SEDECAL

Technical Publication
OM-0310R10_EN_SED

Operation

U-Arm Positioner

SEDECAL X PLUS (LP) PLUS

CE
0120

This product bears a CE marking in accordance with the provisions of the 93/42/EEC MDD dated June 14, 1993, as amended by 2007/47/EC dated September 5, 2007.

Este producto ostenta una marca CE de acuerdo con las disposiciones de la Directiva 93/42/CEE del 14 de Junio de 1993 sobre Productos Médicos, modificada por la directiva 2007/47/CE del 5 de septiembre de 2007.

Ce produit porte la marque CE de conformité aux règlements de la Directive 93/42/CEE du 14 juin 1993 relative aux Produits médicaux, modifiée par la directive 2007/47/CE du 5 septembre 2007.

This manual covers the following equipments / Este manual cubre los siguientes equipos / Ce manuel couvre les équipements suivants
Radiographic System SEDECAL X: **SEDECAL X PLUS LP PLUS**

Manufactured by:
Fabricado por:
Fabriqué par:

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REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	SEP 19, 2006	First edition
1	FEB 19, 2008	Quality Assurance Suggestions
2	SEP 15, 2009	Improved messages tables and EMC
3	SEP 28, 2010	New password
4	OCT 5, 2011	Ralco Automatic Collimator included
5	JAN 25, 2013	IEC Standards Update
6	OCT 10, 2013	Stitching option added.
7	DEC 10, 2013	Fast Stitching and Image Preview options added.
8	JUL 23, 2014	New Handle.
9	MAY 11, 2015	Receptor Assembly for Digital Detectors added.
10	JUL 10, 2018	New Receptor Assembly for Digital Detectors added and IEC Standards Update

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.

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 OR DATA.

Advise of conditions or situations that if not heeded or avoided could cause personal injury or damage to equipment or 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 ***U-Arm Positioner.*** It provides a general description, safety information, operating instructions and specifications concerning the equipment. It is not intended to teach radiology or to make any type of clinical diagnosis.

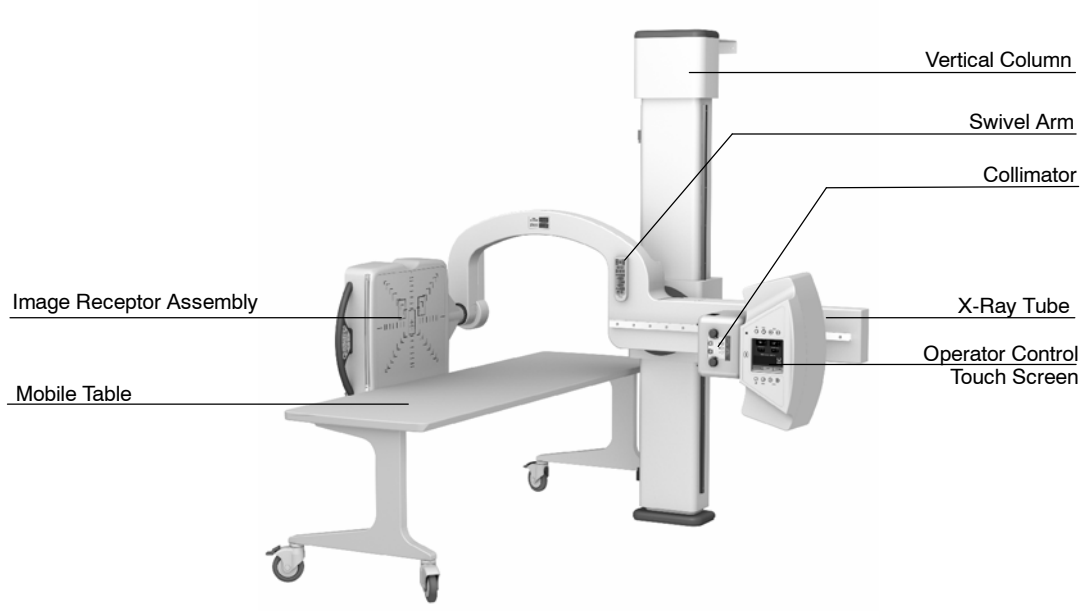
Basically, this Positioner consists of the following associated subassemblies: Vertical Column, Swivel Arm with variable height, X-ray Tube, Collimator, Touch Screen Control and Image Receptor Assembly.

The Positioner and the Patient Mobile Table are associated equipment to the Generator X-ray Unit.

The Control Panel is ergonomically built, equipped with controls and indicators logically arranged and easily accessible. Duplicate of controls are present at the Image Receptor Assembly and Remote Control for a better accessibility and handling of the equipment in accordance with the movement to be performed.

All the movements of the Swivel Arm are motorized. A soft thumb pressure on the control buttons allows the linear and rotation movements. Undertable and Thorax positioning of the Image Receptor are automatically performed by holding pressed the respective controls at the Image Receptor Assembly and Remote Control. The Unit includes different automatic positionings and allows radiographic exposures to patients in standing position and sitting or laying over a mobile table.

Illustration 1-1
U-Arm Positioner



1.1 GENERAL FEATURES

The main features of the **U-Arm Positioner** are:

- A solid and ergonomic design.
- Rotation and vertical motorized movements of Swivel Arm, and motorized SID adjustment of the Tube-Collimator Assembly.
- Automatic motorized and programmable movements for Image Receptor Assembly positioning - Undertable, Thorax and Customized positioning.
- Motorized rotation movement of Image Receptor Assembly in relation to its transverse axis.
- Cassette / Detector (max. 430 x 430 mm).
- Touch Screen PC for operation.
- Remote Control Unit.
- Manual rotation movement of Tube-Collimator Assembly in relation to its transverse axis.
- Universal Radiographic Mobile Table with accessories.
- Grid: Removable Grids or Oscillating Grids according to Receptor version.

1.2 OPTIONS

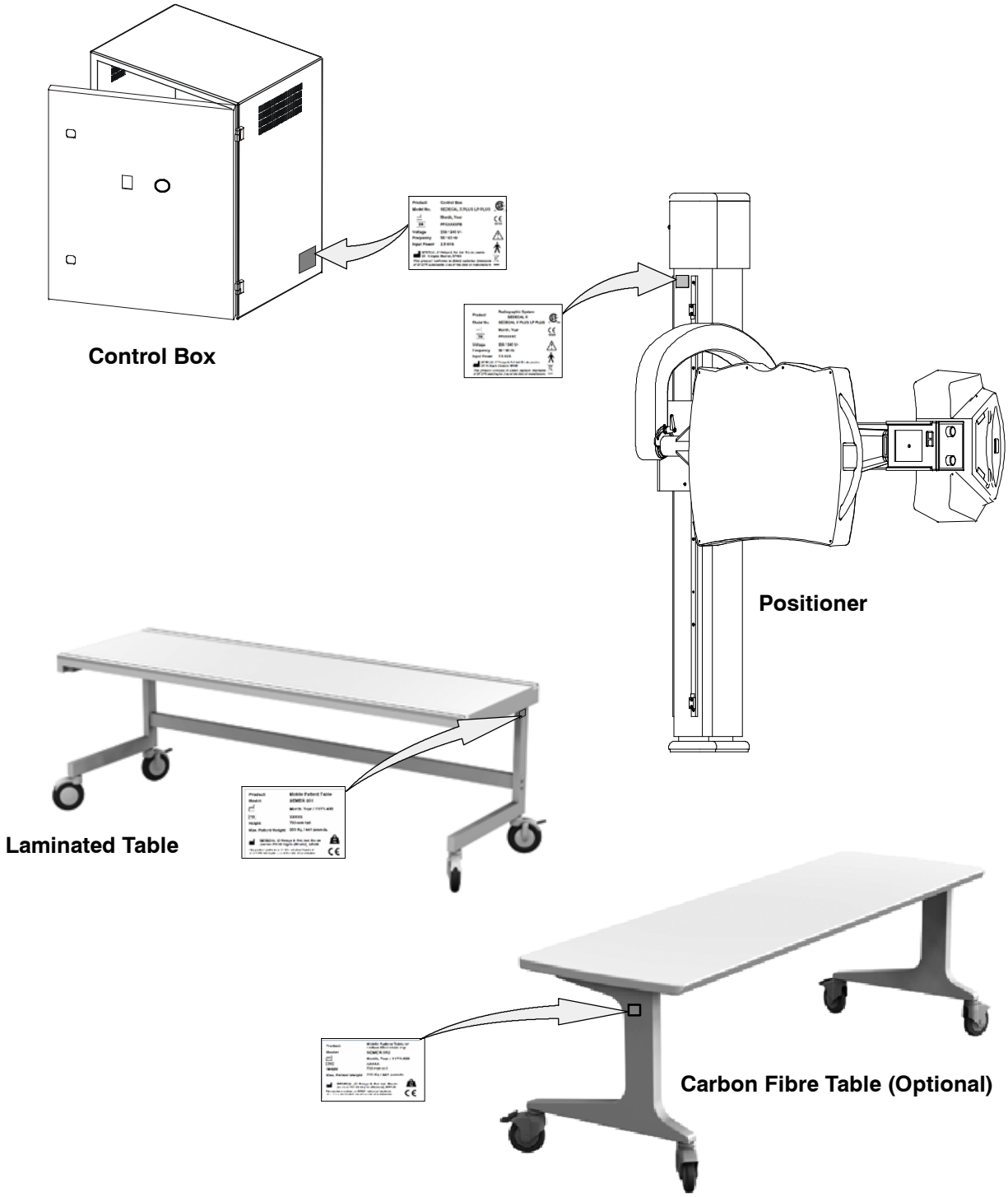
- *Radiographic Mobile Table* with Carbon Fiber Table-Top.
- *Head Support* for Table.
- *Automatic Collimator*.
- *Dosemeter Device*.
- *Arm Support* .
- *Stitching*.

1.3 PRODUCT IDENTIFICATION

The major items in the equipment 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.

Illustration 1-2
Identification Labels



1.4 INDICATIONS FOR USE

1.4.1 INTENDED USE

This equipment is intended for use by qualified personnel only.

The **U-Arm Positioner** is equipment included in a Medical Equipment System designed for general radiography in hospitals, clinics and medical practices to provide X-ray radiographic images of the skeleton, skull, chest, abdomen, extremities and other body parts.

Images can be obtained with the patient in the sitting, standing or lying position. Examinations can be performed to any kind of patient group. Patients may be physically abled, disabled, immobilized or shocked.

As example of X-ray image receptors types that can be used: Cassette with Film, CR (Computed Radiography) or Digital Detector.

1.4.2 NORMAL USE

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

1.4.3 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 especifically designed for paediatric purposes, if children are to be examined, they should always be accompanied by an adult.

1.5 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 Radiographic Mobile Table.
- Tabletop of the Positioner.
- Arm Support (optional).
- Other accessories.

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

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 SAFETY INSTRUCTIONS.

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.

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.

WARNING

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 + 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 panel of 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 articulated joint	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-RAY RADIATION.

THE MANUFACTURER DOES NOT ACCEPT ANY RESPONSIBILITY FOR OVEREXPOSURE OF PATIENTS OR PERSONNEL TO X-RAY RADIATION GENERATED BY THIS EQUIPMENT WHICH IS A RESULT OF POOR OPERATING TECHNIQUES OR PROCEDURES.

NO RESPONSIBILITY WILL BE ASSUMED FOR ANY EQUIPMENT THAT HAS NOT BEEN SERVICED AND MAINTAINED IN ACCORDANCE WITH THE MANUFACTURER INSTRUCTIONS, OR WHICH HAS BEEN MODIFIED OR TAMPERED WITH IN ANY WAY.

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 AND THE 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 dosemeter.

- Use the different 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 with the use of instruments to measure exposure to radiation. 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 thermoluminiscent 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

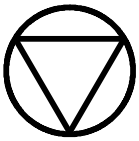
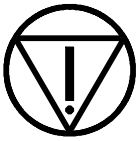
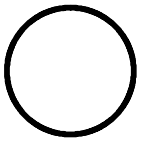
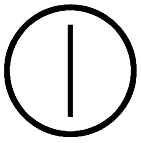
The following safety symbols may appear in the equipment.

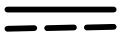
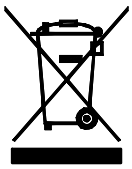
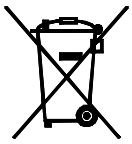
Their meaning are described below.

	**Caution. Consult accompanying documents.**
	**Safety Symbol. Follow instructions for use, especially those instructions 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)*

	**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: Dangerous voltage.**
	**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.**

	**Stop (of action).**
	**Emergency stop.**
	“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 Permanently Installed 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 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.**
 **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 the symbol 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 in excess 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 ***U-Arm Positioner*** covered by this Operation Manual is authorized to be marked with **CE MARKING** in accordance with the provisions of the Council Directive 93 / 42 / EEC as amended by 2007/47/EC concerning Medical Devices.

Statement of Compliance with IEC 60601-1-3: ***U-Arm Positioner*** *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: ***U-Arm Positioner*** *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* ***U-Arm Positioner*** *conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.*

Note ☞ ***U-Arm Positioner*** *model or type references are stated at the back of the cover page of this document.*

2.7.2 ENVIRONMENTAL STATEMENT ON THE LIFE 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-cycle of 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.
- *Permanently Installed Equipment.*

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

Protection against electric shock hazards in accordance with Standards: IEC 60601–1:1988, 2005 and 2012, IEC 60601–2–7:1998, IEC 60601–2–54:2009 and 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/CEE AS AMENDED BY 2007/47/EC, 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, 2005 and 2012.

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

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, 2005 and 2012.

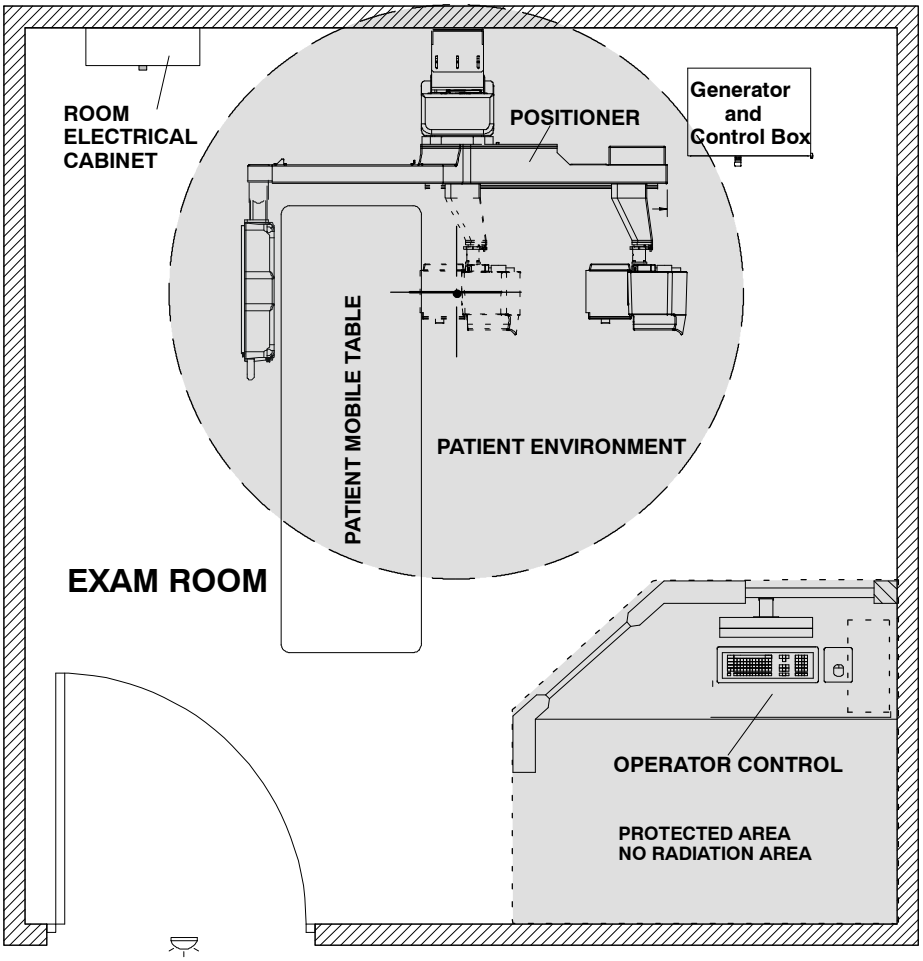
2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Protection against hazards from unwanted or excessive radiation in accordance with Standard IEC 60601–1:1988 and 2005, and IEC 60601–1–3:1994, 2008 and 2013.

2.7.8 DESIGNATED SIGNIFICANT ZONES OF OCCUPANCY

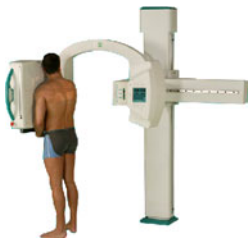
X-ray equipment specified for examinations that do not need the operator or staff to be close to the patient during normal use shall be provided with means to allow the following control functions from a "*Protected Area*" (*refer to illustration below*):

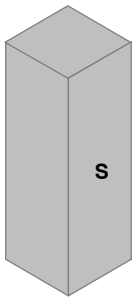
- Selection and control of modes of operation.
- Selection of loading factors for the exposure.
- Actuation of the exposure controls.
- Other necessary controls for the operator during exposure.

