Unitate de radiografie mobila (avansata)				
Descriere	Sistem radiografic digital pe consola mobila, cu sistem de miscare motorizata, destinat pentru investigatii in interventiile traumatologice complexe, usor transportabil dotat cu brat si coloana telescopica de mentinere a tubului radiologic pentru o mai buna manevrabilitate si vizibilitate in timpul utilizarii.			
Parametru	Specificatie	**Parametrii solicitati**	**Parametrii oferiti**	**Referinta manual tehnic/brosura**
Dimensiuni	Greutatea maxima acceptata	600kg	520 kg	8.3 **PHYSICAL CHARACTERISTICS**, OM-0491R0 pag.152
	Inaltime maxima (in pozitia de stationare/ deplasare)	135cm	129 cm	
	Latime maxima	70 cm	54 cm	
Caracteristici generator	Putere generator	minim 32kW	32 kW	SECTION 8 **TECHNICAL SPECIFICATIONS**, OM-0491R0 pag.149 si Raybow XE value 32kW MARS1417X , GENERATOR 32KW pag 4
	kVp Diapazon	>/=40-150, in pasi de 1kVp	40-150, in pasi de 1kVp	
	mA Diapazon	>/=10-500	10-500	
	mAs Diapazon	>/=0,1-500, ajustabil in minim 38 pasi	da	
	Timp de expunere	0.001-10 sec	da	
Caracteristici tehnice Tub Raze X	Pata focala, mm	0,6 mm si 1,2 mm	da	8.2 **X-RAY TUBE INSERT**,OM-0491R0 pag.151 si Brosura ROTANODE XRR-3331X pag. 1-3
	Capacitatea de disipare a căldurii anodului	minim 70 kHU/min	73,56 (1226HU/s)	
	Capacitatea de disipare a căldurii carcasei	>/=15kHU/min	da	
	Capacitate de căldură a carcasei	>/=1,250 kHU	da	
	Capacitatea de căldură anodului	>/=300kHU	da	
SID max, cm		>/=200 cm	202 cm	8.3 **PHYSICAL CHARACTERISTICS**, OM-0491R0 pag.152
Deplasarea tubului pe verticala		minim 145 cm	149 cm	
Rotirea coloanei in jurul axei sale		minim 300 grade	± 317 grade	
Deplasarea bratului telescopic		minim 50 cm	51,5 cm	
Rotație transversală a axei tubului cu raze X		±180°, cu retinere la fiecare 90 de grade	da	**Head-Assembly** and Collimator Movements,
Tub cu raze X Rotația axei orizontale		120°, cu Reținere: -30°, 0° ,90°	da	

Rotația colimatorului		±90°, rotire manuala	da	OM-0491R0 pag. 79
Caracteristici tehnice Detector Digital	Tip	CSI, a-Si TFT	da, iRay Mars 1417X	Raybow XE value 32kW MARS1417X , **DETECTOR IRAY MARS** 1417X, Page 24
	Rezolutie matrice	>/=3500x4300 pixeli	3500x4300	
	Pixel	</=100 um	100 µm	
	Gradatie	16 biti	16	
	Dimensiune, cm	>/=35x43	35x43	
	Timp pana la aparitia imaginii	maxim 3 secunde	3 sec	
	Tip conectare la unitate	WiFi	da	
	Baterie reincarcabila (2 bucati)	Da, cu o autonomie in regim de utilizare de minim 8 ore	8,5 h	
	Incarcator baterie(cu 2 sloturi)	Da, timp de incarcare completa a bateriei </= 3 ore	3 h	
DAP-metru		da,Valorile vor fi afișate prin intermediul software-ului unității mobile.	da	OM-0491R0_EN_PRX RAYBOW XE (220928) , 4.5 **DOSIMETRY (OPTION)**, OM-0491R0 pag.113
Centrare pacient /Lumina colimator		da, LED	da, LED	OM-0491R0_EN_PRX RAYBOW XE (220928), 3.7 **COLLIMATOR CONTROLS**, OM-0491R0 pag 81
Loc de lucru integrat in consola mobila cu	Calculator cu accesorii, display tactil si software integrat dedicat pentru achizitie si prelucrare/stocare a imaginilor x-ray , interfata de control generator.	da	da	Raybow XE value 32kW MARS1417X, **MONITOR AND WORKSTATION** pag 12
	CPU	minim i7 sau echivalent	i7	Raybow XE value 32kW MARS1417X, pag. 12
	Sistem de operare	Windows, Ubuntu sau altele	Windows	
	Memorie operativa RAM	minim 8 Gb	16 DDR4	
	Memorie SSD/HDD	minim 500 Gb sau stocarea a minim 20000 imagini efectuate.	512 GB SSD	
	Tip display	Monitor Medical, Tactil, cu posibilitatea de a fi utilizat si in manusi chirurgicale	da	
	Dimensiune display	minim 17 inch	19 inch	

consola mobila cu software dedicat pentru aplicatiile de diagnostic X-ray	Rezolutie display	minim 1280x1024 pixeli	da	
	Tastatura & Mouse control	Da	da	OM-0491R0_EN_PRX RAYBOW XE (220928), 3.3 **CONNECTIONS PANEL**
	Baza de date pacienti,posibilitatea de vizualizare si redactare a imaginilor captate de pe detector	Da	da	Q-18959_ProductData_XE pagina 19-26
	Managementul dozei acumulate de pacient(legatura cu DAP-metru)	Da	da	
	Posibilitatea de conectare printer(DICOM print)	Da	da	
	WiFi	minim 802.11b/g	da	
	Compatibilitate totale cu standartul DICOM 3.0	Da	da	
Loc lucru (PC2) medic	Loc lucru medic imagist: PC cu accesorii, monitor si SW integrat pentru prelucrare/ stocare, schimb de date cu reteaua DICOM	da	da	Declaratie
	Procesor	≥ Core i5, sau echivalent	i5	
	Sistem de operare	Windows 7 sau echivalent	Windows 10	
	Memorie operativa	≥ 8 Gb	16	
	Memorie HDD	≥ 1 Tb	1 TB	
	Recorder DVD/RW	da	da	
	Accesorii	claviatura, maus, UPS	da	
	Monitor LCD Medical	IPS fara efect de stralucire, ≥ 21 inch, 3Mpx	da EIZO Radiforce RX370	Monitor RadiForce_RX370
	Baza de date pacieti, posibilitate de vizualizare si redactare a imaginelor primite de la locu de lucru 1 si reteua DICOM	da	da	iQ-VIEW_3.1.101_150dpi_Brochure_PUB_INT_EN_001R (1)
	Legatura cu Server DICOM (DICOM MWL SCU)	da	da	
	Posibilitate de lucru cu multiple Servere (DICOM store SCU)	da	da	

	(DICOM print SCU)	da	da	
	imaginilor in format DICOM	da	da	
	de la distanta	da	da	
	Compatibilitate totala	DICOM 3.0	da	
Alimentare electrica	Cu conectare directa la priza electrica	220V, 50 Hz	da	Raybow XE value 32kW MARS1417X, **BATTERY CAPACITY** pag 5
	Baterii interne	Care vor asigura autonomie de minim 8 ore de functionare in regim de utilizare.	da	
Accesorii	Dozimetru digital pentru monitorizarea radiatiei individuale acumulate de tehnicianului care opereaza cu dispozitivul.(1 bucata)	Da, cu posibilitatea de stocare si evidenta a datelor colectate in timp real prin aplicatii software usor accesibile de pe smartphone.	da, (Polimaster Radflash) 1 buc	Brosura **Dozimetru RadFlash_Leaflet** (2023.04)
Instalare/service	Instalare inclusiv raport de evaluare a calitatii(Controlul calitatii sau raport de testare de la producator)	da	da	Declaratie
	Existenta centru de service in RM cu ingineri locali instruiti si autorizati de producatorul dispozitivului care va fi livrat.	da	da	Declaratie
	Posibilitatea de service post garantie (contra cost) pe un termen de minim	7 ani	da, Declaratie	Declaratie
	Termenul de garantie pentru dispozitivul livrat se va calcula din momentul darii in exploatare si inceperii utilizarii si va constitui	minim 12 luni	da	Declaratie
Alte conditii	Certificate CE,ISO	da	Se anexeaza	
	Manual de service in limba engleza	da	da	
	Manual de utilizare in limba engleza/romana	da	da	
	Training utilizatori timp de minim 2 zile ,la locatia beneficiarului.	da	da	

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Date: 2023.11.24 12:41:01 EET
Reason: MoldSign Signature
Location: Moldova

DECLARAȚIE PE PROPRIA RASPUNDERE

Data: 24.11.2023

Către: ***CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE***

Numărul procedurii de achiziție: ocds-b3wdp1-MD-1695389614853 din 24.11.2023

Vipromed Service SRL declară prin prezenta că, pentru lotul 12 va fi asigurata furnizarea statiei de lucru pentru medic (Loc lucru (PC2) medic), cu specificatiile conform cerintelor.

Loc lucru medic imagist:

PC cu accesorii, monitor si SW integrat pentru prelucrare/ stocare, schimb de date cu reteaua DICOM

Procesor	≥ Core i5
Sistem de operare	Windows 10
Memorie operativa	≥ 8 Gb
Memorie HDD	≥ 1 Tb
Recorder DVD/RW	da
Accesorii	claviatura, mouse, UPS

Semnatura: _____
Nume:
Funcţia în cadrul firmei: Director
Denumirea firmei: Vipromed Service SRL

Digitally signed by Savca Octavian
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Operation

RAYBOW XE

Digital Mobile X-ray Unit
with Digital Detectors

Technical Publication
OM-0491R0_EN_PRX

CE
1639

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

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

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

Questo prodotto presenta un marchio CE in ottemperanza a quanto disposto nel 93/42/EEC MDD del 14 giugno 1993, rettificato da 2007/47/CEE il 5 settembre 2007.

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 RAYBOW XE:

RAYBOW XE

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REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
0	SEP 28, 2022	First Edition

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

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

ADVISORY SYMBOLS

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

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

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

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

Note ☞

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

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SECTION 1 INTRODUCTION

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

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

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

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

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

Illustration 1-1
Mobile X-ray Unit

Mobile X-Ray Unit with 3-Sections Arm

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

X-RAY GENERATION COMPONENTS

- *Control Console.*
- *Primo S, Software Application* for image acquisition.
- *Generator*, that comprises:
  - *Power Module*, containing power and control components.
  - *Battery Module,* with batteries and charge/control components.
- *Radiogenic unit*, part of the *Head-Assembly,* that comprises*:*
  - *Power Module*, containing power and control components.
  - *HV Tank, HV Transformer.*
  - *X-Ray Tube inserts; options: E7886, XRR-3331.*

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:* it provides a compact size for handling and storage the system when retracted, plus an extra length when extended. The unit has two Arm versions: the 3-Sections Arm and the optional 4-Sections Arm with second Touch Screen in the Head-Assembly and smooth Head-Assembly movements.
- *Collimator,* part of the Head-Assembly.
- *Digital Detector, Grid* and *Detector Handle (option).* Detector options: *Mars 1013X, Mars 1417X, Mars 1717X*
- *Holders* for *Detectors* storage and charge (option); storage for *Detector Handle, Grid,* and other *Accessories.*

1.1 GENERAL FEATURES

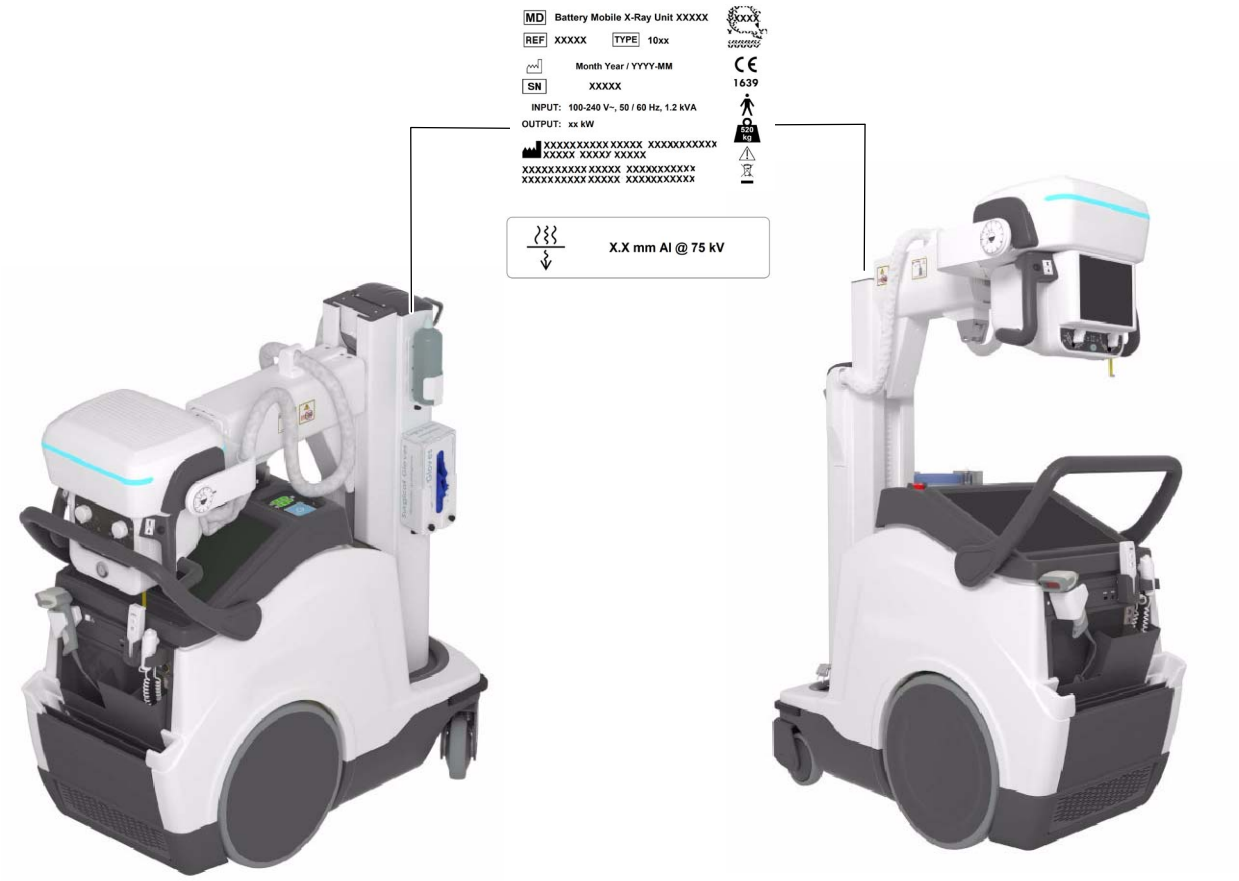
The main features of this Unit are:

- 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 Image Acquisition Software.
- X-ray Handswitch for X-ray exposures and Collimator Light.
- Infrared Remote X-ray Handswitch (option) for X-ray exposures and Collimator Light.
- Dosimetry (option).
- Manual Collimation.
- Heat Unit storage for the X-ray Tube, even after turning ON/OFF the equipment.
- Tube protection circuitry prolongs Tube life and increases system performance.
- Equipped with closed loop control of X-ray Tube current, kVp and filaments, which minimize potential errors and the need for readjustments.

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

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

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

This **Mobile X-ray Unit** contributes to the metrics of imaging performance ensuring the efficient use of radiation. It is designed for multiple uses/cases per day.

The X-ray image receptors used in this Unit are Digital Detectors.

1.3.2 NORMAL USE

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

1.3.3 CONTRAINDICATIONS

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

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

2.3 MAXIMUM PERMISSIBLE DOSE (MPD)

Before 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

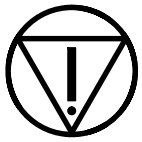
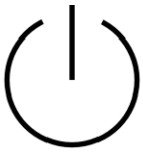
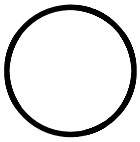
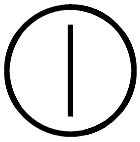
The following safety symbols may appear in the equipment.

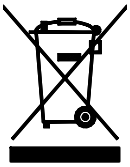
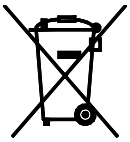
Their meaning are described below.

	**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.**
	**Warning: Electrostatic sensitive devices.**
	**No pushing.**
	**No sitting. Surface unsuitable to sit on.**
	**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 is authorized to be marked with **CE MARKING** in accordance with the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC concerning Medical Devices.

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.

ACCORDING TO MDD/93/42/EEC AS AMENDED BY 2007/47/EC, THIS UNIT IS EQUIPPED WITH EMC FILTERS. THE LACK OF PROPER GROUNDING MAY PRODUCE ELECTRICAL SHOCK TO THE USER.

2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

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

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

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

2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

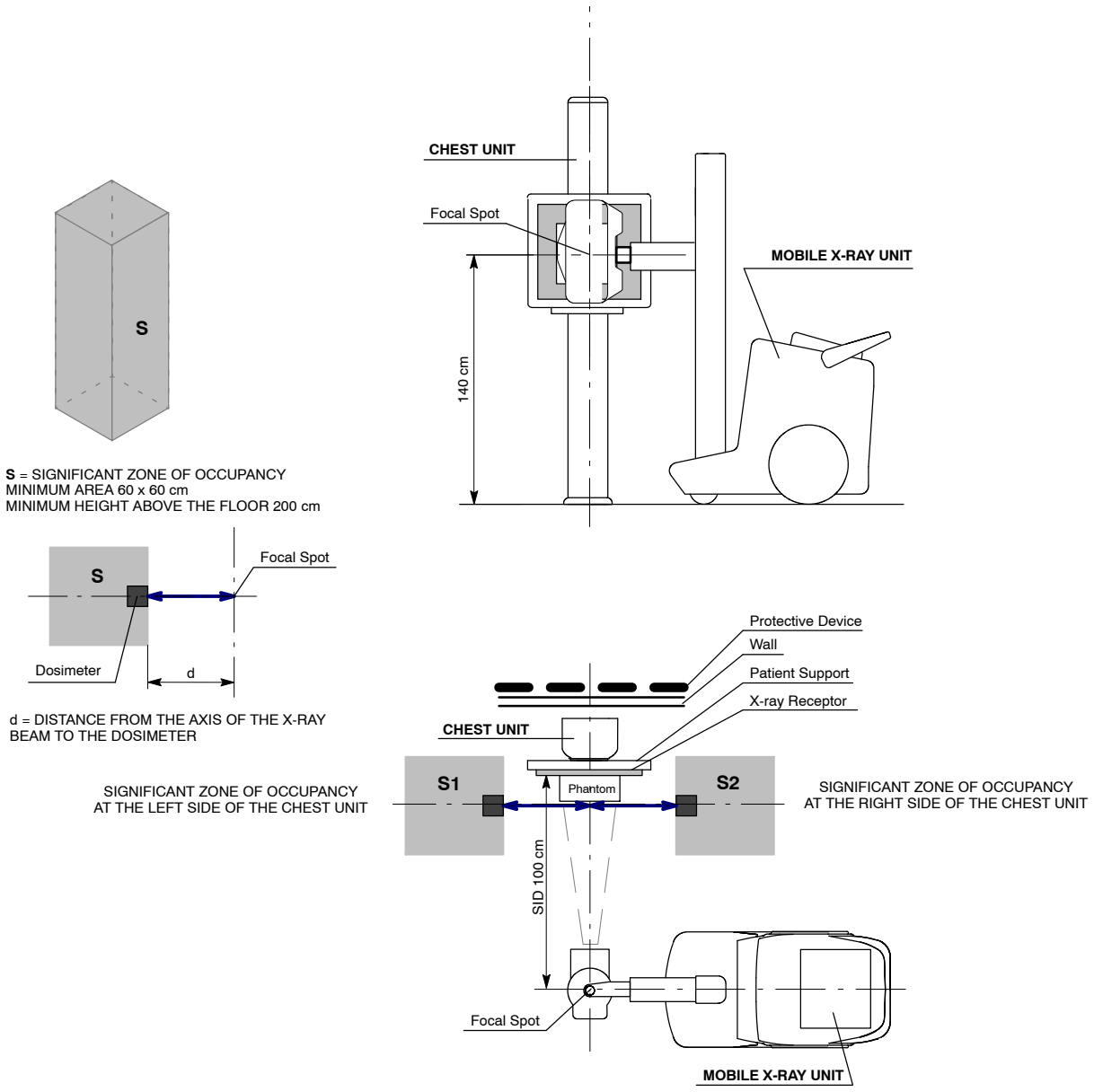
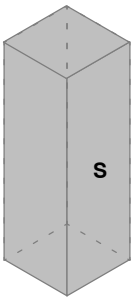
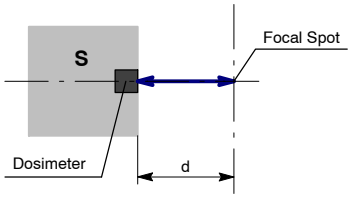


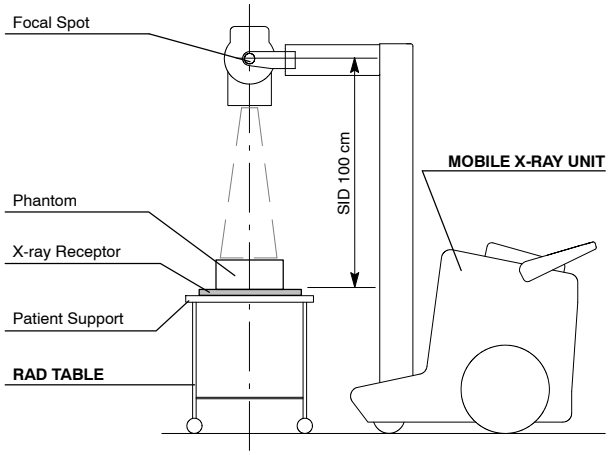
Illustration 2-2
Radiographic Examination on any Patient Support or any Table



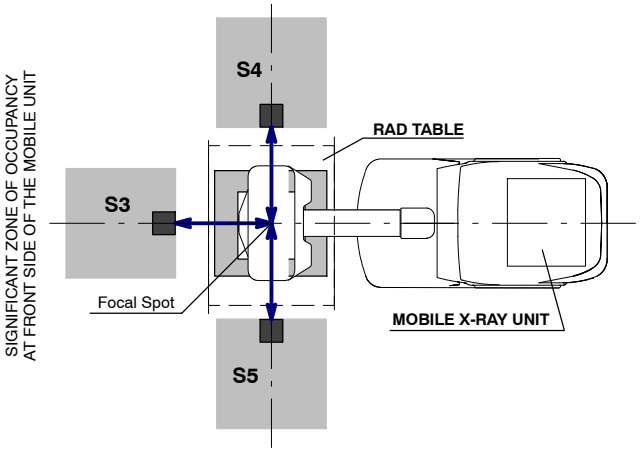
S = SIGNIFICANT ZONE OF OCCUPANCY
MINIMUM AREA 60 x 60 cm
MINIMUM HEIGHT ABOVE THE FLOOR 200 cm



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.

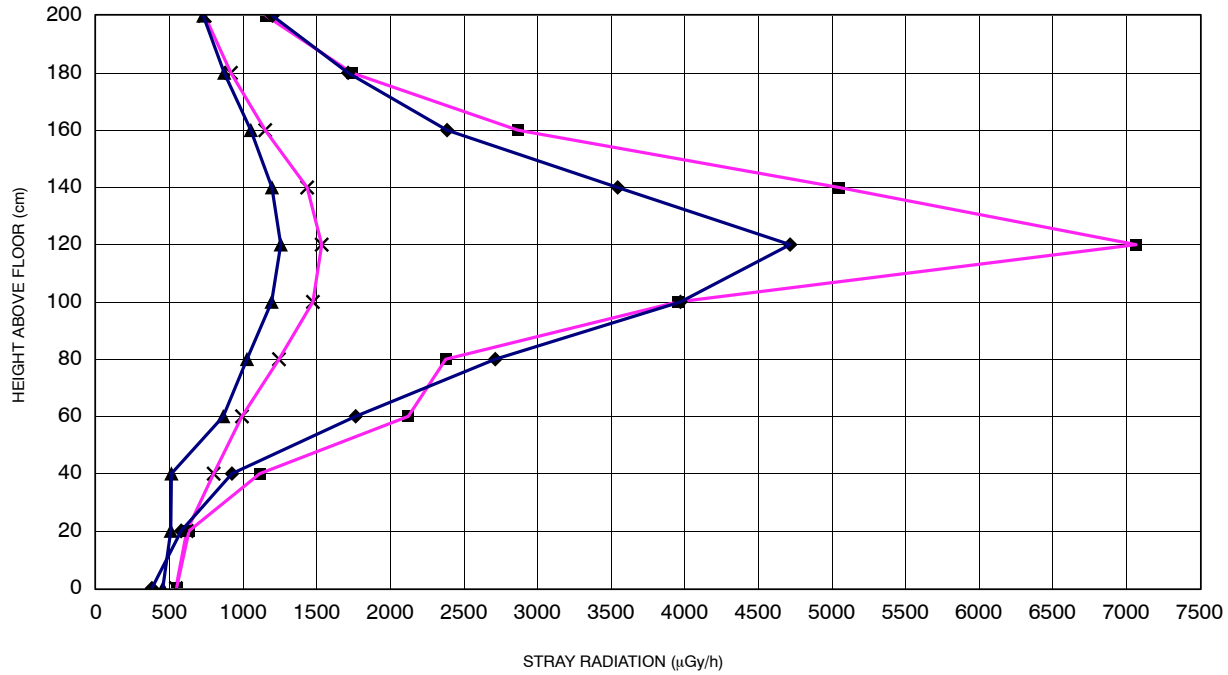
- Exposure Parameters: RAD mode, 150 kVp, 10 mAs.
- Collimator opening for Field Size 18 x 18 cm, SID 100 cm.
- Phantom: Rectangular water phantom of 25 x 25 x 15 cm, or a material having a similar X-ray attenuation coefficient.
- Radiation measuring instrument: Low Radiation Dosimeter.

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	

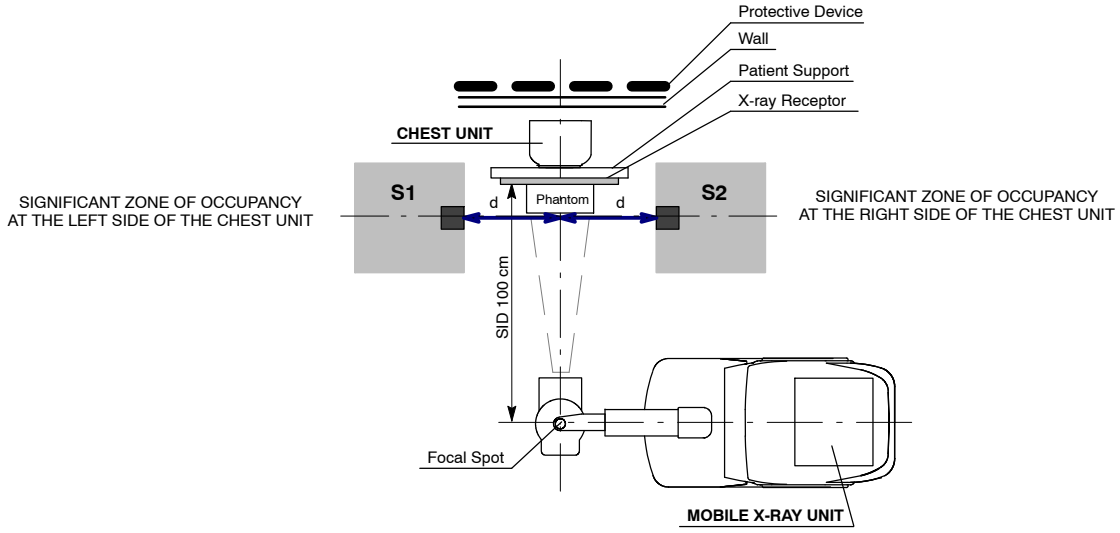
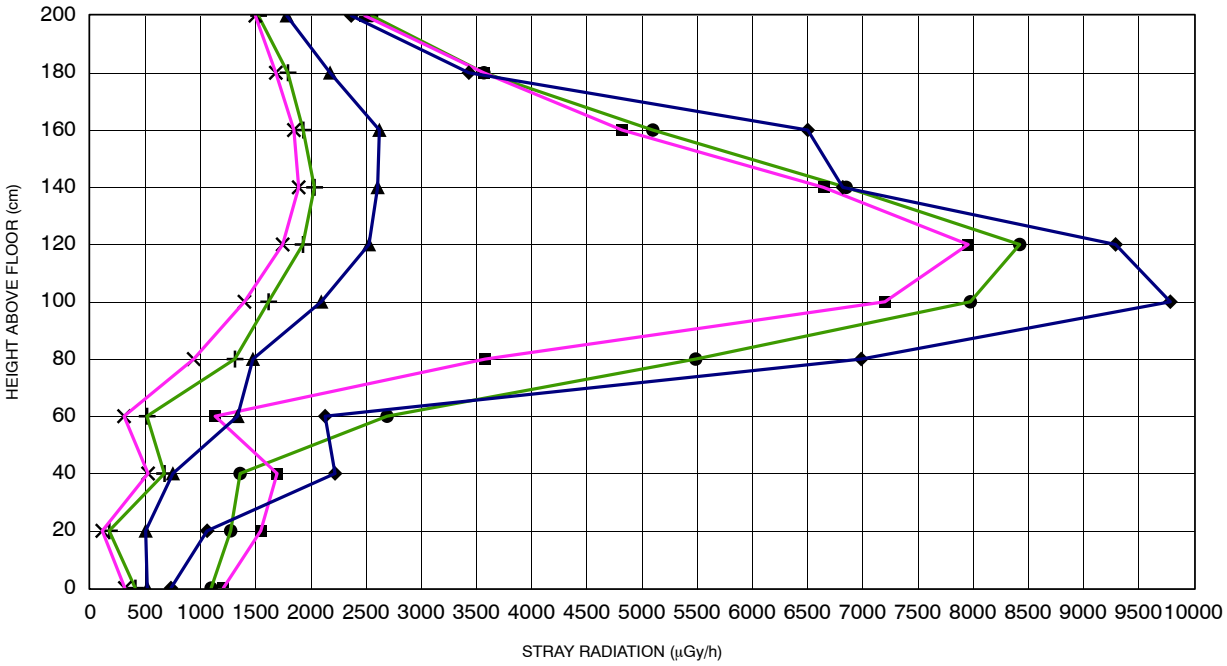
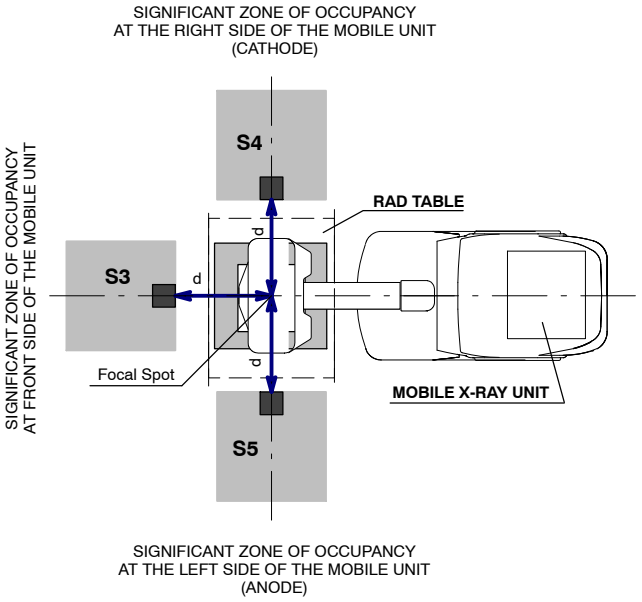


Illustration 2-4
Distribution of Stray Radiation on any Patient Support or any Table



$S3_1$	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 IEC 60601-1-2: 2007 and IEC 60601-1-2:2014. However, there is no guarantee that interference will not occur in a particular installation.

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

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

To comply with the regulations applicable to an electromagnetic interference for a Group 1 - Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the European Union Medical Device Directive and of Federal Communications Commission regulations (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* (only in 4-Section Arm version).
- *X-ray Handswitch*; *Infrared Remote X-ray Handswitch (option).*
- Controls for the unit motion and controls for *Telescopic Column* and *Arm* movements.
- *Manual Collimator Panel* with controls for opening or closing the *Collimator Blades* and to switch ON the *Collimator Light.*

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

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

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

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

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

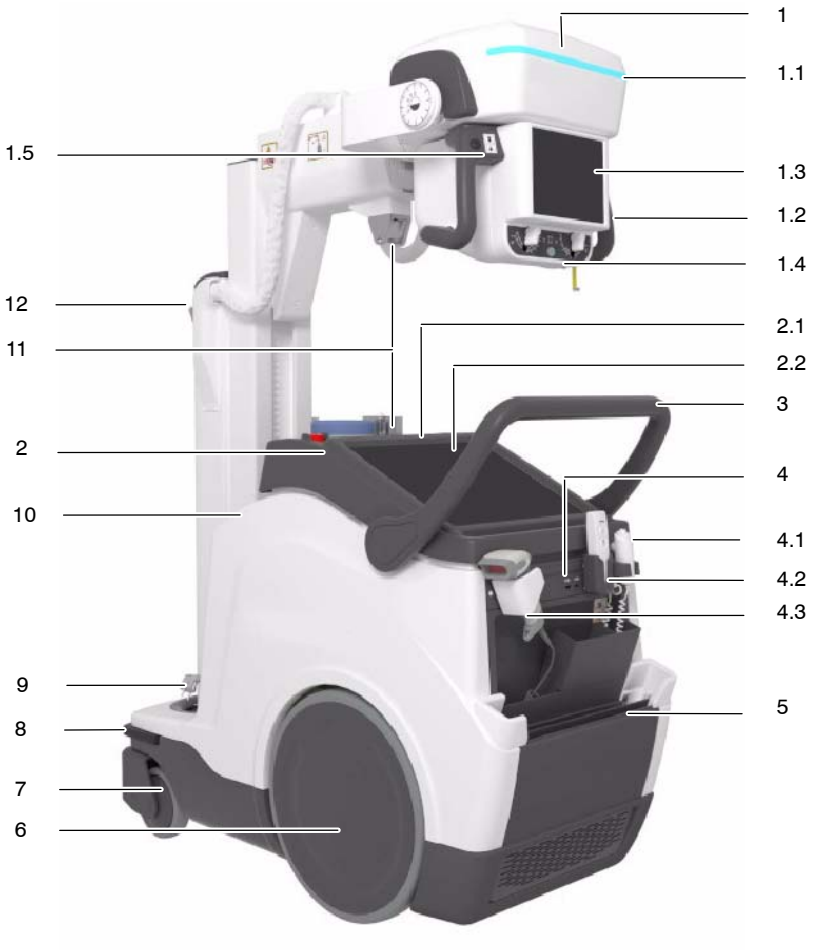


Illustration 3-2
Mobile X-ray unit

Mobile X-Ray Unit with 3-Sections Arm

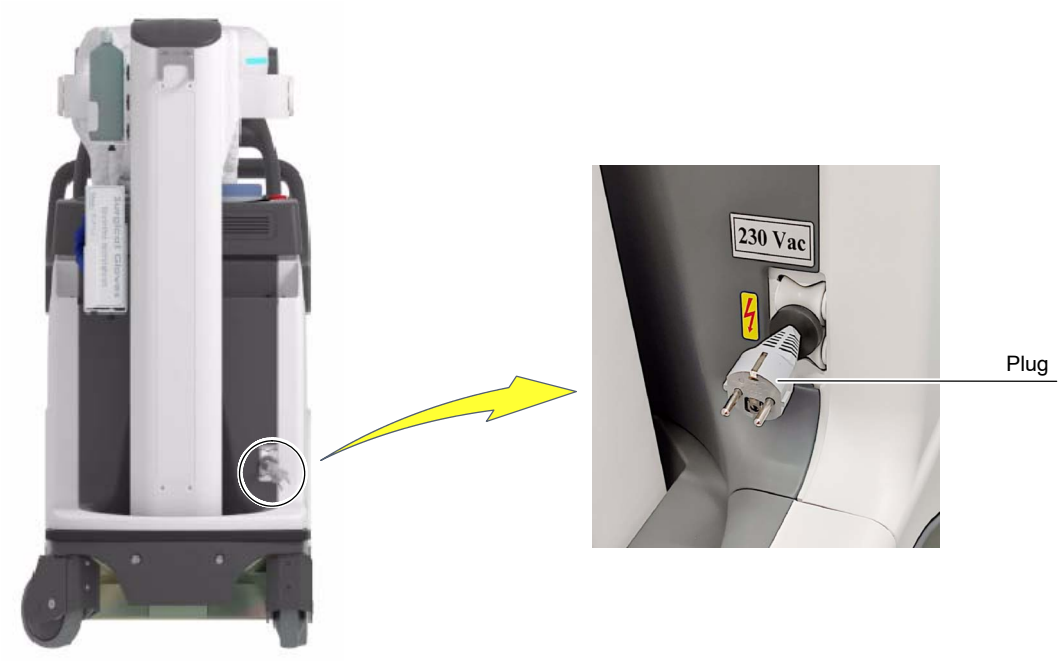
Mobile X-Ray Unit with 4-Sections Arm, Smooth Head-Assembly movements and second Screen (options)

3.1 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.

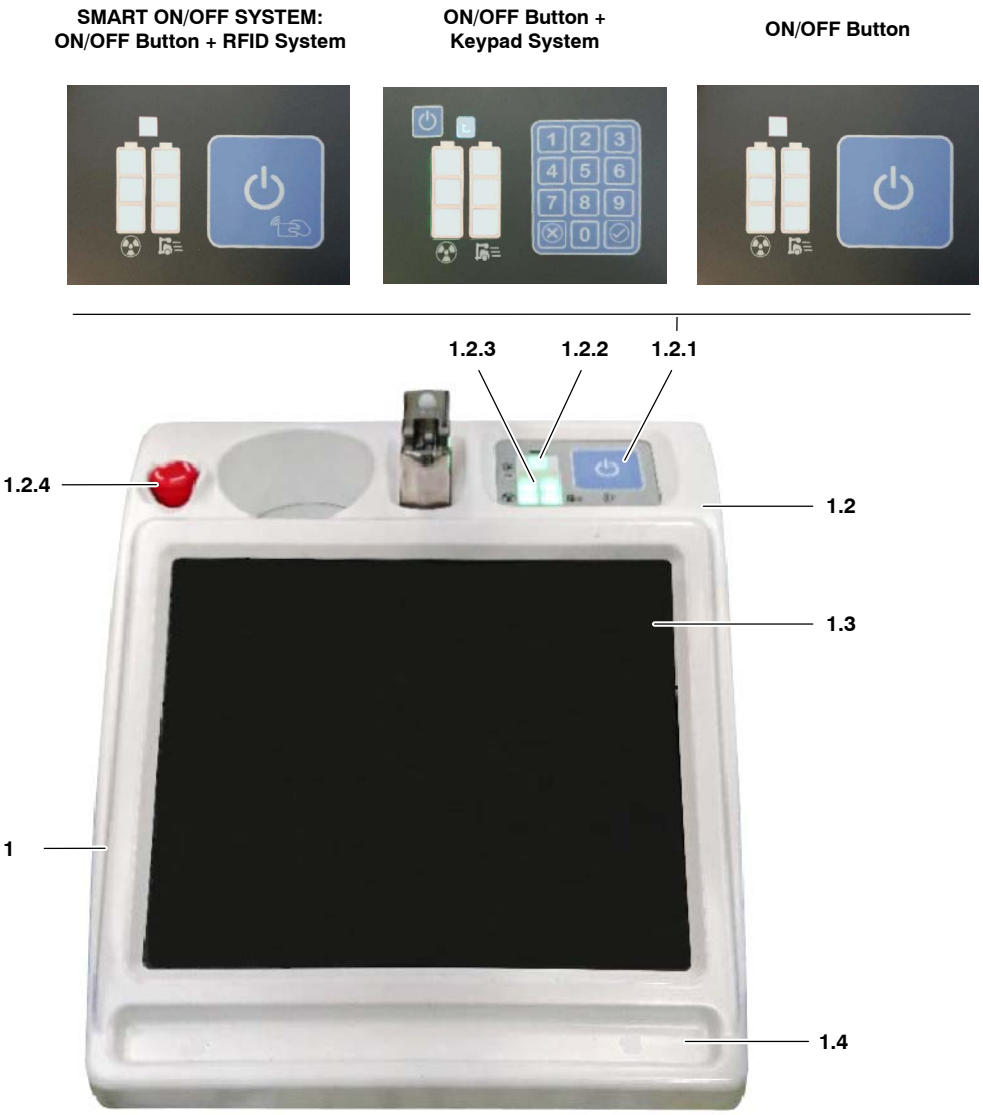
This "Lightning" icon will disappear from the Control Console when the Unit is unplugged from the mains.

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

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, 3.2.1.2 and 3.2.1.3.

▶ 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.

