SEDECAL

Technical Publication
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Operation

HF Series Generators

RAD Console

CE
0120

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

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

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

This manual covers the following equipments / Este manual cubre los siguientes equipos / Ce manuel couvre les équipements suivants
X-Ray Generator SHF: **SHF-310, SHF-315, SHF-320, SHF-325, SHF-330, SHF-335** **SHF-410, SHF-415, SHF-420, SHF-425, SHF-430, SHF-435** **SHF-510, SHF-515, SHF-520, SHF-525, SHF-530, SHF-535** **SHF-610, SHF-615, SHF-620, SHF-625, SHF-630, SHF-635** **SHF-835**

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REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	MAY 18, 2004	First edition.
1	SEP 27, 2010	Electromagnetic Compatibility (EMC)
2	JUN 20, 2012	IEC Standards update
3	OCT 29, 2018	IEC Standards update

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

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

ADVISORY SYMBOLS

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

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

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

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

Note ☞

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

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SECTION 1 INTRODUCTION

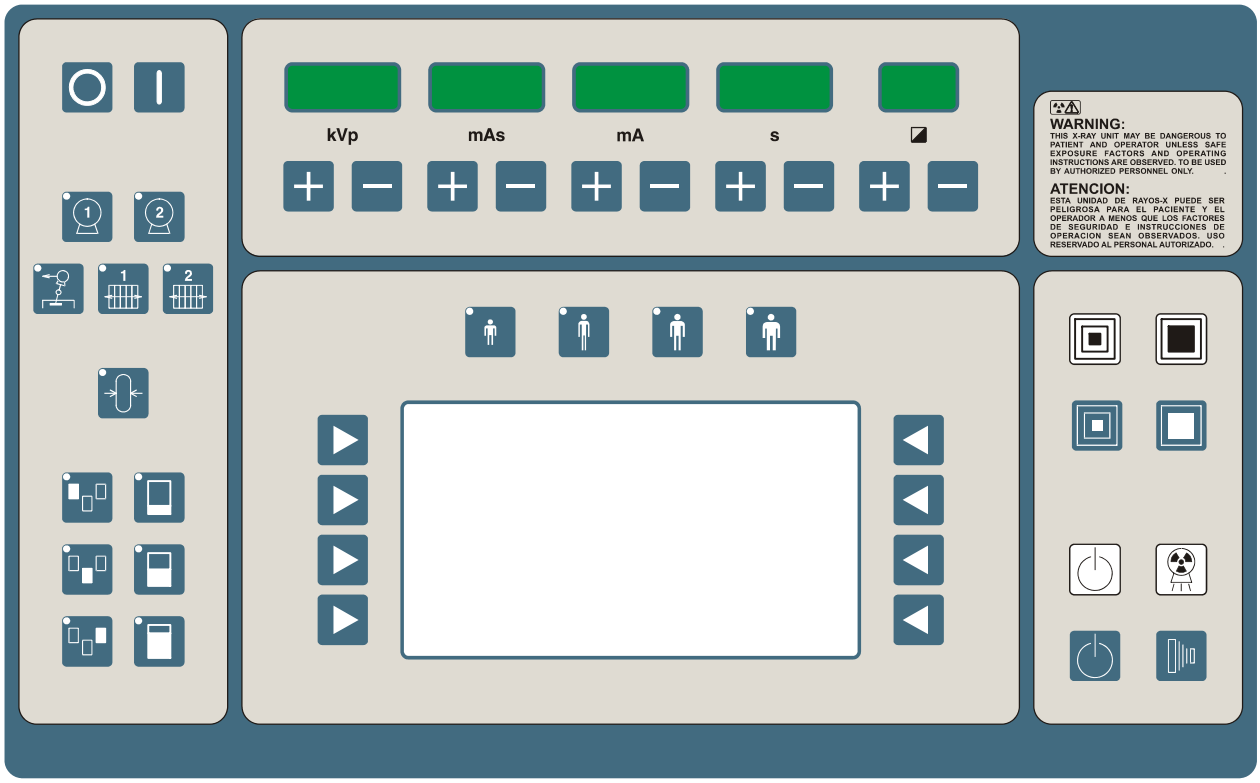
This manual contains all the information necessary to understand and operate the **High Frequency Generators with the RAD Console**. It provides a general description, safety and regulatory information, operating instructions and specifications concerning the equipment. It is not intended to teach radiology or to take any type of clinical diagnosis.

This High Frequency X-ray Generator is designed for general radiography. It provides all the advantages of high frequency waveform Generators including lower patient dose, shorter exposure times and greater accuracy and consistency.

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

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

Illustration 1-1
RAD Console



The Generator consists of the following essential parts:

- *Control Console,* operator controls and displays for radiographic operations. The Console is designed for ease of operation. It is the interface with the Power Cabinet and other related X-ray systems.
- *Power Cabinet,* that comprises:
  - *Power Module,* which contains the power and control components.
  - *High Voltage Transformer.*

1.1 GENERAL FEATURES

The main features of this high frequency Generator are:

- Constant potential high frequency, operating on three phase and single phase lines.
- Three point control by selecting kVp, mA and Exposure time, or two point control by selecting kVp and mAs, or one point control by selecting kVp with AEC operations.
- Two Buckys can be directly connected to the Generator (standard).
- Self-diagnosis indicators identify malfunctions in the system.
- Tube protection circuitry prolongs Tube life and increases system performance.
- Equipped with closed loop control of X-ray Tube current, kVp and filaments, which minimize potential errors and the need for readjustments.
- Automatic line voltage compensation due to closed loop operation of X-ray Tube current and kVp.
- Independent Heat Unit storage for each X-ray Tube, even after turning On / Off the equipment.

1.2 OPTIONS

In addition to the features described above, the Generator can be configured with the following options:

- *Anatomical Programmer* (APR) for six patient sizes (three adults and three children), with pre-programmed anatomical views for automatic selection. The operator may introduce modifications manually in all the original APR techniques and store them for later use.
- *Automatic Exposure Control (AEC),* which accommodates most popular exposure detectors. A total of up to four detectors (Ionization or Solid State types) can be installed on the system. Each one can be independently calibrated.
- *Third / Fourth Bucky,* this option allows to connect of up to four Buckys to the Generator.
- *Tomography,* an adaptation to interface with the Tomo device.
- *Second X-ray Tube,* which extends the system for using two X-ray Tubes.
- *High Speed Rotor Controller,* an optional digital controller consisting of a module which is fitted within the Power Cabinet.

1.3 PRODUCT IDENTIFICATION

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

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

1.4 INDICATIONS FOR USE

1.4.1 INTENDED USE

This equipment is intended for use by qualified personnel only.

The **High Frequency Generator with the RAD Console** is an equipment designed for general radiography in hospitals, clinics, radiology imaging centers and medical practices to perform processes and provide X-ray radiographic images of the skeleton, skull, chest, spine, pelvis, lung, abdomen, extremities and other body parts on the patients.

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

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

1.4.2 NORMAL USE

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

1.4.3 CONTRAINDICATIONS

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

This equipment is not intended for mammographic applications.

SECTION 2 SAFETY AND REGULATORY INFORMATION

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

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

2.1 GENERAL

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

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

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

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

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

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

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

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

WARNING

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

ITEM	MAXIMUM ATTENUATION EQUIVALENT mm AL	
	21 CFR	IEC 60601-2-54:2009 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.

2.3 MAXIMUM PERMISSIBLE DOSE (MPD)

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

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

2.4 RADIATION PROTECTION

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

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

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

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

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

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

- Wear radiation protective clothing.

- Wear a personal dosemeter.

- Use the different recommended protective materials and devices against radiation.

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

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

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

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

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

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

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

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

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

2.5 MONITORING OF PERSONNEL

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

The most effective method of determining whether or not the existing protective measures are adequate is 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

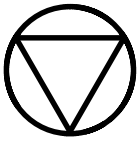
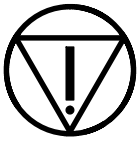
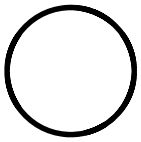
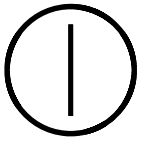
The following safety symbols may appear in the equipment.

