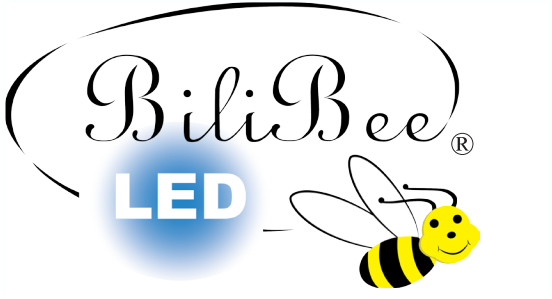
illumination technologies

Bilibee
LED Phototherapy System

User Manual



Important patient safety information inside.
Read this manual before setting up and using this device

Rx only

Table of Contents

Parents, guardians, and/or caregivers, please read the User Manual in its entirety prior to administering phototherapy treatment to the infant. The purpose of this manual is to provide instructions for the proper use of the BiliBee LED Phototherapy System. These instructions provide a system overview with warnings and precautions. The manual also describes the BiliBee LED Phototherapy System's configuration and operation with graphic illustrations of the device.

Initial Inspection (for commercial customers, i.e. DME/HME providers, hospitals, etc.)

Upon receipt, inspect the shipping container and cushioning material for damage. If damaged, keep the damaged shipping materials until the contents of the shipment have been checked for completeness, mechanical integrity and functionality.

If the BiliBee LED Phototherapy System is incomplete or damaged in any way, contact IMEDS. If the shipping container is damaged, keep the shipping materials for the carrier's inspection and contact the carrier and IMEDS at the address below.

Do not use this device until Illumination Technologies has verified the system is fully functional.

Distributed by:
IMEDS, LLC
6300 Button Gwinnett Drive
Atlanta, GA 30340
(phone number 877-772-4445)

www.illuminationtechnologies.net

OVERVIEW

For more than 3 decades, phototherapy has been the standard for treating neonatal jaundice. The benefits of utililizing phototherapy devices instead of sunlight include 24-hour treatment, greater efficacy by narrowing the spectral range to blue light, improved temperature regulation, and the elimination of harmful UV irradiation to the neonate from sunlight exposure.

The BiliBee LED Phototherapy System is a phototherapy device that is to be used for the treatment of neonatal hyperbilirubinemia (jaundice). This device is not a substitute for the services of a medical professional or a certified healthcare professional/provider. The BiliBee LED Phototherapy System can only be ordered by a licensed professional.

The core technology of the BiliBee LED Phototherapy System involves controlled, blue light therapy (phototherapy), a technique which aids in the treatment of neonatal jaundice. Jaundice is a common condition which has been known to impact 60% of the infants born in the United States each year. Bilirubin accumulates in infant's adipose tissue, and it causes a yellow discoloration of the skin.

The BiliBee LED Phototherapy System provides caregivers with a flexible method for treatment of neonatal jaundice and should be used according to the infant's physician's treatment instructions. The system design (patent pending) is DC powered to facilitate mobility while administering effective phototherapy treatment to the infant.

SAFETY INFORMATION

WARNING	Used for instructions intended to alert the user to the risk of death or severe injury should the system be used improperly.
CAUTION	Used for instructions intended to alert the user to the risk of injury or material damage should the system be used improperly. (Material damage refers to damage or other adverse effects caused to the home, its furnishings, and domestic animals or pets).

	The △ symbol alerts the user to important instructions or warnings. The specific meaning of the alert is determined by the symbol inside the triangle. The symbol shown at left is used for Warnings, Cautions, or Danger alerts
	The ⊘ symbol alerts the user to actions that must NOT be done. The specific meaning of the alert is determined by the symbol inside the circle. The symbol shown at left means that you must never open or disassemble the units.
	The ⊘ symbol alerts the user to actions that MUST be done. The specific meaning of the alert is determined by the symbol inside the circle.

	WARNING	**RISK OF ELECTRICAL SHOCK** NO USER-SERVICEABLE PARTS INSIDE

WARNING

	Do not use in the presence of flammable substances such as cleaning products.
	Do not use where oxygen is administered without UL or ETL certification.
	Do not open either of the system units or modify the system in any way.

