

GE Healthcare

BiliSoft™ LED Phototherapy System

Operation and Maintenance Manual



BiliSoft™ LED Phototherapy System
Operation and Maintenance Manual - English
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User Responsibility

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, GE Healthcare recommends that a telephone or written request for service advice be made to the nearest GE Healthcare Regional Service Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by GE Healthcare and by GE Healthcare trained personnel. The Product must not be altered without GE Healthcare's prior written approval. The user of this Product shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than GE Healthcare.

**CAUTION:**

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



GE Healthcare has declared that this product conforms with the European Council Directive 93/42/EEC Medical Device Directive when it is used in accordance with the instructions provided in the Operation and Maintenance Manual.



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 decommissioning of your equipment.

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Care of the Skin

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

The skin serves as a protective barrier against chemical, mechanical, and biological insults. The skin is also important in the regulation of body temperature and serves as a route of water excretion, especially in premature infants. The introduction of new intensive-care techniques has been associated with the increased survival of very small, premature infants. The immaturity of the skin of the very low weight infants, coupled with excessive instrumentation and handling, 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 literature² when utilizing this device with all infants. 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 for prophylactic treatment, particularly of premature infants, is not recommended. These infants have extremely fragile skin³ and various clinical studies have produced inconsistent conclusions concerning the effectiveness of prophylactic phototherapy 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 Hyberbilirubinemia, **Pediatrics**, February , 1988

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Chapter 1

Product Description

Intended Use

The BiliSoft LED Phototherapy System provides light therapy for the treatment of indirect hyperbilirubinemia, commonly known as neonatal jaundice, in a hospital or home setting.

Description

The BiliSoft LED 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 440-460 nanometer).







Units are available with two fiberoptic pad sizes: large (25cm x 30cm) and small (15cm x 30cm). The large pad's nominal spectral irradiance is $35 \mu\text{W} \cdot \text{cm}^{-2} \cdot \text{nm}^{-1}$ through a typical BiliSoft Pad Cover or BiliSoft Nest. The small pad's nominal spectral irradiance is $50 \mu\text{W} \cdot \text{cm}^{-2} \cdot \text{nm}^{-1}$ through a typical BiliSoft Pad Cover or BiliSoft Nest.






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Chapter 2

Safety Information

Symbol Definitions

Symbol	Description
	Next to each WARNING or CAUTION , we have placed an “attention, read accompanying documents” symbol to alert you to the presence of these important statements. When the attention symbol appears in front of text that is printed on the system itself, it means that the text is elaborated upon in the operation manual.
WARNING:	A WARNING statement is used when the possibility of injury exists.
CAUTION:	A CAUTION statement is used when the possibility of damage to the equipment exists.
NOTE:	A NOTE provides additional information to clarify a point in the text.
	Indicates alternating current.
	Indicates IEC Type B equipment.
T	This letter appearing before a fuselink value indicates a time delay fuselink.
	Cover patient's eyes during phototherapy.
	On/Off Standby Switch
	Unit overheated indicator

	Hour meter
	LED failure indicator
	Do not spray cleaner directly onto the fiberoptic lenses. The fiberoptic lenses require special cleaning methods. See cleaning section of this manual for complete details.
	See the Operation Manual for more information.
	European Union Representative
	Manufacturer
	ETL symbol
	CE mark
	WEEE symbol
	Ground/Earthing

General Safety Information



WARNING:

Eye Protection: Direct exposure of the eyes to any phototherapy light may cause eye damage. Always protect the baby's eyes with eye patches or an equivalent appropriate eye protection product. Periodically and/or per your hospital protocol or healthcare provider's instructions, verify that the patient's eyes are protected and free of infection. Care should also be taken to protect the eyes of patients adjacent to the treatment area, when necessary.



WARNING:

Home Users: During phototherapy treatment always follow your healthcare professional's care instructions.



WARNING:

Caregiver Side Effects: Looking at light emitted by any phototherapy device for prolonged periods may cause side effects, such as headache, nausea, or mild vertigo, in some caregivers or visitors.



WARNING:

Bilirubin Levels: The bilirubin levels of patients receiving phototherapy should be regularly measured.



WARNING:

Possible Risks: All phototherapy methods have 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. Monitor the patient closely for signs of these conditions during phototherapy.



WARNING:

Porphyrins/Photoisomers: Bilirubin photoisomers may cause toxic effects. Porphyrins are the by-products of the photochemical break down of the bilirubin molecule. In some cases, exposure of porphyrins to phototherapy may result in a localized reddening of the patient's skin. Therefore, skin assessment is recommended with all types of phototherapy.



WARNING:

Photosensitive Drugs: The light generated by phototherapy devices can degrade photosensitive medications. Do not place or store any drugs near or in the illuminated area.



WARNING:

Water Loss: The radiant energy from phototherapy lights can increase a patient's insensible water loss. Take appropriate measures to maintain the patient's fluid balance while administering phototherapy.



WARNING:

Skin Temperature: Phototherapy light can affect the temperature in thermoregulation devices (incubator, radiant warmers or heated mattresses) and may raise the patient's body temperature. It is recommended to use the incubator or warmer in skin controlled (servo) mode. Always monitor the patient's temperature to avoid temperature fluctuations during phototherapy.



