KONICA MINOLTA

Operation

Digital Mobile X-ray Unit
KONICA MINOLTA

mKDR Xpress

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

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

Battery Mobile X-Ray Unit PHOENIX:
PHOENIX

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REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	OCT 01, 2021	First Edition.
1	MAR 08, 2022	Manual Cover and some rendered images have been updated. New Section: Appendix C – Administrator User. Updated Sections: Safety Symbols, Mains Connection, Smart ON/OFF System: ON/OFF Button + RFID System, Infrared Remote Control, Manual Clutch Screws, Collimator Movements, 3.7 Collimator Controls, Power Reduction, System Snapshot, System Messages, Factors.

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

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

ADVISORY SYMBOLS

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

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

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

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

Note ☞

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

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SECTION 1 INTRODUCTION

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

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

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

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

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

Illustration 1-1
Mobile X-ray Unit

X-RAY GENERATION COMPONENTS

- *Control Console.*
- *Ultra 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,* that comprises*:*
  - *Power Module*, containing power and control components.
  - *HV Tank, HV Transformer.*
  - *X-Ray Tube insert: E7886.*

ASSOCIATED EQUIPMENT AND SUBASSEMBLIES

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

- *Unit Motion Assemblies,* that comprises:
  - *Batteries and Charger Module*, to power the motors.
  - *Motor Assembly*, *Motors* and *Wheels*.
  - *Driving Control Assembly*, *Handlebar*, *Motion Controls* at the 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:* the 4-Sections Arm, provides a compact size for handling and storage the system when retracted, plus an extra length when extended. It also provides smooth Head-Assembly movements and a second Touch Screen on the Head-Assembly.
- *Collimator,* part of the Head-Assembly.
- *Digital Detector, Grid* and *Detector Handle (optional). Detector options: AeroDR 2 1417HQ, AeroDR 2 1417S, AeroDR 3 1417HD, AeroDR 3 1717HD, AeroDR 3 1012HQ*
- *Holders* for *Detectors* storage and charge (option); storage for *Detector Handle, Grid,* and other *Accessories.*

1.1 GENERAL FEATURES

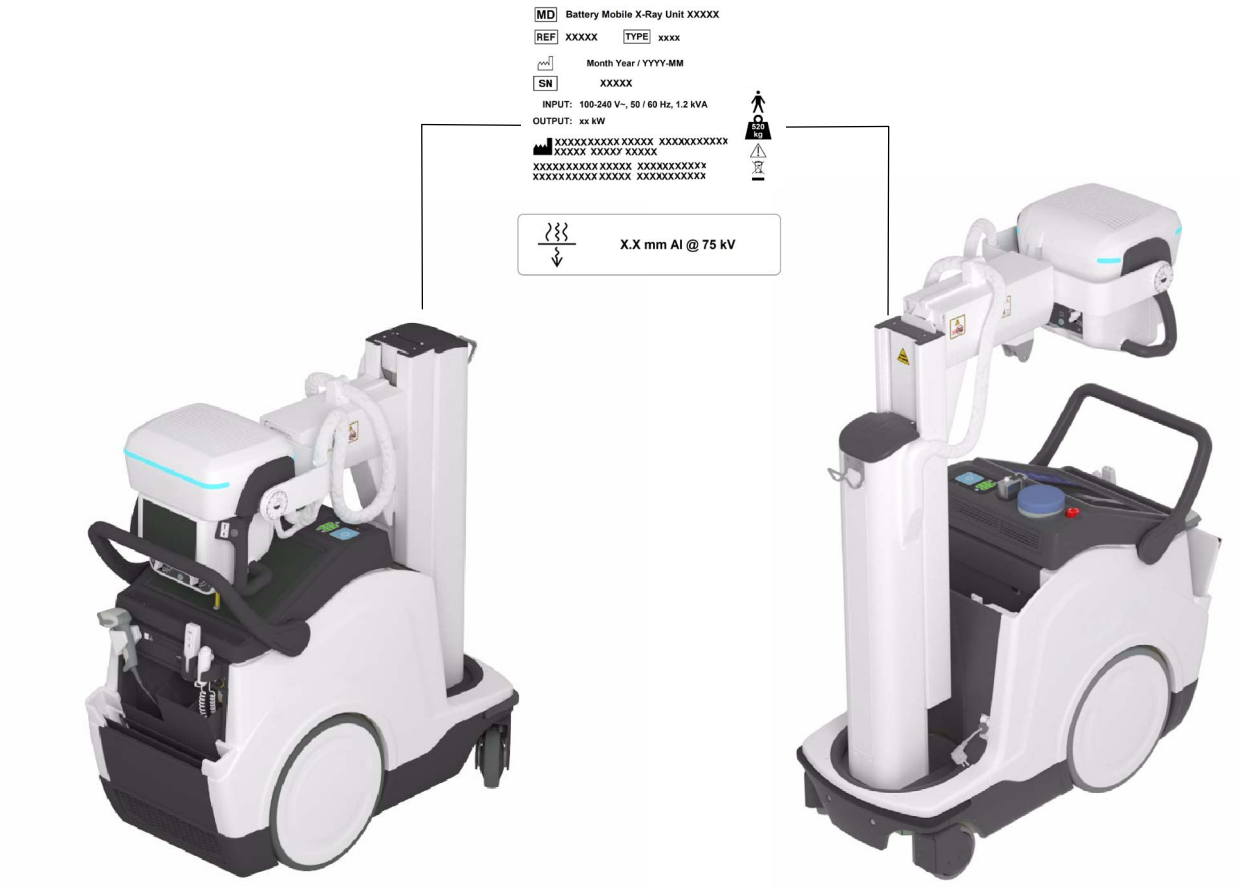
The main features of this Unit are:

- A solid and ergonomic design. Ease of operation; security and precision of all positioning movements relative to the patient.
- Standard electrical outlet operation with single-phase lines at 100 – 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 ($\pm 317^{o}$), telescopic and vertical motion of the Arm.
- Head-Assembly rotation in relation to its transverse axis (360^{o}) and horizontal axis (120^{o}). Collimator rotation in relation to its vertical axis (180^{o}).
- Three Point control by selecting kVp, mA and Exposure Time or Two Point control by selecting kVp and mAs.
- Anatomical Programmer (APR) and operation through the Digital Radiographic Application *Ultra*.
- X-ray Handswitch for X-ray exposures and Collimator Light.
- Infrared Remote X-ray Handswitch (optional) for X-ray exposures and Collimator Light.
- Dosimetry (optional).
- Manual Collimation.
- Heat Unit storage for the X-ray Tube, even after turning ON/OFF the equipment.
- Tube protection circuitry prolongs Tube life and increases system performance.
- Equipped with closed loop control of X-ray Tube current, kVp and filaments, which minimize potential errors and the need for readjustments.

1.2 PRODUCT IDENTIFICATION

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

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



1.3 INDICATIONS FOR USE

1.3.1 INTENDED USE

This is a Digital Mobile Diagnostic X-ray System 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. RX ONLY.

Additional description:

- The **Mobile X-ray Unit** is a piece of equipment designed for general radiography in hospitals, clinics, radiology imaging centers and medical practices.
- 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.
- The X-Ray image receptors used in this unit are Digital Detectors.

1.3.2 NORMAL USE

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

1.3.3 CONTRAINDICATIONS

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

This equipment is not intended for mammographic applications.

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

1.4 APPLIED PARTS

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

This RAD equipment includes the following Applied Parts:

- *Digital Detectors.*
- *Grids (optional)*
- *Other Accessories.*

SECTION 2 SAFETY AND REGULATORY INFORMATION

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

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

2.1 GENERAL

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

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

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

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

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

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

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

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

WARNING

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

ITEM	MAXIMUM ATTENUATION EQUIVALENT mm AL	
	21 CFR	IEC 60601-2-54:2009 , and IEC60601-2-54:2009+AMD1:2015
Total of all layers composing the front panel of cassette holder	1.2	1.2
Total of all layers composing the front panel of FILM CHANGER	1.2	1.2
Total of all layers, excluding detector itself, composing the front panel of DIGITAL X-RAY IMAGING DEVICE	1.2	1.2
Cradle	2.3	2.3
PATIENT SUPPORT, stationary, without articulated joints	1.2	1.2
PATIENT SUPPORT, movable, without articulated joints (including stationary layers)	1.7	1.7
PATIENT SUPPORT, with radiolucent panel having one articulated joint	1.7	1.7
PATIENT SUPPORT, with radiolucent panel having two or more articulated joints	2.3	2.3
PATIENT SUPPORT, cantilevered	2.3	2.3

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

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

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

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

2.2 RESPONSIBILITIES

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

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

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

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

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

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

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

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

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

2.3 MAXIMUM PERMISSIBLE DOSE (MPD)

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

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

2.4 RADIATION PROTECTION

Although this equipment is built to the highest safety standards and incorporates a high degree of protection against X-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 the health, use great care to ensure protection against exposure to the primary beam. Some of the effects of X-ray radiation are cumulative and may extend over a period of months or years. The best safety rule for an X-ray operator is *"Avoid exposure to the primary beam at* ***all times****"*.

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

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

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

- Wear radiation protective clothing.

- Wear a personal 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 body and do not expose hands, wrists, arms or other parts of the body to the primary beam.

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

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

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

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

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

- Use Grids whenever possible.

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

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

2.5 MONITORING OF PERSONNEL

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

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

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

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

2.6 SAFETY SYMBOLS

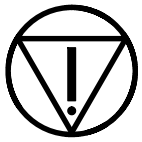
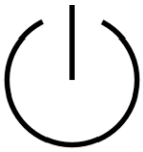
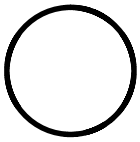
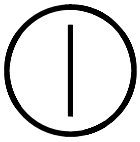
The following safety symbols may appear in the equipment.

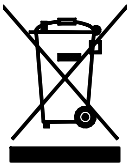
Their meaning are described below.

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

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

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

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

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

2.7 REGULATORY INFORMATION

2.7.1 CERTIFICATIONS

The ***Mobile X-Ray Unit*** covered by this Operation Manual complies with the following certifications:

- Statement of Compliance with IEC 60601-1-3: ***Mobile X-Ray Unit*** *with radiation protection in accordance with IEC 60601-1-3: 1994 and IEC 60601-1-3: 2008 and IEC 60601-1-3:2008+AMD1:2013 .*
- Statement of Compliance with IEC 60601-2-54: ***Mobile X-Ray Unit*** *for Radiography and/or Radioscopy in accordance with IEC 60601-2-54:2009 and IEC60601-2-54:2009+AMD1:2015.*
- Statement of Compliance with 21CFR Subchapter J: *This* ***Mobile X-Ray Unit*** *conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.*

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

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

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

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

2.7.3 MODE OF OPERATION

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

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

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

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

2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

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

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

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

2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Protection against hazards from unwanted or excessive radiation in accordance with Standards IEC 60601-1:1988, IEC 60601-1: 2005 and IEC 60601-1:2005+AMD1:2012 and IEC60601-1-3:1994, IEC 60601-1-3:2008 and IEC 60601-1-3:2008+AMD1:2013.

2.7.8 DESIGNATED SIGNIFICANT ZONES OF OCCUPANCY

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

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

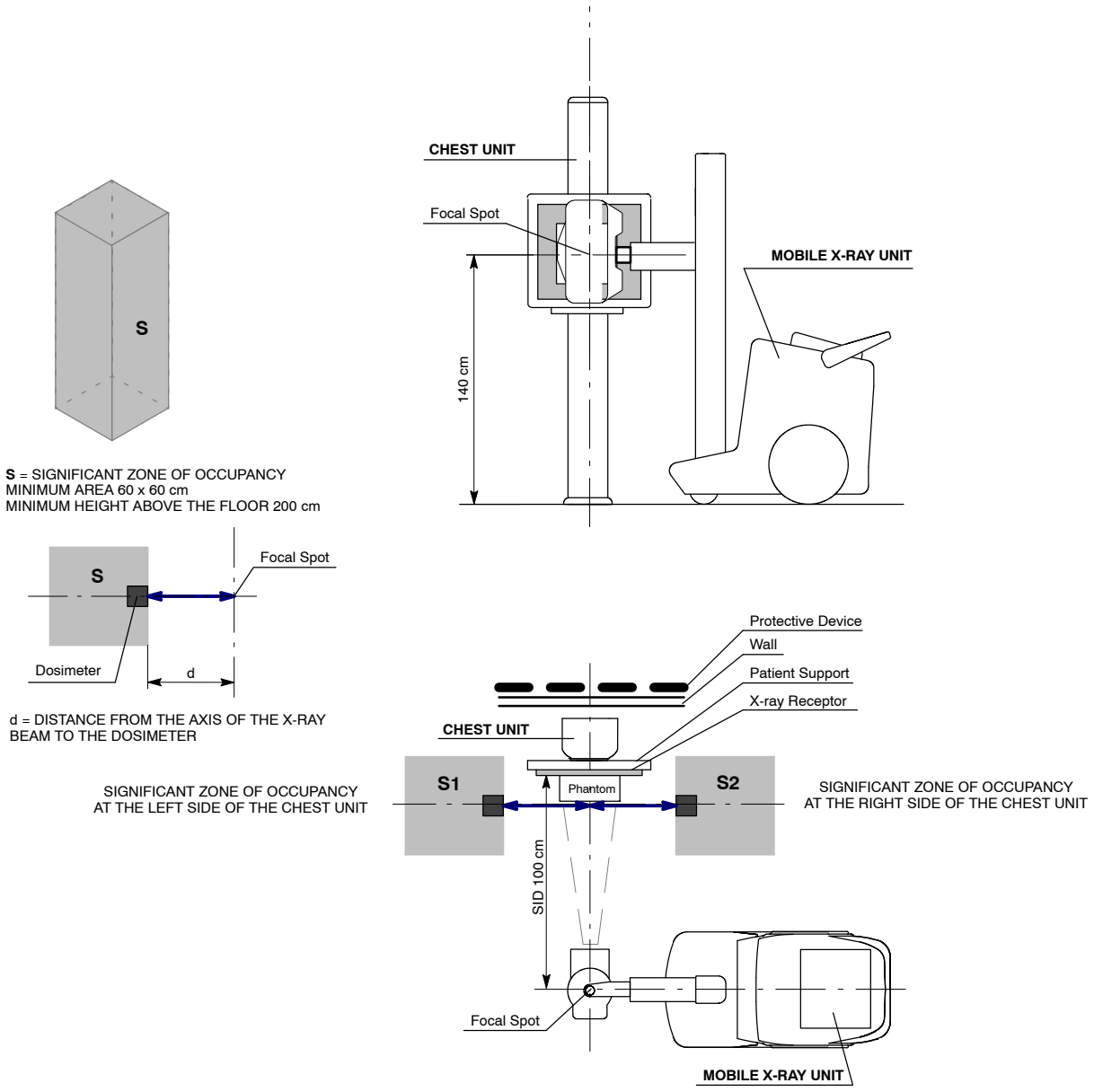
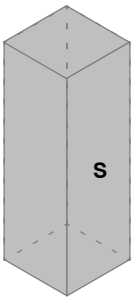
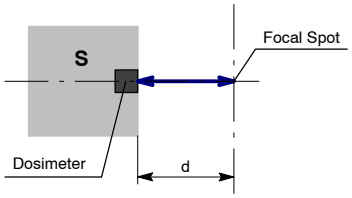


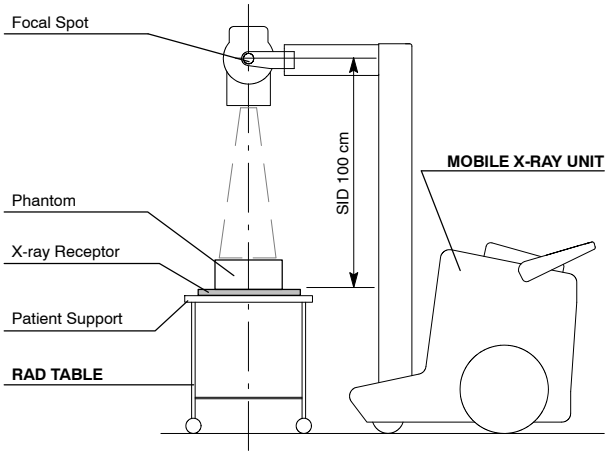
Illustration 2-2
Radiographic Examination on any Patient Support or any Table



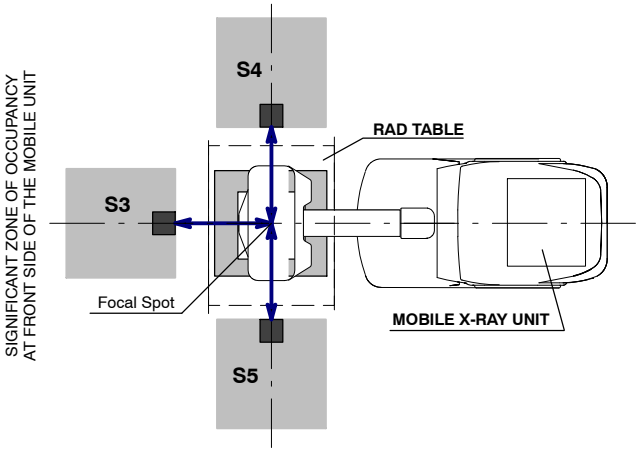
S = SIGNIFICANT ZONE OF OCCUPANCY
MINIMUM AREA 60 x 60 cm
MINIMUM HEIGHT ABOVE THE FLOOR 200 cm



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



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



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

2.7.9 DISTRIBUTION OF STRAY RADIATION

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

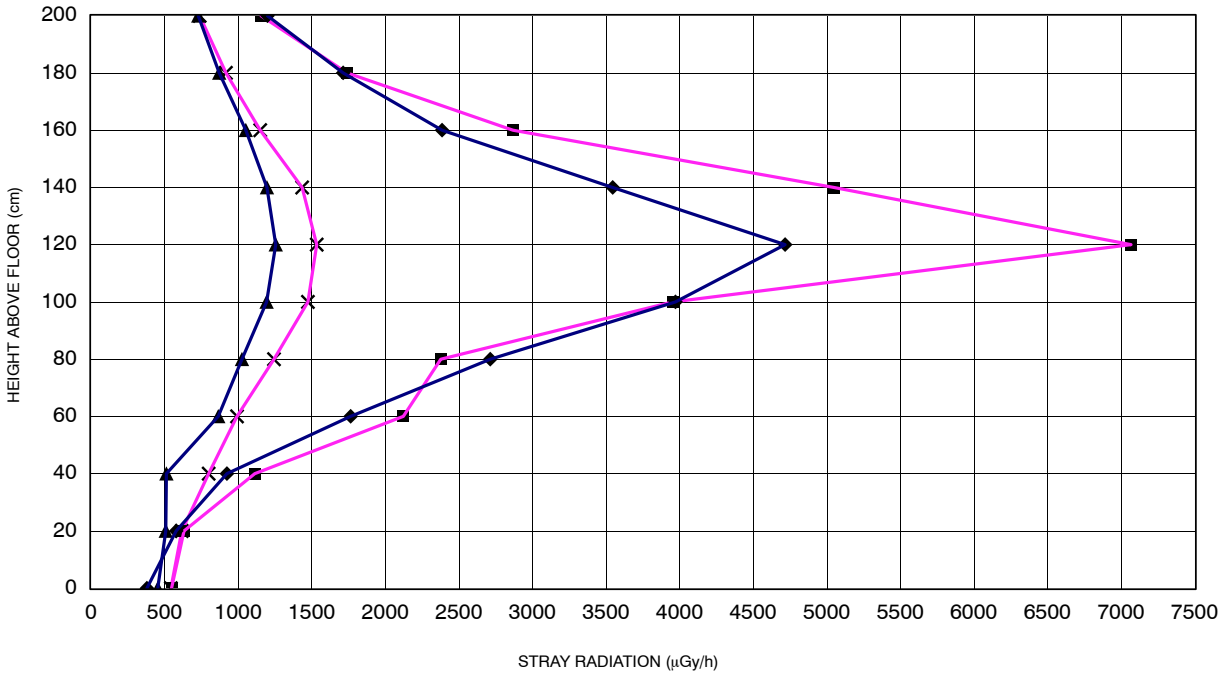
- Exposure Parameters: RAD mode, 150 kVp, 10 mAs.
- Collimator opening for Field Size 18 x 18 cm, SID 100 cm.
- Phantom: Rectangular water phantom of 25 x 25 x 15 cm, or a material having a similar X-ray attenuation coefficient.
- Radiation measuring instrument: Low Radiation Dosimeter.

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

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

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



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

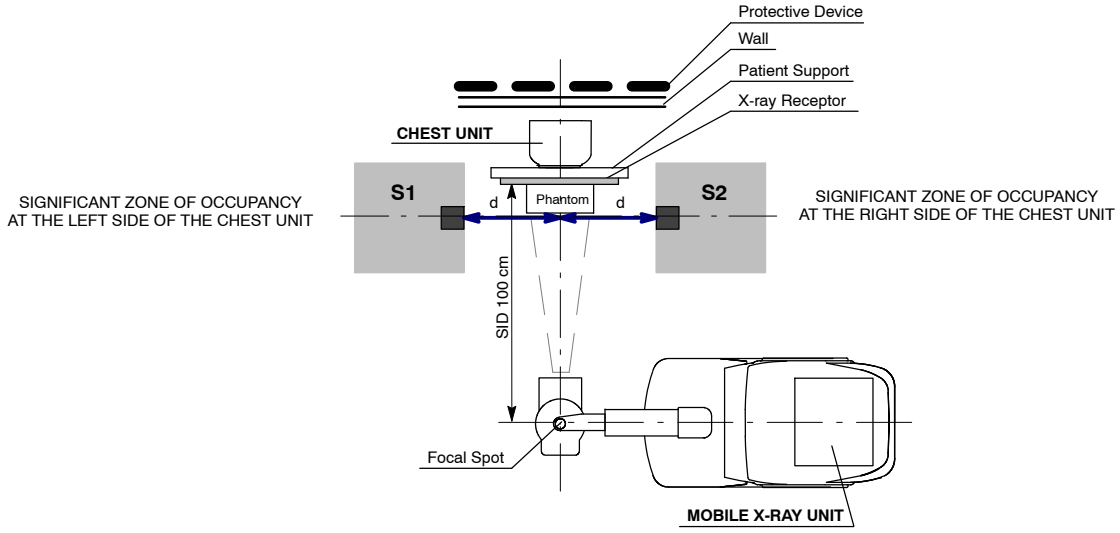
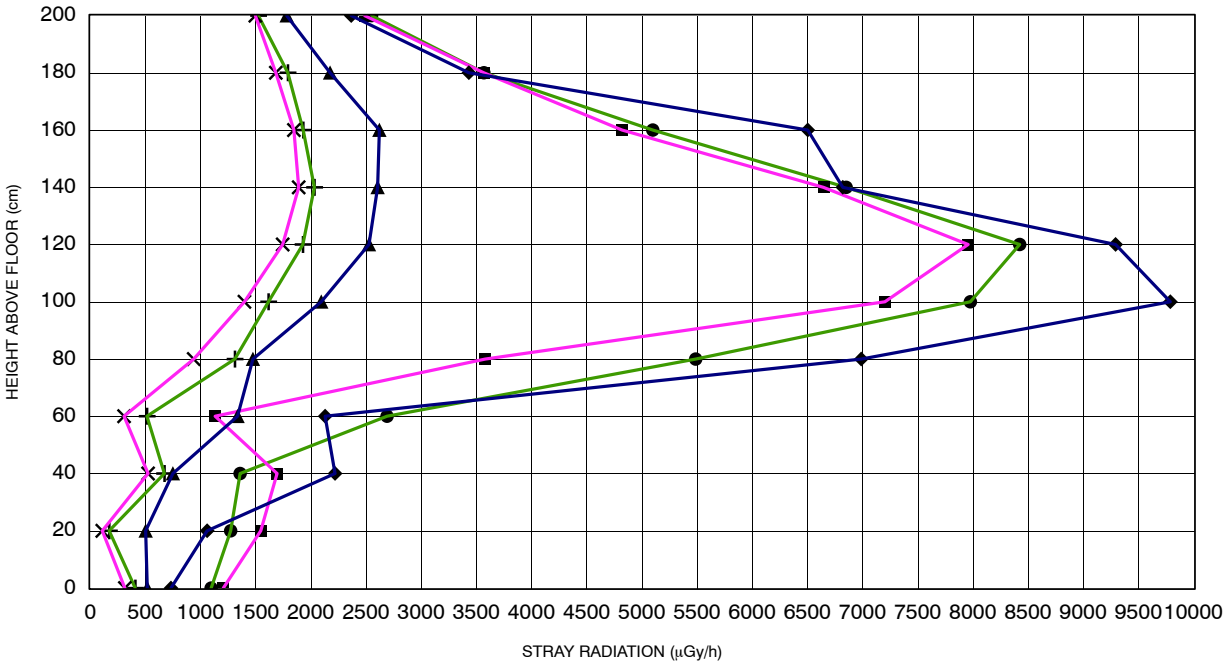
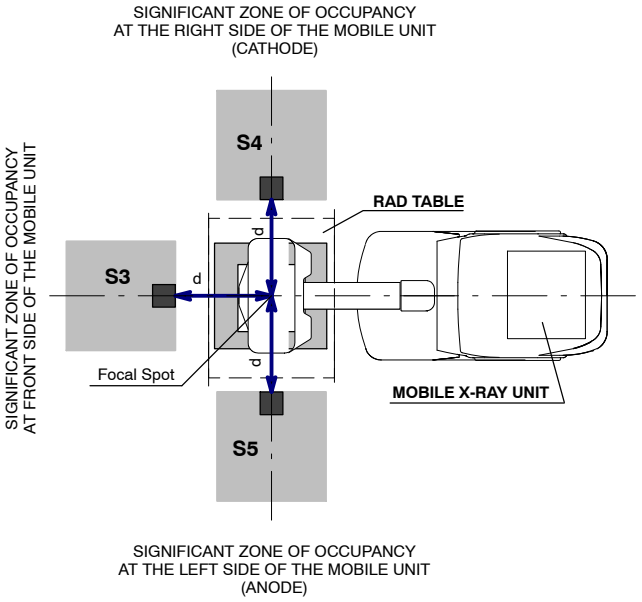


Illustration 2-4
Distribution of Stray Radiation on any Patient Support or any Table



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



2.8 ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

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

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

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

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

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

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

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

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

ESSENTIAL PERFORMANCE

The system 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 patient, user, and others from electrical and mechanical hazards by using adequate EMC measures like using filters, screened cables or housings.

