

IsoLED FLEX I

CUSTOMER MANUAL



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1. REVISION HISTORY

Version	Release Date	Comments
0.1	11/13/2013	Rough Draft
1.0	08/14/2015	Final Document

2. LABELS

2.1 LABEL, NAMEPLATE

<u>LED PORTABLE DIAGNOSTIC LAMP</u>		
MODEL No.: IsoLED Flex I	INPUT	OUTPUT
S/N: XXXXX	16.8 VDC @ 0.9 A	Optical Output: >35 Klux @ 12 in.
	15.1 watts max.	Operating Temp.: 0 to 50 C
		Storage Temp.: -10 to 60 C
<u>ISOLUX LLC</u>		BATTERY OPERATED
NAPLES, FL. USA		14.4 VDC: > 9 hours operation @ full intensity

- 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"

2.2 LABEL, WARNING



Read accompanying documents

Transport should only be undertaken with the light head facing directly down with the gooseneck arm bent over as close as possible to itself.

Transport ne doit être entrepris avec la tête de lampe directement face vers le bas avec le col de cygne bras pliés au plus près possible de lui-même

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 1.50"

Notes:

1. Unit is designed with protection against electric shock as per the requirements of IEC 60601
2. 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



Caution



Protective Earth Ground



Read accompanying documents



Temperature Range: Operating,
Storage and Transportation



Relative Humidity Range



This Side Up



Keep Dry



Recycle

4. Introduction

The IsoLED Flex I is a portable, battery operated Exam / Diagnostic lamp ideal for use in the following environments:

- OB/GYN
- FAMILY PRACTICE
- DERMATOLOGY
- EMERGENCY ROOMS
- OUTPATIENT FACILITIES
- LABOR & DELIVERY SETTINGS
- URGENT CARE CENTERS

It's portability without the encumbrance of a power cord and the flexibility of its gooseneck allows it to be used anywhere at any position.

Its high efficiency design allows for reduced energy consumption and reduced cost of ownership, while its 50,000 hour of LED life provides for a free maintenance device with an end life of around 20 years. Its design follows and surpasses the Energy Star Requirements

Its CRI of 95 rating produces a very high color rendition for accurate diagnosis; and the life of the LEDs used is kept high by limiting their junction temperature to less than 45 ° C for a better than 50,000 hours of operation; while its meager power consumption of 4.3 watts provides for a very efficient and eco-friendly lamp.

Furthermore, the use of sharp cutoff optics allows for a well defined spot with a very small "Halo" effect and good depth of field.

The IsoLED Flex I lamp has been designed taking into account all of the different disciplines that makes up for true latest-state-of-the-art LED technologies:

Efficiency

The LED Driver Board has an efficiency of 76 % and delivers 3.6 watts to power the unit's single LED.

The battery charger efficiency is greater than 80 % and its Hi-Pot insulation is >4,000 VAC for 1 minute.

Color Rendition Index

Typical CRI of 95 for excellent color rendition.

Illumination

The LED optical efficiency plus the optical efficacy of the secondary optics used, provides > 35,000 lux at 12 inches from source, for a Figure of Merit of **8100 lux/watt**

Thermal

The thermal design has been designed around keeping the Junction temperature of the LED lower than 45 ° C (for a 27 ° C ambient). This ensures the long life of 50,000 hours (70% of max.) and the minimum decrease of the lamp's illuminance vs. time.

5. Functional Description

The unit's front panel and interconnect diagram are depicted in Figure 5.1. The Control Box diagram is depicted in Figure 5.2.

The Flex I unit consists of three (3) major components: The Control Box, The Headlight Assembly and the Battery Charger.

