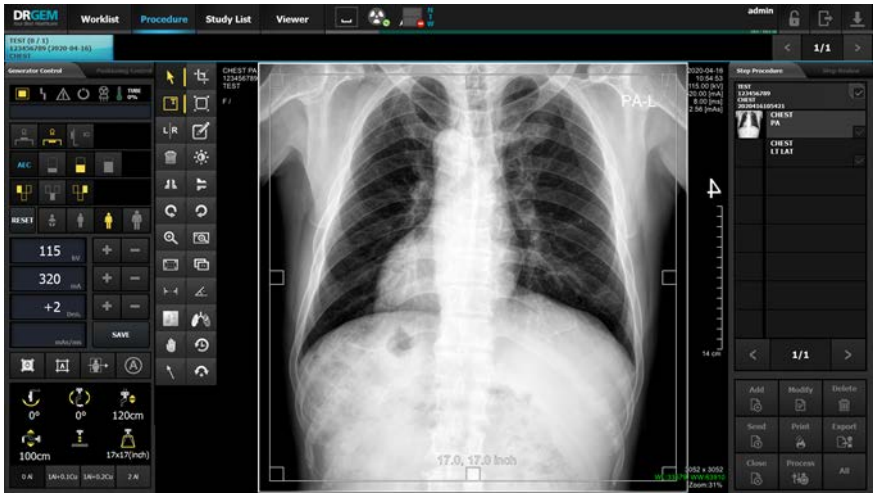
DIAMOND

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

ADVISORY SYMBOLS

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

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.

NOTE

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

NOTE

Consult Accompanying Documents - As Applicable

INDICATIONS for USE STATEMENT:

The DIAMOND DR System, is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in all general-purpose diagnostic procedures.

This Digital diagnostic x-ray system is designed to diagnose human body by providing radiographic x-ray image with anatomical structure.

This digital diagnostic X-ray System consists of a combination of x-ray generator, and associated equipment such as tube stand, patient table, and, digital imaging system. The main power cabinet contains the HT tank and control circuits, the filament drivers, the low speed starter, and interface connections to the room equipment.

The control console allows the operator to select the technique factors, image receptors, etc., and to initiate an X-ray exposure.

Tube stand and patient table allows the operator to position the patient.

Digital imaging system is designed to acquire the image and transfer to the sever

This device is not intended for mammography, bone density, fluoroscopy and angiography applications.

CAUTION **U.S. A. Federal law restricts this device to sale by or on the order of a physician.**

CAUTION **Information provided by the product are adjunctive (supporting) and should not be solely or primarily relied upon to diagnose or treat COVID-19**

CAUTION **This device is not indicated for the diagnosis of COVID-19 and that in vitro diagnostic testing is currently the only definitive method to diagnose COVID-19.**

TABLE OF CONTENTS

1. INTRODUCTION

This manual contains the necessary instructions for proper operation of the 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 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.

1.1.1 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

1.1.2 OPTION

- Touch Screen Console for X-ray Generator
- Diagnostic Monitor (Monochrome, Color)
- Image stitching software with an apparatus for whole spine imaging
- PACS Software (Server/Viewer)
- DAP (Dose Area Product) Function with Sensor
- Additional Removable High Resolution Grid
- UPS for Imaging Workstation

1.2 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 provide an X-ray source for 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 the DIAMOND DR system in a safe manner.

1.2.1 STATEMENT OF LIABILITY

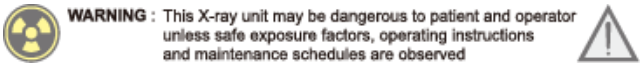
To prevent excess radiation exposure to patient and operator from either primary or secondary radiation, this DIAMOND DR system must be operated and serviced by trained personnel who are familiar with the safety precautions required. While this DIAMOND DR system has been designed for safe operation, 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:

1. Injury or danger to any person from x-ray exposure.
2. Overexposure due to poor technique selection.
3. Injury or danger from improper use of the DIAMOND DR system function.
4. Problems or hazards resulting from failure to maintain the equipment as specified in the Installation chapter.
5. 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.

1.2.2 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.

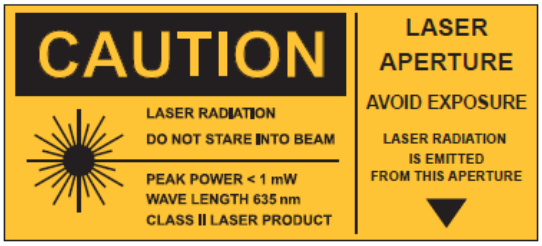


Radiation warning message on console.
Never allow unqualified personnel to operate the X-ray generator.

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.



Caution of laser radiation.
Staring into beam is never allowed.

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.

	Hand jam caution label
	Detector release switch
	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

1.2.3 SAFETY GUIDELINES

The following are general safety precautions:

- Only personnel who qualified to remove the covers and repair or maintain the 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.
- 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.

The following warnings and cautions are specific to the DIAMOND DR system.
Read them carefully - some of them are not obvious to typical equipment use.

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.

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.

- 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.

- 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 operator console, 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 control console or generator main cabinet.
- Always ensure adequate ventilation around the control console and generator main cabinet. Do not operate the equipment near curtains, drapes, etc which may block the ventilation slots.
- Do not operate the console or generator main cabinet in direct sunlight or near any heat sources.
- Do not operate the console near strong magnetic fields (microwave ovens, speakers, etc), and avoid routing the console cables near these devices.
- The console 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 console cannot slip or tip.
- Only trained maintenance staff may remove the covers of the generator cabinet and the control console.

CAUTION

INCORRECT CONNECTIONS OR USE OF UNAPPROVED EQUIPMENT MAY RESULT IN INJURY OR EQUIPMENT DAMAGE.

WARNING

THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.

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.

WARNING

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.

CAUTION

DO NOT EXCEED THE TUBE MAXIMUM OPERATING LIMITS. INTENDED LIFE AND RELIABILITY WILL NOT BE OBTAINED UNLESS GENERATORS ARE OPERATED WITHIN PUBLISHED SPECIFICATIONS.

WARNING

Do not remove flexible high tension cables from X-ray tube housing or X-ray generator and/or access covers from X-ray generator until the main and auxiliary power supplies have been disconnected and allowed to discharge for at least 3 minutes. You can be fatally shocked if you do not.
Voltage as high as 100,000 volts may be present in the DIAMOND DR system circuitry for a few minutes after it has been turned off.

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

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.

WARNING

Operators must meet all state and local requirements and regulations.

WARNING

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

WARNING

Only qualified personnel may operate the 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.

WARNING Before operating the 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.

WARNING The DIAMOND DR system includes no user serviceable parts. For service assistance, contact DRGEM Corporation or service provider.

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

WARNING The DIAMOND DR system and associated cables must not be operated in the presence of moisture.

WARNING Ensure that the earth grounding connections between the DIAMOND DR system and its power source is maintained at all times.

WARNING The DIAMOND DR system is not suitable for operation in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

WARNING Disconnect electrical power from the DIAMOND DR system before servicing. Use care not to drop tools or other objects into the DIAMOND DR system when working on or around the unit. Electrical shock could result.

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

CONTRINDICATION

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 System is not intended to use of 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.

1.2.4 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 0.25 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.

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.

WARNING

THIS UNIT MAY BE DANGEROUS TO OPERATOR UNLESS SAFE OPERATING INSTRUCTIONS ARE OBSERVED.

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

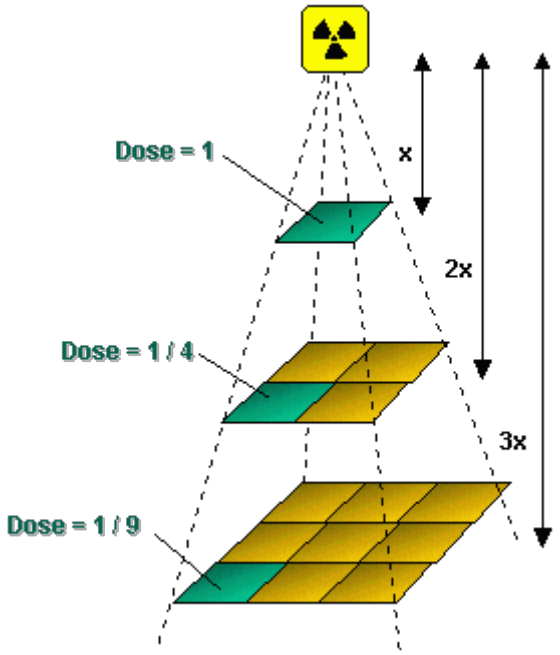
THE MANUFACTURER ACCEPTS NO RESPONSIBILITY FOR ANY DIAMOND DR SYSTEM NOT MAINTAINED OR SERVICED ACCORDING TO THIS MANUAL, OR FOR ANY DIAMOND DR SYSTEM THAT HAS BEEN MODIFIED IN ANY WAY.

WARNING

KEEP AS LARGE A DISTENCE AS POSSIBLE AWAY FROM THE OBJECT BEING EXPOSED AND X-RAY TUBE ASSEMBLY

* **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.

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 system**. The appropriate personnel must be made aware of the inherent dangers associated with the servicing of X-ray equipment.

1.2.5 PEDIATRIC USE : SUMMARY

General Information: Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb.) in weight and 150 cm (59 in) in height, measurements, which approximately correspond to that of an average 12-year-old or a 5th percentile U.S. adult female).

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

1) 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);
2) Use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients; and
3) Younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.

WARNING

USE SPECIAL CARE WHEN IMAGING PATIENTS OUTSIDE THE TYPICAL ADULT SIZE RANGE.

References for pediatric dose optimization: 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-EmittingProducts/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)

1.2.6 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.

CAUTION Incorrectly positioning the X-ray tube and Collimator could cause the X-ray field to be misaligned with the Bucky, resulting in unacceptable images.

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.

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	-

1.2.7 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 components 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 technical Operation Manual, or which has been modified or tampered with in any way.

1.2.8 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.

1.2.9 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.

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.

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

Observe all safety precautions recommended by the accessory equipment manufacturer in the user documentation provided with the equipment.

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.

1.3 APPLICATION SPECIFICATION

1.3.1 INTENDED MEDICAL INDICATION

The DIAMOND DR system is indicated for use in generating radiographic images of human anatomy. 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.

1.3.2 INTENDED PATIENT POPULATION

a) Intended patient population
b) Age: Available all people, but is not intended to use for dedicated pediatric application
c) Weight: not relevant
d) Height: not relevant
e) Nationality: multiple
f) Patient state: PATIENT is not USER

1.3.3 INTENDED USER PROFILE

a) Operator

Considerations		Requirement description
Education	Minimum	• Qualified person (He/she must have license for radiologist or have to meet local regulation) • Educated person by manufacturer
	Maximum	• N/A
Knowledge	Minimum	• Qualified person (He/she must have license for radiologist or have to meet local regulation)
	Maximum	• N/A
Language understanding	Minimum	• Local language
	Maximum	• Understanding of manual that is writing in English
Experience	Minimum	• He/she must have license for radiologist or have to meet local regulation • He/she have to be educated by manufacturer or local distributor
	Maximum	• N/A
Permissible impairments	• N/A	

b) Service engineer

Considerations		Requirement description
Education	Minimum	• Qualified person by manufacturer or local distributer regarding installation, maintenance and service. • Educated person by manufacturer
	Maximum	• N/A
Knowledge	Minimum	• Qualified person (He/she must have knowledge of electrical engineering and/or radiology procedure)
	Maximum	• N/A
Language understanding	Minimum	• Local language
	Maximum	• English
Experience	Minimum	• He/she have to be educated by manufacturer or local distributor
	Maximum	• N/A
Permissible impairments	• N/A	

1.4 SPECIFICATIONS

- 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 at 150kV (optional)
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	

- X-ray Tube Assembly

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°
kV	40/150kV	40/150kV	40/150kV
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	CANON	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 VAREXRAD-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		

Tube Model	RAY-12
Manufacturer	SIEMENS
Maximum Tube Voltage	150kV
Anode Heat Storage Capacity	230kHU
Focal Spot Size	0.6 / 1.2 mm
Maximum Input Energy at 0.1sec	22 / 54kW
Weight	18kg (40lb)

* 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.

- Digital Flat Panel Detector(VAREX)

Model		PaxScan4343R V3		PaxScan4343W		
Active Pixel Area / Matrix		17 x 17 inch (3,052 x 3,052)		17 x 17 inch DRZ+(3,062 x 3,062) CsI(3,052 x 3,052)		
Pixel Pitch		139um		139um		
Limiting Resolution		3.6 lp/mm		3.6 lp/mm		
Screen		DRZ+	CsI	DRZ+	Standard CsI	Premium CsI
Energy Range		40 – 150kVp		40 – 150kVp		
A/D Conversion		16-bits		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	3.3 kg	

* PaxScan4343W detector is NOT used in Brazil installations.

- 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	
Weight		Approx. 4kg(Without Cable)	4.6kg

* Mano4343W detector are NOT used in Brazil installations.

* Mano4343T detector are NOT used in USA installations.

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

Model		DR-ID1272SE	DR-ID1274SE
Active Pixel Area / Matrix		17 x 17 inch (2,836 x 2,832)	
Pixel Pitch		150um	
Limiting Resolution		3.3 lp/mm	
Screen		DRZ+	CsI
Energy Range		40 – 150kVp	
A/D Conversion		16-bits	
MTF	@ 1 lp/mm	75%	80%
	@ 2 lp/mm	42%	54%
DQE	@ 0 lp/mm	45%	72%
	@ 1 lp/mm	31%	54%
Interface		Gigabit Ethernet	
Weight		3.7 kg (8.1 lbs.)	

- Motorized Automatic X-ray Collimator

Rated X-ray Shielding	150kV max.
Inherent Filtration	0,75mm Al eq.
X-ray Field Coverage	Max. 48 x 48cm at 100cm SID
Luminosity	Over 160 Lux
X-ray Field Precision	< 1% SID
Leakage Radiation	< 40mRh at 150kVp / 4mA, 100cm SID
Laser	X 64638 – 100W 24V
Weight	10kg (22lb)
Filter (option)	0.1-0.2mm cupper manual and automatic selected by organ program, display on monitor and film.