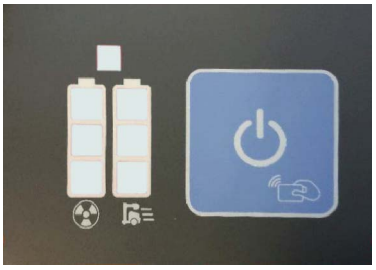
Note ☞ *The unit can operate in Stand-Alone mode, that is, operating without mains being present or unplugged from mains.*

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

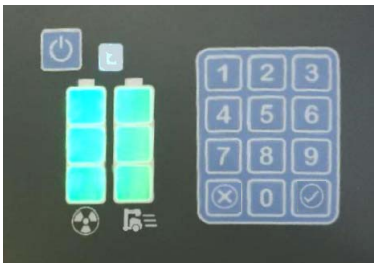
In this case, restart the unit making sure not to touch any part of the system (switches, touch screens, motion controls, or any other control).

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

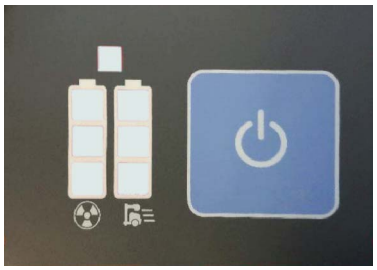
- **Smart ON/OFF system: ON/OFF button and the RFID system (RFID-Card and RFID Card Reader)** (*refer to Section 3.2.1.1).*



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



- **ON/OFF button** (*refer to Section 3.2.1.3).*



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

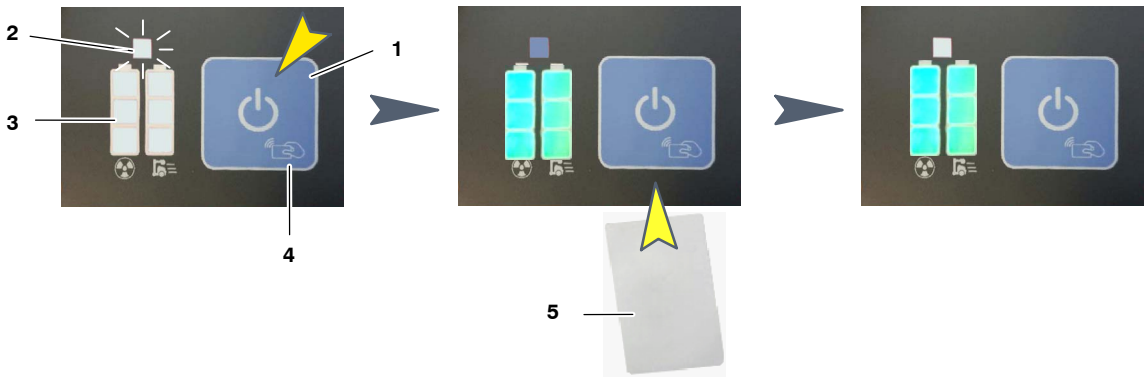
To turn the unit ON, proceed as described in the following steps:

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.

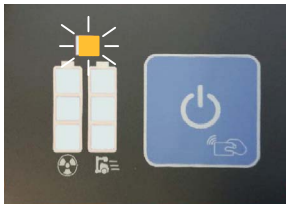
Note ☞ *When the Mobile Unit is in Charging Mode it is not necessary to press the ON/OFF button in the first instance.*

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, Radiographic Operation, 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*).

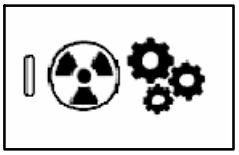
- Maintenance:

  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).*

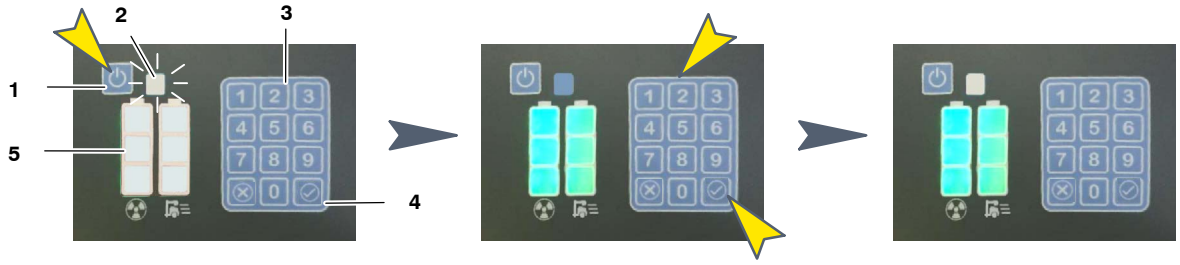
3.2.1.2 ON/OFF BUTTON + KEYPAD SYSTEM

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

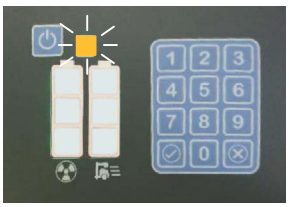
1. Press and hold the *ON/OFF* button (1) for a few seconds; the *System ON/OFF Indicator* (2) will blink white for 5 seconds.

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.*



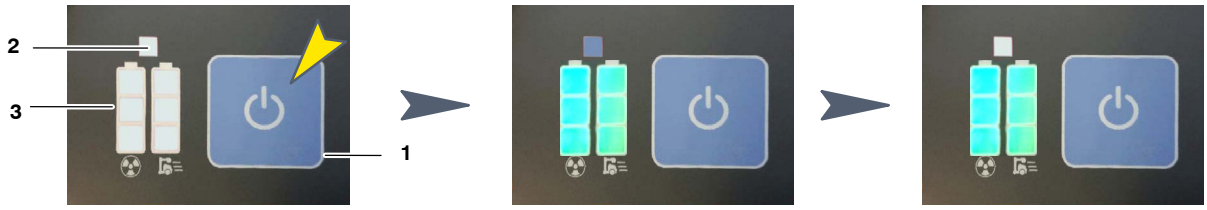
The system in the ON status switches ON the Generator, allowing the Mobile motion and then, the Image Acquisition Software for Radiographic operation will be launched on the Control Console.

3.2.1.3 ON/OFF BUTTON

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 light cyan for a few seconds and the *Battery Charge Level Indicator* (3) will light according to the current battery status.

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



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

3.2.2 SYSTEM OFF

Note ☞ *Only shut down the system as described in this Section (3.2.2). Otherwise, the system will not perform a proper shutdown.*

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.*

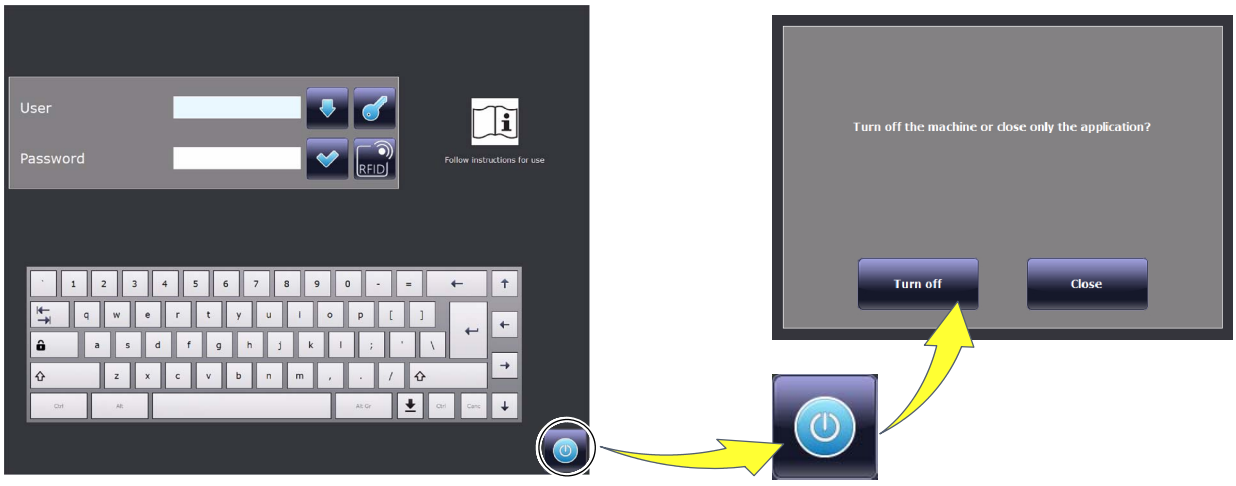
There are two ways to turn OFF the system:

1. From the Control Panel:

   Turn OFF the system from the Control Panel, by holding pressed the *ON/OFF* button for 3 seconds approximately; the system ON/OFF Indicator will light cyan for a few seconds and then, the system will be turned OFF.

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

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



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

3.2.3 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.

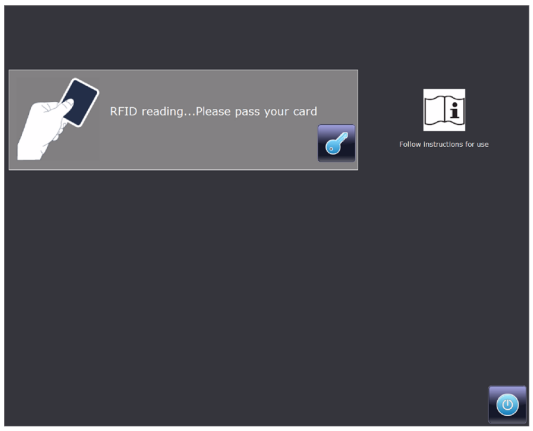
The Emergency Stop must not be used to switch OFF the unit, in order to avoid damaging the software.

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

Smart ON/OFF System



Other ON/OFF Systems

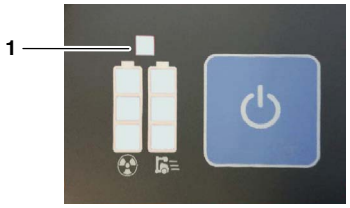
Note ☞ *For further details about Login Operation refer to Primo S User Manual.*

Note ☞ *The user provided with RFID Card for Smart ON/OFF system, with permission for Radiographic operation (refer to Section 3.2.1.1), 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, 3.2.1.2 and 3.2.1.3.*

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.

The *Primo S Software Application* is shown on the Main Screen, including 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 Image Preview, technical settings and patient information.

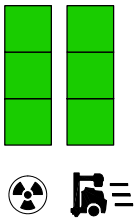
Note ☞ *For further details, refer to Sections 4 and 5.*

1 CONTROL CONSOLE
2 MAIN SCREEN
3 HEAD-ASSEMBLY SCREEN

Mobile X-Ray Unit with 3-Sections Arm

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

3.2.7 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.

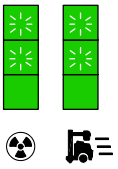
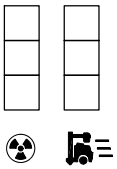
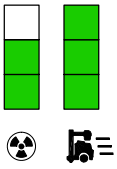
Note ☞ *The Batteries require approximately 8 hours for a fully charge. The batteries requires 4 hours for getting a charge level around 80% (20% per hour during the first 4 hours). Moreover, the Unit allows to perform exposures immediately after be plugged to the mains.*

Note ☞ *To charge the Batteries, there is no need to have the 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.*

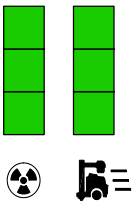
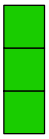
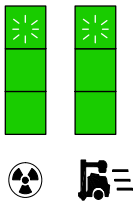
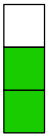
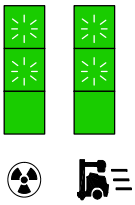
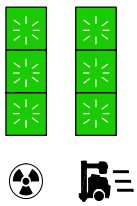
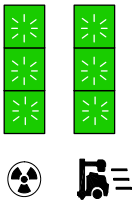
When unplugged from mains, the Batteries discharge independently on their use (X-ray exposures or motors) since the Mobile is provided with one battery module.

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: – For X-ray: The lower indicator lights is blinking orange. Exposures are disabled and a 30-minute timeout countdown for the system shutdown is activated. Operation remains limited as long as the Unit is not plugged into the mains. – For Motors: The lower indicator lights is blinking orange. The system automatically shuts down. The batteries charge level is 0%.
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 Message Bar:

▶ ***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.

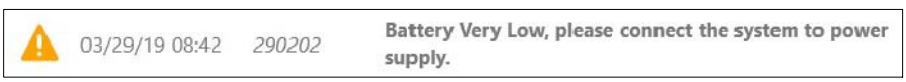
The message disappears after a few seconds or by clicking on the *OK button;* then, the work can be continued.

▶ ***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.

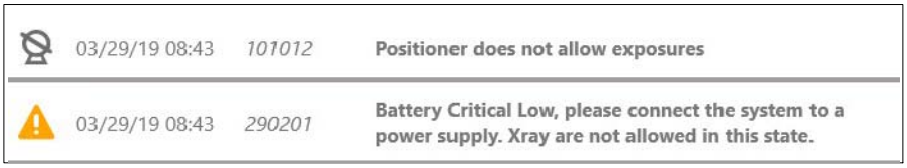
The lower indicator flashes orange, on one or both columns, and the middle and upper indicators are off, with the unit disconnected from mains (not charging).

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 (X-ray exposures), indicates that exposures are disabled.

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

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



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

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:: 40 seconds.*

After holding pressed for 3 seconds the *Switch OFF* button, the system will be completely turned OFF in 40 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 X-ray Generator Console, 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 X-ray Generator Console, 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 (*) Only inside the Safety Area	**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 and within the Safety Area. Otherwise, if the Unit does not have the optional Proximity Sensors installed, the indicator remains OFF during movements (*refer to Section 3.6.1.4*).
CYAN	BLINKS WHITE (*) Only inside the Safety Area	**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 and within the Safety Area. Otherwise, if the Unit does not have the optional Proximity Sensors installed, the indicator remains OFF during movements (*refer to Section 3.6.1.4*).
GREEN	-	**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.

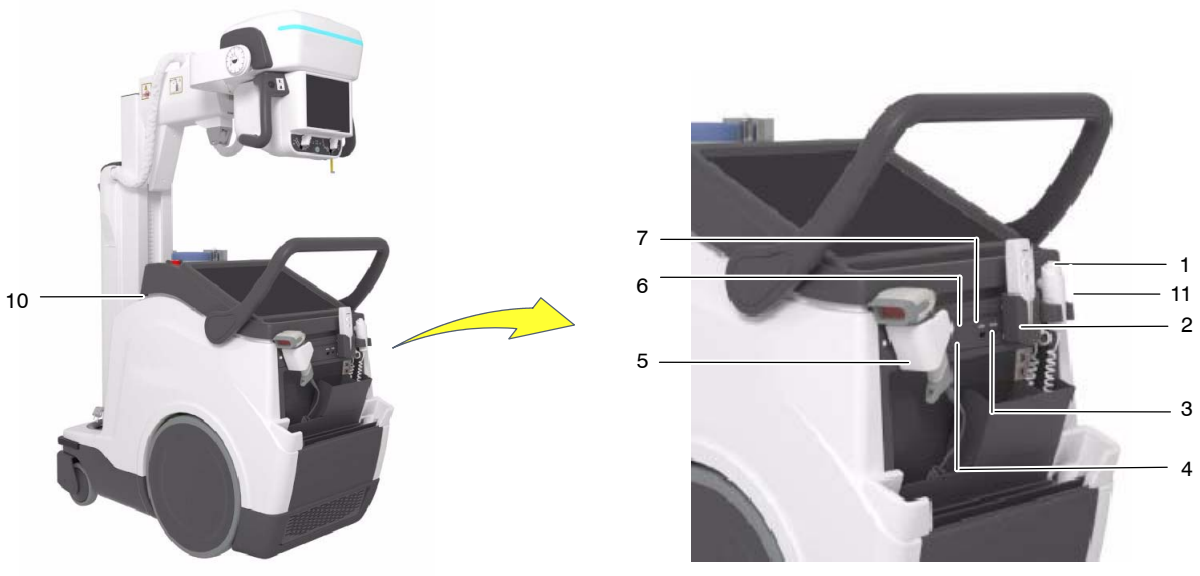
Note ☞ *For further information, refer to Section 3.4 about the Exposure process and to Section 5 about System Messages.*

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

3.3 CONNECTIONS PANEL

WARNING

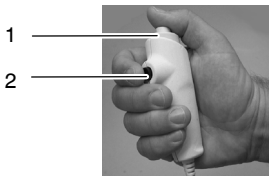
DO NOT CONNECT ANY ACTIVE DEVICES THAT APPLY EXTERNAL VOLTAGE TO THE SYSTEM THROUGH THE USB PORTS; ONLY PASSIVE DEVICES CAN BE CONNECTED.



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. **IR Sensor** for Wireless Digital Detector registration *(refer to section 3.11)*.
5. **Barcode Scanner (option).**
6. **Ethernet (ETH) Connector**, in order to connect to the site Network.
7. **CD/DVD Writer (option).**
8. **WIFI Connection**, in order to connect to the site Network.
9. **WIFI Connection**, in order to connect to the Wireless Digital Detector.
10. **Detector Backup Communication Cable (option)**, to be connected to RJ45 Connector, at the Front Cover (*refer to Section 3.11.3*).
11. **Manual Driving Brake Release Button (option)**, *(refer to Section 3.6.1.6)*.

3.4 X-RAY HANDSWITCH



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: Charging
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 with 3-Sections Arm is provided with a two-position Handlebar (medium and lower position). The unit with 4-Sections Arm 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.

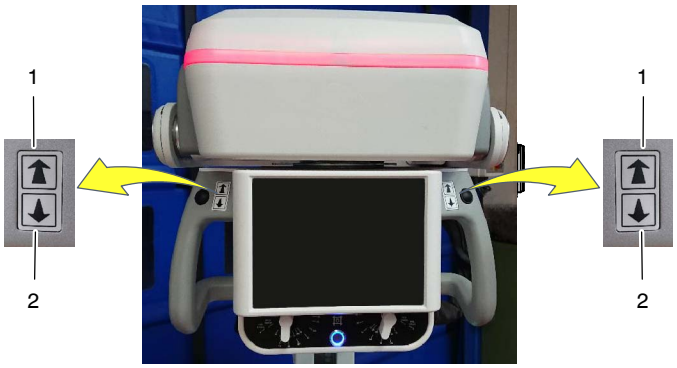
Once any Fine Positioning button is pressed, the Unit starts to move, but displacement will stop after 5 seconds. It is necessary to release the button and press again to resume the movement. This safety measure prevents possible uncontrolled movements due to an internal failure of the Fine Positioning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

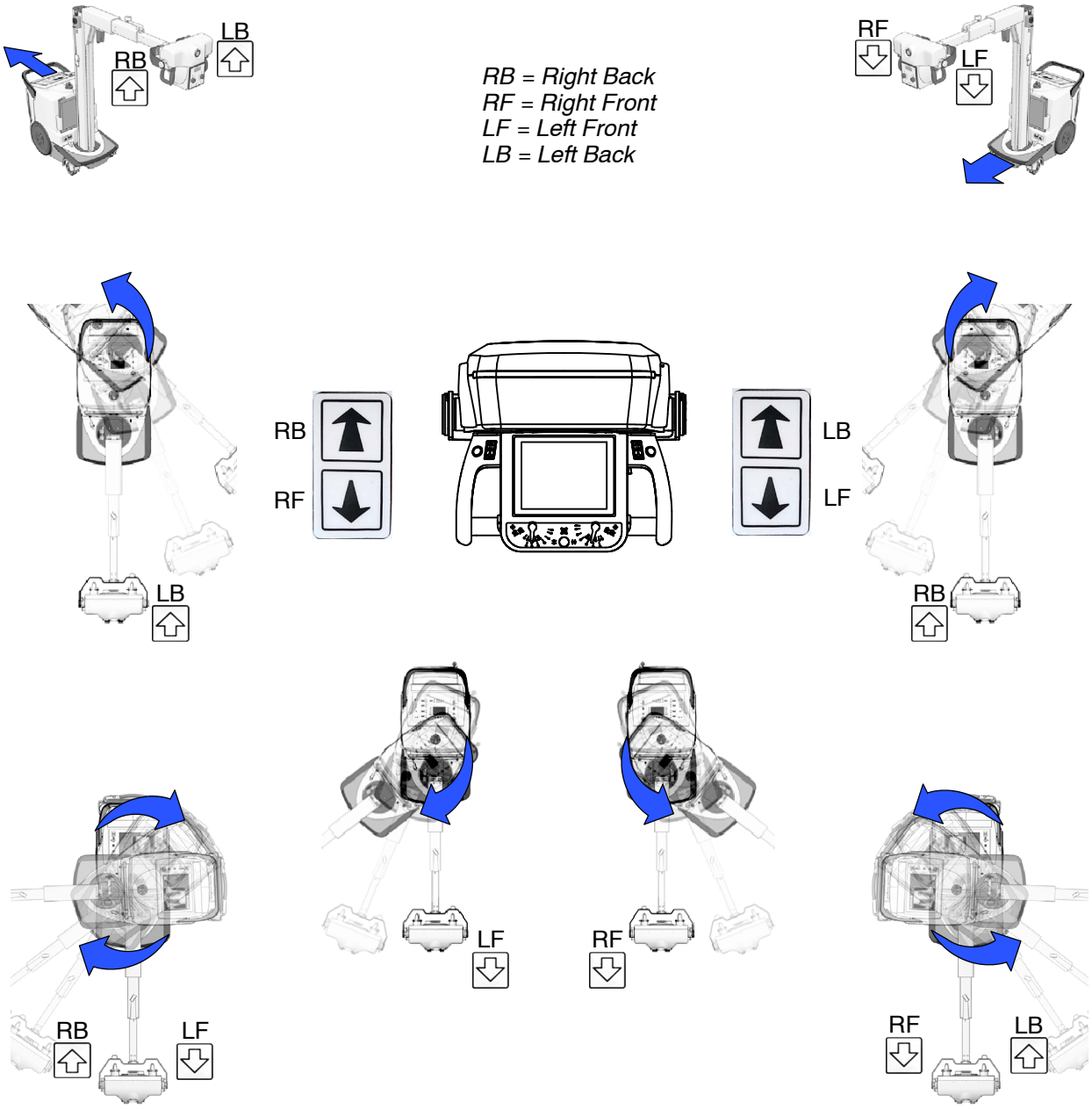
CAUTION

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



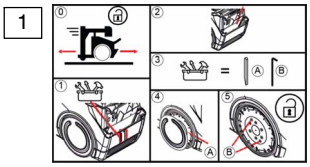
3.6.1.3 MANUAL CLUTCH SCREWS

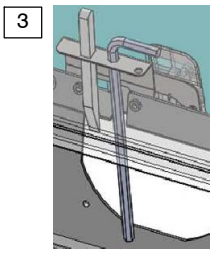
When the unit has to be moved manually, the (x2) Clutch Screws (Allen type) located on each wheel must be removed using the tools provided with the unit.

DANGER!

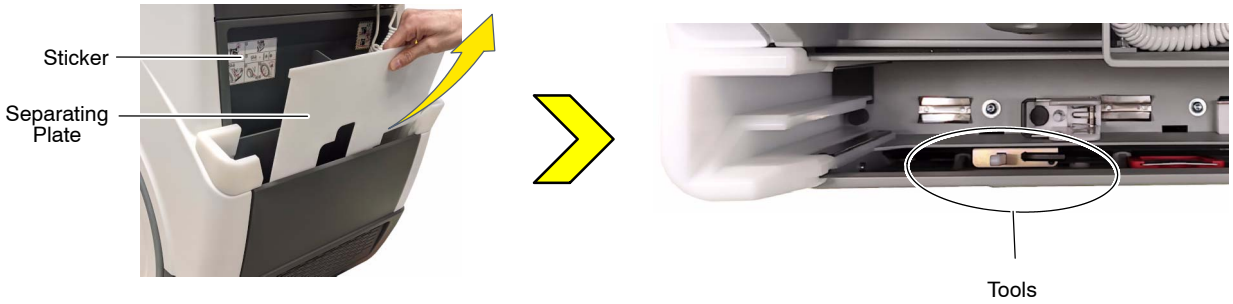
DRIVE THE UNIT MANUALLY ONLY WHEN MOTORIZED MOTIONS CANNOT BE PERFORMED (DUE TO A SYSTEM MALFUNCTION OR THE BATTERIES DISCHARGE).
IN THIS CASE, DO NOT DRIVE THE UNIT ON SLOPES OR INCLINED SURFACES; DRIVE IT ONLY ON LEVEL SURFACES, TO AVOID PERSONAL INJURIES OR DAMAGE TO EQUIPMENT DUE TO ITS HEAVY WEIGHT.

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.*

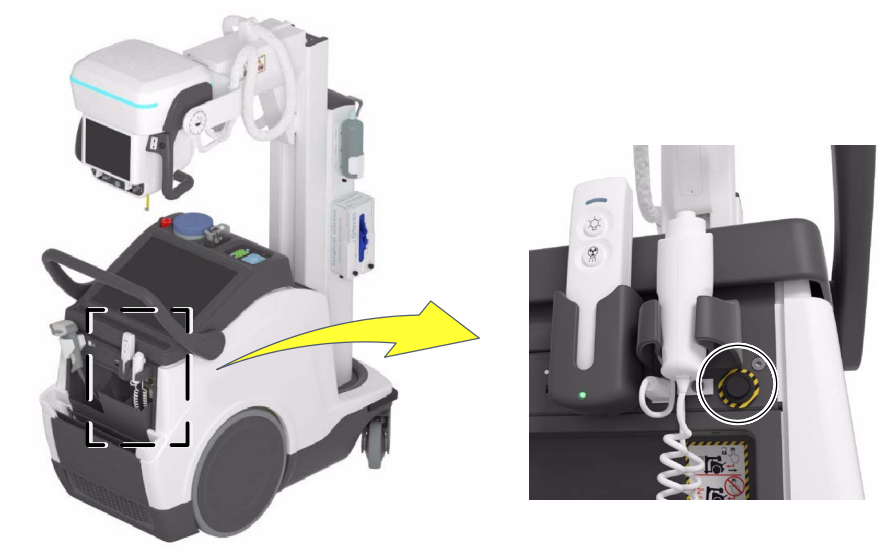
Note ☞ *For further information, refer to Section 3.2.10 of Status Light Indicators.*

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 X-ray Generator Console (*refer to Section 4.1.13*). This icon is also displayed on the Head-Assembly Console (option).

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

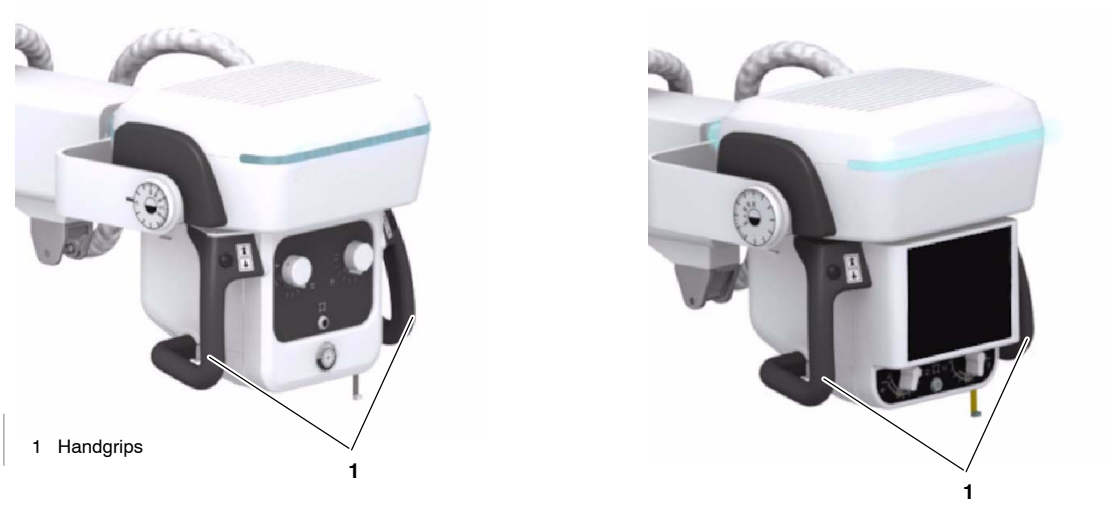
WARNING

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.

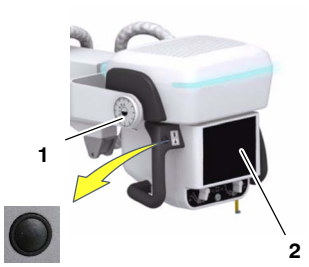
The Column can rotate from its Parking position: $\pm 317^{o}$.

The Arm allows a vertical travel of 1490 mm.

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

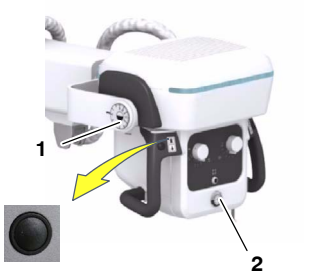
3.6.3.2 HEAD-ASSEMBLY MOVEMENTS

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 it has stops at -180º and 180º.

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

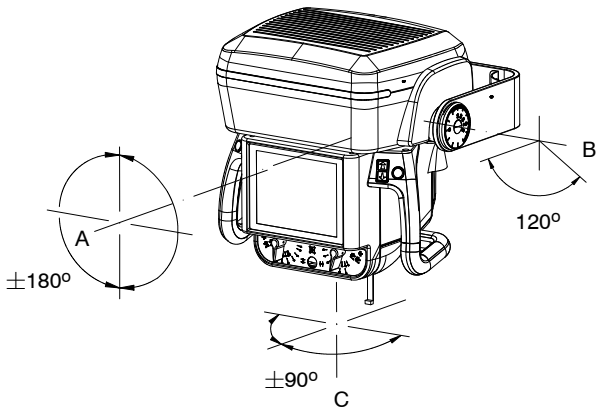


- 120° on its horizontal axis, *i. e.* pitch rotation (see *to Illustration 3-5, B*). This movement has detents at 0º , and it has stops at +90°, 0º and - 30°.

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

Note ☞ *Refer to Section 3.6.3.3 for Collimator movements.*

Illustration 3-5
Head-Assembly and Collimator Movements



3.6.3.3 COLLIMATOR MOVEMENTS

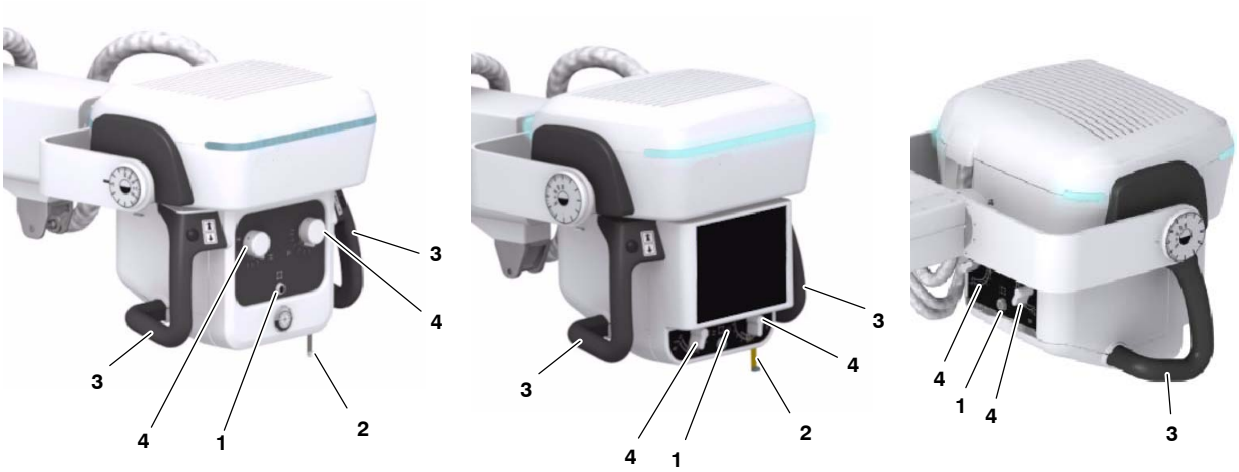
The Collimator can rotate ±90° on its vertical axis (*refer to Illustration 3-5,C*), while the Head-Assembly remains in the same position.

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°
12°	24X30 30X24	SID ⩾ 70 cm	SID ⩾ 100 cm
	35X43 43X35	SID ⩾ 100 cm	SID ⩾ 145 cm
	43X43		
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 corresponding Collimator Manual for extended information about operation or technical description needed to maintain compliance with Standard IEC 60601-1-3:2008.*

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

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

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

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

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

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

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

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

2. **Measuring tape.**

   To measure the SID.

3. **Handgrips with Support .**

   For easily positioning the Head-Assembly.

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

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

Table 3-1
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 Main Screen and/or on the Head-Assembly Screen when it is present.

6. **External Filtration.**

There is a rail system at the rear side of the Collimator, with two guides, in order to install the external additional filters used for pediatric examinations ($\geqslant$0.1 mm Cu or 3.5 mm Al) in the upper guide.

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

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

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

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

3.8 DAP CHAMBER (OPTION)

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

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

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

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

3.9 ESTIMATED DOSE: EDAP / EDOSE (OPTION)

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

- **eDAP**: Calculates an estimation of DAP (Dose Area Product) value according to the values of the X-ray technique used and the Collimator aperture and filter selection values. The DAP value is estimated in *mGy*cm²* with an accuracy of ± (25% + 0.1).
- **eDOSE**: Calculates a Skin Dose estimate from the values mentioned for Dose per Area and the value of the focus-to-skin distance provided by the FSD sensor. The Dose value is provided in *mGy* with an accuracy of ± (25% + 0.1).

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

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

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

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

3.10 FOCAL-SKIN DISTANCE SENSOR (OPTION)

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

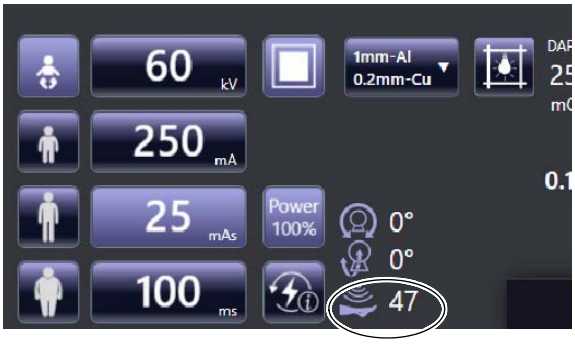
The FSD (Focal-Skin Distance) sensor is installed at the front of the underside of the Collimator. It reads the distance from the focus of the tube to the surface of incidence on a patient, measured along the beam axis.

Illustration 3-6
FSD Sensors Location

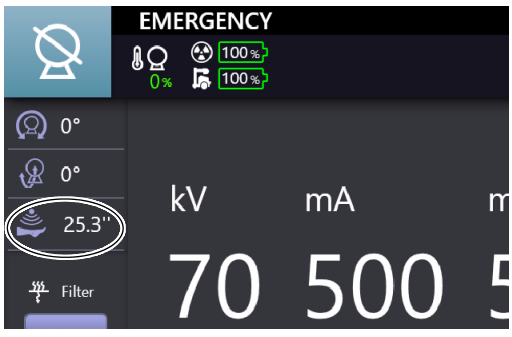
The measured value is displayed on the X-ray Generator Console (within *Primo S*) and on the Head-Assembly Console (if installed) (*refer to Section 4.1.8*).

Illustration 3-7
FSD Value on the Control Consoles

X-ray Generator Console



Head-Assembly Console



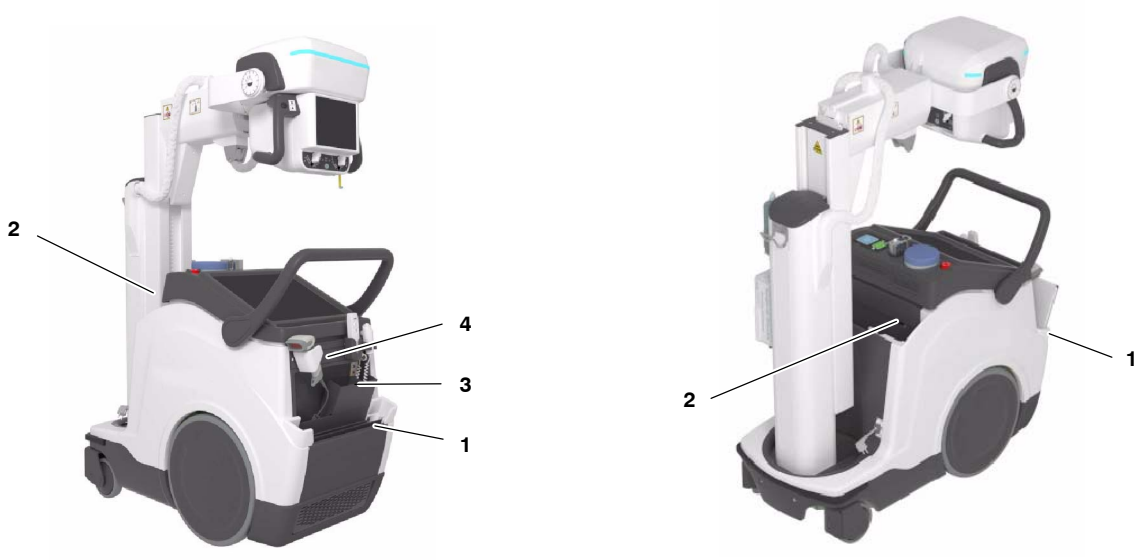
3.11 WIRELESS DIGITAL DETECTORS, OPTIONS AND ACCESSORIES

Wireless Digital Detectors:
Mars 1013X, Mars 1417X, Mars 1717X

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.

Illustration 3-8
Wireless Digital Detectors, Options and Accessories



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

2 Holder for Detector Charge and Storage, with / without Grid (Front Cover)

3 Detector Bags Holder

4 IR Data Communication Sensor (Connections Panel)

3.11.1 WIRELESS DIGITAL DETECTORS

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

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

Mars 1013X

Mars 1417X

Mars 1717X

3.11.2 IR DATA COMMUNICATION UNIT

The IR Data Communication sensor (1) located in the *Connections Panel*, is used for registering the Wireless Digital Detector to the Mobile unit by Infrared (IR) Communication.

3.11.3 DETECTOR 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 RJ45 connector at the Front Cover (2).

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

3.11.4 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.

3.11.5 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.

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

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

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

After every examination, wipe with a cloth slightly 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

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

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

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

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

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

A. IMAGE AREA

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

B. EXAM LIST / PREVIEW LIST

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

C. PATIENT DATA

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

D. MESSAGES AREA

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

E. EXAM MANAGEMENT AREA

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

F. X-RAY GENERATOR CONSOLE

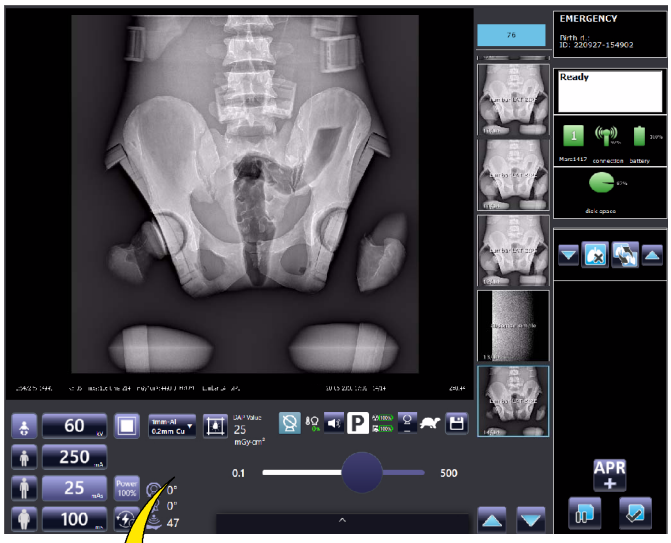
The X-ray Generator parameters are already set by the manufacturer for each kind of exam. The parameters can be adjusted during the installation. *For detailed information refer to Section 4.1*.

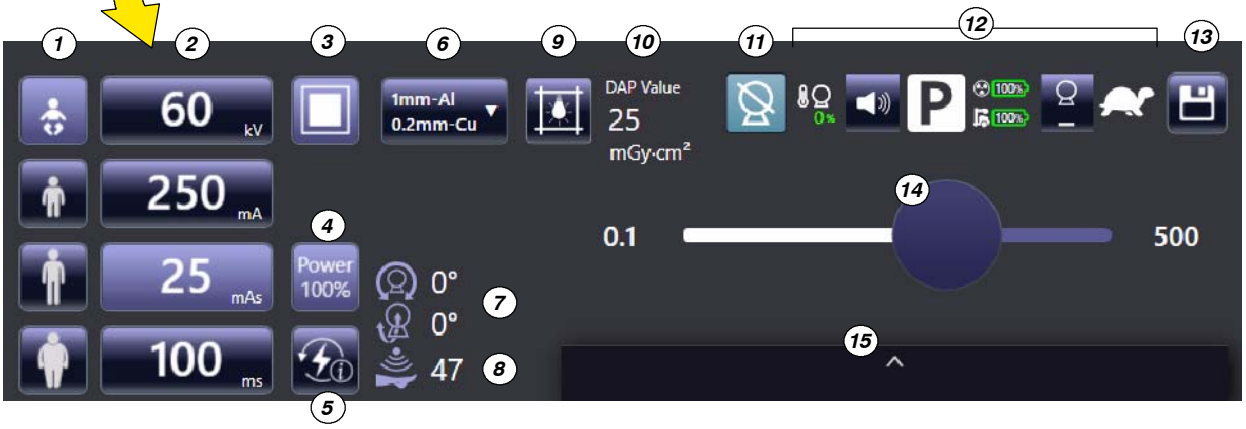
Note ☞ *For further details about operation with controls of Primo S Software Application, refer to Primo S User Manual.*

4.1 X-RAY GENERATOR CONSOLE

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

Illustration 4-1
X-ray Generator Console





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

4.1.1 EXPOSURE INDICATORS

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

NORMAL STATUS: The detector is ready, the RAD technique is correctly set and there is 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 acoustic signal is emitted.

