

This device is covered under US Patents issued and pending.

Handheld LED Light Source (HLS) Operator's Manual

Sales and Service by:

Myriad Fiber Imaging
56 Southbridge Road
Dudley, MA 01571 USA
USA Tel: +1.508.949.3000

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WARNING: This device is not supplied sterile. Clean and disinfect the device prior to use by employing the procedure listed in this manual.



WARNING: This equipment is not suitable for use in the presence of flammable mixtures.



WARNING: the following methods of disinfection will result in damage to the light source and should not be used: Ethylene Oxide, autoclave, ultrasonic, chlorides, formaldehyde, and hydrogen peroxide.



WARNING: In order to avoid potential safety hazards, the user of this device should consult the manuals of all Electrical Equipment used in conjunction with this device. If this device is used with High Frequency Equipment, the attached endoscope should be approved for use with High Frequency Equipment, and the user should consult the manuals of all devices for safe operating voltage levels.

1. Introduction

Summary

The Myriad Handheld Light Source (HLS) provides superior LED illumination for endoscopes, borescopes, video scopes, veterinary and dental examination applications. Patent pending optics collect more light from the LED, for a highly efficient light source. The Myriad HLS replaces fiber-optic light-guide cables or wires common to traditional light sources of the past. Enhanced mobility, ease of use, brightness and quality of light are achieved with this device. It uses a powerful, best-in-class LED, cooled by a comfortable, finned handle. An easy to grip intensity knob provides precise adjustments of light output and a quick-change battery. Internal circuitry protects against accidental reverse polarity, should the battery be inserted in the wrong orientation, and maintains constant current to the LED as the battery voltage drops with use, for more consistent light output. A long life LED eliminates lamp replacement and requires no fan, providing a silent and energy efficient light source which is lightweight, compact and portable.

Please be sure to handle this optical instrument with care at all times. The electrical and optical components can be damaged by physical abuse, extreme temperatures, or fluid invasion into the light source.



IMPORTANT: This instrument is intended for use by persons thoroughly trained in the techniques that employ this light source, such as endoscopy.



WARNING: Avoid direct viewing of the high intensity light at the front of the Handheld Light Source. Always connect and disconnect the light source with the light turned off.

This manual describes the proper procedures for using the light source. The manual also contains pertinent information on the proper care and handling of the light source during use, disinfection and storage.

Please read this entire manual carefully before using the light source. If you have any questions concerning the material contained in this manual or the operation or safety of the equipment, please contact Myriad.

Safety Measures

- Never look directly into the light source when it is on. Point its light away from others.
- Read this Owner's Manual first. Improper use may damage the light source.
- Check all items upon receipt to assure damage has not occurred during shipment.
- Verify compatibility of all scopes and accessories attaching to the HLS by contacting Myriad.
- Avoid storing or charging the HLS in areas of heavy traffic to prevent accidental physical damage.
- Do not disassemble the HLS. There are no user-serviceable parts. Disassembly voids all warranties.
- Avoid immersing the light source for periods of time greater than recommended by the disinfectant manufacturer. Prolonged immersion may damage the exterior of the light source and could result in fluid invasion into the light source.
- Prior to use, check the outer surface of the light source, endoscope and any endoscopically-used accessories for rough surfaces, sharp edges, burrs or protrusions that may cause a safety hazard.

