



Cemar Electro Inc.
MAXX-606/607 Patient Positioning Laser
Installation and Set-up Manual





WARNING

This manual contains the latest information at the time of publication, **Cemar Electro Inc.** reserves the right to revise this manual without notice.

The MAXX-606/607 Patient Positioning Laser is intended for use only by physicians qualified in diagnostic radiology and radiation therapy and experienced in marking patients utilizing patient positioning lasers or by therapists at the specific direction of such a qualified physician. It is the sole responsibility of the physician to judge whether the use of the MAXX-606/607 Patient Positioning Laser is clinically appropriate.



TABLE OF CONTENTS

WARNING	2
1. INTRODUCTION	4
2. INTENDED USAGE	5
3. LASER SAFETY CONSIDERATIONS	6
3.1 Signal Words	6
3.2 General Safety	6
3.3 Protective Eyewear	7
3.4 Laser Specifications	7
3.5 Safety Labels for Maxx-606/607 Units	9
3.6 Storage	10
4. POWER SUPPLY	11
5. GENERAL ROOM LAYOUT	12
5.1 Treatment Room Preparation	13
5.2 Room Specifications	14
6. LASER INSTALLATION	15
6.1 Pre-Installation	15
6.2 Installation Instructions.....	15
6.2.1 Mounting Options.....	15
6.3 Operator Controls	17
7. SYSTEM MAINTENANCE	18
7.1 Repair and Servicing	18
7.2 Maintenance, Cleaning, and Disposal	18
8. TECHNICAL SUPPORT AND CUSTOMER SERVICE	19
9. REGULATORY INFORMATION.....	20
9.1 Manufacturer Information	20
9.2 Compliance Information.....	20
10. WARRANTY	21
11. GLOSSARY OF TERMS & LIST OF SYMBOLS	22
11.1 Glossary of terms:	22
11.2 List of Symbols	24



1. INTRODUCTION

This Installation and User's Guide includes all the information you need to install, operate, and maintain your MAXX-606/607 Patient Positioning Laser safely and efficiently.

The MAXX-606/607 is a manual patient positioning system. The system is based on the original CL-606 series but takes advantage of a streamlined and economic design along with the latest laser technology to offer a simple laser with minimal maintenance. Easy to install, the MAXX-606/607 embodies the essence of simplicity.

With a small footprint, the MAXX-606/607 is a laser diode modular design that allows for low-cost maintenance and replacement components. The unit features 635nm red and 520nm green lasers. Simple controls permit easy use. The MAXX-606/607 includes a two-year warranty from Cemar Electro Inc.

The purpose of this manual is to provide instructions on the installation and setup of the patient positioning lasers within the treatment room.

Note: This Installation and Set-up Manual pertains to the MAXX-606/607 laser, which is similar, but not identical in configuration to the CL-606 model or the MAXX-700 series. Please ensure to follow these instructions for the MAXX-606/607 Patient Positioning Laser only.





2. INTENDED USAGE

The intended use for the MAXX-606/607 patient positioning laser is to align patients to medical diagnostic imaging and radiation therapy equipment utilizing ionizing radiation. MAXX-606/607 lasers are intended to be used in a medical clinic or hospital settings by trained medical staff. The lasers are not designed to be used around flammable anesthetics, which present a risk of explosion or fire. The lasers are not intended to be used in a sterile or corrosive environment. No other uses are intended or implied.

Note: Use of the MAXX-606/607 laser system other than its intended use is carried out entirely at the user's risk.

3. LASER SAFETY CONSIDERATIONS

To help ensure safe operation of your MAXX-606/607 system, please read this section carefully and follow the instructions and procedures in this manual before installing and operating the units.

3.1 Signal Words

Signal words are used according to international standards throughout this manual. The meanings of these signal words are:

- **DANGER:** Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. This signal word is to be limited to the most extreme situations.
- **WARNING:** Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
- **CAUTION:** Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. Permitted for property-damage only accidents.

