Technical Publication
OM-0473R2_EN_KON

Operation

Mobile X-ray Unit
KONICA MINOLTA

mKDR

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

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

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
Battery Mobile X-Ray Unit EASY MOVING: **SM - 20HF - B-D-KM (AeroDR X30)** **SM - 32HF - B-D-KM (AeroDR X30)** **SM - 40HF - B-D-KM (AeroDR X30)** **SM - 50HF - B-D-KM (AeroDR X30)**

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REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	APR 02, 2018	First Edition
1	NOV 13, 2019	Keypad, Collimator Controls, General Update and Illustrations
2	MAR 18, 2020	Batteries Specifications, Mains Connection and Line Circuit Breaker, Manual Clutch Screws, Parking Position of the Arm, Illustrations and General Update

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

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

ADVISORY SYMBOLS

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

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

ADVISE OF CONDITIONS OR SITUATIONS THAT IF NOT HEEDED OR AVOIDED COULD CAUSE SERIOUS PERSONAL INJURY, CATASTROPHIC DAMAGE TO 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 **Mobile X-ray Units**. It provides a general description, safety and regulatory information, operating instructions and specifications concerning the system.

It is not intended to teach radiology or to take any type of clinical diagnosis.

This Unit is designed for general radiography. It provides all the advantages of high frequency waveform Generators including lower patient dose, shorter exposure times as well as greater accuracy and consistency.

The Unit is controlled by multiple microprocessors which render a higher exposure consistency, efficiency in operation and an extended tube life. A high level of self-diagnostics streamlines serviceability, thereby reducing down time.

All functions, displays and controls are logically arranged, easily accessible and identified to prevent confusion. Technique factors and functions are selected on the Control Console.

Illustration 1-1
Mobile X-ray Unit

Mobile X-Ray Unit with Standard Column

Mobile X-Ray Unit with Telescopic Column (optional)

X-RAY GENERATION COMPONENTS

- *Control Console.*
- *Konica-Minolta ULTRA Software Application* for image acquisition.
- *Generator*, that comprises:
  - *Power Module*, containing the power and control components.
  - *High Voltage Transformer*.
  - *Battery Module,* with batteries and charge/control components.
- *X-ray Tube*, part of the Tube-Collimator Assembly.
  Tubes: Canon E7884X, E7886X.

ASSOCIATED EQUIPMENT AND SUBASSEMBLIES

According to IEC 60601-2-32, the following subassemblies are considered Associated Equipment and conform to the applicable safety requirements therein stated.

- *Unit Motion Assemblies,* that comprises:
  - *Batteries and Charger Module*, to power the motors.
  - *Motor Assembly*, motors and wheels.
  - *Driving Control Assembly*, handlebar, motion controls at the Tube-Collimator Assembly, gauges and related electronic components.
- *Rotating Column and Telescopic Arm,* holding the Tube-Collimator Assembly and allowing its positioning. Column types available:
  - *Standard Column.*
  - *Standard Short Column (optional).*
  - *Telescopic Column (optional).* The Telescopic Column in parking position reduces the height of the **Mobile X-ray Unit** in order to have complete visibility and safety when driving the system.
- *Collimator,* part of the Tube-Collimator Assembly:
  RALCO R221/A DHHS-170E, RALCO R221/A DHHS-170D.
- *Digital Detectors and Grid.* Detectors:
  AeroDR 1417HQ, AeroDR 1417S, AeroDR 1717HQ, AeroDR 1012HQ, AeroDR 2 1417HQ, AeroDR 2 1417S, AeroDR 3 1417HD.
- *Holders for Detectors, Grids and Accessories.*

1.1 GENERAL FEATURES

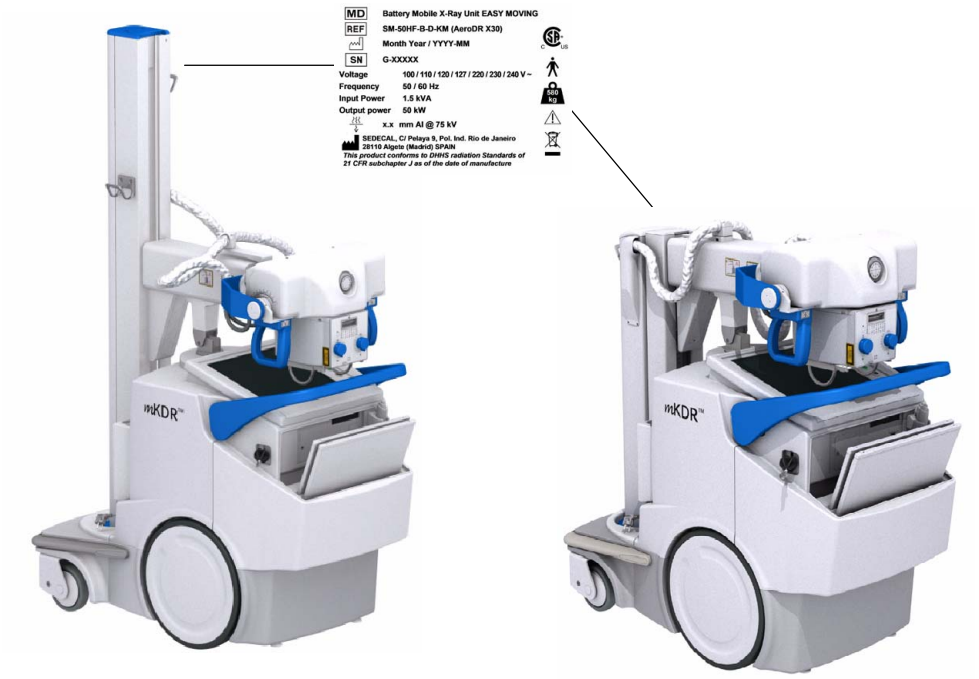
The main features of this Unit are:

- A solid and ergonomic design. Ease of operation; security and precision of all positioning movements relative to the patient.
- Standard electrical outlet operation with single-phase lines at 100 / 110 / 120 / 127 / 220 / 230 / 240 V~. Automatic line voltage compensation.
- Independent operation without mains connection (Stand-Alone). In normal operating conditions, the Battery Charger keeps batteries stable and fully charged, provided the Unit is connected to the mains (charging).
- Constant potential high frequency.
- Controls at the Handlebar and Tube-Collimator Assembly for motorized movements of the equipment.
- Controls for lock release of Rotating Column (Standard or Telescopic) and Telescopic Arm. Column rotation in relation to its vertical axis (±317º), telescopic and vertical motion of the Arm.
- Tube-Collimator Assembly rotation in relation to its transverse axis (360º) and horizontal axis (120º). Collimator rotation in relation to its vertical axis (180º).
- Three Point control by selecting kVp, mA and Exposure Time or Two Point control by selecting kVp and mAs.
- Anatomical Programmer (APR) and operation through the Digital Radiographic Application ULTRA.
- X-ray Handswitch for X-ray exposures.
- Remote infrared X-ray Handswitch (optional).
- Manual Collimation.
- Heat Unit storage for the X-ray Tube, even after turning On / Off the equipment.
- Tube protection circuitry prolongs Tube life and increases system performance.
- Equipped with closed loop control of X-ray Tube current, kVp and filaments, which minimize potential errors and the need for readjustments.

1.2 PRODUCT IDENTIFICATION

To provide manufacturer and product information, each major item in the equipment has identification labels attached. The labels contain the following information:

- Product and Model
- Date of manufacture.
- Serial number.
- Voltage (V), Frequency (Hz), and Power (kVA, kW).
- Inherent Filtration.
- Manufacturer and place of manufacture.
- Certifications and Symbols.



1.3 INDICATIONS FOR USE

1.3.1 INTENDED USE

This equipment is intended for use by qualified personnel only.

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

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

This **Mobile X-Ray Unit** contributes to the metrics of imaging performance ensuring the efficient use of radiation.

The X-Ray image receptors used in this unit are Digital Detectors.

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.

If children are to be examined, they should always be accompanied by an adult.

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SECTION 2 SAFETY AND REGULATORY INFORMATION

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

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

2.1 GENERAL

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

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

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

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

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

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

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

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

WARNING

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

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

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

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

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

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

2.2 RESPONSIBILITIES

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

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

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

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

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

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

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

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

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

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 THE ACCESS TO THE UNIT 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 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 Receptor distance (SID: Source to Image Distance): the greater the SID distance, the lower the radiation dose. The radiation dose is inversely proportional to the distance squared.

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

- Use Grids whenever possible.

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

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

2.5 MONITORING OF PERSONNEL

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

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

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

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

2.6 SAFETY SYMBOLS

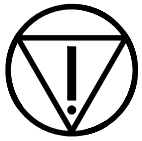
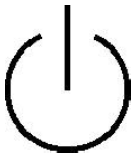
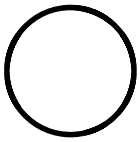
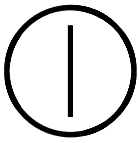
The following safety symbols may appear in the equipment.

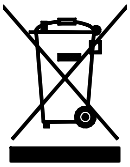
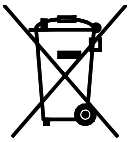
Their meaning are described below.

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

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

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

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

Statement of Compliance with IEC 60601–1–3: ***Mobile X-Ray Unit*** *with radiation protection in accordance with IEC 60601-1-3:1994, IEC 60601-1-3:2008 and IEC 60601-1-3:2008+AMD1:2013.*

Statement of Compliance with IEC 60601-2-54: ***Mobile X-Ray Unit*** *for Radiography and/or Radioscopy in accordance with IEC 60601-2-54:2009 and IEC 60601-2-54:2009+AMD1:2015.*

Statement of Compliance with 21CFR Subchapter J: *This* ***Mobile X-Ray Unit*** *conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.*

Note ☞ ***Mobile X-Ray Unit*** *model or type references are stated at the back cover of this document.*

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

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

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

2.7.3 MODE OF OPERATION

- *Continuous operation with intermittent loading,* in accordance with Standard IEC 60601–1:1988.
- *Continuous operation,* in accordance with Standard IEC 60601-1:2005 and IEC60601-1:2005+AMD1:2012.

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

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

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

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

2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

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

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

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

2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

2.7.8 DESIGNATED SIGNIFICANT ZONES OF OCCUPANCY

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

Illustration 2-1
Radiographic Examination on the Chest Unit or Front Panel

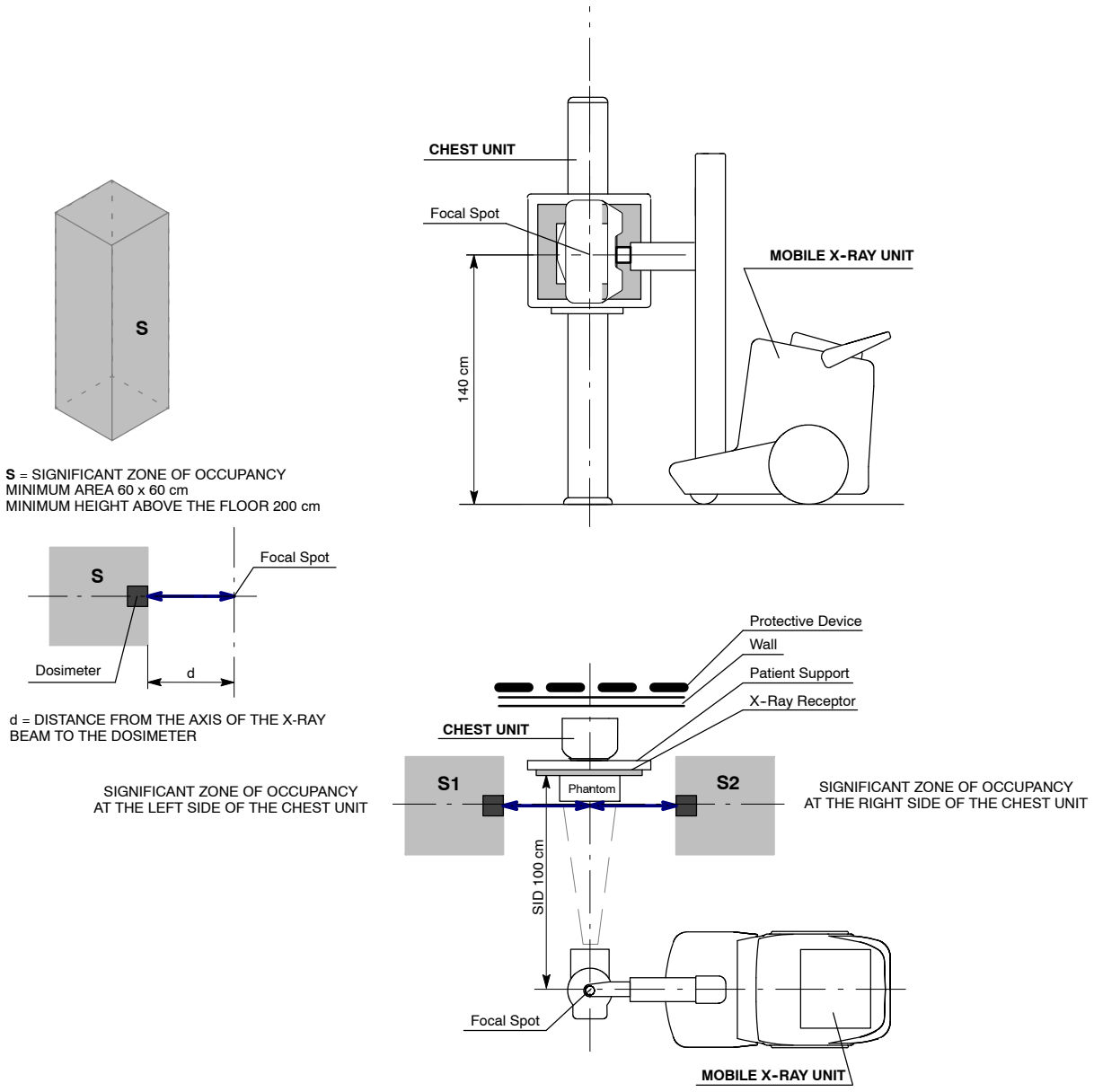
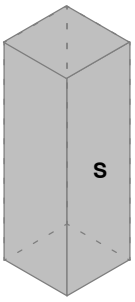
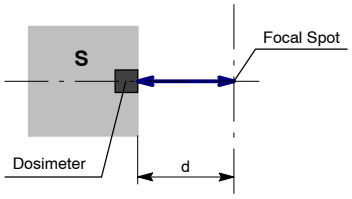


