



User Manual for EM-2151LS Light Source

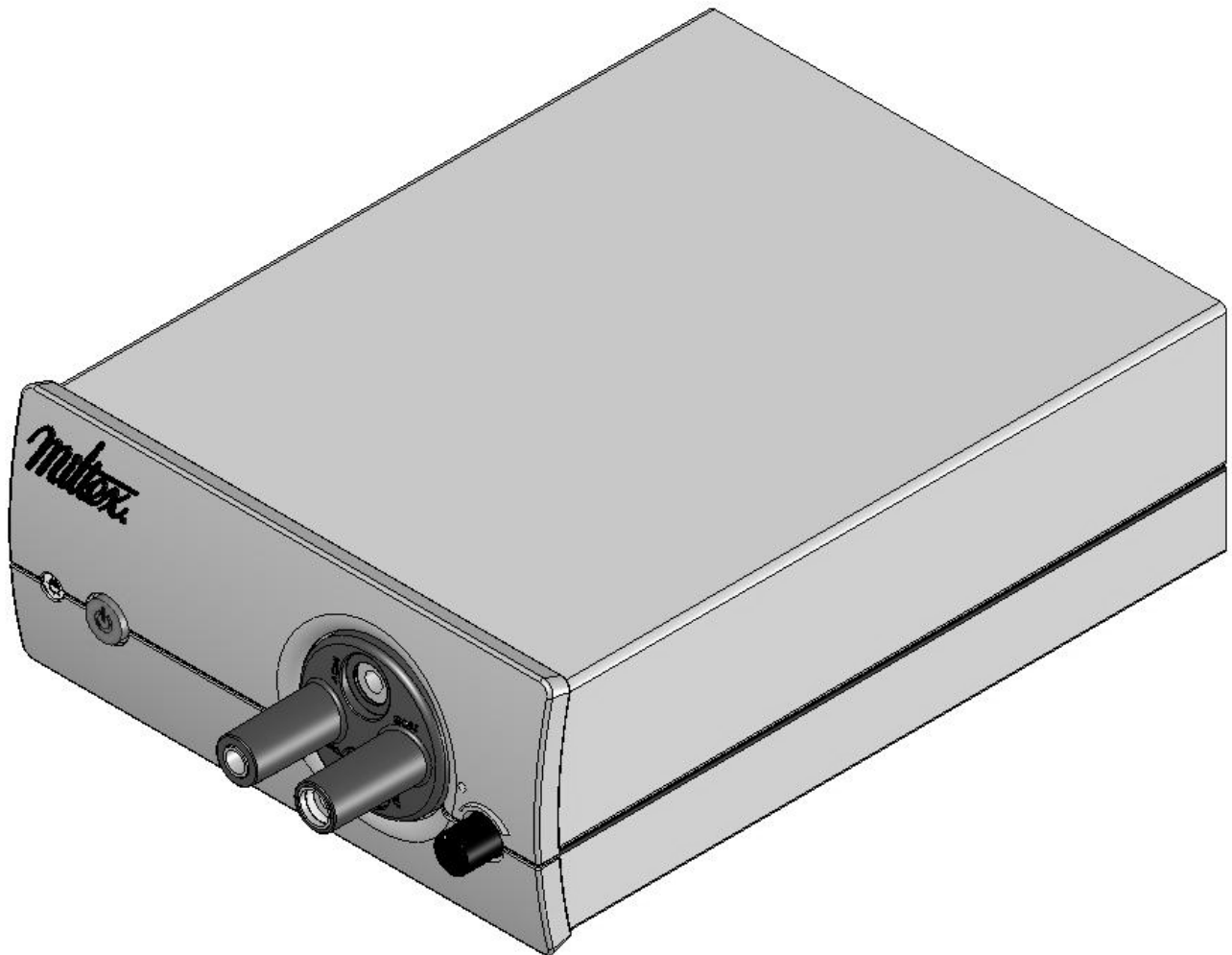


TABLE OF CONTENTS

Table of Symbols 1

General Warnings 2

Overview 3

Operation 4

Xenon Lamp Replacement 5-6

Attaching Floor Stand Bracket 7

Optional Floor Stand Installation 8

Equipment & Parts List 9

Troubleshooting / Maintenance and Cleaning 10

Specifications 11

Electromagnetic Compatibility (EMC) User Information 12-15













Product Warranty / Repair and Return..... 16

Returned Goods Policy / Product Information Disclosure 17

Declaration of Conformity 18

TABLE OF SYMBOLS

Found on Light Source

	Attention: Consult Accompanying Documents		Type CF Equipment		Stand-by
	High Voltage		Fuse		ETL listed
	High Temperature		“ON” (power)		CE marking of conformity (If applicable)
	Equipotentiality		“OFF” (power)		Lamp on indicator

GENERAL WARNINGS

FIRE HAZARD: Do Not drape or cover the light source while it is operating

EXPLOSION HAZARD: Do Not use in the presence of flammable anesthetics.

