DIAMOND

ALL-IN-ONE DIGITAL RADIOGRAPHY SYSTEM

Operation Manual

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REVISION HISTORY

Revision Number	Date	Description
A	NOV 10, 2009	First Edition
B	JUN 26, 2012	Address change, Supplementation
C	AUG 27, 2012	Software name change
D	JUL 12, 2013	Add Vieworks detector
E	JUL 10, 2017	Transition of NB (DNV-GL NB# 0434 -> DNV GL NEMKO PRESAFE AS NB#2460)
F	DEC 10, 2018	Change of section 1.4 and Appendix D, Appendix G, Appendix. I , Add Application specification 1.3 Change the Color of Product. Change name of manufacture for Tube. (TOSHIBA -> CANON, VAREX-> VAREX)
G	OCT 17, 2019	Add the Detector (PaxScan4343RC, Mano4343X, Mano4343T, Agate4343XB, Agate4343XA) Add the GXR-C52 Change the Radmax Design
H	APR 16, 2020	Add the Detector (Paxscan4343W, Mano4343W, DR-ID1272SE, DR-ID1274SE) Exclude detector (Mano4343X, PaxScan4343RC, Agate4343XA, Agate4343XB) Add Detector Insert/Removal check function Add Grid Reverse Direction check function Add Fail Safety function Improve Stand Position Setting Separate RADMAX SOFTWARE content. Refer to the RADMAX Operation manual(RMD1804-001)
I	JUL 24, 2020	Add 9 preset function Add cobb's angle function Add tube & line enhancement function Add detector built-in charger function

		Add APR positioning guide function
J	OCT 29, 2020	Deleted contents related to DR-ID1270 series detector Added D button function Added Screen Locker function Added Auto ROI function Added ROI Masking function Added Authority setting function Added Patient information tag deletion function Added Module3 Processing Type function
J.1	DEC 24, 2020	Added Hip measurement function Added Auto Stitching function to manual type Added Mano Detector Power off function Grouped image tools Added 1.2.10 Safety Warning Lebels
K	APR 30, 2021	Changed filter description Mars1717X detector added Separate Accessory and Options Added ME Equipment classification Added section 6 MAINTENANCE
L	MAY 13, 2021	Add STITCHING STAND
M	JUN 28, 2021	Change Of Representative Identification Label
N	AUG 23, 2021	Change Desktop Specifications Change Monitor Specifications
O	OCT 15, 2021	Change Remote Control Membrane
P	DEC 02, 2021	Changed from RADMAX version 1.01 to version 1.02 Changed overall GUI for touch environment Add Image Processing Module4 Add the Live Streaming Add the Dark Skin GUI Add the DICOM TLS
Q	FEB 25, 2022	Change Specification Add the SCP(SERVICE CLASS PROVIDER) Change form Change of Application Standard
R	APR 28, 2022	Add the Audit Trail Add the Patient movement alarm

S	AUG 16, 2022	Apply Live streaming camera to R302 Collimator
T	JAN 9, 2023	Add the Polygon ROI Function
U	MAY 15, 2023	Label and standard change according to ISO 15223-1_2021 and MDR Article 27 Paragraph 4
V	JUL 7, 2023	Change workstation and monitor information Detector name change (PaxScan4343W -> 4343W(Basic))
0	SEP 8, 2023	Integration of RADMAX operation manual and Generator operation manual Application of Clinical Assessment comments. Bone Suppression Function added. Widget Function added. (Delete guide button in step more menu.) Same patient APR information display added. Change the AEC Screen Icon

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ABOUT THESE INSTRUCTIONS FOR USE

The following advisory symbols are used throughout this manual.
Their application and meaning are described below.

"Bold"	Is used for Product's Name.
<Italic>	Is used for references and for table or figure titles.
'Button'	Is used for Button's Name.
●	Indicates a list item.
*	Indicates additional explanations.
1. 1) a. i .	Indicates steps within operating sequences.

WARNING — Warning symbol is used to indicate a potential hazard for operators and service personnel that can lead to serious injury, death or radiation exposure.

CAUTION — Caution symbol is used to indicate a potential hazard for operators and service personnel that can lead to injury or damage of equipment.

NOTE — Note symbol is used to indicate important information needed for proper use and correct operation of equipment.

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NOTE
Keep this Manual with the equipment at all times, and review the important information whenever required.

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1. INTRODUCTION

This manual contains the necessary instructions for proper operation of ***"DIAMOND"*** DR System. All persons operating this equipment need to have read this manual beforehand. You must have a thorough understanding in the proper use of this product before you make any radiographic exposures.

1.1 USE OF THE PRODUCT

Radiology can refer to two sub –field, diagnostic radiology and therapeutic radiology. Diagnostic radiology is concerned with the use of various imaging modalities to aid in the diagnosis of disease. Therapeutic radiology or, as it is now called, radiation oncology uses radiation to treat diseases such as cancer using a form of treat diseases such as cancer using a form of treatment called radiation therapy.

Commonly used techniques for diagnostic radiology includes.

- Computed tomography (CT)
- Magnetic resonance imaging (MRI)
- Ultrasound
- X-ray
- Nuclear imaging techniques.

This All-In-One Digital Radiography System is designed to diagnose human body by providing radiographic x-ray image with anatomical structure.
This ***"DIAMOND"*** DR System is for use by medical professionals

1.1.1 INTENDED USE

The ***"DIAMOND"*** DR System is indicated for use in generating radiographic images of human anatomy. The All-In-One Digital Radiography System consisting of a high voltage (HV) generator, a tube support unit, an X-ray beam limiting device, patient table, Flat Panel Detector, Workstation, and a tube, operates on a high-frequency inverter method, and is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems. Such as the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

WARNING
This isn't intended to use in fluoroscopy, angiography, mammography and bone density. If you take an X-ray, you can't make an accurate diagnosis.

1.1.2 INTENDED PURPOSE

Intended purpose of this device can be divided into intended medical indication and intended part of the body or type of tissue applied to or interacted with.

.

1) intended medical indication

X-rays are generally used to produce radiographic images of human anatomy. This is the most simple, cost-effective and readily accessible imaging technique available. It provides excellent imaging details of bones, joints and areas of the body where there is substantial soft tissue differences in X-ray absorption. For example, there is a chest with significant X-ray differences between bones, lungs, and soft tissues.

Figure 1 is X-ray images for various purposes.

Typical X-rays(simple chest photography)

Images of fracture.

Images of pneumonia

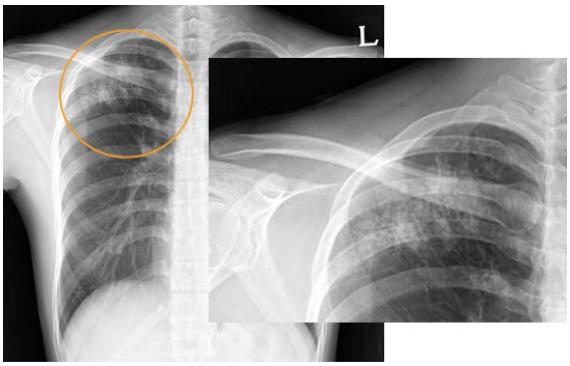


Image of intestinal obstruction.

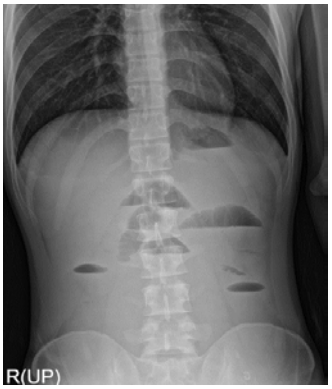


Figure 1 - X-ray images for various purposes

2) intended part of the body or type of tissue applied to or interacted with

It can be used for fracture diagnosis in Clavicle, Humerus, Elbow, Rib, Hand, wrist, Pelvic, hip, Femur, Patella, Growth plate, shinbone, feet and ankles.

Our equipment cannot be used to diagnose facial fractures.

You can diagnose pneumonia by photographing the lungs and finding inflammation in the lungs.

An X-ray shows an expanded bowel area, which can diagnose intestinal obstruction.

It can also show air around or below the intestinal or abdominal and thoracic layers (phren).

Chest X-rays are applied to the heart, lungs, blood vessels, ribs, spine, airway, thorax and bone, body fluids in the lungs or main walls, and surrounding air.

1.1.3 INTENDED PATIENT POPULATION

The intended patient population can be divided into general adults and pediatric except for pregnant.

Normal adult patient population is below.

Item	Content
Age	Everyone can use it, except for pediatric only.
Weight	Normal adult weight (weight above pediatric standard)
Height	Normal adult size height (height above pediatric standard)
Healthy state	People suspected of injury or disease inside the human body, which cannot be identified by appearance, take x-rays.
Nationality	The whole world

Normal pediatric patient population is below.

<table>
<tr><th>Item</th><th>Content</th></tr>
<tr><td>Age</td><td rowspan="2"><table>
<tr><th>Description</th><th>Weight group</th><th>Age group based on weight-for-age charts</th><th>Most common age groups used for the NDRLs (or equivalent)</th></tr>
<tr><td>Neonate</td><td>< 5 kg</td><td>< 1 m</td><td>0 y</td></tr>
<tr><td>Infant, toddler and early childhood</td><td>5 - < 15 kg</td><td>1 m - < 4 y</td><td>1 y</td></tr>
<tr><td>Middle childhood</td><td>15 - < 30 kg</td><td>4 - < 10 y</td><td>5 y</td></tr>
<tr><td>Early adolescence</td><td>30 - < 50 kg</td><td>10 – < 14 y</td><td>10 y</td></tr>
<tr><td>Late adolescence</td><td>50 - < 80 kg</td><td>14 - < 18 y</td><td>15 y</td></tr>
</table></td></tr>
<tr><td>Weight</td></tr>
<tr><td>Healthy state</td><td>People suspected of injury or disease inside the human body, which cannot be identified by appearance, take x-rays.</td></tr>
<tr><td>Nationality</td><td>The whole world</td></tr>
</table>

1.1.4 INTENDED USER PROFILE

This system is intended for use by suitably trained and experienced personnel who have received specific training in the operation and use of the equipment. Medical staff must be suitably qualified to comply with applicable country-specific regulations for the use of x-ray equipment. This requires operating personnel to be familiar with the Operation Manual. This manual must be studied thoroughly prior to starting up the system. Special attention must be paid to general safety information.

The intended users are:

- Radiologists
- Radiographers (Technicians)
- Qualified trained nurses or doctors

NOTE
It is the responsibility of the system operator to ensure that operating personnel are professionally and properly instructed. Instruction is to be repeated at appropriate intervals. We recommend simulating emergency conditions during training so that appropriate conduct can be taught.

NOTE
The specific qualifications required to operate an X-Ray system are defined by local legal regulations.

WARNING
Federal law (USA) restricts this device for sale or use by or on order of a physician or properly licensed practitioner.

WARNING
The ***"DIAMOND"*** DR System produces ionizing radiation. Operators must meet all state and local requirements and regulations.

WARNING
Only qualified personnel may operate ***"DIAMOND"*** DR System. Operation of the equipment by persons who have not been trained or who are unfamiliar with the ***"DIAMOND"*** DR System may cause serious injury to the patient, serious injury to the operator, or equipment damage.

1.1.5 CONTRAINDICATION

- **Contraindication**

This System is not intended to use of fluoroscopy, angiography, mammography and bone density
This System is not suitable for operation in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

- **Precaution**

There are no medical conditions that would make having an X-Ray unsuitable. However, for women who are or might be pregnant, it is advised that certain X-Rays are not undertaken other than in emergency situations. This is because radiation from X-rays causes changes in fetal cell development, which can increase the risk of birth defects or cancer in later life. This risk depends on the gestational age of the fetus and the amount of radiation exposure.
When the chaperone and the patient enter the x-ray room together and have an X-ray exposure, make sure that the chaperone has the means of protection.
Over-sensing associated with the lack of a few pulses may occur in pacemakers under radiation exposed. Since the duration of the over-sensing under the radiation was very short and included transient episodes, this sensing failure, therefore, induced by radiation exposure would not affect the health of pacemaker recipients. But it is recommended that caution be exercised in direct exposure to the pacemaker.
Skin ulcers may be caused by diagnostic x-rays in patients with radiation implants who are obese and diabetic. It is recommended that caution be exercised in exposure to patients with radiation implants.
For patients with pacemaker implants or radioactive implants, use protective devices for the area. (Use a copper sheet of 2.0 mm thickness)

Our equipment cannot be used for the following intended purposes.

- If the ligament is stretched or broken, it is not possible to identify the nerve or the disc that compresses the nerve.
- Soft tissue such as brain and tumor cannot be photographed.
- The range of soft tissue cancers such as breast cancer, liver cancer, ovarian cancer, and cervical cancer cannot be identified.
- Malignant tumors, epilepsy, Alzheimer's disease, and inflammatory diseases cannot be diagnosed.
- Bone density cannot be determined by normal X-ray images.
- It cannot be used for counterfeit English writing purposes.
- It cannot be used as a dental X-ray.

- It cannot be used for perspective purposes.
- The system does not use fluoroscopy, angiography, mammography, and bone density tests.
- The system recommend to be used in the presence of flammable anesthetics mixed with air, oxygen or nitrous oxide.

In addition, table is Symptoms of effective doses when X-rays are received throughout the body at once.

Exposure dose	**Symptom**
0.25 Sv	Very few clinical symptoms.
0.5 Sv	Temporary falling of white blood cells (lymphocyte).
1 Sv	Significantly reduced nausea, vomiting, systemic tachycardia, and lymphocytes.
2 Sv	5 % of people who die.
4 Sv	50 % of people die in 30 days
6 Sv	90 % of people die in 14 days
7 Sv	100 % of people die

References

- Oda N, Nakajima H, Abe H, Koyama S, Kakeda S, Kourogi Y. [Effect of diagnostic X-rays on implantable cardiac pacemakers and implantable cardioverter defibrillators, and its management]. Nihon Hoshasen Gijutsu Gakkai Zasshi. 2008 Jul 20;64(7):805-13. Japanese. doi: 10.6009/jjrt.64.805. PMID: 18719297.

- Thomadsen BR, Paliwal BR, Petereit DG, Ranallo FN. Radiation injury from x-ray exposure during brachytherapy localization. Med Phys. 2000 Jul;27(7):1681-4. doi: 10.1118/1.599036. PMID: 10947273.

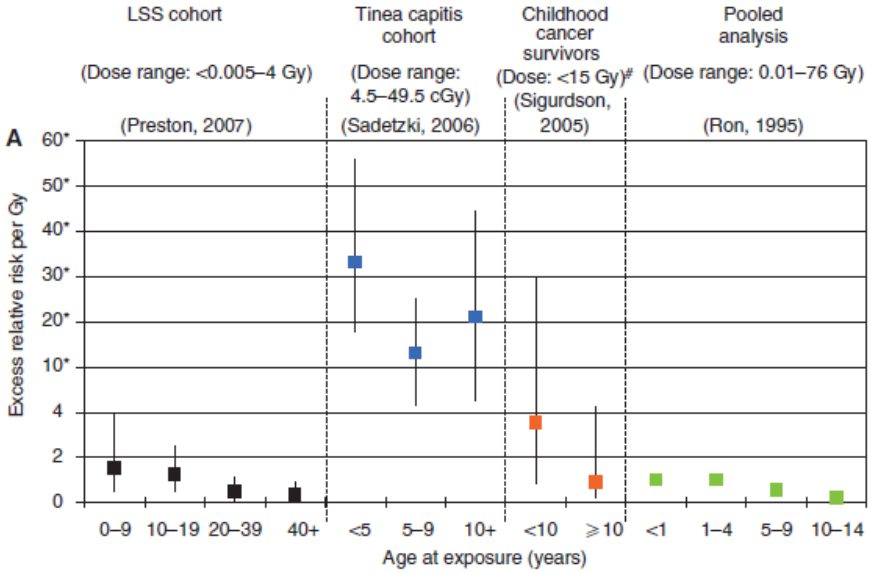
1.1.6 PEDIATRIC USE

General Information:

Normally, pediatric are growing and their reactions to x-rays are different from those of normal adults. Therefore, special care must be taken when X-raying pediatric patients.

Exposure to ionizing radiation is of particular concern in pediatric patients because:

- For certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients);
- Use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients; and
- Pediatric has greater risk from exposure to radiation because of the many years of life ahead of them during which they could develop radiation-induced cancer.
- The younger the pediatric, the more severe the above characteristics, special attention shall be paid to newborns and infants.



<Relative risk of thyroid cancer by age>

References for pediatric dose optimization:

Referring to the European Union's age classification of pediatric, five ranges of pediatric were assigned according to body weight as follows:

Table 7.2. Approximate equivalence of weight and age groups for the purpose of comparing weight-based DRLs with age-based DRLs.

Description	Weight group	Age group based on weight-for-age charts	Most common age groups used for the NDRLs (or equivalent)
Neonate	< 5 kg	< 1 m	0 y
Infant, toddler and early childhood	5 - < 15 kg	1 m - < 4 y	1 y
Middle childhood	15 - < 30 kg	4 - < 10 y	5 y
Early adolescence	30 - < 50 kg	10 – < 14 y	10 y
Late adolescence	50 - < 80 kg	14 - < 18 y	15 y

<European Guidelines on DRLs for Pediatric Imaging>

The concept of Diagnostic Reference Level (DRL) has been introduced to assist in the process of optimizing medical exposure to patients. The picture below compares the resulting DOSE with the DRL values recommended by NRPB [5] and Europe [6] using exposure condition values of similar equipment described in reference papers.

We selected the exposure condition values of ‘Chest PA’, ‘Pelvis AP’, and ‘Skull AP’ from the other company’s experimental conditions and conducted the test under the same conditions on our equipment.

Examination	Age group	KVp		mAs		Own Equipment ESD(μGy)		DRL : ESD(μGy)		E(μSv)
		Range	Mean	Range	Mean	Range	Mean	[5]	[6]	
Chest PA	0	-	-	-	-	-	-	-	-	-
	1	-	-	-	-	-	-	-	-	-
	5	50.9 - 51.5	51.3	1.9 - 2.0	1.9	31.3 - 35.8	**32.7**	70.0	100.0	16
	10	57.0 - 57.6	57.2	2.2 - 2.4	2.3	45.0 - 45.7	**45.5**	120.0	-	15
	15	70.4 - 70.7	70.5	2.2 - 2.2	2.2	68.7 - 69.6	**69.2**	-	-	20
Skull AP	0	-	-	-	-	-	-	-	-	-
	1	64.8 - 64.9	64.8	5.5 - 5.5	5.5	120.1 - 121.0	**120.6**	800.0	-	7
	5	67.2 - 67.6	67.4	7.0 - 7.1	7.1	170.6 - 172.3	**171.5**	1100.0	1500.0	11
	10	69.5 - 69.6	69.5	6.6 - 7.7	6.7	182.1 - 183.5	**182.7**	1100.0	-	9
	15	70.2 - 70.5	70.4	8.3 - 8.4	8.4	236.1 - 238.7	**237.2**	1100.0	-	9
Pelvis AP	0	-	-	-	-	-	-	-	-	-
	1	54.9 - 56.0	55.7	2.5 - 2.8	2.6	31.6 - 31.9	**31.7**	-	200.0	30
	5	50.2 - 50.3	50.3	2.5 - 2.5	2.5	21.8 - 22.0	**21.8**	500.0	-	14
	10	61.2 - 61.3	61.2	4.7 - 4.9	4.9	89.7 - 90.3	**90.1**	600.0	900.0	-
	15	64.9 - 65.0	64.9	5.0 - 5.1	5.1	117.0 - 118.2	**117.6**	700.0	-	49

<Exposure condition values, DRGEM dose values, and comparative dose values according to pediatric patients>

Depending on the exposure conditions, when taking X-rays with our equipment, we confirmed that it came out similar or lower than DRL values recommended by NRPB [5] and Europe [6]. Therefore, if a doctor takes a

picture with appropriate exposure conditions for a pediatric, it can be confirmed that it is safe because it generates a dose that is equal to or less than the recommended DRL for pediatric.

Recommendations for pediatric radiography:

IAEA recommends the following for pediatric radiography.

- If the posture of pediatric patients is properly fixed and the exposure time is reduced, re-radiographing can be lowered, thereby reducing the X-ray radiation dose.
- The X-ray radiation dose shall be reduced by increasing the tube voltage and lowering the tube current as much as possible.
- Pediatric patients have a small body size and can obtain sufficient image information even with scattering lines, so the X-ray radiation dose shall be lowered by removing anti-scatter grid.
- Protective equipment of various types and sizes shall be used to protect against unnecessary radiation exposure.
- Infants and young children usually do not need to use anti-scatter grids or other anti-scatter means because the exposure volume (mass) is relatively low in scatter radiation. Optimally, grids are usually only needed for older children over the age of 8 (Schneider et al., 2000).
- Since the difference in physique of pediatric patients is greater than that of adults, AEC should be optimized accordingly. (AEC Publication 121)

The following resources provide information about pediatric imaging radiation safety and/or radiation safety for general radiography devices:

- FDA's website provides radiation safety information references from a variety of groups including the Image Gently Alliance: Pediatric X-ray Imaging;http://www.fda.gov/Radiation mittingProducts/RadiationEmittingProductsandProcedures/ucm298899.htm
- And Medical X-ray Imaging (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm).
- In addition, FDA's Pediatric X-ray Imaging Website (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm)
- Jeung Seung Hun, Han, Beom Hul, & Jung, Hong Ryang (2017). Evaluation of image quality when using grid during child chest x-ray examination. Journal of Radiological Science and Technology, 40(3), 371-376.
- Gogos KA, Yakoumakis EN, Tsalafoutas IA, Makri TK. Radiation dose considerations in common pediatric X-ray examinations. Pediatr Radiol. 2003 Apr;33(4):236-40. doi: 10.1007/s00247-002-0861-x. Epub 2003 Feb 7. PMID: 12709751.
- Childhood exposure to external ionising radiation and solid cancer risk (2009) British Journal of Cancer

1.1.7 CLINICAL BENEFITS

X-ray imaging exams are recognized as a valuable medical tool for a wide variety of examinations and procedures. The ***"DIAMOND"*** DR System is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems, such as the skull, spinal column, chest, abdomen, extremities, and other body parts. Generic clinical benefits of radiographic examinations within the intended use are applicable for this system.

1.1.8 SIDE EFFECTS

Most diagnostic X-rays will not have an adverse effect. Procedures with higher doses such as CT, interventional procedures or multiple exposures could lead to biological effects in some cases. A higher absorbed dose means a higher risk for adverse effects – the relationship is almost linear. Adverse effects could include skin redness, infertility, cataracts and hair loss. There are no reports of radiation exposure in diagnostic and interventional procedures causing infertility or cataracts. Patients undergoing interventional procedures that require fluoroscopy that lasts one hour or more could in very rare cases experience radiation induced skin injuries (erythema). Diagnostic X-rays and nuclear medicine examinations lead to a slightly increased risk of cancer. This risk increases with the magnitude of the dose and with the number of procedures.

1.1.9 RESIDUAL RISKS

The overall residual risk was reviewed and assessed. And Despite the overall acceptable residual risk, we have provided information such as NOTE, CAUTION and WARNING in the operating to reduce the risk of patients and operators.

1.2 CUSTOMER SUPPORT

Address any questions regarding ***"DIAMOND"*** DR System to:

DRGEM Corporation

7Fl, E-B/D Gwangmyeong Techno-Park, 60 Haan-ro,

Gwangmyeong-si, Gyeonggi-do, 14322, Korea

TEL: +82-2-869-8566, FAX: +82-2-869-8567

E-mail: cs@drgem.co.kr

Web-site: **http://www.drgem.co.kr**

In USA,

Contact *DRGEM USA Inc.*

7018 NW 50TH Terrace, Gainsville, Florida, 32653, USA

TEL: 201-370-6672, FAX: 352-337-1271

E-mail: drgemusa@gmail.com

In Central & South America,

2400 East Devon Ave., Suite 210, Des Plaines, IL 60018, USA

TEL: +1-224-567-9012, FAX: +1-847- 699-8487

E-mail: drgemxray@gmail.com

Obelis s.a.,

Bd.Général Wahis 53,1030 Brussels, Belgium

Tel) +32.2.732.59.54, Fax) +32.2.732.60.03

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2 SAFETY INFORMATION

The policy of DRGEM Corporation is to manufacture X-ray equipment that meets high standards of performance and reliability. We enforce strict quality control techniques to eliminate the potential for defects and hazards in our products. The intended use of this equipment is to acquire the purpose of acquiring X-ray images of the desired parts of a patient's anatomy. Use of this equipment in any other fashion may lead to serious personal injury. The safety guidelines provided in this section of the manual are intended to educate the operator on all safety issues in order to operate and maintain ***"DIAMOND"*** DR System in a safe manner.

The following warnings and cautions are specific to ***"DIAMOND"*** DR System. Read them carefully - some of them are not obvious to typical use.

NOTE
According to Medical Devices Regulation (EU) 2017/745, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established. Contact our official dealer or DRGEM Representative. (Refer to the section 1.2)

NOTE
This manual contains important safety information. An understanding of this information is critical to the safe operation of your equipment. Please ensure that you read the warning notices before using the equipment.

2.1 SAFETY GUIDELINE

The following are general safety precautions:

- Only qualified personnel may use this equipment.
- Do not defeat or bypass built-in equipment safety features.
- Observe all warnings and cautions, stated or implied, in the procedures.
- Follow all safety labels on the equipment.
- Pediatric patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher). Use of equipment and exposure settings designed for adults may result in excessive radiation exposure if used on smaller patients. Pediatric patients have a longer expected lifetime, putting them at higher risk of cancer from the effects of radiation exposure.
- To protect the system and data from Virus, Spam, spoofing, Phishing, Pharming, Spyware, Keylogging, Adware, Botnets, Worms, Trojan, Denial-Of-Service such as online attack and etc., it is important to install the proper Anti-Virus software in the workstation.

No practical design can incorporate complete protection for operators or service personnel who do not take adequate safety precautions. Only authorized and properly trained service and operating personnel should be allowed to work with this X-ray generator equipment. The appropriate personnel must be made aware of the inherent dangers associated with the servicing of high voltage equipment and the danger of excessive exposure to X-ray radiation during system operation.

WARNING
This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.

CAUTION
Observe all safety precautions recommended by the accessory equipment manufacturer in the user documentation provided with the equipment. Failure to do so may result in injury or equipment damage to the patient or user.

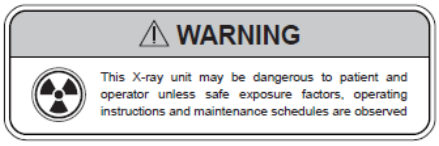
WARNING
Do not install components or accessories that were not intend for use by the system. Failure to comply could result in damage to the equipment or injury to personnel.

WARNING
In the event of a fire in or around the system, shut down the system immediately. Also, do not use water, use a fire extinguisher to ignite.

2.2 SYMBOL DEFINITIONS

The table below defines the meaning of various symbols used on labels on the machine.

Radiation exposure symbol used on operator console. Lights to indicate that an exposure is in progress. This is accompanied by an audible tone from the console.



Radiation warning message on console.
Never allow unqualified personnel to operate the X-ray generator.

Consult accompanying documents (Required to consult for Safety)

Emergency Stop

This symbol means that the product and battery should be recycled separately from household waste. When this product reaches its end of life, follow the local laws and regulations of disposal. The improper disposal of waste electronic equipment from the consumer may be subject to fines.

Hand jam caution label

Detector release switch

High voltage symbol used to indicate the presence of high voltage.

Warning symbol used to indicate a potential hazard to operators, service personnel or to the equipment. It indicates a requirement to refer to the accompanying documentation for details.

PC Install Warning sticker

Protection earth symbol

L Live line among the single phase line powers.

N Neutral line among the single phase line powers.

L1 First phase line power among the three phase line powers.

L2 Second phase line power among the three phase line powers.

L3 Third phase line power among the three phase line powers.

V~ Single phase AC voltage

V3~ Three phase AC voltage

V⎓ DC voltage

Indicates a medical device that needs protection from moisture (Keep dry)

Indicates the temperature limits to which the medical device can be safely exposed

Indicate the correct direction of the package (This way up)

Mark the center of gravity on the packaging

Indicates a medical device that can be broken or damaged if not handled carefully

Do not trample

This subsection defines the safety labels used inside and outside the ***"DIAMOND"*** DR System cover.

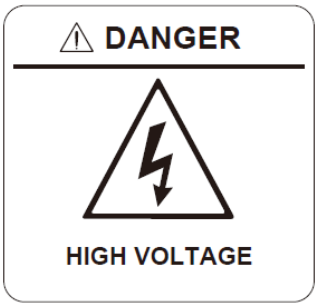
NOTE
These labels and warnings are provided to alert service personnel that serious injury will result if the hazard identified is ignored.

This information is provided to help you establish safe operating conditions for both you and your X-ray generator. Do not operate this X-ray generator except in accordance with these instructions, and any additional information provided by the X-ray generator manufacturer and / or competent safety authorities.

HEAVY WEIGHT WARNING LABEL

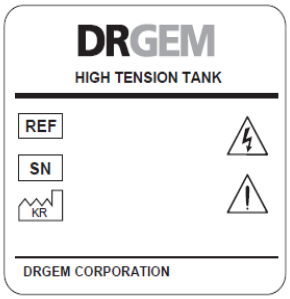
This label is attached to the outside of the radiographic stand and generator cabinet. This label states the approximate weight.
Do not attempt to lift this unit without proper assistance.
(Example)

DANGER HIGH VOLTAGE LABEL



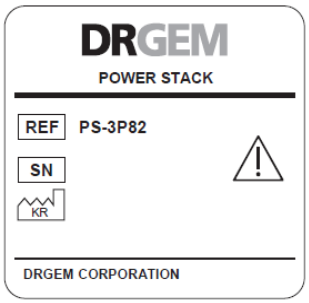
This label is attached to the main fuse cover, main noise filter cover and power stack cover of the generator.
Mains voltage is present inside the generator cabinet whenever the main disconnect is switched on. Additionally, the DC bus capacitors will remain charged for up to 3 minutes after the AC mains is disconnected or the console is switched off.

IDENTIFICATION LABEL – HIGH TENSION TANK



This label is attached to side of the High Tension Tank inside of the generator main cabinet.
(Example)

IDENTIFICATION LABEL – POWER STACK



This label is attached to side of the POWER STACK inside of the generator main cabinet.
(Example PS-3P82)

2.3 RADIATION SAFETY

Everyone associated with X-ray work must be familiar with the recommendations of the Center for Devices and Radiological Health (CDRH), the National Institute for Standards and Technology (NIST), the National Council on Radiation Protection (NCRP), and the International Committee on Radiation Protection (ICRP).

Be sure that all personnel authorized to operate the X-ray system are familiar with the established regulations of the authorities named above. All personnel should be monitored to ensure compliance with recommended procedures.

Current sources of information include:

- National Council on Radiation Protection Report No. 33
  ("Medical X-ray and gamma ray Protection for Energies up to 10 MEV-Equipment Design and Use").
- National Bureau of Standards Handbook No. 76 ("Medical X-ray Protection up to Three Million Volts"). Refer to NCRP Report No. 33.
- Current recommendations of the International Committee on Radiation Protection.

Although X-radiation is hazardous, X-ray equipment does not pose any danger when properly used. Be certain all operating personnel are properly educated concerning the hazards of radiation. Persons responsible for the system must understand the safety requirements and special warnings for X-ray operation. Review this manual and the manuals for each component in the system to become aware of all safety and operational requirements.

WARNING
Ensure exposure parameters are properly adjusted within safety limits. Failure to do so may result in unnecessary exposure to the patient, causing tissue damage.

CAUTION
Incorrect positioning of the X-ray tube and collimator may result in X-ray fields. Misaligned with the detector, resulting in an unacceptable image that may require re-shooting.

CAUTION
When sold in European countries, use with products that have RDSR (Radiation Dose Structured Report) function added according to DICOM regulations.

2.3.1 RADIATION SAFETY NOTICE

X-ray radiation exposure may be damaging to health, with some effects being cumulative and extending over periods of many months or even years. **X-ray operators should avoid any exposure to the primary beam** and take protective measures to safeguard against scatter radiation. Scatter radiation is caused by any object in the path of the primary beam and may be of equal or less intensity than the primary beam that exposes the film.

WARNING
X-rays generate a potential risk for both patients and operators. For this reason, the application of X-rays for a given medical purpose must aim at the minimization of radiation exposition to any persons. Those persons responsible for the application must have the specific knowledge according to legal requirements and regulations and must establish safe exposure procedures for this kind of systems. Those persons responsible for the planning and installation of this equipment must observe the national regulations.

2.3.2 X-RAY PROTECTION

X-ray equipment may cause injury if used improperly. The instructions contained in this manual must be read and followed when operating the ***"DIAMOND"*** DR System. The ***"DIAMOND"*** DR System provides a high degree of protection from unnecessary radiation. However, No practical design can provide complete protection nor prevent operators from exposing themselves or others to unnecessary radiation. Personal radiation monitoring and protective devices are available. You are urged to use them to protect against unnecessary radiation exposure.

Serious unfavorable health effects can result from short term exposure to high levels of ionizing radiation (such as X-rays) as well as from long term exposure to low levels. Personnel who operate the ***"DIAMOND"*** DR System should familiarize themselves with both the short term and the long term effects of radiation exposure and take appropriate measures to minimize the amount of radiation to which they are exposed while performing their duties. Some effects of X-radiation are cumulative, and may extend over a period of months or years. The best safety rule for X-ray operators is to avoid exposure to the primary beam at all times.

Ionizing radiation occurs naturally in the environment. It is generated by astronomical radiation sources such as the sun and the stars, and by the soil under our feet. The atmosphere filters radiation from astronomical sources. As a result, the radiation level from these sources is much lower at sea level than on the summit of high mountains. Radiation generated in the soil varies greatly from place to place depending on the composition of the soil. For example, areas rich in granite rock have a higher level of radiation than other areas.

Any materials placed in the path of the beam absorb natural as well as man-made radiation, such as the X-rays used in the ***"DIAMOND"*** DR System.
Materials with a high atomic number, such as tungsten, lead, and uranium, absorb X-rays much more effectively than materials with a low atomic number such as hydrogen, aluminum, or beryllium. Therefore, lead is used for shielding the radiologist's workstation in most X-ray facilities, including ones using the ***"DIAMOND"*** DR System. If there are windows in the partition separating the operator from the patient, these windows are typically glazed with lead glass and provide effective protection against ionizing radiation.

To minimize dangerous exposure, use movable lead screens, lead-impregnated gloves, and lead-impregnated aprons. These protective devices must contain 0.35 millimeter thickness of lead or the equivalent.
Use such protective devices for all operators, observers, and/or servicing personnel exposed to radiation fields of five or more milli-Roentgens per hour.

- Wear protective clothing. Protective aprons with an equivalent of a minimum of 1/64" (0.35 mm) of lead are recommended.
- To protect the patient against radiation, always use radiation protection accessories in addition to devices which are fitted to the X-ray equipment.
- Keep as large a distance as possible away from the object being exposed and the X-ray tube assembly.
- Operator should be behind the shielding board when X-ray is irradiation.
- The Operator exposure the X-ray at least 2m away from the X-ray tube and wear the lead apron.
  2m away exposure requirement is specified in IEC60601-2-54,203.13.3. Exposure hand switch is for this purpose. When making an exposure operator can expand hand switch curl cord from 2m to 5m upon request. ***"DIAMOND"*** DR System must have over 2m exposure distance by exposure hand switch or remote controller.

The shielding provided for a typical X-ray facility's operator workstation is generally quite effective and reduces the residual radiation from diagnostic X-rays to a level that is comparable to or lowers than natural background radiation. If the operator abandons the protected environment of the workstation, he or she may be exposed to a significantly higher level of radiation. For a single exposure this may still not lead to serious health effects, but repeated carelessness in this regard may lead to serious consequences.

Any object in the path of the primary beam produces scattered radiation. In the absence of proper precautions, scattered radiation can result in a substantial radiation dose to the operator or any other personnel in the facility. Moveable screens may be used to shield occupied areas from scattered radiation.

The X-ray Generator/host system used to power the ***"DIAMOND"*** DR System only produces X-rays when high voltage is applied to the X-ray tube. When the high voltage is removed, X-ray emission ceases without delay.

- X-ray Protection for the patient
  - If possible, protect the patient's thyroid gland during x-rays exposure. (use thyroid shield)
  - For patients with pacemaker implants or radioactive implants, use protective devices for the area. (Use a copper sheet of 2.0 mm thickness)
  - Use a collimator to keep the radiation field as small as possible without reducing the active measuring field.
  - If possible, remove all radiopaque material from the radiographic field.
  - Consider the image quality and set the tube voltage as high as possible.
  - Set the appropriate SID for each examination.

WARNING
Proper use and safe operating practices with respect to ***"DIAMOND"*** DR System are the responsibility of users. DRGEM corporation provides information on its products and associated hazards, but assumes no responsibilities for after-sale operating and safety practices.

WARNING
Check the condition of the product through regular maintenance. Failure to do so may result in injury or equipment damage to the patient or user. The manufacturer accepts no responsibility for any ***"DIAMOND"*** DR System not maintained or serviced according to this manual, or for any ***"DIAMOND"*** DR System that has been modified in any way.

WARNING
Keep as large a distance as possible away from the object being exposed and x-ray tube assembly. Failure to do so may result in unnecessary exposure to the patient or user, causing tissue damage.

2.3.3 MONITORING PERSONNEL

Monitoring personnel to determine the amount of radiation to which they have been exposed provides a valuable crosscheck to determine whether or not safety measures are adequate. This crosscheck may reveal inadequate or improper radiation protection practices and/or serious radiation exposure situations.

The most effective method of determining whether the existing protective measures are adequate is the use of instruments to measure the exposure (in rads). This measurement should be taken at all locations where the operator, or any portion of the operator's body, may be inadequately shielded during exposure. Exposure must never exceed the accepted tolerable dose.

A frequently used, but less accurate, method of determining the amount of exposure is placement of film at strategic locations. After a specified period of time, develop the film to determine the amount of radiation. Fluorescent screens (used in a darkened room) may also be used to detect excessive radiation.

A common method of determining whether personnel have been exposed to excessive radiation is the use of film badges. These are X-ray sensitive film enclosed in a badge that incorporates metal filters of varying degrees of transparency to X-ray radiation. Even though this device only measures the radiation reaching the area of the body on which it is worn, it does provide an indication of the amount of radiation received.

2.3.4 RADIATION PROTECTION SURVEY

A radiation protection survey must be made by a qualified expert after every change in equipment or change in operating conditions which might significantly increase the probability of personnel receiving more than the maximum permissible dose equivalent.

2.4 EQUIPMENT SAFETY

- Never operate this X-ray equipment in areas where there is a risk of explosion. Detergents and disinfectants, including those used on patients, may create explosive mixtures of gases. Please observe the relevant regulations.
- The equipment and PC interface module, or anything electrically connected to it, must never be used within 6 ft (1.8 m) of the patient environment.
- Do not place liquids (coffee, beverages, flowers, etc.) on the equipment, PC interface module or generator main cabinet.
- Always ensure adequate ventilation around the equipment, PC interface module and generator main cabinet. Do not operate the equipment near curtains, drapes, etc. which may block the ventilation slots.
- Do not operate the PC interface module or generator main cabinet in direct sunlight or near any heat sources.
- Do not operate the equipment and PC interface module near strong magnetic fields (microwave ovens, speakers, etc.), and avoid routing the console cables near these devices.
- The equipment, PC interface module and generator main cabinet must be operated in locations that are clean (free of excess dust, dirt, debris, etc), stable (free of vibration), and secure such that the PC interface module cannot slip or tip.
- Only trained maintenance staff may remove the covers of the equipment, generator cabinet and the PC interface module.
- Don't connect more than one multiple socket-outlet.

The user is responsible for ensuring that the application and use of the ***"DIAMOND"*** DR System does not compromise the patient contact rating of any equipment used in the vicinity of, or in conjunction with, the system.

CAUTION
Apply the specified voltage. Failure to do so may result in damage to the equipment.

CAUTION
Incorrect connections or use of unapproved equipment may result in injury or equipment damage.

CAUTION
Do not exceed the tube maximum operating limits. Intended life and reliability will not be obtained unless generators are operated within published specifications, and may result in injury to the patient or user or damage to the equipment.

WARNING
All of the movable assemblies and parts of this equipment should be operated with care and routinely inspected in accordance with the manufacturer's recommendations contained in this manual. Only properly trained and qualified personnel should be permitted access to any internal parts. Live electrical terminals are deadly; be sure line disconnect switches are opened and other appropriate precautions are taken before opening access doors, removing enclosure panels, or attaching accessories. For all components of the equipment, protective earthing means must be provided in compliance with the national regulations.

WARNING
The ***"DIAMOND"*** DR System includes no user serviceable parts. For service assistance, contact DRGEM Corporation or service provider. Repair by an unqualified user may result in injury to the user or damage to the equipment.

WARNING
The ***"DIAMOND"*** DR System and associated cables must not be operated in the presence of moisture or dusty areas. Failure to do so may result in an image that is not acceptable and may require re-imaging, or the patient or user may be electrocuted.

WARNING
Do not let liquids seep into the openings of the system (e.g. air openings, gaps between covers). Electric shock or equipment damage may occur when liquid is introduced.

WARNING
Ensure that the earth grounding connections between the ***"DIAMOND"*** DR System and its power source is maintained at all times. Otherwise, the patient or user may be electrocuted.

WARNING
To avoid risk of electric shock and noise, this equipment must only be connected to a supply mains with protective earth.

WARNING
Due to the risk of fire, the ***"DIAMOND"*** DR System is not suitable for operation in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

WARNING
Keep your hands and fingers away from the Parking Hole as it can incur injury.

WARNING
Do not modify this equipment without authorization of the manufacturer. Failure to do so may result in personal injury or equipment damage

WARNING
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTION
When the equipment is moved, be careful of collisions between equipment and other things. Failure to do so may result in injury or equipment damage to the patient or user.

CAUTION
Do not touch the tube directly as this may cause burns. Refer to the enclosed tube manual to check the normal operating range of the tube housing temperature.

WARNING
Do not look directly at the LEDs or lasers. This can cause damage to your eyes.

CAUTION
This system has a part that generates vibration and noise due to motor movement, so operator is advised to pay attention when using it. Failure to do so may result in retakes and delays in diagnosis.

WARNING
Contact the manufacturer in the event of a problem.

WARNING
Prepare spare equipment that can be used when the system is inoperative in the emergency room, operating room, etc. Otherwise, if this equipment fails, X-rays cannot be taken.

CAUTION
Do not touch the light source, the socket, or the light bracket with your finger. They can be very hot and cause severe burns.

WARNING
Use at least four qualified people when moving equipment in order to prevent injury or strain.

2.4.1 ME EQUIPMENT CLASSIFICATION

The main components of ***"DIAMOND"*** DR System comply with the regulatory requirements and design standards in this section as follows:

- Degree of protection against electric shock: Type B
- Operation Mode: Non-continuous
- Type of protection against electric shock: Class 1
- Degree of protection against liquid penetration: IPX0
  - Detector

IPX1	IP56	IP68
Mano4343W	Mars1717X	4343W(Basic)

- Method of sterilization: Not applicable
- Suitability for use in an OXYGEN RICH ENVIRONMENT: Not applicable

Model name	Generator Model name	Output rating	Output specification of the X-ray tube voltage	Mode of operation (Non-continuous operation mode)
DIAMOND-5A	GXR-52	52kW	640mA/81kV, 500mA/104kV, 400mA/130kV, 320mA/150kV	1 times exposure after reset time 1 minute (1 times exposure: 104kV, 500mA, 100ms)
	GXR-C52		640mA/81kV, 500mA/104kV, 400mA/130kV, 320mA/150kV	
DIAMOND-6A	GXR-68	68kW	800mA/85kV, 640mA/106kV, 500mA/136kV, 400mA/150kV	1 times exposure after reset time 1 minute (1 times exposure: 106kV, 640mA, 100ms)
DIAMOND-8A	GXR-82	82kW	1000mA/82kV, 800mA/102kV, 640mA/128kV, 500mA/150kV	1 times exposure after reset time 1 minute (1 times exposure: 102kV, 800mA, 100ms)

2.4.2 GENERATOR DUTY CYCLE LIMIT

NOTE
The following section contains important information. Please read and understand this material before continuing.

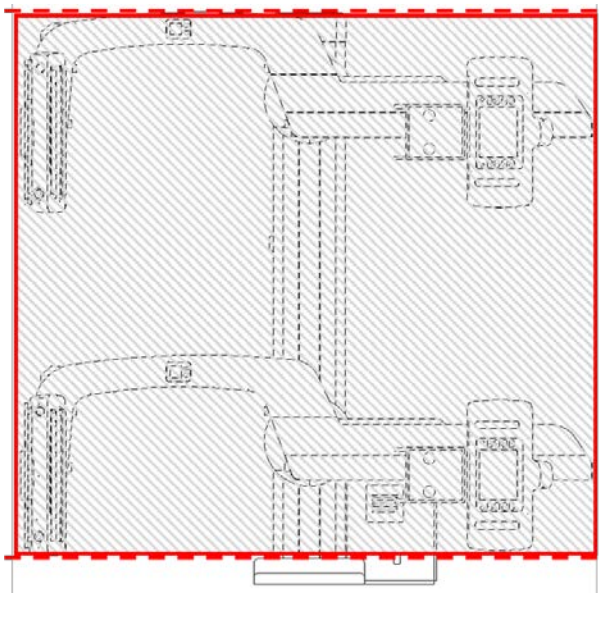
Internal X-ray generator components will heat up during normal use of the generator. This is similar to X-ray tube heating during normal generator operation. The amount of heat produced is proportional to the product of kV, mA, and time.

Modern X-ray generators are designed to operate with the majority of X-ray tubes over their rated power ranges. They are designed for operating duty cycles **consistent with practical patient examination routines that allow for reasonable cooling intervals between X-ray exposures**. Insufficient cooling time between exposures may lead to excessive heat build - up in the generator, which may cause serious generator damage.

CAUTION
This x-ray generator has temperature monitoring of power-stack to protect the excessive heat build-up. If the generator detects the over-heat of power-stack, an error code “e04” or “e05” will be displayed. Exposure will be inhibited when this message is displayed, and it should be understood that continuing to make exposures might cause generator damage due to overheating. The generator should be allowed to cool sufficiently such that this message is no longer displayed.

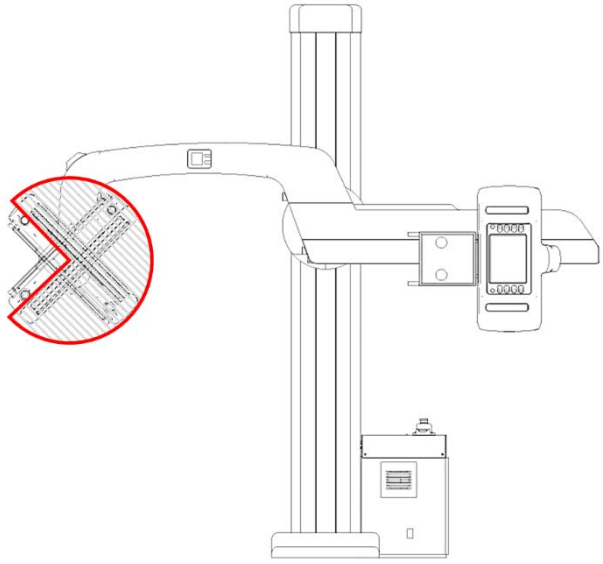
2.4.3 DANGER ZONES/POINTS

The locations and areas shown in the following figures indicate hazardous areas where patient or operator injury could result from collision or crushing.

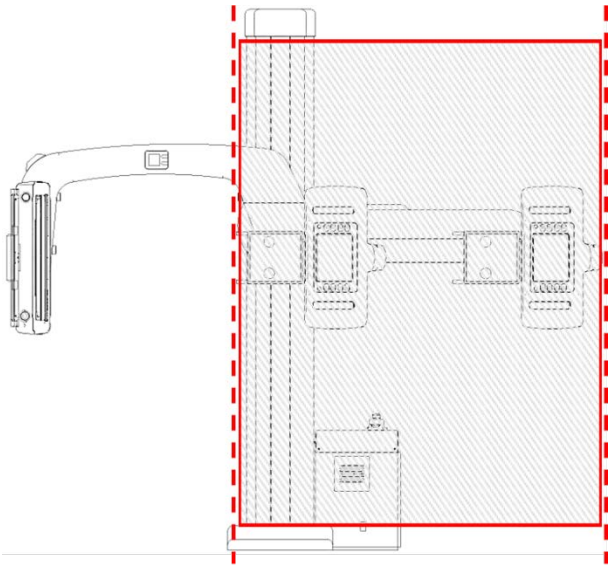


<Danger zones – Vertical movement>

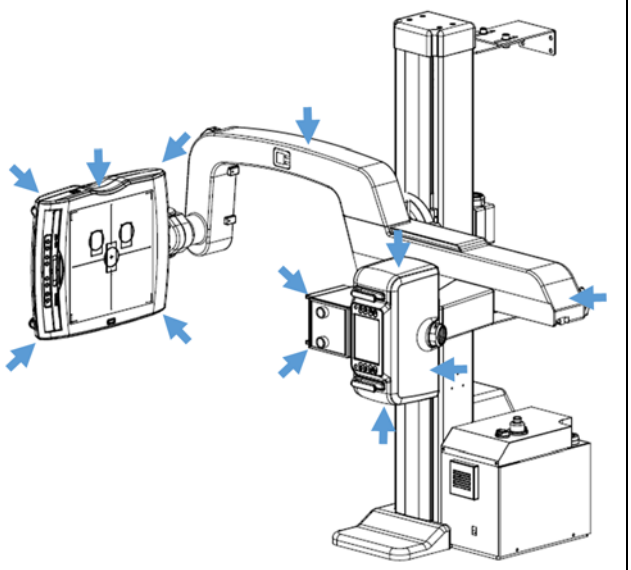
<Danger zones - U-arm Rotation>



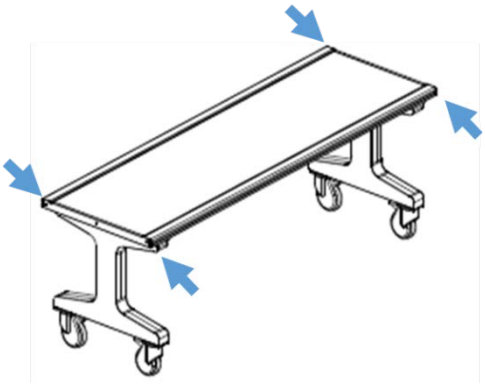
<Danger zones – Bucky tilting>



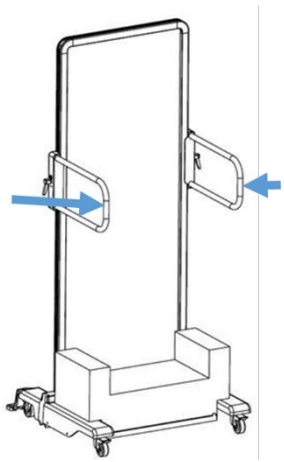
<Danger zones – Tube movement>



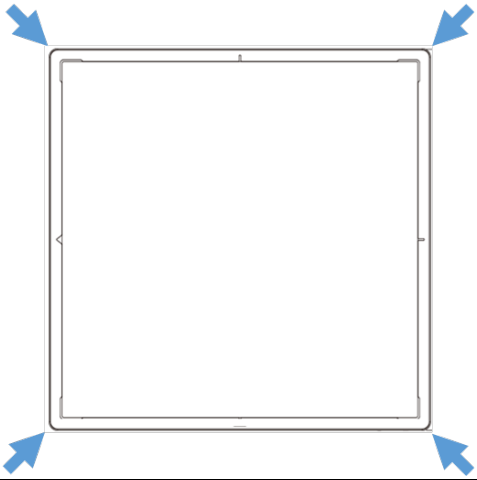
< Danger points - DIAMOND>



< Danger points – PDT-1>



< Danger points – Stitching stand>



<Danger points – Detector>

- There is a risk of injury in certain areas due to the operation of DIAMOND.
- Make sure that there are neither persons nor objects in the vertical or rotation range of the U-arm.
- Make sure there are neither persons nor objects in the tilting movement of the bucky.
- Be careful when moving the U-arm.
- Be careful when moving the PDT-1.
- Be careful when moving the handle bar in stitching stand.
- Avoid standing or sitting immediately adjacent to the system.

2.5 LIABILITY

2.5.1 STATEMENT OF LIABILITY

To prevent excess radiation exposure to patient and operator from either primary or secondary radiation, this ***"DIAMOND"*** DR System must be operated and serviced by trained personnel who are familiar with the safety precautions required. While this ***"DIAMOND"*** DR System has been designed for safe operation, improper operation or carelessness may result in serious injury or damage to equipment. The manufacturer or its agents and representatives assume no responsibility for the following:

- Injury or danger to any person from x-ray exposure.
- Overexposure due to poor technique selection.
- Injury or danger from improper use of the function.
- Problems or hazards resulting from failure to maintain the equipment as specified in the Installation chapter.
- Equipment which has been tampered with or modified. DRGEM Corporation is not liable for any damage or injury arising from failure to follow the instructions and procedures provided within the manuals or associated informational material, or from user failure to use caution when installing, operating, adjusting, or servicing this equipment. DRGEM Corporation is not liable for damage or injury arising from the use of this product for any other use than that intended by the manufacturer.

2.5.2 MANUFACTURER'S RESPONSIBILITY

Although this equipment incorporates protection against X-radiation other than the useful beam, practical design does not provide complete protection. Equipment design does not compel the operator or assistants to take the necessary precautions; nor does it prevent the possibility of improper use (authorized or unauthorized persons carelessly, unwisely, or unknowingly exposing themselves or others to direct or secondary radiation). Allow only authorized, properly trained personnel to operate this equipment.

Be certain that all individuals authorized to use the equipment are aware of the danger of excessive exposure to X-radiation.

This equipment is sold with the understanding that the manufacturer, its agents, and representatives, do not accept any responsibility for overexposure of patients or personnel to X-radiation.

Furthermore, the manufacturer does not accept any responsibility for overexposure of patients or personnel to X-radiation generated by the equipment used in conjunction with the ***"DIAMOND"*** DR System as a result of poor operating techniques or procedures.

No responsibility is assumed for any unit that has not been serviced and maintained in accordance with the Manual, or which has been modified or tampered with in any way.

WARNING
Proper use and safe operating practices with respect to x-ray generators are the responsibility of the users of such generators. Manufacturer provides information on its products and associated hazards, but assumes no responsibilities for after-sale operating and safety practices. Manufacturer accepts no responsibility for any generator not maintained or serviced according to the service manual or any generator that has been modified in any way. Manufacturer also assumes no responsibility for x-ray radiation overexposure of patients or personnel resulting from poor operating techniques or procedures.

2.6 IT NETWORK CHARACTERISTICS

"DIAMOND" DR System may only be run in an environment approved or authorized by the manufacturer.
The manufacturer requests a firewall and an antivirus program preinstalled in user's workstation according to the institution's regulation.
"DIAMOND" DR System provides the user interface for user access that the user can be authorized by entering valid User Name and/or Password.
DICOM communication for receiving/ sending data is made through the Ethernet port on a workstation. Optionally WIFI network can be used.

2.7 WARNING & ERROR MESSAGES AND STATUS INDICATORS

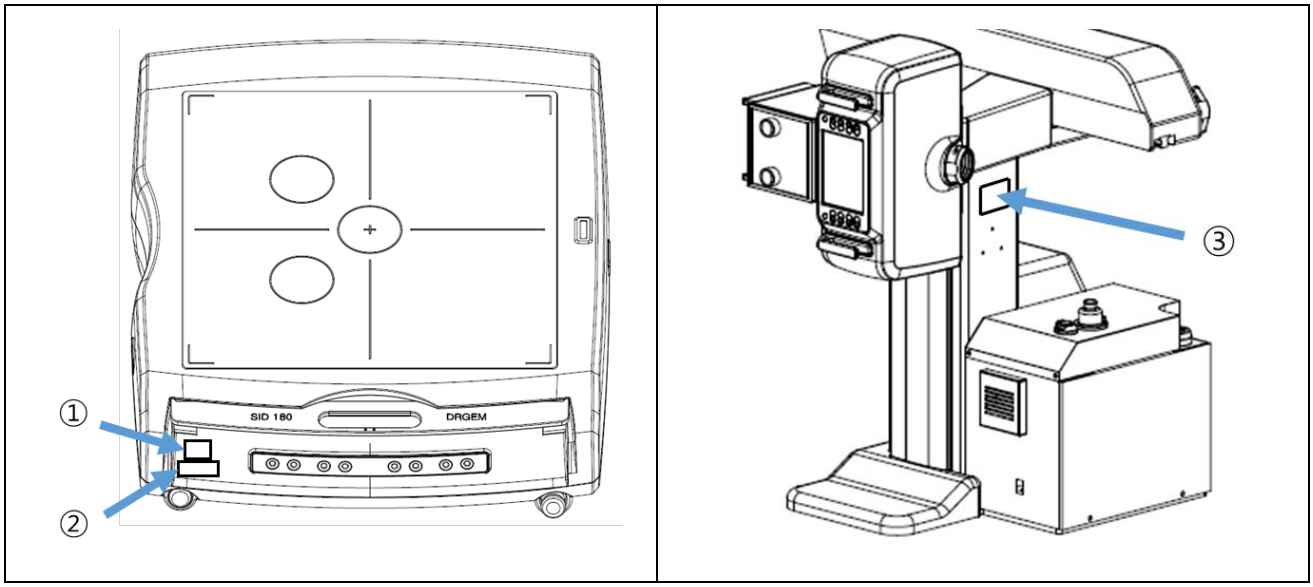
The system displays warnings and error messages status on the system.

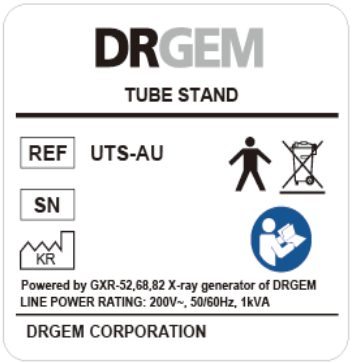
NOTE
Warnings and error messages status are displayed in ***"RADMAX"*** imaging software and UTS-AU.

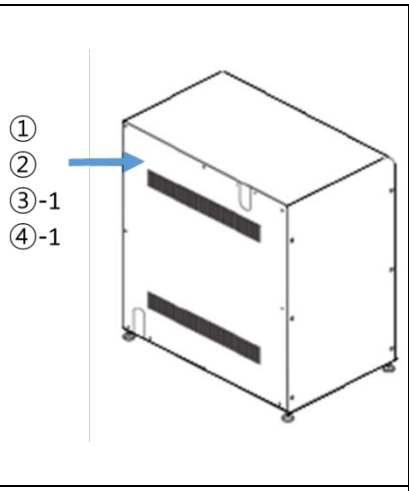
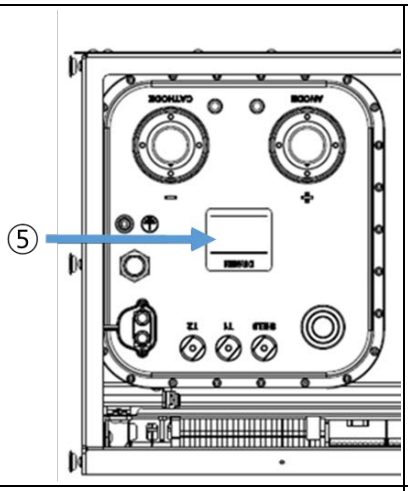
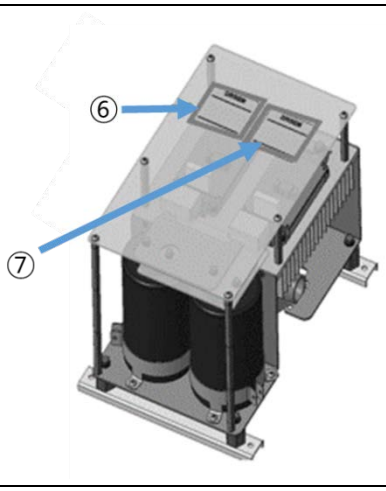
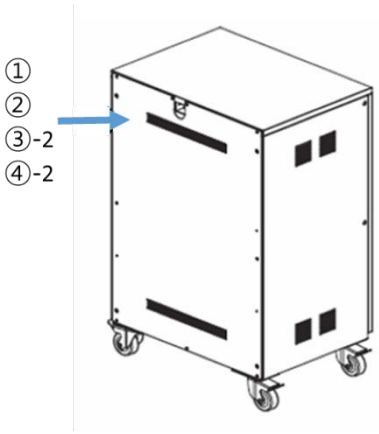
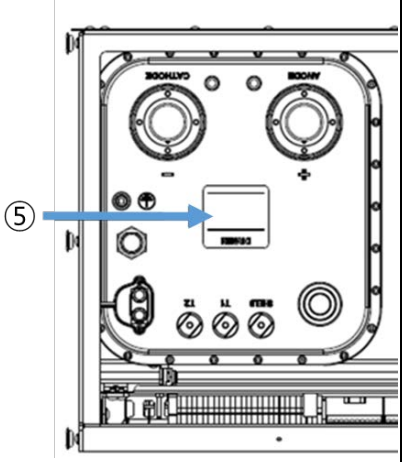
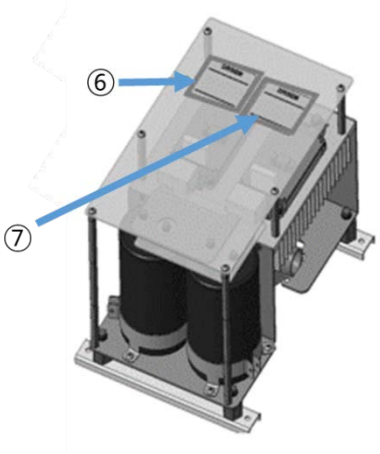
It gives information on what to problem.
For further details refer to the Service Manual of the ***"DIAMOND"*** DR System.

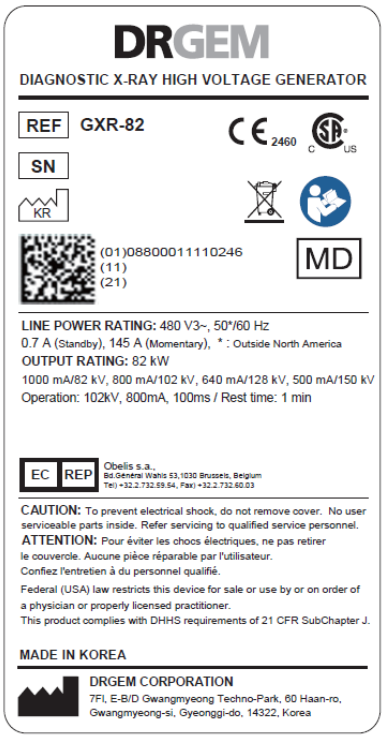
2.8 LABEL ATTACHMENT LOCATION

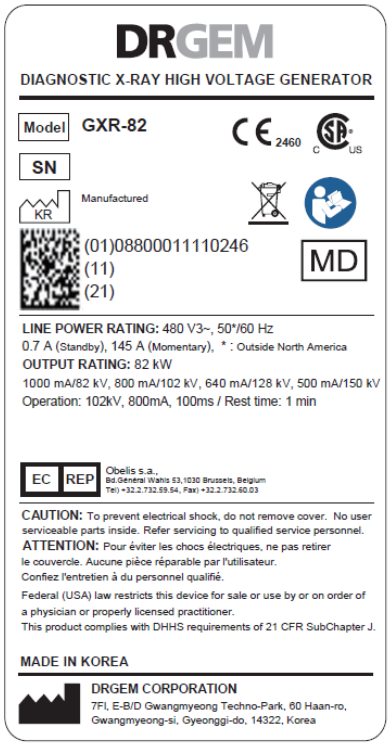
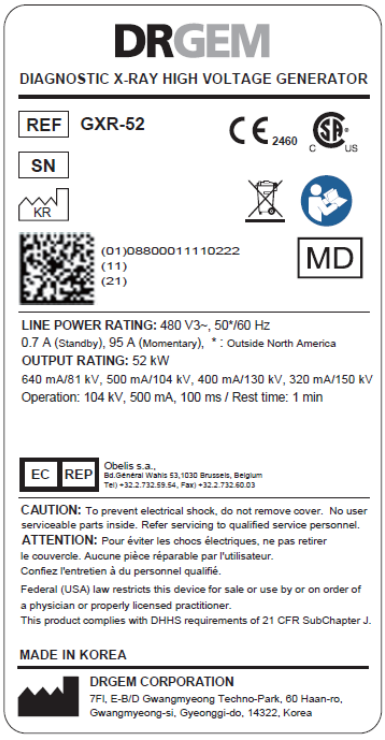
Label Attachment Location

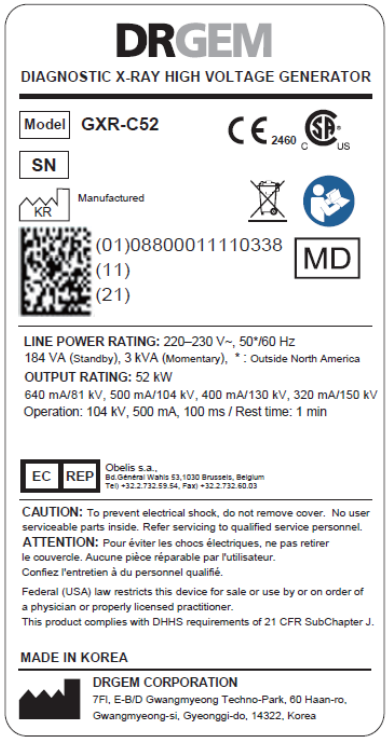
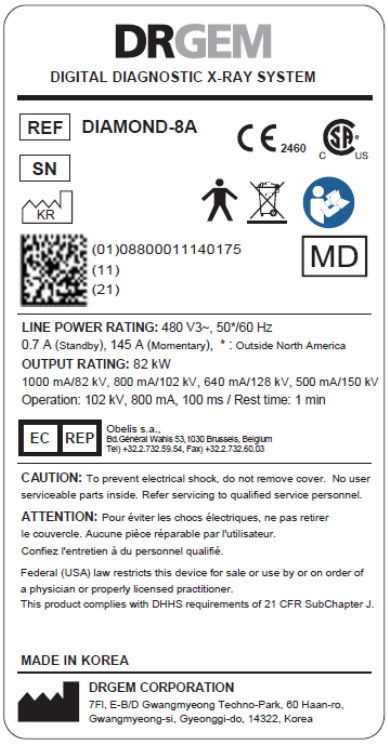


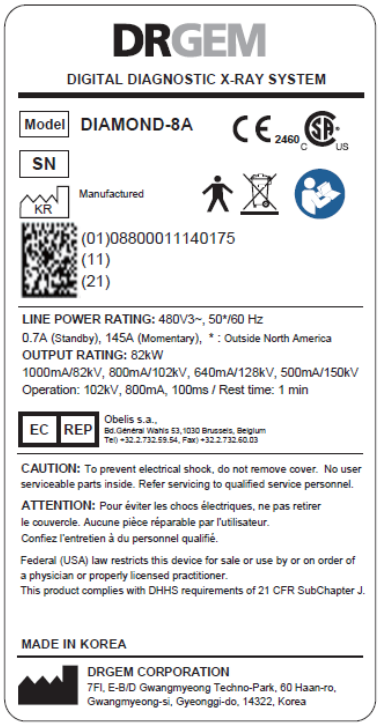
①		Hand jam caution label
②		Detector release switch
③		ID LABEL (UTS-AU)

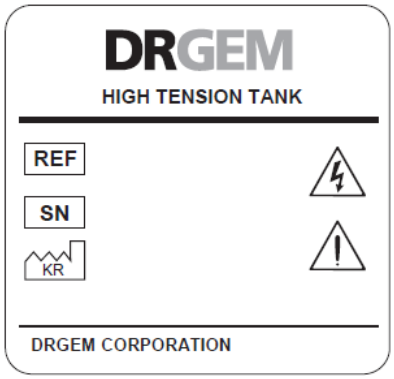
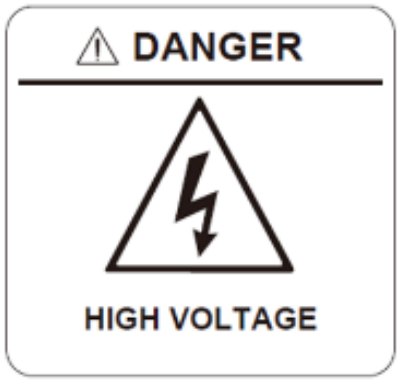
		
<GXR>	<GXR HV TANK>	<GXR POWER STACK>
		
<GXR-C>	<GXR-C HV TANK>	<GXR-C POWER STACK>

①		HV 3 MINUTES WARNING LABEL
②		HEAVY WEIGHT WARNING LABEL
③-1		ID LABEL (GXR) (Example of GXR-82) (CE)

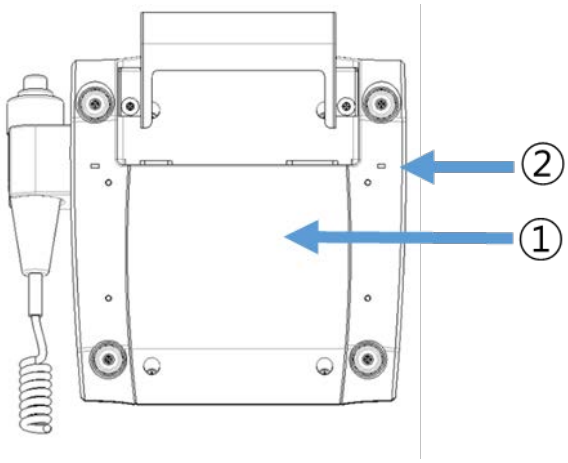
		ID LABEL (GXR) (Example of GXR-82) (FDA)
③-2		ID LABEL (GXR-C) (Example of GXR-C52) (CE)

		ID LABEL (GXR-C) (Example of GXR-C52) (FDA)
④-1		SYSTEM LABEL (DIAMOND) (Example of DIAMOND-8A (GXR)) (CE)

		SYSTEM LABEL (DIAMOND) (Example of DIAMOND-8A (GXR)) (FDA)
④-2		SYSTEM LABEL (DIAMOND) (Example of DIAMOND-5A (GXR-C)) (CE)

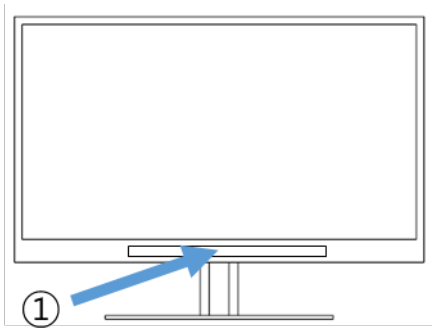
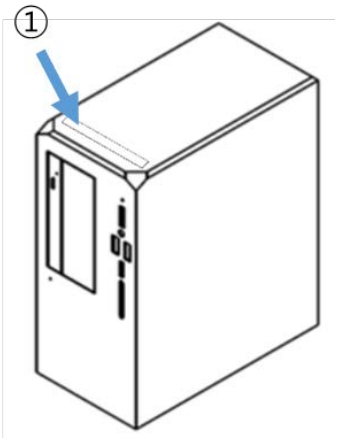
		SYSTEM LABEL (DIAMOND) (Example of DIAMOND-5A (GXR-C)) (FDA)
⑤		ID LABEL (HIGH TENSION TANK)
⑥		DANGER HIGH VOLTAGE LABEL

⑦	DRGEM POWER STACK REF PS-3P82 SN KR DRGEM CORPORATION	ID LABEL (POWER STACK) (Example of PS-3P82)



<PC INTERFACE MODULE>

①	FUJIFILM X-RAY CONTROL CONSOLE LINE POWER RATING: 12V ⎓ , 100mA DRGEM CORPORATION REF XCSD-R1 SN KR	ID LABEL (PC INTERFACE MODULE)
②	⚠ WARNING This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed	RADIATION WARNING MESSAGE STICKER

①	⚠ Use this workstation only with DRGEM Radiography System.	This label is attached to the top of workstation or the bottom of monitor screen

2.9 EMERGENCY PROCEDURE

Press the Emergency Stop Switch immediately if the device does not operate as intended and risk of collision, injury to the patient or operator, or risk of damage to the system.