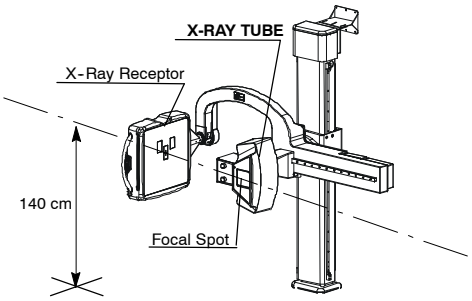


X-Ray equipment specified for any radiological examination that requires the operator or staff to be close to the patient during normal use (e.g. some pediatric examinations or other types of examinations for patients that may require assistance), shall have at least one *"Significant Zone of Occupancy"*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

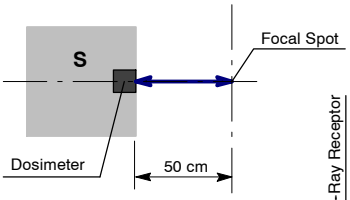
Illustration 2-1
Radiographic Examination in Thorax Position (Receptor in Vertical Position)

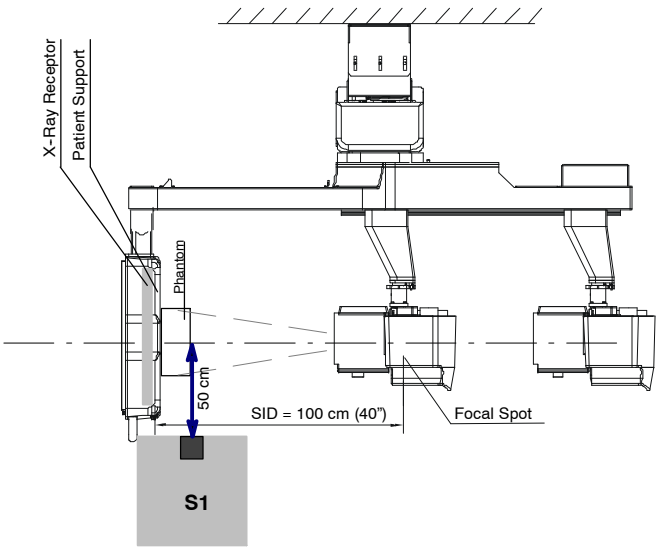






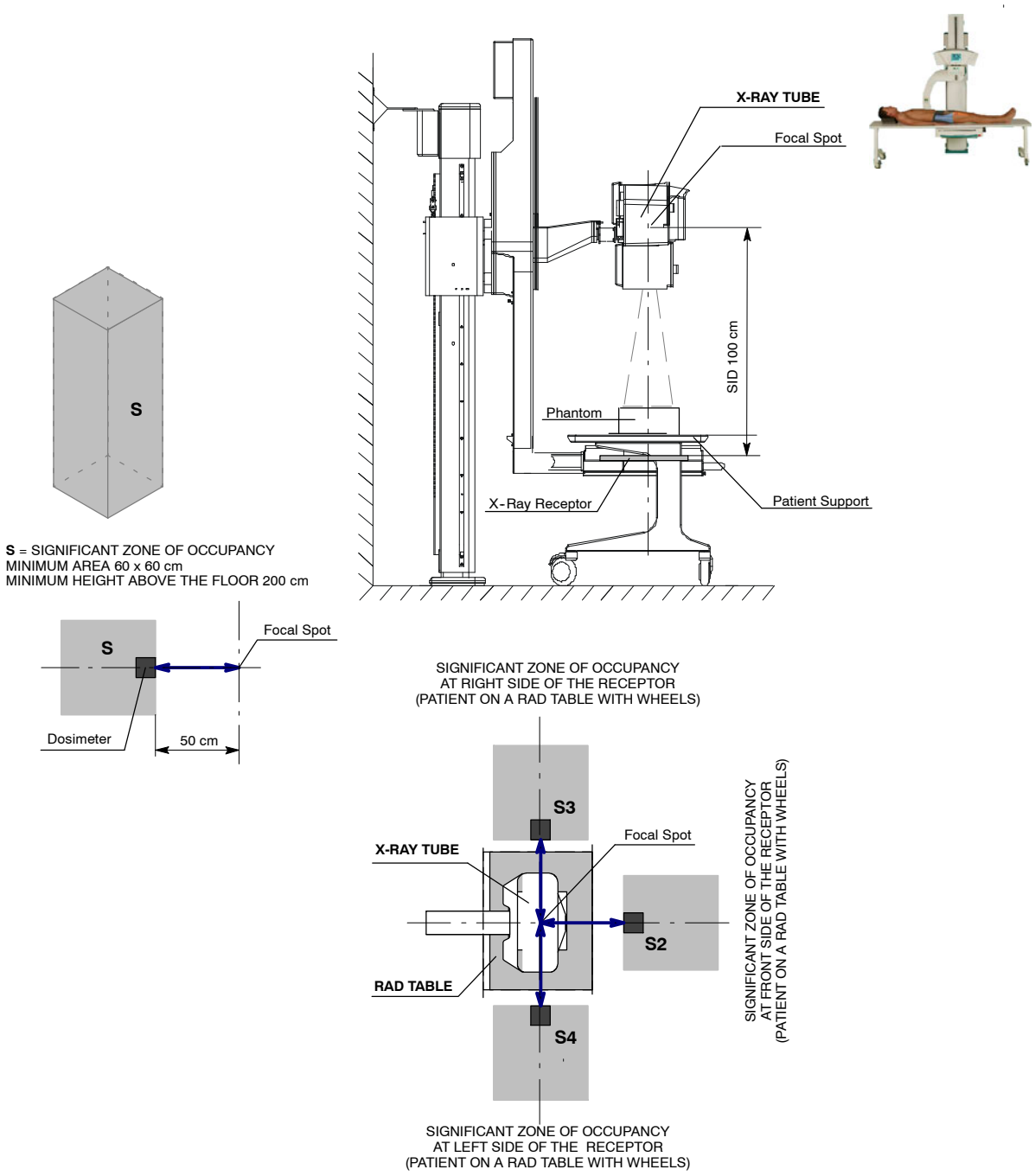
S = SIGNIFICANT ZONE OF OCCUPANCY
MINIMUM AREA 60 x 60 cm
MINIMUM HEIGHT ABOVE THE FLOOR 200 cm





SIGNIFICANT ZONE OF OCCUPANCY
AT THE LEFT SIDE OF THE RECEPTOR UNIT
IN VERTICAL POSITION

Illustration 2-2
Radiographic Examination in Undertable Position (Receptor in Horizontal Position)



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 IEC 60601-1-3:1994, IEC 60601-1-3:2008 + AMD1:2013.

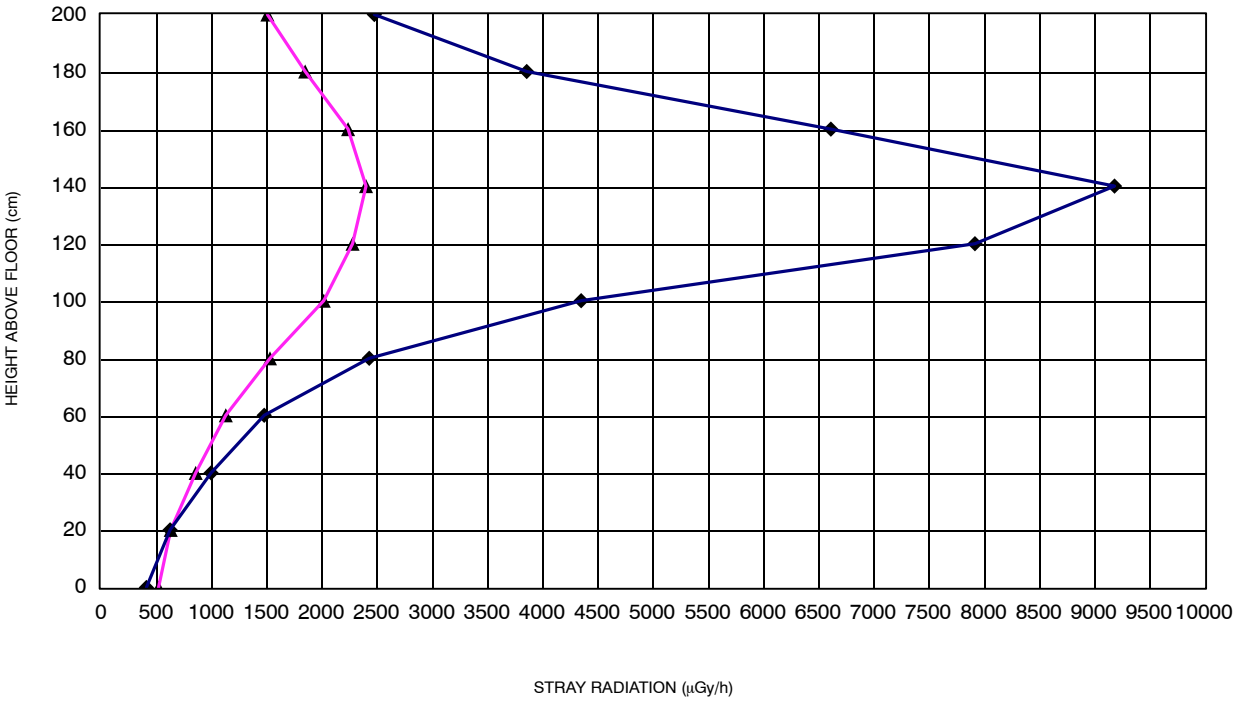
- Exposure Parameters: RAD mode, 150 kVp, 20 mAs.
- Collimator opening for Field Size 18 x 18 cm, SID 100 cm.
- Phantom: Rectangular water phantom of 25 x 25 x 15 cm, or a material having a similar X-Ray attenuation coefficient.
- Radiation measuring instrument: Low Radiation Dosimeter.

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 2-1 for Receptor in Thorax position and refer to Illustration 2-2 for Receptor in Undertable (or horizontal) Position.

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

Illustration 2-3
Distribution of Stray Radiation (S1) with the Receptor inThorax Position.



$S1_1$	d = 50 cm	
$S1_2$	d = 100 cm	

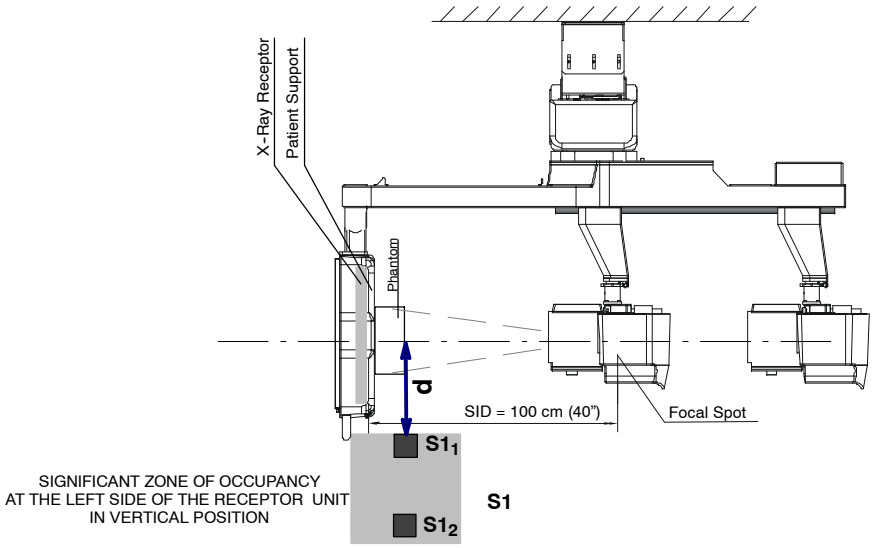
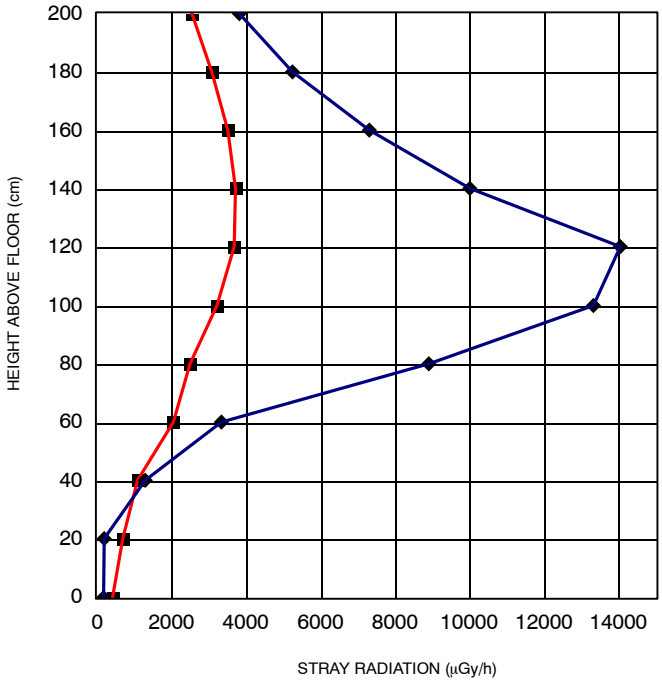


Illustration 2-4
Distribution of Stray Radiation (S2) with the Receptor in Undertable Position.



$S2_1$	d = 50 cm	
$S2_2$	d = 100 cm	

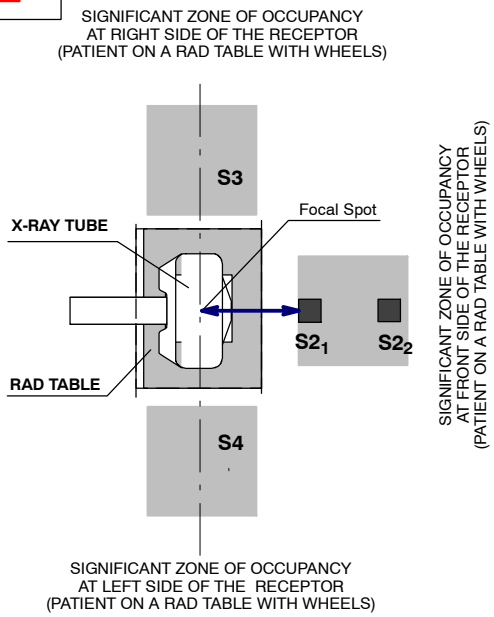
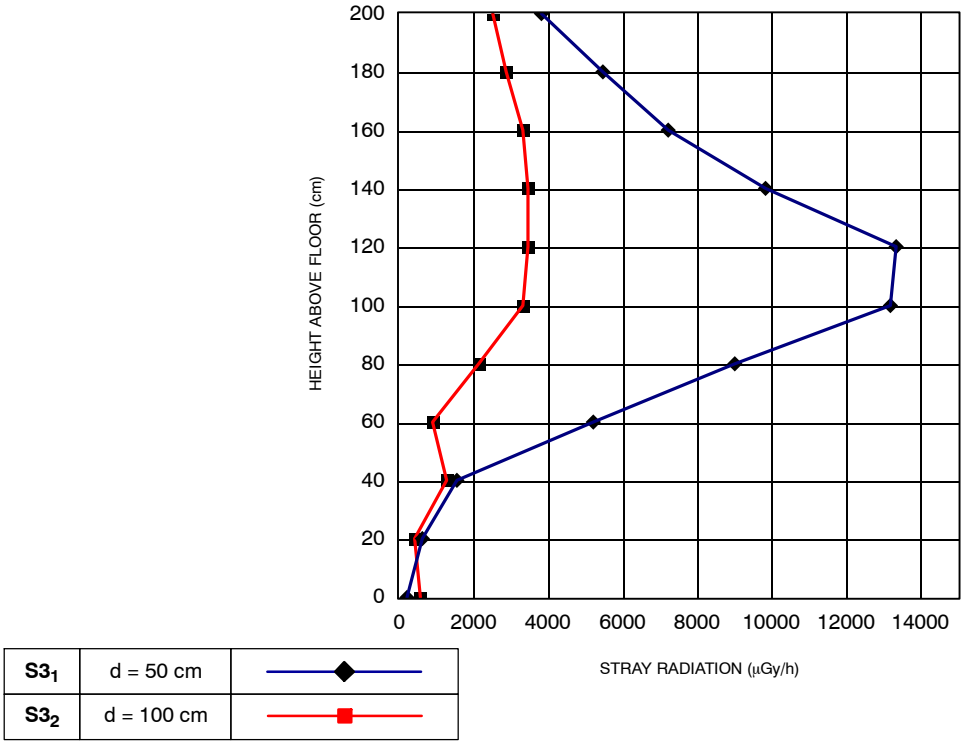


Illustration 2-5
Distribution of Stray Radiation (S3) with the Receptor in Undertable Position.