2. HLS Features, Specifications & Accessories

Light Source Features

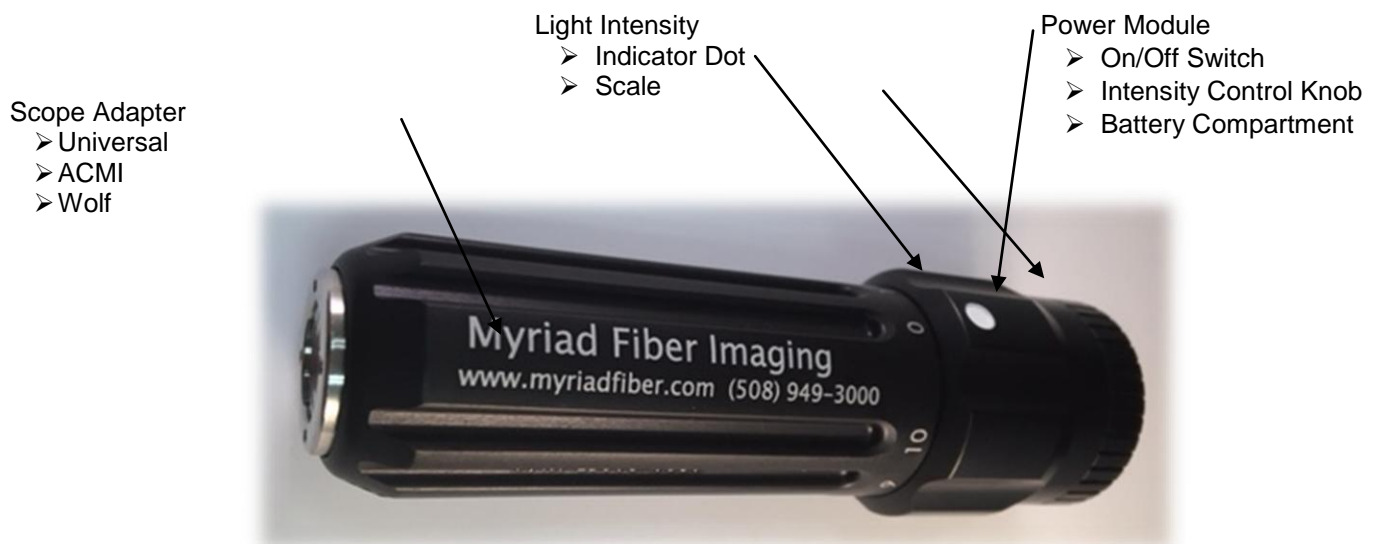


Figure 1. Handheld Light Source Diagram

Scope Adapter: Specified at time of purchase, the Scope Adapter allows the Handheld Light Source to attach to the user's endoscope. Three configurations of the Myriad HLS are available:

- *Universal:* An adapter that threads onto the standard universal light guide post's Storz adapter thread. Rotate the HLS clockwise to attach to an endoscope and counterclockwise to remove it.
- *ACMI:* An adapter for the snap-in quick-connect ACMI light guide post.
- *Wolf:* An adapter for the snap-in quick-connect Wolf light guide post.

Power Module: The battery can be removed and replaced for recharging. Rotating the control to the *Off* position (0) will allow the Power Module to be pulled out. An o-ring seals the battery and electronics when the Power Module is inserted into the Heatsink/Handle.

- **On/Off Switch:** The *On/Off* switch turns the LED on/off at the "0" position.
- **Intensity Control Knob:** The knob will increase/decrease the light intensity of the HLS.
 - Rotate the control towards the larger numbers of the intensity scale to turn the light source on and increase the light intensity.
 - Rotate the control to the zero end of the intensity scale to gradually decrease the light intensity and turn the light source off. Notice a click-in at both the *off* (0) and *maximum* (10) positions.
- **Battery Compartment:** Remove and Replace battery. See section 3 – HLS Function and Operation for complete details.

Specifications

Parameter	Specification
Body Diameter	32mm [1.28in]
Overall Length	103mm [4.06 in]
Weight (with battery)	137g [4.8oz]
Battery Life at Full LED Power	~ 45 minutes
Battery Charge Time	~ 2 hours
Battery Type	RCR123A (16340) Protected Lithium Ion 3.7V, 800mAHr minimum
Power Source	Internal Battery Power
Mode of Operation	Continuous , Adjustable Light Output
Safe Operating Ambient Temperature Range	15 – 33°C [59 - 91°F]
Safe Storage and Transport Temperature Range	-25 – 50°C [-13 - 122°F]
Safe Operating, Storage, and Transport Relative Humidity Range	0 – 95% RH
Battery Recharge Cycles	~ 500 recharges
RoHs Compliant	Yes

