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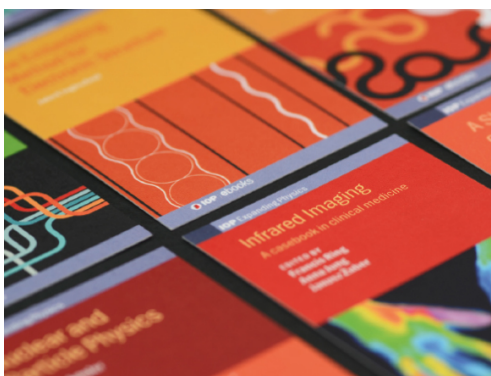
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## **BiliLED low cost neonatal phototherapy, from prototype to industry**

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**Abstract.** BiliLED is a phototherapy instrument designed to reduce bilirubin blood rates in new born babies with jaundice. The light source is centred at 470 nm with a bandwidth of 35 nm and includes a matrix of 196 (14x14) InGaN LEDs. The optical elements are designed to maximize the light intensity useful for treatment, with a small number of LEDs in a compact and low cost unit. The optic array is such that every LED illuminates all the treatment area, which ensures redundancy and, thus, a high reliability not to be found in single-lamp instruments. Thermal dissipation and cost of BiliLED are both an order-of-magnitude smaller than conventional therapy lamps. BiliLED adjusts coetaneous irradiation with a feedback loop to compensate the loss or aging of LEDs achieving a calibrated light source for over a decade of use. A clinical trial in 20 hyperbilirrubinaemia patients shows 16% bilirubin degradation within 24 hours of treatment, higher than most lamp phototherapy instruments. The steps from prototype to commercial model are described.

### **1. Introduction**

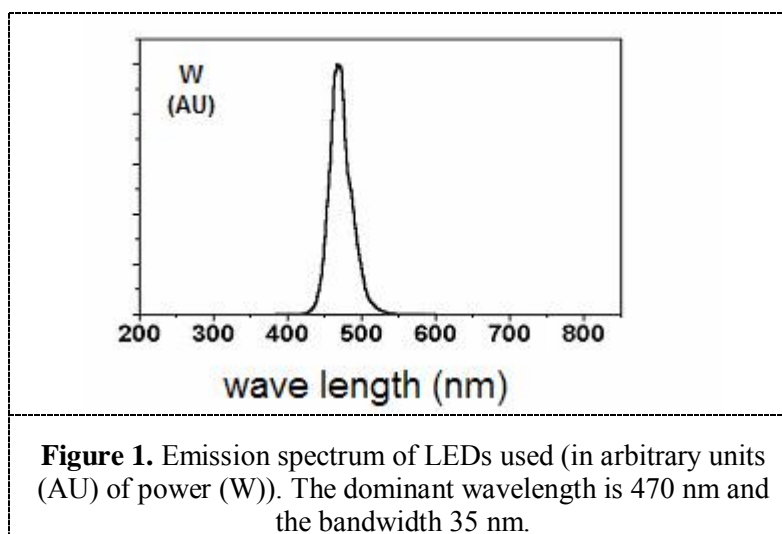
Some term and pre-term babies are born with jaundice, which reveals a high blood rate of bilirubin. Excluding acute cases, the usual treatment is the coetaneous exposition to a light radiation of a specific wave length: Neonatal Phototherapy (NP), which is a very effective and safe procedure. Amongst the biochemical reactions induced by light, the main effect of NP is the irreversible reaction by which the toxic bilirubin is turned into a structural isomeric molecule called lumirubin, easily excreted by the patient. It was found [1] that to induce this reaction the light source must be in the blue band between 425 and 480 nm or even higher frequencies, according to other authors [3]. There is a clear proportionality between the bilirubin degradation rate and blue light intensity. Although Tan [4] measured the saturation intensity (spectral irradiance of approximately 40  $\mu\text{W}/\text{cm}^2 \text{ nm}$ ), beyond which an increase in intensity would not accelerate bilirubin degradation, this limit has been questioned later on [1] [5].