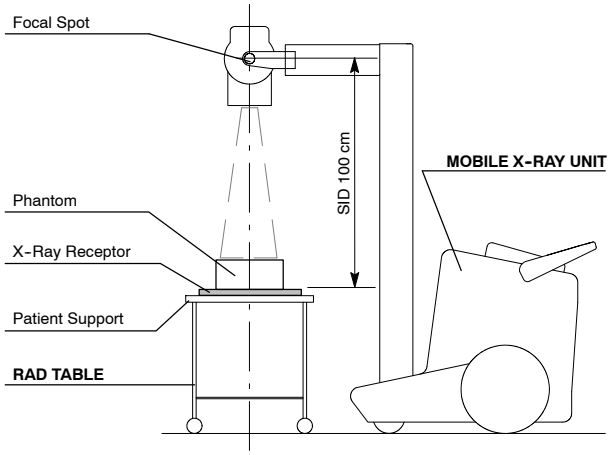
Illustration 2-2
Radiographic Examination on any Patient Support or any Table



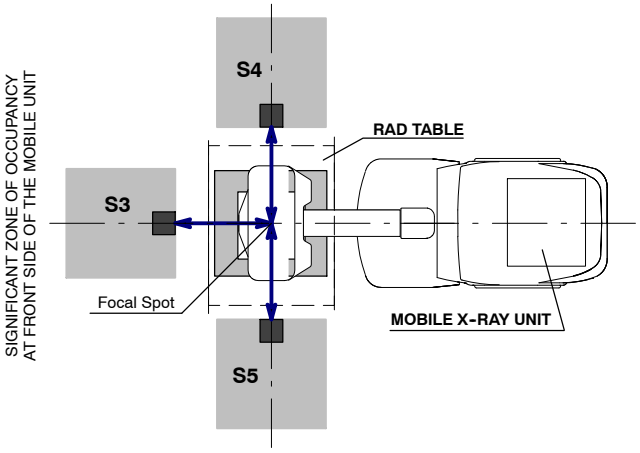
S = SIGNIFICANT ZONE OF OCCUPANCY
MINIMUM AREA 60 x 60 cm
MINIMUM HEIGHT ABOVE THE FLOOR 200 cm



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



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



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

2.7.9 DISTRIBUTION OF STRAY RADIATION

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

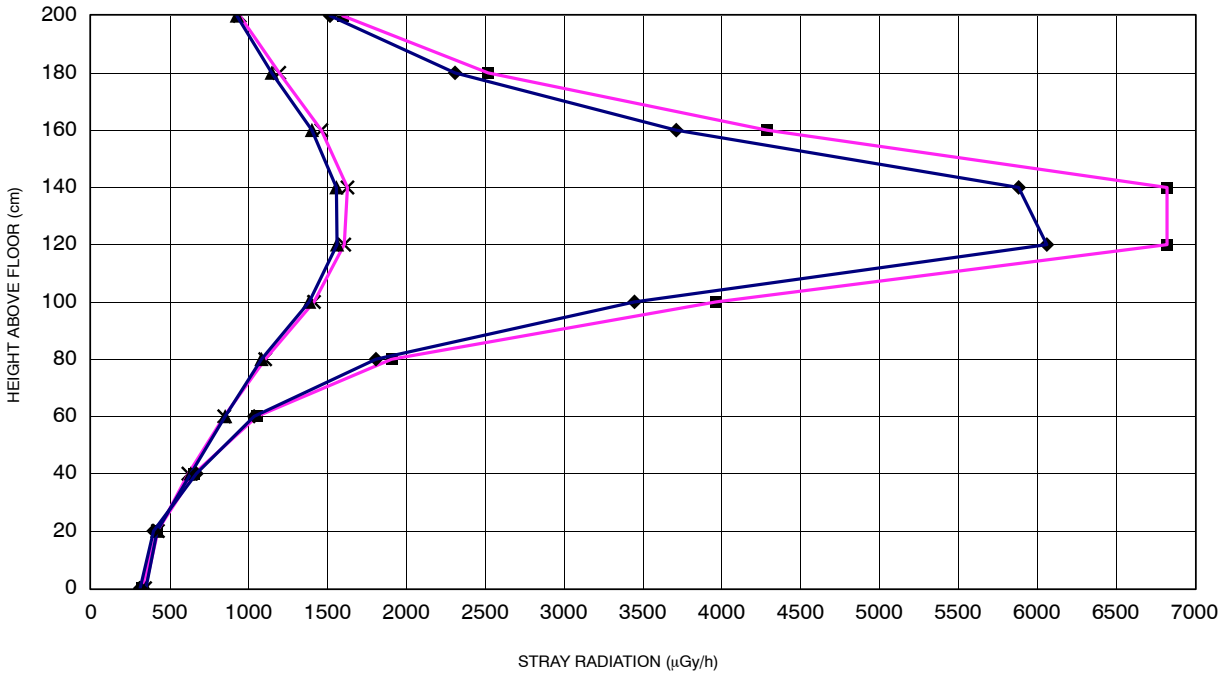
- Exposure Parameters: RAD mode, 150 kVp, 20 mAs.
- Collimator opening for Field Size 18 x 18 cm, SID 100 cm.
- Phantom: Rectangular water phantom of 25 x 25 x 15 cm, or a material having a similar X-Ray attenuation coefficient.
- Radiation measuring instrument: Low Radiation Dosimeter.

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

Refer to Illustration 2-1 for position of the X-ray Unit during radiographic examination on the Chest Unit or Front Panel, and refer to Illustration 2-2 for position of the X-ray Unit during radiographic examination on any Patient Support or any Table.

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

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



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

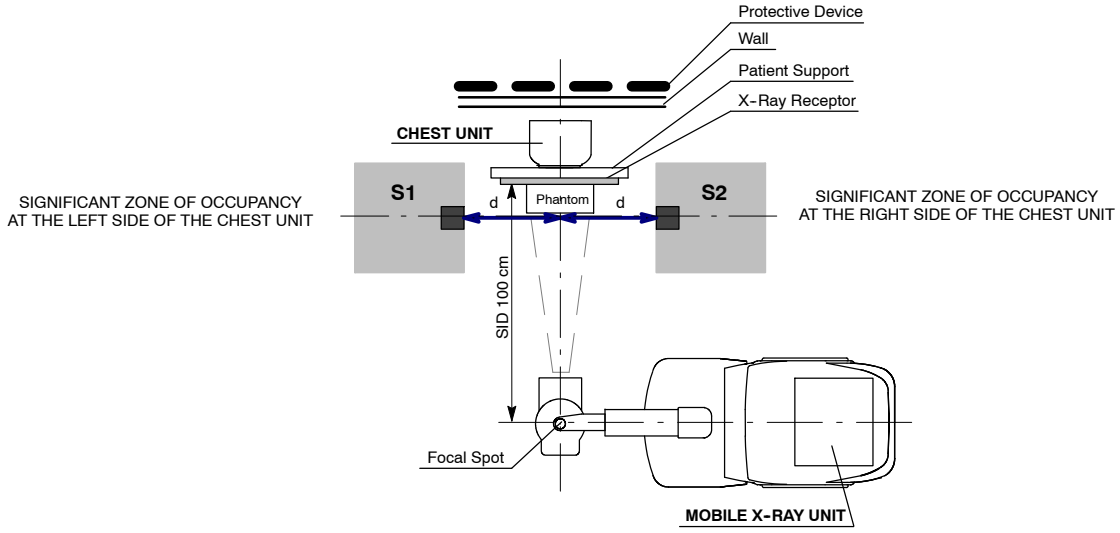
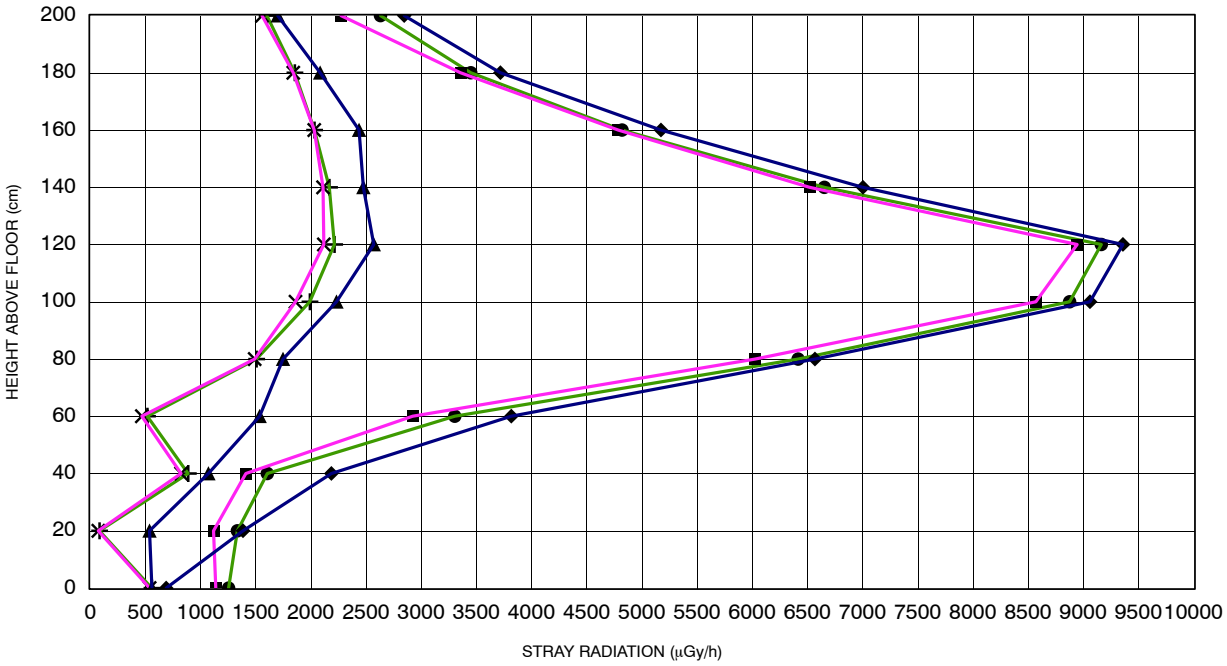
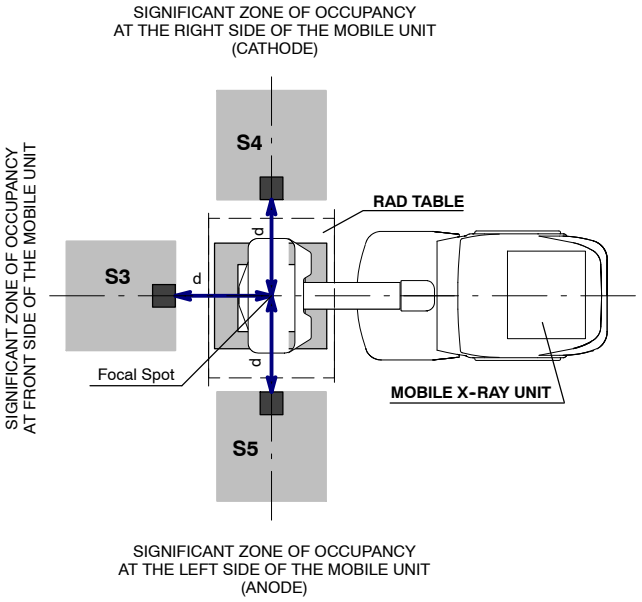


Illustration 2-4
Distribution of Stray Radiation on any Patient Support or any Table



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



2.8 ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

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

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

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

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

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

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

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

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

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

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2007)			
This X-ray System is intended for use in the electromagnetic environment specified below. The customer or the user of this X-ray System should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2:2007 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000–4–5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000–4–11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5s	> 95 % for 0.5 periods 60 % for 5 periods 30 % for 25 periods 100 % for 250 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Mobile Unit requires continued operation during power mains interruptions, it is recommended that the Mobile Unit be powered from a uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000–4–8	3 A/m	3 A/m (50 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE – U_T is the a.c. mains voltage prior to application of the test level.			

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

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE X-RAY SYSTEM (IEC 60601-1-2:2007)

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

TYPICAL RF DEVICES (Worst-Case scenario)

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

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

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

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

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

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014)			
This X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of this X-ray System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T for 0.5 cycle at 0°, 45°, 90°,135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25/30 cycles at 0° 0% U_T 250/300 cycles	0% U_T for 0.5 cycle at 0°, 45°, 90°,135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25/30 cycles at 0° 0% U_T 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the This X-ray System requires continued operation during power mains interruptions, it is recommended that this X-ray System is powered from an Uninterruptible Power Supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE - U_T is the a.c. mains voltage prior to application of the test level.			

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

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

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

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

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

2.9 RADIO FREQUENCY INTERFERENCE NOTICE (USA)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- reorient or relocate the receiving antenna,
- increase the separation between the equipment and the receiver,
- connect the equipment into an outlet on a circuit different from that to which the receiver is connected,
- consult the dealer or an experienced radio/television technician for help.

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment. The customer is responsible for ensuring compliance of the modified product.

Only peripherals (computer input/output devices, terminals, printers, etc.) that comply with FCC class B limits may be attached to this computer product. Operation with noncompliant peripherals is likely to result in interference to radio and television reception.

All cables used to connect to peripherals must be shielded and grounded. Operation with cables, connected to peripherals that are not shielded and grounded may result in interference to radio and television reception.

2.10 QUANTITATIVE INFORMATION

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

2.10.1 FUNCTIONAL TESTS PERFORMED TO OBTAIN THE QUANTITATIVE INFORMATION

Equipment:

Note ☞ *These functional tests have been performed with the following configuration: Digital Detector, maximum power X-Ray Tube (50kW) and Collimator Ralco R221A. The results obtained with this configuration are representative of the worst case within the different configurations of the unit.*

Instrumentation used:

- Dosimeters:
  - VacuDAP Compact
  - Fluke 481
  - Unfors Xi R/F
- Thermohygrometer Testo 608–H2.
- Water Phantom made of Polymethyl-methacrylate (PMMA) layers: 25 cm x 25 cm x 15 cm.

Test details:

- The measurements were made using the most common APR configurations performed with this unit.

