EndoLume®2.0

Operator's Manual

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Table of Contents

Product Description

EndoLume2.0 is an easy to use light measurement device for endoscopic systems and components. It measures the light output, in lumens, from the light source and the transmission of the fiberoptic light cable and endoscope. It can be used to test these components individually or collectively as a system.

EndoLume2.0 produces accurate and repeatable results through the use of its unique integrating sphere, specifically designed for endoscope systems. EndoLume2.0 enables the user to:

- Establish evidence based quality assurance for endoscopic devices.
- Reduce number of “insufficient light” failures in the OR.
- Qualify new and repaired endoscopes before use.
- Reduce number of unnecessary or premature lamp replacements.
- Accurately trend performance changes of endoscopic devices and components.
- Quickly troubleshoot light related endoscopic system failures.
- Allows values displayed on LCD to be held with use of the HOLD button for ease of use in recording measurements.

Fiberoptic light cables are often the weak link in providing satisfactory illumination for the endoscopic surgeon. Diagnosing a bad light cable can often be a “hit or miss” proposition; there are always questions as to whether the problem is in the endoscope, camera, monitor, or light cable. Isolating the light cable endoscope from the system and testing it independently allows the user to quickly find the root cause of a problem and get the surgical staff back in business. EndoLume2.0 can test endoscopic systems from all major manufacturers including both rigid and flexible endoscopes.

User Responsibilities

Users are assumed to have at least a basic technical and operational knowledge of endoscopic systems, in addition to the knowledge of the proper use and precautions associated with battery-operated devices. EndoLume2.0 is intended to be used by adults only.

Users are responsible for reading and following the instructions provided within this manual. Users are also responsible for heeding all warnings and exercising all precautions recommended in the EndoLume2.0 Operator’s Manual and the product labeling included therein.

Warnings

DO NOT use EndoLume2.0 to test light guides or endoscopes that have not been properly cleaned and/or disinfected prior to testing. Follow the manufacturer's recommendations for cleaning the devices.

DO NOT look directly at light emitted from an endoscopic light source.

DO NOT operate EndoLume2.0 if the unit has been submerged in water or any other liquid. Call the EndoLume2.0 Help Desk to arrange for servicing. Contact information is in **Service and Technical Support** section of this manual.

Cautions

DO NOT attempt to service EndoLume2.0. There are no serviceable parts inside. Opening the meter or any part of EndoLume2.0 will void the warranty.

DO NOT use the device at very high temperatures. Otherwise, the Li-ion battery can overheat, combust, or its performance will be degenerated and its service life will be decreased.

DO NOT use device in a location where static electricity is high, otherwise, the Li-ion safety devices in the pack may be damaged, which will cause hidden trouble of safety.

If device gives off an odor, generates heat, or in any way appears abnormal during use, recharging or storage, immediately stop using the device and contact support.

The tip of a light guide or endoscope can become hot in normal usage. Follow the directions in this manual to avoid damaging the inside coating of the integrating sphere.

EndoLume2.0 Specifications

- Accuracy: +/- 10%
- Range: 0-5,000 lumens
- Two button operation, ON/OFF and HOLD
- Endoscope Diameter Range: 2-15mm with included clamping collar; 15-16mm direct connection
- Measures both rigid and flexible fiber endoscopes
- 4-½ digit LCD display
- Silicon photodiode with built-in photopic color correction filter that simulates the spectral response of the human eye
- Calibrated to NIST traceable standards
- Battery powered (Li-ion Polymer Battery)
- Automatic power off: 5 minutes
- Battery life indicator
- Meter Dimensions: 5.4x2.7x0.9” (137x69x24mm)
- Weight (meter/integrating sphere): 10.7oz (303.5g)
- 12-month warranty (excludes failure to operate properly or physical abuse)

