SSL-LX2 - LED Headlight

Operation Manual

CE

Sunoptic Technologies®
6018 Bowdendale Avenue
Jacksonville, FL 32216 USA

Customer Service: 904 737 7611
Toll Free 877 677 2832

EC|REP AJW Technology Consulting GmbH
Breite Straße 3
40213 Düsseldorf, Germany
Telephone: +49 211 54059 6030

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3.1 Jis pasižymi efektyviu, šiuolaikišku galvos šviestuvo modulio dizainu, pagamintu iš tvirto aliuminio, kuris užtikrina didesnį patvarumą transportuojant ir naudojant.

1. INTENDED USE

The SSL-LX2 is the next generation of battery-operated LED headlights. It features an efficient, modern headlight module design made from robust aluminum, which leads to greater durability during transport and handling. The headlight boasts a 3hr runtime at full output with the standard battery pack and up to 6hr runtime with the extended life battery pack at full output. This new battery-operated LED headlight provides unmatched light output and spot quality. 3.1

1.1. Indications for Use

The intended use for the SSL-LX2 is to provide general illumination to a surgical site. The device is not intended to diagnose, prevent, monitor, treat or alleviate disease, injuries, or handicaps, nor for the investigation, replacement, or modification of the anatomy or of a physiological process.

There are no known contraindications.

The SSL-LX2 headlight is intended to be used in a controlled operating room environment with compatible devices by qualified medical personnel. The SSL-LX2 Headlight is provided non-sterile.

1.2. Functions of Design

The SSL-LX2 comprises a headlight module, headband, smart battery pack, and battery holster. Light intensity is controlled via a knob located on the holster, and users can control the light spot size via a lever located on the headlight module. Additionally, the holster control module will signal the user via audible beep that the battery charge is low.

2. WARNINGS AND CAUTIONS

Use of this equipment may present hazards to the user and/or patient. Before operating this device, please read this operating manual thoroughly and follow all warnings, cautions, and instructions for use. The words warning, caution, and note carry special meaning and should be carefully reviewed:

WARNING: Indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.

CAUTION: Indicates risks of improper use and/or damage to the equipment. Failure to follow cautions may result in loss of function or product damage.

NOTE: Indicates special information to clarify instructions or present additional useful information.

The appropriate "WARNING", "CAUTION" or "NOTE" symbol in this manual is intended to alert the user to the presence of important operating and maintenance instructions in the manual.

2.1. Warnings

- The headlight produces highly concentrated light. Avoid looking directly into the light source.
- Qualified personnel must determine a safe distance between the headlight module and patient for each application.
- User is responsible for determining if interruption of light output will create an unacceptable risk. Having a backup headlight or other illuminator is advised.
- User is responsible for providing backup lighting systems for your application when using this device.
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- To prevent fire and/or electric shock, do not open or expose the headlight system to liquids.
- The headlight system should only be used with manufacturer-approved battery packs.
- This device meets CISPR 11 Class A limits and is suitable for use in a hospital environment. Performance of this device may be affected in proximity of another device and/or equipment capable of producing high levels of RF emissions. In the event performance of this device is affected due to high levels of RF emissions, relocation of the suspected device and/or equipment producing high levels of RF emissions or the headlight system may reduce or eliminate the problem.
- Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State and/or Country in which the user and/or patient is established.

2.2. Cautions

- Before each procedure, carefully check the battery state-of-charge and charge battery as necessary to ensure the headlight has enough duration for the procedure.
- All servicing and repair must be performed by the manufacturer or qualified service technicians.
- Ensure that the air vents located on the headlight module are not obstructed to allow the headlight to receive the necessary cooling to prevent an overheating.

2.3. Notes

- **Battery packs supplied from the manufacturer and approved vendors are distributed in a discharged state. Please fully charge the battery packs before using the headlight for the first time.**
- The headlight produces some heat in addition to light, which causes the module and/or holster to become warm. This is normal operation.
- This device may interfere with other electrical equipment if used outside a hospital setting.
- The LED headlight is not provided sterile, nor is sterilizable.

