Cemar Electro Inc.
MAXX-1100 Laser Positioning System

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-1100 Moving Laser Patient Positioning System 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 Maxx1100 Moving Laser Patient Positioning System is clinically appropriate.

CONTENTS

1. INTRODUCTION

This Installation and User's Guide includes all the information you need to install, operate, and maintain your Maxx-1100 Laser Alignment System safely and efficiently.

The Treatment Room Moving Laser Patient Positioning System consists of one to three Maxx -1100 units; the Maxx-1100 Unit(s) is connected to a central system controller. Operators interface with the controller using a remote control. The controller can also be configured for a network interface to the treatment planning system.

The purpose of this manual is to provide instructions on the installation and setup of the moving lasers within the treatment room. This manual also includes basic operating instructions for the Maxx-1100 Unit, its Controller, and its computer software system.

2. SYSTEM OVERVIEW

The Maxx-1100 laser system consists of several moveable crosshair lasers, a handheld remote control, and a PC controller, operated by a comprehensive software system. The lasers within the Maxx-1100 define the planes of the treatment room.

Within an appropriately established treatment room, the Maxx-1100 permits the successful preparation and treatment of patients via radiation therapy. The lasers are adjusted to the offset point of the treatment room. Offset points allow medical personnel easy access to the patient for marking purposes. This system allows medical personnel and system operators to directly identify tumour locations and mark patients for treatment.

Note: Use of the Maxx-1100 laser system other than its intended use is carried out entirely at the user's risk.

3. LASER SAFETY CONSIDERATIONS

3.1 General Safety

To help ensure safe operation of your Maxx-1100 system, please read this section carefully and follow the instructions and procedures in this manual before installing and operating the units.

At all times during installation, operation, or adjustment of a Maxx-1100 unit avoid staring into the beams or other sources of bright light emanating from the unit. The Maxx-1100 is a class ll 1mW laser. The American National Standards Institute (ANSI) notes that Class 2 lasers are CW and repetitively pulsed lasers with wavelengths between 0.4 µm and 0.7 µm that can emit energy in excess of the Class 1 AEL, but do not exceed the Class 1 AEL for an emission duration less than 0.25 seconds and have an average radiant power of 1mW or less.

Should adjustment or alignment be necessary at any time once the laser is activated the patient's eyes should be protected.

3.2 Safety, functionality, and maintenance

For power, the system needs the power cord supplied with each unit, to connect to the 110/240 V plug. The ground line is built in the power cord and goes directly to the 200W medical power supply, which has short circuit / Overload / Overvoltage and Over temperature protection.

For accuracy integrity, Isocentre of diagnostic and treatment equipment must match the Isocentre of alignment lasers.

All positioning equipment in the treatment room should be measured at least twice: once upon initial installation and once before service to ensure that construction materials in the walls, floor, and ceiling have settled into position. Realign lasers to Isocentre before use, if they have moved.

Testing the alignment of lasers to Isocentre of diagnostic or treatment equipment is based on hospital procedures.

The Maxx-1100 is a class ll 1mW laser. Replace laser diode only with assembly provided by Cemar Electro Inc. to ensure that laser power levels do not exceed class ll 1mW limits.

The Maxx-1100 unit is virtually maintenance free requiring only visual inspection and cleaning of the encoder glass annually (with a dry lint free cloth) the exterior can be cleaned with a damp cloth.

3.3 Safety labels for Maxx-1100 units

The labels on all Maxx-1100 units are required for compliance with federal regulations. Do not remove these labels.

Safety labels are located on the laser unit:

Figure 3.1 Safety label.

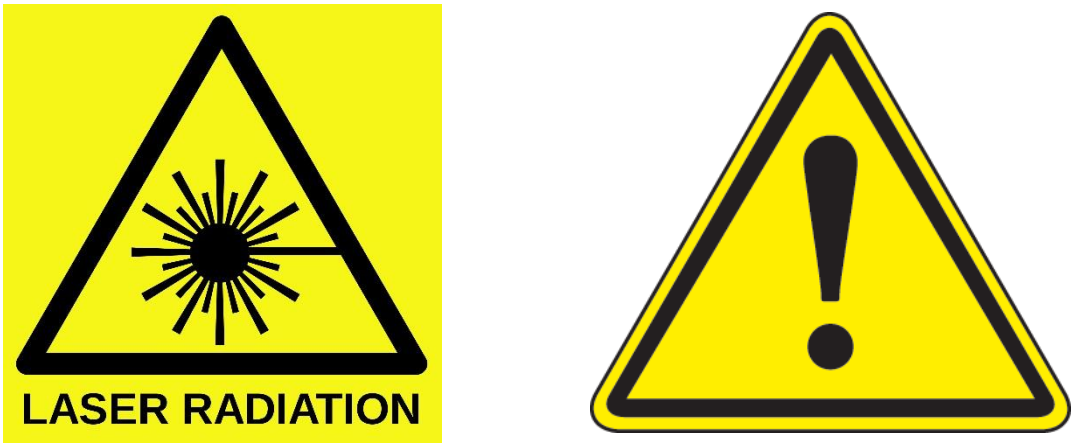
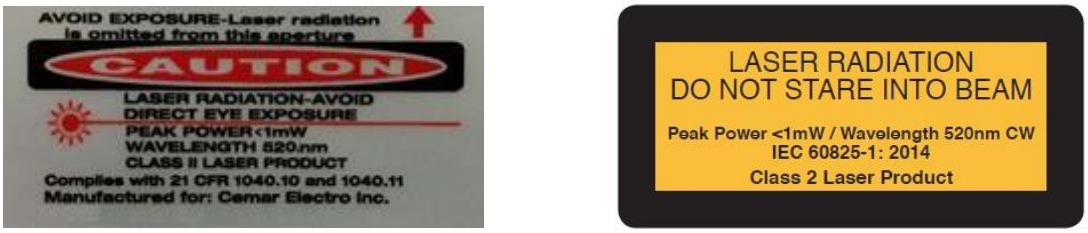


Figure 3.2 Class II laser product label. (North America and EU)



use the power cord supplied with the system, to connect to the 110/220 V plug. The ground line is built in the power cord and goes directly to the 200W medical power supply, which has short circuit / Overload / Overvoltage and Over temperature protection.

3.4 Technical specifications

Specifications for Maxx-1100 used in treatment rooms are as follows:

Technical Specifications for Treatment Room		
Category	**Feature**	**Specification**
Laser control	Number of axes	4
	Focal Distance	3M(10FT)
	X axis: Horizontal movement	600mm total travel.
	Y axis: Vertical movement	25mm total travel.
	Z-axis: X axis line	600mm +/- 300 from encoder zero.
	Roll axis: Horizontal rotation	8 degrees.
	Pitch axis / Yaw axis	8 degrees.
	Micro-step	Minimum 0.2 mm
	Movement Tolerance	0.3 mm
Electrical	Power supply Fuse (line)	100-240V AC, 2.3 – 1.1A, 50/60Hz, 120W 2.0 A 250V
Mechanical	Laser unit dimensions	Length: 1465.6 mm (57.7 in) Width: 198.0 mm (7.79in) Height: 205-240.0 mm (8.07-9.45in)
	Weight	34.0 kg (74.95lbs.)

Technical Specifications for Treatment Room (cont.)		
Environmental	Operating temperature	5°C - 35°C (40°-95°F) No special ventilation is required.
	Operating humidity	0% - 85 % relative humidity. Indoor use only. Ensure no dew or condensation.
	Operating altitude	Up to 2000 m.
	Others Cleaning Instructions	Rating: IP20 Pollution degree: 1 No flammable anaesthetics. No corrosives, (no ammonia); use a soft lint free cloth to wipe down encoder annually or when errors occur and a moist cloth for the unit.
 **Warning**	Protection impairment if used in a manner not specified by the manufacturer.	

