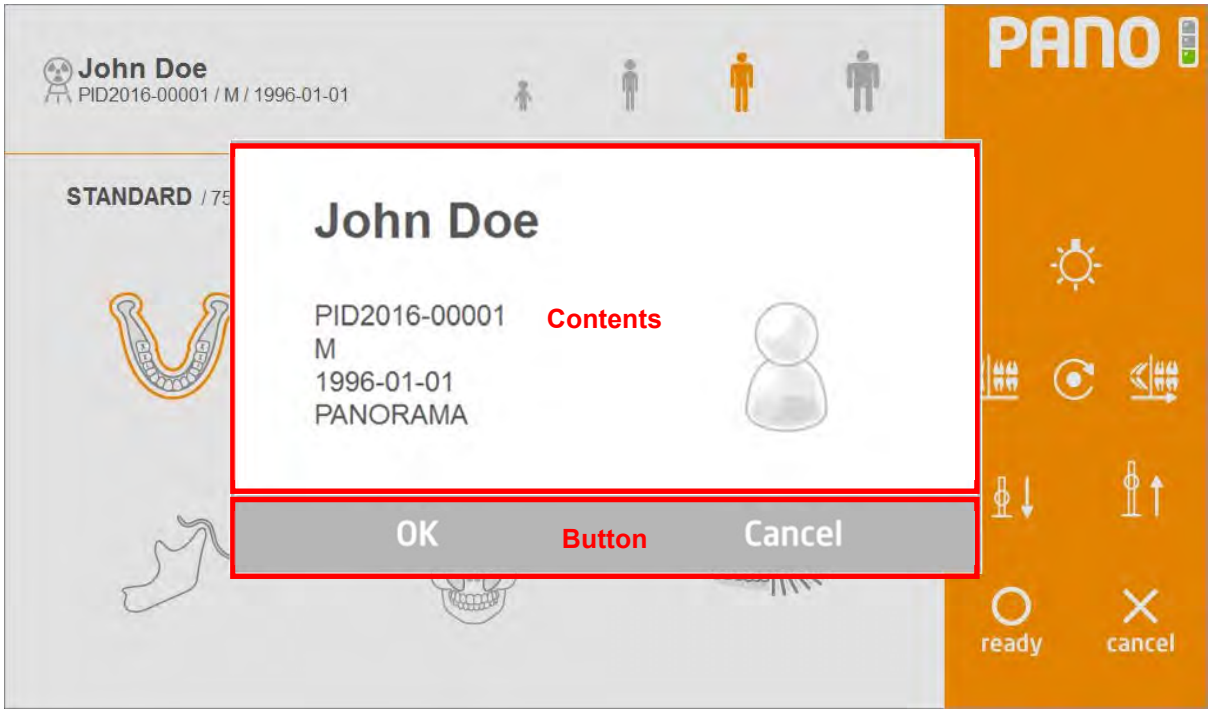


Fig 40 Patient Information

Contents

Item	Description
Portrait	Shows the patient photo when a patient photo is registered. When the photo is not registered, displays default image.
ID	Patient ID.
Name	Patient name
Gender	Type: M (Male), F (Female), O (Other)
Birth Date	Patient birth date
Modality	Type: CT, Pano, Ceph, Intraoral

Button

Item	Description
[Ok]	Confirm patient information and click if correct. Touch to close Patient Information screen and display the scanning screen.
[Cancel]	Touch if Patient Information is incorrect or procedure is cancelled. Touch to cancel scanning, close Patient Information screen and scanning screen, and return to Splash screen.

6.5.3.2 Panoramic Acquisition

Panoramic scanning setup screen.

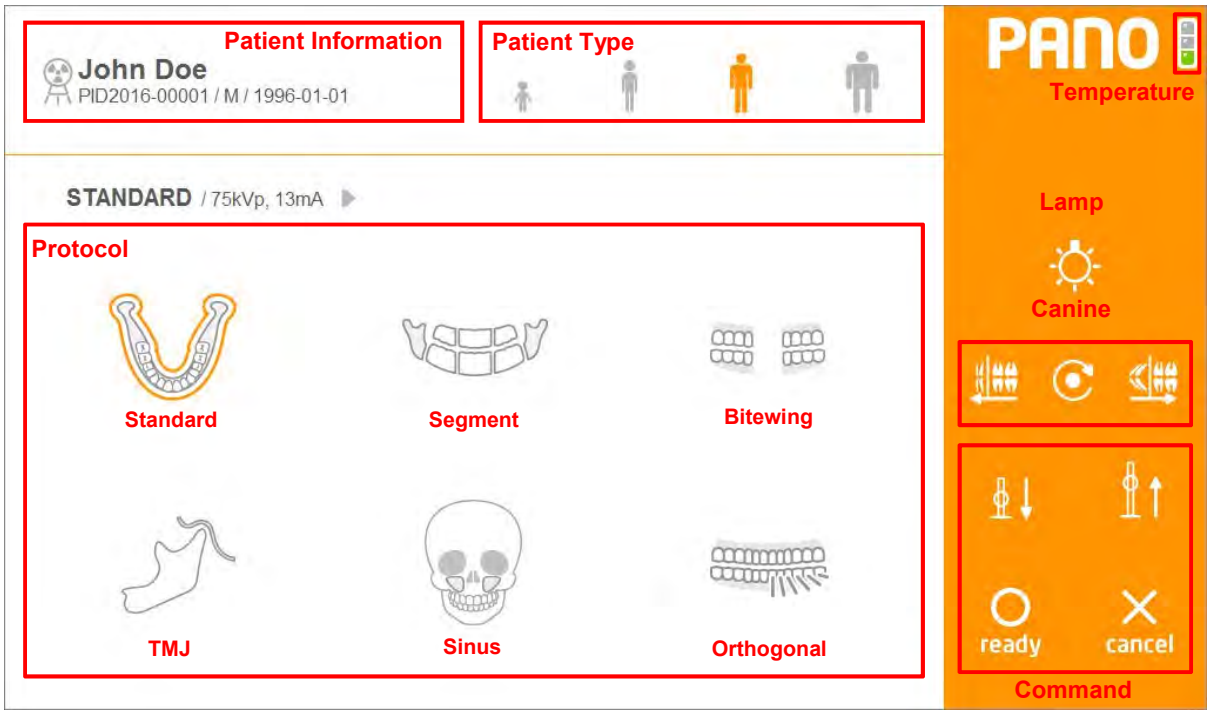


Fig 41 Acquisition: Panoramic

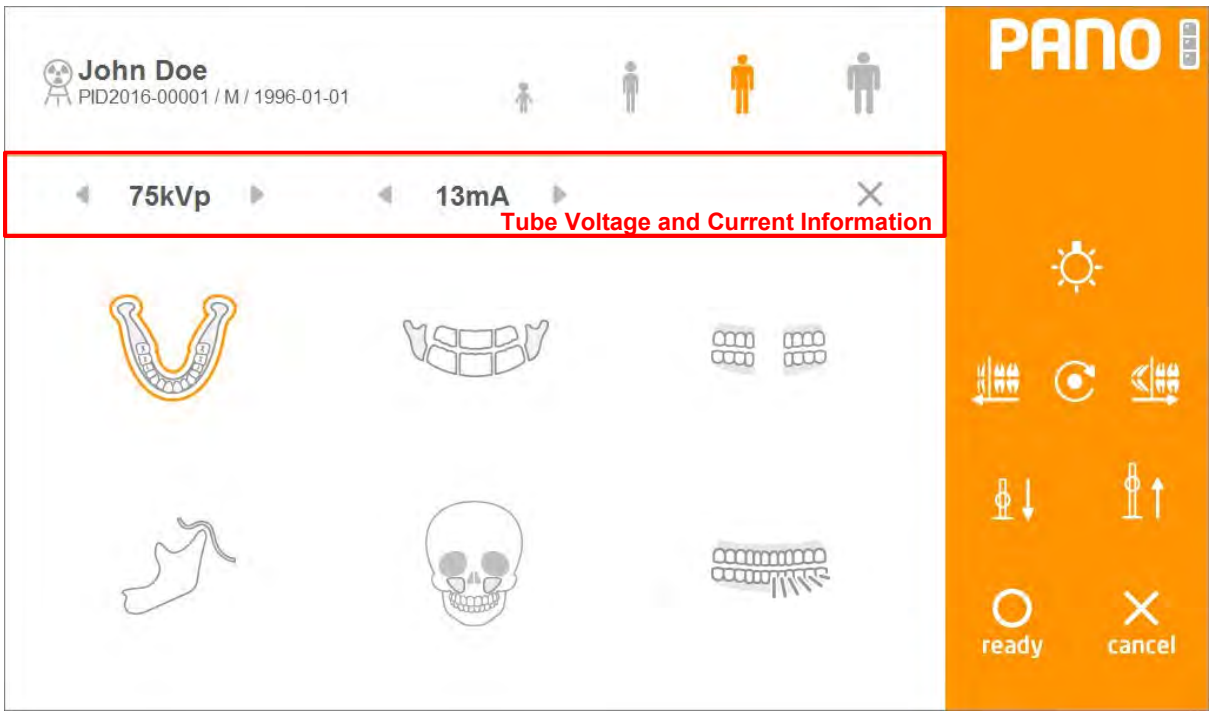


Fig 42 Exposure Condition Adjustment

Patient Information

Item	Description
ID	Patient ID.
Name	Patient name
Gender	Type: M (Male), F (Female), O (Other)
Birth Date	Patient birth date

Patient Type

Item	Description
[Child]	Child build
[Small adult]	Small adult build
[Adult]	Adult build
[Large adult]	Large adult build

Canine Position (Pano): Canine Beam Positioning

Item	Description
[Left] 	Move canine beam forward. Modify canine beam by moving rotator forward.
[Center] 	Move canine beam to the center position. Modify canine beam by moving rotator to the center position.
[Right] 	Move canine beam backward. Modify canine beam by moving the rotator backward.

Tube Voltage and Tube Current

Item	Description
◀	Decrease kVp button. The number decreases by 1 kVp on click.
Tube Voltage(kVp)	Display the voltage kVp setting.
▶	Increase kVp button. The number increases by 1 kVp on click.
◀	Decrease mA button. The number decreases by 1 mA on click.
Tube Current(mA)	Display the current mA setting.
▶	Increase mA button. The number increases by 1 mA on click.

Protocol

Item	Description
[Standard]	Select Standard protocol.
[Segment]	Select Segmentation protocol.
[TMJ]	Select TMJ protocol.
[Sinus]	Select Sinus protocol.
[Bitewing]	Select Bitewing protocol.
[Orthogonal]	Select Orthogonal protocol.

Command

Item	Description
[Lamp]	Alignment beam ON/OFF When clicked, turns the alignment beam OFF (if turned on) and ON (if turned off). ON  OFF 
[Down] 	Equipment Lift Column lower button Equipment is lowered when user maintains touch on the [Down] button.
[Up] 	Equipment Lift Column raise button Equipment is raised when user maintains touch on the [Up] button.
[ready] 	When clicked, system moves to the start position for scanning.
[cancel] 	Touch to cancel scanning, close scanning screen and return to the Splash screen. Click after [ready] button is touched to cancel the scanning preparation process.

Temperature

Monitor the X-ray tube temperature and mark it on the screen as shown in Fig. 43.

During normal operation the green light will be on. If the temperature rises, the green light turns off and the yellow light turns on. If the system becomes overheated the red light will turn on.

When the green light is on, the system will perform a scan. If the red or yellow light is on, cooling time is required before the next scan can be performed. (Yellow zone: 3min., Red zone: 5min.) The remaining cooling time is shown to the left of the temperature indicator lights, above the [Ready] button.

Fig. 43 shows the cooling time procedure.

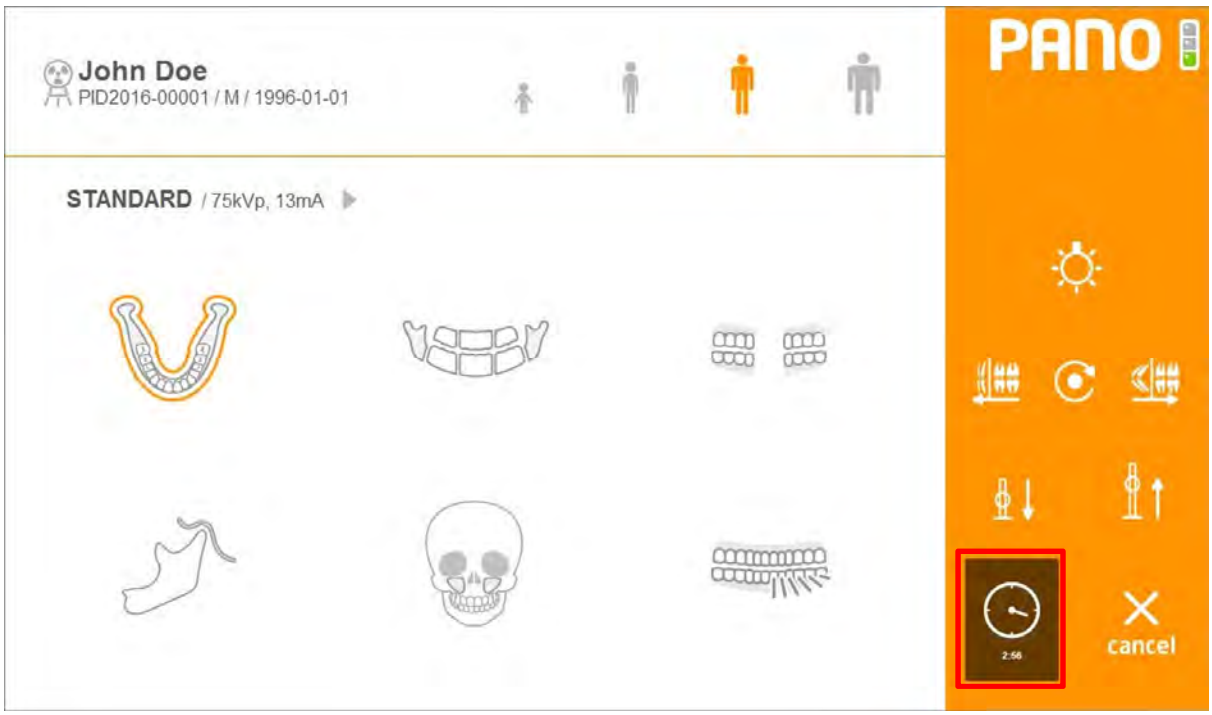


Fig 43 Cooling Time

6.5.3.3 Cephalometric Acquisition (One Shot Type)

Below is the Ceph scanning screen.

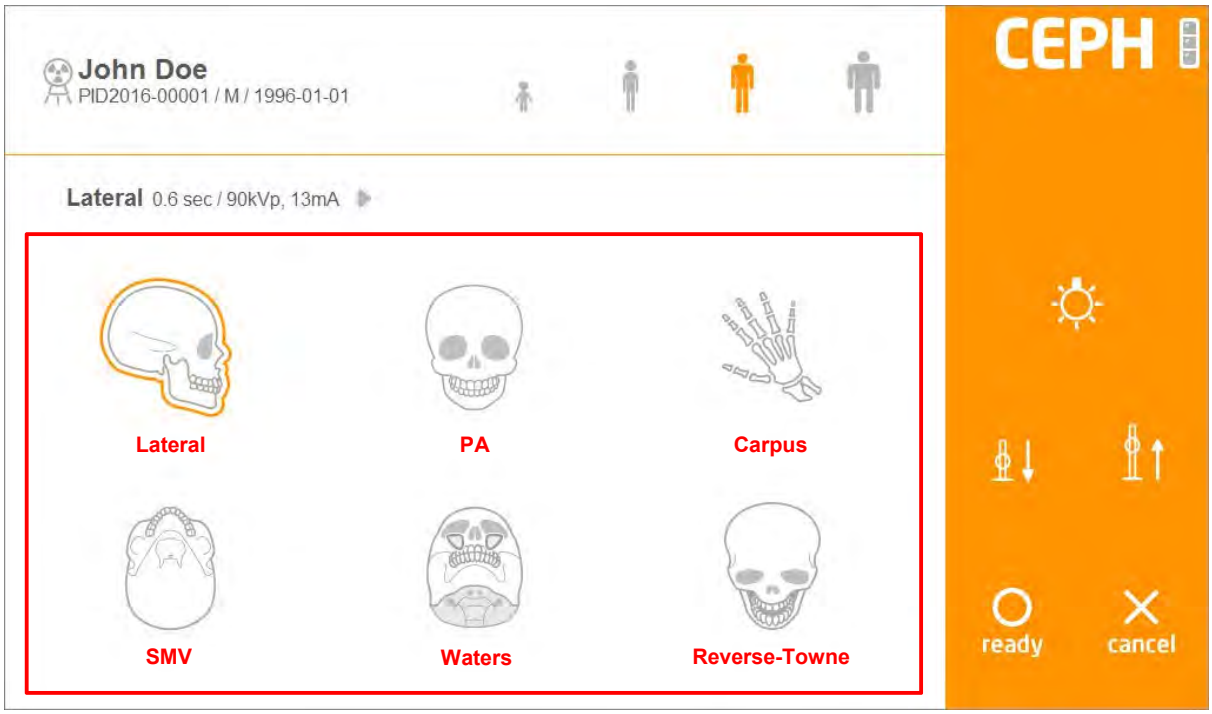


Fig 44 Acquisition: Cephalometric

Protocol

Item	Description
[Lateral]	Select Lateral protocol
[PA]	Select PA protocol
[SMV]	Select SMV protocol
[Carpus]	Select Carpus protocol
[Waters]	Select Waters protocol
[Reverse-Towne]	Select Reverse-Towne protocol

6.5.3.4 Cephalometric Acquisition (Scan Type)

Below is the Ceph screen for setting Ceph scanning.

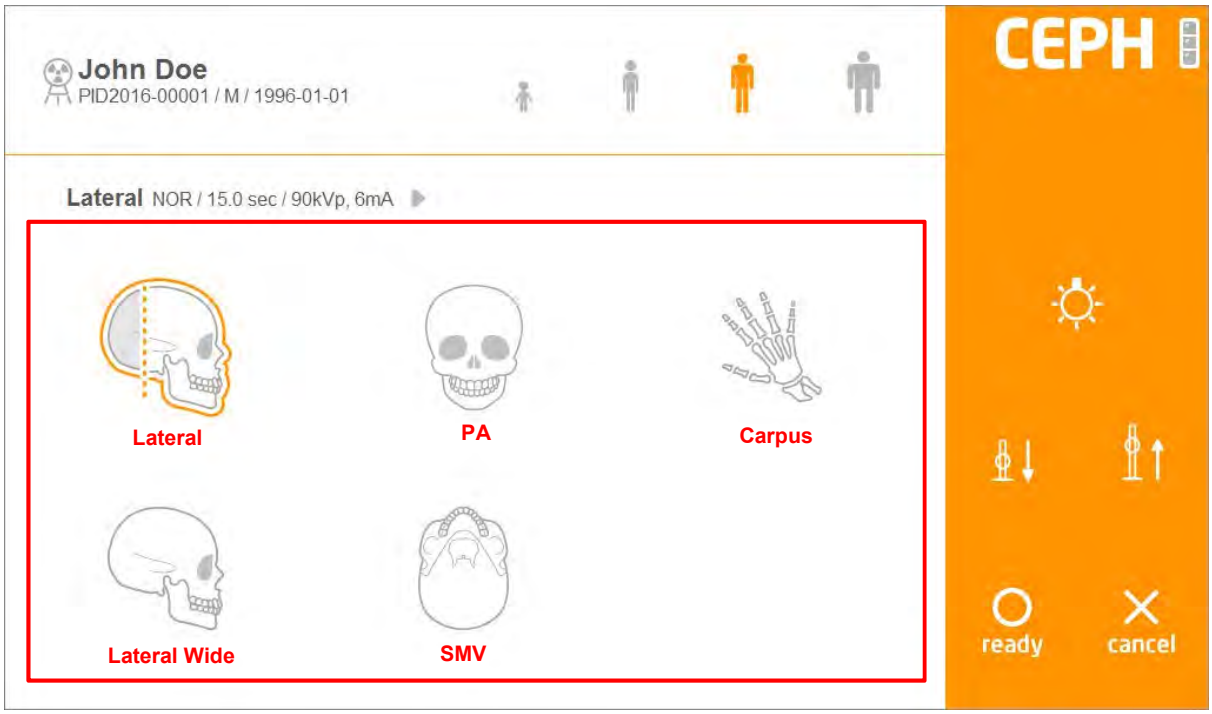


Fig 45 Acquisition: Cephalometric

Protocol

Item	Description
[Lateral]	Select Lateral protocol.
[Lateral Wide]	Select Lateral Wide protocol.
[PA]	Select PA protocol.
[SMV]	Select SMV protocol.
[Carpus]	Select Carpus protocol.

6.5.3.5 CT Acquisition

Below is the screen for setting CT scanning.

