Pro300
Xenon Light Source
Operator Manual

CE

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1. INTRODUCTION

The Pro300 Xenon Light Source is a state-of-the-art medical illumination device with important features like:

- 5600K nominal color temperature.
- Quiet operation.
- Compact and lightweight.
- Four-port turret accepting ACMI, Olympus, Storz, and Wolf light guides
- Auto-shutter feature of turret.
- Intuitive interface and digital dimming.
- Easy lamp replacement.

This document explains how to properly install, setup, use, clean, and maintain the device.

1.1 Intentions of Use

The intended use of this device is to provide light for fiberoptic cables and instruments – providing light for instrumentation via fiberoptic cables for use in surgical fields.

The xenon illuminator is intended to be used in a controlled operating room environment by qualified medical personnel. The illuminator is provided non-sterile and is not intended to be sterilized. The system has no limits to the frequency or duration of normal use and 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. There are no restrictions on patient population. 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 Device

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. Intensity level, lamp runtime, and other information is displayed via LCD screen located on front panel.

2. WARNINGS AND CAUTIONS

Use of this device may present hazards to the user or patient. Before operating device, please read this manual thoroughly and follow all warnings, cautions, and instructions. The words warning, caution, and note carry special meaning and are described below:

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

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

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

The **WARNING**, **CAUTION**, and **NOTE** symbols in this manual are intended to alert the user of important operating and maintenance instructions.

2.1. Warnings

To avoid injury to the user, patient, or damage to the device, please heed the following warnings:

- Failure to follow instructions in this manual may lead to serious injury or damage to the device. Read this manual thoroughly, especially the warnings, and be familiar with its contents before using the device.
- This device is designed to be used by a qualified physician, having complete knowledge of its use and of the procedure being performed.
- The device is NOT to be used in an oxygen-rich environment.
- This device produces a concentrated light beam, and this high energy density is retained through any connected light guides or instruments. The output of a connected instrument left in close proximity or contact with tissue or flammable materials presents the risk of injury or fire. Qualified personnel must determine a safe working distance and intensity setting for each application. The device should never be unattended while on.
- This device should be installed and tested prior to use. A preoperative check should be performed prior to administration of patient anesthesia to ensure all desired functions are operational and there are no signs of damage.
- This device is intended to illuminate a surgical site; the user is responsible for determining if interruption of light output, including effects from electromagnetic disturbances, will create an unacceptable risk. If such a determination is made, alternate arrangements, such as a standby or backup device, should be made by the user to reduce the risk. It is recommended to have a backup device on-hand.
- This device must be connected to a supply mains with protective earth to reduce risk of electric shock.
- This device must not share the same electrical outlet or grounding with life support or life sustaining equipment. In the case of electrical failure, the device may draw excessive power from the supply circuit and interrupt service to other equipment on that same supply circuit.
- An uninterruptible supply circuit is recommended.
- Always set up the device in a location with adequate ventilation (airflow). Insufficient ventilation may cause the device to overheat and shut down or create risk of fire. Always set up the device so the appliance inlet is easily accessible.
- Do not use the device in the presence of flammable liquids, gases, or other materials susceptible to ignition due to electrical sparking.
- This device should be used only with type BF endoscopic instruments which have been certified according to IEC 60601-1 for medical equipment and IEC 60601-2-18 for endoscopic equipment.

Symbol indicates type BF equipment.

- All equipment connecting to this device must be classified as medical equipment. Additional information processing equipment connected to the device as a medical system must be determined by the operator if all equipment complies with the appropriate end-product standards (such as IEC 60950 or IEC 60065 and the Standard for Medical System, IEC 60601-1-1).