NP is effective only if enough light power is delivered within the specified bandwidth to a sufficiently large skin area. Several phototherapy instruments have been developed to deliver spectrally controlled light to the largest possible skin area. As a result, there is a market of high light intensity instruments suitable for NP [1]. Several clinical trials have confirmed the efficacy of monochromatic light [16].

## 2. Design of BiliLED

We have designed a blue monochromatic light source with high treatment intensity, low heat dissipation to allow skin proximity. The sought source designed had to be safe with respect to lateral radiation and to the absence of ultraviolet (UV) power. Besides, it should have a low cost and a longer life than conventional treatment instruments. Therefore, we have adopted a very efficient element as is the Light Emitting Diode (LED) which had previously been tried [2] for phototherapy.

A design criteria was to obtain a uniform light intensity within the treatment area with a steep transition to the dark area outside. This would increase efficiency as no light is wasted outside and there is no over illuminated spot. As a consequence, the number of LEDs is the smallest possible and a compact geometry is obtained.



The light source is made with high luminance InGaN standard light emitting diodes (LED) with 5 mm transparent plastic capsule type T1-3/4, with emission spectrum centered at 470 nm and bandwidth of 35 nm [12], and with no emission at other wavelengths, such as infrared (IR) or UV, as shown in Figure 1. The optic arrangement is capable of collecting all the light emitted by each one of the LEDs to project it onto a circular area of 15 cm diameter (at 40 cm from the source) with homogeneity better than 10% on the whole area and a transition to darkness smaller than 1 cm.

The BiliLED source is build with an array of 14x14 LEDs that produce a high overall spectral irradiance, as shown in Table 1 for five distances. The total spectral irradiance changes less than 30% as the distance to the source varies 10 cm around the typical 40 cm operating length, given by the baby to incubator roof distance. The BiliLED source may be conveniently placed on the transparent incubator top (eventually with antiskid separators). Figure 4 shows an early prototype, 20 cm x 21 cm x 5 cm and 800 grams. The industrial BiliLED available since 2007 weights 400 grams including the control electronics, but not the optional stand.

An interesting characteristic of the optics is that every LED of the matrix contributes by illuminating the complete treatment area. This allows to synthesize the light spectrum delivered by including LEDs of different spectra. By combining different spectra one may obtain practically any “à la carte” spectrum, resulting from a linear combination of weighted spectra [6]. This aspect of BiliLED has proved to be helpful once clinical research determines a more composite spectrum than that of figure 1. To date, only one type of LED has been used, since its wavelength matches the clinical guidelines [1].

BiliLED irradiance was measured with an ORIEL 70260 Power Meter and 70282 Photodetector in Watts (W). To measure light intensity in W/cm<sup>2</sup>, a patch with a known surface opening was affixed

onto the photodetector. Since the OREL detector is calibrated, selecting the wavelength of interest (470 nm) corrects automatically the reading, taking into account the wavelength dependent efficiency of the detector. To determine the spectral power in  $W/cm^2\ nm$ , the light intensity was divided by the LED spectral width (see figure1), as specified in the LED datasheet.

