GE Healthcare

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Revision 6

Radiographic System: Proteus XR/f - Definium XR/f

Operator Manual

CE
1639

Digitally signed by Chicu Natalia
Date: 2022.07.12 16:46:30 EEST
Reason: MoldSign Signature
Location: Moldova

WARNING

THIS EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATORUNLESS MEASURES OF PROTECTION ARE STRICTLY OBSERVED

Though this equipment is built to the highest standards of electrical and mechanical safety, the useful radiation beam becomes a source of danger in the hands of the unauthorized or unqualified operator. Excessive exposure to radiation causes damage to human tissue.

Therefore, adequate precautions must be taken to prevent unauthorized or unqualified persons from operating this equipment or exposing themselves or others to its radiation.

Before operation, persons qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in Annals Number 60 of the ICRP, with applicable National Standards, and should have been trained in use of the equipment.

ENVIRONMENTAL STATEMENT ON THE LIFE CYCLE OF THE EQUIPMENT OR SYSTEM

This equipment or system contains environmentally dangerous components and materials (such as PCB's, electronic components, used dielectric oil, lead, batteries etc.) which, once the life-cycle of the equipment or system comes to an end, becomes dangerous and need to be considered as harmful waste according to the international, domestic and local regulations.

The manufacturer recommends to contact an authorized representative of the manufacturer or an authorized waste management company once the life-cycle of the equipment or system comes to an end to remove this equipment or system.

REVISION HISTORY

REV	DATE	REASON FOR CHANGE	PAGES
1	SEP 25, 2020	First edition.	126
2	DEC 18, 2020	Updated document format, replaced advisory symbols, added system label, amended control Panel illustrations, added Digital Detector to Applied parts, added patient max weight in specifications section, replaced illustrations with new 2250 mm tube stand base, added back page.	126
3	FEB 8, 2021	Cleaning and disinfection section added. Elevating Table up/down Travel updated.	134
4	FEB 22, 2021	Sect. 2, Warning in accordance with Canada Regulations	134
5	MAR 12, 2021	Sect. 2: Warning page 17, Image page 32.Sect. 3: Start**-** up and Shutdown. Sect. 4: Warning page 59. Sect. 5.4.1, 5.5.2, 5.5.3: Images updated. Sect. 10.2.1, 10.2.3: Specifications and illustrations updated.	134
6	AUG 12, 2021	Sect. 2.6 Safety Symbols UDI Symbol added. Sect. 3.1 & 3.2 Start up and Shutdown with new relay.Sect 5.4.5 Images updated. Sect. 10.2.1, 10.2.3: Elevating Table Specifications and illustrations updated. Sect. 6.2, E006 removed (not applicable). Sect. 10.3.1 Max 125 kVp for Single phase Gen.	136

This Document is the English original version, edited and supplied by the manufacturer.

The Revision state of this Document is indicated in the code number shown at the bottom of this page.

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ADVISORY SYMBOLS

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

DANGERS ADVISE OF CONDITIONS OR SITUATIONS THAT IF NOT HEEDED OR AVOIDED WILL CAUSE SERIOUS PERSONAL INJURY OR DEATH.

ADVISE OF CONDITIONS OR SITUATIONS THAT IF NOT HEEDED OR AVOIDED COULD CAUSE SERIOUS PERSONAL INJURY, OR CATASTROPHIC DAMAGE OF EQUIPMENT ORDATA.

Advise of conditions or situations that if not heeded or avoided could cause personal injury or damage to equipmentor data.

Note **.** *Alert readers to pertinent facts and conditions. Notes represent information that is important to know but which do not necessarily relate to possible injury or damage to equipment.*

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SECTION 1 INTRODUCTION

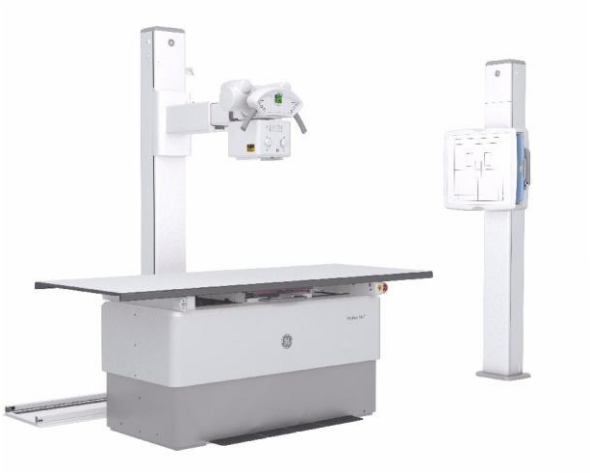
This manual contains all the necessary information to understand and operate the ***Proteus XR/f System.*** It provides a general description, safety information, operating instructions and specifications concerning the equipment. This manual is not intended to teach radiology or to make any type of clinical diagnosis.

The Tube Support Column, the Table and the Wall Stand are associated equipment to the X-ray Generator Unit.

Basically, the System consists of the following associated subassemblies: Tube Support with variable height, X-ray Tube, Collimator, Elevating Table (ET) or non Elevating Table (ST) and Wall Stand. The Table (ET or ST) and the Wall Stand house a Digital Detector (Digital Radiography). An optional Single Panel System without Table is available.

The Control Panel is ergonomically built, equipped with logically arranged and easily accessible controls. Column movements are driven by the Control Panel hand-grips. Brakes are released by a slight thumb pressure on the control push-buttons.

Illustration 1
Radiographic Room Positioners



Elevating Table (ET)

Non Elevating Table (ST)

The Generator Cabinet comprises the Power Module *(*which contains the power and control components) and the High Voltage Transformer.

The operator controls and displays for radiographic operations are shown on one of the Screen Console of the Image Acquisition Workstation. All functions, displays and controls are logically arranged, easily accessible and identified to prevent confusion. Technique factors and functions are selected by pushing the corresponding buttons or by touching directly on the screen, as applicable.

The Image Acquisition Workstation is used for imaging processing and diagnosis in Digital Radiography Systems.

The High Frequency X-ray Generator provides all the advantages of high frequency waveform Generators including lower patient dose, shorter exposure times and greater accuracy and consistency.

The Generator is controlled by multiple microprocessors providing increased exposure consistency, efficient operation and extended Tube life. A high level of self-diagnosis greatly increases serviceability and reduces down time.

1.1 GENERAL FEATURES

The main features of the **Radiographic Room** are:

- A solid and ergonomic design.
- Easy operation, security and precision of all positioning movements with respect to patient.
- Movement Controls for each component of the Radiographic Room.
- Specific System Configurations are detailed in the following table:

FLOOR MOUNTED TUBE STAND	
Control Panel	Digital
Autodiagnostics	n
Horizontal Motion of Column(Configurable Stops)	Manual (3)
Vertical Motion of Arm	Manual
Rotation of the Column on its Vertical Axis (Detents)	Manual ±180^{o} (**-** 180^{o}, --90^{o}, 0^{o}, +90^{o}, +180^{o})
Rotation of the Tube-Collimator Assembly on its Transverse Axis (Detents)	Manual +150^{o}, **-** 130^{o} (Angle Readout) (--90^{o}, 0^{o}, +90^{o})
Transverse Motion of Tube-Collimator Assembly (Telescopic Arm)	Manual with Centering Detent
SID Readout respect to Table Detector	Continuous
SID Readout respect to Wall Stand Detector	Continuous
ELEVATING TABLE or NON ELEVATING TABLE	
Digital Detector Assembly with Longitudinal Motion	n
Ion Chamber Connection	n

WALL STAND	
Digital Detector Assembly with vertical motion and adjusted with Internal Counterweights	n
Ion Chamber Connection	n
Right or Left Detector Panel Loading(as per customer order)	n
OPTIONS	
Table Receptor Centering (mechanical link with the Tube Stand Column)	n
Dosemeter Device	n
ACCESSORIES	
Hand Grips for Table Tabletop	n
Compression Band for Table	n
Table Top Lateral Detector Holder	n
Lateral Detector Holder with trolley	n
Arm Support for Wall Stand	n
Hand Grips for Wall Stand	n

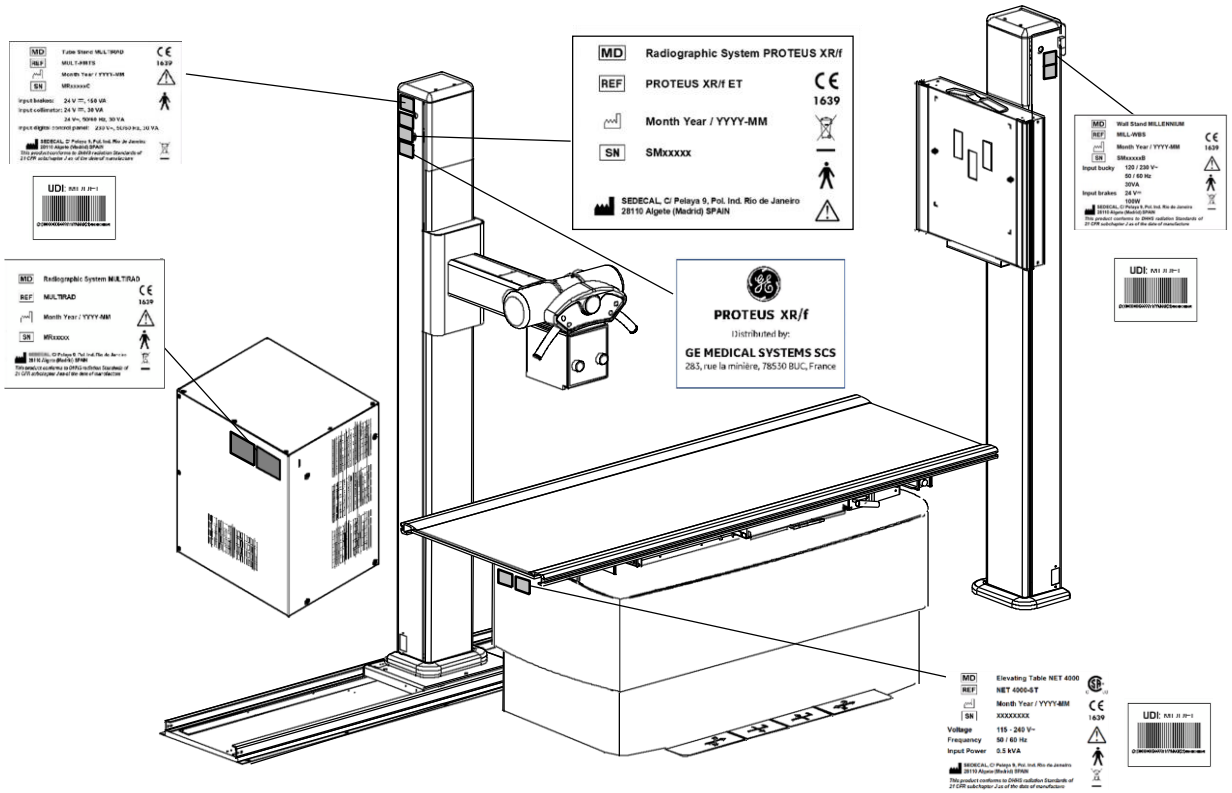
Note **.** *The Handgrips must not be positioned in the trajectory of theX-Ray beam.*

1.2 PRODUCT IDENTIFICATION

The major items in the Radiographic Room have some identification labels attached to them which provide the following manufacturer and product information.

- Product.
- Model.
- Volts (V), Line Phases, Frequency (Hz), and Power (kVA, kW).
- Date of manufacture.
- Serial number.
- Reference.
- Manufacturer.
- Place of manufacture.
- Certification.

RAD Room Label



Note . *For further information on the standardized symbology of this labels, refer to Section 2.*

1.3 INDICATIONS FOR USE

In accordance with FDA 510(k):

The **Proteus XR/f Radiographic Systems** with Digital Detector are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supineposition.

In accordance with IEC Standards:

INTENDED USE

Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

The **Proteus XR/f Radiographic System** are equipment designed for general radiography in hospitals, clinics, radiology imaging centers and medical practices.

Patients may be physically abled, disabled, immobilized or in a state of shock.

This **Proteus XR/f Radiographic System** contributes to the metrics of imaging performance ensuring the efficient use of radiation.

As example of X-ray image receptors types that can be used: Digital Detectors.

NORMAL USE

The Normal Use of this equipment is defined as the Intended Use plus the Maintenance and Service tasks.

CONTRAINDICATIONS

Do not use the equipment for any purposes other than those for which it is intended. Operation of the equipment for unintended purposes could lead to fatal or other serious injury.

This equipment is not intended for mammography applications.

This equipment is not specifically designed for paediatric purposes; if children are to be examined, they should always be accompanied by an adult.

1.4 APPLIED PARTS

Applied Parts refer to parts of medical equipment that in Normal Use necessarily comes into physical contact with the patient for medical equipment to perform its function. This RAD equipment includes the following Applied Parts:

- Tabletop of the RAD Table.
- Tabletop of the RAD Wall Stand.
- Digital Detector.
- Hand Grips (optional).
- Arm Support (optional).
- Compression Band (optional).
- Lateral Detector Holders (optional).
- Other accessories.

BEAR IN MIND THAT SOME APPLIED PARTS MAY HEAT UP TO 48^{o}C (118.4^{o}F) WHEN THE AMBIENT TEMPERATURE FOR OPERATION IS ON THE LIMIT. THIS IS COMPLETELY NORMAL AND DOES NOT MEAN A MALFUNCTION OF THE EQUIPMENT.

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SECTION 2 SAFETY AND REGULATORY INFORMATION

This section describes the safety considerations, general precautions for patient, operator and equipment in order to perform a safe operation and service tasks.

Regulatory information and symbols used in the equipment are detailed in this section to operate it safely.

2.1 GENERAL

FOR CONTINUE SAFE USE OF THIS EQUIPMENT FOLLOW THE INSTRUCTIONS IN THIS OPERATING MANUAL. BOTH OPERATOR AND SERVICE PERSONNEL HAVE TO STUDY THIS MANUAL CAREFULLY, INSTRUCTIONS HEREIN SHOULD BE THOROUGHLY READ AND UNDERSTOOD BEFORE ATTEMPTING TO PLACE THE EQUIPMENT IN OPERATION, ESPECIALLY THE INSTRUCTIONS CONCERNING SAFETY, REGULATIONS, DOSAGE AND RADIATION PROTECTION. KEEP THIS OPERATING MANUAL WITH THE EQUIPMENT AT ALL TIMES AND PERIODICALLY REVIEW THE OPERATING AND SAFETYINSTRUCTIONS.

TECHNICAL INSTRUCTIONS FOR SERVICE PERSONNEL SUCH AS PRE-INSTALLATION REQUIREMENTS, INSTALLATION, CALIBRATION OR MAINTENANCE ARE DESCRIBED IN THE RESPECTIVE CHAPTERS OF THE PRE-INSTALLATION AND SERVICE MANUALS PROVIDED WITH THIS EQUIPMENT.

PLEASE STUDY THIS MANUAL AND THE MANUALS FOR EACH SYSTEM COMPONENT TO BE FULLY AWARE OF ALL THE SAFETY AND OPERATIONAL REQUIREMENTS.

MODIFICATION ON THE EQUIPMENT ARE NOT ALLOWED IN ANY WAY. USE ONLY THE INTERCONNECT CABLES AND ACCESSORIES APPROVED BY THE MANUFACTURER

OPERATOR AND SERVICE PERSONNEL AUTHORIZED TO USE, INSTALL, CALIBRATE AND MAINTAIN THIS EQUIPMENT MUST BE AWARE OF THE DANGER OF EXCESSIVE EXPOSURE TO X-RAY RADIATION. IT IS VITALLY IMPORTANT THAT EVERYONE WORKING WITH X-RAY RADIATION IS PROPERLY TRAINED, INFORMED ON THE HAZARDS OF RADIATION AND TAKE ADEQUATE STEPS TO ENSURE PROTECTION AGAINST INJURY.

OPERATOR MUST HAVE SUFFICIENT KNOWLEDGE TO COMPETENTLY PERFORM THE DIFFERENT DIAGNOSTIC IMAGING PROCEDURES WITH X-RAY DEVICES. THIS KNOWLEDGE IS ACQUIRED THROUGH A VARIETY OF EDUCATIONAL METHODS INCLUDING CLINICAL WORKING EXPERIENCE, AND AS PART OF MANY COLLEGE AND UNIVERSITY RADIOLOGIC TECHNOLOGY PROGRAMS IN ACCORDANCE WITH LOCAL LAWS OR REGULATIONS.

SERVICE PERSONNEL MUST HAVE SUFFICIENT KNOWLEDGE TO COMPETENTLY PERFORM THE SERVICE TASKS RELATED TO X-RAY DEVICES AND PARTICULARLY TO THE EQUIPMENT DESCRIBED IN THIS MANUAL. THIS KNOWLEDGE IS ACQUIRED THROUGH A VARIETY OF EDUCATIONAL METHODS FOR TECHNICIANS IN ACCORDANCE WITH LOCAL LAWS OR REGULATIONS, INCLUDING SPECIFIC TRAINING ON THIS EQUIPMENT.

X-RAY EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATOR UNLESS PROTECTION MEASURES ARE STRICTLY OBSERVED. IF THE EQUIPMENT IS NOT ACCURATELY USED, IT MAY CAUSE INJURY.

ALTHOUGH X-RADIATION CAN BE HAZARDOUS, X-RAY EQUIPMENT DOES NOT POSE ANY DANGER WHEN IT IS PROPERLY USED.

SPECIAL ATTENTION MUST BE GIVEN TO DIAGNOSTIC X-RAY EQUIPMENT SPECIFIED TO BE USED IN COMBINATION WITH ACCESSORIES OR OTHER ITEMS. BE AWARE OF POSSIBLE ADVERSE EFFECT ARISING FROM THESE MATERIALS LOCATED IN THE X- RAY BEAM. (SEE THE TABLE BELOW FOR THE MAXIMUM EQUIVALENT ATTENUATION OF MATERIALS POSSIBLY LOCATED IN THE X-RAY BEAM).

ITEM	MAXIMUM ATTENUATION EQUIVALENT mm AL	
	21 CFR	IEC 60601-2-54:2009 AND IEC 60601-2-54:2009+AMD1:2015
Total of all layers composing the front panel of cassette holder	1.2	1.2
Total of all layers composing the front panel of FILM CHANGER	1.2	1.2
Total of all layers, excluding detector itself, composing the front panelof DIGITAL X-RAY IMAGING DEVICE	1.2	1.2
Cradle	2.3	2.3
PATIENT SUPPORT, stationary, without articulated joints	1.2	1.2
PATIENT SUPPORT, movable, without articulated joints (including stationary layers)	1.7	1.7
PATIENT SUPPORT, with radiolucent panel having one articulatedjoint	1.7	1.7
PATIENT SUPPORT, with radiolucent panel having two or more articulated joints	2.3	2.3
PATIENT SUPPORT, cantilevered	2.3	2.3

*Note 1.***-** *Devices such as RADIATION DETECTORS are not included in the item listed in this table.*

*Note 2.***-** *Requirements concerning the ATTENUATION properties of RADIOGRAPHIC CASSETTES and of INTENSIFYING SCREENS are given in ISO 4090 [3], for ANTI***-** *SCATTER GRIDS in IEC 60627[1].*

*Note 3.***-** *ATTENUATION caused by table mattresses and similar accessories is not included in the maximum ATTENUATION EQUIVALENT for PATIENT SUPPORT.*

*Note 4.***-** *Maximum ATTENUATION EQUIVALENT mm Al is only applied to the corresponding item. If several items given in this table are located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, each corresponding maximum ATTENUATION EQUIVALENT mm Al is separately applied to each item.*

2.2 RESPONSIBILITIES

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

THE EQUIPMENT HEREIN DESCRIBED IS SOLD WITH THE UNDERSTANDING THAT THE MANUFACTURER, ITS AGENTS, AND REPRESENTATIVES ARE NOT LIABLE FOR INJURY OR DAMAGE WHICH MAY RESULT FROM OVEREXPOSURE OF PATIENTS OR PERSONNEL TO X-RAYRADIATION.

IT IS THE RESPONSIBILITY OF THE OPERATOR TO ENSURE THE SAFETY OF THE PATIENT WHILE THE X-RAY EQUIPMENT IS IN OPERATION BY VISUAL OBSERVATION, PROPER PATIENT POSITIONING, AND USE OF THE DEVICES THAT ARE INTENDED TO PREVENT PATIENT INJURY.

ALWAYS WATCH ALL PARTS OF THE SYSTEM TO VERIFY THAT THERE IS NEITHER INTERFERENCE NOR POSSIBILITY OF COLLISION WITH THE PATIENT OR WITH OTHER EQUIPMENTS.

IT IS THE RESPONSIBILITY OF THE PURCHASER / CUSTOMER TO PROVIDE THE MEANS FOR AUDIO AND VISUAL COMMUNICATION BETWEEN THE OPERATOR ANDTHE PATIENT.

IT IS THE RESPONSIBILITY OF THE OPERATOR TO ENSURE THAT ALL THE EXPOSURE PARAMETERS ARE CORRECT BEFORE PERFORMING AN EXAM TO THE PATIENT, BY VERIFYING THAT THE PARAMETER SELECTION HAS NOT BEEN MODIFIED UNINTENTIONALLY OR BY THE CONTACT OF EXTERNAL ELEMENTS ON THE CONTROL CONSOLE, IN ORDER TO AVOID THE OVEREXPOSURE OR THE NEED OF PERFORMING A NEW EXAM TO THE PATIENT.

MAKE SURE THAT THE X-RAY TUBE IS SET IN WORKING POSITION WITH THE REFERENCE AXIS (X-RAY BEAM) POINTING TO THE RECEPTION AREA.

2.3 MAXIMUM PERMISSIBLE DOSE (MPD)

Before operation, people qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in Annals Number 60 of the ICRP, with applicable National Standards; and should have been trained in use of the equipment.

THE OPERATOR SHALL USE THE LARGEST POSSIBLE DISTANCE FROM THE FOCAL SPOT TO SKIN IN ORDER TO KEEP THE ABSORBED DOSE AS LOW AS REASONABLY ACHIEVABLE.

2.4 RADIATION PROTECTION

Although this equipment is built to the highest safety standards and incorporates a high degree of protection against X-radiation other than the useful beam, no practical design of equipment can provide complete protection, nor can any practical design compel the operator to take adequate precautions to prevent the possibility of any persons carelessly, unwisely, or unknowingly exposing themselves or others to X-radiation.

IT IS THE RESPONSIBILITY OF THE OPERATOR TO RESTRICT ACCESS TO THE EQUIPMENT IN ACCORDANCE WITH LOCAL REGULATIONS FOR RADIATION PROTECTION.

Because exposure to X-ray radiation can be damaging to the health, use great care to ensure protection against exposure to the primary beam. Some of the effects of X-ray radiation are cumulative and may extend over a period of months or years. The best safety rule for an X-ray operator is *"Avoid exposure to the primary beam at **all times**"*.

Any object in the path of the primary beam produces secondary (scattered) radiation. The intensity of secondary radiation depends on the energy and intensity of the primary beam and the atomic number of the object material struck by the primary beam. Secondary radiation may be of greater intensity than that of the radiation reaching the receptor. Take protective measures to safeguard against it.

An effective protective measure is the use of lead shielding. To minimize dangerous exposure, use such items as lead screens, lead impregnated gloves, aprons, thyroid collars, etc. Lead screens should contain a minimum of
2.0 mm of lead or equivalent and personal protective devices (aprons, gloves, etc.) must contain a minimum of 0.25 mm of lead or equivalent. For confirmation of the local requirements at your site, please refer to your "Local Radiation Protection Rules" as provided by your Radiation Protection Advisor.

Observe the following rules for radiation protection of the personnel in the examination room during X-ray exposures:

- Wear radiation protective clothing.

- Wear a personal dosimeter.

- Use the recommended protective materials and devices against radiation.

- While operating or servicing X-ray equipment, always keep as large a distance as possible from the Focal Spot and X-ray beam, never shorter than 2 meters, protect body and do not expose hands, wrists, arms or other parts of the body to the primary beam.

- Protect the patient against radiation outside the area of interest by using protection accessories.

- Use the smallest X-ray field collimation. Make sure that the area of interest will be completely exposed and the X-ray field does not exceed the area of interest.

- Select a Focal Spot to patient skin distance (SID) as large as possible to keep the absorbed dose for the patient as low as reasonably possible.

The radiation dose decreases or increases according to the Focal Spot to patient skin distance (SID): the greater the SID distance, the lower the radiation dose. The radiation dose is inversely proportional to the distance squared.

- Select as short an examination time as possible. This will reduce total radiation dose considerably.

- Use Grids and Automatic Exposure Control with Ion Chambers whenever possible.

- Place the region of interest as close as possible to the image receptor. This will reduce exposure to radiation and optimize the exposure.

- Be sure that audible and visual communication between the patient and operator is established throughout the entire examination.

2.5 MONITORING OF PERSONNEL

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

The most effective method of determining whether or not the existing protective measures are adequate is the use of instruments to measure the exposure. These measurements should be taken at all locations where the operator, or any portion of the body may be exposed. Exposure must never exceed the accepted tolerable dose.

A frequently used, but less accurate, method of determining the amount of exposure is the placement of film at strategic locations. After a specified period of time, develop the film to determine the amount of radiation.

A common method of determining whether personnel have been exposed to excessive radiation is the use of personal radiation dosimeters. These consist of X-ray sensitive film or thermoluminescent material enclosed within a holder that may be worn on the body. Even though this device only measures the radiation which reaches the area of the body on which they are worn, they do provide a reasonable indication of the amount of radiation received.

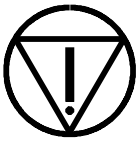
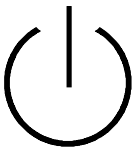
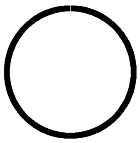
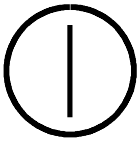
2.6 SAFETY SYMBOLS

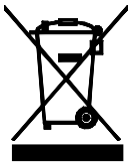
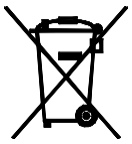
The following safety symbols may appear in the equipment.Their meaning are described below.