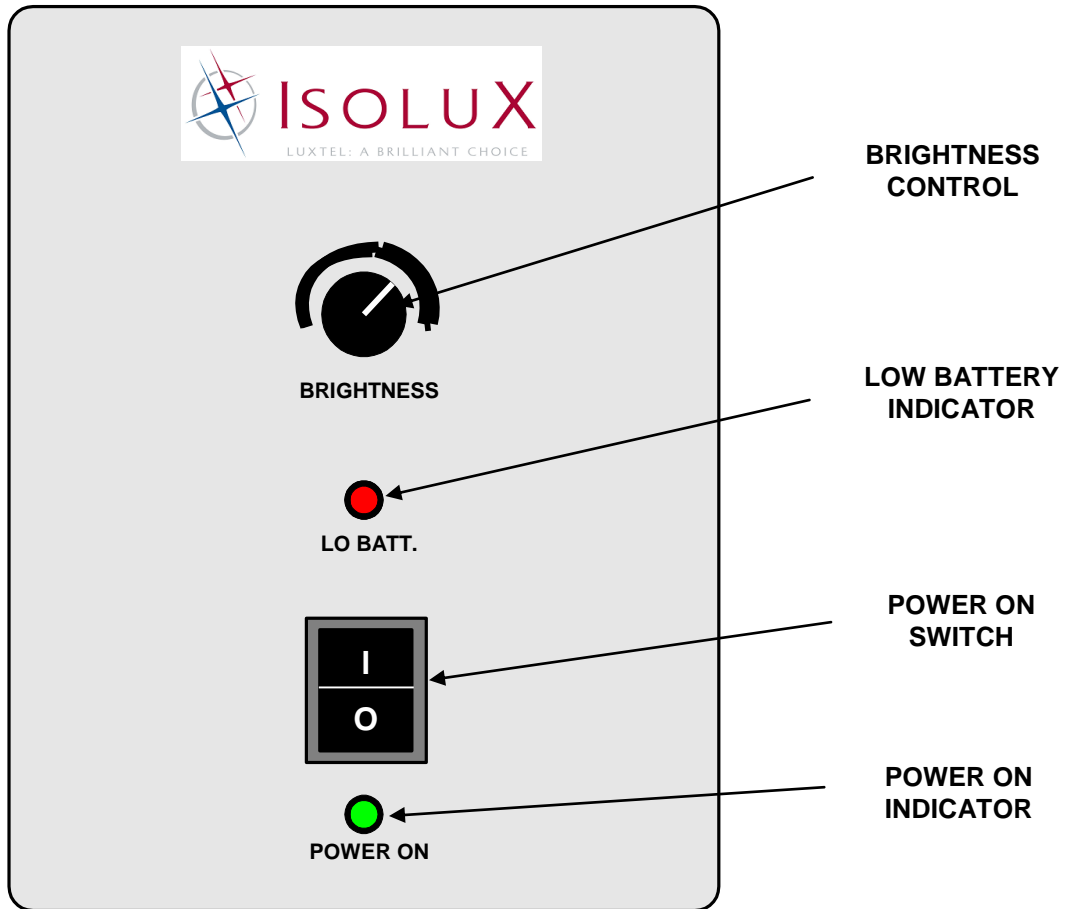
All of the electronics are housed in the Control Box including the unit's two controls and two displays located at its front panel:

- Brightness Control: Controls the light intensity from 3 % to 100 %.
- Power ON Switch: Turns the unit on or off.
- Power ON indicator: Shows unit's status, on or off.
- Low Battery Indicator: Warns the operator that the battery is low

The Control Box houses the 4-cell Battery Pack and the LED Driver.

The Headlight Assembly contains the unit's Light Engine, composed of the single LED, heat sink, optics, 10 K thermistor and Metal Clad PC Board.

The unit's battery charger is a Medical Approved unit certified to UL60601-1, EN60950, EN60601-1, EN60335-2-29 and is also certified to the following EMC Standards: EN60601-1-2, EN61000-6-3 (Emission) and EN61000-6-1 (Immunity). See Figure 8.1: Battery Charger Specifications.