4.2 Šviesos ryškumas 70 000 lux 40 cm atstumu
4.5 Šviesos veikimo laikas pilnu intensyvumu 3 val.
4.1 Šviesos temperatūra 4500 K
4.4 Šviesos lauko diametras 20 - 110 mm

3. SPECIFICATIONS

PARAMETER	VALUE
Light Output	70,000 lux (0-100% infinitely adjustable) 4.2 40cm / 16 inch working distance
Runtime	3hr at full intensity (6hr at 50% intensity) with standard battery 4.5 6hr at full intensity (12hr at 50% intensity) with extended life battery pack
Color Temperature	4500K typ. 4.1
CRI	75 typ.
Spot Diameter	20-110mm (infinitely adjustable) 4.4
Operating Conditions	32 to 86ºF (0 to 30ºC) 30 to 75% RH, non-condensing

4. CERTIFICATIONS

PARAMETER	VALUE
System Classification	FDA Class I, Device Listing 125713 EU Class I, Active device per Annex IX, rule 1
EMC Certifications	CISPR 11 Class A
CE Marking	CE Marking for MDD 93/42/EEC and AMD 2007/47/CE
Degree of protection against harmful ingress of water	IPX-0; no protection.
Degree of safety in the presence of Flammable Anesthetics	Equipment is NOT suitable for use in the presence of flammable anesthetics.
Mode of operation	Continuous

5. OVERVIEW

LED HEADLIGHT

No.	Name	Function
1	Iris Ring	Controls the size of the light spot
2	Headlight module	Houses the high intensity LED and fan
3	Linkage	Allows relocation of the headlight module with respect to the headband
4	Ratchet Knob	Changes the size of the headband
5	Headlight Module power cable	Connects the headlight module to the battery holster
6	Gown Clip	Display Main Menu

BATTERY HOLSTER

No.	Name	Function
1	Battery Pack Compartment	Houses the battery pack
2	Dimming Knob	Turns module ON/OFF and adjusts the light intensity 4.3
3	Holster power cable	Connects the battery holster to the headlight module

4.3 Šviesos intensyvumo reguliavimas

6. SETUP AND OPERATION

6.1. Device Setup

- Fully charge any batteries supplied with the device.
- Remove the rubber protective lens cap from the Headlight Module.
- Attach the Headlight Module to the Battery Holster by connecting the latching connectors located on the power cables. Ensure the cables are lined-up before engaging.

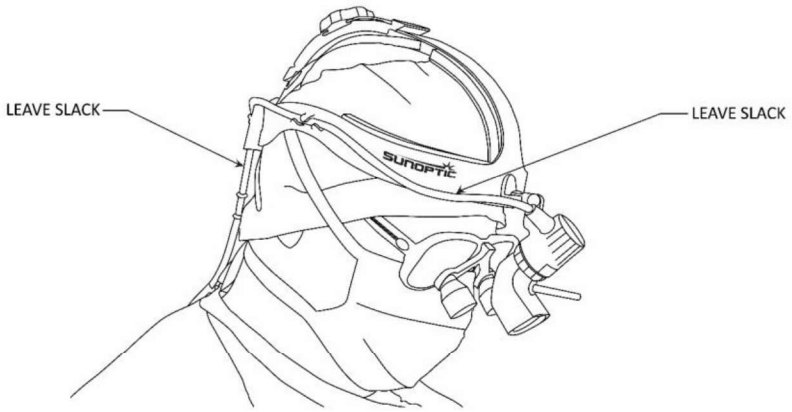
Headlight Module – Battery Holster Connecting Cables

CAUTION: Do not force the power cables to connect as you may damage the pins. Rotate slowly until the connectors engage.

- Insert a fully charged battery pack into the Battery Holster, ensuring the battery pack slots line up with the holster contacts.
- Place headlight on your head and adjust the two ratchet knobs until the headband fit is comfortable and snug upon the head.
- *(Optional)* Attach a power cable gown clip just below the shoulder to reduce cable weight on the headband.

Headband Power Cord Gasket

- Retaining gaskets are installed on the headlight module power cable to prevent cord slippage from the headband. Please adjust the position of these gaskets as necessary to reduce any unnecessary strain on the headlight. Leave enough cable slack to allow module repositioning as shown in the figure below.



6.2. Operation

- Rotate the Dimming Knob located on the Battery Holster clockwise to turn on the device.