	**Caution. Consult accompanying documents.**
	**Safety Symbol. Follow instructions for use, especially thoseinstructions identified with Advisory Symbols to avoid any risk for the Patient or Operator.** *(Only applies to IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012)*
	**Manufacturer.**
	**Date of Manufacture.**
	**Medical Device.**
	**Catalogue Number (Model reference).**
	**Serial Number.**
	**Model Configuration.**
	**Unique Device Identifier.**

	**General Mandatory action.**
	**Type B applied part.**
IPX0	**Protection against harmful ingress of water or particulate matter.IP Classification: Ordinary.**
	**Ionizing radiation.**
	**Non-ionizing electromagnetic radiation.**
	**Radiation of Laser apparatus.** Do not stare into beam. *(Only applicable to equipment with Laser Pointer)*
	**Dangerous voltage.**
	**General warning, caution, risk of danger.**
	**Warning: Ionizing radiation.**

	**Warning: Non-ionizing radiation.**
	**Warning: Laser beam.**
	**Warning: Electricity.**
	**Warning: Do not place fingers between mobile and fixed parts of the equipment, it may cause serious injuries to patient or operator.As well, make sure the patient extremities are correctly positioned into limit areas during operation, movement of parts may cause serious damages to patient.**
	**Electrostatic sensitive devices.**
	**No pushing.**
	**No sitting.**
	**No stepping on surface.**
	**Do not handle.**

	**Emergency stop.**
	**“Stand-by” power.** *(Only applies to IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012)*
	“ON” power.
	**“OFF” power.**
	**“ON” / “OFF” (push-push).** *Each position, “ON” or “OFF”, is a stable position.*
	**Alternating current.**
	**Three-phase alternating current.**
	**Three-phase alternating current with neutral conductor.**
N	**Connection point for the neutral conductor on PermanentlyInstalled equipment.**

	**Direct current.**
	**Both direct and alternating current.**
	**Protective Earth (Ground).**
	**Earth (Ground).**
	**This symbol according to the European Directive indicates that the Waste of Electrical and Electronic Equipment (WEEE) must notbe disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer or an authorized waste management companyfor information concerning the decommissioning of your equipment.**
 **Li/Pb/Cd/Hg**	**This separate collection symbol is affixed to a battery or its packing, to advise that the battery must be recycled or disposed of in accordance with local or country laws. The letters below thesymbol indicate whether certain elements (Li=Lithium, PB=Lead, CD=Cadmium, Hg=Mercury) are contained in the battery. All batteries removed from the equipment must be properly recycled or disposed. Please contact an authorized representative of the manufacturer or an authorized waste management company for information concerning the decommissioning of your equipment.**
	**Pollution Control.** *(Only applicable to People's Republic of China (PRC)).* **This symbol indicates the product contains hazardous materials inexcess of the limits established by the Chinese Standards. It must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer or an authorized waste management company for information concerning the decommissioning of your equipment.**

2.7 REGULATORY INFORMATION

2.7.1 CERTIFICATIONS

The ***Proteus XR/f*** covered by this Operation Manual bears a CE marking in accordance with the provisions of the 93/42/EEC MDD dated June 14, 1993, as amended by 2007/47/EEC dated September 5, 2007, concerning Medical Devices.

Statement of Compliance with IEC 60601-1-3: ***Proteus XR/f*** *with radiation protection in accordance with IEC 60601-1-3:1994, IEC 60601-1-3:2008 and IEC 60601-1-3:2008+AMD1:2013.*

Statement of Compliance with IEC 60601-2-54: ***Proteus XR/f*** *for Radiography and/or Radioscopy in accordance with IEC 60601-2-54:2009 and IEC 60601-2-54:2009+AMD1:2015.*

Statement of Compliance with 21CFR Subchapter J: *This* ***Proteus XR/f*** *conforms to DHHS radiation Standards of 21CFR subchapter J as of the dateof manufacture.*

2.7.2 ENVIRONMENTAL STATEMENT ON THE CYCLE OF THE EQUIPMENT OR SYSTEM

This equipment or system contains environmentally dangerous components and materials (such as PCBs, electronic components, used dielectric oil, lead, batteries etc.) which, once the life-cycle of the equipment or system comes to an end, becomes dangerous and need to be considered as harmful waste according to the international, domestic and local regulations.

The manufacturer recommends to contact an authorized representative of the manufacturer or an authorized waste management company once the life-cycleof the equipment or system comes to an end to remove this equipment or system.

2.7.3 MODE OF OPERATION

- *Continuous operation,* in accordance with Standard IEC 60601-1:2005and IEC 60601-1:2005+AMD1:2012.
- *Continuous operation with intermittent loading,* in accordance with Standard IEC 60601**-** 1:1988.
- *Permanently Installed Equipment.*

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

Protection against electric shock hazards in accordance with Standards: IEC 60601-1:1988, IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012,IEC 60601-2-54:2009 and IEC 60601-2-54:2009+AMD1:2015.

This equipment has been classified as a *type-B (🚹) device,* in accordance with Standard IEC 60601**-** 1 requirements: *Class I* **-** *Type B applied parts.*

TO AVOID THE RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

ACCORDING TO MDD/93/42/EEC AS AMENDED BY 2007/47/EEC, THIS UNIT IS EQUIPPED WITH EMC FILTERS. THE LACK OF PROPER GROUNDING MAY PRODUCE ELECTRICAL SHOCK TO THE USER.

2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

Protection against harmful ingress of water or particulate matter: *Ordinary (IPx0),* in accordance with Standard IEC 60601-1:1988, IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012.

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETICMIXTURES

Degree of Safety in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide: *Not suitable for use in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide*, in accordance with Standard IEC 60601-1:1988, IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012.

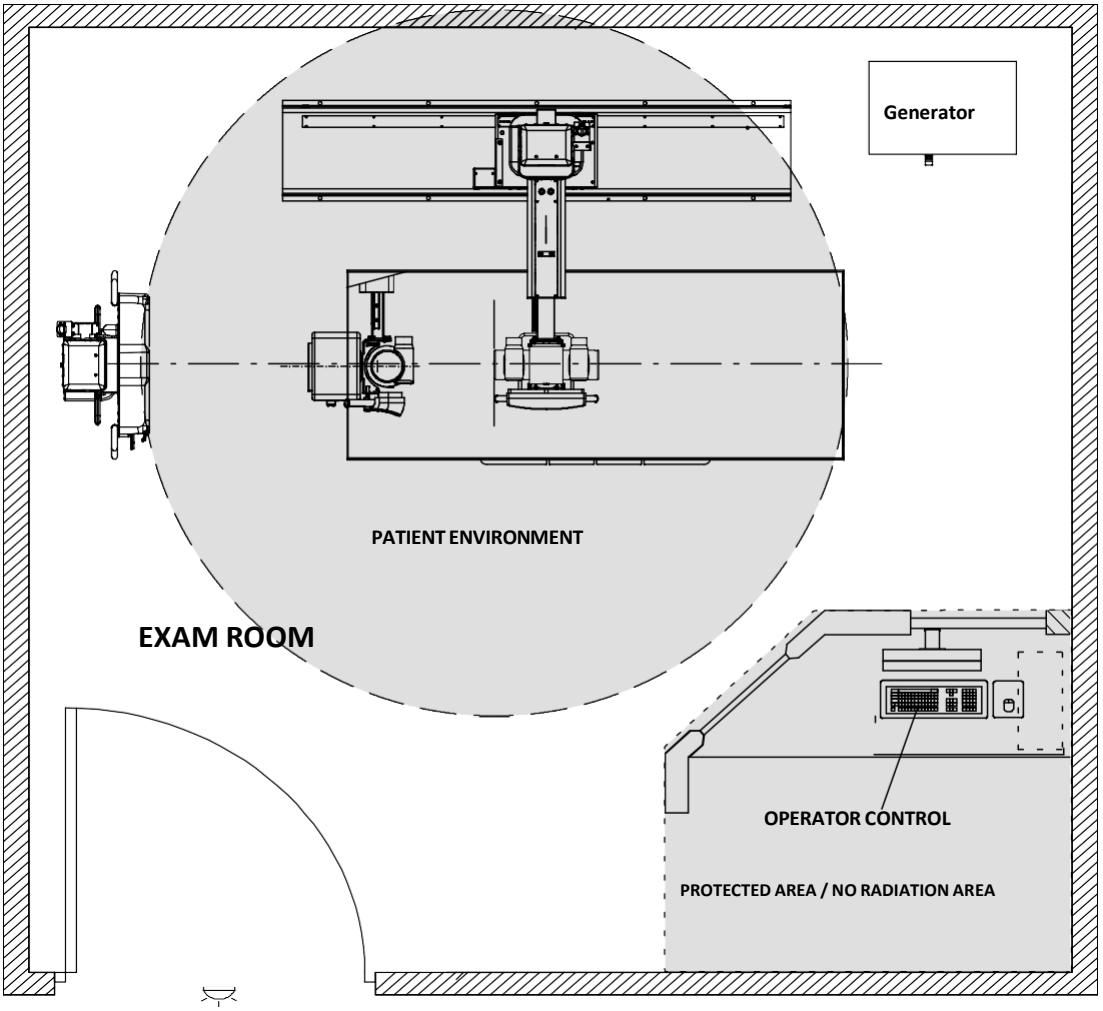
2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Protection against hazards from unwanted or excessive radiation in accordance with Standards IEC 60601-1:1988, IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012, and IEC 60601-1-3:1994, IEC 60601-1-3:2008 and IEC 60601-1-3:2008+AMD1:2013.

2.7.8 DESIGNATED SIGNIFICANT ZONES OF OCCUPANCY

X-ray equipment specified for examinations that do not need the operator or staff to be close to the patient during normal use shall be provided with means to allow the following control functions from a "*Protected Area*" (*refer to illustration below*):

- Selection and control of modes of operation.
- Selection of loading factors for the exposure.
- Actuation of the exposure controls.
- Other necessary controls for the operator during exposure.



X-Ray equipment specified for any radiological examination that requires the operator or staff to be close to the patient during normal use (a.e. some pediatric examinations or other types of examinations for patients that may require assistance), shall have at least one *"Significant Zone of Occupancy"* for the use of the operator and staff, designated as follows:

Illustration 2
Radiographic Examination on the Chest Unit or Front Panel

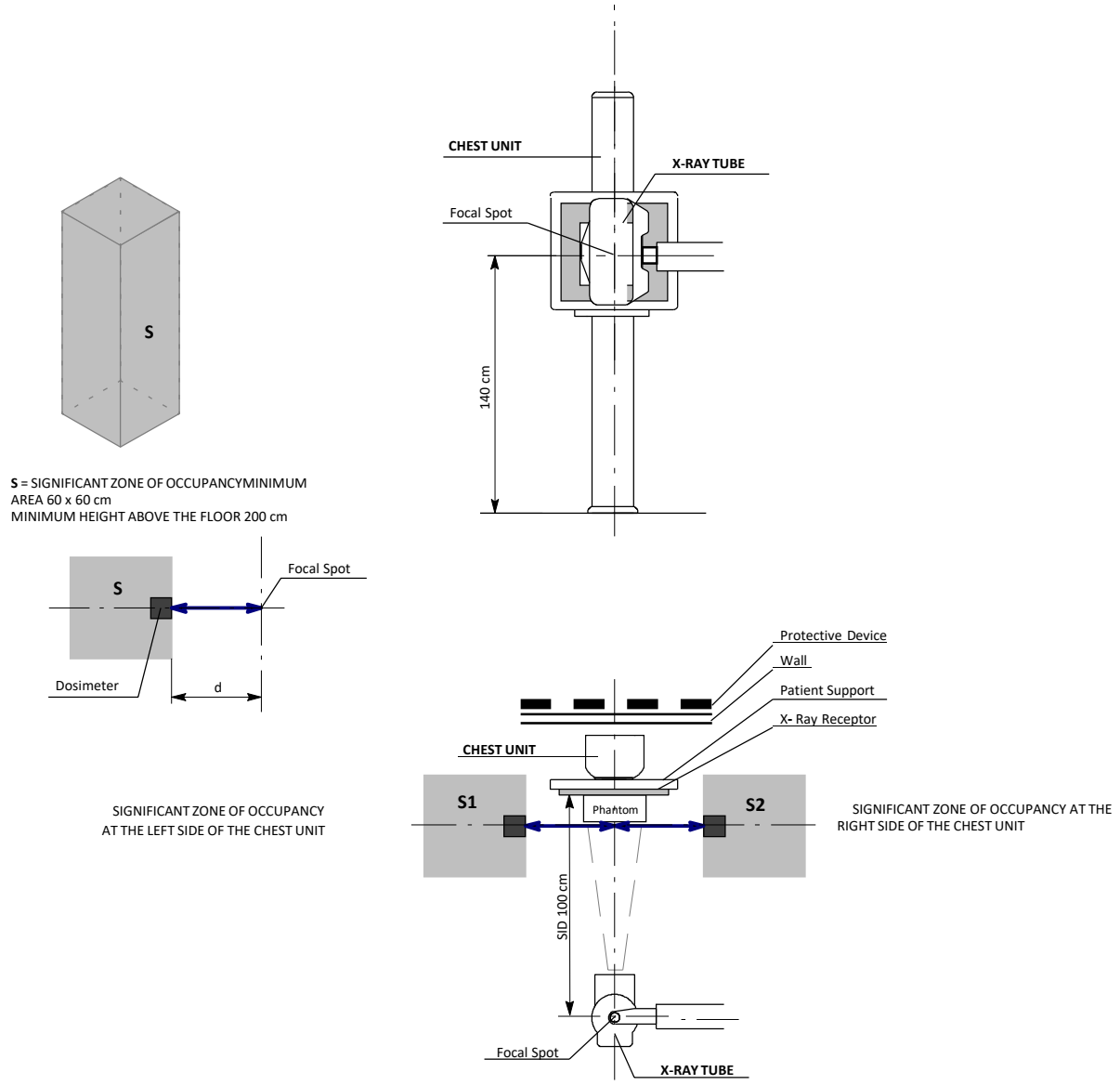
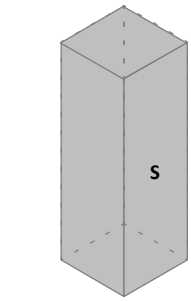
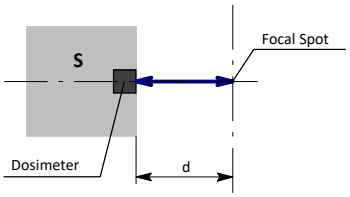
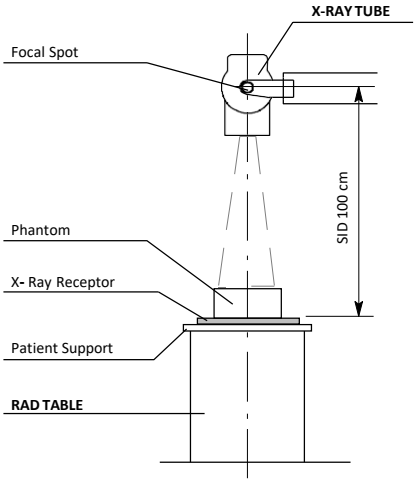


Illustration 3
Radiographic Examination on any Patient Support or any Table

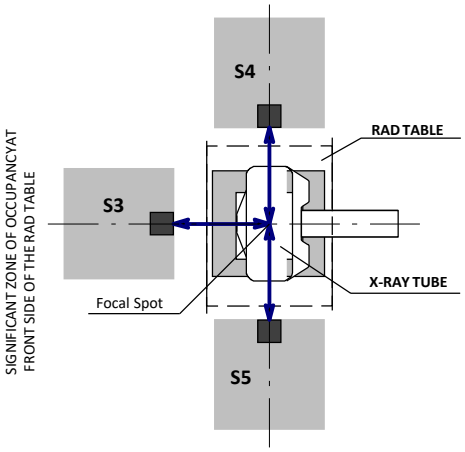


S = SIGNIFICANT ZONE OF OCCUPANCYMINIMUM
AREA 60 x 60 cm
MINIMUM HEIGHT ABOVE THE FLOOR 200 cm





SIGNIFICANT ZONE OF OCCUPANCY AT THE
LEFT SIDE OF THE RAD TABLE(CATHODE)



SIGNIFICANT ZONE OF OCCUPANCY AT THE
RIGHT SIDE OF THE RAD TABLE
(ANODE)

2.7.9 DISTRIBUTION OF STRAY RADIATION

Measurement conditions to determine the distribution of Stray Radiation in the Significant Zone of Occupancy are in accordance with Standard IEC 60601-1-3:1994, IEC 60601-1-3:2008 and IEC 60601-1-3:2008+AMD1:2013.

- Exposure Parameters: RAD mode, 150 kVp, 20 mAs.
- Collimator opening for Field Size 18 x 18 cm, SID 100 cm.
- Phantom: Rectangular water phantom of 25 x 25 x 15 cm, or a materialhaving a similar X-Ray attenuation coefficient.
- Radiation measuring instrument: Low Radiation Dosimeter.

Note . *The results have been obtained with a configuration that is representative of the worst case within the different configurations of the unit.*

Refer to Illustration 2 for Receptor in Vertical position and refer to Illustration 3for Receptor in Horizontal Position.

The following illustrations show the Distribution of Stray Radiation in each examination position.

Illustration 4
Distribution of Stray Radiation with the Receptor in Vertical Position.

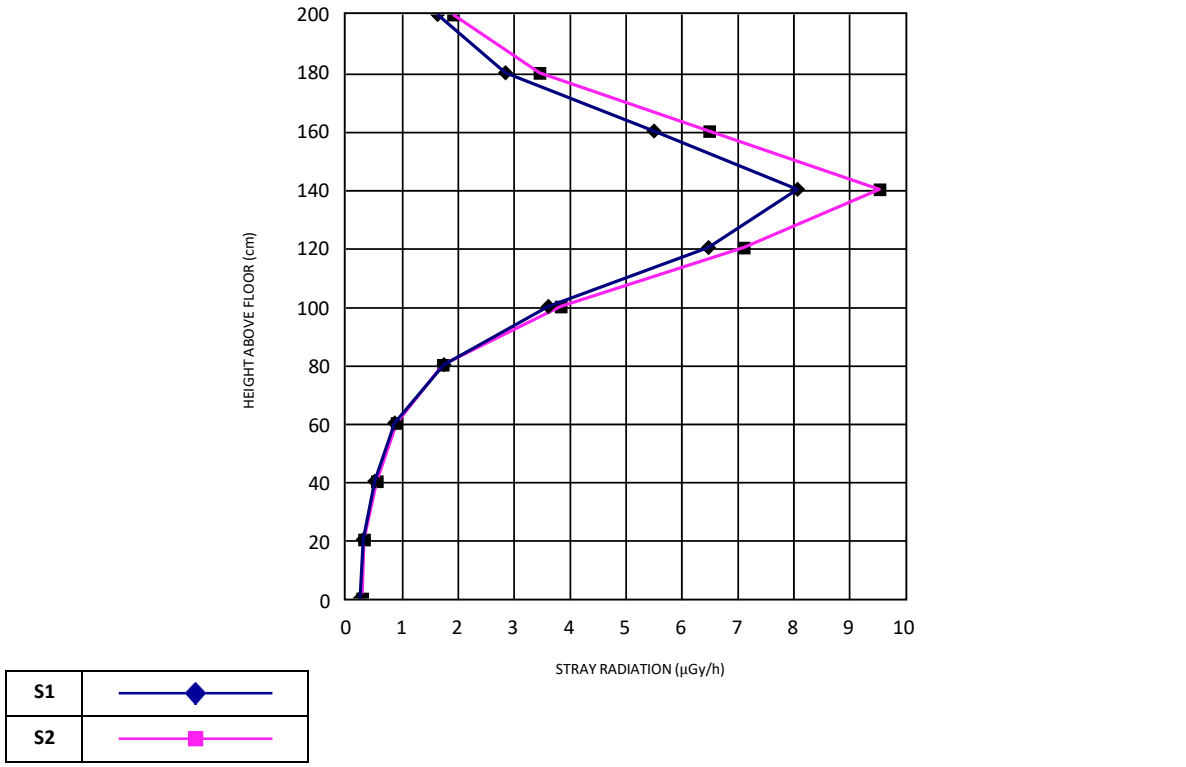
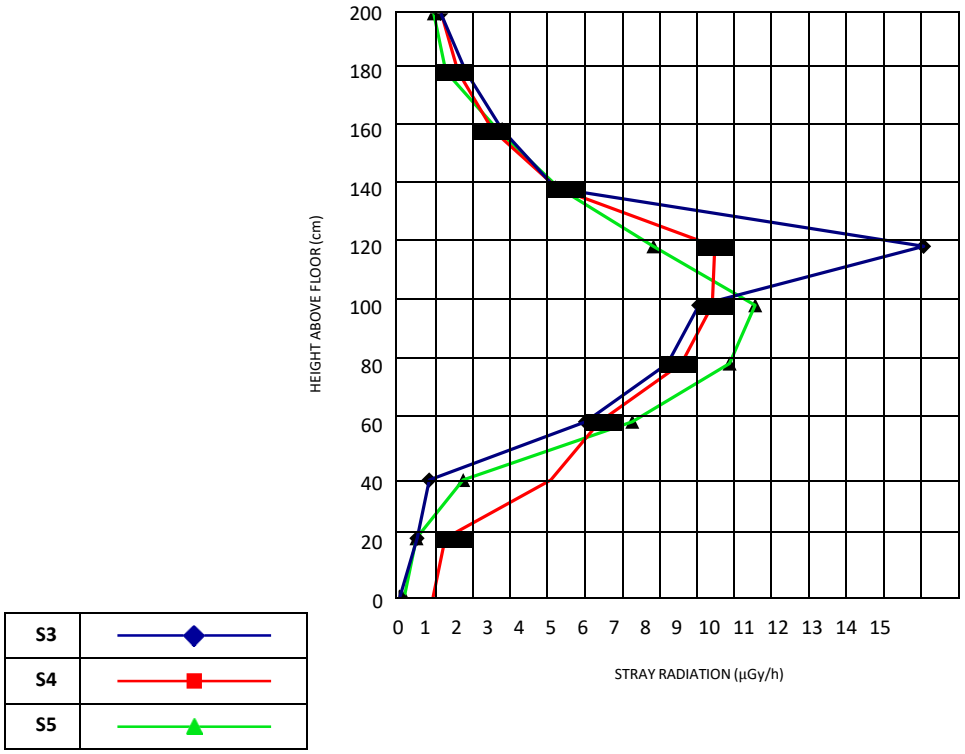
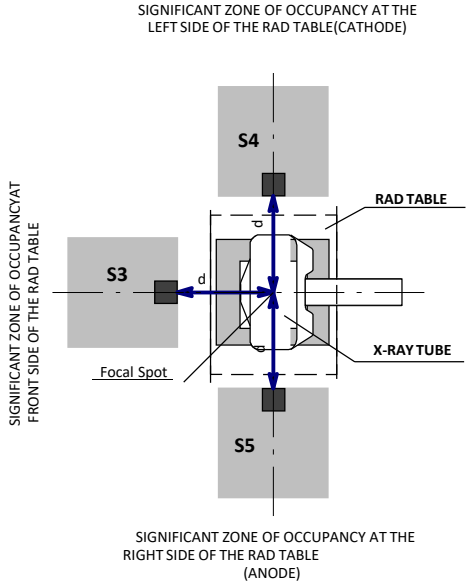


Illustration 5
Distribution of Stray Radiation with the Receptor in Horizontal Position.





2.8 ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment generates, uses, and can radiate radio frequency energy.

The equipment may cause radio frequency interference to other medical or non medical devices and to radio communications.

To provide reasonable protection against such interference, this equipment complies with emissions limits for a Group 1 **-** Class A Medical Devices Directive as stated in IEC 60601-1-2:2007 and IEC 60601-1-2:2014. However,there is no guarantee that interference will not occur in a particular installation.

If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the operator (or qualified service personnel) should attempt to correct the problem by one or more of the following measures:

- reorient or relocate the affected device,
- increase the separation between the equipment and the affected device,
- power the equipment from a source different from that of the affected device,
- consult the service engineers for further suggestions.

To comply with the regulations applicable to an electromagnetic interference for a Group 1 **-** Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the European Union Medical Device Directive and of Federal Communications Commission regulations.

Before using this equipment make sure that all requirements about EMC included in this manual are accomplished.

Should any interference (EMC) be detected with other equipment, please position other equipment away from thisone.

It is customer responsibility to assure that this equipment and vicinity equipment complies the value of radio frequency interferences shown in General Regulation for safety according to IEC 60601-1-2:2007 and IEC 60601-1-2:2014 Tables as described in this section.

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables, accessories and transducers or by unauthorized changes or modifications to this equipment.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS(IEC 60601-1-2:2007 AND IEC 60601-1-2:2014)		
This Radiographic Room is intended for use in the electromagnetic environment specified below. *The customer or the user of this Radiographic Room should assure that it is used in such an environment.*		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This Radiographic *Room* uses RF energy only forits 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	This *Radiographic Room* is suitable for use in all establishments other than domestic and those directly connected to the public low**-** voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissionsIEC 61000-3-3	Complies	
NOTE - In accordance with Standard IEC 61601-1-2:2014, the emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the equipment. (*) Current above 16A		

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY(IEC 60601-1-2:2007)				
The Radiographic Room is intended for use in the electromagnetic environment specified below. The customer or the user of the Radiographic Room should assure that it is used in such an environment.				
Immunity test	**IEC 60601-1-2:2007 Test level**	**Generator Compliance level**	**System Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	¦ 6kV contact ¦ 8kV air	¦ 6kV ¦ 8kV	¦6kV --	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 (*)	¦ 2kV for power supply lines ¦ 1kV for input/output lines	¦ 2kV ¦ 0.5kV	¦ 2kV ¦ 0.5kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000**-** 4**-** 5 (**)	¦ 1kV line(s) to line(s) ¦ 2kV line(s) to earth	¦1kV ¦ 2kV	¦1kV ¦ 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000**-** 4**-** 11	< 5% 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 5s	>95% during 10 ms 60% during 100 ms 30% during 500 ms >95% during 5000 ms	>95% during 10 ms 60% during 100 ms 30% during 500 ms >95% during 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Radiographic Room requires continued operation during power mains interruptions, it is recommended that the X-Ray System is powered from an Uninterruptible Power Supplyor a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000**-** 4**-** 8	3 A/m	3A/m	3A/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.				
*(*) This test has been performed according to the standard IEC 801**-** 4*				
*(**) This test has been performed according to the standard IEC 801**-** 5*				

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY(IEC 60601-1-2:2007)

The Radiographic Room is intended for use in the electromagnetic environment specified below.
The customer or the user of the Radiographic Room should assure that it is used in such an environment.

