Integra® Luxtec®

MLX 300 Watt Xenon Light Source

OPERATION AND SERVICE MANUAL

EN

Integra Luxtec MLX 300 Watt

For use with ACMI, Wolf, Storz and Olympus Fiber Cables

INTEGRA®

Table of Contents

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Indications for use

The Integra® Luxtec MLX Light Source is designed to supply high intensity white light through a fiber optic cable for illumination of a surgical field during a surgical and/or medical procedure.

The Integra® Luxtec MLX Light Source should never be used in ocular surgery or in a surgical procedure requiring direct illumination of the eye.

This device is intended to be used by professional healthcare users.

Symbols

Found on a medical grade light source, other illumination related equipment, fiber optic cables and corresponding packaging.


Caution


Caution: High Voltage


High Temperature


Refer to Instruction Manual


Equipotentiality


Protective Earth


Humidity Limitation


Temperature Limitation


Atmospheric Pressure Limitation


Keep dry

Part Number

Batch Code

Serial Number

Authorized Representative in the European Community


Manufacturer


Date of Manufacture


This device meets CE requirements


Certified by CSA


Consult Instructions for Use


Fuse


Alternating Current


Type CF Equipment


Type BF Equipment


Do Not Dispose


On / Off

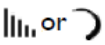

Stand-by


System Status Display


System


Push


Hours



Intensity

Motor


Fan


Over Temperature


Lamp


Brightness

General Warnings

The user should carefully study the Operation and Service Manual before using the equipment in a clinical environment. This Manual contains information about the proper procedures for preparing this product for its use and care. Instructions should be followed, with special attention given to warnings, controls and user specifications. The Manual should be available to the appropriate personnel.

- SAFETY PRECAUTIONS MUST ALWAYS BE EXERCISED WHEN USING ELECTRICAL EQUIPMENT TO PREVENT OPERATOR/ PATIENT SHOCK, FIRE HAZARD OR EQUIPMENT DAMAGE.
- FIRE HAZARD: DO NOT DRAPE OR COVER THE LIGHT SOURCE WHILE IT IS OPERATING.
- Before every procedure, carefully inspect the light source to ensure it has been properly maintained and cleaned, and that it is fully functional. DO NOT use if inspection reveals any damage such as case damage or loose connectors.
- Follow the instructions of other manufacturer's equipment when used in conjunction with this product.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- To reduce the risk of fire and electric shock, do not expose electrical equipment to moisture. When cleaning, do not immerse any electrical device in liquid.
- Do not use or store liquids on or above the light source.
- Electric shock hazard. If unit is not functioning properly, DO NOT OPEN. Please refer to the Repair and Return Section of this Manual.
- All electrical equipment must be used with approved hospital grade power cords and power plugs inserted properly into grounded AC power outlets. If replacement is necessary, replace only with approved power cord.
- The light source should never be used in ocular surgery or in a surgical procedure requiring direct illumination of the eye.
- Use care not to point any fiber optic cable directly at the eye while operating the light source.
- The light source produces high intensity light. Thermal burns can result from improper use of the light source or from the light output of the fiber optic cable.
- Explosion Hazard. Do not use in an oxygen rich environment or in the presence of flammable anesthetics, liquids, vapors, gases or dusts.
- Keep cooling vent and fans free of obstructions.
- When light source is not in use, turn off the power or put the unit in stand-by mode.
- Ensure that the fiber optic cable matches the port type to prevent damaging the optical components of the light source. For user convenience, the light source has a turret with labeled selectable ports.
- Do not use the headlight at distances of less than 10" (25cm).
- Warning: No modification of this equipment is allowed.

Precautions

- Take precautions to verify that the fiber optic cable is appropriately suited for the light source. Xenon and other high illumination light sources require premium fiber optic cables in order to achieve optimal performance and prevent damage to the fibers, thereby diminishing the quality of the light output or the useful life of fiber optic cable. Use only fiber optic light guide cables with the correct proximal fitting for your turret and approved and tested for compatibility with high intensity Xenon lamps of 300W or higher.
- Take precautions not to touch or disconnect the cable end fitting from the turret until the Light Source has been "shut down" for a period of time and allowed to cool. The cable end fitting will remain hot immediately following shut down, which can cause burns.
- Take precautions to not place and rest a hot cable end fitting and/or head light on a patient or allow the system to come in contact with un-protected hands or tissue. The entire system should be allowed to cool following use. Failure to do so can cause burns and/or tissue damage.