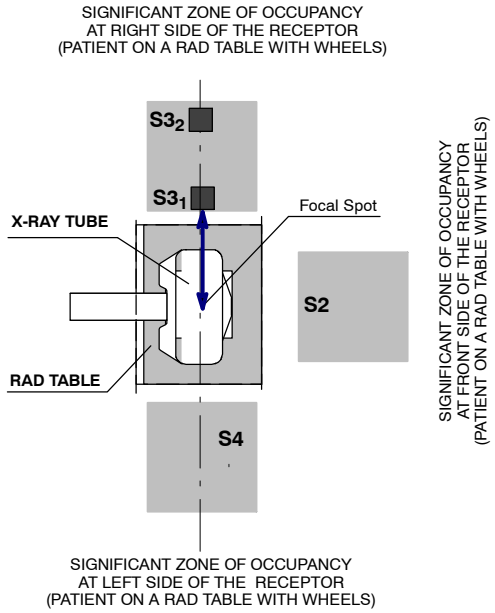
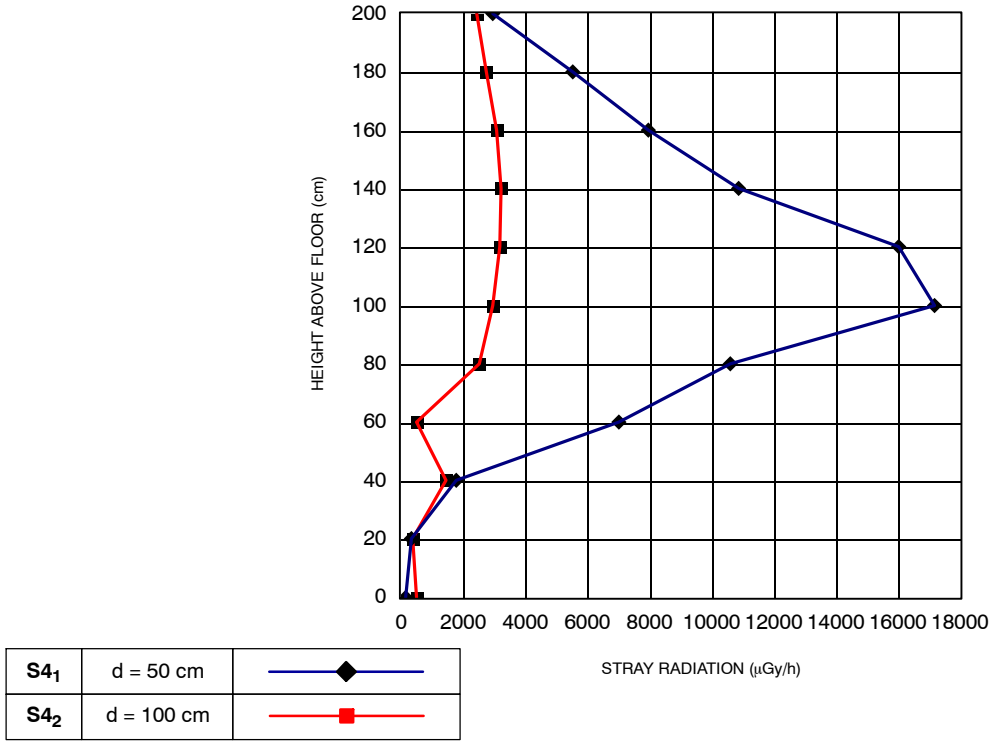
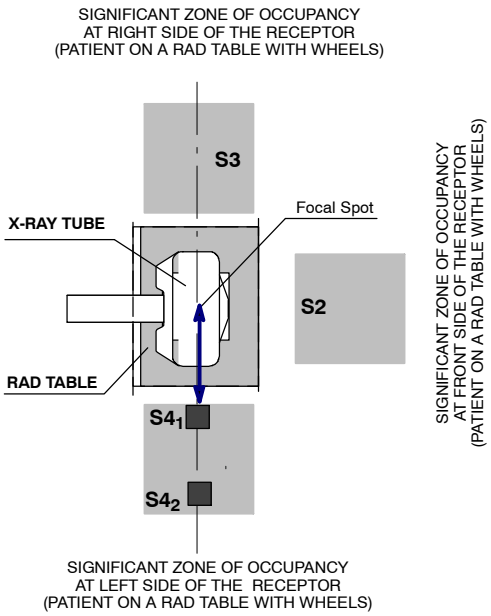


Illustration 2-6
Distribution of Stray Radiation (S4) with the Receptor in Undertable Position.





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 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 this one.

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 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 X-ray Unit is intended for use in the electromagnetic environment specified below. The customer or the user of this Portable X-ray Unit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This *X-ray Unit* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	This X-ray Unit 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 emissions IEC 61000-3-3	Complies	
NOTE - In accordance with Standard IEC 61601-1-2:2014, the emissions 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.		

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2007)			
This X-ray Unit is intended for use in the electromagnetic environment specified below. The customer or the user of this X-ray Unit should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2:2007 Test level**	**Compliance Level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV maximum ± 8kV maximum	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 for power supply lines ± 1kV for input/output lines	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 symmetrical coupling ± 2kV asymmetrical coupling	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% for 0.5 periods 60% for 5 periods 30% >95% for 250 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Portable X-ray Unit requires continued operation during power mains interruptions, it is recommended that the Portable X-ray Unit be powered from a uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/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.			

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2007)			
This X-ray System is intended for use in an electromagnetic environment specified below. The customer or Operator of this X-ray System 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 RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of this X-ray System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$, 80 MHz to 800 MHz $d = 2.3\sqrt{P}$, 800 MHz to 2.5 GHz where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 'd' is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a]), should be less than the compliance level in each frequency range[b]). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies. *NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			
[a]) *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the X-ray System is used exceeds the applicable RF compliance level above, this X-ray System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this X-ray System.* [b]) *Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*			

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

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	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 X-ray System is intended for use in the electromagnetic environment specified below. The customer or Operator of this X-ray System 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 that of 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 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T for 0.5 cycle at 0º, 45º, 90º,135º, 180º, 225º, 270º and 315º 0 % U_T for 1 cycle at 0º 70 % U_T for 25/30 cycles at 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 cycle at 0º 70 % U_T for 25/30 cycles at 0º 0% U_T 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the This X-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 of a typical location in a typical commercial or hospital environment.
NOTE - U_T is the a.c. mains voltage prior to application of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014)			
This X-ray System is intended for use in an electromagnetic environment specified below. The customer or Operator of this X-ray System 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 fields IEC 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)	
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONS EQUIPMENT"	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONS EQUIPMENT"	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 the equipment, including cables specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.
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 X-ray System is intended for use in an electromagnetic environment specified below. The customer or Operator of this X-ray System 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 deviation 1 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 + 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: Vacudap
- Dosimeter: Unfors
- Rectangular Phantom made of Polymethyl-methacrylate (PMMA) layers: 25 cm x 25 cm x 20 cm.

Test Details:

- Minimum SID:100 cm.
- Maximum SID: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 on the 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 the following 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 (ICRP 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.

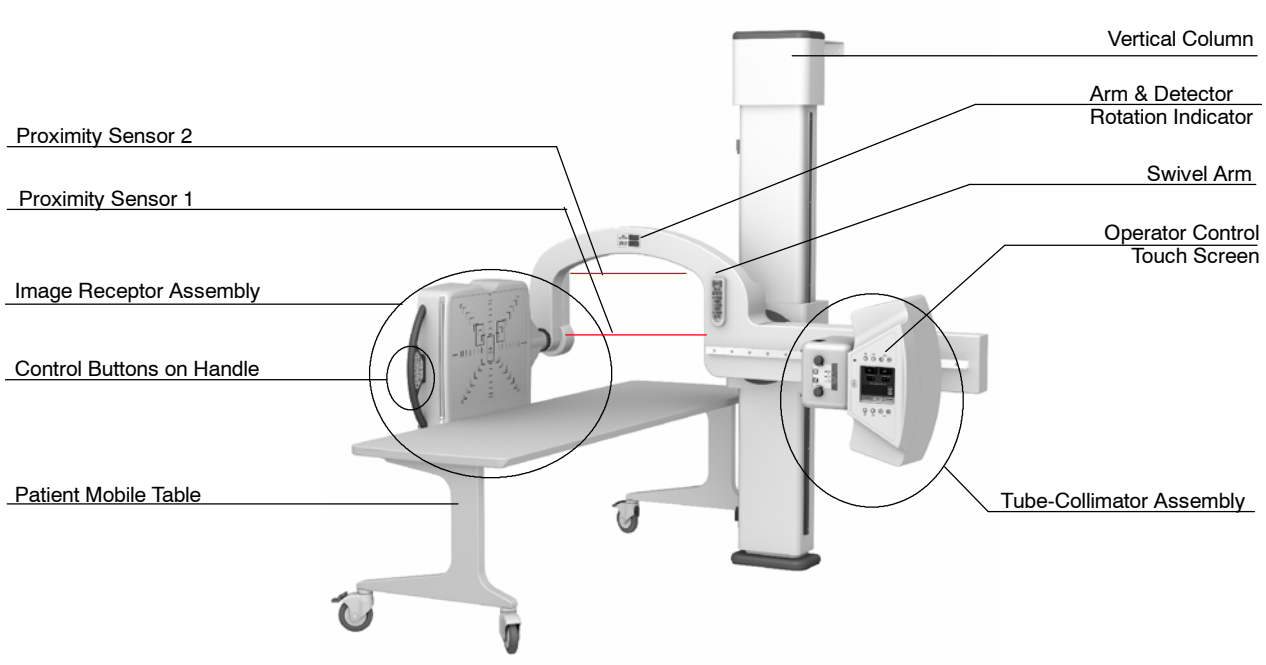
As indicated in the Quantitative Information Tables, the number of exposures needed to reach the previously described maximum radiation values will depend on the selected techniques for each radiographic study.

SECTION 3 OPERATION

The Control Panel comprises the Touch Screen and the Control buttons with their corresponding symbols.

The Movement Buttons on the Control Panel are duplicated on the Image Receptor Handle.

Illustration 3-1
U-Arm Positioner

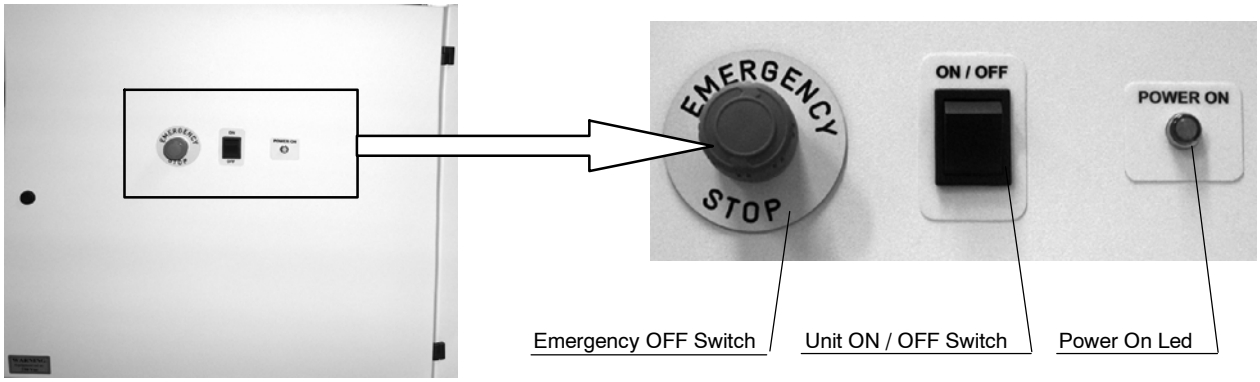


3.1 POWER ON / OFF

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

To turn the Unit ON/OFF, press the Unit ON/OFF Switch located at the Control Unit Door.

Illustration 3-2
Control Unit Switches



The equipment is provided also with an Emergency-OFF Switch that cuts the power supply to the Unit. Once pressed, wait one minute before turning ON the Unit again.

WARNING

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 THE ROOM FOR GREATER ACCESSIBILITY.

WARNING

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

WARNING

BEFORE POWERING ON THE UNIT CHECK THAT THERE IS NOTHING ON THE RECEPTOR ASSEMBLY SURFACE OR ON THE U-ARM.

WARNING

IN THE EVENT OF A STRONG BUMP ON THE DETECTOR DR ASSEMBLY OR ON THE U-ARM, PLACE THE UNIT IN THORAX POSITION, TURN THE UNIT OFF, WAIT ONE MINUTE AND TURN IT ON.

3.2 SYSTEM MOVEMENTS

WARNING

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.

WARNING

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

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

3.2.1 EMERGENCY STOP FOR MOVEMENTS

The Unit includes a Emergency Stop located at the Receptor Assembly that disables all movements of the Swivel Arm in case of emergency. Press the red mushroom shaped switch to block movements. To restore the Swivel arm movements, wait one minute before pulling the red mushroom shaped switch again.

Illustration 3-3
Emergency Stop for Movements

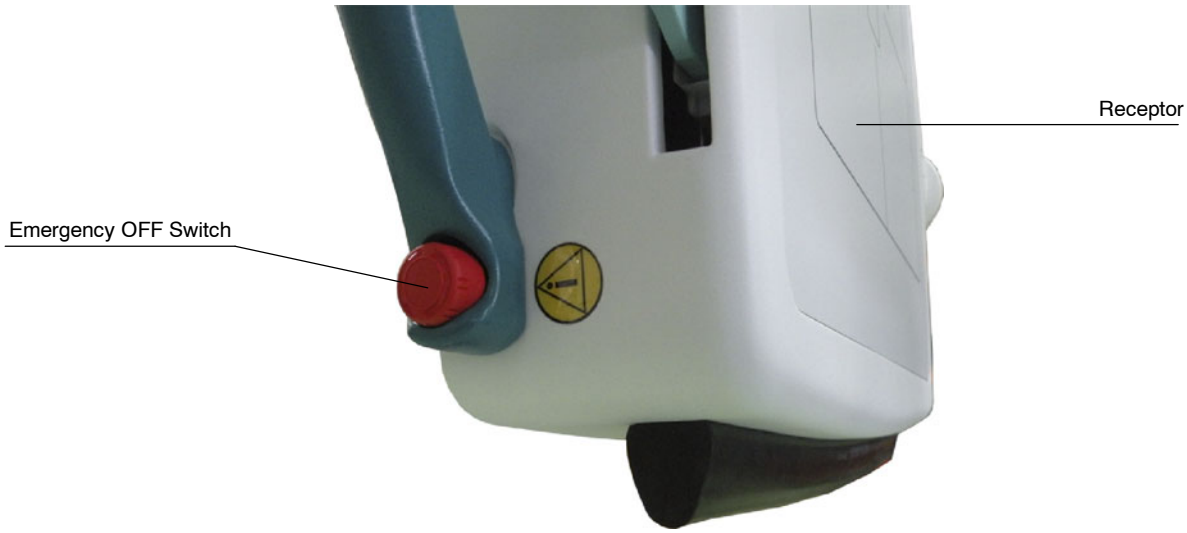
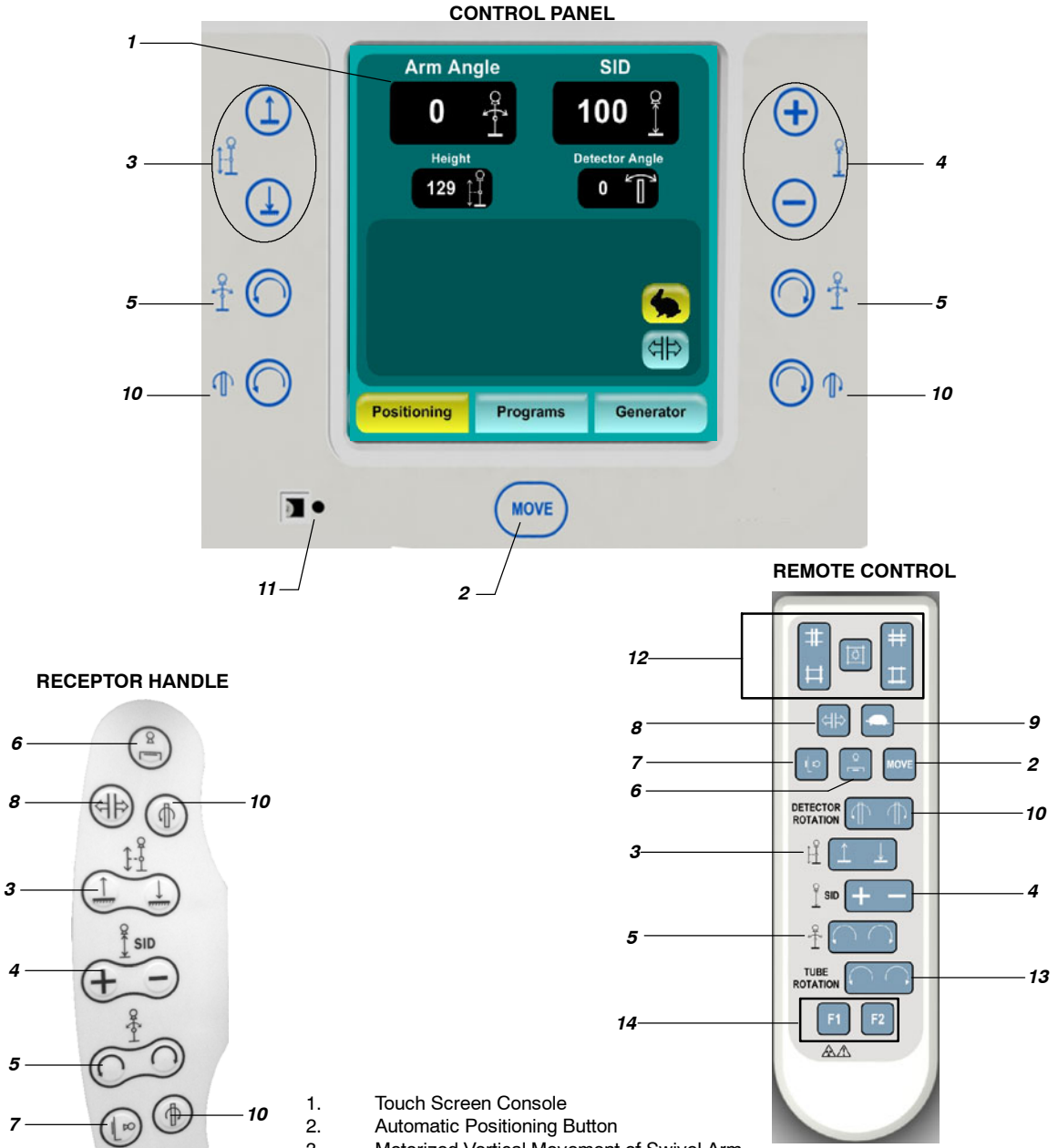


