LED-4500

(US PATENT 8,911,130)

LED Illuminator

Operator Manual

CE

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1. INTRODUCTION

Congratulations on the purchase of your new LED-4500 Light Source!

This user-friendly LED light source is a high efficiency light source utilizing state-of-the-art superior illumination technology. It offers a variety of features such as:

- Whisper quiet operation
- Compact and light weight
- Pulse-width modulation (PWM) LED brightness dimming for color quality
- Ergonomic turret which accepts various light guides including ACMI, WOLF, OLYMPUS, and STORZ
- Auto shutter activates when light guide is removed

In short, you have chosen the best and we would like to make sure you receive the optimal results with your new LED light source by using it correctly.

This Operator Manual will help you to install the device and optimally integrate it with other components of your system. It will also instruct you how to operate the LED light source and how to keep it clean. It will give you maintenance and service guidelines as well as recommendations for best performance results.

1.1 Indications for Use

The LED illuminator is used to illuminate the site of surgery during minimally invasive procedures including, but not limited to arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), and endoscopy (general, gastroenterological, and ENT surgery). Light is typically transmitted from the illuminator through a fiber optic cable and typically a scope or other light guide.

The LED illuminator is intended to be used in a controlled operating room environment by qualified medical personnel. The LED illuminator is provided non-sterile and is not intended to be sterilized. The system has an expected, but not limited, three-year service life.

The illuminator is not intended to be used for monitoring, diagnostic, or other life support functions. This device does not sustain nor support life. The device is not intended to compensate for injury, handicap, replacement or modification of anatomy, or control of conception. No special intervention is necessary in the event of device failure. As such, this device has no essential performance as defined by IEC 60601-1, and should this device fail to operate, a suitable backup should be available for any procedure where it may be used.

There are no contraindications.

1.2 Functions of Design

The LED-4500 comprises a standalone, mains-powered illuminator. The standard CRI model produces 2800lm (typical) in the visible spectrum range. The illuminator is typically used with a fiberoptic light guide that connects to a light port located on the front panel. Light intensity is controlled via pushbuttons located on the front panel of the console.

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

- Federal law restricts this device to sale by or on the on the order of a licensed practitioner.
- The illuminator produces highly concentrated light. Avoid shining light beam into eyes or looking directly into the light beams at the ends of connected instruments and/or light guides. When not using the device, it is advised to fully dim the illuminator or place unit into STANDBY mode.
- Qualified personnel must determine a safe working distance between the ends of connected instruments and/or light guides and the patient for each application. There is a risk of patient injury if a light guide or instrument connected to the light source comes to close to the patient.
- User is responsible for determining if interruption of light output will create an unacceptable risk. Having a backup illuminator is advised.
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- For endoscopic procedures: the illuminator should only be used with type BF endoscopic instruments which have been certified to IEC 60601-1 and IEC 60101-2-18.

This symbol indicates type BF equipment.

- All devices and/or instruments connecting to the illuminator must be classified as medical equipment. It is the user's responsibility to ensure that all equipment used with this device meets all applicable standards such as IEC 60601-1.
- To prevent fire and/or electric shock, do not open or expose the illuminator to liquids.
- The illuminator-side light guide connection may become hot during use. Allow adequate time to for end tip to cool before removal from illuminator.
- Instruments and/or light guides connected to the illuminator must be **NON-CONDUCTIVE.** There should be no conductive shielding or any conductive connection between the illuminator and the patient. Such connections present a risk to patient safety.
- Instruments and/or light guides should be clean and dry before being connected to the illuminator.
- **DO NOT** modify the equipment without authorization from the manufacturer.
- The illuminator is provided non-sterile and is not intended to be sterilized.
- Use only the power cord supplied with illuminator or medically approved power cords with less than 200mΩ of ground impedance and less than 16ft (<5m) of length. If unauthorized cables are used, the device may have increased electromagnetic emissions and/or decreased electromagnetic immunity which may result in improper operation.
- This device meets CISPR 11 Class A limits and is suitable for use in a hospital and industrial environments. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency

communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

- Performance of this device may be affected in proximity of another device and/or equipment capable of producing high levels of RF emissions. The device should be used no closer than 12 inches (30 cm) to any part of RF equipment including cables. 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.

