AirBORNe®

Observation & Phototherapy Light System

Technical Manual

international BIOMEDICAL®

AirBORNE®

Observation & Phototherapy Light System Technical Manual

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SECTION 1: GENERAL INFORMATION

INTENDED USE

The Airborne Observation and Phototherapy Light System™ is intended to be used in one of two modes: observation light mode or phototherapy light mode. The observation light mode utilizes white light and is intended to be used as auxiliary lighting that supplements the ambient lighting. The phototherapy light mode utilizes blue light and is intended to be used in the treatment of neonatal hyperbilirubinemia.

NOTE: *Before using the Observation & Phototherapy Light System, read all sections of this manual carefully. There are safety considerations that should be read and understood before use.*

PHYSICAL CHARACTERISTICS

The Observation and Phototherapy Light System consists of two main sections: the light emitting diode (LED) light bar and the control box.

Light Bar

The light bar is contained within a lightweight anodized aluminum enclosure with two compression mounting feet. The light bar should always be positioned between the inner and outer incubator chambers. The intensity of the light will change with distance from the patient. The light bar has a thin LED diffuser that protects the board from incidental debris or fluid exposure. The white LEDs emit a light in the range of 360 - 830 nm. The blue LEDs emit light in the range of 400 - 500 nm (dominant wavelength range 450 - 465 nm). This range corresponds to the spectral absorption of light by bilirubin, and is thus considered to be the most effective for the degradation of bilirubin. Blue LEDs do not emit significant energy in the ultraviolet (UV) region of the spectrum, so there is no concern about UV exposure to the infant. In addition, blue LEDs do not emit significant energy in the infrared (IR) region of the spectrum, so there is no concern about IR exposure and excessive warming of the infant. As with all phototherapy lights, the operator must ensure protective eyeshades are placed on the infant's eyes to protect them from exposure to the light.

LEDs have minimal light output degradation over their lifetime with proper use. The phototherapy LEDs have a life span of approximately 39,000 hours. The light bar has a red warning light that will illuminate and indicate the LEDs have reached end of life. At that point the light bar should be replaced. The LEDs should also be checked in accordance with the preventative maintenance schedule.

Control Box

The control box plugs into the incubator's lamp connector and mounts to the incubator via two screws. Alternatively the control box can receive power form the optional AC power supply. It has a three position switch: O - OFF (center position), I - Observation Light ON, and II - Phototherapy Light ON. When the phototherapy light is ON, a yellow caution light on the control box is turned on alerting the user that the phototherapy lamp is on.

AC Power Supply (Optional)

There is an optional medically certified AC power supply that can supply power to the control box. The AC power supply be powered with 80 ~ 264 VAC, 47 ~ 63 Hz and outputs 9 VDC. The only power supply approved for use with the Observation & Phototherapy Light System is Mean Well Enterprises GSM40B09-P1J AC-DC Medical Adapter.

CLASSIFICATION

According to the standard EN60601-1 of the International Electrotechnical Commission, Medical electrical equipment, Part 1: General requirements for safety, the Observation & Phototherapy Light System is classified as follows:

- Class II / Externally Powered, according to the type of protection against electric shock
- Ordinary, according to the degree of protection against harmful ingress of water

SECTION 2: SAFETY INFORMATION

The Observation & Phototherapy Light System is designed to be used only by appropriately trained personnel and under the direction of qualified medical personnel operated in a manner consistent with the instructions contained in this manual and according to hospital guidelines. All personnel operating the lighting system must be familiar with the warnings and operating procedures contained in this manual as well as currently known risks and benefits of infant phototherapy equipment use. In addition, please refer to your institution's policy and procedure for administering phototherapy. International Biomedical is not to be held responsible if the Observation & Phototherapy Light System is used in a manner inconsistent with the instructions herein. This device has no performance which is considered essential.

EXPLANATION OF TERMINOLOGY

This manual presents three types of precautionary information. The three types of statements are of equal importance to the safe and effective use of the light system. Each statement is categorized by using an introductory word in **bold** face as follows:

WARNING: **Maintenance or operating procedure, technique, etc., which may result in personal injury or loss of life if not carefully followed.**

CAUTION: Maintenance or operating procedure, technique, etc., which may result in patient harm or damage to equipment if not carefully followed.

NOTE: *Maintenance or operating procedure, technique, etc., which is considered essential to emphasize.*

GENERAL SAFETY INFORMATION

The principal **WARNING** and **CAUTION** notices to be observed in use of the Observation & Phototherapy Light System are brought together here for emphasis.

WARNINGS

- OBSERVE BEST PRACTICE: The instructions in this manual in no way supersede established medical procedures or staff preference concerning patient care.
- INCORRECT USE: Incorrect use of the light or the use of parts and accessories that are not manufactured or supplied by International Biomedical can damage the light and may cause injury to the patient and/or user.
- DAMAGED OR MISSING PARTS: If any part of the system is damaged in any way or missing, discontinue use immediately.