3.5 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).

3.6 Storage

To ensure optimal functionality of the Maxx-1100 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 and167° F).
- Maintain storage humidity between 20% and 85% relative humidity. Do not permit dew condensation.
- If the system is going to be removed temporarily, store the device in a dry place where it will not be exposed to extreme temperature fluctuations.
- If the system is going to be used at another location, make sure the set is complete and all components are in perfect condition.

4. SYSTEM COMPONENTS

The overview of the system configuration for the Maxx-1100 is shown in Figure 4.1. The configuration table should be completed at the time of purchase. Before beginning installation of the laser system, verify that all components shown on the system configuration chart have been provided. If any required system components are missing, please contact **Cemar Electro Inc.** immediately for assistance.

A description of the major system components in a moving laser patient positioning system is given in the following paragraphs. Figure 4.1 shows the typical system components.

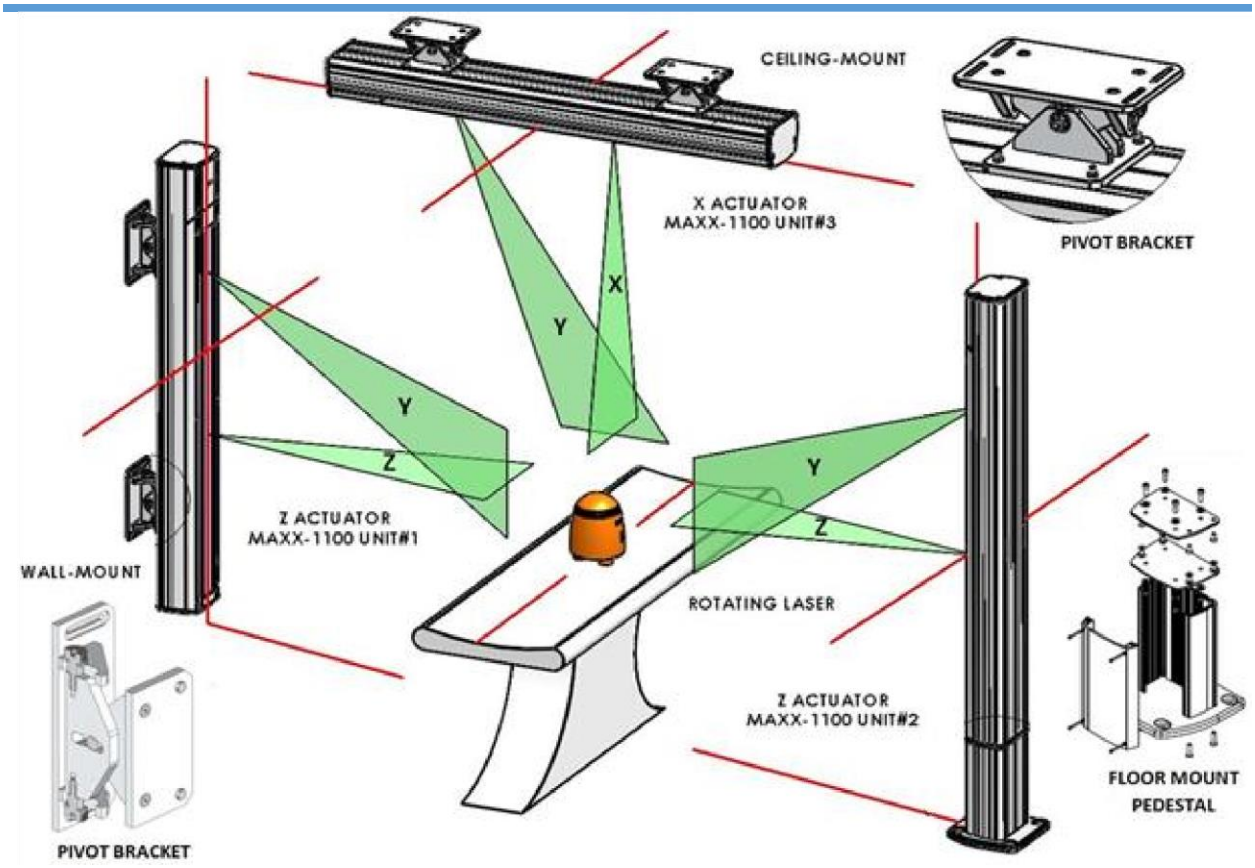


Figure 4.1 System components

4.1 Maxx-1100 Unit

Each Maxx-1100 unit can generate two orthogonal laser lines, one perpendicular to the long axis of the Maxx-1100-unit frame, and one parallel to the long axis of the Maxx-1100-unit frame.

- **Moving laser:** The line perpendicular to the long axis of the Maxx-1100-unit frame is generated by a diode that can be moved along the long axis of the actuator. It has a linear movement of +/-300mm from laser travel zero. (Figure 4.2)
- **Fixed laser:** The line parallel to the long axis of the Maxx-1100-unit frame is generated by a laser diode that is fixed in position at one end of the actuator. It also has a manual linear adjustment of +/-10mm from the center point. (Figure 4.2)

Each Maxx-1100 unit has an identity in the system and can be used as a single unit system, a two-unit set, or a complete three-unit set. (Figure 4.1)

- **Z Actuator:** The Z actuators are located on either side of the treatment couch and are referred to as Maxx-1100 unit 1 or Maxx-1100 unit 2.
- **X Actuator:** The X actuator is mounted directly over the isocenter point and is referred to Maxx-1100 unit 3.

4.1.1 Laser line adjustment

Proper alignment of the laser lines requires precise adjustment of the laser lines within the confines of the treatment room. Two adjustments are possible for each laser diode, namely, tilt adjustment and rotation adjustment. (Figure 4.2)

4.1.1.1 Tilt adjustment

Tilt adjustment allows the laser line to pivot from end to end for the moving laser, adjusting the positioning relative to the moving axis of the Maxx-1100 unit, and side to side for the fixed laser relative to the moving axis of the Maxx-1100 unit. (Figure 4.2)

4.1.1.2 Rotation adjustment

For the moving laser the rotation adjustment alters the angle of the laser line to be parallel to the moving axis of the Maxx-1100 unit by rotating the laser diode. The rotation adjustment alters the fixed laser line angle so that it is perpendicular to the moving laser. (Figure 4.2)

4.2 4.1 System controller pc. (Optional)

The system controller (PC) can control multiple-axis configurations, allowing the movement of up to three Maxx-1100 units. All controllers include a Monitor, a router, a USB to network adapter and all necessary cabling. (Figure 7.1)

4.2.1 Controller connections

The system controller has a multiple output router; this is used to communicate with each Maxx-1100 unit which are connected to the router with a Cat6 cable. (Figure 7.1)