Overview

The MLX light source delivers 300 watts of cool white infrared (IR) filtered light. The lamp is housed in a lamp module that can be easily serviced without special tools.

Set Up And Inspection Before Use

The light source comes with the hospital grade power cord packaged separately. Verify that both components are in good condition.

This device should be used in environments that meet the operating environmental conditions in the specification section of this manual.

Before turning power on to the light source, make sure the unit is plugged into any standard 100VAC to 240VAC 50-60Hz (as appropriate) outlet. Grounding reliability is guaranteed only when connected to a "hospital grade" receptacle.

Allow a minimum of 2 inches (5.08 cm) clearance at the rear and sides of the unit for cooling air flow. Ensure that the unit is not near air exhaust or against other equipment.

Warning
The MLX light source monitors air intake temperature and will turn off if ambient temperature is > 40° C

Operation

1. Insert a fiber optic cable in the proper port in the turret. The active port is indicated by a left facing arrow on the perimeter of the turret (See Figure 1). Available ports are ACMI, Olympus, Storz and Wolf cable-compatible. All ports are identified appropriately.

2. Press the Power Switch in the upper left corner of the front panel (See Figure 2).

3. When the Power Switch is pressed the Stand-by Light (Figure 3) will blink and there will be a 3 – 4 second delay before the Xenon Lamp illuminates while the system does a self-diagnostic check.

4. Press the Stand-by Button.

5. The system will start up at the same light intensity as when last used. For new systems, the light intensity will start at the minimum 20% setting.

6. To adjust the light intensity, push the Membrane Switches (Figure 4): + to increase or - to decrease the light output or intensity. Range is 0%, 20 – 100% in 5% increments. Holding the + or – button will change the intensity more quickly.

Note
It is strongly recommended that the light be used at the minimum intensity for good visualization.

7. The System Status Display can be pressed to show both lamp time and system operation time. A second press of the switch will show the software version of the system monitor. A third press returns to light output. (The system will automatically return to the light intensity reading after 15 seconds).

8. The system may be placed in and out of stand-by mode by using the stand-by switch. The system will emit no light in this state and allow the surgeon to unplug a headlight, move around the table, or change cables in a laparoscopic or endoscopic procedure.

Caution
Cable end fitting can be HOT!!!

Note
If unit is left in stand-by mode for 15 minutes, it will automatically shut off the lamp. Fans will keep running. To re-activate, push the Stand-by Button.

9. To shut the system off, simply press the main Power Switch as in Step 2.

Xenon Lamp Module Replacement

Note
Please adhere to appropriate safety precautions when performing lamp replacement. Only qualified personnel should service this device. Protective facemask and/or proper safety glasses should be worn when replacing the lamp module. Before changing the lamp module, turn power off and allow the light source to cool for at least fifteen (15) minutes.

Please read and comply with all Precautions and General Warnings listed in this manual.

To remove lamp:

1. Make sure the power is off and the hospital grade power cord is disconnected.
2. Remove the retaining screws from the top plate (Figure 5) and retain screws.
3. Slide the top plate towards the back of the unit until it stops.
4. Lift the top cover up and off the unit.
5. Unscrew the lamp module door and remove (Figure 6) and retain screw.
6. Grasp the module by the tabs and pull directly up (Figure 7).

To replace lamp:

1. Orient the lamp module (P/N 001320LX) to face forward.
2. Place the module into the light source.
3. Seat module securely.
4. Replace the lamp module door and secure it with the screw.
5. Align top cover brackets into slots and slide forward.
6. Slide the top plate forward until it engages the front panel.
7. Replace the retaining screws in the rear panel.
8. Replace the hospital grade power cord and turn on power to verify operation.

To reset lamp age meter:

1. Using the membrane switch, turn the display to the lamp age/system age screen.
2. On the rear of the unit insert a pen/pencil or other suitable pointed object into the slot marked RESET (Figure 8).
3. Push until a click is felt.
4. Verify that the lamp age has been reset to 0.

Note
The System Age reading CANNOT be reset.