CAUTION

	Do not drop, step on, or place heavy objects on the system.
	All cords and cables should be kept out of the reach of small children.
	Do not open either of the system units or modify the system in any way.

SAFETY INFORMATION

 	Never use or store the system in places that are: • Subject to temperature extremes, such as enclosed vehicle, or near a heating unit. • Damp, or humid, or exposed to rain. • Dusty or sandy. • Subject to high levels of vibration or movement.
	Do not allow any objects (such as flammable materials, or sharp objects) or liquids of any kind to penetrate the system.
	Immediately turn the power OFF, and system may become inoperable, if any of the following occur: • Smoke or a burning smell is detected. • An object has penetrated or crushed a unit. • The system has become wet, fallen into a liquid, been exposed to rain. • The system does not operate normally.

	Patients directly adjacent to the treatment area require protective eye shields/covers if the lamp is operated without the protective sheath.
	Do not allow any objects (such as flammable materials, or sharp objects) or liquids of any kind to penetrate the system.
	EMC present. Refer to EMC data contained in this manual.

	In the unlikely event that the BiliBee LED Phototherapy System is damaged and cannot be repaired, obtain a RA# calling (phone #877-772-4445) and return the entire system to: IMEDS, LLC 6300 Button Gwinnett Drive Atlanta, GA 30340 Units returned without an RA# will not be accepted by shipping and receiving. Do NOT dispose of in household waste bin.

PATIENT USE & SAFETY INFORMATION

Follow all Physician requests and instructions while using the BiliBee LED Phototherapy.

Prevent the accumulation of heat by using blankets only when necessary. To minimize accumulation of heat between infant and light panel, do not bundle or wrap infant with a thick blanket or too tightly.

Use of reflective foils may cause hazardous body temperatures, and should never be used with the BiliBee system.

Do not use this device without a protective disposable sheath in place. Use only the protective sheath that is provided with the system (part no. MCOO222). Using another cover will diminish phototherapy intensity and alter treatment results.

Do not use in conjunction with other thermotherapy devices (incubators, radiant heaters, heated mattresses, etc. which may impact the infant's body temperature) unless certified by the thermotherapy device manufacturer to meet required safety standards.

Patient may require eye shield/covers. The patient's eyes should not be exposed to the light from the illuminated panel for extended periods of time.

Patients adjacent to the BiliBee may need to be protected with protective eye shields/covers if the light panel is turned on without the protective sheath.

Varying of ambient conditions on the patient outside of the specified operating range will result in lower irradiance levels.

NOTE: *Bilirubin levels should be measured on a regular basis as determined by a physician.*

NOTE: *Photo-isomers of bilirubin may cause toxic effects.*

NOTE: *Some infant's water balance may be disturbed when this device is used.*

continued on page 8

PATIENT USE & SAFETY INFORMATION

Do not use the BiliBee while bathing the infant or if infant is sitting near a water source.

Operate in ambient conditions ranging from 59°F(15°C) to 104°F(40°C) providing maximum treatment.