ELECTRIC SHOCK HAZARD: Do Not Open the light source if it is not functioning properly or if damage is apparent (such as case damage or loose screws). Refer to the Repair and Return Section of this Manual.

- The User of this equipment should carefully read the Users Manual and be familiar with the set-up, use, and care of the light source before using it. The instructions in the Users Manual should be followed carefully with special attention to warnings and control features on the light source. The Users Manual should be readily available to users and other appropriate personnel.
- Before each use ensure that the light source is not damaged and is operating properly. Ensure that cooling vents and fans are free of obstruction.
- This device is not intended to be used in areas with explosive gas concentrations in the area of use of high frequency endoscopically-used accessories.
- The light source generates high intensity light that can heat objects in its path. This light can cause flammable materials to burn or cause burns to skin. Prevent flammable materials from coming into close proximity with the output of the light source and light cable.
- The light emitted from the light source and the light cable can cause eye damage if viewed directly for more than momentary periods of time. This is also true for light emitted by endoscopic equipment and endoscopically-used accessories used with laser equipment. Do not look directly into any light that is emitted by the light source or the cable. Do not point the light cable at another person's eyes. For this reason this product must not be used in ocular surgery or in any surgical procedure requiring direct illumination of the eye.
- Avoid extreme heat or jarring of the light source to maintain the integrity of the Xenon lamp. Refer to the Xenon Lamp Replacement Section of this Manual when replacing the lamp or removing it for any reason.
- Follow the instructions of other manufacturers equipment when using them in conjunction with this light source.
- This product must be removed from the surgical field prior to use of a defibrillator.
- Before any service, disconnect the power cord from the main outlet.

Medical Electrical Equipment such as the EM-2151LS Light Source require special precautions regarding electromagnetic compatibility or EMC. These precautions are defined on pages 11 thru 14 of this Users Manual. The EM-2151LS Light Source must be installed and put into service according to the EMC information provided.

The leakage current of medical electrical devices can be additive. When using the EM-2151LS Light Source in combination with other medical electrical devices, such as endoscopes and/or endoscopy accessories, the leakage current should be verified to ensure it continues to meet requirements.

The EM-2151LS Light Source was verified as meeting the Type CF rating of IEC 60601-1. This turret is not intended for direct cardiac applications.

OVERVIEW

Indication for Use

This device is designed to supply high-intensity white light to a fiber optic cable for illumination of a surgical field or other area of examination or operation. The Light Source should never be used in ocular surgery or in a surgical procedure requiring direct illumination of the eye.

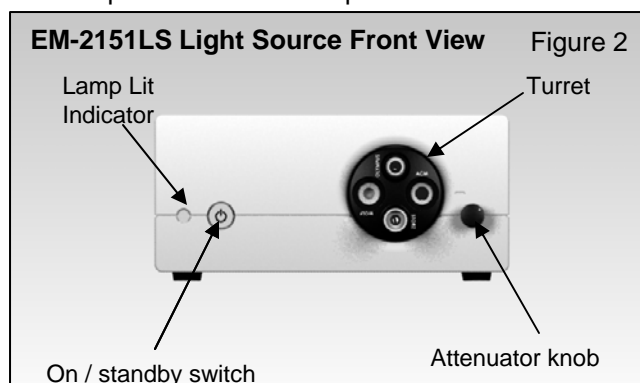
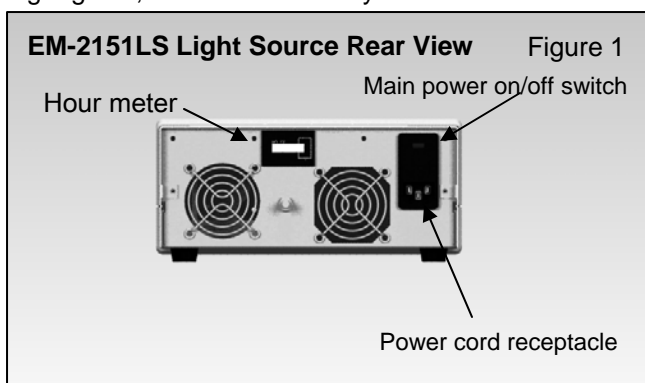
Basics

The EM-2151LS Light Source delivers white Xenon light. The lamp can be easily replaced by the user without special tools.

The rear panel, *main power on/off rocker switch*, is located on the back of the EM-2151LS Light Source . See Figure 1. The front panel push button, *on/standby switch*, is used to select lamp on or lamp standby. See Figure 2.

The intensity of the light output is controlled manually by rotating the attenuator knob, clockwise to increase intensity, counter-clockwise to decrease intensity.

The turret assembly consists of Wolf, ACMI, Storz and Olympus light guide ports. To select the proper port for your light guide, the turret assembly should be rotated to locate the desired port at the 3 o'clock position.