SECTION 2: SAFETY INFORMATION

- PLACEMENT OF LIGHT BAR: Placement should be centered between the top of the inner and outer chambers where the patient cannot access unit. Do not place the light bar inside the inner chamber.
- EYE PROTECTION: Do not look directly into the LEDs. During observation or phototherapy light usage, always protect the patient's eyes with eye shields or equivalent. Per your institution's protocol, periodically verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye shields or equivalent.
- EXPLOSION HAZARD: Do not use the Observation & Phototherapy Light System in the presence of flammable anesthetics or other flammable gases.
- USE OF OXYGEN INCREASES FIRE DANGER: Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitric oxide.
- AMBIENT CONDITIONS: Varying ambient conditions, such as the ambient temperature and/or different radiation sources, may adversely affect the patient. Please refer to your institution's policy and procedure regarding appropriate ambient conditions.
- OPERATOR SAFETY: Sensitive individuals may experience headache, nausea, or mild vertigo if he/she stays too long in the irradiated area. Using the phototherapy system in a well-lit area or wearing glasses with yellow lenses can reduce side effects.
- PHOTOISOMERS: Bilirubin Photoisomers may cause toxic effects.
- PHOTOSENSITIVE DRUGS: The phototherapy light generated can degrade photosensitive medications. Do not place or store any drugs or infusion liquids near or in the radiation area.
- SUNLIGHT AND RADIANT HEAT: Avoid direct sunlight or radiant heat which can cause a dangerous increase in the chamber's air temperature and affect the amount of irradiation being provided to the patient.
- HOT SURFACE: Turn off the light bar and allow the light bar to cool before handling as the light bar can be hot.
- SHOCK HAZARD: Do not touch the lighting system and touch the patient simultaneously.
- TEMPERATURE MONITORING: The use of the baby or skin temperature probes is recommended to track the infant's temperature during phototherapy. In addition, use of reflective foils may cause hazardous body temperatures. Monitor the infant's skin temperature per your institution's policy during phototherapy to avoid fluctuation in body temperature.

- WATER BALANCE: The use of the phototherapy light can disturb the water balance of some patients.
- HEAT SUPPLY: The phototherapy light may impact the heat supply in the incubator and the patient's body temperature.
- ELECTRICAL POWER: Always switch off the power and disconnect the power cord when cleaning the light.
- The blue phototherapy light can hinder clinical observation by making skin color changes, such as cyanosis.
- Do not modify this equipment without authorization of the manufacturer.
- When using the Phototherapy Light, the patient's bilirubin values shall be checked regularly.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use only AirBorne® cables and accessories. Cables and accessories other than those supplied by AirBorne® may result in unacceptable operation of the AirBorne® Observation & Phototherapy Light System and will void AirBorne® equipment warranty.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Observation & Phototherapy Light System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Prior to administering phototherapy, ensure phototherapy has been prescribed for infant.
- Do not use the Observation & Phototherapy Light System during magnetic resonance imaging (MRI) scanning. The Observation & Phototherapy Light System may affect the MRI image and the MRI unit may affect the Observation & Phototherapy Light System output.
- Intensive phototherapy may not be appropriate for all infants (i.e. preterm infants $\leq$ 1000 g).

- Refer to the jaundice management guidelines or regulations in your country to determine the best treatment path for neonatal hyperbilirubinemia; such as the AAP Guidelines (American Academy of Pediatrics Clinical Practice Guideline - Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation); or NICE guidelines (National Institute for Health and Clinical Excellence - Neonatal Jaundice).

CAUTIONS

- The lighting system should be turned off when not in use.
- Route the light power cord carefully to keep out of patient's reach. Route the power cord to the rear right corner of the chamber, down to the bottom of the chamber, then forward so that the cord will pass through the lower ventilation recess on the outer chamber. Avoid setting the outer chamber on the cord.
- Federal Law (U.S.) restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).
- The light bar's electronics contain static sensitive components that can be damaged by improper handling. Use approved grounding techniques for work areas and service personnel.
- Do not autoclave, pressure sterilize, or gas sterilize any portion of the lighting system. Use cleaning solutions sparingly as excessive solution can flow into the light, control box, or cable and cause damage to internal components. Do not spray, soak, or immerse the lighting system in any liquid. Do not use petroleum-based, alcohol, acetone, or other harsh solvents.
- Do not position the end use product, Observation & Phototherapy Light System, or optional power supply to make it difficult to operate the disconnection device.
- The end use product must include a means of isolating the Observation & Phototherapy Light System from supply mains when not used with the optional medically certified power supply.
- Clear objects from the area in the pathway of the light emitted from the Observation & Phototherapy Light System.