WARNING:

Reflective Foils: Using reflective foils to increase the efficacy of phototherapy may cause hazardous patient body temperatures.



WARNING:

Combustible Gases: Do not use the BiliSoft LED Phototherapy System in the presence of gases that support combustion like oxygen, nitrous oxide or other flammable or combustible anesthetics.



WARNING:

Flammable Solutions: Never use flammable solutions to clean the BiliSoft LED Phototherapy System or any of its parts.



CAUTION:

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the service manual.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

The BiliSoft LED Phototherapy System should not be used adjacent to or be stacked on other equipment. If adjacent or stacked use is necessary, the BiliSoft LED Phototherapy System should be observed to verify normal operation in the configuration in which it will be used.

Chapter 3

Home Use

Homecare provider

Ensure when you deliver BiliSoft LED Phototherapy System for use in the home that you provide adequate in-service training for parents or guardians. Be sure to provide this Operation Manual and eye covers.

Parents or Guardians

Ask your healthcare provider for information about monitoring your baby during the phototherapy treatment. Follow your doctor's recommendation for treatment duration.

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

- Phone numbers of doctor, hospital and home healthcare provider
- Thermometer
- Extra BiliSoft Covers or BiliSoft Nests

To properly operate the unit, follow the steps described in "Using the Unit" in Chapter 5 of this manual.

Position your baby according to your doctor's recommendations.

Ensure that as much of the baby's skin as possible is in direct contact with the illuminated section of the covered light pad. The baby, along with the light pad, may be covered or wrapped in a thin blanket. It is possible to hold and feed the baby while continuing treatment. The baby will continue to receive effective phototherapy treatment as long as the covered, light emitting section of the pad remains in direct contact with the skin. You may swaddle the baby.

Cover the baby's eyes when using the BiliSoft LED Phototherapy System to shield them from light emitted by the BiliSoft fiberoptic light pad.



WARNING:

Direct exposure of the eyes to any phototherapy light may cause eye damage. Always protect the baby's eyes with eye patches or an equivalent appropriate eye protection product. Periodically and/or per your hospital protocol or healthcare provider's instructions, verify that the patient's eyes are protected and free of infection. Care should also be taken to protect the eyes of patients adjacent to the treatment area, when necessary.

Recording Daily Activities

You should keep a daily record of your baby's activities and condition. A sample of an easy-to-use chart is provided on the following page. These records will provide your healthcare provider or physician with an accurate account of your baby's activities, enabling them to better assess the progress being made.

Taking Temperatures

It is important to monitor your baby's temperature during phototherapy sessions. Your doctor will tell you the range of acceptable temperatures for your infant and may suggest a method for taking temperatures. For charting purposes, it is important that you 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. 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 healthcare provider determine if your baby is getting enough fluids and will signify any significant changes in their condition. On your record sheet, note occurrences under the appropriate column and describe the stools.

Feeding

Follow your baby's regular feeding schedule. Your healthcare provider can help you determine this. Note feeding times and amount of formula taken, or length of time fed, on the record sheet.

Treatment Time

Your healthcare provider or physician will tell you how long your baby needs to undergo treatment. Record the actual times at which your baby is put on and taken off the BiliSoft LED Phototherapy System during each 24-hour period. Apply phototherapy for as long as possible during each 24-hour period.

Bathing

You may continue your baby's normal bathing routine. Discontinue phototherapy during bathing.



WARNING:

If you have questions or concerns contact your healthcare provider immediately.

Note:

This form is provided as a reference only. To preserve the integrity of this manual, please do not write directly on this page or remove this page from the manual. Reproduce this form, if desired.

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: _____


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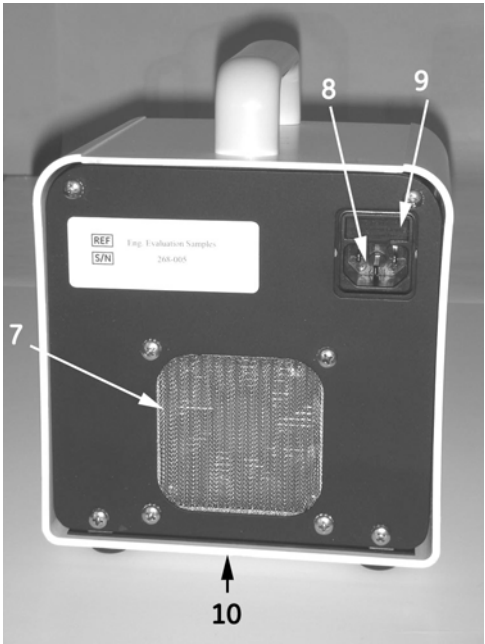
Chapter 4

