BiliSoft™ 2.0 Phototherapy System

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

BiliSoft™ 2.0 LED Phototherapy System is the next generation LED and fiber-optic based technology for treatment of indirect hyperbilirubinemia in newborns. Its large 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 also supports and promotes developmental care, enables infant-parent bonding and provides healing light where it is needed.

Specifications

Electrical specifications	
Input:	0.25A - 0.75A @ 100-240V~, 50/60Hz +10%, -15% (Lowest line 85 VAC)
Leakage touch current:	Allowable values are 100 µA in normal condition and 500 µA in single fault condition @ 264 V~
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
Storage requirements	
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 (bare fiber optic pad):	Large fiberoptic pad – 49 µW•cm^{-2}•nm^{-1} (+/- 25%) 9-point check Small fiberoptic pad – 70 µW•cm^{-2}•nm^{-1} (+/- 25%) 6-point check
Peak Wavelength:	445-470 nm
LED module estimated life:†	Under continuous use, tested at room temperature, a typical LED module will run > 50,000 hours before the light intensity drops 25% † The LED 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. Measure the irradiance of the BiliSoft 2.0 System and replace the LED module when the system is more than 25% below specification. Replace the LED Module if output is below 39 µW cm-2 nm-1 for a small pad or 27 µW cm-2 nm-1 for a large pad.

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 17.5 cm
Light box weight (excluding fiber optic pad):	< 1.7 kg
Light Pad weight:	< 0.6 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
Regulatory standards	
Applied parts are Type BF	
IEC Class II (Continuous Operation)	
FDA Class II device	
Standards: The BiliSoft 2.0 shall meet the following standards. Certification testing shall include CB scheme to accommodate country specific variations, including deviations and power settings of 220V and 60Hz.	IEC/EN 60601-1-2 ed. 4 (2014)
	IEC 60601-1:2012 Ed 3.1
	IEC 60601-2-50 ed. 2.0 (2009)
	IEC 60601-1-11 ed. 2 (2015)
	IEC 60601-1:1988 + A1:1991 + A2:1995
	IEC 60601-2-50 ed. 1.0 (2000)
	ANSI/AAMI ES60601-1:2005/(R)2012
	CAN/CSA-C22.2 No. 60601-1 Third Edition (2014)

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