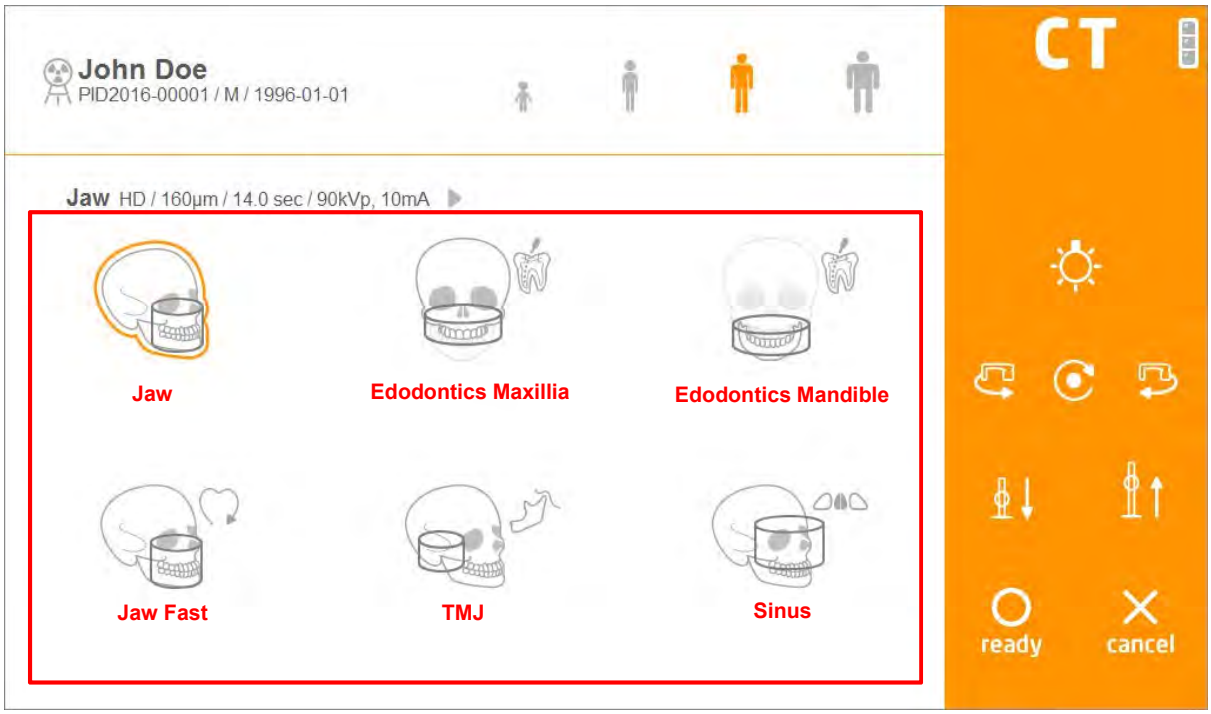


Fig 46 Acquisition: CT

Protocol

Item	Description
[Jaw]	Select Jaw protocol.
[Endodontics Maxilla]	Select Endodontics Maxilla protocol.
[Endodontics Mandible]	Select Endodontics Mandible protocol.
[Jaw Fast]	Select Jaw Fast protocol.
[Sinus]	Select Sinus protocol.
[TMJ]	Select TMJ protocol.

6.5.3.6 Confirm Image View

Image View Confirm screen displayed after scanning completion.

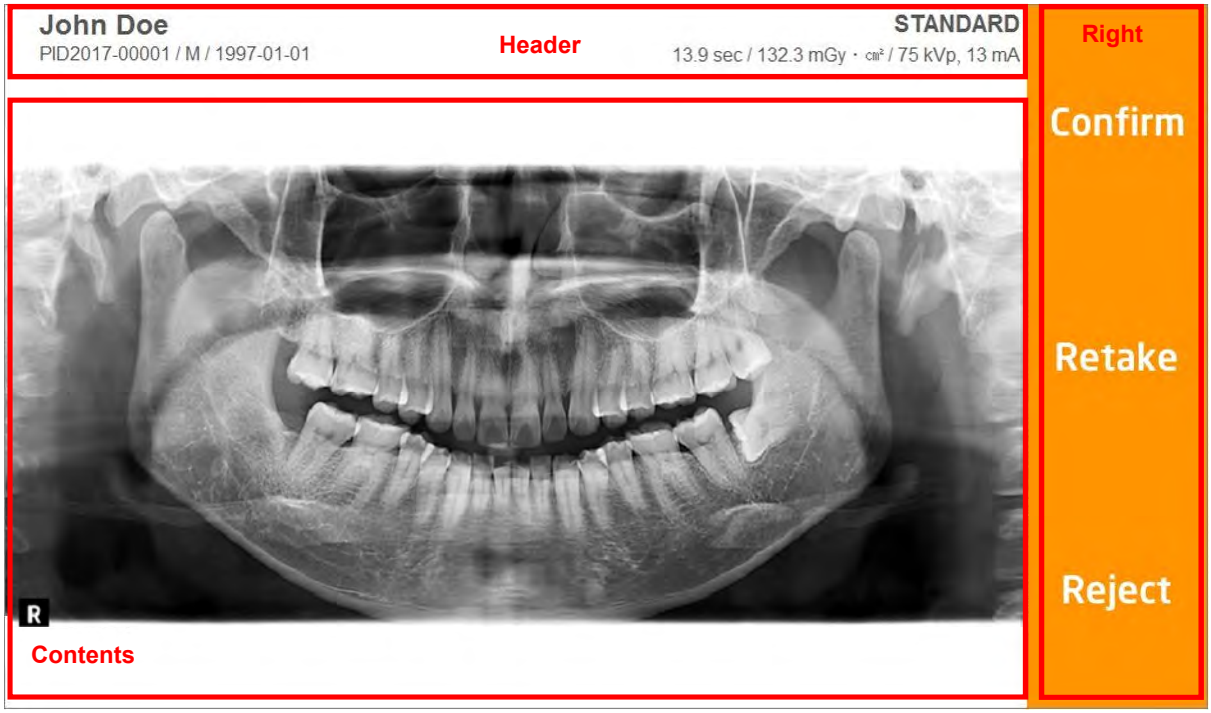


Fig 47 Confirm Image View: Pano

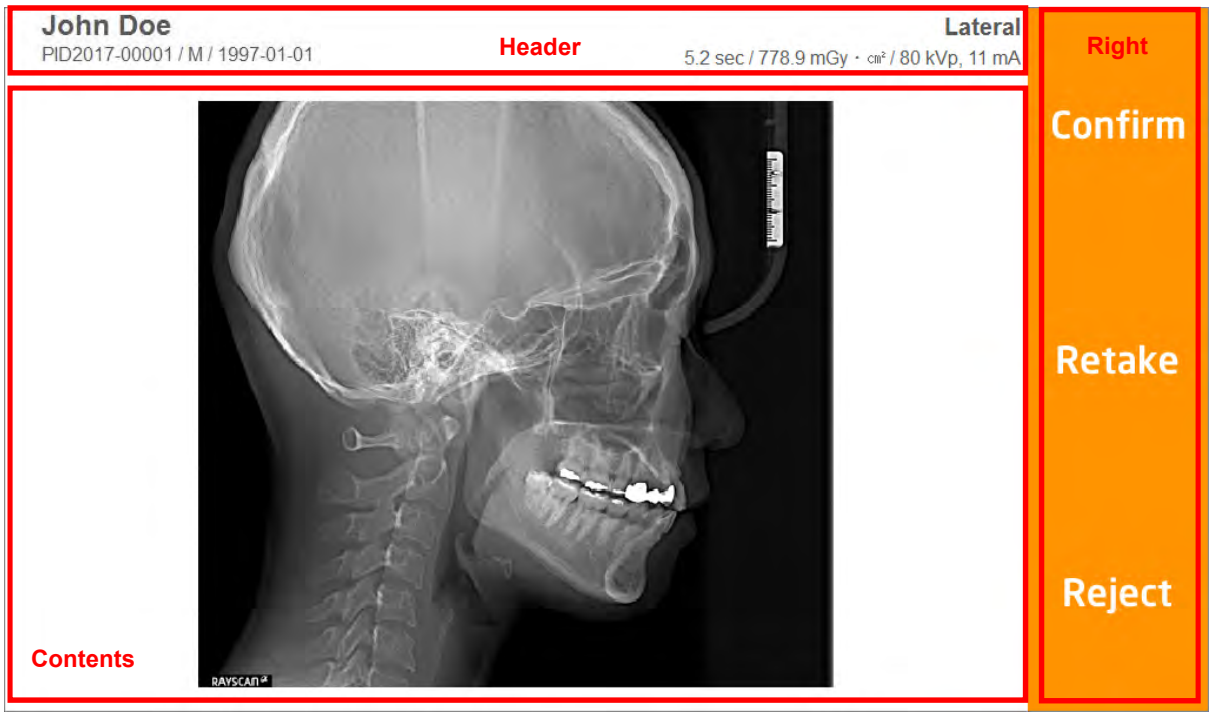


Fig 48 Confirm Image View: Ceph

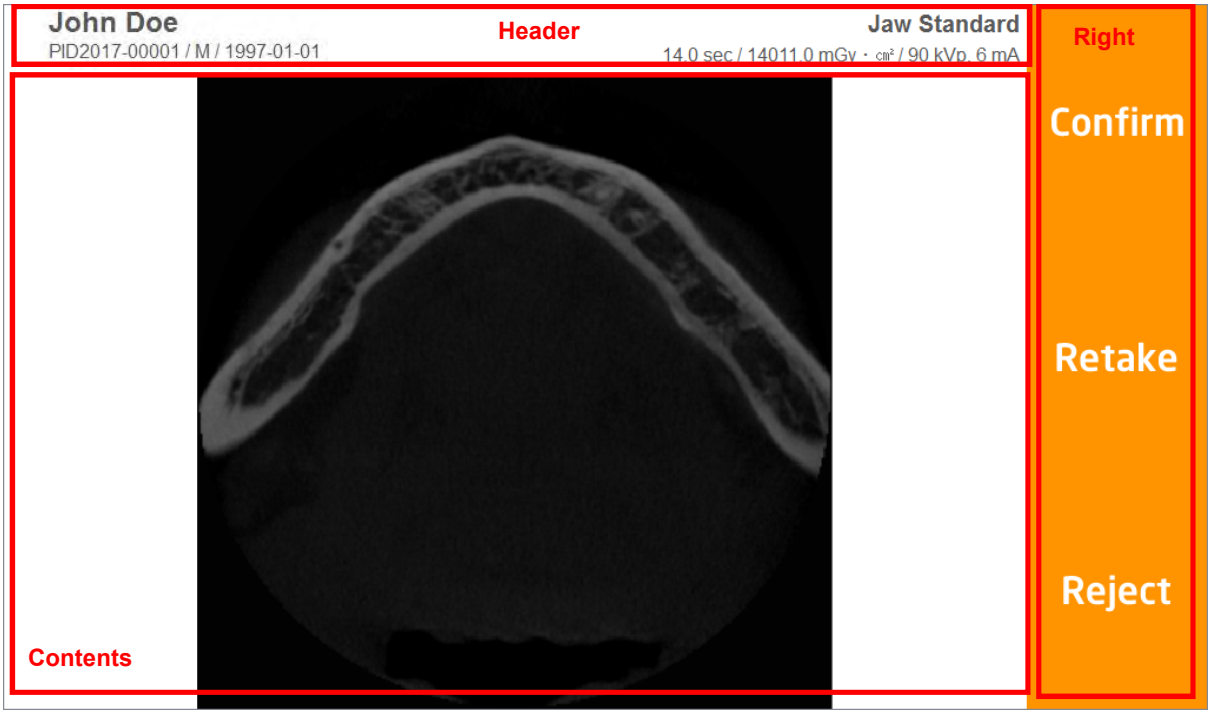


Fig 49 Confirm Image View: CT

Header

Item	Description
ID	Patient ID.
Name	Patient name
Gender	Type: M (Male), F (Female), O (Other)
Birth Date	Patient birth date
Scan Time	Scan Time
Dose	X-ray Dose (mGy * cm^2)

Contents

Item	Description
Image	Completed image

Right

Item	Description
[Confirm]	Image View Confirm button Click to save Image View and return to Splash screen.
[Retake]	Image retake button Click to save Image View and go to Acquisition-Patient Info screen automatically. Resets the equipment.
[Reject]	Reject image

6.6 RAYSCAN^{web}

6.6.1 System configuration

The system configuration for using RAYSCAN^{web} is as below figure. Through the wireless router in local network environment, mobile device can access the RAYServer for using RAYSCAN^{web}.

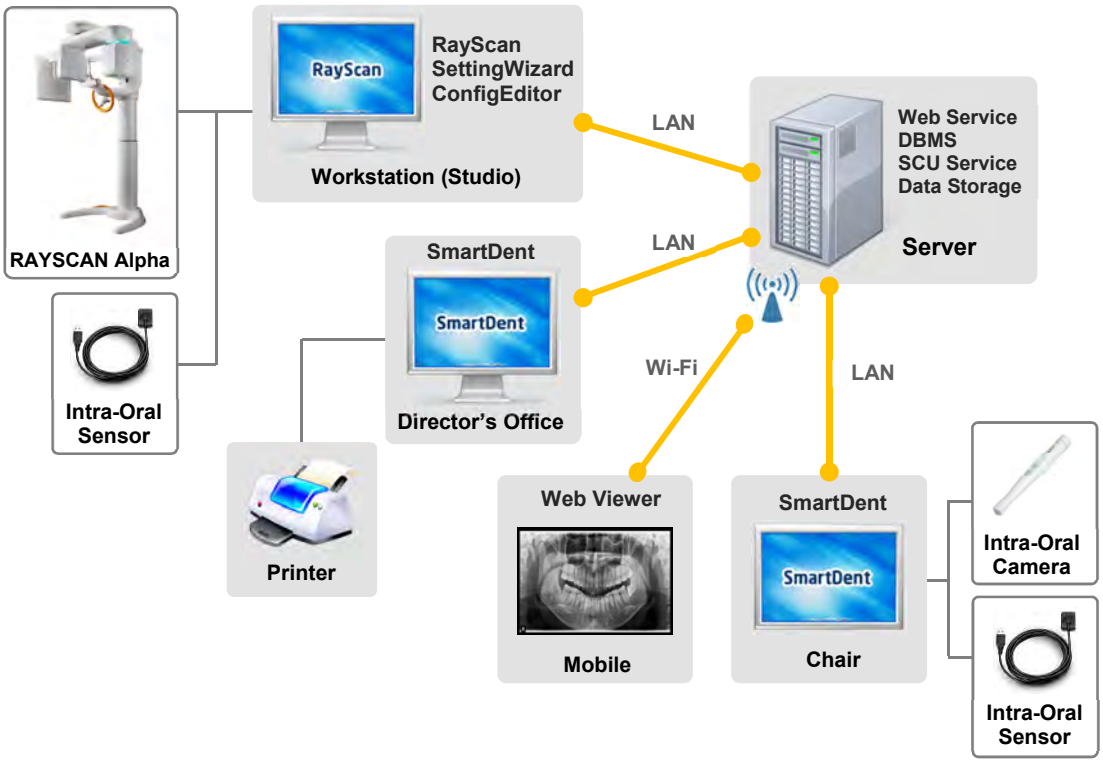
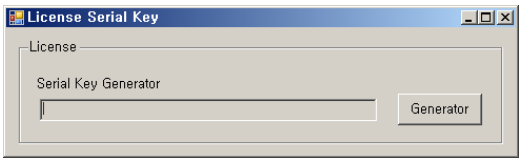
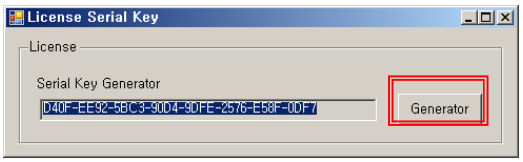


Fig 50 System Configuration of RAYSCAN^{web}

6.6.2 Operating Environment

Class	PC Minimum Requirements	Mobile Minimum Requirements
CPU	Pentium 4 or higher	Dual core 1.2GHz
RAM	1GB or more	1GB or more
Resolution	1024 X 768 or higher	320 X 480 or higher
Operating System	All Windows and MacOS	Android 4.1 or above, iOS 8.0 or above
Browser	Internet Explorer 10 or above, Safari 8.0 or above, and HTML5 supported browser	Internet Explorer 10 or above, Safari 8.0 or above, and HTML5 supported browser

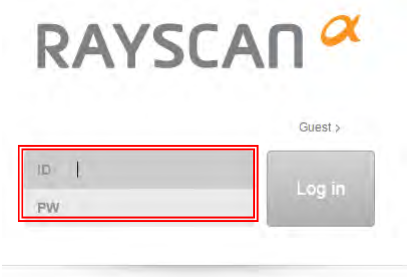
6.6.3 Web License Installation

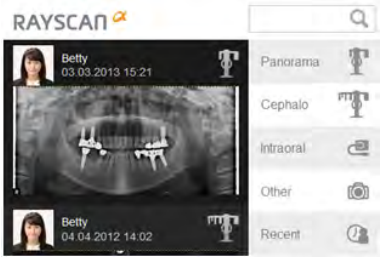
No	Figure	Description
1		Run “C:\Ray\SerialKeyGenerator.exe”.
2		Click [Generator] button to get serial key.
3		Send e-mail to *ray_cs@raymedical.co.kr* You should provide the model name, S/N, and generated serial key. Please send the information to *ray_cs@raymedical.co.kr* to receive the license file. Ray CS Team will follow up with more instructions. ***Note*** RAYSCANweb is optional. Please contact your local representative for more details

6.6.4 Web Log-in

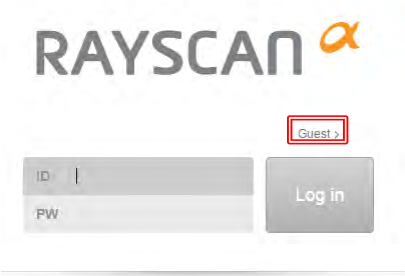
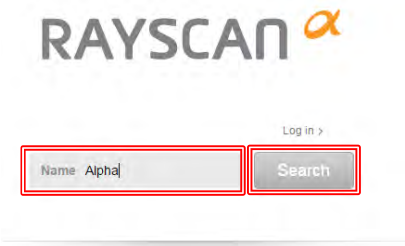
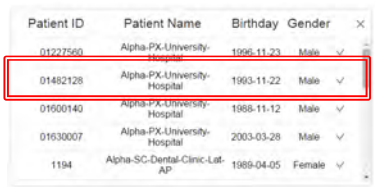
6.6.4.1 Clinic use for all patient images

Run your internet browser and insert RAYSCAN^{web} address on the address bar.
(If IP address of RAYServer is 192.168.1.200, insert “http://192.168.1.200::9091)

No	Figure	Description
1		Enter ID, Password and click [Log in] button.

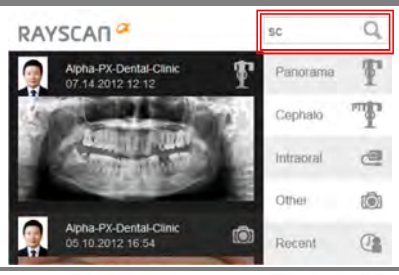
2		After the account have been verified, the main page will be opened as the figure.

6.6.4.2 Personal use for particular patient

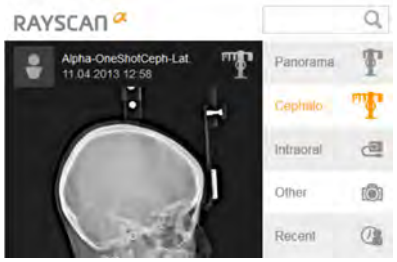
No	Figure	Description
1		Click [Guest>] button on log-in page.
2		Insert particular patient name and click [Search] button.
3		If retrieved patient is not one, this page will be displayed. Select the patient in the retrieved patient list.
4		Patient images will be displayed as the figure.

6.6.5 Image Searching

- Search Patient

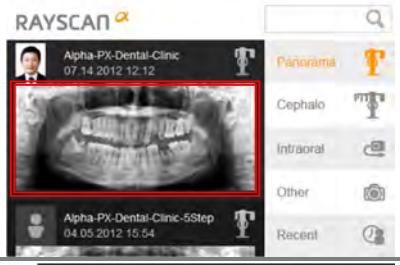
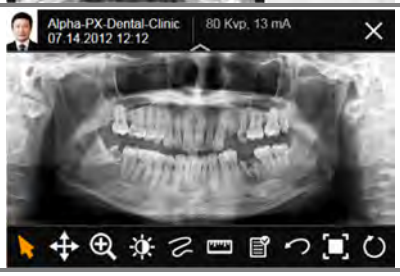
No	Figure	Description
1		Enter patient name or ID in the search bar at the top right corner of the screen. Tip: Entering the first letter of the patient name or ID will retrieve a list of patients whose names begin with the applicable letter.
2		The retrieved patient image will be displayed on-screen.

- Search Recent Image by Modality

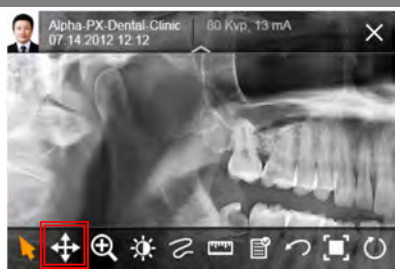
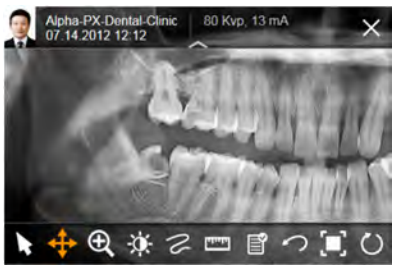
No	Figure	Description
1		Click the modality icon on the right-hand side.
2		Recently acquired images corresponding to the selected modality are displayed.

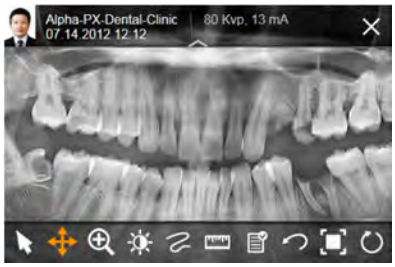
6.6.6 Image Viewing

- Move to Image View Mode

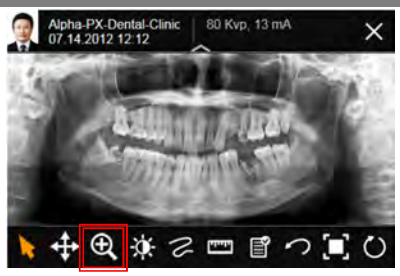
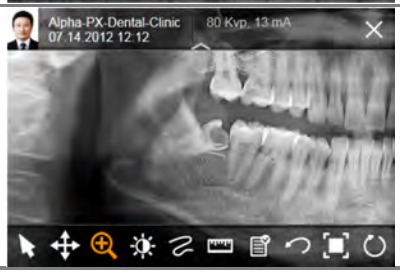
No	Figure	Description
1		Search for the image desired. Tip: If the desired image is not found, search by patient.
2		Click on the image desired.
3		The screen will change to Image View mode.

