DX-D 100 Mobile X-Ray Unit

User Manual

Technical Publication
0188K EN 20201116

AGFA

REVISION HISTORY

REVISION	DATE	REASON FOR CHANGE
A	JUL 06, 2010	First edition
B	JUN 10, 2011	General Update and DR Detector options
C	MAY 27, 2013	IEC Standards; DR Detector options; Battery Charge Level Indicators
D	NOV 21, 2013	Displacement Controls Update and Collimator
E	JAN 29, 2015	Telescopic Column (Option); Lead-Crystal Batteries; Displacement Controls; Storage Bin for Wireless configuration; Factors: Power Line Operation, Maximum Input Power, Battery Capacity, Maximum Symmetrical Radiation Field, Environmental Conditions; General Update
F	JUL 30, 2015	Designated Significant Zones of Occupancy, Distribution of Stray Radiation; Control Panel: ON/OFF Keypad for Access Control (Option); Additional Features: Bluetooth (Option), LED Beacon Light, Tube Rotation Indicators; Advisory Indications in Section 3.8 of Motion Controls; Information for Collimator Rotation; Configuration for Wireless DR Detectors Options, Integrated Battery Charger; Weight for Mobile units with Standard Column; Illustrations, Pictures and General Update
G	OCT 05, 2016	General Update
H	SEP 20, 2018	New Label; Intended Use, IEC Standards Update; General Cautions; Removed information for Gel Batteries; Hand-grips Support (option); New Storage Bin; New Detectors; Back-up Cable and Illustrations
I	NOV 13, 2019	Mains Connection and Line Circuit Breaker; Manual Clutch Screws; Parking Position of the Arm; Collimator Controls, Dosimetry, Optional Wired Configuration for some Wireless DR Detectors and Illustrations
J	MAY 22, 2020	Battery Charge Level Indicators; Appendixes A and B and General Update
K	NOV 16, 2020	Displacement Controls

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 TO EQUIPMENT OR DATA.

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

Note ☞

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

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SECTION 1 INTRODUCTION

This manual contains all the information necessary to understand and operate the ***DX-D 100 Mobile X-ray Unit***. It provides a general description, safety and regulatory information, operating instructions and specifications concerning the system.

This manual is not intended to teach radiology or to make 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 Generator 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.

The Unit consists of the following fundamental parts:

X-RAY GENERATION COMPONENTS

- *Control Console.*
- *Generator*, that comprises:
  - *Power Module*, which contains the power and control components.
  - *High Voltage Transformer*.
  - *Battery Module,* with the batteries and charge / control components.
- *X-ray Tube*, part of the Tube-Collimator Assembly.
  Tubes: E7865X, E7884X.

ASSOCIATED EQUIPMENT AND SUBASSEMBLIES

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

- *Unit Motion Assemblies,* that comprises:
  - *Batteries and Charger Module*, to power the motors.
  - *Motor Assembly*, motors and wheels.
  - *Driving Control Assembly*, handlebar, motion controls at the Tube-Collimator Assembly, gauges and related electronic components.

- *Rotating Column and Telescopic Arm,* holding the Tube-Collimator Assembly and allowing its positioning.

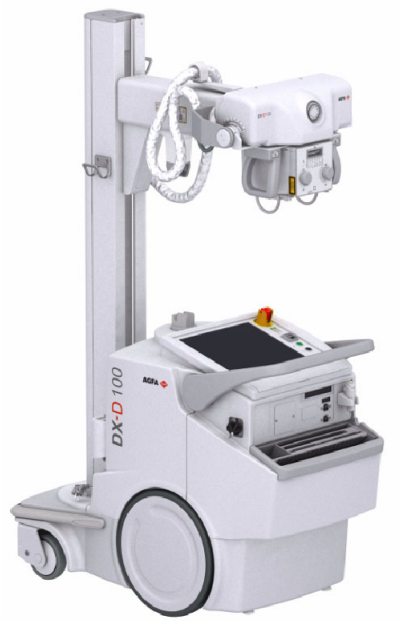
  There are three Column types available:
  - *Standard Column.*
  - *Standard Short Column (optional).*
  - *Telescopic Column (optional, only for Mobile with Wireless DR Detector).* The Telescopic Column in parking position reduces the height of the ***DX-D 100 Mobile X-ray Unit*** in order to have complete visibility and safety when driving the system.

- *Collimator,* part of the Tube-Collimator Assembly:
  RALCO R221/A DHHS-170E, RALCO R221/A DHHS-170D.
- *DR Detectors and Grids.*
- *Holders for DR Detectors, Grids, and Accessories.*

Illustration 1-1
DX-D 100 Mobile X-ray Unit

Configuration for Wireless DR Detector:
with Standard Column (1) / with Telescopic Column, optional (2)

(1)



(2)

Configuration for Portable DR Detector, with Standard Column

1.1 GENERAL FEATURES

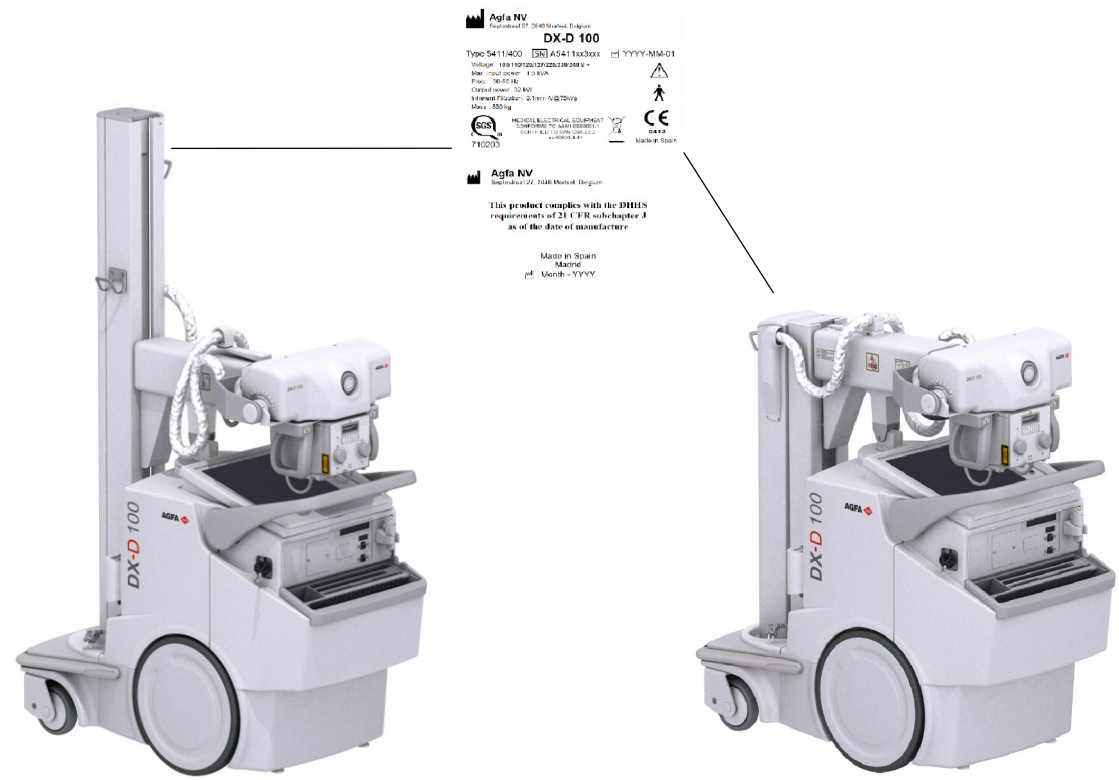
The main features of this Unit are:

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

1.2 PRODUCT IDENTIFICATION

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

- Manufacturer.
- Product.
- Model, serial number and date of manufacture.
- Voltage (V), Input Power (kVA), Frequency (Hz) and Output Power (kW).
- Inherent Filtration.
- Mass.
- Certifications and Symbols.
- Place and date of manufacture.



***** The Label data can vary, depending on the ***DX-D 100 Mobile X-ray Unit*** model

1.3 INDICATIONS FOR USE

1.3.1 INTENDED USE

This equipment is intended for use by qualified personnel only.

The ***DX-D 100 Mobile X-ray Unit*** is an equipment designed for general radiography in hospitals, clinics, radiology imaging centers and medical practices to perform processes and provide X-ray radiographic images of the skeleton, skull, chest, spine, pelvis, lung, abdomen, extremities and other body parts on the patients.

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

This ***DX-D 100 Mobile X-ray Unit*** contributes to the metrics of imaging performance ensuring the efficient use of radiation.

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

1.3.2 NORMAL USE

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

1.3.3 CONTRAINDICATIONS

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

This equipment is not intended for mammographic applications.

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

SECTION 2 SAFETY AND REGULATORY INFORMATION

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

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

2.1 GENERAL

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

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

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

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

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

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

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

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

WARNING

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

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

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

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

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

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

2.2 RESPONSIBILITIES

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

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

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

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

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

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

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

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

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

2.3 MAXIMUM PERMISSIBLE DOSE (MPD)

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

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

2.4 RADIATION PROTECTION

Although this equipment is built to the highest safety standards and incorporates a high degree of protection against X-radiation other than the useful beam, no practical design of equipment can provide complete protection, nor can any practical design compel the operator to take adequate precautions to prevent the possibility of any persons carelessly, unwisely, or unknowingly exposing themselves or others to X-radiation.

IT IS THE RESPONSIBILITY OF THE OPERATOR TO RESTRICT THE ACCESS TO THE UNIT IN ACCORDANCE WITH LOCAL REGULATIONS FOR RADIATION PROTECTION.

Because exposure to X-ray radiation can be damaging to the health, use great care to ensure protection against exposure to the primary beam. Some of the effects of X-ray radiation are cumulative and may extend over a period of months or years. The best safety rule for an X-ray operator is *"Avoid exposure to the primary beam at **all times**"*.

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

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

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

- Wear radiation protective clothing.

- Wear a personal 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 (SID) as large as possible to keep the absorbed dose for the patient as low as reasonably possible.

The radiation dose decreases or increases according to the Focal Spot to 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

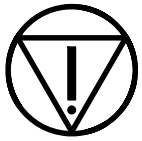
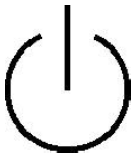
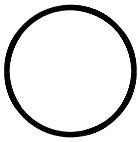
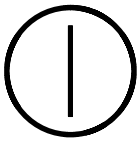
The following safety symbols may appear in the equipment.

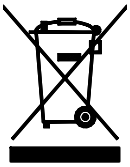
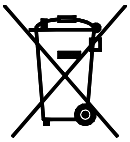
Their meaning are described below.

	**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 Standard IEC 60601-1:2005 and IEC 60601-1:2005+AMD1:2012)*
	**Manufacturer.**
	**Date of Manufacture.**
	**Medical Device.**
	**Catalogue Number (Model reference).**
	**Serial Number.**
	**Model Configuration.**

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

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

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

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

2.7 REGULATORY INFORMATION

2.7.1 CERTIFICATIONS

The ***DX-D 100 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: ***DX-D 100 Mobile X-ray Unit*** *with radiation protection in accordance with IEC 60601-1-3:1994, IEC 60601-1-3:2008 and IEC 60601-1-3:2008+AMD1:2013.*

Statement of Compliance with IEC 60601-2-54: ***DX-D 100 Mobile X-ray Unit*** *for Radiography and/or Radioscopy in accordance with IEC 60601-2-54:2009 and IEC 60601-2-54:2009+AMD1:2015.*

Statement of Compliance with 21CFR Subchapter J: *This* ***DX-D 100 Mobile X-ray Unit*** *conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.*