Quantitative Information													
	Loading Factors				Parameter Selection				Filtration	Measured Doses			
Patient examination (orientative)	kVp	mA	Time (s)	mAs	Focal Spot Selection	SID Source-Image Distance (cm)	Collimator blades opening (cm)	Grid	HVL (mm Al) measured value (min. value allowed)	Collimator Output Dose (µGy*m2)	Phantom Input Dose Rate (µGy/s)	Phantom Input Dose (µGy/mAs)	Phantom Output Dose (µGy/mAs)
CHEST AP	95	160	0.02	3.2	Small	120	35 x 43	No	3.9 (>3.4)	27.3	11210	70.4	0.19
NECK	85	100	0.02	2	Small	100	24 x 30	No	3.7 (>3)	12.7	8246	82.45	0.1
ABDOMEN AP	80	400	0.025	10	Large	100	35 x 43	No	3.5 (>2.9)	59.3	29950	75.87	0.15
HIP AP	75	400	0.04	16	Large	100	35 x 43	No	3.2 (>2.7)	82.5	26270	65.67	0.11
KNEE AP	65	200	0.025	5	Large	100	24 x 30	No	4.1 (>2.3)	9.6	8953	44.56	0.06
ANKLE AP	60	100	0.04	4	Small	100	24 x 30	No	3.8 (>2.1)	4	3973	39.73	0.05
FOOT AP	60	100	0.032	3.2	Small	100	24 x 30	No	3.8 (>2.1)	4.5	3204	32.2	0.094
SHOULDER AP	75	250	0.04	10	Large	100	24 x 30	No	3.2 (>2.7)	28	16200	64.61	0.12
ELBOW AP	60	100	0.04	4	Small	100	24 x 30	No	3.8 (>2.1)	6.7	3992	39.7	0.075
WRIST PA	60	100	0.032	3.2	Small	100	24 x 30	No	3.8 (>2.1)	5.4	3982	39.4	0.063
HAND PA	60	100	0.032	3.2	Small	100	24 x 30	No	3.8 (>2.1)	5.4	4042	40	0.094

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

2.11 DETERMINISTIC EFFECTS

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

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

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

Quantitative Information tables (*Refer to Section 2.10*) illustrate examples of available loading factors for image performance and supply Dose indication, which affect to the radiation quality or to the radiation dose rate applied in normal use.

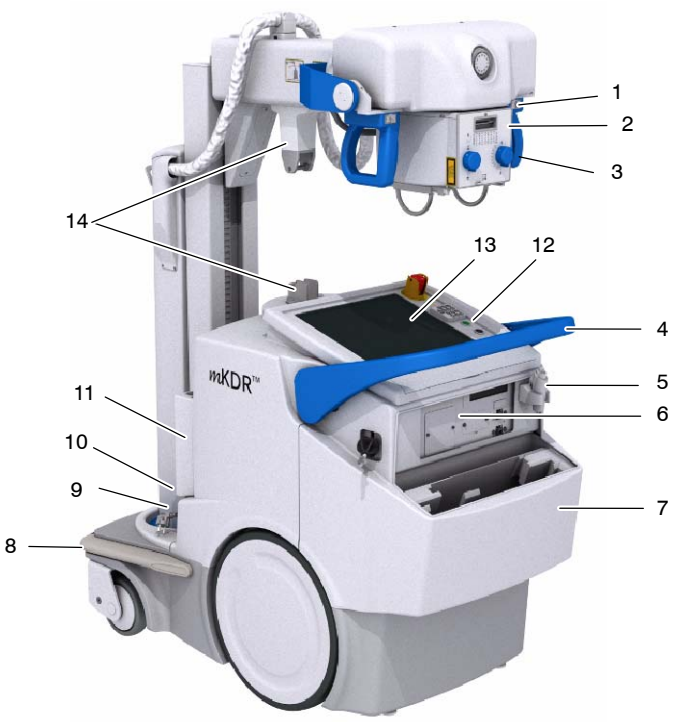
As indicated in the Quantitative Information Tables, the number of exposures needed to reach the previously described maximum radiation values will depend on the selected techniques for each radiographic study.

SECTION 3 GENERAL AND MOTION CONTROLS

Operation is carried out from the different controls:

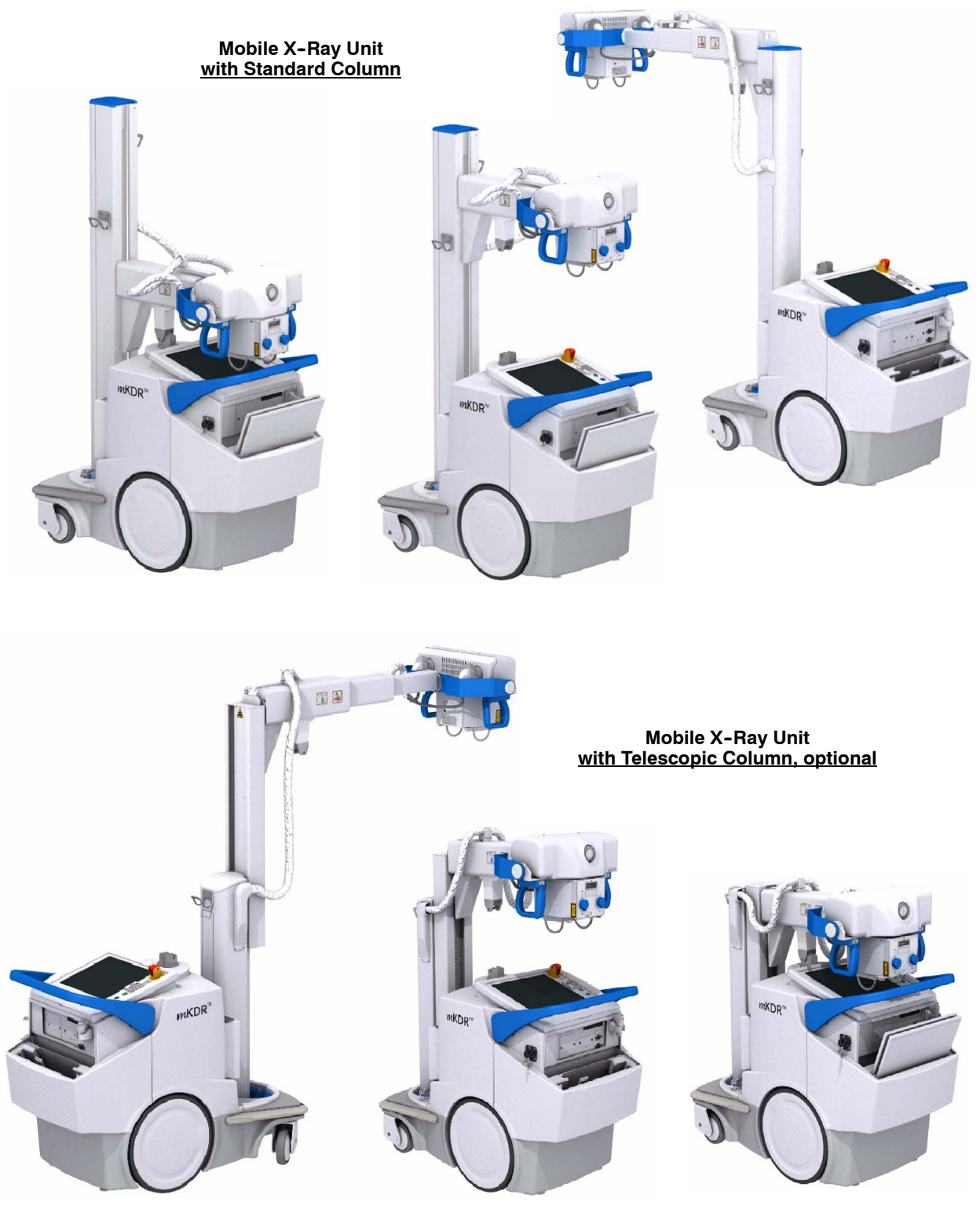
- Control Panel with controls to turn ON / OFF the Unit, Collimator Lamp control, Line connection indicator, Battery Charge Level indicators.
- Control Console.
- Handswitch.
- Remote Infrared Handswitch (optional).
- Line Circuit Breaker for the Battery Charging Circuits.
- Controls for Unit motion and controls for Column and Telescopic Arm movements.
- Manual Collimator Panel with controls for opening or closing the Collimator Blades and to switch ON the Collimator Lamp.

Illustration 3-1
Mobile X-ray Unit : General Features



1 Motion Controls
2 Collimator Panel
3 Tube-Collimator Handles
4 Handlebar
5 Handswitch
6 Peripheral Connections
7 Holder for Detectors and Accesories
8 Anti-Collision Bumper
9 Power Line Cable
10 Line Circuit Breaker
11 Grid/Accesories Box
12 Control Panel
13 Control Console
14 Parking Detent

Illustration 3-2
Mobile X-ray Unit: Column Options



3.1 MAINS CONNECTION AND LINE CIRCUIT BREAKER

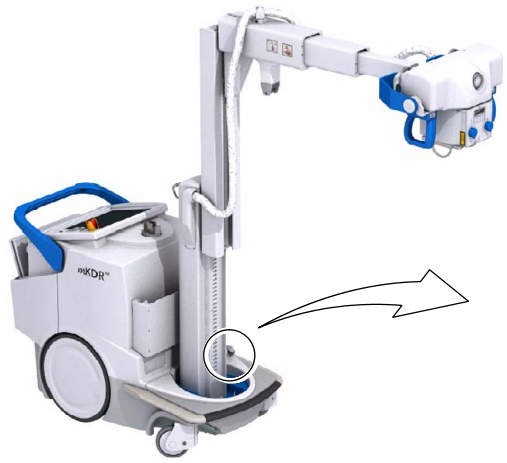
The Unit should be plugged into a wall socket compliant with local regulations and electrical requirements of the equipment (*refer to Section 7 for Technical Specifications*).

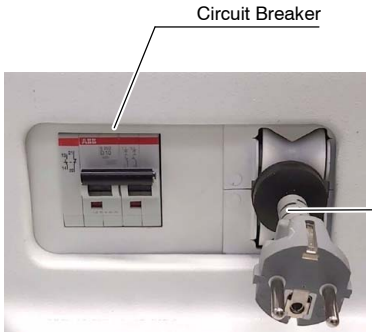
The Power Line Cable can only be replaced by the Service Personnel. The plug is the device used as a means of disconnecting the Unit from mains. Position the Unit so that the plug can be easily disconnected.

CAUTION

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

The Line Circuit Breaker in the ON position allows the Charging Circuits to charge batteries when the Unit is connected to the mains.





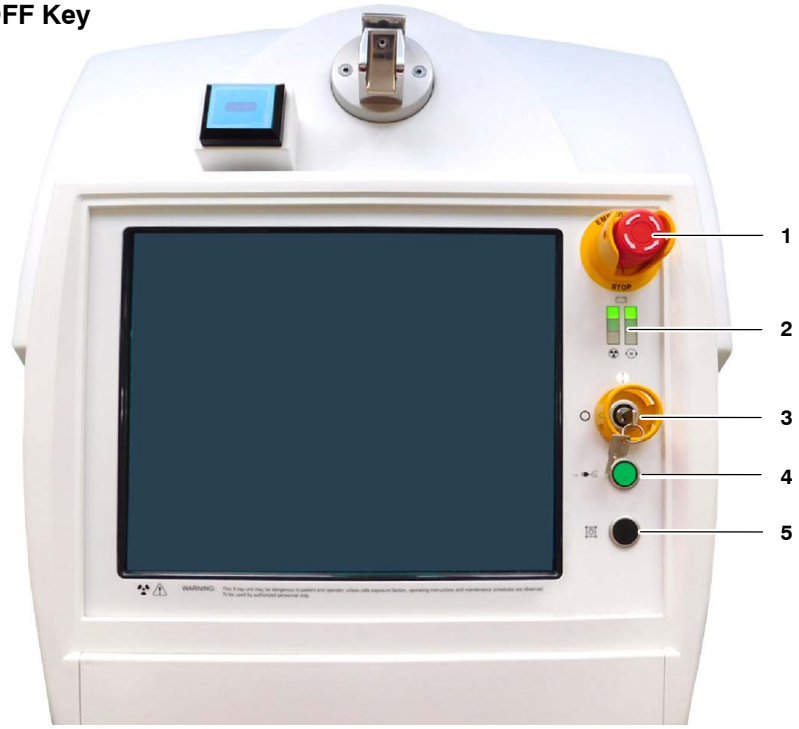
WARNING

WHEN NOT GENERATING X-RAYS, KEEP THE UNIT CONNECTED TO THE MAINS (MAXIMUM 48 HOURS) WITH THE CIRCUIT BREAKER IN THE ON POSITION, EVEN WHEN BATTERIES ARE FULLY CHARGED. THIS ENSURES MAXIMUM STORAGE ENERGY.

3.2 CONTROL PANEL

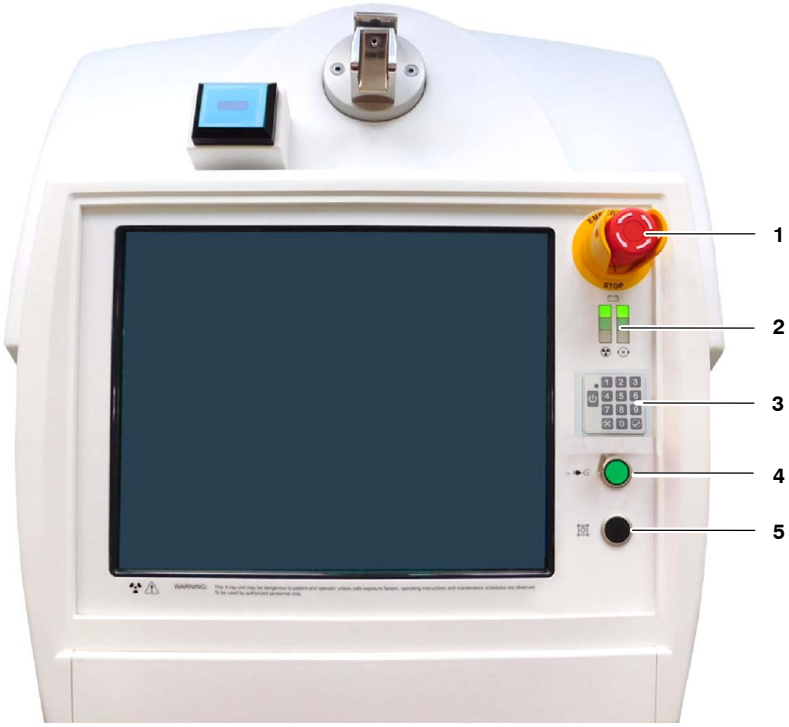
Control Panel with Switch ON / OFF Key

1 EMERGENCY SWITCH OFF
2 BATTERY CHARGE LEVEL
3 SWITCH ON / OFF CONTROL: KEY
4 POWER LINE CONNECTION LAMP
5 COLLIMATOR LAMP BUTTON



Control Panel with Keypad (Optional Configuration)

1 EMERGENCY SWITCH OFF
2 BATTERY CHARGE LEVEL
3 SWITCH ON / OFF CONTROL: KEYPAD
4 POWER LINE CONNECTION LAMP
5 COLLIMATOR LAMP BUTTON



3.2.1 ON / OFF CONTROL: SWITCH ON / OFF KEY

This key in the "*ON*" position is used to start the Unit, allowing the Mobile motion and switching ON the Generator and Console for radiographic operation. When the key is in the "*ON*" position, the symbol is illuminated on the Control Panel.