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

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

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

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

4.1.2 PATIENT SIZE / TYPE

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

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

4.1.3 RADIOGRAPHIC PARAMETERS

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

Illustration 4-2
Radiographic Parameters Selection

kV shows:

- The radiographic kV value selected for the technique.

mA shows:

- The radiographic mA value selected for the technique.

mAs can show:

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

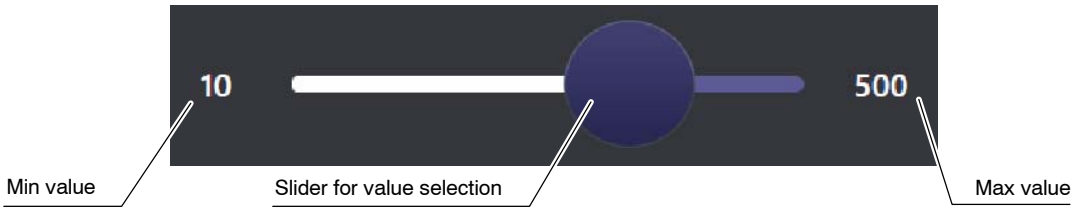
Time (ms/s) can show:

- The Time value (in milliseconds/seconds) selected for the radiographic technique.
- If an exposure is aborted by releasing the Handswitch button, the actual Time (ms/s) value flashes for five seconds, the message "*Aborted Exposure Error*" appears in the Information Area and an 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 4-3
Slider for Value Selection



- **kV**: Selects the X-ray Tube voltage.
- **mA**: Selects the X-ray Tube current, changing the mAs value and keeping constant the 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).*

4.1.4 FOCAL SPOT

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

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

Illustration 4-4
Small and Large Focus Overlap

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

4.1.5 POWER REDUCTION

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

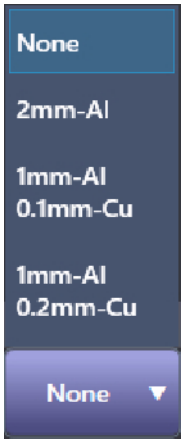
4.1.6 LAST EXPOSURE VALUES

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

All these values are displayed in yellow for five seconds.

Illustration 4-5
Last Exposure Values

4.1.7 COLLIMATOR FILTER SELECTION



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

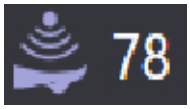
- None
- 2 mm Al
- 1 mm Al + 0.1 mm Cu
- 1 mm Al + 0.2 mm Cu

4.1.8 HEAD-ASSEMBLY ROTATION

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

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

4.1.9 FSD VALUE



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

4.1.10 COLLIMATOR LIGHT

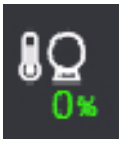
Press the "*Collimator Light*" button to turn the Collimator light ON; it will remain ON for a few seconds before automatically switching OFF.

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

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

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

4.1.11 HEAT UNITS INDICATOR



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

4.1.12 MUTE BUTTON

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

4.1.13 PARKING INDICATOR

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

4.1.14 BATTERIES STATUS

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

4.1.15 MOTION SPEED INDICATOR

This indicator can display:

Limited Motion Speed: *“Turtle”* icon appears when an obstacle is detected and speed limitation is active. It 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.

4.1.16 WORKSTATION INDICATOR

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

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

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

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

Illustration 4-6
Workstation Selection Pop-up Window

4.1.17 SAVE BUTTON

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

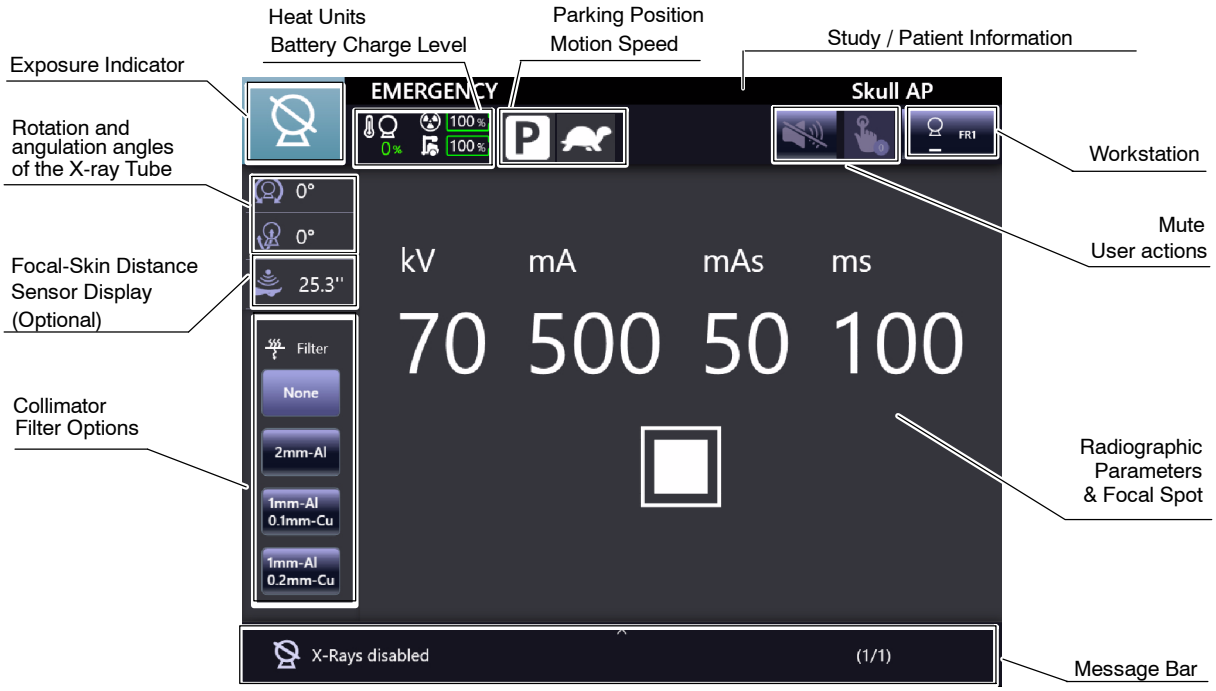
If, after modifying any of the Radiographic Parameters, Focal Spot, etc., it is necessary to save these settings so that they remain associated with the selected technique, press the *Save* button.

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

4.2 HEAD-ASSEMBLY CONSOLE (OPTION)

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

Illustration 4-7
Head-Assembly Console

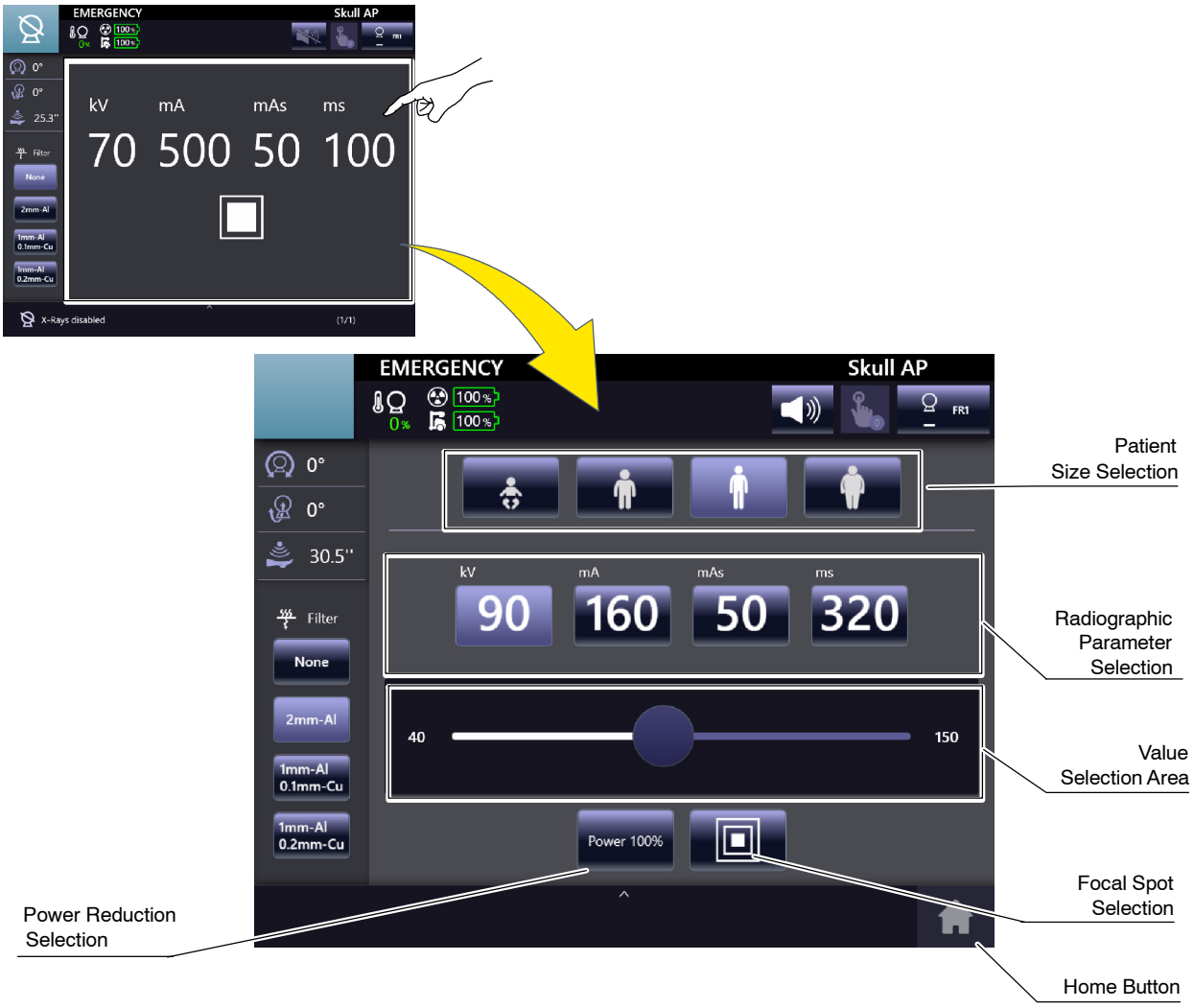


The following indicators and buttons have been previously described in the X-ray Generator Console section:

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

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

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



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

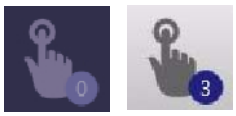
4.2.1 PATIENT INFORMATION PROTECTION

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

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

Illustration 4-9
Patient Information Protection

4.2.2 USER ACTION



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

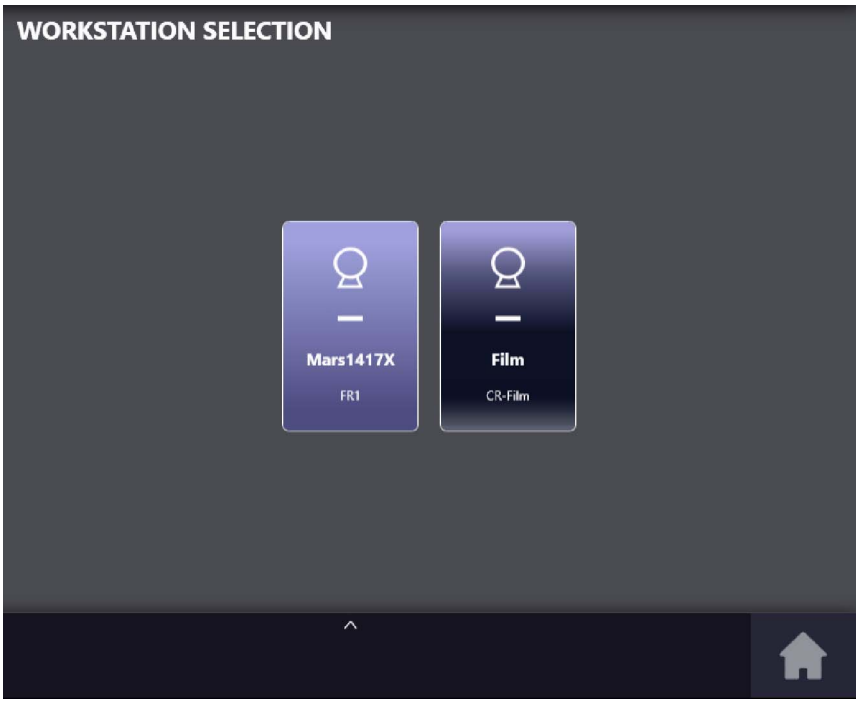
Refer to Section 5 (System Messages) for further information.

4.2.3 WORKSTATION SELECTION

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

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

Illustration 4-10
Workstation Selection Window



4.3 MESSAGE BAR

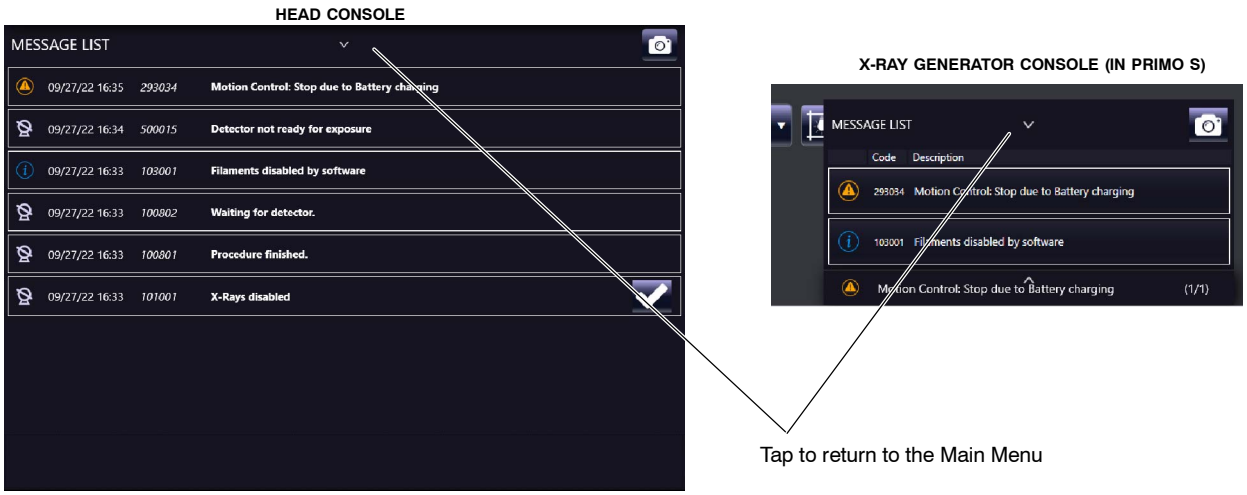
The Message Bar shows informative messages (warning, information, inhibition condition, user action, error).
Active messages, i.e. those that require action by the operator or report an error or a warning, will be displayed consecutively in this area.

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

Illustration 4-11
Message Bar

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

Illustration 4-12
Message List



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

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

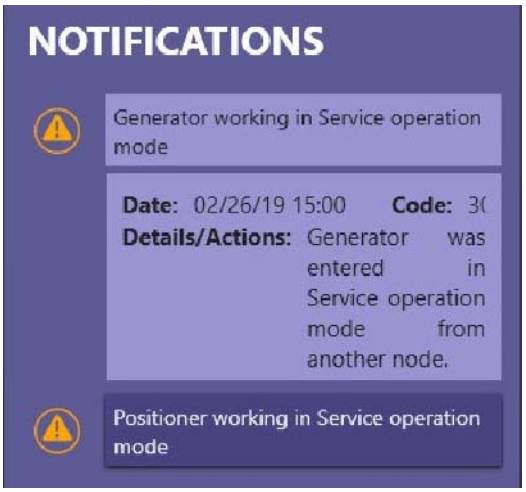
4.3.1 MESSAGE WINDOWS

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

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

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

Illustration 4-13
Message Displayed



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

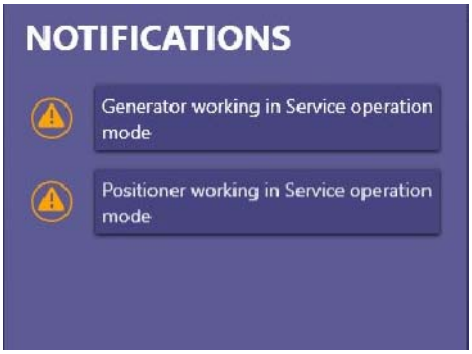
Each of the message windows is detailed below:

NOTIFICATIONS

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

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

Illustration 4-14
Notifications Pop-up Window



INHIBIT CONDITIONS MESSAGES

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

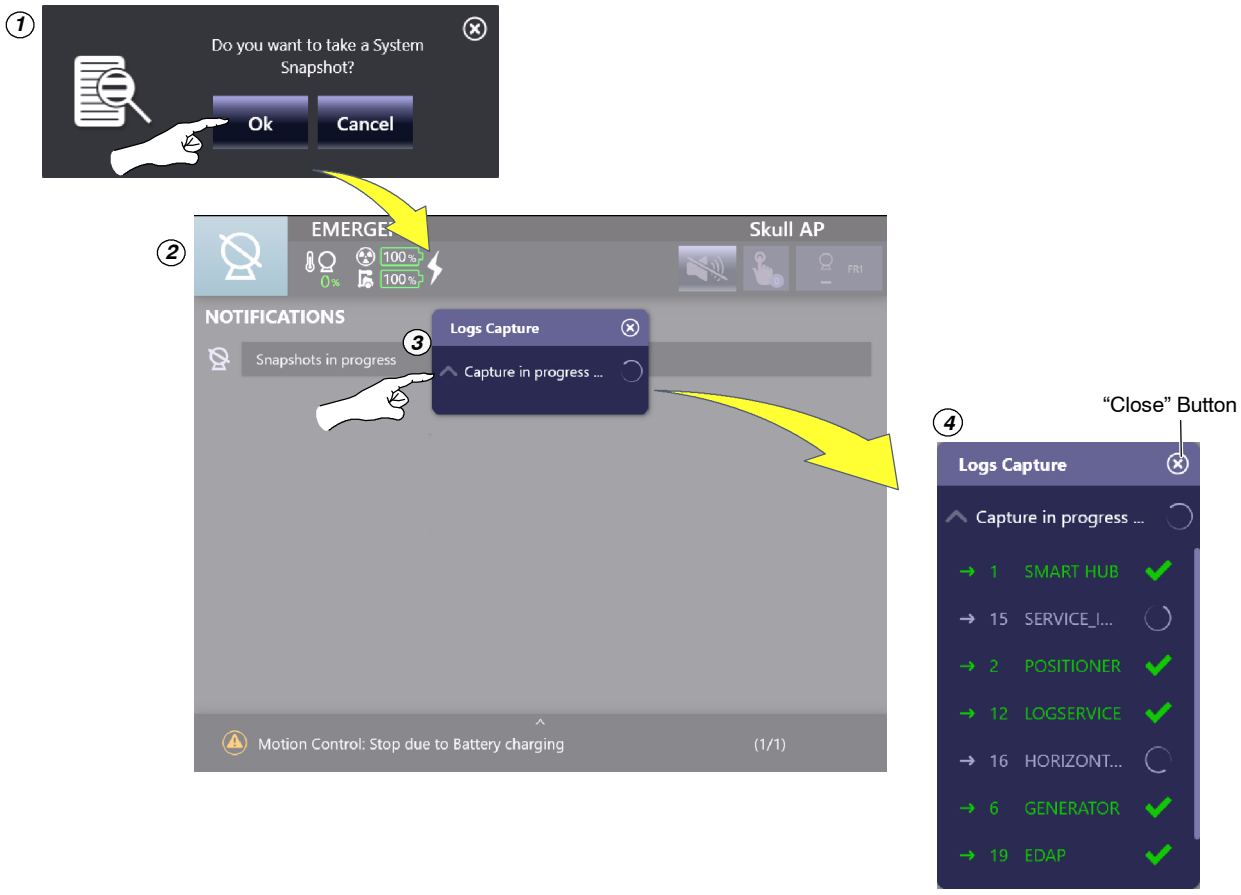
Illustration 4-15
Inhibit Conditions Messages

4.3.2 SYSTEM SNAPSHOT

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

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

Illustration 4-16
System Snapshot Confirmation and Logs Capture Window



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

- Logs export in progress, for that component.

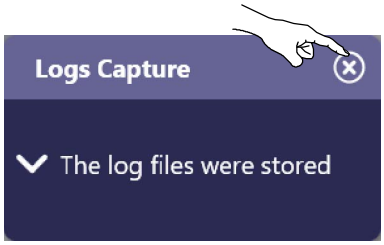
- Successful logs export, for that component.

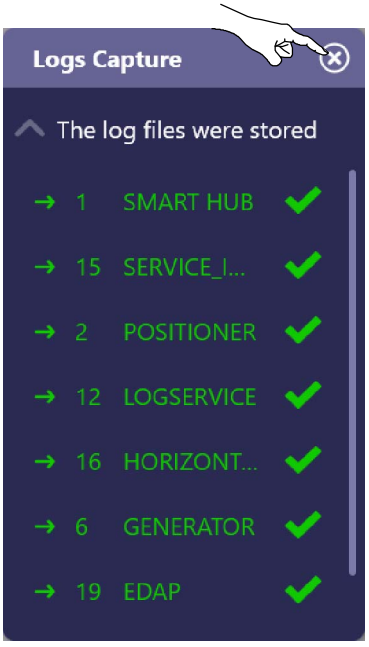
- Failed logs export, for that component.

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

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

Illustration 4-17
Exiting the Logs Capture Window





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

4.4 IMAGE PREVIEW (OPTION)

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

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

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

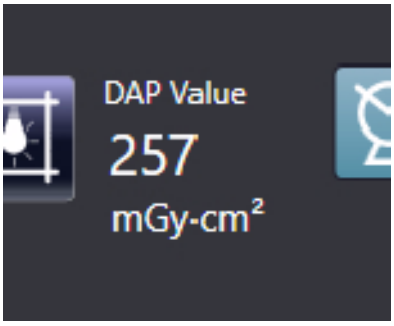
- After being displayed for 10 seconds, when the user modifies any parameter or selects a new procedure.
- When touching on the Head-Assembly Screen.
- When closing the X-ray exam.
- When pressing the X-ray Handswitch.

4.5 DOSIMETRY (OPTION)

The Dose shows the radiation value received by the patient. Radiation measure is read/estimated as *DAP (Dose Area Product)* value in *mGy*cm²* or *Skin Dose* value in *mGy*.

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

- **DAP Value in *mGy*cm²***: If the Unit is equipped with DAP Chamber (measured dose) or eDAP (estimated dose).
- **Dose Value in *mGy***: If the Unit is equipped with eDOSE (estimated dose).

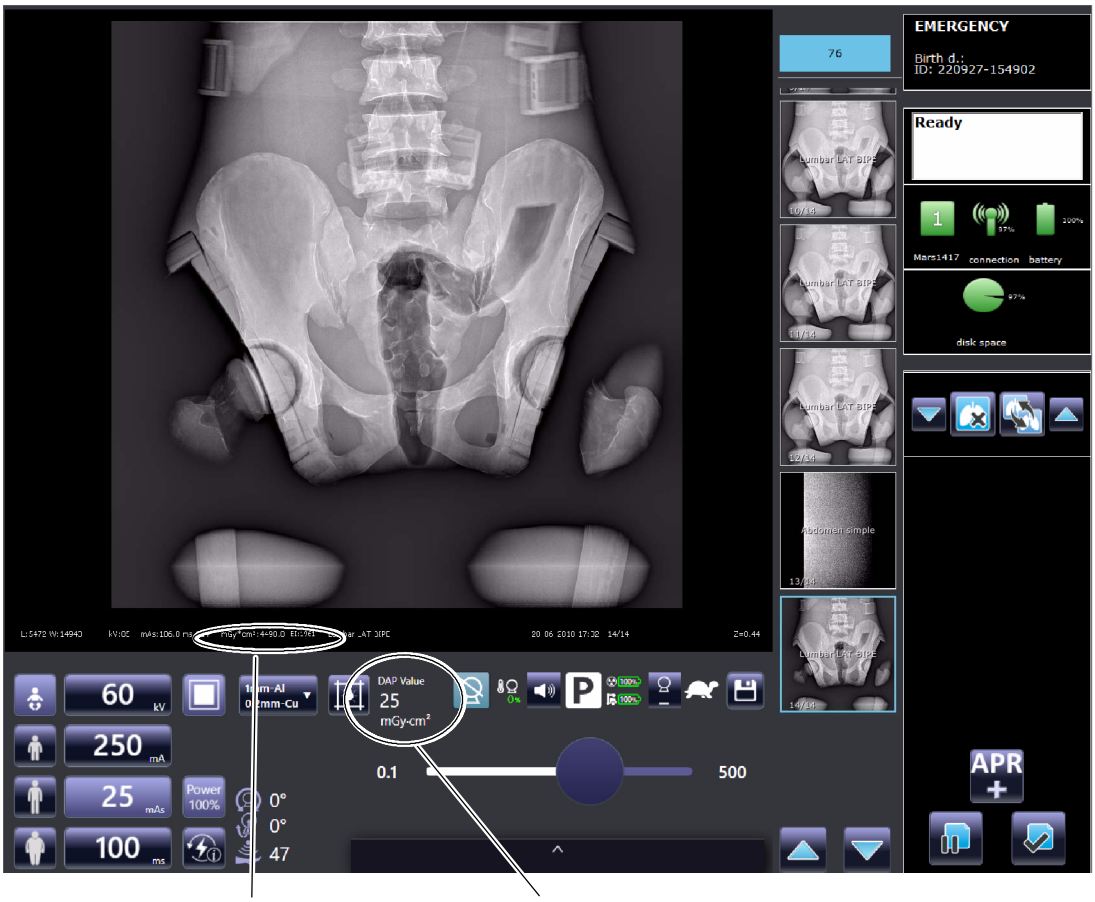


If the Dose value of the last exposure is retrieved by using the "*Post-Exposure*" button, it will be displayed in the same location but in yellow color (*refer to Section 4.1.6*).

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

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

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



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

Dose received by the patient
(including exposures in direct mode).
/
Dose of the last exposure (shown for 5 seconds)

The Dose shows the radiation value received by the patient. Radiation measure is read as DAP value (Dose Area Product) in mGy*cm^2.

SECTION 5 SYSTEM MESSAGES

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

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

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

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

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

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

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

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

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

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

ID	DESCRIPTION	TYPE	USER HELPTEXT
100002	One or more workstations are not properly configured; a default value has been assigned	Error	Press the “Accept” button. If the error code persists, turn the Unit OFF and ON. If the equipment remains inoperative, turn it OFF and call Service.
100005	The Exposure order input signal is active during the Startup sequence	Error	Generator will reboot after user confirmation. If the equipment remains inoperative, turn it OFF and call Service.
100006	The Preparation order input signal is active during the Startup sequence	Error	
100023	Error while writing in the E2PROM	Error	Turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Service.
100024	The timeout for the acknowledge for X-rays from the Bucky or FPD has been exceeded	Error	Press the “Accept” button. If the error code persists, turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Service.
100029	Generator heat capacity exceeded	Error	Turn the Generator OFF and wait 30 minutes before turning it ON again or decrease the exposure parameters. If the equipment remains inoperative, turn it OFF and call Service.
100031	The time stamp checksum is wrong	Error	Press the “Accept“ button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Service.
100032	I2C bus error while trying to access the Real Time Clock (RTC)	Error	Reboot the system and try to repeat the operation. If the error persists, call Service.
100035	The acknowledge for X-rays from the Bucky or FPD has been lost before the end of the exposure	Error	Press the “Accept“ button. If the error code persists, turn the Generator OFF, check the proper external cable connections and then turn the Generator ON. If the equipment remains inoperative, turn it OFF and call Service.
100037	Tube ratings exceeded or not enough Heat Units to perform the selected exposure	Error	Wait for the Tube to cool down or decrease the exposure parameters. If the equipment remains inoperative, turn it OFF and call Service.
100038	+5 V power supply failure	Error	Press the “Accept“ button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Service.
100039	+15 V power supply failure	Error	
100040	Imbalanced kVp, there is not the same voltage in Anode and Cathode branches	Error	
100041	Imbalanced mA, there is not the same current in Anode and Cathode branches	Error	

ID	DESCRIPTION	TYPE	USER HELPTEXT
100042	The counters checksum is wrong	Error	Press the “Accept“ button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Service.
100047	I2C bus error while trying to access the Licence	Error	Reboot the system and try to repeat the operation. If the error persists, call Service.
100049	The generator has lost the communications with the remote console	Error	Press the “Accept“ button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Service.
100050	The user has released the exposure device before the end of the exposure	Error	
100051	The selected exposure time cannot be achieved	Error	Reboot the system and try to repeat the operation. If the error persists, call Service.
100054	The timeout for receiving the Digital/DSI synchronism pulse has elapsed	Error	Press the “Accept“ button. If the error code persists, turn the Generator OFF and ON. If the equipment remains inoperative, turn it OFF and call Service.
100060	The number of exposures to autocalibrate a mA station has run out	Error	
100061	There has been an error while trying to access the Licence data. Default options have been selected	Error	
100063	The Ready from the starter has been lost before the end of the exposure	Error	
100065	+24 V Delayed power supply failure	Error	
100066	+24 V (UNR) power supply failure	Error	
100067	-15 V power supply failure	Error	
100068	+3.3 V power supply failure	Error	
100069	+24 V (UNR) permanent power supply failure	Error	
100071	Interlock error: Exposure aborted because an interlock has been deactivated during the exposure	Error	
100072	Exposure aborted by deactivation of Positioner-OK signal	Error	
100074	COP Generator Reset Error	Inhibit Exposure	Reboot the generator. If the error persists, call Service.
100075	CLK Generator Reset Error	Inhibit Exposure	

ID	DESCRIPTION	TYPE	USER HELPTEXT
100076	TRAP Generator Reset Error	Inhibit Exposure	Reboot the generator. If the error persists, call Service.
100077	Software Interrupt Generator Reset Error	Inhibit Exposure	Reboot the generator. If the error persists, call Service.
100078	Memory Interrupt Generator Reset Error	Inhibit Exposure	Reboot the generator. If the error persists, call Service.
100079	Required mA Stations Calibration Error	Inhibit Exposure	Reboot the generator. If the error persists, call Service.
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		
100259	Calibration Station cannot be performed	Error	Please check the tube and generator ratings.
100801	Procedure finished	Inhibit Exposure	-
100802	Waiting for detector	Inhibit Exposure	Waiting for detector
100803	Activated Procedure is not allowed	Inhibit Exposure	Change the exposure values or wait for the X-ray Tube to cool.
100910	Error in exposure_switches.xml file	Error	-
100920	workstations.xml has not been downloaded	Error	-

ID	DESCRIPTION	TYPE	USER HELPTEXT
100930	Tube file wrong format	Error	-
100921	image_receptors.xml has not been downloaded	Error	-
100922	exposure_switches.xml has not been downloaded	Error	-
100923	generator.xml has not been downloaded	Error	-
100924	Tube_1.xml has not been downloaded	Error	-
100926	uarc_workstations has not been downloaded	Error	-
100941	Current Image Receptor Synchronization Type is not supported. Please, select other workstation.	Error	-
100942	Preheating Filament	Information	Wait for 10 seconds.
100944	Maximum Preparation Time Reached.	Information	Remove preparation and exposure order.
101001	X-rays disabled	Inhibit Exposure	-
101002	Tube overload	Warning	Change the exposure values or wait for the X-ray Tube to cool.
101003	Tube thermostat	Warning	Wait for the Housing to cool. If there is a malfunction of the thermostat/pressurestat, replace it.
101004	Generator model overload	Warning	-
101007	INTERLOCK_1	Inhibit Exposure	-
101008	INTERLOCK_2		
101012	Positioner does not allow exposures. Moving. Interlock		
101014	Generator In Service Mode		
101015	Generator has not been calibrated yet	Information	-
101016	mA Station selected has not been calibrated	User Action	-
101017	Configurated Tube is different to Calibrated Tube	Information	-

ID	DESCRIPTION	TYPE	USER HELPTEXT
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	-
101022	Generator inactivity state, preheating filament	Information	Wait for 10 seconds.
101023	Upgrade is ongoing, xray disabled during this process	Information	-
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	-
101031	System will be reset due to license upgrade		
101032	Filaments disabled by inactivity		
101035	System is connected to mains	Inhibit Exposure	-
102001	Value requested exceeds generator power	Information	-
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		

ID	DESCRIPTION	TYPE	USER HELPTEXT
102009	APR warning	Information	-
102010	Generator thermal limit		
102019	Low speed configured. However, high speed option enabled by license		
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	Information	Call Service.
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		
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.
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		

ID	DESCRIPTION	TYPE	USER HELPTEXT
140310	Generator DSP Control. kV converter Overcurrent	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140311	Generator DSP Control. kV Overvoltage		
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	Error	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.
140322	Generator DSP Control. Overcurrent in small filament.		
140324	Generator DSP Control. Small Filament Current out of range		
140325	Generator DSP Control. Fault on small filament inverter.	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.		
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.
140350	Generator DSP Control. Master Heartbeat error.		
140351	Generator DSP Control. Emergency signal activated by master.		
140352	Generator DSP Control. Synchronism signal (exposure order) has been received before preparation signal.		
140353	Generator DSP Control. Filament current demand is out of range		
140354	Generator DSP Control. Frequency out of range.		
140356	Generator DSP Control. End exposure not detected		
140357	Generator DSP Control. Internal Status Fail		
140358	Generator DSP Control. Monoblock connector error		
140359	Generator DSP Control. mA out of range		
140360	Generator DSP Control. Power Control Calibration data error		
140361			
140362			
140363			
140364			
140365			
140366			
140367			
140368			
140369			
140370			

ID	DESCRIPTION	TYPE	USER HELPTEXT
140390	Generator DSP Control. Power Control Calibration data error.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140394			
140403	Generator DSP Control. Feedback KV error.	Error	Press Accept. Retake exposition. If error persists, restart the system. If error persists, call Service.
140408	Generator DSP Control. Overcurrent in the main inverter	Error	Press Accept. Retake exposition. If the error persists, restart the System. If the error persists, call Service.
140420	Generator DSP Control. ROTOR_UDC undervoltage	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140427	Generator DSP Control. Monoblock temperature error		
140428	Generator DSP Control. 24V Large Focus Fuse error		
140429	Generator DSP Control. 24V Small Focus Fuse error		
140430	Generator DSP Control. Large Focus Inductors Temperature error		
140431	Generator DSP Control. Small Focus Inductors Temperature error		
140460	Generator DSP Control. Main inverter minimum voltage warning	Warning	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140461	Generator DSP Control. mA Following error warning	Warning	Press Accept. Consider a filament calibration, call Service.
140462	Generator DSP Control. kV Following error warning	Warning	Press Accept. Review batteries and power stage, call Service.
140502	X-ray generator internal error.	Error	Restart the System. If the error persists, call Service.
140503			
140505			
140509			

ID	DESCRIPTION	TYPE	USER HELPTEXT
140510	Generator Starter. Tube Configuration. SpinUp Type Mismatch	Error	Call Service.
140511	X-ray generator internal error.	Error	Restart the System. If the error persists, call Service.
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.
140545	Generator Starter. Low Speed Acceration not allowed	Error	Reset error. If the error persists, restart the System. If the error persists, call Service.
140546	Generator Starter. High Speed Acceleration not allowed	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
140558	Generator Starter. Current Error.	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			
140582	Generator Starter. Order rejected by Tube HEAT Interlock	Error	Reset error. Wait for Interlock to be recovered. If error persists restart System. If error persists call Service.
140583	Generator Starter. Current Error.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140584	Generator Starter. Order rejected by DCBUS level	Error	Reset error. Wait for a moment to increase DCBUS Voltage. The interlock will disappear. If error persists, restart System. If error persists call Service.
140585	Generator Starter. Incompatible Tube Format	Error	Reload the tube data. If the problem persists, request the proper tube database.
140586	Generator Starter. Order rejected by configuration ONLY_LS	Error	The starter does not accept HighSpeed Order by Configuration. Call Service.
140587	Generator Starter. Current Error (main)	Error	Reset error. If error persists, restart System. If error persists call Service.
140588	Generator Starter. Current Error (aux)	Error	Reset error. If error persists, restart System. If error persists call Service.
140589	Generator Starter. Current Error.	Error	Press Accept. If the error persists, restart the System. If the error persists, call Service.
140590			
140591			
140592			
140593			
140594			
140595			
140599	Generator Starter. Error Mismatch.	Error	Unknown error type - Generator Starter. Error Mismatch
140612	Generator Starter Interlock.	Error	Wait until the message dissapears.
140613			

ID	DESCRIPTION	TYPE	USER HELPTEXT
140617	Generator Starter. MIN VOLTAGE interlock (DCBUS)	Inhibit Exposure	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		
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

ID	DESCRIPTION	TYPE	USER HELPTEXT
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	-
290402	Remote Handswitch is out of the placement longer than configuration time	Information	Return the remote Handswitch to its placement or click on “Accept button” to disable the warning.
290500	usability_setting.xml is outdated. Please, enter in service mode and update this file	Warning	-
290501	positioner_1.xml is outdated. Please, enter in service mode and update this file		
290700	Inhibit X-ray due to current RFID tag does not allow X-ray	Inhibit Exposure	
290701	Inhibit X-ray due to screen has been powered off		

ID	DESCRIPTION	TYPE	USER HELPTEXT
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.
290714	DAP value cannot be measured	Inhibit Exposure	If the message does not disappear after the start-up is finished, call Service.
290750	Dosemeter values have not been received from GPIO Head	Information	Try to repeat the operation. If the error persists, call Service.
290751	ExposureSoundOn Acknowledge Message has not been received from RFID Board	Information	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			

ID	DESCRIPTION	TYPE	USER HELPTEXT
291014	System communication error located in the battery monitor.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
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			
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			

ID	DESCRIPTION	TYPE	USER HELPTEXT
292004	Internal error located in the RFID.	Error	Restart the System and try to repeat the operation. If the error persists, call Service.
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.
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	Error	Restart the System. If error persists, call Service.
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		

ID	DESCRIPTION	TYPE	USER HELPTEXT
293012	Motion Control: Left 1 Force Sensor Error	Error	Restart the System. If error persists, call Service.
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		
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.

ID	DESCRIPTION	TYPE	USER HELPTEXT
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			
294018	Peripheral communication error located in the head.		
294019			
294020			
294021			
294023	Internal error located in the head.		
294027	Collimator Internal Error		
294028	Collimator Configuration Error		
294030	Dosimeter Internal Error		

ID	DESCRIPTION	TYPE	USER HELPTEXT
294031	Dosimeter Configuration Error	Error	Restart the System and try to repeat the operation. If the error persists, call Service
294032	Dosimeter Communication Error		
294033	Dosimeter restarted error.		
294039	Internal communication bus error located in the head.		
294040	Peripheral communication error located in the head.		
294041			
294046	Internal error located in the head.		
294050	Peripheral communication error located in the head.		
294051	Internal error located in the head.		
294053	Digital accelerometer error located in the head.		
294054	Internal error located in the head.		
294059			
300003	Switches configuration could not be loaded	Error	Call Service.
300006	Generator configuration could not be loaded		
300007	Workstations configuration could not be loaded		
300008	Image receptors configuration could not be loaded		
300009	Positioner disconnected	Error	If the 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

ID	DESCRIPTION	TYPE	USER HELPTEXT
300013	Active Procedure mismatch for Generator and Positioner	Error	Try to select another workstation or another radiographic procedure. If the error persists, restart the System and try to repeat the operation. If the error persists, call Service
300014	Positioner configuration could not be loaded	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		
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		
300028	Calibration in progress	Inhibit Exposure	No exposures are allowed until the calibration is finished.
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.
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.
300039	Processing Downloader. This action can take several minutes, please wait	Information	-

ID	DESCRIPTION	TYPE	USER HELPTEXT
300040	Downloader finished with error code {0}	Information	-
300041	Downloader finished successfully	Information	-
301000	EDAP is not calibrated	Warning	EDAP calibration is needed. Call Service.
301001	DAP value cannot be estimated	Inhibit Exposure	Check for other active messages related to DAP estimation.
301002	DOSE value cannot be estimated	Inhibit Exposure	Check for other active messages related to Skin Dose estimation.
301003	EDAP estimation out of range, please recalibrate	Warning	EDAP calibration is needed. Call Service.
301004	EDAP is not available for these configuration settings	Warning	The Unit settings need to be modified. Call Service.
301005	No license available for DAP estimation	Warning	Request a valid license for this functionality.
301006	Wrong positioner configuration. Cannot estimate Dose	Warning	The Unit settings need to be modified. Call Service.
301007	Wrong positioner configuration. Cannot estimate DAP	Warning	The Unit settings need to be modified. Call Service.
301008	Wrong eDAP calibration value for No filter	Error	It is necessary to repeat the calibration process exposure. Call Service.
301009	Wrong eDAP calibration value for 2mm Al Filter	Error	It is necessary to repeat the calibration process exposure. Call Service.
301010	Wrong eDAP calibration value for 2mm Al+0.2mm Cu Filter	Error	It is necessary to repeat the calibration process exposure. Call Service.
301011	Wrong eDAP calibration value for 2mm Al+0.1mm Cu Filter	Error	It is necessary to repeat the calibration process exposure. Call Service.
301012	Dose values cannot be estimated for this procedure type	Information	Select another RAD Technique from the Acquisition Software.
301013	Restore aborted: system is ciphered and all tags are not ciphered in database	Error	Please, repeat the backup procedure.
301014	Restore aborted: system is not ciphered and all tags are ciphered in database	Error	Please, repeat the backup procedure.