- Use of the device with accessories or attachments requires the end-user to follow all accessory or attachment instructions which could affect setup, usage, or functionality.
- **The fiber optic cables used with this device must be electrically NON-CONDUCTIVE.** Such connections will impair device safety. Cables must be rinsed free of soaking/disinfectant solution and dry before connecting to turret. Ensure light guide optical surface is clean before connecting to turret.
- This light source can cause permanent eye damage if viewed directly with unprotected eye.
- To prevent over-heating, replace lamp with the same type and rating. Read instructions before replacing the lamp.
- Disconnect power supply cord before servicing to avoid electrical shock. Follow instructions when servicing or changing lamp.
- Do not remove cover or reach inside device in order to avoid shock hazard. Servicing must be performed by qualified personnel.
- The device must not be altered in any way. Doing so voids all warranties and statements of suitability for any purpose.
- Avoid dropping or rough handling. Weight and impact of falling device may cause injury.
- 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

To prevent improper use or damage to the device, please note the following cautions:

- Carefully unpack the device and check if any damage occurred during shipping. If damage is encountered, refer to the Warranty and Return Policy section of this manual.
- Cleaning or sterilization methods not approved be the manufacturer can subject the device to damage. To reduce this risk, use only approved cleaning and sterilization methods described herein.
- Setup device where connected cables do not become a tripping hazard during use.
- Avoid dropping or rough handling. Mechanical shock may cause damage to the device.

NOTE: Device warranty will become void if these warnings or cautions are disregarded.

3. SPECIFICATIONS

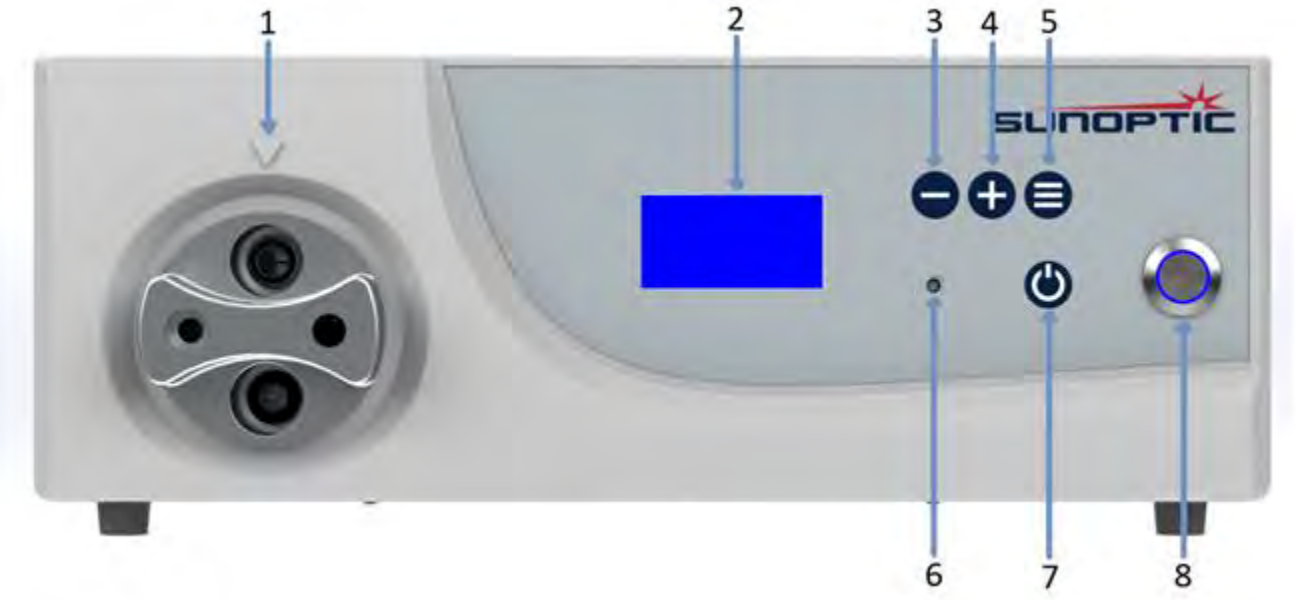
Parameter	Value
Model Number	DPLS-01
Power Requirements	Voltage: 100-240 Vac Frequency: 50/60 Hz Power: 450 Watts (maximum)
Lamp Type	Ceramic 300W Xenon Lamp Part No. SSXP300
Color Temperature	5600K Nominal
Lamp Life	1000 Hours
Light Guide Connections	ACMI, Olympus, Storz, Wolf
Weight in Pounds	15.8 lbs.
Dimensions in Inches	12.0 L x 14.0 W x 5.5 H
Transport & Storage Conditions	-4 to 140ºF (-20 to 60ºC) 0 to 95% RH (non-condensing) 70 to 106 kPa
Operating Conditions	50 to 86ºF (10 to 30ºC) 30 to 75% RH (non-condensing) 70 to 106 kPa
Conditions of Visibility	3 ft (1 m) distance, ±30º viewing angle

