

SSL-5500

LED Headlight System Operator Manual

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1. INTENDED USE

Thank you for your purchase of your new LED-5500 Headlight!

This LED-5500 Headlight system is designed to deliver illumination from a high intensity LED for surgical site illumination. The LED-5500 is a battery powered, portable headlight with an adjustable spot and infinitely dimmable LED.

The LED-5500 also includes a built-in battery gauge located on the control module on one side of the headband. The battery life will increase when decreasing the intensity of the light output. The battery gauge is a convenience and the user should have a plan for backup lighting for any application for using this system; see GENERAL WARNINGS.

2. GENERAL WARNINGS

2.1 Headlight Warnings

- The user of this product should be thoroughly familiar with the use and care of this product.
- The user should carefully study the manual before making any attempts to use this product clinically.
- Before each procedure, carefully check the battery state of charge to assure optimal duration for this procedure, and have a backup charged battery accessible.
- LED high intensity headlights will produce some heat in addition to light. The high output of these headlights may become warm to the touch. This is normal operation.
- Light source can cause damage to the eye if viewed directly with unprotected eye.
- User is responsible for determining if interruption of light output will create an unacceptable risk. If this determination is made, arrangements (such as standby illuminator) should be made to reduce risk.
- Users are responsible for providing backup lighting systems for your application when using this device.
- The illuminator produces a highly concentrated (luminous energy per unit area) light beam. Qualified personnel must determine a safe working distance and intensity setting for each application.
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- To prevent fire or electric shock, do not open or expose the illuminator unit to rain or moisture. Refer all servicing to qualified personnel only.
- The headlight should only be used with approved batteries supplied by Sunoptic Technologies. To order additional batteries, please call customer service 1-877-677-2832 (+1-904-737-7611 International)
- User should ensure that the air vents located on the headlight module are not obstructed or blocked to allow the headlight to receive the necessary cooling to prevent an over temperature shut off.
- The headlight is suitable for operation in ambient environments from 0 to 30°C.
- The headlight meets CISPR 11 Class B limits and is suitable for use in a hospital and residential environment, but not in proximity to RF emitting equipment.

2.2 Battery Warnings

- Upon initial receipt, charge both batteries completely before first use.
- Upon initial receipt and before each use, inspect each battery for damage. Do not attempt to use or charge a damaged battery.
- Do not expose the battery to heat, fire, mechanical shock, or store in direct sunlight.
- Do not open or dismantle the battery pack.
- Do not sterilize, immerse, or expose the battery to water, solvents, lubricants, or other chemicals to clean the battery or charger. Do not allow water to collect in the battery contacts. Keep clean and dry.
- Do not store the batteries haphazardly in a box or drawer in which objects may short circuit the battery.
- Do not use any other charger other than a Li-ion charger supplied by Sunoptic Technologies to charge the battery.
- Ensure correct orientation is followed when installing a battery into a device.
- Do not attempt to force a battery into a device.
- When possible, remove the battery from equipment when not in use.
- Do not store batteries for more than one month in a discharged state.
- Do not store batteries for more than one year without recharge.
- Battery packs can be stored in -20 to 60°C ambient conditions.
- For extended storage periods, it is recommended to store the batteries in conditions < 35°C.

2.3 Charger Warnings

- The battery charger and the battery charger's power supply are not to be used in the operating room theater or patient area.
- Do not attempt to operate the charger if the cord and/or plug appear to be damaged, such as cuts, bent pins or contacts, and/or cracks.
- Do not sterilize, immerse, or expose the charger, or power supply to water, solvents, lubricants, or other chemicals to clean the charger unless otherwise directed. Do not allow water to collect in the bays or on top of the charger. Do not allow water to enter the power connection on the back of the charger. Keep clean and dry.
- Place the charger in a cool spot, away from any heat sources.
- Unplug the power supply from the wall socket during extended periods of non-use. Disconnect the power plug by pulling from the plug housing and not the cord.
- Although the charger may become warm during charging, this is normal and presents no danger.
- Do not cover vent holes on the back of the charger.
- The battery charger must only operate in 10 to 45°C ambient conditions.

3. OPERATION

Before continuing remove the protective lens cap from the headlight module.