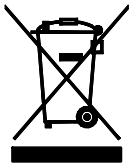
Their meaning are described below.

	**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)*

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

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

	**Stop (of action).**
	**Emergency stop.**
	“ON” power.
	**“OFF” power.**
	**“ON”** / **“OFF” (push-push).** *Each position, “ON” or “OFF”, is a stable position.*
	**Alternating current.**
	**Three-phase alternating current.**
	**Three-phase alternating current with neutral conductor.**
N	**Connection point for the neutral conductor on Permanently Installed equipment.**

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

2.7 REGULATORY INFORMATION

2.7.1 CERTIFICATIONS

The **X-ray High Frequency Generator** covered by this Operation Manual is authorized to be marked with **CE MARKING** in accordance with the provisions of the Council Directive 93 / 42 / EEC as amended by 2007/47/EC concerning Medical Devices.

Statement of Compliance with IEC 60601–1–3: ***X-ray High Frequency Generator*** *with radiation protection in accordance with IEC 60601-1-3:1994, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013.*

Statement of Compliance with IEC 60601–2–7: ***X-ray High Frequency Generator*** *in accordance with IEC 60601–2–7: 1998.*

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

Note ☞ ***X-ray High Frequency Generator*** *model or type references are stated at the back cover of this document.*

2.7.2 ENVIRONMENTAL STATEMENT ON THE LIFE CYCLE OF THE EQUIPMENT OR SYSTEM

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

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

2.7.3 MODE OF OPERATION

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

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

Protection against electric shock hazards in accordance with Standards: IEC 60601-1:1988, 2005 and 2012, IEC 60601–2–7:1998, IEC 60601-2-54:2009 and 2015.

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

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

ACCORDING TO MDD/93/42/CEE, THIS UNIT IS EQUIPPED WITH EMC FILTERS. THE LACK OF PROPER GROUNDING MAY PRODUCE ELECTRICAL SHOCK TO THE USER.

2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

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

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

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

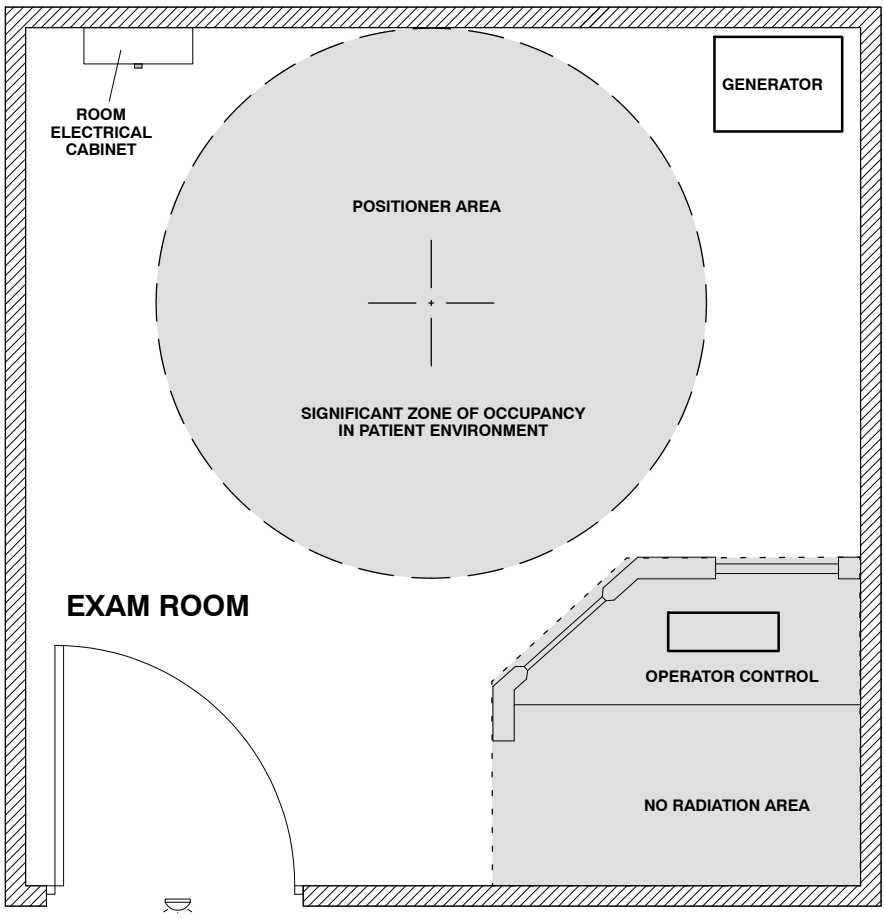
2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

2.7.8 PROTECTION AGAINST STRAY RADIATION

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

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



X-ray equipment specified for examination that requires the operator or staff to be close to the patient during normal use shall have at least one "*Significant Zone of Occupancy*" for the use of the operator and staff. (*For "Significant Zone of Occupancy" refer to the Positioner Manuals).*

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 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 EN 60601–1–2: 2007 and 2014. However, there is no guarantee that interference will not occur in a particular installation.

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

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

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

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

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

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

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2007)			
This X-Ray Generator is intended for use in the electromagnetic environment specified below. The customer or the user of this X-Ray Generator should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2:2007 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV ± 8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV ± 0.5kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000–4–5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	±1kV ± 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000–4–11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5s	>95% during 10 ms 60% during 100 ms 30% during 500 ms >95% during 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X-Ray Generator requires continued operation during power mains interruptions, it is recommended that the X-Ray Generator be powered from an uninterestingly power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000–4–8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE – U_T is the a.c. mains voltage prior to application of the test level.			

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

This X-ray Generator is intended for use in the electromagnetic environment specified below. The customer or user of this X-ray Generator should assure that it is used in such an environment.

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

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 Unit is used exceeds the applicable RF compliance level above, this 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 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 X-RAY GENERATOR (IEC 60601-1-2:2007)

This X-Ray Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this X-Ray Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this X-Ray Generator 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**		
	150KHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = [3.5/E_1]\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	-	0.23
0.1	0.38	-	0.73
1	1.2	-	2.3
10	3.8	-	7.3
100	12	-	23

TYPICAL RF DEVICES (Worst-Case scenario)

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance 'd' in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 - At 80MHz and 800MHz, 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: In the 3rd column for distances, the applicable range for frequencies is between 1GHz and 2.5 GHz.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014)			
This X-ray Generator is intended for use in the electromagnetic environment specified below. The customer or user of this X-ray Generator 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 Generator requires continued operation during power mains interruptions, it is recommended that this X-ray Generator 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 Generator is intended for use in an electromagnetic environment specified below. The customer or user of this X-ray Generator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Radiated RF EM fields IEC 61000-4-3	3 Vrms from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	3 Vrms from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONS EQUIPMENT"	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONS EQUIPMENT"	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the equipment, including cables specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms from 150 kHz to 80 Mhz 6 Vrms in ISM bands from 150 kHz to 80 MHz (80% AM at 1 kHz)	3 Vrms from 150 kHz to 80 Mhz 6 Vrms in ISM bands from 150 kHz to 80 MHz (80% AM at 1 kHz)	
NOTE – The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. *The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz; and 50.0 MHz to 54.0 MHz.*			

IMMUNITY REQUIREMENTS TO RF WIRELESS COMMUNICATIONS EQUIPMENT (IEC 60601-1-2:2014)			
This X-ray Generator is intended for use in an electromagnetic environment specified below. The customer or User of this X-ray Generator 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.*