Accessories

Light Sources & Accessories Listing	Part Number
Handheld Light Source Kit with Universal Adapter	LS010-1001
Handheld Light Source kit with ACMI Adapter	LS010-1002
Handheld Light Source kit with Wolf Adapter	LS010-1003
Rechargeable Battery type RCR123A (16340)	BT003-0079
Battery Charger Cradle	BT003-0080
Battery Charger AC/DC Adapter (US Plug)	BT003-0081
Battery Charger AC/DC Adapter (European Plug)	BT003-0082
Battery Charger AC/DC Adapter (UK Plug)	BT003-0083
Operator's Manual	LS010-0057
Shipping Box	LS003-0058

USA Tel: +1.508.949.3000
www.Myriadfiber.com

3. HLS Function and Operation

Light Source Preparation

- Before use, the light source should be *reprocessed*. **Please refer to the Care & Maintenance Section of this manual for proper disinfection protocol.**

Light Source Operation

NOTE: The endoscope may have included adapters that are supplied attached to the light post prior to shipping. Unthread any adapters prior to attaching the HLS.



Figure 2. Attaching the Handheld Light Source to a rigid scope

- For *Universal*: Insert the light guide post of the endoscope into the Universal Scope Adapter and rotate the HLS clockwise until it is “finger-tight”. Do not over-tighten.
- For *ACM or Wolf*: Insert the light guide post of the endoscope into the Scope Adapter until it snaps into place. It is normal for a small amount of play to exist between the endoscope and HLS.

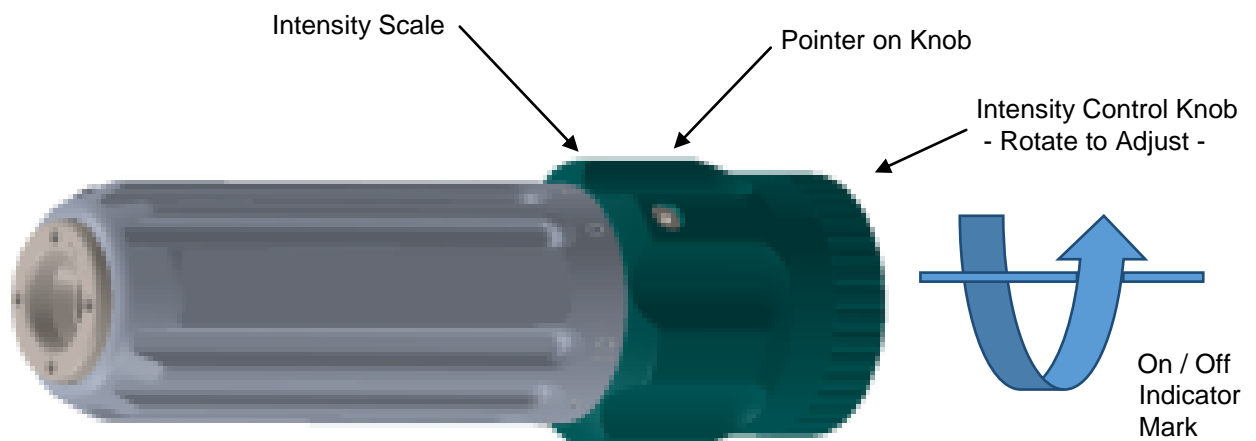


Figure 3. Adjusting Light Intensity

Turn the light source **on** by rotating the light intensity control knob towards the 1-10 numbers of the intensity scale. Adjust the brightness to the desired level by rotating the intensity knob further.

Turn the light source **off** by rotating the intensity control knob to the zero mark (0) of the intensity scale.

- Avoid leaving the light source on for extended periods of time when not in use, as this will drain the battery unnecessarily.