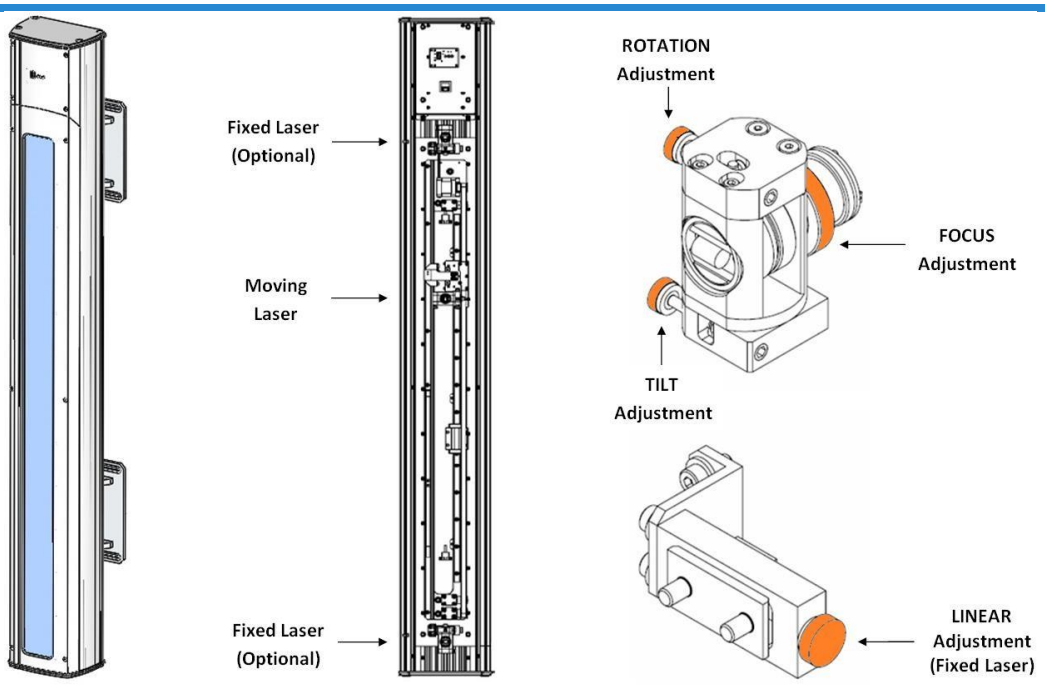


Figure 4.2 Lasers layout and adjustments

5 TREATMENT ROOM PREPARATION

Correct treatment room set-up is crucial to the successful installation of a patient positioning system. This is to be determined by the hospital.

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 (view Maxx-1100-unit Specs).
- Determining the mounting configuration for each laser unit.
- Providing an adequate structure to mount all the laser units in the system (provided by the hospital).
- Determining routings for RJ45 Data Cat6 cables (routing plan done by the hospital).
- Establishing necessary power for the system (provided by the hospital).

In the case where the treatment room is not yet constructed, **Cemar Electro Inc.** recommends that a rigid steel support frame for the Maxx-1100 units is incorporated into the room construction. (Figure 5.1)

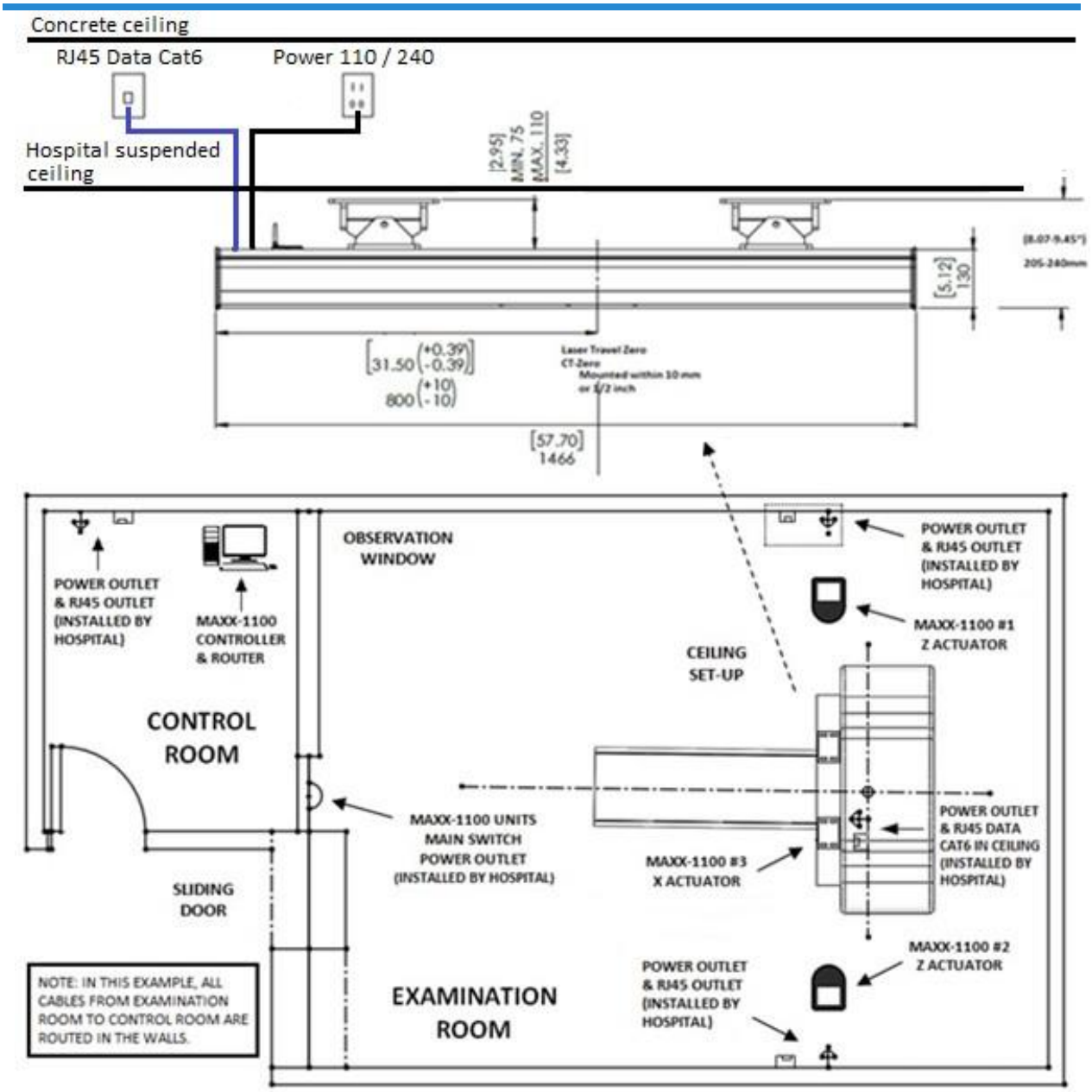


Figure 5.1 Typical room layouts and ceiling mounting

5.1 General room layout

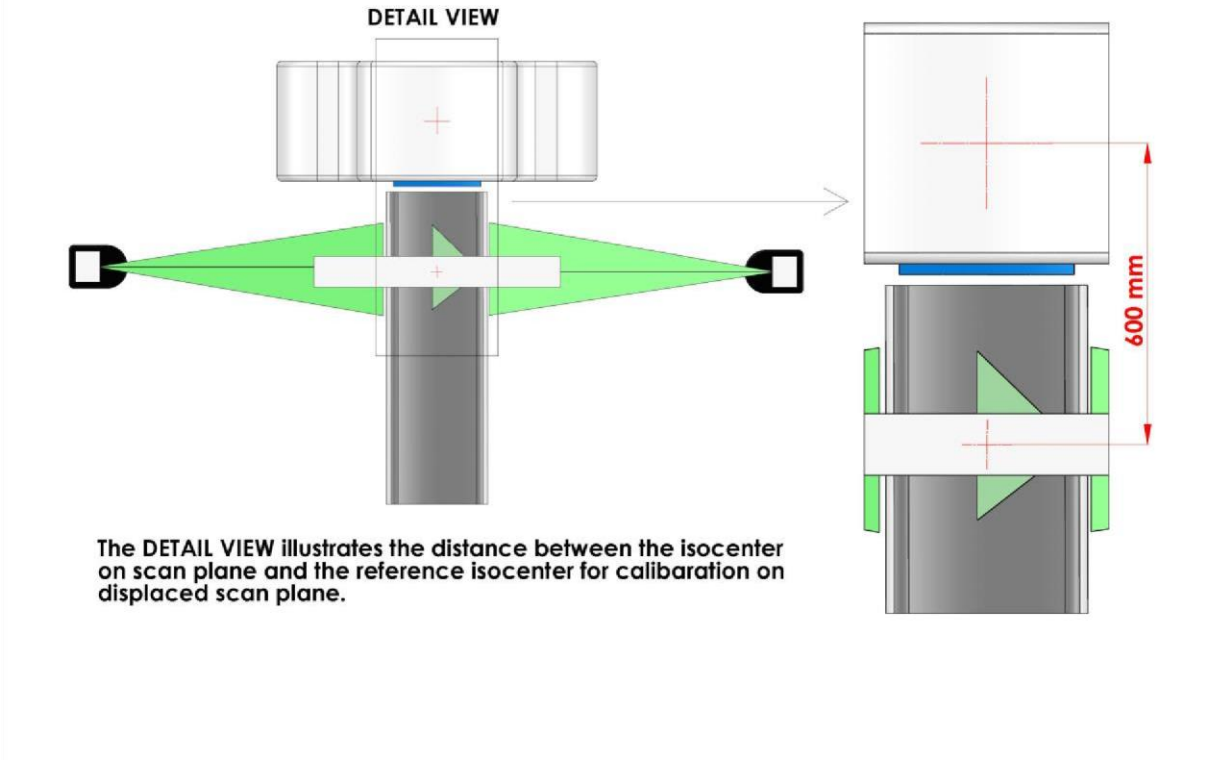
The treatment room must meet the following specifications to permit for installation of the Maxx-1100 unit.

