Technical Publication
OM-0366R4

Operation

HF Series Generators

Generator Console for CXDI Control Software RF with Digital Remote Table

CE
0120

This product bears a CE marking in accordance with the provisions of the 93/42/EEC MDD dated June 14, 1993.

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.

Ce produit porte la marque CE de conformité aux réglements de la Directive 93/42/CEE du 14 juin 1993 relative aux Produits médicaux.

The information comprised in this manual applies to the following equipments La información contenida en este manual se aplica a los siguientes equipos L'information contenue dans ce manuel est appliquée aux équipements suivants
N 32 HF , N 40 HF , N 50 HF , N 65 HF, N 80 HF

Manufactured by:
Fabricado por:
Fabriqué par:

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REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	JUL 02, 2010	First edition.
1	MAY 31, 2011	New screenshoots.
2	JAN 20, 2012	Software Update.
3	FEB 18, 2013	Software and IEC Standards Update.
4	APR 04, 2014	Software 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 Console for CXDI Control Software RF.** It provides a general description, safety and regulatory information, operating instructions and specifications concerning the equipment. This manual is not intended to teach radiology or to make any type of clinical diagnosis.

This High Frequency X-ray Generator is designed for conventional or digital radiography and pulsed fluoroscopy. 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 image / 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 touching directly on the screen.

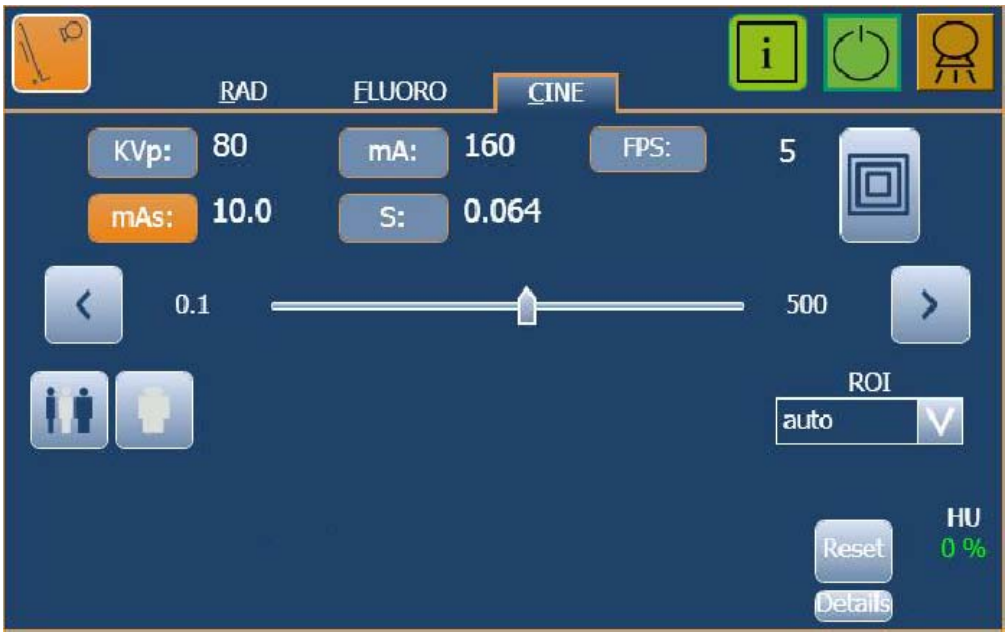
This type of Console can be used in a X-Ray System with a Remote Controlled Table.

Note ☞ *The screen backing color can be configured by the Service Technician during installation.*

Illustration 1-1
RAD Screen

Illustration 1-2
Fluoro Screen

Illustration 1-3
CINE Screen



The Generator consists of the following essential parts:

- *Touch Screen Control Console,* operator controls and displays for radiographic and fluoroscopic operations. The Console is designed for ease of operation. It is the interface with the Power Cabinet and other related X-ray devices.

- *Generator Cabinet,* that comprises:
  - *Power Module,* which contains the power and control components.
  - *High Voltage Transformer.*

1.1 GENERAL FEATURES

The main features of this Generator are:

- Constant potential high frequency.
- 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 minimizes potential errors and the need for readjustments.
- Automatic line 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.
- Independent memory for storing Radiographic, Cine or Fluoroscopic operating parameters. This permits rapid switching from one technique to another.
- 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 operation.
- *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.
- *Multirad*, multiple controlled exposures within the RAD application.

- *Fluoroscopic:*
  - *Pulsed Fluoro at variable rate.*
  - *Automatic Brightness System* (ABS).
  - *Quality Normal* or *Quality Detail.*
  - *High Dose* selection (optional).
- *Cine*, images in frames per second.
- *Region of Interest (ROI)* selection.
- *Second X-ray Tube,* which extends the system for two X-ray Tubes.
- *High Speed Rotor Controller,* an optional digital controller consisting of a module which is fitted within the Power Cabinet.

1.2 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.

1.3 INDICATIONS FOR USE

1.3.1 INTENDED USE

This equipment is intended for use by qualified personnel only.

The **High Frequency Generators with the Console for CXDI Control Software RF** are equipments designed for general radiography and/or fluoroscopy 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 shocked.

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

1.3.2 NORMAL USE

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

1.3.3 CONTRAINDICATIONS

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

This equipment is not intended for mammographic applications.

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
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

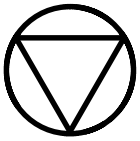
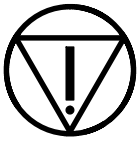
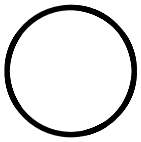
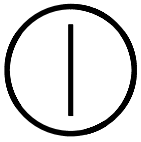
The following safety symbols may appear in the equipment.

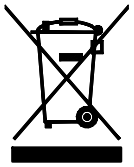
Their meaning are described below.

	**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)*

	**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 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: 2008.*

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.*

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 of the 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 .
- *Permanently Installed Equipment.*

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

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 and 2005.

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 and 2005.

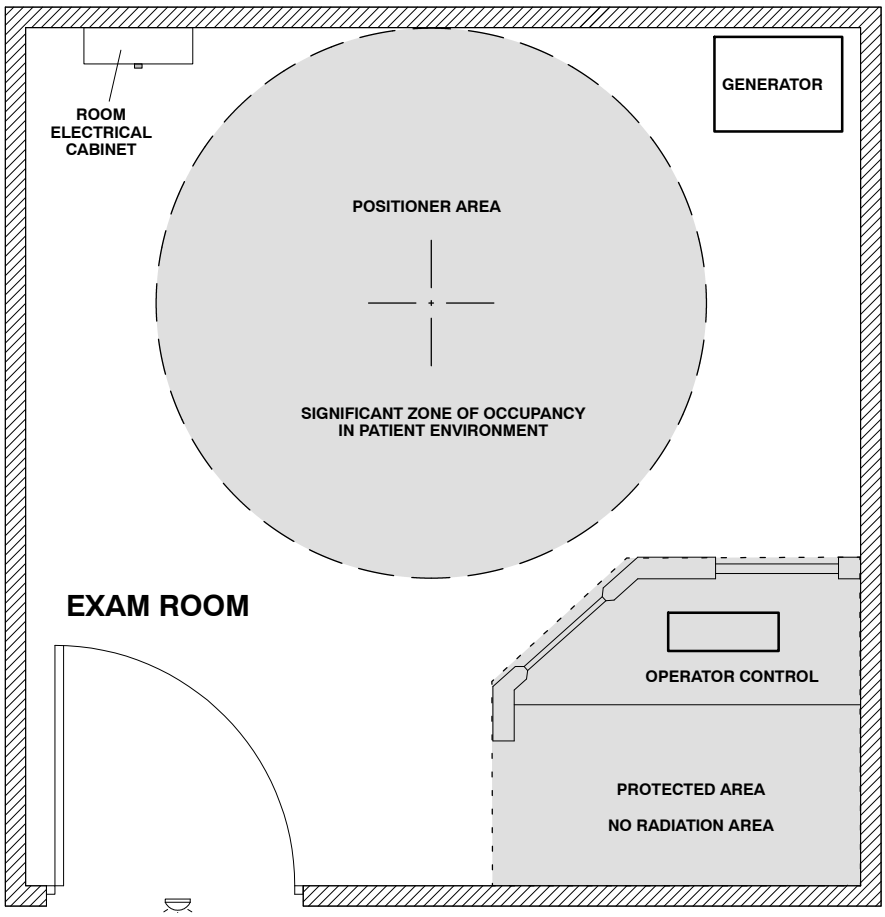
2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

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

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

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

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

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

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

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

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
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 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 uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE - U_T is the a.c. mains voltage prior to application of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
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 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 150kHz to 80MHz 3V/m 1 GHz to 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of this Mobile Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = \left[3.5/E_1\right]\sqrt{P}$, 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 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3 - In the 3rd equation of the 4th column, the constant parameter has a value of 2.3 for frequencies between1GHz and 2.5GHz No information is given for frequencies between 80 MHz and 1 GHz.

a) *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this X-Ray Generator is used exceeds the applicable RF compliance level above, this X-Ray Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this X-Ray Generator.*

b) *Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.*

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE X-RAY GENERATOR

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 3 - In the 3rd column for distances, the applicable range for frequencies is between 1GHz and 2.5 GHz.

SECTION 3 OPERATING CONTROLS

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

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

Controls in the Generator Console are described in this manual. For operation with controls of the CXDI application refer to the corresponding manuals.

3.1 GENERAL CONTROLS

3.1.1 SELECTION OF RAD / FLUORO / CINE

Touch on any of the different tabs to activate the corresponding mode.

Illustration 3-1
TABS for RAD/ FLUORO / CINE

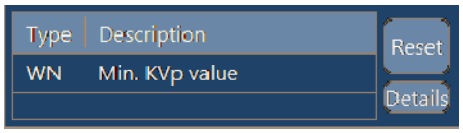
3.1.2 OPERATING STATUS

The "*Status*" icon can vary according to the operating status, as described below.

