Technical Publication
OM-0360R14_EN_NLG

Operation

Portable X-Ray Units

SPSL-HF-4.0, SPSL-HF-8.0, SPSL-HF-4.0-APR, SPSL-HF-8.0-APR

CE
1639

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/EEC 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 Sanitarios, modificada por la directiva 2007/47/CEE del 5 de septiembre de 2007.

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

Questo prodotto presenta un marchio CE in ottemperanza a quanto disposto nel 93/42/EEC MDD del 14 giugno 1993, rettificato da 2007/47/CEE il 5 settembre 2007.

This manual covers the following equipments / Este manual cubre los siguientes equipos

Ce manuel couvre les équipements suivants / Il presente manuale descrive i seguenti dispositivi

Portable X-Ray Unit DRAGON X:

SPSL-HF-4.0, SPSL-HF-8.0,
SPSL-HF-4.0-APR, SPSL-HF-8.0-APR

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REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	APR 14, 2011	First Edition.
1	OCT 11, 2011	APR Update.
2	JAN 31, 2013	IEC Standards Update.
3	MAY 6, 2013	New Aluminium Frame.
4	OCT 9, 2013	Stray Radiation and Specifications update.
5	DEC 03, 2015	Mechanical and Software Updates.
6	FEB 19, 2016	New Options.
7	MAY 11, 2017	TSC new features, Errors and Technical Specifications Update.
8	FEB 15, 2018	New Overlay.
9	JUN 07, 2018	New Leg Locking System.
10	OCT 18, 2018	New Errors and Warming-up Procedure.
11	NOV 25, 2019	General Update II.
12	DEC 12, 2019	CE1639 Marking.
13	FEB 25, 2021	Technical specifications for 5 kW model.
14	NOV 07, 2022	New options added and general 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.

IMPORTANT NOTES

AUTOMATIC LINE POWER DETECTION SYSTEM

By means of this System, the Unit detects the maximum operative Power Line adapting the Exposure Parameters to the Power available and avoiding undesired line breakdowns when operating with poor electricity lines. Refer to Section 3.2.2 for Automatic Line Power Detection Procedure and Section 3.2.4 if Manual Power Reduction is required.

COLLIMATOR LIGHT THERMAL PROTECTION

Collimator Light is provided with a Thermal Protection that may reduce the lighting time of the Light and even turn the light Off in case it is On for an excessive period of time. Refer to the Service Manual to configure the time that the Collimator Light is light On.

X-RAY TUBE SEASONING AND X-RAY TUBE WARMING-UP

*The **Seasoning** and **Warning-up** procedures assure a correct operation of the X-ray Tube and must be properly carried out. Otherwise the X-ray Tube life may be considerably reduced or the X-ray tube will suffer a permanent damage.*

*The **Seasoning** Procedure (Running) must be performed when the Tube is used for the first time or when it has not been in use for more than one month. This action establishes a favorable distribution of the electrical charges and electrostatic stresses in the insulation system of the Tube and the associated equipment. Not performing the Seasoning Procedure causes loss of the X-ray Tube Warranty.*

*The **Warming-up** Procedure must be performed at the start of each day or when the unit has been off for more than four hours.*

Note: Check that the Heat Units capacity is above 80% during this process.

1. Close Collimator Blades fully and make sure that no one will be exposed.
2. Make sure that X-ray Tube is fully cold (at least 30 minutes without making exposures).
3. Reduce the power manually to 20% in case of 4 kW or 5 kW units or 10% in case of 8 kW units. On the X-ray Unit Control Panel, press and hold the “Large Focal Spot” push-button and then press the “kVp Decrease” push-button several times until “P10 or P20” respectively is shown in the kVp display.
4. Select 70 kVp, 10 mAs and Large Focus. Perform one exposure per minute increasing 5 kVp in every exposure up to the maximum Tube voltage.
5. If there are not signs of instability, the tube is ready for normal use.
6. If instability is observed during procedure, reduce 5 kVp of the selected kVp and make two exposures at those KVp, then continue the process.
7. Once the seasoning procedure is completed, set the power at 100% again. On the X-ray Unit Control Panel, press and hold the “Large Focal Spot” push-button and then press the “kVp Increase” push-button several times until “P--” is shown in the kVp display.

WARMING-UP PROCEDURE (every day)

1. Close Collimator Blades fully and make sure that no one will be exposed.
2. For 4kW and 8 kW X-Ray Units, select 60 kVp, 40 mAs and Large Focus.
   For 5 kW X-Ray Units, select 70 kVp, 64 mAs and Large Focus.
3. Perform one exposure.
4. Now the Tube is ready for normal use.

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SECTION 1 INTRODUCTION

This manual contains all the necessary information to understand and operate this **Portable X-Ray Unit with APR**. It provides a general description, safety and regulatory information, operating instructions and specifications concerning the equipment. It is not intended to teach radiology or to take any type of clinical diagnosis.

This **Portable X-Ray Unit** operates from single phase power supplies and provide all the generator advantages of constant potential waveform including lower patient dose, shorter exposure times and greater accuracy and consistency.

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

All functions, displays and controls are logically arranged, easily accessible and identified to prevent confusion. Radiographic technique factors and functions are selected by touch sensitive push-buttons and displayed on the Control Panel.

Illustration 1-1
Portable X-Ray Unit with APR

1.1 GENERAL FEATURES

This **Portable X-Ray Unit** consists of:

X-RAY GENERATOR COMPONENTS

- *X-Ray Unit* comprises:
  - *Power Module* containing control and power components.
  - *High Voltage Transformer.*
  - *Filament Transformer.*
  - *X-Ray Tube.*
  - *Control Panel* for operation and service tasks.
- *Collimator Model* RS72S compatible with the X-Ray source. The Collimator includes controls to limit the X-Ray beam.
- *SID Guard.*

ASSOCIATED EQUIPMENT AND SUBASSEMBLIES

The following subassemblies are considered to be Associated Equipment and conform to the applicable safety requirements therein stated.

- *Touch Screen Console* or *3P Overlay Console* for radiographic operations.
- *Portable Unit* with an *Articulated Arm* and *Receptor Basket*.

The main features of this Portable X-Ray Unit are:

- Safe and easy operation.
- Constant potential high frequency operating on single phase lines.
- Radiographic operation from: Touch Screen Console or 3P Overlay Console located at the Portable Unit Control. In both cases the Unit incorporates a Control Panel located at the head of the X-Ray Unit.
- Tube protection circuitry prolongs Tube life and increases system performance.
- Filament Power Down Mode to increase the Tube Filament life.
- Equipped with closed loop control of X-Ray Tube current, kVp and filaments, which minimize potential errors and the need for readjustments.

- Standard electric outlet operation from 100 to 240 V~ for Portable Units of 4 kW, and from 220 to 240 V~ for Portable Units of 5 kW and 8 kW.
- Automatic line voltage compensation due to closed loop operation of X-ray Tube current and kVp.
- Remaining percentage of the Thermal Capacity of the X-ray Tube and Generator.

1.1.1 OPTIONS AND ACCESSORIES

In addition to the above mentioned features, these Portable Units also include the following options and accessories:

OPTIONS:

- Steel or aluminum chassis.
- *Collimator with laser positioner.*
- *Digital interface.*
- *Long or short front handles.*
- *Inclinometers.*
- Handswitch or footswitch.
- *Y-shaped or T-shaped folding leg.*
- *All-terrain or solid wheels.*
- *Wheels for motion with folded leg.*
- Digitalization kit.
- *Standard or advanced receptor basket*

ACCESSORIES:

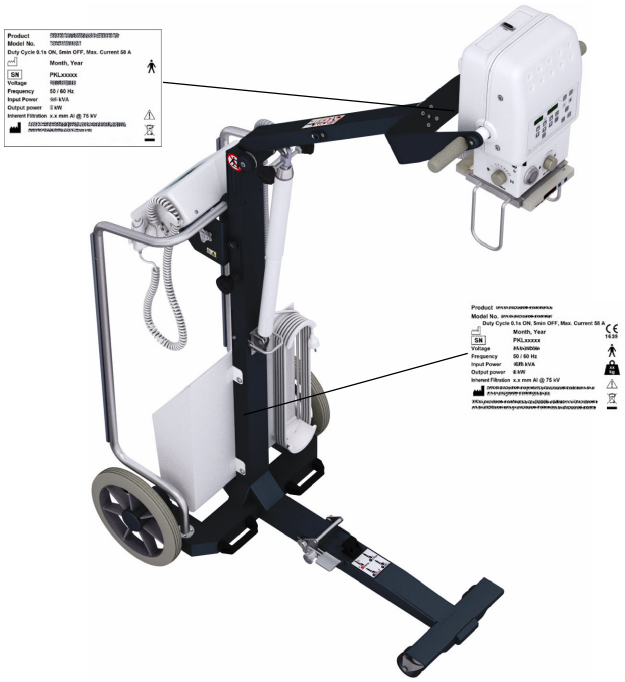
- *Aluminium Filters.*
- *Dosimeters.*
- *Transport boxes.*
- Mobile table for radiological use.
- Fittings for satndard receptor basket.
- Laptop support.

Note ☞ *For detailed information on the Options and Accessories of the X-Ray unit, refer to Section 3.8.*

1.2 PRODUCT IDENTIFICATION

Identification labels of the Portable X-Ray Units provide information on:

- Product.
- Model.
- Volts (V), Line Phases, Frequency (Hz), and Power (kVA, kW).
- Date of manufacture.
- Serial number.
- Reference.
- Manufacturer.
- Manufacturing location.
- Certifications.
- Total Filtration.
- Nominal X-Ray Tube Voltage of the X-Ray Source.
- Manufacturer and Focus Size of the X-Ray Tube.



1.3 INDICATIONS FOR USE

1.3.1 INTENDED USE

This equipment is intended for use by qualified personnel only, as radiology technicians and doctors who have licenses in the radiology field.

The **Portable X-Ray Unit** is an equipment designed for general radiography in hospitals, clinics, radiology imaging centers and medical practices. It is suitable for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts in intensive care units, emergency rooms, radiology departments and physicians' offices. Not for mammography.

Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Examinations can be performed to any kind of patient group. Patients may be physically abled, disabled, immobilized or in a state of shock.

This **Portable X-Ray Unit** contributes to the metrics of imaging performance ensuring the efficient use of radiation. It is designed for multiple uses/cases per day.

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

1.3.2 NORMAL USE

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

1.3.3 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 mammographic applications.

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

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SECTION 2 SAFETY AND REGULATORY INFORMATION

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

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

2.1 GENERAL

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

TECHNICAL INSTRUCTIONS FOR SERVICE PERSONNEL SUCH AS INSTALLATION, CALIBRATION OR MAINTENANCE ARE DESCRIBED IN THE RESPECTIVE CHAPTERS OF THE SERVICE MANUAL 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 and IEC 60601-2-54:2009+AMD1:2015
Total of all layers composing the front panel of cassette holder	1.2	1.2
Total of all layers composing the front panel of FILM CHANGER	1.2	1.2
Total of all layers, excluding detector itself, composing the front 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.

IF ANY SERIOUS INCIDENT INVOLVING THE EQUIPMENT OCCURS, IT MUST BE REPORTED TO THE MANUFACTURER, AS WELL AS TO THE COMPETENT AUTHORITY OF THE COUNTRY/REGION IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED.

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 whenever possible.

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

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

2.5 MONITORING OF PERSONNEL

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

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

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

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

2.6 SAFETY SYMBOLS

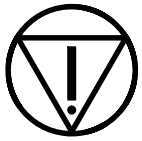
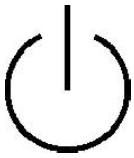
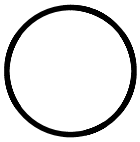
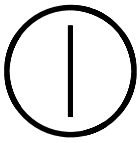
The following safety symbols may appear in the equipment.

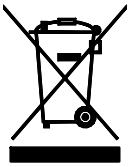
Their meaning are described below.

	**Caution. Consult accompanying documents.**
	**Safety Symbol. Follow instructions for use, especially 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)*
	**Manufacturer.**
	**Date of Manufacture.**
	**Medical Device.**
	**Catalogue Number (Model reference).**
	**Serial Number.**
	**Model Configuration.**
	**Unique Device Identifier.**

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

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

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

Statement of Compliance with IEC 60601-1-3: ***Portable X-ray Unit*** *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 601-2-28: *X-ray source assembly* ***Portable X-ray Unit*** *in accordance with IEC 601-2-28:1993.*

Statement of Compliance with IEC 60601-2-28: *X-ray Tube assembly* ***Portable X-ray Unit*** *in accordance with IEC 60601-2-28:2010.*

Statement of Compliance with IEC 60601-2-54: ***Portable X-ray Unit*** *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* ***Portable X-ray Unit*** *conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.*

Note ☞ ***Portable X-ray Unit*** *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 with intermittent loading,* in accordance with Standard IEC 60601-1:1988, IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012.
- *Non-continuous with Duty Cycle of 0.1 seconds (ON) and 5 minutes (OFF)*, in accordance with Standard IEC 60601-1:1988, IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012.

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

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

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

THIS PORTABLE X-RAY UNIT IS EQUIPPED WITH EMC FILTERS. THE LACK OF PROPER GROUNDING MAY PRODUCE ELECTRICAL SHOCK TO THE USER.

2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

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

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE 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, IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012.

2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

2.7.8 DESIGNATED SIGNIFICANT ZONES OF OCCUPANCY

X-Ray equipment specified for 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 on a Chest Unit or Front Panel

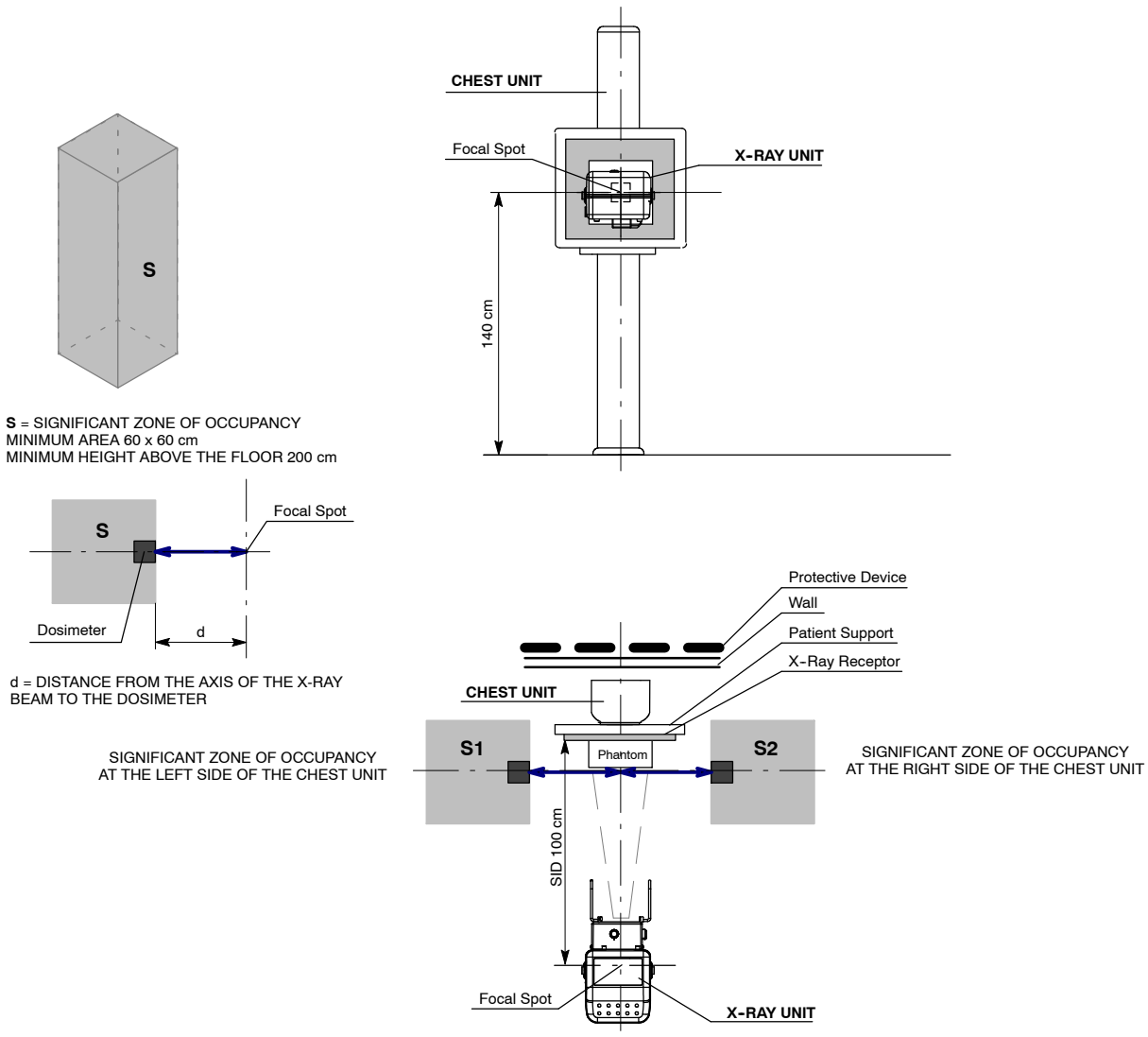
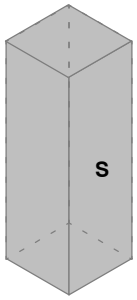
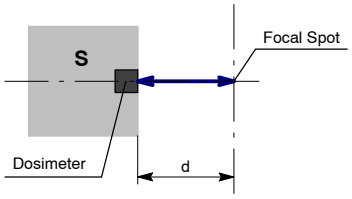


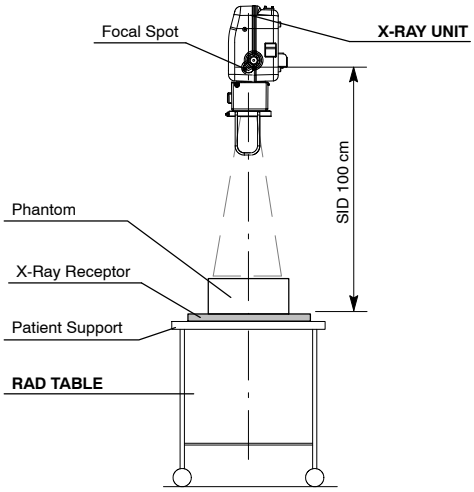
Illustration 2-2
Radiographic Examination on any Patient Support or Table



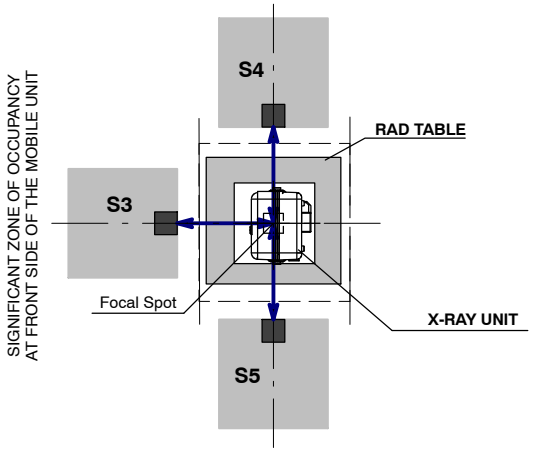
S = SIGNIFICANT ZONE OF OCCUPANCY
MINIMUM AREA 60 x 60 cm
MINIMUM HEIGHT ABOVE THE FLOOR 200 cm



d = DISTANCE FROM THE AXIS OF THE X-RAY BEAM TO THE DOSIMETER



SIGNIFICANT ZONE OF OCCUPANCY
AT THE RIGHT SIDE OF THE MOBILE UNIT
(ANODE)



SIGNIFICANT ZONE OF OCCUPANCY
AT THE LEFT SIDE OF THE MOBILE UNIT
(CATHODE)

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 and IEC 60601-1-3:2008+AMD1:2013.

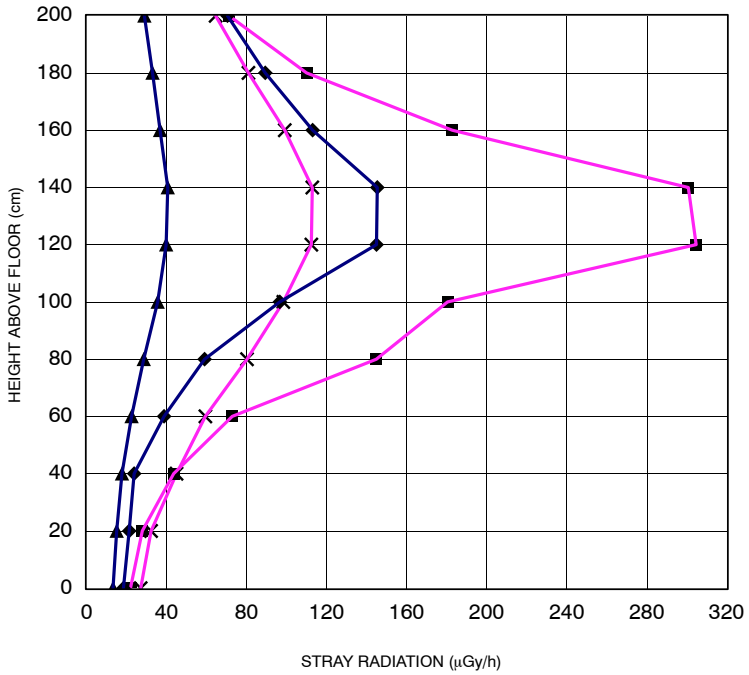
- Exposure Parameters: RAD mode, 125 kVp, 10 mAs, large focus.
- Collimator opening for Field Size 18 x 18 cm, SID 100 cm.
- Phantom: Rectangular water phantom of 25 x 25 x 15 cm, or a material having a similar X-Ray attenuation coefficient.
- Radiation measuring instrument: Low Radiation Dosimeter.

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 position of the X-ray Unit during radiographic examination on the Chest Unit or Front Panel, and refer to Illustration 2-2 for position of the X-ray Unit during radiographic examination on any Patient Support or Table.