Treatment Room Specifications		
Category	**Feature**	**Specification**
Electrical	Power supply	100-240V AC, 2.3 – 1.1A, 50/60Hz, 120W Overvoltage category: II
Mechanical	Laser unit dimensions *Wall / Ceiling Mount*	*Length: 1466.0 mm (57.7in)* *Width: 198.0 mm (7.79 in)* *Height: 240.0 mm (9.44 in) Incl. mount.*
	Floor Mount	Length:250 Width:260 Height:1775.6
	Weight	34.0 kg (74.95 lbs)
Environmental	Room size	3M(9.84ft) x 5M(16.4ft) x 2.3M(7.84ft)
	Operating temperature	5°C - 35°C (40°-95°F) No special ventilation is required.
	Operating humidity	10% - 85 % relative humidity Ensure no dew or condensation
	Others	No flammable anaesthetics No corrosives

Room layout begins by identifying the location of the point in the room that will be the isocenter for the patient positioning system. (Figure 5.1)

Note: The radiographic centre point of the room is not the same as the isocenter of the laser positioning system. Both the radiographic centre and the isocenter typically have the same X and Z coordinate, their Y coordinates differ. In this manual, the isocenter will always be referred to as such.

Figure 5.2 Isocentre position.



Once the isocenter location has been determined, the installation location of the system lasers can be determined. (Figure 5.2)

- The X actuator (Maxx-1100 Unit #3) should ideally be mounted directly over the isocenter point, using a ceiling mount configuration with the Laser Travel Zero near to the centre of the treatment couch. This permits the X line to be viewed at consistent intensities, and full laser travel on treatment couch.
- The Z actuators (Maxx-1100 Unit #1 and Unit #2) should be located on either side of the treatment couch, aligned perpendicularly to the long side of the treatment couch, with the Laser Travel Zero near to the isocenter.

5.2 Mounting base plates

Steel or aluminum base plates (**Hospital Contractor supplied and installed**) can be in the walls and ceiling where the laser units are to be mounted or a reasonable alternative like U-Channel. The location, size, and stability of these base plates or Channels are critical to a satisfactory installation of a moving laser system. (Figure 5.1)

** *This rigid structure is required because any movement of the mounting structure for the Maxx-1100 unit will result in movement of the laser lines.*

5.3 Maxx-1100 mounting options

Two mounting options are available for the X actuator (Unit #3) in the system. (Figure 4.1)

Option 1. The preferred option is a ceiling mount directly over the treatment couch. This allows the optional fixed laser(s) in the X actuator (Unit #3) to be aligned as part of the Y plane in the system. This permits the X line to extend unobstructed over the full length of the patient's body.

Option 2. A second option for the X actuator (Unit #3) is a Gantry system. In this case, the X actuator (Unit #3) is mounted to the tops of the Z actuators (Unit #1 and Unit#2), but the lasers are positioned closer to the treatment couch.

There are three mounting options available for the Z actuators (Unit #1 and Unit#2) in the system. (Figure 4.1)

Option 1. If the walls of the treatment room are within 3 meters of the treatment couch, the actuators can be mounted directly to the walls.

Option 2. A second option for the Z actuators (Unit #1 and Unit#2) is a Gantry system. In this case, the Z actuators are mounted under the X actuator (Unit#3), but the lasers are positioned closer to the treatment couch.

Option 3. If the treatment couch is located far from the walls of the treatment room, a floor mount could be used for the Z actuators (Unit #1 and Unit#2).

The laser lines are pre-focused to 2 to 3 meters from the actuator. If the Z actuators must be mounted at an angle relative to the wall, or at a distance closer to the treatment Couch refocusing may be necessary.

Finally, consider mounting the Z actuators (Unit #1 and Unit#2) on or as close to the walls as possible; this avoids possible interference with treatment room personnel.

5.3.1 Ceiling mount

The ceiling mount arrangement is shown in Figure 4.1.

The ceiling must feature a rigid structure (**Hospital Contractor supplied and installed**) within its construction. Typically, this rigid structure is a metal plate built into or affixed on the ceiling or a channel mounting system. It is to this installation that the pivot-bracket mountings (**Supplied with Maxx-1100 Unit**) will be connected.

5.3.2 Wall mount

As with the ceiling, the walls must feature a rigid structure (**Hospital Contractor supplied and installed**) within their construction. Typically, this rigid structure is a metal plate built into or affixed to the wall or a channel mounting system to which the pivot-bracket mountings (**Supplied with Maxx-1100 Unit**) will be attached.

The wall mount arrangement is shown in Figure 4.1. For a wall mounting, a rigid structure is affixed to each wall.

5.3.3 Floor mount

A Maxx-1100 unit can be secured to the floor in a vertical configuration using a floor mount pedestal (**Supplied with Maxx-1100 Unit**). The floor mount arrangement is shown (Figure 5.1)

Floor mounting allows lasers to be mounted vertically but attached to the floor. This configuration is advantageous in allowing the user to easily orient the Z actuator (Unit #1 or Unit #2) at any distance with respect to the treatment couch. This is particularly convenient in treatment rooms where a couch is installed at a long distance from the walls of the room.

5.4 Cable routing (For the Optional controller)

Maxx-1100 unit in the system must be connected to the computer controller by an Ethernet cable. Cables are provided to connect Maxx-1100 unit to the RJ45 outlets installed by Hospital. Provisions must be made in the treatment room to route cables as directly as possible to the system controller while not posing any hazard to personnel working in the room. (Figure 5.1)

Maxx-1100-unit cables may also be routed through conduit. If this is done, the conduit should be of a minimum inside diameter and any bends should be a large and gradual enough to allow the cable connectors to be pulled through the conduit without undue stress.

5.5 Power requirements

For the Maxx-1100 System, a separate power outlet is required for each Maxx-1100 unit. Each Maxx-1100 unit requires 100-240VAC 1A, 50-60Hz.

The Maxx-1100 unit is equipped with a power on/off switch, but if the treatment room configuration allows, it may be desirable to install a single switch to control outlets to the units. (Figure 5.1)

If the optional system controller is used, one power outlet is required for the system controller PC. The system controller PC requires 100-240V AC 8/4A, 50-60Hz power

Detachable mains supply cords are provided, use of other detachable mains supply cord must meet adequate ratings, (see technical Specification table).