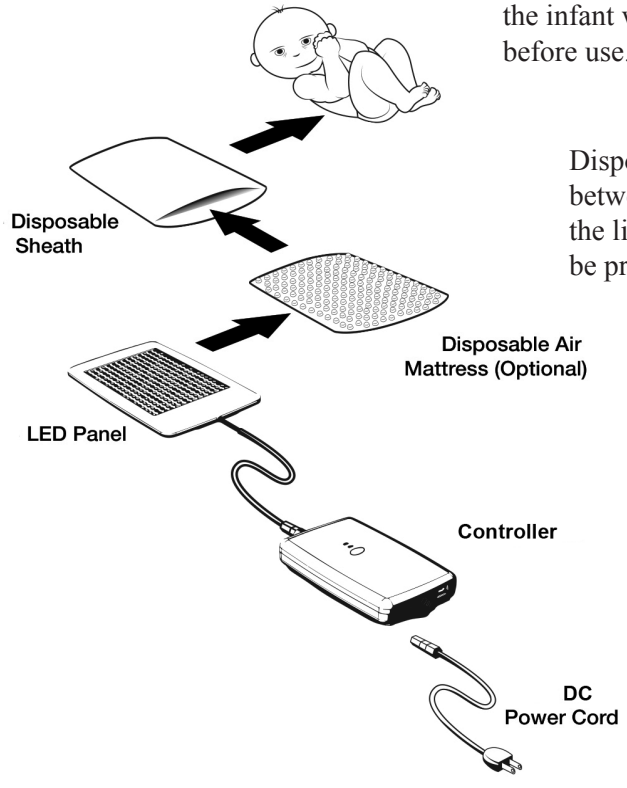
Do not allow any material (blanket, shirt, etc.) to interfere with treatment by getting between the protective sheath containing the BiliBee light panel and the infant's back. The air pillow should always be inside the protective sheath. The disposable sheath, containing the BiliBee and optional airpillow, should always be against bare skin.

Infants receiving treatment should wear a diaper. This is particularly important with male infants as prolonged phototherapy exposure to infant male genitalia can be harmful. A diaper will provide ample protection from the light emitted by the BiliBee.

Prior to new patient use, clean the BiliBee illuminator panel with CaviCide® or a medical grade cleaner (follow product instructions for effective disinfecting/cleaning).

Always monitor patient's temperature to ensure the patient does not get too cold or too warm.

BILIBEE SYSTEM DESCRIPTION



Disposable Sheath - The protective sheath provides comfort and protection to the infant while treatment is being administered. Place the panel in the sheath before use. Replace the sheath if soiled or damaged.

Disposable Air Mattress - The optional air pillow provides a comfort zone between the infant and the illuminator panel. Use of this item will decrease the light intensity, therefore efficiency will be affected, and treatment may be prolonged.

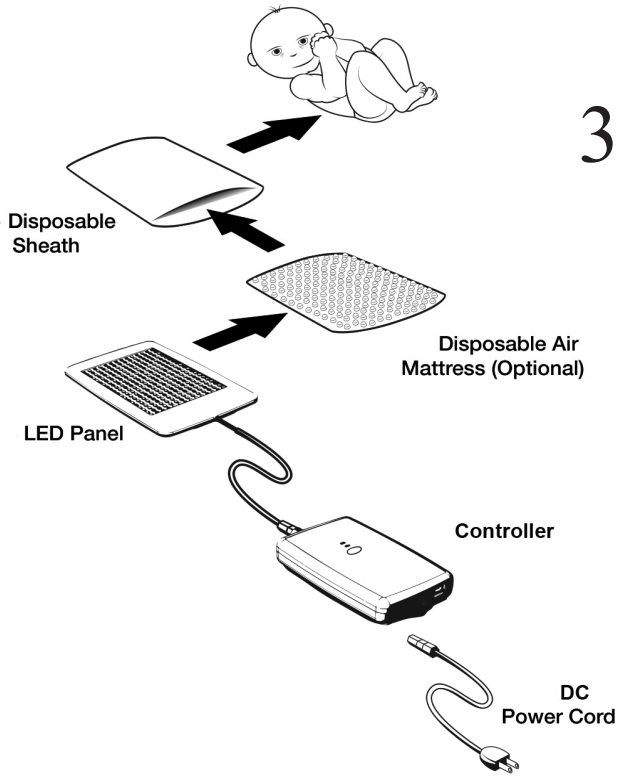
Controller - The controller provides power to the illuminator panel. It can be used when traveling, as a fully charged battery provides four hours of treatment. The rechargeable battery is charging when the unit is connected to the Wallwart DC power.

LED Panel - The BiliBee utilizes an illuminator panel as the light source to administer treatment to the infant. The panel is comprised of blue light-emitting diodes (LEDs) covering a approximatley 4in x 6in treatment area.

