

OPTILUX LED ILLUMINATOR OPERATIONAL MANUAL



Isolux LLC
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OPTILUX OPERATING and SERVICE MANUAL

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1. REVISION HISTORY


| <u>Version</u> | <u>Release Date</u> | <u>Comments</u> |
|----------------|---------------------|------------------------|
| 0.1 | 03/15/2012 | Rough Draft |
| 1.0 | 04/13/2013 | First Draft for Review |
| 2.0 | 06/13/2013 | Final Document Draft |
| 3.0 | 07/25/2013 | Final Document |

2. LABEL

LED ILLUMINATOR

| | | |
|--|---|---|
| <p>MODEL No.: OPTILUX S/N: XXXXX</p> | <p>INPUT 120 VAC @ 60 Hz. 80 Watts</p> | <p>OUTPUT Optical Output: >2200 LUMENS @ 1 m. Operating Temp.: -10 to 40 C Storage Temp.: -20 to 70 C</p> |
|--|---|---|

ISOLUX LLC
NAPLES, FL. USA



- Material:
1. Transparent Gloss Polyester with permanent Acrylic Adhesive backing.
 2. Background color: Transparent.
 3. Lettering and Markings: Black.
 4. Size: 3.00" by 1.00"

Notes:

Unit is designed with protection against electric shock as per the requirements of IEC 60601 – 1.1.

Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

3. SYMBOLS



QPS LISTING MARKING



Protection against Electric Shock



Caution



Protective Earth Ground



Read accompanying documents



Temperature Range: Operating
Storage and Transportation



Relative Humidity Range



This Side Up



Keep Dry



Recycle

4. Definition of Terms

I.E.C.

International Electrotechnical Commission

Medical Electrical Equipment

Electrical equipment intended to diagnose, treat the patient under medical supervision.
Electrical equipment that transfers energy to the patient.

Central Illuminance

Illuminance of light head measured at 1 meter from the light emitting area with no obstructions. Expressed in Foot-candles or Lux.

Light Field Center

Point of maximum illuminance in lighted area. This is the reference point for light field size and light distribution measurements.

Light Field Diameter

Diameter of the circle where illuminance reaches 10% of light field center illuminance.

Depth of Illumination

The overall distance from 1 meter where the central illuminance is reduced to 20%.

Shadow Dilution

Ability of the equipment to minimize the impact of shadows in the working area due to partial obstruction by an operator or other medical personnel.

Correlated Color Temperature

The color temperature of the light fixture when compared to a blackbody radiator stated in degrees Kelvin.

Total Irradiance

The total amount of energy imparted to the patient by the lighting system expressed in Watts/meter squared.

Color Rendering Index (CRI)

A method of how well a light source will render other colors when illuminating them based upon eight CIE chromaticity coordinates measured with a spectral radiometer.

Handle Sterility

Device when properly sterilized maintains a sterile area in order to handle it under aseptic conditions when attached to the equipment.

Neutral Conductor

In an AC circuit, the return line for current.

Protective earth ground

The conductor used to connect the non-current-carrying metal parts of the equipment to the system grounded conductor, the grounding electrode conductor, or both, of the circuit at the service equipment or at the source of a separately derived system.

Ft-Lbs

Foot-pounds; the unit of measurement of torque which is caused by an off-center load.

5. IEC 60601-1 Safety Tests Compliance (Class I, minor surgery)

| REQUIREMENTS | TEST PARAMETERS | COMPLIANCE | REMARKS |
|---------------------|--|----------------------|---|
| Protective Earthing | 40 amps , < 6 volts compliance, for 2 minutes. | ≤ 100 milliohms | Production tests will be done with an audible continuity meter. |
| Dielectric Strength | 1.5 KV AC for 1 seconds | No voltage breakdown | Test will be performed in all production units. |