 GREEN	**Normal status.** Communication is correct and Generator is operative. This icon also appears with Informative messages.
 ORANGE	**System Warning.** WNC: It stays orange until "*Reset*" is pressed (a.e. No APR values defined for that technique). WN: It stays orange for a few seconds and then turns to Normal Status. (a.e. max kV value reached).
 RED	**Error.** A System failure or a Generator error / interlock is present.

Note ☞

Once the "Status" Icon is pressed, the Generator and System Messages (Error, Interlock, Warning and Informative) are shown in the information area, at the lower right corner of the Screen (For further information about Generator and System Messages refer to Section 4).



The *"Exposure"* icons indicate:

 GREEN	**Ready.** When highlighted, it indicates that the technique selected is properly set, there are no interlock failures nor system faults, the anode is rotating and the X-ray Tube is ready for exposure.
 YELLOW	**X-Ray On.** When highlighted, it indicates that the X-ray exposure is in progress. When radiographic exposures are performed, an audible signal sounds.

Note ☞

During Fluoro examinations only the "X-ray On" indicator is activated.

3.1.3 WORKSTATION SELECTION

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

The Workstations shown on the screen depend on the Console version.

The workstations are automatically selected from the CXDI application. The operator can only change the workstation when an Exam is closed.

Write down the configuration of the Workstation assigned to each button in the table.

BUTTON	ICON	WORKSTATION (Detector type, Tube, Device, Ion Chamber, etc.)
1		
2		
3		
4		
5		
6		
Note.- Workstation data such as Icon, X-ray Tube, Bucky, Tomo, Fluoro, DSI, Ion Chambers, etc... must be registered.		

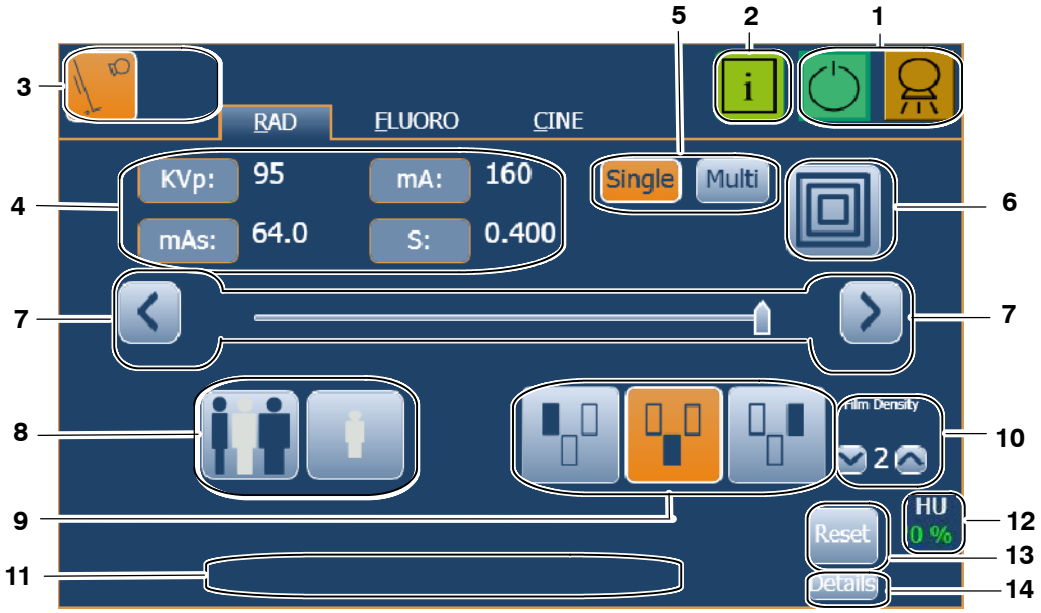
3.1.4 HEAT UNITS

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

The "*HU*" DIsplay shows the percentage of utilized thermal capacity of the Tube. For example, "*25*%" would indicate that 25% of Heat Units capacity is used (although it can be configured by the service engineer to display the remaining thermal capacity instead of the utilized thermal capacity).

3.2 RADIOGRAPHY (RAD)

3.2.1 RADIOGRAPHIC PARAMETERS



1. X-Ray status
2. Information
3. Workstations
4. Radiographic Values
5. Type of exam: Single or MultiRad
6. Focal Spot
7. Parameter Selectors
8. Patient Size (APR)
9. Field selection (AEC)
10. Density (AEC)
11. Error / Information Area
12. Heat Units
13. Reset Error
14. Error Log List (Details)

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

kVp DISPLAY shows the radiographic kVp value selected for the technique.

mA DISPLAY shows the radiographic mA value selected for the technique.

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*" button has not been released.

Time DISPLAY can show:

- The Time value (in seconds) selected for the 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*" button has not been released.

RAD Displays can also show:

- the values (blinking) of the actual Time, the calculated mAs, and the selected kVp and mA radiographic parameters of the last exposure, after touching the "*Reset*" button.
- If an exposure is aborted by releasing the exposure control during the exposure, the Display shows the actual mAs and Time values, the messages "*Last Exposure Parameters*" and "*Error 50: Interrupted Exposure*", until the *"Reset"* button is touched to reset the error condition.

Note ☞ *Single and Multi buttons appear only when the APR selected in the CXDI application allows MultiRad Exposures.*

SINGLE: One RAD exposure.

MULTI: Multi consists of a sequence of RAD exposures at the frame rate (*FPS - Frames per Second*) selected on the Digital Imaging System or Console. Multi is only available in specific studies from the CXDI application.

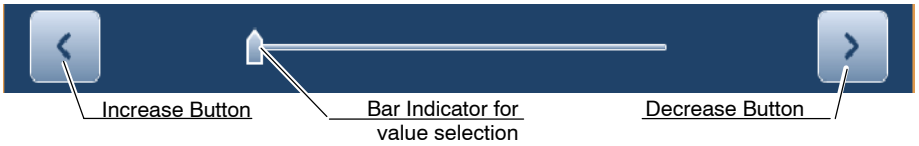
The **FPS** selection can be 0.25, 0.33, 0.50, 1, 2, 4, 5, 7.5, 10, 15, 20, or 30 exposures per second with a pulse width of each exposure defined by the time selected on the Console or by the AEC if activated (in this case, if the exposure is finalized by the backup time, a warning is displayed on the console but the exposure sequence is not aborted).

The **FPS** selection depends on the Magnification set on the Digital Imaging System and the time selected on the Console.

INCREASE / **DECREASE:** Radiographic technique values are increased or decreased by selecting the respective RAD Display (which will be highlighted) and changing the value with the "*Increase*" or "*Decrease*" buttons.

The values increase or decrease step-by-step each time the corresponding button is touched, and change faster when either of them is touched continuously.

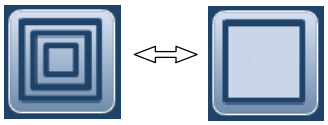
Also, the value can be directly selected by clicking on its position on the bar. When this indicator is positioned over a value not allowed, it goes back to the maximum position allowed by the present conditions of the Generator.



(*Refer to Section 5.3 for Radiographic operating modes and refer to Section 7 for Factor ranges*)

- **kVp**: Selects the X-ray Tube voltage.
- **mA**: Selects the X-ray Tube current. The Focal Spot selection can be changed when the mA value is selected with the "*Increase*" or "*Decrease*" buttons. The slider of the bar can only set the mA values of the selected Focal Spot.
- **mAs**: Selects the exposure in mAs.
- **s**: Selects the exposure Time in seconds. The maximum Time can be limited by the Detector specifications.
- **Multi – FPS**: Selects the frame rate of a sequence of RAD exposures.

3.2.2 FOCAL SPOT INDICATOR



A Focal Spot indicator shows the selected Focal Spot of the X-ray Tube: "*Small*" or "*Large*".

The Focal Spot is changed by touching this indicator. It keeps constant kVp and mAs, whenever possible. The mA value available is set according to maximum power, instantaneous power, space charge, etc.

When a Focal Spot is selected, it sets the highest mA value available for the selected Focal Spot and the respective Exposure Time in order to keep constant mAs. If the highest mA value available coincides with the maximum mA station of the Generator, it sets one mA station below of the maximum mA station of the Generator.

Note ☞

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

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

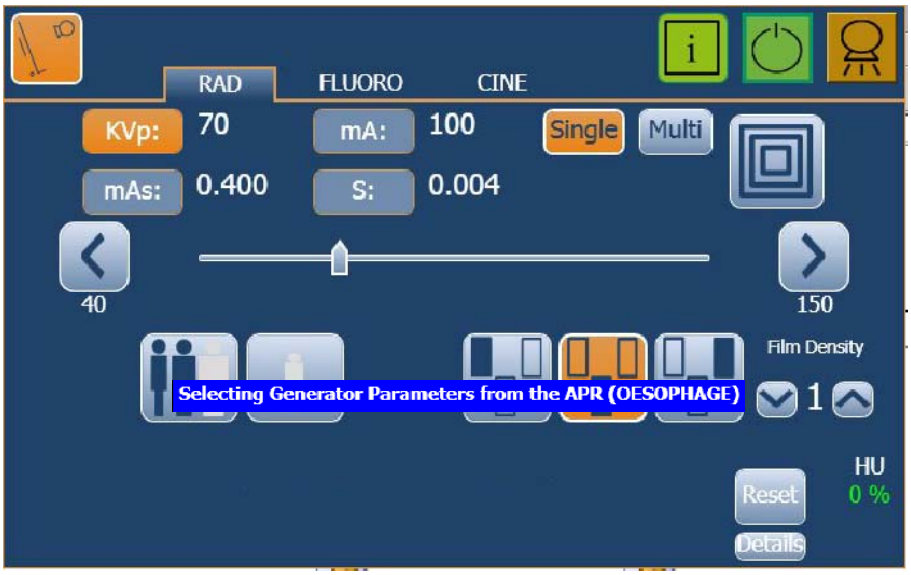
3.2.3 PATIENT SIZE

Patient Size is always activated with one of the three Patient Size (small, medium or large size) icons selected. When an APR technique is chosen in the CXDI application, the medium patient size is selected by default.

