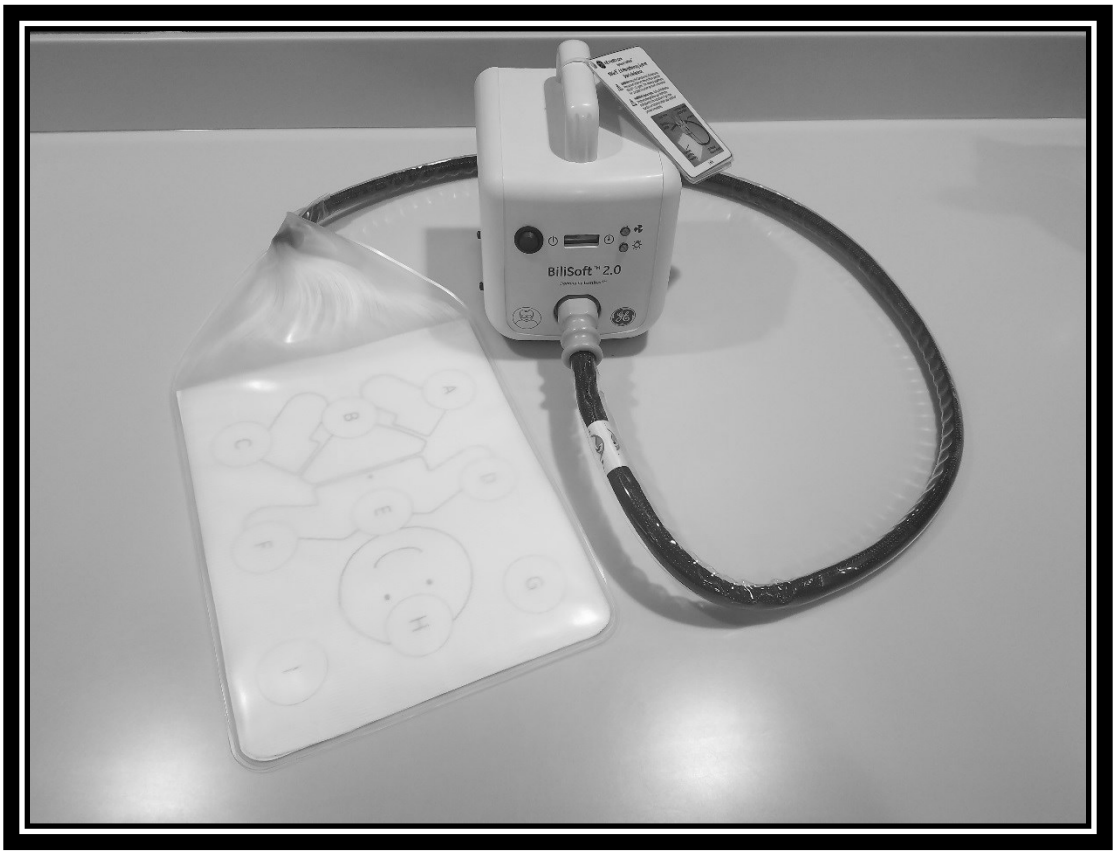
BiliSoft™ 2.0 Phototherapy System

Lighting by Lumitex™



Operation Manual

Warranty

This product is sold by GE Healthcare with a GE depot repair warranty that covers labor and parts under the terms and conditions set forth in the GE Healthcare Warranty Statement presented to the customer at the point of sale. The light pad, light box chassis and cooling fan carry a 12-month warranty. The electronics carry a 24-month warranty. The phototherapy LED carries a 36-month warranty.

The product warranty is only offered through GE service depot. Field service is not covered under warranty for this product.

Table of Contents

Indications for Use

The BiliSoft 2.0 Phototherapy System provides light therapy for the treatment of hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the hospital or home setting. The BiliSoft 2.0 Phototherapy System emits a narrow band of blue light considered to be the most effective in the treatment of hyperbilirubinemia.

About this Manual

Conventions

Various types of pictures or icons are used in this manual or on the product. They reinforce the printed message to alert you to potential safety hazards in one of the following ways:

WARNING:

A WARNING statement is used when the possibility of injury to the patient or the operator exists.

CAUTION:

A CAUTION statement is used when the possibility of damage to the equipment exists.

About this Product

Scope and Intended Users

This manual describes how to use and maintain the BiliSoft 2.0 Phototherapy System (also referred to as BiliSoft 2.0).

The device is intended to be used in hospital and home settings. Intended user groups are trained caregivers/ parents, hospital staff, and biomedical technicians/ biomed service personnel.

BiliSoft 2.0 should be used by direction of qualified medical personnel. Medical personnel should be familiar with currently known risks and benefits of infant phototherapy.

Description

BiliSoft 2.0 Phototherapy System consists of a light box and a detachable fiberoptic light pad with a long, flexible fiberoptic cable. The fiberoptic cable delivers light from a high intensity LED module in the light box to the fiberoptic light pad. The flexible fiberoptic light pad is placed in a soft BiliSoft Pad Cover or BiliSoft Nest that is then brought into contact with the patient's skin. The patient is exposed to light in the wavelength of 430-490 nanometer range (peak 445-470 nanometer).

Units are available with two fiberoptic pad sizes: small (20cm x 25cm) and large (25cm x 30cm).

Carton Contents

The BiliSoft 2.0 Phototherapy System is shipped with the following contents:

1	Light Source Box with language specific warning labels
1	Light Pad (Small 8x10 inch or Large 10x12 inch)
1	Country / Region specific AC Power cord
1	Operation Manual (Language specific)
1	Service Manual (English Language Only)
2	Disposable Pad Cover, Flat
1	Disposable Pad Cover, Nest

Note: A Home Healthcare model sold to equipment providers will substitute (15) flat pad covers for the standard disposables.

Note: Replacement disposable pad covers (Flat and Nest) can be purchased from GE Healthcare, see Chapter 6 for part numbers.

User Responsibility

This product will perform properly, when used and cared for as described in the instructions provided.

This product must be periodically checked. A defective product should not be used. Broken, missing, plainly worn, distorted or contaminated parts should be replaced immediately.

Should repair or replacement become necessary, Lumitex recommends that a request for service be made to the nearest GE Healthcare Regional Service Center listed on the back cover. This Product, or any of its parts, should only be repaired by trained GE Healthcare technicians.

WARNING:

No modification or alteration of this device is allowed.

WARNING:

US Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

If repairs are made by anyone other than GE Healthcare trained personnel, the user shall be solely responsible for any malfunction due to:

- Improper use
- Inadequate maintenance
- Improper repair, damage or alteration

To ensure that the BiliSoft 2.0 Phototherapy System provides effective phototherapy treatment:

- Read this manual
- Pay special attention to **WARNINGs** and **CAUTIONs** that appear in this manual
- Use the product according to your healthcare provider's instructions

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the proper disposal of your equipment.

This page intentionally left blank.

Important Safety Information

WARNINGS:

Eye Protection:

Long exposure to any phototherapy light may cause eye damage. Never look directly at the light. Infants should wear eye protection during therapy. Take care to protect the eyes of nearby infants.

Home Users:

Always follow your healthcare professional's instructions.

Caregiver Side Effects:

Caregivers looking at the blue light for a long time may experience headache, nausea, or mild vertigo.

Bilirubin Levels:

Measure the bilirubin levels during treatment. Follow hospital policies and procedures.

Possible Risks:

All phototherapy has possible risks including, but not limited to:

- Apnea
- Bronze baby syndrome
- Diarrhea
- Hyperpigmentation-reddening
- Patent ductus arteriosus
- Riboflavin-calcium and other deficiencies
- Skin blistering
- Skin irritation and thrombocytopenia

Watch closely for signs of these conditions during treatment.

Porphyrins/Photoisomers:

Bilirubin photoisomers may cause toxic effects. Porphyrins are the result of the breakdown of the bilirubin molecule. Exposure of porphyrins to phototherapy may result in a localized reddening of the patient's skin. Monitoring of the skin is recommended.

Photosensitive Drugs:

The phototherapy light can harm drugs and other infusion liquids. Shield any IV tubing with an appropriate material. Do not store drugs or infusion liquids near the phototherapy light.

Power Cord:

Do not block the power cord plug. It can be disconnected for emergency power shutoff.

Hospital Policy & Procedures:

Follow hospital policies and procedures for assessing

- Bilirubin
- Temperature
- Skin
- Eyes

Disposal:

Dispose of all waste as required by federal, state, and local waste regulations. Improper disposal could result in personal injury or harm the environment.

Skin Color:

The blue light can mask skin color changes such as cyanosis.

Patient Positioning:

Regularly check that the patient is in the treatment area of the device.

Product Mounting and Service:

Do not mount the system to a Dove Rail, or service the unit, while a patient is in the bed, or is receiving treatment.

Patient Water Loss:

Phototherapy treatment can increase a patient's insensible water loss. Maintain the patient's fluid balance while administering phototherapy.

Patient Skin Temperature:

Phototherapy used with warming devices may raise the patient's body temperature. Incubator or warming beds should use skin controlled (servo) mode for warming during treatment. Always monitor the patient's temperature to avoid temperature fluctuations during treatment.

Reflective Foils:

Do not use foils or reflective materials with the treatment. Hazardous patient body temperatures may result.

Combustible Gases:

Do not use the BiliSoft 2.0 in the presence of flammable anesthetics (e.g. ether) mixtures with air or with oxygen or nitrous oxide. These mixtures can support combustion. A possible explosion hazard exists under these conditions.

Flammable Solutions:

Never use flammable solutions to clean the BiliSoft 2.0 Phototherapy System or any of its parts.

Oxygen:

Oxygen rich air greatly reduces the temperature at which materials burn. Remove all opaque materials from the immediate light path when using the light while administering oxygen.

Trip Hazard:

The power cord can be a trip hazard. Do not leave the cord unattended when located in traffic areas.

Unit Damage:

A damaged or defective unit or accessory should not be used.

Electric Shock Hazard :

Do not attempt to insert objects into the intake or exhaust vents on the cover.

CAUTIONS:

Electromagnetic Interference:

The user needs to be aware of electromagnetic interference, or EMC. This device is to be installed and put into service according to the EMC information provided in Chapter 9.

Roll Stand:

If the system is mounted on a portable roll stand, lock the wheels to prevent movement during the therapy.

Trip Hazard:

The power cord can be a trip hazard. Do not leave the cord unattended when located in traffic areas.

Unit Damage :

Do not attempt to insert objects into the intake or exhaust vents on the cover.

Contraindications

The following patient symptoms or conditions make phototherapy treatment inadvisable*.

- Congenital porphyria or family history of porphyria.
- Concomitant use of drugs or agents that are photosensitive.
- Concurrent therapy with metalloporphyrin heme oxygenase inhibitors.

Phototherapy effectiveness may be reduced in presence of cholestasis (direct hyperbilirubinemia).

* MacDonald & Ramasethu (2007). Atlas of Procedures in Neonatology, Lippincott Williams & Wilkins, Philadelphia, PA

This page intentionally left blank.

Care of the Patient's Skin

Important clinical information – please read carefully before using this device.

The skin has a number of roles. It provides a protective barrier against chemical, mechanical, and biological injuries. It helps maintain body temperature. It also serves as a route for water excretion, especially in premature infants.

The introduction of new intensive care techniques has increased survival of very small, premature infants. Very low weight infants do not have fully developed skin. Combined with more instrumentation and handling, this poses previously unrecognized problems for the nursing care of these infants.[1]

Please read, evaluate and implement the following recommendations as appropriate:

1. Please refer to the following standard of skin care recommendations as given in the literature[2] when utilizing this device. Special attention should be given to sanitation and skin integrity.
    - Observe color, rashes, excoriation.
    - Clean skin with warm water.
    - Clean perineal area after stooling.
    - Change infant's position every 2 hours.
2. This device is intended only for the treatment of existing hyperbilirubinemia. Use of this device as preventative treatment is not recommended. Premature infants have extremely fragile skin[3] and various clinical studies have produced different conclusions concerning the effectiveness of preventative treatment. [4, 5]

[1] NAACOG (1992), OGN Nursing Practice Resource, Neonatal Skin Care, NAACOG.

