



# Operation

Digital Mobile X-ray Unit  
with Digital Detectors

## ODYSSEY / ODYSSEY+



**Technical Publication**  
**OM-0491R1\_EN\_AMR**  
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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.

This manual covers the following equipments / Este manual cubre los siguientes equipos  
Ce manuel couvre les équipements suivants / Il presente manuale describe i seguenti dispositivi

**Battery Mobile X-Ray Unit:**  
**ODYSSEY / ODYSSEY+**



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## REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	SEP 28, 2022	First Edition
1	MAR 11, 2024	General spelling, syntax, and grammar checks. General updating of rendered images. Regulatory Information updated. IEC standards updated. Updated Sections: Introduction, Product Identification, Intended Use, Applied Parts, Symbols and Terms, Electromagnetic Compatibility (EMC), General and Motion Controls, Mains Connection, Control Console, Control Panel (renamed), System ON, RFID ON/OFF System (renamed), Keypad ON/OFF System (renamed), System OFF, System ON/OFF Indicator, Battery Charge Level Indicators, Battery State Alerts, Status Light Indicator, Motion Controls, Handlebar, Fine Positioning Controls, Manual Clutch Screws, Manual Driving Brake Release, Parking Position of the Arm, Estimated Dose, Focal-Skin Distance Sensor, Wireless Digital Detectors and Options (and subsections), Motion Speed Indicator, Head-Assembly Console, Message Windows, Dosimetry (Option), System Messages, X-ray Tube Warm-up Procedure, Operating Sequences, Periodic Maintenance, Batteries Maintenance, Factors and Physical Characteristics. Sections removed: Power Off Settings and Appendix C (Administrator User).

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 HEDED OR AVOIDED WILL CAUSE SERIOUS PERSONAL INJURY OR DEATH.***



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



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

Note 

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

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## SECTION 1 INTRODUCTION

This manual contains all the information necessary to understand and operate the **Mobile X-ray Units**. It provides a general description, safety and regulatory information, operating instructions and specifications concerning the system.

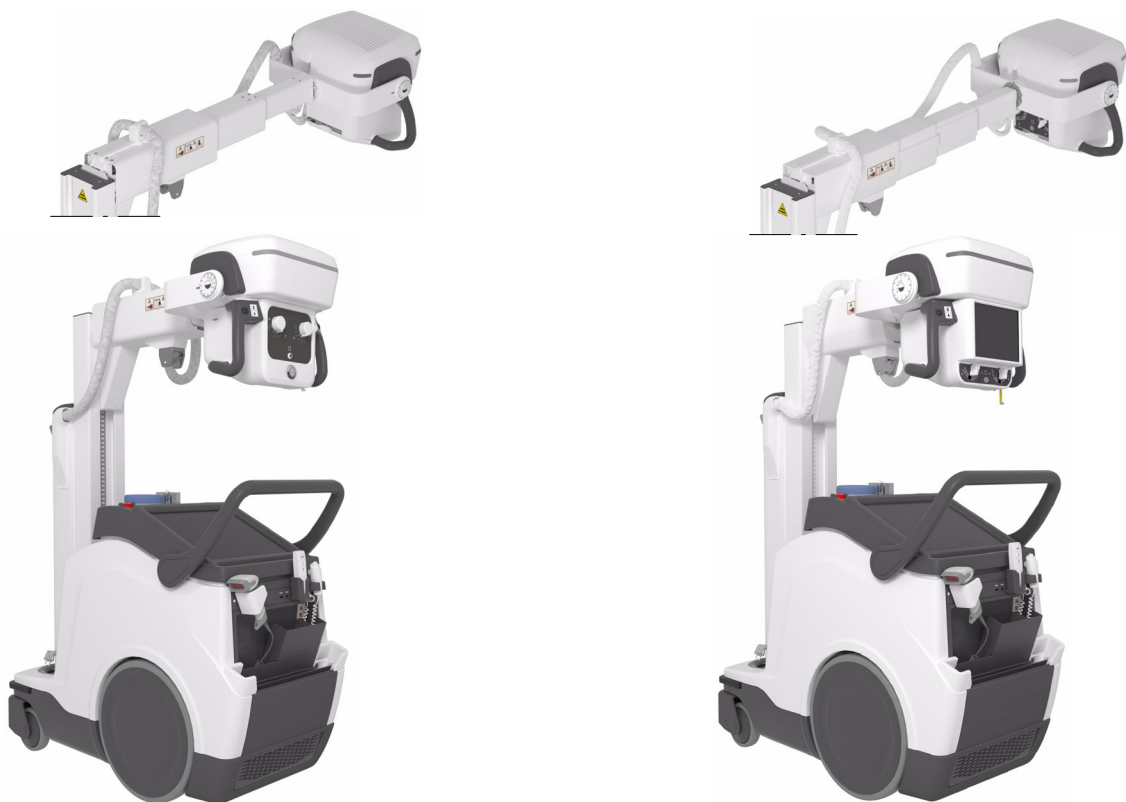
It is not intended to teach radiology or to take any type of clinical diagnosis.

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 3-Sections Arm**

**Mobile X-Ray Unit with 4-Sections Arm,**  
**Smooth Head-Assembly movements**  
**and second Screen (options)**

This **Mobile X-ray Unit** consists of the following components and subassemblies:

- *Control Console.*
- *Primo S, Software Application* for image acquisition.
- *Generator*, that comprises:
  - *Power Module*, containing power and control components.
  - *Battery Module*, with batteries and charge/control components.
- *Radiogenic unit*, part of the *Head-Assembly*, which comprises:
  - *Power Module*, containing power and control components.
  - *HV Tank, HV Transformer.*
  - *X-Ray Tube inserts; options: E7886, XRR-3331.*
- *Unit Motion Assemblies*, which comprises:
  - *Batteries and Charger Module*, to power the motors.
  - *Motor Assembly, Motors and Wheels.*
  - *Driving Control Assembly, Handlebar, Motion Controls* at the *Head-Assembly, Gauges* and the related *Electronic Components.*
- *Telescopic and rotating Column and Arm*, holding the *Head-Assembly*, and allowing its positioning.
  - *Telescopic Column*: the *Telescopic Column* in parking position reduces the height of the system in order to have complete visibility and safety when driving the system.
  - *Telescopic Arm*: it provides a compact size for handling and storage the system when retracted, plus an extra length when extended. The unit has two Arm versions: the 3-Section Arm and the optional 4-Section Arm with second Touch Screen in the *Head-Assembly* and smooth *Head-Assembly* movements.
- *Collimator*, part of the *Head-Assembly*.
- *Digital Detector, Grid and Detector Handle (option).* Detector options: *Mars 1013X, Mars 1417X, Mars 1717X*
- *HOLDERS* for *Detectors* storage and charge (option); storage for *Detector Handle, Grid*, and other *Options.*

## 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 – 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 Head-Assembly for motorized movements of the equipment.
- Controls for lock release of Rotating Column and Telescopic Arm. Column rotation in relation to its vertical axis ( $\pm 317^\circ$ ), telescopic and vertical motion of the Arm.
- Head-Assembly rotation in relation to its transverse axis ( $360^\circ$ ) and horizontal axis ( $120^\circ$ ). Collimator rotation in relation to its vertical axis ( $180^\circ$ ).
- 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 Image Acquisition Software.
- X-ray Handswitch for X-ray exposures and Collimator Light.
- Infrared Remote X-ray Handswitch (option) for X-ray exposures and Collimator Light.
- Dosimetry (option).
- 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.



## **1.3 INDICATIONS FOR USE**

### **1.3.1 INTENDED USE**

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

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

Applications can be performed with the patient sitting, standing, or lying in a prone or supine position. Examinations can be performed for any kind of patient group. Patients may be physically abled, 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. It is designed for multiple uses/cases per day.

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 injuries.

This equipment is not intended for mammographic applications.

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

## **1.4 APPLIED PARTS**

Applied Parts refer to parts of Medical equipment that in Normal Use necessarily come into physical contact with the patient for Medical equipment to perform its function.

This RAD equipment includes the following Applied Parts:

- *Digital Detectors.*
- *Grids (option)*
- *Other Options.*

## SECTION 2 SAFETY AND REGULATORY INFORMATION

This section describes the safety considerations and 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.**



OPERATORS 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.



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



**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 EFFECTS 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	IEC60601-2-54:2009 +AMD1:2015+AMD:2018
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
<p><i>Note 1.- Devices such as RADIATION DETECTORS are not included in the item listed in this table.</i></p> <p><i>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].</i></p> <p><i>Note 3.- ATTENUATION caused by table mattresses and similar accessories is not included in the maximum ATTENUATION EQUIVALENT for PATIENT SUPPORT.</i></p> <p><i>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.</i></p>		

## 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 THE 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'S 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 PIECES OF EQUIPMENT.**



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



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



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



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

### 2.3 MAXIMUM PERMISSIBLE DOSE (MPD)

Before an examination, 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 the 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-ray 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-ray 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 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 dosimeter.**
- **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 the 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 that 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 the 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 SYMBOLS AND TERMS

The following symbols may appear in the equipment.

The meaning of each symbol is described below.







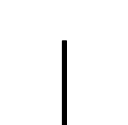
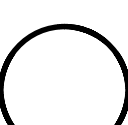
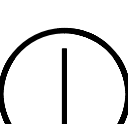
	<p><b>Caution. Consult accompanying documents.</b></p>
	<p><b>Follow instructions for use, especially those instructions identified with Advisory Symbols to avoid any risk for the Patient or Operator.</b></p>
	<p><b>Manufacturer.</b></p>
	<p><b>Date of Manufacture.</b></p>
	<p><b>Medical Device.</b></p>
	<p><b>Catalog Number (Model reference).</b></p>
	<p><b>Serial Number.</b></p>
	<p><b>Model Configuration.</b></p>
	<p><b>Unique Device Identifier.</b></p>









	<p><b>General Mandatory action.</b></p>
	<p><b>Type B applied part.</b></p>
	<p><b>Weight of device.</b></p>
<p><b>IP<sub>X0</sub></b></p>	<p><b>Protection against harmful ingress of water or particulate matter.</b> <b>IP Classification: Ordinary.</b></p>
	<p><b>Ionizing radiation.</b></p>
	<p><b>Non-ionizing electromagnetic radiation.</b></p>
	<p><b>Radiation of Laser apparatus.</b> Do not stare into beam. <i>(Only applicable to equipment with Laser Pointer)</i></p>
	<p><b>Dangerous voltage.</b></p>

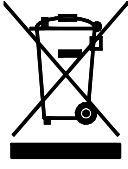
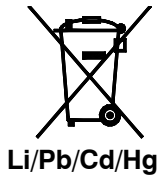

	<p>General warning, caution, risk of danger.</p>
	<p>Warning: Ionizing radiation.</p>
	<p>Warning: Non-ionizing radiation.</p>
	<p>Warning: Laser beam.</p>
	<p>Warning: Electricity.</p>
	<p>Warning: Do not place fingers between mobile and fixed parts of the equipment, it may cause serious injuries to patient or operator. As well, make sure the patient extremities are correctly positioned into limited areas during operation, movement of parts may cause serious damages to the patient.</p>
	<p>Warning: Do not place foot under mobile parts of the equipment, it may cause serious injuries to patient or operator. As well, make sure the patient extremities are correctly positioned into limited areas during operation, movement of parts may cause serious damages to the patient.</p>
	<p>Warning: Electrostatic sensitive devices.</p>

# Mobile X-ray Unit

## Operation

	No pushing.
	No sitting. Surface unsuitable to sit on.
	No stepping on surface.
	Do not handle.
	Emergency stop.
	Stand-By
	“ON” power.
	“OFF” power.
	“ON” / “OFF” (push-push). <i>Each position, “ON” or “OFF”, is a stable position.</i>

	<p>Alternating current.</p>
	<p>Three-phase alternating current.</p>
	<p>Three-phase alternating current with a neutral conductor.</p>
	<p>Connection point for the neutral conductor on Permanently Installed equipment.</p>
	<p>Direct current.</p>
	<p>Both direct and alternating current.</p>
	<p>Protective Earth (Ground).</p>
	<p>Earth (Ground).</p>

	<p>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.</p>
	<p>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.</p>
	<p><b>Pollution Control.</b> <i>(Only applicable to People's Republic of China (PRC)).</i>          This symbol indicates the product contains hazardous materials in excess of the limits established by 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.</p>

## 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 60601-1-3:2008 +AMD1:2013+AMD2:2021.
- 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 +AMD1:2015+AMD2:2018.
- 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 contacting 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*, in accordance with Standard IEC 60601-1:2005 +AMD1:2012+AMD2:2020.

### 2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

Protection against electric shock hazards in accordance with Standards: IEC 60601-1:2005+AMD1:2012+AMD2:2020, and IEC 60601-2-54:2009+AMD1:2015+AMD2:2018.

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 SUPPLY MAINS WITH PROTECTIVE EARTH.***

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

### 2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

Protection against harmful ingress of water or particulate matter: *Ordinary (IPx0)*, in accordance with Standard IEC 60601-1:2005+AMD1:2012+AMD2:2020.

### 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 60601-1:2005+AMD1:2012+AMD2:2020.

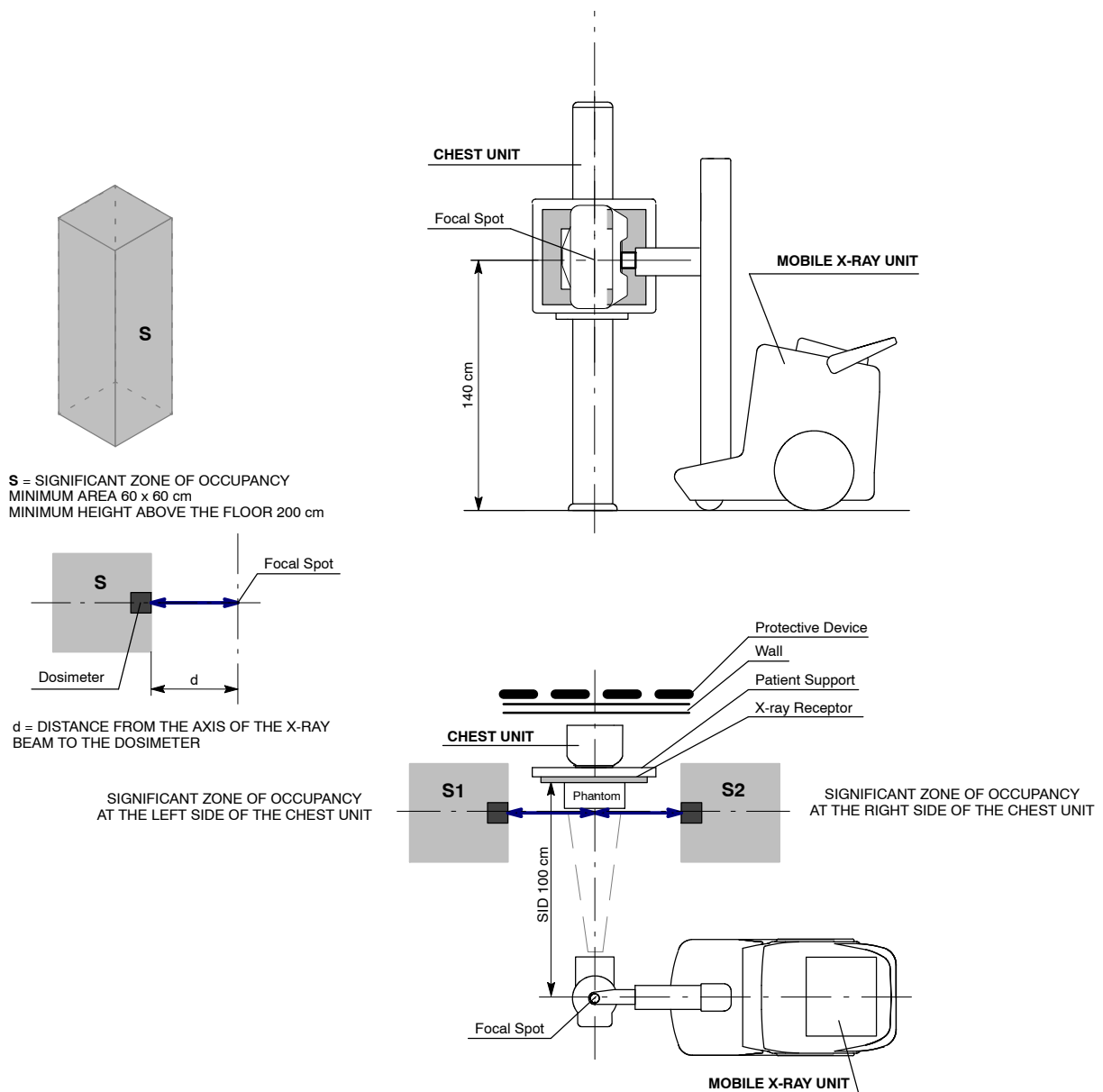
### 2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Protection against hazards from unwanted or excessive radiation in accordance with Standards IEC 60601-1:2005+AMD1:2012+AMD2:2020 and IEC 60601-1-3:2008+AMD1:2013+AMD2:2021.

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 (i.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:

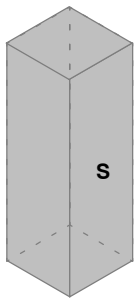
Illustration 2-1  
Radiographic Examination on the Chest Unit or Front Panel



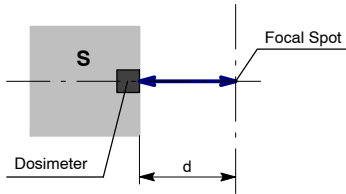
# Mobile X-ray Unit

## Operation

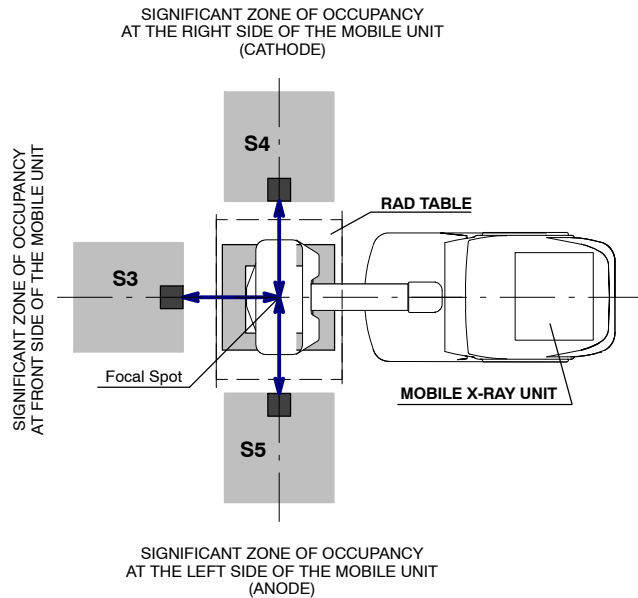
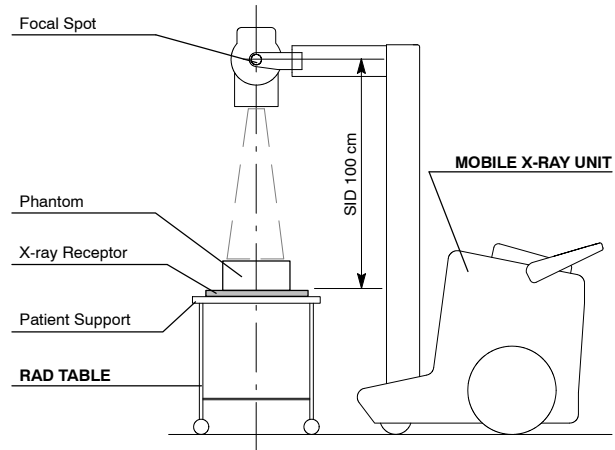
**Illustration 2-2**  
**Radiographic Examination on any Patient Support or any Table**



**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



## 2.7.9 DISTRIBUTION OF STRAY RADIATION

Measurement conditions to determine the distribution of Stray Radiation in the Significant Zone of Occupancy are in accordance with IEC 60601-1-3:2008 +AMD1:2013+AMD2:2021.

- Exposure Parameters: RAD mode, 150 kVp, 10 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** 

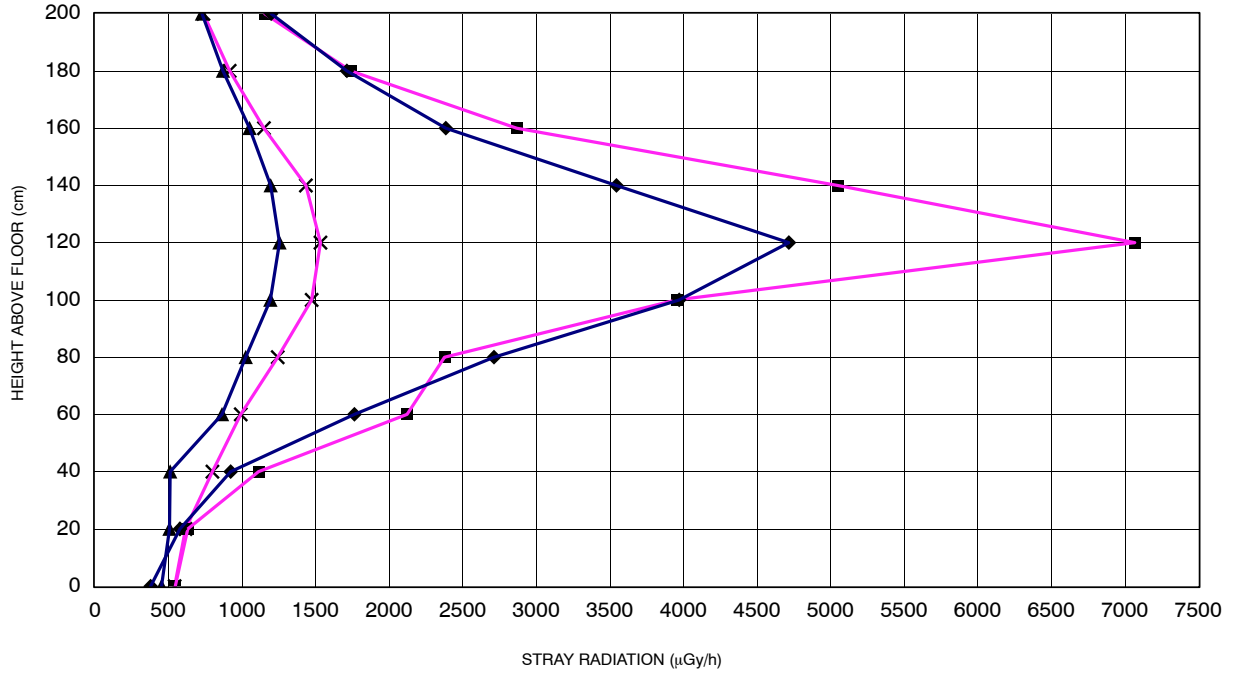
*The results have been obtained with a configuration that is representative of the worst case within the different configurations of the unit.*

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

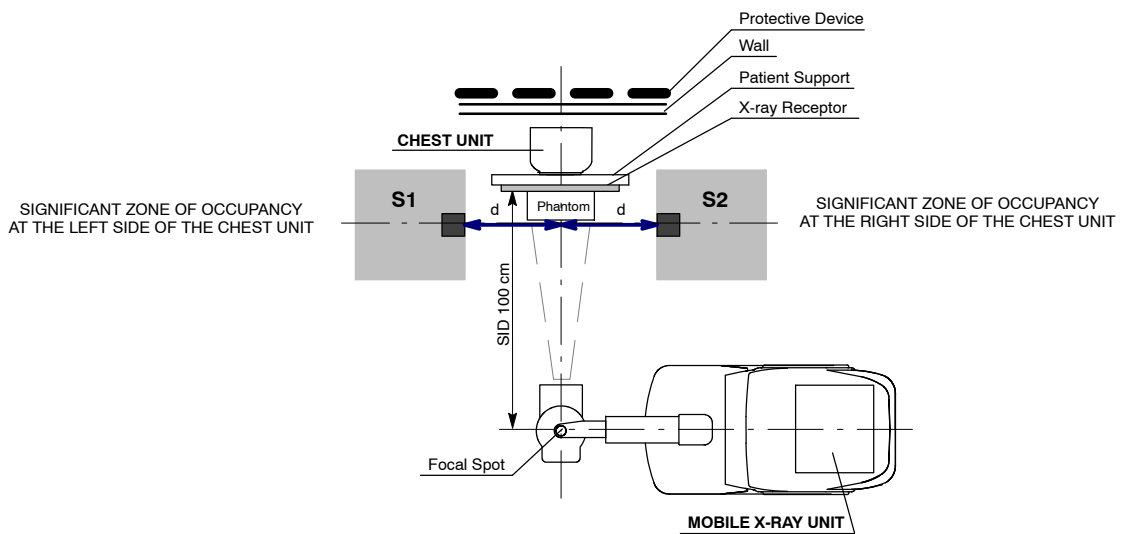
The following illustrations show the Distribution of Stray Radiation in each examination position.

Illustration 2-3

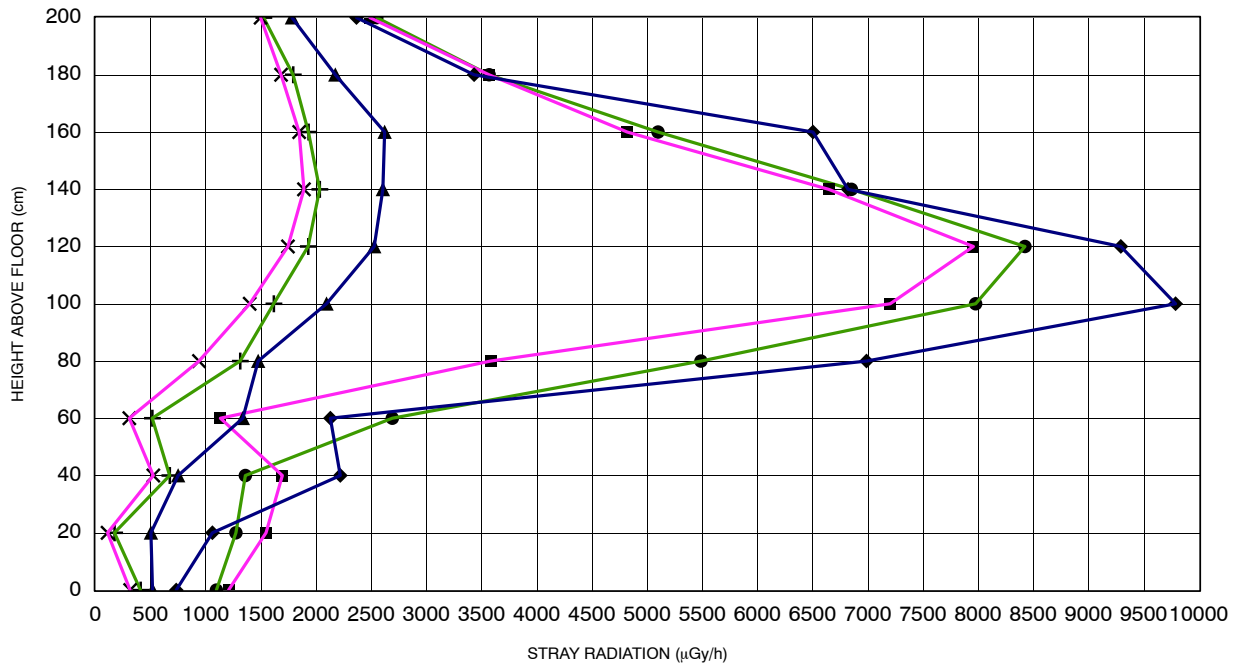
Distribution of Stray Radiation on the Chest Unit or Front Panel



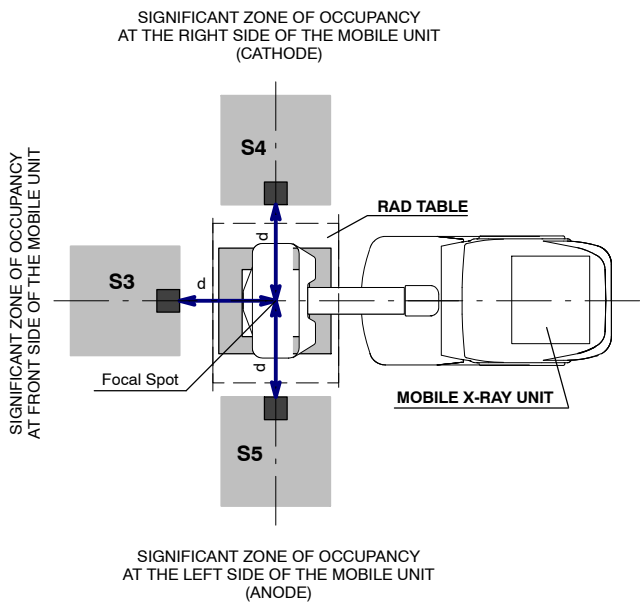
<b>S1<sub>1</sub></b>	d = 50 cm	◆
<b>S1<sub>2</sub></b>	d = 100 cm	▲
<b>S2<sub>1</sub></b>	d = 50 cm	■
<b>S2<sub>2</sub></b>	d = 100 cm	×



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



<b>S3<sub>1</sub></b>	d = 50 cm	—◆—
<b>S3<sub>2</sub></b>	d = 100 cm	—▲—
<b>S4<sub>1</sub></b>	d = 50 cm	—■—
<b>S4<sub>2</sub></b>	d = 100 cm	—×—
<b>S5<sub>1</sub></b>	d = 50 cm	—●—
<b>S5<sub>2</sub></b>	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 equipment complies with emissions limits for a Group 1 – Class A Medical Devices as stated in IEC 60601-1-2:2014+AMD1:2020. 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 electromagnetic interference for a Group 1 - Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the European Union Medical Device Directive and of Federal Communications Commission regulations (FCC).