4. CLASSIFICATIONS

Parameter	Value
System Classification	FDA Class I EU Class I Health Canada Class I BF-type
Safety Certification	IEC 60601-1 Ed. 3.1: 2012
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% U_T / 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°, 40 % U_T / 5 cycles, 70 % U_T / 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
Protection against electric shock.	Class I (grounded)
Degree of protection against harmful ingress of water	IPX-0 (no protection)
Degree of safety in the presence of flammable anesthetics	Device is NOT suitable for use in the presence of flammable anesthetics.
Mode of Operation	Continuous

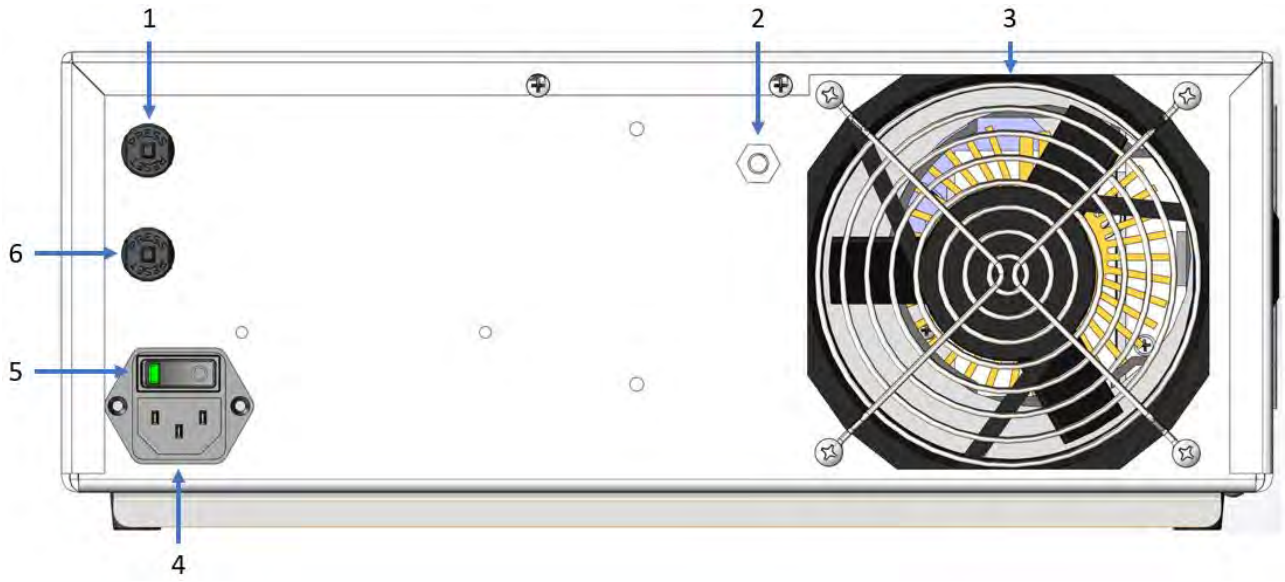
5. OVERVIEW

FRONT PANEL VIEW



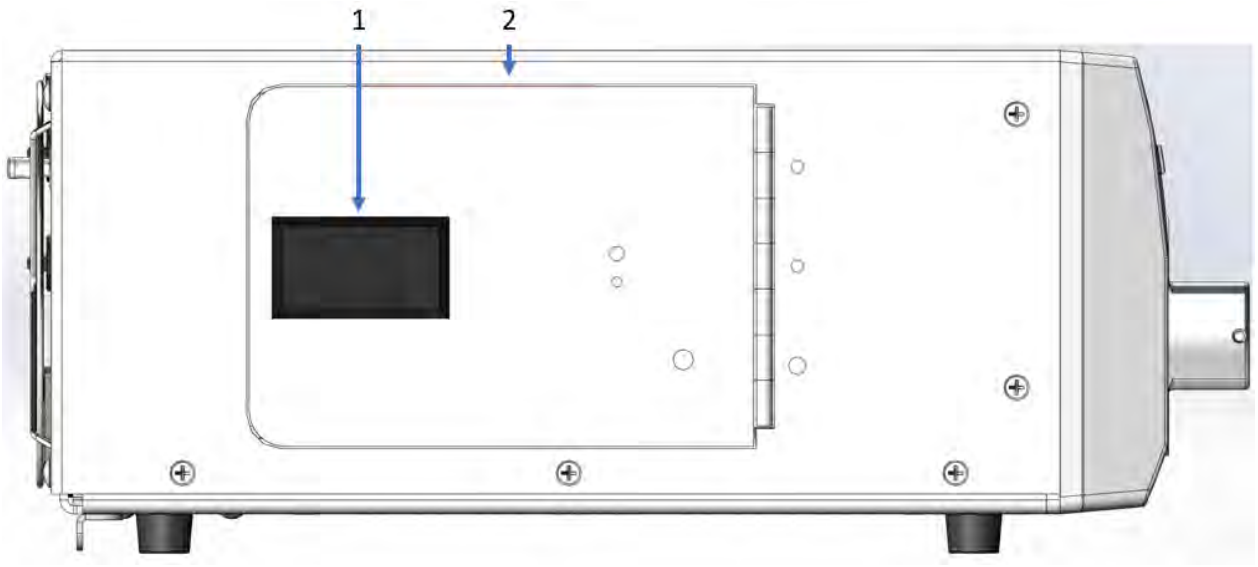
No.	Name	Function
1	Light Guide Turret	Connect light guide to position aligned with triangle.
2	LCD Display	Display for user interface.
3	Minus Button	Decrease light output by 10%.
4	Plus Button	Increase light output by 10%.
5	Menu Button	Device information and lamp time reset.
6	Standby LED	Illuminates when in standby.
7	Standby Button	Decrease light output to 0%. Standby LED illuminates. Display indicates standby.
8	ON / OFF Button	Turn device ON or OFF.

REAR PANEL VIEW



No.	Name	Function
1, 6	Circuit Breakers	Protection from electrical current.
2	Grounding Stud	Connection for equipotential grounding.
3	Fan Exhaust	Device heat removal.
4	AC Mains Receptacle	Connection for power cord.
5	Inlet Switch	Primary power switch. Illuminates green when AC power is ON.

SIDE VIEW / LAMP DOOR



No.	Name	Function