[2] ibid

[3] Rutter, N., The immature skin, ***British Medical Bulletin***, Vol. 44, No. 4, 1988

[4] Curtis-Cohen, M., et al, Randomized trial of prophylactic phototherapy in the infant with very low birth weight, ***The Journal of Pediatrics***, July, 1985

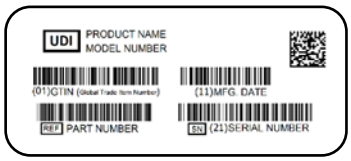
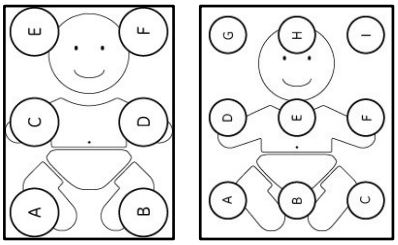
[5] Brown, A., et al, Efficacy of Phototherapy in Prevention and Management of Neonatal Hyperbilirubinemia, ***Pediatrics***, February, 1988

This page intentionally left blank.

Symbol Definitions

Symbol	Description
	Electrical shock hazard possible.
	**WARNING** statements are used when the possibility of injury exists.
	**CAUTION** statements are used when there is a possibility to damage the equipment.
NOTE:	**NOTE** statements are used to provide additional information, or clarify a point.
	Indicates alternating current (AC).
	Type BF applied part.
	Cover the patient's eyes during phototherapy.
	On/Off Standby Switch
	Unit overheated indicator
	Hour meter
	LED failure indicator
	Double Insulated
	See the Operation Manual for more information.

Symbol	Description
	Do not spray cleaner directly onto the fiberoptic lens. The fiberoptic lens require special cleaning methods. See cleaning section of this manual for complete details.
EC REP	European Authorized Representative
	Manufacturer
ETL CLASSIFIED Intertek 56287	ETL approval symbol
R_x Only	US Federal law restricts this device to sale by or on the order of a licensed medical practitioner. (Applicable only in the USA)
	Do not place items in path of radiant heater
	Waste Electrical and Electronic Equipment Directive symbol
CE 0050	CE mark - Lumitex declares that product displaying the CE mark conforms to the Regulation (EU) 2017/745.
	Do Not Reuse
IP21	Protection levels for solid objects and water ingress (light box): 2 - Fingers or similar objects < 12.5mm diameter 1 - Dripping water (vertically falling drops)
IPX4	Protection levels for water ingress (light pad): 4 - Water splashing against the enclosure from any direction shall have no harmful effect.
SN	Serial Number
REF	Part Number
UDI	Unique Device Identifier. The UDI is a unique identifier for a medical device.

Symbol	Description
	Beginning in September 2016, some medical devices sold in the USA must be labeled with a Unique Device Identifier (UDI).
SMALL PAD LARGE PAD 	The baby outline defines the side of the pad upon which to place the baby. Place the baby on this side of the pad.

This page intentionally left blank.

Chapter 1
Components and User Controls

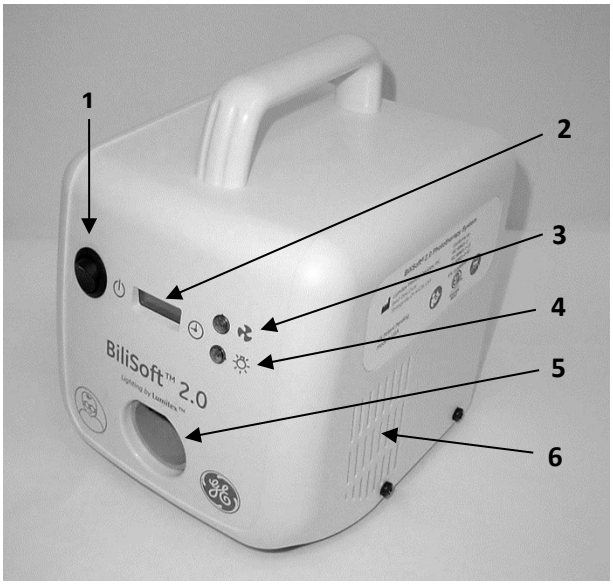
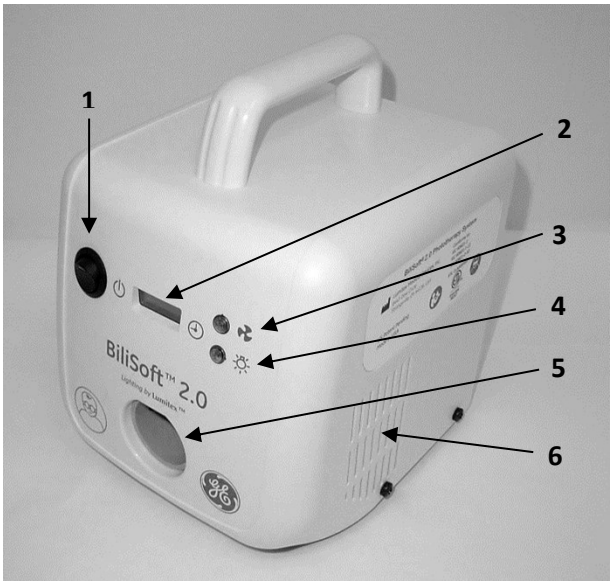
BiliSoft 2.0 Light Box

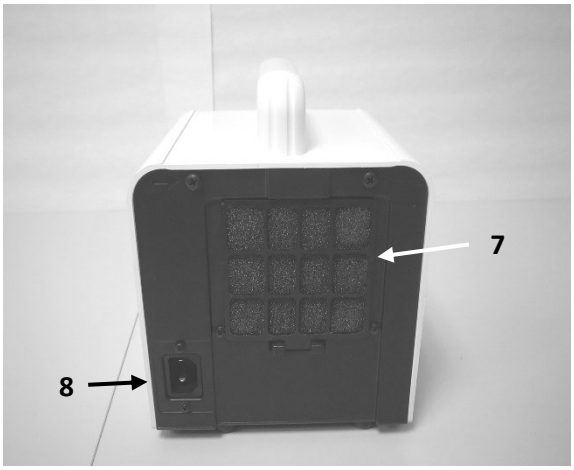
The Light Box contains the output LED module, a power supply, a cooling fan and temperature protection circuitry.

The power supply is universal. The device can be supplied by any standard AC main power source. The rated input voltage is 100-240VAC at 50/60 Hz. The rated input current is 0.25-0.75 Amps.

The LED module emits a very narrow band of blue light with no appreciable amount of ultraviolet or infrared light. The LED module can only be activated when the pad connector is plugged into the system.

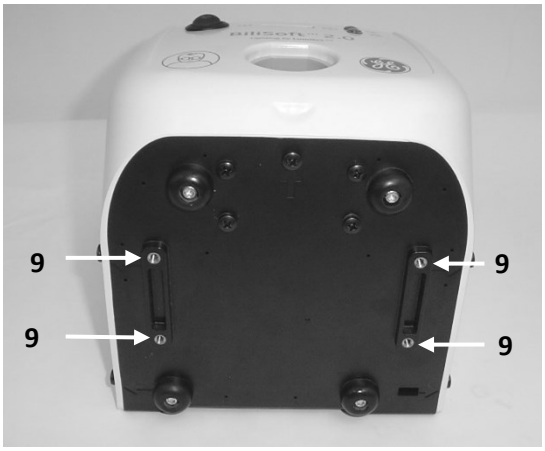
The light box is cooled by a fan. A thermal sensor located on the LED module protects the device from overheating. It also prevents operation if the temperature is below freezing.

Component/Control	Function
	1. **Standby Switch** – Turns the unit ON/OFF. The green light in the switch indicates that the standby switch is turned on and the unit has power. 2. **Hour Meter** –The non-resettable hour meter shows the number of hours a light pad has been active during the life of the light box. If the Light Pad connector is not fully inserted into the light box, the LED is automatically shut off and the hour meter does not run. **Note**: The hour meter is provided to track LED life and is not intended to be used to measure therapy durations.
	3. **Unit Overheated Indicator –** When this red indicator light is ON, the unit has overheated. See Troubleshooting Guide for more details. 4. **LED Module Failure Indicator -** When the red indicator light FLASHES, the LED module has failed. See the Troubleshooting Guide for more details. 5. **Light Pad Connector Port –** Where the light pad assembly connects to the main unit. A shutoff switch inside the port automatically turns off the LED module whenever the fiberoptic light pad assembly is removed**.** 6. **Exhaust Air Vents –** For proper cooling it is important to keep the air vents clear of obstructions**.**



7. **Air Filter & Air Intake Vents –** For proper cooling it is important to keep the air filter clean and clear of obstructions. See the maintenance section of this manual for more details.

8. **AC Power Cord Receptacle** – Is where the AC power cord plugs in.

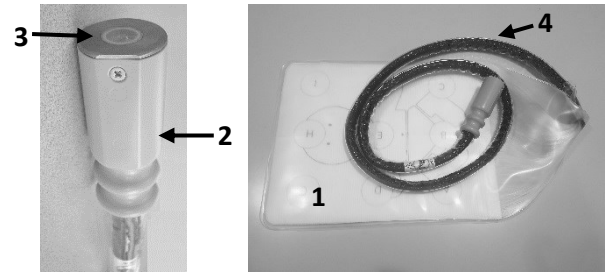


9. **Mounting Bracket Holes –** Four M4 threaded holes on the bottom of the main unit are used to attach the optional mounting bracket. The mounting bracket can be positioned on the left or right side of the light box.

BiliSoft 2.0 Light Pad Assembly

The fiberoptic light pad comes in two sizes, small and large. The small pad surface is 8x10 inches. The large pad surface is 10x12 inches.

The LED light source in the BiliSoft 2.0 light box is focused on the fiberoptic lens at the end of the Light Pad connector. The fiberoptic cable contains plastic fibers that transmit light from the light box to the light pad. The light pad is constructed of these plastic fibers woven into a mat. This patented process produces a light pad that emits light over its entire surface. The average light intensity depends on the size of the light pad. See Chapters 7 and 8 for detailed specifications.

Component/Control	
	1. **Light pad** 2. **Pad connector** 3. **Fiberoptic lens** 4. **Fiberoptic cable**

Warning:
Do not place a baby directly on the bare fiberoptic light pad. The fiberoptic light pad should always be covered with a BiliSoft Pad Cover or Nest when used.

Soft Cover Options (Disposables)

The BiliSoft Pad Covers and Nest are designed for use with both premature and full-term infants. They are available in small and large sizes to match the size of the Light Pad.

Warning:

The soft covers are single-use products. They are not to be reused on a different patient. Reuse may cause a risk of cross-contamination, or affect the system performance.

Repeated use on the same patient, is acceptable. The user must ensure that the product is not damaged or contaminated between uses on the same patient.

BiliSoft Disposable Pad Cover, Flat	BiliSoft Disposable Pad Cover, Nest
	
A flat cushioned cover with straps.	A cushioned cover with developmental positioning foot roll and straps.

This page intentionally left blank.

Chapter 2
Operating Instructions

To ensure that the BiliSoft 2.0 Phototherapy System provides effective phototherapy treatment:

- Read this manual.
- Pay special attention to **WARNING** and **CAUTION** when they appear in this manual.

CAUTION:

Preventative maintenance and pre-use checkout requires that device output is to be tested prior to being put into service.

Pre-use Checkout Procedure

CAUTION:

The BiliSoft 2.0 Phototherapy System should be checked with the Ohmeda Medical BiliBlanket® Meter II for desired therapeutic output before use with each patient.

Do not block the air filter or side vents.

1. Examine the fiberoptic light pad, connector and cable, the power cord, the light box and light box warning labels for obvious signs of damage. Replace if they are damaged.

2. Verify that the side and back vents of the light box are unobstructed. The air filter should be free of lint.

3. Fully insert the fiberoptic light pad connector into the light box.

4. Connect the power cord to the back of the unit, then to an appropriate power source.

5. Turn the BiliSoft 2.0 Phototherapy System on using the Standby Switch on the front of the unit, the Over-Temperature and LED Failure Indicators will briefly illuminate.

