

**LED Light Source for A-Series™
Microscopes**



Owner's/Service Manual



M A801-LED

When contacting Global Surgical Corporation for either Customer Service or Technical Service, it will be helpful if you have your **Customer Identification Number** and your **Customer Order Number** available. Please take a moment to record these numbers (printed on your invoice) in the spaces below.

Customer Identification Number: _____

Customer Order Number: _____



**3610 Tree Court Industrial Blvd.
St. Louis, MO 63122
1-800-861-3585
If outside the USA:1-636-861-3388**

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**Congratulations on your purchase of the
A-Series M A801-LED LED Light Source.
We truly appreciate your business,
and we're grateful for the trust you've placed in us.**

TABLE OF CONTENTS

Section 1 Important Safety Information	1-1
1.1 Symbol Definitions	1-1
1.2 Warnings and Cautions.....	1-2
 Section 2 Product Information	 2-1
2.1 Introduction.....	2-1
2.2 Specifications	2-2
2.3 M A801-LED LED Light Source Components.....	2-3
 Section 3 Operating Instructions	 3-1
3.1 Power ON/OFF	3-1
3.2 Brightness Settings and Memory	3-2
3.3 Filter:.....	3-2
3.4 Filter Lever	3-3
 Section 4 Installation Instructions	 4-1
4.1 Installation of the M A801-LED LED Light Source to the A-Series Microscope	4-1
4.1.1 Horizontal or 45° Arm Cover Removal.....	4-1
4.1.2 Spring Arm Cover Removal.....	4-2
4.1.3 Extension Arm Cover Removal	4-2
4.1.4 Installing the LED to Microscope.....	4-3
4.2 Installing Cables	4-3
4.2.1 Reinstalling the Extension Arm Cover	4-4
4.2.2 Reinstalling the Spring Arm Cover	4-4
4.2.3 Reinstalling Horizontal Arm Cover	4-4
4.2.4 Reinstalling 45° Arm Cover	4-4
 Section 5 Care and Maintenance	 5-1
5.1 Cleaning and Disinfecting	5-1
5.2 Maintenance.....	5-1
5.3 Storage Conditions	5-1
 Section 6 Troubleshooting	 6-1
6.1 Troubleshooting	6-1
 Section 7 Service and Warranty.....	 7-1
7.1 Warranty Information	7-1
7.2 Technical Services Department	7-2
 Section 8 Technical Information	 8-1

**WARNING**

THE SAFETY AND SATISFACTION OF OUR CUSTOMERS AND THEIR PATIENTS ARE THE HIGHEST PRIORITIES OF GLOBAL SURGICAL CORPORATION. THIS MANUAL CONTAINS IMPORTANT INFORMATION REGARDING THE SAFE AND PROPER USE OF THIS EQUIPMENT AND SHOULD BE READ THOROUGHLY BY ALL OPERATORS PRIOR TO THEIR FIRST USE OF THE EQUIPMENT. FAILURE TO READ AND UNDERSTAND THIS MATERIAL COULD RESULT IN INJURY TO PATIENTS OR PERSONNEL OR IN DAMAGE TO THE EQUIPMENT.

1.1 Symbol Definitions

This symbol on the product is an attention symbol, alerting the user to read the Owner's Manual for important installation, operating instructions or safety information.



This symbol on the product indicates a potential electrical shock hazard, and alerts the user to read the Owner's Manual for important safety information.



This symbol alerts the user that this product emits bright light.



This symbol indicates a surface that could be hot to the touch.



For Professional Use Only.



Intensity UP.



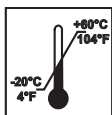
Intensity Down.



On/Off.



Symbol indicating "not for general waste." Recycle per the EUROPEAN WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) DIRECTIVE.



Storage Temperature

**WARNING**

This symbol indicates a situation in which incorrect handling through disregard of a warning might result in death or serious personal injury.

**CAUTION**

This symbol indicates a situation in which incorrect handling through disregard of a caution might result in personal injury or may result in damage to property.

**NOTE**

This symbol indicates a message to avoid property damage or additional information to help complete a procedure.

1.2 Warnings and Cautions

**WARNING**

DISCONNECT ALL ELECTRICAL POWER PRIOR TO CLEANING AND DISINFECTING. RISK OF ELECTRICAL SHOCK RESULTING IN DEATH OR INJURY IS POSSIBLE IF THE ELECTRICAL POWER IS NOT DISCONNECTED.

**WARNING**

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

**WARNING**

CONNECT ONLY THE ITEMS THAT HAVE BEEN SPECIFIED AS PART OF THE MEDICAL EQUIPMENT SYSTEM.

**WARNING**

THE USE OF POWER CORDS, POWER SUPPLY AND DC EXTENSION CABLE OTHER THAN THOSE INCLUDED WITH THE LED LIGHT SOURCE AND ILLUMINATION MODULE AND SUPPLIED BY GLOBAL SURGICAL CORPORATION MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE LED LIGHT SOURCE AND ILLUMINATION MODULE.

**WARNING**

THE LED LIGHT SOURCE SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT AND THAT IF ADJACENT OR STACKED USE IS NECESSARY, THE LED LIGHT SOURCE AND ILLUMINATION MODULE SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

**WARNING**

DO NOT STARE AT OPERATING LAMP. MAY BE HARMFUL TO THE EYES.

**WARNING**

HEAT SINK FINS MAY BECOME HOT TO TOUCH AFTER PROLONGED USE. DISCONNECT UNIT AND ALLOW UNIT TO COOL BEFORE HANDLING.

**WARNING**

SURFACE TEMPERATURE DURING USE CAN REACH 118°F (48°C).

**WARNING**

LIGHT SOURCE CAN CAUSE PERMANENT EYE DAMAGE IF VIEWED DIRECTLY WITH THE UNPROTECTED EYE. TO REDUCE THE CHANCE OF EYE DAMAGE, ALWAYS SET THE INTENSITY CONTROL TO THE MINIMUM LEVEL AND INSERT INTO THE MICROSCOPE BEFORE TURNING ON THE POWER.

**CAUTION**

Possibly hazardous optical radiation emitted from this product.

**CAUTION**

To prevent any potential electromagnetic interference, do not use any kind of cellular phone near the light source.

**CAUTION**

When used in clinical or residential areas near radio or TV units, this equipment may be subject to radio interference. To avoid adverse electromagnetic effects, do not operate this equipment near RF energy equipment.

**CAUTION**

It is highly recommended that the installation of this unit be performed by qualified personnel.

**CAUTION**

Do not block the heat sink fins of the light source. Overheating and possible equipment failure may occur.

**CAUTION**

Do not submerge the light source for cleaning and disinfecting

2.1 Introduction

This manual covers the installation and operation of the M A801-LED LED Light Source for use with the A-Series Microscope Systems. The M A801-LED LED Light Source is a high-efficiency light source utilizing state-of-the-art superior light emitting diode (LED) illumination technology.

The medical equipment system is made up of the M A801-LED LED Light Source, and Extension Cable.