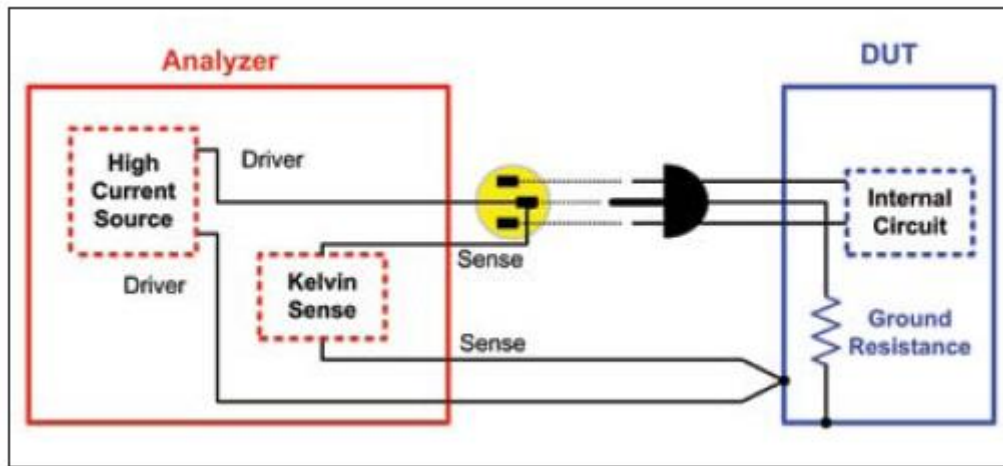


Figure 5.1 Protective Earthing Test Set Up

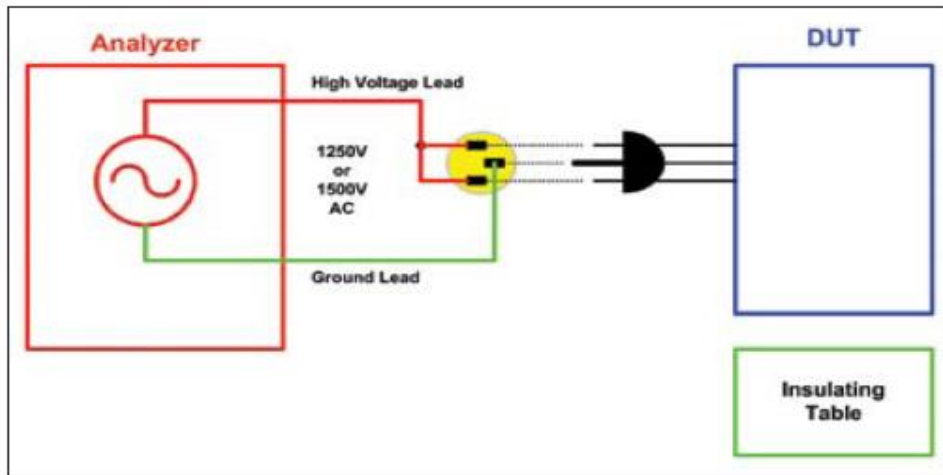


Figure 5.2 Typical AC Dielectric Strength Test Set Up

6. Specifications

6.1 Table 1 – Optical (With LED biased at 16 Amps.)

| | |
|-----------------------------|--|
| Light Intensity | > 2,000 lumens at aperture of unit, (> 2,400 lumens at 21 Amps LED current) |
| Color Rendering Index (CRI) | >92 |
| Color Temperature | 5500 K to 6200 K |
| Nominal Light Output | 800 lumens, measured 1 meter from distal end of 6 mm – 2 meter long Fiber Optic Cable; (1,000 lumens with LED current of 21 Amps.) |
| Dimming Range | Electronic: 5 to 1 minimum |
| LED Life | 50,000 hours for 70% of initial output |

6.2 Table 2 –Electrical – Class 1, continuous duty cycle

| | |
|----------------------|------------------------------|
| Input AC Range | 100 to 240 VAC @ 50 / 60 Hz. |
| Input Power, typical | 80 watts |

6.3 Table 3 - Environmental

| | |
|--------------------------------|--|
| Operating Temperature | 10 to 40 degrees C |
| Storage Temperature | 10 to 70 degrees C |
| Operating Relative Humidity | 10 to 93, non-condensing |
| Storage Relative Humidity | 10 to 80, non-condensing |
| Operating Atmospheric Pressure | 500 hPa to 1060 hPa |
| Storage Atmospheric Pressure | 700 hPa to 1060 hPa |
| Enclosure Rating | IPX0, not protected against ingress of liquids |

6.4 Table 4 – Physical

| | |
|--------------------|---|
| Dimensions | 5.75" H x 7" W x 11" D |
| Weight | 9 # |
| Space Requirements | Open to the rear to allow for proper air flow |

7. Introduction

The Optilux unit is a solid state source of white light intended to be used in Fiber Optic Cable applications, its lack of Ultraviolet (UV) radiation and Infrared radiation (IR), allows for additional uses in cases where UV or IR radiation is not permitted; additionally, its cool operation, high efficiency (lumens per watt rating), high lumens rating and its vastly superior performance in reliability makes it a candidate to replace the low end Xenon and Mercury light sources (<150 watts).

