

Evaluation of an Affordable LED Phototherapy Device for Resource-Limited Settings

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Background

Surveys of phototherapy devices in resource-limited settings have shown that suboptimal phototherapy is often delivered due to limitations in the design and/or maintenance of devices (Fig. 1). Brilliance, a LED-based overhead phototherapy device (Table 1) developed by D-Rev: Design for the Other 90%, USA, and manufactured by Phoenix Medical Systems, India, has low maintenance requirements (its LEDs last 30,000 hours, compared to 3,000 hours for typical fluorescent lamps), is robust to the variable electrical power common to resource-limited settings, and has a low projected production cost (less than \$135 per device).

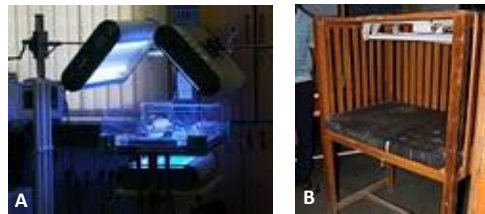


Figure 1. Sample of phototherapy devices currently used in resource-limited settings. (A) Inefficient multi-sided phototherapy administered on a jaundiced newborn. All three devices either lack full functionality (burnt out bulbs) or use ineffective white fluorescent tube lights. (B) Homemade phototherapy device using white fluorescent lights. The lights are at a far distance from the bed.

Objective

To evaluate *in vitro* the potential efficacy and performance of Brilliance for preterm and term infants.

Materials and Methods

The *in vitro* efficacy of Brilliance (prototype) was assessed according to the standardized bench method outlined in Vreman et al¹. Evaluation parameters include light potency (emissions wavelength range and peak in nm), intensity (irradiance in $\mu\text{W}/\text{cm}^2/\text{nm}$), treatable body surface area (BSA) comparable to term infants and *in vitro* photodegradation rate of bilirubin in aqueous human serum albumin solution at 37°C ($t_{1/2}$ in min). The latter is considered to be an index of *in vitro* efficacy for phototherapy devices. The amortized cost of treatment per newborn for all devices was calculated based on a 48-hour treatment time standard.

Device Design and Specifications

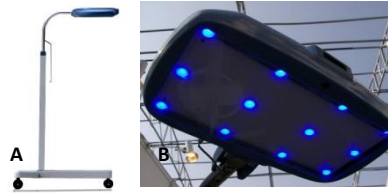


Figure 2. (A) Brilliance technical rendering, side view. (B) Brilliance underside view consisting of 3x4 blue LEDs (attenuated for illustration).

Illumination source	Blue LEDs; 3 W; n=12
Peak spectral irradiance	> 40 $\mu\text{W}/\text{cm}^2/\text{nm}$ at 30 cm (recommended treatment distance)
Peak wavelength	451 nm
Emission Spectrum	410 – 510 nm
Effective surface area	25 cm x 50 cm at 30 cm
Irradiance ratio*	0.45 (minimum /maximum irradiance)
Estimated lifetime	30,000 hours
Power requirements and use	100-240 VAC; 60 W

Table 1. Technical specifications of Brilliance. Irradiance was measured with the Biliblanket Light Meter II (Ohmeda/GE Healthcare). *measure of homogeneity of irradiance distribution to meet IEC 60601-2-50 requirements.

Results

Device	Manufacturer	Light Source	Treatable BSA (% Term)	Peak Wavelength, Spectrum (nm)	Irradiance (Silhouette Mean \pm SD, $\mu\text{W}/\text{cm}^2/\text{nm}$)	Normalized 3-D efficacy ($t_{1/2}$ in min)
Brilliance	Phoenix Medical, India	LED	100	451 (410-510)	35 \pm 9	63
neoBLUE ¹	Natus Medical, USA	LED	100	462 (420-540)	27 \pm 7	80
Bililite BB ¹	Olympic Medical/Natus, USA	Fluorescent	100	445 (400-550)	17 \pm 2	117
MinBililite ¹	Olympic Medical/Natus, USA	Halogen	54	576 (350-800)	7 \pm 5	247
Biliblanket ¹	Ohmeda, Fairfield, CT	Halogen/Fiberoptic	24	533 (390-600)	21 \pm 6	333

Table 2. Characteristics of evaluated phototherapy devices. Irradiance was measured with the Biliblanket Light Meter II (Ohmeda/GE Healthcare). Normalized 3-D efficacy was determined with the photodegradation rate of unconjugated bilirubin in human serum albumin ($t_{1/2}$), adjusted for 3-D BSA.

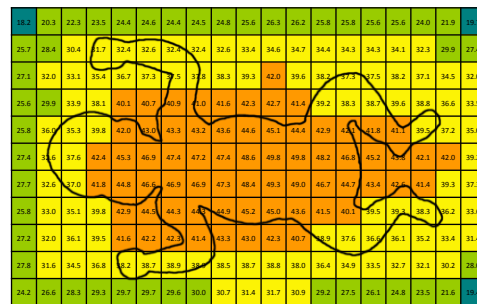


Figure 3. Irradiance footprint with baby silhouette for Brilliance.

Device	Cost of Treatment/ Newborn (USD)
Brilliance	\$ 0.75
neoBLUE	\$ 10.60
Bililite BB	\$ 7.20
MinBililite	\$ 8.70
Biliblanket	\$ 12.10

Table 3. Cost assessment of affordability. Illumination source lifespan and a 48-hour treatment time standard were factored into the retail value of each device to approximate cost.

Conclusions

- This study demonstrates that Brilliance meets the 2004 AAP guideline for effective phototherapy².
- Brilliance yielded superior and lower normalized $t_{1/2}$ values than leading commercial phototherapy devices for the BSA of term infants (Table 2).
- Brilliance also has the lowest cost of treatment per newborn over a 48-hour period—\$0.75 per treatment (Table 3). Cost-of-care and variations in treatment time due to degenerative performance of fluorescent and halogen phototherapy devices were not factored into the comparison.
- Its low cost and ease of maintenance suggest Brilliance is a potentially appropriate device for treating neonatal hyperbilirubinemia in low-resource settings.
- Clinical trials are planned to define its effectiveness at resource-limited hospitals.

References

- Vreman HJ, Wong RJ, Murdock JR, Stevenson DK. Standardized bench method for evaluating the efficacy of phototherapy devices. *Acta Paediatr* 2008; 97: 308-316.
- American Academy of Pediatrics. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. *Pediatrics* 2004; 114; 297-316.

Acknowledgments

This research was supported in part by NCIIA Grant 6885-09.