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

Illustration 2-3
Distribution of Stray Radiation on the Chest Unit or Front Panel



$S1_1$	d = 50 cm	
$S1_2$	d = 100 cm	
$S2_1$	d = 50 cm	
$S2_2$	d = 100 cm	

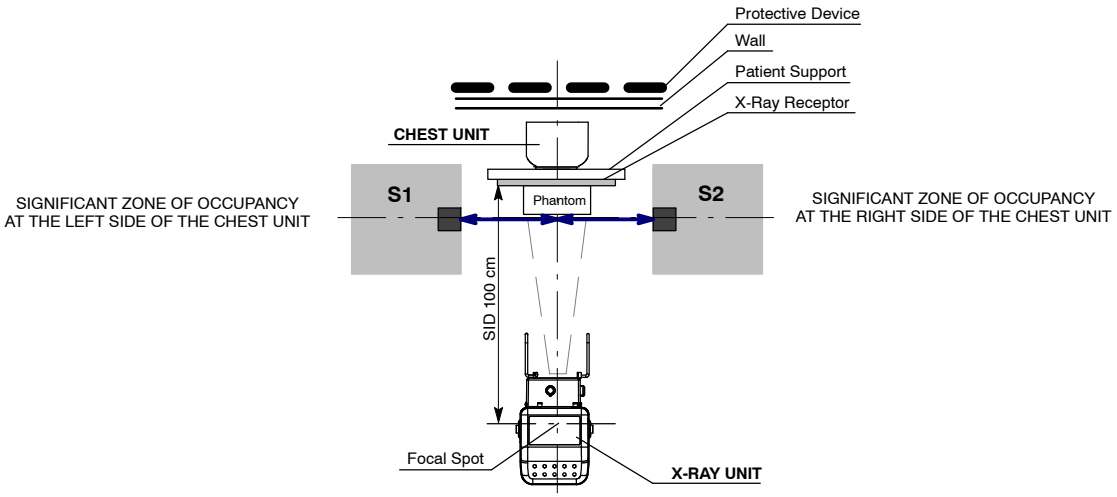
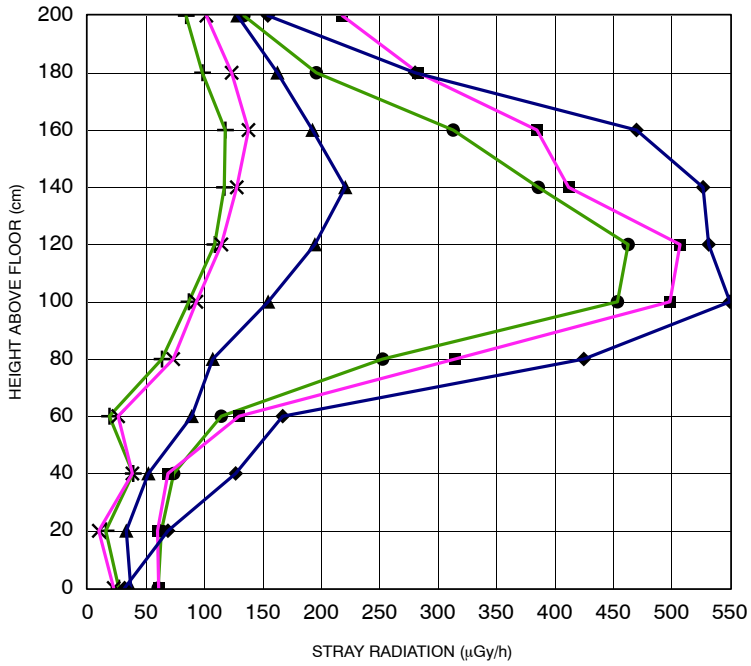
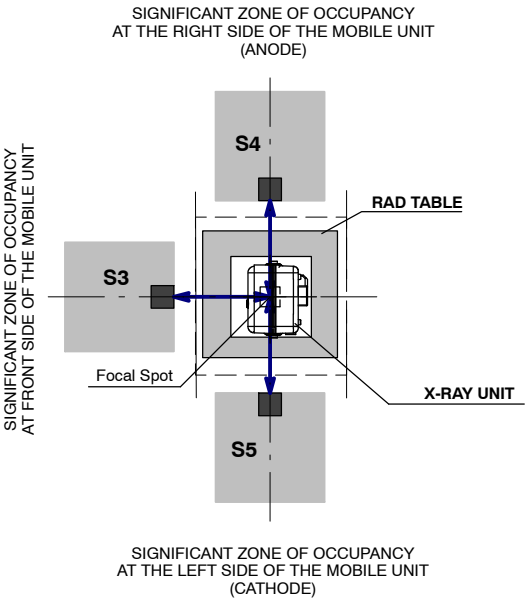


Illustration 2-4
Distribution of Stray Radiation on any Patient Support or any Table



$S3_1$	d = 50 cm	
$S3_2$	d = 100 cm	
$S4_1$	d = 50 cm	
$S4_2$	d = 100 cm	
$S5_1$	d = 50 cm	
$S5_2$	d = 100 cm	



2.8 ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

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

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

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

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

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

Should any interference (EMC) be detected with other equipment, please position other equipment away from 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 IEC 60601-1-2:2014 Tables as described in this section.

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

ESSENTIAL PERFORMANCE

The system (e.g. Genarator, Patient Support, Tube, Detector, etc.) is designed to use X-rays for diagnostic purposes according to international standards, to prevent patient, user, and others from electrical and mechanical hazards by using adequate EMC measures like using filters, screened cables or housings.

EMC-COMPLIANCE CRITERIA DUE TO THE ESSENTIAL PERFORMANCE

- No unintended X-radiation
- No unintended change of generator parameters (kV, mAs)

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS (IEC 60601-1-2:2007 AND IEC 60601-1-2:2014)		
This Portable 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 Portable 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 Portable 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 Portable 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.			
Immunity test	**IEC 60601-1-2:2007 Test Level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV maximum ± 8 kV 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV ± 2 kV	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	30% for 0.5 periods 60% for 5 periods 100% 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	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE - U_T is the a.c. mains voltage prior to application of the test level.			

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

This Portable 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.

Immunity test	IEC 60601-1-2:2007 Test Level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of this Portable X-ray Unit 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

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

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation 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 this Portable X-ray Unit is used exceeds the applicable RF compliance level above, this Portable X-ray Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this Portable X-ray Unit.*

[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 PORTABLE X-RAY UNIT (IEC 60601-1-2:2007)

This Portable X-ray Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this Portable X-ray Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this Portable X-ray Unit 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 metres (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.

NOTE 3 - RFID chips are typically powered from the electromagnetic field, and therefore only the reader can be regarded as an RF transmitter.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014)			
This X-ray Unit is intended for use in the electromagnetic environment specified below. The customer or user of this X-ray Unit 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 Unit requires continued operation during power mains interruptions, it is recommended that this X-ray Unit 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 Unit is intended for use in an electromagnetic environment specified below. The customer or user of this X-ray Unit 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)	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.
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"	
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 Unit is intended for use in an electromagnetic environment specified below. The customer or User of this X-ray Unit 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 and IEC 60601-1-3:2008+AMD1:2013. These tables illustrate loading factors for image performance and supply Dose indication examples. Therefore, these tables are an instance 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:

- Portable X-Ray Unit with Ralco Collimator R72s.

Instrumentation used:

- Dosimeter 1 (for Collimator Output Dose): Vacudap Compact.
- Dosimeter 2 (for Phantom Input Dose): Unfors Xi R/F.
- Thermohygrometer Testo 608-H2.
- Rectangular water Phantom made of Polymethyl-methacrylate (PMMA) layers of 25 cm x 25 cm x 15 cm.

Test Details:

- Environmental Test Conditions:
  - Temperature: 23º C ± 2º C
  - Relative Humidity: 38% - 42%
- SID distance from Table:100 cm.
- Open Collimator size: 24 cm x 30 cm (min.), 35 cm x 43 cm (max.)
- The measurements were made with the exposure parameters (kVp and mAs) shown on the results table, using the most common examinations performed with this Unit.
- Performed measurements:
  - Collimator Output doses
  - Patient (Phantom) Entrance doses

Quantitative Information											
Patient Examination	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)	Phantom Input Dose Rate (µGy/s)	Phantom Input Dose Rate (µGy/mAs)
Skull	**70**	**6.4**	**1.6**	**10**	**Small**	**100**	**24x30**	2.96	23.4	270.81	43.33
Chest	**90**	**6.4**	**0.32**	**2**	**Small**		**35x43**	3.86	15.2	452.81	72.45
Cervical	**65**	**50**	**0.125**	**6.4**	**Large**		**24x30**	2.71	11.8	1755.20	34.28
Elbow	**50**	**80**	**0.025**	**4**	**Large**		**24x30**	2.13	63.4	2686.00	16.79
Hand	**45**	**80**	**0.040**	**3.2**	**Large**		**24x30**	1.95	1.9	952.25	11.90
Ribs	**65**	**50**	**0.250**	**12.5**	**Large**		**35x43**	2.69	37.5	1424.00	28.48
Thorax	**75**	**50**	**0.200**	**10**	**Large**		**35x43**	3.10	52.3	2470.00	49.41
Pelvis	**70**	**50**	**0.320**	**16**	**Large**		**35x43**	2.91	71.8	2121.88	42.43
Knee	**60**	**64**	**0.080**	**5**	**Large**		**24x30**	2.50	7.8	1843.75	29.50
Abdominal	**70**	**40**	**0.640**	**25**	**Large**		**35x43**	2.90	115.6	1709.38	45.58
Hip	**65**	**50**	**0.320**	**16**	**Large**		**35x43**	2.69	60.1	1786.56	35.73
Lumbar	**75**	**40**	**0.400**	**16**	**Large**		**35x43**	3.11	84.3	1991.50	49.79
Femur	**65**	**8**	**1**	**8**	**Small**		**24x30**	2.76	15.3	282.00	35.25
Ankle	**52**	**64**	**0.064**	**4**	**Large**		**24x30**	2.26	4.0	1231.09	19.70
Foot	**50**	**80**	**0.025**	**2**	**Large**		**24x30**	2.19	1.6	1299.60	16.25
Shoulder	**60**	**64**	**0.160**	**10**	**Large**		**24x30**	2.51	15.8	1850.00	29.60

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 OPERATING CONTROLS

Note ☞ *Use the operating controls as described in this manual, any other non-indicated combination may cause an incorrect operation of the equipment.*

- General movements for travelling are controlled with the Front Handles which allow movements in all directions.
- Control Panel. All the controls, indicators and displays are positioned in related groups or modules depending upon their functions.
- Touch Screen Console or 3P Overlay Console. All the controls, indicators and displays are positioned in related groups or modules depending upon their functions for Radiography, APR and General Operation.
- Handswitch and footswitch.
- Panel of the Manual Collimator, with the controls for opening or closing the Collimator Blades and to switch ON the Collimator Light.

3.1 MOTION AND POSIOTIONING

WARNING

ALWAYS DRIVE OR TRANSPORT THE UNIT WITH THE ARM IN PARKING POSITION. FOR SAFETY REASONS, THE FLOOR WILL NOT EXCEED 5º INCLINATION (RAMPS).

WARNING

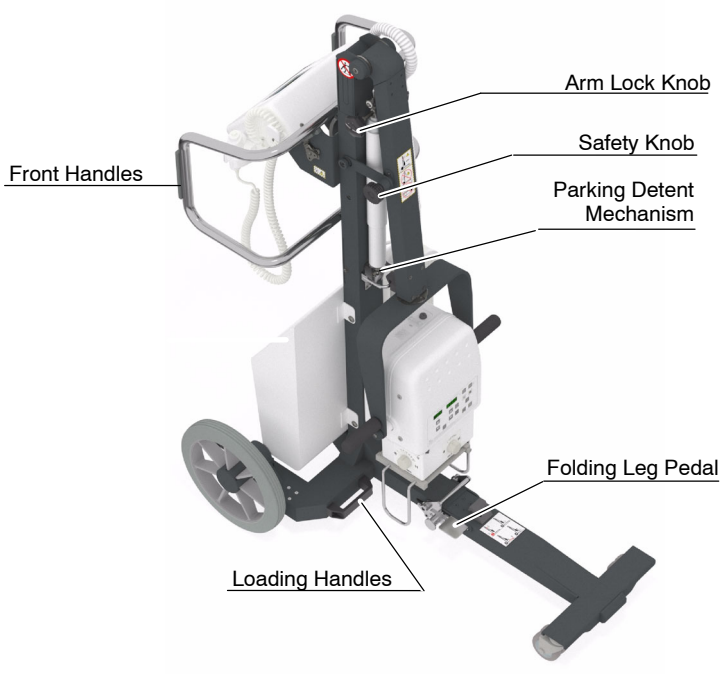
MONITOR THE SYSTEM MOVEMENTS WITH SPECIAL CARE. AVOID ANY IMPACT OF THE UNIT ON WALLS, FURNITURE OR OTHER ELEMENTS IN THE ROOM THAT MAY CAUSE DAMAGE TO THE EQUIPMENT.

WARNING

MONITOR WITH SPECIAL CARE THE PATIENT POSITION OR ANY OTHER PEOPLE, TO AVOID INJURY CAUSED BY UNIT MOVEMENTS. INTRAVENOUS TUBING, CATHETERS AND OTHER PATIENT CONNECTED LINES SHOULD BE ROUTED AWAY FROM MOVING EQUIPMENT.

The Front Handles are designed to facilitate sliding the Unit during vehicle loading / unloading as well as to drive the Unit on the front Casters and Main Wheels. The Brakes block the Main Wheels motion once positioned.

Position the Arm with the Positioning Grips. The Detent Mechanism and Safety Knob maintain the Arm in Parking Position while the Arm Lock Knobs maintain the Arm steady during radiographic examinations.



DANGER !

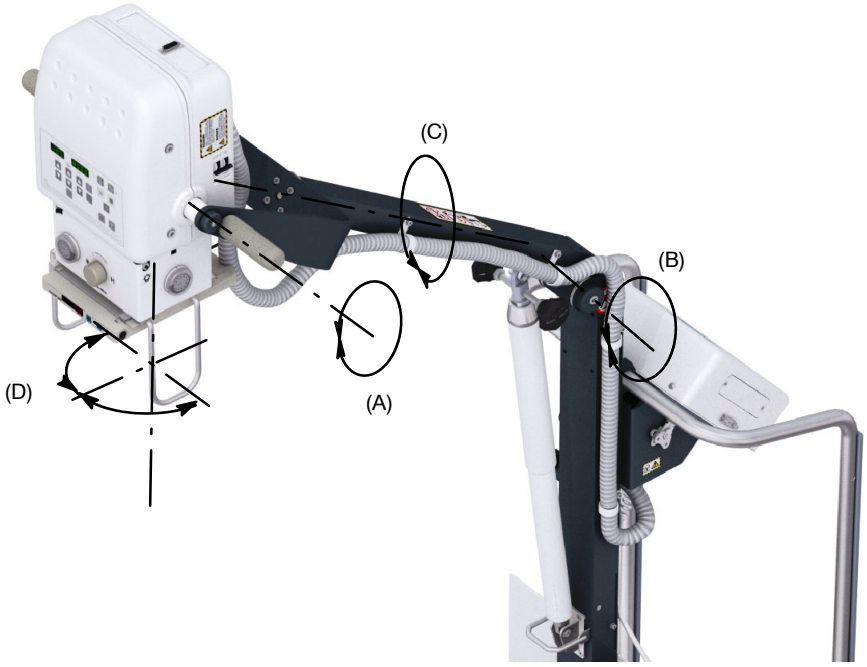
NEVER PUSH THE UNIT LATERALLY FROM THE ARM ELBOW, IT MAY FALL DOWN AND MAY CAUSE INJURIES TO PATIENTS OR PEOPLE AROUND THE UNIT.

Obstacles as kerbs and steps are easily saved by stepping on the Step Plate in order to raise the front wheels.

The Front Handles greatly facilitate the slide of the Unit during vehicle loading or unloading.

The Mobile Arm allows the following movements:

- (A) Rotation of the X-Ray Unit with reference to its Support (360º that can be limited by the SID Guard and Harness).
- (B) Vertical Movement of the Arm to lower or raise the X-Ray Unit which is used to adjust the Vertical SID.
- (C) Rotation of the X-Ray Unit Support (360º that can be limited by the Harness). This movement has detents at 0º, +90º and –90º.
- (D) Rotation of the Collimator with reference to the X-Ray Unit (± 90º). This movement has a detent every 90º.

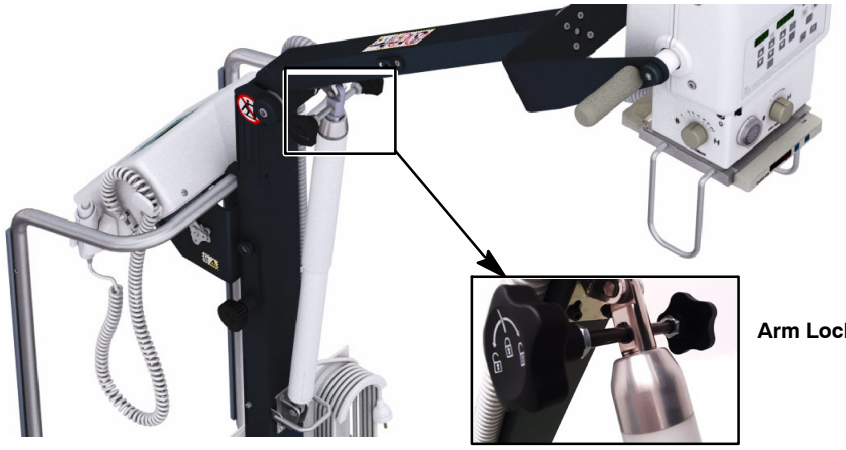


Note ☞ *Release the Arm from its parking position prior to performing any Arm movement.*

3.1.1 ARM LOCK KNOBS

The vertical movement of the Arm is locked / unlocked with the manual Arm Lock Knobs. This manual lock Knobs equips the Unit with an extra protective measure to prevent unwanted or unintended movements during examinations.

To lower or raise the Arm, turn the Arm Lock Knob to the unlocked position. When the Arm has been properly positioned, place the knob in lock position. Locking and Unlocking is as shown in the photo below.



Arm Lock Knobs

NEVER ATTEMPT TO UNFOLD THE UNIT IN LAYING POSITION. UNFOLD ONLY IN VERTICAL POSITION.

3.1.2 BRAKES

Both wheels include a brake. Pull the Levers to prevent the Main Wheels movement.

Push the Levers to release the wheels.

Push the Lever

Pull the Lever

3.1.3 PARKING DETENT MECHANISM

The Parking Detent Mechanism has been designed to maintain the Arm in Parking Position and comprises the Hook and U-support.

To place the Arm into the Parking Detent Mechanism:

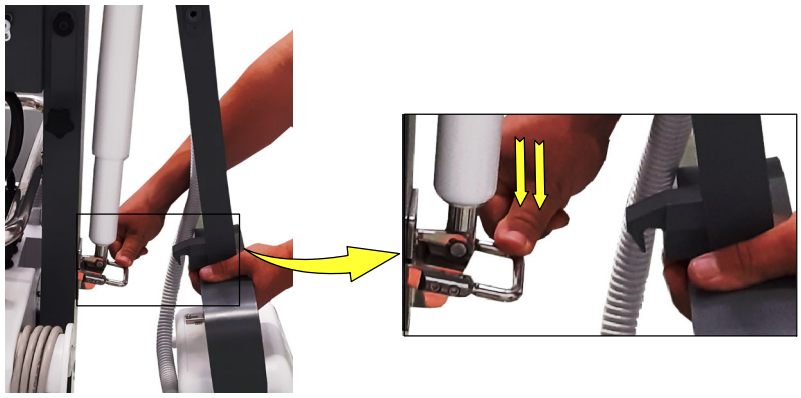
- Unlock the Gas Spring with the Arm Lock Knob.
- Push the X-Ray Unit downwards (using the Positioning Grips) with both hands until the Hook grabs the U-support.

CAUTION

Control arm movements at all times when releasing the Arm Lock Knob and Parking Detent Mechanism.

To release the Arm from the Parking Position:

- The Safety Knob should be unlocked.
- Unlock the Gas Spring with the Arm Lock Knob.
- Push the U-support downwards with one hand while the other supports the X-ray Unit Support.



Note ☞ *To avoid damaging the Unit when travelling, always keep the Arm in the Parking Position.*

Note ☞ *Never push the unit laterally from the arm elbow, it may fall down and may cause injuries to patients or people around the Unit.*

3.1.4 UNFOLDING / FOLDING THE UNIT

UNFOLDING THE UNIT

5. Unfold the Leg:

   a. Check the Arm is in Parking Position (*refer to Section 3.1.3*) and the wheels are locked.

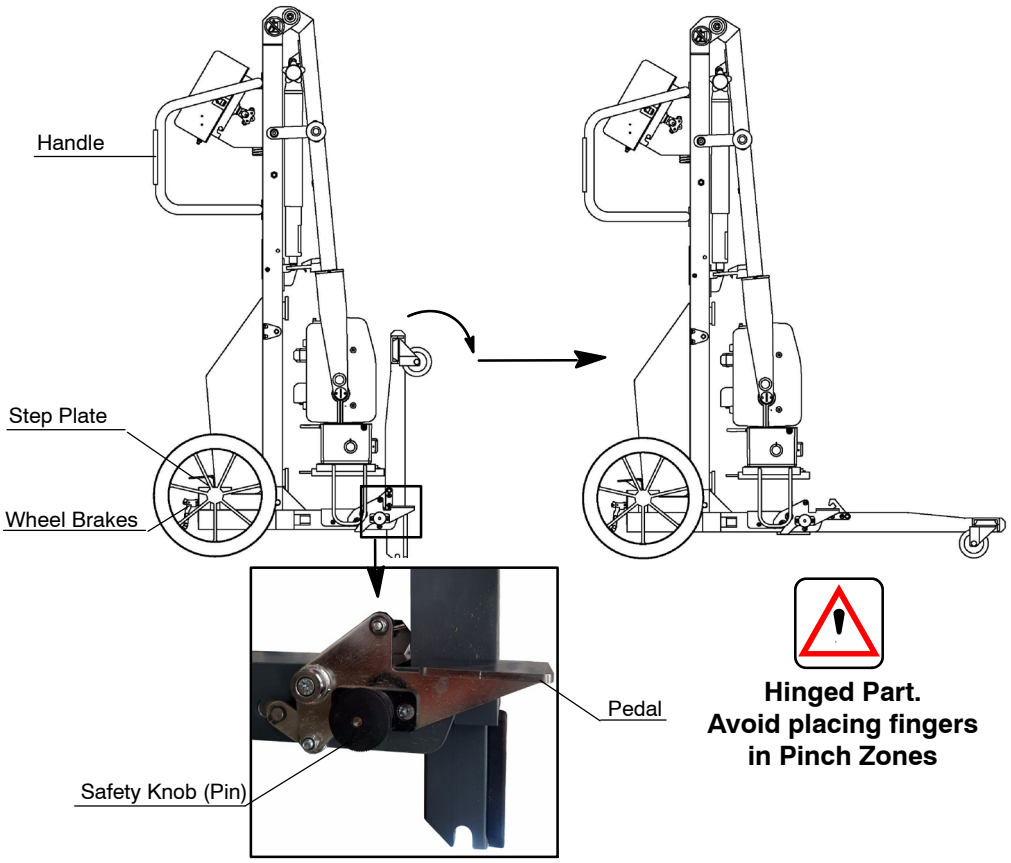
   b. Extract the Safety Knob (Pin).

   c. Holding the Unit laterally from the Handle, step on the pedal.

   d. Extend the leg.

   e. Holding the Handles with both hands and stepping on the step plate, lean back the Unit slightly. The Leg automatically locks in horizontal position.

   f. Insert the Safety Knob (Pin).



6. Unfold the Arm:

   a. Unscrew the Safety Knob from the Arm (*refer to Section 3.1.3*).

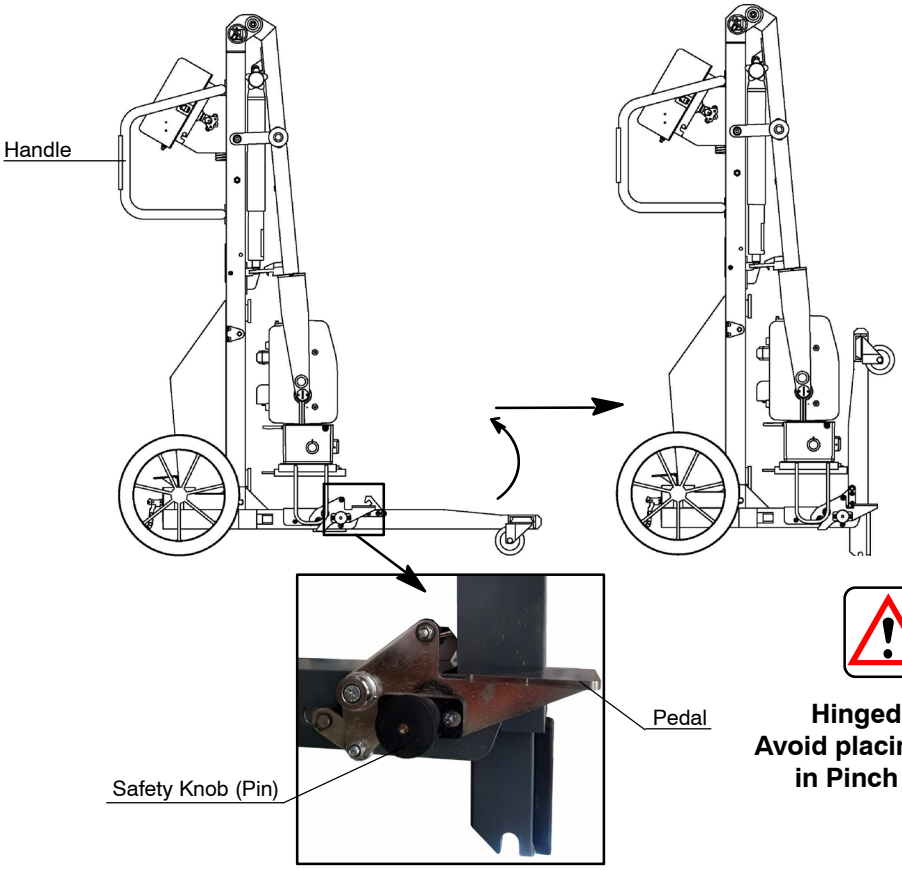
   b. Release the U-Support from the Hook (*refer to Section 3.1.3*).

   c. Hold the Positioning Grips to prevent springback.

   d. Turn the Gas Spring Knob and position the Arm.