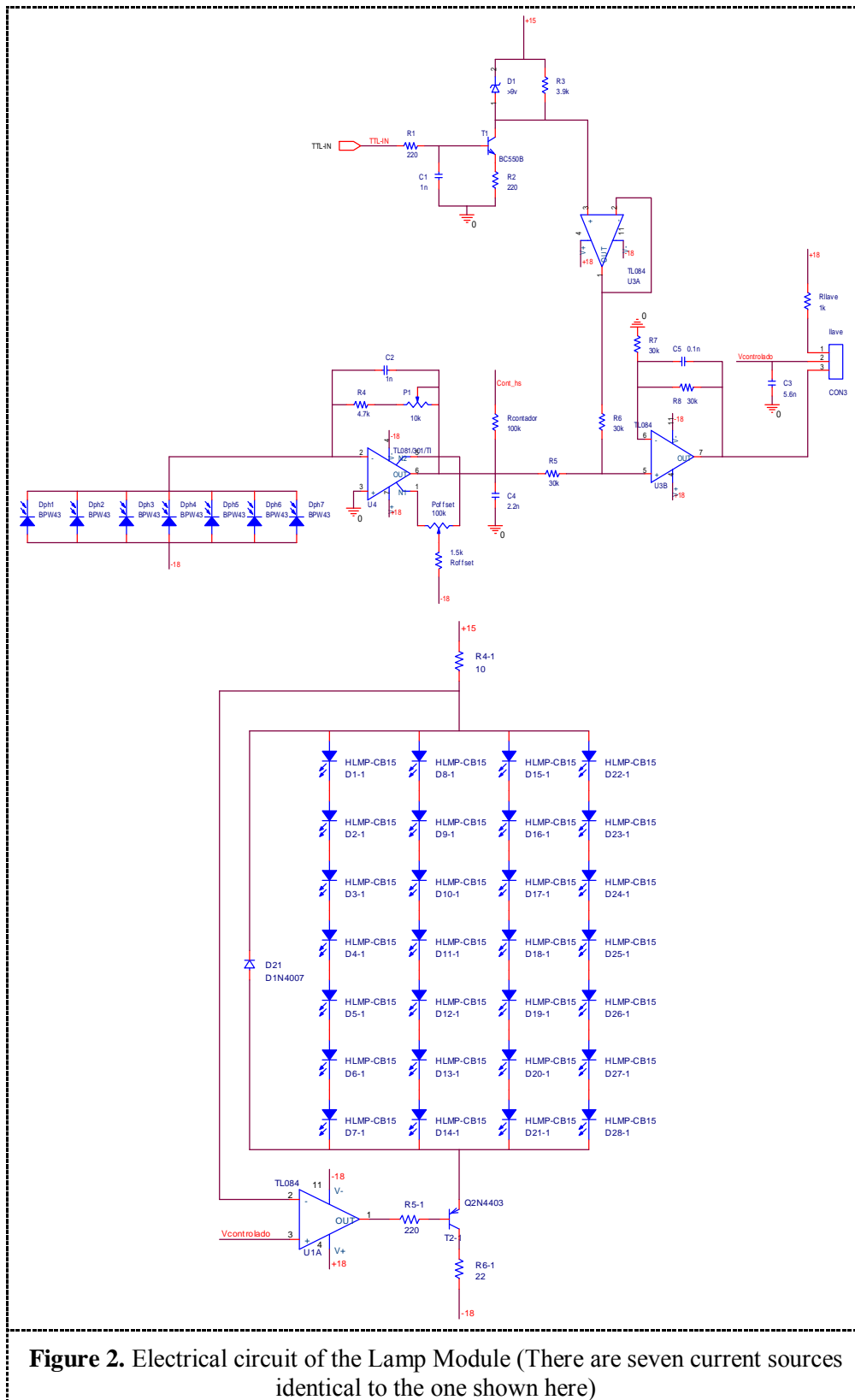
The control electronics of BiliLED allows adjusting the treatment intensity from a minimum therapeutic value up to the maximum power given in table 1. Given a distance to the baby's skin (e.g. the height of the incubator), a calibrated knob allows to attenuate the irradiance down to one eighth of full scale. At 50 cm, with the lowest power position of the knob, BiliLED delivers a calibrated phototherapy treatment as low as  $5\ \mu W/cm^2\ nm$  (1/8 of  $40\ \mu W/cm^2\ nm$ ).

