

Technical Publication
OM-0527R5_EN_NLG

Operation

**Standard & Auto-tracking
Ceiling Suspension**



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.

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

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

The information comprised in this manual applies to the following equipments
La información contenida en este manual se aplica a los siguientes equipos
L'information contenue dans ce manuel est appliquée aux équipements suivants

Ceiling Suspension NOVA:

NOVA ST & NOVA AT

Manufactured by:

Fabricado por:

Fabriqué par:

SEDECAL

Sociedad Española de Electromedicina y Calidad S.A.

Pelaya, 9 - 13. Polígono Industrial "Río de Janeiro"

28110 Algete, Madrid - España (Spain)

Phone: +34 916 280 544 Fax: +34 902 190 385 www.sedecal.com

REVISION HISTORY

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| 1 | OCT 05, 2012 | IEC Standards Update |
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| 3 | FEB 29, 2016 | General Updates |
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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 HEHEDED OR AVOIDED WILL CAUSE SERIOUS PERSONAL INJURY OR DEATH.



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



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

Note 

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

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SECTION 1 INTRODUCTION

This **Positioner** has been designed for general radiography in hospitals, clinics and medical practices to make process and provide X-ray radiographic images of the skeleton, skull, chest, abdomen, extremities and other body parts on the patients. Images can be obtained with the patient in the sitting, standing or lying position. This unit is not intended for mammography applications.

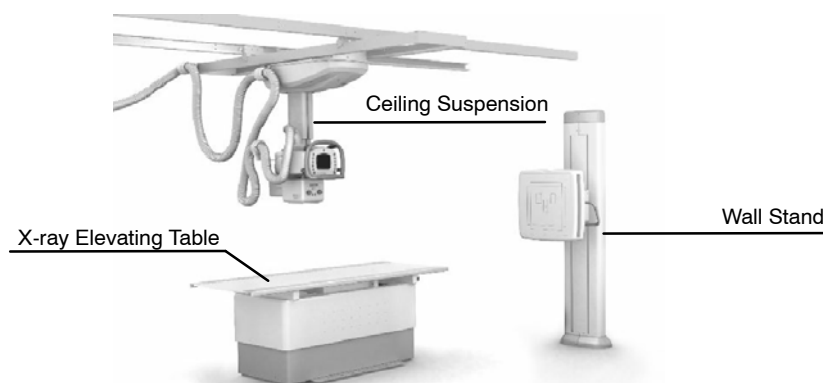
This manual contains all the necessary information to understand and operate the **Ceiling Suspension**. It provides a general description, safety information, operating instructions and specifications concerning the **Standard** and **Auto-tracking** models of the equipment. It is not intended to teach radiology or to make any type of clinical diagnosis.

This equipment is a heavy duty X-ray Tube Overhead Support system characterized by its simple and functional design. Thanks to its vertical and horizontal displacements, the suspension can cover almost all the room in which it is installed. It can operate with a table, Wall Stand or R/F table Bucky/Detector allowing all radiographic and fluoroscopic procedures. With its new lightweight design, the system guarantees highly precise positioning for optimal radiographic results. The new support system can operate on an horizontal or vertical Bucky/Detector, or be installed with an elevating table.

The **Ceiling Suspension** basically consists of a Control Console and the X-ray Tube and Collimator subassemblies. There are two different models available depending on the system configuration:

- **Standard Ceiling Suspension** with the analog Control Console and fully manually moved.
- **Auto-tracking Ceiling Suspension** with the analog Control Console and the Vertical Axis motorized to allow the Auto-tracking function.

Illustration 1-1
X-ray System with Manual / Auto-tracking Ceiling Suspension



1.1 GENERAL FEATURES

The main features of the **Ceiling Suspension** are:

- Ergonomic, robust and light weight design, to withstand intensive hospital use.
- Controls for lock release of the equipment.
- The Control Console of the Ceiling Suspension is ergonomically built, equipped with controls logically arranged and easily accessible in every angle and position of the X-ray Tube and Collimator assembly.
- Light weight Telescopic Column design with four independent parts guided by a high precision alignment mechanism for a smooth and quiet operation. This rigid and durable design reduces instability and vibration to the minimum, to facilitate precision in positioning.
- Optimal mechanical balancing system for manual movements with almost no efforts.
- X-ray Support with 360° for X-ray Tube rotation and 270° for X-ray Tube angulation.
- Provided with analog Control Console, which indicates the SID and X-ray Tube angulation (ANG).
- This equipment is compatible with a high range of Cassette/Detector Trays (max. 430x430 mm).
- On Alpha and Beta Axis the Tube and Collimator are rotated around the vertical (Alpha) or horizontal (Beta) axis of the Tube and Collimator Assembly. Both movements are manually controlled, press and hold the corresponding Control Console Brake Button also to rotated the Tube.
- Vertical movement is motorized assisted, it means that it is helped by the Vertical Motor as soon as the user initiates the motion after releasing the Brake and moves up/down the Tube and Collimator Assembly.

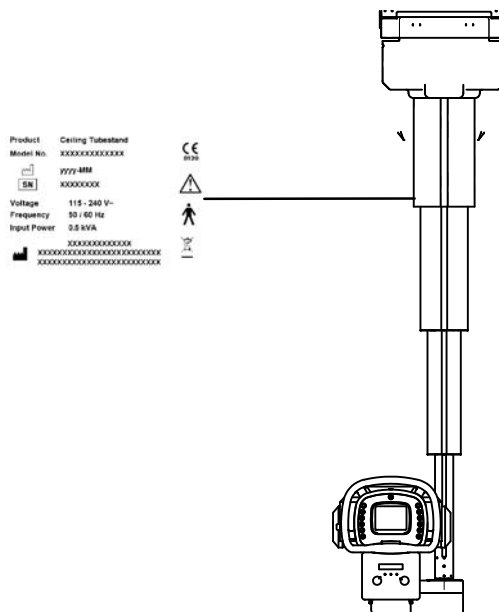
Beside the mentioned features, the difference between both models is that the Standard Ceiling Suspension is not provided with the Auto-tracking function. This function is activated and controlled by means the Control Console which is provided with one or two Auto-tracking ON/OFF Buttons.

1.2 PRODUCT IDENTIFICATION

The major items in the equipment have some identification labels attached to them which provide the following manufacturer and product information.

- Product.
- Model.
- Date of manufacture.
- Serial number.
- Volts (V), Frequency (Hz), and Power (kVA).
- Manufacturer.
- Place of manufacture.
- Certification.

Illustration 1-2
Ceiling Suspension Labeling



1.3 INDICATIONS FOR USE

1.3.1 INTENDED USE

This equipment is intended for use by qualified personnel only.

The **Ceiling Suspension** is an equipment included in a Medical Equipment System designed for general radiography in hospitals, clinics and medical practices to provide X-ray radiographic images of the skeleton, skull, chest, abdomen, extremities and other body parts.

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, disable, immobilized or in a state of shock.

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 mammography applications.

This equipment is not specifically designed for paediatric purposes; if children are to be examined, they should always be accompanied by an adult.

1.4 APPLIED PARTS

Applied Parts refer to parts of ME Equipment that in Normal Use necessarily comes into physical contact with the patient for ME Equipment to perform its function. **This RAD equipment does not include any Applied Parts.**

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

2.1 GENERAL



FOR CONTINUE 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, REGULATORY, 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 PRE-INSTALLATION REQUIREMENTS, INSTALLATION, CALIBRATION OR MAINTENANCE ARE DESCRIBED IN THE RESPECTIVE CHAPTERS OF THE PRE-INSTALLATION AND SERVICE MANUALS 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.



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 ACCESS TO THE EQUIPMENT 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 this.

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 patient skin distance (SID): 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 and Automatic Exposure Control with Ion Chambers 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.

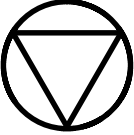


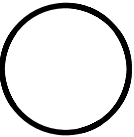
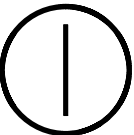




| | |
|---|---|
|  | <p>Caution. Consult accompanying documents.</p> |
|  | <p>General Symbol. Follow operating instructions. <i>(Only applies to IEC 60601-1 Standard - Third edition)</i></p> |
|  | <p>Safety Symbol. Follow instructions for use, especially those instructions identified with Advisory Symbols to avoid any risk for the Patient or Operator. <i>(Only applies to Standard IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012)</i></p> |

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

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|---|--|
|  | Warning: Non-ionizing radiation. |
|  | Warning: Laser beam. |
|  | Warning: Dangerous voltage. |
|  | 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. |

| | |
|---|---|
|  | <p>Stop (of action).</p> |
|  | <p>Emergency stop.</p> |
|  | <p>“ON” power.</p> |
|  | <p>“OFF” power.</p> |
|  | <p>“ON” / “OFF” (push-push). <i>Each position, “ON” or “OFF”, is a stable position.</i></p> |
|  | <p>Alternating current.</p> |
|  | <p>Three-phase alternating current.</p> |
|  | <p>Three-phase alternating current with neutral conductor.</p> |
|  | <p>Connection point for the neutral conductor on Permanently Installed equipment.</p> |

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

2.7 REGULATORY

2.7.1 CERTIFICATIONS

The **Positioners** covered by this Operation Manual are authorized to be marked with **CE MARKING** in accordance with the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices.

Statement of Compliance with IEC 60601-1-3: **Positioners** 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: **Positioners** 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 product conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.

Note 

***Positioners** model or type references are stated at the back of the cover page of this document.*

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

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

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

2.7.3 MODE OF OPERATION

- *Continuous operation*, in accordance with Standard IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.
- *Permanently Installed Equipment*.

2.7.4 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

2.7.7 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

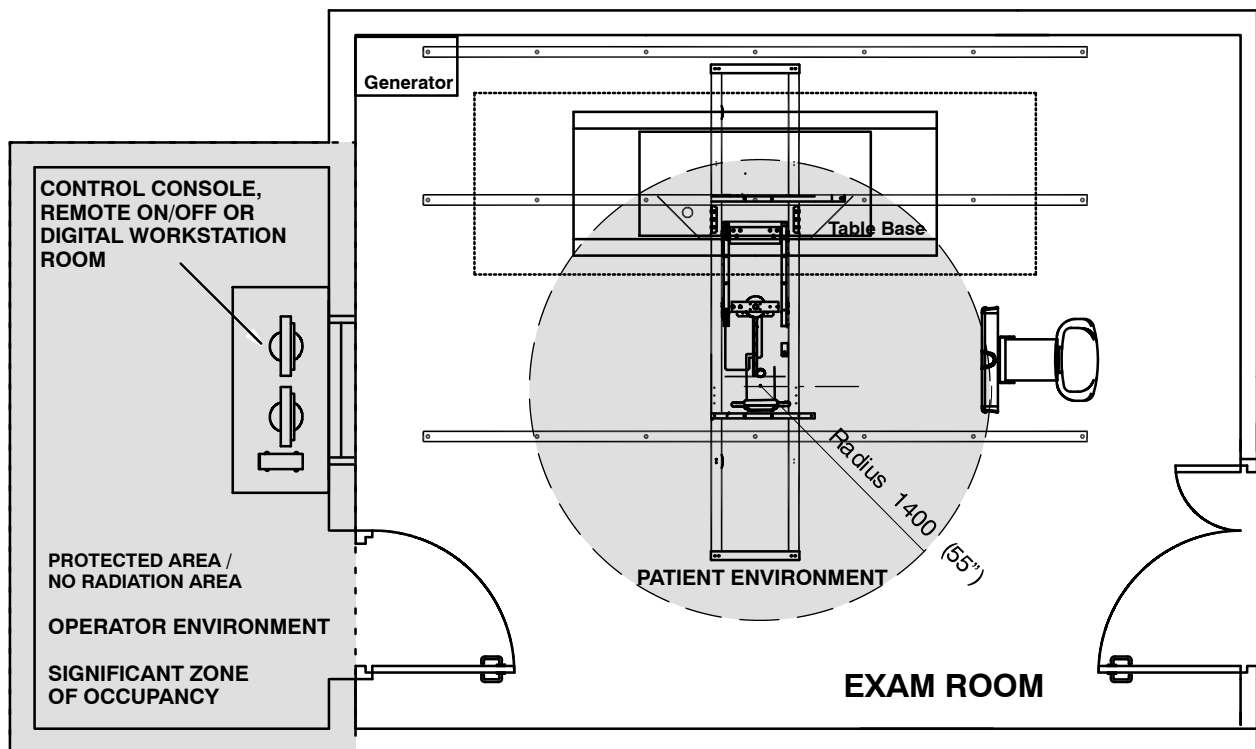
Protection against hazards from unwanted or excessive radiation in accordance with Standard IEC 60601-1:1988, 2005 and 2012, and IEC 60601-1-3:1994, 2008 and 2013.