- Radiographic Stand & Mobile Patient Table

Vertical Movement		Max. 1,200mm (47.2inch)
U-arm Rotation		+120° (CW) ~ -30° (CCW) , motorised
SID Movement		1,000 ~ 1,800mm (40~72inch)
Detector Rotation		+45° ~ -45°
Tube Rotation		+180° ~ -90°, manual
Lower Position		~ 300mm
Weight	Radiographic Stand	400kg (882lb)
	Mobile Patient Table	Table Weight 60kg (132lb). Patient Weight - Max. 250kg (550lbs)

- Ion-Chamber and Preamplifier for AEC

Model	ICX1162(ICX1192B)	Amplimat 5-Field
Manufacturer	AID	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)

- Removable High Resolution Grids

Size	17 x 17 inch
Resolution	78line/cm (200 line/inch)
Ratio	12:1
Focal Distance	100 / 180cm (40 / 72inch), two grids
Cover Material	Carbon Fiber
Weight	2kg (4.4lb)

- Imaging Workstation

CPU	Intel Core i5-8500 3.2GHz(up to 3.6GHz) 6M or higher
Memory	8GB (2x4GB) DDR4 2400Mhz or Higher
Display	Intel® HD Graphics 630
Storage	500GB x 2, 7200RPM SATA HDD
Monitor	23 inch Color LED, Medical Display , resolution: Full HD)
Maker	DELL International
Weight	Desktop: 9.86 kg (21.73 lbs.) Monitor: 5.8 kg (12.78 lbs.)

- **Software Version**

Software/Firmware	Version	Description
RADMAX	1.01	RADMAX is the main software provides top level graphics user interface on whole system control and imaging process. RADMAX 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. 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. Also this module transmits whole system control data between System Control Module in RADMAX 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 via System Control Board

- Imaging Software

1. General Features
   - Windows 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 changing and creation feature
   - Maker feature (support the creation of unlimited number of maker 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)
   - Default anatomic program more than 700
   - 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

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 : -1.00 ~ 1.00
  - Skin line Weight : -1.00 ~ 1.00
  - Latitude Compression : -1.00 ~ 1.00
  - Contrast Enhancement : -1.00 ~ 1.00
  - Edge Enhancement : -1.00 ~ 1.00
  - Noise Suppression : -1.00 ~ 1.00

- MODULE 3
  - Global Brightness : -10.00 ~ 10.00
  - Global Contrast : -10.00 ~ 10.00
  - Latitude Compression : -10.00 ~ 10.00
  - S-Structure Enhancement : -10.00 ~ 10.00
  - Noise Suppression : -10.00 ~ 10.00

3. Image Maintenance (All functions are supported by the pop-up menu)
   - ROI : Default 8 ROI support / Unlimited support for anatomic projection
   - MARK : Unlimited support (User preset support)
   - Horizontal Flip
   - Vertical Flip
   - Rotate CW
   - Rotate CCW
   - 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
   - Image Cut : Image crop/cut function
   - Image Copy : Copy of image in the region of interest(ROI)
   - Image Recovery : Recover the original image
   - Image Bright/Contrast control : Supported by right-click mouse

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
   - DICOM Grayscale print
   - Support image swap in layout

6. DICOM Feature : DICOM 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 GSPS
   - 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. 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
    - Image Stitching
    - Stitches whole spine/long bone images to single image
    - Support 2 or 3 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 windows of single or all images simultaneously
    - Provide full-spine imaging apparatus

OPERATING ENVIRONMENT

Ambient temperature range	10 to 35 °C (50 to 95 °F).
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure range	800 hPa to 1060 hPa

TRANSPORT AND STORAGE ENVIRONMENT

Ambient temperature range	-10 to 70 °C (14 to 158 °F)..
Relative humidity	10 to 90%, non-condensing.
Atmospheric pressure range	700 hPa to 1060 hPa

WARNING

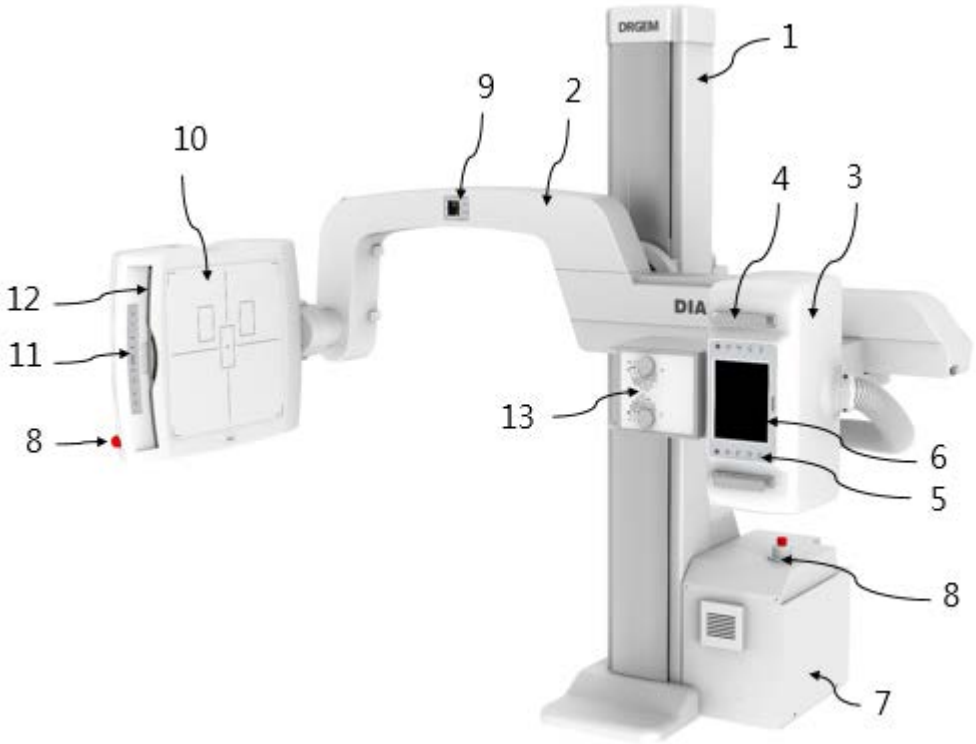
Do not operate this system except in accordance with information included in this section, and any additional information provided by the manufacturer and / or competent safety authorities.

1.5 PART DESCRIPTION

1. X-ray Generator: Refer to service manual.

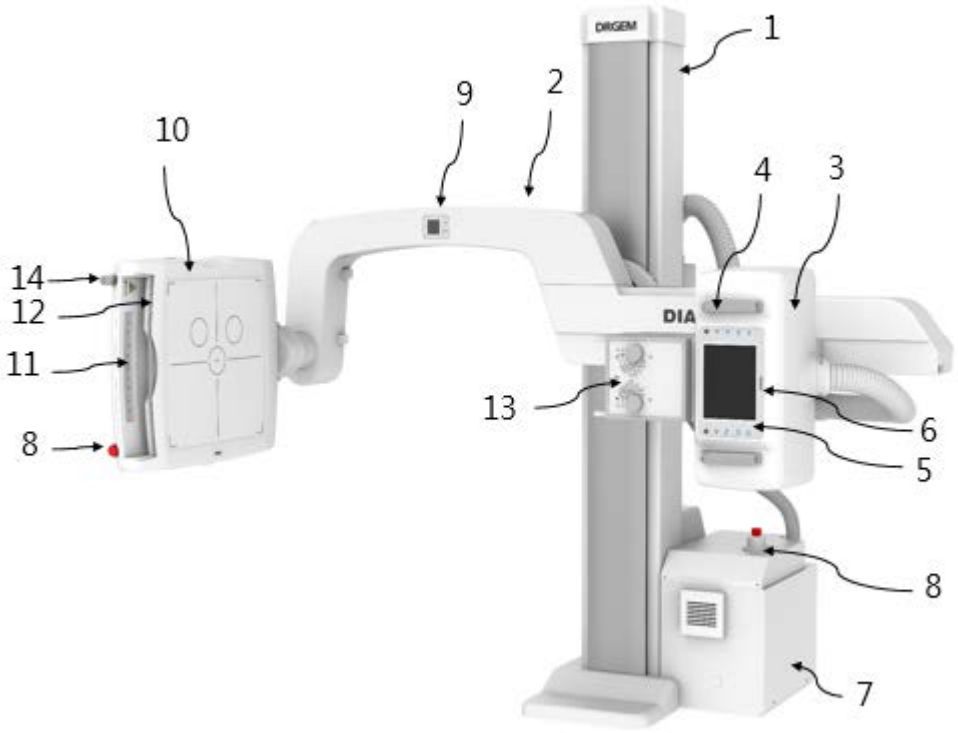
2. X-ray Tube Assembly: Refer to accompanying manuals of X-ray tube assembly.

3. Radiographic Stand



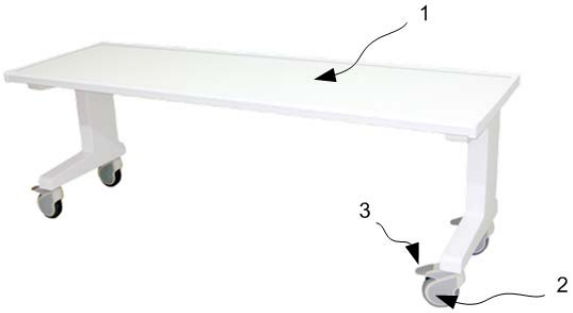
1 Stand Column
2 Swivel U-arm
3 Tube Cover
4 Tube Handle
5 Stand control membrane switch (Tube side)
6 Integrated Touch Screen Console
7 Stand Control Box
8 Emergency Switch
9 Angle Display Panel (Detector, Swivel U-arm)
10 Detector Assy.
11 Stand control membrane switch (Detector side)
12 Removable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

4. 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

5. Mobile Patient Table



1 Tabletop

2 Wheel

3 Foot Brake

6. Motorized Automatic Collimator

1 Lateral X-ray coverage control knob

2 Longitudinal X-ray coverage control knob

3 Collimation lamp on/off switch (30sec timer)

1.6 APPLICABLE STANDARDS

The DIAMOND DR System complies with FDA Radiation Performance Standards under Title 21 CFR, Subchapter J, Parts 1020.30 and 1020.31.

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

■ EN60601-1-3:2008/A11:2016
Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC60601-1-3:2008/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
■ EN55011:2009/A1:2010
■ CISPR11:2014
■ EN61000-3-2:2006
■ EN61000-3-3:2013
■ EN61000-4-2:2009
■ EN61000-4-3:2006/A1:2008/A2:2010
■ EN61000-4-4:2012
■ EN61000-4-5:2006
■ EN61000-4-6:2014
■ EN61000-4-8:2010
■ EN61000-4-11:2004

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 FDR Smart FGXR-S is intended for use in the electromagnetic environment specified below. The customer or the user of the FDR Smart FGXR-S should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The FDR Smart FGXR-S 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 FDR Smart FGXR-S 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 purpose. For information purpose the system complies with IEC61000-3-11 and is suitable for connection to public mains network if the impedance is 0,32 Ohm or lower
Harmonic emissions	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	± 6 kV contact ± 8 kV air	± 6kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines n/a. for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2kV common mode	± 1 kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	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**
			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 $d = 1,2\sqrt{p}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = 1,2\sqrt{p}$ 80 MHz to 800 MHz $d = 2,3\sqrt{p}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 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: 

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.

3) CLINICAL EVALUATION

■ MEDDEV 2.7/1 Rev.4

EVALUATION OF CLINICAL DATA:

A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

4) OTHERS

■ EN ISO 15223-1:2016

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

ISO 15223-1:2016

■ IEC TR60878:2015

Graphical Symbols for electrical equipment in medical practice

■ IEC60417-1:2002DB

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

■ EN ISO14971:2012

Medical devices - Application of risk management to medical devices

ISO 14971:2012

■ EN ISO13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

ISO13485:2016

■ 93/42/EEC as amended by 2007/47/EC

Council Directive concerning medical devices

■ EN1041:2008/A1:2013

Information supplied by the manufacturer with medical devices

■ EN62304:2006

Medical device software — Software lifecycle processes

IEC62304:2006

■ EN62366:2008

Medical devices - Application of usability engineering to medical devices

IEC62366:2007

1.7 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

EC REP

Obelis s.a.,

Bd.Général Wahis 53,1030 Brussels, Belgium

Tel) +32.2.732.59.54, Fax) +32.2.732.60.03

2 GRAPHIC USER INTERFACE

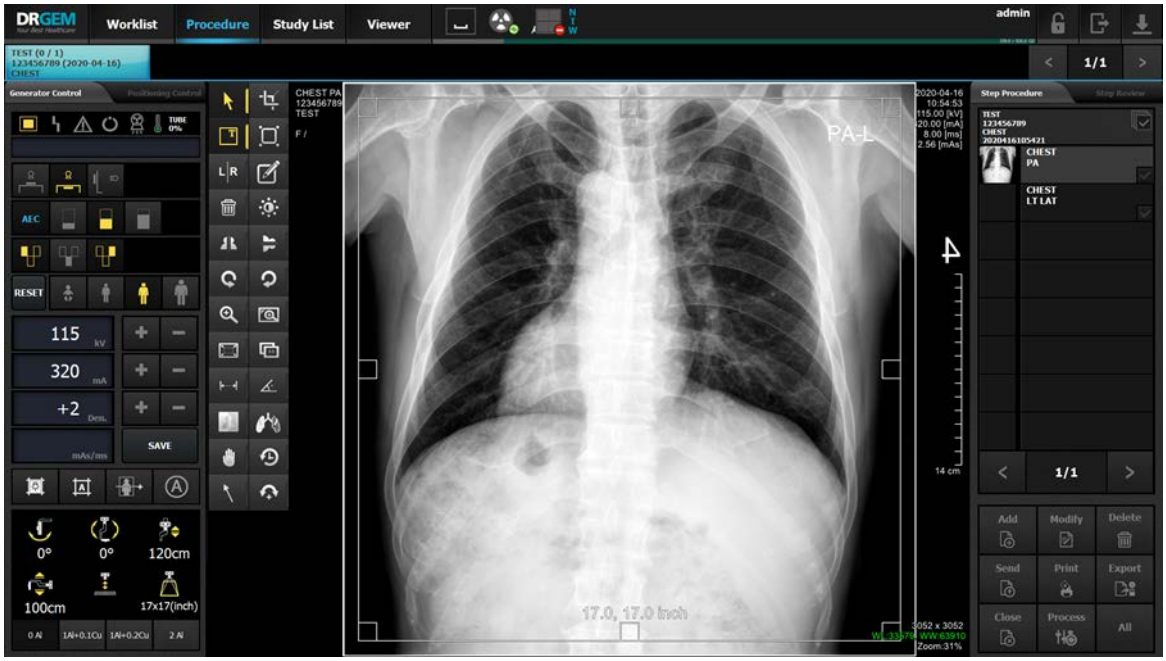
The RADMAX software offers user interfaces like below.

The RADMAX software is an application program which is based on Microsoft Windows operating system. It offers many kinds of functions that are related to hospital situation and needed to take a lot of process and work flows.

2.1 RADMAX IMAGING SOFTWARE

The RADMAX imaging software offers graphic user interface for patient registration and examination.

The interface window is like below.