Intended Use: The light source is intended to be installed on surgical microscopes that are manufactured by Global Surgical Corporation for the purpose of illuminating the area of interest. The illumination allows for visible observation and camera documentation. It is intended to be operated by trained medical professionals in surgical and dental operatories, examination rooms, offices and clinics, and it should be protected from unauthorized use.

Contraindications: The light source is not intended to be used as a curing light.

The frequently used functions include powering on/off and adjusting the brightness intensity.

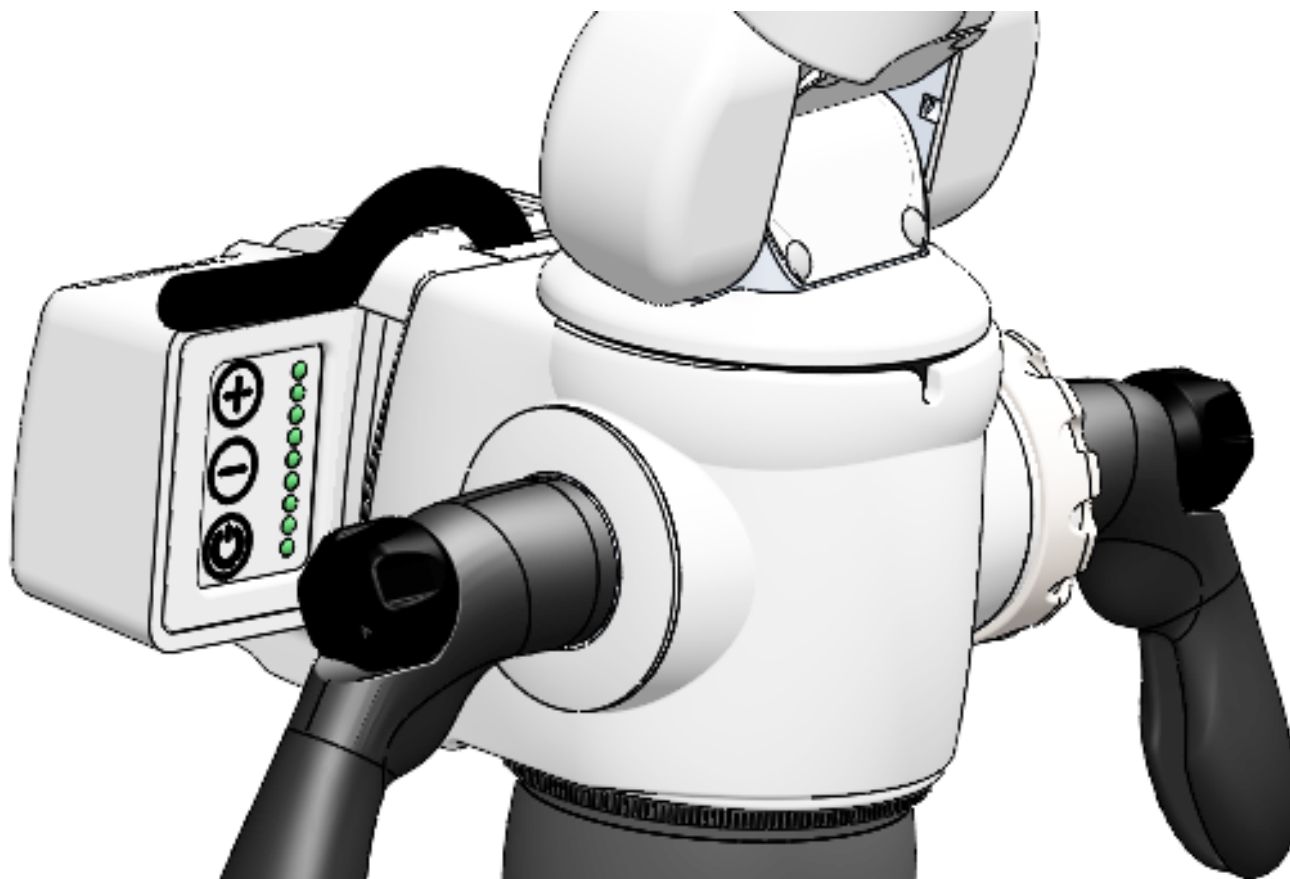


Figure 2-1 The M A801-LED LED Light Source

2.2 Specifications

Below lists the general specifications for the M 801-LED LED Light Source.

Table 2-1 Specifications

ITEM	SPECIFICATION
Light Source Type	Light Emitting Diode (LED)
Color Temperature	5500°K
LED Life	50,000 Hours (typical)
Brightness Control	Controls Light Output Range from 30%-100%
Power Consumption	25 Watts
Input Voltage	90-240 VAC, 50/60 Hz, 0.9A
Output Voltage	25-35 VDC,(Variable, Dependant on Brightness) Constant 0.70A
Mode of Operation	Continuous Operation
Water Resistant	Non-Protected Equipment, IPX0
Operation Environment: Temperature Relative Humidity Air Pressure	+10° to +40°C (50° to 104°F) 0 to 95% 700 to 1060 kPa
Storage Environment: Temperature Relative Humidity Air Pressure	-20° to +60°C (-4° to 140°F) 0 to 95% 700 to 1060 kPa
Dimensions	4.70 in (119 mm) W x 3.25 in (83 mm) H x 3.0 in (76 mm) D
Weight	1.65 lbs (74 kg 140g)
IEC 62471 Risk Group	0
Regulations / Standards	Conforms to AAMI Std ES60601-1 & IEC 60601-1-6 Certified to CSA Stds C22.2 #s 60601-1 & 60601-1-6 FCC 47CFR 15B 15.103 IEC 60601-2-57
Maximum Optical Radiation Output	118.2 Lx
Maximum Variation of Output	147 Lx
Spectral Irradiance	$3.7 \times 10^{-3} \frac{W}{M^2} @ 400nm, 3.23 \times 10^{-3} \frac{W}{M^2} @ 750nm, 3.32 \times 10^{-3} \frac{W}{M^2} @ 1000nm$

2.3 M A801-LED LED Light Source Components

1. Table 2-2 Lists the main components of the M A801-LED LED Light Source and See Figure 2-2 for the location of each component.

Table 2-2 M A800-LED LED Light Source Components

ITEM NO.	ITEM	FUNCTION
1	Power Input Cable	Power to the LED.
2	Intensity Control	Controls the light output range from 30% - 100%.
3	Power Switch	Turns the LED Light Source on and off.
4	Filter Lever	Allows Dental Composite Filter or Green Filter to be moved into place.
5	Light Level Indicator	Displays the intensity level of the LED. The number of lights displayed corresponds to the intensity level.

