

INSTRUCTIONS FOR USE

Portable Red LED Light Source

Read all instructions prior to use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

1. INTRODUCTION

Intended Use

The Entellus Medical Portable Red LED Light Source™ is intended for use in a physician's office during endoscopic procedures. The Light Source is not intended for use in the sterile field.

Indication for Use

The Light Source is indicated for use in endoscopic procedures to locate, illuminate within, and transilluminate across nasal and sinus structures when used with the Entellus Medical MiniFESS™ Light Seeker™.

Description

The Light Source is a non-sterile, reusable device that is designed to be attached to the Light Seeker. The internal red LED provides sufficient light to allow the Light Seeker to locate, illuminate and transilluminate across nasal and sinus structures by providing three levels of intensity. The Light Source is powered by an internal lithium-ion rechargeable battery.

The Light Source package includes the Light Source (with ACMI connector), battery charger (with AC/DC adapter), and two lithium ion battery cells. Refer to Figure 1 below.

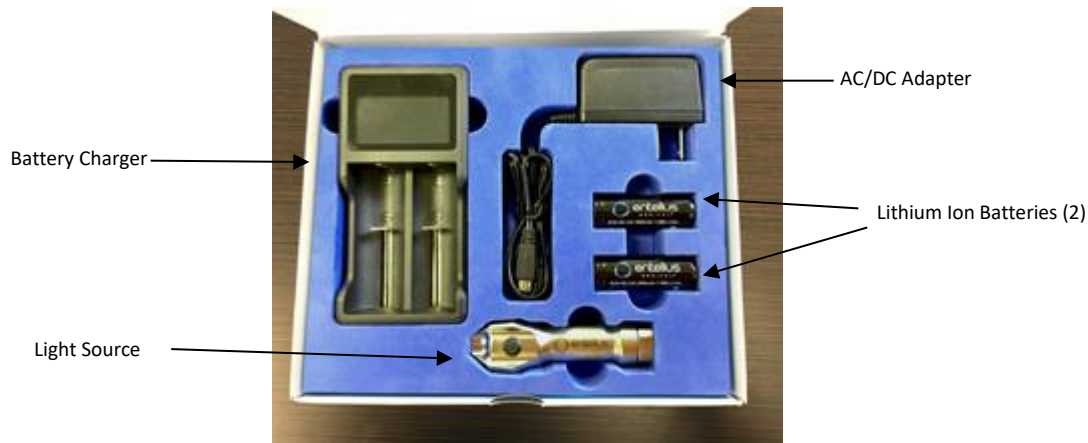


Figure 1 – Portable Red LED Light Source (Catalog Number PRLS-100)

Contraindications

None known

Warnings

- Do not use the Light Source within a sterile field as this may result in cross contamination, since the device is unable to be sterilized.
- Use only the supplied battery charger (RLC-100) with the Entellus Medical (RLB-100) battery cells. Use of another battery may present a risk of fire or explosion.
- Do not attempt to modify or disassemble the Light Source or any component. Doing so may damage the device or create a safety hazard.
- Do not use if rear battery cap is not completely tightened to the Light Source. Operating with the rear cap loose may increase the risk of electric shock.

Precautions

- Clean and low-level disinfect the Light Source prior to use and after every subsequent use, employing only the procedures listed in this manual.
- Do not sterilize the Light Source using any method, as this will destroy the Light Source.
- Do not submerge or allow liquids to enter the Light Source as it is not waterproof and this will destroy the device.
- Use only the supplied AC/DC adapter with the battery charger.
- Test the Light Source prior to any procedure to ensure functionality.
- Do not stare directly at the Light Source or point it directly at anyone's eyes while illumination is active.

Recommended Supplies and Compatible Equipment

The following supplies and/or equipment are not provided but are required to use the Portable Red LED Light Source:

- Compatible ENT equipment such as the Entellus Medical MiniFESS Light Seeker.
 - CaviWipes low-level disinfectant, or equivalent product
 - 70% Isopropyl alcohol (IPA)
 - Lint-free cloths
- Refer to appropriate Instructions for Use and safety procedures when preparing and using compatible supplies or equipment.

Care and Handling

- The Light Source is constructed of sensitive electronics and illumination components. Special care must be taken to prevent damage to the device and to maintain functionality and longevity. Negligent care and/or handling may void warranty. Refer to Section 3. Cleaning, Disinfection & Maintenance for additional information.

2. INSTRUCTIONS FOR USE

Using the Portable Red LED Light Source Battery Charger

1. Plug the power cord into a 110V wall outlet. Then connect the AC/DC power adapter to the DC input jack of the battery charger.
2. Place one or both of the supplied battery cells into the charging bays by aligning the negative end of the battery cell with the negative symbol in the charging bay. Push on the battery cell until it is fully inserted. The dual charging bays allow both battery cells to be charged at the same time.
3. The charger indicates the charging status on the LCD screen. The LCD screen displays the word "FULL" when charging is complete.