Insert a fully charged battery into the battery compartment module located on the left side of the headlight when in use. To do so, line up the battery rails located in the compartment with the slots located on the sides of the battery pack. Push battery into the housing then slide forward toward the contacts until the locking tab clicks into place. See figures 1, 2, and 3 for further detail. To remove the battery pack from the battery compartment, press

down on the locking tab, and perform the reverse of the above operations. While pressing down on the locking tab, slide the battery pack back and pull straight out.

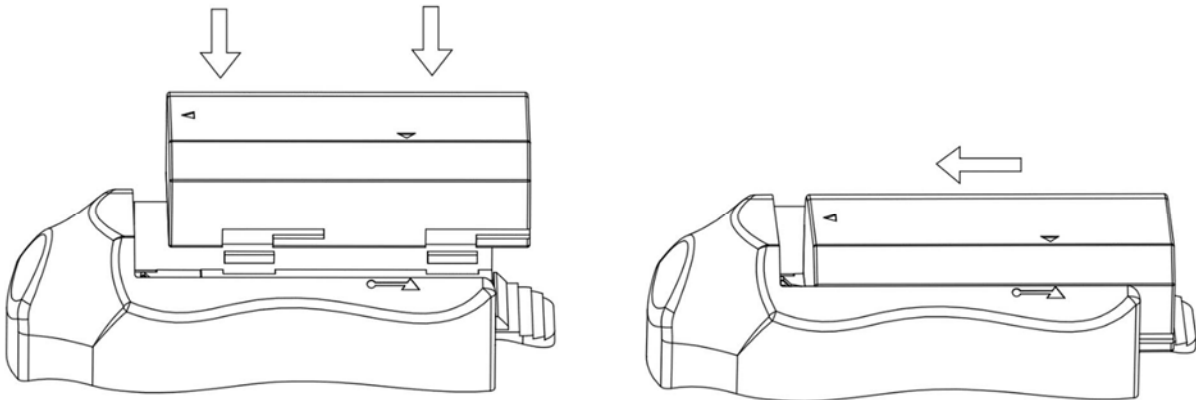


FIGURE 1 (above). Inserting the battery pack

FIGURE 2 (right). Fully inserted battery pack

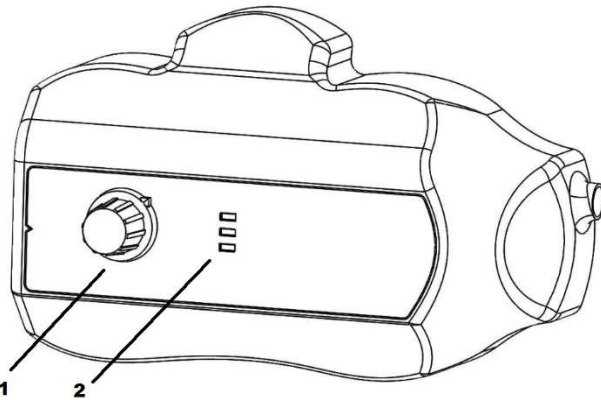
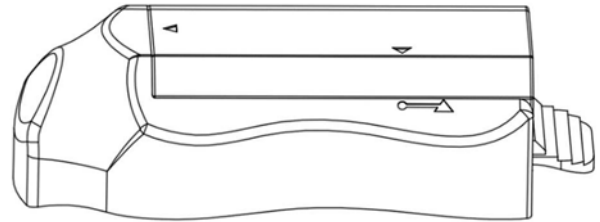


FIGURE 3 (left). Control Module

1. Intensity Knob and Power Switch
2. Green LED battery gauge

Once the battery is installed, turn the unit on by turning the intensity control knob clockwise. The intensity control knob will click to signify turn-on and turn-off. Adjust the intensity control until the desired brightness is achieved. Note that less intense brightness settings can produce longer runtimes.

Located next to the intensity control is the battery gauge consisting of three small green LEDs. Each LED tile represents approximately 30% of battery charge. Refer to Table 1 to see the complete battery gauge legend. NOTE: the unit will run approximately five minutes after the last green LED extinguishes. After this time, the main LED will shut off to prevent over discharging of the battery, and a new battery should be installed.

1. LED Mode	1. Battery Capacity
2. All three green LEDs are illuminated	2. Capacity > 60%
3. Two green LEDs are illuminated	3. 60% > Capacity > 30%
4. One green LED is illuminated	4. 30% > Capacity > 5%
5. No green LEDs are illuminated	5. Capacity < 5%; shortly enters shutdown mode

TABLE 1. Battery Gauge Legend

The headlight features an iris to allow adjustment to the diameter of the light beam. Rotate the fluted iris ring on the headlight for the appropriate spot diameter. The headband features two different ratcheting mechanisms that allows the user to make size adjustments to fit any sized head. Turn the knob on the rear of the headband and the top of the headband until comfortable.

