

GE Healthcare

BiliSoft LED Phototherapy System

Intensive therapy, as easy as
wrapping a baby in a blanket



BiliSoft, a new generation of soft, intensive phototherapy

BiliSoft™ LED Phototherapy System is the next generation LED and fiberoptic based technology for treatment of indirect hyperbilirubinemia in newborns. Its increased surface area, high spectral irradiance, and long lasting blue narrow-band LED light are the features that are needed for intensive, efficacious phototherapy as recommended by AAP Guidelines. It is also the only product on the market that supports and promotes developmental care, enables infant-parent bonding and provides healing light where it is needed – in Neonatal ICU, Pediatrics, Well Baby Nursery and at home.

The BiliSoft's blue LED light delivers healing phototherapy that meets and exceeds the recommendations of the American Academy of Pediatrics* – including the following critical specifications:

Components of Intensive Phototherapy	AAP Guideline	BiliSoft LED Phototherapy System
Light Intensity	Irradiance level at least $30 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$	$35 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (large pad) $50 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (small pad)
Light Spectrum	Wavelength between 430-490 nm	430-490 nm (peak 440-460 nm, matching the peak absorption wavelength at which bilirubin is broken down (458 nm))**
Surface Area Coverage	Larger surface area, especially for combating extremely high bilirubin levels	Provides greater surface area than other fiberoptic devices and many overhead lamps
Distance	Distance between the infant and the light source is critical to spectral irradiance level	In contact with infant's skin, eliminating distance deficiencies entirely

*American Academy of Pediatrics, clinical practice guideline, subcommittee on hyperbilirubinemia: Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation, 2004; 297-316.
 **Light-emitting diodes: a novel light source for phototherapy. Pediatric Research. 1998; 44(5):804-809.

Meeting the AAP's most precise guidelines



Healing light, right where it's needed

BiliSoft delivers phototherapy anywhere – in the Neonatal ICU, Pediatrics, Well Baby Nursery or at home. BiliSoft can be used in any environment – in a radiant warmer, incubator, bassinet, crib, or in a caregiver's arms.

Mounting options

Bed mounted units conserve space in all care areas. Roll stand mounted option provides added flexibility. Either option ensures quick and easy access to the newborn.



BiliSoft's long, lightweight fiber optic cable and quiet operation make it ideal for in-home application. It's exceptionally easy to set up and use.



BiliSoft is an excellent solution for infants in the Neonatal ICU, where fast, effective treatment can be most critical.



Well Baby Nursery and Pediatrics – baby can be covered or wrapped in a blanket during therapy.



BiliSoft's whisper-quiet operation helps you maintain a quiet environment to promote sleep and growth.

A design that promotes bonding and supports development



With BiliSoft, there's no barrier to bonding between infant and parents or caregivers. The baby can be held, fed, even rocked throughout the therapy session.

Comfort is the keyword, whichever cover options you select. The flat, cushioned BiliSoft cover lets you swaddle baby and phototherapy pad together. The BiliSoft nest offers sick babies the boundaries and support they need, via a cushy footroll and gentle, transparent straps.

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



Irradiance level*

- There's no distance factor to diminish treatment intensity
- Small pad irradiance is $50 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$
- Large pad irradiance is $35 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$

*irradiance through the typical BiliSoft covers and nests

BiliSoft fiberoptic pad covers

- Ultra-soft, disposable BiliSoft covers are made of flame-retardant, skin-friendly fabric
- BiliSoft covers and nests have soft straps which help swaddle a baby in comfort and transmit phototherapy light too, if an additional overhead phototherapy source is required

Easy positioning

- A long, flexible, fiberoptic cable makes positioning easier than ever

Double intensive phototherapy

If double phototherapy is warranted in an intensive care setting, BiliSoft, along with Giraffe® Spot PT Lite, can effectively provide double intensive phototherapy treatment. GE offers a complete portfolio of phototherapy products for treatment of hyperbilirubinemia – meeting the AAP Guidelines for intensive phototherapy.



BiliSoft along with Giraffe Spot PT Lite can effectively provide double intensive phototherapy treatment.

We asked a number of neonatal caregivers what they thought of the new BiliSoft LED Phototherapy System.

"That's incredible," said one, noting in particular its generous surface area.

"Wow, that's amazing," said another.

"Striking how quiet it is. Awesome!"

"How soft is that!!!" said yet another. "When can I get it?"

No wonder BiliSoft is receiving rave reviews: It's the result of continuous feedback from customers and a design engineering team that created the ideal system for infants, care providers and parents alike.

Product designed by customers



Specifications



Electrical specifications

Input:

- 1.5 A @ 100 – 240 V, ~ 50/60 Hz

Fuses:

- T3.15 A @ 250 V, ~ 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°F 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°F to 158°F)

Humidity:

- 0% to 100% RH noncondensing

Atmospheric pressure:

- 50 kPa to 106 kPa

Performance specifications

Spectral irradiance (bare fiberoptic pad):*

- Large fiberoptic pad – $49 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (+/- 25%) 9-point check
- Small fiberoptic pad – $70 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (+/- 25%) 6-point check

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).

*Using an Ohmeda Medical BiliBlanket® Light Meter

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%

† 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.

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

IEC Type B equipment

IEC Class 1 (continuous operation)

FDA Class II

Product certified to the following standards:

- 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)

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

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Healthcare Re-imagined

GE is dedicated to helping you transform healthcare delivery by driving critical breakthroughs in biology and technology. Our expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, and biopharmaceutical manufacturing technologies is enabling healthcare professionals around the world to discover new ways to predict, diagnose and treat disease earlier. We call this model of care “Early Health.” The goal: to help clinicians detect disease earlier, access more information and intervene earlier with more targeted treatments, so they can help their patients live their lives to the fullest. Re-think, Re-discover, Re-invent, Re-imagine.

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imagination at work