

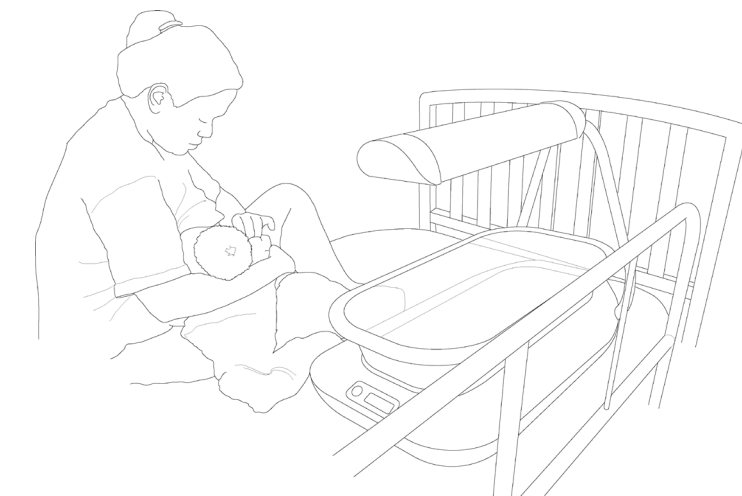
Firefly

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 severe brain damage, lifelong disability, and death. Firefly's high-intensity double-sided LED phototherapy equips you to treat this potentially hazardous condition.

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.*

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.¹ 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.² A 2003 study in The Lancet showed that improved breastfeeding could save 1.3 million lives each year.³

Reduces Staff Workload, Keeps Mom Comfortable*

In crowded facilities with limited staff, Firefly is designed to support 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.¹

* Claims soon to be studied through ongoing clinical trials.

¹ During 2012, Firefly treated 3 infants on the mother's bed in Vietnam and the Philippines.

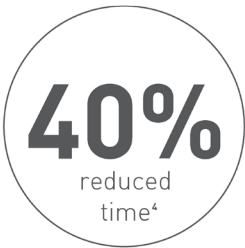
² <http://www.who.int/features/factfiles/breastfeeding/en/index.html>

³ Jones, G. et al. How many child deaths can we prevent this year? Lancet. 362: 65-71 [2003].

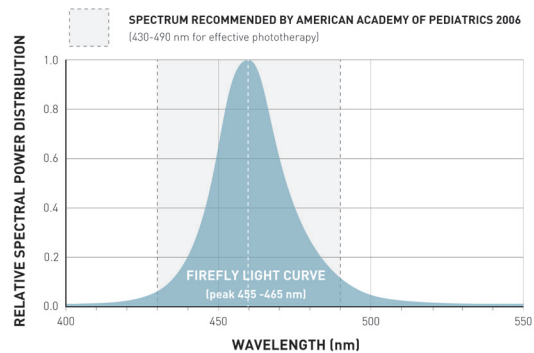
In one study, Firefly’s unique 2-sided design reduced total treatment time by 40%, showing potential for earlier hospital discharge, lower incidence of newborn infection and freeing resources to treat more infants.*

Shown to Reduce Treatment Time

A 2011 Clinical Evaluation of 17 infant treatments indicated Firefly reduces treatment time for a typical patient by at least 40% compared to state-of-the-art single-sided LED phototherapy.⁴ Reduced treatment time meant discharge from the highly infectious hospital environment after 20 hours on average instead of the typical 35 hours or often much longer in low-resource settings.



Optimal Emissions Spectrum



Shown to Decrease Number of Exchange Blood Transfusions

Intensive two-sided LED lighting makes Firefly one of the most effective phototherapy devices in the world. In one study, Firefly allowed some patients with severe jaundice to avoid exchange transfusions, an expensive, high risk treatment of last resort at risk of developing hyperbilirubinemia and kernicterus.⁵

Designed for More Efficient Treatment*

Reduced treatment time makes hospital resources available to more children. Typical treatment time can extend for days due to expiring halogen or fluorescent bulbs, and to hospitals placing multiple infants under a single light that can only provides clinically effective treatment to the patient in the center.