Preparation of the Portable Red LED Light Source

1. Verify that the Light Source has been manually cleaned and low-level disinfected prior to device preparation and use. Refer to Section 3. Cleaning, Disinfection & Maintenance for additional information.
2. Ensure that the battery has sufficient charge prior to initiating the ENT procedure. If necessary, charge batteries using the supplied 110V AC battery charger.
 - If the Light Source power indicator is visibly lit blue and blinking, this indicates that the battery power is low and has at a minimum of two minutes of illumination time remaining.
 - The Light Source equipped with a fully charged battery will have enough power to achieve a minimum of 60 minutes of illumination time using the maximum brightness setting.
3. Unscrew and remove the rear battery cap and slide the battery completely forward into the Light Source. Replace the rear battery cap and tighten to finger-tight. Note: the negative terminal of the battery should line up with the negative icon symbol located on the Light Source towards the rear battery cap.
4. Attach the Light Source to the Light Seeker using the following method:
 - Grasp both the Light Source and the Light Seeker.
 - Screw the Light Seeker (clockwise) until it forms a tight seal. Do not over-tighten.

Portable Red LED Light Source Instructions for Use.

1. Power ON the Light Source using the power button. The Light Source power indicator will be visibly lit blue.
2. Push the power button of the Light Source 1-3 times to provide the desired light intensity.
3. Manipulate the device into the desired anatomy to illuminate and transilluminate across nasal and sinus structures during the procedure.
4. Remove the Light Seeker from the nasal cavity.
5. Power OFF the Light Source
6. Remove the Light Seeker from the Light Source by unscrewing (counter clockwise) until disengaged.

3. CLEANING, DISINFECTION & MAINTENANCE

The Portable Red LED Light Source is not intended to come into contact with the patient. The Portable Red LED Light Source may be cleaned and low level disinfected, but not sterilized. Light Seekers used with the Portable Red LED Light Source are non-sterile and shall be handled according to their labeling.

Cleaning of the Portable Red LED Light Source

1. Power OFF the Light Source
2. Using a wipe such as a CaviWipe, thoroughly wipe the Light Source for a minimum of 2 minutes, ensuring surfaces remain visibly wet for the entire exposure duration. Use new wipes as needed.
3. Allow the Light Source to air dry. Once dry, visually inspect the device for any residual soil. Repeat cleaning instructions if visible soil is present.
4. Proceed with disinfection process

Low-level Disinfection of the Portable Red LED Light Source

1. Low-level disinfection should be performed immediately prior to use in a procedure.
2. Ensure that the Light Source has been cleaned and no residual soil remains.
3. Using a wipe such as a CaviWipe, thoroughly wipe the device for a minimum of 3 minutes, ensuring surfaces remain visibly wet the entire exposure duration. Use new wipes as needed.
4. Perform a final wipe of all surfaces with 70% IPA for a minimum of 1 minute.
5. Allow the Light Source to air dry before continuing with procedure.

Additional Maintenance

The glass covering of the LED may be cleaned with a lint-free cloth as necessary.

4. STORAGE & DISPOSAL

The Light Source and components may be stored at normal room temperature. There are no special storage requirements.

Follow local governing ordinances and recycling plans regarding the recycling or disposal of the device or components. Lithium ion batteries in particular may have specific regional requirements for recycling or disposal.

5. MAINTENANCE OF QUALITY OF SERVICE & SECURITY

The Portable Red LED Light Source is designed to maintain an adequate quality of service during its use in an office environment.

6. TROUBLESHOOTING, TECHNICAL SPECIFICATIONS & COMPLIANCE

Troubleshooting

Problem	Possible Cause	Action
The Light Source power button is blinking	Battery not charged	-Place the battery into the charger.
The Light Source will not power up	Battery not fully inserted	-Slide the battery completely forward into the base of the Light Source. -Replace the rear battery cap and tighten to finger-tight. Note: the negative terminal of the battery should line up with the negative icon symbol located on the Light Source towards the rear battery cap.
	Battery not charged	-Place the battery into the charger. -When the charger indicator blinks and the display reads "full", the battery is fully charged and ready for use.
	Battery Polarity is reversed	Remove batteries and reverse polarity.

No illumination or Loss of light from Light Source	Light Seeker not connected to Light Source	-Disconnect Light Seeker. -Ensure Light Seeker threads are fully seated on Light Source. -Consult IFU for Light Seeker.
	Debris on LED glass cover	-Disconnect Light Seeker. -Clean glass covering at distal end of Light Source. -Clean light post of Light Seeker. -Ensure Light Seeker threads are fully seated on Light Source.
	Light intensity setting too low	-Adjust light setting to higher light intensity using Power Button.