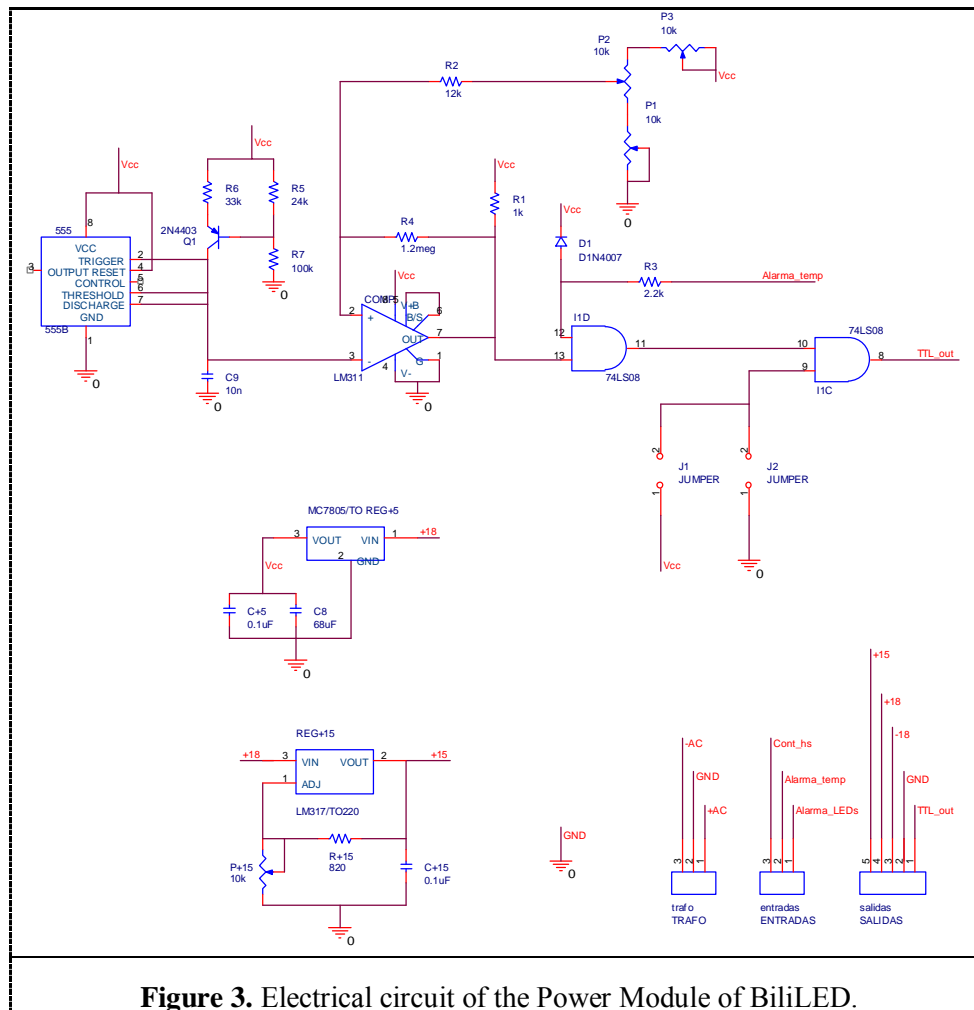
**Table 1.** Irradiance of BiliLED light source and distance to the baby

Distance to the source (cm)	Spectral Irradiance ( $\mu W/cm^2\ nm$ )
20	95
30	74
40	55
50	40
60	33

The light intensity of BiliLED is kept constant over time with an active feedback control to compensate any possible slow aging of LEDs, to reduce maintenance actions over the years. Thanks to this compensation, intensity variations are smaller than 10% throughout the operating life of the instrument. An alarm warns the operator that the LED assembly is to be replaced based on either an hour counter or a threshold reached for compensation. This mechanism frees BiliLED from checks all lamp NP instruments are submitted to periodically [1]. Despite the mean life of every LED is longer than 50.000 hours of continuous operation, the overall operating life is difficult to estimate until industrial trials and modeling are performed. BiliLED is extremely robust compared to instruments using incandescent or halogen lamps and fibre optics pads.

BiliLED includes the Lamp Module with feedback and the Power Module, pictured in Figure 2 and 3 respectively.

