

# Firefly

a cost-effective, intuitive phototherapy device designed to treat newborns with mild to severe jaundice in low-resource settings



10% of all newborns worldwide require treatment for jaundice to prevent lifelong disability, severe brain damage, and death. Firefly double-sided LED phototherapy equips you to deliver high-intensity phototherapy to treat this potentially hazardous condition.

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**Firefly phototherapy was designed to fit the needs of rural health care centers, unburdening national hospitals by rapidly treating mild to severe newborn jaundice in the mother's room during the first weeks of life.**

Our key innovation is providing top and bottom phototherapy with long-life, high power LEDs, providing state-of-the-art intensive treatment in a compact package. Firefly was designed through a partnership between Design that Matters (Massachusetts, USA), East Meets West Foundation (California, USA), and Medical Technology Transfer & Services (Hanoi, Vietnam).



**Firefly is designed to function in the mother's recovery room, the best context to reduce staff workload and promote in-hospital breastfeeding.\***

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#### **Promotes In-Hospital Breastfeeding\***

Firefly is sufficiently robust and compact to install in the mother's recovery room, promoting regular breastfeeding in the first days of life. Both phototherapy and regular feeding are required to cure jaundice as phototherapy changes the bilirubin so it can be passed out through urine and stool. According to the World Health Organization (WHO), breastfeeding is one of the most effective ways to ensure child health and survival. A 2003 study in *The Lancet* showed that improved breastfeeding could save 1.3 million lives each year.<sup>2</sup>

#### **Reduces Staff Workload, Keeps Mom Comfortable\***

In facilities with low staff-to-patient ratios, Firefly supports superior patient observation by bringing the infant into the mother's recovery room. In addition, mom is able to sit or lie down comfortably instead of standing or sitting on the floor of a neonatal intensive care unit.



\* Claims soon to be studied through ongoing clinical trials.

<sup>2</sup> Jones, G. et al. How many child deaths can we prevent this year? *Lancet*. 362: 65-71 (2003).

## Firefly Key Features

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### Overall

compact form fits in an infant cart or mother's bed  
handholds facilitate easy portability  
tight seams to prevent dirt build-up  
curved surfaces for easy cleaning  
sealed to keep out most bugs, dust, and liquids  
no moving parts, no internal fans  
medical-grade power supply (not pictured)

### 1. Top Light

fixed at the most clinically effective height  
slim form for easy patient observation  
curved top prevents placement of objects that fall on infant  
soft edges to protect infant during placement

### 2. Bottom Light

durable thick-walled plastic  
tilted bottom directs heat off back edge of device

### 3. Bassinet

removable for patient transport and diagnostics  
comfortable handhold around the rim  
smooth surface for quick wipe-down  
clear scratch-resistant plastic for easy observation

### 4. Control Panel

single power button controls both lights  
single light intensity setting  
treatment hours and total device hours display



## Durable, low-power design dramatically reduces the cost to cure one infant to as low as US\$1.50.

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### Prevents a Lifelong Disability Extremely Cost-Effectively

For as little as US\$1.50 Firefly can permanently cure newborn jaundice in one infant, averting death or a lifetime of disability that places a heavy burden on both families and society. Compare with estimated treatment costs of US\$5/infant for Medela Bilibed © (fluorescent), US\$8/infant for Natus NeoBlue© overhead (LED), and US\$21/infant for Draeger Photo-Therapy 4000 (fluorescent).<sup>3</sup>

### Designed for 5 Years of Night and Day Performance

Firefly LEDs are rated to last up to 44,000 hours<sup>4</sup> before requiring replacement: 44X longer than compact fluorescent tubes that require replacement every 1000-2000 hours. In addition, Firefly has eliminated all moving parts, including fans and adjustable components, that can easily be broken. In order to prevent most insects, dust, and liquids from entering and damaging the device or dimming the lights, the outer casings have tight seams and no holes.

### Saves Energy

Operating at just 30 watts – up to 70% less than other common phototherapy systems – Firefly LED phototherapy can offer almost US\$300 in energy savings and reduce carbon footprint by 2 metric tons of CO<sub>2</sub> over the 5-year lifetime of the LEDs.<sup>5</sup>

as low as  
**\$1.50**  
per child<sup>2</sup>

\* Claims soon to be studied through ongoing clinical trials.