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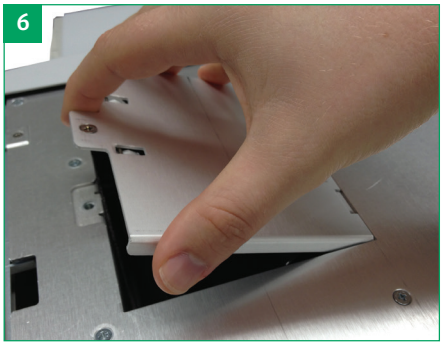

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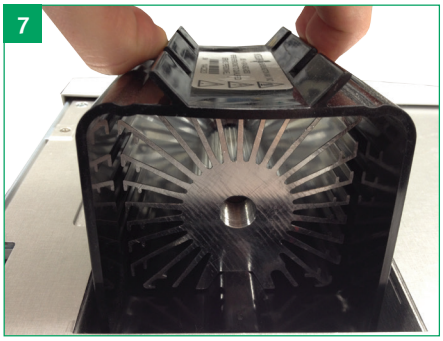

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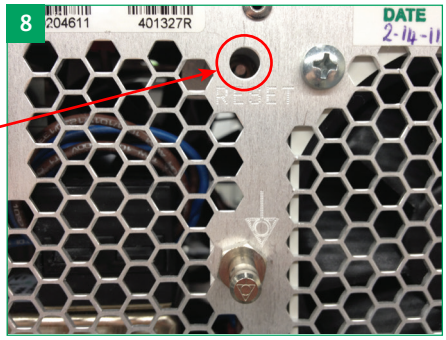

RESET

Fuse Replacement

The fuses for the light source are located in the power entry module in the rear of the unit and may require replacement if the system does not respond to the power switch.

To replace a fuse:

1. Remove the hospital grade power cord from the back of the light source.
2. Using a small flat screwdriver, pry open the retaining door (Figure 9) and pry out the red plastic block from the power entry module (Figure 10).
3. Check to see if either fuse is blown; if blown, replace with a fuse of the same rating (Integra P/N 600987).
4. Replace the red block in the housing.
5. Snap the retaining door into place.
6. Plug cord back into light source and retest the unit.

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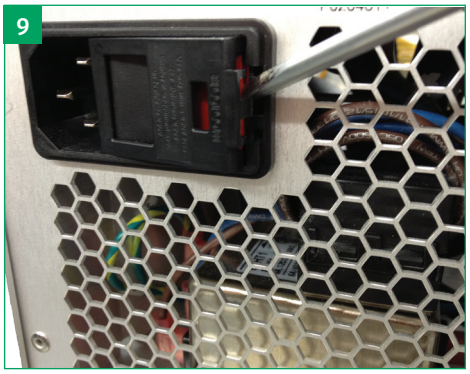

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Optional Floor Stand Assembly

The floor stand assembly includes the following components along with the necessary Phillips head screwdriver:

1. Base with five (5) casters (2 locking)
2. One column with light source base plate
3. Handle
4. MLX light source base

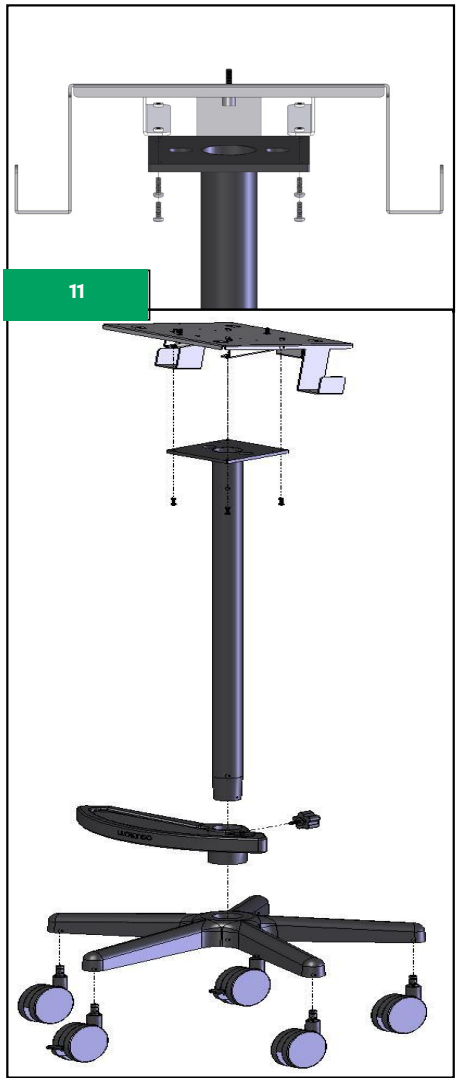
Floor stand assembly instructions:

1. With the handle positioned so that the Luxtec® logo is properly aligned, slide the handle onto the column and center the handle about 5 inches (13cm) below the light source base plate. Tighten handle screw to hold in place.