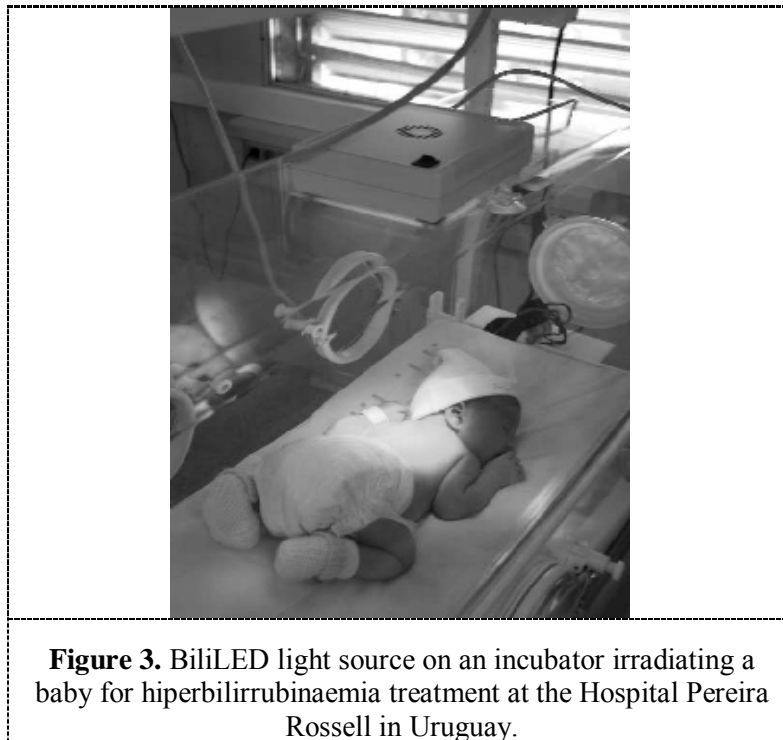




**Figure 3.** Electrical circuit of the Power Module of BiliLED.

### 3. Clinical Trials

From 2003 to 2006, four BiliLED prototypes were produced to verify the design, to refine the optics and to introduce the feedback loop and the alarm. These instruments were used at the Hospital Pereira Rossell and at the Hospital de Clínicas, both belonging to the Universidad de la República (UR), for an estimated 40.000 hours of operation. The performance of BiliLED was evaluated with a protocol on 20 new born babies of over 35 weeks of gestational age with an indication of phototherapy. Every patient had its total serum bilirubin (**TSB**) monitored, the evolution of which was adjusted to the following exponential decay:  $TSB = TSB_0 e^{-st}$ , where **TSB<sub>0</sub>** is the initial concentration and **s** the rate of decay, estimated by a mean value of  $7.10^{-3} \text{ hour}^{-1}$ , which corresponds to 16 % of TSB degraded in the first 24 hours of treatment. This figure is indicative of a very good NP instrument [1].



#### 4. Comparison of Phototherapy Instruments

Table 2 shows the result of a market research for NP instruments. Fluorescent and LED based systems are comparable, from the clinical point of view, except for the greater heat and broader spectra of the former. Halogen lamps require longer treatment times because their power is limited, so as not to overheat incubators, besides having a short life (800 hours). Since the conception of BiliLED to its industrial production, standard LEDs increased their life time from 10.000 to 50.000 hours, which is a conservative estimate for BiliLED, due to the redundancy of 196 LEDs, which will not all fail at 50.000 hours. The pad of some models [10] using fibre optics to convey light directly to the skin avoids dispersion in the ambient at the cost of a fragile unit of limited power.

Source	Spectral Power (mW/nm)	Variation ( $\Delta I / I$ ) <sup>a</sup>	Life Time (1.000 hours)	Size
Fluorescent	25	35%	9	Large
Halogen	10	50%	0.8	medium
Pad/fibber [10]	7	-	0.8	small
LED source [7]	20	30%	4	small
mini LED [8]	15	15%	3	very small
<b>BiliLED</b>	18	30%	10	very small

<sup>a</sup> variation when changing the distance to the source by 10 cm, <sup>b</sup> at 20 cm, <sup>c</sup> at 50 cm, <sup>d</sup> at 30 cm:

**Table 3.** Phototherapy with Light Emitting Diodes (LED)

	BabyBlue	NeoBlue	Billitron	BiliLED
Wavelength (nm)	450 - 470	450 - 470	400 - 550	453 - 487
Max Intensity (uWcm <sup>2</sup> nm) at 40 cm	n/a	20	50	56
Illuminated Surface (cm <sup>2</sup> ) at 40 cm	n/a	1250	707	200
Homogeneity (%)	n/a	10 %	n/a	< 10 %
Number of LEDs	640 blue	852 blue, 320 yellow, 13 red	5 blue super LEDs	196 blue
Weight (Kg)	8.3	3.6	n/a	1.4
Company	DBUP	Natus Inc	Fanem	Controles

Note: n/a is information not specified by the Company in data sheets.