The left-hand button containing three human bodies selects Small, Medium and Large adult sizes (only one selected each time the button is touched). The right-hand "*Pediatric*" button changes the function of the left-hand button from Adult to Pediatric patient size when it is highlighted. (In this mode, the "*Pediatric*" button and one of the other three human bodies are selected at the same time).

Six patient sizes are available: three for Adult and three for Pediatric.

(*Refer to the CXDI application for APR selection*).



Label indicating that the selection is in progress is displayed along with the Study Name

3.2.4 AUTOMATIC EXPOSURE CONTROL (AEC)

Automatic Exposure Control (AEC) produces consistent 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), Density Compensation and AEC Reset.

The AEC mode is activated by touching any of the three AEC Field buttons. The AEC mode is deactivated by touching all the selected AEC Field buttons until none of them is selected.

Double check the backup time when using manually the AEC.

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 button indicates its related physical location of the selected field in the AEC Exposure Detector, and it may be selected or deselected by touching it. Any combination of fields can be selected and the color of buttons changes (highlighted) when active.

DENSITY: These buttons are used to adjust the radiographic Density. The selected value is shown on the Density Display. Normal Density is 0 (default value) and the Density range is from –4 to 4.

Density can be increased or decreased in several 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 12.5%). The Density value can be modified only when at least one AEC Field is selected.

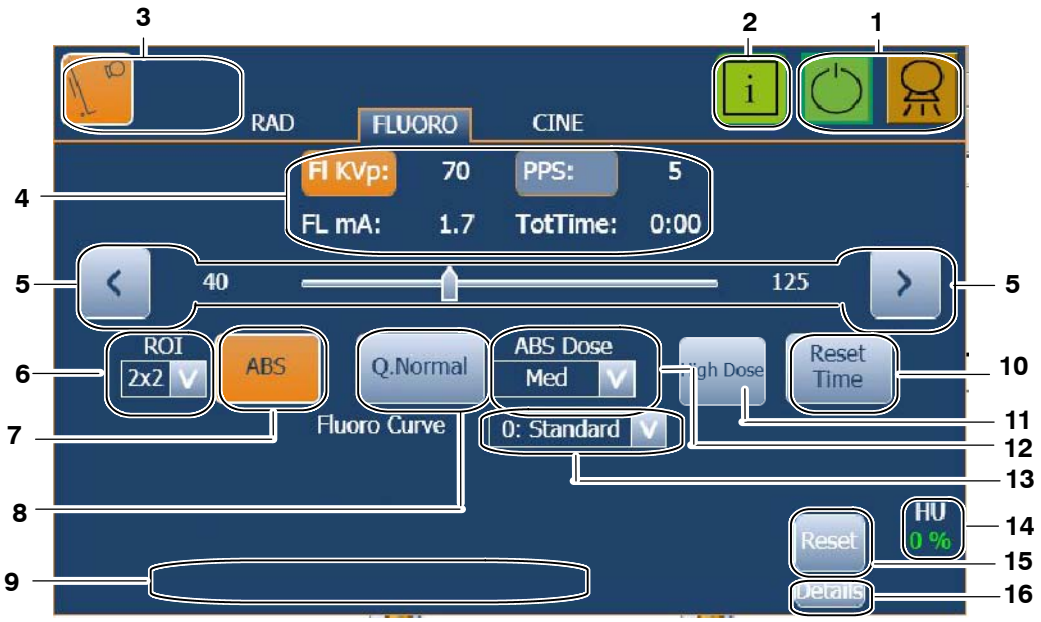
RESET: If the exposure is aborted by the AEC back-up timer, the "*Reset*" button blinks accompanied by an audible alarm and the message "*Not Enough Dose*" is shown on the Console. Next exposure is inhibited until the AEC function is reset by touching the *"Reset"* button. When the Generator is in "*Prep"* mode, the AEC function can not be reset.

Before the exposure, if the message "*Wrong AEC Selection*" is shown on the Console, it means that the selected kVp value, AEC Density and/or Film/Screen Combination set a technique that is out of the operative range with AEC and the next exposure will be inhibited. Change any parameter (kVp value, AEC Density) in order to obtain a technique enabled for AEC.

3.3 FLUOROSCOPY (FLUORO)

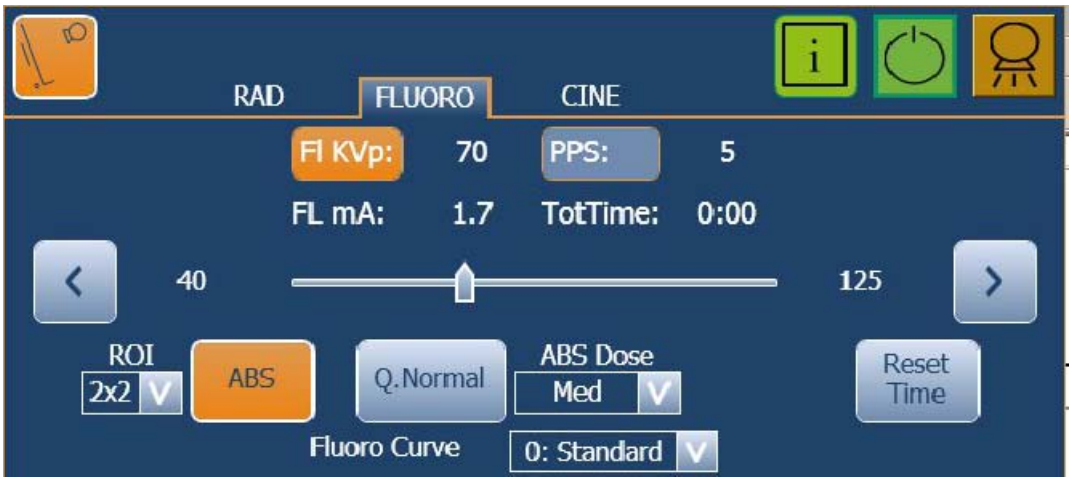
This Generator can operate in different modes:

- Pulsed Fluoro at variable rate.
- Manual or Automatic Brightness System (ABS) with High Dose.
- Quality Normal / Quality Detail with ABS Doses (Low Low, Low, Medium, High) and Fluoro Curves (0: Standard, 1: Barium, 2: Iodine, 3: Low kV).



1. X-Ray status
2. Information
3. Workstations
4. Fluoroscopic Values
5. Parameter Selector
6. ROI (Region of Interest)
7. ABS
8. Quality Normal / Quality Detail
9. Error / Information Area
10. Reset Time
11 High Dose
12 ABS Dose
13. Fluoro Curve
14. Heat Units
15. Reset Error
16. Error log list

FLUOROSCOPIC DISPLAYS: Show the values for kVp, mA, PPS, and Fluoro accumulated time of the Fluoro exam.



FLUORO kVp INCREASE / DECREASE: Selects the X-ray Tube voltage in Manual mode (no ABS mode). Fluoro kVp value is increased or decreased by selecting the "*Fluoro kVp*" Display (which will be highlighted) and changing the value with the "*Increase*" or "*Decrease*" buttons.

Fluoro kVp value increases or decreases step-by-step each time the corresponding button is touched, and changes faster when either of them is touched continuously.

Except during Fluoro examinations, the Fluoro kVp value can be directly selected by clicking on its position on the bar. When this indicator is positioned over a value not allowed, it comes back to the previous position and the parameter value does not change.

(*Refer to Section 7 for Factor ranges*)

Note ☞

*The **Fluoro mA** values are tied up with the Fluoro kVp values (when the Fluoro kVp increases, the Fluoro mA increases). Fluoroscopic mA are set during calibration so they do not exceed the maximum Entrance Skin Exposure (ESE) dose rate on the patient.*

During a Fluoro exposure:

- The "*X-ray On*" indicator of the Console is activated.
- The RAD Displays show the selected parameters for a Radiographic exposure with that same Tube. Radiographic parameters can be modified without cutting the Fluoro exam.

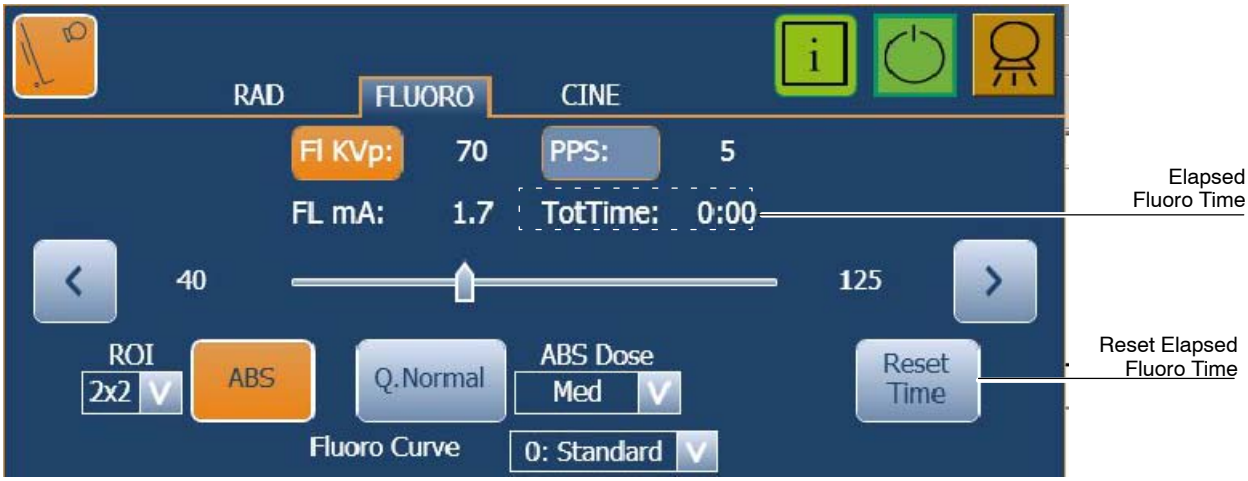
PULSES PER SECOND SELECTION: This control is used to select the Pulses per Second for X-ray exposure synchronization in Digital Fluoroscopy. PPS value is increased or decreased by selecting the "*PPS*" Display (which will be highlighted) and changing the value with the "*Increase*" or "*Decrease*" buttons or with the Bar Indicator.