6 LASER INSTALLATION

Before the Maxx-1100 units can be correctly installed in the treatment room, the system isocenter must first be identified. Once identified, templates (**Supplied with Maxx-1100 Unit**) should be placed on the wall to determine the precise location of the mounting.

In the following sections on laser installation, it is assumed that a mounting base plate or alternately a Channel system (**Hospital Contractor supplied and installed**) has already been installed in the correct location to mount the lasers.

6.1 Establishing isocentre reference marks

The primary task in patient positioning system installation is establishing reference marks for each of the three planes for the lasers. (Figure 6.1)

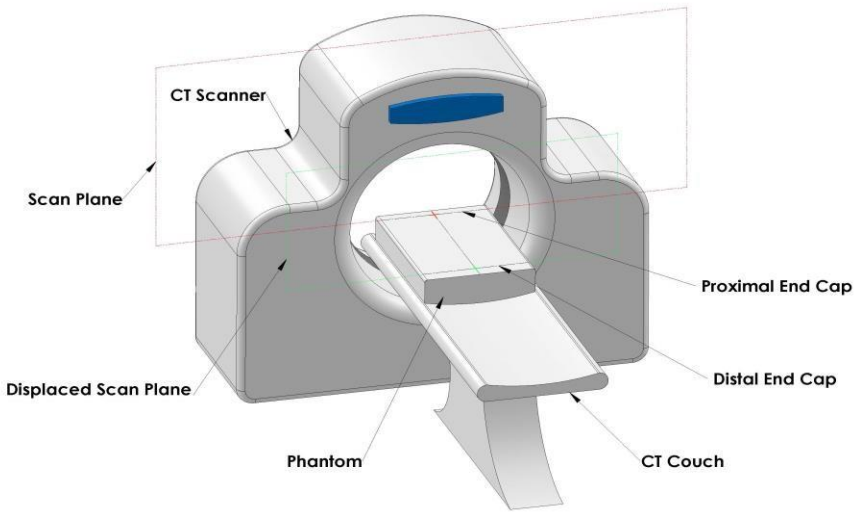
Ideally, the X actuator and Z actuator coordinates of the laser system centre will correspond with the radiographic zero of the treatment room. Y-axis of the laser system is typically offset some distance from the centre of the radiographic scan plane (*i.e.,* 600 mm). This offset value should be noted for future use in patient setup. (Figure 5.2)

6.2 Finding the treatment room radiographic centre

Three options are possible for determining the treatment room radiographic centre; options are listed in order of accuracy:

1. Using a scan to find the radiographic centre
2. Using treatment equipment's internal lasers to find the radiographic centre
3. Using physical measurement to find the radiographic centre

Figure 6.1 Phantom overview



6.3 Using the rotating laser

A rotating laser can be used to establish the Y, Z, and X planes for the Maxx-1100 system based on the scan of the installation phantom. (Figure 4.1) and (Figure 6.1)

Note: When moving the phantom side to side, be careful not to change the angle of the phantom, or else the steps to align the phantom with the scan plan will need to be repeated. While performing the above scan procedures, the grooves on the sides of the phantom may not line up with the grid on the scan image (i.e., the image of the phantom is rotated relative to the grid). If this occurs, verify that the phantom is level and adjust and re-Scan as necessary. The patient positioning lasers should be installed in a coplanar orientation with no Parallax. If the image in the CT simulator is not oriented correctly with respect to the horizontal plane, it will be difficult or impossible to correctly mark and position the patient for treatment.

6.4 Installing lasers

6.4.1 Floor mounting

A floor mount requires four studs to be installed in the floor, a floor template (**Supplied with Maxx-1100 Unit**) is used; wall/ceiling mounting template cannot be used. For the laser centre to be in the Y reference plane, the Floor Mount Pedestal for the Maxx-1100 unit must be mounted in the correct location. (Figure 4.1)

The holes in the base plate of the pedestal are elongated to allow for some adjustment of both angle and the lateral position.

Step 1. Position the floor template so that the reference line for the centre of the laser corresponds with the line determined by the marks made on the floor to define the Maxx-1100 unit's Y reference plane.

Step 2. Mark, drill and install mounting studs.

Step 3. Place and loosely secure the Floor Mount Pedestal.

Step 4. Remove front covers for the Floor Mount Pedestal and Maxx-1100 unit.

Step 5. Position and mount the Maxx-1100 unit to the top of the Floor Mount Pedestal and secure them together using the provided 8mm bolts.

Step 6. Align to the Y plane of the room; shim under the base plate as required so all plate holes are in contact with the floor.

Step 7. Tighten in this position. Repeat for another unit.

Step 8. To verify that the Laser Travel Zero of the two Maxx-1100 units is aligned, use any line-generating device to project a line on the Laser Travel Zero indicator stickers. This projected line should intersect the reference stickers, if not shims may be required if the different is more than 5mm.

Step 9. The Maxx-1100 unit is now ready to have power turned on. (Section 7)

Step 10. Adjust the lasers to Z and Y planes using tilt and rotation adjustments. (Section 8.2)

Step 11. Replace front covers.

Note: Before applying power to the system, remove the Maxx-1100-unit cover from each actuator and confirm that the strapping tape that secures the laser carriage during shipment has been removed.

6.4.2 Wall mounting

For Pivot-bracket mounting, the laser(s) must be placed in the correct laser reference plane.

The pivot-brackets included have pivoting angles in two directions and linear adjustment slots in two directions, and an adjustment channel located in the frame of the Maxx-1100 unit. (Figure 4.1)

Step 1. Place the pivot-bracket mounting template (with Laser Travel Zero) aligned +/5mm to isocenter.

Step 2. Mark, drill and tap holes for pivot-bracket mounting hardware (M6 bolts), if mount plate was installed. If U-channel was installed, use a M6 channel nut / strut nut to connect pivot-bracket.

Step 3. Split the pivot-bracket by removing the middle bolt. So, one part is still connected to the Maxx-1100 unit and the second half is free to mount to the wall.

tep 4. After mounting the half pivot–bracket to the wall, position the Maxx-1100 unit and reconnect the halves of the pivot-bracket.

Step 5. Adjust the pivot-brackets so that the Maxx-1100 unit is square and level, and that the Laser Travel Zero is aligned to the opposite Maxx-1100 unit.

Step 6. Tighten the pivot-brackets in this position. Repeat for another unit.

Step 7. To verify that the Laser Travel Zero of the two Maxx-1100 units is aligned, use any line-generating device to project a line on the Laser Travel Zero indicator stickers. This projected line should intersect the reference stickers, if not repeat Step 5.

Step 8. The Maxx-1100 unit is now ready to have power turned on. (Section 7)

Step 9. Remove front cover.

Step 10. Adjust the lasers to Z and Y planes using tilt and rotation adjustments. (Section 8.2)

Step 11. Replace front covers.

Note: Before applying power to the system, remove the Maxx-1100-unit cover from each actuator and confirm that the strapping tape that secures the laser carriage during shipment has been removed.

6.4.3 Ceiling mounting

A ceiling mount system is required, the recommended system is U channel mount which can be installed so that its long axis is parallel to the Y line in the system and an X-Axis will give full flexibility, also a plate could be mounted to the U-channel for added support (**Hospital Contractor Installed**). (Figure 5.1)

The pivot-brackets included have pivoting angles in two directions and linear adjustment slots in each plate and an adjustment channel in the frame of the Maxx-1100 unit.

Step 1. Use a M6 channel nut/strut nut to connect pivot–brackets.

Step 2. Split the pivot-bracket by removing the middle bolt. So, one part is still connected to the Maxx-1100 unit and the second half is free to mount to the U channel.

Step 3. After mounting the half pivot–bracket to the U channel, position the Maxx1100 unit and reconnect the halves of the pivot-bracket.