ID	DESCRIPTION	TYPE	USER HELPTEXT
500004	Selecting technique	Inhibit Exposure	-
500008	Generator parameters modified	Information	
500012	There is no workstation configured for this request		
500014	Technique not loaded in generator	Inhibit Exposure	Check the APR settings and configuration for this technique.
500015	Detector not ready for exposure	Inhibit Exposure	Check the detector is charged and on. Only exposures in film mode are allowed if pressing Accept and change the workstation to film.
500016	Error loading APR Technique, please retry.	Inhibit Exposure	Check that the workstation and workspace names matches. Check the APR settings and configuration for this technique.
500020	APR settings not defined	Inhibit Exposure	Please, check APR settings
500022	Console not available	Inhibit Exposure	Restart the System and try to repeat the operation. If the error persists, call Service.
500024	Please, reselect technique	Inhibit Exposure	Try to select another technique or another radiographic procedure. If the error persists, restart the System and try to repeat the operation. If the error persists, call Service.
500025	Please, select a protocol from Image System	Inhibit Exposure	-
500033	eDAP not available	Information	No user action required.
500037	Please review last RFID card operation	Error	Try to repeat the operation. If the error persists, call Service.
500043	Please, press the handswitch to start the exposure	Information	Please, press the handswitch to start the exposure.
500044	Image System not available	Inhibit Exposure	Image System not available, restart the System. If the problem persists, call Service.

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SECTION 6 OPERATING SEQUENCES

6.1 X-RAY TUBE WARM-UP PROCEDURE

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

Do not perform routine exposures unless the Tube is previously warmed-up, to preserve an optimal X-ray Tube life.

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

This warm-up procedure is used for a typical X-ray Tube. 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.

WARNING

ALWAYS SELECT THE CORRECT FIELD SIZE TO AVOID EXCESSIVE RADIATION.

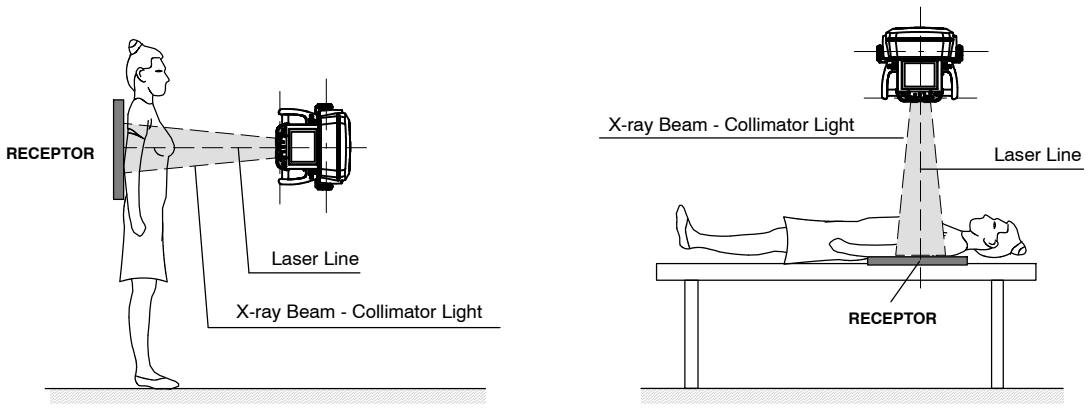
WARNING

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

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

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

Illustration 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

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

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

Tasks for a proper maintenance of the batteries:

- Recharge the batteries for at least 30 minutes at the beginning of the day before using the unit.
- Recharge the batteries for at least 30 minutes at the end of the day after using the unit.

- 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 BLEACH, AMMONIA OR ANY OTHER ABRASIVE OR SOLVENT LIQUID, IT COULD CAUSE DAMAGE TO THE EQUIPMENT.

7.2 SERVICE TASKS

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

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SECTION 8 TECHNICAL SPECIFICATIONS

8.1 FACTORS

Maximum Power kW *(Refer to Identification Label)*	**20 kW**	**32 kW**	**40 kW**	**50 kW**
kVp Range	40 kVp to 150 kVp			
	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		10 to 500 *(10 to 630)**
	From 10 mA to 500 mA or 630 mA, through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630. *(Depending on the Generator model)* **(with X-ray Tube Insert XRR3331)*			
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, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630, 800. Seconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.3, 8, 10. Maximum Exposure Time Range for DR: From 1 millisecond to 2.5 seconds.			
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 *(79 kVp @ 630 mA)**
	**(with X-ray Tube Insert XRR3331)*			
Duty Cycle	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 different options depending on the Collimator model)* *Refer to Section 3.7*			
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

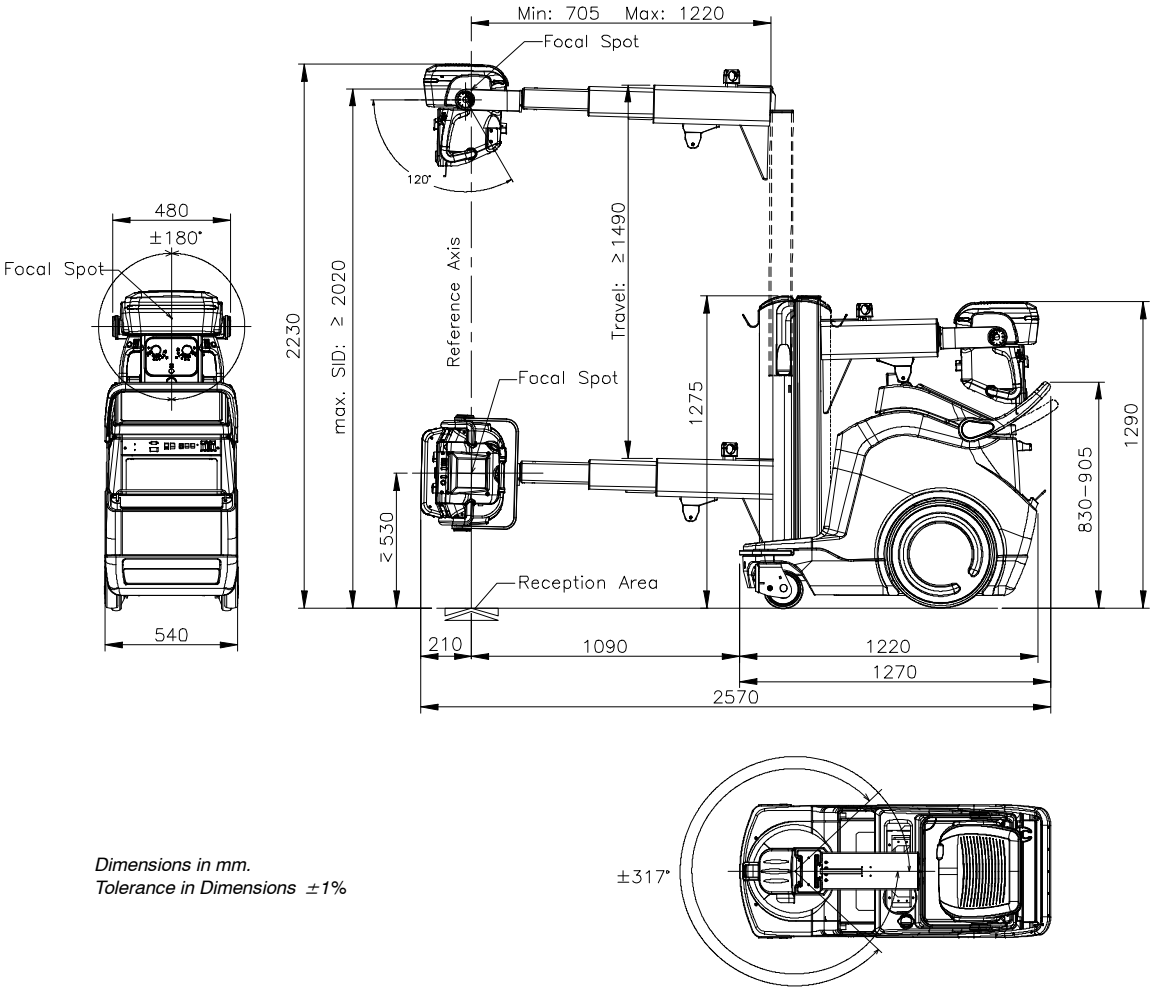
Maximum Power kW *(Refer to Identification Label)*	**20 kW**	**32 kW**	**40 kW**	**50 kW**
X-ray Tube Inserts	E7886 Low Speed / High Speed			E7886 High Speed
	XRR3331 Low Speed / High Speed			

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

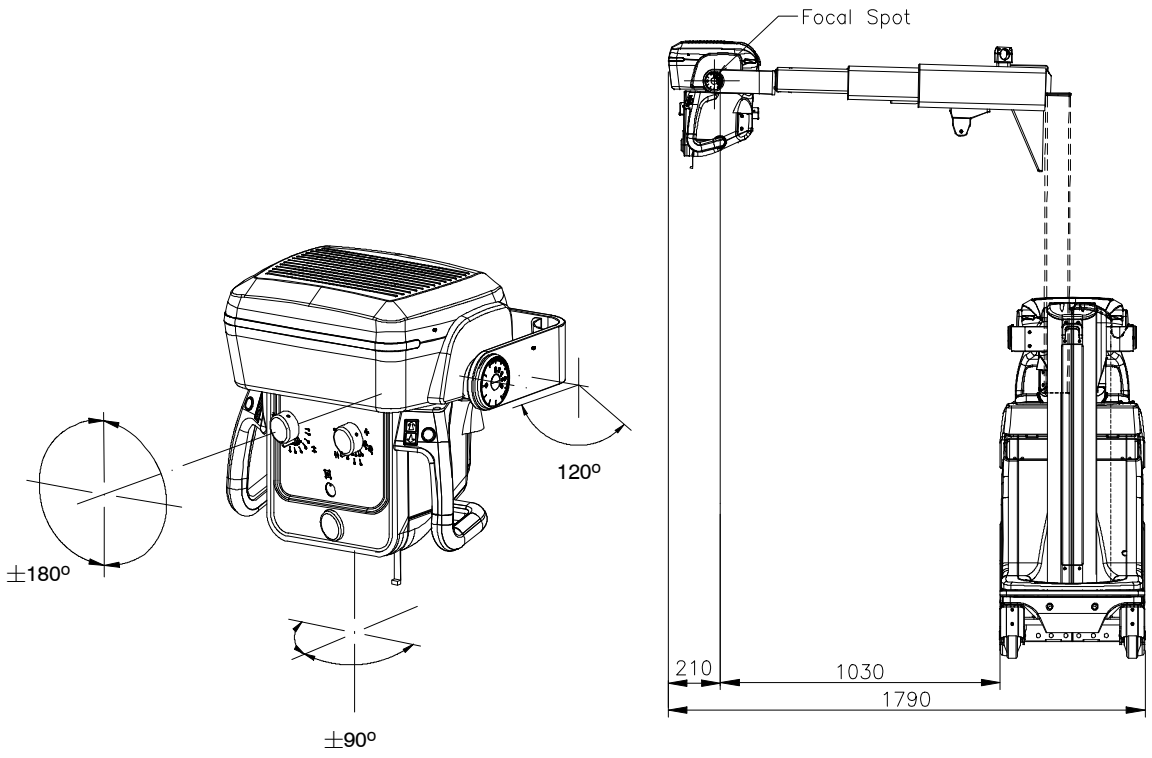
8.3 PHYSICAL CHARACTERISTICS

8.3.1 MOBILE UNIT WITH 3-SECTIONS ARM

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



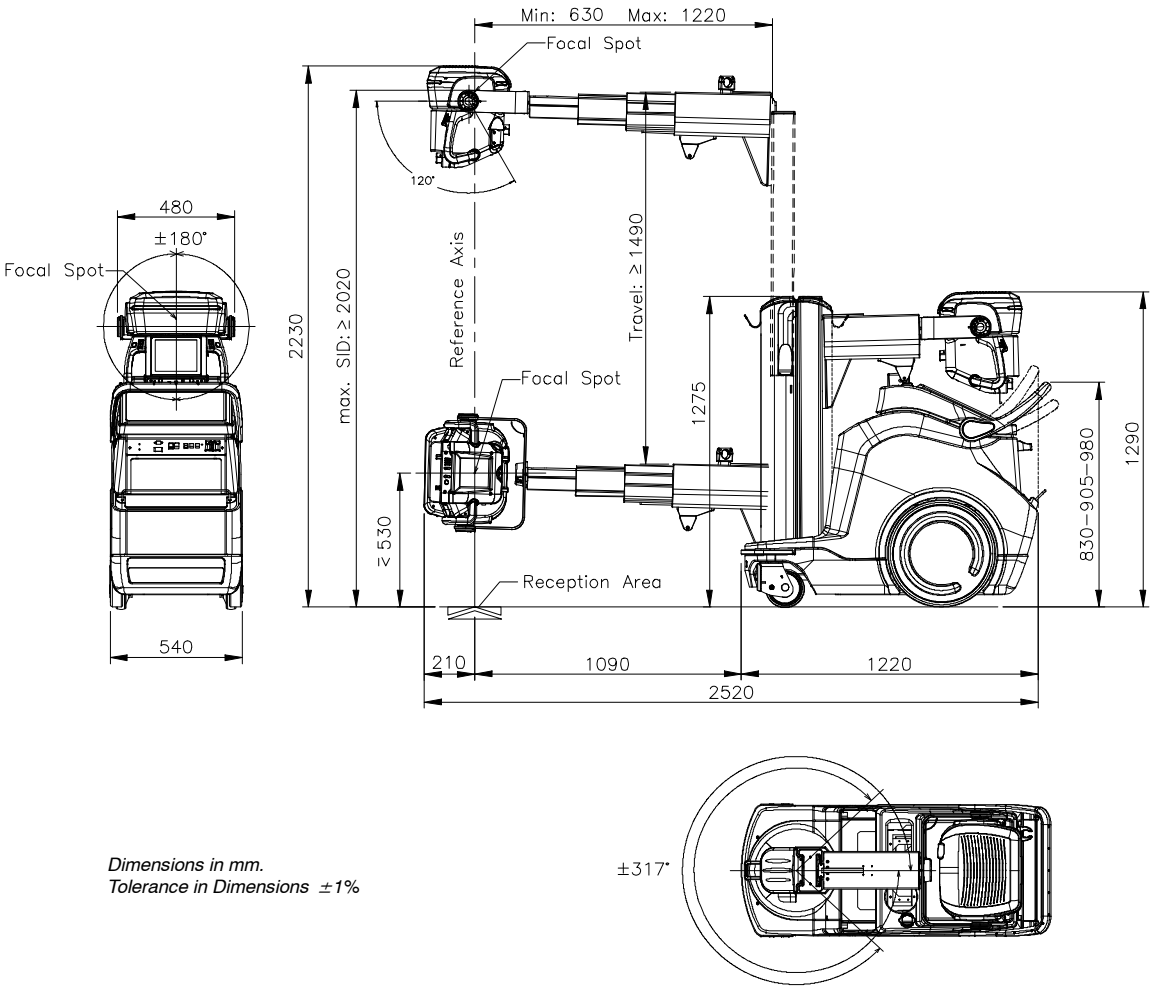
Dimensions in mm.
Tolerance in Dimensions ±1%



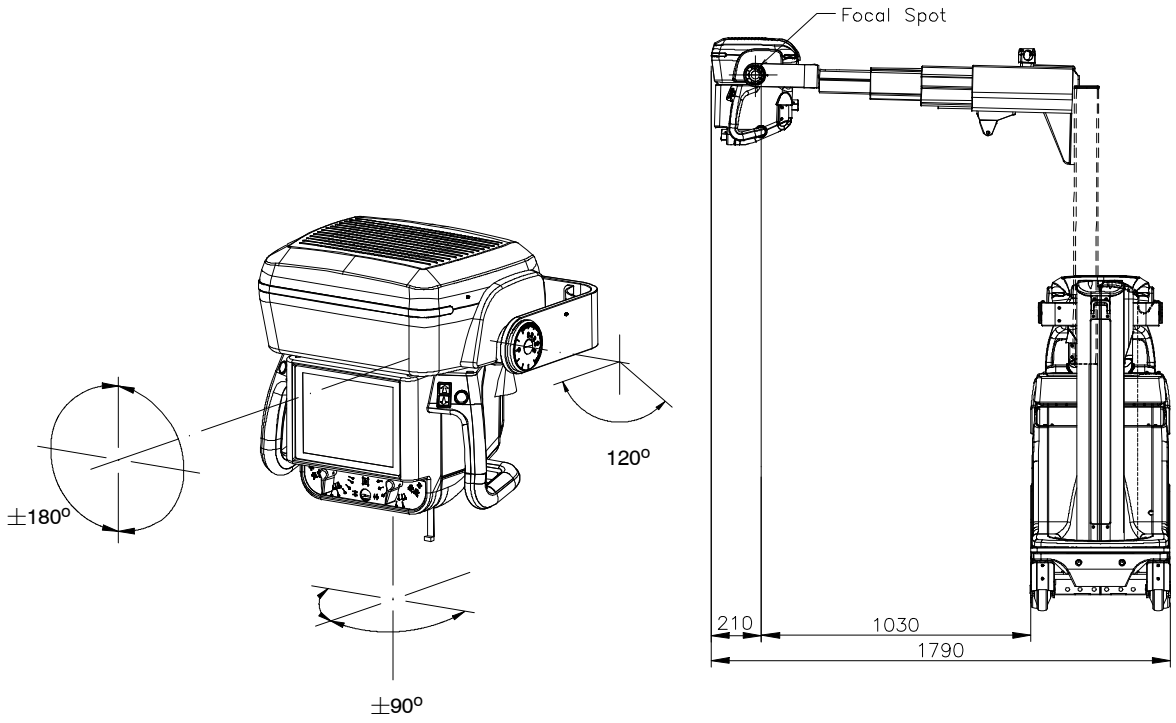
Dimensions in mm.
Tolerance in Dimensions ±1%

8.3.2 MOBILE UNIT WITH 4-SECTIONS ARM

LENGTH	WIDTH	HEIGHT	WEIGHT
minimum 1220 mm (48”) maximum 2520 mm (99.2”)	540 mm (21.3”)	minimum 1290 mm (50.8”) maximum 2230 mm (87.8”)	520 kg (1145 lbs) (without Detectors and/or 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 (WITH 4-SECTION ARM ONLY)

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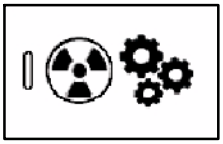
C.1 INTRODUCTION

Administrator users have permissions to access certain system settings from 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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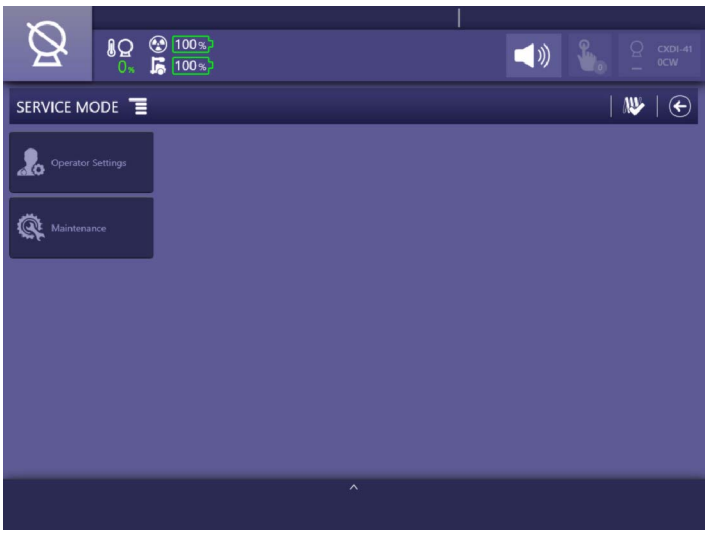
C.2 ADMINISTRATOR MENU

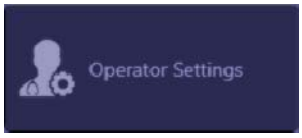
C.2.1 ENTERING ADMINISTRATOR MENU

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 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.

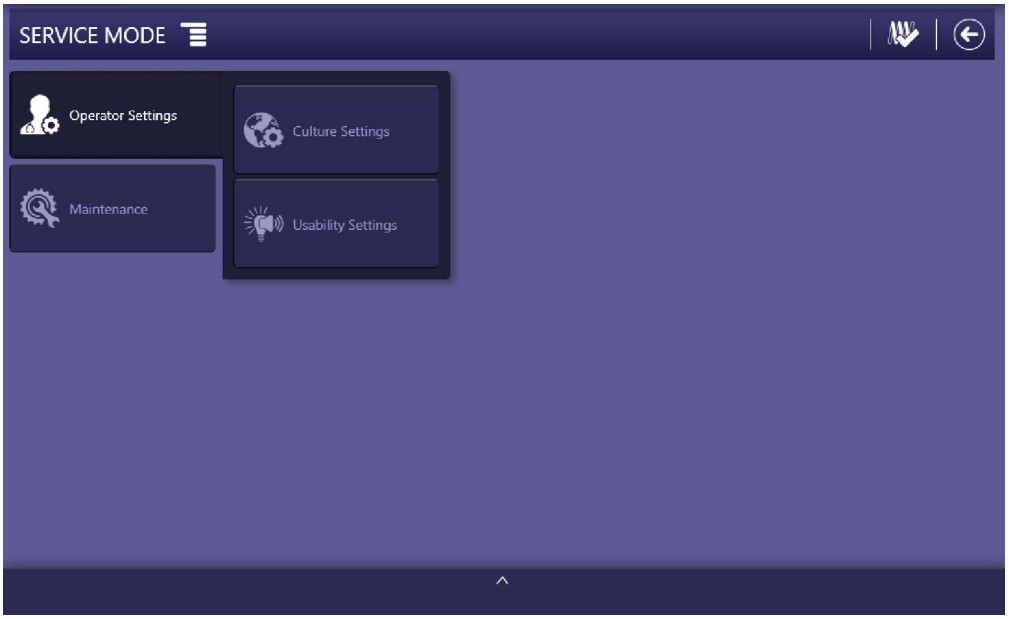
Note ☞ *All the other buttons and indicators on the upper toolbar (common in the Operation Mode) are described in Section 4 of the Operation Manual.*

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



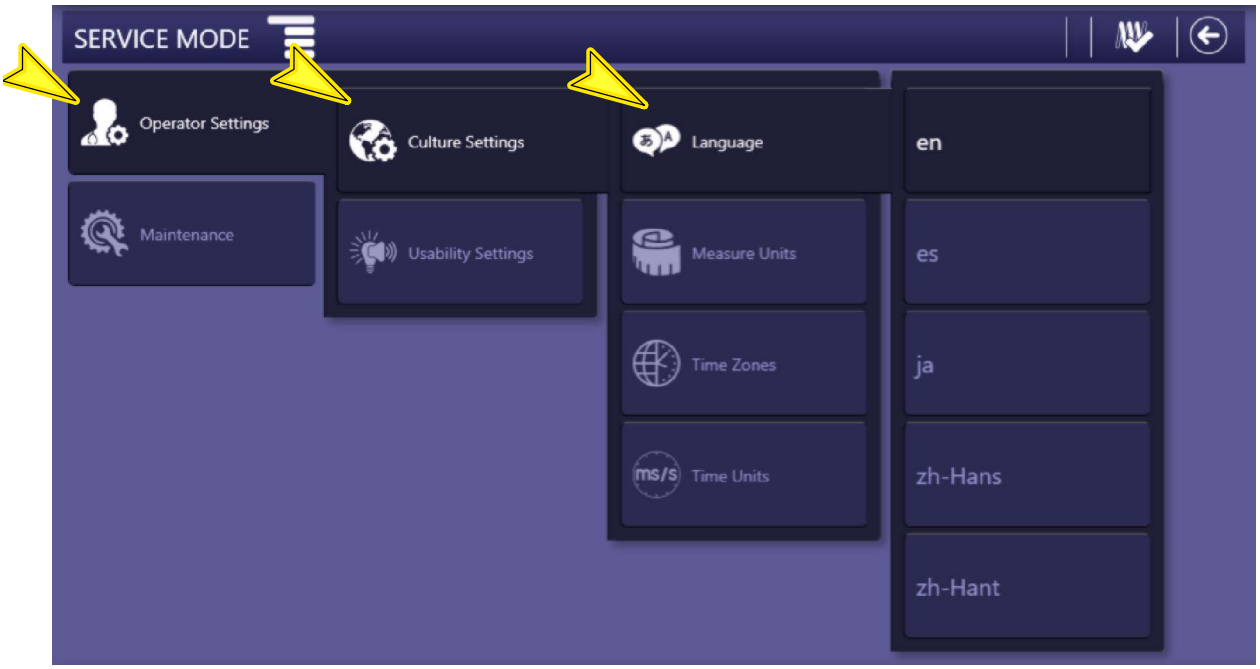
C.2.3.1 CULTURE SETTINGS

▶ **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

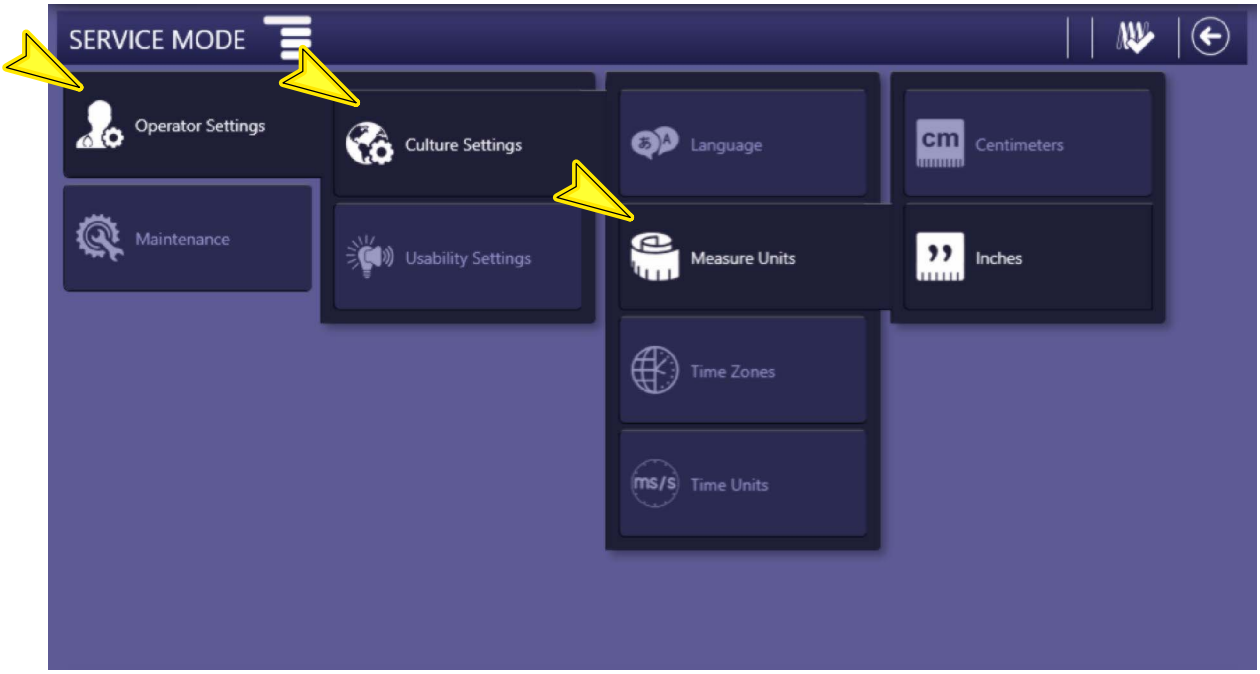


▶ MEASURE UNITS

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.

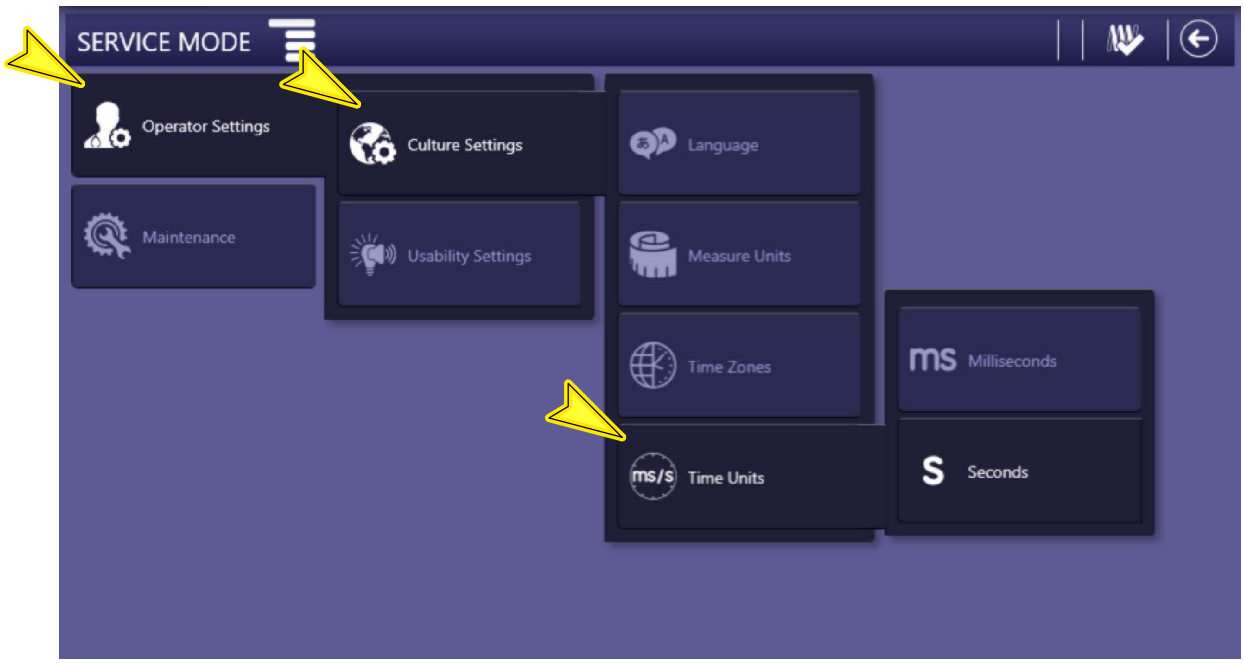
Illustration C-4
Time Zone Selection

▶ TIME UNITS

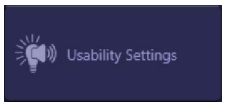
Use the “Time Units” menu to select “Milliseconds” or “Seconds” as the time unit in the exposure parameters.

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

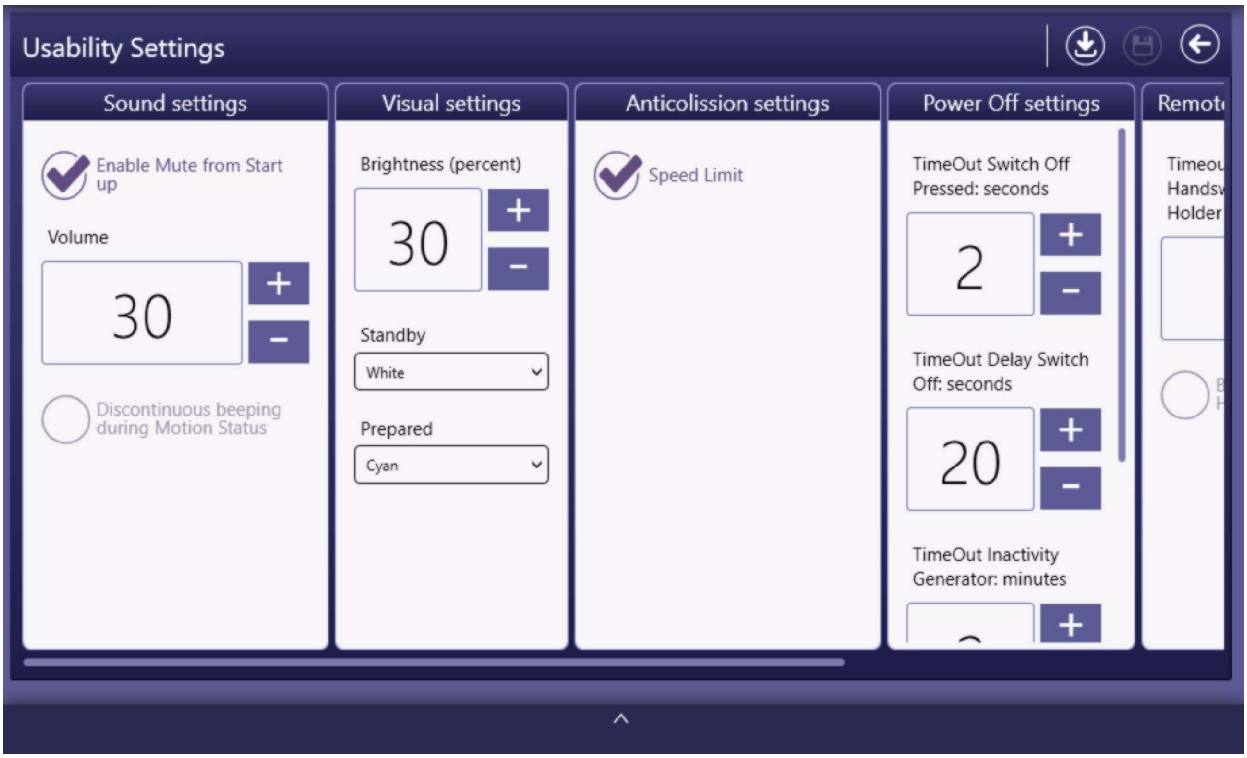


C.2.3.2 USABILITY SETTINGS



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: 60 seconds.

After holding pressed for 3 seconds the *Switch OFF* button, the system will be completely turned OFF in 60 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 configured time: 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 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 configured time: 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/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.

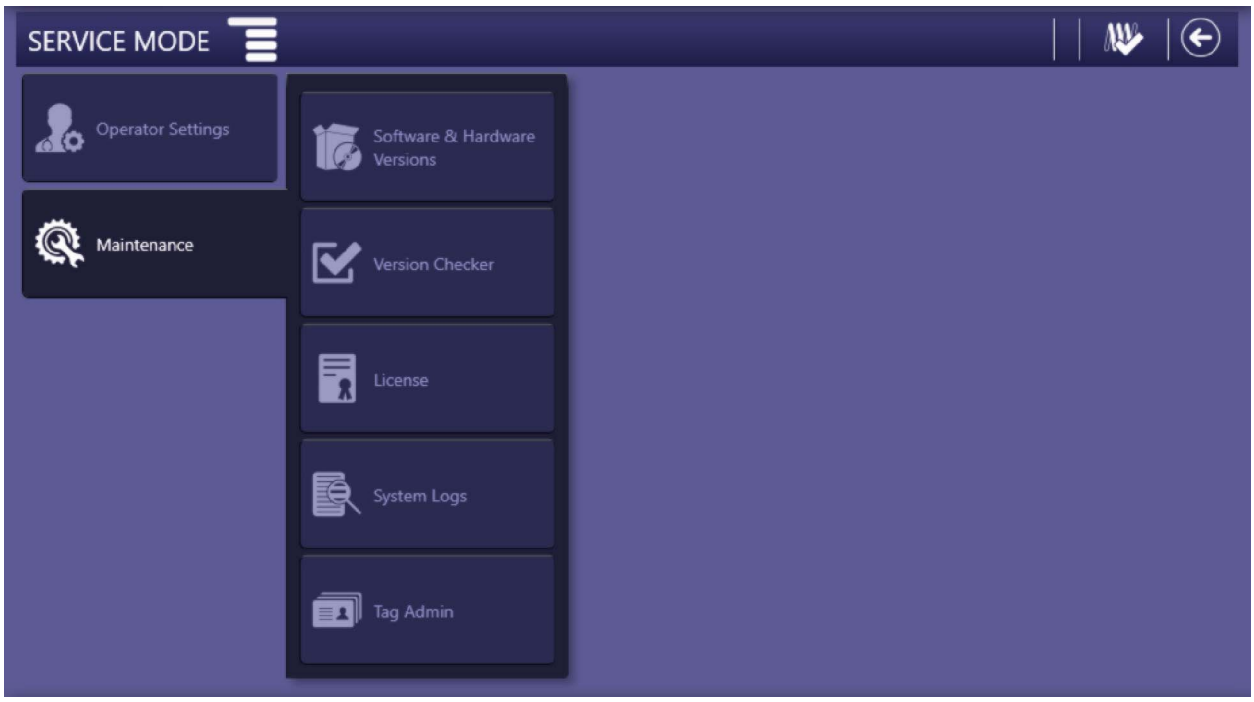
Disabled by default.

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.

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.

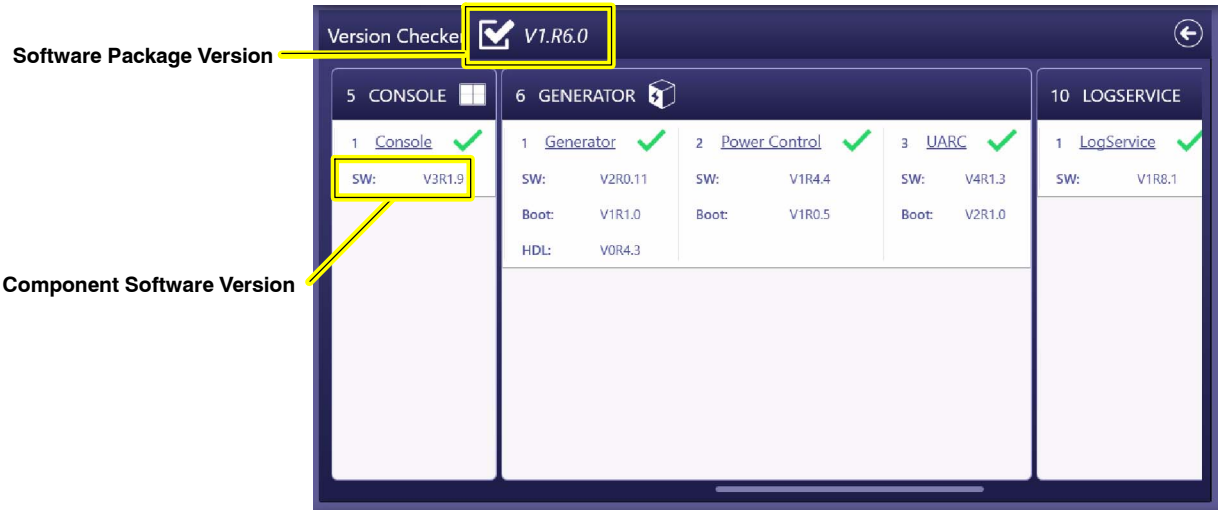
Illustration C-8
Software / Hardware Versions Screen

C.2.4.2 VERSION CHECKER

The “Version Checker” functionality enables to check the software versions of the different equipment components (PCBAs, Consoles, Acquisition Software, etc.) to ensure they match with the installed software package version.

The “Version Checker” window displays the versions of the software components and their matching with the installed software package version.

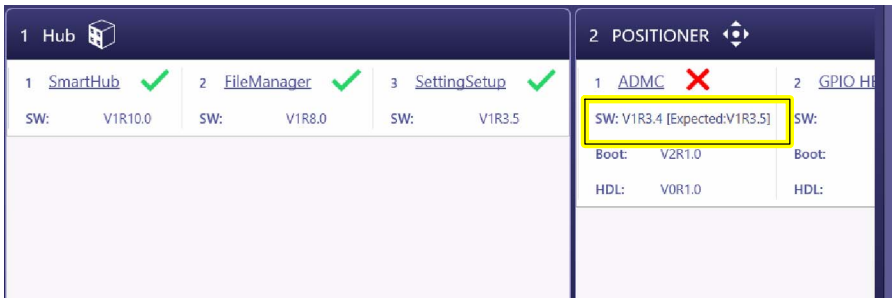
Illustration C-9
Version Checker



A green check mark will indicate that the component software version matches the corresponding version of the installed software package.

On the contrary, a red cross icon will indicate that there is no match between the component and the software package, and the expected software version for that component will be displayed.

Illustration C-10
Version Matching



In some cases, the software for a component that has not been properly updated may not be listed in the “Version Checker” window. Check the component listing to verify that all components are being displayed

The *components* to be displayed in the “Version Checker” window are:

- 1 HUB
  - *SmartHub*
  - *FileManager*
  - *SettingSetup*
- 2 POSITIONER
  - *ADMC*
  - *GPIO HEAD*
  - G*PIO ON/OFF*
- 5 CONSOLE: (*Console*)
- 6 GENERATOR
  - *Generator*
  - *Power Control*
  - *UARC*
- 9 SERVICE_TOOL: (*ServiceTool*) – *[Only if running]*
- 10 LOGSERVICE: (*LogService*)
- 19 EDAP: (*Console*) – *[If installed]*
- *[Acquisition Software Integration components] – [Only if running]*

Note ☞ *These components can also be checked in the “Software / Hardware Versions” window. Refer to Section C.2.4.1.*

Once the version check is complete, press the “Back” button to go back to the main menu.