EMC-COMPLIANCE CRITERIA DUE TO THE ESSENTIAL PERFORMANCE

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

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

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

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

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

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

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

TYPICAL RF DEVICES (Worst-Case scenario)

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

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

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

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

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

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

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

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

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

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

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

2.9 RADIO FREQUENCY INTERFERENCE NOTICE (USA)

This equipment has been tested and found to comply with the limits for a Class 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 and IEC 60601-1-3:2008+AMD1:2013. This information illustrates loading factors for image performance and supplies Dose indication examples. Therefore, these tables are an instance of the adjustment of Loading Factors, Focal Spot Selection, SID and Collimator opening, which affect to the radiation quality or to the radiation dose rate applied in normal use.*

2.10.1 FUNCTIONAL TESTS PERFORMED TO OBTAIN THE QUANTITATIVE INFORMATION

Equipment:

Note ☞ *These functional tests have been performed with 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											
	Loading Factors				Parameter Selection				Measured Doses		
Patient examination (orientative)	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 (µGy*m2)	Phantom Input Dose Rate (µGy/s)	Phantom Input Dose (µGy/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 ± 35% (IEC 60580:2000 / IEC 60601-2-54:2009 and IEC 60601-2-54:2009+AMD1:2015).*

2.11 DETERMINISTIC EFFECTS

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

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

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

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

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

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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*.
- *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.*

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

1 Head-Assembly
1.1 Status Light Indicator
1.2 Handgrips
1.3 Head Assembly Screen (option)
1.4 Collimator Panel (option)
1.5 Motion Controls (on the Handgrips)
2 Control Console
2.1 Control Panel
2.2 Main Screen
3 Handlebar
4 Connections Panel
4.1 Handswitch
4.2 Infrared Remote Control (option)
4.3 Barcode Scanner
5 Detector Storage/Charge
6 Back Wheel, Hubcap
7 Front Wheel
8 Anti-Collision Bumper
9 Power Line Plug
10 Detector Storage/Charge
11 Parking System
12 Apron Hook

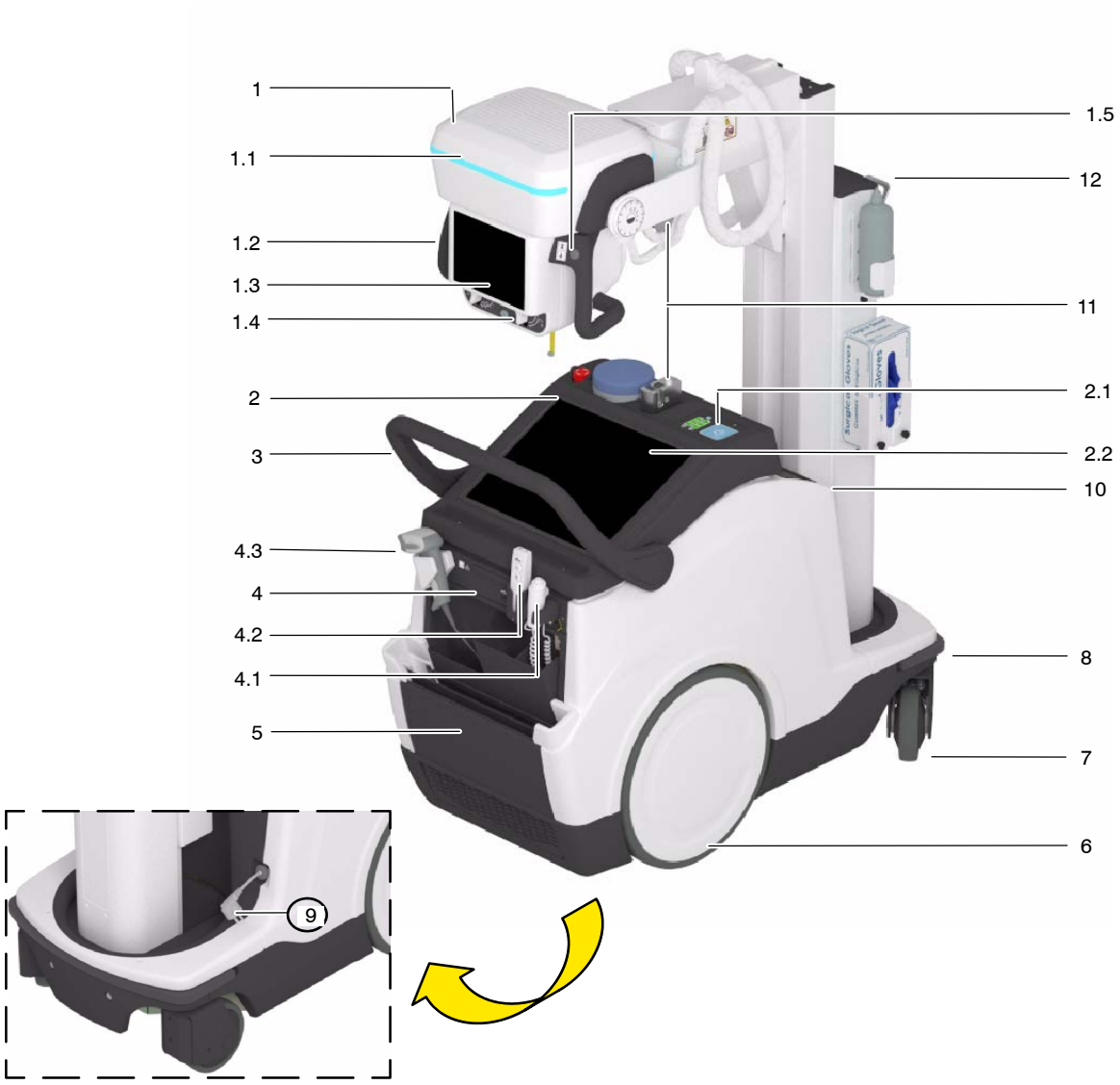


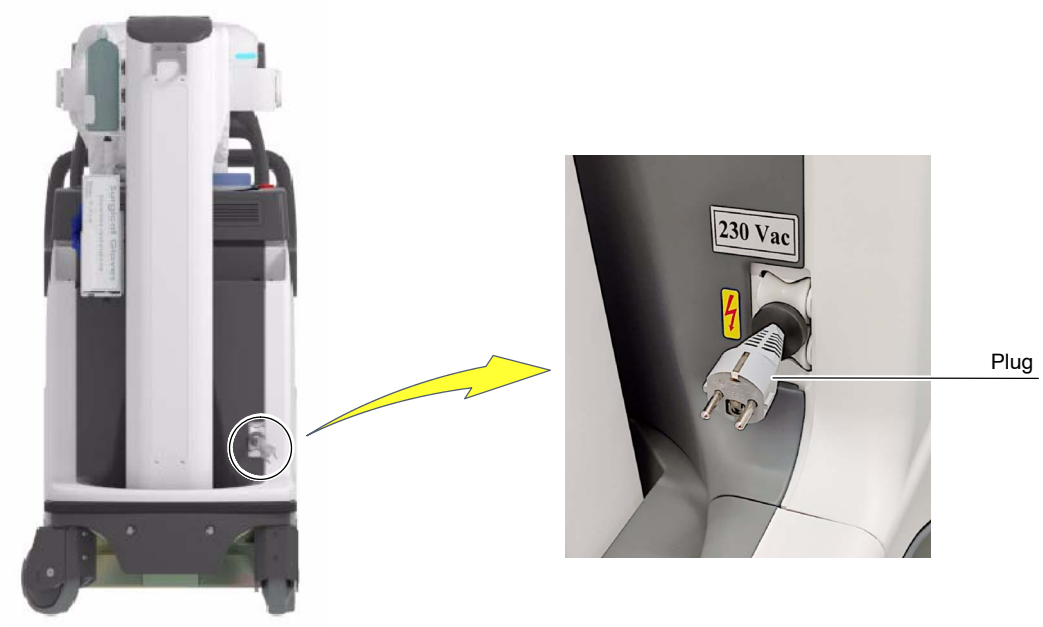
Illustration 3-2
Mobile X-ray unit

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.*



CAUTION

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

WARNING

THE MOBILE UNIT OPERATES AT AN UNIVERSAL INPUT RANGE FROM 100 V~ TO 240 V~ THAT MAY BE LIMITED BY THE POWER LINE CABLE AND/OR PLUG ACCORDING TO THE LOCAL REGULATIONS.

THE MAIN FUSES INSTALLED IN THE UNIT TO PROTECT THE EQUIPMENT ARE FACTORY SET ACCORDING TO THE COUNTRY DESTINATION AND ITS LOCAL REGULATION. PLEASE, CONTACT TO THE SERVICE PERSONNEL OR MANUFACTURER IN CASE THAT DESTINATION IS CHANGED AND ELECTRICAL REQUIREMENTS ARE DIFFERENT BECAUSE THE EQUIPMENT MAY NOT BE PROPERLY PROTECTED.

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

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.

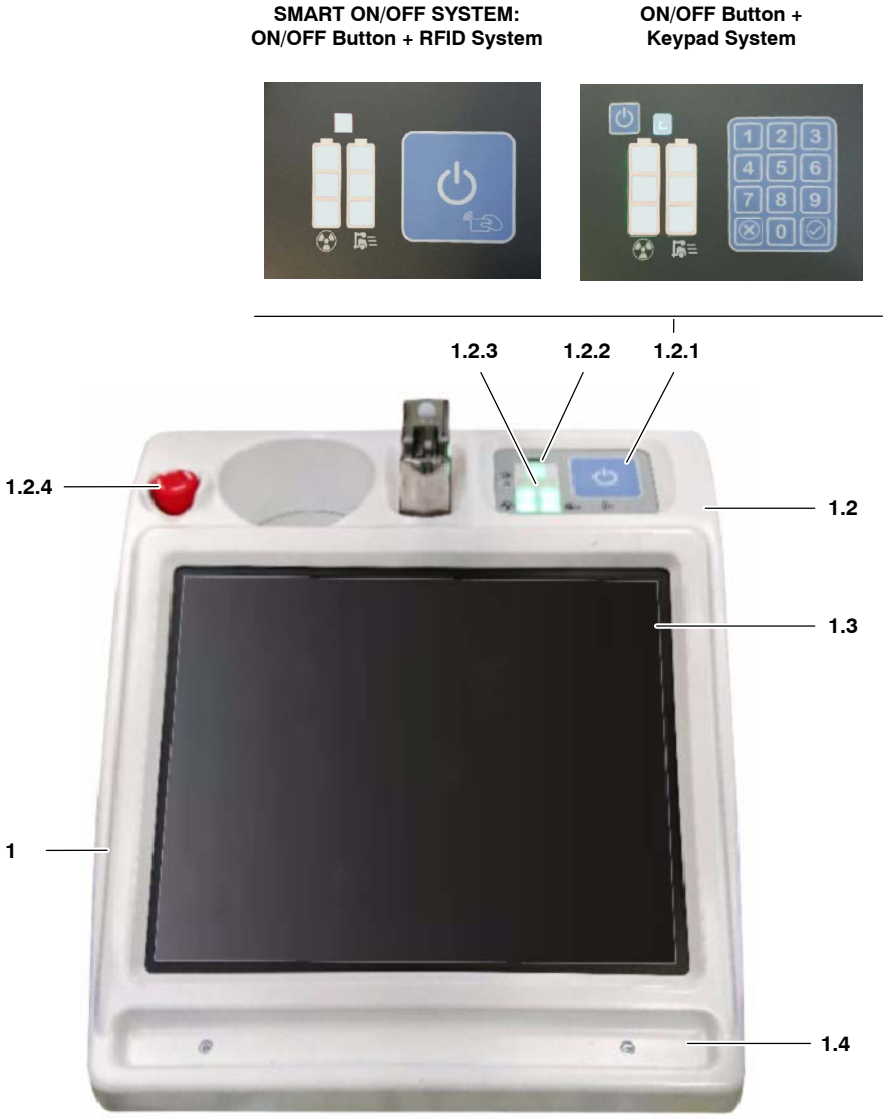
This "Lightning" icon will disappear from the Control Console when the Unit is unplugged from the mains.

For further information about Batteries Status Indicators, refer to Section 4.2.3.

Note ☞

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

3.2 CONTROL CONSOLE



1	Control Console	1.2.3	Battery Charge Level Indicators
1.2	Control Panel	1.2.4	Emergency Switch Off
1.2.1	On/Off Control	1.3	Main Screen
1.2.2	System On/Off Indicator	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 3.2.1.1 and 3.2.1.2.

▶ 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 3.2.1.1 of Smart 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 3.2.1.2 of ON/OFF and Keypad 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.

3.2.1 SYSTEM ON

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

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

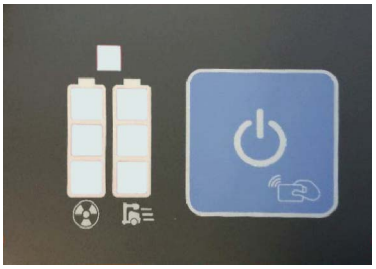
CAUTION

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

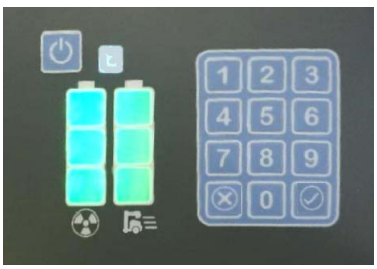
In this case, restart the unit making sure not to touch any part of the system (switches, touch screens, motion controls, or any other control).

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

- **Smart ON/OFF system: ON/OFF button and the RFID system (RFID-Card and RFID Card Reader)** (*refer to Section 3.2.1.1).*



- **ON/OFF button and the Keypad** (*refer to Section 3.2.1.2).*



3.2.1.1 SMART ON/OFF SYSTEM: ON/OFF BUTTON + RFID SYSTEM

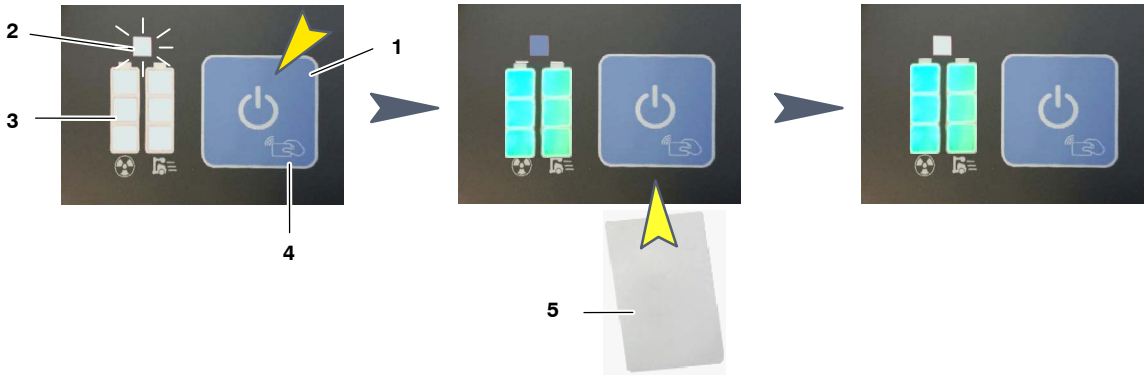
To turn the unit ON, proceed as described in the following steps:

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.

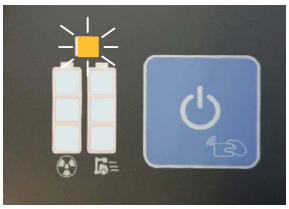
Note ☞ *When the Mobile Unit is in Charging Mode it is not necessary to press the ON/OFF button in the first instance.*

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 cyan 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.

- **Admin:**

  It includes all the previous permissions for Movements; Panel Out, X-Rays, and the following User Administrator permissions:

  - RFID Cards administration:

    For registering new cards and for adding, disabling or modifying the RFID card permissions.

  - Usability Settings:

    To configure Sound settings, Visual settings, Anticollision settings, Power OFF settings (*for further information, refer to section 3.2.9 of Power OFF Settings*).

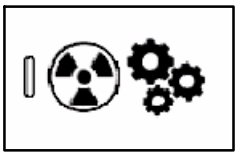
  - Maintenance:

    Useful to consult License data and logs compilation.

Each mobile unit is provided with several different RFID cards:

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

- **OPERATOR RFID Cards**, with permission for:
  - Movements.
  - Panel Out.
  - X-rays (Radiographic Operation).



- **ADMINISTRATOR RFID Card**, with permission for:
  - Movements.
  - Panel Out.
  - X-rays (Radiographic Operation).
  - User Management.

Note ☞ *For detailed information on the Administrator User, System Permissions and RFID Card Management, refer to Appendix C (Administrator User).*

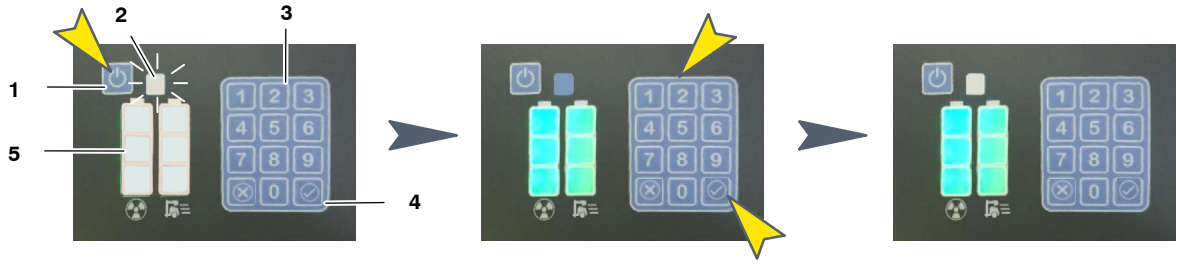
3.2.1.2 ON/OFF BUTTON + KEYPAD SYSTEM

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

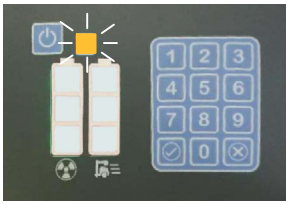
1. Press and hold the *ON/OFF* button (1) for a few seconds; the *System ON/OFF Indicator* (2) will blink white for 5 seconds.

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 cyan 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 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, *Konica-Minolta "Ultra" Software Application* for Radiographic operation will be launched on the Control Console.

3.2.2 SYSTEM OFF

CAUTION

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

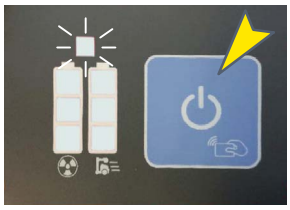
Note ☞

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.

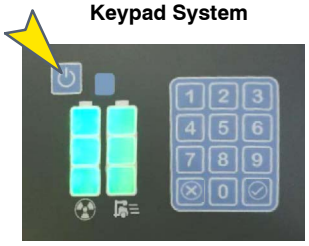
To turn the Unit OFF, proceed as described in the following steps:

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

Smart ON/OFF System

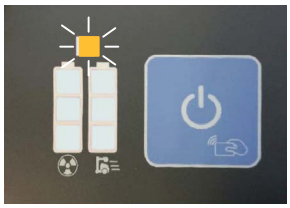


Keypad System

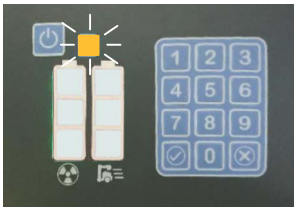


2. The system ON/OFF Indicator will light cyan for a few seconds and then, the system will be turned OFF.

Smart ON/OFF System



Keypad System



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.

3.2.3 EMERGENCY STOP

In the event of an emergency, the unit is turned OFF by forcibly pressing this switch (red mushroom-shaped switch). The 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 3.2.2 in order to turn it OFF safely.*

3.2.4 SYSTEM ON/OFF ROUTINE

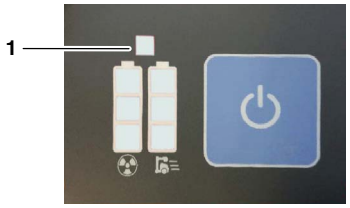
After turning the unit ON as described in *Section 3.2.1, Konica-Minolta "Ultra" Software Application* is launched on the Control Console.

Note ☞ *The user provided with RFID Card for Smart ON/OFF system, with permission for Radiographic operation (refer to Section 3.2.1.1), has direct access to the radiographic operation.*

Turn OFF the system as described in *Section 3.2.2.*

3.2.5 SYSTEM ON/OFF INDICATOR

The system ON/OFF Indicator (1) 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
OFF	**SYSTEM OFF** The ON/OFF Indicator is not illuminated when the system is OFF.
WHITE	**WAITING FOR USER IDENTIFICATION** 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. *(Refer to Sections 3.2.1.1 and 3.2.1.2).*
ORANGE	**USER REJECTED** 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. *(Refer to Sections 3.2.1.1 and 3.2.1.2.).*
CYAN	**SYSTEM INITIALIZATION / SHUTDOWN** The ON/OFF Indicator lights cyan during the System initialization process (after entering a valid RFID Card / Code) and during the Shutdown process. *(Refer to Sections 3.2.1.1, 3.2.1.2 and 3.2.2).*
WHITE	**SYSTEM ON/STANDBY** The ON/OFF Indicator lights white when the initialization process is completed and the Positioner is operational, in Standby status.
MAGENTA	**WAITING FOR NEW ACCESS CODE** 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. (*For Service personnel only*).