The **PPS** selection can be 1, 2, 4, 5, 7.5, 10, 15, 20, or 30 PPS depending on the Magnification selection. The whole PPS range is only selectable with high Magnification (9x9 inches).

Note ☞ *Refer to the Remote Controlled Table Manuals.*

ELAPSED FLUORO TIME AND RESET TIME: The *"Reset Time"* button resets the audio alarm and the Fluoroscopic Timers.

It is recommended to reset the Fluoroscopic parameters and timers by touching the "*Reset Time*" button for 2 seconds before examining a new patient.



The following table indicates the operative of the different Fluoro Timers.

FLUORO TIMER	AUDIO ALARM	RESET / EXPOSURE STATUS
Fluoro Display Timer. The Fluoro Time Display can show minutes up to 99 minutes and 59 seconds	With or without alarm activated.	Touch the "*Reset Time*" button at any moment. Value on the Fluoro Time Display is reset to 0.
Alarm Timer.	Continuous sound after 5 minutes of accumulated exposure.	The "*Reset Time*" button changes to "*Reset Alarm*" blinking, touch the button to reset the alarm. The alarm will sound every 5 minutes of accumulated exposure after it is reset. This Timer does not reset the value shown on the Fluoro Time Display.
Fluoro Pedal Timer.	Intermittent sound (beep) after 9 minutes of continued exposure (with no stop).	It will indicate to the operator that exposure will stop when reaching 10 minutes of continued exposure. This internal timer and the alarm are reset each time that the Fluoro Pedal is released. This timer does not reset the value shown on the Fluoro Time Display.

REGION OF INTEREST (ROI): It is the central area analyzed by the System in order to obtain a specific brightness (kVp) in Automatic mode (ABS). The selected ROI is always smaller or equal to the collimated area and the Magnification set on the Digital Imaging System.

The following values are possible depending on the Magnification selection: 1x1, 2x2, 4x4, 6x6, 8x8, 10x10, 12x12, 14x14 inches.

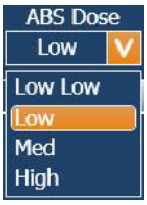
Note ☞ *Refer to the Remote Controlled Table Manuals.*

AUTOMATIC BRIGHTNESS SYSTEM (ABS): Selects the Fluoro X-ray Tube voltage in Automatic mode (highlighted). This control automatically adjusts the kVp values to maintain constant brightness (constant entrance dose rate) on the viewing screen.

The ABS mode is deactivated by touching the button again.

When ABS is selected, *"Quality Normal"* is automatically activated by default, allowing manual selection of the ABS Dose. The operator can change from *"Quality Normal"* to *"Quality Detail"*; in this case, ABS Dose is automatically selected.

QUALITY NORMAL: By means of this functionality, the image quality can be increased by increasing the Dose per Frame. The system obtains automatically the same penetration (kV) for each Dose per Frame at any PPS value by means of the ABS.



Once the *"Quality Normal"* is selected, the Dose per Frame can be set to Low-Low, Low, Medium or High depending on the image quality needed by the operator.

The High Dose per Frame is only obtained with lower PPS, the Low-Low Dose can be obtained in all PPS range.

The table below shows the relation of the applied Dose per Frame according to the selected PPS:

ABS DOSE PER FRAME	PPS								
	1	2	4	5	7.5	10	15	20	30
LOW LOW	x								
LOW	x							-	
MEDIUM	x					-			
HIGH	x			-					

QUALITY DETAIL: By means of this functionality, the Dose per Frame increases automatically while the selected PPS decrease, offering the greatest dose per frame values according to the selected PPS. The ABS Dose selection is deactivated.

The table below shows the relation of the applied Dose per frame according to the selected PPS:

ABS DOSE PER FRAME	PPS								
	1	2	4	5	7.5	10	15	20	30
LOW LOW	-							x	
LOW	-					x		-	
MEDIUM	-			x			-		
HIGH	x			-					

In this case, the system obtains automatically the same penetration (kV) for any PPS value by means of the ABS.

FLUORO CURVES: This functionality is available when ABS is selected, modifying the kV and mA balance, in order to enhance penetration or image contrast.

0: Standard, for Standard Fluoro exams.
1: Barium, for Fluoro exams in which Barium is applied.
2: Iodine, for Fluoro exams in which Iodine is applied.
3: Low kV, for High Contrast Fluoro exams.

HIGH DOSE: When this button is selected the average tube current increases to obtain more contrast in the image during the fluoroscopic exam and, consequently, the maximum radiation dose is increased.

Note ☞

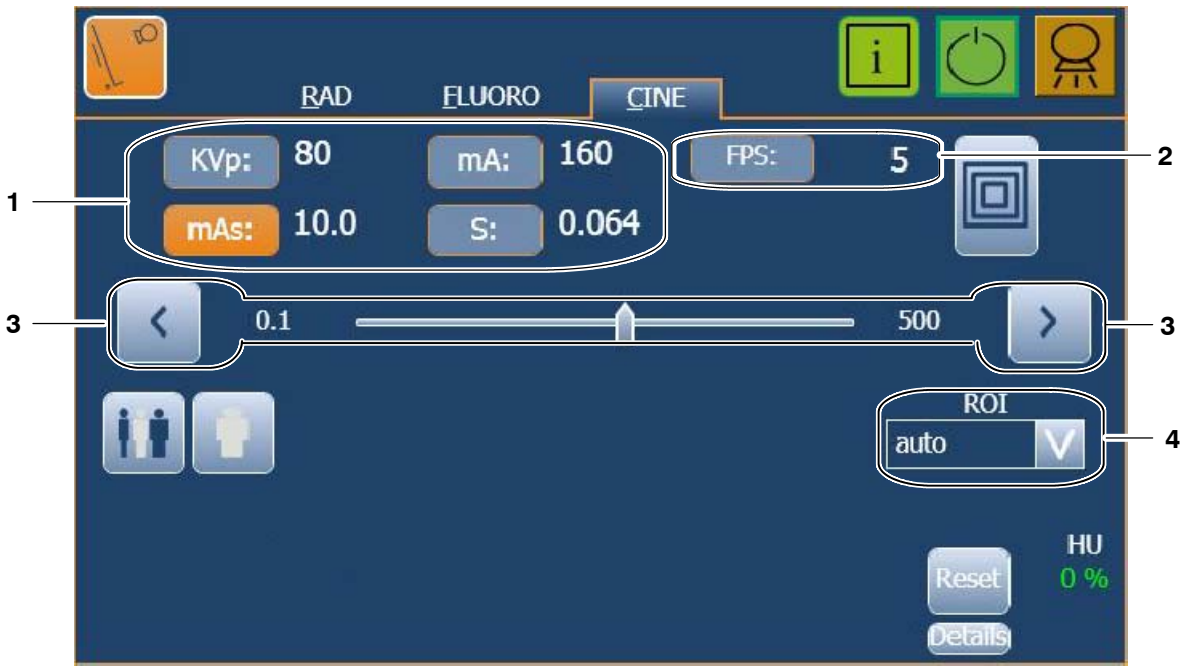
The High Dose option is available if it has been configured by the field engineer during the installation. The Dose limits in this mode must be calibrated according to local regulations.

High Dose can be only activated in Automatic mode (ABS) during fluoro exams, by stepping the High Dose pedal (optional) or by touching the "*High Dose*" button. During High Dose exams a continuous alarm sounds.

It is automatically deactivated once the pedal is released or the "*High Dose*" button is pressed again.

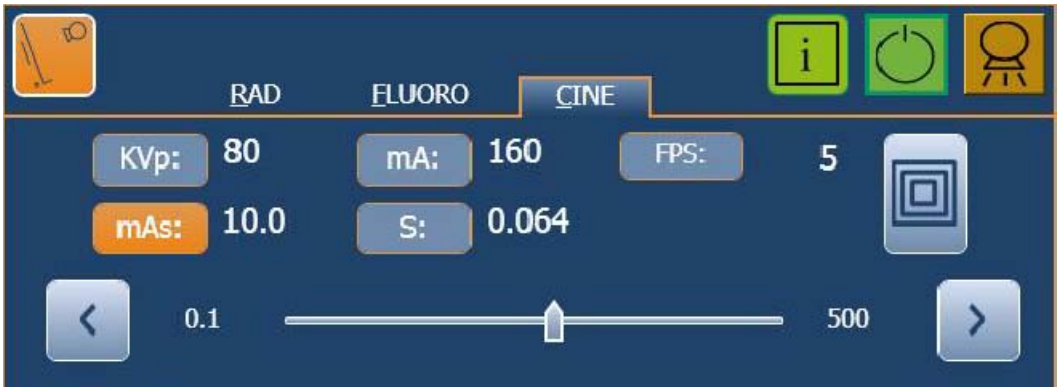
3.4 CINE

CINE is used for dynamic examinations in order to obtain a response of automatic brightness control as Fluoro imaging provides but with a radiographic image quality for diagnosis. Cine always works in Automatic mode (ABS).