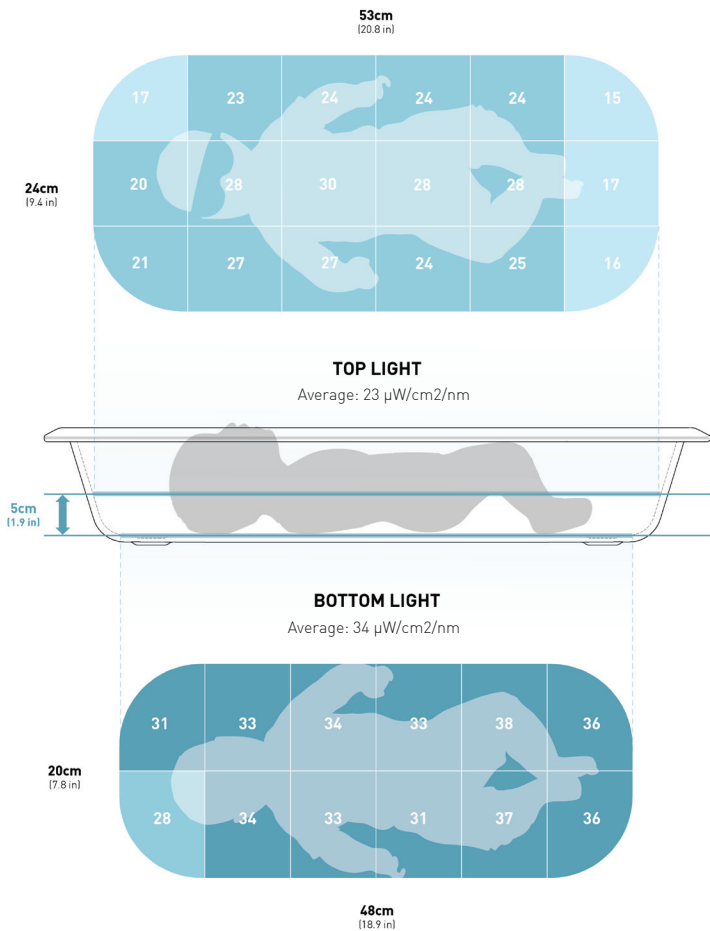
Designed to Lower Incidence of Infection*

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

Designed to Send 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	

American Academy of Pediatrics 2006 definitions

Measurement method

Measurements of one device 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. Region sizes determined by phototherapy international standard IEC 60601-2-50.

* Claims soon to be studied through ongoing clinical trials.

⁴ 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].

⁵ As of July 18, 2012, local clinical trial doctors report 3 out of 55 infants treated with Firefly would have had to undergo an exchange blood transfusion if Firefly had not been available.



Firefly Key Features

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.

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 2012 Medela Bilibed ® (fluorescent model 038.4001); US\$8/infant for 2012 Natus NeoBlue® overhead (LED model 010066); and US\$21/infant for 2012 Draeger Photo-Therapy 4000 (fluorescent model 2M 22 310).⁶

as low as
\$1.50
per child⁶

Designed for 5 Years of 24-Hour Operation

Firefly's high-power LED lights are rated to last up to 44,000 hours⁷ before requiring replacement, while compact fluorescent tubes require replacement every 1000-2000 hours. In addition, Firefly has eliminated all moving parts which can easily be broken including fans and adjustable components. The outer casings have tight seams and no holes in order to prevent most insects, dust, and liquids from entering and damaging the device or dimming the lights.

Saves Energy, Saves Money

Firefly's low-power, high-intensity LED lights operate with only 30 watts. Firefly can offer as much as US\$300 in energy savings and reduce carbon footprint by 2 metric tons of CO₂ over the 5-year lifetime of the LEDs compared to conventional 100W phototherapy systems.⁸

* Claims soon to be studied through ongoing clinical trials.