C.2.4.3 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-11
License Screen

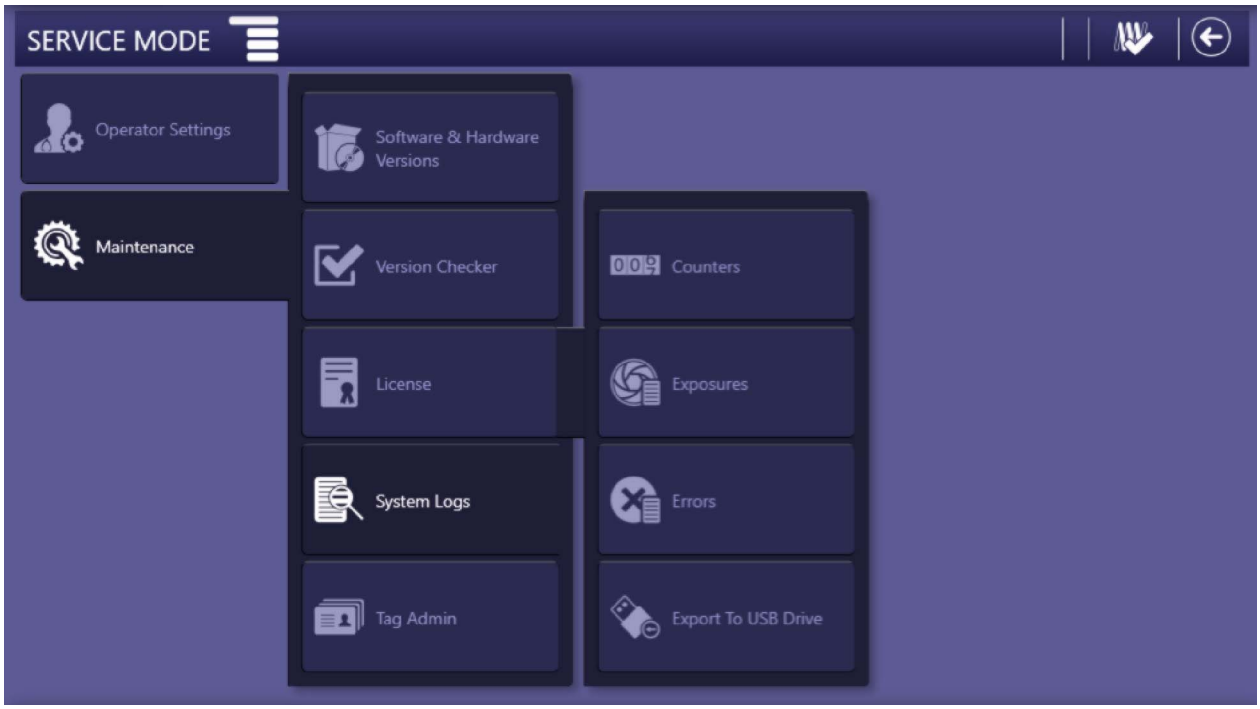
Note ☞ *To use an external dosimeter, the “DAP” license must display ”Dosimeter”.*

To operate with the eDAP/eDOSE functionalities, the “DAP” license must display “Estimated”.

C.2.4.4 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-12
System Logs Menu



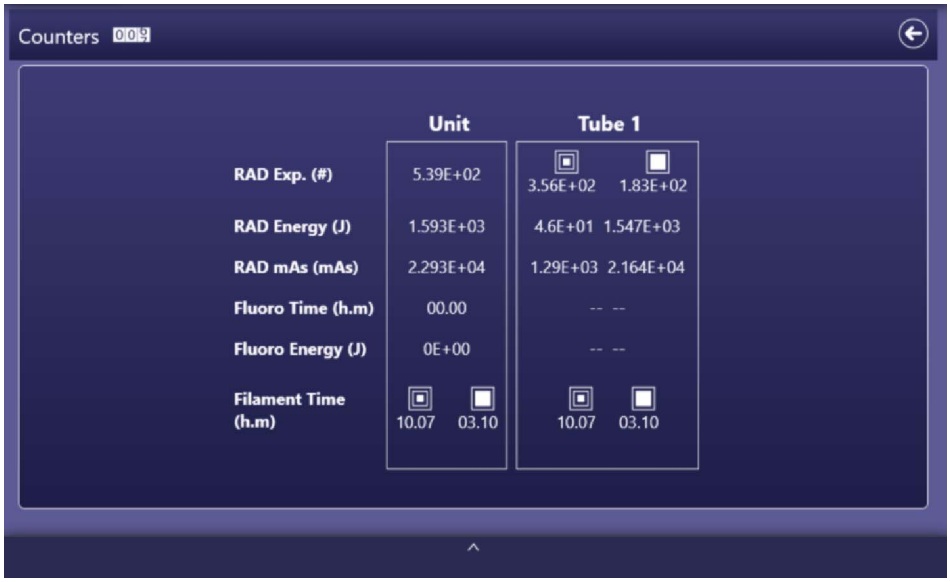
The available options are:

- **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-13
Counters

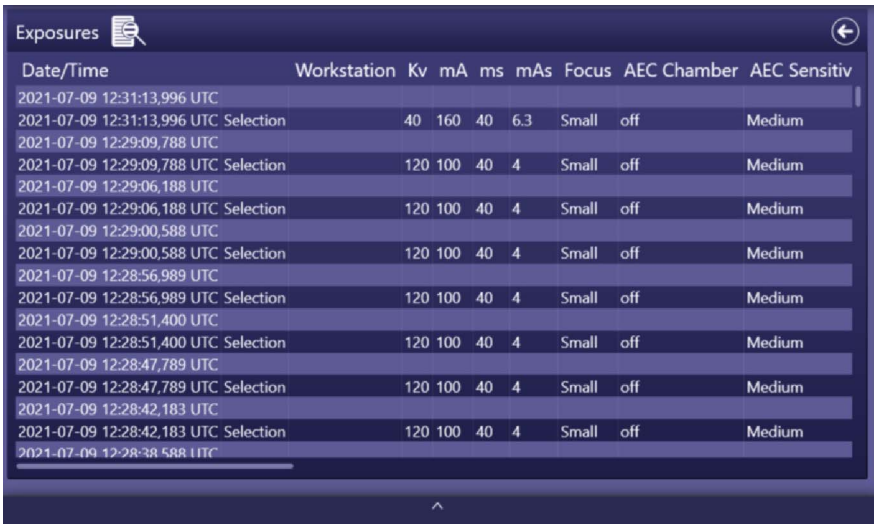


Note ☞ *The values are displayed in Scientific E Notation.*

- **Exposures**

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

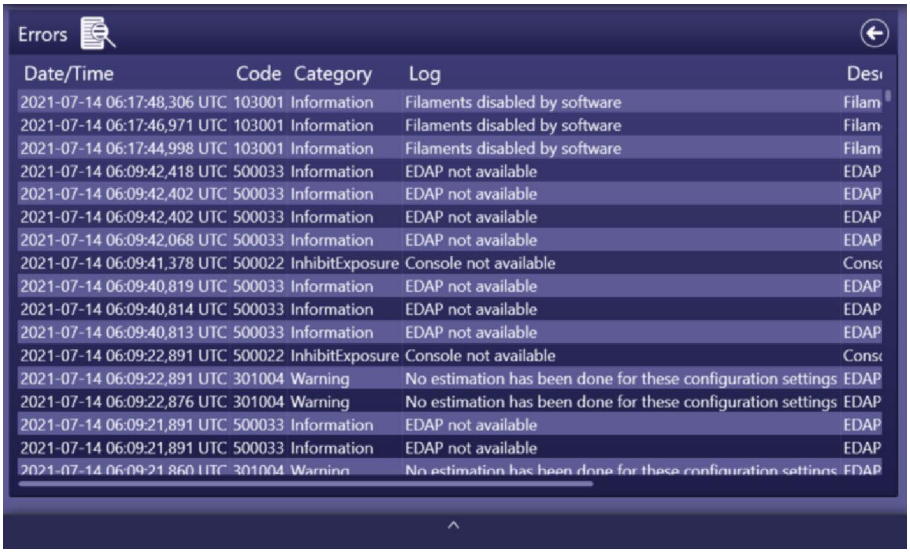
Illustration C-14
Exposures



- **Errors**

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

Illustration C-15
Errors

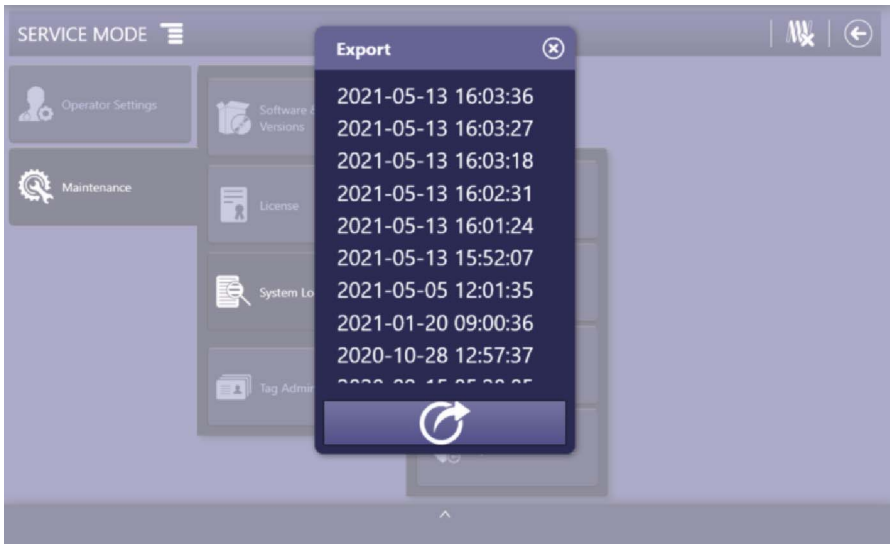


Note ☞ *The generation of error log files (System Snapshot) is available in the Message History window of the Operator Mode (refer to Operation Manual for further details).*

- **Export to USB Drive**

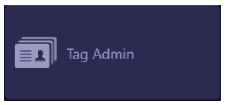
  Use this functionality to export the log files to a USB flash drive. (This option is only available when an operating memory stick is connected to a USB port).

Illustration C-16
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.2.4.5 TAG ADMIN

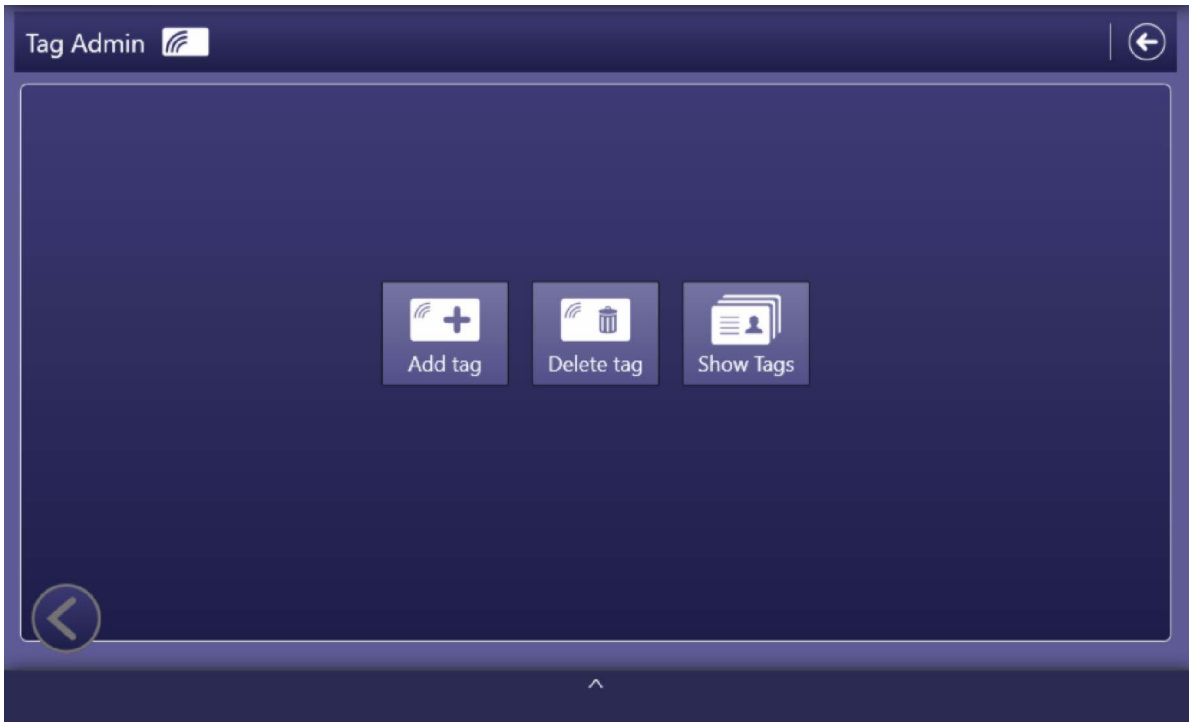


The “Tag Admin” screen enables the local tags (RFID Cards) management used to initiate the system and access it with the privileges assigned to them.

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 corresponding Acquisition Software.*

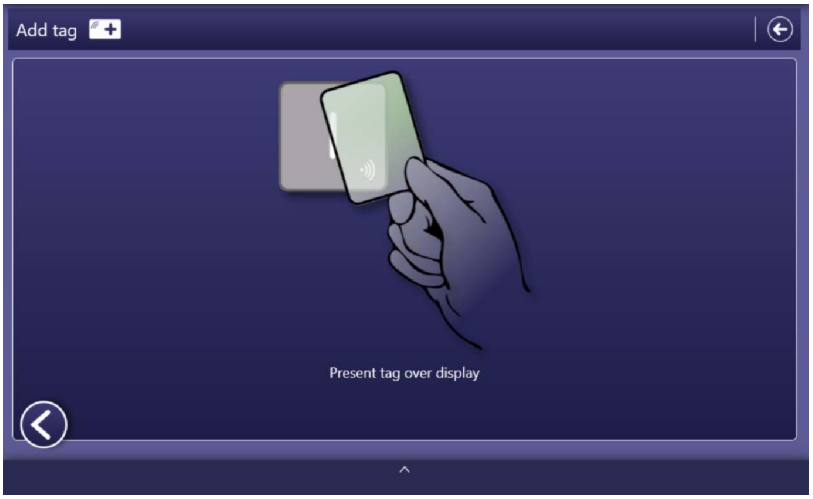
Illustration C-17
Tag Admin Window



ADDING A NEW TAG

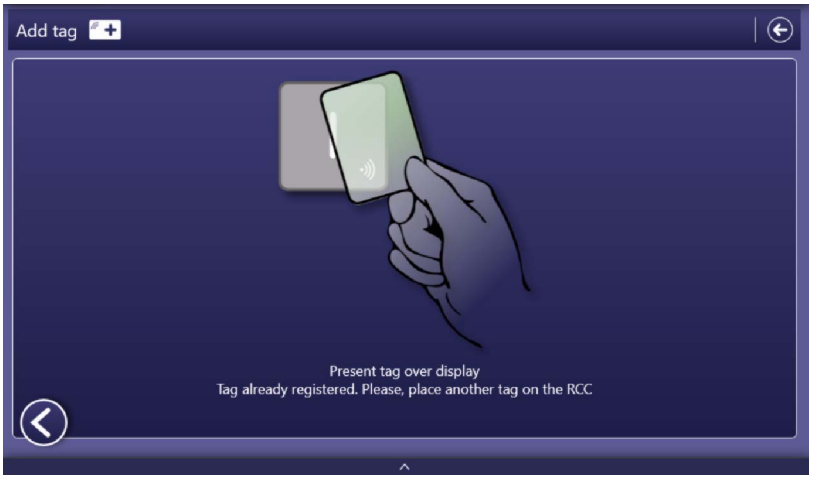
1. Press on the “Add tag” button. Swipe the RFID card through the RCC reader to register the tag, according to the instructions in the new window displayed.

Illustration C-18
Add Tag Window



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

Illustration C-19
Tag Already Registered Message



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

Illustration C-20
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:**

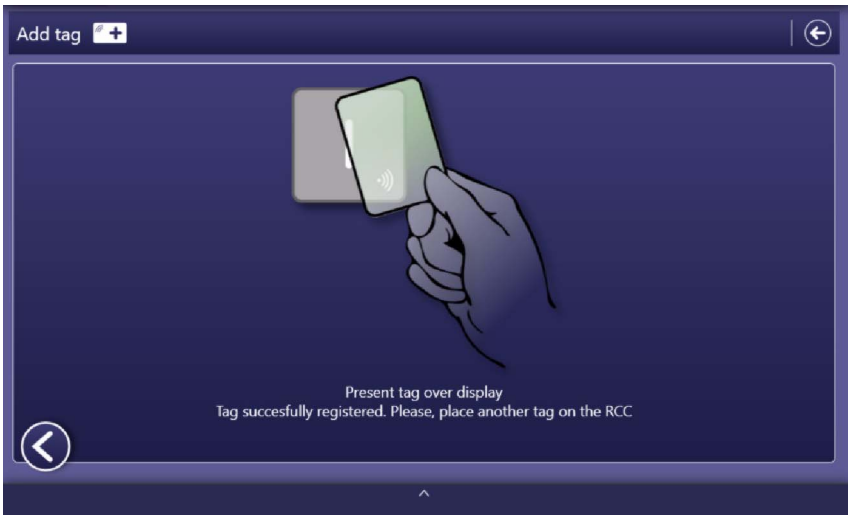
  It allows the user to perform any action needed for Radiographic Operation.

- **Admin:**

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

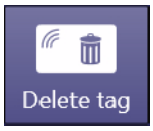
3. Press the “Store” button to register the tag. If the registration is successful, a message will be displayed in the previous window.

Illustration C-21
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.



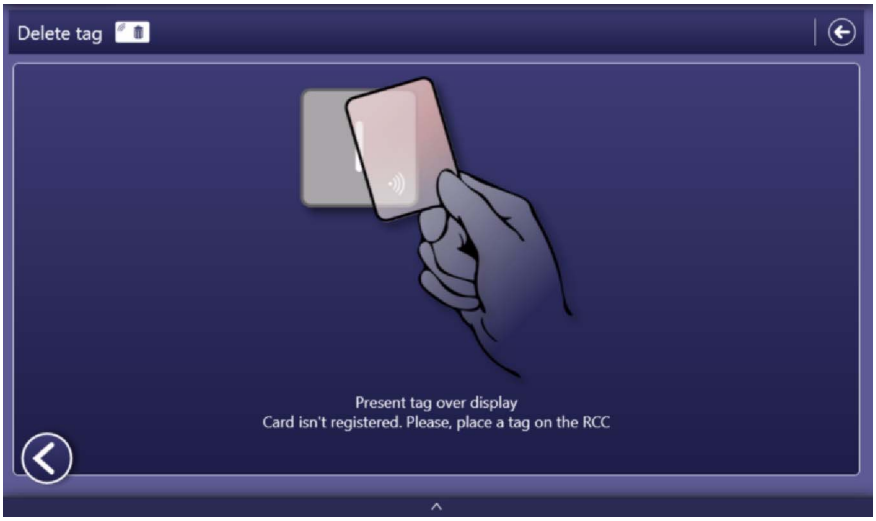
DELETING A TAG

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-22
Delete Tag Window

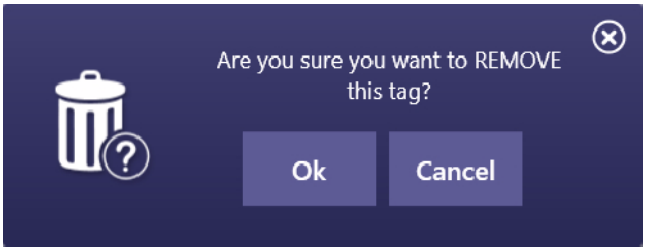
If the entered card has not been previously registered in the RFID tag record, the following message will be displayed:

Illustration C-23
Tag Not Registered Message



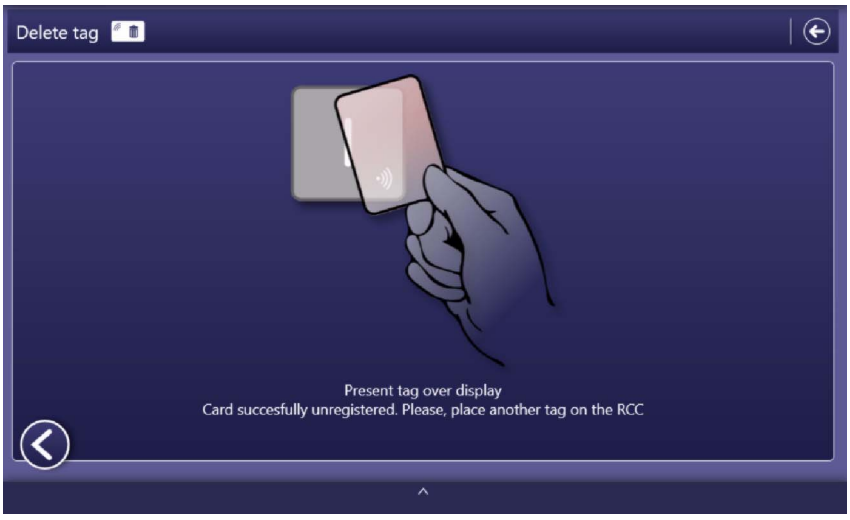
2. A pop-up window requests confirmation of the tag unregistration.

Illustration C-24
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-25
Tag Deletion Confirmation Message

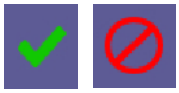


4. Now it is possible to delete other tag or press the “Previous Step” button to return to the Tag Admin menu.

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-26
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.

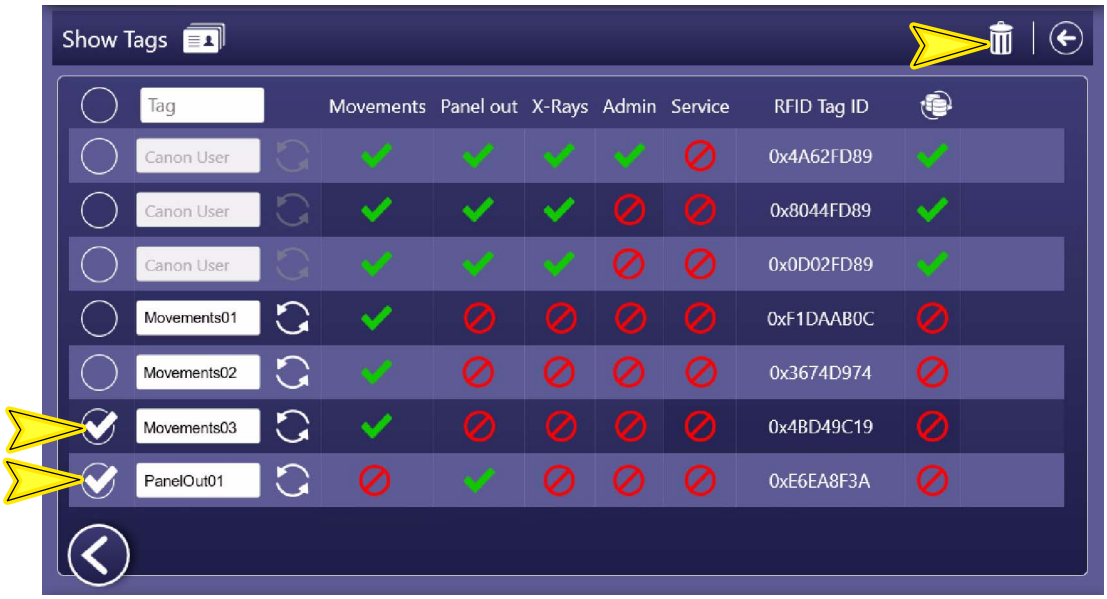
REMOVING MULTIPLE TAGS

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.*

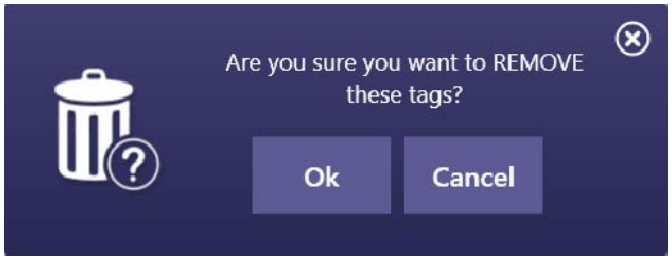
2. Once selected, press the “Trash” button to proceed.

Illustration C-27
Removing Tag(s) - Selection and Trash Button



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

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

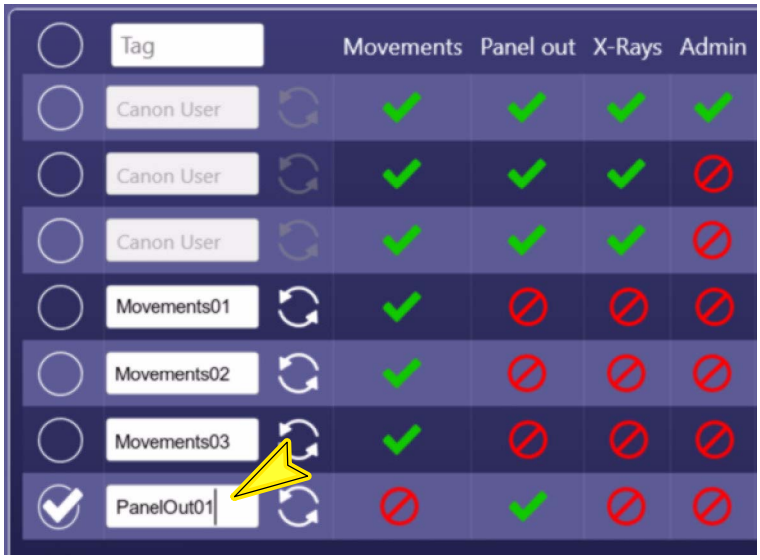


RENAMING TAGS

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.

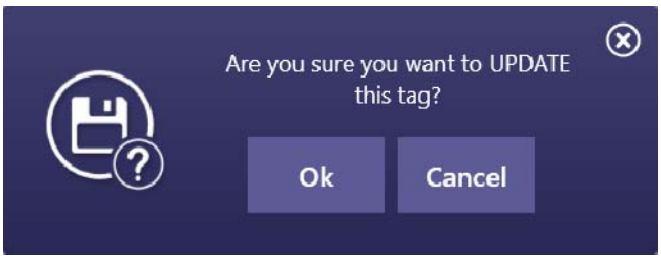
Illustration C-29
Renaming Tag



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-30
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.

primax
INTERNATIONAL

RAYBOW XE

GENERATOR

TXP32

Dedicated to patient care, our advanced generator technology is housed in a compact and modular design with the following benefits:

- **Constant Potential High-Voltage Generator** with all advantages, including lower patient dose, shorter exposure times as well as greater accuracy and consistency.
- Monoblock **without high voltage cables**.
- Minimum rise & fall time in kV for higher patient protection.
- The Unit is controlled by multiple microprocessors for a better exposure consistency, efficiency in operation and an extended tube life.
- Independent operation without connection to the mains, except to recharge the batteries.
- Equipped with closed loop control of X-ray tube current, kVp and filaments, which minimize potential errors and the need for readjustments.

MAXIMUM POWER kW	32 kW, According to IEC definition IEC (0.1s, 100Kv)
MINIMUM POWER	0.4 KW (40kVp 10 mA)
kVp RANGE	From 40kVp to 150kVp. In steps of 1kVp
mAs RANGE	From 0,1mAs to 500mAs in 38 steps, Renard10 Scale.
mA RANGE	From 10 mA to 500 mA in 18 steps, Renard10 Scale. 10,12.5,16,20,25,32,40,50,63,80,100,125,160,200,250,320,400,500
EXPOSURE TIME RANGE	From 1,0 msec to 10.000 msec (0.001 to 10 seconds) Maximum Exposure Time Range for DR: From 1 millisecond to 2.5 sec.
POWER OUTPUT (@ 0.1s)	150kVp @ 200mA 128kVp @ 250mA 100kVp @ 320mA 80kVp @ 400mA 64kVp @ 500mA
RIPPLE FACTOR	< 4 %
ACCURACY KVP	± (3 % +1kV)
AUTOMATIC COMPENSATION LINE	±10VAC
DUTY CYCLE	18 exposures per hour at maximum mAs (lapse time between exposures: 3min.)

X RAY TUBE XR3331

TXP-XR3331

Maximum Tension	150 kV
Type	Rotating anode
Focus sizes	• Small Focus 0.6 mm. • Large Focus 1.2 mm.
Maximum Power	• Small focus 22 kW (60 Hz), 32 kW (180 Hz), • Large focus 54 kW (60 Hz), 78 kW (180 Hz).
Maximum Current	• Small focus 1,000 mA. • Large focus 400 mA
Anode degree target angle	12°
Anode heat capacity	300 KHU
Anode Heat Dissipation Capacity	73.56 KHU/min
Housing Heat capacity	1,250 KHU
Housing Heat Dissipation Capacity	15 KHU
Anode rotation	2,700rpm (50Hz), 3,200rpm (60Hz), 9,700rpm (180Hz)
Anode composition	Rhenium - Tungsten
Anode Diameter	74 mm
Filtration equivalent	0.9 mm Al equivalent (at 75kV)

DIGITAL MOBILE SYSTEM

TXP-BT

RAYBOW XE Mobile, a unique digital radiographic system to transform the Delivery Care.
Maximum efficiency and energy autonomy thanks to its exclusive patented Easy Moving System with Energy Recovery Technology where the system utilizes braking energy to recharge its batteries.

Its telescopic column provides complete visibility during driving and easy access to any exposition area, along with its Effortless maneuverability and secure positioning the operator has a faster and optimized workflow.

The innovative application of the most powerful high-frequency X-ray generator in its class provides unparalleled high constant output power from any standard wall outlet or unplugged (Stand Alone).
Thanks to the battery-charger with recovery technology, the generator can be operated much longer in any Clinic/Hospital area, Operating Rooms, Intensive Care, Emergency, etc. Images can be obtained with the patient in the sitting, standing or lying position.
The selected WIFI portable detector & software provides the application suitability and profitability demanded by new clinics and hospitals.

MAIN TECHNICAL FEATURES

Energy Recovery Technology
Motor-Assisted and Lightweight driving:
Compact and Ergonomic Design

Maximum Power in compact dimensions.

Access to any type of patient thanks to its Telescopic Arm (3 steps) and Telescopic Column of 317° rotation.

LED Status Indicator

Omnidirectional movements.

One-Hand Maneuverability.
Capacitive Touch Technology on the Dead-man Handlebar

Accurate Diagnostic for Bedridden patients. Control Console with 19" color Touch Screen.

Precision Positioning to maneuver the system easily at the patient´s bedside. Quick collimator access.

Doors access unlimited. Compact and narrow Design (only 54cm wide).

Anticollision Proximity Sensors (optional).

MOVEMENTS

- Transform the way you work: New Motor-Drive control movement smoother, safer and very easy to use. Only one hand to move the whole unit.
- Speed up to 5.5 km/h.
- Dead-man handle with capacitive touch technology.
- Ramps up to 8°.
- When the system is out of parking position or being moved backwards, the speed is limited.

Maximum Speed (Parking Position)	Forwards: approx. 5.5 km/h	Backwards: 2.5 km/h
Column Rotation	±317°	
Areas with maximum step	2cm	
Maximum slope	8°	

PARKING POSITION

The telescopic column allows you to reduce the column height, maintaining a clear view ahead when driving the system. When not in use, the retracted column is in the perfect position to store or park it in a totally compact way.

Smoothly and effortlessly, we reach the parking position by sliding the Head-assembly down until it locks into the clutch. Vice versa for the head-assembly release.

Parking Dimensions and weight (H x W x D)	129x54x127cm (
Height	Max: 223cm Min: 129cm
Weight	520Kg

FINE POSITIONING

- It is possible to move each wheel independently, at low speed, for fine positioning.
- The four buttons on the handgrips control the motion of each driving wheel (forwards / backwards). This permits fine positioning respecting the patient, with the operator positioned opposite the Tube-Collimator Assembly.
- When the mobile is plugged to mains, only fine positioning movements are allowed.

DRIVING & MANEUVERABILITY

New Motor-Assisted Design lighter and more compact. Smart, ergonomic, simple, super smooth and silent driving. Provides less disruption and less stress even in the quietest environments (Clinic/Hospital).
Thanks to its easy manoeuvrability and flexibility in positioning, we can reach any type of patient or location (bed, wheelchair, narrow aisles), improving productivity and helping staff to work with complete safety and ease. It offers an extraordinary image consistency for a completely accurate diagnostic power.

Max. Distance from Focal Spot of X-Ray tube to Floor (SID)	202 cm
Min. Distance from Focal Spot of X-Ray tube to Floor	53cm
Vertical Travel (X ray beam parallel to the floor)	149cm
Telescopic-Arm Max Distance:	122cm
Telescopic-Arm Min. Distance	70.5cm
Collimator Rotation**:**	±90°
Head Rotation around arm axis	±180°
Head rotation around axis perpendicular to arm	- 30° / +90°
Head Assembly Movement Brakes	By friction

- Head Rotation around arm axis: ±180°
- Detents: -90° 0°,+90°.

- Head rotation around axis perpendicular to arm: -30° - +90°).
- Detents: 0°.

- Collimator Rotation: ±90°.
- Detent 0°.

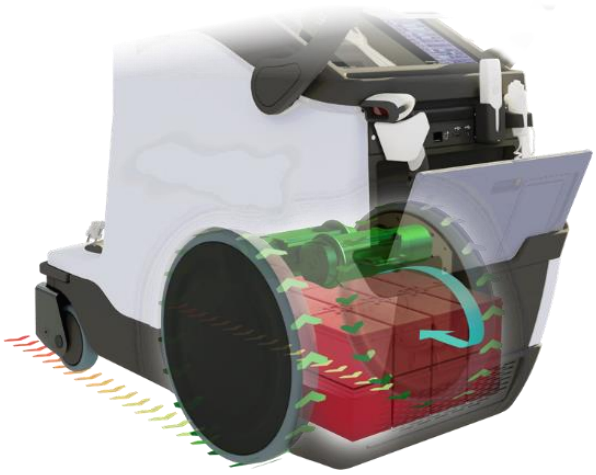
- Electromagnetic brakes for omni-directional movement (optional).

Column Rotation: ±317°

Telescopic Column:
Max SID: 202cm
Min Focus-Floor distance: <53cm

Telescopic Arm:
Max: 122cm (48")
Min: 70,5cm (27,7")

ENERGY RECOVERY TECHNOLOGY



Focus on what is important: the patient. Stop worrying. The unit takes advantage of it´s own braking energy to recharge the batteries.

Achieve 800 exposures of autonomy of "unplugged" autonomy and operate without limit, attending to your bedside patients, sending faster high-quality images to PACs and reaching an accurate diagnosis at first glance.

BATTERY CAPACITY

- **OBM System patented (Optimized Battery management)**: for extended battery life
- **Charge Capacity** per battery: 15 Ah.
- **Total energy storage** capacity: 5760Wh.
- **X-Ray Exposition Autonomy**: More than **800 expositions** (80 kV - 400 mA - 5ms).
- **Autonomy**:
  - More than 11 hours in stand-by (system ready to work).
  - More than 25 km @ 5.5 km/h.
  - Up to 1 km moving the unit once the exposure capacity is exhausted.
- **Charging Time**:
  - In 4 hours, 80% of the charge is available.
  - In 8 hours, 100% total charge is available.
  - 20% is charged every hour during the first 4 hours.
- **Charging Immediacy**: Allows exposures as soon as it is plugged into the mains.

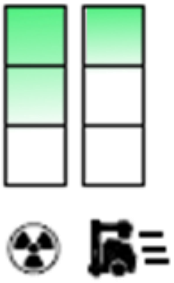
MANUAL DRIVING BRAKE RELEASE PUSH-BUTTON

In case of emergency or breakdown, possibility to release brakes to change to "manual movement" by simply pressing the easily accessible button next to the hand switch.

CONTROL PANEL

Control Panel, with:

- System ON/OFF Indicator.
- Battery Charge Level Indicator.
- Emergency Switch OFF.



- Battery Charge level indicator for radiographic operations (X-ray exposures).
- Battery Charge level indicator for the Mobile motion (motors).
- When plugged into the mains the Batteries will automatically charge.
- The Batteries require approximately 8 hours for a full charge.

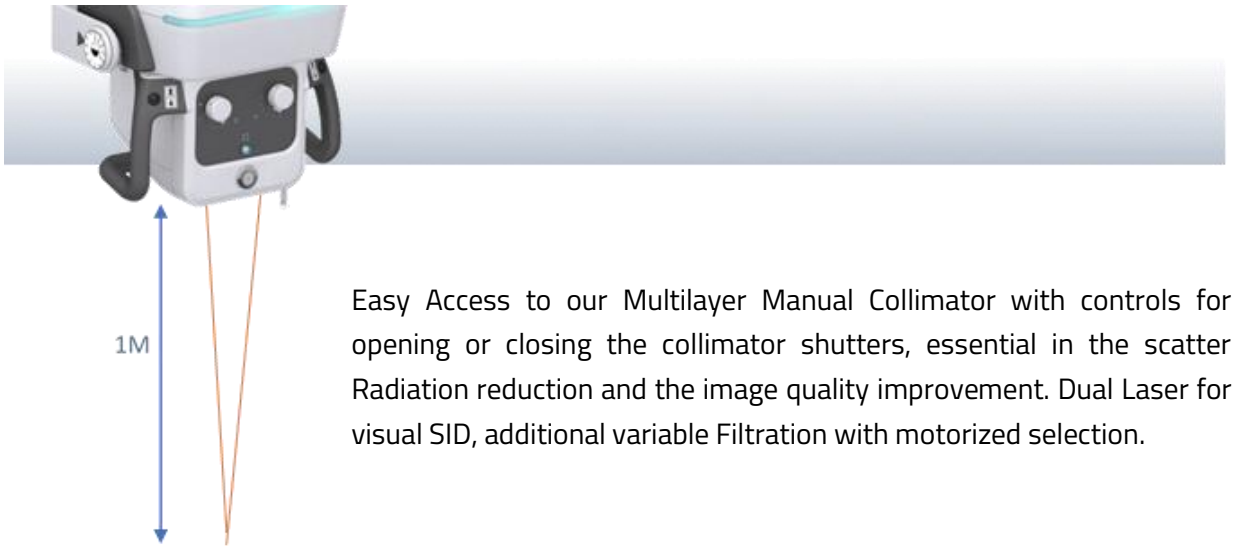
X-Ray hand switch to control X ray exposures:

- PREP.
- EXP: to complete the X-Ray exposure.
- With Collimator Lamp Button to help patient positioning,

Connectivity:

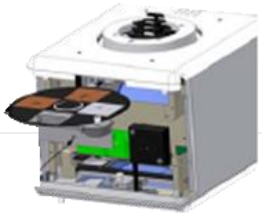
- Hospital network:
  - Wi-Fi connectivity: 802.11ac.
  - Wired connectivity: Ethernet connector (RJ45: 10/100/1000 Base-Tx Fast Ethernet compatible).
- 2 x USBs accessible for the operator.
- IR sensor for detector registration.
- 5m retractable mains cable

MANUAL COLLIMATOR

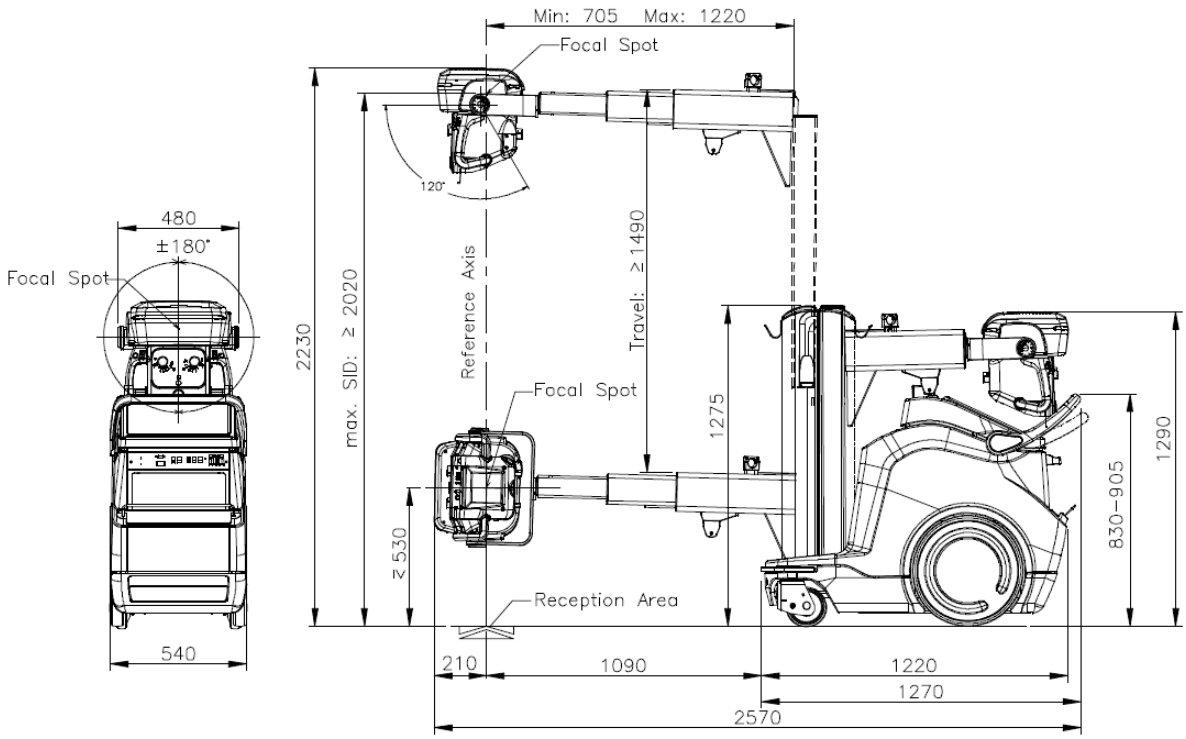


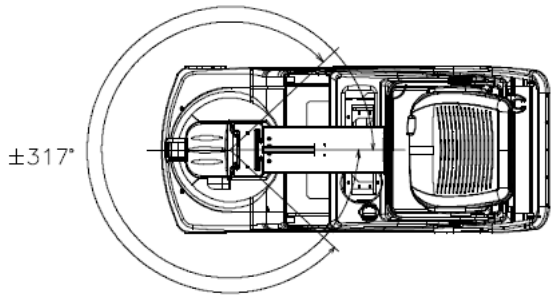
Easy Access to our Multilayer Manual Collimator with controls for opening or closing the collimator shutters, essential in the scatter Radiation reduction and the image quality improvement. Dual Laser for visual SID, additional variable Filtration with motorized selection.