FOLDING THE UNIT

1. Place the Arm in Parking Position (*refer to Section 3.1.3*) and lock both wheels with the Brakes.
2. Extract the Safety Knob (Pin).
3. Holding the Unit from the Handle, step on the pedal. Hard the Leg falls down.
4. Fold the Leg until it is locked in vertical position.
5. Insert the Safety Knob (Pin).



3.2 X-RAY UNIT

All controls, indicators and displays are positioned depending upon their functions.

Note ☞ *Use the operating controls as described in this manual, any other non-indicated combination may cause an incorrect operation of the equipment.*

Illustration 3-1
Portable X-ray Unit

3.2.1 POWER ON/OFF

The Unit should be plugged into a wall socket that accomplishes with local regulations and electrical requirements of the equipment (*refer to Section 8 for Technical Specifications*). The Power Line Cable can only be replaced by the Service Personnel. The plug is the device used as a means of disconnecting the Unit from mains. Position the Unit so that the plug can be easily disconnected.

For safety reasons and for proper functioning make sure that the Unit is connected to a standard outlet with GND.

This Circuit Breaker Switch is used to power the generator ON / OFF. After the generator is turned ON a power-up routine is shown on the Control Panel displaying:

1. Lines (- - - - - - - -).
2. The software version (e.g. P01 01.03 = Vers.01 R01.03).
3. The selected Power percentage (e.g. Po= 100).
4. Scrolling dash (- - - - - - - -).
5. And finally the Technique Parameters, e.g.:

Note ☞ *In case of a Touch Screen Console, if startup is not successfully completed, the message "Internal Error. Please, restart system" may be displayed. If this occurs, press "OK".*

3.2.2 AUTOMATIC LINE POWER DETECTION SYSTEM

By means of this System, the Unit detects the maximum operative Power Line adapting the Exposure Parameters to the Power available and avoiding undesired line breakdowns when operating with poor electricity lines.

1. Press and hold the *"Collimator Light"* push-button and then turn the Unit *"ON"*. The Display shows *"LPd ACT"* (Line Power Detection Active).
2. Release the *"Collimator Light"* push-button, the Display shows *"LPd P-E"* (Line Power Detection Preparation-Exposition).
3. Press "Prep", then press and hold *"X-Ray ON"* to perform consecutive exposures. At this moment, if the X-ray Tube is too hot, the Display shows *"LPd StP"* (very uncommon), if this is the case, wait for the Tube to cool and continue procedure when the Display shows "*LPd P-E*".

4. The Display shows "*LPd End*" when the procedure has finished (approximately ten (10) exposures). Release *"X-Ray ON"* button, then the Display shows normal parameters. Now the Unit has detected the Maximum Power Line that can be used during normal operation.

   If error code *"E95"* appears at this moment, it means that the line is not good enough and exposures will not be allowed, if possible, change the Unit Plug to another socket (line).

   If error code *"E96"* appears during the procedure at any mA station, it means that the corresponding station is not calibrated and power is limited to the previous mA station. The procedure ends and the Unit should be calibrated again.

Note ☞ *If any error code appears on Display during procedure, press "Reset" push-button.*

Once the Line Power Detection Procedure is performed:

- It is **necessary** to perform the Warm Up procedure.
- Perform the procedure every time the Unit is plugged into a different socket as the Unit **applies the data of the last Power Line acknowledged.**
- After finishing the procedure, the remaining thermal capacity (%) is **reduced and certain techniques could be temporarily inhibited.** Wait a few minutes for the Tube to cool.
- This procedure does not take into account the limitations of the **Circuit Breaker (Thermomagnetic Switch) installed at site.** If the Circuit Breaker (Thermomagnetic Switch) installed at site still goes down, perform the Manual Power Reduction procedure below.

To restore default values (which means that no restrictions will be set due to the Line Power Detection System):

1. Press and hold the *"Collimator Light"* push-button and turn the Unit *"ON"*. After a few seconds, the Display will show *"LPd ACT"* (Line Power Detection Active).
2. At this point press and hold the *"Reset"* push-button.
3. Release the *"Collimator Light"* push-button.
4. Release the *"Reset"* push-button. The values will be set to the maximum range available (no restrictions due to the line) and the *"LPd rSt"* (Line Power Detection Reset) message will be shown on the displays. When the kVp and mAs parameters are displayed, the X-Ray Unit will be ready for operation.

3.2.3 mAs-METER MODE

This automatic mode allows the generator to adapt the Exposure Parameters in order to avoid interrupted exposures due to poor electricity lines.

If the Unit detects undesired voltage drops when operating with poor electricity lines, mA are automatically reduced, Exposure Time is increased and the exposure finishes once the mAs selected by the operator are reached.

Note ☞ *Exposure Parameters values selected by the operator may vary when this mode is enabled. In order to visualize time, mA average during exposure and mAs actual values, press the "Reset" button and they will be shown on the displays for a while.*

Note ☞ *If the electricity line is so poor that the exposure cannot be completed (e.g. generator time-out (10 seconds) or receptor time-out (2.5), if applicable), E17 or E49 may occur.*

Note ☞ *The mAs-Meter Mode is factory set and it can only be disabled by a Service Engineer. The minimum Exposure Time in mAs-Meter Mode is 0.01 seconds.*

3.2.4 MANUAL POWER REDUCTION

The operator may reduce the Unit maximum Power in order to avoid blown fuses or Circuit Breakers down in poor electricity lines. For that, press and hold any *"Focal Spot"* push-button and increase or decrease the percentage by pressing the *"kVp Increase o Decrease"* push-buttons respectively.

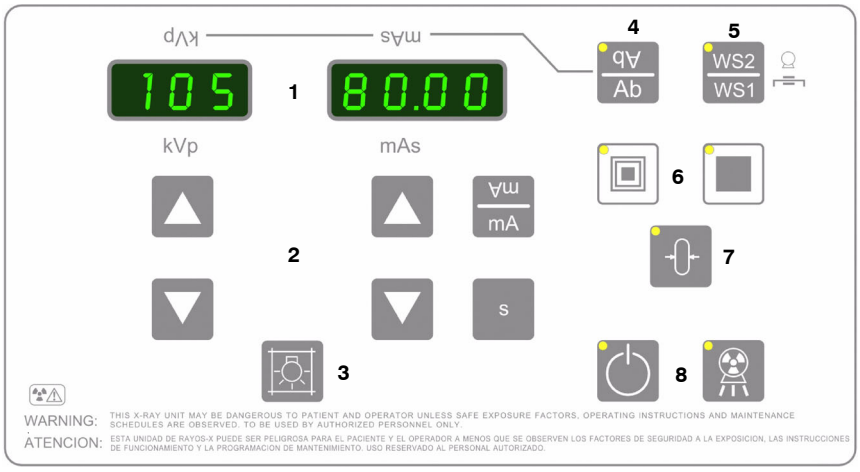
The kVp Display shows the selected Power Percentage in 10% steps, preceded by the letter "*P*", from 10% up to 100%. For example, a display of *"P80"* would indicate that the Power of the Unit will be limited to a maximum of 80%. *"P - - "* indicates that the Unit will operate at full Power (100% - factory set).

In case a technique exceeds the power required, the kVp and mAs displays will blink, modify the technique or modify Power percentage.

Note ☞ *The Power Percentage selected by the Operator is stored in memory and applied each time the Unit is turned ON.*

3.2.5 CONTROL PANEL

All controls and displays on the Control Panel are positioned according to their function.



1. Radiographic Displays
2. RAD parameters
3. Collimator Light
4. Rotation of the Control Panel
5. Workstations
6. Focal Spots
7. Reset
8. Exposure Controls

3.2.5.1 ROTATION OF THE CONTROL PANEL

The readout of the Radiographic displays and the function of the increase/decrease RAD parameters (kVp and mAs) and APR buttons can be inverted (180º) by pressing the button "*Rotation of the Control Panel*". Two beeps and the light on the button indicate that the Control Panel is now inverted.

To rotate the Control Panel to the 0º position again, press the "*Rotation of the Control Panel*" button.

3.2.5.2 WORKSTATIONS

The Workstations are configured according to the customer preferences during the installation procedure (X-ray Tube, Device, etc.).

This button selects the Workstation "*Direct*" (WS1) or "*Receptor*" (WS2).

The *"Direct"* (WS1) Workstation is automatically selected after turning ON the Unit. The button is not illuminated.

The *"Receptor"* (WS2) Workstation (Bucky, Digital Detector) is selected when the button is illuminated.

3.2.5.3 FOCAL SPOT INDICATORS

LARGE FOCAL SPOT: Selects the "*Large Focal Spot*" of the X-ray Tube.

SMALL FOCAL SPOT: Selects the "*Small Focal Spot*" of the X-ray Tube.

The Led of a Focal Spot turns ON when selected.

The Focal Spot change keeps kVp and constant mAs, whenever it is possible according to maximum power, space charge, etc.

When a Focal Spot is selected, it sets the highest mA value available for the selected Focal Spot and the respective Exposure Time in order to keep constant mAs.

Note ☞ *The Focal Spot change is related to the mA stations configured by the field engineer during installation.*

Note ☞ *The Focal Spot change can be done whenever the present conditions of the X-ray Tube allow it. A blinking light on the push-button and an audible alarm will alert the operator if present conditions of X-ray Tube unable the change.*

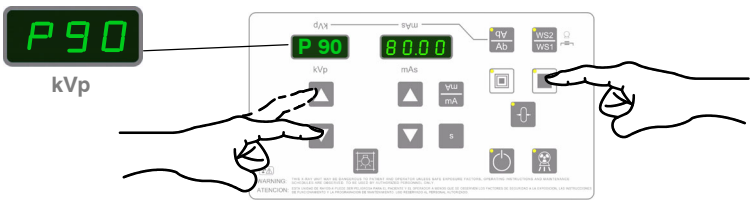
Focal Spot Buttons can also enable the Filament Power Down Mode (*Refer to Section 3.3).*

3.2.5.4 RADIOGRAPHIC PARAMETERS

Note ☞ *Refer to Section 8 for parameter ranges with reference to equipment model.*

kVp DISPLAY can show:

- The radiographic **kVp value** selected for the technique.
- The **Power percentage** after pressing at the same time any *"Focal Spot"* and *"kVp Increase or Decrease"* push-buttons *(refer to Section 3.2.4)*.



- The **Error messages** during a system fault, preceded by the letter "E" (e.g., E03) (*refer to Section 3.6*).

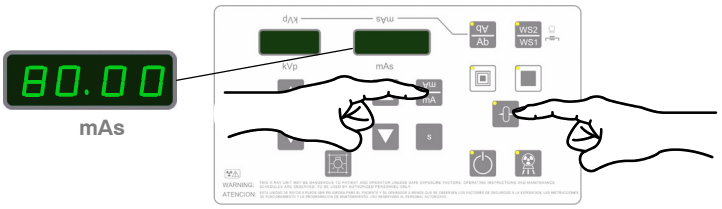
mAs DISPLAY can show:

- The radiographic **mAs value** selected for the technique, keeping the maximum mA and minimum exposure time values according to the Tube power percentage adjusted by the field engineer (factory set at 100%), to the Manual Power Reduction, the mAs-Meter Mode, the Line Power Detection, the remaining Thermal Capacity (%) of the X-ray Tube and Generator.
- If an exposure is aborted when releasing the *"Exp"* or *"Prep"* push-buttons, or because of a system failure, an alarm sounds until the error condition is reset. The **actual mAs value** of the exposure is shown for a while when the Error condition is produced, and again when the *"Reset"* push-button is pressed.

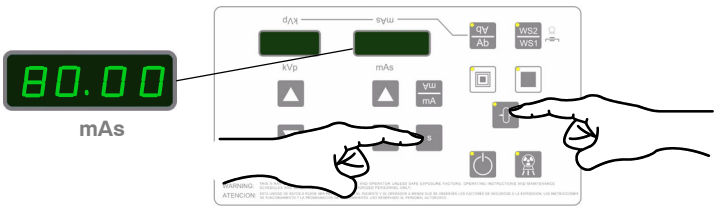
- **mA:** Pressing *"mA"* push-button, the mAs display shows the mA value selected. This parameter can not be modified by the operator because it relies on the mAs value.

- **s (Exposure Time in seconds)**: Pressing *"s"* push-button, the mAs display shows the selected Exposure Time in seconds. This parameter can not be modified by the operator because it relies on the mAs value.

- **mA of the last exposure**, by pressing *"Reset"* plus *"mA"* push-button.

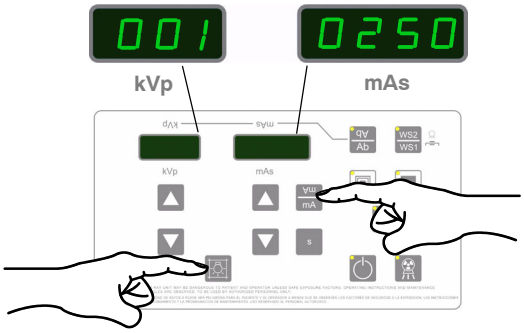


- **s (Exposure Time in seconds) of the last exposure**, by pressing *"Reset"* plus *"s"* push-button.

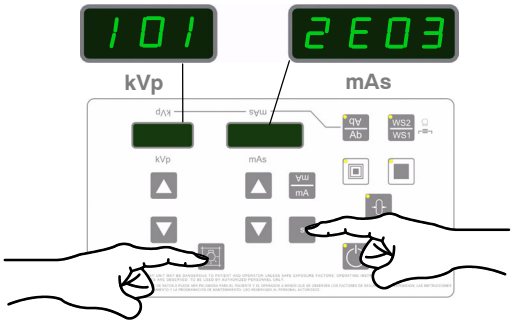


***"kVp"* Display in combination with *"mAs"* Display** can also show:

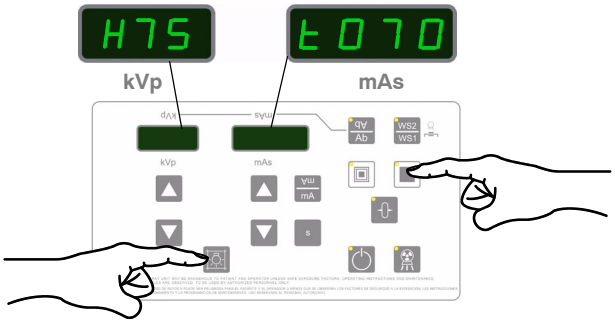
- **kVp and mAs from the last exposure** after pressing *"Reset"* push-button, whenever an error condition is not present.
- **Exposures Counter** (only in Service Mode), of the selected Focal Spot, while pressing simultaneously *"Collimator Light"* and *"mA"* push-buttons, e.g. (001) (0250) = 10.250 exposures *(refer to Section 3.4.1)*.



- **Energy Counter** (only in Service Mode), that is, the cumulative energy of all exposures of the selected Focal Spot expressed in Joules (J), while pressing simultaneously *"Collimator Light"* and *"s"* push-buttons, e.g. (1.01) (2E03) = 1.012 * 10^3 *(refer to Section 3.4.2)*.



- **Remaining Thermal Capacity (%) of the X-ray Tube and Generator**, by pressing simultaneously *"Collimator Light"* and any *"Focal Spot"* push-buttons (*refer to Section 3.5*).



INCREASE / **DECREASE**: Radiographic technique values increase or decrease step-by-step each time its related push-button is pressed, and changes faster when either of them is pressed and held.

- **kVp:** Selects the X-ray Tube voltage.
- **mAs**: Selects the mAs exposure (X-ray Tube current * exposure time).

Note ☞

If after pressing any of these push-buttons, the technique value is blocked and an acoustic signal is emitted it could mean that:

Radiographic Parameters Blockage. *When any of the maximum or minimum radiographic parameter limit is reached, its related display begins flashing accompanied of an acoustic signal.*

Generator Power Limit. *If the power limit (kV x mA) is reached by increasing the kVp or mAs up to a maximum possible value, the mAs value is blocked. Flashing values on kV and mAs displays and an audible signal will alert operator about the situation.*

If required, kV could be increased up to its maximum value while mA value may automatically decrease, as long as mAs value is kept the same.

Space Charge*. If a variation of the kV or mAs induces to reach space charge limit, the parameter is blocked, and a flashing value on the kV display and an acoustic signal will alert operator about the situation.*

X-ray Tube Ratings or X-ray Tube Overheating*. If a technique reaches the X-ray Tube ratings limit or the X-ray Tube is momentarily overheated, some technique could not be selected. Flashing values on the kV / mAs displays and an acoustic signal will alert operator about the situation.*

Cold X-Ray Tube Protection. *If trying to select a greater kVp value than 100 kVp when the Tube is cold after powering ON the Unit (if the Unit has been off for more than 4 hours, the Tube will be completely cold), the kVp parameter is blocked. Flashing values on the kV / mAs displays and an acoustic signal will alert operator about the situation. (Refer to Section 3.5.1)*

mA: Pressing this push-button, the mAs display shows the selected X-ray Tube current. This parameter can not be modified by the operator because it relies on the mAs value.

Exposure Time (s): Pressing this push-button, the mAs display shows the selected Exposure Time in seconds. This parameter can not be modified by the operator because it relies on the mAs value.

3.2.5.5 EXPOSURE CONTROLS

Radiographic exposures can be performed with the Exposure Controls placed on the Control Panel or with the Handswitch. The status of the exposure is shown by the "*Ready*" and "*X-ray ON*" light indicators (located on the respective push-buttons) for the duration of the exposure.

PREP: Press the *"Prep"* push-button to prepare the X-ray Tube for exposure. The push-button indicator will light when the X-ray Tube is prepared, indicating that the technique selected is properly set, there are no interlock failures or system faults and the X-ray Tube is ready for exposure.

After pressing this push-button filament current switches from stand-by to the mA emission level.

X-RAY ON: When the indicator on the *"Prep"* push-button is illuminated, press this push-button to start a X-ray exposure.

During the exposure the light indicator of this push-button remains illuminated and a beep sounds.

Note ☞ *If any of these push-buttons are released before the generator completes the selected time, the exposure will be aborted. E50 appears on "kVp" Display with the actual mAs accompanied with an alarm until "Reset" is pressed.*

3.2.5.6 COLLIMATOR LIGHT

After pressing this push-button, the Collimator Light remains illuminated for 30 seconds.

Refer to Section 3.7 Collimator.

In combination with other push-buttons enables different functions of the Unit.

3.2.5.7 RESET BUTTON

This push-button resets error messages.

It can also show the last exposure parameters.

Pressing at the same time:

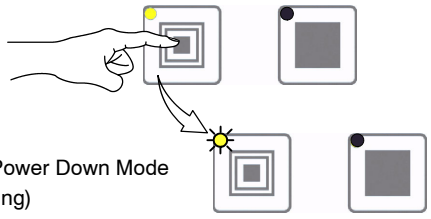
Reset + *Collimator Light* + *mA / s*,

the Exposure counter (totalled number of exposures) and the Energy counter (totalled Energy) of both Focal Spots are reset.

3.3 FILAMENT POWER DOWN MODE

The Filament Power Down Mode preserves the Tube service life.

To enter this mode, press the selected Focal Spot (its Led is already ON), a beep sounds and the Led starts blinking which means that the Filament is powered Off.



Filament Power Down Mode
(Led Blinking)

To exit, press once any Focal Spot or press *"Prep".*

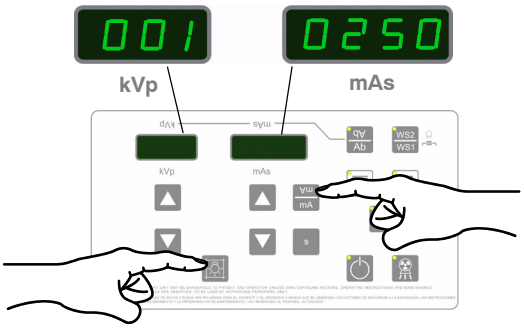
Note ☞ *After exiting Filament Power Down Mode it takes 5 seconds to allow the exposure ("Ready"* Led ON*). It also happens after an Error is "Reset" and when shifting from one Focal Spot to the other.*

3.4 COUNTERS FOR SERVICE PURPOSES

Note ☞ *These counters are only accessible to Service Engineer.*

3.4.1 EXPOSURE COUNTER

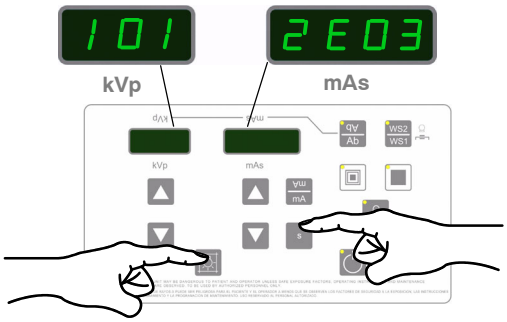
To display the totalled number of performed exposures of the selected Focal Spot, press simultaneously *"Collimator Light"* and *"mA"* push-buttons, e.g. (001) (0250) = 10.250 exposures.



To reset the Exposure Counter value (totalled number of exposures for the selected focal spot), press and hold simultaneously *"Collimator Light", "mA"* and *"Reset"*.

3.4.2 ENERGY COUNTER

To display the totalled Energy of performed exposures of the selected Focal Spot expressed in Joules (J), press simultaneously *"Collimator Light"* and *"s"* push-buttons, e.g. (1.01) (2E03) = $1.012 * 10^3$.



To reset the Energy counter (totalled Energy for the selected focal Spot), press and hold simultaneously *"Collimator Light", "s"* and *"Reset"*.

3.5 REMAINING THERMAL CAPACITY

The percentage of the remaining Thermal Capacity of the X-ray Tube and Generator are both calculated and totalled during exposures. They can be displayed on the Unit after pressing the *"Collimator Light"* and any of the *"Focal Spot"* push-buttons.

kVp

The kVp Display shows the percentage of remaining Thermal Capacity of the X-ray Tube, preceded by the letter "*H*". For example, a display of *"H75"* would indicate that 75% of the X-ray Tube capacity remains. *"H – – "* indicates that full capacity remains (100%).

mAs

The mAs Display shows the percentage of remaining Thermal Capacity of the Generator, preceded by the letter *"t"*. For example, a display of *"t032"* would indicate that 32% of the Generator capacity remains. *"t100"* indicates that full capacity remains (100%).

If the Unit detects that the new selection of parameters overpass the remaining Thermal Capacity, exposure is inhibited and values in displays blink accompanied by an alarm. Reduce parameter values or wait for the unit to cool.

Both displays revert to its normal function after releasing any of the push-buttons.

3.5.1 COLD X-RAY TUBE PROTECTION

To protect the X-ray Tube when it is cold just after powering ON the Unit, high kVp exposures (over 100 kVp) cannot be performed until the Tube Thermal Capacity (HU) used reaches at least 8%. In that case, the kVp Display would show *"H92"*, that is, 92% of the X-ray Tube capacity remains.