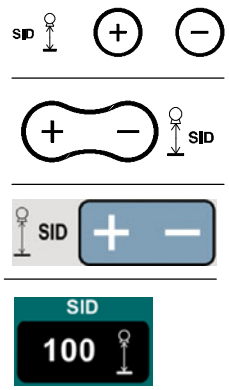
Illustration 3-4
Control Panel, Receptor Handle and Remote Control



1. Touch Screen Console
2. Automatic Positioning Button
3. Motorized Vertical Movement of Swivel Arm
4. Motorized SID Adjustment
5. Motorized Rotation Movement of Swivel Arm
6. Automatic Undertable Positioning
7. Automatic Thorax Positioning
8. Safety Lock
9. Low Speed
10. Motorized Rotation Movement of Image Receptor
11. Remote Control Sensor
12. Collimator Control Button (At Remote Control)
13. Tube Rotation (Not Available)
14. Pre-programmed Functions (Not Available)

3.2.2 CONTROL PANEL

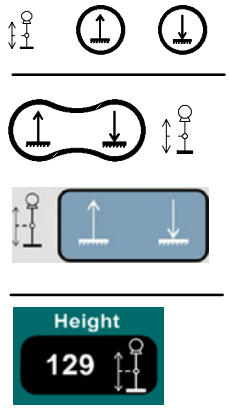
TOUCH SCREEN CONSOLE: *Refer to Section 3.2.3*



SID: These two buttons are used to increase or decrease the SID (Source-Image Distance). Release them to lock in position.

This movement has SID detents at 100 cm (40") and 180 (72"). Also a third SID detent position can be configured by the Service Engineer during the installation process. When one of these positions is reached, the movement is blocked, press the button again to continue movement.

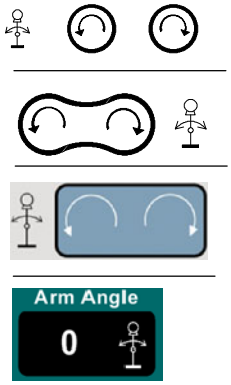
The SID position is continuously indicated in the Touch Screen Console. When the Tube Assembly has reached to a limit, a message appears on the Screen: *"SW LIMIT DEC SID"* or *"SW LIMIT INC SID CW"*.



VERTICAL: These buttons are used to control the vertical motorized movement of Central Carriage and consequently the vertical adjustment of the Swivel Arm. Release them to lock in position.

When the Central Carriage has reached to the highest or lowest vertical position a message appears on the Screen: *"SW LIMIT MIN HEIGHT"* or *"SW LIMIT MAX HEIGHT"* .

The Swivel Arm height (from the Center of the Detector axis to the floor) is continuously indicated in the Touch Screen Console (Height).



SWIVEL ARM ROTATION: Press and hold the respective button to enable clockwise or counterclockwise rotation of the Swivel Arm. Release button to lock in position. When the Swivel Arm detects a not allowed movement (close to floor or ceiling), the motion is Locked.

This movement is provided with detents at 0º and 90º. Press again Rotation buttons to continue motion.

The Swivel Arm rotation is continuously indicated in the Touch Screen Console (Arm Angle). When the Arm has reached to an Angle limit, a message appears on the Screen: *"SW LIMIT ARM CCW"* or *"SW LIMIT ARM CW"*.

Rotation angle of the Swivel Arm is limited to +120º/-30º from its vertical position 0º. Over rotation could damage external cables.

UNDERTABLE POSITION: Press and hold this button to place automatically the Swivel Arm in Undertable position. When the Swivel Arm arrives to Undertable Position, the movement stops and the "*Safety Lock*" button lights up. Also refer to Section 3.2.3

THORAX POSITION: Press and hold this button to place automatically the Swivel Arm in Thorax position. When the Swivel Arm arrives to Thorax Position, the movement stops and the "*Safety Lock*" button lights up. Also refer to Section 3.2.3.

UNDERTABLE AND THORAX POSITIONING ARE PROVIDED WITH AUTOMATIC MOVEMENT OF THE SWIVEL ARM, CHECK THAT NO PERSONS OR OBJECTS ARE WITHIN THE RANGE OF THE SWIVEL ARM.

LOW / **HIGH SPEED**: Movements are performed by default at High Speed. Press this button (lights up in the Touch Screen Console) to perform movements at Low Speed. Press again to deselect Low Speed.

SAFETY LOCK: This button lights up in the Touch Screen Console when Undertable or Thorax positioning is reached. Also when any other safety device is activated, for example the Receptor Safety Band or the Swivel Arm Gauges. The Operator must press it before performing any other motion. The Safety Lock stops any motion of the Swivel Arm. Also, this button resets all recoverable errors.

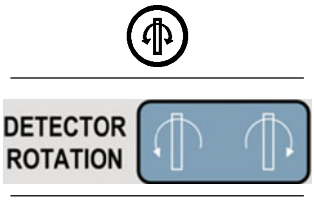


IMAGE RECEPTOR ROTATION (DETECTOR ROTATION): This motorized movement allows a maximum of +45º Clockwise movement and a minimum of -45º Counterclockwise movement. It includes a detent at 0º and also a detent when the Receptor is in parallel with respect to the floor. Press button and release at desired position. The angle reached is shown in the Rotation Display and in the Touch Screen.

The Image Receptor Rotation (Detector Rotation) is continuously indicated in the Touch Screen Console (Detector Angle) and when the Detector has reached to an Angle limit, a message appears on the Screen: *"SW LIMIT DET CCW"* or *"SW LIMIT DET CW"*.

MOVE BUTTON: Press and hold this button once a Program number is selected in the Program Screen of the Touch Screen Console. The Arm moves automatically to the selected position. In case the button is released before reaching the selected position, a message appears on the Screen: *"Move button released. Press Move Button to continue"*. Once the Program position is reached, a message appears on the Screen: *"Position reached"* and the Safety Lock button is activated, the Operator must press it before performing any other motion. If the operator modifies the Program position, the screen displays: *"Programmed position modified by the operator"*. Also refer to Section 3.2.3.

\+
Any movement Button

MOVE + ANY MOVEMENT BUTTON: In case the Unit remains continuously blocked (the Safety Lock button is activated), it can be moved by pressing and holding the *"Move"* button and then pressing the movement button required.

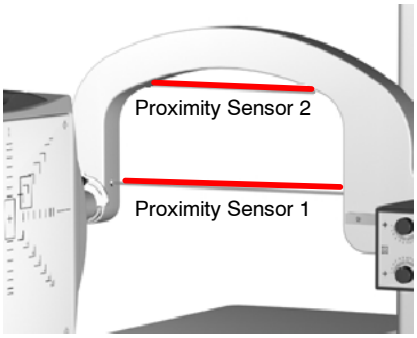
ROTATION DISPLAY: This Display shows the angle performed by the Arm and the angle performed by the Detector.
It also displays some error messages.

PROXIMITY SENSOR 1: The Swivel Arm is provided with a photocell light that detects the patient on the Table, once this happens, Low Speed is automatically activated.

Also lowering the Arm below the Table-Top and rotation will not be allowed.

PROXIMITY SENSOR 2: This second photocell disables all movements (except for Arm up movement) when the photocell light is interrupted. Once the beam is cleared all movements are enabled.

The Touch Screen shows a message when the Proximity Sensor is activated.



3.2.3 TOUCH SCREEN CONSOLE

Illustration 3-5
Touch Screen Console - Positioning Screen

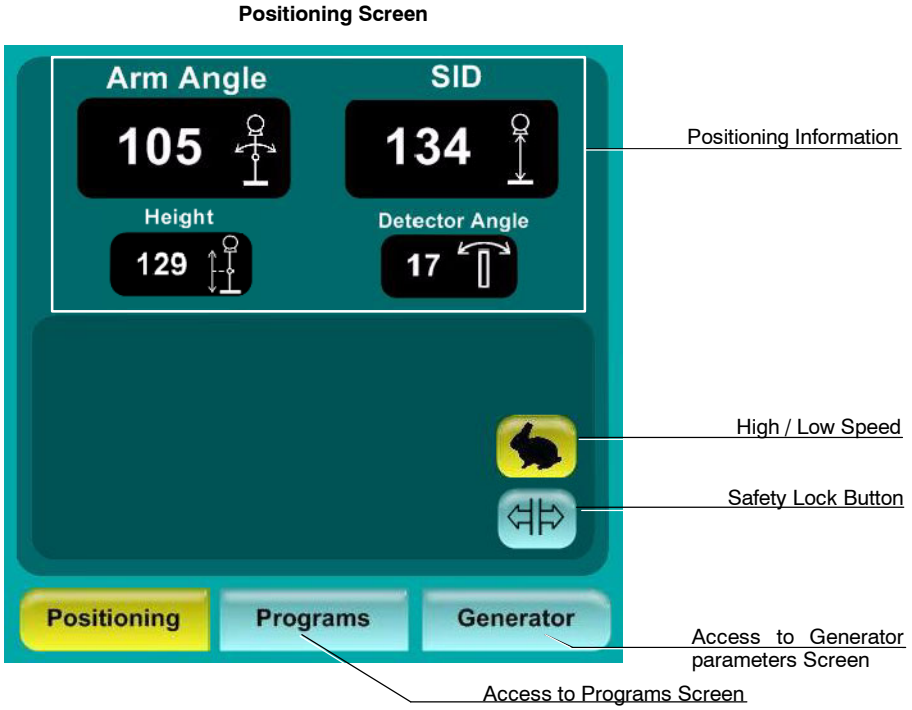
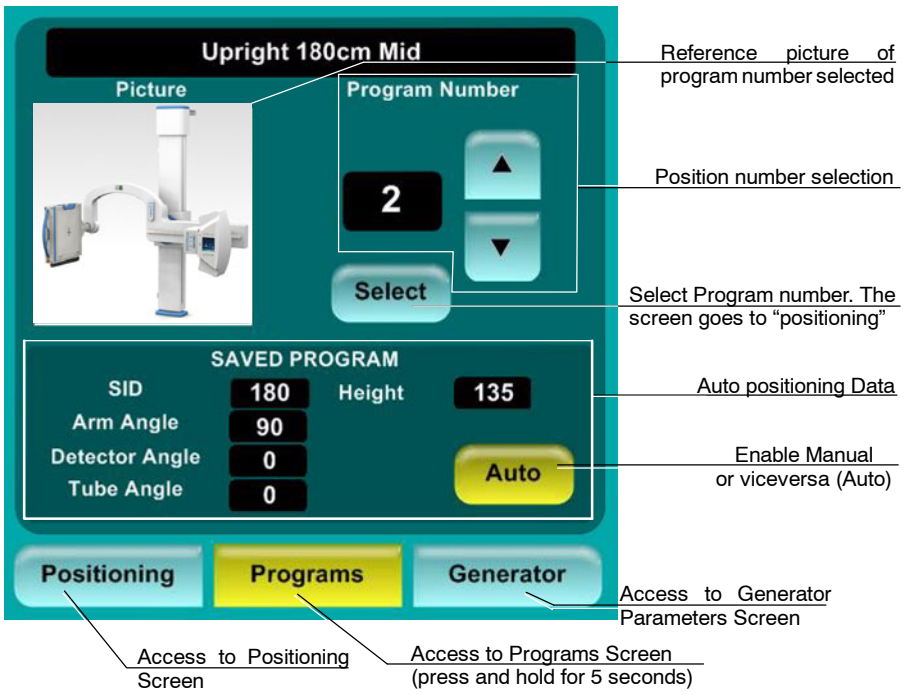


Illustration 3-6
Touch Screen Console - Programs Screen

1.- Select the program number with the Up and Down arrow buttons.

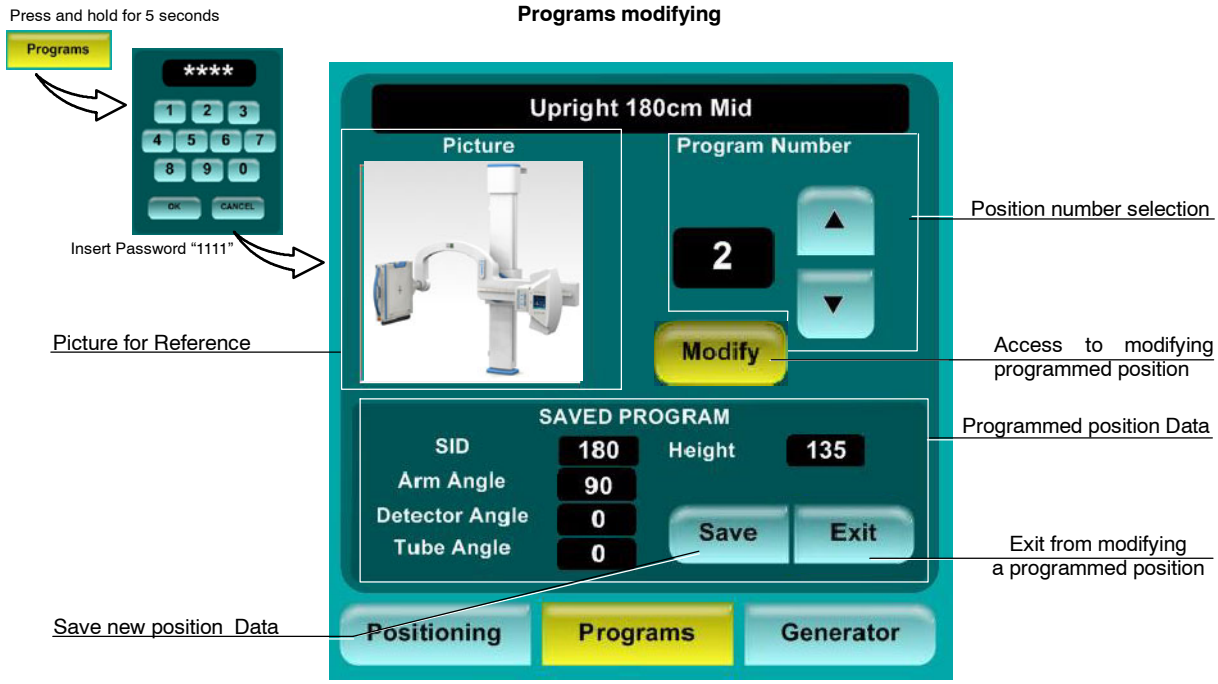
2.- Press "Select", the screen changes to Positioning screen (with the picture of the selected Programmed Position)

3.- Press and hold the "Move" button for auto positioning. The Unit positions itself in the Programmed Position.



A saved Program can be modified for operator convenience. The SID, Arm Angle, Arm Height and Detector Angle of a Program Number can be customized and saved for further use.

Illustration 3-7
Programs modifying



1.- Press and hold "Programs" for 5 seconds.

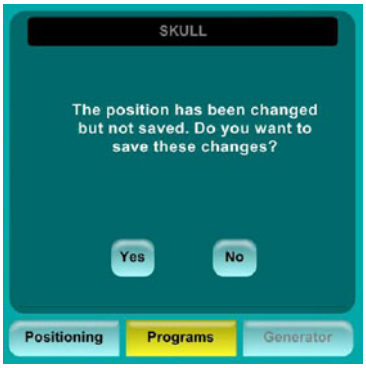
2.- Insert the password (1111) and press "OK".