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



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



*It is customer 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 60601-1-2:2014+AMD1:2020 tables as described in this section.*



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

#### **ESSENTIAL PERFORMANCE**

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

#### **EMC-COMPLIANCE CRITERIA DUE TO THE ESSENTIAL PERFORMANCE**

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

## Mobile X-ray Unit

### Operation

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS (IEC 60601-1-2:2014+AMD1:2020)		
<p><i>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.</i></p>		
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	
<p><i>NOTE - In accordance with Standard IEC 60601-1-2:2014+AMD1:2020, 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.</i></p>		

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014+AMD1:2020)			
<p><i>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.</i></p>			
Immunity Test	IEC 60601-1-2:2014+AMD1:2020 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.
Proximity magnetic fields IEC 61000-4-39	Refer to the table "IMMUNITY REQUIREMENTS FOR PROXIMITY MAGNETIC FIELDS"	Refer to the table "IMMUNITY REQUIREMENTS FOR PROXIMITY MAGNETIC FIELDS"	
<p><i>NOTE - <math>U_T</math> is the a.c. mains voltage prior to application of the test level.</i></p>			

## Mobile X-ray Unit

### Operation

<b>GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014+AMD1:2020)</b>			
<i>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.</i>			
<b>Immunity Test</b>	<b>IEC 60601-1-2:2014+AMD1:2020 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic environment - guidance</b>
Radiated RF EM fields IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	3 V/m from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the equipment, including cables specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONS EQUIPMENT"	Refer to next table "IMMUNITY REQUIREMENTS FOR RF WIRELESS COMMUNICATIONS EQUIPMENT"	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms from 150 kHz to 80 Mhz  6 Vrms in ISM bands from 150 kHz to 80 MHz  (80% AM at 1 kHz)	3 Vrms from 150 kHz to 80 Mhz  6 Vrms in ISM bands from 150 kHz to 80 MHz  (80% AM at 1 kHz)	
<p><i>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.</i></p>			

<b>IMMUNITY REQUIREMENTS FOR PROXIMITY MAGNETIC FIELDS (IEC 60601-1-2:2014+AMD1:2020)</b>		
<i>This X-ray System is intended for use in an electromagnetic environment specified below. The customer or Operator of this X-ray System should assure that it is used in such an environment.</i>		
<b>Test Frequency</b>	<b>Modulation</b>	<b>Immunity Test Level (A/m)</b>
30 kHz <sup>a)</sup>	CW	8
134.2 kHz	Pulse modulation <sup>b)</sup> 2.1 kHz	65 <sup>c)</sup>
13.56 MHz	Pulse modulation <sup>b)</sup> 50 kHz	75 <sup>c)</sup>
<p><sup>a)</sup> <i>This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.</i></p> <p><sup>b)</sup> <i>The carrier shall be modulated using a 50 % duty cycle square wave signal.</i></p> <p><sup>c)</sup> <i>r.m.s., before modulation is applied.</i></p>		

## Mobile X-ray Unit

### Operation

<b>IMMUNITY REQUIREMENTS TO RF WIRELESS COMMUNICATIONS EQUIPMENT (IEC 60601-1-2:2014+AMD1:2020)</b>			
<i>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.</i>			
<b>Band <sup>a)</sup> (MHz)</b>	<b>Modulation <sup>b)</sup></b>	<b>Distance (m)</b>	<b>Immunity Test Level (V/m)</b>
380 - 390	Pulse modulation <sup>b)</sup> 18 Hz	0.3	27
430 - 470	FM <sup>c)</sup> ±5 kHz deviation 1 kHz sine		28
704 - 787	Pulse modulation <sup>b)</sup> 217Hz		9
800 - 960	Pulse modulation <sup>b)</sup> 18Hz		28
1700 - 1990	Pulse modulation <sup>b)</sup> 217Hz		28
2400 - 2570	Pulse modulation <sup>b)</sup> 217Hz		28
5100 - 5800	Pulse modulation <sup>b)</sup> 217Hz		9
<p><sup>a)</sup> For some services, only the uplink frequencies are included.</p> <p><sup>b)</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.</p> <p><sup>c)</sup> 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.</p>			

## 2.9 RADIO FREQUENCY INTERFERENCE NOTICE (USA)

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. 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 +AMD1:2013+AMD2:2021. 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 a specific configuration of Digital Detector, maximum power X-ray Tube and Collimator. The results obtained with this configuration are representative of the worst case within the different configurations of the unit.*

Instrumentation used:

- Dosimeters:
  - IBA KermaX 120-131 MIC CAN
  - 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											
Patient examination (orientative)	Loading Factors				Parameter Selection				Measured Doses		
	Voltage - kV	Current - mA	Time (s)	Time Current - mAs	Focal Spot Selection	SID Source-Image Distance (cm)	Collimator blades opening (cm)	Grid	Collimator Output Dose ( $\mu\text{Gy}/\text{m}^2$ )	Phantom Input Dose Rate ( $\mu\text{Gy}/\text{s}$ )	Phantom Input Dose ( $\mu\text{Gy}/\text{mAs}$ )
CHEST AP	95	160	0.020	3.2	Small	120	35 x 43	No	22.39	11035	69.97
NECK	85	100	0.020	2	Small	100	24 x 30	No	96.10	8870	88.70
ABDOMEN AP	80	400	0.025	10	Large	100	35 x 43	No	69.72	31300	78.25
HIP/PELVIS AP	75	400	0.040	16	Large	100	35 x 43	No	99.13	27575	68.94
KNEE AP	65	200	0.025	5	Large	100	24 x 30	No	14.11	10228	51.14
ANKLE AP	50	200	0.050	10	Small	100	18 x 24	No	8.96	5324	26.62
FOOT AP	45	100	0.125	12.5	Small	100	24 x 30	No	13.20	2081.60	20.82
SHOULDER AP	65	250	0.100	25	Large	100	24 x 30	No	69.00	12650	50.60
ELBOW AP	60	100	0.040	4	Small	100	24 x 30	No	9.42	4320	43.20
WRIST PA	45	100	0.100	10	Small	100	18 x 24	No	6.77	2045	20.45
HAND PA	60	100	0.032	3.2	Small	100	24 x 30	No	7.54	4318.75	43.19
SKULL	75	160	0.200	32	Small	120	24 x 30	No	72.12	6920	43.25

Note 

Combined standard uncertainty is  $\pm 35\%$   
( IEC 60601-2-54:2009+AMD1:2015+AMD2:2018).

## **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 system, *System ON/OFF Indicator*, *Battery Charge Level Indicator*, *Emergency Switch OFF*.
- *Control Console Screen*; *Head-Assembly Screen* (only in 4-Section Arm version).
- *X-ray Handswitch*; *Infrared Remote X-ray Handswitch* (option).
- Controls for the unit motion and controls for *Telescopic Column* and *Arm* movements.
- *Manual Collimator Panel* with controls for opening or closing the *Collimator Blades* and to switch ON the *Collimator Light*.



**FOR THE CORRECT OPERATION OF THE X-RAY MOBILE UNIT, THE USER MUST HAVE DRY HANDS WHEN WORKING WITH THE SYSTEM.**

**DO NOT USE OR DRIVE THE SYSTEM WITH WET HANDS OR IMPREGNATED WITH DISINFECTANT GEL OR ANY OTHER SUBSTANCE OR LIQUID, SPECIALLY WHEN USING THE CAPACITIVE TOUCHSCREEN (MAIN SCREEN AND/OR HEAD-ASSEMBLY SCREEN) AND WHEN MANAGING THE CAPACITIVE MOVEMENT CONTROLS (HANDLEBAR, HEAD-ASSEMBLY HANDGRIPS); OTHERWISE, THESE SUBSTANCES COULD CAUSE SYSTEM MALFUNCTION AND/OR AN INCORRECT OPERATION OF THE MOTION CONTROLS.**

**IN THIS CASE, TURN OFF THE UNIT AND CLEAN THE AFFECTED PARTS.**

Note 

*For further information about Cleaning and Disinfection, refer to Section 7.1.3.*

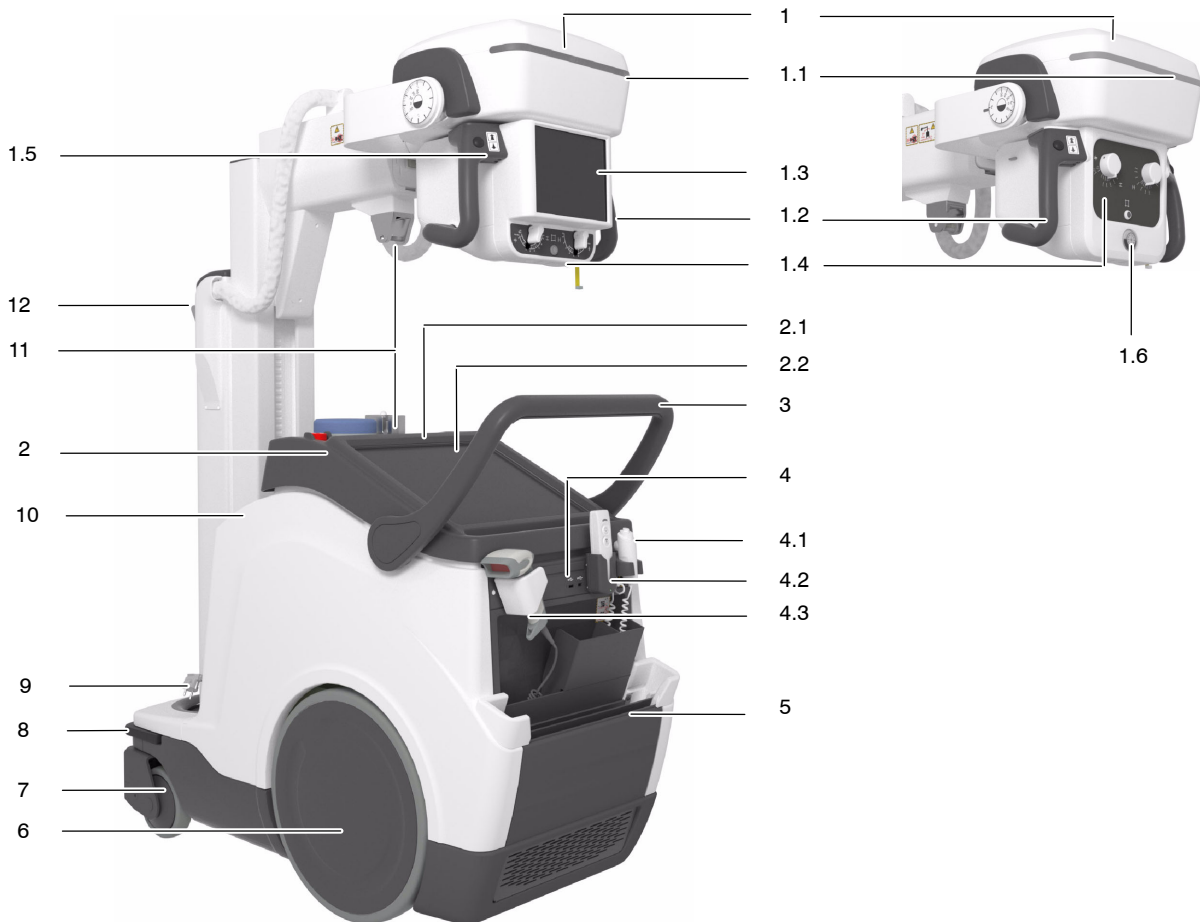
**GENERAL FEATURURES**

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

- |   |  |  |
|---|--|--|
| <ul style="list-style-type: none"> <li>1 Head-Assembly</li> <li>1.1 Status Light Indicator</li> <li>1.2 Handgrips</li> <li>1.3 Head Assembly Screen (option)</li> <li>1.4 Collimator Panel</li> <li>1.5 Motion Controls (on the Handgrips)</li> <li>1.6 Inclinometer</li> </ul> | <ul style="list-style-type: none"> <li>2 Control Console</li> <li>2.1 Control Panel</li> <li>2.2 Main Screen</li> <li>3 Handlebar</li> <li>4 Connections Panel</li> <li>4.1 Handswitch</li> <li>4.2 Infrared Remote Control (option)</li> <li>4.3 Barcode Scanner</li> </ul> | <ul style="list-style-type: none"> <li>5 Detector Storage/Charge</li> <li>6 Back Wheel, Hubcap</li> <li>7 Front Wheel</li> <li>8 Anti-Collision Bumper</li> <li>9 Power Line Plug</li> <li>10 Detector Storage/Charge</li> <li>11 Parking System</li> <li>12 Apron Hook</li> </ul> |
|---|--|--|

**Mobile X-Ray Unit  
with 4-Section Arm and second screen**

**Mobile X-Ray Unit  
with 3-Section Arm**



**Note**

*Throughout this Manual, images of the 4-Section Arm Unit will be used mainly as an example to illustrate the functionalities and equipment.*

OVERVIEW

**Illustration 3-2**  
**Mobile X-ray Unit: Overview**

*Mobile X-Ray Unit  
with 3-Section Arm*



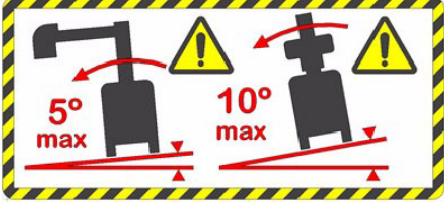


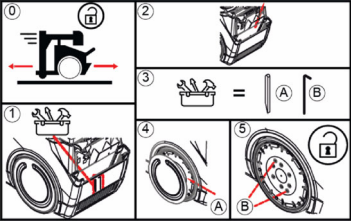


*Mobile X-Ray Unit with 4-Section Arm,  
Smooth Head-Assembly movements  
and second Screen (options)*





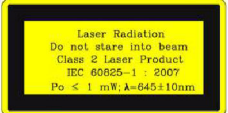



INFORMATION LABELS

Table 3-1  
Mobile X-ray Unit: Information Labels and Location

LABEL	TERMS	LOCATION
	<p>Follow instructions for Use</p>	<p>A</p>
	<p>Pinch Warning</p>	<p>B</p>
	<p>Unit Overbalance Risk Warning</p>	<p>C</p>
	<p>Overturned Unit Risk Warning</p>	<p>D</p>
	<p>Brake Release Warning <i>(Only with the Manual Driving Release Button system option. Refer to Section 3.6.1.6)</i></p>	<p>E</p>
	<p>Instructions for unlocking wheels for manual movement of the Unit <i>(Refer to Section 3.6.1.3).</i></p>	<p>F</p>

**Table 3-1 (Cont.)  
Mobile X-ray Unit: Information Labels and Location**

LABEL	TERMS	LOCATION
	<p>High Voltage on Mains Connection</p>	<p>G</p>
	<p>Ionizing Radiation Warning</p>	<p>H</p>
	<p>Laser Beam Warning</p>	<p>I</p>
	<p>Collimator Laser Aperture (x2)</p>	<p>J</p>
	<p>Collimator Laser Radiation</p>	<p>K</p>
	<p>Collimator LED Radiation</p>	<p>L</p>

**Note** 

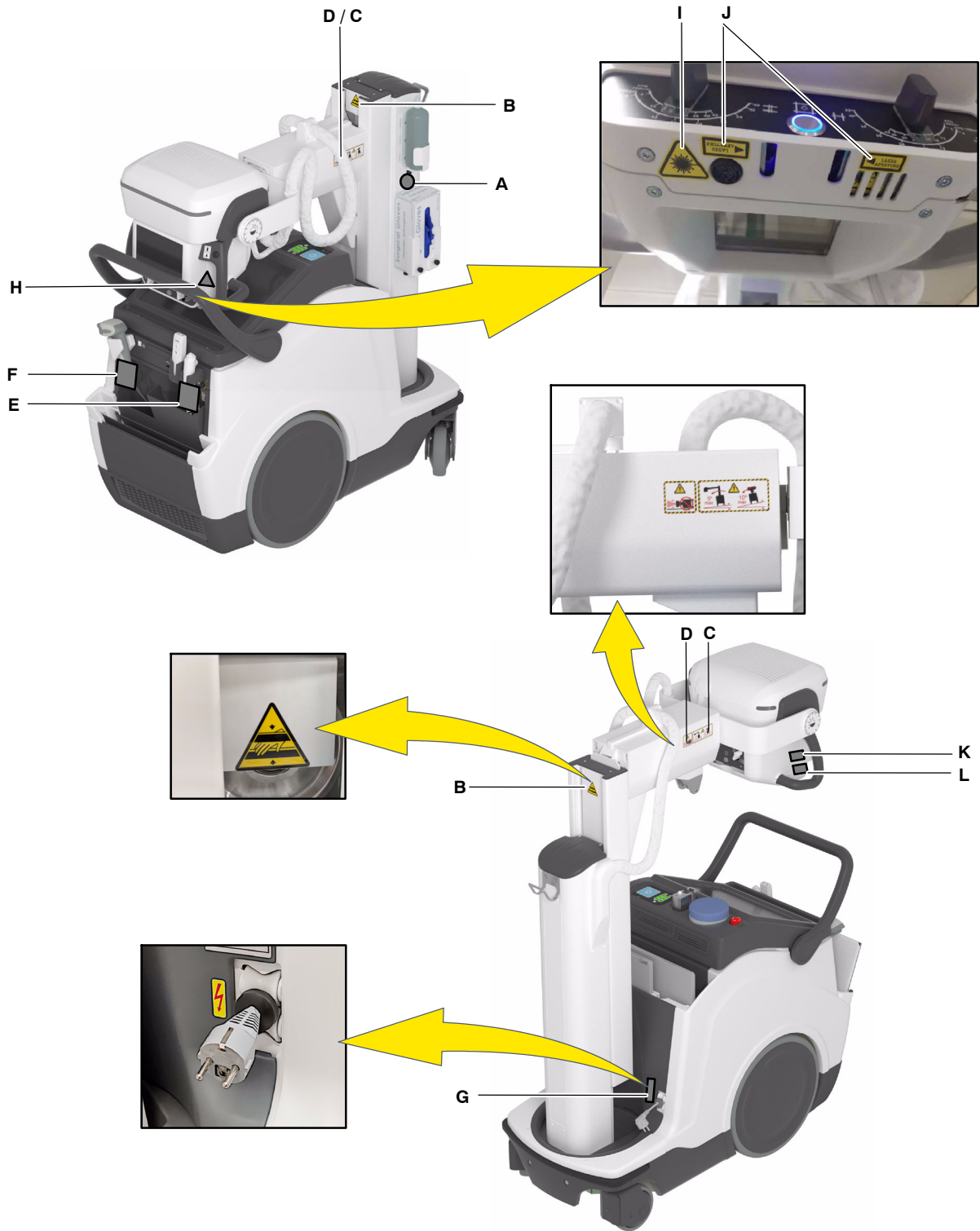
*Refer to Section 3.6 for more detailed information on safety precautions to be considered during Unit movement.*

# Mobile X-ray Unit

## Operation

Illustration 3-3

Mobile X-ray Unit: Information Labels and Location



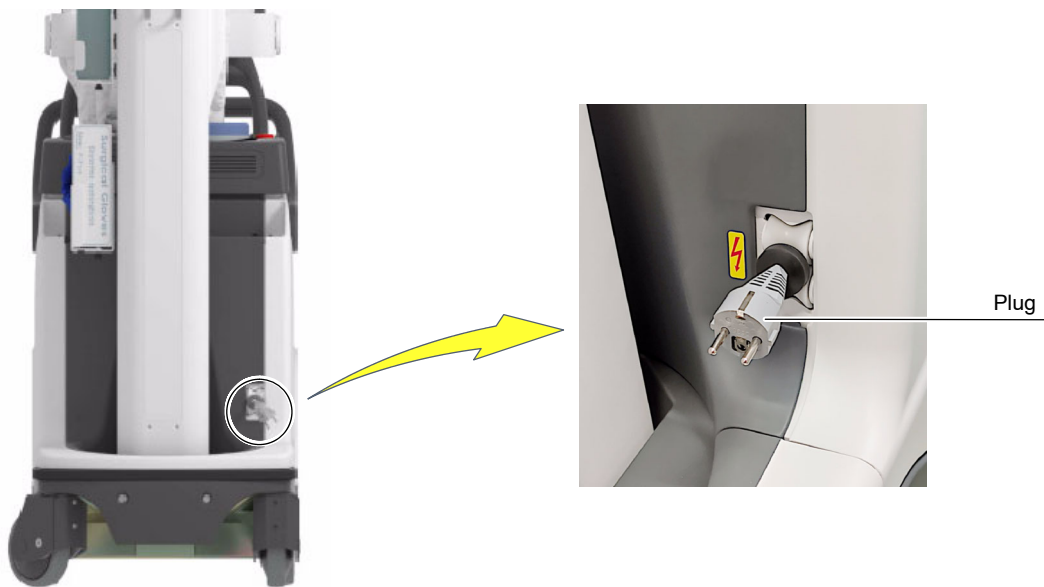
### 3.1 MAINS CONNECTION

The Unit should be plugged into a wall socket compliant with local regulations and electrical requirements of the equipment.

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.

**Note** 

*Refer to Section 8 for Technical Specifications.*



**THE MOBILE UNIT OPERATES ON A UNIVERSAL INPUT RANGE FROM 100 V~ TO 240 V~.**

**PLEASE, CONTACT TO THE SERVICE PERSONNEL IN CASE THAT POWER LINE CABLE AND/OR PLUG HAVE TO BE REPLACED IN ACCORDANCE WITH THE LOCAL REGULATION.**



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



**WHEN NOT GENERATING X-RAYS, KEEP THE UNIT CONNECTED TO THE MAINS, EVEN WHEN BATTERIES ARE FULLY CHARGED. THIS ENSURES MAXIMUM STORAGE ENERGY.**

*Note* 

*It is recommended, that at least once a week, a full charge of the batteries be performed by connecting the unit to the mains for at least 8 continuous hours.*

Connect the Power Line Cable to the mains in order to allow the Charging Circuits to charge the Batteries.

*Note* 

*When the Unit is ON and plugged into the mains, a “Lightning” icon appears on the Control Console (next to the Batteries Indicators) to display that the battery is charging.*

*This “Lightning” icon will disappear from the Control Console when the Unit is unplugged from the mains.*

*For further information about Batteries Status Indicators, refer to Section 4.1.14.*

*Note* 

*The Power Line Cable can only be replaced by the Service Engineer.*

### 3.2 CONTROL CONSOLE

The Control Console houses the Main Screen which consists of a 19" capacitive Touchscreen Monitor, with pinch and zoom functionalities.

The *Primo S Software Application* is shown on the Main Screen, including the Generator Control Panel with the controls, indicators and displays needed to perform radiographic examinations.

The system can comprise a second Touchscreen Monitor (9") located in the Head-Assembly useful for Image Preview, technical settings and patient information.

The Control Panel enables control of the Unit's power off and on, as well as the display of the system initialization status and battery charge status.

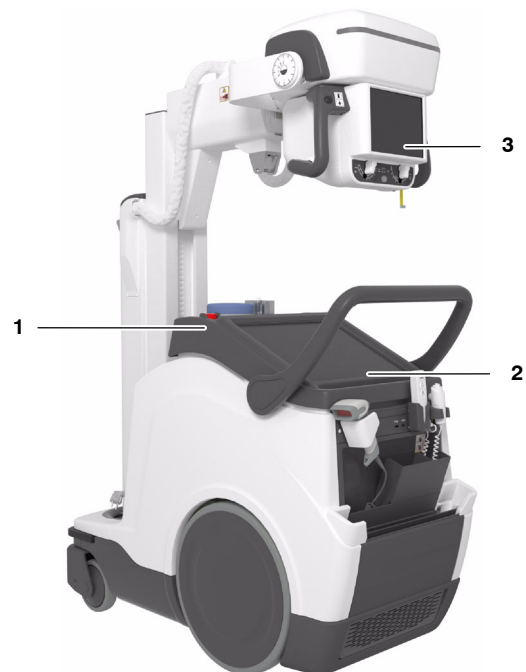
Note 

For further details, refer to Sections 4 and 5.

- 1 CONTROL PANEL
- 2 MAIN SCREEN
- 3 HEAD-ASSEMBLY SCREEN



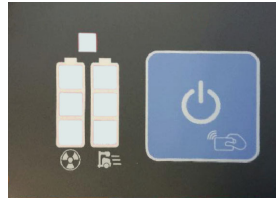
**Mobile X-Ray Unit  
with 3-Sections Arm**



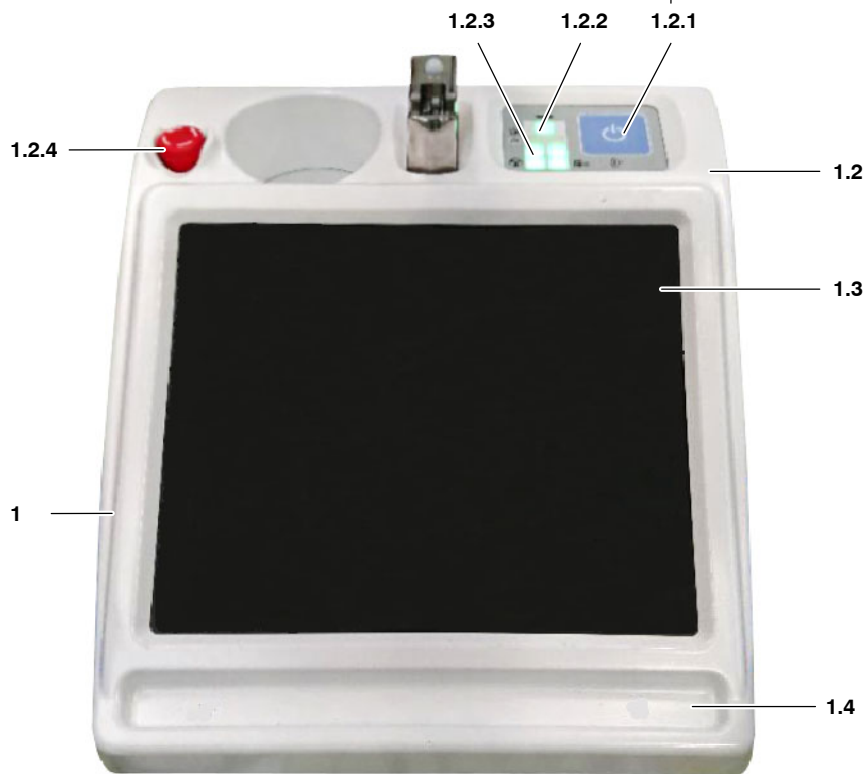
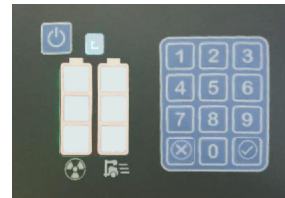
**Mobile X-Ray Unit with 4-Sections Arm,  
Smooth Head-Assembly movements  
and second Screen (options)**

3.2.1 CONTROL PANEL

RFID ON/OFF SYSTEM:  
ON/OFF Button + RFID System



KEYPAD ON/OFF SYSTEM  
ON/OFF Button + Keypad



- 1 Control Console
- 1.2 Control Panel
- 1.2.1 On/Off Control
- 1.2.2 System On/Off Indicator

- 1.2.3 Battery Charge Level Indicators
- 1.2.4 Emergency Switch Off
- 1.3 Main Screen
- 1.4 Pencil Tray

The following icons can be displayed on the *Control Panel*:

► **ON/OFF**



The ON/OFF button icon enables the user to ON/OFF the unit.

*Refer to Sections 3.2.2.1 and 3.2.2.2.*

► **RFID Symbol**



The ON/OFF button with the *RFID Card Reader* symbol (*RFID-Radio Frequency IDentification*) enables the user to ON/OFF and access the system with the *RFID Card*.

*Refer to Section 3.2.2.1 (RFID ON/OFF System).*

► **Keypad Symbols**

The buttons with the symbols at the bottom of the ON/OFF Keypad, enable the user:



To Accept the Access Code entered (symbol with the checkmark).



To Cancel the system Access (symbol with the crossed circle).

*Refer to Section 3.2.2.2 (Keypad ON/OFF System).*

► **Battery Charge Level Indicators: X-ray and Motion**

The symbols at the bottom of the *Battery Charge Level Indicators*, show:



The Battery Level for the unit Motion (right column symbol).



The Battery Level for X-Ray operation (left column symbol).

*Refer to Section 3.2.7 of Battery Charge Level Indicators.*

### 3.2.2 SYSTEM ON

The ON/OFF controls are the means to turn the unit ON and OFF.



**Do not touch any system control during the starting-up process; it could cause system malfunction.**

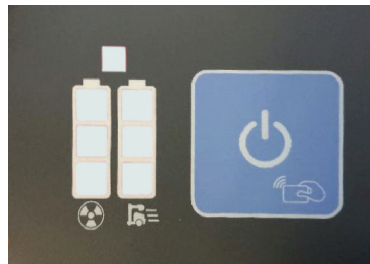
**In this case, restart the unit making sure not to touch any part of the system (switches, touch screens, motion controls, or any other control).**

Note 

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

There are two ways to turn ON the Unit, depending on the system configuration:

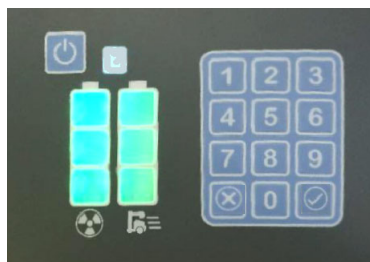
- **RFID System: ON/OFF button and RFID device (RFID-Card and RFID Card Reader)** (refer to Section 3.2.2.1).