Step 4. Adjust the pivot-brackets so that the Maxx-1100 is level in both directions, and that the Laser Travel Zero is aligned to the treatment couch centre.

Step 5. Tighten the pivot-brackets in this position.

Step 6. The Maxx-1100 unit is now ready to have power turned on. (Section 7)

Step 7. Remove front cover.

Step 8. Adjust the lasers to X and Y planes using tilt and rotation adjustments. (Section 8.2)

Step 9. Replace front cover.

Note: Before applying power to the system, remove the Maxx-1100-unit cover from each actuator and confirm that the strapping tape that secures the laser carriage during shipment has been removed.

7 MAXX-1100 CONNECTIONS

7.1 Maxx-1100-unit power-up

Each Maxx-1100 unit has a detachable main power supply cord; the on switch is located near the entry point of this cord. Plug in unit with the switch in the off position then switch unit on.

Refer to Section 9 for the Maxx-1100 unit start sequence at power-up. Automatic power-up procedures are executed any time power is applied to the Maxx-1100 unit.

> *Note: The power input also contains a replaceable fuse which Cemar Electro recommends replacing with a rated 2.3 – 1.1 A fuse.*
>
> *Before applying power to the system, remove the Maxx-1100-unit cover from each actuator and confirm that the strapping tape that secures the laser carriage during shipment has been removed.*

7.2 System cable connections (with optional computer for DICOM protocol)

Before you can finalize the install of the Maxx-1100 system the following system connections must be made, the Maxx-1100 unit(s) be powered on, and their position appropriately situated. The power cords connect to the power connection on the controller (PC) and router. The Maxx-1100 unit(s) and Controller (PC); connected to the router. Maxx-1100 unit#1 is connected to LAN#1, Maxx-1100 unit#2 to LAN#2, and Maxx-1100 unit#3 to LAN#3 on router. Then the Maxx-1100 Controller (PC) is connected through the USB adapter to LAN#4. Connect Maxx1100 Controller's LAN to the CT Control Computer or Hospital Network.

The system cable connections can be seen in Figure 7.1.

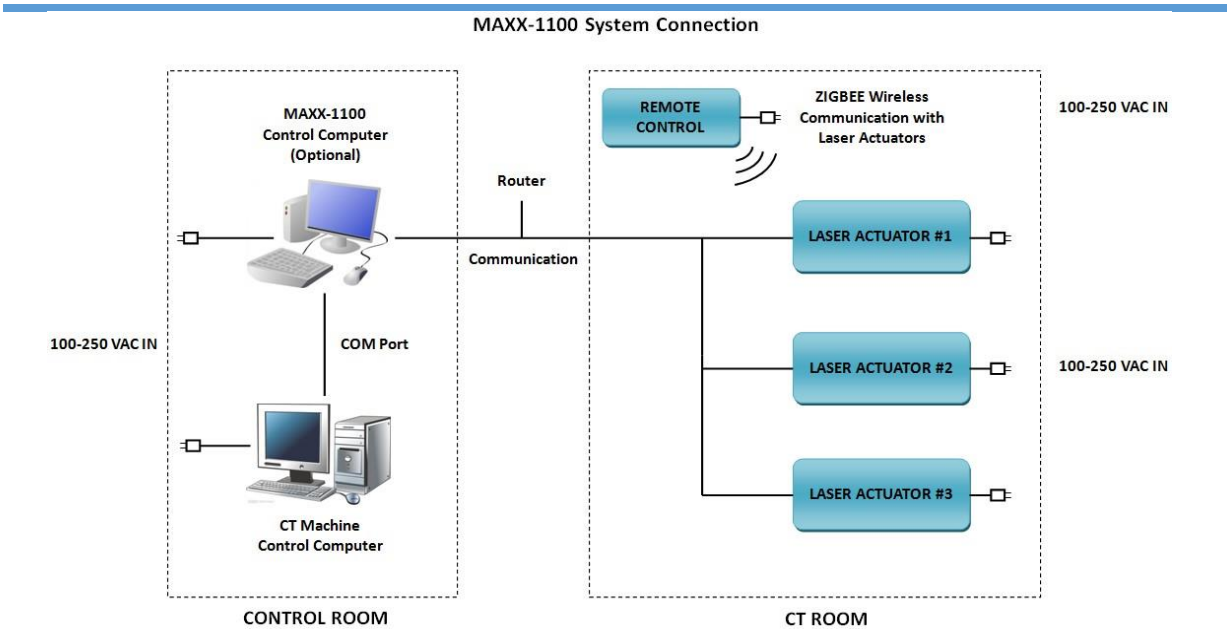


Figure 7.1 System connection

7.3 System controller power-up

The system controller provides control to the entire MAXX-1100 system. Power is applied by turning on the power switch on the control enclosure (PC); then run the Maxx-1100 control software. Power-up operations for the system controller and for the remote control are outlined in Section 9.1.3.

8 SYSTEM ALIGNMENT

8.1 Basic laser alignment concepts

The following basic principles apply to alignment of laser lines independent of the model or application. For each individual laser line, the following steps must be followed in sequence.

8.1.1 Laser origin point must be in the correct plane

The Laser Origin Point (LOP) is the point where the laser line exits the line-generating optics on the laser module. This is typically a point at the end of the laser module, in the centre of the laser diode barrel. If more than one laser line defines a plane, then the LOP for each of the lasers must lie in that plane before other alignment adjustments can be made effectively.

8.1.2 Tilt the laser plane to the correct alignment

The tilt adjustment (Figure 4.2) for each laser allows the laser diode barrel to be tilted about the LOP. The LOP does not change position as a result of this adjustment. The requirements for this adjustment are slightly different for each plane in the system. Tilt adjustment cannot be made correctly until the LOP has been located accurately in the correct plane

8.1.2.1 Y plane

Lasers that form the Y plane (Figure 4.1) in the Maxx-1100 system (*e.g.*, the fixed lasers in the Z actuators (Maxx-1100 unit#1, unit#2) and fixed laser in the X actuator (Maxx-1100 unit#3) must be tilted to be coplanar. This can be accomplished by using the tilt control on the fixed laser to move the laser line until it passes through the LOP of the laser on the opposite wall.

Note: If the rotation adjustment of the two opposing lasers is not correct, then the tilt adjustment described above may not be correct. Therefore, in the case of the Y plane, it may be more efficient to adjust rotation before tilt is adjusted.

8.1.2.2 X plane

The X plane (Figure 4.1) is a vertical plane. The moving laser on the ceiling mounted X actuator (Maxx-1100 unit#3) defines the X plane. The tilt control for this laser is used to adjust the X plane so that it is perfectly vertical (plumb).

8.1.2.3 Z plane

The Z plane (Figure 4.1) is a horizontal plane formed by two moving lasers (*e.g.*, the moving lasers on the Z actuators (Maxx-1100 unit#1, unit#2) mounted on either side of the treatment room couch) must be in the same horizontal plane (*i.e.*, level across the room). If the two opposing lasers have been correctly located with their LOP in the Z plane, then the tilt control can be used to move the projected laser line until it passes through the LOP of the opposing laser.

8.1.3 Rotate the laser plane to the correct alignment

When the first two adjustments have been made correctly, rotation (Figure 4.2) of the laser plane should be the final required adjustment. This adjustment consists of rotating the laser line about its long axis.

In the case of the Y plane, laser alignment is most effectively accomplished if rotation adjustment of the fixed lasers precedes the tilt adjustment of these lasers. Again, the requirements for this adjustment are slightly different for each plane of the system, as described in the following sections.

8.1.3.1 Y plane

In the case of the two fixed lasers on either side of the couch (Z actuators Maxx-1100 unit#1, unit#2) that help define the Y plane (Figure 4.1), the laser lines must be rotated so that the lines are vertical (plumb).