All system drives are shut down and movements are stopped immediately.

If necessary, turn off key switch.

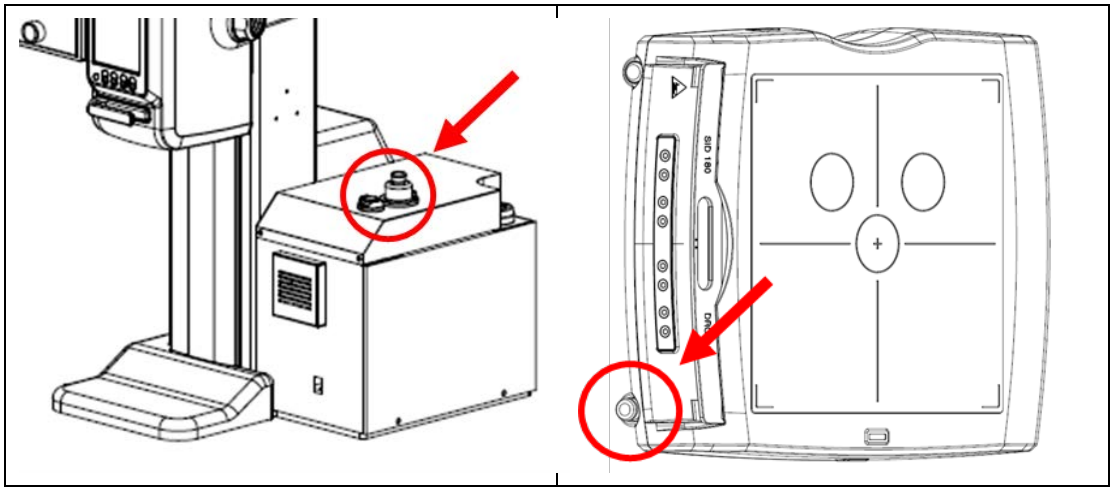
Only when the cause of the danger has been unequivocally identified and remedied, should the emergency STOP button be disengaged.

Turn the emergency stop switch clockwise to release.

CAUTION

The location of the Emergency Stop Switch is as follows.

Use the emergency switch only in emergency situations.



WARNING

Before operating ***"DIAMOND"*** DR System, operators must familiarize themselves with the location of the room's main power switch or the generator's main switch in order to enable immediate shutdown of the x-ray tube in the event of unintended motion or other catastrophic equipment failure.

3. SYSTEM OVERVIEW

3.1 PRODUCT FEATURES

The ***"DIAMOND"*** DR System is a fully automatic digital radiographic system providing state-of-the-art image quality, image processing and user interface; making the system easy to use and reliable while providing high quality digital radiographic images with reduced dose.

The ***"DIAMOND"*** DR System incorporates the digital flat panel detector technology, along with an automatic motorized U-arm radiographic stand and mobile patient table that can fit into smaller rooms without the need of ceiling support structures for X-Ray tube suspensions.

Direct radiography via flat panel detector improves your workflow, exam speed and comfort with efficiency. Digital flat panel detector with CsI screen provides excellent spatial resolution, MTF, DQE and stability based on fine pixel pitch. A 3-field ion-chamber is provided for AEC function.

The core part of x-ray source adopts high quality tube assembly (VAREX, SIEMENS and CANON), motorized x-ray collimator, HV cable assembly and DRGEM's high frequency x-ray generator which has worldwide reputation on excellent performance, lifetime and stability. Touch screen LCD based x-ray control console provides user-friendly interface and easy technique selection. Automatic collimator supports high accuracy for selected x-ray field size over any SID.

Selection of an anatomical study on the imaging software automatically sets up the x-ray generator's pre-programmed exposure technique setting, motorized radiographic stand positioning, x-ray collimation and post image processing for selected study. Also, removable high resolution grids which have 100 and 180cm (40 and 72 inch) focal distance supplies excellent image quality per each SID.

Thanks to the integrated touch screen console located in tube side, operator can easily controls the radiographic techniques and stand positioning. Furthermore, operator can verify the digital x-ray image on this screen. The GUI is automatically rotates corresponds to rotation angle of U-arm.

Radiographic stand has four motorized joints, and automatic positioning can be accomplished by pre-programmed data which can be easily reprogrammed by operator. Total of seven safety sensors are located over U-arm, detector and tube side to protect against collision with patient or obstacles to control the speed or stop the positioning. Also, a mobile patient table with heavy patient load is provided for radiographic study which needs table. The remote-control is provided for remote motorized control of stand, and the movement stops as soon as you lift your finger from the key by dead-man control type.

A high performance imaging workstation and software serves you a convenient interface and easy operation. Anatomical view-based digital image processing automatically optimizes and enhances the quality of the captured images. Automatic image storage and print with DICOM 3.0 networking capability increases exam throughput and decreases examination time. Remote diagnosis function enables fast and accurate diagnosis on problems and saves service cost and system downtime.

The types of ***"DIAMOND"*** Diagnostic X-ray System are divided into DIAMOND-5A, DIAMOND-6A, and DIAMOND-8A according to maximum power and mA. The higher the maximum output, the wider the mA range to choose from, giving the user more technical options to choose from.

NOTE
The following section contains important information. Please read and understand this material before continuing.

3.1.1 STANDARD

- Digital Flat-panel Detector
- High Frequency X-ray Generator
- X-ray Tube Assembly
- Motorized Automatic Collimator
- Motorized Radiographic Stand
- Mobile Patient Table
- 26ft (8m) Claymount High Voltage Cables and stator cable
- AEC sensor
- Removable High Resolution Grids (100/180cm SID)
- Imaging Software and Workstation

3.2 SPECIFICATIONS

The hardware specified for use with the ***"DIAMOND"*** DR System has been selected, tested, and verified by DRGEM Corporation to meet the intended applications. All specified hardware meets applicable regulatory agency requirements for those countries where it is offered for sale with respect to its intended applications.

In DIAOND-5A/6A/8A, only the maximum output for each model is different, and there is no clinical benefit. This is because the image quality is determined by the detector and the film quality.

WARNING
Do not operate this system except in accordance with information included in this section, and any additional information provided by the manufacturer and / or competent safety authorities. Failure to do so may result in injury or equipment damage to the patient or user.

NOTE
The product life of the ***"DIAMOND"*** DR System is 10 years.

3.2.1 DIAMOND CONFIGURATION PART

Part		Configuration			
		DIAMOND-5A		DIAMOND-6B	DIAMOND-8B
Radiographic Stand	Type	Universal type			
	Software/Firmware	System Control Board			
		OP Control Board			
X-ray Generator	Model	GXR-52	GXR-C52	GXR-68	GXR-82
	Type	High Frequency			
	Nominal Output	52kW		68kW	82kW
	kV Range	40~150kV			
	mA Range	10~640mA		10~800mA	10~1,000mA
	Timer Range	0.001~10 sec			
	mAs Range	0.1 ~ 500mAs			
	Software/Firmware	HT Control Board	GXR_HTC	HT Control Board	
		DSS board	GXR_CHG	DSS board	
X-ray Tube Assembly	Tube	E7884X, E7252X, DXT-12M, DXT-14U, DXT-15U, RAD-14 RAD-21, RAD-60, RAD-92		E7252X, DXT-14U, DXT-15U RAD-14 RAD-21, RAD-60, RAD-92	RAD-21, RAD-60, RAD-92
	Type of Collimator	R302MLP/A, R302 MLPI/A DHHS, R302MFMLP/A			
Patient Table	Mobile Patient Table	PDT-1			
Generator controller	Generator controller	PC interface module			
	Software/Firmware	GXR_PCI			
SW	Workstation	Workstation (Include Monitor)			
	Operating software	RADMAX			
Detector	Detector	PaxScan4343R V3, 4343W(Basic), Mano4343T, Mano4343W, Mars1717X			
Options & Accessories	DAP (Dose Area Product) meter	120-131HS (RS485)			
	Detachable High Resolution Grid	Grid 1000			
	AEC Ion Chamber	ICX1162 (ICX1192B), 9890 000 70006 (Amplimat 5-Field)			

	STITCHING STAND	STITCHING STAND
	Remote Control	Ready-Exposure
	Detachable High Resolution Grid Holder	Grid Holder

NOTE
For detailed specifications, please refer to the detailed specifications of the model below.

NOTE
Collimators and tubes can be used in any combination

CAUTION
When sold in European countries, use with products that have RDSR (Radiation Dose Structured Report) function added according to DICOM regulations.

CAUTION
Use a detector that provides an imaging calibration program. Otherwise, the quality of the X-ray image may be lowered.

3.2.2 DIAMOND HIGH FREQUENCY X-RAY GENERATOR

System Model	**DIAMOND-5A**	
Model	GXR-52	GXR-C52
Output Rating	52kW	
Line Power	380/400/480V3~, 50*/60Hz, * : Outside North America	220-230V~, ±10% (Frequency: 50*/60Hz), * : Outside North America
kV Range	40~150kV, 1kV step	
mA Range	10~640mA, 19 steps	
Max. Output	640mA/81kV, 500mA/104kV, 400mA/130kV, 320mA/150kV	640mA/81kV, 500mA/104kV, 400mA/130kV 320mA/150kV
Timer Range	0.001~10 sec, 38 steps	
mAs Range	0.1 ~ 500mAs	
Rotor Supply	Low Speed (Optional Dual Speed)	Low Speed
Reproducibility	Coefficient of Variation: kV < 0.005, Time < 0.005, mAs < 0.01	
Accuracy	kV<±(1%+1kV), mA<±(3%+1mA), Time<±(1%+0.5ms), mAs<±(3%+0.1mAs)	
Linearity	Coefficient of Linearity < 0.01 : CL = (X1-X2)/(X1+X2), where X is mR/mAs	
DAP	Dose Area Product: continuous follow-up on monitor	

System Model	DIAMOND-6A	DIAMOND-8A
Model	GXR-68	GXR-82
Output Rating	68kW	82kW
Line Power	380/400/480V3~, 50*/60Hz, * : Outside North America	
kV Range	40~150kV, 1kV step	
mA Range	10~800mA, 20 steps	10~1,000mA, 21 steps
Max. Output	800mA/85kV, 640mA/106kV, 500mA/136kV, 400mA/150kV	1,000mA/82kV, 800mA/102kV, 640mA/128kV, 500mA/150kV
Timer Range	0.001~10 sec, 38 steps	
mAs Range	0.1 ~ 500mAs	
Rotor Supply	Dual Speed	
Reproducibility	Coefficient of Variation: kV < 0.005, Time < 0.005, mAs < 0.01	
Accuracy	kV<±(1%+1kV), mA<±(3%+1mA), Time<±(1%+0.5ms), mAs<±(3%+0.1mAs)	
Linearity	Coefficient of Linearity < 0.01 : CL = (X1-X2)/(X1+X2), where X is mR/mAs	
DAP	Dose Area Product: continuous follow-up on monitor	

3.2.3 DETECTOR

- **Digital flat panel detector (VAREX)**

Model		PaxScan4343R V3		4343W(Basic)		
Active Pixel Area / Matrix		17 x 17 inch (3,052 x 3,052)		17 x 17 inch (3,062 x 3,062)	17 x 17 inch (3,052 x 3,052)	
Pixel Pitch		139um				
Limiting Resolution		3.6 lp/mm				
Screen		DRZ+	CsI	DRZ+	Standard CsI	Premium CsI
Energy Range		40 – 150kVp				
A/D Conversion		16-bits				
MTF	@ 1 lp/mm	54%	56%	56%	61%	57%
	@ 2 lp/mm	23%	27%	24%	32%	28%
	@ 3 lp/mm	9%	14%	10%	17%	14%
DQE	@ 0 lp/mm	38%	78%	39%	64%	79%
	@ 1 lp/mm	27%	55%	28%	54%	63%
	@ 2 lp/mm	16%	42%	18%	42%	48%
	@ 3 lp/mm	7%	28%	9%	29%	33%
Interface		Gigabit Ethernet		WiFi(802.11 n/ac)		
Weight		6.1kg (13.4lbs)	6.2kg (13.6lbs)	3.1 kg (6.8 lbs.)	3.3 kg (7.3 lbs.)	

- **Digital flat panel detector (iRay)**

Model		Mano4343T	Mano4343W
Active Pixel Area / Matrix		17 x 17 inch (3,072 x 3,072)	
Pixel Pitch		139um	
Limiting Resolution		3.6 lp/mm	
Screen		CsI	
Energy Range		40 – 150kVp	
A/D Conversion		16-bits	
MTF	@ 1 lp/mm	70%	71%
	@ 2 lp/mm	45%	44%
	@ 3 lp/mm	26%	26%
DQE	@ 0 lp/mm	65%	65%
	@ 1 lp/mm	47%	47%
	@ 2 lp/mm	35%	35%
Interface		Gigabit Ethernet	Gigabit Ethernet / WiFi(802.11ac)
Weight		Approx. 4kg (8.8 lbs.) (Without Cable)	4.6kg (10.1 lbs.)

Model		Mars1717X
Active Pixel Area / Matrix		17 x 17 inch (4,267 x 4,267)
Pixel Pitch		100um
Limiting Resolution		4.3 lp/mm
Screen		CsI
Energy Range		40 – 150kVp
A/D Conversion		16-bits
MTF	@ 1 lp/mm	65%
	@ 2 lp/mm	35%
	@ 3 lp/mm	19%
DQE	@ 0 lp/mm	68%
	@ 1 lp/mm	54%
	@ 2 lp/mm	38%
Interface		Gigabit Ethernet / WiFi(802.11ac)
Weight		3.4kg (7.5 lbs.)

NOTE

Depending on the country, there are detectors that cannot be installed and used. Please refer to the table below.

Nation	List of detectors that cannot be installed
USA	Mano series (Mano4343T)

NOTE

Mars1717X detector is not applied FDA Certificate.

Nation	List of detectors that cannot be installed
FDA	Mars1717X

3.2.4 WORKSTATION

- **Workstation**

CPU	Intel Core i5 10th or higher
Memory	8GB (1x8GB) DDR4 2400Mhz or higher
Display	Intel® HD Graphics 630 or Higher
Storage	256GB SSD, 1TB 7200RPM SATA HDD
OS	Windows 10 IoT Enterprise
Monitor	23 inch Color LED or Higher, Display resolution: 1920 x 1080 pixels (16:9)

- **AP (Access Point)**

Model	RT-AC68U (AC 1900)
Product Picture	
Manufacturer	ASUS
Standards	IEEE 802.11n, IEEE 802.11ac
Frequency	5GHz / 2.4GHz
Wireless LAN (max.)	1.3Gbps(5GHz)/600Mbps (2.4GHz)
Weight Antennas Type	3 external antennas
AC Power Adapter	19V / 1.75A
Regulatory Compliance	CE, FCC, RoHS, KCC

3.2.5 IMAGING SOFTWARE

1) General Features

- Windows OS based graphic user interface
- Multi-image display (1x1 ~ 4x4)
- Multi-image selection
- Auto display layout changing function
- X-ray generator control panel
- Unlimited procedure step
- Quick step add feature and image maintenance feature by popup menu
- ROI feature (support the creation of ROI for each APR by user)
- Maker feature (support the creation of maker for each APR by user)
- Multi-language support
- EXCEL sheet for language support (only possible on Microsoft Office automation environ ment)
- DAP meter (Optional)
- Unlimited PACS code (CPT code)
- Unlimited Anatomically programmed radiography (APR) support
- Support DICOM Worklist SCU, DICOM Storage SCU and transfer function
- Support DICOM Multi-transfer function
- High-performance post-processing feature
- Copy & Move Images
- Dose monitoring function
- Built-in memory function
- Grid line suppression function
- Reject analysis function
- 9 Preset function
- Cobb's angle function
- Tube & Line Enhancement function
- Detector Built-in Charger function
- APR Positioning Guide function
- Auto ROI function
- Screen Locker function
- ROI Masking function
- Authority setting function
- Patient information tag deletion function
- Auto Stitching function to manual type
- MANO Detector power off function

- Live Streaming function
- Blue and Dark Skin GUI
- Support SCP(SERVICE CLASS PROVIDER)
- Support Audit Trail
- Support Period Setting
- Support DICOM Send Monitoring
- Support DICOM Tag Matching
- Support Scatter Reduction image processing parameter
- Support C-Store SCP function
- Support Widget function
- Support Bone Suppression function

2) Post processing parameters

- MODULE 1
  - Edge Enhancement: 0 ~ 50
  - Contrast Factor : 1 ~ 200
  - Image Frequency : 0 ~ 20
  - Image Latitude : -10 ~ 10
  - Sharpness : 0 ~ 100

- MODULE 2
  - Histogram Optimization : -100 ~ 100
  - Skin line Weight : -100 ~ 100
  - Latitude Compression : -100 ~ 100
  - Contrast Enhancement : -100 ~ 100
  - Edge Enhancement : -100 ~ 100
  - Noise Suppression : -100 ~ 100
  - Gamma : -20 ~ 20

- MODULE 3
  - Global Brightness : -100 ~ 100
  - Global Contrast : -100 ~ 100
  - Latitude Compression : -100 ~ 100
  - S-Structure Enhancement : -100 ~ 100
  - Noise Suppression : -100 ~ 100
  - Gamma : -20 ~ 20

- MODULE 4
  - Global Brightness : -20 ~ 20
  - Global Contrast : -20 ~ 20
  - Local Contrast : 0 ~ 20
  - Small Enhancement : 0 ~ 20
  - Latitude Reduction : -20 ~ 20
  - Noise Suppression : 0 ~ 20
  - Gamma : -20 ~ 20

3) Image Maintenance (All functions are supported by the pop-up menu)
   - ROI : Support the creation of up to 30 of ROI by user
   - ROI Shape : Support the shape of rectangle, circle and polygon
   - MARK : Support the creation of up to 30 of MARKER by user (User preset support)
   - Arrow Marker
   - Overlay Display On/Off
   - Horizontal Flip
   - Vertical Flip
   - Rotate CW
   - Rotate CCW
   - Fine Rotation : Rotate the image with fine angle (1,2,3,45 degree)
   - Line Rotation: Rotate the image by the line angle.
   - Inverse (Black or White)
   - Text Annotation
   - Ruler : Distance tool
   - Angle : Angle measurement tool
   - Zoom : Image zoom in/out
   - Magnify : Image magnify glass window
   - Pan : Image panning
   - Fit Image : Auto fitting to window size
   - 1:1 View : Display 1:1 mapped image between monitor pixels and detector pixels or the re al size on screen
   - Image Crop : Image crop function / Supported by left double-click mouse
   - Image Recovery : Recover the original image
   - Image Bright/Contrast control : Supported by right-click mouse
   - Module3 Processing Type function (Soft, Standard, Strong)
   - Hip Measurement

4) CD Burning
   - DICOMDIR based CDR data generation
   - Support CD/DVD Recording
   - Include internal DICOM Viewer
   - Support multi-study data

5) DICOM Features : DICOM PRINT
   - DICOM 3.0 compatible
   - Support Print Preview
   - Support Film Orientation : Portrait / Landscape
   - Support Film Size : 8X10 / 10X12 / 10X14 / 11X14 / 14X14 / 14X17 / 24X24 / 24X30 / 25X30
   - Support Film Layout : 1:1 / 1:2 / 2:1 / 2:2 / 3:1 / 1:3 / 3:3 / 4:4
   - Support Real size printing
   - Support image swap in layout

6) DICOM Feature : STORAGE
   - DICOM 3.0 compatible
   - Support DX/CR modality (can be extended for DR and other)
   - Support RDSR(Radiation Dose Structured Report)
   - Support the modification of Transfer Syntax

7) DICOM Feature : MPPS
   - Support Modality Performed Procedure Step feature
   - Provides only three state : FAILED / IN PROGRESS / COMPLETED

8) DICOM Feature : WORKLIST
   - Support DICOM Modality Worklist Standard
   - Support DICOM Query/Retrieve
   - Support Search Filter (ID / Name / Access Number)
   - Support Import Filter

9) DICOM Feature : STORAGE COMMITMENT

10) DICOM Feature : QUERY/RETRIEVE

11) DICOM Feature : VERIFICATION

12) DICOM Feature : TLS

13) Overlay Display on image
- Projection description
- Patient Name / Sex / Age
- kV / mA / Time / mAs
- Feed-back mAs / Feed-back Time for AEC
- EI(Exposure Index) / DI(Deviation Index)
- Window Width / Level
- Overlay can be set by user

14) Image Stitching
- Stitches whole spine/long bone images to single image
- Support 2 ~ 5 images stitching
- Support zoom in/out of all images simultaneously
- Moves single image or all images simultaneously
- Support automatic stitching using 2 point
- Support image clipping
- Automatically remove non-exposure area
- Adjust window level of single image or all images simultaneously
- Provide full-spine imaging apparatus

3.2.6 RADIOGRAPHIC STAND & MOBILE PATIENT TABLE (WITH TUBE & COLLIMATOR)

- **Radiographic Stand & Mobile Patient Table**

Model		UTS-AU & PDT-1
Vertical Movement		Max. 1,200mm (47.2inch)
U-arm Rotation		+120° (CW) ~ -30° (CCW)
SID Movement		1,000 ~ 1,800mm (40~72inch)
Detector Rotation		+45° ~ -45°
Tube Rotation		+180° ~ -90°, manual
Max. Patient Weight		Max. 250kg (550lbs)
Weight	Radiographic Stand	400kg (882lb)
	Mobile Patient Table	60kg (132lb)

- **X-ray Tube**

Tube Model	E7884X	DXT-12M	E7252X
Manufacturer	CANON	DRGEM	CANON
Focal Spot Size	0.6/1.2mm	0.6/1.2mm	0.6/1.2mm
Rating(0.1s)	22/54kW@60Hz	22/54kW@60Hz	27/75kW
Max. Anode HU	300kHU(210kJ)	300kHU(210kJ)	300kHU(210kJ)
Target Angle	12°	12°	12°
Max. kV	150kV	150kV	150kV
Weight	16kg(35.3lbs)	16kg(35.3lbs)	18kg(39.7lbs)
Inherent Filtration	0.9mmAl/75kV	1.0mmAl/75kV	0.9mmAl/75kV
Half Value Layer	More than 2.9mmAl eq. at 80kVp		
Leakage Radiation	Less than 100mR/hr		

Tube Model	DXT-14U	RAD-14	DXT-15U *
Manufacturer	DRGEM	VAREX	DRGEM
Focal Spot Size	0.6/1.2mm	0.6/1.2mm	0.6/1.2mm
Rating(0.1s)	27/75kW	32/77kW	32/77kW
Max. Anode HU	300kHU(210kJ)	300kHU(210kJ)	300kHU(210kJ)
Target Angle	12°	12°	12°
Max. kV	150kV	150kV	150kV
Weight	18kg(39.7lbs)	16.4kg(36.2lbs)	16.4kg(36.2lbs)
Inherent Filtration	1.0mmAl/75kV	0.6mmAl/75kV	0.7mmAl/75kV
Additional Filtration		0.5mmAl	0.5mmAl
Half Value Layer	More than 2.9mmAl eq. at 80kVp		
Leakage Radiation	Less than 100mR/hr		

*Adopting VAREX RAD-14 Insert.

Tube Model	RAD-21	RAD-60	RAD-92
Manufacturer	VAREX	VAREX	VAREX
Focal Spot Size	0.6/1.2mm	0.6/1.2mm	0.6/1.2mm
Rating(0.1s)	36/100kW	40/100kW	40/100kW
Max. Anode HU	300kHU(210kJ)	400kHU(285kJ)	600kHU(444kJ)
Target Angle	12°	12°	12°
Max. kV	150kV	150kV	150kV
Weight	18.9kg(41.7lbs)	18.9kg(41.7lbs)	18.9kg(41.7lbs)
Inherent Filtration	0.7mmAl/75kV	0.7mmAl/75kV	0.7mmAl/75kV
Additional Filtration	0.5mmAl		
Half Value Layer	More than 2.9mmAl eq. at 80kVp		
Leakage Radiation	Less than 100mR/hr		

NOTE
Total filtration including X-ray tube assembly and collimator will be matched by appropriate additional filters to within the range from 3.0 to 3.2mmAl. eq.

- **Collimator**

Model	R302MLP/A, R302MFMLP/A
Manufacturer	RALCO
Rated X-ray Shielding	150kV max.
Inherent Filtration	2.0mm Al eq.
X-ray Field Coverage	Max. 48 x 48cm at 100cm SID
Luminosity	Over 160 Lux
X-ray Field Precision	< 2% SID
Leakage Radiation	< 40mRh at 150kVp / 4mA, 100cm SID
Lamp	OSRAM HLX 64638 – 100W 24V (Option: LED type)
Weight	10kg (22lb)
Filter (option)	0.1-0.2mm cupper manual and automatic selected by organ program, display on monitor and film.

3.2.7 OPTION & ACCESSORIES

- **Option**

- AEC Ion Chamber

Model	ICX1162 (ICX1192B)	9890 000 70006 (Amplimat 5-Field)
Manufacturer	Claymount	Philips
Field	3 Fields	5 Fields
X-ray Energy Range	40~150kV	40~150kV
Exposure time Range	1ms to 10s	1ms to 6s
Inherent Filtration	0.4 mm Al eq.	0.8 mm Al eq.
Weight	2kg (4.4lb)	1.8kg (4lb)

- Stitching Stand

Model	STITCHING STAND
Dimension / Weight	927.6(W) x 945.9(D) X 2064.7(H)mm / 47.1kg (103.8lb)

- Live streaming camera

Model	HU205
Manufacturer	HUENTEK
Display resolution	1920×1080
Max. Image Transfer Rate	30FPS @ FHD
Electrical Rating	5VDC, 210mA

NOTE
Live streaming camera images are used only for reference.

- Touch Screen Console for X-ray Generator
- Diagnostic Monitor (Monochrome, Color)
- Image stitching software with an apparatus for whole spine imaging
- UPS for Imaging Workstation

- **Accessory**

- DAP (Dose Area Product) meter

Model	120-131HS (RS485)
Manufacturer	IBA
DAP Resolution	0.01 μGym²
Interface	RS485
Active area	115 x 115mm / 146 x 146mm
Display	Integrated or separate display (single or dual line)
Dimension	158 x 134.5 x 17mm / 180 x 156 x 17mm
Inherent Filtration	0.5 mm AI
Power input	12 – 29 VDC,100mA
Measurement Uncertainty	±25%

- Detachable High Resolution Grid

Model	Grid 1000
Manufacturer	JPI
Size	17 X 17 inch
Focal distance	100, 180cm (40 / 72inch), two grids
Line number	200 lpi
Reason	12:1
Cover Material	Carbon Fiber
Weight	2kg (4.4lb)

- DAP (Dose Area Product) meter with display
- Detachable High Resolution Grid Holder

3.2.8 SOFTWARE FIRMWARE INFORMATION

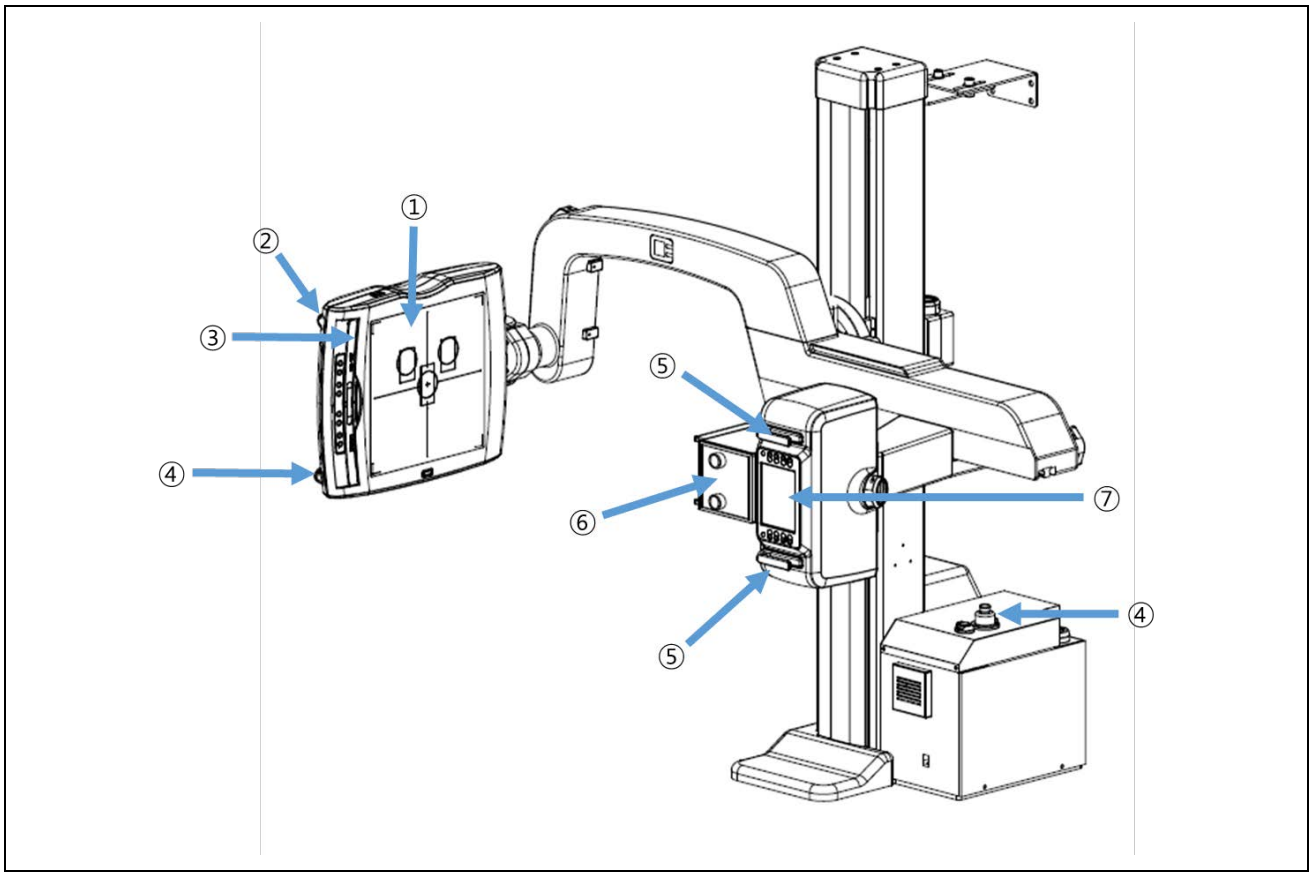
- **Software Version**

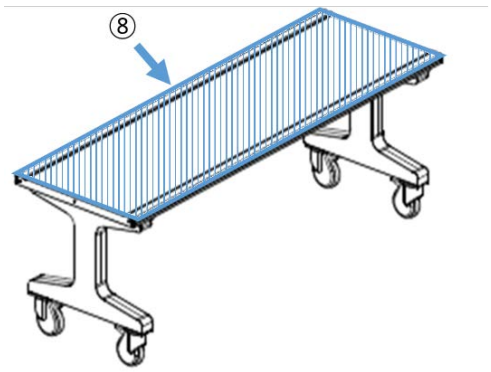
Software/Firmware	Version	Description
RADMAX	1.02	***"RADMAX"*** imaging software is the main software provides top level graphics user interface on whole system control and imaging process. ***"RADMAX"*** imaging software consists of System Control Module, Imaging Module, DICOM Module, Database Module, System Diagnosis Module and Display Module.
HT Control Board	1.5a	HT Control Board is x-ray generator controls whole x-ray generation process by the control of System Control Module in ***"RADMAX"*** imaging software. This module controls x-ray parameters such as kV, mA and exposure time, and controls the filament and rotor driving and detector interfacing.
DSS board	1.00	DSS board is x-ray generator controls starter operation which drives tube's anode rotation by the control of GXR DSS board at x-ray generator.
GXR_HTC(C-Type)	1.2a	GXR_HTC at HT control board in x-ray generator controls whole x-ray generation process by the control of System Control Module in RADMAX. This module controls x-ray parameters such as kV, mA and exposure time, and controls the filament and rotor driving and detector interfacing.
GXR_CHG(C-Type)	1.00	GXR_CHG at Charger board in X-ray generator charges the capacitor modules in the power stack of the generator to save the energy for X-ray exposure. This module detects voltage and current of capacitor modules to protect capacitor modules.
GXR_PCI	1.00	GXR_PCI at PC Interface Module consist of communication relay module between GXR-HTC and CPC_SDK.
System Control Board	1.00	System Control Board is motorized radiographic stand controls the motorized radiographic stand, controls the motorized x-ray collimator by the control of System Control Module in ***"RADMAX"*** imaging software. Also this module transmits whole system control data between System Control Module in ***"RADMAX"*** imaging software and all other software in x-ray generator and motorized radiographic stand.

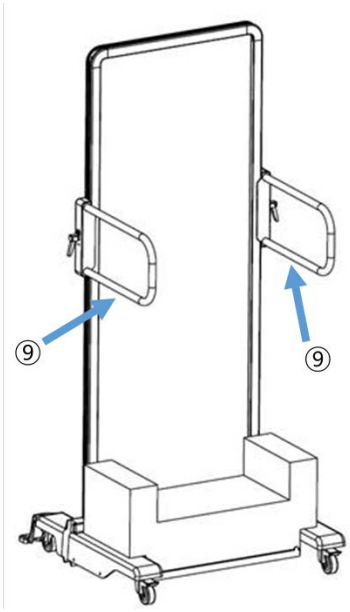
OP Control Board	1.00	OP Control Board is motorized radiographic stand receives and transmits the control input of motorized radiographic stand to System Control Board for motorized control of radiographic stand. Also this module receives and transmits the touch screen control input at integrated control panel to System Control Module in ***"RADMAX"*** imaging software via System Control Board

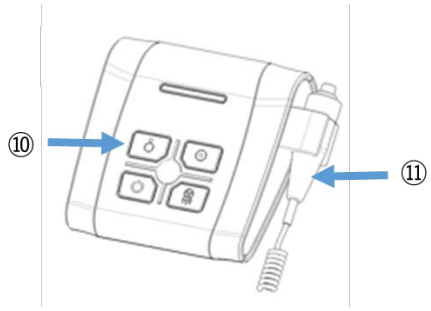
3.3 TOUCHABLE PARTS

The applied parts of patients and users in ***"DIAMOND"*** DR System are as follows.









- Operator applied parts

①	Bucky Cover	②	Detector release switch
③	Grid	④	Emergency switch
⑤	Tube Handle	⑥	Collimator Knob
⑦	Integrated Touch Screen & Membrane	⑧	PDT-1 Tabletop
⑨	Stitching Stand : Handle	⑩	Interface Module
⑪	Handswitch		

- Patient applied parts

①	Bucky Cover	⑨	PDT-1 Tabletop

WARNING
Do not contact the patient with the marked area at the same time. Failure to do so may result in an electric shock. - X-ray tube - Control console - Collimator - Handle bar on the tube stand - USB Port - LAN Port

3.4 ENVIRONMENT OF USE

OPERATING ENVIRONMENT

Ambient temperature range	10 °C to 35°C (50 °F to 95 °F)
Relative humidity range	30% to 75%, non-condensing
Atmospheric pressure range	800 hPa to 1060 hPa
Altitude Limit	This product is rated to operate at an altitude ≤3000m

TRANSPORT AND STORAGE

Ambient temperature range	-10 °C to 50 °C (14 °F to 122 °F).
Relative humidity range	35% to 75%, non-condensing.
Atmospheric pressure range	700 hPa to 1060 hPa

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4. SYSTEM OPERATION

- Operating principle and Mode

  - Exposure Mode

    The Exposure mode is a mode for X-ray exposure.

    When an electrode with a negative charge is heated with electricity, electrons are emitted and energy is generated.

  - Motorized Mode

    The column part of DIAMOND moves using a motor.

NOTE
Refer to the manuals of X-ray generator that accompany this unit for information on operating the X-ray generator.

WARNING
No foreign objects which can attenuate or scatter the X-ray beam are allowed between x-ray tube and tabletop during exposure. Failure to follow this may result in serious injury.

WARNING
The tube stand and patient table is intended to be used as part of a system for the intended generation of X-rays for diagnostic use. X-rays generate a potential risk for both patients and operators. For this reason, the application of X-rays for a given purpose must aim at the minimization of radiation exposure to any persons. Those persons responsible for the application must have the specific knowledge according to legal requirements and regulations and must establish safe exposure procedures for this kind of systems. Those persons responsible for the planning and installation of this equipment must observe the national regulations.

NOTE
If the booting of generator is not completed, the ***"DIAMOND"*** DR System will not work.

WARNING

Before control the positioning of radiographic, remove any obstacles including mobile patient table to prevent the collision by motorized moving. Failure to do so may result in injury to the patient or user. The radiographic stand has total seven safety sensors around its apparatus, but this may be insufficient to prevent the collision on some cases.

NOTE

The LCD screen on the ***"DIAMOND"*** DR stand is supplied electric power from X-ray generator after generator is booting up.

CAUTION

Be careful when handling the equipment as there is a risk of breakage.

CAUTION

If the exterior of the contact area is damaged, do not touch the damaged area (do not use it), contact the service engineer. Failure to do so may result in skin damage.

CAUTION

Be careful not to hit the corners of the ***"DIAMOND"*** DR stand. Otherwise, patient or user injury may result.

CAUTION

If the temperature of the tube exceeds a certain level, exposure is prohibited.

WARNING

Be careful if your fingers get caught in the following positions as it may cause injury.

- Detector and Grid insertion inlet
- Patient table accessory movement gap
- Stitching stand handle movement gap

NOTE

A communication buffer is applied to prevent loss of communication data. When pressing buttons, do not press them in quick succession. If it does not work normally, stop using the remote control and contact a service engineer.

4.1 PRE-PREPARE FOR OPERATION

For stable equipment operation, perform the following procedures before using the equipment every day. Refer to the maintenance section for detailed preparation methods.

What to Do	Who to Do It	Related Section
Daily X-ray tube warm-up procedure	Operator	5.1.1
Test of Emergency Stop Switch	Operator	5.1.2
Visually check in the appearance of the device	Operator	5.1.5
Checking the visible damaged of DAP	Operator	5.1.7

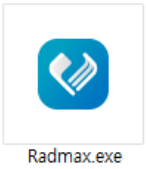
NOTE
Refer to the manuals of X-ray generator that accompany this unit for information on that part of the generator.

4.2 WORKFLOW OF SYSTEM

1. Turn on the monitor and Imaging Workstation.

2. Press ON of PC interface module to turn on the ***"DIAMOND"*** DR System.

3. Run the ***"RADMAX"*** imaging software.



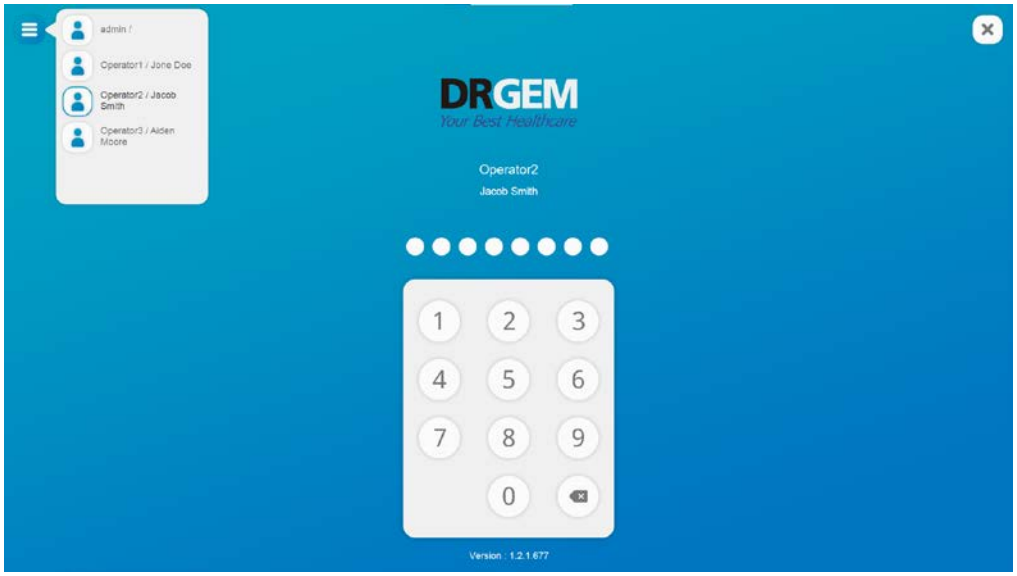
NOTE
DB is automatically backed up.

NOTE
Both RADMAX and the software provided by RADMAX are not run in duplicated. Also, if the license key is not recognized, it will not run.

4. Wait until generator and detector booting sequences are finished.

NOTE
The software version is displayed at the top of the boot gauge.

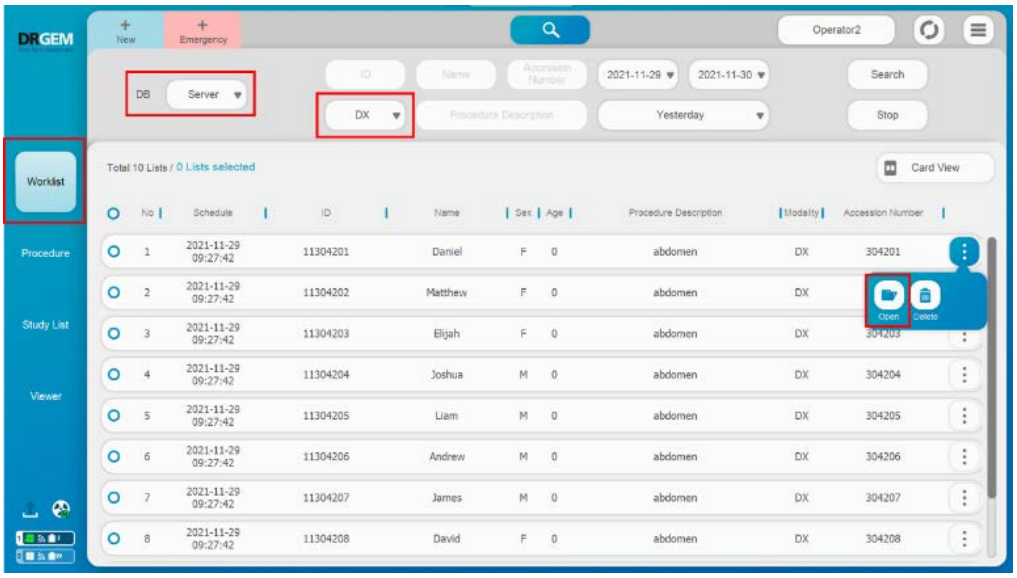
5. Select the account and Log on



6. Check the generator interlock and detector communication status.

7. Open the patient information.

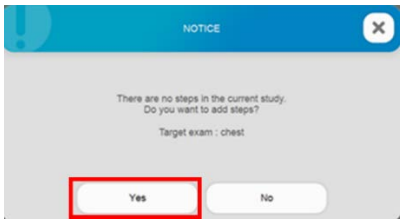
   1) Press WORKLIST to select the patient to be taken and press open. (Check DB and MODALITY) (Refer to the 4.4.3.1 Search)



NOTE

If RIS-CODE is not registered, Click **'Yes'** button on the Notice dialog to add new step for the procedure.

Please refer to the '4.4.4.1 Procedure List, 'Study More Menu' RIS-CODE' section.



   2) The user registers the patient. If patient information of the same patient ID is registered, all relevant studies are opened.
   (Refer to the '4.4.3.3 New' section.)

8. Set up the program and equipment according to the patient's examination method.
   If necessary, adjust control the X-ray condition. (Refer to the '4.4.4 Procedure' section.)

NOTE
In the case of pediatric, X-rays should not be examined under the same conditions as adults because they are highly sensitive to radiation and their cells divide very quickly. Images with high diagnostic value should be examined under minimal examination conditions. In order to minimize radiation exposure, the inspection must be performed considering various factors, such as not using a grid and using AEC as a necessity.

CAUTION
If there are foreign objects in the table top and bucky cover, use it after cleaning. Otherwise, there is a risk of retake or infection or equipment breakdown.

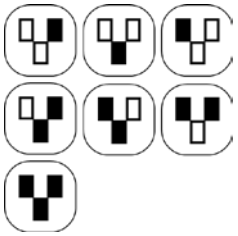
9. X-ray exposure conditions and sizes are determined according to the size and condition of the patient.
   Set the investigation condition value parameter or select the APR value.
   However, basic survey conditions are not provided for pediatric imaging. Refer to the pediatric X-ray recommended amount described in Section 1.1.6 and set the exposure condition value parameters according to the doctor's judgment.
   (Refer to Section 4.5.4 RADIOGRAPHY CONTROLS AND DISPLAY and 4.7.1 DIAMOND)

Body Size 4	Body Size 9

10. Set up the program and equipment according to the patient's examination method.
    If necessary, AEC and Grid can be additionally used.

    < When using AEC (optional)>

    1) When using AEC mode , select sensitivity and field



< When using Grid (optional)>

1) To use the Removable High Resolution Grid, put the Grid in bucky.

NOTE
In the case of pediatric, X-rays should not be examined under the same conditions as adults because they are highly sensitive to radiation and their cells divide very quickly. Images with high diagnostic value should be examined under minimal examination conditions. In order to minimize radiation exposure, the inspection must be performed considering various factors, such as not using a grid and using AEC as a necessity.

CAUTION
If there are foreign objects in the detector, use it after cleaning. Otherwise, there is a risk of retake or infection or equipment breakdown.

11. Select the bucky you want to examination in the Bucky selection & indicator.

Select button when examining at the detector.

Select button when examining at the other image receptor.

12. Set up additional filters. (R302 only)

Turn on the collimation lamp and confirm the x-ray field. Change the collimation size by manually.

<When using R302 additional filter (optional)>

For pediatric, an additional filter must be set

An optional additional filter (auto filter) makes it easy to replace the various filters.

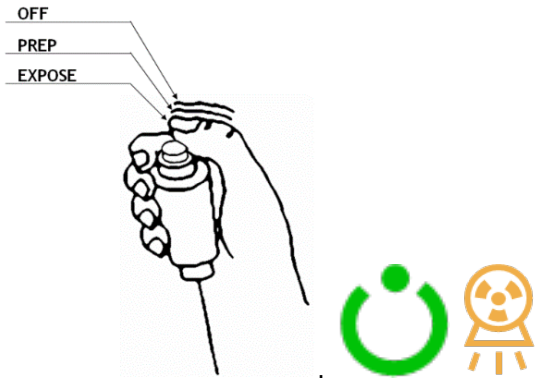
WARNING
Take extra care when imaging patients outside the normal adult size range (ex) pediatric). Use a collimator to keep the radiation field as small as possible without reducing the active measuring field. Failure to do so may result in unnecessary exposure to the patient, causing tissue damage

CAUTION
The temperature of the collimator will increase when it is used due to the operation of the lamp. According to Table 24 of the general IEC 60601-1 standard, contact with the collimator cover must be less than 1 minute for the operator and failure to comply may result in burns. Refer to the enclosed collimator manual to check the normal operating range of the collimator temperature.

13. Run the auto positioning or manually set the radiographic stand positioning.
    Place the patient table if required.
    (Refer to the section 4.7 Apparatus Operation)

CAUTION
Secure the table casters before the patient sits down. Otherwise, the patient may be injured.

14. Make the exposure. Press the **'Exposure hand switch'** halfway and keep it pressed halfway, the X-ray tube will enter the prep mode. When the X-ray tube is ready and the patient is in correct position, press the switch all the way to make the exposure.



WARNING
For pregnant or likely pregnant women, it is not recommended to take specific X-rays except in emergencies. Failure to do so may result in a possible mutation.

WARNING
For patients wearing pacemakers or radioactive implants, doctors should be careful before X-ray exposure. Use protective devices such as a copper sheet of 2.0 mm thickness for the implant area. Otherwise, the pacemaker may malfunction or cause cancer.

WARNING
Wear protective equipment if the scope of the X-ray includes the thyroid gland. Otherwise, it can cause thyroid microcancerous disease or tissue damage.

WARNING
Remove all radiopaque material from the radiographic field. Otherwise, an unacceptable image may be created and may need to be retaken.

WARNING
Have the patient take a fixed posture and do not let the patient touch parts unnecessarily. If the patient touches connectors or switches, it may result in electric shock or malfunction.

15. Adjust the contrast and density by dragging up, down, left and right with the right mouse on the acquired image after make the exposure

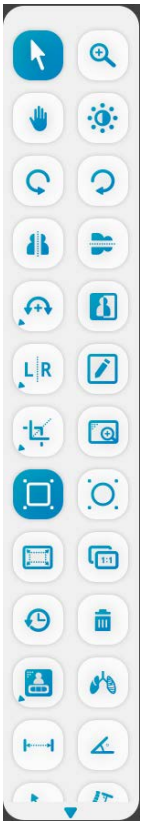
- Left-right drag: Contrast adjustment
- Top-down drag: Concentration adjustment

NOTE
Unselected detector do not acquire image even when exposed to X-ray.

NOTE
When using the Last Image Hold function, if you select STEP without an image, the Last Image is displayed.

NOTE
If image quality is not good, user must adjust image processing parameter.

16. You can change the marker on the image or adjust the ROI size using the tool box, and also the image direction change.

		Select ROI SIZE.
		Select the registered marker
		direction switching
		Return to the initial image
		Fine rotation

17. Make sure that the ROI and marker are correctly entered before image transmission.

CAUTION
Errors in diagnosis can occur if ROIs and markers are not entered correctly. Make sure ROIs and markers are correct before transfer.

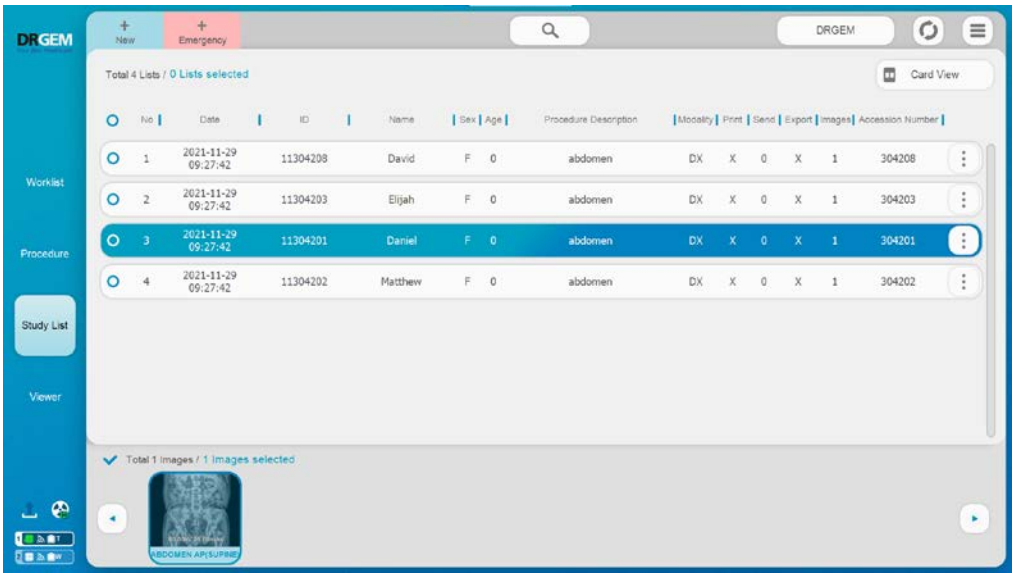
18. Press the send button to send the image to PACS.

NOTE
Please check the network status before sending the image to PACS. If necessary, connect to the in-hospital network via LAN line.

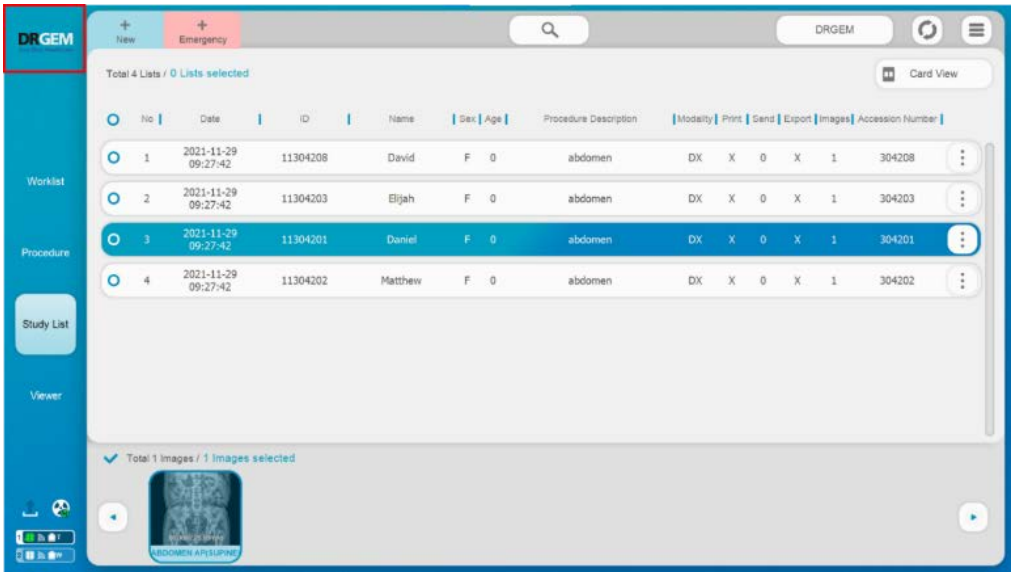
CAUTION
Do not expose X-ray while data transmission is running with LAN, DVD-player and USB memory stick. It may cause reason of false operation.

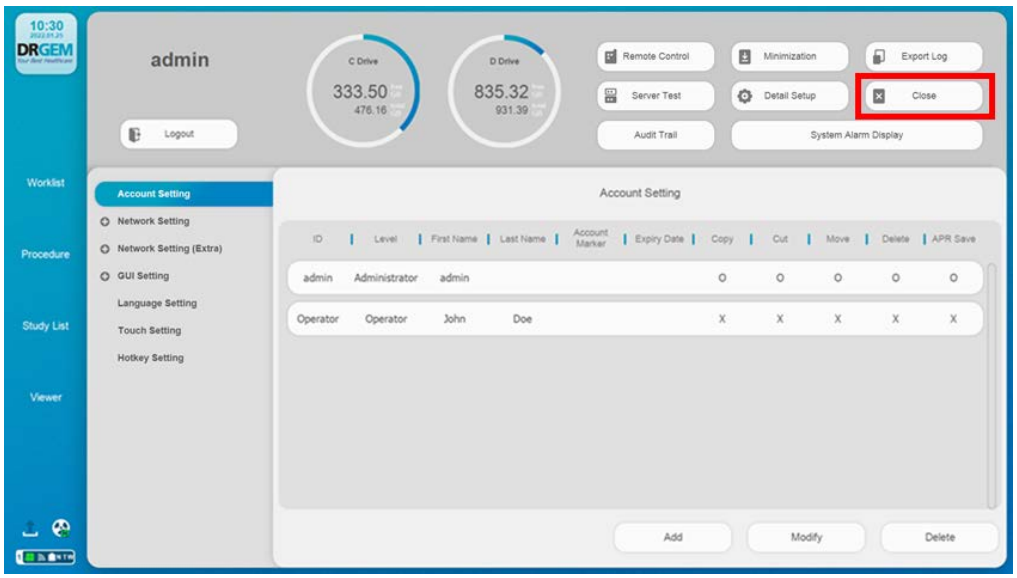
19. Recorded images can be checked in the STUDY LIST.

20. If additional tests are taken for a patient who has already been exposure, select the patient again and open to enter test mode.



21. When make the exposure is complete, click the DRGEM button in the upper left and click the exit button in the upper right to exit the ***"RADMAX"*** imaging software.





22. Press OFF of PC interface module to turn off the ***"DIAMOND"*** DR System.

23. Click on the **'Exit'** menu on the ***"RADMAX"*** imaging software.

24. Shutdown the Imaging Workstation.

4.3 FREQUENTLY OCCURRING MALFUNCTIONS

The following problems can be solved by simple confirmation.

Please contact the service engineer if the following does not solve the problem.

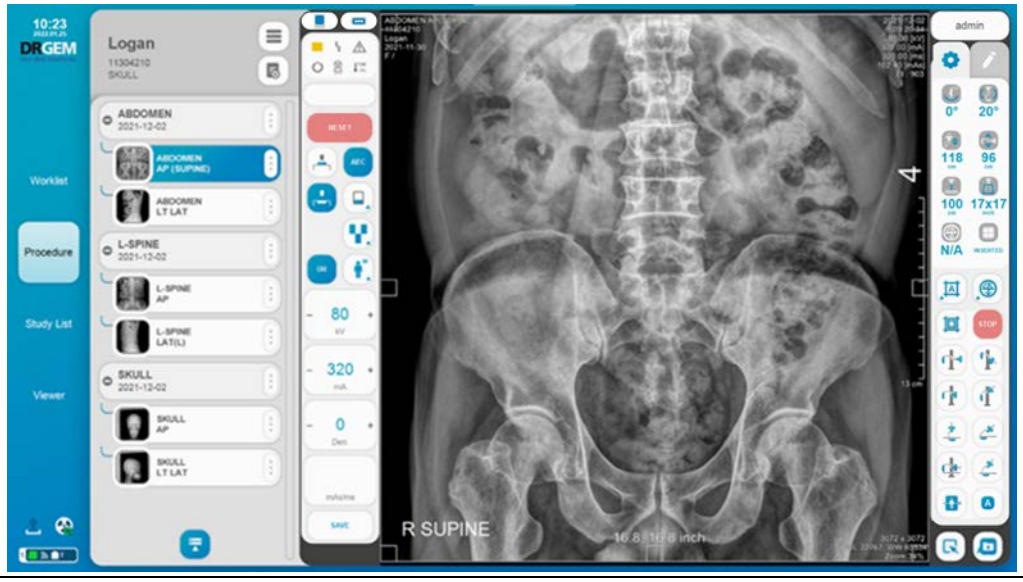
Problem	Possible Cause	Remedy
Device does not drive.	No power.	Check that the device is powered on.
	Emergency stop switch is pressed	Check the emergency stop switch is pressed.
	Detect foreign objects and objects	Remove the object recognized by the safety sensor.

4.4 RADMAX SOFTWARE

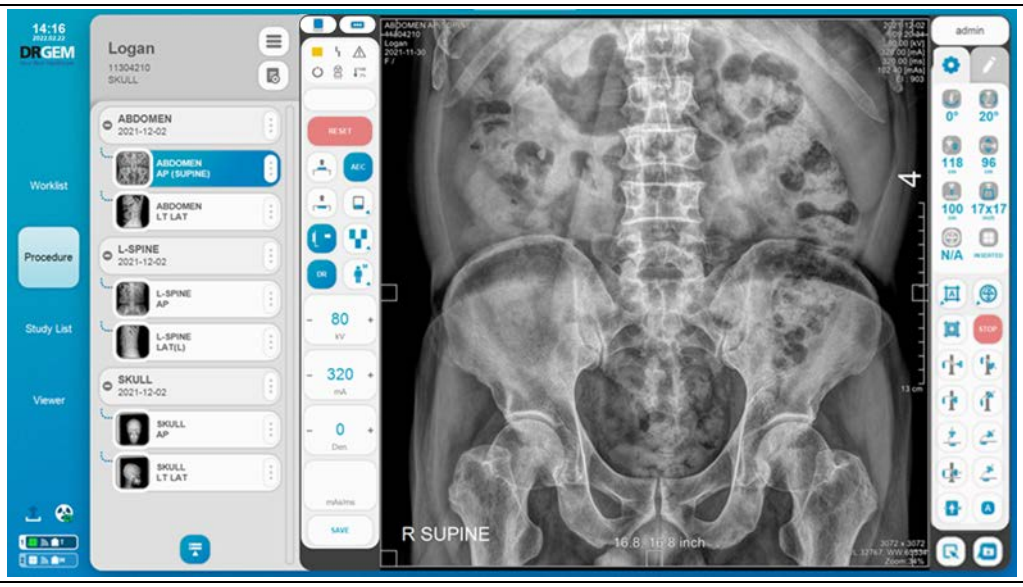
4.4.1 MAIN GUI

The ***"RADMAX"*** imaging software offers graphical user interface (GUI) like below. There are 4 main menus (Worklist, Procedure, Study List, Viewer) on the left side of the software.

The system control buttons and indicators in Procedure menu are depends on the model of X-ray system.



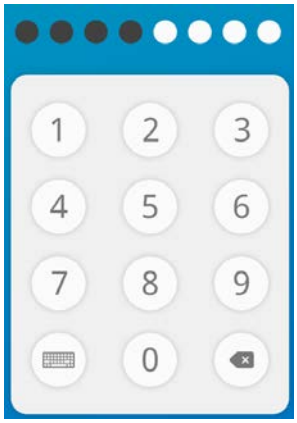
There are two types of GUI skin color (Blue and Dark mode). ***"RADMAX"*** imaging software will show differently by user selection. Please refer to the 'APPENDIX F5 Setting Page On RADMAX' for the GUI skin color setting.



<Blue Mode>

<Dark Mode>

4.4.1.1 LOGIN

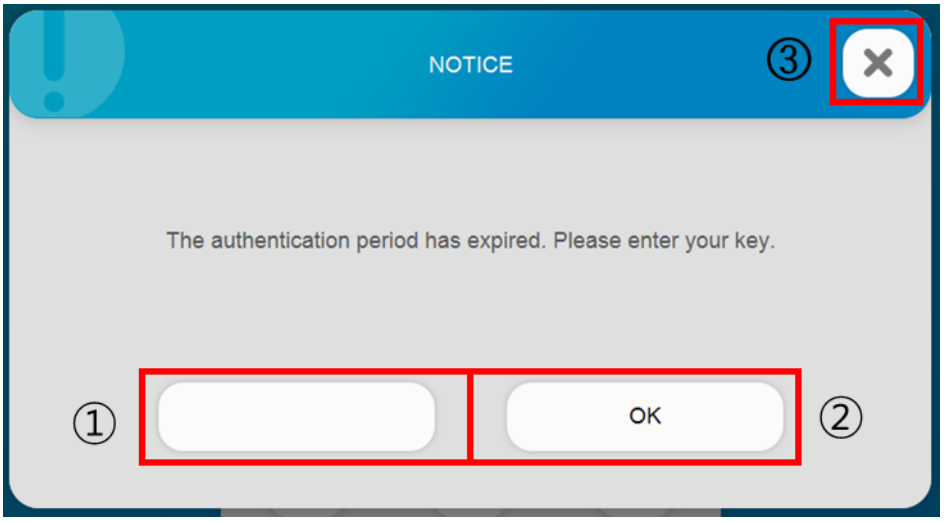
①	Collapsed Menu Button		Select User account.
②	Password keypad		Enter the password by using the keypad
③	Cancel		Terminate the program.
④	Expiry date		Displays the program expiration date.

NOTE
If it is not used for a certain period, it returns to the login screen.

NOTE
After installing the program, the default ID and password are ‘admin’. The account type for ‘admin’ is administrator. To register an account, please refer to the ‘APPENDIX F5. Setting Page On RADMAX’ section.

NOTE
The expiration date is displayed only when license expiration or period expiration are set.

- Enter the key if the period has expired.



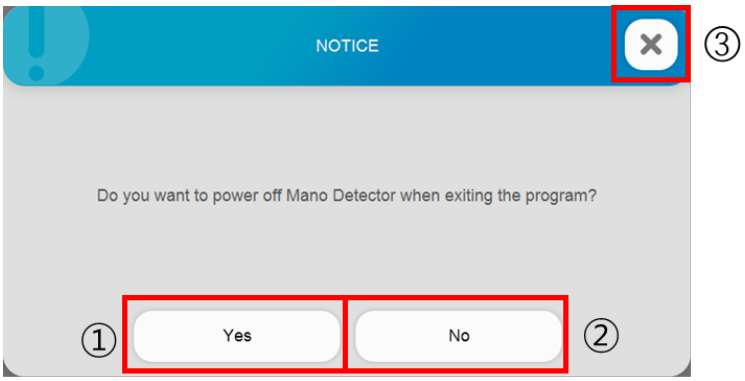
<Period Expiration Notification>

①	Edit		Enter the key to extend the period.
②	OK Button	OK	Register the key you entered.
③	Cancel Button	✕	Unregister the key.

NOTE
When the period expires, RADMAX is not available.

- When using the Mano detector, press the ✕ button.

In the case of Mano detector, ***"RADMAX"*** imaging software guides whether user would like to power off the Mano detector or not via the dialog message as shown below. When user exit the ***"RADMAX"*** imaging software and user forget to turn the power off of the detector, after then by continuously exhausting the battery, the battery life can be shortened.

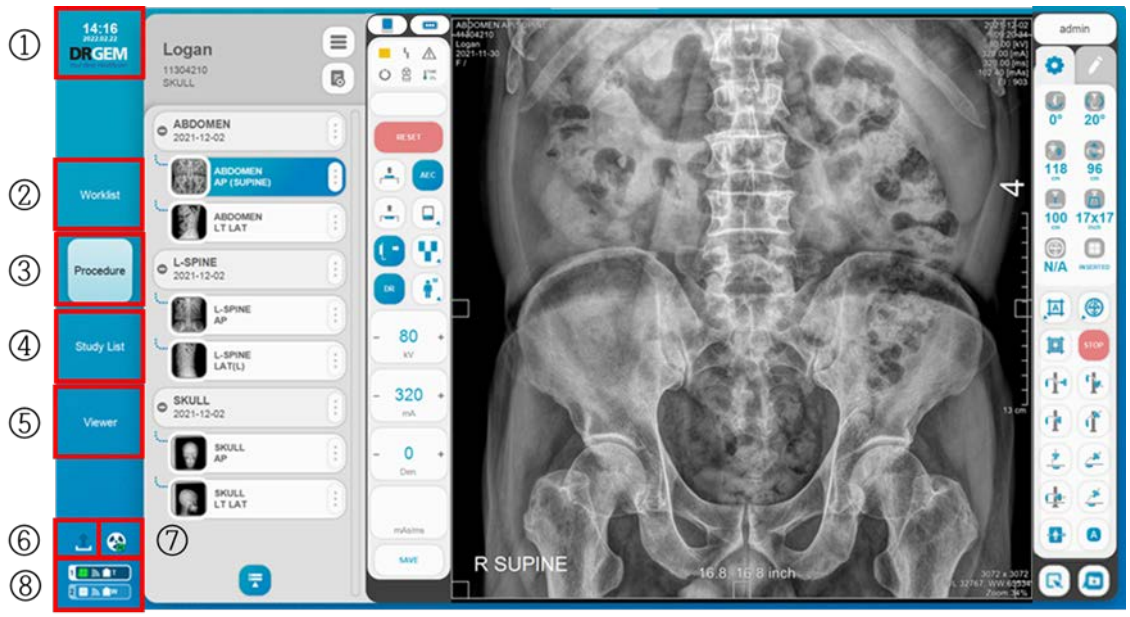


<Detector Power Off Notification>

①	Yes Button	Yes	***"RADMAX"*** imaging software waits until it receives a signal that the detector power is off. When the imaging software receives a signal, be closed.
②	No Button	No	***"RADMAX"*** imaging software is immediately closed.
③	Cancel Button	✕	Exiting the ***"RADMAX"*** imaging software is canceled.

NOTE
To use this function, please refer to the '4.3.9.2 Optional Function Setting' section in the ***"DIAMOND"*** Service Manual.

4.4.1.2 MAIN MENU



①	DRGEM Logo (Dashboard / Admin Menu)	17:36 2022.04.04 DRGEM Your Best Healthcare	Offer Admin Menu for quickly accessing frequently used functions. (Support Essential or Simple Settings for Operators and Directly modify and apply immediately)
②	Worklist	Worklist	Offer patient and study registration from PACS (worklist server) or Manual.
③	Procedure	Procedure	Offer exposure conditions, X-Ray System control menu and submenus. Also, offer interface for APR (Anatomic Programming Radiographic) selection, GXR X-Ray generator, thumbnail window, image processing menu and etc.
④	Study List	Study List	Offer patient management menu, deletion study, sending study image, exporting study image and etc.
⑤	Viewer	Viewer	Offer various Image manipulation functions.
⑥	DICOM Network Sending Indicator		Normal

			DICOM transmission is in progress
			Warning Indicator
⑦	Generator Status Indicator		Normal.
			Disconnection.
⑧	Detector Selection Indicator		Indicate the selected detector with number. When the detector is ready, it is displayed in a blue-black area on a white background.

NOTE
DICOM Network Sending Indicator also works as a **'DICOM Queue'** button. Please refer to 'APPENDIX P. DICOM QUEUE' Section for more detail information.

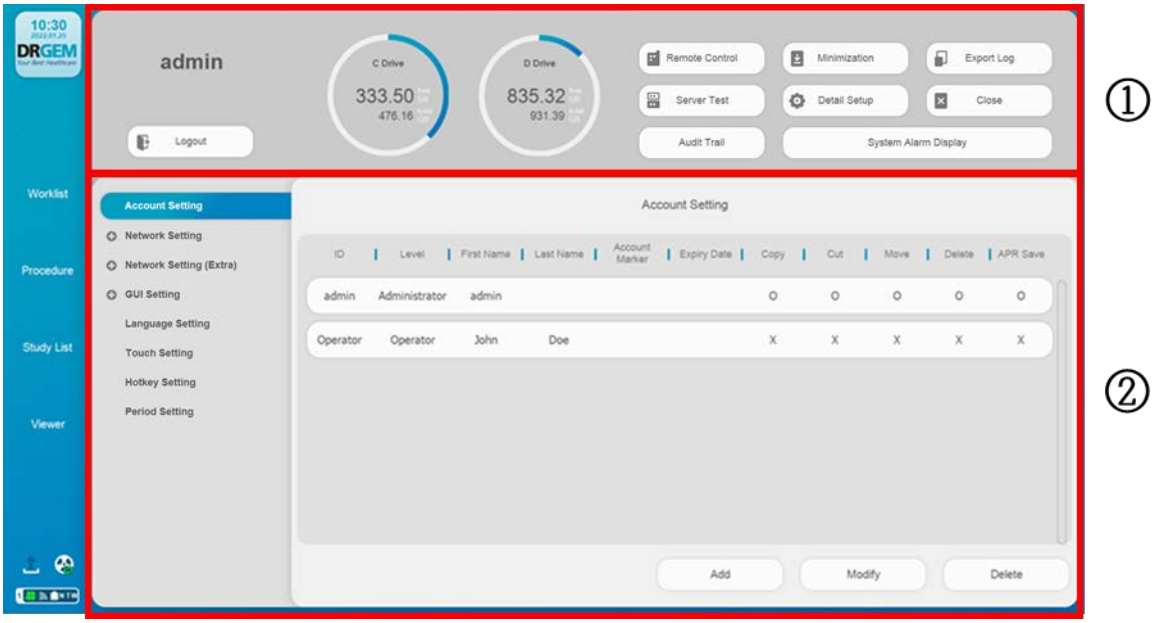
- Detector Selection Indicator

①	Detector Status Indicator		Standby
			Busy in Detector
			Disconnection
			Connected (Ready)
②	Detector Wireless Status & Tether Cable Indicator		Wireless signal is very bad or Unable to connect.
			Wireless signal strength is bad.
			Wireless signal strength is normal.
			Wireless signal strength is good.
			Wireless signal strength is very good.
			Tether Cable is connected.
③	Detector Battery Status Indicator		Unknown
			Unable to check the battery status 1 ~ 5%
			6 ~ 10%
			11 ~ 40%
			41 ~ 70%

			71 ~ 90%
			91 ~ 100%
	Detector Battery Status Indicator (Charging)		1 ~ 5%
			6 ~ 10%
			11 ~ 40%
			41 ~ 70%
			71 ~ 90%
			91 ~ 100%
④	Detector Bucky Status Indicator		Non-Bucky
			Bucky

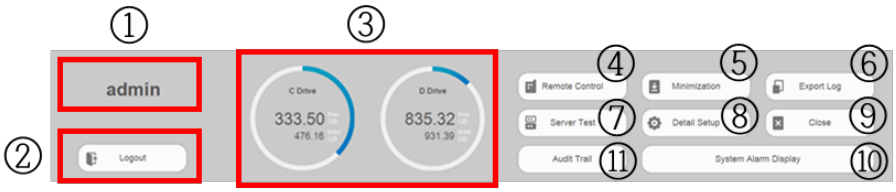
4.4.2 ADMIN MENU

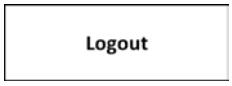
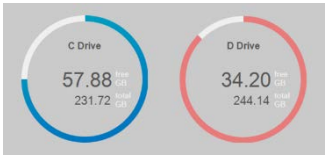
Admin Menu provide software information, setting and utility functions.