Note 

*The contactless cards that support the RFID ON/OFF System comply with standard ISO/IEC 14443 type A.*

- **Keypad System (ON/OFF Button and Numeric Keypad)** (refer to Section 3.2.2.2).



### 3.2.2.1 RFID ON/OFF SYSTEM

To turn the unit ON, proceed as described in the following steps:

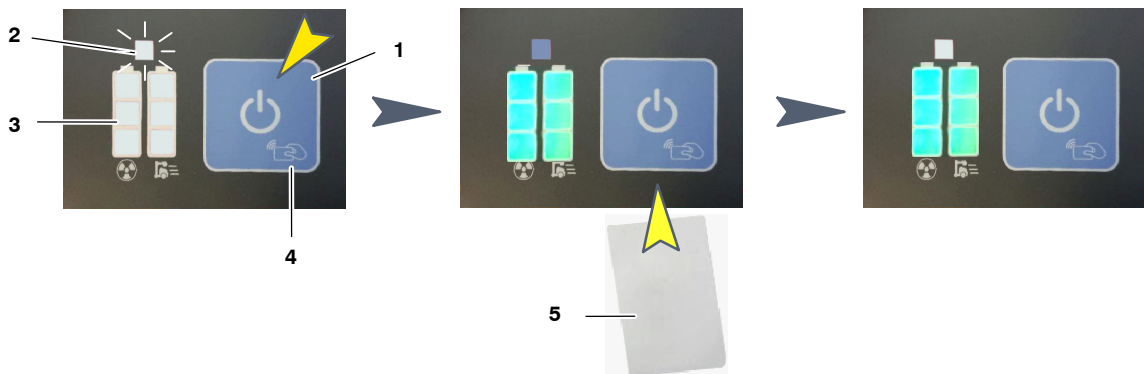
1. Press and hold the *ON/OFF* button (1) for a few seconds; the *System ON/OFF Indicator* (2) will blink white for 5 seconds.

**Note** 

*When the Mobile Unit is in Charging Mode it is not necessary to press the ON/OFF button in the first instance.*

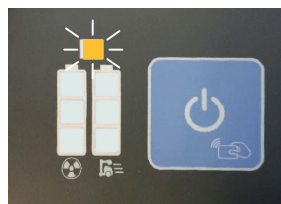
2. Within 5 seconds from turning the unit ON, pass the *RFID Card* (5) over *RFID Reader* symbol (4), there is no need to contact the reader. The system emits a double beep, the *ON/OFF Indicator* (2) will light blue and the *Battery Charge Level Indicator* (3) will light according to the current battery status.

3. When the system is ON the *System ON/OFF Indicator* (2) will light white.



**Note** 

*The system emits 3-beeps and the System ON/OFF Indicator (2) blinks orange to indicate a wrong RFID Card. In this case, repeat the ON/OFF process using the right Card.*



**Note** 

*The RFID Card is detected automatically by the system.*

Depending on the system permissions assigned to each RFID Card, the user can perform the following actions:

- **Movements:**

It allows the user to drive the system in Parking position.

When the system is out of the Parking position, it allows the user to move the Column and the Arm in order to put the system in parking position.

- **Panel Out:**

It allows the user to unlock the system from the Parking position and to move the Arm and the Column in order to get access to the Detectors.

- **X-Rays:**

It allows the user to perform any action needed for Radiographic Operation.

Each mobile unit is provided with different RFID cards:



- **MOVEMENTS RFID Cards**, with permission for:

- Movements.



- **OPERATOR RFID Cards**, with permission for:

- Movements.
- Panel Out.
- X-rays (Radiographic Operation).

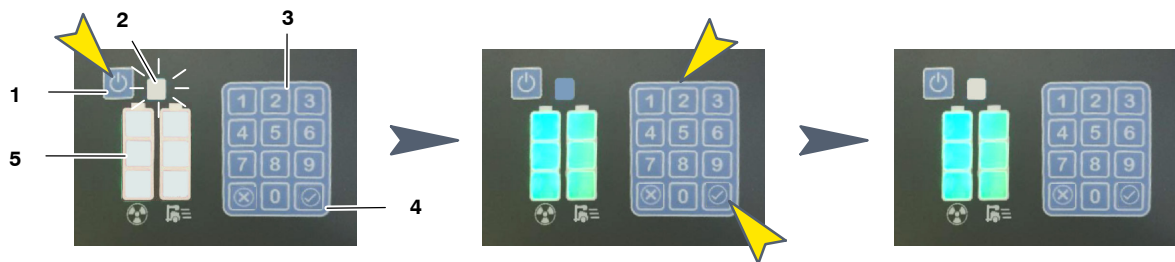
**Note** 

*Service personnel are able to assign the permission named "Admin" for access with administrator privileges to the Image Acquisition Software.*

### 3.2.2.2 KEYPAD ON/OFF SYSTEM

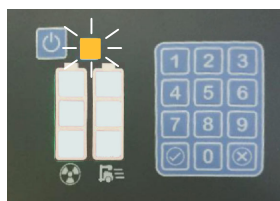
To turn the unit ON, proceed as described in the following steps:

1. Press and hold the *ON/OFF* button (1) for a few seconds; the *System ON/OFF Indicator* (2) will blink white for 5 seconds.
2. Enter the four-digit Access Code into the Keypad (3), within 5 seconds from turning the unit ON, and press the OK button (4); the *System ON/OFF Indicator* (2) will light blue and the *Battery Charge Level Indicator* (5) will light according to the current battery status.
3. When the system is ON, the *System ON/OFF Indicator* (2) will light white.



#### Note

The system emits 3-beeps and the *System ON/OFF Indicator* (2) blinks orange to indicate that a wrong code has been entered; in this case, repeat the ON/OFF process.



The system in the ON status switches ON the Generator, allowing the Mobile motion and then, the Image Acquisition Software for Radiographic operation will be launched on the Control Console.

3.2.3 SYSTEM OFF

Note 

Only shut down the system as described in this Section (3.2.3). Otherwise, the system will not perform a proper shutdown.



**Place the unit in the Parking position right after turning the system OFF since positioning controls will remain enabled for 15 seconds approximately.**

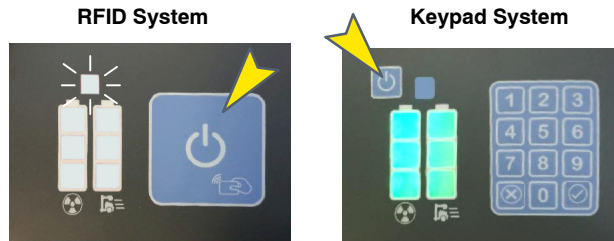
Note 

After turning OFF the unit, wait at least 10 seconds before turning it ON again. This action assures a safely start-up of the system.

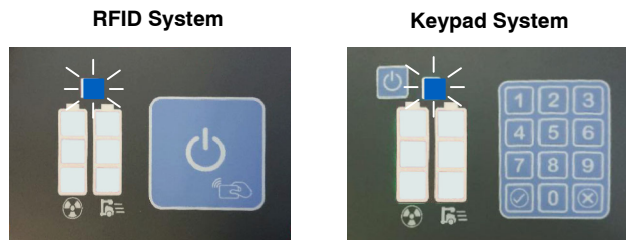
There are two ways to turn OFF the system:

1. From the Control Panel:

a. Turn OFF the system from the Control Panel, by holding pressed the ON/OFF button for 3 seconds approximately.



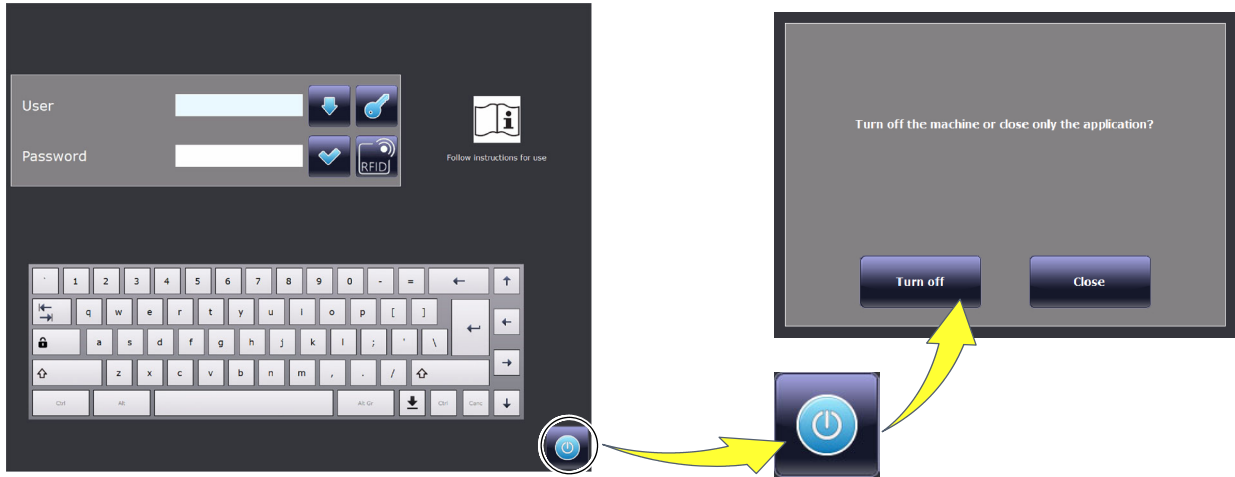
b. The system ON/OFF Indicator will light blue for a few seconds and then, the system will be turned OFF.



Note 

If the system does not turn OFF after pressing the ON/OFF button for 3 seconds, try it again by holding pressed the ON/OFF button for 12 seconds approximately; it will turn OFF the system safely.

- In the *Primo S* Software Application, firstly by pressing the “Shutdown” button in the Login Screen and then confirming it.



**Note** 

For further details about System Off, refer to *Primo S User Manual*.

### 3.2.4 EMERGENCY STOP



In the event of an emergency, the unit is turned OFF by forcibly pressing this switch (red mushroom-shaped switch). The switch is protected by the Cover, in order to prevent it from being accidentally pressed.

The Emergency Stop must not be used to switch OFF the unit, in order to avoid damaging the software.

**Note** 

Whenever possible, turn OFF the system as indicated in Section 3.2.3 in order to turn it OFF safely.

3.2.5 SYSTEM ON/OFF ROUTINE

After turning the unit ON as described in *Section 3.2.2, Primo S Software Application* is launched on the Control Console, displaying the *Login Screen*. Swipe a registered RFID Card (if Smart ON/OFF System is installed) or enter the Username, the Password and press *Login* for radiographic operation.



Note 

*For further details about Login Operation refer to Primo S User Manual.*

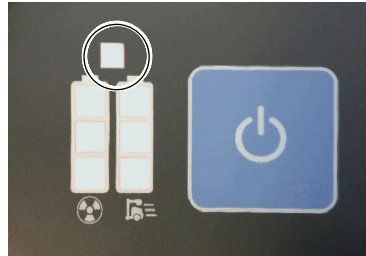
Note 

*The user provided with RFID Card for Smart ON/OFF system, with permission for Radiographic operation (refer to Section 3.2.2.1), has direct access to the radiographic operation.*







Turn OFF the system as described in *Section 3.2.3*.

**3.2.6 SYSTEM ON/OFF INDICATOR**

The system ON/OFF Indicator is on the Control Panel, over the Battery Charge Level Indicators.



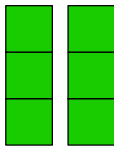
The System ON/OFF Indicator lights up in different colors, indicating different system status:

COLORS	SYSTEM STATUS
 <b>OFF</b>	<b>SYSTEM OFF</b> The ON/OFF Indicator is not illuminated when the system is OFF.
 <b>WHITE</b>	<b>WAITING FOR USER IDENTIFICATION</b> The ON/OFF Indicator blinks white to indicate that the system is waiting for the user identification; e. g. by passing the RFID Card over the RFID Card Reader, or by entering the Access Code in the Keypad. <i>(Refer to Sections 3.2.2.1 and 3.2.2.2).</i>
 <b>ORANGE</b>	<b>USER REJECTED</b> The ON/OFF Indicator blinks orange indicating that the user has been rejected by the system; e. g. when a wrong RFID Card has been passed, or when a wrong Code has been entered in the Keypad. <i>(Refer to Sections 3.2.2.1 and 3.2.2.2).</i>
 <b>BLUE</b>	<b>SYSTEM INITIALIZATION / SHUTDOWN</b> The ON/OFF Indicator lights blue during the System initialization process (after entering a valid RFID Card / Code) and during the Shutdown process. <i>(Refer to Sections 3.2.2.1, 3.2.2.2 and 3.2.3).</i>
 <b>WHITE</b>	<b>SYSTEM ON/STANDBY</b> The ON/OFF Indicator lights white when the initialization process is completed and the Positioner is operational, in Standby status.
 <b>MAGENTA</b>	<b>WAITING FOR NEW ACCESS CODE</b> The ON/OFF Indicator lights magenta indicating that the system is waiting for a new four-digit Access Code which has to be entered within the next 10 seconds. <i>(For Service personnel only).</i>

Note 

For further information, refer to Sections 3.2.2.1, 3.2.2.2 and 3.2.3.

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 *Mobile X-Ray unit* symbol indicates the charge level of the Batteries used for the Mobile motion (motors).

When plugged into the mains (with 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 8 hours to fully charge. The batteries requires 4 hours for getting a charge level around 80% (20% per hour during the first 4 hours). Moreover, the Unit allows to perform exposures immediately after be plugged to the mains.*

**Note**

*To charge the Batteries, there is no need to have the Unit turned ON. When the Batteries are fully charged, the Battery charge level Indicators on both columns stop scrolling and all the Indicators remain illuminated in green.*

When unplugged from mains, the Batteries discharge independently on their use (X-ray exposures or motors) since the Unit is provided with one battery module.

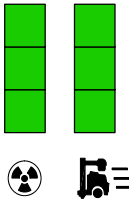
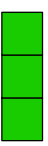
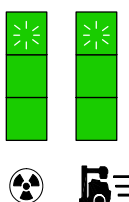
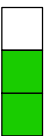
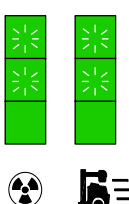
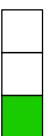
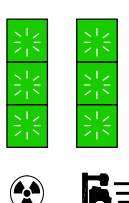
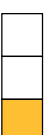
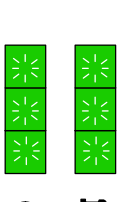





**Note**

*Upon disconnecting the unit from the mains if the unit has been connected for a short period of time, or 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 Indicator can be:

MOBILE unit PLUGGED INTO MAINS	MOBILE unit UNPLUGGED FROM MAINS	
System in "OFF" or "ON" position	System in "OFF" position	System in "ON" position and Console turned ON
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.

Both columns comprise three Indicators, representing a battery status as described below: Battery Full, Medium, Low, Very Low and Critically Low.

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	
 <p><b>Full Charge:</b> After a complete charge of the system (during approx. 8 hours), the upper indicators on both columns (1+1) light blinking green for a few seconds and then, all the Indicators (3+3) light steady green, indicating that the system Batteries are at <i>Full Charge</i> status. The batteries charge level is at 100% of the total charge.</p>	 <p>When the system is at <i>Full charge</i> status, all the indicators light steady green and normal operation is allowed. The batteries charge level is between 60% and 100%</p>		
 <p><b>Medium Charge:</b> The lower 4 indicators on both columns (2+2) light steady green and the upper 2 indicators on both columns (1+1) light blinking green and scrolling upward, indicating that the system Batteries are at <i>Medium Charge</i> status.</p>	 <p>When the system is at <i>Medium Charge</i> status, the lower indicators light green and normal operation is allowed. The batteries charge level is between 31% and 59%.</p>		
 <p><b>Low Charge:</b> The lower 2 indicators on both columns (1+1) light steady green and the upper 4 indicators light blinking green and scrolling upward, indicating that the system Batteries are at <i>Low Charge</i> status.</p>	 <p>When the system is at <i>Low Charge</i> status, the lower indicator lights green steady, on one or both columns; normal operation is allowed although it is recommended to charge the system. The batteries charge level is between 20% and 30%.</p>		
 <p><b>Very Low Charge:</b> All the indicators on both columns (3+3) are blinking green and scrolling upward, indicating that the system Batteries are at <i>Very Low Charge</i> status.</p>	 <p>When the system is at <i>Very Low Charge</i> status, the lower indicator lights orange steady, on one or both columns; normal operation is allowed although it is urgent to charge the system. The batteries charge level is between 1% and 19%.</p>		
 <p><b>Critically Low Charge:</b> All the indicators on both columns (3+3) are blinking green and scrolling upward, indicating that the system Batteries are at <i>Critically Charge</i> status.</p>	 <p>When the system is at <i>Critically Low Charge</i> status: – For X-ray: The lower indicator lights is blinking orange. Exposures are disabled and a 30-minute timeout countdown for the system shutdown is activated. Operation remains limited as long as the Unit is not plugged into the mains. – For Motors: The lower indicator lights is blinking orange. The system automatically shuts down. The batteries charge level is 0%.</p>		
<p>Indicator colors:  Green     Orange     Indicator OFF     Blinking / Scrolling</p>			

### 3.2.8 BATTERY STATE ALERTS

Note 

The following functions may be configured by the Service Engineer.

For further information, refer to Section 4 of Control Console and Section 5 of System Messages.

The Following Battery State Alerts can be displayed on the Control Console:

► **Battery Low:**

This alert appears when the system batteries are at *Low Charge* status.

The lower indicators light solid green and the middle and upper indicators are off, with the Unit disconnected from the mains (not charging).

It indicates that normal operation is allowed although it is recommended to connect the Unit to the power supply, for better battery usage.

The message disappears after a few seconds or by clicking on the *OK button*; the operation can then be continued.

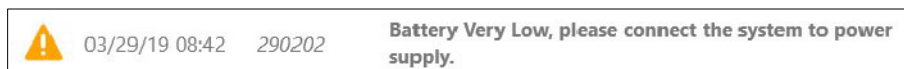


► **Battery Very Low:**

This alert appears when the system batteries are at *Very Low Charge* status.

The lower indicators light solid orange and the middle and upper indicators are off, with the Unit disconnected from the mains (not charging). It indicates that normal operation is allowed although it is urgent to connect the Unit to the power supply.

The message disappears after a few seconds or by clicking on the *OK button*; the operation can then be continued.



► **Battery Critical Low:**

This alert appears when the system batteries are at *Critically Low Charge* status.



The lower indicator flashes orange, on one or both columns, and the middle and upper indicators are off, with the Unit disconnected from the mains (not charging).

This alert indicates that it is necessary to connect the system to a power source for battery charging, although the operation is limited:

- If the indicator is on the X-ray column (X-ray exposures), indicates that exposures are disabled.

The system initiates a shutdown with a 30-minute countdown, which can be stopped by plugging the Unit into the mains.

- If the indicator is on the Motion column (Motors), and the Unit is still unplugged, the system will automatically shut down.

	03/29/19 08:43 101012	Positioner does not allow exposures
	03/29/19 08:43 290201	Battery Critical Low, please connect the system to a power supply. Xray are not allowed in this state.



**IN ORDER TO AVOID A SIGNIFICANT DECREASE IN THE LIFE EXPECTANCY OF THE BATTERIES, DO NOT PERFORM EXPOSURES JUST AFTER PLUGGING THE UNIT INTO MAINS WHEN THE BATTERIES ARE AT *CRITICALLY LOW CHARGE* STATUS.**

**3.2.9 STATUS LIGHT INDICATOR (OPTION)**












The system can be provided with the *Status Light Indicator*, located at the Head Assembly, which indicates different system status by colors, as described in the following table.

**Mobile X-Ray Unit  
with 3-Section Arm**



**Mobile X-Ray Unit with  
4-Section Arm and 2<sup>nd</sup> Screen**



COLORS		SYSTEM STATUS
NOT MOVING	MOVING	
 LIGHT OFF	 BLINKS WHITE <small>(*) Only inside the Safety Area</small>	<b>SYSTEM STANDBY</b> X-rays are disabled. The Status Light Indicator is OFF when the system is on Standby. It blinks white when the system is moving and within the Safety Area. Otherwise, if the Unit does not have the optional Proximity Sensors installed, the indicator remains OFF during movements (refer to Section 3.6.1.4).
 BLUE	 BLINKS WHITE <small>(*) Only inside the Safety Area</small>	<b>SYSTEM READY FOR EXPOSURE</b> The Status Light Indicator lights solid blue when the system is ready, i.e., the user only needs to press the Handswitch for making an exposure: the Detector is ready, the RAD technique is correctly set, and there is no System Error or Interlock condition. It blinks white when the system is moving and within the Safety Area. Otherwise, if the Unit does not have the optional Proximity Sensors installed, the indicator remains OFF during movements (refer to Section 3.6.1.4).
 GREEN	-	<b>SYSTEM PREPARED FOR EXPOSURE</b> The Status Light Indicator lights solid green when the Handswitch has been pressed halfway to the "Prep" status. Movements are not allowed.
 YELLOW	-	<b>EXPOSURE ON</b> The Status Light Indicator lights solid yellow during the X-ray Exposure: the Handswitch has been fully pressed to the "Exp" status. Movements are not allowed.
 ORANGE	 BLINKS ORANGE	<b>SYSTEM ERROR</b> The Status Light Indicator lights solid orange indicating that there is a system Error and it blinks orange when it is moving. The Status Light Indicator blinks orange too when the system has been at a Battery Critical Low status for 25 minutes, without being connected to mains.
-	 BLINKS MAGENTA	<b>FRONT BUMPER ACTIVATED</b> The Status Light Indicator blinks magenta when the Front Bumper is activated.
 RED	 BLINKS RED	<b>SERVICE MODE</b> Only in Service Mode.

Note 

For further information, refer to Section 3.4 about the Exposure process and to Section 5 about System Messages.

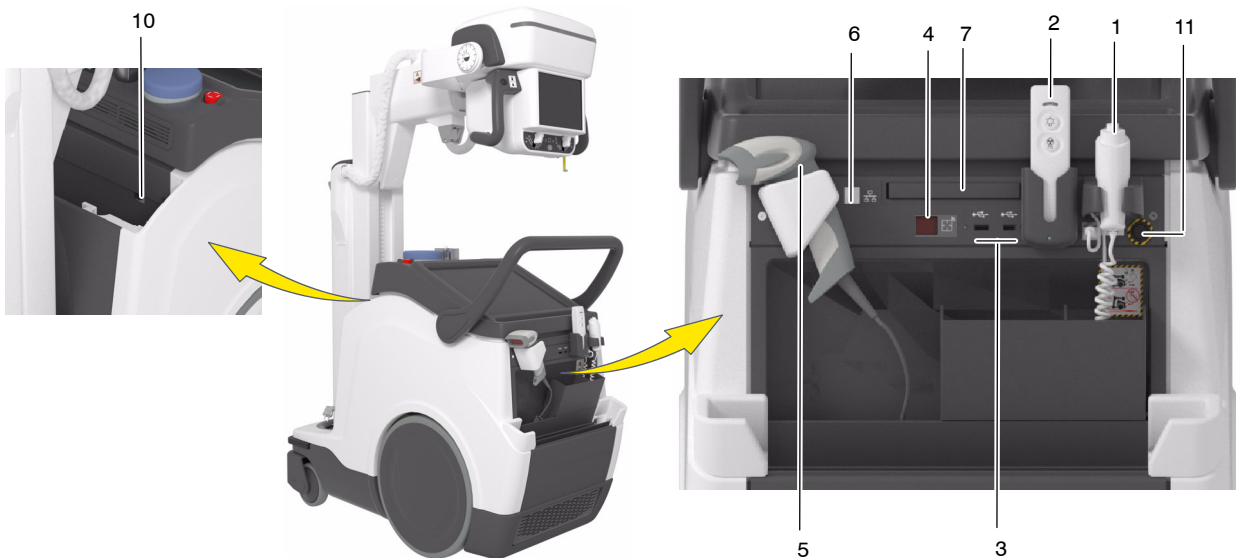
Note 

If the Focal Spot is switched, the newly selected filament may need time to warm up. It may take up to 13 seconds of additional waiting time before turning the system status from "Preparation" to "Ready". Refer to Section 4.1.4.

### 3.3 CONNECTIONS PANEL



**DO NOT CONNECT ANY ACTIVE DEVICES THAT APPLY EXTERNAL VOLTAGE TO THE SYSTEM THROUGH THE USB PORTS; ONLY PASSIVE DEVICES CAN BE CONNECTED.**



The Mobile unit is provided with a *Connections Panel* with:

1. **Hand Switch (HS)**, HS Connector, HS Support, (*Refer to Section 3.4*).
2. **Infrared Remote Control (option)**, (*Refer to Section 3.5*).
3. **USB Ports**, to connect USB-powered devices; only for Service personnel (only for passive devices; a. e. Keyboard, Mouse, etc.).
4. **IR Sensor** for Wireless Digital Detector registration (*refer to Section 3.11*).
5. **Barcode Scanner (option)**.
6. **Ethernet (ETH) Connector**, in order to connect to the site Network.
7. **CD/DVD Writer (option)**.
8. **WIFI Connection**, in order to connect to the site Network.
9. **WIFI Connection**, in order to connect to the Wireless Digital Detector.
10. **Detector Backup Communication Cable (option)**, to be connected to RJ45 Connector, at the Front Cover (*refer to Section 3.11.3*).
11. **Manual Driving Brake Release Button (option)**, (*refer to Section 3.6.1.6*).

### 3.4 X-RAY HANDSWITCH



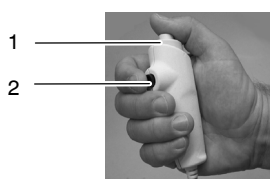
Radiographic exposures are controlled with the “*Prep*” (preparation) and “*Exp*” buttons on the X-ray Handswitch.

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 halfway (“*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.



- 1 OFF / Prep / Exp
- 2 Collimator Light

**Note** 

*The unit cannot perform exposures when the Column is in Parking position; it only can perform exposures out of the 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 exposure.

**Note** 

*For further information, refer to Section 3.2.9 of Status Light Indicators.*

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



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

### 3.5 INFRARED REMOTE CONTROL (OPTION)

Note 

*The unit cannot perform exposures when the Column is in the Parking position; it only can perform exposures out of the Parking position.*



**DURING AN EXPOSURE, THE IR REMOTE CONTROL MUST BE POINTED DIRECTLY AT THE MOBILE UNIT AT ALL TIMES.**

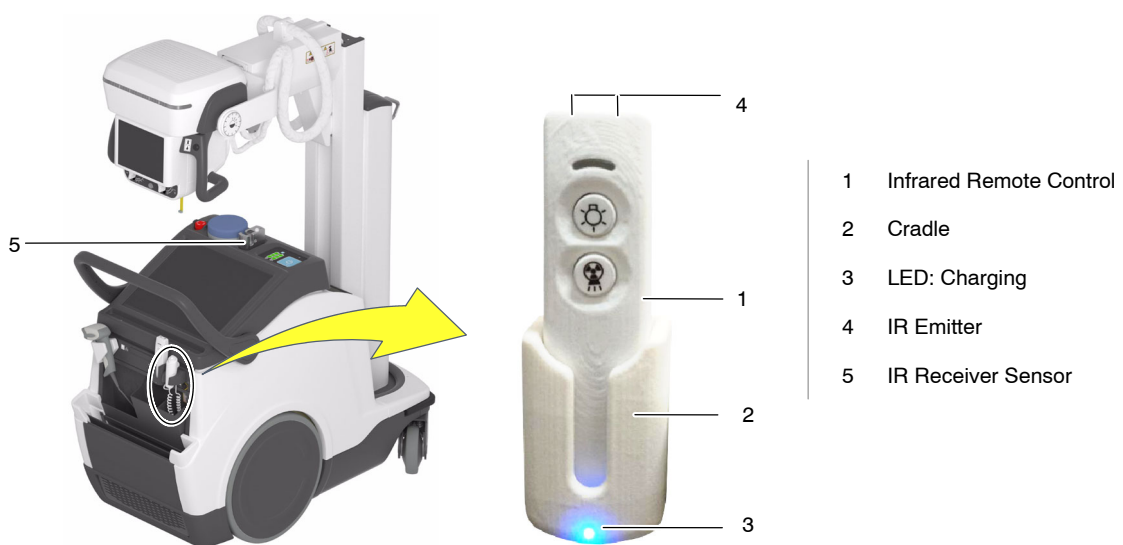
The Infrared Remote Control permits the operator to perform exposures at a distance from the X-ray beam (Head-Assembly) to protect against radiation.

When not in use, place the Infrared Remote Control back into the cradle in order to charge the battery; the Status LED lighting blue indicates that the Remote Control has been placed in the correct position and its battery is charging (the light will remain on as long as the IR Remote Control is stored in its cradle).

Note 

*A System Message will be displayed on the screen when the IR Remote Control is not placed into its cradle.*

*A Service Engineer may set the time it would take to display this informational message, as well as whether it is accompanied by an acoustic signal (discontinuous beeping).*



Take the Remote Exposure Control device out of its cradle. Aim the Remote Control at the IR Receiver Sensor on the Mobile unit from a maximum distance of 10 meters.



#### COLLIMATOR LIGHT BUTTON:

Press this push-button to turn on the Collimator Light.  
The status LED lights blue.