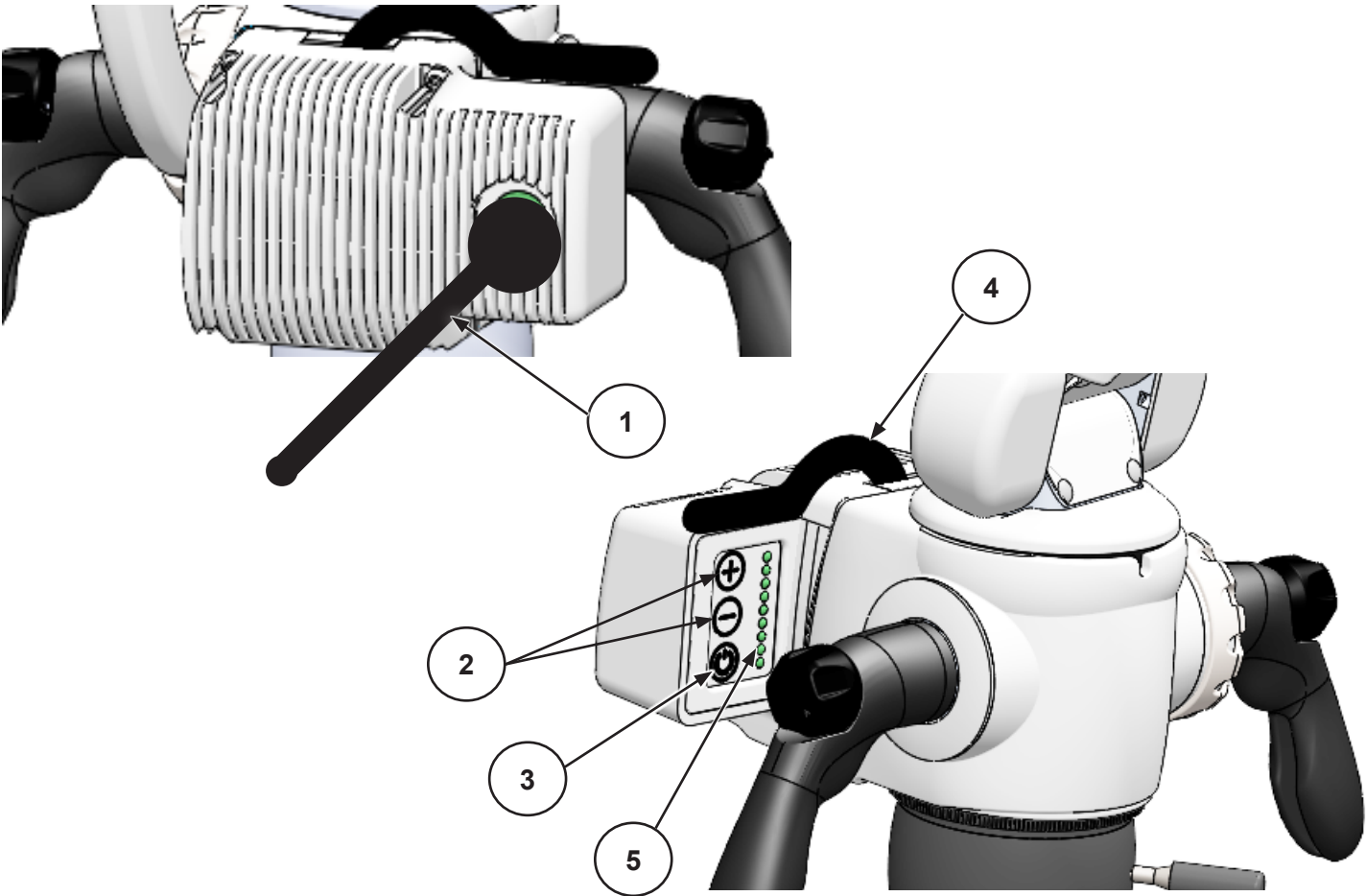


Figure 2-2 M A800-LED LED Light Source Components

2-3

3.1 Power ON/OFF

Plug in the system into a hospital grade earth-ground AC outlet. Turn power on to the system by depressing the LED power button. The green indicator light at the lowest setting will come on indicating that there is power to the system. When the LED power button is depressed again the lights will extinguish indicating that the power to the system is turned off. Depress the power button again and the LED will come on at the last intensity setting used.

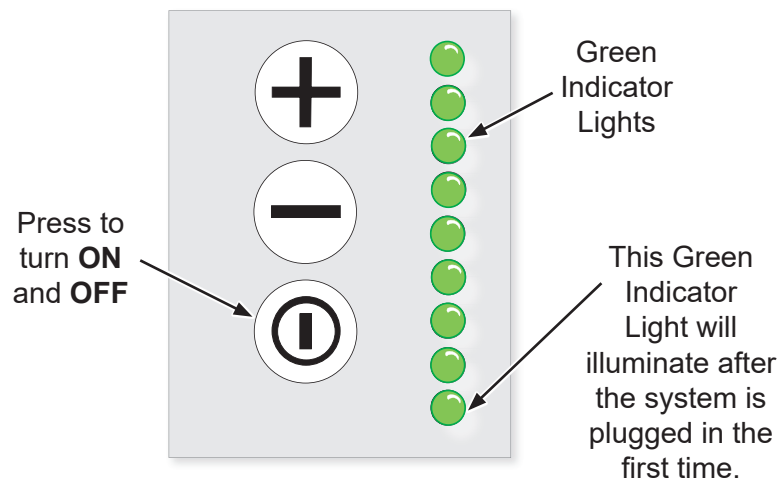


Figure 3-1 Power On/Off



WARNING SURFACE TEMPERATURES DURING USE CAN REACH 118°F (48°C)



WARNING HEAT SINK FINS MAY BECOME HOT TO TOUCH AFTER PROLONGED USE. DISCONNECT UNIT AND ALLOW UNIT TO COOL BEFORE HANDLING.



WARNING LIGHT SOURCE CAN CAUSE PERMANENT EYE DAMAGE IF VIEWED DIRECTLY WITH THE UNPROTECTED EYE. TO REDUCE THE CHANCE OF EYE DAMAGE, SET THE INTENSITY CONTROL ALWAYS TO THE MINIMUM LEVEL AND INSERT INTO THE MICROSCOPE BEFORE TURNING ON THE POWER



CAUTION When used in clinical or residential areas near radio or TV units, this equipment may be subjected to radio interference to avoid adverse electromagnetic effects, do not operate this equipment near RF energy equipment.



CAUTION To prevent any potential electromagnetic interference, do not use any kind of cellular phone near the light source



NOTE Use of tinted eye wear such as sunglasses is recommended for patients, assistants, etc. to reduce any visual discomfort associated with the use of the LED Light Source.

3.2 Brightness Settings and Memory

1. There are 9 levels of brightness which can be selected using the $\oplus$ and $\ominus$ buttons while the power is on. The level of brightness is indicated by the green indicator lights located on the keypad/control panel. An indicator light will light up for each increase in brightness. See Figure 3-2.
2. The $\oplus$ button is used to increase the brightness setting. Each press will increase the light source brightness. Any additional press of $\oplus$ will have no effect once the highest setting is reached.
3. The $\ominus$ button is used to decrease the brightness setting. Each press will decrease the light source brightness. Any additional press of $\ominus$ will have no effect once the lowest setting is reached.
4. Each button performs its intended function when the button is pressed. Holding a button has no effect. For example to increase the brightness from minimum to maximum, the user must press and release the $\oplus$ button 8 times. Pressing and holding the $\oplus$ button will only increase the brightness to the next higher setting.
5. The light source has a recall feature. This feature remembers the last level of brightness used before being powered off. Any time the light source is powered on, the brightness level will be at the last level used.