7.1 System Description

The Optilux LED Illuminator is a source of continuous high intensity daylight illumination for demanding surgical vision applications. This is a Class I device per CE MDD 93/42/EEC, Class I per UL 2601-1, and a Class II device per FDA regulations. Its mode of operation is continuous and its degree of electrical isolation is type "B".

The IsoLux Optilux Light Source is intended to be used with IsoLux fiber optic cables for surgical headlamps and other lighted instruments that contain fiber optic bundles, and other fiber optic cables manufactured specifically for use with LED illumination systems.

Illumination from this device when interfaced to an endoscope, could be used for observation of body cavities, hollow organs and other surgical sites. This device is also intended for use as a light source for surgical headlights used in various surgical procedures.

The distal end of the Optilux Fiber Optic cable does not come in contact with the patient, but it provides for a way to provide illumination through a headlight interface or an endoscopic interface.

8. Functional Description

The Optilux unit consists of four (4) major assemblies:

1. Front Panel
2. Light Engine
3. Dimming Control Board
4. Constant Current Dimmable Power Supply

The unit's functional diagram is depicted in Figure 8.1

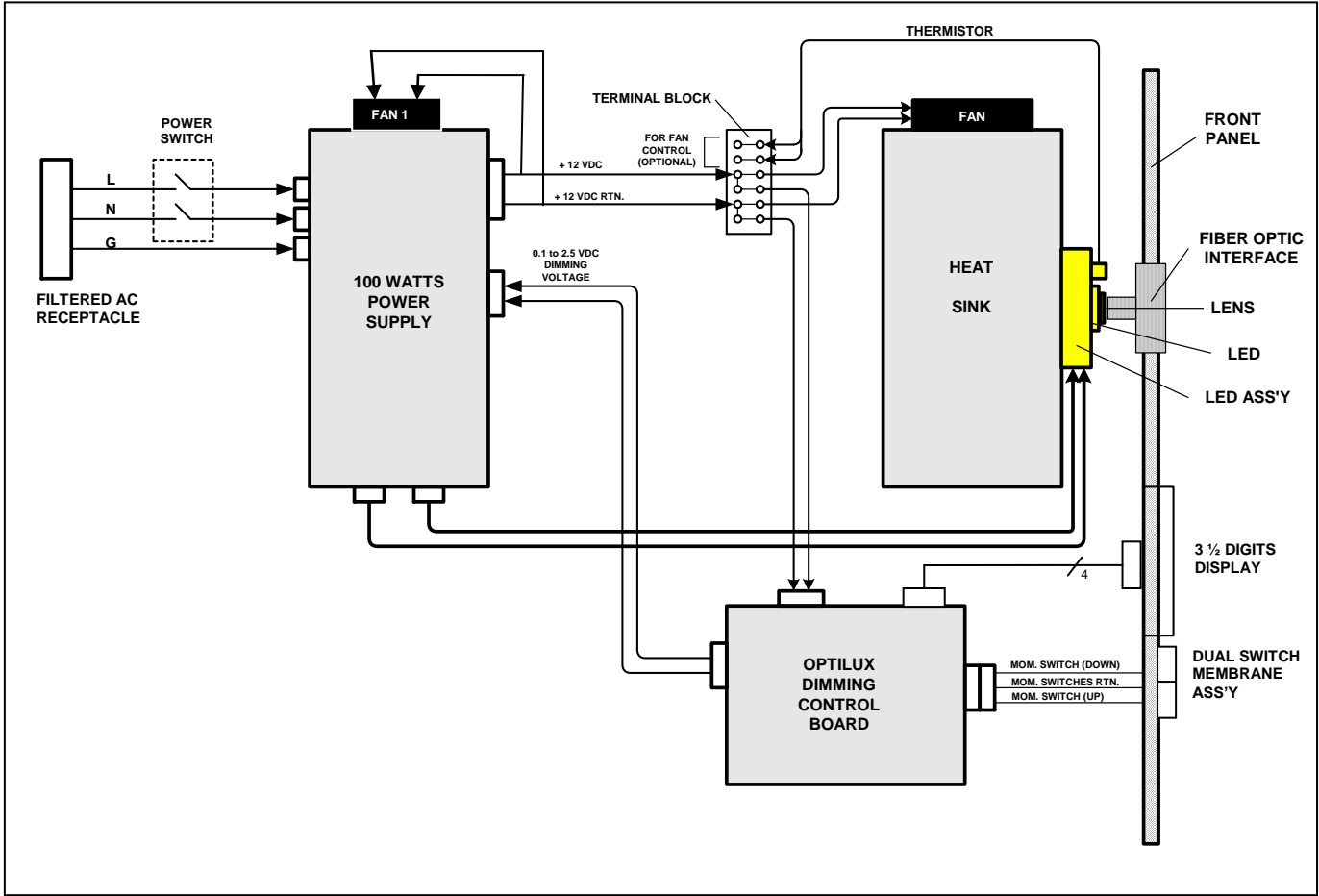


Fig. 8.1 Optilux Functional Diagram

8.1 Front Panel

The front panel contains the man-machine interface consisting of two momentary push bottom membrane switches that sets the intensity of the light source; the down switch lowers the intensity setting, while the up switch raises it until a maximum level has been reached; and a 3 ½ digit LED display that shows the setting of the light intensity. The display will read 100.0 when the intensity is at maximum.

It also contains the Fiber Optic Interface consisting of a female WOLF connector and an Optical Interface to the large 9 mm² LED that contains some built-in proprietary optics. This special optical interface increases the lumens out of the LED by an additional 30 to 35 %.

The ON-OFF power switch is located at the unit's back panel.

8.2 Light Engine