Inspection Before Use

The EM-2151LS Light Source comes with a hospital grade power cord. Please verify that both the light source and the power cord have been received undamaged.

All fiber optic light guides should be properly cleaned and sterilized prior to first time use. See light guide manufacturer's manual for information.

Warnings

FIRE HAZARD: DO NOT DRAPE OR COVER THE LIGHT SOURCE WHILE IT IS OPERATING.

Explosion Hazard: Do not use in the presence of flammable anesthetics, liquids, vapors, gases or dusts.

Electric shock hazard: If unit is not functioning properly, DO NOT OPEN.

Please refer to the Repair and Return Section of this Manual.

Use care not to point any light guide directly at the eye while operating the Light Source.

Keep cooling and fan vents free of obstructions.

Do not use or store liquids on or above the Light Source.

When Light Source is not in use, turn off the power switches on both the front and the back of the EM-2151LS Light Source.

Setting Up

Before turning power on, make sure the unit is plugged into any standard 100-120VAC or 200-240VAC 50/60Hz (as appropriate) three-conductor outlet. Grounding reliability is guaranteed only when connected to a "hospital grade" receptacle.

OPERATION

Controlling Lamp Operation

The main power on/off switch is used to power the unit on or off. See Figure 3.

The on / standby switch is used to select lamp on or lamp standby. See Figure 4.

The light source requires both the main power and the standby switches to be in the "on" state for the lamp to operate.

When the lamp starts operating, there is a brief clicking sound, which is normal. If the main power on/off switch is used to toggle lamp operation, leaving the standby switch in the "on" state, then there will be a short delay (3 or 4 seconds), after turning the main power switch to the "on" position, before the lamp will energize. This delay will not occur when the standby switch is used to control the lamp.

Note that if the light source is left in standby, with power applied, with the main power on/off switch in the "on" position and the on / standby switch in the standby state, the unit will consume a small amount of power and be slightly warm to the touch. This is normal and permits the lamp to quickly energize with the on / standby switch.

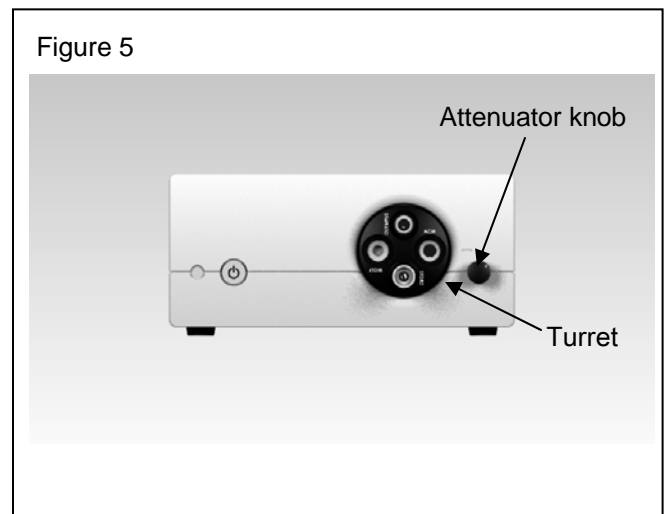
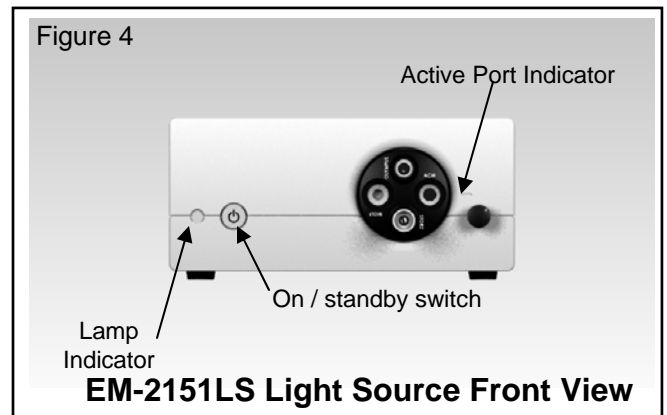
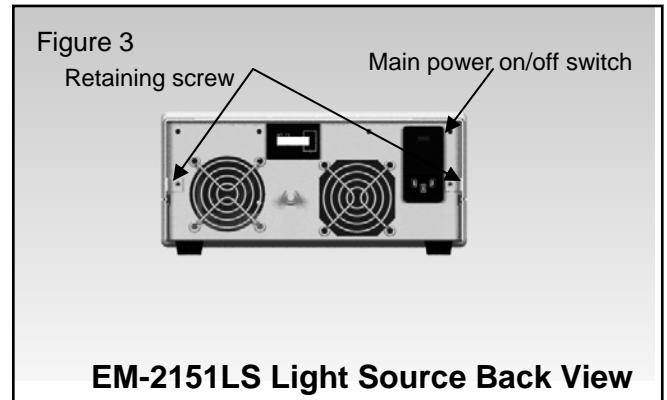
When the lamp is operating the lamp indicator will illuminate. See Figure 4.