2.7.8 DESIGNATED SIGNIFICANT ZONES OF OCCUPANCY

X-ray equipment specified for any radiological examination shall have at least one Significant zone of Occupancy for the use of the operator and staff, designated as follows:

- Selection and control of modes of operation.
- Selection of loading factors for the exposure.
- Actuation of the exposure controls.
- Other necessary controls for the operator during exposure.

Next illustration shows an example of the “Significant Zone of Occupancy”.



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 to radio communications.

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

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

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

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



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



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



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




The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables, accessories and transducers 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) | | |
|--|------------|---|
| <p><i>This X-ray Unit is intended for use in the electromagnetic environment specified below. The customer or the user of this Portable X-ray Unit should assure that it is used in such an environment.</i></p> | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | This X-ray Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | This X-ray Unit is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |
| <p><i>NOTE - In accordance with Standard IEC 61601-1-2:2014, 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.</i></p> | | |

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| GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2007) | | | |
|--|--|--|--|
| <i>This X-ray Unit is intended for use in the electromagnetic environment specified below. The customer or the user of this X-ray Unit should assure that it is used in such an environment.</i> | | | |
| Immunity Test | IEC 60601-1-2:2007 Test level | Compliance Level | Electromagnetic environment - Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6kV contact ± 8kV air | ± 6kV maximum ± 8kV maximum | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical transient/burst fast IEC 61000-4-4 | ± 2kV for power supply lines ± 1kV for input/output lines | ± 2kV for power supply lines ± 1kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1kV line(s) to line(s) ± 2kV line(s) to earth | ± 1kV symmetrical coupling ± 2kV asymmetrical coupling | 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% >95% for 250 periods | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Portable X-ray Unit requires continued operation during power mains interruptions, it is recommended that the Portable X-ray Unit be powered from a uninterruptible power supply or a battery |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3A/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 60601-1-2:2007) | | | |
|---|--|--|--|
| <p><i>This X-ray System is intended for use in an electromagnetic environment specified below. The customer or Operator of this X-ray System should assure that it is used in such an environment.</i></p> | | | |
| Immunity Test | IEC 60601-1-2:2007 Test Level | Compliance Level | Electromagnetic environment - guidance |
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p> | <p>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.</p> <p>Recommended separation distance</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$, 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$, 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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)}.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |
| <p>^{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 the 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.</p> <p>^{b)} Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

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| RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE X-RAY SYSTEM (IEC 61601-1-2:2007) | | | |
|--|--|---|--|
| <p><i>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 the X-ray System as recommended below, according to the maximum output power of the communications equipment.</i></p> | | | |
| 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 |
| <p><i>For transmitters rated at a maximum output power not listed above, the recommended separation distance 'd' in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</i></p> | | | |
| <p>NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> | | | |
| <p>NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |

| GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 61601-1-2:2014) | | | |
|---|--|--|--|
| <p><i>This X-ray System is intended for use in the electromagnetic environment specified below. The customer or Operator of this X-ray System should assure that it is used in such an environment.</i></p> | | | |
| 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. |
| <p><i>NOTE - U_T is the a.c. mains voltage prior to application of the test level.</i></p> | | | |

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| GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014) | | | |
|--|--|--|---|
| <p><i>This X-ray System is intended for use in an electromagnetic environment specified below. The customer or Operator of this X-ray System should assure that it is used in such an environment.</i></p> | | | |
| 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) | | | |
|--|--|-------------------------|--------------------------------------|
| <i>This X-ray System is intended for use in an electromagnetic environment specified below. The customer or Operator of this X-ray System should assure that it is used in such an environment.</i> | | | |
| 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 |
| <p>^{a)} For some services, only the uplink frequencies are included.</p> <p>^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.</p> <p>^{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.</p> | | | |

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. These tables illustrate loading factors for image performance and supply 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:

- Rad Positioner with Ralco Collimator.

Instrumentation used:

- Dosimeter: Vacudap
- Dosimeter: Unfors
- Rectangular Phantom made of Polymethyl-methacrylate (PMMA) layers: 25 cm x 25 cm x 20 cm.

Test Details:

- Minimum SID distance from Table:100 cm.
- Maximum SID distance from Wall Stand:180 cm.
- Open Collimator size: 13 cm x 13 cm (min.), 43 cm x 43 cm (max.)
- The measurements were made with the exposure parameters shown on the results table:
KVp Range: 40 KVp, 60 KVp, 80 KVp, 100 KVp, 125 KVp
mAs Range: 1 mAs, 2 mAs, 10 mAs, 50 mAs, 100 mAs
- Performed measurements of Air Kerma or Air Kerma Rate at the following designated positions:
 - Distance SID doses
 - Patient (Phantom) Entrance doses and Entrance doses Rate
 - Patient (Phantom) Output doses and Output doses Rate
 - Collimator Output doses

| Quantitative Information | | | | | | | | | | | | | | |
|--------------------------|-----|----------|-----|----------------------|--------------------------------------|--------------------------------------|---------------------------------------|--|-------------------|--------------------------------|--------------------------------------|--|--|-------|
| Loading Factors | | | | Parameter Selection | | | Filtrat. | Measured Doses | | | | | | |
| KVP | mA | Time (s) | mAs | Focal Spot Selection | SID Source-Image Distance (cm) | Collimator blades opening (cm) | HVL (min. value allowed) (mmAl) | Collimator Output Dose ($\mu\text{Gy}\cdot\text{m}^2$) | SID Dose (mGy) | Phantom Input Dose (mGy) | Phantom Input Dose Rate (Gy/h) | Phantom Output Dose Rate (mGy/h) | Phantom Output Dose (μGy) | |
| 40 | 160 | 0.012 | 2 | Small | 100 | 13x13 | 1.6 | 0.2 | 0.016 | 0.025 | 7.479 | 10.795 | 0.036 | |
| | 100 | 0.1 | 10 | Small | | | | 1.1 | 0.087 | 0.136 | 4.906 | 7.682 | 0.213 | |
| | 200 | 0.5 | 100 | Large | | | | 11 | 0.836 | 1.307 | 9.407 | 14.125 | 1.962 | |
| | 400 | 1 | 400 | Large | | | | 40 | 3.073 | 4.802 | 17.286 | 23.863 | 6.629 | |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 2.1 | 0.016 | 0.025 | 7.615 | 18.691 | 0.062 | |
| | 100 | 0.1 | 10 | Small | | | | 11.8 | 0.090 | 0.140 | 5.038 | 13.354 | 0.371 | |
| | 200 | 0.5 | 100 | Large | | | | 107.1 | 0.862 | 1.347 | 9.698 | 23.798 | 3.305 | |
| | 400 | 1 | 400 | Large | | | | 391.3 | 3.166 | 4.947 | 17.809 | 41.228 | 11.452 | |
| | 160 | 0.012 | 2 | Small | 180 | | | 13x13 | 0.2 | 0.005 | 0.006 | 1.865 | 4.273 | 0.014 |
| | 100 | 0.1 | 10 | Small | | | | | 1.1 | 0.027 | 0.034 | 1.214 | 3.453 | 0.096 |
| | 200 | 0.5 | 100 | Large | | | | | 11 | 0.257 | 0.325 | 2.343 | 5.985 | 0.831 |
| | 400 | 1 | 400 | Large | | | | | 40 | 0.940 | 1.190 | 4.283 | 11.723 | 3.257 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 2.1 | 0.005 | 0.007 | 1.962 | 6.243 | 0.021 | |
| | 100 | 0.1 | 10 | Small | | | | 11.8 | 0.028 | 0.035 | 1.269 | 4.420 | 0.123 | |
| | 200 | 0.5 | 100 | Large | | | | 107.1 | 0.267 | 0.338 | 2.432 | 7.400 | 1.028 | |
| | 400 | 1 | 400 | Large | | | | 391.3 | 0.979 | 1.239 | 4.461 | 12.763 | 3.545 | |

Note 

Combined standard uncertainty is $\pm 35\%$
 (IEC 60580:2000 / 60601-2-54:2009
 and IEC 60601-2-54:2009/AMD1:2015).

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| Quantitative Information | | | | | | | | | | | | | |
|--------------------------|-----|----------|-----|----------------------|--------------------------------------|--------------------------------------|---------------------------------------|--|-------------------|--------------------------------|--------------------------------------|--|--|
| Loading Factors | | | | Parameter Selection | | | Filtrat. | Measured Doses | | | | | |
| KVp | mA | Time (s) | mAs | Focal Spot Selection | SID Source-Image Distance (cm) | Collimator blades opening (cm) | HVL (min. value allowed) (mmAl) | Collimator Output Dose ($\mu\text{Gy}\cdot\text{m}^2$) | SID Dose (mGy) | Phantom Input Dose (mGy) | Phantom Input Dose Rate (Gy/h) | Phantom Output Dose Rate (mGy/h) | Phantom Output Dose (μGy) |
| 60 | 160 | 0.012 | 2 | Small | 100 | 13x13 | 2.2 | 0.6 | 0.046 | 0.072 | 21.746 | 113.713 | 0.379 |
| | 100 | 0.1 | 10 | Small | | | | 3.9 | 0.252 | 0.394 | 14.195 | 79.388 | 2.205 |
| | 200 | 0.5 | 100 | Large | | | | 39.4 | 2.587 | 4.042 | 29.103 | 157.649 | 21.896 |
| | 400 | 1 | 400 | Large | | | | 191.4 | 10.009 | 15.639 | 56.299 | 295.137 | 81.983 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 7.5 | 0.048 | 0.074 | 22.299 | 233.322 | 0.778 |
| | 100 | 0.1 | 10 | Small | | | | 40.6 | 0.265 | 0.414 | 14.894 | 161.562 | 4.488 |
| | 200 | 0.5 | 100 | Large | | | | 389.3 | 2.691 | 4.205 | 30.277 | 320.682 | 44.539 |
| | 400 | 1 | 400 | Large | | | | 1491.3 | 10.435 | 16.304 | 58.696 | 596.348 | 165.652 |
| | 160 | 0.012 | 2 | Small | 180 | 13x13 | | 0.6 | 0.014 | 0.018 | 5.345 | 53.374 | 0.178 |
| | 100 | 0.1 | 10 | Small | | | | 3.9 | 0.078 | 0.098 | 3.538 | 36.438 | 1.012 |
| | 200 | 0.5 | 100 | Large | | | | 39.4 | 0.796 | 1.007 | 7.251 | 72.125 | 10.017 |
| | 400 | 1 | 400 | Large | | | | 191.4 | 3.078 | 3.896 | 14.025 | 145.377 | 40.383 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 7.5 | 0.015 | 0.019 | 5.677 | 71.217 | 0.237 |
| | 100 | 0.1 | 10 | Small | | | | 40.6 | 0.082 | 0.103 | 3.717 | 48.584 | 1.350 |
| | 200 | 0.5 | 100 | Large | | | | 389.3 | 0.832 | 1.053 | 7.582 | 96.355 | 13.383 |
| | 400 | 1 | 400 | Large | | | | 1491.4 | 3.219 | 4.074 | 14.667 | 179.186 | 49.774 |