2. Insert assembled column into the base. Seat firmly.

3. Attach the light source base onto the base plate (Figure 11) with the four (4) screws provided, using the Phillips head screwdriver provided.

4. Secure the light source to base plate by aligning the feet to the holes on the surface of the plate. Tighten the two screws on the bottom of the plate to the light source (Figure 12).



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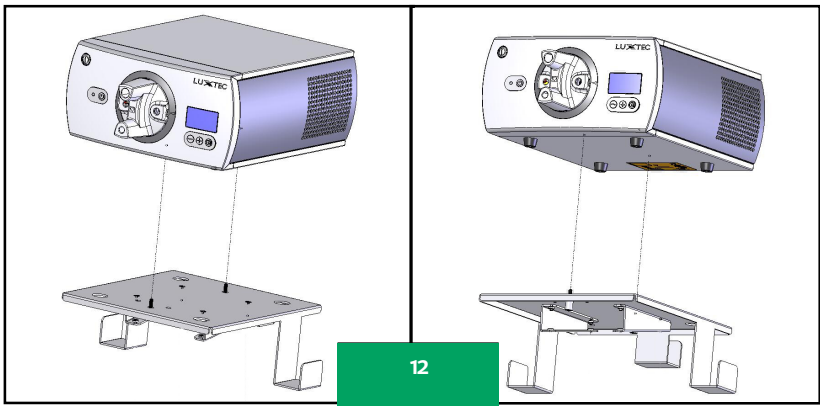

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Replacement Parts And Accessories

To place an order, contact your local Integra distributor or call Integra Customer Service at 1-800-431-1123 (USA & Canada only) or +1-914-789-7094 to identify your local Integra representative.

Light Source

Reference	Description
00MLX	300 Watt Xenon Light Source with Turret (ACMI, Wolf, Storz and Olympus)

Accessories

Reference	Description
001320LX	Xenon Lamp Module
600987	Fuse 6.3 Amp, Slow Blow

Optional Accessories

Reference	Description
AX2100BIF	UltraLite® Pro headlight with 9ft (275cm) premium bifurcated cable, Mark II module and gown clips.
001337	MLX Floorstand

Maintenance and Cleaning

- Allow unit to cool for at least 15 minutes prior to cleaning.
- Unplug the power cord before cleaning. The light source exterior can be cleaned and disinfected using 70% isopropyl alcohol. Allow 5 minutes for alcohol to evaporate before reconnecting to power.
- Use a vacuum cleaner and a soft brush to remove visible dust accumulation from fan and vent holes whenever necessary and always when replacing the lamp.

Troubleshooting

Trouble Area	Possible Cause	Corrective Action
No power	Light source not plugged in	Plug in light source
	Top cover not closed	Close and secure top cover
No light output	Light source not turned on	Turn power on
	Bad/no lamp	Check lamp seating/replace lamp module
	Attenuator closed	Check position of knob on front panel
	Turret mispositioned	Rotate turret to desired adapter fitting
	Blown fuse	Replace fuse as indicated in maintenance section
Reduced Light Output	Cable mismatched to turret	Rotate turret to matching adapter fitting
	Attenuator mispositioned	Check position of knob on front panel
	Bad lamp	Replace lamp module

Fault Symbol	Possible Cause	Corrective Action
	Lamp change (will blink after 1000 hours)	Change lamp. Module Part number 001320LX
	Fan failure	Shut off system to reset. If it does not reset contact Integra for service
	Lamp overheat	Shut off system to reset. If it does not reset contact Integra for service
	Attenuator motor failure	Shut off system to reset. If it does not reset contact Integra for service