Table 3 shows four LED based commercial models. The careful mechanical and optical design of BiliLED concentrates the light on the smallest surface, which also helps reduce light dispersion to ambient and increases the protection of the eyes of the baby. One model blends spectra, and two models at least double the weight of BiliLED to illuminate an unnecessarily large area, considering the size of the back of a new born baby.

### 5. From Academia to Industry

Within the mission framework of UR, with main endeavors on teaching, research and tangible contributions to society, our group has developed a number of original medical equipment to be further enhanced and used externally the academia [11]. Once BiliLED had shown its clinical effectiveness and having included suggestions derived from its use, industrial transfer was sought after patent protection was secured by UR on behalf of the individual developers [13]. It is well known that the best protection of an invention is its continuous use and perfectioning, as the mere intellectual property protection often gives away the ideas to “patent browsers”. BiliLED was therefore object of negotiations with a Uruguayan industrial company (CONTROLES [www.controles.com](http://www.controles.com)) with decades of experience on medical equipment, though mostly on industrial electronics design and production. A transfer contract was signed by UR and CONTROLES [13] giving BiliLED free of royalties unless more than 20 units are sold yearly, in which case a small percentage on sales is paid. The transfer contract included the payment of the first five instruments by UR, obtained from an AMSUD-Pasteur Program grant in 2005. CONTROLES adapted BiliLED in 2006 and put it in the regional market with success, due to a competitive price and the very low heat dissipated (less than 10 W). Before production and marketing, technical clearance from the Ministry of Health MSP [15] was obtained and similar certifications for other foreign markets are presently sought (FDA, Euro, etc.). The five BiliLED were donated in 2007 by UR to State and University Hospitals as a contribution to health care and to disseminate the new model.

### 6. Conclusions

We have obtained a NP light source specially designed with LEDs to treat neonatal jaundice. LEDs have a very long life, are robust and have a stable and defined spectrum, which are all properties inherited by the BiliLED source. The original optics developed allows to use hundreds of very low



intensity light source as building blocks of a high intensity collimated source, which delivers high irradiances at incubator distances. The light energy per unit area does not vary significantly with distance variations of the order of magnitude found in incubators. The light source life time, not considering redundancy of LED, is in excess of five years of 24 hours operation, or over a decade with a 50% clinical use mean pattern. BiliLED is the result of a close collaboration between neonatologists and engineers oriented towards both physics and biomedical applications, which gave rise to a practicality and technical soundness, not possible otherwise. BiliLED includes a careful optical design and advanced electronics for power and feedback. Finally, the industrial phase reduced the size of the power source, simplified the electronics and enhanced the mechanical robustness of BiliLED. It is noteworthy to mention that the complete project made available a reliable NP instrument for the region thanks to the convergence of several generousities: that of medical and engineering scholars, students, funding bodies and industry, all accepting risks on behalf of a common cause.

## 7. Acknowledgements

The authors thank Octavio Failache M.D., pediatrician neonatologist, for defining the first desirable characteristics of BiliLED, as a result of the disappointing results obtained in the years 2000-2003 with the instruments available. Thanks are due to Antonio Sáez for the machining and assembly of the first prototypes, to the Biomedical Engineering students Viviana Berenfus, Natalia Casas and Gabriela Rezk, supervised by Jorge Lobo, who duplicated a prototype for the Neonatology Department of the Hospital de Clínicas directed by Professor Miguel Martell M.D. who secured specific funding. A sincere acknowledgement is expressed to Beatriz Salgueiro M.D. and Gloria Sicca M.D. for the clinical data. On the industrial side, the authors thank specially Enrique Sallés and Alvaro Delacoste, directors of CONTROLES S.A. who shared the risks of BiliLED with investments for product engineering, implemented in part by Fernando Balducci. In 2007 BiliLED is under further clinical protocol use at the Hospital Escuela of Paysandú, Hospital of Maldonado, Sanatorio of the Banco de Seguros del Estado, in addition to the mentioned Hospital Pereira Rossell and Hospital de Clínicas, all in Uruguay. The authors thank in advance the nurse and medical staff of these hospitals for the information being collected to enhance furthermore the characteristics of BiliLED.

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