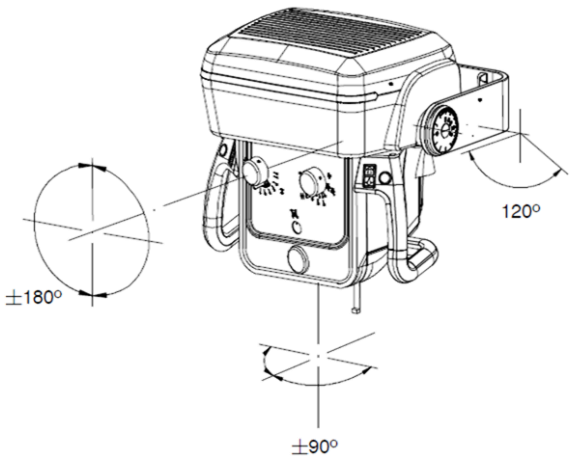
Square Field	• Max FOV 43x43cm at SID 1meter • 6 pair of shutters
LED Light Field	• High Luminosity (white LED electronic timer). • Over 200LUX guaranteed at 1m
Measuring Tape	• Included for accurate SID measurements
Radiation Leakage Protection	• 150kVp
Inherent Filtration Equivalent to	• 2mm AL
Dual Laser	• The projection of a single line means that the two lines overlap and consequently the lasers are correctly focused at 1m SID.
Additional Variable Filtration	**Motorized** • 1mm AL + 0,1mm Cu • 1mm AL 0,2 mm Cu • 2 mm Al.

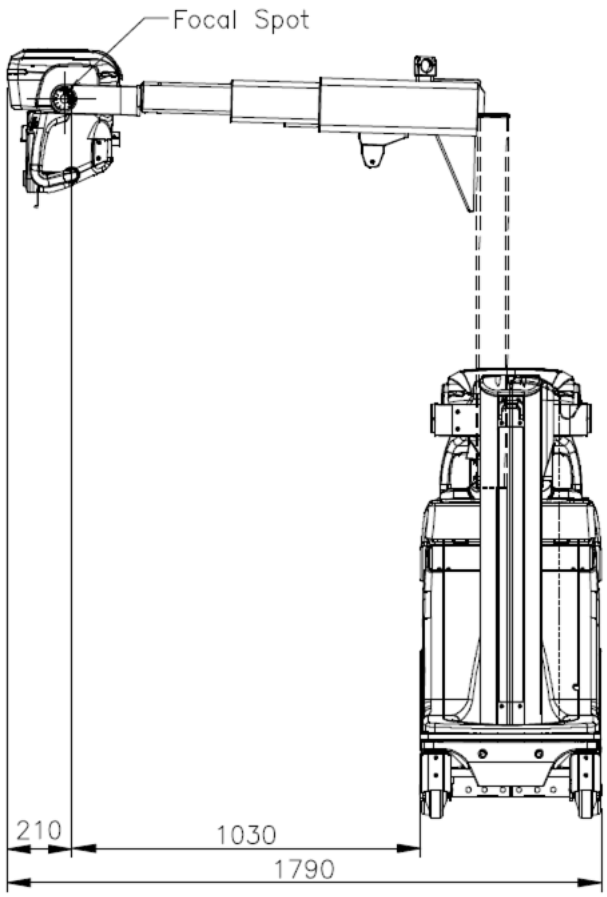


DIMENSIONS


Min: 705 Max: 1220
Focal Spot
120°
480
±180°
Focal Spot
2230
max. SID: ≥ 2020
Reference Axis
Travel: ≥1490
Focal Spot
1275
1290
830-905
≥ 530
Reception Area
540
210
1090
1220
1270
2570


±317°


120°
±180°
±90°


Focal Spot
210
1030
1790

MONITOR COLOR WITH DICOM PRESET

TXP-ADMON

Access at relevant data where and when you need it. Thanks to the integrated workstation you can easily take the hospital applications (RIS) to the patient´s bedside. Possibility of managing the operations more efficiently, spending more time with your patient without moving to a separate Workstation.

ADVANCED TOUCH SCREEN MONITOR SPECIFICATIONS			
Size and Format (H-V)	19" Aspect Ratio 5:4	Grayscale levels	1,024
Touch screen	Working even wearing surgical gloves	Viewing angle (H-V)	178°
Native Resolution	1280 x 1024 pixel	Viewing angle (H-V)	330 cd/m^2
Pixel Pitch	0.294mm	Contrast ratio (panel typical)	1,000:1
Surface treatment	Anti-reflective (matte)	Response time (Tr + Tf) (typical)	30ms
Bit Depth:	10 bits	Closed-loop brightness control	Yes
Ambient light presets	Yes	DICOM calibrated luminance	250 cd/m^2

PC TECHNICAL SPECIFICATIONS:

- Operative System: Windows 10
- CPU: Intel® Core™ i5-7500T Processor
- System Chipset: Intel® Q170 Chipset
- System Memory RAM: 16GB (2x8GB) DDR4 2133MHz SDRAM SODIMM (Dual Channel)
- Graphics: Integrated Intel® HD Graphics 630 TPM: Infineon SL9665 TPM2.0
- HD Hard Disc: SSD, 512GB Sandisk X600 (1 TB with SM-HDD option)

STORAGE

> 20,000 images as a standard.

> 40,000 images with SM-HDD option

The system allows the configuration of auto-deletion rules for the oldest images by date or by size on the hard disk

NUMERIC KEYPAD FOR ACCESS

TXP-KEYPAD

Numeric keypad for secure on/off system routine, with Four-digit access code.
High Security Standard to protect the use of the unit and prevent unauthorized access.

ADAPTING KIT

KIT-MARSX

Large storage for detectors and their batteries arranged for a maximum ease of handling and usability: 2 detectors +2 batteries at the front and 1 detector at the rear of the unit.
Designed with internal stops to facilitate hygienic detector bags insertion/removal and additional storage for two batteries (detector), ensuring simple and constant workflow.
The unit incorporates a Detector safety blockage to prevent unauthorized use when the unit is alone.

Front Storage Cabinet	Detector Size	• Large Detector. • Pediatric Detector. • Detector-frame with handle (with/without grid)
	Storage for batteries	• 2 detector batteries
	Detector Lock	• When the unit is power off. • When the user has no permission (with Smart RFID option).
Back Storage Cabinet	Detector Size	• Large or pediatric detectors or Detector-frame with handle (with/without grid).
	Stops for detector	• For easy insertion/removal of hygiene bags

ANTICOLLISION PROXIMITY SENSORS

TXP-PS

Absolutely safe driving. **Anti-collision proximity sensors and collision full stop**:

- The mobile system **reduces speed** automatically when an object/person is close to it.
- **Visual & acoustic indications**, when an object comes close to it.

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.

LED STRIP STATUS INDICATOR

TXP-SL

Status visual range. Led strip with changing color indicator to help the operator quickly identify the system operation status.

WHITE	Blinking when an obstacle has been detected
BLUE	Detector ready and technique correctly set.
GREEN	Ready for exposure.
YELLOW	Exposure on.
ORANGE	System error, user intervention required.
MAGENTA	Bumper activated.

INTEGRATED DOSE AREA METER

TXP-DAP

Measuring device to determinate the radiation level the patient is exposed to in radiological diagnostics. The values will be displayed and saved with the image.

Radiation quality kV	From 40 to 150 kV
DAP Range	From 0.1 a 99,999,999.99 μGy·m²
DAP Rate Resolution	0.01 μGy·m²/s
Precision	±20%.
Active Area Dimensions (Compact)	115x115mm
Operation Temperature Range	From +10°C to +50°C
Optical Transparency	≥ 73%.
Attenuation equivalent	< 0,5mm Al.
Connecting cable	15m long
Guides and rails	Integrated in the unit, under the collimator.

* Canon Software Screen example: It may vary depending on the software chosen.

DIGITAL SYSTEM PRIMO – MARS1417X PANEL

SM-MARS1417X

Primo is a complete innovative and technological advanced digital DR system with multi-detector operations

- Professional acquisition software for X-ray images from flat panel systems (DR)
- The software controls X-ray generator, providing a smooth and systematic workflow.
- The professional image processing can be adapted to individual user needs and provides a complete control of all image capture
- functions within the examination room, enhancing the entire workflow by delivering diagnostic images instantly, and allowing users to move X-ray images electronically to remote workstations, image archives, and printers.
- Integrated functions and intuitive operation greatly simplify daily routine tasks.

PATIENT CREATION FRAME

Possibility of Creating manually a new study:

- Last Name and First Name
- Patient ID
- Date of birth
- Weight & Height, sex
- Accession Number
- Technician and doctor
- Patient´s notes, study description

ACCESSING THE STUDY LIST (WORKLIST)

- Possibility of Creating a new study from the Worklist.
- Possibility of requesting the Worklist from the RIS.
- Transfer one/more selected studies to the Study List.
- Associate the selected study with a previous study.
- Delete one or more selected studies.
- Delete the entire list of studies received from the RIS.
- On the right-hand side of the study list frame, you find the following keys:
- DICOM Store.
- Export studies to CD/DVD or USB.
- Report Tools.
- Patient´s data Edit.
- Rejected images (statistics).
- RDSR (Radiation Dose Structured Report):
- dose report of the selected study.
- DICOM SPOOLER shows the queue for DICOM store and print services.
- Browse the list, if there is more than one page.

WORKING FRAME AND IMAGE ACQUISITION

To start the radiographic exam the Working Frame lead you to the exam selection window to choose the anatomical region required, then the anatomical part and finally the right exam:

- Head
- Chest
- Abdomen
- Cervical spine
- Pelvic measurement
- Humerus
- Femur
- AEC adjustment

Disposition of the Working Frame Information:

- Image area
- Exam List / Preview List
- Patient Data
- Messages Area:

This area contains indications of the detector connection status, the battery charge level, the amount of free space (%) on the archive disk and equipment status warnings and alarms.

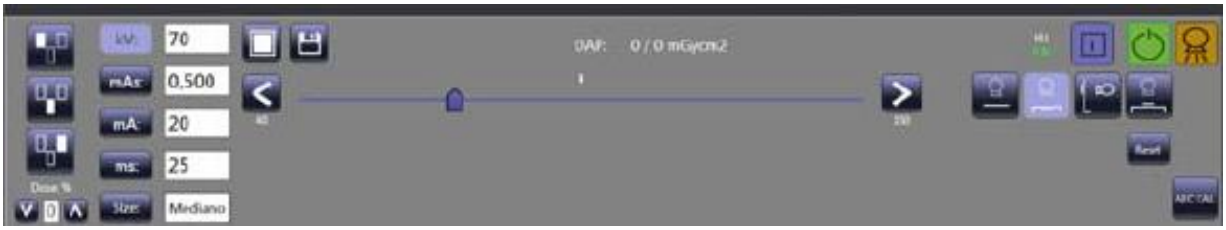
- **Generator Console** (X-ray parameters): Information about X-ray generator controls and parameters is shown in this area whenever the generator communicates directly with application. If this is not the case, information on the techniques to be selected in the generator can be displayed in this area.
- **Exam Management Area**: contains keys to delete, move or add procedure to your study, and to suspend or close the study.
- **Anatomical Region and exam selection.**

PROCEDURES TECHNIQUE

For an easy use is possible to set a Procedure to guide you through the performance of the exposures required for a study. Procedures define the exam/projection types needed for the study.

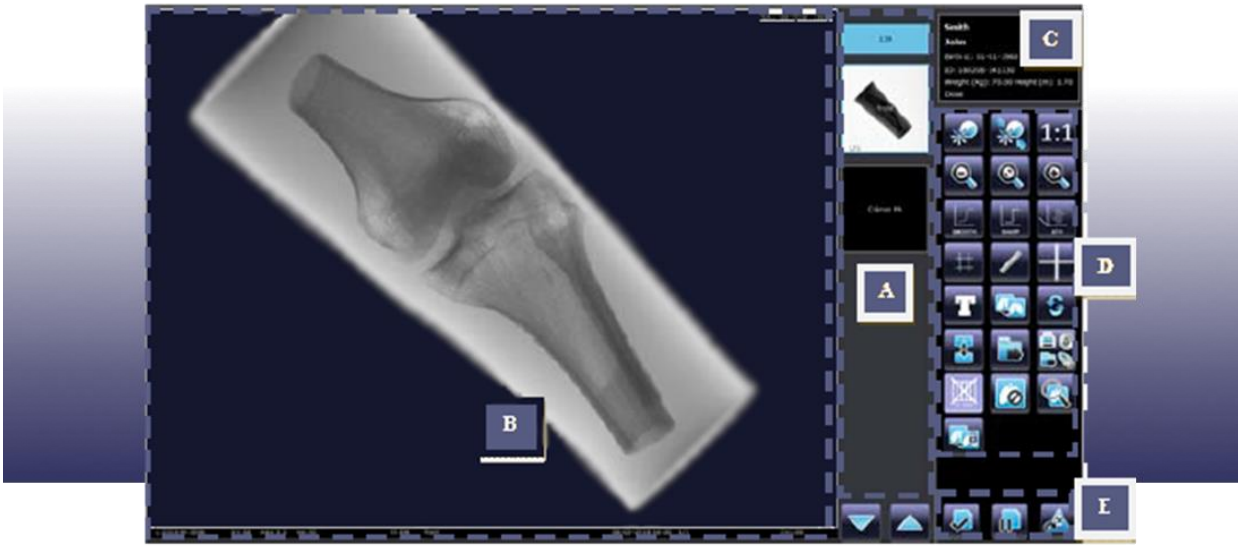
- Procedures are defined during installation of the system, in accordance with the operators and depending on the type of work required in the radiology theatre.
- A procedure can be associated to:
  - A single exam (projection) (e.g.: Std Thorax with just the PA projection of the thorax).
  - Several exams (projections) (e.g.: Full Thorax with both PA and LAT projections).
- You can either receive the Procedure from RIS via the Worklist function or chose it manually, e.g. when creating a new study manually.
- If a procedure is associated to a study, the system guides you during image acquisition and automatically presents the exams required.
- Otherwise, you need to select the exam type manually pressing the button PROC as in indicated below. All the procedures set in the system will be displayed.

X RAY GENERATION SETTING AND IMAGE ACQUISITION



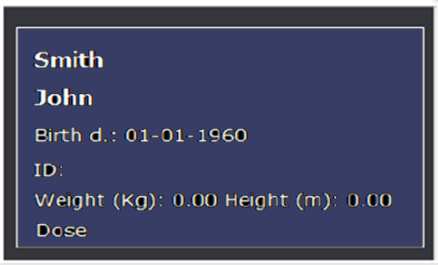
- The exposure parameters for the X-ray generator must be set to suit the exam and the patient size selected.
- To make things easier, the equipment shows the best X-ray generator settings for each exam and patient size (pre-set in the database during installation, as agreed with the users.)
- The following parameters are shown:
  - 2-point technique (kV and mAs) or 3-point technique (kV, mA, and ms),
  - kV, mAs, mA and ms, to suit the technique,
  - Patient size.
  - Status warning: "Ready for acquisition"

IMAGE PROCESSING FRAME



A. Previews / Exams List
B. Image area and dose information
C. Patient data
D. Image Processing commands
E. Study commands

Grey Scale	Exposure Values	Radiation Dose (DAP)	• ELT: Exposure index target according to the data of the selected technique. • EI: Exposure Index detected in the acquired image. • DI: Deviation of the Exposure index achieved from the target.	Exam / Projection	Acquisition date and time	• Image N° • Digital Zoom

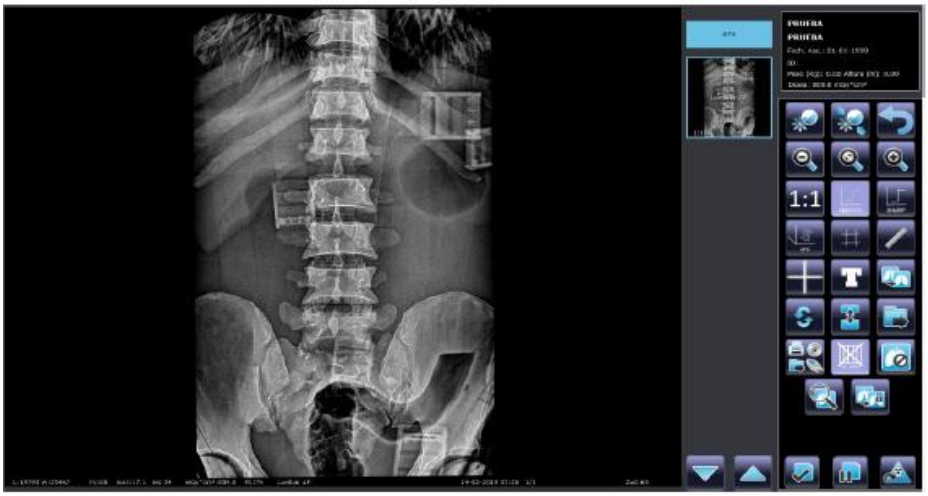


- Patient´s name
- Birth Date
- Patient ID
- Weight and height
- Total Dose

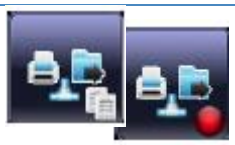
IMAGE POST- PROCESSING

- Vertical/Horizontal image flip.
- Digital Zoom
- Spatial filters
- SMOOTH filter: this softens the edges of the image
- SHARP filter: this hardens the edges of the image
- SMOOTH + SHARP filters: both types of correction are applied.
- Images Cropping.
- Add object and text
- Duplicate images
- Store DICOM
- No grid function
- Protect an image
- Image Multiview
- ATH Harmonization
- Measurements
- Distance calculation (with calibration function)
- Angle calculation.
- Rotate images
- Report Tool
- Magnifying glass
- Reject and image/Restore images
- Thumbnail.
- Brightness and contrast control.
- STATISTICS: The statistics function is used by the Technical Service when checking the system and so can only be accessed by the Advanced user.
  - Allow to find the co-ordinates and pixel values for the image.
  - Rectangle of a size set by the operator.
  - Raw image statistics (RAW).
    - Equalized image statistics applied parameters:
    - Harmonization algorithm (ATH).
    - ROI for automatic W and L correction.
    - Gamma correction curve (LUT).
  - Possibilities to export image to a removable device (CD or PEN DRIVE) in either DICOM or RAW format.
- OVERVIEW You can view more than one image in a study on the monitor at the same time. Select the overview function by pressing the relevant command.

IMAGES RECORDS



The following DICOM functions can be used to produce image records:

Export images to PENDRIVE or CD/DVD	Send images TO WORKSTATION/ PACS DICOM (Store DICOM)	Send images to DICOM printer	SPOOLER DICOM
			

STUDIES REPORT

The software incorporates a powerful reporting tool System with immediate on-screen information display or the possibility of a later analysis by exporting the report to a folder into the hard disk.

The exported data include the following information for each study:

- Acquisition date.
- Patient Surname and first name.
- Study image number.
- Image N° and % removed from the study
- Image N° and % rejected from the study.
- Image N° and % accepted from the study.
- The reasons why an image has been rejected.

GRIDLESS IMAGING. DIRECT EXPOSURES FREEDOM

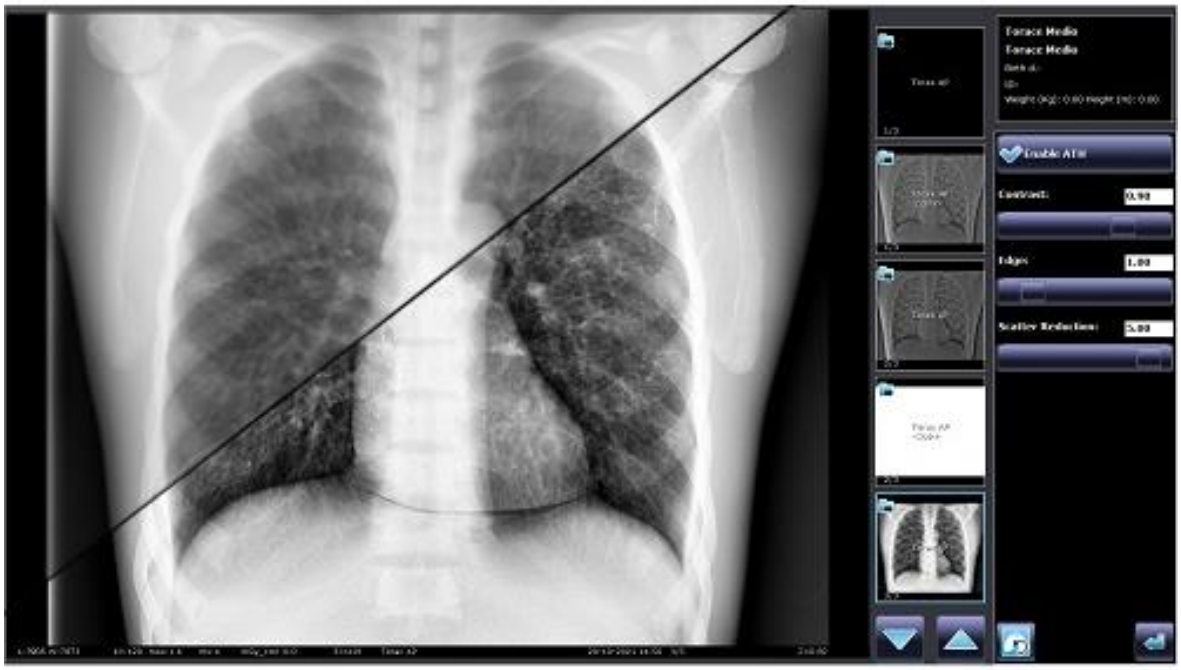
The software includes **Dynamic Range Algorithm (DRC)**, a complex image processing technique which allows the detector to be used live without the need to incorporate a grid while maintaining high image quality:

Scatter Reduction
corrects the effects of scattered radiation from the acquired image. This led to an improvement in both contrast and clarity of the image.

Edge Enhancement
enhances the edge contrast of an image to improve its acutance (apparent sharpness).

Adaptative Contrast Enhancement
the contrast of the image, or the difference in light between parts of it, is modified adaptative by this algorithm to improve its perception by human eye.

WITHOUT SCATTER CORRECTION



WITH SCATTER CORRECTION

Software algorithm advantages compared to conventional grids:

- Up to 60% of patient dose reduction.
- Enhance high-contrast structures.
- No extra handling and weight during patient preparation.
- Patient Workflow improved.
- Fewer retakes caused by grid misalignment.
- Algorithm applicable to images of any anatomical area.

STITCHING IMAGE RECONSTRUCTION

The Stitching function creates an image of great length by joining several images which were acquired during a longitudinal scan of the patient. The reconstructed image can consist of **2, 3 or 4 images**. With scanning steps of 30cm, for example, the reconstructed image will have a length **up to 120cm**. Three types of reconstructions are available: Automatic, Manual, Definition of dots, Manual, Superposed images.

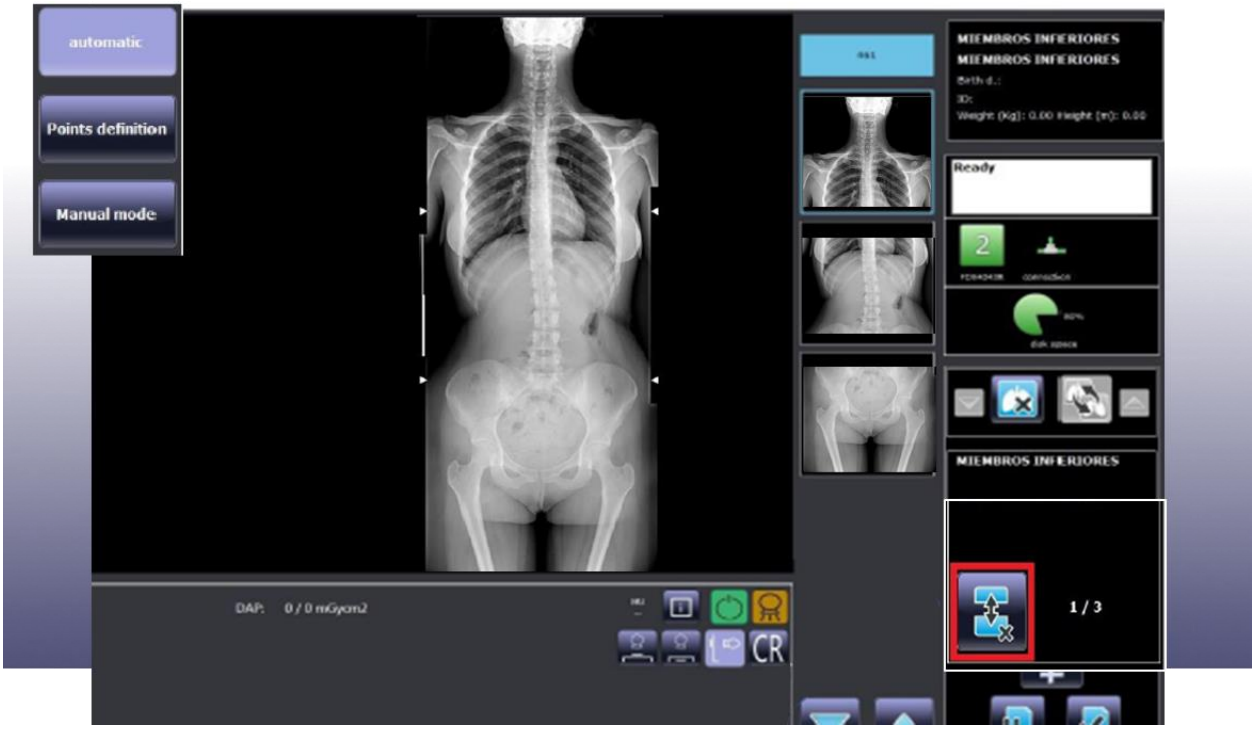


IMAGE QUALITY CONTROL TOOLS

The software allows the acquisition of images in "Raw" format (RAW) from the same user station. RAW images have a DICOM extension so they can be opened from external image control applications such as those specific to some quality control phantoms. Additionally, the verification of the images can be done from the application itself, as a complete module is available with the possibility of selecting ROIs and tools for measuring the average pixel value and noise.

SYSTEM CONNECTIVITY

The acquisition station incorporates the following functionalities in accordance with the standard DICOM 3.0:

- Modality Worklist.
- Storage.
- Modality Performed Procedure Step (MPPS).
- Basic Greyscale Print.
- Storage Commitment
- Verification.
- Query / Retrive
- Grayscale Standard Display Function (GSDF).
- Radiation Dose Structured Report (RDSR).

DETECTOR IRAY MARS 1417X

MARS1417X

Designed to provide the highest quality of X-Ray images with an active matrix of 3500 × 4300 and **100µm pitch** (CSI).
With a Gigabit Ethernet connection for high data transfer rates and equipped with the possibility of query/upload images from detector to workstation, enable easy interchangeability between different X-Ray modalities (X-Ray mobile and fix ones).
It is the optimal choice for both retrofit and new DR System solutions, offering an effective and fast work flow.

- Wireless cassette detector. ISO 4090, fits in any bucky.
- Software with Auto-Exposure Detection.
- Best-in-class 100 µm pixel pitch with 16-bit ADC for more image details.
- Large capacity battery design, with **8+ hours battery life.**
- Lightweight design with IP56 ingress water protection.
- Supports a fast workflow for a better user experience.
- **With 200 images internal storage**
- Direct deposition CsI, with excellent DQE at all frequencies **.**

Very High trigger Sensitivity even with the thickest patients. Equipped with **internal X-ray sensors** which automatically detect the X-ray and synchronize image acquisition.

drop monitoring

Equipped with a unique drop monitoring system which serves as a real time tracker of panel dropping and shocking.

back up power cable, online charging solution

With its Charging connector is easy to keep the panel continuously charging without needing to replace the battery. The additional ethernet interface makes extremely easy to switch between wireless and wired mode.

long lasting battery

Faster operation, at least 500 exposures and **8,5 hours of continuous operation** before to recharge the battery. A few seconds to replace and restart the detector.

dual battery charger

Battery charger with capacity of charging two batteries simultaneously for a non-interrupted workflow.

With Battery charging capacity indicator.

Pack of **two batteries included**.

robust wifi signals

Both 2.4G and 5G wireless mode is supported. With higher speed and stability under 5G modes.

Faster readout speed reaching the smallest pixels for better resolution and lower noise for improved low-dose DQE and less leakage for higher dynamic range.

TECHNICAL DATA – MAIN CHARACTERISTICS	
Detector Technology	Amorphous Silicon (a-Si) TFT
Scintillator	CsI (Cesium Iodide)
Active Area	350 x430mm
Pixel Matrix	3.500 x 4300
Pixel Pitch	100 µm
Gray Scale	16bit
Spartial Resolution	4.3 lp/mm
AD Conversion	16bit
Battery Autonomy	8.5h
WiFi	2.4G and 5G
Trigger Mode	• Software (with Auto-Exposure Detection). • AED (Optional).
Full Image Time	Typ. 3.5s
Dimensions	460x384x15mm
Weight with battery	3.0 kg
Drop Monitoring	70cm @3mm PVC
Static Loading	300Kg (over the surface)
Protection Index	IP56
MTF	70% (1.0 lp/mm) 40.4% (2.0 lp/mm) 22.8% (3.0 lp/mm)
DQE	73.4% (0 lp/mm) @RQA5 55.9% (1.0 lp/mm) @RQA5 40.4% (2.0 lp/mm) @RQA5 28% (3.0 lp/mm) @RQA5
Operating Temperature	10-40 °C
Image Acquisition Time	3 sec
BATTERIES	
Rated Capacity	Min. 4,700mAh, Typ. 4,900mAh @ Discharge 0.2C
Nominal Voltage	11.55V
BATTERY CHARGER	
Simultaneous Charging	Pack of 2 batteries
Full charging time	3 hours
Rated power supply	24V(DC)
COMPONENTS	
Components included	1 Adapter for detector and battery charger 2 Batteries (Pack) 1 Gigabit Ethernet cable 1 AC Power Cable 1 DC Power Cable

DETECTOR HOLDER

SCDF-2

- Protective frame and holder for detectors 35x43, for easy transport lightweight feel and safe use
- It has a lock on the handle to prevent the detector from accidentally slipping out of the frame.
- With **optional** integrated grid, designed to fit the Digital Detector.

WITHOUT GRID

WITH GRID

ADDITIONAL LOCK

All data provided by the manufacturer:

RADIOLOGÍA
Pelaya, 13. Polígono Industrial "Río de Janeiro"
28110 Algete, Madrid - España (Spain)
Phone: +34 902 195 770
Fax: +34 902 103 367 www.radiologia-sa.com

CE 1639

PRIMAX INTERNATIONAL srl
Via A. Volta 10, 24060
Torre de Roveri ITALY
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primax INTERNATIONAL

primax
INTERNATIONAL

RAYBOW XE

DIGITAL MOBILE SYSTEM

RAYBOW XE Mobile System is the unique Digital Radiographic Mobile System to transform the Delivery Care.

Maximum Efficiency and energy autonomy thanks to its exclusive **patented Easy Moving System with Energy Recovery Technology** where the unit take advantage of the braking energy to recharge its batteries.

Its **Telescopic Column** provides complete visibility during driving and easy access to any exposition area, along with its **Effortless maneuverability** and **secure positioning** the operator has a faster and optimized workflow.

The most innovative technology application for the H**igh Frequency X-ray Generator** permits a high constant output power from any standard power socket or without it (**Stand Alone**).

Thanks to the **battery-charger with recovery Technology**, the generator can be operated much longer in any Clinic/Hospital area, Operating Rooms, Intensive Care, Emergency, etc. Images can be obtained with the patient in the sitting, standing or lying position.

The selected WIFI portable detector & software allows us the operability and profitability **demanded by new clinics and hospitals.**

MAIN TECHNICAL FEATURES

Access to any type of patient thanks to its **Telescopic Arm** and **Telescopic Column.**

Maximum Power in compact dimensions.

Accurate Diagnostic for Bedridden patients. Control Console with **19" color Touch Screen**.

LED Status Indicator

One-Hand Maneuverability. **Capacitive Touch Technology** on the Dead-man Handlebar

Fine Positioning to handle the Unit easily at the patient´s bedside. Quick collimator access.

Compact and narrow Design (only 54cm wide).

Energy Recovery Technology
Motor-Assisted and Lightweight driving:
Compact and Ergonomic Design

Anti-collision Proximity Sensors (optional).

GENERATOR 32KW

- Advanced technology for our Generator in a compact and modular design:
- **Constant Potential High-Voltage Generator** with all advantages, including lower patient dose, shorter exposure times as well as greater accuracy and consistency.
- Monoblock **without high voltage cables**.
- Minimum rise time for higher patient protection.
- The Unit is controlled by multiple microprocessors which offer a higher exposure consistency, efficiency in operation and an extended Tube life.

- Independent operation without connection to the mains, except to recharge the batteries.
- Equipped with closed loop control of X-ray Tube current, kVp and filaments, which minimize potential errors and the need for readjustments.

INPUT LINE OPERATION	100/240Vac automatic compensation ±10VAC
MAXIMUM POWER kW	32 kW, According to IEC definition IEC (0.1s, 100Kv)
MINIMUM POWER	0.4 kW (40kVp 10mA)
kVp RANGE	From 40kVp to 150kVp. In steps of 1kVp
mA RANGE	From 0.1mAs to 500mAs in 38 steps, Renard10 Scale.
mA RANGE	From 10 mA to 500 mA in 18 steps, Renard10 Scale. 10,12.5,16,20,25,32,40,50,63,80,100,125,160,200,250,320,400,500
EXPOSURE TIME RANGE	From 1,0 ms to 10.000 ms (0,001 to 10 seconds) Maximum Exposure Time Range for DR: From 1 millisecond to 2.5 seconds.
POWER OUTPUT (@ 0.1s)	150 kVp @ 200 mA 100 kVp @ 320 mA 80 kVp @ 400 mA 64 kVp @ 500 mA
RIPPLE FACTOR	<4 %
DUTY CYCLE	18 exposures per hour at maximum mAs (lapse time between exposures: 3min.)

ENERGY RECOVERY TECHNOLOGY

Focus on what is important: the patient. The unit takes advantage of its own braking energy to recharge the batteries.

Achieve 800 exposures of autonomy of unplugged autonomy and operate without limit, attending to your bedside patients, sending faster high-quality images to PACs and reaching an accurate diagnosis at first glance.

BATTERY CAPACITY

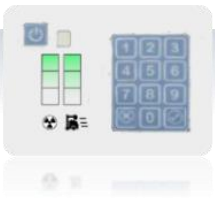
- **OBM System patented (Optimized Battery management)**: for extended battery life
- **Charge Capacity** per battery: 15 Ah.
- **Total energy storage** capacity: 5760Wh.
- **X-Ray Exposition Autonomy**: More than **800 expositions** (80 kV - 400 mA - 5ms).
- **Autonomy**:
  - More than 11 hours in stand-by (system ready to work).
  - More than 25 km @ 5.5 km/h.
  - Up to 1 km moving the unit once the exposure capacity is exhausted.
- **Charging Time**:
  - In 4 hours, 80% of the charge is available.
  - In 8 hours, 100% total charge is available.
  - 20% is charged every hour during the first 4 hours.
- **Charging Immediacy**: Allows exposures as soon as it is plugged into the mains.

X-RAY TUBE XR3331

Maximum Tension	150 KV
Type	• Rotating anode
Focus sizes	- Small Focus 0.6 mm. • Large Focus 1.2 mm.
Maximum Power	- Small focus 22 kW (60 Hz), 32 kW (180 Hz), • Large focus 54 kW (60 Hz), 78 kW (180 Hz).
Maximum Current	- Small focus 1,000 mA. Large focus 400 mA
Anode degree target angle	12°
Anode heat capacity	300 KHU
Anode Heat Dissipation Capacity	73.56 KHU/min
Housing Heat capacity	1,250 KHU
Housing Heat Dissipation Capacity	15 KHU
Anode rotation	2,700rpm (50Hz), 3,200rpm (60Hz), 9,700rpm (180Hz)

ON/OFF SYSTEM ROUTINE BY NUMERIC KEYPAD

High Security Standard to protect the use of the unit and prevent unauthorized access.



Numeric keypad for secure on/off system routine, with Four-digit access code.

MOVEMENTS

- Transform the way you work: new Motor-Drive control movement smoother, safer and very easy to use. Only one hand to move the whole unit.
- Speed up to 5.5 km/h.
- Dead-man handle with capacitive touch technology.
- Ramps up to 8°.

- When the system is out of parking position or being moved backwards, the speed is limited.

Maximum Speed (Parking Position)	Forwards: approx. 5.5 km/h Backwards: 2.5 km/h
Column Rotation	±317°
Max step	5 cm (1.9")
Max gradient	8 °

PARKING POSITION

Stress-Free driving. Parking position allows you to reduce collapsible column maintaining a clear view ahead when driving the system. When not in use, is a perfect position to store or park it in a totally compact way.

Smoothly and effortlessly, we reach the parking position by sliding the Head-assembly down until it locks into the clutch. Vice versa for the head-assembly releasement.

Dimensions and weight (H x W x D)	129x122x54cm
Height	• Max: 223cm • Min: 129cm
Weight	520 Kg

FINE POSITIONING

- It is possible to move each wheel independently, at low speed, for fine positioning.
- The four buttons on the handgrips control the motion of each driving wheel (forwards / backwards). This permits fine positioning respecting the patient, with the operator positioned opposite the Tube-Collimator Assembly.
- When the mobile is plugged to mains, only fine positioning movements are allowed.

Max. Distance from Focal Spot of X-Ray tube to Floor (SID)	202 cm
Min. Distance from Focal Spot of X-Ray tube to Floor	53 cm
Vertical Travel (X ray beam parallel to the floor)	149 cm
Telescopic-Arm Max Distance:	122 cm
Telescopic-Arm Min. Distance	70.5 cm
Collimator Rotation:	±90°
Head Rotation around arm axis	±180°
Head rotation around axis perpendicular to arm	- 30° /+90°
Head Assembly Movement Brakes	Electromagnetic Brakes (Optional)

LED STRIP STATUS INDICATOR

Status Visibility at any time. Led strip with changing color indicators to help the operator know the state of the equipment easily.

◦ **WHITE**	• The System is in standby. • Blinking when the System is moving, or an obstacle has been detected 2.5m ahead.
◦ **BLUE**	Detector ready and technique correctly set.
◦ **GREEN**	Ready for exposure.
◦ **YELLOW**	Exposure on.
◦ **ORANGE**	System error, user intervention required.
◦ **MAGENTA**	Bumper activated.

- Head Rotation around arm axis: ±180°
- Detents: -90° 0°,+90°.

- Head rotation around axis perpendicular to arm: -30° - +90°).
- Detents: 0°.

- Collimator Rotation: ±90°.
- Detent 0°.

- Electromagnetic brakes for omni-directional movement (optional).

- Telescopic Column:
  - Max SID:202 cm
  - Min Focus-Floor distance: 53 cm

- Telescopic Arm:
  - Max: 122 cm
  - Min:62.5 cm

- Column Rotation: ±317°

DRIVING & MANEUVERABILITY

New Motor-Assisted Design lighter and more compact. Smart, ergonomic, simple, super smooth and silent driving. Provides less disruption and less stress even in the quietest environments (Clinic/Hospital).

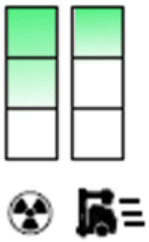
Thanks to its easy maneuverability and flexibility in positioning, we can reach any type of patient (bed, wheelchair, narrow aisles), improving productivity and helping staff to work with complete safety and ease. It offers an extraordinary image consistency for a completely accurate diagnostic.