<sup>3</sup> Firefly cost based on Medical Technology Transfer and Services estimated purchase price with sustainable profit margins, treating 3 infants every 4 days for 5 years. Assume other devices treat 2 infants every 4 days for 5 years. All estimates include device purchase price, bulb replacement cost, electricity cost, covers. Estimates do not include hospital overhead, blood testing, service.

<sup>4</sup> Before a 30% drop in irradiance. Rating is estimated from LED manufacturer light degradation data indicating 50% drop in irradiance after 200,000 hours under specified maximum thermal operating conditions.

<sup>5</sup> Over lifetime of 44,000 hours compared to a 100 Watt phototherapy system, assuming a rate of \$0.1 per kWh of electricity. Metric tons CO<sub>2</sub> per kWh of electricity source: (EPA 2011) eGRID2010 Version 1.1, U.S. annual non-baseload CO<sub>2</sub> output emission rate, year 2007 data U.S. Environmental Protection Agency, Washington, DC.

# User-friendly and context-appropriate device design reduces referrals of otherwise healthy newborns and transforms allocation of national health resources for newborn care.\*

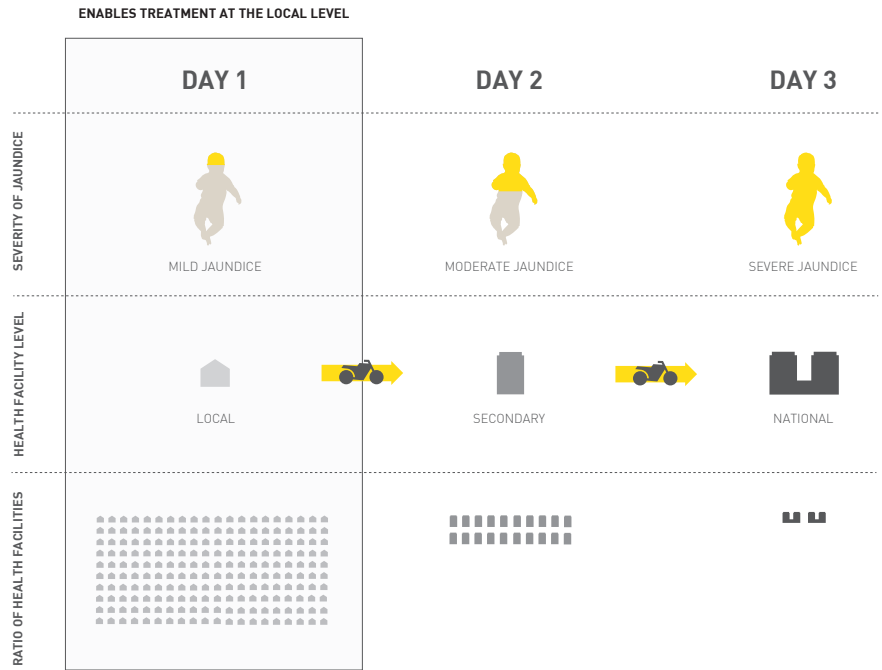
## Reduces Patient Transfer by Increasing Clinical Confidence\*

Firefly's intuitive design is intended to improve staff confidence in retaining and treating otherwise healthy newborns with jaundice in rural facilities, leading to reduced referral to higher-level hospitals and increased willingness to learn to treat additional newborn conditions at the local level.