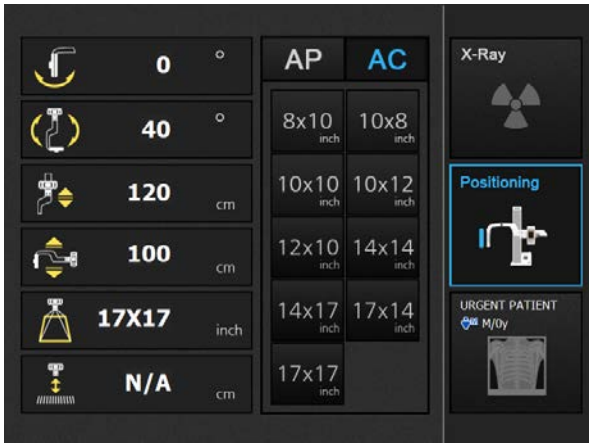


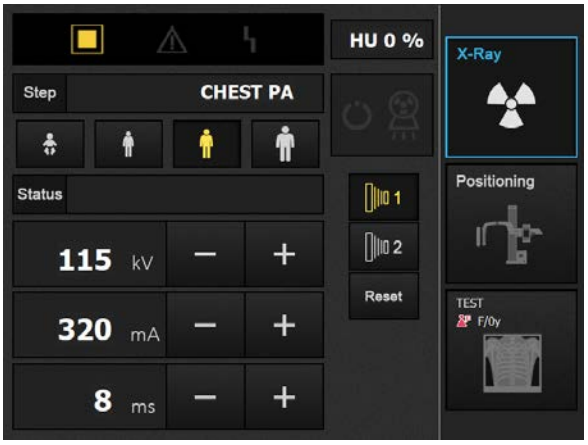
2.2 INTEGRATED TOUCH SCREEN CONSOLE

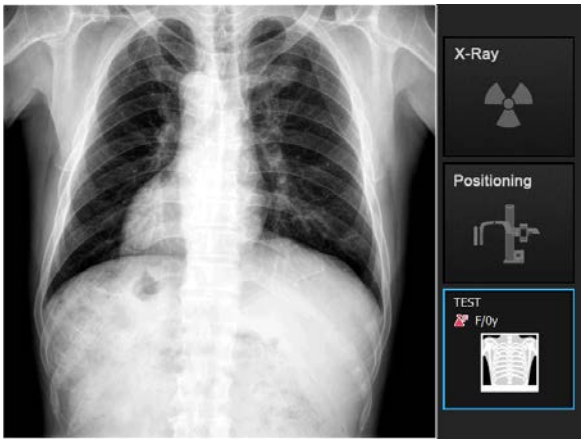
This software offers touch screen interface through graphic color LCD screen on the radiographic stand.

Operator can control radiographic stand, automatic collimator and x-ray generator.

This interface also shows image after examination to operator.







3. OPERATION PROCEDURE

This section describes the controls of the DIAMOND DR system.

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.

Before starting the RADMAX software, turn on the DIAMOND Imaging Workstation.
Turn off the DIAMOND Imaging Workstation when all of your works are finished.

3.1 TURN ON THE DIAMOND DR SYSTEM

1. Supply main power to the DIAMOND system.
2. Turn on the monitor of DIAMOND Imaging Workstation.
3. Turn on the DIAMOND Imaging Workstation.
4. Turn on the GXR X-Ray generator.
5. Run the RADMAX software.
6. Wait until generator booting sequences are finished.

NOTE

IF THE BOOTING OF GXR GENERATOR IS NOT COMPLETED, THE DIAMOND SYSTEM WILL NOT WORK.

NOTE

THE LCD SCREEN ON THE DIAMOND DR STAND IS SUPPLIED ELECTRIC POWER FROM GXR X-RAY GENERATOR AFTER GENERATOR IS BOOTING UP.

3.2 OPERATION

1. Patient registration.
2. Select APR for examination.
3. Run the auto positioning or manually set the radiographic stand positioning.
4. Change the collimation size by automatically or manually if required.
5. Place the patient table if required.
6. Place the patient on the table or in front of the detector of the radiographic stand.
7. Trim the positioning if required.
8. Turn on the collimation lamp and confirm the x-ray field.
9. Make 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.
10. Confirm the acquired digital image is correct and adjust the window width and level for the optimized view.
11. Transfer the image to the storage server if PACS is prepared.

3.3 TURN OFF THE DIAMOND DR SYTSTEM

1. Turn off the generator.
2. Click on the ‘Exit’ menu on the RADMAX software.
3. Shutdown the DIAMOND Imaging Workstation.
4. Cut off the main power that supply to system.

4 IMAGING SOFTWARE

For user instructions on RADMAX, refer to the RADMAX Operation Manual (RMD1804-001).

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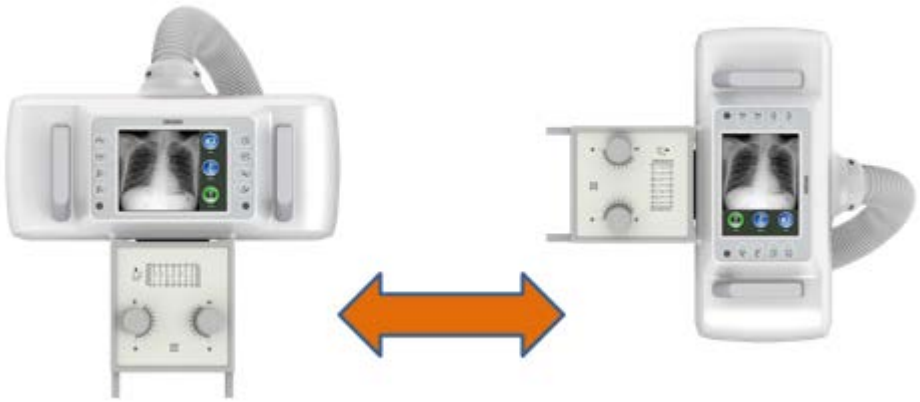
5. INTEGRATED TOUCH SCREEN CONSOLE

DIAMOND DR System provides integrated touch screen control console at the tube side of radiographic stand. This console provides three main functions for operator's convenience.

1) X-ray Generator Control
2) Radiographic Stand and X-ray Collimator Control
3) Acquired Image Display

Also, the GUI is automatically rotates corresponds to rotation angle of U-arm.

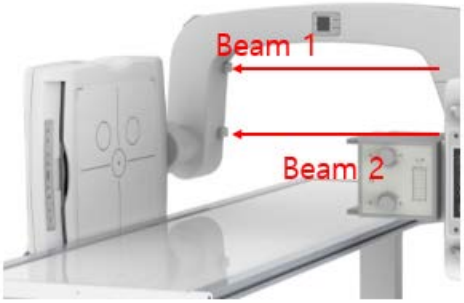


WARNING

BEFORE CONTROL THE POSITIONING OF RADIOGRAPHIC, REMOVE ANY OBSTACLES INCLUDING MOBILE PATIENT TABLE TO PREVENT THE COLLISION BY MOTORIZED MOVING.

RADIOGRAPHIC STAND HAS TOTAL SEVEN SAFETY SENSORS AROUND ITS APPARATUS, BUT THIS MAY INSUFFCIENT TO PREVENT THE COLLISION ON SOME CASES.

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

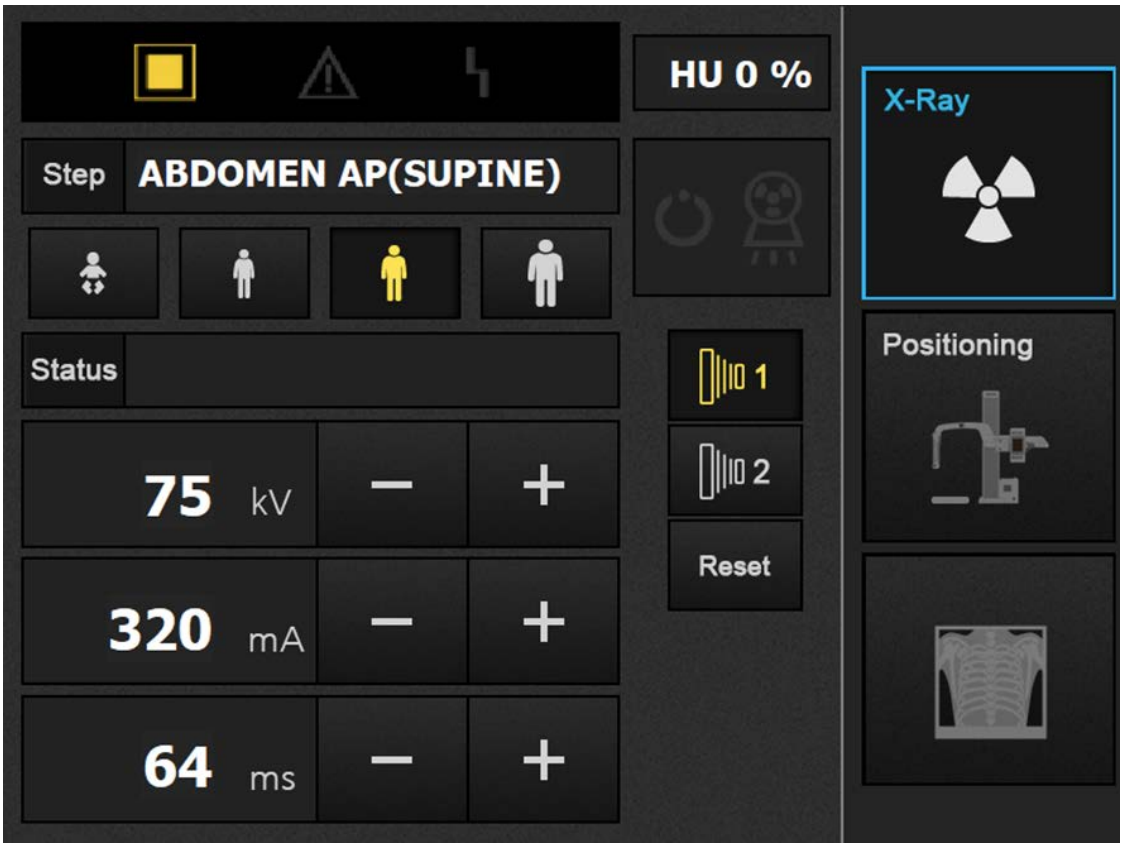


When Beam1 detect an obstacle, the movement speed will lower.

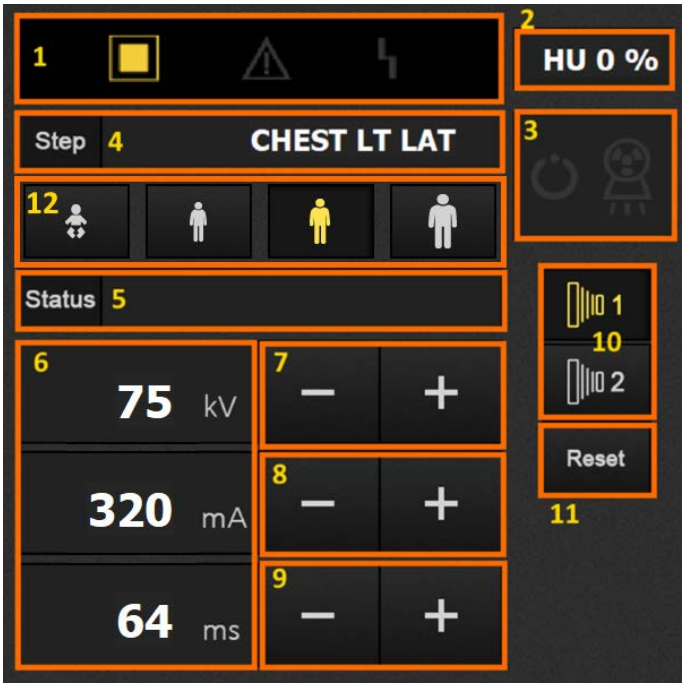
When Beam2 detect an obstacle, the movement speed will stop except increase the U-arm height.

5.1 X-RAY GENERATOR CONTROL

The GUI for x-ray generator control of integrated touch screen console is like below



The detail of GUI of The GUI for x-ray generator control of integrated touch screen console is like below.



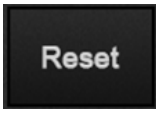
1) Indicator window (focus, Warning, Error)
2) Heat Unit of x-ray tube anode
3) X-ray indicators (Preparation, X-ray exposure)
4) Projection display window
5) Patient body size selection buttons
6) X-ray parameter display window (kV, mA, time)
7) kV parameter control buttons
8) mA parameter control buttons
9) ms parameter control buttons
10) Image receptor selection buttons (DIAMOND: Receptor 1, Other: Receptor 2)
11) Error Reset button
12) Body size buttons

5.1.1 POWER ON/OFF CONTROLS

Press **ON**  of generator interface module to turn on the DIAMOND DR System.

Around 10 seconds late, all data will displays normally if there is no problem on turning on.

Press **OFF**  of generator interface module to turn off the DIAMOND DR System.

Press the 

button to continue if any error messages are presented.

5.1.2 INDICATOR

Each function of indicator is like below.

(1) (2) (3)

(1) Small or Large Focal spot size indicator
(2) Warning Indicator
(3) Error Indicator

5.1.3 PROCEDURE DISPLAY

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

5.1.4 PREP, X-RAY EXPOSURE CONTROL

The dead-man type exposure hand-switch is located at side of the generator interface module. To make an x-ray exposure, release from the switch holder and press the buttons like following operating sequences.

Press and hold the **PREP** button to spin the rotor.

Status window displays 'x-ray preparation' message.

The **prep indicator**  will light and status window displays 'X-ray exposure ready' message when ready to make an exposure.

While pressing the prep button, press and hold the **EXPOSE** button to make an X-ray exposure.

The **X-ray exposure indicator**  will light and status window displays 'X-ray exposure' message when an X-ray exposure is being taken.

Pressing the **EXPOSE** button only will cycle the generator through prep and then exposure.

After the exposure, status window displays 'X-ray exposed' message.

5.1.5 RADIOGRAPHY CONTROLS

- **X-ray parameter Control Button**

Increase or decrease the x-ray parameters.

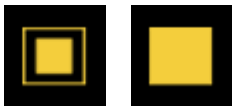
kV, mA, exposure time

- **Image Receptor Selection Button**

Image receptor selection enables to use the x-ray source of DIAMOND system with other image receptors (IP for CR, film). DIAMOND DR detector is assigned to Receptor 1. 

In order to use other image receptor, use Receptor 2. 

- **Focal Spot Size Indicator**



Focal spot size indicator shows currently selected x-ray tube focal spot size.

-  for small focus.
-  for large focus.

DIAMOND DR System's x-ray generator support auto focal spot selection feature and small focus will be selected if the selected x-ray parameter is in the possible range of small 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.

- **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.