NOTES

- *Only mount the light bar in between the chambers. The distance between the light bar and the effective surface area should be 8.8 inches. If the distance between the light bar and the infant is increased the irradiance intensity will decrease. If the distance between the light bar and the infant is decreased the irradiance intensity will increase.*

- *Check Irradiance intensity monthly with a calibrated meter to ensure the light is outputting correctly, such as the LifeBorne® Light Meter (PN 736-0001).*
- *Before installing the Observation & Phototherapy Light System and administering phototherapy, read all sections of this manual carefully. There are safety considerations that should be read and understood before use.*
- *The unit uses a specific type of LED. Consult International Biomedical for repair and replacement of LEDs. Use of incorrect LEDs can adversely affect performance and/or damage the light.*
- *If using pulse oximetry during phototherapy, keep the sensor out of the irradiation field. If the sensor is exposed to irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.*

SECTION 2: SAFETY INFORMATION

SYMBOLS

The following symbols appear in the Observation & Phototherapy Light System documentation and labels. These internationally recognized symbols are defined by the International Electrotechnical Commission, IEC 60878 and IEC 60417.

I	Observation Light Power On (when incubator is ON)
II	Phototherapy Light Power On (when incubator is ON)
O	OFF
 (Yellow background)	Attention, consult accompanying documents
 (Yellow background)	Warning! Hot Surface
 (Blue background)	Always protect the baby's eyes with eye patches or equivalent
 (Blue background)	Follow Operator's Instructions

SECTION 3: SET-UP INSTRUCTIONS

UNPACKING AND ASSEMBLY

The Observation & Phototherapy Light System consists of the light bar with cable attached and the control box. Upon arrival, inspect all parts for any damage.

1. Locate the lamp connector on the back, right hand corner of the incubator (this may be inside the incubator chassis) and connect to the connector extending from the bottom of the control box. Alternatively, if using the optional AC power supply, connect the power supply connector to the connector extending from the bottom of the control box and plug the power supply input cable into an AC power source.

2. Carefully push the wires into the incubator chassis to allow the control box to sit flush on the incubator.

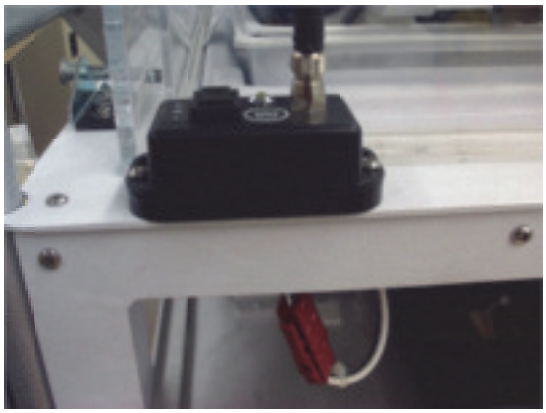


Figure 1 Incubator Light Bar Connector

3. Attach the control box to the incubator using two #6 pan-head Phillips machine screws (and nuts, if required for incubator model) provided.

4. Screw the power cable connector into the control box.

   NOTE: *The connector is keyed to facilitate proper insulation.*

5. Mount the light between the inner and outer chamber by compressing the light between the two chamber layers and securing the outer chamber with the latch pins.

6. Carefully route the cable such that, when the outer chamber is mounted, the cable runs down the right hand side and out the bottom slot between the gasket and the outer chamber. If there is a head door on the right side of the chamber, route the cable towards the back of the chamber and then out the bottom slot between the gasket and the outer chamber ensuring the cable does not interfere with the function of the door.

SECTION 4: OPERATING INSTRUCTIONS

This section contains operating procedures for the Observation & Phototherapy Light System. Operation in both modes and indicators are detailed. The light should be off when not in use to conserve power.

WARNING: **Avoid direct sunlight or radiant heat which can cause a dangerous increase in chamber air temperature.**

CONTROL BOX FEATURES

The lighting system controls are located on the control box in the back right of the incubator.

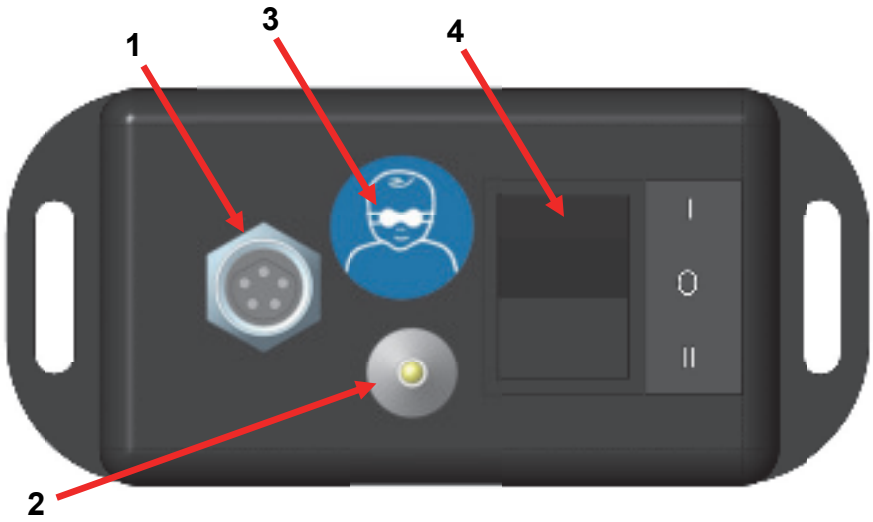


Figure 2 Control Box

1. Light Bar Power Cord Connector
2. Phototherapy ON Warning Indicator
3. Eye Shields Required Warning
4. Selector Switch

1: Light Bar Power Cord Connector

Connect the power cord from the light bar to the control box power connector. The connector is keyed to ensure proper orientation. Twist clockwise until the connector is completely secured.