## Transforms National Health Systems by Enabling Treatment at the Local Level\*

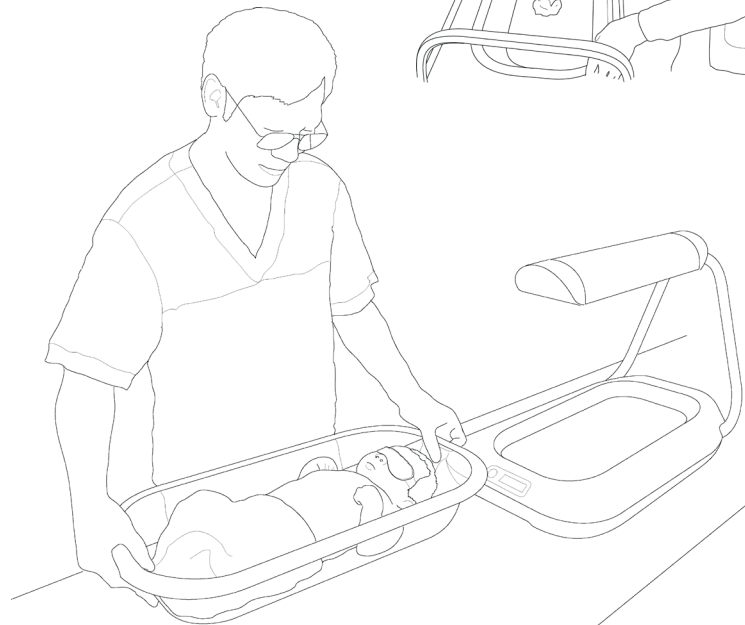
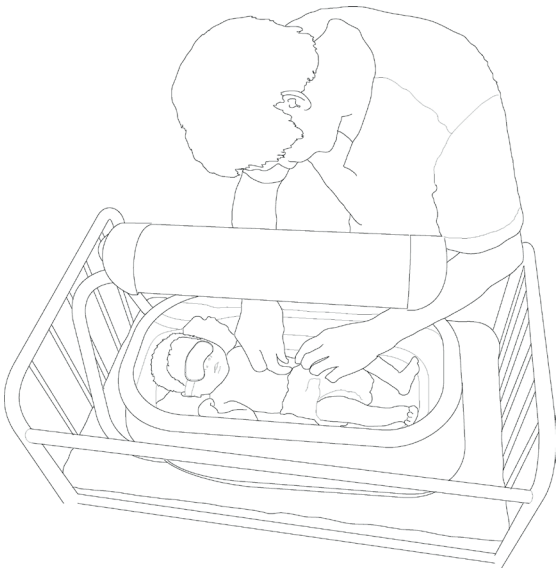
Providing care at the local level alleviates days of family travel by motorbike to distant secondary or national facilities while jaundice worsens often beyond treatment. Reducing jaundice cases at higher levels frees up resources to treat more complicated conditions, enabling the health care system to better address infant mortality and morbidity at all levels.

**COMMON INFANT JAUNDICE TRANSFER TIMELINE**



## Simple to Use, Hard to Use Incorrectly

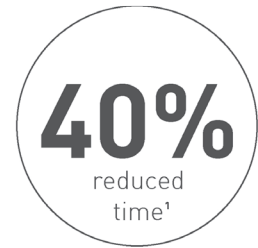
Firefly phototherapy provides one-button, above-and-below, long-life LED phototherapy at a fixed distance from the infant, eliminating the possibility that users will install the lights incorrectly, ensuring effective phototherapy regardless of infant orientation. The single-infant bassinet discourages multiple infants from sharing the treatment, which can lead to blocked light or inadequate treatment for infants on the edges. The removable bassinet with smooth surface enables comfortable infant transport, and quick cleaning between treatments to reduce spread of infection.



\* Claims soon to be studied through ongoing clinical trials.



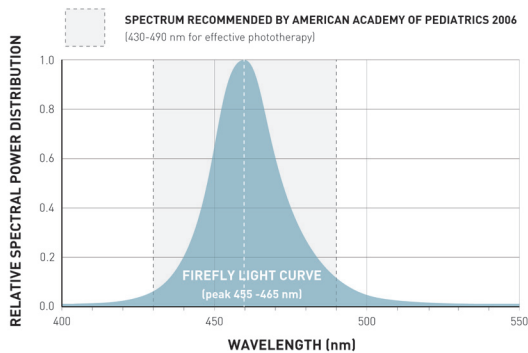
**Firefly's unique 2-sided design reduces total treatment time by 40%, allowing earlier discharge from the hospital, lowering incidence of newborn infection\* and freeing resources to treat more infants.**



**Reduces Treatment Time**

Data from 17 infant treatments predict Firefly reduces treatment time for a typical patient by at least 40% compared to state-of-the-art single-sided LED phototherapy.<sup>1</sup> Reduced treatment time means discharge from the highly infectious hospital environment and into the safer home environment after 20 hours instead of the typical 35 hours or often much longer in low-resource settings.

**Optimal Emissions Spectrum**



**Lowers Incidence of Infection\***

The longer an infant stays in the hospital, the more likely they are to contract an infection. Firefly's reduced treatment time combined with its easy-to-clean, removable, single-infant bassinet are designed to reduce spread of infection from infant to infant.

**Decreases Number of Exchange Blood Transfusions\***

Intensive two-sided LED lighting makes Firefly one of the most effective phototherapy devices in the world, with the potential to avoid costly and dangerous exchange blood transfusions by treating the most severe cases of jaundice.