When the Console is turned ON, it starts a power-up routine for a few minutes until displaying the Login Screen of the *ULTRA* Application on the Console.

The key in the "*OFF*" position switches OFF all the equipment functions except for the Charging Circuits that are turned ON/OFF with the Line Circuit Breaker.

Note ☞ *After turning OFF the Unit, wait at least 10 seconds before turning it ON again. This action assures a proper start-up of the computer.*

3.2.2 ON / OFF CONTROL: KEYPAD

The Keypad is the means to turn the unit ON and OFF.

To turn the unit ON, press the "*ON*" button and the Led lights white.
Enter the Access Code digits, press the "*tick mark*" (✓) button and the Led lights blue.

When the Console is turned ON, it starts a power-up routine for a few minutes until displaying the Login Screen of the *ULTRA* Application on the Console.

To turn the unit OFF, press the "*OFF*" button for more than three seconds. The Keypad in the "*OFF*" position switches OFF all the equipment functions except for the Charging Circuits that are turned ON/OFF with the Line Circuit Breaker.

Note ☞ *After turning OFF the Unit, wait at least 10 seconds before turning it ON again. This action assures a proper start-up of the computer.*

3.2.3 EMERGENCY STOP

In the event of an emergency, the Unit is turned OFF by forcibly pressing this switch (red mushroom-shaped switch).

The Emergency Stop must not be used to switch OFF the Unit to avoid damaging the software. The switch is protected by a safety shield in order to prevent it from being accidentally pressed.

Note ☞ *For moving the Unit or charging the batteries, this device should not be pressed.*

3.2.4 POWER LINE CONNECTION LAMP

It indicates that the Mobile Unit is connected to the mains power supply for battery charging whenever the Line Circuit Breaker for Charging Circuits is in the "*ON*" position and the Emergency Switch-Off is not pressed.

IF THIS INDICATOR IS OFF DURING THE BATTERIES CHARGING PROCESS, AND THE VOLTAGE IS PRESENT IN THE MAINS, IT MAY BE DUE TO A DEFECTIVE BATTERY. IN THIS CASE, THE UNIT TURNS OFF AUTOMATICALLY TO AVOID OVERHEATING THE REMAINING BATTERIES. CONTACT TO THE TECHNICAL SERVICE.

The Unit can operate in Stand-Alone mode, that is, operating without mains being present or unplugged from mains.

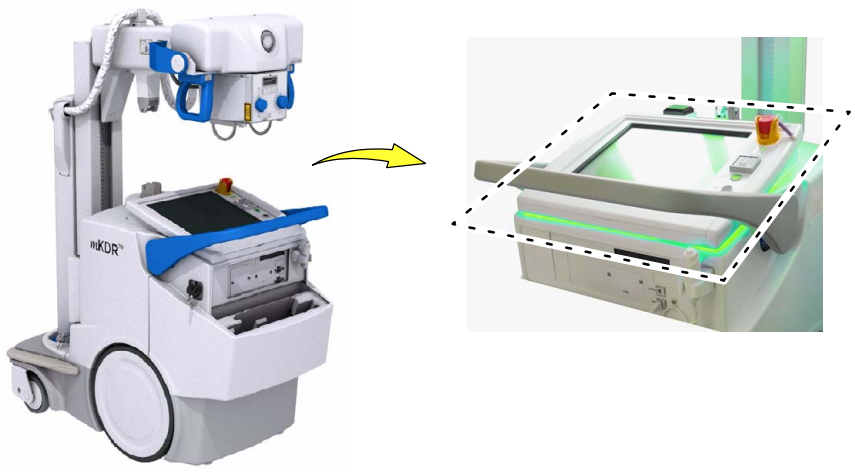
3.2.5 COLLIMATOR LAMP

This button is used to turn ON the Collimator Lamp from the Control Panel.

The Lamp remains illuminated for a few seconds before automatically switching off.

3.2.6 LED BEACON LIGHTS (OPTION)

The unit with Wireless Detectors can be provided with LED Beacon Lights, placed under the Control Console frame, indicating different status.



LIGHTS OFF → SYSTEM NOT PREPARED.
The LED Beacon lights are OFF when the Detector and/or the Generator are not prepared.

BLUE → SYSTEM PREPARED.
It lights when the Detector is ready, the RAD technique is correctly set and there is not Error or Interlock condition in the system.

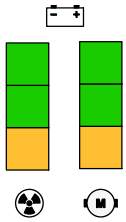
GREEN → READY STATE.
It lights when the System is READY for exposure. One single action initiates the exposure (loading state).

YELLOW → EXPOSURE (LOADING STATE).
It lights during the X-Ray Exposure.

MAGENTA (BLINKING)→ ERROR / INTERLOCK (ER/IL).
It lights during an Error or an Interlock (ER/IL) condition.
The exposure is not allowed until the Error or Interlock condition disappears.

Note ☞ *For further information, refer to Section 3.6 about the Exposure process and to Section 4 about Generator and System Messages.*

3.2.7 BATTERY CHARGE LEVEL INDICATORS



The column with the "*exposure*" symbol indicates the charge level of the Batteries used for radiographic operations (X-ray exposures) and the column with the "*motor*" symbol indicates the charge level of the batteries used for the Mobile motion (motors).

When plugged into the mains (with the Line Circuit Breaker ON and the Emergency Switch-Off deactivated), the Batteries automatically charge. The color Indicators on both columns illuminate and scroll from the current Generator battery charge level to 100%, until the Batteries are fully charged. During the charging process both columns scroll up from the same level.

Note ☞

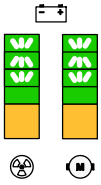
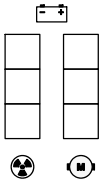
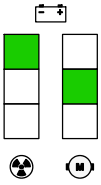
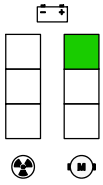
The Batteries require approximately 9-10 hours for a fully charge, depending on the type of Batteries installed in the Unit (refer to Section 7.1). To charge the Batteries, there is not need to have the Console turned ON. When the Batteries are fully charged, the Battery charge level Indicators on both columns stop scrolling and only the Upper Green Indicators remain illuminated.

When unplugged from mains, the Batteries discharge independently depending on their use (X-ray exposures or motors) since the Mobile is provided with two independent battery modules.

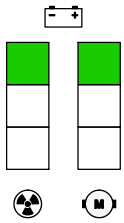
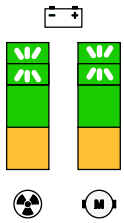
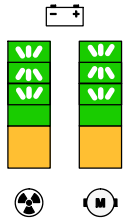
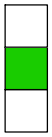
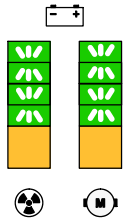
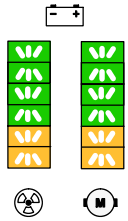
Note ☞

Upon disconnecting the Unit from the mains, if the Unit has been connected for a short period of time, after several exposures or after one heavy duty exposure, the Batteries need at least 30 seconds to stabilize the charge, after which the correct charge level is shown on the Indicator.

The Battery Charge Level Indicators can be:

MOBILE UNIT PLUGGED INTO MAINS	**MOBILE UNIT UNPLUGGED FROM MAINS**		
Key in "*OFF*" or "*ON*" position	Key in "*OFF*" position	Key in "*ON*" position and Console turned ON	Key in "*ON*" position and Console turned OFF
			
Both Columns are scrolling as described in the following Table.	Both Columns are OFF.	Each Column shows the respective Battery charge level as described in the following Table.	Only the Motors Column shows the respective Battery charge level as described in the following Table.

Both columns comprise three Indicators, each one representing a battery status as described below:

MOBILE UNIT IN CHARGING MODE (PLUGGED TO MAINS)		MOBILE UNIT IN STAND-ALONE MODE (UNPLUGGED FROM MAINS)	
LED INDICATORS AND STATUS		**LED INDICATORS AND STATUS**	
	After charging during approximately 9-10 hours, the upper Green Indicators are lighting steady and the rest of the Indicators below are off. The batteries charge level is 100 % of the total charge.		When the upper Green Indicators light steady, normal operation is allowed.
	After charging during approximately 5 to 9–10 hours, the upper Green Indicators are scrolling up and the lower Green Indicators and the Orange Indicators are lighting steady.		
	After charging during approximately 3 to 5 hours, Indicators are scrolling up from the upper half of the lower Green Indicators and the rest of the Indicators below are lighting steady.		When the lower Green Indicators light steady, normal operation is allowed although it is recommended to charge the Batteries.
	After charging during approximately 1 to 3 hours, all Green Indicators are scrolling up and the Orange Indicators are lighting steady.		When the lower Green Indicators start blinking, normal operation is allowed but it is urgent to charge the Batteries.
	After charging during approximately less than 1 hour, all the Indicators are scrolling up.		When the Orange Indicator blinks, exposures are not allowed. It is necessary to charge the Batteries.

Indicator colors: *Green* *Orange* *Indicator Off* *Blinking / Scrolling*

3.3 BATTERY STATE ALERT SCREENS

The following functions may be activated by the Service Engineer during configuration of the Console applications. Two Battery State Alerts can be shown on the RAD screen:

- ***Autoshutdown Alert*** – After 30 minutes without activity in Stand-Alone mode, the PC beeps and the RAD screen alerts the User of an automatic shutdown within 15 minutes unless the operator presses on "*OK*" or until the Unit is connected to the mains. It delays the *"Autoshutdown Alert"* for another 30 minutes without activity.

  If the Operator does not respond to the prompt within 15 minutes, the Unit will automatically shutdown in one minute.

- ***Battery Charge Level Alerts.***

  - *Low Battery Level Alert* – This alert appears on the Console when the lower Green Indicator lights steady on the Console, with the unit disconnected from mains (not charging). It means that normal operation is allowed and recommends the operator to connect the unit to a power source for better battery usage. The message disappears after a few seconds or by clicking on the "*Exit*" symbol, then the work can be continued.

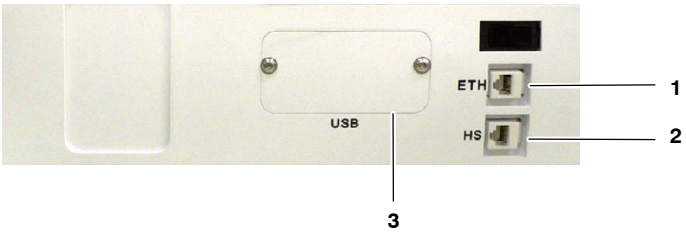
  - *Very Low Battery Level Alert* – When the lower Green Indicator begins to blink, with the unit disconnected from mains, a new message pops up indicating that the unit has reached a "*Very Low Battery Level*". It means that normal operation is allowed although it is urgent to connect the unit to mains. The message disappears after a few seconds or by clicking on the "*Exit*" symbol, then the work can be continued.

  - *Critical Battery Level Alert* – When the Orange Indicator blinks on the Console, with the unit disconnected from mains, a new message is shown on the screen to inform that the unit has reached a "*Critical Battery Level*". This means that operation is not allowed and the Unit should be connected to a power source for battery charging. The application initiates a shutdown with a 30 minutes countdown, that can be stopped connecting the unit to the mains. If still unplugged after the countdown has expired, the Unit will automatically shutdown.

3.4 PERIPHERAL CONNECTIONS

The Mobile Unit has a Peripheral Connections Panel with:

1. **Ethernet (ETH)** connector.
2. **Handswitch (HS)** connector.
3. **USB** Ports, Keyboard and Mouse connections (for Technical Service).

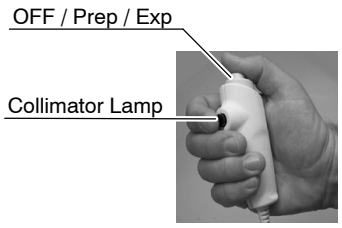


3.5 CONTROL CONSOLE

Konica-Minolta ULTRA Software Application is shown on the Control Console, it includes the Generator Control Panel with the controls, indicators and displays needed to perform radiographic exams.

For further details, refer to the User Manual of the Konica-Minolta ULTRA Software Application.

3.6 X-RAY HANDSWITCH



Radiographic exposures are controlled with the "*Prep*" (preparation) and "*Exp*" buttons on the X-ray Handswitch. The status of the exposure is shown by the "*Ready*" and "*X-ray On*" indicators for the duration of the exposure.

PREP: Press the Handswitch button half-way (*"Prep"* position) to prepare the X-ray Tube for exposure. The *"Ready"* indicator on the Console lights when the X-ray Tube is prepared and there are neither interlock failures nor system faults.

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

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

Note ☞ *The Unit cannot perform exposures when the Column is rotated towards parking position.*

EXP: After the "*Ready*" indicator is illuminated, fully press the Handswitch button to start an X-ray exposure. If the button is released before the Generator completes the selected time, the system aborts exposure and the actual mAs and Exposure Time will be displayed.