①	Dashboard Menu	Display the software information, and select the utility functions.
②	Setting Menu	Configure the ***"RADMAX"*** imaging software. Please refer to 'APPENDIX F5. Setting Page On RADMAX' Section for more detail information.

- Dashboard Menu



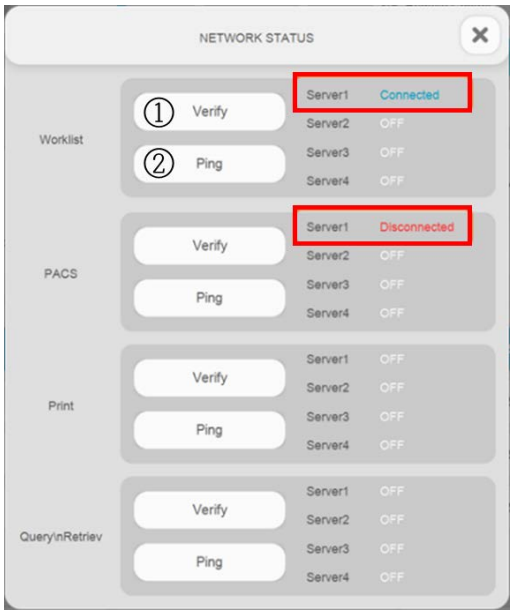
①	User Account		Display the user account ID and name.
②	Logout Button		Click **'Yes'** button on the Notice dialog, your account is logged out and the screen is moved to the Login menu automatically.
③	HDD(or SSD) Status		Display the hard disk (or SSD) storage status of current workstation. If workstation has only C Drive storage, D drive status is not displayed. - Unit: Giga-byte (GB) - Color ■ Red: insufficient storage space ■ Blue: sufficient storage space
④	Remote Control Button		Click **'Yes'** button on the Notice dialog, execute the remote control service software (Team Viewer).

⑤	Minimization Button	Minimization	Minimize ***"RADMAX"*** imaging software and show desktop window or Screen Locker.
⑥	Export Log Button	Export Log	Make compressed a log file that corresponding recently 1 month.
⑦	Server Test Button	Server Test	Display the NETWORK STATUS dialog.
⑧	Detail Setup Button	Detail Setup	Execute the configuration software for detail settings. Please refer to the 'APPENDIX F. Configuration Software' section for more information.
⑨	Close Button	Close	Click **'Yes'** button on the Notice dialog, terminate ***"RADMAX"*** imaging software.
⑩	System Alarm Display Button	System Alarm Display	Check the system warning and error information.
⑪	Audit Trail Button	Audit Trail	Check the user's activity history.

NOTE
The following functions are available only in the Administrator account type. - **'Minimization'**, **'Close', 'System Alarm Display'** and **'Audit Trail'** function

1) NETWORK STATUS dialog

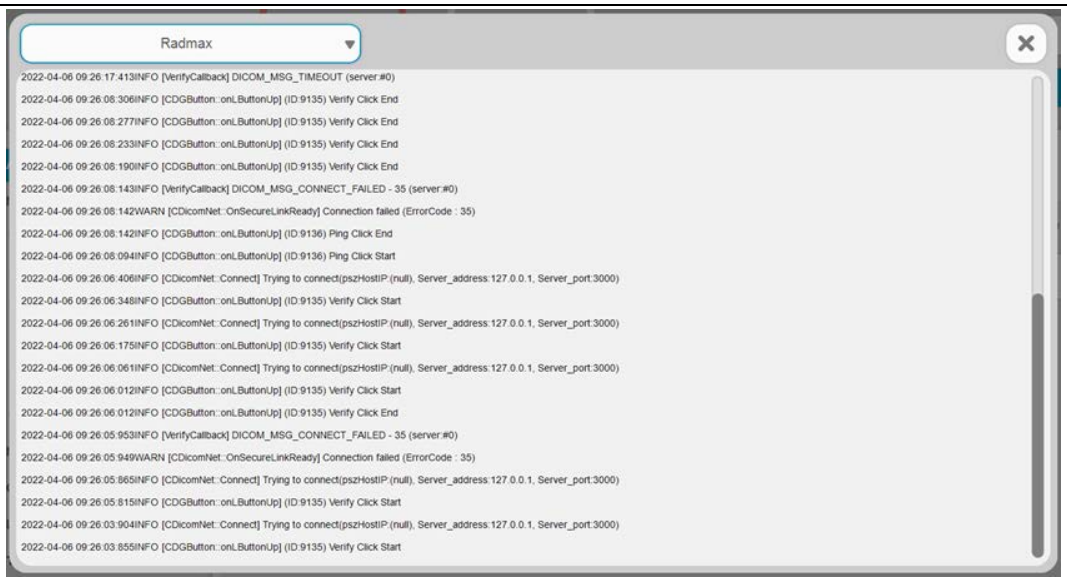
Press the **'Server Test'** button, display the NETWORK STATUS dialog.



①	Verify Button	**Verify**	Check the network status of DICOM communication via - Display 'Connected' in blue. - Display 'Disconnected' in red.
②	Ping Button	**Ping**	Check network condition. - Success: Display the data response time. - Fail: Display 'Not responding'.

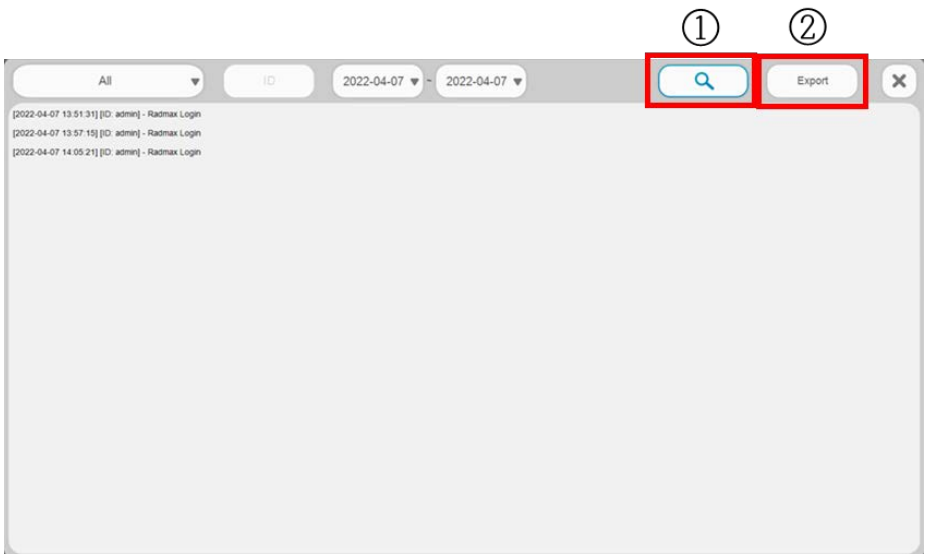
2) System Warning and Error Information

Press the **'System Alarm Display'** button, display the system warning and error information.



3) Audit Trail

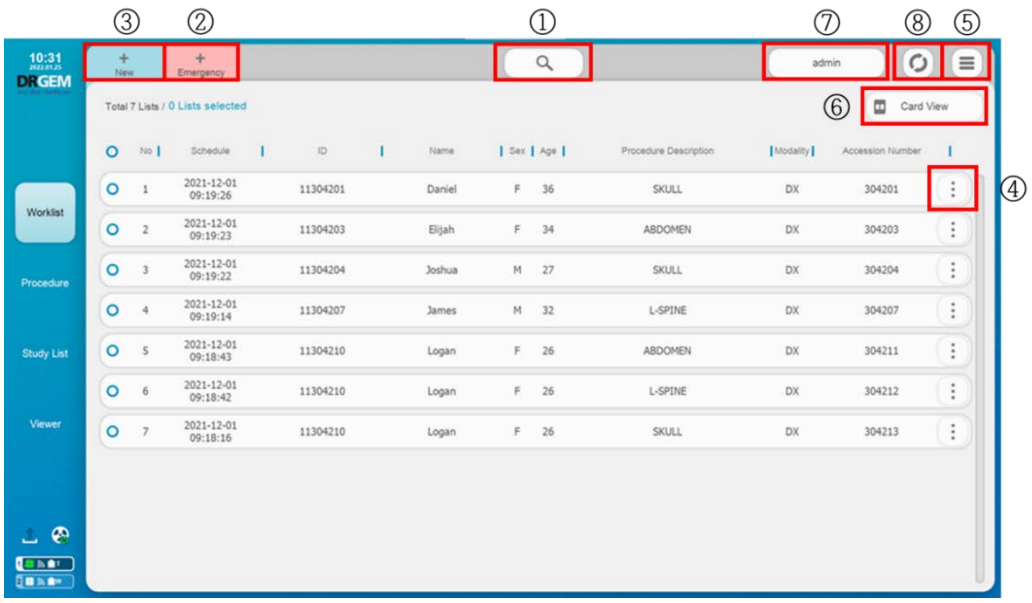
Press the **'Audit Trail'** button, display the user's activity history.



①	Search Button		Search for a user's login, logout, create, open, edit, delete, acquire, transfer, export, print, copy, move, cut activity history.
②	Export Button		View the discovered activity history as a TXT file

4.4.3 WORKLIST

Worklist menu offers patient registration from worklist server (PACS) or Manual.

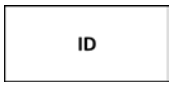
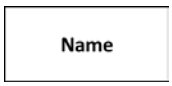
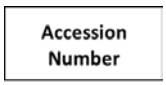
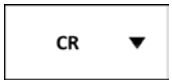
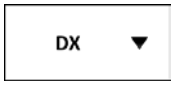
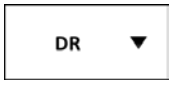
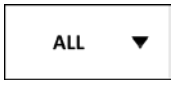
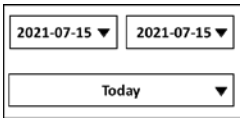


①	Search (Query From Worklist Server) Button		Display the hidden search area.
②	Emergency Button	+ Emergency	Use to register patient information urgently.
③	New Button	+ New	Register new study for exam manually.
④	More Button		Display the **'Open'**, **'Modify'** and **'Delete'** button.
⑤	Collapsed Menu Button		Display the **'Delete'** button.
⑥	Card View Button	Card View	Display the Card view mode of worklist
	List View Button	List View	Display the List view mode of worklist
⑦	Admin ID Button (Quick Login)	admin	Display Administrator list and quick login.
⑧	Refresh Button		Search again with current search condition.

4.4.3.1 SEARCH (QUERY FROM WORKLIST SERVER)

Click ‘ ’ button to display the hidden search area.

The search area has 8 search filters like below.

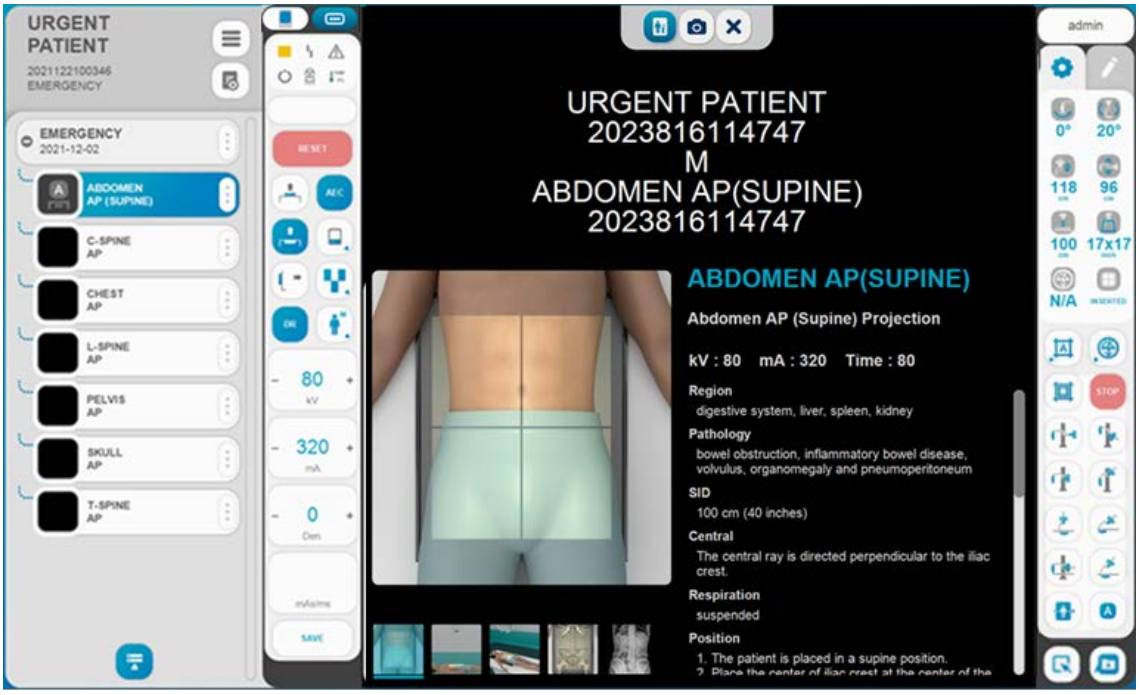
①	DB Filter		Display the worklists from server.
			Display the manually registered worklist from local DB
②	Editor Filter		Apply the Patient ID in search condition.
			Apply the Name in search condition.
			Apply the Access Number in search condition.
			Apply the Procedure Description in search condition.
③	Modality Filter		Apply the modality information in search condition as CR.
			Apply the modality information in search condition as DX.
			Apply the modality information in search condition as DR.
			Apply the modality information in search condition as All.
④	Schedule (Time/Data) Filter		Apply the Schedule (Time/Date) information in search condition.
⑤	Search Button		Search (Perform the query) from the worklist server with the search condition.

⑥	Stop Button	Stop	Stop worklist searching. If operator wants to re-query or there are too many worklist items to get, it is needed to stop searching.

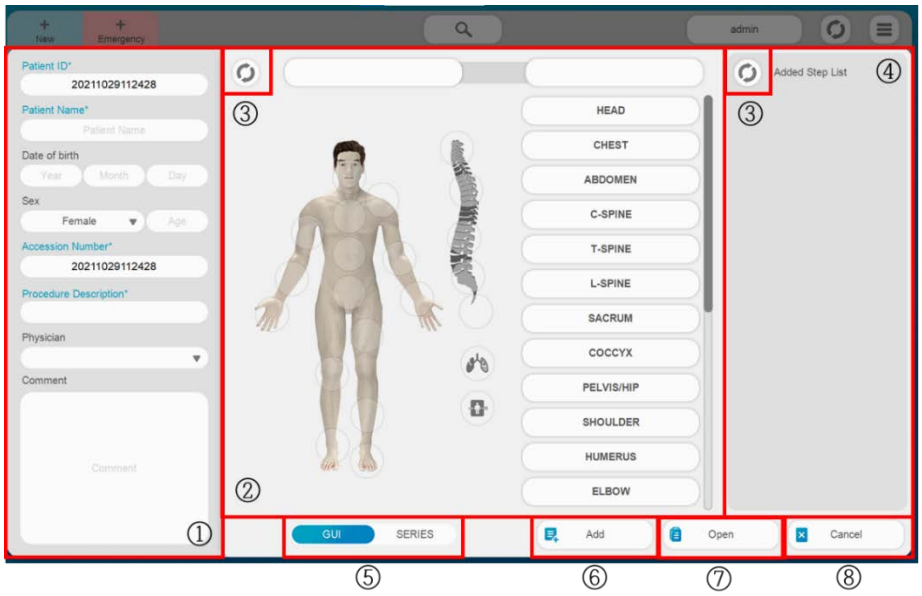
4.4.3.2 EMERGENCY

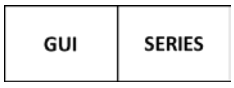
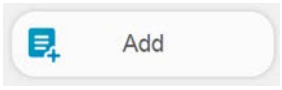
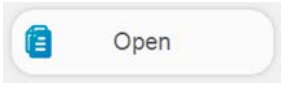
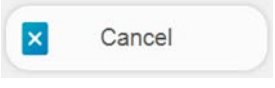
If there is no time to register patient information through Worklist or Study List menu, use the ‘ Emergency ’ button.

New study for emergency is registered and the current menu is moved to Procedure menu automatically.



4.4.3.3 NEW



①	Patient Information	-	Enter the patient information on required input field (*: asterisk)
②	Body part on the GUI	-	Select the procedure steps via selecting the graphical user APR (Anatomic Programming Radiography).
③	Refresh Button		Go to the previous step or remove all procedure steps of Added Step List.
④	Added Step List	-	Display the Added Step List.
⑤	GUI / Series		Select the **'GUI type'** and **'Series type'** procedure mode.
⑥	Add Button		The entered patient information is registered in the Worklist menu.
⑦	Open Button		The entered patient information is registered in the Worklist and move on the Procedure Menu automatically.
⑧	Cancel Button		Cancel patient registration.

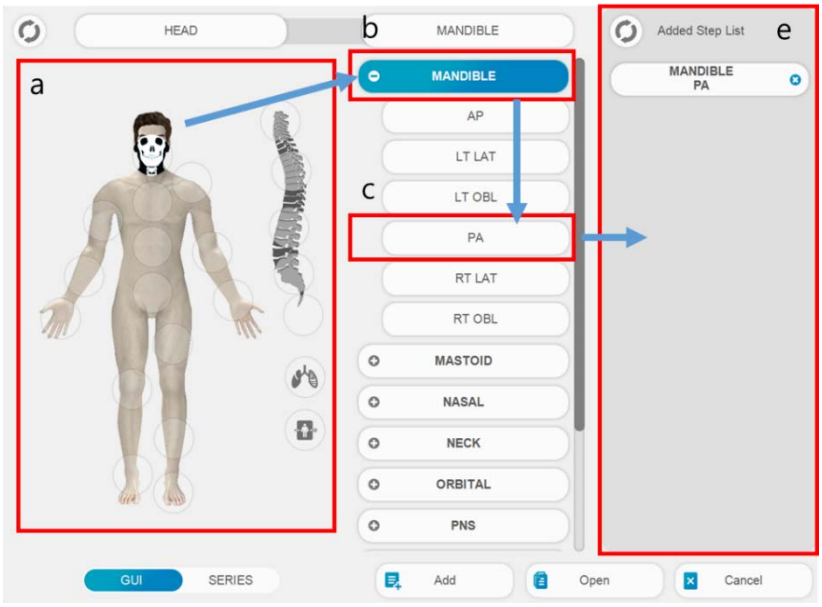
NOTE

The Required input field (*: asterisk) is that operator must enter information. If operator attempts to process without entering the required information, the message dialog will showes up.

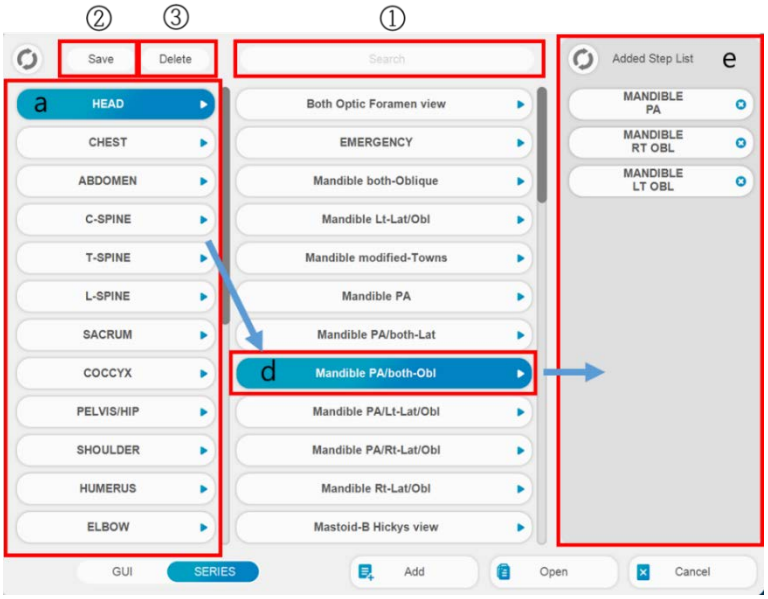
NOTE

Age is calculated automatically when operator enter the date of birth.

- GUI / Series Type procedure mode & Added Step List



<GUI type>



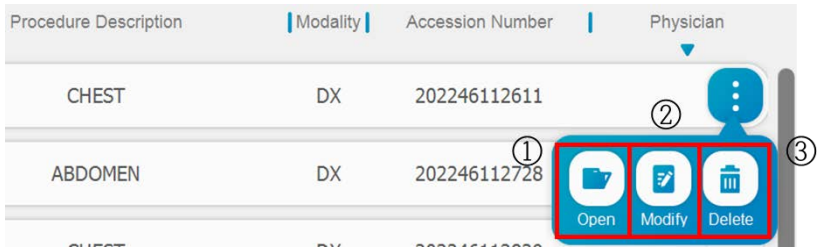
<Series type>

①	Search Edit Box	Search	Search the Series procedure information via.
②	Save Button	Save	Click **'Yes'** button on the Notice dialog, save matched Series procedure in new Exam item.
③	Delete Button	Delete	Delete the series

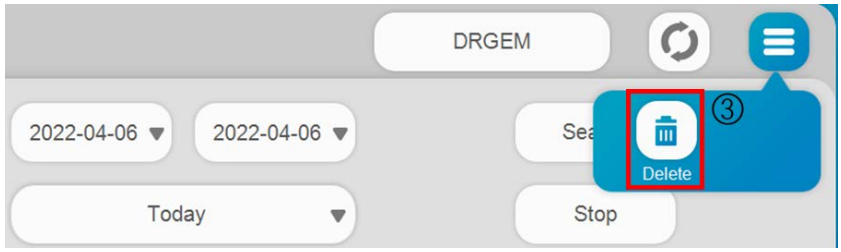
1. Select the GUI type procedure mode.
   a) Select the Body part on the GUI (a)
   b) Select the examination. (b)
   c) Select the procedure steps (c)
   d) Display the selected procedure steps on Added Step List. (d)

2. Select the Series type procedure mode.
   a) Select the Body part. (a)
   b) Select the Series procedure steps. (d)
   c) Display the selected Series procedure steps on Added Step List. (e)

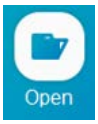
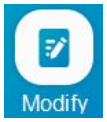
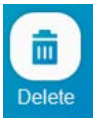
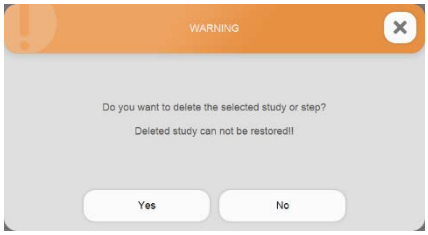
4.4.3.4 OPEN & MODIFY & DELETE



<More Button>



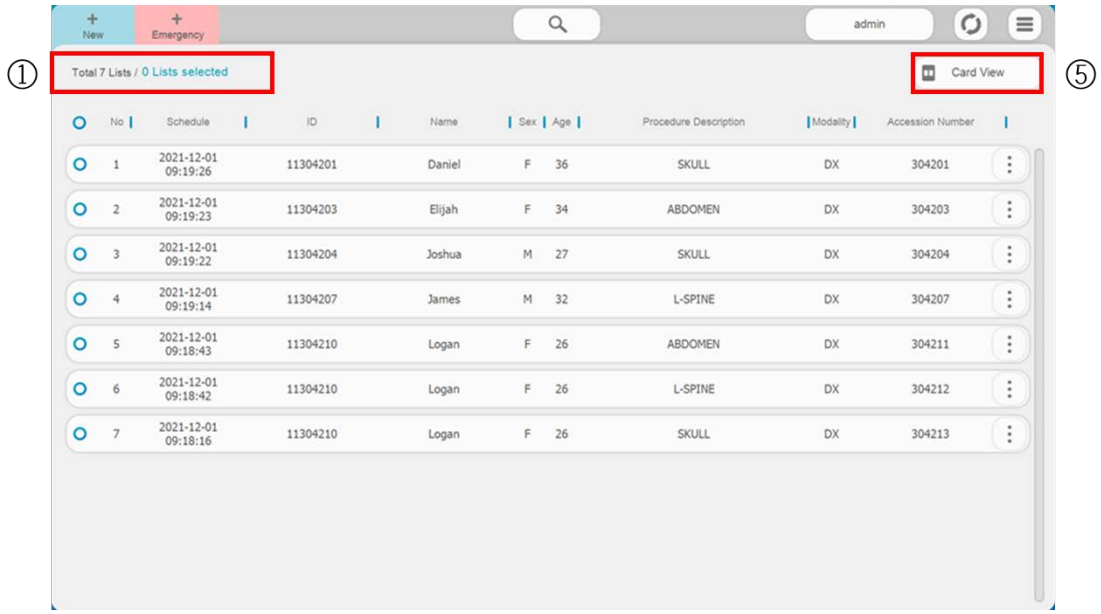
<Collapsed Menu button>

①	Open Button		Register the selected study into Database and open the study in Procedure menu for X-ray exposure. Double clicking the each list of Worklist is exactly same action.
②	Modify Button		Open the window to modify the selected worklist. (Only when local DB is selected)
③	Delete Button		Click **'Yes'** button on the Notice dialog, and delete the selected worklist. 

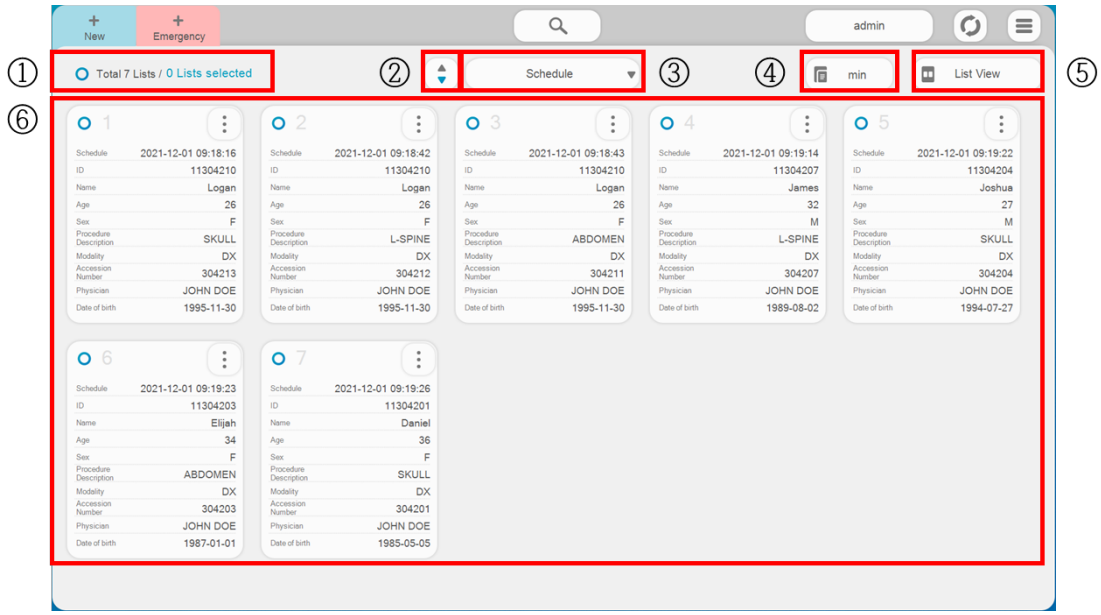
NOTE
If there are same patient studies on the Worklist currently searched, it will be opened together.

NOTE
You must log in as the Administrator account type to use Delete function.

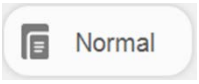
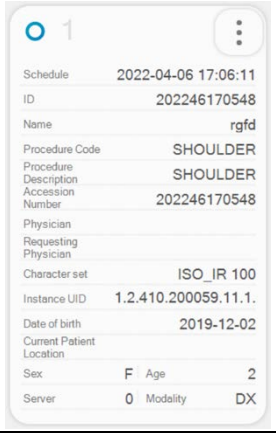
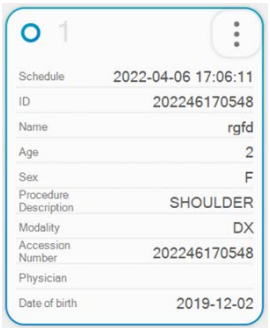
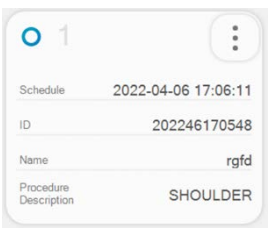
4.4.3.5 LIST VIEW AND CARD VIEW



<List View>

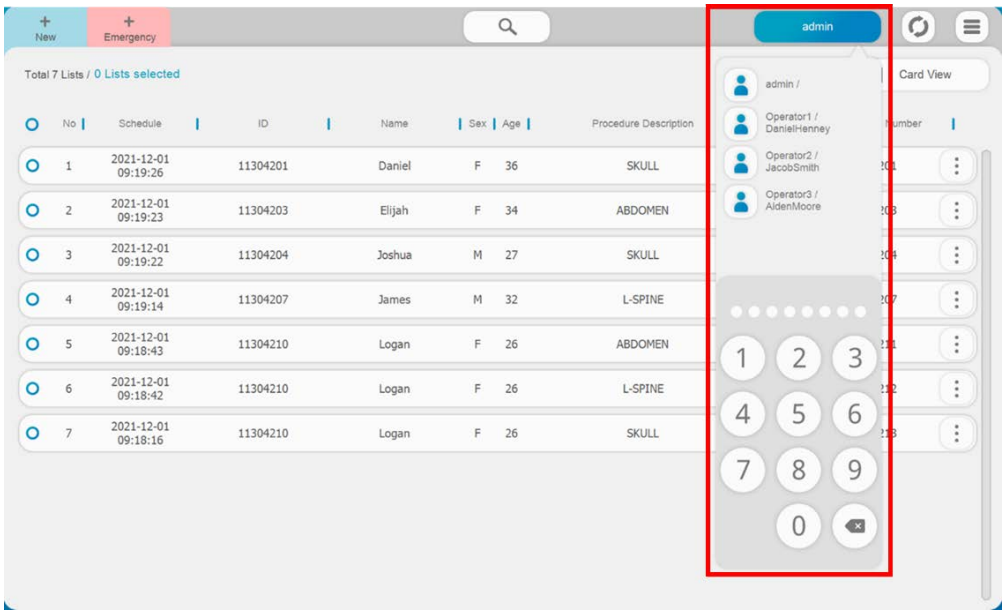


<Card View>

①			Show the total number of lists and the number of selected lists.
②	Ascending or descending sort		Sort in descending or ascending order for the selected filter.
③	Filter		Select the filter to sort in descending or ascending.
④	Normal Mode		Select the normal mode of card view mode.
	Min Mode		Select the min mode of card view mode.
	Max Mode		Select the max mode of card view mode.
⑤	Card View Button		Display the Card view mode of worklist
	List View Button		Display the List view mode of worklist
⑥	Card View Mode		Display the max mode of card view mode.
			Display the normal mode of card view mode.
			Display the min mode of card view mode.

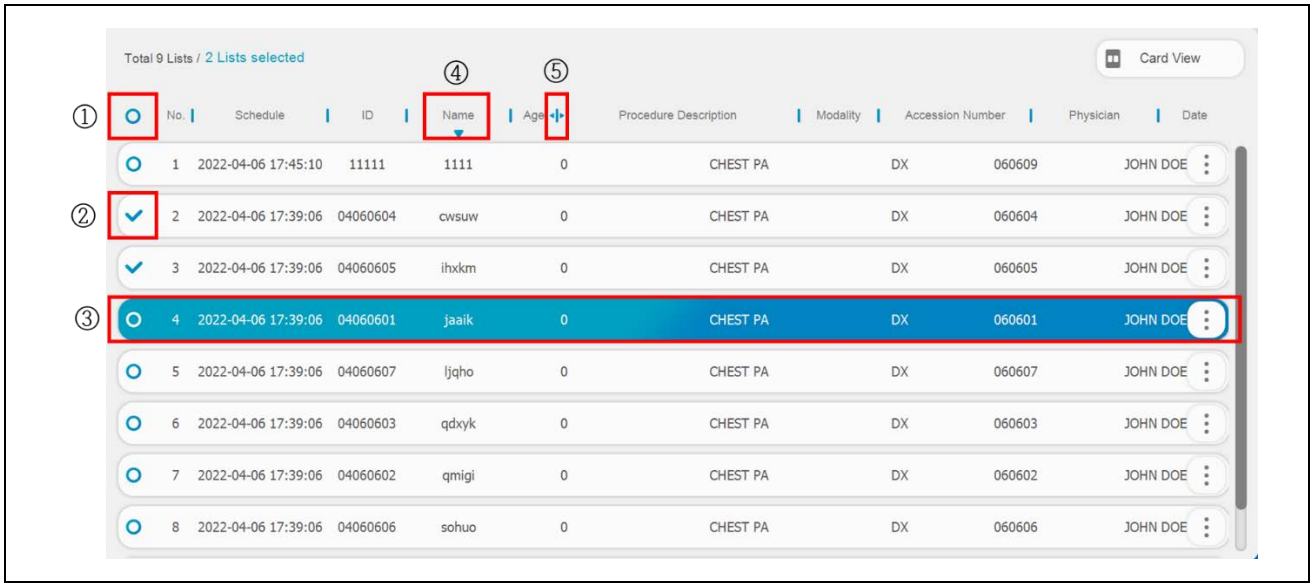
4.4.3.6 QUICK LOGIN

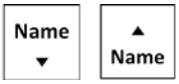
Click ‘ admin ’ button to see Administrator list and quick login. User can login their own account ID with this quick login screen. There are same button and function on Procedure menu, Study List, Viewer panel for quick login function.



4.4.3.7 ADJUST LIST

The following functions are commonly used in Worklists and Study Lists.

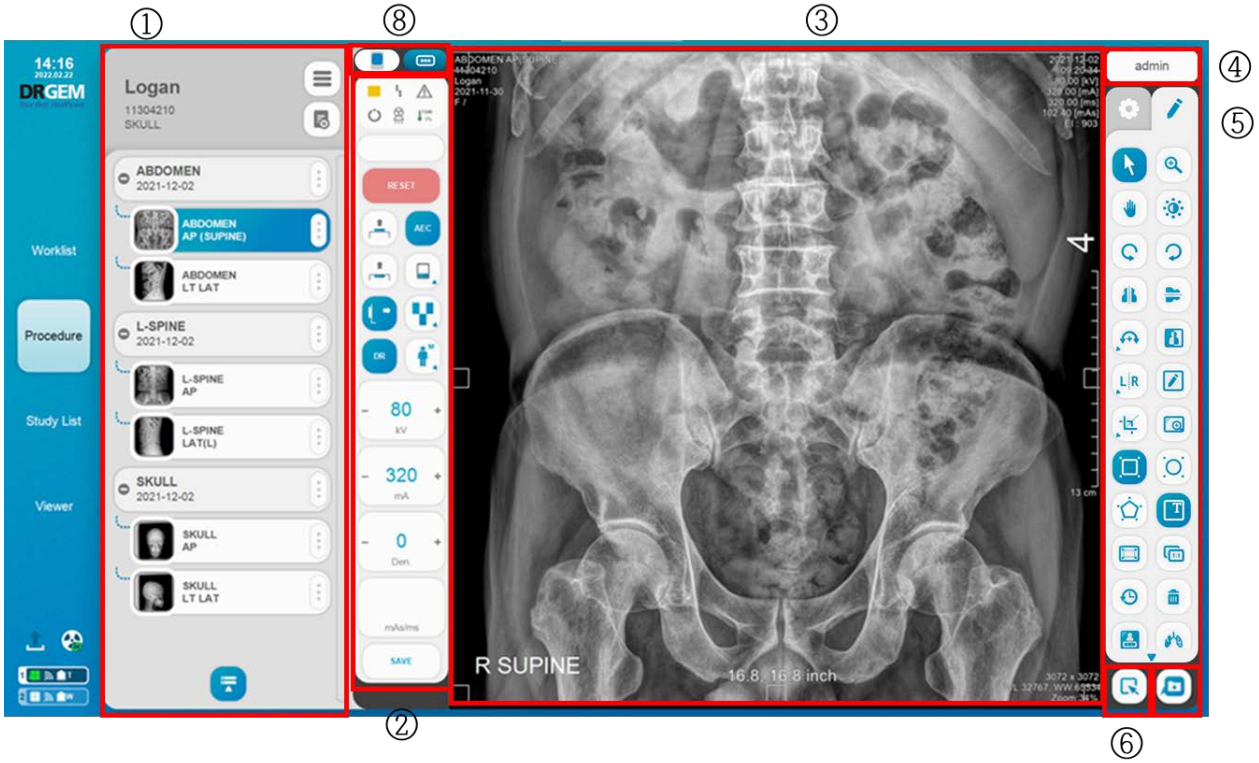


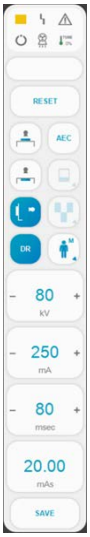
①	Select All Button	-	Select all lists or studies about current searched list.
②	Selection Check Box	-	Click the selection check box in left side of each Worklist or Study List items. The number of currently selected lists is displayed on the upper side of Worklist or Study List.
③	Selection	-	Click single list of Worklist or Study List menu, and then background color of selected list item is changed.
④	Sort Of Worklist		Sort in descending or ascending order for the selected filter.
⑤	Column Resize		Readjust column width via clicking and dragging the column border line.

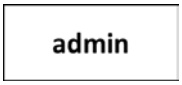
4.4.4 PROCEDURE

This menu is used to acquire X-ray image from detector and apply the image processing with image.

This menu offers X-Ray System control menu, submenus, interface for APR selection, GXR X-Ray generator control menu and etc.



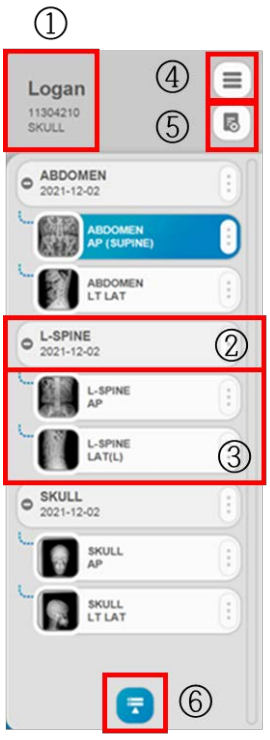
①	Procedure list		Patient Information. Study Information. Step Information.
②	X-Ray Control GUI		Offer the x-ray control GUI for x-ray parameter control and various status displays.

③	Image Viewing		Display the Image viewing area.
④	Admin ID button (Quick Login)		Display Administrator list and quick login.
⑤	Toolbox		Offer the image edit functions.
	System Control		Check the condition of the device and offer the operation control functions.
⑥	Image Full Mode		Enlarge the acquired image.
⑦	Built-In Memory Screen		Enter the built-in memory screen. Please refer to the ‘APPENDIX J. Built-In Memory’ Section for more information.
⑧	Widget		A small window will appear, allowing you to use additional functions.
			A full screen window will appear, allowing you to use additional functions.

NOTE
When you click on the **'Widget'** icon, it provides the following three additional functions. 1) APR Positioning Guide (Please refer to the 'APPENDIX M. APR Positioning Guide' section.) 2) Live Streaming (Please refer to the '4.4.4.7 Live Streaming' Section for more information.)

NOTE
To use 'Same Patient APR Info Display' function, please refer to the 'APPENDIX Q. SAME PATIENT APR INFO DISPLAY' section

4.4.4.1 PROCEDURE LIST

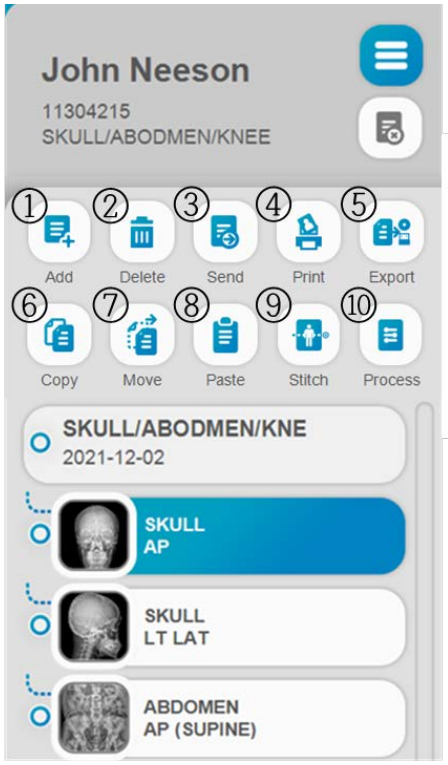


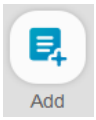
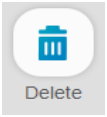
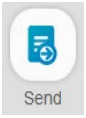
①	Patient Information.		Display the patient information.
②	Study Information.		Display the study information and select functions through **'Study More Menu'** button.

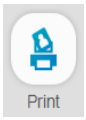
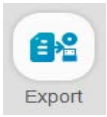
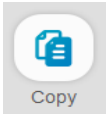
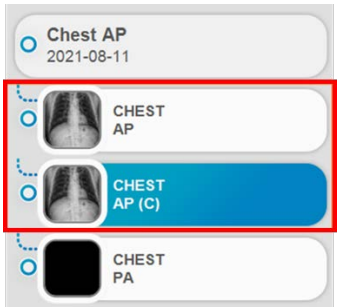
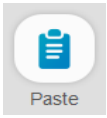
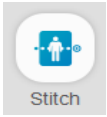
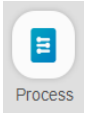
③	Step Information.		Display the step information and select functions through **'Step More Menu'** button.
④	Collapsed Menu Button		Display the hidden menu on Procedure list and the check box on study and step information. If click this menu again, menus and check boxes are disappeared.
⑤	Close Button		Close Procedure mode and move to Study List menu.
⑥	All Spread Button		Fold all steps in studies.
			Open all steps in studies.

- Procedure Collapsed Menu

Those buttons are only work with checked (Checkbox) steps.



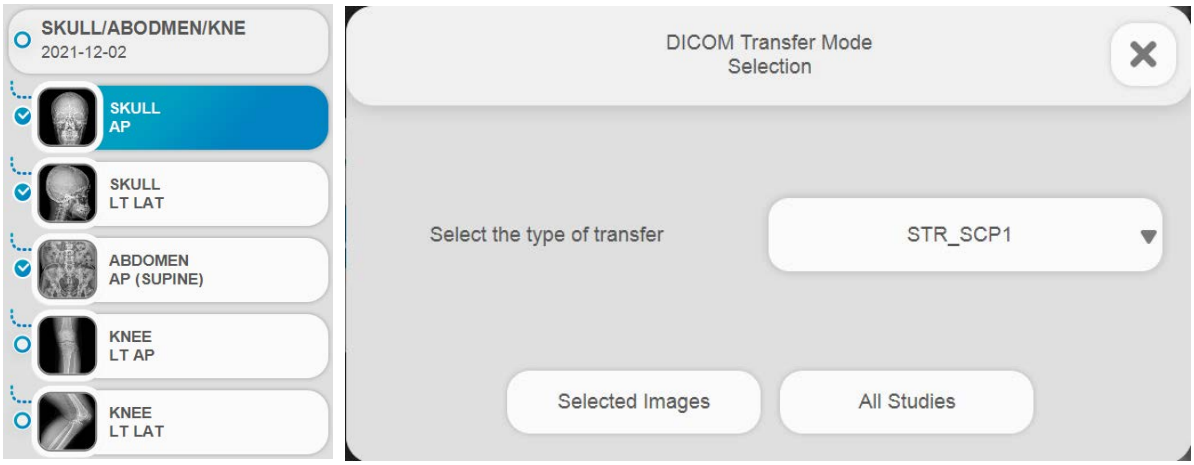
①	Add Button		Add new step in current opened study.
②	Delete Button		Click **'Yes'** button on the Notice dialog, and delete the selected steps.
	Reject Button		When the Reject Function Setting is on, **'Reject'** button is display instead **'Delete'** button. Reject the checked steps.
③	Send Button		Send study images to the available PACS server.

④	Print Button		DICOM Print dialog showing currently selected step images is displayed. Please refer to the '4.4.4.4 DICOM Print' Section for more information.
⑤	Export Button		Export selected step image(s) to the external HDD, USB or CD Drive. (Support BMP, JPG, PNG, DCM).
⑥	Copy Button		In current opened study, copy selected step image(s) and information. The copied step description has '(C)' text for differentiation between original step and copied step. 
⑦	Move Button		Select the image to move.
⑧	Paste Button		Click **'Yes'** button on the Notice dialog, and move selected step image(s) to another study.
⑨	Stitch Button		Combine multiple images and make a stitching image. Please refer to the '4.4.4.6 Image Stitch' Section for more information
⑩	Process Button		Tune and perform image processing of X-ray image. Please refer to the '4.4.4.5 Image Processing' Section for more information

1. Send

   Click check box(es) of step(s), and then click **'Send'** button to send image(s) to PACS server.

   Select target server, and then choice 'Selected images' or 'All studies' on dialog window.



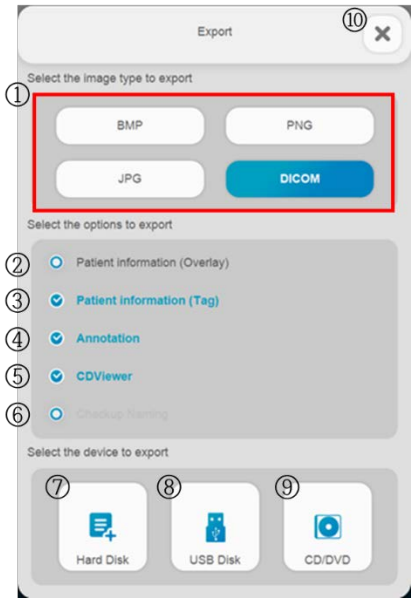
After then, ***"RADMAX"*** imaging software sends selected image(s) to PACS server.

During the DICOM sending process, DICOM Network Sending Indicator and Step Information's border are noticing (changing icon) until it is over.

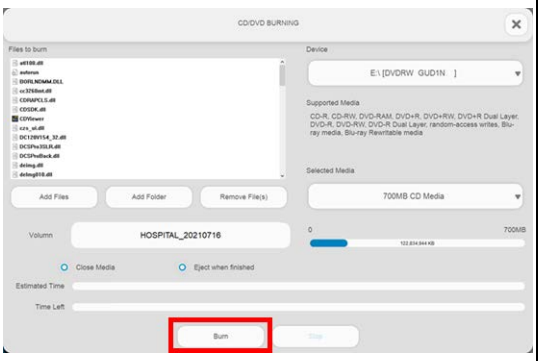
DICOM Network Sending Indicator		Normal
		DICOM transmission is in progress
		Warning Indicator
Step Information		White: Before sending image(s)
		Yellow: Sending Blue: Sending Success Gray: Sending Failed.

2. Export

   Select check box on the Study List or thumbnail window. After then click '**Export'** button and select **'Hard Disk'**, **'USB Disk'** or **'CD/DVD'** Button.



①	Image Type	BMP PNG JPG DICOM	Select the image type to export.
②	Patient Information (Overlay)	Patient Information (Overlay)	Burning patient information to the image
③	Patient Information (TAG)	Patient Information (TAG)	Burning patient information to DICOM TAG
④	Burn Annotation	Annotation	Burning annotations to the image
⑤	CDViewer	CDViewer	Including the CDViewer for DCM export.
⑥	Checkup Naming	Checkup Naming	Applying the naming option in Checkup Mode.
⑦	Hard Disk Button	Hard Disk	Select folder and click **'Yes'** button on the Notice dialog, and recording process is start with Hard Disk.
⑧	USB Disk Button	USB Disk	Select folder and click **'Yes'** button on the Notice dialog, and recording process is start with USB Disk.

⑨	CD/DVD Button		Click **'Burn'** button on the Notice dialog, and recording process is start with CD/DVD. 
⑩	Cancel		Close the Export mode and change to normal mode.

NOTE
DICOM viewer will be included automatically on HDD, USB or CD/DVD for operator.

3. Move & Paste

   Click check box(es) on the step(s), and then click **'Move'** button. Select another study to move selected step image, and then click **'Paste'** button.

4. Reject

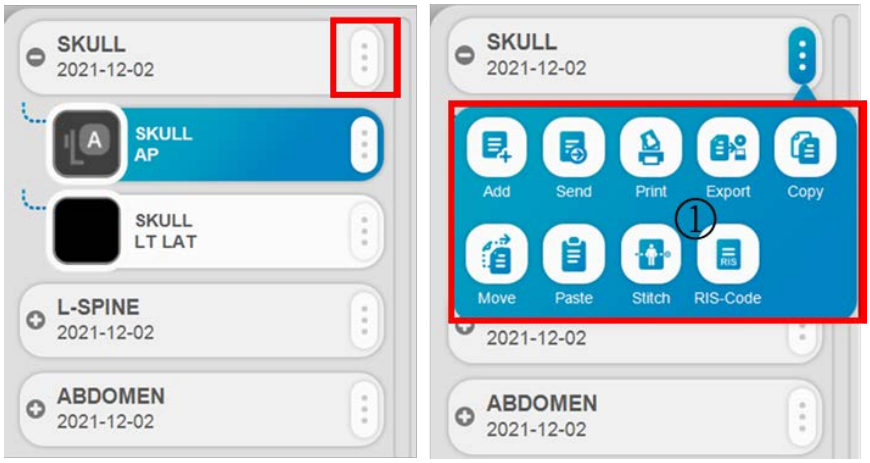
To use reject function, click image, and then Reject Registration dialog will be showed up to enter or select reason.

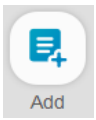
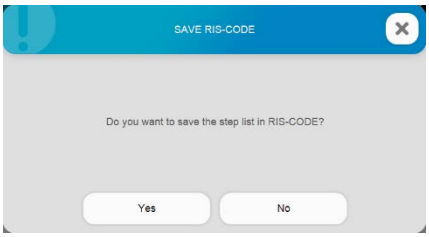
①	Reject Button	Reject	Select and enter reject reason and mark reject indicator on the image.
②	Initialize Button	Initialize	Click rejected image and cancel the rejection.
③	Modify Button	Modify	Click rejected image and modify reject reason.
④	Cancel Button	Cancel	Reject is canceled.

- Study More Menu

Click ‘ ’ button to display hidden menu of study.

Operation method of each functions is same as functions in Procedure Collapsed menu.

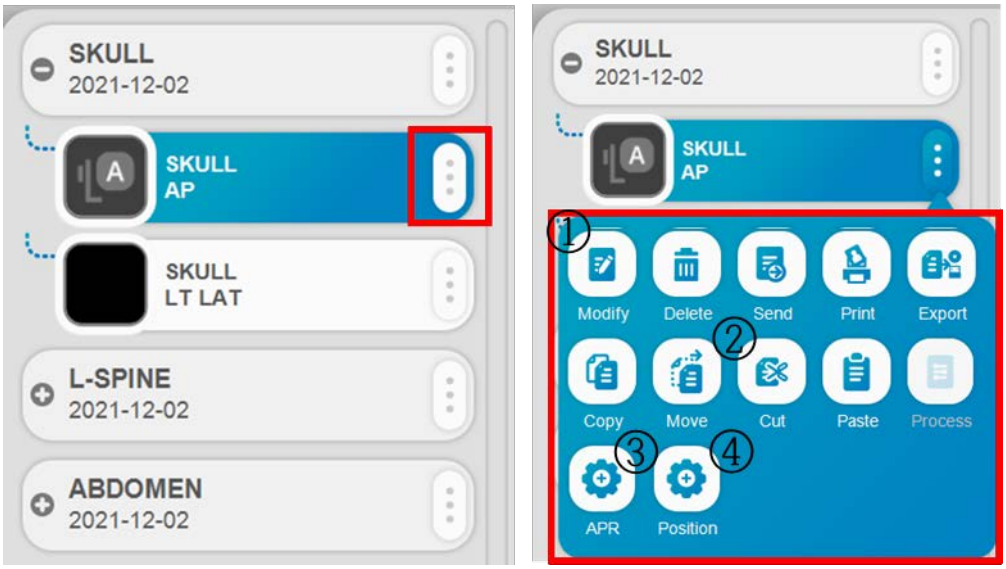


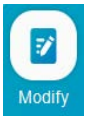
①	RIS-Code Button		Click **‘Yes’** button on the Notice dialog, and save current step list of study in RIS-Code. 

- Step More Menu

Click ‘ ’ button to display hidden menu of study.

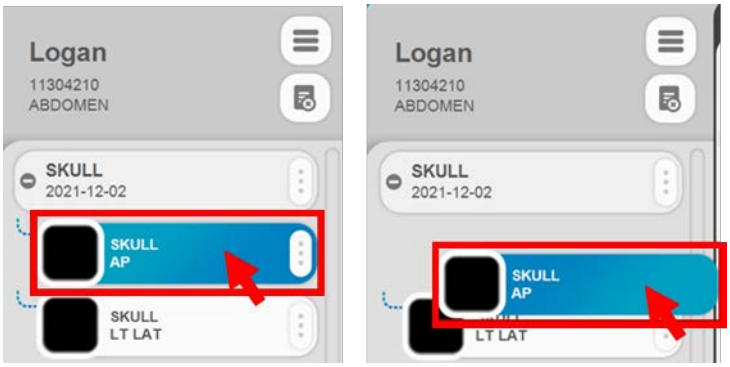
Operation method of each functions is same as functions in Procedure Collapsed menu.



①	Modify Button		Modify current step information.
②	Cut Button		Select the image to cut. Select another step, and then click ‘**Paste**’ button.
③	APR Button		Execute Procedure Manager for APR setting. Please refer to the ‘APPENDIX E. Procedure Manager’ section.
④	Position Button		Execute Procedure Manager for position setting.

- Step Order Change

Move to step order via drag & drop in same study.

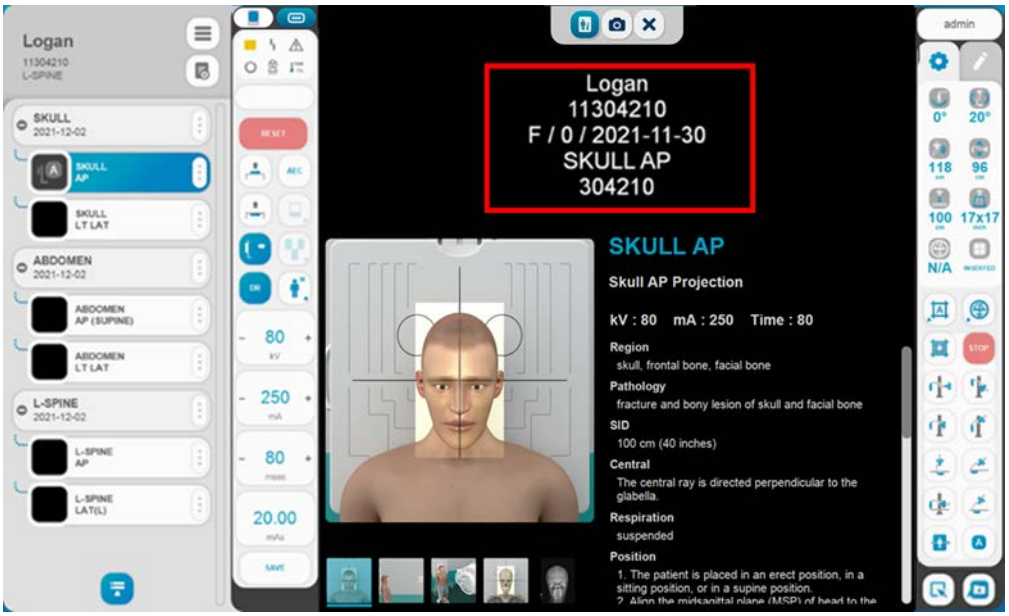


NOTE
When you use touch monitor or touch devices, please press and hold step to use drag & drop function for more than 1 second.

4.4.4.2 IMAGE VIEWING

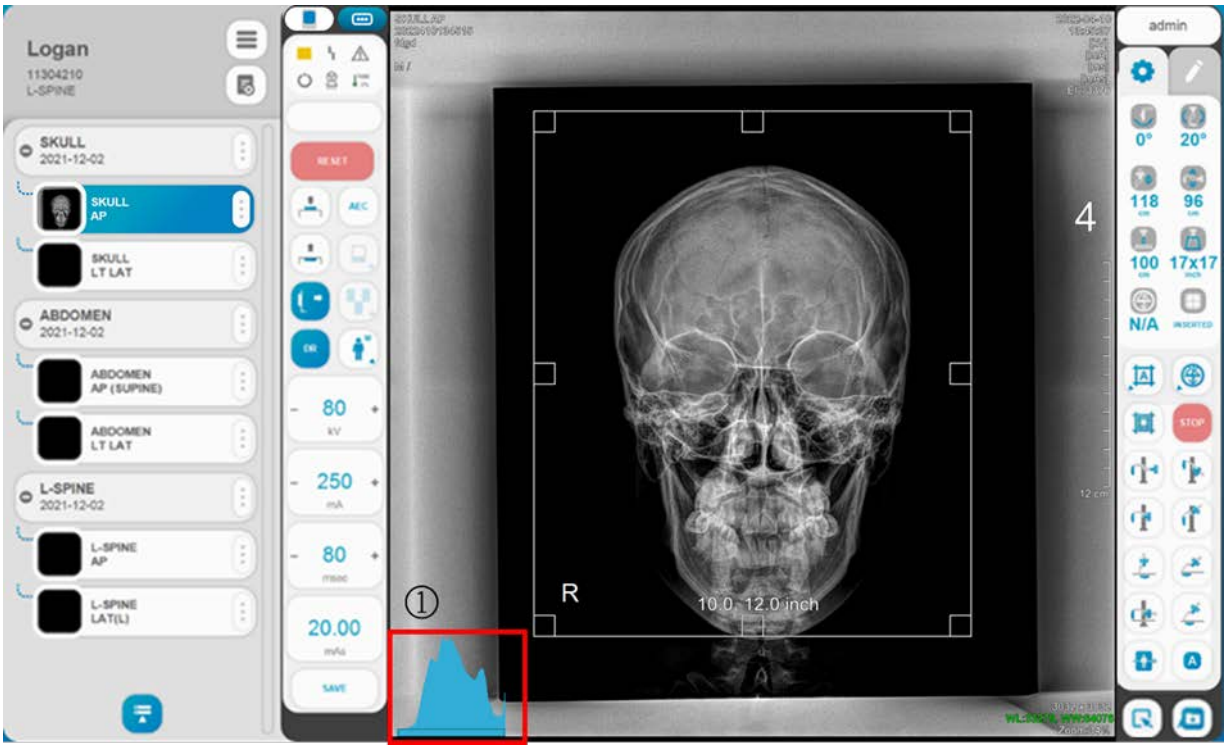
- Before Acquisition

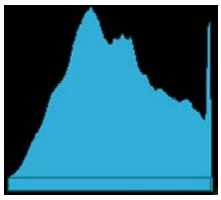
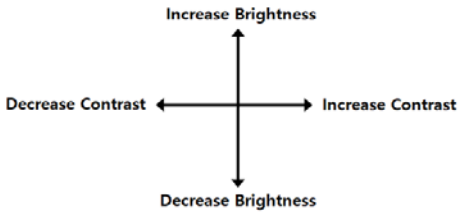
Before X-ray image acquisition, patient and step information is displayed on viewing area.
(Patient ID, Name, gender, Bodypart and projection, Accession number)



- Contrast/Brightness Control

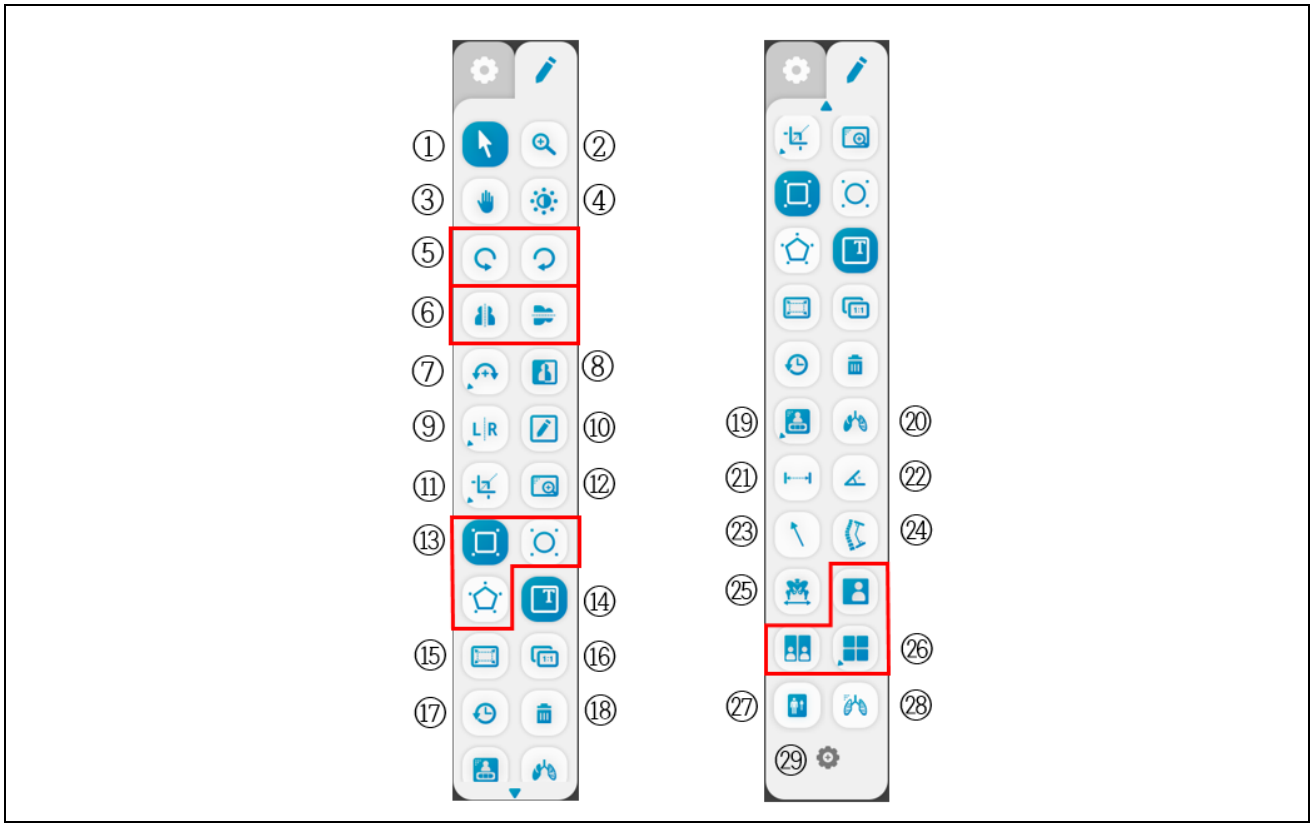
Adjust contrast & brightness by holding down the right mouse button and moving as shown below. At that time, the histogram information will be displayed at the right bottom side of the image. When the right mouse button is released, the histogram information will be hidden automatically.



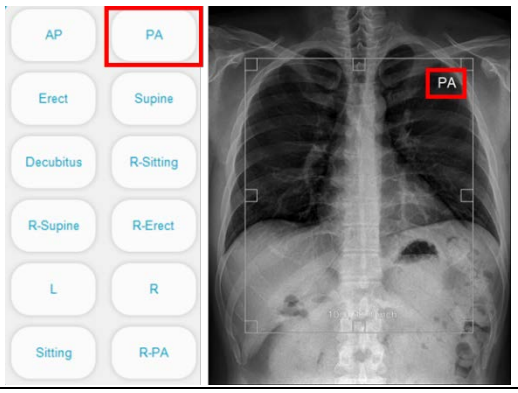
①	Contrast/Brightness Control		Press the right mouse button, - Left and right movement: Adjust contrast - Up and down movement: Adjust brightness 

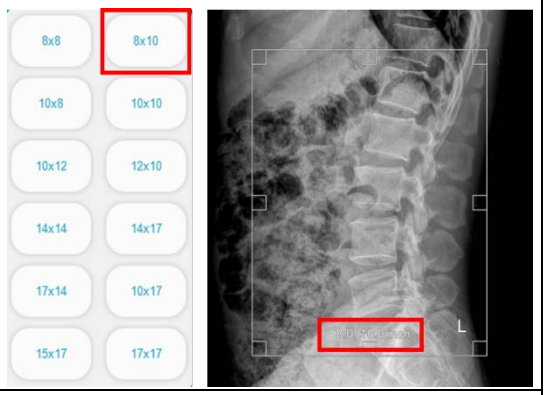
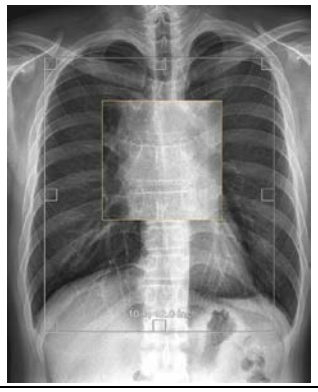
4.4.4.3 TOOLBOX

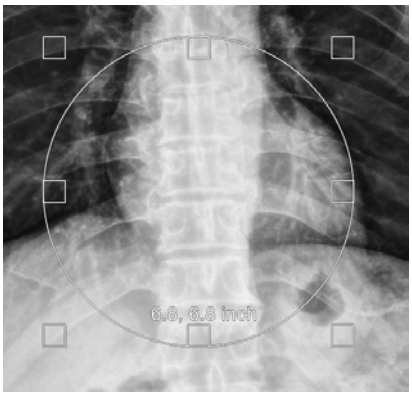
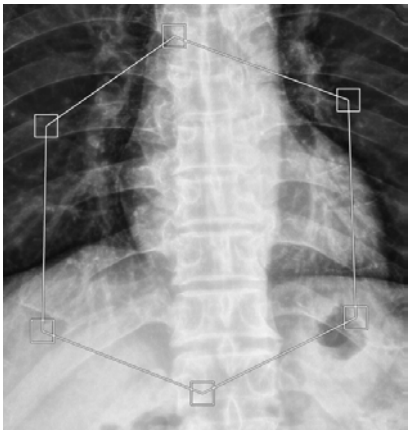
The Toolbox offers the following functions.

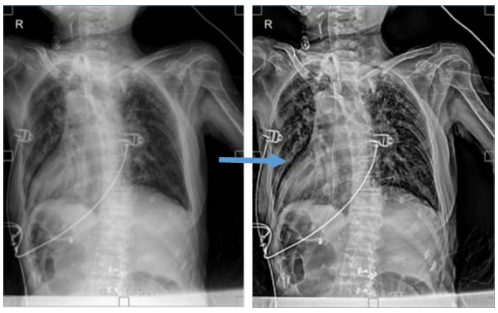


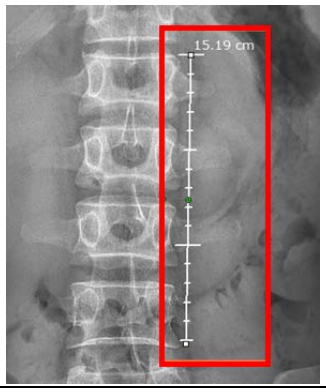
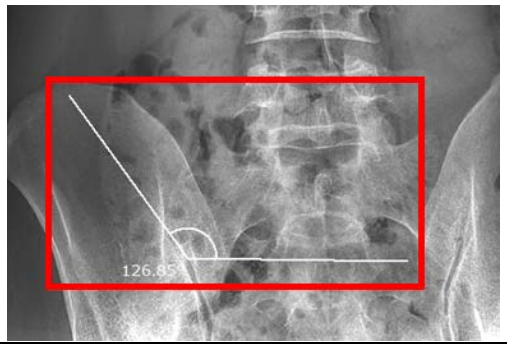
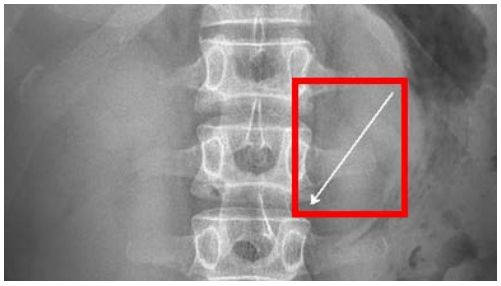
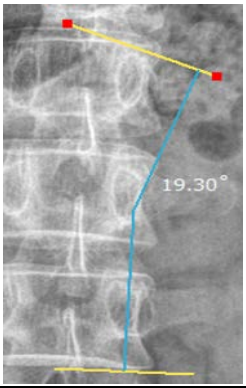
①	Select Button		Select and drag annotation(s) or markers or ROI area via click left button of mouse to adjust the size or position. Also modify annotation to double-click.
②	Zoom Button		Offer zoom-in, zoom-out function by click left button and drag on the image. - Zoom-in: Move the mouse to up direction - Zoon-out: Move the mouse to down direction
③	Pan Button		Pan image with clicking left button of mouse.

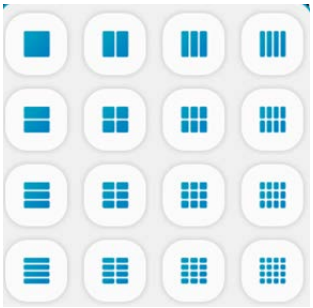
④	W/L Button		Change the window width & level (W/L) value in ROI area. When user makes ROI area with mouse drag, after then change the W/L to fit corresponding area.
⑤	CCW Button		Rotate an image counterclockwise by 90°.
	CW Button		Rotate an image clockwise by 90°
⑥	Horizontal Mirror Button		Transform an image to horizontally mirrored image.
	Vertical Mirror Button		Transform an image to vertically mirrored image.
⑦	Fine Rotation Button		Rotate an image by select the CCW/CW 1°~3°, 45°and Line Rotation buttons.
⑧	Inverse Button		Invert black and white of image.
⑨	Marker Button		Add position marker on image. 
⑩	Text Button		Insert text on the image.

⑪	ROI Button		Select ROI size and add ROI marker on image. 
⑫	Magic Glass Button		Magnify some regional part of image. Select this function and move with left button of mouse, the magnifier window will be showed up and moved. 
⑬	Rectangle ROI Button		Change ROI shape between rectangle type.
	Circle ROI Button		Change ROI shape between circle type.

			
	Polygon ROI Button		Change ROI shape between polygon type.  Successively select at least three points which will be the vertices of the polygon. Then, click the first point again in order to close the polygon.
⑭	Overlay Button		Hide and show patient and image information on image.
⑮	Screen Fit Button		Fit an image to the main image window size. Basically, it is function is activated automatically when image is opened.

⑯	1:1 View Button		Display 1:1 mapped image between monitor pixels and detector pixels or the real size on screen To select this option, please refer to the '4.3.9.3 Calibration Coefficient Setting' section in the ***"DIAMOND"*** Service Manual.
⑰	Reset Button		Restore the image to the original image. Marker annotation, W/L, ROI and etc. goes back to initial status.
⑱	Delete Button		Delete selected annotation or marker.
⑲	Re-processing Button		Perform image processing again. (MODULE1, MODULE2, MODULE4)
			Perform image processing again. (Soft) (Only MODULE3)
			Perform image processing again. (Standard) (Only MODULE3)
			Perform image processing again. (Strong) (Only MODULE3)
⑳	Tube & Line Enhancement Button		Enhance and highlight catheter shape of inside patient body. 