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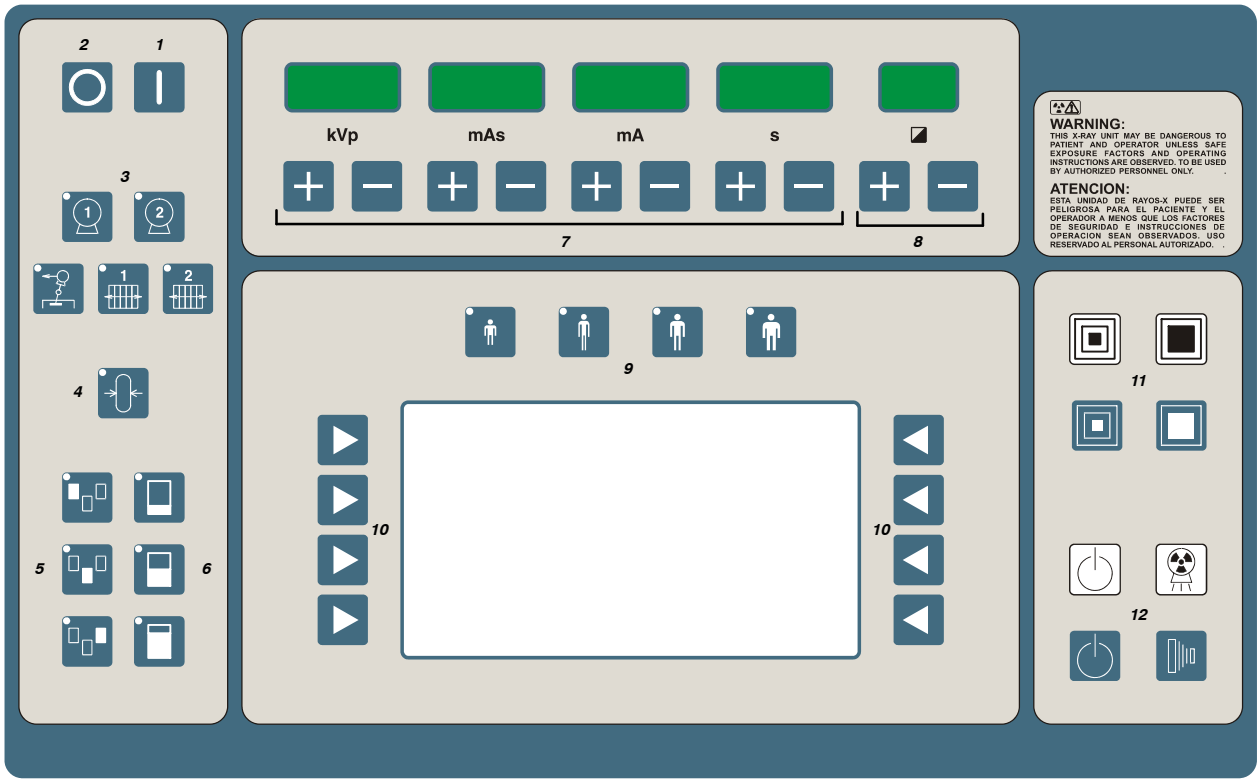
SECTION 3 OPERATING CONTROLS

All controls, indicators and displays located on the Control Console are positioned depending upon their functions.

Note ☞ *Use the operating controls as described in this manual, any other no-indicated combination may cause an incorrect operation of the equipment.*

Illustration 3-1
Rad Console



1. Power On
2. Power Off
3. Workstations Selection
4. AEC Reset
5. AEC Field Selection
6. Film / Screen Combination
7. Radiographic Values
8. AEC Density Values
9. Patient Size Selection (APR)
10. Body Regions / Anatomical View Selection (APR)
11. Focal Spot Indicators and Selectors
12. Exposure Indicators and Controls

3.1 RADIOGRAPHY AND GENERAL CONTROLS

3.1.1 POWER ON / OFF

ON: The Generator is turned ON by pressing this push-button. This starts a power-up routine which is shown on the Console (a.e. P05.3 = Vers.5, Rev.3). After the power-up routine the last workstation used will be automatically selected.

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

For Generators equipped with "High Speed Rotor Controller", if the X-ray Tube is rotating when pressing the "*OFF*" push-button, the Generator will stop the anode immediately and then the unit will be turned off (approx. 3 seconds). The equipment only turns off if "*Preparation*" is not activated.

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

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

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

3.1.2 WORKSTATIONS SELECTION

The workstations are configured according to the customer preferences during the installation procedure. The following push-buttons select their respective workstation (illuminated push-buttons).

If a push-button is not configured during the installation, the respective push-button(s) can not be selected during operation.

Note in the following table the configuration of the Workstation assigned for each push-button.

PUSH-BUTTONS	WORKSTATION (Tube, Bucky, etc.)
	
	
	
	
	
	
	
	
Note.- Workstation data such as X-ray Tube, Bucky, Tomo, Fluoro, Spot Film, Cine, DSI, DSA, Ion Chambers, etc... must be registered.	

3.1.3 FOCAL SPOT INDICATORS AND SELECTORS

LARGE FOCAL SPOT: Indicates that the "*Large Focal Spot*" of the X-ray Tube has been selected.

SMALL FOCAL SPOT: Indicates that the "*Small Focal Spot*" of the X-ray Tube has been selected.

FOCAL SPOT SELECTORS: Each push-button selects the related Focal Spot of the X-ray Tube, keeping kVp and mAs constant (maximum mA available and minimum Exposure Time).

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

Note ☞ *The mA station set for the Focal Spot change is configured by the field engineer during the installation.*

The Focal Spot may also be selected:

- according to the selected mA station.
- by pressing "*ON*" + "*mA or mAs increase*" push-buttons to select Large Focal Spot, or by pressing "*ON*" + "*mA or mAs decrease*" push-buttons to select Small Focal Spot.

3.1.4 RADIOGRAPHIC PARAMETERS

kV DISPLAY can show:

- The radiographic kV value selected for the technique.
- The actual X-ray Tube heat unit value after pressing the "*On*" push-button (*Refer to Section 3.6*).
- The error messages during a system fault, preceded by the letter "E" (a.e., E02) (*Refer to Section 3.9*).

mAs DISPLAY can show:

- The radiographic mAs value selected for the technique.
- When an exposure is made with AEC, it shows the actual mAs at the end of the exposure whenever the "*Prep*" push-button has not been released.
- If an exposure is aborted by releasing the "*Exp*" push-button during the exposure, it shows the actual mAs value until the "*AEC Reset*" push-button is pressed to reset the error condition.

mA DISPLAY: Shows the radiographic mA value selected for the technique.

Time DISPLAY can show:

- The Time value (in seconds) selected for the radiographic technique.
- When an exposure is made with AEC, it shows the back-up time during the exposure and the actual Time at the end of the exposure whenever the "*Prep*" push-button has not been released.
- If an exposure is aborted by releasing the "*Exp*" push-button during the exposure, it shows the actual Time until the "*AEC Reset*" push-button is pressed to reset the error condition.

RAD Displays can also show:

- The actual Time, the calculated mAs, and the selected kVp and mA radiographic parameters of the last exposure, with or without AEC, after pressing the "*AEC Reset*" push-button (values flashing).
- The exposure counters (*Refer to Section 3.7*).

INCREASE / **DECREASE**: Radiographic technique values are increased or decreased by pressing the respective push-buttons. The values increase or decrease step-by-step each time the corresponding push-button is pressed, and changes faster when either of them is pressed continuously.

- **kV:** Selects the X-ray Tube voltage.
- **mAs**: Selects the exposure in mAs.
- **mA**: Selects the X-ray Tube current.
- **s**: Selects the exposure time in seconds.

(Refer to Section 6 for Factor ranges)

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 blinks.*

Generator Power Limit. *If the power limit (kV x mA) is reached by increasing the mA up to a maximum possible value, the mA value is blocked. Flashing values on kV and mA Displays 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 mA induces to reach space charge limit in the selected tube, the parameter is blocked, and flashing value on the kV Display will alert operator about the situation.*

Maximum Energy (60 kJ)*. Only in AEC mode, if a variation of the parameters means that the maximum energy (60 kJ) will be exceed, the parameter is blocked. Flashing values on kV and mAs Displays will alert operator about the situation.*

Instantaneous Power. *If a technique reaches the instantaneous power limit of the X-ray Tube (ratings limit or the X-ray Tube is momentarily overheated), some techniques cannot be selected. Flashing values on kV and mAs Displays will alert operator about the situation.*

3.2 AUTOMATIC EXPOSURE CONTROL (AEC)

Automatic Exposure Control (AEC) produces consistent film density with excellent contrast regardless of the radiographic technique selected. The AEC module comprises the controls for the selection of the Exposure Detector Fields (Ion Chamber), the Film/Screen Combination, Film Density Compensation and AEC Reset.

The AEC mode is selected by pressing any of the three AEC Field push-buttons. To exit the AEC mode, press all the illuminated AEC Field push-buttons until none are lit.