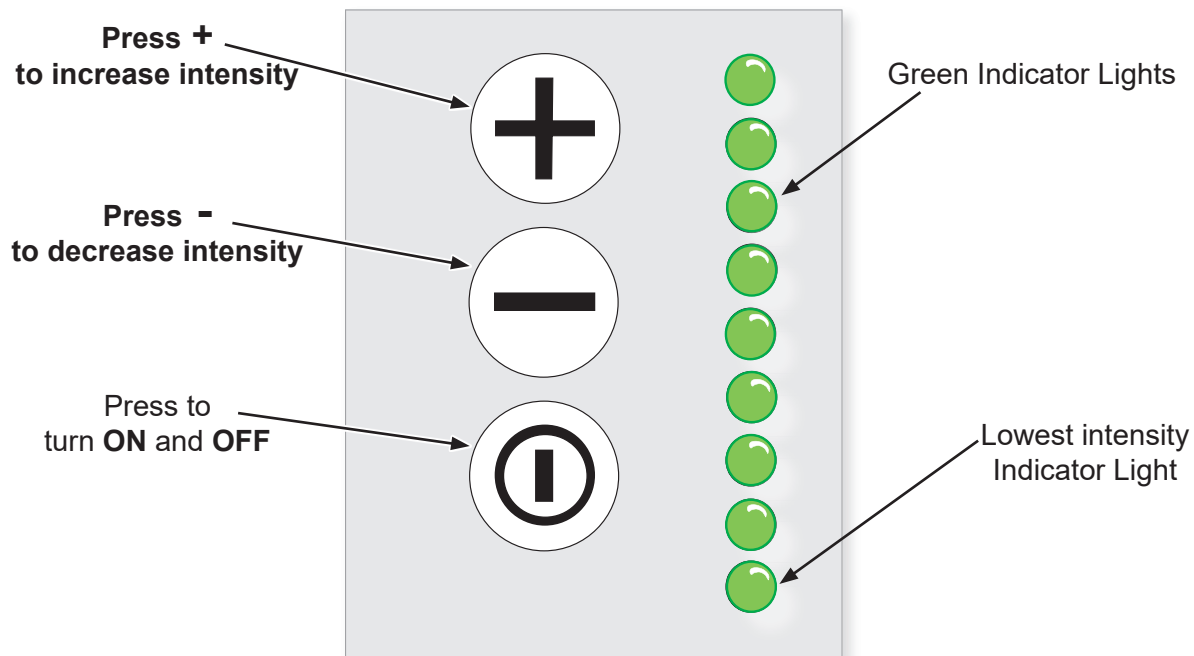


Figure 3-2 Adjusting the Intensity

3.3 Filter:

1. The LED Light Source emits white light, which includes all the colors of light combined in the visible light spectrum. Depending on what area of the patient is illuminated, a filter may be used to enhance the observation through the microscope. Global Surgical offers two kinds of filters: an amber filter (composite) and a green filter.
2. The use of the amber filter (composite) helps reduce the emissions of wavelengths below 520 nm (blue light) which are used to cure dental resins.
3. The use of the green filter provides a higher contrast of tissue by reducing the emissions of wavelengths around 650 nm (red light).

3.4 Filter Lever

1. Ensure the M A801-LED LED Light Source is plugged in and turn on the power switch. The filter lever can be positioned, DOWN for no filter, or in the CENTER for Amber Dental Composite Filter, and UP for the Green Filter. **See Figure 3-3**

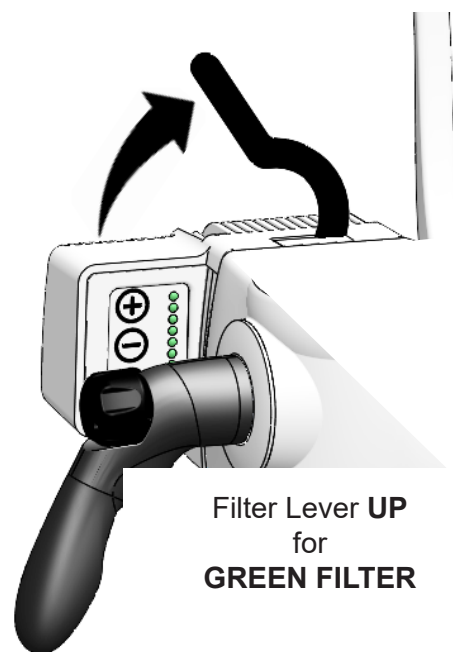
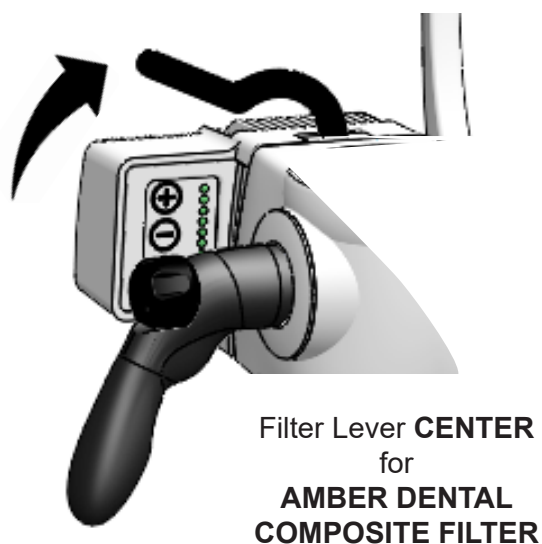


Figure 3-3 Adjusting the Filter
3-3

4.1 Installation of the M A801-LED LED Light Source to the A-Series Microscope

**WARNING**

IT IS HIGHLY RECOMMENDED THAT THE INSTALLATION OF THIS EQUIPMENT BE PERFORMED BY QUALIFIED TECHNICIANS. INSTALLATION BY UNQUALIFIED INDIVIDUALS COULD RESULT IN PERSONAL INJURY.

**WARNING**

CONNECT ONLY THE ITEMS THAT HAVE BEEN SPECIFIED AS PART OF THE MEDICAL EQUIPMENT SYSTEM.

**CAUTION**

It is recommended that eye protection be worn while performing the following procedure.

**CAUTION**

The edge of the spring arm cover may be sharp and could cut fingers.