Battery and Charger

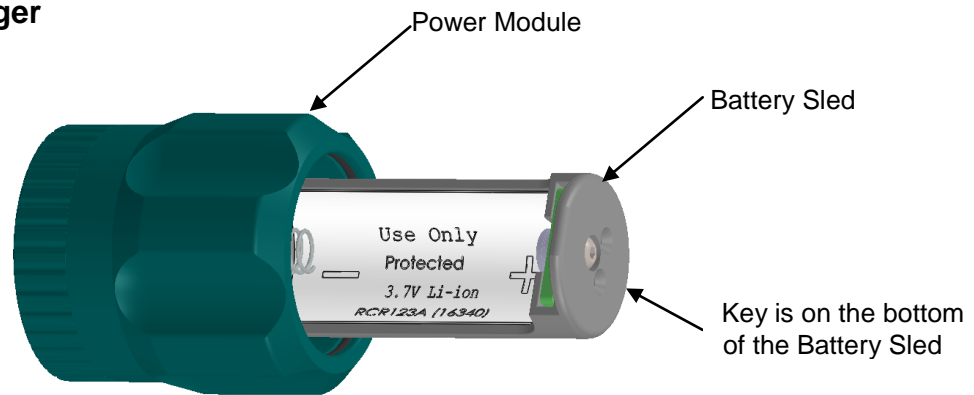


Figure 4. Removing the Power Module and inserting and removing the Li-Ion Battery

The HLS's internal LED light source operates on a single, Lithium-ion battery and provides approximately 45 minutes of continuous operation with a fully-charged new battery. Use only Protected RCR123A (16340) Lithium Ion (Li-ion) 3.7V Button Top Battery. This type of battery provides important internal PCB protection against: Over-Discharge, Over-Charge & Short Circuit, which otherwise could be hazardous.

To insert a new battery, turn HLS to off position and pull Power Module out from the Heatsink/Handle, then remove the old and install a new battery in the Battery Sled, making sure the "+" end of the battery is inserted in the correct orientation. Once a charged battery is inserted into the Power Module, reinstall the Power Module by carefully aligning the key on the bottom of the Battery Sled with the keyway cut in the Heatsink/Handle. NOTE: The key must be aligned with the keyway before full insertion is possible.

Please take care not to let the battery fall to the floor or onto a hard object, which could damage the battery.



CAUTION:

- Do not puncture or incinerate the battery. Contains explosive/flammable material.
- Do not expose the battery to high temperatures above 122°F/50°C
- Do not disassemble or short circuit the battery
- Do not use a damaged or leaking battery.



WARNING: The battery should be removed if the equipment is not likely to be used for some time. Store battery in a cool dry location out of direct sunlight.



Do not discard Li-ion Batteries in the trash, they must be sent to a recycling center. See www.call2recycle.org or call 1-877-2-RECYCLE for the nearest drop-off location. This non-profit Organization has over 30,000 drop-offs in North America.