The light engine is the heart of the system. It contains a 3 mm x 3 mm die LED packaged in a 1" x 1" metal clad board, the heat sink and a fan. The LED assembly is mounted directly to the heat sink using a very low thermal resistance medium and the combination gets forced air cooled by the use of a low noise 80 mm fan. The mounting and alignment of it to the optical interface is critical; this is accomplished by a two point set mechanical design that allows for accurate x and y axis alignment including a z-axis constant position setting.

8.3 Dimming Control Board

The dimming control board, gets mounted to the front panel; it receives the input from the two momentary switches and provides a 0.1 VDC to 2.5 VDC variable control voltage to the power supply and the analog voltage to drive the 3 ½ digit display.

8.4 Constant Current Dimmable Power Supply

The 100 watts power supply is a universal input, power factor corrected (PFC) constant current supply, capable of providing better than 5 to 1 light dimming range from a DC voltage range from 0.1 VDC to 2.5 VDC.

It powers the High Power LED with a constant current of up to 21 Amps. at a voltage of up to 4.2 VDC. The supply provides also up to 0.9 amps @ 12 VDC of auxiliary voltage to power the two fans, the dimming control board and for future options and/or expansions.

9. Theory of Operation

The Optilux unit is a solid state light source for fiber optics systems requiring a **very stable** white light source with no UV or IR radiation; its reliability is in the order of years; better than 50,000 hours. Its luminous output is typically 2000 lumens @ a current of 16.0 amps and >2400 lumens @ an LED current of 21 Amps.

The power dissipated by the device of: $P_d = V_f \times I_f = 4.2 \times 16 = 67.2$ watts requires a low thermal resistance in the form of a 3.5" dia. x 7" heat sink and a fan producing an air flow of at least 20 CFM. At an ambient temperature of 25° C, the measured junction temperature on two of the units was < 55° C each; at 40° C ambient, the junction temperature will be 70° C, still a low junction temperature and acceptable for very reliable operation.

The power supply is a constant current supply with a universal input range from 100 to 240 VAC, power factor corrected and capable of delivering better than 100 watts into a load. The use of high rel. components throughout the design provides for a very rugged and reliable supply. Its estimated MTBF running at 70 watts is over 200,000 hours, as the hottest component, the output rectifier runs at 55° C (mounted directly on the power supply's bracket) and the single electrolytic capacitor is a long life, low ESR 105° C rating component.