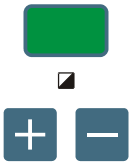
In AEC mode the back-up time (or back-up mAs) MUST BE SET MANUALLY by the operator using the Console controls.

Note ☞

The value of the back-up time (or mAs) must be set at a greater value than the previously considered for the exposure time (or mAs). A value above 50% of the considered value is the recommended. Very extreme values of back-up time (or mAs) should be avoided to prevent patient from excessive exposure when a control error is produced.

FIELD SELECTION: Each push-button indicates its related physical location of the selected field in the AEC Exposure Detector, and it may be selected or deselected by pressing it. Any combination of fields can be selected and the push-buttons illuminate when active.

FILM / SCREEN COMBINATION: Each of these push-buttons allows adjustment of the mAs in relation to a programmed Film / Screen combination that may be in use slow, medium, or fast respectively (200, 400, 800). Each time a Film / Screen push-button is selected (illuminated), the others are automatically deselected.



DENSITY: These push-buttons are used to adjust the radiographic film density. Normal film density (0) is the automatic default value when AEC is selected.

Film density can be proportionally increased or decreased in steps. The variation percentage density between steps can be changed during the equipment calibration by the engineer according to customer preferences (the percentage by default is 25%).

AEC RESET: If the exposure is aborted by the AEC back-up timer, the indicator on the "*AEC Reset*" push-button blinks accompanied of an audible alarm. Next exposure is inhibited until the AEC function is reset by pressing the "*AEC Reset*" push-button. When the Generator is in *"Prep"* mode, the AEC function can not be reset.

The "*AEC Reset*" push-button may blink when the kVp value, AEC Density and Film / Screen Combination select a technique that is out of the operative range with AEC, it inhibits the next exposure. Change any parameter (kVp value, AEC Density or Film / Screen Combination) in order to obtain a technique enabled for AEC.

3.3 ANATOMICAL PROGRAMMER (APR)

Anatomical Programmer (APR) module is comprised of the controls which select the Patient Size and Display Selectors. The process is shown on the APR Display.

The APR techniques are factory pre-programmed according to different standard technique sets in a X-Y matrix format that combines eight Body Regions (Y-axis) with eight Anatomical Views (X-axis). Besides the radiographic parameters, selections of the workstation or AEC (density, fields and film / screen combination) can be assigned to the APR techniques. These selections will be always 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 only as a guide line, they are only starting points that can be replaced by more specific protocols developed by the operator. Accurate exposure factors are dependent among other things on grid factors, table top absorption, screen film combinations, film processing or detector features.

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

Note ☞

APR language may be changed, just after selecting one of the patient size (APR activation), pressing the "Power ON" push-button. Language selected remains stored even after the equipment is turned Off. (Only for Generators equipped with this option).

APR DISPLAY: Shows the different Body Regions and Anatomical Views available for each APR technique, and the final APR selection.

Because each area of the APR Display is limited in length to eight characters, some regions and views are abbreviated.

PATIENT SIZE: These push-buttons are used to adapt the APR technique chosen according to patient size. Six patient sizes are available. The three right-hand push-buttons select Small, Medium and Large adult sizes (one only illuminated when selected). The left-hand paediatric push-button changes the function of the right-hand three push-buttons from adult patient size to paediatric patient size. (In this mode, the paediatric push-button and one of the other three buttons may be illuminated at the same time).

ANATOMICAL VIEW SELECTORS: Each push-button is related with the nearest area of the APR Display and they are used to select one of the displayed Body Regions and Anatomical Views.

The APR Display shows the following Body Regions: "*Skull*", "*Facial*", "*Upper Trunk*", "*Lower Trunk*", "*Chest*", "*Extremity on Bucky*", "*Extremity on Table Top*" and "*Special*". When a Body Region has been selected, the APR Display shows directly all its respective Anatomical Views. In some cases an Anatomical View may show a sub-menu with its respective Anatomical Views. (*Refer to Table 3-1*).

When the APR selection is finished, the APR Displays shows the final selection (Body Region and Anatomical View) and the Console indicates the respective position, the AEC selections and the technique parameters.

Press on the push-buttons related to the final Body Region and/or Anatomical View selection showed on the APR Display, to go back to the previous Anatomical Views level or to the Body Regions level.

Table 3-1
APR Matrix (English)

APR MATRIX	ANATOMICAL VIEWS							
	View-1	**View-2**	**View-3**	**View-4**	**View-5**	**View-6**	**View-7**	**View-8**
SKULL	AP / PA	LATERAL	TOWNES	MASTOID	MASTOID LATERAL	TEMPORO-MANDIBULAR JOINT	SELLA TURCICA AP	SELLA TURCICA LATERAL
FACIAL	AP / PA	LATERAL	WATERS	ZYGOMA ARCH	OPTIC FORAMINA	MANDIBLE LATERAL	STENVERS	LAW'S
UPPER TRUNK	CERVICAL AP	CERVICAL LATERAL	THORACIC AP	THORACIC LATERAL	THORACIC SWIMMER	SCAPULA LATERAL	SHOULDER	CLAVICLE
LOWER TRUNK	LUMBAR AP	LUMBAR LATERAL	PELVIS AP	SACRUM AP	SACRUM LATERAL	ABDOMEN AP	ABDOMEN LATERAL	PELVI-METRY
CHEST	AP / PA	LATERAL	60" CART	UPPER RIBS	LOWER RIBS	STERNUM	STERNUM LATERAL	LORDOTIC
EXTREM BUCKY	HIP AP	HIP FROG	FEMUR	KNEE AP	KNEE LATERAL	KNEE AXIAL	HUMERUS	HUMERUS TRANS-THORACIC
EXTREM TBL TOP	HAND	WRIST	FOREARM	ELBOW	FOOT	ANKLE	TIBIA	KNEE
SPECIAL	TOMO	AUX	CHANGER 1	CHANGER 2	USER-1	USER-2	USER-3	CONTRAST

SUB-MENU OF EXTREM TBL TOP	ANATOMICAL VIEWS							
	View-1	**View-2**	**View-3**	**View-4**	**View-5**	**View-6**	**View-7**	**View-8**
HAND	PA	LATERAL	OBLIQUE	FINGERS	–	–	–	–
WRIST	PA	LATERAL	OBLIQUE	–	–	–	–	–
FOREARM	PA	LATERAL	OBLIQUE	–	–	–	–	–
ELBOW	PA	LATERAL	AXIAL	–	–	–	–	–
FOOT	PA	LATERAL	OBLIQUE	TOES	–	–	–	–
ANKLE	PA	LATERAL	OBLIQUE	–	–	–	–	–
TIBIA	PA	LATERAL	OBLIQUE	–	–	–	–	–
KNEE	PA	LATERAL	AXIAL	–	–	–	–	–

SUB-MENU OF SPECIAL	ANATOMICAL VIEWS							
	View-1	**View-2**	**View-3**	**View-4**	**View-5**	**View-6**	**View-7**	**View-8**
CONTRAST	GALL BLADDER	STOMACH AP	STOMACH LATERAL	COLON	AIR CONTRAST	IVP	ESOPH 40	ESOPH 72

Table 3-1 (cont.)
APR Matrix (Spanish)

MATRIZ DEL APR	VISTAS ANATOMICAS							
	Vista-1	**Vista-2**	**Vista-3**	**Vista-4**	**Vista-5**	**Vista-6**	**Vista-7**	**Vista-8**
CRANEO	AP / PA	LATERAL	TOWNES	MASTOIDES	MASTOIDES LATERAL	ARTICULAC. TEMPORO-MANDIBULAR	SILLA TURCA AP	SILLA TURCA LATERAL
CARA	AP / PA	LATERAL	SENOS WATERS	ARCO CIGOMATICO	AGUJEROS OPTICOS	MANDIBULA LATERAL	STENVERS	LAW'S
TRONCO SUPERIOR	CERVICAL AP	CERVICAL LATERAL	DORSAL AP	DORSAL LATERAL	CERVICO-DORSAL	ESCAPULA LATERAL	HOMBRO	CLAVICULA
TRONCO INFERIOR	LUMBAR AP	LUMBAR LATERAL	PELVIS AP	SACRO AP	SACRO LATERAL	ABDOMEN AP	ABDOMEN LATERAL	PELVI-METRIA
PECHO	AP / PA	LATERAL	60" CART	COSTILLAS SUPERIOR	COSTILLAS INFERIOR	ESTERNON	ESTERNON LATERAL	LORDOTIC
EXTREMIDADES SOBRE BUCKY	CADERA AP	CADERA FROG	FEMUR	RODILLA AP	RODILLA LATERAL	RODILLA AXIAL	HUMERO	HUMERO TRANS-TORACICA
EXTREMIDADES SOBRE TABLERO	MANO	MUÑECA	ANTEBRAZO	CODO	PIE	TOBILLO	TIBIA	RODILLA
ESPECIAL	TOMO	AUXILIAR	CAMBIADOR 1	CAMBIADOR 2	USUARIO-1	USUARIO-2	USUARIO-3	CONTRASTE