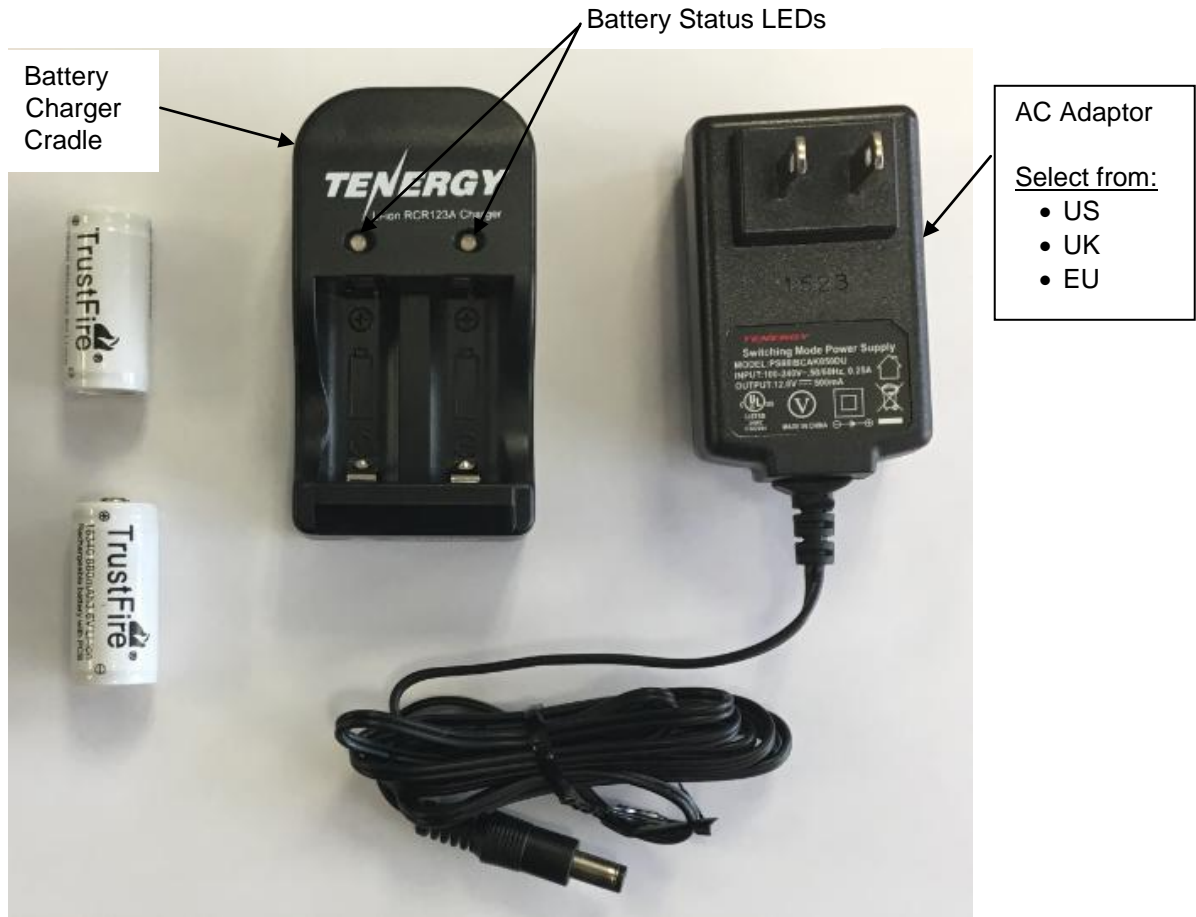


Figure 5. Battery Charger, AC Adaptor, and two Batteries

To charge a battery:

- Plug the AC adapter into an AC outlet first, then plug the AC adapter's wire into the charger.
- The LED above each battery will change color to indicate charging status.
- Insert one or two batteries into the charger. Match +/- polarity as marked on battery and charger.
- A solid RED LED indicates the battery is charging.
- A solid GREEN LED indicates the battery is fully charged or no battery is present.
- After the battery is fully charged, pull the battery out of the charger.
- Unplug the AC adapter when not in use to conserve energy.



CAUTION:

- Never expose the charger to water or moisture; do not use if wet.
- Charge batteries on a fire-proof surface and away from flammables.
- Do not disassemble the charger; there are no user-serviceable parts inside.
- Follow local regulations for disposal of electrical components or batteries (page 7).



WARNING: The battery charger is not a medical device.

4. Care and Maintenance

I – Method of Light Source Disinfection



WARNING: Do not use: Ethylene Oxide, autoclave, ultrasonic, chlorides, formaldehyde, or hydrogen peroxide. Using any of these may damage the light source and will void the product warranty.

The HLS is sealed for protection against ingress of fluids only when assembled. The entire light source is submersible in water and disinfectant solutions. However, the light source should not remain immersed in water or cleaning solutions for prolonged periods of time. After the disinfection cycle has concluded, remove the light source from the disinfection solution, dry and store it in a clean and dry environment.