Note ☞ *For further information, refer to Sections 3.2.1.1 and 3.2.1.2.*

3.2.6 CONTROL CONSOLE

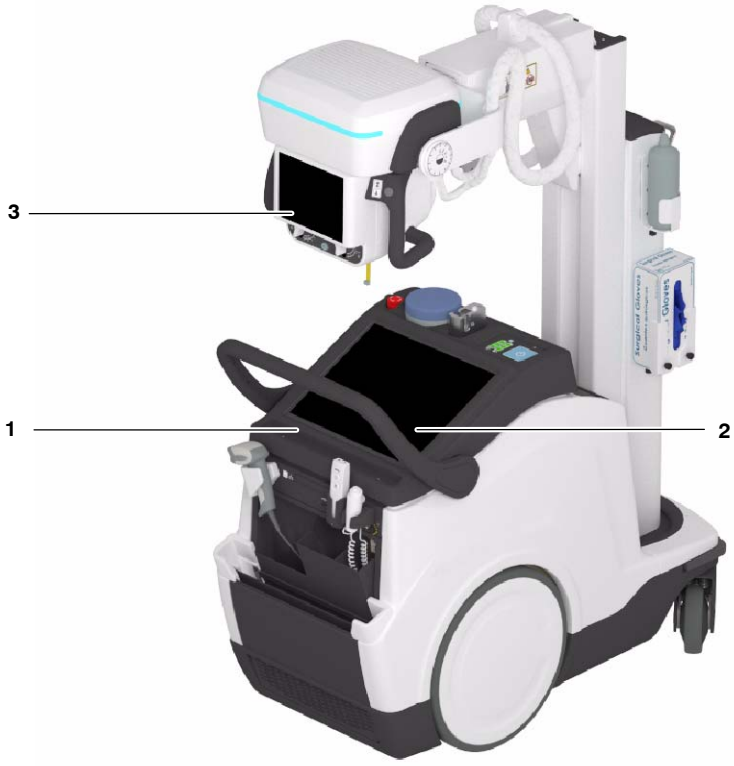
The Control Console houses the Main Screen which consists of a 19" capacitive Touchscreen Monitor, with pinch and zoom functionalities.

Konica-Minolta "Ultra" Software Application is shown on the Main Screen, including the RAD Screen (Generator Control Panel) with the controls, indicators and displays needed to perform radiographic exams.

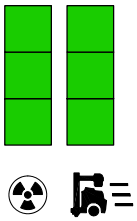
The system can comprise a second Touchscreen Monitor (9") located in the Head-Assembly useful for radiographic parameters selection, technical settings and patient information.

Note ☞ *For further details, refer to Sections 4 and 5.*

1 CONTROL CONSOLE
2 MAIN SCREEN
3 HEAD-ASSEMBLYSCREEN



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 ☞

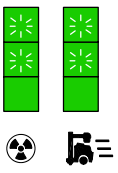
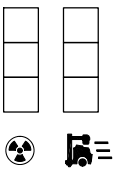
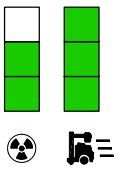
The Batteries require approximately 8 hours for a fully charge. To charge the Batteries, there is no need to have the Console turned ON. When the Batteries are fully charged, the Battery charge level Indicators on both columns stop scrolling and all the Indicators remain illuminated in green.

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

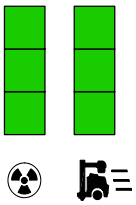
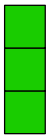
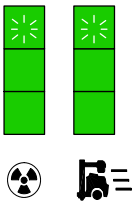
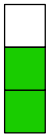
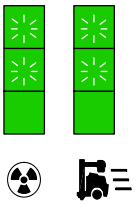
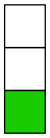
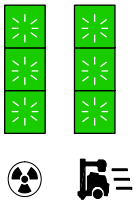
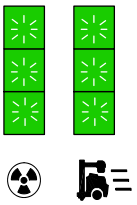
Note ☞

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	
	**Full Charge:** 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 *Full Charge* status. The batteries charge level is at 100% of the total charge.		When the system is at *Full charge* status, all the indicators light steady green and normal operation is allowed. The batteries charge level is between 60% and 100%
	**Medium Charge:** 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 upwards, indicating that the system Batteries are at *Medium Charge* status.		When the system is at *Medium Charge* status, the lower indicators light green and normal operation is allowed. The batteries charge level is between 31% and 59%.
	**Low Charge:** The lower 2 indicators on both columns (1+1) light steady green and the upper 4 indicators light blinking green and scrolling upwards, indicating that the system Batteries are at *Low Charge* status.		When the system is at *Low Charge* 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%.
	**Very Low Charge:** All the indicators on both columns (3+3) are blinking green and scrolling upwards, indicating that the system Batteries are at *Very Low Charge* status.		When the system is at *Very Low Charge* 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%.
	**Critically Low Charge:** All the indicators on both columns (3+3) are blinking green and scrolling upwards, indicating that the system Batteries are at *Critically Charge* status.		When the system is at *Critically Low Charge* status, the lower indicator lights blinking orange, on one or both columns, operation is limited but it is necessary to charge the system: the indicator on the X-Ray column, indicates that exposures are disabled; if is on the Motion column, indicates that motion is enabled for 30 minutes or 1 km after which, all the indicators will be OFF. The batteries charge level is 0%.
Indicator colors:  *Green*  *Orange*  *Indicator OFF*  *Blinking / Scrolling*			

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 RAD screen:

▶ ***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 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;* then, the work can 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 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;* then, the work can 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 mains (not charging).

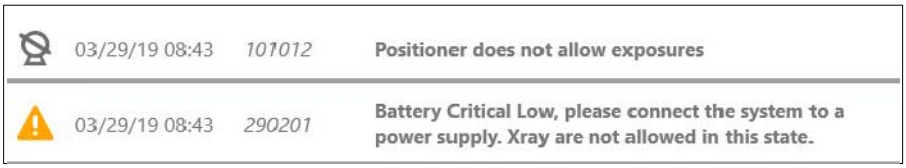
This alert indicates that it is necessary to connect the system to a power source for battery charging, although the operation is limited:

- If the indicator is on the X-ray column, indicates that exposures are disabled.
- If the indicator on the Motion column, indicates that motion is enabled for 30 minutes or 1 km after which, all the indicators will be OFF.

  The system initiates a shutdown with a 30 minutes countdown, that can be stopped connecting the unit to the mains.

  After 25 minutes without connection, the Status Light Indicator on the Head-Assembly flashes orange.

  If the system is still unplugged when the countdown expires, the unit will automatically shut down.



3.2.9 POWER OFF SETTINGS

Note ☞ *Power OFF settings can be configured by the User Administrator or the Service Engineer.*

▶ ***Time Out Switch Off Pressed.*** *Time set by default:: 3 seconds.*

Press and hold the *Switch OFF* button for 3 seconds; the system will start the turning OFF process.

▶ ***Time Out Delay Switch Off.*** *Time set by default:: 50 seconds.*

After holding pressed for 3 seconds the *Switch OFF* button, the system will be completely turned OFF in 50 seconds; during this time only movements are enabled (e. g. it is useful for the user to put the system in the Parking position, if necessary).

▶ ***Time Out Inactivity Generator.*** *Time set by default:: 2 minutes.*

When the system is disconnected from mains and there is not any Generator activity during 2 minutes, the Generator Tube Filaments turn off, unless the user performs any action on the RAD Screen, presses any control of the Handswitch or Infrared Remote Handswitch, or connects the system to the mains; it will delay the *Time Out Inactivity Generator* for another 2 minutes without any Generator activity.

▶ ***Time Out Inactivity Warning.*** *Time Set by default: 15 minutes.*

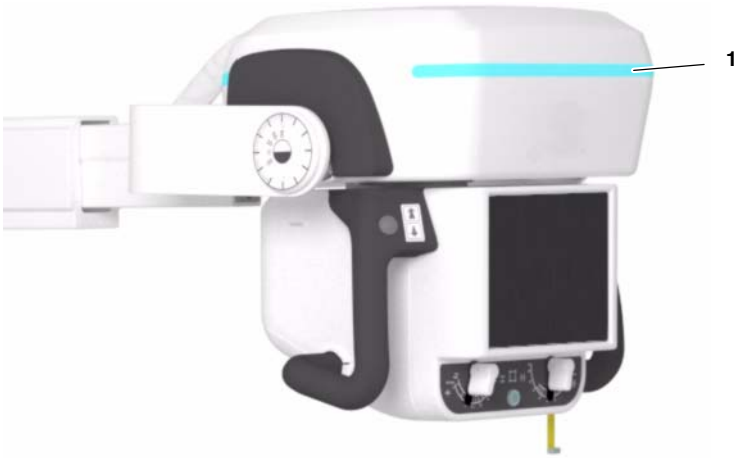
When the system is disconnected from the mains and there is not any Generator activity for 15 minutes, a Warning message is displayed on the screens to alert the user of an automatic shutdown after finishing a countdown timer for another 15 minutes.

If the Operator presses on *Accept* button or performs any system action (touches on the RAD Screen, activates any of the movement controls, presses the Handswitch or Infrared Remote Handswitch, or connects the system to the mains), within the configured time; it will delay the *Time Out Inactivity Warning* for another 15 minutes.

If the Operator does not respond within the countdown time of 15 minutes, the system will automatically shut down; that is, the system will be completely turned OFF after 30 minutes without activity.

3.2.10 STATUS LIGHT INDICATOR (OPTION)

The system can be provided with the *Status Light Indicator (1)*, located at the Head Assembly, which indicates different system status by colors, as described in the following table.



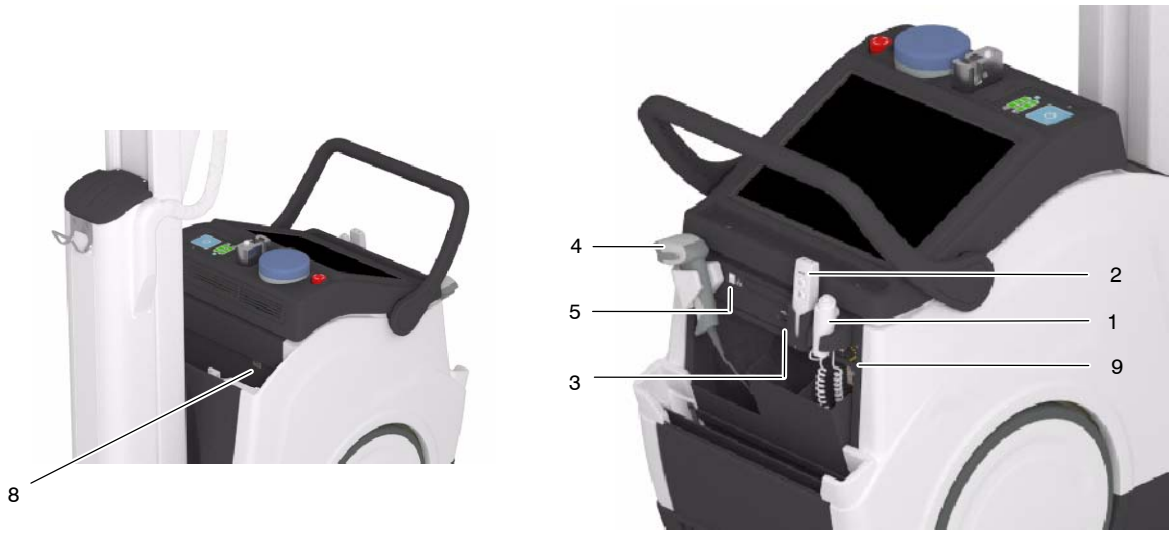
COLORS		SYSTEM STATUS
NOT MOVING	**MOVING**	
LIGHT OFF	 BLINKS WHITE	**SYSTEM STANDBY** X-rays are disabled. The Status Light Indicator is OFF when the system is in Standby. It blinks white when the system is moving.
CYAN	 BLINKS WHITE	**SYSTEM READY FOR EXPOSURE** The Status Light Indicator lights solid cyan 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 not System Error or Interlock condition. It blinks white when the system is moving.
GREEN	-	**SYSTEM PREPARED FOR EXPOSURE** The Status Light Indicator lights solid green when the handswitch has been pressed halfway to the “Prep” status. Movements are not allowed.
YELLOW	-	**EXPOSURE ON** 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	**SYSTEM ERROR** 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	**FRONT BUMPER ACTIVATED** The Status Light Indicator blinks magenta when the Front Bumper is activated.
RED	 BLINKS RED	**SERVICE MODE** Only in Service Mode.

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

3.3 CONNECTIONS PANEL

WARNING

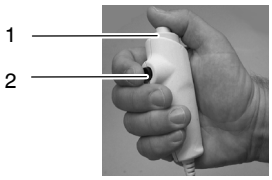
DO NOT CONNECT ANY ACTIVE DEVICES THAT APPLY EXTERNAL VOLTAGE TO THE SYSTEM THROUGH THE USB PORTS; ONLY PASSIVE DEVICES CAN BE CONNECTED.



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. **Barcode Scanner (option).**
5. **Ethernet (ETH) Connector**, in order to connect to the site Network.
6. **WIFI Connection**, in order to connect to the site Network.
7. **WIFI Connection**, in order to connect to the Wireless Digital Detector.
8. **Detector Backup Communication Cable (option)**, to be connected at the Front Cover (*refer to Section 3.10.2*).
9. **Manual Driving Brake Release Button (option)**, *(refer to Section 3.6.1.6)*.

3.4 X-RAY HANDSWITCH



1 OFF / Prep / Exp
2 Collimator Light

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

The status of the exposure is shown by the "*Ready*" and "*X-ray On*" indicators for the duration of the exposure.

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

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

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

Note ☞ *The unit cannot perform exposures when the Column is 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 3.2.10 of Status Light Indicators.*

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

CAUTION ***The handswitch cable must be placed in such a way as not to interfere 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 Parking position; it only can perform exposures out of the Parking position.*

WARNING

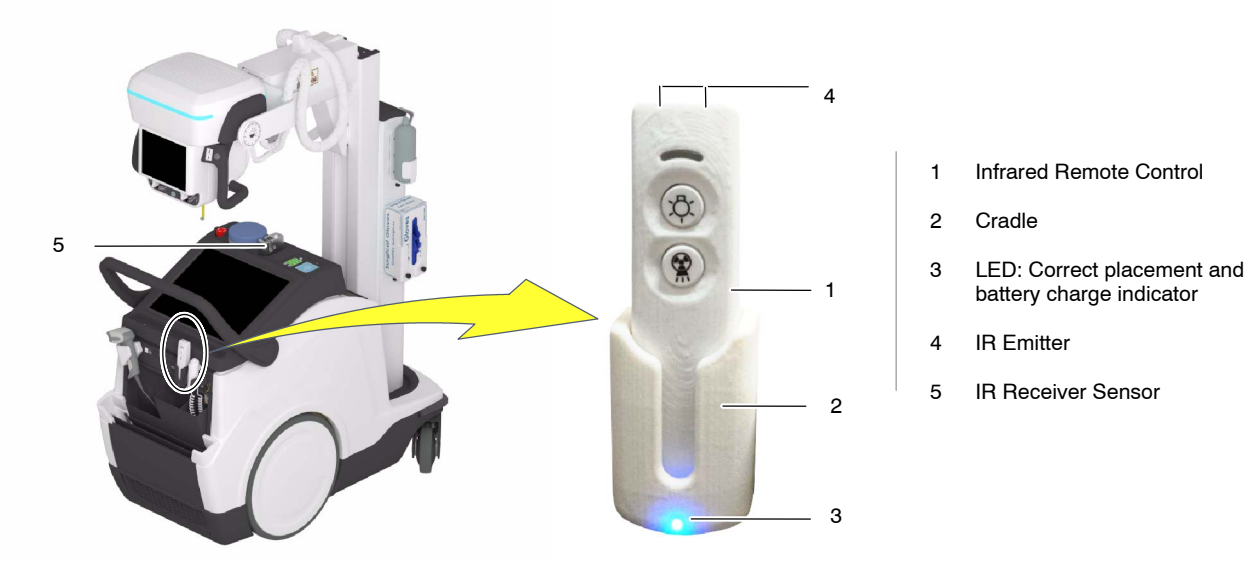
DURING AN EXPOSURE, THE IR REMOTE CONTROL MUST BE POINTED DIRECTLY AT THE MOBILE UNIT AT ALL TIMES.

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 cyan 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 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).



1 Infrared Remote Control
2 Cradle
3 LED: Correct placement and battery charge indicator
4 IR Emitter
5 IR Receiver Sensor

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.

1 OFF / Prep / Exp
2 Collimator Light
3 Status LED

COLLIMATOR LIGHT BUTTON:

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

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 cyan 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 3.2.10 of Status Light Indicators.*

3.6 MOTION CONTROLS

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

FOR SAFETY REASONS, DO NOT DRIVE THE UNIT OVER RAMPS WITH AN INCLINATION ANGLE >8º.

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

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

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

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

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

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

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

ALWAYS USE THE HAND-GRIPS 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 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 is provided with a three-position Handlebar (higher, medium and lower position) (*for further information, refer to Section 8.3 of Physical Characteristics).*

When the Arm is in Parking position, the unit travels at the configured velocity (approx. 5.5 km/h (3.42 mph) forwards and 2.5 km/h (1.6 mph) backwards).

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

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

In order 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 permit 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.

Fine Positioning Controls:

1 Backward

2 Forward

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

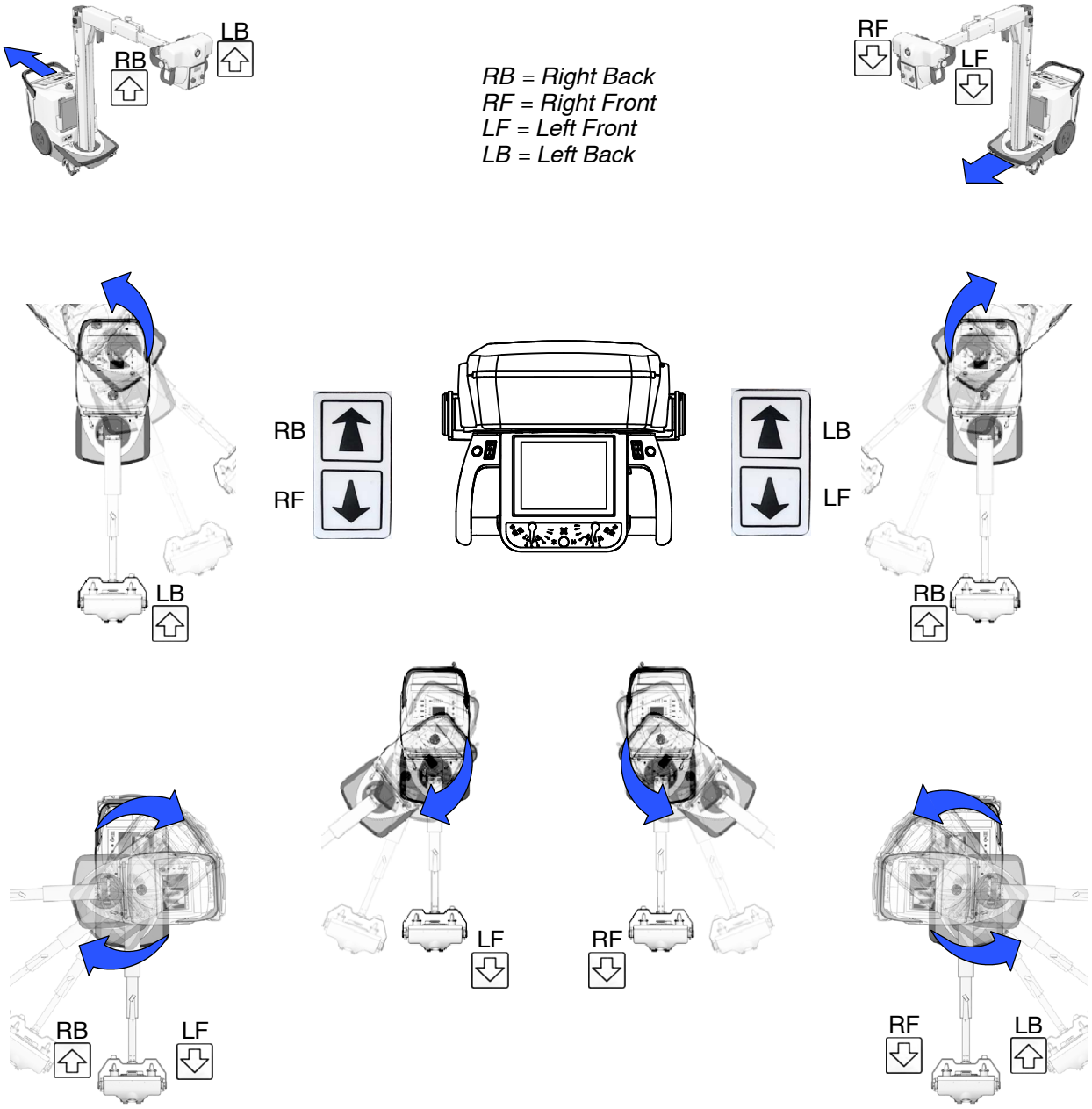
CAUTION

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.

The illustration below, details the corresponding movements.

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

Illustration 3-3
Fine Positioning Controls



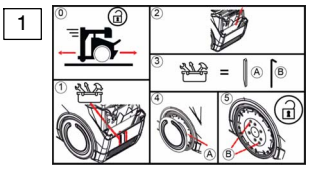
3.6.1.3 MANUAL CLUTCH SCREWS

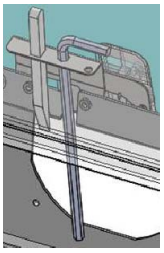
When the unit has to be moved manually, the (x2) Clutch Screws (Allen type) located on each wheel must be removed using the tools provided with the unit.

DANGER!

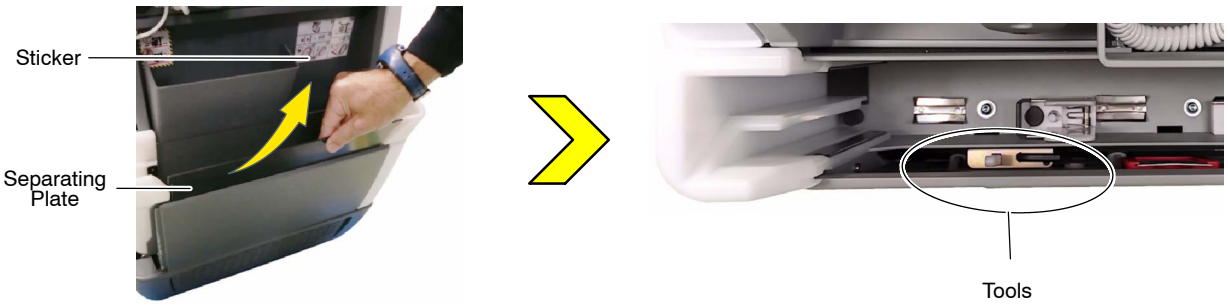
DRIVE THE UNIT MANUALLY ONLY WHEN MOTORIZED MOTIONS CANNOT BE PERFORMED (DUE TO A SYSTEM MALFUNCTION OR THE BATTERIES DISCHARGE).
IN THIS CASE, DO NOT DRIVE THE UNIT ON SLOPES OR INCLINED SURFACES; DRIVE IT ONLY ON LEVEL SURFACES, TO AVOID PERSONAL INJURIES OR DAMAGE TO EQUIPMENT DUE TO ITS HEAVY WEIGHT.

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





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



- Take both tools from the holder.

- Use the Wedge tool to dismount the magnetic Hubcap.

- 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 motion of the unit.