1	Lamp Door Latch	Secures or opens door for lamp access.
2	Lamp Door	Access to Xenon lamp.

6. INSTALLATION

6.1 Setup

CAUTION: Always perform a visual inspection of the device prior to use. Look for signs of wear and tear, damage, and/or corrosion. Do not attempt to use a damaged light source.

Place device on a stable surface such as a table, counter, stand, etc.

NOTE: Avoid placing device in areas that may be splashed with liquid.

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

CAUTION: The device has vents located along its bottom and rear structure. DO NOT block airflow in front of, below, or behind the device.

NOTE: The device requires minimum clearance of 5-inch (13 cm) above and behind for adequate air ventilation.

CAUTION: The device should be isolated from other devices so heat generated by it shall not affect other devices and vice versa.
Ensure rear power inlet switch is in the OFF position.

Ensure lamp is properly positioned for use. Open the lamp compartment door, and ensure the lamp is fully seated into the lamp plug.

Close lamp compartment door ensuring the latch engages.

Connect AC power cord to power inlet on rear panel. Ensure plug is fully seated.

CAUTION: Use only power cords provided with the device.

WARNING: To reduce risk of electric shock, connect power cords of peripheral equipment through a medical isolation transformer.

NOTE: When using a medical isolation transformer, ensure the transformer is adequately rated to handle the load.

Connect power cord to AC mains supply.

CAUTION: DO NOT operate this device near strong RF energy equipment.