CONTROL BOX

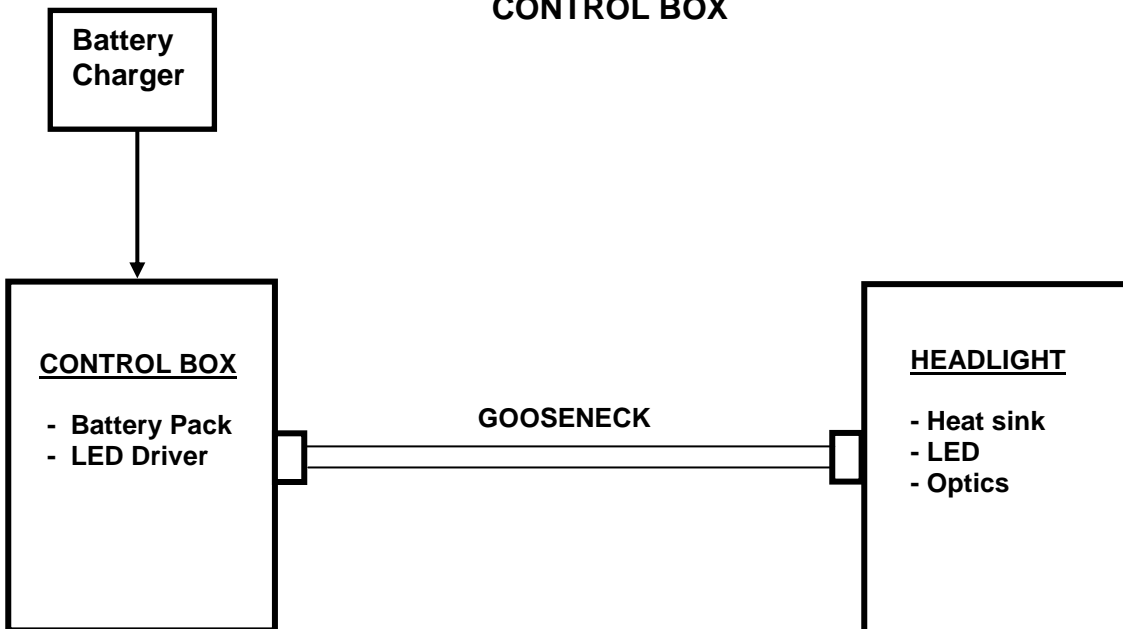


Figure 5.1 IsoLED Flex I Interconnect Diagram

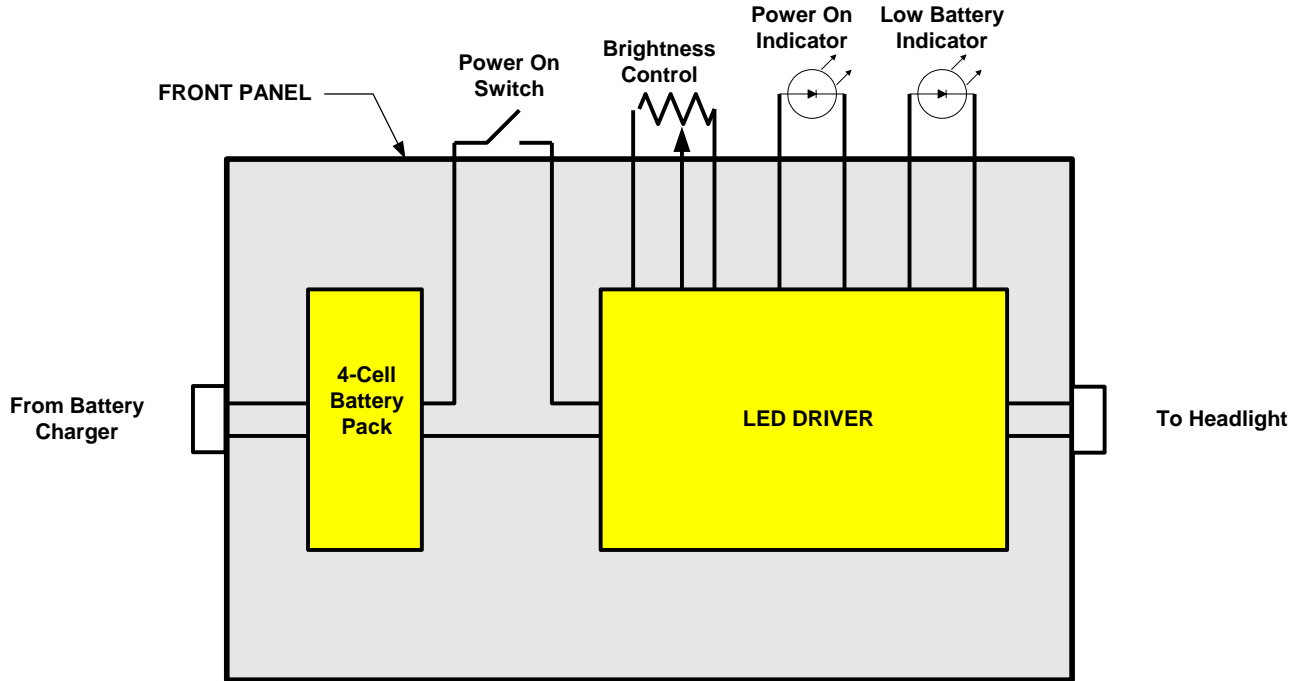


Figure 5.2 Control Box Diagram

NOTES:

1. The Battery Charger is only used when the unit is charging and non-operative.
2. The maximum voltage in the unit is 14.8 VDC.
3. There is no connection to any AC power source during unit's operation

6. Theory of Operation

The Control Box houses the 4-Cell Battery Pack and the LED Driver Board.

The Battery Pack, when low, gets charged when the Battery Charger is connected to the DC Jack located at the back of the Control Box. When the battery pack is fully charged, the battery charger indicator turns from red to green.

The battery pack 14.4 VDC powers the LED Driver Board, which in turn, provides the 1.1 amps constant current that drives the unit's single LED.

The Brightness Control provides a dimming range from 3 to 100 % of full optical power.