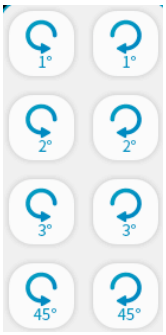
㉑	Ruler Button		Draw a line between two points. When the line is drawn, the distance between two points is shown automatically. 
㉒	Angle Button		Measure angle value by setting three points on image. 
㉓	Arrow Button		Draw an arrow on image. 
㉔	Cobb's Angle Button		Measure the degree of side-to-side spinal curvature. 

㉕	Hip Measurement Button		Measure degree of scoliosis in the pelvis. - White & Yellow line: Base line - Blue line: Measurement line
㉖	Single Layout Button		Display the single view mode.
	Comparison Button		Display the comparison view mode.
	Multi-Layout Button		Display the multi-layout view mode. 
㉗	Scatter Reduction		Enable or disable scatter reduction function on image. This function only work at Non-Bucky status. - Low : Low intensity - MEDIUM : Medium intensity - HIGH : High intensity
㉘	Bone Suppression		Suppress rib ingredient on chest images.

□	Setting Button		Select Toolbox Configuration.

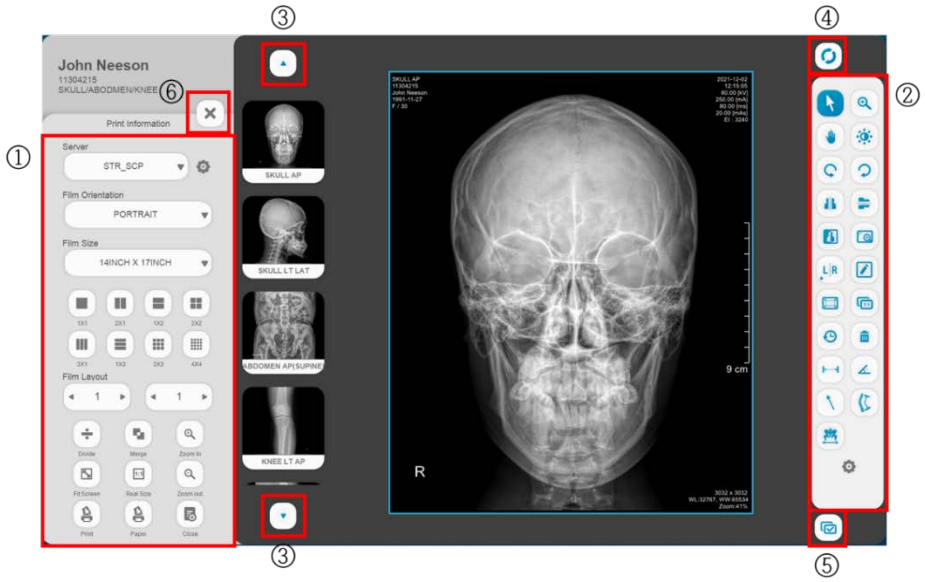
NOTE
The measured distance and angle may differ from the actual measurement, so please only refer to it.

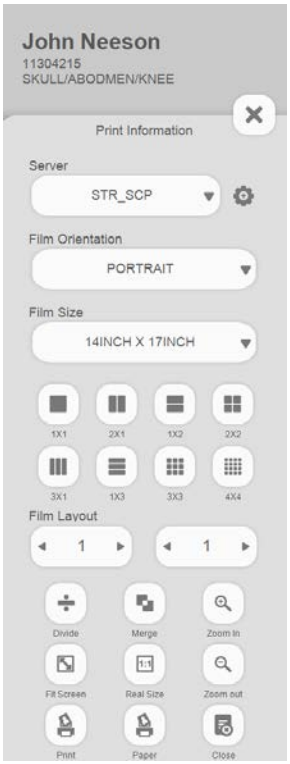
- Fine Rotation

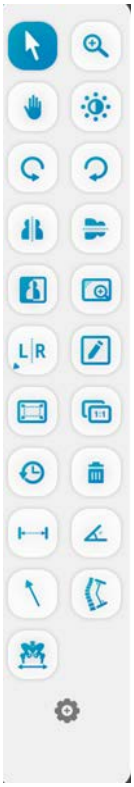
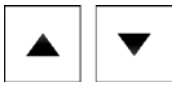
Fine Rotation Button		Select the CCW/CW 1°~3° and 45° buttons to rotate the image
		Draw the line with clicking left button of mouse, and then rotate it by the line angle

NOTE
This function will be operate separately with 90° rotation function (CW, CCW). It can be used among -90° ~ 90° range.

4.4.4.4 DICOM PRINT



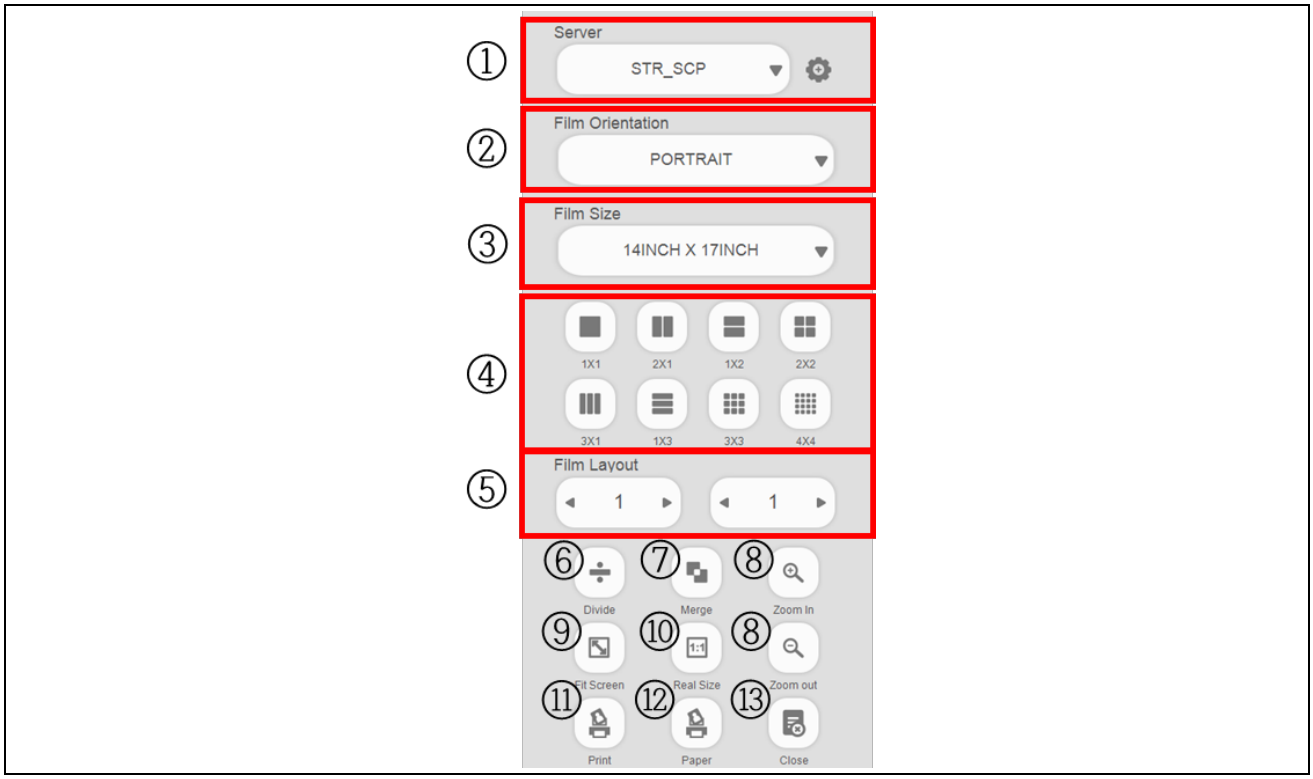
①	Print Toolbox		Offer the image edit functions.

②	Image Toolbox		Offer the image edit functions. Please refer to the '4.4.4.3 Toolbox' Section.
③	Page Navigator Button		If there are more than 5 thumbnail images, move the scroll up and down.
④	Refresh Button		Initialize changes.
⑤	Select Multiple Images Button		Select the Multiple Images.
⑥	Cancel Button		Close the DICOM Print mode and change to normal mode.

NOTE
ROI buttons do not work. (ROI & Rectangle/Circle/Polygon ROI buttons) The Reset button clears the selected image area.

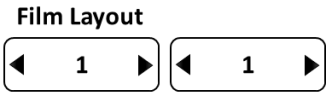
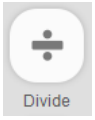
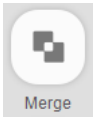
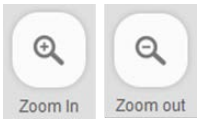
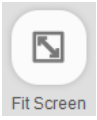
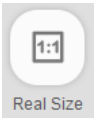
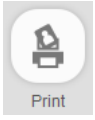
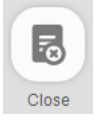
NOTE
To insert thumbnail image into image area, double click thumbnail image(s).

- Print Toolbox



①	Select Print	Server STR_SCP	Select the DICOM Print. - : Display the DICOM Print dialog menu
②	Select Film Orientation	Film Orientation PORTRAIT	Set the orientation of film to be printed.
③	Select Film Size	Film Size 14INCH X 17INCH	Set the size of film to be printed. There are 9 sizes of film print as show below, and image viewer size is changed base on film ratio.

Film Size
8 INCH X 10 INCH
10 INCH X 12 INCH
10 INCH X 14 INCH
11 INCH X 14 INCH
14 INCH X 14 INCH
14 INCH X 17 INCH

			24 CM X 24 CM 24 CM X 30 CM 25 CM X 30 CM
④	Divide Film Area		Divide the selected image area by buttons
⑤	Film Layout		Select layout.
⑥	Divide Button		Divide the selected image by selected Film Layout.
⑦	Merge Button		Combine the divided image areas into one.
⑧	Zoom in / out Button		Zoom in / out the selected image. When these functions are used, each image can be applied individually.
⑨	Fit Screen Button		Fit all images in each image area.
⑩	Real Size Button		Fit all images in each real image area.
⑪	DICOM Print Button		Send image(s) in the film area to DICOM print.
⑫	Paper Print Button		Send image(s) in the film area to paper print.
⑬	Close Button		Exit DICOM print mode.

NOTE
In order to combine the image areas, adjacent image areas must be selected.

NOTE
To select multiple images, select each image areas with pressing **'CTRL'** key or clicking ' ' button.

1. DICOM Print dialog menu

   Change DICOM Print options, network settings and overlay information.

a) Check the **'Display the entire overlay only on firs**t'.
   To avoid duplicate display of patient information on the DICOM Print mode, it can be set overlay for 1st image and other images separately. If necessary, click the **'Other'** button instead of **'First'** button.

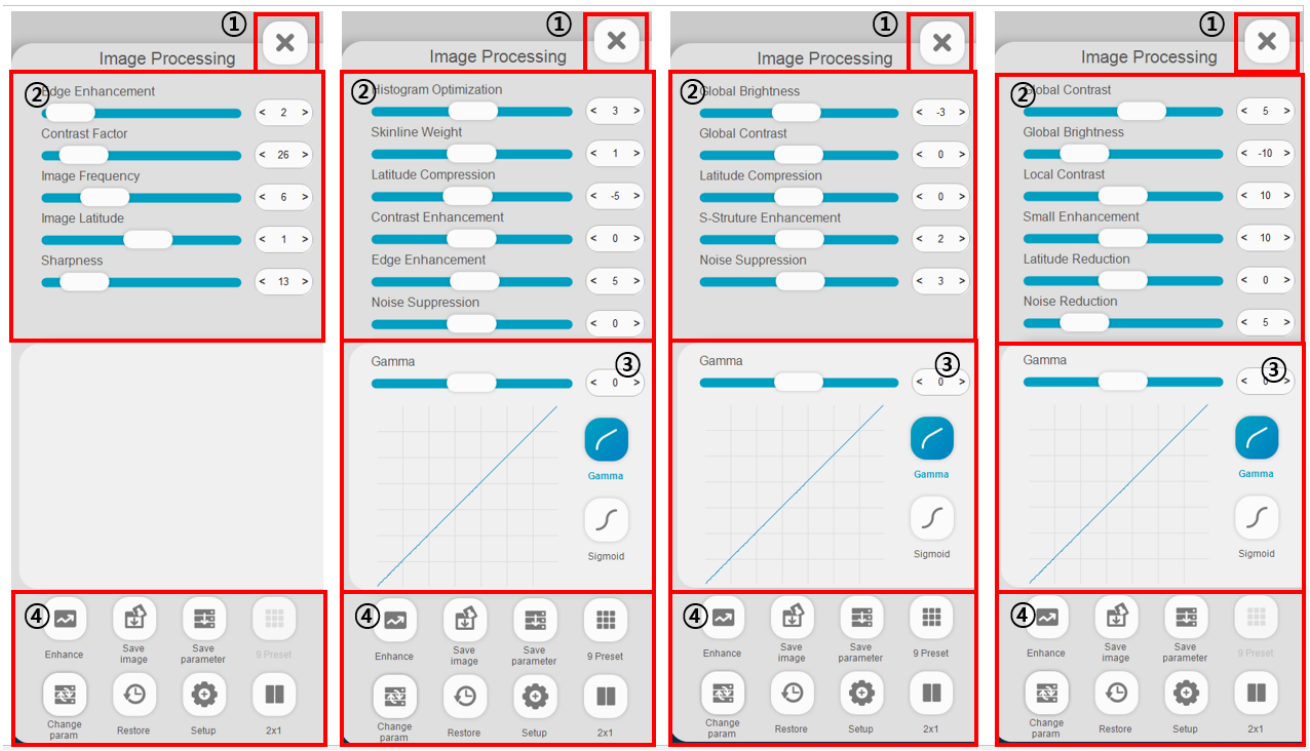
b) Put an item into left top / left bottom / right top / right bottom side via drag & drop of mouse as shown below.

c) Click **'Save'** button to save the overlay settings.

d) Click **'Close'** button to terminate the DICOM Print dialog menu

4.4.4.5 IMAGE PROCESSING

Image Processing menu has parameters (slider controls), curve grid window and control buttons for image processing functions.



< MODULE 1, MODULE 2, MODULE 3, MODULE 4>

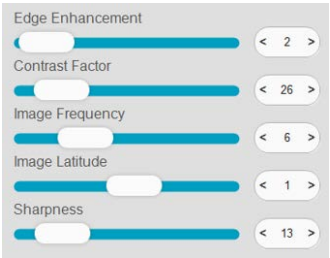
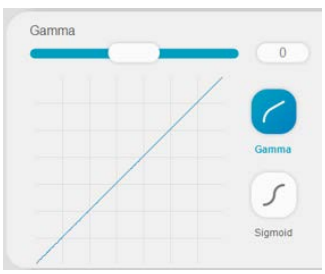
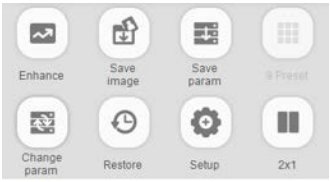
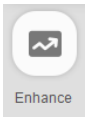
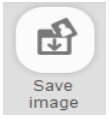
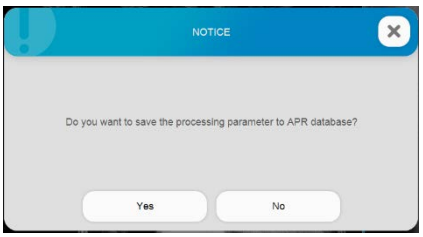
①	Cancel Button	✕	Close the image processing mode and change to normal mode.
②	Image Processing Parameters (slider controls)		Image Processing Item and range of MODULE 1.

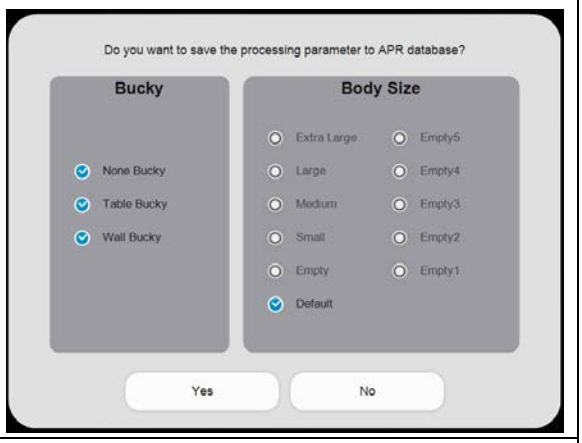
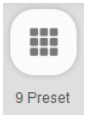
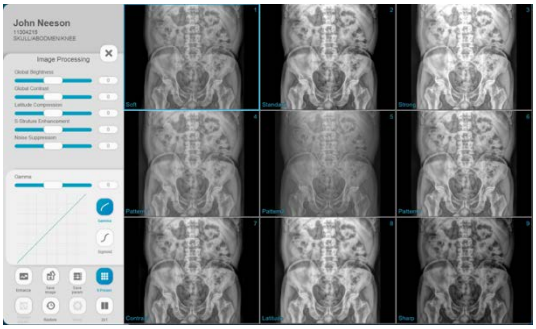
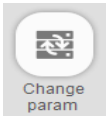
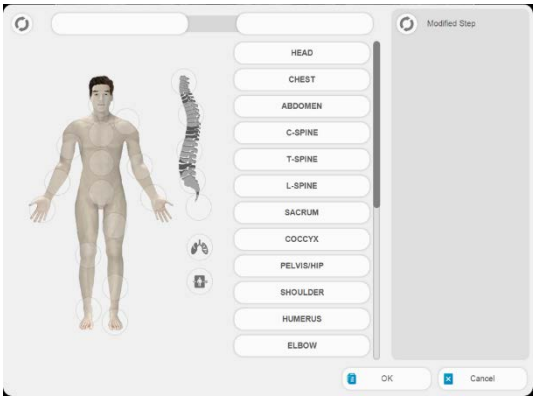
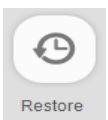
Image Processing Item	Range
Edge Enhance	0 ~ 50
Contrast Factor	1 ~ 200
Image Frequency	0 ~ 20
Image Latitude	-10 ~ 10
Sharpness	0 ~ 100

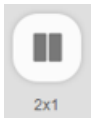
<table>
<tr>
<td rowspan="3"></td>
<td rowspan="3"></td>
<td>
</td>
<td>Image Processing Item and range of MODULE 2.
<table>
<tr><th>Image Processing Item</th><th>Range</th></tr>
<tr><td>Histogram Optimization</td><td>-100 ~ 100</td></tr>
<tr><td>Skinline Weight</td><td>-100 ~ 100</td></tr>
<tr><td>Latitude Compression</td><td>-100 ~ 100</td></tr>
<tr><td>Contrast Enhancement</td><td>-100 ~ 100</td></tr>
<tr><td>Edge Enhancement</td><td>-100 ~ 100</td></tr>
<tr><td>Noise Suppression</td><td>-100 ~ 100</td></tr>
<tr><td>Gamma</td><td>-20 ~ 20</td></tr>
</table></td>
</tr>
<tr>
<td>
</td>
<td>Image Processing Item and range of MODULE 3.
<table>
<tr><th>Image Processing Item</th><th>Range</th></tr>
<tr><td>Global Brightness</td><td>-100 ~ 100</td></tr>
<tr><td>Global Contrast</td><td>-100 ~ 100</td></tr>
<tr><td>Latitude Compression</td><td>-100 ~ 100</td></tr>
<tr><td>S-Structured Enhancement</td><td>-100 ~ 100</td></tr>
<tr><td>Noise Suppression</td><td>-100 ~ 100</td></tr>
<tr><td>Gamma</td><td>-20 ~ 20</td></tr>
</table></td>
</tr>
<tr>
<td>
</td>
<td>Image Processing Item and range of MODULE 4.
<table>
<tr><th>Image Processing Item</th><th>Range</th></tr>
<tr><td>Global Brightness</td><td>-20 ~ 20</td></tr>
<tr><td>Global Contrast</td><td>-20 ~ 20</td></tr>
<tr><td>Local Contrast</td><td>0 ~ 20</td></tr>
<tr><td>Small Enhancement</td><td>0 ~ 20</td></tr>
<tr><td>Latitude Reduction</td><td>-20 ~ 20</td></tr>
<tr><td>Noise Suppression</td><td>0 ~ 20</td></tr>
<tr><td>Gamma</td><td>-20 ~ 20</td></tr>
</table></td>
</tr>
<tr>
<td>③</td>
<td>Curve Grid Window</td>
<td> 
</td>
<td>Apply gamma and sigmoid curves to the image.</td>
</tr>
</table>

④	Control Buttons		Control buttons for image processing functions.

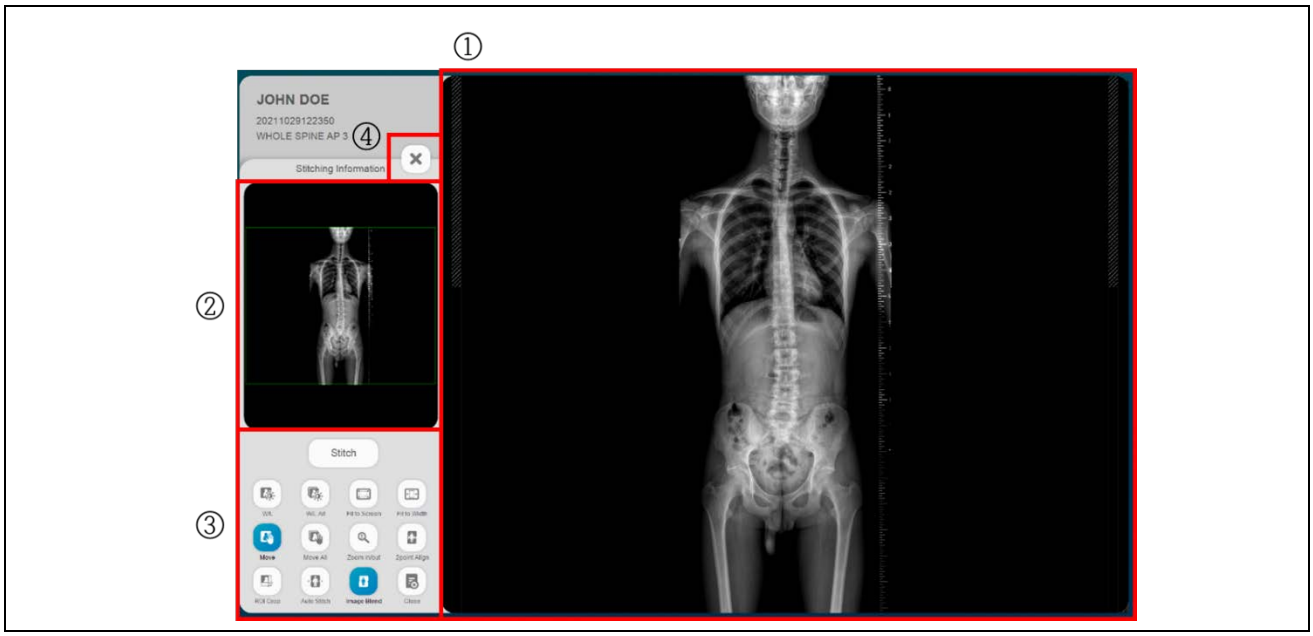
- Control Buttons

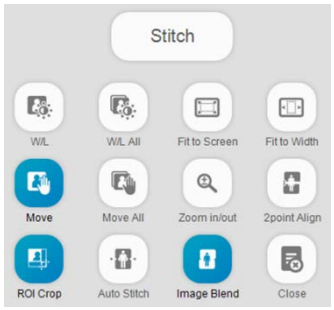
①	Enhance Button		Enhance image with selected parameter values
②	Save Image Button		Click **'Yes'** button on the Notice dialog, and save the image.
③	Save Parameter Button		Module 1,2 : Click **'Yes'** button on the Notice dialog, and save the image processing parameters. 

			Module 3,4 : Select bucky and body size for individual parameter setting. And Click 'Yes' button on the Notice dialog to save the image processing parameters. 
④	9 Preset Button		Select prefer image type among 9 different image processing type. (Only MODULE 2 and 3) 
⑤	Change Parameter Button		Change image processing parameter of other step 
⑥	Restore Button		Restore the image processing with default parameters.

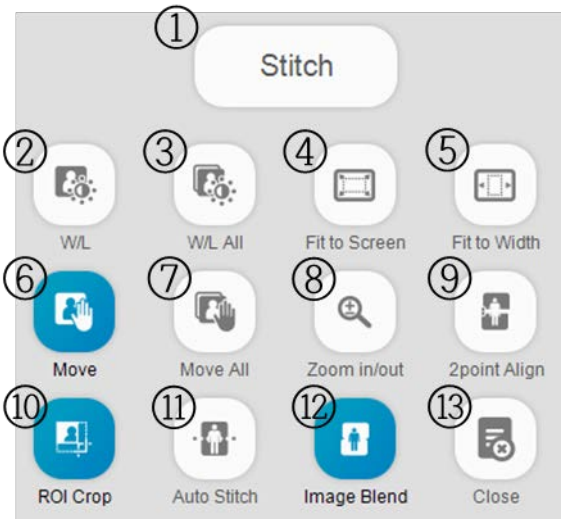
⑦	Setup Button		Perform more detailed image processing through additional image processing parameters.
⑧	2x1 Button		Compare two different image processing type images.

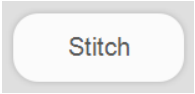
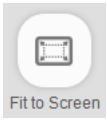
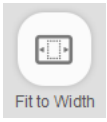
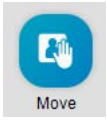
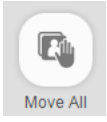
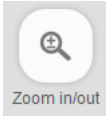
4.4.4.6 IMAGE STITCH

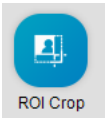
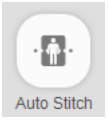
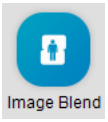
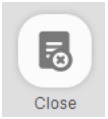


①	Main Display Area	-	Display the x-ray images as a composite image.
②	Preview Display Area	-	Display the full view with the green box indicating the current zoom-in area.
③	Tools Area		Contain buttons for several image manipulation tools.
④	Cancel Button		Close the Image Stitch mode and change to normal mode.

- Tools Area



①	Stitch Button		-	Save the stitch image and return to previous screen
②	W/L Button		Q	W/L single image.
③	W/L All Button		W	W/L all images.
④	Fit to Screen Button		E	Fit image to window size.
⑤	Fit to Width Button		R	Fit image to window width.
⑥	Move Button		A	Pan single image.
⑦	Move All Button		S	Pan all images.
⑧	Zoom in/out Button		D	Click the left mouse button in the main display area, and drag the mouse pointer up and down to zoom out and zoom in

⑨	2 Point Align Button		F	Align two images by selecting two matching points.
⑩	ROI Crop Button		Z	Show or hide clipping lines.
⑪	Auto Stitch Button		X	Automatically synthesizes 2 or more individual images into single long-view image.
⑫	Image Blend Button		C	Turn blend function on or off. Blend function applies fade in/out effect to overlapping areas for a smooth transition between images.
⑬	Close Button		-	Cancel and return to previous screen.

1) Contrast/Brightness Control

- Select **'W/L'** button and then change the contrast/ brightness an image by dragging it with the mouse.
- Click an image with the right mouse button and then move the mouse left/right to change the contrast or up/down to change the brightness of the image.
- Hold down the **'Shift'** key while moving the mouse to change contrast/brightness of the composite image.

2) Pan Images

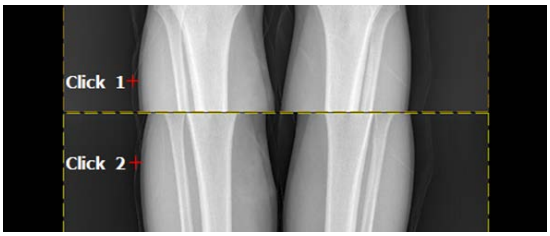
- Select **'Move'** button and then move an image by dragging it with the mouse.
- Move selected image in small incremental amounts using the arrow keys on the keyboard.
- Pan into different areas of the composite image by panning the green box in the preview display.

3) ROI Crop

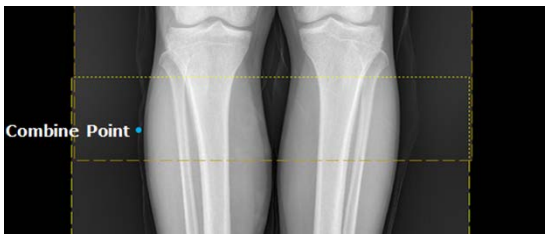
- Select the **'ROI Crop'** button tool.
- Dotted lines will be drawn around individual images.
- Pressing the Shift key will draw dotted line around the whole composite image.
- Moving the mouse pointer over the dotted line will change the cursor shape to an arrow.
- Click and hold the left mouse button and drag the line to desired position.

4) Two Point Align Tool

- Select **'2 point Align'** button and click a point in the first image. A red cross will be drawn at the selected point.
- Click matching point on the second image.
- The second point will move to the combine point in the first image.



Two points are clicked in two images.

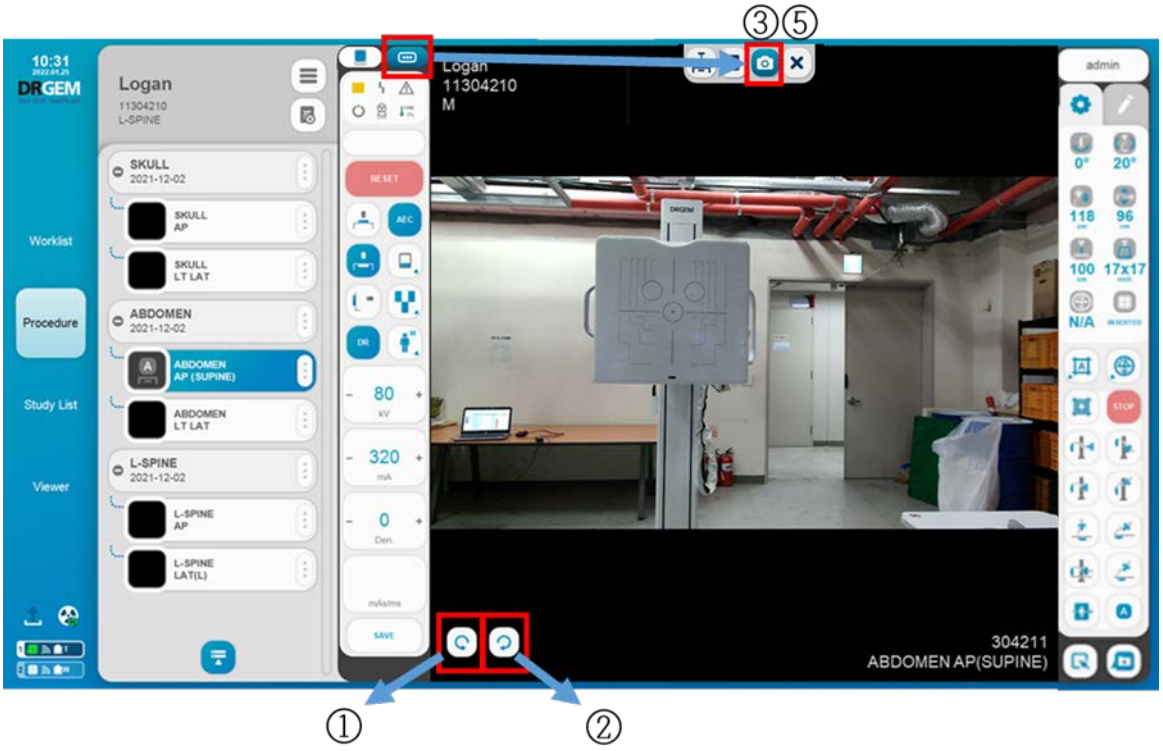


The second point moves to the combine point.

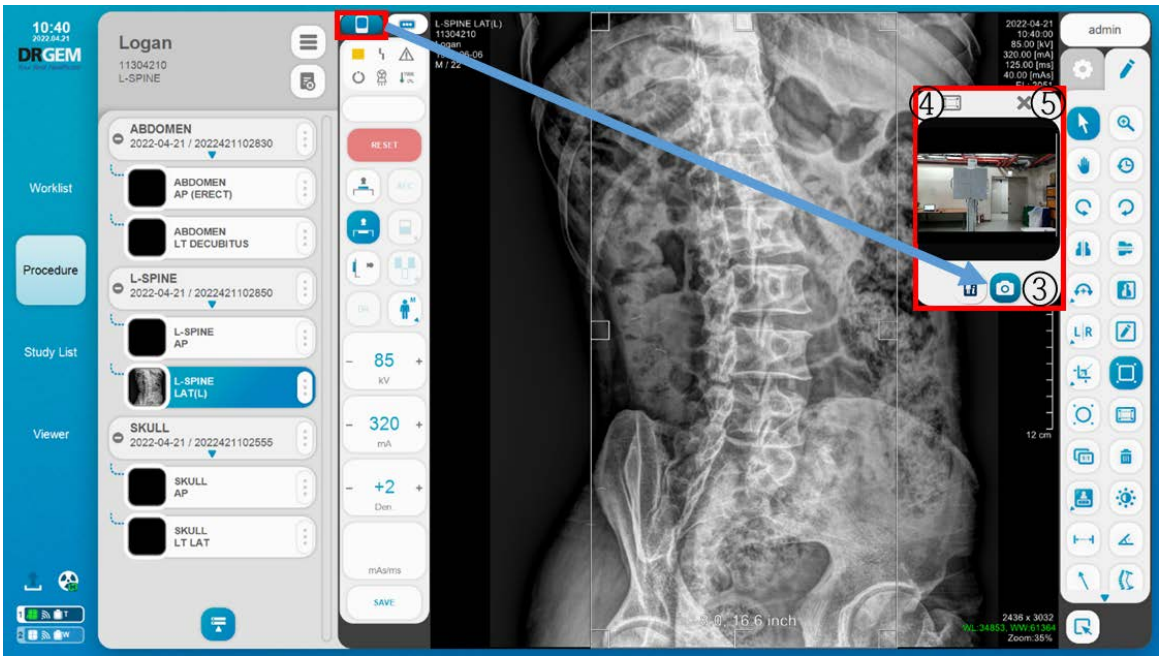
NOTE
Please refer to the 'APPENDIX H. Image Stitching Module' section.

4.4.4.7 LIVE STREAMING

If the live streaming function is enabled, outputs a real-time video signal from the camera which is mounted on the collimator. This function will show the area to be X-rayed in more detail and intuitively. It also lets operator know patient moving or wrong direction while the X-ray is being taken.



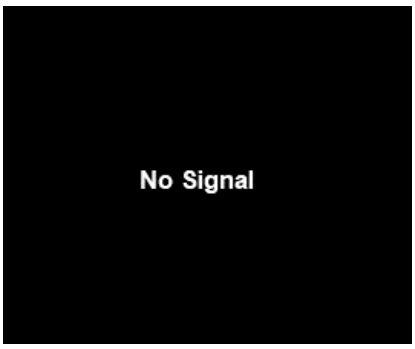
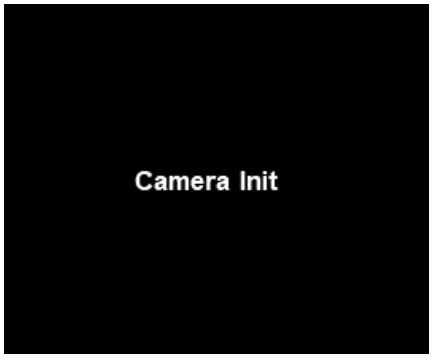
<Enable live streaming function in full screen>



<Enable live streaming function in small widget screen>

①	Left Rotation Button		Rotate live streaming screen to the left.
②	Right Rotation Button		Rotate live streaming screen to the right.
③	Live Streaming Button		Display live streaming on screen.
④	Full Screen Button		Expand a small widget screen to full screen.
⑤	Exit Button		Exit the widget screen.

When camera cable is unconnected, there will be displayed ‘No Signal’ message. In this case, re-connect the cable, and then stream screen will be displayed after 5~10 sec later with ‘Camera Init’ message.

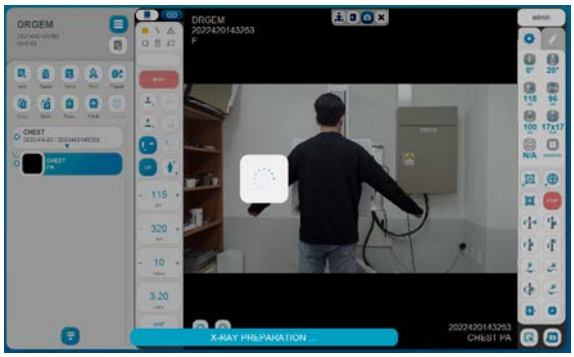
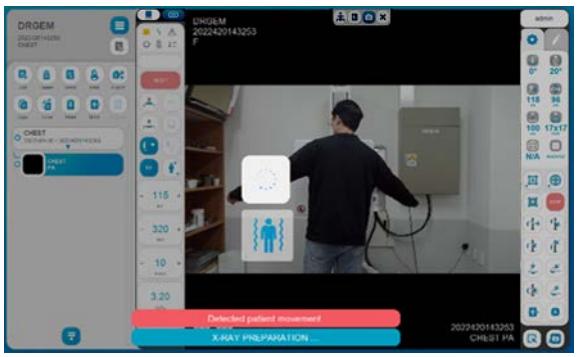
	
<Unconnect the camera cable>	*<Re-connect the camera cable>*

NOTE
Move the Small widget screen position by right-clicking and dragging. It is always displayed only on the procedure screen.

- Patient Movement Alarm Function

When using live streaming camera, there is function for patient movement alarm. This function will notice a patient has been move on X-ray exposure. Also, only work from X-ray preparation to completion of exposure.

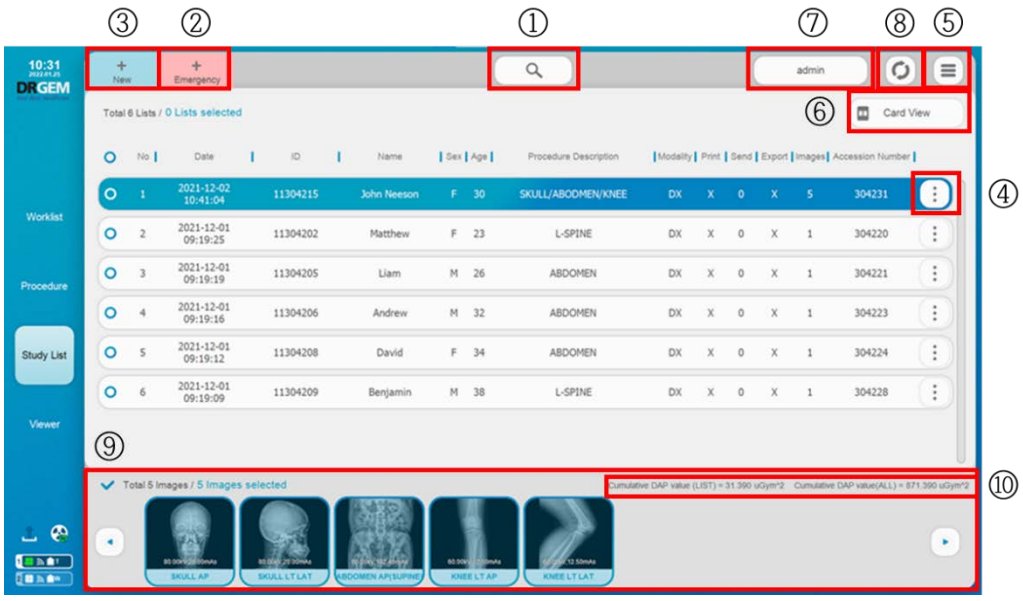
*This function only notice for patient movement. It won't affect about X-ray imaging acquisition.

	
<Normal State>	*<Patient Movement Detect State>*

NOTE
To turn on/off this function and change for sensitivity, please refer to the '4.3.8.3 Camera Module Setting' section in the ***"DIAMOND"*** service manual. There may be differences depending on the SID, so please set the sensitivity again if necessary.

4.4.5 STUDY LIST

Study List menu offers patient / study registration and management menu and submenus.



①	Search (Query From Worklist Server) Button		Display the hidden search area.
②	Emergency Button		Use to register patient information urgently. Please refer to the '4.4.3.2 Emergency' section
③	New Button		Register new study for exam manually. Please refer to the '4.4.3.3 New' section
④	More Button		Display the function icon group.
⑤	Collapsed Menu Button		Display the function icon group.
⑥	Card View Button		Display the Card view mode of worklist Please refer to the '4.4.3.5 List View And Card View' section
	List View Button		Display the List view mode of worklist Please refer to the '4.4.3.5 List View And Card View' section
⑦	Admin ID button (Quick Login)		Display Administrator list and quick login. Please refer to the '4.4.3.6 Quick Login' section

⑧	Refresh Button		Search again with current search condition.
⑨	Thumbnail Image Display	-	When select an item of Study List, thumbnail images are displayed on the bottom side of list. Please refer to the '4.4.5.2 Thumbnail Image Display' section
⑩	Dose Monitoring	-	Display the Cumulative DAP values (Selected list or studies) for selected study in the Study list. It will be displayed LIST (a selected study) and ALL (corresponding patient's total).

NOTE
Dose Monitoring function is available when DAP (Dose Area Product) was installed with X-ray system.

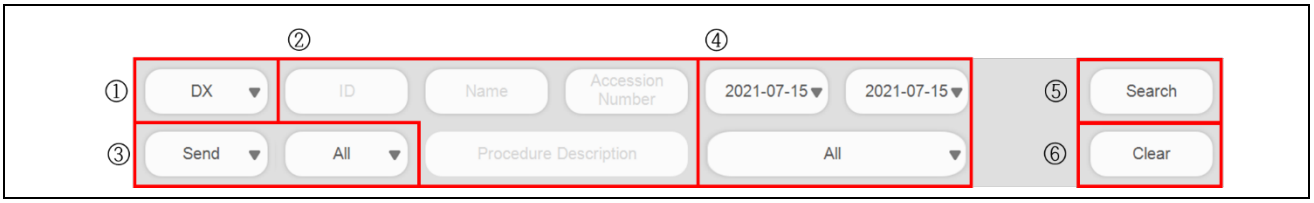
NOTE
Please refer to the '4.4.3.7 Adjust List' Section for basic study list usage.

NOTE
Double click one of list to open the study (studies) on Procedure menu.

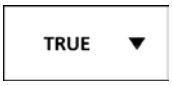
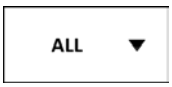
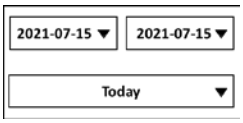
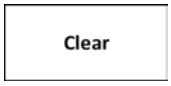
4.4.5.1 SEARCH (QUERY FROM DATABASE)

Click ' ' button to display the hidden search area.

The search area has 8 search filters like below.



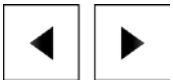
①	Modality Filter	CR	Apply the modality information in search condition as CR.
		DX	Apply the modality information in search condition as DX.
		DR	Apply the modality information in search condition as DR.
		ALL	Apply the modality information in search condition as All.
②	Editor Filter	ID	Apply the Patient ID in search condition.
		Name	Apply the Name in search condition.
		Accession Number	Apply the Access Number in search condition.
		Procedure Description	Apply the Procedure Description in search condition.
③	State Filter	Send	Apply the status information to 'Send'.
		Export	Apply the status information to 'Export'.
		Print	Apply the status information to ' Print'.
		Built-in Memory	Apply the status information to 'Built-in Memory'.
		FALSE	Apply the false value among the applied state information.

			Apply the true value among the applied state information.
			Apply the all value among the applied state information.
④	Schedule (Time/Data) Filter		Apply the Schedule (Time/Date) information in search condition.
⑤	Search Button		Search from the database with the setting search condition.
⑥	Stop Button		Clear the search condition in search filter.

NOTE
When you use touch monitor / panel / devices with ***"RADMAX"*** imaging software, please press and hold for more than 1 second and then release.

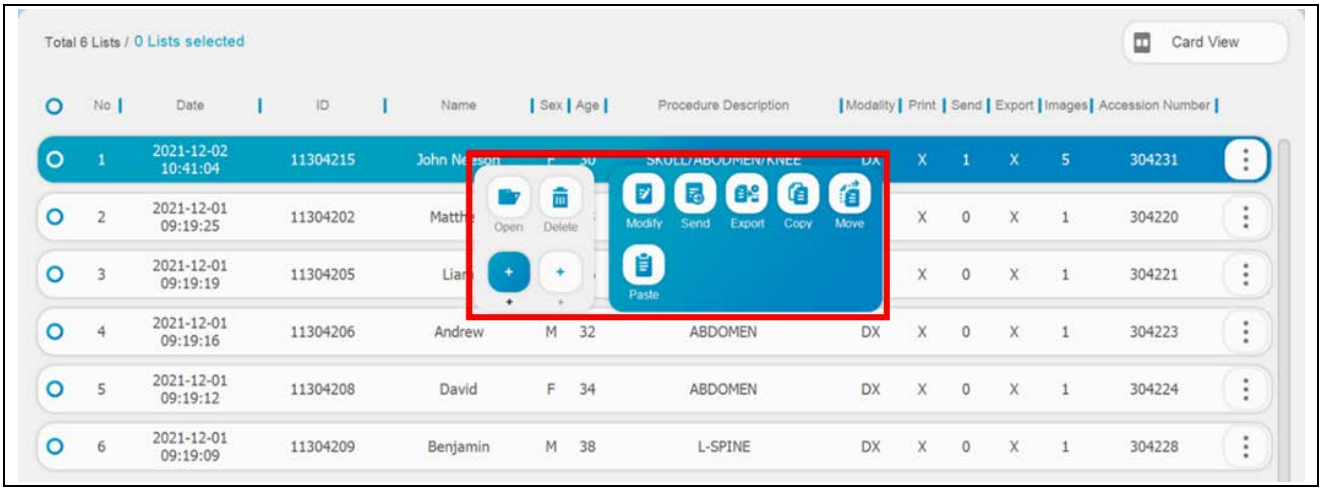
NOTE
To use 'Built-in Memory' function, please refer to the 'APPENDIX J. Built-In Memory' section

4.4.5.2 THUMBNAIL IMAGE DISPLAY

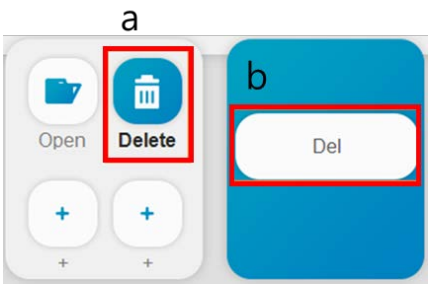
①	State Indicator		Reject the image.
			PACS transmission is successful
			Export is successful
			Print is successful
②	Exposure Conditions		Display the exposure conditions (kV, mA, exposure time) on the thumbnail image. Only if the generator (GXR, GXR-C) is connected to ***"RADMAX"*** imaging software.
③	Total / Selected List Number		Show the total number of lists and the number of selected lists.
④	Page Navigator Button		If there are more than 8 thumbnail images, move the scroll left and right

4.4.5.3 QUICK SLOT

Right click on study list to display quick slot function. This function is performed with selected study and it provides customizing for frequent using function.



To delete an added feature, follow these steps.

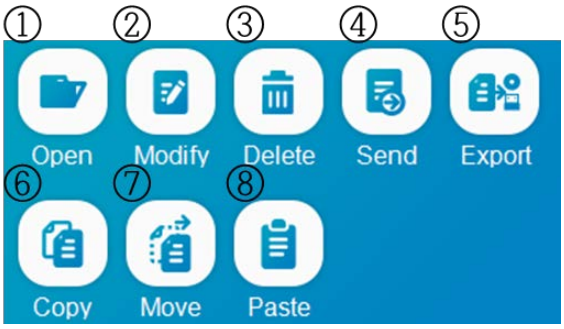


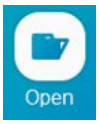
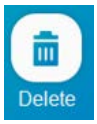
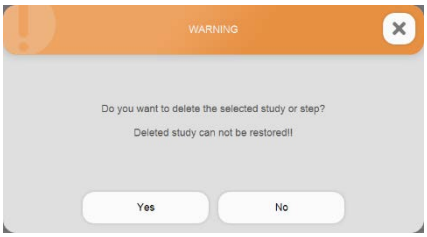
a. Click the function icon you want to delete with right button on mouse

b. Click the **'Del'** button

NOTE
When you use touch monitor / panel / devices with ***"RADMAX"*** imaging software, please press and hold for more than 1 second and then release.

4.4.5.4 FUNCTION LIST

	
<More Menu>	*<Collapsed Menu>*

①	Open Button		Open the study (studies) on Viewer menu. When you click the open button in the Collapsed menu, it can be used to compare images of selected studies.
②	Modify Button		Modify the registered study. (Only More menu)
③	Delete Button		Click **'Yes'** button on the Notice dialog, and delete the selected Study List. 
	Reject Button		When the Reject Function Setting is on, **'Reject'** button is display instead **'Delete'** button. Reject the checked studies. Please refer to the '4.4.4.1 Procedure List' Section for more information. To use this function, please refer to the '4.3.9.8 Reject Setting' section in the ***"DIAMOND"*** Service Manual.

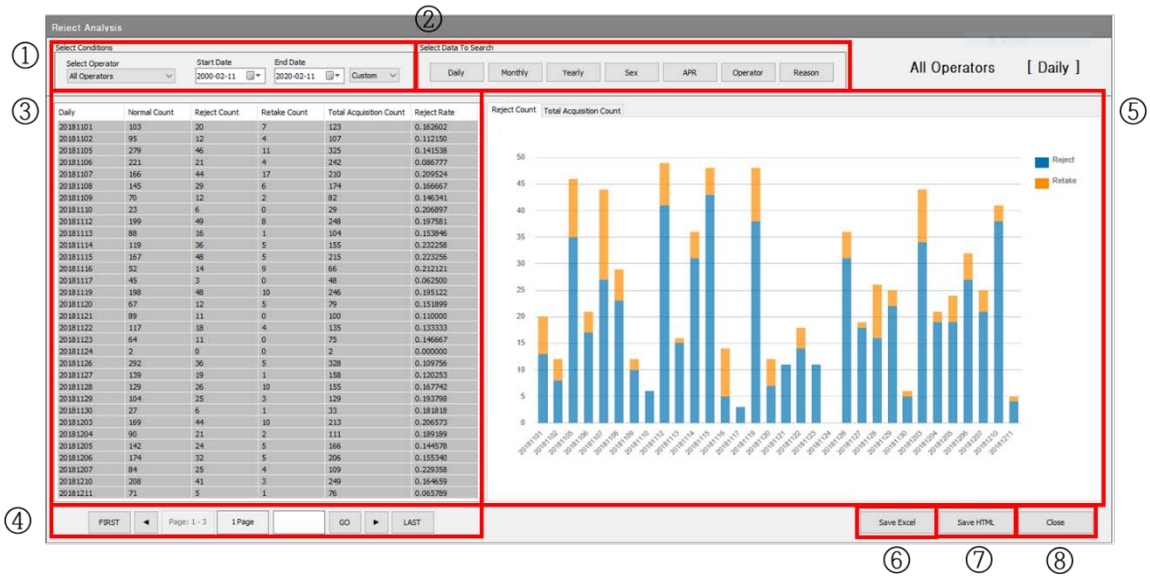
④	Send Button		Send the selected study images except reject image(s) to the available PACS server. Please refer to the '4.4.4.1 Procedure List' Section for more information.
⑤	Export Button		Export selected step image(s) to the external HDD, USB or CD Drive. (Support BMP, JPG, PNG, DCM). Please refer to the '4.4.4.1 Procedure List' Section for more information.
⑥	Copy Button		In current opened study, copy selected thumbnail image(s) and information.
⑦	Move Button		Select the thumbnail image(s) to move to another study.
⑧	Paste Button		Click **'Yes'** button on the Notice dialog, and move selected thumbnail image(s) to another study.
⑨	Statistics Button		Please refer to the '4.4.5.5 Reject Analysis' section. To use this function, please refer to the "4.3.9.8 Reject Setting" section in the ***"DIAMOND"*** Service Manual.

NOTE
If you want to apply a function to multiple studies at the same time, use the function in the Collapsed Menu Button.

NOTE
You must log in as the Administrator account type to use Delete, Reject, Copy, Move and Paste function.

4.4.5.5 REJECT ANALYSIS

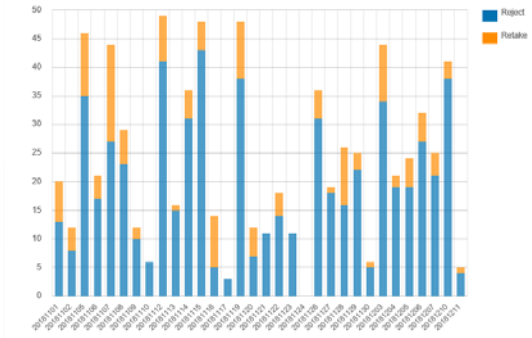
Reject Analysis is a program for statistics about reject issues when reject function is used in ***"RADMAX"*** imaging software. To run the Reject Analysis, select the **'Use Reject'** option in the RadmaxConfig to activate the **'Statistics'** button in the study list. Press this button to execute 'Reject Analysis' program and it will be linked based on the account that is currently logged in from ***"RADMAX"*** imaging software. Statistical documents has number of reject, retake, reject reasons and etc.



<Reject Analysis function>

①	Select Conditions Menu	Select Operator: All Operator	Set the operator for statistics. The default setting value is **'All Operators'.**
		Start Date: 2000-02-07	Set start date for statistics. The date can be set either by entering it directly or by pressing the '▼' button.
		End Date: 2000-02-07	Set the end date for statistics. The date can be set either by entering it directly or by pressing the '▼' button.
		Custom	Select a date of 'Today', '1Week', '1Month', '3Month', '6Month', '1Year'. When Start Date and End Date is set, **'Custom'** item is selected automatically.

②	Select Data To Search Menu	Daily Monthly Yearly	Search daily or monthly or yearly statistics based on the date.
		Sex	Search sex statistics based on gender.
		APR	Search APR statistics.
		Operator	Search operator statistics
		Reason	Search reason statistics.
③	Statistics Table	-	Display the data that matches the current search conditions. The table shows search criteria, Count, Reject Count, Retake Count, Total Acquisition Count, and Reject Rate. (Reason Statistics shows 'Reason' and 'Image' information.)
④	Statistics Table Control	FIRST	Go to the '1 Page' of the table.
		◀ ▶	Go to the previous or next page of the table.
		Page: 1 - 3	Display the total page of table.
		1 Page	Display the current page of the data in the table.
		GO	Enter the page number, and then press the **'GO'** button to go page.
		LAST	Go to the last page of the table.
⑤	Statistics Graph	-	The data in the table is shown in graph form and the graph can be viewed by selecting **'Reject Count'** or **'Total Acquisition Count'**.

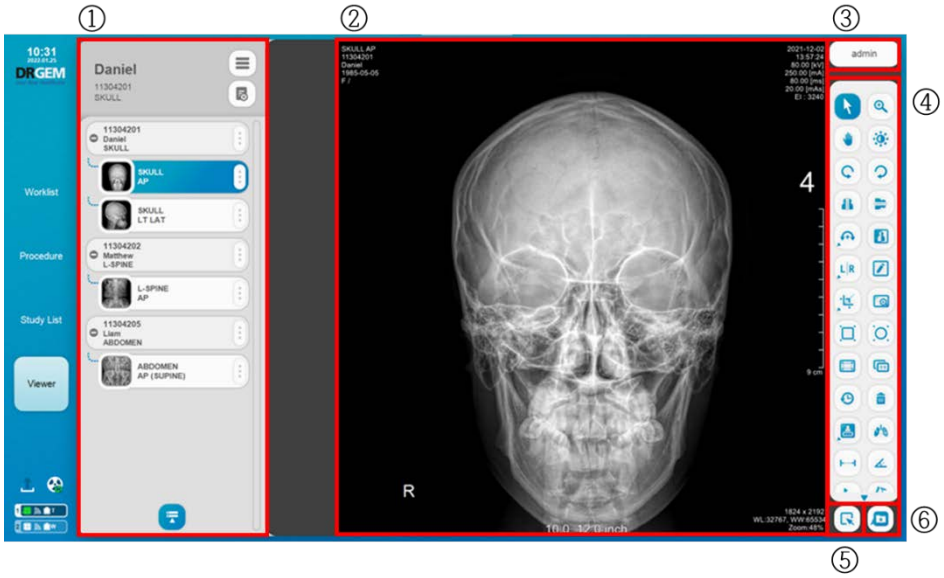
<table>
<tr>
<td>⑥</td>
<td>Save EXCEL Button</td>
<td>Save EXCEL</td>
<td>Save data from the table of Excel format
<table>
<tr><th></th><th>A</th><th>B</th><th>C</th><th>D</th><th>E</th><th>F</th></tr>
<tr><td>1</td><td>Daily</td><td>Normal</td><td>Reject</td><td>Retake</td><td>Total</td><td>Rate</td></tr>
<tr><td>2</td><td>20181101</td><td>103</td><td>20</td><td>7</td><td>123</td><td>0.162602</td></tr>
<tr><td>3</td><td>20181102</td><td>95</td><td>12</td><td>4</td><td>107</td><td>0.11215</td></tr>
<tr><td>4</td><td>20181105</td><td>279</td><td>46</td><td>11</td><td>325</td><td>0.141538</td></tr>
<tr><td>5</td><td>20181106</td><td>221</td><td>21</td><td>4</td><td>242</td><td>0.086777</td></tr>
<tr><td>6</td><td>20181107</td><td>166</td><td>44</td><td>17</td><td>210</td><td>0.209524</td></tr>
<tr><td>7</td><td>20181108</td><td>145</td><td>29</td><td>6</td><td>174</td><td>0.166667</td></tr>
<tr><td>8</td><td>20181109</td><td>70</td><td>12</td><td>2</td><td>82</td><td>0.146341</td></tr>
</table>
</td>
</tr>
<tr>
<td>⑦</td>
<td>Save HTML Button</td>
<td>Save HTML</td>
<td>Save data from the table of HTML format


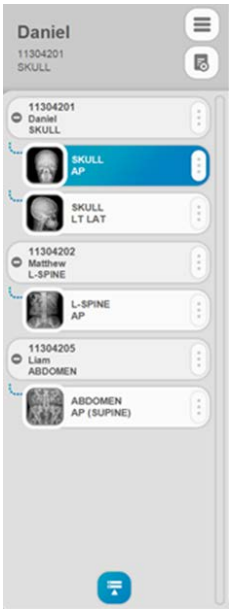
<table>
<tr><th>Daily</th><th>Normal</th><th>Reject</th><th>Retake</th><th>Total</th><th>Rate</th></tr>
<tr><td>20181101</td><td>103</td><td>20</td><td>7</td><td>123</td><td>0.162602</td></tr>
<tr><td>20181102</td><td>95</td><td>12</td><td>4</td><td>107</td><td>0.112150</td></tr>
<tr><td>20181105</td><td>279</td><td>46</td><td>11</td><td>325</td><td>0.141538</td></tr>
<tr><td>20181106</td><td>221</td><td>21</td><td>4</td><td>242</td><td>0.086777</td></tr>
<tr><td>20181107</td><td>166</td><td>44</td><td>17</td><td>210</td><td>0.209524</td></tr>
<tr><td>20181108</td><td>145</td><td>29</td><td>6</td><td>174</td><td>0.166667</td></tr>
<tr><td>20181109</td><td>70</td><td>12</td><td>2</td><td>82</td><td>0.146341</td></tr>
<tr><td>20181110</td><td>23</td><td>6</td><td>0</td><td>29</td><td>0.206897</td></tr>
<tr><td>20181112</td><td>199</td><td>49</td><td>8</td><td>248</td><td>0.197581</td></tr>
<tr><td>20181113</td><td>88</td><td>16</td><td>1</td><td>104</td><td>0.153846</td></tr>
<tr><td>20181114</td><td>119</td><td>36</td><td>5</td><td>155</td><td>0.232258</td></tr>
<tr><td>20181115</td><td>167</td><td>48</td><td>5</td><td>215</td><td>0.223256</td></tr>
<tr><td>20181116</td><td>52</td><td>14</td><td>9</td><td>66</td><td>0.212121</td></tr>
<tr><td>20181117</td><td>45</td><td>3</td><td>0</td><td>48</td><td>0.062500</td></tr>
<tr><td>20181119</td><td>198</td><td>48</td><td>10</td><td>246</td><td>0.195122</td></tr>
<tr><td>20181120</td><td>67</td><td>12</td><td>5</td><td>79</td><td>0.151899</td></tr>
<tr><td>20181121</td><td>89</td><td>11</td><td>0</td><td>100</td><td>0.110000</td></tr>
<tr><td>20181122</td><td>117</td><td>18</td><td>4</td><td>135</td><td>0.133333</td></tr>
<tr><td>20181123</td><td>64</td><td>11</td><td>0</td><td>75</td><td>0.146667</td></tr>
</table>
</td>
</tr>
<tr>
<td>⑧</td>
<td>Close Button</td>
<td>Close</td>
<td>Exit the ‘Reject Analysis’ program.</td>
</tr>
</table>

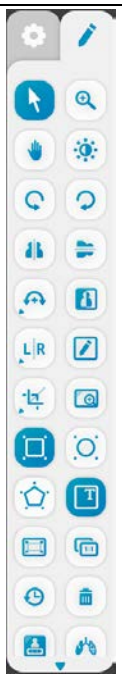
NOTE
In Statistics Graph mode, Reject Count includes ‘Retake Count’, but it does not include the ‘Retake Count’.

4.4.6 VIEWER

The current image is displayed at the center of the screen. Viewer menu offers various Image manipulation functions.

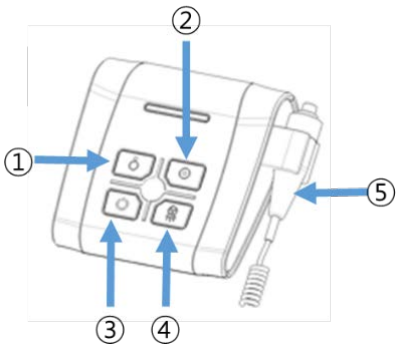


①	Procedure list		Patient Information. Study Information. Step Information. Basic operation of procedure list (Viewer menu) is same as Procedure menu, but the Viewer menu can open not only single study but also multiple studies for many patients. Viewer mode shows multiple patient ID and name on the step of procedure list. Please refer to the '4.4.4.1 Procedure List' section for more information.
②	Image Viewing		Display the Image viewing area. Please refer to the '4.4.4.2 Image Viewing' section

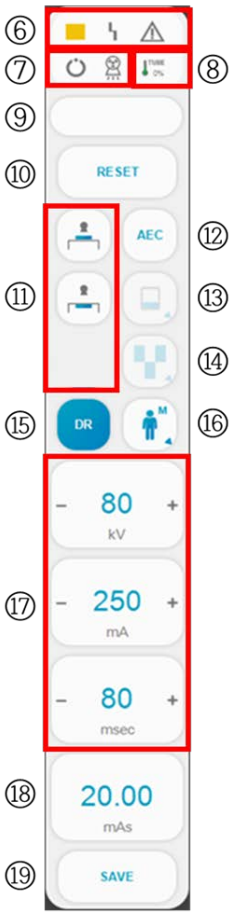
③	Admin ID button (Quick Login)	admin	Display Administrator list and quick login.
④	Toolbox		Offer the image edit functions. Please refer to the '4.4.4.3 Toolbox' section. The functions of toolbox on Viewer menu are same as Procedure Menu.
⑤	Image Full Mode		Enlarge the acquired image.
⑥	Built-In Memory Screen		Enter the built-in memory screen. Please refer to the 'APPENDIX J. Built-In Memory' Section for more information.

4.5 X-RAY CONTROL

NOTE
Symbol icons may differ depending on the X-ray Control Console.

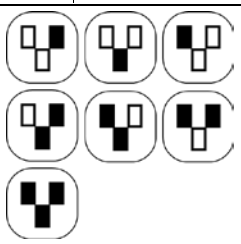
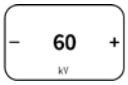


<PC Interface Module>



<RADMAX >

①	Power OFF Switch		Turn off the ***"DIAMOND"*** DR system.
②	Power ON Switch		Turn on the ***"DIAMOND"*** DR system.
③	Exp. Ready Switch		The X-ray tube will enter the prep mode
④	Exp. Switch		Make the exposure.
⑤	Exp. Hand Switch		The dead-man type exposure hand-switch
⑥	State Indicators		X-ray small focus Status display
			X-ray large focus Status display
			Warning Status display
			Error Status display
⑦	PREP and X-RAY EXPOSURE indicators		Lights up when X-ray exposure is ready.
			Lights up when X-rays are exposed.
⑧	Anode Heat Unit Indicator		Indicates the tube anode heat unit for the selected X-ray tube in percentage.
⑨	X-ray Generator Status Message Bar		This area shows generator status, warning, and error messages.
⑩	Error reset button		Use this menu to initialize the error.
⑪	Bucky selection & indicator		Non-Bucky Status display Usually means not used in Bucky and this can be assignable
			Bucky Status display
⑫	AEC selection & indicator		This menu allows you to control on/off operation of AEC.

⑬	Screen selection & indicator		Slow, Low Sensitivity
			Middle, Medium Sensitivity
			Fast, High Sensitivity
⑭	AEC field selection & indicator		This menu allows you to specify where the AEC will be applied. Field selection is possible within three fields, and minimum one field should be selected.
⑮	DR button		Exposure synchronization is enabled. Generator will x-ray expose when the detector gives Exposure signal.
⑯	Patient Body Size selection & indicator	 or 	When the patient size is selected, the X-ray conditions are changed to the APR conditions of the selected patient size.
⑰	Display X-ray Exposure Parameter.		KV set & indicator Press the '+' (Increase) or '-' (Decrease) button to control the parameter.
			mA set & indicator Press the '+' (Increase) or '-' (Decrease) button to control the parameter.
			Exposure. Time set & indicator Press the '+' (Increase) or '-' (Decrease) button to control the parameter.
⑱	mAs Indicator		Display mAs value.
⑲	Save Button		The current X-ray conditions are stored in the APR conditions of the selected patient size.

NOTE
Each selection button lights when selected, and turns off when selected again.

WARNING
Wrong selection by the operator may result the reexamination of the patient.

NOTE
When AEC is selected, it is changed to a density indication instead of the exposure time set & indicator. The density range is -8 to +8. This varies the optical density by changing the dose.

4.5.1 POWER ON/OFF CONTROLS

	Power ON Switch	Press Power ON Switch of PC interface module to turn on the ***"DIAMOND"*** DR system. Around 10 seconds late, all data will display normally if there is no problem on turning on.
	Power OFF Switch	Press Power OFF Switch of PC interface module to turn off the ***"DIAMOND"*** DR system.

When pressed **'Power ON Switch'**, all front panel LEDs and indicators, including the X-ray exposure indicator should light shortly. This is an LED self-test and does NOT indicate the presence of X-RAYS. Immediately after light blinks, stand-by indicator will light on.

NOTE
Press the button to continue if any error messages are presented.

4.5.2 PROCEDURE DISPLAY

The procedure display window displays information of selected procedure in imaging software for examination.

4.5.3 PREP, X-RAY EXPOSURE CONTROLS AND INDICATOR / DISPLAY

X-rays can be exposed using the **'Exp. Ready Switch'**, **'Exp. Switch'**, and **'Hand switch'** in the PC Interface Module.

Press and hold the **'Exp. Ready Switch'** to spin the rotor. X-ray Generator Status Message Bar displays 'x-ray preparation' message.

X-ray Preparation···
<X-ray Generator Status Message Bar >

The 'prep indicator will light on and the X-ray Generator Status Message Bar will display 'X-ray exposure ready' message when the system is ready to make an exposure.

X-ray Exposure Ready
<X-ray Generator Status Message Bar >

While pressing the **'Exp. Ready Switch'**, press and hold the **'Exp. Switch'** to make an X-ray exposure.

The 'X-ray exposure indicator will light on and the X-ray Generator Status Message Bar will display 'X-ray exposure' message when X-ray exposure is being made.

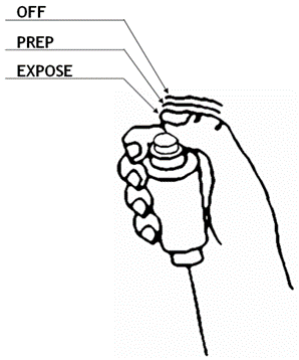
X-ray Exposure
<X-ray Generator Status Message Bar >

After the exposure, X-ray Generator Status Message Bar displays 'X-ray exposed' message for 1 second.

X-ray Exposed
<X-ray Generator Status Message Bar >

NOTE

The **'Exp. Hand Switch'** has an alternate function of **'PREP/EXPOSE'** buttons. The dead-man type **'Exp. Hand Switch'** is located at side of the control console. To use the switch, release from the switch holder and press the buttons following operating sequences as below.



NOTE

Pressing the **'Exp. Switch'** only will cycle the generator through prep and then exposure.

NOTE

Be sure to confirm the completion of X-ray exposure before releasing the hand switch for exposure. If you release the hand switch during X-ray exposure, X-ray exposure is stopped and an appropriate image may not be acquired.

4.5.4 RADIOGRAPHY CONTROLS AND DISPLAY

- X-ray parameters set & indicator

Increase or decrease the x-ray parameters.

kV, mA, exposure time, Density

- Console display Density (Range: -8 to +8) when AEC is selected.

- AEC selection & indicator

Pressing AEC button allows operator to use AEC function.

Selected button lights up and previous AEC field combination & screen speed used before is selected automatically.

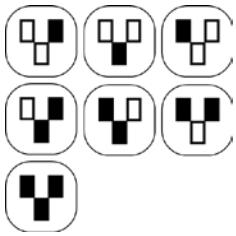
- Screen selection & indicator

If the AEC feature is saved to be used with Procedure, the selection of APR will automatically select stored Screen speed and AEC field combination.

		Slow, Low Sensitivity
		Middle, Medium Sensitivity
		Fast, High Sensitivity

NOTE
When selecting each button, the adjacent indicator light is turned on. If you press the button while the light is on, the selection will be released.

- AEC field selection & indicator



AEC Field can be selected by pressing the specific field positions.
Once selected, the FIELD button will light on.
Field selection is possible within three fields, and minimum one field should be selected.
To cancel the selected field, press the field button once.

- Save Button

The current X-ray conditions are stored in the APR conditions of the selected patient size.
(kV, mA, exposure time, and Bucky information, field, scene speed, density)

- Focal Spot Size Indicator

RADMAX Software's x-ray generator support auto focal spot selection feature.

	Small focus
	Large focus

NOTE
Indicator of selected focus will blink and X-ray exposure is unavailable for 2 cases below. • When focal spot size has changed, generator requires filament preheat time for selected focus. Filament preheat time is about 4 seconds. • When X-ray exposed over 100mAs, generator requires cooling time of IGBT in proportional to mA step and mAs.

NOTE
"GXR", ***"GXR-C"*** series generators support auto focal spot selection feature which is controlled by a reference mA value accessible only to installation/service engineer.

- Anode Heat Unit Indicator

Console displays the tube anode heat unit in percentage.
An anode HU warning message will be displayed at programmed safety level; typically 75 % of the tube anode HU rating.
An anode HU Error message (E18) will be displayed at programmed safety level; typically 90 % of the maximum tube anode HU rating and exposures will be inhibited.

- Bucky selection & indicator

	Receptor 1	Usually means not used in Bucky and this can be assignable
	Receptor 2.	Usually, this button is used to Bucky.

NOTE
Each Image Receiver Selection Buttons can be assignable. When selecting each button, the adjacent indicator light is turned on. If you press the button while the light is on, the selection will be released.

WARNING
Wrong selection by the operator may result the reexamination of the patient.

- Patient Body Size selection & indicator

	Body Size 4	When the patient size is selected, the X-ray conditions are changed to the APR conditions of the selected patient size.
	Body Size 9	

NOTE
Body Size 9 is only applicable to TS-CSP.

NOTE
The 5 buttons added to Body Size 9 are preset buttons and can be renamed in settings. For body size setting, refer to "4.3.9.2 Optional Function Setting" section of “DIAMOND" service manual.