- Move Image

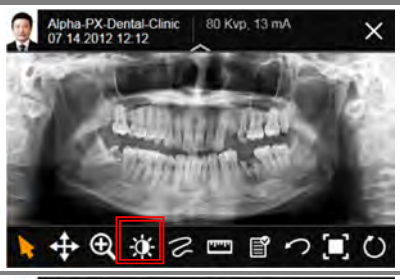
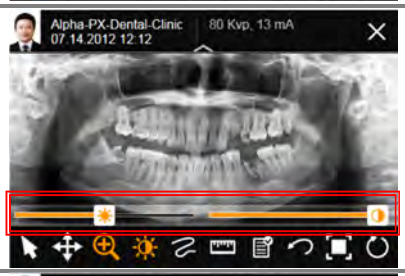
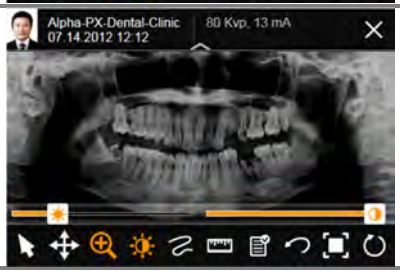
No	Figure	Description
1		Click [Move] button in Tool Menu. Tip: On mobile device, [Move] and [Zoom] buttons are not displayed, but the image can be controlled by touch function.
2		Click and hold to move.

3		Move image to desired position and release.

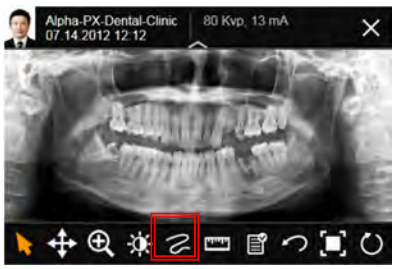
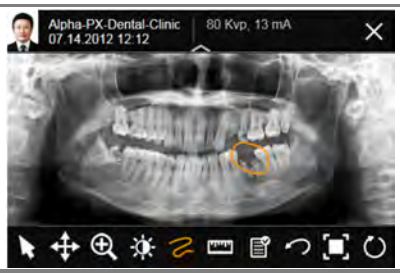
- Image Zoom

No	Figure	Description
1		Click [Zoom] button in Tool Menu. Tip: If used from a mobile device, [Move] and [Zoom] buttons are not displayed, but the image can be controlled by touch function.
2		Click the left mouse button on top of the image, and move the mouse right to zoom. For tablets and smart phones, touch function provides zoom as in standard photo applications.
3		Click the left mouse button on top of the image, and move the mouse left to shrink the image.

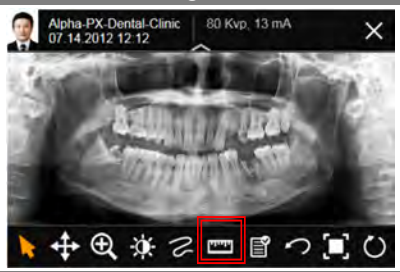
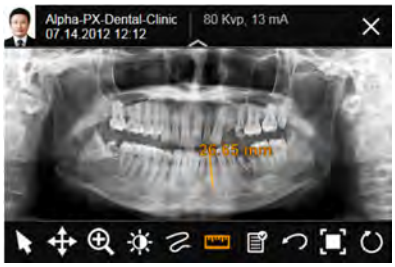
- Windowing

No	Figure	Description
1		Click [Windowing] button in Tool menu.
2		The Brightness and Contrast control interface is displayed in the figure to the left.
3		Use the left slide control for adjusting image brightness. Use the right slide control for adjusting image contrast.

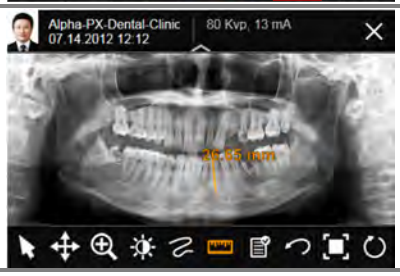
- Draw Free Curve

No	Figure	Description
1		Click [Free Curve] button in Tool menu. Caution: Additional overlays will not be saved in web.
2		With the left mouse button held down, draw the desired shape. The shape drawn will appear on the screen.

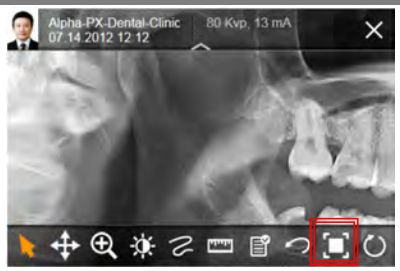
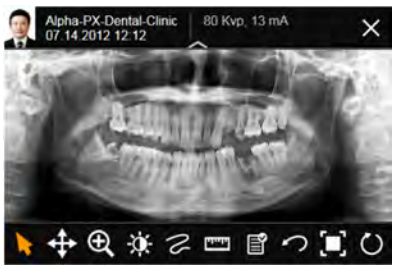
- Length Measurement

No	Figure	Description
1		Click [Length] button in Tool Menu. Caution: Additional overlays will not be saved in web.
2		Click the start and end points of the area to be measured. The length indicated will be displayed. Units of length are in “mms” which represent the actual measurement unit. Tip: Click the [Select] button to change to Mouse Mode then select the appropriate overlay to move position or modify start and end points.

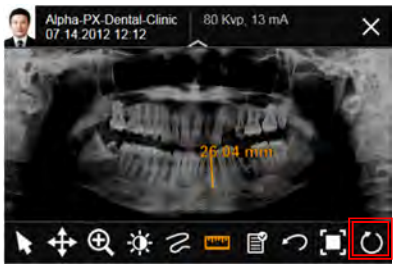
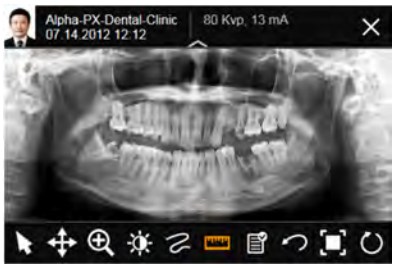
- Delete Overlay

No	Figure	Description
1		Click [Cancel] button in Tool Menu.
2		The most recently entered overlay is deleted.

- Fit Image to Screen

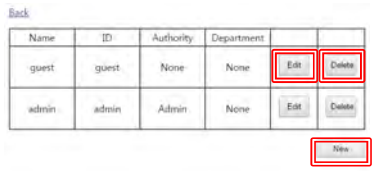
No	Figure	Description
1		Click [Fit-on] button in Tool Menu.
2		Image is changed as in figure.

- Initialize Image

No	Figure	Description
1		Click [Initialize] button in Tool Menu.
2		All overlays entered in web version are deleted and windowing is initialized. Caution: Overlays entered in the PC version are retained.

6.6.7 Web Management

6.6.7.1 User Account Management

No	Figure	Description
1		Log in with admin account. * When you install, ID and Password are admin/admin.
2		You can add, modify, and delete the user account.
3		After adding or modifying the information, click [Submit] button to save.

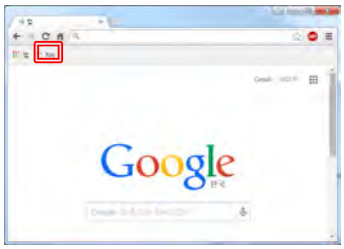
6.6.7.2 Bookmark Setting

- Add Bookmarks on Internet Explorer 11

No	Figure	Description
1		Go to RAYSCAN[web] page on Internet Explorer 11.
2		Click [Add Bookmark] button on left top corner.

3		On next, easy to run RAYSCAN^{web} by clicking Bookmark.

▪ Add Bookmark on Google Chrome

No	Figure	Description
1		Go to RAYSCAN^{web} page on Google Chrome.
2		Click [Add Bookmark] button on the top.
3		On next, easy to run RAYSCAN^{web} by clicking Bookmark.

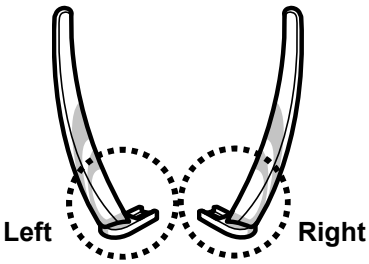
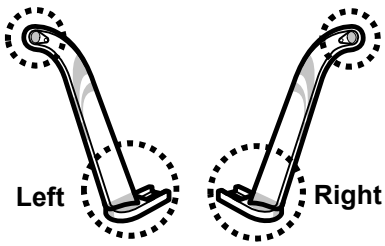
Note	Please note that as a generic viewing application RAYSCANweb (optional software for RAYSCANα) is not suited for diagnostic purposes. However, it is an excellent tool for communicating a diagnosis made at SMARTDent for desktop.

Scanning

7

7 SCANNING

Bite Block, Chinrest, Sinus Chinrest, Edentulous Chinrest, TMJ Chinrest, TMJ Guide, and Temple Support

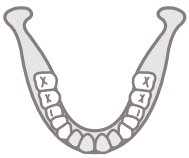
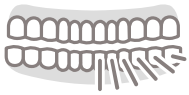
Accessory	Figure	Description
Bite Block		Use for normal position of Panoramic and CT. Assist with placing the front teeth into the groove of the bite block.
Chinrest		Use for normal position of Panoramic and CT.
Sinus Chinrest		Use for Sinus position of Panoramic and CT. Use for TMJ position of CT. Sinus Chinrest is lower than Chinrest.
Edentulous Chinrest		Used for panoramic and general CT position of edentulous patients.
TMJ Chinrest		Used for TMJ position of CT. TMJ Chinrest is mounted on the Sinus Chinrest.
Temple Support		Used for Normal and Sinus postion of panoramic, and TMJ position of CT. The rounded part of temple support must be mounted on the inner-side. Check the marker “L”, “R” in Temple support.
TMJ Guide		Use for TMJ Position of panoramic. TMJ guide is shorter than the Temple Support, and has cone-shaped protrusions that fit inside the ears.

Note Sterilize by using sterilizing liquids such as ethyl alcohol.

7.1 Panoramic Scanning

7.1.1 Description of Panoramic Protocol

The Panoramic Scanning programs include automatic spinal compensation for an excellent view of the anterior teeth without a distracting spinal shadow.

No	Figure	Description
1		**Normal** Radiate the entire region of the maxilla and mandible. Typically used to observe both the maxilla and mandible
2		**Segment** Select scanning area to reduce radiation exposure.
3		**TMJ (Temporomandibular Joint)** Radiate on left and right TMJ section while mouth is opened and/or closed. Used to observe TMJ.
4		**Sinus** Radiate the sinus. Used commonly to observe maxillary sinus.
5		**Bitewing** Effective in the diagnosis of occlusal surfaces of the posterior teeth.
6		**Orthogonal** For effective diagnosis of the proximal surfaces of the teeth.

7.1.2 Cautionary Measures for Pre-Scanning

① Make sure chinrest is installed properly.

② Install hygienic cover over Bite Block.

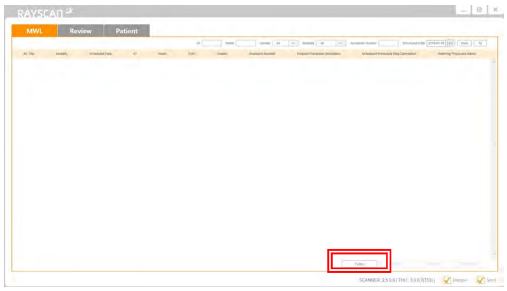
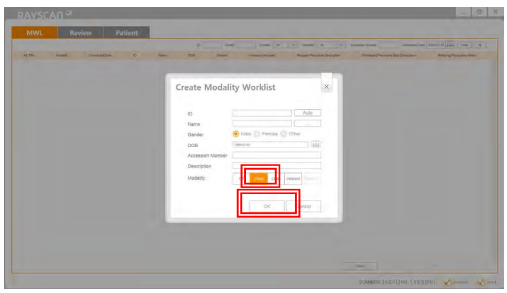
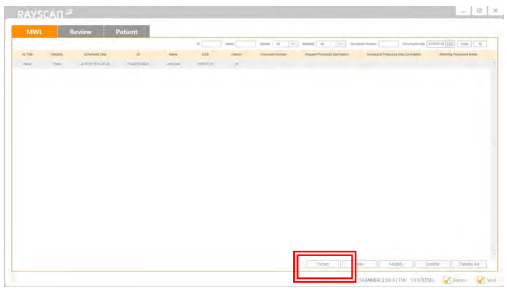
③ Open Temple Support to facilitate patient positioning.

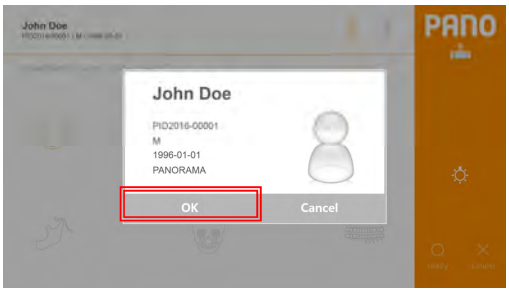
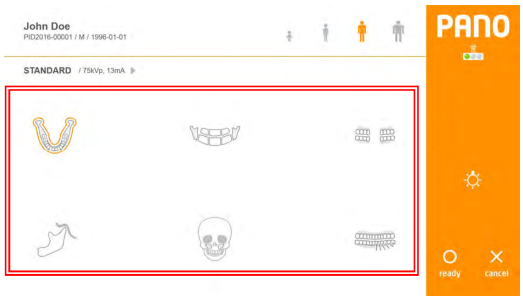
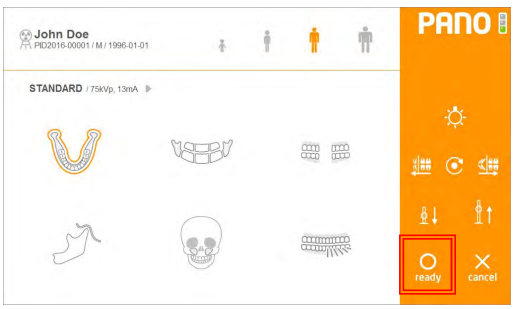
④ Patient must remove all metal when undergoing scanning, including glasses, necklaces, earrings, hearing aids, etc.

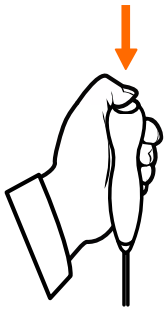
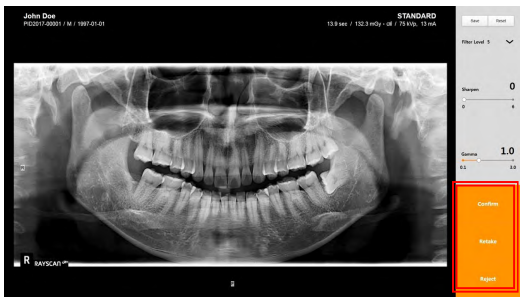
⑤ Patient must wear a protective lead apron.

7.1.3 Panoramic Scanning Method

7.1.3.1 Panoramic (Normal) Scanning Method

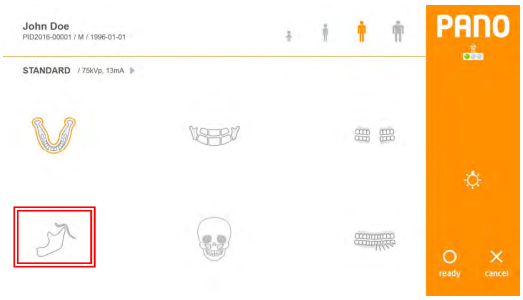
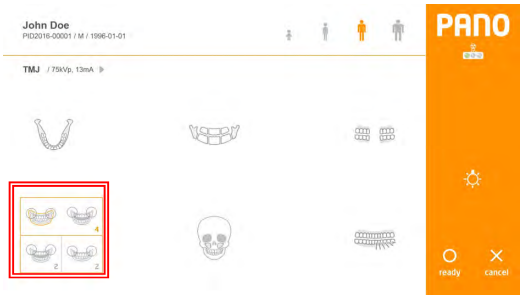
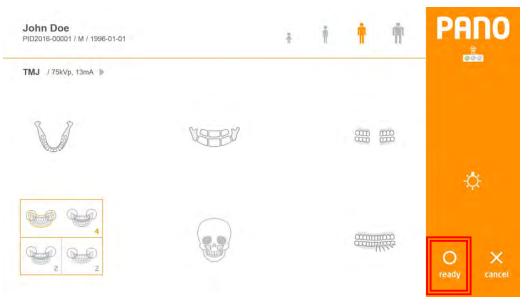
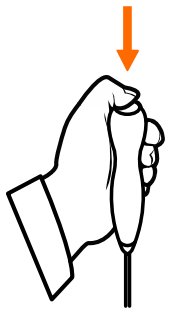
No	Figure	Description
1		Click MWL on top left side of the screen and [New] button on the bottom right to register a new patient.
2		In the Modality Worklist screen, select [Pano] for Modality and click [OK] button.
3		Select the MWL created above and click [Scan] button on the bottom right.

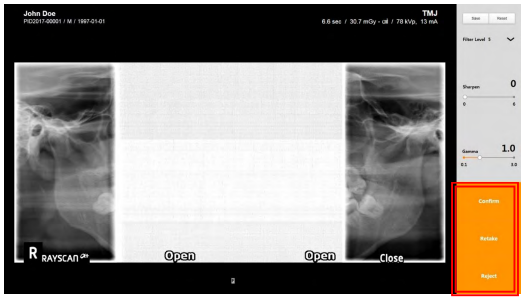
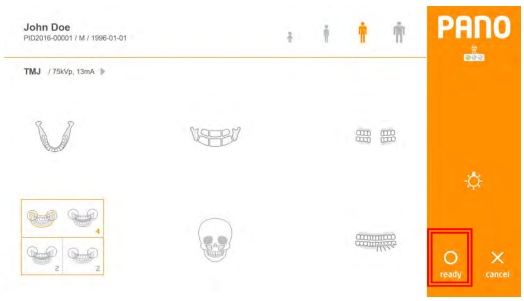
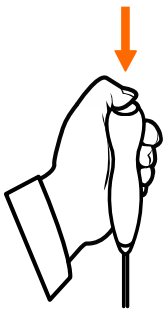
4		Confirm Patient Information, click [OK] button, then proceed to next step.
5		Select the intended scanning protocol.
6		Select Patient Type, Resolution, Tube Voltage and Tube Current based on the patient. Using the remote control or touch screen, adjust equipment height to patient height and make sure that the patient's neck is as straight as possible. Once positioned, allow patient to hold on to the Patient Handle. ※ The remote control is not provided in Canada. Position the patient according to the intended scanning protocol. (Refer to paragraph 7.1.4 for the positioning method.)
7		Once patient positioning is complete, press [Ready] button on the touch screen.

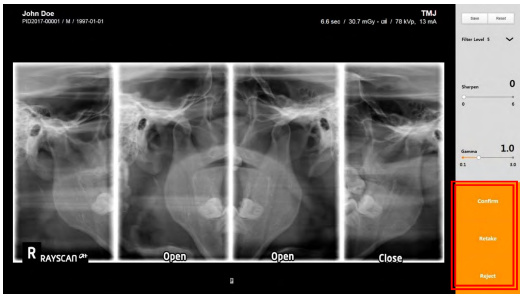
8		After the green light on the exposure switch has been illuminated, continue to press the switch until scanning has been completed. ***Note*** Take care not to release the button during scanning as doing so will stop the scanning process. Maintain audio and visual contact with the patient and x-ray unit during exposure. if the c-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately
9		Once scanning is complete, select among the [Confirm/Retake/Reject] buttons. ※ **Operation Description** **[Confirm]**: Save image and go to MWL screen. **[Retake]**: Save image and automatically go to Acquisition-Patient Info screen for retake. **[Reject]**: Save Image View, indicate rejected image in the database, then go to MWL screen.

Note	The system monitors a temperature sensor that is embedded in the X-ray tube and will automatically cool the X-ray tube to maintain safe operation.

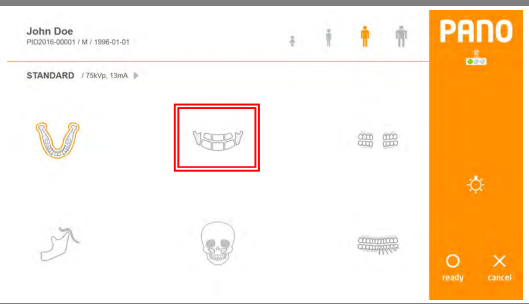
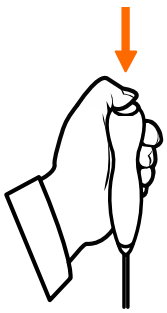
7.1.3.2 Panoramic (TMJ) Scanning Method

No	Figure	Description
1		Select TMJ protocol.
2		Choose either Open or Close mouth on the THU. ***Note*** Select either Open or Close mode on 2-View.
3		Once patient positioning is complete, press [ready] button on the touch screen.
4		After the green light on the exposure switch has been illuminated, continue to press the switch until scanning has been completed. ***Note*** Take care not to release the button during scanning as doing so will stop the scanning process. Maintain audio and visual contact with the patient and x-ray unit during exposure. if the c-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately

5		After scanning is completed, click [Confirm/ Retake/Reject] buttons. **※ Operation Description** **[Confirm]:** Saves image and shows 4-View scanning mode screen. **[Retake]:** Automatically moves to scanned Patient Information screen and proceeds with rescan. **[Reject]:** Saves image, including rejected information, then moves to scan list and stands by.
6		Once patient positioning is complete, press [ready] button on the touch screen.
7		After the green light on the exposure switch has been illuminated, continue to press the switch until scanning has been completed. ***Note*** Take care not to release the button during scanning as doing so will stop the scanning process. Maintain audio and visual contact with the patient and x-ray unit during exposure. if the c-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately

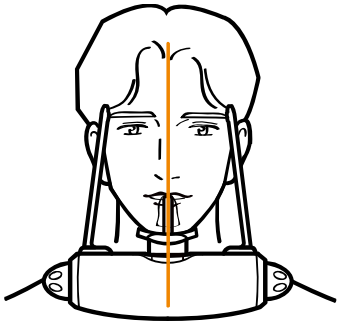
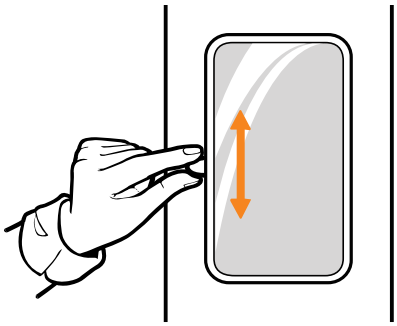
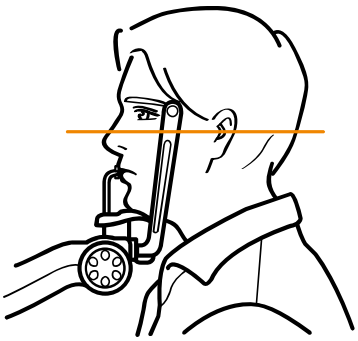
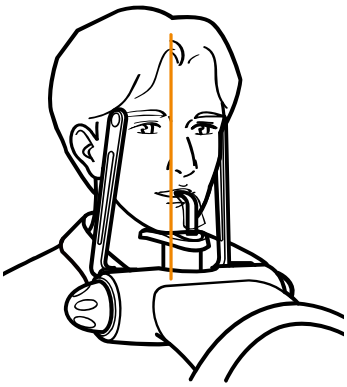
8		After 4-View scanning is completed, click [Confirm/Retake/Reject] buttons. First scanned image locates in the middle and second image on both ends. ※ **Operation Description** **[Confirm]**: Saves image, moves to scanning list screen and stands by. (Only 4-View image gets saved.) **[Retake]**: Automatically moves to the scanned Patient Information screen and proceeds with rescan. (First scanned 2-View image does not change, only second image is rescanned.) **[Reject]**: Saves image, including rejected information, then moves to scan list and stands by.