The Low Battery Indicator turns from green to red when the battery pack voltage drops below 12 VDC.

7. IsoLED Flex I Performance

The unit's performance is depicted in Figure 7.1: Flex I Specifications.

8. Battery Charger Specifications

The unit's battery charger is a Medical Approved unit certified to UL60601-1, EN60950, EN60601-1, EN60335-2-29 and is also certified to the following EMC Standards: EN60601-1-2, EN61000-6-3 (Emission) and EN61000-6-1 (Immunity). See Figure 8.1: Battery Charger Specifications.

Figure 7.1 Flex 1 Specifications

# of LEDs	One Warm White LED
Color Temperature	4000 to 4500 ° K
CRI (Color Rendition Index)	95 Typical
Light Intensity @ 12"	> 35, 000 lux
Working Distance	12" to 24"
Spot Size (Iris control)	½" to 3 ½ "
LEDs Life	> 50,000 Hours
Operating Temperature	-10 ° C to +40 ° C
Electrical Power	14.4 volts Battery Pack (4 x 3.7 cells) rechargeable ion lithium batteries – 2.6 A-Hour Capacity
Minimum Operating Time	10 hours of continuous operation at maximum light intensity.
Power Consumption	4.3 watts
Efficiency	Meets Energy Star Guidelines
Dimming	3 % to 100 %
Controls:	<ul style="list-style-type: none"> - On/Off power switch - Power On green indicator - Low Battery green / red indicator - Brightness Control
Battery Charger, 15.1 watts Universal AC Input	- UL certified per IEC 60601-1, 1988, 2 nd edition.
Weight	12.5 lbs

Figure 8.1 Battery Charger Specifications

AC Input Voltage Range	Universal: 100 to 240 VAC
Input Frequency	47 to 63 Hz.
Efficiency	80 %
Charge Current	0.9 A, ± 5 %
Charge Voltage	16.8 \pm 0.1 VDC
Terminal Charge	0.1 A \pm 25 %
Output Power	15.1 watts
Ripple	< 100 mV p-p
Operating Temperature	-25 °C to +40°C
Insulation Class	Class II
Insulation Voltage	4,000 VAC (primary) / 5,640 VDC (secondary)
Electrical Safety Approvals	UL60601 – 1, EN60950, EN60601-1, EN60335-2-29
EMC Standards	EN60601-1-2, EN61000-6-3 (Emissions), EN61000-6-1 (Immunity)
Reliability (MIL-GDBK-217F)	MTBF > 250,000 hours at 30 °C and full load
Dimensions	4" x 1.8" x 1.5"
Weight	0.29 lbs

9. Operating Instructions

The IsoLED Flex I battery operated unit is an ambulatory unit that could be moved to any location by means of its 5 – wheel base; in addition, It's extremely flexible arm (gooseneck) allows it to be positioned at any angle and distance from the patient. The operation of the IsoLED Flex I unit is simplicity on itself:

- Turn power ON and observe the unit's brightness, turning the brightness control clockwise increases the light intensity. At full brightness, the battery pack will last approximately 10 hours.
- Low battery indicator will turn from green to red when the battery voltage has decreased to < 12 VDC. When that happens, move the unit to its charging station and plug the battery charger to its DC jack located at the back of the Control Box. The charging time will be around 3 hours (overnight charge)

10. Cleaning Instructions

Overall appearance

- Check the general aesthetics of the IsoLED Flex I Diagnostics Lamp. The unit should be kept clean and dust free. Clean and dust as necessary.

Optical Window

- The front lens is made from a UV resistant polycarbonate plastic that has an external hard coating to resist scratching. Clean the lens using glass/plastic cleaner or mild soap and water mix. It is very important to use a clean, soft cloth to avoid any scratching of the lens. Never spray the cleaning fluid directly onto the lens surface, but instead spray into clean cloth and then wipe the lens.

Do not expose the unit to excessive moisture. Failure to do so could result in personal injury and/or property damage.

11. Care and Maintenance

Unit does not require any special handling. The only maintenance required is to wipe the unit's window with a soft non-lint cloth as required with its use (as needed).

Unit should perform to over 50,000 hours with a minimum 70 % degradation of its light output. If unit fails to turn on, send back to factory for repairs.

The IsoLED Flex I will give you years of failure free performance and no maintenance cost except for the meager 4.3 watts of power consumed, for a very low cost of ownership.

The battery pack, after many recharge cycles (>800) may require replacement. Unit should be sent to Isolux LLC to replace the battery pack.