3.- Select the Program position number to be modified and Press "Modify".

4.- Then, press the "Positioning" button and press on the different motion buttons in order to place the Arm at the desired position.

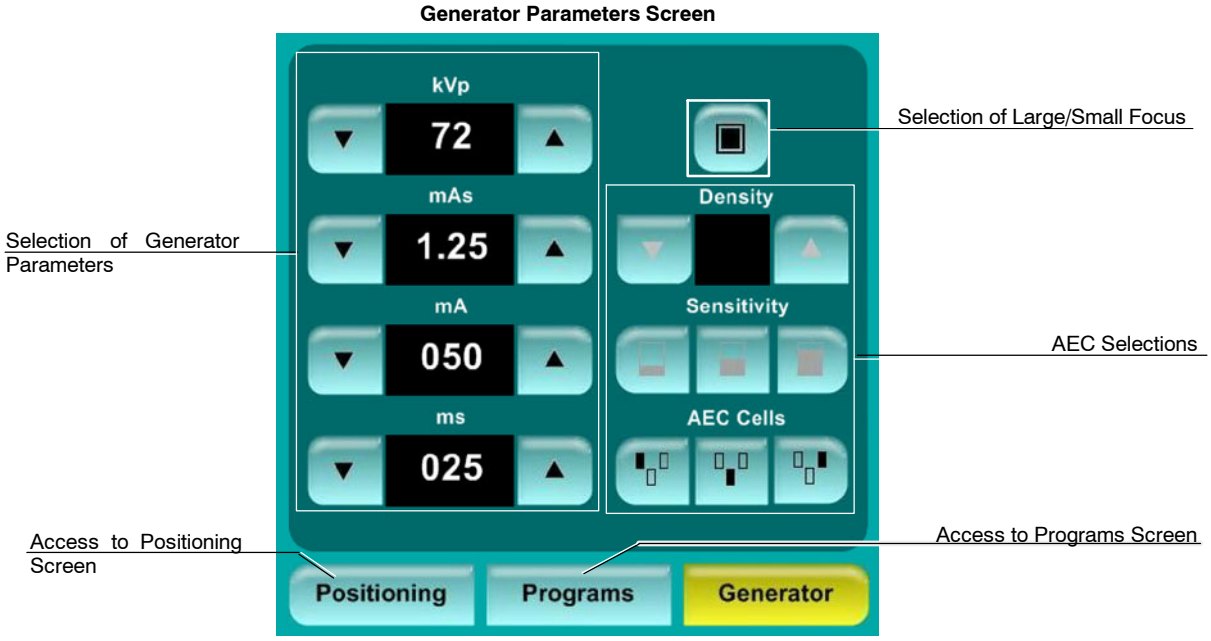
5.- Then, go back to Programs Screen (the screen shows actual position data) and press "Save".

6.- Press "Exit", to go back to previous screen.



This screen does not allow exiting without taking a decision

Illustration 3-8
Touch Screen Console - Generator Parameters Screen

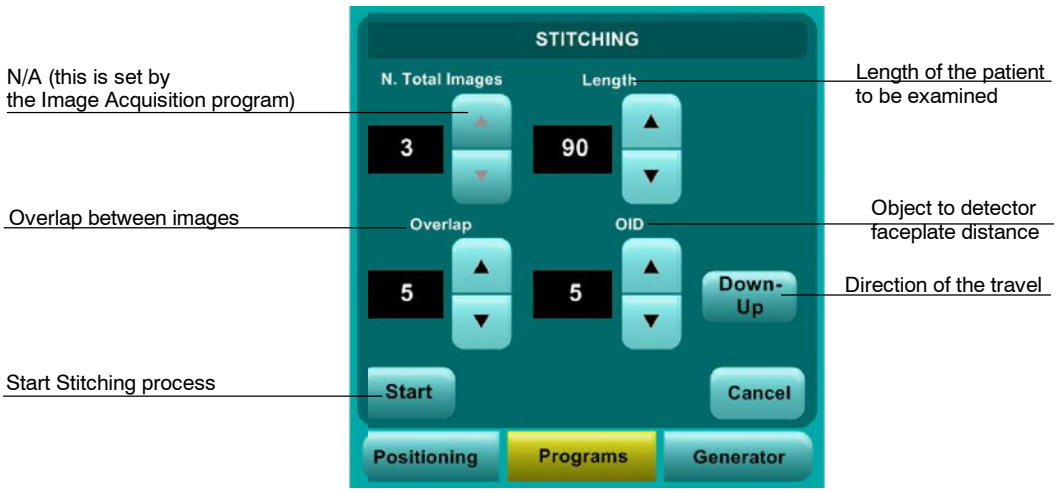


3.3 STITCHING (OPTIONAL)

Some Image Acquisition Software Applications include the Stitching option, the Positioner can be configured to provide an accurate detector positioning in the Stitching process. It needs a Dongle device connected to the Control Box PC.

There are two optional types of Stitching processes: Fast Stitching and Slow Stitching. The Service Engineer should have enabled one of the options during the installation process.

Illustration 3-9
Touch Screen Console - Stitching Screen



3.3.1 FAST STITCHING

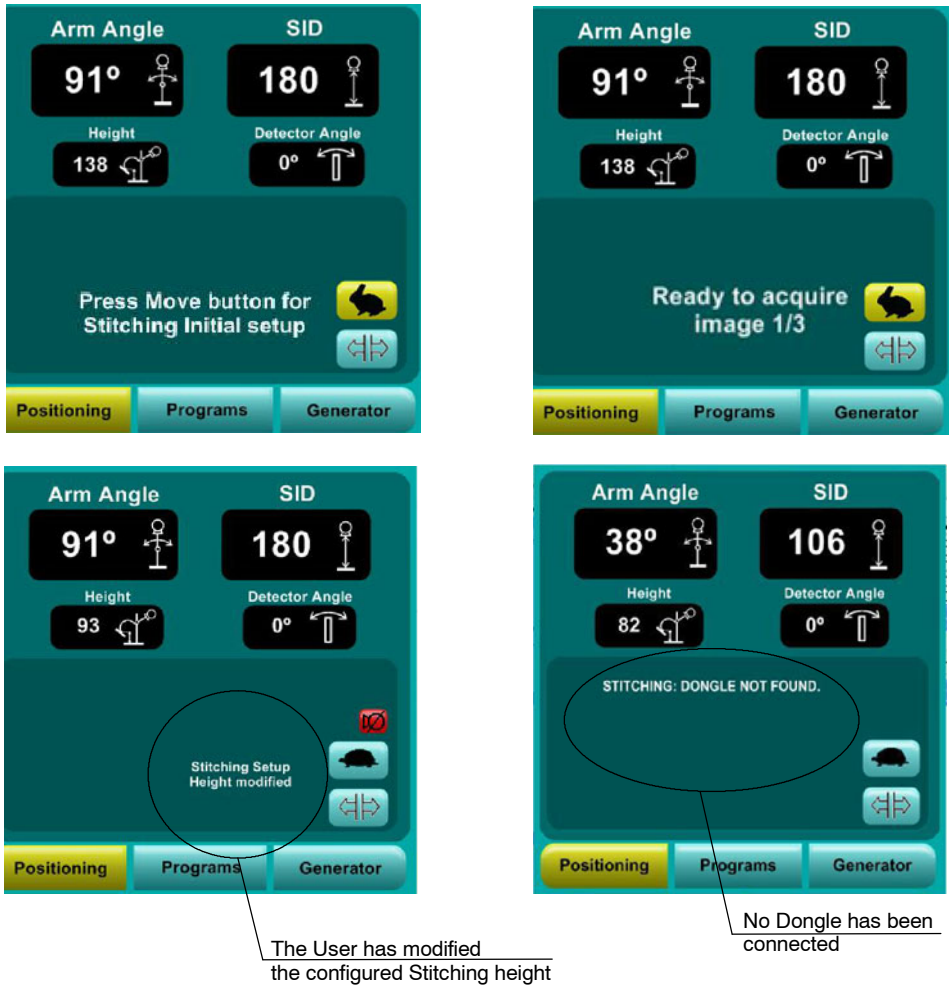
Once the Positioner receives the Stitching Mode Order from the Image Acquisition program, position the patient and press and hold the X-Ray Handswitch until the Stitching process is completed.

It is not necessary to validate each image, all of them are acquired steadily.

3.3.2 SLOW STITCHING

Once the Positioner receives the Stitching Mode Order from the Image Acquisition program, position the patient and follow the steps shown in the screen. The Button “F1” of the Remote Control accepts the image. “F2” cancels the image and goes back to previous step.

Illustration 3-10
Touch Screen Console - some Stitching Screens



3.3.2.1 SLOW STITCHING PROCEDURE

1. Open the Image Acquisition Application and select the Stitching procedure.
2. Select the first exposure.
3. The Positioner should enter Stitching mode and display: *"Press Move button for Stitching Initial setup"*.
4. Press Move button to reach the initial setup position (initial height defined, SID=180, Arm Angle = 0, Detector Angle =0). During movement, positioner should display: *"Moving to Stitching Setup position".* When the position is reached, the positioner should display: *"Stitching Setup position reached".*

Adjust height:

5. Press start button on the remote controller. Positioner will display: *"Ready to Acquire Image 1/3".*
6. Make the exposure.
7. Accept the image, do not press retake button.
8. Positioner should display: *"Press Move button to Stitching position"*.
9. Next stitching position is reached. Positioner will display: *"Ready to Acquire Image 2/3".*
10. Select second body part on the stitching program.
11. Make the exposure.
12. Accept the image, do not press the retake button.
13. Select third body part on the stitching program.
14. Make the exposure.
15. Accept the image, do not press the retake button.
16. The Positioner should quit the stitching mode.

Correct Stitching Sequence with Retake:

1. Open the Image Acquisition Application.
2. Select stitching procedure.
3. Select first exposure.

4. The Positioner should enter stitching mode and display: *"Press Move button for Stitching Initial setup".*

5. Press move button to reach initial setup position (initial height defined, SID=180, Arm Angle = 0, Detector Angle =0). During movement, positioner should display: *"Moving to Stitching Setup position".* When the position is reached, positioner should display: *"Stitching Setup position reached".*

Adjust height:

6. Press start button on the remote controller. Positioner will display: *"Ready to Acquire Image 1/3".*

7. Make the exposure.

8. DO NOT ACCEPT the image, press retake button.

9. Positioner should display: *"Ready to Acquire Image 1/3".*

10. Make the exposure and accept it.

11. Positioner should display: *"Press Move button to Stitching position"*.

12. Next stitching position is reached. Positioner will display: *"Ready to Acquire Image 2/3".*

13. Select the second body part on the stitching program.

14. Make the exposure.

15. Accept the image, do not press retake button.

16. Select the third body part on the stitching program.

17. Make the exposure.

18. Accept the image, do not press retake button.

19. The Positioner should quit the Stitching mode.

3.4 IMAGE PREVIEW (OPTIONAL)

The Image Preview function is only available in Systems with an Image Acquisition Software Application. It obtains a preview of the image at the same time that the Workstation does get it.

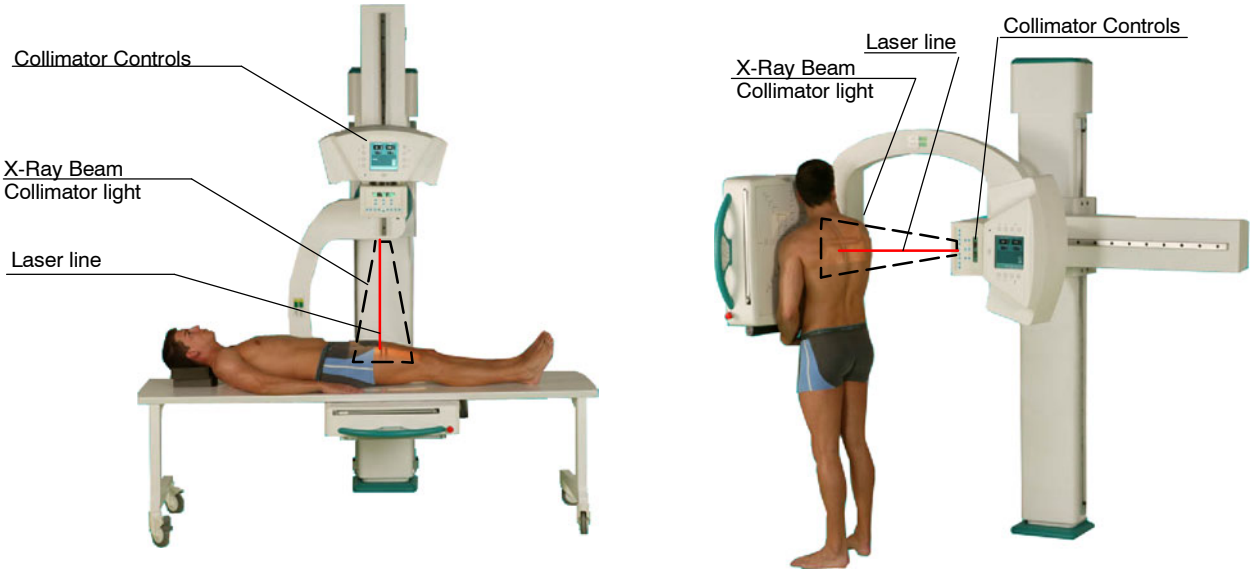
Once the exposition is completed, it automatically appears on the Positioner Screen and disappears as soon as the Operator touches the Positioner Screen or modifies any parameter.

3.5 X-RAY BEAM ALIGNMENT WITH RESPECT TO PATIENT

After selecting RAD parameters for the technique to be performed:

1. Press and hold the Undertable Position Button or Thorax Position Button. This depends on the type exam. The Unit automatically moves to the specified position. The Collimator Lamp automatically turns on.
2. Adjust the field size with the Collimator Lamp knobs (only for Manual Collimators).
3. Position the patient for the examination.
4. Perform any adjustment on the Unit position with respect to the Patient to assure that the X-Ray beam is correctly positioned.

Illustration 3-11
Patient Positioning



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 IMAGE RECEPTOR PERPENDICULARLY POSITIONED WITH RESPECT TO THE TUBE-COLLIMATOR ASSEMBLY.

IN CASE OF EXAMS WHERE THE IMAGE RECEPTOR 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, THE RESULTING IMAGE WILL BE DEFORMED.

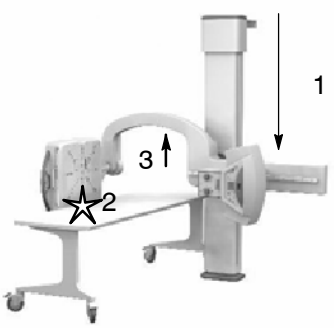
IT IS THE OPERATOR RESPONSIBILITY THE PROPER POSITIONING OF THE PATIENT AND EQUIPMENT BEFORE PERFORMING AN EXAM.

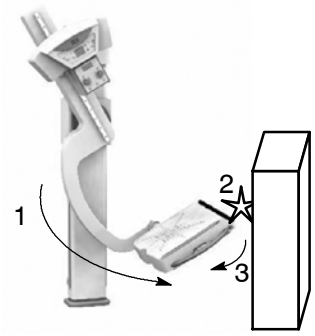
3.6 DETECTOR BUMPER AND ANTICRUSHING SYSTEM

Besides the Light beams installed in the Arm that slow down the speed and stops motion in case the light beam is cut, this unit includes two Safety Devices that will react to any unintentional bump into the Arm Assembly (Anticrushing System) or into the Detector (Detector Bumper).

These safety Devices are designed to prevent high risk situations with patients, that is, in the extremely rare case of collision into the Arm or the Detector, it will automatically stop or reverse (in low speed and during 1.5 seconds in rotational movement and during 3 seconds in up or down movement), the following is an explanation of when the unit stops or reverses.

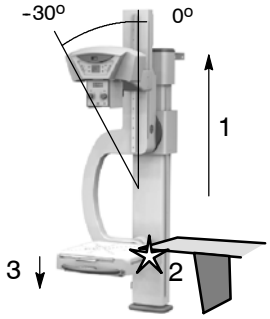
Detector Bumper: When the Arm of the U-Arm Positioner is **moving down** or **when it rotates**, it will always reverse the movement if the Detector Bumper is activated to avoid something kept between the detector and the floor.