The Dimming Control board takes the output of the two membrane switches and converts the duration that they are pressed into a digital value that drives an 8 bit A/D converter that provides the dimming control for the Power supply and the analog voltage for the display. The set intensity value is stored in memory while unit is operating, eliminating any set ability drift.

10. Optical performance

The illuminance measured ¼" from the distal end of a 5 mm dia., 2 meters long fiber optic cable has been better than 10⁶ lux. Typical values at the end of a 6 mm dia. 0.66 NA fiber optic cable 2 meters long, and a 4.8 mm dia. 0.66 NA fiber optic cable 2 meters long are as shown in Table 11.1. This includes extrapolated junction temperatures. **(The distal end was positioned 2.75" from detector)**

The measured Luminous Flux has been recorded at > 1000 lumens; 1 meter away from the distal end of a 6 mm diameter / 8 ft. long fiber optic cable at an LED current of 21 Amps.

Table 10.1 Optical and Thermal performance of two Optilux units (Distal end 2.75" from detector)

| Optilux Units | OUTPUT 6 mm F.O. | OUTPUT 4.8 mm F.O. | TEMPERATURE |
|----------------------|-------------------------|---------------------------|--------------------|
| S/N 0004 | 172,000 Lux | 110,000 Lux | 51 ° C |
| S/N 0005 | 180,000 Lux | 111,000 Lux | 51 ° C |

The above measurements were taken at a current of 16.0 amps. and the detector placed at a distance of 2.75" from the distal end of the fiber optic cables.

11. Electrical and General Specifications

The electrical specifications deal mostly with that of the power supply, the Dimmer Control board requires 12 VDC at 0.12 amps. from the power supply and the two fans need 12 VDC at 0.4 amps. Below is Table 5.1 depicting the complete specifications of the 100 watts power supply, except for the compliance to the required safety, EMC, Harmonics currents, etc.documents.

Input _____

| | |
|---------------------------|------------------------------------|
| Input Voltage Range: | 100 – 240 VAC |
| Input Frequency: | 50 / 60 Hz. |
| Input Current @ 100 watts | 1.2 A at 115 VAC, 0.6 A at 230 VAC |
| Inrush Current: | 25 A. at 115 VAC |
| Power Factor: | > 0.95 at all input voltages |
| No load input power: | < 1.0 watts |

Output _____

| | |
|-------------------|---|
| Output Current: | Set at 17.0 amps. maximum, dimmable from 1 amps to 17.0 amps. |
| Output voltage: | 3.5 to 4.2 VDC |
| Start up delay: | 2 secs. Maximum |
| Line Regulation: | ± 1 % maximum |
| Load Regulation: | ± 3 % maximum |
| Ripple and Noise: | < 5 % pk – pk |
| Protection: | Short circuit (trip & reset) Over temperature shutdown, trip 90° C |

Auxiliary Output _____

| | |
|-----------------|------------------|
| Output Voltage: | 12 \pm 0.2 VDC |
| Output Current: | 0.9 A |

General _____

| | |
|-------------|-----------------------------------|
| Efficiency: | > 90 % excluding auxiliary supply |
|-------------|-----------------------------------|

Isolation: 3000 VAC input to case
Switching Frequency: PFC: 45 to 90 Khz.
DC to DC converter: 100 Khz. \pm 5 %
MTBF: > 200, 000 hours at ½ power and 25° C
Cooling: Conduction and Convection

Environmental _____

Operating Temperature: - 20° C to 40° C
Storage Temperature: - 30° C to 70° C
Operating Humidity: 10 to 93 % RH, non-condensing
Operating Altitude: 3,000 meters

Safety Standards

UL 60601-1 ; EN 60601-1-2

Withstand Voltage I/P-O/P:4KVAC I/P-FG:1.5KVAC O/P-FG;1.5KVAC
Isolation Resistance I/P-O/P, I/P-F/G, O/P-F/G: 100 M ohms / 500 VDC
EMI Conduction & Radiation Compliance and Tested Under EN 60601-1-2
Harmonic Current Compliance and Tested Under EN 60601-1-2
EMS Immunity Compliance and Tested Under EN 60601-1-2

12. Operating Instructions

The Optilux unit is simplicity on itself:

- Turn power ON and observe that unit is set at maximum intensity, shown by the 100.0 reading at the unit's 3 ½ digit display.(The display is in % of maximum Light Output).
- Adjust the intensity to the desired setting by depressing the down switch or the up switch
- Connect the Fiber Optic Cable to the unit's optical interface, observe that the connector is fully engaged.