SUB-MENU EXTREMIDAD SOBRE TABLERO	VISTAS ANATOMICAS							
	Vista-1	**Vista-2**	**Vista-3**	**Vista-4**	**Vista-5**	**Vista-6**	**Vista-7**	**Vista-8**
MANO	PA	LATERAL	OBLICUO	DEDOS	–	–	–	–
MUÑECA	PA	LATERAL	OBLICUO	–	–	–	–	–
ANTEBRAZO	PA	LATERAL	OBLICUO	–	–	–	–	–
CODO	PA	LATERAL	AXIAL	–	–	–	–	–
PIE	PA	LATERAL	OBLICUO	DEDOS	–	–	–	–
TOBILLO	PA	LATERAL	OBLICUO	–	–	–	–	–
TIBIA	PA	LATERAL	OBLICUO	–	–	–	–	–
RODILLA	PA	LATERAL	AXIAL	–	–	–	–	–

SUB-MENU ESPECIAL	VISTAS ANATOMICAS							
	Vista-1	**Vista-2**	**Vista-3**	**Vista-4**	**Vista-5**	**Vista-6**	**Vista-7**	**Vista-8**
CONTRASTE	VESICULA BILIAR	ESTOMAGO AP	ESTOMAGO LATERAL	COLON	CONTRASTE	IVP	ESOFAGO 40"	ESOFAGO 72"

Table 3-1 (cont.)
APR Matrix (French)

MATRICE APR	VUES ANATOMIQUES							
	Vue-1	**Vue-2**	**Vue-3**	**Vue-4**	**Vue-5**	**Vue-6**	**Vue-7**	**Vue-8**
CRANE	AP / PA	LATERAL	TOWNES	MASTOIDE	MASTOIDE LATERAL	ARTICULAT. TEMPORO MAXILAIRE	SELLE TURCIQUE AP	SELLE TURCIQUE LATERAL
FACIAL	AP / PA	LATERAL	SINUS WATERS	ARCADE MALAIRE	ORIFICE OCULAIRE	MAXILAIRE LATERAL	STENVERS	LAW'S
TRONC SUPERIEUR	CERVICAL AP	CERVICAL LATERAL	THORACIQUE AP	THORACIQUE LATERAL	THORACIQUE SWINNER	OMOPLATE LATERAL	EPAULE	CLAVICULE
TRONC INFERIEUR	LOMBAIRE AP	LOMBAIRE LATERAL	BASSIN AP	SACRUM AP	SACRUM LATERAL	ABDOMEN AP	ABDOMEN LATERAL	PELVI-GRAPHIE
POITRINE	AP / PA	LATERAL	60" CARTILAGE	COTES SUPERIEUR	COSTES INFERIEUR	STERNUM	STERNUM LATERAL	LORDOTIQUE
EXTREMITES BUCKY	HANCHE AP	HANCHE OB	FEMUR	GENOU AP	GENOU LATERAL	GENOU AXIAL	HUMERUS	HUMERUS TRANS-THORACIQUE
EXTREMITES TABLE	MAIN	POIGNET	AVANT BRAS	COUDE	PIED	CHEVILLE	TIBIA	GENOU
SPECIAL	TOMOGRAPH	AUXILIAIRE	CHANGEUR 1	CHANGEUR 2	UTILISATEUR 1	UTILISATEUR 2	UTILISATEUR 3	CONTRASTE

SUB-MENU EXTREMITES TABLE	VUES ANATOMIQUES							
	Vue-1	**Vue-2**	**Vue-3**	**Vue-4**	**Vue-5**	**Vue-6**	**Vue-7**	**Vue-8**
MAIN	PA	LATERAL	OBLIQUE	DOIGTS	–	–	–	–
POIGNET	PA	LATERAL	OBLIQUE	–	–	–	–	–
AVANT BRAS	PA	LATERAL	OBLIQUE	–	–	–	–	–
COUDE	PA	LATERAL	AXIAL	–	–	–	–	–
PIED	PA	LATERAL	OBLIQUE	ORTEILS	–	–	–	–
CHEVILLE	PA	LATERAL	OBLIQUE	–	–	–	–	–
TIBIA	PA	LATERAL	OBLIQUE	–	–	–	–	–
GENOU	PA	LATERAL	AXIAL	–	–	–	–	–

SUB-MENU SPECIAL - CONTRASTE	VUES ANATOMIQUES							
	Vue-1	**Vue-2**	**Vue-3**	**Vue-4**	**Vue-5**	**Vue-6**	**Vue-7**	**Vue-8**
CONTRASTE	VESICULE BILIAIRE	ESTOMAC AP	ESTOMAC LATERAL	COLON	CONTRASTE AIR	IVP	OESOPHAGE 40"	OESOPHAGE 72"

Table 3-1 (cont.)
APR Matrix (German)

APR MATRIZE	ANATOMISCHE SICHT							
	Sicht-1	**Sicht-2**	**Sicht-3**	**Sicht-4**	**Sicht-5**	**Sicht-6**	**Sicht-7**	**Sicht-8**
SCHÄEDEL	AP / PA	SEITLICH	TOWNES	MASTOID	MASTOID SEITLICH	CONDYLUS	SELLA AP	SELLA SEITLICH
GESICHT	AP / PA	SEITLICH	WATERS	JOCHBEIN	OPT-ÏFFN	UKIEFERS	STENVERS	LAW'S
OBERER RUMPF	ZERVIKAL AP	ZERVIKAL SEITLICH	BWS AP	BWS SEITLICH	BWS DORSAL	SCAPULA SEITLICH	SCHULTER	SCHLOSBN
UNTERER RUMPF	LENDEM AP	LENDEM-SEITLICH	BECKEN AP	SAKRUM AP	SAKRUM SEITLICH	ABDOMEN AP	ABDOMEN SEITLICH	BECKEN MASS
BRUST	AP / PA	SEITLICH	60" KAR	UNTERER RIPPEN	OBERER RIPPEN	STERNUM	STERNUM SEITLICH	LORDOTIC
EXTREMITÄTEN BUCKY	HUEFTE AP	HUEFTE OB	SCHENKEL	KNIE AP	KNIE SEITLICH	KNIE AXIAL	OBERARM-BEIN	OBERARM-BEIN TRANS-BRUST
EXTREMITÄTEN OBERTISCH	HAND	HAND-GELENK	UNTERARM	ELLBOGEN	FUSS	KHÏCHEL	TIBIA	KNIE
SPEZIAL	TOMO	HILFS	WECHSL 1	WECHSL 2	BENUTZ-1	BENUTZ-2	BENUTZ-3	KONTRAST

UNTER-SPEISEKARTE EXTREMITÄTEN OBERTISCH	ANATOMISCHE SICHT							
	Sicht-1	**Sicht-2**	**Sicht-3**	**Sicht-4**	**Sicht-5**	**Sicht-6**	**Sicht-7**	**Sicht-8**
HAND	PA	SEITLICH	SCHEIF	FINGER	–	–	–	–
HANDGELENK	PA	SEITLICH	SCHEIF	–	–	–	–	–
UNTERARM	PA	SEITLICH	SCHEIF	–	–	–	–	–
ELLBOGEN	PA	SEITLICH	AXIAL	–	–	–	–	–
FUSS	PA	SEITLICH	OBLIQUE	ZEHE	–	–	–	–
KHÏCHEL	PA	SEITLICH	SCHEIF	–	–	–	–	–
TIBIA	PA	SEITLICH	SCHEIF	–	–	–	–	–
KNIE	PA	SEITLICH	AXIAL	–	–	–	–	–