4.4.5 STATE MESSAGE DISPLAY

State message window displays state message, warning message and error message.

Normal	Displayed after initialized and indicate generator is normal.
X-ray Preparation…	Displayed when prep state is active.
X-ray Exposure Ready	Displayed when generator is ready to expose
X-ray Exposure	Displayed when x-ray exposure
X-ray Exposed	Displayed after x-ray exposure during 1 second

- Warning Message

Warning message is issued to warn the operator of generation of troubles which is not critical for the system operation except ‘HU Warning Level’.

Therefore, it is not necessary to press RESET button when Warning message appears.

When the Warning message is issued, warning indicator is turned on for 4 second before the message disappears.

Refer to Service Manual about warning messages.

- Error Message

It will display error messages during abnormal operation of the ***“DIAMOND”*** DR system.

When error occurs, error indicator is turns on with alarm sound.

Messages may be cleared by pressing the RESET button.

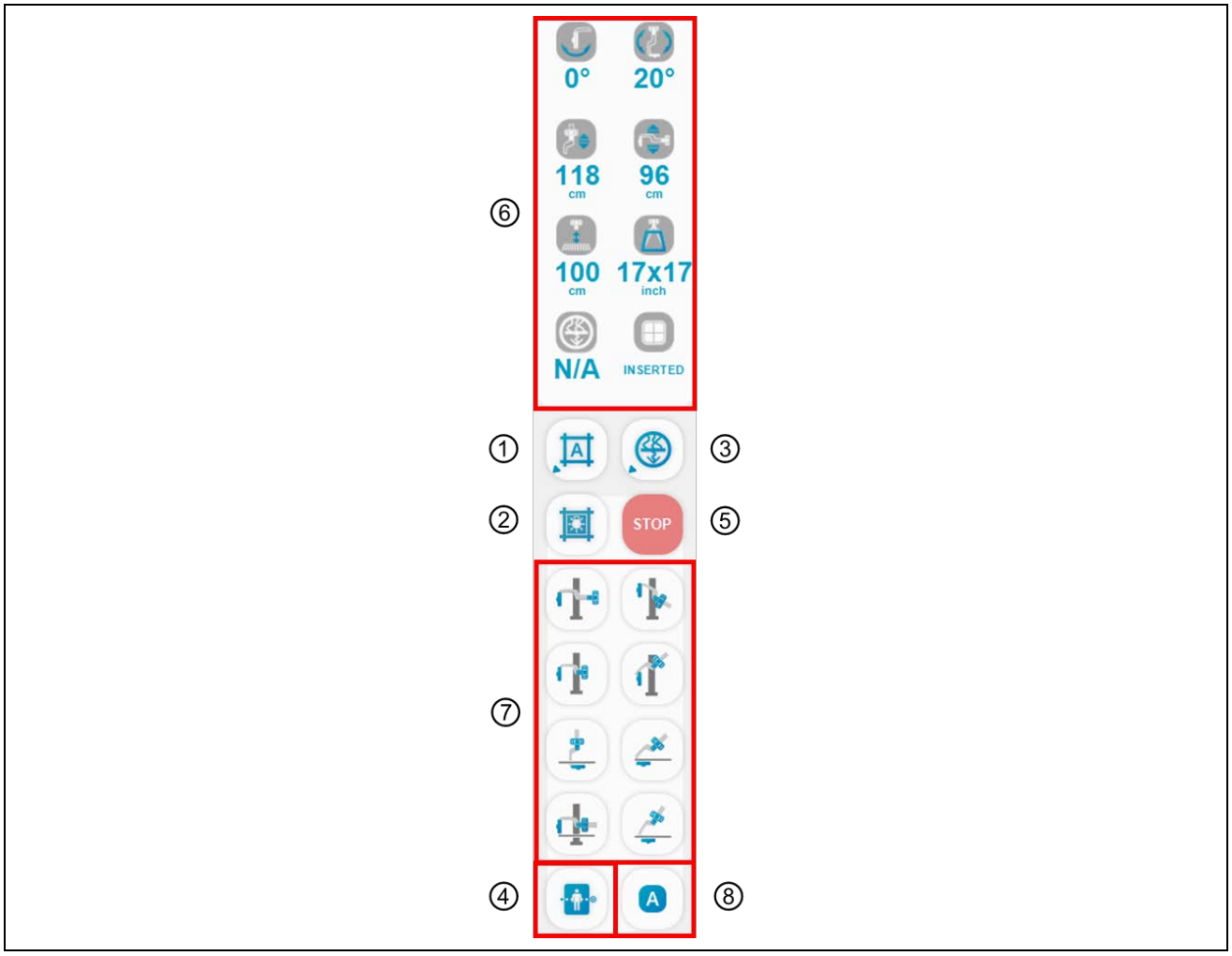
If the error message is not cleared or following corrective actions are not working, contact the service representative.

Refer to Service Manual about error messages.

CAUTION
Do not exceed the tube maximum operating limits. Intended life and reliability will not be obtained unless generators are operated within published specifications.

NOTE
Up to three (3) recent Error Messages are displayed.

4.6 CONSOLE CONTROL



①	Auto Collimation Size Selection Button		Choice the light field size of the collimator. (Only Auto Collimator)
②	Collimation Lamp On Button		Turn on the collimator lamp. (Only Auto Collimator)
③	Auto Filter Selection Button		Enter the Selection filter (None or 1.0mmAl or 0.1mmCu or 0.2mmCu)
④	Run Stitching Button		Enter the setting screen for the stitching function. (Refer to the '4.4.4.6 Image Stitch' section.)
⑤	Stand Move Stop Button		Stop the movement.
⑥	Stand Indicator		Detector rotation angel
			U-arm's rotation angle
			Distance from U-arm's center to tube.
			U-arm's vertical movement
			Grid type
			Collimation size
			Filter type
			State of insertion / removal of Detector in Detector Assay
⑦	Stand Move Preset Button		Move the radiography stand as shown by the icon.
⑧	APR stand move button		Auto button is for Moving stand position of Activated APR in step list.

NOTE

Each selection button lights when selected, and turns off when selected again.

NOTE

- **AUTO**: Set the collimation size stored in the database of the selected procedure step.
- **MANUAL**: Set the selected collimation size. Even if the procedure step is changed, the selected size remains unchanged.

NOTE

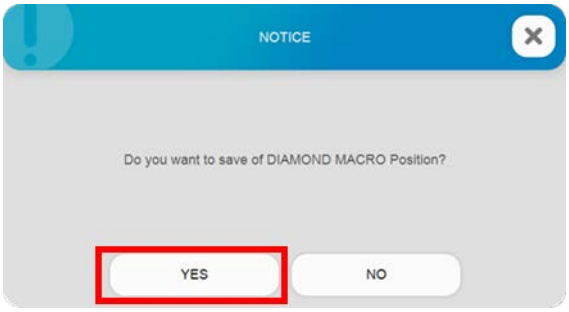
For selection filter when Special Collimator Filter option is ON. If Collimator Filter option is OFF, user can't selection filter and button for selection filter is disabled on Procedure mode.

Press the button to select Filter as below.

NOTE

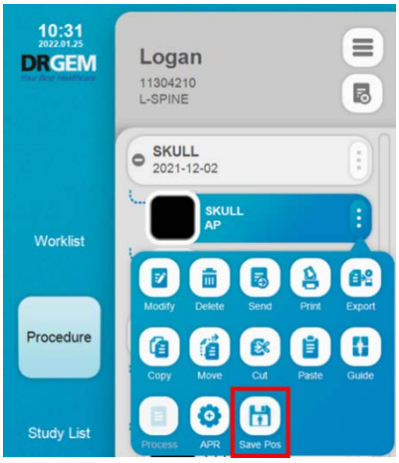
'Stand Move Preset' Button support registration of preset position data. The method follow the steps below.

1) Stand Positioning for save
2) Location mouse pointer on **'Stand Move Preset'** button.
   After done, it will be shown the message like the below. Clicked **'YES'** button.



NOTE

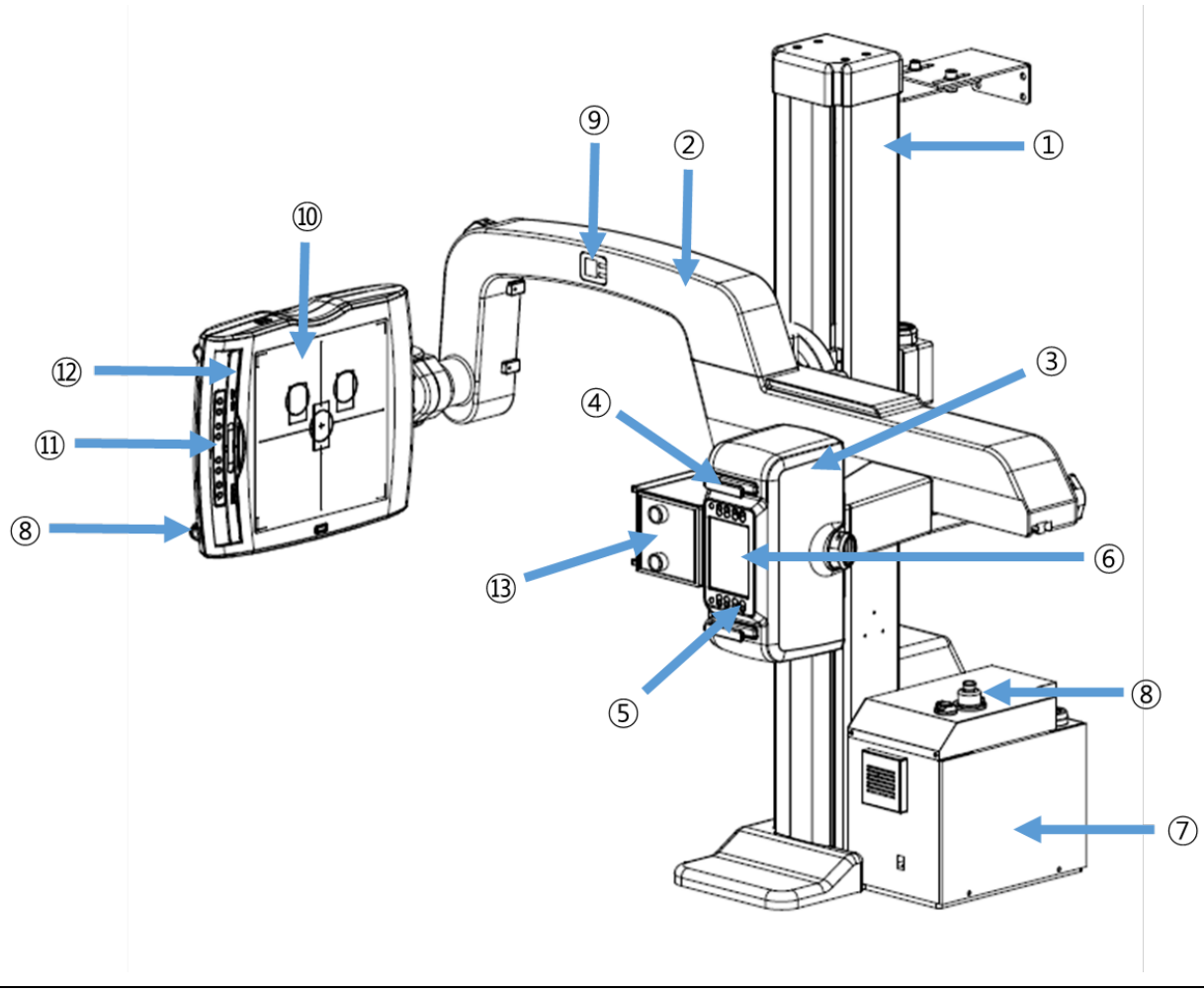
'Save Pos' button is for saving position information of APR. It is located inside step more group. User can save current position of activated APR in step list via this button.



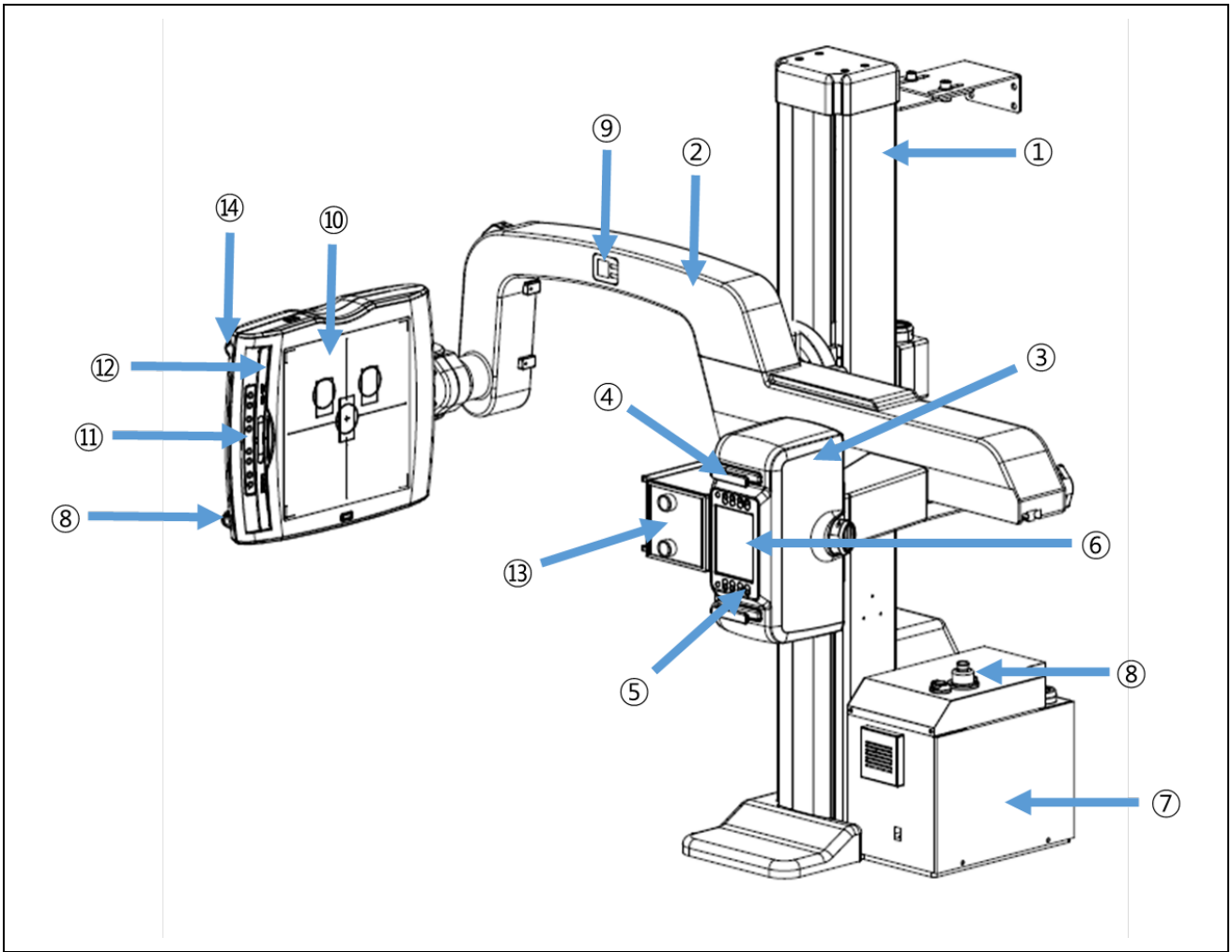
4.7 APPARATUS OPERATION

4.7.1 DIAMOND

- Parts Description



<Radiographic Stand>



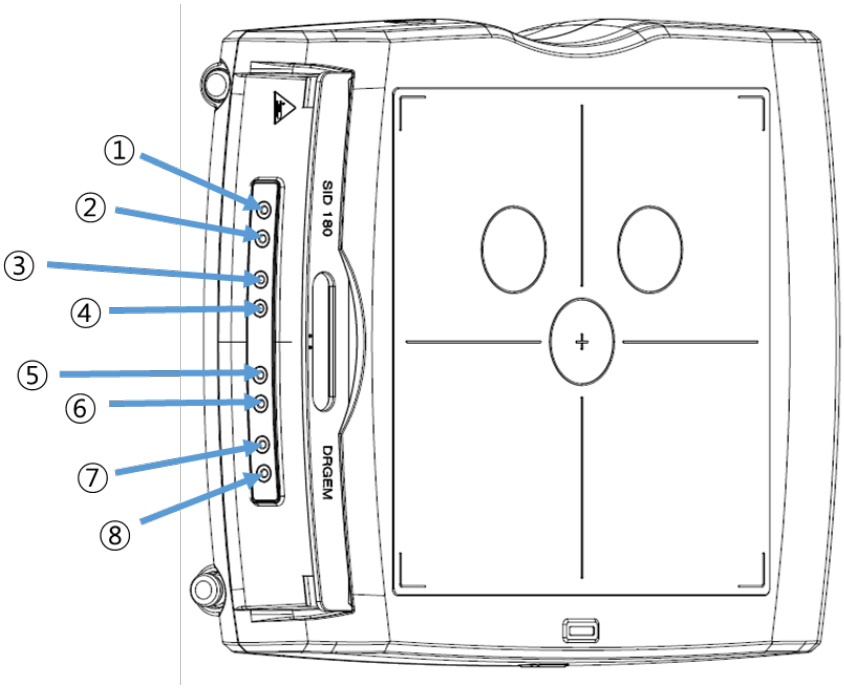
<Radiographic Stand (Wireless type)>

①	Stand Column	②	Swivel U-arm
③	Tube Cover	④	Tube Handle
⑤	Stand control membrane switch (Tube side)	⑥	Integrated Touch Screen Console
⑦	Stand Control Box	⑧	Emergency Switch
⑨	Angle Display Panel (Detector, Swivel U-arm)	⑩	Detector Assy.
⑪	Stand control membrane switch (Detector side)	⑫	Removable Grid
⑬	Motorized Automatic Collimator	⑭	Detector release switch

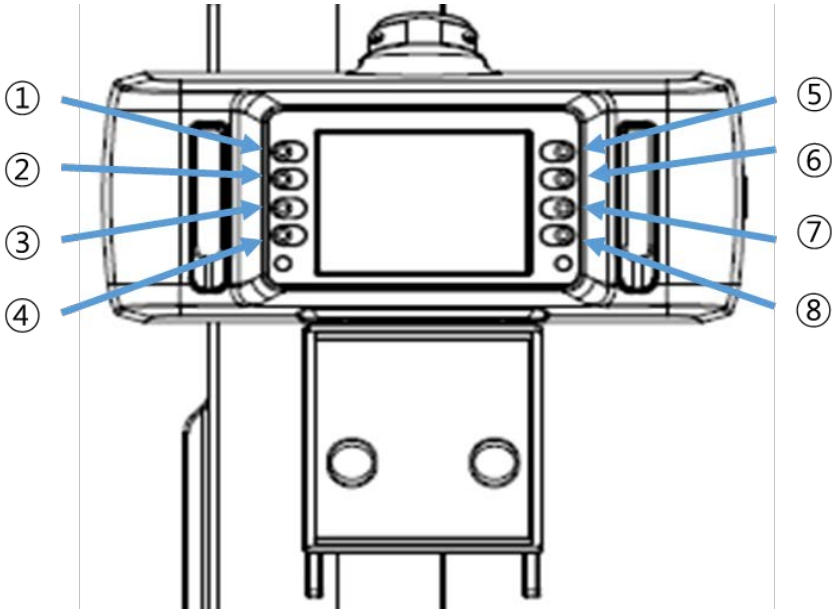
- Tube head Membrane & Detector Cover & Remote Controller

The control buttons for the electric control of the radiography stand are as follows.

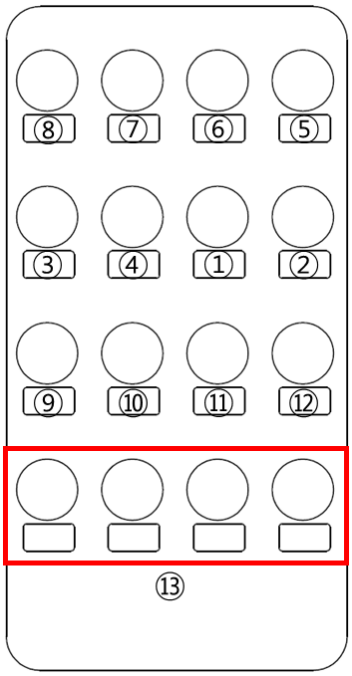
The radiography stand moves to the target position only while the button is pressed, and stops moving immediately when you release the button on the remote control.



<Detector Cover>



<Tube head Membrane>



<Remote Controller>

①	Control Button		Increase the U-arm height
②			Decrease the U-arm height
③			Increase SID
④			Decrease SID
⑤			Rotate U-arm to CW direction
⑥			Rotate U-arm to CCW direction
⑦			Rotate Detector to CW direction

⑧			Rotate Detector to CCW direction
⑨	Programmed Representative Position Selection Button		Move the radiography stand as shown by the icon.
⑩			Move the radiography stand as shown by the icon.
⑪			Move the radiography stand as shown by the icon.
⑫			Move the radiography stand as shown by the icon.
⑬			Specify the location of the radiography stand directly.

WARNING

Radiographic stand will not move although current position is inside the moving range with the cases like below.

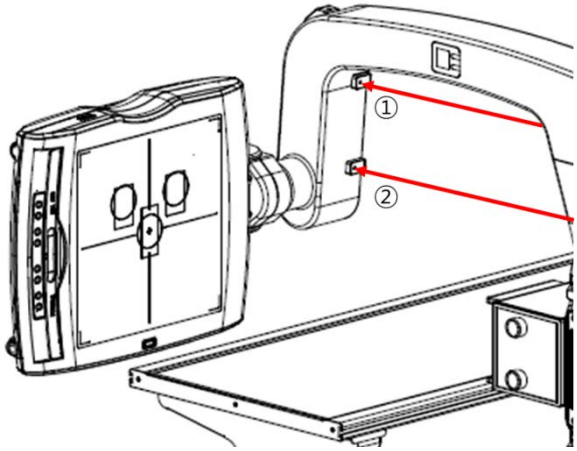
- If Current position is in the high or low limit of movement.
- If any one of safety sensors detect the obstacle on its sensing range.
- If the control distance or angle is over the range of remote controller when operator try to move the radiographic stand using remote controller.

NOTE

The GUI is automatically rotates corresponds to rotation angle of U-arm.

NOTE

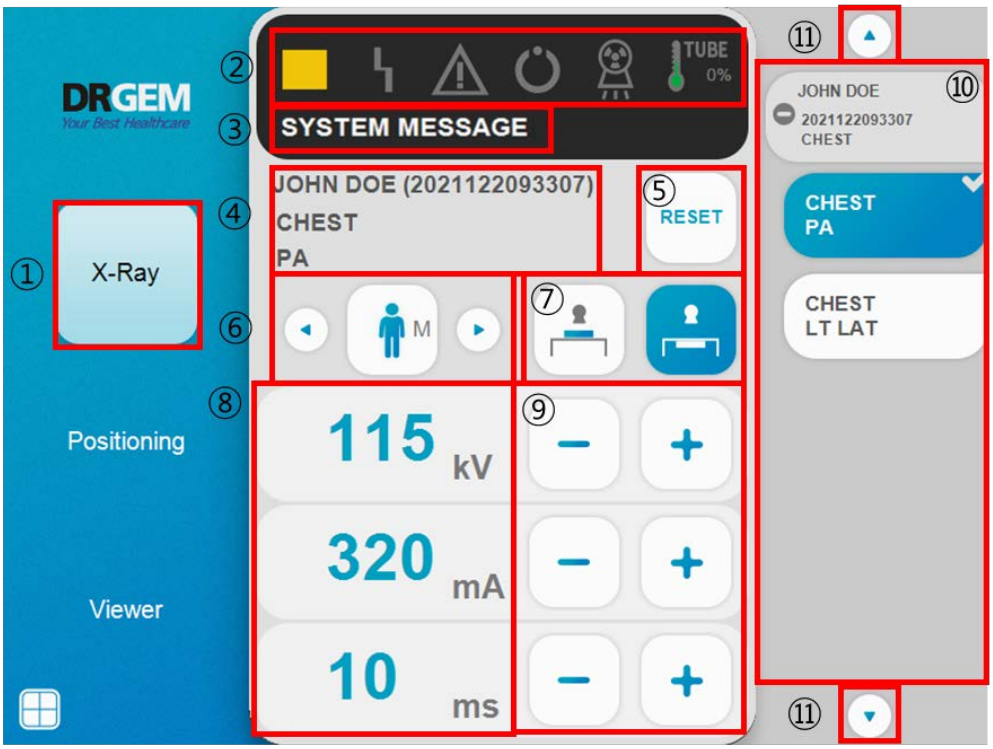
Among the nine safety sensors, two safety sensors which are located inside the U-arm detect the obstacle between these.



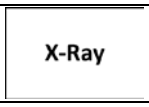
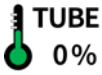
<Safety Sensors>

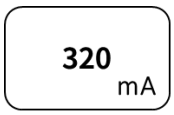
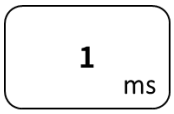
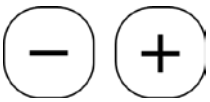
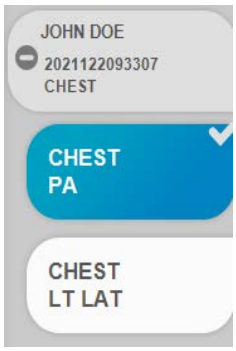
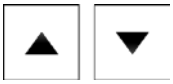
①	When Beam1 detect an obstacle, the movement speed will stop except increase the U-arm height.
②	When Beam2 detect an obstacle, the movement speed will lower.

- Tube head Membrane & Indicator (X-Ray Generator Control)



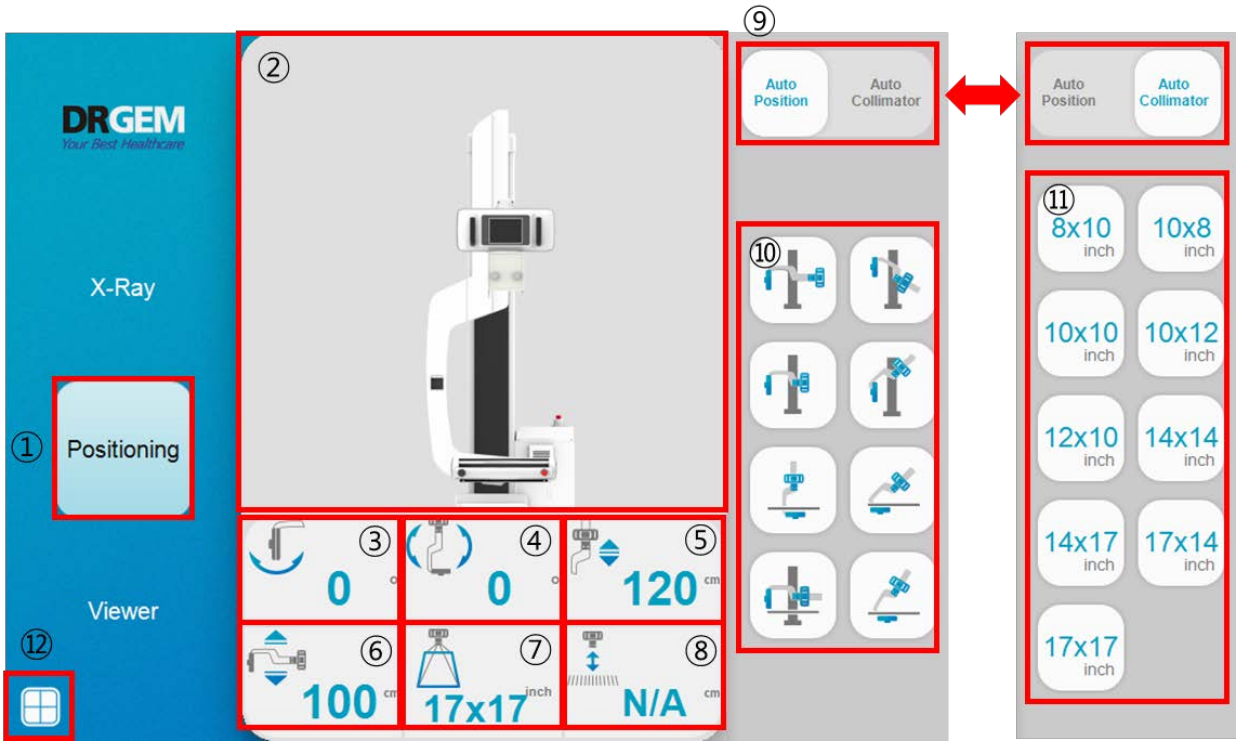
<X-Ray Screen>

①	X-Ray		The GUI for x-ray generator control of integrated touch screen console.
②	Indicator window		X-ray small focus Status display
			X-ray large focus Status display
			Warning Status display
			Error Status display
			Lights up when X-ray exposure is ready.
			Lights up when X-rays are exposed.
			Indicates the tube anode heat unit for the selected X-ray tube in percentage.
③	System message box		This area shows generator status, warning, and error messages.
④	Current Study Information window		Display the patient's name, patient's ID, description of exam and description of projection
⑤	Error reset button.		Use this menu to initialize the error.
⑥	Patient body size selection buttons		When the patient size is selected, the X-ray conditions are changed to the APR conditions of the selected patient size.
⑦	Bucky selection buttons		Use the detector
			Use other image receptor (IP for CR, film)

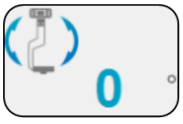
⑧	X-ray parameter display window		KV set & indicator
			mA set & indicator
			Exposure. Time set & indicator
⑨	kV, mA, exposure time(ms) parameter control buttons		Press the '+' (Increase) or '-' (Decrease) button to control the parameter.
⑩	Step list		Display steps of current study. If operator selects step on step list, change the conditions of x-ray for selected APR.
⑪	Step list Up, down scroll button		When the step list is full, move the scroll up and down.

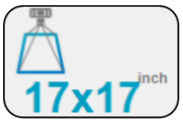
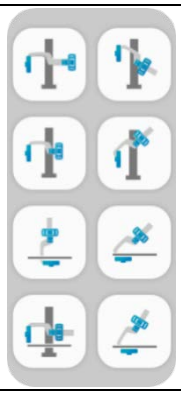
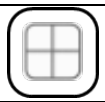
NOTE
Refer to the ***"RADMAX"*** Operation Manual for more information regarding X-ray control.

- Tube head Membrane & Indicator (Automatic Positioning Control)



<Positioning Screen>

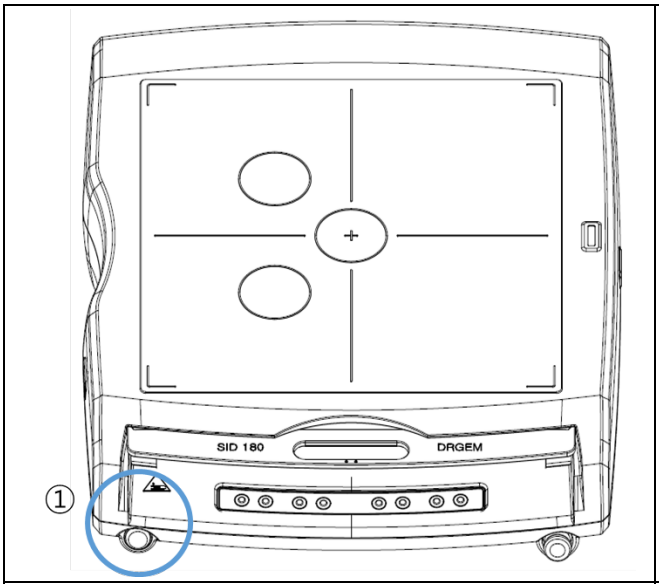
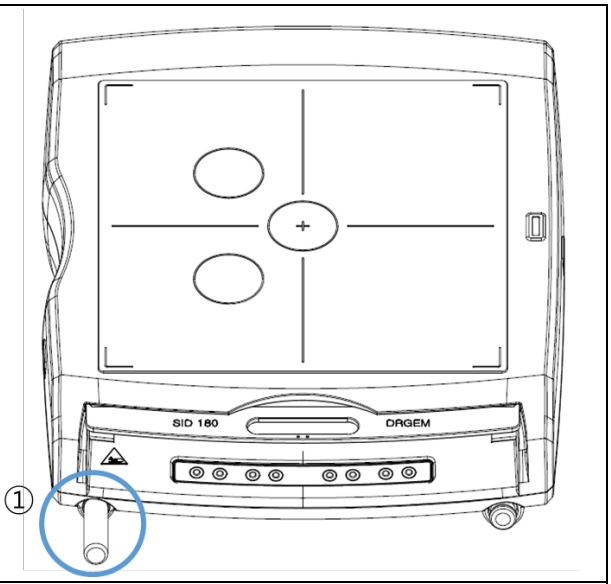
①	Positioning		Display the Radiographic Stand and X-ray Collimator Control Selection Menu and display Detector Insertion/Removal state.
②	Real time Stand Display Window.		Display the real time stand.
③	Detector Angle (degree)		Display the detector angle in real time.
④	Arm Rotation Angle (degree)		Display the arm rotation angle in real time.

⑤	Source to Detector Distance (cm)		Display the source to detector distance in real time.
⑥	Arm Height (cm)		Display the arm height in real time.
⑦	Collimation Size (ROI) (inch)		Display the collimation size.
⑧	Focal Distance of Inserted Grid (cm)		Display the focal distance of inserted grid
⑨	Auto Position and Auto Collimation Menu switching Tab		Select Auto Position (AP) Menu or Auto Collimation (AC) Menu.
⑩	Auto Position Buttons		Select the eight representative radiographic positions, and this will automatically make the target positioning with motorized movement.
⑪	Auto Collimation Buttons		Select the desired Auto Collimation size.
⑫	Detector state		Display the state of insertion / removal of Detector in Detector Assy.

NOTE
In order to stop the motorized movement, push any buttons of tube side or detector side or touch tube touch panel on positioning mode. This action will stop the movement and cancel the order.

1. Detector Insert & Release

When detector assay is removal type, the detector release switch exists for removal of detector from detector assay.

	
<Detector Off>	*<Detector On>*

①	Detector Release Switch	-	When the detector is inserted, the switch comes out and the Status Indicator of the detector is turned on. Press the switch to release the detector, and the indicator turns off.

NOTE
If detector is removed or direction of grid is reverse, a warning message 'W6A: UKY_FAIL_SAFE_WARNING' is displayed in the X-ray mode of the ***"RADMAX"*** imaging software. Operator can't expose X-Ray. If operator clicks **'Reset'** button, state of generator about warning is reset.

2. Automatic Collimation Control

There are mostly used x-ray field sizes on screen, and operator can select collimation size by one touch.
After collimation is completed, collimation light will turns on to indicate the collimation area to operator.
X-ray collimation size will be controlled by programmed data of selected procedure in imaging software.
If one x-ray collimation size is selected, this size will be automatically maintained by motorized control even though SID is varies by operator's manual control.
Operator also control the x-ray field size by manually rotate the knobs in front of the x-ray collimator, and can manually turns on and off the collimation lamp.

3. Removable High Resolution Grid

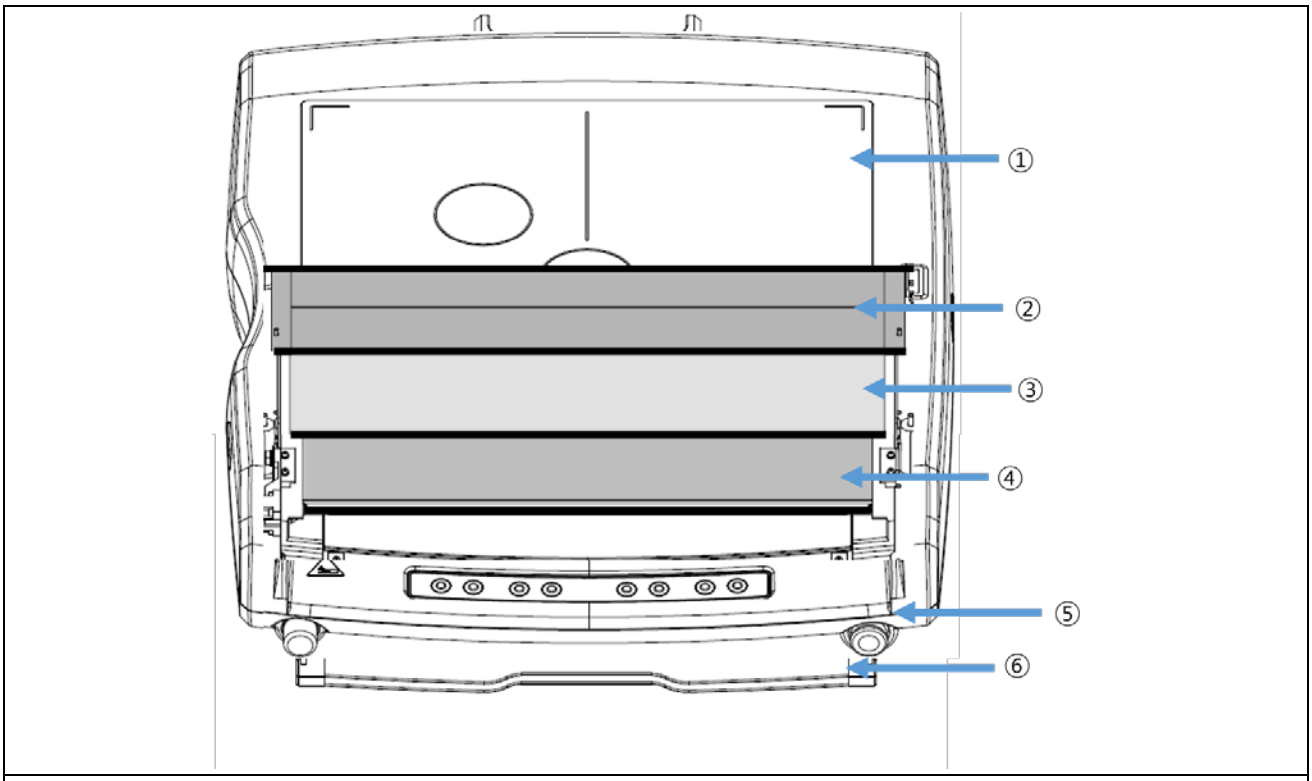
The ***"DIAMOND"*** DR System provides two removable high resolution grids for high quality radiographic imaging.
The focal distance of inserted grid will be displayed on LCD screen.

- If the SID is less than 140: Use the grid with 100cm focal distance.
- If the SID is more than 140: Use the grid with 180cm focal distance.
- The removable grids with other focal distance are can be provided by manufacturer with purchase order.

If there is no grid inside the detector assembly, or a grid that does not match the SID is inserted, the GUI displays a warning message.

There is spare grid holder in the rear side of detector assembly.
Insert the grid which is not used currently in this holder.

The picture below shows the structure of detector assembly.

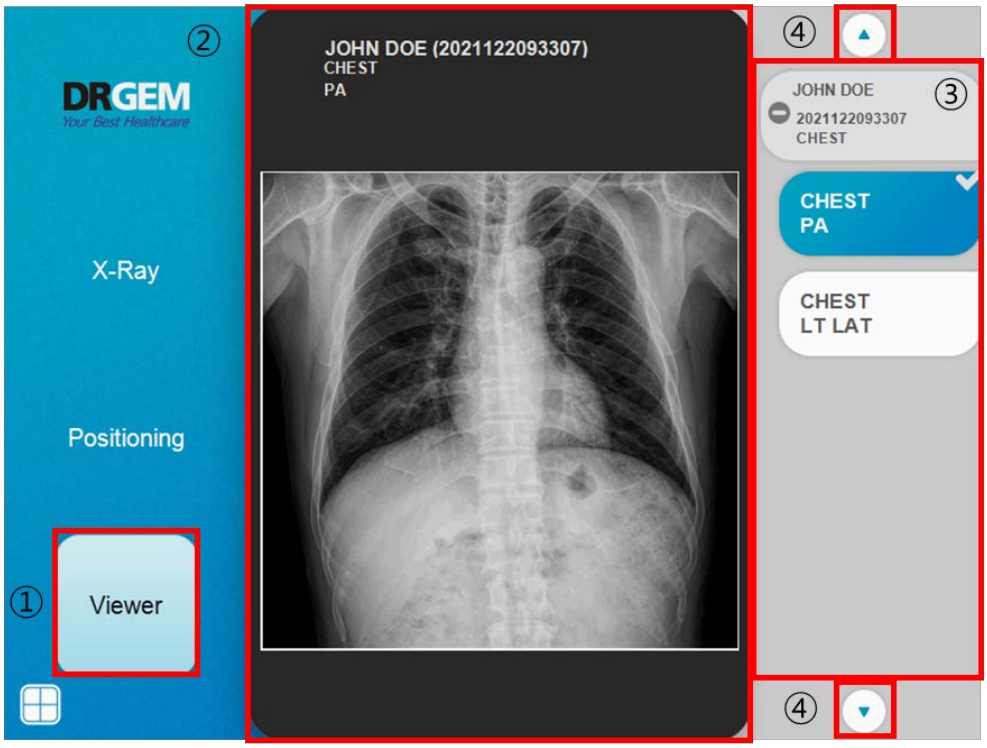


<Digital Detector Assembly>

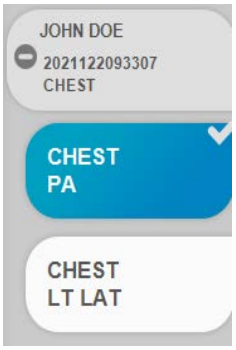
①	Front Cover	②	Removable Grid
③	AEC Ion Chamber	④	Digital Flat Panel Detector
⑤	Detector Case	⑥	Spare Grid Holder

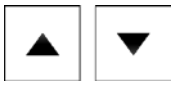
WARNING
Be caution during handle the grid to do not have damage on its surface.

- Tube head Membrane & Indicator (Step Viewer)



<Viewer Screen>

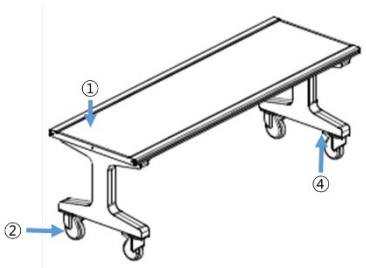
①	Viewer	Viewer	Display the acquired Image.
②	Image Viewing		Display the Image viewing area.
③	Step List		Display the step information The step list is synchronized with the step list in ***"RADMAX"*** imaging software.

④	Step List Up, Down Scroll Button		When the step list is full, move the scroll up and down.

NOTE
This function is for the simple confirmation of radiographic imaging, and detail image control or diagnosis should be done at the imaging workstation.

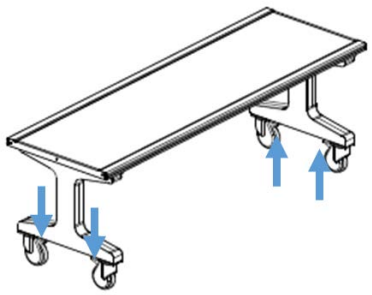
4.7.2 PATIENT TABLE (PDT-1)

- Parts Description

	①	Tabletop
	②	Caster
	③	Caster Lock Pedal

- How to use

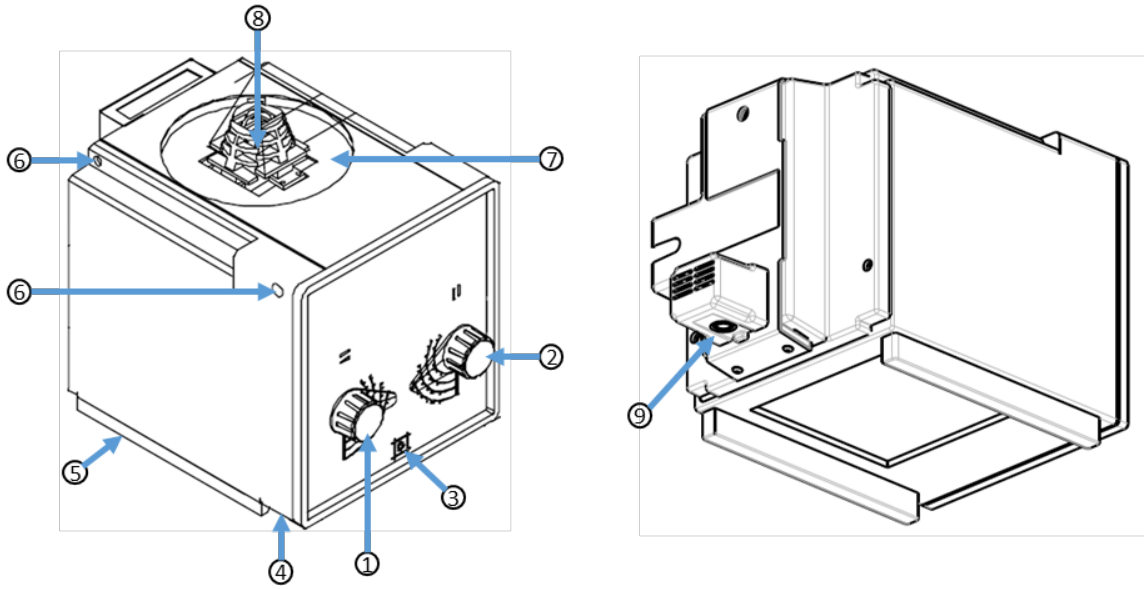
1. Move the table to the desired position and fix it using the Caster Lock Pedal (long side).



2. When the exposure is complete, after the patient gets off, Unlock using Caster Lock Pedal (short side) to move the table.

WARNING
During move the mobile patient table to radiographic stand, be caution to prevent the collision with any part of the radiographic stand.

4.7.3 COLLIMATOR

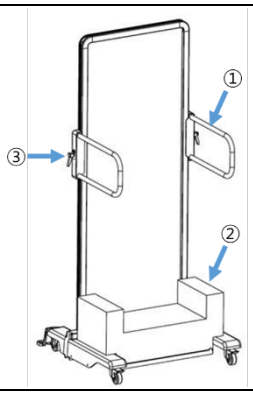


<R302A, R302MLP/A, R302MFMLP/A>

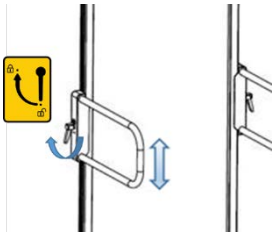
①	Lateral X-ray coverage control knob	②	Longitudinal X-ray coverage control knob
③	Collimation lamp on switch (30sec timer)	④	Beam out port
⑤	Rail for additional filter or beam limiter (cone)	⑥	Rotation fixing Bolt
⑦	Tube assembling area	⑧	Beam in port (optional near port shutters)
⑨	Live streaming camera (optional)		

4.7.4 STITCHING STAND

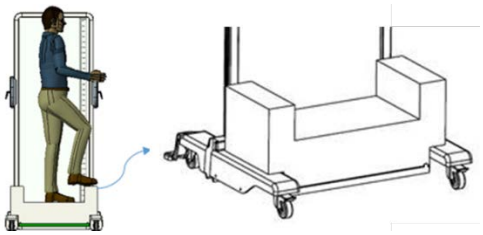
1. Position the patient in front of WBS-TA Stitching Stand

	①	Patient Handle-Bar(Height adjustable)
	②	Patient Foam Step
	③	Patient Handle-Bar Lock Lever

- Patient Handle-Bar (Height adjustable)
  - The handlebar can be height adjusted by operating the lever.



- Patient Foam Step
  - It is available in various direction as below.



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5. MAINTENANCE

The user must routinely check the X-ray equipment for apparent defects or damage. Report any apparent defects or irregular operation of any equipment to service personnel immediately, and discontinue use of the suspected faulty equipment until repairs are made. Continuing operation with faulty equipment may present various safety hazards, including risk of increased radiation.

WARNING
Maintenance should only be carried out by competent and trained personnel who are well aware of the potential risks associated with this equipment. Failure to do so may result in injury or equipment damage to the patient or user.

NOTE
Refer to the manuals of X-ray generator that accompany this unit for maintenance information on that part of the system.

NOTE
Due to varying operating conditions, the maintenance may have to be performed at greater or lesser intervals. It may adjust intervals according to system's performance.

WARNING
This equipment is NOT classified as anesthetic-proof and may ignite flammable anesthetics. Flammable agents used for skin cleaning or disinfecting may also produce an explosion hazard.

5.1 OPERATOR TASKS

Frequency of maintenance	What to Do	Who to Do It	Related Section
Every day after installation or as Required	DAILY X-RAY TUBE WARM-UP PROCEDURE	Operator	5.1.1
	Test of Emergency Stop Switch	Operator	5.1.2
	Checking the visible damaged and installed of DAP	Operator	5.1.7
Once a month after installation or as Required	Exposed Tracks	Operator	5.1.3
Every three months after installation or as Required	Apparatus operation	Operator	4.4
Every 6 months after installation or as Required	Clean External Surfaces	Operator	5.1.3
	Clean Grid Surface	Operator	5.1.4
	Tube Head Membrane Checks	Operator	5.1.5
Every 1 years after installation or as Required	Checking the visible damaged components	Operator	5.1.5
	Replacing the remote controller battery	Operator	5.1.8
whenever a related certifiable X-ray component is replaced, when not used for several days	Tube Seasoning	Operator	5.1.6
As required or when the remote control does not work	Remote control battery replacement cycle	Operator	5.1.8

5.1.1 DAILY X-RAY TUBE WARM-UP PROCEDURE

WARNING
The following procedure produces x-rays, which can cause tissue damage. Observe all safety precautions to protect personnel.

Use this procedure when the generator has not been used for several days. This procedure provides for exposures at medium power before the tube is used at maximum mA or kV values. This will reduce the possibility of damaging the anode and high voltage components. No test setup is required.

For maximum stability and reliability, use the following techniques at start up:
Select the following:

- Large focal spot.
- 80 kV.
- Normal 50/60 Hz anode rotation.

For a 300 kHU to a 400 kHU tube, use approximately 80 mAs per exposure.
For a 200 kHU to 300 kHU tube, use approximately 64 mAs per exposure.
For a below 200 kHU tube, use approximately 50 mAs per exposure.

Depending on the X-ray tube power rating, select either 100 mA or 200 mA.

Make three to five exposures (depending on tube loading) at 30 second intervals.

5.1.2 TEST OF EMERGENCY STOP SWITCH

Emergency stop switches should be checked regularly to prevent the risk of collisions, injury to the patient or operator, or damage to the system.

After pressing the Emergency stop switch, check that all system drives are shut down and stop moving immediately.

Check the normal operation of the emergency stop switch and turn it clockwise to release it.

5.1.3 CLEANING EXTERNAL SURFACES

- Tools Required:
  - cleaning wipes
  - non-abrasive, hospital-grade cleaner

Use cleaning wipes and non-abrasive, hospital-grade cleaner to clean external surfaces of ***"DIAMOND"*** DR System

- Ensure the power has been disconnected before starting any cleaning operation.
- Ensure no liquid gets into the unit.
- Do not immerse the equipment, including any components or accessories, in liquid.
- Do not autoclave the equipment, including any component or accessories.
- Do not use water. Water can short-circuit the electrical insulation and cause corrosion to mechanical parts.
- Do not use acid or abrasive products.
- Use only a dry cloth to clean chrome-plated parts.
- Only the surface areas of unit parts, including accessories and connection cables, should be disinfected using a gaseous disinfectant. For safety reasons, do not spray disinfectants.
- Clean painted parts with a cloth and products appropriate for cleaning plastic materials; after cleaning wipe the surfaces with a clean, dry cloth.
- Do not spray cleaning or disinfection solution directly on the equipment. To disinfect, moisten a cloth with a 70% Isopropyl alcohol solution or equivalent and wipe the surface of the equipment.
- When disinfecting the examination room, ensure the unit is covered with plastic sheets.

5.1.4 CLEANING GRID SURFACE

- Tools Required:
  - Dry cloth

Use a cloth to wipe off any dust build-up or any other foreign material.

- Ensure the power has been disconnected before starting any cleaning operation.
- Ensure no liquid gets into the unit.
- Do not immerse the equipment, including any components or accessories, in liquid.
- Do not autoclave the equipment, including any component or accessories.
- Do not use water. Water can short-circuit the electrical insulation and cause corrosion to mechanical parts.
- Do not use acid or abrasive products.
- Use only a dry cloth to clean the bucky and detector
- For safety reasons, do not spray disinfectants.

5.1.5 TUBE HEAD MEMBRANE CHECKS

The user must routinely check the X-ray equipment for apparent defects or damage. Report any apparent defects or irregular operation of any equipment to service personnel immediately, and discontinue use of the suspected faulty equipment until repairs are made. Continuing operation with faulty equipment may present various safety hazards, including risk of increased radiation.

1. Check all visual displays (warning and status lights, technique displays and indicators, etc) and components for normal operation.

2. Check all audible indicators for normal operation, and check that the loudness settings are adequate for the environment.

3. Check all interconnect cables and connectors for damage.

5.1.6 TUBE SEASONING

Tube “seasoning” is particularly important for new tubes or tubes that have not been used for several days. This should be performed on each X-ray tube before attempting auto calibration, as an unseasoned tube may not operate properly at higher kV values without arcing. Refer to the X-ray tube manufacturer’s instructions, if available, for the tube conditioning or “seasoning” procedure. If the X-ray tube manufacturer’s instructions are not available, the following procedure may be used:

NOTE
The tube manufacturer’s recommended seasoning procedure, if available, must always be used in place of the following procedure.

NOTE
Low speed only exposures are recommended for the seasoning exposures, to prevent excessive heat build-up in the housing from the stator windings or the rotor bearings.

X-ray tubes that have not been used for more than 8 hours may suffer thermal shock if operated at high mA and kV without a warm-up procedure. A cold anode (Molybdenum) is very brittle and when suddenly heated over a small area may experience thermal cracking of the anode surface, eventually leading to permanent tube damage.

The procedure below is intended for seasoning an X-ray tube and, that does not need to be calibrated.

1. Season the tube at 70 kV by taking approximately 10 exposures of 200 mA and 100 ms.
   These exposures should be taken at the rate of approximately one every 15 seconds.

2. Season the tube at 100 kV by taking approximately 5 exposures of 160 mA and 100 ms.
   These exposures should be taken at the rate of approximately one every 15 seconds.

3. Season the tube at 120 kV by taking approximately 5 exposures of 100 mA and 100 ms.
   These exposures should be taken at the rate of approximately one every 15 seconds.

5.1.7 DAP METER

DAP meter has no user serviceable parts which can be classified as replaceable material. The power supply and cables can be changed at any time, since these components do not have any influence on the calibration.

DAP meter was designed to give long and reliable service and does not require special maintenance. In case one of the components becomes defective a repair should not be attempted but the faulty component once identified should be replaced by authorized and qualified service engineers. The respective part numbers are given in the system components section of ***"DIAMOND"*** DR System service manual.

Daily ensure that it is tightly installed and not damaged mechanically

NOTE
MAINTAINANCE DETAILS Refer to accompanying DAP meter manufacturer's manuals.

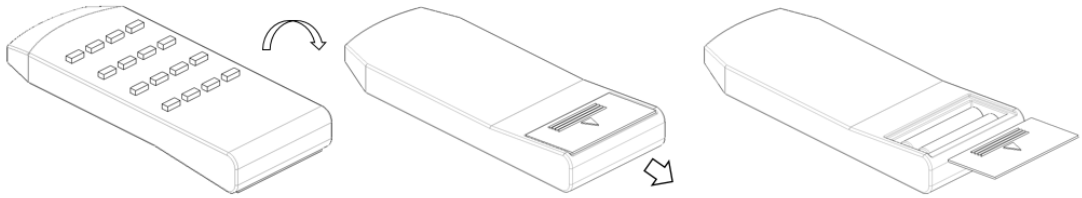
5.1.8 REPLACING THE REMOTE CONTROLLER BATTERY

- Tools Required:
  - LR03(AAA) battery - 2ea

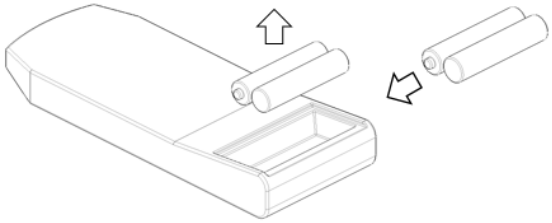
New batteries are not provided. Buy a battery of the same size and replace it.

Replace the battery by following the procedure below.

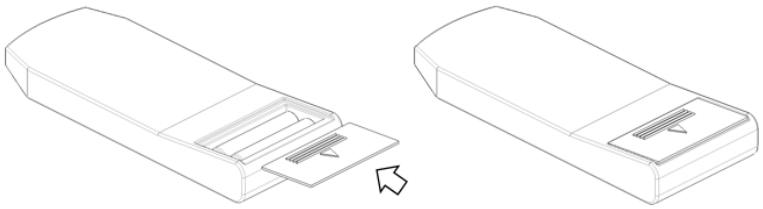
1. Turn the remote controller upside down to remove the battery cover.



2. Remove waste batteries and place new batteries in the same direction as before.



3. Close the battery cover and verify that the remote controller is functioning normally.



4. Waste batteries shall be disposed of at collection facilities or collection sites in accordance with the regulations.

5.2 THE END OF PRODUCT LIFE

If the generator has completed its useful service life, local environmental regulations must be complied with in regard to disposal of possible hazardous materials used in the construction of the generator.
In order to assist with this determination, the noteworthy materials used in the construction of this generator are itemized below:

ITEM

- Electrical insulating oil in HT tank. This is a mineral oil with trace additives (11 Liter)
- Counter weight in radiographic stand (lead)
- Solder (lead/tin).
- Epoxy fiberglass circuit board materials, tracks are soldering on copper.
- Wire, tinned copper. Insulated with PVC or silicone.
- Steel and / or aluminum (radiographic stand, generator cabinet, etc).
- Plastic (console enclosure and console membrane).
- Electrical and electronic components: IC's, transistors, diodes, resistors, capacitors, etc.

CAUTION

System components which are hazardous to persons or the environment must be disposed of with care and in compliance with all applicable national regulations.
Equipment bearing following symbol are subject to EC directive 2002/96/EC on waste electrical and electronic equipment (WEEE), amended by 2003/108/EC.

For details on equipment disposal, contact our official dealer or DRGEM Representative.

NOTE

Part of the components contains harmful substances which may pollute the ambient environment if disposed carelessly.
In particular, lead is contained in concentrations > 0.1 wt% in Radiographic Stand, X-ray tube and collimator.
For details on product disposal, contact our official dealer or DRGEM Representative.

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APPENDIX A. EXPOSURE TABLE

Table 1 following shows nominal exposure times resulting from pre-selected mAs and mA values.
Discrete values of loading factors were chosen from the series R'10 according to ISO 497.
This table also shows the range and interrelation of these loading factors. For example, if 20 mAs is selected at 200 mA, it can be seen that the exposure time will be approximately 100 ms. This is determined by reading down the 200 mA column to 20 mAs; then by reading the nominal exposure time 100 ms as shown at the left side of the table, along the 20 mAs row.

Table 2, following show the maximum exposure table without mA sliding down for each model.
Within these maximum regions, X-ray generation will be done with its rated levels only using the stored energy in the capacitor bank. The generator will enter the mA sliding down section above these levels and consume the line power in this region. mA level of mA sliding down section will be automatically selected from 10 to 20mA by the generator with referring the charge limit level and input line power status.

Exposure table may be photocopied as required and placed in a suitable location as per local requirements.

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GXR Series GENERATOR TECHNIQUE SELECTION

Time (ms)	mA Selected																				
	10	**12.5**	**16**	**20**	**25**	**32**	**40**	**50**	**64**	**80**	**100**	**125**	**160**	**200**	**250**	**320**	**400**	**500**	**640**	**800**	**1000**
1.0											0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0
1.2										0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25
1.6									0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6
2								0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0
2.5							0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5
3.2						0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2
4					0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0
5				0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0
6.4			0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4
8		0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8
10	0.1	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10
12.5	0.125	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5
16	0.16	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16
20	0.2	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20
25	0.25	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25
32	0.32	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32
40	0.4	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40
50	0.5	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50
64	0.64	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64
80	0.8	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64	80
100	1.0	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100
125	1.25	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125
160	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160
200	2.0	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200
250	2.5	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250
320	3.2	4.0	5.0	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250	320

Table 1: mAs values vs. mA & time selected

Table 1 continued on next page

Time (ms)	mA Selected																				
	10	**12.5**	**16**	**20**	**25**	**32**	**40**	**50**	**64**	**80**	**100**	**125**	**160**	**200**	**250**	**320**	**400**	**500**	**640**	**800**	**1000**
400	4	5	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250	320	400
500	5	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250	320	400	500
640	6.4	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250	320	400	500	
800	8	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250	320	400	500		
1000	10	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250	320	400	500			
1250	12.5	16	20	25	32	40	50	64	80	100	125	160	200	250	320	400	500				
1600	16	20	25	32	40	50	64	80	100	125	160	200	250	320	400	500					
2000	20	25	32	40	50	64	80	100	125	160	200	250	320	400	500						
2500	25	32	40	50	64	80	100	125	160	200	250	320	400	500							
3200	32	40	50	64	80	100	125	160	200	250	320	400	500								
4000	40	50	64	80	100	125	160	200	250	320	400	500									
5000	50	64	80	100	125	160	200	250	320	400	500										
6400	64	80	100	125	160	200	250	320	400	500											
8000	80	100	125	160	200	250	320	400	500												
10000	100	125	160	200	250	320	400	500													

Table 1 (Cont): mAs values vs. mA & time selected

kV/mA values are generator's output rating dependent.
mA/ms values are tube rating dependent.
For certain tubes, some mA/ms selections are not available at higher kV selections.

640mA is only available for output rating of x-ray generator from 52kW.
800mA is only available for output rating of x-ray generator from 68kW.
1000mA is only available for output rating of x-ray generator from 82kW

GXR-C GENERATOR TECHNIQUE SELECTION (Table 2)
GXR-C52 Maximum Exposure Table without mA sliding down

mA	kV	sec	mAs
10	40	10	100
	125		
	126	10	100
	150		
12.5	40	10	125
	125		
	126	10	125
	150		
16	40	10	160
	125		
	126	8	128
	150		
20	40	10	200
	110		
	111	8	160
	125		
	126	5	100
	150		
25	40	10	250
	100		
	101	6.4	160
	125		
	126	4	100
	150		
32	40	10	320
	70		
	71	8	256
	80		
	81	6.4	204.8
	100		
	101	5	160
	110		
	111	4	128
	125		
	126	3.2	102.4
	150		

mA	kV	sec	mAs
40	40	10	400
	60		
	61	8	320
	70		
	71	6.4	256
	80		
	81	5	200
	100		
	101	4	160
	110		
	111	3.2	128
	125		
	126	2.5	100
	150		
50	40	6.4	320
	60		
	61	5	250
	80		
	81	4	200
	90		
	91	3.2	160
	110		
	111	2.5	125
	125		
	126	2	100
	150		
64	40	5	320
	60		
	61	4	256
	70		
	71	3.2	204.8
	90		
	91	2.5	160
	100		
	101	2	128
	125		
	126	1.25	80
	150		

mA	kV	sec	mAs
80	40	4	320
	50		
	51	3.2	256
	70		
	71	2.5	200
	80		
	81	2	160
	100		
	101	1.6	128
	125		
	126	1	80
	150		
100	40	3.2	320
	50		
	51	2.5	250
	70		
	71	2	200
	80		
	81	1.6	160
	100		
	101	1.25	125
	110		
100	40	3.2	320
	50		
	51	2.5	250
	70		
	71	2	200
	80		
	81	1.6	160
	100		
	101	1.25	125
	110		
	111	1	100
	125		
	126	0.8	80
	150		
80	40	4	320
	50		
	51	3.2	256
	70		
	71	2.5	200
	80		
	81	2	160
	100		
	101	1.6	128
	125		
	126	1	80
	150		

mA	kV	sec	mAs
100	40	3.2	320
	50		
	51	2.5	250
	70		
	71	2	200
	80		
	81	1.6	160
	100		
100	101	1.25	125
	110		
	111	1	100
	125		
	126	0.8	80
	150		
125	40	2.5	312.5
	50		
	51	2	250
	70		
	71	1.6	200
	80		
	81	1.25	156.25
	100		
	101	1	125
	110		
	111	0.8	100
	125		
	126	0.64	80
	150		
160	40	2	320
	50		
	51	1.6	256
	60		
	61	1.25	200
	80		
	81	1	160
	100		
	101	0.8	128
	110		
	111	0.64	102.4
	125		
	126	0.5	80
	150		

mA	kV	sec	mAs
200	40	1.25	250
	60		
	61	1	200
	70		
	71	0.8	160
	90		
	91	0.64	128
	110		
	111	0.5	100
	125		
	126	0.4	80
	150		
250	40	1	250
	50		
	51	0.8	200
	70		
	71	0.64	160
	90		
	91	0.5	125
	110		
	111	0.4	100
	125		
	126	0.25	62.5
	150		
320	40	0.8	256
	50		
	51	0.64	204.8
	60		
	61	0.5	160
	80		
	81	0.4	128
	100		
	101	0.32	102.4
	110		
	111	0.25	80
	125		
	126	0.2	64
	150		

mA	kV	sec	mAs
400	40	0.5	200
	60		
	61	0.4	160
	70		
	71	0.32	128
	90		
	91	0.25	100
	110		
	111	0.125	50
	125		
	126	0.08	32
	130		
500	50	0.32	160
	70		
	71	0.25	125
	80		
	81	0.2	100
	90		
	91	0.16	80
	100		
	101	0.125	62.5
	104		
640	50	0.25	160
	60		
	61	0.2	128
	70		
	71	0.16	102.4
	81		

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APPENDIX B. MATTERS REQUIRING ATTENTION FOR SAFETY

B1. APPLICABLE STANDARDS

The main components of ***"DIAMOND"*** DR System comply with the regulatory requirements and design standards in this section as follows:

1) SAFETY

- EN60601-1:2006+A1:2013
  Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
  IEC60601-1:2005/A1:2012

- EN 60601-1-3:2008+A1:2013
  Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
  IEC 60601-1-3:2008+A1:2013

- EN60601-1-6:2010+A1:2015
  Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
  IEC60601-1-6:2010+A1:2013

- EN60601-2-28:2010
  Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
  IEC60601-2-28:2010

- EN60601-2-54:2009+A1:2015
  Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
  IEC60601-2-54:2009+A1:2015

2) EMC

- EN60601-1-2:2015
  Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
  IEC 60601-1-2:2014

3) CLINICAL EVALUATION

- MEDDEV 2.7/1 Rev.4
  EVALUATION OF CLINICAL DATA:
  A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

4) OTHERS

- EN ISO 15223-1:2021
  Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
  ISO 15223-1:2021

- IEC TR60878:2015
  Graphical Symbols for electrical equipment in medical practice

- IEC60417:2002DB
  Graphical Symbols for use on equipment-part1: overview and application

- EN ISO14971:2019
  Medical devices - Application of risk management to medical devices
  ISO 14971:2019

- EN ISO13485:2016
  Medical devices - Quality management systems - Requirements for regulatory purposes
  ISO13485:2016

- Regulation (EU) 2017/745
  Medical Devices Regulation

- EN ISO 20417:2021
  Information supplied by the manufacturer with medical devices
  ISO 20417:2021

- EN 62304:2006+A1:2015
  Medical device software — Software lifecycle processes
  IEC 62304:2006+A1:2015

- EN 62366-1:2015+A1:2020
  Medical devices - Application of usability engineering to medical devices
  IEC 62366-1:2015+A1:2020

B2. RADIATION

Radiation Effects

Acute Effects: Short term effects
Very large radiation exposures can kill humans. The lethal dose (LD) for half the population (50%) within 60 days is termed the $LD_{50/60d}$. The $LD_{50/60d}$ in humans from acute, whole body radiation exposure is approximately 400 to 500 rads (4-5 Gy). The temperature elevation in tissue caused by the energy imparted is much less than 1° C. The severe biological response is due to ionizing nature of X-ray radiation, causing the removal of electrons, and thereby chemical changes in molecular structures.

Deterministic Radiation Effects

A number of ionizing radiation effects occur at high doses. These all seem to appear only above a **threshold** dose. While the threshold may vary from one person to another, these effects can be eliminated by keeping doses below 100 rad. The severity of these effects increases with increasing dose above the threshold. These so-called deterministic (non-stochastic) effects are usually divided into tissue-specific local changes and whole body effects, which lead to acute radiation syndrome (Table below)

Acute Whole Body Radiation Effects

Table: Acute Radiation Syndrome Sorenson, 2000

Syndrome	Symptoms	Dose (rad)
Radiation sickness	Nausea, vomiting	> 100 rad
Hemopoietic	Significant disruption of ability t o produce blood products)	> 250 rad
$LD_{50/60d}$	Death in half the population	> 250 - 450 rad
GI	Failure of GI tract lining, loss o f fluids, infections	> 500 rad
CNS	Brain death	> 2,000 rad

These whole body (to entire body) doses are very unlikely for patients and staff from fluoroscopy or any diagnostic radiology study.

Several factors, such as total dose, dose rate, fractionation scheme, volume of irradiated tissue and radiation sensitivity all affect a given organ's response to radiation. Radiation is more effective at causing damage when the dose is higher and delivered over a short period of time. Fractionating the dose (i.e. spreading the dose out over time) reduces the total damage since it allows the body time for repair. Patient exposures are higher than attending staff but they occur over short periods of time whereas staff exposures are normally low and occur over several years.

***Deterministic effects*.**

These effects are observed after large absorbed doses of radiation and are mainly a consequence of radiation induced cellular death. They occur only if a large proportion of cells in an irradiated tissue have been killed by radiation, and the loss cannot be compensated by increased cellular proliferation. The ensuing tissue loss is further complicated by inflammatory 4processes and, if the damage is sufficiently extensive, also by secondary phenomena at the systemic level (e.g. fever, dehydration, bacteremia etc.). In addition, eventual effects of healing processes, e.g. fibrosis, may contribute to additional damage and loss of function of a tissue or an organ.

Clinical examples of such effects are: necrotic changes in skin, necrosis and fibrotic changes in internal organs, acute radiation sickness after whole body irradiation, cataract, and sterility (table below).

Doses required to produce deterministic changes are in most cases large (usually in excess of 1-2 Gy). Some of those occur in a small proportion of patients as side effects of radiotherapy. They can also be found after complex interventional investigations (such as vascular stenting) when long fluoroscopy times have been used.

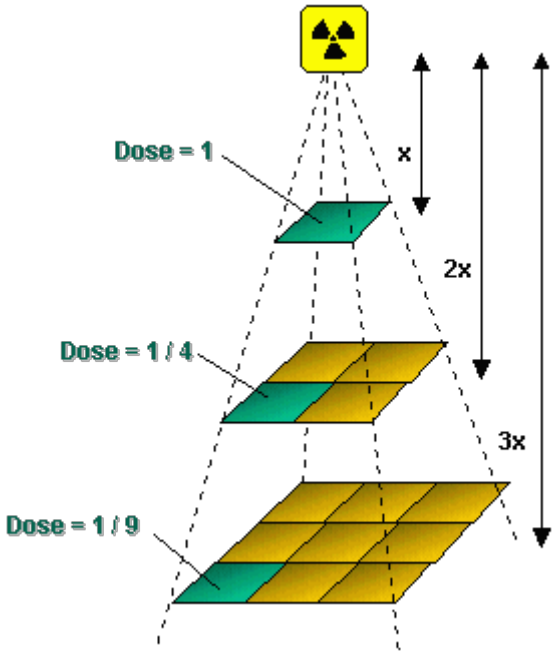
But in the case of our equipment, when using DIAMOND-8A, assuming that the maximum exposure condition value (82 kW) is irradiated for 0.5s (but, in reality, irradiation is less than 0.1s), it is 20.39mGy/s, so DIAMOND DR System is difficult to reach the Acute Radiation Effects risk level listed in the table below. Of the approximately 3 mSv annual global per caput effective dose estimated for the year 2000, 2.4 mSv is from natural background and 0.4 mSv from diagnostic medical exams. Therefore, it is difficult to reach the long-term radiation impact risk levels listed in the table below, but in the case of pregnant women, pediatric, or radioactive implant transplant patients, there is a possibility that radiation exposure may be dangerous, so caution is needed.