3.6.1.4 PROXIMITY SENSORS

WARNING

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 3.2.10 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

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 backwards; 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.*

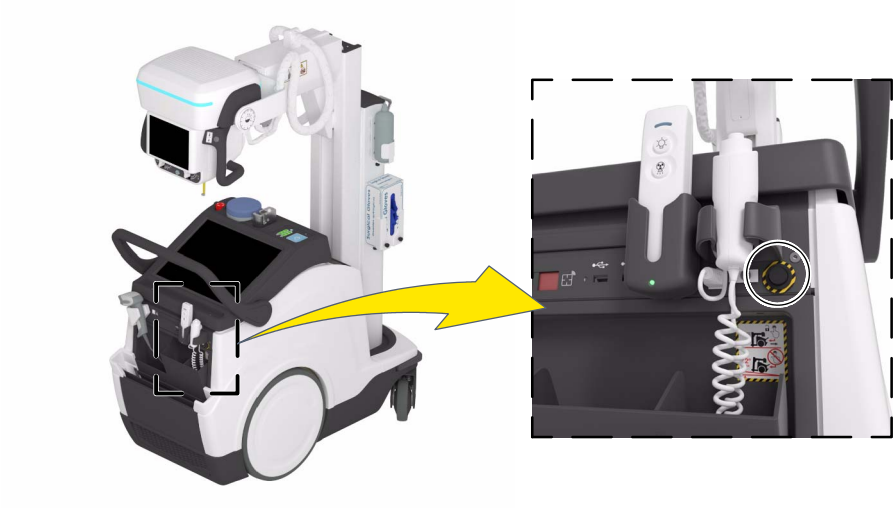
Note ☞ *For further information, refer to Section 3.2.10 of Status Light Indicators.*

3.6.1.6 MANUAL DRIVING BRAKE RELEASE (OPTION)

The Manual Driving Brake Release consists of a push-button that allows to release 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 3-4
Manual Driving Brake Release Push-Button



3.6.2 PARKING POSITION OF THE ARM

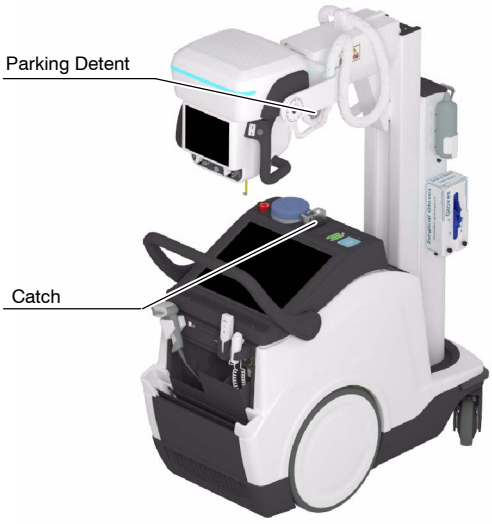
The unit is in Parking Position when the Parking Detent is secure in the Catch.

Place the Arm in Parking Position as follows:

- Fully retract the Telescopic Arm and turn the Column until the Parking Detent is aligned with the Catch.
- Lower the Arm and fully insert the Parking Detent into the Catch, until a “click” is heard; 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 (*refer to Section 4.2.4*).

To release the Arm from Parking Position, press on the Brake Control at the Head-Assembly.



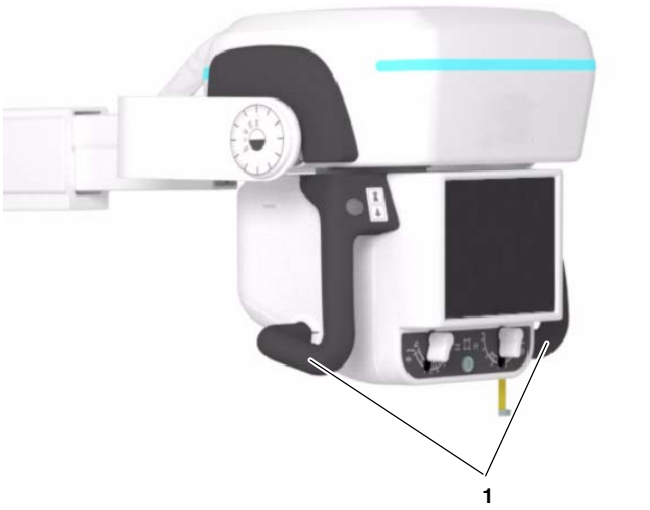
WARNING

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

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 Parking position.



1 Handgrips

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.

WARNING

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

WARNING

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.

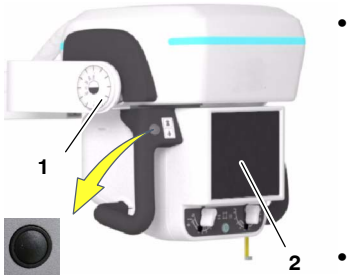
The Column can rotate from its Parking position: $\pm 317^{o}$.

The Arm allows a vertical travel 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:



- ±180º on its transversal axis, *i. e.* roll rotation (see *Illustration 3-5, A*). This movement has detents at –90º, 0º and +90º, and at –180º and 180º.

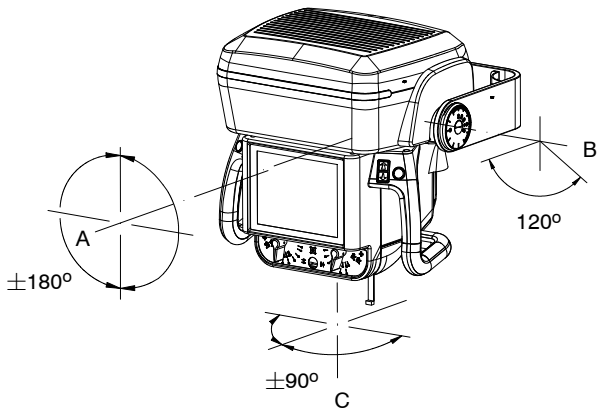
  The angle can be indicated on the Head-Assembly Screen (2).

- 120° on its horizontal axis, *i. e.* pitch rotation (see *to Illustration 3-5, B*). This movement has detents at 0º , and it has stops at +90°, 0º and – 30°.

  The angle is indicated in the *Inclinometer* (1) located on the Head-Assembly Support and on the Head-Assembly Screen (2).

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

Illustration 3-5
Head-Assembly and Collimator Movements



3.6.3.3 COLLIMATOR MOVEMENTS

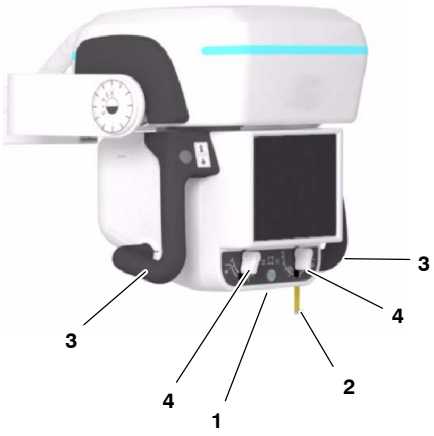
The Collimator can rotate ±90° on its vertical axis (*refer to Illustration 3-5,C*), while the Head-Assembly remains in the same position.

This movement is performed by manually turning the Collimator and has detents at –90º, 0º and +90º.

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

X-ray Tube Anode Angle	Receptor Size	Required SID with Collimator rotated at:	
		0° or ±90°	±45°
16°	24X30 30X24	SID ⩾ 70 cm	SID ⩾ 70 cm
	35X43 43X35	SID ⩾ 100 cm	SID ⩾ 100 cm
	43X43		

3.7 COLLIMATOR CONTROLS



1 Collimator Light 2 Measuring Tape 3 Handgrips 4 Collimator Knobs

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.*

The Mobile unit is supplied with the following Collimator:

Collimator Type	LED Light	Measuring Tape	Front Knobs	Rear Knobs	Dual Laser	Motorized Filters	Ready for EDAP option	Ready for external DAP Chamber
Manual Collimator with front and rear side Knobs, double Laser, Motorized Filters and ready for both Estimated Dose (EDAP) option and DAP Chamber option	✓	✓	✓	✓	✓	✓	✓	✓

The Collimator has the following functions:

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 3-1
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 Head-Assembly Screen.

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 (⩾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.

Press two times the *Collimator Light push-button* within 5 seconds to turn ON the Double Laser in order to adjust the SID.

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*cm^2.

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

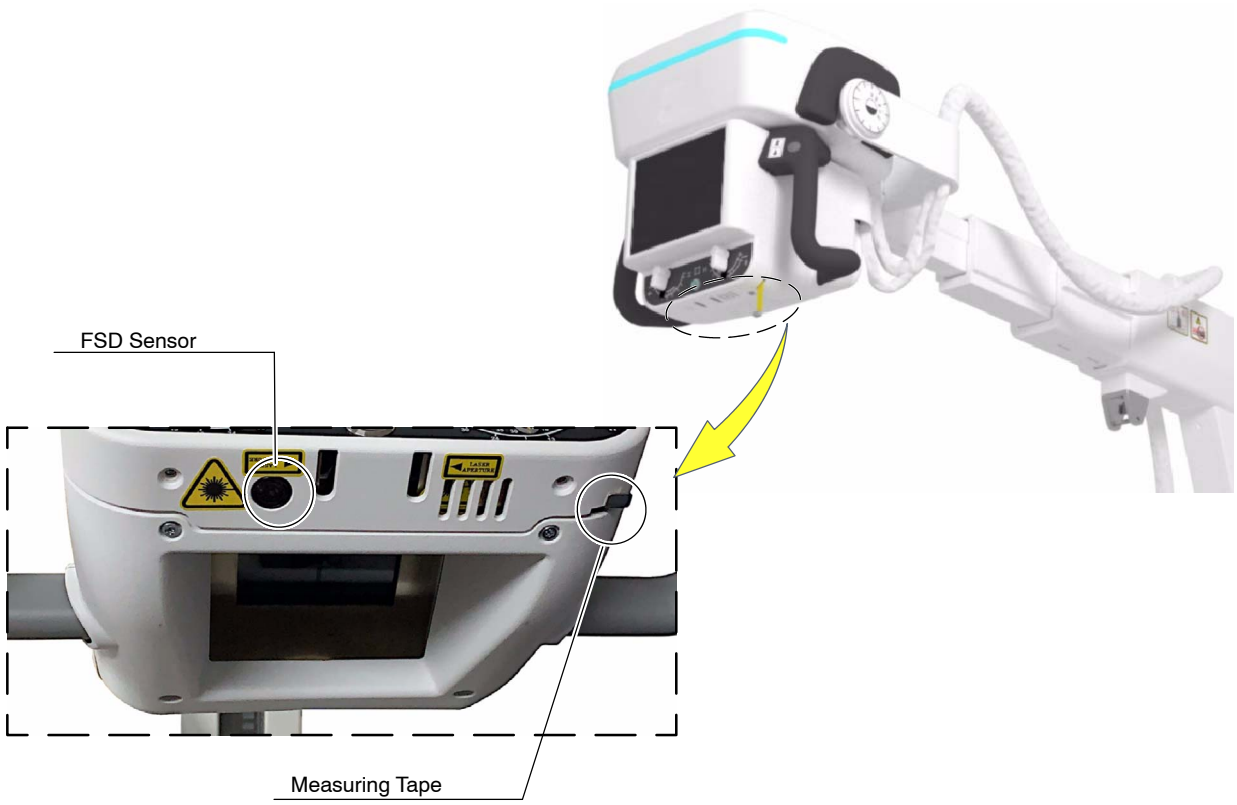
Note ☞ *Refer to the corresponding Dosemeter Manual for extended information about operation or technical description needed to maintain compliance with Standard IEC 60601-1-3:2008.*

3.9 FOCAL-SKIN DISTANCE SENSOR (OPTION)

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 measured value is displayed on the Head-Assembly Console (*refer to Section 4.2.13*).

Illustration 3-6
FSD Sensors Location



3.10 WIRELESS DIGITAL DETECTORS, OPTIONS AND ACCESSORIES

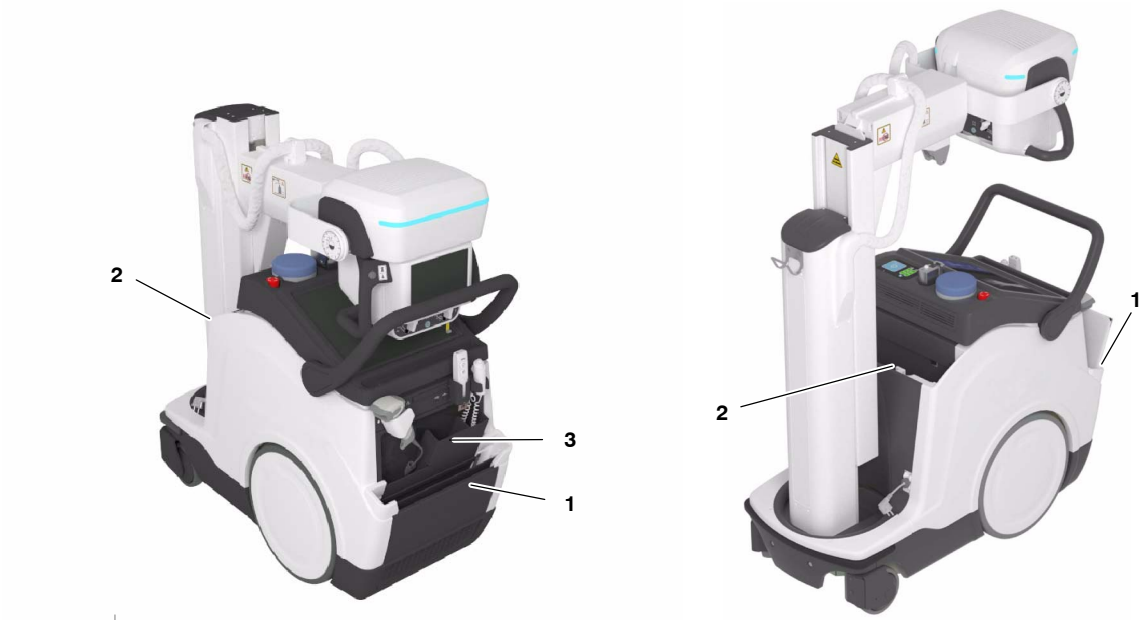
Wireless Digital Detectors:
AeroDR 2 1417HQ, AeroDR 2 1417S,
AeroDR 3 1717HD, AeroDR 3 1417HD, AeroDR 3 1012HQ

Some *Wireless Digital Detectors* can be fitted in an optional *Detector Handle Support* with an *Antiscatter 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. The behavior regarding the power supply of the Holders for Detectors charging is as follows:

- Whenever one or two Detectors are being charged in the Unit's Holders, power is continuously supplied to the charging slots.
- In case three Detectors are being charged at the same time:
  - Charging will be always continuous in the slot of the Back Holder (1).
  - Power is supplied alternately every 30 seconds at the charging slots of the Front Bracket (2).

Illustration 3-7
Wireless Digital Detectors, Options and Accessories



1 Back Cover Holder for Detector Charge and Storage, with / without Grid (1 Slot for Charging + 1 Slot for Storage)

2 Front Cover Holder for Detector Charge and Storage, with / without Grid (2 Slots for Charging + 1 Slot for Storage)

3 Detector Bags Holder

3.10.1 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 Back-up Cable.

AeroDR 2 1417HQ

AeroDR 2 1417S

AeroDR 3 1717HD

AeroDR 3 1417HD

AeroDR 3 1012HQ

3.10.2 DETECTOR BACK-UP COMMUNICATION CABLE (OPTION)

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

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

When not in use, the Back-up Cable can be stored at the Detector Holders.

3.10.3 BARCODE SCANNER (OPTION)

The Mobile unit can be equipped with a Barcode Scanner (1), for registering patient information.

The Barcode Scanner is placed in the Connections Panel.

3.10.4 GENERAL USE AND MAINTENANCE OF WIRELESS DIGITAL DETECTORS, OPTIONS AND ACCESSORIES

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

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 damped the patient contact surfaces as well as the Handle and Grid with disinfectants such as ethanol. For cleaning, wipe with a cloth damped in neutral detergent.

Note ☞ *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.

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SECTION 4 CONTROL CONSOLE

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

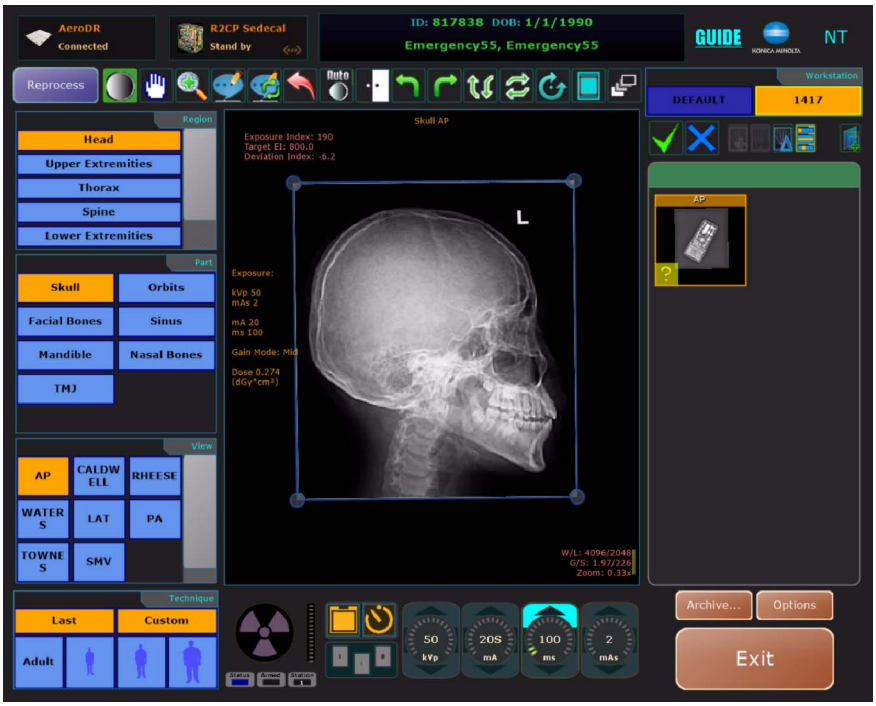
Note ☞ *Use the operating controls as described in this manual. Any other non-indicated combination may cause an incorrect operation.*

4.1 MAIN SCREEN

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

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

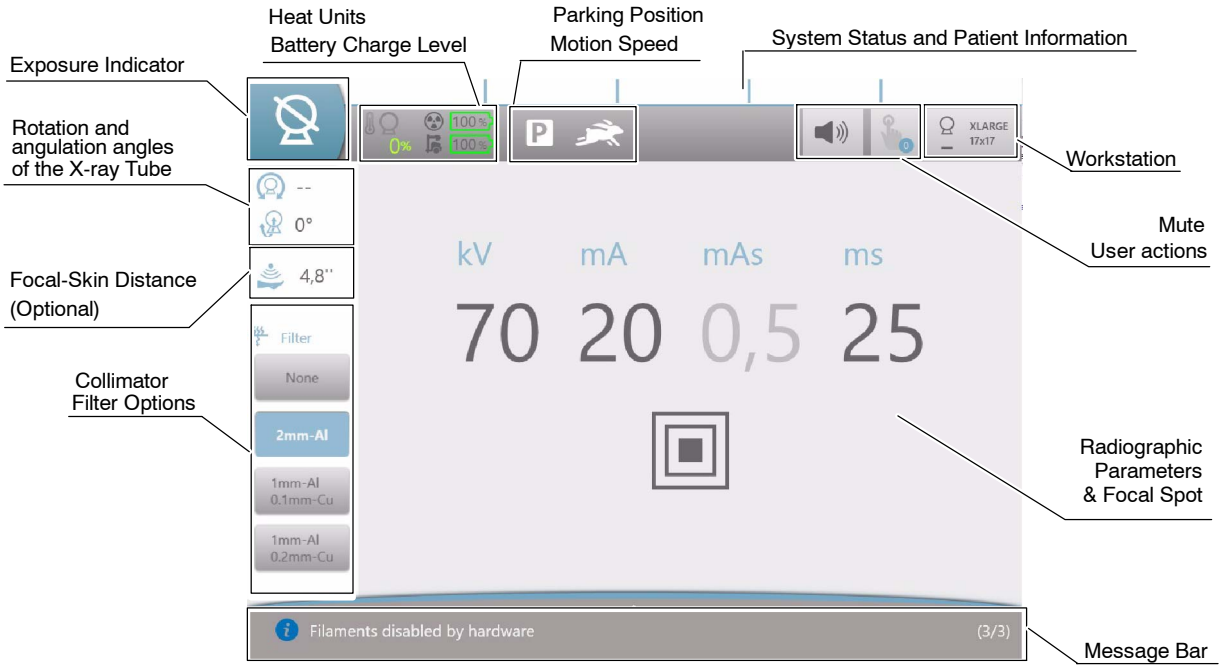
Illustration 4-1
Ultra Software Application



4.2 HEAD-ASSEMBLY CONSOLE

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

Illustration 4-2
Head-Assembly Console



4.2.1 EXPOSURE INDICATORS

The "*Status*" icon of the Head-Assembly 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 not Error or Interlock condition in the system.

HANDSWITCH PRESSED: The Handswitch half-way 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 audible signal sounds.

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

INHIBITION CONDITIONS (DISABLED FILAMENTS): There are one or more reasons causing an inhibition of exposure. When the Filaments are disabled (regardless of whether they have been deactivated via software or some other issue), the inhibit 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 APPROPRIATED FOR EACH EXAM.

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

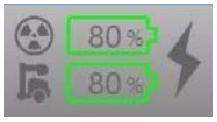
4.2.2 HEAT UNITS INDICATOR

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

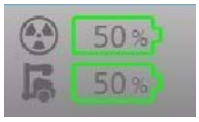
The "*Heat Units*" shows the percentage of utilized thermal capacity of the Tube. For example, "*25*%" would indicate that 25% of Heat Units capacity is used (it can be configured by the service engineer).

4.2.3 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 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 to 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 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.

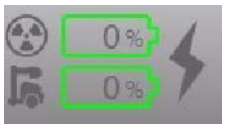
Low Charge (Stand-alone mode): The Battery icons are displayed in steady green when the battery charge levels for X-ray and Motion are between 20% and 30%, and the unit is unplugged from mains.

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

4.2.4 PARKING INDICATOR

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

4.2.5 MOTION SPEED INDICATOR

This indicator can display:

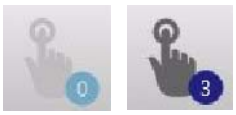
Limited Motion Speed: “Turtle” icon appears when an obstacle is detected and speed limitation is active. It also appears when using the Fine Positioning Controls on the Head-Assembly handles.

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

4.2.6 MUTE BUTTON

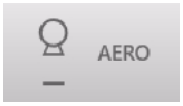
This button displays the selected sound option. Press on it to activate/deactivate the acoustic signals of the Mobile Unit.

4.2.7 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.

4.2.8 WORKSTATION SELECTION



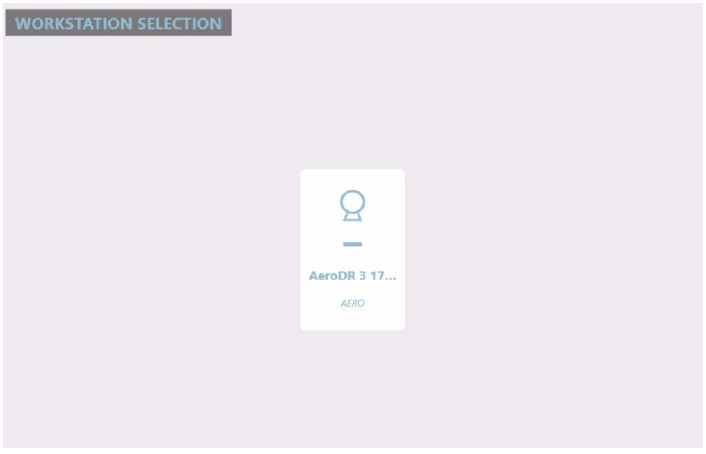
Press on this button to display the Workstation Selection window.

Workstations are automatically selected by the APR configuration. Each icon corresponds to its related workstation and remains highlighted on the RAD Screen 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.

Press on the desired Workstation to select it and return to the main menu by pressing again on this icon or on the *"Home"* icon.

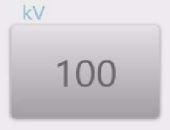
Illustration 4-3
Workstation Selection Window



4.2.9 RADIOGRAPHIC PARAMETERS

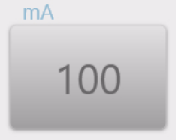
Radiographic Parameters are divided into kV, mAs, mA, and Time (seconds “s”).

Illustration 4-4
Radiographic Parameters Selection



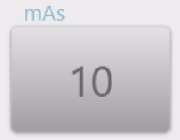
kV shows:

- The radiographic kV value selected for the technique.



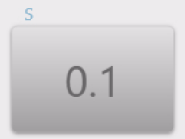
mA shows:

- 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.



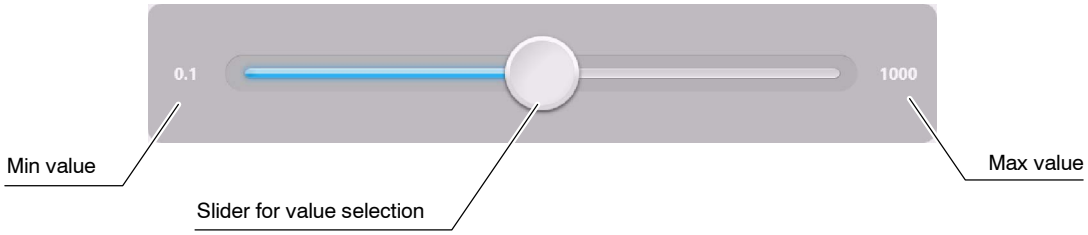
Time (s) can show:

- The Time value (in seconds) selected for the radiographic technique.
- If an exposure is aborted by releasing the Handswitch button, the actual Time (s) 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.