Note ☞ *Flashing values on the kV / mAs displays and an acoustic signal will alert operator if trying to select a greater kVp value than 100 kVp when the Tube is cold after powering ON the Unit (if the Unit has been off for more than 4 hours, the Tube will be completely cold). To prevent that situation, a warming-up procedure is recommended (refer to Section 6.2.2).*

Once the Tube has been warmed-up, any kVp value could be selected according to the X-ray Tube condition and kVp limits.

3.6 ERROR CODES

Error codes indicate the potential cause of a system failure. They are intermittently shown on the kV Display at the same time an alarm sounds. In general, to remove the error condition press *"Reset" (Refer to Table 3-1).*

All these error codes are preceded by the letter *"E"* (e.g. E03) and they will enable the operator to indirectly convey the possible source of error to service personnel. This may prevent the need for a service call or enable service personnel to anticipate corrective actions prior to arriving in site.

Table 3-1
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
No Error Code	System does not Start-up (No indication of Activity).	Ensure that the unit is connected to mains. If the problem persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E01	Backup Timer I2C error.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E02	Wrong Workstation configuration.	Turn the Unit OFF and call Field Service.
E03	No Workstation configured.	
E04	Fluoro Order error.	
E05	"*Exposure*" order is active during power-up.	Release all the controls. Turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E06	"*Preparation*" order is active during power-up.	
E08	Wrong index configuration for X-ray Tube 1.	Turn the Unit OFF and call Field Service.
E10	Corrupted data in E2PROM.	
E11	Load Capacitor error.	Turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E12	mA is out of range during exposure.	Press the "*Reset*" push-button. Repeat exposure with same technique values, If the error code persists try exposure with another combination of technique values. If the equipment remains inoperative, turn it OFF and call Field Service.

Table 3-1 (cont.)
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E13	kVp is out of range during exposure.	Press the "*Reset*" push-button. Repeat exposure with same technique values, If the error code persists try exposure with another combination of technique values. If the equipment remains inoperative, turn it OFF and call Field Service.
E14	kVp ramp error.	
E15	Large Filament current is out of range.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E16	Small Filament current is out of range.	
E17	DC BUS is out of range.	
E19	mA without exposure order.	
E20	kVp without exposure order.	
E23	EEPROM error.	Turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E24	Bucky / Digital Panel error.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF. Check cable connections of Image Receptor and turn the Unit ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E25	Large Filament current demand is over the limit.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E26	Small Filament current demand is over the limit.	
E27	Collimator current is out of range.	
E28	Current in the Collimator Light without order.	
E30	Wrong date/time at the RTC (Real Time Clock).	
E31	Wrong TimeStamp.	
E32	Bus I2C error while accessing the RTC.	
E33	Serial Communication error.	
E34	Exposure Timer error. If it activates during exposure it means that the exposure has been interrupted by the "Security Timer" because of a system failure	Turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E35	The acknowledge for X-Rays from the Bucky or Flat Panel Detector has been lost before the end of the exposure	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF. Check cable connections of Image Receptor and turn the Unit ON. If the equipment remains inoperative, turn it OFF and call Field Service.

Table 3-1 (cont.)
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E36	Presostat / Thermostat error.	This error does not require to press the "*Reset*" push-button, the signal indicator disappears automatically. Wait for the X-ray Unit to cool. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E38	System error – Chopper failure.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E39	System error – Power supply error.	
E40	System error – kV Unbalanced.	
E41	System error – mA Unbalanced.	
E42	Corrupted Counters.	
E43	Corrupted Error Log.	
E44	I2C Bus error while accessing the Potentiometer.	
E45	I2C Bus error while accessing the Multiplexer.	
E46	Busy I2C Bus.	
E47	APR Lite check error.	
E48	Bucky / Digital Interface error.	
E49	Exposure Timeout - mAs-Meter Error	Press the "*Reset*" push-button. Check the selected parameters and modify them. In case of poor electricity line reduce the mAs (mA / exposure time) or connect the Unit to a better power line (*refer to Section 3.2.3*). Try a new exposure. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E50	Exposure has been aborted by the Operator or defective Handswitch.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E51	Incorrect Exposure Time.	Press the "*Reset*" push-button. Change the exposure parameters. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E53	The timeout for receiving the Fluoro synchronism pulse has elapsed.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.

Table 3-1 (cont.)
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E60	The preprogrammed Exposures for Autocalibration have finished without finding the corresponding Stations.	This Error only affects Service Engineer during Autocalibration Process. *Refer to Service Manual.*
E61	There has been an error while trying to access the license data. Default options have been selected.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E74	The generator has been reset because of the COP module.	Call Field Service.
E75	The generator has been reset because of the CLK module.	
E76	The generator has been reset because of an illegal operation code.	
E77	The generator has been reset because of a software interrupt.	
E78	The generator has been reset because of a memory overflow interrupt.	
E95	Power Line not good enough for operation.	Perform the Automatic Line Power Detection procedure if it has not been done previously. If the error persists, turn the Unit OFF, change the Unit plug to another socket line and try again the Automatic Line Power Detection procedure. If the Error persists turn it OFF and call Field Service.
E96	Line Power Non Calibrated Technique.	Press the "*Reset*" push-button. Perform the Automatic Line Power Detection procedure again. If the Error persists, turn the Unit OFF and call Field Service.
E97	License – I2C Error.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
Err rAn	Defective RAM memory.	Press the "*Reset*" push-button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
Err nrAn	Defective NVRAM memory.	
OL	Tube or Generator Overload. The selected technique is beyond the X-ray Tube ratings, the present conditions of the X-ray Tube/Generator inhibit the exposure (anode/inverter overheated) or the calculated remaining thermal capacity (%) for the next exposure is beyond the Generator capacity. Parameters for next exposure may be temporally limited by the Unit.	This error does not require to press the "*Reset*" push-button, the signal indicator disappears automatically. Change the exposure parameters or wait for the X-ray Unit to cool. Check that the remaining thermal capacity (%) is lower than the calculated for the next exposure (thermal capacity close to 0%). If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.

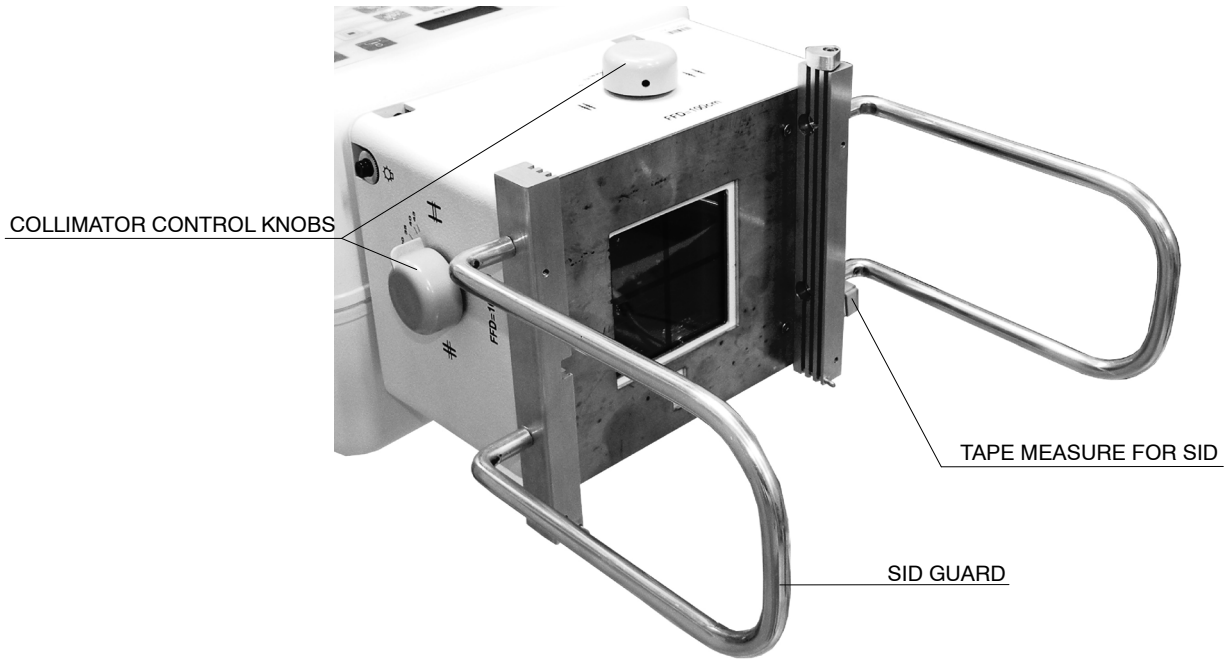
3.7 COLLIMATOR

Collimator controls consist of a push-button to switch ON / OFF the Collimator Light (located on the Control Panel and on the Collimator Assembly) and two knobs to open or close the internal blades of the Collimator.

The Collimator is supplied with a SID Guard, Aluminium Filters and DAP Rails. *(Refer to Section 3.7.1)*

The retractable Collimator Tape Measure indicates the distance from the Focal Spot (X-Ray Source) to the Reception Area (SID).

Illustration 3-2
Collimator Controls



COLLIMATOR LIGHT: After pressing this push-button, the Collimator Light remains ON for 30 seconds before the light switches OFF automatically. The operator can turn it OFF at any moment within this lapse by pressing the *"Collimator Light"* push-button again. The ON time may also be configured between 10 and 50 seconds by the engineer during the installation.

Collimator Light may also be switched ON / OFF by pressing the Handswitch *"Collimator Light"* button.

COLLIMATOR LIGHT WITH LASER POSITIONER (OPTIONAL): After pressing the Collimator Light push-button, a cross-shaped Laser light points at the patient in the middle of the Collimator Light field. They remain lighting for 30 seconds before they switch OFF automatically. The ON time may also be configured between 10 and 50 seconds by the engineer during the installation.

The Laser pointer also lights when the Handswitch *"Collimator Light"* button is pressed.

COLLIMATOR CONTROL KNOBS: These knobs are used to open or close the Collimator blades in order to limit the X-ray beam. The final image field may be checked switching on the Collimator Light.

The numbers located around these knobs show the Collimator opening to be set to open the blades according to the SID (Source-Image Distance) and image size to be used.

In order to apply the lowest Dose to patient, it is recommended to use the larger SID that image size allows.

Table 3-2
Image Size according to the SID and Collimator Opening

COLLIMATOR OPENING	SID		
	90 cm (36")	**100 cm (40")**	**180 cm (72")**
13	11.5 cm (4.5")	13 cm (5")	23.5 cm (9.5")
18	16 cm (6.5")	18 cm (7")	32.5 cm (13")
24	21.5 cm (8.5")	24 cm (10")	43 cm (17")
30	27 cm (11")	30 cm (12")	54 cm (21.5")
35	31.5 cm (12.5")	35 cm (14") *	63 cm (25")
40	36 cm (14.5") *	40 cm (16") *	72 cm (29")
43	38.5 cm (15.5") *	43 cm (17") *	77.5 cm (31")

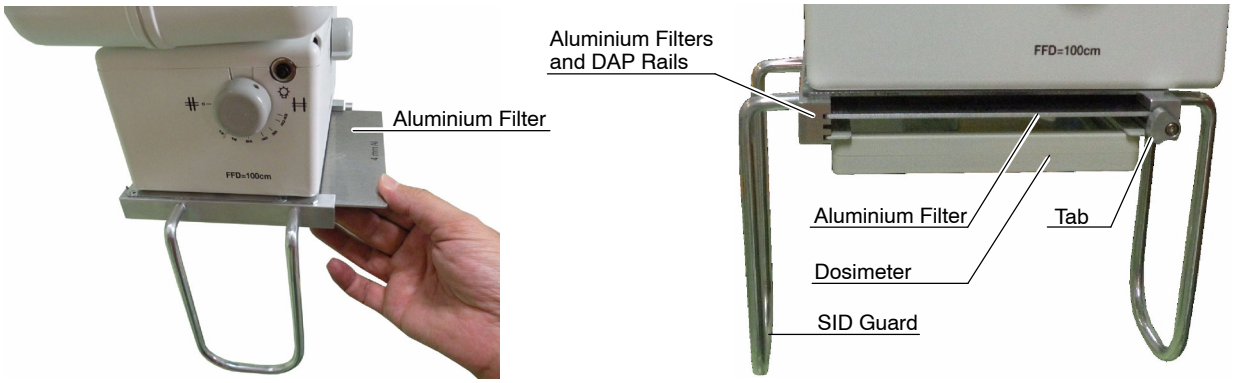
IMAGE AREA: The Collimator projects a lighted area with reference axis on the image reception area that coincides with X-ray projection area.

3.7.1 SID GUARD, ALUMINIUM FILTERS AND DOSIMETER

The Unit is supplied with a SID Guard with rails for accessories (Dosimeter and Aluminium Filters).

To place the Aluminium Filter and the Dosimeter, insert them in the rails and lock them with the tab as shown in the illustration below.

Illustration 3-3
Aluminium Filters and Dosimeter



INHERENT FILTRATION OF EXTERNAL ADDED FILTERS	
Filter	**Quality equivalent Filtration**
2.0 mm Al.	2.0 mm Al. 75 kV / HVL 2.9 mm Al.
3.0 mm Al.	2.9 mm Al. 75 kV / HVL 2.9 mm Al.
4.0 mm Al.	3.8 mm Al. 75 kV / HVL 2.9 mm Al.

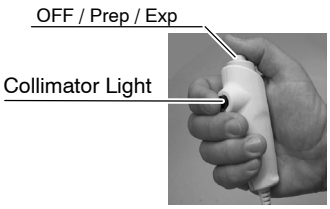
3.8 OPTIONS AND ACCESSORIES

3.8.1 RADIOGRAPHIC EXPOSURES

Radiographic exposures can be made with the X-Ray handswitch or the X-Ray footswitch, which are connected to the side of the X-Ray unit detector.

As an option, it can be equipped with an infrared remote control.

3.8.1.1 X-RAY HANDSWITCH



Radiographic exposures may also be initiated with the X-Ray handswitch which is connected to the Control Panel.

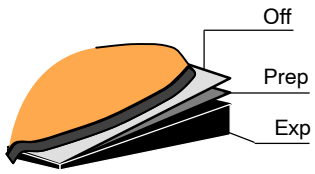
PREP: Press the Handswitch button half-way (*"Prep"* position) to prepare the X-Ray Tube for exposure.

EXP: After the "*Ready*" indicator is illuminated, fully press the Handswitch button to start an X-Ray exposure.

The "*X-Ray ON*" indicator remains illuminated and a sound is emitted during the length of the exposure.

COLLIMATOR LIGHT: This X-Ray Handswitch includes an extra *"Collimator Light"* button that helps patient positioning. Pushing this button will turn ON the Collimator Light.

3.8.1.2 X-RAY FOOTSWITCH



Radiographic exposures may also be initiated with the X-Ray footswitch which is connected to the Control Panel.

PREP: Press the footswitch button half-way (*"Prep"* position) to prepare the X-Ray Tube for exposure.

EXP: After the "*Ready*" indicator is illuminated, fully press the footswitch button to start an X-Ray exposure.

The "*X-Ray ON*" indicator remains illuminated and a sound is emitted during the length of the exposure.

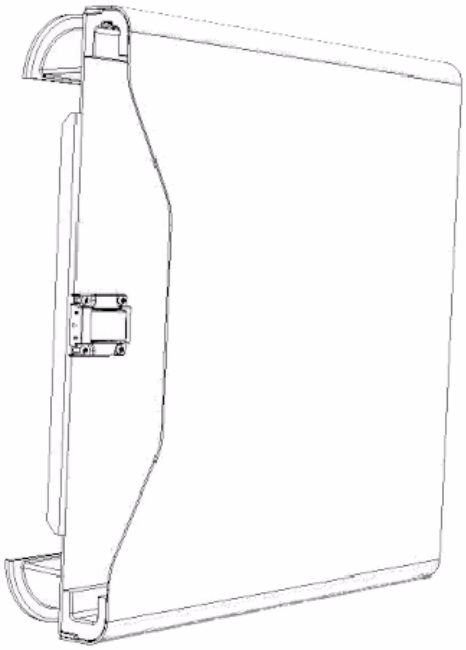
3.8.2 RECEPTOR BASKET OPTIONS

3.8.2.1 STANDARD RECEPTOR BASKET

As an option, the standard receptor basket may includes fittings for 35 x 43 Detectors

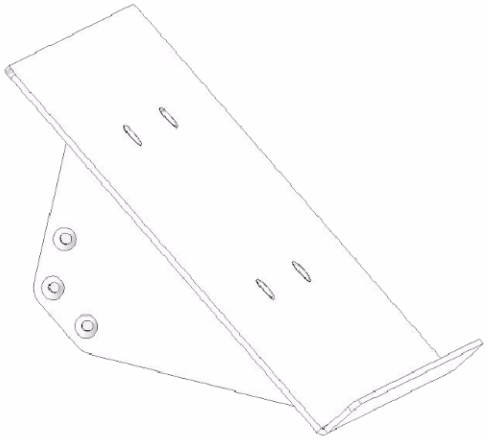
3.8.2.2 ADVANCED RECEPTOR BASKET

There is also the option of the advanced receptor box.



3.8.3 LAPTOP SUPPORT

A laptop support can also be mounted on the chassis as an option.



3.8.4 LONG OR SHORT FRONT HANDLES

The optional long or short front handles greatly facilitate the slide of the Unit during vehicle loading or unloading.

3.8.4.1 Y-SHAPED OR T-SHAPED FOLDING LEG WITH CASTERS

Designed for improved Undertable positioning, the Y-shaped Folding Leg works best when performing studies with single leg radiographic tables while the T-Shaped folding leg fits the rest of radiographic tables.

T-Shaped folding leg

Y-Shaped folding leg

3.8.4.2 WHEELS

There are two types of Wheels:

- **STANDARD**
- **ALL-TERRAIN**

Standard Wheel

All-Terrain Wheel (Flat-free)

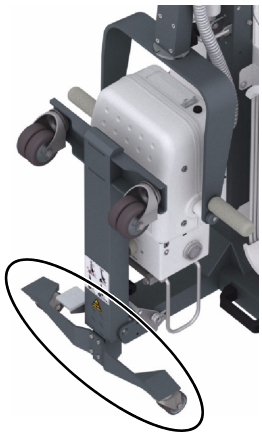
Table 3-3
Wheels Specifications

Type	Diameter	Width	Weight
Standard	315 mm (12.4”)	42 mm (1.65”)	1.5 kg (3.30 lbs)
All-Terrain (Flat-Free)	315 mm (12.4”)	100 mm (3.9”)	3.5 kg (7.71 lbs)

3.8.4.3 WHEELS FOR MOTION WITH FOLDED LEG

The Wheels for Motion with folded Leg are designed to facilitate motion of the Unit in narrow spaces, thus avoiding bumps with the extended Leg in furniture or corners.

Refer to Section 3.1.4 on how to fold the Leg.



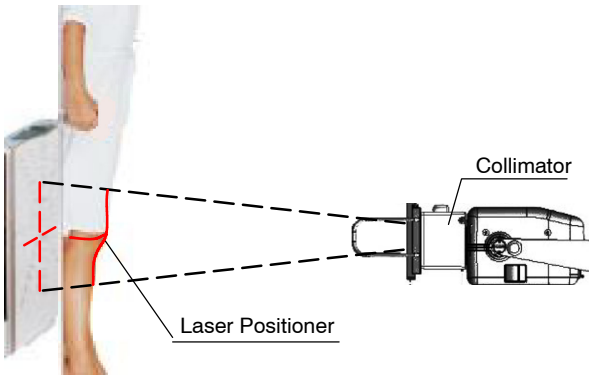
3.8.5 INCLINOMETERS

Three inclinometers are optionally added to the X-Ray Unit: one inclinometer is located on the front side and one inclinometer at every lateral side.

They show the angle inclination of every side, helping the operator position the X-Ray Unit.

3.8.6 COLLIMATOR WITH LASER POSITIONER

The Laser Positioner, a cross-shaped Laser light, is a Collimator option that helps the operator accurately center the collimator with respect to the receptor and correctly position the patient.

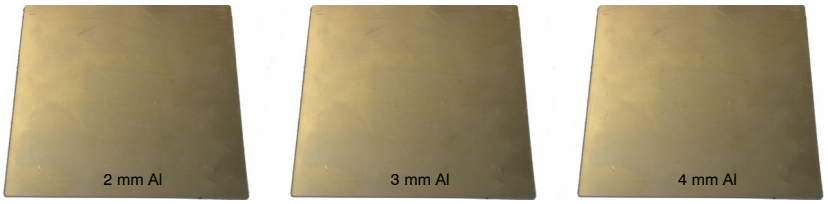


The Laser Positioner can be activated by pressing the *"Collimator Light"* push-button. It remains lighting for 30 seconds before it switches off automatically (lighting time can be configured from 10 to 50 seconds during installation by the Service Engineer).

The Laser Positioner also lights when the Handswitch *"Collimator Light"* button is pressed.

3.8.7 ALUMINIUM FILTERS

A kit comprising 2 mm, 3 mm and 4 mm Aluminium Filters may additionally be supplied with the Portable X-Ray Units.



INHERENT FILTRATION OF EXTERNAL ADDED FILTERS	
Filter	**Quality equivalent Filtration**
2.0 mm Al.	2.0 mm Al. 75 kV / HVL 2.9 mm Al.
3.0 mm Al.	2.9 mm Al. 75 kV / HVL 2.9 mm Al.
4.0 mm Al.	3.8 mm Al. 75 kV / HVL 2.9 mm Al.

3.8.7.1 DOSIMETERS

VACUDAP COMPACT

The VacuDAP Compact is a Dosimeter device related to the Collimator installed in the X-Ray Unit. It comprises a transparent square Ionization Chamber, controls and display for dose readout.

The VacuDAP Compact is compatible with all the Portable X-Ray Units.

VACUDAP OEM

The VacuDAP OEM is a Dosimeter device related to the Collimator installed in the X-Ray Unit. It comprises a transparent square Ionization Chamber.

The VacuDAP OEM is compatible with Portable X-Ray Units with Touch Screen Console. Dose measured values are shown on the Touch Screen Console *(refer to Section 5.12)*.

Note ☞ *Refer to the corresponding Dosimeter Manual for extended information about operation or technical description.*

3.8.7.2 TRANSPORT BOX

Aluminium Transport Box
with wheels and ramp

Dimensions
Length: 1710 mm
Width: 900 mm
Height: 1030 mm

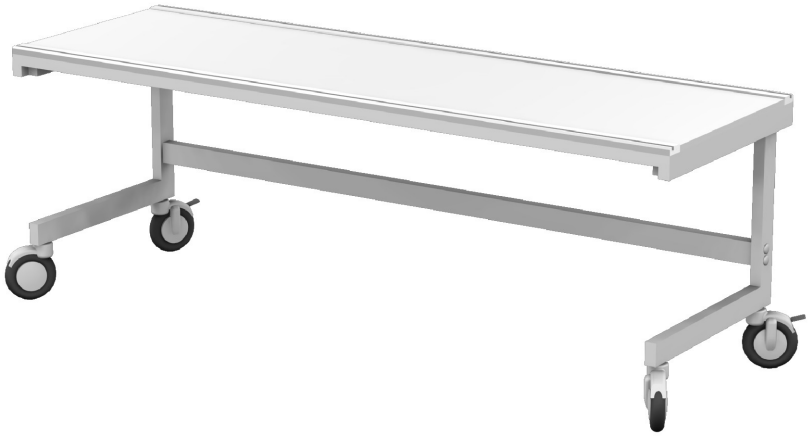
P-BOX-M

Transport Box
with wheels

Dimensions
Length: 1540 mm
Width: 930 mm
Height: 960 mm

3.8.8 MOBILE TABLE

This Laminated Mobile Table is intended for patient positioning during radiographic examinations.