2.2 Cautions

- Before each procedure, carefully check the illuminator for damage. DO NOT use a damaged illuminator.
- The user should verify the light guide end tip and the active illumination port are of the same type before insertion. DO NOT attempt to force an end tip into an incorrect port.
- All servicing and repair must be performed by the manufacturer or qualified service technicians.
- Ensure that the air vents located on the illuminator are not obstructed to allow the device to receive the necessary cooling to prevent an overheating.
- The illuminator is designed to only be used with Sunoptic Technologies® fused light guides. Other light guides may damage the unit due to the high levels of light intensity produced by the unit.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2.3 Notes

- If there is a power interruption during use, the illuminator will shut down and automatically restart if the power switch remains in the ON position. There may be a short delay as the unit reboots.

3. SPECIFICATIONS

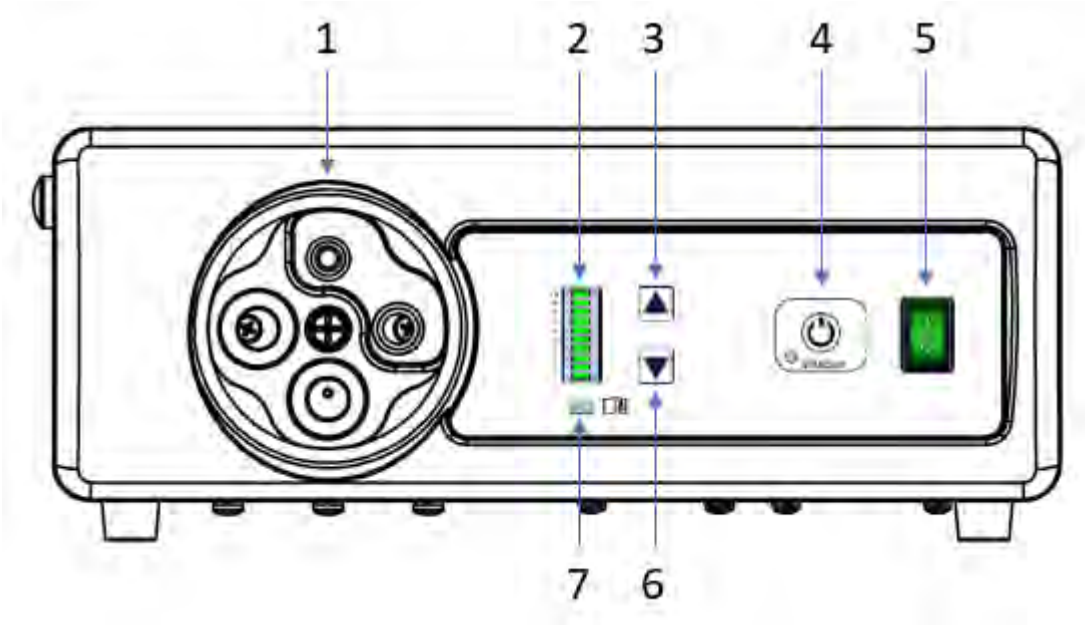
PARAMETER	VALUE
Light Source Type	LED (Light Emitting Diode)
Color Temperature	6500K nominal
LED life	30,000 hours (typ.)
CRI	70 (typ.)
Brightness Control	PWM (Pulse-width Modulation) 0-100% dimming
Light guide adaptor	Rotating turret with STORZ, ACMI, WOLF, and OLYMPUS (if equipped)
Input Power	100-240 VAC, 50/60 Hz 0.7 – 1.5A (max.)
Fuses	5 x 20 mm, 250V, 2A, Type F
Operating Conditions	32 to 86ºF (0 to 30ºC), 30 to 85% RH non-condensing, 700 to 1060 hPa
Storage Conditions	-4 to 140ºF (-20 to 60ºC), 0 to 95% RH non-condensing, 700 to 1060 hPa
Dimensions	11.2” x 4.5” x 13.2” (W x H x D) 28.5 x 11.4 x 33.6 cm (W x H x D)
Weight	7.55 lbs / 3.42 kg