CONTROLLER

DC Power	1. DC Input Jack.
READY CHARGING LOW BATTERY	2. Battery Charge lamp indicates capacity level of battery and state of charge.
on/off	3. Illumination panel ON/OFF switch.
	4. ON/OFF lamp indicates illumination panel enabled.
	5. USB Data Port is used for factory recalibration of the lamp circuitry and software updates
	6. Hour display indicates the number of hours the unit has been on.

4 Place infant on sheath. Press ⏻ to turn illumination panel on. Refer to the patient use and safety data in this manual.



3 Place sheath around illumination panel and air pillow.

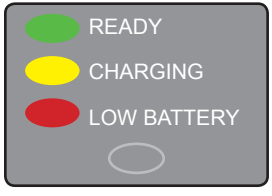
2 Insert LED panel into optional air mattress. Use of the pillow will reduce lamp intensity 10-15%

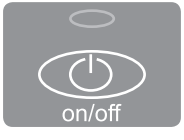
1 Plug wallwart into AC outlet and into DC power jack.

BATTERY CHARGING SYSTEM

The internal battery of the control unit allows 4 hours of run time when unplugged from DC source. To achieve the maximum run time, the battery must be fully charged. The battery automatically recharges when the control unit is plugged into the supplied DC wallwart. The control unit monitors and reports the capacity of the battery. The front side LED battery lamp reports capacity based on illuminated color.

GREEN indicates a fully charged battery. YELLOW indicates a charge is taking place. A charge occurs only when the control unit is plugged into the DC wallwart shipped with the unit. SOLID RED indicates the battery capacity is below 25%. BLINKING RED alerts the user to immediately plug the control unit into the supplied DC wallwart. The illumination panel will automatically disable when the battery capacity is below 2%. When the illumination panel switch is ON ⏻ with DC wallwart power unplugged, the battery lamp will remain SOLID GREEN indicating the battery has sufficient charge to operate the device.





The illumination panel illuminates pressing the ON/OFF switch. A SOLID BLUE lamp indicates the illumination panel is ON.

BILIBEE MAINTENANCE

The following section explains how to check and maintain the Bilibee Phototherapy System.

Check Light Output

It is recommended that the BiliBee system be regularly monitored for consistent performance. Ensure irradiance levels stay equal to or greater than 45µW/cm^2/nm.

Disposable Sheath

Replace disposable sheath prior to new patient use. Replace sheath if soiled.

Disposable Pillow

Replace disposable pillow prior to new patient use. The disposable pillow can be cleaned by the caregiver/parent if it is soiled. To clean the disposable pillow use warm soapy water to remove soil, rinse, and dry using a soft cloth or paper towel.

Patient Usage Log

Maintain a usage log of system activity by patient (see page 15). Note: The BiliBee has a programmed “life” of 3000 hours that is monitored by internal software. Upon completion of 3000 hours of use, the BiliBee LED Phototherapy System may be returned for recalibration/reactivation for another programmed “life” of 3000 hours.

BiliBee Illuminator Panel Cleaning

Prior to new patient use, clean the BiliBee illuminator panel with CaviCide® or CaviWipes® (RECOMMENDED), or other medical grade cleaner.

REPLACEMENT PARTS

Disposable Sheath
PN# MC00222

Disposable Air Pillow
PN# MC00221

Complete BiliBee Unit
PN# M00114

Manual
PN# UM00114

Wallwart DC Adapter
PN# EM00114

Case with Foam Inserts Only
PN# MC00223

SYSTEM USAGE LOG (OPTIONAL)

Illumination Technologies, LLC permits the copying of this log for commercial use.

Patient Name	Date Out/Ordered	Date In / DC'd	Days Used	Irradiance Output	Notes

TROUBLESHOOTING

The BiliBee LED Phototherapy System is a medical Class II system.