1. Exposure Values
2. Frame per Second
3. Parameter Selectors
4. ROI (Region of Interest)

CINE DISPLAYS: They are divided in the kVp, mA, mAs, Time (s) and FPS Displays, where the respective values of the technique are shown.



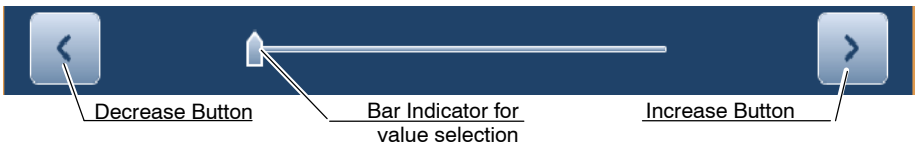
CINE Displays can also show the values (blinking) of the parameters of the last exposure, after touching the "*Reset*" button.

INCREASE / **DECREASE:** exposure values are increased or decreased by selecting the respective CINE Display (which will be highlighted) and changing the value with the "*Increase*" or "*Decrease*" buttons.

Note ☞ *None of the parameters (kVp, mA, ms, mAs, FPS) can be modified during the Cine exposure sequence.*

The values increase or decrease step-by-step each time the corresponding button is touched, and change faster when either of them is touched continuously.

Also, the value can be directly selected by clicking on its position on the bar. When this indicator is positioned over a value not allowed, it goes back to the maximum position allowed by the present conditions of the Generator.



(*Refer to Section 7 for Factor ranges. The Radiographic factor ranges are the same for Cine).*

- **kVp**: Selects the X-ray Tube voltage. The kVp value must be set by the operator as an initial value, but it is automatically adjusted during the examination by the ABS to maintain constant brightness (constant entrance dose rate) on the viewing screen.
- **mA**: Selects the X-ray Tube current. The Focal Spot selection can be changed when the mA value is selected with the "*Increase*" or "*Decrease*" buttons. The slider of the bar can only set the mA values of the selected Focal Spot.
- **mAs**: Selects the exposure in mAs.
- **s**: Selects the exposure Time in seconds, that is, the pulse width of each exposure during the examination sequence. The maximum Time can be limited by the Detector specifications.

- **FPS**: (*FPS - Frames per Second*) selects the frame rate of the examination sequence. FPS is selected on the Digital Imaging System or Console.

  The **FPS** selection can be 0.25, 0.33, 0.50, 1, 2, 4, 5, 7.5, 10, 15, 20, or 30 exposures per second with a pulse width of each exposure of the time selected on the Console.

  The **FPS** selection depends on the Magnification set on the Digital Imaging System and the time selected on the Console.

REGION OF INTEREST (ROI): It is the central area analyzed by the System in order to obtain a specific brightness (kVp) in Automatic mode (ABS). The selected ROI is always smaller or equal to the collimated area and the Magnification set on the Digital Imaging System.

The following values are possible depending on the Magnification selection: 1x1, 2x2, 4x4, 6x6, 8x8, 10x10, 12x12, 14x14 inches, and Auto.

Note ☞ *Refer to the Remote Controlled Table Manuals.*

3.5 CONTROL PEDALS

The Unit is equipped with two exposure pedals for each mode, that is, RAD, RF, CINE and HIGH DOSE (optional). Those pedals are installed in two groups, one group in the Control Room and the other group in the X-Ray Room (for specific techniques).

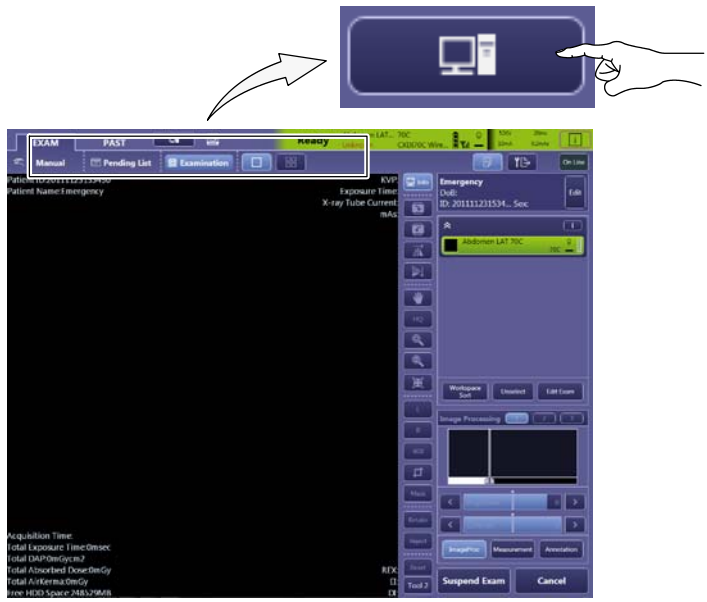
Control Pedals

3.6 EDITING A PROTOCOL

Note ☞ *The Protocols include parameters that can be used as a guide, but the final values of each technique must be revised / contrasted / verified and / or modified if necessary, by the operator. For APR further information refer to CXDI Control Software RF Manuals.*

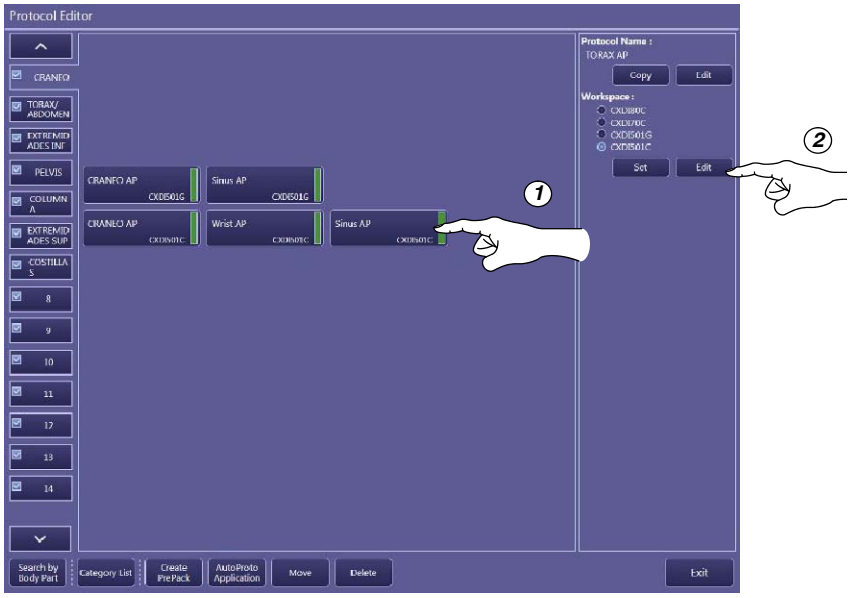
To edit a Protocol, proceed as described in the following steps.

1. Press the *PC icon* located at the top of the screen.

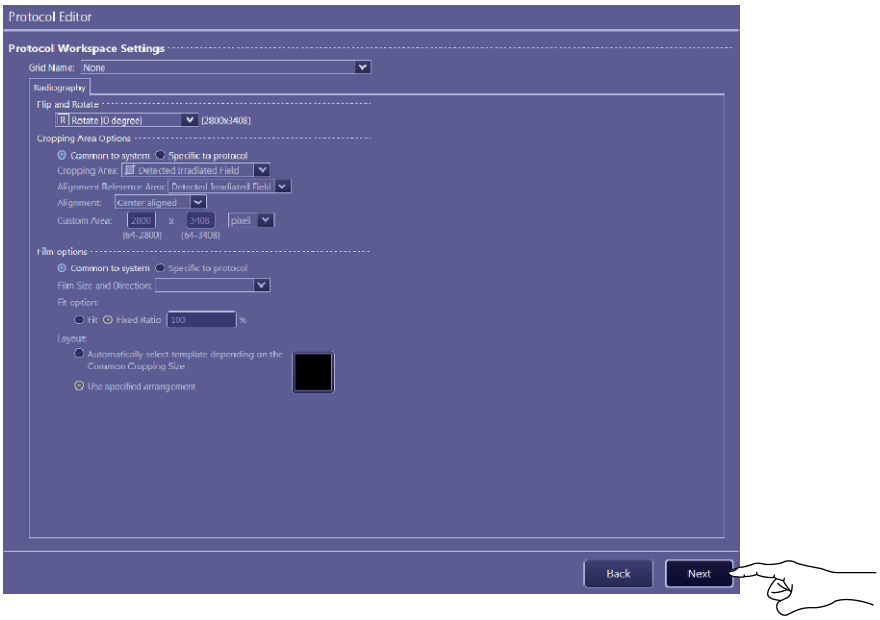


2. Touch the "*Protocol Editor*" button to access the *Protocol Editor menu*.

3. In the *Protocol Editor menu*, touch the button of the technique to be edited, and then press the *"Edit"* button located in section *"Workspace"*.