Note 

Combined standard uncertainty is $\pm 35\%$
 (IEC 60580:2000 / 60601-2-54:2009
 and IEC 60601-2-54:2009/AMD1:2015).

| Quantitative Information | | | | | | | | | | | | | |
|--------------------------|-----|----------|-----|----------------------|--------------------------------------|--------------------------------------|---------------------------------------|--|-------------------|--------------------------------|--------------------------------------|--|--|
| Loading Factors | | | | Parameter Selection | | | Filtrat. | Measured Doses | | | | | |
| KVp | mA | Time (s) | mAs | Focal Spot Selection | SID Source-Image Distance (cm) | Collimator blades opening (cm) | HVL (min. value allowed) (mmAl) | Collimator Output Dose ($\mu\text{Gy}\cdot\text{m}^2$) | SID Dose (mGy) | Phantom Input Dose (mGy) | Phantom Input Dose Rate (Gy/h) | Phantom Output Dose Rate (mGy/h) | Phantom Output Dose (μGy) |
| 80 | 160 | 0.012 | 2 | Small | 100 | 13x13 | 2.9 | 1.4 | 0.087 | 0.136 | 40.753 | 378.000 | 1.260 |
| | 100 | 0.1 | 10 | Small | | | | 7.4 | 0.461 | 0.702 | 25.909 | 256.070 | 7.113 |
| | 200 | 0.5 | 100 | Large | | | | 74.5 | 4.674 | 7.303 | 52.582 | 511.763 | 71.078 |
| | 400 | 1 | 400 | Large | | | | 366.7 | 18.374 | 28.709 | 103.353 | 982.017 | 272.783 |
| | 160 | 0.012 | 2 | Small | | 14.3 | | 0.090 | 0.141 | 42.391 | 829.043 | 2.763 | |
| | 100 | 0.1 | 10 | Small | | 77 | | 0.483 | 0.754 | 27.162 | 553.148 | 15.365 | |
| | 200 | 0.5 | 100 | Large | | 735.9 | | 4.884 | 7.632 | 54.949 | 1099.409 | 152.696 | |
| | 400 | 1 | 400 | Large | | 2856.2 | | 19.209 | 30.014 | 108.049 | 2111.165 | 586.435 | |
| | 160 | 0.012 | 2 | Small | 180 | 13x13 | | 1.4 | 0.026 | 0.033 | 9.931 | 181.096 | 0.604 |
| | 100 | 0.1 | 10 | Small | | | | 7.2 | 0.142 | 0.179 | 6.462 | 120.177 | 3.338 |
| | 200 | 0.5 | 100 | Large | | | | 74.5 | 1.449 | 1.834 | 13.201 | 239.228 | 33.226 |
| | 400 | 1 | 400 | Large | | | | 366.7 | 5.703 | 7.218 | 25.986 | 480.835 | 133.565 |
| | 160 | 0.012 | 2 | Small | | 14.3 | | 0.027 | 0.035 | 10.419 | 249.574 | 0.832 | |
| | 100 | 0.1 | 10 | Small | | 77 | | 0.149 | 0.189 | 6.799 | 162.094 | 4.503 | |
| | 200 | 0.5 | 100 | Large | | 735.9 | | 1.520 | 1.924 | 13.851 | 328.883 | 45.678 | |
| | 400 | 1 | 400 | Large | | 2856.2 | | 5.988 | 7.578 | 27.282 | 632.661 | 175.739 | |

Note 

Combined standard uncertainty is $\pm 35\%$
 (IEC 60580:2000 / 60601-2-54:2009
 and IEC 60601-2-54:2009/AMD1:2015).

Standard and Auto-tracking Ceiling Suspension

Operation

| Quantitative Information | | | | | | | | | | | | | |
|--------------------------|-----|----------|-----|----------------------|--------------------------------|--------------------------------|---------------------------------|--|----------------|--------------------------|--------------------------------|----------------------------------|--|
| Loading Factors | | | | Parameter Selection | | | Filtrat. | Measured Doses | | | | | |
| KVp | mA | Time (s) | mAs | Focal Spot Selection | SID Source-Image Distance (cm) | Collimator blades opening (cm) | HVL (min. value allowed) (mmAl) | Collimator Output Dose ($\mu\text{Gy}\cdot\text{m}^2$) | SID Dose (mGy) | Phantom Input Dose (mGy) | Phantom Input Dose Rate (Gy/h) | Phantom Output Dose Rate (mGy/h) | Phantom Output Dose (μGy) |
| 100 | 160 | 0.012 | 2 | Small | 100 | 13x13 | 3.6 | 2.1 | 0.131 | 0.205 | 61.550 | 854.348 | 2.848 |
| | 100 | 0.1 | 10 | Large | | | | 11.2 | 0.698 | 1.091 | 39.282 | 562.852 | 15.635 |
| | 200 | 0.5 | 100 | Large | | | | 113 | 7.136 | 11.149 | 80.276 | 1132.591 | 157.304 |
| | 400 | 1 | 400 | Large | | | | 448.9 | 28.400 | 44.375 | 127.800 | 1784.097 | 619.478 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 21 | 0.137 | 0.215 | 64.362 | 1829.478 | 6.098 |
| | 100 | 0.1 | 10 | Large | | | | 114.8 | 0.735 | 0.140 | 41.371 | 1221.809 | 33.939 |
| | 200 | 0.5 | 100 | Large | | | | 1067.6 | 7.491 | 1.347 | 84.277 | 2346.574 | 325.913 |
| | 400 | 1 | 400 | Large | | | | 4373 | 29.791 | 4.947 | 134.061 | 3901.774 | 1354.784 |
| | 160 | 0.012 | 2 | Small | 180 | 13x13 | | 2.1 | 0.040 | 0.006 | 15.334 | 396.261 | 1.321 |
| | 100 | 0.1 | 10 | Large | | | | 11.2 | 0.217 | 0.034 | 9.877 | 263.614 | 7.323 |
| | 200 | 0.5 | 100 | Large | | | | 113 | 2.224 | 0.325 | 20.269 | 536.807 | 74.557 |
| | 400 | 1 | 400 | Large | | | | 448.9 | 8.878 | 1.190 | 32.361 | 861.997 | 299.304 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 21 | 0.043 | 0.007 | 16.187 | 555.391 | 1.851 |
| | 100 | 0.1 | 10 | Large | | | | 114.8 | 0.228 | 0.035 | 10.404 | 363.757 | 10.104 |
| | 200 | 0.5 | 100 | Large | | | | 1067.6 | 2.334 | 0.338 | 21.268 | 743.791 | 103.304 |
| | 400 | 1 | 400 | Large | | | | 4373 | 9.313 | 1.239 | 33.946 | 1173.788 | 407.565 |

Note 

Combined standard uncertainty is $\pm 35\%$
 (IEC 60580:2000 / 60601-2-54:2009
 and IEC 60601-2-54:2009/AMD1:2015).

| Quantitative Information | | | | | | | | | | | | | |
|--------------------------|-----|----------|-----|----------------------|--------------------------------------|--------------------------------------|---------------------------------------|--|-------------------|--------------------------------|--------------------------------------|--|--|
| Loading Factors | | | | Parameter Selection | | | Filtrat. | Measured Doses | | | | | |
| KVp | mA | Time (s) | mAs | Focal Spot Selection | SID Source-Image Distance (cm) | Collimator blades opening (cm) | HVL (min. value allowed) (mmAl) | Collimator Output Dose ($\mu\text{Gy}\cdot\text{m}^2$) | SID Dose (mGy) | Phantom Input Dose (mGy) | Phantom Input Dose Rate (Gy/h) | Phantom Output Dose Rate (mGy/h) | Phantom Output Dose (μGy) |
| 125 | 160 | 0.012 | 2 | Small | 100 | 13x13 | 4.5 | 2.9 | 0.194 | 0.303 | 90.897 | 1611.652 | 5.372 |
| | 100 | 0.1 | 10 | Large | | | | 19.1 | 1.037 | 1.620 | 58.304 | 7.682 | 0.213 |
| | 200 | 0.5 | 100 | Large | | | | 164.1 | 10.722 | 16.753 | 120.620 | 2195.06 | 304.870 |
| | 400 | 1 | 400 | Large | | | | 823.7 | 43.078 | 67.310 | 121.158 | 2211.652 | 1228.696 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 29.7 | 0.204 | 0.319 | 95.666 | 3558.26 | 11.861 |
| | 100 | 0.1 | 10 | Large | | | | 163.4 | 1.090 | 1.704 | 61.337 | 2407.61 | 66.878 |
| | 200 | 0.5 | 100 | Large | | | | 1595.2 | 11.243 | 17.568 | 126.489 | 4963.61 | 689.391 |
| | 400 | 1 | 400 | Large | | | | 5679.6 | 45.270 | 70.734 | 127.321 | 4418.60 | 2454.783 |
| | 160 | 0.012 | 2 | Small | 180 | 13x13 | | 2.9 | 0.058 | 0.073 | 21.923 | 776.609 | 2.589 |
| | 100 | 0.1 | 10 | Large | | | | 19.1 | 0.317 | 0.401 | 14.449 | 520.278 | 14.452 |
| | 200 | 0.5 | 100 | Large | | | | 164.1 | 3.349 | 4.238 | 30.515 | 1068.73 | 148.435 |
| | 400 | 1 | 400 | Large | | | | 823.7 | 13.470 | 17.047 | 30.685 | 1072.48 | 595.826 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 29.7 | 0.062 | 0.078 | 23.395 | 1085.47 | 3.618 |
| | 100 | 0.1 | 10 | Large | | | | 163.4 | 0.338 | 0.428 | 15.416 | 728.765 | 20.243 |
| | 200 | 0.5 | 100 | Large | | | | 1595.2 | 3.523 | 4.459 | 32.108 | 1509.49 | 209.652 |
| | 400 | 1 | 400 | Large | | | | 5679.6 | 14.191 | 17.961 | 32.330 | 1515.91 | 842.174 |

Note 

Combined standard uncertainty is $\pm 35\%$
 (IEC 60580:2000 / 60601-2-54:2009
 and IEC 60601-2-54:2009/AMD1:2015).