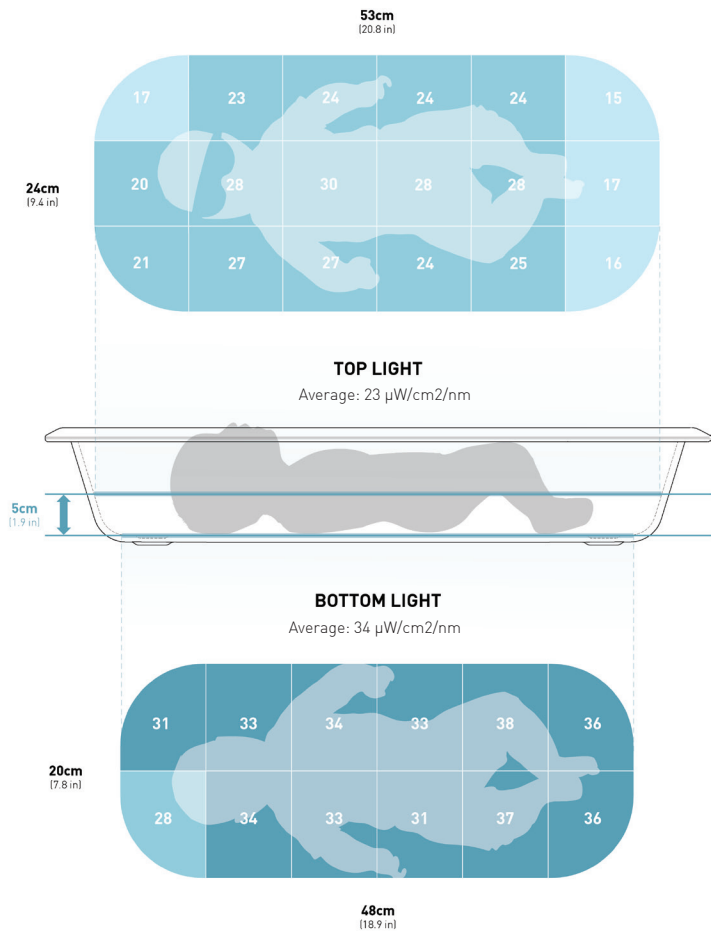
**Treats More Infants**

Reduced treatment time makes hospital resources available to more children. Typical treatment time in many hospitals is even longer than 35 hours due to expiring halogen or fluorescent bulbs, and placing multiple infants under a single light that only provides clinically effective treatment to the patient in the center.

**Sends Families Home Earlier**

Earlier hospital discharge reduces family medical costs, allowing the family to return to work and the mother to breastfeed and bond with her child at home.

**Two-Sided Irradiance Footprint**



**IRRADIANCE**  
µW/cm²/nm

|         |           |
|---------|-----------|
| 10 - 20 | Standard  |
| 20 - 30 |           |
| 30 - 40 | Intensive |

**Measurement method**

Measurements taken in center of each region with Ohmeda Biliblanket Light Meter II™. Bottom light irradiance measured on inside bottom of infant bed, top light irradiance measured on a plane 5cm above. Regions determined by phototherapy international standard IEC 60601-2-50.

\* Claims soon to be studied through ongoing clinical trials.

<sup>1</sup> Firefly data from 17 infant treatments with average initial TSB 305 µMol/L (17.8 mg/dL) yielded median serum bilirubin reduction rate of -6.7 µMol/L/hr [-0.39 mg/dL/hr]. Multiple linear regression of Firefly data based on study of 66 infants in 2-sided phototherapy predicts Firefly rate of -5.3 µMol/L/hr [-0.31 mg/dL/hr] given initial TSB of 265 µMol/L (15.5 mg/dL) [Maisels, M.J., et al., Randomized controlled trial of light-emitting diode phototherapy. Journal of Perinatology, 2007. 27(9): p. 565-7]. Single-sided LED phototherapy average total serum bilirubin reduction rate of -3.0 µMol/L/hr [-0.18 mg/dL/hr] determined from 5 randomized control trials with 262 patients undergoing LED phototherapy and 280 patients undergoing Fluorescent or Halogen phototherapy, average initial TSB of 275 µMol/L [Seidman 2000, Seidman 2003, Martins 2007, Bertini 2008, Kumar 2010].