INCREASE / **DECREASE**: Radiographic technique values are increased or decreased by changing the value moving the "*Slider*" position.

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 4-5
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 select 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*)

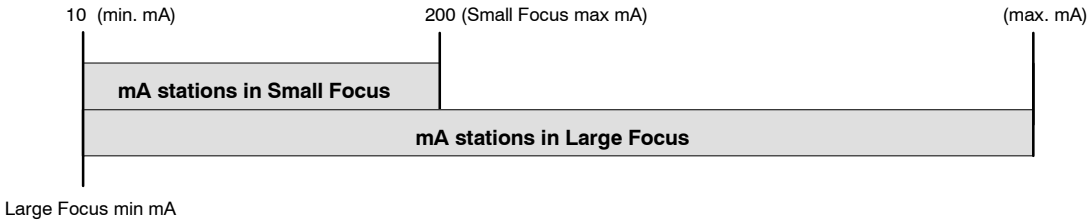
Note ☞ *If after pressing any of these buttons, the technique value is blocked, it could mean that it may have been selected a wrong combination of radiographic parameters that could have caused a warning condition (for further information about System Messages, refer to Section 5).*

4.2.10 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.

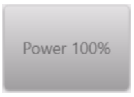
Small and Large Focal Spots can overlap each other, refer to the graphic below to view an example of Focal Spot change.

Illustration 4-6
Small and Large Focus Overlap



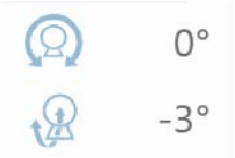
Note ☞ *The maximum mA station for the Small Focal Spot and the minimum mA station for the Large Focal Spot can be configured by the field engineer during the installation.*

4.2.11 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 values selection could be automatically adjusted.

4.2.12 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).

4.2.13 FSD VALUE

This option displays the value of the current distance between focus and patient measured by the Focal-Skin Distance sensor (*refer to Section 3.9*).

4.2.14 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):

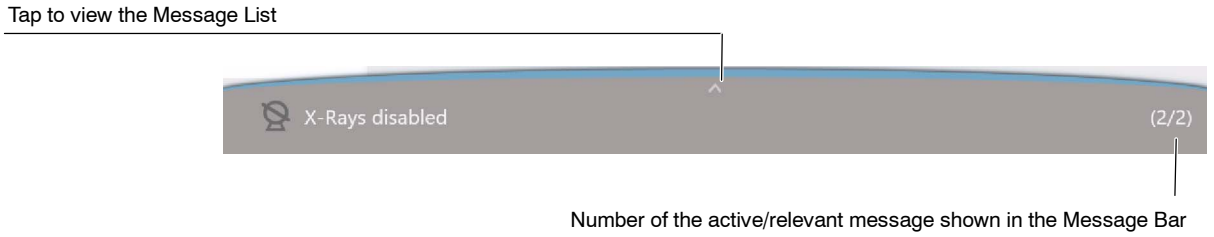
- None.
- 2 mm Al
- 1 mm Al + 0.1 mm Cu
- 1 mm Al + 0.2 mm Cu

4.3 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.

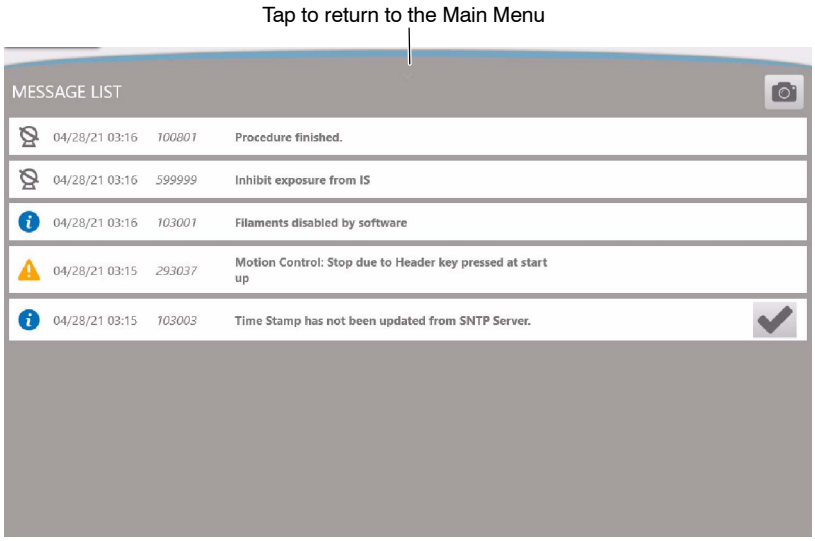
The Message Bar is located in the bottom area of the Main Menu of the Head-Assembly Console.

Illustration 4-7
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 4-8
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".

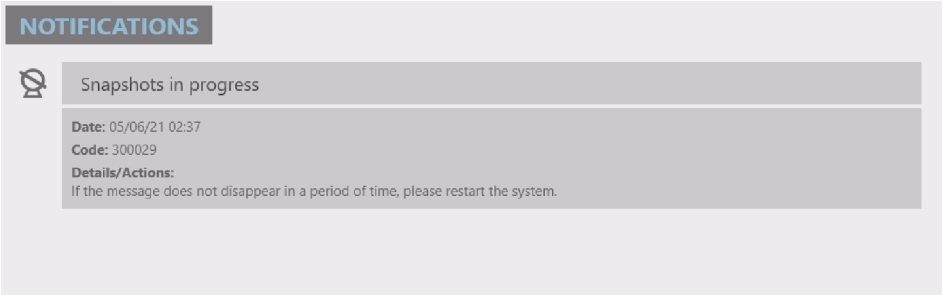
4.3.1 MESSAGE WINDOWS

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 4-9
Message Displayed



Press the "*Start*" button in any of these windows to return to the Main Menu.

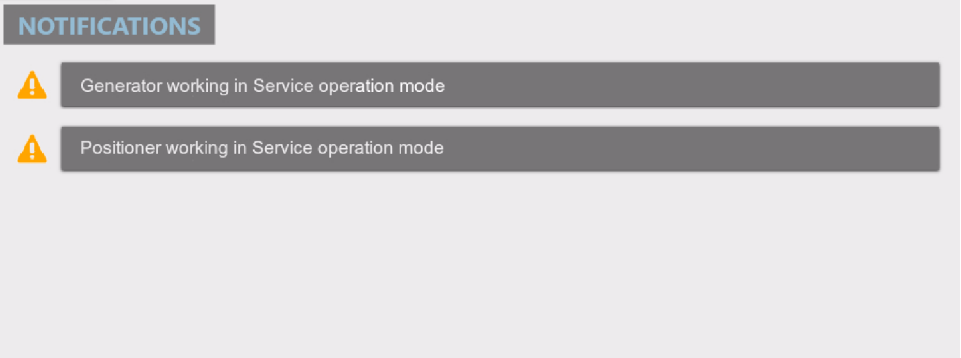
Each of the message windows is detailed below:

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 4-10
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*).

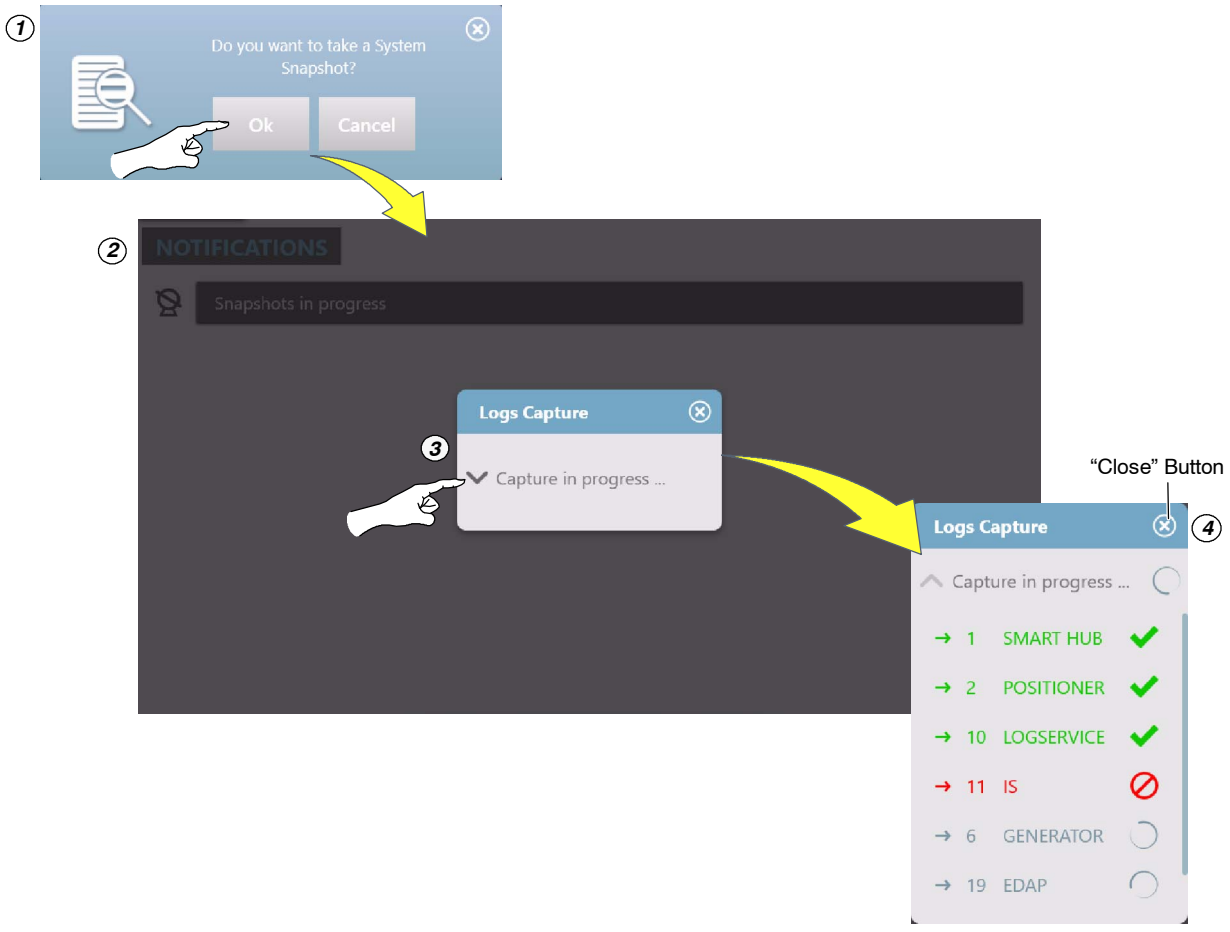
Illustration 4-11
Inhibit Conditions Messages

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 a pop-up window in order to return to the Main Menu.

Illustration 4-12
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.

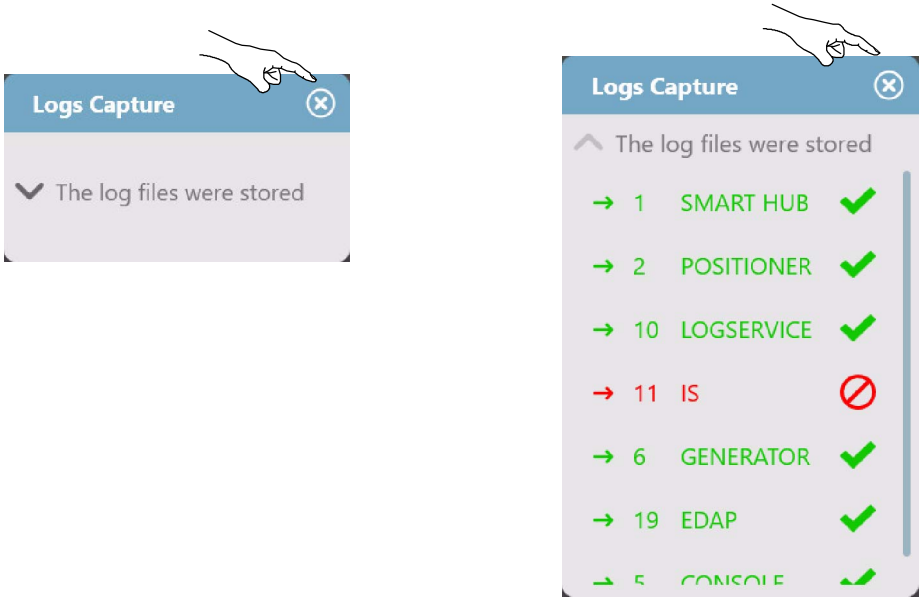
- Successful logs export, for that component.

- 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 4-13
Exiting the Logs Capture Window



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

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SECTION 5 SYSTEM MESSAGES

The System Messages are displayed in the Head-Assembly Console. The console shows 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.

- **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.

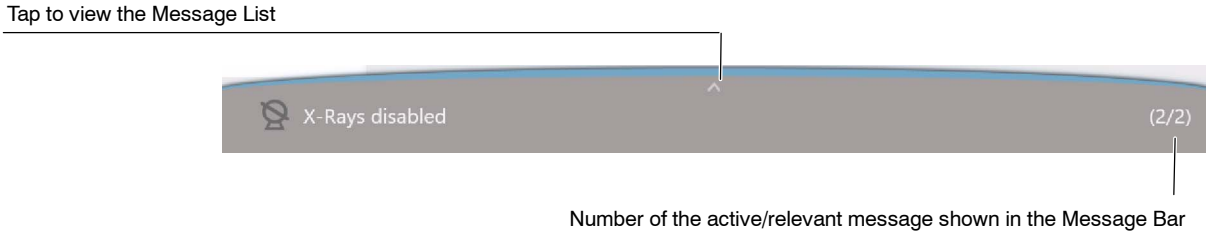
- **User action.** These messages disappear once the required action is performed by the user.

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

Illustration 5-1
Message Bar

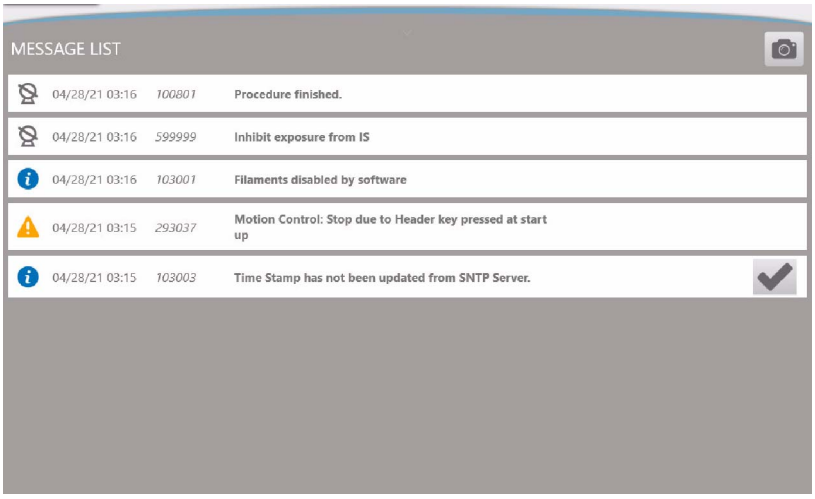


Note ☞ *For additional information about the Message Area refer to the Section 4.3.*

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.

Illustration 5-2
Message List



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

ID	DESCRIPTION	TYPE	USER HELPTEXT
100250	Communication lost with UARC Device	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
100251	Communication lost with Power Control Device		
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		
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	Error	Call Service.
100257	High Speed is not supported by License	Error	-
100258	FPGA running with Golden Firmware		
100803	Activated Procedure is not allowed	Inhibit Exposure	Change the exposure values or wait for the X-ray Tube to cool.
100930	Tube file wrong format	Error	-
100941	Current Image Receptor Synchronization Type is not supported. Please, select other workstation.		
100942	Preheating Filament	Information	Wait for 10 seconds.
100944	Maximum Preparation Time Reached.	Information	Remove preparation and exposure order.
101008	INTERLOCK_2	Inhibit Exposure	-
101015	Generator has not been calibrated yet	Information	
101017	Configurated Tube is different to Calibrated Tube		
101018	Exposure does not allowed in this Desktop	Inhibit Exposure	
101019	The system has to be rebooted for being upgraded	Information	Press Accept and wait for the System to restart
101021	Inhibit Xray due to system communication lost	Inhibit Exposure	-

ID	DESCRIPTION	TYPE	USER HELPTEXT
101022	Generator inactivity state, preheating filament	Information	Wait for 10 seconds.
101023	Upgrade is ongoing, xray disabled during this process	Information	-
101024	KVM button has been pressed, switching between computers	Inhibit Exposure	If KVM has not been pressed, call Service
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	-
102001	Value requested exceeds generator power		
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		
102023	Number of exposure reached. Exposure finished.	Information	No user action required.
102024	Exposure finished due to limit mAs reached.	Information	No user action required.
102025	Exposure finished due to limit energy for serial radiographic exposures.	Information	No user action required.
103001	Filaments disabled by software	Information	Call Service.
103002	Filaments disabled by hardware		

ID	DESCRIPTION	TYPE	USER HELPTEXT
103003	Time Stamp has not been updated from SNTP Server	Information	Call Service.
103008	File has not been uploaded. File Manager Service has not found	Information	Call Service.
103009	Demo Mode Enabled by License		
103010	Upgrade only allowed in Service Mode	Information	-
103011	Demo Mode enabled by Dip Switch	Information	Call Service.
140301	Generator DSP Control. Register configuration	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140302	Xray generator internal error.	Error	Restart the System. If the error persists, call Service.
140303			
140304			
140305			
140306			
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		
140312	Generator DSP Control. kV Converter Undercurrent		
140313	Generator DSP Control. Internal HW protection		
140314			
140315	Generator DSP Control. IGBT bridge fault.		

ID	DESCRIPTION	TYPE	USER HELPTEXT
140316	Generator DSP Control. IGBT bridge fault branch	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140317			
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		Press Accept. If the error persists, restart the System and reduce mA of the exposition. If the error persists, call Service.
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.
140321	Generator DSP Control. Undercurrent in the power converter using small filament during exposure.		
140322	Generator DSP Control. Overcurrent in small filament.		
140323			
140324	Generator DSP Control. Small Filament Current out of range		
140325	Generator DSP Control. Fault on small filament inverter.	Error	Restart the System. If the error persists, call Service.
140326	Generator DSP Control. Thermal fault on small filament inverter.		
140330	Generator DSP Control. Undercurrent in large filament during exposure.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140331	Generator DSP Control. Undercurrent in the power converter using large filament during exposure.		
140332	Generator DSP Control. Overcurrent in large filament.		
140333			
140334	Generator DSP Control. Large Filament Current out of range		
140335	Generator DSP Control. Fault on large filament inverter.		

ID	DESCRIPTION	TYPE	USER HELPTEXT
140336	Generator DSP Control. Thermal fault on large filament inverter.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140340	Generator DSP Control. Undercurrent in super small filament during exposure.		
140341	Generator DSP Control. Undercurrent in the power converter using super small filament during exposure.		
140342	Generator DSP Control. Overvoltage in super small filament.		
140343			
140344	Generator DSP Control. Following error loop on super small filament.		
140345	Generator DSP Control. IGBT fault on the super small filament.		
140346	Generator DSP Control. Thermal fault on the super small filament.		
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.		
140355	Generator DSP Control. UDC undervoltage		
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		

ID	DESCRIPTION	TYPE	USER HELPTEXT
140360	Generator DSP Control. Power Control Calibration data error	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140361			
140362			
140363			
140364			
140365			
140366			
140367			
140368			
140369			
140370			
140371			
140372			
140373			
140374			
140375			
140376			
140377			
140378			
140379			
140380			
140381			

ID	DESCRIPTION	TYPE	USER HELPTEXT
140382	Generator DSP Control. Power Control Calibration data error.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140383			
140384			
140385			
140386			
140387			
140388			
140389			
140390			
140391			
140392			
140393			
140394			
140395			
140396			
140397			
140398			
140399			
140400			
140401			
140402			
140403	Generator DSP Control. Feedback KV error.	Error	Press Accept. Retake exposition. If error persists, restart the system. If error persists, call Service.
140404	Generator DSP Control. Generator Wrong mA. Filament calibration.		Press Accept. If error persists, restart the system. If error persists after the restart, autocalibrate the Tube.

ID	DESCRIPTION	TYPE	USER HELPTEXT
140408	Generator DSP Control. Overcurrent in the main inverter	Error	Press Accept. Retake exposition. If error persists, restart the system. If 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.
140501	X-ray generator internal error.	Error	Restart the System. If the error persists, call Service.
140502			
140503			
140505			
140506			
140509			
140511			
140512	Generator Starter powered Off	Information	Information - Generator Starter. System Powered Off.
140533	Generator Starter comms error.	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.		
140542			
140543	HW version mismatch.		
140544	Wrong Dropout Station selection	Error	Reset error. If the error persists, restart the System. If the error persists, call Service.
140554	Generator Starter. Minimum input voltage Error.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140555	Generator Starter. Maximum input voltage Error.		

ID	DESCRIPTION	TYPE	USER HELPTEXT
140557	Generator Chopper Time Out.	Error	Reboot is required. If the error persists, restart the System. If the error persists, call Service.
140558	Generator Starter. Current Error.		Press Accept. If the error persists, restart the System. If the error persists, call Service.
140559			
140560			
140561			
140562			
140563			
140564			
140565			
140566			
140567			
140568			
140569			
140570			
140571			
140572			
140573			
140574			
140575			
140576			
140577			
140578			
140579			

ID	DESCRIPTION	TYPE	USER HELPTEXT
140580	Generator Starter. Current Error.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140581			
140583			
140589			
140590			
140591			
140592			
140593			
140594			
140595			
140598	Generator Starter. Acceleration rejected Error.		
140599	Generator Starter. Error Mismatch.	Error	Unknown error type - Generator Starter. Error Mismatch
140601	Generator Starter. Internal debug information.	Information	Generator Starter will be reset. If the error persists, call Service. Generator Starter. Internal debug information.
140602	Generator Starter. Software Warning.	Information	Design Information - Generator Starter. ADC_Mailbox_Input_ADCSWI_Warning
140603	Generator Starter. Internal test interlock.	Error	Generator Starter will be reset. Enable UARC logs. If the error persists, call Service.
140604	Generator Starter. Tube 1 Thermal Switch Interlock.	Error	Tube 1 Temperature. Interlock. - Generator Starter. Tube 1 Thermal Switch
140606	Generator Starter. Default Tube.	Information	Default tube is selected. - Generator Starter. Hardcoded Tube definition.

ID	DESCRIPTION	TYPE	USER HELPTEXT
140608	Generator Starter. Voltage Warning.	Information	Design Information - Generator Starter. V_ACC Maximum Duty Warning.
140609	Generator Starter. Voltage Warning.	Information	Design Information - Generator Starter. V_HOLD Maximum Duty Warning.
140610	Generator Starter. Voltage Warning.	Information	Design Information - Generator Starter. V_DC Maximum Duty Warning.
140611	Generator Starter. Tube Impedance Read Information.	Information	Design Information - Generator Starter. Tube Impedance Read Value.
140612	Generator Starter Interlock.	Error	Wait until the message dissapears.
140613			
140616	Generator Starter powered Off	Information	No user action required.
290001	System Communication Error with GPIO Head	Error	Restart the System. If the error persists, call Service.
290002	System Communication Error with Battery Monitor	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
290003	System Communication Error with RFID		
290004	System Communication Error with ADMC		
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	Error	Restart the System. If the error persists, call Service.
290102	Configuration file not loaded		

ID	DESCRIPTION	TYPE	USER HELPTEXT
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	-
290200	Collision detected	Inhibit Movement	
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.	Warning	-
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	
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	-
290401	System is powering off. Please wait...	Information	

ID	DESCRIPTION	TYPE	USER HELPTEXT
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.
290454	Internal error located in the head	Error	Reboot the system and try to repeat the operation.
290500	usability_setting.xml is outdated. Please, enter in service mode and update this file	Warning	-
290501	positioner_1.xml is outdated. Please, enter in service mode and update this file	Warning	-
290700	Inhibit X-ray due to current RFID tag does not allow X-ray	Inhibit Exposure	
290701	Inhibit X-ray due to screen has been powered off		
290702	Inhibit X-ray due to parking position	Inhibit Exposure	Check if unit is in parking position. If it is not, call Service.
290703	Inhibit X-ray due to system is moving	Inhibit Exposure	-
290704	Inhibit X-ray due to brakes are released		
290705	Inhibit X-ray due to board configuration pending	Inhibit Exposure	Call Service.
290706	Inhbit X-ray due to System in Critical Battery Level	Inhibit Exposure	If after charging the unit the error persists, call Service
290707	Inhibit X-ray due to Dosimeter is not ready	Inhibit Exposure	Call Service.
290708	Inhibit X-ray due to Collimator filters are moving	Inhibit Exposure	-
290709	Inhibit X-ray due to tube thermostat is released	Inhibit Exposure	Wait for the X-ray Tube to cool. If the error persists, call Service
290710	Inhibit X-ray due to tube fan is released	Inhibit Exposure	Call Service.
290711	Fan Tube released	Information	No user action required.
290712	Fine positioning buttons pressed longer than allowed	Information	Release the Fine positioning buttons.