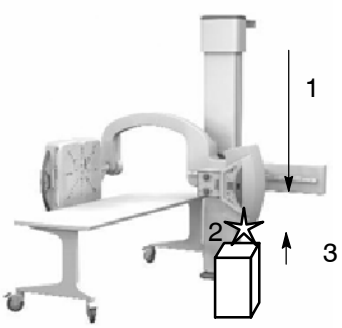
When the Arm of the U-Arm Positioner is **moving up** and the Detector Bumper is activated, it will make the reverse movement or stop depending on the following situations:

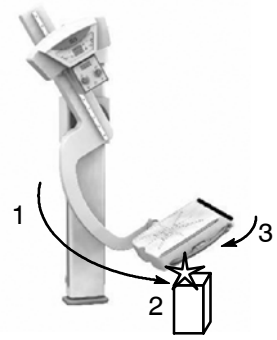
- The system only reverses down automatically when the Detector Bumper is activated and the angle is between 0º and -30º (the angle interval where the detector could be under the table to avoid something kept between the table and the detector).



- In the rest of the angle ranges (from 1º to 120º) and in horizontal position, the system never reverses automatically, it stops.

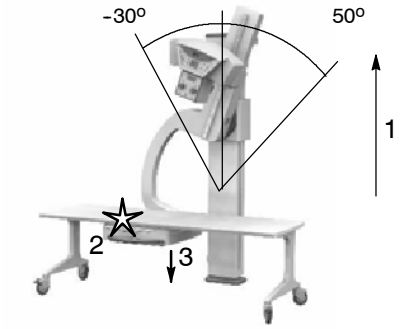
Anticrushing System: When the Arm of the U-Arm Positioner is **moving down** or **when it rotates**, it will always reverse the movement if the Anticrushing System is activated to avoid something kept between the detector and the floor.



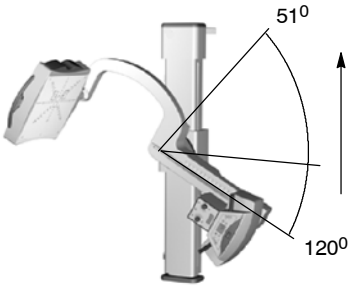


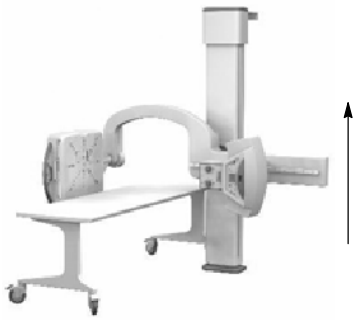
When the Arm of the U-Arm Positioner is **moving up** and the Anticrushing System is activated, it will make the reverse movement or stop depending on the following situations:

- The system only reverses down automatically when the Anticrushing System is activated and the angle is between -30º and 50º (the angle interval where the detector could be under the table). In any other case it stops.



- In the rest of the angle ranges (from 51º to 120º) and in horizontal position, the system just stops.



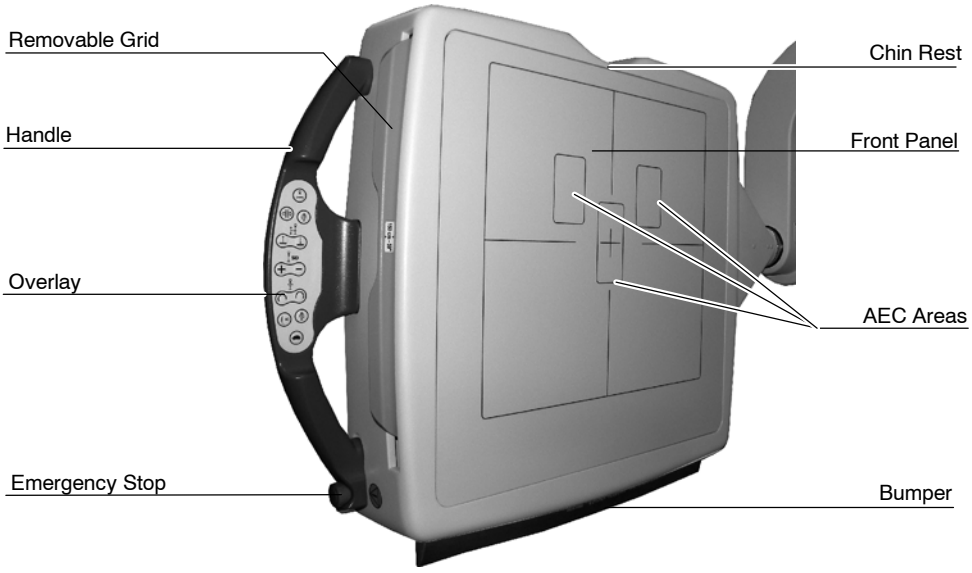


Note ☞ *In case the Unit remains continuously blocked, it can be moved by pressing and holding the Move button and then pressing the movement button required.*

3.7 RECEPTOR ASSEMBLY

The Receptor Assembly includes:

- One of the following Receptors:
  - Fixed Detector or
  - Portable Detector with Non-Rotating Tray Assembly or
  - Portable Detector with Rotating Tray Assembly or
  - Cassette Film / CR with Bucky Tray.
- Ion Chamber Housing.
- Front Panel with AEC Detector Areas and very low absorption level.
- Fixed or Removable Grid.
- Chin Rest.
- Handle with movement buttons.
- Emergency Stop.
- Bumper.



3.7.1 FIXED DETECTOR ASSEMBLY

This Detector Assembly includes the Fixed Digital Detector, removable Grid and the Ion Chamber Housing.

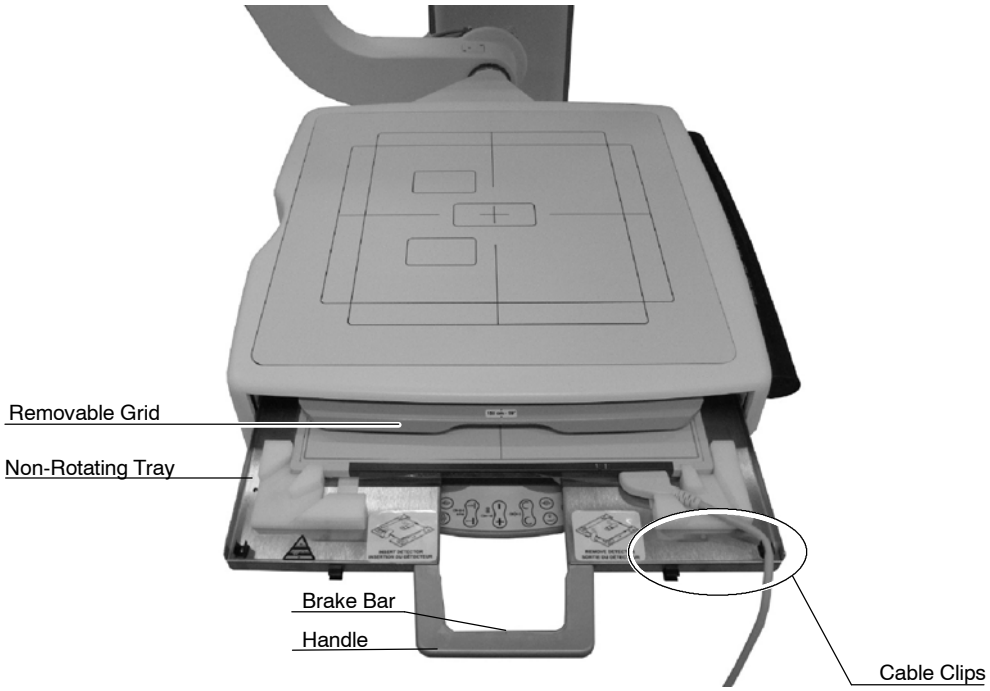
Fixed Detector Assembly

3.7.2 PORTABLE DETECTOR ASSEMBLY WITH NON-ROTATING TRAY

The Portable Detector 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 Detector Assembly includes a Brake Bar for pulling out or inserting the Tray.

Illustration 3-12
Detector Assembly with Non-Rotating Tray

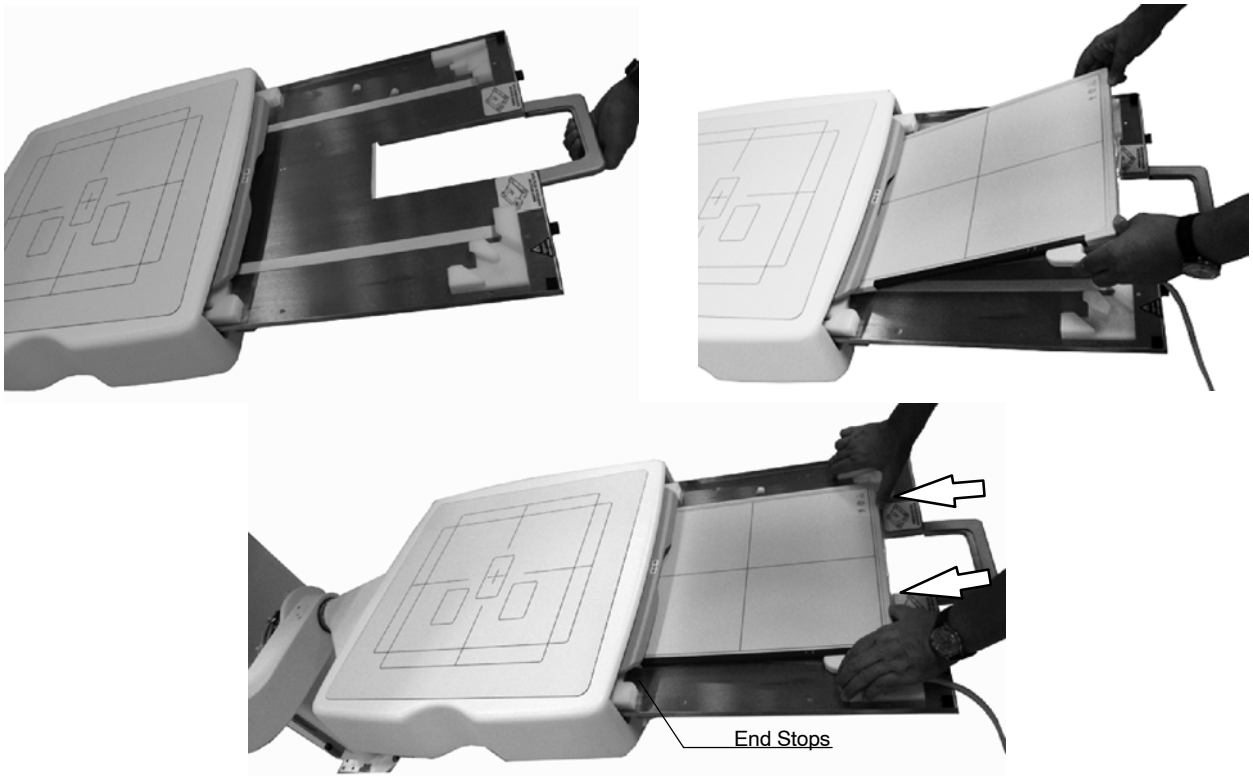


3.7.2.1 LOADING AND UNLOADING THE TRAY

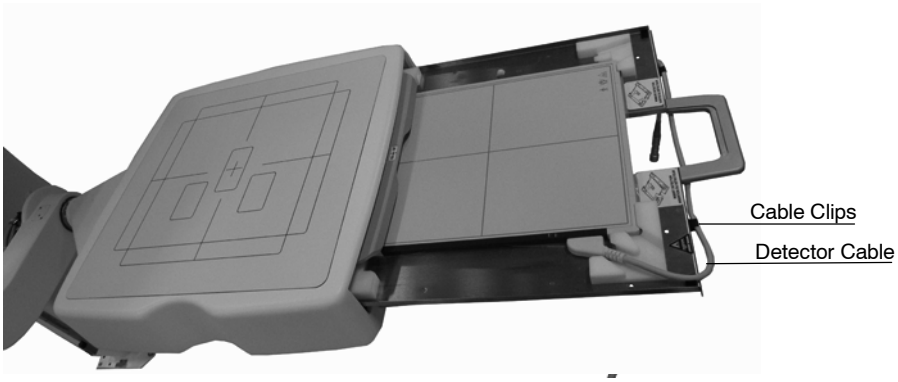
1. Grab the Handle (pressing the Brake Bar) and pull the Tray until it is completely out.

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

Illustration 3-13
Detector Loading



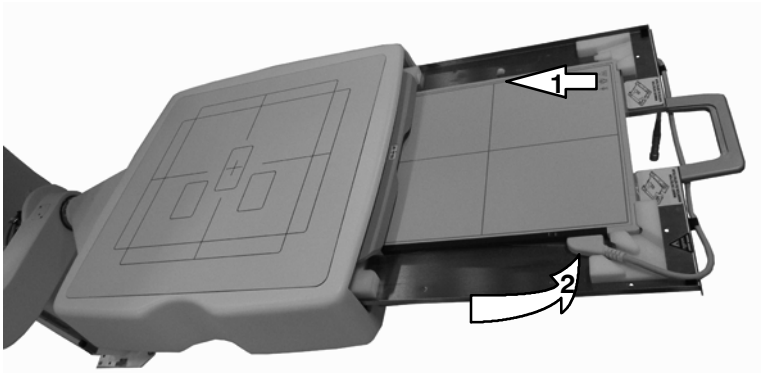
3. Guide the Detector Cable out through the Cable Clips (if applicable) to avoid damages in the Cable when inserting the Tray and fully insert the Tray.



4. To unload the Detector, grab the Handle (pressing the Brake Bar) and pull the Tray until it is completely out.

5. Disengage the Detector cable from the Cable clips.

6. Push the Detector towards the end Stops and raise the Detector with both hands.



3.7.2.2 ROTATING THE DETECTOR

The shape of the end stops is designed to house the Detector in Landscape and Portrait positions.

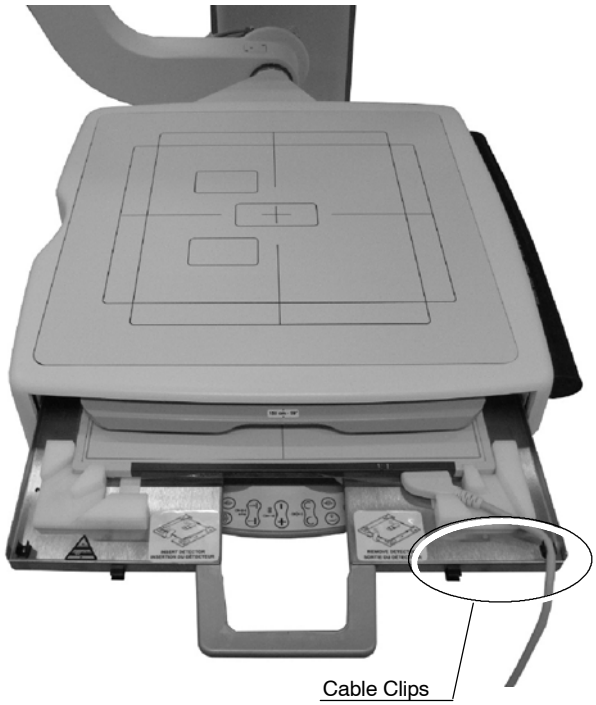
With the Detector inserted in the Tray in Portrait position and the Tray inserted in the Detector Assembly:

1. Pull out the Tray to the end of its travel and pick up the Detector with both hands.

2. Turn the Detector 90º counterclockwise (Landscape position).

3. Place the Detector centered in the Tray and push slightly the end-stops until it is fitted in the four stops of the tray.

4. Guide the Detector Cable out through the Cable Clips (if applicable) to avoid damages in the Cable when inserting the Tray and fully insert the Tray.

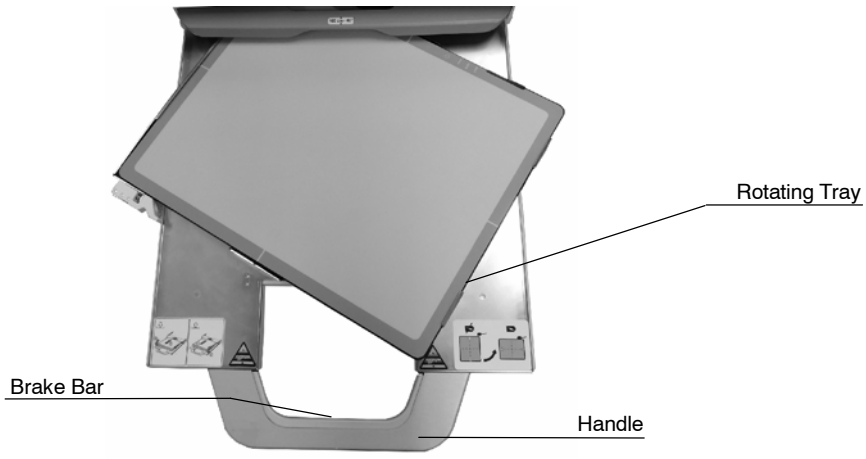


3.7.3 PORTABLE DETECTOR ASSEMBLY WITH ROTATING TRAY

The Portable Detector Assembly with Rotating Tray is designed to conveniently house a Portable Detector, an Ion Chamber and a Grid. The Tray can be rotated in Portrait or Landscape position.

The Handle of the Detector Assembly includes a Brake Bar for pulling out or inserting the Tray.