Immunity test	**IEC 60601-1-2:2007 Test Level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RFIEC 61000**-** 4**-** 6	3Vrms 150kHz to 80MHz	3Vrms 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Radiographic Room, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$, 80 MHz to 800 MHz (Generator) $d = 1.2\sqrt{P}$, 80 MHz to 800 MHz (System) $d = 2.3\sqrt{P}$, 800 MHz to 2.5 GHz (*) where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 'd' is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a]), should be less than the compliance level in each frequency range[b]). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000**-** 4**-** 3	3V/m 80MHz to 2.5GHz	3V/m 1 GHz to 2.5GHz	

NOTE 1 **-** *At 80MHz and 800MHz, the higher frequency range applies.*

NOTE 2 **-** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection fromstructures, objects and people.*

NOTE 3 **-** *In the 3rd equation of the 4th column, the constant parameter has a value of 2.3 for frequencies between 1 GHz and 2.5 GHz.No information is given for frequencies between 80 MHz and 1 GHz.*

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 this Radiographic Room is used exceeds the applicable RF compliance level above, this Radiographic Room should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re**-** orienting or relocating this Radiographic Room.*

b) *Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*
(*) The radiated RF value is defined for a frequency range 1 GHz to 2.5 GHz. There are no values defined for frequencies between 80MHz and1 GHz.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE ANDMOBILE RF COMMUNICATIONS EQUIPMENT AND THE X-RAY SYSTEM(IEC 61601-1-2:2007)

The Radiographic Room is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Thecustomer or the user of this Radiographic Room can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Radiographic Room 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 transmitterm**			
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	**(GENERATOR) 80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**(SYSTEM) 80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	--	0.12	0.23
0.1	0.38	--	0.38	0.73
1	1.2	--	1.2	2.3
10	3.8	--	3.8	7.3
100	12	--	12	23

TYPICAL RF DEVICES (Worst-Case scenario)

Device: Power @ Frequency	**Recommended distance(m)**
GMRS device (Professional Walkie**-** Talkie): 5 W @ 462**-** 467 MHz	2.7
GSM / UMTS cell phone: 2 W @ 850/1700/1900 MHz	3.3
FRS device (Amateur Walkie**-** Talkie): 500 mW @ 462**-** 467 MHz	0.9
WiFi / Bluetooth devices: 100 mW @ 2400**-** 2500 MHz	0.8
DECT devices (modern cordless phones): 100mW @ 1880**-** 1900 MHz	0.8
RFID reader (3): 10 mW @ 125**-** 150 KHz / 13.56 MHz	0.12
RFID reader (3): 10 mW @ 902**-** 928 MHz / 2400**-** 2500 MHz	0.23
Station transmitter ATSC TV broadcasting: 100 kW @ 54**-** 800 MHz	380
Station transmitter ATSC TV broadcasting: 100 kW @ 800**-** 890 MHz	730
Station transmitter FM radio broadcasting: 100 kW @ 87.5**-** 108 MHz	380

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.*

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY(IEC 61601-1-2:2014)			
This Radiographic Room is intended for use in the electromagnetic environment specified below. The customer or Operator of this Radiographic Room should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD)IEC 61000-4-2	¦ 8 kV contact ¦ 2 kV, ¦ 4 kV, ¦ 8 kV, ¦ 15 kV air	¦ 8 kV contact ¦ 2 kV, ¦ 4 kV, ¦ 8 kV, ¦ 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	¦ 2 kV for power supply lines ¦ 1 kV for input/output lines (100 kHz repetition frequency)	¦ 2 kV for power supply lines ¦ 1 kV for input/output lines (100 kHz repetition frequency)	Mains power quality should be thatof a typical commercial or hospital environment.
Surge IEC 61000-4-5	¦ 0.5 kV, ¦ 1 kV line(s) to line(s) ¦ 0.5 kV, ¦ 1 kV, ¦ 2 kVline(s) to earth	¦ 0.5 kV, ¦ 1 kV line(s) to line(s) ¦ 0.5 kV, ¦ 1 kV, ¦ 2 kVline(s) to earth	Mains power quality should be thatof a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T for 0.5 cycle at 0º, 45º, 90º,135º, 180º, 225º, 270º and 315º 0 % U_T for 1 cycleat 0º 70 % U_T for 25/30 cyclesat 0º 0% U_T 250/300 cycles	0% U_T for 0.5 cycle at 0º, 45º, 90º,135º, 180º, 225º, 270º and 315º 0 % U_T for 1 cycleat 0º 70 % U_T for 25/30 cyclesat 0º 0% U_T 250/300 cycles	Mains power quality should be thatof a typical commercial or hospital environment. If the user of the ThisX-ray System requires continued operation during power mains interruptions, it is recommended that this X-ray System is powered from an Uninterruptible Power Supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic ofa 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(IEC 60601-1-2:2014)			
This Radiographic Room is intended for use in an electromagnetic environment specified below. The customer or Operator of this Radiographic Room should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Radiated RF EM fieldsIEC 61000-4-3	3 Vrms from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	3 Vrms from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of theequipment, including cables specified by manufacturer. Otherwise, degradation of theperformance of this equipment could result.
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONSEQUIPMENT"	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONSEQUIPMENT"	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms from 150 kHz to 80 Mhz 6 Vrms in ISM bands from 150 kHz to 80 MHz (80% AM at 1 kHz)	3 Vrms from 150 kHz to 80 Mhz 6 Vrms in ISM bands from 150 kHz to 80 MHz (80% AM at 1 kHz)	
NOTE - The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. *The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz; and 50.0 MHz to 54.0 MHz.*			

IMMUNITY REQUIREMENTS TO RF WIRELESS COMMUNICATIONS EQUIPMENT(IEC 60601-1-2:2014)			
This Radiographic Room is intended for use in an electromagnetic environment specified below. The customer or Operator of this Radiographic Room should assure that it is used in such an environment.			
Band [a] **(MHz)**	**Modulation** [b]	**Distance (m)**	**Immunity Test Level (V/m)**
380 **-** 390	Pulse modulation [b] 18 Hz	0.3	27
430 **-** 470	FM [c] ¦5 kHz deviation1 kHz sine		28
704 **-** 787	Pulse modulation [b] 217Hz		9
800 **-** 960	Pulse modulation [b] 18Hz		28
1700 **-** 1990	Pulse modulation [b] 217Hz		28
2400 **-** 2570	Pulse modulation [b] 217Hz		28
5100 **-** 5800	Pulse modulation [b] 217Hz		9

[a] *For some services, only the uplink frequencies are included.*

[b] *The carrier shall be modulated using a 50 % duty cycle square wave signal.*

[c] *As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.*

2.9 QUANTITATIVE INFORMATION

Note . *The following tables show the Quantitative Information associated to this equipment according to the Standard IEC 60601-1-3:2008 and IEC 60601-1-3:2008+AMD1:2013. These tables illustrate loading factors for image performance and supply Dose indication examples. Therefore, they are an example of the adjustment of Loading Factors, Focal Spot Selection, SID and Collimator opening, which affect to the radiation quality or to the radiation dose rate applied in normal use.*

2.9.1 FUNCTIONAL TESTS PERFORMED TO OBTAIN THE QUANTITATIVE INFORMATION

Equipment:

- Rad Positioner with Ralco Collimator.

Instrumentation used:

- Dosimeter: Vacuda
- Dosimeter: Unfors
- Rectangular Phantom made of Polymethyl-methacrylate (PMMA) layers: 25 cm x 25 cm x 20 cm.

Test Details:

- Minimum SID distance: 100 cm.
- Maximum SID distance: 180 cm.
- Open Collimator size: 13 cm x 13 cm (min.), 43 cm x 43 cm (max.)
- The measurements were made with the exposure parameters shown onthe results table:
- KVp Range: 40 KVp, 60 KVp, 80 KVp, 100 KVp, 125 KVp
- mAs Range: 1 mAs, 2 mAs, 10 mAs, 50 mAs, 100 mAs
- Performed measurements of Air Kerma or Air Kerma Rate at thefollowing designated positions:
  - Distance SID doses
  - Patient (Phantom) Entrance doses and Entrance doses Rate
  - Patient (Phantom) Output doses and Output doses Rate
  - Collimator Output doses

Quantitative Information													
Loading Factors				**Parameter Selection**			**Filtrat.**	**Measured Doses**					
KVp	**mA**	**Time (s)**	**mAs**	**Focal Spot Selection**	**SID** Source-Image Distance **(cm)**	**Collimator blades opening (cm)**	**HVL (min. value allowed) (mmAl)**	**Collimator Output Dose (µGy*m2)**	**SID Dose(mGy)**	**Phantom Input Dose (mGy)**	**Phantom Input Dose Rate (Gy/h)**	**Phantom Output Dose Rate (mGy/h)**	**Phantom Output Dose (µGy)**
40	**160**	**0.012**	**2**	**Small**	**100**	**13x13**	**1.6**	0.2	0.016	0.025	7.479	10.795	0.036
	100	**0.1**	**10**	**Small**				1.1	0.087	0.136	4.906	7.682	0.213
	200	**0.5**	**100**	**Large**				11	0.836	1.307	9.407	14.125	1.962
	400	**1**	**400**	**Large**				40	3.073	4.802	17.286	23.863	6.629
	160	**0.012**	**2**	**Small**		**43x43**		2.1	0.016	0.025	7.615	18.691	0.062
	100	**0.1**	**10**	**Small**				11.8	0.090	0.140	5.038	13.354	0.371
	200	**0.5**	**100**	**Large**				107.1	0.862	1.347	9.698	23.798	3.305
	400	**1**	**400**	**Large**				391.3	3.166	4.947	17.809	41.228	11.452
	160	**0.012**	**2**	**Small**	**180**	**13x13**		0.2	0.005	0.006	1.865	4.273	0.014
	100	**0.1**	**10**	**Small**				1.1	0.027	0.034	1.214	3.453	0.096
	200	**0.5**	**100**	**Large**				11	0.257	0.325	2.343	5.985	0.831
	400	**1**	**400**	**Large**				40	0.940	1.190	4.283	11.723	3.257
	160	**0.012**	**2**	**Small**		**43x43**		2.1	0.005	0.007	1.962	6.243	0.021
	100	**0.1**	**10**	**Small**				11.8	0.028	0.035	1.269	4.420	0.123
	200	**0.5**	**100**	**Large**				107.1	0.267	0.338	2.432	7.400	1.028
	400	**1**	**400**	**Large**				391.3	0.979	1.239	4.461	12.763	3.545

Note **.** *Combined standard uncertainty is ±35% (IEC 60580 : 2000 / IEC 60601-2-54:2009 and IEC 60601-2-54: 2009+ AMD1:2015).*

Quantitative Information													
Loading Factors				Parameter Selection			Filtrat.	Measured Doses					
KVp	mA	Time (s)	mAs	Focal Spot Selection	SID Source-Image Distance (cm)	Collimator blades opening (cm)	HVL (min. value allowed) (mmAl)	Collimator Output Dose (µGy*m2)	SID Dose(mGy)	Phantom Input Dose (mGy)	Phantom Input Dose Rate (Gy/h)	Phantom Output Dose Rate (mGy/h)	Phantom Output Dose (µGy)
60	160	0.012	2	Small	100	13x13	2.2	0.6	0.046	0.072	21.746	113.713	0.379
	100	0.1	10	Small				3.9	0.252	0.394	14.195	79.388	2.205
	200	0.5	100	Large				39.4	2.587	4.042	29.103	157.649	21.896
	400	1	400	Large				191.4	10.009	15.639	56.299	295.137	81.983
	160	0.012	2	Small		43x43		7.5	0.048	0.074	22.299	233.322	0.778
	100	0.1	10	Small				40.6	0.265	0.414	14.894	161.562	4.488
	200	0.5	100	Large				389.3	2.691	4.205	30.277	320.682	44.539
	400	1	400	Large				1491.3	10.435	16.304	58.696	596.348	165.652
	160	0.012	2	Small	180	13x13		0.6	0.014	0.018	5.345	53.374	0.178
	100	0.1	10	Small				3.9	0.078	0.098	3.538	36.438	1.012
	200	0.5	100	Large				39.4	0.796	1.007	7.251	72.125	10.017
	400	1	400	Large				191.4	3.078	3.896	14.025	145.377	40.383
	160	0.012	2	Small		43x43		7.5	0.015	0.019	5.677	71.217	0.237
	100	0.1	10	Small				40.6	0.082	0.103	3.717	48.584	1.350
	200	0.5	100	Large				389.3	0.832	1.053	7.582	96.355	13.383
	400	1	400	Large				1491.4	3.219	4.074	14.667	179.186	49.774

Note **.** *Combined standard uncertainty is ±35% (IEC 60580 : 2000 / IEC 60601-2-54:2009 and IEC 60601-2-54: 2009+ AMD1:2015).*

Quantitative Information													
Loading Factors				**Parameter Selection**			**Filtrat.**	**Measured Doses**					
KVp	**mA**	**Time (s)**	**mAs**	**Focal Spot Selection**	**SID** Source-Image Distance **(cm)**	**Collimator blades opening (cm)**	**HVL (min. value allowed) (mmAl)**	**Collimator Output Dose (µGy*m2)**	**SID Dose(mGy)**	**Phantom Input Dose (mGy)**	**Phantom Input Dose Rate (Gy/h)**	**Phantom Output Dose Rate (mGy/h)**	**Phantom Output Dose (µGy)**
80	**160**	**0.012**	**2**	**Small**	**100**	**13x13**	**2.9**	1.4	0.087	0.136	40.753	378.000	1.260
	100	**0.1**	**10**	**Small**				7.4	0.461	0.702	25.909	256.070	7.113
	200	**0.5**	**100**	**Large**				74.5	4.674	7.303	52.582	511.763	71.078
	400	**1**	**400**	**Large**				366.7	18.374	28.709	103.353	982.017	272.783
	160	**0.012**	**2**	**Small**		**43x43**		14.3	0.090	0.141	42.391	829.043	2.763
	100	**0.1**	**10**	**Small**				77	0.483	0.754	27.162	553.148	15.365
	200	**0.5**	**100**	**Large**				735.9	4.884	7.632	54.949	1099.409	152.696
	400	**1**	**400**	**Large**				2856.2	19.209	30.014	108.049	2111.165	586.435
	160	**0.012**	**2**	**Small**	**180**	**13x13**		1.4	0.026	0.033	9.931	181.096	0.604
	100	**0.1**	**10**	**Small**				7.2	0.142	0.179	6.462	120.177	3.338
	200	**0.5**	**100**	**Large**				74.5	1.449	1.834	13.201	239.228	33.226
	400	**1**	**400**	**Large**				366.7	5.703	7.218	25.986	480.835	133.565
	160	**0.012**	**2**	**Small**		**43x43**		14.3	0.027	0.035	10.419	249.574	0.832
	100	**0.1**	**10**	**Small**				77	0.149	0.189	6.799	162.094	4.503
	200	**0.5**	**100**	**Large**				735.9	1.520	1.924	13.851	328.883	45.678
	400	**1**	**400**	**Large**				2856.2	5.988	7.578	27.282	632.661	175.739

Note **.** *Combined standard uncertainty is ±35% (IEC 60580 : 2000 / IEC 60601-2-54:2009 and IEC 60601-2-54: 2009+ AMD1:2015).*

Quantitative Information													
Loading Factors				Parameter Selection			Filtrat.	Measured Doses					
KVp	mA	Time (s)	mAs	Focal Spot Selection	SID Source-Image Distance (cm)	Collimator blades opening (cm)	HVL (min. value allowed) (mmAl)	Collimator Output Dose (µGy*m2)	SID Dose(mGy)	Phantom Input Dose (mGy)	Phantom Input Dose Rate (Gy/h)	Phantom Output Dose Rate (mGy/h)	Phantom Output Dose (µGy)
100	160	0.012	2	Small	100	13x13	3.6	2.1	0.131	0.205	61.550	854.348	2.848
	100	0.1	10	Large				11.2	0.698	1.091	39.282	562.852	15.635
	200	0.5	100	Large				113	7.136	11.149	80.276	1132.591	157.304
	400	1	400	Large				448.9	28.400	44.375	127.800	1784.097	619.478
	160	0.012	2	Small		43x43		21	0.137	0.215	64.362	1829.478	6.098
	100	0.1	10	Large				114.8	0.735	0.140	41.371	1221.809	33.939
	200	0.5	100	Large				1067.6	7.491	1.347	84.277	2346.574	325.913
	400	1	400	Large				4373	29.791	4.947	134.061	3901.774	1354.78
	160	0.012	2	Small	180	13x13		2.1	0.040	0.006	15.334	396.261	1.321
	100	0.1	10	Large				11.2	0.217	0.034	9.877	263.614	7.323
	200	0.5	100	Large				113	2.224	0.325	20.269	536.807	74.557
	400	1	400	Large				448.9	8.878	1.190	32.361	861.997	299.304
	160	0.012	2	Small		43x43		21	0.043	0.007	16.187	555.391	1.851
	100	0.1	10	Large				114.8	0.228	0.035	10.404	363.757	10.104
	200	0.5	100	Large				1067.6	2.334	0.338	21.268	743.791	103.304
	400	1	400	Large				4373	9.313	1.239	33.946	1173.788	407.565

Note **.** *Combined standard uncertainty is ±35% (IEC 60580 : 2000 / IEC 60601-2-54:2009 and IEC 60601-2-54: 2009+ AMD1:2015).*

Quantitative Information													
Loading Factors				Parameter Selection			Filtrat.	Measured Doses					
KVp	mA	Time (s)	mAs	Focal Spot Selection	SID Source-Image Distance (cm)	Collimator blades opening (cm)	HVL (min. value allowed) (mmAl)	Collimator Output Dose (µGy*m2)	SID Dose(mGy)	Phantom Input Dose (mGy)	Phantom Input Dose Rate (Gy/h)	Phantom Output Dose Rate (mGy/h)	Phantom Output Dose (µGy)
125	160	0.012	2	Small	100	13x13	4.5	2.9	0.194	0.303	90.897	1611.652	5.372
	100	0.1	10	Large				19.1	1.037	1.620	58.304	7.682	0.213
	200	0.5	100	Large				164.1	10.722	16.753	120.620	2195.061	304.870
	400	1	400	Large				823.7	43.078	67.310	121.158	2211.652	1228.696
	160	0.012	2	Small		43x43		29.7	0.204	0.319	95.666	3558.261	11.861
	100	0.1	10	Large				163.4	1.090	1.704	61.337	2407.617	66.878
	200	0.5	100	Large				1595.2	11.243	17.568	126.489	4963.617	689.391
	400	1	400	Large				5679.6	45.270	70.734	127.321	4418.609	2454.783
	160	0.012	2	Small	180	13x13		2.9	0.058	0.073	21.923	776.609	2.589
	100	0.1	10	Large				19.1	0.317	0.401	14.449	520.278	14.452
	200	0.5	100	Large				164.1	3.349	4.238	30.515	1068.730	148.435
	400	1	400	Large				823.7	13.470	17.047	30.685	1072.487	595.826
	160	0.012	2	Small		43x43		29.7	0.062	0.078	23.395	1085.478	3.618
	100	0.1	10	Large				163.4	0.338	0.428	15.416	728.765	20.243
	200	0.5	100	Large				1595.2	3.523	4.459	32.108	1509.496	209.652
	400	1	400	Large				5679.6	14.191	17.961	32.330	1515.913	842.174

Note **.** *Combined standard uncertainty is ±35% (IEC 60580 : 2000 / IEC 60601-2-54:2009 and IEC 60601-2-54: 2009+ AMD1:2015).*

Quantitative Information													
Loading Factors				Parameter Selection			Filtrat.	Measured Doses					
KVp	mA	Time (s)	mAs	Focal Spot Selection	SID Source-Image Distance (cm)	Collimator blades opening (cm)	HVL (min. value allowed) (mmAl)	Collimator Output Dose (µGy*m2)	SID Dose(mGy)	Phantom Input Dose (mGy)	Phantom Input Dose Rate (Gy/h)	Phantom Output Dose Rate (mGy/h)	Phantom Output Dose (µGy)
150	160	0.012	2	Small	100	13x13	5.4	3.8	0.253	0.395	118.573	2493.391	8.311
	100	0.1	10	Large				24.4	1.375	2.148	77.331	1679.791	46.661
	200	0.5	100	Large				239.3	14.530	22.704	163.467	3508.591	487.304
	400	1	400	Large				882.9	59.548	93.043	133.983	2882.504	2001.739
	160	0.012	2	Small		43x43		38.5	0.262	0.409	122.731	5744.348	19.148
	100	0.1	10	Large				210.7	1.444	2.257	81.244	3862.957	107.304
	200	0.5	100	Large				2124.2	15.252	23.832	171.587	8057.739	1119.130
	400	1	400	Large				8581.3	62.748	98.043	141.183	6629.009	4603.478
	160	0.012	2	Small	180	13x13		3.8	0.077	0.098	29.337	1208.087	4.027
	100	0.1	10	Large				24.4	0.426	0.539	19.410	819.235	22.757
	200	0.5	100	Large				239.3	4.548	5.756	41.442	1714.226	238.087
	400	1	400	Large				882.9	18.687	23.651	34.057	1409.948	979.130
	160	0.012	2	Small		43x43		38.5	0.080	0.102	30.467	1700.870	5.670
	100	0.1	10	Large				210.7	0.453	0.573	20.646	1152.939	32.026
	200	0.5	100	Large				2124.2	4.803	6.078	43.764	2436.730	338.435
	400	1	400	Large				8581.3	19.748	24.993	35.990	2005.983	1393.043

Note **.** *Combined standard uncertainty is ±35% (IEC 60580 : 2000 / IEC 60601-2-54:2009 and IEC 60601-2-54: 2009+ AMD1:2015).*

2.10 DETERMINISTIC EFFECTS

Deterministic effects may occur when the Radiation dose to a certain organ or tissue exceeds a specific threshold. Particular organs or tissues of such concern in diagnostic Radiology are the skin and the eye lens. The numerical value of the threshold dose is in the range between 1 Gy and 3 Gy.

As shown in the Quantitative Information Tables, the radiation dose effects measured in this equipment are below the threshold in which the severity of certain effects would take place on human skin or eyes lens.

This mentioned threshold was established by the International Commission on Radiological Protection (IRCP Publication No 60).

Quantitative Information tables (*Refer to Section 2.9*) illustrate examples of available loading factors for image performance and supply Dose indication, which affect to the radiation quality or to the radiation dose rate applied in normal use.

As indicated in the Quantitative Information Tables, the number of exposures needed to reach the previously described maximum radiation values will depend on the selected techniques for each radiographic study.

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SECTION 3 START UP AND SHUTDOWN

3.1 START UP

The System should be powered by the same Room Electrical Cabinet where the X-ray Generator is connected, that is, the whole System will be powered from the same ON/OFF Main Breaker in the Room Electrical Cabinet.

To turn the System ON:

1. Turn ON the Main Breaker of the Room Electrical Cabinet. The Emergency OFF Switch must not be activated in the Room Electrical Cabinet.

IN THE EVENT OF AN EMERGENCY FORCIBLY DEPRESS THE X-RAY ROOM "EMERGENCY OFF SWITCH" (USUALLY A RED MUSHROOM-SHAPED SWITCH).

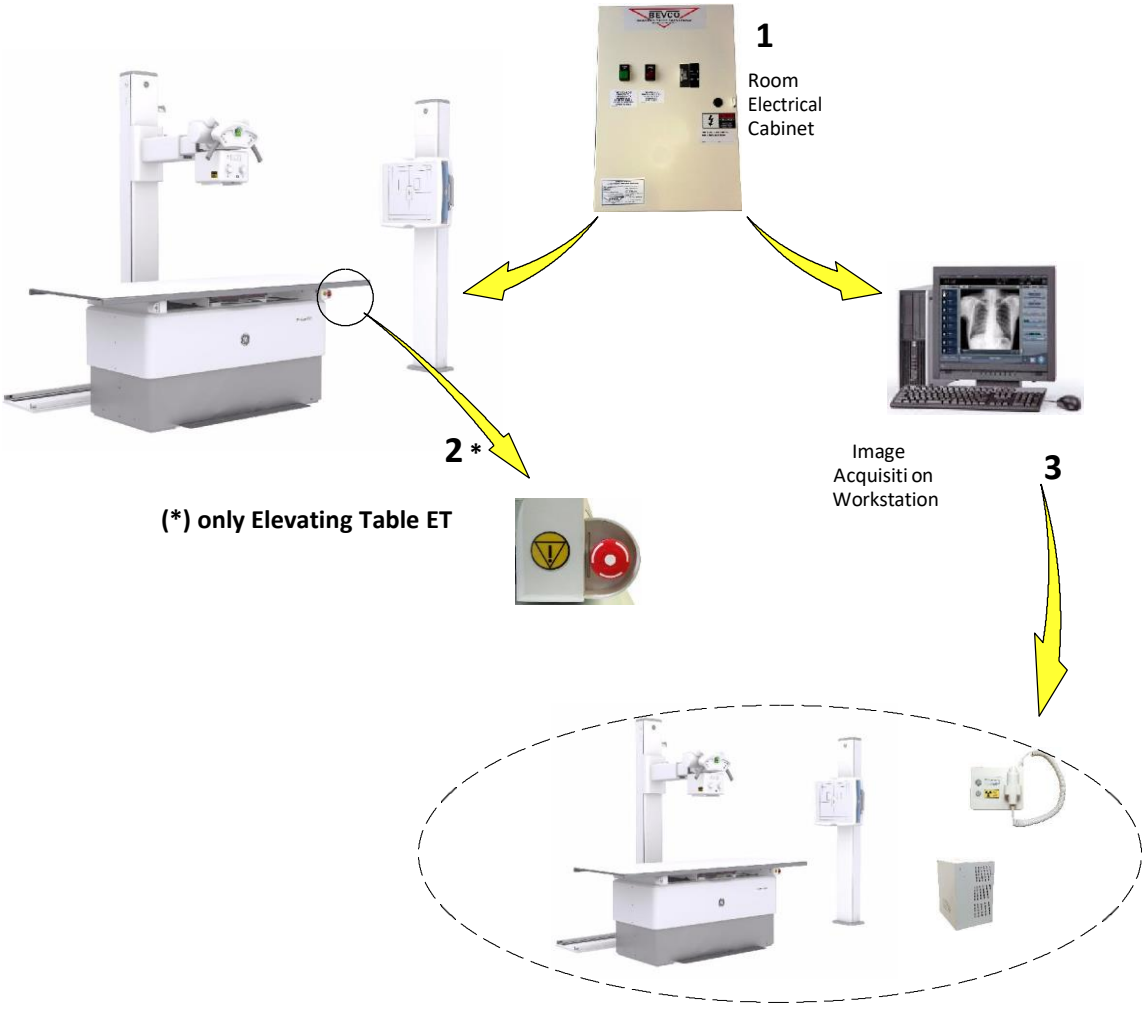
THIS SWITCH SHOULD BE LOCATED ON OR NEAR THE X-RAY ROOM ELECTRICAL CABINET, USUALLY PLACED NEAR THE GENERATOR CONTROL CONSOLE. MORE THAN ONE OF THESE SWITCHES MAY BE PLACED AROUND THEROOM FOR GREATER ACCESSIBILITY.

TO ISOLATE THE EQUIPMENT FROM MAINS, TURN OFF THE SWITCH LOCATED AT THE ROOM ELECTRICAL CABINET.

2. In the case of the Elevating Table, check that the Emergency OFF Switch (E-stop button) of the Table to allow operation of the Table, Tube Stand and Wall Stand.

3. Turn ON the Workstation. This action automatically starts the X-Ray Generator, Table, Wall Stand and Tube Stand.

Illustration 6
Start-up sequence



3.2 SHUTDOWN ROUTINE

To turn the System OFF (Proteus XR/f ET, ST or Single Panel):

1. Turn OFF the Image Acquisition Workstation. This action turns OFF the Workstation and then the Generator, Positioners and Floor Mounted Tube Stand.

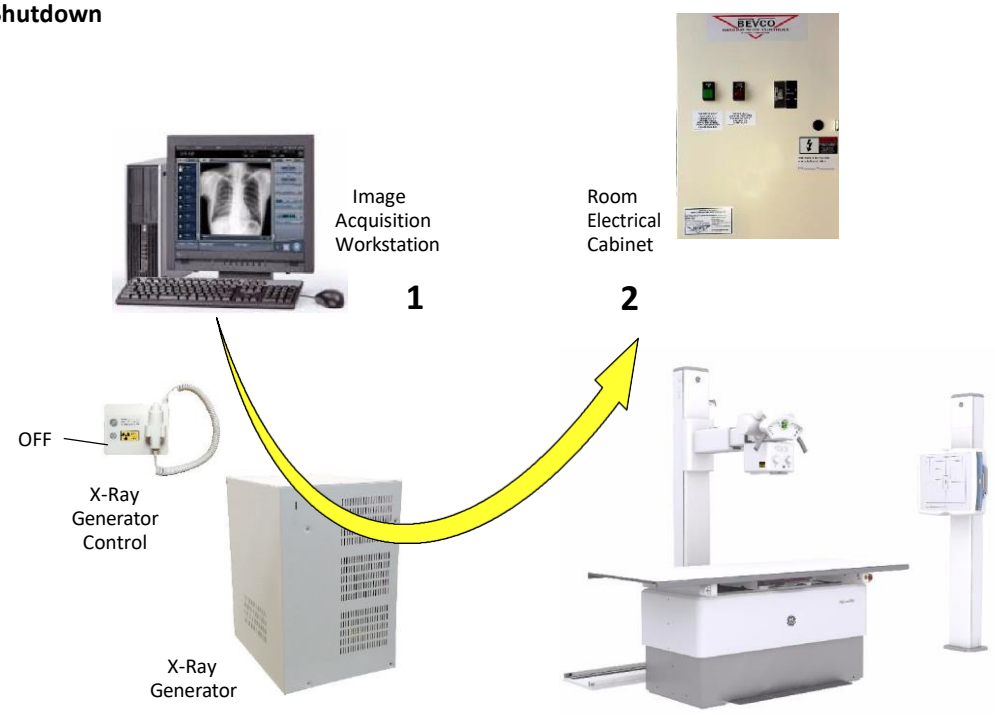
   Independently to the Image Acquisition Workstation, the Generator can be turned OFF by pressing the OFF button of the X-Ray Generator Control (PC Interface Box), the Green Lamp turns OFF.