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

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

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

2.7.3 MODE OF OPERATION

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

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

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

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

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

2.7.5 PROTECTION AGAINST HARMFUL INGRESS OF WATER OR PARTICULATE MATTER

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

2.7.6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

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

2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

2.7.8 DESIGNATED SIGNIFICANT ZONES OF OCCUPANCY

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

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

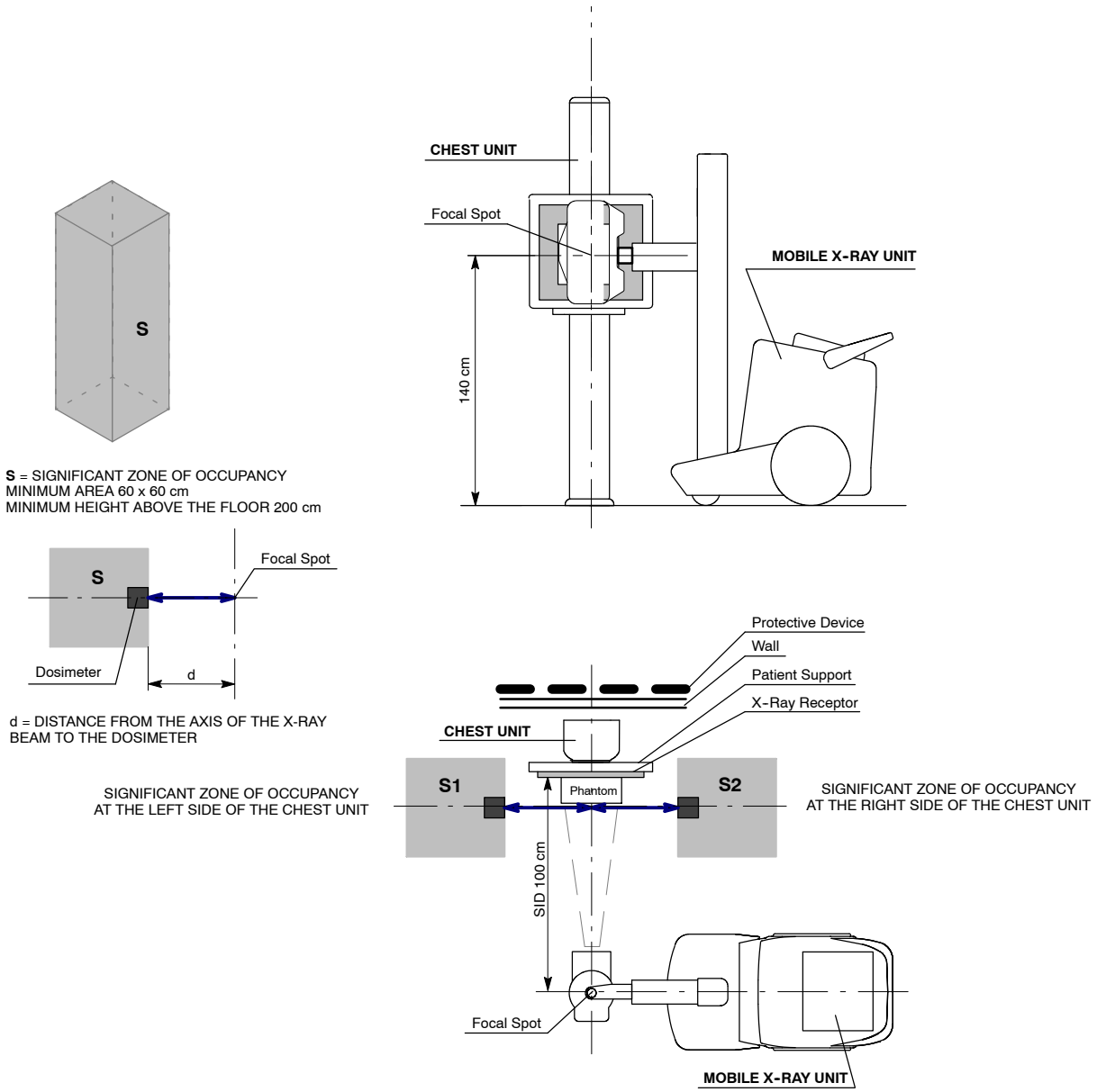
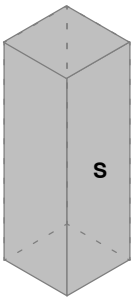
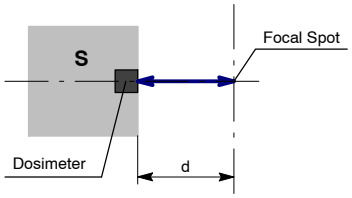


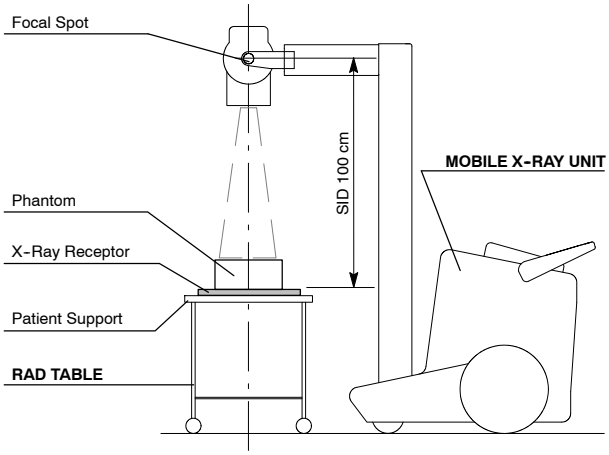
Illustration 2-2
Radiographic Examination on any Patient Support or any Table



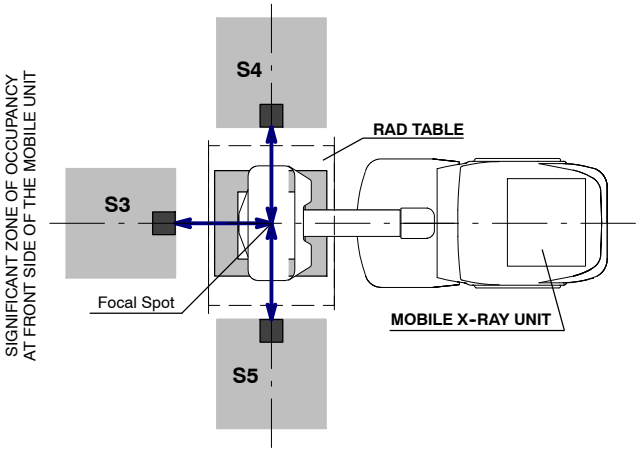
S = SIGNIFICANT ZONE OF OCCUPANCY
MINIMUM AREA 60 x 60 cm
MINIMUM HEIGHT ABOVE THE FLOOR 200 cm



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



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



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

2.7.9 DISTRIBUTION OF STRAY RADIATION

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

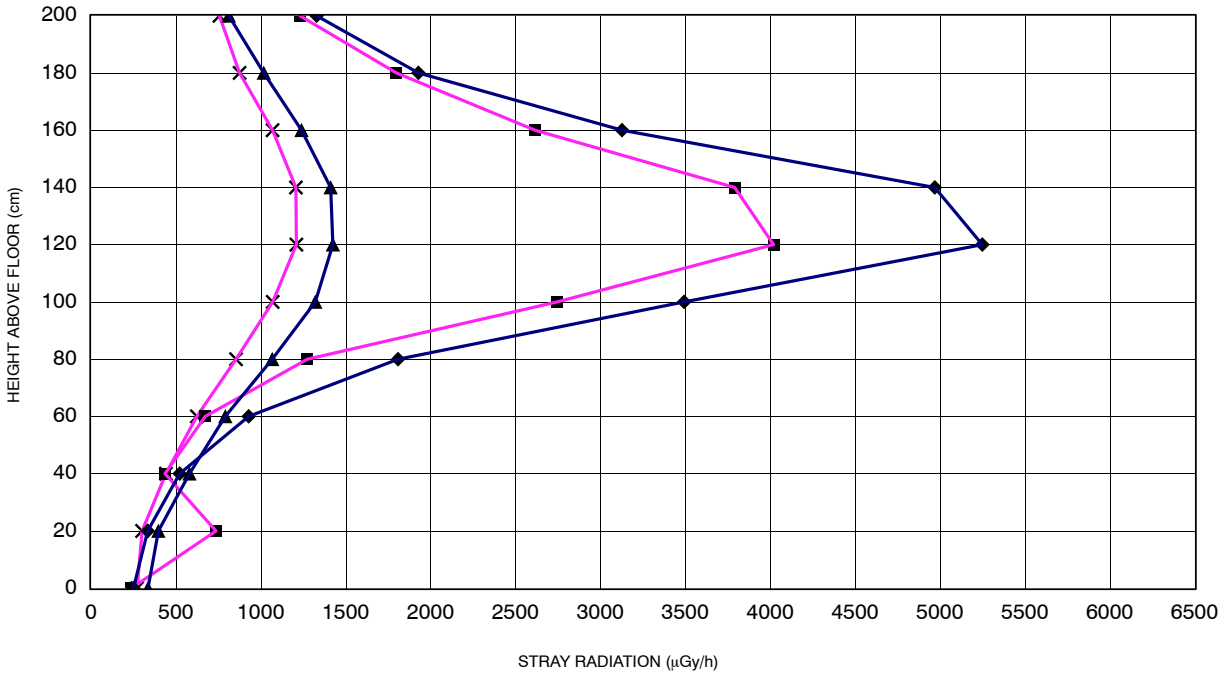
- Exposure Parameters: RAD mode, 150 kVp, 20 mAs.
- Collimator opening for Field Size 18 x 18 cm, SID 100 cm.
- Phantom: Rectangular water phantom of 25 x 25 x 15 cm, or a material having a similar X-Ray attenuation coefficient.
- Radiation measuring instrument: Low Radiation Dosimeter.

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

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

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

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



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

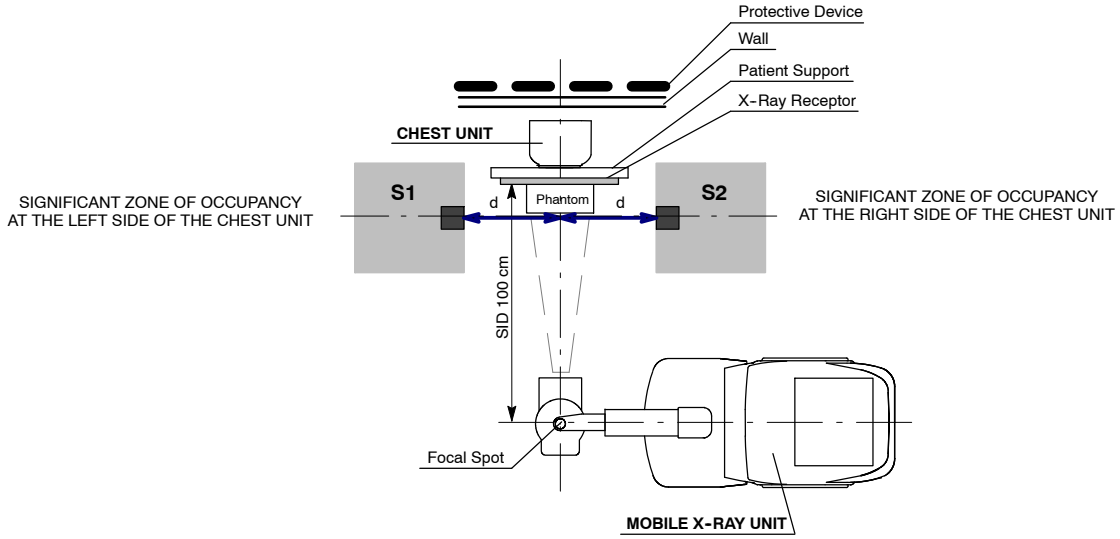
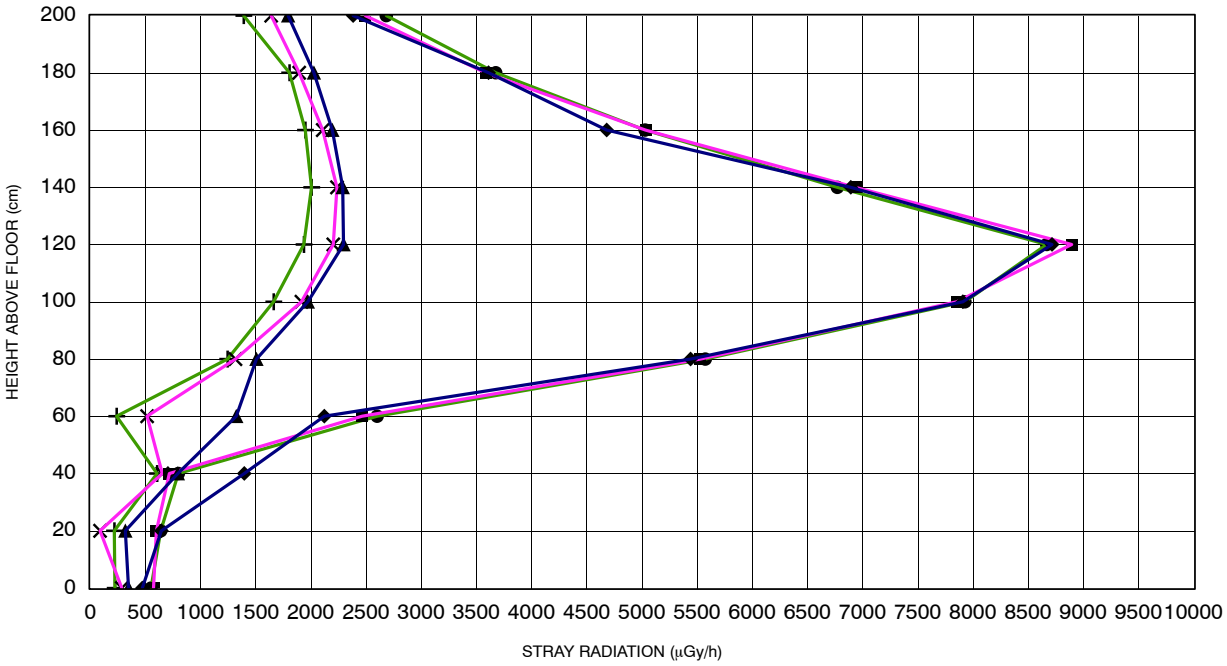
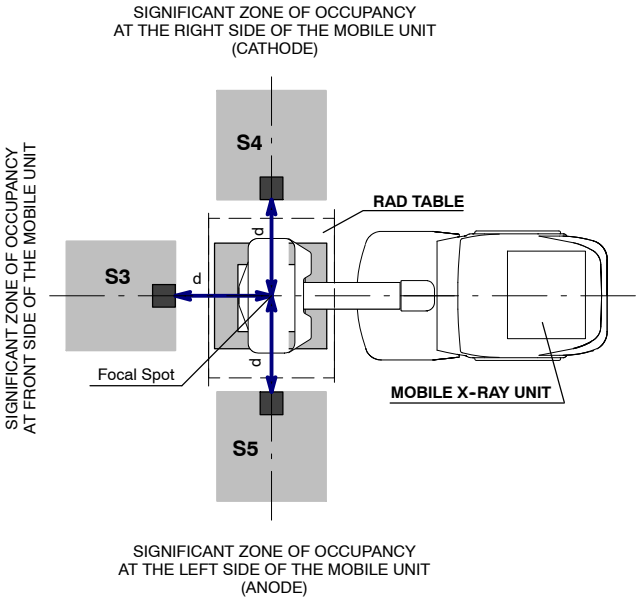