If panel does not illuminate upon pressing on/off button

1. Plug supplied wallwart into driver module.

2. Plug wallwart into AC outlet and allow 2 hours to charge.

3. If unit does not illuminate after two hours of charge, return to provider.

SPECIFICATIONS

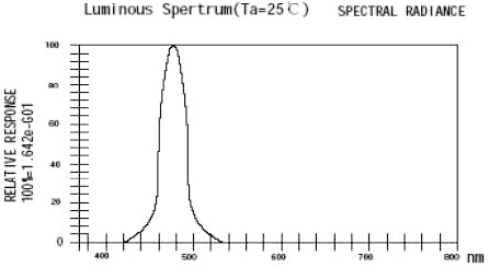
The BiliBee LED Phototherapy System is a medical Class II system.

Controller

Input Power:	5V @ 2 Amps
Internal Battery	3.7Vdc @ 3000mA/H
Data Port	Mini USB Type AB
Environment	CISPR228 / EN55022B IEC950, UL1950 Class II Type BF shock protection
Storage Temperate	1°F(-17°C) to 140°F(60°C), RH 95%
Transportation Temperature	41°F(5°C) to 140°F(60°C), RH 95%
Operating Temperature	59°F(15°C) to 140°F(40°C)
Weight	5.3oz
Size	5.185in x 3.212in x 0.787in

SPECIFICATIONS

Illumination Panel



Intensity and Wavelength	
Average irradiance E_{bi} level of illuminated area with protective sheath	E60μW/cm²/nm
Ratio of E_{bi} Bilirubin Irradiance to E_{bi} max Bilirubin Irradiance.	0.45
Average spectral wavelength	470nm peak 455nm to 485nm upper range
Storage Temperate	1°F(-17°C) to 140°F(60°C), RH 95%
Transportation Temperature	41°F(5°C) to 140°F(60°C), RH 95%
Operating Temperature	59°F(15°C) to 140°F(40°C)
Weight	8oz
Size	8.252in x 5.063in x 0.257in

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environmental guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ± kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environmental guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (> 95% dip in U_T for 0,5 cycle. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (60% dip in U_T) for 25 cycles <5%U_T (60% dip in U_T) for 5 seconds	<5% U_T (> 95% dip in U_T for 0,5 cycle. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (60% dip in U_T) for 25 cycles <5%U_T (60% dip in U_T) for 5 seconds	Main power quality should be that of a typical commercial or hospital environment. If the user of BiliBee requires continued operation during power mains interrupts, it is recommended that the BiliBee be powered from an uninterruptible power supply or a battery.
Power frequency (50/60)Hz magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

FEDERAL COMMUNICATIONS COMMISION
RADIO FREQUENCY INTERFERENCE STATEMENT

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:
1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may casue undesired operation.

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used correctly in accordance with the instructions provided, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation or location. If this equipment odes cause harmful interference to medical or communicatin equipment, that can be determined by turning the equipment OFF and then back ON. The user is encouraged to try to correct the interference by one or more of the following methods:

• Increase the distance between the units that are being interfered with.

• Move the unit to another power outlet on a circuit different from the one being interfered with.

Contact Illumination Technologies for additional support if needed to eliminate the interference if the above measures are not helpful. The FCC requires that you stop using your equipment if the interference to others connot be eliminated.

Changes or modifications to the equipment not expressly approved by Illumination Technologies may cause interference and could void the user's authority to operate the equipment.

NOTICE

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

AVIS

Cet appareil numerique de la classe B respecte toutes les exigences du Reglement sur le materiel brouilleur du Canada.

Recommended Separation Distance Between Mobile RF Communications Equipment and the BiliBee.

The BiliBee is intended for ue in an electromagnetic environment in which RF disturbances are controlled. The user can minimize electromagnetic interference by maintaining a minimum distance between RF communications equipment (transmitter) and the bilibee as recommend below.

	Seperation distance according frequency of transmitter (meters)		
Transmitter max rated output power **Watts**	150khz to 80Mhz	80Mhz to 800Mhz	80Mhz to 2.5Ghz
0.01	0.12	1.2	0.23
0.1	0.38	3.8	0.73
1	1.2	12	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommend separation distance d in meters(m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (w) according to the transmitter manufacturer.

NOTES:
At 80Mhz and 800Mhz, the seperation distance for the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTES

NOTES