4.1.1 Horizontal or 45° Arm Cover Removal

1. Using a #2 Phillips screwdriver, remove the machine screw securing the cover and remove the cover, as shown in Figure 4-1

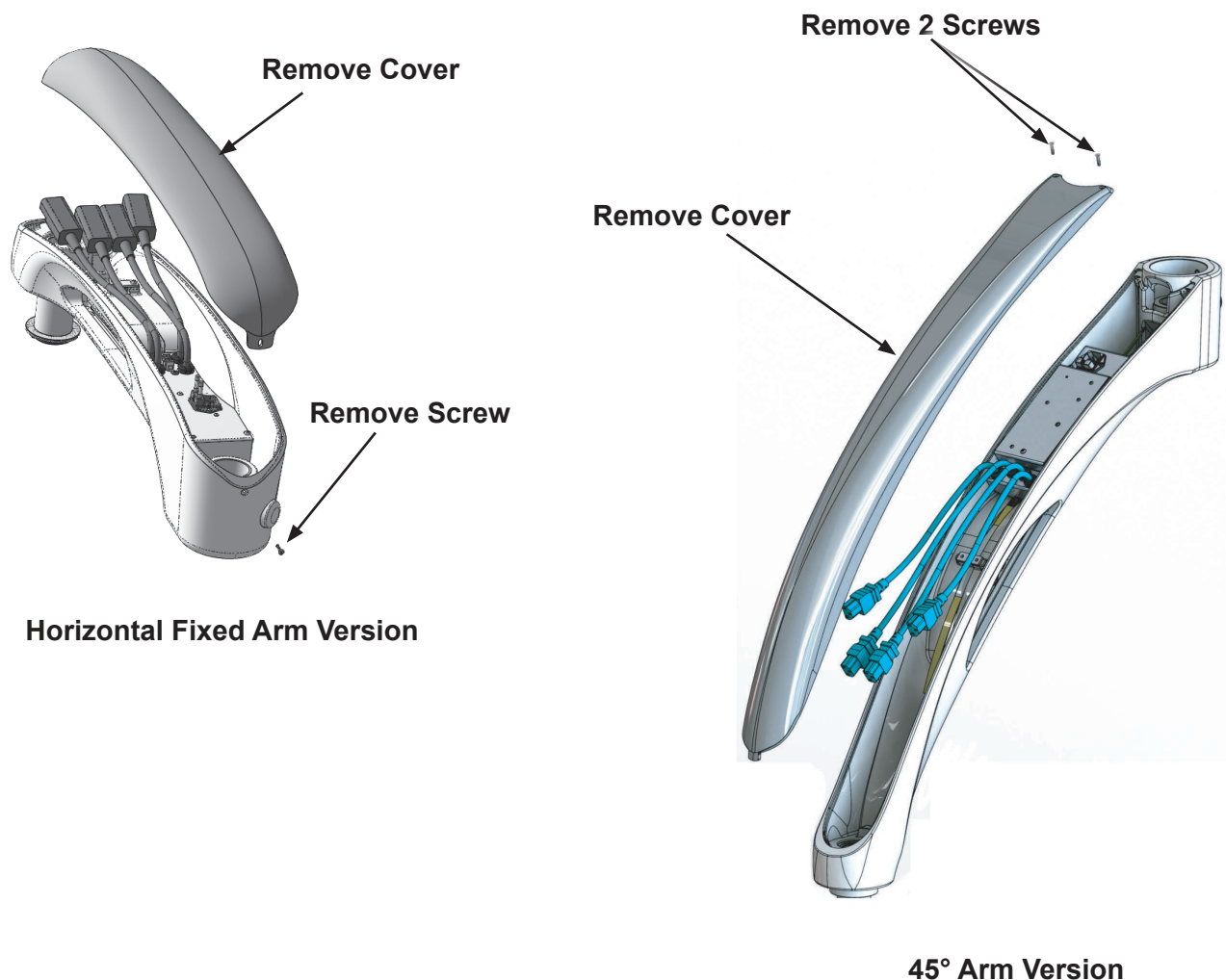


Figure 4-1. Removing the Horizontal and 45° Covers

4.1.2 Spring Arm Cover Removal

1. Secure the spring arm in the maximum upward position by tightening the tension and rotation tension knobs.
2. Using a small flat blade screwdriver, pry off the four (4) caps on both sides of the arm assembly.
3. Remove the four (4) Phillips head screws with a #2 Phillips screwdriver.
4. Grip the underside of the spring arm cover near the microscope end with your thumbs and lift upwards, guide the cover up and off of the spring arm.

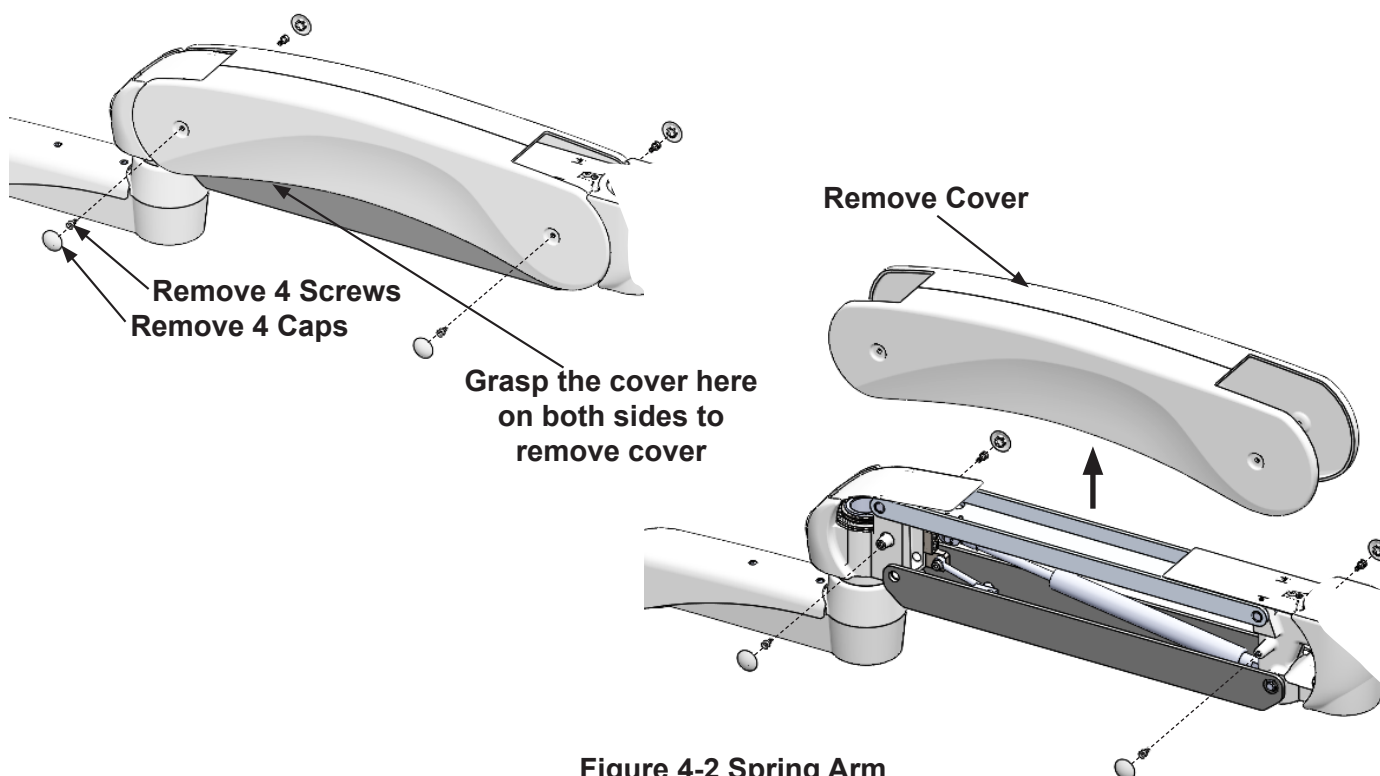


Figure 4-2 Spring Arm

4.1.3 Extension Arm Cover Removal

1. Rotate the extension arm 90 degrees to the spring arm and remove the machine screws from the top of the cover and lift up.