12. Packing and unpacking

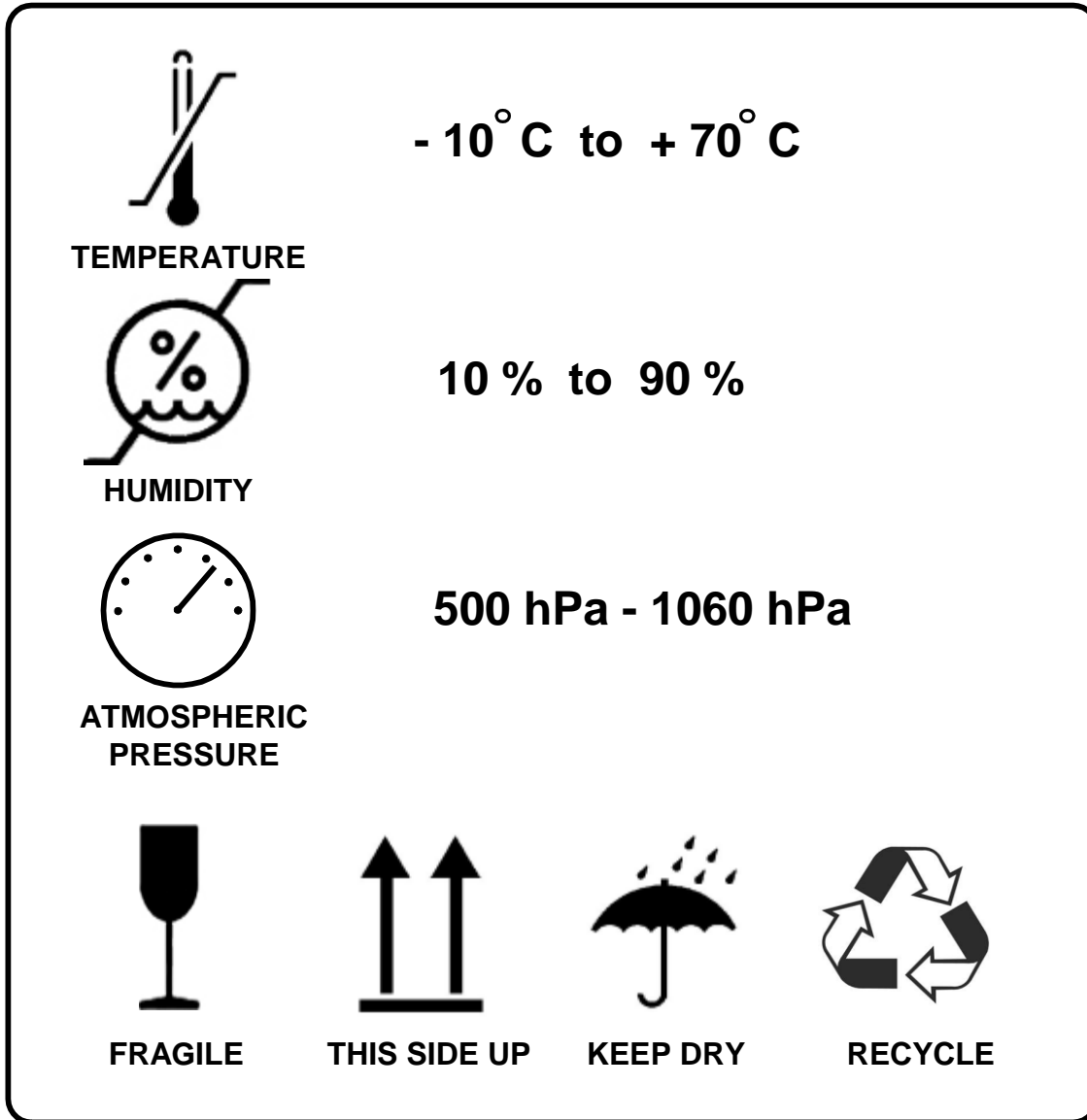
The Isolux LLC packing label shows three symbols depicting the environmental ranges of the unit under transportation. The additional four symbols relates to the conditions required for shipping the unit.



Special care should be exercised when transporting the Flex I as per warning label on the back of the Control Unit.

Unit shall be packaged with the head light and gooseneck bend tightly together and the head light facing down into the bottom of container.

12.1 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

12.2 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.

13. TROUBLESHOOTING



ONLY FACILITY AUTHORIZED MAINTENANCE PERSONNEL SHOULD TROUBLESHOOT THE ISOLED FLEX I SYSTEM. TROUBLESHOOTING BY UNAUTHORIZED PERSONNEL COULD RESULT IN PERSONAL INJURY AND/OR PROPERTY DAMAGE AND COULD VOID WARRANTY.

14. Disposal of Waste Products



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