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

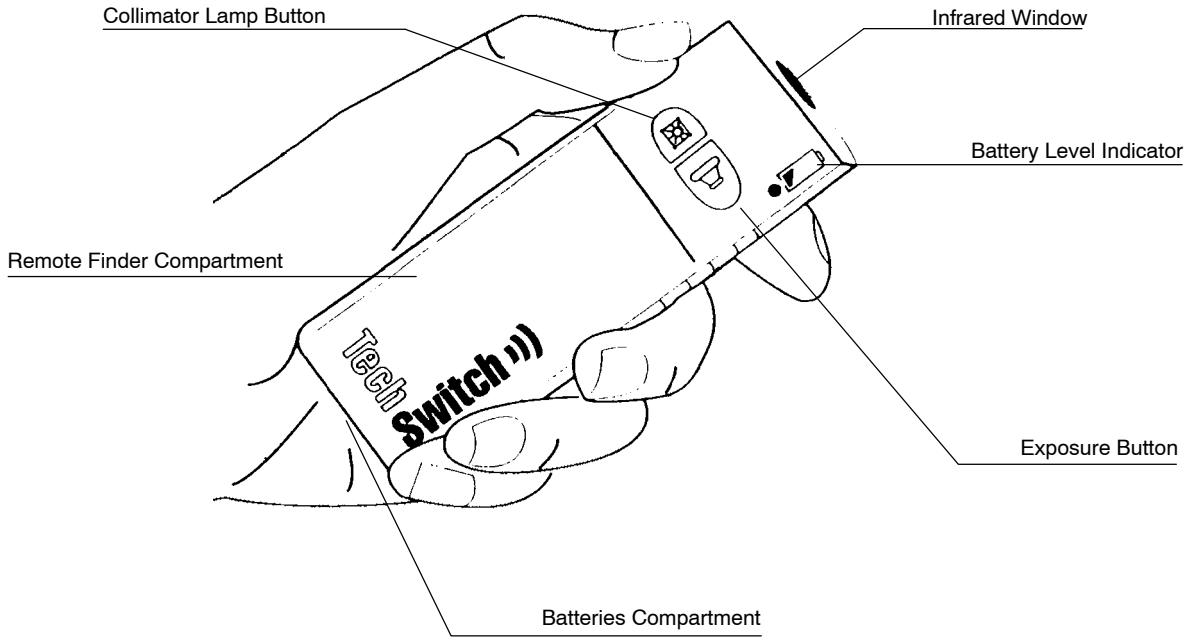
COLLIMATOR LAMP: This X-ray Handswitch includes an extra Collimator Lamp Button that helps patient positioning. Pushing this button will turn on the Collimator Lamp. The Lamp remains illuminated for a few seconds before automatically switching off.

CAUTION

The handswitch cable must be placed in such a way not to interfere the extraction or insertion of the Detector in its housing inside the Holder.

3.7 INFRARED REMOTE CONTROL (OPTIONAL)

The Infrared Remote Control permits the operator to perform exposures at a distance from the X-Ray Tube to protect against radiation.



CAUTION

Before starting the exposure, ensure that there are no other equipment operating with an Infrared Remote Control at the same time, neither close to nor behind windows or lead glass screens in the room. Before carrying out an exposure with this device, turn off any other units operating with an Infrared Remote Control that might be affected by this control.

CAUTION

Unused devices must be switched off, use only one device with remote control per room.

3.7.1 OPERATION

Take the Remote Exposure Control device out of its cradle. Aim the Remote Control at the sensor on the Mobile Unit from a maximum distance of 10 meters.

COLLIMATOR LAMP BUTTON: Press this push-button to turn on the Collimator Lamp.

EXPOSURE CONTROL : Press this button once to prepare the X-ray Tube for exposure ("*Prep"* position). When the X-ray Tube is *"Ready"* (green light ON), press this push-button again and hold it down until the X-ray Unit completes the exposure ("*Exp"* position).

Note ☞ *The Unit cannot perform exposures when the Column is rotated towards parking position.*

When the exposure is completed the green light indicator turns OFF. Return the Control Remote device back to its cradle on the Mobile Unit.

The preparation cycle automatically aborts and returns to Stand-by Mode if an exposure is not initiated within 15 seconds after the *"Prep"* command or if the Collimator Lamp is turned ON during this cycle.

The exposure aborts if the *"Exposure"* button is released.

3.7.2 THE "REMOTE FINDER" DEVICE

The Remote Exposure Control has a built-in remote finder which is very useful for locating the remote control device should it become misplaced.

If the Remote Exposure Control is not returned back to its cradle within three minutes after use, the device will repeat a series of beeps. This series of beeps will continue indefinitely until the device is located and put back into its cradle.

3.8 MOTION CONTROLS

DRIVE THE UNIT WITH THE ARM IN PARKING POSITION. WHEN NOT IN PARKING POSITION, MOVEMENT VELOCITY IS REDUCED SIGNIFICANTLY.

FOR SAFETY REASONS, DO NOT DRIVE THE UNIT OVER SURFACES WITH AN INCLINATION ANGLE >5º.

TO AVOID THE RISK OF OVERBALANCE, THE MOBILE UNIT MUST NOT BE IN STATIONARY POSITION ON SURFACES WITH THE FOLLOWING INCLINATION ANGLES:

- **WITH THE ARM IN PARKING POSITION: >10º**
- **WITH THE ARM OUT OF PARKING POSITION: >5º**

IF FOR ANY REASON THE UNIT EXCEEDS THE INDICATED INCLINATION ANGLES AND LOSES THE VERTICALITY, THE ARM COULD RISE SHARPLY TO THE TOP OF THE COLUMN; THIS COULD CAUSE PERSONAL INJURY AND/OR DAMAGE TO THE EQUIPMENT.

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

DO NOT DRIVE THE MOBILE UNIT OVER WET SURFACES AND / OR IMPREGNATED WITH CLEANING PRODUCTS (SPECIALLY BLEACH, AMMONIA, ETC), THE UNIT COULD SLIP AND MOMENTARILY LOSE CONTROL. IT ALSO MAY BLEACH THE WHEELS CAUSING DAMAGES TO THE FLOOR.

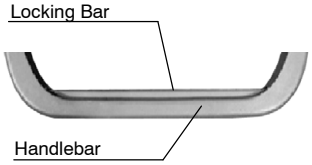
MONITOR WITH SPECIAL CARE THE PATIENT POSITION OR ANYONE PRESENT, TO AVOID INJURY CAUSED BY UNIT MOVEMENTS.

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

Motion Controls are only enabled when the Switch-Key on the Control Panel is in the "ON" position.

Always place the Unit in Parking position before turning the Generator and Console off, even though lock controls will remain enabled for 15 seconds after turning off both the Generator and Console in order to place the Unit in Parking position.

3.8.1 DISPLACEMENT CONTROLS



HANDLEBAR:

It is provided with internal sensors that control the direction and speed of each wheel, based on the pressure that the operator applies upon the Handlebar.

The Unit is driven by first gripping and holding the Locking Bar towards the Handlebar. The Locking Bar is released to block motion.

CAUTION

When the Arm is in parking position, the Unit travels at the configured velocity (approx. 5 km/h (3.1 mph) forwards and 2.5 km/h (1.6 mph) backwards).

This velocity reduces considerably when the Arm is not in Parking Position (approx. 1.6 km/h (1 mph)).

Velocity can be configured by service personnel.

WARNING

DUE TO THE WEIGHT OF THE MOBILE UNIT, THE BRAKING DISTANCE AT FULL SPEED ON A SMOOTH SURFACE IS 1 METER MAXIMUM.

Note ☞

Displacement cannot be performed when the Unit is connected to the mains.

CAUTION

In order to avoid uncontrolled displacement of the Unit during the Start-up, due to a failure of the displacement controls (Handlebar pressed, pulled or short-circuited), movements controlled with the Handlebar are blocked although the unit can be controlled with the Fine Positioning Controls.

The unit displacement can also be blocked during the driving.

An audio signal is emitted (beep sequence in 2 seconds intervals) to alert the user about a failure condition (refer to Table 3-1).

Table 3-1
Beep Sequence – Failure condition

BEEP SEQUENCE	DESCRIPTION	DESCRIPTION	ACTION
1 beep	Handlebar activated during startup (deadman).	Mobile movements are only allowed using the Fine Positioning Controls.	Ensure that the Handlebar (deadman) is not pressed and then, try to drive the unit using the Handlebar. If the problem persists, restart the unit. If the handlebar (deadman) is still blocked or any of the displacement controls does not respond, contact Technical Service.
2 beeps	Motor Current Error.	Mobile movements are not allowed.	Restart the unit and try to drive the unit again. If the problem persists, contact Technical Service.
3 beeps	Handlebar pressed or pulled during startup.	Mobile movements are only allowed using the Fine Positioning Controls.	Ensure that the Handlebar is not pressed nor pulled and then try to drive the unit using the Handlebar. If the problem persists, restart the unit. If the handlebar is still blocked or any of the displacement controls does not respond, contact Technical Service.
4 beeps	Fine Positioning Controls on the Handgrips activated during startup.	Mobile movements are only allowed using the Handlebar.	Ensure that the Fine Positioning Controls are not pressed and restart the unit. Try to drive the unit using the Fine Positioning Controls. If the problem persists, contact Technical Service.
6 beeps	Motor Encoder Error.	Mobile movements are not allowed.	After releasing the Handlebar and pressing on it again, it is allowed driving the unit at slow speed, in order to move it to an adequate area for servicing purposes. Contact Technical Service.
8 beeps	Gauges Failure.	Mobile movements are only allowed using the Fine Positioning Controls.	Move the unit to an adequate area for servicing purposes. Contact Technical Service.
No Beep	Fatal error.	Mobile movements are blocked.	Contact Technical Service.
Continuous Beep	Fatal error.	Mobile movements are blocked.	Contact Technical Service.

FINE POSITIONING CONTROLS:

The four buttons on the Hand-grips control the motion of each driving wheel (forwards / backwards). This permits fine positioning adjustment of the Unit respecting the patient, with the operator positioned opposite the Tube-Collimator Assembly.

Fine Positioning velocity is reduced as this control is not designed for displacements.

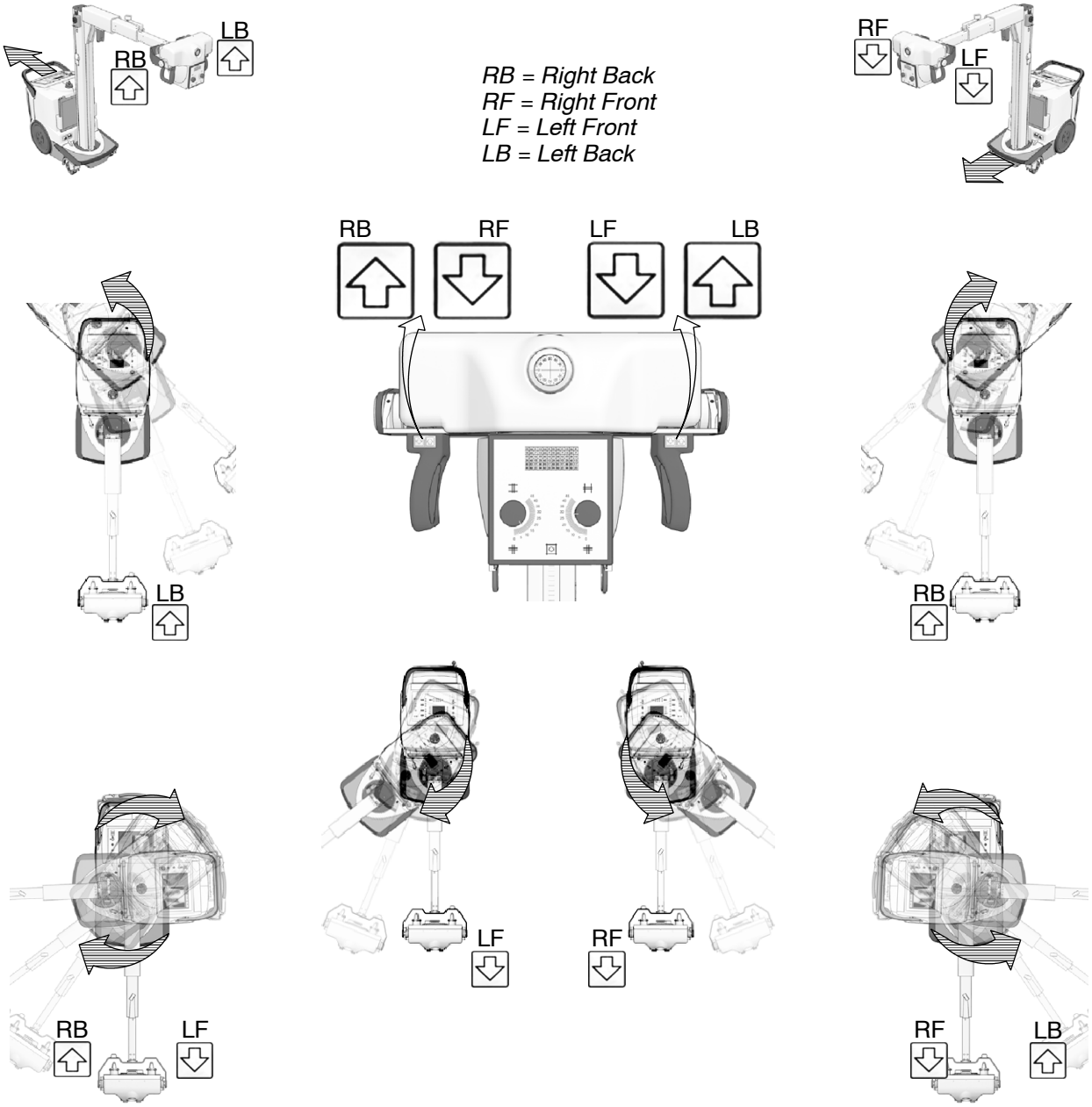
The buttons correspond to each motor and do not change when the Unit is in Parking Position.

In order to avoid uncontrolled displacement of the Unit during the Start-up, due to a failure of the displacement controls (Fine Positioning Controls pressed or short-circuited), movements controlled with these commands are blocked although the unit can be controlled with the Handlebar.

The unit displacement can also be blocked during the driving.

An audio signal is emitted (beep sequence in 2 seconds intervals) to alert the user about a failure condition (refer to Table 3-1).

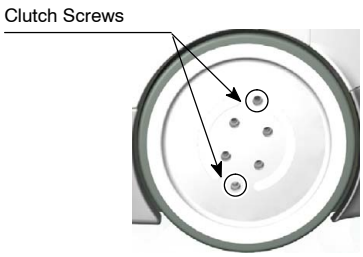
The illustration below details the corresponding movements. The buttons correspond to each motor and do not change when the Unit is in Parking Position.



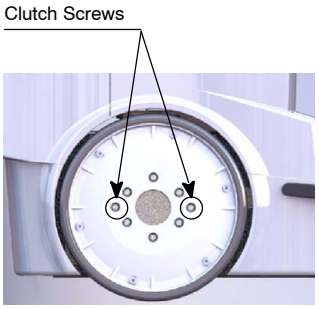
MANUAL CLUTCH SCREWS:

In case the Unit has to be moved manually, dismount the Hubcap and remove the two (2) Clutch Screws (Allen type) located on each wheel. This will uncouple the wheels from the motors (releasing the brakes) allowing the free motion of the Unit.