Standard and Auto-tracking Ceiling Suspension

Operation

| Quantitative Information | | | | | | | | | | | | | |
|--------------------------|-----|----------|-----|----------------------|--------------------------------------|--------------------------------------|---------------------------------------|--|-------------------|--------------------------------|--------------------------------------|--|--|
| Loading Factors | | | | Parameter Selection | | | Filtrat. | Measured Doses | | | | | |
| KVp | mA | Time (s) | mAs | Focal Spot Selection | SID Source-Image Distance (cm) | Collimator blades opening (cm) | HVL (min. value allowed) (mmAl) | Collimator Output Dose ($\mu\text{Gy}\cdot\text{m}^2$) | SID Dose (mGy) | Phantom Input Dose (mGy) | Phantom Input Dose Rate (Gy/h) | Phantom Output Dose Rate (mGy/h) | Phantom Output Dose (μGy) |
| 150 | 160 | 0.012 | 2 | Small | 100 | 13x13 | 5.4 | 3.8 | 0.253 | 0.395 | 118.573 | 2493.39 1 | 8.311 |
| | 100 | 0.1 | 10 | Large | | | | 24.4 | 1.375 | 2.148 | 77.331 | 1679.79 1 | 46.661 |
| | 200 | 0.5 | 100 | Large | | | | 239.3 | 14.530 | 22.704 | 163.467 | 3508.59 1 | 487.304 |
| | 400 | 1 | 400 | Large | | | | 882.9 | 59.548 | 93.043 | 133.983 | 2882.50 4 | 2001.739 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 38.5 | 0.262 | 0.409 | 122.731 | 5744.34 8 | 19.148 |
| | 100 | 0.1 | 10 | Large | | | | 210.7 | 1.444 | 2.257 | 81.244 | 3862.95 7 | 107.304 |
| | 200 | 0.5 | 100 | Large | | | | 2124.2 | 15.252 | 23.832 | 171.587 | 8057.73 9 | 1119.130 |
| | 400 | 1 | 400 | Large | | | | 8581.3 | 62.748 | 98.043 | 141.183 | 6629.00 9 | 4603.478 |
| | 160 | 0.012 | 2 | Small | 180 | 13x13 | | 3.8 | 0.077 | 0.098 | 29.337 | 1208.08 7 | 4.027 |
| | 100 | 0.1 | 10 | Large | | | | 24.4 | 0.426 | 0.539 | 19.410 | 819.235 | 22.757 |
| | 200 | 0.5 | 100 | Large | | | | 239.3 | 4.548 | 5.756 | 41.442 | 1714.22 6 | 238.087 |
| | 400 | 1 | 400 | Large | | | | 882.9 | 18.687 | 23.651 | 34.057 | 1409.94 8 | 979.130 |
| | 160 | 0.012 | 2 | Small | | 43x43 | | 38.5 | 0.080 | 0.102 | 30.467 | 1700.87 0 | 5.670 |
| | 100 | 0.1 | 10 | Large | | | | 210.7 | 0.453 | 0.573 | 20.646 | 1152.939 | 32.026 |
| | 200 | 0.5 | 100 | Large | | | | 2124.2 | 4.803 | 6.078 | 43.764 | 2436.73 0 | 338.435 |
| | 400 | 1 | 400 | Large | | | | 8581.3 | 19.748 | 24.993 | 35.990 | 2005.98 3 | 1393.043 |

Note 

Combined standard uncertainty is $\pm 35\%$
(IEC 60580:2000 / 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.

Standard and Auto-tracking Ceiling Suspension

Operation

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SECTION 3 OPERATING SEQUENCES

3.1 POWER ON/OFF

All the equipments of the X-ray Room and the X-ray Generator should be powered by the same Room Cabinet, so the whole System will be turned ON/OFF at the same time.

The Suspension is connected to the Electrical Cabinet and feeds the Table. At the same time, the table feeds the Wall Stand. Switch ON/OFF the Room Electrical Cabinet to power ON/OFF the Ceiling Suspension and the Whole Room.



BEFORE POWERING ON THE UNIT, CHECK THAT THERE IS NO OBJECT OR OBSTACLE ON THE TUBE SUPPORT OR THE L-BLOCK SURFACE FOR THE CORRECT MOTION OF THE SUSPENSION.

3.2 X-RAY TUBE WARM-UP PROCEDURE



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

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

It is recommended that the following procedure will be performed for X-ray Tube warm-up, at the start of each day and when the X-ray 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 current X-ray Tube in use, comparing its recommendations with this procedure. If there is conflict with this procedure, comply with the X-ray Tube manufacturer's instructions.

Perform X-ray Tube warm-up as follows:

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



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

3.3 RADIOGRAPHIC OPERATION

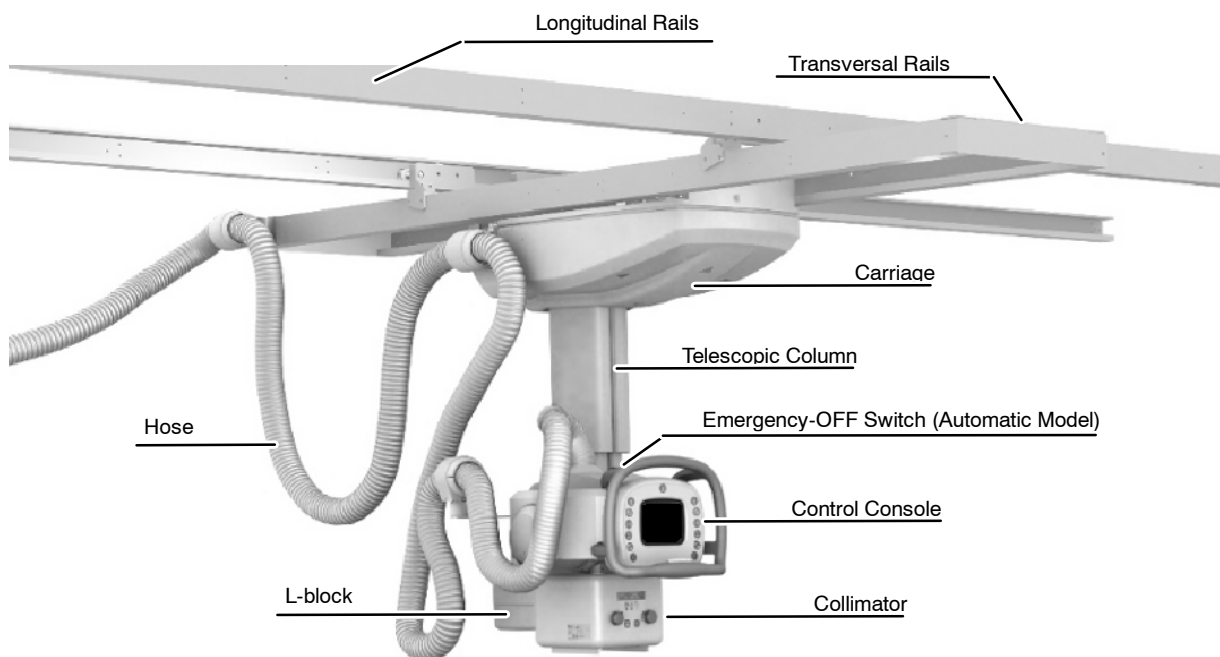
A typical examination sequence is as indicated below:

1. Make sure that the X-ray Tube is properly warmed-up.
2. Position the patient for the examination.
3. Maintain the patient at the required position. Prepare the X-ray Tube by pressing the Handswitch button to the "Prep" position and maintain it until the "Ready" indicator is illuminated.
4. Carry out an X-ray exposure by pressing the Handswitch button fully to the "Exp" position, maintaining it pressed throughout the exposure. The "X-ray On" indicator will light and an audible signal will sound during the exposure.
5. When the exposure is finished, release the push-button.
6. Repeat the procedure if additional exposures are desired.

SECTION 4 OPERATION

4.1 COMPONENTS OF THE EQUIPMENT

Illustration 4-1
Ceiling Suspension Nomenclature



RAIL SYSTEM

The Rail System is formed by two pairs of rails made of aluminum and available in different lengths. The rails allow the displacement of the Carriage along the Longitudinal and Transversal Axis.

Longitudinal Rails or Axis (X), different lengths extrusion bars which fix the Ceiling Suspension to the ceiling. Longitudinal rails are available in the following lengths: 3358 mm (132.22"), 4019 mm (158.22"), 4679 mm (184.22"), 5340 mm (210.22") and 6000 mm (236.22").

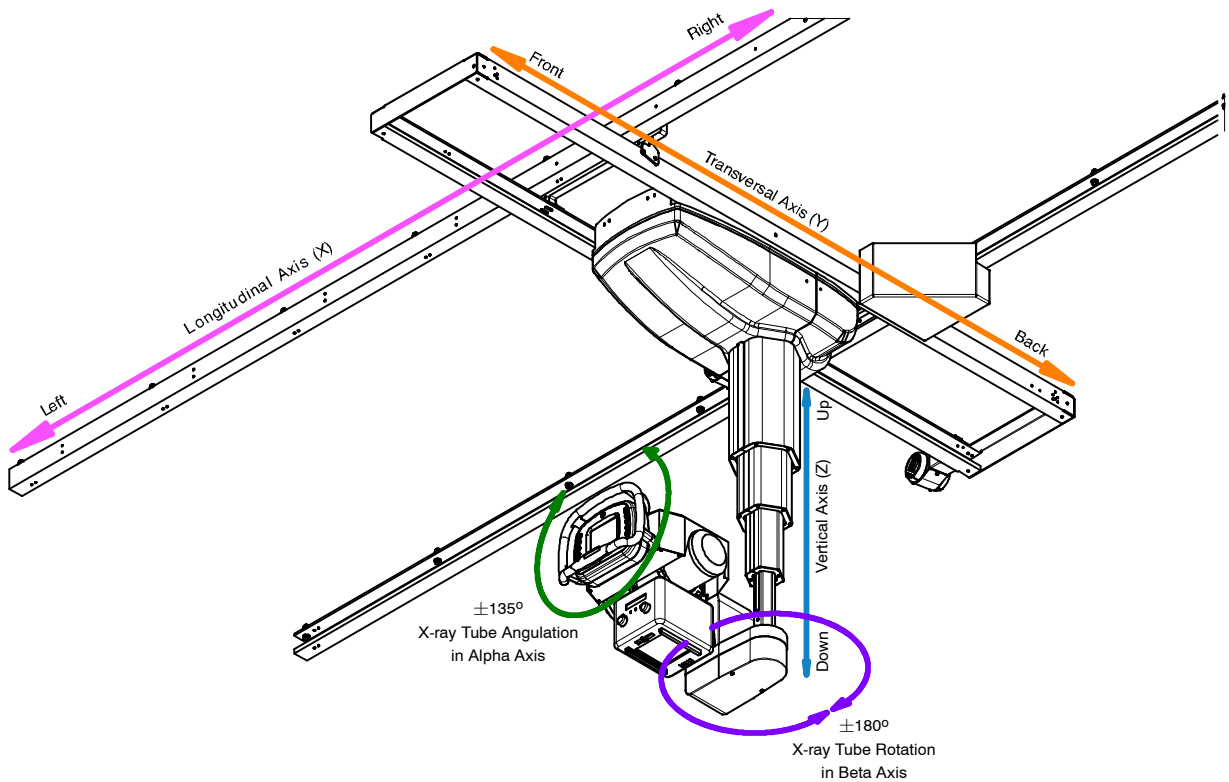
Transversal Rails or Axis (Y), an horizontal structure fixed to the Longitudinal Rails by two bearings assemblies that allow the movement along the Longitudinal Rails. The bearings also maintain the alignment of the Transversal Rails with the Table. Transversal rails are available in the following lengths: 2000 mm (78.74"), 2250 mm (88.58"), 2500 mm (98.42"), 2750 mm (108.27"), 3000 mm (118.11") and 3500 mm (137.80").

Standard and Auto-tracking Ceiling Suspension

Operation

The equipment may be provided with a Cable Support Rail, an unistrut rail with the same length of the Longitudinal Rails, located behind the back Longitudinal Rail.

Illustration 4-2
Ceiling Suspension Axes and travels

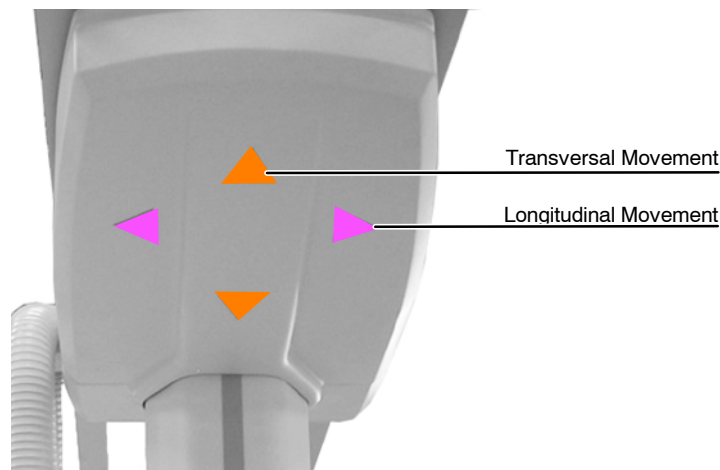


CARRIAGE

The Carriage contains some electronic and mechanical components of the Ceiling Suspension and supports the Telescopic Column, L-Block Assembly, X-ray Tube Support with the Tube, Collimator and Control Console.