3.2 General Safety

The MAXX-606/607 is a Class 2M laser product which meets the requirements of IEC/EN 60825-1:2007. The American National Standards Institute (ANSI) notes that Class 2M lasers emit laser pulses in the visible portion of the spectrum (wavelengths of 0.4 μm to 0.7 μm) and are potentially hazardous when viewed with an optical instrument. Any emissions outside this wavelength region must be below the Class 1M AEL.

WARNING: Risk of incorrect diagnosis or treatment.

- Isocentre of alignment lasers must coincide with isocentre of diagnostic or treatment equipment. Testing the alignment of lasers to isocentre of diagnostic or treatment equipment is based on hospital procedures.
- Newly installed equipment can possibly shift as building walls and floor settle and as building materials dry out. Realign lasers to isocentre before use if they have moved.



CAUTION: Laser light, risk of eye damage.

- To prevent eye damage, physicians, patients, and/or operators should not stare into the laser beam. The normal blink reflex will prevent eye damage; however, if a patient is unable to normally blink the laser operator must prevent the laser from shining in the patient's eye.
- Replace laser diode only with assembly provided by Cemar Electro Inc. to ensure that laser power levels do not exceed Class 2M limits.

3.3 Protective Eyewear

Protective eyewear is not necessary for typical applications where direct papillary impingement by the beams is a random momentary event. Under typical conditions requiring more protracted ocular exposure, protective eyewear or other protective measures may be required. Consult the user standards of the ANSI for further guidance (<https://www.rli.com/resources/articles/classification.aspx>).

3.4 Laser Specifications

Specifications for MAXX-606/607 are as follows:

External Housing Specifications	
Housing Dimensions	210.0 mm x 118.0 mm x 100.0 mm (1.81 kg)
Housing Material	Aluminum Hard black anodized T6061 Electrically isolated
Exit Aperture Protection	Window
Electrical Specifications	
Operating Voltage	90-240V AC
Load Current	1.0A
Power Consumption	1 W
Power Supply	110/240V AC 50-60Hz 0.8A 9.0V DC-1.7A
Interconnect Cable	6ft DC input

Environmental Specifications	
Operating Temperature	15°C to 35°C (59°F to 95°F)
Storage Temperature	-40°C to 80°C (-40°F to 176°F)
Dust/Water Resistant	IP50
Optical Specifications	
Wavelengths	635nm (red) and 520nm (green) wavelengths
Wavelength Stability	0.3nm/°C nominal
Optical Output Power	1 mW to 10mW (at the exit aperture)
Power Output Stability at 25°C	± 1%
Line Generator	Customized, fan angle 60°
Beam Divergence	< 5 mrad
Focal Distance	User defined
Line Thickness	1 mm @ 3 m distance 3/16" @ 10' (@1/e ²)
Line Thickness Divergence	< 1 mRad
Line Intensity Profile	Gaussian
Lens Material	Glass
Pointing Specifications	
Accuracy	< 1 mrad
Stability vs. Temperature	< 10 μrad/°C
Reliability/Regulatory Specifications	
Laser Lifetime Expected	> 10,000 hours @ 25°C
Certification/Regulatory	FDA/CDRH
Warranty	2 years

3.5 Safety Labels for Maxx-606/607 Units

The labels on all MAXX-606/607 units are required for compliance with federal regulations. Do not remove these labels.

Safety labels are located on the laser unit:

Figure 3.1 Warning labels.



Figure 3.2 Safety labels. (EU and North America)



Figure 3.3 Safety labels as displayed on MAXX-606/607 unit.



3.6 Storage

To ensure optimal functioning of the MAXX-606/607 unit, ensure the following:

- Do not drop
- Store all components in a non-corrosive environment
- Maintain storage temperature between -20°C and +75°C (-4° F and 167° F)
- Maintain storage humidity between 20% and 85% relative humidity. Do not permit dew condensation

4. POWER SUPPLY

Each MAXX-606/607 laser includes a universal power supply (transformer) with an input of 100V to 240V at 50/60Hz-0.8A.