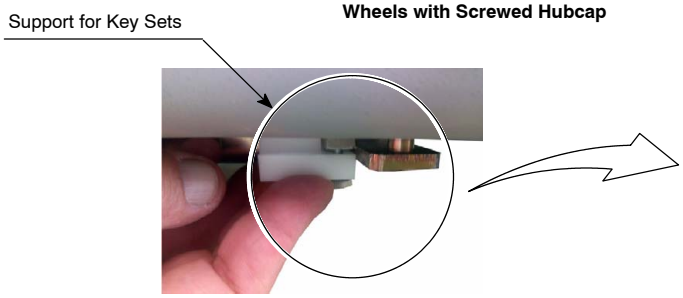
Depending on the type of Wheel, a Key Set is provided, located near the left Back Wheel of the Unit. For accessing this Key Set, dismount the Support from the lower side of the Mobile Unit.



Wheels with Screwed Hubcap



Wheels with Magnetic Hubcap



DANGER!

DRIVE THE UNIT MANUALLY ONLY WHEN MOTORIZED MOTIONS CANNOT BE PERFORMED (DUE TO MALFUNCTIONING OR MOTOR BATTERY DISCHARGE).

IN THIS CASE, NEVER DRIVE THE UNIT ALONG A RAMP OR INCLINED SURFACES, DRIVE IT ONLY IN FLAT SURFACES TO AVOID PERSONAL INJURIES OR DAMAGE TO EQUIPMENT DUE TO ITS HEAVY WEIGHT.

Front Bumper

FRONT BUMPER:

It is equipped with several sensors that stop motor movement in the event of a frontal collision.

Note ☞ *The Lateral Bumpers are not equipped with sensors.*

3.8.2 PARKING POSITION OF THE ARM

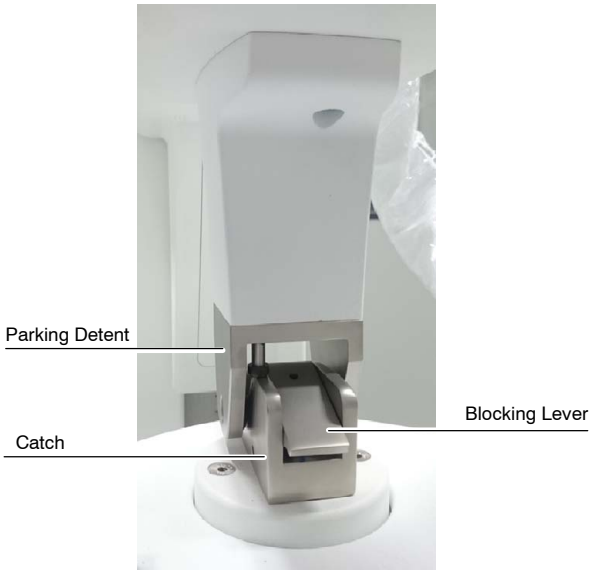
The Unit is in Parking Position when the Parking Detent is secure in the Catch.

Place the Arm in Parking Position as follows:

- Fully retract the Telescopic Arm and turn the Column until the Parking Detent is aligned with the Catch.
- Lower the Arm and fully insert the Parking Detent into the Catch, until a “click” is heard. The Blocking Lever down indicates that it has been properly placed in Parking Position.

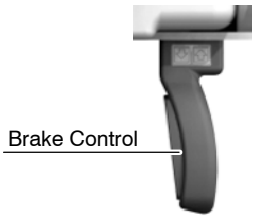
To release the Arm from Parking Position. push down the Arm while pressing on the Brake Control at the Tube-Collimator Assembly.

or



ALWAYS KEEP THE ARM IN PARKING POSITION EXCEPT WHEN PERFORMING RADIOGRAPHIC EXAMS. THIS WILL PREVENT INJURIES OR UNIT DAMAGE DURING DISPLACEMENT.

3.8.3 MOVEMENT CONTROLS OF THE COLUMN AND TELESCOPIC ARM



Both Tube-Collimator Assembly Handgrips have a Brake Control that releases or locks Column rotation and vertical and telescopic Arm movements. This control also releases the Arm Catch when in parking position.

Press and hold the Brake Control to move the Column and Arm until the Tube-Collimator Assembly is positioned. Release the control to lock in place.

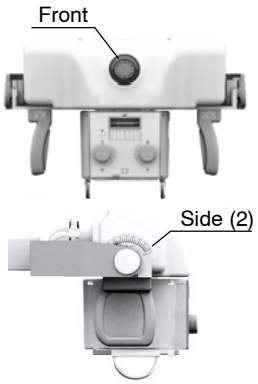
WARNING

ALWAYS USE THESE HAND-GRIPS TO CONTROL AND DRIVE THE COLUMN AND ARM MOVEMENTS, NEVER PUSH DIRECTLY ON X-RAY TUBE OR COLLIMATOR.

The Column can rotate from its parking position: ±317º.

The Arm allows a vertical travel of 1470 mm for Standard Column, 1340 mm for Short Column or 1490 mm for Telescopic Column, and a telescopic travel of 540 mm for Standard Column or for Telescopic Column.

Rotation Indicators



These Hand-grips are also used (without having to press the Brake Control) to rotate the Tube-Collimator Assembly from its vertical position:

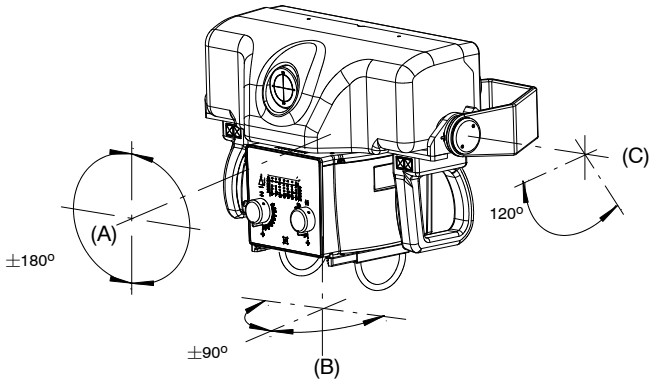
- ±180º on its transversal axis (A).
  This movement has detents every 90º.

  The angle is indicated in the rotation indicator located on the X-Ray Tube.

- 120° on its horizontal axis (B).

  The angle can be indicated in the Rotation Indicators (optional), at both sides on the X-Ray Tube.

The Collimator can rotate ±90° on its vertical axis (C) while the Tube remains in the same position. This movement is performed by manually turning the Collimator and has detents every 90°.

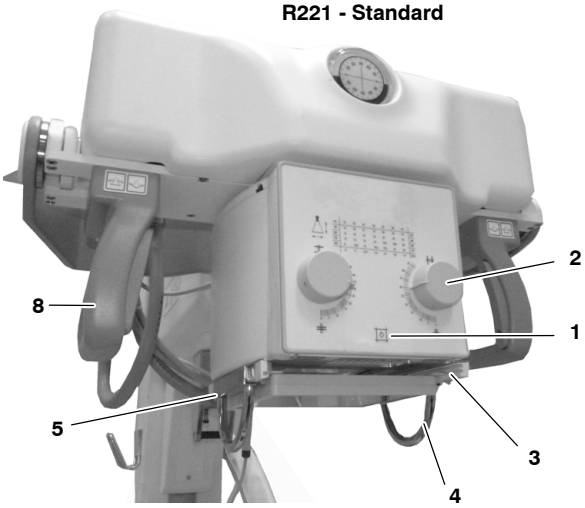


Note ☞ *Due to geometric restrictions related to the anode angle of the X-Ray Tube, a minimum SID is required to cover the full image size of the Detector, depending on the Collimator position:*

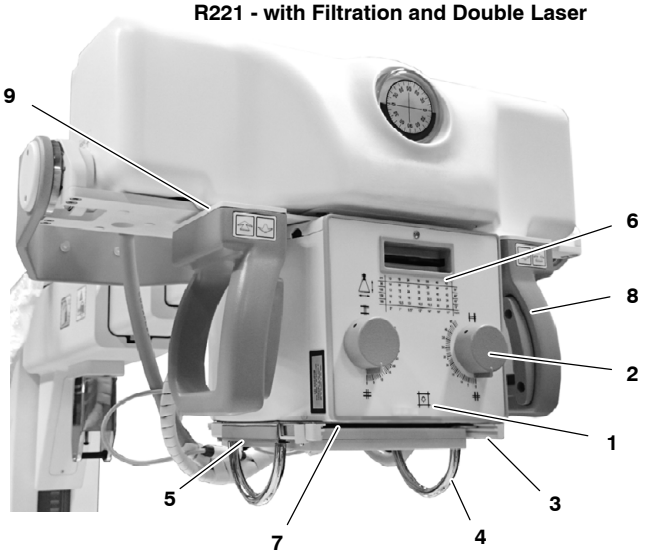
X-Ray Tube Anode Angle	Receptor Size	Required SID with Collimator rotated at:	
		0° or ±90°	±45°
12°	24X30 30X24	SID ⩾ 65 cm	SID ⩾ 85 cm
	35X43 43X35	SID ⩾ 90 cm	SID ⩾ 125 cm
	43X43		
16°	24X30 30X24	SID ⩾ 55 cm	SID ⩾ 65 cm
	35X43 43X35	SID ⩾ 75 cm	SID ⩾ 90 cm
	43X43		

3.9 COLLIMATOR CONTROLS

R221 - Standard



R221 - with Filtration and Double Laser



Collimator controls *(Refer to the Collimator Manual for further information)*:

1. **Collimator Light** push-button. After pressing the Collimator Light push-button, the Light remains illuminated for a few seconds before automatically switching off.

2. **Two knobs to adjust the internal blades**. The Exposure Field is adjusted by setting the two knobs. The table on the Collimator Panel shows the number to set with the knobs to open the blades.

3. **Rail System with two guides** in order to install the external additional filters used for pediatric examinations ($\geq$ 0.1 mm Cu or 3.5 mm Al) in the upper guide.

4. **SID Guard** (Source-Image Distance).

5. **Measuring tape** to measure the SID.

6. **Variable Filtration** (optional), with the following filtration options:

0 mm AL	1 mm Al + 0.1 mm Cu ■	1 mm Al + 0.2 mm Cu ■ ■	2 mm AL ■ ■ ■

   The LED over the filters wheel will lit when selecting a filtration option.

7. **Double Laser** selector (optional), for Image-Receptor alignment.

8. **Hand-grips** for positioning the Tube-Collimator Assembly.

9. **Hand-grips Support** (option) for easily positioning the Tube-Collimator.

3.10 DIGITAL DETECTOR, OPTIONS AND ACCESSORIES

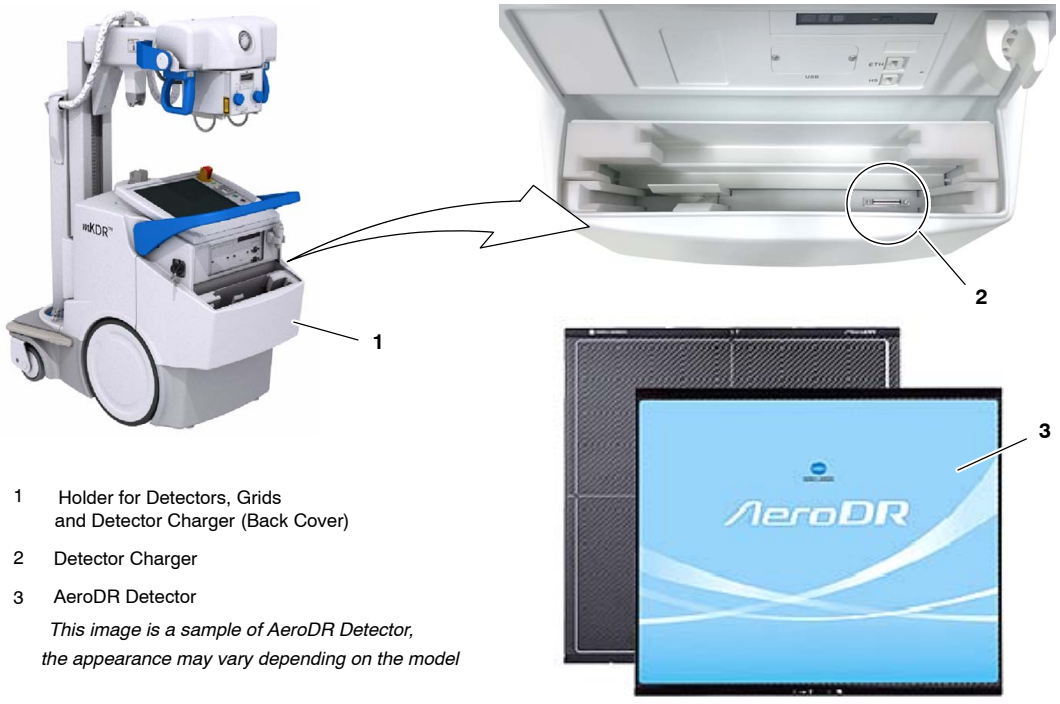
Wireless DR Detectors communicate with the Mobile Unit through the Antenna integrated in the Wireless Access Point (internal).

Depending on the options, the Wireless DR Detectors can be placed in the Holder for Detector/Grid and Accessories at the Back Cover and/or in the Detector/Grid Support at the Front Cover.

It can be provided an optional Antiscatter Grid Support designed to fit the Digital Detector inside. Grid Supports are available for all Detector options.

DETECTOR	SIZE	DIMENSIONS	IMAGE AREA	PIXEL SIZE
AeroDR 1417HQ (AeroDR P-11)	35 x 43 cm (14" x 17")	383.7 x 460.2 x 15.9 mm	348.95 x 425.25 mm (1994 x 2430 pixels)	175 µm
AeroDR 1417S (AeroDR P-12)	35 x 43 cm (14" x 17")	383.7 x 460.2 x 15.9 mm	348.95 x 425.25 mm (1994 x 2430 pixels)	175 µm
AeroDR 1717HQ (AeroDR P-21)	43 x 43 cm (17" x 17")	459.8 x 460.2 x 15.9 mm	424.9 x 424.9 mm (2428 x 2428 pixels)	175 µm
AeroDR 1012HQ (AeroDR P-31)	24 x 30 cm (10" x 12")	281.8 x 333.0 x 15.9 mm	245.7 x 296.8 mm (1404 x 1696 pixels)	175 µm
AeroDR 2 1417HQ (AeroDR P-51)	35 x 43 cm (14" x 17")	383.7 x 460.2 x 15.9 mm	348.95 x 425.25 mm (1994 x 2430 pixels)	175 µm
AeroDR 2 1417S (AeroDR P-52)	35 x 43 cm (14" x 17")	383.7 x 460.2 x 15.9 mm	348.95 x 425.25 mm (1994 x 2430 pixels)	175 µm
AeroDR 3 1417HD (AeroDR P-61)	35 x 43 cm (14" x 17")	384 x 460 x 15 mm	348.8 x 425.6 mm (3488 x 4256 pixels)	100 µm

Wireless DR Detectors include a Detector Charger inside the Holder for Detector/Grid and Accessories, at the Back Cover of the unit.



