SSL-2000

LED Light Source
Operator Manual

CE

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1. INTRODUCTION

Congratulations on the purchase of your new SSL-2000 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:

- 6500 K daylight brightness for good color definition
- Quiet operation
- Long life, 50,000 hrs.
- Compact and light weight
- Turret which adapts to various types of light guides
- Pulse-width Modulation (PWM) Electrical Dimming

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.

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

No illuminator is intended to be used for monitoring, diagnostic, or other life support functions. No device sustains nor supports 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-2000 comprises a standalone, mains-powered illuminator that produces 1000lm (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 rotating dimming knob 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

- 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. To reduce risk, always install a fiberoptic cable when the illuminator is OFF or when the dimming knob is turned to the fully dim position. When not using the device, it is advised to fully dim the illuminator.
- 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.
- 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.
- 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 **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.
- Any serious incident occurring in connection with the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

3. SPECIFICATIONS

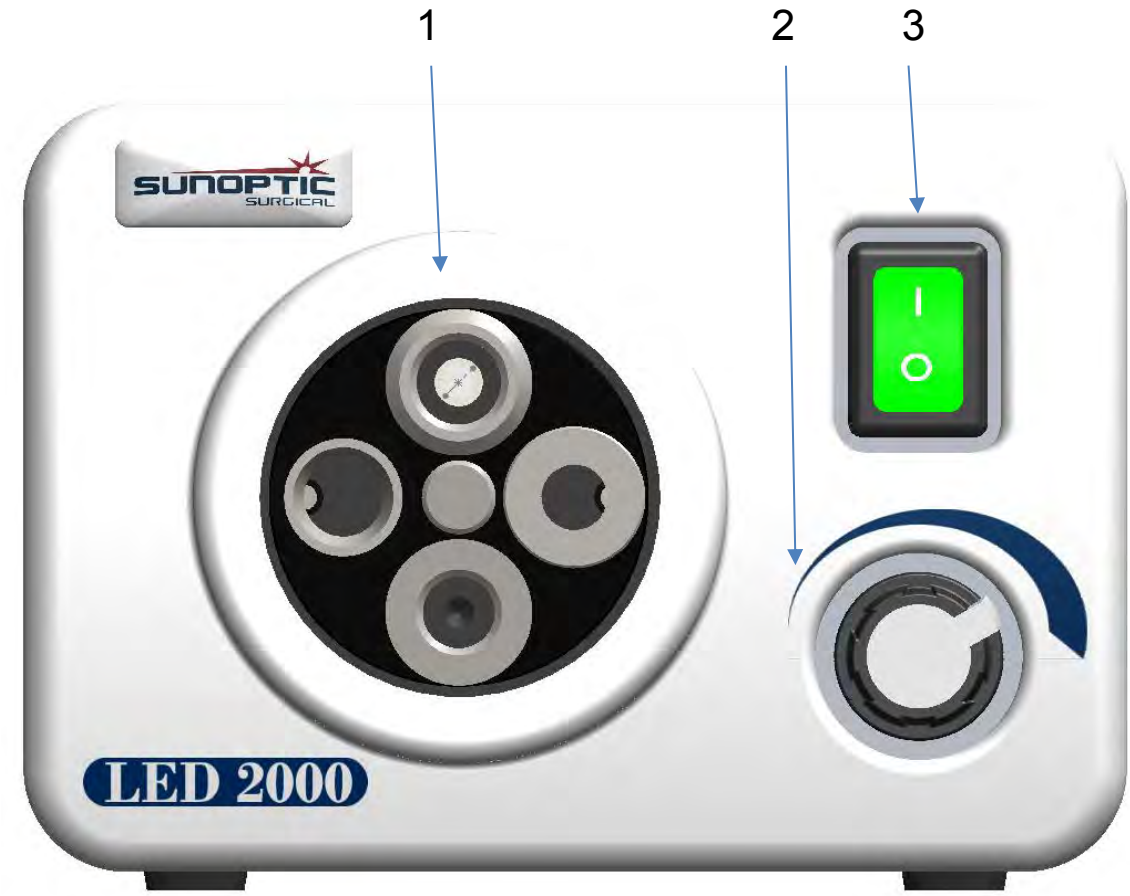
PARAMETER	VALUE
Light Source Type	LED (Light Emitting Diode)
Color Temperature	6500 K (typ.)
LED life	50,000 hours (typ.)
CRI	70 (typ.)
Brightness Control	PWM (Pulse-width Modulation) 0-100% dimming
Light guide adaptor	Rotating turret with STORZ, ACMI, WOLF, and OLYMPUS (if equipped)
Input Power	100-240 VAC, 50/60 Hz 0.5 – 1A (max.)
Fuses	¼" x 1-1/4" (6.4 x 31.7mm), 250V, 2A, Time Delay
Operating Conditions	32 to 104ºF (0 to 40ºC), 30 to 85% RH non-condensing, 700 to 1060 hPa
Storage Conditions	-4 to 140ºF (-20 to 60ºC), 30 to 95% RH non-condensing, 700 to 1060 hPa
Dimensions	4.65" x 3.32" x 7.25" (W x H x D) 11.8 x 8.4 x 18.4 cm (W x H x D)
Weight	2.5 lbs / 1.14 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, ±2 kV unsym 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