6. Confirm that the fan is operating by placing your hand close to the exhaust vent when the device is operating to feel for air flow coming out of the device. See the Trouble-Shooting Section if there is no air flow. Allow system to run for six (6) minutes.

7. Place the fiberoptic light pad on a flat surface. Do not place the fiberoptic light pad inside of a BiliSoft Pad Cover or BiliSoft Nest at this time.

8. Use a calibrated Ohmeda Medical BiliBlanket Meter II to check the light output of the unit. Take measurements on the lit side of the pad using the meter placed at points as shown on the back of the pad. There are two ways to check the output. The center-row check uses only the readings from the center row positions. For a small pad, the center row points are labeled C and D. For a large pad, the center row points are labeled D, E and F. The more comprehensive measurement uses all the points shown on the back of the pad. The small pad will have six (6) points. The large pad will have nine (9).

Light Pad Output

New BiliSoft 2.0 devices are shipped with light outputs that fall within a range. This range is the rated output. The rated output is different between the small and large pads. With proper care, the Light Pad output will match the Light Box output for the life of the product.

A new unit leaves the factory with measured outputs falling within the ranges shown in the table below. The left column provides the average value for the center row readings. The middle column provides the average output for the full measurement.

As the LED module ages beyond 50,000 hours, its output may decrease. The full output may eventually fall below the rated range. However, effective treatment will continue until the full output falls below 27 $\mu W \bullet cm^{-2} \bullet nm^{-1}$. Compliance standards recommend replacing the LED module when the full output falls 25% below the minimum rated output. These values are shown in the far right column of the table.

If the measured output is at, or below, the values shown under "Replacement", see the Troubleshooting chapter of this manual. If troubleshooting does not improve the average reading, the LED should be replaced.

Once the check is completed, the unit is ready for use.

	Factory Rated Outputs - Settings		**Replacement**
	Center-Row Output[2] (bare fiberoptic light pad) $\mu W \bullet cm^{-2} \bullet nm^{-1}$	**Full Output[2]** (bare light pad) $\mu W \bullet cm^{-2} \bullet nm^{-1}$	**Output[2] Requiring LED Replacement[1]** (bare light pad) $\mu W \bullet cm^{-2} \bullet nm^{-1}$
Large Pad	(D + E + F)/3 ≥ **40.0**	(A + B + C + D + E + F + G + H + I)/9 = **49** (+/- 25%) Rated output range (36.75 – 61.25)	(A + B + C + D + E + F + G + H + I)/9 = ≤ **27**
Small Pad	(C + D)/2 ≥ **60.0**	(A + B + C + D + E + F) /6 = **70** (+/- 25%) Rated output range (52.50 – 87.50)	(A + B + C + D + E + F) /6 = ≤ **39**

Note[1]: IEC standards recommend LED module replacement at 25% output reduction from minimum output rating. Those values are 27 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ for the large pad and 39 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ for the small pad. This should not occur until hours of use significantly exceeds 50,000 hours.

Note[2]: Using an Ohmeda Medical BiliBlanket Meter II. Measurement points for front of pad are shown on back panel of pad and in Chapter 10.

Note: When the BiliSoft 2.0 fiberoptic light pad is inserted into a BiliSoft Pad Cover or Nest, the measured output will reduce. The average full output for a new large pad system is 35 $\mu W \bullet cm^{-2} \bullet nm^{-1}$. The average full output for a new small pad system 50 $\mu W \bullet cm^{-2} \bullet nm^{-1}$.

Positioning the Unit

WARNINGS:

Never position the unit where it could fall and injure a patient or caregiver.

Never place the light box inside of an incubator, warmer or bassinet with the patient. This could cause possible injury to the patient.

Never position the unit in the path of, or next to, sources of heat. For example, near a fireplace or in the path of radiant heaters.

To avoid patient injury, do not mount the system using a dove tail rail or service the unit while a patient occupies the bed or is receiving treatment.

WARNING SHOCK HAZARD:

The light box is not waterproof. Never position the unit next sources of liquid or steam. Do not place the device next to devices that supplement room humidity e.g. humidifiers.

CAUTIONS:

Never position the unit where it could interfere with the performance of other equipment.

Use care when moving beds, or roll stands using a Dovetail Rail with a BiliSoft 2.0 attached. Protect the unit from impacting door jambs or any other obstacles.

Follow these guidelines to prevent damage to the Light Pad coverings and optical fibers. Failure to do so could decrease light intensity at the light pad:

- Do not allow the fiberoptic cable to be crushed, or bent at a sharp angle. This could damage the cable's outer protective cover and the optical fibers.
- Do not place anything on the fiberoptic cable.
- Do not store the Light Box on top of the Light Pad.
- Protect the Light Pad from contacting sharp or abrasive surfaces. The protective coverings and optical fibers may be damaged.

To avoid damage to the equipment or injury to users and patients, keep the Light Box and the Light Pad out of the reach of children and pets.

If the fiberoptic cable or light pad is ripped, punctured or otherwise damaged, it must be replaced.

The BiliSoft 2.0 Phototherapy system Light Pad is placed under the patient. The pad can be placed on top of a crib, bed or basinet, mattress and the patient is then placed on top of the light pad. Alternatively, the Light Pad and the patient can be wrapped together using a blanket.

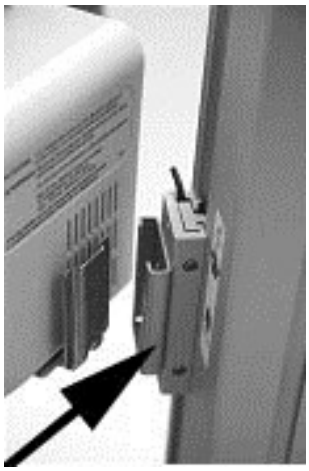
The Light Box can be placed on any of the following:

- **On the floor, on a table, or another stable, flat surface.**
- **On Hospital Beds or Incubators equipped with an Ohmeda Medical Dovetail Rail.** (Optional - mounting brackets sold separately)
- **On Hospital Roll Stands equipped with an Ohmeda Medical Dovetail Rail.** (Optional - mounting brackets and stands sold separately)

The BiliSoft mounting bracket to allow use with an Ohmeda Medical Dovetail Rail is sold separately. The bracket is attached to the Light Box using screws provided with the bracket. The Light Box has four matching inserts on the bottom of the unit. The bracket can be positioned on the left or right side of the unit. When installed, there may be a small amount of tilt to the bracket.

See the Optional Parts List in this manual for the bracket part number.

Attaching the Mounting Bracket

		
Mounting bracket, male (for dovetail rail and mobile stand).	Mounting bracket, female (for dovetail rail and Giraffe Spot PT Lite roll stand).	Mounting bracket, female (for Ohmeda mobile stand).

Using the Unit

WARNINGS:

Handle the Light Pad Connector with caution. Patients and caregivers can be injured if struck by the pad connector.

Use the BiliSoft Cover and Nest with caution. The cloth tie straps should be tied together when they are not being used. Loose straps can cause strangulation or a choking hazard.

Monitor the patient during use to ensure that they do not become entangled with the pad cable or that the disposable covers. Either could result in strangulation or choking.

CAUTIONS:

The light from the Light Pad is intended to shine through the padded side of the BiliSoft Cover and Nest.

Handle the Light Pad Connector with caution. The fiberoptic lens can be damaged or scratched if struck.

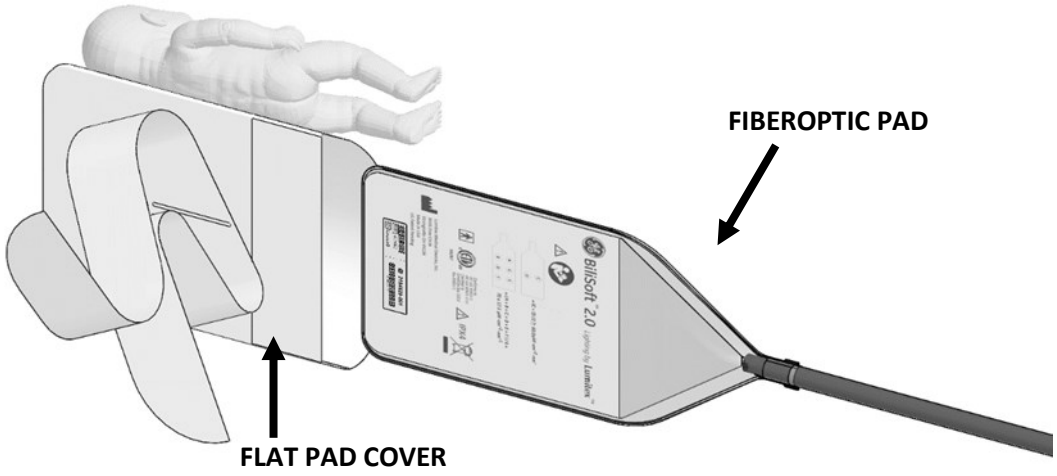
The eyes of babies can be damaged from direct exposure to any phototherapy light. Always protect the baby's eyes with eye patches or equivalent eye protection products. Periodically confirm that the patient's eyes are protected. Perform this check more frequently if required by healthcare provider's instructions. Care should be taken to protect the eyes of other infants nearby.

Installing Pad Covers

Installing Flat Pad Covers Onto Pad

1. After the Pre-Use Checkout, gently insert the fiberoptic pad into a flat pad cover (shown below). The back of pad should face the strap side of the cover as shown.

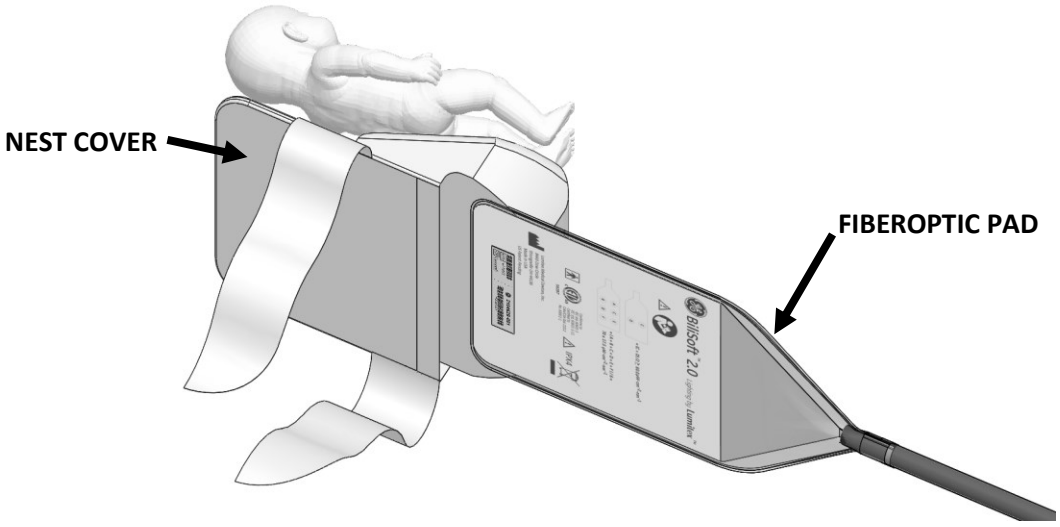
   For patient comfort and hygiene, never place a baby directly on the bare fiberoptic light pad. The light pad should be covered with the BiliSoft Flat Pad Cover or Nest.



Installing Pad Nest Covers Onto Pad

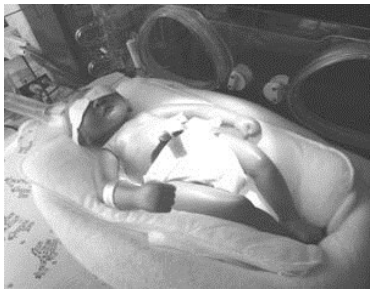
2. After the Pre-Use Checkout, gently insert the fiberoptic pad into a Nest cover (shown below). The back of pad should face the strap side of the cover as shown.

   For patient comfort and hygiene, never place a baby directly on the bare fiberoptic light pad. The light pad should be covered with the BiliSoft Flat Pad Cover or Nest.