1 Holder for Detectors, Grids and Detector Charger (Back Cover)

2 Detector Charger

3 AeroDR Detector

This image is a sample of AeroDR Detector, the appearance may vary depending on the model

3.10.1 GENERAL USE AND MAINTENANCE OF DIGITAL DETECTORS, OPTIONS AND ACCESSORIES

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

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

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

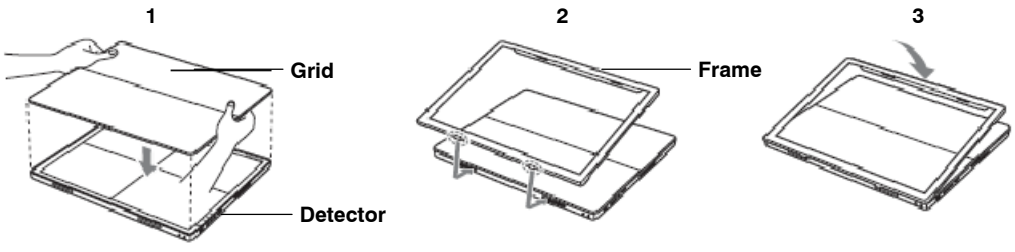
Note ☞ *For further information on the Digital Detector Handling and Maintenance, refer to the Digital Detector manuals.*

Grids are intended to reduce scattered radiation and significantly enhance image quality. Each Grid has an attached label that specifies its features (size, focal distance, ratio, density).

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

Digital Detectors are prepared to fit into a Frame with a Removable Grid. Follow the corresponding installation instructions found in the Digital Detector Manuals.

Here is an example of Grid installation, for Wireless Detector:



Check that the Grid is correctly mounted. A click sound means that the Grid is in place.

SECTION 4 GENERATOR MESSAGES

Generator messages are shown on the Control Console. They indicate the potential cause of an Error, a Warning condition or an Information.

Note ☞ *The Codes listed in the following tables are only a reference for Field Service.*

4.1 ERROR MESSAGES

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.** 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 signals active 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.	Press the "*Reset*" control. 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.** Generator Overload error. The exposure has been interrupted because 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 cold tube (X-ray Tube has not been warmed-up) will also show this error.	This error does not require to press the "*Reset*" control, 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.

Table 4-1 (cont.)
Error Messages

CODE	MESSAGE / DESCRIPTION	ACTION
ER10	**EEPROM corrupted or no initialized in ATP Console or HT Controller.** System failure.	Press the "*Reset*" control. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER11	**No Voltage detection in the main storage capacitors (Inverter module)** System failure.	
ER12	**Wrong Filament current.** No mA during exposure or mA value is out of range.	Press the "*Reset*" control. 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.	Press the "*Reset*" control. 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.	Press the "*Reset*" control. 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.	Press the "*Reset*" control. 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.	Press the "*Reset*" control. 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/Bucky not ready.** Detector/Bucky not ready for an exposure.	Press the "*Reset*" control. 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.
ER25	**Battery Fault.** The batteries charge level is momentarily low, or some batteries are discharged or damaged.	Press the "*Reset*" control. Wait 5 minutes before making a new exposure. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.

Table 4-1 (cont.)
Error Messages

CODE	MESSAGE / DESCRIPTION	ACTION
ER27	**Failure in ATP Console EPROM.** System failure.	Press the "*Reset*" control. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER31	**Please, release the Handswitch.** "Exposure" and/or "Preparation" commands are active when releasing the unit from Parking position.	Release the Handswitch. Press the "*Reset*" control. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER33	**Generator not communicating.** Serial Communication error.	Press the "*Reset*" control. 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" because of a system failure. Call Field Service. This error can also be shown after an APR technique selection to advise that exposure parameters displayed on the console are not the values stored for this APR technique. Exposure parameters are adapted by the Generator to another enable values.	These errors do not require to press the "*Reset*" control, 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.
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.	
ER50	**Exposure interrupted by the operator.** Exposure has been aborted by the Operator.	Press the "*Reset*" control. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
ER97	**X-Ray order not acknowledged** Exposure Switch (Handswitch / Remote Control) released before starting the exposure.	
ER98	**Calibration switch active.** Service Mode Active.	Press the "*Reset*" control and call Field Service. This error does not inhibit normal operation.

4.1.1 INTERLOCK MESSAGES

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

Table 4-2
Interlock Messages

MESSAGE / DESCRIPTION	ACTION
Generator overload. Indicates that the exposure was interrupted because arcing or malfunctioning occurred during exposure on the HV circuitry (X-ray Tube, HV Transformer and/or HV Cables) or a failure of IGBT module (overheated or defective IGBTs) was detected. It can also appear when making a lengthy or high powered exposure with the X-ray Tube cool (X-ray Tube has not been sufficiently warmed-up).	If the message persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Field Service.
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 enable values.	
Rotor error. Indicates that the X-ray Tube anode is not rotating while "*Prep*" is active, then exposures are inhibited.	If the indication disappears, try it again. If the message persists, turn the Generator OFF and ON. If the equipment remains inoperative after several attempts, turn it OFF and call Field Service.
Overheat. Tube Thermal Switch. Indicates that the X-ray Tube thermostat / pressurestat is open due to an overheating of the Tube housing (housing is too hot, wait for the housing to cool) or to a thermostat / pressurestat malfunction (housing is cool). Heat units may rise to any value.	If the housing is too hot, wait for the housing to cool. If the housing is cool, call Field Service.
Overheat. Maximum 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.
Tube overload. Indicates that either the technique selected is beyond the X-ray Tube ratings or the present conditions of the X-ray Tube inhibit the exposure (anode overheated). Parameters for the 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 those calculated for the next exposure (heat units close to zero). Reduce exposure factors or wait for the X-ray Tube to cool.

4.1.2 WARNING MESSAGES

The Warning messages indicate a limit or an inhibit during the parameter selection. Warnings show a condition that inhibits exposures temporarily, when the warning source disappears, the warning message disappears.

Table 4-3
Warning Messages

MESSAGE / DESCRIPTION	ACTION
Battery Level. Operation is not allowed due to a critical battery level. The application initiates a shutdown with a 30 minutes countdown.	Connect the Unit to a power source for battery charging. If still unplugged after the countdown has expired, the Unit will automatically shutdown. Then, connect the Unit for the required time (*refer to Section 7.1 Factors*).
Battery Inactivity. After 30 minutes without activity in Stand-Alone mode, the RAD screen alerts the User of an automatic shutdown within 15 minutes.	The shutdown will be stopped by pressing on *"OK"* control or connecting the Unit to the mains. The *"Autoshutdown Alert"* will be delayed for another 30 minutes without activity. If the Operator does not respond to the prompt within 15 minutes, the Unit will automatically shutdown.
Battery Charging. This message appears after plugging the unit and disappears in five seconds.	These messages do not require any user action. The indication disappears automatically.
Battery Stop Charging. This message appears after unplugging the unit and disappears in five seconds.	
Generator Power ON.	
Generator Power OFF.	
The mAs value is too high (regulatory restrictions). Regulatory mAs limit.	Decrease mA, ms or mAs.
The technique set is too high (more than 60KJ, Regulatory restrictions) Regulatory Energy limit.	Decrease kVp or mAs.
The minimum kVp value has been reached It appears when the value exceeds the limits while decreasing the kVp.	Keep the limit value or increase kVp.
The maximum kVp value has been reached It appears when the value exceeds the limits while increasing the kVp.	Keep the limit value or decrease kVp.
The minimum mA value has been reached. It appears when the value exceeds the limits for the current focus while decreasing the mA.	Keep the limit value or increase mA.
The maximum mA value has been reached. It appears when the value exceeds the limits for the current focus while increasing the mA.	Keep the limit value or decrease mA.
The minimum ms value has been reached. It appears when the value exceeds the limits while decreasing the exposure time.	Keep the limit value or increase ms.
The maximum ms value has been reached. It appears when the value exceeds the limits while increasing the exposure time.	Keep the limit value or decrease ms.

Table 4-3 (cont.)
Warning Messages

MESSAGE / DESCRIPTION	ACTION
The minimum mAs value has been reached. It appears when the value exceeds the limits while decreasing the mAs.	Keep the limit value or increase mAs.
The maximum mAs value has been reached. It appears when the value reaches the limits while increasing the mAs.	Keep the limit value or decrease mAs.
For the kVp, mA selected values, the maximum generator power has been reached. 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.
The selected kVp value exceeds the tube limits. kVp limit by the Tube protection curves.	Decrease kVp value.
The kVp, mA and ms values selected cannot be used to take an exposure, due to spatial charge tube limitation. 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.
The kVp, mA and ms values selected cannot be used to take an exposure, due to tube power limits. 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.
The kVp, mA and ms values selected cannot be used to take an exposure, due to security tube power limits. It appears when the selected technique is beyond the security X-ray tube ratings (percentage configured) or the present conditions of the Tube inhibit the exposure (anode momentarily overheated).	
For the mAs selection, there is no mA - ms possible values.	Modify the selected Parameters.
Maximum ms for DR (Digital Radiography)	Keep the limit value or decrease ms.

SECTION 5 OPERATING SEQUENCES

5.1 X-RAY TUBE WARM-UP PROCEDURE

Before effecting X-ray exposures, ensure that the Tube is properly warmed-up. Make sure that no one 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 preserves an optimal X-ray Tube life.

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

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

Perform X-ray Tube warm-up as follows:

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

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

5.2 RADIOGRAPHIC OPERATION

RAD operation can be performed in the following modes:

- Three Point control by selecting kV, 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. If the maximum 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.
- Anatomical Programs (APR).

A typical RAD examination sequence is as indicated below:

1. Make sure that the X-ray Tube is properly warmed-up.
2. Position the patient for the examination.
3. Select the technique parameters using the 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 his 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 audible signal will sound during the exposure.
6. When the exposure is finished, release the Handswitch button.
7. Repeat the procedure if additional exposures are desired.

5.3 X-RAY BEAM ALIGNMENT WITH RESPECT TO PATIENT

After selecting RAD parameters for the technique to be performed:

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

3. Position the patient for the examination.

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

5. Perform any adjustment on the patient position, receptor or tube collimator assembly to assure that the X-Ray beam is correctly positioned.

WARNING

ALWAYS SELECT THE CORRECT FIELD SIZE TO AVOID EXCESSIVE RADIATION.

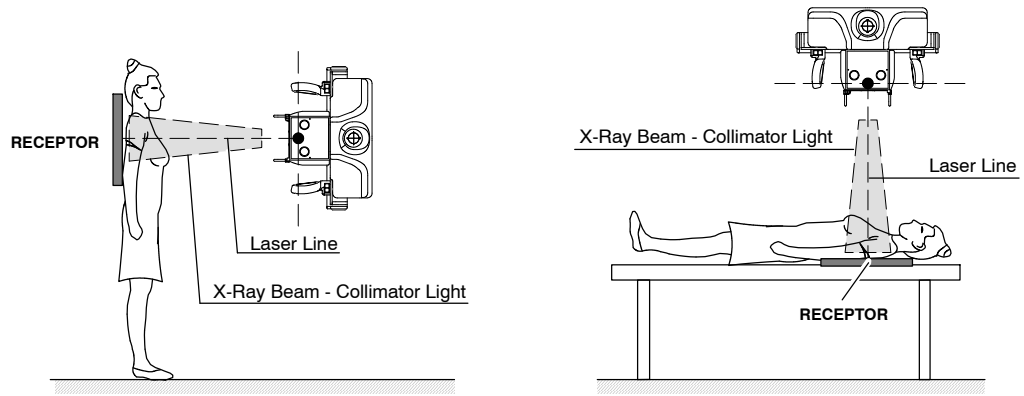
WARNING

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

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

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

Illustration 5-1
Patient Positioning



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SECTION 6 PERIODIC MAINTENANCE

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

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

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

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

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

6.1 OPERATOR TASKS

6.1.1 BATTERIES MAINTENANCE

If the unit has not been used or it has been stored for two months, it should be energized to prevent deep discharge of the batteries. A deep discharge will cause permanent damage to the batteries.

Tasks for a proper maintenance of the batteries:

- Recharge the batteries for at least 30 minutes at the beginning of the day before using the unit.
- Recharge the batteries for at least 30 minutes at the end of the day after using the unit.
- Fully recharge the batteries when the unit is going to be disconnected for more than 3 weeks.
- Fully recharge the batteries when the unit has been disconnected for more than 3 weeks.
- Keep the unit connected to the mains whenever possible (maximum 48 hours) to maintain the batteries at the floating maintenance level. This increases their lifetime.

- Do not allow the batteries to be deeply discharged because they will lose storage capacity and will never be able to recover the 100% of their original capacity.

Note ☞ *For more information, refer to "Battery Charge Level Indicators" in Section 3.2.7 and "Battery Capacity for the Generator and the Motors" in Section 7.1.*

6.1.2 PERIODIC MAINTENANCE

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

Periodic maintenance tasks 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.

1. With the Unit OFF, plug it in and leave it sufficient time to completely charge. The recommended time is approximately 9-10 hours, until the Battery Charge Level Indicators on both columns stop scrolling and the upper Green Indicators remain illuminated.

2. Once fully charged, unplug the Unit from the mains power. Wait a few minutes and reconnect the Unit to the mains. The upper Green Indicators should scroll up for approximately one minute.

   If the Battery charge level Indicators begin to scroll up from any other Indicator below, contact the Service Department.

3. Switch the equipment OFF by shutting down the computer. Remove Switch-key and unplug from mains.

4. Check the external cable connections.

6.1.3 CLEANING AND DISINFECTION

NEVER ATTEMPT TO CLEAN ANY PART OF THE UNIT WHEN IT IS SWITCHED ON.

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

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

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

DO NOT APPLY DIRECTLY ANY LIQUID ON THE SCREEN OR OTHER SURFACES, NOR USE CLEANERS CONTAINING BLEACH, AMMONIA OR ANY OTHER ABRASIVE OR SOLVENT LIQUID, IT COULD CAUSE DAMAGE TO THE EQUIPMENT.