Note ☞ *For further information, refer to the specific manual of the table.*

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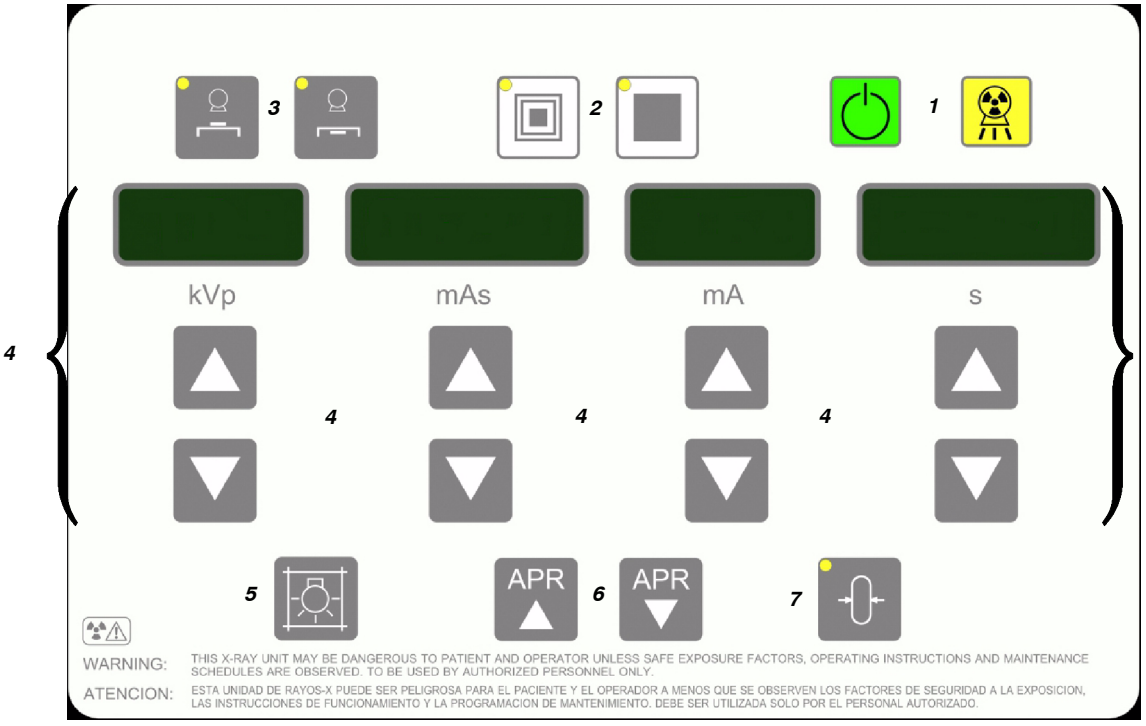
SECTION 4 3P OVERLAY CONSOLE

All controls, indicators and displays located on the Overlay Console are functionally grouped.

Note ☞ *Use the operating controls as described in this manual. Any other non-indicated combination may result in the incorrect operation of the equipment.*

Illustration 4-1
3P Overlay Console



1. Exposure Indicators
2. Focal Spot
3. Workstations
4. Radiographic Values
5. Collimator Lamp
6. APR Module
7. Reset

4.1 WORKSTATIONS

The Workstations are configured according to the customer preferences during the installation procedure (Icon, X-ray Tube, Device, etc.). Each button selects its respective Workstation (only the selected button is illuminated).

Workstations are directly selected by pressing the respective push-button:

"Direct" Workstation.

"Direct" Workstation is automatically selected after turning ON de equipment.

"Receptor" Workstation (Bucky, Digital Detector).

4.2 FOCAL SPOT INDICATORS

LARGE FOCAL SPOT: Selects the "*Large Focal Spot*" of the X-ray Tube.

SMALL FOCAL SPOT: Selects the "*Small Focal Spot*" of the X-ray Tube.

The Led of a Focal Spot turns ON when selected.

The Focal Spot change keeps kVp and constant mAs, whenever it is possible according to maximum power, space charge, etc.

When a Focal Spot is selected working in Two Point Mode (2P), it sets the highest mA value available for the selected Focal Spot and the respective Exposure Time in order to keep constant mAs.

Note ☞ *The Focal Spot change is related to the mA stations configured by the field engineer during installation.*

Note ☞ *The Focal Spot change can be done whenever the present conditions of the X-ray Tube allow it. A blinking light on the push-button and an audible alarm will alert the operator if present conditions of X-ray Tube unable the change.*

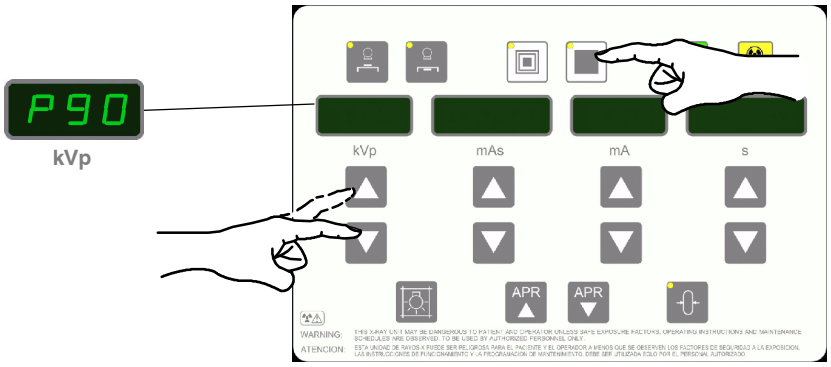
The **Filament Power Down Mode** can be enabled with the Focal Spot Buttons of the 3P Overlay Console or with the Focal Spot Buttons of the Generator Control Panel (*Refer to Section 3.3).*

4.3 RADIOGRAPHIC PARAMETERS

Note ☞ *Refer to Section 8 for parameter ranges with reference to equipment model.*

kVp DISPLAY can show:

- The radiographic **kVp value** selected for the technique.
- The **Power percentage** after pressing at the same time any *"Focal Spot"* and *"kVp Increase or Decrease"* push-buttons *(refer to Section 3.2.4)*.



- The **Error messages** during a system fault, preceded by the letter "E" (e.g., E03) (*refer to Section 3.6*).

mAs DISPLAY can show:

- The radiographic **mAs value** selected for the technique, keeping the maximum mA and minimum exposure time values according to the Tube power percentage adjusted by the field engineer (Factory set at 100%), to the Manual Power Reduction, the mAs-Meter Mode, the Line Power Detection, the remaining Thermal Capacity (%) of the X-ray Tube and Generator.
- If an exposure is aborted when releasing the *"Exp"* or *"Prep"* push-buttons, or because of a system failure, an alarm sounds until the error condition is reset. The **actual mAs value** of the exposure is shown for a while when the error condition is produced, and again when the *"Reset"* push-button is pressed.

mA DISPLAY can show:

- The radiographic **mA value** selected for the technique.
- If an exposure is aborted when releasing the *"Exp"* or *"Prep"* push-buttons, or because of a system failure, an alarm sounds until the error condition is reset. The **actual mA value** of the exposure is shown for a while when the error condition is produced, and again when the *"Reset"* push-button is pressed (last exposure).

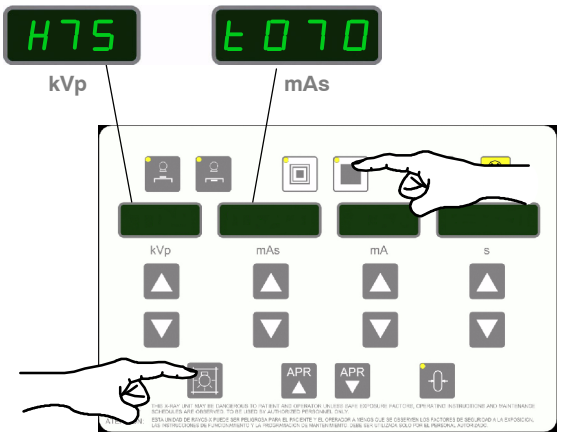
s (Exposure Time in seconds) can show:

- The radiographic **Exposure Time in seconds** selected for the technique.
- If an exposure is aborted when releasing the *"Exp"* or *"Prep"* push-buttons, or because of a system failure, an alarm sounds until the error condition is reset. The **actual Exposure Time value** of the exposure is shown for a while when the error condition is produced, and again when the *"Reset"* push-button is pressed (last exposure).

Displays can also show:

- **kVp, mAs, mA** and **Exposure Time from the last exposure** after pressing *"Reset"* push-button, whenever an error condition is not present.
- **kVp** (selected)**, mAs** (selected)**, mA** (reduced) and **Exposure Time** (increased) during the exposure, if the Generator adapts the Exposure Parameters automatically in order to avoid interrupted exposures due to poor electricity lines (**mAs-Meter Mode**). (*Refer to Section 3.2.3*).

- **Remaining Thermal Capacity (%) of the X-Ray Tube and Generator**, by pressing simultaneously *"Collimator Light"* and any *"Focal Spot"* push-buttons (*refer to Section 3.5*).



INCREASE / **DECREASE**: Radiographic technique values increase or decrease step-by-step each time its related push-button is pressed, and changes faster when either of them is pressed and held.

- **kVp:** Selects the X-ray Tube voltage.

- **mAs**: Selects the mAs exposure (X-ray Tube current * exposure time).

  The mAs selection sets the highest mA value available for the selected Focal Spot and the respective Exposure Time. The mA value available is set according to the maximum power, percentage limit configured for the X-ray Tube power, space charge, etc.

  To avoid some limit situations (i.e. maximum power, space charge, etc.), when the kVp value is increased, the mA value is automatically decreased and the Exposure Time is increased in order to keep a constant mAs value.

  mAs selection involves working in Two Point Mode (2P) (kVp and mAs).

- **mA:** Selects the X-ray Tube current.

  The mA selection does not modify the Exposure Time selection, but it changes the mAs value. The mA value available is set according to the maximum power, percentage limit configured for the X-ray Tube power, space charge, etc.

  mA selection involves working in Three Point Mode (3P) (kVp, mA and Exposure Time).

- **s**: Selects the Exposure Time in seconds.

  The Exposure Time selection does not modify the mA selection, but it changes the mAs value.

  Exposure Time selection involves working in Three Point Mode (3P) (kVp, mA and Exposure Time).

Note ☞ *If after pressing any of these push-buttons, the technique value is blocked and an acoustic signal is emitted it could mean that:*

Radiographic Parameters Blockage. *When any of the maximum or minimum radiographic parameter limit is reached, its related display begins flashing accompanied of an acoustic signal.*

Generator Power Limit. *If the power limit (kV x mA) is reached by increasing the kVp or mAs up to a maximum possible value, the mAs value is blocked. Flashing values on kV and mAs displays and an audible signal will alert operator about the situation.*

If required, working in Two Point Mode (2P), kV could be increased up to its maximum value while mA value may automatically decrease, as long as mAs value is kept the same.

Space Charge*. If a variation of the kV or mAs induces to reach space charge limit, the parameter is blocked, and a flashing value on the kV display and an acoustic signal will alert operator about the situation.*

X-ray Tube Ratings or X-ray Tube Overheating*. If a technique reaches the X-ray Tube ratings limit or the X-ray Tube is momentarily overheated, some technique could not be selected. Flashing values on the kV / mAs displays and an acoustic signal will alert operator about the situation.*

Cold X-Ray Tube Protection*. If trying to select a greater kVp value than 100 kVp when the Tube is cold after powering ON the Unit (if the Unit has been off for more than 4 hours, the Tube will be completely cold), the kVp parameter is blocked. Flashing values on the kV / mAs displays and an acoustic signal will alert operator about the situation. (Refer to Section 3.5.1)*

4.4 EXPOSURE CONTROLS

Radiographic exposures can be performed with the Exposure Controls placed on the Control Console or with the Handswitch. The status of the exposure is shown by the "*Ready*" and "*X-ray ON*" light indicators (located on the respective push-buttons) for the duration of the exposure.

PREP: Press the *"Prep"* push-button to prepare the X-ray Tube for exposure. The push-button indicator will light when the X-ray Tube is prepared, indicating that the technique selected is properly set, there are no interlock failures or system faults and the X-ray Tube is ready for exposure.

After pressing this push-button filament current switches from stand-by to the mA emission level.

X-RAY ON: When the indicator on the *"Prep"* push-button is illuminated, press this push-button to start a X-ray exposure.

During the exposure the light indicator of this push-button remains illuminated and a beep sounds.

Note ☞

If any of these push-buttons are released before the generator completes the selected time, the exposure will be aborted. "E50" appears on "kVp" Display with the actual mAs accompanied with an alarm until "Reset" is pressed.

4.5 COLLIMATOR LIGHT

After pressing this push-button, the Collimator Light remains ON for 30 seconds before the light switches OFF automatically. The operator can turn it OFF at any moment within this lapse by pressing the *"Collimator Light"* push-button again. The ON time may also be configured between 10 and 50 seconds by the engineer during the installation.

Collimator Light may also be switched ON / OFF by pressing the Handswitch *"Collimator Light"* button.

4.6 RESET BUTTON

This push-button resets error messages.

It can also show the last exposure parameters and save the APR techniques.

4.7 ANATOMICAL PROGRAMMER (APR)

4.7.1 APR SELECTION

The unit includes an Automatic Programming with 20 editable positions. By means of this feature, the operator can edit and store up to 20 Radiographic Techniques.

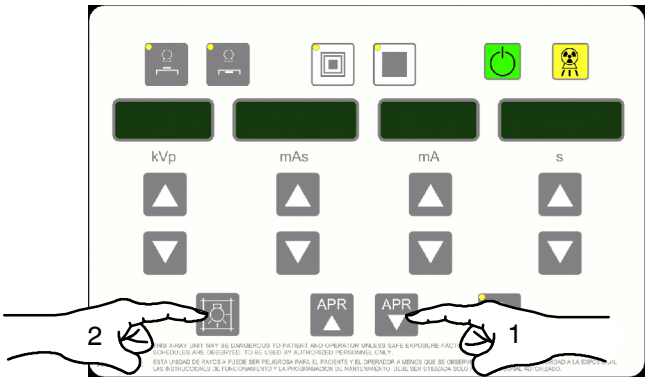
Note ☞ *Once the APR button is pressed and no other button is pressed in a period of 5 seconds, the Unit goes back to standard mode.*

To select an APR technique:

1. Press any "*APR*" button, the text "*APR MODE*" appears in the display. Once released, the last selected APR position appears in the kVp and mAs display e.g.: P01 SKUL *(refer to Table 4-1).*

2. Press and hold the "*Collimator Lamp*" button to load the technique. The different displays show the selected technique.

Note ☞ *APR techniques can be modified without restriction and can be stored or not.*



Note ☞ *The following table shows the Anatomical Programming distribution. The Anatomical Programming includes Radiographic parameters that can be used as a guide but the final values of each technique must be revised / contrasted / verified and / or modified if necessary, by the operator.*

Table 4-1
APR Programs

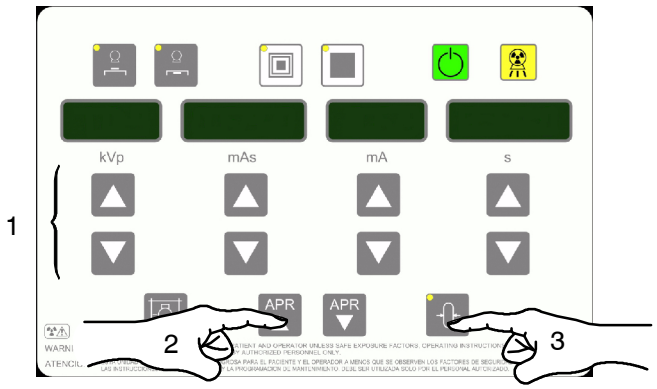
Displayed APR		Anatomical views
P 01	SKUL	SKULL
P 02	-lat	LATERAL SKULL
P 03	CHES	THORAX
P 04	RIBS	RIBS
P 05	CERV	CERVICAL
P 06	THOR	THORACIC
P 07	-lat	LATERAL THORACIC
P 08	LUMB	LUMBAR
P 09	-lat	LATERAL LUMBAR
P 10	ABDO	ABDOMEN
P 11	PELV	PELVIS
P 12	HIP-	HIP
P 13	FEMU	FEMUR
P 14	KNEE	KNEE
P 15	ANKL	ANKLE
P 16	FOOT	FOOT
P 17	SHOU	SHOULDER
P 18	ELBO	ELBOW
P 19	VRIS	WRIST
P 20	HAND	HAND

4.7.2 APR TECHNIQUE EDITION

1. Select the parameters for the technique: kVp, mAs, mA, s, the Workstation and the Focus.

2. Select the APR number to be edited with the "*APR Up or Down*" buttons. (P01, P02, etc.).

3. Press and hold the "*Reset*" button until the characters "APR -0-" are displayed and a beep sounds to save all changes.

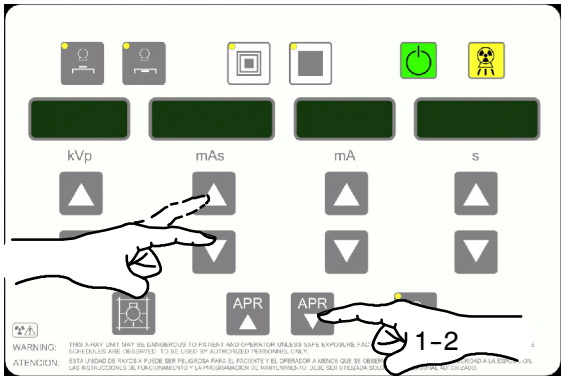


4.7.3 APR NAME EDITION

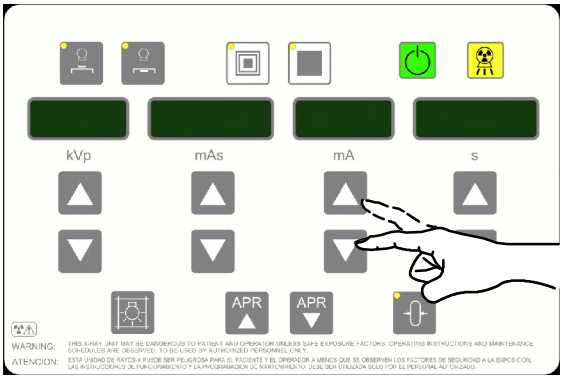
1. In order to change the name of a technique, press "*APR Up or Down*" in order to find a specific APR number.

2. Press and hold "*APR Up or Down*" until the first character of the name starts to blink.

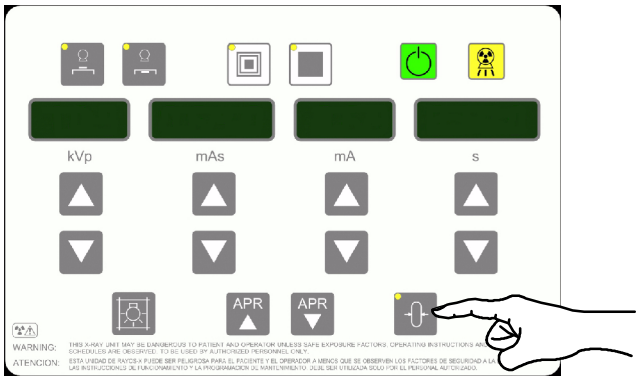
3. Press "*mAs*" arrow buttons to scroll in the alphanumeric character list until the character required is found .



4. Press "*mA*" arrow buttons to move forward case to case and repeat step 3 as required.



5. When the required word for the technique is displayed, press once the "*Reset*" button to save the changes.



4.8 ERROR CODES

Note ☞ *Refer to Section 3.6. for Error Code list.*

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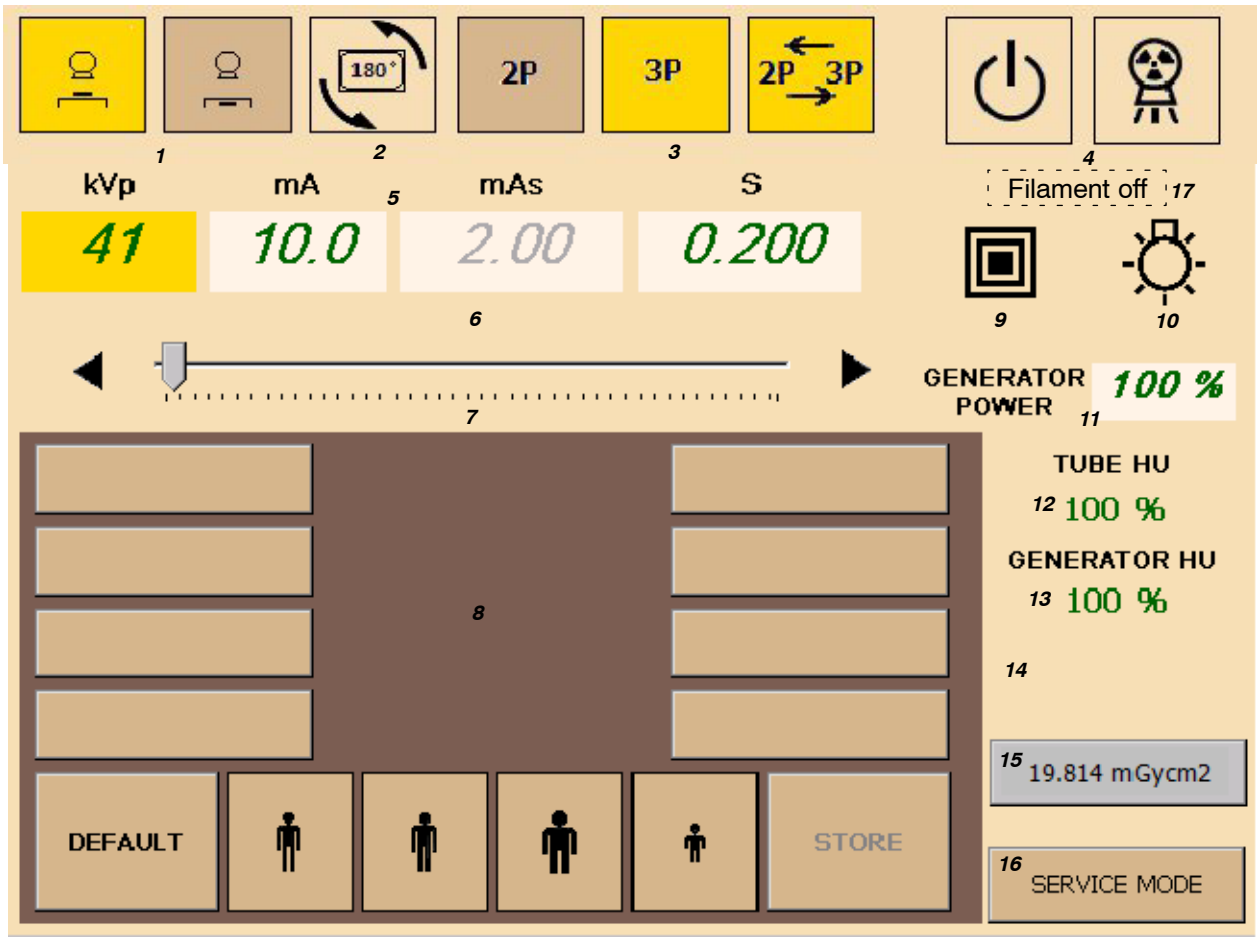
SECTION 5 TOUCH SCREEN CONSOLE

All controls, indicators and displays located on the Touch Screen Console are functionally grouped. As well, this Console shows different menus (screens) according to the selected operations.

Note ☞ *Use the operating controls as described in this manual. Any other non-indicated combination may result in the incorrect operation of the equipment.*

Illustration 5-1
Touch Screen Console - General Controls



1. Workstations
2. Rotation of the Touch Screen
3. Working Modes: 2P, 3P, Auto
4. Exposure Indicators
5. Radiographic Values
6. Information Area
7. Slider
8. APR Module
9. Focal Spot
10. Collimator Lamp
11. Generator Working Power
12. Tube Heat Units
13. Generator Heat Units
14. Warning Information Area
15. Dosimetry
16. Access to Service Mode
17. Information Area.

5.1 SERVICE MODE

This button is the access to the "*Service Mode*" menus.