A 1.2-meter (4 foot) power cord supplies 9V DC 1.7A power to the laser unit with a screw-on power plug. For servicing switch off the unit and remove power from the supply using the appliance inlet.

Figure 4.1. Power supply.



Figure 4.2. Power controls.

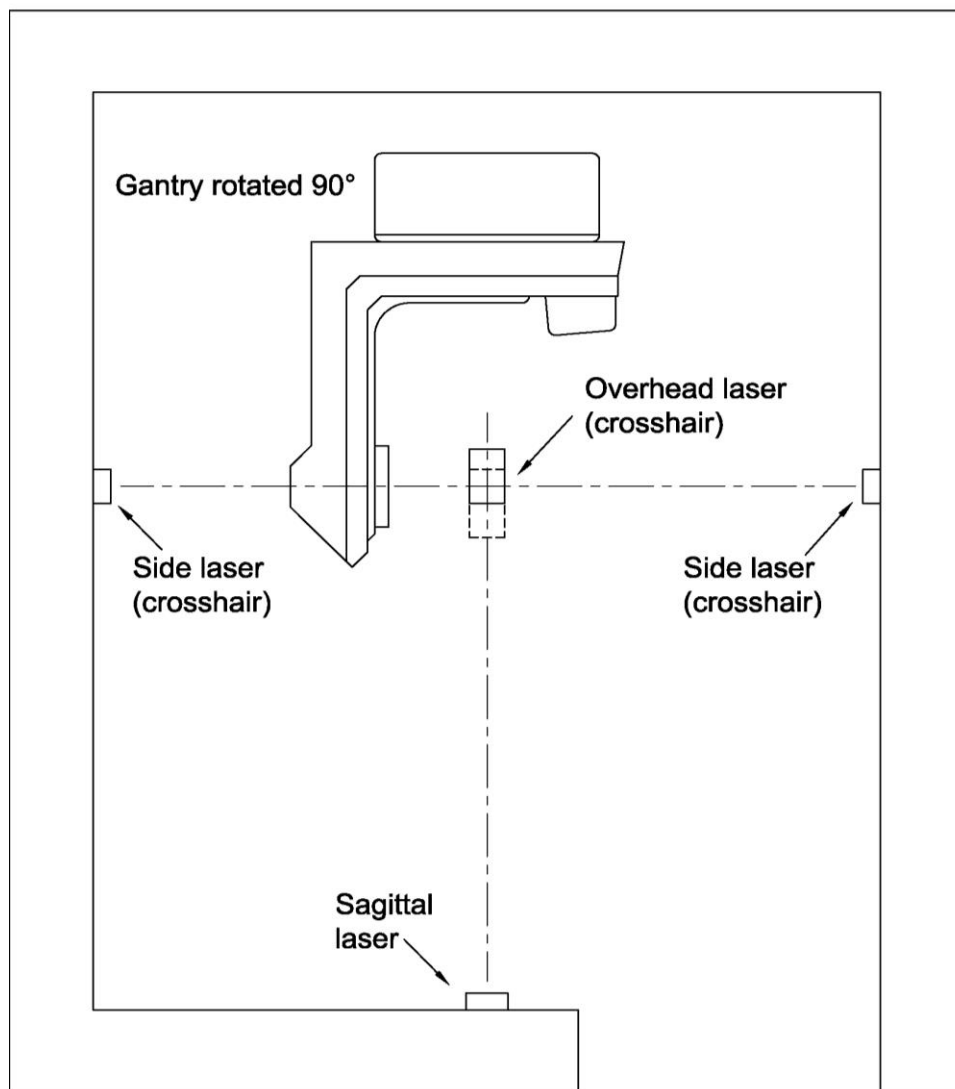


5. GENERAL ROOM LAYOUT

Before the MAXX-606/607 can be correctly installed in the treatment room, the system isocentre must first be identified. Once identified, appropriate reference marks should be placed on the wall to determine the precise location of the mounting, as well as aid in the alignment of the laser lines once the lasers have been installed.