Remove 2 Screws

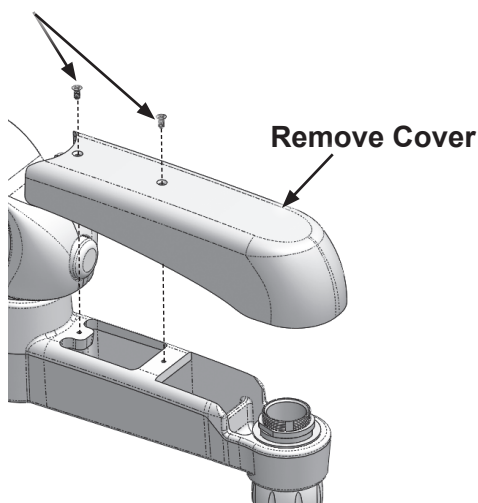


Figure 4-3 Extension Arm

NOTE Allow enough slack in the LED power cord to permit free movement of the microscope assembly and the horizontal/45 degree and spring arm assemblies.

4.1.4 Installing the LED to Microscope

1. Place the LED Light Source against the back of the microscope body so that the control panel is on the left side of the microscope and the filter lever is on the top.
2. Connect the LED to the microscope body using the 5/64" allen wrench to install the four (4) 6-32 button head screws (provided). **See Figure 4-4**
3. Route the LED power cord up into the bottom of the coupler arm and into the extension arm body.
4. Route the power cord through the spring arm and into the horizontal arm.
5. Connect the cable from the LED to the power supply module.

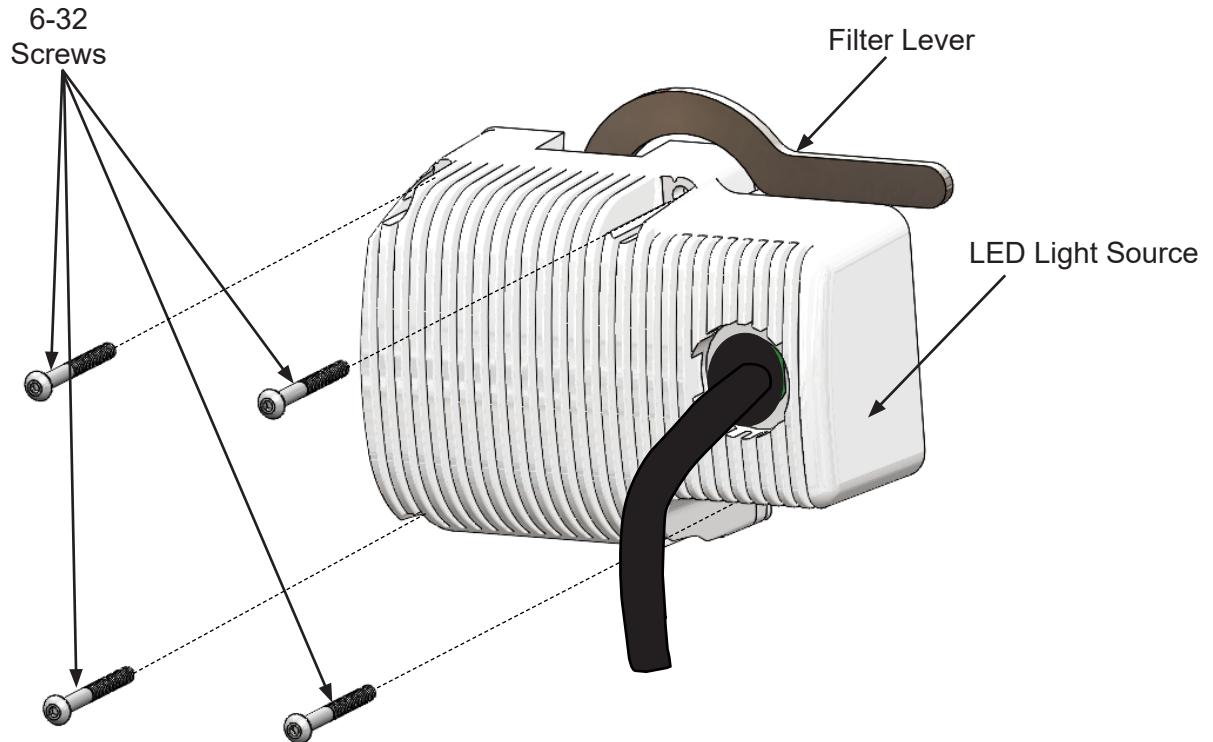


Figure 4-4 Installing the LED Light Source

4.2 Installing Cables

If it is necessary to add or replace a cable, complete the following steps.

1. Using a #2 Phillips screwdriver, remove the seven (7) screws (horizontal arm assy) and eight (8) (45 degree arm assembly) from the covers as shown. **See Figure 4-1, 4-2, and 4-3**

NOTE To access the spring arm screws, you first need to remove the four (4) covers by prying them off.

2. Gently lift off all the covers and set aside.
3. To remove the spring arm cover, the arm must be in a slightly upward orientation.

NOTE It maybe necessary to gently spread the spring arm cover apart from the bottom to remove it.

4. Route the cable through the arms, following the route of the installed wiring.
5. Once the cable is routed, carefully move the microscope to assure unobstructed movement.
6. Adjust cables as necessary and replace covers in reverse of the steps used to remove them.

4.2.1 Reinstalling the Extension Arm Cover

1. Reinstall the cover on the extension arm. Install the machine screws on the top of the cover.

4.2.2 Reinstalling the Spring Arm Cover

1. Reinstall the spring arm cover.
2. Install the four screws. Tighten securely with a #2 Phillips screwdriver.
3. Snap the four (4) white caps over the four (4) screws and press firmly to snap in place.

4.2.3 Reinstalling Horizontal Arm Cover

1. Place the plastic cover on the arm with the front tab in the slot.
2. Pivot the cover downward until it is firmly seated on the arm.
3. Reinstall the arm cover screw on the rear of the arm using a #2 Phillips screwdriver.

4.2.4 Reinstalling 45° Arm Cover

1. Place the plastic cover on the arm with the front tab in the slot.
2. Pivot the cover downward until it is firmly seated on the arm.
3. Reinstall the screws on the rear of the arm using a #2 Phillips screwdriver.