   In the case of the Elevating Table, the Table, Tube Stand and Wall Stand can be turned off by pressing the Emergency OFF Switch (E**-** stop button) of the Table.

Note **.** *It is not necessary to turn OFF the Emergency Off Switch of the Table before turning off the Main Breaker of the Room ElectricalCabinet.*

2. Turn OFF the Main Breaker of the Room Electrical Cabinet.

Illustration 7 Shutdown sequence



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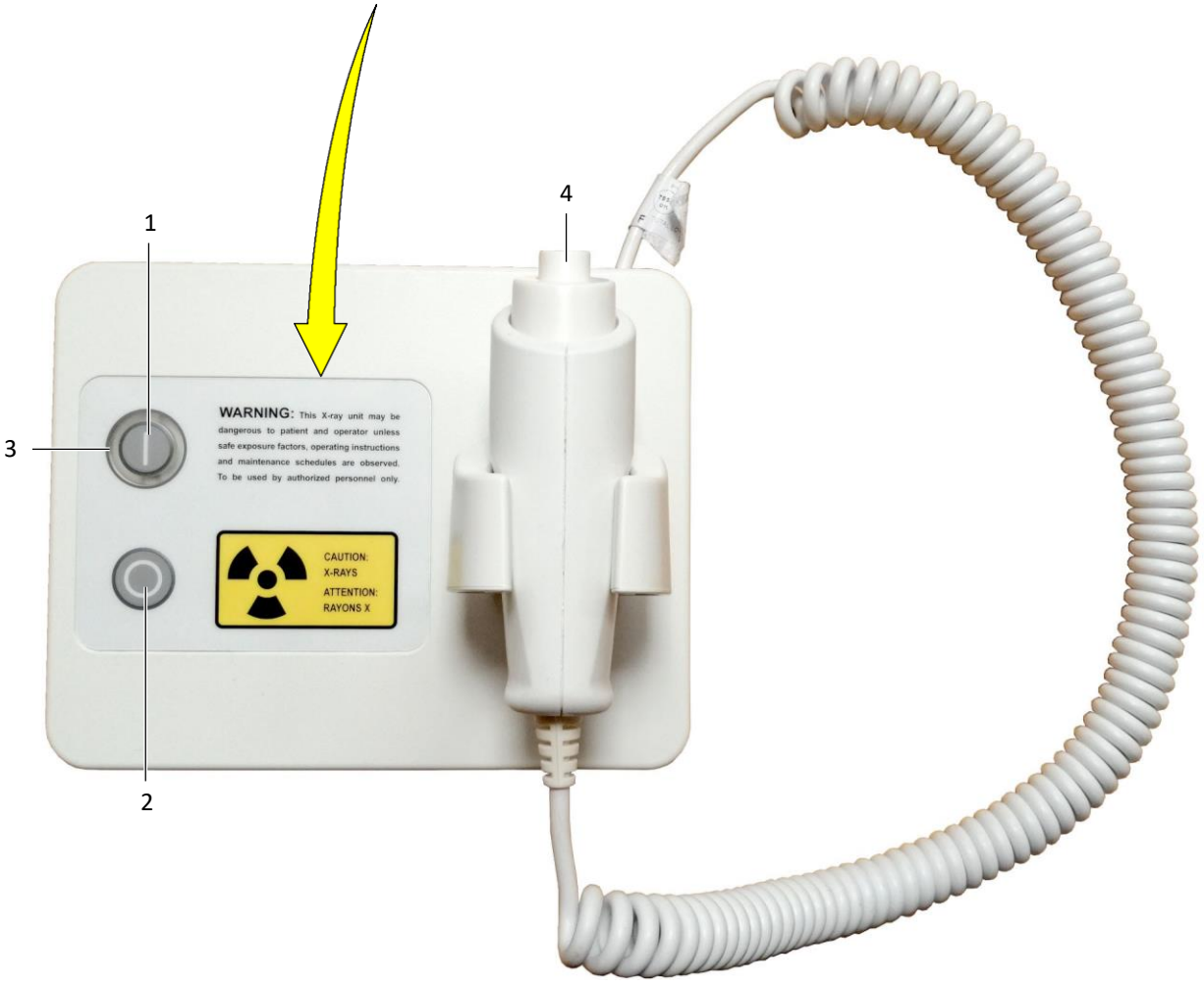
SECTION 4 X-RAY GENERATOR CONTROL

The Generator parameters are controlled through the Console of the Image Acquisition Workstation. The Generator is equipped with a PC Interface Box that comprises the following controls:

1. Generator Power ON.
2. Generator Power OFF.
3. "*Generator Power ON*" Indicator, it lights when the Generator is ON.
4. Handswitch, with the controls for radiographic "*Preparation*" and "*Exposure*".

WARNING

THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS, OPERATING INSTRUCTIONS AND MAINTENANCE SCHEDULES ARE OBSERVED. TO BE USED BY AUTHORIZED PERSONNEL ONLY.



4.1 POWER ON / OFF

ON: The Generator is turned ON by pressing this push-button (Pilot light is ON).

OFF: The Generator is turned OFF by pressing this push-button.

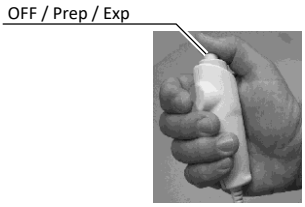
If the X-ray Tube is rotating when pressing the "*OFF*" push-button, the Generator will stop the anode immediately and then the unit will be turned off (approx. 5 seconds). The equipment only turns off if "*Preparation*" is not activated.

IN THE EVENT OF AN EMERGENCY FORCIBLY DEPRESS THE X-RAY ROOM "EMERGENCY OFF SWITCH" (USUALLY A RED MUSHROOM-SHAPED SWITCH).

THIS SWITCH SHOULD BE LOCATED ON OR NEAR THE X-RAY ROOM ELECTRICAL CABINET, USUALLY PLACED NEAR THE GENERATOR CONTROL CONSOLE. MORE THAN ONE OF THESE SWITCHES MAY BE PLACED AROUND THEROOM FOR GREATER ACCESSIBILITY.

TO ISOLATE THE EQUIPMENT FROM MAINS, TURN OFF THE SWITCH LOCATED AT THE ROOM ELECTRICAL CABINET.

4.2 EXPOSURE CONTROLS



Radiographic exposures from are made with the "*Prep*" (preparation) and"*Expose*" buttons on the Handswitch.

The X-ray Handswitch button has three positions: "*Off*", "*Preparation*", and *"X-ray Exposure"*.

Press the handswitch half-way for *"Prep"* and fully for *"Exp"*.

PREP: Press the handswitch half-way (*"Prep"* position) to prepare the selected X-ray tube for exposure. The *"Ready"* indicator on the Console will light when the X-ray tube is prepared and there are no interlock failure or system faults.

After pressing this push-button, the following functions are activated:

- Anode rotation.
- Filament current switches from stand-by to the selected mA.

Note .

Press "Prep" only when the technique is selected on the Console and the Patient is ready for the exposure. The Generator can be configured so that the anode remains running for the time established during installation when "Prep" is pressed a predetermined number of times in less than a minute.

EXP: After the "*Ready*" indicator is illuminated on the Control Console,fully press the handswitch to start a X-ray exposure. If the button is released before the Generator completes the selected time or the AEC time, the exposure will be prematurely terminated and the actual mAs and Exposure Time will be displayed.

The "*X-ray On*" indicator remains illuminated on the Control Console during the length of exposure.

READY: Indicates that the technique selected is properly set, there are no interlock failures or system faults, the anode is rotating and the X-ray Tube is ready for exposure. The "*Ready*" indicator should be shown on the Control Console.

X-RAY ON: Indicates that the X-ray exposure is in progress. At the same time that radiographic exposures are being made, an audible signal sounds. The "*X-ray On*" indicator should be shown on the Control Console.

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SECTION 5 OPERATION

Illustration 8
Proteus XR/f ET Positioners

Illustration 9
Proteus XR/f ST Positioners

USE THE EQUIPMENT HAND-GRIPS TO CONTROL AND DRIVE MANUAL MOVEMENTS, NEVER PUSH DIRECTLY ON THE RECEPTOR, X-RAY TUBE OR COLLIMATOR.

MONITOR THE SYSTEM MOVEMENTS WITH SPECIAL CARE. AVOID ANY IMPACT OF THE SYSTEM ON FLOOR, CEILING OR OTHER ELEMENTS IN THE ROOM. IT MAY CAUSE SERIOUS DAMAGE TO THE EQUIPMENT.

DO NOT CONNECT ITEMS NOT SPECIFIED AS PART OF THE SYSTEM OR BEEN SPECIFIED AS BEING COMPATIBLEWITH THE SYSTEM.

MONITOR WITH SPECIAL CARE THE PATIENT POSITION (HANDS, FEET, FINGERS, ETC.) AND USE THE PATIENT HAND-GRIPS TO AVOID INJURY TO PATIENT CAUSED BY TABLE-TOP MOVEMENTS. PATIENT HANDS MUST BE KEPT AWAY FROM MOBILE COMPONENTS OF THE UNIT.

OPERATOR SHOULD NEVER MOVE TABLE-TOP FROM LATERAL SIDE (PATIENT HEAD OR FEET). IT MAY CAUSE FINGERPINCH UNDER THE TABLE-TOP.

INTRAVENOUS TUBING, CATHETERS AND OTHER PATIENT CONNECTED LINES SHOULD BE ROUTED AWAY FROM MOVING EQUIPMENT.

5.1 FLOOR MOUNTED TUBE STAND

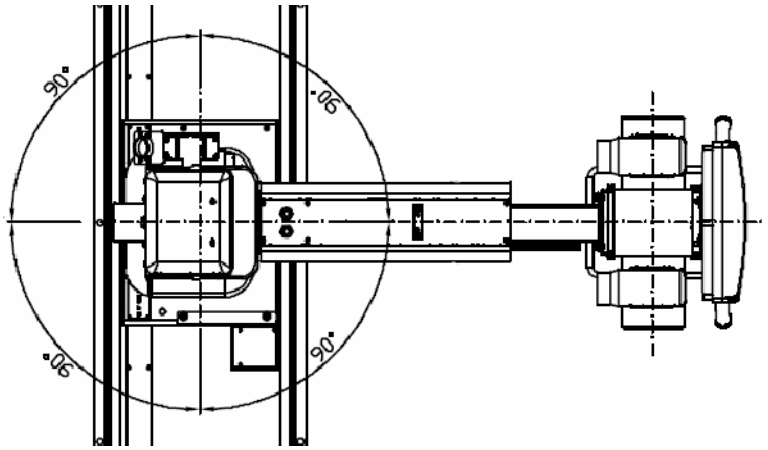
Operation controls for the Floor Mounted Tube Stand are located at the ControlPanel.

5.1.1 COLUMN ROTATION CONTROL

The Column rotation must be manually positioned by the Operator. Press the column rotation button and then rotate the Column to the desired angle.

This motion can reach ±180^{o} with detents at 0^{o}, 90^{o} and **-** 90^{o}.

If the System includes Mechanical Tracking Link, before attempting to rotate the Column, disengage the Linking Bar of the Mechanical Tracking device *(refer to Section 5.6 Mechanical Tracking Link).*

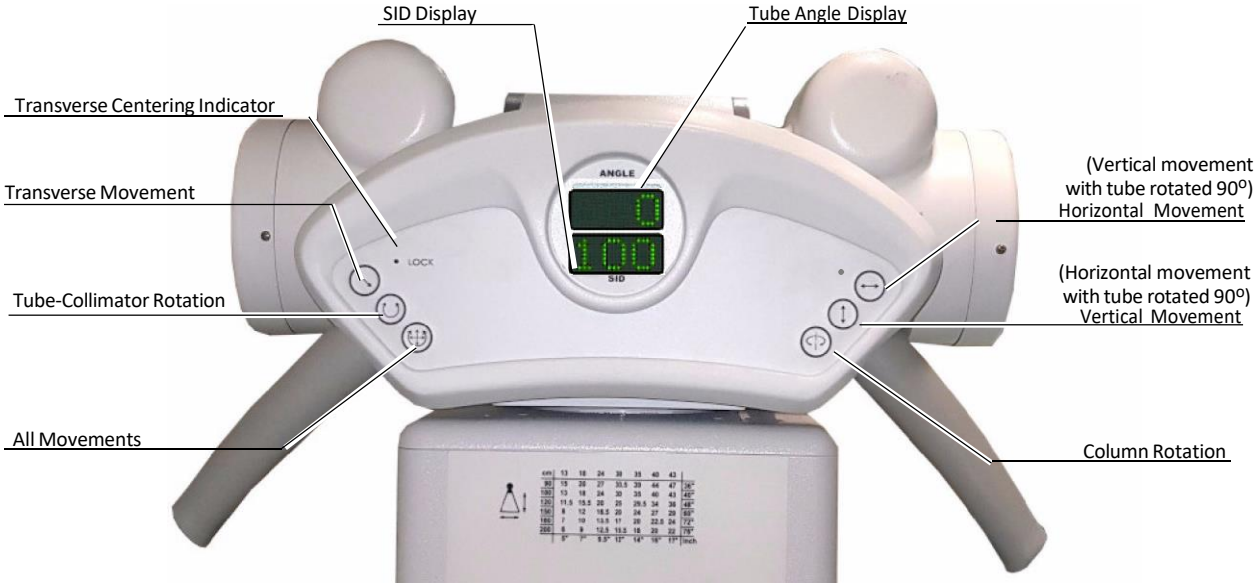


CAUTION

Rotation may be limited by cables. Avoid strain on the cableswhen rotating the Column.

5.1.2 CONTROL PANEL

Illustration 10Control Panel



After the System is turned ON, a startup routine begins and the Control Panel momentarily shows the software version (e.g., V01 R0.0 = Vers.01 R0.0).

The Display then shows the position data of the Tube-Collimator Assembly.(Angle and SID).

ANGLE DISPLAY: Indicates the Angle of the Tube-Collimator Assembly on itsvertical axis. In case of error, this Display flashes the error code (e.g., E06).

SID DISPLAY: Indicates the Source-Image Distance (SID). The SID Display shows "**- - -** " when the SID value is not defined, that is, when the Tube-Collimator Assembly is not within the range of ±45° on its vertical axis or when it is not perpendicular (±45°) to the Vertical Receptor.

ERROR CODES IN THE DIGITAL CONTROL PANEL: Error codes appear on the Digital Control Panel Display and indicate the potential cause of a system failure (*refer to Section 6.2 for further information on Error Codes).*

Note **.**

Note **.**

LOCK

HORIZONTAL MOVEMENT: Press and hold this button to allow horizontal movement of the Column in order to establish the desired SID (Source-Image Distance) with the Vertical Receptor. This control is used to horizontally position the Column with respect to the Horizontal Receptor. Release this button to lockthe Column in position.

Horizontal movement is provided with detents related to the distance from the Vertical Receptor that can be modified during System Configuration. Detent points are shown on the SID Display when the distance is reached with respect to the Vertical Receptor. Press this button again to continue movement.

VERTICAL MOVEMENT: Press and hold this button to allow vertical movement of the Tube-Collimator Assembly in order to achieve the desired SID with respect to the Horizontal Receptor. This control is also used to vertically position the Tube-Collimator Assembly with respect to the Vertical Receptor. Release this button to lock the Tube-Collimator Assembly in vertical position.

Horizontal and vertical movements always correspond to the button arrow direction, that is, the buttons for horizontal and vertical movement interchange its function when the Tube-Collimator is turned 60^{o} left or right.

COLUMN ROTATION: Refer to Section 5.1.1.

TUBE-COLLIMATOR ROTATION: Press and hold this button to allow rotation of the Tube-Collimator Assembly to the desired angle. Release this button to lock in position.

This movement has detents at 0^{o}, 90^{o} and **-** 90^{o} which are shown on the Angle Display. Press this button again to continue with movement.

TRANSVERSE MOVEMENT: Press and hold this button to allow transverse movement of the Tube-Collimator Assembly. Release this button to lock the Tube-Collimator Assembly in position.

This movement is provided with a detent when the Tube-Collimator Assembly is centered with respect to the Horizontal Receptor (“LOCK” indicator lit). Press this button again to continue with movement.

FREE MOVEMENTS: Press and hold this button to allow Horizontal, Vertical and Rotation movements at the same time. Release button to lock in position.

This button pushed disables the corresponding detents.

5.2 RALCO MANUAL COLLIMATOR R225/R225 DHHS

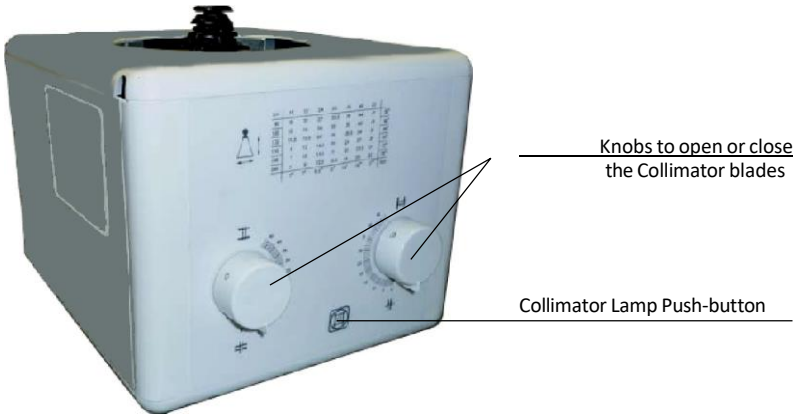
Collimator controls consist of a button to switch on the Collimator lamp and two knobs to open or close the internal blades of the Collimator.

When pressing the Collimator Lamp push-button, the Collimator light and the Laser light turn on. They remain lighting for 30 seconds before they switch Off automatically (lighting time can be configured).

Exposure field on the Receptor is adjusted by setting the two knobs. The table on the Front Panel shows the number to set with the knobs to open the blades according to the SID and X-ray field to be used.

The Collimator can rotate ¦90^{o} on its vertical axis while the Tube remains in the same position. This movement is performed by manually turning the Collimator and has detents every 90^{o}.

Illustration 11
Collimator Controls



Note **.** *Refer to the corresponding Collimator Manual for extended information about operation or technical description needed to maintain compliance with Standard IEC 60601-1-3:2008.*

For patient positioning, the Collimator Lamp is also turned on when any lock related to the receptor is activated: All Table movement pedals, Wall Stand vertical Lock, or Table Receptor Handle. It remains on for 30 seconds before they switch Off automatically (light on time can be configured by the Service Engineer).

5.3 DOSEMETER DEVICE (OPTIONAL)

The optional Dosemeter device is related to the Collimator installed in the TubeStand. It is used for simultaneously determining the dose area product, dose area product rate and irradiation time.

Note **.** *Refer to the corresponding Dosemeter Manual for extended information about operation or technical description needed to maintain compliance with Standard IEC 60601**-** 1**-** 3: 2008.*

5.4 TABLE

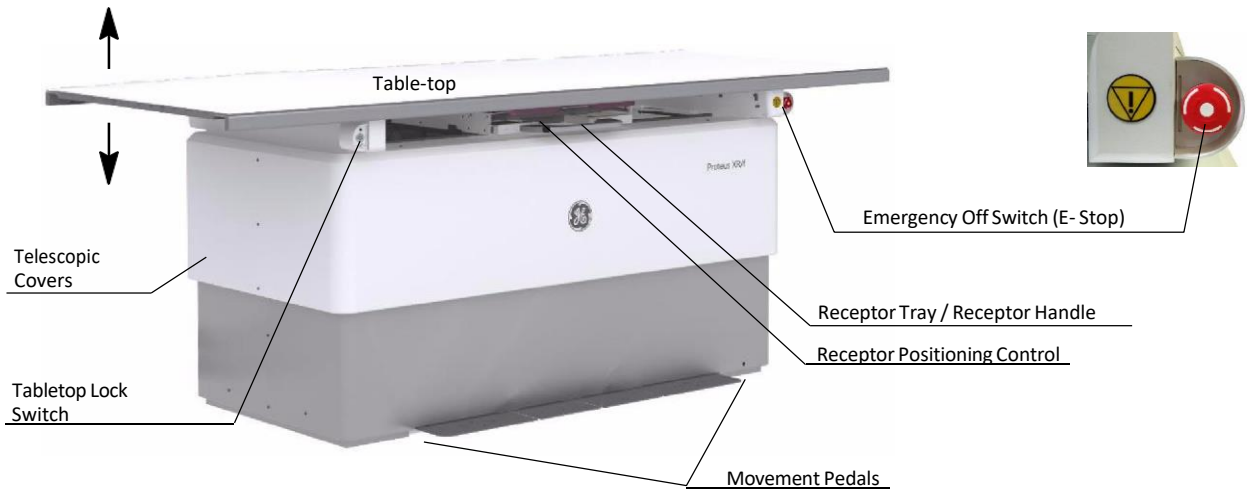
The Proteus XR/f System may include an ET Table (Elevating Table), *refer toSection 5.4.1*. or a ST Table (non Elevating Table), *refer to Section 5.4.2.*

5.4.1 ET TABLE

The Elevating Table with its variable height has been designed for easy access from beds, wheelchairs or stretchers with patient care and comfort in mind.

The Table-Top travels are controlled with the Pedals located at the Table Base. Also the Table incorporates two safety devices and a control for the Horizontal Receptor positioning.

Illustration 12
Elevating Table



WARNING

THE MAXIMUM PATIENT WEIGHT SUPPORTED WITH THE TABLE-TOP AT ANY POSITION IS 350 KG (771 LBS) EVENLY DISTRIBUTED OVER THE SURFACE OF THE TABLE-TOP. EXCEEDING THIS LIMIT MAY CAUSE EQUIPMENT DAMAGE OR INJURY TO THE PATIENT.

TABLE MOVEMENT PEDALS: A row of pedals located at the Table Base provide a comfortable control of the Table movements.

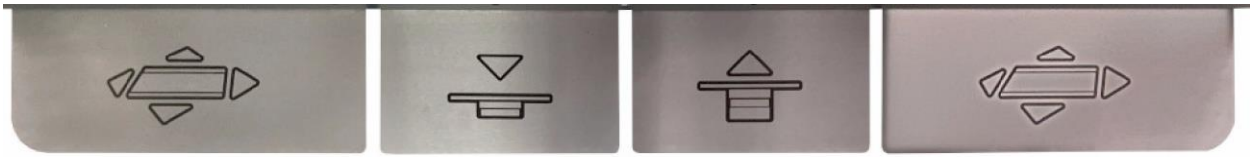


Table-top **Down** **Up** **Table-top**

TABLE-TOP MOVEMENT PEDALS: Double tap on any of the two pedals (at both ends of the Pedal row) to release longitudinal and transverse brakes, this allows free movement of Table-top for better positioning of patient. Release Pedal to block movement.

UP PEDAL: Double tap on Pedal to lift Table-top to desired height. Release Pedal to stop movement.

DOWN PEDAL: Double tap on Pedal to lower Table-top to desired height. Release Pedal to stop movement.

The Service Engineer can modify the configuration of the pedals and change the brake releasing from the double tap to a single tap.

Note **.** *A Height Detent in the Up and Down travel of the Table-top can be set by the Service Engineer to stop the Table-top automatically at the operator desired height.*

TABLE-TOP LOCK SWITCH: This security switch disables Table-top horizontal movement avoiding any unexpected Table-top motion (e.g. patient steps on Pedal while sitting on Table before positioning or getting off the Table).

BEFORE PATIENT SITS OR GETS OFF THE TABLE PRESS TABLE-TOP LOCK SWITCH TO AVOID PATIENT INJURY OR DAMAGE TO EQUIPMENT.

THIS ELEVATING TABLE PROVIDES A SAFETY SYSTEM UNDER TABLE-TOP WHICH STOPS DOWN PEDAL MOVEMENT WHEN TRAVEL FINDS AN OBSTACLE.

5.4.2 ST TABLE

WARNING

THE MAXIMUM PATIENT WEIGHT SUPPORTED WITH THE TABLE-TOP AT ANY POSITION IS 300 KG (661.3 LBS) EVENLY DISTRIBUTED OVER THE SURFACE OF THE TABLE-TOP. EXCESSIVE WEIGHT AT ONE POINT MAY CAUSE EQUIPMENT DAMAGE OR INJURY TO THE PATIENT.