In the case of the optional fixed laser(s) in the ceiling mounted X actuator (Maxx-1100 unit#3) that helps define the Y plane, the line must be rotated until it is parallel with the Y plane defined in the room.

8.1.3.2 X plane (figure 4.1)

Rotation of the X line (generated by the moving laser in the ceiling mounted X actuator (Maxx1100 unit#3)) allows it to be made perpendicular to the Y plane.

8.1.3.3 Z plane

The rotation adjustment for the two moving lasers (Maxx-1100 unit#1, unit#2) that define the Z plane (Figure 4.1) for the Maxx-1100 system allow these lines to be adjusted so that the line that is generated is horizontal (level) from end to end, parallel to the treatment couch.

8.2 Specific laser alignment procedures

Once power to the Maxx-1100 units has been established (see Section 7 for more details on system and power connections) and the moving lasers are positioned to the Laser Travel Zero position, final system alignment can take place as follows:

Step 1. Locate each moving laser or fixed laser in the system so that the LOP for each laser is accurately located in the correct plane.

Step 2. Use tilt and rotation controls to align laser lines so that the vertical and horizontal lines are aligned with their respective counterpart.

Step 3. Adjust the zero position of the moving laser on each actuator so that the laser corresponds with the isocenter and that the Maxx-1100 unit#1 and Maxx-1100 unit#2 are aligned at the same zero position.

8.2.1 Locating the lop for all Maxx-1100 system lasers in the correct plane

The purpose of this task is to physically move the lasers so that the LOP of each laser is in the correct plane. Once the LOP of all the lasers are correctly positioned, the rotation and tilt of each fixed laser can be adjusted so that all the laser lines in the room fall within the correct plane.

> *Note: This task must be completed accurately; otherwise subsequent adjustment(s) cannot be made correctly. The procedures for this task vary depending on the equipment that is being used to align the Maxx-1100 system.*

8.2.1.1 Lop location of Maxx-1100 using a rotating laser

The primary purpose of the rotating laser in this procedure is to locate the fixed lasers and moving lasers in all units in the correct plane. (Figure 4.1)

8.2.1.1.1 Z plane

Is easiest done using a rotating laser, set up at the isocenter Z plane (horizontal orientation) on the treatment room couch. (Figure 4.1)

Position the Z actuators (Maxx-1100 unit#1, unit#2) laser line in the correct vertical position. The vertical position of the moving lasers must be adjusted so that the rotating laser passes through their LOP. After positioning use the remote control to set this as the new zero position. (When using the save feature all three Maxx-1100 units positions are updated.)

8.2.1.1.2 Y plane

A rotating laser can be used to locate the LOP for the fixed lasers that form the Y plane in the Maxx-1100 system. For a Maxx-1100 Unit#3, with no fixed laser, or with three Maxx-1100 units that includes the fixed laser. This is accomplished as follows:

Step 1. Set up the rotating laser at the isocenter in the Y plane. (Figure 4.1)

Step 2. Reposition linearly (+/-10mm from its centre point) the fixed laser(s) until the rotating laser passes directly through the LOP. Repeat for each fixed laser.

8.2.2 Aligning lasers in the y plane

Aligning lasers in the Y plane (Figure 4.1) is usually the most difficult part of Maxx-1100 system alignment because you must align all three fixed lasers in this plane (If Maxx-1100 unit#3 is equipped with a fixed laser). Again, this can only be accomplished successfully if the LOP for these three lasers has been located correctly in the Y plane, as described in the previous procedures (Section 8.2.1). Once this LOP is correct for all three lasers, use the tilt and rotation controls for the lasers for final alignment.

8.2.2.1 Align the fixed laser

Depending on the alignment tools that are being used, some of the steps outlined below may have been completed in previous procedures.

Step 1. Set up the rotating laser at the isocenter in the Y plane. (Figure 4.1)

Step 2. Use the rotation controls on the fixed lasers of Maxx-1100 unit#1 and unit#2 to make both projected lines vertical. This can be done by making the lines parallel to the rotating laser line, or to the marks for the Y plane on the opposite wall or using a plumb bob.

Step 3. Use the tilt control on the fixed lasers of Maxx-1100 unit#1 and unit#2 to move the line until it is directly on top the rotating laser line, or marks on the floor that identified the Y plane.

Step 4. Use a plumb bob to verify that the plane of the laser is vertical. If the plane is vertical and the plumb bob is held in the laser plane, the laser will simultaneously illuminate the entire length of the plumb bob string.

Step 5. If the laser line is not vertical, then the LOP of the fixed laser is not located in the same vertical plane as the isocenter, and corrective steps must be taken to locate the LOP of this laser correctly (Section 8.2.1).

Step 6. Use the rotation control on the Maxx-1100 unit#3 fixed laser to adjust the line until it is parallel with the two lines from unit#1 and unit#2.

Step 7. Use the tilt control on the Maxx-1100 unit#3 fixed laser to move the line until it is directly on top of the lines from unit#1 and unit#2 and the rotating laser line or passes through marks on the floor that identified the Y plane.

At this point, all three fixed lasers that define the Y plane for the Maxx-1100 system should be coplanar. This can be confirmed with a piece of white paper and verifying that when one laser is obstructed at any given time or position in the room, the position of the line on the paper does not change. If this is not the case, revisit the preceding alignment steps to determine which was not carried out correctly or with enough accuracy.

8.2.3 Aligning lasers in the z plane

Only two lasers are involved in aligning lasers in the Z plane (Figure 4.1); the process is thus simpler than that required for aligning lasers in the Y plane. The same principles do apply. Once the LOP for the two lasers involved is correct, then only rotation and tilt adjustments need to be made.

8.2.3.1 Align the moving lasers

Correct laser alignment requires that the laser LOP is first correctly set. The ability to move the Z lasers on the Maxx-1100 will be used, some of the steps outlined below may have been completed in previous procedures.

Step 1. Set up rotating laser at the isocenter Z plane (horizontal orientation) on the treatment room couch. (Figure 4.1)

Step 2. Start with both moving lasers (Maxx-1100 Unit#1 and Unit#2) at the laser travel zero, move each laser until the rotating laser passes through their LOP. Use the remote control to set this as the new zero position. (When using the save feature all three Maxx-1100 units positions are updated.)

Step 3. Use the rotation control on the moving laser in the Maxx-1100 unit#1 to adjust the line parallel to the rotating laser line defining the Z plane, or so that it is parallel to the marks on the opposite wall.

Step 4. Use the tilt control on the moving laser in the Maxx-1100 unit#1 to move the line until it is directly on top the rotating laser line that defines the Z plane, or both marks on the opposite wall.

Step 5. Use the rotation control on the moving laser in the Maxx-1100 unit#2 to adjust the line parallel to the rotating laser line defining the Z plane, or so that it is parallel to the marks on the opposite wall.

Step 6. Use the tilt control on the moving laser in the Maxx-1100 unit#2 to move the line until it is directly on top the rotating laser line that defines the Z plane, or marks on the opposite wall and through the LOP of the Maxx-1100 unit#1 moving laser, and are coplanar with each.

At this point, the two moving lasers that define the Z plane for the Maxx-1100 system should be coplanar. *If the two Z lasers are not co-planar at this point, you must determine which of the preceding alignment steps was not carried out correctly or carefully enough.*

8.2.4 Aligning the laser in the x plane

There is only a single moving laser to align, the moving laser in the ceiling-mounted Maxx-1100 unit#3. This process is as follows:

Step 1. Set up rotating laser at the isocenter X plane defined by a line on the installation phantom that is marked perpendicular to the Y plane in the system. (Figure 4.1)

Step 2. Start with the moving laser (Maxx-1100 Unit#3) at the laser travel zero, move the laser's LOP close to the centre of the treatment couch, and use the remote control to set this as the new zero position (When using the save feature all three Maxx-1100 units positions are updated. Make sure that Maxx-1100 unit#1 and unit#2 moving lasers have not been moved from the isocentre).