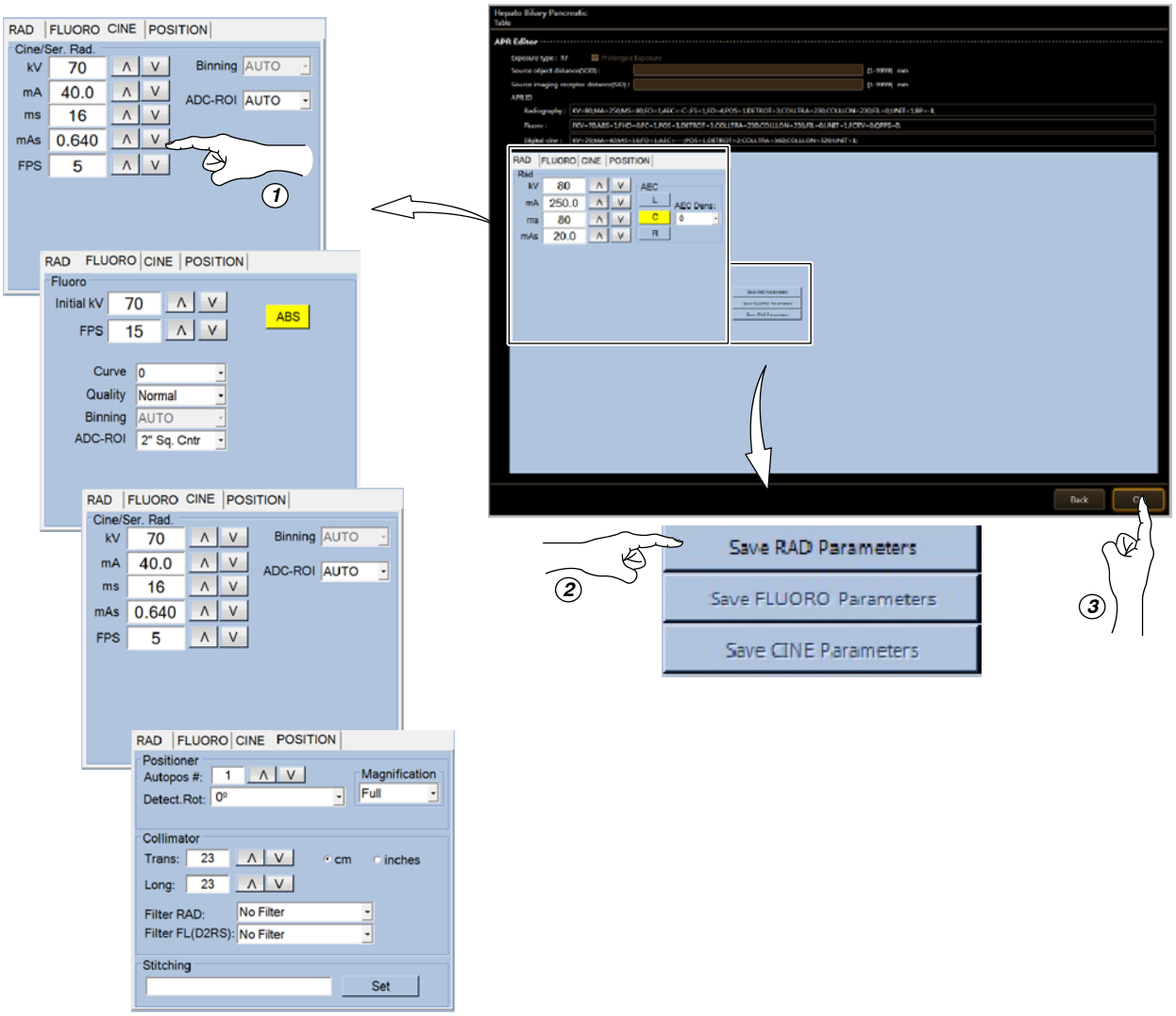
4. In the *Protocol Editor screen*, press the button *"Next"* of the succeeding screens, until reaching the *APR Editor screen*.



5. Once in the *APR Editor screen,* modify the required parameters of the technique to be edited.

   Touch on the button *"Save RAD Parameters"* to set the new values in the protocol.

   Then, press *"OK".*



6. In the next *Protocol Editor screen* press *"Exit".*

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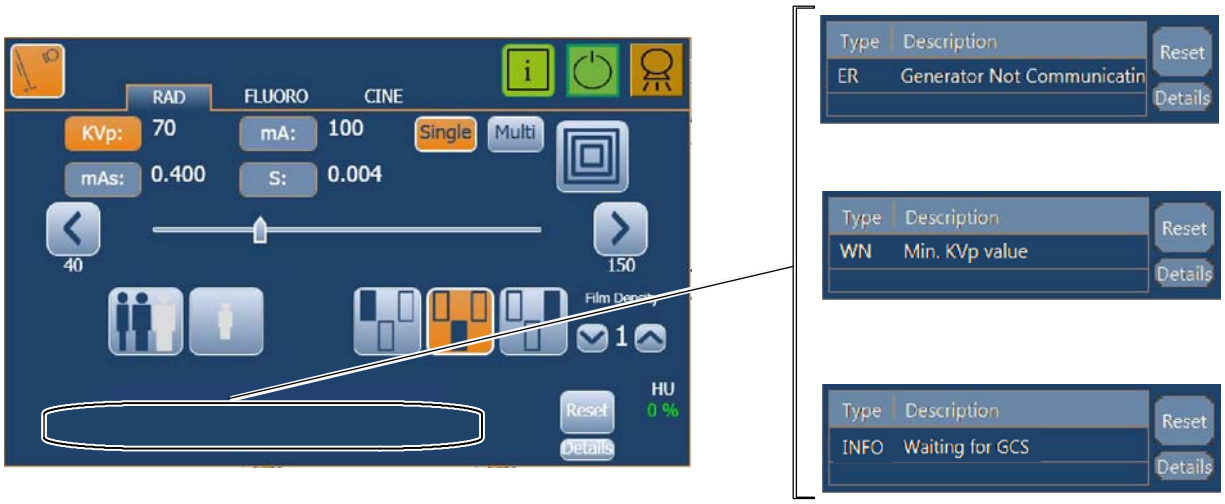
SECTION 4 GENERATOR AND SYSTEM MESSAGES

Generator and System messages are shown in the "*Information Area*", at the bottom of the Screen. There, it is shown the type of message and a short description, beside the "*Reset*" and "*Details*" controls.



Generator and System Messages indicate the potential cause of an Error, a Warning condition or an Information:

RED

- **ERROR (ER)**: Error messages indicate the potential cause of a failure. In general, to remove the error indication, the "*Reset*" button have to be pressed.

RED

- **INTERLOCK (IL)**: Interlock messages indicate a transitory situation that prevents the use of the system. This condition disappears when the cause of the inhibition expires. It is not required the user confirmation.

ORANGE

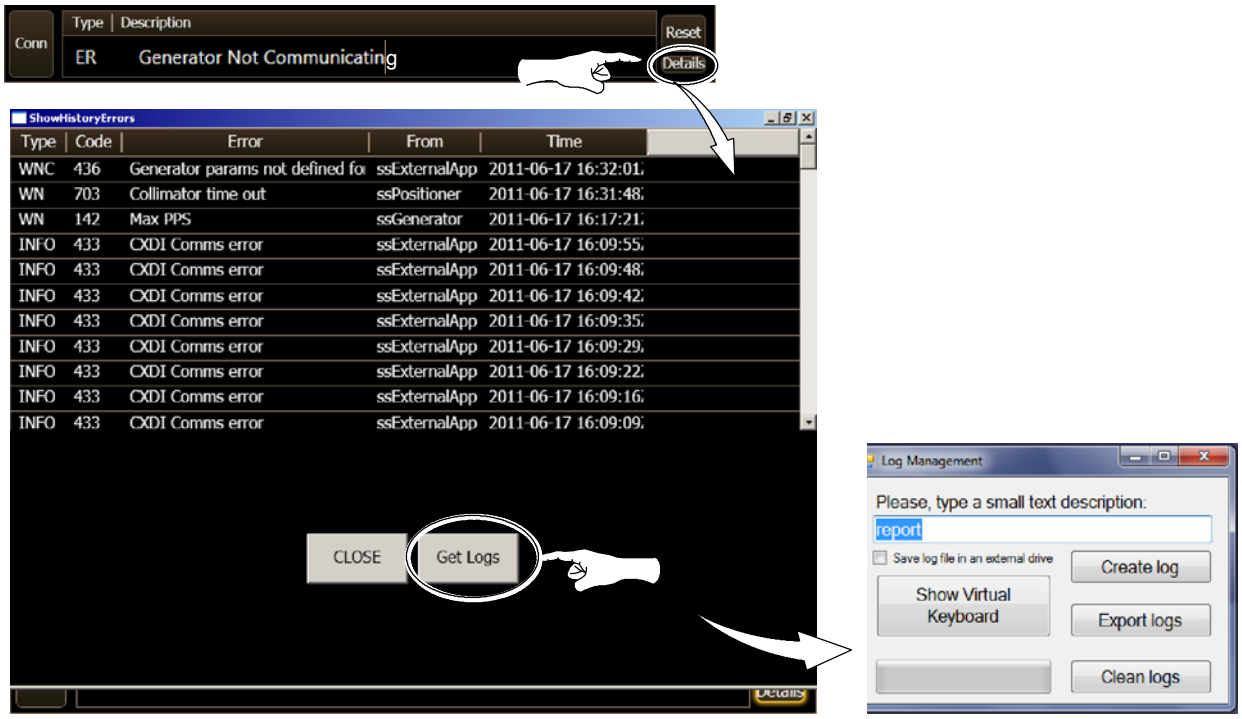
- **WARNING (WN-WNC):** Warning messages indicate a limit or a restriction. The warning condition for "*WN*" codes disappears after a few seconds, whilst for "*WNC*" codes it is required in general to press the "*Reset*" button.

GREEN

- **INFORMATIVE (INFO).** When this control is pressed, a new window containing the last error or warning appears at the bottom of the screen.

Pressing on "*Details*" control, the screen "*Show History Errors*" will be opened, including a list with the Messages that have appeared since the last starting up of the system, as well as the details: type of message, code, description, source and date.

This information will enable the operator to convey the possible source of the failure to the Service Personnel so they can anticipate corrective actions prior to arriving in site.



Pressing on the control "*Get Logs*", at the lower area of the screen "*Show History Errors*", the window "*Log Management*" will be opened. Here, the user can type a small description and create a Log, for its later use by the Technical Service in order to solve the reported issues.

4.1 GENERATOR MESSAGES

Generator messages indicate the potential cause of an Error, a Warning condition or an Information related to the Generator.