Specifications

Lamp	
Type	Xenon Short Arc Lamp
Wattage	300 Watts
Lamp Life	1000 Hours

Light Source	
Dimensions	15.4"L x 11.2"W x 5.9"H (390mm L x 285mm W x 150mm H)
Weight	12.5 lbs. (5.7 kg)
Power Input	100~240VAC, 50/60Hz, 6.3A
Fuses (2)	6.3A, 250VAC, 5x20 mm, Slo-Blo, IEC Standard
Protection Class	Class 1
AC Power Leakage	Leakage current to chassis (with ground wire intact), less than 100 microamps Leakage current to chassis (with ground wire interrupted), less than 500 microamps
Applied Part Classification	Type CF
Electrical Safety	Conforms to UL 60601-1, IEC 60601-1, and CSA C22.2 NO. 601.1
Electromagnetic Compatibility	IEC60601-1-2
Environment: **Storage Temperature** **Operating Temperature** **Storage Humidity** **Operating Humidity**	 0 to 50°C (32 to 122°F) 10 to 40°C (41 to 104°F) 10 to 85% non-condensing 10 to 85% non-condensing
Atmosphere Pressure: **Storage** **Operating**	 500 to 1060hPa 700 to 1060hPa
Power Cord	Hospital grade
Mode of Operation	Continuous
Ingress Protection	IP20
Power Dissipation	450 Watts

Electromagnetic Compatibility (EMC) User Information

Warning
Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic Compatibility [EMC] information provided in the accompanying documents.

Warning
Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

Warning
The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Note
The EMC tables and other guidelines that are included in the Instruction Manual provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the Equipment or System to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.

Table 201: Guidance and Manufacturer's Declaration – Emissions All Equipment and Systems

The MLX light source is intended for use in the electromagnetic environment specified below. The customer or user of the MLX light source should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Enforcement – guidance
RF Emissions CISPR 11	Group 1	The MLX 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 B Radiated and Conducted Emissions	The MLX unit is suitable for use in all establishments including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Conducted Emissions Tests Performed at both 240VAC, 50Hz and 120VAC, 60Hz
Harmonics **IEC 61000-3-2**	N/A	Equipment intended for Professional Use Only
Flicker **IEC 61000-3-3**	N/A	Equipment intended for Professional Use Only

Electromagnetic Compatibility (EMC) User Information

Table 202: Guidance and Manufacturer's Declaration—Immunity All Equipment and Systems

The MLX light source is intended for use in the electromagnetic environment specified below. The customer or user of the MLX light source should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/ burst IEC 61000-4-4	±2kV on AC Mains	±2kV on AC Mains	Mains power quality should be that of a typical commercial or hospital environment. Note - Tests Performed at both 240VAC, 50Hz and 120VAC, 60Hz
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment. Note - Tests Performed at both 240VAC, 50Hz and 120VAC, 60Hz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MLX unit requires continued operation during power mains interruptions, it is recommended that the MLX unit be powered from an uninterruptible power supply or battery. Note - Tests Performed at both 240VAC, 50Hz and 120VAC, 60Hz
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment. Note - Tests Performed at both 50Hz and 60Hz

Electromagnetic Compatibility (EMC) User Information

Table 204: Guidance and Manufacturer's Declaration – Emissions Equipment and Systems that are NOT Life-Supporting

The MLX light source is intended for use in the electromagnetic environment specified below. The customer or user of the MLX light source should assure that it is used in such an environment.