NOTE: If the Battery Holster beeps twice and fails to turn on, an incorrect battery pack has been installed, and should be changed to the correct pack.

- Continuing to rotate the Dimming Knob clockwise will increase the intensity of the LED, while rotating counterclockwise will dim the LED.
- Fully rotating the Dimming Knob counterclockwise until it clicks will turn off the device.

NOTE: Lower light intensities will result in longer runtimes.

- The spot size of the headlight may be adjusted by rotating the Iris Ring located on the headlight.
- The Headlight Module position may be adjusted my manipulating the Linkages connected to the Headband.
- The Battery Holster will produce a single audible beep when the battery is running low on charge. Two beeps signify that the battery is very low and should be replaced with a fully charged battery.

CAUTION: To avoid over-discharging of the battery pack, install the battery pack in an approved charger once the Battery Holster begins to notify of low charge. **DO NOT** store battery packs with low charge for extended periods of time, and **DO NOT** leave discharged batteries in the Battery Holster.

- To disconnect the Headlight Module from the Battery Holster, press the retaining button located on the power cord connectors and disengage.
- When storing the device, reinstall the protective lens cap on the Headlight Module to prevent damage to the Headlight Module lens.

6.3. Battery Pack and Charger Information

Please refer to the separate Battery Pack and Charger Instructions for Use on how to safely handle and operate these devices.

7. CLEANING AND DISINFECTION

The headlight module and headband can be wiped down with commercially available cleansers commonly used for disinfection of electronic equipment in hospitals such as ethyl or isopropyl alcohols, disinfecting sprays containing quaternary ammonium compounds, or hydrogen peroxide. The Headlight Module lens should be cleaned only with lens tissue.

WARNING: DO NOT use strongly caustic or acidic cleansers such as “Clorox” hypochlorite bleach, ammonia, muriatic acid, or similar products. **DO NOT** use acetone, methyl ethyl ketone, or halogenated / chlorinated hydrocarbon solvents or cleansers containing any of these restricted compounds.

Apply cleaning agents by light spray or dampened towels. Do not pour liquids onto the device. Do not allow liquids to enter the device seams or ventilation openings.

Follow all applicable bloodborne pathogen procedures as required by OSHA and/or your hospital when cleaning and disinfecting the product.

WARNING: The Headlight is not sterilizable. **DO NOT** autoclave the Headlight Module, Headband, or Battery Pack**.**

8. MAINTENANCE, SERVICING, REPAIR & WARRANTY

The LED Headlight has no user or field serviceable components. It can only be serviced by the manufacturer or by manufacturer-trained technicians.

8.1. Warranty

The LED Headlight and Battery Holster each carry a 3-year warranty from the date of shipment on workmanship and all defects of material.

Should your product prove to have such defects within three years of shipment, Sunoptic Technologies® will repair or replace the product or component part without charge. Should your product(s) need servicing under this warranty, please contact Sunoptic Technologies® or a local distributor for return authorization documentation.

Please carefully pack the unit in a sturdy carton and ship it to the factory. Please include a note describing the defects, your name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, normal wear, and tear or if transferred to a new owner without authorization from Sunoptic Technologies®. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

8.2. Repair

You may return your product(s) for repair, shipping prepaid to the factory. Your product will be inspected, and an estimate of repair charges will be submitted to you for approval.

PHONE: +1 (877) 677-2832 INTERNATIONAL: +1 (904) 737-7611
FAX: +1 (904) 733-4832

9. END OF PRODUCT LIFE

In accordance with the European Waste from Electrical and Electronic Equipment (WEEE) directive, we encourage our customers to recycle this product whenever possible. Disposal of this unit must be performed in accordance with the applicable local environmental regulations.

In the US, a list of recyclers in your area can be found at: *http:/www.eiae.org/.*

Please contact customer service to issue a return authorization to return product to manufacturer at the end of product life.

10. SYMBOLOGY

	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	Symbol for Authorized Representative in the European Community
	Caution, consult accompanying documents
	Consult Instructions for Use
	CE mark
	Not for disposal in general waste
	Medical device
	Non-Sterile
	Storage / Shipping Temperature
	Storage / Shipping Humidity
	Barometric Pressure
	Unique Device Identifier
	Keep Dry