The Carriage is marked with orange and pink arrows to match the Transversal and Longitudinal Brake Buttons of the Control Console, respectively.

Illustration 4-3
Carriage



TELESCOPIC COLUMN

It is composed of four different sized hexagonal tubes of steel. Fixed to the Carriage, the Telescopic Column allows vertical movement of the X-ray Tube Assembly in the **Vertical Axis (Z)**. This motion is controlled by the Vertical Brake.

The Focal Spot vertical travel is 1570 mm (61.8"). The minimum distance Focus-Ceiling is 737 mm (29") and the maximum distance is 2307 mm (90.8").

L-BLOCK ASSEMBLY

This assembly is the junction between the Telescopic Column and the X-ray Tube and Collimator Assembly. It contains electronic and the mechanical components to allow the movement of the X-ray Tube in the **Alpha Axis (Angulation)** and **Beta Axis (Rotation)**.

Standard and Auto-tracking Ceiling Suspension

Operation

X-RAY TUBE SUPPORT

It is designed to support the X-ray Tube, which can rotate around the vertical Axis of the Telescopic Column (Beta Axis) $\pm 180^\circ$ from the front position (0°), and it can rotate around its transversal Axis (Alpha Axis) $\pm 135^\circ$ from 0° position (perpendicular to the floor).

The Suspension can be associated with the following X-ray tubes:

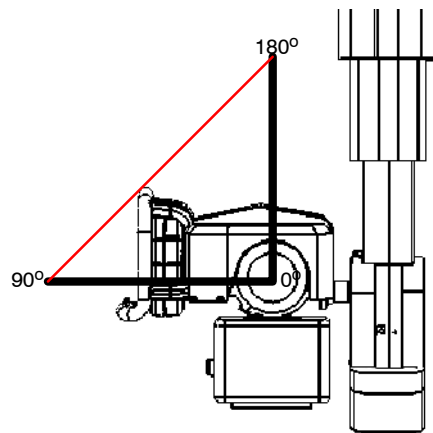
| HOUSING | INSERT | FOCAL SPOT | TARGET ANGLE | ANODE HEAT CAPACITY (KHU) | SPEED |
|---------------------|-------------------------|----------------------------------|--------------|---------------------------|----------|
| Toshiba E7100X | N/A | 0.6 - 1.2 | 12° | 300 | High/Low |
| Toshiba E7239X & FX | N/A | 1.0 - 2.0 | 16° | 140 | Low |
| Toshiba E7240X & FX | N/A | 0.6 - 1.2 | 12° | 140 | Low |
| Toshiba E7242X & FX | N/A | 0.6 - 1.5 | 14° | 200 | Low |
| Toshiba E7252X & FX | N/A | 0.6 - 1.2 | 12° | 300 | High/Low |
| Toshiba E7254X & FX | N/A | 0.6 - 1.2 | 12° | 400 | High/Low |
| Toshiba E7299X | N/A | 0.3 - 1 | 12° | 140 | Low |
| Toshiba E7843X | N/A | 0.6 - 1.2 | 12° | 150 | Low |
| Toshiba E7865X | N/A | 0.3 - 1 | 12° | 140 | Low |
| Toshiba E7869X | N/A | 0.6 - 1.2 | 12° | 600 | High/Low |
| Toshiba E7876X | N/A | 0.6 - 1.2 | 12° | 230 | Low |
| Toshiba E7884X | N/A | 0.6 - 1.2 | 12° | 300 | Low |
| Varian B130 | Any one of 100 mm (4") | Variable depending on the insert | | | High/Low |
| Varian Sapphire | Any one of 100 mm (4") | Variable depending on the insert | | | High/Low |
| Varian Diamond | Any one of 71 mm (2,8") | Variable depending on the insert | | | High/Low |

Tube adaptation kits will be supplied to allow the correct assembly and fixation of the X-ray tubes to the ceiling suspension and provide compatibility. Each of these adaptation kits is compound of fixation rings, console fixture and suspension fixture. All components are designed for the specific characteristics of the X-ray tubes (type, dimensions, weight...).

Note 

Only tubes with a horn angle between 90° and 180° can be mounted on the suspension.

Illustration 4-4
Allowed orientations for Tubes



COLLIMATOR

The Suspension can be associated with three Collimation options:

- **Ralco R225/R225 DHHS Manual Collimator.**
- **Ralco R225ACS Automatic Collimator.**

Illustration 4-5
Collimators

Manual Collimator



Automatic Collimator



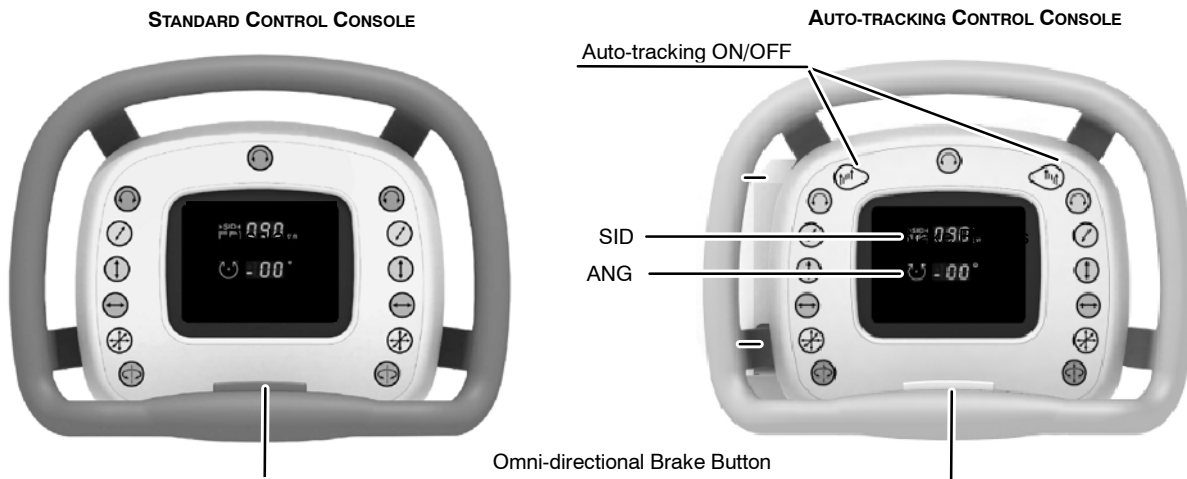
CONTROL CONSOLE







The Control Console enables the operator to control the movements of the Ceiling Suspension and also the Auto-tracking function.

Brake Buttons are used to control each axis brake/movement. When a button is pressed and held, the brake is released, so the equipment can be moved in the free axis. Once released the button, the brake is activated and the motion stops.

There are two different types of Control Consoles depending on the Suspension model: the Standard and the Auto-tracking Control Console. Both are similar but the Auto-tracking Control Console is provided with an additional button to control the Auto-tracking function.

**Illustration 4-6
Control Consoles and Brake Buttons**



| | |
|--|--|
|  <p>Alpha Axis Brake. Angle of the X-ray Tube.</p> |  <p>Longitudinal Axis Brake. Right & Left.</p> |
|  <p>Transversal Axis Brake. Back & Front.</p> |  <p>Omni-directional Brake. Transversal and Longitudinal. Other Axes could be also activated according to the configuration during installation.</p> |
|  <p>Vertical Axis Brake. Up & Down.</p> |  <p>Beta Axis Brake. Rotation of the X-ray Tube.</p> |
| <p>Wheel Omni-directional Brake. Transversal and Longitudinal. Other Axes could be also activated according to the configuration during installation.</p> | |

Use always the Control Console Wheel to drive all manual movements of the Ceiling Suspension. Otherwise, operator could get injured due to the potential pinch points areas.

In the analog Control Console it is displayed:



Note 

When working on RSA MODE, the SID indicates in all cases the distance to the Table Detector or the floor, depending on the configured reference point.

- **SID.** Distance from the Focal Spot to the Receptor. It is displayed in cm or inches, depending on the Console Display configuration. SID can be:
 - **Vertical.** The X-ray Tube beam points to the Table Receptor.
 - **Horizontal.** The X-ray Tube beam points to the Wall Stand Receptor.



- **ANG or X-Ray Tube Angulation.** It indicates the Angulation degrees of the Tube Support, values are ranged between:
 - **0°.** The X-ray tube beam points the Table Receptor.
 - **90°.** The X-ray tube beam points to the Wall Stand Receptor.

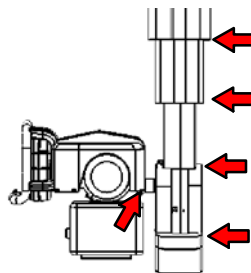
4.2 MOVEMENTS



THIS EQUIPMENT CAN BE MOVED IN DIFFERENT AXIS. PLEASE TAKE CARE THAT NEITHER THE PATIENT IS IN THE MIDDLE OF THE TRAVEL. REMOVE ALL OBJECTS FROM THE COLLISION AREA.



THE FOLLOWING SKETCH INDICATES DANGEROUS LOCATIONS WHERE PATIENT OR OPERATOR CAN BE INJURED OR PINCHED. PLEASE PAY ATTENTION THAT NEITHER THE PATIENT NOR OPERATOR GET PINCHED OR HURT IN THIS AREA.



4.2.1 MANUAL MOVEMENTS

The Ceiling Suspension can be moved in one direction, two directions at the same time or even simultaneously on vertical, transversal and longitudinal directions. In case of moving the Suspension in just one axis, proceed as follow:

1. Press and hold the corresponding Button on the console. The brake will be released.



BEFORE POWERING ON AND MOVING THE UNIT, CHECK THAT THERE IS NO OBJECT OR OBSTACLE ON THE TUBE SUPPORT OR ON THE L-BLOCK SURFACE FOR THE CORRECT MOTION OF THE SUSPENSION.

2. Move manually the Suspension to the desired position.
3. Release the Button. This will activate the brake again.

To carry out simultaneous movements on different axes use the Omni-directional pushbutton or the button located on the Wheel of the Console. Then move manually the Suspension up to the desired direction. It is just possible to move the Ceiling Suspension on Alpha and Beta Axes when their corresponding Brake Button is pressed and held.

Note 

Due to the motorized assisted movement in the Vertical Axis. move up/down slowly the X-ray Tube Assembly because, in case of making higher effort than the required, more difficult will be to raise and lower it.