WARNING: **OBSERVE BEST PRACTICE. The instructions in this manual in no way supersede established medical procedures or staff preference concerning patient care.**

2: Phototherapy ON Warning Indicator

The Phototherapy ON Warning Indicator consists of a yellow LED that illuminates when the Phototherapy is turned ON.

3: Eye Shields Required Warning

When the light is in use, eye shields or equivalent should be used to protect the patient from the spot lighting effect and the irradiation being provided by phototherapy.

4: Selector Switch

When the power to the incubator is ON, the selector switch can be used to turn ON the light system and select between the two modes. In position I, the observation light turns ON. In position II, the phototherapy light turns ON. The center position, O, is the OFF position.

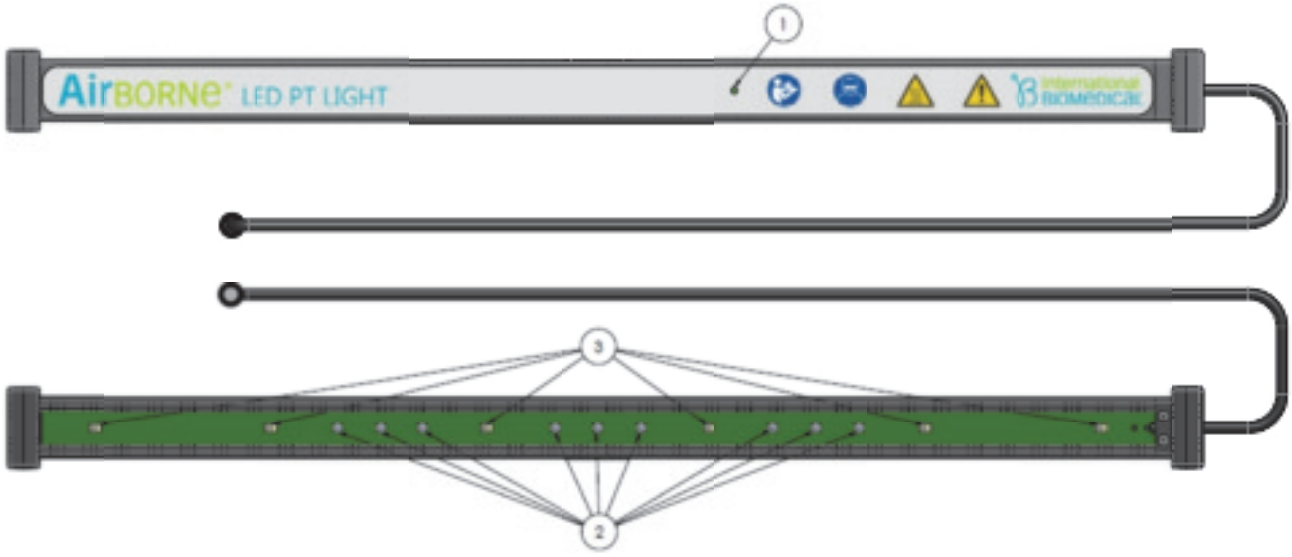
WARNING: **EYE PROTECTION. Do not look directly into the LEDs. During observation or phototherapy light usage, always protect the patient's eyes with eye shields or equivalent. Per your institution's protocol, periodically verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye shields or equivalent.**

NOTE: *If using pulse oximetry during phototherapy, keep the sensor out of the irradiation field. If the sensor is exposed to irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.*

LIGHT BAR FEATURES

The light bar has several indicators which should be observed.

WARNING: **HOT SURFACE. Turn off the light bar and allow the light bar to cool before handling.**



SECTION 4: OPERATING INSTRUCTIONS

1: Phototherapy Light Lifetime Indicator

When the red phototherapy lifetime indicator on the light bar is illuminated, the blue LEDs have exceeded their 39,000 hour limit and it is time to replace the light bar.

2: Phototherapy LEDs

NOTE: *Check irradiance intensity monthly with a calibrated light meter to ensure that the light is outputting correctly.*

NOTE: *The unit uses a specific type of LED. The use of incorrect LEDs can adversely affect performance and/or damage the light.*

Nine blue LEDs are used for the Phototherapy. If one or more of these LEDs goes out, the intensity should immediately be checked and the light bar should be replaced.

3: Observation LEDs

NOTE: *The unit uses a specific type of LED. The use of incorrect LEDs can adversely affect performance and/or damage the light.*

Six white LEDs are used for the Observation Light. If one or more of these LEDs goes out, the light intensity should be checked and the light bar should be replaced if the lighting is determined not to be sufficient for use.