Components and User Controls

BiliSoft Light Box

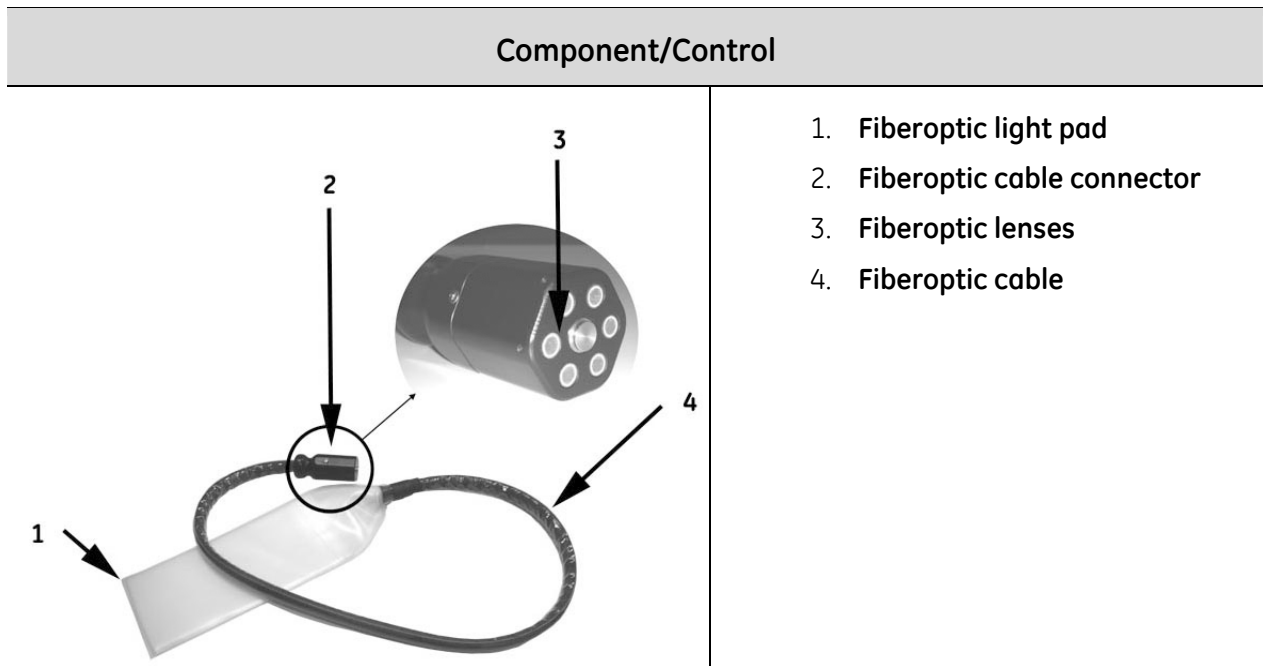
The light box contains the LED module, a power supply, a cooling system, and an overheating protection. The universal power supply allows the unit to be supplied via any standard AC main power source at either 50 or 60 Hertz that has voltages in the range of 90 to 264 V~. The LED module produces a very narrow bandwidth of light with no appreciable amount of ultraviolet or infrared light. The light box is cooled by a fan, and a thermal cutout switch located on the LED module protects the light box from overheating. The LED module in the light box is activated only when the fiber optic cable is plugged into the system.

Component/Control	Function
	<ol style="list-style-type: none">1. Standby Switch – Turns the unit on/off. The green light on the switch indicates that the standby switch is turned on and the unit is powered.2. Hour Meter – The non-resettable hour meter runs whenever the fiberoptic light pad is illuminated. If the fiberoptic cable is not fully inserted into the light box, the LEDs are 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 the 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, at least one of the three LED pairs has failed. See the Troubleshooting Guide for more details.

Component/Control	Function
	<p>5. Fiberoptic Light Pad Assembly Port - Where the fiberoptic light pad assembly connects to the main unit. An LED shutoff switch inside the port automatically shuts off the LED module whenever the fiberoptic light pad assembly is disconnected.</p> <p>6. Air Vents - For proper cooling it is important to keep the air vents clear of obstruction.</p>
	<p>7. Air Filter - For proper cooling it is important to keep the air filter clear of obstruction. See the maintenance section of this manual for more details.</p> <p>8. Power Cord Receptacle</p> <p>9. Fuse Cover - Houses two power inlet fuses</p> <p>10. Mounting Bracket Holes - Four 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.</p>

BiliSoft Fiberoptic Light Pad Assembly

The fiberoptic light pad comes in two sizes – large and small. The LED light source in the BiliSoft light box is focused on the fiberoptic lenses at the end of the fiberoptic cable 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. Average light intensity depends on the size of the light pad. See Chapter 9 for detailed specifications.





Warning:

Never place a baby directly on the bare fiberoptic light pad. The fiberoptic light pad should always be covered with a BiliSoft Pad Cover or BiliSoft Nest when used with the patient.

Soft Cover Options (Disposables)

The BiliSoft Pad Cover and BiliSoft Nest are designed for use with both premature and full-term infants. The BiliSoft Pad Cover and BiliSoft Nest are available in small and large sizes to accommodate whichever fiberoptic light pad is used.

BiliSoft Pad Cover	BiliSoft Nest
 <p>A flat cushioned cover with straps.</p>	 <p>A cushioned cover with developmental positioning foot roll and straps.</p>

Chapter 5

Operating Instructions

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

- Read this manual.
- Pay special attention to the **WARNINGS** and **CAUTIONS** that appear in this manual.
- Read the User Responsibility statement located on the inside front cover of this manual; it describes what is expected of the user to maintain a safe and accurate product.
- Use according to your healthcare provider's instructions.