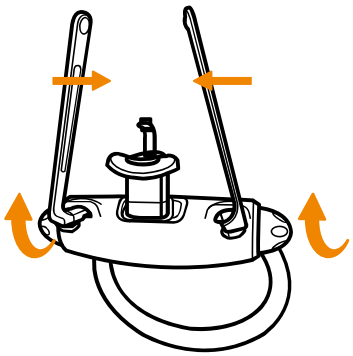
7.1.3.3 Panoramic Segment Scanning Method

No	Figure	Description
1		Select Segmented Pano protocol. ***Note*** To modify scanning protocol, click on the Segmented Pano button.
2		Specify area for scanning within selected window. ***Note*** Image will be converted into a full Panoramic if all 5 areas are selected. Dark gray section is unscanned area.
3		Once patient positioning is complete, press [Ready] button on the touch screen.
4		After the green light on the exposure switch has been illuminated, continue to press the switch until scanning has been completed. ***Note*** Take care not to release the button during scanning as doing so will stop the scanning process. Maintain audio and visual contact with the patient and x-ray unit during exposure. if the c-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately

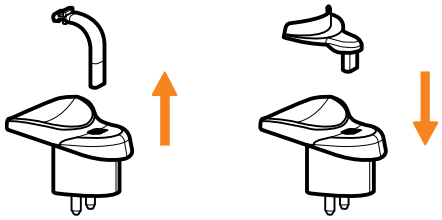
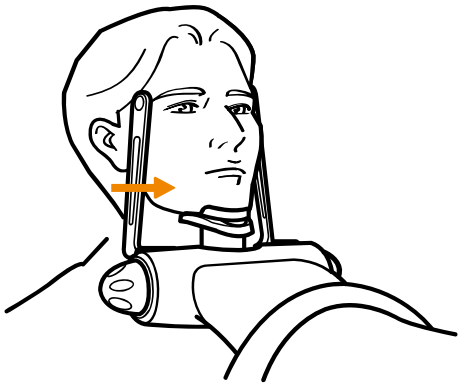
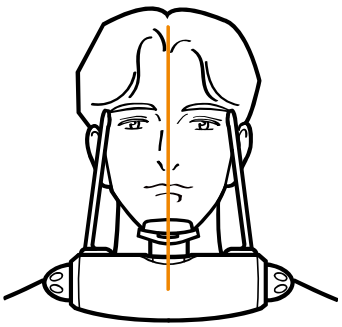
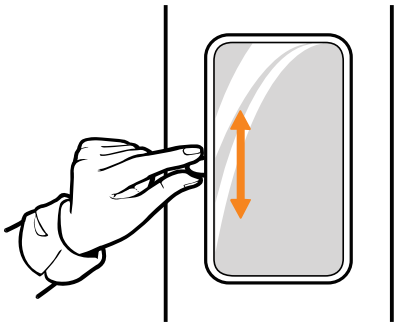
7.1.4 Patient Positioning Method

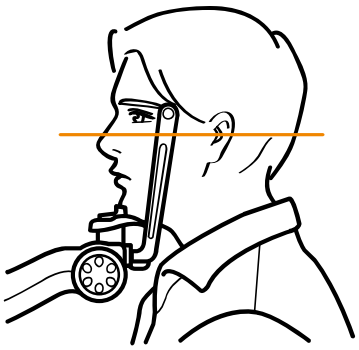
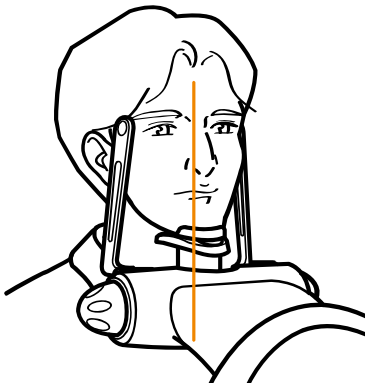
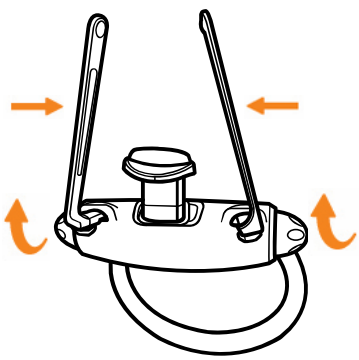
7.1.4.1 Panoramic (Normal, Segment) Positioning Method

No	Figure	Description
1		Align center of the patient's head (midsagittal plane, for example, middle of the forehead, nose, philtrum etc.) with the vertical alignment beam as shown in the figure on the left. Avoid tilting to either side.
2		Adjust patient's head angle to align the Frankfort plane with the horizontal alignment beam. Make sure that the patient's neck is fully straightened and not tipped forward.
3		Use the horizontal alignment beam lever, mounted on the equipment Lift Column, to align the patient's Frankfort plane parallel to the laser.
4		Confirm the position of Canine Beam is on the center of right canine tooth.

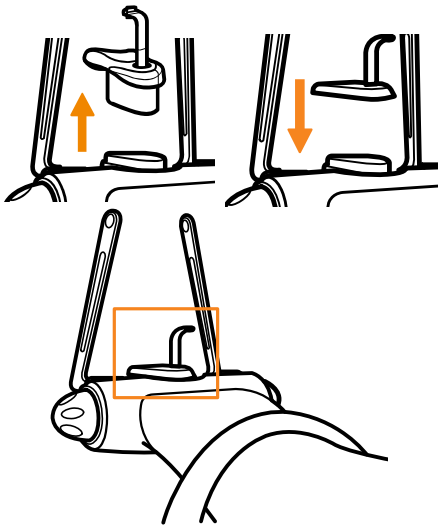
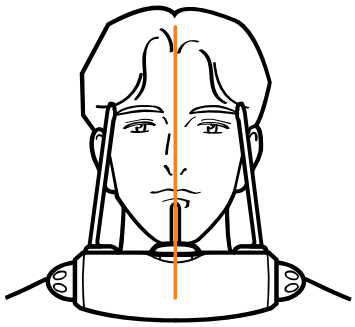
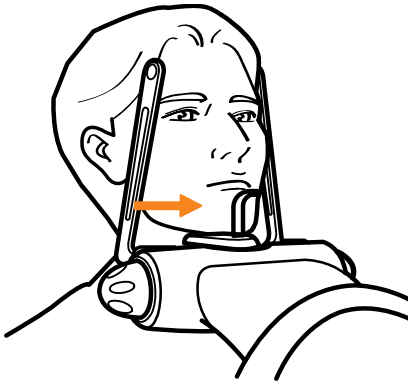
5		Adjust the position of Canine Beam by using touch screen or remote control. **[Left]**: Move canine beam to forward. **[Center]**: Place canine beam to the initial position. **[Right]**: Move canine beam to backwards. ***Note*** It is important step to get optimal image. Do not skip this process.
6		Once patient positioning is completed, turn the lever so that the Chinrest and Temple Support can hold the patient's head in place.

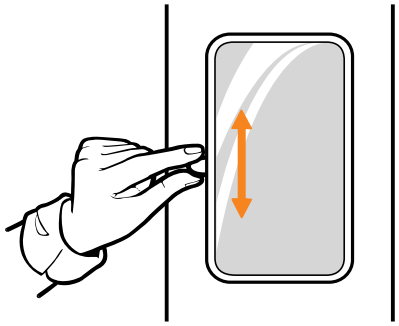
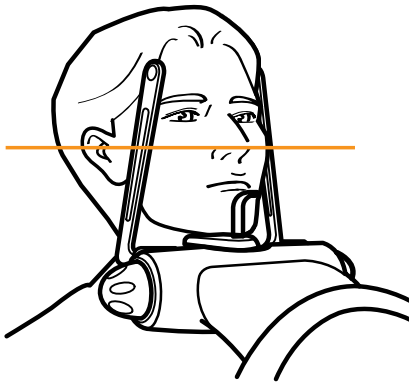
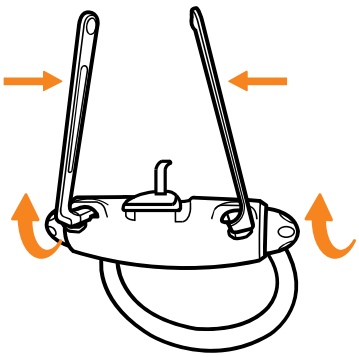
7.1.4.2 Panoramic (Normal, Segment) Edentulous Position Method

No	Figure	Description
1		Detach the Bite Block and install the Edentulous Chinrest. The center of the Edentulous Chinrest is designed to match the Bite Stick hole of the chinrest.
2		Push the patient's lower jaw forward, to rest in the cup of the Edentulous Chinrest.
3		Align the center of the patient's head (midsagittal plane, for example, middle of the forehead, nose, philtrum etc.) with the vertical alignment beam as shown in the figure on the left. Avoid tilting to either side.
4		Adjust patient's head to align the Frankfort plane with the horizontal alignment beam. Make sure that the patient's neck is fully straightened and not tipped forward.

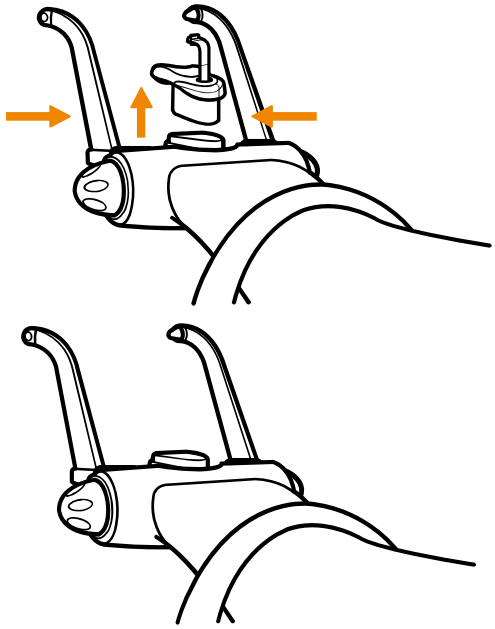
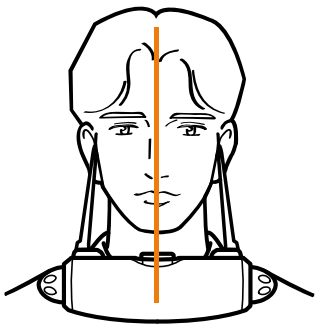
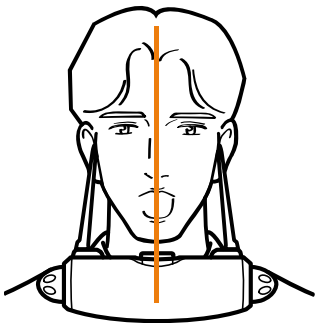
5		Use the horizontal alignment beam lever, mounted on the equipment Lift Column, to align the patient's Frankfort plane parallel to the laser.
6		Position the patient so that the canine alignment beam is aligned with the patient's canine tooth.
7		Adjust the position of Canine Beam by using touch screen or remote control. **[Left]:** Move canine beam forward. Modify canine beam by moving rotator forward. **[Center]:** Move canine beam to center. Modify canine beam by moving rotator to the center. **[Right]:** Move canine beam backward. Modify canine beam by moving rotator backward. ***Note*** These steps are very important for optimal image quality, and must be completed accurately.
8		Once patient positioning is completed, turn the lever so the Chinrest and Temple Support can hold the patient's head in place.

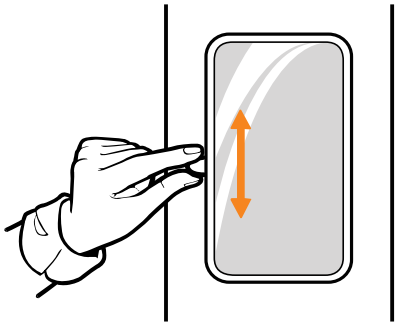
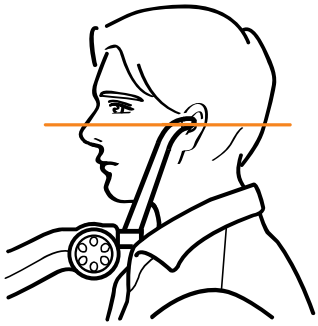
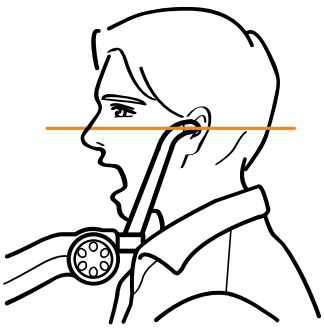
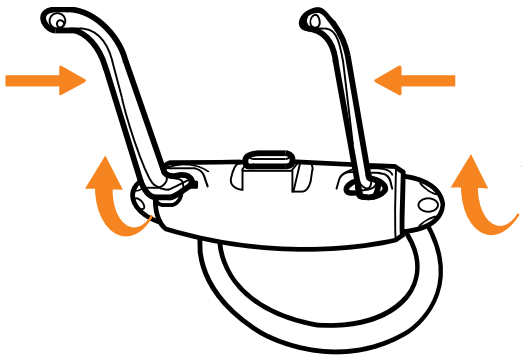
7.1.4.3 Panoramic (Sinus) Position Method

No	Figure	Description
1		Push the Chinrest upward to detach, then install the Sinus Chinrest. Turn the Bite Block in the opposite direction for installation.
2		Align center of the patient's head (midsagittal plane, for example, middle of the forehead, nose, philtrum etc.) with the vertical alignment beam as shown in the figure on the left. Avoid tilting to either side.
3		Push patient's chin forward and support it using the installed Bite Block.

4		Use the horizontal alignment beam lever (mounted on the equipment Lift Column) to check the patient's head angle in preparation for sinus scanning.
5		Adjust the patient's head angle so that the horizontal alignment beam, the tip of the nose and the external auditory meatus are on the same horizontal plane, then stabilize the patient in a straight position and make sure that the neck is not tilted forward.
6		After patient positioning, turn the lever so the Chinrest and Temple Support can secure the patient's head.

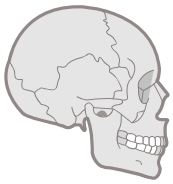
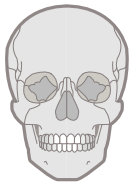
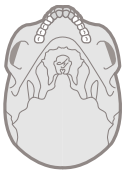
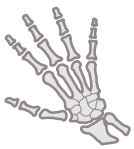
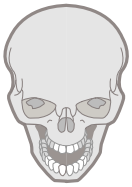
7.1.4.4 Panoramic (TMJ) Position Method

No	Figure	Description
1		Push the Chinrest or Sinus Chinrest upward to detach. (TMJ scanning should be conducted with the Chinrest detached.) Turn the screw underneath the Temple Guide to detach and install the TMJ Guide, then tighten the Locking Screw. Insert the TMJ Guide into the patient's ear. ***Note*** Scan with TMJ Chinrest removed.
2	 <Close Mouth>  <Open Mouth>	Insert TMJ Guide into patient's ears. Align center of the patient's head (midsagittal plane, for example, middle of the forehead, nose, philtrum etc.) with the vertical alignment beam as shown in the figure on the left. Avoid tilting to either side.

3		Adjust the horizontal laser beam lever to check patient's head angle in preparation for TMJ scanning.
4	 <Close Mouth>  <Open Mouth>	Adjust patient's head angle until the horizontal laser beam matches the Frankfort plane.
5		After patient positioning, turn the lever so the TMJ Guide can hold the patient in position.

7.2 CEPH Scanning (One Shot Type)

7.2.1 Description of CEPH Protocol

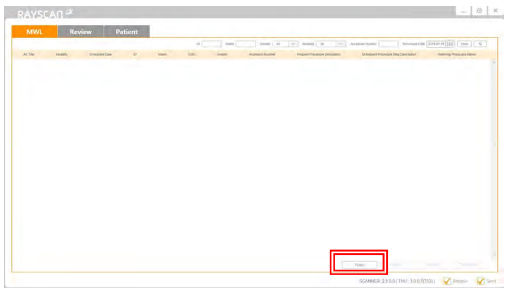
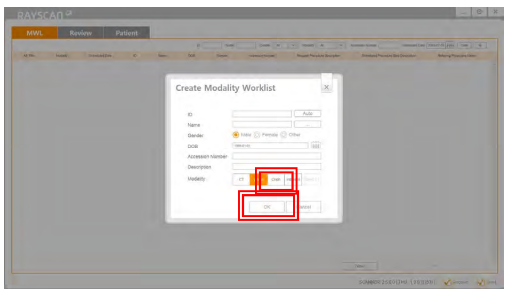
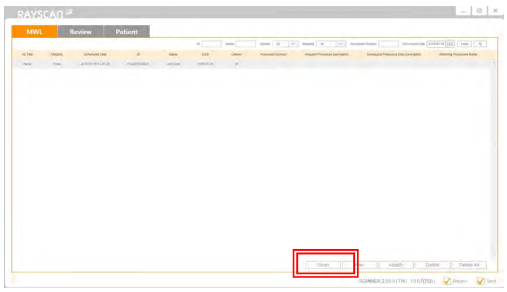
No	Figure	Description
1		**Lateral** Taken with the X-ray beam perpendicular to the patient's midsagittal plane. The center of the X-ray exposure should penetrate the external auditory meatus. Used to observe cranial and facial disorders, superficial wounds, nasopharyngeal soft tissues and paranasal sinus.
2		**PA (Posterior-Anterior)** Radiate from back to front. Used to observe illnesses of the cranium, superficial wounds, facial lateral growth and frontal sinus.
3		**SMV (Sub-Mento Vertex)** Radiate from the bottom of the maxilla looking up toward the epicranium. Used to observe the cranial base, position of the mandibular condylar and zygomatic arch.
4		**Carpus** Radiate the hand and wrist. Skeletal maturity of the hand can be compared to cranial development.
5		**Waters** When the midsagittal plane of the patient is vertical in relation to the detector, the X-ray should penetrate the center of the maxillary sinus. Used to observe maxillary sinus, etc.
6		**Reverse-Towne** X-ray should penetrate the occipital bone while mouth is fully opened. Used in observation of maxillary condylar fractures or maxillary condylar displacement.

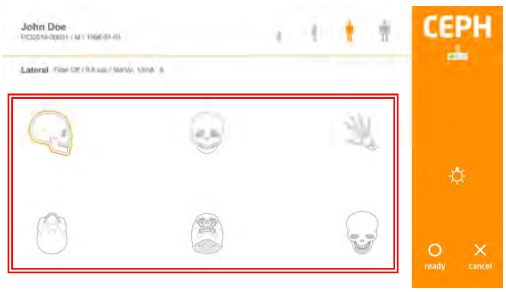
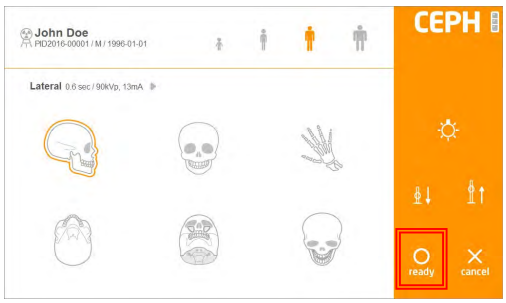
7.2.2 Cautionary Measures for Pre-Scanning

① When undergoing scanning, patients must remove all metals including glasses, necklaces, earrings, hearing aids, etc.

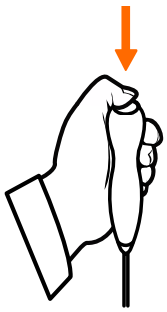
② Patient must wear a lead apron for protection against radiation.

7.2.3 CEPH Scanning Method (One Shot Type)

No	Figure	Description
1		Click MWL on the top left side of the screen and click the [New] button on the bottom right to register a new patient.
2		In the Modality Worklist screen, select [Ceph] for Modality and click [OK] button.
3		Select the MWL created above and click [Scan] button on the bottom right.
4		Verify Patient Information and click [OK] button.

5		Select the intended scanning protocol.
6		Select Patient Type, Resolution, Tube Voltage and Tube Current based on the patient. Using the remote control or touch screen, adjust equipment height to patient height and make sure the patient's neck is as straight as possible. Once positioned, allow patient to hold on to the Patient Handle. ※ The remote control is not provided in Canada. Position the patient according to the intended scanning protocol. (Refer to paragraph 7.2.4 for the positioning method.)
7		Once patient positioning is complete, press [Ready] button on the touch screen.

8



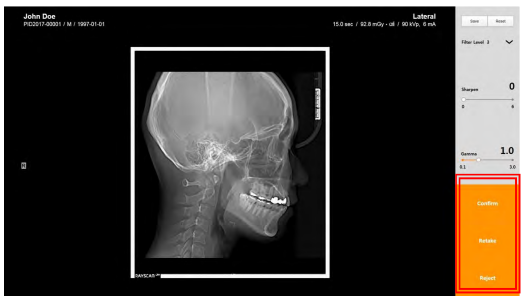
After the green light on the exposure switch has been illuminated, continue to press the switch until scanning has been completed.

Note

Take care not to release the button during scanning as doing so will stop the scanning process.

Maintain audio and visual contact with the patient and x-ray unit during exposure. if the c-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately

9



Once scanning is complete, select among the [Confirm/Retake/Reject] buttons.