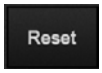
5.1.6 STATE MESSAGE DISPLAY

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 

button when Warning message appears.

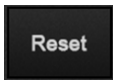
When the Warning message is issued, warning indicator  is turned on for 2 second before the message disappears.

Refer to Service Manual about warning messages.

- **Error Message**

The GXR console will display error messages during abnormal operation of the generator.

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

Messages may be cleared by pressing the 

button.

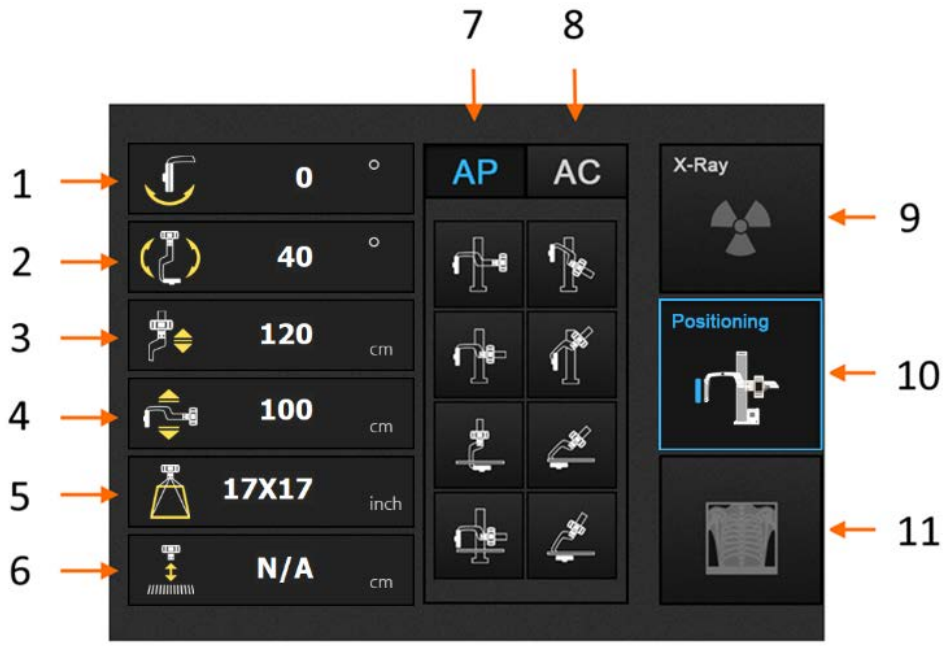
If the error message is not cleared or following corrective actions are not working, contact the service representative.

Refer to Service Manual about error messages.

5.2 RADIOGRAPHIC STAND AND X-RAY COLLIMATOR CONTROL

This GUI has functions of automatic radiographic stand control and automatic x-ray collimator control.

Main description of this GUI is like below.



1) Detector Angle (degree)
2) Arm Rotation Angle (degree)
3) Source to Detector Distance (cm)
4) Arm Height (cm)
5) Collimation Size (ROI) - inch
6) Focal Distance of Inserted Grid (cm)
7) Auto Position Menu Tab
8) Auto Collimation Menu Tab
9) X-Ray Generator Control Selection Menu
10) Radiographic Stand and X-ray Collimator Control Selection Menu and display Detector Insertion/Removal state.
11) Acquired Image Display Selection Menu

When operator expose X-Ray, if detector is removed, RADMAX show warring message on X-Ray mode like the below. Operator can't expose X-Ray.

If operator click "OK" button, state of generator about warning is reset.

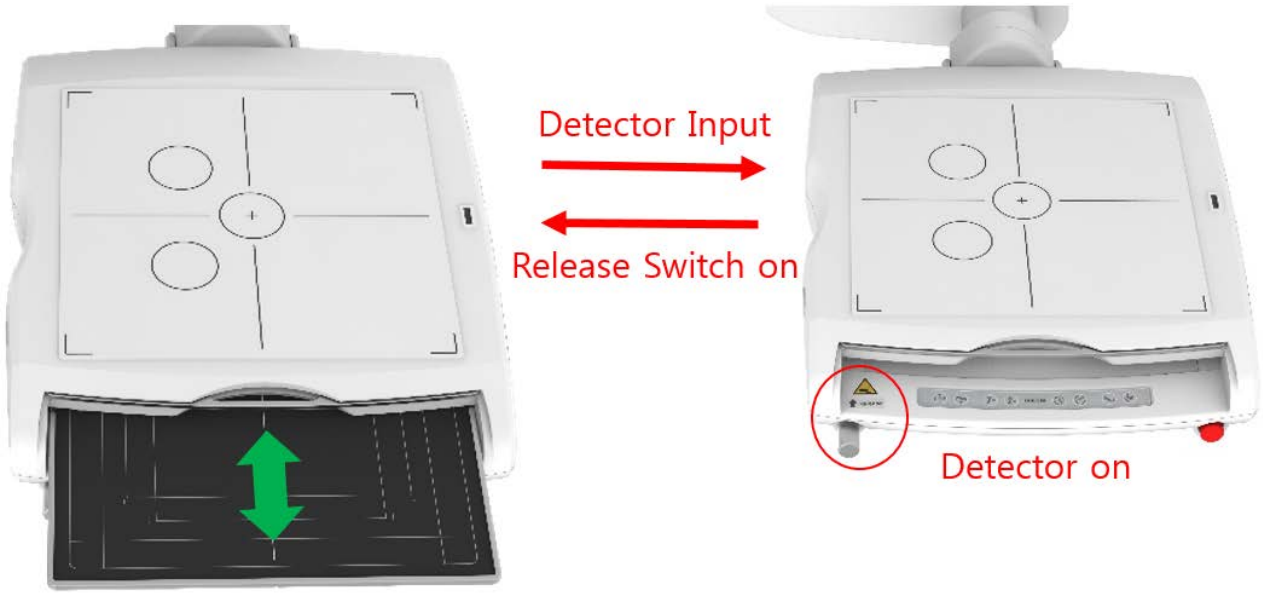
When operator expose X-Ray, if direction of grid is reverse, RADMAX show warning message on X-Ray mode like the below. Operator can't expose X-Ray.

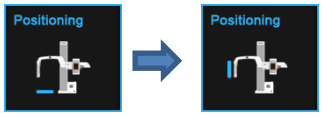
Whenever there is a system event such as change in stand position, collimation size , insertion/removal of Detector or Grid, the touch screen console will automatically change to Positioning menu.

In the removed detector type, when the detector is not mounted, it is in the form of a release button. The Positioning menu button remains as shown below.

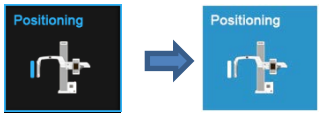
As for the method of starting the detector, cover the detector over the detector tray as shown in the picture, and then push the detector all the way to the tray. When the detector is installed, the release button will appear. the Positioning menu button will flash for 5seconds and change like below.

To remove the detector, press the Release Button and the detector will appear.





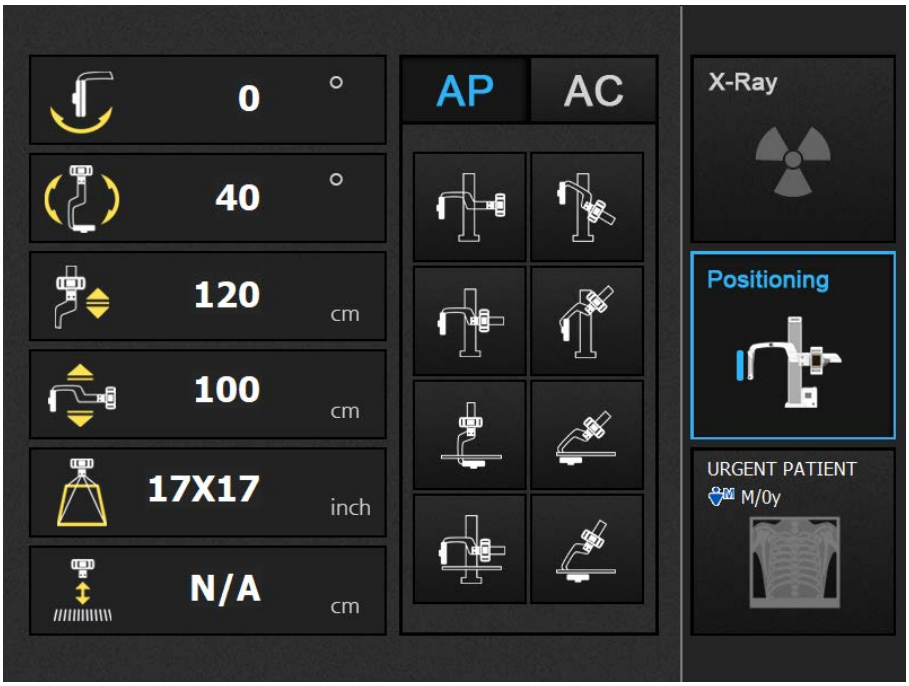
<change button icon>



<flash button>

5.2.1 AUTOMATIC POSITIONING CONTROL

The main GUI of automatic positioning control is like below.



This GUI displays four values concerning radiographic stand positioning.

- Detector rotation angle
- U-arm rotation angle
- SID (Distance from tube's focus to detector)
- Height of U-arm rotation center from floor.

Rotation angle of detector and U-arm will be also displayed in the middle of U-arm.

Touching 'AP' will displays this control GUI.
This GUI also displays the x-ray collimation size and focal distance of inserted grid.

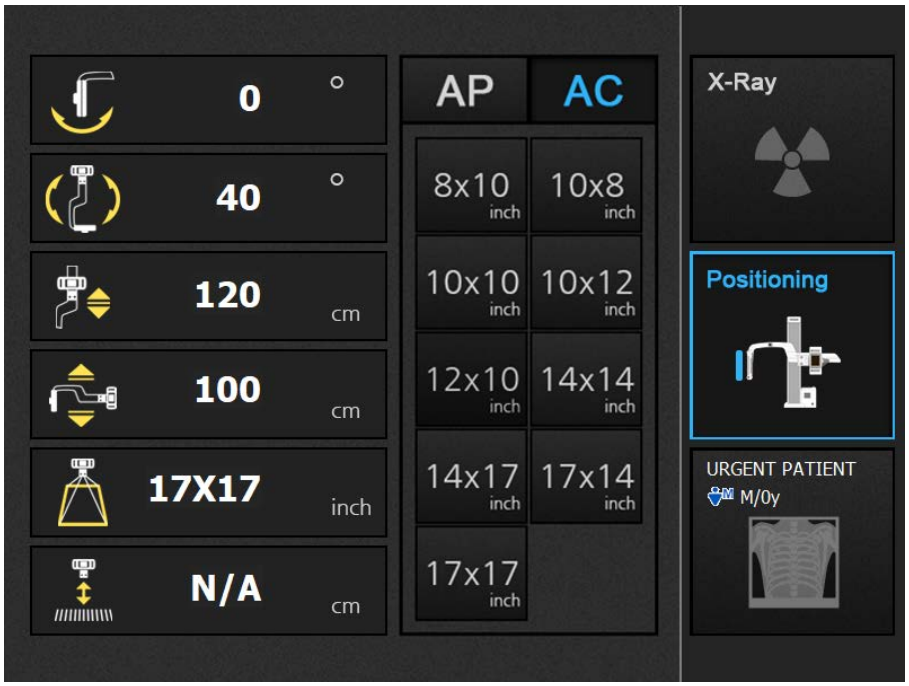
The eight representative radiographic positions can be selected by one touch, and this will automatically make the target positioning with motorized movement.

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.

5.2.2 AUTOMATIC COLLIMATION CONTROL

Touching ‘AC’ will displays this x-ray collimation control GUI like below.



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.

5.2.3 REMOVABLE HIGH RESOLUTION GRID

DIAMOND DR System provides two removable high resolution grids for high quality radiographic imaging.

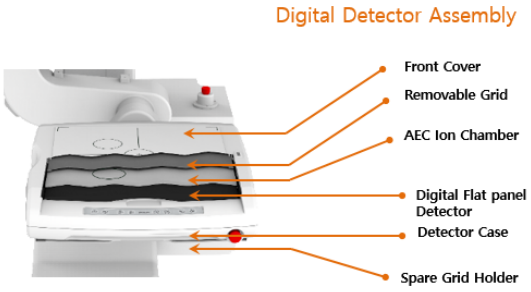
The focal distance of inserted grid will be displayed on LCD screen.

If the SID is same of lower than 140cm, operator should use the grid with 100cm focal distance.
With other SIDs, operator should 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, GUI will warns you this information.
If there is incongruent grid is inserted in detector assembly comparing to SID, GUI will also warns you this information.

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.



WARNING **BE CAUTION DURING HANDLE THE GRID TO DO NOT HAVE DAMAGE ON ITS SURFACE.**

5.2.4 MANUAL MOTORIZED RADIOGRAPHIC STAND CONTROL

Control buttons for motorized control of radiographic stand are located in following positions.

- Each side of tube cover's front side.
- End of top side of detector cover.

Operator can easily control the radiographic stand position using these buttons.

When using the buttons of tube side, grab the handles with two hands, and press the button with thumb.

When using the buttons of detector side, grab the front body of detector assembly with hand, and press the button with thumb.

The meanings of symbols for manual radiographic stand control are like below.


Increase SID


Decrease SID


Rotate Detector to CW direction


Rotate Detector to CCW direction


Increase the U-arm height


Decrease the U-arm height


Rotate U-arm to CW direction


Rotate U-arm to CCW direction

Also, Operator can control the radiographic stand position using remote controller.

Remote controller has eight manual control buttons and eight programmed representative position selection button.

Radiographic stand will moves to target position only while pushing the button, and will stop the movement immediately after press off the button of remote controller.

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.**

5.2.5 MOBILE PATIENT TABLE POSITIONING

If it is required for patient table should be used for radiographic imaging, operator can use the mobile patient table for this.

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

Mobile patient table has four casters and each caster has foot brake for table fixation.
Step on and press the long side of caster's lever to lock up the caster, and step on and press the short side of caster's lever to release the brake.

5.2.6 EMERGENCY STOP

Press the emergency switch if it is required to stop the motorized movement of radiographic stand urgently.
Emergency switches are located in following positions.