#### EXPOSURE CONTROL:

Press this button halfway to prepare the X-ray Tube for exposure (“Prep” position). When the X-ray Tube is “Ready” (green light on, at the Control Console), fully press and hold this button (“Exp” position) until the X-ray unit completes the exposure (yellow light on, at the Control Console).  
The status LED lights blue in “Prep” and “Exp” positions.

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 Light is turned ON during this cycle.

The exposure aborts if the “Exposure” button is released.

When the exposure is completed the icon on the console turns OFF.

Return the Control Remote device back to its cradle on the Mobile unit.

**Note** 

*For further information, refer to Section 3.2.9 of Status Light Indicators.*

### 3.6 MOTION CONTROLS



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

- WITH THE ARM IN PARKING POSITION:  $>10^\circ$
- WITH THE ARM OUT OF PARKING POSITION:  $>5^\circ$

*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.*



**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 RAMPS WITH AN INCLINATION ANGLE  $>8^\circ$ .**

**ON RAMPS, DRIVE THE UNIT WITH TWO HANDS AT NORMAL VELOCITY AND STOP COMPLETELY THE UNIT BEFORE RELEASING THE HANDLEBAR. NEVER RELEASE THE UNIT WHILE IN MOTION IN AN UNCONTROLLED MANNER.**



**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 DAMAGE TO THE FLOOR.**



MONITOR WITH SPECIAL CARE THE PATIENT'S 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.



ALWAYS USE THE HANDGRIPS OF THE HEAD-ASSEMBLY TO CONTROL AND DRIVE THE COLUMN AND ARM MOVEMENTS, NEVER PUSH DIRECTLY ON HEAD-ASSEMBLY OR COLLIMATOR.



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



*Motion Controls are only enabled when the System is ON.*



*Place the unit in the Parking position right after turning the system OFF since positioning controls will remain enabled for 15 seconds approximately.*

#### 3.6.1 DISPLACEMENT CONTROLS

**Note** 

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

**Note** 

*Velocity and visual signals (Status Light Indicator) can be configured by the Service Engineer.*

##### 3.6.1.1 HANDLEBAR



The unit is driven by holding the Handlebar with the hands, and it stops when the Handlebar is released by the user.

The Handlebar is provided with internal sensors that control the direction and speed of each wheel, operating when the Handlebar is touched and released.

The Handlebar height can be adjusted by the Service Engineer to several positions, in order to fit the user's height. The Unit with 3-Section Arm is provided with a two-position Handlebar (medium and lower position). The Unit with 4-Section Arm is provided with a three-position Handlebar (higher, medium and lower position) (*for further information, refer to Section 8.3 of Physical Characteristics*).



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



***When the Arm is in the Parking position, the Unit travels at the configured velocity (approx. 5.5 km/h [3.42 mph] forward and 2.5 km/h [1.6 mph] backward).***

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



***To avoid uncontrolled displacement of the Unit during the Starting-up, due to a failure of the displacement controls (Handlebar activated or short-circuited), movements controlled with the Handlebar are blocked although the Unit can be controlled with the Fine Positioning Controls.***

***A warning message alerts the user about a failure condition.***

**3.6.1.2 FINE POSITIONING CONTROLS**



Fine Positioning Controls enable the fine positioning adjustment of the system respecting the patient, with the operator positioned opposite the Head-Assembly.

The buttons with the arrow icons located on each Handgrip, control the motion of each driving wheel independently, at low speed, backward/forward.

The buttons correspond to each motor and operate with the unit in/out of the Parking Position.

Once any Fine Positioning button is pressed, the Unit starts to move, but displacement will stop after 5 seconds. It is necessary to release the button and press again to resume the movement. This safety measure prevents possible uncontrolled movements due to an internal failure of the Fine Positioning Controls.

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



**Note**

*For further information on Fine Positioning Controls, refer to Illustration 3-4.*



***In order to avoid uncontrolled displacement of the unit during the Start-up, due to a failure of the displacement controls (Fine Positioning Controls activated or short-circuited), movements controlled with these commands are blocked although the unit can be controlled with the Handlebar. A warning message alerts the user about a failure condition.***

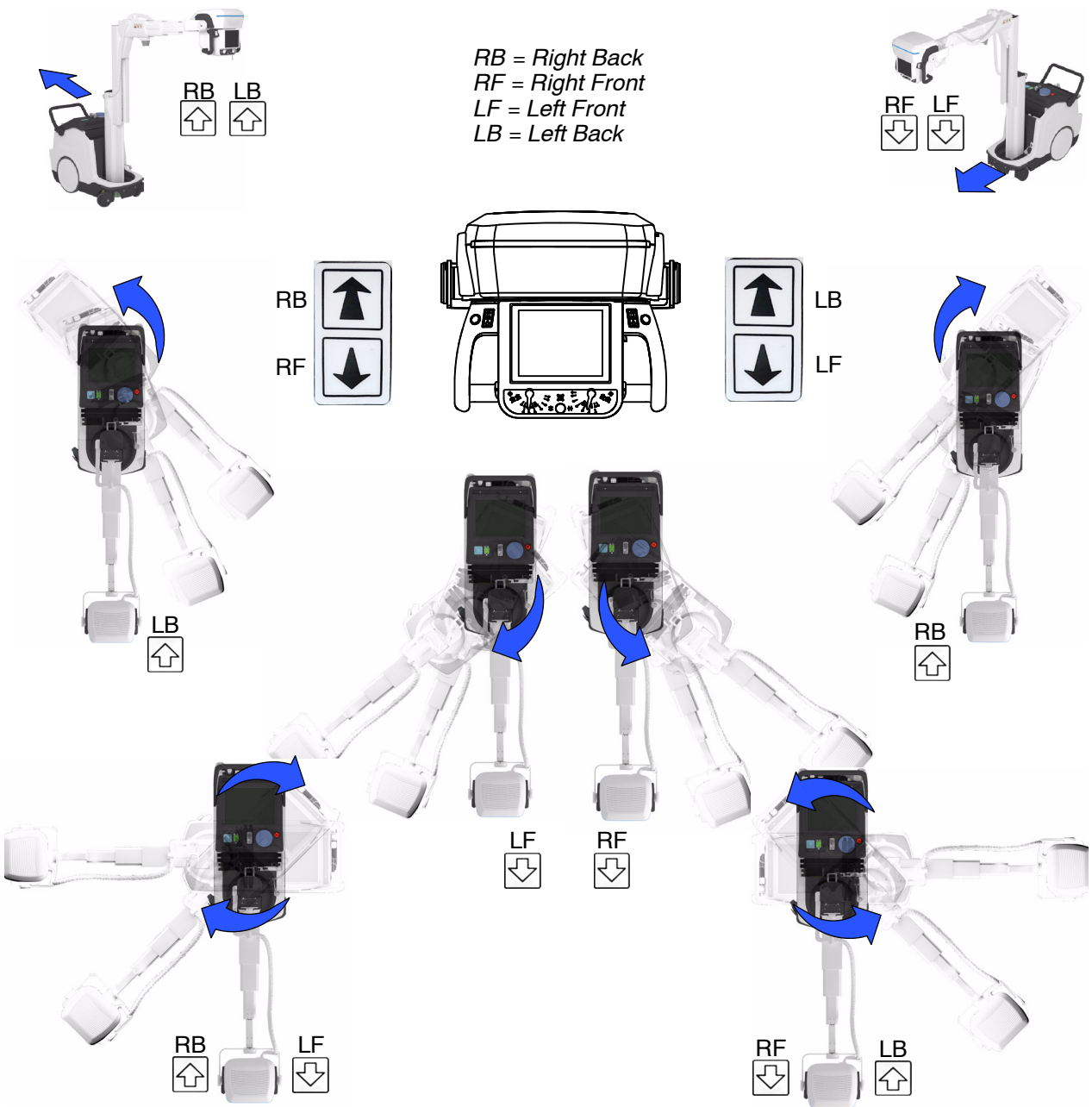
# Mobile X-ray Unit

## Operation

Illustration 3-4 details the corresponding movements.

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

**Illustration 3-4**  
**Fine Positioning Controls**



3.6.1.3 MANUAL CLUTCH SCREWS

When the unit has to be moved manually, the (x2) Clutch Screws (Allen type) located on each wheel must be removed using the tools provided with the unit.



**DRIVE THE UNIT MANUALLY ONLY WHEN MOTORIZED MOTIONS CANNOT BE PERFORMED (DUE TO A SYSTEM MALFUNCTION OR THE BATTERIES DISCHARGE). IN THIS CASE, DO NOT DRIVE THE UNIT ON SLOPES OR INCLINED SURFACES; DRIVE IT ONLY ON LEVEL SURFACES, TO AVOID PERSONAL INJURIES OR DAMAGE TO EQUIPMENT DUE TO ITS HEAVY WEIGHT.**



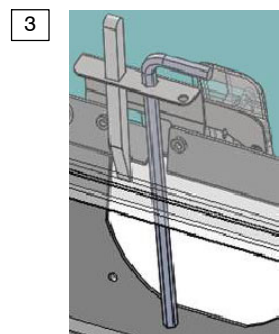
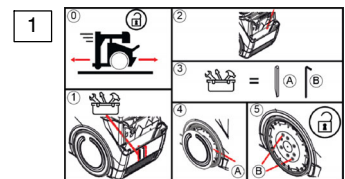
**PLACE THE UNIT ON A FLAT, HORIZONTAL SURFACE, AVOIDING ANY INCLINATION.**

**THE UNIT MUST BE FREE OF ANY BLOCKAGE AND HAVE FREE SPACE AROUND IT TO BE ABLE TO DISPLACE, ONCE THE PROCEDURE HAS BEEN CARRIED OUT.**



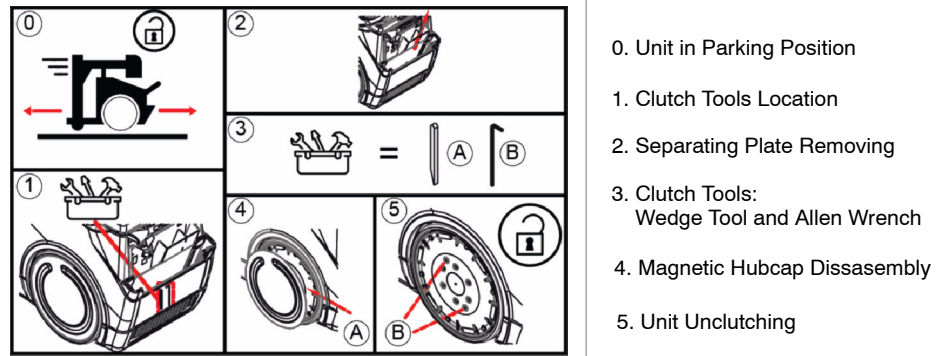
***This procedure is intended to be carried out by Specialized Operators.***

- 1. Sticker with instructions
- 2. Separating Plate (Back Holder)
- 3. Tools Support (located inside the Unit)
- 4. Magnetic Hubcap

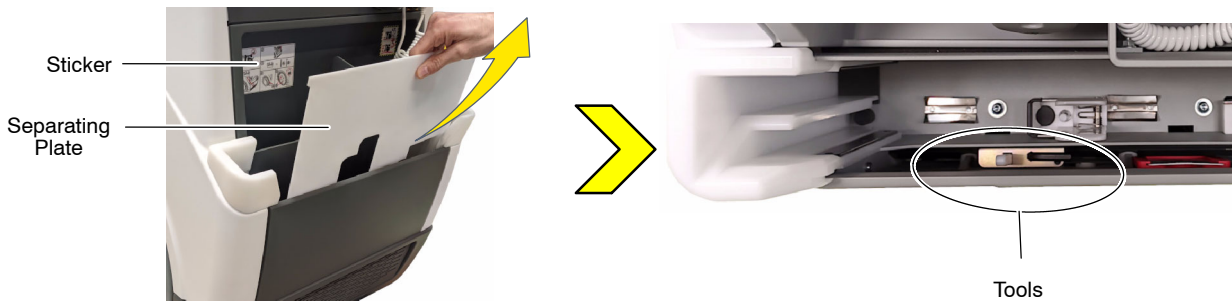


Proceed as following:

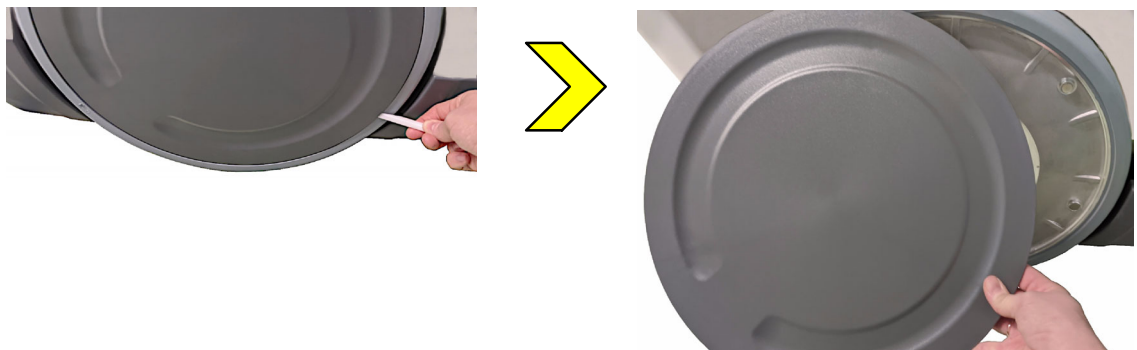
1. Check the indications given on the instruction sticker.



2. Dismount the Separating Plate of the Back Holder, in order to gain access to the Tools Holder mounted inside of the Unit.



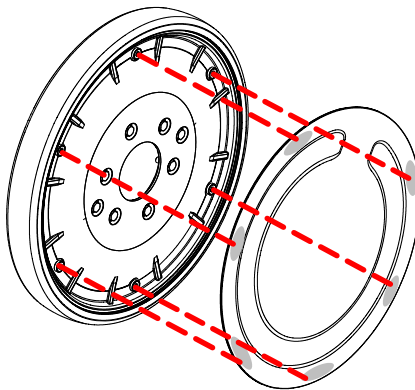
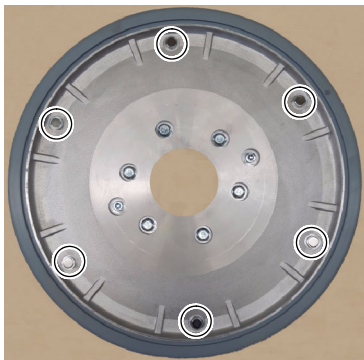
3. Take both tools (Wedge Tool and Allen Wrench) from the holder.
4. Use the Wedge Tool to dismount the Magnetic Hubcap.



5. Use the Allen Wrench to remove the Clutch Screws (x2) of each wheel. This will uncouple the wheels from the motors (releasing the brakes) allowing the free movement of the Unit.



6. In order to reattach the Magnetic Hubcaps, be sure to center the Hubcap plates with respect to the wheel magnets.



7. Finally, put the Clutch Tools and the Separating Plate back in place.

#### 3.6.1.4 PROXIMITY SENSORS (OPTION)



**PROXIMITY SENSORS ARE NOT A SAFETY SYSTEM OR AN ANTI-COLLISION MECHANISM, BUT A DRIVING AID SYSTEM THAT ACTS BY REDUCING THE SPEED AND ALERTING THE USER WHEN AN OBSTACLE IS DETECTED.**



Proximity Sensors

The Proximity Sensors located under the Front Bumper, reduce the system speed when detecting an obstacle, at a configured distance.

The system alerts the user with the Status Light Indicator blinking white.

**Note** 

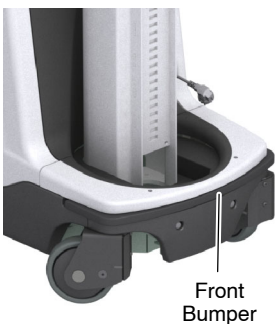
*Distance and Status Light Indicator can be configured by the Service Engineer.*

**Note** 

*For further information, refer to Section 3.2.9 of Status Light Indicators.*

Proximity Sensors are automatically deactivated by activating the system motion controls, once the obstacle has been avoided.

#### 3.6.1.5 BUMPERS



Front Bumper

The Front Bumper is provided with several sensors that stop the motor movement in the event of a frontal collision.

The Status Light Indicator lights magenta when the Front Bumper is activated.

The Front Bumper is automatically deactivated by using the system motion controls backward; the Status Light Indicator blinks magenta when the system is being moved away and becomes white once the bumper sensors deactivate.

**Note** 

*The Lateral Bumpers are not equipped with sensors.*

**Note** 

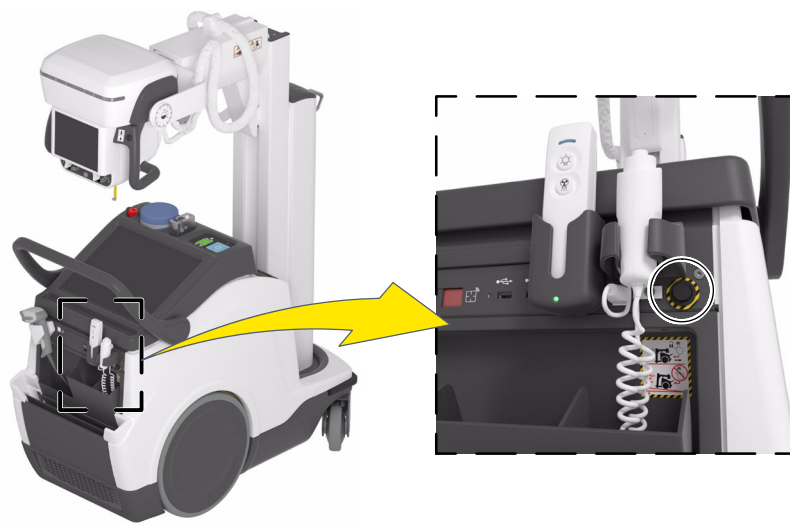
*For further information, refer to Section 3.2.9 of Status Light Indicators.*

**3.6.1.6 MANUAL DRIVING BRAKE RELEASE (OPTION)**

The Manual Driving Brake Release consists of a push-button that allows to releasing the displacement of the Mobile Unit in emergency or breakdown situations.

To do this, press and hold the release button while using the Handlebar to move the Unit.

**Illustration 3-5  
Manual Driving Brake Release Push-Button**



**FOR SAFETY REASONS, DO NOT DRIVE THE UNIT OVER RAMPS WITH AN INCLINATION ANGLE  $>2^\circ$  WHEN THE PUSH-BUTTON IS PRESSED AND THE BRAKES ARE RELEASED. REFER TO TABLE 3-1 IN SECTION 3.**



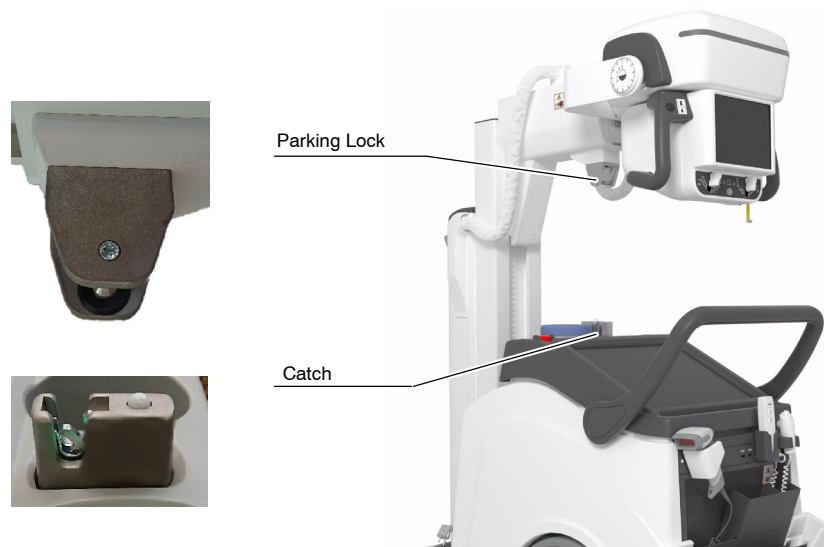
#### 3.6.2 PARKING POSITION OF THE ARM



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

The Parking Detent Device is composed of the Parking Lock (on the Telescopic Arm) and the Catch (on the Main Module next to the Control Console).

The system is in Parking Position when the Parking Lock 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 Lock is aligned with the Catch.
- Lower the Arm and fully insert the Parking Lock into the Catch, until a “click” is heard; it indicates that it has been properly placed in Parking Position.

The Parking Position status is indicated by a System Message and an icon displayed on the Head-Assembly Console (this icon could also be displayed on the Main Screen through the Acquisition Software).

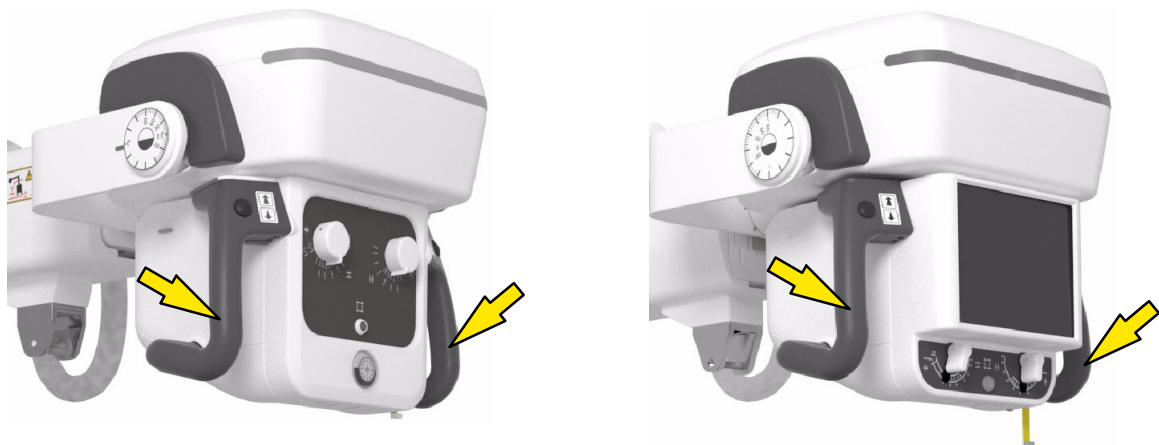
To release the Arm from Parking Position, grab the Handgrips of the Head-Assembly, in order to activate the Brake Control, and lift the Telescopic Arm upward.



### 3.6.3 MOVEMENT CONTROLS

#### 3.6.3.1 COLUMN AND TELESCOPIC ARM MOVEMENTS

Head-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 the Parking position.



Hold the Handgrips to activate the Brake Control to move the Column and Arm until the Head-Assembly is positioned. Release the control to lock in place.



**ALWAYS USE THE HANDGRIPS TO CONTROL AND DRIVE THE COLUMN AND ARM MOVEMENTS. NEVER PUSH DIRECTLY ON THE HEAD-ASSEMBLY OR COLLIMATOR.**



**CAREFULLY DRIVE THE COLUMN AND ARM MOVEMENTS AVOIDING ANY POSSIBLE COLLISION WITH THE PATIENT, THE DETECTOR, THE CONTROL CONSOLE SCREEN OR ANY OTHER PART OF THE EQUIPMENT OR OTHER ELEMENTS AROUND IT.**

The Column can rotate from its Parking position:  $\pm 317^\circ$ .

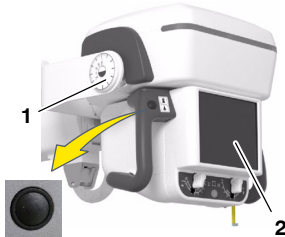
The Arm features a vertical travel range of 1490 mm.

Note 

*For further information, refer to Section 8.3 of Physical Characteristics.*

### 3.6.3.2 HEAD-ASSEMBLY MOVEMENTS

Press the black buttons located on the Handgrips to rotate the Head-Assembly from its vertical position:



- $\pm 180^\circ$  on its transversal axis, *i. e.* roll rotation (see *Illustration 3-6, A*). This movement has detents at  $-90^\circ$ ,  $0^\circ$  and  $+90^\circ$ , and it has stops at  $-180^\circ$  and  $180^\circ$ .

The angle can be indicated in the *Inclinometer* (2) located on the Head-Assembly (for unit with 3-Section Arm) or on the Head-Assembly Screen (for unit with 4-Section Arm).



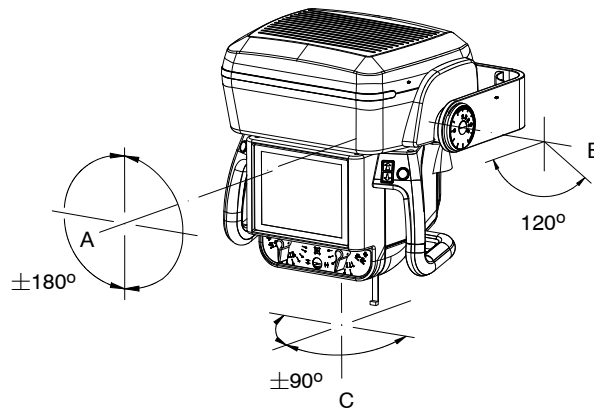
- $120^\circ$  on its horizontal axis, *i. e.* pitch rotation (see *to Illustration 3-6, B*). This movement has detents at  $0^\circ$ , and it has stops at  $+90^\circ$ ,  $0^\circ$  and  $-30^\circ$ .

The angle is indicated in the *Inclinometer* (1) located on the Head-Assembly Support, and on the Head-Assembly Screen when it is present.

Note 

*Refer to Section 3.6.3.3 for Collimator movements, and Section 4.2 for information on the Head-Assembly Console.*

**Illustration 3-6**  
**Head-Assembly and Collimator Movements**



**3.6.3.3 COLLIMATOR MOVEMENTS**

The Collimator can rotate  $\pm 90^\circ$  on its vertical axis (refer to Illustration 3-6,C), while the Head-Assembly remains in the same position.

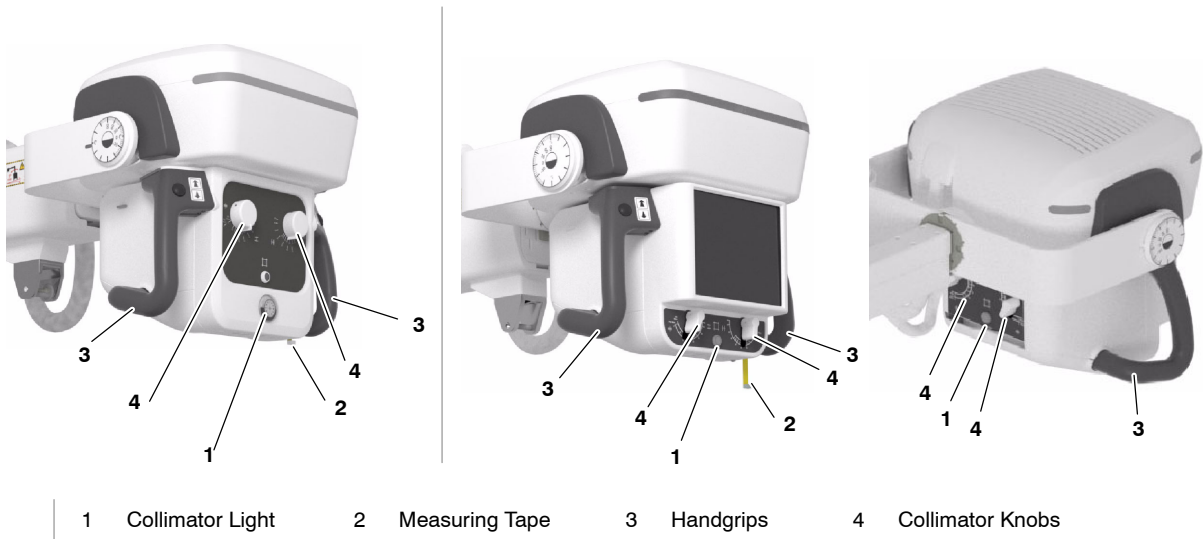
This movement is performed by manually turning the Collimator and has detents at  $-90^\circ$ ,  $0^\circ$ , and  $+90^\circ$ .

**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:	
		$0^\circ$ or $\pm 90^\circ$	$\pm 45^\circ$
12°	24X30 30X24	SID $\geq$ 70 cm	SID $\geq$ 100 cm
	35X43 43X35	SID $\geq$ 100 cm	SID $\geq$ 145 cm
	43X43		
16°	24X30 30X24	SID $\geq$ 70 cm	SID $\geq$ 70 cm
	35X43 43X35	SID $\geq$ 100 cm	SID $\geq$ 100 cm
	43X43		

### 3.7 COLLIMATOR CONTROLS



**Note**

Refer to the Collimator Manual for extended information about operation or technical description needed to maintain compliance with Standard IEC 60601-1-3:2008+AMD1:2013+AMD2:2021.

The Mobile unit can be supplied with different types of collimators depending on the options/configuration of the equipment:

Mobile Unit	Collimator Type	LED Light	Measuring Tape	Front Knobs	Rear Knobs	Dual Laser	Motorized Filters	Ready for EDAP option	Ready for external DAP Chamber
Mobile unit with 3-Sections Arm	Manual Collimator with double Laser, Motorized Filters and ready for both Estimated Dose (EDAP) option and DAP Chamber option	✓	✓	✓		✓	✓	✓	✓
Mobile unit with 4-Sections Arm and Head-Assembly Console	Manual Collimator with front and rear side Knobs, double Laser, Motorized Filters and ready for both Estimated Dose (EDAP) option and DAP Chamber option	✓	✓	✓	✓	✓	✓	✓	✓

Depending on the Collimator model, the following features can be included:

1. **Collimator LED Light push-button.**

Press once the *Collimator Light push-button* to turn the light ON; it will remain ON for a few seconds before automatically switching OFF.