Light Attenuation

The EM-2151LS Light Source has a manually operated light intensity knob to control the desired light output level. To increase the light output, rotate the knob clockwise until the desired level is reached. See Figure 5.

Turret Operation

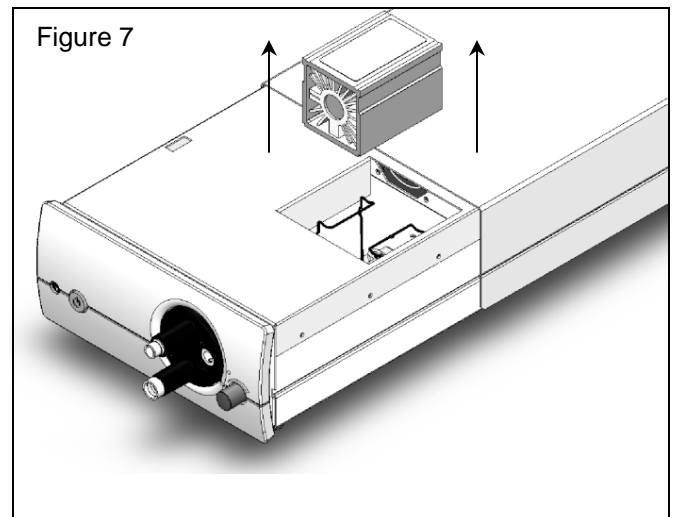
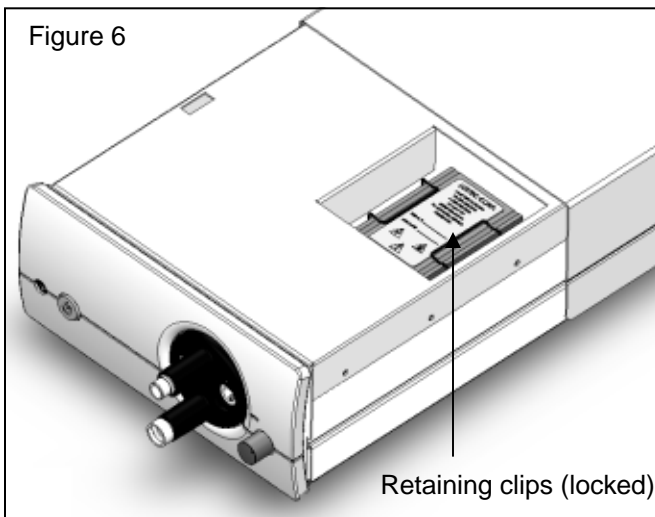
Rotate the Turret (Fig. 5) to select the appropriate port for your light guide. The turret has ports for Wolf, ACMI, Storz and Olympus light guides. The active port is at the 3 o'clock position.



XENON LAMP REPLACEMENT

Warnings:

Disconnect the light source from main power and allow the equipment to cool before handling the Xenon lamp. Use protective eye, face, and hand equipment when handling the Xenon lamp. *Please know that Xenon lamps have been known to explode. The chance of this happening when the lamp is handled properly is very low. The chance of injury if the lamp should explode are very high if the proper precautions are not taken. The chance of a lamp failure while the light source is not in operation is very rare. Each lamp is tested thoroughly during manufacture to ensure against failure.*



It is recommended that the Xenon lamp be replaced at 500 hours of usage. Lamp usage is monitored by the hour meter on the rear panel of the EM-2151LS Light Source. When replacing the lamp, the date and number of hours should be recorded to track the aging of the new lamp.

To remove the lamp:

1. Make sure the main power on/off switch is turned off. Disconnect the power cord.
2. Allow the unit to cool down for a minimum of 15 minutes before replacing the lamp. The lamp may represent a burn hazard if not allowed to cool sufficiently prior to servicing the unit and may increase the chance of explosion (see above warning).
3. Remove the retaining screws located on the back of the EM-2151LS Light Source. See Figure 3.
4. Slide the top cover of the EM-2151LS Light Source towards the back of the unit. Do not slide the cover off completely, rather just enough to remove and replace the lamp. See Figure 6. The cover also acts as a power interlock switch. Once the cover is removed the unit cannot be turned on. The cover must be replaced prior to turning the unit on.
5. Unlock the lamp retaining clips holding the lamp in the EM-2151LS Light Source. Grasp and pull the lamp straight up. See Figure 7.

XENON LAMP REPLACEMENT

To replace the lamp:

1. Orient lamp to face forward. See Figure 8. Lower lamp into the EM-2151LS Light Source with lamp against fan. See figure 9. The lamp receptacles must engage with lamp base plugs. Press firmly into place to seat lamp.