SECTION 5: PREVENTATIVE MAINTENANCE

To ensure proper operation, standby readiness, malfunction reporting, and performance of required maintenance, International Biomedical recommends following a preventative maintenance program. The daily preventative maintenance can be performed and recorded by knowledgeable incubator transport personnel. Monthly maintenance should be performed and recorded by a qualified biomedical technician. No other preventative maintenance is required.

DAILY MAINTENANCE

The following maintenance procedures should be performed on a daily basis by a knowledgeable incubator transport person.

OPERATIONAL CHECK

1. Turn the Incubator ON and then turn ON the observation light. By looking at a reflection of the LEDs, verify that all six white LEDs are illuminated. If they are not, check that the intensity level is high enough to adequately view the patient.
2. Turn ON the Phototherapy. By looking at a reflection of the LEDs, verify that all nine blue LEDs are illuminated. If they are not, have the light bar checked by a qualified biomedical technician.
3. Inspect the power cable for wear or damage and replace if necessary. Verify that the cable is routed appropriately and not pinched at any point.

CLEANING THE LIGHT BAR

CAUTION: CLEANING AND CARE: Do not autoclave, pressure sterilize, or gas sterilize any portion of the lighting system. Use cleaning solutions sparingly as excessive solution can flow into the light, control box, or cable and cause damage to internal components. Do not spray, soak, or immerse lighting system in any liquid. Do not use petroleum-based, alcohol, acetone, or other harsh solvents.

Clean the light bar and control box with mild soap or detergent and water solution.

Household ammonia diluted in water in the concentrations recommended for hospital cleaning may also be used. These solutions may be applied with a soft absorbent cloth, followed by rinsing with clean water. Wipe away residue with soft chamois or cellulose sponge material.

SECTION 5: PREVENTATIVE MAINTENANCE

MONTHLY MAINTENANCE

Turn on the Phototherapy and using the LightBorne® Light Meter (PN 736-0001) measure the irradiance intensity in the center of the incubator. Verify that it is 11 $\mu W/cm^2/nm$ or greater. If using the optional power supply, the irradiance intensity should measure 20 $\mu W/cm^2/nm$ or greater. If it is not, take the unit out of service and replace the light bar.

PRODUCT RECYCLING

The lighting system should be returned to International Biomedical for recycling when it reaches the end of its life (8 years).

SECTION 6: TROUBLESHOOTING AND REPLACEMENTS

Problem	Possible Solutions
Neither set of LEDs comes on, and in Phototherapy mode the yellow warning LED does not illuminate.	• Turn the incubator ON. • Plug in the control box. • Ensure the power switch is in the “I” or the “II” position. • If using the optional AC power supply, ensure that it is plugged into an AC power source • If problem persists, the wiring to the control box has been damaged; service needed.
Neither set of LEDs comes ON, although in Phototherapy mode the yellow warning LED is illuminated.	• Ensure the power cable is plugged in at both ends. • If problem persists, the power cable or the LED board has been damaged; service needed.
The irradiation intensity of blue LEDs are working to specification but the red end of life LED is ON.	• The blue LEDs are working beyond specification; the unit may be used but the light intensity must be checked frequently to ensure the patient is getting prescribed treatment.
The irradiation intensity of blue LEDs is not up to specification, but the end of life LED is not ON.	• Clean chamber and light bar lens. • If the blue LEDs are working below specification, the unit should immediately be taken out of service and should be replaced.
The irradiation intensity of blue LEDs is not up to specification, and the end of life LED is ON.	• The unit should immediately be taken out of service and be replaced.
The white observation LEDs are ON, but the light is too dim and the red end of life LED is not ON.	• Clean chamber and light bar lens. • The white LEDs have reached their life span and needs replacing; the red end of life LED is ONLY for the blue LEDs.
In Phototherapy mode, the blue LEDs are ON, but the yellow warning LED is not ON.	• The yellow LED has gone bad and the control box needs replacing.
The white LEDs turn ON in Observation Light mode and in Phototherapy Light mode, the yellow warning LED comes ON, but all of the blue LEDs are not illuminating.	• Ensure the power cable is connected. • If problem persists, the power cable or the printed circuit board has been damaged; the unit needs to be replaced.

SECTION 6: TROUBLESHOOTING AND REPLACEMENTS

Problem	Possible Solutions
In observation light mode, the white LEDs turn ON, but in Phototherapy Light mode, all of the blue LEDs and the yellow warning LED are not illuminated.	• The switch in the control box has gone bad and the control box needs replacing, service needed.
In Phototherapy Light mode, the blue LEDs illuminate, but in Observation Light mode, none of the white LEDs illuminate.	• The power cable has been damaged and the unit needs replacing • The cable is not properly attached. • The LED board has gone bad and the unit needs replacing.
One or more of the white LEDs are not ON in Observation Light mode.	• The LEDs on the printed circuit board have gone bad and the unit needs replacing.
One or more of the blue LEDs are not ON in Phototherapy Light mode.	• The LEDs on the printed circuit board have gone bad and the unit needs replacing.
The cable will not screw into the control box.	• The connectors are keyed and not properly aligned. • The cable or the control box power connector has been stripped and needs replacing.