Checking the Unit

1. Examine the power cord, fiberoptic light pad and cable, and light box for obvious signs of damage. Replace them if they are damaged.
2. Verify that the air circulation vents on the sides and back of the light box are unobstructed. The air filter should be free of lint.



CAUTION:

Do not block the air filter or side vents.

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



WARNING:

When handling the fiberoptic cable connector (during insertion, removal or positioning of the fiberoptic light pad) use caution to prevent the fiberoptic cable connector from dropping, which can damage the fiberoptic cable connector and/or injure the patient or caregiver.

4. Connect the power cord to the back of the unit, then to an appropriately grounded power source.
5. Turn the BiliSoft LED Phototherapy System on using the standby switch on the front of the unit and allow it to run for five (5) minutes.
6. Place the fiberoptic light pad on a flat surface. Do not place the fiberoptic light pad inside of the BiliSoft Pad Cover or BiliSoft Nest at this time.
7. Use a properly-calibrated Ohmeda Medical BiliBlanket Meter II to check the irradiance level of the unit using the template printed on the fiberoptic light pad. There are two ways to check the irradiance level - a center-row quick check, which provides approximate irradiance values, and the more comprehensive 6-point (for small

fiberoptic light pad) or 9-point (for large fiberoptic light pad) check, which provides more accurate irradiance values.

To perform the center-row check, measure the irradiance level at each point on the center row using the template printed on the fiberoptic light pad. For a small pad, the center row points are C and D. For the large pad, the center row points are D, E and F. Calculate the average of the center row irradiance measurements. Use the first column of the chart below to determine if the minimum acceptable center-row irradiance has been met. If the average of the light meter readings meets or exceeds the acceptable minimum irradiance, then the unit is ready for use.

If the meter readings are lower than these values, perform the more comprehensive 6-point (small pad) or 9-point (large pad) check. Measure the irradiance level at each point using the template printed on the fiberoptic light pad. Calculate the average of the irradiance measurements. Use the second column of the chart below to determine if the average irradiance is within specification. If the average irradiance is outside of the acceptable range, see the troubleshooting section of this manual.

	Center-Row Irradiance* (bare fiberoptic light pad) $\mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$	Average Irradiance * (bare fiberoptic light pad) (+/- 25%) $\mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$
Large Pad	$(D + E + F)/3 \geq 48.5$	$(A + B + C + D + E + F + G + H + I)/9 = 49$
Small Pad	$(C + D)/2 \geq 70.0$	$(A + B + C + D + E + F) / 6 = 70$

* Using an Ohmeda Medical BiliBlanket Meter II

Note: When the BiliSoft fiberoptic light pad is inserted into a BiliSoft Pad Cover or BiliSoft Nest, the nominal spectral irradiance is $35 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (large pad) and $50 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (small pad).

Once the check is complete, turn the unit off. The unit is ready for use.

It is recommended that the BiliSoft LED Phototherapy System be checked with the Ohmeda Medical BiliBlanket® Meter II for desired therapeutic intensity before use with each patient.

Positioning the Unit



WARNING:

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



WARNING:

When handling the fiberoptic cable connector (during insertion, removal or positioning of the fiberoptic light pad) use caution to prevent the fiberoptic cable connector from dropping, which can damage the fiberoptic cable connector and/or injure the patient or caregiver.



CAUTION:

Never position the unit where it could interfere with the performance of other equipment, e.g. opening the hood of the Giraffe® OmniBed, preventing the side panels from opening in Infant Warmer Systems, etc.

The following options are available to position the BiliSoft LED Phototherapy system:

- **On a shelf or other stable, flat surface** (no additional mounting bracket required)
- **On the Ohmeda Medical Dovetail Rail** (mounting brackets sold separately)
- **On the Ohmeda Medical Mobile Stand or Giraffe Spot PT Lite Roll Stand** (mounting brackets and stands sold separately)

The BiliSoft mounting bracket (sold separately) allows the BiliSoft LED Phototherapy System to be mounted to an Ohmeda dovetail rail, Ohmeda mobile stand, or Giraffe Spot PT Lite roll stand. Attach the male mounting bracket accessory to the four holes at the bottom of the main unit using the hardware provided with the bracket. For added convenience, the bracket can be positioned on the left or right side of the unit. See the accessory parts list in this manual for relevant stock numbers.

Note: Due to manufacturing tolerances in the mounting bracket and the receptacle, a small amount of tilt may be noticed in the unit.

Note: To avoid damage to the BiliSoft unit, use care when the BiliSoft is attached to other equipment that is being transported to ensure that the unit is protected from impacting door jams or any other obstacles.

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).

**CAUTION:**

Do not allow the fiberoptic cable or light pad to rub on sharp or abrasive surfaces. The protective coverings and optical fibers may be damaged.

**CAUTION:**

To prevent damage to the fiberoptic light pad, fiberoptic cable protective covering, and optical fibers, observe these guidelines. Failure to do so could decrease light intensity at the light pad:

- Do not lay or hang the fiberoptic cable where it could be crushed, this could damage the cable's outer protective cover and the optical fibers.
- Do not bend the fiberoptic light pad or cable at a sharp angle.
- Do not place anything on the fiberoptic cable.