4.1.1 ERROR MESSAGES

Error messages indicate the potential cause of a failure. They are shown on the "*Information Area*" of the Screen while an alarm sounds. In general, to remove the error indication on the Console press the "*Reset*" button, then the alarm goes off.

Table 4-1
Error Messages

CODE	MESSAGE / DESCRIPTION	ACTION
ER01	**HT Controller not communicating.** Communication error.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER02	**Failure in power-up routine.** Communication error.	
ER03	**All Workstations configured as tube 0.** System failure.	
ER04	**"*Prep*" signal received without Console order.** "*Preparation*" has been activated by the unit without a Console command intervention.	
ER05	**"*Exposure*" signal active without request / Wrong handswitch**. Exposure signal activated during power-up.	Release the exposure controls. Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER06	**Preparation/Exposure orders activated during power-up** "Exposure" and/or "Preparation" orders are activated during power-up.	
ER07	**Wrong data for X-ray Tube 2.** X-ray Tube configuration error.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER08	**Wrong data for X-ray Tube 1.** X-ray Tube configuration error.	
ER09	**Tube Spits or HV Inverter Overheat / Arcing or IGBT fault.** Generator Overload error. The exposure has been interrupted due to an arcing or malfunction on the HV circuitry (X-ray Tube, HV Transformer and/or HV Cables) has occurred during the exposure; or a failure of IGBT module (overheated or defective IGBTs) has been detected. A high powered lengthy exposure with the Tube still cold (X-ray Tube has not been warmed-up) will also provoke this error.	This error does not require to touch the "*Reset*" 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.
ER10	**EEPROM corrupted or not initialized in ATP Console or HT Controller.** System failure.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.

Table 4-1 (cont.)
Error Messages

CODE	MESSAGE / DESCRIPTION	ACTION
ER11	**No Voltage detection in the main storage capacitors (Inverter module)** System failure.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER12	**Wrong Filament current.** No mA during exposure or mA value is out of range.	Touch the "*Reset*" button. Repeat with same technique values. If the error code persists, try with another combinations of kV and mA values. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER13	**No kVp during exposure.** No kV during exposure or kV value is out of range.	
ER14	**Generator internal exposure signal active without X-ray exposure console command.** System failure.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER15	**No current detection on filament circuit.** System failure.	
ER16	**Selected mA, kVp or kW of the exposure selection is not correct.** Invalid value of kV, mA or kW.	Touch the "*Reset*" button. Decrease kV, mA or both. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER17	**No communication with HTC PCB during normal operation.** Communication error or system failure.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER18	**Rotor not running or detected to be running without order.** 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.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER19	**mA detected without exposure command.** System failure.	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER20	**kV detected without exposure command.** System failure.	
ER21	**Wrong Tube 1 selection.** Incorrect selection of the X-ray Tube.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER22	**Wrong Tube 2 selection.** Incorrect selection of the X-ray Tube.	
ER23	**Last calibration data not stored.** System failure.	
ER24	**Detector not ready; detector timeout.** Detector/Bucky not ready for an exposure.	Touch the "*Reset*" button. Ensure that the Detector is ready for exposure, then select the study again. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER27	**Failure in ATP Console EPROM.** System failure.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER28	**External Power Box signal response time out (Falling edge).**	Touch the "*Reset*" button, retry to expose and check the Detector ready status, If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER29	**External Power Box signal response time out (Rising edge).**	
ER30	**No Fluoro pulses from external power box.**	

Table 4-1 (cont.)
Error Messages

CODE	MESSAGE / DESCRIPTION	ACTION
ER33	**Generator not communicating.** Serial Communication error.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER34	**Technique Error.** If it activates during exposure it means that the exposure has been interrupted by the "Security Timer". It can also be shown: – 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 enabled values. – after the "*ABS*" selection, when "*ABS*" is not enabled. – if a failure on the Automatic Collimator has been detected.	These errors do not require to touch the "*Reset*" button, the 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.
ER35	**Door Open.** The X-ray room door is open when the X-ray equipment is in use.	
ER36	**Heat Unit.** 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.	
ER37	**Tube Overload.** 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.	
ER41	**Communication failure between Tube 1, Dosimeter and Generator.** System failure related to Dosimeter.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER42	**Auto-test error on Tube 1 Dosimeter.** System failure related to Dosimeter.	
ER43	**Tube 1 Ion Chamber status check error.** System failure related to Dosimeter.	
ER44	**Communication failure between Tube 2, Dosimeter and Generator.** System failure related to Dosimeter.	
ER45	**Auto-test error on Tube 2 Dosimeter.** System failure related to Dosimeter.	
ER46	**Tube 2 Ion Chamber status check error.** System failure related to Dosimeter.	
ER48	**Collimator Error.** A failure on the Automatic Collimator has been detected.	These errors do not require to touch the "*Reset*" button, the 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.
ER50	**Exposure interrupted by the operator.** Exposure has been aborted by the Operator.	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.

Table 4-1 (cont.)
Error Messages

CODE	MESSAGE / DESCRIPTION	ACTION
E51 to E93	**System failure related to High Speed Rotor Controller.**	Touch the "*Reset*" button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER95	**AEC Rapid termination: Insufficient dose.** Exposure aborted by the AEC Rapid Termination.	Touch the "*Reset*" button. Select the correct Receptor / Ion Chamber or modify parameters. Repeat the exposure. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER98	**Calibration dip switch active.** Service Mode Active.	Touch the "*Reset*" button and call Field Service. This error does not inhibit normal operation.
ER100	**AEC Backup time.**	Touch the "*Reset*" button. Select the correct Receptor / Ion Chamber or modify parameters. Repeat the exposure. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER101	**AEC Wrong Technique.**	

4.1.2 INTERLOCK MESSAGES

Interlock messages indicate a transitory situation that prevents the use of the system. This condition disappears when the cause of the inhibition is solved.

Table 4-2
Interlock Messages

CODE	MESSAGE / DESCRIPTION	ACTION
IL102	**Door open**.	Refer to ER35.
IL103	**Generator overload**.	Refer to ER09.
IL104	**Technique error**.	Refer to ER34.
IL105	**Rotor error.**	Refer to ER18.
IL106	**Tube Thermal Switch**.	Refer to ER36.
IL107	**Max. HU limit**. Indicates that there are not enough remaining HU to make an X-ray exposure with the selected parameters.	Reduce exposure factors in order to reduce the Energy, or wait for the X-ray Tube to cool. If the message persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
IL108	**Tube overload.**	Refer to ER37.

4.1.3 WARNING MESSAGES

The Warning messages described in this section indicate a limit or a restriction during the parameter selection, e.g. while increasing or decreasing kVp, when the value reaches the limits, the message *"Maximum/Minimun kVp Value"* is shown and the variation above or below limits is inhibited.

Warnings show a condition that inhibits exposures temporarily, when the warning source disappears, the warning message disappears.

Table 4-3
Warning Messages

CODE	MESSAGE / DESCRIPTION	ACTION
WN116	**Legal max mAs**. Regulatory mAs limit.	Decrease mA, ms or mAs.
WN117	**Maximum Energy**. The Maximum Energy can not exceed 60 kJ (kVp x mAs = 60 kJ) (Regulatory limit for AEC).	Decrease kVp or mAs.
WN118	**Minimun kVp Value.**	Generator limit. Keep the limit value or modify the parameter.
WN119	**Maximum kVp Value.**	
WN120	**Minimun mA Value.**	
WN121	**Maximum mA Value.**	
WN122	**Minimum ms Value.**	
WN123	**Maximum ms Value.**	
WN124	**Minimum mAs Value.**	
WN125	**Maximum mAs Value.**	
WN126	**Maximum Instant Power.** It appears when the Generator Power Limit (kVp x mA) is exceeded while increasing kVp or mA, then the corresponding value is blocked.	Keep the limit value or modify kVp or mA.
WN127	**Maximum kVp Tube.** kVp limit by the Tube protection curves or limited during the Generator configuration.	Decrease kVp value.
WN128	**Space Charge for Selected Technique.** Filament emission limit for a combination of kVp and mA in the selected Focal Spot. If a variation of the kVp or mA values means that the Tube space charge limit will be exceeded in the selected Focal Spot, the parameter is blocked.	Increase kV or decrease mA values.
WN129	**Instant Power Absolute Limit.** It appears when the selected technique is beyond the absolute X-ray tube ratings or the present conditions of the Tube inhibit the exposure (anode momentarily overheated).	Reduce exposure factors (kVp, mA or ms), or wait for the X-ray tube to cool.

Table 4-3 (cont.)
Warning Messages

CODE	MESSAGE / DESCRIPTION	ACTION
WN130	**Instant Power Percentage Limit.**	These messages do not require any user action. The indication disappears automatically.
WN131	**Generator Working in 3P mode (kVp, mA and Time)**	
WN132	**High Contrast Fluoro.**	
WN133	**Tomo mode.**	
WN134	**Minimum ms vs Minimum mA combination.**	Generator limits. Modify the selected Parameters.
WN135	**Maximum ms vs Maximum mA combination.**	
WN142	**Maximum PPS.**	

4.2 SYSTEM MESSAGES

System Messages indicate the potential cause of a System Error (ER), a Warning condition (WN/WNC) or an Informative message (INFO) related to the System.