Illustration 13 Radiographic Table

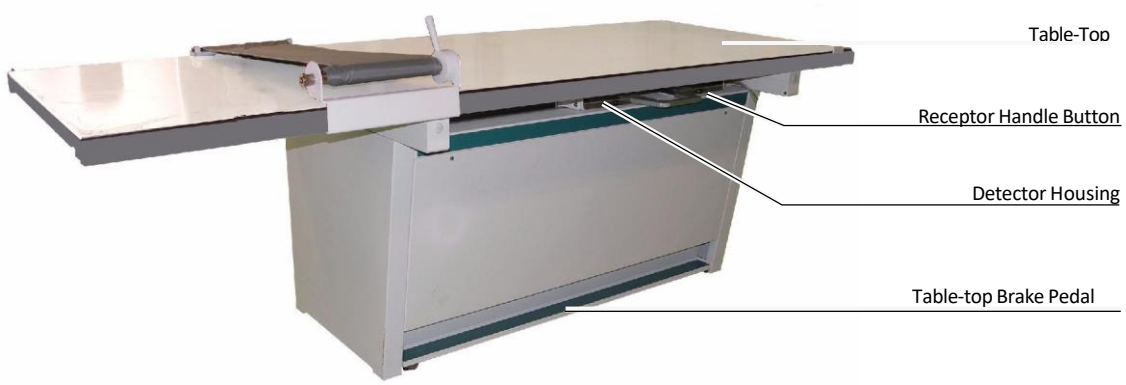
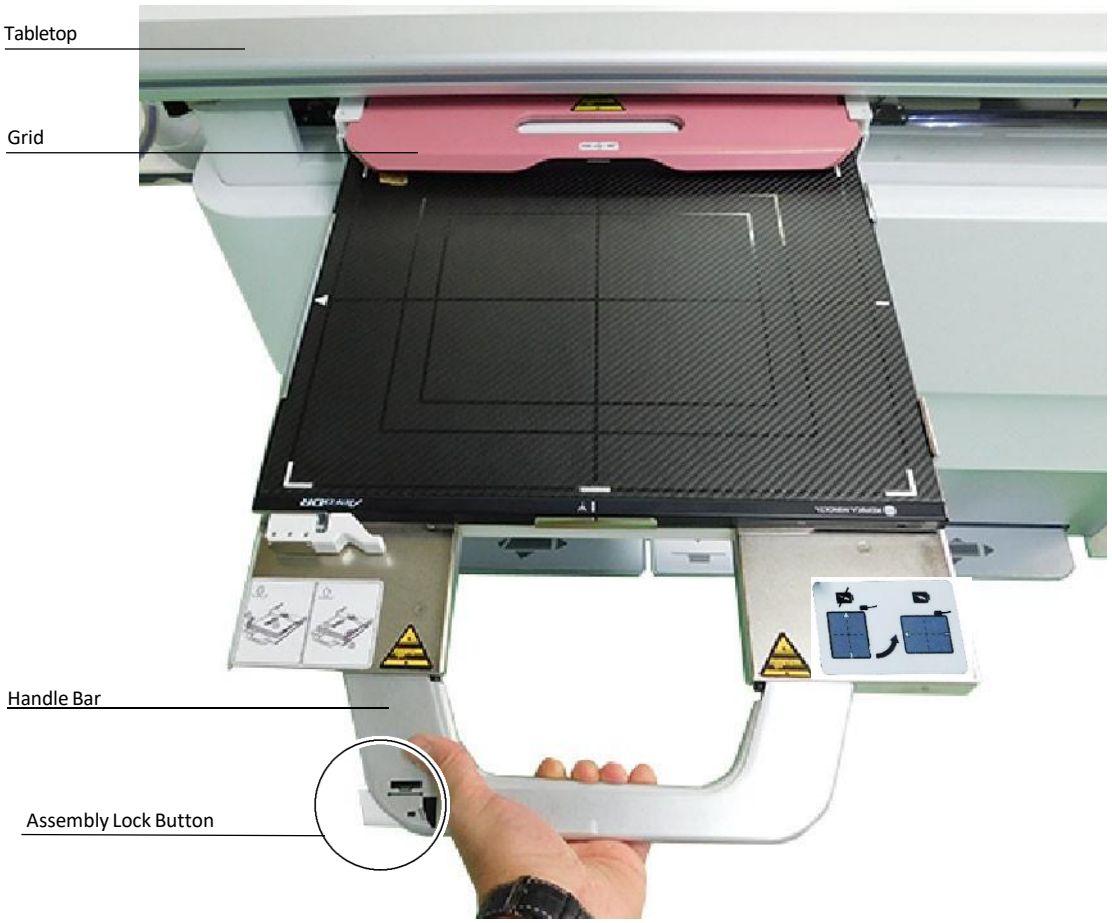


TABLE-TOP BRAKE PEDAL: The Table-Top is provided with a four-way floating movement for improved patient positioning. Pressing and maintaining the pedal down will release the longitudinal and transverse brakes of the Table-Top. Release the pedal to lock into position.

5.4.3 PORTABLE RECEPTOR ASSEMBLY FOR TABLE

Illustration 14
Portable Receptor Assembly in the Rad Table



5.4.3.1 PORTABLE RECEPTOR ASSEMBLY WITH NON-ROTATING TRAY

The Portable Receptor Assembly with Non-Rotating Tray is designed to conveniently house a Portable Detector, an Ion Chamber and a Grid. The Operator can load the Digital Detector in Portrait or Landscape position.

The Handle of the Assembly includes a Handle Bar for extracting the Tray.

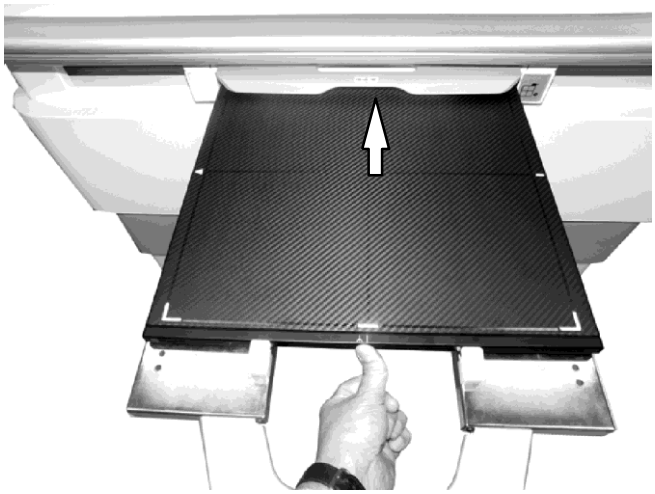
The Handle also contains a Lock Button to move horizontally the Receptor Assembly.

LOADING AND UNLOADING THE TRAY

1. Grab the Handle and pull the Tray until it is completely out.

2. Then place the Detector centered in the Tray and push slightly theend-stop with the Detector end until it is fitted in the four stops of the tray.

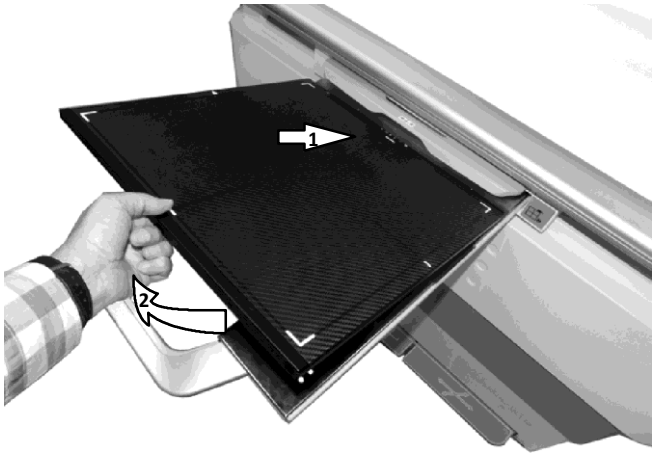
Illustration 15
Detector Loading



3. To unload the Detector, grab the Handle and pull the Tray until it is completely out.

4. Push the Detector towards the end Stop and carefully remove the Detector.

Illustration 16 Detector Unloading



5.4.3.2 PORTABLE RECEPTOR ASSEMBLY WITH ROTATING TRAY

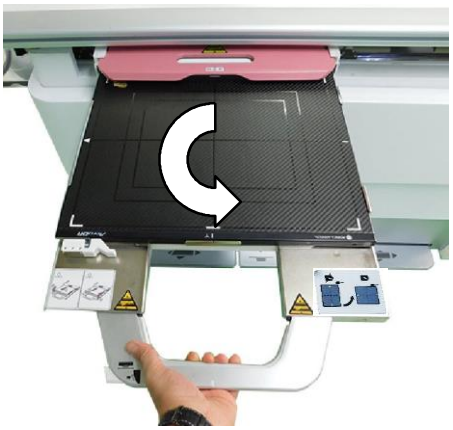
The Portable Receptor Assembly with Rotating Tray is designed to conveniently house a Portable Detector, an Ion Chamber and a Grid. It can also provide the system with information about the position and status of the Grid and Detector. The Digital Detector can be loaded in Portrait or Landscape position by rotating the Tray.

The Handle of the Assembly includes a Handle Bar for extracting the Tray. The Lock Button allows also the horizontal movement of the Receptor Assembly.

ROTATING THE TRAY

1. Pull out the Detector Tray to the end of its travel (Rotating Position).
2. Insert the Detector in the Tray.
3. Push the Tray Counterclockwise until it rotates 90^{O} to achieve Portrait or Landscape position.

Illustration 17
Rotation of the Portable Receptor Assembly in the Rad Table



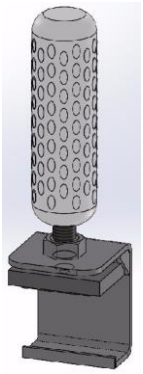
4. Insert the Tray.

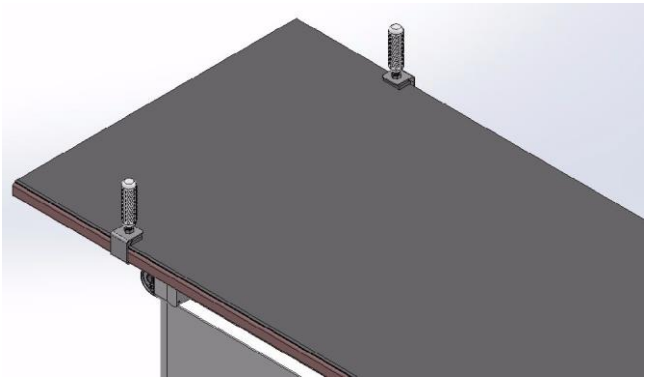
Due to moving parts within the Detector Assembly, all body parts and objects must be clear of possible Pinch Areas between the Detector Assembly and the Rotating Tray.

5.4.4 HAND GRIPS (OPTIONAL)

The Hand Grips are used by patients and operators to keep their hands away from the Tabletop edges and make the patient feel safe while the table-top is being positioned.

The Hand Grips are hand tightened along the Tabletop rails and locked at any position.





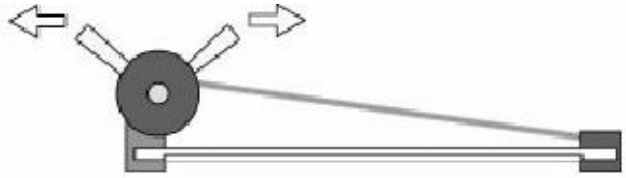
USE ALWAYS THE HAND GRIPS TO AVOID INJURIES IN PATIENT HANDS OR FINGERS WHEN THE TABLETOP IS IN MOVEMENT. PATIENT'S HANDS MUST BE KEPT AWAY FROM THE TABLETOP EDGES IN EVERY MOMENT.

5.4.5 COMPRESSION BAND (OPTIONAL)

This device supplies compression to the anatomical area of interest in order to avoid unnecessary movements.

It is mounted on the Tabletop rails. Install both brackets of the Compression Band in the Table-top rails, roll the band in the shaft, engage the end of the band in with the hooks and use the lever lock or unlock the Compression Band to get the required tension of the Band.

Insert the Band Support and the opposite Support in the Table-top Rails



Extend the Band, hook one end and obtain the required tension with the Lock Lever

5.4.6 LATERAL DETECTOR HOLDER ON TABLE (OPTIONAL)

The Lateral Detector Holder is used for Table lateral work, including knee,shoulder, skull, etc.

This Lateral Detector Holder is placed directly on the Tabletop.It can

hold a Detector of 35 x 43 cm.

5.4.7 LATERAL DETECTOR HOLDER WITH TROLLEY (OPTIONAL)

This mobile detector holder is designed to accommodate portable DR detectorsof 35x43 cm (14”x17”).

WARNING

DRIVE THE EQUIPMENT WITH CARE. AVOID ANY IMPACT OF THE UNIT WITH WALLS, FURNITURE OR OTHER ELEMENTS IN THE ROOM THAT MAY CAUSE DAMAGE TO THE EQUIPMENT AND/OR THE OTHER ROOM ELEMENTS.

WARNING

DRIVE THE EQUIPMENT IN FLAT SURFACES. IF IT IS NOTPOSSIBLE, TRAVEL SURFACES SHOULD NOT EXCEED 5ºINCLINATION RAMPS, EXCEEDING THIS ANGLE COULDCAUSE SERIOUS DAMAGE TO THE EQUIPMENT, AND BYUSING IT UNDER THESE CONDITIONS COULDEVENTUALLY REPRESENT A DANGER FOR THE USER. HOLD ALWAYS THE VERTICAL BAR TO DRIVE CORRECTLYTHIS ACCESSORY EQUIPMENT.

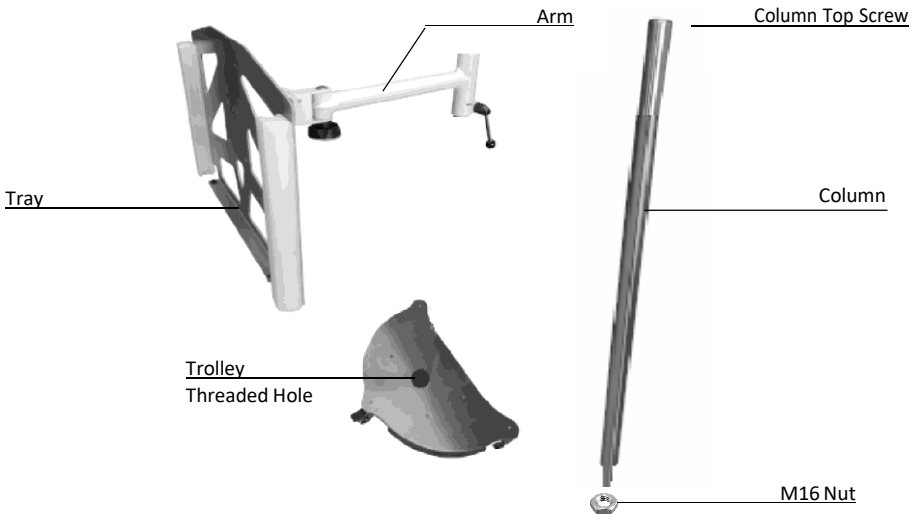
CAUTION

Do not try to step over any possible obstacle when movingthe holder, the equipment could fall over.

ASSEMBLY PROCEDURE

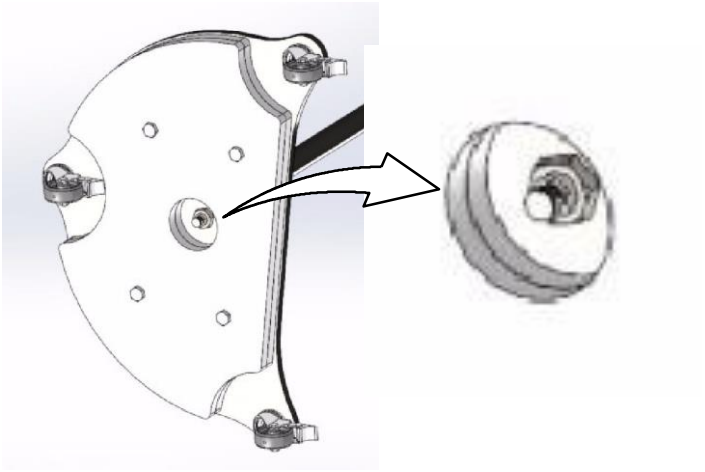
1. Remove the M16 nut attached to the Column and install the Column inthe Trolley threaded hole.

Illustration 18
Assembly Parts



2. Once the Column is inserted and hand tightened, install the M16 nut atthe end of the Column, apply a torque of 20 Nm.

Illustration 19
Nut Installation below the Trolley



3. Remove the screw at the top of the Column and insert the Arm in the Column. Tighten the locking lever.

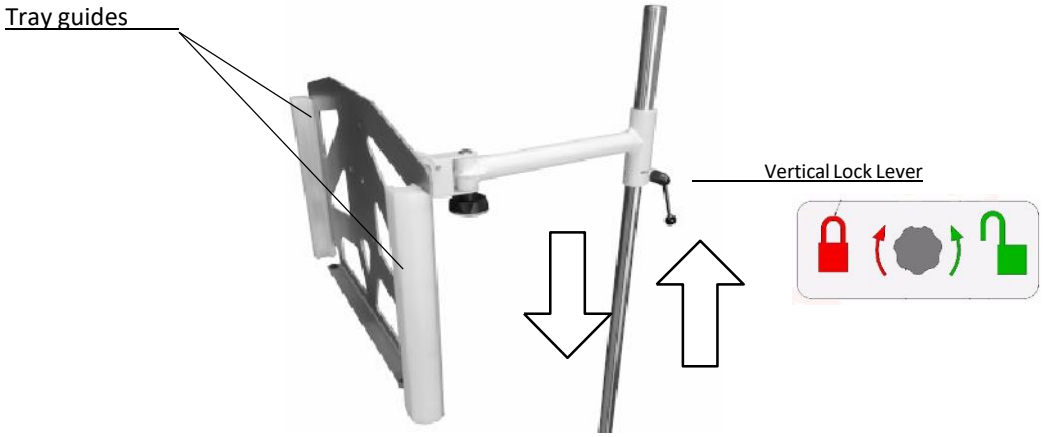
4. Reinstall the Screw at the Top of the Column.

USAGE

1. Make sure the Vertical Lock Lever is tightened and carefully insert the DR detector in the Tray (between the Guides), the orientation is always landscape.

2. Release the Arm Lock Lever to position the Detector at the desired height. Hold the Detector Support during this procedure to avoid the Armto fall down.

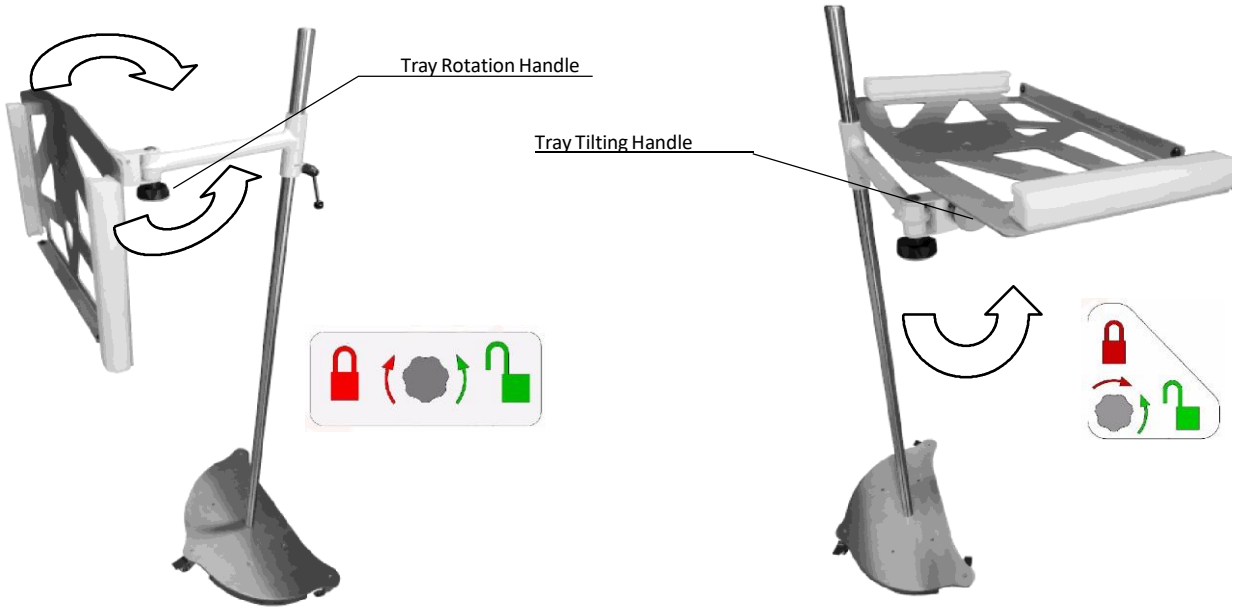
Illustration 20
Tray Guides and Vertical Lock Lever



3. The DR detector Tray includes a rotation adjustment handle of +/**-** 90^{o}from the Arm.

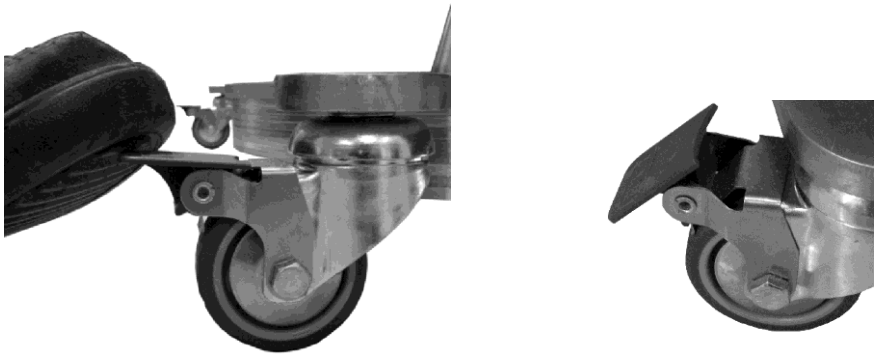
4. Also, the DR detector Tray includes a Tray Tilting adjustment handle of90^{o}.

Illustration 21
Tray Rotation and Tray Tilting



The mobile detector holder is provided with three wheels and each with its ownbrake pedal. Step on the brake pedal to lock the wheel.

Illustration 22 Wheel
Brake Pedal



5.5 WALL STAND

The Wall Stand enables radiographic operations at different positions within the range of the Vertical Carriage travel.

Electrical Lock

ON / OFF: The Wall Stand is turned ON / OFF when the Table or the Control Unit, in case of Single Panel system, is turned ON / OFF.

VERTICAL CARRIAGE ASSEMBLY: The carriage slides vertically along the Column. It is controlled by an Electrical Lock.

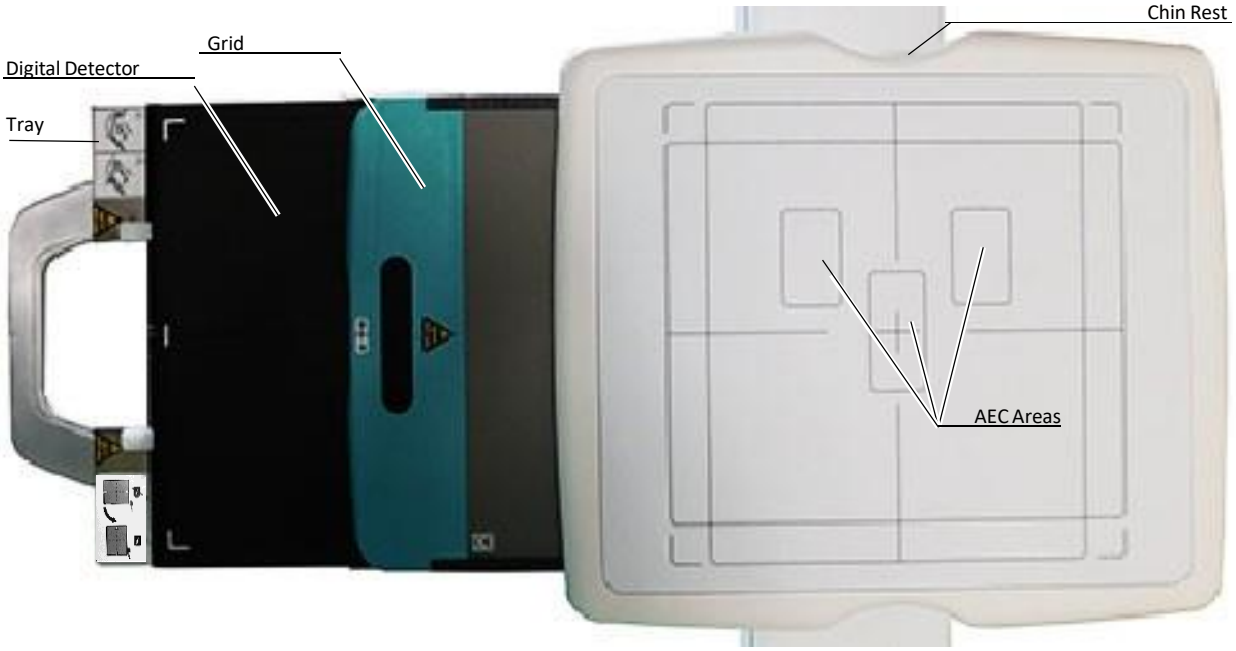
The lock is released by pressing the Carriage Handle Button in order to allow vertical movement and positioning with respect to patient. Release the button to lock in position. As well, the vertical movement is locked when the equipmentis turned OFF.

5.5.1 PORTABLE RECEPTOR ASSEMBLY FOR WALL STAND

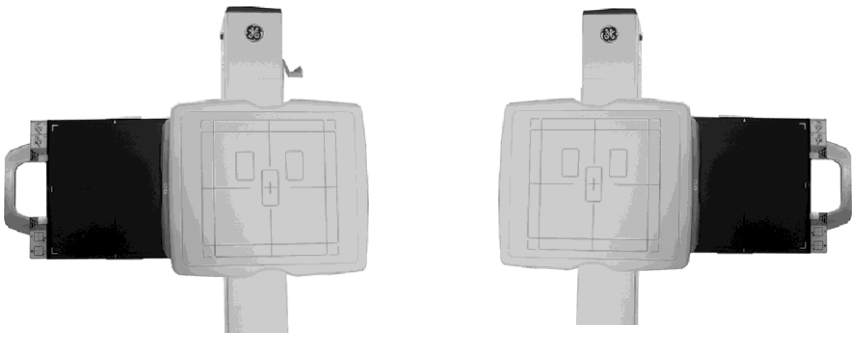
The Wall Stand can house a Portable Digital Detector. The Receptor Assemblyhas the following characteristics:

- Chin Rest.
- Ion Chamber Housing.
- Front Panel with AEC Detector Areas and very low absorption level.
- Removable Grid.

Illustration 23
Portable Receptor Assembly with Rotating Tray in the Wall Stand



Note **.** Loading of Receptor can be adapted at right or left side as percustomer order requirements.



5.5.1.1 PORTABLE RECEPTOR ASSEMBLY WITH NON-ROTATING TRAY

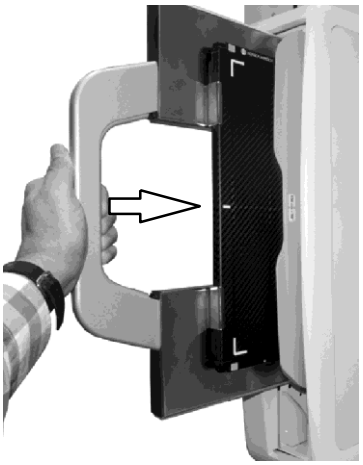
The Portable Receptor Assembly with Non-Rotating Tray is designed to conveniently house a Portable Detector, an Ion Chamber and a Grid. The Operator can load the Digital Detector in Portrait or Landscape position.

The Handle of the Assembly includes a Handle Bar for extracting the Tray.

LOADING AND UNLOADING THE TRAY

1. Grab the Handle and pull the Tray until it is completely out.
2. Then place the Detector centered on the Tray and insert it in the tray. Push slightly the end-stops with the Detector end until it is fitted in the frame of the tray.