UNTER-SPEISEKARTE SPEZIAL - KONTRAST	ANATOMISCHE SICHT							
	Sicht-1	**Sicht-2**	**Sicht-3**	**Sicht-4**	**Sicht-5**	**Sicht-6**	**Sicht-7**	**Sicht-8**
KONTRAST	GALLEN BLASE	MAGEN AP	MAGEN SEITLICH	KOLON	LUFTKON-TRASTE	IVP	SPEIROH 40"	SPEIROH 72"

Table 3-1 (cont.)
APR Matrix (Russian)

МАТРИЦА ПЗR	АНАТОМИЧЕСКИЕ ВИДЫ							
	ВИД-1	ВИД-2	ВИД-3	ВИД-4	ВИД-5	ВИД-6	ВИД-7	ВИД-8
ЧЕРЕП	ПЗ/ЗП	БОК	ОСН	СОС ОТР	СОС ОТР БОК	ВНЧС	СЕДЛО ПЗ	СЕДЛО БОК
ЛИЦЕВОЙ	ПЗ/ЗП	БОК	СЛЮН	СКУЛ ДУГ	ЗРИТ КАН	НЧ БК	СТЕНВЕРС	ЛОУС
ВХ.Ч.ТУЛ	ШОП ПРЯМ	ШОП БК	ПОП ПРЯМ	ПОП БК	ПОП КОС	ЛОПАТ. БК	ПЛЕЧО	КЛЮЧИЦА
НЖ.Ч.ТУЛ	ПОЖ ПР	ПОЖ БК	ТАЗ ПР	КРЕСТ. ПР	КРЕСТ. БК	ЖИВОТ ПР	ЖИВОТ БК	ПЕЛЬВ.
ГРУДЬ	ПЗ/ЗП	БОК	КОСОЙ 60º	ВЕРХ РЕБ	НИЖ РЕБ	ГРУДИНА	ГРУД БК	ЛОРТОДИЧ
СУПЕР РАСТР	ТАЗ БК	ТАЗ ПЕР	БЕДРО	КОЛЕНО П	КОЛЕНО Б	КОЛЕНО К	ПЛЕЧ СУС	Т-Т ПЛЕЧ
СУПЕР СТОЛ	РУКА	ЛУЧЕЗАП	ПРЕДПЛЕЧ	ЛОК СУС	СТОПА	ГОЛЕНОСТ	ГОЛЕНЬ	КОЛЕНО
ДОП	ТОМО	ДОП	ПРЕОБР 1	ПРЕОБР 2	ПОЛЬЗ-1	ПОЛЬЗ-2	ПОЛЬЗ-3	КОНТРАСТ

МАТРИЦА СУПЕР СТОЛ	АНАТОМИЧЕСКИЕ ВИДЫ							
	ВИД-1	ВИД-2	ВИД-3	ВИД-4	ВИД-5	ВИД-6	ВИД-7	ВИД-8
СУПЕР СТОЛ	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	ПАЛЬЦЫ	-	-	-	-
ЛУЧЕЗАП	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	-	-	-	-	-
ПРЕДПЛЕЧ	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	-	-	-	-	-
ЛОК СУС	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	-	-	-	-	-
СТОПА	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	ПАЛЬЦЫ	-	-	-	-
ГОЛЕНОСТ	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	-	-	-	-	-
ГОЛЕНЬ	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	-	-	-	-	-
КОЛЕНО	ПРЯМОЙ	БОКОВОЙ	КОСОЙ	-	-	-	-	-

МАТРИЦА КОНТРАСТ	АНАТОМИЧЕСКИЕ ВИДЫ							
	ВИД-1	ВИД-2	ВИД-3	ВИД-4	ВИД-5	ВИД-6	ВИД-7	ВИД-8
КОНТРАСТ	желч.пуз	желуд.пз	желуд.бк	толст.кш	возд.кнт	ввп	п-вод 40	п-вод 72

APR TECHNIQUE CHANGES

The APR techniques are factory pre-programmed to standard technique sets. All parameters of the APR techniques may be manually modified by the operator and stored in the non-volatile memory for later use.

If the operator determines that some factors in an APR technique should be re-programmed, use the following procedure:

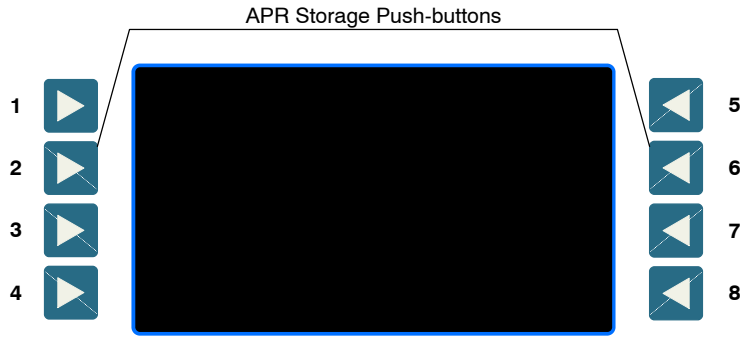
1. Select an APR technique and modify the factors and selections of Workstations or AEC which require to be re-programmed.
2. Verify that all factors of the technique are at the required values.
3. Simultaneously press the push-buttons 2–6 of the APR Display to store the new technique. (*Refer to Illustration 3-2*.)

   The newly selected technique is now stored in memory and can be recalled for future examinations.

Note ☞ *This procedure only changes the technique values of the selected Patient Size, repeat the procedure for other Patient Sizes.*

Note ☞ *If an APR technique is to be stored with AEC parameters, a suitable back-up Time (or mAs) MUST be stored by the operator for this APR technique.*

Illustration 3-2
APR Storage Push-buttons



3.4 EXPOSURE CONTROLS AND INDICATORS

Radiographic exposures from the Control Console are made with the "*Prep*" (preparation) and "*Expose*" (X-ray exposure) push-buttons or with the Handswitch. The status of the exposure is indicated by the "*Ready*" and "*X-ray On*" indicators for the duration of the exposure.

Tomographic exposures controlled from the Generator are performed with the exposure controls at the Console or with the Handswitch.

PREP: Press the *"Prep"* push-button to prepare the selected X-ray Tube for exposure. The *"Ready"* indicator on the Console will light when the X-ray Tube is prepared and there are no interlock failure or system faults.

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

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

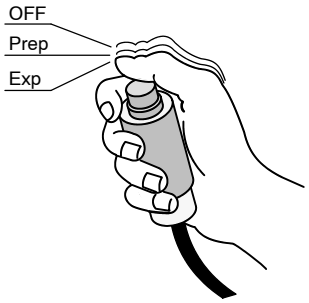
EXP: After the "*Ready*" indicator is illuminated, press this push-button to start a X-ray exposure. If the push-button is released before the Generator completes the selected time or the AEC time, the exposure will be prematurely terminated and the actual mAs and Exposure Time will be displayed.

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

READY: Indicates that the technique selected is properly set, there are no interlock failures or system faults, the anode is rotating and the X-ray Tube is ready for exposure.

X-RAY ON: Indicates that the X-ray exposure is in progress. At the same time that radiographic exposures are being made, an audible signal sounds.

3.5 X-RAY HANDSWITCH



Radiographic exposures can also be initiated with the X-ray Handswitch which is connected to the Control Console.

The X-ray Handswitch button has three positions: "*Off*", "*Preparation*", and *"X-ray Exposure"*, which operate in the same way that "*Prep*" and "*Exp*" push-buttons on the Control Console.

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

3.6 HEAT UNITS

This X-ray Generator is equipped with a Heat Unit Calculator. During exposures, the Heat Units are calculated and totalled.

To view the remaining Heat Units, press the "*On*" push-button. The kVp Display shows the percentage of Heat Units that remain preceded by the letter "H". For example, a display of "H75" would indicate that 75% of Heat Units capacity of the X-ray Tube remains. "H - - " indicates that all the capacity remains. The kVp Display reverts to its normal function after releasing the "*On*" push-button.