CONTROL PANEL & SWITCHES

Control Panel, with:

- System ON/OFF Indicator.
- Battery Charge Level Indicator.
- Emergency Switch OFF.

.



- The Exposure symbol Column indicates the charge level of the Batteries used for radiographic operations (X-ray exposures).
- Mobile X-Ray Column indicates the charge level of the Batteries used for the Mobile motion (motors).
- When unplugged from mains, the Batteries discharge independently on their use (X-ray exposures or motors).
- When plugged into the mains the Batteries will automatically charge.
- The Batteries require approximately 9 hours for a fully charge.
- It is possible to move manually the unit when battery is completely discharged (Service needed).

X-Ray hand-switch to control X ray exposures:

- PREP.
- EXP: to complete the X-Ray exposure.
- With Collimator Lamp Button to help patient positioning
- Coiled cable length from 80 to 500 cm

Connectivity:

- Hospital network:
- Wi-Fi connectivity: 802.11ac.
- Wired connectivity: Ethernet connector (RJ45: 10/100/1000 Base-Tx Fast Ethernet compatible).
- 2 x USBs accessible for the operator.
- *IR sensor for detector registration (optional)
- 5 m retractable mains cable.

Absolutely safe driving. Anti-collision proximity sensors and collision full stop:

- The mobile system slows down speed automatically when an object/person is close to it.
- Visual & acoustic indications when an object comes close to it.
- Automatic full stop of the unit when an imminent risk of collision has been detected.

MONITOR AND WORKSTATION

Get access at relevant data where and when you need it.
Thanks to the integrated workstation you can easily take the hospital applications (RIS) to the patient´s bedside. Possibility of managing the operations more efficiently, spending more time with your patient without moving to a separate Workstation.

ADVANCED TOUCH SCREEN MONITOR SPECIFICATIONS

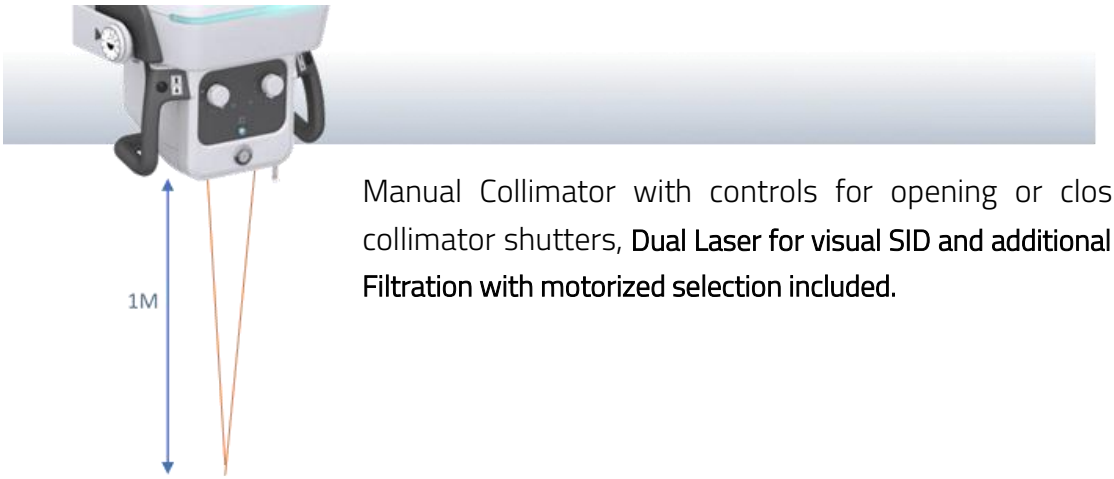
Size and Format (H-V)	**19"** Aspect Ratio 5:4	*Grayscale levels*	1,024
Touch screen	Working even wearing surgical gloves	*Viewing angle (H-V)*	178°
Native Resolution	1,280 x 1,024 pixels	*Maximum luminance (panel typical)*	330 cd/m^2
Pixel Pitch	0.294mm	*Contrast ratio (panel typical)*	1,000:1
Surface treatment	Anti-reflective (matte)	*Response time (Tr + Tf) (typical)*	30 ms
Ambient light presets	Yes	*Closed-loop brightness control*	Yes
Bit Depth:	10 bits	*DICOM Calibrated luminance*	250 cd/m2

PC TECHNICAL SPECIFICATIONS

Operative System: Windows 10
CPU: Intel® Core™ i7 Processor
System Chipset: Intel® Q170 Chipset
System Memory RAM: 16GB (2x8GB) DDR4 2133MHz SDRAM SODIMM (Dual Channel
Graphics: Integrated Intel® HD Graphics 630
TPM: Infineon SL9665 TPM2.0
HD Hard Disc: SSD, 512GB Sandisk X600

Boot time: average 3 minutes
Possibility of storage for more than **20,000 images**. The system allows the configuration of auto-deletion rules for the oldest images by date or by size on the hard disk.
More than 500 pre-set programs, and unlimited capacity for additional new programs.

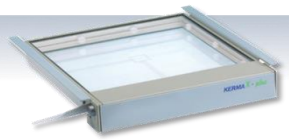
MANUAL COLLIMATOR

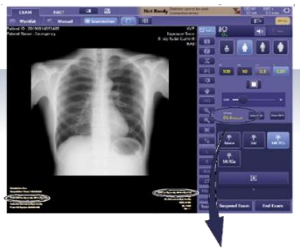


Manual Collimator with controls for opening or closing the collimator shutters, **Dual Laser for visual SID and additional variable Filtration with motorized selection included.**

Square Field	Max FOV 43x43cm at SID 1meter	**LED Light Field**	· High Luminosity (High White LED wit electronic timer). · Over 200LUX Guaranteed at 1m
Radiation Leakage Protection	· 150kVp	**Measuring Tape Shutter N°**	· Included for SID Measurements · 6 pair of shutters
Inherent Filtration Equivalent at	· 2mm AL	**Collimator Lamp Button and laser activation**	· To turn on the collimator lamp and laser lights.
Dual Laser	The projection of a single line means that the two lines overlap and consequently the lasers are correctly focused at 1m SID.	**Additional Variable Filtration** 	· **Motorized** · 1mm AL + 0,1mm Cu · 1mm AL 0,2 mm Cu · 2 mm Al.

Integrated DAP meter





◦ Radiation quality kV	From 40 to 150 kV
◦ DAP Range	From 0.1 a 99,999,999.99 µGy·m²
◦ DAP Rate Resolution	0.01 µGy·m²/s
◦ Precision	±20%.

ADAPTING KIT FOR IRAY DETECTOR

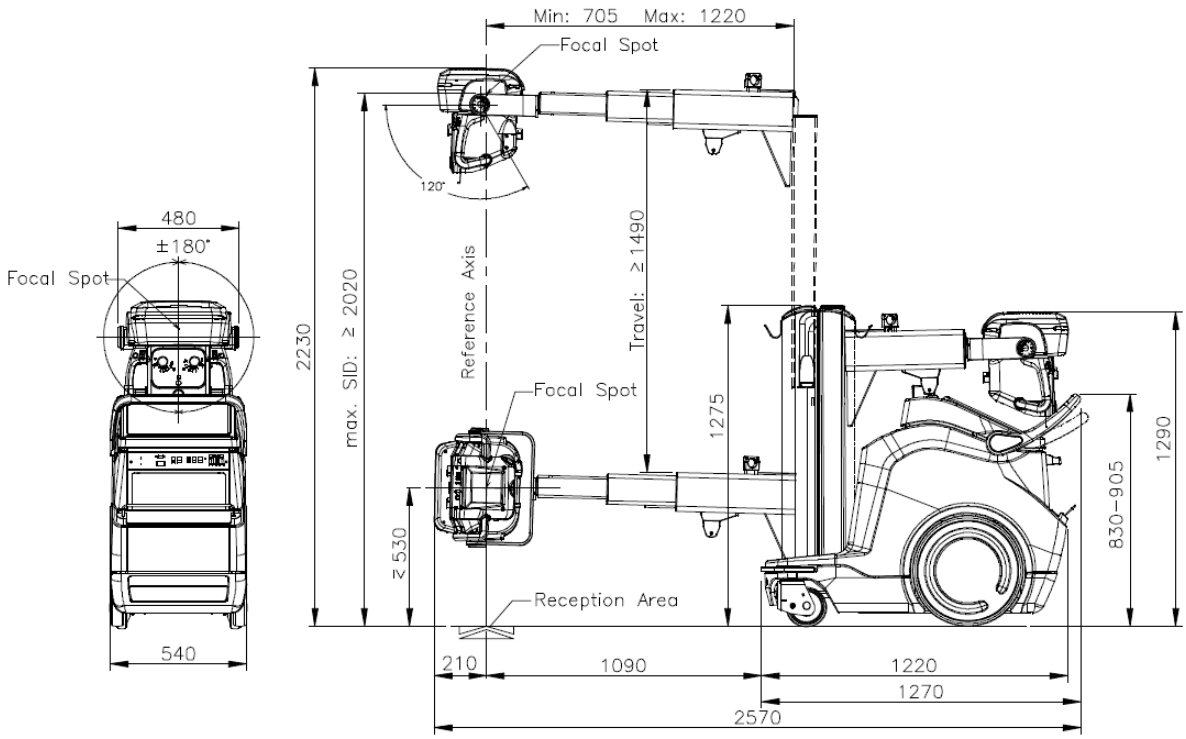
Abundant storage for detectors and their batteries arranged for a maximum ease of handling and usability: 2 detectors +2 batteries at the front and 1 detector at the rear of the unit.

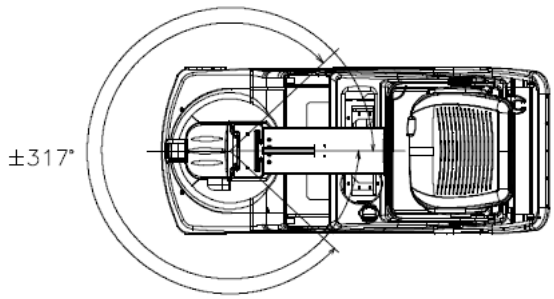
Designed with internal stops to facilitate hygienic detector bags insertion/removal and additional storage for two batteries (detector), ensuring simple and constant workflow.

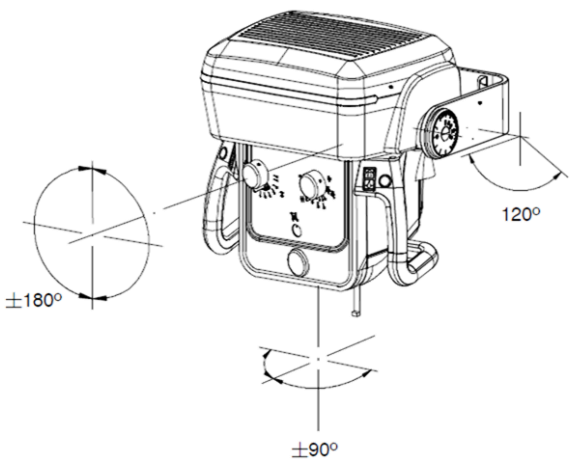
The unit incorporates a Detector safety blockage to prevent unauthorized use when the unit is alone.

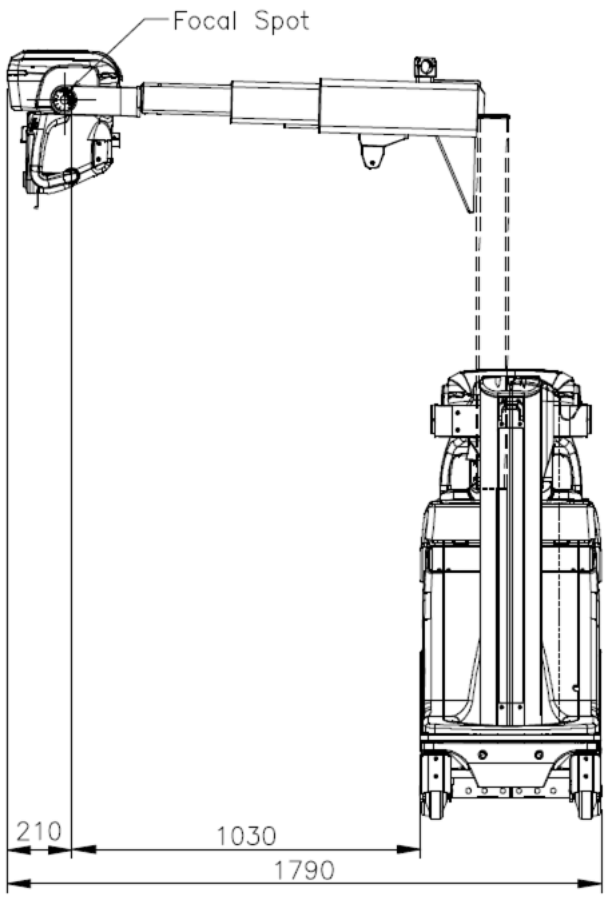
Front Storage Cabinet	• Detector Size	• Large Detector. • Pediatric Detector. • *D*etector-frame with handle *(*with/without grid).
	• Storage for detector Batteries	• 2 batteries
	• Detector **Lock Activation**	• When the unit is power off. • When the user has no permission (with Smart RFID option).
Back Storage Cabinet	• Detector Size	• Large or pediatric detectors or Detector-frame with handle (with/without grid).
	• Inner Stops for detector positioning	• For easy insertion/removal of hygiene bags

DIMENSIONS


Min: 705 Max: 1220
Focal Spot
120°
480
±180°
Focal Spot
2230
max. SID: ≥ 2020
Reference Axis
Travel: ≥1490
Focal Spot
1275
1290
830–905
≥ 530
Reception Area
540
210
1090
1220
1270
2570


±317°


120°
±180°
±90°


Focal Spot
210
1030
1790

PRIMO ACQUISITION SOFTWARE

Primo is a complete innovative and technological advanced digital DR system with multi-detector operations

- Professional acquisition software for X-ray images from flat panel systems (DR)
- The software controls X-ray generator, providing a smooth and systematic workflow.
- The professional image processing can be adapted to individual user needs and provides a complete control of all image capture
- functions within the examination room, enhancing the entire workflow by delivering diagnostic images instantly, and allowing users to move X-ray images electronically to remote workstations, image archives, and printers.
- Integrated functions and intuitive operation greatly simplify daily routine tasks.

PATIENT CREATION FRAME

Possibility of Creating manually a new study:

- Last Name and First Name
- Patient ID
- Date of birth
- Weight & Height, sex
- Accession Number
- Technician and doctor
- Patient´s notes, study description

ACCESSING THE STUDY LIST (WORKLIST)

- Possibility of Creating a new study from the Worklist.
- Possibility of requesting the Worklist from the RIS.
- Transfer one or more selected studies to the Study List.
- Associate the selected study with a previous study.
- Delete one or more selected studies.
- Delete the entire list of studies received from the RIS.
- Browse the list, if there is more than one page.
-

- On the right-hand side of the study list frame, you find the following keys:
- DICOM Store.
- Export studies to CD/DVD or USB.
- Report Tools.
- Patient´s data Edit.
- Rejected images (statistics).
- RDSR (Radiation Dose Structured Report):
- dose report of the selected study.
- DICOM SPOOLER shows the queue for DICOM store and print services.

WORKING FRAME AND IMAGE ACQUISITION

To start the radiographic exam the Working Frame led you to the exam selection window to choose the anatomical region required, then the anatomical part and finally the right exam:

- Head
- Chest
- Abdomen
- Cervical spine
- Pelvic measurement
- Humerus
- Femur
- AEC adjustment

Disposition of the Working Frame Information:

- Image area
- Exam List / Preview List
- Patient Data
- Messages Area:

This area contains indications of the detector connection status, the battery charge level, the amount of free space (%) on the archive disk and equipment status warnings and alarms.

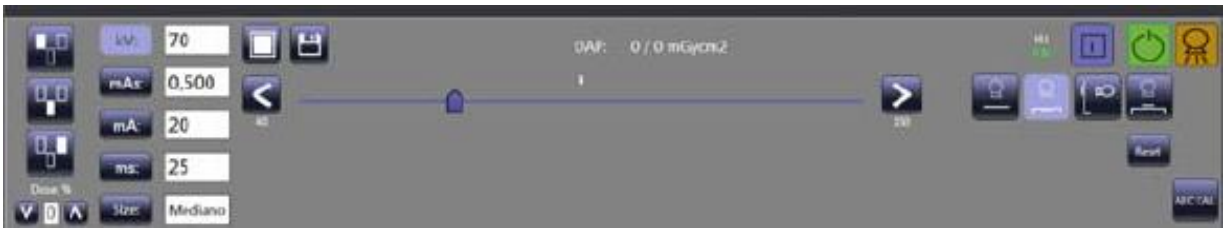
- **Generator Console** (X-ray parameters): Information about X-ray generator controls and parameters is shown in this area whenever the generator communicates directly with application. If this is not the case, information on the techniques to be selected in the generator can be displayed in this area.
- **Exam Management Area**: contains keys to delete, move or add procedure to your study, and to suspend or close the study.
- **Anatomical Region and exam selection.**

PROCEDURES TECHNIQUE

For an easy use is possible to set a Procedure to guide you through the performance of the exposures required for a study. Procedures define the exam/projection types needed for the study.

- Procedures are defined during installation of the system, in accordance with the operators and depending on the type of work required in the radiology theatre.
- A procedure can be associated to:
  - A single exam (projection) (e.g.: Std Thorax with just the PA projection of the thorax).
  - Several exams (projections) (e.g.: Full Thorax with both PA and LAT projections).
- You can either receive the Procedure from RIS via the Worklist function or chose it manually, e.g. when creating a new study manually.
- If a procedure is associated to a study, the system guides you during image acquisition and automatically presents the exams required.
- Otherwise, you need to select the exam type manually pressing the button PROC as in indicated below. All the procedures set in the system will be displayed.

X RAY GENERATION SETTING AND IMAGE ACQUISITION

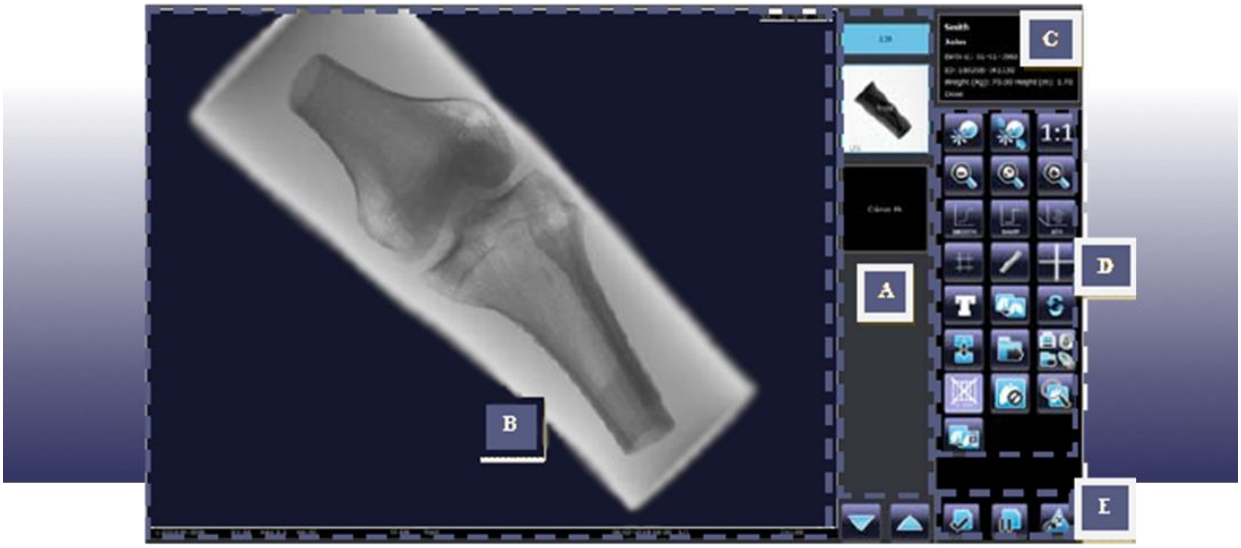


- The exposure parameters for the X-ray generator must be set to suit the exam and the patient size selected.
- To make things easier, the equipment shows the best X-ray generator settings for each exam and patient size (pre-set in the database during installation, as agreed with the users.)
- The following parameters are shown:

- 2-point technique (kV and mAs) or 3-point technique (kV, mA, and ms),
- kV, mAs, mA and ms, to suit the technique,

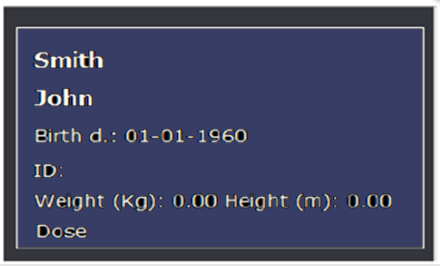
- Patient size.
- Status warning: “Ready for acquisition”

IMAGE PROCESSING FRAME



A. Previews / Exams List
B. Image area and dose information
C. Patient data
D. Image Processing commands
E. Study commands

Grey Scale	Exposure Values	Radiation Dose (DAP)	• ELT: Exposure index target according to the data of the selected technique. • EI: Exposure Index detected in the acquired image. • DI: Deviation of the Exposure index achieved from the target.	Exam / Projection	Acquisition date and time	• Image N° • Digital Zoom



- Patient´s name
- Birth Date
- Patient ID
- Weight and height
- Total Dose

IMAGE POST- PROCESSING

- Vertical/Horizontal image flip.
- Digital Zoom
- Spatial filters
- SMOOTH filter: this softens the edges of the image
- SHARP filter: this hardens the edges of the image
- SMOOTH + SHARP filters: both types of correction are applied.
- Images Cropping.
- Add object and text
- Duplicate images
- Store DICOM
- No grid functions
- Protect an image
- Image Multiview
- ATH Harmonization
- Measurements
- Distance calculation (with calibration function)
- Angle calculation.
- Rotate images
- Report Tool
- Magnifying glass
- Reject and image/Restore images
- Thumbnail.
- Brightness and contrast control.
- STATISTICS: The statistics function is used by the Technical Service when checking the system and so can only be accessed by the Advanced user.
- Allow to find the co-ordinates and pixel values for the image.
- Rectangle of a size set by the operator.
- Raw image statistics (RAW).
  - Equalized image statistics applied parameters:
  - Harmonization algorithm (ATH).
  - ROI for automatic W and L correction.
  - Gamma correction curve (LUT).
- Possibilities to export image to a removable device (CD or PEN DRIVE) in either DICOM or RAW format.
- OVERVIEW You can view more than one image in a study on the monitor at the same time. Select the overview function by pressing the relevant command.

IMAGES RECORDS

The following DICOM functions can be used to produce image records:

Export images to PENDRIVE or CD/DVD:

- The Study List frame, for exporting all the images in one or more studies,
- The Report Tool frame, for exporting specific images selected from within a study.

SEND IMAGES TO WORKSTATION/ PACS DICOM (Store DICOM):

- The Study List frame, for transferring all the images in one or more studies,
- The Report Tool frame, for transferring specific images selected from a study,
- The Working Frame, to transfer single images after post processing.

SEND IMAGES TO DICOM PRINTER:

The PRINT DICOM function is found in the Report Tool frame and lets you get a print-out of specific images selected from within a study.

SPOOLER DICOM:

This function manages the transmission of images to the DICOM network via a buffer memory (on the Hard Disk) where the images to be transmitted are stored in a queue.

DETECTOR IRAY MARS 1417X

Designed to provide the highest quality of X-Ray images with an active matrix of 2,304×2,800 pixels and **100µm pitch** (CSI).
With a Gigabit Ethernet connection for high data transfer rates and equipped with the possibility of query/upload images from detector to workstation, enable easy interchangeability between different X-Ray modalities (X-Ray mobile and fix ones).
It is the optimal choice for both retrofit and new DR System solutions, offering an effective and fast workflow.

- Wireless cassette detector. ISO 4090 fits in any bucky.
- Software with Auto-Exposure Detection.
- Best-in-class 100 µm pixel pitch with 16-bit ADC for more image details.
- Large capacity battery design, with **8+ hours battery life.**
- Lightweight design with IP56 ingress water protection.
- Supports a fast workflow for a better user experience.
- **With 200 images internal storage**
- Direct deposition CsI, with excellent DQE at all frequencies .

Very High trigger Sensitivity even with the thickest patients. Equipped with **internal X-ray sensors** which automatically detect the X-ray and synchronize image acquisition.

drop monitoring

Equipped with a unique drop monitoring system which serves as a real time tracker of panel dropping and shocking.

backup power cable, online charging solution

With its Charging connector is easy to keep the panel continuously charging without needing to replace the battery. The additional ethernet interface makes extremely easy to switch between wireless and wired mode.

long lasting battery

Faster operation, at least 500 exposures and **8,5 hours of continuous operation** before to recharge the battery. A few seconds to replace and restart the detector.

dual battery charger

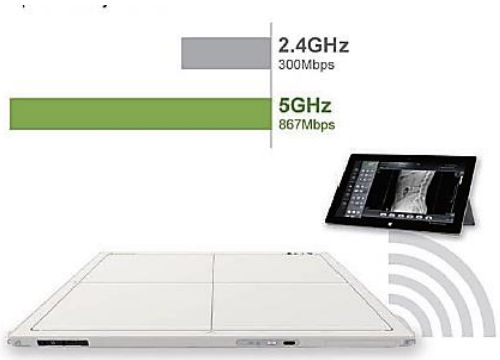
Battery charger with capacity of charging two batteries simultaneously for a non-interrupted workflow.

With Battery charging capacity indicator.

Pack of **two batteries included**.

robust wifi signals

Both 2.4G and 5G wireless mode is supported. With higher speed and stability under 5G modes.



IGZO

Faster readout speed reaching the smallest pixels for better resolution and lower noise for improved low-dose DQE and less leakage for higher dynamic range.

TECHNICAL DATA – MAIN CHARACTERISTICS	
Detector Technology	Amorphous Silicon (a-Si) TFT
Scintillator	CsI (Cesium Iodide)
Active Area	350 x430mm
Pixel Matrix	3.500 x 4300
Pixel Pitch	100 µm
Gray Scale	16bit
Spatial Resolution	4.3 lp/mm
AD Conversion	16bit
Battery Autonomy	8.5h
WiFi	2.4G and 5G
Trigger Mode	• Software (with Auto-Exposure Detection). • AED (Optional).
Full Image Time	Typ. 3.5s
Dimensions	460x384x15mm
Weight with battery	3.0 kg
Drop Monitoring	70cm @3mm PVC
Static Loading	300Kg (over the surface) 150kg (on an area 4cm diameter)
Protection Index	IP56
MTF	70% (1.0 lp/mm) 40.4% (2.0 lp/mm) 22.8% (3.0 lp/mm)
DQE	73.4% (0 lp/mm) @RQA5 55.9% (1.0 lp/mm) @RQA5 40.4% (2.0 lp/mm) @RQA5 28% (3.0 lp/mm) @RQA5
Operating Temperature	10-40 °C
Image Acquisition Time	3 sec
BATTERIES	
Rated Capacity	Min. 4,700mAh, Typ. 4,900mAh @ Discharge 0.2C
Nominal Voltage	11.55V
BATTERY CHARGER	
Simultaneous Charging	Pack of 2 batteries
Full charging time	3 hours
Rated power supply	24V(DC)
COMPONENTS	
Components included	1 Adapter for detector and battery charger 2 Batteries (Pack) 1 Gigabit Ethernet cable 1 AC Power Cable 1 DC Power Cable

PRIMAX INTERNATIONAL srl

Via A. Volta 10, 24060

Torre de Roveri ITALY

Phone +39 035 4500002


primax
INTERNATIONAL

ROTANODE™
XRR-3331X

Rotating Anode X-ray Tube Assembly

- This X-ray tube assembly is a part of medical X-ray diagnostic equipment applied for high energy X-ray radiography and fluoroscopy.
- The heavy anode is constructed with specially processed rhenium-tungsten faced molybdenum target which is 74 mm diameter and has an improved coating to increase thermal emissivity.
- This tube has foci 1.2 and 0.6, and is available for a maximum tube voltage 150 kV.
- Accommodated with IEC60526 type high-voltage cable receptacles.
- This X-ray tube assembly is used for medical diagnosis.

General Data

IEC Classification (IEC60601-1:2005+A1:2012) ..... Class Ⅰ ME EQUIPMENT

Electrical:

Circuit:

High Voltage Generator ..... Constant Potential High-Voltage Generator

Grounding ..... Center-grounded

Nominal X-ray Tube Voltage:

Radiographic ..... 150 kV

Fluoroscopic ..... 125 kV

Nominal Focal Spot Value:

Large Focus 1.2

Small Focus 0.6

Nominal Anode Input Power (at 0.1s):

	180 Hz	60 Hz	50 Hz
Large Focus	78 kW	54 kW	50 kW
Small Focus	32 kW	22 kW	20 kW

Nominal Radiographic Anode Input Power:

	180 Hz	60 Hz	50 Hz
Large Focus	70 kW	46 kW	42 kW
Small Focus	27 kW	17 kW	16 kW

Motor Ratings:

Stator: XS-AL

		Starting		Running	
Driven Frequency	[Hz]	180 [2)]	50/60	180 [2)]	50/60
Input power	[W]	1100	910	83	83
Voltage [3)]	[V]	220	130	60	40
Current	[A]	5.7	7.8	1.6	2.3
Min. Speed up [1) 5)]	[s]	1.2	0.8	-	-
Capacitor	[μF]	6	44	6	44
Min. Braking [2)]	[s]	3 / 90 V (DC)			

Note 1) The speed up time from normal speed to high speed is 2/3 times of the specified speed up time from 0 to high speed, which is described on motor rating table.
2) To be applied for high speed rotation.
3) The every applied voltage must be never exceeded 110% of the above specification.
4) No more than two high speed starts per minute are permissible.
5) The speed-up time is allowed up to 110% of the above specification.

Anode Speed:

180 Hz ..... Minimum 9700 min^{-1}
60 Hz ..... Minimum 3200 min^{-1}
50 Hz ..... Minimum 2700 min^{-1}

Stator Resistance:

Common-Main Winding ..... 9.4 Ω
Common-Auxiliary Winding ..... 28.3 Ω

Resistance Between Housing and Low Voltage Terminals ..... Minimum 2 MΩ
Normal Operating Range of the Housing Temperature ..... 16 ~ 75 ℃
Mode of Operating ..... Intermittent

Mechanical:

Dimensions ..... See dimensional outline
Overall Length ..... 479 mm
Maximum Diameter ..... 152.4 mm

Target:

Anode Angle ..... 12 degrees
Diameter ..... 74 mm
Construction ..... Rhenium-Tungsten faced Molybdenum

Filtration:

Permanent Filtration ..... 0.9 mm Al / 75 kV IEC60522:1999
Available Additional Filter Combination (0.4 - 1.5 mm) ..... Maximum 2.4 mm Al / 75 kV

Radiation Protection (In accordance with IEC60601-1-3:2008):

Leakage Technique Factor ..... 150 kV, 3.4 mA

X-ray Coverage ..... 430 × 430 mm at SID 1000 mm
Weight (Approx.) ..... 16 kg
High Voltage Receptacle ..... To meet requirements of IEC60526 Corrigendum1:2010
Cooling Method ..... Natural or forced air
Tube Housing Model Number XH-121

Absolute Maximum and Minimum Ratings
(At any time, these values must not be exceeded.)

Maximum X-ray Tube Voltage:
- Radiographic ..... 150 kV
- Fluoroscopic ..... 125 kV

Between Anode (or Cathode) and Ground ..... 75 kV

Minimum X-ray Tube Voltage:
- Radiographic ..... 40 kV
- Fluoroscopic ..... 50 kV

Maximum X-ray Tube Current:
- Large Focus ..... 1000 mA
- Small Focus ..... 400 mA

Maximum Filament Current:
- Large Focus ..... 5.5 A
- Small Focus ..... 5.2 A

Filament Voltage:
- Large Focus (At maximum filament current 5.5 A) ..... 10.9 ~ 16.6 V
- Small Focus (At maximum filament current 5.2 A) ..... 6.8 ~ 9.2 V

Filament Frequency Limits ..... 0 ~ 25 kHz

Continuous Anode Input Power ..... 142 W (200 HU/s)
(Fluoroscopic, Radiographic or mixed exposure)

Thermal Characteristics:
- Anode Heat Content ..... 210 kJ (300 kHU)
- Maximum Anode Heat Dissipation ..... 870 W (1226 HU/s)
- X-ray Tube Assembly Heat Content ..... 900 kJ (1250 kHU)
- Nominal Continuous Input Power:
  - Without Air-circulator ..... 180 W (15 kHU/min)

Environmental Limits

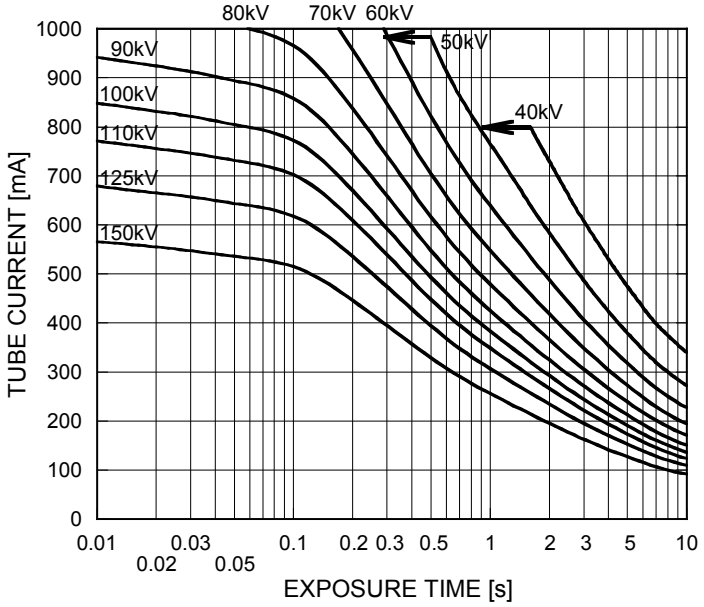
Operating Limits:
- Temperature ..... 10 ~ 40 ℃
- Humidity ..... 30 ~ 85 %
  (No condensation)
- Atmospheric Pressure ..... 70 ~ 106 kPa

Shipping and Storage Limits:
- Temperature ..... -20 ~ 70 ℃
- Humidity ..... 20 ~ 90 %
  (No condensation)
- Atmospheric Pressure ..... 50 ~ 106 kPa

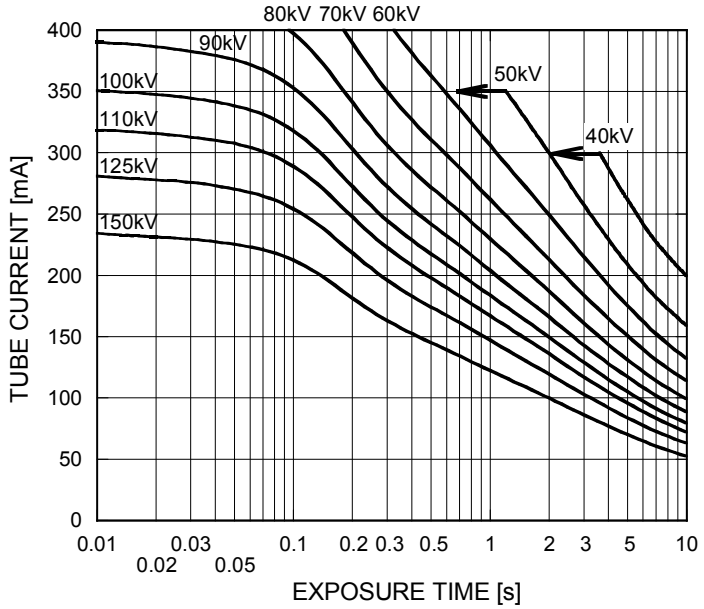
Maximum Rating Charts
(Absolute Maximum Rating Charts)

Conditions: Tube Voltage
Constant potential high-voltage generator
Stator Power Frequency 180Hz

Nominal Focal Spot Value: 1.2 ■



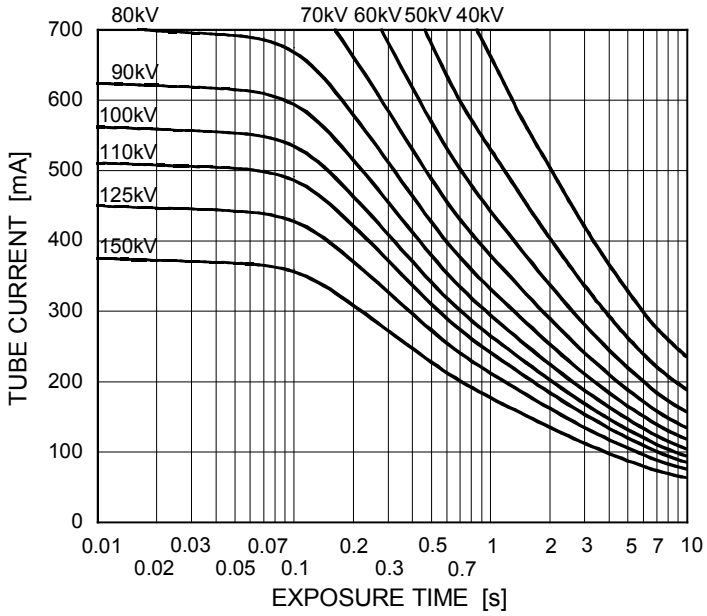
Nominal Focal Spot Value: 0.6 ▣



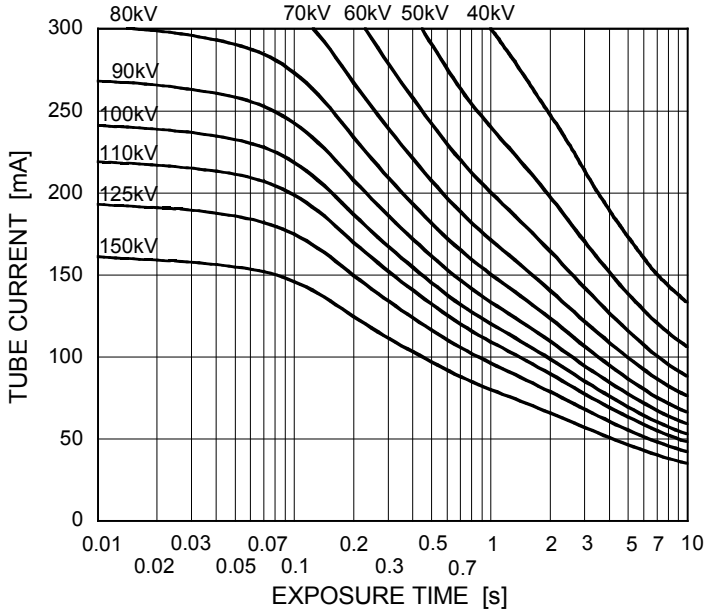
Maximum Rating Charts
(Absolute Maximum Rating Charts)

Conditions: Tube Voltage
Constant potential high-voltage generator
Stator Power Frequency 60Hz

Nominal Focal Spot Value: 1.2 ■



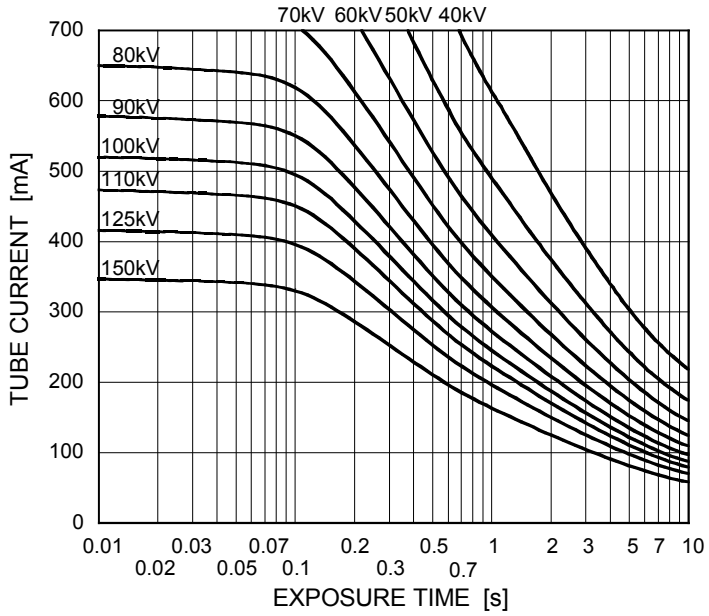
Nominal Focal Spot Value: 0.6 ▣



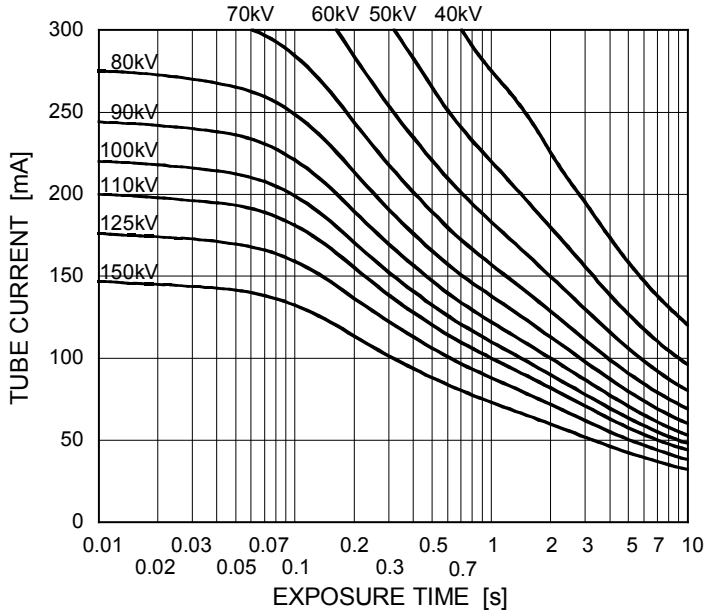
Maximum Rating Charts
(Absolute Maximum Rating Charts)