ID	DESCRIPTION	TYPE	USER HELPTEXT
290750	Dosemeter values have not been received from GPIO Head	Information	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
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.		
291015			
291016			
291017			
291018	Peripheral communication error located in the battery monitor.	Error	-
291019			
291020			
291021			
291023	Internal error located in the battery monitor.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
291024	System communication error located in the battery monitor.		
291039	Internal error located in the battery monitor.	Error	-
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			

ID	DESCRIPTION	TYPE	USER HELPTEXT
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			
291100	Battery below critically low, shutting down the system.	Warning	-
291101	Download not performed due to a hardware failure	Information	Download not performed due to a hardware failure.
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.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
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.
292101	RFID not available	Information	Check RFID device.

ID	DESCRIPTION	TYPE	USER HELPTEXT
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		
293009	Motion Control: Right Motor IGBTs error		
293010	Motion Control: Left Motor AC Overcurrent error		
293011	Motion Control: Right Motor AC Overcurrent error	Error	Restart the System. If error persists, call Service.
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	Error	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	Error	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		

ID	DESCRIPTION	TYPE	USER HELPTEXT
293034	Motion Control: Stop due to Battery charging	Information	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	Information	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.
293036	Motion Control: Stop due to Handle bar pressed at start up	Information	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	Information	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.
293038	Motion Control: Stop due to Force Sensors Calibration Fault	Information	Please, verify the force sensors connection. Calibrate the force sensors again. Restart the unit and if error persists, call Service.
293051	Motion Control: Header key not working properly	Warning	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			

ID	DESCRIPTION	TYPE	USER HELPTEXT
294018	Peripheral communication error located in the head.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
294019			
294020			
294021			
294023	Internal error located in the head.		Restart the System and try to repeat the operation. If the error persists, call Service.
294024	System communication error located in the head.		
294027	Collimator Internal Error		
294028	Collimator Configuration Error		
294030	Dosimeter Internal Error		
294031	Dosimeter Configuration Error		
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			
294045	Internal error located in the head.		
294046			
294050	Peripheral communication error located in the head.		
294051	Internal error located in the head.		
294052			
294053	Digital accelerometer error located in the head.		
294054	Internal error located in the head.		
294059			

ID	DESCRIPTION	TYPE	USER HELPTEXT
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	Error	Call Service.
300009	Positioner disconnected	Error	If the error appears 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	Error	Restart the System and try to repeat the operation. If the error persists, call Service
300011	Generator disconnected		
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		
300014	Positioner configuration could not be loaded	Error	Call Service.
300015	Configuration changes could not be saved	Error	-
300016	Initializing communications ...	Information	If message does not disappear after the start-up is finished, call Service
300019	Generator working in Service mode	Warning	Please restart the System
300020	Positioner working in Service mode	Warning	Please restart the System
300021	Could not verify Service access	Warning	-
300024	Usability settings configuration could not be loaded	Error	Call Service.
300025	Layout settings calibration data could not be loaded		
300029	Snapshots in progress	Inhibit Exposure	If the message does not disappear in a period of time, please restart the System.
300031	The exposure settings have been modified during calibration. Please make sure to recover the exposure settings from the Image System application.	Inhibit Exposure	Recover the exposure settings from the Image System application.

ID	DESCRIPTION	TYPE	USER HELPTEXT
300032	Error loading Fluoro technique.	Inhibit Exposure	Restart fluoro calibration.
300035	Calibration file could not be loaded.	Error	Call Service.
300036	Waiting for generator license...	Information	If message does not disappear after the start up is finished, call Service.
300037	Waiting for generator operation mode to be initialized...	Information	If message does not disappear after the start up is finished, call Service.
300038	Waiting for positioner operation mode to be initialized...	Information	If message does not disappear after the start up is finished, call Service.
599999	Inhibit Exposure from IS	Inhibit Exposure	Refer to the detailed information displayed by the Acquisition Software on the Main Screen.

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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 one hour.

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

Perform X-ray Tube warm-up as follows:

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

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

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 patient to maintain the required position. Prepare the X-ray Tube by pressing the Handswitch button to the "*Prep*" position and maintain it until the "*Ready*" indicator is illuminated.
5. Instruct patient to remain still and to hold his breath as required, then make the X-ray exposure by pressing the Handswitch button fully to the "*Exp*" position and maintain it throughout the exposure. The "*X-ray On*" indicator will light and an audible signal will sound during the exposure.
6. When the exposure is finished, release the Handswitch button.
7. Repeat the procedure if additional exposures are desired.

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 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.

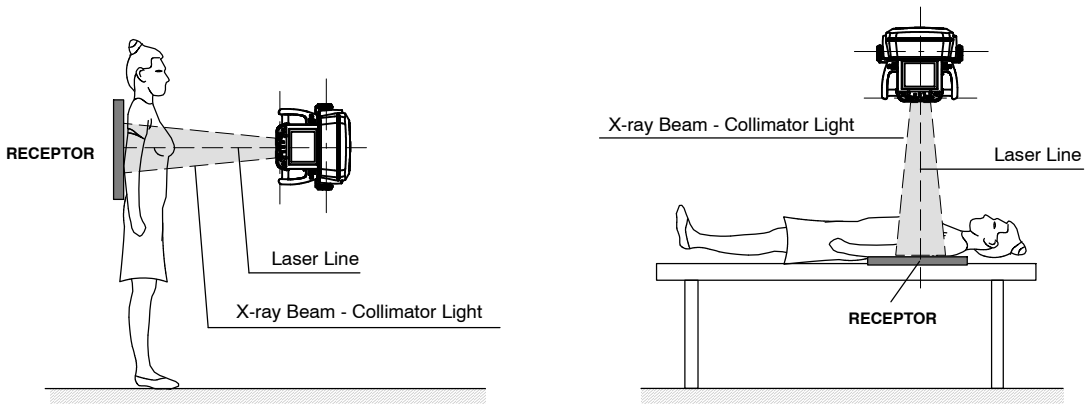
ALWAYS SELECT THE CORRECT FIELD SIZE TO AVOID EXCESSIVE RADIATION.

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

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

Illustration 6-1
Patient Positioning



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SECTION 7 PERIODIC MAINTENANCE

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

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

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

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

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

7.1 OPERATOR TASKS

7.1.1 BATTERIES MAINTENANCE

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

Tasks for a proper maintenance of the batteries:

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

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

Note ☞ *For more information, refer to "Battery Charge Level Indicators" in Section 3.2.7 and "Battery Capacity for the Generator and the Motors" in Section 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 power. Wait a few minutes and reconnect the Unit to the mains. The upper Green Indicators should scroll up for approximately one minute.

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

3. Switch the equipment OFF by shutting down the computer. Turn OFF the switch ON/OFF control and unplug the unit from 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 which 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 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 (r*efer 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 *(Refer to Identification Label)*	**20 kW**	**32 kW**	**40 kW**	**50 kW**
kVp Range	40 to 150			
	From 40 kVp to 150 kVp in 1 kVp steps			
mAs Range	Product of mA x Time values from 0.1 mAs to 500 mAs			
mA Range	10 to 400	10 to 500		
	From 10 mA to 400 mA or 500 mA, through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 63/64, 80, 100, 125, 160, 200, 250, 320, 400, 500. *(Depending on the Generator model)*			
Exposure Time Range	From 1 millisecond to 10 seconds through the following Time stations: Milliseconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.3/6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 63/64, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630/640, 800. Seconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.3/6.4, 8, 10. Maximum Exposure Time Range for DR: From 1 millisecond to 4 seconds.			
Focal Spot Size	Small / Large			
Power Output (@ 0,1s)	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
Duty Cycle	18 exposures per hour at 100 kV, 200 mA, 320 ms (lapse time between exposure: 3 min.)	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)			
Ripple Factor	< 4% (constant voltage)			
Collimator	Manual Collimator with front and rear side Knobs, double Laser, Motorized Filters and ready for both Estimated Dose (EDAP) option and DAP Chamber option			
X-ray Tube	*Refer to Section 8.2*			

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 ±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 mΩ for 100 V~, 1 Ω for 110 V~, 2.5 Ω for 230 V~, 2.6 Ω 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	Optimized Battery Management for extended Battery life. Charge Capacity: 15 Ah. 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). Total Energy storage Capacity: 5760 Wh 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. The Mobile Unit in Stand-Alone (disconnected from the mains) will be 100% discharged from full charge in approximately: 11 hours.			
Radiation Output Accuracy (Reproducibility related to loading factors)	C.V. (Coefficient of variation) ≤ 0.05			
Maximum Symmetrical Radiation Field	Measured at 75 kV: 220 mm in “X” axis and 240 mm in “Y” axis. Measured at 125 kV: 210 mm in “X” axis and 250 mm in “Y” axis. *(Test performed at a distance from the Focal Spot of 1200 mm, in accordance with IEC 60806:1984).*			
Maximum Heat Output	260 W (1130 BTU/h)			
Storage / Transport Environmental Conditions	Temperature range of -10ºC to 40ºC Relative Humidity range of 20% to 90% Atmospheric Pressure range of 700 hPa to 1060 hPa			
Operating Environmental Conditions	Temperature range of 10ºC to 35ºC (*the recommended temperature for a longer life cycle of batteries is around 22ºC*) Relative Humidity (no condensing) range of 30% to 75% Atmospheric Pressure range of 700 hPa to 1060 hPa			

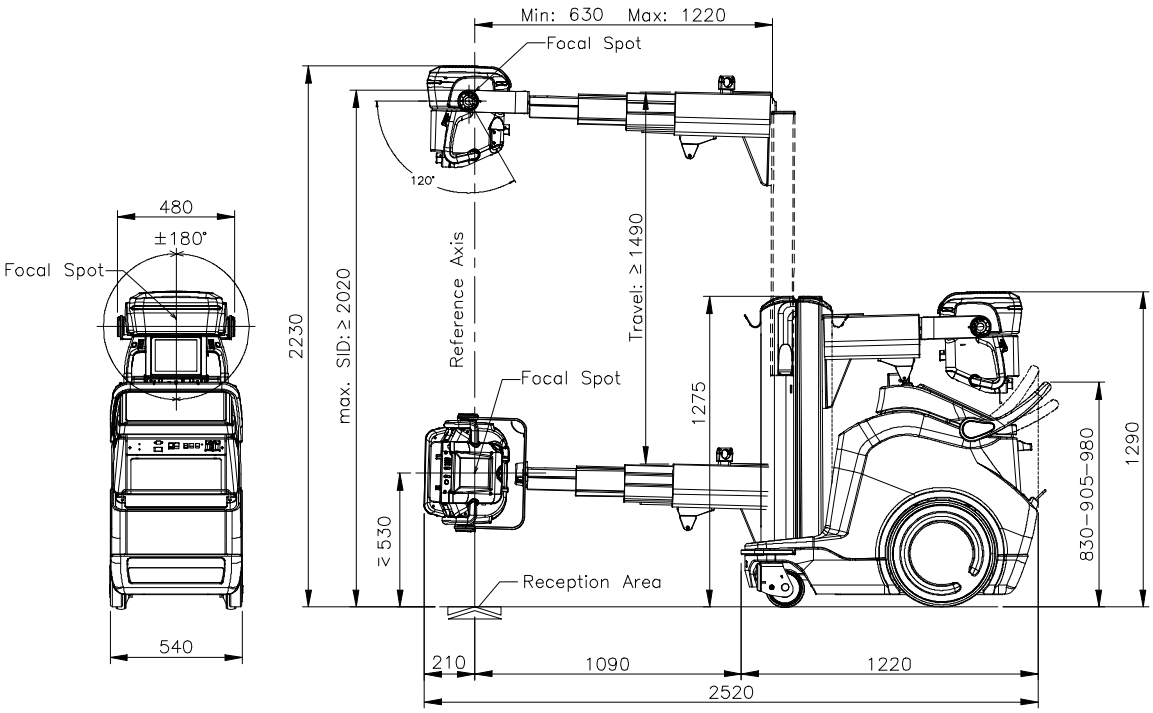
8.2 X-RAY TUBE INSERT

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

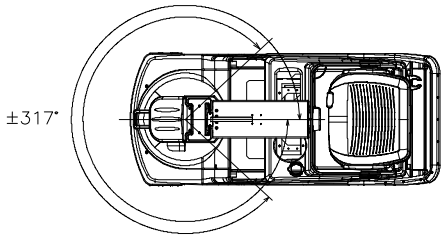
E7886	Low Speed / High Speed – Rotating Anode Focal Spots: 0.7 mm / 1.3 mm Anode kHU / kVp: 300 kHU / 150 kVp Target Angle: 16° Inherent Filtration of X-ray Source: Tube + Collimator: 3.1 mm Al Tube + Collimator + eDAP: 3.1 mm Al Tube + Collimator + DAP: 3.4 mm Al

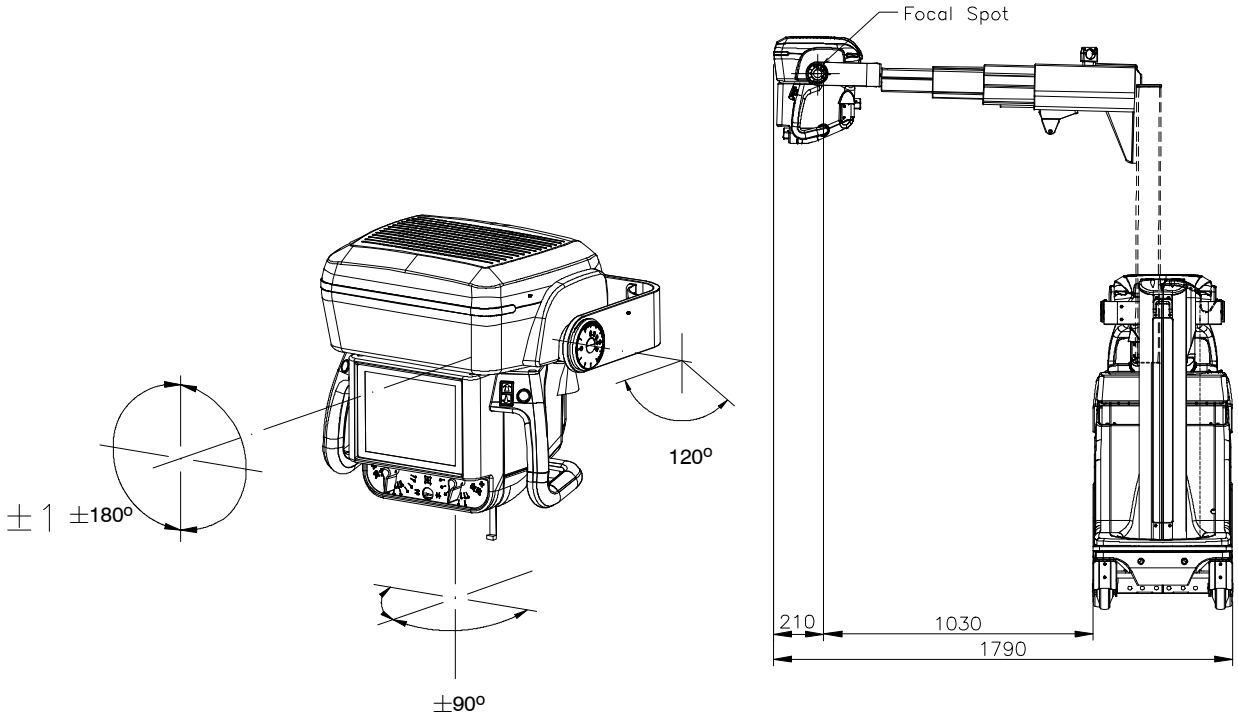
8.3 PHYSICAL CHARACTERISTICS

LENGTH	WIDTH	HEIGHT	WEIGHT
minimum 1220 mm maximum 2520 mm	540 mm	minimum 1290 mm maximum 2230 mm	520 kg (without Detectors and/or Accessories



Dimensions in mm.
Tolerance in Dimensions ±1%





Dimensions in mm.
Tolerance in Dimensions ±1%

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APPENDIX A GUIDELINES FOR PEDIATRIC APPLICATIONS

THE PRACTITIONER WILL BE THE ULTIMATE RESPONSIBLE OF APPLYING THO 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.

APPENDIX C ADMINISTRATOR USER

TABLE OF CONTENTS

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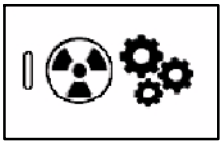
C.1 INTRODUCTION

Note ☞ *This Appendix only applies to Units equipped with RFID ON/OFF System.*

Administrator users have permissions to access certain system settings from both the Acquisition Software and the Head-Assembly Console.

Administrator users can access a specific window of the Head-Assembly Control Console (Service Mode Protection) where several Administrator settings for Base Unit can be managed. *Refer to Section C.2 of this Appendix for detailed information.*



Use the corresponding RFID Card to turn on the unit and access the software with Administrator permissions. (*Refer to System ON Section in the Operation Manual for detailed information*).

Note ☞ *Depending on the installed Acquisition Software or Customer Configuration, the appearance of the graphical interface may be different from the one shown in these illustrations.*

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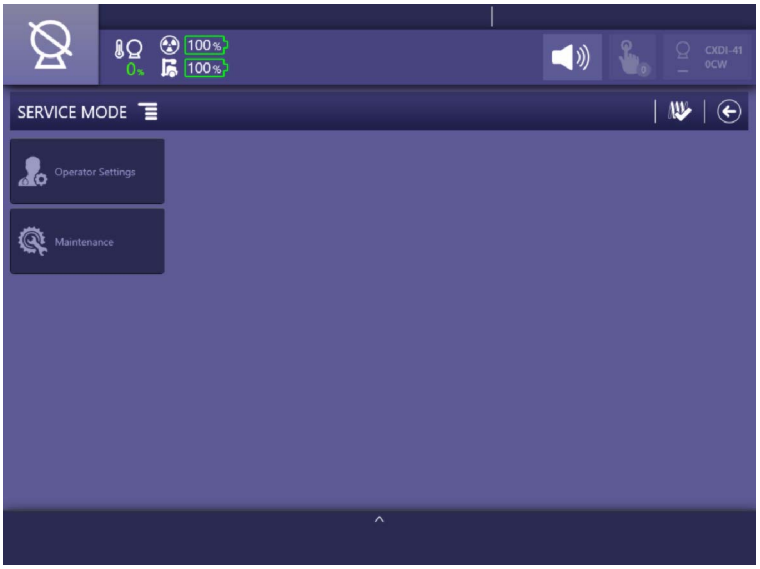
C.2 ADMINISTRATOR MENU

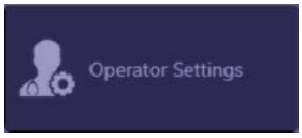
C.2.1 ENTERING ADMINISTRATOR MENU

Press and hold for a few seconds on the System Status icon, located at the upper left corner of the Head-Assembly Control Console Screen.

After a few seconds, the Administrator Menu (Service Mode Protection utility) screen will be displayed.



The following options are displayed in Administrator Menu main screen:



OPERATOR SETTINGS

Refer to Section C.2.3.

Press the “Operator Settings” button to display the configurations related to the system operation.

MAINTENANCE

Refer to Section C.2.4.

Press the “Maintenance” button to access to the equipment maintenance information.

C.2.2 ADMINISTRATOR MENU CONTROLS

The following icons and buttons can be displayed in the Administrator Menu main screen:

ENABLED FILAMENTS

This button indicates that filaments are enabled; radiation will be produced during the exposure. Press on this icon to disable filaments.

DISABLED FILAMENTS

This button indicates that filaments are disabled; no radiation will be produced during the exposure. Press on this icon to enable filaments.

BACK

Press on the “Back” button to leave the current menu. This button can be found in every screen of the Administrator Menu to turn back to the Main Menu.

Note ☞ *Every time the “Back” button is used to leave the Administrator Settings Menu, after making configuration changes, the System requires a reboot to transfer the new data.*

Press this button from the main menu window to return to the Control Console in operation mode.

The following buttons may appear along some menus:

SAVE DATA

Press to save the modified values.

RESTORE DATA

Press to load the previous initial configuration.

NEXT STEP

Press to proceed to the next Calibration step or to skip the current one before starting its Calibration.

PREVIOUS STEP

Press to return to the previous Calibration step.

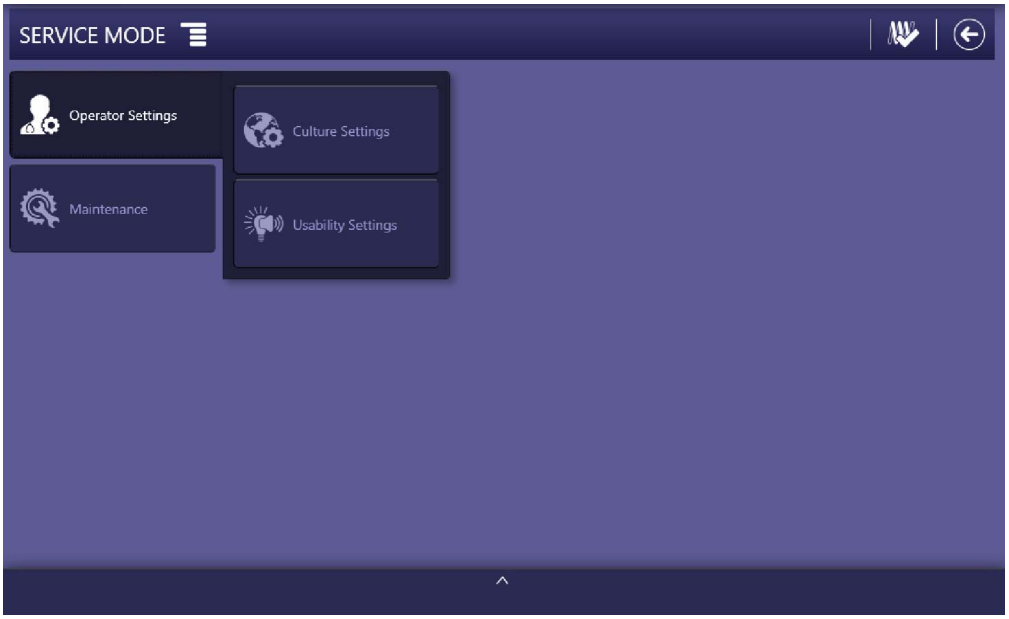
Note ☞ *All the other buttons and indicators on the upper toolbar (common in the Operation Mode) are described in Section 4 of the Operation Manual.*

Note ☞ *The lower toolbar (System Messages Area) is described in Section 5 of the Operation Manual.*

C.2.3 OPERATOR SETTINGS

"Operator Settings" menu comprises two configuration options for system operation: Culture Settings and Usability Settings.