3.7 EXPOSURE COUNTERS

The operator can read the number of exposures made by the Generator, as indicated below:

RAD EXPOSURES IN TUBE-1	Press and hold  and press once 
RAD EXPOSURES IN TUBE-2	Press and hold  and press once 

The number of exposures is shown on the kVp and mAs Displays, up to a maximum of 999,999 exposures.

kV **mAs**

= 123.456 exposures

3.8 SELF-DIAGNOSIS INDICATORS

Self-Diagnosis indicators identify a malfunction in the system alerting operator about error existence that inhibits exposure. During normal operation of the system, these indicators are directly shown on the APR Display or as an error code on the kV Display. (*Also refer to Section 3.9*).

DOOR

DOOR OPEN: Indicates the X-ray room door is open when the X-ray equipment is in use.

G.OVL

GENERATOR OVERLOAD: Indicates that the exposure has been interrupted because during exposure has been produced arcing or bad function on the HV circuitry (X-ray Tube, HV Transformer and/or HV Cables) or a failure of IGBT module (overheated or defective IGBTs) has been detected.

It can be also shown making a high power and long exposure with the X-ray Tube cool (X-ray Tube has not been warmed-up).

T.OVL

TUBE OVERLOAD: Indicates that either the technique selected is beyond the X-ray Tube ratings or the present conditions of the X-ray Tube inhibit the exposure (anode overheated). Parameters for next exposure may be temporally limited by the Generator (change the exposure values or wait for the X-ray Tube to cool).

Check that heat units available are lower than the calculated for the next exposure (heat units close to zero). Reduce exposure factors or wait for the X-ray Tube to cool. *(To display the Heat Units refer to Section 3.6).*

ROTOR

ROTOR ERROR: Indicates that the X-ray Tube anode is not rotating while "*Prep*" is active, then exposures are inhibited.

HEAT

HEAT: Indicates that the X-ray Tube thermostat / pressurestat is open due to overheating of the Tube housing (housing is too hot, wait for the housing to cool) or to a thermostat / pressurestat mal-function (housing is cool). Heat units may raise to any value.

TECH

TECHNIQUE ERROR: If activates during exposure it means that:

The exposure has been interrupted by "Security Timer" because of a failure in the system. Call Field Service.

This error can also be shown:

- after an APR technique selection to advise that exposure parameters displayed on the Console are not the values stored for this APR technique. Exposure parameters are adapted by the Generator to another enable values.
- if a failure on the Automatic Collimator has been detected (blades are full open or in movement during exposure, etc.). In this case the indicator lights continuously.

3.9 ERROR CODES

Error codes indicate the potential cause of a system failure. Error codes are shown on the kVp Display at the same time an audio signal is emitted. Correct the error cause and keep pressed the "*AEC Reset*" push-button till the Console indication disappears. *(Refer to Table 3-2).*

All these error codes are preceded by the letter "E" (i.e., E01) 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 on site.

Table 3-2
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
- - - - - - on Display	System failure. This indication may appear together with an error on the Console, and indicates that the error is not correctable unless the equipment is turned OFF.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E01, E02	Communication error.	Turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E03	System failure.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E04	The Power Cabinet has activated "*Preparation*" without a Console command intervention.	
E05	External exposure activated during power-up.	Release any external exposure device or push-buttons. Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E06	"*Exposure*" or/and "*Preparation*" orders are activated during power-up.	Release all the controls. Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E07, E08	X-ray Tube configuration error.	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E09	Generator Overload error. The exposure has been interrupted because during exposure has been produced arcing or bad function on the HV circuitry (X-ray Tube, HV Transformer and/or HV Cables) or a failure of IGBT module (overheated or defective IGBTs) has been detected. It can be also shown making a high power and long exposure with the X-ray tube cool (X-ray Tube has not been warmed-up).	This error does not require to press the "*AEC Reset*" push-button, its indication disappears automatically. If the error code persists, turn the Generator OFF and wait 30 minutes before turning it ON again. If the equipment remains inoperative, turn it OFF and call Field Service.
E10, E11	System failure.	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E12	No mA during exposure or mA value is out of range.	Press the "*AEC Reset*" push-button. Repeat with same technique values, If the error code persists try with another combinations of kV and mA values. If the equipment remains inoperative, turn it OFF and call Field Service.
E13	No kV during exposure or kV value is out of range.	
E14, E15	System failure.	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON again. If the equipment remains inoperative, turn it OFF and call Field Service.
E16	Invalid value of: kV, mA or kW.	Decrease kV, mA or both. Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E17	Communication error or system failure.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E18	Rotor error. The X-ray tube anode is not rotating while "*Prep*" is active, then exposures are inhibited, or the X-ray tube anode is rotating without console command.	This error does not require to press the "*AEC Reset*" push-button, its indication disappears automatically. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E19, E20	System failure.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E21, E22	Incorrect selection of the X-ray Tube.	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E23	System failure.	
E24	Bucky not ready for an exposure.	

Table 3-2 (cont.)
Error Codes

ERROR	DESCRIPTION	WHAT TO DO
E25	Battery Fault. The batteries charge level is momentarily low, or some batteries are discharged or damaged. *(Only in Generators working with batteries).*	Press the "*AEC Reset*" push-button. Wait 5 minutes before making a new exposure. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E26, E27	System failure.	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E33	Serial Communication error.	Press the "*AEC Reset*" push-button. Check that communication cable between Generator and console is properly connected. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E34	Technique error. If it activates during exposure it means that the exposure has been interrupted by the "*Security Timer*" because of a system failure. Call Field Service. This error can also be shown: – after an APR technique selection to advise that exposure parameters displayed on the console are not the values stored for this APR technique. Exposure parameters are adapted by the Generator to another enable values. – after the "ABC" push-button selection, when ABC is not enable.	These errors do not require to press the "*AEC Reset*" push-button, theirs indications disappear automatically. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E35	Door Open error. The X-ray room door is open when the X-ray equipment is in use.	
E36	Heat Units error. The X-ray Tube thermostat / pressurestat is open due to the tube housing is overheated (housing is too hot, wait for the housing to cool) or a thermostat / pressurestat mal-function (housing is cool). Heat units may raise to any value.	
E37	Tube Overload error. The technique selected is beyond the X-ray tube ratings or present conditions of the X-ray tube inhibit the exposure (anode overheated). Parameters for next exposure may be temporally limited by the Generator (change the exposure values or wait for the X-ray tube to cool). Check that heat units available are lower than the calculated for the next exposure (heat units close to zero). Reduce exposure factors or wait for the X-ray tube to cool.	
E41 to E46	System failure related to Dosimeter.	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E47	Capacitors are not charged when "*Prep*" control is activated. The exposure is inhibited until the Capacitors are charged.	Press the "*AEC Reset*" push-button. Wait one minute for Capacitor charging before activating "*Prep*" control. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E48	Collimator Error. A failure on the Automatic Collimator has been detected (blades are full open or in movement during exposure, etc.)	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E50	Exposure has been aborted by the Operator.	
E51 to E93	System failure related to High Speed Rotor Controller.	
E95	Exposure aborted by the AEC Rapid Termination.	Press the "*AEC Reset*" push-button. Select the correct Ion Chamber or modify parameters. Repeat the exposure. If the equipment remains inoperative, turn it OFF and call Field Service.
E96, E97	System failure related to Capacitor charge (only for Capacitor Powered Generator).	Press the "*AEC Reset*" push-button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
E98	Service Mode Active.	Press the "*AEC Reset*" push-button and call Field Service. This error does not inhibit normal operation.

SECTION 4 OPERATING SEQUENCES

4.1 START-UP ROUTINE

System power is applied by pressing the "*Power On*" push-button on the Control Console. The Generator will go through a start-up routine conducting an automatic self-test that will show on the RAD kV Display information usable only by service personnel.

After the power-up has been completed the Console should display normal radiographic factors. If there is a malfunction, error messages will be displayed on the RAD kV Display specifying the fault.