Table: Deterministic effects after whole-body and localized irradiation by X and gamma rays; approximate absorbed threshold doses for single (short-term) and fractionated or low dose-rate (long-term) exposures [5, 6]

Organ/tissue	Effect	Threshold absorbed dose Gy	
		Short-term exposure (single doses)	Long-term exposure (Yearly - repeated for many years)
Testicles	Temporal sterility permanent sterility	0.15 3.5 - 6.0	0.4 2.0
Ovaries	Sterility	2.5 - 6.0	> 0.2
Ocular lens Detectable	opacities Visual impairment (cataract)	0.5 - 2.0 5.0	> 0.1 > 0.15
Bone marrow	Haemopoiesis impairment	0.5	> 0.4
Skin	1. Erythema (dry desquamation). 2. Moist desquamation. 3. Epidermal and deep skin necrosis 4. Skin atrophy with Complications and telangiectasia	2 18 25 10-12	- - - 1.0
Whole body	Acute radiation sickness (mild)	1.0	-

Inverse square law

A bundle of X-rays corresponds to the shape of a cone, with the tube at its tip. The intensity or dose of the radiation emitted from the source of the X-ray beam diminishes with the square of its distance from the source. If you double the distance x, the dose changes by a factor of $1/(2^2)$, and if you triple it, the dose changes by a factor of $1/(3^2)$.



Distance	Relative dose
50	4.00
60	2.78
70	2.04
80	1.56
90	1.23
100	1.00
110	0.83
120	0.69
130	0.59
140	0.51
150	0.44
160	0.39
170	0.35
180	0.31
190	0.28
200	0.25

Fig: Inverse square law

In general, the dose amounts to $1/x^2$. Therefore, if you double the film-to-target distance, you will need four times as much radiation to achieve the same image blackening. If you did not change the patient's position, this would lead to radiation stress in the patient; thus, increasing the distance between X-ray tube and patient helps to reduce the dose.

B3. ELECTROMAGNETIC COMPATIBILITY (EMC)

The ***"DIAMOND"*** DR System complies with the requirements of IEC 60601-1-2:2014 regarding electromagnetic compatibility. Surrounding equipment shall follow the standard IEC 60601-1-2:2014.

CAUTION
Mobile telephones or other radiating equipment can interfere with the function of the ***"DIAMOND"*** DR System and can therefore cause safety hazards.

Guidance and manufacturer´s declaration - electromagnetic emissions		
The ***"DIAMOND"*** DR System is intended for use in the electromagnetic environment specified below. The customer or the user of the ***"DIAMOND"*** DR System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***"DIAMOND"*** DR System 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.
RF emissions CISPR 11	Class A	The ***"DIAMOND"*** DR System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer´s declaration - electromagnetic immunity			
The ***"DIAMOND"*** DR System is intended for use in the electromagnetic environment specified below. The customer or the user of the ***"DIAMOND"*** DR System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV Line to Line ± 0.5 kV, ± 1 kV, ± 2kV Line to	± 0.5 kV, ± 1 kV Line to Line ± 0.5 kV, ± 1 kV, ± 2kV Line to	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	0% U_T 0, 5 cycle at 0, 45, 90, 135, 180, 225, 270, 315 deg. 0% U_T 1 cycle at 0 deg. 70 % U_T 25(50Hz)/30(60Hz) cycles at 0 deg. 0% U_T 250(50Hz)/300(60Hz) cycles at 0 deg.	0% U_T 0, 5 cycle at 0, 45, 90, 135, 180, 225, 270, 315 deg. 0% U_T 1 cycle at 0 deg. 70 % U_T 25(50Hz)/30(60Hz) cycles at 0 deg. 0% U_T 250(50Hz)/300(60Hz) cycles at 0 deg.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DR- XD 200 requires continued operation during power mains interruptions, it is recommended that the ***"DIAMOND"*** DR System be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration - electromagnetic immunity

The ***"DIAMOND"*** DR System is intended for use in the electromagnetic environment specified below.

The customer or the user of the ***"DIAMOND"*** DR System should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ***"DIAMOND"*** DR System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{p}$ $d = 1,2\sqrt{p}$ 80 MHz to 800 MHz $d = 2,3\sqrt{p}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	

NOTE 1: At 80 Mhz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation i affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***"DIAMOND"*** DR System is used exceeds the applicable RF compliance level above, the ***"DIAMOND"*** DR System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***"DIAMOND"*** DR System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and *"DIAMOND"* DR System

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1,17\sqrt{p}$	80 MHz to 800 MHz $d = 0,35\sqrt{p}$	800 MHz to 2,5 GHz $d = 0,7\sqrt{p}$
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,17	0,35	0,7
10	3,69	1,11	2,21
100	11,67	3,5	7

For transmitters 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.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

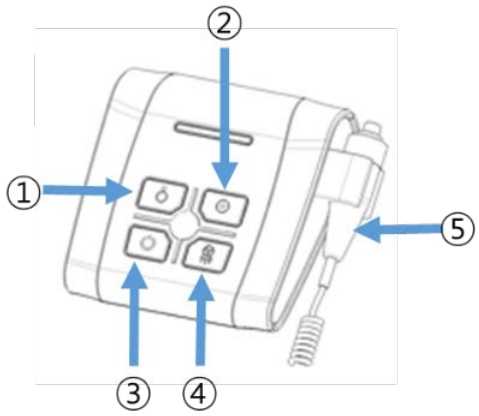
APPENDIX C. GENERATOR SETUP

This chapter describes the procedures for the generator setup.

For detector calibration, please follow the steps below.

1. If the ***"RADMAX"*** imaging software or GXR SDK is running, exit the ***"RADMAX"*** imaging software and GXR SDK.
   If the RadmaxConfiguration program is running, close the program.
   If the generator is powered on, power off the generator.

2. Turn on the generator power. Press the **'Power ON Switch'**.
   "RADMAX" imaging software provides generator interface module to control x-ray generator by the workstation.

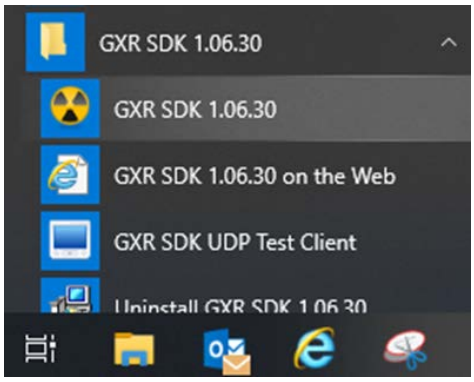


<PC Interface Module>

①	Power OFF Switch		Turn off the ***"DIAMOND"*** DR System.
②	Power ON Switch		Turn on the ***"DIAMOND"*** DR System. The console will light up and a brief self - check will be performed. If there is no problem, all data will be displayed normally a few seconds after power on.
③	Exp. Ready Switch		The X-ray tube will enter the prep mode
④	Exp. Switch		Make the exposure.

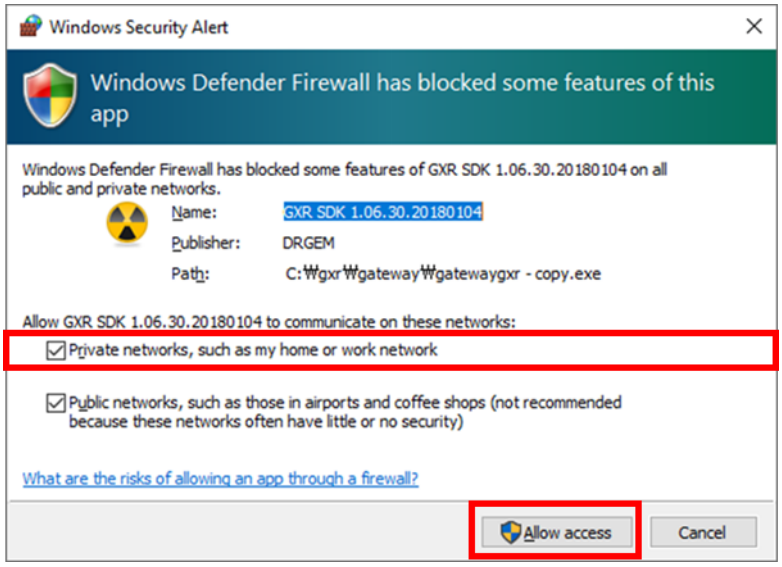
⑤	Exp. Hand Switch		The dead-man type exposure hand-switch

3. Run the GXR SDK from the Windows Start menu.

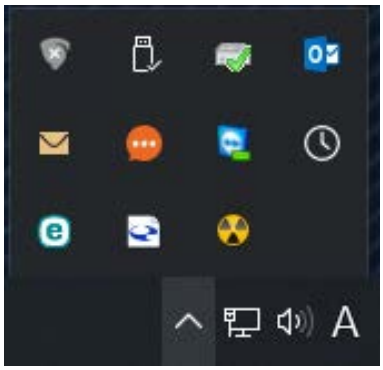


4. Following Windows Security Alert dialog appears.
   Please check **'Private networks, such as my home or work network'** option.
   And click on the **'Allow access'** button like below.

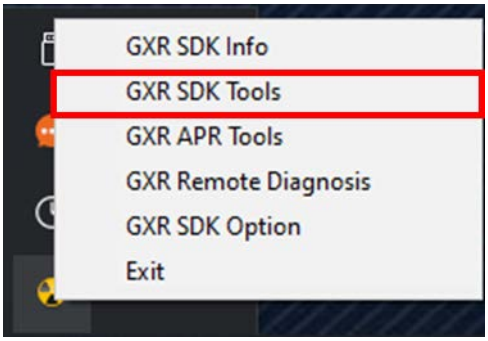
NOTE
If do not click the **'allow access'** button, the GXR SDK software may lead to communication failure.



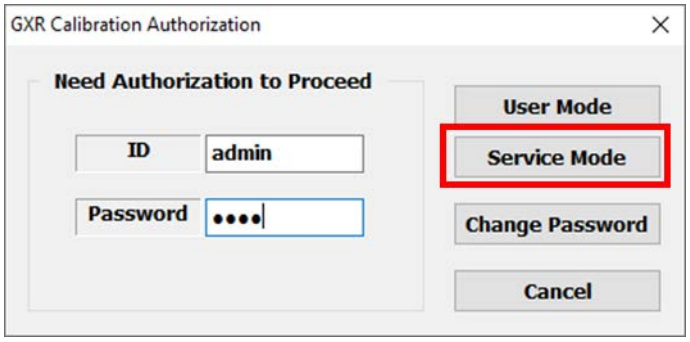
5. If the GXR SDK software is running, you can see the GXR SDK icon on the tray.



6. Click on the GXR SDK tray icon, you can see the GXR SDK pop-up menu.
   Select the '**GXR SDK Tools**' menu.

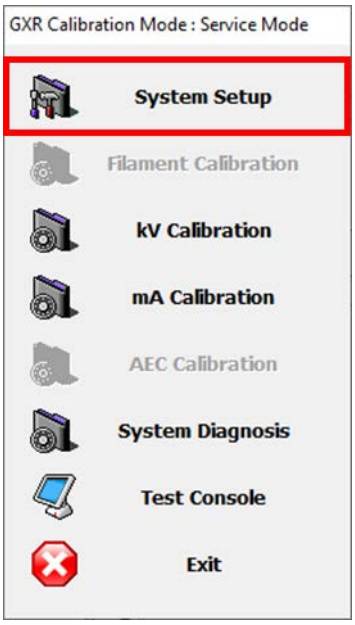


7. GXR Calibration Authorization dialog appears as shown below.
   Please input the following information (ID**: admin / Password: 1234**)
   And click on the '**Service Mode**' button.



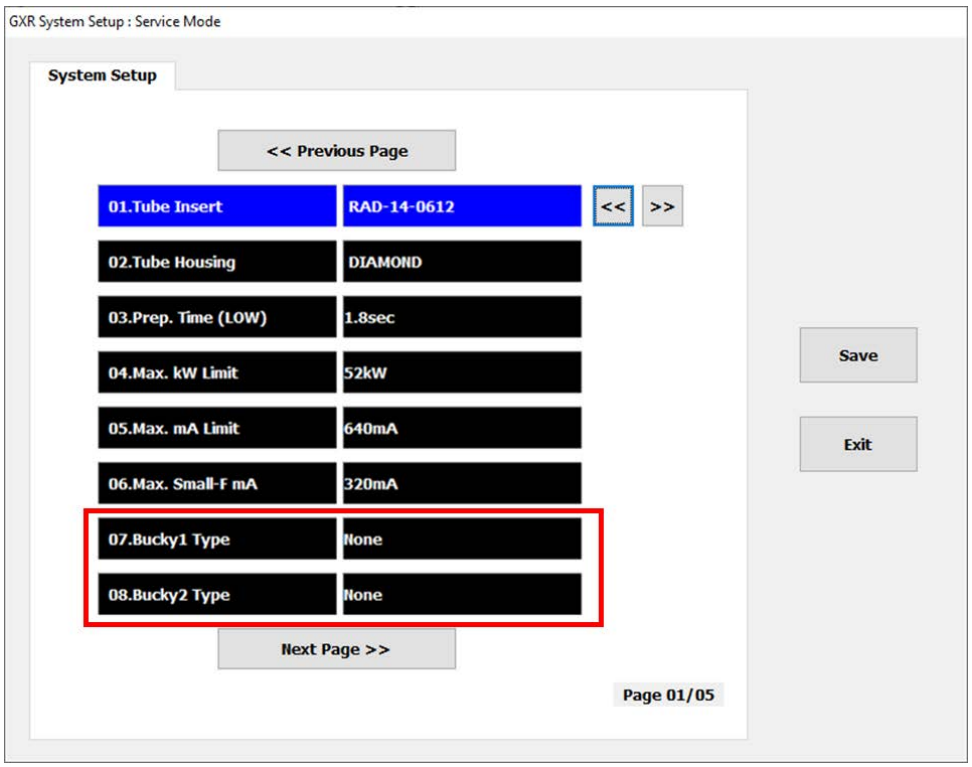
8. The following menu dialog will appear.

   Click on the '**System Setup**' menu.

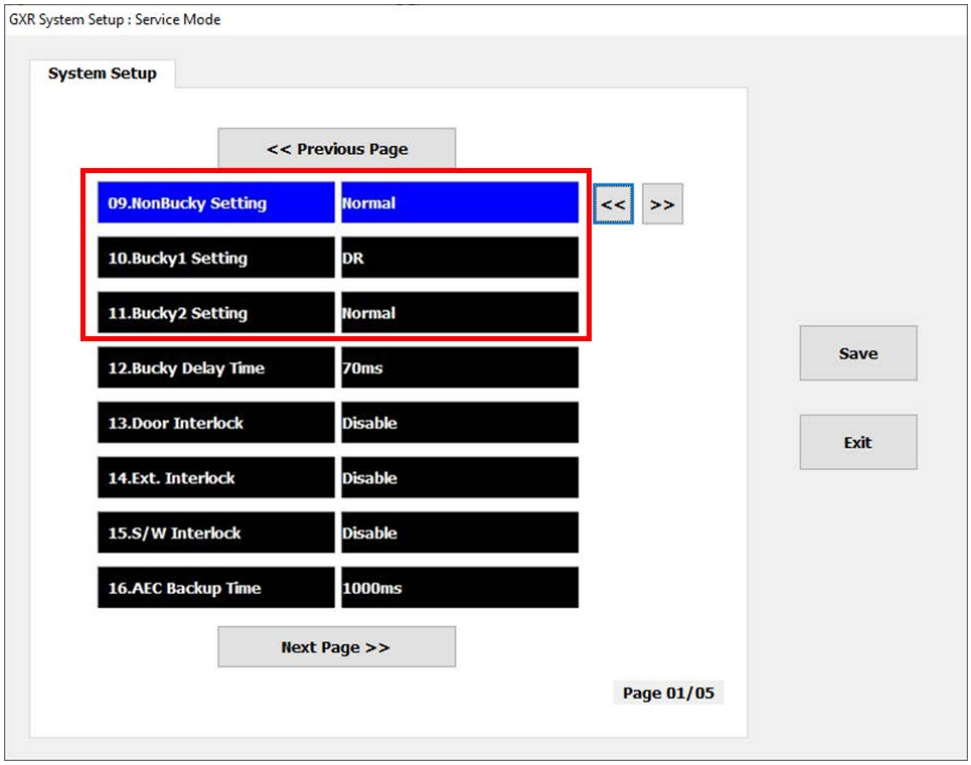


9. If the Tube Insert and Housing setting is not correct, please fix it.

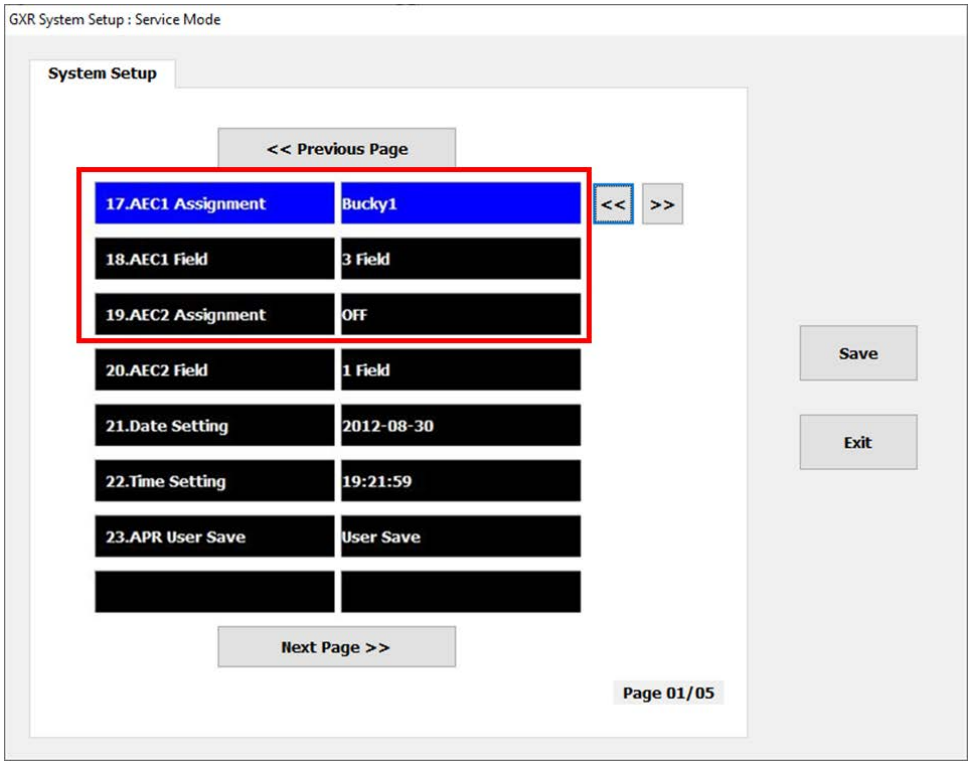
   Change '**Bucky1 Type**' and '**Bucky2 Type**' to '**None**' as shown below.



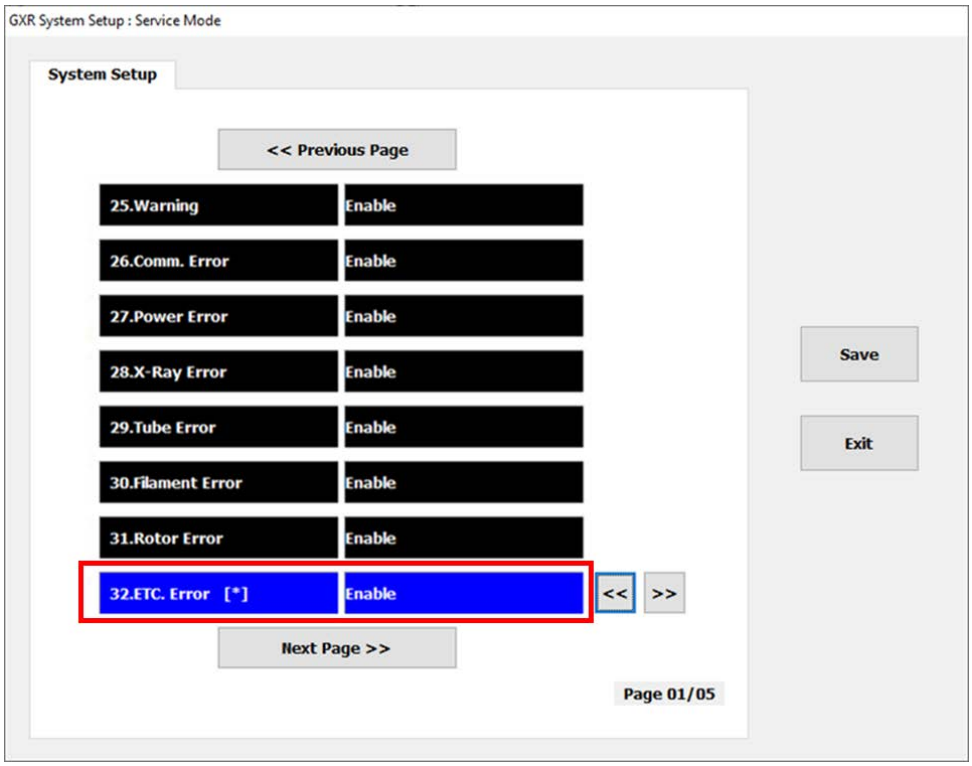
10. Change '**NonBucky Setting**' and '**Bucky2 Setting**' to '**Normal**' as shown below.
    Change '**Bucky1 Setting**' to '**DR**'.



11. Change '**AEC1 Assignment**' to '**Bucky1**' and '**AEC1 Field**' to '**3 Field**' as shown below.
    If there is second AEC chamber, change '**AEC2 Assignment**' to '**OFF**'.

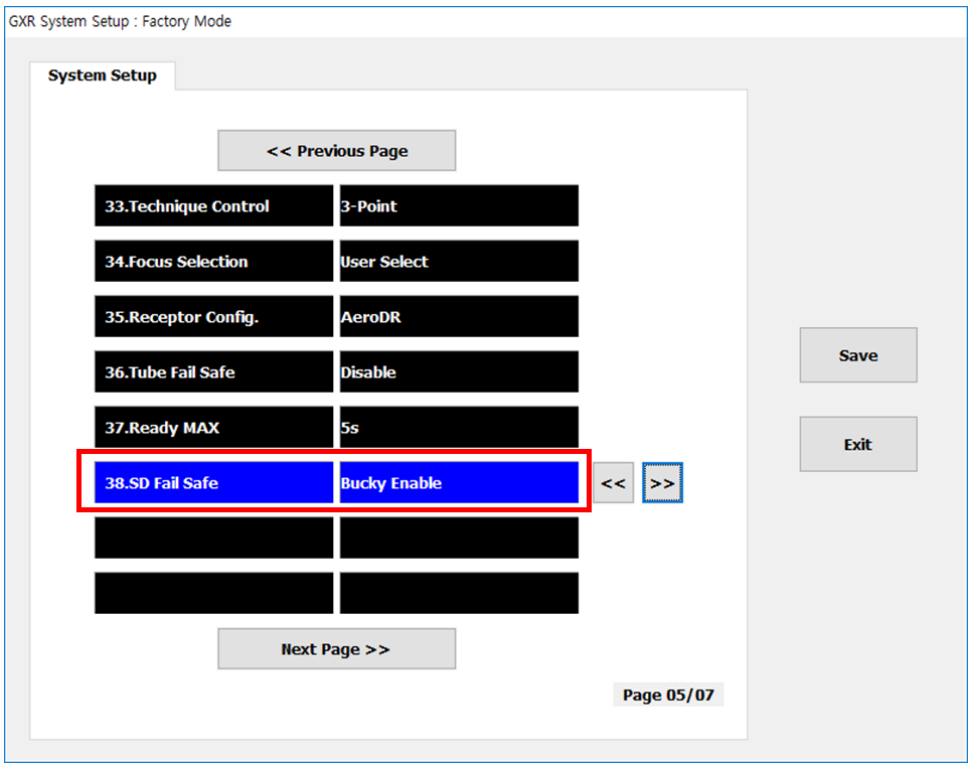


12. Change '**ETC. Error**' to '**Enable**' as shown below.



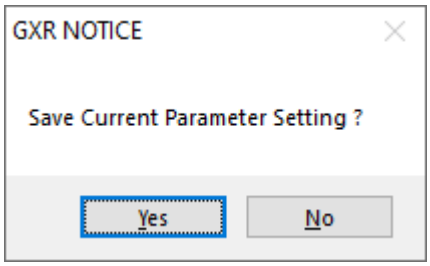
13. Change **'SD Fail Safe'** to **'Bucky Endable** as shown below.

    This is for fail safety function of diamond from detachable type.



14. Click **'Save'** button.

    After then, click **'Yes'** button when the dialog window shows up like below.



15. Click **'Exit'** button.

16. Close GXR SDK.

17. Power off the generator.

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APPENDIX D. APR PROGRAMMING WORKSHEET

(THIS IS A MASTER, MAKE WORKING COPIES AS NEEDED)

Part	**Technique**

kV [ ] mA [ ] ms [ ] Density [ ]

Image Receptor Select

Non-Bucky ☐

Bucky 1 ☐

Bucky 2 ☐

Technique Select

AEC ☐

mAs ☐

ms ☐

Patient Body Size

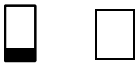
CHILD ☐

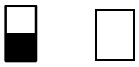
SMALL ☐

MEDIUM ☐

LARGE ☐

Film/Screen Select

 ☐

 ☐

☐

AEC Field Select

☐

☐

☐

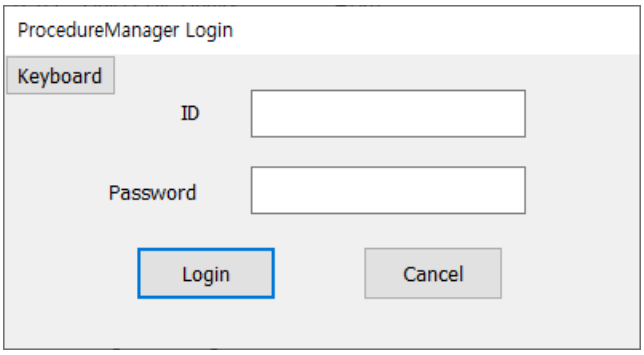
APPENDIX E. PROCEDURE MANAGER

The Procedure Manager program is a program for setting, modifying, and creating for APR and PACS Code for ***"RADMAX"*** imaging software.

To run the Procedure Manager program, click **'Procedure Manager.exe'** file in the "C:\Radmax" folder.

E1. LOGIN

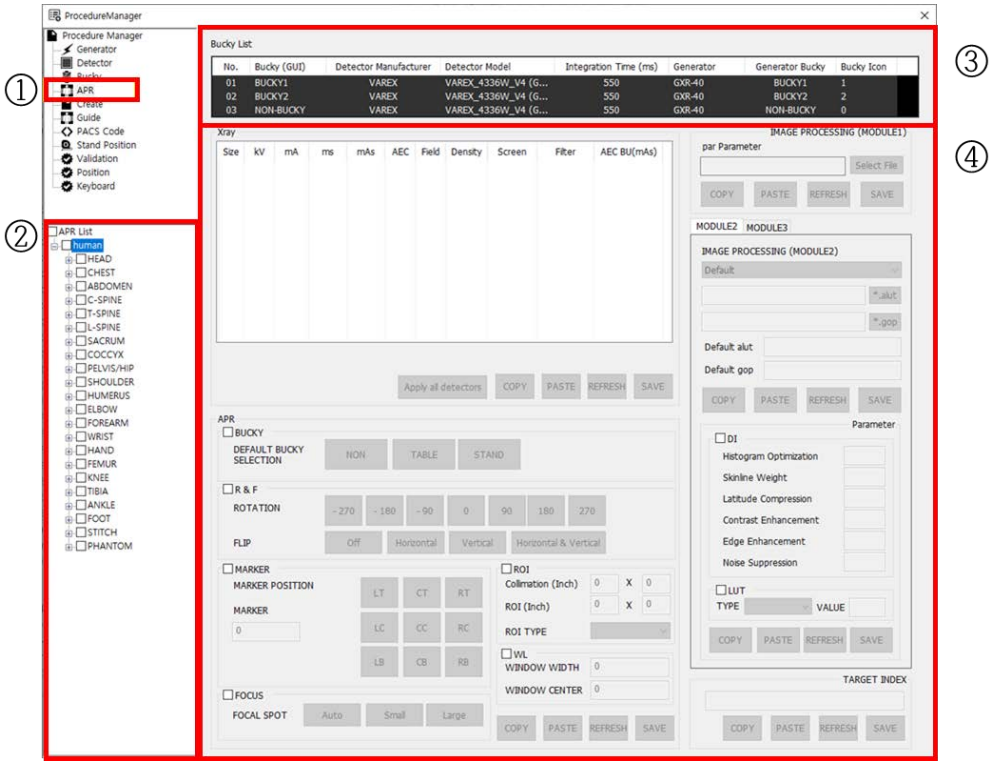
Enter the account information of the administrator who is registered in ***"RADMAX"*** imaging software and log in.



NOTE
After installing the program, the default ID is 'admin' and password is '11111111'. The account type for 'admin' is administrator.

E2. APR SETTING

In this mode, the administrator can set the APR registered in ***"RADMAX"*** imaging software.

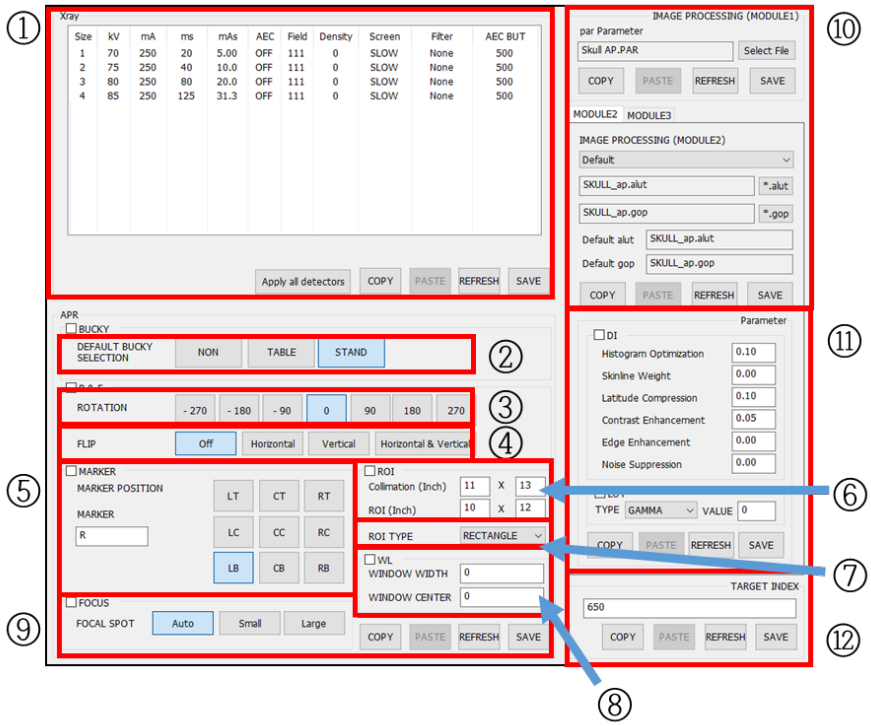


<APR Setting screen>

NOTE
Click **'APR'** in ***"RADMAX"*** imaging software to access APR settings.

①	APR	Display the APR Setting screen.
②	APR List	Display the list of APRs registered in ***"RADMAX"*** imaging software in a tree structure.
③	Bucky List	Display the list of Bucky registered in ***"RADMAX"*** imaging software.
④	APR information	Display the APR setting information registered in ***"RADMAX"*** imaging software. Select Projection of APR List and at least 1 Bucky of Bucky List to view the APR setting screen.

- Detector Selection Indicator



<APR information>

①	X-ray Setting	Sets the kV, mA, ms, AEC, Field, Density, Screen, Filter and AEC BUT value among the shooting conditions of the selected APR. Double click the value in the above list and it will be listed as the preset item. Select the item to set the value.	
		Apply all detectors	Applies the APR information to all registered Detectors.
		COPY	Copy the X-ray data of activated APR information.
		PASTE	Paste the X-ray data of checked APR information.
		REFRESH	Refresh the X-ray data of activated APR information.
		SAVE	Save the X-ray data of activated APR information by editing values.
②	Default Bucky Selection	Sets the default Bucky of the selected APR.	
③	Rotation	Sets the basic rotation information for each Bucky of the selected APR.	

④	Flip	Sets the basic flip information for each Bucky of the selected APR.	
⑤	Marker and Marker Position	Sets the basic marker and marker position information for each Bucky of the selected APR.	
⑥	Collimation, ROI	Sets the basic ROI and Collimation information for each Bucky of the selected APR. If the input value exceeds the specified range, a message is displayed.	
⑦	ROI Type	Sets the basic ROI type (Rectangle, Circle) information for each Bucky of the selected APR.	
⑧	Window Width, Window Center	Sets the basic window width and window center information for each Bucky of the selected APR.	
⑨	Focal Spot	Sets the default Focal Spot information of the selected APR.	
		COPY	Copy the checked Image data of activated APR information.
		PASTE	Paste the copied image data of checked APR information.
		REFRESH	Refresh the Image data of active APR information.
		SAVE	Save the image data of activated APR information by editing values.
⑩	Image Processing (MODULE1 ~ 4)	Sets the image processing file of the currently selected APR. It is valid when MODULE1 ~ 4 are applied for image processing in ***"RADMAX"*** imaging software.	
		Select File	Select another parameter file. (Only MODULE1)
		*.alut	Select default parameter file (alut file) (Only MODULE2)
		*.gop	Select default parameter file (gop file) (Only MODULE2)
		*.xray3	Select default parameter file (xray3 file) (Only MODULE3)
		*.gem	Select default parameter file (gem file) (Only MODULE4)
		COPY	Copy parameter file information for MODULE1 ~ 4 for selected APR.
		PASTE	Paste parameter file information for MODULE1 ~ 4 for selected APR.

		REFRESH	Paste parameter file information for MODULE1 ~ 4 for selected APR.
		SAVE	Save parameter file information for MODULE1 ~ 4 for selected APR.
⑪	MODULE1 ~ 4 DI, LUT	COPY	Copy the DI (Doctor Interface) and LUT of activated APR information.
		PASTE	Paste the DI (Doctor Interface) and LUT of checked APR information.
		REFRESH	Refresh the DI (Doctor Interface) and LUT of activated APR information.
		SAVE	Save the DI (Doctor Interface) and LUT of activated APR information by editing values.
⑫	Target Index	COPY	Copy the target index of active APR information.
		PASTE	Paste the target index of active APR information.
		REFRESH	Refresh the target index of active APR information.
		SAVE	Sets the target index selected APR.

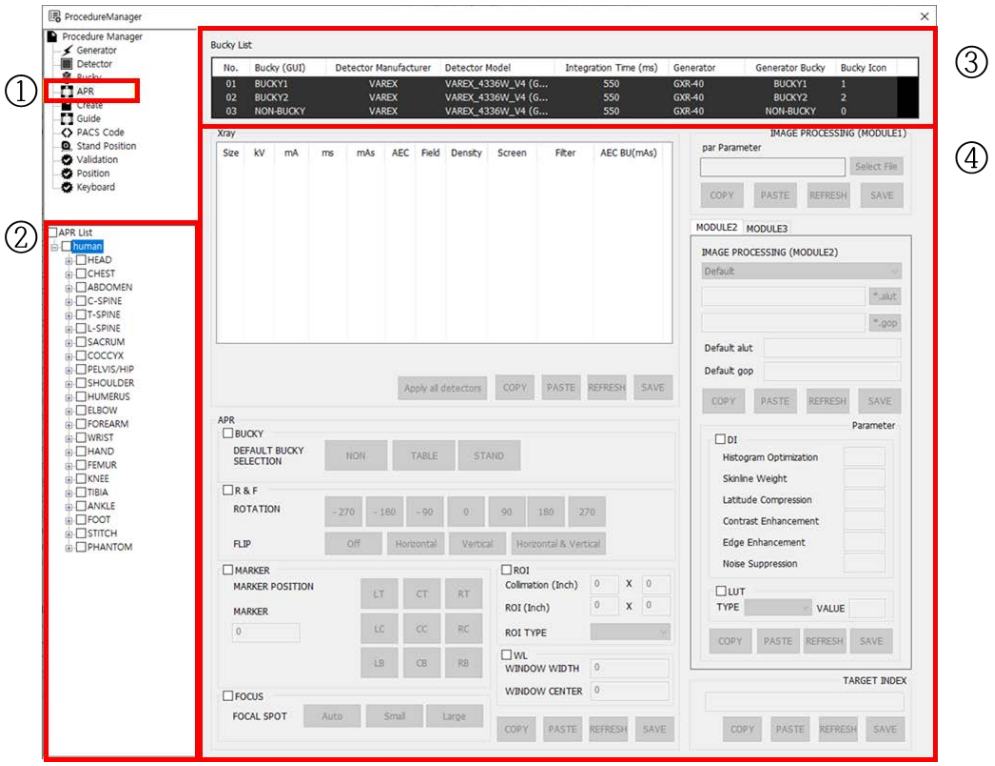
NOTE

Detection field can be distinguished by three-digit configuration of field.

(0 for non-use, 1 for use)

- First Number: left field
- Second Number: center field
- Third Number: right field

E3. PACS CODE SETTING



<PACS Code Setting screen>

①	PACS Code	Display the PACS Code Setting screen.	
②	APR List	Display the list of APRs registered in ***"RADMAX"*** imaging software in a tree structure.	
③	Bucky List	Display the list of Bucky registered in ***"RADMAX"*** imaging software.	
④	Step List	Display a list of the steps to be matched to the PACS code.	
		Add	Add the step of the selected APR List to the Step List.
		Delete	Deletes the step of the selected Step List.

⑤	PACS Code List	Display the list of registered PACS Code.	
		Add	Add any PACS code.
		Delete	Deletes the code of the selected PACS Code List.
		Import	Import PACS Code from the Excel file(*.xls) (specified format form)
		Export	Export PACS Code registered in RADMAX by the Excel file(*.xls) (specified format form)
⑥	Code Step List	Display the list of matching step to the PACS Code selected in the current PACS Code List.	
		Add	Add the step selected in the Step List to the PACS Code of the selected PACS Code List.
		Delete	Delete the step selected in the Code Step List from the PACS Code of the selected PACS Code List.
		Up	Change the step order of selected step. The step order is up.
		Down	Change the step order of selected step. The step order is down.

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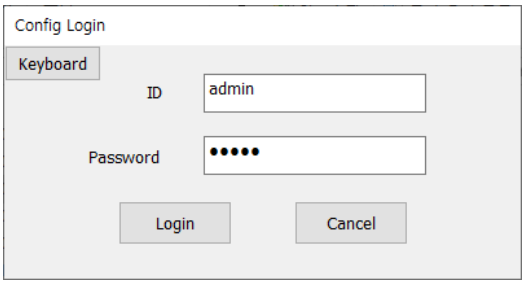
APPENDIX F. CONFIGURATION SOFTWARE

F1. LOGIN

This chapter describes the configuration utility of software.

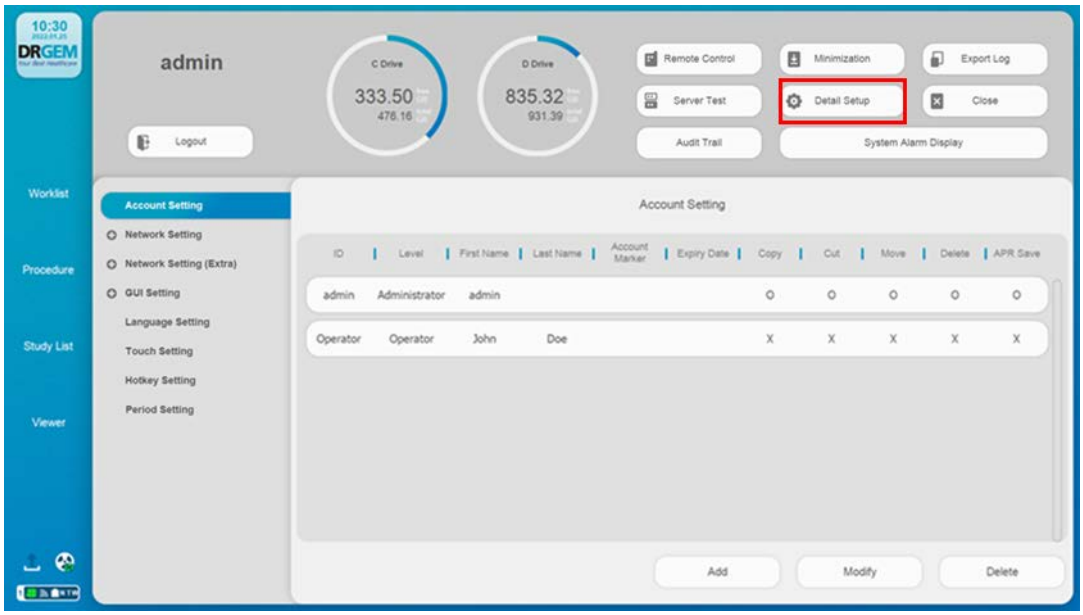
The configuration software will be automatically installed during ***"RADMAX"*** imaging software installation.

RadmaxConfig.exe file is located on the 'C:\Radmax' folder. Click 'RadmaxConfig.exe' file for setting of configuration.



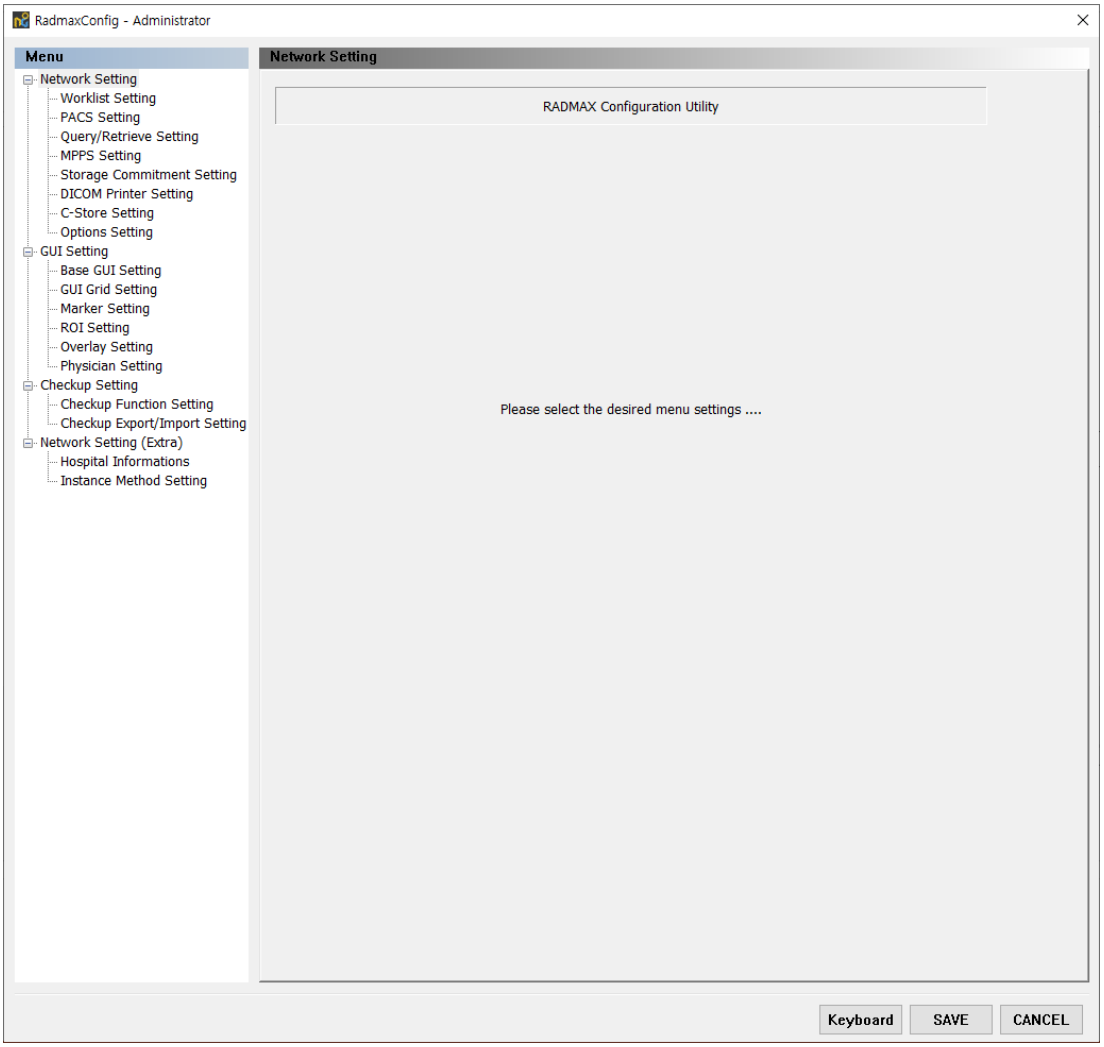
You can use the configuration program in another ways as shown below.

"RADMAX" imaging software admin page as shown below and click the **'Detail Setup'** button.



NOTE
After installing the program, the default ID is 'admin' and password is '11111111'. The account type for 'admin' is administrator. - The Administrator account is only available for Account, Network, GUI settings, Network Setting (Extra), Touch Setting, Hotkey Setting.

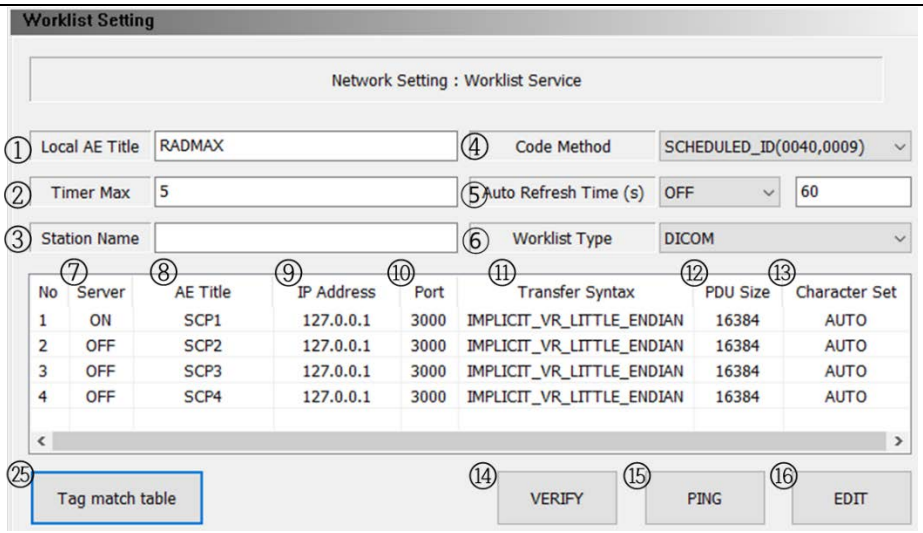
The RadmaxConfig program is executed as shown below.



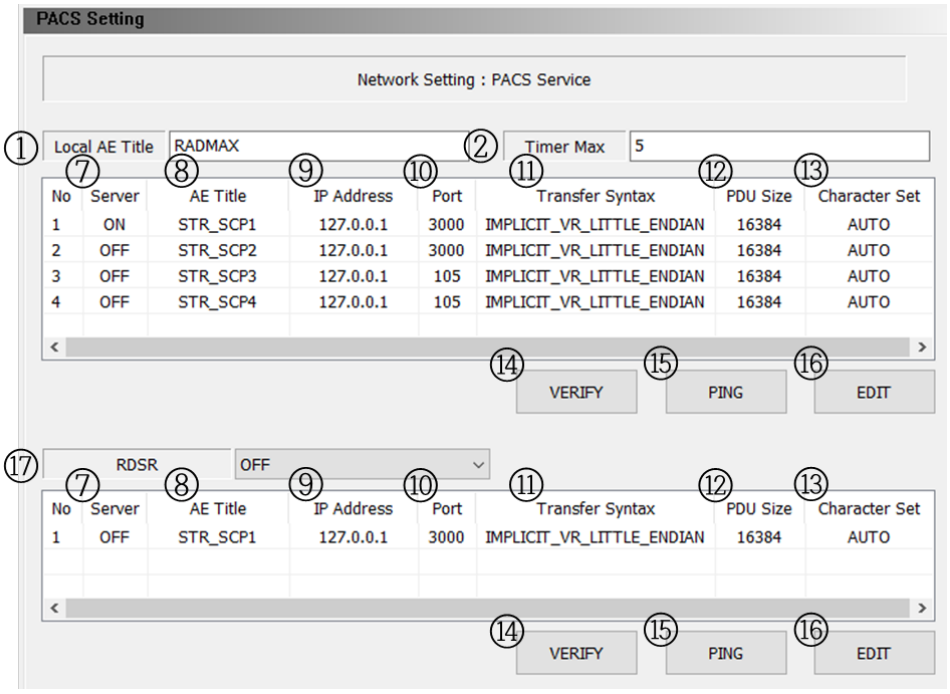
NOTE
When all the settings are complete, you must click ' ' button to save and apply the changed settings to the file.

F2. NETWORK SETTING

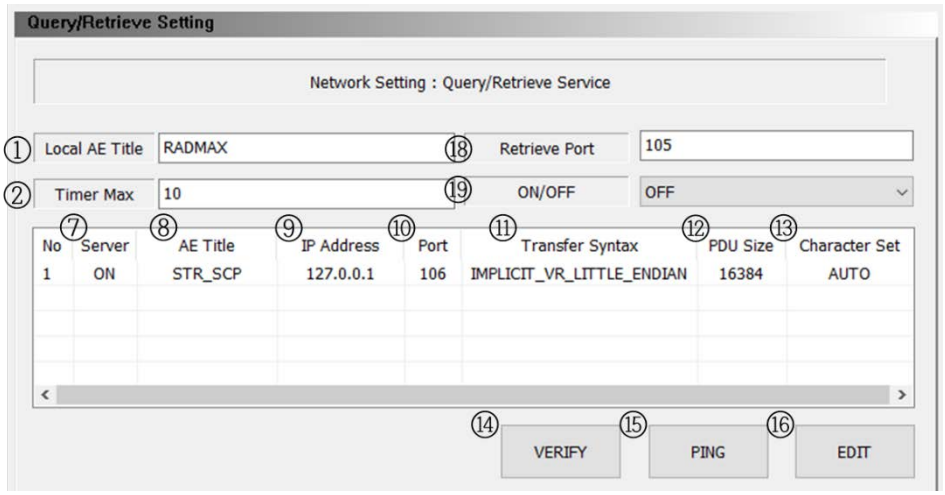
NOTE
Modifying theses setting is not recommended. If the modification is needed, please contact the service provider.



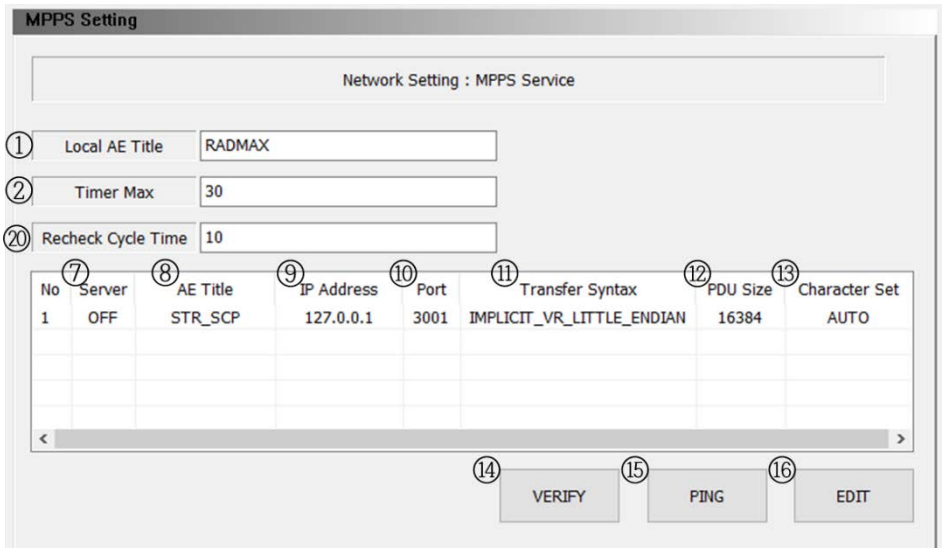
<Worklist Setting screen>



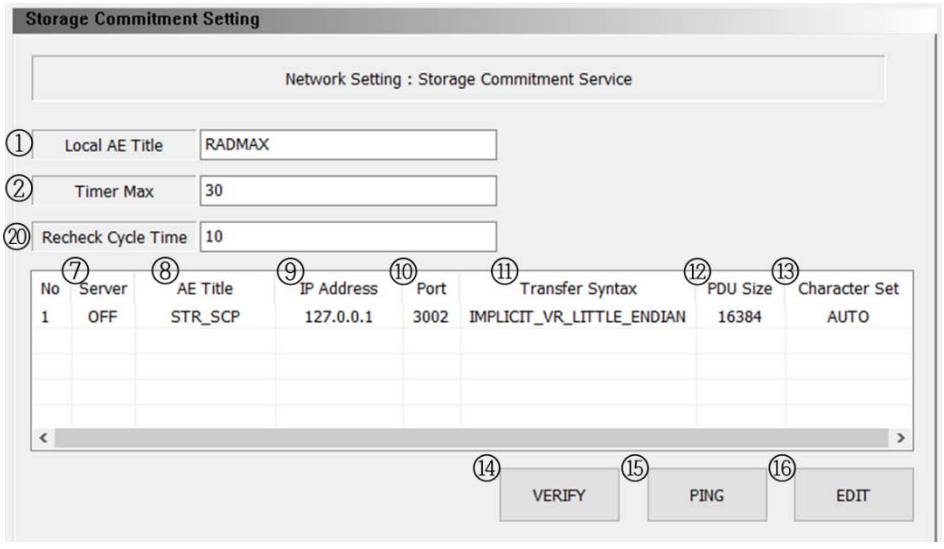
<PACS Setting screen>



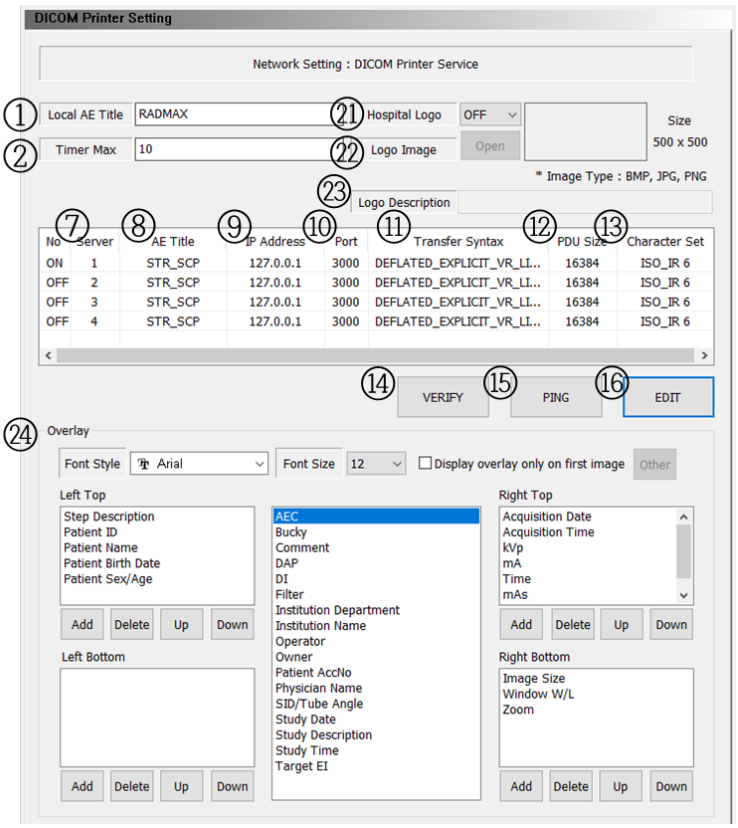
<Query/Retrieve Setting screen>



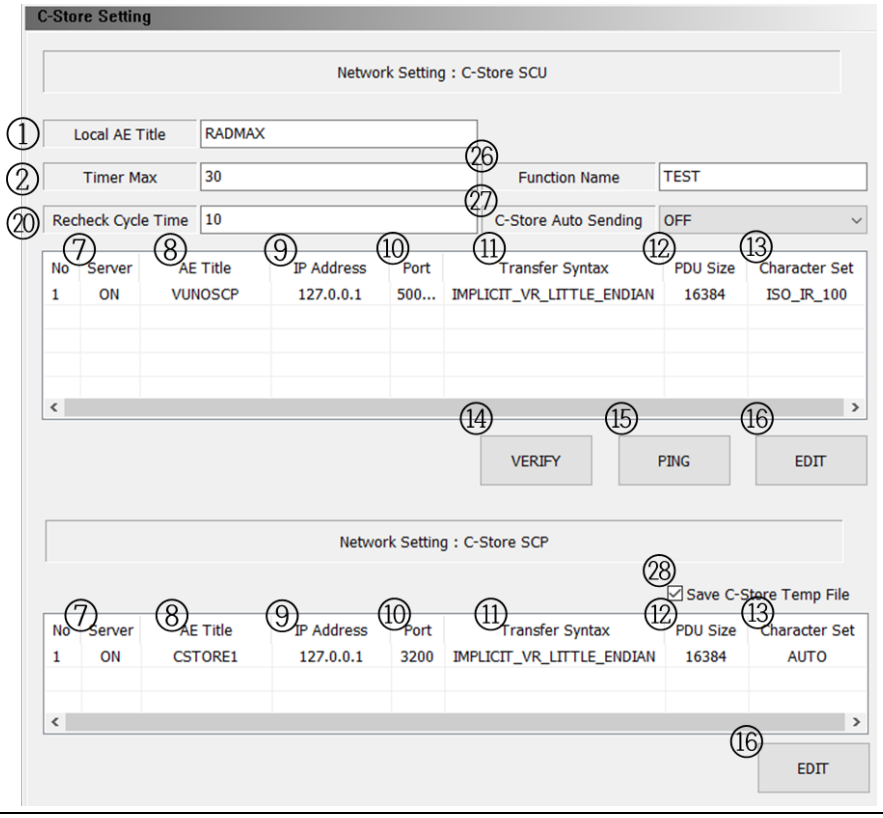
<MPPS Setting screen>



<Storage Commitment Setting screen>

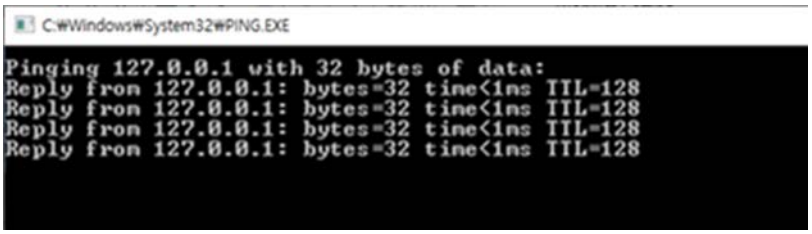
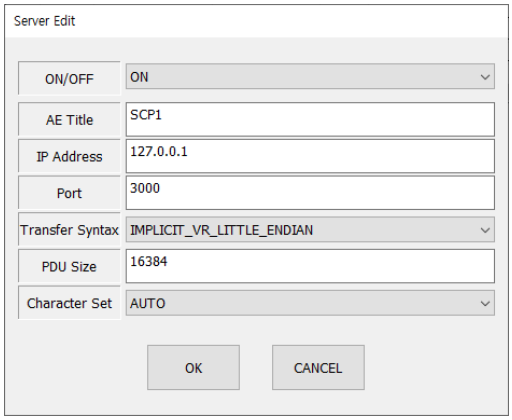
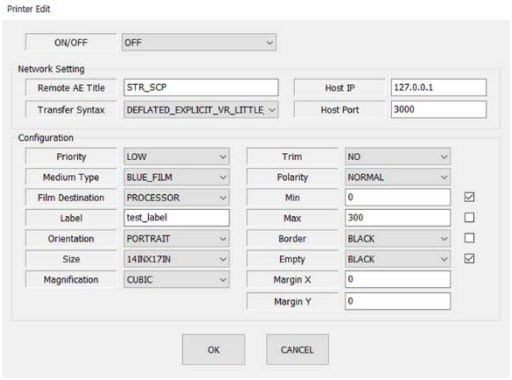


<DICOM Printer Setting screen>



<C-Store Setting screen>

①	Local AE Title	Set the AE Title of the current Modality.
②	Timer Max	Set the Timeout of the server query of each setting screen.
③	Station name	Set the station name for identifying the x-ray system.
④	Code Method	Set the worklist code matching method. - SCHEDULED_ID: Order Code will be matched based on Scheduled Procedure Step ID. - SCHEDULED_DESC: Order code will be matched based on Scheduled Procedure Step Description. - REQUESTED_ID: Order Code will be matched based on Requested Procedure ID. - REQUESTED_DESC: Order code will be matched based on Requested Procedure Description.
⑤	Auto Refresh Time (s)	Set whether to use the function to automatically refresh the Worklist, and set cycle of automatic refresh.
⑥	Worklist Type	Set the worklist type from the server. - DICOM: The worklist is received by DICOM protocol. - HL7: The worklist is received by HL7 protocol.
⑦	Server	Set the available the server of each setting screen. - ON: Use the server of each setting screen. - OFF: Do not use the server of each setting screen.
⑧	AE Title	Set the AE Title of the server of each setting screen.
⑨	IP Address	Set the IP Address of the server of each setting screen.
⑩	Port	Set the network port of the server of each setting screen.
⑪	Transfer Syntax	Set the DICOM Transfer Syntax.
⑫	PDU Size	Set the PDU Size of the server of each setting screen.
⑬	Character set	Set the Character set of the server of each setting screen.
⑭	Verify	Check the network status according to DICOM standard.

⑮	Ping	Send packets of data to a specific IP address on a network, and then lets you know how long it took to transmit that data and get a response. 
⑯	EDIT	Modify the each setting information. Click **'EDIT'** button and **'Server Edit'** screen will appear. Enter each information as shown below and click **'OK'** button. Changed information is displayed.  *<Other Setting screen>*  *<DICOM Printer Setting screen screen>*
⑰	RDSR	Set the RDSR option. - ON: Send the image & RDSR DICOM files to PACS. - OFF: Send the image DICOM files to PACS.
⑱	Retrieve Port	Set the port number of the local AE.
⑲	ON/OFF	Set whether or not to use Query/Retrieve. If you use this function, the Query / Retrieve menu appears.

		- ON: Use Query/Retrieve. - OFF: Do not use Query/Retrieve.
⑳	Recheck Cycle time	Set the Recheck Cycle time of the server of each setting screen.
☐	Hospital Logo	Support printing hospital logo on film. - ON: Use The hospital logo is added to film. - OFF: The hospital logo is not added to film.
☐	Logo Image	Click the **'Open'** button and select the image file.
☐	Logo Description	Set the Description which will be printed on film with the hospital logo.
☐	Overlay	Set the overlay of DICOM Print Image. Please refer to the '4.4.4.4 DICOM Print, 1. DICOM Print dialog menu' section
☐	Tag Match table	Change the DICOM Tag for correct integration with the server. DB Column / Data Type / Tag / Name scheduled_procedure_step_id / var16 / 0040,0009 / scheduled procedure step ID scheduled_procedure_step_description / var128 / 0040,0007 / scheduled procedure step description requested_procedure_id / var16 / 0040,1001 / requested procedure ID requested_procedure_description / var128 / 0032,1060 / requested procedure description
☐	Function Name	Set the Function Name that appears in the software.
☐	C-Store Auto Sending	Set whether to automatically include requested images when sending images.
☐	Save C-Store Temp File	Set whether to save the requested image in the TEMP folder

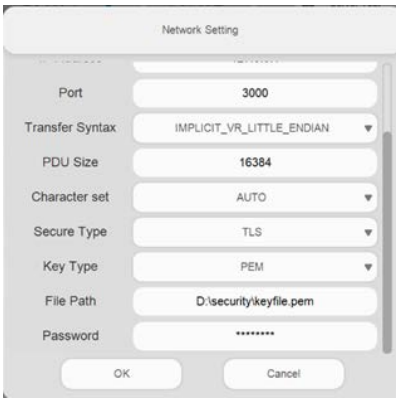
NOTE
Only BMP and JPG and PNG formats are supported. The image size needs to be 500x500 pixels.

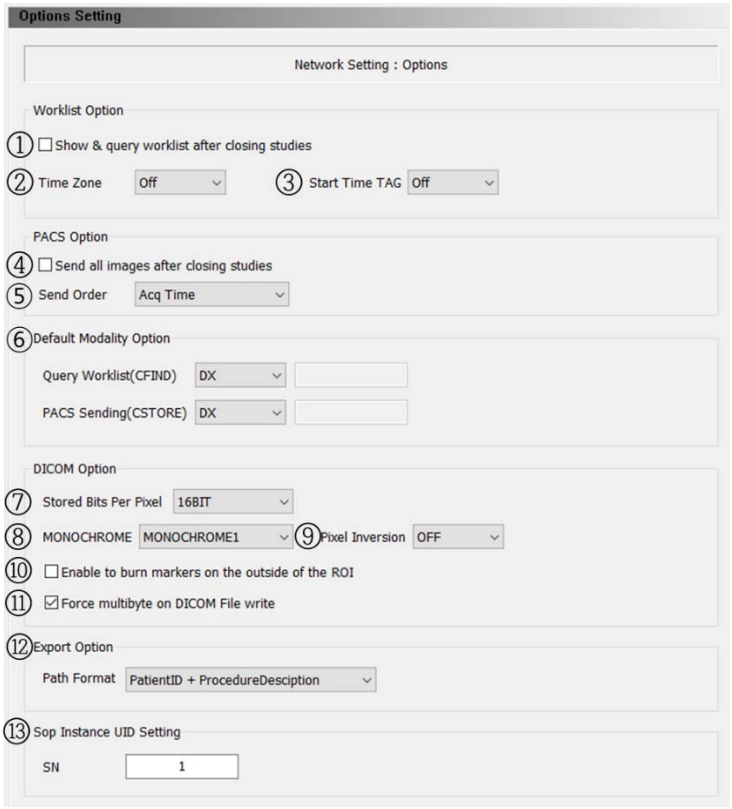
NOTE
The Hospital Logo and Description are not displayed in the Print GUI screen. The Hospital Logo and Description will be visible only on film.

NOTE

Modify the Worklist Setting information in ***"RADMAX"*** imaging software.

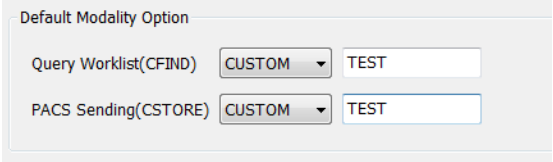
Most setting information are same. But there are security options. Following the DICOM TLS protocol, can be select key type, key file path and password. This setting supports up to DICOM TLS 1.2 and require PACS server should be support for using.





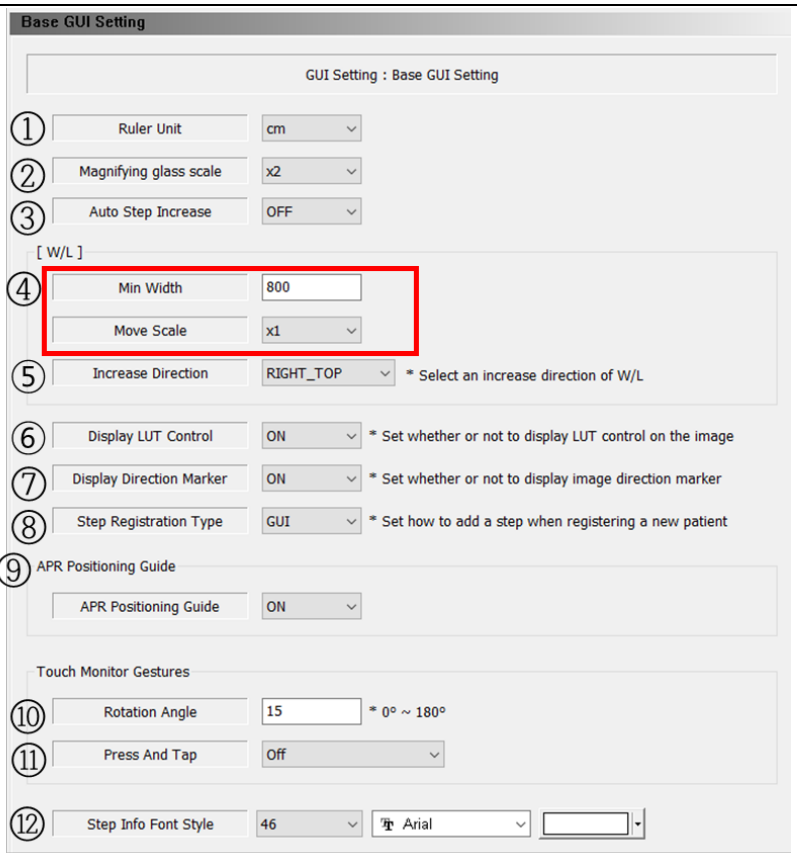
<Options Setting screen>

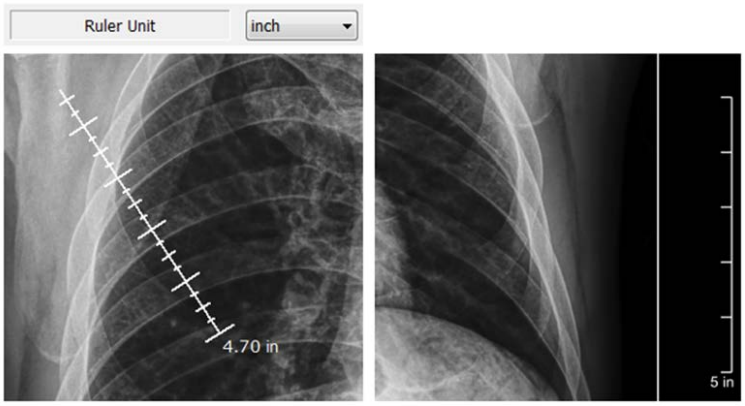
①	Worklist Option	When the study is over, it moves to the task list and proceeds with the query.
②		Set whether to use Time Zone TAG in the worklist.
③		Set whether to use Start Time TAG in the worklist.
④	PACS Option	Set to send the studies to the PACS server when the studies is closed.
⑤		Set the Send order to Server.
⑥	Default Modality Option	Set the default modality. - Query Worklist (CFIND): Set the default modality of Worklist. (CR, DX, DR, CUSTOM) - PACS Sending (CSTORE): Set the default modality of DICOM encoding. (CR, DX, DR, CUSTOM) When you select **'CUSTOM'**, you can set the desired modality name as below.