Technical Specifications & Compliance

Item	Specification
Weight	< 83 grams
Expected service life	Minimum of 1040 hours of use
Battery type	Lithium Ion, 3.6V, 2000 mAh
Mode of operation	Continuous
Battery life at full LED power	Minimum of 60 minutes
Battery lifetime/recharge cycles	250 recharges
Safe operating ambient temperature range	15 – 33°C (59 - 91°F)
Safe storage and transport temperature range	-10 – 50°C (14 - 122°F)
Safe operating, storage, & transport relative humidity range	0 – 90% RH
Complies with industrial electrical standards:	UL, IEC 60950, IEC 62133:2012, RoHS, WEEE
Complies with medical safety standards:	IEC 60601-1:2005/(R)2012; CAN/CSA-C22.2 No. 60601-1-08
Complies with medical EMC standard:	IEC 60601-1-2:2007; Type B Applied Part


Electromagnetic Compatibility (EMC)

Medical Electrical Equipment needs special precautions regarding 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.

Guidance and Manufacturer's Declaration - Emissions		
The Light Source is intended for use in the electromagnetic environments specified below. The customer or the user of the Light Source should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Portable Red LED Light Source uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electrical equipment. The Red LED 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.
RF Emissions CISPR 11	Class B	
Harmonics IEC 61000-3-2	N/A	
Flicker IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration – Immunity			
The Light Source is intended for use in the electromagnetic environments specified below. The customer or the user of the Light Source should assure that it is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD EN/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 RH should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains, ±1kV I/Os	N/A (Portable Red LED is powered by an internal battery)	
Surge EN/IEC 61000-4-5	±1kV Differential, ±2kV Common		
Voltage Dips/Dropout EN/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		N/A
Power Frequency 50/60Hz, Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity			
The Light Source is intended for use in the electromagnetic environments specified below. The customer or the user of the LED Light Source should assure that it is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF EN/IEC 61000-4-6	3V _{rm} , 150kHz to 80MHz	N/A (Portable Red LED is powered by an internal battery)	Portable and mobile RF communications equipment should be used no closer to the Light Source than the distances calculated or listed below. Recommended Separation Distance

Radiated RF EN/IEC 61000-4-3	3Vm, 80MHz to 2.7GHz	3V/m (E1)	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7MHz Where P is the maximum output power rating of the transmitter 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 level (E1). Interference may occur in the vicinity of equipment containing a transmitter or marked with the following symbol: 
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Recommended Separation Distances between portable and mobile RF communications equipment and the Portable Red LED Light Source			
The Light Source is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Light Source can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power of Transmitter (Watts)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d=(1.2)(\sqrt{P})$	80MHz to 800MHz $d=(1.2)(\sqrt{P})$	800MHz to 2.7GHz $d=(2.3)(\sqrt{P})$
0.01	N/A	0.12	0.23
0.1	(Portable Red LED is powered by an internal battery)	0.38	0.73
1		1.2	2.3
10		3.8	7.3
100	Conducted RF Immunity testing does not apply, resulting in no separation data from 150kHz to 80MHz.	12	23

7. WARRANTY & REPAIR SERVICE

Limited Warranty

Entellus Medical, Inc. warrants for a period of one (1) year following purchase of the product that the product will be free from defects in material and workmanship. Within the warranty period, upon receipt of Customer's prior written notice, Entellus may either repair or replace defective parts/products at no charge to Customer. Entellus Medical warrants that reasonable care has been used in the design and manufacture of this device. Entellus Medical excludes all other warranties, whether expressed or implied, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness since handling and storage as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical's control directly affect the device and the results obtained from its use. Entellus Medical shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Entellus Medical neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this device. Refer to *Entellus Medical, Inc. Standard Terms and Conditions*.

8. SYMBOL DESCRIPTIONS & MANUFACTURER INFORMATION

 Consult Instructions for Use ISO 15223-1:5.4.3	 Lot Number ISO 15223-1:5.1.5	 Model Number	 Catalog Number ISO 15223-1:5.1.6	 Caution ISO 15223-1:5.4.4	 Quantity	 Manufacturer ISO 15223-1:5.1.1	 Standby - Power On/Off Switch IEC 60417-5009
 Non-ionizing radiation IEC/TR 60878-5140	 Type B Applied Part IEC 60417:5840	 Li-ion Lithium-ion Battery – recycle per local regulations	 Device Is Non Sterile ISO 15223-1:5.2.7	 Serial Number ISO 15223-1:5.1.7	 Prescription Use Only 21 CFR 801.109	Symbols Reference ISO 15223-1:2012 – Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements IEC 60417:2002 – Graphical symbols for use on equipment IEC/TR 60878:2015 – Graphical symbols for electrical medical practice Not made with natural rubber latex	

CaviWipes are a registered trademark of Metrex Research LLC.



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