Illustration 2-4
Distribution of Stray Radiation on any Patient Support or any Table



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



2.8 ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

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

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

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

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

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

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

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

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

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2007)			
This X-ray System is intended for use in the electromagnetic environment specified below. The customer or the user of this X-ray System should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2:2007 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of this X-ray System, 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 X-ray System is used exceeds the applicable RF compliance level above, this X-ray System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this X-ray System.*

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

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

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

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

TYPICAL RF DEVICES (Worst-Case scenario)

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

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

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

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

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

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

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

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

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

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

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

2.9 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.*

2.9.1 FUNCTIONAL TESTS PERFORMED TO OBTAIN THE QUANTITATIVE INFORMATION

Equipment:

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

Instrumentation used:

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

Test details:

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

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

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

2.10 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 2.9*) 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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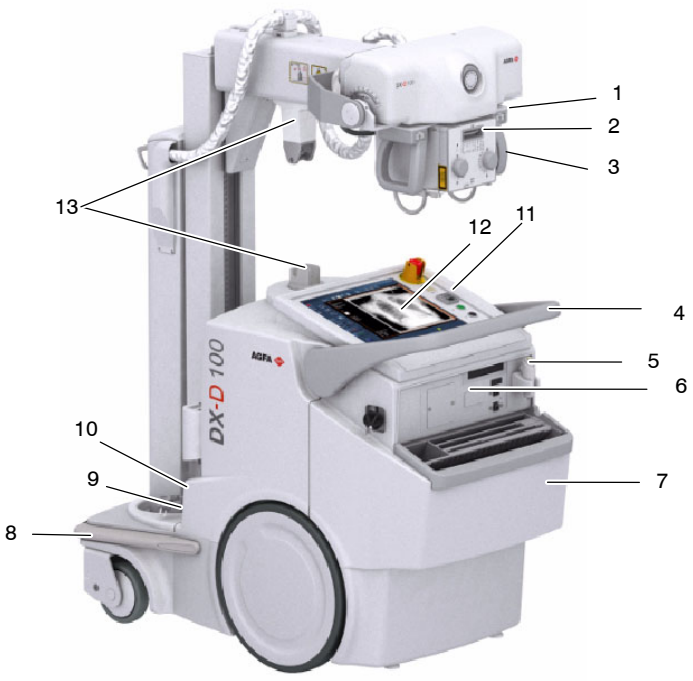
SECTION 3 GENERAL AND MOTION CONTROLS

Operation is carried out from the different controls:

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

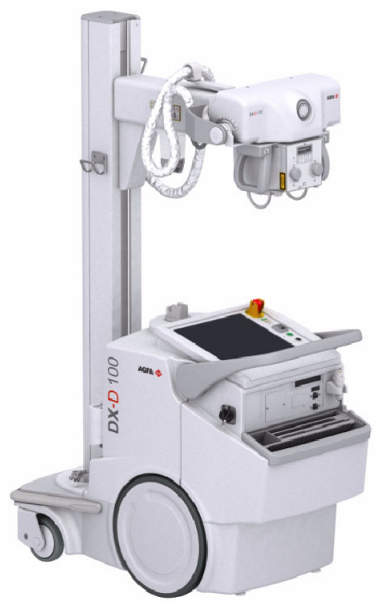
Illustration 3-1
DX-D 100 Mobile X-ray Unit : General Features

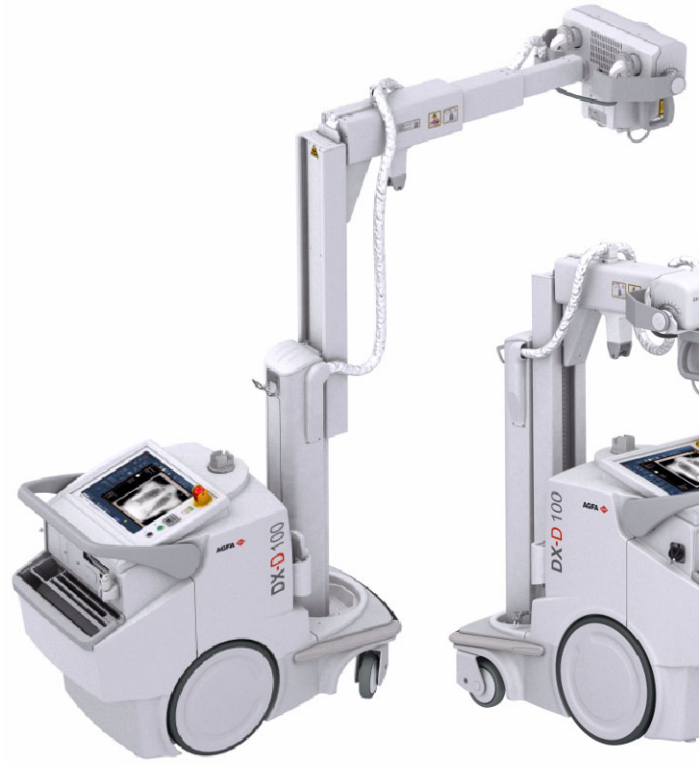


1 Motion Controls
2 Collimator Panel
3 Tube-Collimator Handles
4 Handlebar
5 Handswitch
6 Peripheral Connections CD / DVD
7 Holder for Detectors and Accessories
8 Anti-Collision Bumper
9 Power Line Cable
10 Line Circuit Breaker
11 Control Panel
12 Control Console
13 Parking Detent

Illustration 3-2
DX-D 100 Mobile X-ray Unit: Wireless Configuration Options

Standard Column





Telescopic Column, optional

Illustration 3-3
DX-D 100 Mobile X-ray Unit: Portable Configuration Options

Standard Column

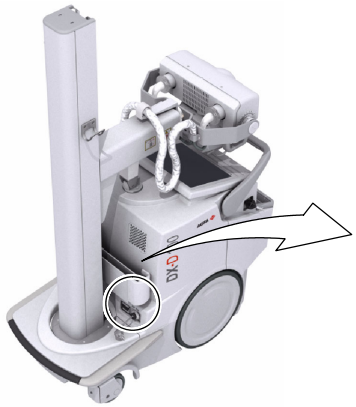
3.1 MAINS CONNECTION AND LINE CIRCUIT BREAKER

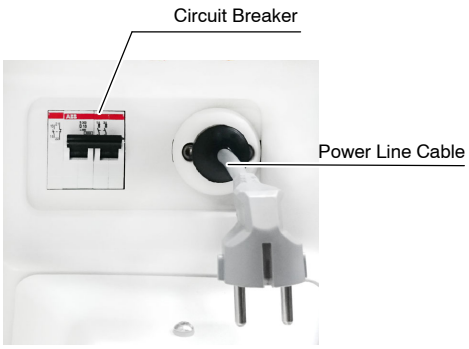
The Unit should be plugged into a wall socket compliant with local regulations and equipment electrical requirements (*refer to Section 6 for Technical Specifications*).

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

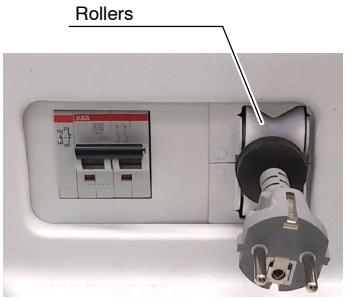
For safety reasons and for proper functioning, make sure that the Unit is connected to a standard outlet with GND.

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





Cable Reel

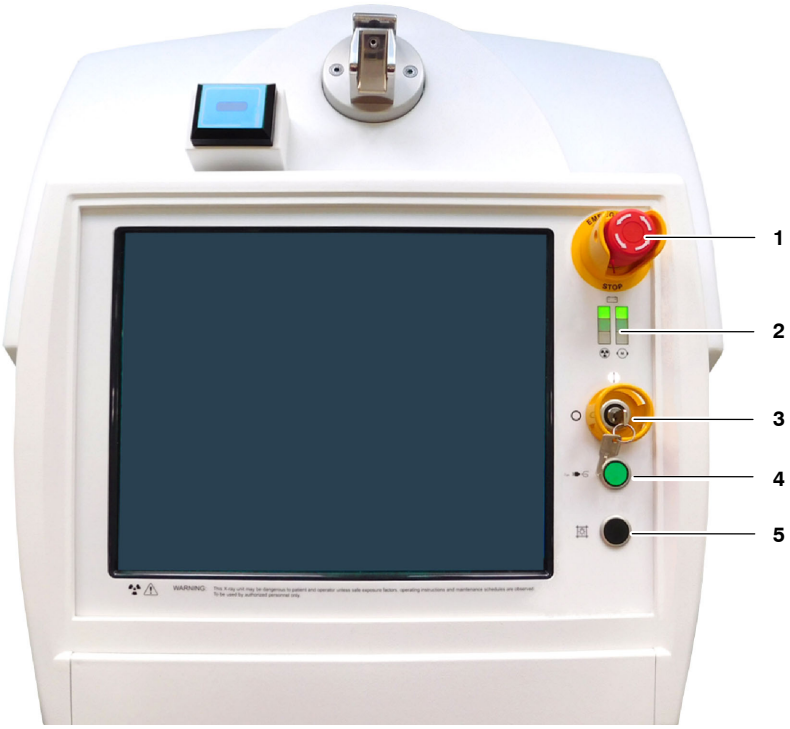


Cable Reel with Rollers

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

3.2 CONTROL PANEL

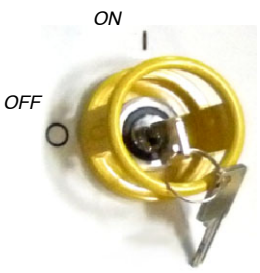
1 EMERGENCY SWITCH OFF
2 BATTERY CHARGE LEVEL
3 SWITCH ON / OFF CONTROL: KEY
4 POWER LINE CONNECTION LAMP
5 COLLIMATOR LAMP BUTTON



3.2.1 ON / OFF CONTROL

This control is used to turn the unit ON and OFF.

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



SWITCH ON / OFF KEY

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

The key in the "*OFF*" position switches OFF all the equipment functions, after a delay to allow the user to shut down the Software Applications on the Control Console and to move the Arm to Parking Position. The Charging Circuits are not switched off and can only be switched ON/OFF with the Line Circuit Breaker.

3.2.2 EMERGENCY STOP

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

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

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

3.2.3 POWER LINE CONNECTION LAMP

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

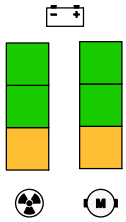
IF THIS INDICATOR IS OFF DURING THE BATTERIES CHARGING PROCESS, AND THE VOLTAGE IS PRESENT IN THE MAINS, IT MAY BE DUE TO A DEFECTIVE BATTERY.
IN THIS CASE, THE UNIT TURNS OFF AUTOMATICALLY TO AVOID OVERHEATING THE REMAINING BATTERIES.
CONTACT TO THE TECHNICAL SERVICE.