Only service personnel specifically trained on this medical X-ray equipment should access to Service Mode for service tasks or maintenance of the equipment.

5.2 COLLIMATOR LIGHT

After pressing this button, the Collimator Light remains ON for 30 seconds before the light switches OFF automatically. The operator can turn it OFF at any moment within this lapse by pressing the *"Collimator Light"* push-button again. The ON time may also be configured between 10 and 50 seconds by the engineer during the installation.

Collimator Light may also be switched ON / OFF by pressing the Handswitch *"Collimator Light"* button.

5.3 MANUAL POWER REDUCTION

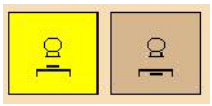
The operator may reduce the Unit maximum Power in order to avoid blown fuses or Circuit Breakers down in poor electricity lines. For that, touch on the Power percentage (it turns to yellow) and increase or decrease the percentage by pressing the *"Increase o Decrease"* arrows.

The Touch Screen shows the selected Power percentage in 10% steps, "*100*% " indicates that the Unit will operate at full Power (100% – factory set).

In case a technique exceeds the power required, a warning message will alert the operator. Modify the technique or modify Power percentage.

Note ☞ *The Power Percentage selected by the Operator is stored in memory and applied each time the Unit is turned ON.*

5.4 WORKSTATIONS SELECTION



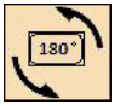
The Workstations are configured according to the customer preferences during the installation procedure (Icon, X-ray Tube, Device, etc.). Each button selects its respective Workstation (only the selected button is highlighted).

"Direct" Workstation.

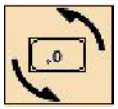
"Direct" Workstation is automatically selected after turning ON de equipment.

"Receptor" Workstation (Bucky, Digital Detector).

5.5 ROTATION OF THE TOUCH SCREEN

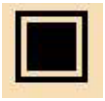


This button allows to rotate the Touch Screen Console 180 degrees.



When the screen is rotated, the figure *180º* on the button changes to *0º*. Press this button to rotate the Touch Screen to the 0º position again.

5.6 FOCAL SPOT INDICATOR



Large

Small

A Focal Spot indicator shows the selected Focal Spot of the X-ray Tube: "*Small*" or "*Large*". The Focal Spot is changed by touching this indicator.

The Focal Spot change keeps kVp and constant mAs, whenever it is possible according to maximum power, space charge, etc.

When a Focal Spot is selected, it sets the highest mA value available for the selected Focal Spot and the respective Exposure Time in order to keep constant mAs.

Note ☞ *The Focal Spot change is related to the mA stations configured by the field engineer during installation.*

Note ☞ *The Focal Spot change can be done whenever the present conditions of the X-ray Tube allow it.*

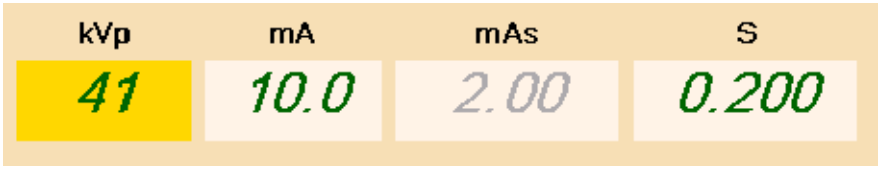
The **Filament Power Down Mode** can be enabled with the Focal Spot Buttons of the Generator Control Panel (*Refer to Section 3.3).*

5.7 RADIOGRAPHIC PARAMETERS

Note ☞ *Refer to Section 5.9 for Radiographic Operating Modes.*

Refer to Section 8 for parameter ranges with reference to equipment model.

RADIOGRAPHIC DISPLAYS: They are divided in the kVp, mA, mAs and Time (s) Displays where the technique radiographic values are shown.



Displays can also show:

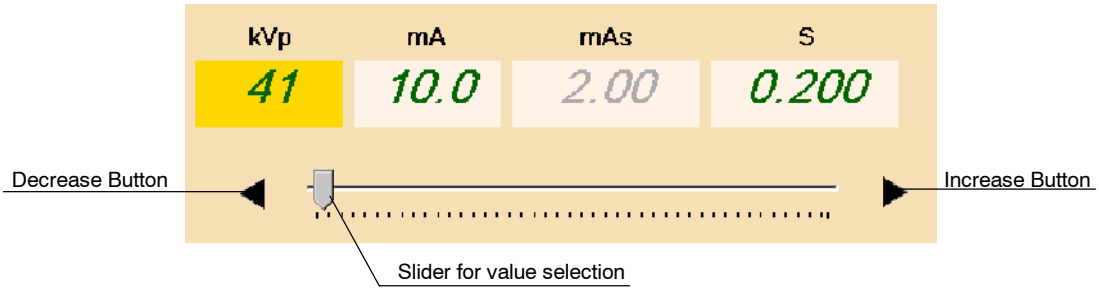
- If the exposure is aborted by releasing the exposure control, or because of a system failure, an alarm sounds until the error condition is reset. The **actual radiographic values** of the exposure are shown for a while when the error condition is produced. The messages "***Last Exposure Parameters***" and "***Error 50: Interrupted Exposure***" appear on the Console until the error condition is reset.

- **kVp, mA, mAs** and **Exposure Time from the last exposure** after pressing *"Reset"* push-button, whenever an error condition is not present.

- **kVp** (selected)**, mAs** (selected)**, mA** (reduced) and **Exposure Time** (increased) during the exposure, if the Generator adapts the Exposure Parameters automatically in order to avoid interrupted exposures due to poor electricity lines (**mAs-Meter Mode**). (*Refer to Section 5.9.1*).

INCREASE / DECREASE: Radiographic technique values are increased or decreased by first selecting the respective RAD Display (which will be highlighted) and then changing the value step-by-step each time the corresponding arrow button is touched, also the slider can be dragged to the desired position.

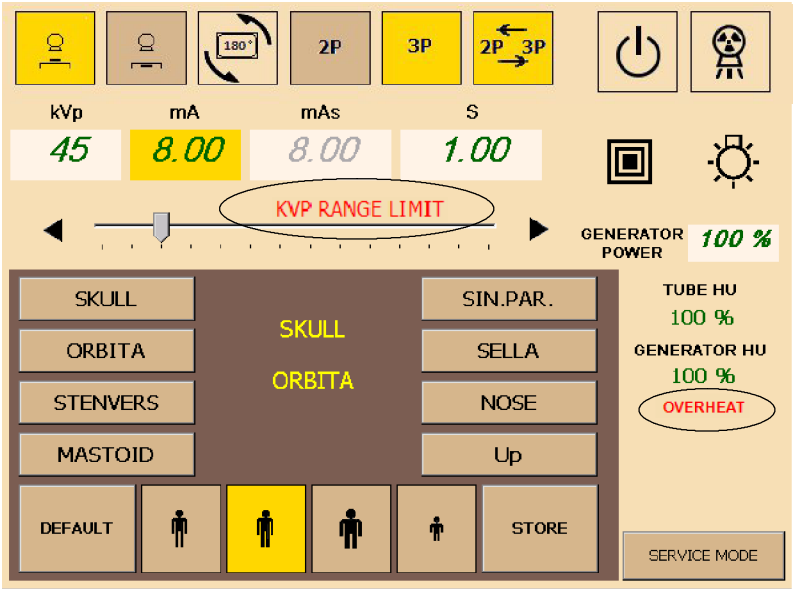
Also, the value changes faster by pressing on its position on the bar. When this slider is positioned over a value not allowed, it comes back to the previous position and the parameter value does not change.



- **kVp**: Selects the X-ray Tube voltage.
- **mA**: Selects the X-ray Tube current. The slider of the bar can only set the mA values of the selected Focal Spot.
- **mAs**: Selects the mAs exposure (X-ray Tube current * exposure time).
- **s**: Selects the exposure Time in seconds.

5.8 MESSAGES ON THE TOUCH SCREEN CONSOLE

The Console may show the following messages, together with an acoustic signal that alerts the operator about the situation.



- If the exposure is aborted by releasing the exposure control, or because of a system failure, an alarm sounds until the error condition is reset. The messages "***Last Exposure Parameters***" and "***Error 50: Interrupted Exposure***" appear on the Console until the error condition is reset.

- **Radiographic Parameters Blockage.** If the maximum or minimum limit is reached by modifying any radiographic parameter, the technique value is blocked, showing one of the following messages:

  "KVP RANGE LIMIT"
  "MAS RANGE LIMIT"
  "MA RANGE LIMIT"
  "MS RANGE LIMIT"

- **"SPACE CHARGE LIMIT"**. If a variation of the kV or mAs induces to reach space charge limit, the parameter is blocked.

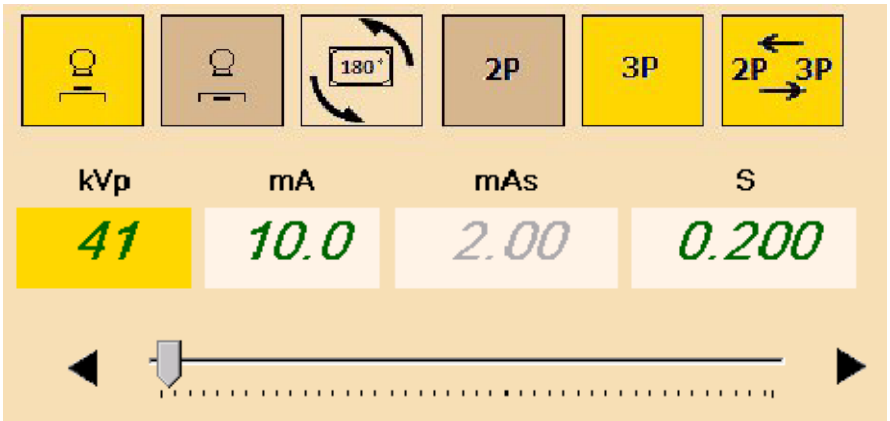
- **"OVERHEAT", "TUBE OVERHEAT", "INVERTER OVERHEAT"** or **"INVERTER LOAD LIMIT".** If the X-ray Tube or Generator ratings limit are reached or they are momentarily overheated when selecting a technique, it could not be selected. Change the parameter values or wait for the Tube or Generator to cool.

- **"X-RAY KEY":** The X-Ray Key is not in position. (Only for Generators with the X-Ray Key option.)
- "**GENERATOR POWER LIMIT":** The technique overpasses the Generator Power Limit.
- "**TUBE POWER LIMIT":** The technique overpasses the Tube Power Limit. This message is also shown if trying to select a greater kVp value than 110 kVp when the Tube is cold after powering ON the Unit. *(Refer to Section 5.13.1)*
- **"FOCUS CHANGE INHIBIT":** The selected technique does not allow the Focus change.
- **"WRONG APR TECHNIQUE"**: The APR Technique selected is not allowed.
- **"LINE POWER TOO LOW"**:The Power Line where the unit is connected is too poor to allow the usage of the Unit.
- **"WRONG APR WORKSTATION":** The selected workstation is not allowed for the APR.

5.9 RAD WORKING MODES

Three different RAD Working Modes can be selected according to the parameters to be controlled by the operator and the degree of automation:

- Three Point (3P) mode by selecting kVp, mA and Exposure Time.
- Two Point (2P) mode by selecting kVp and mAs.
- Auto Mode (2P --> <-- 3P), allows the automatic change between 2P and 3P modes.



TWO POINT MODE (2P): kVp and mAs are controlled independently. The mAs selection sets the highest mA value available for the selected Focal Spot and the respective Exposure Time. The mA value available is set according to the maximum power, percentage limit configured for the X-ray Tube power, space charge, etc.

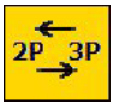
To avoid some limit situations (i.e. maximum power, space charge, etc.), when the kVp value is increased, the mA value is automatically decreased and the Exposure Time is increased in order to keep a constant mAs value.

Also, the mA and Exposure Time values can be modified directly keeping constant the selected mAs value.

In "*2P*" Working Mode, the Console shows the kVp and mAs Displays enabled (*parameter value in black*), and the mA and Exposure Time Displays disabled (*parameter value grayed out)*.

THREE POINT MODE (3P): kVp, mA and Exposure Time are controlled independently, without any relationship between them. If the mAs Display is selected, the mAs value can not be modified directly. In this case, the "*MAS RANGE LIMIT*" message appears on the Console when trying to modify the mAs value.

In "*3P*" Working Mode, the Console shows the kVp, mA and Exposure Time Displays enabled (*parameter values in black)*, and the mAs Display disabled (*parameter value grayed out)*.



AUTO MODE: This mode allows the control of all the radiographic parameters.

With "*AUTO MODE*" and "*2P*" selected, if the operator modifies the mA or Exposure Time values, the Unit automatically selects the 3P mode and does not keep constant mAs.

With "*AUTO MODE*" and "*3P*" selected, if the operator modifies the mAs value, the unit automatically selects the 2P mode.

5.9.1 mAs-METER MODE

Note ☞ *mAs-Meter Mode is complementary to the three RAD Working Modes (2P, 3P or Auto), and the generator activates it only if required by the electricity line conditions.*

This automatic mode allows the generator to adapt the Exposure Parameters in order to avoid interrupted exposures due to poor electricity lines.

If the Unit detects undesired voltage drops when operating with poor electricity lines, mA are automatically reduced, Exposure Time is increased and the exposure finishes once the mAs selected by the operator are reached.

Note ☞ *Exposure Parameters values selected by the operator may vary when this mode is enabled. In order to visualize time, mA average during exposure and mAs actual values, press the "Reset" button and they will be shown on the displays for a while.*

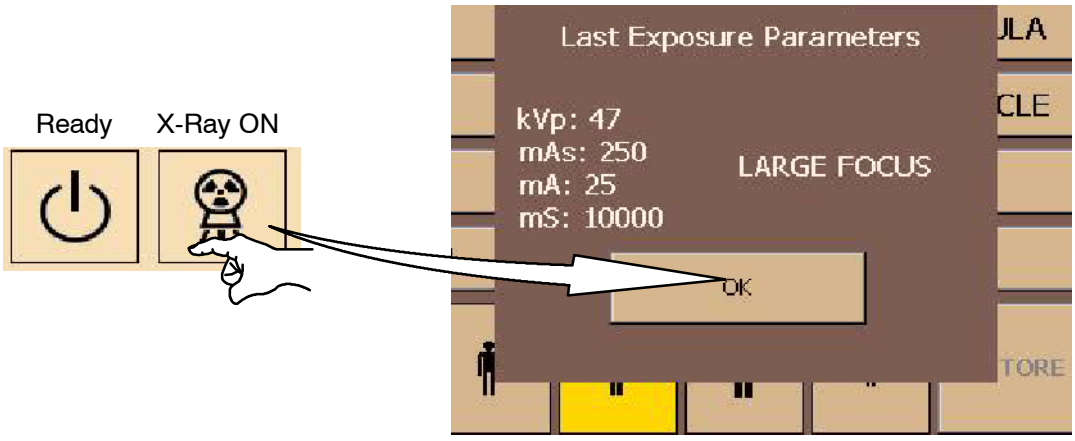
Note ☞ *If the electricity line is so poor that the exposure cannot be completed (e.g. generator time-out (10 seconds) or receptor time-out (2.5), if applicable), E17 or E49 may occur.*

Note ☞ *The mAs-Meter Mode is factory set and it can only be disabled by a Service Engineer. The minimum Exposure Time in mAs-Meter Mode is 0.01 seconds.*

5.10 EXPOSURE INDICATORS

Radiographic exposures are performed with the Handswitch. The status of the exposure is shown by the "*Ready*" and "*X-ray ON*" indicators located on the Touch Screen Console.

When the *"X-Ray ON"* button is pressed, the last Exposure values are shown.



5.11 ANATOMICAL PROGRAMMER (APR)

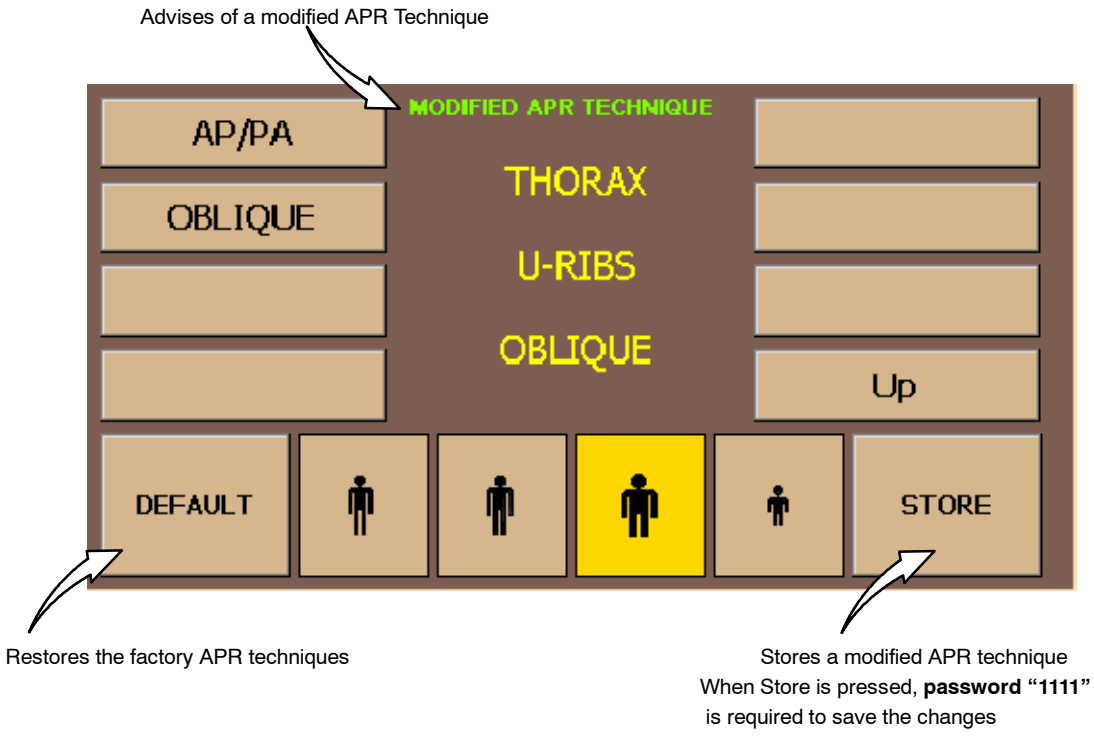
The Anatomical Programmer (APR) module is comprised of the controls which select the Patient Size and its corresponding “Body Region / Anatomical View / Projection”. The process is shown on the APR Display.

The APR techniques are factory pre-programmed according to different standard techniques that combine six Body Regions with their Anatomical Views and Projections. These selections will always be common for all the patient sizes of each Anatomical View. These techniques may be modified and stored anew into non-volatile memory by the operator.

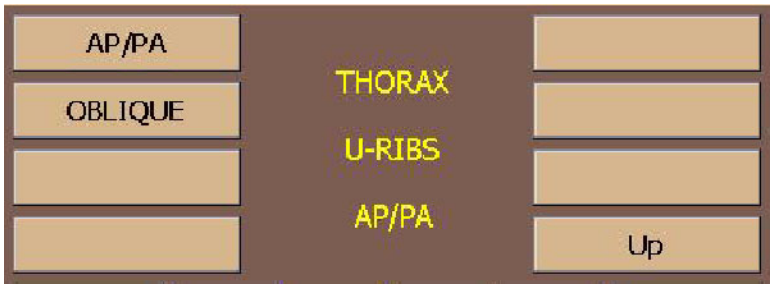
The APR techniques are intended as a guide line only. Accurate exposure factors are dependent among other things on the Receptor (Film or Detector), Grid factors, Table Top absorption, Screen-Film combinations and Film processing.

APR is activated when one of the three Patient Size (small, medium or large size) is selected (highlighted) and it is deactivated when all of them are deselected.

Note ☞ ***The language of the factory pre-programmed APR techniques is configured according to the customer order and it can not be changed by the operator.***



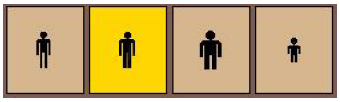
APR DISPLAY: It shows the different Body Regions, Anatomical Views and Projections available for each APR technique and the final APR selection. As the area of the APR Display is limited in length, the name of some Regions, Views or Projections is abbreviated.



When a Body Region has been selected, its indication is locked on the screen and the APR Display show directly all its respective Anatomical Views and then its respective Projections (if the Anatomical View has different Projections). *(Refer to Table 5-1 for the APR Regions / Views / Projections factory pre-programmed. The APR language is configured according to the customer order).*

When the APR selection is finished, the Console shows the final selection (APR Display), the Workstation and its respective parameters (RAD Displays).

To go back to the previous level, touch on the right-lower APR selector ("*Up*").



PATIENT SIZE: APR is activated when one of the three Patient Sizes (small, medium or large) is selected. These buttons are used to adapt the APR technique chosen according to patient size. Six patient sizes are available.

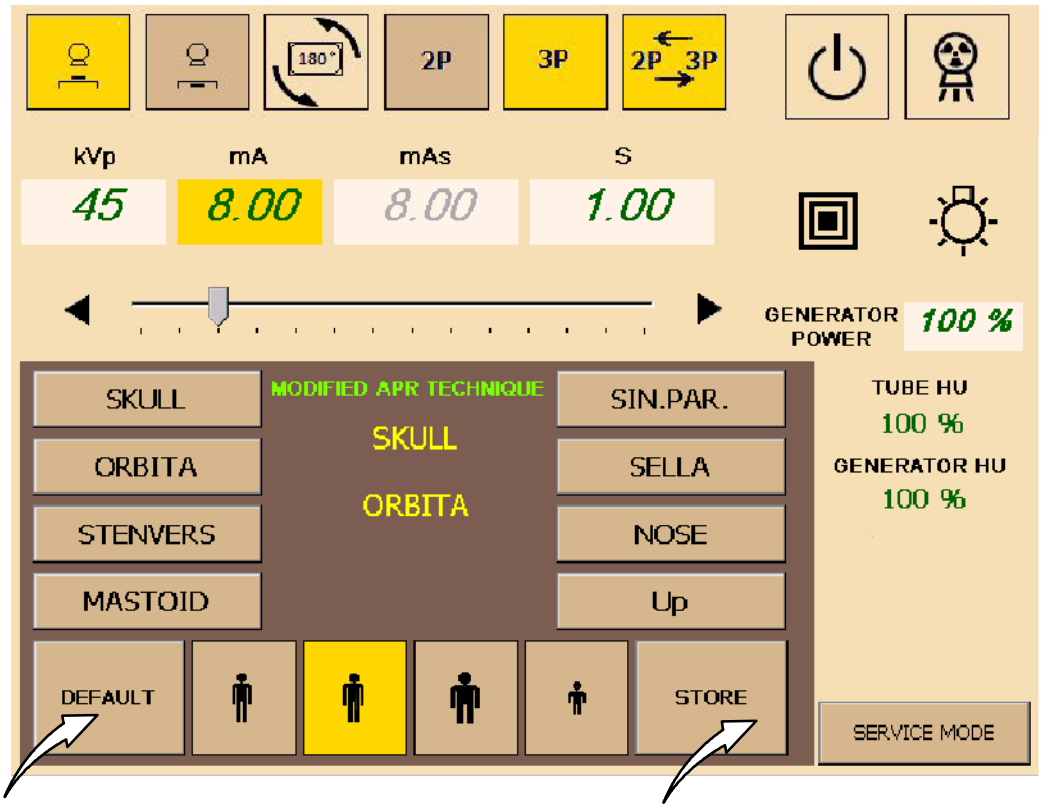
The three left-hand buttons select Small, Medium and Large adult sizes (only one selected at the same time). The right-hand "*Pediatric*" button changes the function of the left-hand three buttons from adult patient size to Pediatric patient size.