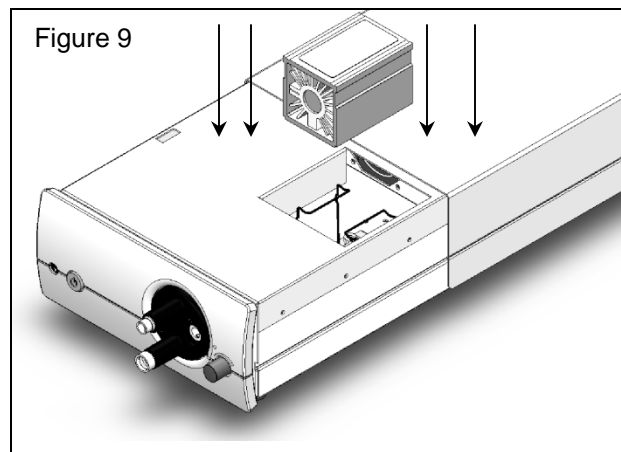
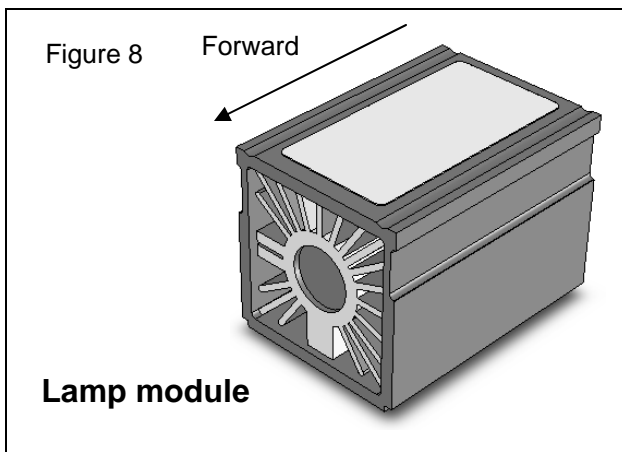
Note: Do not touch lamp glass window. Touching the lamp glass may lead to premature lamp failure.

2. Snap the lamp retainer clips, located on each side of the lamp, onto the top of the lamp. The lamp is now in a locked position. See Figure 6.

3. Fully slide the top cover of the EM-2151LS Light Source forward. Install the retaining screws (Figure 3) using a screwdriver.

4. Connect power cord to the back of the EM-2151LS Light Source. Set main power on/off switch to the "on" position, then press on / standby switch to turn the unit "on".

5. Verify the unit emits light.



Lamp disposal:

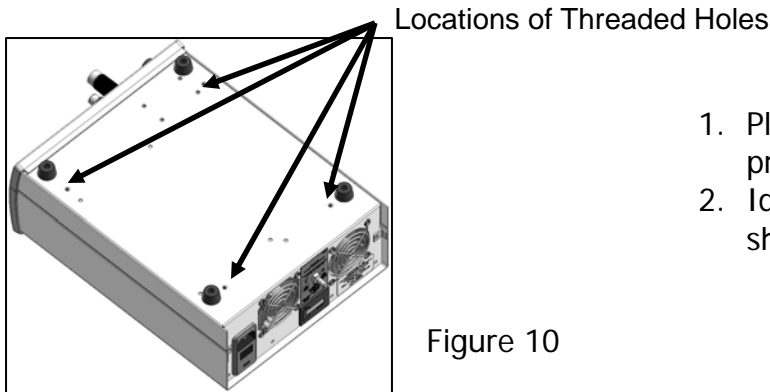
No disposal restrictions are known for the Xenon lamp. User should check and follow any applicable federal, state and/or local regulations.

To dispose of the Xenon lamps supplied by the manufacturer, break the fill tab to release any remaining gas and then dispose of the lamp (no environmental concerns are known at this time). Manufacturer supplied lamps are constructed entirely of metal, sapphire and ceramic. No organic (carbon-based) materials, mercury, rare-earth elements, or any other materials with known disposal requirements are used in the construction of manufacturer supplied lamps. The Xenon gas is an inert gas and is non-toxic.

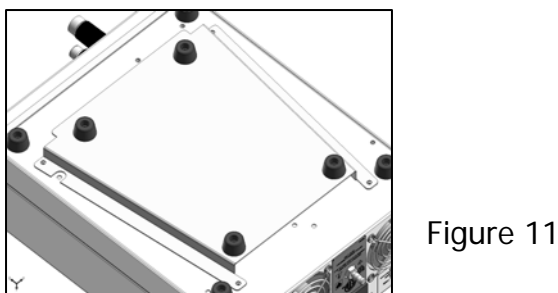
Attaching Floor Stand Bracket

Materials Required: EM-2151BRACK (EM-2151LS Light Source Floor Stand Mounting Bracket)