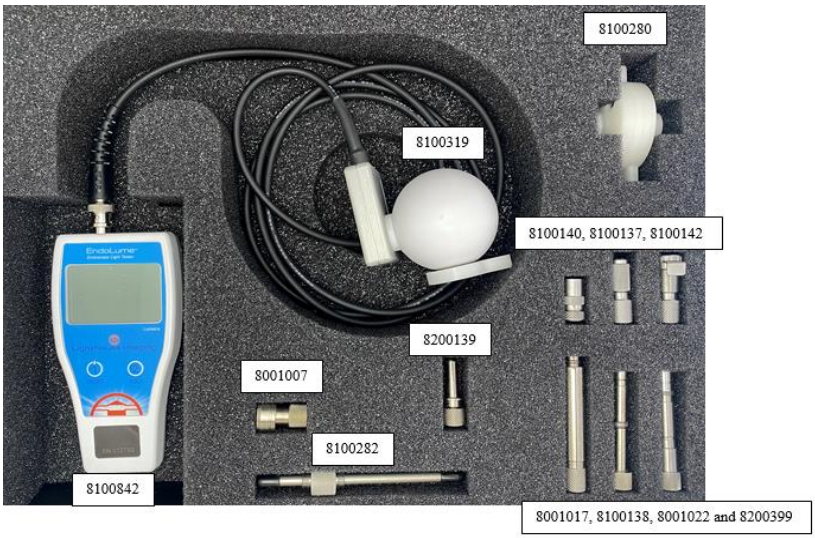
Getting Started

In addition to this Operator's Manual, you may want to access information located at the Ross Optical website which has information on the basics of endoscope optics as well as descriptions of other devices that can be used to test endoscope quality.

The EndoLume2.0 carrying case contains the EndoLume2.0 device, optical bridge, light source adapters, light guide adapters, and the endoscope clamp. EndoLume2.0 comes with the battery inserted and ready to use.

Figure 1 illustrates all of the items included with EndoLume2.0.

Figure 1

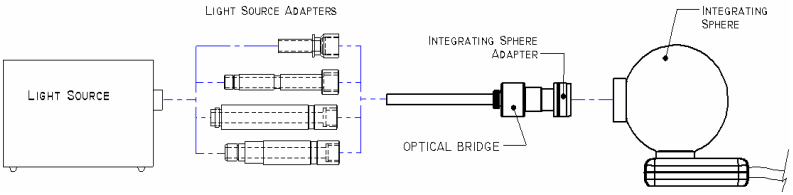


Using EndoLume2.0 to Test a Light Source

Reference Figure 2.

1. Attach a light source adapter to the long end of the optical bridge. If the light source has a turret port use any of the light source adapters provided. Either the Storz or Olympus adapters are recommended because their longer engagement length provides a more stable connection.
2. Attach the integrating sphere adapter to the short end of the optical bridge.
3. Attach the optical bridge to the integrating sphere.
4. Plug the integrating sphere assembly into the light source output port.
5. Press and hold the ON button of EndoLume2.0 until the device turns on.
6. With the intensity control of the light source at maximum, read and record the lumen value displayed on the LCD.

Figure 2

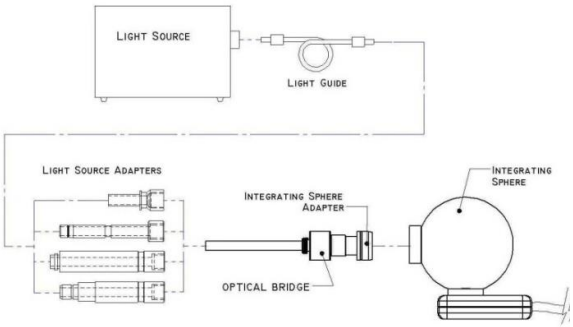


Using EndoLume2.0 to Test a Light Guide

Reference Figure 3.