13. Cleaning Instructions

Overall appearance

- Check the general aesthetics of the Optilux LED Illuminator. The unit should be kept clean and dust free. Clean and dust as necessary.

Sterilization

- No portion of the Optilux unit and its Fiber Optic cable will be in direct contact with the patient, the distal end of the Fiber Optic cable will interface with a headlight or an endoscopic cable. The endoscopic cable assembly is an item provided by a 3rd party. Therefore, no sterilization will be needed for the F.O. cable. The Optilux is an illuminator that could be used in an endoscopic exam, not an endoscope by itself

14. Care and Maintenance

Unit does not require any special handling. Optilux maintenance is not required, unit should perform to over 70,000 hours with a 70 % degradation of light output after 50,000 hours. The unit has a build – in fuse in its power supply rated 230 VAC / 5.0 amp slow blow. If unit still doesn't work, send back to factory for repairs.

The LED should last for over 50,000 hours. LED replacement will be done at the Isolux's facility.

15. Replacement Parts

- | | |
|---|--------|
| • LED Fiber Optic Cable Assembly (2 meters) | LEDA10 |
| • FAN, small | LEDA11 |
| • FAN, Large | LEDA12 |
| • LED / HEATSINK Assembly | LEDA13 |
| • 100 WATTS Power Supply | LEDA14 |

16. WARNINGS AND CAUTIONS

16.1 Warnings

The unit shall be operated with the Fiber Optic cable connected to its output port, With Fiber Optic cable connected to its optical output, care should also be taken, as the distal end of the cable contains high intensity light.

16.2 Cautions



Do not look directly into illuminator aperture and distal end of fiber optic cable when cable is connected . Eye injury may result.

**General practice to minimize harm to the eyes from optical radiation hazards include:
Avoiding looking at bright lights and their reflections, and to protect eyes when normal aversion responses are not present.**

17. WARRANTY AND SERVICE

17.1 Illuminator

The Isolux Solid State Illuminator is guaranteed against all defects in materials and workmanship under normal use and service for a period of one year from the date of first shipment from Isolux llc.

This warranty covers the replacement of the parts only and does not include any on-site labor costs. This warranty is void if service is performed by persons other than authorized IsoLux llc distributors or representatives or if equipment is interconnected with components not manufactured by IsoLux llc and/or have been approved by IsoLux llc for compatibility.