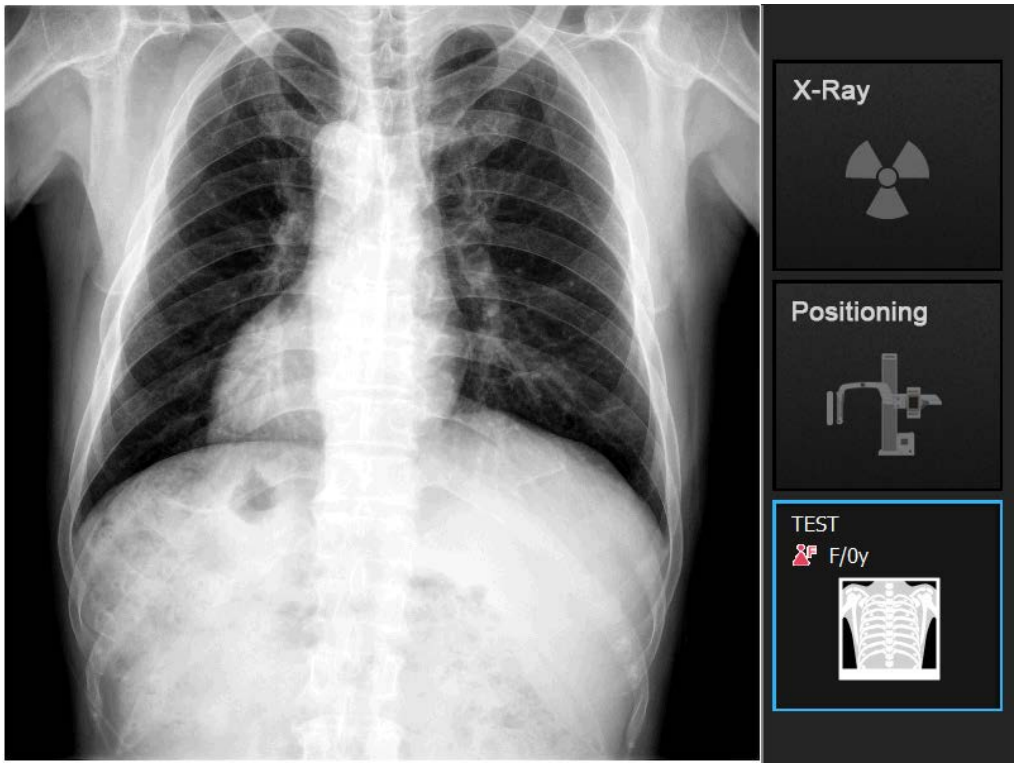
- In front of the detector assembly.
- On top of the table of imaging workstation.

Rotate the emergency stop switch to CW direction for release.

5.3 ACQUIRED IMAGE DISPLAY

Integrated touch screen console has a feature to display an acquired image in its screen for operator.

The sample of GUI is like below.

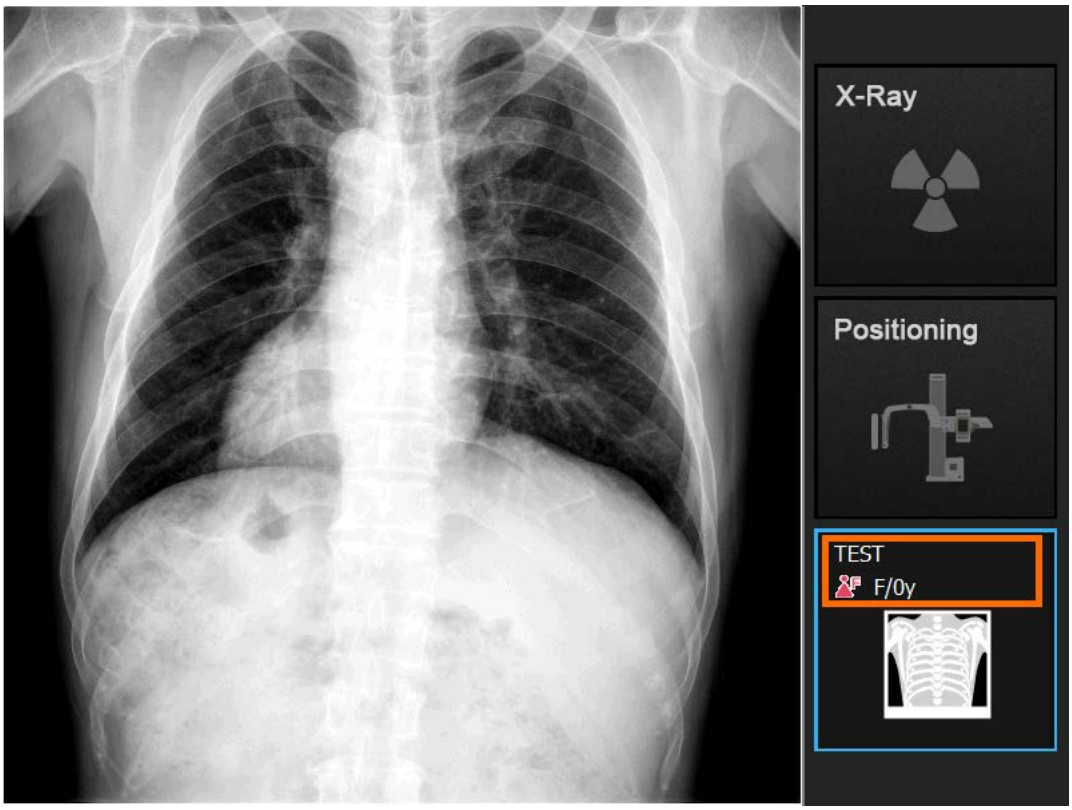


NOTE This function is for the simple confirmation of radiographic imaging, and detail image control or diagnosis should be done at the imaging workstation.

NOTE This GUI only shows an acquired image with current examination, and do not displays the image opened by imaging software from its database.

Integrated touch screen console has a feature to display an information of patient on Viewer button in its screen for operator.

The sample of GUI is like below.



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.

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

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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.

APPENDIX B. GENERATOR SETUP

This chapter describes the procedures for the generator setup.

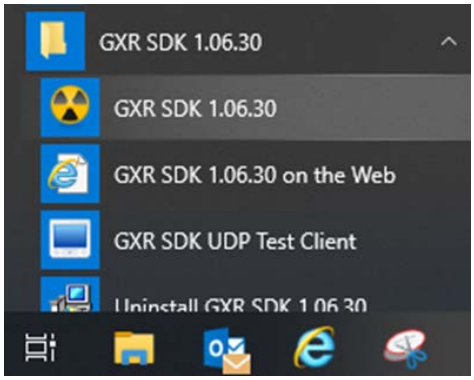
For detector calibration, please follow the steps below.

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

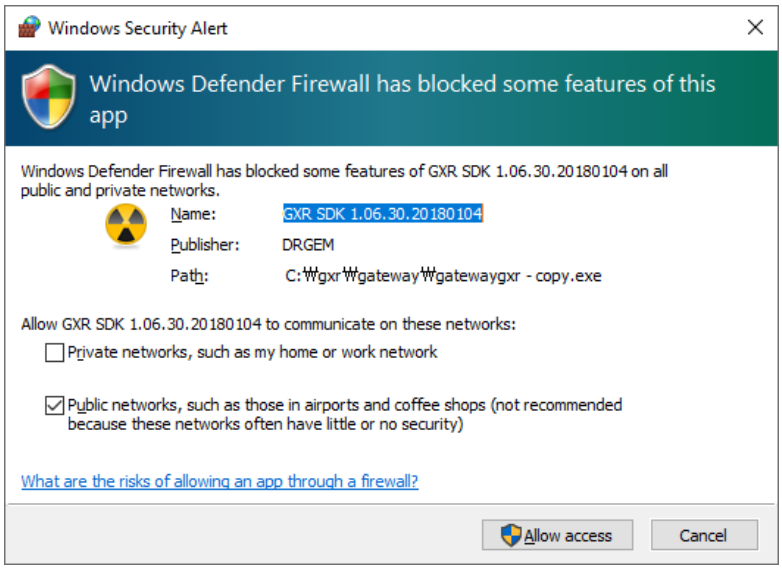
2. Turn on the generator power.
   Press the '**Power ON Switch**' shown in the figure below.

   RADMAX software provides generator interface module to control x-ray generator by the workstation.
   This module has power on and off switches of system, and has exposure hand switch.

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

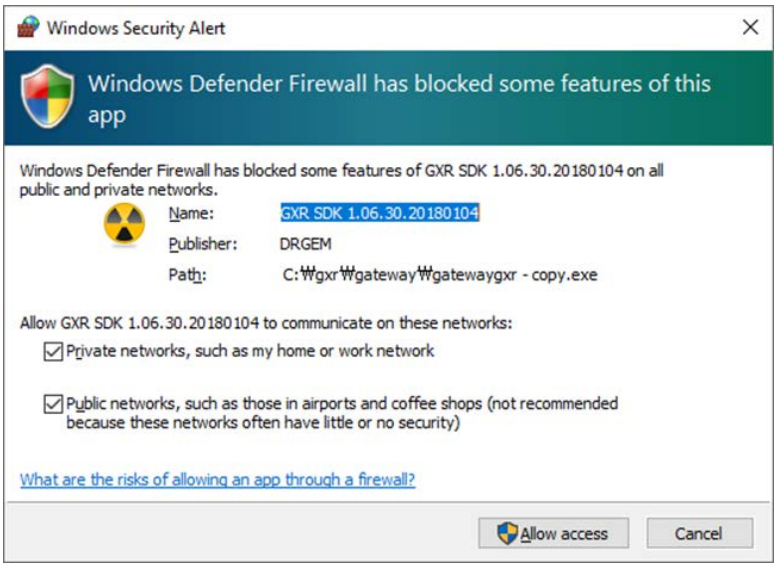


4. Following Windows Security Alert dialog appears.

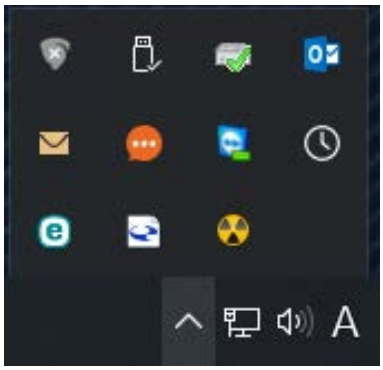


5. Please check '**Private networks, such as my home or work network**' option.
   And click on the '**Allow access**' button like below.

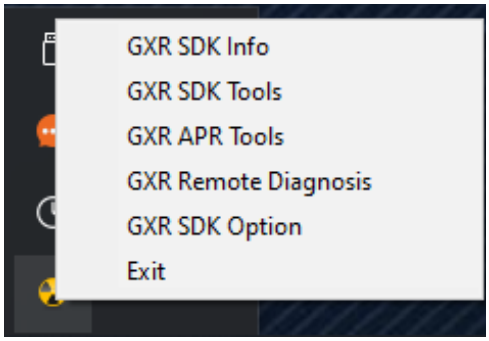
NOTE **IF DO NOT CLICK THE 'ALLOW ACCESS' BUTTON, THE GXR SDK SOFTWARE MAY LEAD TO COMMUNICATION FAILURE.**



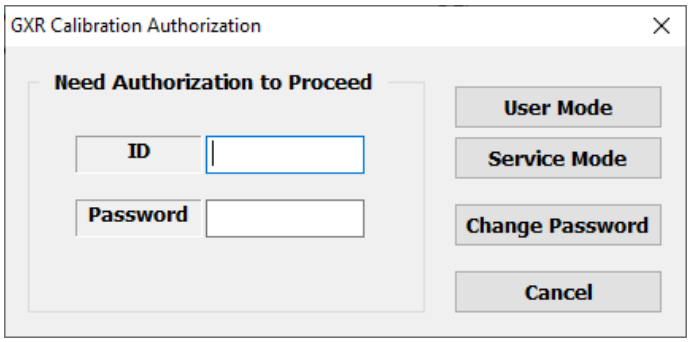
6. If the GXR SDK software is running, you can see the GXR SDK icon on the tray.



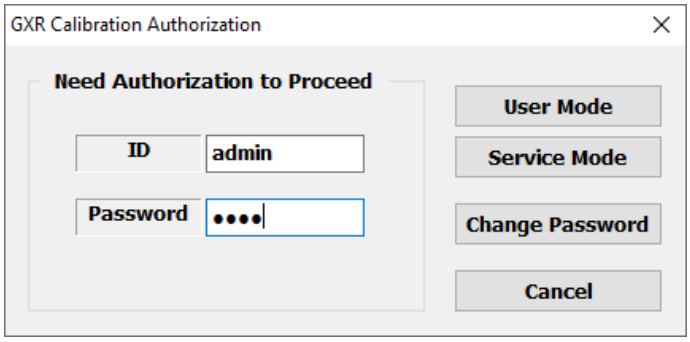
7. Click on the GXR SDK tray icon, you can see the GXR SDK pop-up menu.
   Select the '**GXR SDK Tools**' menu.



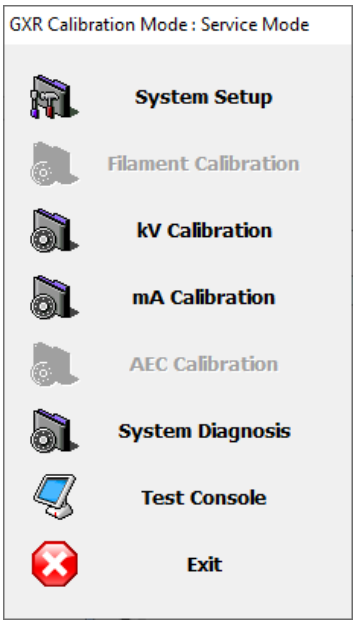
8. GXR Calibration Authorization dialog appears as shown below.



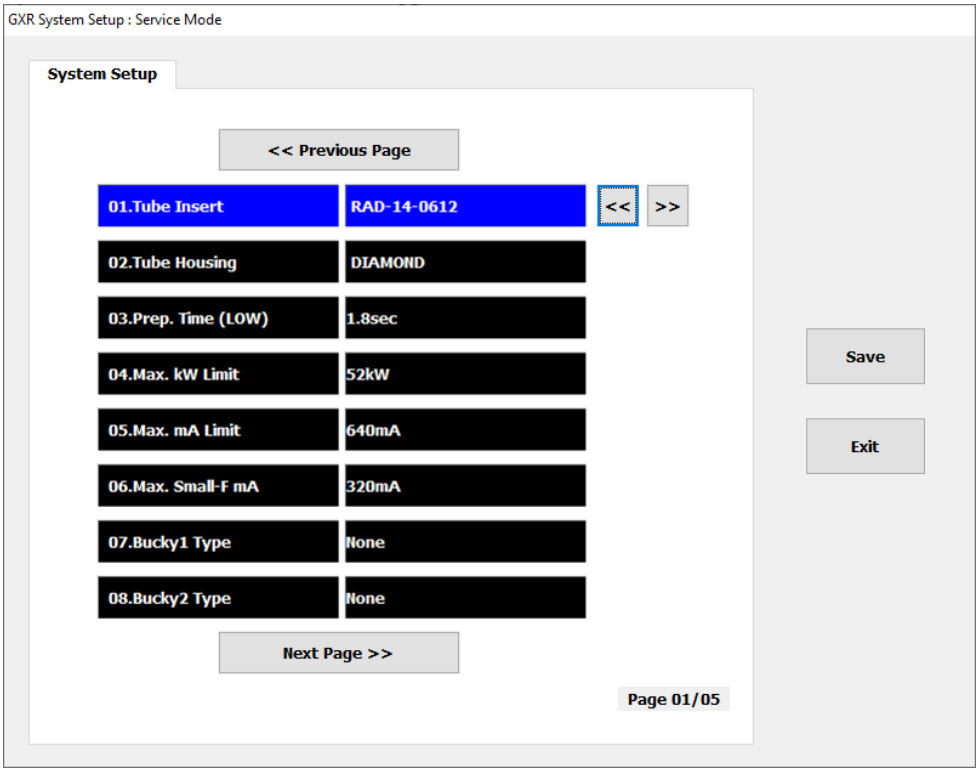
   Please input the following information (ID**: admin / Password: 1234**)
   And click on the '**Service Mode**' button.