Collimator light may also be switched ON/OFF by clicking the *Collimator Light push-button* located at the *Handswitch*.

Press two times within 5 seconds to turn ON the Double Laser in order to adjust the SID.

Press three times to turn OFF the light (if it remains ON).

2. **Measuring tape.**

To measure the SID.

3. **Handgrips with Support .**

For easily positioning the Head-Assembly.

4. **Collimator knobs to adjust the internal blades.**

The Exposure Field is adjusted by setting the Knobs in order to open/close the internal blades.

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

COLLIMATOR OPENING	SID		
	90 cm (35.4")	100 cm (39.4")	180 cm (70.9")
13	11.7 cm (4.6")	13 cm (5.1")	23.4 cm (9.2")
15	13.5 cm (5.3")	15 cm (5.9")	27 cm (10.6")
18	16.2 cm (6.4")	18 cm (7.1")	32.4 cm (12.8")
24	21.6 cm (8.5")	24 cm (9.4")	43.2 cm (17")
30	27 cm (10.6")	30 cm (11.8")	54 cm (21.3")
35	31.5 cm (12.4")	35 cm (13.8")	63 cm (24.8")
40	36 cm (14.2")	40 cm (15.7")	72 cm (28.3")
43	38.7 cm (15.2")	43 cm (16.9")	77.4 cm (30.5")

5. **Additional Variable Filtration** with the following Motorized Filters:

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

Select the filtration option on the Main Screen and/or on the Head-Assembly Screen when it is present.

6. **External Filtration.**

There is a rail system at the rear side of the Collimator, 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.

7. **Minimum Source-Skin Distance:** 30 cm.

8. **Double Laser** selector (option), for Image-Receptor alignment (*refer to step 1.*).

9. **Radiation Meter** (option), it can be ready for Estimated Dose (EDAP) option and/or ready for external DAP Chamber option.

If the DAP Chamber is present, it is placed in the lower guide of the rail system, at the rear side of the Collimator.

### 3.8 DAP CHAMBER (OPTION)



The external DAP Chamber (Radiation Meter) is installed in the lower guide of the Collimator rails. It reads the radiation as Dose Area Product (DAP) in  $mGy \cdot cm^2$  (*for further information, refer to Section 4.5 of "Dosimetry"*).

**Note** 

*Do not install any accessories between the DAP Chamber and the patient. This will disturb the radiation reading.*

**Note** 

*Refer to the corresponding Dosemeter Manual for extended information about the operation or technical description needed to maintain compliance with Standard IEC 60601-1-3:2008 +AMD1:2013+AMD2:2021.*

**Note** 

*This option is not compatible with the Estimated Dose option.*

### 3.9 ESTIMATED DOSE: EDAP / EDOSE (OPTION)

Dose estimation can be performed using the eDAP or eDOSE functionalities. These system options enable dose estimation instead of dose measurement with a DAP Chamber.

- **eDAP:** Calculates an estimation of DAP (Dose Area Product) value according to the values of the X-ray technique used and the Collimator aperture and filter selection values. The DAP value is estimated in  $mGy \cdot cm^2$  with an accuracy of  $\pm (25\% + 0.1)$ .
- **eDOSE:** Calculates a Skin Dose estimate from the values mentioned for Dose per Area and the value of the focus-to-skin distance provided by the FSD sensor. The Dose value is provided in  $mGy$  with an accuracy of  $\pm (25\% + 0.1)$ .

Note 

*For further information about the Focal-Skin Distance Sensor, refer to Section 3.10.*

The Acquisition Software will display the Estimated Dose information of the exposures performed with a Digital Detector (*for further information, refer to Section 4.5 "Dosimetry"*).

Note 

*Any adjustment or recalibration of the Focal-Skin Distance Sensor, Collimator Aperture and eDAP, necessary for the correct calculation of the Estimated Dose, must be carried out by Service Personnel.*

Note 

*This option is not compatible with the DAP Chamber option.*

Note 

*Do not install additional filters or any accessories between the X-ray source and the patient when the Unit has installed the Dose Estimation options. This may result in a potential mismatch between the received dose and the estimated dose calculation.*

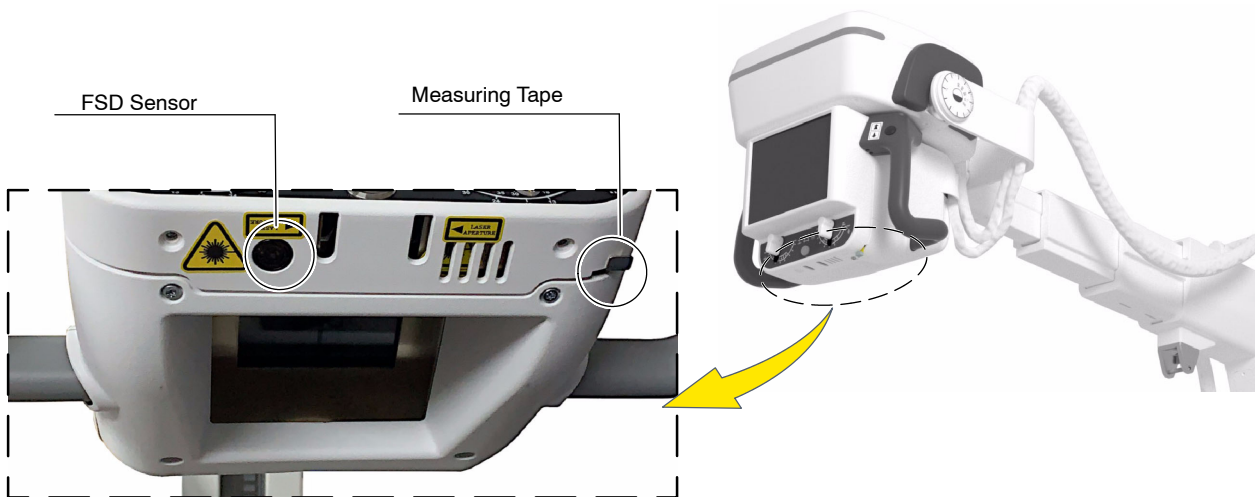
### 3.10 FOCAL-SKIN DISTANCE SENSOR (OPTION)

Note 

If eDOSE functionality for dose estimation is installed in the Unit, the FSD Sensor option is mandatory.

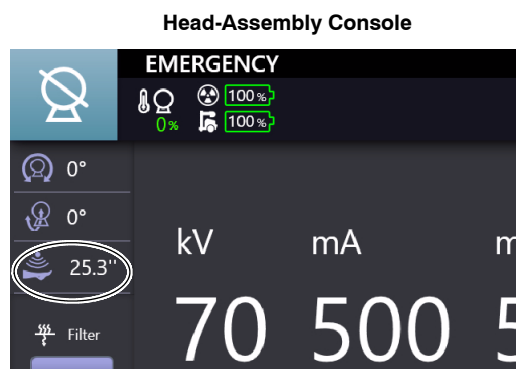
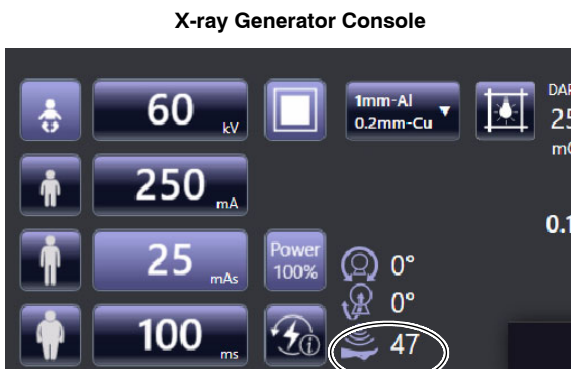
The FSD (Focal-Skin Distance) sensor is installed at the front of the underside of the Collimator. It reads the distance from the focus of the tube to the surface of incidence on a patient, measured along the beam axis. The accuracy of FSD sensor is  $\pm 2$  cm ( $\pm 0.8$ ").

Illustration 3-7  
FSD Sensors Location



The measured value is displayed on the X-ray Generator Console (within *Primo S*) and on the Head-Assembly Console (if installed) (refer to Section 4.1.9).

Illustration 3-8  
FSD Value on the Control Consoles



### 3.11 WIRELESS DIGITAL DETECTORS AND OPTIONS

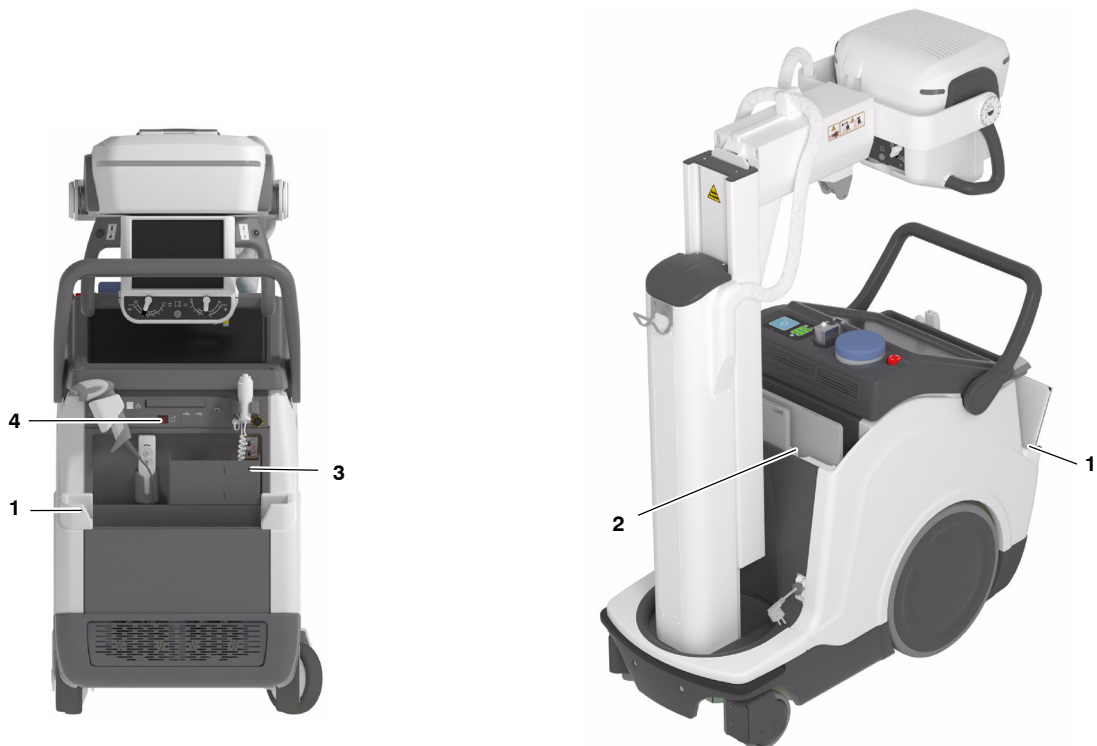
*Wireless Digital Detectors:*

*Mars 1013X, Mars 1417X, Mars 1717X*

Some *Wireless Digital Detectors* can be fitted in an optional *Detector Handle Support* with an *Anti-scatter Grid*.

Depending on the option, the *Digital Detector* can be stored and/or charged in the *Holders* at the *Back* and/or at the *Front Cover*.

**Illustration 3-9**  
**Wireless Digital Detectors and Options**



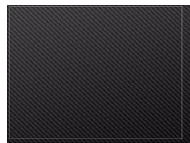
- 1 Holder for Detector Charge and Storage, with / without Grid (Back Cover)
- 2 Holder for Detector Charge and Storage, with / without Grid (Front Cover)
- 3 Detector Bags Holder
- 4 IR Data Communication Sensor (Connections Panel)

### 3.11.1 WIRELESS DIGITAL DETECTORS

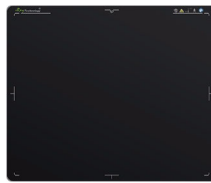
Wireless Digital Detectors communicate with the Mobile unit through the internal Access Point.

Wireless Digital Detector configuration can include a built-in Detector Battery Charger (option), and a Backup Cable.

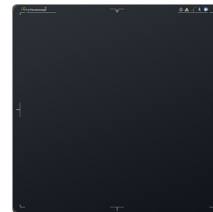
Mars 1013X



Mars 1417X



Mars 1717X



### 3.11.2 IR DATA COMMUNICATION UNIT

The IR Data Communication sensor located in the *Connections Panel*, is used for registering the Wireless Digital Detector to the Mobile Unit by Infrared (IR) Communication.

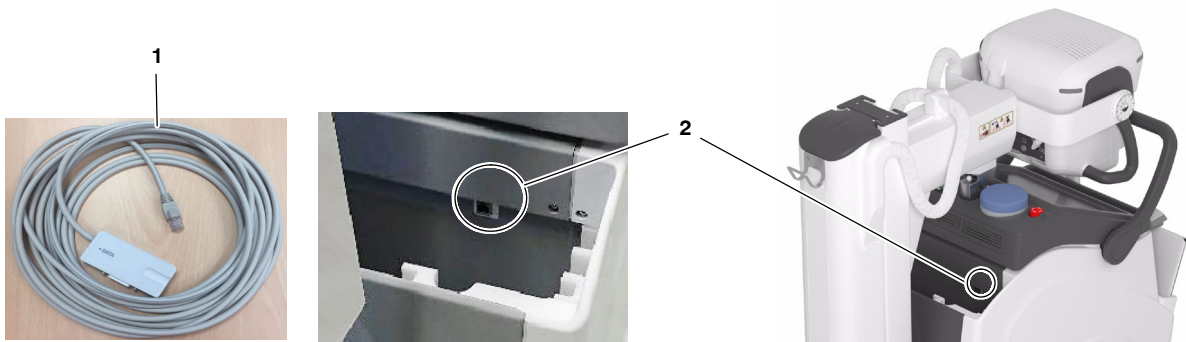


**3.11.3 DETECTOR BACKUP COMMUNICATION CABLE (OPTION)**

Detector Backup Communication Cable (1) allows to expand the Wireless Digital Detector, from wireless to wired configuration.

Connect the Cable to the Detector and to the RJ45 connector at the Front Cover (2).

When not in use, the Backup Cable can be stored at the Detector Holders.



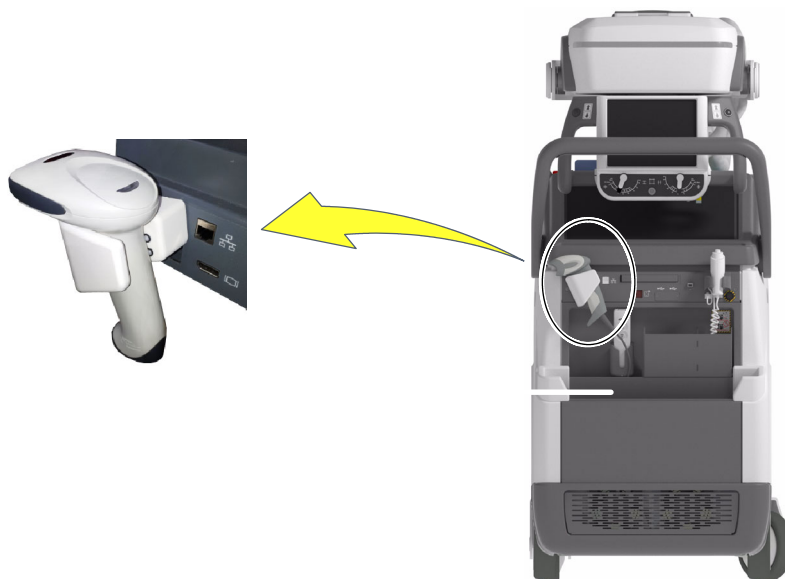
**Note** 

*The Backup Cable is not intended for battery charging.*

**3.11.4 BARCODE SCANNER (OPTION)**

The Mobile Unit can be equipped with a Barcode Scanner, for registering patient information.

The Barcode Scanner is placed in the Connections Panel.



#### 3.11.5 GENERAL USE AND MAINTENANCE OF WIRELESS DIGITAL DETECTORS AND OPTIONS

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.

For Wireless Digital Detectors, do not cover the IR Data Port with hands or other parts of the body and do not use the selected frequency channel (2.4 GHz band) for other wireless devices.

**Note** 

*If at any time the Detector does not connect properly after starting, try again by turning on the Detector once the unit and the Image Acquisition Software are operative.*

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

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

**Note** 

*It is recommended that Digital Detectors be placed in a plastic radio-transparent bag for each use, thus avoiding the excess of cleaning and disinfection processes directly on the Digital Detector surfaces.*

**Note** 

*For further information on the Wireless Digital Detector Handling and Maintenance, refer to the Wireless 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.

Wireless Digital Detectors are prepared to fit into a Frame with a Removable Grid. Consult the corresponding installation instructions and check that the Grid is correctly mounted. Usually, a click sound means that the Grid is in place.

## SECTION 4 CONTROL CONSOLE

The Control Console enables operation of the Mobile X-ray Unit through the *Primo S Software Application* (which runs on the Main Screen).

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

**Note** 

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

The *Primo S* working frame is split into the following sections:

- A. Image Area
- B. Exam List / Preview List
- C. Patient Data
- D. Messages Area
- E. Exam Management Area
- F. X-ray Generator Console



X-ray Generator Console

Exam List

#### **A. IMAGE AREA**

This area shows the image of the exam selected in the preview list.

#### **B. EXAM LIST / PREVIEW LIST**

When a new exam is added to the study, a black box with the name of the procedure chosen is created. When the image associated to a certain procedure is acquired, a preview of the acquired image will be displayed in the black box.

#### **C. PATIENT DATA**

This section shows the patient's personal data: patient's name (or emergency number is the emergency mode is being used), birth date, patient ID, weight (kg), height (m), and dose.

#### **D. MESSAGES AREA**

This area provides information about the status of the equipment and alarm messages, the connection status of the detector and the amount of free storage space on the archive disk.

#### **E. EXAM MANAGEMENT AREA**

This area contains keys to delete, move or add procedure to the study and to suspend or close the study.

#### **F. X-RAY GENERATOR CONSOLE**

The X-ray Generator parameters are already set by the manufacturer for each kind of exam. The parameters can be adjusted during the installation. *For detailed information refer to Section 4.1.*

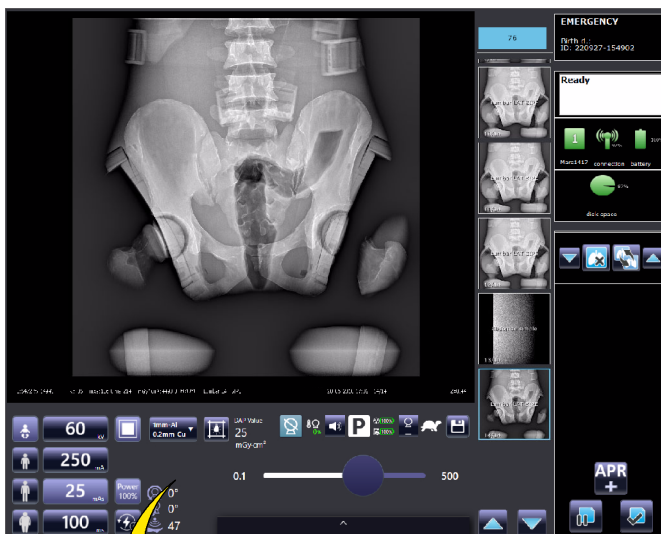
**Note** 

*For further details about operation with controls of Primo S Software Application, refer to Primo S User Manual.*

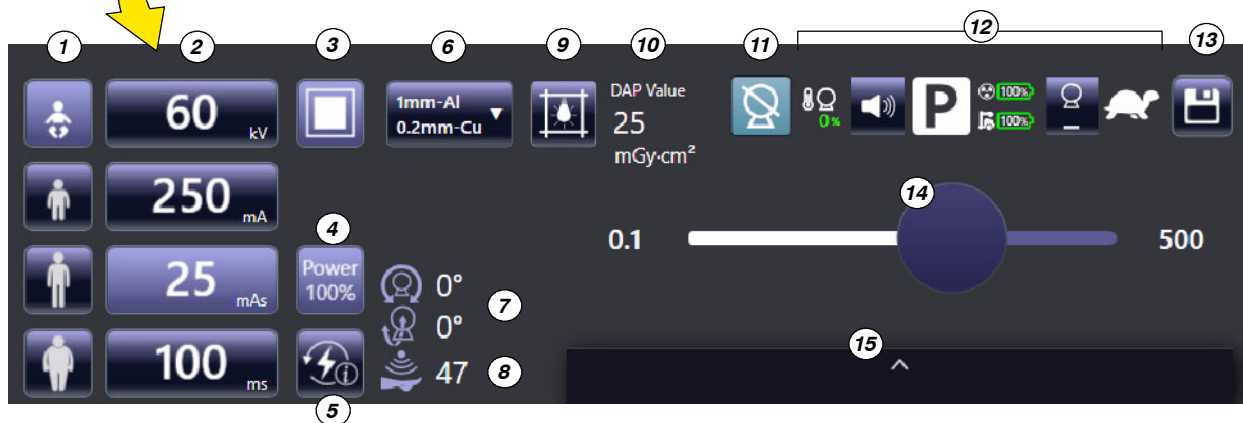
### 4.1 X-RAY GENERATOR CONSOLE

The X-ray Generator Console is enclosed in *Primo S Software Application Main Screen*. Controls in the X-ray Generator Console are described in this manual; for operation with *Primo S Software Application*, refer to *Primo S manuals*.

**Illustration 4-1**  
**X-ray Generator Console**



1. Patient Size / Type
2. Radiographic Parameters
3. Focal Spot
4. Power Reduction
5. *Last Exposure* Button
6. Collimator Filter Selection
7. Head-Assembly Rotation Indicator
8. FSD Value Indicator
9. Collimator Light
10. Dosimetry
11. Exposure Indicator
12. Unit Indicators: Heat Units, Mute, Parking Position, Batteries Status, Workstation and Motion Speed.
13. Save Button
14. Radiographic Parameters Slider
15. Message Bar



#### 4.1.1 EXPOSURE INDICATORS

The “*Status*” icon of the Control Console can vary according to the operating status, as described below.



**NORMAL STATUS:** The detector is ready; the RAD technique is correctly set and there is no Error or Interlock condition in the system.



**HANDSWITCH PRESSED:** The Handswitch halfway has been pressed (“Prep” position) to prepare the X-ray Tube for exposure.



**READY:** Indicates that the technique selected is properly set, there are no interlock failures nor system faults, the anode is rotating and the X-ray Tube is ready for exposure.



**EXPOSURE:** Indicates that the X-ray exposure is in progress. It remains illuminated during the length of exposure. At the same time that radiographic exposure is being made, an acoustic signal is emitted.



**INHIBITION CONDITIONS (FILAMENTS ENABLED):** There are one or more events causing an inhibition of exposure, despite the Tube Filaments being properly enabled.



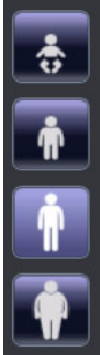
**INHIBITION CONDITIONS (FILAMENTS DISABLED):** There are one or more events causing an inhibition of exposure. When the Filaments are disabled (regardless of whether they have been deactivated via software or some other issue), the inhibition status icon is shown in blue.



**BEFORE PERFORMING AN EXPOSURE, IT IS THE RESPONSIBILITY OF THE OPERATOR TO CHECK THAT THE RADIOGRAPHIC PARAMETERS AND SELECTIONS ARE APPROPRIATE FOR EACH EXAMINATION.**

**BE SURE THAT NO LIQUID DROPS NOR OBJECTS ON THE CONTROL CONSOLE HAVE MODIFIED THE RADIOGRAPHIC PARAMETERS / SELECTIONS.**

#### 4.1.2 PATIENT SIZE / TYPE



These controls allow the adjustment of the RAD parameters according to:

- Patient size: small, medium and large (three for adult and one for pediatric). It modifies mAs value.
- Patient type: adult or pediatric. It modifies kV value.

#### 4.1.3 RADIOGRAPHIC PARAMETERS

Radiographic Parameters are divided into kV, mAs, mA, and Time (seconds "s").

##### Illustration 4-2 Radiographic Parameters Selection



**kV** shows:

- The radiographic kV value selected for the technique.



**mA** shows:

- The radiographic mA value selected for the technique.



**mAs** can show:

- The radiographic mAs value selected for the technique.
- If an exposure is aborted by releasing the Handswitch button, the actual mAs value flashes for five seconds, the message “*Aborted Exposure Error*” appears in the Information Area and an alarm sounds, until the “*Accept*” control is pressed to reset the error condition.



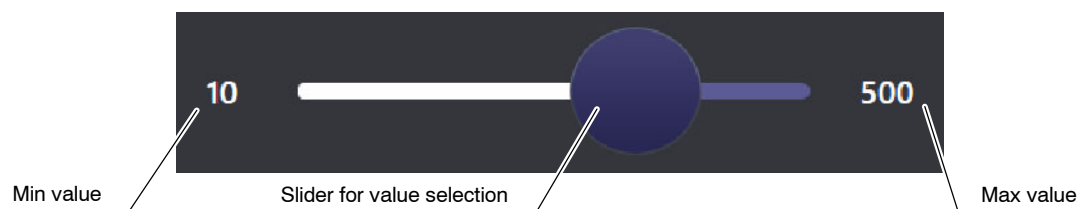
**Time (ms/s)** can show:

- The Time value (in milliseconds/seconds) selected for the radiographic technique.
- If an exposure is aborted by releasing the Handswitch button, the actual Time (ms/s) value flashes for five seconds, the message “*Aborted Exposure Error*” appears in the Information Area, and an acoustic signal is emitted until the “*Accept*” control is pressed to reset the error condition.

**INCREASE / DECREASE:** Radiographic technique values are increased or decreased by moving the “*Slider*” position to change the value.

When the “*Slider*” is positioned over a value not allowed, its pointer comes back to the nearest allowed value, according to the limit of the Tube and the Unit.

**Illustration 4-3**  
**Slider for Value Selection**



- **kV:** Selects the X-ray Tube voltage.
- **mA:** Selects the X-ray Tube current, changing the mAs value and keeping constant the selected Exposure Time, whenever possible.
- **mAs:** Selects the exposure in mAs, setting the maximum mA available for the selected Focal Spot and the respective Exposure Time.
- **s:** Selects the Exposure Time in seconds.

(Refer to Section 8 for Factor ranges)

**Note** 

If after pressing any of these buttons, the technique value is blocked, it could mean that it may have selected a wrong combination of radiographic parameters that could have caused a warning condition (for further information about System Messages, refer to Section 5).

**4.1.4 FOCAL SPOT**

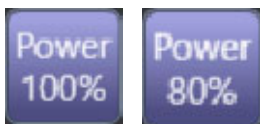
This indicator displays the selected Focal Spot of the X-ray Tube: “Small” or “Large”. The Focal Spot is changed by pressing on this indicator. It keeps kVp and constant mAs, whenever it is possible.

Small and Large Focal Spots can overlap each other, refer to the graphic below to view an example of Focal Spot change.

**Illustration 4-4**  
**Small and Large Focus Overlap**

**Note** 

The maximum mA station for the Small Focal Spot and the minimum mA station for the Large Focal Spot can be configured by the field engineer during the installation.

**4.1.5 POWER REDUCTION**

Tube Capability can be limited to 80% by pressing on the “Power Reduction” button and selecting the desired power percentage (100% or 80%). In this case, if the 80% limitation is selected, the range of radiographic parameters may be conditioned and the selection of the values could be automatically adjusted.

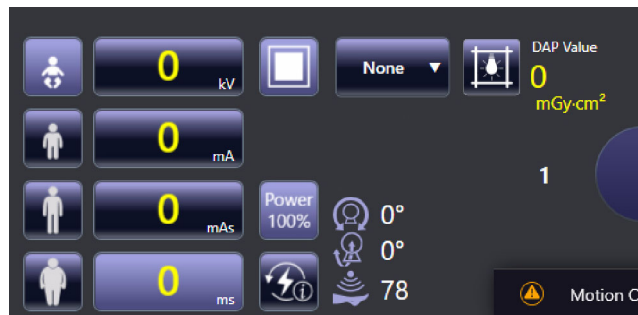
#### 4.1.6 LAST EXPOSURE VALUES



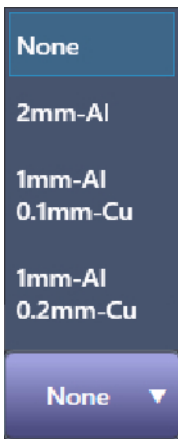
Press on the “*Post-Exposure*” button to recover the values of the Time, the calculated mAs, and the selected kV and mA radiographic parameters of the last exposure. The Dose value of the last exposure will also be displayed on the Dosimetry indicator (*refer to Section 4.5*).

All these values are displayed in yellow for five seconds.

**Illustration 4-5**  
**Last Exposure Values**



#### 4.1.7 COLLIMATOR FILTER SELECTION



To set a Collimator filter, press on the option to be selected. Filter Selection is always displayed on the screen with one of the four available filter options selected (“None”, by default):

- None
- 2 mm Al
- 1 mm Al + 0.1 mm Cu
- 1 mm Al + 0.2 mm Cu

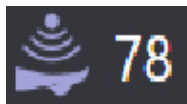
#### 4.1.8 HEAD-ASSEMBLY ROTATION



It displays the rotation and angulation of the X-ray Tube.