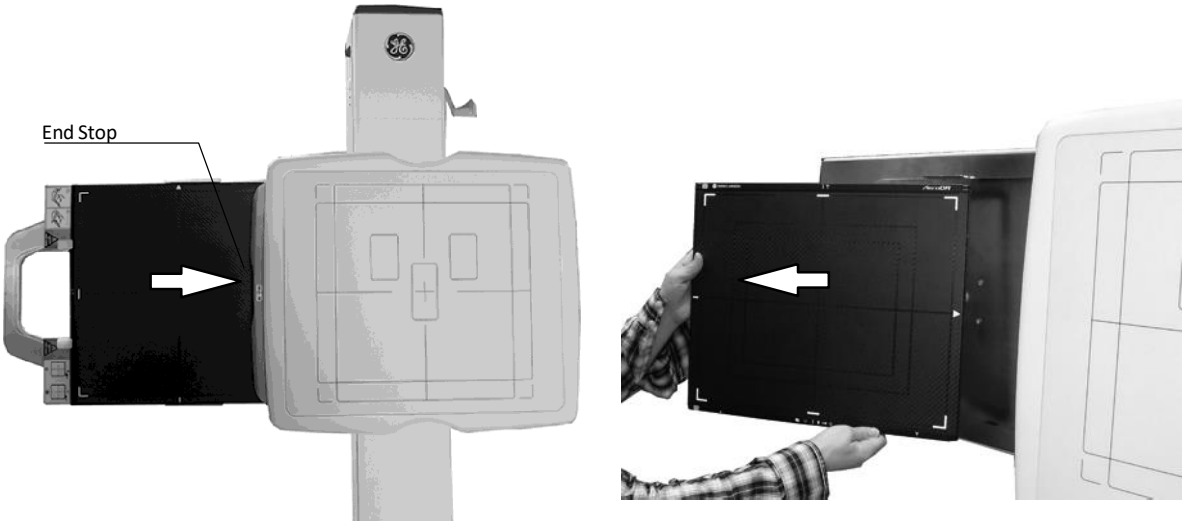
Illustration 24 Detector Loading



3. Fully insert the Tray inside the Detector Assembly.

4. To unload the Detector, grab the Handle and pull the Tray until it is completely out.

5. Push the Detector towards the end Stop and carefully lift and remove the Detector with both hands.



5.5.1.2 PORTABLE RECEPTOR ASSEMBLY WITH ROTATING TRAY

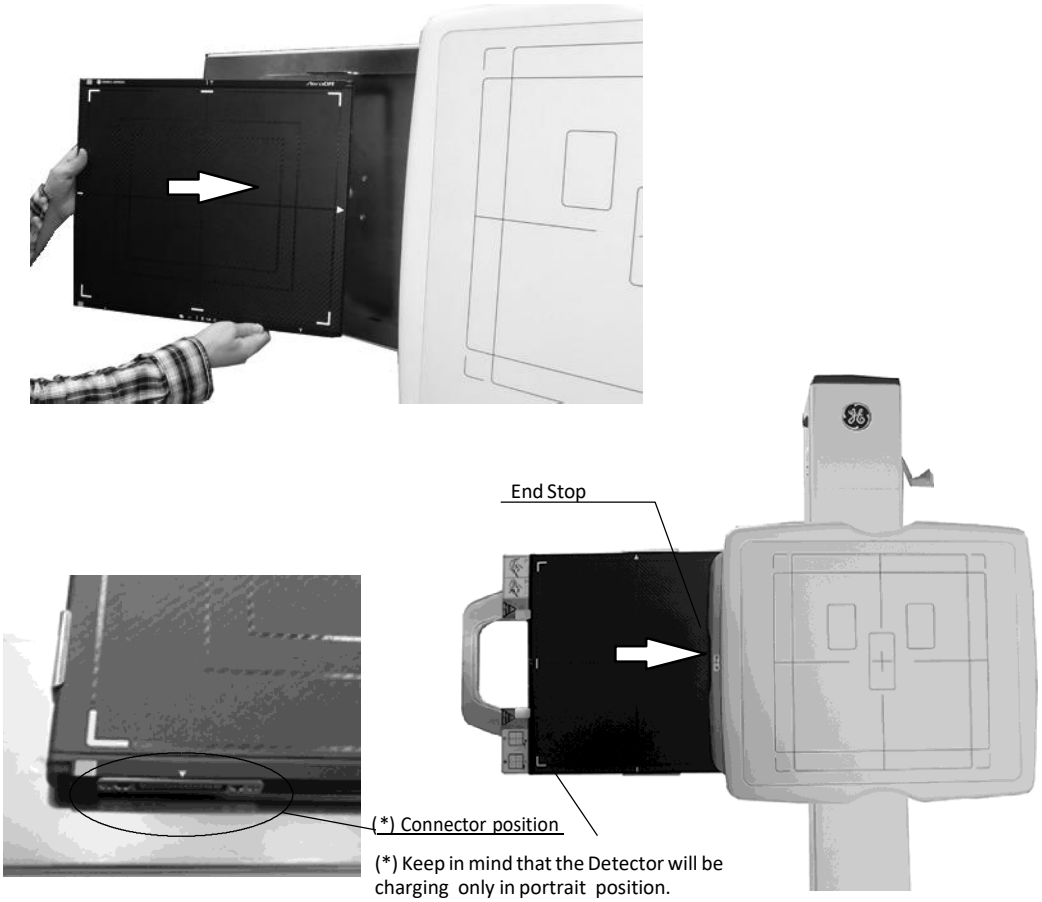
The Portable Receptor Assembly with Rotating Tray is designed to conveniently house a Portable Digital Detector, an Ion Chamber and a Grid. It can also provide the system with information about the position and status of the Grid and Detector. The Digital Detector is always loaded in Landscape position and can be manually rotated to Portrait position.

The Handle of the Assembly includes a Bar for extracting the Tray.

LOADING AND UNLOADING THE TRAY

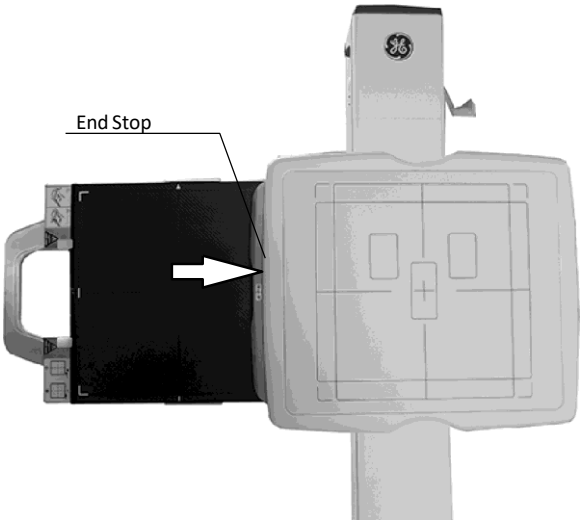
1. Grab the Handle and pull the Tray until it is completely out.
2. Then place the **Detector in Landscape position** and insert it in the tray. Push slightly the end-stops with the Detector end until it is fitted in the frame of the tray.
3. Fully insert the Tray inside the Detector Assembly.
4. Keep in mind that the Detector is not connected when loaded in landscape position (the “loading” indicator is located at the Detector Interface Box).

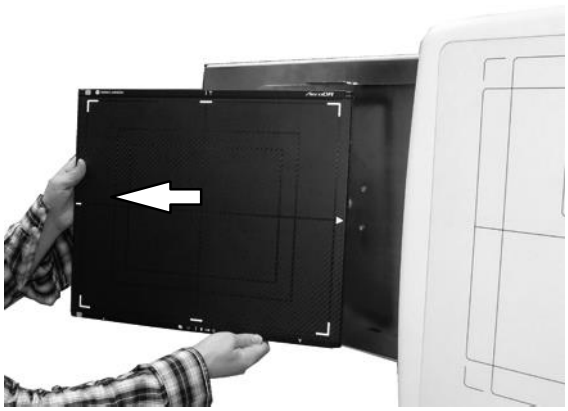
Illustration 25
Detector Loading



5. To unload the Detector, grab the Handle and pull the Tray until it is completely out.

6. Push the Detector towards the end Stop and carefully lift and remove the Detector with both hands.

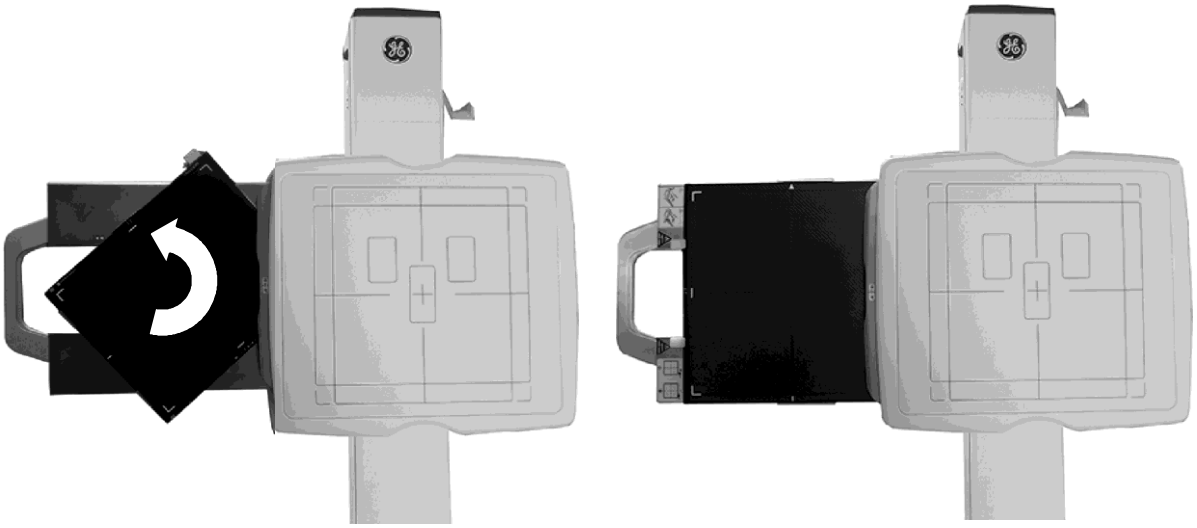




ROTATING THE TRAY

1. If the Detector is not inside the Tray, pull out the Detector Tray to the endof its travel (Rotating Position) and insert the Detector in the Tray.

2. Push carefully the Tray Counterclockwise with both hands until it rotates90^{o} to achieve Portrait position.



3. Insert the Tray.

CAUTION

Due to moving parts within the Detector Assembly, all body parts and objects must be clear of possible Pinch Areas between the Detector Assembly and the Rotating Tray.

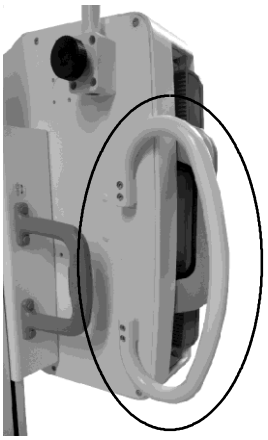
5.5.2 ARM SUPPORT (OPTIONAL)

The Wall Stand can be prepared to hold an Arm Support. In that case, the sideof the Column Carriage includes an Arm Support holder with a knob.

Insert the Arm Support in the holder and screw the knob.

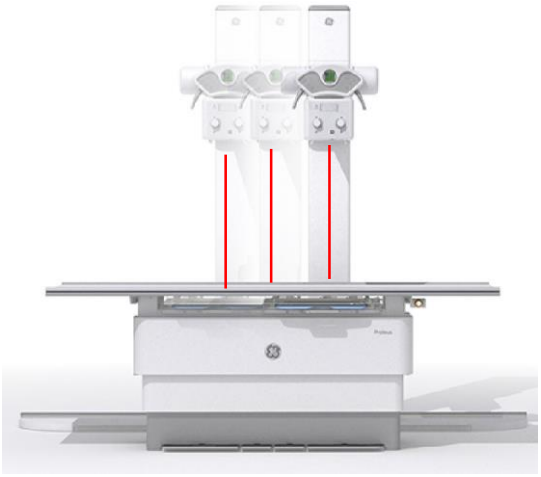
5.5.3 HAND GRIPS FOR WALL STAND (OPTIONAL)

The Wall Stand can be provided with Hand Grips. In that case, the Assemblyincludes the corresponding Hand Grips (x2) on two sides of it.



5.6 MECHANICAL TRACKING OF TABLE RECEPTOR (OPTIONAL)

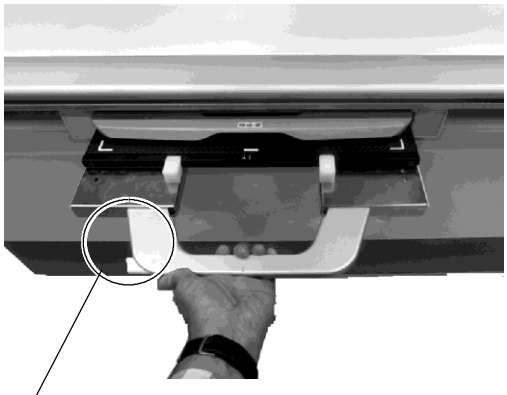
The system can be provided with an optional Mechanical Tracking Link of the Table Receptor when it is centered with respect to the Tube-Collimator. This Tracking Link device transmits the horizontal Column motion to the Receptor Assembly so the Receptor and the Column remain centered.



To engage the assembly, press the Table Receptor Lock Button and push the Receptor assembly toward the tracking link until the linking bar is engaged in the Tracking link channel.

To disengage the assembly, press the Column horizontal movement button of the Column Control panel and push the assembly to the right or left travel end until the Table Receptor Assembly is disengaged.

To mechanically engage:

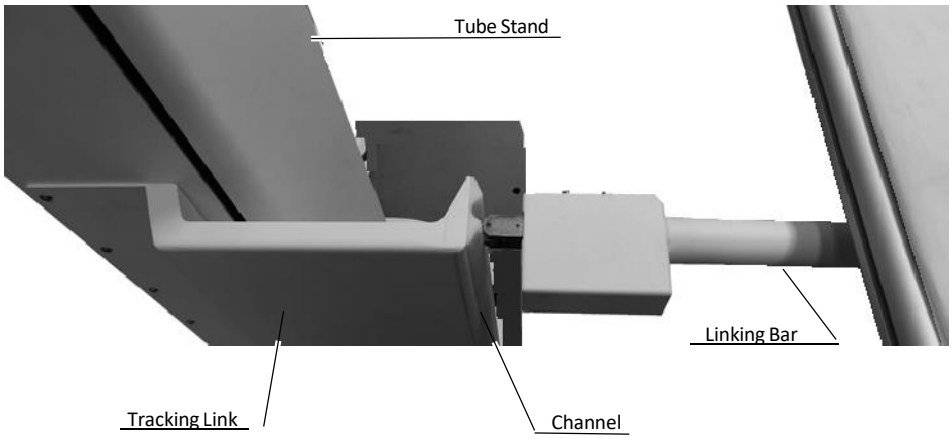


Press the Table Receptor Lock Button
and push the assembly to engage the device

To disengage the Assembly:

Press the Column Horizontal Movement Button and carry the assembly to the left or right travel end until theReceptor Assembly is disengaged

When the operator engages this device, (Linking Bar inside the Channel of the Column Tracking Link device), the Brake of the Receptor Assembly remains released.



5.7 GRIDS

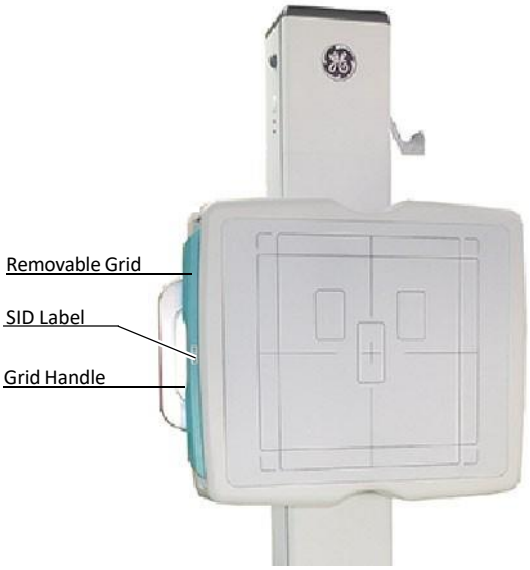
Grids are intended to reduce scattered radiation and significantly enhance image quality. Before using the Grid, clean the front and back side with a dry cloth to remove dust and dirt.

The Wall Stand and the Table may hold a Removable Grid. The Grids are labelled 100 cm (40”), 150 cm (59”) or 180 cm (70”). Use the corresponding Grid according to the SID (Source to Image Distance).

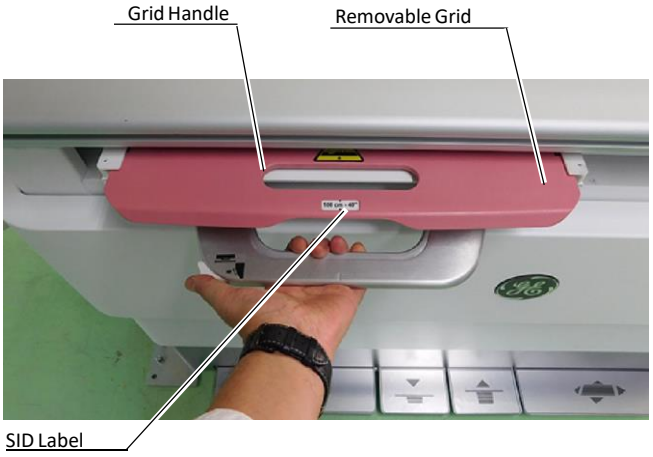
When inserting the Grid in the Grid Slot, pay special attention to the type of focalization distance of each Grid.

Check the correct insertion of the Grid in the slot with the label side facing the Tube. A click sound means that the Grid is in place.

Handle the Grid with care. Dropping the Grid could causedamage and reduced image quality.



Wall Stand



Table

Standard Grids:

40 lines/cm (103 lines/inch), 10:1 focalized at 1 m (40”).

40 lines/cm (103 lines/inch), 10:1 focalized at 1.5 m (59”).

40 lines/cm (103 lines/inch), 12:1 focalized at 1.8 m (70”).

5.8 X-RAY BEAM ALIGNMENT WITH RESPECT TO PATIENT

After selecting RAD parameters for the technique to be performed:

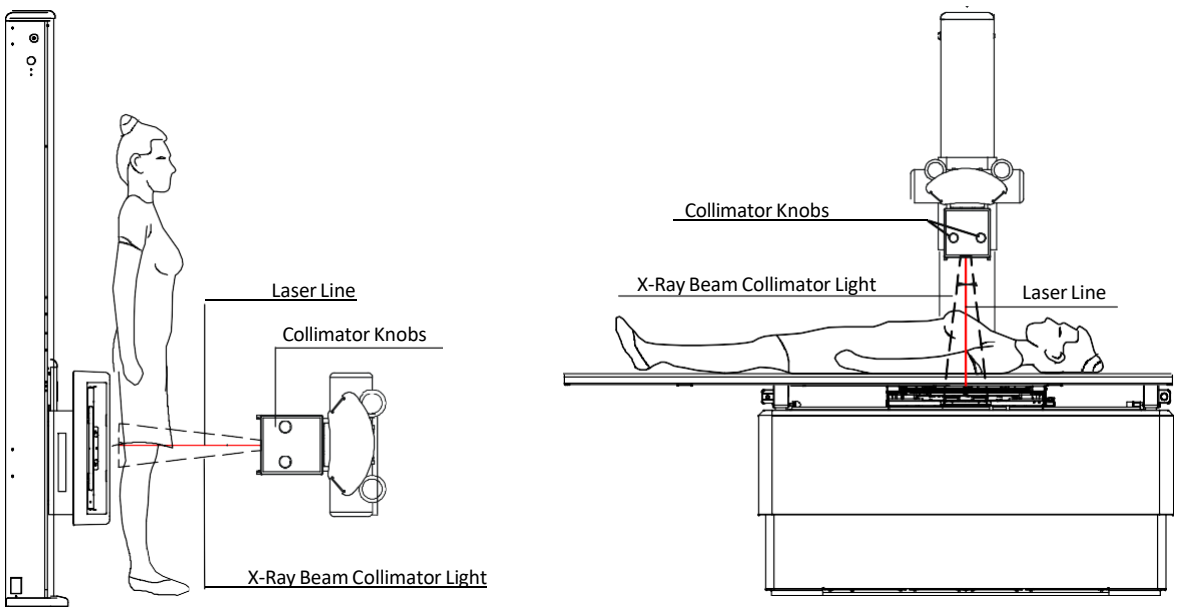
1. Point the X-Ray Tube-Collimator Assembly to the Image Receptor.

2. Center the Collimator light, which corresponds to the X-Ray beam, with respect to receptor. For that, use the Collimator Light centering marks and the laser line on the receptor handle if applicable.

3. Position the patient for the examination.

4. Turn ON the Collimator Lamp and adjust the field size with the Collimator controls.

Illustration 26 Patient Positioning



5. Perform any adjustment on the patient position, Receptor or Tube Collimator Assembly to assure that the X-Ray beam is correctly positioned.

ALWAYS SELECT THE CORRECT FIELD SIZE TO AVOID EXCESSIVE RADIATION.

THE X-RAY BEAM AXIS AND THE REFERENCE AXIS OF THE PLANE OF INTEREST COINCIDE AND ARE ORTHOGONAL WITH RESPECT TO THE PLANE OF INTEREST, IN EXAMS PERFORMED WITH THE DR DETECTOR PERPENDICULARLY POSITIONED WITH RESPECT TO THE TUBE-COLLIMATOR ASSEMBLY.

IN CASE OF EXAMS WHERE THE DR DETECTOR IS NOT PERPENDICULARLY POSITIONED WITH RESPECT TO THE TUBE-COLLIMATOR ASSEMBLY, THE X-RAY BEAM AXIS DOES NOT COINCIDE WITH THE REFERENCE AXIS OF THE PLANE OF INTEREST AND IT IS NOT ORTHOGONAL WITH RESPECT TO THE PLANE OF INTEREST. THEREFORE, THERESULTING IMAGE WILL BE DEFORMED.

IT IS THE OPERATOR RESPONSIBILITY THE PROPER POSITIONING OF THE PATIENT AND EQUIPMENT BEFOREPERFORMING AN EXAM.

SECTION 6 ERROR CODES

6.1 GENERATOR ERROR CODES

Error codes indicate the potential cause of a system failure. Error codes are shown on the operator Console, at the same time an alarm sounds. Correct the error cause and reset the error indication. *(Refer to Table 1).*

All these error codes can be preceded by the letter "*E*" (i.e., E01) (depends on the software application) and they will enable the operator to indirectly convey the possible source of error to service personnel. This may prevent the need for a service call or enable service personnel to anticipate corrective actions prior to arriving in site.

Table 1
Generator Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E001	BACKUP TIMER **-** I2C ERROR I2C bus error while trying to access the external redundant backup timer.	Turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E002	WRONG WS CONFIGURATION ERROR One or more workstations are not properly configured; a default value has been assigned.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E003	NO WS CONFIGURED ERROR No tube has been configured for any of the workstations, there is no workstation available and a default value has been assigned.	
E004	FLUORO ORDER ERROR The Fluoro order input signal is active during the Start**-** upsequence.	Release any external exposure device or buttons.Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E005	EXP ORDER ERROR The Exposure order input signal is active during the Start**-** up sequence.	
E006	PREP ORDER ERROR The Preparation order input signal is active during the Start**-** up sequence.	
E007	TUBE2 MODEL ERROR The tube index (related to a tube in the tube list) configuredfor the tube 2 is outside boundaries, a default value has been assigned.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E008	TUBE1 MODEL ERROR The tube index (related to a tube in the tube list) configuredfor the tube 1 is outside boundaries, a default value has been assigned.	
E009	INVERTER ERROR (IGBT FAULT) The inverter module has been overloaded.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and wait 30 minutesbefore turning it ON again. If the equipment remains inoperative, turn it OFF and call Field Service.

Table 1 (*cont.*) Generator Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E010	EEPROM CHECK ERROR Erroneous data stored in the EEPROM.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E011	LOAD CAPACITOR ERROR Error while charging the load capacitors. The DC bus voltagedoes not reach the right value during Start**-** Up.	
E012	MA RANGE ERROR Tube current out of range during exposure.	Press the "*Reset*" button. Repeat with same technique values, If the error code persists try withanother combinations of kV and mA values. If the equipment remains inoperative, turn it OFF and call Field Service.
E013	KVP RANGE ERROR Anode**-** Cathode voltage out of range during exposure.	
E014	KVP RAMP ERROR Anode**-** Cathode voltage does not reach the final value in the designated rise time.	
E015	LARGE FIL CURRENT RANGE ERROR Large filament current out of range.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E016	SMALL FIL CURRENT RANGE ERROR Small filament current out of range.	
E018	ROTOR ERROR The Anode Rotor Controller (starter) is not sending back the Ready condition within the designated time.	
E019	MA WITHOUT EXP ERROR Tube current without exposure order from the microcontroller.	
E020	KVP WITHOUT EXP ERROR Anode-Cathode voltage without exposure order from the microcontroller.	
E023	EEPROM ERROR Error while writing in the EEPROM.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E024	BUCKY/DIGITAL PANEL ERROR The designated time has elapsed since the exposure signalwas activated while the equipment was "Ready" without any acknowledge from the WorkStation configured as Bucky or Digital Panel.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF, check the properexternal cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E025	LARGE FIL DEMAND ERROR Large filament current demand above the limit.	Press the "*Reset*" button. **Repeat with same technique values, If the error code persists try with** another combinations of kV and mA values. If the equipment remains inoperative, turn it OFF and call Field Service.
E026	SMALL FIL DEMAND ERROR Small filament current demand above the limit.	
E027	KVP POTENTIOMETER - I2C ERROR I2C bus error while trying to access the digital potentiometerthat adjusts the kV oscillator.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E028	ABC POTENTIOMETER - I2C ERROR I2C bus error while trying to access the digital potentiometersthat adjust the ABC window.	
E029	GENERATOR OVERHEAT ERROR Generator heat capacity exceeded. "Warning".	Turn the Generator OFF and wait 30 minutes before turning it ON againor decrease the exposure parameters. If the equipment remains inoperative, turn it OFF and call Field Service

Table 1 (*cont.*) Generator Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E030	CORRUPT RTC ERROR Wrong date stored in the Real Time Clock (RTC) and/or inthe time stamp.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E031	TIME STAMP CHECK ERROR The time stamp checksum is wrong.	
E032	RTC **-** I2C ERROR I2C bus error while trying to access the Real Time Clock(RTC).	
E033	COMMUNICATIONS ERROR (Comms lost at the Console)The remote console has lost the communications with the generator.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF, check the properexternal cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E034	TANK PRESOSTAT ERROR Tank presostat opened.	Turn the Generator OFF and wait 30 minutes before turning it ON again.If the equipment remains inoperative, turn it OFF and call Field Service.
E035	BUCKY MOTION (X-RAY ACK) ERROR The acknowledge for X-rays from the Bucky or FPD hasbeen lost before the end of the exposure.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E036	TUBE THERMOSTAT ERROR Tube thermostat opened. "Warning".	Turn the Generator OFF and wait 30 minutes before turning it ON again.If the equipment remains inoperative, turn it OFF and call Field Service.
E037	TUBE OVERLOAD ERROR Tube ratings exceeded or not enough Heat Units to performthe selected exposure. "Warning".	Wait for the Tube to cool down or decrease the exposure parameters. If the equipment remains inoperative, turn it OFF and call Field Service.
E038	+5V POWER SUPPLY FAILURE +5V power supply is out of range.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E039	+15V POWER SUPPLY FAILURE +15V power supply is out of range.	
E040	IMBALANCED KVP ERROR Imbalanced kVp, there is not the same voltage in Anode and Cathode branches.	
E041	IMBALANCED MA ERROR Imbalanced mA, there is not the same current in Anode and Cathode branches.	
E042	CORRUPT COUNTERS ERROR The counters checksum is wrong.	
E043	CORRUPT ERROR LOG ERROR The error log checksum is wrong.	
E044	EEPROM **-** I2C ERROR I2C bus error while trying to access the EEPROM.	
E045	CORRUPT TUBE DATA ERROR The tube data checksum is wrong.	
E046	BUSY BUS **-** I2C ERROR I2C bus error, the bus remains always busy.	
E047	LICENCE — I2C ERROR I2C bus error while trying to access the Licence.	