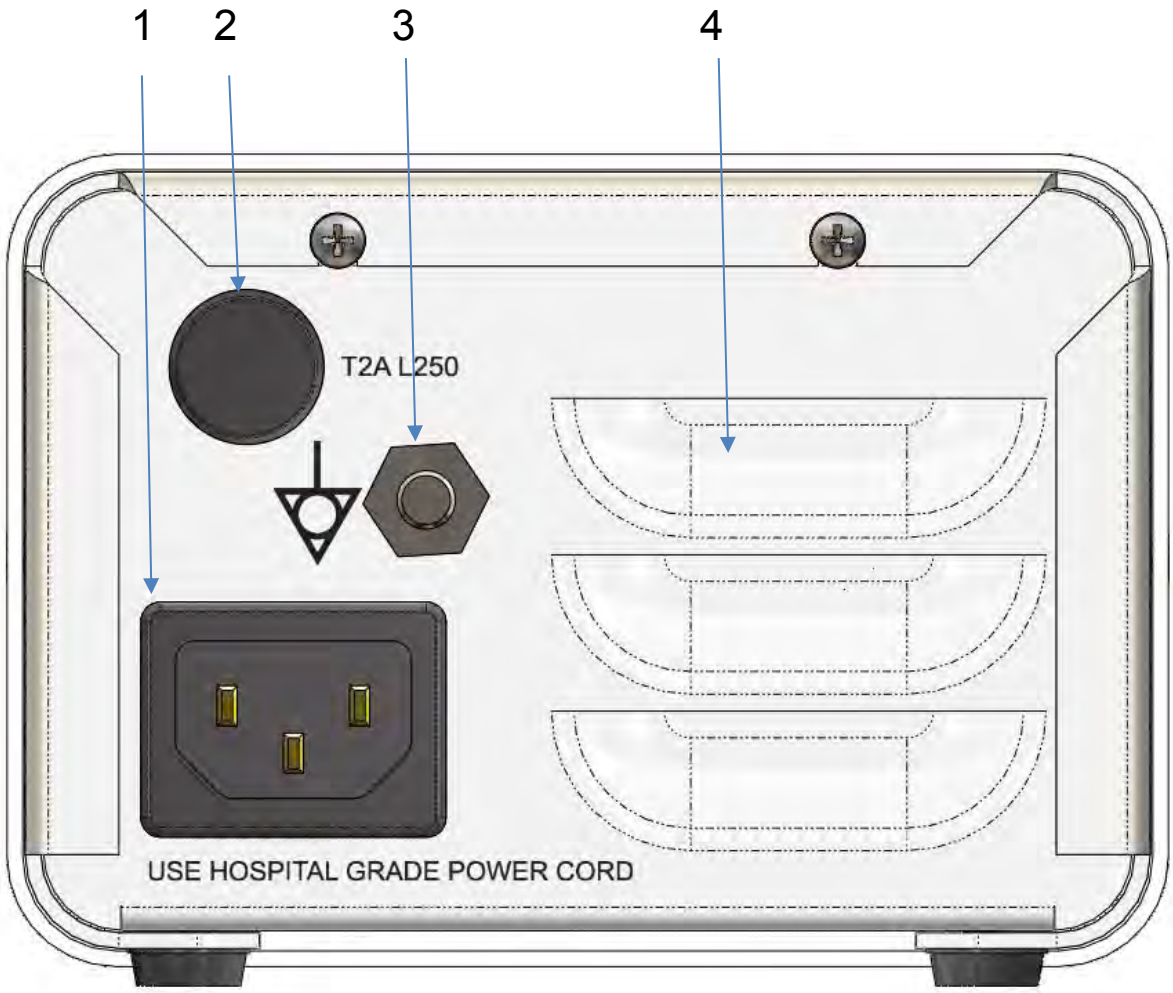
5. OVERVIEW

FRONT PANEL



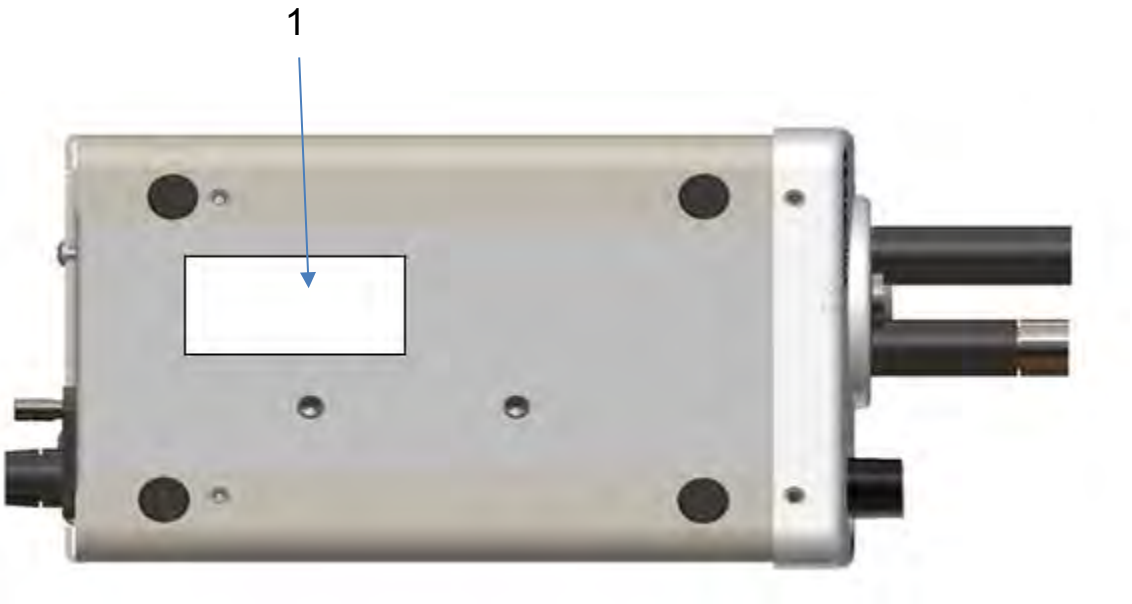
No.	Name	Function
1	Power Switch	Turns illuminator ON and OFF.
2	Light Guide Connection	Rotating turret light guide connection point. The active illumination port is always in the top-most position.
3	Intensity Control Knob	Brightens and dims light source via PWM dimming

REAR PANEL



No.	Name	Function
1	Appliance Inlet	Accepts AC power cords
2	Fuse	¼" x 1-1/4" (6.4 x 31.7mm), 250V, 2A, Time Delay
3	Grounding Stud	For potential equalization
4	Exhaust Vents	Allows adequate ventilation and cooling of illuminator

BOTTOM PANEL



No.	Name	Function
1	Product Label	Contains product information

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.

WARNING: Ensure that any cables and/or instruments connected to the device are not obtrusive to the procedure.

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.

WARNING: To avoid adverse electromagnetic effects, DO NOT operate this equipment near high RF energy equipment.

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

6.2. Operation

After the power cable and light guide are properly connected, rotate the dimming knob to the dimmest position, and turn on the illuminator by pressing the mains power switch located on the front panel. The power indicator light within the switch should illuminate. Ensure the connected light guide is safely positioned and adjust the brightness to the desired level by rotating the intensity control knob.

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.

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. Remove the defective fuse by rotating the fuse holder cover and extracting the fuse from the holder. Replace blown fuse with ¼" x 1-1/4" (6.4 x 31.7mm), 250V, 2A, Time Delay fuse. Reinstall fuse holder cover.

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
The power indicator (refer to 5.) is not lit.	Check that the AC power cord is properly connected.
	Check the unit fuses and replace if necessary.
The power indicator is lit but the lamp will not ignite.	Turn intensity control knob clockwise to increase light output intensity.

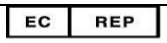
9. END OF PRODUCT LIFE

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)
	"Authorized Representative" in the European Community
	Caution
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Consult Instructions for Use
	CE mark
	Not disposable in general waste,
	Caution: Hot Surface
	Caution: Dangerous Voltage
	Product Safety Mark
	Do not use if package is damaged
	Medical device
	Non-Sterile
	Storage / Shipping Temperature
	Storage / Shipping Humidity
	Barometric Pressure
	Unique Device Identifier
	Keep Dry
	AC Current
	Equipotentiality
	Power on
	Power off
	Type BF
	Protective Earth (Ground)