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 (r*efer to the respective Sections of the Service Manual provided with this equipment).*

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SECTION 7 TECHNICAL SPECIFICATIONS

7.1 FACTORS

Maximum Power kW *(Refer to Identification Label)*	**20 kW**	**32 kW**	**40 kW**	**50 kW**
kVp Range	40 to 125 (40 to 150 optional)	40 to 150	40 to 150	40 to 150
	From 40 kV to 125 kV or 150 kV in 1 kV steps. *(Depending on the Generator model)*			
mAs Range	Product of mA x Time values from 0.1 mAs to 500 mAs			
mA Range	10 to 320	10 to 500	10 to 500	10 to 500
	From 10 mA to 320 or 500 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. *(Depending on the Generator model)*			
Exposure Time Range	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.			
Power Output (@ 0,1s)	125 kVp @ 160 mA 100 kVp @ 200 mA 80 kVp @ 250 mA 62 kVp @ 320 mA	150 kVp @ 200 mA 128 kVp @ 250 mA 100 kVp @ 320 mA 80 kVp @ 400 mA 64 kVp @ 500 mA	150 kVp @ 250 mA 125 kVp @ 320 mA 100 kVp @ 400 mA 80 kVp @ 500 mA	150 kVp @ 320 mA 125 kVp @ 400 mA 100 kVp @ 500 mA
Duty Cycle	18 exposures per hour at maximum mAs (lapse time between exposures: 3 min.)			
	Maximum leakage radiation depends on the type of X-ray Tube (<0.88 mGy/h)			
Collimator	Manual with electronic timer and meter			
X-ray Tube	*Refer to Section 7.2*			

Maximum Power kW *(Refer to Identification Label)*	**20 kW**	**32 kW**	**40 kW**	**50 kW**
Power Line Operation	100 / 110 / 120 / 127 / 220 / 230 / 240 V~ – Single-Phase 50 / 60 Hz Automatic Line Compensation ±10% V~ Connection to standard outlets with GND that complies with local regulations			
	The General Circuit Breaker installed in the Mobile Unit is 10 A (1P+N curve type D), the Power Line Installation should be provided with a Differential of 30 mA Sensitivity and with a Thermomagnetic Interruptor / Circuit Breaker of: ≥ 13 A (curve type D) or ≥ 20 A (curve type C) or ≥ 32 A (curve type B) Power Line Impedance must be less than the maximum indicated value: 1.2 Ω for 110 V~, 2.5 Ω for 230 V~			
Maximum Input Power	1.5 kVA			
Operation independent from mains supply (Stand-Alone)	Standard			
Battery Capacity for the Generator	Batteries fully charged float voltage of approx. 420 Volts at nominal of approx. 382 Volts. Charge Capacity: 15 Ah for Standard Batteries and 14 Ah for Lead-Crystal Batteries The required time for the Batteries to be fully charged is approximately: 10 hours for Standard Batteries and 9 hours for Lead-Crystal Batteries The maximum Storage Energy Capacity is: 137500 mAs @ 80 kVp *(This is the maximum energy available for making Exposures and supplying energy to the Generator)* The Mobile Unit in Stand–Alone (disconnected from the mains) will be 100% discharged from full charge in approximately: 6 hours for Standard Batteries and 9 hours for Lead-Crystal Batteries			
Battery Capacity for the Motors	Batteries fully charged float voltage of approx. 112 Volts at nominal of approx. 102 Volts. Charge Capacity 9 Ah The required time for the Batteries to be fully charged is 6 hours. With the Batteries fully charged and disconnected from the mains, the Mobile Unit can be in continuous movement during 4 hours (around 20 km). If the Mobile Unit is left on in Stand-Alone (disconnected from the mains) during 40 hours, it will be 100% discharged from full charge.			
Radiation Output Accuracy (Reproducibility related to loading factors)	C.V. (Coefficient of variation) ≤ 0.05			
Maximum Symmetrical Radiation Field	Measured at 75 kV: 200 mm in “X” axis and 260 mm in “Y” axis. Measured at 125 kV: 200 mm in “X” axis and 260 mm in “Y” axis. *(Test performed at a distance from the Focal Spot of 1200 mm, in accordance with IEC 60806:1984).*			
Maximum Heat Output	260 W (1130 BTU/h)			
Storage / Transport Environmental Conditions	Temperature range of -10ºC to 40ºC Relative Humidity range of 20% to 90% Atmospheric Pressure range of 700 hPa to 1060 hPa			
Operating Environmental Conditions	Temperature range of 10ºC to 30ºC* (*the recommended temperature for a longer life cycle of batteries is around 22ºC for Standard Batteries and between 15ºC ~ 25ºC for Lead-Crystal Batteries*) Relative Humidity (no condensing) range of 30% to 75% Atmospheric Pressure range of 700 hPa to 1060 hPa **The maximum temperature is limited by Aero DR System*			

7.2 X-RAY TUBES

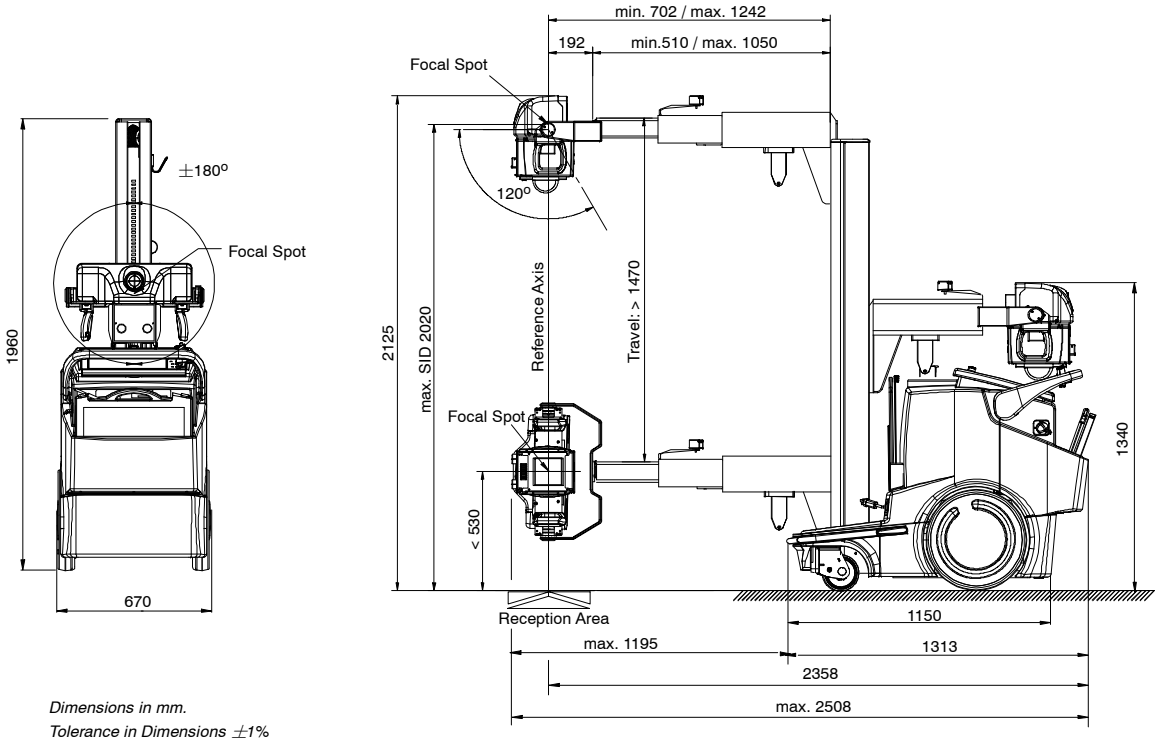
Maximum Power kW *(Refer to Identification Label)*	**20 kW**	**32 kW**	**40 kW**	**50 kW**
Standard X-ray Tubes	Canon E7886X			Canon E7884X
Optional X-ray Tubes	Canon E7884X			-

Canon E7884X	Low Speed - Rotating Anode, Focal Spots: 0.6 mm / 1.2 mm Anode kHU / kVp: 300 kHU / 150 kVp, Target Angle: 12° Maximum Specified Energy Input in 1 hour: 150 kVp @ 3408 mAs Inherent Filtration of X-ray Source (Tube + Collimator): refer to Identification Label
Canon E7886X	Low Speed - Rotating Anode, Focal Spots: 0.7 mm / 1.3 mm Anode kHU / kVp: 300 kHU / 150 kVp, Target Angle: 16° Maximum Specified Energy Input in 1 hour: 150 kVp @ 1440 mAs Inherent Filtration of X-ray Source (Tube + Collimator): refer to Identification Label

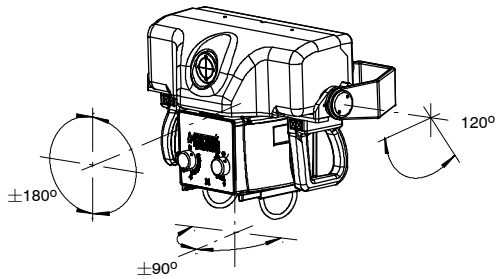
7.3 PHYSICAL CHARACTERISTICS

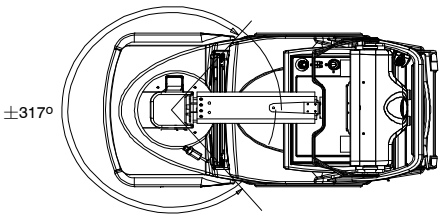
7.3.1 MOBILE UNIT WITH STANDARD COLUMN

LENGTH	WIDTH	HEIGHT *	WEIGHT
minimum 1313 mm maximum 2508 mm	670 mm	minimum 1960 mm maximum 2125 mm	560 kg (without Detectors and/or Accessories)
** Note: There is an optional "Short Column" that reduces in 130 mm the Column height, the maximum SID and the Vertical Travelling of the Arm.*			



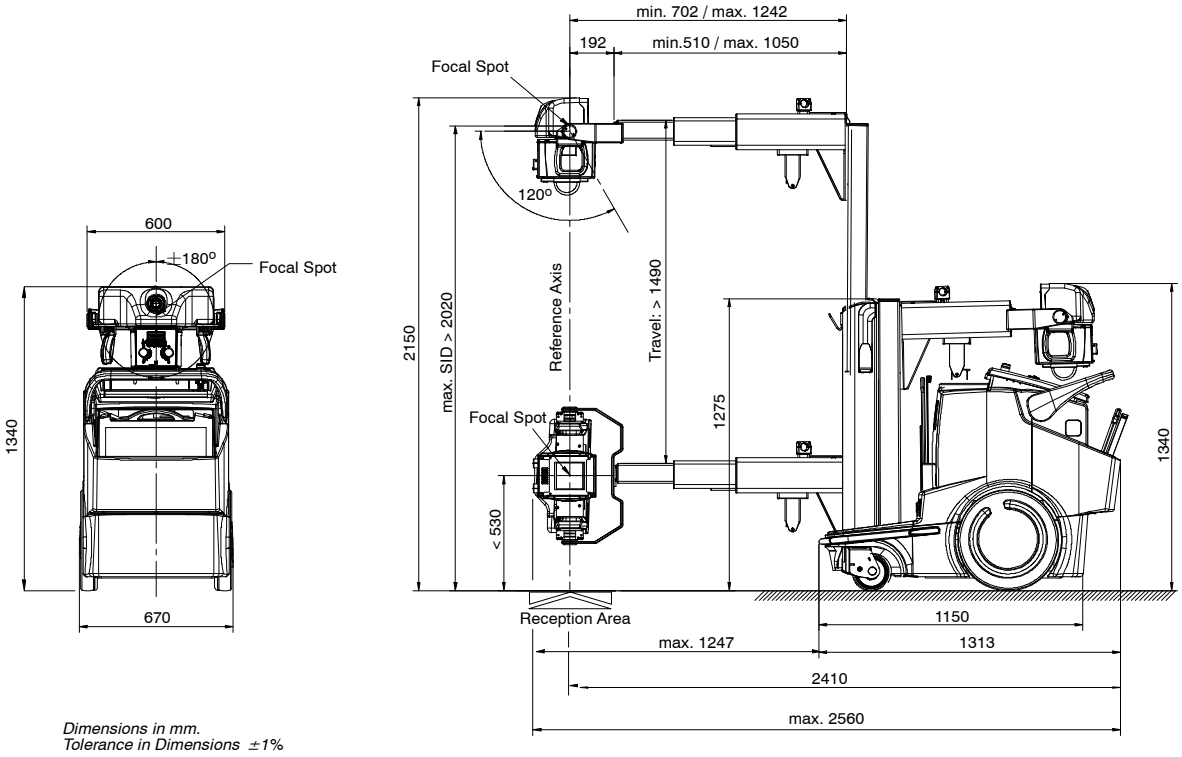
Dimensions in mm.
Tolerance in Dimensions ±1%



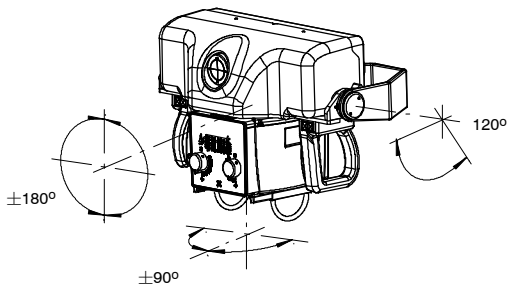


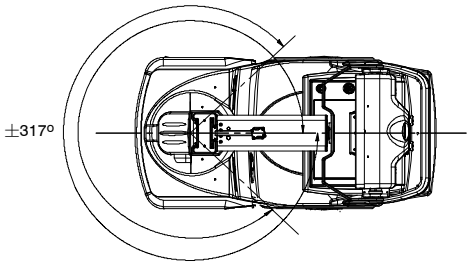
7.3.2 MOBILE UNIT WITH TELESCOPIC COLUMN (OPTION)

LENGTH	WIDTH	HEIGHT	WEIGHT
minimum 1313 mm maximum 2560 mm	670 mm	minimum 1340 mm maximum 2150 mm	580 kg (without Detectors and/or Accessories)



Dimensions in mm.
Tolerance in Dimensions ±1%





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APPENDIX A GUIDELINES FOR PEDIATRIC APPLICATIONS

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

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

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

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

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

- X-Ray Generator must have short exposures times.
- AEC must be used carefully, preferably use manual technique setting, applying lower doses.
- If possible, use high kVp techniques.
- As the use of Grids 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.

APPENDIX B PROTECT YOUR IMAGING SYSTEM FROM CYBERSECURITY THREATS

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

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

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

REQUIRED STRATEGIES BY THE OWNER / OPERATOR

Antivirus protection:

Use antivirus programs such as:

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

Keep these products up to date.

Limit access to trusted users only:

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

Ensure trusted content:

Restrict software or firmware updates to authenticated code.

Detect, respond, recover:

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

REQUIRED STRATEGIES BY THE MEDICAL DEVICE MANUFACTURER / SOFTWARE MANUFACTURER

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

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

A summary of our integrity controls:

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

CONCLUSION

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