REMOVAL/REPLACEMENT OF CONTROL BOX

1. Turn lighting system and incubator power OFF.
2. Unscrew power cable from the control box.
3. Unscrew two Phillips pan head #6 screws using a #2 screw driver.
4. Lift up control box and wiring carefully and disconnect control box connector from incubator harness. It may be necessary to disconnect the connector prior to lifting the control box on some models.

   On the Aviator™, it may be necessary to remove the lamp plate by removing two 6-32 × 3/8” socket cap head screws, using 7/64” hex head wrench. Maneuver the connectors through the opening and disconnect.
5. Reverse the above steps to replace the control box.

SECTION 7: CIRCUIT DESCRIPTION

The theory of operation of the lighting system is described. The individual schematics for the LED board and display board should be referred to when reading the theory of operation.

CONTROL BOX

This section describes the theory of operation of the Lighting Systems Control Box.

The power comes into the control box through connector J1, but only when the incubator is ON (or when plugged into the option AC power supply which is receiving AC power). The switch then regulates whether the power line goes nowhere (in the OFF position), out to connector J2 pin 1 (observation mode position), or out to connector J2 pin 4 and the warning LED and its current limiting resistor (phototherapy position). The ground goes out to connect J2 pin 3 and to the warning LED and its current limiting resistor.

LED BOARD

This section describes the theory of operation of the Lighting Systems LED Board.

PHOTOTHERAPY AND OBSERVATION LEDS

The power comes into the control box through connector J1, but only when the incubator is ON and either the observation light is ON or the phototherapy light is ON.

When the observation light is turned on, two parallel sets of LEDs will illuminate and are fused. The fuses are auto resetting, designed in for current surges above 0.5 amps.

When the phototherapy is turned on, three parallel sets of LEDs will illuminate and are fused. The fuses are auto resetting, designed in for current surges above 0.5 amps.

PHOTOTHERAPY LIFETIME WARNING LED

The lifetime warning LED will illuminate after 39,000 hours of running the phototherapy light. The event timer chip calculates the time by counting when phototherapy is powered and stopping when an OFF event occurs. Capacitors keep power on the event timer chip for saving the time before shutting down.

SECTION 8: SPECIFICATIONS

GENERAL MECHANICAL SPECIFICATIONS

	Height inches (cm)	**Width** inches (cm)	**Depth** inches (cm)	**Weight** oz. (g)
Light Bar	.64 (1.63)	18.27 (46.40)	1.13 (2.86)	6.5 (184)
Control Box	1.12 (2.84)	3.00 (7.63)	1.38 (3.50)	1.2 (33)
AC Power Supply	1.24 (3.15)	4.92 (12.5)	1.97 (5.00)	10.2 (290)

ELECTRICAL SPECIFICATIONS

DC Power---------- 8.9 V Minimum @ 420 milliamps

AC Power (When equipped with optional AC power supply)---------- 80 ~ 264 VAC, 47 ~ 63 Hz input, 9 VDC output

OPERATIONAL SPECIFICATIONS

Audible Noise---------- < 60 dB

Observation Lighting Intensity (Minimum)---------- 150 Lumens

Phototherapy Light Blue LEDs Wavelength---------- Peak between 450 and 465 nm

Phototherapy Light Variation in Intensity over 6 hrs after Warm-Up - 10%

Heat Output (over 5 hrs)---------- < 0.5° C Warmer than Ambient @ 5”

Phototherapy Intensity Ratio---------- > 0.4 Minimum to Maximum

DC Power Input - Measured with the LightBorne® Light Meter (PN 736-0001)

Phototherapy Average Central Intensity at 8.8 inches --------- 12 $\mu W/cm^2/nm$ (distance includes .118” thick clear Plexiglas G)

Phototherapy Maximum Central Intensity at 8.8 inches-------- 15 $\mu W/cm^2/nm$ (distance includes .118” thick clear Plexiglas G)

AC Power Input - Measured with the LightBorne® Light Meter (PN 736-0001)