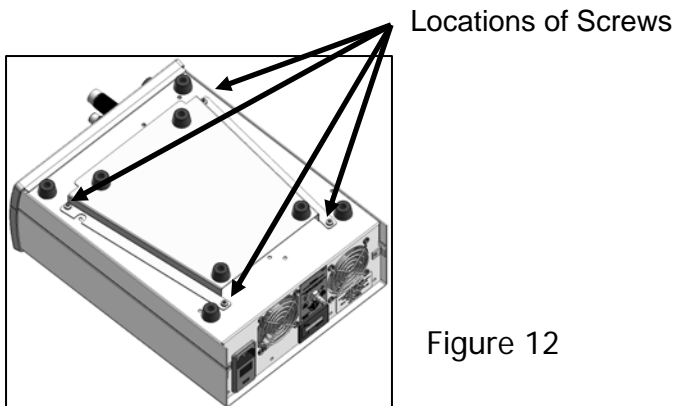
Tools Required: #2 Phillips Screwdriver



1. Place light source top side down on protected surface.
2. Identify four threaded holes as shown in Figure 10.



3. Place and orient floor stand bracket (EM-2151BRACK) as shown.
4. Verify all four threaded holes of light source are visible through holes in floor stand bracket



5. Thread supplied screws into threaded holes in light source.
6. Tighten using screwdriver until very snug.
7. Turn Light Source upright.
8. Assembly is complete.

OPTIONAL FLOOR STAND INSTALLATION

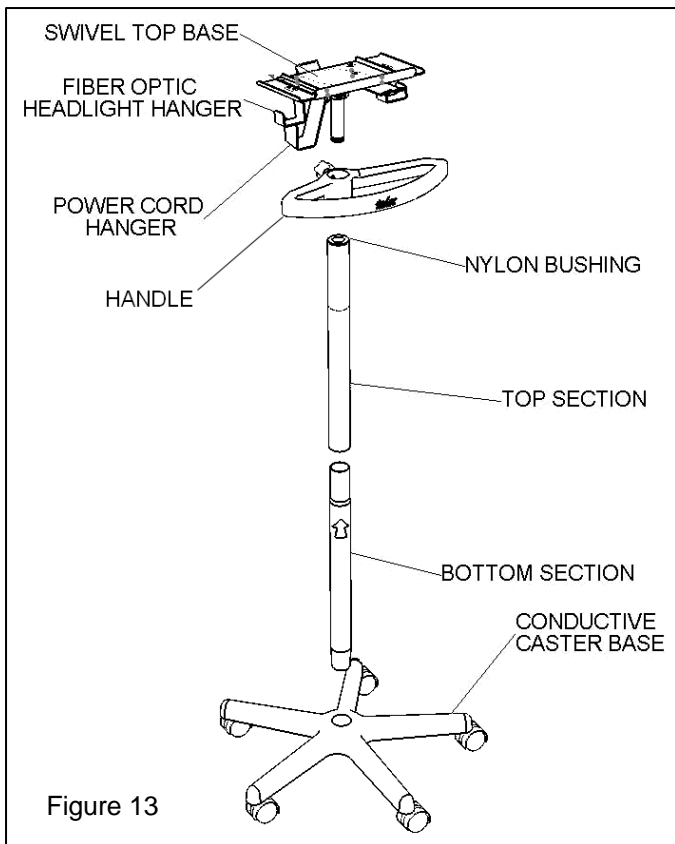


Figure 13

There are four (4) parts to the floor stand assembly:
See Figure 13.

1. Caster base
2. Two-piece column
3. Light source base with cable hangers
4. Handle

Floor stand assembly instructions:

1. Assemble the column. Note arrow on the lower column must point up. Slide the upper column over the arrow end of the lower column. Seat firmly.
2. Insert assembled column into base. Seat firmly.
3. Slide handle over top of column. Tighten Knob at desired height.
4. Fully insert post of the light source base plate into plastic bushing on top of upper column. The base should rotate freely within this bushing. Rotate to desired position.
5. Open the interlocking adapter on the swivel top base by pulling down on the plunger and sliding the lever to the "open" position as labeled. See Figure 14. The swivel top base is now ready to receive the Light Source.

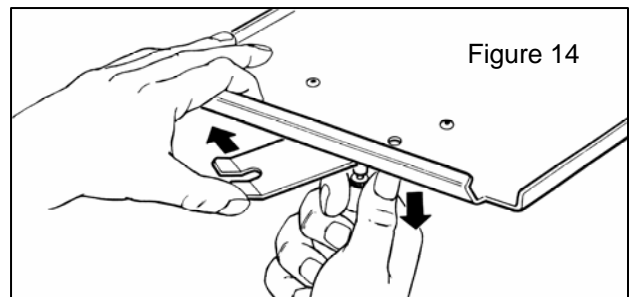


Figure 14

Installation to Floor Stand

1. Place Light Source on the floor stand base so the front edge of the floor stand bracket engages rim of the base. Verify that all rubber feet of the Light Source are positioned on the base and centered.
2. Slide the interlocking adapter plate to the lock position. The plate plunger will snap into the locked position as shown in Figure 15.
3. Check the rear of the Light Source to be sure the floorstand plate captures the support plate underneath the Light Source and is secure.