※ Operation Description

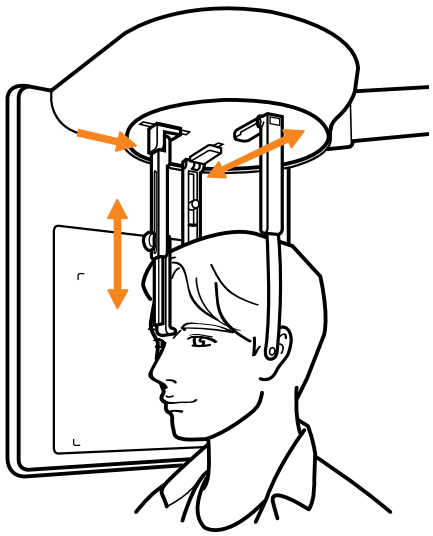
[Confirm]: Save Image View and go to MWL screen.

[Retake]: Save Image View and automatically go to Acquisition-Patient Info screen for retake.

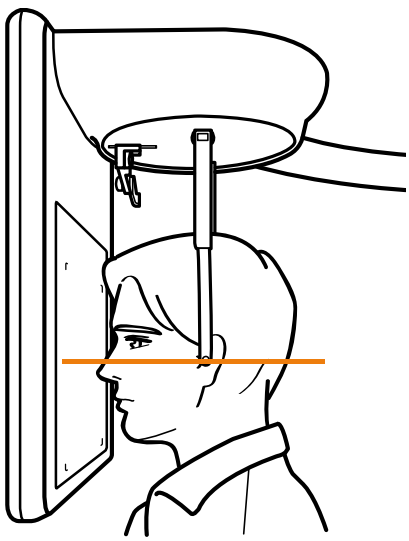
[Reject]: Save Image View, indicate rejected image in the database, then go to MWL screen.

7.2.4 Patient Position Method

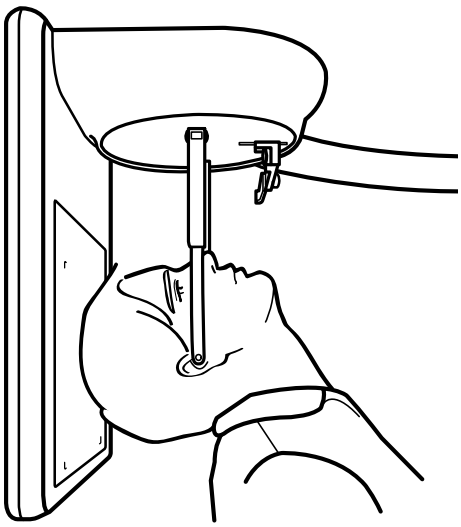
7.2.4.1 CEPH (Lateral) Position Method

No	Figure	Description
1		Position the patient's head as shown in the figure to the left, with the ala-tragus line parallel to the floor. ***Note*** Place detector on the patient's right-hand side.

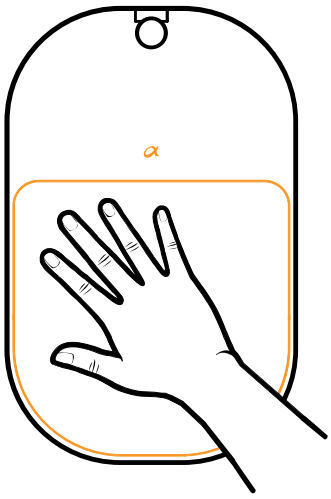
7.2.4.2 CEPH (PA) Position Method

No	Figure	Description
1		Turn the Ear Rods as shown in the figure on the left. Fold up the Nasion Bar, then position the patient's head with the ala-tragus line parallel to the floor.

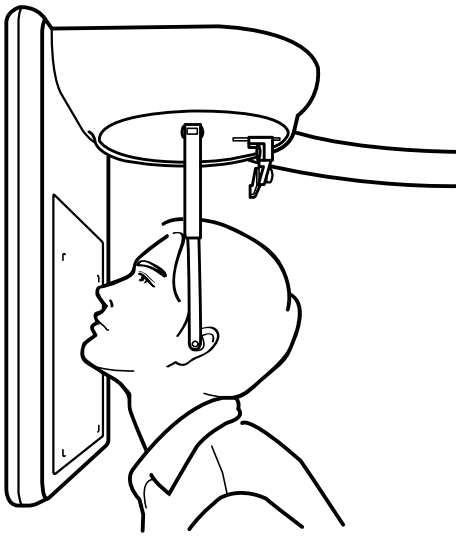
7.2.4.3 CEPH (SMV) Position Method

No	Figure	Description
1		Turn the Ear Rods as shown in the figure on the left and fold-up the Nasion Bar. Position the patient's head vertically, with the ala-tragus line perpendicular to the floor. ***Note*** Place the patient in a sitting position when scanning SMV.

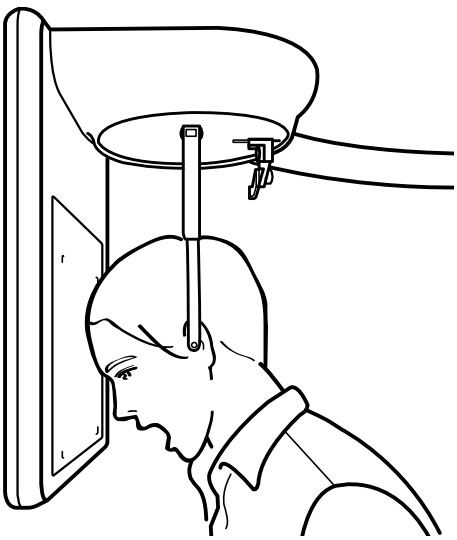
7.2.4.4 CEPH (Carpus) Position Method

No	Figure	Description
1		Gently place the patient's hand palm down on the sensor, inside the marked region.

7.2.4.5 CEPH (Waters) Position Method

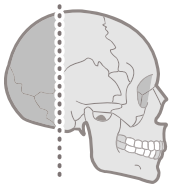
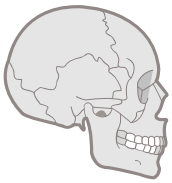
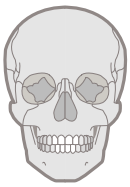
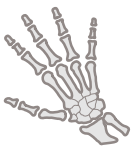
No	Figure	Description
1		Position the patient's head as depicted in the figure to the left. Place the head of the patient so that the angle between the Alar-targal line and the Detector is 37~40°.

7.2.4.6 CEPH (Reverse Towne) Position Method

No	Figure	Description
1		Position the patient's head as depicted in the figure to the left. Place the head of the patient so that the angle between the Alar-targal line and the Detector is 25~30 ° . The mouth is positioned at the maximum open position.

7.3 CEPH Scanning (Scan Type)

7.3.1 Description of CEPH Protocol

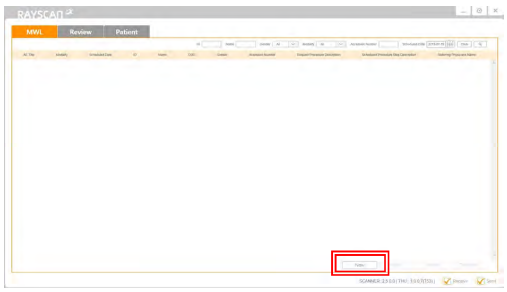
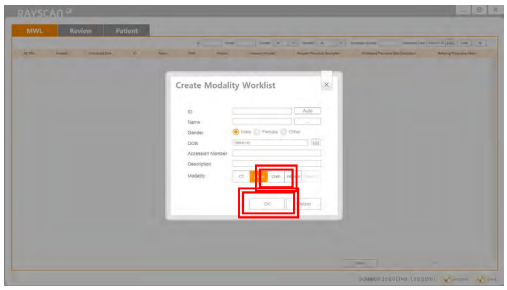
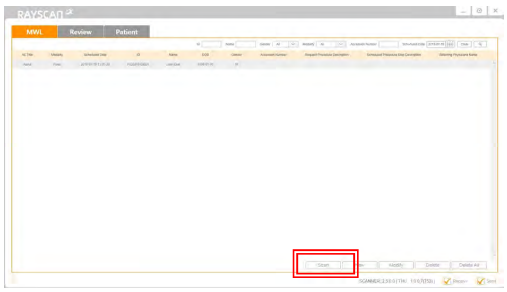
No	Figure	Description
1		**Lateral** Taken with the X-ray beam perpendicular to the patient's sagittal plane. The center of the X-ray exposure should penetrate the external auditory meatus. Used to observe cranial and facial disorders, superficial wounds, nasopharyngeal soft tissues and paranasal sinus.
2		**Lateral Wide** Provides a wider FOV than the upper Lateral prtocol. Use it to see the occiput of the patient.
3		**PA (Posterior-Anterior)** Radiate from back to front. Used to observe illnesses of the cranium, superficial wounds, facial lateral growth and frontal sinus.
4		**SMV (Sub-Mento Vertex)** Radiate from the bottom of the maxilla looking up toward the epicranium. Used to observe the cranial base, position of the mandibular condylar and zygomatic arch.
5		**Carpus** Radiate the hand and wrist. Skeletal maturity of the hand can be compared to cranial development.

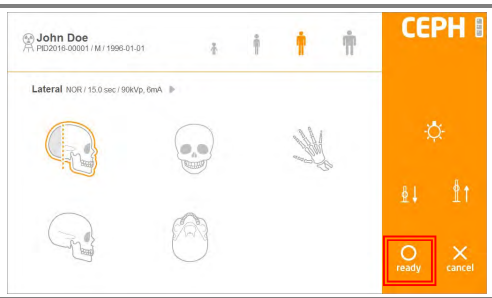
7.3.2 Cautionary Measures for Pre-Scanning

① Patient must remove all metals including glasses, necklaces, earrings, hearing aids, etc., when undergoing scanning.

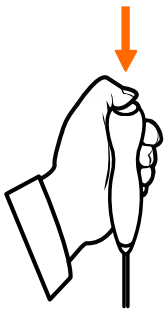
② Patient must wear a lead apron for protection against radiation.

7.3.3 CEPH Scanning Method

No	Figure	Description
1		Click MWL on the top left side of the screen, then click the [New] button on the bottom right to register a new patient.
2		In the Modality Worklist screen, select [Ceph] for Modality and click [OK] button.
3		Select the MWL created above and click [Scan] button on the bottom right.
4		Verify patient information and click [OK] button, then proceed to the next step.

5		Select the intended scanning protocol.
6		Select Patient Type, Resolution, Tube Voltage and Tube Current based on the patient. Using the remote control or touch screen, adjust equipment height to patient height and make sure that the patient's neck is as straight as possible. Once positioned, allow patient to hold on to the Patient Handle. Once patient positioning is complete, press [Ready] button on the touch screen. ※ The remote control is not provided in Canada. Position the patient according to the intended scanning protocol. (Refer to paragraph 7.3.4 for the positioning method.)
7		Once patient positioning is complete, press [Ready] button on the touch screen.

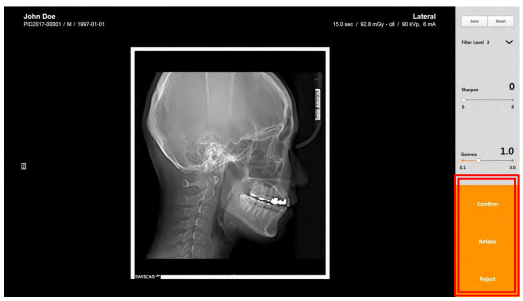
8



After the green light on the exposure switch has been illuminated, continue to press the switch until scanning has been completed.

Note	Take care not to release the button during scanning as doing so will stop the scanning process. Maintain audio and visual contact with the patient and x-ray unit during exposure. if the c-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately

9



Once scanning is complete, select among the [Confirm/Retake/Reject] buttons.

※ **Operation Description**

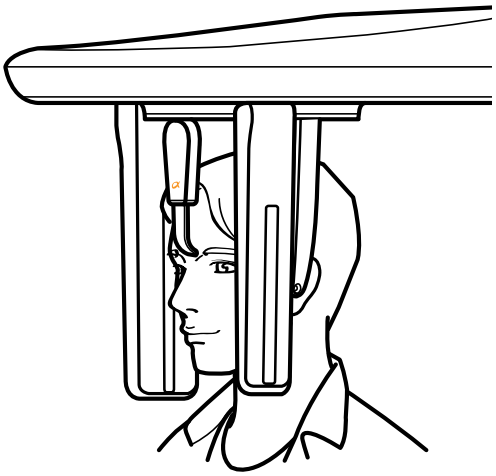
[Confirm]: Save Image View and go to MWL screen.

[Retake]: Save Image View and automatically go to Acquisition-Patient Info screen for retake.

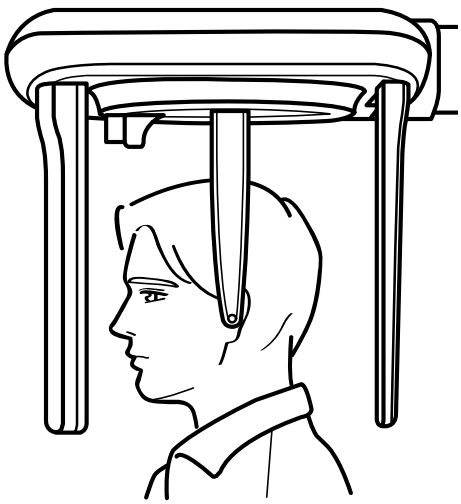
[Reject]: Save Image View, indicate rejected image in the database, then go to the MWL screen.

7.3.4 Patient Position Method

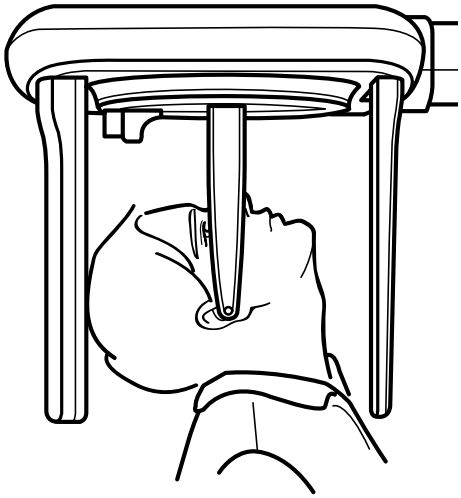
7.3.4.1 CEPH (Lateral) Position Method

No	Figure	Description
1		Place detector on the patient's right-hand side. ***Note*** Place detector on patient's right-hand side.

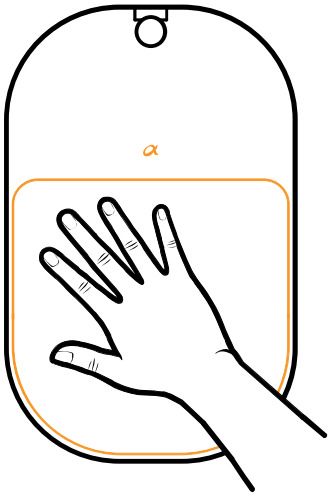
7.3.4.2 CEPH (PA) Position Method

No	Figure	Description
1		Turn the Temple Support as shown in the figure on the left and fold-up the Nasion Bar. Position the patient's head with the ala-tragus line parallel to the floor.

7.3.4.3 CEPH (SMV) Position Method

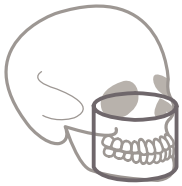
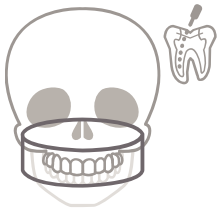
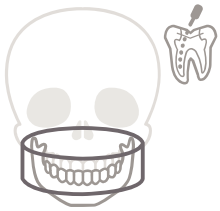
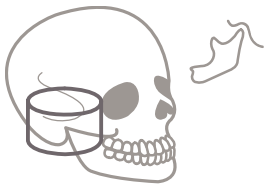
No	Figure	Description
1		Turn the Temple Support as shown in the figure on the left and fold-up the Nasion Bar. Position the patient's with the ala-tragus line perpendicular to the floor. ***Note*** Place the patient in a sitting position when scanning SMV.

7.3.4.4 CEPH (Carpus) Position Method

No	Figure	Description
1		Gently place the patient's hand palm down on the sensor, inside the marked region.

7.4 CT Scanning

7.4.1 Description of CT Protocol

No	Figure	Description
1		***Jaw*** Commonly used to observe the patient's maxilla and mandible.
2		***Jaw-Fast*** Observing maxilla and mandible of the patient in fast scan (4.9sec) and low dose.
3		***Endodontics Maxilla*** Used to observe Endodontics Maxilla in high resolution.
4		***Endodontics Mandible*** Used to observe Endodontics Mandible in high resolution.
5		***Sinus*** Used to observe Sinus..
6		***TMJ (Temporomandibular Joint)*** Used to observe TMJ.

7.4.2 Cautionary Measures for Pre-Scanning

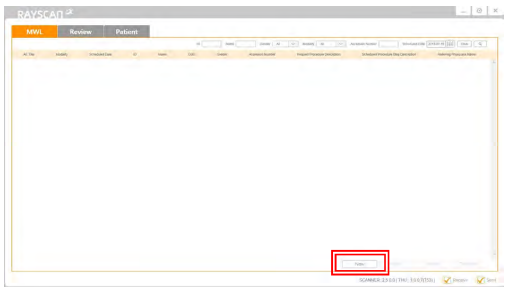
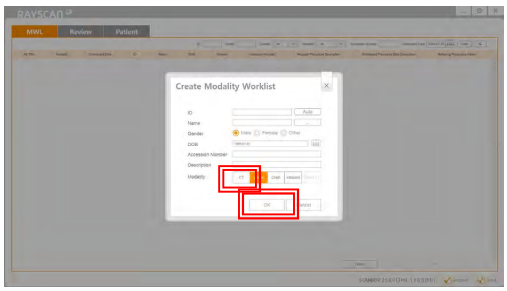
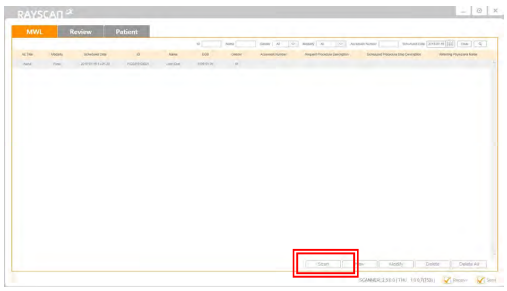
① Install hygienic cover over Bite Block and Chinrest.

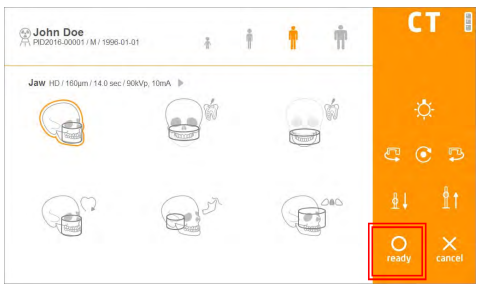
② Open Temple Support to facilitate patient positioning.

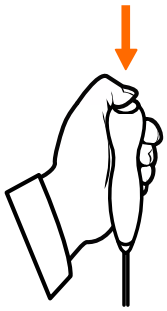
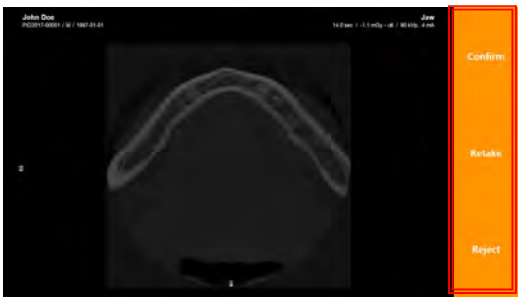
③ Patient must remove all metal when undergoing scanning, including glasses, necklaces, earrings, hearing aids, etc.

④ Patient must wear a lead apron to protect against radiation.

7.4.3 CT Scanning Method

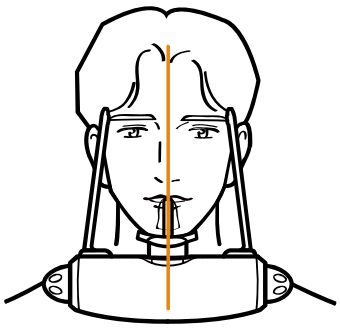
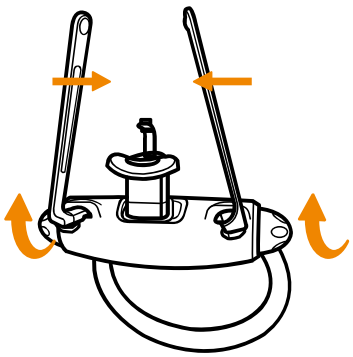
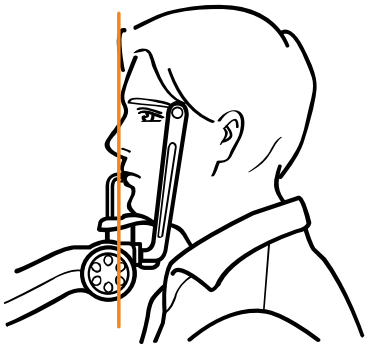
No	Figure	Description
1		Click MWL on the top left side of the screen and [New] button on the bottom right to register a new patient.
2		In the Modality Worklist screen, select [CT] for Modality and click [OK] button.
3		Select the MWL created above and click [Scan] button on the bottom right.
4		Verify patient information and click [OK] button, then proceed to next step.

5		Select the intended scanning protocol.
6		Select Patient Type, Tube Voltage and Tube Current based on the patient. Using the remote control or touch screen, adjust equipment height to patient height and make sure that the patient's neck is as straight as possible. Once positioned, allow patient to hold on to the Patient Handle. ※ The remote control is not provided in Canada. Position the patient according to the intended scanning protocol. (Refer to paragraph 7.4.4 for the positioning method.)
7		Once patient positioning is complete, press [Ready] button on the touch screen.