⁶ 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.

⁷ 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.

⁸ 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 CO₂ per kWh of electricity source: (EPA 2011) eGRID2010 Version 1.1, U.S. annual non-baseload CO₂ output emission rate, year 2007 data U.S. Environmental Protection Agency, Washington, DC.

User-friendly and context-appropriate device is designed to reduces referrals of otherwise healthy newborns and transform allocation of national health resources for newborn care

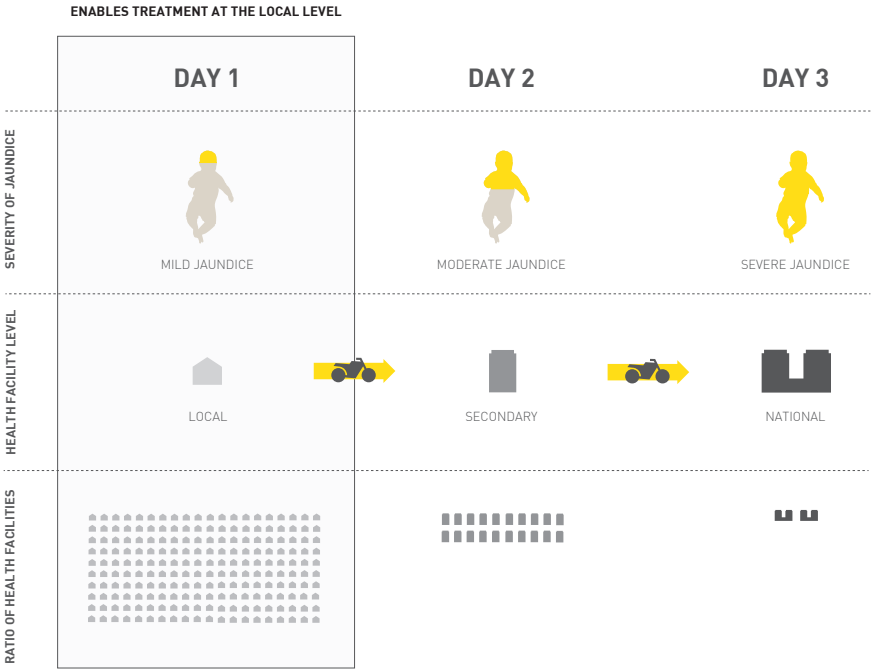
Designed to Reduce Patient Transfer by Increasing Clinical Confidence*

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.