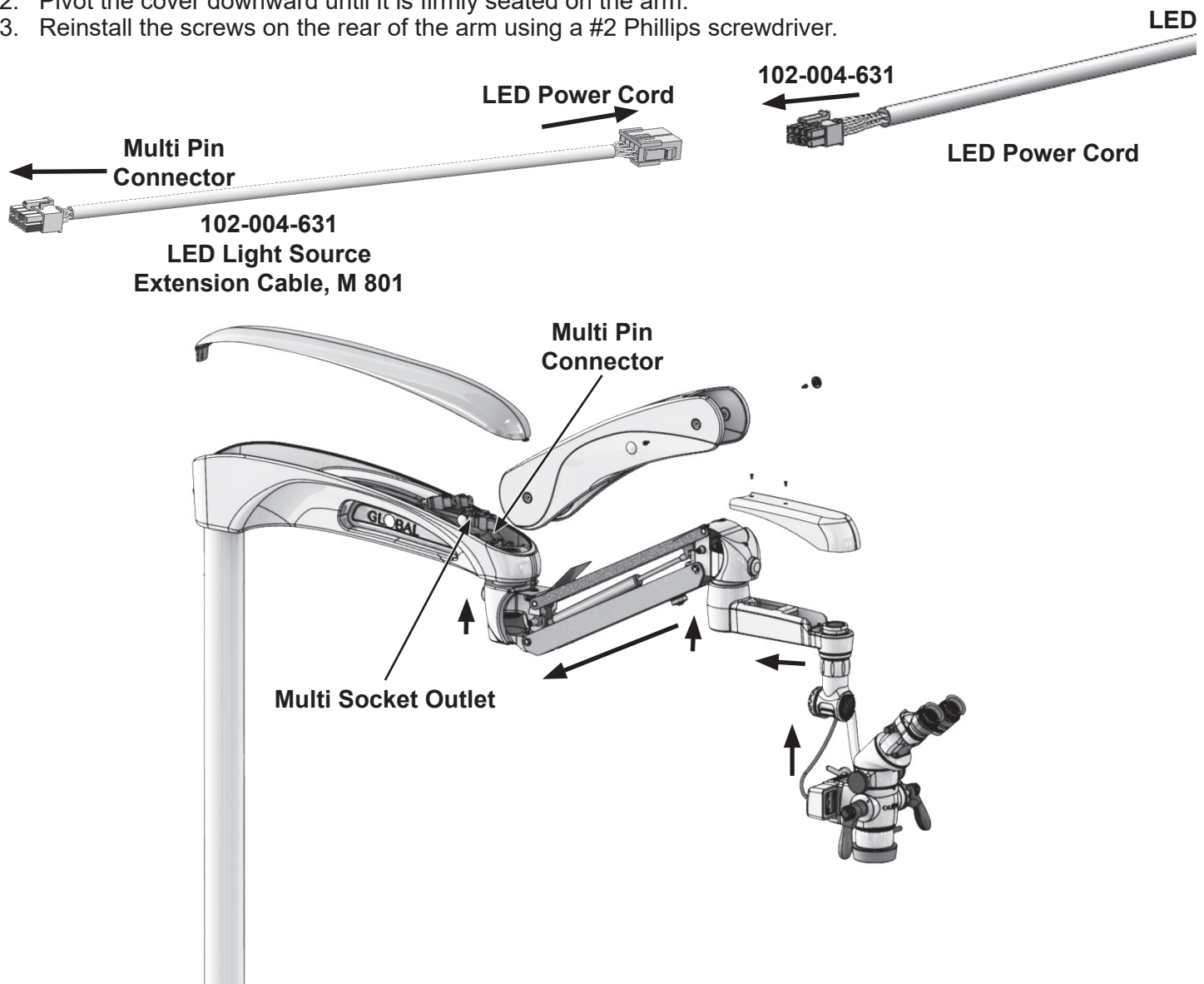


Figure 4-5 Routing the Cable

**WARNING**

DISCONNECT ALL ELECTRICAL POWER PRIOR TO CLEANING AND DISINFECTING. RISK OF ELECTRICAL SHOCK RESULTING IN DEATH OR INJURY IS POSSIBLE IF THE ELECTRICAL POWER IS NOT DISCONNECTED.

**CAUTION**

Do not submerge the light source for cleaning and disinfecting.

**NOTE**

Clean and disinfect after every patient according to CDC and OSHA requirements for non-critical devices.

5.1 Cleaning and Disinfecting

See the M A730 Series Surgical Operating Microscope System Owner's Manual, (110-013-079) Section 6 for cleaning and disinfecting instructions.

5.2 Maintenance

This product has no serviceable parts inside. Do not attempt to open the power unit. Preventive maintenance of the LED light source is not essential and will not affect the performance of the product.

5.3 Storage Conditions

The LED Light source should be stored in a normal medical office environment with 68-77°F (20-25°C) temperatures and relative humidity approximately 50% to reduce the possibility of damage to the LED. It is also recommended to cover the LED to keep dust and other debris off of the unit. If possible, the original packaging or other protective padding should be used to protect the unit from physical damage when stored before installation.

 **CAUTION** The LED Light Source should be returned to Global Surgical for service.

6.1 Troubleshooting

Table 6-1 (below) lists some symptoms, possible causes, and solutions

Table 6-1 Troubleshooting Guide

Symptoms	Solutions
No Power to the system	Ensure that the AC power cord is properly connected.
	Verify building circuit breaker is not tripped, or that another device works in the same outlet.
	Check the systems fuses. If necessary, replace. Replace both fuses if either is blown. See the M A730 Surgical Operating Microscope System Owner's Manual (110-013-079) for fuse replacement instructions.
LED Light Source does not turn on.	Remove horizontal arm, spring, 45 degree, extension cover, check for damaged or pinched cable.
	Ensure filter wheel is located at one of the three correct positions.
	Ensure the LED extension cable is properly connected to the LED cable, and to the multi-socket outlet.
For all other issues not covered above	Call Global Surgical Technical Support See Section 7.2 for contact information.

7.1 Warranty Information

Global Surgical™ Corporation warranty information is located at:

<http://www.globalsurgical.com/Home/Warranty.html>

90-Day Money-back Guarantee on Microscopes and Accessories

The microscope and microscope accessories you purchase will be unconditionally guaranteed and risk-free. You may return a product to Global in good condition for any reason within 90 days of invoice and receive a full product refund. Custom microscope parts are excluded from this policy.

Microscope Limited Lifetime Warranty

Your microscope will include an unprecedented lifetime warranty, including parts and labor, for all optical and support components. Please refer to detailed Limited Lifetime Warranty below.

Upgradeable

We will continue to do our best to design our microscopes to be modular and upgradeable, thus greatly minimizing the possibility of obsolescence.

Microscope Limited Lifetime Warranty

Except as set forth in this Limited Lifetime Warranty, Global Surgical Corporation (the "Company") hereby warrants that each microscope product manufactured and sold by the company ("Product") shall be free from defects in materials and workmanship under normal use and service for the life of the Product. This warranty is non-transferable and is valid only with respect to the original purchase of the Product. The Company's obligation under this warranty shall be limited to repairing or replacing, at the Company's facility and at the Company's expense, any parts of components that are demonstrated to be defective. The purchaser shall be responsible for shipment of the Product to and from the Company's facility at 3610 Tree Court Industrial Boulevard, St. Louis, Missouri, 63122, Attention: Technical Service, or such other facility as the Company may otherwise designate. Under certain circumstances which are pre-approved by the Company, necessary repairs may be made at the purchaser's facility.