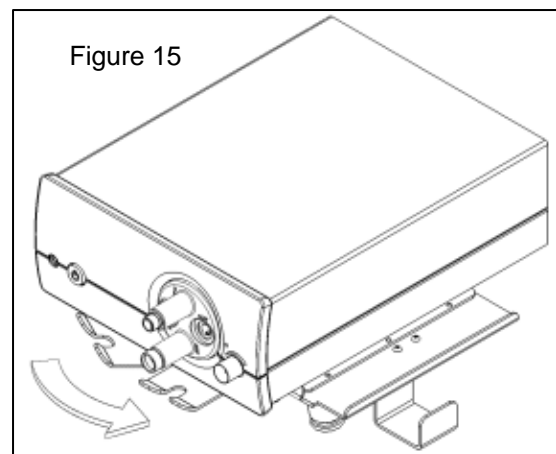


Figure 15

EQUIPMENT & PARTS LIST

To place an order, contact your local the manufacturer distributor or call the manufacturer Customer Service at 866-854-8300 (USA).

Light Source

EM-2151LS	EM-2151LS Light Source, Xenon
IFU-EM2151LS	User Manual for the EM-2151LS Light Source

Lamp

410417LX	150 Watt Lamp replacement module
----------	----------------------------------

Power Cords

601949-US6.1M	Hospital Grade USA Power Cord 20'
---------------	-----------------------------------

Other parts

EM-2151BRACK	EM-2151LS Light Source floor stand mounting bracket
EM-2151STAND	EM-2151LS Light Source floor stand
601919	Fuse, 3.15A 250VAC, 5x20mm, Slo-Blo IEC Standard

TROUBLESHOOTING

Problem	Cause	Action
No light output	Attenuator closed Both switches are not "on" Power not applied to the unit Blown fuse	Rotate attenuator clockwise Turn main power switch on/off and on/ standby switch "on" Ensure the power cord is connected to a live, hospital-grade, receptacle Replace fuse as indicated in maintenance section
No light output and unit is making clicking sound	Lamp is too old or is defective A lamp is not installed	Replace/Install lamp. See lamp replacement section of this user manual
Reduced light output	Attenuator mis-positioned Aged or defective lamp Instrument or fiber optic light guide is damaged	Rotate attenuator Replace lamp Check or replace faulty component
Unit feels warm when not on	Main power switch is on (Figure 3)	This is normal when main power switch is on and stand by switch is off
Enclosure is overheated	Possible fan failure	Return the unit (See Return and Repair section of this user manual)

MAINTENANCE AND CLEANING

Maintenance:

If the Light Source does not operate properly when connected to a grounded receptacle, disconnect the power cord and check the fuse (see below). Do not attempt to repair the unit if the lamp fails in use. Turn off the unit and allow it to cool for at least 15 minutes, then try to restart the unit. If the lamp still fails to illuminate, it may need to be replaced. If you still experience difficulties, return the unit to the Miltex or an authorized distributor for evaluation.

To replace the fuse:

The fuses for the Light Source are located in the power entry module in the rear of the unit. Remove the power cord from the unit. Using a small flat head screwdriver, pry out the plastic fuse holder from the power entry module. Check to see if the fuses are blown. If necessary, replace the fuse(s) with a new one of the same rating (Fuse 3.15A, 250VAC, 5x20 mm, Slo-Blo, IEC Standard, the manufacturer part number 601919). After replacing fuse(s), push the plastic fuse holder fully back into the power entry module until it snaps into place. Plug the cord back into Light Source and re-test the unit.

Cleaning:

Allow unit to cool for at least 15 minutes prior to cleaning.

The Light Source exterior can be cleaned and disinfected using 70% isopropyl alcohol. Unplug the power cord before cleaning. 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.

SPECIFICATIONS

Lamp

Type	Xenon Short Arc Lamp
Wattage	150 Watts
Lamp life	500 Hours

Light Source

Dimensions	14.0"L x 9.3"W x 4.3"H (356mm L x 236mm W x 110mm H)
Weight	12.2 lbs. (5.53kg)
Power Input	100-120VAC, 200-240VAC 50-60 Hz \pm 10%
Fuses (2)	3.15A, 250VAC, 5x20 mm, Slo-Blo, IEC Standard
Power Consumption	225 Watt nominal
AC Power Leakage	Leakage current to chassis (with ground wire intact), less than 100 micro amps Leakage current to chassis (with ground wire interrupted), less than 500 micro amps
Classification	Type CF, Class 1, IEC 60601-1
Conducted and radiated emissions	Class B, IEC 60601-1-2
PFC Conformance	Harmonics and Flicker IEC1000-3-2 and IEC61000-3-3
Environment:	
Storage	0°C - 50°C (32° - 122°F) 10-85% Relative Humidity Non-Condensing
Transport	0°C - 50°C (32° - 122°F) 10-85% Relative Humidity Non-Condensing
Operating	5°C – 40°C (41° - 104°F) 10-85% Relative Humidity Non-Condensing

Electromagnetic Compatibility (EMC) User Information

WARNING: Medical Electrical Equipment, such as the EM-2151LS Light Source, needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

WARNING: Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

WARNING: The EM-2151LS Light Source should not be used adjacent to or stacked with other equipment. If this becomes necessary the EM-2151LS Light Source should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The EMC tables and other guidelines below provide information to the customer or user that is essential in determining the suitability of the EM-2151LS Light Source for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the EM-2151LS Light Source to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.