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

3.2.4 COLLIMATOR LAMP

This button is used to turn ON the Collimator Lamp from the Control Panel. The Lamp remains illuminated for a few seconds before automatically switching off.

3.2.5 BATTERY CHARGE LEVEL INDICATORS



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

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

Note ☞

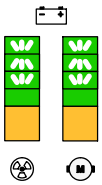
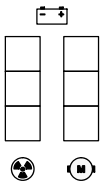
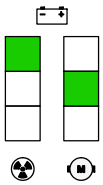
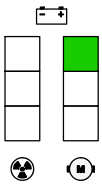
The Batteries require approximately 9 hours for a fully charge. To charge the Batteries, there is not need to have the Console turned ON. When the Batteries are fully charged, the Battery charge level Indicators on both columns stop scrolling and only the Upper Green Indicators remain illuminated.

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

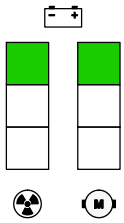
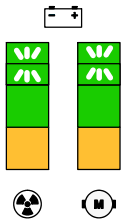
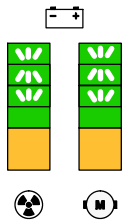
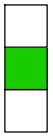
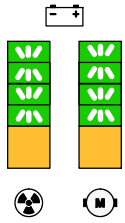
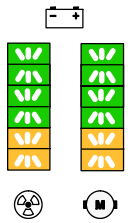
Note ☞

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

The Battery Charge Level Indicators can be:

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

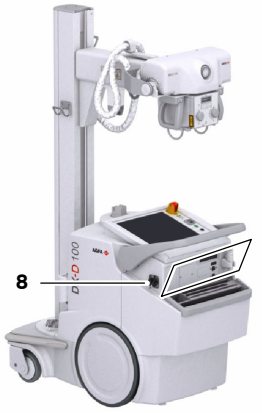
Both columns comprise three Indicators, each one representing a battery status as described below:

MOBILE UNIT IN CHARGING MODE (PLUGGED TO MAINS)		MOBILE UNIT IN STAND-ALONE MODE (UNPLUGGED FROM MAINS)	
LED INDICATORS AND STATUS		LED INDICATORS AND STATUS	
	After charging during approximately 9 hours, the upper Green Indicators are lighting steady and the rest of the Indicators below are off. The batteries charge level is 100 % of the total charge.		When the upper Green Indicators light steady, normal operation is allowed.
	After charging during approximately 2.5 to 6 hours, the upper Green Indicators are scrolling up and the lower Green Indicators and the Orange Indicators are lighting steady. In 4 hours, the batteries charge level is 80% of the total charge.		
	After charging during approximately 1.5 to 2.5 hours, Indicators are scrolling up from the upper half of the lower Green Indicators and the rest of the Indicators below are lighting steady.		When the lower Green Indicators light steady, normal operation is allowed although it is recommended to charge the Batteries.
	After charging during approximately 30 to 90 minutes, all Green Indicators are scrolling up and the Orange Indicators are lighting steady.		When the lower Green Indicators start blinking, normal operation is allowed but it is urgent to charge the Batteries.
	After charging during approximately less than 30 minutes, all the Indicators are scrolling up.		When the Orange Indicator blinks, exposures are not allowed. It is necessary to charge the Batteries.

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

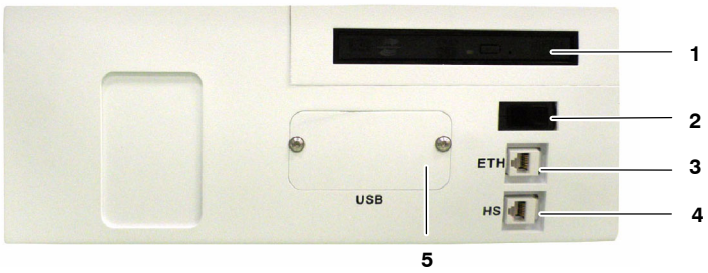
3.3 PERIPHERAL CONNECTIONS - CD / DVD

3.3.1 CONFIGURATION WITH WIRELESS DR DETECTOR

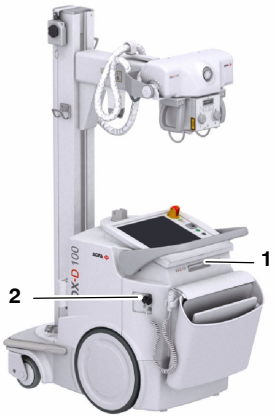


The Mobile Unit has a Peripheral Connections Panel provided with:

1. **CD / DVD Writer** .
2. **IR Data Communication**, for registration of some models of Wireless DR Detectors *(for further information, refer to section 3.11.1*).
3. **Detector Back-up Cable (ETH)** connector for registration of some models of Wireless DR Detectors and for connecting the optional Detector Back-up Cable *(for further information, refer to section 3.11.1*).
4. **Handswitch (HS)** connector.
5. **USB** Ports: Keyboard and Mouse connections, for Technical Service.
6. **WI-FI** Connection (internal).
7. **Bluetooth** Connection (option; internal) in order to connect other accessories (Mouse, Keyboard, Barcode Reader, Touchpad, etc).
8. **Ethernet Cable Reel**



3.3.2 CONFIGURATION WITH PORTABLE DR DETECTOR



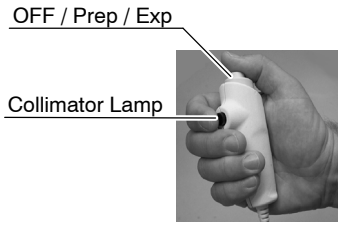
The Mobile Unit is provided with:

1. **CD / DVD Writer** .
2. **USB** Ports: Keyboard and Mouse connections, for Technical Service.
3. **WI-FI** Connection (internal).

3.4 CONTROL CONSOLE

The Control Console includes the controls, indicators and displays needed to perform radiographic exams (*Refer to the NX User Manual and the DX-D 100 Software Console User Manual*).

3.5 X-RAY HANDSWITCH



Radiographic exposures are initiated with the "*Prep*" (preparation) and "*Exp*" (X-ray exposure) two-stage Handswitch. The status of the exposure is indicated by the "*Ready*", *"Prep"* and "*X-ray On*" indicators for the duration of the exposure.

The X-ray Handswitch button has three positions: "*Off*", "*Preparation*", and *"X-ray Exposure".*

Press the Handswitch half-way for *"Prep"* and fully for *"Exp".*


Not Ready


Ready

READY: Indicates that the selected technique is properly set and there are no interlock failures or system faults.

PREP: Press the Handswitch half-way ("*Prep"* position) to prepare the X-ray Tube for exposure. The *"Prep"* indicator will light when the X-ray Tube is prepared and there are no interlock failures or system faults.

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

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

X-RAY EXPOSURE: After pressing the Handswitch completely, the X-ray exposure is made, the "*X-ray On*" indicator on the Console will light and an audible signal sounds during the length of exposure.

Note ☞

The unit cannot perform exposures when the Arm is secured in the parking position.

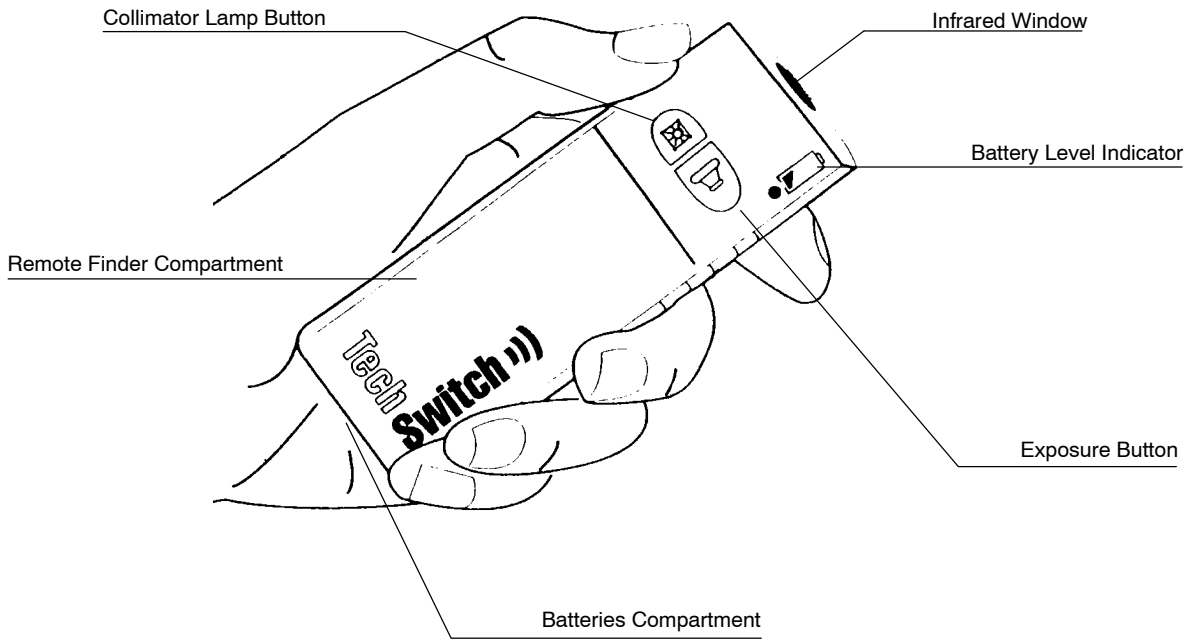
Depending on the configuration, the unit cannot perform exposures when the Arm with the Tube-Collimator Assembly is straight above the Control Panel (but not secured in the parking position); in this configuration the Column must be taken out of the 0 ° rotation position to be able to make exposures.

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

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

3.6 INFRARED REMOTE CONTROL (OPTIONAL)

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



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

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

3.6.1 OPERATION

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

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

EXPOSURE CONTROL: Press this button once to prepare the X-ray Tube for exposure (*"Prep"* position). When the *"Prep"* indicator lights on the Control Console, press this push-button again and hold it down until the X-ray Unit completes the exposure ("*Exp"* position).

Note ☞

The unit cannot perform exposures when the Arm is secured in the parking position.

Depending on the configuration, the unit cannot perform exposures when the Arm with the Tube-Collimator Assembly is straight above the Control Panel (but not secured in the parking position); in this configuration the Column must be taken out of the 0 ° rotation position to be able to make exposures.

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

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

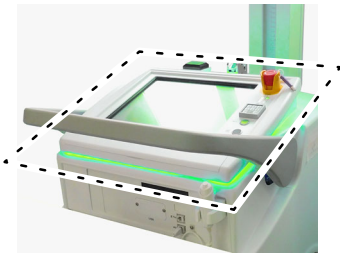
The exposure aborts if the *"Exposure"* button is released.

3.6.2 THE "REMOTE FINDER" DEVICE

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

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

3.7 LED BEACON LIGHT (OPTION)



The unit with Wireless DR Detectors can be provided with LED Beacon Light, placed under the Control Console frame, indicating the following status:

GREEN → READY / PREP Status.
It lights when the Detector is ready and the RAD technique is correctly set (READY status) and keeps lighting up during the Preparation of the X-Ray Tube (PREP status) before the exposure.

YELLOW → EXP Status.
It lights during the X-Ray Exposure (EXP status).

3.8 MOTION CONTROLS

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

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

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

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

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

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

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

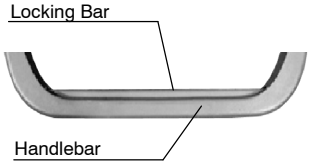
MONITOR WITH SPECIAL CARE THE PATIENT POSITION OR ANYONE PRESENT, TO AVOID INJURY CAUSED BY UNIT MOVEMENTS.

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

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

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

3.8.1 DISPLACEMENT CONTROLS



HANDLEBAR:

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

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

CAUTION

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

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

Velocity can be configured by service personnel.

WARNING

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

Note ☞

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

CAUTION

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

The unit displacement can also be blocked during the driving.

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

Table 3-1
Beep Sequence – Failure condition

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

FINE POSITIONING CONTROLS:

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

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

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

After eight seconds pressing any of the buttons (Fine Positioning Controls) on the Hand-grips, the Unit stops moving. Release these buttons and press them again to enable the Unit displacement.

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 MOVEMENT CONTROLS (HANDLEBAR, HEAD-ASSEMBLY HANDGRIPS); OTHERWISE, THESE SUBSTANCES COULD CAUSE SYSTEM MALFUNCTION AND/OR AN INCORRECT OPERATION OF THE MOTION CONTROLS.