A thorough cleaning and rinsing are the first and most important steps in disinfection this light source. Without a thorough cleaning and rinsing, it may not be possible to achieve high-level disinfection. Cleaning is the removal of all adherent visible soil (i.e. blood, protein substances and/or other debris) from the surface, crevices and joints of the light source.

Use caution when cleaning and disinfecting as some methods may be harmful to the light source and could result in extensive damage. Manual cleaning is the recommended method for cleaning the light source. To be effective, cleaning agents must assist in the removal of residual organic debris without damaging the device. No single cleaning agent removes all types of debris or is safe to use with every type of reusable device. Certain cleaning agents may damage the device's materials. Cleaning agents should be used in the correct dilution/concentration and at the correct temperature in accordance with the cleaning agent manufacturer's directions. Please contact Myriad Fiber at 1-508-949-3000 to verify the compatibility of a cleaning method not listed below under Section II - *Light Source Disinfection Protocol*.



WARNING: Remove battery prior to disinfection. Ensure Power Module is fully inserted on the Heatsink, so that the o-ring seal will prevent liquid intrusion into the battery compartment.



WARNING: With battery removed, rotate Intensity Control Knob until it clicks into the maximum brightness setting of 10, thereby preventing accidental separation while handling.

II - Light Source Disinfection Protocol:

1. Pre-Cleaning with detergent
2. Enzymatic Cleaning and Rinsing; Enzol Fast Acting Enzymatic Cleaner or equivalent
3. High-Level Disinfection with CIDEX OPA (0.55% ortho-Phthalaldehyde Solution)

Pre-Cleaning:

Myriad recommends the light source be pre-cleaned immediately after the device has become contaminated. This will prevent patient material from adhering to the light source. Dried material is difficult to remove and can render the disinfection process ineffective. Gently wipe all debris from the exterior surfaces using a soft, lint-free cloth and water to which you have added a low sudsing detergent, diluted in accordance with the detergent manufacturer's instructions.

Enzymatic Cleaning and Rinsing:

1. Fill a basin with a freshly made solution of water and a low sudsing detergent, diluted in accordance with the detergent manufacturer's instructions.
2. With battery removed and Intensity Control Knob set to 10, Immerse the light source in solution.
3. Wash all debris from the exterior of the light source by gently brushing and wiping the instrument while submerged in the detergent solution.
4. Rinse the light source in clean water.
5. Wipe dry the exterior of the light source with a soft, clean cloth.

High-Level Disinfection with CIDEX OPA (0.55% ortho-Phthalaldehyde Solution):

1. Prepare the disinfectant solution in accordance with the solution manufacturer's label.
2. Remove battery and set Intensity Control knob to 10, to prevent separation while handling.
3. Completely immerse the light source in the disinfectant solution for the recommended time and temperature as indicated on the label of the disinfectant.
4. Thoroughly rinse the exterior of the light source with large amounts of clean water. NOTE: "It is suggested that all rinsing after disinfection should be done with water that has been filtered by passage through a 0.2 micron filter or otherwise treated by a method documented to improve the microbiological quality of water." ASTM F 1518
5. A final rinse using 70% isopropyl alcohol solution can be used to speed the drying process and reduce the numbers of any organisms present as a result of rinsing with potable water.
6. Dry the exterior of the light source with a soft, clean towel.

III - Drying the Light Source:

After the HLS becomes wet, either from water or cleaning fluids, thoroughly dry the exterior immediately. Rinse with isopropyl alcohol, followed by drying with a compressed gas. Use of compressed air or commercial compressed gas canisters is highly recommended to reduce contamination of the window, and to reduce the possibility of oxidation of other materials used in the construction of the light source.



WARNING: Do not permit the light source to remain in cleaning or disinfectant solutions longer than the manufacturer's recommended treatment time. Do not permit the light source to remain in any liquids or remain wet for prolonged periods of time.