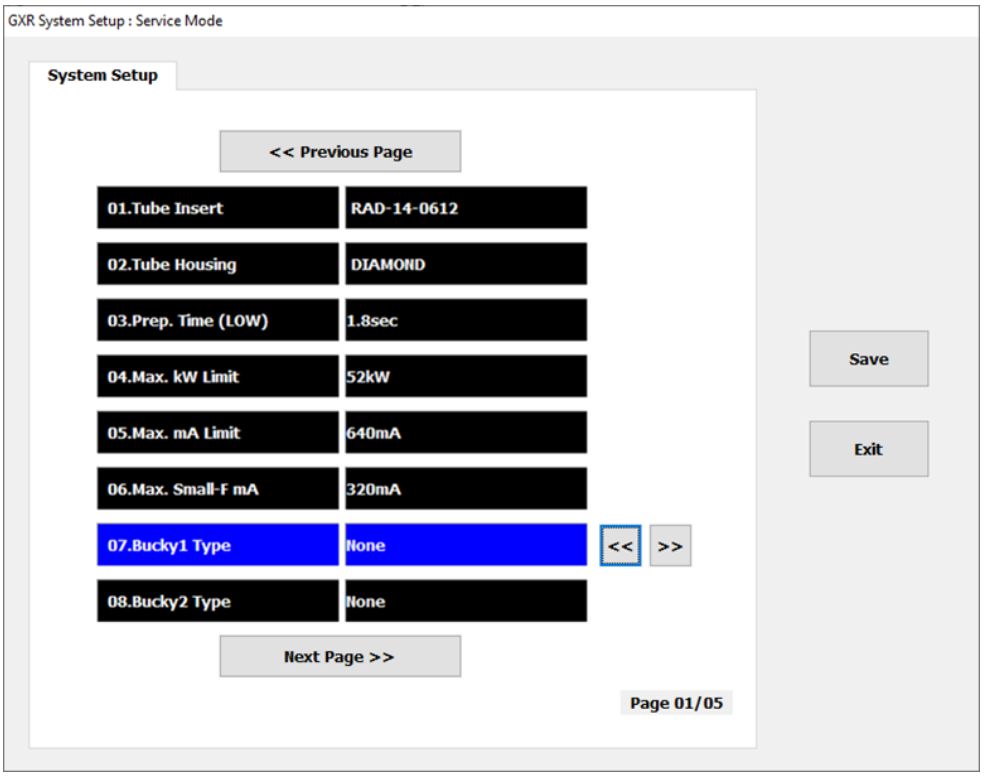
9. The following menu dialog will appear.
   Click on the '**System Setup**' menu.



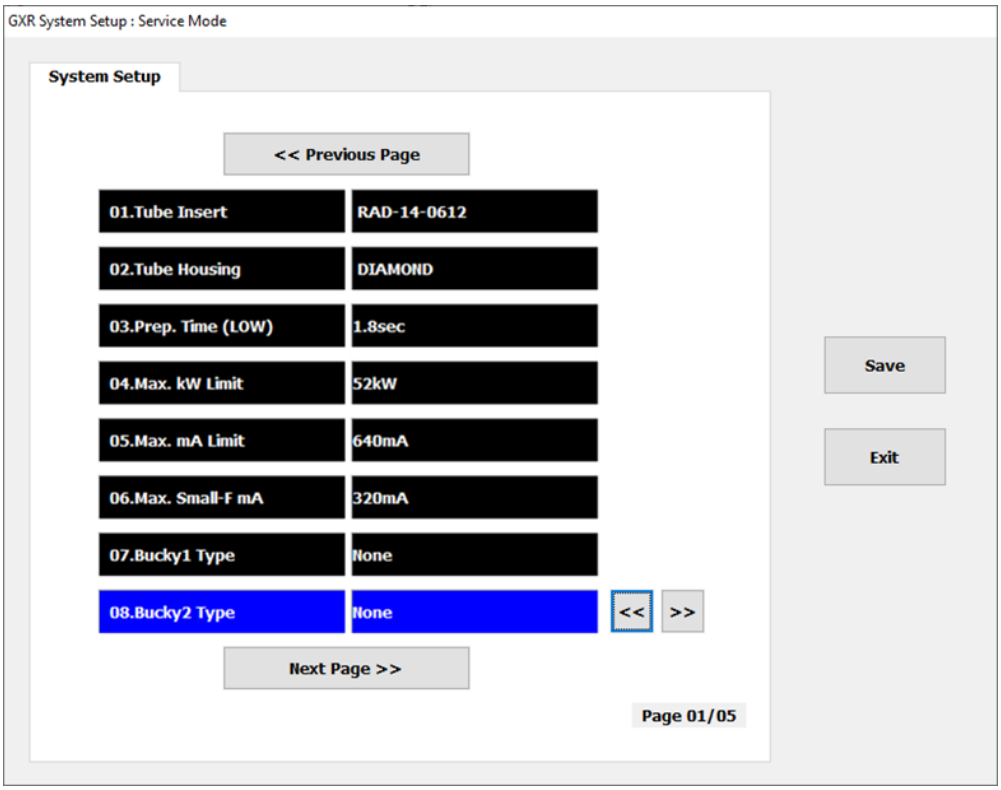
10. If the Tube Insert and Housing setting is not correct, please fix it.



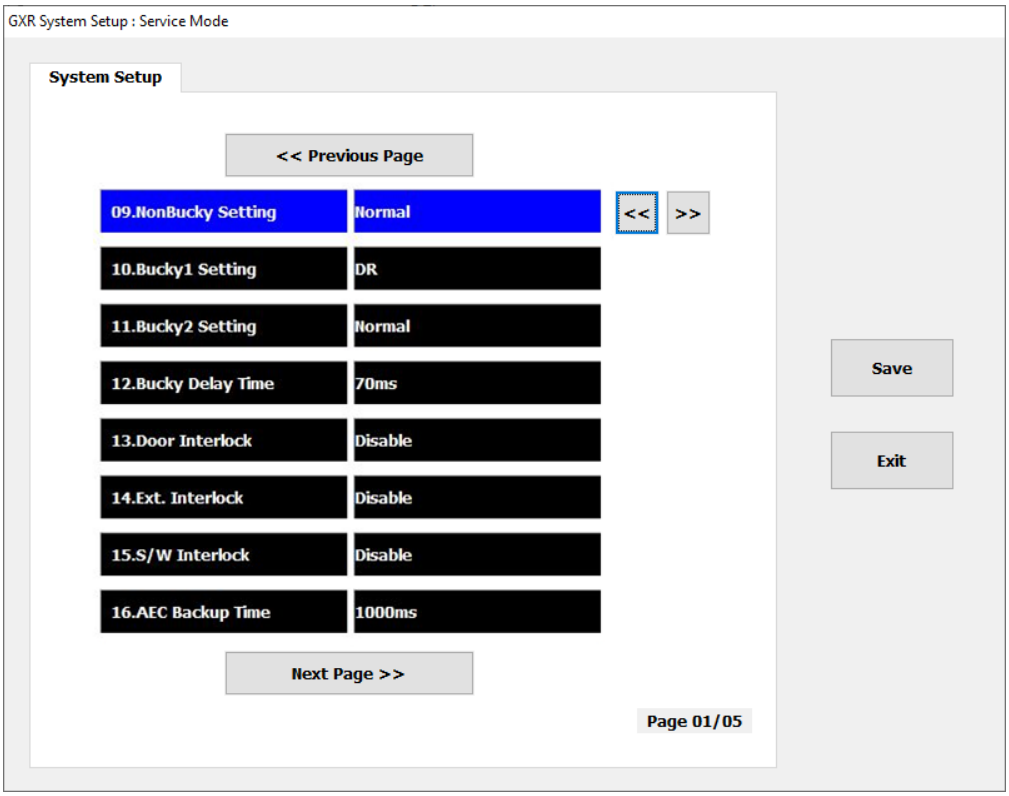
11. Change '**Bucky1 Type**' to '**None**' as shown below.



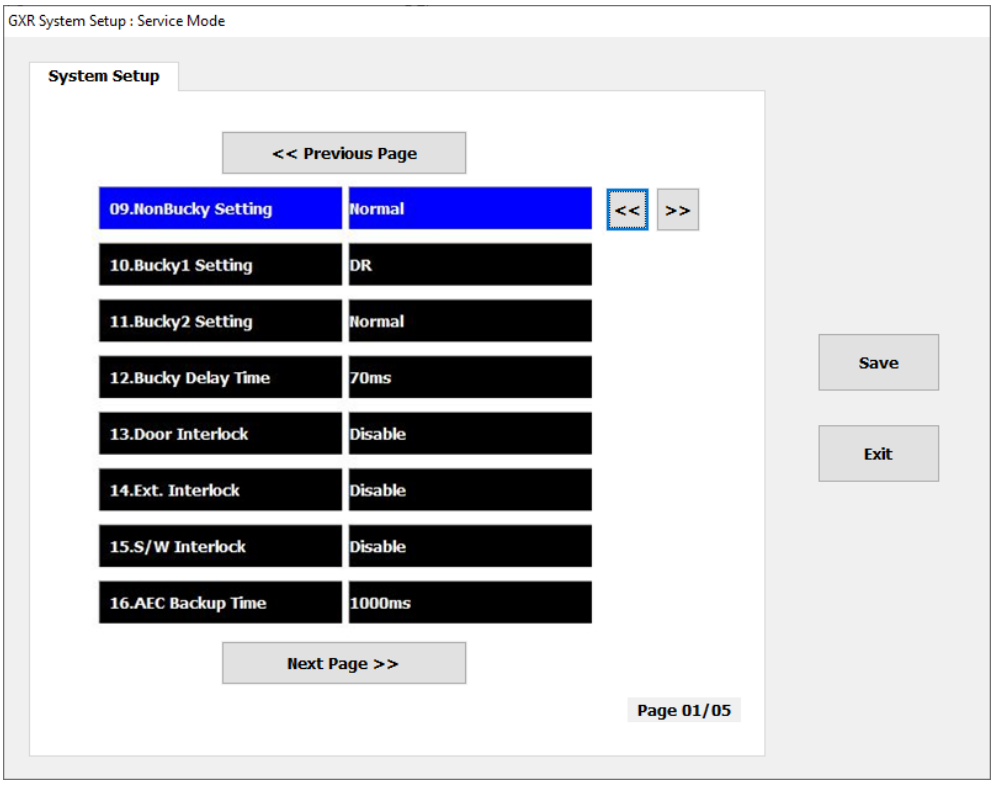
12. Change '**Bucky2 Type**' to '**None**' as shown below.



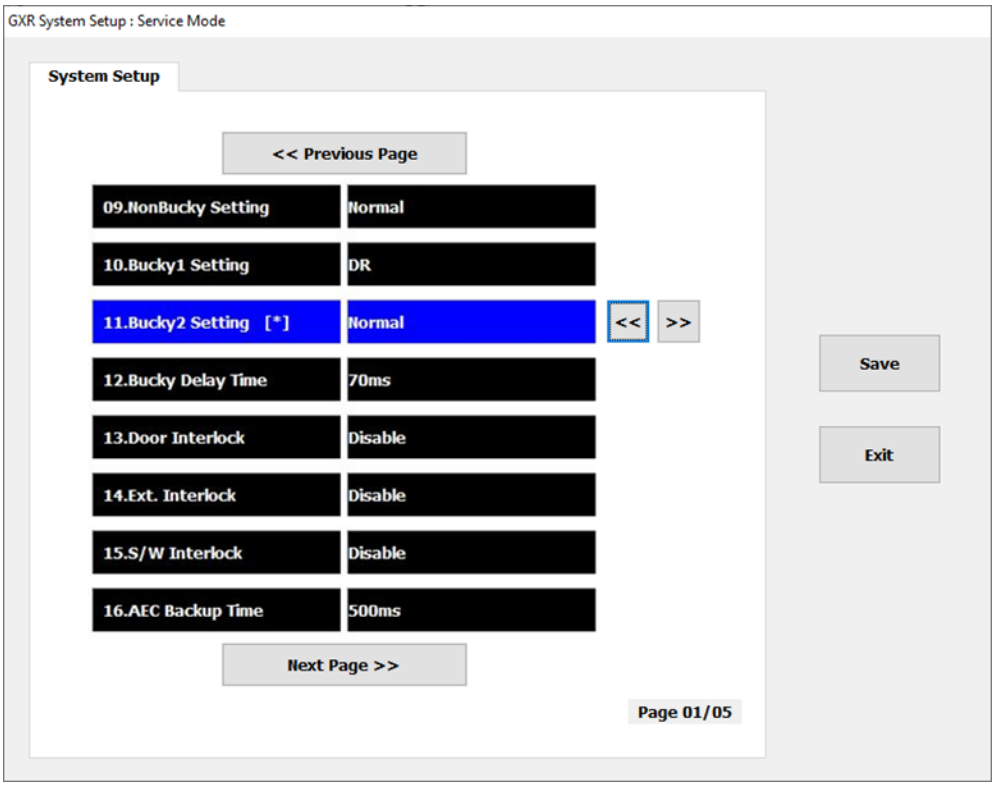
13. Change '**NonBucky Setting**' to '**Normal**' as shown below.