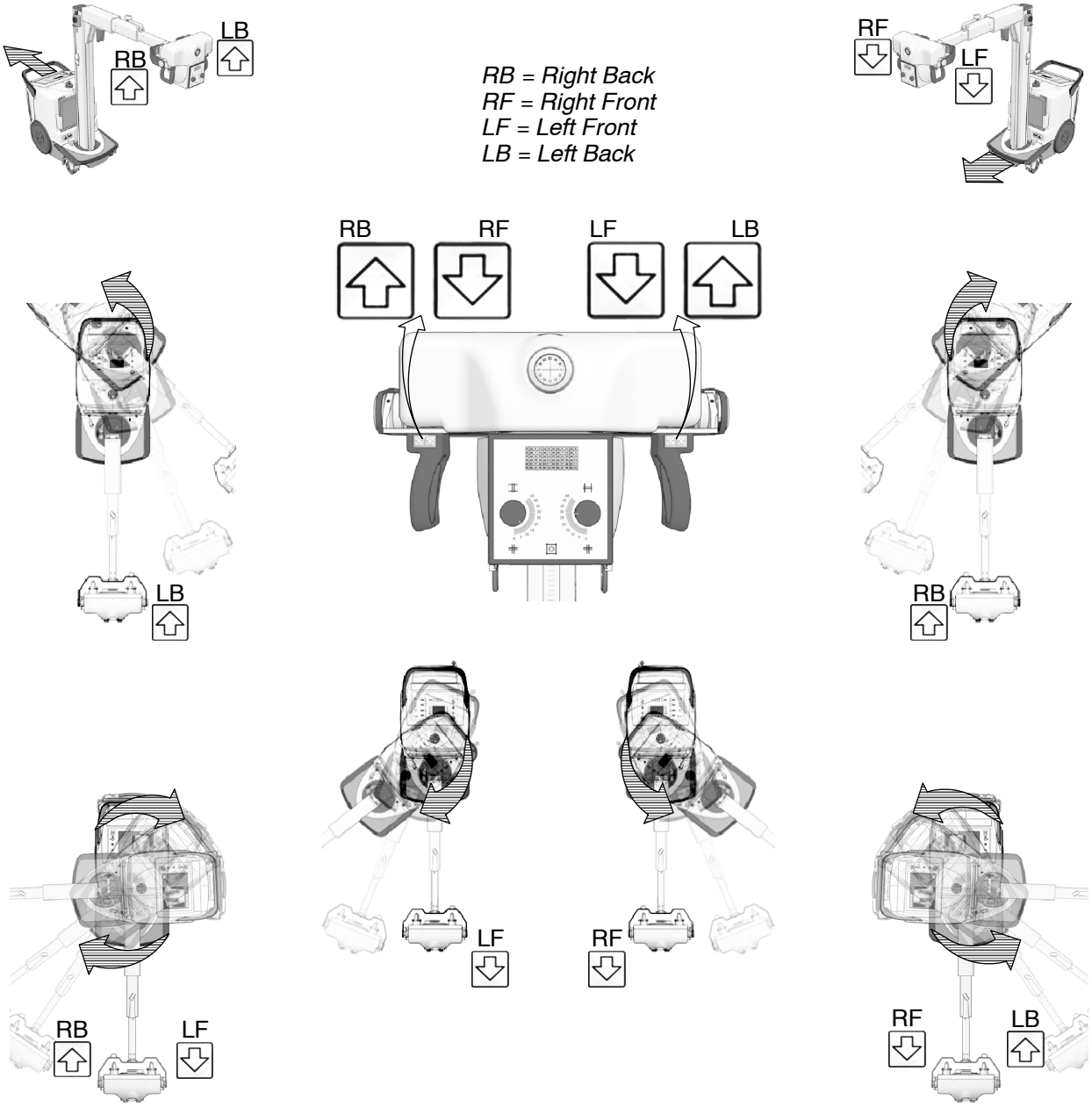
IN THIS CASE, TURN OFF THE UNIT AND CLEAN THE AFFECTED PARTS.

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

The unit displacement can also be blocked during the driving.

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

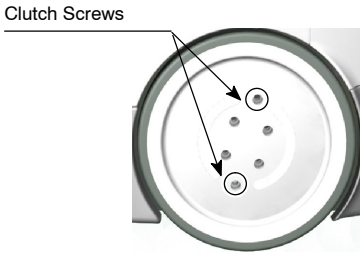
The illustration below details the corresponding movements. The buttons correspond to each motor and do not change when the Unit is in Parking Position.



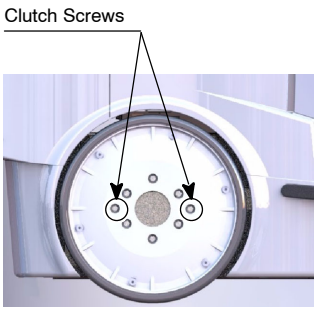
MANUAL CLUTCH SCREWS:

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

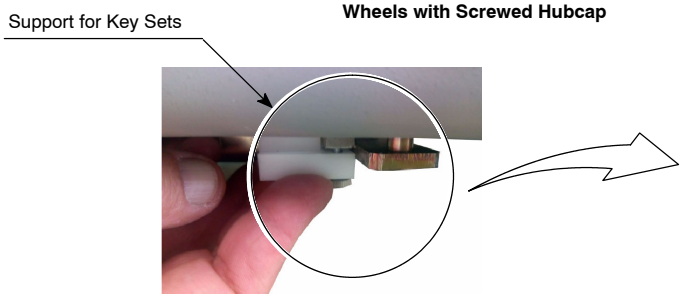
Depending on the type of Wheel, a Key Set is provided, located near the left Back Wheel of the Unit. For accessing this Key Set, dismount the Support from the lower side of the Mobile Unit.

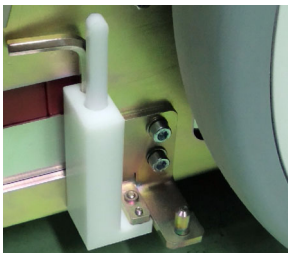


Wheels with Screwed Hubcap



Wheels with Magnetic Hubcap





DANGER!

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

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

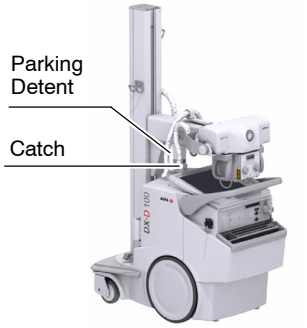
Front Bumper

FRONT BUMPER:

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

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

3.8.2 PARKING POSITION OF THE ARM

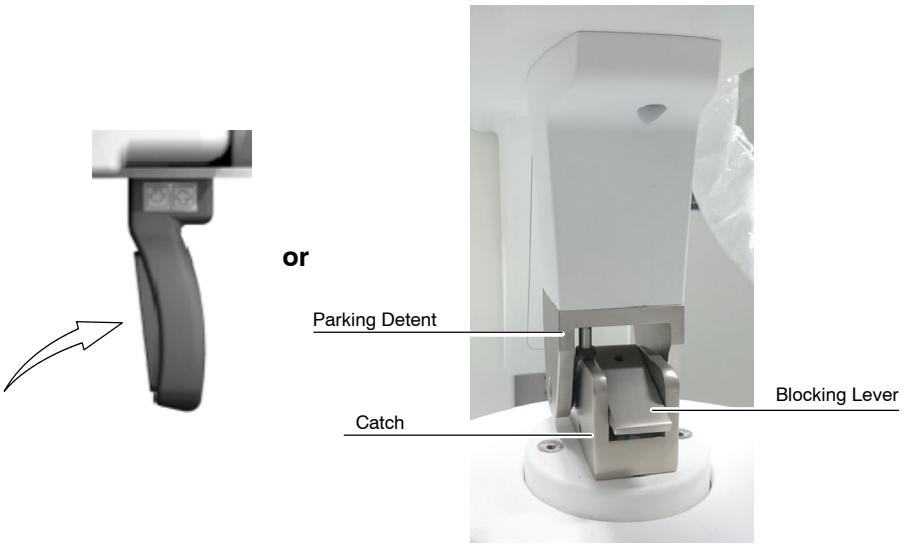


The Unit is in Parking Position when the Parking Detent is secure in the Catch.

Place the Arm in Parking Position as follows:

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

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



WARNING

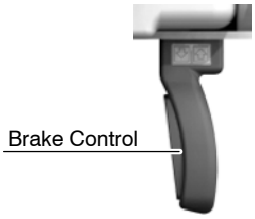
ALWAYS KEEP THE ARM IN PARKING POSITION EXCEPT WHEN PERFORMING RADIOGRAPHIC EXAMS. THIS WILL PREVENT INJURIES OR UNIT DAMAGE DURING DISPLACEMENT.

Note ☞

The unit cannot perform exposures when the Arm is secured in the parking position.

Depending on the configuration, the unit cannot perform exposures when the Arm with the Tube-Collimator Assembly is straight above the Control Panel (but not secured in the parking position); in this configuration the Column must be taken out of the 0 ° rotation position to be able to make exposures.

3.8.3 MOVEMENT CONTROLS OF THE COLUMN AND TELESCOPIC ARM



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

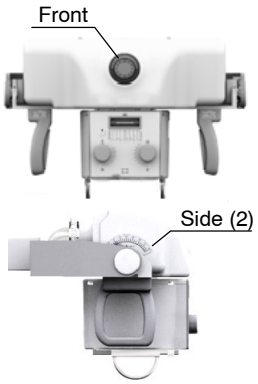
Press and hold the Brake Control to move the Column and Arm until the Tube-Collimator Assembly is positioned. Release the control to lock in place.

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

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

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

Rotation Indicators



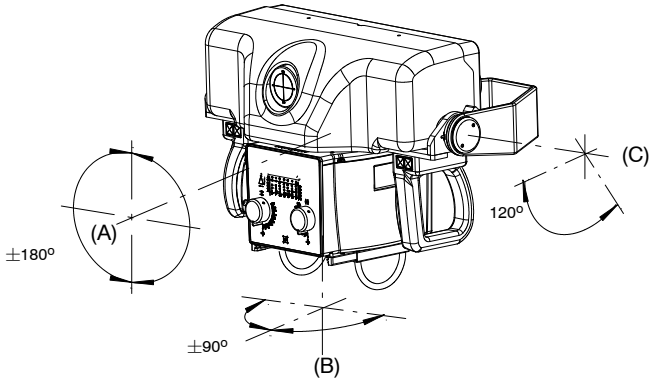
These Hand-grips are also used (without having to press the Brake Control) to rotate the Tube-Collimator Assembly from its vertical position:

- ±180° on its transversal axis (A).
  This movement has detents every 90°, but there is an option without detents.

  The angle is indicated in the rotation indicator located on the X-Ray Tube.
- 120° on its horizontal axis (B).

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

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

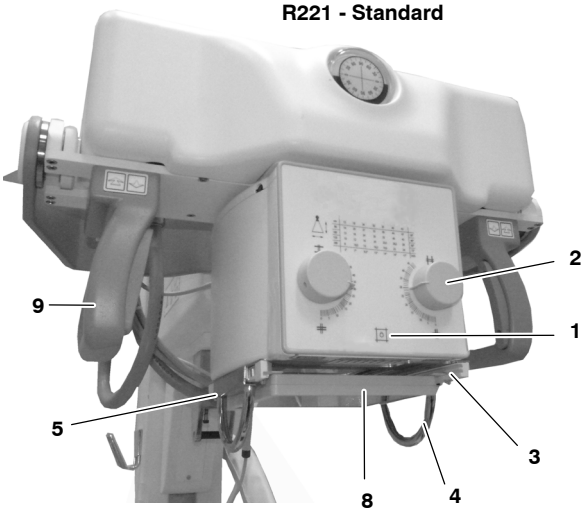


Note ☞ *Due to geometric restrictions related to the anode angle of the X-Ray Tube, a minimum SID is required to cover the full image size of the Detector, depending on the Collimator position:*

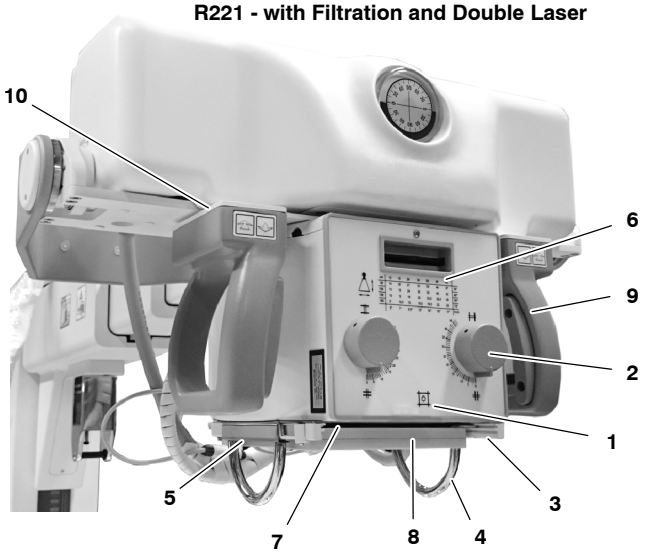
X-Ray Tube Anode Angle	Detector Size	Required SID with Collimator rotated at:	
		0° or ±90°	±45°
12°	24X30 30X24	SID ⩾ 65 cm	SID ⩾ 85 cm
	35X43 43X35	SID ⩾ 90 cm	SID ⩾ 125 cm
	43X43		
16°	24X30 30X24	SID ⩾ 55 cm	SID ⩾ 65 cm
	35X43 43X35	SID ⩾ 75 cm	SID ⩾ 90 cm
	43X43		

3.9 COLLIMATOR CONTROLS

R221 - Standard



R221 - with Filtration and Double Laser



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

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

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

3. **Rail System with two guides** in order to install the external additional filters used for pediatric examinations (⩾ 0.1 mm Cu or 3.5 mm Al) in the upper guide and the Radiation Meter in the lower one.