Once all outside surfaces of the HLS are dry, remove the Power Module and ensure no liquids or moisture droplets have entered the battery compartment. If the inside ever becomes wet, wipe away any excess liquid from this area and thoroughly dry with compressed gas. You must remove any trapped moisture remaining in the battery compartment before use. Do not expose the battery or electronics to fluids.



WARNING: Ensure there is no moisture or liquid trapped in the battery compartment or Heatsink body prior to use.

IV - Preventative Maintenance:

Over time the O-ring on your HLS Power Module may become dry. Lubricate the O-ring with silicone grease as needed or every 3 months or 500 cleaning cycles. This is usually when the battery should be replaced also. Remove and replace worn out or cracked o-rings immediately to maintain a proper seal.

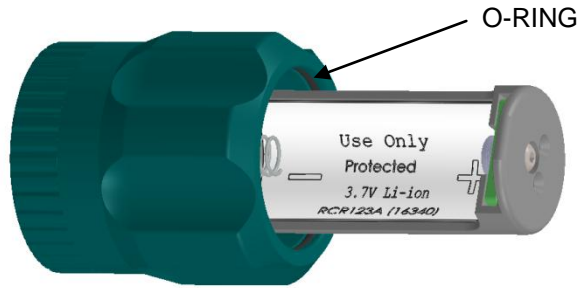


Figure 6. Lubricating/Replacing the O-ring

5. Troubleshooting

PROBLEM	POSSIBLE CAUSE	ACTION
Loss of Illumination	Battery power is low.	Replace battery with a freshly charged battery.
	Battery cannot supply sufficient current at this power setting.	Change battery for a freshly charged battery. Reduce the light intensity and continue using the current battery. Recharge the battery as soon as possible.
Light Guide does not attach properly to the endoscope	The endoscope has an adapter on its light post	Refer to the guide below and remove the adapter
	The endoscope and light source do not have a compatible coupling system	Contact Myriad Fiber Imaging at 1-508-949-3000
Light intensity is low	Foreign material or film on HLS window or attached endoscope.	Clean window with a cotton swab wet with isopropyl alcohol until the debris or film is cleared off. Dry with compressed air or gas.
Light source becomes hot after prolonged use at full power.	Light source has been left on for more than 30 minutes at full power.	Turn the light source to a lower intensity setting if the examination must continue past 30 minutes. Or, turn the light source off for a few minutes to permit adequate cool down of the light source body.

Note: The standard light guide post consists of a snap-ring groove for an ACMI fitting connection, a Wolf adapter thread, and a Storz adapter thread. The HLS attaches to the Storz adapter thread if marked "UNIVERSAL" or the ACMI if marked "ACMI". If an adapter sleeve (see Figure 8 below) is installed on the light guide post, it must be removed prior to connecting the HLS. Unscrew the adapter sleeve to remove it if it is present. If the HLS is equipped with the Wolf Scope Adapter, it will fit the wolf style light post.



Figure 7. Standard Universal Light Guide Post



Figure 8. Standard Light Guide Post (left), with Wolf Adapter (center), with Storz Adapter (right)

6. Agency Compliance Statements and Guidance Tables

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this section.

Portable and Mobile RF communications Equipment can affect Medical Electrical Equipment.



WARNING: The equipment 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 prior to actual use.

Guidance and Manufacturer's Declaration – Emissions

Guidance and Manufacturer's Declaration – Immunity

Recommended Separation Distances between portable and mobile RF Communications Equipment and the HLS: Equipment and Systems that are NOT Life-supporting

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

Note: The HLS is internally battery powered and has no I/Os. Conducted RF Immunity testing does not apply, resulting in no separation data from 150kHz to 80MHz.

7. Repair Service

Customer Service

The HLS is serviced by Myriad. Use the following procedure for evaluation, repair or replacement.

1. Call Myriad at 1-508-949-3000 to request our RMA Form
2. Provide a detailed description of the problem and include the serial number.
3. If the light source needs to be returned, a Returned Material Authorization # will be issued.
4. The light source should then be sent to the address below for repair or replacement.
5. Include a copy of the RMA inside the package.
6. Have RMA number visible on the outside of the package.