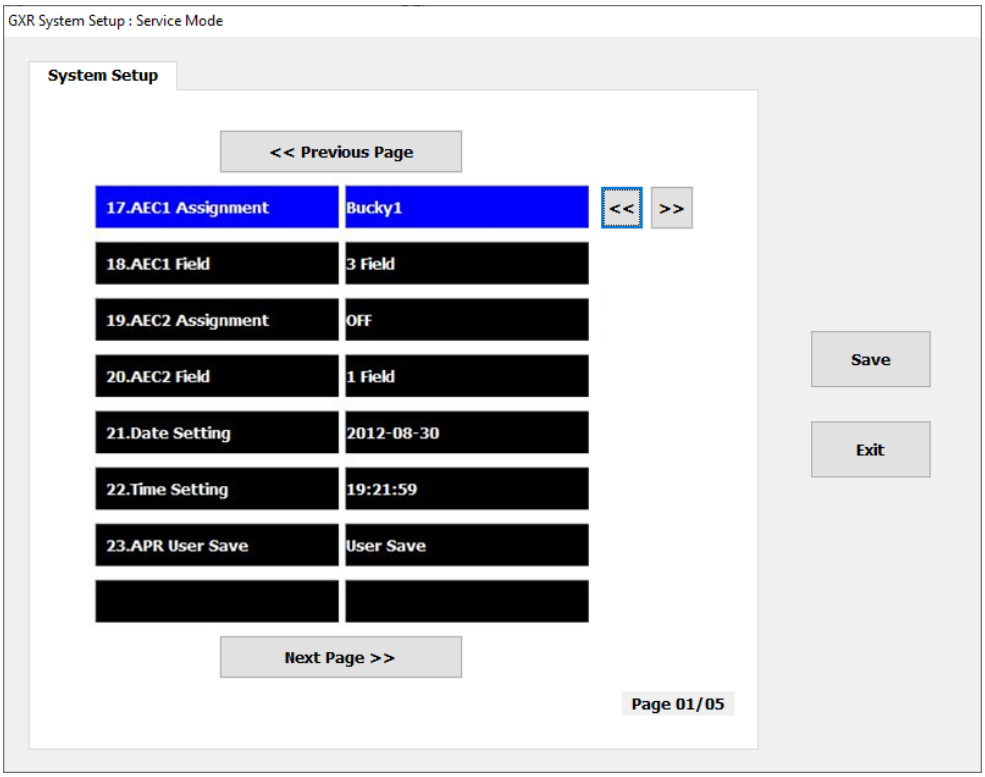
14. Change '**Bucky1 Setting**' to '**DR**' as shown below.



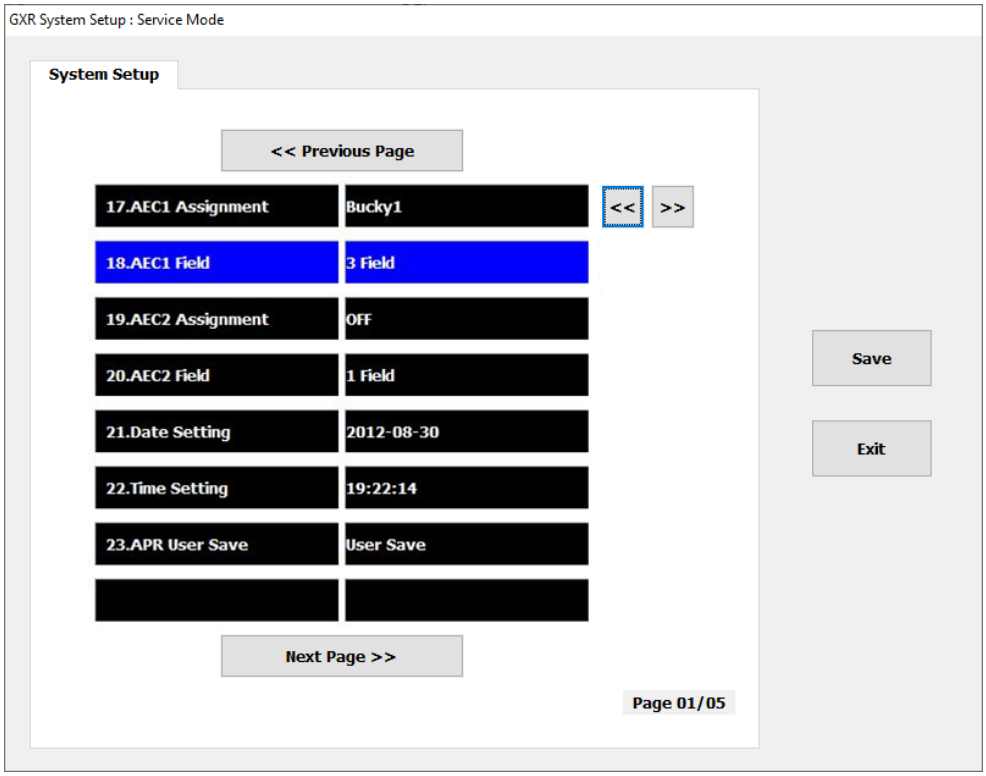
15. Change '**Bucky2 Setting**' to '**Normal**' as shown below.



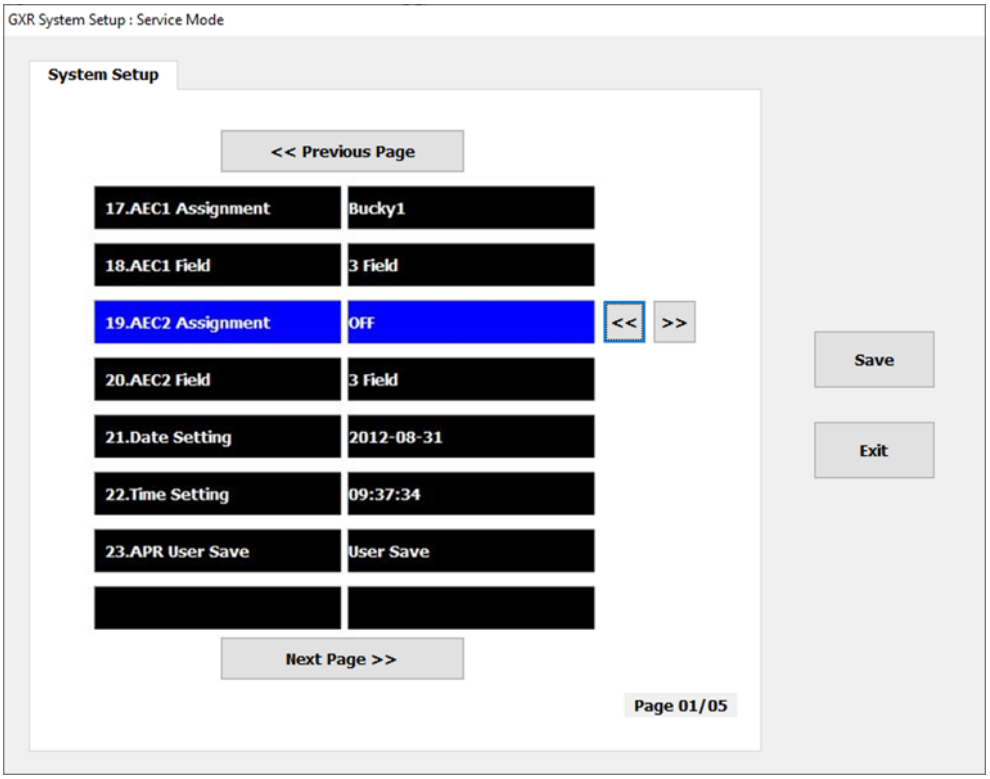
16. Change '**AEC1 Assignment**' to '**Bucky1**' as shown below.



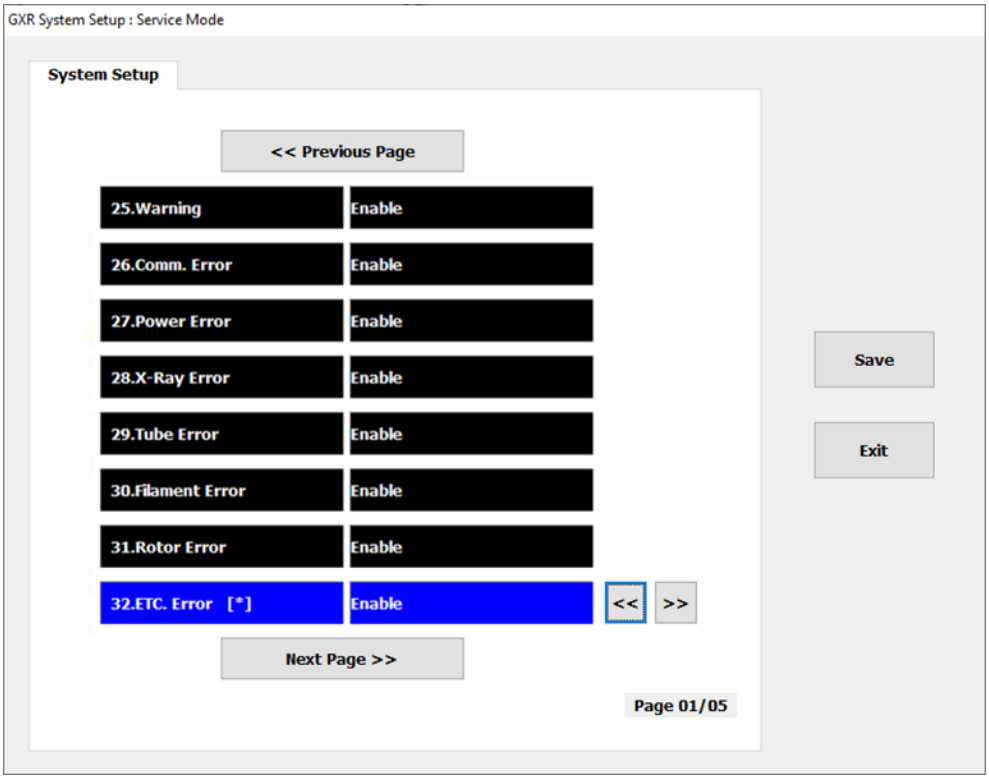
17. Change '**AEC1 Field**' to '**3 Field**' as shown below.



18. If there is second AEC chamber, change '**AEC2 Assignment**' to '**OFF**' as shown below.

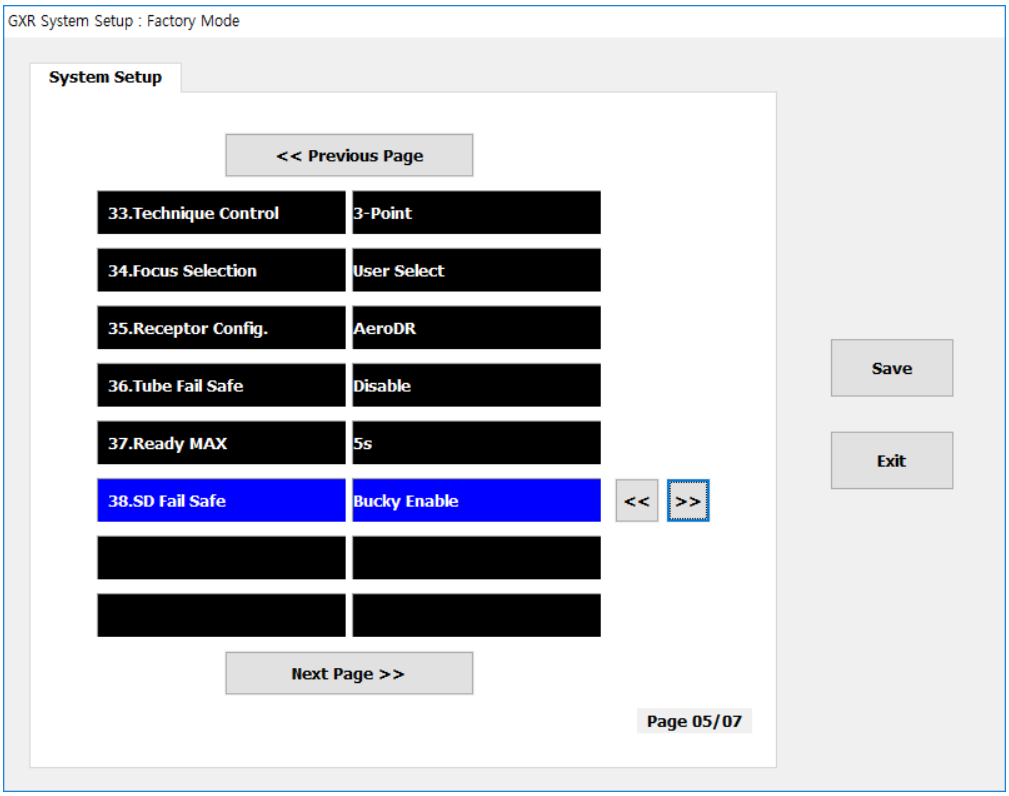


19. Change '**ETC. Error**' to '**Enable**' as shown below.



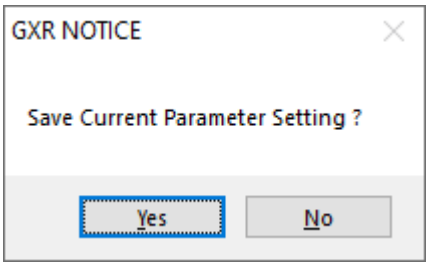
20. Change **'SD Fail Safe'** to **'Bucky Endable** as shown below.

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



21. Click ‘Save’ button.

    After then, click ‘Yes’ button when the dialog window shows up like below.



22. Click ‘Exit’ button.

23. Close GXR SDK.

24. Power off the generator.

APPENDIX C. IMAGE STITCHING MODULE

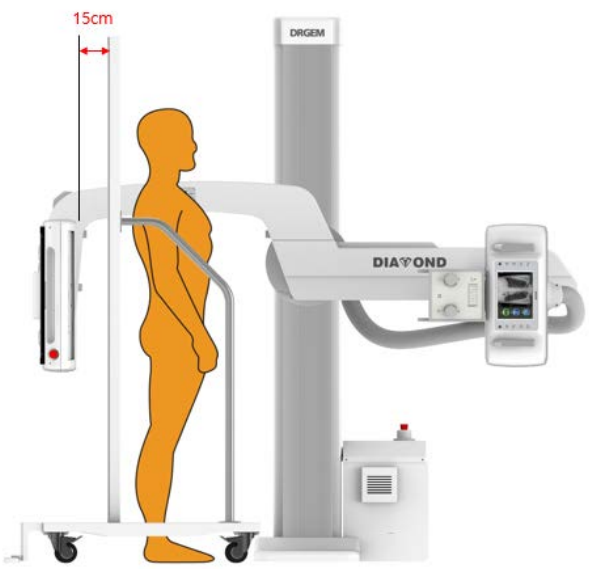
1. Introduction

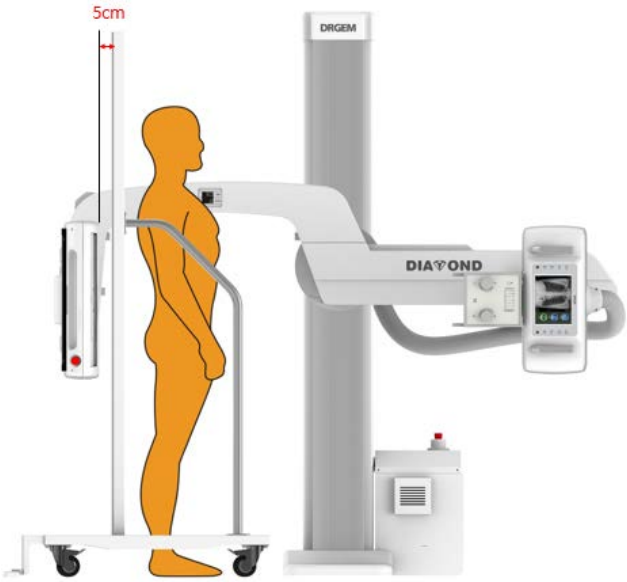
The DIAMOND Stitch function acquires two or three x-rays in sequence and then combines them into a single long image. The process is automatic from the acquisition to the creation of the long image. In case the component images are not accurately aligned, the user may utilize stitching tool to accurately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

2. Requirements

The following requirements should be verified by the operator or the service engineer before operating the stitch function.