Illustration C-1
Operator Settings



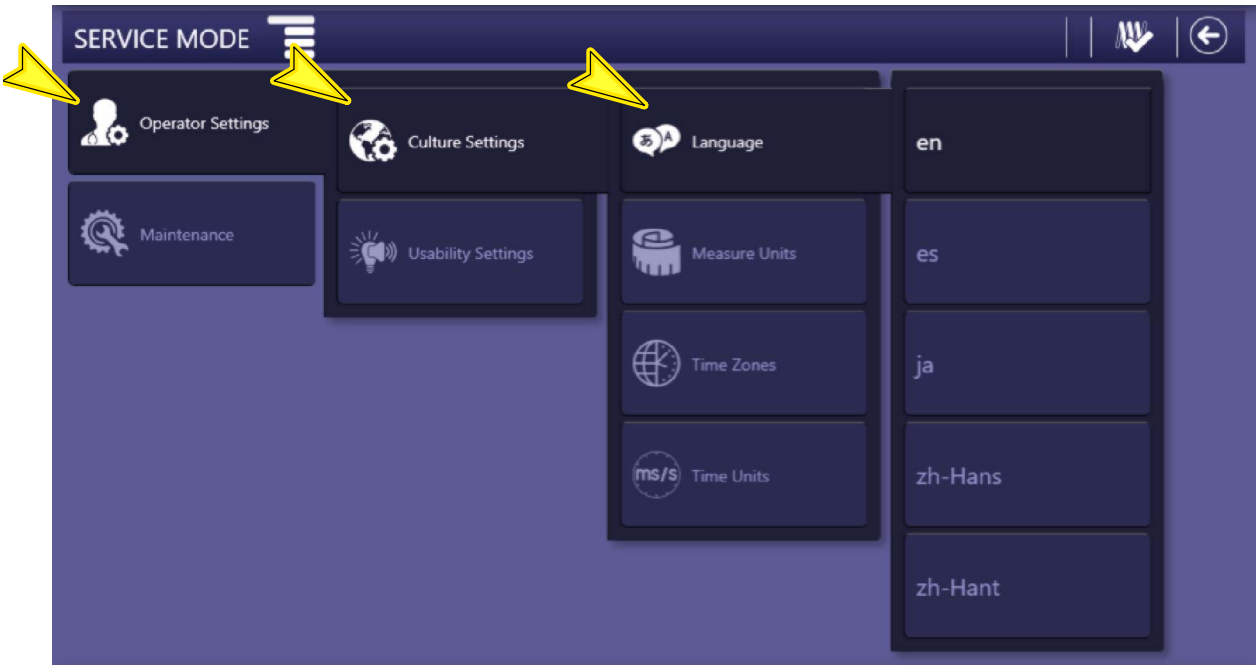
C.2.3.1 CULTURE SETTINGS

▶ **LANGUAGE**

Press the “Language” icon to switch between the available languages.

The Administrator Menu and the Operator application will be automatically updated to match the selected language.

Illustration C-2
Operator Settings: Culture Settings, Language Selection

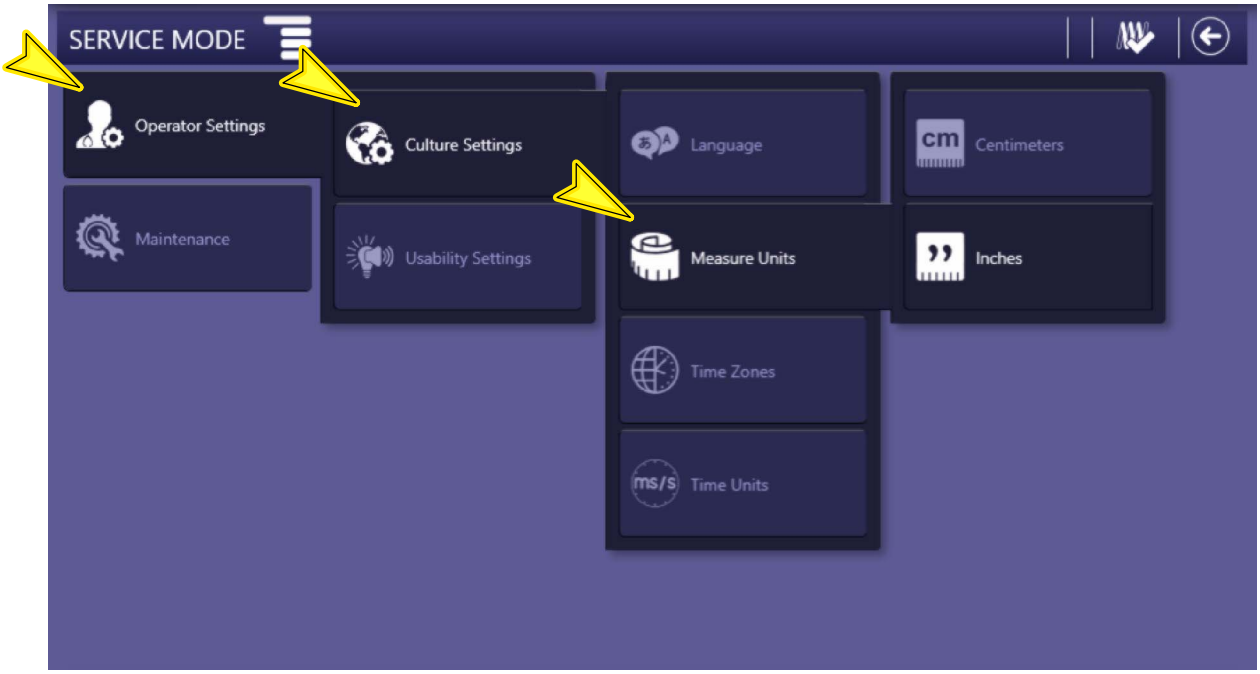


▶ MEASURE UNITS

Use the “Measure Units” button to switch between the Metric system and the American/Imperial system. Available options are “Centimeters” or “Inches”.

Note ☞ *It is necessary to reboot the Console to apply the change of Measurement Units.*

Illustration C-3
Operator Settings: Culture Settings, Measuring units



▶ TIME ZONES

Use the “Time Zones” button to to select the relevant time zone. Press the “Store” button to save the selected zone.

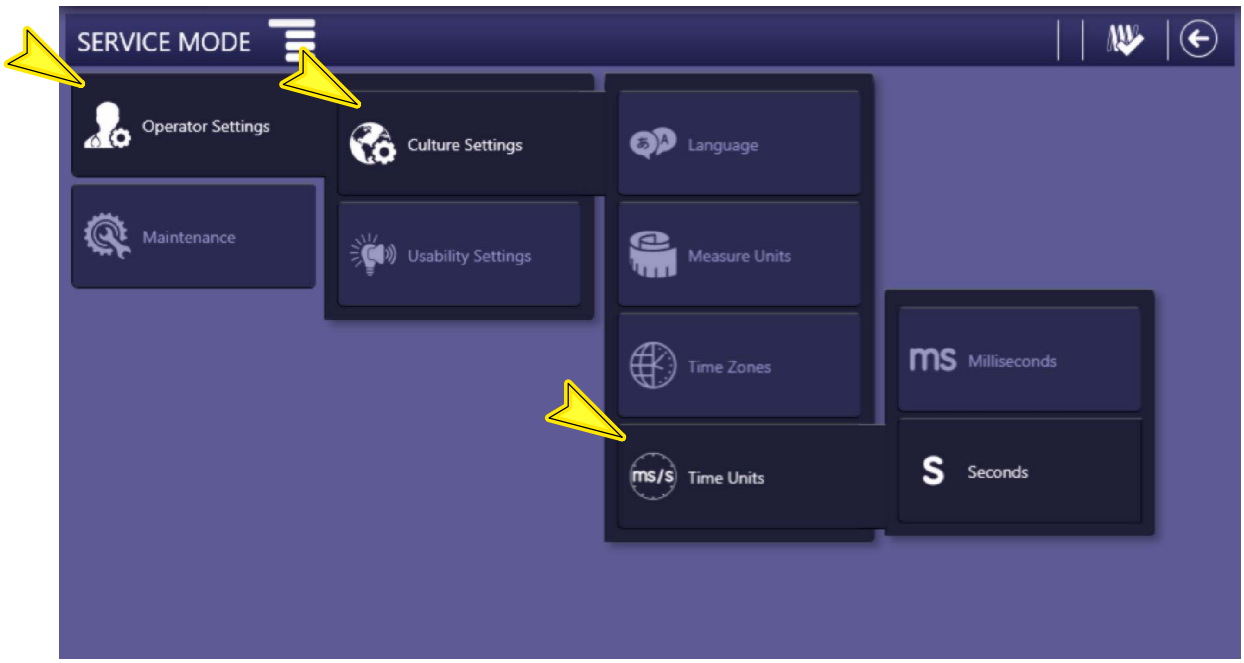
Illustration C-4
Time Zone Selection

▶ TIME UNITS

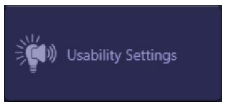
Use the “Time Units” menu to select “Milliseconds” or “Seconds” as the time unit in the exposure parameters.

Note ☞ *It is necessary to reboot the Console to apply the change of Time Units, but not the whole system.*

Illustration C-5
Operator Settings: Culture Settings, Time Units

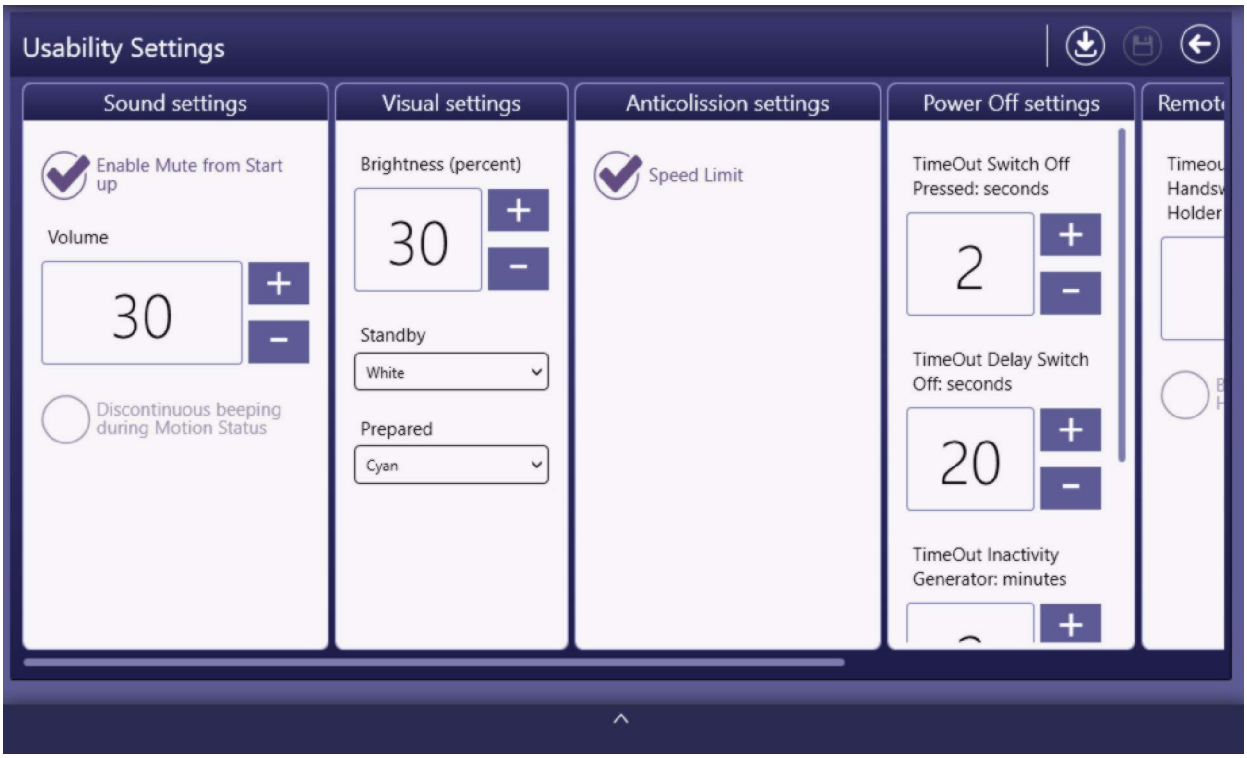


C.2.3.2 USABILITY SETTINGS



The “Usability Settings” screen is used to set the Sound Settings, Visual Settings, Anticollision Settings and the Power Off settings of the system.

Illustration C-6
Usability Settings



▶ SOUND SETTINGS

To set parameters such as enable mute, Volume, and discontinuous beeping during Motion.

▶ VISUAL SETTINGS

To set the brightness percentage and the colors for Standby and Prepared status of the Mobile Unit.

▶ ANTICOLLISION SETTINGS

Speed Limit option can be selected in this Section.

▶ POWER OFF SETTINGS

Time Out Switch Off Pressed.

Default configured time: 3 seconds.

Press and hold the *Switch OFF* button for 3 seconds; the system will start the turning OFF process.

Time Out Delay Switch Off.

Default configured time: 50 seconds.

After holding pressed for 3 seconds the *Switch OFF* button, the system will be completely turned OFF in 50 seconds; during this time only movements are enabled (e.g., it is useful for the user to put the system in the Parking position, if necessary).

Time Out Inactivity Generator.

Default value: 0 (Disabled).

Filaments deactivation due to inactivity is disabled. The following is an example of how the equipment would behave if the value *"2" (minutes)* were entered:

> *When the system is disconnected from mains and there is not any Generator activity during 2 minutes, the Generator Tube Filaments turn off, unless the user performs any action on the RAD screen, presses the handswitch/remote control (option) or connects the system to the mains; it will delay the "Time Out Inactivity Generator" for another 2 minutes without any Generator activity.*

Time Out Inactivity Warning.

Default value: 0 (Disabled).

No system shutdown due to inactivity. The following is an example of how the equipment would behave if the value *"15" (minutes)* were entered:

> *When the system is disconnected from the mains and there is not any Generator activity for 15 minutes, a Warning message is displayed on the screens to alert the user of an automatic shutdown after finishing a countdown timer for another 15 minutes.*

If the Operator presses on Accept button or performs any system action (touches on the RAD Screen, activates any of the movement controls, presses the handswitch/remote control (option) or connects the system to the mains), within the configured time; it will delay the "Time Out Inactivity Warning" for another 15 minutes.

If the Operator does not respond within the countdown time of 15 minutes, the system will automatically shut down; i.e., the system will be completely turned OFF after 30 minutes without activity.

▶ REMOTE HANDSWITCH SETTINGS

Timeout Remote Handswitch Out of Holder.

Default configured time: 0.

To configure the time (in minutes) that the system will take to display an informational message if the IR Remote Control is not placed in its holder.

Beeping Remote Handswitch.

Disabled by default.

Enable this radio button to add a discontinuous beeping to the previous informational message each time the timeout specified in the "Timeout Remote Handswitch Out of Holder" field is exceeded.

▶ FINE POSITIONING BUTTONS SETTINGS

Timeout: Seconds.

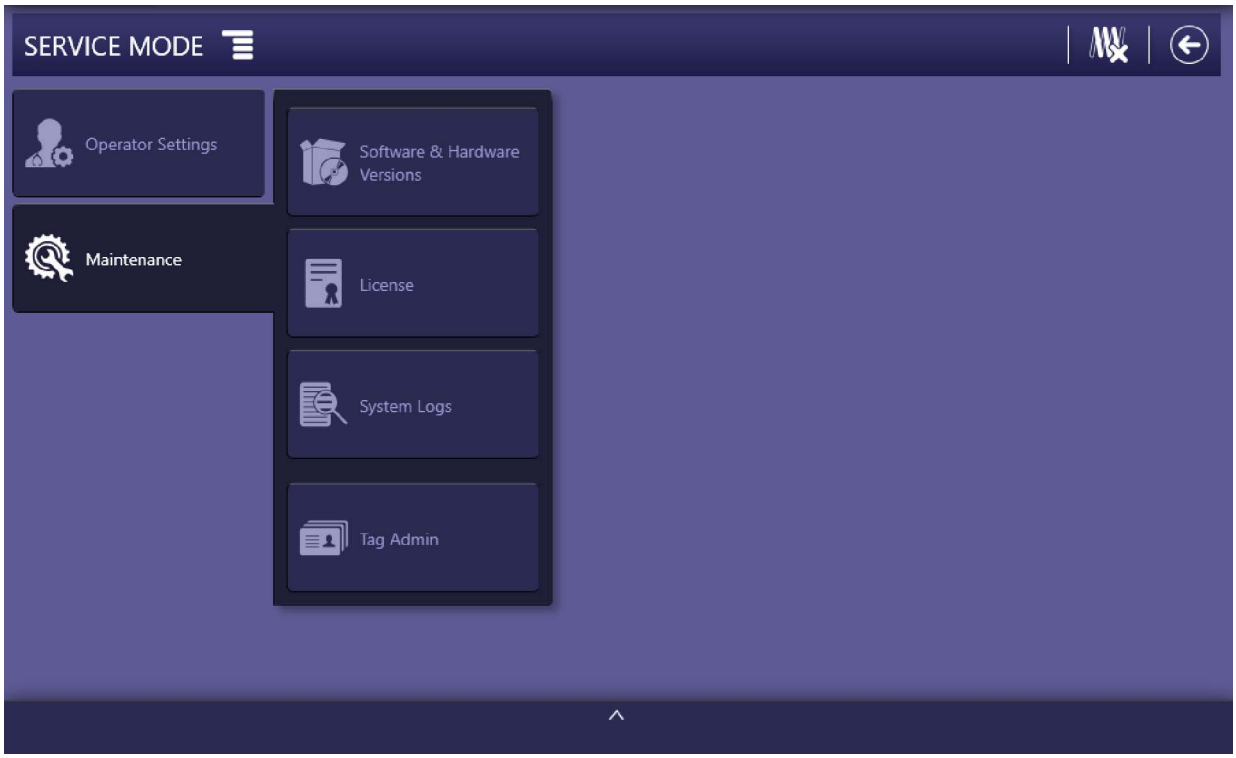
Default configured time: 5.

Allows to set the time it will take for the Unit to stop automatically when a displacement is being performed using the Fine Positioning buttons.

C.2.4 MAINTENANCE

The “Maintenance” menu is used to check the system information (components versions, license functionalities), check the system logs and configure RFID tags.

Illustration C-7
Maintenance Options



C.2.4.1 SOFTWARE / HARDWARE VERSIONS

Press the “Software / Hardware Versions” button to display the software and hardware versions of all the system components.

Press the “Back” button to go back to the main menu.

Illustration C-8
Software / Hardware Versions Screen

C.2.4.2 LICENSE

Press the “License” button to display all the system functionalities (Standard and Extended) enabled by license.

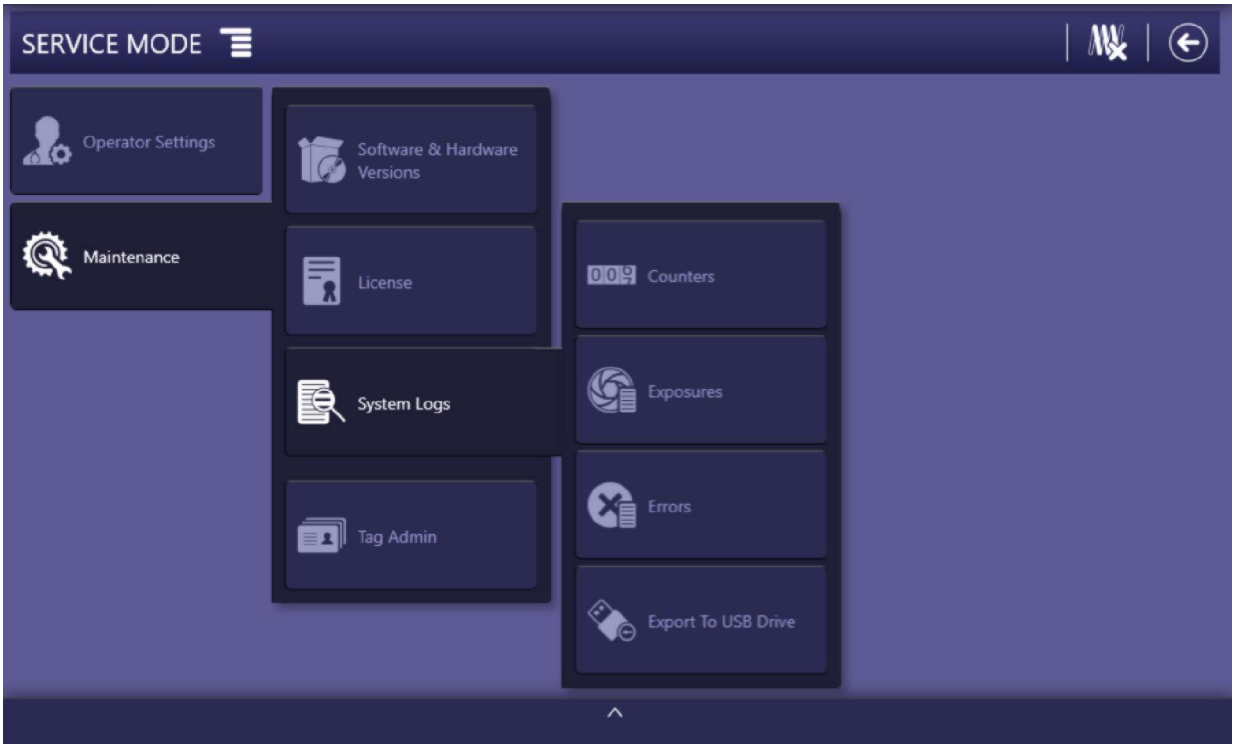
Press the “Back” button to go back to the main menu.

Illustration C-9
License Screen

C.2.4.3 SYSTEM LOGS

The purpose of the “System Logs” menu is to display the logs files generated by the system, as well as to enable them to be exported.

Illustration C-10
System Logs Menu



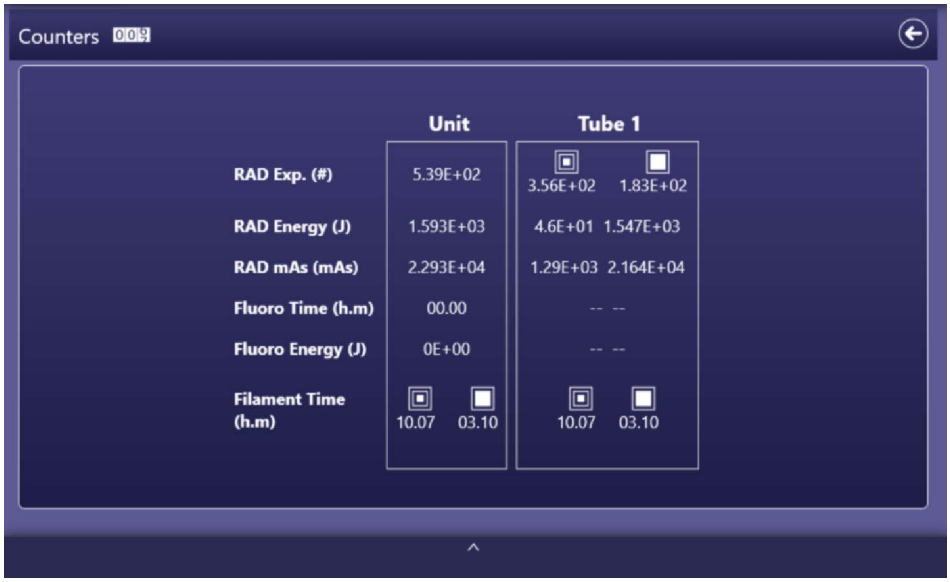
The available options are:

- **Counters**

  Press this button to display a counter with accumulated data of exposures performed with the system (corresponding to each focus selection of the tube as the cumulative of the Unit), counting the following elements:

  - **RAD Exp. (#)**: Number of exposures registered.
  - **RAD Energy (J)**: Accumulated energy (in joules) used in exposures.
  - **RAD mAs (mAs)**: Accumulated mAs in exposures.
  - **Flouro Time (h.m)**: *[Not Applicable]*.
  - **Flouro Energy (J)**: *[Not Applicable]*.
  - **Filament Time (h.m)**: Time period of operation (in hours and minutes) with selected *Small Focus* or *Large Focus*.