The "*Pediatric*" button and one of the other three buttons may be selected at the same time. Always subject to the operator's expertise, the small pediatric corresponds to 2–5 year–old patients; the medium pediatric corresponds to 5–10 year–old patients; and the large pediatric corresponds to 10–16 year–old patients.

APR SELECTORS: Each button is related to the nearest area of the APR Display and they are used to select one of the displayed Body Regions, Anatomical Views or Projections. The selected Region, View or Projection appears in the middle of the APR Display.

APR MODIFICATION: The operator may modify and store the APR parameters associated to a specific technique. (KVp-mA-S and Focal Spot).

When an APR technique is modified, the system displays a message: *"Modified APR Technique"* and the operator may store the modification by touching the "Store" button. At that moment, a pop-up screen requires the password "1111" to validate the modification.



Restores the factory APR techniques

Stores a modified APR technique
When Store is pressed, **password "1111"** is required to save the changes

Note ☞ *The following table show the Anatomical Programming distribution. The Anatomical Programming includes Radiographic parameters that can be used as a guide but the final values of each technique must be revised / contrasted / verified and / or modified if necessary, by the operator.*

Table 5-1
APR Projections (English version)

BODY REGION / ORGAN / PROJECTION								
SKULL	**SKULL**	AP/PA LATERAL	**THORAX**	**THORAX**	AP/PA LATERAL	**SPINE**	**C-SPINE**	AP LATERAL OBLIQUE
	ORBIT	-		**UPPER RIBS**	AP/PA OBLIQUE		**T-SPINE**	AP LATERAL OBLIQUE
	PARANASAL SINUSES	-		**LOWER RIBS**	AP/PA OBLIQUE		**L-SPINE**	AP LATERAL OBLIQUE
	NOSE	LAT		**SCAPULA**	AP/PA LATERAL OBLIQUE		**L5-S1**	AP LATERAL
				CLAVICULE	AP / PA		**SACRUM**	AP LATERAL
ABDOMEN / PELVIS	**ABDOMEN**	AP / PA	**LOWER EXTREMITIES**	**FEMUR**	AP LATERAL	**UPPER EXTREMITIES**	**SHOULDER**	AP SEMI-AXIAL OBLIQUE
	KIDNEY	AP		**KNEE**	AP LATERAL		**HUMERUS**	PA LATERAL
	URETER	AP		**PATELLA**	LATERAL AXIAL		**ELBOW**	PA LATERAL
	GALL-BLADDER	AP OBLIQUE		**LOWER LEG**	AP LATERAL		**FOREARM**	PA LATERAL
	PELVIS	AP		**ANKLE**	AP LATERAL OBLIQUE		**WRIST**	AP LATERAL OBLIQUE
	HIP	AP AXIAL		**FOOT**	AP LATERAL OBLIQUE		**HAND**	AP LATERAL OBLIQUE
				TOES	AP/L/OBLIQ		**FINGERS**	AP LATERAL

Table 5-1 (cont.)
APR Projections (Spanish version)

ZONA CUERPO / ORGANO / PROYECCION								
CRANEO	CRANEO	AP/PA LATERAL	TORAX	TORAX	AP/PA LATERAL	COLUMNA	COLUMNA CERVICAL	AP LATERAL OBLICUO
	ORBITA	-		COSTILLAS SUPERIORES	AP/PA OBLICUO		COLUMNA DORSAL	AP LATERAL OBLICUO
	SENOS PARA-NASALES	-		COSTILLAS INFERIORES	AP/PA OBLICUO		COLUMNA LUMBAR	AP LATERAL OBLICUO
	NARIZ	LAT		ESCAPULA	AP/PA LATERAL OBLICUO		L5-S1	AP LATERAL
				CLAVICULA	AP / PA		SACRO	AP LATERAL
ABDOMEN / PELVIS	ABDOMEN	AP / PA	EXTREMIDADES INFERIORES	FEMUR	AP LATERAL	EXTREMIDADES SUPERIORES	HOMBRO	AP SEMIAXIAL OBLICUO
	RINON	AP		RODILLA	AP LATERAL		HUMERO	PA LATERAL
	URETER	AP		ROTULA	LATERAL AXIAL		CODO	PA LATERAL
	VESICULA BILIAR	AP OBLICUO		PIERNA INFERIOR	AP LATERAL		ANTEBRAZO	PA LATERAL
	PELVIS	AP		TOBILLO	AP LATERAL OBLICUO		MUNECA	AP LATERAL OBLICUO
	CADERA	AP AXIAL		PIE	AP LATERAL OBLICUO		MANO	AP / OBLICUO LATERAL
				DEDOS DEL PIE	AP/L/OBL		DEDOS DE LA MANO	AP LATERAL

Table 5-1 (cont.)
APR Projections (French version)

REGION DU CORPS / ORGANE / PROJECTION								
CRANE	**CRANE**	AP/PA LATERAL	**THORAX**	**THORAX**	AP/PA LATERAL	**COLONNE**	**CERVICAL**	AP LATERAL OBLIQUE
	ORBITE	-		**COTES SUPERIEURES**	AP/PA OBLIQUE		**DORSAL**	AP LATERAL OBLIQUE
	SINUS	-		**COTES INFERIEURES**	AP/PA OBLIQUE		**LOMBAIRE**	AP LATERAL OBLIQUE
	NEZ	LAT		**OMOPLATE**	AP/PA LATERAL OBLIQUE		**L5-S1**	AP LATERAL
				CLAVICULE	AP / PA		**SACRUM**	AP LATERAL
ABDOMEN / BASSIN	**ABDOMEN**	AP / PA	**MEMBRES INFÉRIEURS**	**FEMUR**	AP LATERAL	**MEMBRES SUPÉRIEURS**	**EPAULE**	AP SEMI-AXIAL OBLIQUE
	REINS	AP		**GENOU**	AP LATERAL		**HUMERUS**	PA LATERAL
	URETERE	AP		**ROTULE**	LATERAL AXIAL		**COUDE**	PA LATERAL
	VESICULE BILIAIRE	AP OBLIQUE		**JAMBE INF.**	AP LATERAL		**AVANT-BRAS**	PA LATERAL
	PELVIS	AP		**CHEVILLE**	AP LATERAL OBLIQUE		**POIGNET**	AP LATERAL OBLIQUE
	HANCHE	AP AXIAL		**PIED**	AP LATERAL OBLIQUE		**MAIN**	AP/OBLIQUE LATERAL
				ORTEILS	AP/L/OBLIQ		**DOIGTS**	AP LATERAL

Table 5-1 (cont.)
APR Projections (Portuguese version)

REGIÃO DO CORPO / ORGÃO / PROJEÇÃO								
CRÂNIO	**CRÂNIO**	AP/PA LATERAL	**TÓRAX**	**TÓRAX**	AP/PA LATERAL	**COLUNA**	**COL. CERV.**	AP LATERAL OBLIQUO
	ÓRBITA	-		**COST. SUP.**	AP/PA OBLIQUO		**COL. DORS.**	AP LATERAL OBLIQUO
	SEN. PAR.	-		**COST. INF.**	AP/PA OBLIQUO		**COL. LOMB.**	AP LATERAL OBLIQUO
	NARIZ	LAT		**ESCÁPULA**	AP/PA LATERAL OBLIQUO		**L5-S1**	AP LATERAL
				CLAVÍCUL	AP / PA		**SACRO**	AP LATERAL
ABD / PÉLV	**ABDÔMEN**	AP / PA	**EXTR. INF**	**FÊMUR**	AP LATERAL	**EXTR. SUP.**	**OMBRO**	AP SEMI-AXIAL OBLIQUO
	RIM	AP		**JOELHO**	AP LATERAL		**ÚMERO**	PA LATERAL
	RIM / URET	AP		**RÓTULA**	LATERAL AXIAL		**COTOVELO**	PA LATERAL
	VES. BIL.	AP OBLIQUO		**PERNA INF.**	AP LATERAL		**ANTEBRAÇO**	PA LATERAL
	PÉLVIS	AP		**TORNOZELO**	AP LATERAL OBLIQUO		**PUNHO**	AP LATERAL OBLIQUO
	QUADRIL	AP AXIAL		**PÉ**	AP LATERAL OBLIQUO		**MÃO**	AP/OBLIQUO LATERAL
				DEDO PÉ	AP/L/OBLIQ		**DEDO MÃO**	AP LATERAL

Table 5-1 (cont.)
APR Projections (German version)

KÖRPERREGION / ORGAN / PROJEKTION								
SCHAEDEL	SCHAEDEL	AP/PA SEITLICH	THORAX	THORAX	AP/PA SEITLICH	WIRBEL-SAEULE	HWS	AP SEITLICH SCHRAEG
	ORBITA	AP/PA		OBERE RIPPEN	AP/PA SCHRAEG		BWS	AP SEITLICH SCHRAEG
	NASEN-NEBEN-HOEHLEN	-		UNTERE RIPPEN	AP/PA SCHRAEG		LWS	AP SEITLICH SCHRAEG
	NASE	LAT		SCHULTER-BLATT	AP/PA SEITLICH SCHRAEG		L5-S1	AP SEITLICH
				CLAVICUL	AP/PA		SACRUM	AP SEITLICH
ABDOMEN / BECKEN	ABDOMEN	AP/PA	UNTERE EXTREMI-TAETEN	OBERSCHEN-KEL	AP SEITLICH	OBERE EXTREMI-TAETEN	SCHULTER	AP SEMIAXIAL SCHRAEG
	NIERE	AP		KNIE	AP SEITLICH		OBERARM	PA SEITLICH
	URETER	AP		PATELLA	SEITLICH AXIAL		ELLENBOGEN	PA SEITLICH
	GALLEN-BLASE	AP SCHRAEG		UNTERER SCHENKEL	AP LATERAL		UNTERARM	PA SEITLICH
	BECKEN	AP		KNÖCHEL	AP SEITLICH SCHRAEG		HANDGELENK	AP SEITLICH SCHRAEG
	HUEFTE	AP AXIAL		FUSS	AP SEITLICH SCHRAEG		HAND	AP SEITLICH SCHRAEG
				ZEHEN	AP/L/SCHRÄG		FINGER	AP SEITLICH

Table 5-1 (cont.)
APR Projections (Russian version)

АНАТОМИЧЕСКИЕ ВИДЫ								
череп	череп	пп/зп бок	грудь	грудь	пп бок	позв	C–SPINE	пп бок косой
	глазн	пп/зп		верх реб	пп/зп косой		T–SPINE	пп бок косой
	нос	бок		нижн реб	пп/зп косой		L–SPINE	пп бок косой
	sin. par.	-		лопат	пп/зп бок косой		L5-S1	пп бок
				ключица	пп/зп		крестец	пп бок
абд/поч	живот	пп/зп	н. кон	бедро	пп бок	в.кон	пл суст	пп п осев косой
	почка	пп		бедро	пп бок		плечо	пп бок
	урет	пп		кол чаш	бок осев		локоть	зп бок
	желч пуз	пп косой		голень	зп бок		предпл	зп бок
	таз	пп		лодыжка	пп бок косой		лучезап	пп бок косой
	бедро	пп осев		ступня	пп бок косой		кисть	Пп / бок косой
				пальц ног	пп/бок/ косой		пальцы	пп бок

Table 5-1 (cont.)
APR Projections (Polish version)

REGION APR / ORGAN / PROJEKCJA								
CZASZKA	CZASZKA	AP/PA BOCZNE	KLATKA P	KLATKA P	AP/PA BOCZNE	KREGOSL.	KR. SZYJ.	AP BOCZNE SKOS
	OCZODOLY	AP/PA		ZEBRA G.	AP/PA SKOS		KR. PIER.	AP BOCZNE SKOS
	ZATOKI	-		ZEBRA D.	AP/PA SKOS		KR. LEDZ.	AP BOCZNE SKOS
	NOS	BOCZNE		LOPATKA	AP/PA BOCZNE SKOS		C. L5-S1	AP BOCZNE
				OBOJCZYK	AP/PA		K. KRZYZ.	AP BOCZNE
J. BRZUSZ	J. BRZUSZ	AP/PA	KONCZ D.	UDO	AP BOCZNE	KONCZ G.	BARK	AP POLOSIOWE SKOS
	NERKI	AP		KOLANO	AP BOCZNE		RAMIE	PA BOCZNE
	P. MOCZ.	AP		RZEPKA	BOCZNE OSIOWE		LOKIEC	PA BOCZNE
	P. ZOLCI.	AP SKOS		GOLEN	AP BOCZNE		PRZEDR.	PA BOCZNE
	MIEDNICA	AP		STAW ZK.	AP BOCZNE SKOS		NADGARS.	AP BOCZNE SKOS
	BIODRA	AP OSIOWE		STOPA	AP BOCZNE SKOS		DLON	AP/SKOS BOCZNE
				PALCE	AP/L/BOK		PALCE	AP BOCZNE

Table 5-1 (cont.)
APR Projections (Turkish version)

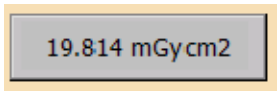
VÜCUT KISMI / ORGAN / PROJEKSIYON								
KAFA	KAFA	AP/PA LATERAL	TORAKS	TORAKS	AP/PA LATERAL	OMURGA	C. OMUR	AP LATERAL OBLIK
	GÖZ ÇUK	AP/PA		Ü. KABUR.	AP/PA OBLIK		T. OMUR	AP LATERAL OBLIK
	SIN.PAR.	-		A. KABUR.	AP/PA OBLIK		L. OMUR	AP LATERAL OBLIK
	BURUN	LATERAL		SKAPULA	AP/PA LATERAL OBLIK		L5-S1	AP LATERAL
				KLAVICU.	AP/PA		SAKRUM	AP LATERAL
BATIN/PELVIS	BATIN	AP/PA	A. EXTREM	FEMUR	AP LATERAL	Ü. EXTREM	OMUZ	AP SEMIAKS OBLIK
	BÖBREK	AP		DIZ	AP LATERAL		KOL	PA LATERAL
	ÜRINER	AP		PATELLA	LATERAL AKSIYAL		DIRSEK	PA LATERAL
	SAFRA K.	AP OBLIK		CRURAL	AP LATERAL		ÖN KOL	PA LATERAL
	PELVIS	AP LATERAL		A. BILEGI	AP LATERAL OBLIK		BILEK	AP LATERAL OBLIK
	KALÇA	AP AKSIYAL		AYAK	AP LATERAL OBLIK		EL	AP/OBLIK LATERAL
				A. PARMAK	AP/L/OBLIK		PARMAK	AP LATERAL

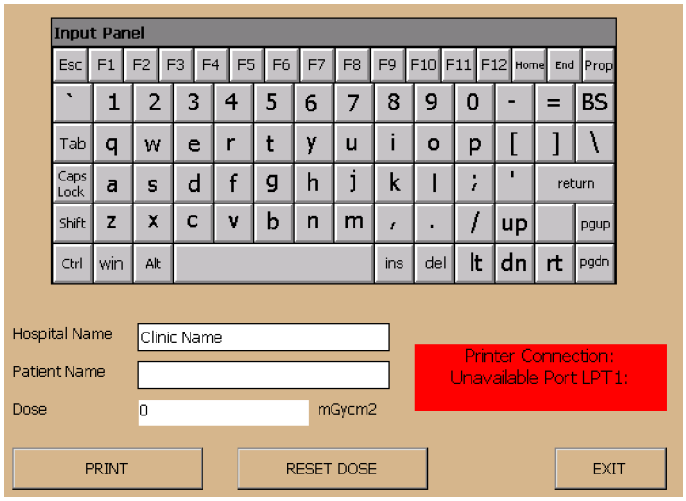
5.12 DOSIMETRY (OPTIONAL)

The Dose Display shows the accumulated radiation value of the X-ray Tube related to the selected Workstation. The radiation value of each exposure is added to the accumulated radiation value for the selected X-ray Tube. The accumulated radiation value is reset by touching the "*Reset Dose*" button.

Radiation measure is read as DAP value (Dose Area Product) in mGy*cm2 (*for example: 19.814 mGycm^2*).

Accumulated Dose of a patient can be printed (whenever a printer is connected to the Console) by Touching the *"Dosimetry"* button. At this moment, a keyboard appears on the Console to enter the Patient Name and Hospital. Then touch "*OK*" to print the Dose information.

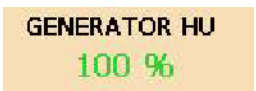




5.13 REMAINING THERMAL CAPACITY

The percentage of the remaining Thermal Capacity of the X-ray Tube and Generator are both calculated and totalled during exposures. They are displayed on the Touch Screen.

The Touch Screen shows the percentage of remaining Thermal Capacity of the X-ray Tube. For example, a display of "*100*%*"* would indicate that 100% of Heat Units capacity of the X-ray Tube remains.



The Touch Screen shows the percentage of remaining Thermal Capacity of the Generator that is available at that moment. For example, a display of *"100%"* would indicate 100 % of availability.

If the Unit detects that the new selection of parameters overpass the temperature threshold, the exposure is inhibited. Reduce parameter values or wait for the unit to cool.

5.13.1 COLD X-RAY TUBE PROTECTION

To protect the X-ray Tube when it is cold just after powering ON the Unit, high kVp exposures (over 100 kVp) cannot be performed until the Tube Thermal Capacity used reaches at least 8%. In that case, the "*TUBE HU*" Display would show "*92%*", that is, 92% of the X-ray Tube capacity remains.

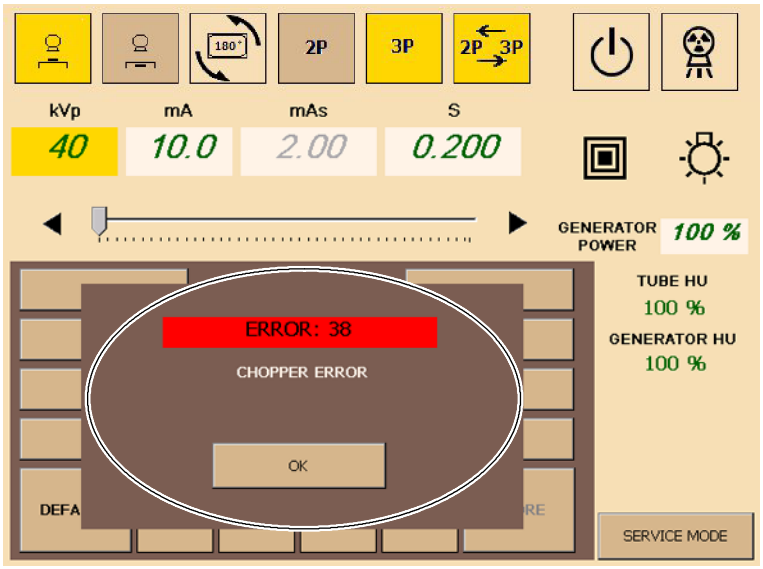
Note ☞

"TUBE POWER LIMIT" message is shown on the Console and an acoustic signal will alert operator if trying to select a greater kVp value than 100 kVp when the Tube is cold after powering ON the Unit (if the Unit has been off for more than 4 hours, the Tube will be completely cold). To prevent that situation, a warming-up procedure is recommended (refer to Section 6.2.2).

Once the Tube has been warmed-up, any kVp value could be selected according to the X-ray Tube condition and kVp limits.

5.14 ERROR CODES

Error codes are shown on the Touch Screen Console as a prompt message at the same time an alarm sounds. In general, to remove the error condition press *"OK" (= Reset).*



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.

Note ☞

Refer to Section 3.6. for Error Code list.

SECTION 6 OPERATING SEQUENCES

6.1 START-UP ROUTINE

The Unit turns ON when the magnetothermic switch is set upward (ON). The Unit will go through a start-up routine conducting an automatic self-test. The Display will show information usable only by service personnel.

Once the power-up has been completed, the Control Panel should display normal radiographic factors. If a malfunction is found, error messages will be displayed.

Note ☞ *Some indicators on the Control Panel are used to provide service information during the start-up process. These indicators should be ignored by the operator until the unit has completed its power-up sequence.*

6.2 X-RAY TUBE SEASONING AND X-RAY TUBE WARMING-UP

The **Seasoning** and **Warning-up** procedures assure a correct operation of the X-ray Tube and must be properly carried out. Otherwise the X-ray Tube life may be considerably reduced or the X-ray tube will suffer a permanent damage.

The **Seasoning** Procedure (Running) must be performed when the Tube is used for the first time or when it has not been in use for more than one month. This action establishes a favorable distribution of the electrical charges and electrostatic stresses in the insulation system of the Tube and the associated equipment. Not performing the Seasoning Procedure causes loss of the X-ray Tube Warranty.

The **Warming-up** Procedure must be performed at the start of each day or when the unit has been off for more than four hours.

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

6.2.1 SEASONING PROCEDURE (RUNNING) (AFTER ONE MONTH)

1. Close Collimator Blades fully and make sure that no one will be exposed.
2. Make sure that X-ray Tube is fully cold (at least 30 minutes without making exposures).
3. Reduce the power manually to 20% in case of 4 kW or 5 kW units or 10% in case of 8 kW units. On the X-ray Unit Control Panel, press and hold the “Large Focal Spot” push-button and then press the “kVp Decrease” push-button several times until “P10 or P20” respectively is shown in the kVp display.
4. Select 70 kVp, 10 mAs and Large Focus. Perform one exposure per minute increasing 5 kVp in every exposure up to the maximum Tube voltage.
5. If there are not signs of instability, the tube is ready for normal use.
6. If instability is observed during procedure, reduce 5 kVp of the selected kVp and make two exposures at those KVp, then continue the process.
7. Once the seasoning procedure is completed, set the power at 100% again. On the X-ray Unit Control Panel, press and hold the “Large Focal Spot” push-button and then press the “kVp Increase” push-button several times until “P--” is shown in the kVp display.

Note ☞ *Check that the remaining Thermal Capacity of the X-ray Tube is above 80% during this process.*

6.2.2 WARMING-UP PROCEDURE (EVERY DAY)

1. Close Collimator Blades fully and make sure that no one will be exposed.
2. For 4 kW and 8 kW X-Ray Units, select 60 kVp, 40 mAs and Large Focus. For 5 kW X-Ray Units, select 70 kVp, 64 mAs and Large Focus.
3. Perform one exposure.
4. Now the Tube is ready for normal use.

Excessive filament evaporation shortens X-ray tube life. Minimize evaporation by keeping Exposure “Preparation” time to an absolute minimum.

6.3 RADIOGRAPHIC OPERATION

A typical examination sequence is as indicated below:

1. Make sure that the X-ray tube is properly warmed-up.

2. Position the patient for the examination.

3. Select the radiographic technique to be performed.

4. Maintain the patient at the required position. Prepare the X-ray tube by pressing the handswitch push-button to the "*Prep*" position and maintain it until the "*Ready*" indicator is illuminated.

5. Make the X-ray exposure pressing the handswitch push-button fully to the "*Exp*" position and maintain it throughout the exposure. Then, the "*X-ray On*" indicator will light and an audible signal will sound during the exposure.

6. When the exposure is finished, release the push-button.

7. Repeat the procedure if additional exposures are desired.

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SECTION 7 PERIODIC MAINTENANCE

In order to assure continuous safe performance of the X-ray Unit, 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.

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.

7.1 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 DAMAGE TO EQUIPMENT.

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 Unit OFF.
2. Externally, check the proper cable connections between each component in the X-ray system.

3. Clean the equipment frequently, particularly if corroding chemicals are present.

   Clean external covers and surfaces, especially parts which might be in contact with patients, with a cloth moistened in warm water with mild soap. Wipe with a cloth moistened in clean water.

   When it is needed to disinfect the Control Console, clean it with a cloth impregnated with isopropyl alcohol.