Table 4-4
System Messages

CODE	MESSAGE / DESCRIPTION	ACTION
ER426	**Wrong CXDI IP address or PC power OFF.** The configured IP address in the Control Software RF application is wrong.	Turn the unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER427	**Wrong GCS IP address.** The configured IP address in the Control Software RF application is wrong.	
ER428	**GCS Error / Socket Error.** Communication error between the Generator and GCS module.	
WNC429	**Waiting for CXDI.** Control Software RF application is active, waiting for communication with CXDI application.	Wait for the CXDI application to start up. If the warning message does not disappear after few seconds, press on the control "*connect GEN*" of the CXDI application (*refer to the User Manual of the CXDI application*). If the problem persists, turn the unit OFF and ON. If the application remains inoperative, turn it OFF and call Field Service.
WNC430	**Waiting for GCS.** Control Software RF application is active, waiting for communication with GCS module.	Wait for the system to start up. Press on the control "*connect GEN*" of the CXDI application (*refer to the User Manual of the CXDI application*). If the problem persists, turn the unit OFF and ON. If the application remains inoperative, turn it OFF and call Field Service.
INFO431	**Connected.** All the modules are communicating properly.	
ER432	**GCS communications Error.** Communication error between Control Software RF application and GCS module.	Turn the unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER433	**CXDI communications Error.** Communication error between Control Software RF application and CXDI application.	Close the current Exam, press on the control "*connect GEN*" of the CXDI application (*refer to the User Manual of the CXDI application*). If the error code persists, turn the unit OFF and ON. If possible, check that the startup sequence is: 1.- Generator, 2.- Generator Console and 3.- CXDI application. This information will help the Service engineer. If the error persists, turn it OFF and call Field Service.
INFO434	**GCS closed.** GCS application has been turned OFF properly.	
INFO435	**CXDI closed**. CXDI application has been turned OFF properly.	
WNC436	**Generator parameters not defined for this study.**	Check the APR editor in CXDI application in order to define a technique (*refer to the User Manual of the CXDI application*).
ER437	**Table not communicating.**	Refer to Remote Controlled Table Manual.
WNC438	**Table application closed.**	
WNC439	**Waiting for Table.**	

Table 4-4 (cont.)
System Messages

CODE	MESSAGE / DESCRIPTION	ACTION
INFO501	**Please, open a study.** A new exam needs to be created on CXDI application before using the digital X-ray unit. Open a study in CXDI application.	
ER502	**Rad Technique not selected, please retry.**	Select the Technique again.
ER503	**Fluoro Technique not selected, please retry.**	
ER504	**Cine Technique not selected, please retry.**	
WN506	**Selection rejected by CXDI.** CXDI application detects a wrong selection of the Digital Panel orientation, Magnification, Fluoro PPS or Multirad FPS.	Repeat / check the parameters selection of the Digital Panel orientation, Magnification, Fluoro PPS or Multirad FPS. Check if CXDI application is running properly. If the problem happens frequently, call Field Service.
WN553	**Command temporary rejected by CXDI.** A parameters selection has not been properly communicated to CXDI because the CXDI application or the Digital Panel are temporarily inactive.	Repeat the parameters selection. Check if CXDI application is running properly. If the problem happens frequently, call Field Service.
WN554	**Wrong command format sent to CXDI.** The parameters sent to the CXDI application were wrong.	Change the parameters. If the problem happens frequently, call Field Service.
WN555	**ROI too large**.	Select an adequate ROI.
WN556	**Wrong magnification & PPS combination**.	Select an adequate magnification and PPS combination.
WN557	**Trying to modify fluoro parameters while exposing**.	
WN701	**Filter not selected, please retry.**	
WN702	**Autoposition not selected, please retry.**	
WN703	**Collimator Time Out.**	
WNC705	**Tray out.**	
WNC706	**Wrong Detector Orientation.**	
WN707	**DAP timeout.**	

SECTION 5 OPERATING SEQUENCES

5.1 START-UP ROUTINE

Once the System is on and the power-up has been completed, the Console should display the last values and selections previous to turn the Console off. If there is a malfunction, error messages will be displayed on the Console 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.*

5.2 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.

Perform this warm up procedure at the start of the working 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 kVp, 100 mAs, 200 mA and 500 ms exposure.
- Make sure 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.

5.3 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 order to keep constant mAs. If the highest mA value available coincides with the maximum mA station of the Generator, it sets one mA station below of the maximum mA station of the Generator.
- One point control by selecting kVp with AEC operations.
- Zero point control by means of a formula that relates the RAD kVp with the Fluoro kVp and AEC operations. This mode requires Fluoro and 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 button to the "*Prep*" position and maintain it until the "*Ready*" indicator is illuminated.
5. Instruct patient to remain still and to hold their breath as required, then make the X-ray exposure by pressing the handswitch button fully to the "*Exp*" position and maintain it throughout the exposure. The "*X-ray On*" indicator will light and an alarm will sound during the exposure.
6. When the exposure is finished, release the handswitch button.
7. Repeat the procedure if additional exposures are desired.

5.4 AEC OPERATION

To 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. Adjust the "*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 5.3 – step 4.)*

5.4.1 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 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 “*Reset*” 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 “*Reset*” 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 “*Reset*” 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 "*Reset*" button is flashing. If not, contact Service.

5.5 APR OPERATION

Refer to CXDI application.

5.6 FLUOROSCOPIC OPERATION

A typical Fluoroscopic examination sequence is as indicated below:

1. Select the “Exam” configured on the CXDI Application to perform Fluoroscopic examinations.
2. Position the patient for the examination.
3. Press the “*Reset Time*” button for 2 seconds to monitor the total time of the exposure that the patient will receive.
4. Manually adjust the kVp value by pressing the “*Increase*” and “*Decrease*” buttons on the Fluoro module, or select the “*ABS*” button for automatic kVp adjustment.
5. Instruct patient to maintain the required position. Begin the examination sequence by using the corresponding “*Fluoro Exposure*” control.
6. Observe that the Fluoro time starts at 0 minutes. An alarm (continuous sound) starts each 5 minutes of accumulated exposure (it can be turned off by pressing the “*Reset Time*” button). An alarm (intermittent sound) starts after 9 minutes of continued exposure indicating to the operator that the exposure will stop when it reaches 10 minutes of continued exposure. If required to continue, release the Fluoro pedal and step down it again.
7. If needed during the examination, select and change the “*Image Intensifier*” mode by pressing the corresponding buttons.
8. The “*X-ray On*” indicator will remain illuminated during the exposure.

5.6.1 HOW TO VERIFY THE PROPER FUNCTIONING OF THE AUTOMATIC BRIGHTNESS CONTROL

Note ☞ *This procedure is not mandatory, it is only a method so that the operator can verify the proper functioning of the Automatic Brightness 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 the entire field of the Digital Panel.
5. Place on the Table-Top and within the X-Ray beam a homogeneous phantom (e.g. a bucket with 5 liters of water) that covers the entire field of the Digital Panel.
6. Select a Fluoro workstation.
7. Set for example: 80 kVp Fluoro, 15 PPS, NO ABC (Manual mode). Make a Fluoro exam for 10 seconds. Verify during the exam the Fluoro kVp is always 80 kVp displayed on the screen.
8. Set for example: 80 kVp Fluoro, 15 PPS, ABC (Automatic mode). Make a Fluoro exam for 10 seconds. Write down the Fluoro kVp value automatically selected on the screen during the exam.
9. Set for example: 40 kVp Fluoro, 15 PPS, ABC (Automatic mode). Make a Fluoro exam for 10 seconds. Check during the exam, the Fluoro kVp value goes automatically to the value noted in step 8. If not, contact Service.
10. Set for example: 120 kVp Fluoro, 15 PPS, ABC (Automatic mode). Make a Fluoro exam for 10 seconds. Check during the exam, the Fluoro kVp value goes automatically to the value noted in step 8. If not, contact Service.

5.7 CINE OPERATION

A typical Cine examination sequence is as indicated below:

1. Select the “Exam” configured on the CXDI Application to perform the examination.
2. Position the patient for the examination.
3. Select the “*workstation*”.
4. Select a Region of Interest (ROI) or Auto, and the Frame per Second (FPS).
5. Select the technique parameters using the CINE controls on the Console.
6. Instruct patient to maintain the required position.
7. Start the sequence by stepping the “*Cine*” pedal. The “*Ready*” and “*X-ray On*” indicators will light and an alarm will sound during the exposures.

   During the examination, kVp are automatically adjusted.
8. When the exposure is finished, release the “*Cine*” pedal.
9. Repeat the procedure if additional exposures are desired.

SECTION 6 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 level 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 to have available spare parts for this equipment at least for five (5) years after the unit manufacturing.

6.1 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, especially 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.

6.2 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 7 TECHNICAL SPECIFICATIONS

7.1 FACTORS

FACTORS	GENERATOR MODEL *(Refer to Identification Label)*			
	N 32 HF		**N 40 HF**	
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)*				
	N 50 HF		**N 65 HF**		**N 80 HF**
Maximum Power kW	50 kW		64 kW		80 kW
Maximum mA	640 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

7.2 RANGE OF RADIOGRAPHIC / CINE PARAMETERS

PARAMETER	RANGE
kVp	From 40 kVp to 125 kVp or 150 kVp 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 mA 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.
FPS	1, 2, 4, 7.5, 10, 15, 20, 30 Frames pr second.
AEC	mAs: 0.1 mAs to 500 mAs
	Exposure Time: Nominal shortest irradiation Time = 1 ms

7.3 RANGE OF FLUOROSCOPIC PARAMETERS

PARAMETER	RANGE
kVp	From 40 kVp to 125 kVp in 1 kVp steps.
mA	Fluoroscopic mA are set during calibration so as not exceed the maximum Entrance Skin Exposure (ESE) dose rate on the patient.
Exposure Time	From 0 to 100 minutes.
PPS	1, 2, 4, 7.5, 10, 15, 20, 30 Pulses pr second.

7.4 DUTY CYCLE

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

7.5 ENVIRONMENTAL REQUIREMENTS

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

7.6 POWER LINE REQUIREMENTS

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

7.7 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

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.
- As the use of Grids require higher doses, **never use Grids in pediatric exams**. Remove the Grid from the receptor assembly and select the lower possible doses. If the Grid can not be detached, pediatric exams can not be performed using this device.

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

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

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

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

Summary:

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