4.2.2 DETENT POINTS

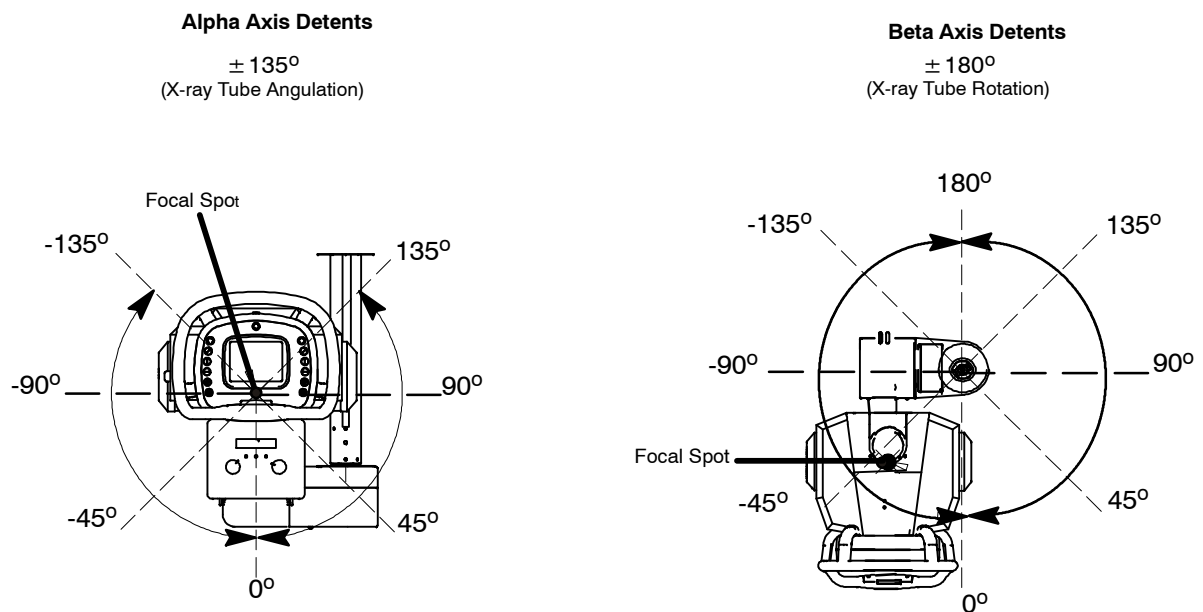
Each axis can be configured to have several Detent Points that allow to get the Suspension exactly at the correct position to work with the Table and Wall Stand.

Move slowly the equipment to get the Detent Assembly locked at the correct position. Once the equipment is locked, the Brakes get activated. Release again any brake to move and get unlocked the Ceiling Suspension.

Depending on the System Layout these working positions are different.

- On the Longitudinal and Transversal Axes, the Detent Assemblies are mechanical, they are composed by Position Markers and the Detent Assemblies. The Position Markers are installed on the Transversal Rail and the Carriage, they indicate the exact position for the proper alignment of the X-ray Tube with both Receptors and the SID distances from the Wall Stand.
- On the Vertical Axis there is just one electromechanical Detent Point available to be defined during installation. It is configured at the desired default SID to the Table.
- On the Alpha and Beta Axes, Detent Points are configured by default at each 45°.

Illustration 4-7
Alpha and Beta Detents



4.2.3 AUTO-TRACKING FUNCTION

This function is just available for Auto-tracking Ceiling Suspensions. It allows the Suspension X-ray Tube to track the selected Receptor once it initiates the movement to change its position.

First of all, both equipment must be properly aligned. The relative distance and the SID are kept constant. The Receptor is always the Master (the equipment which initiates the movement), and the Tube of the Suspension is the slave (the equipment which follows them to get aligned again with the Receptor).

Illustration 4-8
Auto-tracking Ceiling Suspension Control Console



The Auto-tracking ON/OFF Led can be:

- **GREEN.** It means that the Auto-tracking function is allowed.
- **RED.** It means that the Auto-tracking function is not allowed because the Tube angle is out of the range $0^{\circ} \pm 2^{\circ}$ and $90^{\circ} \pm 2^{\circ}$.

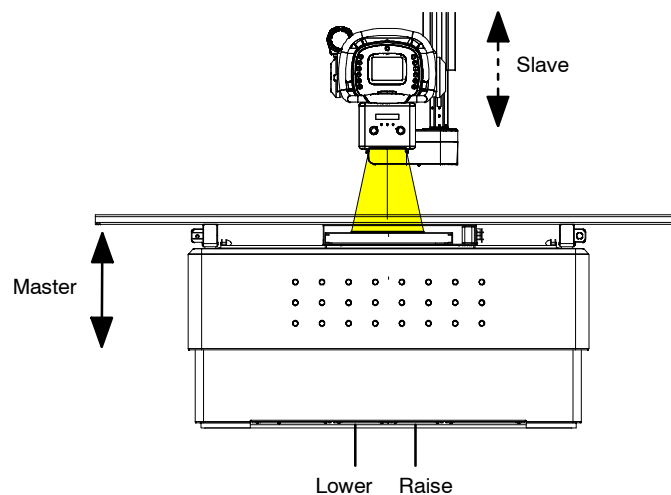
4.2.3.1 OPERATION WITH ELEVATING TABLES

With the “Auto-tracking ON/OFF” Button OFF:

1. Turn the X-ray Tube to 0°, pointing to the Receptor of the Table.
2. Release manually the brakes and locate the Suspension on Transversal and Longitudinal Detent position, centered with the Receptor of the Table.
3. Push once the console “Auto-tracking ON/OFF” button to activate the Autotracking function.
4. The Suspension will move vertically to reach the default SID distance for the Auto-tracking function.
5. When the Table, which is always the master equipment, moves up and down, the Suspension, always the slave equipment, tracks its movement and moves up or down too, maintaining the same SID.

Illustration 4-9

Auto-tracking Movement Policy for Auto-tracking Ceiling Suspension with Elevating Table



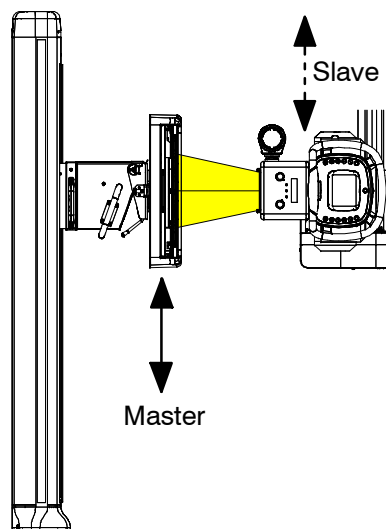
4.2.3.2 OPERATION WITH WALL STAND

With the “Auto-tracking ON/OFF” Button OFF:

1. Turn the X-ray Tube $\pm 90^\circ$ pointing to the Receptor of the Wall Stand.
2. Locate the Suspension on Longitudinal and Transversal Detents, at specific horizontal SID from the Wall Stand.
3. Push once the console “Auto-tracking ON/OFF” Button to activate the Autotracking function. The Suspension will move vertically to align the central X-ray beam with the center position of the Wall Stand Receptor, as Master equipment.
4. When the Wall Stand, which is always the master equipment, moves up and down, the Suspension, always the slave equipment, tracks its movement and moves up or down too, maintaining the same SID.

Illustration 4-10

Auto-tracking Movement Policy for Auto-tracking Ceiling Suspension with Wall Stand



4.3 RSA MODE

The **Standard Ceiling Suspension** can operate within RSA Systems as the secondary suspension. In this case, the Ceiling Suspension operates just in these mode, so it gets modified in several features, as Detents Points, which electronics are deactivated, and the Display.

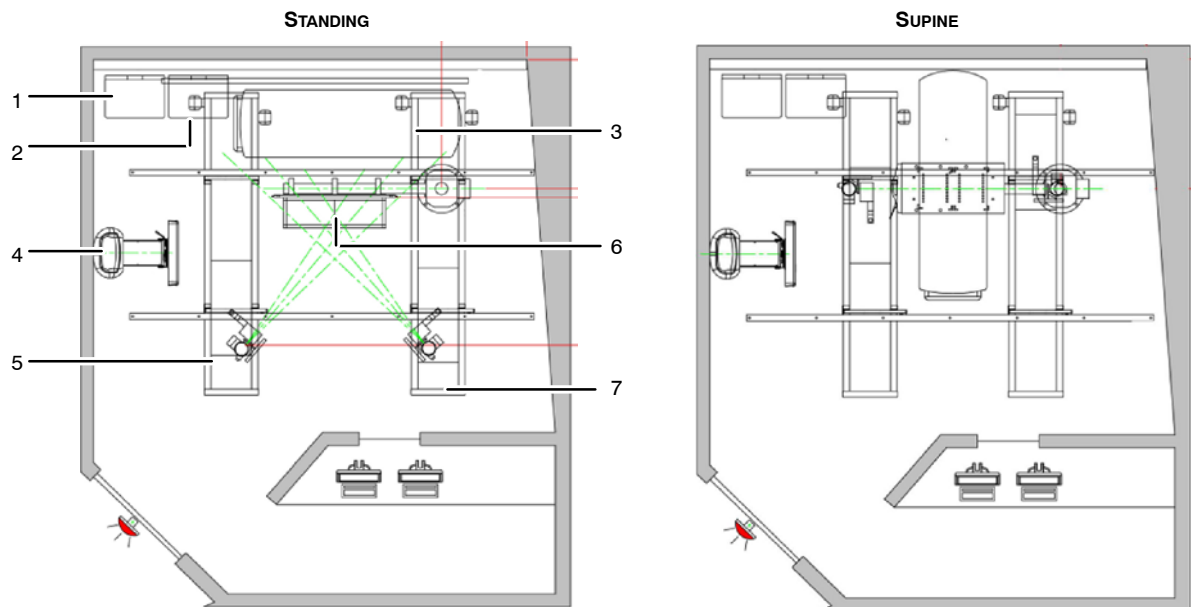
The **Auto-tracking Ceiling Suspension** can operate within RSA Systems as the main suspension. In this case, it operates in both available modes, Clinical and RSA. However, it gets modified in several features, as Detent Points configuration and the Display.

The Display in RSA Mode is modified in order to get the same lecture in the SID whichever is the position of the Console. The value of the SID, even the Led indicator indicates Vertical or Horizontal, is always the Vertical lecture, indicating the distance to the Receptor in horizontal position.

There are two different positions on the RSA Mode:

- **STANDING**
- **SUPINE**

Illustration 4-11
RSA Modes



| | | | | | |
|---|---------------------|---|---------------|---------------------------|-----------|
| 1 | CLINICAL GENERATOR | 2 | RSA GENERATOR | 3 | RSA TABLE |
| 4 | CLINICAL WALL STAND | | 5 | CLINICAL SUSPENSION | |
| 6 | RSA DETECTOR | | 7 | RSA SUSPENSION (STANDARD) | |

Standard and Auto-tracking Ceiling Suspension

Operation

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SECTION 5 COLLIMATION

5.1 RALCO AUTOMATIC COLLIMATOR

Note 

Refer to the own Collimator Manual for further details and information about its operation.

Collimator controls consist of the following buttons and knobs:

| | | | |
|---|----------------------------------|----|----------------------------------|
| 1 | COLLIMATOR DISPLAY | 6 | CHANGE OF FILTER |
| 2 | MANUAL BLADE CONTROL | 7 | COLLIMATOR LAMP CONTROL (LED ON) |
| 3 | AUTOMATIC MODE INDICATOR (GREEN) | 8 | RETRACTABLE METRIC TAPE |
| 4 | BUSY MODE INDICATOR (RED) | 9 | LASER POINTER WINDOW |
| 5 | MANUAL MODE INDICATOR (YELLOW) | 10 | LASER POINTER ON/OFF BUTTON |

Illustration 5-1
Ralco Automatic Collimator



After pressing the Collimator Lamp control, the Lamp remains ON for several seconds to allow for patient/grid alignment before turning OFF automatically. An optional Laser positioner may be included with the Collimator Light in order to facilitate patient positioning.

Exposure field on the Bucky/Detector is adjusted by setting the two knobs. The table on the Front Panel shows the number to set with the knobs to open the blades according to the SID and image size to be used.

The Collimator can rotate $\pm 90^\circ$ on its vertical axis while the Tube remains in the same position. This movement is performed by manually turning the Collimator and it has detents every 90° .