Note ☞ *Some indicators on the Console 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.*

4.2 X-RAY TUBE WARM-UP PROCEDURE

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

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

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

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

Perform X-ray Tube warm-up as follows:

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

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

4.3 RADIOGRAPHIC OPERATION

RAD operation can be performed in the following modes:

- Three point control by selecting kVp, mA and Exposure Time independently.
- Two point control by selecting kVp and mAs independently. mAs selection sets the maximum mA available for the selected Focal Spot and the respective Exposure Time. In this control mode, when kVp value is increased, the Generator will automatically look for the adequate combination of mA and Exposure Time factors to avoid the "*Tube Overload*" warning, keeping constant mAs.
- One point control by selecting kVp with AEC operations.
- Anatomical Programs (APR).

A typical RAD examination sequence is as indicated below:

1. Make sure that the X-ray Tube to be used is properly warmed-up.
2. Position the patient for the examination.
3. Select the "*workstation*", and technique parameters using the RAD controls on the Console.
4. Instruct patient to maintain the required position. Prepare the X-ray Tube by pressing the handswitch push-button to the "*Prep*" position and maintain it until the "*Ready*" indicator is illuminated.
5. Instruct patient to remain still and to hold his breath as required, then make the X-ray exposure by pressing the handswitch push-button fully to the "*Exp*" position and maintain it throughout the exposure. The "*X-ray On*" indicator will light and an audible signal will sound during the exposure.
6. When the exposure is finished, release the handswitch push-button.
7. Repeat the procedure if additional exposures are desired.

4.4 AEC OPERATION

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

1. Make sure that the X-ray Tube to be used is properly warmed-up.
2. Position the patient for the examination.
3. Select the "*workstation*" and enter in AEC mode by selecting at least one Area Detector "*Field*" on the Console.
4. If required, choose another "*Film Screen Combination*" and adjust the "*Film Density*" setting ("*0*" is the normal setting).
5. Select the technique parameters (back-up time / mAs) using the RAD controls on the Console.
6. Continue with the radiographic operation. *(Refer to Section 4.3 – step 4.)*

4.4.1 HOW TO VERIFY THE PROPER FUNCTIONING OF THE AUTOMATIC EXPOSURE CONTROL

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

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

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

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

   Make a RAD exposure and note the exposure mAs and time. For a proper functioning of the AEC, the exposure must not be aborted by the AEC back-up timer, that is, the “*AEC Reset*” push-button is not flashing.
10. The noted Exposure mAs and time have to be equal ±10% between all three Ion Chambers. If not, contact Service.

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

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

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

    The exposure must be finished by the AEC back-up timer, that is, the exposure length is 1.0 second and the "*AEC Reset*" Push-button is flashing. If not, contact Service.

4.5 APR OPERATION

An examination using an APR technique could consist of the following:

1. Make sure that the X-ray Tube to be used is properly warmed-up.
2. Position the patient for the examination.
3. Select the "*Patient Size*" corresponding to the patients anatomy. This operation starts the APR mode. Select the "*Pediatric*" push-button if the patient is not an adult.
4. Select a general "*Body Region*" and an "*Anatomical View*" of the indicated on the APR Display.
5. Technique parameters, Workstation information, Focal Spot, AEC, etc... corresponding to the APR selection are displayed and indicated on the Control Console. If needed, the parameters and selections can be directly modified by the operator.
6. Continue with the normal procedure for a typical RAD examination. (*Refer to Section 4.3 - step 4.*)

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SECTION 5 PERIODIC MAINTENANCE

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

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

The first periodic maintenance service should be performed six (6) months after installation, and the subsequent services at twelve (12) month intervals.

The manufacturer undertakes the responsibility to have available spare parts for this equipment for at least ten (10) years from the date of manufacturing.

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

5.1 OPERATOR TASKS

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

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

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

1. Switch the Generator OFF.
2. Externally, check the proper cable connections between each major component in the X-ray system (Power Cabinet, Consoles, etc ...).
3. Clean the equipment frequently, particularly if corroding chemicals are present. Clean external covers and surfaces, specially parts in contact with the patient, with a cloth moistened in warm water with mild soap. Wipe with a cloth moistened in clean water. Do not use cleaners or solvents of any kind.

5.2 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 6 TECHNICAL SPECIFICATIONS

Note ☞ *Technical specifications indicated in this Section apply to the Line Powered Generators. In case of Battery Powered Generators or Capacitor Assisted Generators some specifications can be different, refer to the corresponding documents (AP-0002Rx for Battery Powered Generators or AP-0017Rx for Capacitor Assisted Generators) provided with the equipment.*

6.1 FACTORS

FACTORS	GENERATOR MODEL *(Refer to Identification Label)*			
	SHF-310 SHF-320 SHF-330	**SHF-315 SHF-325 SHF-335**	**SHF-410 SHF-420 SHF-430**	**SHF-415 SHF-425 SHF-435**
Maximum Power kW	32 kW		40 kW	
Maximum mA	400 mA		500 mA	
Maximum kVp	125 kVp	150 kVp	125 kVp	150 kVp
Power Output (@ 0.1 s)	400 mA @ 80 kVp 320 mA @ 100 kVp 250 mA @ 125 kVp	400 mA @ 80 kVp 320 mA @ 100 kVp 250 mA @ 128 kVp 200 mA @ 150 kVp	500 mA @ 80 kVp 400 mA @ 100 kVp 320 mA @ 125 kVp	500 mA @ 80 kVp 400 mA @ 100 kVp 320 mA @ 125 kVp 250 mA @ 150 kVp

FACTORS	GENERATOR MODEL *(Refer to Identification Label)*				
	SHF-510 SHF-520 SHF-530	**SHF-515 SHF-525 SHF-535**	**SHF-610 SHF-620 SHF-630**	**SHF-615 SHF-625 SHF-635**	**SHF-835**
Maximum Power kW	50 kW		64 kW		80 kW
Maximum mA	640 mA		640 mA		800 mA
Maximum kVp	125 kVp	150 kVp	125 kVp	150 kVp	150 kVp
Power Output (@ 0.1 s)	640 mA @ 78 kVp 500 mA @ 100 kVp 400 mA @ 125 kVp	640 mA @ 78 kVp 500 mA @ 100 kVp 400 mA @ 125 kVp 320 mA @ 150 kVp	640 mA @ 100 kVp 500 mA @ 125 kVp	640 mA @ 100 kVp 500 mA @ 128 kVp 400 mA @ 150 kVp	800 mA @ 100 kVp 640 mA @ 125 kVp 500 mA @ 150 kVp

6.2 RANGE OF RADIOGRAPHIC PARAMETERS

PARAMETER	RANGE
kV	From 40 kV to 125 kV or 150 kV in 1 kV steps. *(Depending on the Generator model)*
mA	From 10 mA to 800 mA through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 200, 250, 320, 400, 500, 640, 800. *(Depending on the Generator model)*
mAs	Product of mA x Time values from 0.1 mAs to 500 mAs (*640 mAs on request*)
Exposure Time	From 1 millisecond to 10 seconds through the following Time stations: Milliseconds: 1, 2, 3, 4, 5, 6, 8, 10, 12, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 200, 250, 320, 400, 500, 640, 800. Seconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.4, 8, 10.
AEC	mAs: 0.1 mAs to 500 mAs
	Exposure Time: Nominal shortest irradiation Time = 1ms

6.3 DUTY CYCLE

The Generator duty cycle is continuous, but limits should be set during installation depending on the capacity of the X-ray Tube.

6.4 ENVIRONMENTAL REQUIREMENTS

Refer to the Pre-Installation Manual provided with the equipment.

6.5 POWER LINE REQUIREMENTS

Refer to the Pre-Installation Manual provided with the equipment.

6.6 PHYSICAL CHARACTERISTICS

COMPONENT	DIMENSIONS			WEIGHT
	Length	Width	Height	

LINE POWERED GENERATORS

Compact Generator Cabinet (for only 1 Tube (LSS))	445 mm	360 mm	568 mm	72 kg
Compact Generator Cabinet (for 1 or 2 Tubes (LSS or HSS))	592 mm	360 mm	690 mm	95 kg

CONTROL CONSOLE

RAD Console Graphic Display	with Handswitch support	545 mm	290 mm	50 mm	6 kg
	w/o Handswitch support	430 mm	290 mm	50 mm	6 kg

Refer to the Pre-Installation Manual provided with the equipment for more detailed information.

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APPENDIX A GUIDELINES FOR PEDIATRIC APPLICATIONS

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.

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.