Accurate positioning is crucial; a failure in installation can result in inaccurate laser readings. Please contact **Cemar Electro Inc.** if you wish to coordinate installation by one of our professionals.

Figure 5.1. Typical room layout.





5.1 Treatment Room Preparation

Correct treatment room set-up is crucial to the successful installation of a patient positioning laser system.

Preparation work on the treatment room should be completed before the system components are shipped to the installation site. Necessary preparation work comprises:

- Establishing where various system components will be located within the room
- Determining the mounting configuration for each laser unit
- Providing an adequate structure to mount all the laser units in the system
- Determining routings for cables
- Establishing necessary power for the system

In the case where the treatment room is not yet constructed, **Cemar Electro Inc.** recommends that a rigid steel support frame for the moving lasers is incorporated into the room construction.

5.2 Room Specifications

The treatment room must meet the following specifications to permit for installation of the MAXX-606/607 unit.

Treatment Room Specifications		
Category	Feature	Specification
Electrical	Power supply	90-240V AC, 0.8A, 50-60Hz Output voltage: 9.0V DC-1.7A
	Laser unit dimensions	Length: 210.0 mm (8.2 in) Width: 118.0 mm (4.6 in) Height: 100.0 mm (3.9 in)
Mechanical	Weight	1.81 kg (4 lbs)
	Room size	Minimum: 10' by 16' by 7.5' Maximum: 40' by 60' by 20'
Environmental	Operating temperature	15°C to 35°C (59°F to 95°F)
	Others	No flammable anaesthetics No corrosives



6. LASER INSTALLATION

6.1 Pre-Installation

The MAXX-606/607 Patient Positioning Laser System provides an optical aid for rapid, accurate patient positioning and repositioning for therapy and simulator machines.

Various combinations of the MAXX-606 (crosshair) and the MAXX-607 (sagittal) are used with different systems.

- Option 1.** Two MAXX-606 crosshair lasers—mounted on each side—beam crosshairs along the X-axis.
- Option 2.** One MAXX-606 crosshair laser—mounted on the ceiling—beams a crosshair vertically along the Z-axis.
- Option 3.** The MAXX-607 sagittal laser beams a straight line in the Z-Y plane.

6.2 Installation Instructions

The following instructions do not supersede hospital procedure for room laser setup and are suggested procedure only.

Note: Manually align the lasers as close as possible when mounting the laser to the wall, then fine tune using controls.

- Step 1.** Scan a phantom to determine isocentre.
- Step 2.** Install MAXX-607 (sagittal) laser according to the phantom location and indication marks.
- Step 3.** Rotate head and project to wall locations to mount MAXX-606 (crosshair) lasers.
- Step 4.** *Note: Optional laser level or water levels may be used for accuracy.*
- Step 5.** Verify all laser intersections.
- Step 6.** Lasers should be installed as co-planer with no parallax.

6.2.1 Mounting Options

Steel or aluminum base plates must be installed in the walls and ceiling where laser units are to be mounted. The location, size, and stability of these base plates are critical to a satisfactory installation of a patient positioning laser system.

Lasers can be installed to either mounting plates (Figure 6.1) or adjustable mounting brackets (Figure 6.2).

Figure 6.1. Mounting plate.



For the MAXX-606 laser, mount plates (Figure 6.1) to walls first, then attach the MAXX-606 laser units to the plates.

Figure 6.2. Mounting brackets (front and side).



Adjustable mounting brackets can be used to install all units. **Cemar Electro Inc.** highly recommends using these specific brackets for ceiling-mounted crosshair laser (MAXX-606-CHG) as well as sagittal laser (MAXX-607-SAG).