Returning Goods to Myriad Fiber Imaging

Ship the HLS in a corrugated box to prevent damage during shipment. DO NOT INCLUDE BATTERIES.

Ship to: Myriad Fiber Imaging
56 Southbridge Road
Dudley, MA 01571 USA
Attention: Customer Service / RMA# _____



ATTENTION: If the light source has been used in a clinical setting, the light source must be disinfected according to procedures outlined in the Care & Maintenance section of this manual before shipment.

Upon evaluation, the customer will be contacted and advised of the findings and estimated repair cost. Repairs will not begin until authorization or a purchase order is issued indicating the approval of charges.

8. Warranty

The Myriad Handheld Light Source (HLS) is warranted to be free from defects in materials and workmanship for a period of one (1) year from the date of purchase.

All non-warranty repairs will be warranted to be free from defects in materials and workmanship for a period of ninety (90) days from the date of the invoice.

Accidental damage and damage resulting from misuse, abuse, excessive sterilization, disinfection and sterilization methods not approved by Myriad, as well as fluid invasion and normal wear and tear, will be subject to prevailing repair charges. Disassembly, alteration, or repair performed by any person not authorized by Myriad will result in immediate loss of warranty.

THE ABOVE WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Suitability for use of the medical device for any surgical procedure shall be determined by the user. Myriad Fiber Imaging shall not be liable for incidental or consequential damages of any kind.

All shipping charges to and from Myriad's facility is the responsibility of the customer.

9. Symbol Descriptions:



Attention: Read Operating Manual for Warnings, Cautions, and Instructions for Use

S/N This symbol indicates the product's Serial Number.



In the European Union, this symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or landfills will be reduced and natural resources will thus be conserved.

Purchase Date: _____

Part No: _____

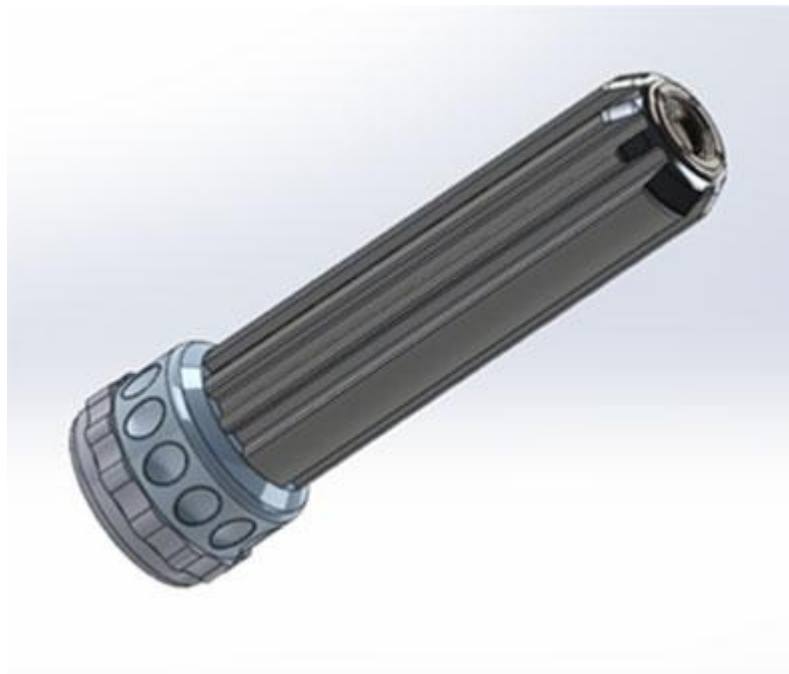
Serial No: _____

NOTES:



Myriad Fiber Imaging Tech., Inc, MA 01571

USA TEL: +1-508-949-3000
Website: Myriadfiber.com



Sales & Service Email: t.gauvin@myriadfiber.com