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

7.2 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.)*

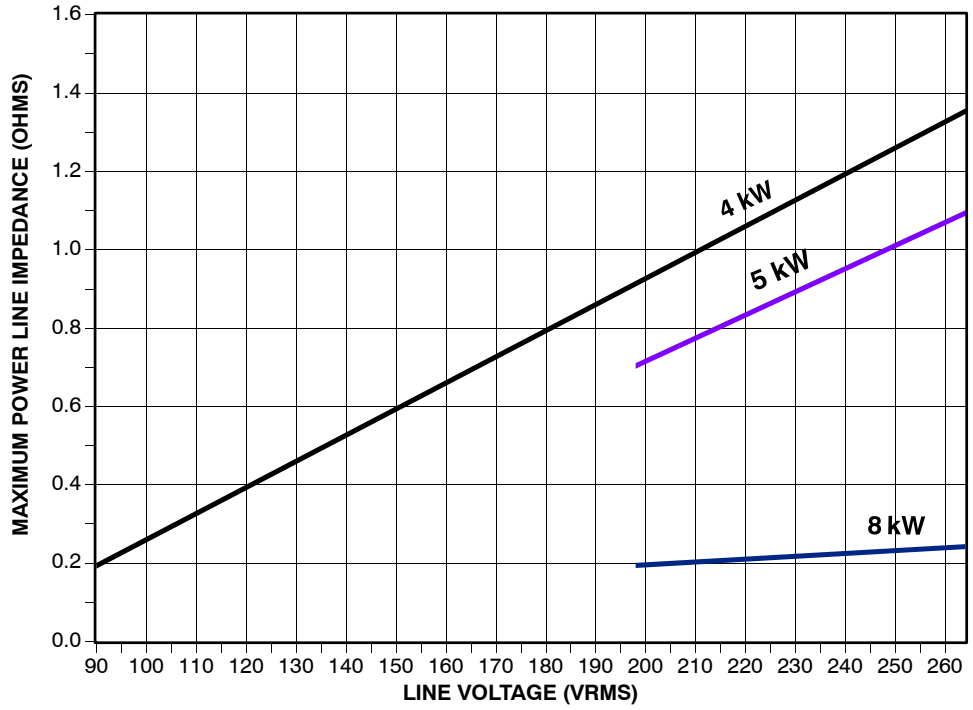
SECTION 8 TECHNICAL SPECIFICATIONS

Note ☞ *Specified accuracy does not include test equipment accuracy.*

Maximum Power kW	4.0	5.0	8.0
kVp Range and Accuracy	40 to 125 kVp (in 1 kVp steps) ±(3% +1 kVp)		
kVp High Frequency Ripple	300 kHz		
mAs Range and Accuracy	0.1 - 250 mAs (in 25% steps according to R'10 series) ±(5% + 0.1 mAs)		
mA Stations and Accuracy	5, 6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100 ±(4% + 1 mA)		
Exposure Time Range and Accuracy	0.001 - 10 seconds (in 25% steps according to R'10 series) ±(2% + 0.1 ms)		
Output Power (@ 0,1s)	121 – 125 kVp @ 20 mA 111 – 120 kVp @ 25 mA 101 – 110 kVp @ 32 mA 100 kVp @ 40 mA 50 kVp @ 80 mA 40 kVp @ 100 mA	121 – 125 kVp @ 25 mA 111 – 120 kVp @ 32 mA 101 – 110 kVp @ 40 mA 100 kVp @ 50 mA 60 kVp @ 80 mA 50 kVp @ 100 mA	121 – 125 kVp @ 40 mA 111 – 120 kVp @ 50 mA 101 – 110 kVp @ 64 mA 100 kVp @ 80 mA 80 kVp @ 100 mA
Input Power	6.6 kVA	7.5 kVA	12.5 kVA
Radiation Output Accuracy *(Reproducibility related to loading factors)*	C.V. (Coefficient of variation) $\leq$ 0.05		
Maximum Specified Energy input in one hour	125 kVp @ 700 mAs		
Equivalent Current	The equivalent current in continuous mode of the maximum specified energy corresponds to 0.194 mA at a nominal voltage of 125 kVp		
Maximum leakage radiation	<0.88 mGy per hour or 100 mR per hour.		

Maximum Power kW	**4.0**	**5.0**	**8.0**
X-ray Source Assembly:			
Anode Type	Stationary		Stationary
Nominal X-Ray Tube Voltage	125 kV		125 kV
Two Focal Spots	0.5 mm - 1.8 mm		0.6 mm - 2.8 mm
Target Angle	16°		15°
Anode Heat Content	35500 J (47215 HU)		28000 J (40000 HU)
Nominal Radiographic Anode Input Power (0.1 s per minute)	5.3 kW (Large Focus) 1.1 kW (Small Focus)		8.0 kW (Large Focus) 0.6 kW (Small Focus)
(For extended information about "Heating and Cooling Curves" and "Loading Ratings", refer to Appendix AP0074 for 4 kW and 5 kW units or Appendix AP0075 for 8 kW units)			
Inherent Filtration:			
Added Filter	0.5 mm Al @ 75 kVp		
X-Ray Tube Assembly	1.3 mm Al @ 75 kVp		
Collimator Assembly	2.0 mm Al @ 75 kVp		
Total Inherent Filtration	3.8 mm Al @ 75 kVp		
Power Line Operation	Single-Phase, 100 – 240 V~ , 50 / 60 Hz.	Single-Phase, 220 – 240 V~ , 50 / 60 Hz.	
	Line voltage automatic compensation: ±10%		
	Power line cable of the Portable Unit: 6 meters. Connection to standard outlets with GND that accomplishes local regulations.		
Maximum Power Line Impedance	*Refer to Illustration 8-1*		
Minimum recommended Thermomagnetic / Circuit Breaker	The General Circuit Breaker installed in the Portable Unit is 32 A (curve type C) with a 30 mA Sensitivity Differential. The Power Line Installation should be provided with a 30 mA Sensitivity Differential and with a Thermomagnetic Interruptor / Circuit Breaker of at least:		
	≥30 A (curve type C) or ≥16 A (curve type D) for 100 – 120 V~ ≥16 A (curve type C) or ≥10 A (curve type D) for 220 – 240 V~	≥20 A (curve type C) or ≥13 A (curve type D) for 220 – 240 V~	≥30 A (curve type C) or ≥16 A (curve type D) for 220 – 240 V~
	Momentary Line Current based on 100 ms X-ray exposure (RMS)		

Illustration 8-1
Maximum Power Line Impedance



8.1 ENVIRONMENTAL REQUIREMENTS

Note ☞ *STORAGE values only refer to equipment that is still in shipping containers. If the equipment is partially or completely installed, refer to IN USE values.*

8.1.1 RELATIVE HUMIDITY AND TEMPERATURE

RELATIVE HUMIDITY (Non-Condensing)				TEMPERATURE			
IN USE		STORAGE		IN USE		STORAGE	
MIN.	MAX.	MIN.	MAX.	MIN.	MAX.	MIN.	MAX.
30%	75%	10%	100%	10° C (50° F)	40° C (104 °F)	-40° C (-40° F)	70°C (158° F)

8.1.2 ATMOSPHERIC PRESSURE

ATMOSPHERIC PRESSURE			
IN USE		STORAGE	
MIN.	MAX.	MIN.	MAX.
700 hPa (units without Dosimeter)	1060 hPa	500 hPa	1060 hPa
* 800 hPa (units with Dosimeter)			
**Note: The default Dosimeter calibration is valid up to a minimum atmospheric pressure of 800 hPa. In order to operate at 700 hPa, the Dosimeter must be recalibrated at the installation site.*			

8.2 DIMENSIONS

Dimensions	Length	Width		Height
		Standard Wheels	All-Terrain Wheels	
	1664 mm (max) (65.5") (max)	669 mm (26.3")	759 mm (29.8")	2228 mm (max) (87.7") (max)

Weight	Aluminium Column		Steel Column	
	Minimum Weight	Maximum Weight	Minimum Weight	Maximum Weight
	50 kg (110 lbs)	59 kg (130 lbs)	56 kg (123 lbs)	65 kg (143 lbs)
	Note: Weight varies depending on the options added to the Unit			

Illustration 8-2
Dimensions (X-Ray Unit)

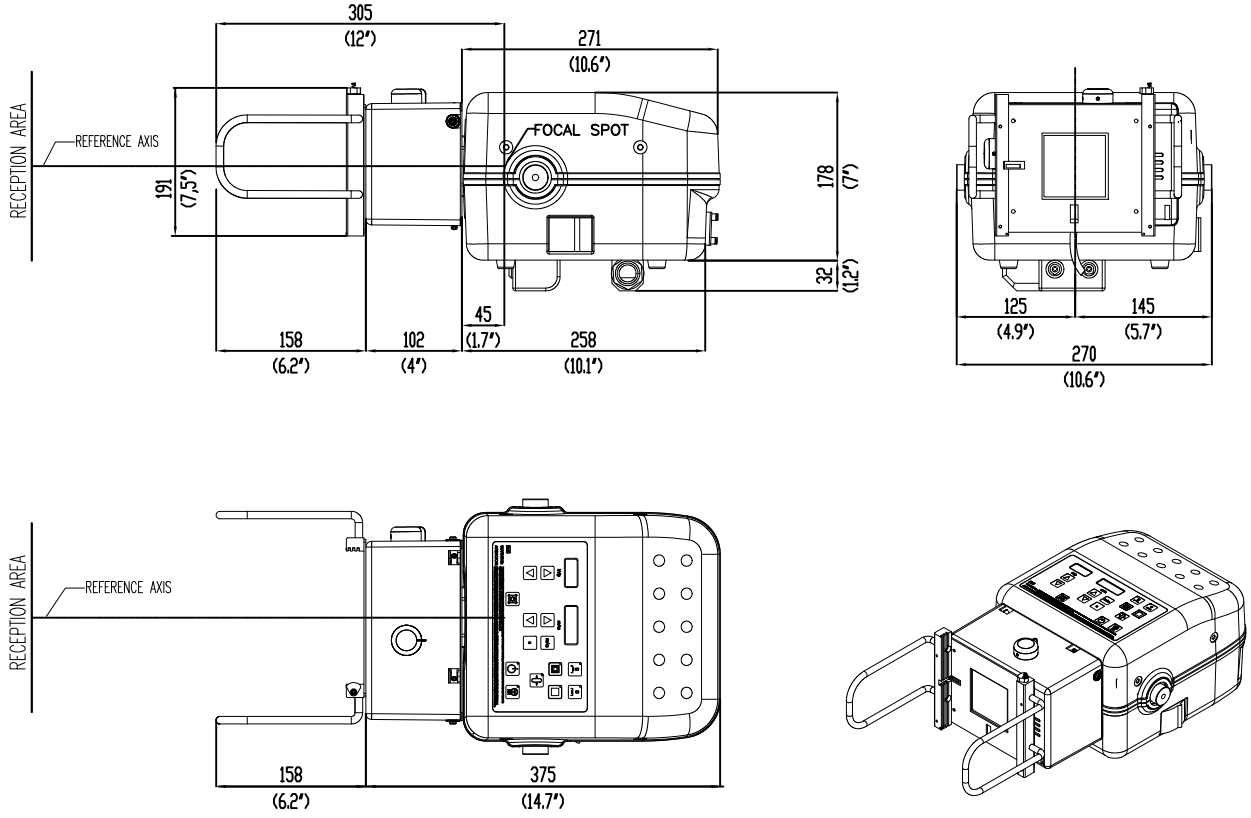


Illustration 8-3
Dimensions (Standard)

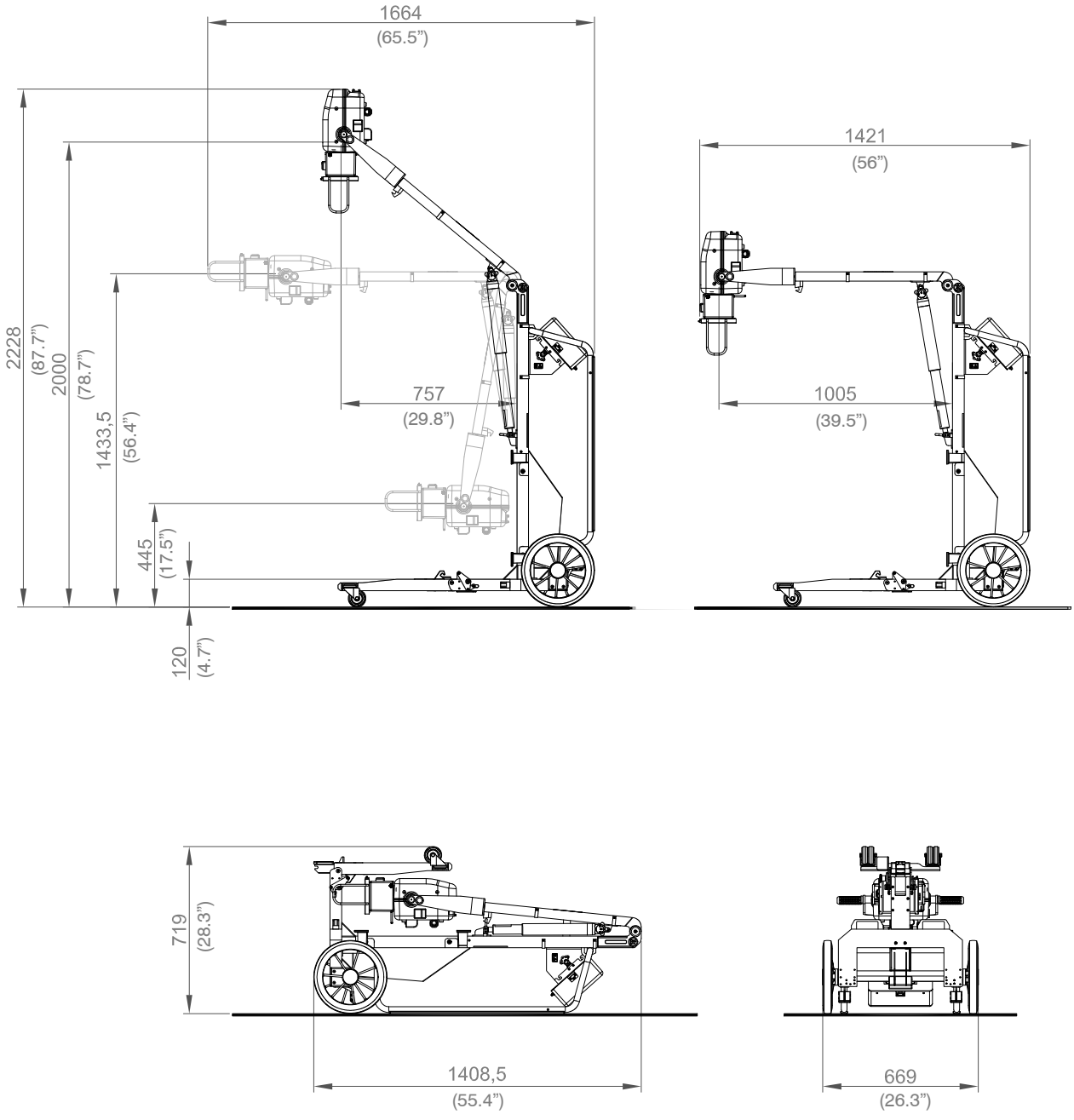


Illustration 8-4
Dimensions (All-Terrain Wheels)

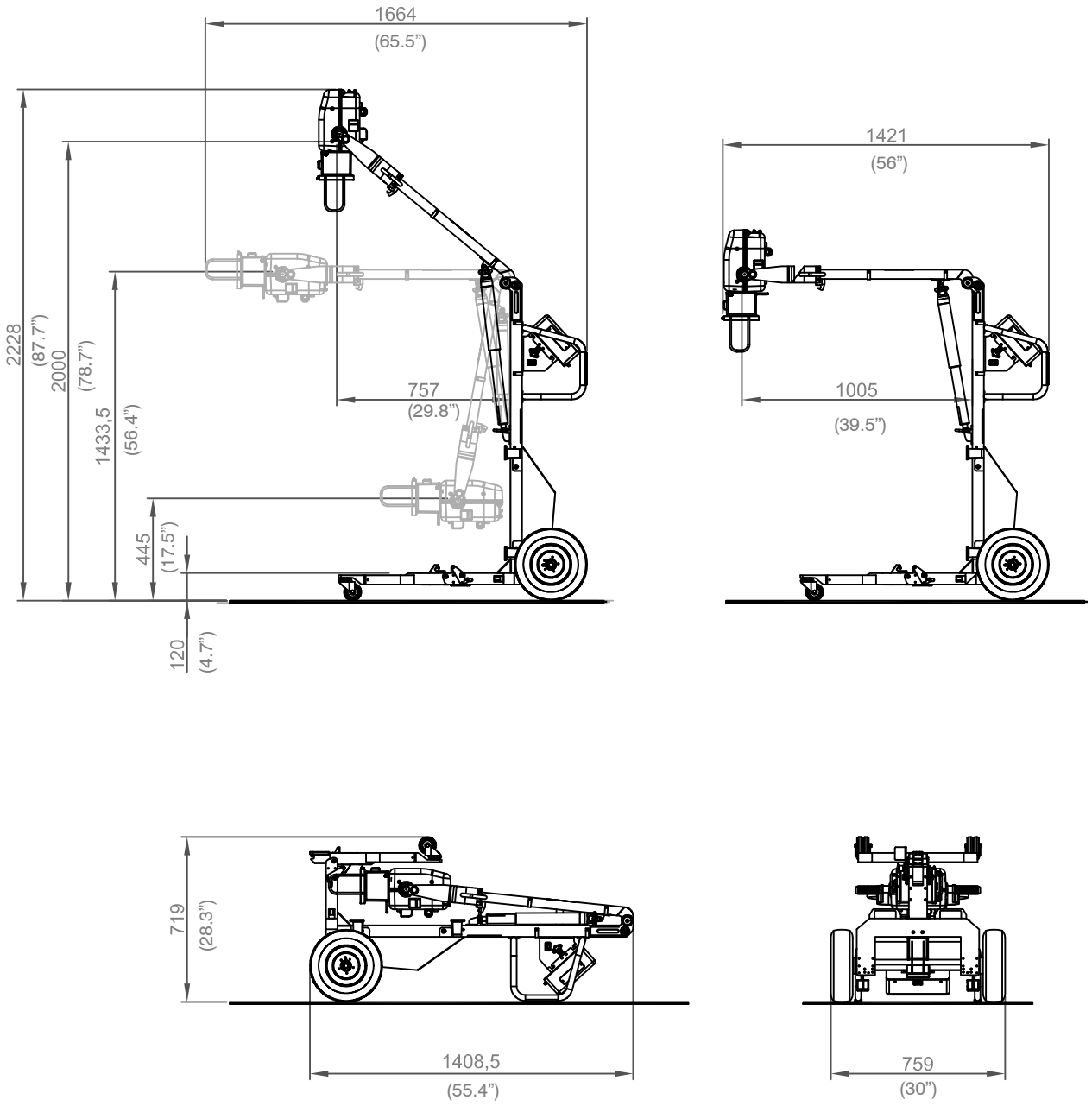
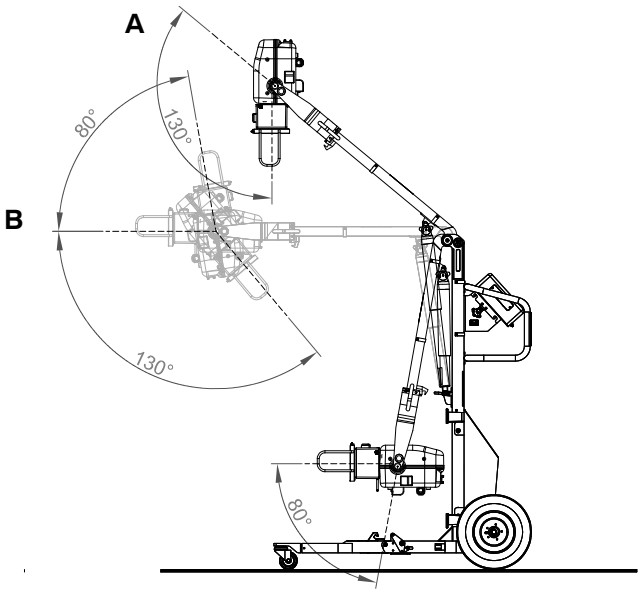
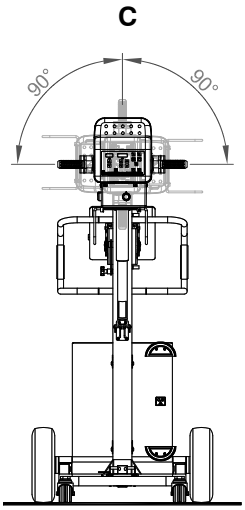


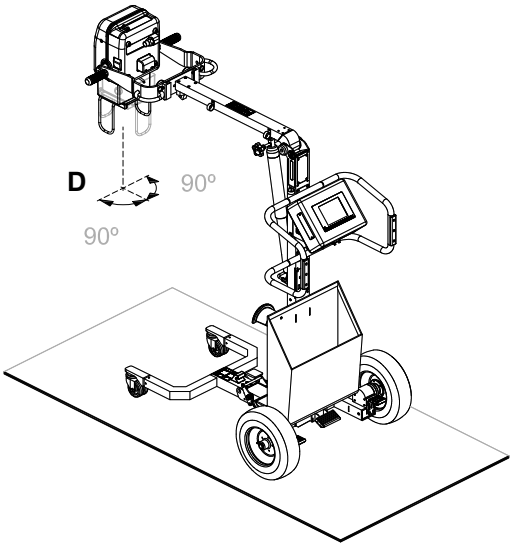
Illustration 8-5
Movements



A. Rotation of the X-Ray Unit with reference to its Support
B. Vertical Movement of the Arm to adjust Vertical SID



C. Rotation of the X-Ray Unit Support



D. Rotation of the Collimator

APPENDIX A GUIDELINES FOR PEDIATRIC APPLICATIONS

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

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

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

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

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

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

Positioning the pediatric patient:

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

Shielding:

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

Technique factors:

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

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

Summary:

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

APPENDIX B PROTECT YOUR IMAGING SYSTEM FROM CYBERSECURITY THREATS

Because Digital Radiography Systems may be connected by Wi-Fi or Ethernet to the Host Computer containing the Software, and the Host Computer may in turn be connected to the hospital information system, and ultimately the Internet, cybersecurity may become an issue for you. Here are some tips to keep your system and your medical images secure.

The medical devices security is a shared responsibility between manufacturer and responsible organization.

Use only materials supplied by Official Support/Technical Service for your Image Management software updates.

REQUIRED STRATEGIES BY THE OWNER / OPERATOR

Antivirus protection:

Use antivirus programs such as:

- Total AV
- ScanGuard Security Suite
- Norton by Symantec
- PC Protect
- Mcafee Antivirus Plus.
- Microsoft Security Essentials.
- Microsoft Windows Defender.

Keep these products up to date.

Limit access to trusted users only:

Limit access to devices through the authentication of users (e.g. user ID and password or smart card).

Ensure trusted content:

Restrict software or firmware updates to authenticated code.

Detect, respond, recover:

- Watch for on-screen warnings of possible virus infections.
- Respond by scanning for and removing possible virus infections.
- Recover from possible virus infections by having up to date backups of your host computer.

REQUIRED STRATEGIES BY THE MEDICAL DEVICE MANUFACTURER / SOFTWARE MANUFACTURER

We affirm our commitment to providing you with validated software updates and patches as needed throughout the life cycle of the medical device to continue to assure its continued safety and effectiveness.

Please promptly apply software updates and patches provided by us and never use image management software supplied by anyone else. Our development process utilizes the CISCO AMP protection. We are constantly scanning our development computers for malware. We hope you are doing the same.

A summary of our integrity controls:

- Our development computers are constantly being scanned for malware, and our supplier for anti-virus software automatically updates the software continuously as new threats are revealed.
- We perform daily backups to our external hard drives. The backups are in other place.
- During software development we disconnect from the Internet to prevent external attacks.
- Our development process utilizes the CISCO AMP protection.
- Copies of software updates we will be sending you are individually scanned for malware.

CONCLUSION

It is our JOINT responsibility to ensure your medical image software and image collection is safe and secure. We must both do our parts.