## Performance Specifications

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|                                    |              |   |                                   |
|------------------------------------|--------------|---|-----------------------------------|
| <b>Illumination source</b>         |              | High-power blue LEDs, 1-1.25W standard operating  |                                   |
| <b>Peak wavelength range</b>       |              | 455-465 nm  |                                   |
| <b>Lamp duration</b>               |              | LEDs rated to last 44,000 hours at max temp       |                                   |
| <b>Average spectral irradiance</b> | top light    | 23 $\mu\text{W}/\text{cm}^2/\text{nm}$            | Measured with:                    |
|                                    | bottom light | 34 $\mu\text{W}/\text{cm}^2/\text{nm}$            | Ohmeda Biliblanket Light Meter II |
| <b>Effective surface area</b>      | top light    | 53 cm x 24 cm                                     | 20.9 in x 9.4 in                  |
|                                    | bottom light | 48 cm x 20 cm                                     | 18.9 in x 7.8 in                  |
| <b>Irradiance Uniformity Ratio</b> | top light    | 0.51 (IEC Compliant >0.4)                         |                                   |
|                                    | bottom light | 0.72 (IEC Compliant >0.4)                         |                                   |
| <b>Time totalizer</b>              |              | Device run time totalizer, therapy time totalizer |                                   |

## Physical Specifications

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|                           |              |  |                        |
|---------------------------|--------------|--|------------------------|
| <b>Key features</b>       |              | No moving parts<br>Enclosure designed toward NEMA Type 5 |                        |
| <b>Dimensions (LxWxH)</b> | overall      | 66 cm x 38 cm x 49.5 cm                                  | 26in x 15in x 19.5in   |
|                           | top light    | 51.6 cm x 12.5 cm x 6.3 cm                               | 20.3in x 4.9in x 2.5in |
|                           | bottom light | 64.7 cm x 38 cm x 10 cm                                  | 25.5in x 15in x 3.9in  |
| <b>Total unit mass</b>    |              | 11.8 kg  | 26lbs                  |

## Electrical Specifications

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|  |   |
|--|---|
| <b>Power characteristics</b>               | 30W max, 24VDC input  |
| <b>Off-the-shelf external power supply</b> | 60W, 90-264VAC, 47/63Hz<br>International medical safety approvals<br>78-84% efficiency<br>No minimum load requirements<br>Class I construction is standard (ground required)<br>Optional class II construction (no ground required)<br>50k hours MTBF<br>CEC and Energy Star Efficiency Level IV compliant<br>RoHS compliant<br>EN6100-3-2 compliance active power correction<br>Over voltage / over current protection<br>Class B emissions<br>UL94V-1 rated enclosure |
| <b>Overheat protection</b>                 | $\geq 65^\circ\text{C}$   |

## Environmental Specifications

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|                              |   |
|------------------------------|---|
| <b>Operating</b>             | Ambient temperature: $+10^\circ\text{C}$ to $+28^\circ\text{C}/+35^\circ\text{C}^*$<br>* tested in environment up to $28^\circ\text{C}$ ,<br>designed to treat infants in environments up to $35^\circ\text{C}$<br>Humidity: 0% to 90% RH non-condensing<br>Atmospheric pressure: 70-106kPa |
| <b>Transport and storage</b> | Ambient temperature: $+10^\circ\text{C}$ to $+85^\circ\text{C}$<br>Humidity: 0% to 90% RH non-condensing<br>Atmospheric pressure: 70-106kPa   |
| <b>Exclusions</b>            | Not for use inside an incubator   |

## Standards for Reference

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We referred to the following standards to guide the Firefly design:

IEC 60601-1:2005: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-2-50:2009: Medical Electrical Equipment - Part 2-50: Particular requirements for the safety of infant phototherapy equipment

## About Design that Matters

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Design that Matters (DtM), a non-profit based in Cambridge, Massachusetts, forms cooperative partnerships with organizations in developing countries to create world class products, enabling them to offer improved services and scale. A trail-blazer in creating designs for social impact, DtM has built a state-of-the-art open and collaborative design process through which hundreds of volunteer and reduced-rate collaborators in academia and industry donate their expertise and resources to the creation of breakthrough products for communities in need.

Our deep commitment to social impact compels us to partner with organizations that have extensive local community connections and proven ability to make and distribute solutions with systemic effects. Over the past decade, with the help of over 850 collaborators, DtM has transformed each of our partner organizations through the launch of products that improve the quality of life for beneficiaries in Africa and Asia, and has inspired countless others to do the same.

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14 May 2012.