Step 3. Use the rotation control to rotate the laser until it is parallel to the X plane in the system.

Step 4. Use the tilt control on the Maxx-1100 unit#3 moving laser to adjust the laser until it is vertical. Use a rotating laser line, or a plumb bob to verify that the plane is vertical; the laser will simultaneously illuminate the entire length of the plumb bob string.

8.2.5 Final alignment verification

All lasers that define the X plane, Y plane, and Z plane for the Maxx-1100 system should be coplanar. This can be confirmed with a piece of white paper and verifying that when one laser is obstructed at any given time or position in the room, the position of the line on the paper does not change. If this is not the case, revisit the preceding alignment steps to determine which was not carried out correctly or with enough accuracy.

9 LASER UNIT DISPLAYS

Figure 9-1. LED Display Panel on top of Maxx-1100 unit. These LEDs indicate status of different modules of the unit.

WARNING: Repeatedly turning on and off the laser units can cause damage to your laser units.

- Unit Number Display: This 8-segment LED displays the unit number, which should be 1, 2, or 3 for this revision. No two units can have the same unit number in a single room.
- System LED: The green LED indicates the system status of the unit. It is dark during calibration at power up and turns solid green when calibration is successfully completed. It blinks in different patterns indicating errors encountered during calibration or regular operation. Refer to Table 9-1 for details about System LED blinking.
- Ethernet LED: The amber LED indicates status of Ethernet connection between the unit and the router. Solid amber indicates the connection is correctly established. A dark LED indicates there is no valid Ethernet connection between the router and the unit. It starts blinking when Ethernet initialization and static IP address assignment cannot be completed.
- Wireless LED: The red LED indicates status of Zigbee wireless connection between the unit and the remote control. Solid red indicates the connection is correctly established. A blinking LED means the connection cannot be established.

During power up, the following events should occur in order.

Step 1. *Unit Number Display* will become illuminated.

Step 2. Establishing wireless connection: wireless LED starts blinking, indicating the unit firmware is searching for a remote control with the same PAN ID. Wireless LED turns solid red once it is connected to the remote control.

Step 3. Starting laser beams: Both the fixed and movable lasers start beaming. If laser beams cannot be started, the subsequent events will not occur.

Step 4. Establishing Ethernet connection: Ethernet LED is solid amber if the unit is connected to a router via Ethernet cable; otherwise, the Ethernet LED is off. If

neither wireless connection nor Ethernet connection can be established, the subsequent events will not occur.

Step 5. Encoder checking and calibration: The movable laser starts moving in the default negative direction (*i.e.,* moving further away from the fixed laser). It changes direction when it hits the stopper on the negative end. The movable laser will travel the length of the encoder rail and hits the stopper on the positive end, close to the fixed laser. If no error is detected during the process, System LED becomes solid green indicating the calibration was successful.

Note: For assistance in all aspects of troubleshooting, contact ***Cemar Electro Inc.*** *for technical support.*

Step 6. Moving to CT zero: The movable laser keeps moving towards CT zero, if available. At initial power up, the laser will remain at the positive end as CT zero has not yet been established. Refer to Section 9.5.5.1 for instructions on how to set up CT Zero of Maxx-1100 system.

Step 7. Following successful completion of the above steps, the laser unit is ready to accept commands from desktop application via the Ethernet interface and/or from remote control via the Zigbee interface.

Table 9-1. Summary of LED blinking patterns during laser unit power up			
Code	**Blinking LED**	**Blinking Pattern (per second)**	**Cause**
Z0	Wireless LED		Zigbee module in the laser unit cannot connect to remote control
E0	Ethernet LED		Fails to assign static IP address based on unit number
E1	System LED		Fails to detect encoder zero
E2	System LED		Receives bad data signal from encoder
E3	System LED		Motor has jammed
E4	System LED		Bad communication to encoder controller

Note: In case of code E0, E1, E2, E3, or E4, and/or associated blinking, contact ***Cemar Electro Inc.*** *immediately to provide error information to technical support personnel.*

10 TROUBLESHOOTING

If any operation cannot be completed successfully, the status bar on the remote control turns red after timeout. In most cases, this is due to wireless communication problem. Follow instructions in Section 9.3 to check if the target unit can be linked.

If linking to the unit is successful, try repeating the failed operation. In cases of continued failure, confirm the following:

Step 1. Make sure there is no other wireless device in the room.

Step 2. Check the wireless LED on the target unit. If the LED is solid red, simply restart the unit and try linking it again. If it is blinking, continue with Step 3.

Step 3. Check the wireless LED on other laser units in the same room. If all the other units have their wireless LEDs solid, simply restart the unit and try linking it again. If it is blinking, continue with Step 4.

Step 4. Power down all the units and the remote control. Wait at least 10 seconds, then power up the remote control first, followed by the laser units. The wireless LEDs should become solid shortly after power-up. Verify wireless connection to each laser unit.

The following tables cover handling of most special cases of communication abnormality.

Moving laser to a target position

Observation	Action
All lasers have moved to target positions, but remote control still shows that lasers are moving.	No user action is required. The current position will be updated after a short delay.
At least one of the lasers does not move immediately at button click.	No user action is required. After a short delay, all lasers move to target positions.
The selected laser has stopped moving when command button is released, but remote control still shows that the laser is moving.	No user action is required. After a short delay, remote control shows that laser has stopped moving and current position is updated.
The selected laser does not stop immediately when command button is released.	No user action is required. After a short delay, the laser stops moving, and remote control updates the current position.
The selected laser does not stop immediately when command button is released.	Case 1: no user action is required.

Observation (cont.)	Action (cont.)
The selected laser does not stop immediately when command button is released. (continue)	After a short delay, the laser stops moving, but remote control fails to update its current position. If user must know the laser's precise position, go back to Laser Functions page and click "Refresh" icon.
	Case 2: laser does not stop after two-second delay. **User must press the continuous command button again for one second and release it to stop laser** and get the updated position.

Note: For assistance in all aspects of troubleshooting, contact ***Cemar Electro Inc.*** *for technical support.*

11 REMOVAL AND TRANSPORT

- **Removal**

Personnel: qualified technician.

If the equipment is no longer to be used, disconnect it from the power supply and remove it.

- **Transport**

The system must be transported in its original packaging whenever possible or use enough protection. Once the laser unit is properly protected, gently move it with a dolly, always in a vertical position, taking care of that the indicator lights are on the top.

Tip it backward and slide the equipment onto the dolly. You may want to secure it to the dolly with moving straps or rope. Slowly and carefully roll the dolly make sure someone is behind holding the equipment in place while someone else rolls the dolly.

12 WARRANTY

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.** Any necessary spare parts will be installed in our facilities because it is necessary to verify the calibration of the units, which can only be done in our laboratory.

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 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.

13 CUSTOMER SERVICE & 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 Phone: 518-298-3065
Fax: 514-631-7505 Fax: 518-298-2927
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14 REGULATORY INFORMATION

14.1 Manufacturer Information

Manufacturer:
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Lachine, QC H8T 3J8
Canada

Authorised Representative (Europe):
P. Spirig GmbH, Baunstrasse 23
CH-9435 Heerbrugg,
Switzerland

14.2 Compliance Information

EU Radio Equipment Type Compliance Declaration:

The Maxx-1100 series which comprises wireless communication equipment complies with Directive 2014/53/EU.

The full text of the EU Declaration of Conformity is available at the following internet address: **http://www.cemarmedical.com**

15 LIST OF SYMBOLS

CE	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
REF	Part Number
SN	Serial Number
LOT	Lot Number
EC REP	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