ASB-XE-E180

Xenon Light source

Operator Manual

CE

111 Highland Drive
Putnam, Connecticut 06260
USA

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1. INTRODUCTION

Congratulations on the purchase of your new ASB-XE-E180 Xenon Illuminator!

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:

- 5600 K daylight brightness for perfect color definition
- Quiet operation
- Compact and lightweight
- Turret which adapts to various types of light guides
- Mechanical Iris
- Easy lamp replacement
- Lamp life display indication

In short, you have chosen the best and we would like to make sure you receive the optimal results with your new illuminator 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 illuminator 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 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 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 ASB-XE-E180 comprises a standalone, mains-powered illuminator that produces 120klux (minimum) with a standard headlight at 16-inch (40cm) distance 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 a 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

- Federal law restricts this device to sale by or on the order of a licensed practitioner.
- The illuminator produces highly concentrated light. Avoid shining light beams into the 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. Additionally, the unit should be turned to fully dim when not using a fiberoptic cable.
- 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.
- The 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 the presence of a 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 the 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 for the end tip to cool before removal from the 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 the 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.
- The performance of this device may be affected in the 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 the 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 overheating.

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

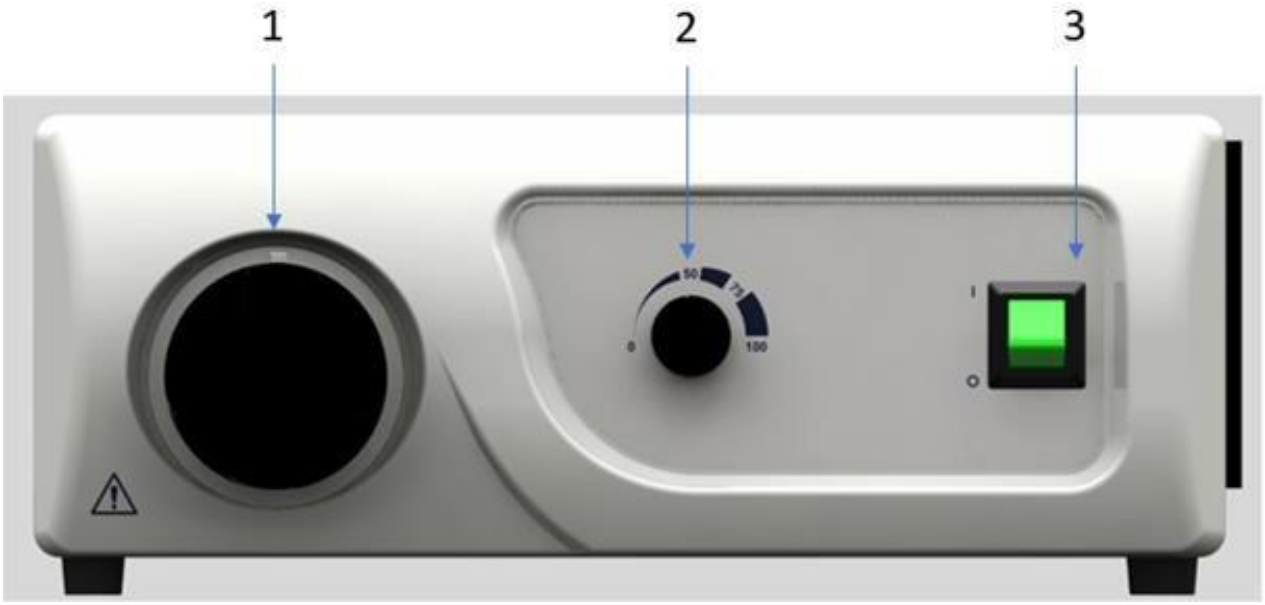
PARAMETER	VALUE
Model Number	ASB-XE-E180
Light Source Type	Ceramic 175W Xenon
Color Temperature	5600 K (typ.)
Lamp Life	650 hours (typ.)
Lamp Replacement	Cartridge replacement
Brightness Control	Mechanical iris control
Input Power	100-240 VAC, 50/60 Hz 250W (max.)
Fuses	Type ACG 3A
Operating Conditions	50 to 104ºF (10 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	14” x 5” x 10” (W x H x D) 35.5 x 13 x 25 cm (W x H x D)
Weight	9.5 lbs / 3.6 kg

4. CLASSIFICATION

PARAMETER	VALUE
System Classification	FDA Class I, 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	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