Illustration 3-14
Portable Detector Assembly with Rotating Tray



3.7.3.1 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 3-15
Tray Loading

3. To unload de Receptor, fully extract the tray.

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

ROTATING THE TRAY

1. Pull out the Receptor Tray to the end of its travel (Rotating Position).
2. Insert the Receptor in the Tray.
3. Push the Tray Counterclockwise until it rotates 90º to achieve Portrait position.
4. If applicable, guide the Receptor Cable through the Cable Clips and insert the Tray.

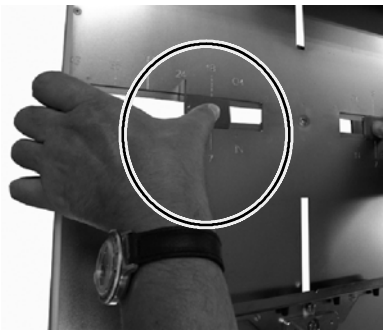
Due to moving parts within the Detector Cabinet, all body parts and objects must be clear of possible Pinch Areas between the Detector Cabinet and the Rotating Tray.

3.7.4 TRAY FOR CASSETTE FILM / CR

The Bucky Assembly is installed below the Tabletop. It contains a manual Cassette Tray, which accepts all the standard Cassette Film / CR sizes from 13x18 cm to 35x43 cm (5x7” to 14x17”).

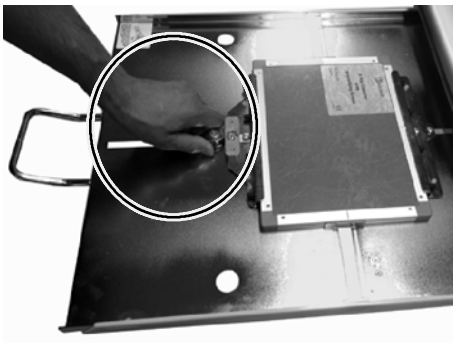
Pull out the Tray to load a Detector according to its size and orientation. Place manual clamps at corresponding numbered notch, open the automatic clamp and insert the Cassette. This Tray accepts all standard Cassette/CR sizes.

Fully open the Tray



Set the manual clamps at the corresponding number

Open the Automatic Clamp, Insert the Cassette and adjust it to the Cassette



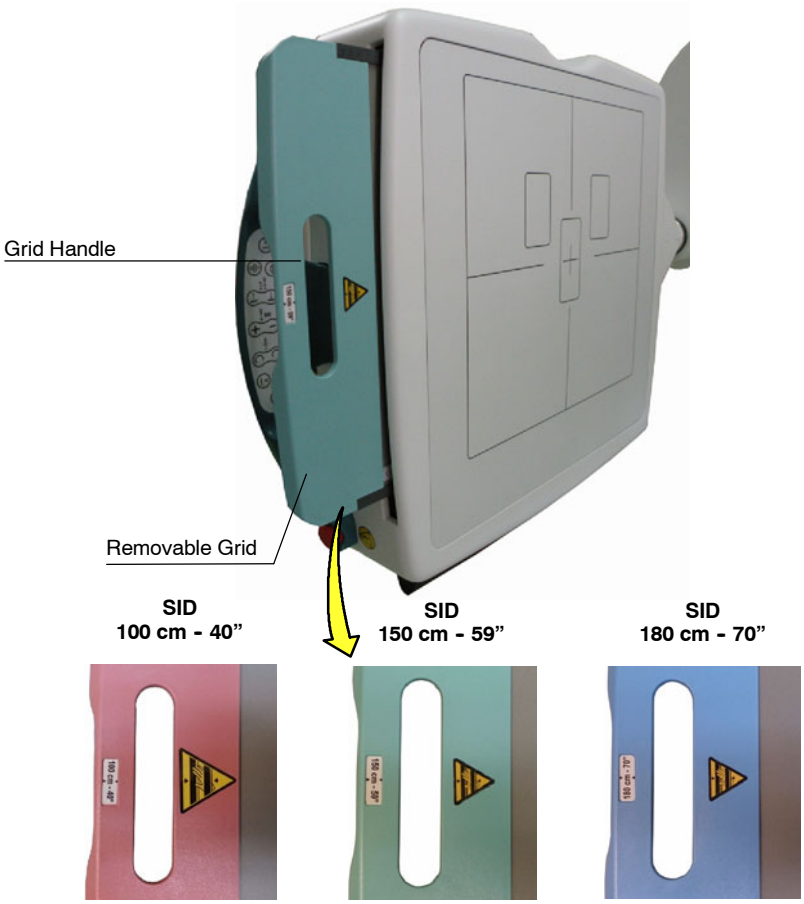
Lock the Cassette and insert the Tray

3.8 REMOVABLE GRIDS

Grids are intended to reduce scattered radiation and significantly enhance image quality.

Assemblies with removable Grids are supplied with two Grids and two Slots (Slot for exposure Grid and Slot for Replacing Grid). Each Slot includes a Finger Lever to remove the Grid from the Slot.

The range of the standard Grids is:
12:1 – 1 m – 80 lines/cm and 12:1 – 1.80 m – 80 lines/cm.



Before making an exposure using a Grid, check that:

- the focus distance of the Grid matches the actual SID.
- the Tube side of the Grid faces the X-Ray Tube.
- the Grid is fully inserted.

Before using the Grid, clean the front and back side with a dry cloth to remove dust and dirt.

Follow the procedure below for Grid loading. For Grid removal, follow the procedure below in reverse order.

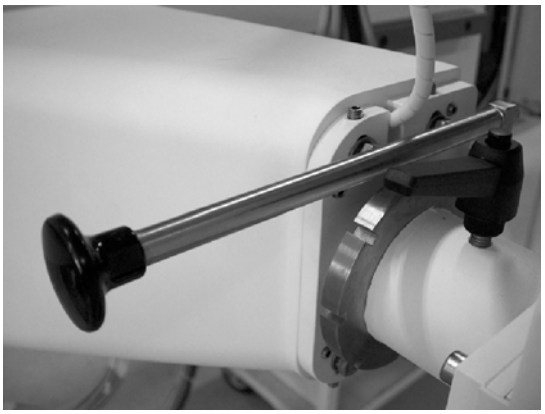
1. Insert the Grid in the slot with the label side facing the tube.
2. Check that the Grid is correctly inserted in the slot. A click sound means that the Grid is in place.

CAUTION

Handle the Grid with care and put it in a safe place when not in use. Dropping the Grid could cause damage and reduced image quality.

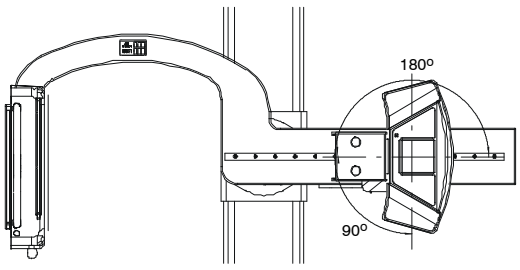
3.9 TUBE-COLLIMATOR ASSEMBLY POSITIONING

Tube-Collimator Assembly is equipped with a blocking system (on top) consisting of a lock-lever and a ratchet. In order to change angle position of the Tube-Collimator Assembly in relation to its transverse axis, loose the lock-lever and lift the ratchet. Ratchet has position detents every 45º.



CAUTION

The Tube-Collimator Assembly can be clockwise rotated up to +180º and counterclockwise rotated up to -90º. Rotation over these limits may damage the U-Arm cables.



3.10 COLLIMATOR

The following Collimators are compatible with the equipment covered by this manual:

- Ralco Manual Collimator R225/R225 DHHS.
- Ralco Automatic Collimator R225ACS.

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.*

3.10.1 RALCO MANUAL COLLIMATOR R225/R225 DHHS

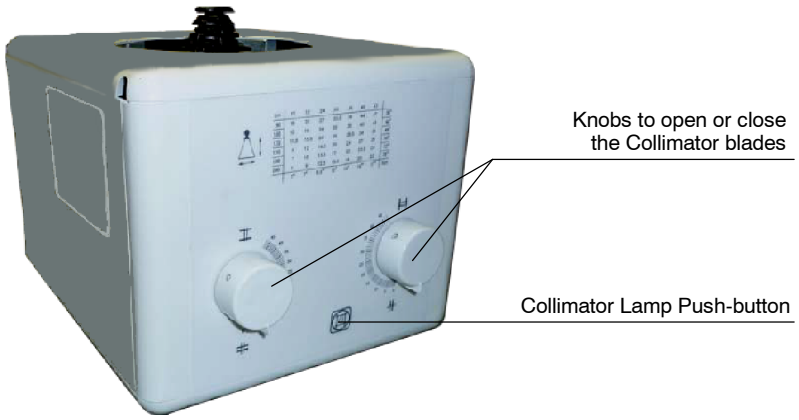
Collimator controls consist of a button to switch on the Collimator lamp and two knobs to open or close the internal blades of the Collimator.

When pressing the Collimator Lamp push-button, the Collimator light and an optional 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 ±90º in its vertical axis without the tube rotating. This movement is done manually and has locks every 90º.

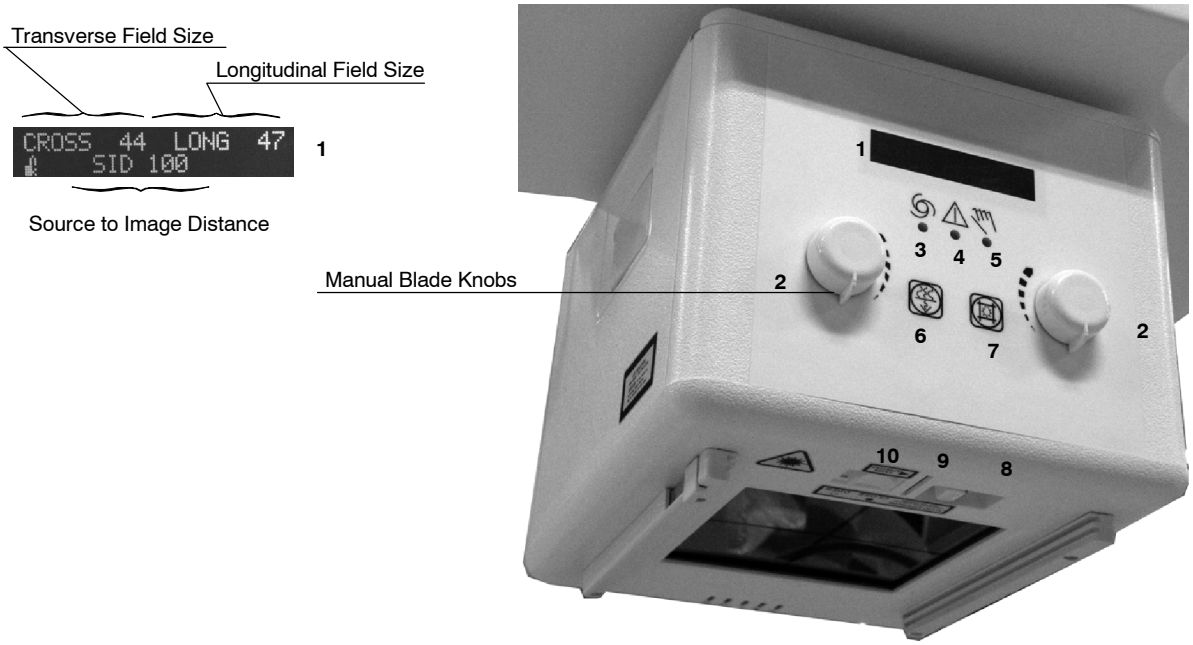
Illustration 3-16
Collimator Controls



3.10.2 RALCO AUTOMATIC COLLIMATOR R225ACS

Collimator controls:

1. Collimator Display
2. Manual Blade Control
3. Automatic Mode Indicator (Green)
4. System not ready Indicator (Red)
5. Manual Mode Indicator (Yellow)
6. Change of Filter
7. Collimator Lamp Control (Led “ON”)
8. Retractable Metric Tape
9. Laser Pointer Window
10. Laser Pointer On/Off Button



When pressing the Collimator Lamp push-button, the Collimator light and an optional 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 automatically adjusted, or when in manual mode by setting the two knobs. The Collimator Display shows the selected field size (cross / long).

The collimator can rotate $\pm 90^{o}$ in its vertical axis without the tube rotating. This movement is done manually and has locks every 90^{o}.

3.11 DOSEMETER DEVICE (OPTIONAL)

The optional Dosemeter device is related to the Collimator installed in the equipment. The compatible Dosemeter devices are:

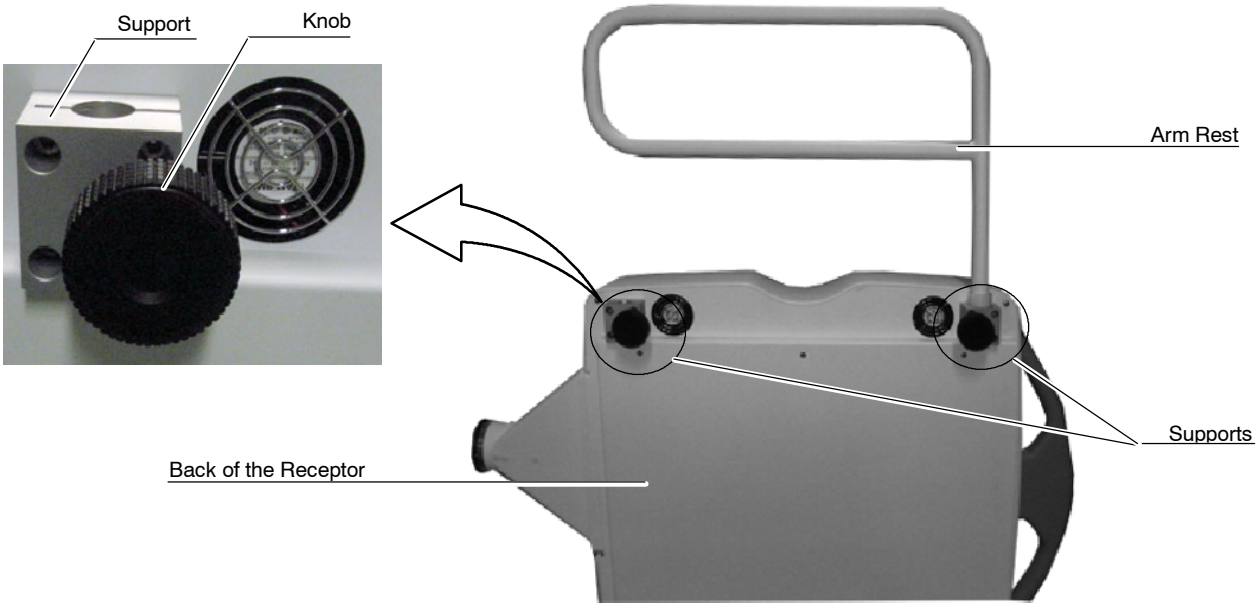
- Vacudap 2000 / 2004 Series.

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.*

3.12 ARM SUPPORT (OPTIONAL)

Positioners equipped with this option are supplied with two Supports installed at the back side of the Receptor Assembly.

The User only has to insert the Arm Support in one of the Supports, place it in desired position and manually tighten the knob.



3.13 ERROR MESSAGES

Error messages indicate the potential cause of a system failure. They are shown on the Display after pressing the Display Error button. *(Refer to Table 3-1).*

All these error codes 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 3-1
Error and Warning Messages

Error No	DESCRIPTION (IN SCREEN)	WHAT TO DO
1	*Initialize EEPROM in Service Mode*	Turn the Unit OFF/ON, if error remains, call field service.
2	*EEPROM could not be initialized*	
3	*Move without Order: Call Service*	
4	*Fatal RAM ERROR: Call Service*	
5	*Movement Order active during Start-up*	
6	*Security: Call Service*	Turn the Unit OFF and call field service.
7	*Initial Gauge Check: Restart*	Turn the Unit OFF/ON, if error remains, call field service.
8	*Communication Lost*	
9	*Inconsistent Relay Input*	
10	*Order without move*	
11	*Potentiometer*	
12	*Calibration*	
13	*External*	
14	*Potentiometer out of Range*	
15	*Movements locked*	Release the Safety Lock Button
16	*Move Button Released*	Operator stopped pressing the Auto positioning button. Press and hold until auto positioning has finished.
17	*Incompatible Movements*	A movement button has been pressed while auto positioning was in progress. Release the movement button.
18	*Opposite Move*	An opposite movement button has been pressed while other movement was in progress. Release the opposite movement button.
19	*Calibration Warning*	Turn the Unit OFF/ON, if error remains, call field service.
20	*Program not Selected*	Move button has been pressed without having selected a auto-position.
21	*Movement not enabled*	Turn the Unit OFF/ON, if error remains, call field service.
22	*Movement stop*	Information message. The Unit has reached a position.
23	*Collimator not communicating*	Turn the Unit OFF/ON, if error remains, call field service.
24	*Emergency Stop Inverters Off Cnt Bd.*	Information message associated to a Fatal Error. Turn the Unit OFF/ON, if error remains, call field service.