If the fiberoptic cable or light pad is ripped, punctured or otherwise damaged, it must be taken out of service and replaced.

**CAUTION:**

Do not scratch, touch or soil the fiberoptic lenses at the end of the fiberoptic cable.

**WARNING:**

The light box is not waterproof. Locate the unit where it will not be exposed to liquids. Liquids that enter the unit can damage it and create an electric shock hazard.


**WARNING:**

Never place the light box inside the infant compartment of an incubator, warmer or bassinet; these conditions expose the patient to possible injury.

Using the Unit

**WARNING:**

When handling the fiberoptic cable connector (during insertion, removal or positioning of the fiberoptic light pad) use caution to prevent the fiberoptic cable connector from dropping, which can damage the fiberoptic cable connector and/or injure the patient or caregiver.

Graphic	Description
	<ol style="list-style-type: none">1. Gently insert the BiliSoft fiberoptic pad into a BiliSoft Pad Cover or BiliSoft Nest. The illuminated side should face up and should be against the padded side of the cover.



2. Place the baby on the padded side of the BiliSoft cover or BiliSoft Nest. Adjust the straps as needed.

IMPORTANT: Be sure the maximum area of illumination is in contact with the patient's skin.



WARNING:

Improper use of the BiliSoft Pad Cover straps, BiliSoft Nest straps or fiberoptic cable may cause a strangulation or choking hazard.



3. Swaddle the baby as needed. The patient, along with the light pad, may be covered or wrapped in a thin blanket. It is possible to hold and feed the patient while continuing treatment. The patient will continue to receive effective phototherapy treatment as long as the covered, light emitting section of the pad remains in direct contact with the skin.

If a baby cannot be swaddled, positioning aids may be placed under the light pad to bring more light to the sides of a baby's body for greater skin surface area exposure to the light.



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



WARNING:

Direct exposure of the eyes to any phototherapy light may cause eye damage. Always protect the baby's eyes with eye patches or an equivalent appropriate eye protection product. Periodically and/or per your hospital protocol or healthcare provider's instructions, verify that the patient's eyes are protected and free of infection. Care should also be taken to protect the eyes of patients adjacent to the treatment area, when necessary.



5. Turn the BiliSoft box on.



6. Insert the fiberoptic cable in the box.

IMPORTANT: For hygienic purposes, never place a baby directly on the bare fiberoptic light pad. The light pad must be covered with the BiliSoft Pad Cover or BiliSoft Nest as described above. BiliSoft Pad Covers and BiliSoft Nests are for single-patient use only. The BiliSoft Pad Cover or BiliSoft Nest must be changed between patients and whenever it is soiled. Follow all local and national regulations for disposing of this type of product.





WARNING:

The light is intended to shine through the padded surface of the BiliSoft Pad Cover or BiliSoft Nest. If the BiliSoft Pad Cover or BiliSoft Nest is installed incorrectly and light shines through the unpadded side, the light intensity will be higher.

Chapter 6

Troubleshooting

Alarm/Troubleshooting Guide

Symptom	Likely causes	Troubleshooting steps
<p>Unit Overheated Indicator light is on.</p> 	<p>Clogged air filter, blocked vents, fan failure.</p>	<ol style="list-style-type: none"> 1. Turn off the standby switch and disconnect the power cord from the outlet. <p>Note: It can take up to 10 minutes for the thermal cutout switch to reset and allow the unit to be used again.</p> <ol style="list-style-type: none"> 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. If the air filter needs to be removed, take the unit out of service and seek assistance from service personnel. 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.
<p>LED failure indicator light is blinking.</p> 	<p>At least one of the three LED pairs is not operating.</p>	<ol style="list-style-type: none"> 1. LED module needs to be replaced by service personnel. <p>Note: The system may still be used until the LED module is replaced. However the intensity will be lower than the specification.</p>

Symptom	Likely causes	Troubleshooting steps
Fiberoptic light pad, cable or connector is damaged.	Fiberoptic light pad, cable or connector was ripped, punctured or otherwise damaged.	<ol style="list-style-type: none"> 1. Damaged fiberoptic light pad, cable, or connector must be replaced.
Light output measurement is out of specification.	<p>Fiberoptic cable is not fully inserted into the light box.</p> <p>Fiberoptic light pad and/or fiberoptic lenses are discolored or damaged.</p> <p>Improper measurement setup.</p> <p>LED module needs replacing.</p>	<ol style="list-style-type: none"> 1. Ensure that the fiberoptic cable is fully inserted into the light box. 2. Check that the surface of the fiberoptic light pad is not damaged or discolored. Similarly, check the fiberoptic lenses to ensure that the fiberoptic lenses have not been damaged or discolored. 3. Make sure that the irradiance measurement is taken with the fiberoptic light pad on a flat surface and that the pad is not covered with a BiliSoft Pad Cover or BiliSoft Nest when taking the measurement. 4. Make sure that the light output is being measured with a properly calibrated Ohmeda Medical BiliBlanket Meter II. 5. Perform a comprehensive 6-point (small pad) or 9-point (large pad) check. 6. If the light output is still out of specification, remove the unit from service and seek assistance from service personnel.
Main unit cover, handle or back plate is cracked or damaged.	Unit was dropped or sustained damage through impact with another object.	<ol style="list-style-type: none"> 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.