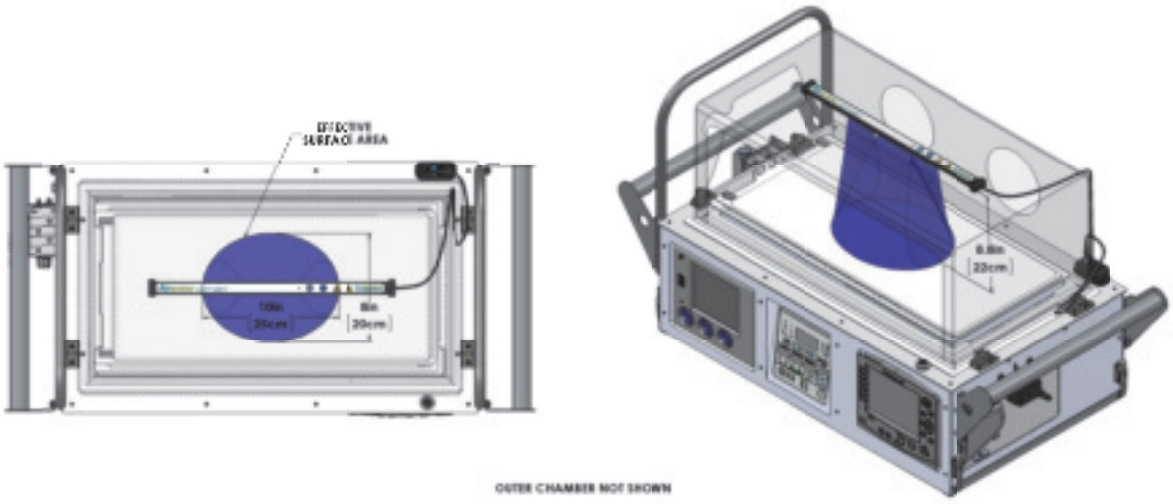
Phototherapy Average Central Intensity at 8.8 inches --------- 22 $\mu W/cm^2/nm$ (distance includes .118” thick clear Plexiglas G)

Phototherapy Maximum Central Intensity at 8.8 inches-------- 27 $\mu W/cm^2/nm$ (distance includes .118” thick clear Plexiglas G)

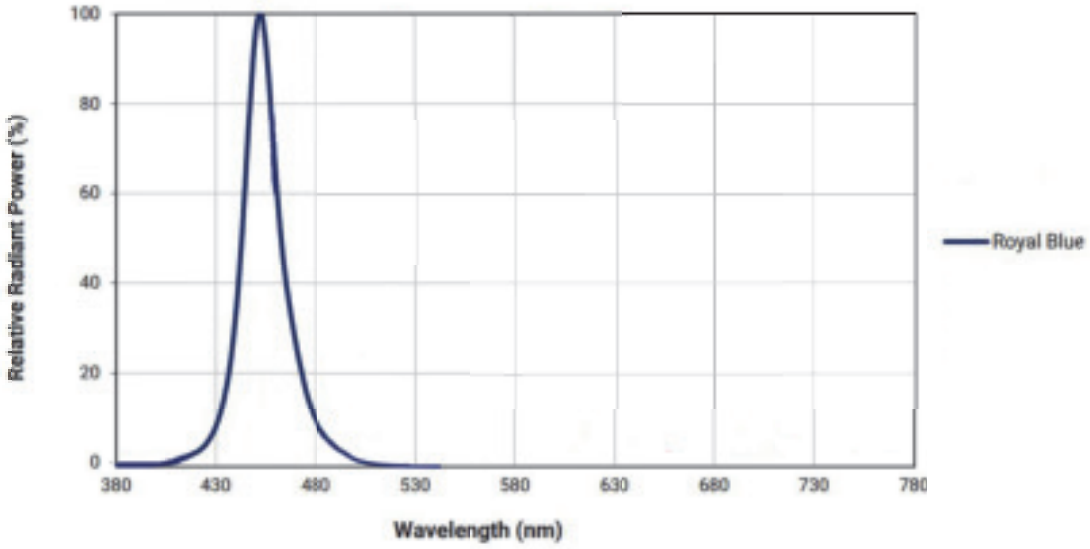
Total Irradiance for Bilirubin from 400-550nm ----------13.11 W/m^2

SECTION 8: SPECIFICATIONS

NOTE: *Only mount the light bar in between the chambers. The distance between the light bar and the effective surface area should be 8.8 inches. If the distance between the light bar and the infant is increased the irradiance intensity will decrease. If the distance between the light bar and the infant is decreased the irradiance intensity will increase.*



Phototherapy Light Effective Surface Area



Spectral Intensity Distribution

OPERATING, STORAGE, AND TRANSPORT ENVIRONMENT

The Observation and Phototherapy Light System requires the following environmental conditions for transport and storage:

Temperature ---------- -15° C to 40° C

Humidity---------- 10% to 95% non-condensing

Pressure ---------- 50 kPa to 106 kPa

The requirements of the International Standard, EN60601-2-20:2001 are met. The environment, if not further specified in the standard, is:

Temperature ---------- 21° C to 25° C

Humidity---------- 45% to 75% non-condensing

Pressure ---------- 86 kPa to 106 kPa

EMC COMPLIANCE

- The Observation and Phototherapy Light has been tested and found to comply with limits for electromagnetic interference and susceptibility as defined by IEC60601-1-2:2014. However, this equipment may radiate radio frequency (RF) energy and may cause harmful interference to other devices.