3.14 INFORMATION MESSAGES

The Positioner messages are self explanatory and provide additional information to the user.

Table 3-2
Information Messages

MESSAGE ON SCREEN	WHAT TO DO
SID movement without order	Refer to Section 3.13
SID order without movement	
Arm Rotation movement without order	
Arm Rotation order without movement	
Height movement without order	
Height order without movement	
Detector movement without order	
Arm rotation potentiometer error	
Broken Cable: Call Service	
Gauge Active	
Communication lost with Control Board	
Collimator not communicating	
Control Board not communicating	
Interface Board not communicating	
Interface Board not communicating	
RCC not communicating	
CAN BUS COMMUNICATION LOST	
Physical Limit: Column Rotation Left.	Turn the Unit OFF/ON, if error remains, call field service.
Physical Limit: Column Rotation Right.	
Physical Limit: Detector Left.	
Physical Limit: Detector Right.	
Physical Limit: Arm Rotation Left.	
Physical Limit: Arm Rotation Right.	
Physical Limit: SID minimum.	
Physical Limit: SID maximum.	
Physical Limit: Height minimum.	
Physical Limit: Height maximum.	

Table 3-2 (Cont.)
Information Messages

MESSAGE ON SCREEN	WHAT TO DO
Detected by: Control Board	
Detected by: Interface Board	
FREE MOVE MODE	
Limit: Arm Rotation Left	
Limit: Arm Rotation Right	
Limit: Detector Rotation Left	
Limit: Detector Rotation Right	
Limit: Detector Left	
Limit: Detector Right	
Limit: Column Rotation Left	
Limit: Column Rotation Right	
Limit: Tube Rotation Left	
Limit: Tube Rotation Right	
Collimator Rot	
Tube Rot	
Proximity Sensor activated	
Photocell 1 activated	Informative Message
Photocell 2 activated	
Limit: SID minimum	
Limit: SID maximum	
Limit: Height minimum	
Limit: Height maximum	
Inverters Powering Up	
Emergency Move: Press and Hold MOVE button + any Movement button	
Position Adjusted by User	
Position Reached	
Press and Hold MOVE button	
MOVE button released. Press and Hold MOVE button to continue	
Undertable position reached	
Chest button released: Press and Hold CHEST button to continue	
Undertable button released: Press and Hold UNDERTABLE button to continue	

Table 3-2 (Cont.)
Information Messages

MESSAGE ON SCREEN	WHAT TO DO
Limit: Detector Left	
Grid Range	
Cannot Open Collimator Port	
Door Open	
Detector In Tray Out	
Grid partially inserted	
Dosimeter not Communicating	
Free technique	
Detector angle out of -3/+3º range	
Tube not perpendicular	
Collimator rotated	
Collimator Manual Mode Variable SID	
Collimator Auto Mode	
Follow the instructions to generate and send a new code	
Stitching: target positions not reachable. Press Height Up	
Stitching: target positions not reachable. Press Height Down	
Stitching Setup Height and SID modified	
Stitching Setup SID modified	Informative Message
Moving to Stitching Setup position	
Press Move button to Stitching position	
Stitching Setup position reached	
Stitching Setup Height modified	
Stitching Aborted: Incorrect button pressed	
Stitching Setup error: invalid parameters	
Stitching Setup error: number of images exceeded	
Stitching Setup error: initial height limit	
Stitching Finished	
Stitching Canceled	
Ready to acquire extra image	
Ready to acquire image	
Collimator Manual Mode Fixed SID	
Filter feature not available	
Detector out of Radax docking stations	
Program Aborted: Incorrect button pressed	

Table 3-2 (Cont.)
Information Messages

MESSAGE ON SCREEN	WHAT TO DO
Bumper activated	Press the Safety Lock Button
Program Aborted: Invalid Parameters	Press the Safety Lock Button and try again
Program Aborted: Incorrect button pressed	Press “Move“ Button
Stitching	
Press Move button for Stitching Initial setup	
Press Move button to extra image position	

SECTION 4 PERIODIC MAINTENANCE

In order to ensure 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.

Service tasks here described must be performed exclusively by service personnel specifically trained on medical X-ray Units. The first periodic maintenance service should be performed six (6) months after installation, and the subsequent services at twelve (12) month intervals.

Heavy duty installations (more than125 patients per day) require a regular six (6) month maintenance.

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 IS IN USE WITH A PATIENT.

4.1 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 ELECTRICAL SUPPLY BEFORE CLEANING.

1. Switch the System OFF.
2. Externally, check the proper cable connections between each major component in the X-ray system (Power Cabinet, Consoles, etc ...).

3. Clean the equipment frequently, particularly if corroding chemicals are present. Clean external covers and surfaces, specially parts in contact with patients, with a cloth moistened in warm water with mild soap. Wipe with a cloth moistened in clean water. Do not use cleaners or solvents of any kind.

   When it is needed to disinfect any surface, clean it with a cloth impregnated with isopropyl alcohol.

   Do not apply directly any liquid on the surfaces, nor use cleaners containing bleach, ammonia or any other abrasive or solvent liquid, it could cause damage to the equipment.

4.2 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 5 TECHNICAL SPECIFICATIONS

POWER LINE REQUIREMENTS

Power Line	Single phase, 50 / 60 Hz, 230 / 240 V~ ±10%
Minimum input power required	2.5 kVA
Power Consumption in stand-by	80 W

OPERATING ENVIRONMENTAL CONDITIONS

Temperature range	10°C to 40°C (50°F to 104°C)
Relative Humidity range (no condensing) . .	30% to 75%
Atmospheric Pressure range	700 hPa to 1060 hPa

STORAGE / TRANSPORT ENVIRONMENTAL CONDITIONS

Temperature range	-40°C to 70°C (-40°F to 158°C)
Relative Humidity range	10% to 100%
Atmospheric Pressure range	500 hPa to 1060 hPa

Note ☞ *These environmental conditions do not include the Digital Detector. Refer to the Digital Detector Documentation if applicable.*

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: 160 mm in “X” axis and 240 mm in “Y” axis.
Measured at 125 kVp: 80 mm in “X” axis and 240 mm in “Y” axis.
(Test performed at a distance from the Focal Spot of 1200 mm, in accordance with IEC 60806: 1984)

DIMENSIONS AND WEIGHT OF THE COLUMN

Maximum Height (Undertable Position)	2650 mm (104.3”)
Maximum Height (of positioner)	2775 mm (109.25”)
Maximum Length	2135 mm (84”)
Maximum Width	1680 mm (66”)
Weight	324 kg (714.3 lb)

COLUMN DATA

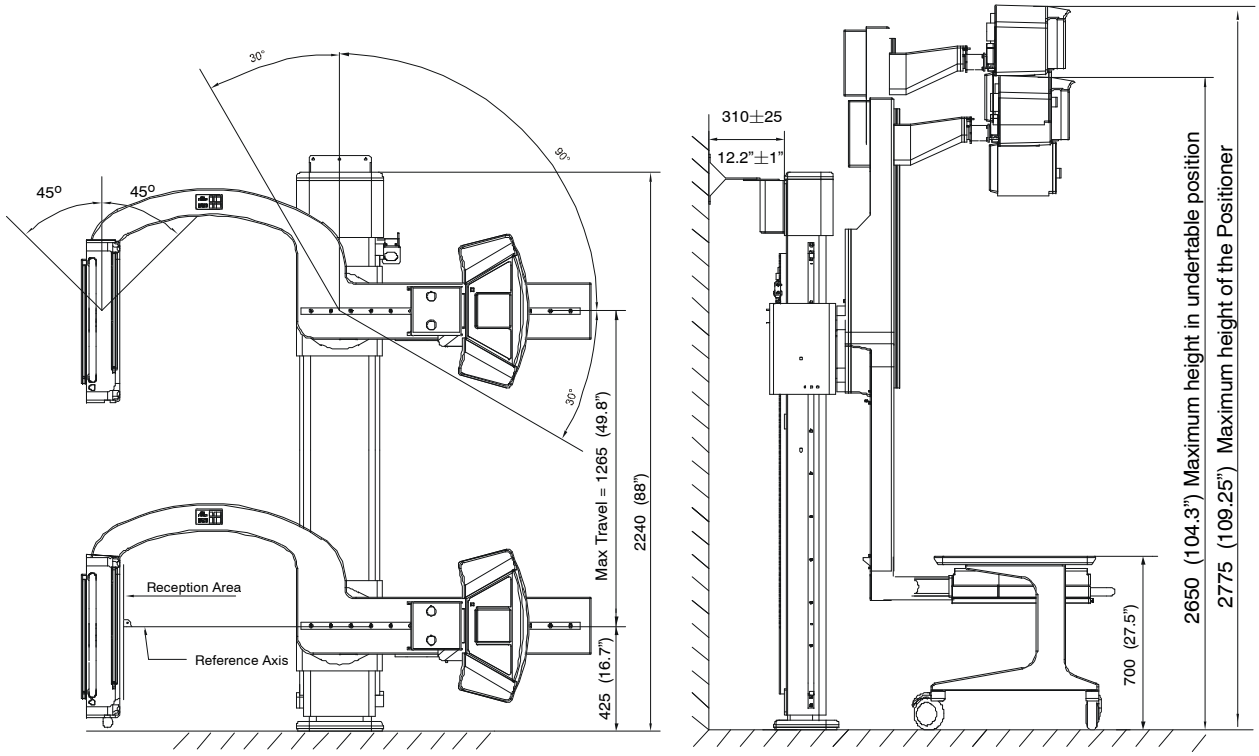
Vertical Travel of Central Carriage	1265 mm (49.8”)
Minimum Source-Image Distance (SID)	1000 mm (40”)
Maximum Source-Image Distance (SID) . .	1800 mm (70.8”)
SID adjustment speed	87 mm/s (3.4”/s)
Rotation of Swivel Arm . . . . . *(rotation may be limited by cables)*	$+120^{o}/-30^{o}$
Rotation of Tube-Collimator Assembly . . . . *(rotation may be limited by cables)*	$\pm 180^{o}$
Rotation of Receptor Assembly	$\pm 45^{o}$
Table-Top Attenuation	<0.85 mm Al eq.
(*) Grids: Removable Grids	12:1 –1 m – 80 lines/cm 12:1 –1.80m – 80 lines/cm
Oscillating Grid	12:1 –1.50m – 40 lines/cm

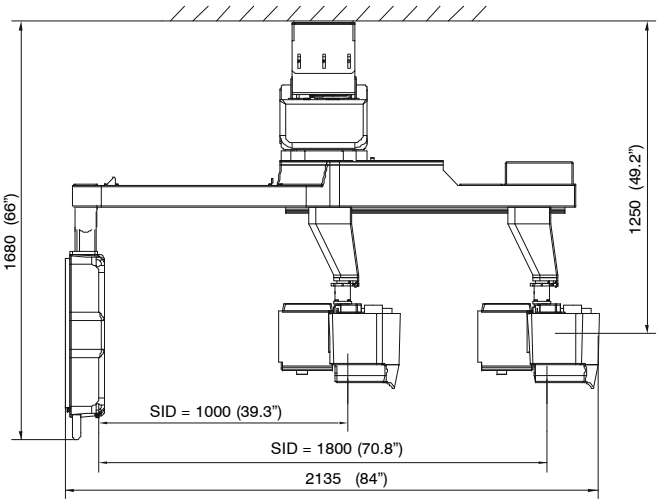
(*) Grids depends on type of receptor

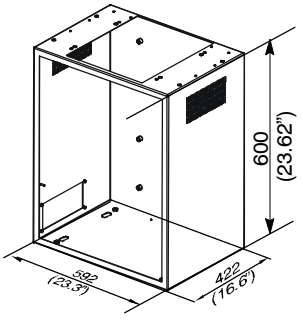
DIMENSIONS AND WEIGHT OF THE CONTROL UNIT

Height x Width x Length	600 x 592 x 422 mm 23.6 x 23.3 x 16.6 ”
Weight	63 kg (139 lb)

Illustration 5-1
Dimensions of the U-Arm Positioner and Control Unit







DIMENSIONS AND WEIGHT OF THE UNIVERSAL RADIOGRAPHIC MOBILE TABLE

Height x Length x Width	700 x 2000 x 650 mm (27.5 x 78.7 x 25.5 ”)
Weight	40 kg (88.1 lb)
Maximum Patient weight	200 kg (440 lb)
X-ray Transparency Area (L x W) . . .	1880 x 528 mm (74 x 20.8 ”)
X-ray Absorption Factor	< 1.05 mm Al. equivalent

DIMENSIONS AND WEIGHT OF THE CARBON FIBER MOBILE TABLE (OPTIONAL)

Height x Length x Width	700 x 2200 x 650 mm (27.5 x 86.6 x 25.5 ”)
Weight	32 kg (70.5 lb)
Maximum Patient weight	200 kg (440 lb)
X-ray Transparency Area (L x W) . . .	1940 x 650 mm (76.4 x 25.5 ”)
X-ray Absorption Factor	< 0.8 mm Al. equivalent

Illustration 5-2
Dimensions of Laminated Mobile Table

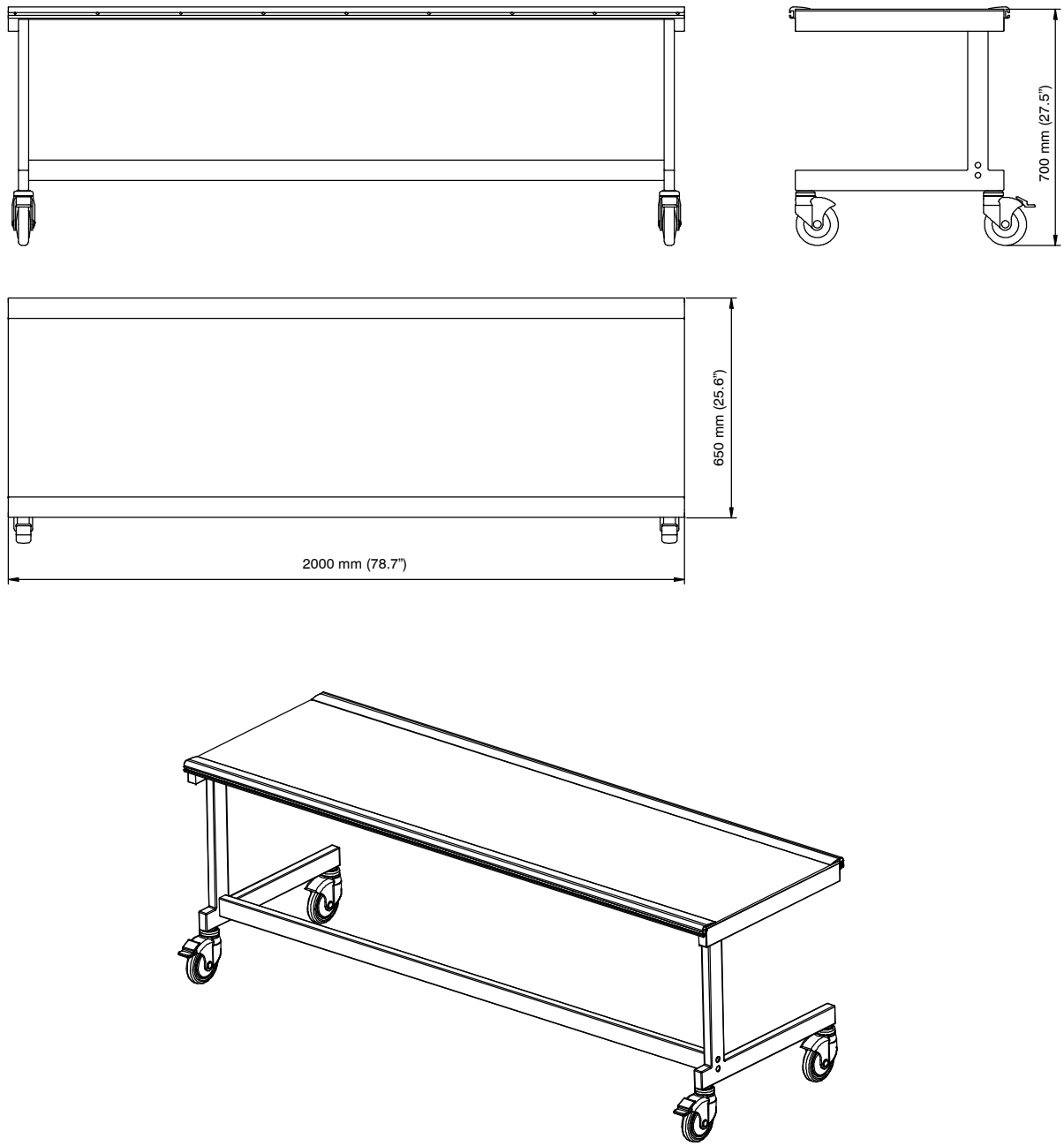


Illustration 5-3
Dimensions of Carbon Fiber Mobile Table