1. Attach the light guide adapter corresponding to the light guide's manufacturer to the long end of the optical bridge.
2. Attach the integrating sphere adapter to the short end of the optical bridge.
3. Attach the optical bridge to the integrating sphere.
4. Plug the light source end of the light guide into the light source.
5. Attach the endoscope end of the light guide to the optical bridge
6. Press and release the ON button of EndoLume2.0.
7. With the intensity control of the light source at maximum, read and record the lumen value displayed on the LCD.
8. To calculate the transmission of the light guide, divide this reading into the reading obtained when the light source was measured alone. Record the calculated value.

Figure 3



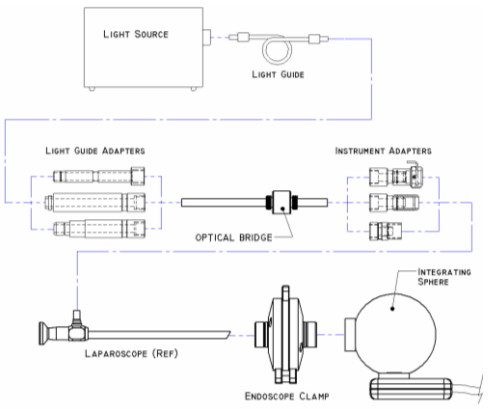
Using EndoLume2.0 to Test a Rigid Endoscope *(Laparoscope, Arthroscope, etc.)*

Note: For flexible endoscopes (colonoscope, gastroscope, etc.) use the instructions in the section **Using EndoLume2.0 to Test a Flexible Endoscope**.

Reference Figure 4.

1. Plug the light guide into the light source.
2. Attach the adapter corresponding to the light guide's manufacturer to the long end of the optical bridge.
3. Attach the adapter corresponding to the endoscope's manufacturer to the short end of the optical bridge.
4. Attach the long end of the optical bridge to the instrument end of the light guide.
5. Plug the short end of the optical bridge onto the sidearm of the endoscope.

Figure 4



6. Slide the endoscope clamp (either side) over the tip of the endoscope by depressing the two clamp levers.
    a. The tip of the endoscope should extend just slightly, 1/16” (1-2mm) out the opposite end of the endoscope clamp.
    b. For inclined direction-of-view endoscopes the entire tip should extend slightly, 1/16” (1-2mm) out of the endoscope clamp.
7. Attach the scope/endoscope clamp to the integrating sphere.
8. Press and release the ON button of EndoLume2.0.
9. With the intensity control of the light source at maximum, read and record the lumen value displayed on the LCD.
10. To calculate the transmission of the endoscope, divide this reading into the reading obtained when the light guide was measured alone.

Using EndoLume2.0 to Test a Flexible Endoscope *(Colonoscope, Gastroscope, etc.)*

Note: Although the instructions for rigid endoscopes work with both rigid and flexible endoscopes, because of the fragile nature of flexible endoscopes it is recommended that the following procedure be followed for flexible endoscopes. Flexible endoscope light sources are measured following the directions in the section **Using EndoLume2.0 to Test a Light Source**.

Reference Figure 5.

1. Plug the endoscope into the light source.
2. Slide the endoscope clamp (either side) over the tip of the endoscope by depressing the two clamp levers. The tip of the endoscope should extend just slightly, approximately 1/16" or 1-2mm out the opposite end of the endoscope clamp.
3. Attach the scope/endoscope clamp to the integrating sphere.
4. Press and release the ON button of EndoLume2.0.
5. With the intensity control of the light source at maximum, read the lumen value displayed on the LCD. Record this value.
6. To calculate the transmission of the endoscope, divide this reading into the reading obtained when the light guide was measured alone.