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

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

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

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

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

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

8. **Radiation Meter** (optional). *Refer to Section 3.10 of Dosimetry.*

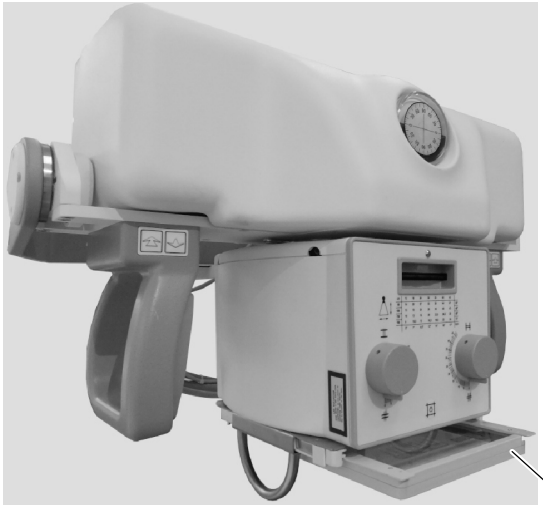
9. **Hand-grips** for positioning the Tube-Collimator Assembly.

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

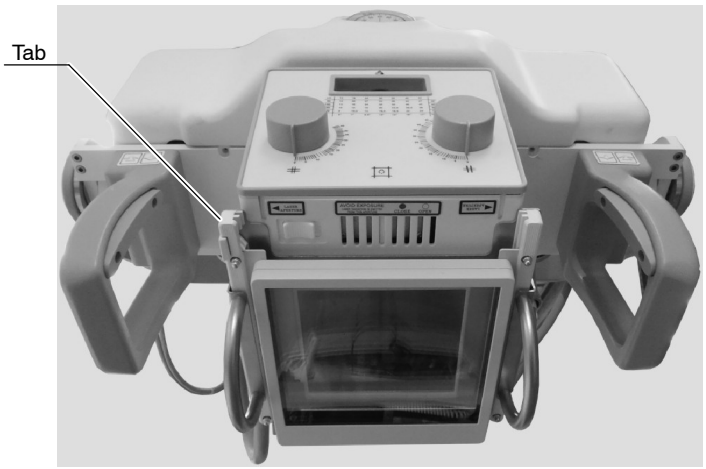
3.10 DOSIMETRY (OPTIONAL)

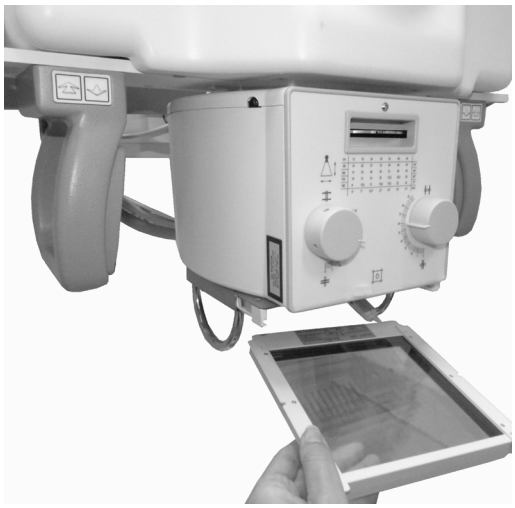
The optional Radiation Meter is installed under the Collimator and reads radiation as Dose Area Product (DAP) in mGy*cm^2 *(refer to the manual of the Radiation Meter).*

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



The Radiation Meter can be removed from the rail system to be cleaned or serviced. To remove the Radiation Meter, pull back on the two tabs which lock the Radiation Meter to the rails and pull out the Radiation Meter. The cable connection to the PC is found behind the Collimator.





3.11 DR DETECTOR

3.11.1 CONFIGURATION FOR WIRELESS DR DETECTORS

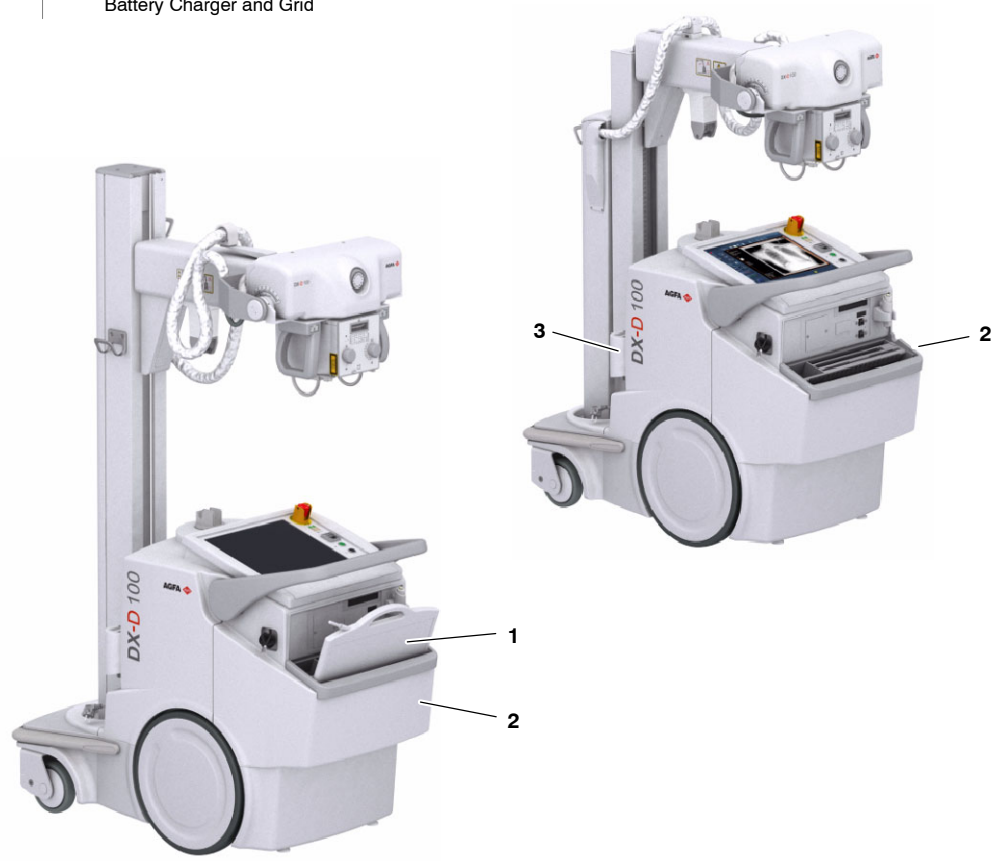
Wireless DR Detectors are placed in the Storage Bin at the Back Cover (for Detectors, Grid and Accessories).

Wireless DR Detectors communicate with the Mobile Unit through an internal Wireless Access Point.

1 Wireless DR Detector

2 Storage Bin for Wireless DR Detectors, Grid and Accessories (Font Cover)

3 Support for optional Battery Charger and Grid



The configuration for Wireless DR Detectors includes a **Storage Bin** with slots for the specific components of the system as detailed below in ***figure 1***.

To cover the DR Detector in a Protective Bag, refer to ***figure 2***.

Figure 1. Storage Bin:

1. Box/Roll of Protective Bags for DR Detector
2. Wireless DR Detector, Large format
   Slot for positioning the DR Detector to cover it with Protective Bags
3. One slot for DR Detector Batteries
   (Battery size depends on Detector Model)
4. Wireless DR Detector, Small format
5. Notepad

Figure 2. To cover the DR Detector in a Protective Bag:

1. Position the DR Detector tilted forward in the front slot of the Storage Bin
2. Take a Protective Bag from slot 1.
3. Slide the Protective Bag over the DR Detector

To clean inside the Storage Bin, take out all the partitions.

The Wireless DR Detectors include a Desk Battery Charger and Batteries. Some Wireless DR Detectors can also be provided with an optional Back-up Cable for Wired connection mode.

Wireless DR Detectors

35X43

24X30

43X43 *

35X43 *

24X30 *

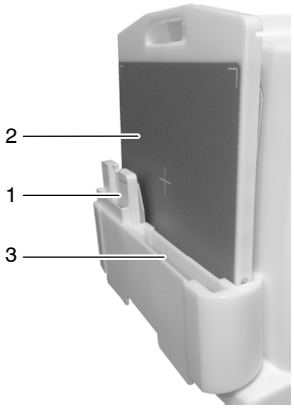
** Wireless DR Detectors with optional Back-up Cable*

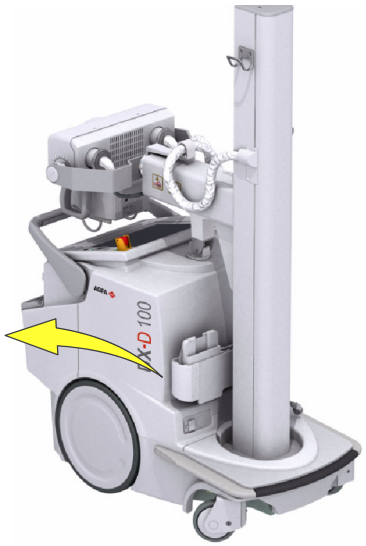
The unit is provided with a Grid Support at the Front Cover, and for some Wireless DR Detectors with a Battery Charger Support. (*For further information about supported Batteries and DR Detector models refer to the DR Detector manuals.)*

1 Battery Charger (optional, it depends on the Wireless DR Detector Model)

2 Grid

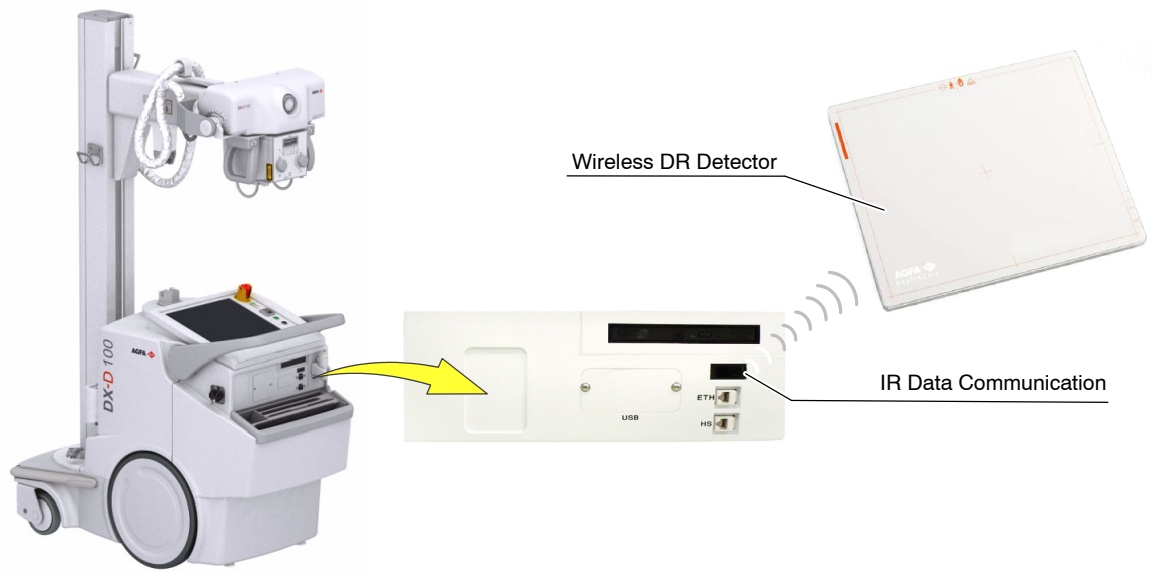
3 Paper Holder





IR Data Communication unit for some Wireless DR Detectors

The Mobile Unit is equipped with an IR Data Communication unit, in the Peripheral Connections Panel, used for registering some Wireless DR Detectors to the Mobile unit by infrared (IR) communication.