- The value displayed beside the upper symbol, indicates the Head-Assembly rotation on its transversal axis (roll rotation).
- The value displayed beside the lower symbol, indicates the Head-Assembly rotation on its horizontal axis (pitch rotation).

#### 4.1.9 FSD VALUE



This option displays the value of the current distance (cm/inches) between focus and patient measured by the Focal-Skin Distance sensor (*refer to Section 3.10*).

#### 4.1.10 COLLIMATOR LIGHT



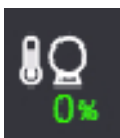
Press the “*Collimator Light*” button to turn the Collimator light ON; it will remain ON for a few seconds before automatically switching OFF.

Press it twice within 5 seconds to turn ON the Collimator Laser.

Press three times to turn OFF the light (if it remains ON).

*Refer to Section 3.7, for detailed information on Collimator Controls.*

#### 4.1.11 HEAT UNITS INDICATOR



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

The “*Heat Units*” shows the percentage of utilized thermal capacity of the Tube. For example, “25%” would indicate that 25% of Heat Units capacity is used.

#### 4.1.12 MUTE BUTTON



This button displays the selected sound option. Press on it to activate/deactivate the acoustic signals of the Mobile Unit.

#### 4.1.13 PARKING INDICATOR



When the Mobile Unit is in Parking Position, this indicator is displayed.

#### 4.1.14 BATTERIES STATUS



**Full Charge (Stand-alone mode):** The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 60% and 100%, and the unit is unplugged from the mains.

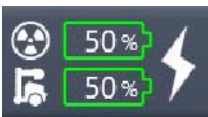


**Full Charge (Charging mode):** The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 60% and 100%, and the unit is plugged into the mains.

The “Lightning” icon indicates that the batteries are charging.



**Medium Charge (Stand-alone mode):** The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 31% and 59%, and the unit is unplugged from the mains.



**Medium Charge (Charging mode):** The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 31% and 59%, and the unit is plugged to mains.

The “Lightning” icon indicates that the batteries are charging.



**Low Charge (Stand-alone mode):** The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 20% and 30%, and the unit is unplugged from the mains.



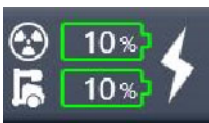
**Low Charge (Charging mode):** The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 20% and 30%, and the unit is plugged into the mains.

The “Lightning” icon indicates that the batteries are charging.



**Very Low Charge (Stand-alone mode):** The Battery icons are displayed in steady orange when the battery charge levels for X-ray and Motion are between 1% and 19%, and the unit is unplugged from the mains.

The icons change the color from steady orange to steady green when the unit is plugged into the mains.



**Very Low Charge (Charging mode):** The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 1% and 19%, and the unit is plugged into the mains.

The “Lightning” icon indicates that the batteries are charging.



**Critically Low Charge (Stand-alone mode):** The Battery icons are displayed in blinking orange when the battery charge level for X-ray and Motion is 0%, and the unit is unplugged from the mains.

The icons change color from blinking orange to steady green when the unit is plugged into the mains.



**Critically Low Charge (Charging mode):** The Battery icons are displayed in steady green when the battery charge level for X-ray and Motion is 0%, and the unit is plugged into the mains.

The “Lightning” icon indicates that the batteries are charging.

**Note**

*The battery charge level is displayed on a scale from 0% to 100% in 10% increments (i.e. 10%, 20%, 30%, etc.).*

**4.1.15 MOTION SPEED INDICATOR**

This indicator can display:



**Limited Motion Speed:** “Turtle” icon appears when an obstacle is detected and speed limitation is active. It can also be displayed with movements out of the Parking Position (e.g., when using the Fine Positioning Controls on the Head-Assembly handles).



**Free Motion Speed:** “Rabbit” icon appears when the Mobile Unit is in movement and there is no obstacle.

#### 4.1.16 WORKSTATION INDICATOR



Press on this button to display the Workstation Selection pop-up window.

Workstations are automatically selected by the APR configuration. Each icon corresponds to its related workstation and remains highlighted on the X-ray Generator Console when selected.

Although the operator does not need to select any workstation as they are always associated to an APR technique, a specific workstation may be selected if needed.

Although the operator does not need to select any workstation as they are always associated with an APR technique, a specific workstation may be selected if needed (refer to *Primo S* manuals).

Press on the desired Workstation to select it and return to the main menu by pressing the “Workstation” button again.

**Illustration 4-6**  
**Workstation Selection Pop-up Window**



#### 4.1.17 SAVE BUTTON



The *Save* button is only available to *Administrator* user.

If, after modifying any of the Radiographic Parameters, Focal Spot, etc., it is necessary to save these settings so that they remain associated with the selected technique, press the *Save* button.

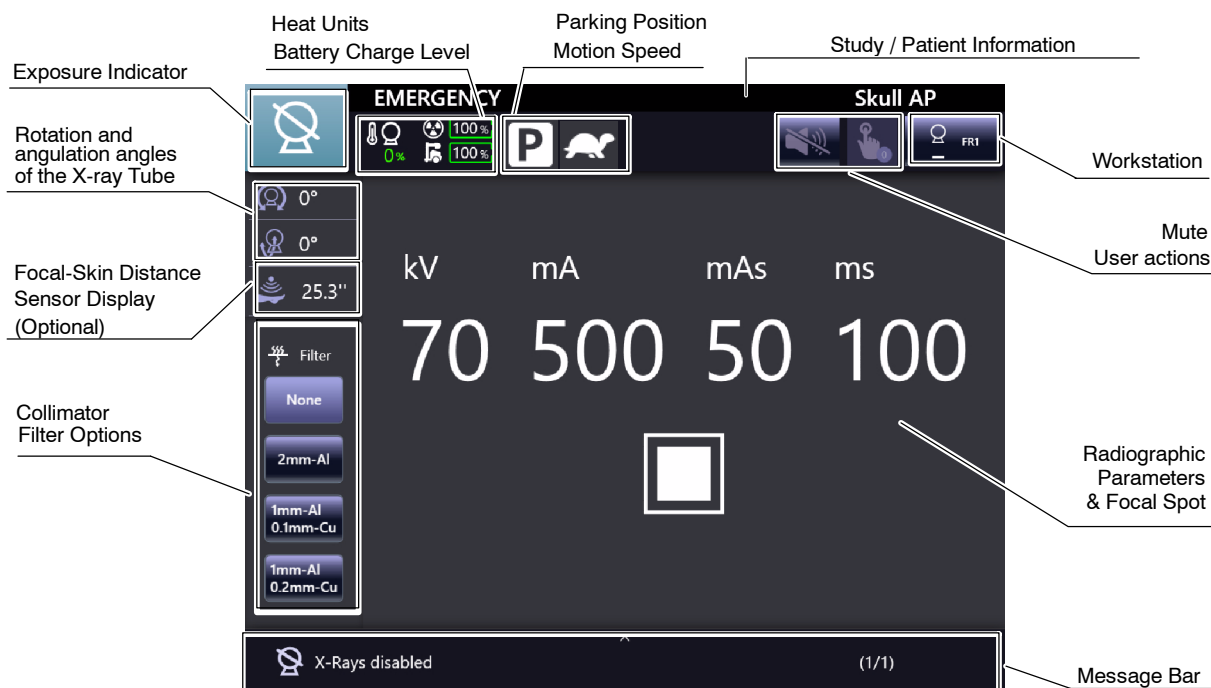
**Note**

*Once the Save button is pressed, the values of the selected technique will be overwritten in the APR.*

## 4.2 HEAD-ASSEMBLY CONSOLE (OPTION)

The Head-Assembly Console displays the Radiographic Parameters, System Messages, Image Preview and some other useful information for the operator.

**Illustration 4-7**  
**Head-Assembly Console**

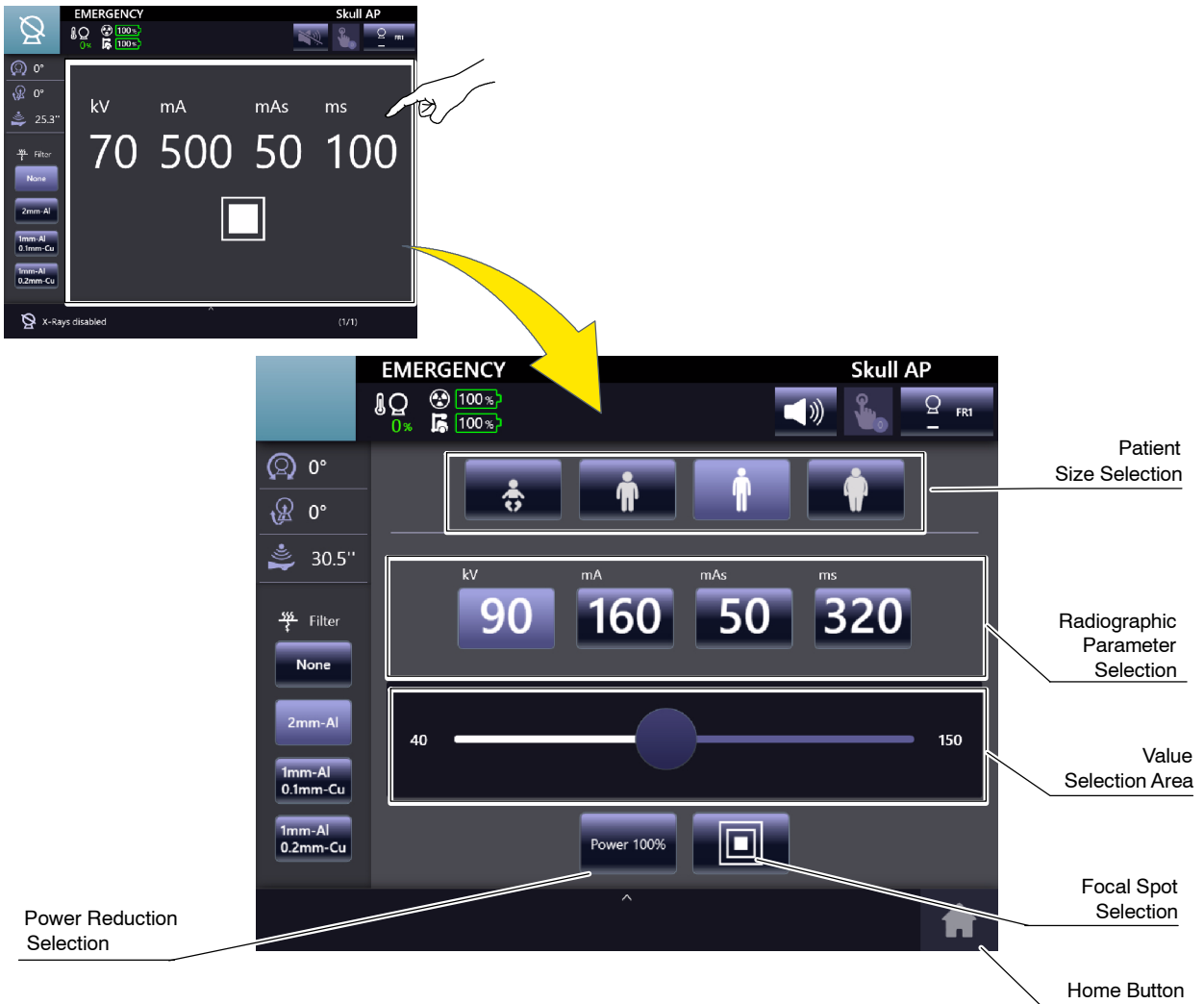


The following indicators and buttons have been previously described in the X-ray Generator Console section:

- Exposure Indicator (*Refer to Section 4.1.1*).
- Heat Units (*Refer to Section 4.1.11*).
- Battery Charge Level Indicator (*Refer to Section 4.1.14*).
- Parking Position Indicator (*Refer to Section 4.1.13*).
- Motion Speed Indicator (*Refer to Section 4.1.15*).
- Mute Button (*Refer to Section 4.1.12*).
- Patient Size / Type (*Refer to Section 4.1.2*).
- Focal Spot (*Refer to Section 4.1.4*).
- Radiographic Parameters (*Refer to Section 4.1.6*).
- Collimator Filter Selection (*Refer to Section 4.1.7*).

Tap on the Radiographic Parameters Display frame to access the Parameters Selection Window.

**Illustration 4-8**  
**Head-Assembly Console (Parameters Selection Window)**



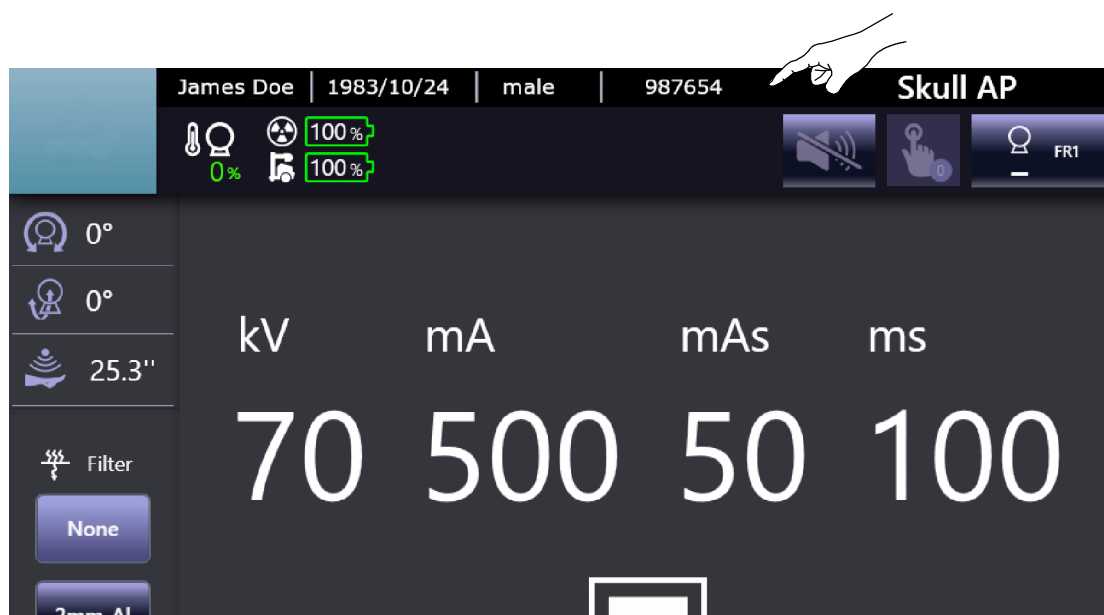
Press the "Home" button to return to the Main Window.

#### 4.2.1 PATIENT INFORMATION PROTECTION

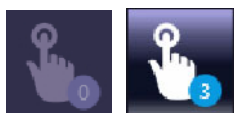
After selecting a patient and choosing a study, the patient's name, date of birth, gender, acquisition ID, and procedure type are displayed in the upper bar of the Head-Assembly Screen.

To protect the patient information, tap on the information bar to hide this data in the Head-Assembly Screen.

**Illustration 4-9**  
Patient Information Protection



#### 4.2.2 USER ACTION



Active when manual adjustments from the operator are required before making the exposure (e.g. if the Grid is not inserted). If more than one action is required, the number of actions to perform is shown in the icon.

*Refer to Section 5 (System Messages) for further information.*

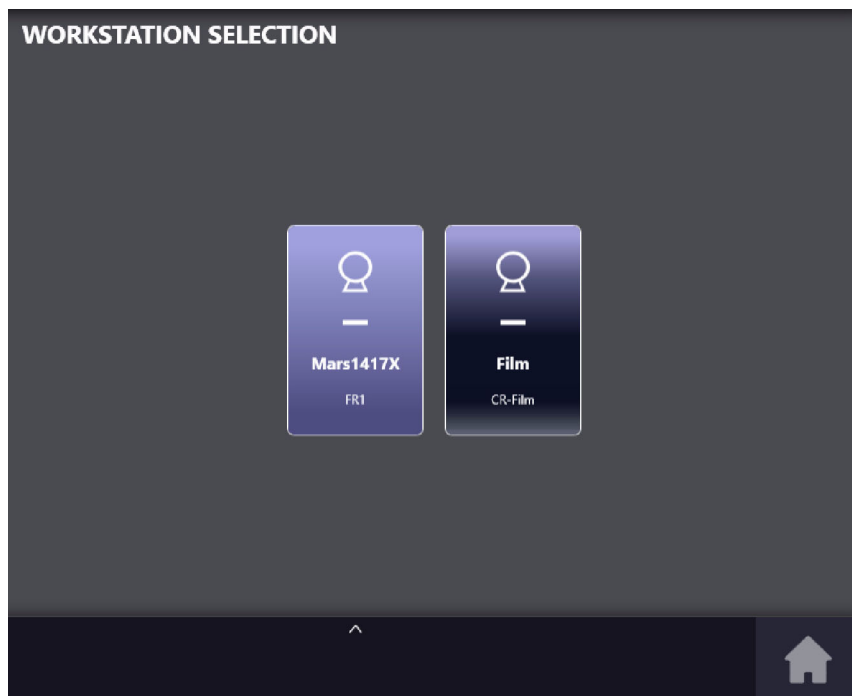
### 4.2.3 WORKSTATION SELECTION



Shows the selected Workstation (Direct or Free Technique). Press on it to modify the Workstation selection. A new window will be opened with the available Workstations. Press on the desired one to select it and return to the main menu by pressing again on this icon or on the “Home” icon.

*This functionality is equivalent to that described in Section 4.1.16 for the X-ray Generator Console.*

**Illustration 4-10**  
**Workstation Selection Window**



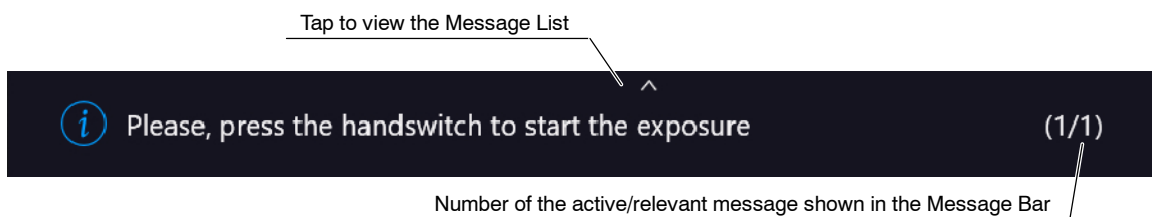
### 4.3 MESSAGE BAR

The Message Bar shows informative messages (warning, information, inhibition condition, user action, error).

Active messages, i.e. those that require action by the operator or report an error or a warning, will be displayed consecutively in this area.

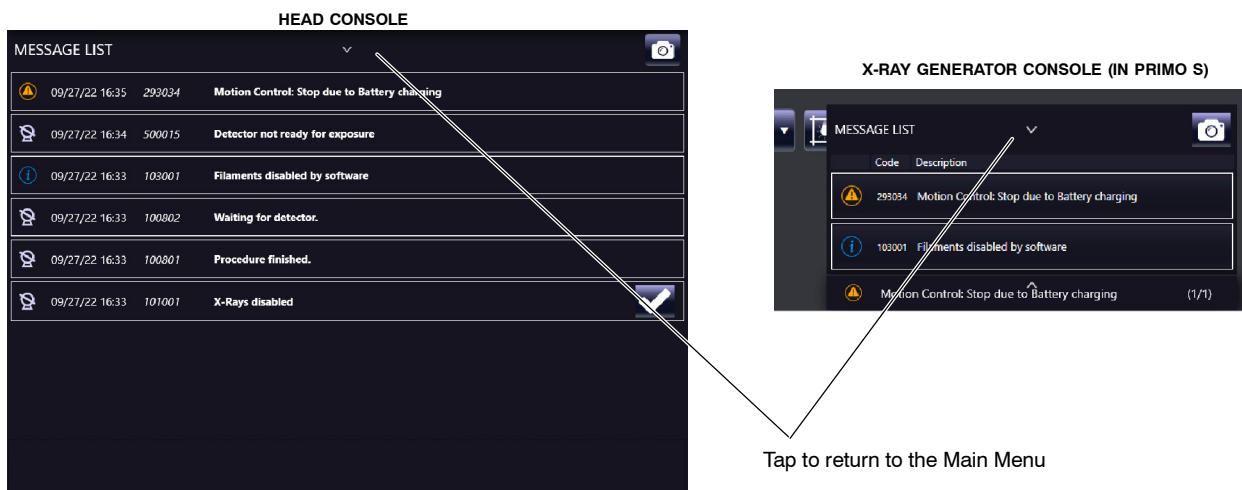
The Message Bar is located in the bottom area of the Head Console Main Menu (option) and in the X-ray Generator Console (embedded in *Primo S*).

**Illustration 4-11**  
**Message Bar**



To check the message history, press on the Message bar. A pop-up window (titled “*Message List*”) will be displayed. To close it, tap on the upper arrow of the Message List window and go back to the previous screen.

**Illustration 4-12**  
**Message List**



**Note**

For information about the different message windows refer to the Section 4.3.1.

For information about the Types of Messages and Messages List refer to the Section 5 “System Messages”.

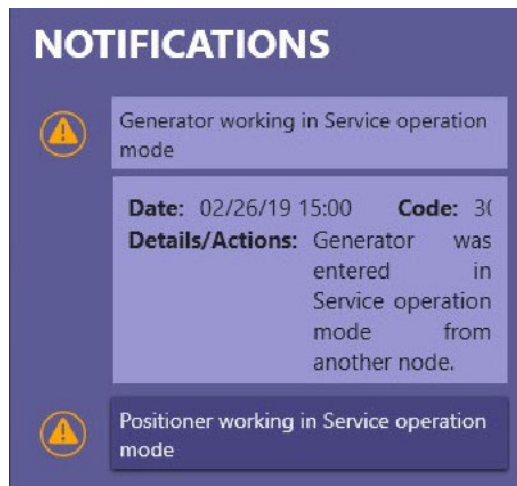
### 4.3.1 MESSAGE WINDOWS

The main message window is the Message List, available from the Message Bar of the Main Menu, which contains all system messages.

In addition, there are different pop-up message windows depending on the source of the messages and how to access them. General features of these windows are described in *Section 4.3 “Message Bar”*, however some of their particularities are described as follows.

Press on any message to display the date, code and a brief description.

**Illustration 4-13**  
**Message Displayed**



Press the “Start” icon in any of these windows to return to the Main Menu.

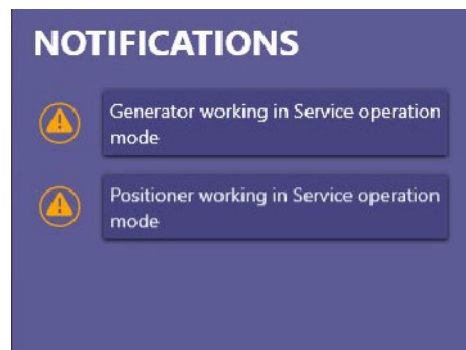
Each of the message windows is detailed below:

#### NOTIFICATIONS

Notifications of important information to be noticed by the operator can appear during normal operation as pop-up messages in Message Bar, allowing to access the Notifications window. Two types of different messages can appear in this pop-up window during normal operation:

- Information messages that do not require confirmation by the user. Automatically cleared by the system after a few seconds.
- Messages that require user confirmation. It is needed to tap on the “Accept” button to continue.

**Illustration 4-14**  
**Notifications Pop-up Window**



#### **INHIBIT CONDITIONS MESSAGES**

Whenever the System Status is "*Inhibit Conditions*", it is possible to press the status icon to display the messages of conditions that inhibit exposures (*refer to Section 5*).

**Illustration 4-15**  
**Inhibit Conditions Messages**



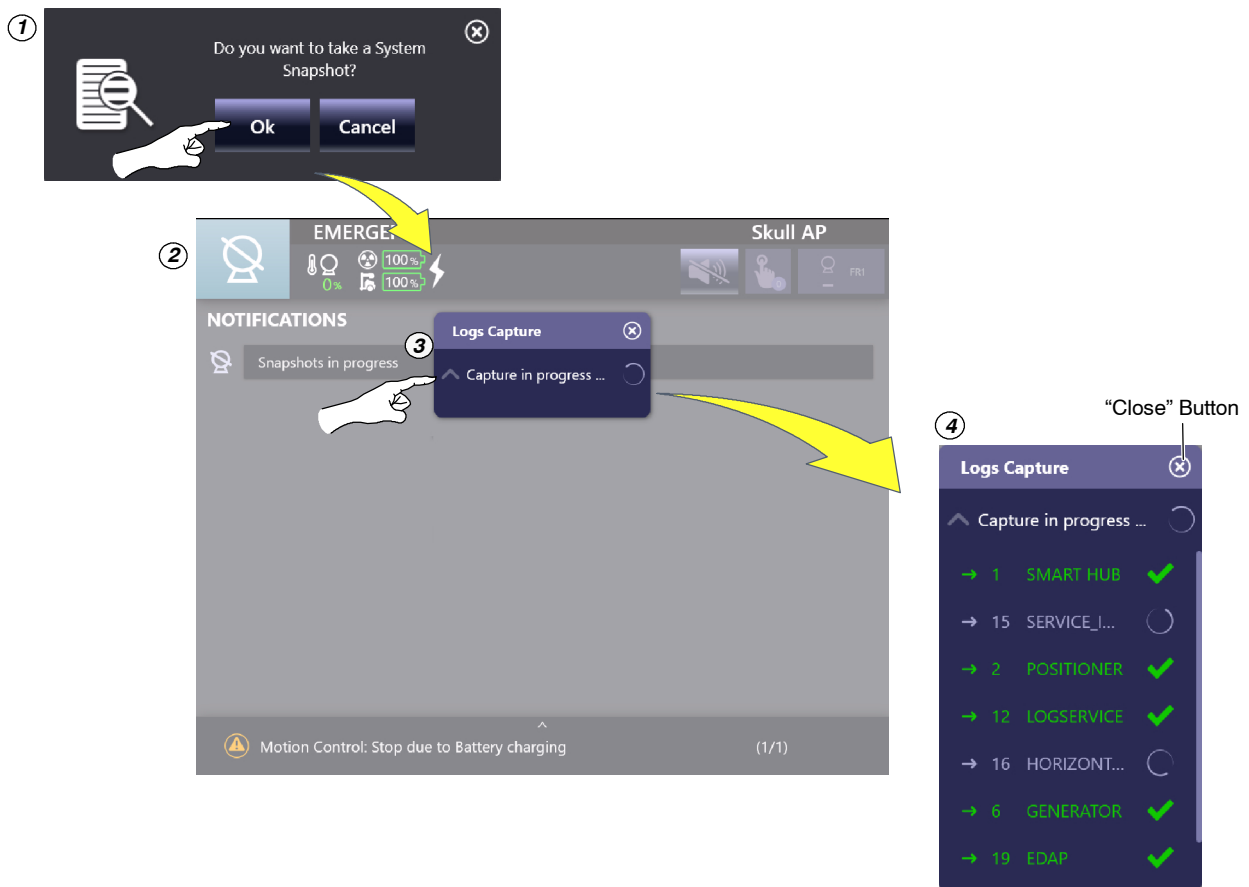
### 4.3.2 SYSTEM SNAPSHOT



The “*System Snapshot*” button, located in the upper right corner of the “*Message List*” screen, allows the user to generate event logs files, collecting general information about the system status, which could be useful for the Service personnel.

1. Press the “*System Snapshot*” button and confirm the pop-up message.
2. The “*Logs Capture*” window will be displayed indicating that the process is in progress.
3. Tap on the arrow in order to expand this window and display the export progress for each system component and the results. Tap it again in order to hide this view.
4. To cancel the System Snapshot in progress, touch the “*Close*” button and then confirm on the pop-up window in order to return to the Main Menu.

**Illustration 4-16**  
**System Snapshot Confirmation and Logs Capture Window**



The following icons indicate a different status of the Logs Capture, for each system component:



- Logs export in progress, for that component.



- Successful logs export, for that component.



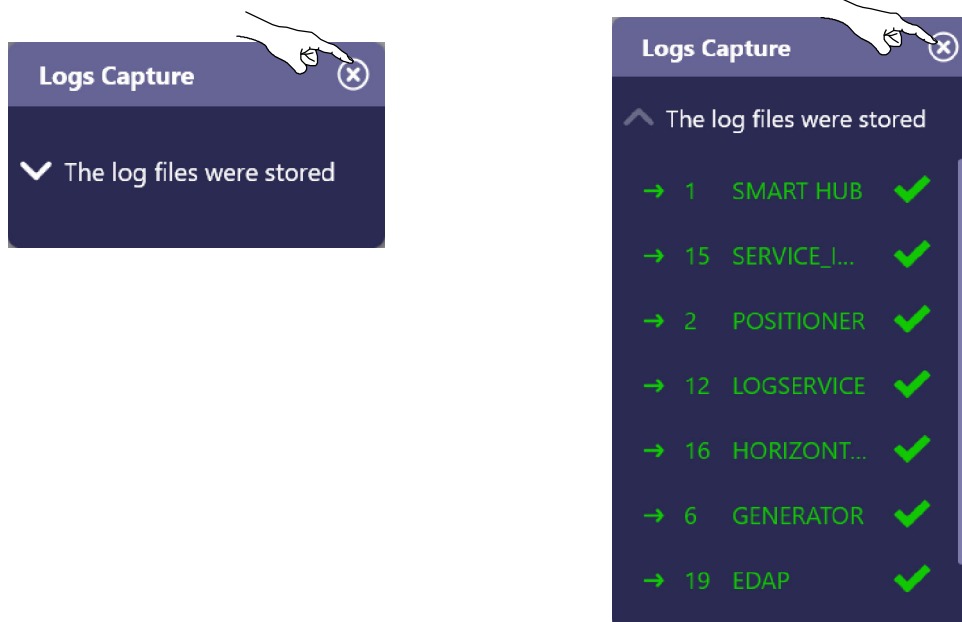
- Failed logs export, for that component.