Designed to Transform National Health Systems by Enabling Local Level Treatment*

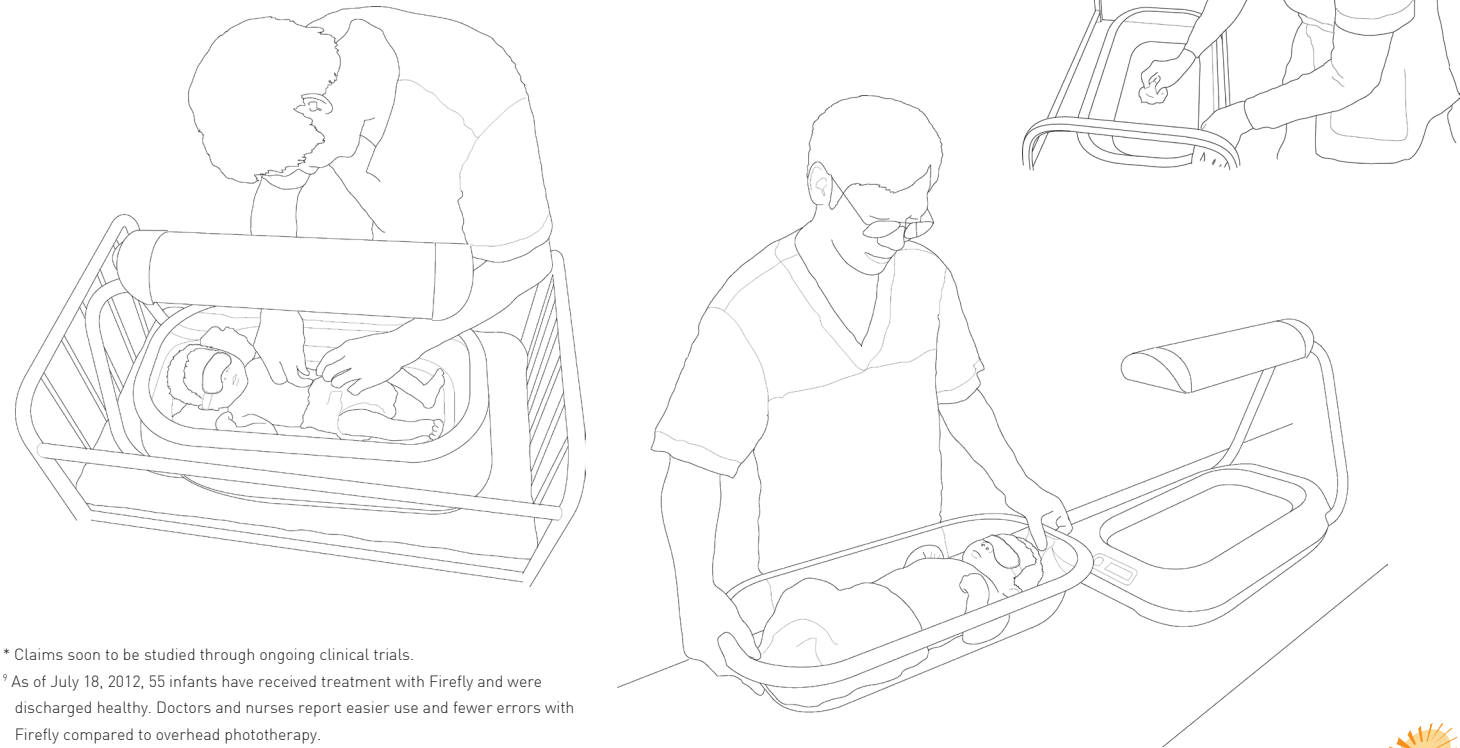
Providing care at the local level alleviates days of family travel by motorbike to distant secondary or national facilities while jaundice worsens often beyond treatment. Reducing jaundice cases at higher levels frees up resources to treat more complicated conditions, enabling the health care system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

COMMON INFANT HOSPITAL TRANSFER TIMELINE



Simple to Use, More Difficult to Use Incorrectly

Firefly phototherapy provides one-button, above-and-below, long-life LED phototherapy at a fixed distance from the infant, eliminating incorrect user installation, better ensuring effective phototherapy regardless of infant orientation. The single-infant bassinet is designed to discourage 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 is designed for comfortable infant transport, and quick cleaning between treatments to reduce spread of infection.⁹



* Claims soon to be studied through ongoing clinical trials.
⁹ As of July 18, 2012, 55 infants have received treatment with Firefly and were discharged healthy. Doctors and nurses report easier use and fewer errors with Firefly compared to overhead phototherapy.



Performance Specifications

Illumination source		High-power blue LEDs, 1-1.25W standard operating	
Peak wavelength range		455-465 nm	
Lamp duration		LEDs rated to last 44,000 hours at max temp	
Average spectral irradiance	top light	23 μW/cm2/nm	Measured with:
	bottom light	34 μW/cm2/nm	Ohmeda Biliblanket Light Meter II
Effective surface area	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
Irradiance Uniformity Ratio	top light	0.51 (IEC Compliant >0.4)	
	bottom light	0.72 (IEC Compliant >0.4)	
Time totalizer		Device run time totalizer, therapy time totalizer	

Physical Specifications

Key features	No moving parts Enclosure designed toward NEMA Type 5		
Dimensions (LxWxH)	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
Total unit mass		11.8 kg	26lbs

Electrical Specifications

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

Environmental Specifications

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

Standards for Reference

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

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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