3. Place the baby on the padded side of the flat cover or Nest. Adjust the straps as needed to help swaddle the patient.

   IMPORTANT: Be sure to position the patient to expose the most amount of their skin to the pad light.



3. The patient on the light pad may be covered or wrapped in a thin blanket to help swaddle. The patient can be held and fed during the treatment. The patient will continue to receive effective treatment as long as their skin remains exposed the pad light.

   Positioning aids may be placed under the light pad edges to bring more light to the sides of a baby's body. This will allow expose more patient skin to the light.

4. Protect the baby's eyes with eye patches or an equivalent appropriate eye protection product.

5. Insert the fiberoptic cable in the box.

6. Turn the Light Box on.
7. During treatment:
   a. Periodically monitor the patient for its position on the light pad.
   b. Monitor the patient for items found in the Important Safety Instructions as required by hospital policy or as instructed by health care professionals.

This page intentionally left blank.

Chapter 3
Troubleshooting

Indicator Lights/Troubleshooting Guide

Symptom	Likely causes	Troubleshooting steps
Unit Overheated Indicator light is on. 	Clogged air filter, blocked vents, fan or hardware failure.	1. Turn off the standby switch and disconnect the power cord from the outlet. 2. Make sure that the air filter in the back of the unit and the air vents on either side of the unit are unobstructed. Clean air filter if necessary. 3. Plug the power cord into an outlet. Make sure a fiberoptic light pad is attached. Turn the standby switch on. 4. Verify that the fan is on and allow the unit to run with the fiberoptic light pad attached. 5. If the fan is not running while the unit is turned on or if the Unit Overheated indicator light turns on again, remove the unit from service and seek assistance from service personnel.
LED failure indicator light is blinking. 	The LED is not operating.	1. The LED module needs to be evaluated or serviced by service personnel.
Fiberoptic light pad, cable or connector is visibly damaged.	Fiberoptic light pad, cable or connector was ripped, punctured or otherwise damaged.	1. A damaged Light Pad, cable, or connector cannot be serviced. 2. Components of the fiberoptic light pad are not replaceable.

Symptom	Likely causes	Troubleshooting steps
Light output measurement is 25% below minimum rated value. Small Pad average: (≤27 µW · cm-2 · nm-1.) Large Pad average: (≤39 µW · cm-2 · nm-1.).	Fiberoptic pad connector is not fully inserted into the light box. Fiberoptic light pad and/or fiberoptic lens are discolored or damaged. Improper measurement setup. LED module needs replacing.	1. Make sure that the fiberoptic cable connector is fully inserted into the light box. 2. Make sure that the surface of the fiberoptic light pad is not damaged or discolored. 3. Make sure that the fiberoptic lens has not been damaged or discolored. 4. Make sure that the average light output measurement is taken with the light pad on a flat surface and that the pad is not covered with a BiliSoft Pad Cover or Nest. 5. Make sure to use a calibrated Ohmeda Medical BiliBlanket Meter II to take the light output readings. 6. Perform the comprehensive 6-point (small pad) or 9-point (large pad) check. 7. If the light output is still 25% below minimum rated value, remove the unit from service and seek assistance from service personnel.
Main unit cover, handle or base plate is cracked or damaged.	Unit was dropped or damage by impact with another object.	1. Remove the unit from service and seek assistance from service personnel. 2. All damaged parts must be replaced and unit checked to ensure no internal damage has occurred.
Hour meter is not working.	Fiberoptic pad connector is not fully inserted into the light box. Hour meter failure.	1. The hour meter only runs when the fiberoptic light pad is illuminated. If the fiberoptic cable connector is not fully inserted in the light box, the LED module is automatically shut off and the hour meter does not run. 2. If the fiberoptic cable connector is fully inserted and the hour meter still does not work, remove the unit from service and seek assistance from service personnel.

Symptom	Likely causes	Troubleshooting steps
No light output.	Fiberoptic pad connector is not fully inserted into the light box. Unit is not powered. Failure of the LED module.	1. Confirm that the fiberoptic cable connector is fully inserted in the light box. If the fiberoptic cable connector is not fully inserted in the light box, the LED module is automatically shut off. 2. Confirm that the front panel standby switch is in the “on” position and illuminated green. 3. If the front panel standby switch is in the “on” position and not and illuminated green, confirm that the unit is plugged into an active outlet. 4. If the connector is fully inserted and the standby switch is illuminated green and there is still no light to the fiberoptic light pad, remove the unit from service and seek assistance from trained service personnel.
Fiberoptic light pad connector fails to stay inserted.	Loss of magnetic latch.	1. The Light Pad connector is designed to be retained by magnets. If Light Pad connector is jerked while in use the connector will break free from the magnets. 2. Check to see if there is an obstruction in the Light Pad connector port. 3. If the Light Pad cable is not stretched tight and the connector does not stay in place, remove the unit from service and seek assistance from trained service personnel.

This page intentionally left blank.

Chapter 4
Routine Cleaning and Maintenance

This chapter describes routine cleaning and maintenance to be performed by the operator for low level disinfection of non-critical devices.

Planned maintenance procedures are to be performed by hospital biomedical engineering services. Consult the BiliSoft 2.0 Service Manual.

Cleaning and Disinfecting

WARNINGS:

Never use flammable solutions to clean any part of the BiliSoft 2.0.

Do not use a phenolic compound based cleaner. Phenolic compounds can increase bilirubin levels in infants.

CAUTIONS:

Do not autoclave or gas sterilize the any part of the BiliSoft 2.0

DO NOT use any of the following cleaners. They will damage the device.

- Isopropyl Alcohol (in concentrations greater than 15%)
- Solvents (such as acetone)
- Wescodyne

Approved Cleaning Solutions

For continued long life of the Light Box or Light Pad, use only the following solutions and disinfectants.

Generic Formulation	Maximum concentration level
Hydrogen peroxide	6%
Sodium hypochlorite (bleach)	100 parts per million (ppm)
Cavicide®	100% spray (sprayed on cloth – not directly on equipment)

NOTE: Do not soak parts in cleaning solutions. Always wipe parts dry of all cleaning solutions.

NOTE: Any parts cleaned with iodophor solution will stain yellow.

Point of Use Cleaning

CAUTIONS:

The light pad connector requires special cleaning methods to avoid damage. See Cleaning the Light Pad Connector and Lens.

Never immerse the fiberoptic light pad, cable or connector in liquid.

Do not use iodine, strong acid, strong alkali, or bleach solutions to clean any part of the Light Pad, the Connector or lens, or the Connector Port (in the Light Box).

Strong cleaning solutions, alcohol, or ultraviolet light can cause premature breakdown of the Light Pad plastic coverings. Use only approved cleaning solutions. Do not leave the light pad in direct sunlight.

Iodine and other cleaning solutions that discolor the light pad will reduce the pad's light output.

While the BiliSoft 2.0 is in use, the pad, in particular, may be exposed to bodily fluids and matter. The cloth pad covers will help contain such materials, but if during the course of changing the pad cover it is noticed that these materials leeched onto the pad, the user should wipe the surface to remove the debris before applying a new cover.

The pad can be wiped down using a cloth moistened with the cleaning solutions listed above (except for bleach solution), or with a mild hand soap, or with a standard baby wipe. **Never submerge** any portion of the pad during the course of cleaning or rinsing.

If the recommended solutions are used, follow the manufacturer's instructions for rinsing and/or wiping dry the surface using a separate cloth if required. If a hand soap is used, rinse the surface by using a separate cloth/sponge moistened with clean, drinkable water.

Cleaning the Light Box between Patients

WARNING:

Make sure the light box power cord is disconnected from the power source before cleaning. Make sure the device is completely dry before using again.

WARNING SHOCK HAZARD:

Never immerse the Light Box or Light Pad in water or cleaning solutions. Liquids will short electronic circuitry, causing permanent damage or potential electric shock hazards.

CAUTION:

Use approved cleaning solution sparingly on a cloth when cleaning the exterior of the light box. Do not saturate the cloth - excessive solution may flow into the light box causing damage to internal components.

1. Unplug the power cord.
2. Do not use cleaners on the inside of the Light Pad Connector Port. To clean the Connector Port, refer to "Cleaning the Light Pad Connector, Fiberoptic Lens and Connector Port between Patients" section.
3. Thoroughly pre-clean heavily soiled areas using an approved cleaning solution applied to a clean cloth, or sponge, after wringing out the excess. Clean the outside of the light box with the moistened cloth or sponge until visible debris and blood are removed. **Do not spray** cleaner directly onto the unit. If necessary a soft bristle brush (e.g. a soft toothbrush) can be used to help remove stubborn materials. Finish the pre-cleaning by drying the parts with a clean, soft cloth to avoid scratches.
4. Once all visible contaminants and blood are removed from the device surfaces, apply one of the recommended cleaning solutions per the manufacturer's instructions to perform disinfection.
5. Always dry the parts with a clean, damp, soft cloth to avoid scratches.

Cleaning the Light Pad and Cable between Patients

CAUTIONS:

The light pad connector requires special cleaning methods to avoid damage. See Cleaning the Light Pad Connector, Fiberoptic Lens and Connector Port between Patients.

Never immerse the fiberoptic light pad, cable or connector in liquid.

Do not use iodine, strong acid, strong alkali, or bleach solutions to clean any part of the Light Pad, the Connector or lens, or the Connector Port (in the Light Box).

Strong cleaning solutions, alcohol, or ultraviolet light can cause premature breakdown of the Light Pad plastic coverings. Use only approved cleaning solutions. Do not leave the light pad in direct sunlight.

Iodine and other cleaning solutions that discolor the light pad will reduce the pad's light output.

Never use an abrasive cleaner on the light pad or the cable.

1. Thoroughly pre-clean heavily soiled areas using an approved cleaning solution (except for bleach solution), applied to a clean cloth, or sponge, after wringing out the excess. Clean the outside of the light pad and cable with the moistened cloth or sponge until visible debris and blood are removed. **Do not spray** cleaner directly onto the light pad and cable. If necessary a soft bristle brush (e.g. a soft toothbrush) can be used to help remove stubborn materials. Finish the pre-cleaning by drying the parts with a clean, soft cloth to avoid scratches.
2. Once all visible contaminants and blood are removed from the device surfaces, apply one of the recommended cleaning solutions per the manufacturer's instructions to perform disinfection.
3. Remove any cleaning residue with a clean, soft cloth soaked with clean water only.
4. Always dry the parts with a clean, soft cloth to avoid scratches.

Cleaning the Light Pad Connector, Fiberoptic Lens and Connector Port Between Patients

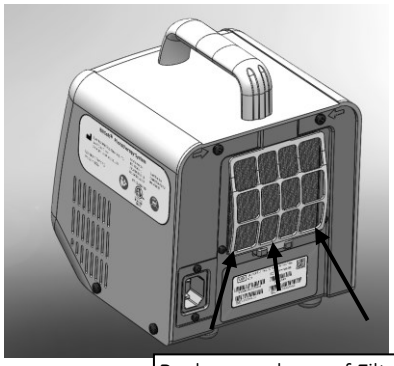
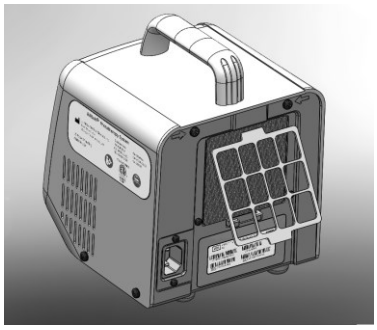
	**CAUTIONS:** Never immerse the Light Pad Connector in liquid.
	Do not use iodine, strong acid, strong alkali, or bleach solutions to clean any part of the Light Pad Connector, lens, or the Connector Port (in the Light Box).
	Iodine and other cleaning solutions that discolor the light pad will reduce the pad's light output.
	Never use an abrasive cleaner on the light pad connector, fiberoptic lens or the connector port.