Symptom	Likely causes	Troubleshooting steps
Hour meter is not working.	Fiberoptic cable is not fully inserted into the light box. Hour meter failure.	<ol style="list-style-type: none"> 1. The hour meter only runs when the fiberoptic light pad is illuminated. If the fiberoptic cable is not fully inserted in the light box, the LEDs are automatically shut off and the hour meter does not run. 2. If the fiberoptic cable is fully inserted and the hour meter still does not work, remove the unit from service and seek assistance from service personnel.
No light output.	Fiberoptic cable is not fully inserted in the light box. Unit is not powered.	<ol style="list-style-type: none"> 1. Confirm that the fiberoptic cable is fully inserted in the light box. If the fiberoptic cable is not fully inserted in the light box, the LEDs are automatically shut off. 2. If the front panel standby switch is in the "on" position and the small green LED on the switch is lit and there is still no light to the fiberoptic light pad, remove the unit from service and seek assistance from trained service personnel. 3. If the front panel standby switch is in the "on" position and the small green LED on the switch is not lit, then confirm that the unit is plugged into a powered outlet.
Fiberoptic light pad connection is too loose.	"Breakaway" feature.	<ol style="list-style-type: none"> 1. The fiberoptic cable connection is designed with a "breakaway" feature to protect the unit if the fiberoptic cable is pulled. If the fiberoptic cable has slack and the fiberoptic cable connector will not stay connected, remove the unit from service and seek assistance from trained service personnel.

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Chapter 7

Routine Cleaning and Maintenance

Maintenance Schedule

Maintain the unit in accordance with the information listed in the Operator maintenance table on this page. This schedule lists the minimum maintenance frequencies. Always follow hospital and local regulations for required maintenance frequencies.

Operator Maintenance

Weekly or after each patient: Clean the BiliSoft LED Phototherapy System with soap and water. Disinfect the unit only if required per the hospital or home health care protocol.

IMPORTANT: For hygienic purposes, never place a baby directly on the bare fiberoptic light pad. The light pad must be covered with the BiliSoft Pad Cover or BiliSoft Nest as described in the Operating Instructions. BiliSoft Pad Covers and BiliSoft Nests are for single-patient use only. The BiliSoft Pad Cover or BiliSoft Nest must be changed between patients and whenever it is soiled. Follow all local and national regulations for disposing of this type of product.

Quarterly: Inspect the air filter and clean or replace as required.

Note: This is the minimum inspection frequency. The filter must be cleaned or replaced whenever it appears dirty.

Approximately every 8,000 to 10,000 hours: Replace the LED module when the BiliSoft irradiance is below the specification. See service manual for details.

Cleaning and Disinfecting

BiliSoft Light Box



WARNING:

Make sure the light box power cord is disconnected from the power source before cleaning and that the unit is completely dry before using it.



WARNING:

Never immerse the light box in liquid. Water will short circuit electronic circuitry, causing permanent damage.



CAUTION:

Use the 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.



CAUTION:

Do not autoclave or gas sterilize the Light Box.

1. Unplug the power cord.
2. Clean the outside of the light box using a mild detergent solution. Aqueous solutions, which are both hospital disinfectants and microbactericides, may be used. Do not allow liquids to seep into the housing. Apply the cleaning solutions with a clean cloth or sponge. Always dry the parts with a clean damp soft cloth to avoid scratches and remove cleaner residue. Do not spray cleaner directly on the unit. Take caution if wiping inside of the fiberoptic light pad assembly port not to damage the LED shutoff switch. See table on page 7-4 for a list of approved cleaners.

BiliSoft Fiberoptic Light Pad and Cable

**CAUTION:**

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

**CAUTION:**

Do not autoclave or gas sterilize the fiberoptic light pad or fiberoptic cable.

**CAUTION:**

The fiberoptic cable connector requires special cleaning methods to avoid damage to the fiberoptic lenses. (See page 7-4 for detailed instructions on cleaning the fiberoptic cable connector.)

**WARNING:**

Do not use a phenolic compound based cleaner. Phenolic compounds have been associated with elevated bilirubin levels in infants.

**CAUTION:**

Exposing the fiberoptic light pad's plastic cover to strong cleaning solutions, alcohol, or ultraviolet light can cause premature breakdown of the plastic material. Cleaning solutions that discolor the fiberoptic light pad, such as iodine solutions, will reduce the pad's light output. Do not place the fiberoptic light pad in direct sunlight. Do not use iodine solutions, strong acids, strong alkali, or bleach solutions to clean the pad.

Clean the fiberoptic light pad and cable using a mild detergent solution. Never use an abrasive cleaner on the fiberoptic light pad or the cable. Aqueous solutions, which are both hospital disinfectants and microbactericides, may be used. Apply the cleaning solutions with a clean soft cloth. Remove any cleaning residue with a clean soft cloth soaked with water only. Do not spray cleaner directly on the fiberoptic light pad or cable. See table on page 7-4 for a list of approved cleaners.

BiliSoft Cable Connector and Fiberoptic Lenses



CAUTION:

Never immerse the fiberoptic lenses in liquid.