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.





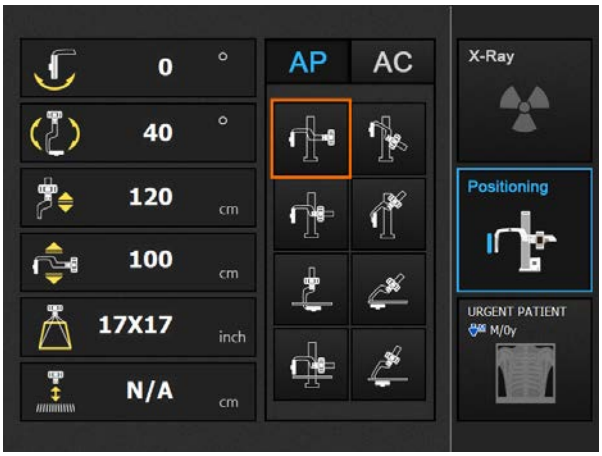
(a) OK. Stitch stand is correctly placed 15 cm in front of the Bucky.

(b) Not OK. Stitch stand is placed too closely to the Bucky.

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.



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. Refer to section 5.3, “STAND GEOMETRY CALIBRATION” of Diamond Service Manual for instructions.

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

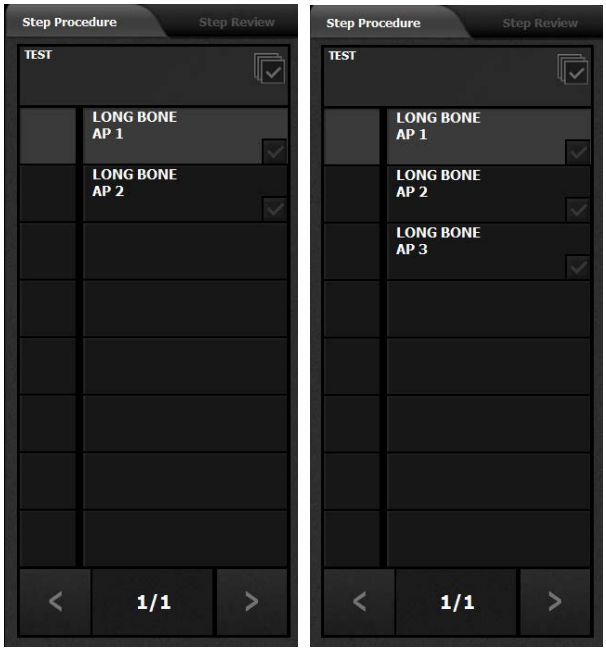
3. Stitch Procedure

1) Insert stitch dongle in any empty USB port of the workstation.

2) Start DIAMOND software.

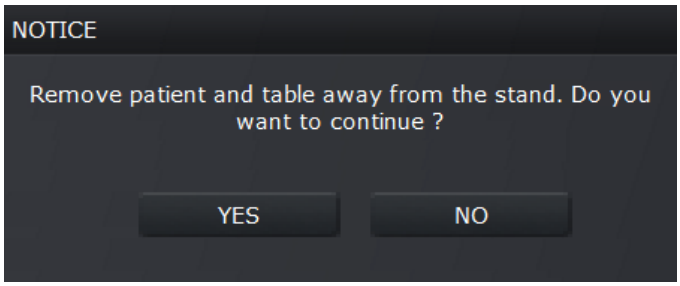
3) Perform patient registration.

4) Add two or three APR projections to procedure for each of the imaging areas as follows.

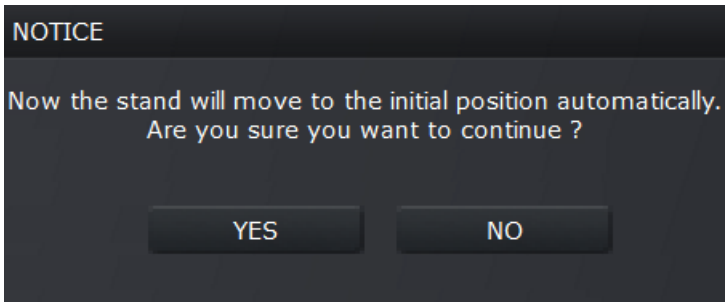


Two or Three steps registered.

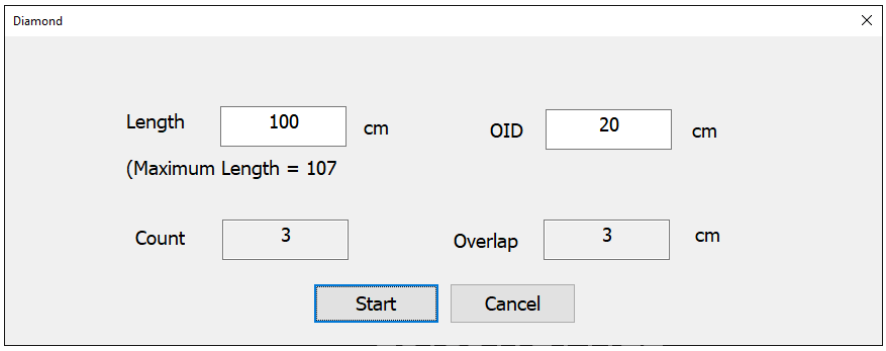
5) Click on the Stitch button. If the following message appears, remove the patient or table away from the stand and then click “Yes”.



6) The following message box will appear. Click “Yes” and the U-Arm will move to the default stitch position.

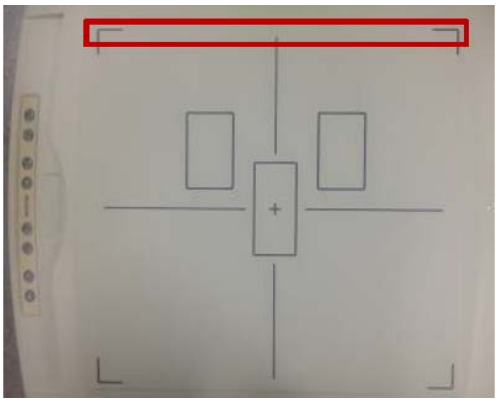


7) Wait for the stitch setup dialog to appear on screen as below.



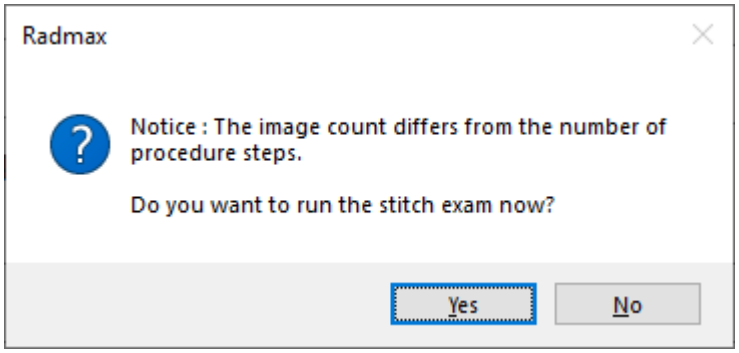
8) Place the stitch stand 15cm in front of the Bucky cover and then position the patient on the stand. The 15 cm spacing is necessary for U-Arm rotation movement.

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 setup dialog. Note that the maximum length from the current starting position is indicated beneath the length input box.

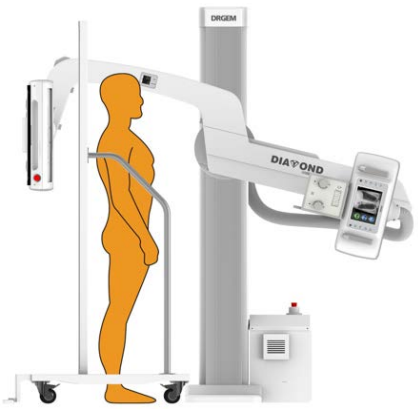
11) Clicking the “START” button will perform a final check on the input parameters and bring up a message box like below.



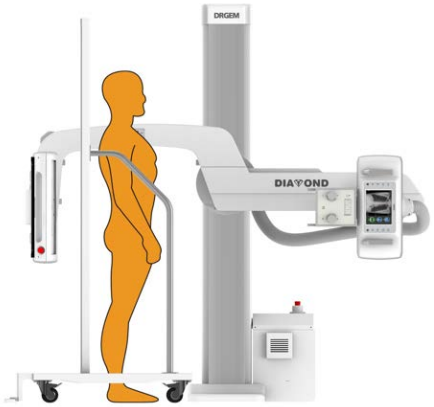
12) Click “Yes” to run the procedure. If the image count is greater than the number of examination steps, extra steps will be added automatically as needed. The exposure conditions in the added steps will be identical to the last registered step.

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.

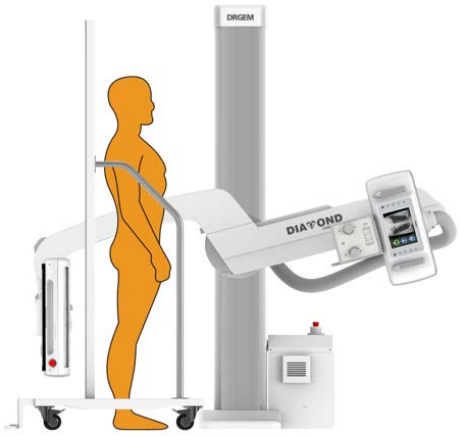
14) The U-Arm moves to the first position and makes x-ray exposure.



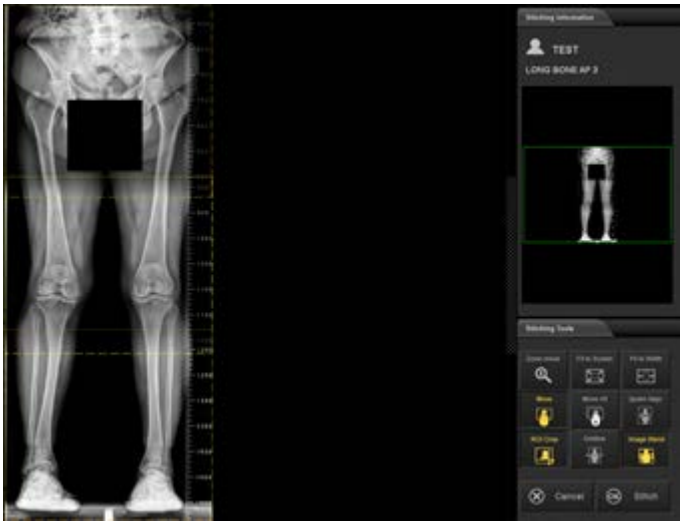
15) The U-Arm moves to the second position and makes x-ray exposure. If the image count is two, then skip to step 14.



16) The U-Arm moves to the third position and makes the x-ray exposure.



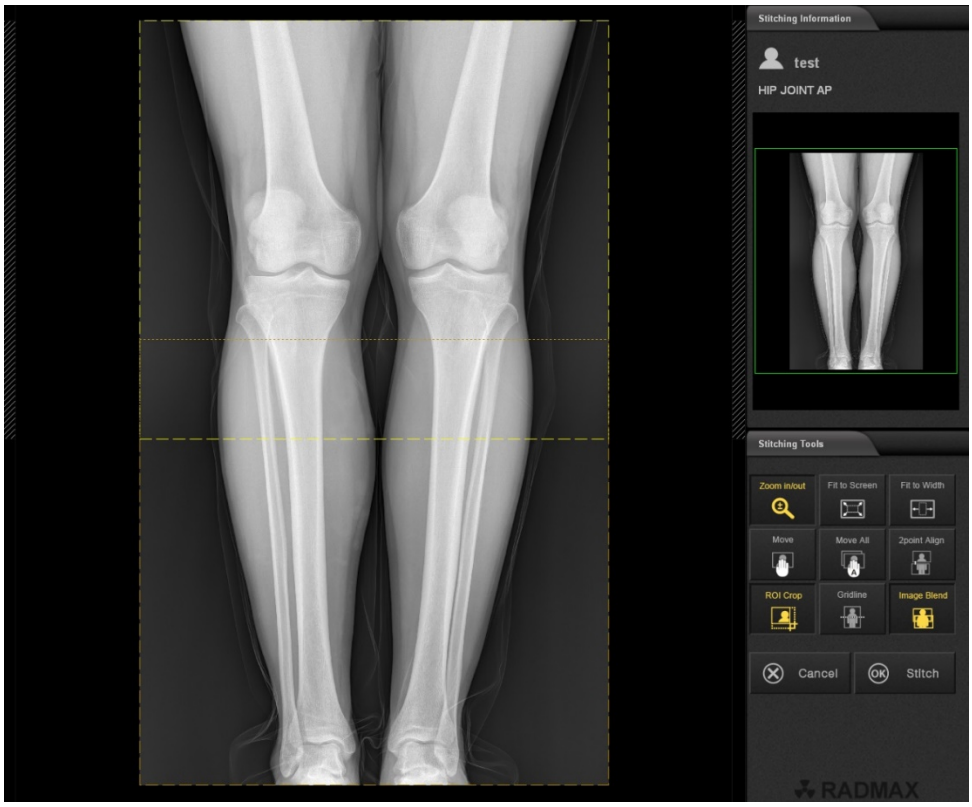
17) When the procedure is completed the stitch module will open with the images automatically stitched as in the screen shot below.



18) In case the images are not accurately stitched, the image positions can be manually adjusted to produce accurate stitch image.

19) Finally, press the OK button to save the image.

4. Image Stitching Tool



Screen Description

Section 1: Main Display Area

The main display area displays the x-ray images as a composite image.

Section 2: Tools Area

The tools area contains buttons for several image manipulation tools.

Section 3: Preview Display Area

The preview display area shows the full view with the green box indicating the current zoom-in area.

NOTE Please refer to the RADMAX Operation Manual Appendix H

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