6.2 Connecting a Light Guide

Rotate device turret until the port matches the type of fiber optic cable being connected. Connect fiber optic cable to distal end (endoscope or other instrument) then insert cable light guide into light source turret. Leave slack on cable when installing onto head band *(Figure 1)*.

NOTE: Some resistance is normal when inserting light guide into device turret.

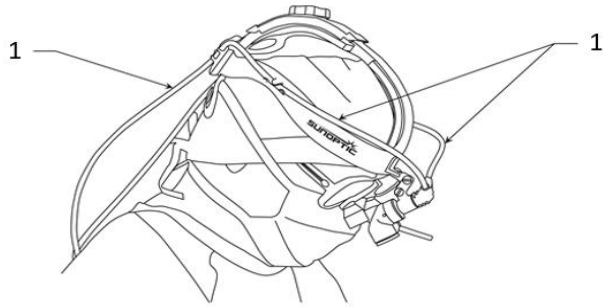


Figure 1. Headlight cable positioning. (1) Leave slack

7. OPERATION

7.1 Turn ON

NOTE: Ensure that the unit is functional before attempting to use in a surgical procedure.

Connect power cord and insert fiber optic cable. Ensure lamp is seated and door is closed.

Flip rear AC power switch to ON (illuminates green) then press front panel ON / OFF button. The front ON / OFF button illuminates blue when ON.

NOTE: the light source will default to 50% brightness upon initialization.

7.2 Functions

Light Setting

- Press MINUS button to decrease light output by 10%.
- Press and hold MINUS to decrease output by 10% until setting reaches 0%.
- Press PLUS button to increase light output by 10%.
- Press and hold PLUS to increase output by 10% until setting reaches 100%.
- Light output setting is saved whenever changed, and the device will turn-on with the last known light setting.

Standby

- Press STANDBY button to temporarily block light output.
- Light output decreases to 0%.
- Standby LED illuminates and display indicates standby.
- Press STANDBY button again to exit standby and return to previous brightness setting.

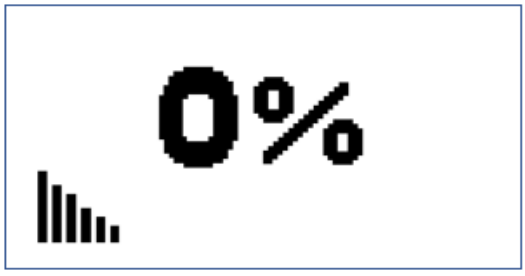
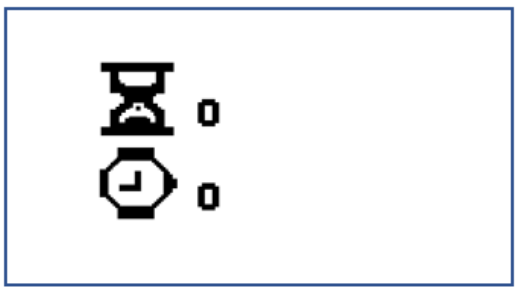


Figure 2. Standby Screen

Menu

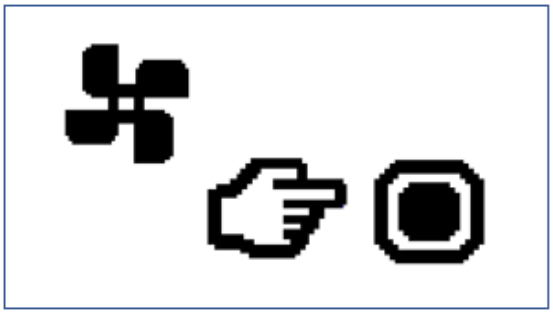
- Press MENU button to view the following:
  - Lamp time in hours.
  - Device time in hours.
  - Device software version.
- Lamp time reset: Press and hold STANDBY button until STANDBY LED illuminates (two seconds). Lamp time changes to zero hours on menu screen.
- Unit time cannot be reset.



Fault Screens

- Door Fault: Displays when lamp door is not fully closed.
  - Close lamp compartment door.
  - Device will need servicing if error persists.