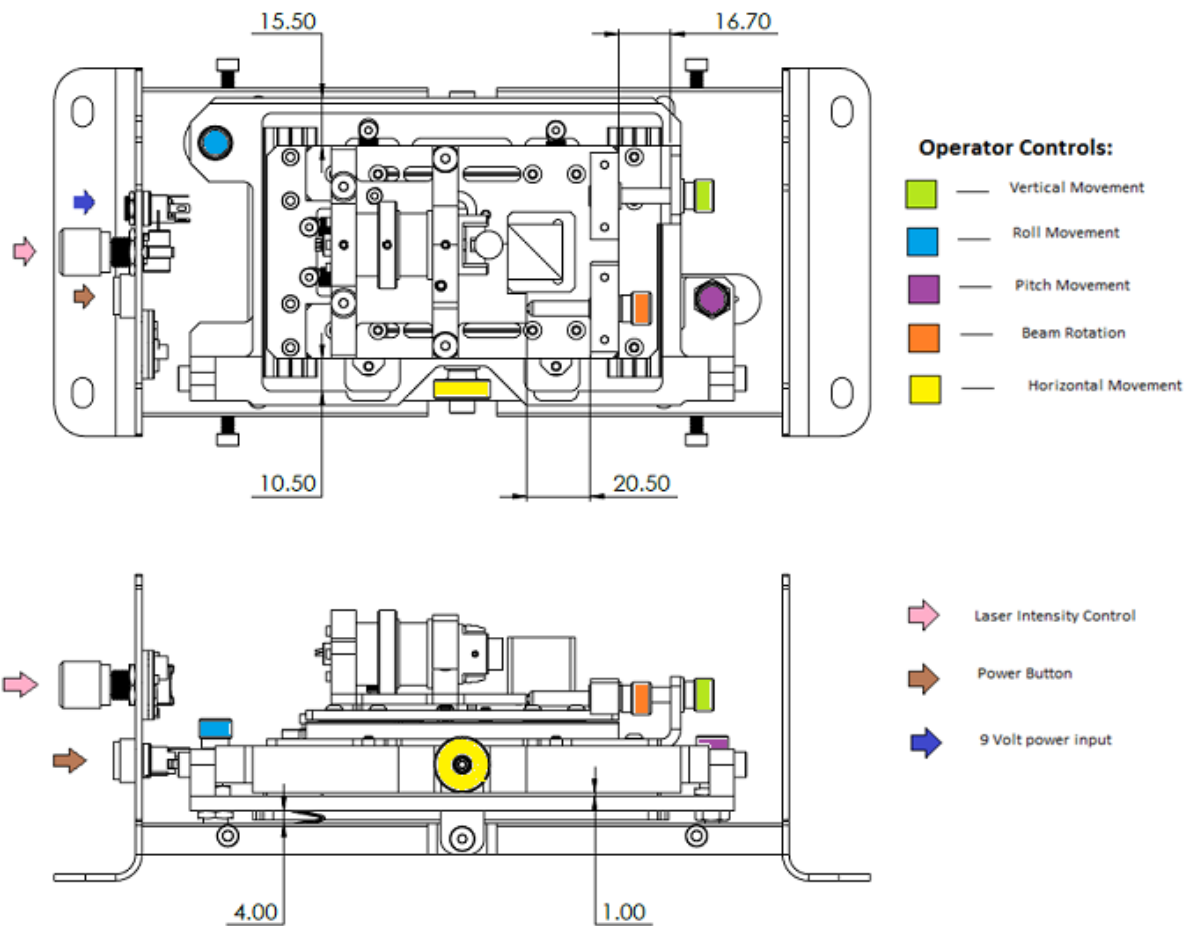
Note: The mounting bracket can be adjusted to a maximum of 45°.

6.3 Operator Controls

Operator controls facilitate the movement and operation of the patient positioning laser.

- Option 1.** All lasers are connected to one wall switch; lasers can be powered on and off simultaneously from a single convenient location.
- Option 2.** Lasers are connected to a timer so that the lasers are automatically turned on or off at a set time.

Figure 6.3. Overview of operator controls.



NOTE: Reference dimensions for neutral position (all axes).



7. SYSTEM MAINTENANCE

7.1 Repair and Servicing

WARNING: Only certified **Cemar Electro Inc.** technicians should carry out any repairs to your laser units other than changing the laser module; if authorized, note replacement of the laser module will affect the 90° angle in the cross.