A return authorization is required before returning any Product for warranty service by calling 1-800-861-3610. The customer is responsible for all shipping expenses. Global Surgical suggests using a method that will allow you to track the package in the event it does not arrive. Global also recommends you insure the package.

This warranty shall not be applicable to: (I) any electrically-driven products sold by the Company, (II) any products which are not manufactured by the Company which may be attached to the Product, such as video equipment, camera equipment, recording devices, monitors, printers (III) any components which are consumable or are required to be replaced or disposed of in connection with normal use of the Product, such as lamps, fiber optic cables, rubber eyecups and drapes, or (IV) any product which was purchased prior to April 27, 1994.

This warranty shall be void and of no effect: (I) if the Product is damaged due to misuse, use in a manner other than pursuant to the instructions for the use of Product, abuse, physical mishandling or natural causes such as flood, fire, earthquake, or other perils, as determined by the Company, or (II) if any repairs or replacements are made by persons not authorized by the Company to perform such services.

The warranties set forth herein are in lieu of any and all other warranties, expressed or implied, including, without limitation, warranties of merchantability and fitness for a particular purpose. Purchaser's rights thereunder are granted in lieu of any other rights purchaser may have and purchaser hereby waives all other rights, warranties, remedies or guarantees whatsoever with respect to the product. The Company shall not be liable for any third parties with respect to the product or its performance. Further, the Company shall not be liable for, and purchaser hereby releases the Company from any direct, or indirect, consequential, special, and incidental or punitive damages with respect to the product. In no event shall the Company be liable for any breach of warranty or other claim in an amount exceeding the purchase price of the product.

Warranty for Microscope products not included in the Limited Lifetime Warranty:

Electrical and electronic components, except for the LED lightsource, have a one-year warranty. The LED lightsource has a three-year warranty.

Consumables such as fiber optic cables, eyecups etc., have a one-year warranty. Light bulbs have a warranty equal to that given by the manufacturer.

This warranty applies to the U.S. and Canada only.

For International warranty information: Email: international@globalsurgical.com

Phone: 1-636-861-3388, Fax: 1-636-861-2969

7.2 Technical Services Department

When contacting our Technical Support Department, you will be served by highly knowledgeable representatives in an efficient manner. If service is required at your location, a skilled technician will be dispatched within 24 hours.

If you have questions that are not covered in this manual, please call the Global Surgical Technical Services Department as listed below:

Toll Free Number: 1-800-861-3610

Technical Services Representatives: 1-636-861-3388

Fax Number: 1-636-861-5284

Email: techservice@globalsurgical.com

The staffing hours for the Global Surgical Technical Services Department are Monday through Friday from 8:00 am to 5:00 pm Central Standard Time.

Internet Access

The Global Surgical Technical Services web site has information about additional products and services and can be reached online at: <http://www.globalsurgical.com>.

Service Information

In the event of any malfunction, you should immediately contact the Global Surgical Technical Services Department for assistance. A **Customer Identification Number** and **Customer Order Number** will be needed when contacting the Technical Services Department. These numbers are printed on your invoice. To save time in the event service is needed, record these numbers in the spaces provided in the front of this manual.

A **Return Material Authorization (RMA) number** must be obtained from the Global Surgical Technical Services Department prior to returning a product for repair. The following information must accompany all returned units:

1. Your name, address and telephone number
2. The RMA number
3. A description of the problem

Ship or return the product to:

Global Surgical Corporation
3610 Tree Court Industrial Blvd.
St. Louis, MO 63122
Attention: Technical Services Department

Appendix A

Guidance and manufacturer's declaration

Appendix A-1 Electromagnetic emissions

Appendix A-2 Electromagnetic immunity

Appendix A-3 Recommended separation distances between portable and mobile RF communications equipment and the M A801 LED Light Source

WARNING

THE USE OF POWER CORD AND PLUG OTHER THAN THOSE INCLUDED WITH THE M A801-LED LED LIGHT SOURCE SUPPORT SYSTEM AND SUPPLIED BY GLOBAL SURGICAL CORPORATION MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE M A801-LED LED LIGHT SOURCE.

WARNING

THE M A801-LED LED LIGHT SOURCE SHOULD NOT BE USED ADJACENT OR STACKED WITH OTHER EQUIPMENT AND IF ADJACENT OR STACKED USE IS NECESSARY, IT SHOULD BE VERIFIED THAT THE M A801-LED LED LIGHT SOURCE OPERATES NORMALLY IN THE CONFIGURATION IN WHICH IT WILL BE USED.

CAUTION

When used in clinical or residential areas near radio or TV units, this equipment may be subjected to radio interference. To avoid adverse electromagnetic effects, do not operate this equipment near RF energy equipment.

CAUTION

To prevent any potential electromagnetic interference, do not use any kind of cellular phone near the equipment.

CAUTION

This equipment needs special precautions regarding EMC (Electromagnetic Compatibility) and needs to be installed and put into service according to the EMC information provided in Appendix A of this manual.

CAUTION

Replacement parts, such as cables, must be purchased through Global Surgical Corporation to ensure proper compliance requirements. The use of other cables may affect EMC performance. Unauthorized use of these items will void warranty and may cause injury to you, others and/or the equipment.

CAUTION

Portable and mobile RF communications equipment can affect medical electrical equipment.

Appendix A-1

Guidance and manufacturer's declaration – electromagnetic emissions		
The M A801-LED LED Light Source is intended for use in the electromagnetic environment specified below. The customer or the user of the M A801-LED LED Light Source should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The M A801-LED LED 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 A	The M A801-LED LED Light Source is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	Warning: This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating M A801-LED LED Light Source or shielding the location.

Appendix A-2

Guidance and manufacturer's declaration – electromagnetic immunity			
The M A801-LED LED Light Source is intended for use in the electromagnetic environment specified below. The customer or the user of the M A801-LED LED 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ ($>95\%$ dip in U_T) for 0,5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 s	$<5\% U_T$ ($>95\%$ dip in U_T) for 0,5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the M A801-LED LED Light Source requires continued operation during power mains interruptions, it is recommended that the M A801-LED LED Light Source be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Appendix A-2

Guidance and manufacturer's declaration – electromagnetic immunity

The M A801-LED LED Light Source is intended for use in the electromagnetic environment specified below. The customer or the user of the M A801-LED LED 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communication equipment should be used no closer to any part of the M A801-LED LED Light Source, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.3 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 

Appendix A-2

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the M A801-LED LED Light Source is used exceeds the applicable RF compliance level above, the M A801-LED LED Light Source should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the M A801-LED LED Light Source.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Appendix A-3

Recommended separation distances between portable and mobile RF communications equipment and them M A801-LED LED Light Source.

The M A801-LED LED Light Source is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the M A801-LED LED Light Source can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and M A801-LED LED Light Source as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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