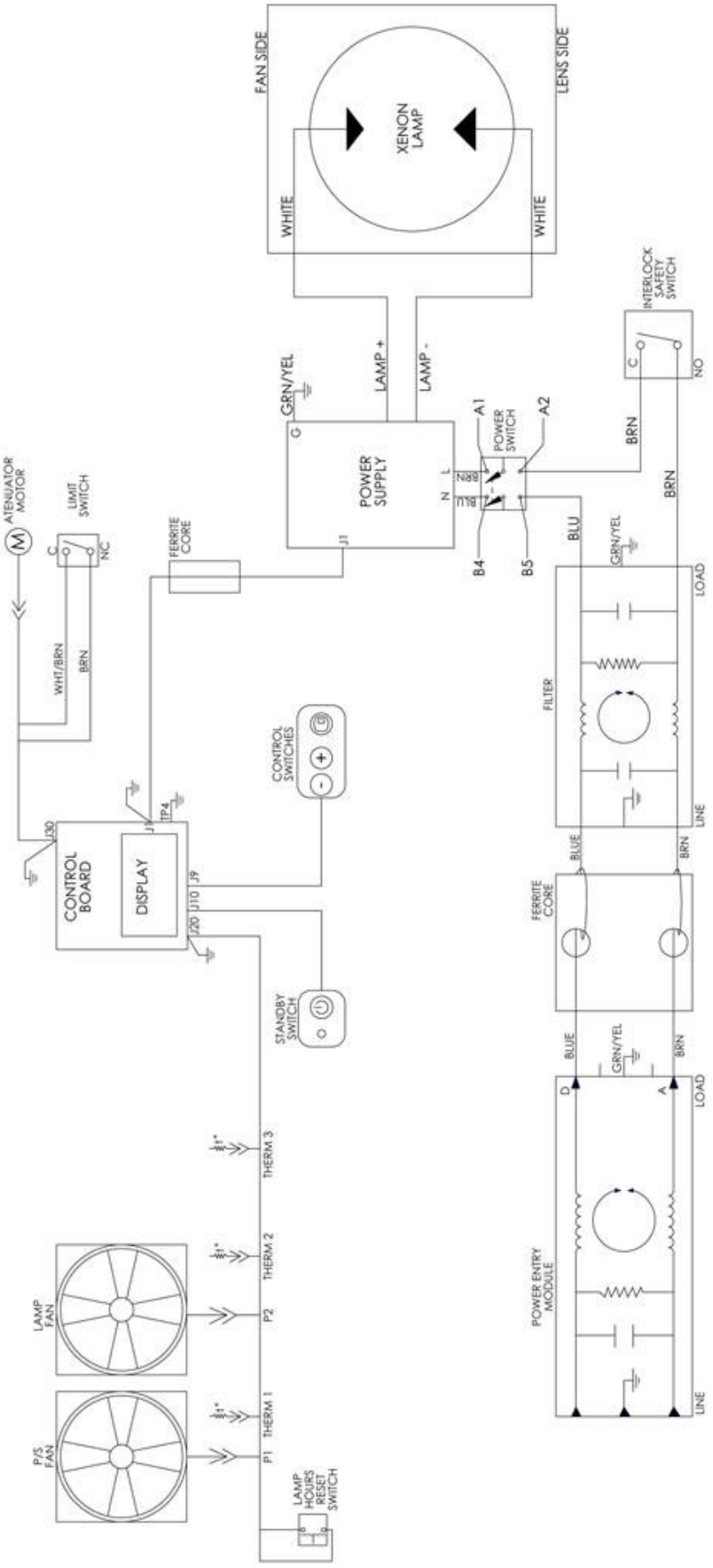
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz	V1 = 3 Vrms	Portable and mobile RF communications equipment should be separated from the MLX light source by no less than the recommended separation distances calculated/listed below: $D = (3.5/V1)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 3V/m	$D = (3.5/E1)\sqrt{P}$ 80 to 800 MHz $D = (7/E1)\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power rating in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter

Table 206: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MLX Equipment and Systems that are NOT Life-Supporting

The MLX light source is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the MLX light source can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the MLX light source as recommended below, according to the maximum output power of the communications equipment.

	Recommended Separation Distances for the MLX (meters)		
Maximum Output Power (Watts)	150 kHz to 80 MHz $d = 1.1667\sqrt{P}$	80 to 800 MHz $d = 1.1667\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3333\sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Block Diagram



Repair And Return Information

This device must be clean and decontaminated prior to return to Integra. Integra reserves the right to return unrepaired any equipment that is contaminated with blood or other organic material.

Warranty Service and Repair:
To obtain service under warranty or return product for repair, the customer should contact your local Integra representative or call Integra Customer Service at 1-800-431-1123 or +1-914-789-7094.

Limited Express Warranty

Integra warrants that the new MLX light source shall be free from defects in material and workmanship under normal use and service for a period of three (3) years from the date of shipment. Integra's sole and exclusive liability under the warranty shall be, at Integra's option, either to repair any component which fails during the warranty period due to any defect in workmanship or material F.O.B. factory if:

1. Customer promptly reports such defect to Integra in writing,
2. If requested by Integra, customer returns equipment to Integra with shipping charges, and
3. Upon inspection, Integra finds the equipment to be defective.

This warranty is contingent upon normal and proper use of the equipment. It does not cover equipment that has been modified with non-Integra parts without the written approval of Integra, subjected to unusual physical or electrical stress, or damaged during shipment. This warranty is non-transferable unless authorized in writing by Integra.

Integra reserves the right to make design changes on its products without liability to incorporate said changes in Integra products previously designed or sold.

Upon receipt of the product, it should be carefully inspected. If any defect is discovered, notification must be given immediately to the manufacturer or authorized distributor.

Disposal of the Product, Packing Material, and Accessories

For disposal, observe the relevant regulations and laws valid in your country. For further information, please contact Integra.

EC REP

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