*Note: Without written permission of **Cemar Electro Inc.**, any unauthorized repairs to the laser unit can cause further damages and will result in the warranty extended by **Cemar Electro Inc.** to be rendered null and void.*

7.2 Maintenance, Cleaning, and Disposal

Once installed, the MAXX-606/607 laser requires no maintenance other than a light cleaning. All cleaning efforts should be undertaken with a soft lint-free cloth and, if necessary, mild soap containing no ammonia or abrasives.

- An occasional outside dusting of the antireflective window in the cover may be necessary. Use only standard lens cleaner with clean wipes.
- Clean other outside surfaces of the laser unit with a soft cloth slightly moistened with water or a mild detergent solution and then wipe the surface with a dry cloth.
- Do not use any type of abrasive pad, scouring powder, or chemical solvents such as thinner, benzene, alcohol, or disposable wipes as these may damage the finish.
- Do not mix this device with general waste upon disposal. For proper treatment, recovery, and recycling, please contact your disposal local supplier for further information.



In case that a laser fails to function properly, please contact Cemar Electro Inc. Customer Service as soon as possible (see Section 8 for Contact Information).



8. TECHNICAL SUPPORT AND CUSTOMER SERVICE

Cemar Electro Inc. is committed to satisfying our customer's needs. If you have any questions, comments or suggestions regarding our products and service, please call or email us. Please contact a **Cemar Electro Inc.** distributor or our representative for a quotation or for a detailed description of our ordering policies, warranties, delivery policy, conditions of sale, damaged goods policy, and returned goods policy.

Cemar Electro Inc. Service Representatives are available to work with facility planners, architects, and hospital personnel throughout the planning and installation process.

Service Department hours are: 8.00 a.m. through 4.30 p.m. (Eastern Time).



Phone: 514-631-5807
Fax: 514-631-7505
Toll free: 1-800-298-5273



Phone: 518-298-3065
Fax: 518-298-2927
Toll free: 1-800-298-5273

support@cemarelectro.com

9.1 Manufacturer Information

Manufacturer:



Cemar Electro Inc.
1370 55th Ave,
Lachine, QC H8T 3J8
Canada

Authorised Representative (Europe):



P. Spirig GmbH
Baunstrasse 23
CH-9435 Heerbrugg,
Switzerland

9.2 Compliance Information



Cemar Electro Inc. warrants its patient positioning equipment to be free from defects in materials and workmanship under normal use and service for two years from the date of shipment. The sole obligation of **Cemar Electro Inc.** under this warranty is to repair or replace without charge or to refund the purchase price, at the option of **Cemar Electro Inc.**, of any parts which its examination shall have disclosed to be defective, provided that buyer shall have given to **Cemar Electro Inc.** a written notice of the claimed defect no later than seven days after the end of the warranty period (two years of the date of shipment of such equipment to buyer). At the request of **Cemar Electro Inc.**, the buyer, at their expense, shall return the claimed defective part to **Cemar Electro Inc.**

Disclaimer of Other Warranties

The aforesaid warranty rights are buyer's exclusive remedies and are in lieu of any other remedies, obligations, or rights, including, without limitation, any other warranties, expressed or implied (e.g., implied warranties of merchantability or fitness for a particular purpose).

Under no circumstances shall **Cemar Electro Inc.** be liable for any incidental, indirect, special, or consequential damages or for any other loss, damage, penalty, or expense of any kind including, without limitation, loss of profits or overhead, reimbursement, personal injury, or property damage. The aforesaid warranty obligation of **Cemar Electro Inc.** constitutes its sole liability and under no circumstances shall the maximum liability of **Cemar Electro Inc.**, under any legal theory (e.g., contract, warranty, negligence, promissory estoppel, strict liability, misrepresentation, tort) and for any reason whatsoever (e.g., defect, delay, or otherwise) exceed the purchase price of the defective part regardless whether the claim is asserted by the buyer or any other person or entity.