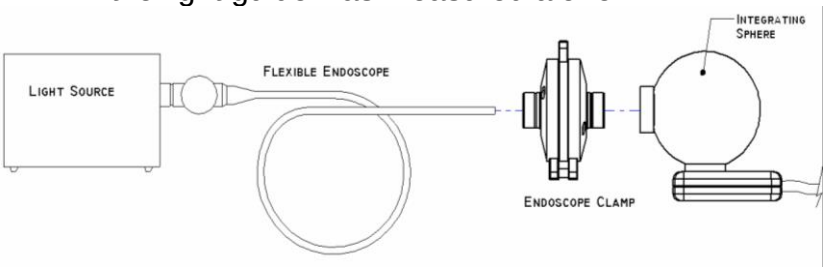


Figure 5

EndoLume2.0 Maintenance and Calibration

Cleaning

The outside of the EndoLume2.0 meter and integrating sphere may be wiped with a damp (not wet) cloth to remove dust and debris. Do not attempt to clean the inside of the integrating sphere as the special interior paint can be easily scratched or damaged.

The glass ends of the optical bridge should be inspected before starting a measurement and, if necessary, cleaned with alcohol and a soft cloth or tissue if necessary. Debris on the ends of the optical bridge will lead to errors in the results.

Calibration

EndoLume2.0 should be returned to Ross Optical Corporation on an annual basis for recalibration. See **Service and Technical Support** section of this manual for contact information.

Battery Life

Under normal usage battery life is approximately 5 hours of continuous use.

Storage

EndoLume2.0 should not be exposed to extreme cold (less than 32 ºF/0 ºC) or heat (more than 104 ºF/40º C). Store EndoLume2.0 in its carrying case when not in use.

FAQ and EndoLume2.0 Troubleshooting Guide

Problem: When making a measurement the lumen readings vary when the light source adapter is moved.

This is a function of the manufacturer's design of the light source connection. EndoLume2.0 is actually measuring changes in the light level which will also be present clinically.

Problem: When measuring an inclined direction-of-view endoscope the lumen reading changes when the scope is rotated in the endoscope clamp.

A variation of +/-10% in the reading is normal because of multiple reflections within the integrating sphere which vary depending on the direction of the optical axis. If the variation exceeds +/-10%, the interior of the sphere may be dirty. Please contact the EndoLume2.0 Help Desk for cleaning and re-calibration.

Question: What is a lumen and how is it different from a foot candle or lux?

A lumen is the total amount of visible light emitted from a source. It is the basic measure of light source brightness. Foot candles are the number of lumens per square foot incident on a surface. Lux is the number of lumens per square meter incident on a surface.

Question: Can I use EndoLume2.0 to measure head lamps?

Yes. EndoLume2.0 can test light sources and light guides used in head lamps if standard connectors are utilized and the distal lens system can be detached from the light guide.

Question: Can EndoLume2.0 test operating room lights?

No. EndoLume2.0 is not designed to test operating room lights.

Question: Can I interchange parts if I own several EndoLume2.0s?

No. EndoLume2.0 is calibrated as a system. Interchanging the meter, integrating sphere assembly, or optical bridge requires a factory recalibration. Adapters may be interchanged without recalibration.

EndoLume2.0 Replacement Parts List

Description	Part Number
Integrating sphere/detector assembly	8100319
EndoLume2.0 Handheld meter	8100842
Endoscope clamp assembly	8100280
Optical bridge	8100282
Storz source adapter	8200139
Olympus / ACMI source adapter	8200138
Storz male adapter	8001017
Wolf / Smith & Nephew female adapter	8200142
ACMI female adapter	8200137
Storz / Olympus female adapter	8200140
Olympus WA Adapter	8001022
Wolf Adapter	8200399
Integrating sphere adapter	8001007
Carrying case	8200301
Operator’s manual	8700125

Service and Technical Support

For service and technical support; contact Test and Measurement Support at Ross Optical.

Phone: 1-915-595-5417 - Ask to speak with Test & Measurement Support.

Fax: 915-595-5466 - Mark to the attention of Test & Measurement Support.

E-mail: sales@rossoptical.com

Note: EndoLume2.0 is not a medical device as defined by the United States Food and Drug Administration (FDA). Therefore, no 510(k) is required to market this product in the United States.

Notice: U.S. and international patents are pending on this device.

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