CAUTION:

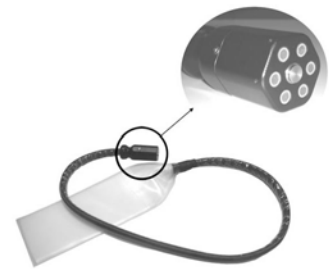
Do not autoclave or gas sterilize the fiberoptic light pad, fiberoptic cable or fiberoptic cable connector.



CAUTION:

Exposing the light input end of the fiberoptic cable connector to strong cleaning solutions, alcohol, or ultraviolet light can cause premature breakdown of the fiberoptic lenses. Cleaning solutions that discolor the lenses, such as iodine solutions, will reduce the pad's light output. Do not place the fiberoptic cable connector in direct sunlight. Do not use iodine solutions, strong acids, strong alkali, or bleach solutions to clean the fiberoptic cable connector.

Clean the fiberoptic cable connector using a mild detergent solution. Never use an abrasive cleaner on the fiberoptic cable connector. If disinfection is required, aqueous solutions, which are both hospital disinfectants and microbactericides, may be **used sparingly**, minimizing their exposure to the fiberoptic lenses. Apply the cleaning solutions with a clean soft cloth. Do not saturate. Remove any cleaning residue from the fiberoptic lenses with a clean damp soft cloth soaked with water only. **Do not spray cleaner directly on the fiberoptic cable connector** (see illustration, right). See table on this page for a list of approved cleaners.



The following table lists approved disinfecting solutions (minimize exposure to fiberoptic lenses):



WARNING:

Never use flammable solutions to treat the BiliSoft LED Phototherapy System or any of its parts.

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

Air Filter

The air filter on the rear of the light box should be visually checked and cleaned if needed to prevent air blockage that may cause overheating. The filter may be cleaned by vacuuming it. The filter can also be removed for cleaning. If the filter needs to be removed, take the unit out of service and seek assistance from service personnel.

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Chapter 8

Accessories and Replacement Parts

Accessories	Stock Number
BiliSoft Fiberoptic Pad, Small	M1093118
BiliSoft Fiberoptic Pad, Large	M1093119
BiliSoft Pad Cover, Disposable, Small (Box of 50)	M1093120
BiliSoft Pad Cover, Disposable, Small (Box of 20)	M1097108
BiliSoft Pad Cover, Disposable, Large (Box of 50)	M1093121
BiliSoft Pad Cover, Disposable, Large (Box of 20)	M1097109
BiliSoft Nest, Disposable, Small (Box of 15)	M1093122
BiliSoft Nest, Disposable, Large (Box of 15)	M1093123
BiliSoft Carrying Case	M1110051
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 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
Replacement Parts	Stock Number
LED module kit (replacement light source)	M1098188



WARNING:

The use of accessories, replacement parts or power cords other than those specified by the manufacturer may affect the performance of the unit and could result in damage to the unit or unsafe operating conditions.

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Chapter 9

Specifications

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

Electrical Specifications	
Input	1.5 A @ 100 – 240 V~, 50/60 Hz
Fuses	T3.15A @ 250V~, slo-blo type (qty. 2)
Leakage Current	< 300 μ A @ 264 V~
Ground impedance	< 0.1 ohm from ground pin of the power inlet module to any exposed metal surface.
Environmental Operating Conditions	
Ambient temperature	+10°C to +35°C (50 to 95°F).
Humidity	10% to 90% RH non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Storage Requirements	
Temperature	-40°C to +70°C (-40 to 158°F).
Humidity	0% to 100% RH non-condensing
Atmospheric pressure	50 kPa to 106 kPa