1. Direct cleaning of the Fiberoptic Lens and the Connector Port should be kept to a minimum.

   IMPORTANT: Inside the connector port is a micro switch lever. Do not allow a cleaning cloth or sponge to catch the lever and damage the switch.
2. Clean the fiberoptic cable connector or the connector port using a mild detergent solution. Never use an abrasive cleaner. If disinfection is required, aqueous solutions, which are both hospital disinfectants and microbactericides, may be **used sparingly**, minimizing their exposure to the fiberoptic lens. Apply the cleaning solutions with a clean soft cloth. Do not saturate. Remove any cleaning residue from the fiberoptic lens or the connector port with a clean damp soft cloth soaked with clean, drinkable water only. **Do not spray cleaner directly on the fiberoptic cable connector**.
3. Always dry the parts with a clean, soft cloth to avoid scratches.

Air Filter Cleaning/Replacement

The air filter on the rear of the light box should be kept clean and free of lint to prevent overheating. The filter can be removed for cleaning without needing a tool.

Figure	Procedure
 Push up on base of Filter Plate until tab is exposed	1. Disconnect power to the unit. 2. To remove the Air Filter, flex the Filter Cover and remove the tabs from the lower and upper slots that secure the Filter Cover. 3. Clean by rinsing in water or replace if necessary. 4. Pat dry the filter.
	5. Once the filter is dry, place filter on back of unit and re-install Filter Plate 6. Insert tab in upper slot while flexing the plate and inserting the lower tab into the lower slot.

Factors that affect product life

Factor	Description
Thermal stress	Operating without the cooling fan running or operating with clogged filters will reduce LED life.
Light Pad folding or excessive bending	Do not fold or bend the light pad or the pad cable any tighter than 45 degrees.

Product storage

CAUTION:

Never store the lightbox on top of the light pad. The light box feet will discolor the pad.

Exposing the light pad's plastic cover ultraviolet light can cause premature breakdown of the plastic material. Do not leave the light pad in direct sunlight.

It is recommended to disconnect the Light Pad and hang straight, or lay flat during storage between uses.

The light box should be stored upright with the power cord provided.

Both the Light Box and the Light Pad should be protected from excessive dust and dirt.

Chapter 5

This chapter has been intentionally left blank

This page intentionally left blank.

Chapter 6
Optional Equipment and Replacement Parts

Optional Equipment & Replacement Parts	Stock Number
BiliSoft 2.0 Fiberoptic Pad, Small	2104629-001
BiliSoft 2.0 Fiberoptic Pad, Large	2104628-001
BiliSoft 2.0 Pad Cover, Disposable, Small (Box of 50)	2105418-001
BiliSoft 2.0 Pad Cover, Disposable, Small (Box of 20)	2105422-001
BiliSoft 2.0 Pad Cover, Disposable, Large (Box of 50)	2105419-001
BiliSoft 2.0 Pad Cover, Disposable, Large (Box of 20)	2105423-001
BiliSoft 2.0 Nest, Disposable, Small (Box of 15)	2105420-001
BiliSoft 2.0 Nest, Disposable, Large (Box of 15)	2105421-001
BiliSoft Carrying Case (non-operating)	M1110051
BiliSoft 2.0 Operation Manual	2105857-001
BiliSoft 2.0 Service and Maintenance Manual	2105858-001
Ohmeda Mobile Stand (mounting brackets must be ordered separately)	6700-0025-800
Giraffe Spot PT Lite Roll Stand (mounting brackets must be ordered separately)	6600-0894-216
Bracket, Ohmeda Mobile Stand, female (for mounting to the Ohmeda mobile stand - order male bracket separately)	6700-0014-800
Bracket, Dovetail Rail, female (for mounting to an Ohmeda dovetail rail or Giraffe Spot PT Lite roll stand – order male bracket separately)	6600-0031-900
BiliSoft Mounting Bracket, male (mounts the BiliSoft 2.0 to Ohmeda mobile stand, Giraffe Spot PT Lite roll stand, or Ohmeda dovetail rail – order the appropriate female bracket separately)	M1097110
Ohmeda Medical BiliBlanket Meter II	6600-0198-900

WARNINGS:

Do not use replacement parts other than those specified by the manufacturer. Substitute parts may affect the performance of the unit and could result in damage or unsafe operating conditions.

Use only the power cord provided with the BiliSoft 2.0.

This page intentionally left blank.

Chapter 7
Specifications

Note: All specifications are nominal and are subject to change without notice.

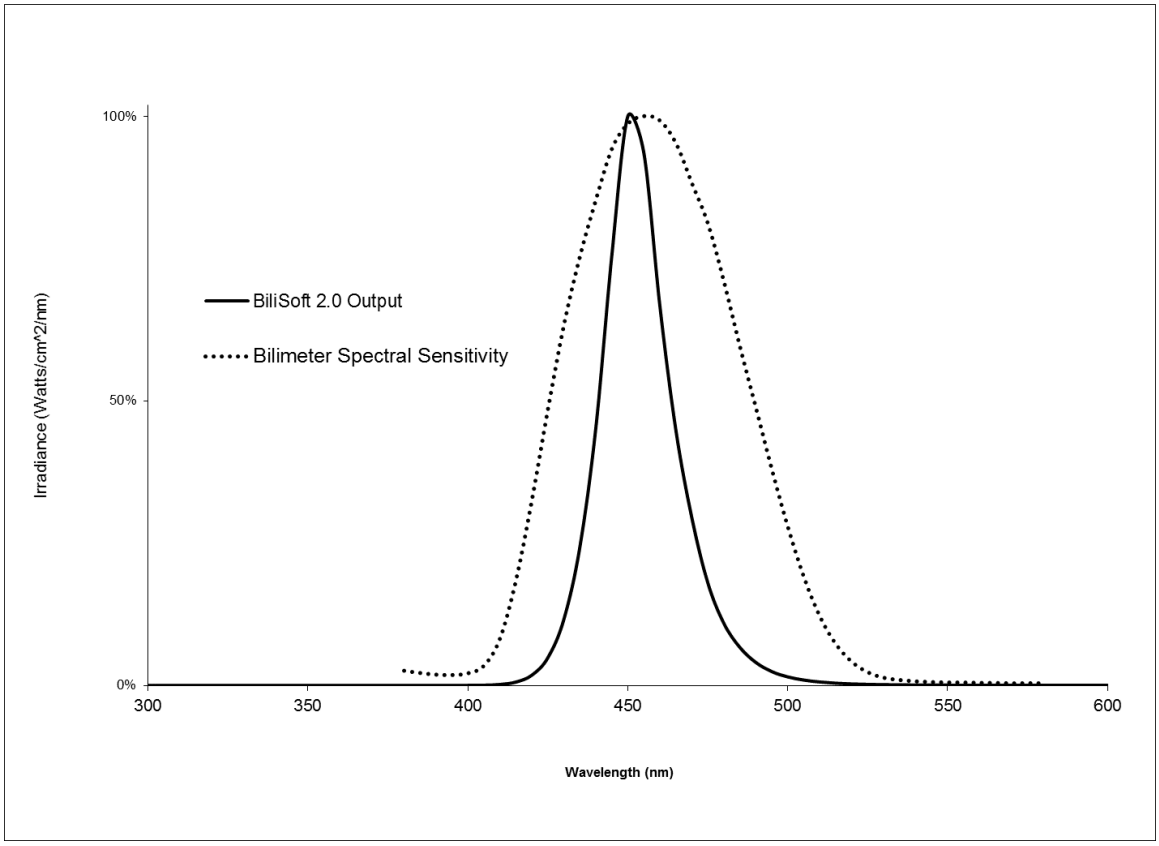
Electrical Specifications	
Device Insulation Class	Class II Double Insulated
Applied Parts (Light Pad)	Type BF
Input Voltage	100 – 240 V~, 50/60 Hz
Input Current	0.25A – 0.75A
Leakage Touch Current	≤ 100 µA in normal condition
	≤ 500 µA in single fault condition
Environmental Operating Conditions	
Temperature	+5°C to +35°C (41°F to 95°F).
Humidity	15% to 90% RH, non-condensing, but not requiring a water vapor partial pressure > 5 kPa
Atmospheric pressure	70 kPa to 106 kPa (10,000 ft. to -1,250 ft.)
Light Box	IP21
Light Pad	IPX4
Transportation Conditions & Storage Conditions (while sealed in shipping carton)	
Temperature	-25°C to +5°C (-13°F to 41°F) without humidity control.
Temperature	+5°C to +35°C (41°F to 95°F) up to 90% RH, non-condensing
Temperature	+35°C to +70°C (95°F to 158°F) at a water vapor pressure up to 5 kPa

Performance Specifications	
Spectral Irradiance when shipped (bare fiberoptic pad) Using an Ohmeda Medical BiliBlanket Meter II	Large Pad – 49 μW•cm^{-2}•nm^{-1} (+/- 25%) 9-point check Small Pad – 70 μW•cm^{-2}•nm^{-1} (+/- 25%) 6-point check Note: When the BiliSoft 2.0 fiberoptic light pad is inserted into a BiliSoft Pad Cover or BiliSoft Nest, the average spectral irradiance is 35 μW•cm^{-2}•nm^{-1} (large pad) and 50 μW•cm^{-2}•nm^{-1} (small pad)
Peak Wavelength	445-470 nm
LED module estimated life[1]	Under continuous use, at room temperature, a typical LED module will run over 50,000 hours before the light intensity drops 25% below minimum the rated output.
Sound level	< 44 dB(A) at 1 meter
X-ray	Light Pad is X-ray compatible
Physical Specifications	
Light box (W x H x L)	16.5 x 21 x 17.5 cm
Light box weight (excluding fiberoptic pad)	< 1.7 kg
Light Pad weight	< .5 kg (large or small)
Light Pad, size small	20 x 25 cm (light-emitting area)
Light pad, large	25 x 30 cm (light-emitting area)
Light Pad cable length	137 ± 5 cm
Product Life Span	
Service Life	The Light Box is designed to meet a life span of 7 years. The Light Pad is designed for a life of 3.5 years. However, with proper maintenance and repairs, the service life can be extended as longs as service parts are available.
Regulatory Standards	
IEC 60601-1; IEC 60601-1-11; IEC 60601-2-50; IEC 60601-1-2; IEC 60601-1-6 ISO 10993-5; ISO 10993-10; AAMI ES60601-1, CSA C22.2 No. 60601; 16CFR Part 1632.6 (for disposable pad covers)	

Note 1: The LED module life may vary when used in the actual clinical environment. Factors such as duty cycle and ambient temperature may impact the life of the LED module.

Chapter 8
Technical Reference

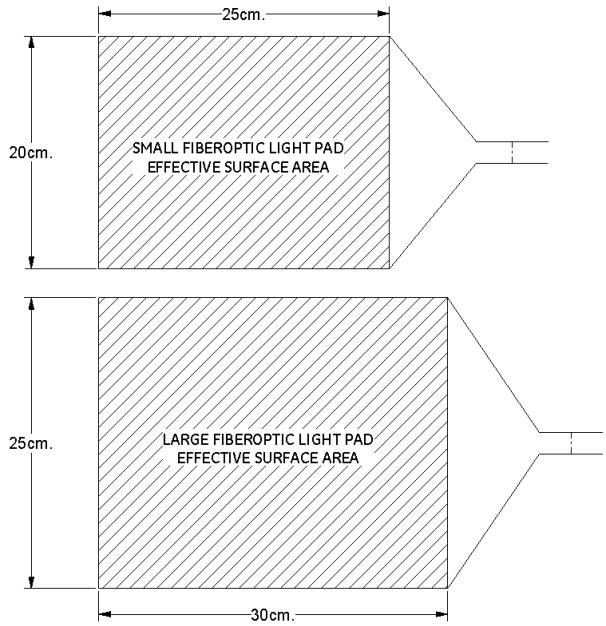
Spectral Irradiance Light Output



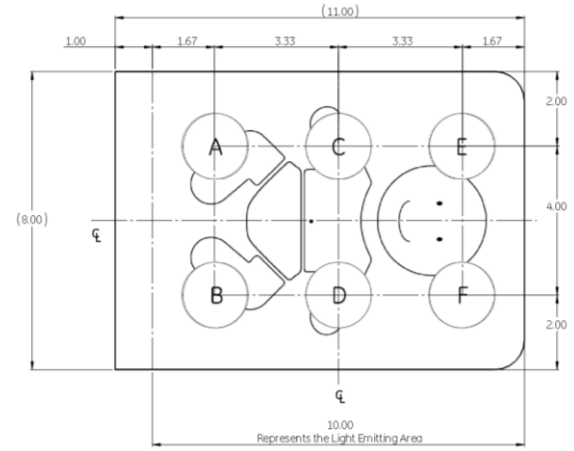
Average Total Irradiance for Bilirubin*	8.9 mW/cm^2 (bare fiberoptic pad, small)
	6.1 mW/cm^2 (bare fiberoptic pad, large)