Conditions: Tube Voltage
Constant potential high-voltage generator
Stator Power Frequency 50Hz

Nominal Focal Spot Value: 1.2 ■



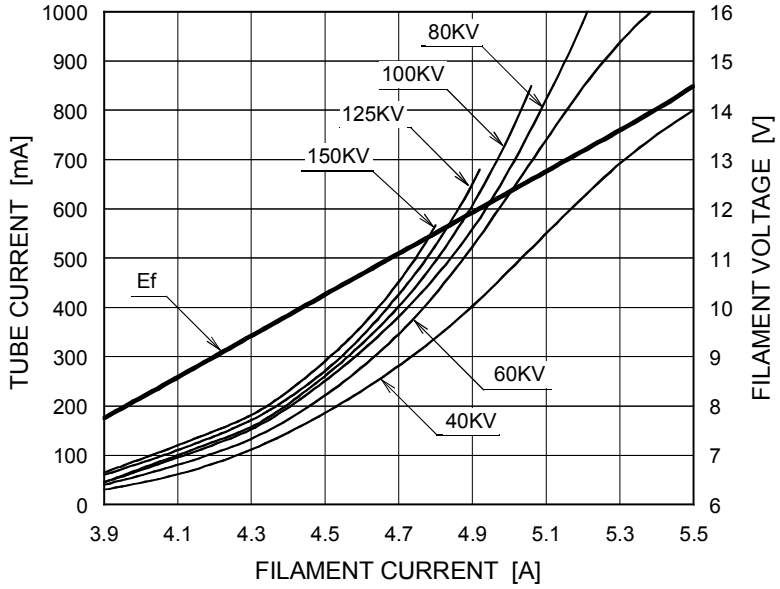
Nominal Focal Spot Value: 0.6 ▣



Emission & Filament Characteristics

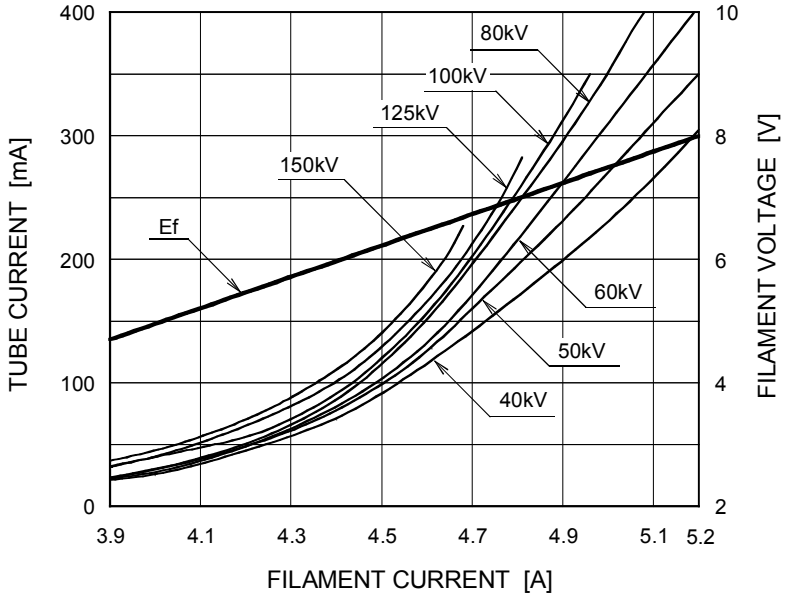
Constant potential high-voltage generator

Nominal Focal Spot Value: 1.2 ■



For Reference Only

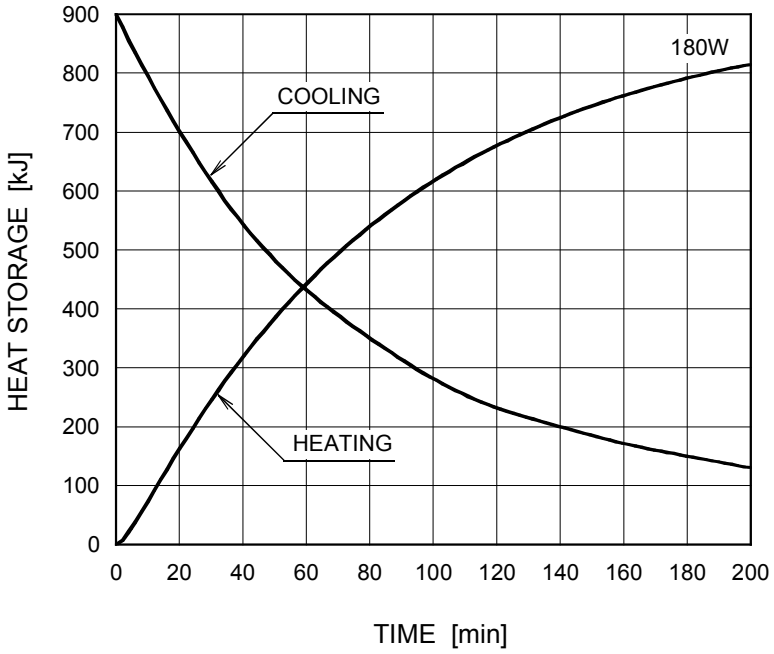
Nominal Focal Spot Value: 0.6 ▣



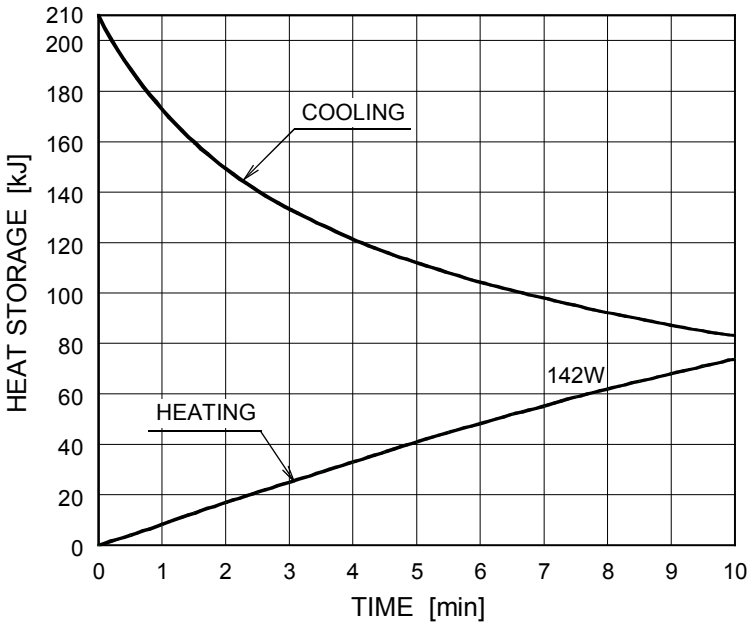
For Reference Only

Thermal Characteristics

X-ray Tube Assembly Heating / Cooling Curve



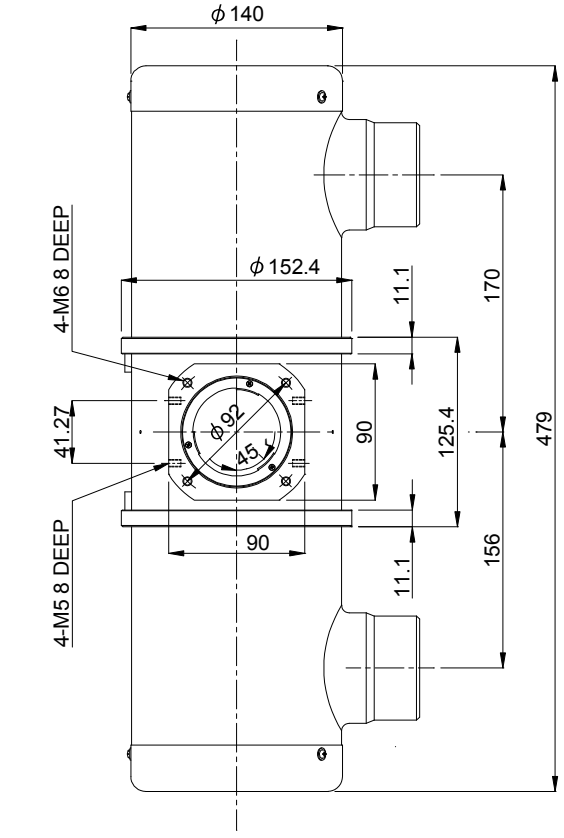
Anode Heating / Cooling Curve

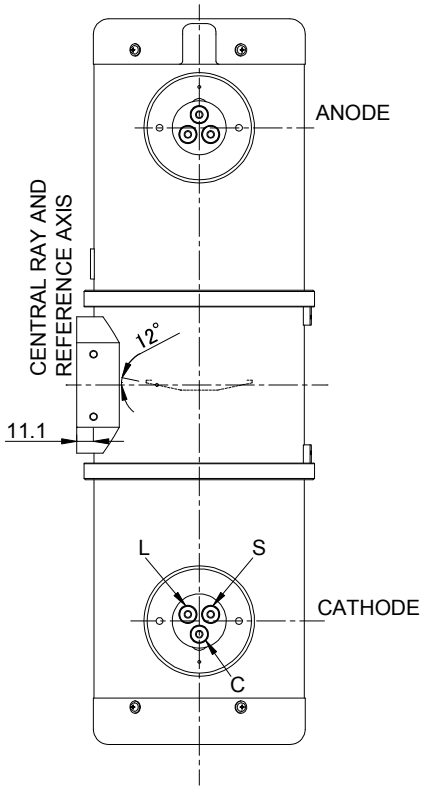


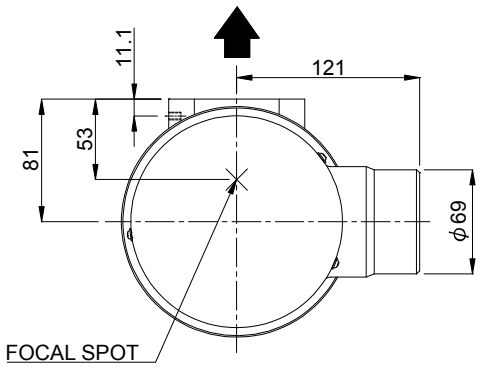
The heating curves are showing example of average input power to anode in operation.

Dimensional Outline

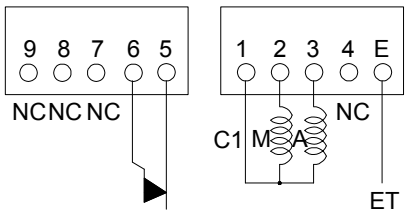
Unit: mm







TERMINAL CONNECTIONS

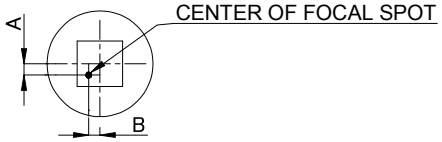


TEMPERATURE RELAY
(NORMALLY CLOSED)

Note) Do not connect terminal No.1 and No.5 or 6 in series circuit.

CATHODE TERMINAL
- C : COMMON
- L : LARGE FOCUS
- S : SMALL FOCUS

TERMINAL CONNECTIONS
- C1 : COMMON
- M : MAIN WINDING OF THE STATOR
- A : AUX. WINDING OF THE STATOR
- NC : NON-CONNECTION
- ET : EARTH TERMINAL



-1.5mm≦A≦1.5mm
-1.5mm≦B≦1.5mm

⬆: CENTRAL X-RAY

ANODE & CATHODE TERMINAL
: IEC60526 TYPE

CANON ELECTRON TUBES & DEVICES CO., LTD.
Marketing Engineering Group, Sales Department
1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan
Tel: +81-287-26-6666 Fax: +81-287-26-6060
https://etd.canon

PE-XRR-3331X 2018-11

21.3" Color LCD Monitor

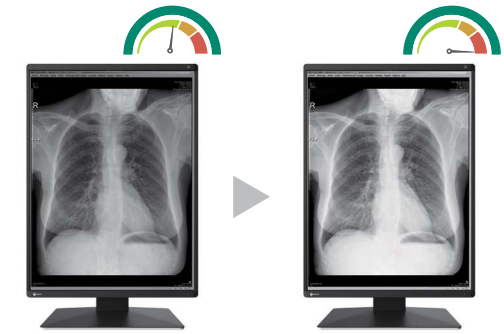
RadiForce® RX370

A 3 megapixel high-brightness monitor ideal for accurate display of monochrome and color images.

Boost Images for Easy Viewing

The Instant Backlight Booster function temporarily maxes the brightness of the monitor for quickly making detailed medical images easier to see. A single hotkey allows users to turn the function on for multiple monitors at once so they can easily view more than one screen under the same high-brightness conditions.

DICOM® Part 14 is not supported while Instant Backlight Booster is on.

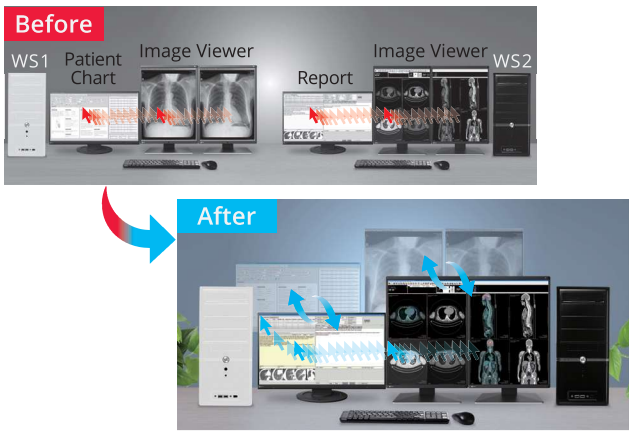


Instant Backlight Booster Off

Instant Backlight Booster On

Barrier-Free Workstyle

With the Switch-and-Go function, you can operate two different workstations at the same time with a single mouse and keyboard. Work across several monitors by moving the cursor from one screen to the other or switch the signals between workstations as needed without having to change your mouse or keyboard each time. This makes it possible to reduce the number of monitors in the workflow and improves work efficiency.



RadiForce® RX370

Display Both Monochrome and Color

The Hybrid Gamma PXL function automatically distinguishes between monochrome and color images pixel by pixel, creating a hybrid display where each pixel has optimum grayscale.

As a result, monochrome images such as CR and DR are displayed in the ideal grayscale that corresponds to DICOM Part 14, while color images such as those used in endoscopy, nuclear medicine, 3D rendering, and fusion imaging are faithfully reproduced corresponding to Gamma 2.2. This improves the efficiency of viewing both monochrome and color images together on one screen.

Make the Precise Diagnosis

EIZO carefully measures and sets the grayscale at the factory to ensure each monitor is compliant with DICOM Part 14. Furthermore, at startup or upon wakeup, the EIZO patented drift correction function quickly stabilizes the brightness level and compensates the brightness fluctuations caused by the ambient temperature and the passage of time, allowing medical images to be faithfully reproduced with stable brightness and grayscale.

Achieve Clarity True to the Source Data

A medical monitor needs to be capable of high brightness in order to meet performance standards. However, in order to achieve high brightness in an LCD panel, the pixel aperture ratio has to be increased. This causes a typically unavoidable decline in sharpness. With EIZO's unique Sharpness Recovery technology, the decrease in sharpness (MTF) is restored. This allows you to display an image that is true to the original source data safely on the monitor, even at high brightness levels.

Hassle-Free Multi-Monitor Configuration

Using the DisplayPort connection, you can drive several monitors in a daisy chain sequence. This allows you to configure a multi-monitor setup without the complicated hassle of excessive cabling.

A graphics board that supports daisy chain is necessary.

Maintain Image Quality Over Time

With the Integrated Front Sensor (IFS) built into the front bezel of the monitor and RadiCS LE software (included) , you can easily calibrate to DICOM Part 14 without having to mount, run, and remove an external sensor.

Simple calibration using the monitor backlight sensor is also supported.

Eye Relief with Gentle Light

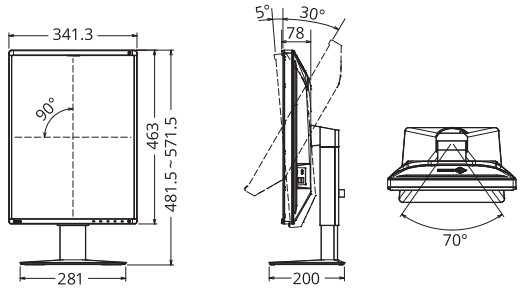
RadiLight is an optional light that attaches to the back of a RadiForce monitor and illuminates the wall behind it. This reduces eye strain for the radiologist viewing a bright monitor in a dark environment, while ensuring there are no reflections on the screen to interfere with reading. It can be attached directly to the monitor without removing the stand and does not take up additional desk space.

Specifications

Panel	Type		Color (IPS)
	Backlight		LED
	Size		21.3" (54.1 cm)
	Native Resolution		1536 x 2048 (3:4 aspect ratio)
	Viewable Image Size (H x V)		324.9 x 433.2 mm
	Pixel Pitch		0.2115 x 0.2115 mm
	Display Colors		10-bit (DisplayPort): 1.07 billion from a palette of 543 billion (13-bit) colors 8-bit: 16.77 million from a palette of 543 billion (13-bit) colors
	Viewing Angles (H / V, typical)		178° / 178°
	Brightness (typical)		1100 cd/m²
	Recommended Brightness for Calibration		500 cd/m²
	Contrast Ratio (typical)		1800:1
	Response Time (typical)		25 ms (black-white-black)
Video Signals	Input Terminals		DisplayPort x 2, DVI-D (dual link)
	Output Terminals		DisplayPort (daisy chain)
	Digital Scanning Frequency (H / V)		31 - 127 kHz / 29 - 61.5 Hz
USB	Upstream		USB 2.0: Type-B x 2
	Downstream		USB 2.0: Type-A x 2
	Dedicated Charging Port		USB Type-C (Power Supply 15 W max.)
Power	Power Requirements		AC 100 - 240 V: 50 / 60 Hz
	Typical Power Consumption		36 W
	Maximum Power Consumption		105 W
	Power Save Mode		1 W or less
Sensor			Backlight Sensor, Integrated Front Sensor, Ambient Light Sensor
Features & Functions	Brightness Stabilization		Yes
	Digital Uniformity Equalizer		Yes
	Hybrid Gamma PXL		Yes
	Work-and-Flow		Hide-and-Seek, Switch-and-Go, Point-and-Focus, Instant Backlight Booster
	Preset Modes		CAL Switch (DICOM, CAL1, CAL2, Custom, sRGB, Text)
	OSD Languages		English, German, French, Italian, Japanese, Simplified Chinese, Spanish, Swedish, Traditional Chinese
Physical Specifications	Net Weight		8 kg
	Net Weight (Without Stand)		5.2 kg
	Hole Spacing (VESA Standard)		100 x 100 mm
Certifications & Standards (Please contact EIZO for the latest information)			CE (Medical Device), EN60601-1, ANSI/AAMI ES60601-1, CSA C22.2 No. 601-1, IEC60601-1, VCCI-B, FCC-B, CAN ICES-3 (B), RCM, RoHS, China RoHS, WEEE, CCC, EAC
FDA			510(k) Clearance for General Radiography*
Dedicated Software		Monitor Quality Control Software RadiCS	Supported
Supplied Accessories (May vary by country. Please contact EIZO for details.)		Signal Cables	DisplayPort (3 m) x 2
		Others	AC power cord (3 m), USB Type-A - USB Type-B cable (3 m) x 2, Utility Disk (RadiCS LE, PDF instructions for use, PDF installation manual), instructions for use
Warranty			Five Years

** Display of mammography images for diagnosis is not supported.*

Dimensions (Unit: mm)



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VIEW / PRO

THE RADIOLOGY READING STATION

BY RADIOLOGISTS FOR IMAGING SPECIALISTS

VERSION 3.1

RADIOLOGY READING AT YOUR FINGERTIPS

The key factor for physicians who frequently read medical imaging studies is selecting the appropriate reading station.

The perfect reading station needs to be user-friendly and provide the highest level of functionality. iQ-VIEW fulfills both of these requirements since it has been designed by radiologists for imaging specialists.

BASIC and PRO

The software is available in two editions. The BASIC edition - iQ-VIEW - was developed as a reading and reviewing station for all physicians, including orthopedic surgeons, chiropractors and internal specialists, while iQ-VIEW PRO is optimized for radiologists.

Quick and Easy

iQ-VIEW offers quick and intuitive access to tools for improved efficiency. All image processing tools can be selected via buttons, menu items or keyboard shortcuts. A configurable toolbar in the viewer facilitates the easy selection of functionalities needed for processing images. The most relevant buttons can simply be set up in the user's own default toolbar.

Previous Studies - Automatically

iQ-VIEW PRO provides a unique automatic previous studies management, which helps the radiologist save time by searching for relevant previous studies of a patient and loading them automatically into the viewer.

Through matching similar patient names in addition to searching for the same patient ID the number of missed relevant priors is reduced significantly.

Hanging Protocols

The PRO edition includes further a Hanging Protocol tool, allowing the creation of individually customizable hanging protocols. As a result, studies and images can be loaded automatically as physicians wish to read them. Hanging protocol sequences offer the possibility to easily switch between different formats for the same study. It is furthermore possible to set up modality-specific toolbars.

Flexible integration
iQ-VIEW can be integrated into virtually any RIS, EMR or HIS available on today's market. Specialty readers find interfaces to further image analysis tools, such as 3D post-processing and orthopedic templating.

Versatile uses:
Import - Export - Report
iQ-VIEW can function as an image acquisition station by importing images from scanners, directories and portable media, including options for patient reconciliation offered in the PRO version. It is also possible to attach scanned documents to an already existing study.

The software can further be used as an exporting station by writing imaging data and reports to CDs, DVDs or memory sticks, by printing on Windows® laser printers or DICOM medical imagers (including true-size DICOM printing), or by emailing any study to a colleague (even in diagnostic quality). iQ-VIEW may be used as a manual radiological media burning station – or alternatively, as a semi-automatic one in connection with iQ-ROBOT.*

iQ-VIEW cannot only be used to read studies and reports, but it also comes with a basic reporting module, that enables users to create, edit, store and send their own structured reports.

Teleradiology? No problem.
iQ-VIEW is also ideal for teleradiology purposes. Encrypted DICOM email makes it possible – ask any colleague anywhere in the world for a second opinion – with only one mouse click! This technology allows the quick, easy exchange of information among colleagues by email. Or, use the email feature to send out your image data as JPEG files.

Licensing
Depending on your needs, iQ-VIEW is available either with a single or a concurrent license. A single license is bound to the computer on which the application is installed. Concurrent licensing (i.e. floating licensing or network licensing) is an alternative licensing model allowing to use a specified number of workstations installed within a network at the same time without having to license each application individually.

Certified quality and reliable service
Of course, iQ-VIEW is CE and FDA 510(k) certified and complies with the DICOM and IHE standards. The application is compatible with virtually all medical imaging DICOM devices on the market, regardless of the manufacturer.

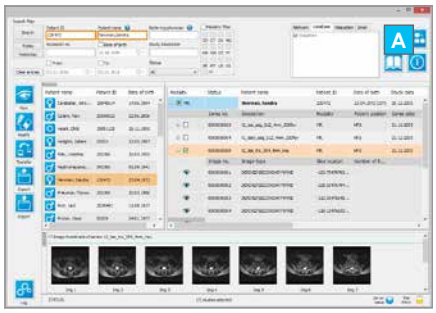
Continuous improvements to the software, combined with intensive testing in IMAGE Information Systems' quality assurance labs, guarantee that iQ-VIEW's high level of stability is maintained at all times.

Low maintenance costs assure a quick return on investment.

IMAGE's worldwide network of manufacturer-trained service engineers ensures that guidance and support is just around the corner.

*Please note: iQ-ROBOT must not be sold or used in the United States of America and the United Kingdom.

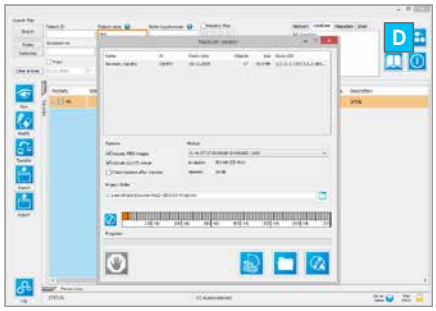
iQ-VIEW/PRO SCREENSHOTS



A *The Study Browser provides a clear overview of all imaging data including structured reports. A patient list automatically sorts all available studies by patient.*

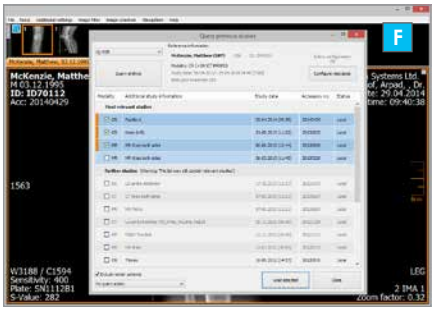
B *All image processing tools can be accessed either by selecting buttons or menu items, or even by using shortcuts. For an easy orientation within a series, the user-friendly viewer offers several scoutpilot tools, such as the lines mode and the 3D position display.*

C *iQ-VIEW can be used as a printing station; the integrated print manager allows for a flexible optimization of the printouts.*



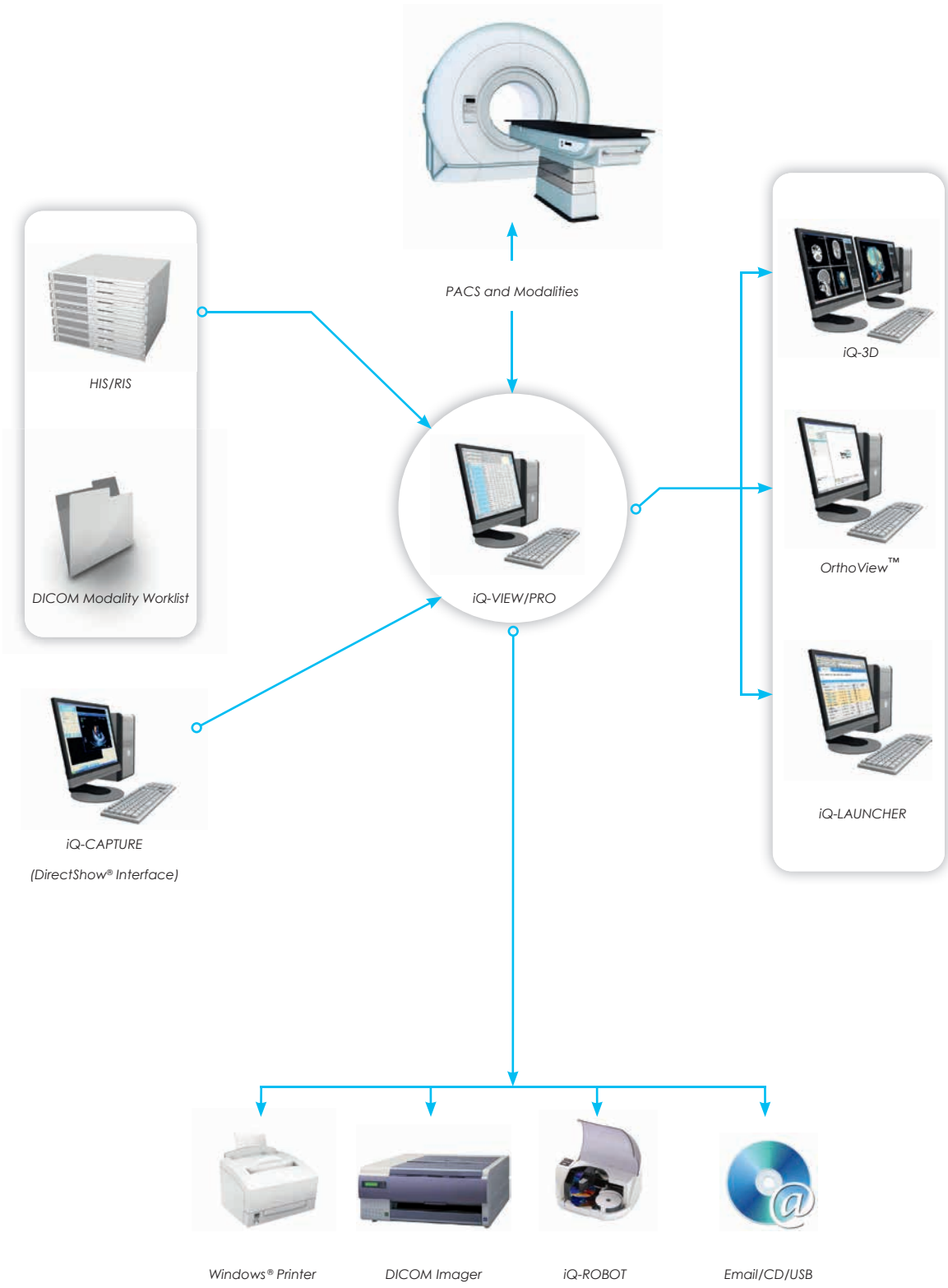
D *Single and multiple studies and series can be exported to a CD, DVD or USB memory stick, all containing an iQ-LITE media viewer. Exporting to DICOM email, to directories and different file formats is also possible.*

E *The import module is a comprehensive tool for the acquisition of images from different sources (such as scanners, capture devices, cameras, microscopes or file directories) and their conversion to DICOM.*



F *iQ-VIEW PRO searches for relevant previous studies of a patient and loads them automatically into the viewer for study comparison. The search can be extended to include similar spellings or typing errors in patient names.*

iQ-VIEW/PRO WORKFLOW



iQ-VIEW places you, the reading physician, at the heart of all diagnostic processes. Receive studies from all modalities or a PACS in your reading station, be connected with your colleagues and referring physicians via DICOM or DICOM email or easily run iQ-VIEW integrated with your HIS or RIS. You can even use specialty tools closely interfaced with your viewer for 3D post-processing or orthopedic templating.

iQ-VIEW FEATURES

GENERAL

- Support of DICOM datasets with specific character sets other than ISO_IR 100 (incl. Unicode; see DICOM conformance statement for further details)
- Scalable buttons and possibility to set font size (for high-resolution displays)
- Multimonitor support
- Visual styles to create a more comfortable working experience, especially in reading room conditions

STUDY BROWSER

- Study table
- Virtual patient list and thumbnail preview
- Display of patient age in addition to date of birth (NEW!)

VIEWER

- Image processing (including comparison of multiple studies and image filters, synchronization/desynchronization of series)
- Speedy zooming, panning, cine mode and windowing
- Additional zoom presets 1/3 and 1/2 (NEW!)
- Faster reading through improved functions
  - Right-click context menu for quick access to frequently used processing functions
  - Enhanced "Magnifier" tool with real 16 bit interpolation and zoom factor presets
  - Easily synchronize cranio-caudal acquired series with caudo-cranial series without manual preparations
  - Possibility to reset "Windowing" changes
  - "Cine mode" combined with "Bind mode"
- Measurements (including distance, angle, Cobb angle, hip dysplasia angle, ROI, ratio, and modify/delete options)
- Basic annotation of images (incl. Secondary Capture image creation)
- Thumbnail selection for series preview (image from the middle of the series is shown to better present the content of the series)
- Mouse cursors available in different sizes
- DICOM presentation states on image level
- Configurable scoutlines to display plane projections/plane intersections
- Support of look-up tables, bitmap overlays and DICOM shutter sequences
- Lightbox window* (white screen) for easy comparison of digital medical images with images on film
- Configurable bottom toolbar and creation of viewer shortcuts
- Open tomosynthesis studies
- Fast opening of enhanced DICOM objects, e.g. enhanced CT, enhanced MR

REPORTING

- Structured reporting with read/write/edit support of Basic SR objects
- Read-only support for other SR formats

EXPORT

- Patient CD/DVD/USB
- Integration of direct interface to iQ-ROBOT for patient CD/DVD creation
- DICOM email and JPEG images by email
- Image export to image file or AVI video file** (including measurements, windowing, color remapping, annotations and more)
- Support of modern 32-bit and 64-bit email clients to send DICOM email, e.g. Outlook (Microsoft 365) (NEW!)

*Only permitted for diagnostic use if legal requirements are met. Ask your local dealer for details.
** Depending on local configuration

iQ-VIEW FEATURES*

IMPORT
- Patient CD/DVD/USB import
- TWAIN interface (scanner, CR reader system, camera etc.)
- Image file import (BMP, JPEG, TIFF, RAW)
- Drop box interface

PRINTING
- Support of additional paper formats for DICOM Print to imagers of any brand, incl. true-size (1:1) DICOM printing (NEW!)
- Windows® Print

COMMUNICATION
- DICOM Query/Retrieve, C-FIND, C-STORE, DICOM print client and DICOM email
- Server administration tool for easier DICOM configuration
- HIS/RIS interface (accession number or GDT/BDT) (others on request)

ADD-ONS
- Optional 3D post-processing (iQ-3D)
- Optional orthopedic templating (OrthoView™)
- Optional integration of 3rd party image processing or image analysis tools (iQ-LAUNCHER)

LICENSING
- Single (PC-based) or concurrent (floating user) licenses
- New license library (from v3.1.101) for a more stable operation and central management of concurrent iQ-VIEW (and iQ-ROUTER, iQ-ROBOT, DICOMReader) licenses (NEW!)

LANGUAGES
- Bulgarian, Chinese, Czech, Dutch, English, Estonian, Finnish, French, German, Italian, Japanese, Korean, Latvian, Polish, Portuguese, Russian, Spanish, Ukrainian (NEW!)

CERTIFICATION
- CE 0482 / FDA 510(k)**

iQ-VIEW PRO FEATURES*

IN ADDITION TO iQ-VIEW FEATURES

VIEWER
- Customizable automatic previous study management
- Finding previous studies by matching similar patient names (NEW!)
- Hanging Protocols (incl. HP sequences and modality-specific toolbars)
- Further measurements: perpendicular distance, point-to-line distance (e.g. to assess the lumbar vertebral rotation), polygonal ROI, interior angle (e.g. to easily measure the distal radiometacarpal joint angle, the radial inclination or many more important clinical values)
- Copy of measurements to other images for 3D measurements, e.g. TTTG
- Dynamic magnifier window for seamless image zooming
- Annotation of images (incl. storing and sending as Presentation States)
- Color schemes for nuclear medicine, e.g. GE Color, Hot Iron

COMMUNICATION
- DICOM Modality Worklist Client

IMPORT
- Optional video capture interface iQ-CAPTURE (DirectShow®)

* Detailed information on iQ-VIEW/PRO's system requirements is available in the iQ-VIEW Administration Guide or the iQ-SYSTEM PACS Hardware Purchasing Guide.
** iQ-VIEW/PRO is a component of iQ-SYSTEM PACS 1.6 (FDA UDI B403IQS160).

OUR COMPANY AT A GLANCE

IMAGE Information Systems is an international company group with offices in Germany and the USA which offers complete, user friendly and cost-effective medical imaging solutions.

Thousands of satisfied clients all over the world benefit from our state-of-the-art products for PACS, RIS, X-ray solutions, 3D processing and teleradiology.

We have pioneered several innovations in the market:

- We have introduced MED-TAB, the first DICOM-calibrated portable display for medical image analysis
- Our iQ-ROUTER supports virtually all DICOM image formats and transfer syntaxes in data transmission
- DICOMReader has the highest available read-in rate of patient media, ensuring compatibility with almost all available imaging modalities and vendors

IMAGE Information Systems provides the second largest digital imaging user forum on earth, enabling users to share knowledge and best practice.

To learn more about us and our products, please visit our website.

www.image-systems.biz

OUR PRODUCTS FOR YOUR IMAGING NEEDS

iQ-SYSTEM PACS	Full featured, reliable and affordable PACS
iQ-RIS	Smooth radiology information system
MED-TAB™	Superior portable image analysis

Stamp of sales partner

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POLIMASTER®

Radiation Detection Technologies

X-RAY AND GAMMA RADIATION PERSONAL DOSIMETER

RadFlash

RadFlash® X-ray and Gamma Radiation Personal Dosimeter is a miniature electronic dosimeter capable of solving a wide range of personal dose monitoring tasks, including measurement of **personal dose equivalent** and **personal dose equivalent rate of X-ray (continuous and pulsed) and gamma radiation**.

When used with PM530 and PM531 dosimetry software, RadFlash provides assurance that occupational radiation exposures are accurately measured, analyzed, and reported. RadFlash allows for avoiding overexposure by providing **real-time** measurements and timely warning the wearer that the dose and dose rate thresholds are exceeded. This ensures that specialists can respond quickly and minimize potential health risks.

RadFlash is compatible with the free Polismart® App that delivers radiation exposure analytics and insights to users and enables wireless transfer, analysis, and reporting of the exposure data captured by the dosimeter. Polismart allows for tracking exposure and adjusting dosimeter settings anytime, anywhere, solely with your smartphone.

Applications

- Healthcare workers
  - Interventional radiology
  - Medical physicists
  - Radioisotope labs
  - X-ray diagnostics
- Customs and border control officers working with X-ray inspection equipment
- Anyone working under the risk of X–ray and gamma radiation exposure

Features

- Simple dose reads via smartphone or PC at any time
- Easy setup via free Polismart® iOS and Android app
- Clips and a wristband for different wearing options
- Resistance to cleaning and disinfection agents
- On-screen, audible and visual (LED) alarms
- Data transfer via Bluetooth
- Small and lightweight
- Single control button
- Wireless charging

γ X-RAY IP67

RadFlash
X-RAY AND GAMMA RADIATION PERSONAL DOSIMETER

POLIMASTER®
Radiation Detection Technologies

SPECIFICATIONS

Detector	Geiger-Mueller tube
Dose rate measurement range	0.1 μSv/h to 1 Sv/h
Dose rate measurement accuracy	±15 %
Dose measurement range	1 μSv to 10 Sv
Dose measurement accuracy	±15 %
Energy range	15 keV to 1.5 MeV
Energy response relative to 0.662 MeV (^{137}Cs)	–29 % to +45 %
Minimum pulse duration of pulsed X-ray radiation	2 ms

Memory	6000 events
Alarms	visual, audible
Communication	Bluetooth 4.0 (FCC ID: QOQ13, IC: 5123A-13)
Power supply	rechargeable battery (wireless charger provided)

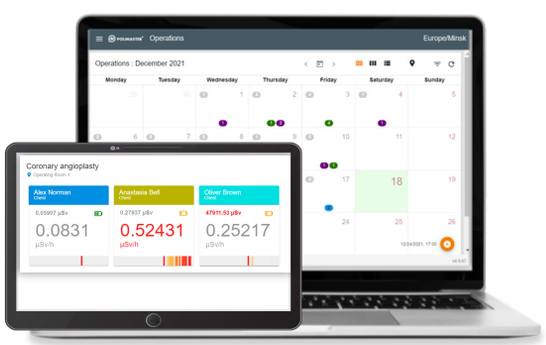
Battery lifetime

– Bluetooth off, dose rate < 0.3 μSv/h	≥ 2 months
– Bluetooth on, dose rate < 0.3 μSv/h	≥ 10 days
– Bluetooth on, dose rate < 1 Sv/h	≥ 8 hours

Ingress protection	IP67
Drop test	1.5 m
Dimensions	≤ 63 × 50 × 18 mm
Weight	≤ 50 g

Operating conditions

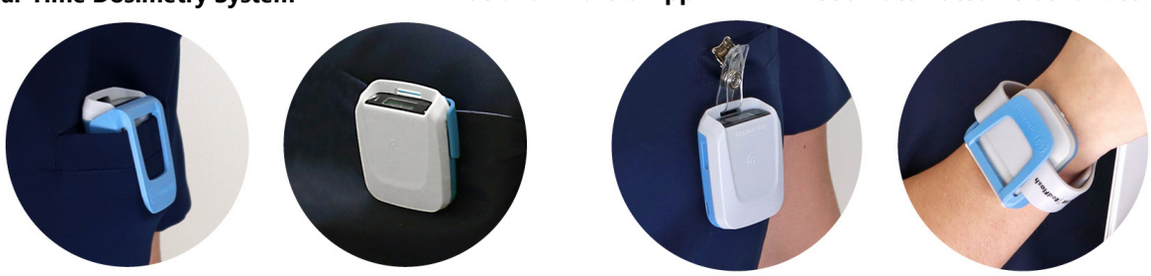
– ambient temperature	–10 °C to 50 °C
– atmospheric pressure	84 kPa to 106.7 kPa
– relative humidity	up to 98 % at 35 °C



Compatible with PM531 Real-Time Dosimetry System

Compatible with free Polismart iOS and Android App

Compatible with PM530 Automated Personal Dosimetry System



Three clips and a silicone wrist band for multiple wearing options

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