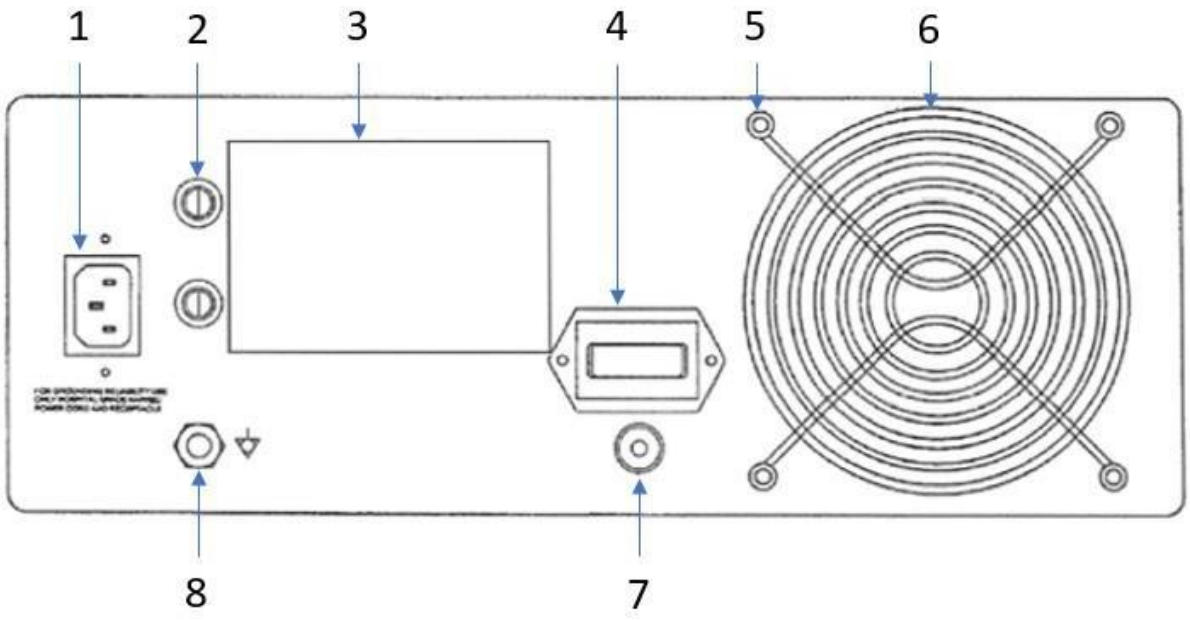
5. OVERVIEW

FRONT PANEL



No.	Name	Function
1	Light Output Interface	Connection point for light guide
2	Intensity Control	Mechanically adjusts light intensity
3	Power Button	Turns light source ON and OFF. Illuminates green when energized.

REAR PANEL



No.	Name	Function
1	AC Main Inlet	Accepts AC Cord Mains Power
2	Fuses	Overcurrent protection, Type AGC 3A
3	Product Label	Device information
4	Hour Meter	Allows tracking of total running time on unit and provides tracking of individual lamp running hours
5	Vent grid	Allows ventilation and cooling of light source
6	Fan	12VDC Fan cools the lamp
7	Hour Meter Reset	Resets hour meter to zero hours. Press when installing a new lamp.
8	Ground Stud	For potential equalization

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. The user must ensure that environmental 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.

6.2 Operation

After the power cable and light guide are properly connected, ensure the illuminator is turned to the lowest dimming 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.

Ensuring that the light output from the attached light guide is directed to a safe area, adjust the intensity control knob until the desired brightness is achieved.

The hour meter located on the rear of the unit shows the total elapsed running time of the unit. When the lamp is replaced, reset the hour meter to track the total lamp usage hours on the replacement lamp.

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 Lamp Replacement

WARNING: Ensure that the illuminator is unplugged from mains power and de-energized before attempting to replace the lamp.

WARNING: Ceramic Xenon lamps are at high internal pressure when cold and at operating temperature. Ceramic Xenon lamps may unexpectedly rupture resulting in the discharge of hot fragments of quartz and/or glass and metal. Only handle lamps with protective covers in place.

WARNING: Do not change the lamp while the power is plugged.

Turn the unit off and unplug from the main power. Open the lamp door located on the side of the illuminator.

Replace the lamp cartridge with a new unit and log the serial number and hours on the hour meter. Close the lamp compartment door. Re-connect the power cord and turn the light source ON. Reset the hour meter to zero by pressing the Hour Meter Reset Button on the rear panel.

8.2 Fuse Replacement

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

Turn off the illuminator and unplug the power cord. On the rear panel of the console, remove the fuse holder located in the appliance inlet. Replace blown fuse with Type AGC 3A rated fuses. Insert holder back into fuse housing.

8.3 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, Spectral Products will repair or replace the product or part without charge. Should your product(s) need servicing under this warranty, please contact Spectral Products 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. The warranty does not cover equipment subject to misuse, accidental damage, normal wear, and tear, or if transferred to a new owner without authorization from Spectral Products. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

8.4 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 (860) 928-5834
FAX: +1 (860) 928-2676

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 the product to the manufacturer at the end of the product life.

10. TROUBLESHOOTING

Problem	**Solution**
The power indicator (refer to 4.1) is not lit.	A. Check that the AC power cord is properly connected. B. Check the fuses. If necessary, replace.
The power indicator is lit, but the xenon lamp will not ignite.	A. Check lamp connection. B. Check that the lamp door cover is secured. C. Check the hour meter if lamp hours exceed the rated lamp life. D. Replace the lamp (refer to 8.1)

11. SYMBOLOGY

	Manufacturer
	Date of manufacture (YYYY-MM-DD)
EC | REP	Symbol for Authorized Representative in the European Community
	Caution, consult accompanying documents
	Consult Instructions for Use
CE	CE mark
	Do not use if package is damaged.
	Not for disposal in general waste
MD	Medical device

	Caution: Hot Surface
	Caution: Dangerous Voltage
	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)