**Note**

*When the Logs Capture process is not completed for one or more components, the system continues with the processing.*

5. Once the logs Capture process has finished successfully, touch the “Close” button and the system will return to the Main Menu.

**Illustration 4-17**  
**Exiting the Logs Capture Window**



**Note**

*Only for Service purposes: the resulting system logs files are generated in folder C:\OEM\Snapshots.*

### 4.4 IMAGE PREVIEW (OPTION)

The Image Preview function allows the immediate preview of the X-ray image acquired, at the same time that the system does get it.



Once the X-ray exposure is completed, the image preview is automatically displayed on the Head-Assembly Screen.

Image Preview disappears from the Head-Assembly Screen in the following cases:

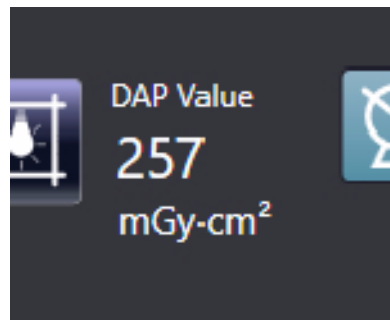
- After being displayed for 10 seconds, when the user modifies any parameter or selects a new procedure.
- When touching on the Head-Assembly Screen.
- When closing the X-ray exam.
- When pressing the X-ray Handswitch.

#### 4.5 DOSIMETRY (OPTION)

The Dose shows the radiation value received by the patient. Radiation measure is read/estimated as *DAP (Dose Area Product)* value in  $mGy \cdot cm^2$  or *Skin Dose* value in  $mGy$ .

The Dose value is displayed next to the Collimator Light Button on the X-ray Generator Console (embedded in *Primo S*).

- **DAP Value in  $mGy \cdot cm^2$ :** If the Unit is equipped with DAP Chamber (measured dose) or eDAP (estimated dose).
- **Dose Value in  $mGy$ :** If the Unit is equipped with eDOSE (estimated dose).



If the Dose value of the last exposure is retrieved by using the “*Post-Exposure*” button, it will be displayed in the same location but in yellow color (refer to Section 4.1.6).

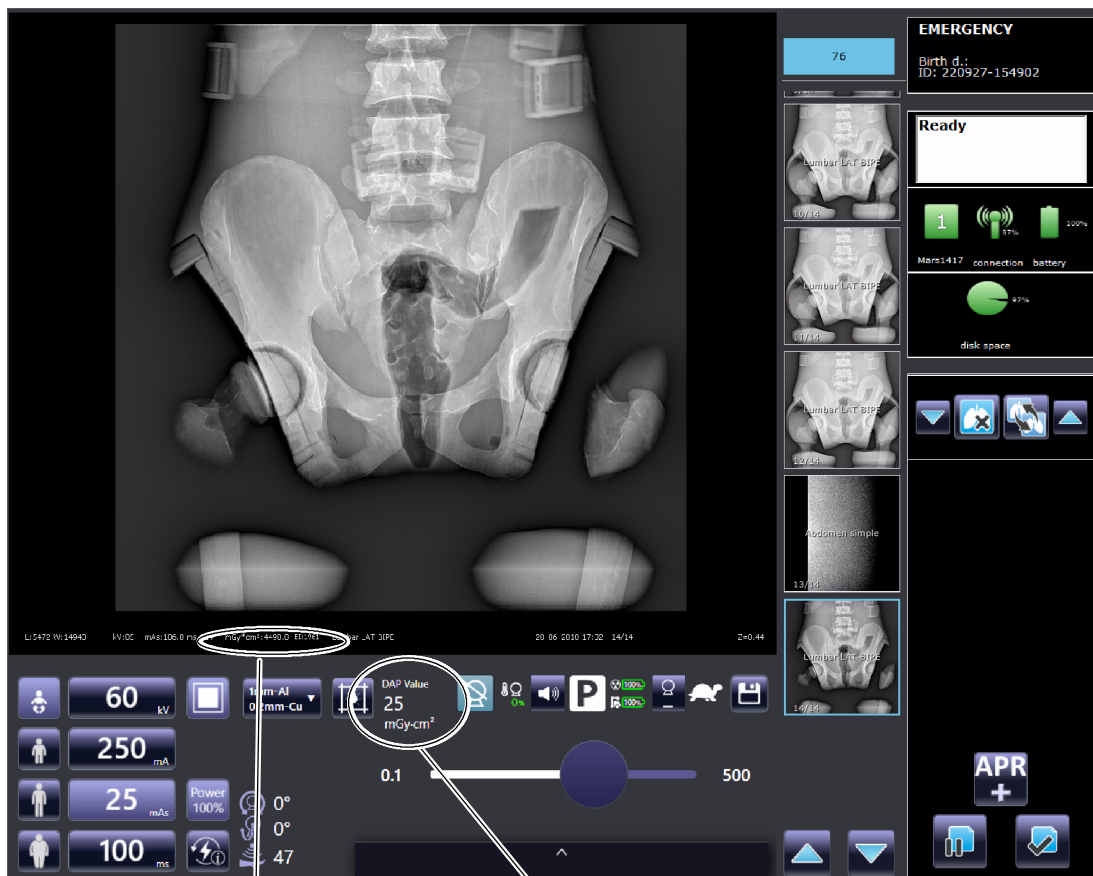


The Working Frame of *Primo S Software Application* the Dose information of the total dose of the exposures performed with a Digital Detector.

Note 

*DAP values on Primo S Software Application may differ from those on the X-ray Generator Console, after taking an exposure in Direct mode.*

An example of the *Primo S Software Application* Working Frame with DAP Values is shown below:



Total Dose received by the patient  
(only exposures with Digital Detector)

Dose received by the patient  
(including exposures in direct mode).

Dose of the last exposure (shown for 5 seconds)

## SECTION 5 SYSTEM MESSAGES

The System Messages are displayed in both the Main Control Console and the Head Console. The consoles show inhibit conditions, informative and error messages related to the whole operative of the Mobile X-ray Unit, including messages related to the Image Acquisition software.



- **Warning.** Alerts the operator about conditions that do not disable or abort exposures (e.g. maximum kV value reached while modifying the exposure parameters).

A blinking message is displayed to the Operator for a few seconds notifying this event.



- **Information.** Indicates to the operator any information related to the status of the different Mobile X-ray Unit components, status of the procedure that is being accomplished, and also to issues related to the configuration of the exposure, etc. Causes can be many of them, originated by the Unit itself, the X-ray Generator or the Acquisition Workstation.

The messages are displayed momentarily, do not require any action of the operator and disappear once the cause has been solved automatically by the System.



- **Exposure Inhibit condition.** These messages are displayed when the Unit itself or the Image Acquisition System request the Generator not to expose or inhibit a movement because of multiple reasons: the tube is not pointing to the detector, acquisition workstation is not ready, etc. But also, there are originated by the same X-ray Generator. There are different kind of Interlocks: those that cause an exposure inhibition, movements inhibition or both at the same time.

There can be more than one active Inhibition message or Interlock message at the same time. They will disappear when all the reasons are corrected by the operator one by one.



- **Movement inhibit condition.** Movements are inhibited. More than one inhibit condition could be active at the same time.



- **User action.** These messages disappear once the required action is performed by the user.



- **Error.** Indicates to the operator the potential cause of a system failure that abort or inhibit the exposure or procedure. At the same time that they are displayed an alarm sounds.

Correct the error cause and keep touched the “Accept” button until the Console indication disappears and exposure or procedure can be accomplished.

All these System Messages are reported in the Message Bar, which is located in the bottom area of the Head Console Main Menu and the Main Control Console Screen. Active messages, i.e. those that require action by the operator or report an error or warning, will be displayed consecutively in this area.

**Note**

*For additional information about the Message Area refer to the Section 4.3.*

There are also different Message Windows, which are accessed depending on the origin of the messages, in which detailed information about them can be consulted (*refer to Section 4.3.1*).

The main message window is the Message List. To enter it, press on the Message Bar. A pop-up window will be displayed. To close it, tap on the message area again to go back to the previous screen.

**Note**

*The following pages show a complete list of System Messages ordered by their Identifier (ID).*

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
100002	One or more workstations are not properly configured; a default value has been assigned.	Error	Generator configuration error. Reboot the system. If the problem persists, call service.
100005	The Exposure order input signal is active during the Startup sequence.		The handswitch was pressed during system startup. Reboot the system. If the problem persists, call Service.
100006	The Preparation order input signal is active during the Startup sequence.		The handswitch was pressed during system startup. Reboot the system. If the problem persists, call Service.
100023	Error while writing in the E2PROM		Reboot the system. If the problem persists, call Service.
100024	The timeout for the acknowledge for X-rays from the Bucky or FPD has been exceeded		Press the "Accept" button. If the error message persists, turn the Unit OFF, check the proper external cable connections to the receptor (if applicable) and then turn the Unit ON. If the Unit remains inoperative, turn it OFF and call Service.
100029	Generator heat capacity exceeded		The Generator is too hot. Wait 30 minutes or decrease the exposure parameters.
100031	The time stamp checksum is wrong		Generator error. Reboot the system. If the problem persists, call service.
100032	I2C bus error while trying to access the Real Time Clock (RTC)		Generator error. Reboot the system. If the problem persists, call Service.
100035	The acknowledge for X-rays from the Bucky or FPD has been lost before the end of the exposure		Press the "Accept" button. If the error message persists, turn the Unit OFF the system (Unit and Receptor), check the proper external cable connections to the receptor (if applicable) and then turn the system ON. If the problem persists, call Service.
100037	Tube ratings exceeded or not enough Heat Units to perform the selected exposure		Tube is too hot. Wait for the tube to cool down or decrease the exposure parameters.
100038	+5 V power supply failure		Generator Power supply error. Reboot the system. If the problem persists, call Service.
100039	+15 V power supply failure		Generator Power supply error. Reboot the system. If the problem persists, call Service.
100040	Imbalanced kVp, there is not the same voltage in Anode and Cathode branches		Generator error. Reboot the system. If the problem persists, call Service.
100041	Imbalanced mA, there is not the same current in Anode and Cathode branches		
100042	The counters checksum is wrong		

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTXT
100047	I2C bus error while trying to access the Licence	Error	Generator error. Reboot the system. If the problem persists, call Service.
100049	The generator has lost the communications with the remote console		
100050	The user has released the exposure device before the end of the exposure		Handswitch released before exposure ended. Try again for exposure. If the problem persists, call Service.
100051	The selected exposure time cannot be achieved		Select another technique.
100060	The number of exposures to autocalibrate a mA station has run out	Error	Generator error. Reboot the system. If the problem persists, call Service.
100061	There has been an error while trying to access the Licence data. Default options have been selected	Information	
100063	The Ready from the starter has been lost before the end of the exposure	Error	
100067	-15 V power supply failure		
100068	+3.3 V power supply failure		
100072	Exposure aborted by deactivation of Positioner-OK signal		
100074	COP Generator Reset Error	Inhibit Exposure	
100075	CLK Generator Reset Error		
100076	TRAP Generator Reset Error		
100077	Software Interrupt Generator Reset Error		
100078	Memory Interrupt Generator Reset Error		
100079	Required mA Stations Calibration Error		Generator error. Call Service.
100250	Communication lost with UARC Device	Error	Press Accept. If the error persists, restart the System.
100251	Communication lost with Power Control Device		If the error persists, call Service.
100252	Timeout for receiving the Ready State from Power Control has elapsed	Error	Press Accept. Release the PREP and EXP orders from the Handswitch and try the exposure again. If the error persists, call Service.
100253	Timeout for receiving the Synch State from Power Control has elapsed		

ID	MESSAGE TEXT	TYPE	USER HELPTEXT
100254	Power Control Protocol Version mismatch	Error	Restart the System. If the error persists, call Service.
100255	UARC Protocol Version mismatch		
100256	Starter is not supported by License		Call Service.
100257	High Speed is not supported by License		
100258	FPGA running with Golden Firmware		
100259	Calibration Station cannot be performed	Try to select another technique. If the problem persists, call Service.	
100801	Procedure finished	Inhibit Exposure	Wait until the message disappears.
100802	Waiting for detector		Waiting for detector
100803	Activated Procedure is not allowed		Change the exposure values or wait for the X-ray Tube to cool.
100910	Error in exposure_switches.xml file	Error	Call Service.
100920	workstations.xml has not been downloaded		
100921	image_receptors.xml has not been downloaded		
100922	exposure_switches.xml has not been downloaded		
100923	generator.xml has not been downloaded		
100924	Tube_1.xml has not been downloaded		
100926	uarc_workstations has not been downloaded		
100930	Tube file wrong format	Generator error. Reboot the system. If the problem persists, call Service.	
100941	Current Image Receptor Synchronization Type is not supported. Please, select other workstation.	Call Service.	
100942	Preheating Filament	Information	Wait for 10 seconds.
100944	Maximum Preparation Time Reached.	Inhibit Exposure	Release the handswitch in order to remove Prep and Exp order. If the problem persists, call Service.

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
101001	X-rays disabled	Inhibit Exposure	No user action required.
101002	Tube overload	Warning	Change the exposure values (or technique) or wait for the X-ray Tube to cool.
101003	Tube thermostat		Wait for the Housing to cool.
101004	Generator model overload		Wait for the Inverter Module to cool.
101007	INTERLOCK_1	Inhibit Exposure	No user action required.
101008	INTERLOCK_2		
101012	Positioner does not allow exposures. Moving. Interlock		
101014	Generator In Service Mode		
101015	Generator has not been calibrated yet	Warning	Call Service.
101016	mA Station selected has not been calibrated	User Action	Call Service.
101017	Configurated Tube is different to Calibrated Tube		
101018	Exposure does not allowed in this Desktop	Inhibit Exposure	Call Service.
101019	The system has to be rebooted for being upgraded	Information	Wait for the System to restart.
101021	Inhibit X-ray due to system communication lost	Inhibit Exposure	Call Service.
101022	Generator inactivity state, preheating filament	Information	Wait for 10 seconds.
101023	Upgrade is ongoing, X-ray disabled during this process		No user action required.
101025	The exposure selected exceeds the current battery capacity power. Exposures are not allowed in this state.	Inhibit Exposure	Please, decrease mA and increase ms to keep mAs. Otherwise, connect the system to power source and wait. If the error persists, call Service.
101026	Upgrading is performing, when the process finishes click on accept to apply the changes.	Information	No user action required.
101031	System will be reset due to license upgrade		

ID	MESSAGE TEXT	TYPE	USER HELPTXT
101032	Filaments disabled by inactivity	Information	No user action required.
101035	System is connected to main	Inhibit Exposure	No user action required.
102001	Value requested exceeds generator power	Information	No user action required.
102002	Value requested exceeds tube maximum rating		
102003	Technique requested not allowed due to tube space charge		
102004	kVp requested out of range		
102005	mAs requested out of range		
102006	mA requested out of range		
102007	ms requested out of range		
102008	Focal spot change not allowed due to mA-mAs selection		
102009	APR warning		
102010	Generator thermal limit		
102019	Low speed configured. However, high speed option enabled by license		
102023	Number of exposure reached. Exposure finished.		
102024	Exposure finished due to limit mAs reached.		
102025	Exposure finished due to limit energy for serial radiographic exposures.		
103001	Filaments disabled by software		
103002	Filaments disabled by hardware		
103003	Time Stamp has not been updated from SNTP Server		
103008	File has not been uploaded. File Manager Service has not found		
103009	Demo Mode Enabled by License		

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
103011	Demo Mode enabled by Dip Switch	Information	No user action required.
140302	Xray generator internal error.	Error	Restart the System. If the error persists, call Service.
140305	Xray generator internal error.		
140307	Generator DSP Control. Internal temperature	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140308	Xray generator internal error.		
140309	Generator DSP Control. Exposition Safety Timer		
140310	Generator DSP Control. kV converter Overcurrent		
140311	Generator DSP Control. kV Overvoltage		
140316	Generator DSP Control. IGBT bridge fault branch		
140317	Generator DSP Control. IGBT bridge fault branch		
140318	Generator DSP Control. kV out of range	Error	Press Accept. If the error persists, restart the System and reduce power of the exposition. If the error persists, call Service.
140319	Generator DSP Control. mA Overcurrent		
140320	Generator DSP Control. Undercurrent in small filament during exposure.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140322	Generator DSP Control. Overcurrent in small filament.		
140324	Generator DSP Control. Small Filament Current out of range		
140325	Generator DSP Control. Fault on small filament inverter.		
140326	Generator DSP Control. Thermal fault on small filament inverter.		
140330	Generator DSP Control. Undercurrent in large filament during exposure.		
140332	Generator DSP Control. Overcurrent in large filament.		

ID	MESSAGE TEXT	TYPE	USER HELPTEXT
140334	Generator DSP Control. Large Filament Current out of range	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140335	Generator DSP Control. Fault on large filament inverter.		
140336	Generator DSP Control. Thermal fault on large filament inverter.		
140350	Generator DSP Control. Master Heartbeat error.		
140351	Generator DSP Control. Emergency signal activated by master.		
140352	Generator DSP Control. Synchronism signal (exposure order) has been received before preparation signal.		
140353	Generator DSP Control. Filament current demand is out of range		
140354	Generator DSP Control. Frequency out of range.		
140356	Generator DSP Control. End exposure not detected		
140357	Generator DSP Control. Internal Status Fail		
140358	Generator DSP Control. Monoblock connector error		
140359	Generator DSP Control. mA out of range		
140360	Generator DSP Control. Power Control Calibration data error		
140361			
140362			
140363			
140364			
140365			
140366			
140367			
140368			

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
140369	Generator DSP Control. Power Control Calibration data error	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140370			
140403	Generator DSP Control. Feedback KV error.	Error	Press Accept. Retake exposition. If error persists, restart the system. If error persists, call Service.
140406	Generator DSP Control. Generator High mA Scale Error.	Error	Restart the system. If error persists, call Service.
140408	Generator DSP Control. Overcurrent in the main inverter	Error	Press Accept. Retake exposition. If the error persists, restart the System. If the error persists, call Service.
140420	Generator DSP Control. ROTOR_UDC undervoltage	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140502	X-ray generator internal error.	Error	Restart the System. If the error persists, call Service.
140503			
140505			
140510	Generator Starter. Tube Configuration. SpinUp Type Mismatch	Error	Call Service.
140533	Generator Starter comms error (heartbeat).	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140534	Generator Starter. Tube1 mismatch error.		
140539	Generator Starter Configuration Error.		
140540	Generator Starter EEPROM Error.		
140541	Generator Starter communications Error (Rx).		
140542	Generator Starter communications Error (Tx).		
140543	Generator Starter. HW version mismatch.		
140544	Generator Starter. Wrong Dropout Station selection.		

ID	MESSAGE TEXT	TYPE	USER HELPTXT
140545	Generator Starter. Low Speed Acceration not allowed	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140546	Generator Starter. High Speed Acceleration not allowed		
140554	Generator Starter. Minimum input voltage Error.		
140555	Generator Starter. Maximum input voltage Error.		
140558	Generator Starter. Current Error (58)		
140559	Generator Starter. Current Error (59)		
140560	Generator Starter. Current Error (60)		
140561	Generator Starter. Current Error (61)		
140562	Generator Starter. Current Error (62)		
140563	Generator Starter. Current Error (63)		
140564	Generator Starter. Current Error (64)		
140565	Generator Starter. Current Error (65)		
140566	Generator Starter. Current Error (66)		
140567	Generator Starter. Current Error (67)		
140568	Generator Starter. Current Error (68)		
140569	Generator Starter. Current Error (69)		
140570	Generator Starter. Current Error (70)		
140571	Generator Starter. Current Error (71)		
140572	Generator Starter. Current Error (72)		
140573	Generator Starter. Current Error (73)		
140574	Generator Starter. Current Error (74)		
140575	Generator Starter. Current Error (75)		

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTEXT
140576	Generator Starter. Current Error (76)	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140577	Generator Starter. Current Error (77)		
140578	Generator Starter. Current Error (78)		
140579	Generator Starter. Current Error (79)		
140580	Generator Starter. Current Error (80)		
140581	Generator Starter. Current Error (81)		
140583	Generator Starter. Order rejected by SAFEMODE	Error	Press Accept. Exit SafeMode to enable X-rays. If the error persists restart System. If error persists call Service.
140584	Generator Starter. Order rejected by DCBUS level	Error	Press Accept. Wait for a moment to increase DCBUS Voltage. The interlock will disappear. If error persists, restart System. If error persists call Service.
140585	Generator Starter. Incompatible Tube Format	Error	Call Service.
140586	Generator Starter. Order rejected by configuration ONLY_LS	Error	The starter does not accept HighSpeed Order by Configuration. Call Service.
140587	Generator Starter. Current Error (main)	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140588	Generator Starter. Current Error (aux)		
140589	Generator Starter. Current Error.		
140590	Generator Starter. Current Error (90).		
140591	Generator Starter. Current Error (91).		
140592	Generator Starter. Current Error (92).		
140593	Generator Starter. Current Error (93).		
140594	Generator Starter. Current Error (94).		
140595	Generator Starter. Current Error (95).		
140607	Generator Starter. Legacy Tube Conversion.	Information	Legacy Tube Conversion. Recommended update.
140612	Generator Starter. HW OL Interlock.	Inhibit Exposure	Wait until the message disappears.

ID	MESSAGE TEXT	TYPE	USER HELPTEXT
140613	Generator Starter. T1 OL Interlock.	Inhibit Exposure	Wait until the message disappears.
140617	Generator Starter. MIN VOLTAGE interlock (DCBUS)	Inhibit Exposure	No user action required.
140618	Generator Starter: Ignore ERRORS Test Mode	Information	No user action required.
140619	Generator Starter: Ignore DCBUS Test Mode		
140620	Generator Starter: DEMO Simulation Test Mode		
140621	Generator Starter. Insufficient DCbus to accelerate Interlock	Inhibit Exposure	Wait until the message disappears.
140622	Generator Starter warning HW OL	Information	Acknowledge the message. Reached max. accelerations per minute for HW. Tube dropouts configuration could be improved.
140623	Generator Starter warning T1 OL		Acknowledge the message. Reached max. accelerations per minute for T1. Tube dropouts configuration could be improved.
290001	System Communication Error with GPIO Head	Error	Restart the System. If the error persists, call Service.
290002	System Communication Error with Battery Monitor		
290003	System Communication Error with RFID		
290004	System Communication Error with ADCM		
290005	Component Identification Mismatch	Error	Call Service.
290006			
290007			
290008			
290020	Collimator Apertures Error	Warning	Call Service.
290100	Positioner configuration checksum is wrong	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
290101	Configuration file not loaded		Restart the System.
290102	Configuration file not loaded		If the error persists, call Service.

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
290103	Invalid configuration parameters according to the license installed.	Error	Call Service.
290104	System will power off: Incorrect system in license		
290105	System will power off: Incorrect startup mode in license		
290106	Updating license client.	Information	No user action required.
290200	Collision detected	Inhibit Movement	Inspect the equipment and remove possible obstacles.
290201	CRITICAL BATTERY LEVEL. Operation is not allowed. Please, connect the system to a power source. Time remaining before shutdown 00:{0};{1}	Warning	Connect the System to mains. If the error persists, call service
290202	Battery Very Low, please connect the system to power supply.		No user action required.
290203	Battery Low, please connect the system to power supply	Information	
290205	Collimator Apertures have not been calibrated	Warning	Collimator Blades calibration is needed. Call Service.
290206	Focal Skin Distance has not been calibrated		Focal Skin Distance sensor calibration is needed. Call Service.
290207	Head-assembly handles pressed during booting up		Restart the System and try to repeat the operation. If the error persists, call Service.
290208	Head-assembly buttons pressed during booting up		
290300	System communication error located in the Head.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
290301	System communication error located in the smart on/off.		
290302	System communication error located in the RFID.		
290303	System communication error located in the motion control.		
290400	The system has not been used for long time and will shutdown in 00:{0};{1} unless you connect it to power source or click here.	Warning	No user action required.
290401	System is powering off. Please wait...	Information	

ID	MESSAGE TEXT	TYPE	USER HELPTXT
290402	Remote Handswitch is out of the placement longer than configuration time	Information	Return the remote Handswitch to its placement or click on "Accept button" to disable the warning.
290500	usability_setting.xml is outdated. Please, enter in service mode and update this file	Warning	No user action required.
290501	positioner_1.xml is outdated. Please, enter in service mode and update this file		
290700	Inhibit X-ray due to current RFID tag does not allow X-ray	Inhibit Exposure	Check if unit is in parking position. If it is not, call Service.
290701	Inhibit X-ray due to screen has been powered off		
290702	Inhibit X-ray due to parking position		
290703	Inhibit X-ray due to system is moving		
290704	Inhibit X-ray due to brakes are released		
290705	Inhibit X-ray due to board configuration pending		
290706	Inhibit X-ray due to System in Critical Battery Level		
290707	Inhibit X-ray due to Dosimeter is not ready		
290708	Inhibit X-ray due to Collimator filters are moving		
290709	Inhibit X-ray due to tube thermostat is released		
290710	Inhibit X-ray due to tube fan is released		
290711	Fan Tube released	Information	-
290712	Fine positioning buttons pressed longer than allowed	Information	Release the Fine positioning buttons.
290714	DAP value cannot be measured	Inhibit Exposure	If the message does not disappear after the start-up is finished, call Service.
290750	Dosemeter values have not been received from GPIO Head	Warning	Try to repeat the operation. If the error persists, call Service.
290751	ExposureSoundOn Acknowledge Message has not been received from RFID Board		If the problem persists, call Service

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT				
291001	Internal error located in the battery monitor.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.				
291002							
291003							
291004							
291005							
291014	System communication error located in the battery monitor.		Error	Call Service.			
291015							
291016							
291017							
291018	Peripheral communication error located in the battery monitor.			Error	Restart the System and try to repeat the operation. If the error persists, call Service.		
291019							
291020							
291021							
291023	Internal error located in the battery monitor.				Error	Call Service.	
291024	System communication error located in the battery monitor.					Restart the System and try to repeat the operation. If the error persists, call Service.	
291039	Internal error located in the battery monitor.					Call Service.	
291040	Peripheral communication error located in the battery monitor.					Error	Restart the System and try to repeat the operation. If the error persists, call Service.
291041							
291050	Internal error located in the battery monitor.	Error					Restart the System and try to repeat the operation. If the error persists, call Service.
291051							
291052							
291053							

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
291100	Battery below critically low, shutting down the system.	Warning	The System will shut down after 30 seconds. Please plug the unit into the mains.
291101	Download not performed due to a hardware failure	Information	No user action required.
292001	Internal error located in the RFID.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
292002			
292003			
292004			
292005			
292014	System communication error located in the RFID.		
292015			
292016			
292017			
292023	Internal error located in the RFID.		
292024	RFID System Communication Error		
292040	RFID Peripheral Communication Error		
292041			
292100	RFID reset by WDT	Information	No user action required.
292101	RFID not available		Check RFID device. If the error persists, call Service.
293004	Motion Control: Left Motor Differential Signal error	Error	Restart the System. If error persists, call Service.
293005	Motion Control: Right Motor Differential Signal error		
293006	Motion Control: Power Supply error in left motor power isolated area		
293007	Motion Control: Power Supply error in right motor power isolated area		
293008	Motion Control: Left Motor IGBTs error		

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
293009	Motion Control: Right Motor IGBTs error	Error	Restart the System. If error persists, call Service.
293010	Motion Control: Left Motor AC Overcurrent error		
293011	Motion Control: Right Motor AC Overcurrent error		
293012	Motion Control: Left 1 Force Sensor Error		
293013	Motion Control: Left 2 Force Sensor Error		
293014	Motion Control: Right 1 Force Sensor error		
293015	Motion Control: Right 2 Force Sensor error		
293019	Motion Control: Left Motor AC Current Presence previously to start up error		
293020	Motion Control: Right Motor AC Current Presence previous to start up error		
293024	Motion Control: Overheating error	Warning	Wait for the System to cool up during half an hour. If error persists, restart the System. If the error persists, call Service.
293029	Motion Control: FPGA Heartbeat error	Error	Restart the System. If error persists, call Service.
293030	Motion control: FPGA Golden FW		Restart the System and try to repeat the operation. If error persists, call Service.
293032	Motion Control: Proximity Sensors fault detection	Warning	Restart the System. If error persists, call Service.
293033	Motion Control: Bumper fault		
293034	Motion Control: Stop due to Battery charging		Unplugged and plug the System again. If failure persists, restart the System. If the error persists, call Service.
293035	Motion Control: Stop due to Deadman pressed at start up		Release and push the deadman. If failure persists, push the Handlebar. If failure persists, restart the System and try to repeat the operation. If the error persists, call Service.