Guidance and Manufacturer's Declaration – Emissions All Equipment and Systems		
The EM-2151LS Light Source is intended for use in the electromagnetic environment specified below. The customer or user of the EM-2151LS 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 EM-2151LS Light Source 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	The EM-2151LS Light Source 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.
Harmonics IEC 61000-3-2	Complies or Not applicable	Complies
Flicker IEC 61000-3-3	Complies or Not applicable	Complies

Electromagnetic Compatibility (EMC) User Information

Guidance and Manufacturer's Declaration—Immunity All Equipment and Systems			
The EM-2151LS Light Source is intended for use in the electromagnetic environment specified below. The customer or user of the EM-2151LS 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.
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.
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 EM-2151LS Light Source requires continued operation during power mains interruptions, it is recommended that the EM-2151LS Light Source be powered from an uninterruptible power supply or battery.
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.

Electromagnetic Compatibility (EMC) User Information

Please note: The EM-2151LS Light Source has been successfully tested to IEC 60601-2-25. The EM-2151LS Light Source was in the presence of an electrical-surgical generator, ESG, generating a field strength of between 18 and 23 V/m. During the testing the energized probes of the ESG were at a distance of 6" from the EM-2151LS Light Source and the ESG was energized in the cut and coagulate modes. The functioning of the EM-2151LS Light Source was not effected by exposure to this energy. The results of this testing are available from the Miltex.

Guidance and Manufacturer's Declaration – Emissions Equipment and Systems that are NOT Life-Supporting			
The EM-2151LS Light Source is intended for use in the electromagnetic environment specified below. The customer or user of the EM-2151LS Light Source should ensure 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 EM-2151LS Light Source by no less than the recommended separation distances calculated/listed below: $D = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 3V/m	$D = 1.17\sqrt{P}$ 80 to 800 MHz $D = 2.33\sqrt{P}$ 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.

Electromagnetic Compatibility (EMC) User Information

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the EM-2151LS Light Source Equipment and Systems that are NOT Life-Supporting			
The EM-2151LS Light Source is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the EM-2151LS Light Source can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the EM-2151LS Light Source as recommended below, according to the maximum output power of the communications equipment.			
Maximum Output Power (Watts)	Recommended Separation Distances for the EM-2151LS Light Source (meters)		
	150 kHz to 80 MHz	80 to 800MHz	800 MHz to 2.5 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$
0.01	0.12	0.12	.023
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

PRODUCT WARRANTY

Miltex Inc. warrants that the EM-2151LS Light Source (except the lamp) shall be free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of shipment from the Miltex. Miltex's sole and exclusive liability under the warranty shall be, at the manufacturer's option, either to repair or to replace 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 Miltex in writing,
2. If requested by the Miltex, customer returns equipment to Miltex with shipping charges prepaid and,
3. Upon inspection, the manufacturer finds the equipment to be defective.

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

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

Upon receipt of the product, it should be carefully inspected. If any defect is discovered, Miltex must be notified immediately.

REPAIR AND RETURN

This device must be clean of all blood or other organic material prior to returning to the Miltex. Miltex reserves the right to return un-repaired 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 Miltex distributor or call Miltex Customer Service at 866.854.8300 (US only) or 717.840.9335.

RETURNED GOODS POLICY

Products must be returned with proof of purchase and in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint or product defect. Determination of a product defect will be by Miltex. Products will not be accepted for replacement if they have been in the possession of the customer for more than 120 days.

PRODUCT INFORMATION DISCLOSURE

Miltex, Integra and manufacturer exclude all warranties, whether expressed or implied, including but not limited to, any implied warranties or merchantability or fitness for a particular purpose. Neither Miltex, Integra nor manufacturer shall be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Neither Miltex, Integra nor Manufacturer assume nor authorize any person to assume for them any other or additional liability of responsibility in connection with these products.

Information contained in this manual is subject to change without notice.

Manufactured for:
Miltex, Inc.
589 Davies Drive
York, PA 17402
toll free phone: 866.854.8300
phone: 717.840.9335
toll free fax: 866.854.8400
fax: 717.840.9347
www.miltex.com

Padgett and Miltex are registered trademarks of Integra LifeSciences Corporation. The Integra wave logo is a trademark of Integra LifeSciences Corporation. ©2006 Integra LifeSciences Corporation. All Rights Reserved.