Illustration C-11
Counters

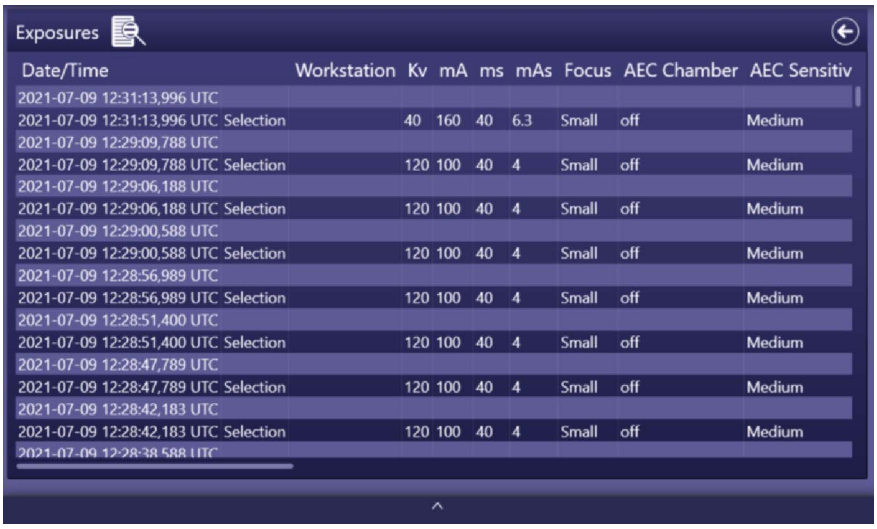


Note ☞ *The values are displayed in Scientific E Notation.*

- **Exposures**

  Press this button to display the a detailed record of all the exposures performed with the system.

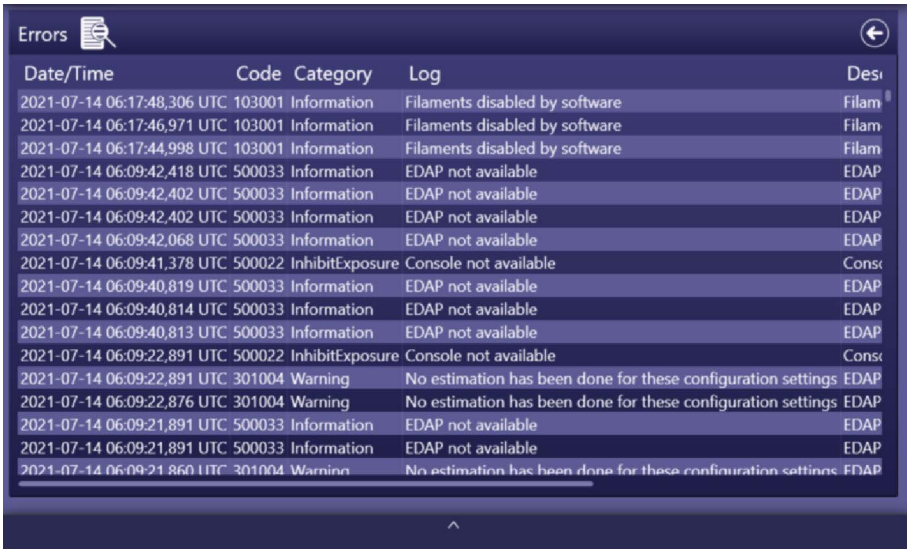
Illustration C-12
Exposures



- **Errors**

  Press this button to display a detailed list with all the system messages stored during system operation.

Illustration C-13
Errors

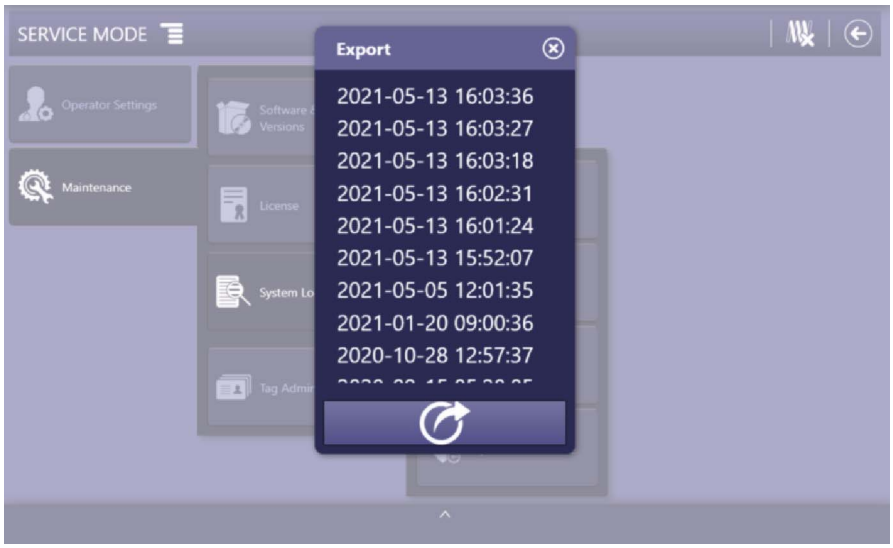


Note ☞ *The generation of error log files (System Snapshot) is available in the Message History window of the Operator Mode (refer to Operation Manual for further details).*

- **Export to USB Drive**

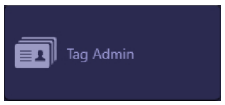
  Use this functionality to export the log files to a USB flash drive. (This option is only available when an operating memory stick is connected to a USB port).

Illustration C-14
Log Export



Select an stored log file by its date and press the “Export” button. When the export process is finished, a confirmation message will indicate that the files have been successfully copied to the USB drive.

C.2.4.4 TAG ADMIN

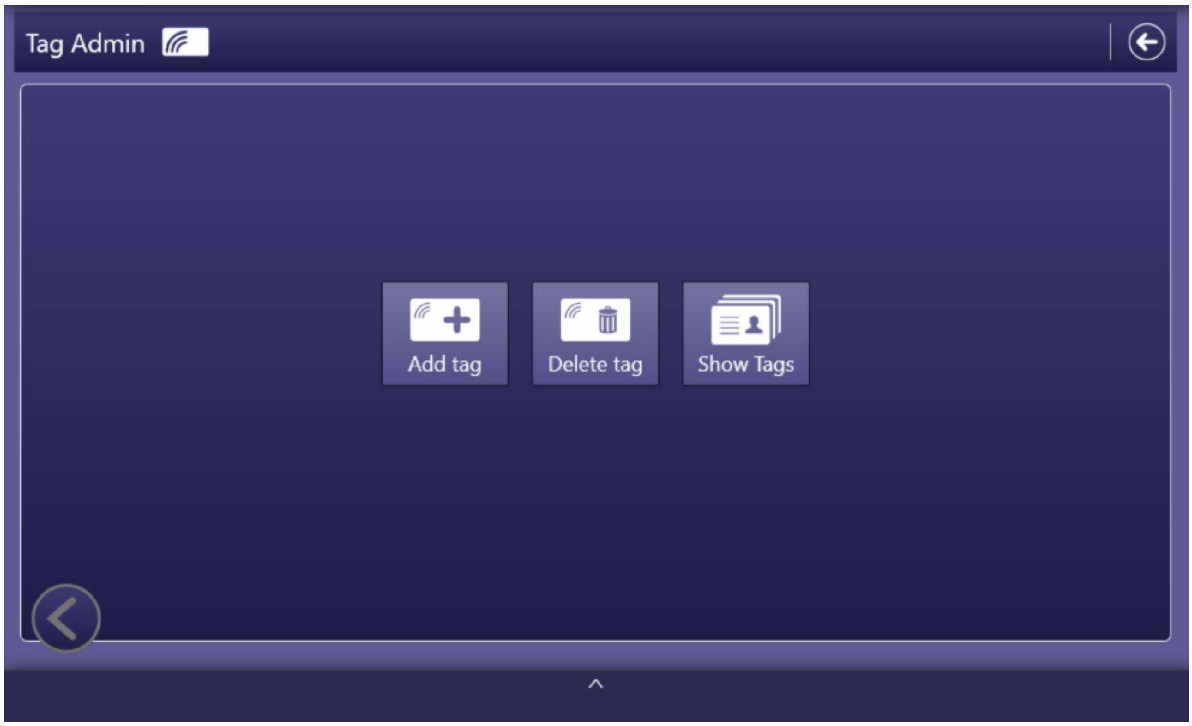


The “Tag Admin” screen enables the local tags (RFID Cards) management used to initiate the system and access it with the privileges assigned to them.

The available options in the “Tag Admin” window are “Add tag”, “Delete tag” and “Show tags”.

Note ☞ *The tags (RFID Cards) managed in this menu only apply to the local database of the Base Unit and are not synchronized with the Acquisition Software.*

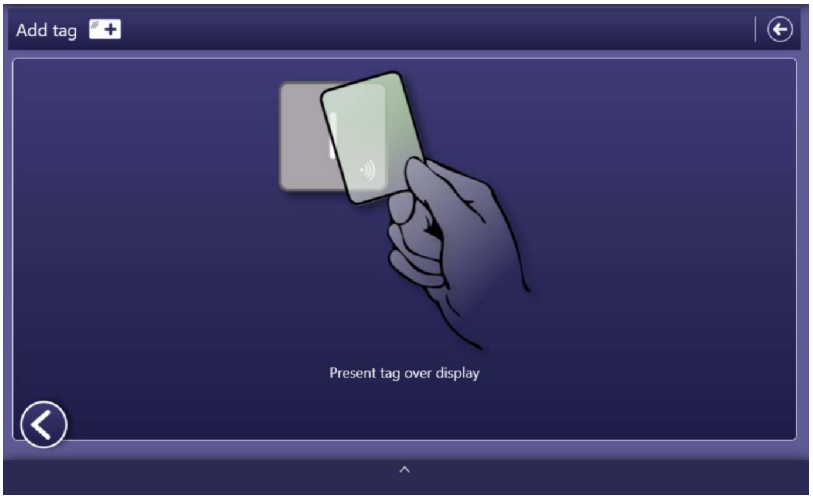
Illustration C-15
Tag Admin Window



ADDING A NEW TAG

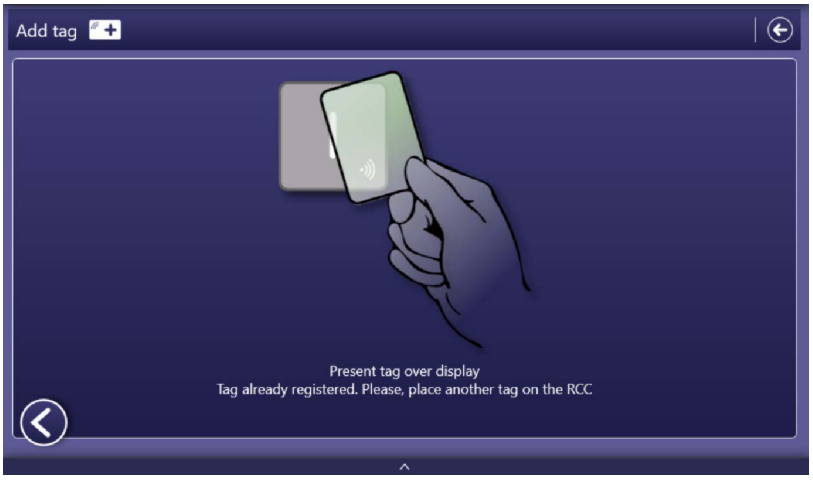
1. Press on the “Add tag” button. Swipe the RFID card through the RCC reader to register the tag, according to the instructions in the new window displayed.

Illustration C-16
Add Tag Window



If the entered card is already included in the RFID tag record, the following message will be displayed:

Illustration C-17
Tag Already Registered Message



2. In the next window, the tag name and the user's access permissions, can be defined.

Illustration C-18
Tag Edition Window

Depending on the system permissions assigned to the tag (RFID Card) in this window, 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:**

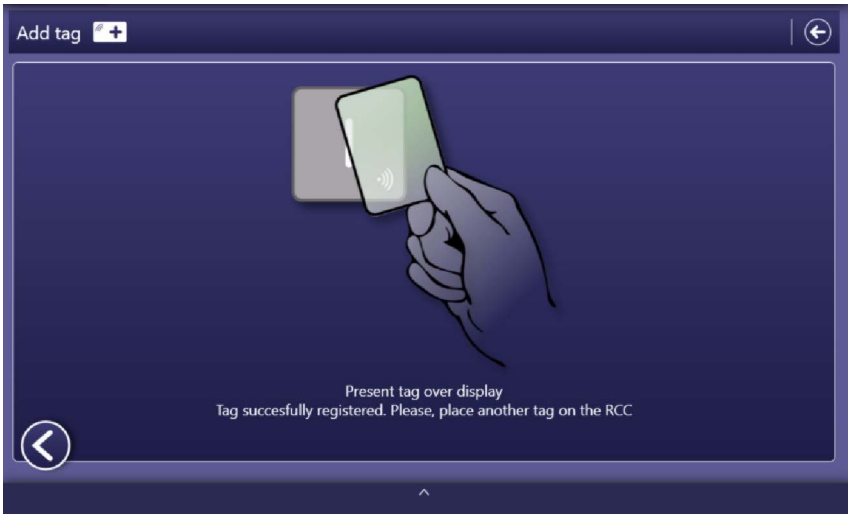
  It allows the user to perform any action needed for Radiographic Operation.

- **Admin:**

  It includes all the previous permissions for Movements; Panel Out, Radiographic Operation, and the facility to access the Administrator Menu.

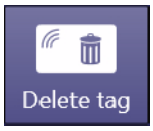
3. Press the “Store” button to register the tag. If the registration is successful, a message will be displayed in the previous window.

Illustration C-19
Registration Confirmation Message



4. Now it is possible to register another tag or press the “Previous Step” button to return to the Tag Admin menu.

5. Press the “Back” button to return to the main menu.



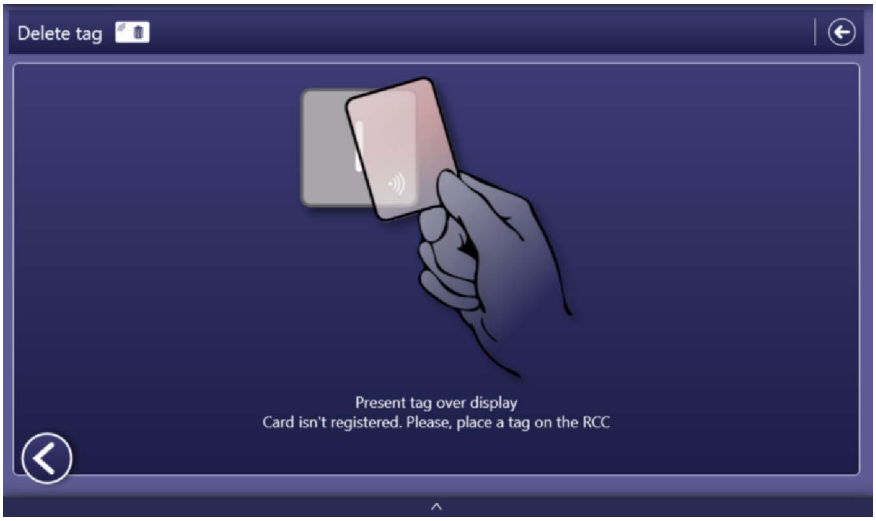
DELETING A TAG

1. Press on the “Delete tag” button. Swipe the RFID card through the RCC reader to unregister the tag, according to the instructions in the new window displayed.

Illustration C-20
Delete Tag Window

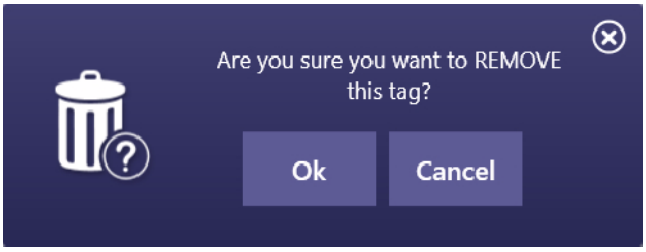
If the entered card has not been previously registered in the RFID tag record, the following message will be displayed:

Illustration C-21
Tag Not Registered Message



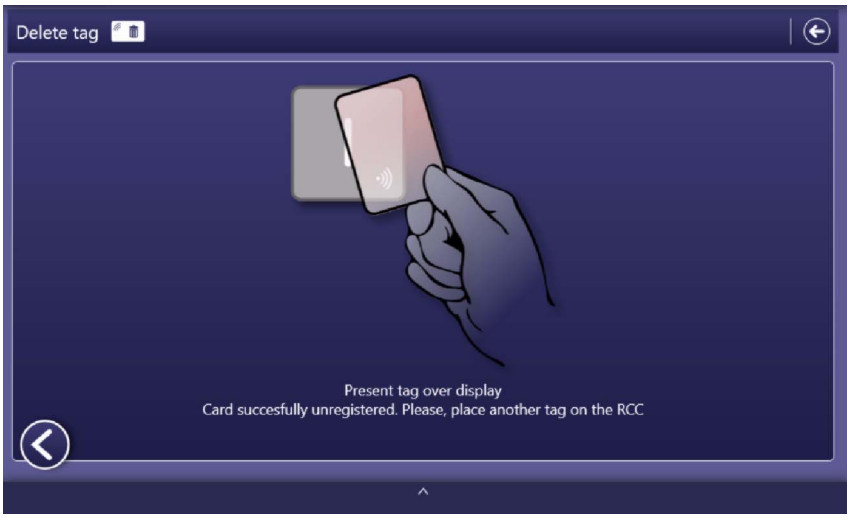
2. A pop-up window requests confirmation of the tag unregistration.

Illustration C-22
Confirmation Window of the Tag Removal



3. Press the “Store” button to finish unregistering the tag. If the tag deletion is successful, a message will be displayed in the previous window.

Illustration C-23
Tag Deletion Confirmation Message

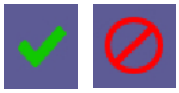


4. Now it is possible to delete other tag or press the “Previous Step” button to return to the Tag Admin menu.

5. Press the “Back” button to return to the main menu.

EDITING TAGS

Press on the “Show tags” button to display a list of the different tags with the name and permissions with which they were registered.



This window displays, for each tag, a text box with the name registered and the permissions assigned to it (Movements, Panel out, X-rays, Admin, Service, RFID Tag ID and Sync). Assigned permissions are represented with a green check mark, while those that have not been granted are shown with a red ban icon.

Illustration C-24
Show Tags Window

The “Synchronization” icon is used to indicate that the tag is also registered in the Acquisition Software.

Note ☞

A tag registered in the Acquisition Software will show a green check mark at the Synchronization icon.

Deleting a sync tag from this window may cause inconsistencies in the system.

The code displayed in the ”RFID Tag ID” would allow the RFID Card to be identified in the Acquisition Software.

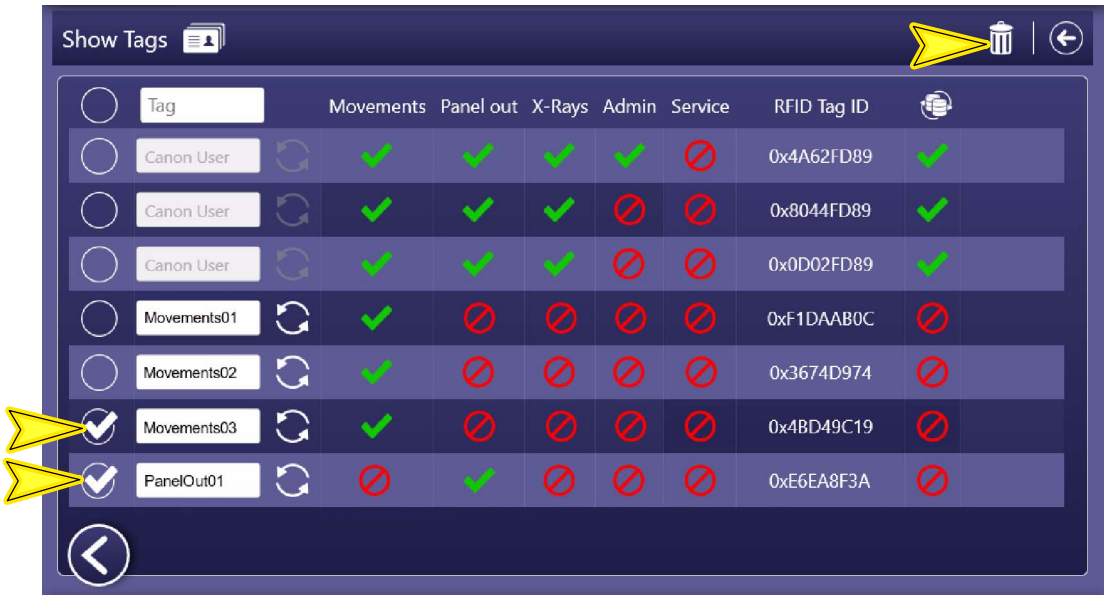
REMOVING MULTIPLE TAGS

1. From the “Show Tags” menu, multiple tags can be selected to be removed. Select one or more Tags by pressing on its corresponding radio button.

Note ☞ *The radio button on the first row allows to select all the listed tags.*

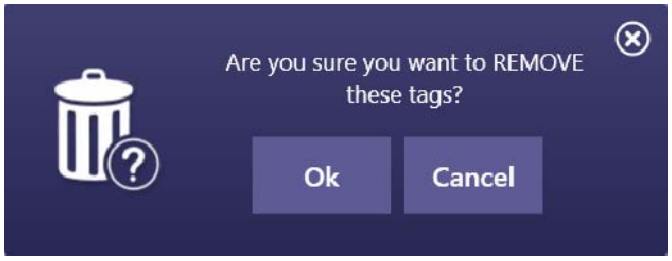
2. Once selected, press the “Trash” button to proceed.

Illustration C-25
Removing Tag(s) - Selection and Trash Button



3. A confirmation message appears on screen. Press “Ok” to confirm.

Illustration C-26
Removing Tag(s) - Confirmation Message

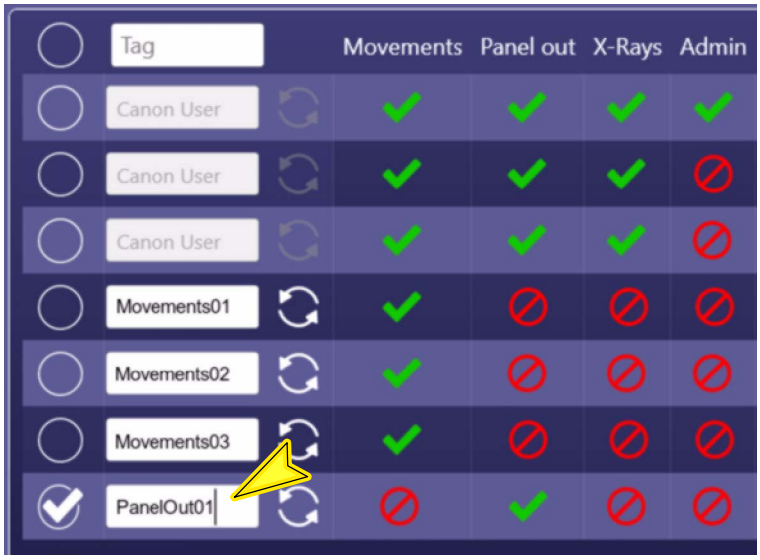


RENAMING TAGS

From the “Show tags” menu, each tag can be renamed.

1. Press on the text box of the tag name.
2. Use a keyboard to enter a new tag name.
3. Once renamed, press on the “Update” button.

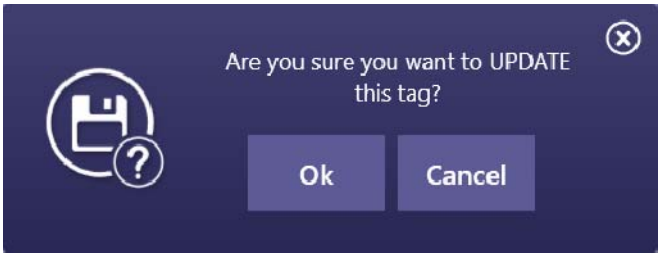
Illustration C-27
Renaming Tag



Note ☞ *When a green check mark is related to the “Synchronization” icon, renaming that tag is not allowed.*

4. A confirmation message appears on screen. Press “Ok” to confirm.

Illustration C-28
Renaming Tag(s) - Confirmation Message



5. Now it is possible to rename/delete other tag or press the “Previous Step” button to return to the Tag Admin menu.

6. Press the “Back” button to return to the main menu.