The liabilities of **Cemar Electro Inc.** as above set forth, shall not be extended because of advice given by it in connection with the design, installation, or use of the equipment or parts, therefore.

11. GLOSSARY OF TERMS & LIST OF SYMBOLS

11.1 Glossary of terms:

American National Standards Institute (ANSI)

The primary organization for fostering the development of technology standards in the United States. ANSI facilitates the development of American National Standards (ANS) by accrediting the procedures of standards developing organizations (SDOs). Accreditation by ANSI signifies that the procedures used by the standards body in connection with the development of American National Standards meet the Institute's essential requirements for openness, balance, consensus, and due process.

Anodized T6061

A type of aluminum alloy whose properties include its structural strength and toughness. It offers good finishing characteristics and responds well to anodizing, including clear and colored dye, and hardcoat. T6061 aluminum alloy is also easily welded and joined. T6061 alloy conducts and dissipates heat well. Since it can be extruded, it can be formed into almost any imaginable shape.

Crosshair laser

Crosshair lasers mark the point where a tool will start working or an angle for alignment in two directions.

Co-planer

Three or more points which lie in the same plane.

Diagnostic imaging

Diagnostic or medical imaging is the technique and process of creating visual representations of the interior of a body for clinical analysis and medical intervention, as well as visual representation of the function of some organs or tissues (physiology).

Ionizing radiation

A form of radiation consisting of particles, X-rays, or gamma rays with sufficient energy to cause ionization in the medium through which it passes.

International Electrotechnical Commission (IEC)

The International Electrotechnical Commission is the leading global organization that publishes consensus-based International Standards and manages conformity assessment systems for electric and electronic products, systems and services, collectively known as electrotechnology. IEC publications serve as a basis for national standardization and as references when drafting international tenders and contracts.

Isocentre

The convergence of the three axes of rotation in radiation therapy; the intersecting point of the axis of rotation of the gantry, the collimator, and the treatment couch.

Laser (diode) modular design

Modular laser design are modules specifically designed for applications where space is a key consideration. The laser modules are compact in size while offering the same high reliability and constant power output of larger lasers.

Mounting bracket

A mounting bracket is support, composed of metal, which projects from a wall with the purpose of holding or bearing weight.

Mounting plate

A mounting plate is the part of a hinge, handle, or latch that mounts an object to a wall. The plate is attached directly to the wall, which the object mounted thereupon attaches to the plate.

Parallax

The effect whereby the position or direction of an object appears to differ when viewed from different positions, (e.g., through the viewfinder and the lens of a camera).

Phantom

A phantom is a specially designed object that is scanned or imaged in the field of medical imaging to evaluate, analyze, and tune the performance of various imaging devices. A phantom is more readily available and provides more consistent results than the use of a living subject or cadaver, and likewise avoids subjecting a living subject to direct risk.








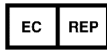




Sagittal laser

Ceiling or wall-mounted single laser, preferably moveable. The scanner couch can move up/down and in/out but cannot move left/right, therefore the sagittal laser should move left/right to allow marking away from patient mid-line. Ceiling lasers that can move in lateral as well as longitudinal direction can improve the efficiency of CT simulations and potentially reduce errors due to manual control errors.

Treatment room

Room in a patient care unit (e.g., a hospital, medical center, clinic, etc.) in which treatments, procedures, or examinations are conducted. The room houses specific equipment and/or machinery to execute the necessary procedures.

11.2 List of Symbols

	This device complies with the Medical Devices Directive & EMC Directive of the European Economic Community.
	Do not mix this device with general waste upon disposal. For proper treatment, recovery and recycling, please contact your dealer or supplier for further information.
	Date of Manufacture
	Manufacturer
	Part Number
	Serial Number
	Lot Number
	Authorized Representative (Europe)
	Direct Current (DC)
IP	Ingress Protection
	Caution to the user and/or patient
	Refer to instruction manual
	Keep dry
FCC ID	Federal Communications Commission (USA) ID number
IC	Industry Canada ID number