4. CERTIFICATIONS

PARAMETER	VALUE
System Classification	FDA Class I, Device Listing D095692, 510(k) exempt EU Class I, Active device per Annex IX, rule 1
Isolation	Type BF
EMC Certifications	CISPR 11 Class A, IEC 60601-1-2 4th Edition Electrostatic discharge: ±8 kV contact, ±15 kV air Radiated RF EM Fields: 3 V/m, 80 – 2700 MHz EFT / Burst: ±2 kV, ±1 kV signal lines, 100 kHz SURGE: ±0.5, ±1 kV Conducted disturbance: 3 V 150 kHz – 80 MHz and 6 V in ISM bands Power frequency magnetic fields: 30 A/m Voltage dips: 0% Un / 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°, 40 % Un / 5 cycles, 70 % Un / 25 cycles Voltage interruptions: 0% for 5000 ms Proximity fields: in accordance with EN 60601-1-2: 2015 table 9
CE Marking	Regulation (EU) 2017/745
Other Approvals	CAN/CSA-C22.2 No. 60601-1-08, TC 2:2011 (Corrigendum 2) CAN/CSA-C22.2 No. 60601-2-18:11
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

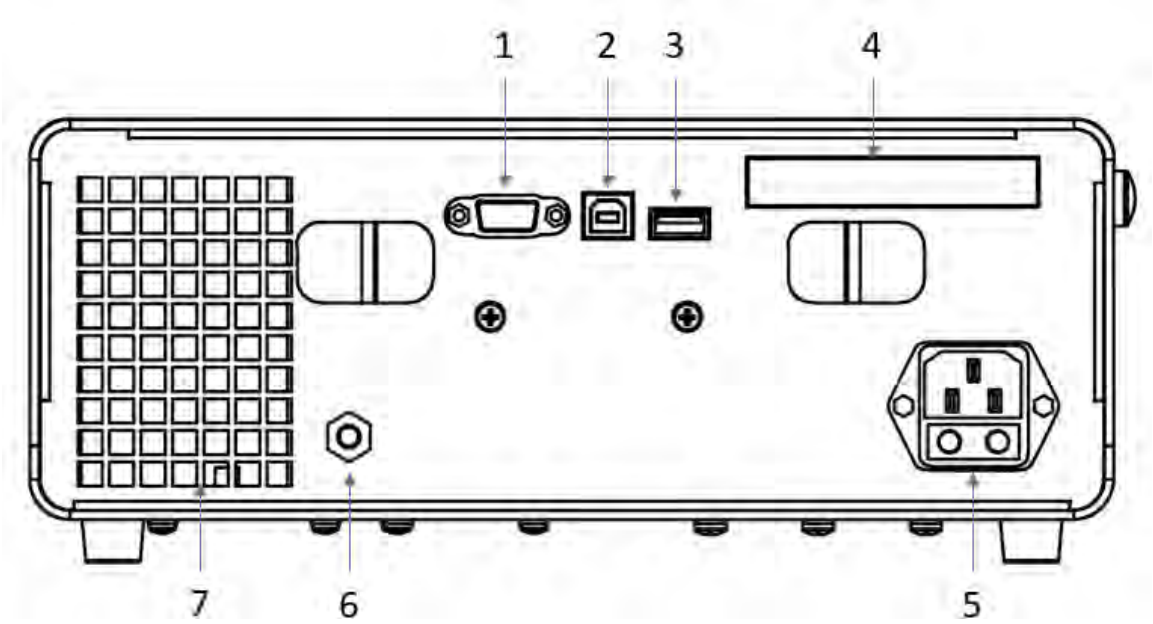
5. OVERVIEW

FRONT PANEL



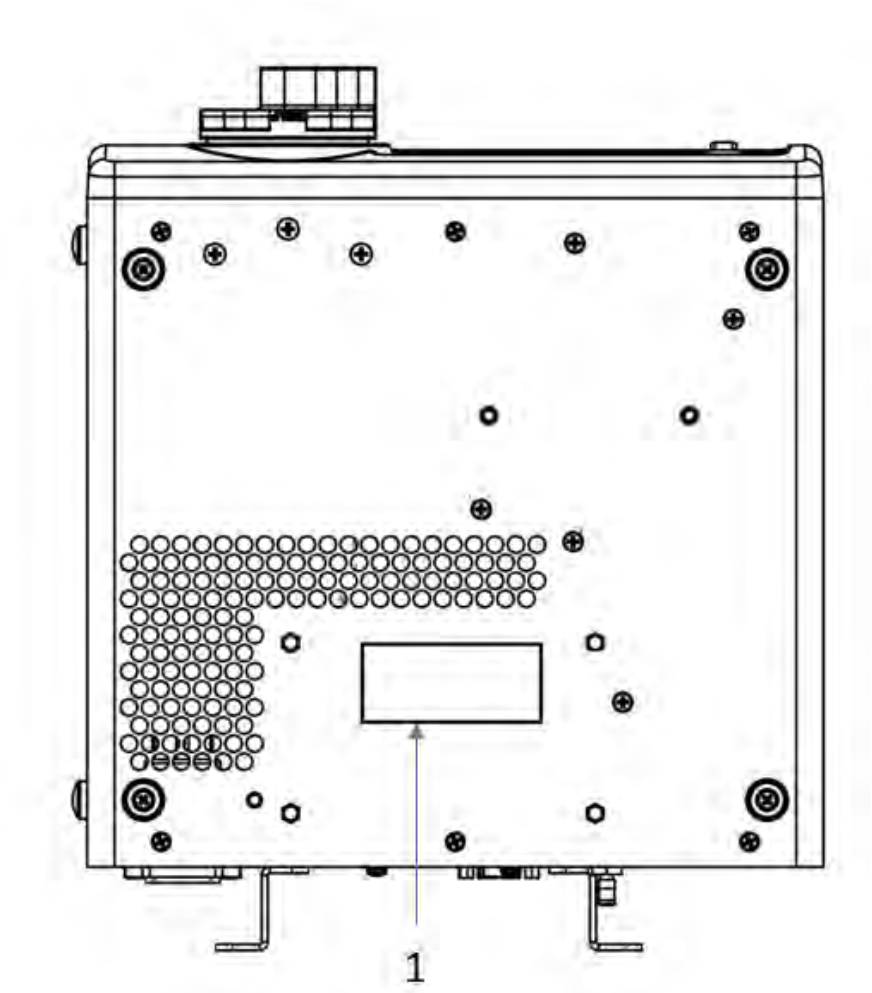
No.	Name	Function
1	Light Guide Adaptor	Light guide connection point. The active illumination port is always in the top-most position.
2	LCD Intensity Display	Displays the current intensity level of illumination. Each fully lit tile indicates approximately 10% increase of brightness.
3	Intensity increase button	Button that increases illumination brightness
4	STANDBY mode button	Activates or de-activates STANDBY mode. STANDBY mode extinguishes the illumination LED but allows the unit to remain energized.
5	Mains power switch	Turns unit ON/OFF
6	Intensity decrease button	Button that decreases illumination brightness
7	Warning Indicator	When illuminated, indicates device fault

REAR PANEL



No.	Name	Function
1	Serial Port	Data communication port
2	USB-B	Data communication port
3	USB-A	Firmware update port (factory use only)
4	Software Part Label	Label stating the software part number installed on the unit
5	Appliance Inlet	AC power cord connection Also contains fuses: 2A, 250V (5 x 20 mm) time delay
6	Equipotentiality Stud	Potential equalization connection
7	Exhaust Vent	Warm air exhaust venting which facilitates device cooling

BOTTOM VIEW



No.	Name	Function
1	Product Label	Product Label containing: Model Number, Serial Number, Part Number, Electrical Ratings, Manufacturer Name and Date, Regulatory Marks, UDI Information and FDA "Rx Only" Symbol.