Note: (measured with a spectroradiometer between 400-550 nm)

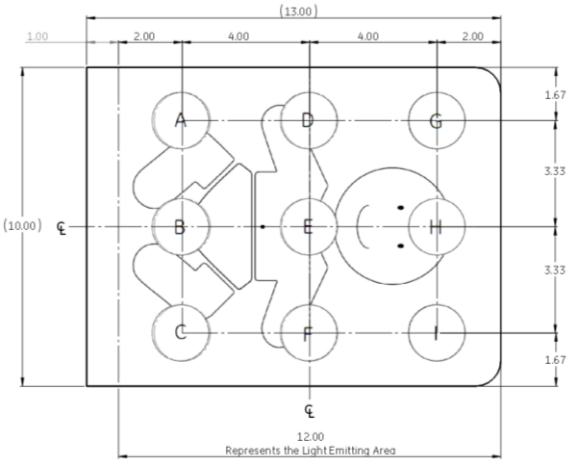
Effective Pad Area for Irradiance Output



Pad Output Measurement Points



Small Pad Measurement Grid



Large Pad Measurement Grid

Chapter 9
EMC Guidance

	**CAUTIONS:** Do not use the BiliSoft 2.0 near High Frequency Surgical or MRI equipment
	Cell phones, walkie-talkies and other portable radio devices can degrade the BiliSoft 2.0 performance. Do not use such devices within 30 cm (12 inches) of the BiliSoft 2.0 Light Box power cord.
	The BiliSoft 2.0 may disrupt other nearby equipment. Relocate or reorient the devices to stop the interference.
	Stacking the BiliSoft 2.0 with other equipment should be avoided. All equipment should be checked that it is operating properly if the equipment is stacked. Improper operation of the BiliSoft or the other devices can result.
	To keep disruption of equipment at a minimum, only use replacement parts or power cords provided by the manufacturer. Do not use extension cords.

The BiliSoft 2.0 is intended to be used in a hospital and home setting. Use of the BiliSoft 2.0 in other settings may result in disruption of nearby devices, or the BiliSoft 2.0 itself.

Hospital personnel or caregivers trained in the use of the BiliSoft 2.0 are the intended users.

Degraded Performance Characteristics

High levels of electromagnetic disturbance near the BiliSoft 2.0 can cause:

- Jumbled Hour Meter display.
- Blinking of the blue light output.
- Failure of the unit to emit blue light.

If any occur, relocated the unit, or the device causing the disturbance. Cycle power to the BiliSoft 2.0. The BiliSoft 2.0 should return to normal operation. Seek service assistance if the unit does not operate.

Note: This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-2014 4th edition. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation.

Manufacturer's Guidance and Declaration Regarding Electromagnetic Emissions

The BiliSoft 2.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the BiliSoft 2.0 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Class B	The BiliSoft 2.0 uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby equipment.
Harmonic emissions IEC 61000-3-2	Class A	The BiliSoft 2.0 is suitable for use in all hospitals and domestic residences directly connected to a public low voltage power utility.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Manufacturer's Guidance and Declaration Regarding Electromagnetic Immunity

The BiliSoft 2.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the BiliSoft 2.0 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8kV contact +/- 15kV air	+/- 8kV contact +/- 15kV air	Floors should be wood, concrete or tile. If floors are carpeted, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2kV for power supply line. 100 kHz Repetition Rate	+/- 2kV for power supply line. 100 kHz Repetition Rate	Electric power supplied should be that of a typical public low voltage power utility.
Surge IEC 61000-4-5	+/- 1kV line to line	+/- 1kV line to line	Electric power supplied should be that of a typical public low voltage power utility.
Voltage dips, shorts interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle At phase angles of :	<5 % Ut (>95 % dip in Ut) for 0.5 cycle At phase angles of :	Electric power supplied should be that of a typical public low voltage power utility[1].

	0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % Ut (>95 % dip in Ut) for 1.0 cycle AND 70% Ut (30% dip in Ut) for 0.5 sec At a phase angle of 0° <5% Ut (>95% dip in Ut) for 5 sec.	0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % Ut (>95 % dip in Ut) for 1.0 cycle AND 70% Ut (30% dip in Ut) for 0.5 sec At a phase angle of 0° <5% Ut (>95% dip in Ut) for 5 sec.	If the BiliSoft 2.0 requires continued operation during a power outage, it is recommended to use an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field environment IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields should be at levels common to a hospital or home setting.
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m over 80 MHz – 2.7 GHz Modulation: 80% AM at 1 kHz	10 V/m over 80 MHz – 2.7 GHz Modulation: 80% AM at 1 kHz	Radio devices such as cell phones and walkie-talkies should not be used within 30 cm (12 inches) of the BiliSoft 2.0 Light Box or power cord[2].
Conducted disturbances induced by RF electromagnetic fields IEC 61000-4-6	3 V rms over 150 kHz – 80 GHz 6 V rms in ISM and amateur radio bands between 150 kHz – 80 GHz Modulation: 80% AM at 1 kHz	3 V rms over 150 kHz – 80 GHz 6 V rms in ISM and amateur radio bands between 150 kHz – 80 GHz Modulation: 80% AM at 1 kHz	

NOTE 1: Ut stands for the AC main voltage prior to application of the test level.

NOTE 2: The BiliSoft 2.0 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BiliSoft 2.0.

Manufacturer's Guidance and Declaration Regarding Electromagnetic Immunity to RF Wireless Communication Devices

The BiliSoft 2.0 is intended for use in the RF Wireless environment specified below. The customer or the user of the BiliSoft 2.0 should assure that it is used in such an environment.

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13,17	Pulse Modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse Modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9
5500						
5785						

EMC Service Life

The EMC Service Life will match the Expected Service Life of the product defined in Chapter 7 by:

- Following the recommended service and maintenance schedule found in the Service and Maintenance manual.
- Using only recommended service parts as found in Chapter 8 or within the Service manual.

This page intentionally left blank.

Appendix A1 - Additional Safety Information

Statements

WARNING:

Properly dispose all the waste as required by federal, state, and local waste regulations. Improper disposal could result in personal injury or harm the environment.

- This device is only to be used by those trained in the use of the BiliSoft 2.0.
- The BiliSoft 2.0 should be used by direction of qualified medical personnel. Medical personnel should be familiar with currently known risks and benefits of infant phototherapy.
- No additional tasks are required to turn off the unit after completing the therapy session. Clean the unit in preparation for storage or the next patient.
- Isolation of the unit from the supply mains can be achieved by unplugging the device.

This page intentionally left blank.

Appendix A2 - Home Use

Homecare Providers

When delivering the BiliSoft 2.0 System for use in the home, make sure to provide adequate training for the caregivers. Make sure to thoroughly explain this manual. Leave this manual with the caregivers. Provide eye covers.

Parents or Guardians

	**WARNING:** If you have questions or concerns contact your healthcare provider immediately.
	**Caregiver Side Effects:** Caregivers looking at the blue light for a long time may experience headache, nausea, or mild vertigo.

	The eyes of babies can be damaged from direct exposure to any phototherapy light. Always protect the baby's eyes with eye patches or equivalent eye protection products. Periodically confirm that the baby's eyes are protected. Perform this check more frequently if required by healthcare provider's instructions. Care should be taken to protect the eyes of other infants nearby.

Before You Begin Treatment

Ask your healthcare provider for information on how to care for your baby during the treatment. Follow your doctor's recommendation for the treatment duration.

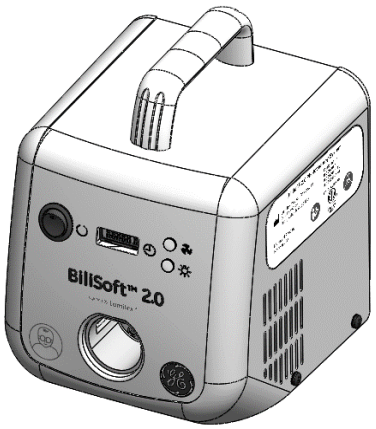
Before you begin treatment, have the following items close to the treatment area:

- Phone numbers for doctor, hospital and homecare provider
- An infant thermometer
- Extra BiliSoft Covers or Nests

Quick Reference Guide

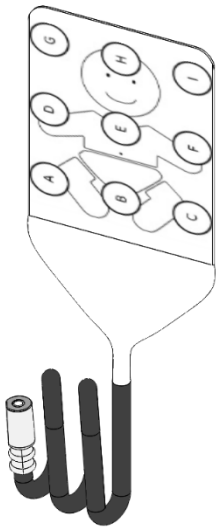
A quick reference guide, based on the instructions found in this appendix, is found inside the back cover.

The BiliSoft 2.0 Phototherapy System Components

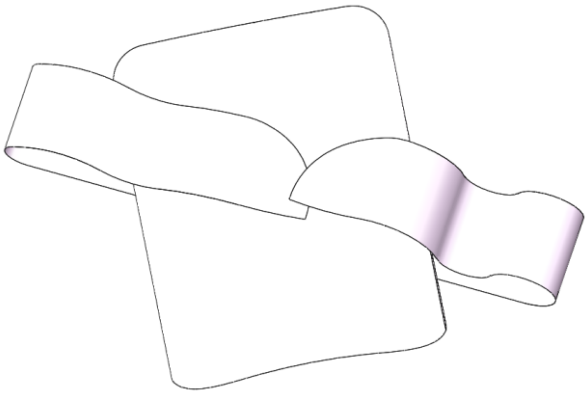


LIGHT BOX

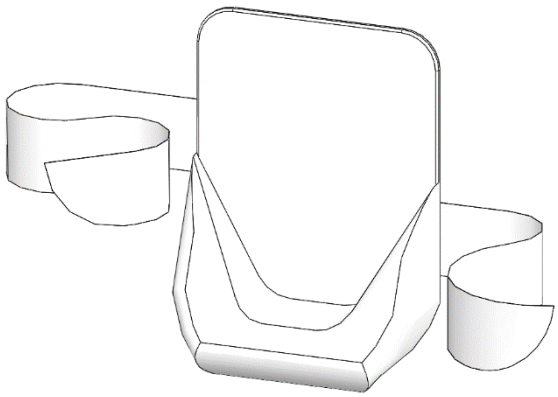
POWER CORD



FIBEROPTIC PAD
(large pad shown)



FLAT PAD COVER



PAD COVER NEST

This Product must be periodically checked. A defective Product should not be used. Broken, missing, plainly worn, distorted or contaminated parts should be replaced immediately. No modification or alteration of this device is allowed.

How it works

Many newborn infants are born with jaundice. Jaundice occurs because your baby's liver has not fully developed and the body has more bilirubin than it can get rid of. Bilirubin is a yellow substance that's made when the body breaks down old red blood cells. It leaves the body through urine and stool.

The blue light provided by the device passes through your baby's skin and breaks down the Bilirubin into compounds that your baby can more easily process into waste. Therefore it is important to expose your baby's skin to as much of the blue light as possible.