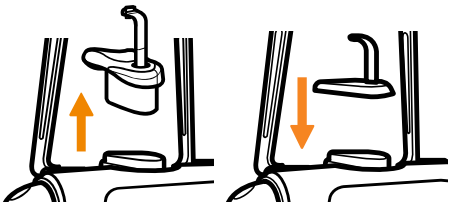
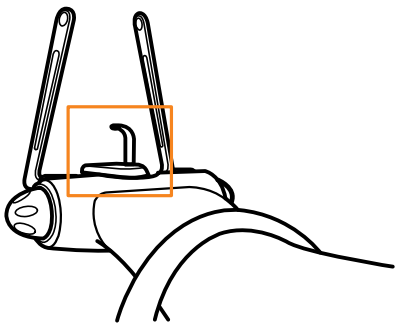
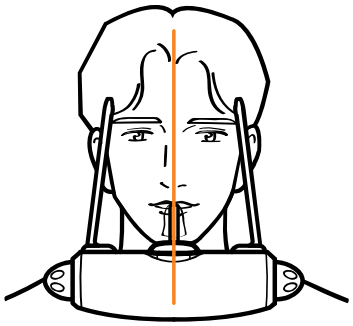
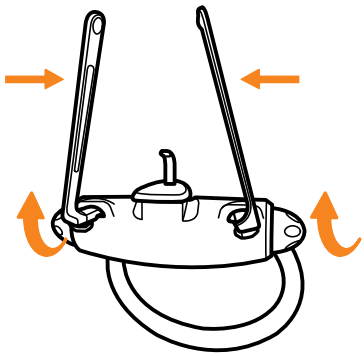
8		After the green light on the exposure switch has been illuminated, continue to press the switch until scanning has been completed. ***Note*** Take care not to release the button during scanning as doing so will stop the scanning process. Maintain audio and visual contact with the patient and x-ray unit during exposure. if the c-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately
9		Once scanning is complete, select among the [Confirm/Retake/Reject] buttons. ※ **Operation Description** **[Confirm]:** Save Image View and go to MWL screen. **[Retake]:** Save Image View and automatically go to Acquisition-Patient Info screen for retake. **[Reject]:** Save Image View, indicate rejected image in the database, then go to MWL screen.

7.4.4 CT Patient Positioning Method

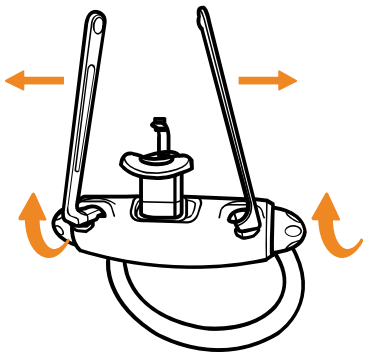
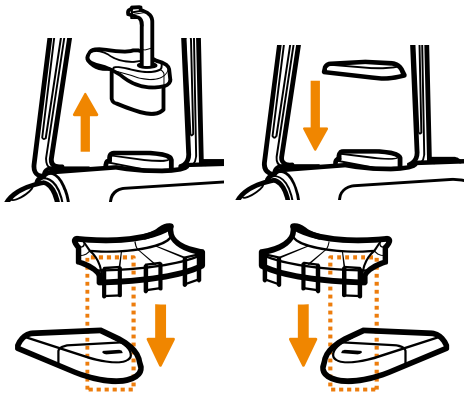
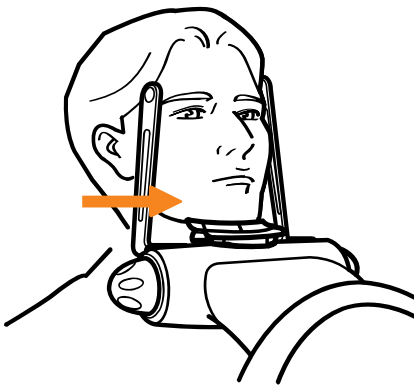
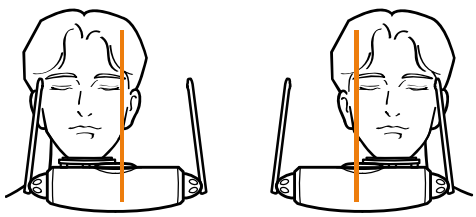
7.4.4.1 CT (Jaw, Endodontics Maxilla/Mandible) Position Method

No	Figure	Description
1		As shown in the figure on the left, position the center of the patient's head (midsagittal plane, for example, middle of the forehead, nose, philtrum, etc.) in alignment with the vertical alignment beam. Avoid tilting the head to either side.
2		Once the patient is properly positioned, turn the lever to secure the patient with the Temple Support.
3		Position the laser beam anterior to the patient.

7.4.4.2 CT (Sinus) Position Method

No	Figure	Description
1	 	Push the Chinrest upward to detach. Install the Sinus Chinrest.
2		As shown in the figure on the left, position the center of the patient's head (midsagittal plane, for example, middle of the forehead, nose, philtrum, etc.) in alignment with the vertical alignment beam. Avoid tilting the head to either side.
3		Once the patient is properly positioned, turn the lever to secure the patient with the Temple Support.

7.4.4.3 CT (TMJ) Position Method

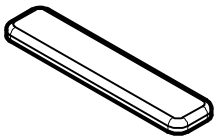
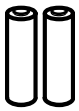
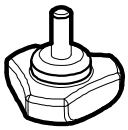
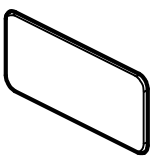
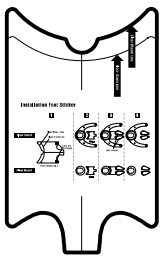
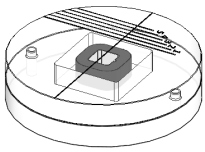
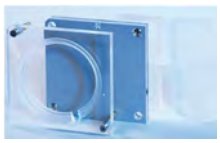
No	Figure	Description
1		Before positioning the patient, turn the lever to spread the Temple Support.
2		Push the Chinrest upward to detach, then install the Sinus Chinrest. Install the TMJ Chinrest on the top of the Sinus Chinrest. Install it to the proper position you want to take image.
3		Push the patient's lower jaw forward, to rest in the cup of the Edentulous Chinrest.
4		Instruct the patient to close their eyes. To capture the left TMJ, align the vertical beam to the edge of the patient's left eye. The patient's right temple should contact the Temple Support. When capturing the right TMJ, perform the above procedure with the opposite directions.

Accessories

8

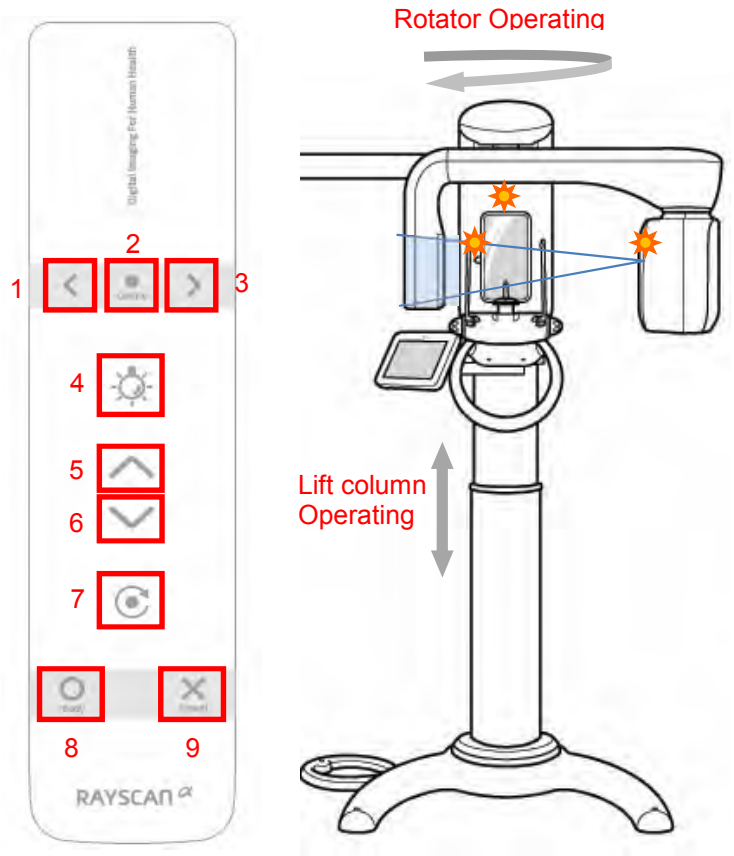
8 ACCESSORIES

8.1 Accessories List

				
CHINREST	SINUS CHINREST	EDENTULOUS CHINREST	TMJ CHINREST	BITE BLOCK
				
FOOT STICKER	REMOTE CONTROL	AAA Battery [2EA]	REMOTE CONTROL STAND	REMOTE CONTROL STAND STICKER
				
TMJ Guide (L)	TMJ Guide (R)	PANO/CT Temple Support (L)	PANO/CT Temple Support (R)	ADJUSTMENT KNOB [2EA]
				
EXPOSURE SWITCH HOLDER	EXPOSURE SWITCH HOLDER STICKER	FOOT STICKER JIG	RayDVT	Dent/Digitest 2.1

※ The remote control is not provided in Canada.

8.2 Remote Control Operating Procedure



- Remote Control can control 9 motions

No	Item	Description
1	Canine Left	Move Canine Beam forward.
2	Canine Center	Move Canine Beam to center.
3	Canine Right	Move Canine Beam backward.
4	Lamp On/Off	Laser beam ON/OFF.
5	Lift Column Up	Raises system when pressed.
6	Lift Column Down	Lowers system when pressed.
7	Home	The position of the Rotator part moves to the initial state.
8	Ready	Scanner ready button. When clicked, system moves to the start position.
9	Cancel	Touch to cancel scanning, close scanning screen and return to the Splash screen.

- Omnidirectional Remote Control allows the user freedom of movement.
  - User can easily control the device while taking care of the patient.
  - Distinct button configuration facilitates ease-of-use.
  - Remote Control can be attached to the wall with the Remote Control Stand (included).
  - 2 AAA sized batteries are required. Replace when batteries are exhausted.

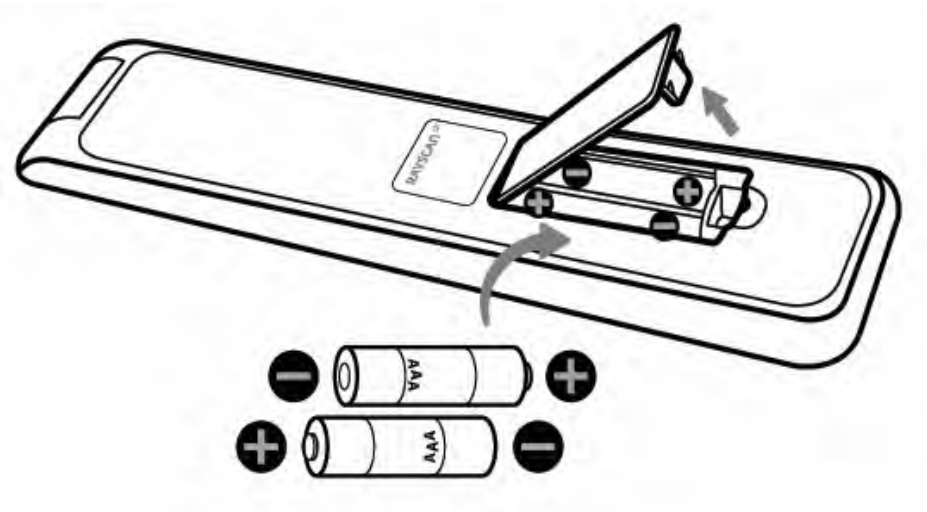
Warning

Stop holding the button from the wireless remote controller in case of hitting a patient due to movements such as up / down Lift Column and rotation of Rotator. Use pre-motion function if it is needed to check clearly hitting a patient during the motions. Do not press remote buttons when device is out of sight. Always use the Remote Control with the device in sight. If the Remote Control will be inactive for a significant length of time, please remove the batteries.

※ The remote control is not provided in Canada.

8.2.1 How to Insert Batteries in the Remote Control

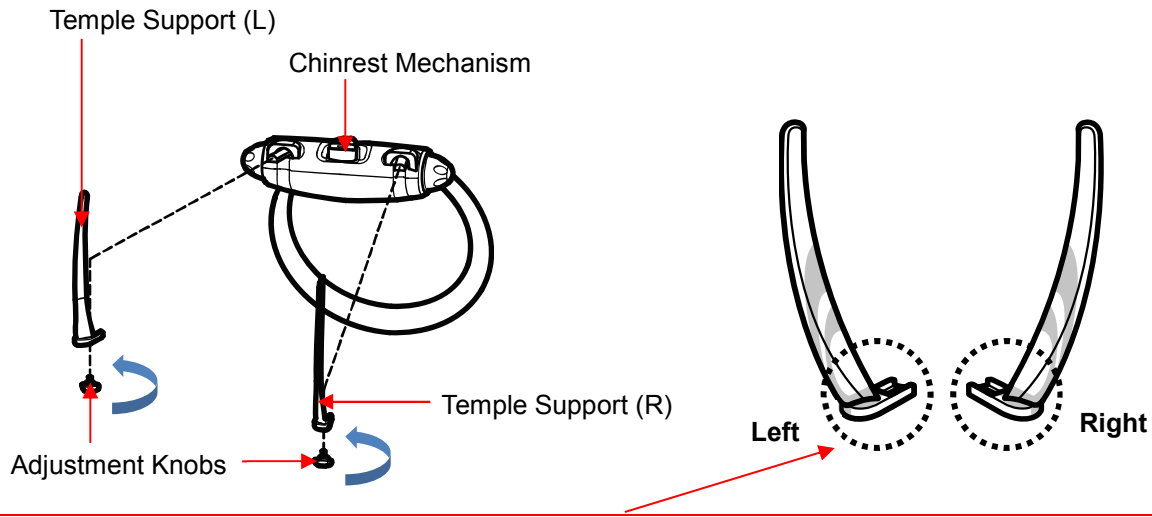
① Open the cover on the back side, as seen in the image below.
② Check +/- and insert two AAA size 1.5V batteries.
③ Close the cover.



※ The remote control is not provided in Canada.

8.3 Temple Support Assembly

1) Piece together Pano/CT Temple Support (L) and Pano/CT Temple Support (R) into the Chinrest Mechanism, then screw in 2 Adjustment Knobs to secure.



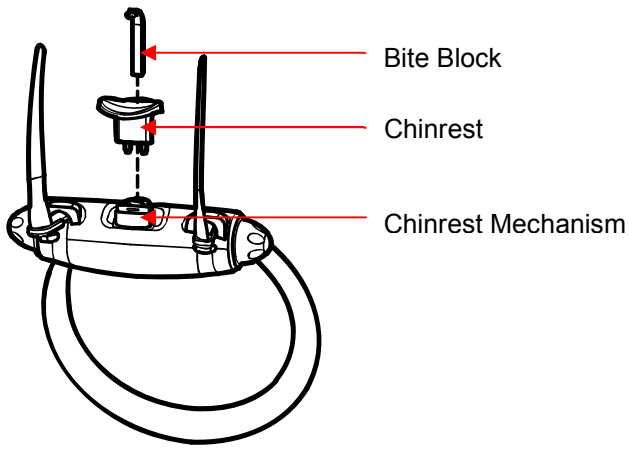
Caution

The rounded part of temple support must be mounted on the inner-side.

Check the marker “L”, “R” in Temple support.

8.4 Bite Block and Chinrest Assembly

1) Attach Chinrest to upper part of Chinrest Mechanism then insert the Bite Block.

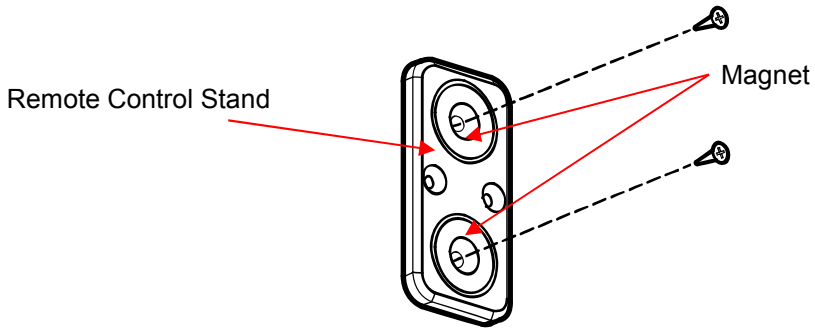


Caution

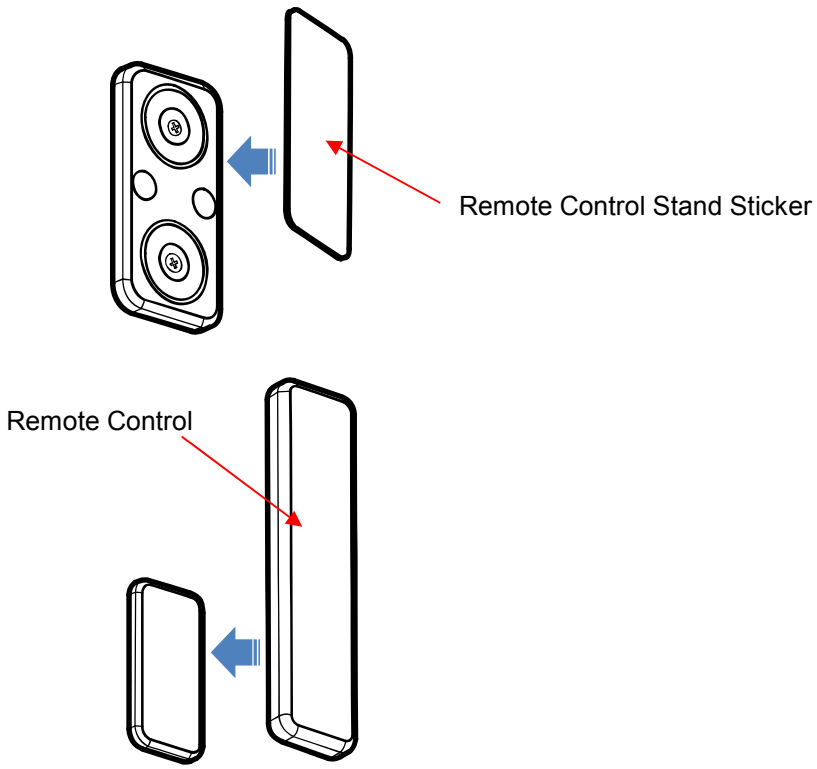
There are four kind of chinrest. Place with the proper chinrest.

8.5 Remote Control Stand Assembly

1) Use a Phillips screwdriver to secure 2 Φ4x20 Flat Head Tapping Screws on the wall in the location chosen for the remote control stand.



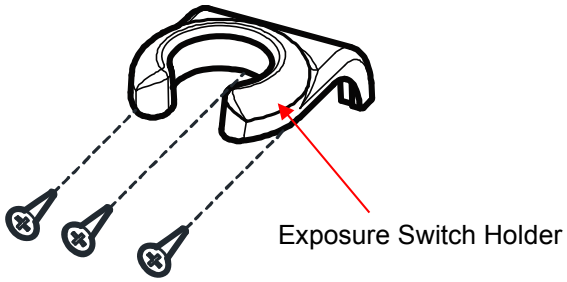
2) Attach the Remote Control Stand to the wall and cover surface with included Remote Control Stand Sticker.



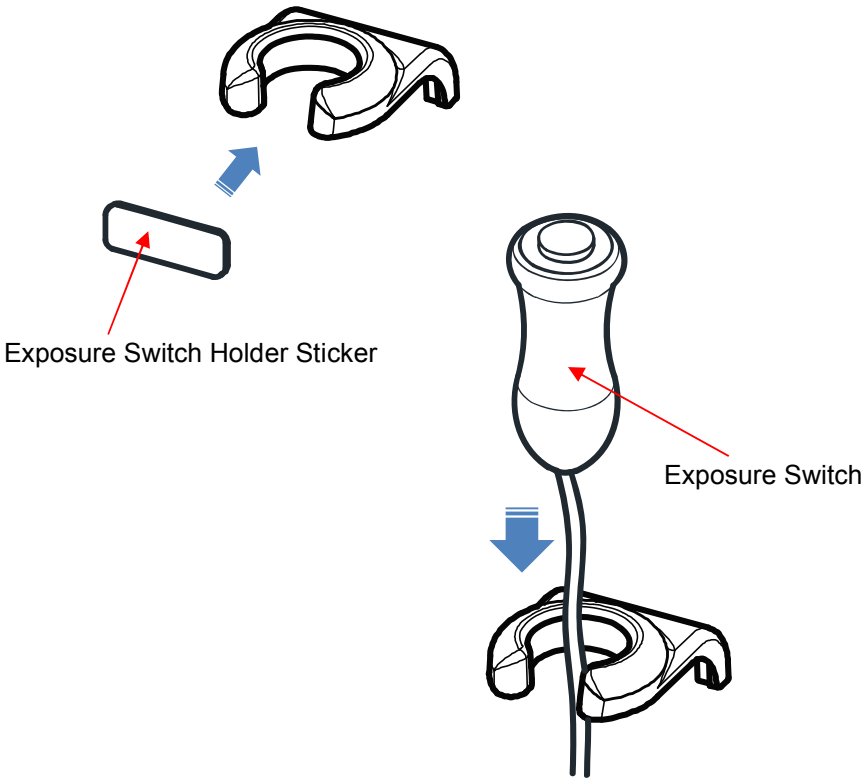
※ The remote control is not provided in Canada.

8.6 Exposure Switch Stand Assembly

1) Use a Phillips screwdriver to secure 3 Φ4x20 Flat Head Tapping Screws in the wall chosen for the Exposure Switch Holder.



2) Mount the Exposure Switch Holder to the wall, then attach an Exposure Switch Holder Sticker to the surface of the Exposure Switch Holder.