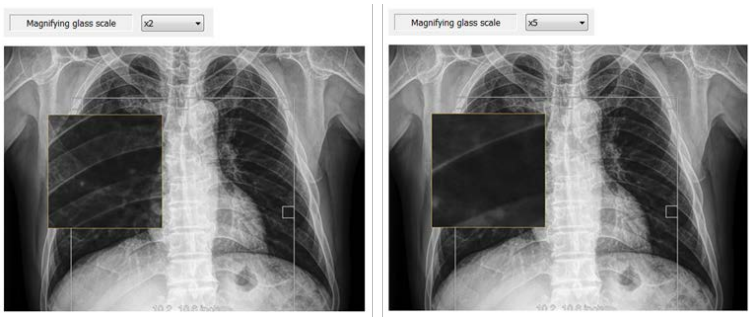
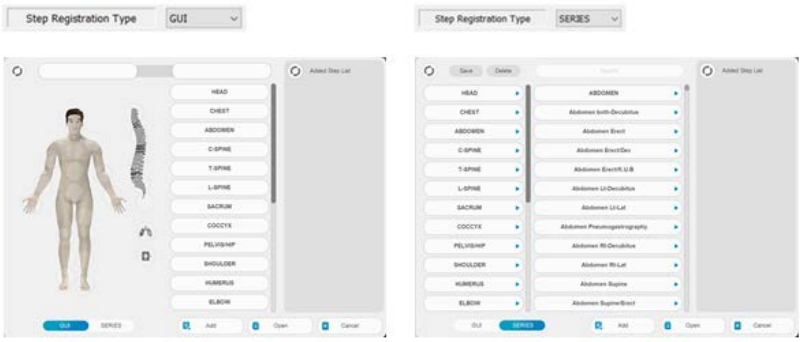
		
⑦	DICOM option	DICOM Encoding Set the bits stored per pixel when DICOM encoding.
⑧		Set the monochrome to be applied when sending a PACS.
⑨		Set the image Pixel Inversion when sending a PACS.
⑩		Set the whether to burn markers on the outside if there is a ROI.
⑪		Set whether to write multibyte when DICOM encoding
⑫	Export Option	Set the information about path references for export.
⑬	Sop Instance UID Setting	Set the Sop instance UID

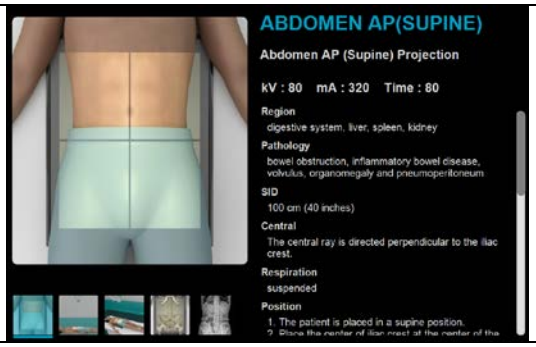
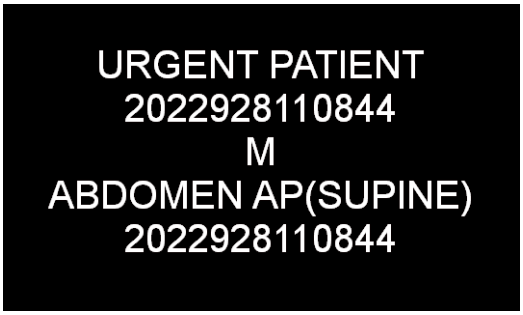
F3. GUI SETTING

- Base GUI Setting



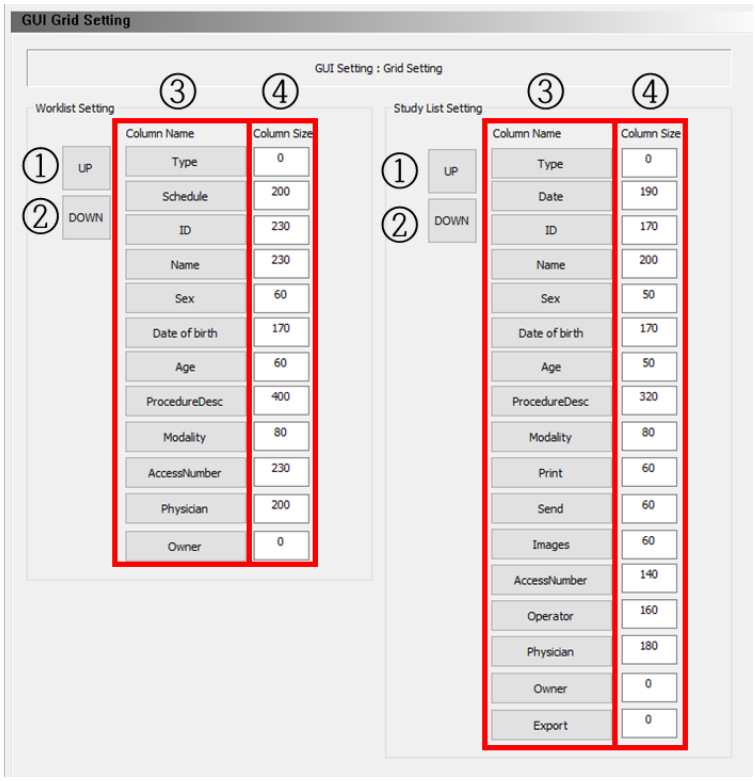
①	Ruler Unit	Set the unit for the Caliper on the image. (mm, cm, inch) 
②	Magnifying glass scale	Set the Magnifying glass scale for the magnifier on the image.

		
③	Auto STEP Increase	Set automatic step progression on or off. - ON: Procedure Step list is selected manually. - OFF: Procedure Step list is move to next step after X-ray image is received.
④	W/L (Windwoing Width/Level)	The W/L option can be selected like below. - Min Width: Set the Minimum width of windowing. - Move Scale: Set the control speed of contrast & brightness.
⑤	Increase Direction	Set the increase direction of W/L. - RIGHT_TOP: Set the increasing direction to Right Top. - LEFT_BOTTOM: Set the increasing direction to Left Bottom.
⑥	Display LUT Control	Set whether or not to display LUT control on the image. - ON: Display LUT control on the image. - OFF: Do not display LUT control on the image.
⑦	Display Direction Marker	Set whether or not to display image direction marker. - ON: Display image direction marker. - OFF: Do not display image direction marker.
⑧	Step Registration Type	Set how to add a step when registering a new patient. 
⑨	APR Positioning Guide	Set whether or not to Use APR Positioning Guide.

		
⑩	Rotation Angle	Set the angle to apply the rotation gesture. (Procedure)
⑪	Press And Tap	Set the function to use as a Press And Tap gesture. (Procedure)
⑫	Step Info Font Style	Set the font style for step information. (Image Viewer in Procedure) 

- GUI Grid Setting

The Worklist and Study List Column Custom Setting can be selected like below.

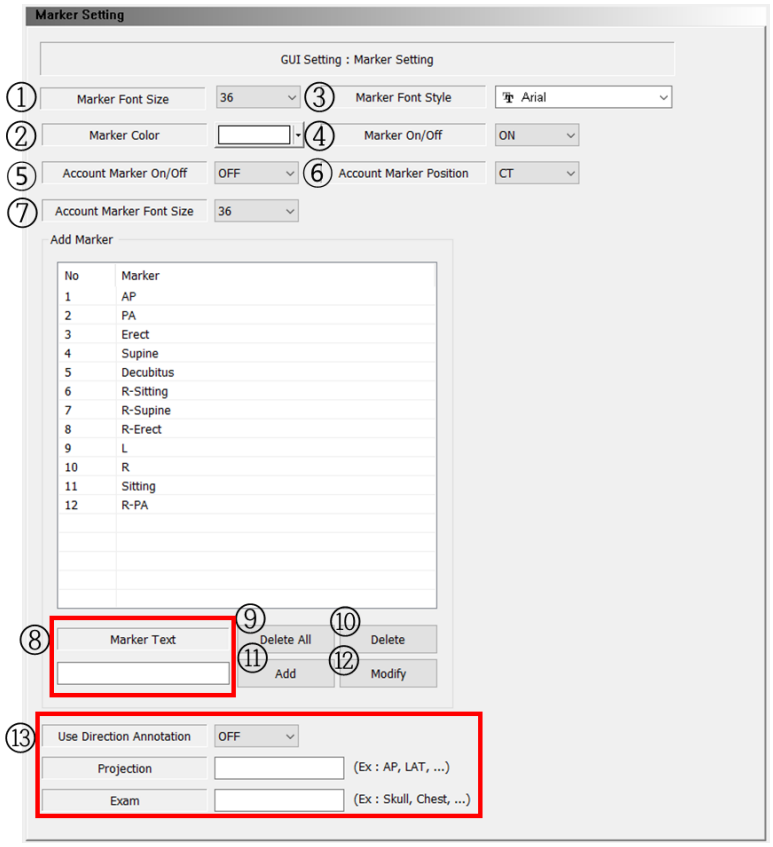


<GUI Grid Setting screen>

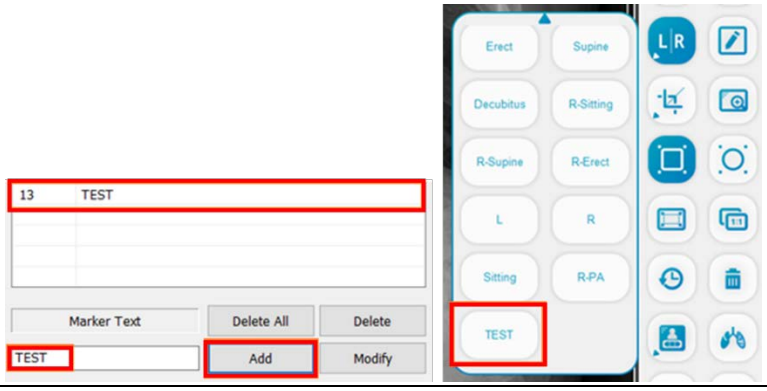
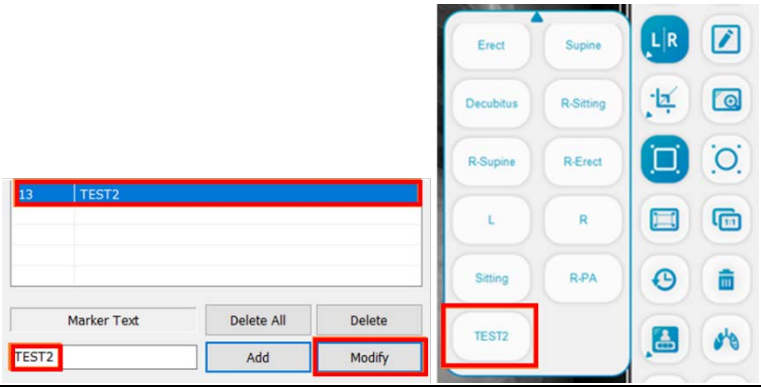
<Worklist and Study List Column>

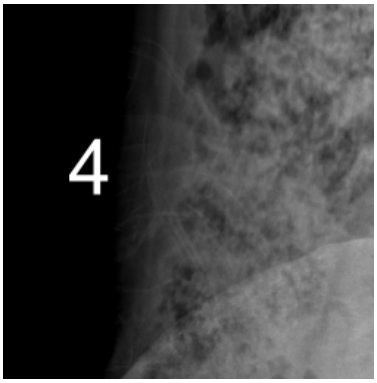
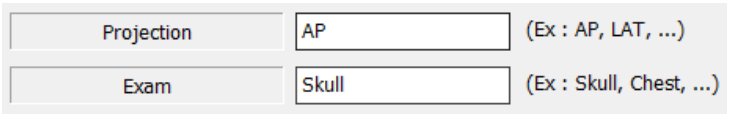
①	Column Name	Set columns in the list in order	
②	Column Size	Set the column size	
③	UP Button	UP	Move up the order of the selected columns
④	DOWN Button	DOWN	Move down the order of the selected columns

- Marker Setting



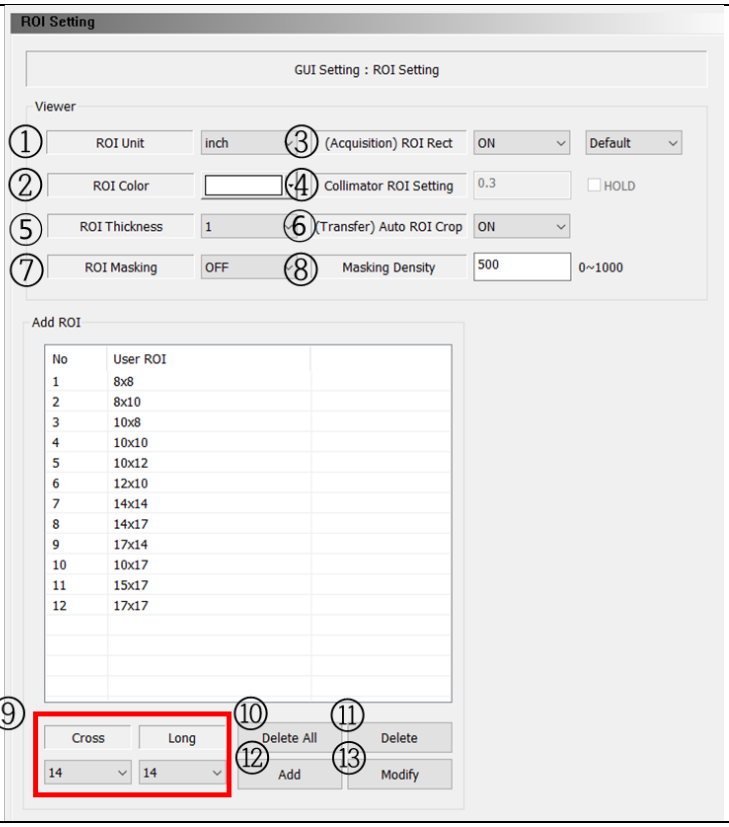
①	Marker Font Size	Select the font size of Marker
②	Marker Color	Select the color of Marker
③	Marker Font Style	Select the font style of Marke
④	Marker On/Off	Set whether to automatically display marker when X-ray image is acquired. - ON: Marker will be displayed on the image. - OFF: Marker will not be displayed on the image.
⑤	Account Marker On/Off	Set whether to automatically display account marker when X-ray image is acquired. - ON: Account Marker will be displayed on the image. - OFF: Account Marker will not be displayed on the image.

<table>
<tr><td>⑥</td><td>Account Marker Position</td><td>Set the position of the Account Marker.
<table>
<tr><td>LT</td><td>Left Top</td><td>CT</td><td>Center Top</td><td>RT</td><td>Right Top</td></tr>
<tr><td>LC</td><td>Left Center</td><td>CC</td><td>Center Center</td><td>RC</td><td>Right Center</td></tr>
<tr><td>LB</td><td>Left Bottom</td><td>CB</td><td>Center Bottom</td><td>RB</td><td>Right Bottom</td></tr>
</table></td></tr>
<tr><td>⑦</td><td>Account Marker Font Size</td><td>Select the font size of Account Marker.</td></tr>
<tr><td>⑧</td><td>Marker Text</td><td>This sets the content of the Marker to be displayed on the screen.</td></tr>
<tr><td>⑨</td><td>Delete All Button</td><td>Delete all lists.</td></tr>
<tr><td>⑩</td><td>Delete Button</td><td>Delete the selected list.</td></tr>
<tr><td>⑪</td><td>Add Button</td><td>Click ‘Add’ button to add it to the ‘Add Marker’ list as shown below.
 
</td></tr>
<tr><td>⑫</td><td>Modify Button</td><td>Click the ‘Modify’ button to modify the marker text added to the ‘Add marker’ list.
 
</td></tr>
</table>

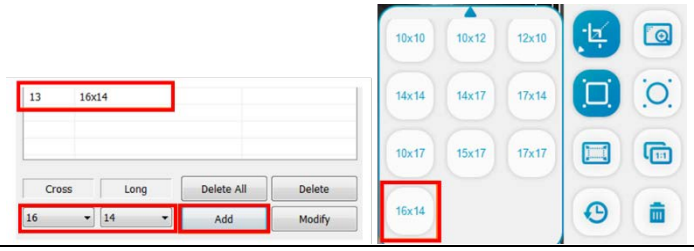
⑬	Direction Annotation	Set whether or not to display image direction annotation. - ON: Display image direction annotation. - OFF: Do not display image direction annotation.  Set the Projection and Exam to display only in the configured position. 

NOTE
Up to 30 markers can be added.

- ROI Setting



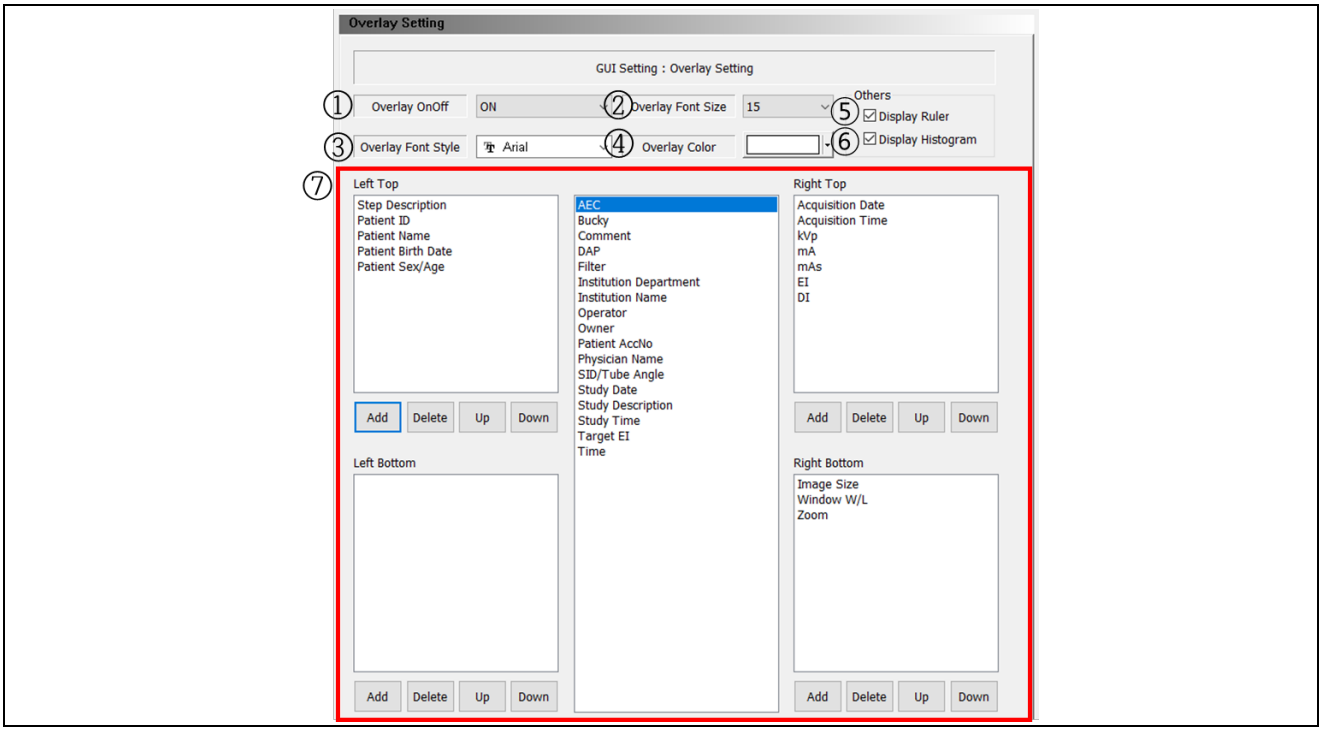
①	ROI Unit	Set the unit the ROI on the image. (mm, cm, inch)
②	ROI Color	Select the color of ROI.
③	(Acquisition) ROI Rect	Select to use ROI Rect on or off. - ON: Default ROI is displayed after image acquisition. - OFF: Default ROI is not displayed after image acquisition.
④	Collimator ROI Setting	Select the collimator ROI. Cannot be changed by the user.
⑤	ROI Thickness	Select the thickness of ROI.
⑥	(Transfer) Auto ROI Crop	Set to transmit only ROI area when sending to PACS. - ON: Only the ROI area of image is sent when sending the image to PACS. - OFF: Entire image is sent when sending the image to PACS.
⑦	ROI Masking	Set up masking on ROI.

⑧	Masking Density	Setting the masking density. (As the density increases, it darkens.)	
⑨	ROI Size Setting	Set the ROI size.	
⑩	Delete All Button	Delete All	Delete all lists.
⑪	Delete Button	Delete	Delete the selected list.
⑫	Add Button	Add	Click **'Add'** button to add it to the **'Add ROI'** list as shown below. 
⑬	Modify Button	Modify	Click the **'Modify'** button to modify the ROI added to the **'Add ROI'** list as shown below.

NOTE
Up to 12 markers can be added.

- Overlay Setting

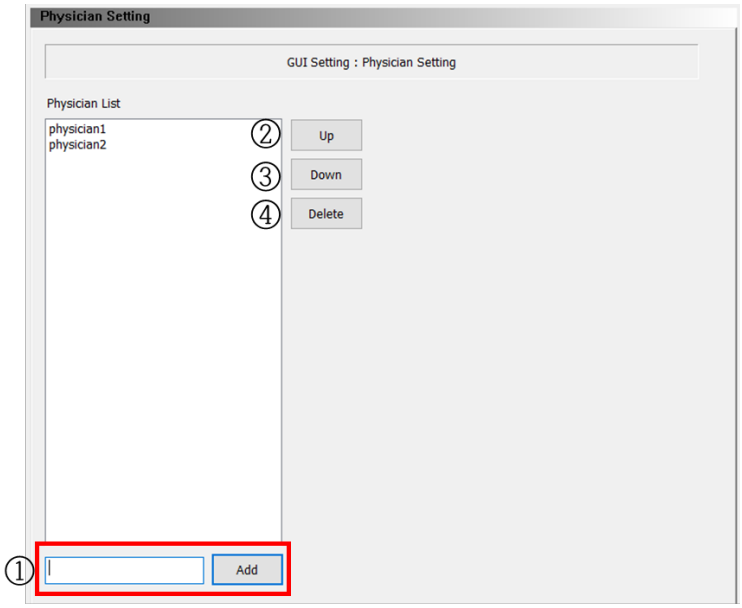
The configuration of overlay display can be set here.



①	Overlay On/Off	- ON: Overlay will be displayed on the image. - OFF: Overlay will not be displayed on the image.
②	Overlay Font Style	Select the font style of Overlay.
③	Overlay Font Size	Select the font size Overlay.
④	Overlay Color	Select the color of Overlay.
⑤	Display Ruler	Vertical ruler on the right side of the image will be displayed.
⑥	Display Histogram	Histogram will be displayed on the image when the WL of the image is adjusted.

⑦	Overlay Position	Set the desired overlay information at the desired position.	
		Add	Add the currently selected overlay of the entire list to the current position.
		Delete	Delete the selected item from the added overlays. Deleted items are added to the list in the center
		UP	Move the order of the selected overlays up.
		DOWN	Move the order of the selected overlays down.

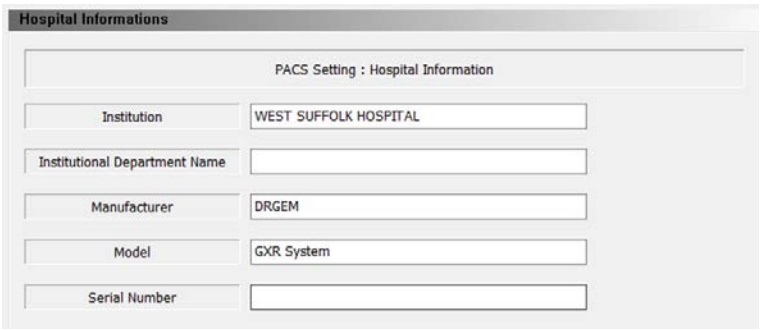
- Physician Setting



①	Add Button	Add	Add the currently entered physician.
②	Delete Button	Delete	Delete the selected item from the added physicians.
③	Up Button	UP	Move the order of the selected physicians up.
④	Down Button	DOWN	Move the order of the selected physicians down.

F4. NETWORK SETTING (EXTRA)

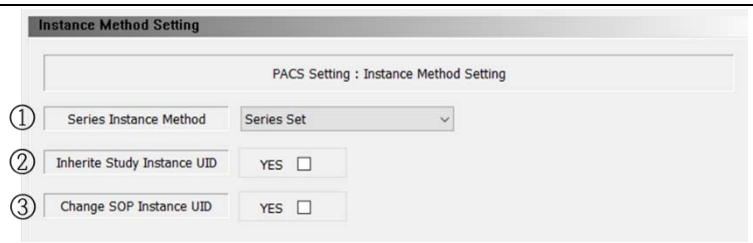
- Hospital Information



NOTE
This hospital information will be stored in DICOM tag.

- Instance Method Setting

NOTE
Modifying these settings is not recommended. If the modification is required, please contact to service provider.

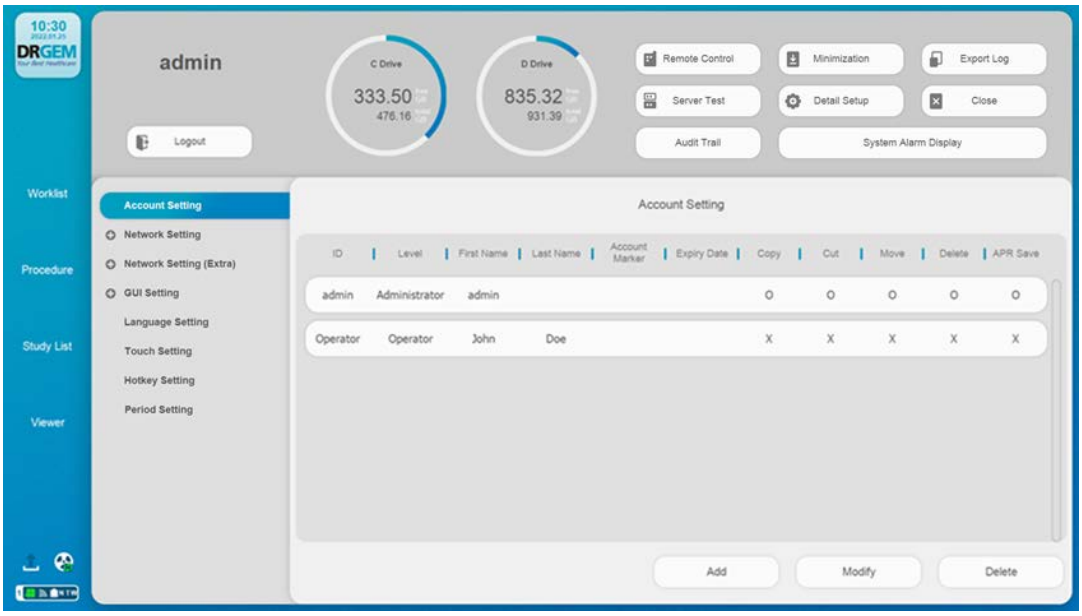


①	Series Instance Method	Set the Series composition method to be used when the exposed images is composed into series. - Series Set: Study will consist of only one Series. - Auto Increment: Study will consist of multiple series with each series containing one instance. The series instance number will be incremented over all studies. - Single Series: Study will consist of multiple series with each series containing one instance.
②	Inherite Study Instance UID	- YES: Use the study instance UID generated by ***"RADMAX"*** imaging software unique identification. - NO: Use the Study Instance UID from the Worklist.
③	Change SOP Instance UID	- YES: Set to change the SOP instance UID every time it is transmitted. - NO: SOP Instance UID change not used.

F5. SETTING PAGE ON RADMAX

There is another way for configuration ***"RADMAX"*** imaging software. Click by **'DRGEM logo'** button, display the admin page.

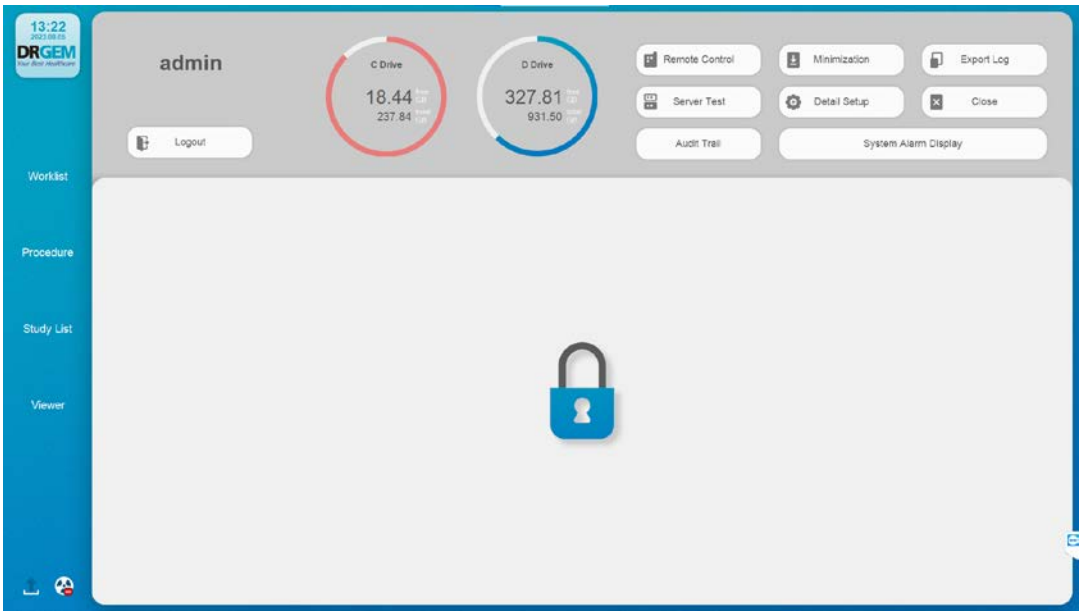
The admin page has same setting screen like configuration software.



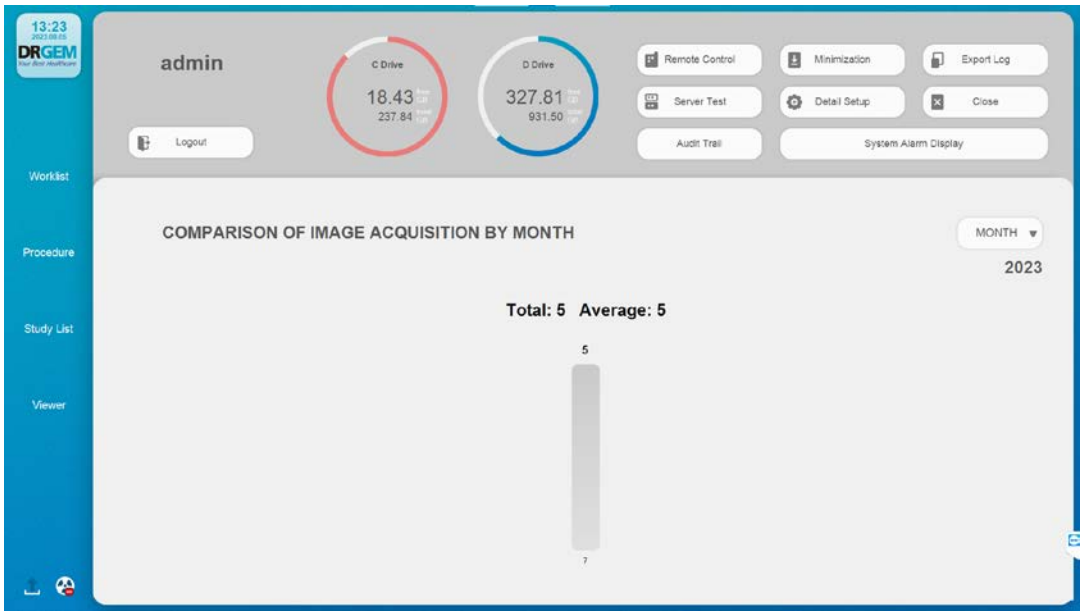
<Admin Setting Screen>

If the Display Admin Settings is Lock, the lock screen is displayed.

If the Display Admin Settings is statistics, the user statistics screen is displayed.



<Lock Screen>



<Statistics Screen>

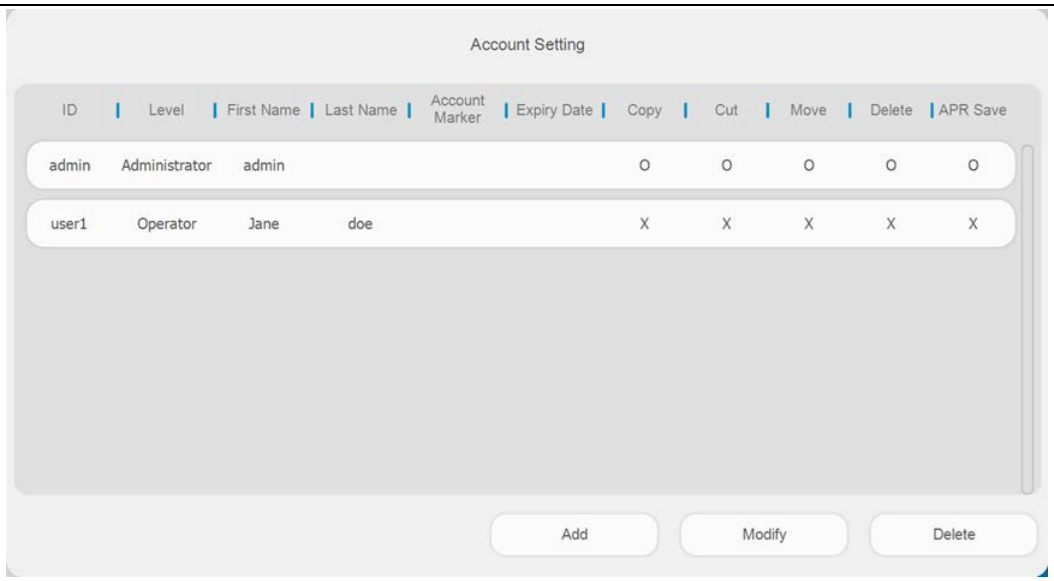
NOTE
'Display Admin Settings' setting can only be set by the administrator. (GUI Setting -> Base -> Display Admin Setting)

The following settings are the same as the configuration software. But '*GUI Setting: Positioning Guide'* and 'Hotkey Setting' are excepted. Make sure clicking **'Save'** button when configuration ends. If won't click **'Save'** button, configuration information might be lost.

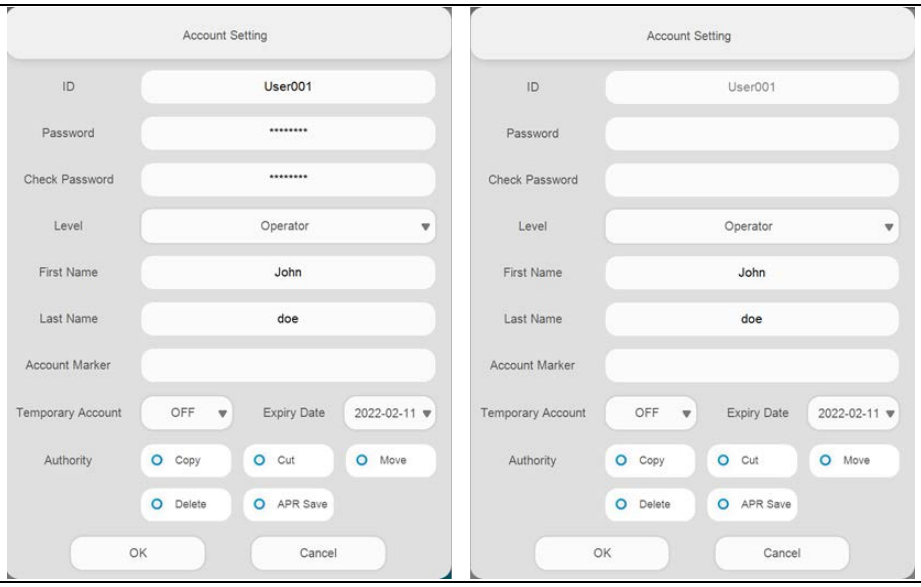
- Account Setting

Account setting will display administrator user and operator user list. If your login account is administrator, the screen display administrators and operators. When your login account is operator only display current operator account.

As we can see, add button can make new account, modify button can modify selected account information, delete button can delete selected account. But if your current login account is operator only can use modify button.



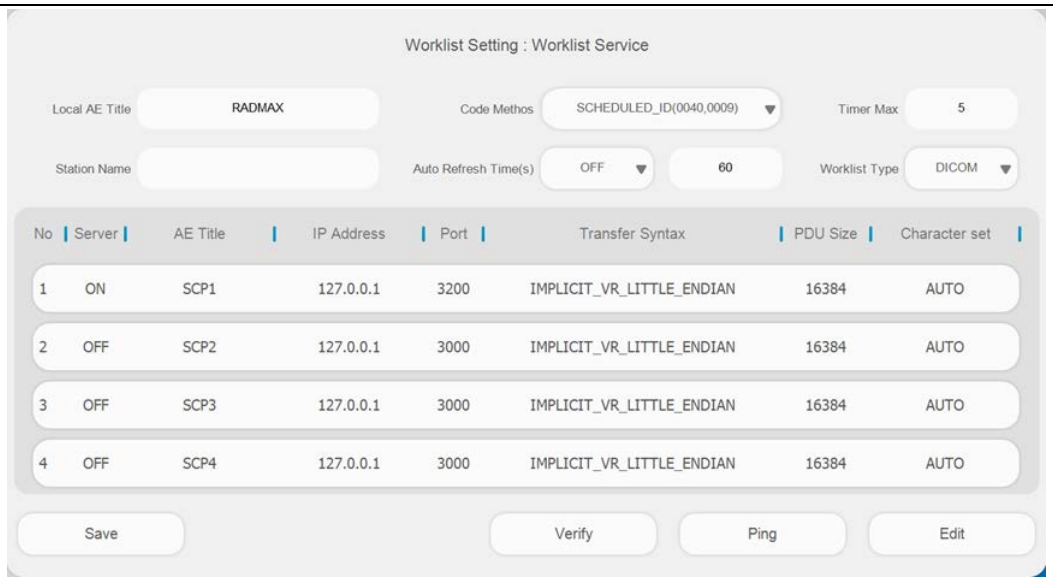
<Account Setting>



<Add Account and Modify Account Screen>

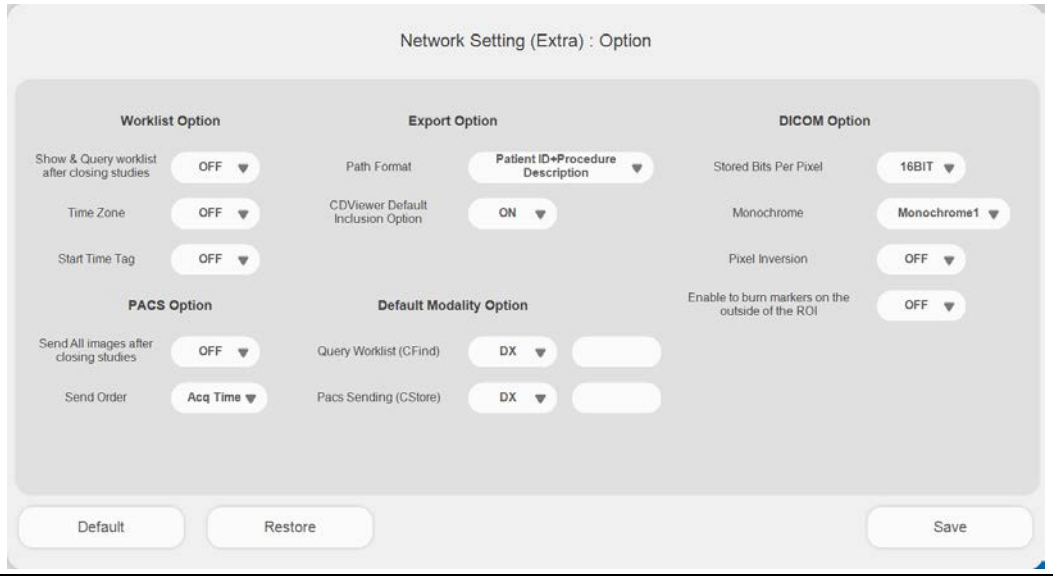
- Network Setting

Network Setting has worklist, PACS, MPPS, storage commitment, DICOM printer setting screen for network configuration. Each setting screen has **'Save'**, **'Verify'**, **'Ping'** and **'Edit'** button. Make sure clicking **'Save'** button when configuration ends.

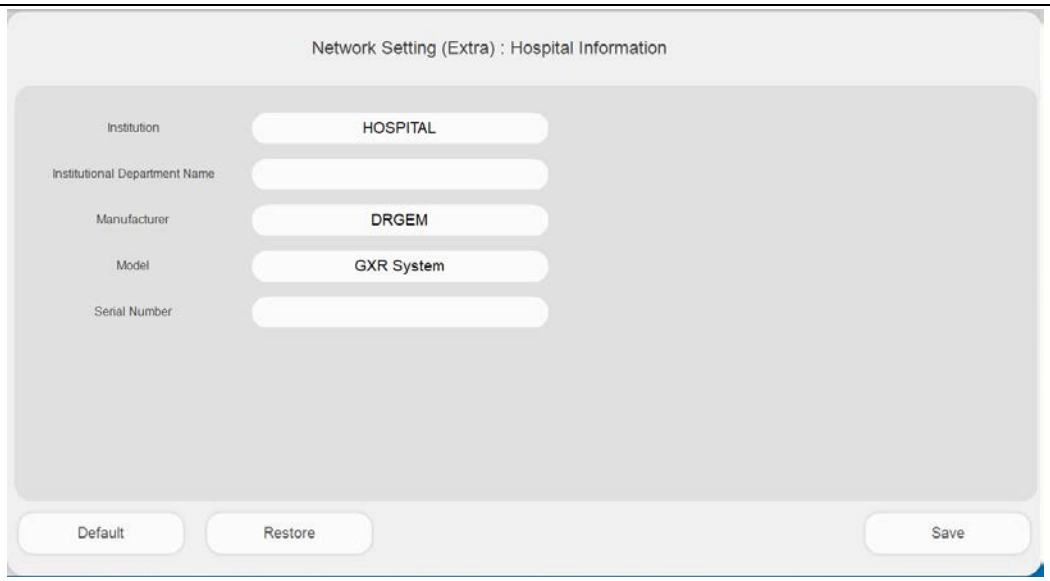


- Network Setting (Extra)

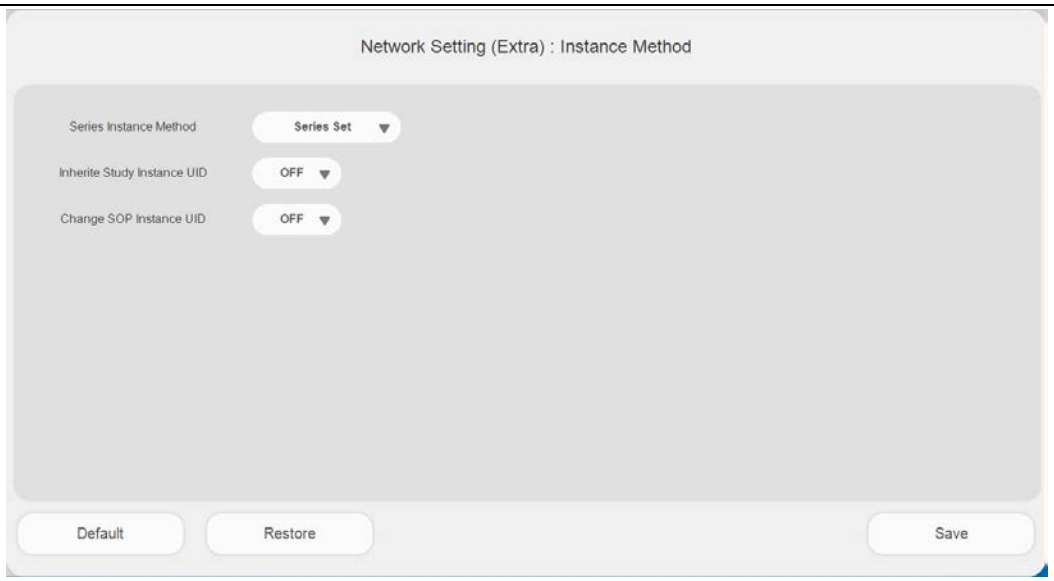
Network Setting (Extra) has option setting, Hospital Information Setting, Instance Method Setting screen for network extra configuration.



<Network Setting (Extra): Option>



<Network Setting (Extra): Hospital Information>

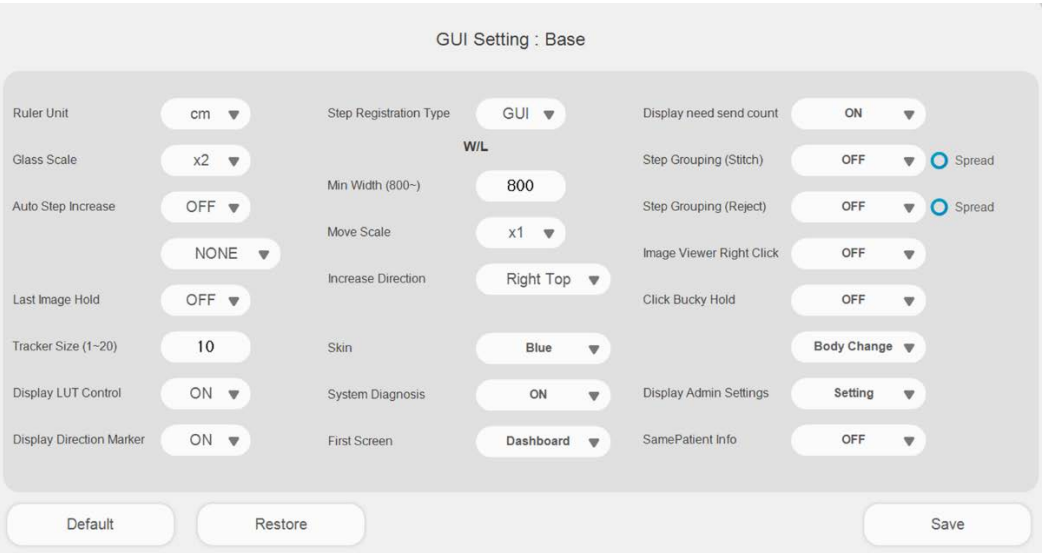


<Network Setting (Extra): Instance Method>

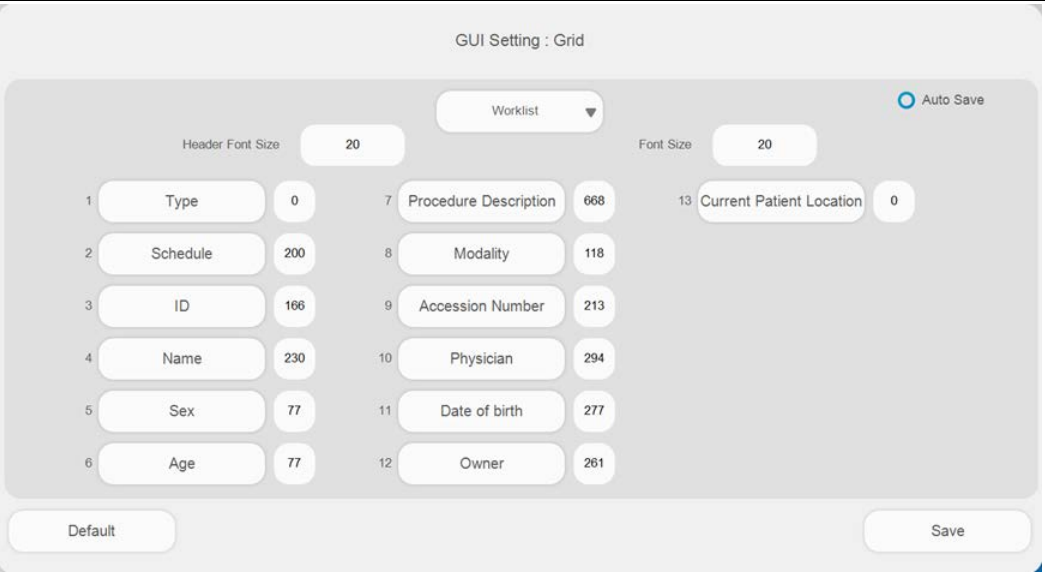
- GUI Setting

GUI Setting menu has sub menu as Base, GUI Grid, Position Guide, Base, GUI Grid, Marker, ROI, Overlay, Physician menu.

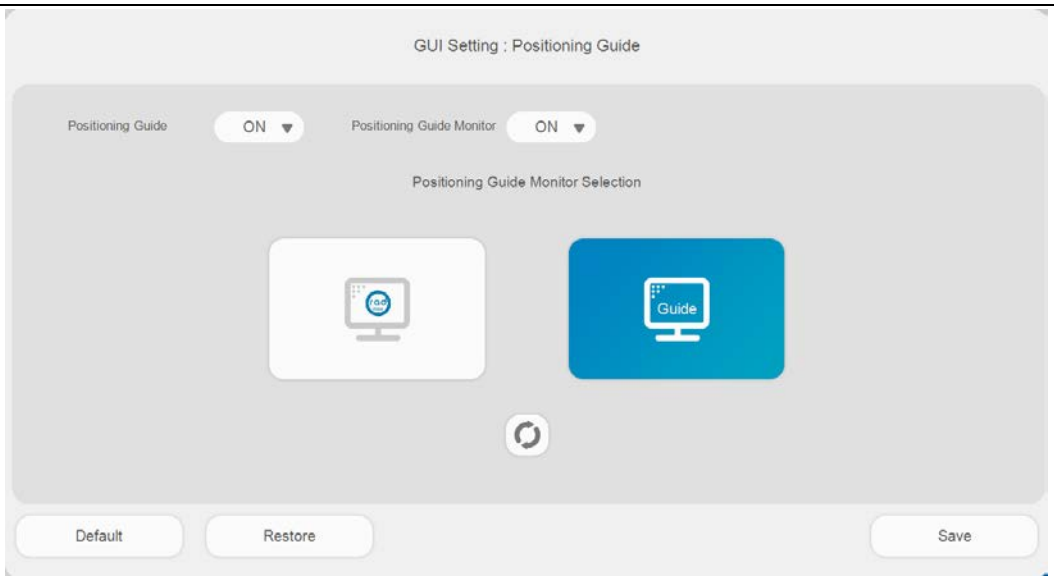
GUI setting has **'Default', 'Restore', 'Save'** buttons. **'Default'** button can make current setting to default and **'Restore'** button can make restore from saved setting value, and **'Save'** button can use current setting to save at configuration file.



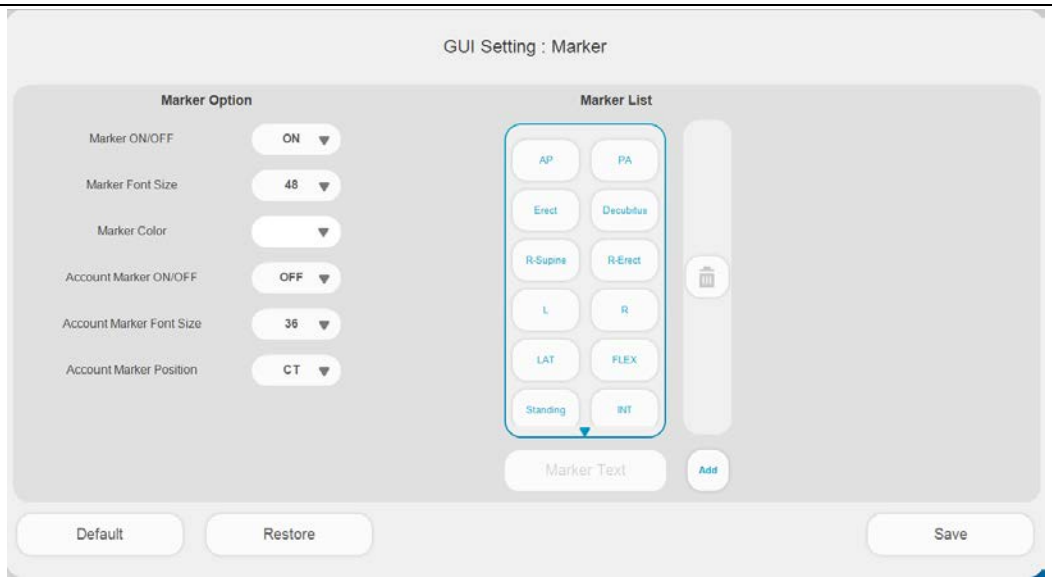
<GUI Setting: Base>



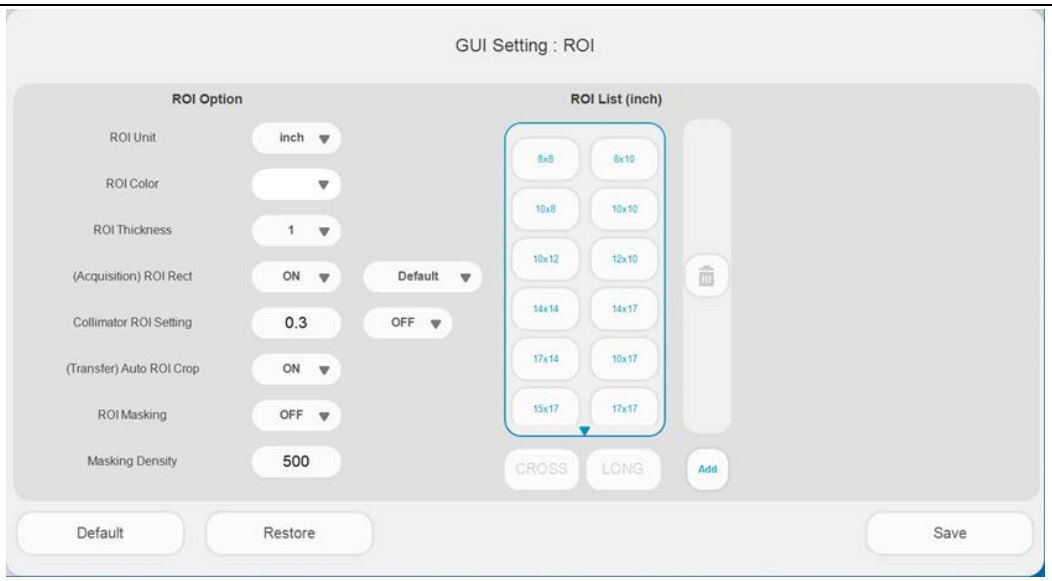
<GUI Setting: Grid>



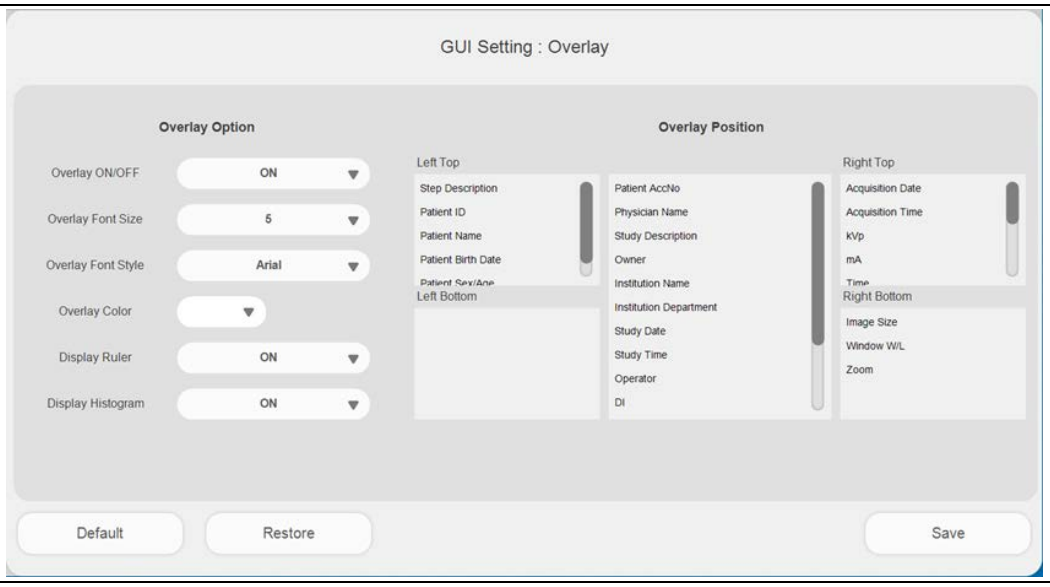
<GUI Setting: Positioning Guide>



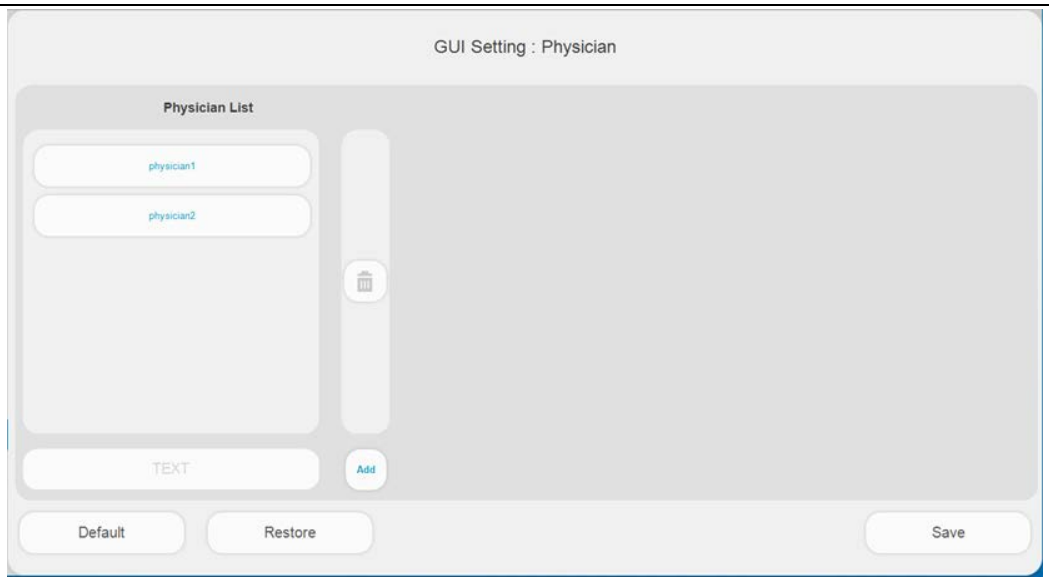
<GUI Setting: Marker>



<GUI Setting: ROI>



<GUI Setting: Overlay>



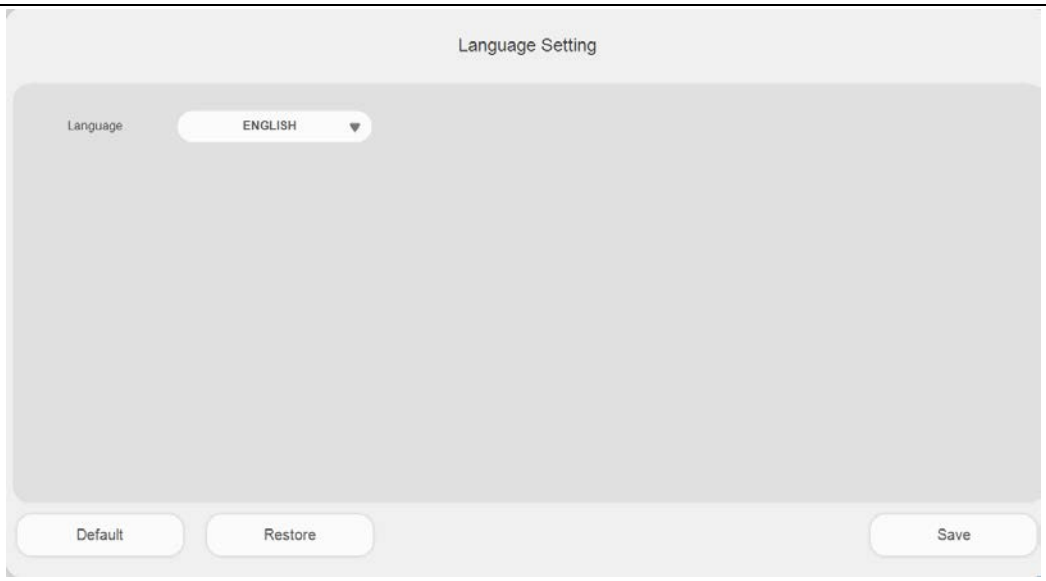
<GUI Setting: Physician>

NOTE
In GUI Grid setting, skin function will be change software GUI skin color. There are two types of GUI skin blue and dark currently. If change this option and save, then software restart automatically.

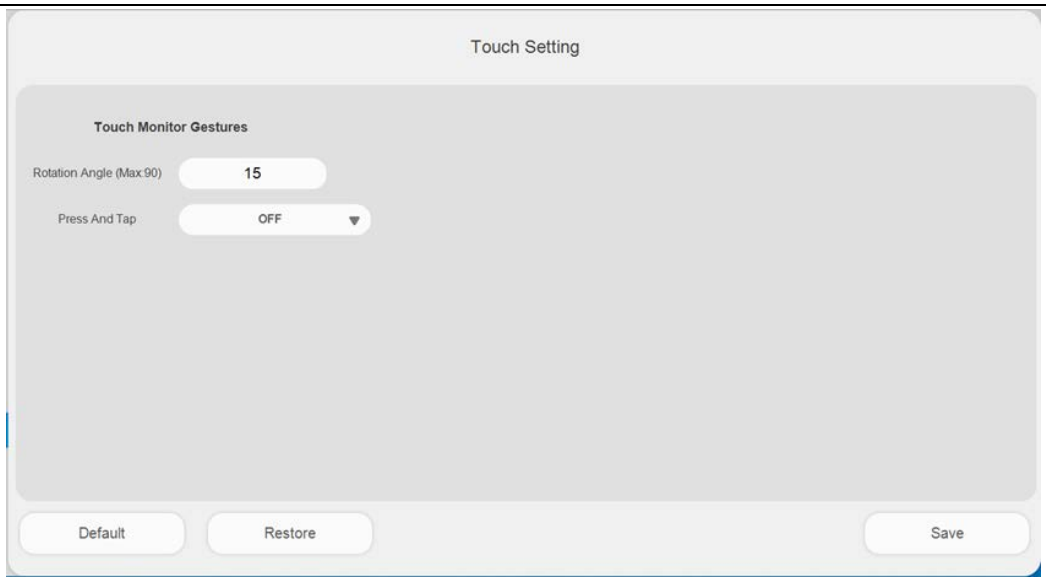
NOTE
In GUI Grid setting, using drag and drop can change column order instead up, down buttons in configuration software.

NOTE
Positioning Guide Monitor function is displaying patient position guide screen with full screen when using at least 2 more monitor. If the function is on you can make a choice to displayed screen monitor.

- Language Setting

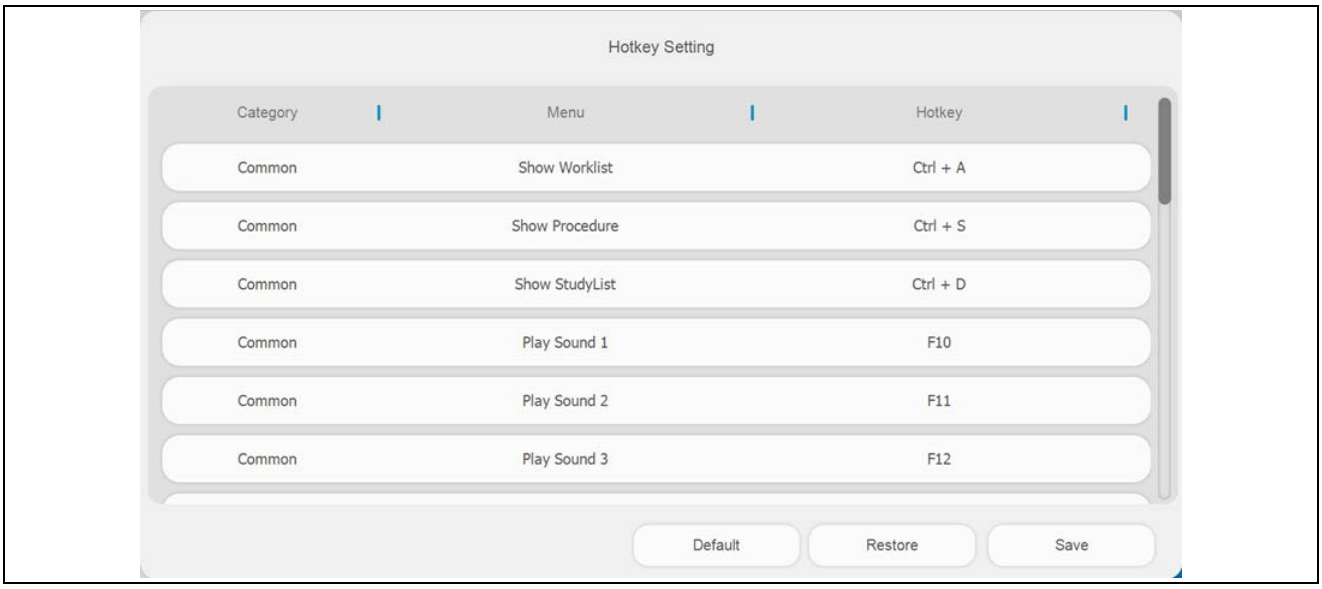


- Touch Setting



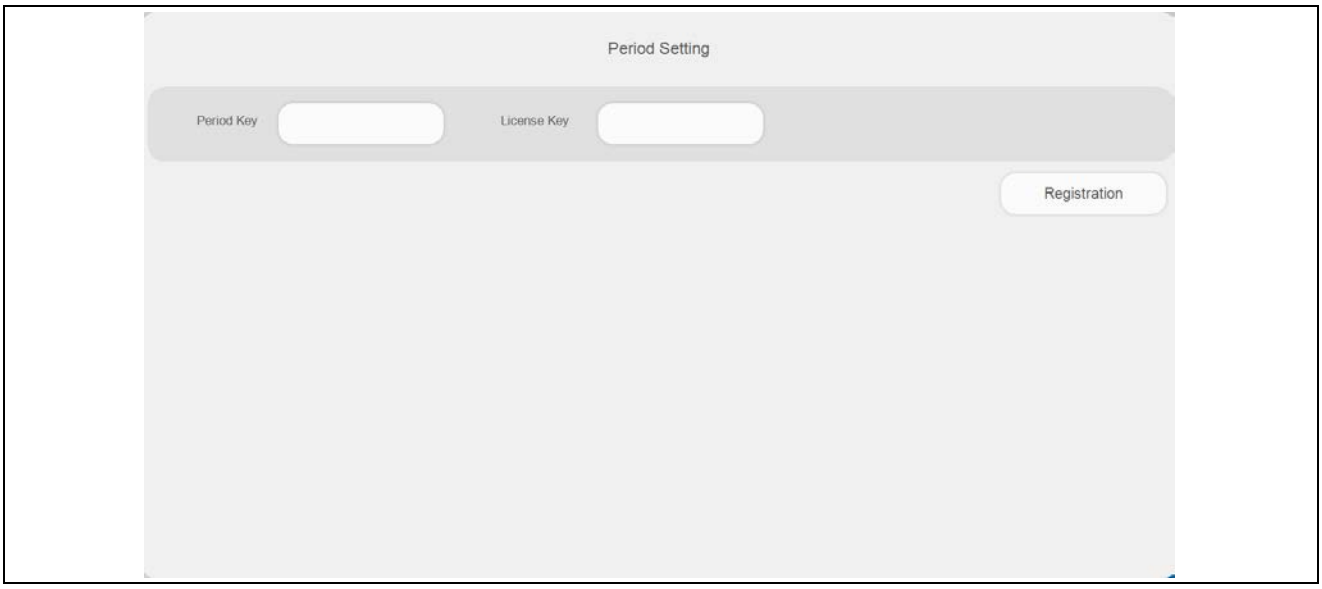
- Hotkey Setting

This menu can change hotkey setting. It can using by double Click hotkey list and press key combination. And also provide default, restore, save function for usage.



- Period Setting

In this menu, license key and period extension key can be registered. Enter the license key or period extension key and click the Registration button to register.



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APPENDIX G. VOICE OUTPUT

"RADMAX" imaging software can output a voice to guide the patient for exposing X-ray. The speaker must be connected to the workstation in order to output voice.

Press F10 ~ F12 keys to output voice. The voice output for each key is as follows

Function Key	Voice Content
F10	Take a deep breath and hold
F11	Breathe out
F12	Breathe out and hold

If you want to change the language for voice output, click the language shown below.
The list of languages that can be changed appears.

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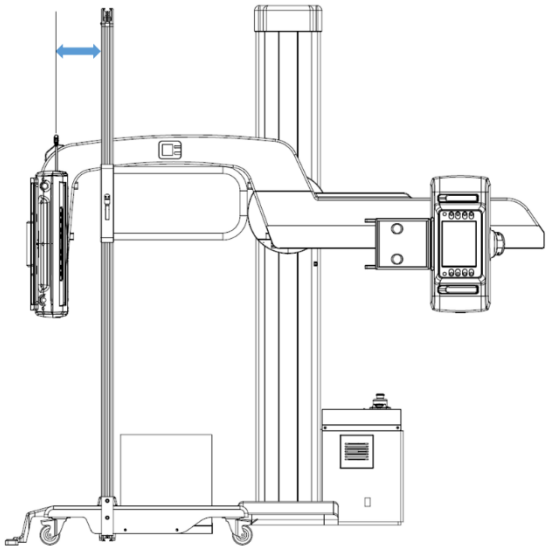
APPENDIX H. IMAGE STITCHING MODULE

The ***"DIAMOND"*** Stitch function acquires two or three x-rays in sequence and then combines them into a single long image. The process is automatic from the acquisition to the creation of the long image. In case the component images are not accurately aligned, the user may utilize stitching tool to accurately position the images.

H1. REQUIREMENTS

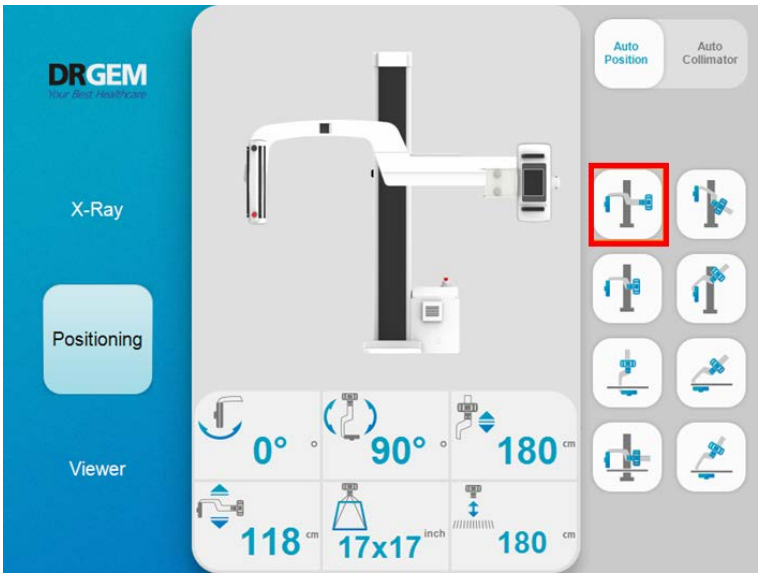
The main components of ***"DIAMOND"*** DR System comply with the regulatory requirements and design standards in this section as follows:

1. The stitch stand stopper must be installed so that the spacing between the front of the Bucky cover and the stitch stand is 15 cm as in the figure (a) below.



WARNING
If the stitch stand is placed nearer than 15 cm from the bucky cover, there can be contact during operation damaging the equipment.

2. The U-Arm rotation should be calibrated correctly for accurate stitching.
   To check this, first, press the indicated AP button in tube touch console to bring the U-Arm to 90 degree angle and maximum SID position.



3. Next, check with a bubble level gauge whether the U-Arm is horizontally level.
   If the U-Arm is not horizontally level, stand calibration may need to be re-performed.

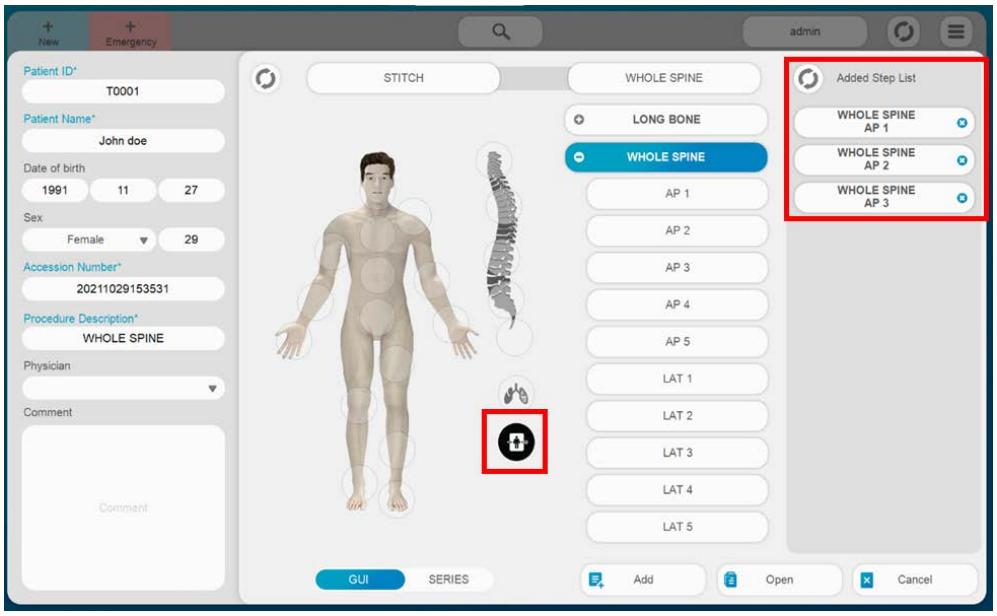
NOTE
For long leg imaging, an elevated foot padding of 15cm height should be used to allow lower part of patient leg to be imaged.