Optional Detector Back-Up Cable for some Wireless DR Detectors

With the optional Back-up Cable connected to the Detector it is possible to expand from a wireless configuration to a wired configuration. This cable has to be plugged to connector RJ45 (ETH) at the Peripheral Connections Panel of the Mobile Unit.

Optional Wired Configuration for some Wireless DR Detectors

Some wireless DR Detectors can be configured as a wired DR Detector. In this configuration, the Mobile Unit has no wireless Access Point and the DR Detector communicates with the Mobile Unit through the DR detector cable.

3.11.2 CONFIGURATION FOR PORTABLE DR DETECTORS

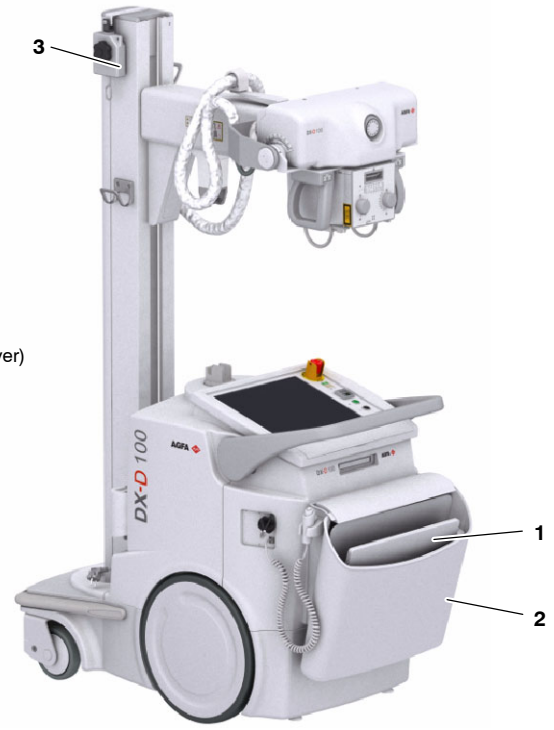
Portable DR Detector DX-D10

Portable DR Detector DX-D20

It can be provided an **optional Anti-Scatter Grid Support** designed to fit the Portable DR Detector inside. It is placed inside the DR Detector/Grid Holder.

The Portable DR Detector is placed in the DR Detector/Grid Holder, at the Back Cover.

1 Portable DR Detector / Grid
2 Detector / Grid Holder (Front Cover)
3 Detector Cable Tether



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

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

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

For Wireless DR 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.

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

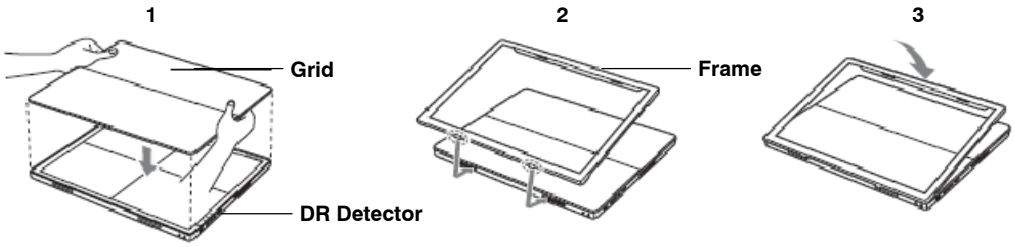
Note ☞ *For further information on the DR Detector Handling and Maintenance, refer to the DR Detector manuals.*

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.

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

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



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

SECTION 4 OPERATING SEQUENCES

4.1 X-RAY TUBE WARM-UP PROCEDURE

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

Routine exposures should not be effected unless the Tube is previously warmed-up, this preserves an optimal X-ray Tube life.

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

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

Perform X-ray Tube warm-up as follows:

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

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

4.2 RADIOGRAPHIC OPERATIONS

For Radiographic Operations refer to the NX application User Manual.

4.3 X-RAY BEAM ALIGNMENT WITH RESPECT TO PATIENT

After selecting RAD parameters for the technique to be performed:

1. Point the X-Ray Tube-Collimator Assembly to the Image Receptor.
2. Center the Collimator light, which corresponds to the X-Ray beam, with respect to receptor. For that, use the Collimator Light centering marks and the laser line on the receptor handle if applicable.
3. Position the patient for the examination.
4. Turn ON the Collimator Lamp and adjust the field size with the Collimator controls.
5. Perform any adjustment on the patient position, receptor or tube collimator assembly to assure that the X-Ray beam is correctly positioned.

ALWAYS SELECT THE CORRECT FIELD SIZE TO AVOID EXCESSIVE RADIATION.

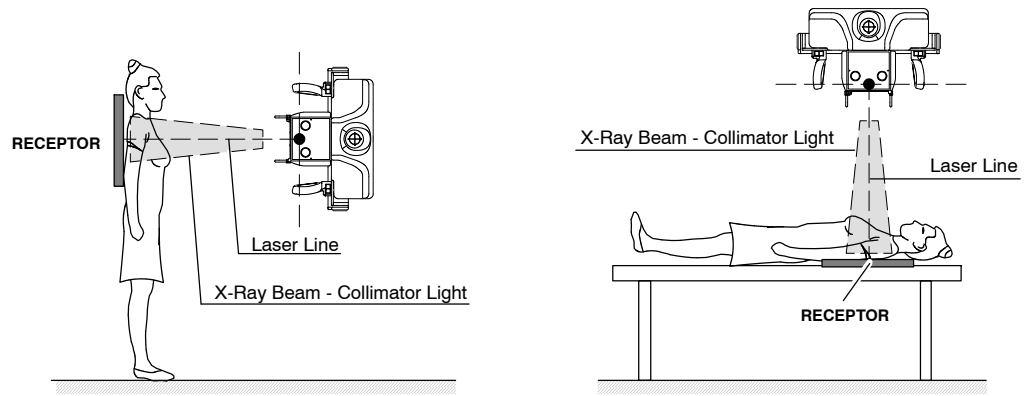
WARNING

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 4-1
Patient Positioning



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SECTION 5 PERIODIC MAINTENANCE

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

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

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

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

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

5.1 OPERATOR TASKS

5.1.1 BATTERIES MAINTENANCE

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

Tasks for a proper maintenance of the batteries:

- Recharge the batteries for at least 30 minutes at the beginning of the day before using the unit.
- Recharge the batteries for at least 30 minutes at the end of the day after using the unit.
- Fully recharge the batteries when the unit is going to be disconnected for more than 3 weeks.
- Fully recharge the batteries when the unit has been disconnected for more than 3 weeks.

- Keep the unit connected to the mains whenever possible to maintain the batteries at the floating maintenance level. This increases their lifetime.
- Do not allow the batteries to be deeply discharged because they will lose storage capacity and will never be able to recover the 100% of their original capacity.

Note ☞ *For more information, refer to "Battery Charge Level Indicators" in Section 3.2 and "Battery Capacity for the Generator and the Motors" in Section 6.1.*

5.1.2 PERIODIC MAINTENANCE

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

Periodic maintenance tasks shall include the following items:

DO NOT REMOVE ANY COVER, DISASSEMBLE OR MANIPULATE INTERNAL COMPONENTS IN THE UNIT. THESE ACTIONS COULD CAUSE SERIOUS PERSONAL INJURIES AND / OR EQUIPMENT DAMAGE.

1. With the Unit OFF, plug it in and leave it sufficient time to completely charge. The recommended time is approximately 9 hours, until the Battery Charge Level Indicators on both columns stop scrolling and the upper Green Indicators remain illuminated.
2. Once fully charged, unplug the Unit from the mains power. Wait a few minutes and reconnect the Unit to the mains. The upper Green Indicators should scroll up for approximately one minute.

   If the Battery charge level Indicators begin to scroll up from any other Indicator below, contact the Service Department.
3. Switch the equipment OFF by shutting down the computer. Remove Switch-key and unplug from mains.
4. Check the external cable connections.

5.1.3 CLEANING AND DISINFECTION

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

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

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

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

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

5.2 SERVICE TASKS

Only service personnel specifically trained on this medical X-ray equipment should work on service tasks (installation, calibration or maintenance) of the equipment (r*efer to the respective Sections of the Service Manual provided with this equipment).*

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SECTION 6 TECHNICAL SPECIFICATIONS

6.1 FACTORS

Generator Model	DX-D 100			
Maximum Power kW *(Refer to Identification Label)*	20 kW	32 kW	40 kW	50 kW
kVp Range	40 to 125 (40 to 150 optional)	40 to 150	40 to 150	40 to 150
	From 40 kV to 125 kV or 150 kV in 1 kV steps. *(Depending on the Generator model)*			
mAs Range	Product of mA x Time values from 0.1 mAs to 500 mAs			
mA Range	10 to 320	10 to 500	10 to 500	10 to 500
	From 10 mA to 320 or 500 mA through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 200, 250, 320, 400, 500. *(Depending on the Generator model)*			
Exposure Time Range	From 1 millisecond to 10 seconds through the following Time stations: Milliseconds: 1, 2, 3, 4, 5, 6, 8, 10, 12, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 200, 250, 320, 400, 500, 640, 800. Seconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.4, 8, 10.			
Power Output (@ 0,1s)	125 kVp @ 160 mA 100 kVp @ 200 mA 80 kVp @ 250 mA 62 kVp @ 320 mA	150 kVp @ 200 mA 128 kVp @ 250 mA 100 kVp @ 320 mA 80 kVp @ 400 mA 64 kVp @ 500 mA	150 kVp @ 250 mA 125 kVp @ 320 mA 100 kVp @ 400 mA 80 kVp @ 500 mA	150 kVp @ 320 mA 125 kVp @ 400 mA 100 kVp @ 500 mA
Duty Cycle	18 exposures per hour at maximum mAs (lapse time between exposures: 3 min.)			
	Maximum leakage radiation depends on the type of X-ray Tube (<0.88 mGy/h)			
Collimator	Manual with electronic timer and meter			
X-ray Tube	*Refer to Section 6.2*			

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

6.2 X-RAY TUBES

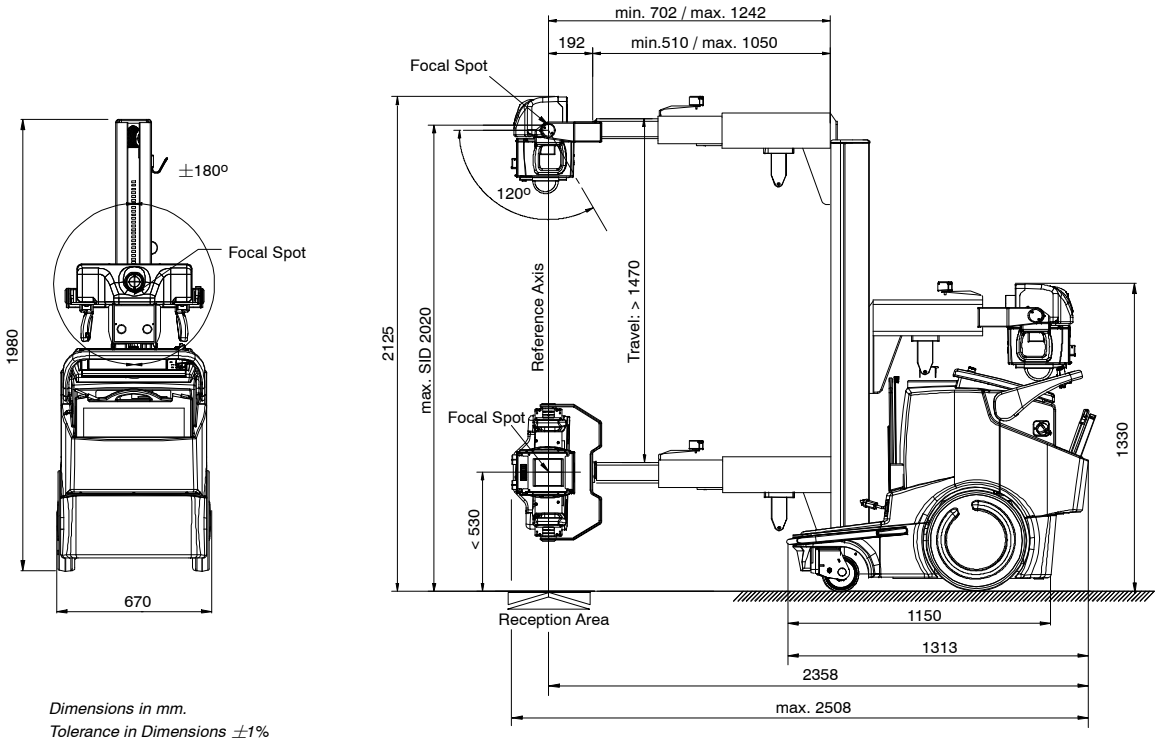
Maximum Power kW *(Refer to Identification Label)*	**20 kW**	**32 kW**	**40 kW**	**50 kW**
Standard X-ray Tubes	E7865X		E7884X	
Optional X-ray Tubes	E7884X		-	