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System Specifications

9

9 SYSTEM SPECIFICATIONS

9.1 Technical Specifications

Classification		Specification	Remark
Rated Voltage		100-240V~, 50/60Hz	
Power Consumption		2.5kVA Max	
Operation Mode		Continuous operation with intermittent loading.	
Max.permissible apparent impedance of supply mains		0.8Ω(100V)	
Overcurrent Circuit		30A	
Form and Degree of Electric Shock		Class 1, Type B	
Total Filtration		2.8mmAl / 90IEC60522	
X-ray	X-ray Tube	Tube Voltage: 50~100kV Tube Current: Max 22mA Focal Point Size: 0.5mm Target Angle: 5° Heat Capacity: 35kJ	
	High-Voltage Generator	Tube Voltage: 60~100kV(±10%) Tube Current: 4~17mA(±20%) Power Input: 2.185kW Power Output: 1.7kW (less than 3s exposure) Inherent Filtration: 1.8mmAl (Tube+insulating oil+case) Added Filtration: 1.0mmAl	
	Cooling Time	Temperature is monitored and displayed on the screen with a color code. Green indicates that another scan can be performed immediately. Yellow or Red indicates that the user must wait either 3 or 5 minutes respectively.	
	Loading Factor	Max. kV when mA : 100kV/17mA Max. mA when kV : 17mA/100kV	

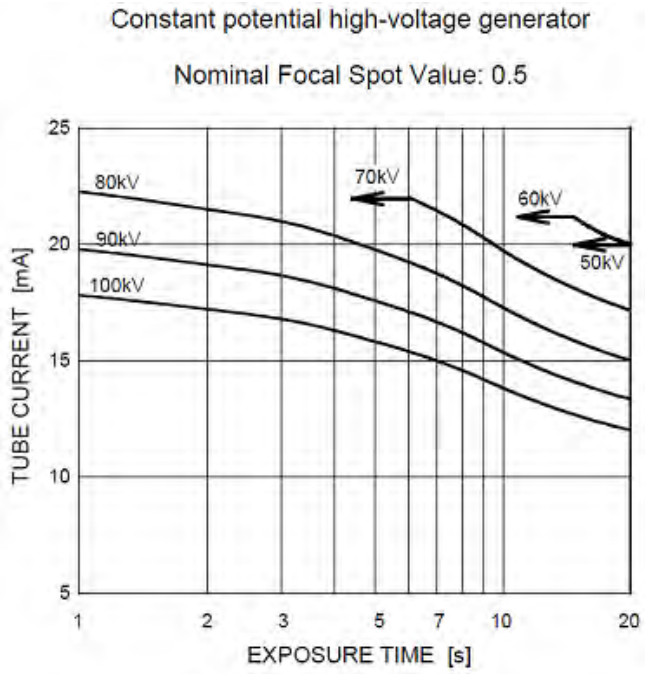
X-ray Detector	For Panoramic Use	Pixel Size: 100um Pixel Matrix: 60x1512 Pixel Area: 6.0mm(W)x151.2mm(H)	
	For Panoramic Use	Pixel Size: 119um Pixel Matrix: 1256x1256 Pixel Area: 149.5mmW)x149.5mm(H)	
	For CEPH Use (One Shot S Type)	Pixel Size: 139um Pixel Matrix: 2176x1792 Pixel Area: 302mm(W)x249mm(H)	Option
	For CEPH Use (One Shot L Type)	Pixel Size: 139um Pixel Matrix: 3072x2560 Pixel Area: 427mm(W)x356mm(H)	Option
	For CEPH Use (One Shot L Type)	Pixel Size: 127um Pixel Matrix: 3328x3328 Pixel Area: 422.7mm(W)x422.7mm(H)	
	For CEPH Use (Scan Type)	Pixel Size: 100um Pixel Matrix: 48x2400 Pixel Area: 4.8mm(W)x240mm(H)	Option
	For CT Use	Pixel Size: 200um Pixel Matrix: 624x624 Pixel Area: 124.8mm(W)x124.8mm(H) Pixel resolution: above 1lp/mm	Option
	For CT Use	Pixel Size: 119um Pixel Matrix: 1256x1256 Pixel Area: 149.5mm(W)x149.5mm(H) Pixel resolution: above 1lp/mm	Option
SID		CT: 677mm Pano: 677mm Ceph(Scan): 1650mm Ceph(Oneshot-S): 1660mm Ceph(Oneshot-L): 1507mm	
Tube Voltage	CT	Child: 60~100kV, Adult: 60~100kV	
	Pano	Child: 60~100kV, Adult: 60~100kV	
	Ceph	Child: 60~100kV, Adult: 60~100kV	

Tube Current	CT	Child : 4~17mA, Adult : 4~17mA	
	Pano	Child : 4~17mA, Adult : 4~17mA	
	Ceph	Child : 4~17mA, Adult : 4~17mA	
Exposure Time	CT	Child : ~14s, Adult : ~14s	
	Pano	Child : ~14s, Adult : ~14s	
	Ceph(Scan)	Child : ~20s, Adult : ~20s	
	Ceph(Oneshot)	Child : ~0.8s, Adult : ~0.8s	
Magnification		CT : 1.44 PANO : 1.3 Scan Ceph : 1.11 Oneshot Ceph(S): 1.12 Oneshot Ceph(L): 1.13	
Alignment Beam	IEC60825-1 Safety Ratings	Class I	
	Wavelength	650nm±20nm	
	Output power	<1mW	
Apparatus Specifications	Size	1,118mm(W)×1,481mm(D)×2,296mm(H)	
	One Shot S Type CEPH Inclusive	1,831mm(W)x1,481mm(D)x2,296mm(H)	
	One Shot L Type CEPH Inclusive	1,672mm(W)×1,481mm(D)×2,296mm(H)	
	Scan Ceph Inclusive	1,831mm(W)x1,481mm(D)x2,296mm(H)	
	Weight	150kg±10%	
	One Shot S Type CEPH Inclusive	176kg±10%	
	One Shot L Type CEPH Inclusive	176kg±10%	
	Scan Ceph Inclusive	177.5kg±10%	
Quantity per pack		1 SET	
Lift Column Height Control	Stroke	670mm	

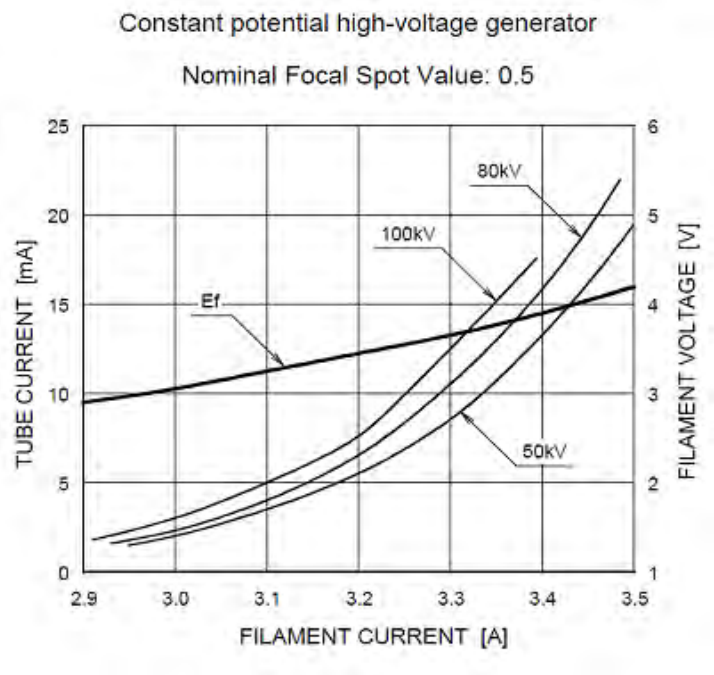
Software		RayScan ver. 2.0 or higher	
Workstation	OS	Windows 10, 64Bit	Use products with certificate from National or Accredited Organization.
	CPU	Intel Dual Core or higher	
	RAM	8GB or higher	
	HDD	1TB or higher	
	Network	Gigabit Ethernet	
Operating Environment	Ambient Temperature Range	15℃ ~ 25℃	
	Relative Humidity	20% ~ 60%	
	Atmospheric Pressure Range	700hPa ~ 1060hPa	
Transport & Storage Environment	Temperature Range	-10℃ ~ 50℃	
	Relative Humidity	10%~ 90%	
	Atmospheric Pressure Range	700hPa ~1060hPa	

9.1.1 X-ray Tube

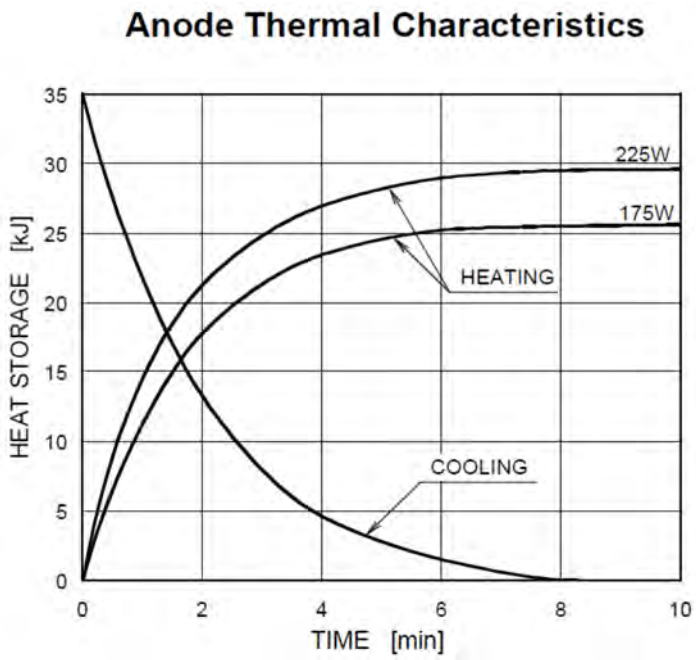
9.1.1.1 Maximum Rating Charts



9.1.1.2 Emission & Filament Characteristics

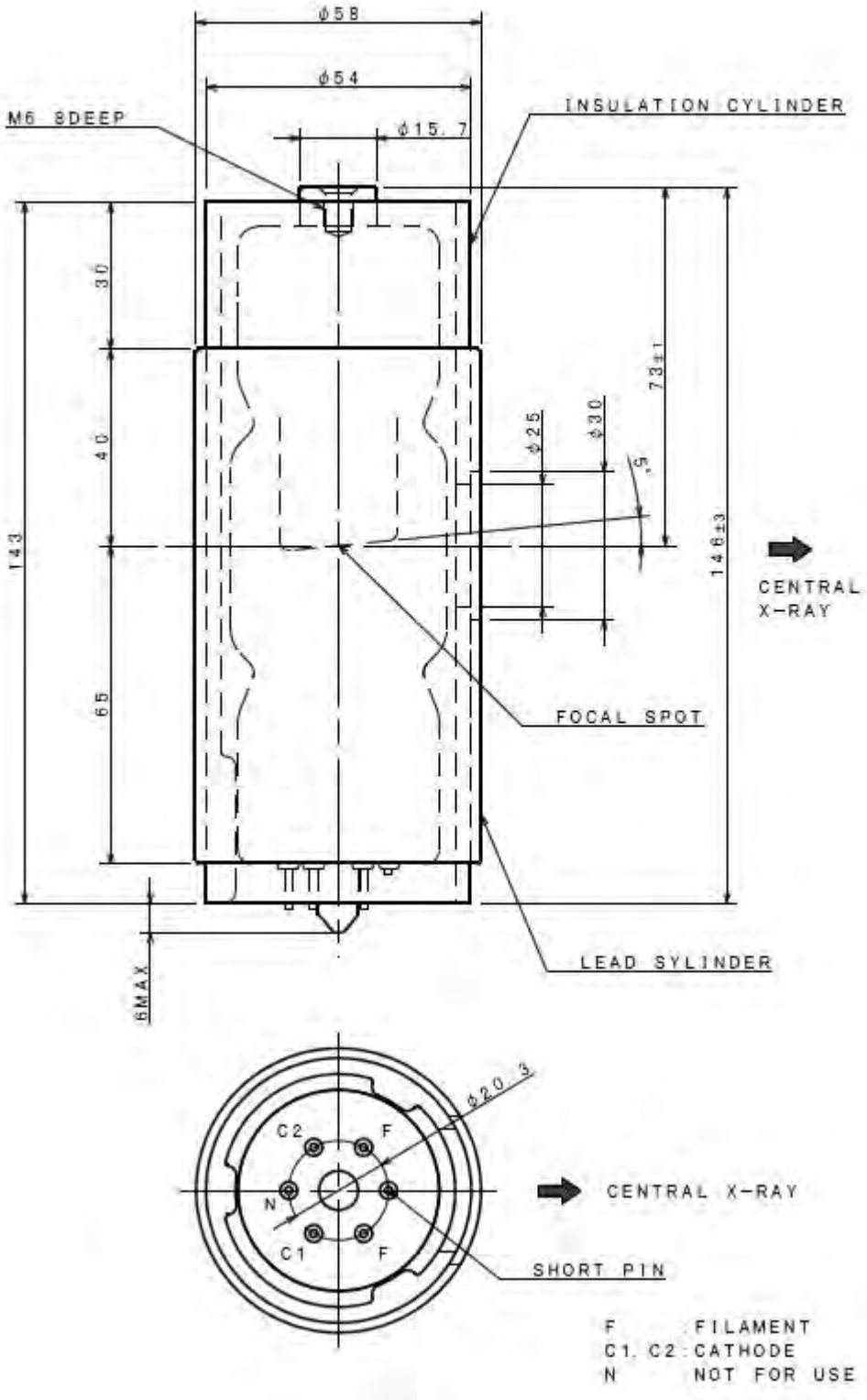


9.1.1.3 Anode Thermal Characteristics



9.1.1.4 Dimensional Outline

Unit: mm



9.2 Dose Information

9.2.1 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 patients for X-ray diagnostic radiation exposure to be over 5 years old.

9.2.2 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 year old according to FDA guidance “Pediatric Information for X-ray Imaging Device Premarket Notifications. (Draft Guidance)”

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
c. 21 year old [~80 kg, 170 cm height]: Adult
d. Adult [more than 80 kg, 180 cm standing height]: Large Adult

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 to the child. There is no need for these larger doses to children, and X-ray settings can be adjusted to reduce dose significantly while maintaining diagnostic image quality.

Please refer the web pages regarding additional pediatric information.

- FDA’s Pediatric X-ray Imaging webpage:
http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures

9.2.3 Procedures Performed

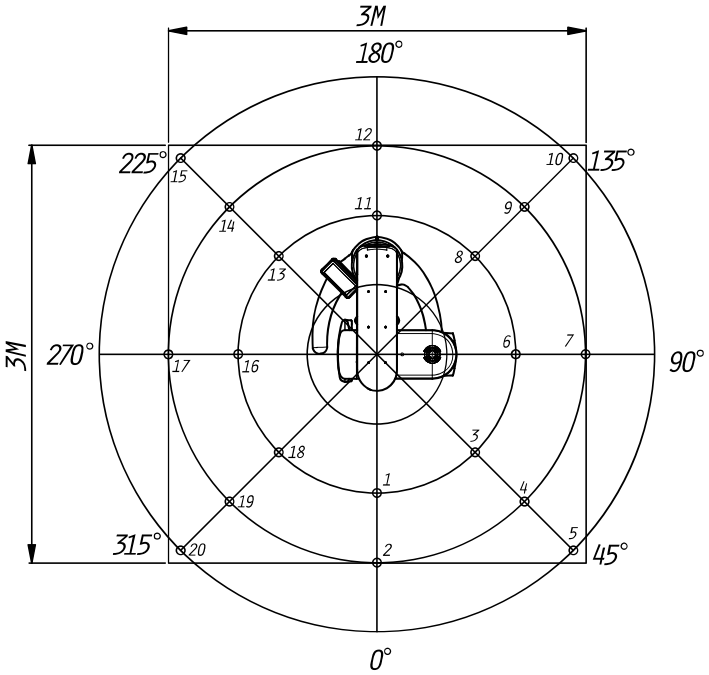
9.2.3.1 Panoramic/CEPH

- X-ray dosage is noted as mGy.cm^2 (dose area product) and measured in the primary collimator. The dosage has ±25% tolerance.

9.2.3.2 CT

- X-ray dosage is noted as CTDIvol (mGy) and has ±25% tolerance.
- X-ray dosage is measured at the center of the patient position and 3, 6, 9, 12 o'clock.
- Positions in the pencil ionization chamber.
- The measured value is used to calculate CTDIw.
- CTDI100 = [f X measured value]/(beam width), conversion factor f=0.0087mGy/mR
- CTDIw = 1/3CTDI100 center + 2/3CTDI100 (mean value of 4 positions)
- CT consists of 1 revolution imaging, therefore CTDIw and CTDIvol are equivalent.
- CTDIvol ≤ 20mGy at CT condition of operation. (Tube voltage: 85kV, Tube current: 5mA, Exposure time: 14s)

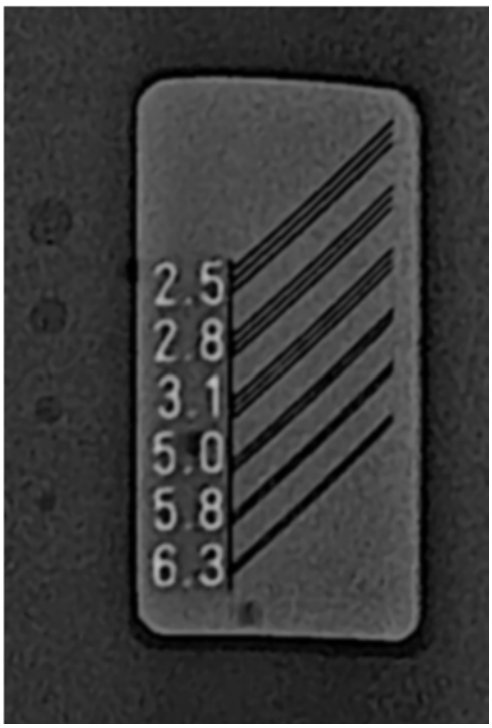
9.3 Stray Radiation



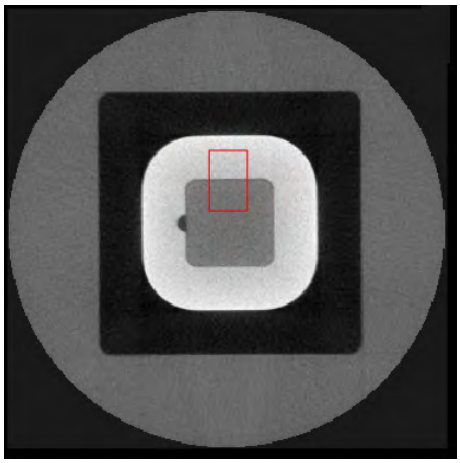
Angle (º)	Measuring Point	Distance (m)	uGy/mAs
0	1	1	2.53E-02
	2	1.5	7.27E-03
45	3	1	2.53E-02
	4	1.5	1.68E-02
	5	2	6.23E-03
90	6	1	3.41E-02
	7	1.5	2.14E-02
135	8	1	6.71E-02
	9	1.5	1.92E-02
	10	2	8.90E-03
180	11	1	6.19E-05
	12	1.5	2.53E-05
225	13	1	8.91E-02
	14	1.5	2.29E-02
	15	2	1.12E-02
270	16	1	7.32E-02
	17	1.5	2.84E-02
315	18	1	4.40E-02
	19	1.5	7.73E-03
	20	2	1.10E-03

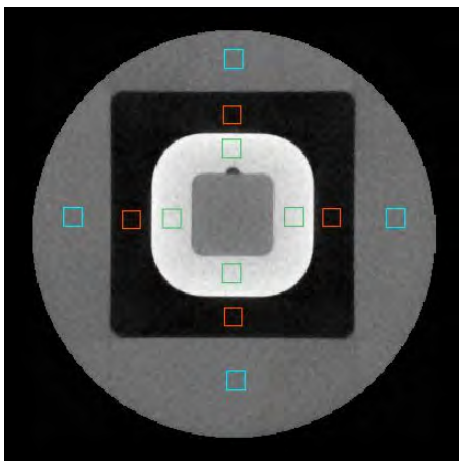
9.4 Imaging Performance

9.4.1 Panoramic

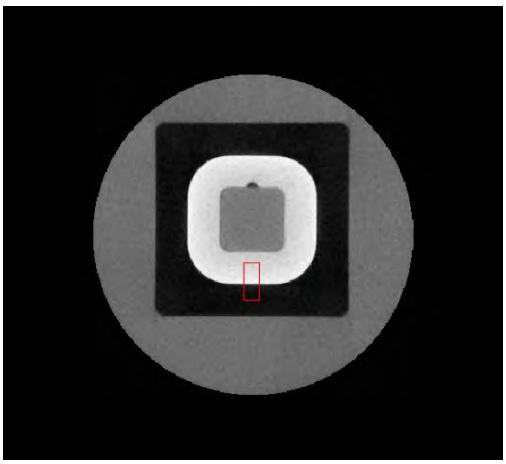
<table>
<tr><td colspan="3">Low Pair Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage (kV)</td><td>Current (mA)</td><td>Line Pair Resolution (LP/mm)</td></tr>
<tr><td>75</td><td>13</td><td>3.1</td><td>Line Pair Resolution ≥ 2.5</td></tr>
<tr><td colspan="3">Line Contrast Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage (kV)</td><td>Current (mA)</td><td>Low Contrast Resolution (Step)</td></tr>
<tr><td>75</td><td>13</td><td>4</td><td>Producing Low Contrast Resolution ≥ 2 step</td></tr>
<tr><td colspan="4">Image</td></tr>
<tr><td colspan="4"> 
</td></tr>
</table>

9.4.2 CT

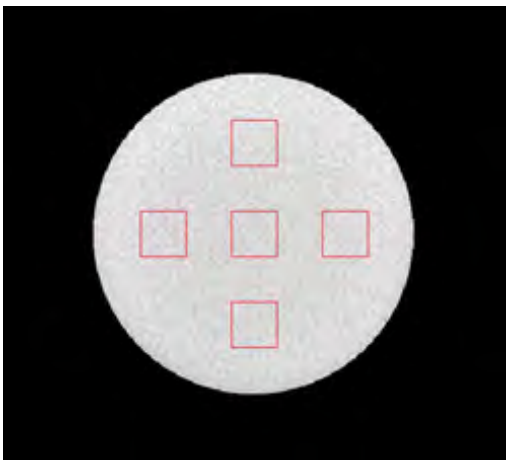
Noise			Verdict
			P
X-ray Tube Condition		Measured Value	Criteria
Voltage (kV)	Current (mA)	CT Number (HU)	
90	4	50.42	PMMA Noise ≤ 200
Image			
			