GUIDANCE AND MANUFACTURER'S DECLARATION - EMISSIONS

The Observation and Phototherapy Light is intended for use in the electromagnetic environment specified below. The customer or user of the Observation and Phototherapy Light should ensure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The Observation and Phototherapy Light uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted Emissions CISPR 11	Class B	The Observation and Phototherapy Light is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

SECTION 8: SPECIFICATIONS

GUIDANCE AND MANUFACTURER'S DECLARATION - IMMUNITY

The Observation and Phototherapy Light is intended for use in the electromagnetic environment specified below. The customer or user of the Observation and Phototherapy Light should ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
ESD IEC 61000-4-2	± 8 kV Contact ± 2/4/8/15 kV Air	± 8 kV Contact ± 2/4/8/15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5/1 kV Differential ± 0.5/1/2 kV Common	± 0.5/1 kV Differential ± 0.5/1/2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	100% Dip for 0.5 Cycle (At 0,45,90,135,180, 225,270,315°) 100% Dip for 1 Cycle 60% Dip for 5 Cycles 30% Dip for 25/35 Cycles 100% Dip for 250/350 Cycles	100% Dip for 0.5 Cycle (At 0, 45, 90, 135, 180, 225, 270, 315°) 100% Dip for 1 Cycle 60% Dip for 5 Cycles 30% Dip for 25/35 Cycles During the 5 Second event, the Transport Incubator switches to internal battery power.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Observation and Phototherapy Light requires continued operation during power mains interruption, it is recommended that the Observation and Phototherapy Light be powered from an uninterruptible power supply or from the Transport Incubator.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power Frequency magnetic fields should be that of a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION - IMMUNITY

The Observation and Phototherapy Light is intended for use in the electromagnetic environment specified below. The customer or user of the Observation and Phototherapy Light should ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (AC/DC) 6 Vrms (in ISM Bands between 150kHz and 80MHz)	3 Vrms 150 kHz to 80 MHz (AC/DC) 6 Vrms (in ISM Bands between 150kHz and 80MHz)	Portable and mobile communications equipment should be separated from the Transport Incubator by no less than the distances calculated/listed below: D= $\frac{3.5}{V_1}\sqrt{P}$ D= $\frac{3.5}{E_1}\sqrt{P}$ 80 to 800 MHz D= $\frac{7}{E_1}\sqrt{P}$ 800 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz (V_1) Vrms (E_1) V/m	Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Proximity fields from RF Wireless Communication Equipment IEC61000-4-3	See IEC60601-1-2:2014 8.10	See IEC60601-1-2:2014 8.10	This equipment should be placed no closer than 30cm from the nearest RF Wireless communication device.

SECTION 9: WARRANTY

Unless otherwise specified, International Biomedical warrants all products of its manufacture at the time of shipment to be free from defects of material and workmanship for a period of twelve months from the date of shipment when owned by the original purchaser. Any product which is believed to be defective, if returned within twelve months after date of shipment by the Company with freight prepaid and found by the Company's inspection to be defective within the terms of this warranty, will be repaired or replaced free of charge and shipped, freight prepaid, to any point in the United States. If inspection by the Company of any such product does not disclose any defect within the terms of this warranty, the Company's regular charges for repairs or replacement and freight shall apply. All consumable and disposable products are guaranteed to be free from defects upon shipment only. The warranty period for batteries is limited to 90 days from date of shipment.

This warranty specifically excludes and replaces all other express and implied warranties. The Company shall have no liability under any warranty in any amount greater than the Company receives for the sale of the product involved. The use and manner of use of the Company's products shall be the responsibility of the purchaser and the purchaser covenants and agrees to indemnify and save harmless the Company in respect to any loss and damage that may arise through the use by the purchaser, or others, of any of the Company's products.

This warranty is rendered void and International Biomedical cannot be held liable for conditions resultant therefrom if:

1. Damage to the unit is incurred as a result of mishandling.
2. The customer fails to maintain the unit in a proper manner.
3. The customer uses any parts, accessories, or fittings not specified or sold by International Biomedical.
4. Sale or Service is performed by a non-certified service / dealer agency or any other unauthorized agency.

All shipping claims must be made within 30 days from date of shipment from International Biomedical; otherwise factory will not be liable for claims of missing items. Any item ordered in error and returned to the factory for credit, will be subject to a minimum restocking charge of 15%. Requests for returning items must be made within 30 days of factory shipment date.

International Biomedical will accept no returned goods without a Returned Goods Authorization number (RGA) obtained from Customer Service Department.

SECTION 10: SYSTEM DOCUMENTATION

EUROPEAN REGULATORY AFFAIRS REPRESENTATIVE

The authorized regulatory affairs representative in Europe for the Airborne Observation and Phototherapy Light System™ is:

Emergo Europe
Prinsessegracht 20
2514 AP
The Hague, The Netherlands

PARTS AND ACCESSORIES

For general Airborne Observation and Phototherapy Light System™ assistance or for parts and accessories, contact:

International Biomedical
8206 Cross Park Drive
Austin, TX 78754

512-873-0033

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