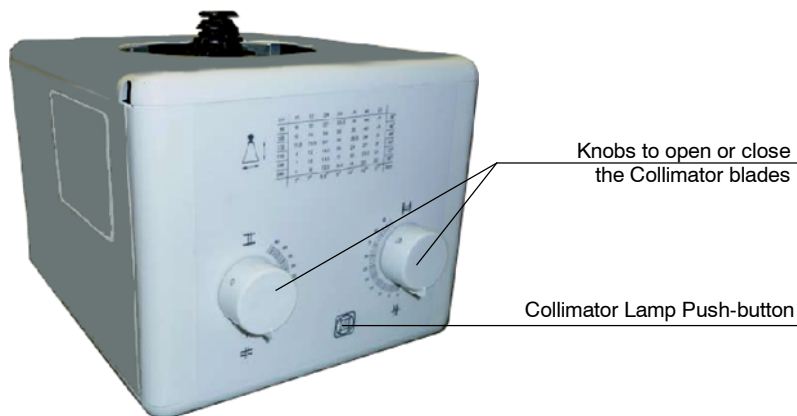
5.2 RALCO MANUAL COLLIMATOR R225/R225 DHHS

Collimator controls consist of a button to switch on the Collimator lamp and two knobs to open or close the internal blades of the Collimator.

When pressing the Collimator Lamp push-button, the Collimator light and an optional Laser light turn on. They remain lighting for 30 seconds before they switch Off automatically (lighting time can be configured)

Exposure field on the Receptor is adjusted by setting the two knobs. The table on the Front Panel shows the number to set with the knobs to open the blades according to the SID and X-ray field to be used.

Illustration 5-2
Collimator Controls



The Collimator can rotate $\pm 90^\circ$ on its vertical axis while the Tube remains in the same position. This movement is performed by manually turning the Collimator and has detents every 90° .

Note 

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

5.3 DOSIMETER DEVICE (OPTIONAL)

The optional Dosimeter device is related to the Collimator installed in the equipment. The usual compatible Dosimeter devices are:

- Vacudap 2000 / 2004 Series
- Iba Kermax Plus
- Diamentor E2 and CI

Note 

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

5.4 X-RAY BEAM ALIGNMENT WITH RESPECT TO PATIENT

After selecting RAD parameters for the technique to be performed:

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



ALWAYS SELECT THE CORRECT FIELD SIZE TO AVOID EXCESSIVE RADIATION.

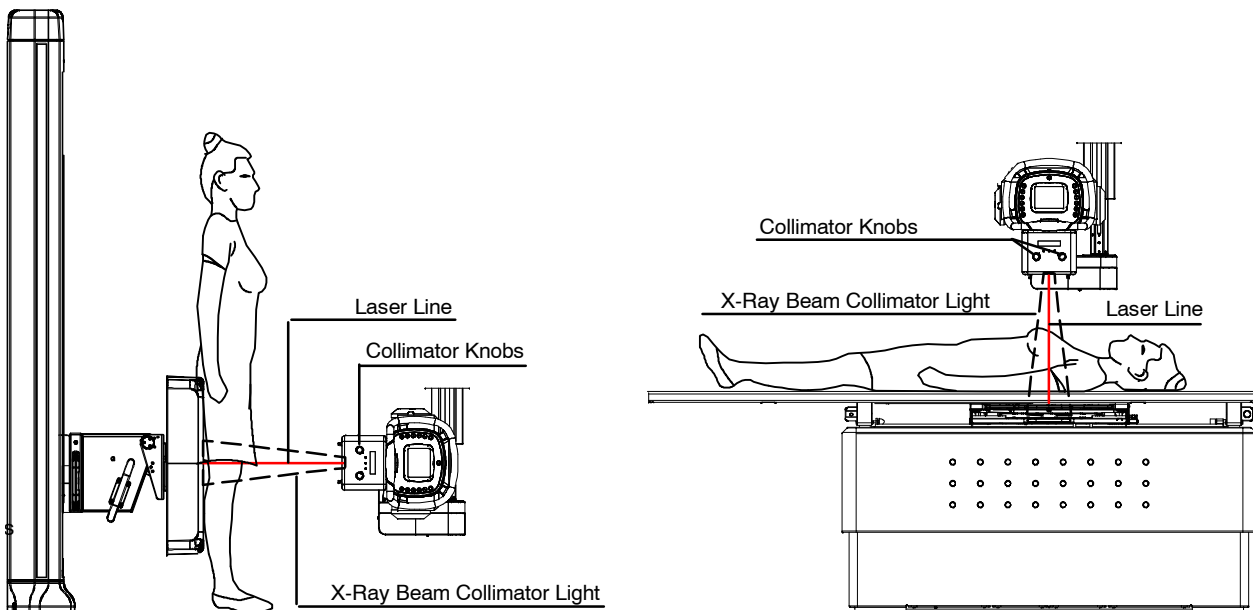


THE X-RAY BEAM AXIS AND THE REFERENCE AXIS OF THE PLANE OF INTEREST COINCIDE AND ARE ORTHOGONAL WITH RESPECT TO THE PLANE OF INTEREST, IN EXAMS PERFORMED WITH THE IMAGE RECEPTOR PERPENDICULARLY POSITIONED WITH RESPECT TO THE TUBE-COLLIMATOR ASSEMBLY.

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

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

Illustration 5-3
Patient Positioning



SECTION 6 TROUBLESHOOTING GUIDE

A guide for a quick solution of main typical problems in the use of this equipment follows. It is recommended to keep this troubleshooting guide with you when operating with the equipment.

Table 6-1
Standard and Auto-tracking Ceiling Suspension Error list

| PROBLEM | CHECK IF | ACTION |
|--|---|--|
| CEILING SUSPENSION CAN NOT BE SWITCHED ON | There is not power enough. | Check that the Line Power is provided to the Ceiling Suspension from the Room Electrical Cabinet. If it is correct but it can not be turned ON, contact Service. |
| CEILING SUSPENSION ON, CONTROL CONSOLE OFF | Check Control Console Cables connections. | Contact Service. |
| WRONG DISPLAY MEASURES | Wrong calibration. | Contact Service. |
| BRAKES NOT WORKING PROPERLY | Other brakes are working properly. | If the rest of the brakes are not working properly either, turn the unit OFF and ON. If it still does not work, contact Service. |
| | There is not power enough. | If the rest of the brakes work properly, contact Service. |
| DETENTS NOT WORKING PROPERLY | Other Detents are working properly. | Check that the Line Power is provided to the Ceiling Suspension from the Room Electrical Cabinet. If it is correct but it can not be turned ON, contact Service. |
| | There is not power enough. | If the rest of the Detents are not working properly either, turn the unit OFF and ON. If it still does not work, contact Service. |
| | There is not power enough. | If the rest of the Detents work properly, contact Service. |
| LONGITUDINAL MOVING EFFORT TOO HIGH | Longitudinal Brake button is pressed. | If there is still too much effort needed to move the Ceiling Suspension, contact Service. |
| TRANSVERSAL MOVING EFFORT TOO HIGH | Transversal Brake button is pressed. | If there is still too much effort needed to move the Ceiling Suspension, contact Service. |
| VERTICAL MOVING EFFORT TOO HIGH | Vertical Brake button is pressed. | If there is still too much effort needed to move the Ceiling Suspension, contact Service. |
| INCORRECT ALIGNMENT WHEN THE TUBE IS ANGLED | X-ray Tube is properly angled. | Turn the X-ray Tube to 0° in the Alpha axis and angle it again. If it still does not work, call Service. |

Standard and Auto-tracking Ceiling Suspension

Operation

Table 6-2
Auto-tracking Ceiling Suspension Error list

| PROBLEM | CHECK IF | ACTION |
|---|---|---|
| SUSPENSION DOES NOT MAKE TRACKER WITH TABLE | Tube angulation is $0^{\circ} \pm 2^{\circ}$. | angle the Tube properly and push the console Auto-tracking ON/OFF button to activate the tracking function. |
| | Auto-tracking function is activated. | If the Auto-tracking ON/OFF Led is Red, push once the console Auto-tracking ON/OFF button to activate the tracking function, led must be Green. |
| | | If the Auto-tracking ON/OFF Led is Green and Auto-tracking still does not work, call Service. |
| SUSPENSION DOES NOT MAKE TRACKER WITH WALL STAND | Tube angulation is $90^{\circ} \pm 2^{\circ}$. | angle the Tube properly and push the console Auto-tracking ON/OFF button to activate the tracking function. |
| | Auto-tracking function is activated. | If the Auto-tracking ON/OFF Led is Red, push once the console Auto-tracking ON/OFF button to activate the tracking function, led must be Green. |
| | | If the Auto-tracking ON/OFF Led is Green and Auto-tracking still does not work, call Service. |

SECTION 7 PERIODIC MAINTENANCE

In order to assure a continuous and 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.

A periodic maintenance service should be performed every six or twelve (6 or 12) months after installation.

The manufacturer undertakes to have available spare parts for this equipment for at least ten (10) years after the unit manufacturing.



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

7.1 OPERATOR TASKS

The tasks of this periodic maintenance shall include the following items:



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



NEVER ATTEMPT TO CLEAN ANY EQUIPMENT PART WHEN IT IS SWITCHED ON. ALWAYS SWITCH OFF THE SYSTEM BEFORE CLEANING AND ISOLATE THE MAINS ELECTRICAL SUPPLY BEFORE CLEANING.

1. Switch the system OFF.
2. Externally check the proper cable connections between each major component in the X-Ray System.

3. Clean the equipment frequently, particularly if corroding chemicals are present. Clean external covers and surfaces, especially parts in contact with patients, with a cloth moistened in warm water with mild soap. Wipe with a cloth moistened in clean water. Do not use cleaners or solvents of any kind.

7.2 SERVICE TASKS

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

SECTION 8 TECHNICAL SPECIFICATIONS

This section provides product information and illustrations showing physical dimensions, weight and general requirements for normal operation.

POWER LINE REQUIREMENTS

Power Line for Ceiling Suspension:

| | |
|-----------------------|--------------|
| Voltage | 115 - 240 V~ |
| Maximum Current | 3.5 - 1.6 A |
| Frequency | 50 / 60 Hz |
| Input Power | 0.5 kVA |

| | |
|--------------------------------|--------------------------------|
| Power line for Collimator Lamp | 24 VAC, 6.5 A 50 / 60 Hz |
|--------------------------------|--------------------------------|

OPERATING ENVIRONMENTAL CONDITIONS

| | |
|--|-----------------|
| Temperature range | 10 °C to 40 °C |
| Relative Humidity range (non-condensing) | 20% to 85% |
| Atmospheric Pressure range | 700 to 1060 hPa |

STORAGE / TRANSPORT ENVIRONMENTAL CONDITIONS

| | |
|--|-----------------|
| Temperature range | -20 °C to 70 °C |
| Relative Humidity range (non-condensing) | 10% to 95% |
| Atmospheric Pressure range | 500 to 1060 hPa |

PRODUCT CHARACTERISTICS

- Dimensions
 - Maximum Height 2641 mm (103.98")
 - Minimum Height 1068 mm (42.05")
 - Width 3500 mm (137.80") Max
 - Length 6000 mm (236.22") Max

- Distance between Longitudinal Rails 1432 +5/-15 mm
(56.38" +0.2/-0.6)