Table 1 (*cont.*) Generator
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E048	DOOR ABORTED EXPOSURE The door switch has been opened before the end of the exposure.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E049	COMMUNICATIONS ERROR (Comms lost at the generator) The generator has lost the communications with the remoteconsole.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E050	ABORTED EXPOSURE ERROR The user has released the exposure device/s before the endof the exposure (Prep and/or Exp).	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E051	WRONG EXPOSURE TIME ERROR The exposure time is above the maximum (very unlikely) or itis so short that it is not reachable according to the present configuration (rise time and kVp decay/high voltage capacity).	Press the "*Reset*" button. If the error code persists, increase the exposure time. If the equipment remains inoperative, turn it OFF and call Field Service.
E053	FLUORO SYNC ERROR The timeout for receiving the fluoro synchronism pulse has elapsed.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E054	DIGITAL SYNC ERROR The timeout for receiving the Digital/DSI synchronism pulsehas elapsed.	
E055	NOT ENOUGH DOSE ERROR The backup timer has elapsed before the AEC or the Systemends the exposure.	
E056	NOT ENOUGH BACKUP TIME ERROR The backup timer has elapsed before the Tomograph endsthe exposure.	
E057	DUAL ENERGY ERROR It is not possible to load the Dual Energy parameters for thenext exposure.	Press the "*Reset*" button. Wait for the Tube/Generator to cool down or select a more suitable technique for the current thermal status. If the equipment remains inoperative, turn it OFF and call Field Service.
E058	TUBE1 DATA ERROR The tube data pointed by the tube 1 index are not defined, a default tube has been selected.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E059	TUBE2 DATA ERROR The tube data pointed by the tube 2 index are not defined, a default tube has been selected.	
E060	AUTOCAL ERROR The number of exposures to autocalibrate a mA station hasrun out.	
E061	LICENCE ERROR There has been an error while trying to access the Licencedata. Default options have been selected.	
E062	AEC ERROR AEC selection error.	Press the "*Reset*" button. If the error code persists, try selecting different parameters. If the equipment remains inoperative, turn it OFF and call Field Service.
E063	ROTOR READY ERROR The Ready from the starter has been lost before the end ofthe exposure.	

Table 1 (*cont.*) Generator Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E064	TANK FEEDBACK ERROR The Feedback connector from the tank is not plugged in.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E065	+24 DELAYED POWER SUPPLY FAILURE +24V delayed power is out of range.	
E066	+24 (UNR) POWER SUPPLY FAILURE +24V (unregulated) power supply is out of range.	
E067	**-** 15 POWER SUPPLY FAILURE **-** 15V power supply is out of range.	
E068	+3.3 POWER SUPPLY FAILURE +3.3V power supply is out of range.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E069	+24 PERMANENT (UNR) POWER SUPPLY FAILURE +24 permanent (unregulated) power supply is out of range.	
E070	AEC RAPID TERMINATION Exposure was aborted because a lack of radiation receivedon the AEC.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E071	INTERLOCK ERROR Exposure was aborted because an interlock configured to abort exposures has been deactivated during the exposure.	Press the "*Reset*" button. **If the e**rro**r code** per**sist**s, **t**u**rn the G**ener**at**or **OFF** an**d ON.** If the equipment remains inoperative, turn it OFF and call Field Service.
E072	POSITIONER OK ERROR Exposure was aborted because the signal Positioner OK (configured to be used as an interlock) has been deactivated during the exposure.	
E073	XON FEEDBACK ERROR Exposure was aborted because the signal XON Feedback has not been activated or has been deactivated during theexposure.	
E074	COP GENERATOR RESET ERROR The generator has been reset because of the COP module.	
E075	CLK GENERATOR RESET ERROR The generator has been reset because of the CLK module.	
E076	TRAP GENERATOR RESET ERROR The generator has been reset because of an illegal operationcode.	
E077	SOFTWARE INTERRUPT GENERATOR RESET ERROR The generator has been reset because of a software interrupt.	
E078	MEMORY OVERFLOW INTERRUPT GENERATOR RESETERROR The generator has been reset because of a memory overflow interrupt.	
E079	REQUIRED MA STATIONS CAL ERROR The required mA stations have not been calibrated.	At least one required mA station has not been properly calibrated.Call Field Service for mA stations recalibration.

Table 1 (*cont.*) Generator
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E091	HEARTBEAT ERROR (R2CP Protocol) The main controller is not receiving the Heartbeat messages within the configured timeout. R2CP (CAN) protocol functionality.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E099	INCORRECT MESSAGE Last message was not recognized as a SHFR protocol message.	
E101	NO SPEED AVAILABLE The starter does not allow starting the tube neither in high speed nor in low one.	
E102	LOW SPEED UNAVAILABLE The starter does not allow starting the tube in low speed.	
E103	HIGH SPEED UNAVAILABLE The starter does not allow starting the tube in high speed.	
E104	DOSIMETER TUBE 1 NO ANSWER ERROR The dosimeter of the tube 1 doesn't respond.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF, check the proper external cable connections and integrity of the dosimeter and then turnthe Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E105	DOSIMETER TUBE 1 TEST ERROR The dosimeter of the tube 1 didn't complete initialization test.	
E106	DOSIMETER TUBE 1 STATUS ERROR The dosimeter of the tube 1 answered a wrong or unexpected status.	
E107	DOSIMETER TUBE 2 NO ANSWER ERROR The dosimeter of the tube 2 doesn't respond.	
E108	DOSIMETER TUBE 2 TEST ERROR The dosimeter of the tube 2 didn't complete initialization test.	
E109	DOSIMETER TUBE 2 STATUS ERROR The dosimeter of the tube 2 answered a wrong or unexpected status.	
E125 to E240	System failure related to Dual Speed Starter.	Press the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.

6.2 SYSTEM ERROR CODES IN THE CONTROL PANEL

Error codes indicate the potential cause of a system failure. They appear on the Digital Control Panel Display and will enable the operator to indirectly convey the possible source of error to service personnel. This may prevent the need for a service call or enable service personnel to anticipate corrective actions prior to arriving on site.

Table 2
System Error Codes

ERROR	DESCRIPTION	WHAT TO DO
"E10"	Failure in memory Integrated Circuit.	Turn the System OFF / ON. If the error remains, turn it OFFand call Field Service.
"rAN Err"	Failure in Microcontroller.	Turn the System OFF / ON. If the error remains, turn it OFFand call Field Service.

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SECTION 7 OPERATING SEQUENCES

7.1 START-UP ROUTINE

Start-up the system as described in Section 3.

7.2 X-RAY TUBE WARM-UP PROCEDURE

Before effecting X-ray exposures ensure that the Tube is properly warmed-up. Make sure that no persons will be inadvertently exposed to unnecessary X-rays during this procedure.

Routine exposures should not be effected unless the Tube is previously warmed-up, this prolongs X-ray Tube life.

It is recommended that the following procedure will be performed for X-ray Tube warm-up, at the start of each day and when the Tube selected has not been in use for approximately one hour.

This warm-up procedure is used for a typical X-ray Tube. Consult the X-ray Tube manufacturer instructions for the actual Tube in use, comparing its recommendations with this procedure. If there is conflict with this procedure, comply with the Tube manufacturer's instructions.

Perform X-ray Tube warm-up as follows:

- Close the collimator blades fully.
- Select 70 kV, 100 mAs, 200 mA and 500 ms exposure.
- Insure that no one will be exposed.
- Make a total of three exposures, 15 seconds apart.

Excessive filament evaporation shortens X-ray Tube life. Minimize evaporation by keeping Exposure "Preparation" time to an absolute minimum.

7.3 RADIOGRAPHIC OPERATION

RAD operation can be performed in the following modes:

- One point control by selecting kV with AEC operations.
- Two point control by selecting kVp and mAs independently.
- Three point control by selecting kV, mA and Exposure Time independently.

A typical RAD examination sequence is as indicated below:

1. Make sure that the X-ray Tube is properly warmed-up.
2. Position the patient for the examination.
3. Select the "*DR Detector*" or "*Free Exposure*" *workstation*, and technique parameters using the Generator controls on the software Console.

Confirm the detector is in the proper receptor for the selectedworkflow prior to exposure.

4. Instruct patient to maintain the required position. Prepare the X-ray Tube by pressing the Handswitch push-button to the "*Prep*" position and maintain it until the "*Prep*" indicator is illuminated.
5. Instruct patient to remain still and to hold his breath as required, then make the X-ray exposure by pressing the Handswitch push-button fully to the "*Exp*" position and maintain it throughout the exposure. The "*X-ray On*" indicator will light and an alarm will sound during the exposure.
6. When the exposure is finished, release the Handswitch push-button.
7. Repeat the procedure if additional exposures are desired.

7.4 AEC OPERATION

The proper use of AEC requires accurate patient positioning. For examination using AEC, the operator will need to select the desired AEC parameters as follows:

1. Make sure that the X-ray Tube is properly warmed-up.
2. Position the patient for the examination.
3. Select the "*DR Detector*" workstation and enter in AEC mode byselecting at least one Area Detector "*Field*" on the Software Console.
4. If required, choose another *"Sensitivity"* and adjust the "*Density*" setting("*0*" is the normal setting).
5. Select the technique parameters using the Generator controls on the Console.
6. Continue with the radiographic operation. *(Refer to Section 7.3 - step 4.)*

7.4.1 AEC RAPID TERMINATION

Rapid Termination is a Safety device that cuts the X-ray exposure in case of an error with the selected Ion Chamber or the selected parameters (short backup time) are not appropriate for an exposure with AEC.

AEC Rapid Termination compares the AEC ramp with a 25% of the final value at the 30% of the Backup Time. It is activated after 30% of the exposure back-up time and after 10 ms of exposure, both conditions have to be fulfilled.

For a proper operation of the Rapid Termination feature, the operator must select an exposure back-up time higher or equal to 40 ms whenever the AEC is ON. Anyway, the back-up time must be selected according to the examination and patient, this exposure time is slightly higher than the worse case expected.

When AEC Rapid Termination is activated, Error Code "E070" is shown.

7.4.2 HOW TO VERIFY THE PROPER FUNCTIONING OF THE AUTOMATIC EXPOSURECONTROL

Note **.** *This procedure is not mandatory, it is only a method so that the operator can verify the proper functioning of the Automatic Exposure Control.*

1. Ensure that X-ray Tube has been properly warmed up.
2. Align and center the X-Ray Tube to the DR Detector.
3. Set a SID of 1 m (40”).
4. Collimate the X-Ray beam so that it completely covers all three Ion Chambers (Left, Center and Right).
5. Place on the Table-Top and within the X-Ray beam a homogeneous phantom (e.g. a bucket with 10 cm of water) that covers all three Ion Chambers.
6. Set a technique, for example: 70 kVp, 250 mA, 1.0 second back-up time.
7. Select “*Center*” Ion Chamber and Density “*Normal - 0*”.

   Make a RAD exposure and note the exposure mAs and time. For a proper functioning of the AEC, the exposure must not be aborted by the AEC back-up timer.
8. Deselect “*Center*” and select “*Left*” Ion Chamber.

   Make a RAD exposure and note the exposure mAs and time. For a proper functioning of the AEC, the exposure must not be aborted by the AEC back-up timer.
9. Deselect “*Left*” and select “*Right*” Ion Chamber.

   Make a RAD exposure and note the exposure mAs and time. For a proper functioning of the AEC, the exposure must not be aborted by the AEC back-up timer.
10. The noted Exposure mAs and time have to be equal ¦10% betweenall three Ion Chambers. If not, contact Service.

11. Repeat the above steps changing the Density and/or the homogeneous phantom (e.g. a bucket with 5 cm of water).

    Compare the Exposure mAs and time between each Ion Chamber and between the values noted before (for a lower density or less water, lower mAs and a shorter time; for half of density or half of water, half of mAs / time). If not, contact Service.

12. Finally, check the proper functioning of the AEC back-up timer by making a RAD exposure with the selections indicated in step 6., but with the Collimator blades fully closed.

    The exposure must be finished by the AEC back-up timer, that is, the exposure length is 1.0 second. If not, contact Service.

7.5 USING AND MAINTAINING THE DIGITAL DETECTOR

Before Exposure, check the equipment daily and confirm that it works properly.

The action of the Air-Conditioning or Heating may produce condensation in the equipment, wait until the condensation evaporates before performing an exposure. As a general rule, raise or lower the room temperature gradually to avoid condensation.

During exposure, do not use the Detector near devices generating a strong magnetic field.

For Wireless Detectors, do not cover the IR Data Port with hands or other parts of the body and do not use the selected frequency channel (2.4 GHz band) for other wireless devices.

After every examination, wipe with a cloth slightly damped the patient contact surfaces as well as the handle and Grid with disinfectants such as ethanol. For cleaning, wipe with a cloth damped in neutral detergent.

Note **.** *For further information on the Digital Detector Handling and Maintenance, refer to the Digital Detector manuals.*

7.6 GUIDELINES FOR PEDIATRIC APPLICATIONS

THE PRACTITIONER WILL BE THE ULTIMATE RESPONSIBLE OF APPLYING THE PROPER DOSE TO THE PATIENT FOR RADIOGRAPHIC PROCEDURES. THE PURPOSE OF THESE GUIDELINES IS TO HELP THE PRACTITIONER TO MINIMIZE POTENTIAL RISKS.

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

Children are more radiosensitive than adults. Adopting the Image Gently campaign guidelines and reducing dose for radiographic procedures while maintaining acceptable clinical image quality will benefit patients.

Please review the following link and reduce pediatric technique factorsaccordingly:
http://www.pedrad.org/associations/5364/ig/

As a general rule, next recommendations shall be observed in pediatrics:

- X-Ray Generator must have short exposures times.
- AEC must be used carefully, preferably use manual technique setting, applying lower doses.
- If possible, use high kVp techniques.
- As the use of Grids require higher doses, never use Grids in pediatric exams. Remove the Grid from the receptor assembly and select the lower possible doses. If the Grid can not be detached, pediatric exams can not be performed using this device.

Positioning the pediatric patient:

Pediatric patients are not as likely as adults to understand the need to remain still during the procedure. Therefore it makes sense to provide aids to maintaining stable positioning. It is strongly recommended the use **of immobilizing devices** such as bean bags and restraint systems (foam wedges, adhesive tapes, etc.) to avoid the need of repeating exposures due to the movement of the pediatric patients. Whenever possible use techniques based on the lowest exposure times.

Shielding:

We recommend you provide extra **shielding of radiosensitive organs or tissues such as eyes, gonads and thyroid glands.** Applying a correct collimation will help to protect the patient against excessive radiation as well. Please review the following scientific literature regarding pediatric radiosensitivity: *GROSSMAN, Herman. "Radiation Protection in Diagnostic Radiography of Children". Pediatric Radiology, Vol. 51, (No. 1): 141- 144,*
January, 1973: http://pediatrics.aappublications.org/cgi/reprint/51/1/141.

Technique factors:

You should take steps to reduce technique factors to the lowest possible levels consistent with good image acquisition.

For example if your adult abdomen settings are: 70**-** 85 kVp, 200**-** 400 mA, 15**-** 80 mAs, consider starting at 65**-** 75 kVp, 100**-** 160 mA, 2.5**-** 10 mAs for a pediatric patient. Whenever possible use high kVp techniques and large SID (Source Image Distance).

Summary:

- Image only when there is a clear medical benefit.
- Image only the indicated area.
- Use the lowest amount of radiation for adequate imaging based on size of the child (reducing tube output - kVp and mAs).
- Try to use always short exposure times, large SID values and immobilizing devices.
- Avoid multiple scans and use alternative diagnostic studies (such as ultrasound or MRI) when possible.

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SECTION 8 PERIODIC MAINTENANCE

In order to assure continued safe performance of the equipment, a periodic maintenance program must be established. It is the **owner's responsibility** to supply or arrange for this service.

There are two levels of maintenance, the first consists of tasks which are performed by the user/operator, and the second are those tasks to be performed by qualified X-ray service personnel.

The first periodic maintenance service should be performed twelve (12) months after installation, and the subsequent services at twelve (12) month intervals.

The manufacturer undertakes to have available spare parts for this equipment at least for ten (10) years after the unit manufacturing.

NEVER ATTEMPT TO PERFORM MAINTENANCE TASKS WHILE THE ME EQUIPMENT IN USE WITH A PATIENT.

8.1 OPERATOR TASKS

The tasks of this periodic maintenance shall include the following items:

DO NOT REMOVE ANY COVER, DISASSEMBLE OR MANIPULATE INTERNAL COMPONENTS IN THE UNIT. THESE ACTIONS COULD CAUSE SERIOUS PERSONAL INJURIES AND / OR EQUIPMENT DAMAGE.

NEVER ATTEMPT TO CLEAN ANY PART OF THE UNIT WHEN IT IS SWITCHED ON. ALWAYS SWITCH OFF THE EQUIPMENT AND ISOLATE THE MAINS ELECTRICALSUPPLY BEFORE CLEANING.

1. Switch the generator OFF.
2. Externally, check the proper cable connections between each major component in the X-ray system.
3. Cleaning and disinfection. *(Refer to Section 9).*

8.2 SERVICE TASKS

Only service personnel specifically trained on this medical X-ray equipment should work on service tasks (installation, calibration or maintenance) of the equipment. (*Refer to the respective chapters of the Service Manual provided with this equipment.)*

SECTION 9 CLEANING AND DISINFECTION

9.1 SCOPE

This section is part of the accompanying documents for the supplied equipment used in radiological diagnosis and is in accordance with the cleaning and disinfection requirements described in ISO-17664 in its 2017 revision.

DO NOT ATTEMPT TO CLEAN / DISINFECT ANY PART OF THE EQUIPMENT WHEN IN OPERATION.

BEFORE STARTING CLEANING / DISINFECTION MAKE SURE THE EQUIPMENT IS CORRECTLY OFF, WITH THE POWER CABLE DISCONNECTED FROM THE MAINS (IN CASE OF EQUIPMENT WITH A MAINS PLUG) OR WITH THE POWER SUPPLY CUT FROM THE ELECTRICAL PANEL IN THE ROOM (IN CASE OF EQUIPMENT PERMANENTLY CONNECTED TO THE ROOM ELECTRICAL CABINET).

DO NOT REMOVE ANY COVERS, OR DISASSEMBLE OR MANIPULATE INTERNAL COMPONENTS OF THE UNIT. THESE ACTIONS CAN CAUSE SERIOUS PERSONAL INJURYAND EQUIPMENT DAMAGE.

The operator must follow the personal cleaning processes before and after each performance.

The waste and utensils used for cleaning and disinfecting the equipment must be disposed of locally in the waste containers specifically designated for this purpose by the person in charge of the installation according to local regulations.

9.2 DESCRIPTION

The document describes the cleaning and disinfection step by step of all thesurfaces of the equipment used for radiological diagnosis.

Likewise, the products and techniques to be used to carry out the cleaning and disinfection process are indicated.

IN CASE OF CLEANING AND DISINFECTION PROCESSES WITH RISK OF CONTACT WITH BLOOD OR TISSUE REMAINS, THE OPERATOR MUST USE PERSONAL PROTECTION MEANS SUCH AS GOWNS, GOGGLES AND MASKS TO AVOID CONTAGION.

FOR CLEANING OR DISINFECTING THE EQUIPMENT, DO NOT USE SPRAYERS, OR APPLY LIQUIDS DIRECTLY ON SCREENS OR OTHER SURFACES.

BEFORE USING THE EQUIPMENT AGAIN, THE USER MUST HAVE HANDS CLEAN AND COMPLETELY DRY, WITHOUT REMAINING DISINFECTING PRODUCTS LIKE WIPES ORHYDROALCOHOLIC GEL.

DO NOT USE ANY CLEANING OR DISINFECTION PRODUCTS NOT INCLUDED IN THIS DOCUMENT SINCE THE EQUIPMENT COULD BE DAMAGED.

Note **.**

It is recommended that the Receptors used outside the equipment (Radiographic Film in Cassette, CR or Digital Detectors) are placed inside a plastic radiotransparent bag for each use, thus avoiding the excess of cleaning and disinfection processes directly on the surfaces of the Receptors. Do not use fabric bags.

9.3 MANUAL CLEANING

Note **.** *The cleaning of the equipment must be carried out according to the frequency of use and the environmental conditions of the place where it is located, these times must be marked according to theuser's criteria.*

9.3.1 CHEMICAL AGENTS AND WATER QUALITY

Prepare the solution to be used with:

a. Drinking water at room temperature.

b. PH Neutral soap (for example Universal Cleaner**-** PH Neutral by Frosch or equivalent). To determine the amount and time of application, see the manufacturer's instructions.

The total amount of solution depends on the surface to be cleaned. Change the solution as many times as necessary to maintain the quality of the cleaning, flush the drain and redo another solution.

9.3.2 DESCRIPTION OF MATERIALS AND ACCESSORIES

- Vinyl, nitrile, latex or similar gloves. Discard gloves after cleaning is complete. Attention to possible allergic reactions to the components.
- Other recommended personal protection material: mask, gown,goggles.
- Lint-free cloths for rubbing (e.g. microfiber, suede, etc.)
- Lint-free cloths to dry (e.g. cotton, etc.)
- Container to dissolve.
- Lint-free cloths for specific surfaces such as for touch screens or monitors.
- Brushes for slots and grids.

9.3.3 CLEANING STEP BY STEP

1. Wash hands, cover wounds if any, and put on the personal protection material required for cleaning as indicated by the corresponding regulations and the guidelines of the center where the equipment is located. Gloves and protective glasses are recommended.

2. Prepare the solution to use. (See section 2.1 Chemical Agents and Water Quality.)

3. Prepare the material to use for cleaning. (See section 2.2 Description of Materials and Accessories.)

DURING THE EQUIPMENT CLEANING PROCEDURE, DO NOT USE SPRAYERS, OR APPLY LIQUIDS DIRECTLY TO SCREENS OR OTHER SURFACES.

4. Rub the covers and external surfaces, especially those in contact with the patient, with a soft and Lint-free cloth impregnated in the solution and manually wrung out (moistened so as not to drop drops) and that does not damage the surfaces or release fibers.

5. Wash the cloth with clean water after each use.

6. Rinse the surface with a cloth dampened in clean water. The cloth must be manually wrung out so that it does not leave liquid remains.

7. Repeat the operation, rinsing and draining the cloth until the surface isclean.

8. Dry surfaces with a soft dry cloth that does not release fibers, especially on rough surfaces.

IN THOSE PARTS IN CONTACT WITH THE PATIENT (E.G. TABLETOPS OR HANDLES) OR IN FREQUENT CONTACT BY THE USER (E.G. CONSOLES, TOUCH SCREENS, CONTROL PANELS, CONTROLS TO PERFORM EQUIPMENT MOVEMENTS, ETC.). CARRY OUT THE SAME CLEANING OPERATION BUT USE A CLEAN LINT-FREE CLOTH IMPREGNATED WITH ISOPROPYL ALCOHOL IN A 70% SOLUTION INSTEAD.

9.4 MANUAL DISINFECTION

Note **.** *The disinfection of the equipment must be carried out according to the frequency of use and the environmental conditions of the place where it is located, these times must be marked according to the user's criteria.*

9.4.1 CHEMICAL AGENTS AND WATER QUALITY

The following chemical agents are those validated by the equipment manufacturer to carry out the disinfection tasks. Only use these agents in the indicated proportions.

Never mix the indicated chemical agents, they could cause chemical reactions and / or damage to the equipment surfaces.

- **Drinking water at room temperature with household bleach in 1:50 ratio.**
- Contact time: 5 minutes.

  To prepare the 1:50 bleach-water mix, put 20 ml. of household bleach into a 1**-** liter bottle and fill the bottle with water to completion. Close and flipseveral times to mix.
- **70% isopropyl alcohol.**

  Contact time: 2 minutes for touchscreens or monitors and 5 minutes forthe rest. Times to mix.
- **Ethyl alcohol (ethanol) 70%.**

  Contact time: 5 minutes for Digital Detectors.

- **0.036% alkyldimethyl benzyl ammonium chloride** in hydroalcoholic solution.

  Contact time: 5 minutes

Table 3
Disinfectants to be used according to surfaces

Disinfecting Agent	Types of surfaces to be disinfected			
	(*) Screens or monitor	Digital Detectors	(*) Laptops	Rest of surfaces
Drinking water at room temperature with household bleach in 1:50 ratio	p			p
70% isopropyl alcohol.	p		p	p
Ethyl alcohol (ethanol) 70%.		p		p
Alkyl dimethyl benzyl ammonium chloride 0.036% in hydroalcoholic solution.				p

Notes:
- The contact time of the disinfecting agent on screens or monitors should not exceed 2 minutes.
- Laptops should never be disinfected with bleach.

9.4.2 DESCRIPTION OF MATERIALS AND ACCESSORIES

- Vinyl, nitrile, latex or similar gloves. Discard gloves after cleaning is complete. Attention to possible allergic reactions to the components.
- Other recommended personal protection material: mask, gown, goggles.
- Lint-free cloths for rubbing (e.g. microfiber, suede, etc.)
- Lint-free cloths to dry (e.g. cotton, etc.)
- Container to dissolve.
- Lint-free cloths for specific surfaces such as for touch screens o monitors.
- Brushes for slots and grids.
- Disinfecting wet wipes. Use only in cases where the container with the solution cannot be moved and make sure not to leave residues of disinfectant on the wipe or fibers, especially on the cracks or rough surfaces.

9.4.3 DISINFECTING STEP BY STEP

1. Wash hands, cover wounds if any, and put on the personal protection material required for cleaning as indicated by the corresponding regulations and the guidelines of the center where the equipment is located. Gloves and protective glasses are recommended.

2. Prepare the solution to use. (See section 3.1 Chemical Agents and Water Quality.)

3. Prepare the material to use for cleaning. (See section 3.2 Description of Materials and Accessories.)

DURING THE EQUIPMENT DISINFECTION, DO NOT USE SPRAYERS, OR APPLY LIQUIDS DIRECTLY TO SCREENS OR OTHER SURFACES.

4. Rub the covers and external surfaces, especially those in contact with the patient, with a soft and clean cloth impregnated in the solution and manually wrung out (moistened so as not to drop drops) and that does not damage the surfaces or release fibers.

5. Allow sufficient time for the chemical to have a disinfecting effect on surfaces (contact time is indicated in section 3.1 Chemical Agents and Water Quality).

6. Rinse the surface with a cloth dampened in clean water. The cloth must be manually wrung out so that it does not leave liquid remains.