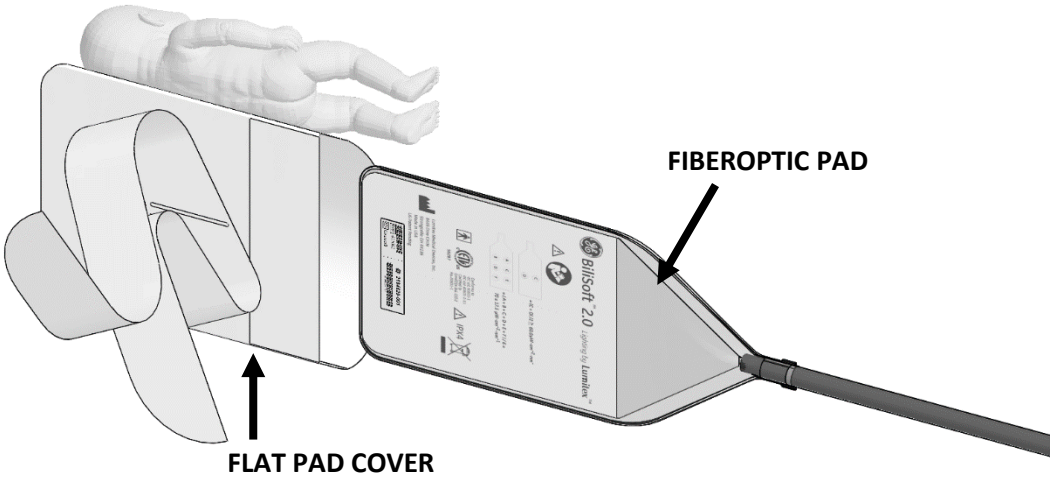
Installing Pad Covers

IMPORTANT: All BiliSoft pads have one side that emits blue light, this side is identified with a graphical symbol of a baby. The other side of the pad contains printed instructions, and does not emit blue light. It is important to have the blue light side with baby symbol directed toward the baby.

Installing Flat Pad Covers Onto Pad

1. Gently insert the BiliSoft 2.0 fiberoptic pad into a BiliSoft flat pad cover (shown below). The back of pad should face the strap side of the cover as shown.

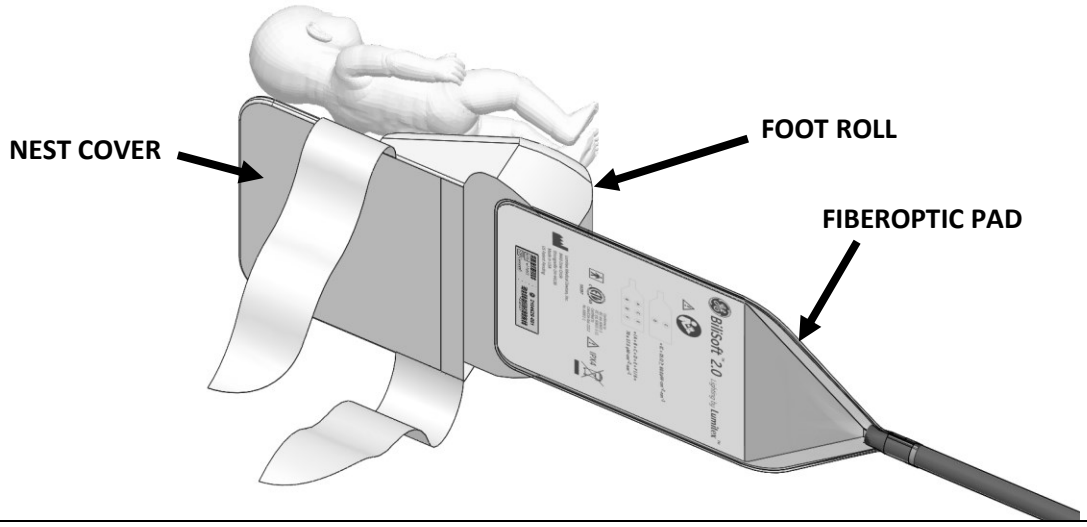
   For baby's comfort and hygiene, never place a baby directly on the bare fiberoptic light pad. The light pad should be covered with the BiliSoft Flat Pad Cover or Nest.

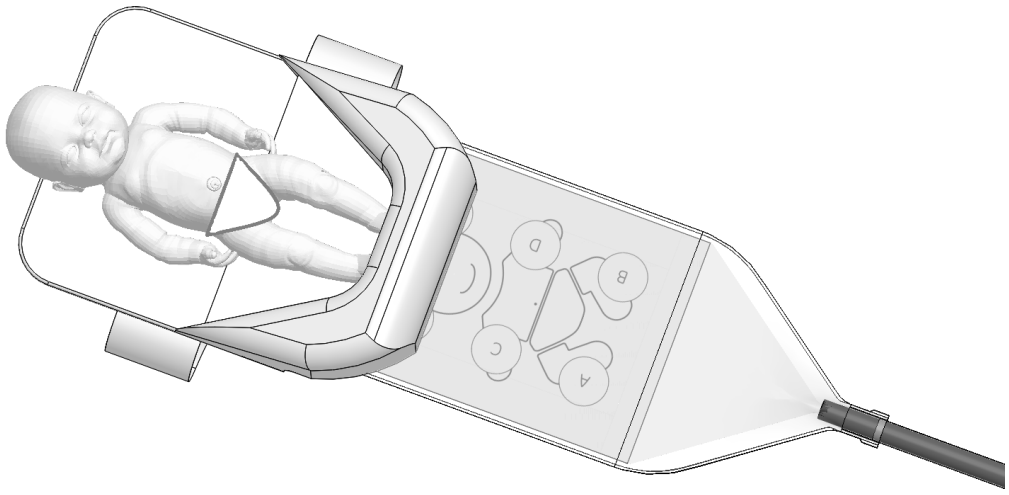


Installing Pad Nest Covers Onto Pad

1. Gently insert the BiliSoft 2.0 fiberoptic pad into a BiliSoft 2.0 Nest cover (shown below). The back of pad should face away from the foot roll as shown.

   For baby's comfort and hygiene, never place a baby directly on the bare fiberoptic light pad. The light pad should be covered with the BiliSoft Flat Pad Cover or Nest.



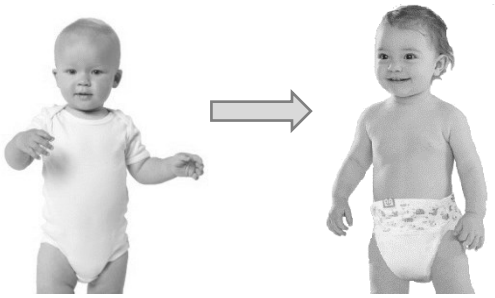


Soiled Pad Covers

Remove soiled disposable cover, replace with a fresh disposable cover. Wipe clean the fiberoptic pad with baby wipes.

Prepare the Baby – Remove Clothing

Prior to positioning the baby on the pad it is important to remove all clothing but your baby's diaper. The therapy is only effective if the baby's skin is exposed to the blue light. Clothing such as sleepers will prevent the light from reaching the baby skin



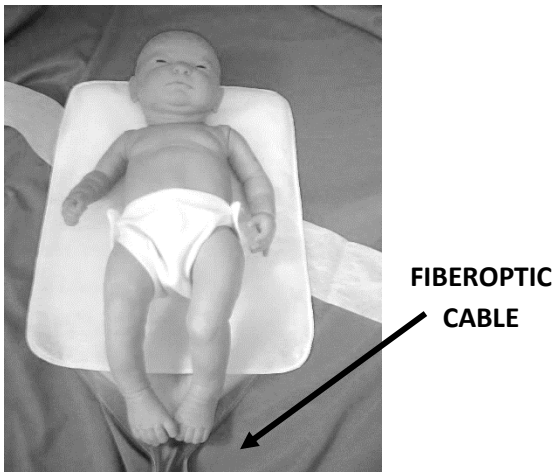
Positioning the Baby

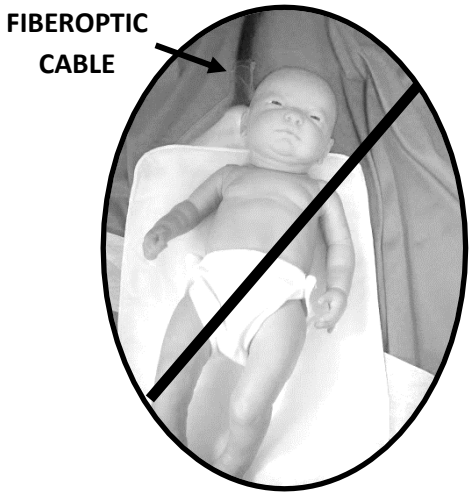
Regularly check that the patient is in the treatment area of the device.

PLACING BABY ON FLAT PAD COVER

1. Place the baby on the <u>padded side</u> of the **flat cover**. (**The straps are on the bottom**.) Fiberoptic cable is at the baby's feet.

   IMPORTANT: Be sure to position the baby to expose the most amount of their skin to the pad light. Baby should wear diaper only.



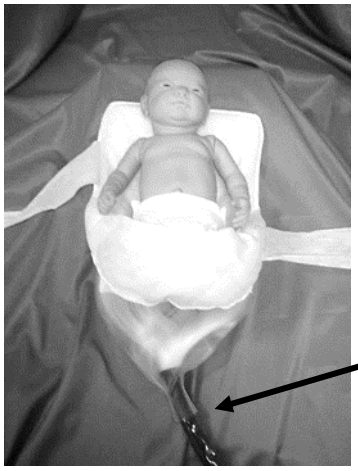


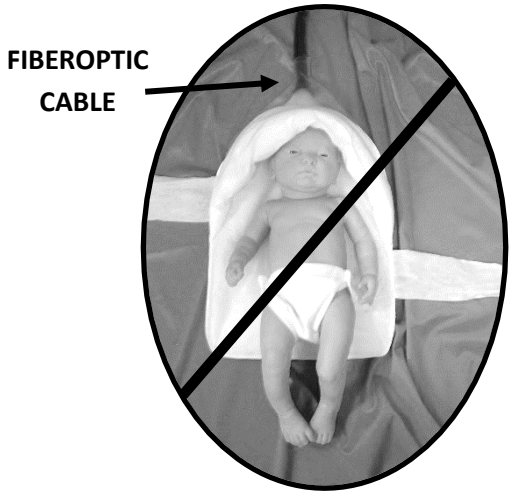
PLACING BABY ON NEST

1. Place the baby on the <u>padded side</u> of the **Nest**. (The straps are on the sides.) Fiberoptic cable is at the baby's feet.

   The foot roll is for the baby's feet, not the head.

   IMPORTANT: Be sure to position the baby to expose the most amount of their skin to the pad light. Baby should wear diaper only.