E7865X	Low Speed - Rotating Anode, Focal Spots: 0.3 mm / 1.0 mm Anode kHU / kVp: 140 kHU / 150 kVp, Target Angle: 12° Maximum Specified Energy Input in 1 hour: 150 kVp @ 1440 mAs Inherent Filtration of X-ray Source (Tube + Collimator): refer to Identification Label
E7884X	Low Speed - Rotating Anode, Focal Spots: 0.6 mm / 1.2 mm Anode kHU / kVp: 300 kHU / 150 kVp, Target Angle: 12° Maximum Specified Energy Input in 1 hour: 150 kVp @ 3408 mAs Inherent Filtration of X-ray Source (Tube + Collimator): refer to Identification Label

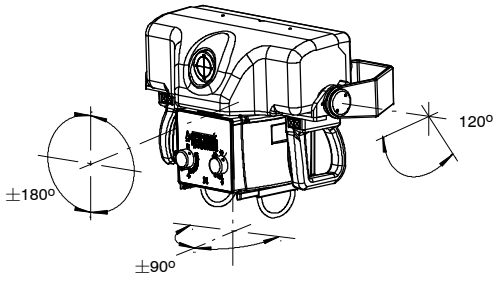
6.3 PHYSICAL CHARACTERISTICS: MOBILE WITH WIRELESS DR DETECTOR

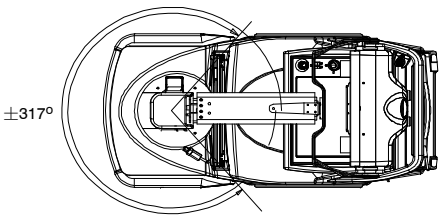
6.3.1 MOBILE WITH WIRELESS DR DETECTOR AND STANDARD COLUMN

LENGTH	WIDTH	HEIGHT*	WEIGHT
minimum 1313 mm maximum 2508 mm	670 mm	minimum 1980 mm maximum 2125 mm	560 kg (without Detectors and/or Accessories)
** Note: There is an optional "Short Column" that reduces in 130 mm the Column height, the maximum SID and the Vertical Travelling of the Arm.*			



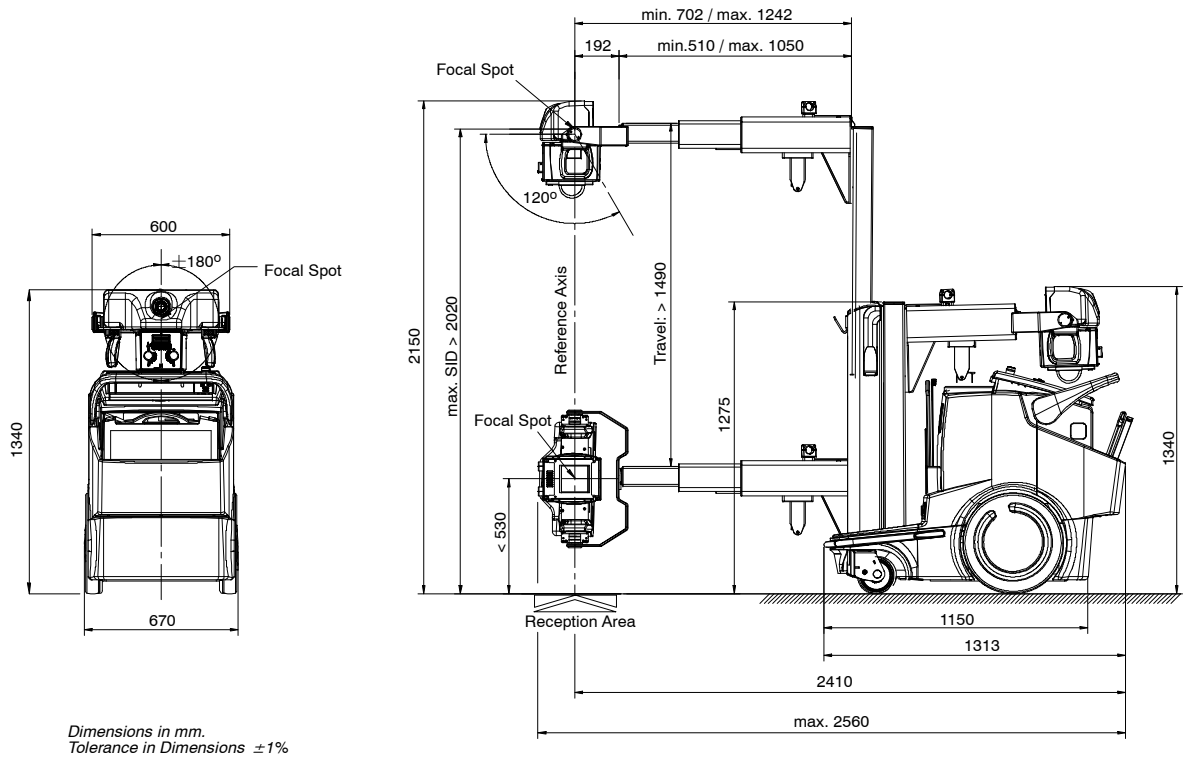
Dimensions in mm.
Tolerance in Dimensions ±1%



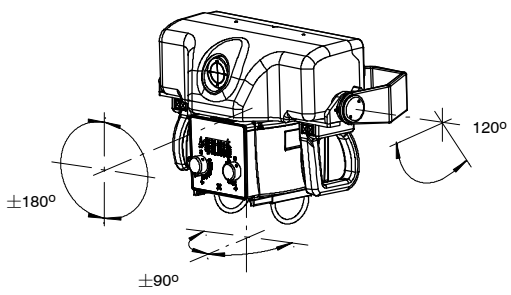


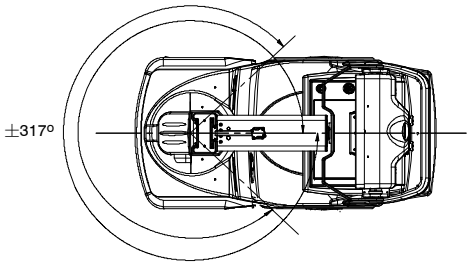
6.3.2 MOBILE WITH WIRELESS DR DETECTOR AND TELESCOPIC COLUMN

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



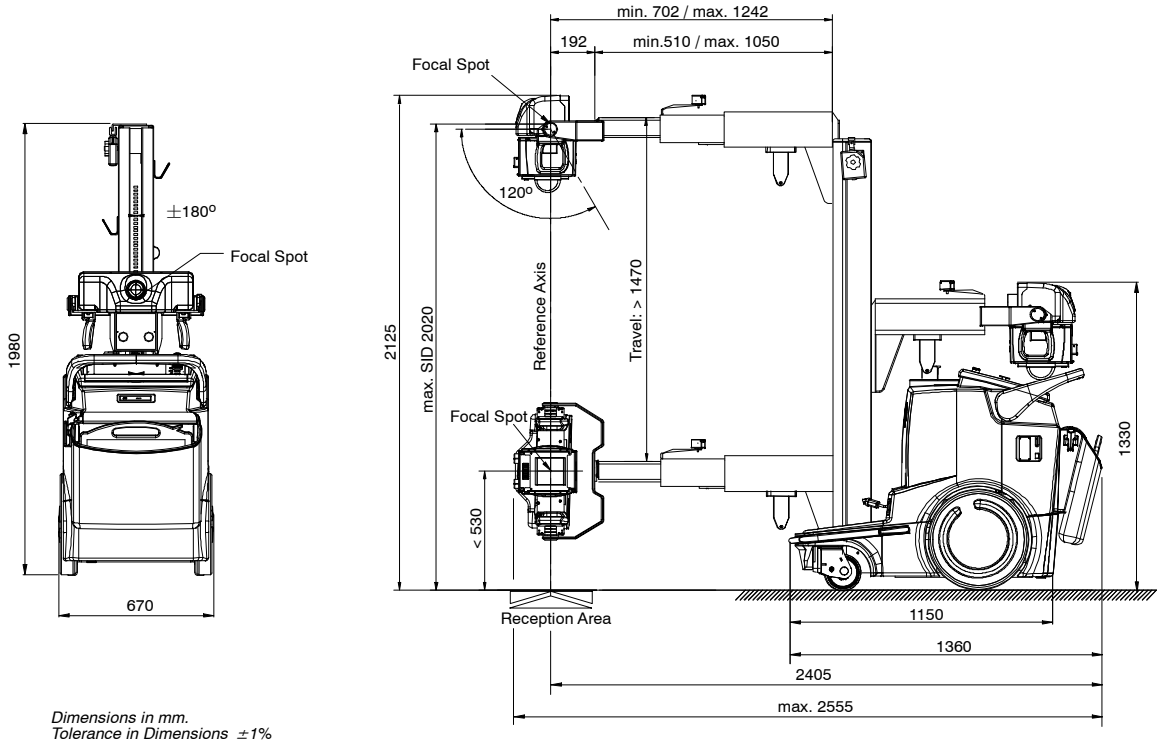
Dimensions in mm.
Tolerance in Dimensions ±1%



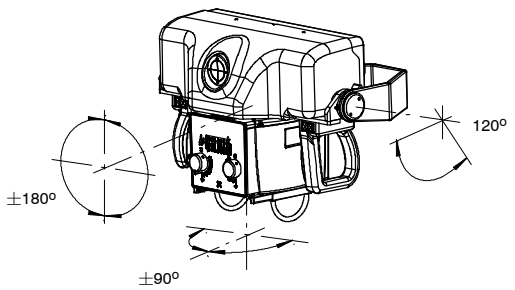


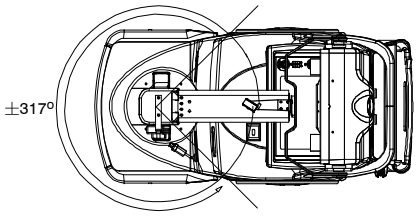
6.4 PHYSICAL CHARACTERISTICS: MOBILE WITH PORTABLE DR DETECTOR

LENGTH	WIDTH	HEIGHT*	WEIGHT
minimum 1360 mm maximum 2555 mm	670 mm	minimum 1980 mm maximum 2125 mm	560 kg (without Detectors and/or Accessories)
** Note: There is an optional "Short Column" that reduces in 130 mm the Column height, the maximum SID and the Vertical Travelling of the Arm.*			



Dimensions in mm.
Tolerance in Dimensions ±1%





APPENDIX A GUIDELINES FOR PEDIATRIC APPLICATIONS

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

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

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

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

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

- X-Ray Generator must have short exposures times.
- AEC must be used carefully, preferably use manual technique setting, applying lower doses.
- If possible, use high kVp techniques.
- As the use of Grids require higher doses, **never use Grids in pediatric exams**. Remove the Grid from the receptor assembly and select the lower possible doses. If the Grid 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 radiosensitivity: *GROSSMAN, Herman. "Radiation Protection in Diagnostic Radiography of Children". Pediatric Radiology, Vol. 51, (No. 1): 141-144, January, 1973: http://pediatrics.aappublications.org/cgi/reprint/51/1/141*.

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

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

Summary:

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

APPENDIX B PROTECT YOUR IMAGING SYSTEM FROM CYBERSECURITY THREATS

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

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

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

REQUIRED STRATEGIES BY THE OWNER / OPERATOR

Antivirus protection:

Use antivirus programs such as:

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

Keep these products up to date.

Limit access to trusted users only:

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

Ensure trusted content:

Restrict software or firmware updates to authenticated code.

Detect, respond, recover:

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

REQUIRED STRATEGIES BY THE MEDICAL DEVICE MANUFACTURER / SOFTWARE MANUFACTURER

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

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

A summary of our integrity controls:

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

CONCLUSION

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

**Manufacturer: AGFA NV, Septestraat 27,
B-2640 Mortsel - Belgium**

CE
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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/EC dated September 5, 2007.

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