The unit is now ready for use.

4. MAINTENANCE

Storing the headlight system in a safe place will prolong the life of the unit.

The following guidelines will help in sustaining the headlight system useful life:

- Keep the optical faces of the LED Headlight lens from touching hard surfaces, which may cause scratches on the surface. Scratches on the surface will diminish the light output. Using the lens cap during transport will help protect the lens.

5. CLEANING

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 lens should be cleaned only with lens tissue, available in any camera store; follow the directions on the package.

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 frank liquids to enter the device seams or ventilation openings.

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



Do not autoclave the LED Headlight module, headband, or battery.

6. CHARGER OPERATION INSTRUCTIONS

6.1 Charger Setup

- The charger should only be powered by the AC adaptor supplied with the unit.
- Check the AC adaptor and install the appropriate plug assembly that fits the supply mains outlet.
- Depending on the AC adaptor model, change the plug assembly by either sliding down the retaining clip and pulling out the plug assembly or by pushing in the retaining clip and sliding out the plug assembly. Insert the correct plug assembly by performing the reverse operation.
- Plug the AC adaptor into mains power
- Plug the output of the AC adaptor into the input jack on the rear of the battery charger noted in figure 4.
- When power is correctly applied, the status indicator will be **GREEN**.

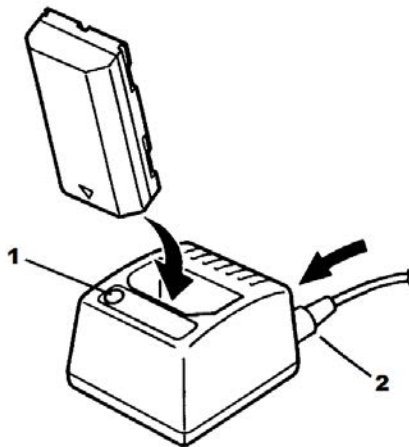


Figure 4. Battery Charger Diagram

1. Status Indicator
2. AC Adaptor Connector

6.2 Battery Charger Operation

- The operation of the charger is automatic.
- Simply place the battery pack into the charger pocket as displayed in figure 4. Ensure that the two gold contacts on the battery pack are placed face down into the pocket.
- The status indicator will change to **RED** to indicate that the charger is charging the battery.
- When the battery is fully charged, the status indicator will change to **GREEN**.
- The status indicator will start flashing in the event that the charger is operating outside of its temperature range.

NOTE: Ensure that the battery pack is fully inserted into the charger by pushing down on the battery pack when inserting into the charger. If the battery pack is not fully inserted, it will not charge.

7. REPLACEMENT PARTS

For replacement parts, additional, or optional equipment please call Customer Service (877)-677-2832 (+1-904-737-7611 International).

8. USER SERVICE

The LED headlight has no user or field serviceable components. It can only be serviced at the factory by factory trained technicians.

9. WARRANTY AND REPAIR

Your LED headlight carries a two year warranty from the date of shipment on workmanship and all defects of material.

Your original batteries and charger carry a one year warranty from the date of original shipment on workmanship and all defects of material. Should your product prove to have such defects **SUNOPTIC TECHNOLOGIES®** will repair or replace the product or component part without charge. Please contact **SUNOPTIC TECHNOLOGIES®** for return authorization documentation.

You should carefully pack 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.

POST WARRANTY REPAIRS: 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. Payment must be received before repairs are completed.

- Telephone: toll free 877-677-2832
- FAX number: 904 733-0012
- Customer Service: 904 737-7611

10. END OF PRODUCT LIFE



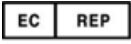


In accordance with the European Waste from Electrical and Electronic Equipment (WEEE) directive, we encourage our customers to recycle this product whenever possible. Disposal of this unit must be performed in accordance with the applicable local environmental regulations.

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.



11. CHART OF MEDICAL SYMBOLS USED

	CE mark
	Manufacturer
	"Authorized Representative in the European Community."
	Caution, consult accompanying documents
	Do not dispose of in ordinary municipal waste, Recycle.