- Fan Fault: Displays when fan is not operating correctly.
  - Turn device OFF.
  - Inspect fan area and ensure nothing is obstructing the fan.
  - Device will need servicing if error persists.



- Lamp Fault: Displays when lamp is not functioning.
  - Turn device OFF.
  - Ensure lamp is correctly installed or install different lamp.
  - Device will need servicing if error persists.

- Dimmer Fault: Displays when dimming mechanism is not functioning.
  - Restart device.
  - Device will need servicing if error persists.

8. CLEANING and DISINFECTION

CAUTION: Disconnect power cord before cleaning and while the device is drying.

Disinfecting agents should be commercially available cleansers commonly used for disinfecting electronic equipment in hospitals. Such cleansers include ethyl or isopropyl alcohols or disinfecting sprays containing ammonium compounds or hydrogen peroxide.

WARNING: Do not use caustic or acidic cleansers such as “Clorox” hypochlorite bleach, ammonia, muriatic acid, or similar products. Do not use acetone, methyl ethyl ketone, chlorinated hydrocarbon solvents, or cleaners containing any of these restricted compounds.

Apply cleaning agents by light spray or dampened cloth.

WARNING: Do not pour liquids over device or allow them to enter seams or openings.

9. MAINTENANCE, SERVICING & REPAIR, WARRANTY

Defective items or equipment shall be serviced and repaired exclusively by persons authorized by the manufacturer, and all repair work shall include original manufacturer parts.

9.1 Lamp Replacement

WARNING: Xenon ceramic lamps have high internal pressure when cold and at operating temperatures. As a result, these lamps may rupture causing discharge or hot fragments of glass or metal to be present: HANDLE WITH CARE.

WARNING: Only handle lamps with plastic protective covers in place. DO NOT handle lamps without protective cover unless safety glasses, face masks (with neck and chest protectors), and gauntlets are worn.

CAUTION: Always disconnect power cord from device when changing a lamp.

CAUTION: DO NOT touch the patient and the lamp simultaneously.

CAUTION: Lamp may be very hot. DO NOT touch lamp heat sink when removing lamp.

WARNING: To reduce risk of electric shock, DO NOT touch lamp power connectors located inside the device lamp compartment as they may have stored energy.

WARNING: Use only **SSXP300** Xenon lamp modules with this device.

Lamp Replacement Procedure:

- Disconnect AC power cord.
- Open lamp compartment door.
- Remove lamp by grasping and pulling from plastic protective cover.
- Install new lamp ensuring the glass face is pointed toward front panel.
- Push lamp in until fully seated.
- Close lamp compartment door.

9.2 Warranty

The light source carries a 3-year warranty from the date of shipment. The warranty covers workmanship and all defects of material, excluding fiber optic cables. Should the device prove to have such defects within three years of shipment, **Sunoptic Technologies®** will repair or replace the device or component part without charge. Should your device need servicing under this warranty, please contact **Sunoptic Technologies®** or a local distributor for return authorization procedure. Please carefully pack the device in a sturdy carton and ship to the manufacturer. Include a note describing the defects, your name, telephone number, and a return address. Warranty does not cover product subjected 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 have other rights which vary from state to state.

9.3 Repair

You may return the device for repair with shipping prepaid to the manufacturer. Your product will be inspected, and an estimate of repair charges will be submitted for approval.

PHONE: +1 (877) 677-2832 FAX: +1 (904) 733-4832
INTERNATIONAL: +1 (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 device must be performed in accordance with the applicable local environmental regulations.

A list of US recycle centers can be found at: *http:/www.eiae.org/.*

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

11. SYMBOLOGY

	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	Symbol for authorized representative in the European Community
	Caution: consult accompanying documents
	Product safety mark
	Consult instructions for use
	CE mark
	Not for disposal in general waste
	Caution: hot surface
	Caution: dangerous voltage
	Do not use if package is damaged
	Medical device
	Storage / Shipping Humidity
	Barometric Pressure
	Unique Device Identifier
	AC current

	Equipotential
	Power ON
	Power OFF
	Protective earth (ground)
	Type BF equipment