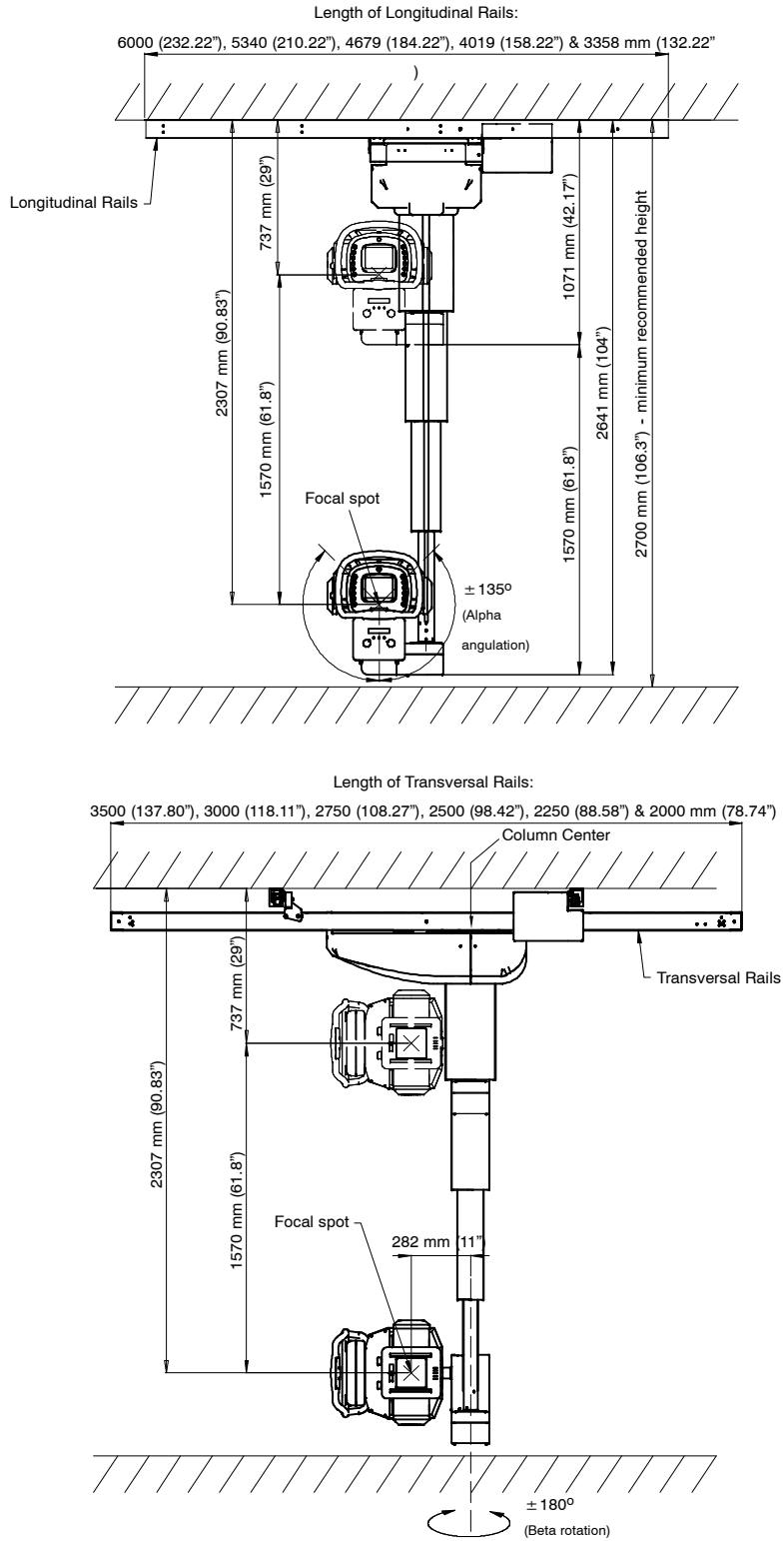
- Weights
 - Main assembly and Control Console 230 kg (507.06 lb)
 - Longitudinal and Transversal Rails 85 kg (187.39 lb) Max
 - X-ray Tube, Collimator, Hose and cables .. 80 kg (176.37 lb)

- Travels
 - Longitudinal travel 4866 mm (191.6") Max
 - Transversal travel 1901 mm (74.84") Max
 - Vertical travel 1570 mm (61.81")

- X-ray Tube rotation (Beta Axis) $\pm 180^\circ$
- X-ray Tube angulation (Alpha Axis) $\pm 135^\circ$

- Maximum and Minimum SID from X-ray Tube facing the Table and Wall Stand depends on the Room dimensions and longitudinal Rails of the unit.

Illustration 8-1
Dimensions and Travels



Standard and Auto-tracking Ceiling Suspension

Operation

Table 8-1
Rails Dimensions and Carriage Travels

| Longitudinal Rails Length | Carriage Travel | Distance from the column's center | |
|---------------------------|-------------------|-----------------------------------|------------------------------|
| | | To the Left | To the Right |
| 3358 mm (132.22") | 2224 mm (87.57") | 405 mm (min) 15.94" (min) | 729 mm (min) 28.70" (min) |
| 4019 mm (158.22") | 2885 mm (113.57") | | |
| 4679 mm (184.22") | 3545 mm (139.57") | | |
| 5340 mm (210.22") | 4206 mm (165.57") | | |
| 6000 mm (236.22") | 4866 mm (191.57") | | |

| Transversal Rails Length | Carriage Travel | Distance from the column's center | |
|--------------------------|-----------------|-----------------------------------|------------------------------|
| | | To the Front | To the Back |
| 2000 mm (78.74") | 901 mm (35.4") | 762 mm (min) 30" (min) | 343 mm (min) 13.50" (min) |
| 2250 mm (88.58") | 1151 mm (45.3") | | |
| 2500 mm (98.42") | 1401 mm (55.1") | | |
| 2750 mm (108.27") | 1651 mm (65") | | |
| 3000 mm (118.11") | 1901 mm (74.8") | | |
| 3500 mm (137.80") | 2401 mm (94.5") | | |

Illustration 8-2
Focal Spot Travel

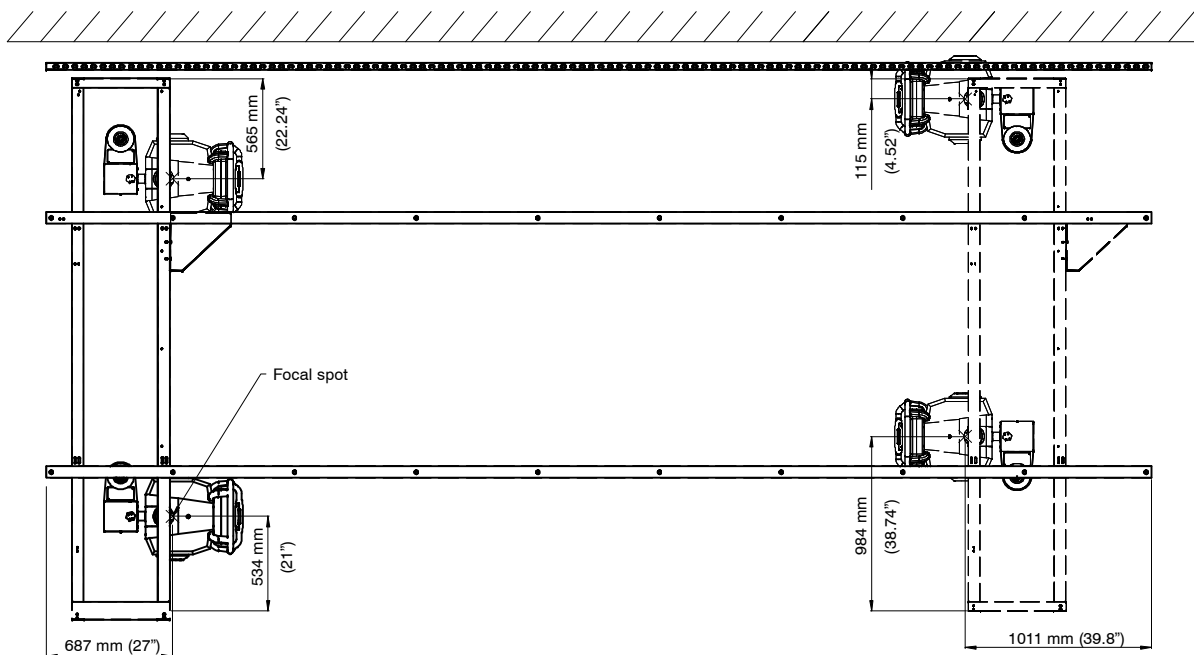


Illustration 8-3
Rails Dimensions and Travels

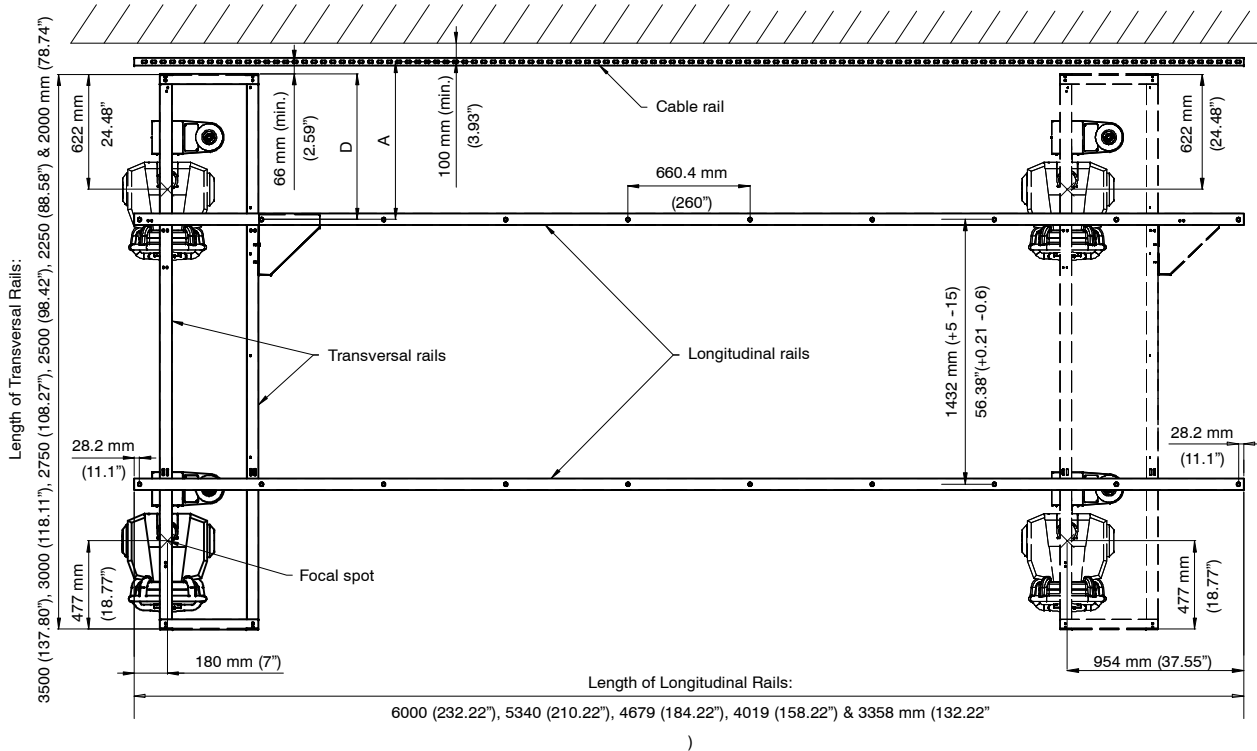


Table 8-2
Distances between Longitudinal rail and transversal and cable rails

| Transversal Rails Length | D | A |
|--------------------------|------------------|------------------|
| 2000 mm (78.74") | 284 mm (11.18") | 330 mm (12.99") |
| 2250 mm (88.58") | 409 mm (16.10") | 455 mm (17.91") |
| 2500 mm (98.42") | 534 mm (21.02") | 580 mm (22.83") |
| 2750 mm (108.27") | 659 mm (25.94") | 705 mm (27.75") |
| 3000 mm (118.11") | 784 mm (30.87") | 830 mm (32.68") |
| 3500 mm (137.80") | 1034 mm (40.71") | 1080 mm (42.52") |

D = (Length of transversal rail - 1432 mm [56.38"]) / 2
A = D + 46 mm

Standard and Auto-tracking Ceiling Suspension

Operation

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APPENDIX A GUIDELINES FOR PEDIATRIC APPLICATIONS



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.

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.