CT Number				Verdict
				P
X-ray Tube Condition		Measured Value		Criteria
Voltage (kV)	Current (mA)	CT Number (HU)		
90	4	Area	CT Number	Air(HU) = -1000 ± 100 PMMA(HU) = 0 ± 100 PVC(HU) ≥ 500
		Air	-1000.75	
		PMMA	-7.69	
		PVC	1191.42	
Image				
				

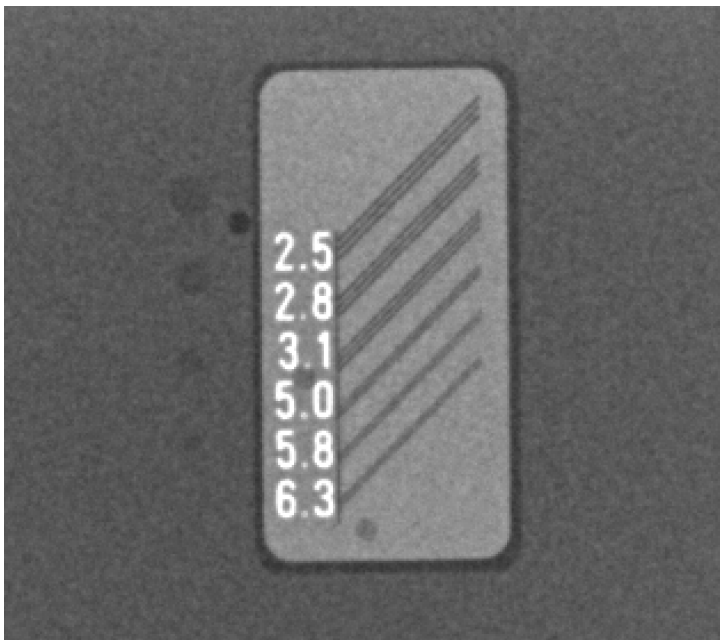
High Contrast Resolution			Verdict
			P
X-ray Tube Condition		Measured Value	Criteria
Voltage (kV)	Current (mA)	MTF 10% (lp/mm)	
90	4	1.65	MTF10% ≥ 1.0lp/mm
Image			



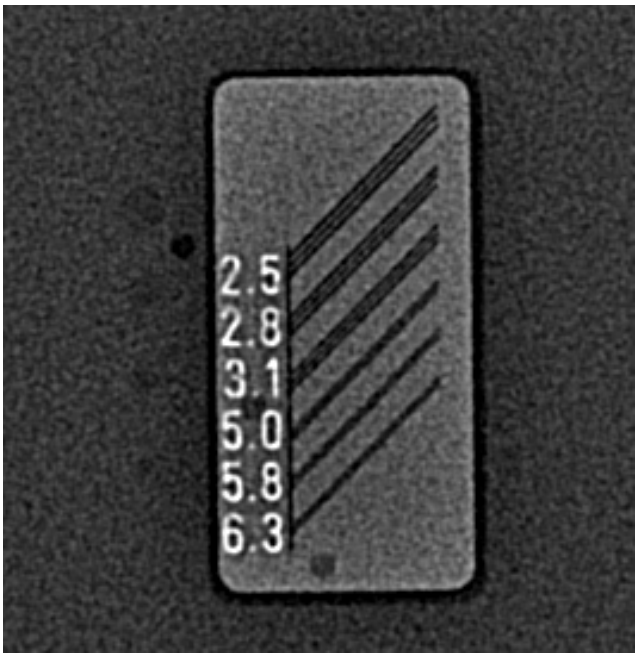
Uniformity			Verdict
			P
X-ray Tube Condition		Measured Value	Criteria
Voltage (kV)	Current (mA)	Homogeneity	
90	4	31.22	Homogeneity ≥ 25
Image			



9.4.3 CEPH (One Shot L Type)

<table>
<tr><td colspan="3">Line Pair Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Line Pair Resolution
(lp/mm)</td></tr>
<tr><td>90</td><td>15</td><td>3.1</td><td>Line Pair Resolution
≥2.5</td></tr>
<tr><td colspan="3">Low Contrast Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Low Contrast
Resolution (Step)</td></tr>
<tr><td>90</td><td>15</td><td>4</td><td>Producing Low Contrast
Resolution ≥ 1 step</td></tr>
<tr><td colspan="4">Image</td></tr>
<tr><td colspan="4"> 
</td></tr>
</table>

9.4.4 CEPH (One Shot S Type)

<table>
<tr><td colspan="3">Line Pair Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Line Pair Resolution
(lp/mm)</td></tr>
<tr><td>90</td><td>16</td><td>2.8</td><td>Line Pair Resolution
≥ 2.5</td></tr>
<tr><td colspan="3">Low Contrast Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Low Contrast
Resolution (Step)</td></tr>
<tr><td>90</td><td>16</td><td>3</td><td>Producing Low Contrast
Resolution ≥ 1 step</td></tr>
<tr><td colspan="4">Image</td></tr>
<tr><td colspan="4"> 
</td></tr>
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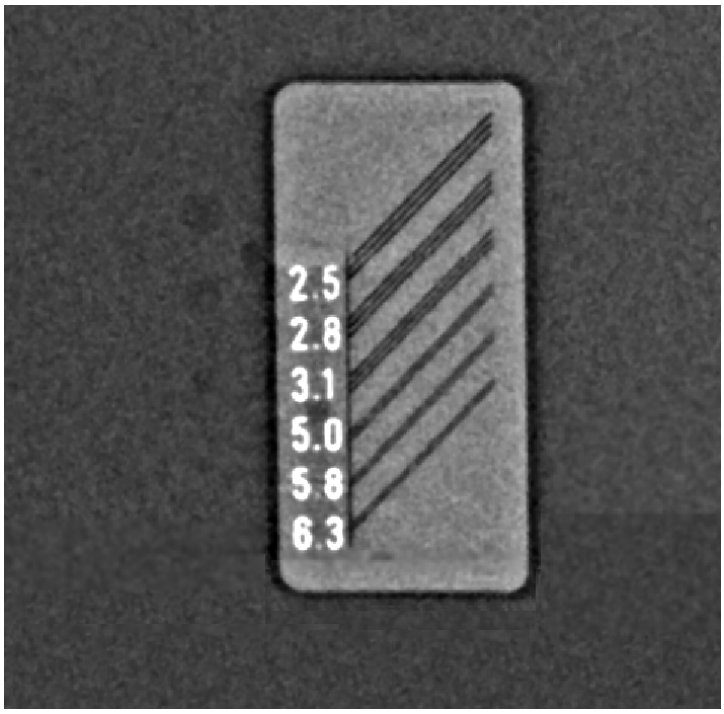
9.4.5 CEPH (Scan Type)

<table>
<tr><td colspan="3">Line Pair Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Line Pair Resolution
(lp/mm)</td></tr>
<tr><td>90</td><td>6</td><td>3.1</td><td>Line Pair Resolution
≥ 2.5</td></tr>
<tr><td colspan="3">Low Contrast Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Low Contrast
Resolution (Step)</td></tr>
<tr><td>90</td><td>6</td><td>4</td><td>Producing Low Contrast
Resolution ≥ 1 step</td></tr>
<tr><td colspan="4">Image</td></tr>
<tr><td colspan="4"> 
</td></tr>
</table>

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Quality Assurance Control

10

10 QUALITY ASSURANCE CONTROL

10.1 CT Quality Assurance Control

10.1.1 Qualification and Monitoring Frequency

In order to ensure the operational safety and functional reliability of your product, operator or physician who reads this instruction for use should check the equipment at regular intervals (at least 6 months) or contact Ray service center or your local Ray representative.

10.1.2 Quality Control Test and Acceptance Limit

① Quality control test tool

- RayDVT: test tool for QA/QC within the full range of Cone Beam CT for CT

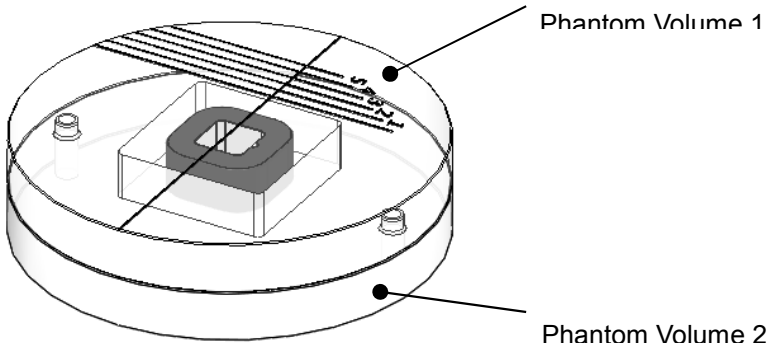
② Quality control test & Acceptance limit

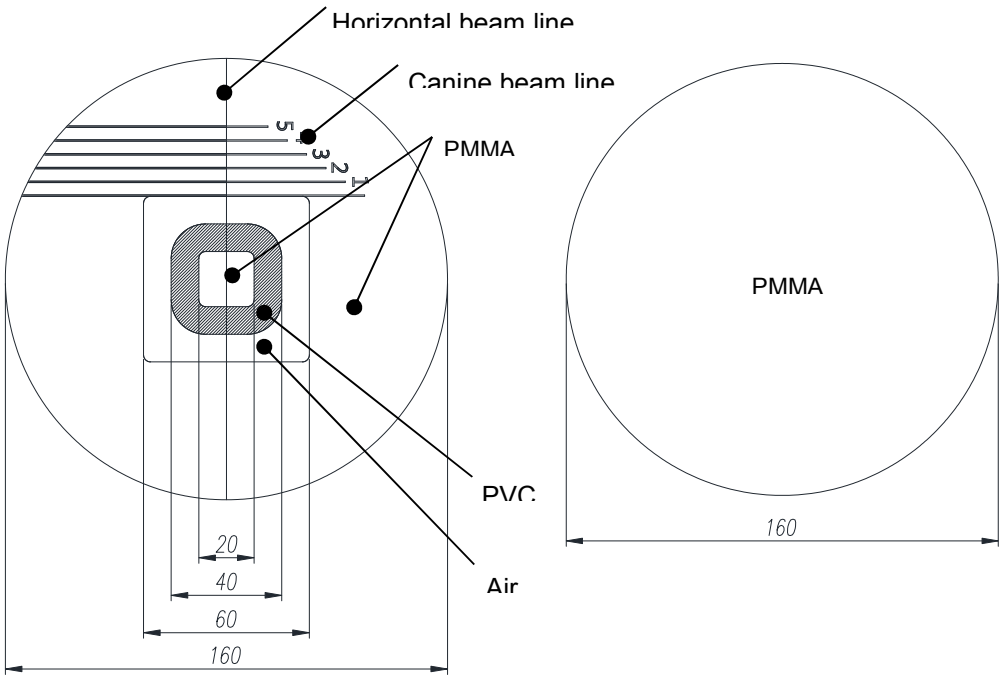
No.	Required Test or Procedure	Frequency	Substitute Test or Procedure	Standard
1	Noise	Daily & Initial & Annually	QC Manual	PMMA Noise ≤ 200
2	CT Number	Daily & Initial & Annually	QC Manual	Air(HU)= -1000 ± 100 PMMA (HU)= 0 ± 100 PVC: ≥ 500
3	High Contrast Resolution	Daily & Initial & Annually	QC Manual	MTF 10% ≥ 1 lp/mm
4	Uniformity	Daily & Initial & Annually	QC Manual	Homogeneity ≥ 25

10.1.3 Quality Control Maintenance Tool (Phantom Information)

① RayDVT

The phantom is made of polymethyl-methacrylate (PMMA) containing all required test objects for quality control as well as positioning tools for reproducible placement.





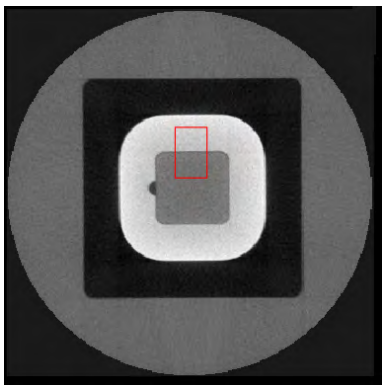
< Phantom Volume 1> **< Phantom Volume 2>**

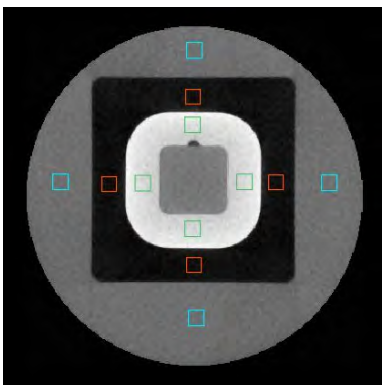
Dimension: Diameter 160mm

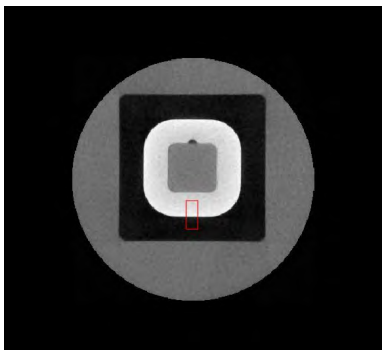
Thickness: 20mm (each Phantom Volumn 1 and 2)

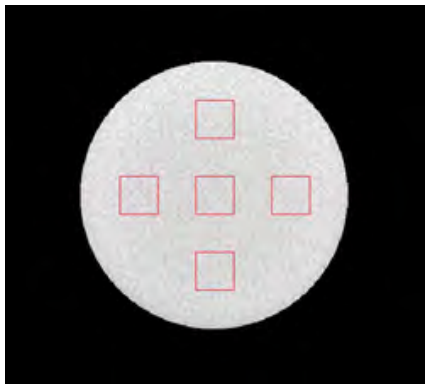
Physical Properties: Density PMMA 1.19 g/cm3 (± 1%) / Density PVC 1.41 g/cm3 (± 3%)

10.1.4 Quality Assurance Control Test (CT)

Noise	
Test Method	1. Place the phantom in CT FOV. 2. Scan CT 3. Measure the Noise after scanning.  * Worst case Condition * Prototype, Production and Assembler tests use same methods
Quality Criteria	PMMA Noise ≤ 200

CT Number	
Test Method	1. Place the phantom in CT FOV. 2. Scan CT 3. Measure the CT number after scanning.  * Worst case Condition * Prototype, Production and Assembler tests use same methods
Quality Criteria	Air = -1000 ± 100 HU / PMMA = 0 ± 100 HU / PVC ≥ 500

High contrast resolution	
Test Method	1. Place the phantom in CT FOV. 2. Scan CT 3. Check the phantom resolution after scanning.  * Worst case Condition * Prototype, Production and Assembler tests use same methods
Quality Criteria	MTF10% ≥ 1.0 lp/mm

Uniformity	
Test Method	1. Place the phantom in CT FOV. 2. Scan CT 3. Measure the homogeneity after scanning.  * Worst case Condition * Prototype, Production and Assembler tests use same methods
Quality Criteria	Homogeneity ≥ 25

10.2 Panoramic and CEPH Quality Assurance Control

10.2.1 Qualification and Monitoring Frequency

In order to ensure the operational safety and functional reliability of your product, operator or physician who reads this instruction for use should check the equipment at regular intervals (at least 6 months) or contact Ray service center or your local Ray representative.

10.2.2 Quality Control Test and Acceptance Limit

① Quality Control Test Tool

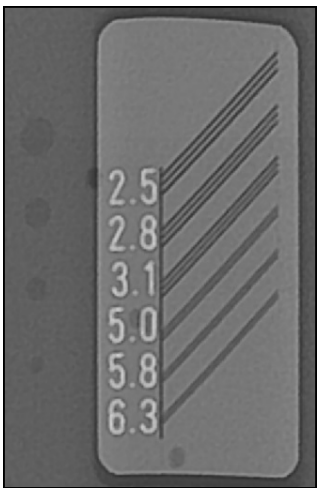
- QUART Dent/Digitset 2.1 (Art. No 12107, QUART, Germany): Universal OPG Testing (IEC 61223-3-4, IEC 61223-2-7, DIN 6868-151, DIN 6868-5)

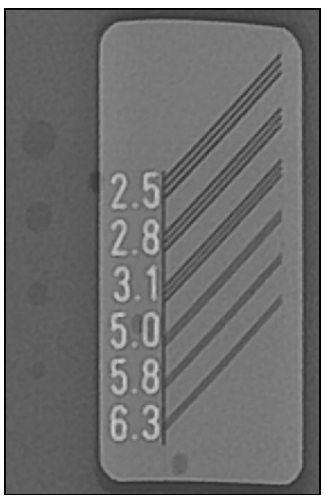
② Quality Control Test & Acceptance Limit

No.	Required Test or Procedure	Frequency	Substitute Test or Procedure	Standard
1	Panorama Line Pair Resolution Test	Initial & Annually	QC Manual	Line Pair Resolution ≥ 2.5 lp/mm
2	Panorama Low Contrast Test	Initial & Annually	QC Manual	Low Contrast ≥ 2 Steps
3	Ceph Line Pair Resolution Test	Initial & Annually	QC Manual	Line Pair Resolution ≥ 2.5 lp/mm
4	Ceph Low Contrast Test	Initial & Annually	QC Manual	Low Contrast ≥ 1 Steps

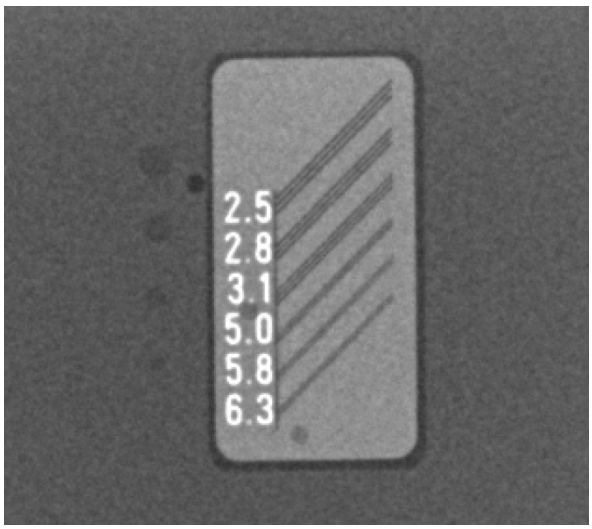
10.2.3 Quality Assurance Control Test

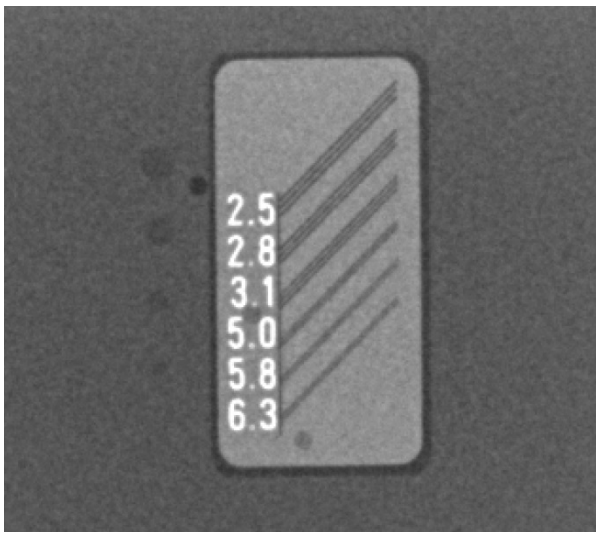
10.2.3.1 Panoramic

Line Pair Resolution Test	
Test Method	1. Place Digitest 2.1 phantom in Canine Beam. 2. Scan Panoramic Standard protocol. 3. Measure the Line pair after scanning. 
Quality Criteria	Line Pair Resolution ≥ 2.5 lp/mm

Low Contrast Test	
Test Method	1. Place Digitest 2.1 phantom in Carpus plate or Detector case. 2. Scan Panoramic Standard protocol. 3. Measure the Line pair after scanning. 
Quality Criteria	Low contrast ≥ 2 step

10.2.3.2 CEPH

Line Pair Resolution Test	
Test Method	1. Place Digitest 2.1 phantom in Carpus plate or Detector case. 2. Scan CEPH LA protocol. 3. Measure the Line pair after scanning. 
Quality Criteria	Line Pair Resolution ≥ 2.5 lp/mm

Low Contrast Test	
Test Method	1. Place Digitest 2.1 phantom in Caprus plate or Detector case. 2. Scan CEPH LA Standard protocol. 3. Measure the Line pair after scanning. 
Quality Criteria	Low contrast ≥ 1 step

10.3 Quality Assurance Training Material

Please refer to Quality Assurance Training material. (Ray QAT Phantom Kit_G User Manual_EN)

10.4 Prcedure to be Followed if Tested Parameter Fail

If operator or physician (who reads this instruction for use) fail the QA test, Please retest more one time accordance with Quality Assurance Training material. (Ray QAT Phantom Kit_G User Manual_EN)

If the value of retest is still not on criteria value or failed, please contact manufacturer or your local Ray representative for the inspection.

10.5 Quality Assurance Control Tool

The phantoms identified in Section 8.1 (Accessories) are included with this system. Users can purchase replacement Phantoms directly from Ray HQ or through a local Ray representative.

Appendix A. RELATED STANDARDS

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: Medical electrical equipment Part1-2: General requirements Collateral standard: Electromagnetic compatibility.
- IEC 60601-1-3: Medical electrical equipment Part 1-3: General requirements for safety and essential Performance Collateral standard: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-1-6: Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 60601-2-28: Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
- IEC 60601-2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.
- IEC 61223-3-4: Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment.
- IEC 61223-3-5: Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests –Imaging performance of computed tomography X-ray equipment.
- IEC 62220-1: Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency.
- IEC 61674: Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics.
- EN ISO 14971: Medical devices – Risk Application of Risk management to medical Devices.
- IEC 62366: Medical devices - Application of usability engineering to medical devices.
- ISO 62304: Medical device software - Software life-cycle processes.

Appendix B. GLOSSARY OF ACRONYMS

Description of acronyms commonly referenced in the User Manual.

Glossary	Acronyms
CBVT	Cone-Beam Volumetric Tomography
CT	Computed Tomography
PANO/Pano/PX	Panoramic
CEPH/Ceph/DX	Cephalometric
MWL	Modality Work List
S/W	Software
IO	Intra Oral Sensor
OT	Camera
THU	Touch Monitor
TMJ	Temporomandibular Joint
PA	Posterior-Anterior
SMV	Submentovertex
IS	Implant Surgery
SG	Surgical Guide
ET	Endo Treatment