17.2 LEDs

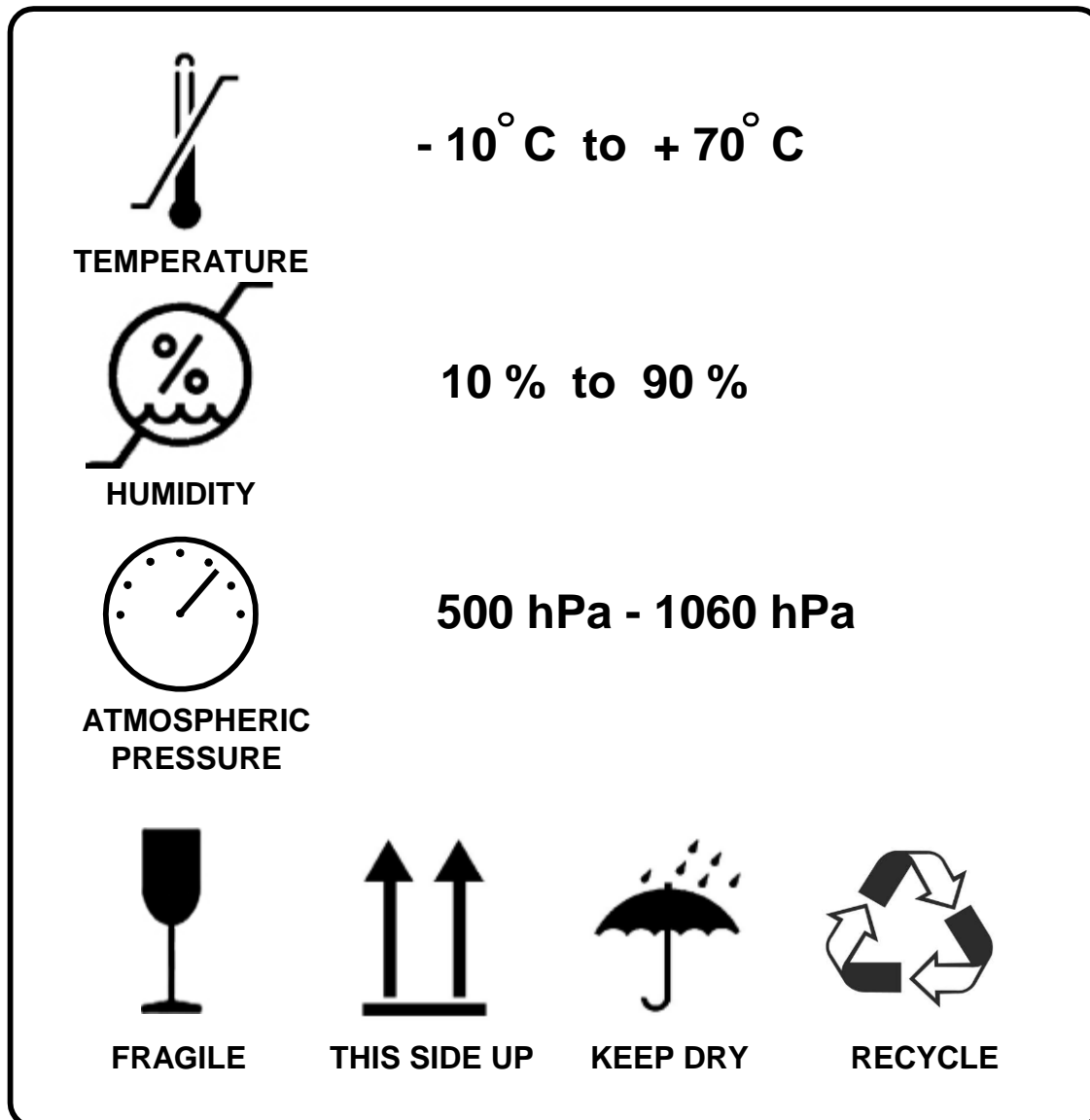
IsoLux llc warrants the High Power LED a full five (5) years, by normal use only. Isolux reserves the right to void this warranty if any non authorized power source is used in conjunction with the unit or if liquids are allowed to ingress the Optilux unit.

- **Please Refer All Questions To Customer Service at Isolux llc, 1045 Collier Center Way, Suite #6, Naples, Fl 34110 by Email at info@isoluxllc.com , Phone (239)514-7475 or Fax (239)514-7476.**

18. Packing and unpacking

The Isolux LLC packing label shows three symbols depicting the environmental ranges of the unit under transportation. The additional four symbols relates to the conditions required for shipping the unit.

18.1 Transportation Label



- Material:
1. Transparent Gloss Polyester with permanent acrylic adhesive backing.
 2. Background color: White
 3. Lettering and Markings: Black.
 4. Size: 4.00" High by 3.00" Wide

18.2 Unpacking



**WHEN REMOVING PARTS FROM THE SHIPPING CARTONS, BE CAREFUL NOT TO DAMAGE THE COMPONENTS.
IMPORTANT: THOROUGHLY CHECK EACH BOX FOR PARTS THAT MAY BE LOCATED IN AREAS THAT CAN BE OVERLOOKED.**

19. TROUBLESHOOTING



ONLY FACILITY AUTHORIZED MAINTENANCE PERSONNEL SHOULD TROUBLESHOOT THE OPTILUX LED ILLUMINATOR. TROUBLESHOOTING BY UNAUTHORIZED PERSONNEL COULD RESULT IN PERSONAL INJURY AND/OR PROPERTY DAMAGE AND COULD VOID WARRANTY.

20. Disposal of Waste Products



NO WASTE PRODUCTS ARE PRODUCED BY THE OPTILUX LED ILLUMINATOR. THE UNIT IS COMPOSED OF NON-TOXIC MATERIALS AND COULD BE DISPOSED OF IN A STANDARD WAY AT THE END OF ITS LIFE.