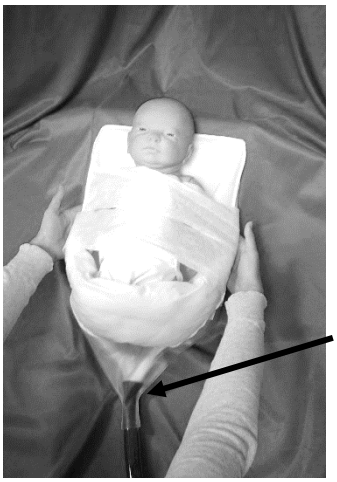


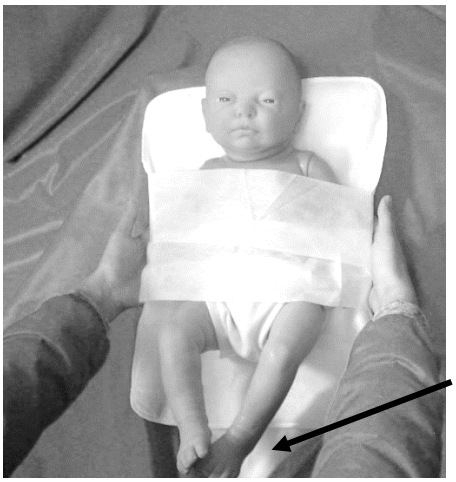


Using the Pad Straps to Swaddle the Baby

SWADDLE BABY WITH STRAPS

NEST **FLAT COVER**

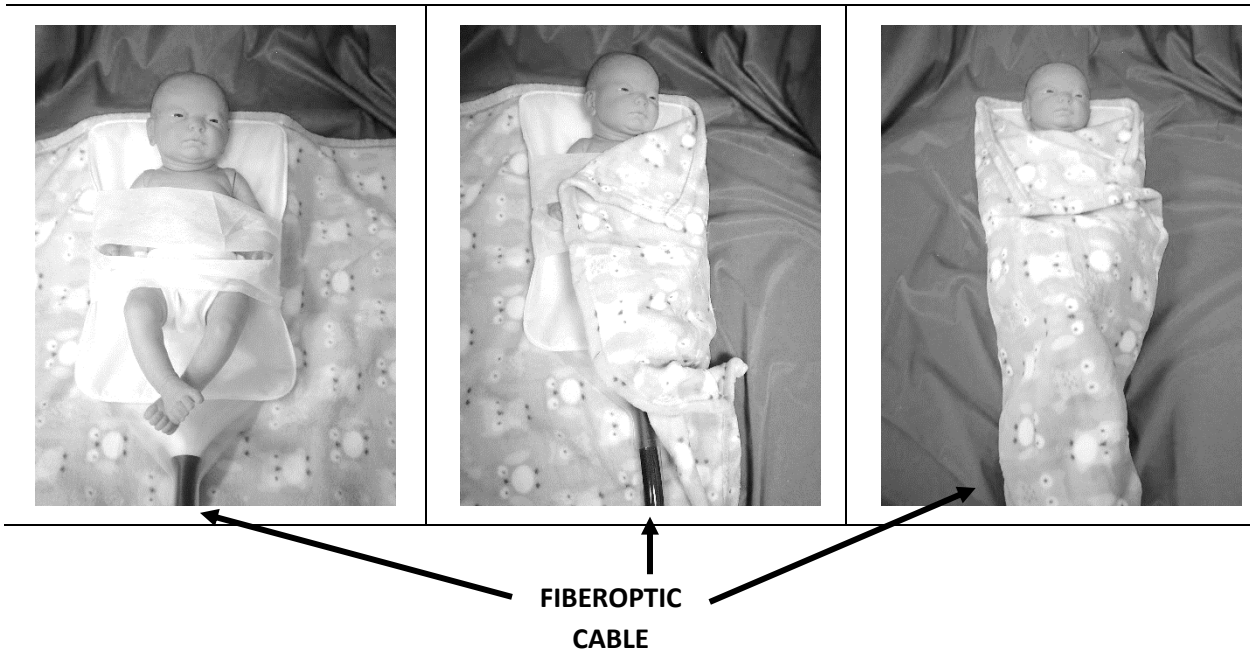




<u>When not in use</u>, tie cloth straps together and place under the pad. Loose straps can cause strangulation or a choking hazard.

Use of Additional Blankets

USE of ADDITIONAL BLANKET
1. The baby on the light pad may be covered or wrapped in an additional thin blanket to help swaddle. The baby can be held and fed during the treatment. The baby will continue to receive effective treatment as long as their skin remains exposed the pad light.



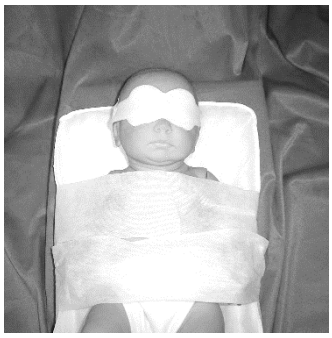
Eye Protection for the Baby

PROTECT and COVER BABY'S EYES	
	The eyes of babies can be damaged from direct exposure to any phototherapy light. Always protect the baby's eyes with eye patches or equivalent eye protection products. Periodically confirm that the baby's eyes are protected. Perform this check more frequently if required by healthcare provider's instructions. Care should be taken to protect the eyes of other infants nearby. Children and adult caregivers do not need to use eye protection.

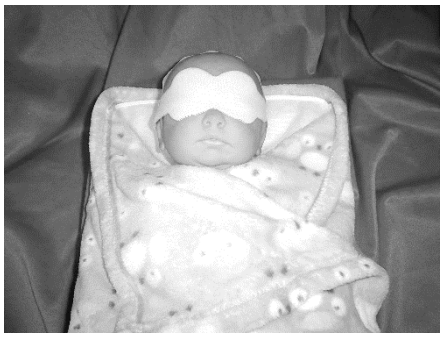
=

Protect the baby's eyes with eye patches or an equivalent appropriate eye protection product.

Without Blanket



With Blanket



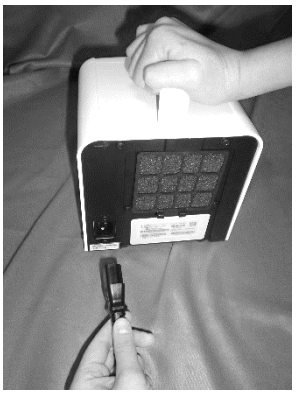
Ready the Unit for Operation

Placement of Light Box

Place the light box on a smooth flat surface such as a table top so that it is out of the reach of other children or pets. Position the power cord and pad so that you do not trip over them.

⚠	Never place the light box inside of an incubator, warmer or bassinet with the patient. This could cause possible injury to the patient.
⚠	Never position the unit in the path of, or next to, sources of heat. For example, near a fireplace or in the path of radiant heaters.
⚠	To avoid damage to the equipment or injury to users and patients, keep the Light Box and the Light Pad out of the reach of children and pets.

Ready the Unit and Begin Treatment



1. Attach power cord by firmly inserting connector into Light Box receptacle.
2. Plug power cord into wall socket.
3. Route power cord to prevent tripping over it.

4. Insert the fiberoptic cable connector in the box.
5. Ensure that the air vents on the sides and the back of the unit are not obstructed or covered.

6. Turn the Light Box on.
7. Confirm that the fan is operating by placing your hand close to the exhaust vent when the device is operating to feel for air flow coming out of the device
8. During treatment:
   a. Periodically monitor the baby for its position on the light pad.
   b. Monitor the baby for items found in the Important Safety Instructions as instructed by health care professionals.

Frequently Asked Questions

Feeding Time

You can feed your baby while continuing to provide treatment. Follow your baby's regular feeding schedule. Your healthcare provider can help you determine the proper schedule. Note the feeding times and amount of breast milk or formula taken, or length of time fed, on the record form.

Make sure to give your baby plenty of fluids during treatment periods. Phototherapy can increase your baby's water loss through the skin.

Bathing

You may continue your baby's normal bathing routine ***after first discontinuing treatment.***

Turn off the unit and remove the baby from the pad. Proceed to bath the baby as normal. Baby can be returned to the pad for further treatment after being dried.

WARNING SHOCK HAZARD:
Never use the unit while bathing the baby. Keep the unit away from bath basins and tubs. Keep all parts of the unit away from water.

Taking Temperatures

It is important to track your baby's temperature during phototherapy sessions. Your doctor will tell you the range of acceptable temperatures for your baby. The doctor may also suggest a method for taking temperatures. It is important to use the same method each time you take your baby's temperature.

Urine/Stools

It is essential that you count and record the number of stools and wet diapers made by the baby. You will also be asked to describe stools. Loose stools, black or dark green sticky stools are common during phototherapy. These observations will help your doctor determine if your baby is getting enough fluids. These items can also indicate any significant changes in their condition. Note occurrences under the appropriate column and describe the stools on the record form.

Treatment Time

Your doctor will tell you how long your baby needs to undergo treatment. Record the actual start and stop times of each treatment session during each 24-hour period. Apply phototherapy for as long as possible during each 24-hour period.

Recording Daily Treatment

Keep a daily record of your baby's activities and condition. Use the example template of a simple record form shown here. This will provide your doctor with an accurate account of your baby's activities, and allow them to better assess the progress being made.

Daily Record Sheet

Name:_____	Date:_____
Birth Date:_____	Bilirubin Level:_____
Method of Temperature Taking:_____	

Time	Temperature	Number of Diapers (indicate wet and/or stool with description)	Amount Fed

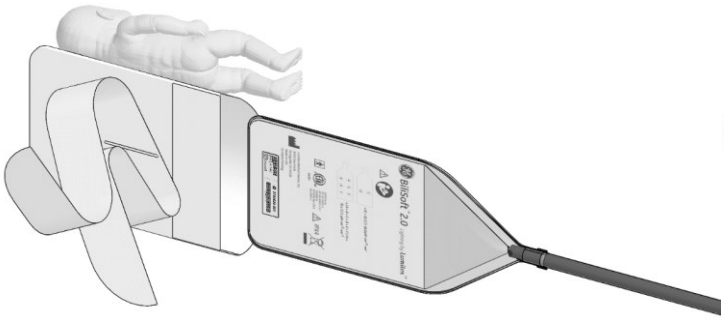
Times when baby is put on and taken off phototherapy treatment:

On	_____	Off	_____	On	_____	Off	_____	On	_____	Off	_____

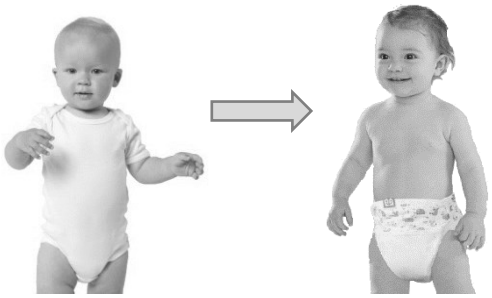
Comments: _____

Homecare Use - Quick Reference

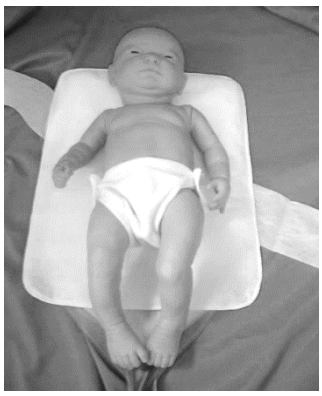
1: Cover Pad



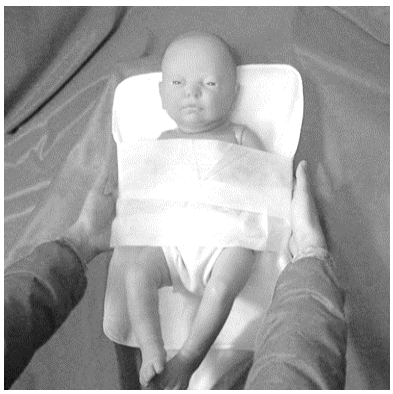
2: Undress Baby



3: Position Baby



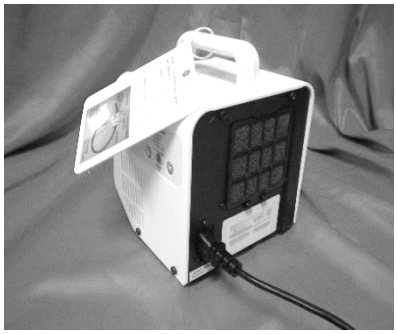
4: Swaddle With Straps



5: (Optional Blanket)

6: Cover Baby's Eyes

7: Plug in Cord



8: Plug in Pad

9: Turn on Unit

This page intentionally left blank.

Authorized Lumitex service is provided by GE Healthcare. See list of service centers below.

World Headquarters

GE Healthcare
9900 West Innovation Drive
Wauwatosa, WI 53226-4856
USA
Tel 1 800 345 2700

Europe, Middle East, Africa

GE Healthcare
P.O. Box 900
FIN-00031 GE
Finland
Tel +358 10 39411
Fax +358 9 146 3310

Latin America Representatives

GE Healthcare
3350 SW 148 Avenue
Suite 301
Miramar, Florida, 33027
USA
Tel + 1 954 744 5600

Brazil Only

GE Healthcare Clinical Systems
Equipamentos Médicos Ltda
Av. Paulista, 37 - 13º andar
CEP: 01311-902 - Cerqueira César
São Paulo, SP - Brasil
Tel +55 11 3053 2500
Fax +55 11 3053 2573

Russia Only

ООО GE Healthcare
123112, Russia, Moscow, Presnenskaya naberezhnaya, 10
Tel (Service) 8 800 333 6967
Tel (Office) +7 495 739 6931
Fax +7 495 739 6932

Russia Only

ООО "ДжиИ Хэлскеа"
123112, Российская Федерация, Москва, Пресненская набережная, д. 10
Тел. сервисной службы: 8 800 333 6967
Тел. офиса: +7 495 739 6931
Факс: +7 495 739 6932

Lumitex Medical Devices, Inc.
8443 Dow Circle
Strongsville, Oh 44136
USA

BiliSoft™ 2.0 Phototherapy System
Operation Manual
Printed in USA

Lumitex 009811 Revision G

GE 2105857-001 Revision A

Language: English