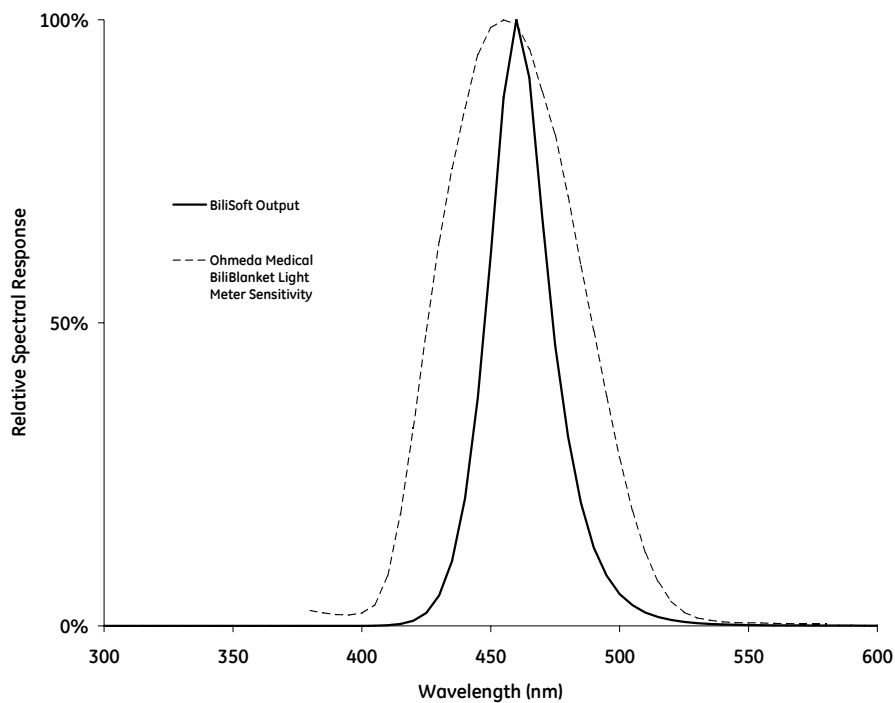
Performance Specifications	
Spectral Irradiance (bare fiberoptic pad)*	<p>Large Fiberoptic Pad – $49 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (+/- 25%) 9-point check</p> <p>Small Fiberoptic Pad – $70 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (+/- 25%) 6-point check</p> <p>Note: When the BiliSoft fiberoptic light pad is inserted into a BiliSoft Pad Cover or BiliSoft Nest, the nominal spectral irradiance is $35 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (large pad) and $50 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (small pad)</p>
*Using an Ohmeda Medical BiliBlanket Meter II	
Wavelength	430-490 nm (peak 440-460 nm)
LED module estimated life*	Under continuous use, tested at room temperature, a typical LED module will run for approximately 8,000 to 10,000 hours before the light intensity drops 25%.
Sound level	< 44 dB(A) at 1 meter
X-ray	X-ray compatible
Physical Specifications	
Light box (W x H x L)	16.5 x 21 x 16.5 cm
Light box weight (excluding fiberoptic pad)	< 2.5 kg
Fiberoptic Pad weight	< 1.1 kg
Fiberoptic light pad, small	15 x 30 cm (light-emitting area)
Fiberoptic light pad, large	25 x 30 cm (light-emitting area)
Fiberoptic cable length	137 ± 5 cm
Regulatory Standards	
<p>IEC Type B equipment.</p> <p>IEC Class 1 (continuous operation)</p> <p>FDA Class II</p>	<p>Product certified to the following standards:</p> <p>EN60601-1; EN60601-1-2; EN60601-2-50; ISO 10993-5; ISO 10993-10; UL 60601-1; CSA C22.2 No 601.1-M90; IEC 60601-1-8; BS EN 980; 16CFR Part 1632.6 (for BiliSoft Pad Covers and BiliSoft Nests)</p>

*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. Measure the irradiance of the BiliSoft System and replace the LED module when the system is below specifications.

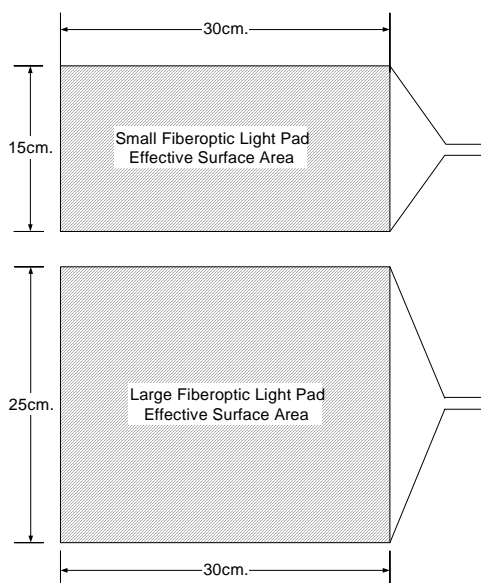
Chapter 10

Technical Reference

The following information is provided for compliance to IEC 6001-2-50.



Average Total Irradiance for Bilirubin (measured with a spectroradiometer between 400-550 nm)
= 10.5 mW•cm⁻² (bare fiberoptic pad, small)
= 7.9 mW•cm⁻² (bare fiberoptic pad, large)

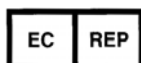


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Warranty

This Product is sold by GE Healthcare under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this Product directly from GE Healthcare or GE Healthcare's Authorized Dealers as new merchandise and are extended to the Buyer thereof, other than for the purpose of resale. For a period of twelve (12) months for the light box and the pad from the date of original delivery to Buyer or to Buyer's order, but in no event for a period of more than two years from the date of original delivery by GE Healthcare to an GE Healthcare Authorized Dealer, this Product, other than its expendable parts, is warranted to be free from functional defects in materials and workmanship and to conform to the description of the Product contained in this operation manual and accompanying labels and/or inserts, provided that the same is properly operated under the conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided. This same warranty is made for a period of thirty (30) days with respect to expendable parts. The foregoing warranties shall not apply if the Product has been repaired other than by GE Healthcare or in accordance with written instructions provided by GE Healthcare, or altered by anyone other than GE Healthcare, or if the Product has been subject to abuse, misuse, negligence, or accident. GE Healthcare's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at GE Healthcare's option, a Product, which is telephonically reported to the nearest GE Healthcare Regional Service Office and which, if so advised by GE Healthcare, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the applicable warranty, to the designated GE Healthcare Service Center during normal business hours, transportation charges prepaid, and which, upon GE Healthcare's examination, is found not to conform with above warranties. GE Healthcare shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages, or special damages. There are no express or implied warranties that extend beyond the warranties hereinabove set forth. GE Healthcare makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.



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