7. Repeat the operation, rinsing and draining the cloth until the surface is clean.

8. Dry surfaces with a soft dry cloth that does not release fibers, especially on rough surfaces.

SECTION 10 TECHNICAL SPECIFICATIONS

Note **.** *These Technical Specifications do not include the Digital Detector nor the Image Acquisition Computer and Screen. Refer to the Digital Detector and Image Acquisition Computer and Screen Documentation.*

10.1 ENVIRONMENTAL CONDITIONS

ATMOSPHERIC PRESSURE (hPa)		RELATIVE HUMIDITY (%)		AMBIENT TEMPERATURE	
MIN	MAX	MIN	MAX	MIN	MAX
WORKING					
700 hPa (20.7 inHg)	1060 hPa (31.3 inHg)	30%	75%	10 ^{O}C (50 ^{O}F)	35 ^{O}C (95 ^{O}F)
TRANSPORT & STORAGE					
500 hPa (14.7 inHg)	1060 hPa (31.3 inHg)	10%	90%	-20 ^{O}C (-4 ^{O}F)	70 ^{O}C (158 ^{O}F)

10.2 POSITIONERS

10.2.1 POWER LINE REQUIREMENTS

Note **.** *The Tube Stand and the Wall Stand (ET or ST) are power supplied through the Table. In the case of Single Panel system, the Tube Stand and Wall Stand are supplied from the Control Unit.*

- ET TABLE (Elevating Table) ..... 115**-** 240 V~, 500 VA, 50 / 60 Hz,
  (supplied from the Room Electrical Cabinet)
- ST TABLE (Non Elevating Table) .... 115**-** 240 V~, 250 VA, 50 / 60 Hz,
  (supplied from the Room Electrical Cabinet)
- TUBE STAND
  Input Brakes . . . . . 24 V⎓, 100 VA
  Input Collimator . . . . . 24 V⎓, 30 VA
  . . . . . 24 V~, 50 / 60 Hz, 30 VA
  Input Digital Control Panel . . . . . 230 V~, 50 / 60 Hz, 30 VA
  (supplied from the Table or Control Unit in case of Single Panel system)
- WALL STAND
  Input Brakes . . . . . 24 V⎓, 100 W
  (supplied from the Table or Control Unit in case of Single Panel system)

10.2.2 INFORMATION RELATED TO RADIATION

Radiation Output Accuracy: C.V. (Coefficient of Variation) ≤ 0.05
(Reproducibility related to loading factors)

Maximum Symmetrical Radiation Field:
Measured at 75 kVp: 230 mm in “X” axis and 260 mm in “Y” axis. Measured at 125 kVp: 220 mm in “X” axis and 260 mm in “Y” axis.
(Test performed at a distance from the Focal Spot of 1200 mm, in accordance with IEC 60806: 1984)

10.2.3 PHYSICAL CHARACTERISTICS

FLOOR MOUNTED TUBE STAND

Dimensions	
Height	2319.5 mm (91.3”)
Width	2250 mm (88.6”)
Length	1413.6 mm (55.6”)
Weight	224 kg (493 lb)
Maximum Height of X-ray Tube focus (vertical position)	1981 mm (78”)
SID from horizontal axis of X-Ray Tube facing the ET Table (maximum)	1458.8 mm (57.4”)
SID from horizontal axis of X-Ray Tube facing the ST Table	1260.8 mm (49.6”)
Distances from the floor to Focal Spot ofthe X-Ray tube facing the Wall Stand	
Minimum height	397.1 mm (15.6”)
Maximum height	1950.9 mm (76.8”)
Arm vertical travel	1553.8 mm (61.2”)
SID from Horizontal axis of X-Ray Tube facing the Wall Stand (typical room layout)	
Minimum SID	1000 mm (39.4”)
Maximum SID	2645 mm (104.1”)
Column longitudinal motion	1645 mm (64.7”)
Rotation of Column with respect to its vertical axis *(Rotation may be limited by cables)*	±180^{o}
Rotation of Tube-Collimator Assembly with respect to its transverse axis *(Rotation may be limited by cables)*	+180^{o} --130^{o}

ET TABLE

Dimensions

Maximum HeightMinimum	895 mm (35.2”)
Height	550 mm (21.6”)
Length	2200 mm (86.6”)
Width	868 mm (34.2”)
Weight	335 Kg (738.5 lbs)
Dimensions of Floating Table-Top	2200 x 868 mm (86.6” x 34.2”)
Radiotransparent area of Table-top	2100 x 618 mm (83” x 24”)
Table-Top / Digital Detector distance	90 mm ± 5 mm (3.5” ± 0.2”)
Tabletop Attenuation	<1.2 mm eq. Al at 100 kV.
Vertical Tabletop Travel	340 mm (13.4”)
Longitudinal Travel of Table-top	1100 mm (43.3”)
Transverse Tabletop Travel	250 mm (9.8”)
Maximum patient weight . . . . . (evenly distributed on the Table-top) Detector	350 Kg (771 lbs)
size	max. 43 x 43 cm (17 x 17”)

ST TABLE

Dimensions	
Height	770 mm (30.3”)
Length	2200 mm (86.6”)
Width	825 mm (32.5”)
Weight	155 kg (341.7lb)
Dimensions of Floating Table-Top	2200 x 825 mm (86.6” x 32.5”)
Radiotransparent Area of Table-Top	1980 x 681 mm (78” x 26”)
Table-Top / Digital Detector distance	80 mm (±4) (3.14”, ±0.15”)
Table-Top Attenuation	<1.2 mm Al eq. at 100 kW900
Longitudinal travel of Table-Top	mm (35.4”)
Transverse travel of Table-Top	230 mm (9.1”)
Maximum patient weight . . . . . (evenly distributed on the Table-top) Detector	300 Kg (661.3 lbs)
size	max. 43 x 43 cm (17 x 17”)

WALL STAND

Dimensions	
Height	2235 mm (88”)
Width	712.2 mm (28”)
Length	381 mm (15”)
Weight	145 kg (319.6 lb)
Table-Top Dimensions	559 x 485 mm (22” x 19”)
Table-Top / Detector distance	40 mm (¦ 3) (1.57” (¦0.11”))
Table-Top Attenuation	<0.85 mm Al eq.
Height from horizontal axis of receptor	
Maximum heightMinimum	1900 mm (74.8”)
height	345.5 mm (13.6”)
Table-Top Vertical Travel	1554.5 mm (61.2”)
Detector size	max. 43 x 43 cm (17 x 17”)

Illustration 27
Dimensions of the Radiographic Room - Proteus XR/f ET (Elevating Table)

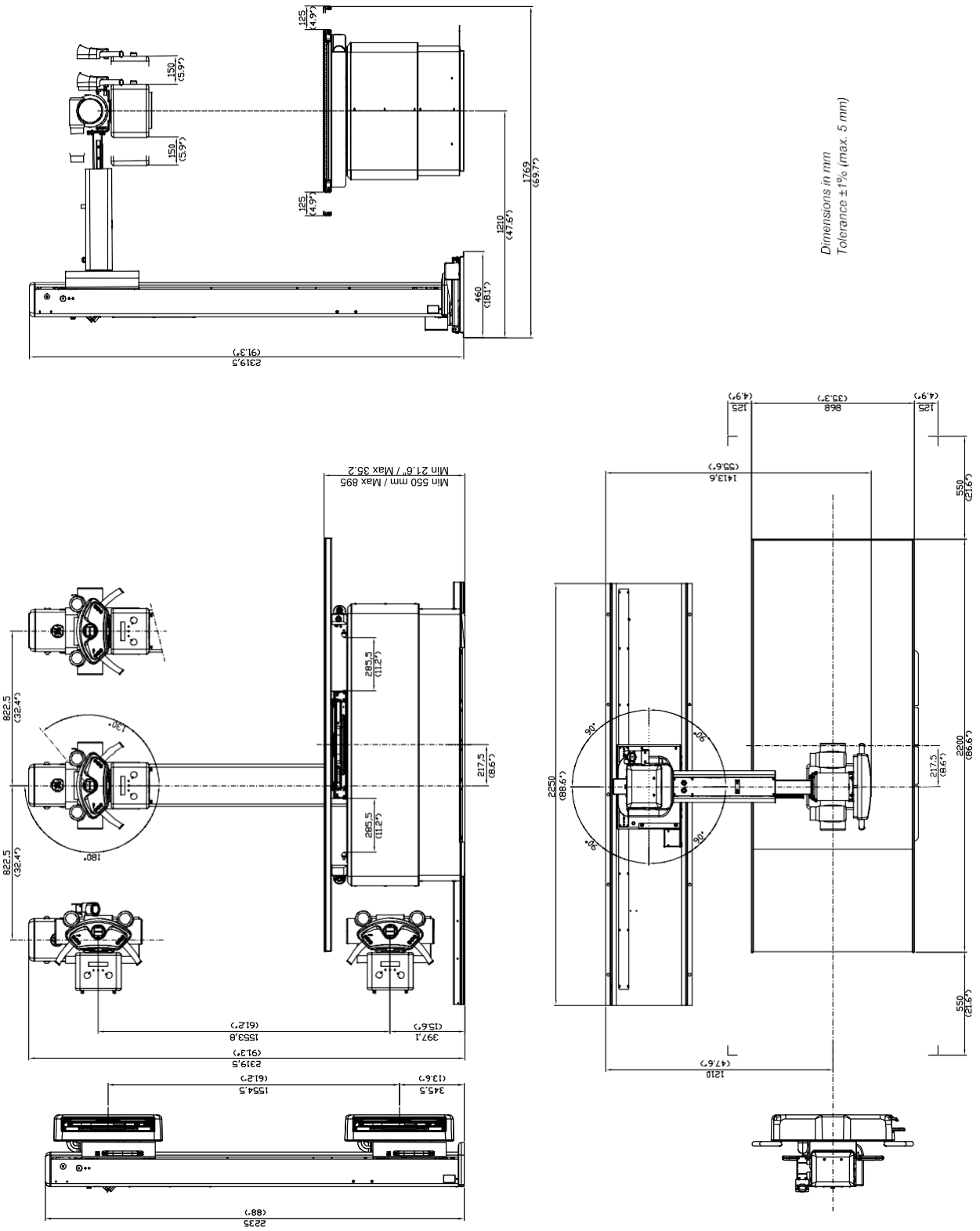


Illustration 28
Dimensions of the Radiographic Room - Proteus XR/f ST (non Elevating Table)

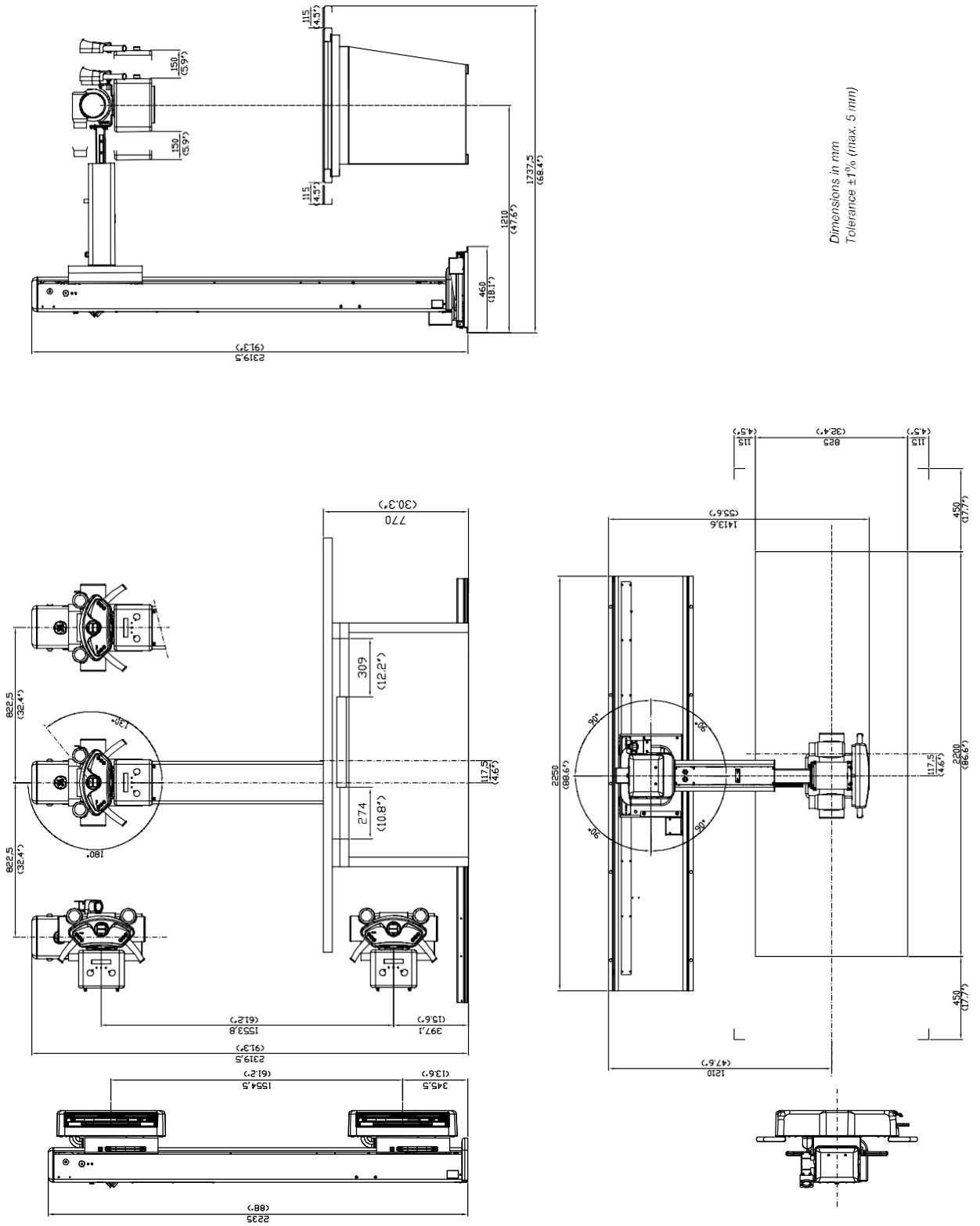


Illustration 29
Dimensions of the Radiographic Room - Proteus XR/f Single Panel Option

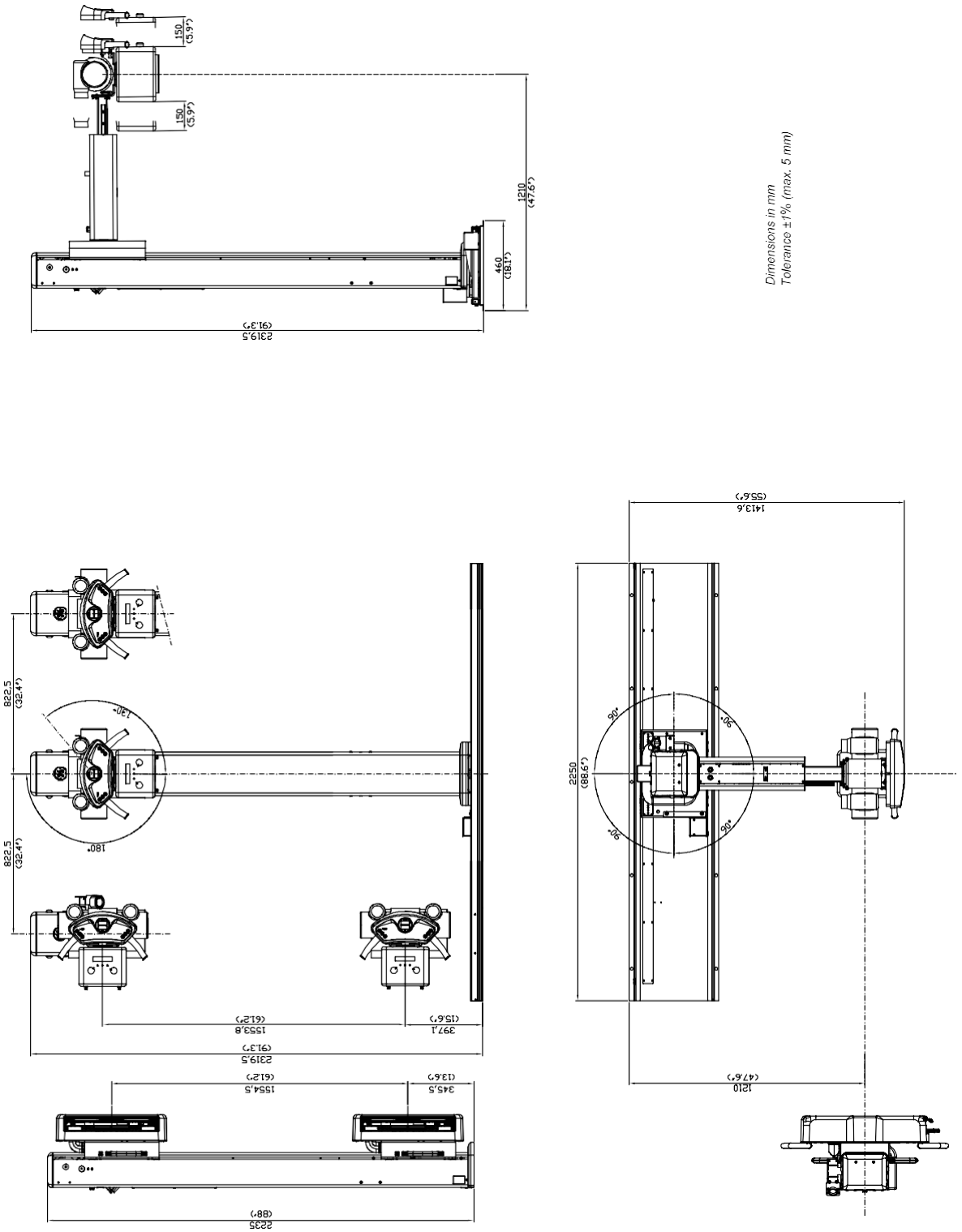
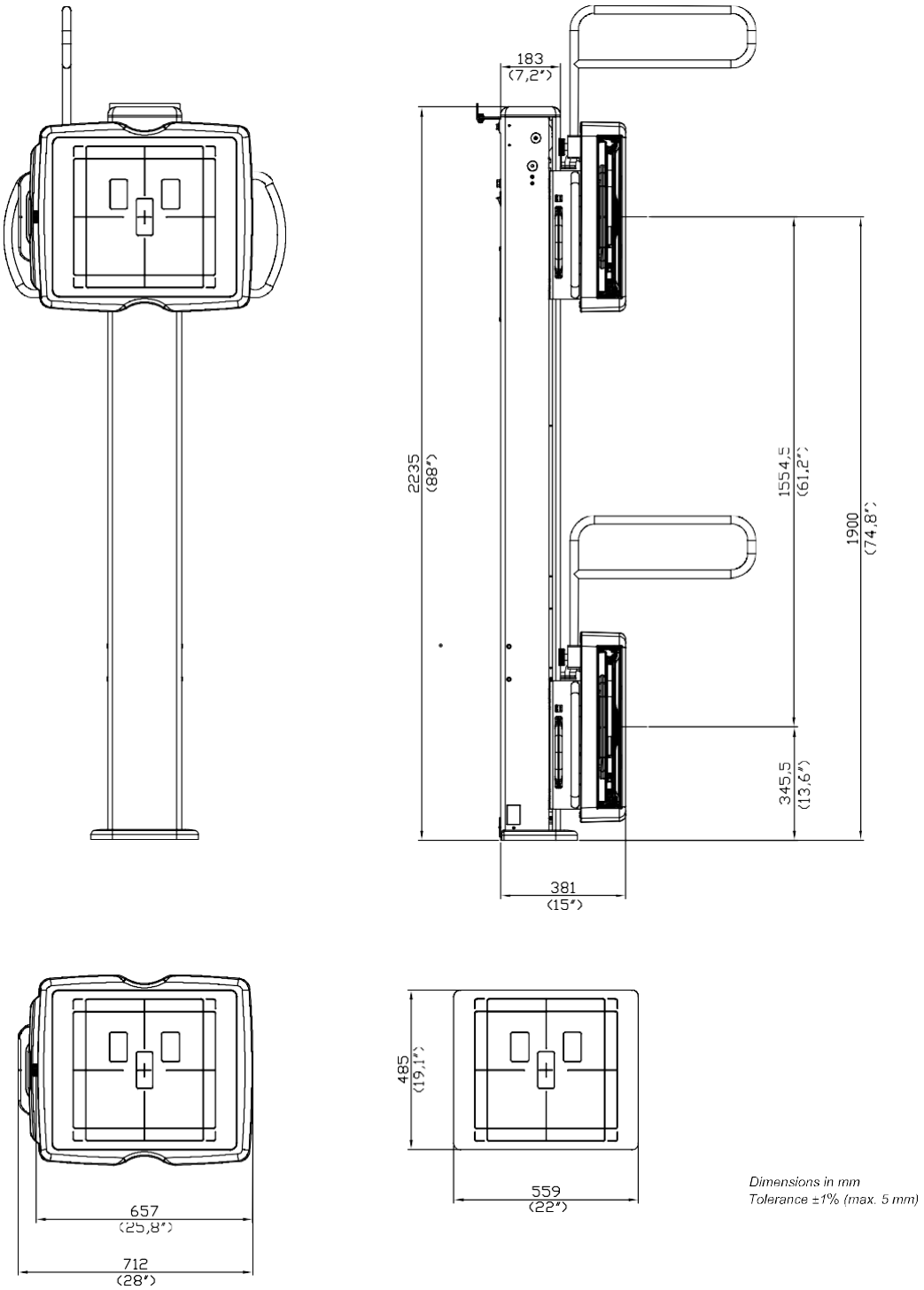


Illustration 30
Dimensions of the Wall Stand for Portable Detector



10.3 X-RAY GENERATOR

10.3.1 FACTORS

GENERATOR MODEL *(Refer to Identification Label)*	**SINGLE-PHASE GENERATOR**
Maximum Power kW	**50 kW**
Maximum mA	650 mA
Maximum kVp	125 kVp
Power Line	208*/230 V~ **-** 50/60 Hz
	Line voltage automatic compensation: ±10%.
	Maximum line regulation for maximum kVA demand: 6%.
*NOTE: * For Generators operating with lines at 208* V~ *or below, an auxiliary boost transformer is required to adequate the line voltage to 230* V~*.*	

GENERATOR MODEL *(Refer to Identification Label)*	**THREE-PHASE GENERATOR**		
Maximum Power kW	**50 kW**	**65 kW**	**80 kW**
Maximum mA	650 mA	650 mA	800 mA
Maximum kVp	150 kVp		
Power Line	208/230/400/415/440/480 V~ **-** 50 / 60 Hz		
	Line voltage automatic compensation: ±10%.		
	Maximum line regulation for maximum kVA demand: 6%.		

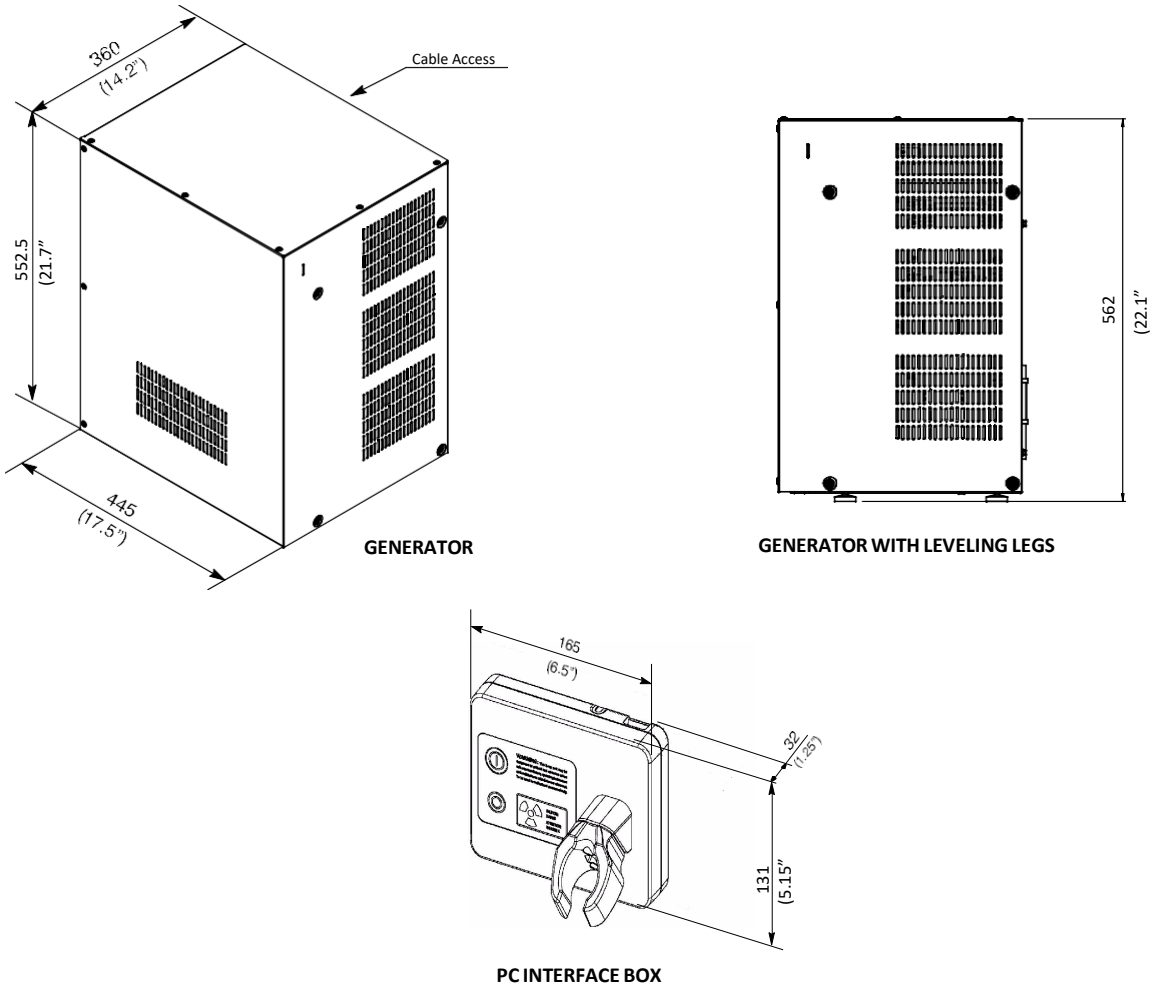
10.3.2 RANGE OF RADIOGRAPHIC PARAMETERS

PARAMETER	RANGE
kVp	From 40 kV to 150 kV in 1 kV steps Accuracy: ±(3% + 1 kVp)
mA	From 10 mA to 800 mA through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 65, 80, 100, 125, 160, 200, 250, 320, 400, 500, 650, 800. *(Depending on the Generator model)* Accuracy: ±(4% + 1 mA)
mAs	Product of mA x Time values from 0.1 mAs to 650 mAs Accuracy: ±(10% + 0.2 mAs)
ms	From 1 to 10000 milliseconds through the following Time stations: 1, 2, 3, 4, 5, 6, 8, 10, 12, 16, 20, 25, 32, 40, 50, 65, 80, 100, 125, 160, 200, 250, 320, 400, 500, 650, 800, 1000, 1250, 1600, 2000, 2500, 3200, 4000, 5000. 6500, 8000 and 10000. *(Depending on the Generator model)* Accuracy: ±(2% + 0.1 ms)
AEC	mAs: 0.1 mAs to 500 mAs
	Exposure Time: Nominal shortest irradiation Time = 11 ms
Max ms (with Digital Detector)	Refer to the Digital Detector specifications
Duty Cycle	1 maximum power exposure at 100 ms, every minute during 8 hours.
	The Duty Cycle of the Generator is continuous, but limits must be programmed during installation according to the X-ray Tube capacity to be used. Maximum leakage radiation depends on the type of X-ray Tube.
Radiation Output Accuracy (Reproducibility related toloading factors)	C. V. (Coefficient of Variation) ≤ 0.05

10.3.3 PHYSICAL CHARACTERISTICS

COMPONENT	DIMENSIONS			WEIGHT
	Length	Width	Height	
X-ray Generator with Leveling Legs	445 mm (17.5”)	360 mm (14.2”)	min. 562 mm (22.1”)	65 kg (143 lb)
PC Interface Box	131 mm (5.2”)	165 mm (6.5”)	32 mm (1.25”)	0.5 kg (1.1 lb)

Illustration 31
Generator and PC Interface Box Dimensions



GENERATOR

GENERATOR WITH LEVELING LEGS

PC INTERFACE BOX

10.4 X-RAY TUBE

Canon E7254FX	High Speed **-** Rotating Anode, Focal Spots: 0.6 mm / 1.2 mm Anode kHU / kVp: 400 kHU / 150 kVp, Target Angle: 12° Maximum Specified Energy Input in 1 hour: 150 kVp @ 4800 mAs Inherent Filtration of X-ray Source (Tube + Collimator): refer to Identification Label

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