H2. STITCH PROCEDURE

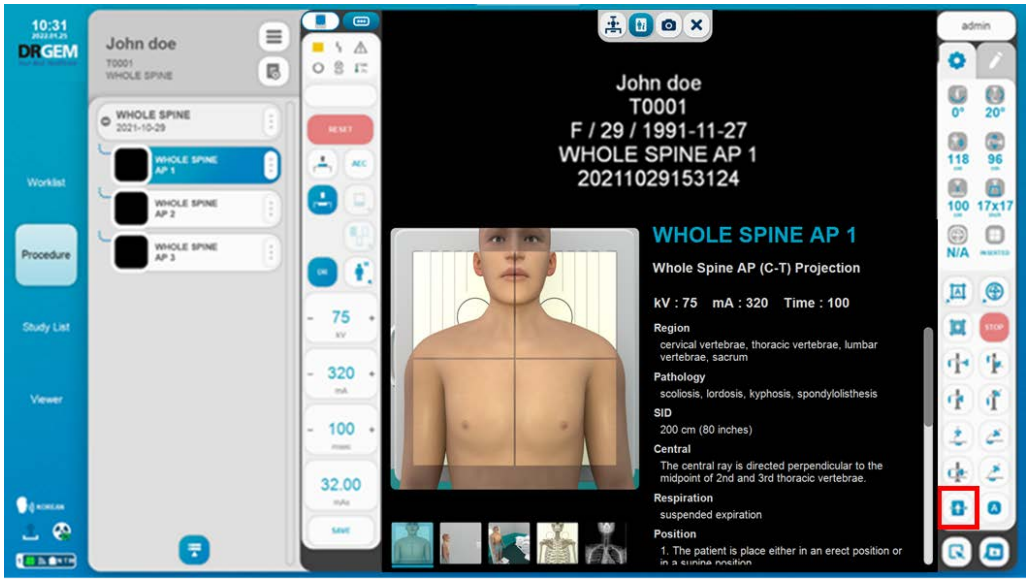
1. Run the ***"RADMAX"*** imaging software.

2. Perform patient registration.

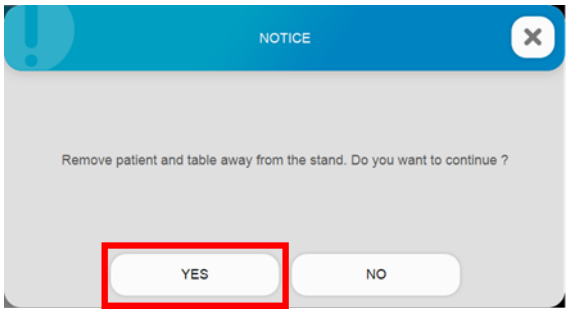
3. Add two or three APR projections to procedure for each of the imaging areas as follows. For stitching it must be added APR projection for stitching.



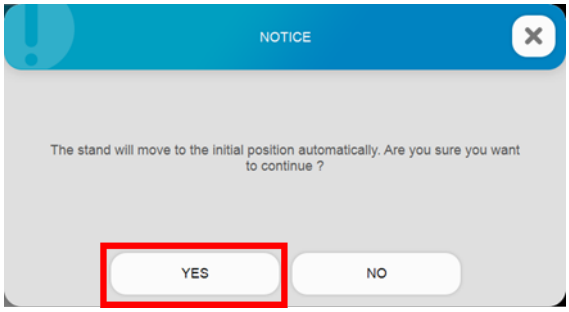
4. Click on the ' ' button.



5. If the following message appears, remove the patient or table away from the stand and then click **'Yes'** button.



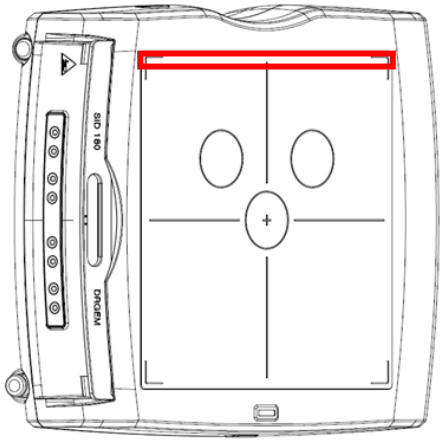
6. The following message box will appear. Click **'Yes'** button and the U-Arm will move to the default stitch position.



7. Wait for the stitch setup dialog to appear on screen as below.

8. Place the stitching stand 15cm in front of the Bucky cover and then position the patient on the stand. The 15 cm spacing is necessary for U-Arm rotation movement.

9. Adjust the U-Arm height until the top part of the detector (indicated by the red rectangle in the image below) is at the desired start height.



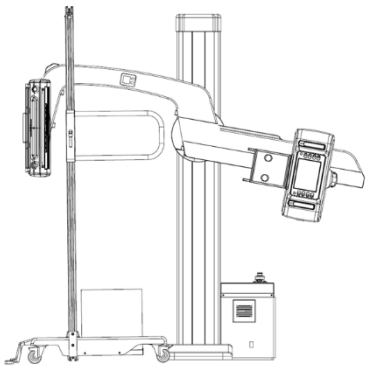
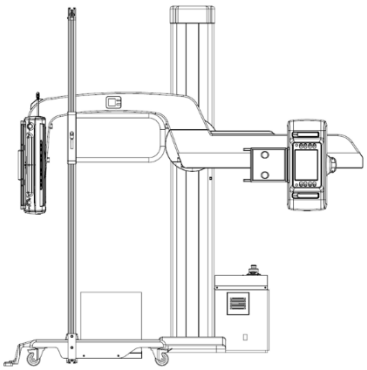
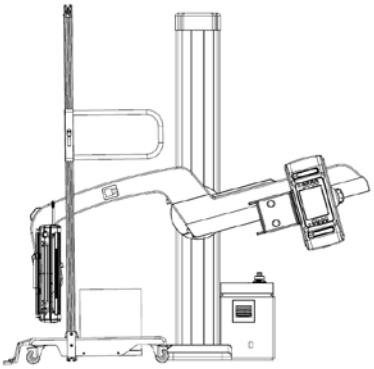
10. Enter the length and object to image distance value in the stitch setup dialog. Note that the maximum length from the current starting position is indicated beneath the length input box.

11. After click the **'START'** button, the stitch procedure will proceed automatically. Be sure to observe the patient during this process. You can stop the procedure at any time by clicking the **'stop'** button on the screen. The process takes about 30 seconds for two image count and 45 seconds for three image count.

12. Click **'Yes'** to run the procedure. If the image count is greater than the number of examination steps, extra steps will be added automatically as needed. The exposure conditions in the added steps will be identical to the last registered step.

13. The stitch procedure will proceed automatically. Be sure to observe the patient during this process. You can stop the procedure at any time by clicking the **'stop'** button on the screen. The process takes about 30 seconds for two image count and 45 seconds for three image count.

14. The U-Arm moves to each position and makes x-ray exposure. (If the image count is two, skip the second position).

		
<First Position>	*<Second Position>*	*<Third Position>*

15. When the procedure is completed, the stitch module will open with the images automatically stitched as in the screen shot below.
    In case the images are not accurately stitched, the image positions can be manually adjusted to produce accurate stitch image

NOTE
Please refer to the '4.4.4.6 Image Stitch' for a detailed description of the Image Stitching Tool

16. Finally, press the **'OK'** button to save the image.

APPENDIX I. DICOM VIEWER

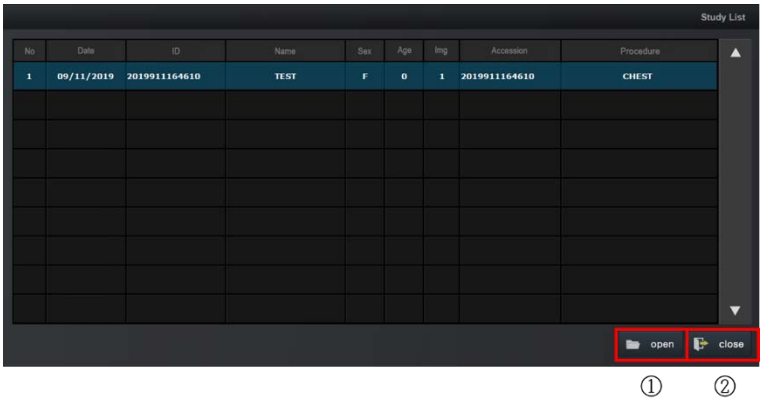
"RADMAX" imaging software DICOM viewer will be automatically included if the acquired images are burned to CD/DVD.

DICOM viewer will be automatically executed if the CD or DVD is inserted in drive at workstation.

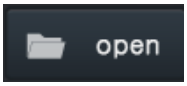
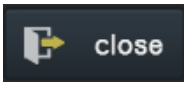
If exporting the study images to USB memory & HDD is done by software, execute CDViewer.

The DICOM viewer is as below.

<CDViewer Icon>

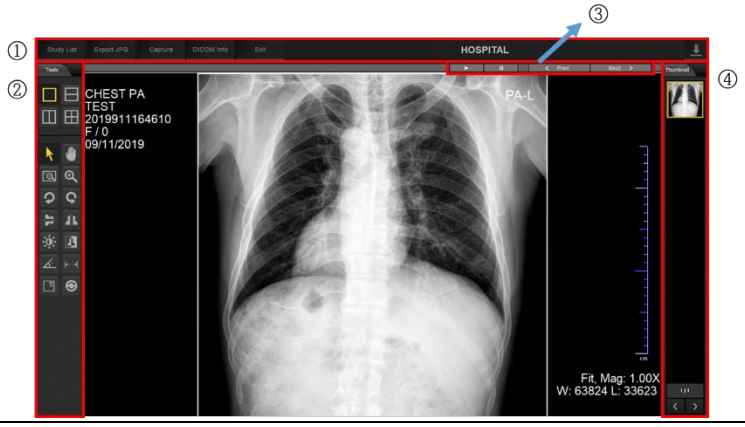


<DICOM Viewer>

①	Open Button		Display the images on the viewer area and the thumbnail images. Double-clicking a study is the same function as this button.
②	Close Button		Terminate the DICOM viewer.

NOTE
"RADMAX" imaging software DICOM viewer only can view the DICOM images created by ***"RADMAX"*** imaging software and cannot view the DICOM images which made by other software.

- Open



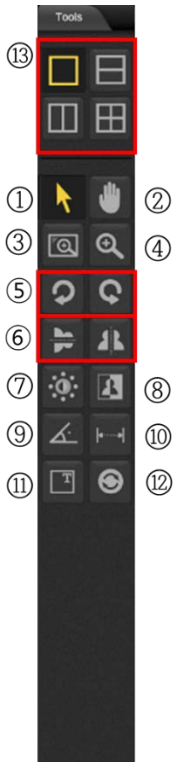
①	Menu Bar	-	Offer the DICOM viewer menu.
②	Image Tools		Offer the image edit functions.
③	Image Tools2	-	Offer the image display functions.

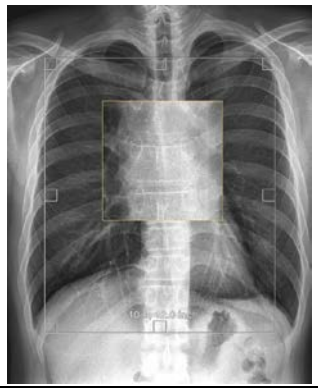
④	Thumbnail		View thumbnail images of opened study.

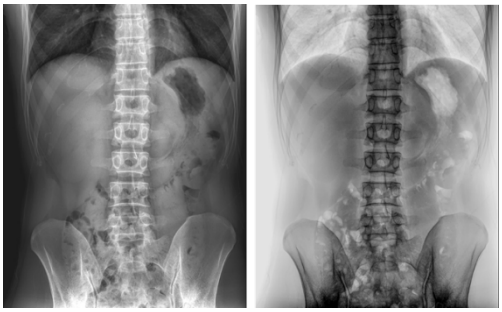
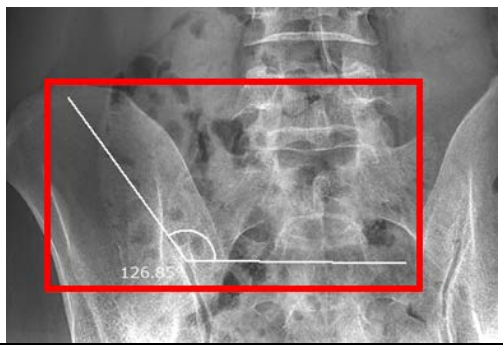
I1. MENU BAR

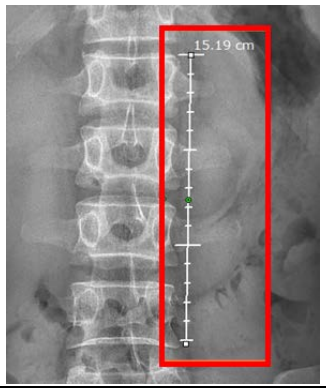
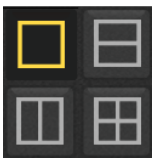
①	Study List Button	Study List	Change to Study List.
②	Export JPG Button	Export JPG	Save the image by JPG format.
③	Capture Button	Capture	Capture screen on viewer image area. It is like scree capture function on Windows.
④	DICOM Info Button	DICOM Info	Display DICOM header information.
⑤	Exit Button	Exit	Close the DICOM Mini Viewer program.
⑥	Minimize Button		Minimize the viewer.

I2. IMAGE TOOLS

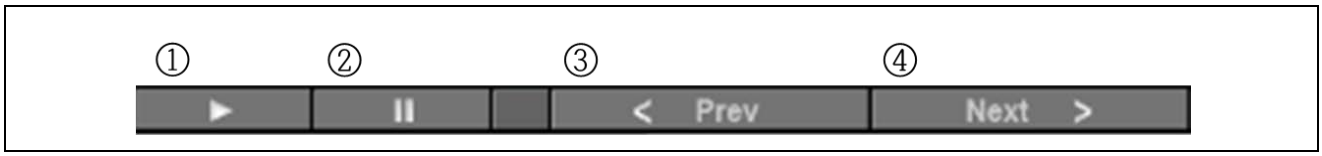


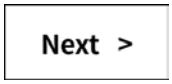
①	Select Button		Select an annotation including angle and ruler, the selected annotation is activated as shown in the figure.
②	Pan Button		Pan image with clicking left button of mouse.
③	Magic Glass Button		Magnify some regional part of image. Select this function and move with left button of mouse, the magnifier window will be showed up and moved. 

④	Zoom Button		Offer zoom-in, zoom-out function by click left button and drag on the image. - Zoom-in: Move the mouse to up direction - Zoon-out: Move the mouse to down direction
⑤	CCW Button		Rotate an image counterclockwise by 90°.
	CW Button		Rotate an image clockwise by 90°
⑥	Horizontal Mirror Button		Transform an image to horizontally mirrored image.
	Vertical Mirror Button		Transform an image to vertically mirrored image.
⑦	W/L Button		Change the window width & level (W/L) value in ROI area. When user makes ROI area with mouse drag, after then change the W/L to fit corresponding area.
⑧	Inverse Button		Invert black and white of image. 
⑨	Angle Button		Measure angle value by setting three points on image. 

⑩	Ruler Button		Draw a line between two points. When the line is drawn, the distance between two points is shown automatically. 
⑪	Overlay Button		Hide and show patient and image information on image.
⑫	Reset Button		Restore the image to the original image. Everything goes back to initial status when the image was acquired.
⑬	Layout Button		Change lay out of viewer. The entry is 1X1, 1X2, 2X1, 2X2.

I3. IMAGE TOOLS2



①	Play Button		Play opened images.
②	Pause Button		Pause playing of images.
③	Preview Button		View preview image from current image.
④	Next Button		View next image from current image.

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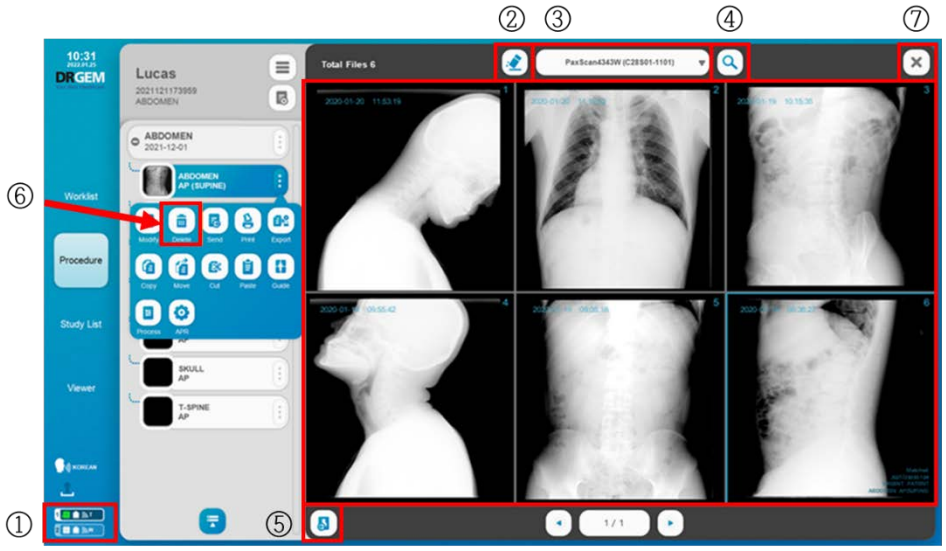
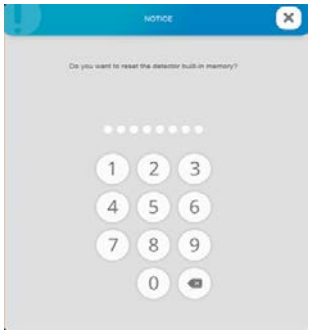
APPENDIX J. BUILT-IN MEMORY

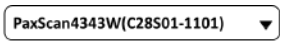
The built-in memory function saves 200 images in detector built-in memory, uploading the images and applying them to procedure step.

J1. FUNCTIONS



<Built-In Memory Screen>

①	Detector Setting		Change the operation mode of detector. When you click on a detector 1 or 2, each detector setup screen appears.
②	Reset Button		Delete and reset all images. Click **'Yes'** button on the Notice dialog to delete and reset. The password is the account you are logged in to. 

③	Detector Selection Filter		Select detector from the list.
④	Search Button		Upload the images from the built-in memory and display them in the viewer.
⑤	Apply Image Button		Apply the image to procedure step.
⑥	Delete Image Button		Delete the image selected in STEP LIST
⑦	Close Button		Exit the built-in memory screen.

NOTE
The operation mode must be set to ‘Normal Mode’ to use the ‘search’ and ‘reset’ function or use the normal acquisition mode.

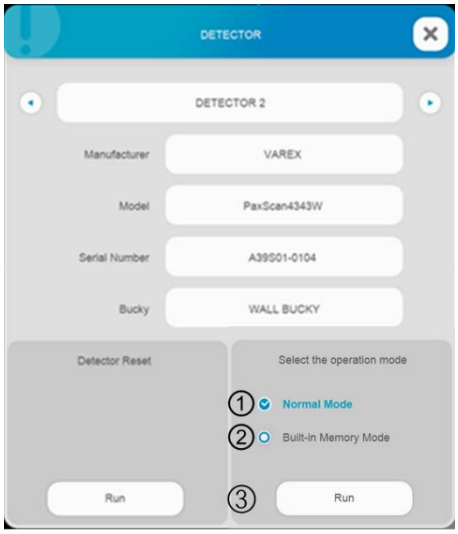
NOTE
Images are arrange chronologically from most recent to oldest. It takes about 2-3 seconds per image. If you get the message to check the detector status, check the detector connection.

NOTE
The acquisition time is displayed in the upper left of each image.

NOTE
If you reset the built-in memory, you cannot restore it again.

NOTE
If you use ‘ ’ or ‘ ’ button, overlays such as ‘Matched’, ‘Patient id’, ‘Patient name’, ‘Procedure step description’ are displayed or removed on the image. Procedure step is displayed or removed ‘(B.M)’ mark. Images that have already been applied cannot be applied to other procedure step.

- Detector Setting



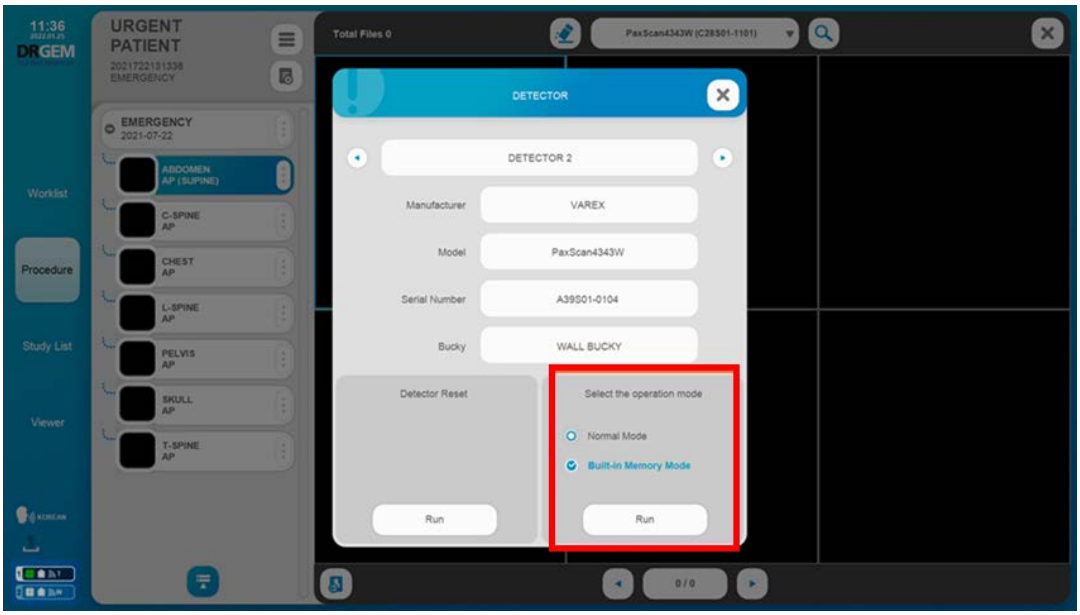
①	Normal Mode	Normal Mode	You can use the normal acquisition mode. Communication between PC (***"RADMAX"*** imaging software) and detector is connect
②	Built-in Memory Mode	Built-in Memory Mode	You can image acquire without a PC (RADMAX) connection. Communication between PC (***"RADMAX"*** imaging software) and detector is disconnect
③	Run Button	Run	Run the selected mode.

NOTE
The operation mode must be set to 'Built-in Memory Mode' to acquire the image without a PC (***"RADMAX"*** imaging software) connection

J2. BUILT-IN MEMORY PROCEDURE

1. Connect between ***"RADMAX"*** imaging software and detector.
2. Click the ' ' button to go to the built-in memory screen.
3. Please select detector from the list.

4. Click the ' ' button to reset the built-in memory before the image is acquired.
5. Please set the operation mode to **'Built-in Memory Mode'**



NOTE
Do not reboot the detector. Do not turn off the software. If you turn off the software or reboot the detector, the operation mode will change to 'Normal Mode'.

6. Take the detector to the x-ray room to expose the X-RAY and acquire an image.

NOTE
You can image acquire without a PC (***"RADMAX"*** imaging software) connection. The detector responds to the X-RAY and acquires an image of itself.

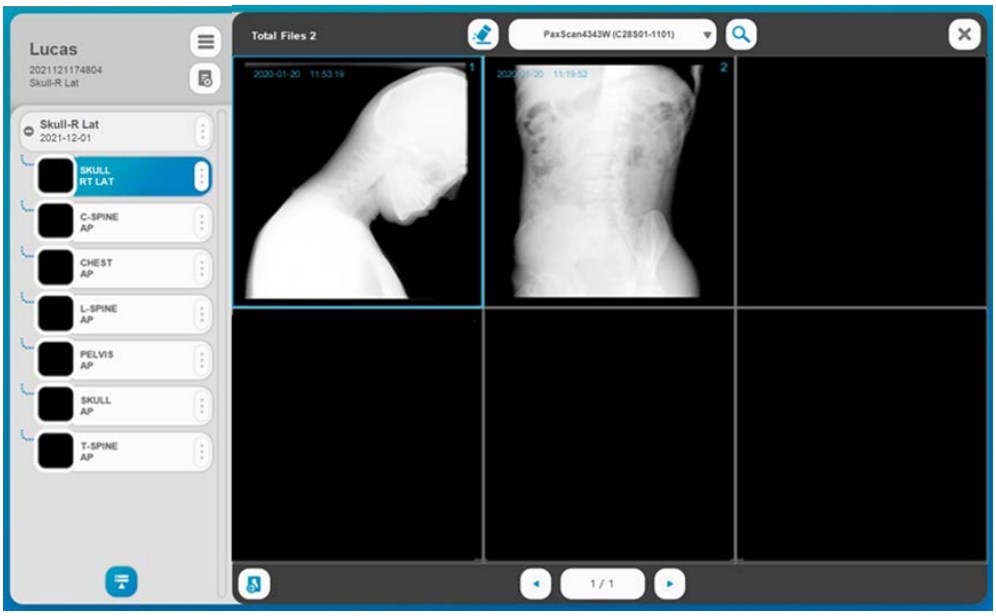
NOTE
Make sure the detector is turned on before X-RAY exposure. After exposing the X-RAY, Wait at least 10 seconds for the image acquisition to complete, and then proceed to the next shot. Otherwise, the image may not be acquired.

NOTE
The acquired image does not have information to identify the patient. In order to distinguish the patient from the acquired image, the image should be taken with a marker (lead) or whenever taking the image, it's required to record identifying information such as patient ID, patient name and STEP name.

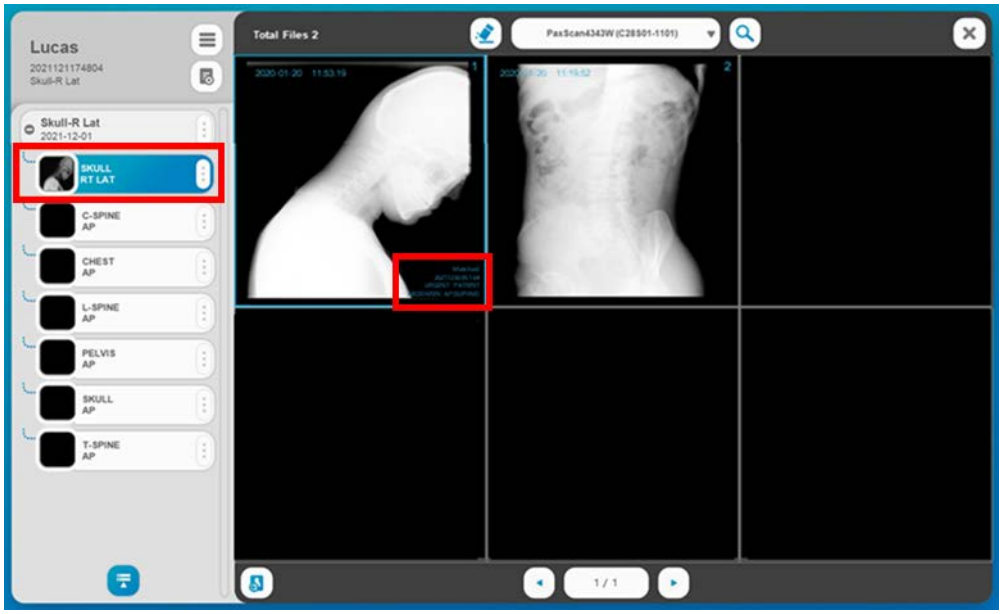
7. After acquiring an image, go to PC and connect between ***"RADMAX"*** imaging software and detector.

8. Please set the operation mode to **'Normal Mode'**

9. Click the ‘ ’ button to upload the acquired image.



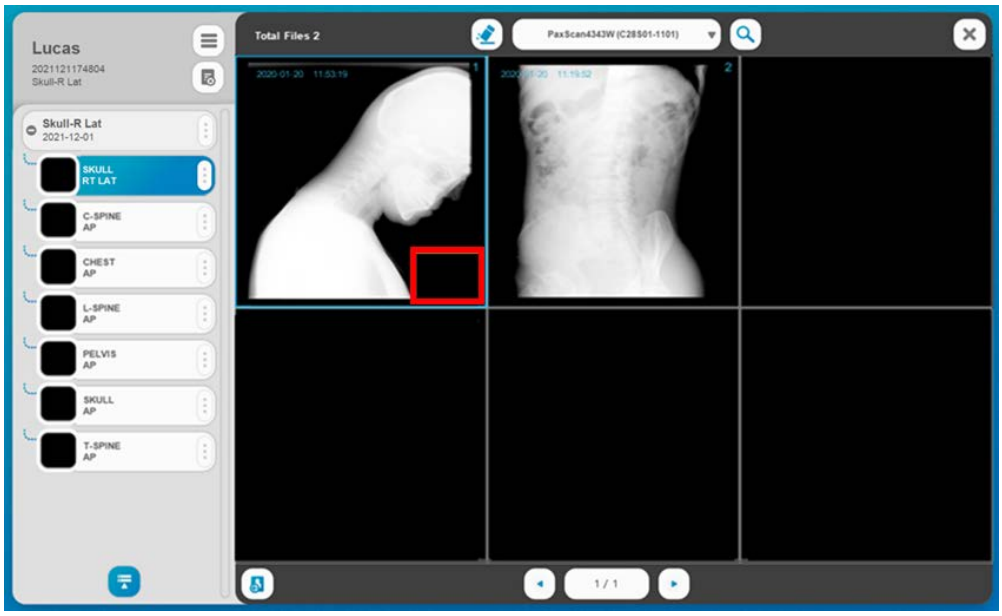
10. Click the ‘ ’ button to apply the selected image to the selected procedure step.



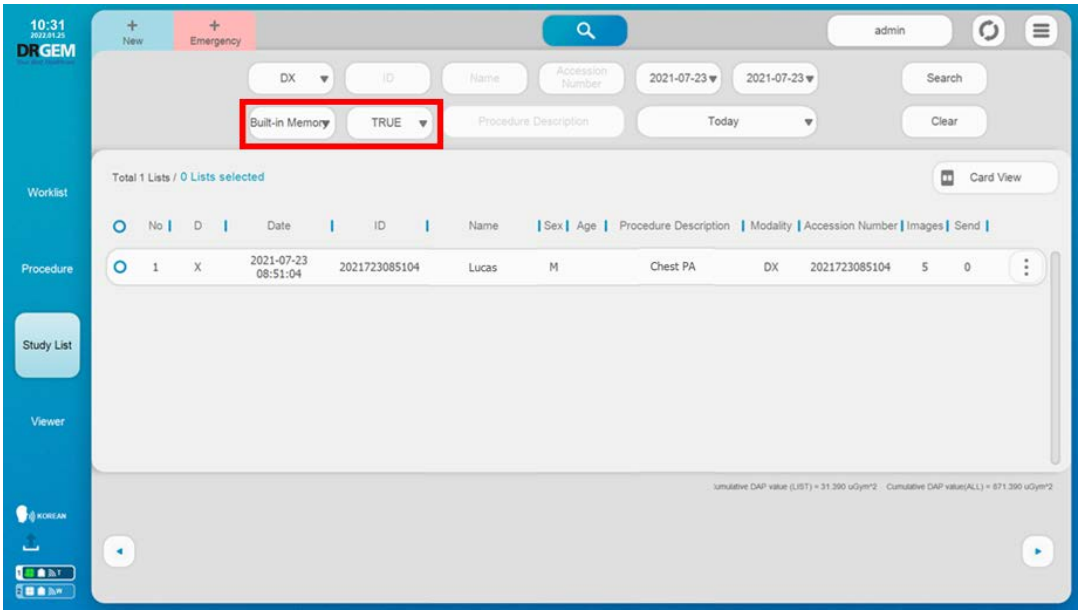
CAUTION
Correct matching should be made by referring to the information (patient ID, patient name, procedure step description, etc.) recorded at the time of image acquisition.

NOTE
The manufacturer is not responsible for the problem of applying the incorrect image to the patient without checking the documented procedure.

11. If the Incorrect image is applied to procedure step, delete the image.



12. On the 'Study List' screen, select **'Built-in memory'** and **'TRUE'** and check the study that contains the built-in memory image.



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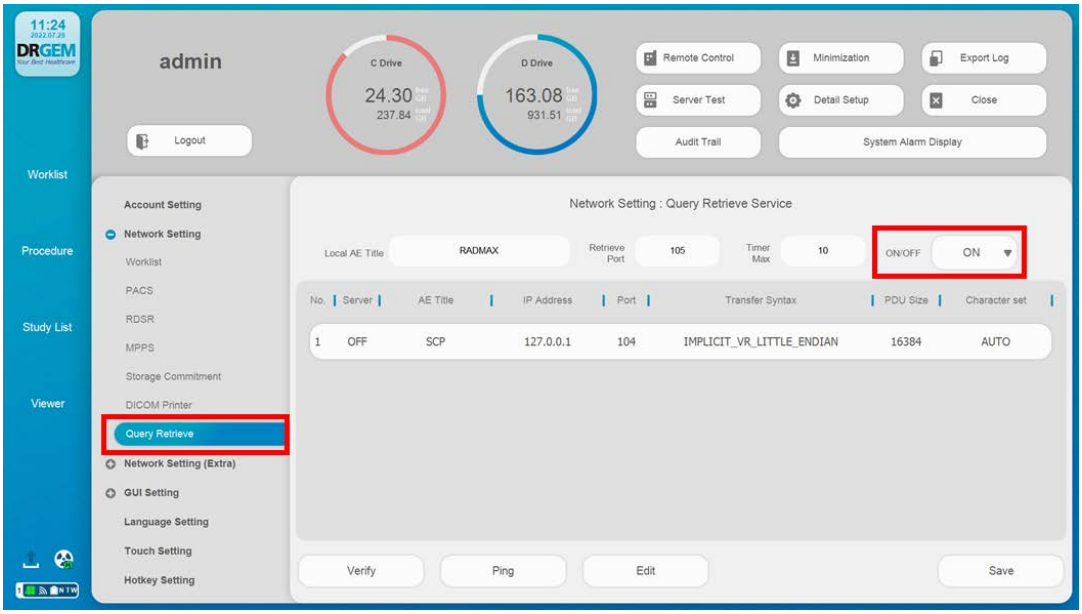
APPENDIX K. QUERY/RETRIEVE

Query is a function to search the study list stored in PACS, and Retrieve is a function to retrieve the image of the searched study list. It outputs the received image on the display and provides a function for the user to check and manipulate the image

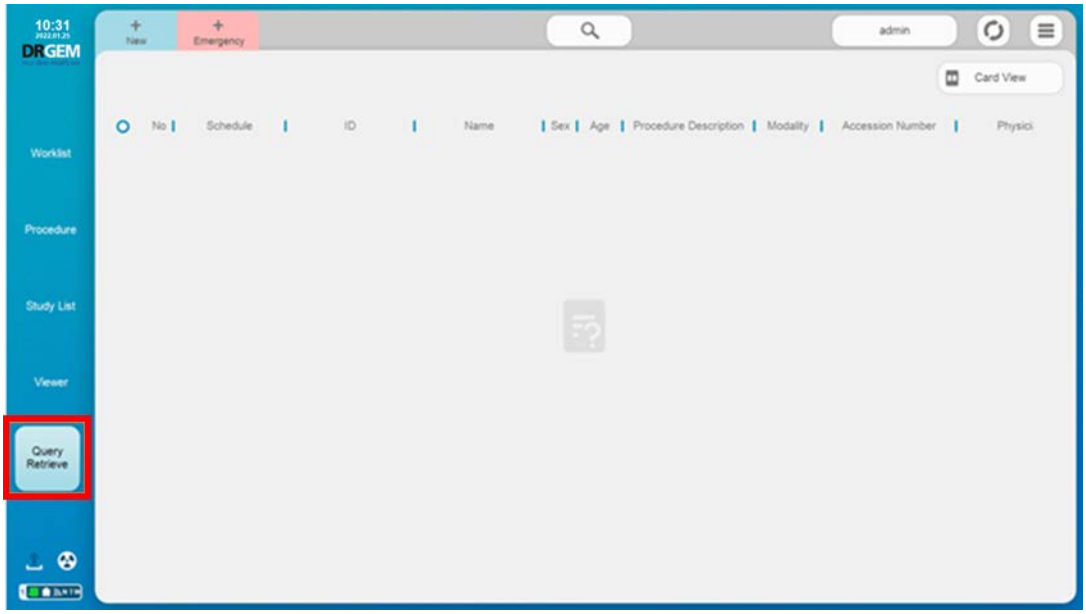
K1. OPTION SETTING



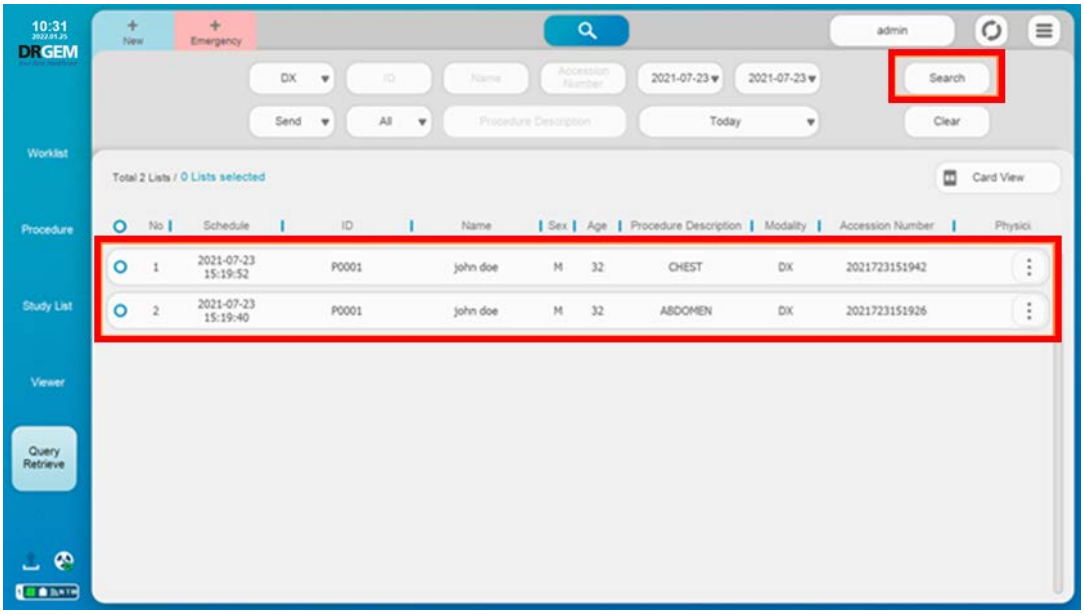
NOTE
To use Query/Retrieve function, please refer to the ‘APPENDIX F2.Network Setting Query/Retrieve Setting’ section.

K2. HOW TO QUERY

1. Select the **'Query/Retrieve'** menu.



2. Enter the conditions to query the study list from a PACS server. And click the **'Search'** button. The study list matching the search conditions appears as shown below.



NOTE
Please refer to the "4.4.3.1 Search (Query From Worklist Server)" section for a detail information of the conditions to search.

3. Select the list to be received from the PACS server and double-click the selected list click the **'Open'** button. The progress of retrieving images appears as shown below.

4. The received images are displayed on the right thumbnail image, and when a thumbnail image is selected, the image is displayed on the screen

NOTE
Please refer to the '4.4.4.3 Toolbox' section for image tool buttons on the left side. ROI & Marker buttons do not work.

NOTE
The received images are not stored in the local database, and when the current screen is closed, the images disappear.

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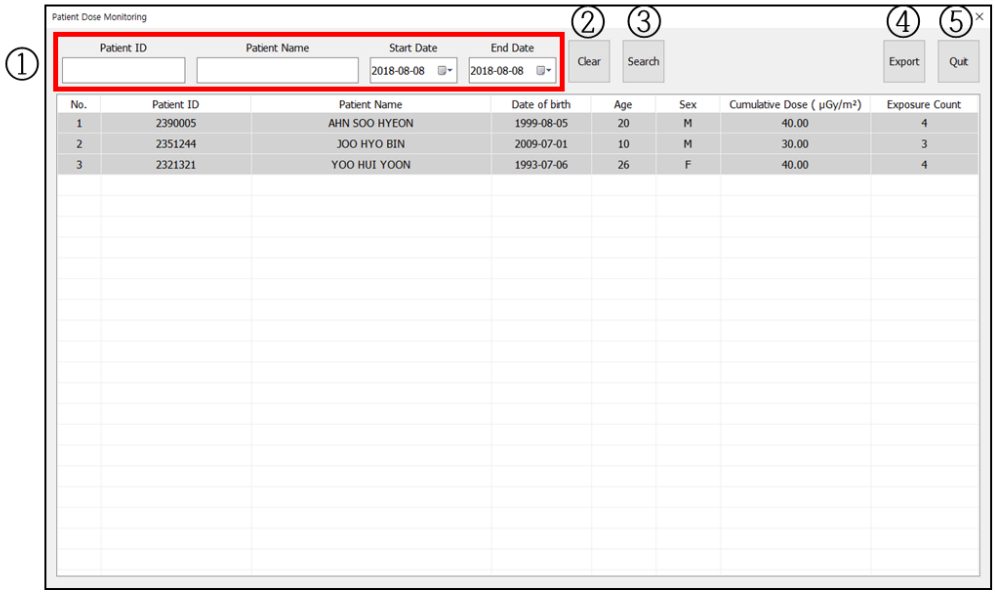
APPENDIX L. PATIENT DOSE MONITORING

The Patient Dose Monitoring program display accumulated DAP value of the patient.

To run the Patient Dose Monitoring program, click the 'PatientDoseMonitoring.exe' file in the 'C:\Radmax' folder.



<Patient Dose Monitoring Screen>

①	Search Condition	-	Enter the search conditions
②	Clear Button	Clear	Delete the search conditions
③	Search Button	Search	Display a list matching the search conditions.
④	Export Button	Export	Export the list as an excel file.
⑤	Quit Button	Quit	Exit the program

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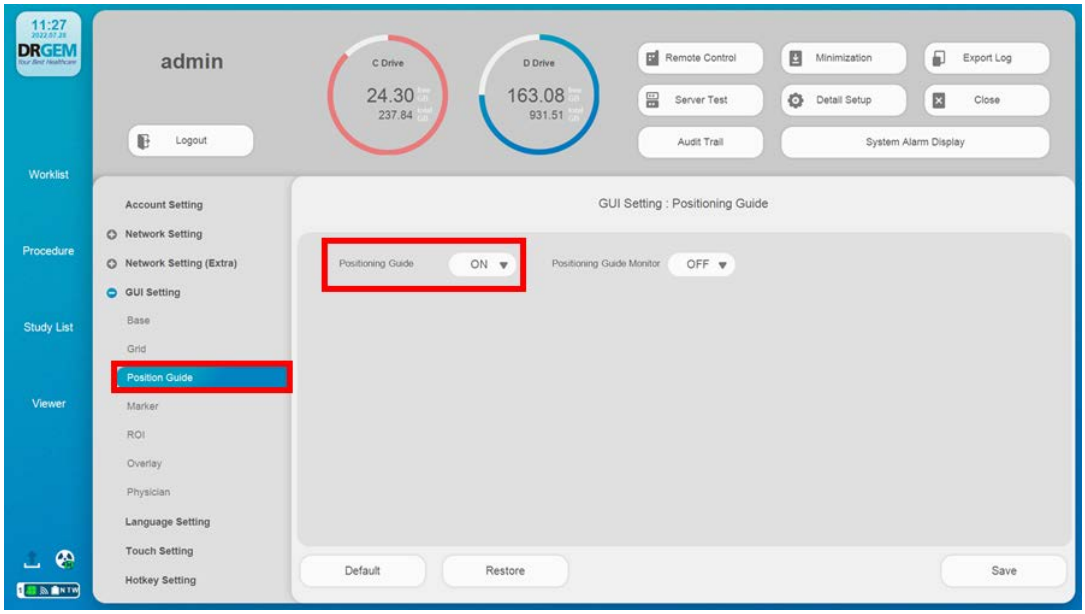
APPENDIX M. APR POSITIONING GUIDE

The APR Positioning Guide function provides the way to take an X-ray for each APR

M1. OPTION SETTING

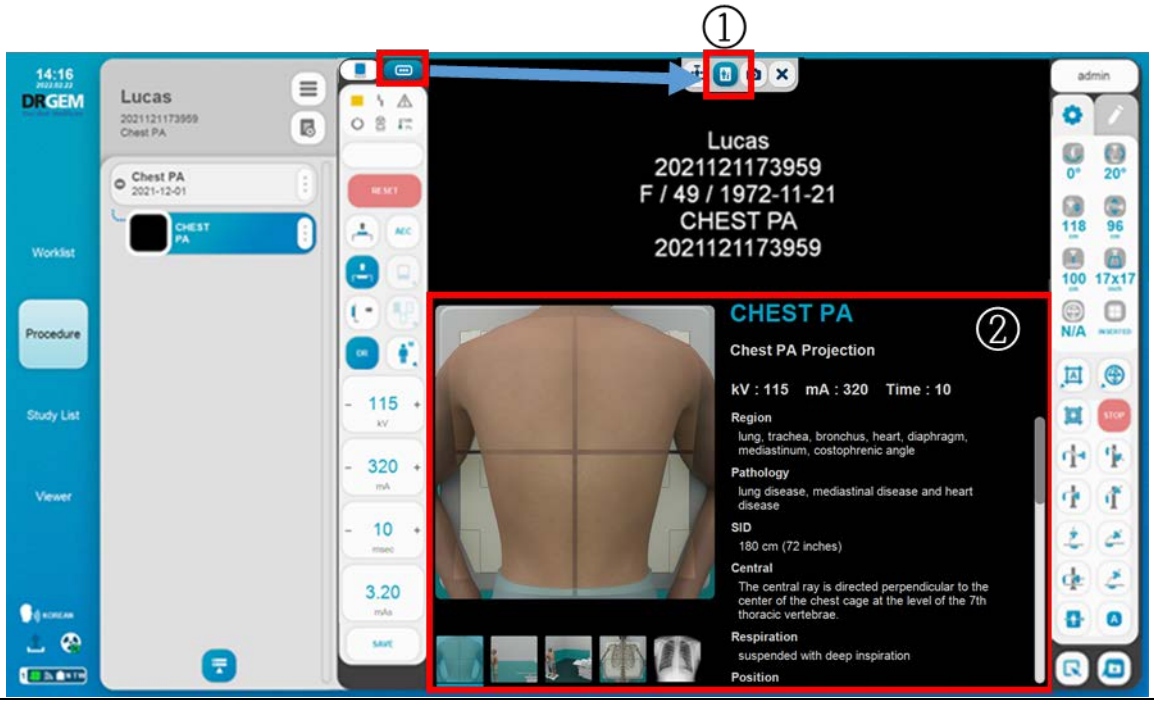


NOTE
To use APR Positioning Guide function, please set APR Positioning Guide to ‘ON’

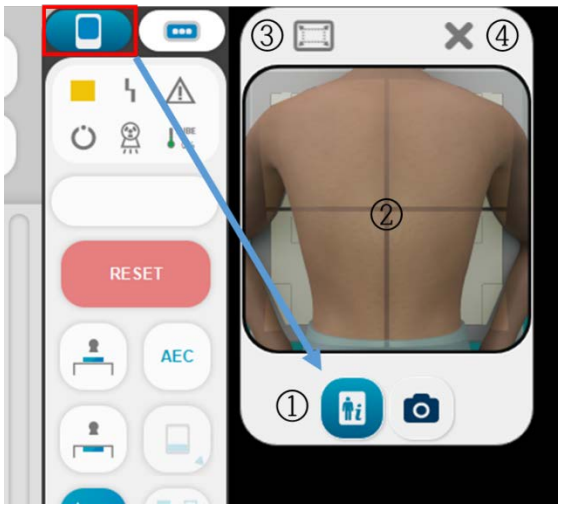
M2. HOW TO USE

1. Select the procedure step.

2. Click the ‘ or ’ button, then click the " " button, and the guide will display on the screen.



<Enable APR positioning guide function in full screen>



<Enable APR positioning guide function in small widget screen>

①	APR Positioning Guide Button		Display APR Positioning Guide on screen.
②	APR Positioning Guide	-	Display APR positioning Guide information
③	Full Screen Button		Expand a small widget screen to full screen.
④	Exit Button		Exit the widget screen.

NOTE
Move the widget screen position by right-clicking and dragging. It is always displayed only on the procedure screen.

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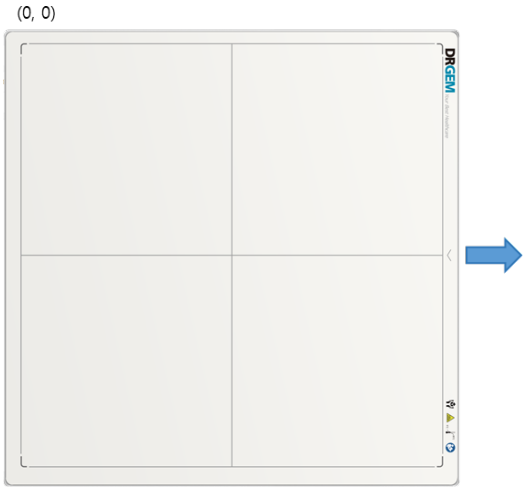
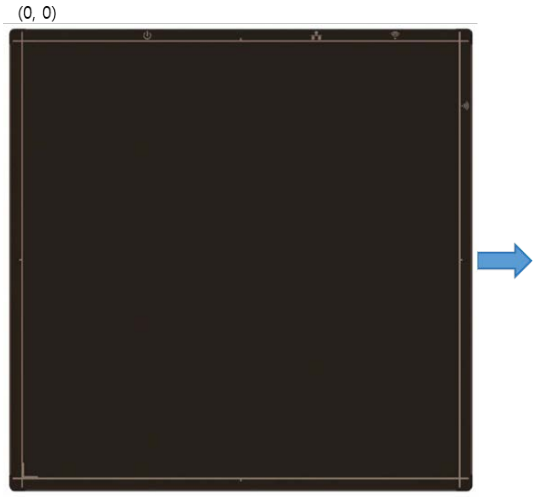
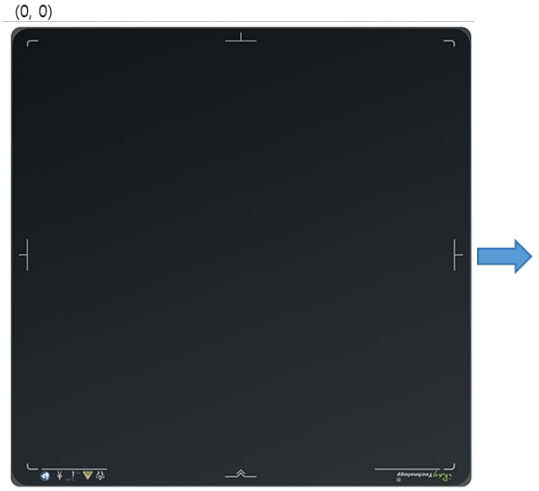
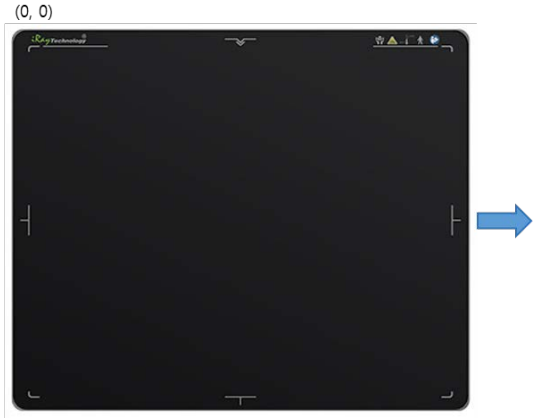
APPENDIX N. DETECTOR INSERTION DIRECTION

	
<Mano4343W>	<4343W(Basic)>
	
<Mars1717X>	*<Mars1417X>*

NOTE
Depending on the location of the WBS, it may be necessary to change the ***"RADMAX"*** imaging software setting.

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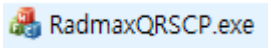
APPENDIX O. SERVICE CLASS PROVIDER

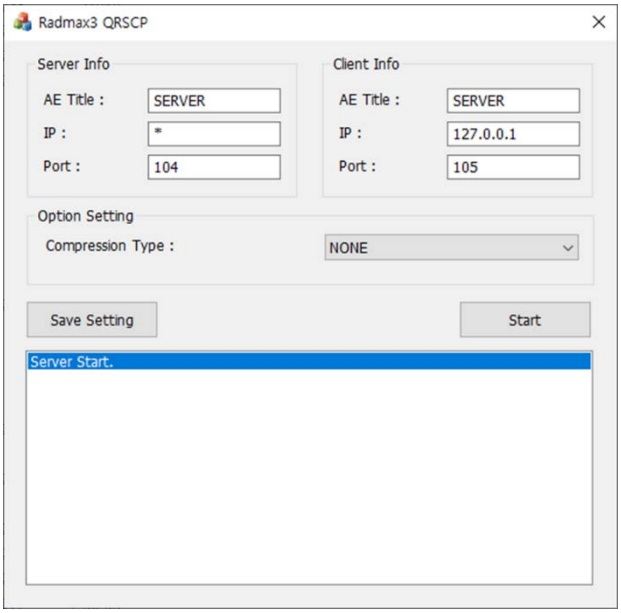
"RADMAX" imaging software supports the SCP (Service Class Provider) function. SCP is as follows.

O1. SCP SERVICE SETTINGS.

1. Run the 'RadmaxQRSCP.exe' program on the path where ***"RADMAX"*** imaging software is installed.



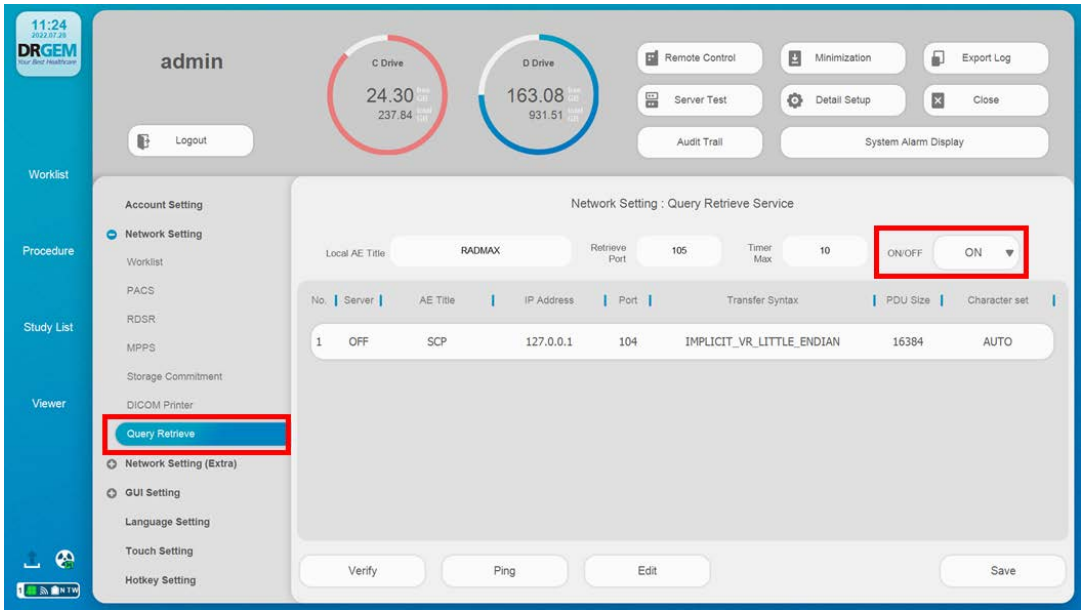
2. Enter server and client information.



NOTE
RadmaxQRSCP.exe must be run and set on the Workstation that sends the image. The server information is the information of the current workstation, and the client information is the information of the workstation to be checked by receiving the image.

O2. SCP CLIENT SETTINGS.

1. Run ***"RADMAX"*** imaging software on the workstation to be used as a client and enter the information set in the SCP server in the Query/Retrieve settings.



NOTE
The SCP Client uses the Query/Retrieve function. To use Query/Retrieve function, please refer to the 'APPENDIX F2.Network Setting 3) Query/Retrieve Setting' section.

O3. HOW TO SCP CLIENT

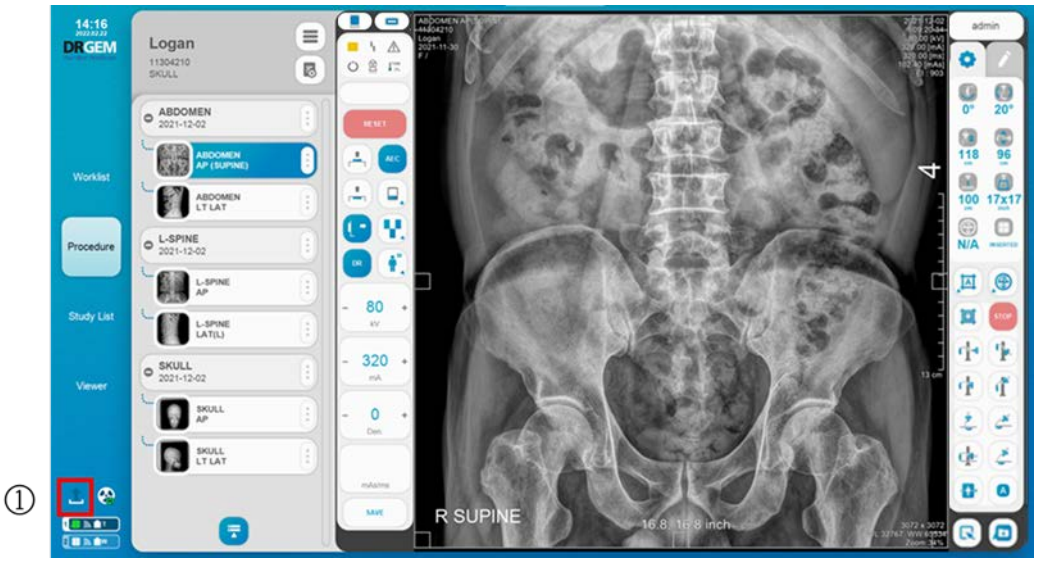
Please refer to the 'APPENDIX K2. How to Query' section for HOW TO SCP CLIENT.

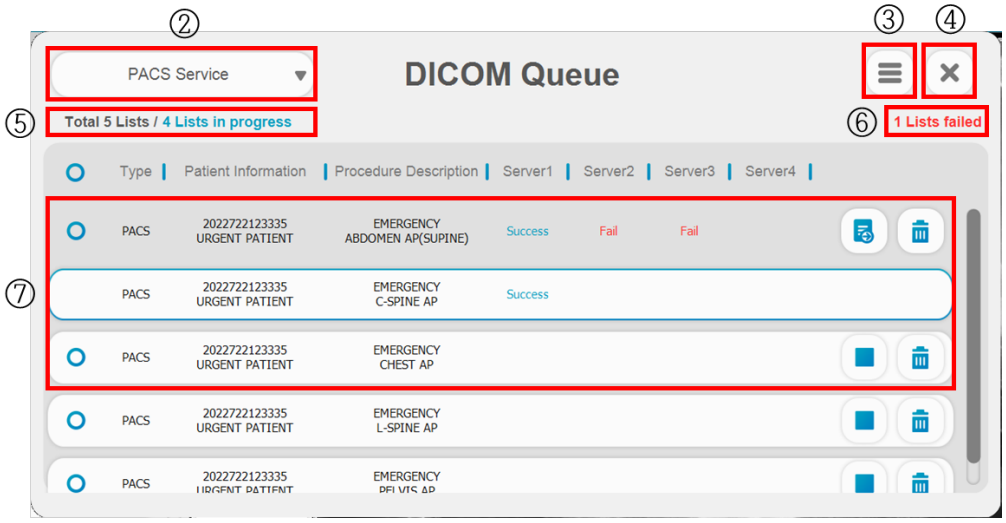
But enter the conditions to query the study list from a SCP server.

APPENDIX P. DICOM QUEUE

This is the DICOM Queue. Here you can see a list of all Studies that have been sent or are in the process of being sent.

P1. FUNCTIONS



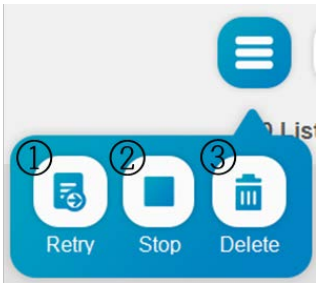


<DICOM QUEUE>

①	DICOM Queue Button		Click the button to go to the DICOM Queue screen.
②	DICOM Server type Selection Filter		Select DICOM Server type from the list.
③	More Button		Display the **'Retry'**, **'Stop'** and **'Delete'** button.
④	Exit Button		Exit DICOM Queue screen.
⑤	Total Lists / Lists in Progress		Display the total list and the list that is being sent.
⑥	Lists failed		Displays a list of failures.
⑦		Display the Transfer completed state (transfer success or fail state)
		Display the Waiting state for send.
		Display the Sending state.

- More Button

Those buttons are only work with checked (Checkbox) steps.



<More Button>

①	Retry Button		Retry sending failed items
②	Stop Button		Stop items in waiting state for send.
③	Delete Button		Delete items

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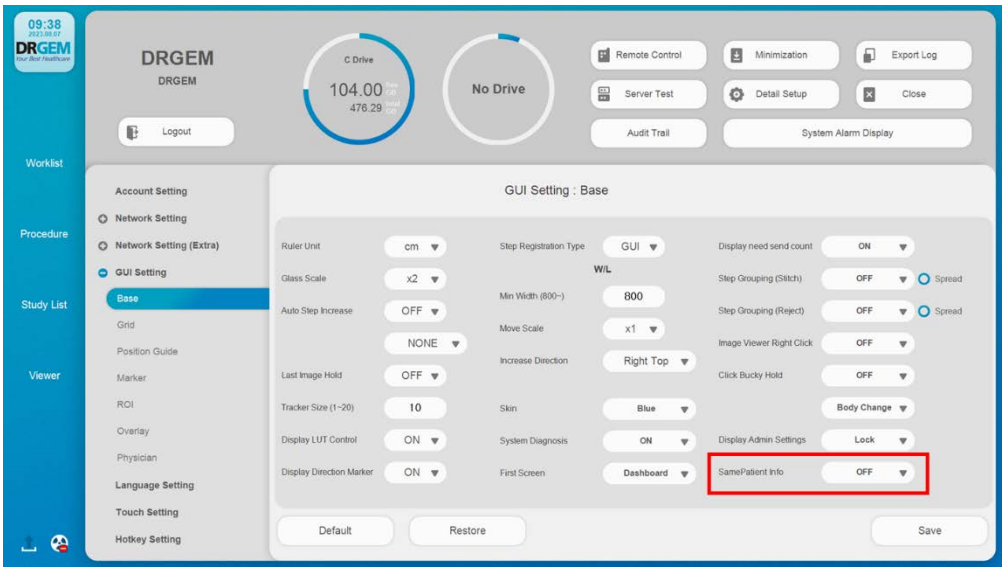
APPENDIX Q. SAME PATIENT APR INFO DISPLAY

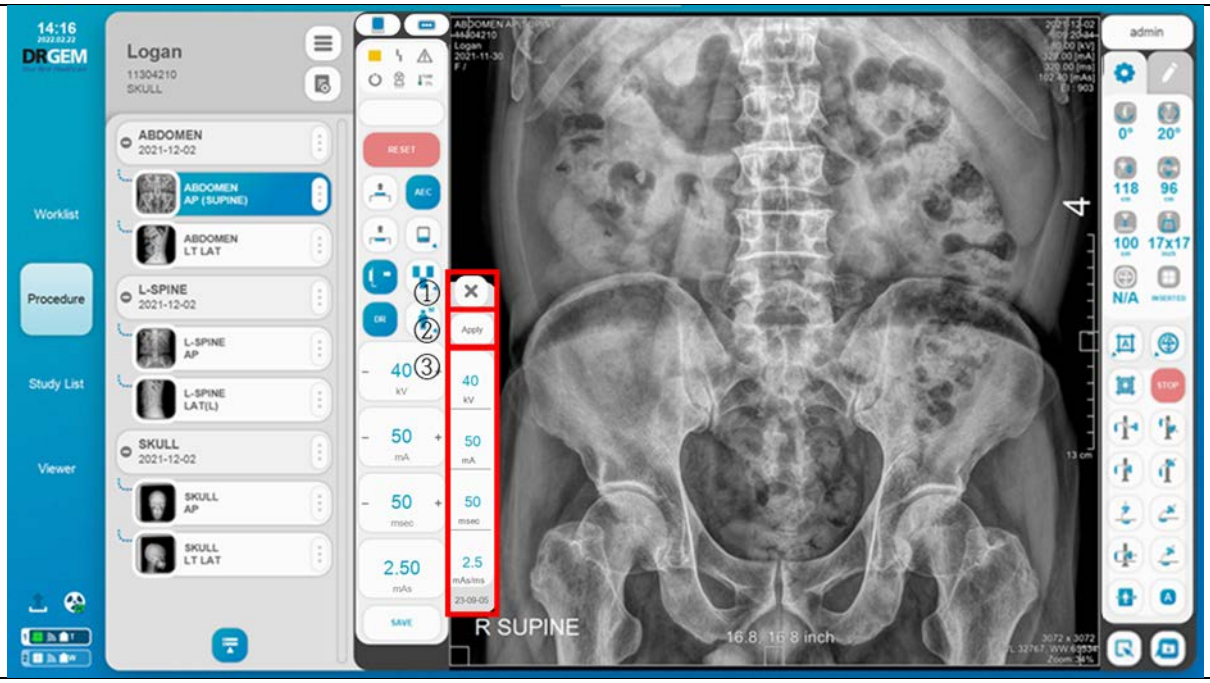
The APR Positioning Guide function provides the way to take an X-ray for each APR

Q1. OPTION SETTING

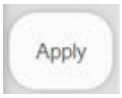


NOTE
To use Same Patient Guide function, please set Same Patient Guide to ‘ON’ Default Status ‘OFF”

Q2. FUNCTIONS



<SAME PATIENT APR INFO DISPLAY>

①	Close Button		Close same patient info pop-up.
②	Apply Button		Apply the exposure conditions (kV, mA, exposure time) shown on the APR information display to the X-ray control.
③	APR Info Display		Displays the most recent exposure conditions (kV, mA, exposure time) and date information that matches the patient name and patient ID in the selected step.

APPENDIX R. BENEFITS BY GENERATOR TYPE

The following is description, figure, benefit by generator type.

	GXR-52/68/82 (Three-phase)	**GXR-C52 (Capacitor Type)**
Description	General type for hospitals with sufficient power supply	Capacitor type for hospitals with insufficient power supply
Figure		
Benefit	- For hospitals with sufficient power supply	- For hospitals with insufficient power supply - Capacitor life is unlimited - For a low-carbon, green energy environment - There is no need for power expansion work. - Savings on basic electricity bills

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APPENDIX S. IRRADIATION CONDITIONS AND MEASURED VALUES

We provide APR values only for adult patients. Selecting a patient size changes the X-ray condition to the APR condition of the selected patient size.

Patient sizes are classified into S, M, L, and XL depending on the thickness of the irradiation area, and are applicable to all adults except children (0 to 18 years old). See Section 1.1.6 for information on pediatric.

Representatively, the APR values and dose values of 'Chest PA', 'Pelvis AP', and 'Skull AP' are presented as follows. If you want to check other APR values, contact the manufacturer.

Examination	Body size	Body part size	KVp		mAs		ESD(mGy)		Technique				
			Range	Mean	Range	Mean	Range	Mean	Additional filter	Irradiation field size	Shooting distance	Focus	Grid
chest PA	S	~20cm	103.0 - 106.0	104.2	1.9 - 2.0	1.99	0.022 - 0.023	**0.0230**	1mmAl+0.1mm Cu	14*17	180cm	Large	Non Grid
	M	21~25cm	105.0 - 106.0	105.6	2.5 - 2.6	2.54	0.028 - 0.029	**0.0291**	1mmAl+0.1mm Cu	14*17	180cm	Large	Non Grid
	L	26~30cm	110.2 - 111.8	111.1	3.2 - 3.4	3.33	0.040 - 0.043	**0.0423**	1mmAl+0.1mm Cu	14*17	180cm	Large	Non Grid
	XL	30cm~	113.1 - 142.2	113.9	4.8 - 4.9	4.87	0.064 - 0.066	**0.0650**	1mmAl+0.1mm Cu	17*17	180cm	Large	Non Grid
Skull AP	S	~17cm	62.7 - 62.9	62.8	13.3 - 13.5	13.4	0.461 - 0.458	**0.4592**	X	10*12	100cm	Large	Non Grid
	M	18~21cm	65.5 - 65.6	65.5	16.72 - 16.89	16.82	0.632 - 0.635	**0.6326**	X	10*12	100cm	Large	Non Grid
	L	21~24cm	68.3 - 68.4	68.3	20.65 - 20.94	20.85	0.851 - 0.864	**0.8602**	X	10*12	100cm	Large	Non Grid
	XL	24cm~	71.0 - 71.1	71.1	26.39 - 26.56	26.51	1.186 - 1.194	**1.1910**	X	10*12	100cm	Large	Non Grid
Pelvis AP	S	~18cm	62.6 - 62.9	62.7	10.85 - 10.9	10.87	0.368 - 0.370	**0.3700**	X	17*14	100cm	Large	Non Grid
	M	19~23cm	65.5 - 65.6	65.5	13.48 - 13.63	13.54	0.507 - 0.511	**0.5085**	X	17*14	100cm	Large	Non Grid
	L	24~28cm	68.2 - 68.3	68.3	16.74 - 16.79	16.77	0.689 - 0.691	**0.6906**	X	17*14	100cm	Large	Non Grid
	XL	29cm~	71.0 - 71.2	71.1	20.85 - 20.99	20.99	0.932 - 0.943	**0.9387**	X	17*17	100cm	Large	Non Grid

<APR condition value and dose value according to adult patient size>

- The dose value according to the suggested APR value is the result of measurement according to the stated technique value, and the dose value may change if the technique condition changes.
- In the case of the same APR value, there is no difference according to the generator rated output

The dose according to the APR value provided by the company is safe as it is less than the recommended dose for adults in the UK.

3a. Individual radiographs on adult patients

Radiograph	ESD per radiograph (mGy)	DAP per radiograph (Gy cm 2)	Year NDRL adopted
Abdomen AP	4	2.5	2016
Chest AP	0.2	0.15	2016
Chest LAT	0.5		2016
Chest PA	0.15	0.1	2016
Cervical spine AP		0.15	2016
Cervical spine LAT		0.15	2016
Knee AP	0.3		2016
Knee LAT	0.3		2016
Lumbar spine AP	5.7	1.5	2016
Lumbar spine LAT	10	2.5	2016
Pelvis AP	4	2.2	2016
Shoulder AP	0.5		2016
Skull AP/PA	1.8		2016
Skull LAT	1.1		2016
Thoracic spine AP	3.5	1.0	2016

< National DRLs for general radiography and fluoroscopy>

References

National DRLs< National DRLs for general radiography and fluoroscopy>

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