6. SETUP AND OPERATION

6.1 Device Setup

Place the Illuminator on a stable surface such as a cart, counter, stand, etc.

WARNING: DO NOT use the device in any environment with explosive or flammable gases.

WARNING: Avoid placing the device in an area where the illuminator may be splashed with liquids.

WARNING: DO NOT obstruct the exhaust or cooling vents of the illuminator. User must ensure that environment air temperatures surrounding the unit are within the allowable limits.

Make sure the power switch is in the OFF position.

Connect AC power cord to the appliance inlet located on the rear panel of the light source.

CAUTION: Use only power cords provided with the unit or cables approved for medical use.

WARNING: To prevent electric shock, connect power cords of peripheral equipment through medical isolation transformers.

NOTE: When using a medical isolation transformer, ensure that the transformer has sufficient power ratings. Ensure that the power cord is connected to mains power with a three-prong plug.

Connect a fiberoptic light guide to the topmost position of the rotating turret, ensuring that the fiberoptic end tip type matches the accepting port.

NOTE: The illuminator has a light guide sensing feature in which the main illumination LED will not turn-on until a light guide is connected to the console.

6.2 Operation

After the power cable and light guide are properly connected, turn on the illuminator by pressing the mains power switch located on the front panel. The power indicator light within the switch should illuminate.

NOTE: Upon startup, the illuminator will default to minimum illumination brightness.

STANDBY Button

Activates or deactivates STANDBY mode. STANDBY mode allows the user to turn the main LED ON or OFF while the unit is still energized.

Press and HOLD for at least one second for this operation.

Light Intensity Control and Display

The light intensity may be controlled by repeatedly pressing the up or down buttons located on the front panel until the desired brightness is reached.
The intensity level is depicted by the LCD tile display. Each fully illuminated tile represents approximately 10% of the available light intensity.

Data Ports

There are three DATA transfers ports located on the rear panel: USB Type A, USB Type B, and a RS-232 Serial Port. These ports allow communications between the illuminator and other monitoring or controlling equipment.

For technical information concerning the DATA ports or assistance, please contact Customer Service.

7. CLEANING AND DISINFECTION

WARNING: Ensure that the illuminator is de-energized and disconnected from mains power before attempting to clean and disinfect.

The illuminator 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.

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 illuminator is not sterilizable. **DO NOT** attempt to autoclave the device**.**

7.1 Cleaning the Optic

- The optic is located in the topmost port of the rotating turret.
- Remove loose dust and surface contaminants on the optic by using compressed air.
- Soak a cotton-tipped swab or lens tissue with a solvent mentioned above, then wipe the surface of the optic in a circular motion starting from the outer edge of the optic.
- Repeat as necessary, using a new swab or tissue each time.

8. MAINTENANCE, SERVICING, REPAIR & WARRANTY

8.1 Fuse Replacement

WARNING: Always TURN OFF and UNPLUG the illuminator from mains power before attempting to replace a fuse.

Turn off illuminator and unplug power cord. On rear panel of the console, remove the fuse holder located in the appliance inlet. Replace blown fuse with 2A, 5x20mm, fast acting, 250VAC rated fuses. Insert holder back into fuse housing.

8.2 Warranty

The illuminator carries 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.

8.3 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

8.4 Troubleshooting

Problem	Solutions
Main switch power indicator (refer to 5) is not lit when switched on.	Check that the AC power cord is properly connected to an energized circuit and the device AC receptical.
	Check the unit fuses and replace if necessary.
	Contact customer service.
The power indicator is lit but the main LED is still off.	Press Stand-By switch to turn on the LED.
	Check that the light guide is inserted in the active turret port (top).
	Increase the LED intensity.
	Contact customer service.

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
	Do not use if package is damaged.
	Not for disposal in general waste
	Medical device

	Non-Sterile
	Storage / Shipping Temperature
	Storage / Shipping Humidity
	Barometric Pressure
	Unique Device Identifier
	Keep Dry
	AC Current
	Product Safety Mark
	Equipotentiality
	Power on
	Power off
	Type BF
	Protective Earth (Ground)