ID	MESSAGE TEXT	TYPE	USER HELPTXT
293036	Motion Control: Stop due to Handle bar pressed at start up	Warning	Release the Handlebar and push it again. If failure persists, restart the System and try to repeat the operation. If the error persists, call Service.
293037	Motion Control: Stop due to Header key pressed at start up		Release the Header key pressed. If fine positioning is desired, press the desired key again. If failure persists, restart the System. If the error persists, call Service.
293051	Motion Control: Header key not working properly		Restart System. If error persists call Service.
294001	Internal error located in the head.	Error	Restart the System and try to repeat the operation If the error persists, call Service.
294002			
294003			
294004			
294005			
294014	System communication error located in the head.		
294015			
294016			
294017			
294018	Peripheral communication error located in the head.		
294019			
294020			
294021			
294023	Internal error located in the head.		
294027	Collimator Internal Error		
294028	Collimator Configuration Error		
294030	Dosimeter Internal Error		

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTTEXT
294031	Dosimeter Configuration Error	Error	Restart the System and try to repeat the operation. If the error persists, call Service
294032	Dosimeter Communication Error		
294033	Dosimeter restarted error.		
294039	Internal communication bus error located in the head.		
294040	Peripheral communication error located in the head.		
294041			
294046	Error in any of the proximity sensors.		
294050	Peripheral communication error located in the head.		
294051	Internal error located in the head.		
294053	Digital accelerometer error located in the head.		
294054	Error in the Focal Skin distance sensor.		
294059	Internal error located in the head.		
300002	Positioner configuration could not be loaded	Error	Call Service.
300003	Switches configuration could not be loaded		
300006	Generator configuration could not be loaded		
300007	Workstations configuration could not be loaded		
300008	Image receptors configuration could not be loaded		
300009	Positioner disconnected	Error	If the system message is displayed during start-up, please wait. If it is not the case, restart the System and try to repeat the operation. If the error persists, call Service.
300010	Console disconnected		Restart the System and try to repeat the operation. If the error persists, call Service.
300011	Generator disconnected		

ID	MESSAGE TEXT	TYPE	USER HELPTXT
300012	Workstation mismatch for Generator and Positioner	Error	Try to select another workstation or another radiographic procedure. If the error persists, restart the System and try to repeat the operation. If the error persists, call Service.
300013	Active Procedure mismatch for Generator and Positioner	Error	Try to select another workstation or another radiographic procedure. If the error persists, restart the System and try to repeat the operation. If the error persists, call Service.
300014	Positioner configuration could not be loaded		Call Service.
300015	Configuration changes could not be saved		
300016	Initializing communications ...	Information	If the message does not disappear after the start-up is finished, restart the System. If the message persist, call Service.
300019	Generator working in Service mode	Warning	If this message is displayed, restart the System. If the message persists, call Service.
300020	Positioner working in Service mode		
300021	Could not verify Service access		No user action required.
300024	Usability settings configuration could not be loaded	Error	Call Service.
300028	Calibration in progress	Inhibit Exposure	No exposures are allowed until the calibration is finished.
300029	Snapshots in progress		If the message does not disappear in a period of time, please restart the System.
300035	Calibration file could not be loaded	Error	Call Service.
300036	Waiting for generator license...	Information	If the message does not disappear after the start-up is finished, call Service.
300037	Waiting for generator operation mode to be initialized...		
300038	Waiting for positioner operation mode to be initialized...	Information	If the message does not disappear after the start-up is finished, call Service.
300039	Processing Downloader. This action can take several minutes, please wait	Information	No user action required.

## Mobile X-ray Unit

### Operation

ID	MESSAGE TEXT	TYPE	USER HELPTXT
300040	Downloader finished with error code {0}	Information	No user action required.
300041	Downloader finished successfully		
301000	EDAP is not calibrated	Warning	EDAP calibration is needed. Call Service.
301001	DAP value cannot be estimated	Error	Check for other active messages related to DAP estimation.
301002	DOSE value cannot be estimated		Check for other active messages related to Skin Dose estimation.
301003	EDAP estimation out of range, please recalibrate	Warning	EDAP calibration is needed. Call Service.
301004	EDAP is not available for these configuration settings		The Unit settings need to be modified. Call Service.
301005	No license available for DAP estimation		The license is not enabled for DAP estimation functionality.
301006	Wrong positioner configuration. Cannot estimate Dose		The Unit settings need to be modified. Call Service.
301007	Wrong positioner configuration. Cannot estimate DAP		The Unit settings need to be modified. Call Service.
301008	Wrong EDAP calibration value on collimator filters ({0})	Error	Call Service.
301013	Restore aborted: system is ciphered and all tags are not ciphered in database		
301014	Restore aborted: system is not ciphered and all tags are ciphered in database		
500004	Selecting technique	Inhibit Exposure	No user action required.
500008	Generator parameters modified	Information	No user action required.
500012	There is no workstation configured for this request		No user action required.
500014	Technique not loaded in generator	Inhibit Exposure	Check the APR settings and configuration for this technique.
500015	Detector not ready for exposure	Inhibit Exposure	Check the detector is charged and on. Only exposures in film mode are allowed if pressing Accept and change the workstation to film.

ID	MESSAGE TEXT	TYPE	USER HELPTXT
500016	Error loading APR Technique, please retry.	Inhibit Exposure	Check that the workstation and workspace names matches. Check the APR settings and configuration for this technique.
500020	APR settings not defined	Inhibit Exposure	Please, check APR settings.
500022	Console not available		Restart the System and try to repeat the operation. If the error persists, call Service.
500024	Please, reselect technique		Try to select another technique or another radiographic procedure. If the error persists, restart the System and try to repeat the operation. If the error persists, call Service
500033	EDAP not available	Information	No user action required.
500043	Please, press the handswitch to start the exposure	Information	Please, press the handswitch to start the exposure.
500044	Image System not available	Inhibit Exposure	Image System not available, restart the System. If the problem persists, call Service.

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## SECTION 6 OPERATING SEQUENCES

### 6.1 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.***

Do not perform routine exposures unless the Tube is previously warmed-up, to preserve 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 four hours.



***This warm-up procedure is used for a typical X-ray Tube. Refer to the X-ray Tube manufacturer's 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 and select *Large Focus*.
- Select *70 kV, 100 mAs, 200 mA, and 500 ms* exposure.
- Make sure that no one will be exposed.
- Make a total of three (3) exposures, *15 seconds* apart.

**Note** 

***In case the indicated parameters cannot be selected with Large Focus or the three exposures are not allowed, select a technique with the nearest values for Large Focus and try to reduce the exposure time (ms).***



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

## **6.2 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.
- Anatomical Programs (APR) through the Image Acquisition Software.

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 the 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 the 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.

## **6.3 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 the 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.



**ALWAYS SELECT THE CORRECT FIELD SIZE TO AVOID EXCESSIVE RADIATION.**

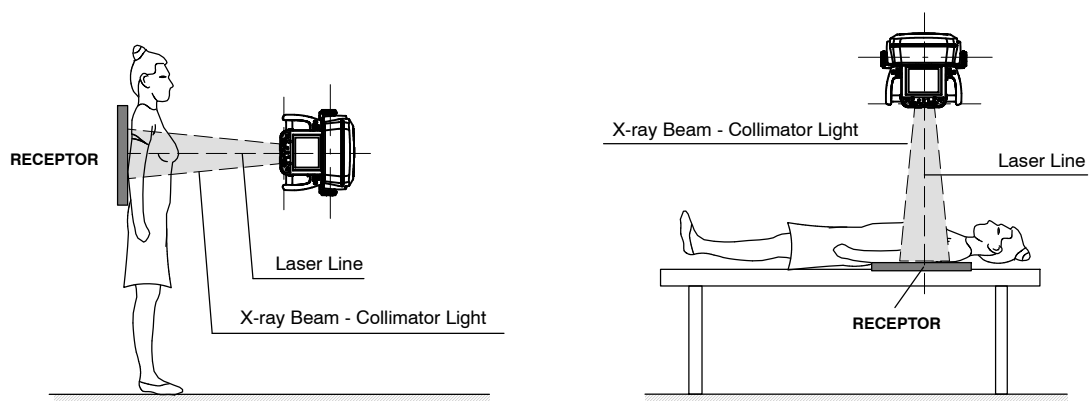


**THE X-RAY BEAM AXIS AND THE REFERENCE AXIS OF THE PLANE OF INTEREST COINCIDE AND ARE ORTHOGONAL WITH RESPECT TO THE PLANE OF INTEREST, IN EXAMS PERFORMED WITH THE IMAGE RECEPTOR PERPENDICULARLY POSITIONED WITH RESPECT TO THE TUBE-COLLIMATOR ASSEMBLY.**

**IN THE 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'S RESPONSIBILITY THE PROPER POSITION OF THE PATIENT AND EQUIPMENT BEFORE PERFORMING AN EXAMINATION.**

**Illustration 6-1  
Patient Positioning**



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## SECTION 7 PERIODIC MAINTENANCE

In order to assure the 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 that are performed by the user/operator, and the second is 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 MEDICAL EQUIPMENT IS IN USE WITH A PATIENT.**

### 7.1 OPERATOR TASKS

#### 7.1.1 BATTERIES MAINTENANCE



**IN ORDER TO AVOID A SIGNIFICANT DECREASE IN THE LIFE EXPECTANCY OF THE BATTERIES, DO NOT PERFORM EXPOSURES JUST AFTER PLUGGING THE UNIT TO MAINS WHEN THE BATTERIES ARE AT *CRITICALLY LOW CHARGE* STATUS.**



***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.

- Keep the unit connected to the mains whenever possible to maintain the batteries at the floating maintenance level, this increases their lifetime. It is recommended, that at least once a week, a full charge of the batteries be performed by connecting the unit to the mains for at least 8 continuous hours.
- Do not allow the batteries to be deeply discharged because they will lose storage capacity and will never be able to recover 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 8.1.*

#### 7.1.2 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 8 hours until the Battery Charge Level Indicators on both columns stop scrolling and all the Indicators light Green.
2. Once fully charged, unplug the Unit from the mains. Wait a few minutes and reconnect the Unit into 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. Turn OFF the switch ON/OFF control and unplug the unit from the mains.
4. Check the external cable connections.

### 7.1.3 CLEANING AND DISINFECTION



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

Clean the equipment frequently. Clean external covers and surfaces, especially parts that might be in contact with patients, with a cloth moistened in warm water with neutral soap. Wipe with a cloth moistened in clean water.

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



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

## 7.2 SERVICE TASKS

Only service personnel specifically trained on this medical X-ray equipment should work on service tasks (Installation, Calibration or Maintenance) of the equipment (*refer to the respective Sections of the Service Manual provided with this equipment*).

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## SECTION 8 TECHNICAL SPECIFICATIONS

### 8.1 FACTORS

Maximum Power kW <i>(Refer to Identification Label)</i>	20 kW	32 kW	40 kW	50 kW
<b>kVp Range</b>	40 kVp to 150 kVp			
	From 40 kVp to 150 kVp in 1 kVp steps			
<b>mAs Range</b>	Product of mA x Time values from 0.1 mAs to 500 mAs			
<b>mA Range</b>	10 to 400	10 to 500		10 to 500 <i>(10 to 630)*</i>
	From 10 mA to 500 mA or 630 mA, through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630. <i>(Depending on the Generator model)</i> <i>*(with X-ray Tube Insert XRR3331)</i>			
<b>Exposure Time Range</b>	From 1 millisecond to 10 seconds through the following Time stations:  Milliseconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.3, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630, 800. Seconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.3, 8, 10.  Maximum Exposure Time Range for DR: From 1 millisecond to 2.5 seconds.			
<b>Power Output (@ 0,1s)</b>	150 kVp @ 125 mA 125 kVp @ 160 mA 100 kVp @ 200 mA 80 kVp @ 250 mA 62 kVp @ 320 mA 50 kVp @ 400 mA	150 kVp @ 200 mA 128 kVp @ 250 mA 125 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 <i>(79 kVp @ 630 mA)*</i>
<b>Duty Cycle</b>	18 exposures per hour at 120 kV, 250 mA, 250 ms (lapse time between exposure: 3 min.)			
	Maximum leakage radiation depends on the type of X-ray Tube (<0.88 mGy/h)			
<b>Ripple Factor</b>	< 4% (constant voltage)			
<b>Collimator</b>	Manual Collimator <i>(with different options depending on the Collimator model)</i> <i>Refer to Section 3.7</i>			
<b>X-ray Tube</b>	<i>Refer to Section 8.2</i>			

## Mobile X-ray Unit

### Operation

Maximum Power kW (Refer to Identification Label)	20 kW	32 kW	40 kW	50 kW
Power Line Operation (Depends on Region Configuration)	100-240 V~ - Single-Phase 50/60 Hz Automatic Line Compensation $\pm 10\%$ V~ Connection to standard outlets with GND that complies with local regulations			
	The Power Line Installation should be provided with a Differential of 30 mA Sensitivity  Power Line Impedance must be less than the maximum indicated value: 300 m $\Omega$ for 100 V~, 1 $\Omega$ for 110 V~, 2.5 $\Omega$ for 230 V~, 2.6 $\Omega$ for 240 V~			
Power Line Cable	Total Cable Length: 5 m Usable Cable Length: 4.75 m			
Maximum Input Power	1.2 kVA			
Operation independent from mains supply (Stand-Alone)	Standard			
Battery Capacity	<p>Optimized Battery Management for extended Battery life.</p> <p>Charge Capacity: 15 Ah.</p> <p>The required time for the Batteries to be 100% charged is approximately: 8 hours, (80% of the total charge is available after 4 hours charging; approximately 20% per hour).</p> <p>Total Energy storage Capacity: 5760 Wh</p> <p>With the Batteries fully charged and disconnected from the mains, the Mobile system can be in continuous movement during approximately 25 km, at 5.5 km/h. Once the exposure capacity is exhausted, the system motion is enabled for 1 km.</p> <p>The Mobile Unit in Stand-Alone (disconnected from the mains) will be 100% discharged from full charge in approximately: 11 hours.</p>			
Radiation Output Accuracy (Reproducibility related to loading factors)	C.V. (Coefficient of variation) $\leq$ 0.05			
Maximum Symmetrical Radiation Field	<p>Maximum Symmetrical Radiation Field 220 mm / 240 mm for High Voltage of 75kV at a distance from the Focal Spot of 1200 mm according to IEC 60806:2022. For the assembly, the smallest distance from the Focal Spot is 1000 mm.</p> <p>Maximum Symmetrical Radiation Field 210 mm / 250 mm for High Voltage of 125kV at a distance from the Focal Spot of 1200 mm according to IEC 60806:2022. For the assembly, the smallest distance from the Focal Spot is 1000 mm.</p>			
Maximum Heat Output	260 W (1130 BTU/h)			
Storage / Transport Environmental Conditions	<p>Temperature range of -10°C to 40°C</p> <p>Relative Humidity range of 20% to 85%</p> <p>Atmospheric Pressure range of 700 hPa to 1060 hPa</p>			
Operating Environmental Conditions	<p>Temperature range of 10°C to 35°C (the recommended temperature for a longer life cycle of batteries is around 22°C)</p> <p>Relative Humidity (no condensing) range of 30% to 75%</p> <p>Atmospheric Pressure range of 700 hPa to 1060 hPa</p>			

## 8.2 X-RAY TUBE INSERT

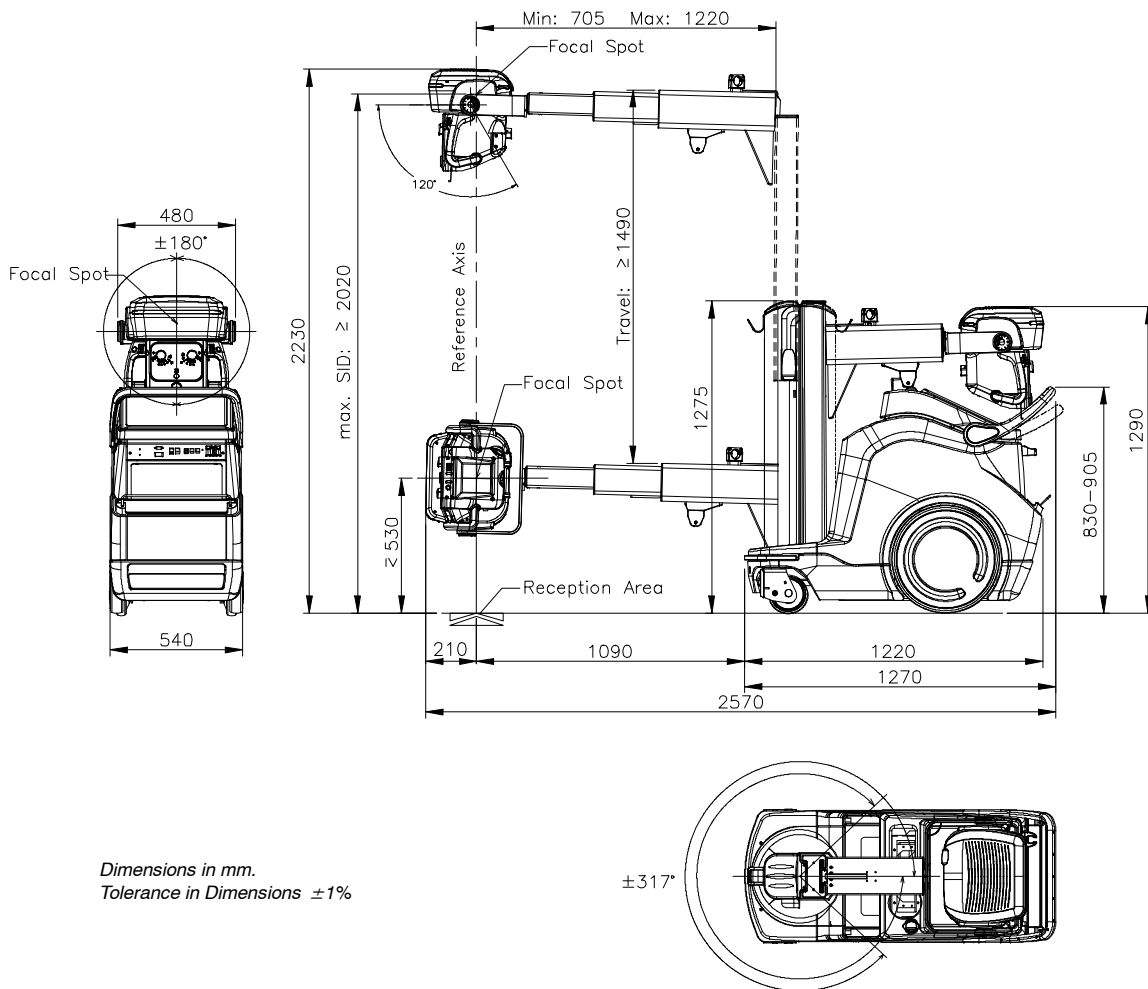
Maximum Power kW <i>(Refer to Identification Label)</i>	20 kW	32 kW	40 kW	50 kW
X-ray Tube Inserts	E7886 Low Speed / High Speed			E7886 High Speed
	XRR3331 Low Speed / High Speed			

E7886	<p>Low Speed / High Speed - Rotating Anode                      Focal Spots: 0.7 mm / 1.3 mm                      Anode kHU / kVp: 300 kHU / 150 kVp                      Target Angle: 16°                      Inherent Filtration of X-ray Source (Tube + Collimator): refer to Identification Label</p>
XRR-3331	<p>Low Speed / High Speed - Rotating Anode                      Focal Spots: 0.6 mm / 1.2 mm                      Anode kHU / kVp: 300 kHU / 150 kVp                      Target Angle: 12°                      Inherent Filtration of X-ray Source (Tube + Collimator): refer to Identification Label</p>

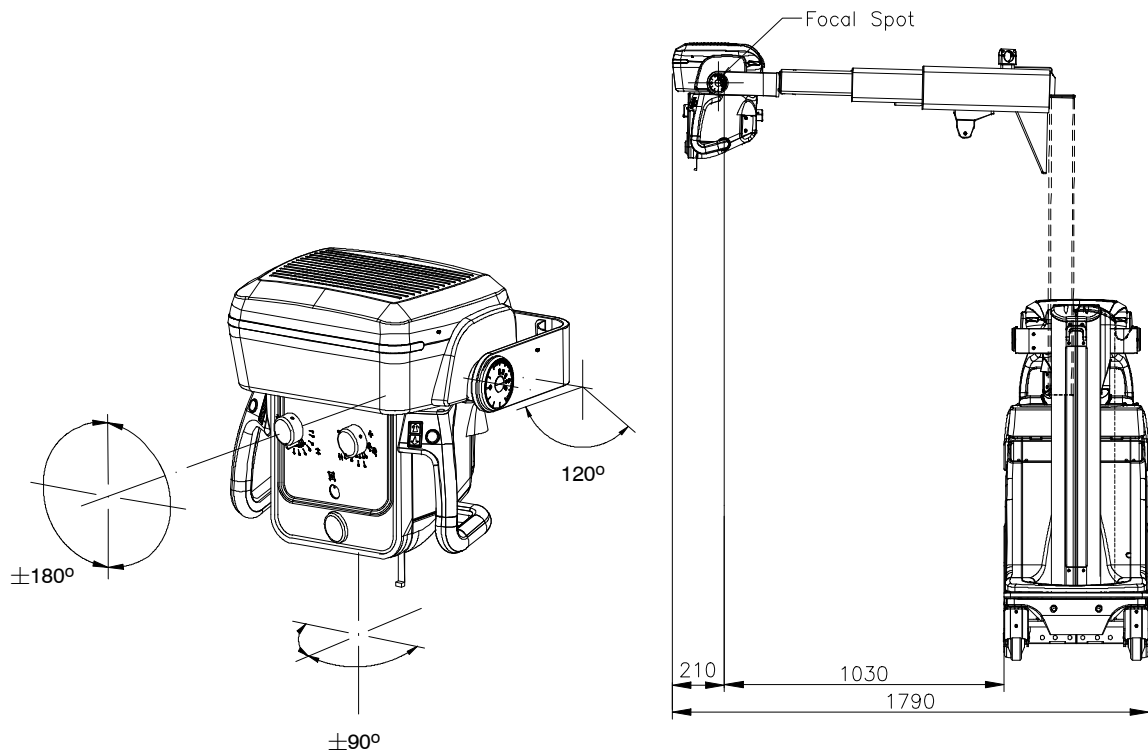
**8.3 PHYSICAL CHARACTERISTICS**

**8.3.1 MOBILE UNIT WITH 3-SECTIONS ARM**

LENGTH	WIDTH	HEIGHT	WEIGHT
minimum 1270 mm (50") maximum 2570 mm (101.2")	540 mm (21.3")	minimum 1290 mm (50.8") maximum 2230 mm (87.8")	520 kg (1145 lbs) (without Detectors and/or Options)



Dimensions in mm.  
Tolerance in Dimensions  $\pm 1\%$



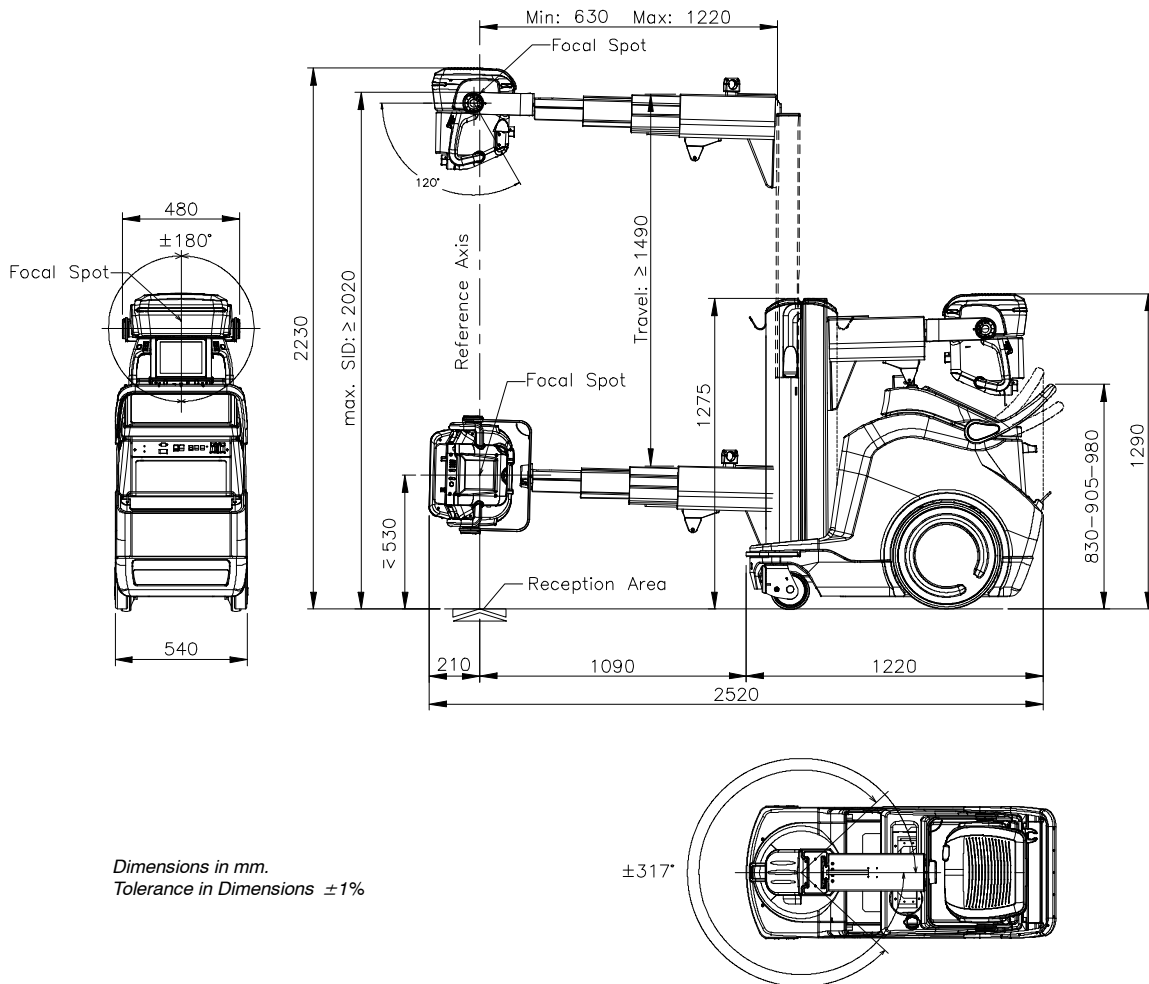
Dimensions in mm.  
Tolerance in Dimensions  $\pm 1\%$

# Mobile X-ray Unit

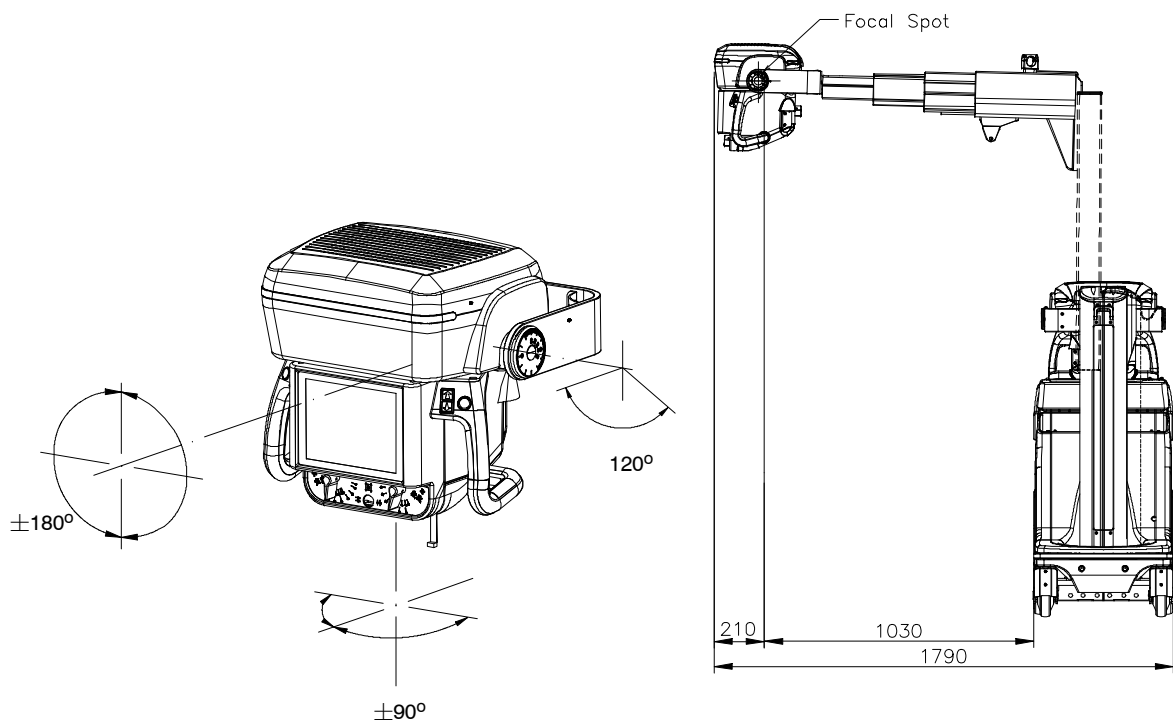
## Operation

### 8.3.2 MOBILE UNIT WITH 4-SECTIONS ARM

LENGTH	WIDTH	HEIGHT	WEIGHT
minimum 1220 mm (48") maximum 2520 mm (99.2")	540 mm (21.3")	minimum 1290 mm (50.8") maximum 2230 mm (87.8")	520 kg (1145 lbs) (without Detectors and/or Options)



Dimensions in mm.  
Tolerance in Dimensions  $\pm 1\%$



Dimensions in mm.  
Tolerance in Dimensions  $\pm 1\%$

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## APPENDIX A GUIDELINES FOR PEDIATRIC APPLICATIONS



THE PRACTITIONER WILL BE THE ULTIMATE RESPONSIBLE OF APPLYING TO THE PATIENT THE PROPER DOSE 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 rule, the 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 cannot be detached, pediatric exams cannot 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 radio sensitivity: *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 another 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.