

Firefly Phototherapy Case Study

April 2016



Index

I. Developing A Point of View for Firefly

- The need: to achieve positive social impact, always start with a need (not just a desire).
- The users: who are the end users? What other stakeholders must be satisfied?
- The context: where and when will your design be used? What else must it interface with?

II. Rapid Prototyping for Refining Product Design

- Avoiding overheating in the pursuit of cozy babies
- Getting the size just right
- Avoiding bumps and bruises
- Many settings, or no settings?
- Finding firefly's home
- Bringing mom and baby together

III. Safety and Regulations

- A more sustainable cooling solution
- A more robust electrical system

With visionary support from The Lemelson Foundation 2011-2013, Design that Matters formed a partnership with Thrive Networks (formally known as East Meets West) and Vietnamese manufacturer Medical Technology Transfer and Services to invent, design, test, manufacture, and deliver innovations to serve the needs of poor communities around the world. Our first product is Firefly Newborn Phototherapy, a world-class technology to treat newborns with jaundice. Firefly has won many awards including the Edison Award Gold, the top Spark! design award, IDSA IDEA Silver, and was featured in the October 2013 Fast Company Innovation by Design Award issue. Firefly is listed in the 2013 World Health Organization Compendium of Medical Devices highlighting the most innovative health technologies for low resource settings. As of April 2016, Firefly devices have treated over 40,000 newborns in twenty developing countries across Asia (Cambodia, East Timor, Laos, Malaysia, Mongolia, Myanmar, Nepal, Philippines, Singapore, Thailand, Vietnam), sub-Saharan Africa (Benin, Burundi, Ghana, Nigeria, Somaliland, Tanzania, Uganda, Zimbabwe) and the Caribbean (Haiti). Together, we expect to distribute at least 1,000 Firefly devices, reaching over 500,000 newborns.



I. Developing A Point of View for Firefly

At the beginning of each new project, Design that Matters creates a point of view statement to focus the project on the need, users, and contexts will be included AND excluded from our design. During Project Firefly, we focused on treating otherwise healthy newborns with jaundice using a phototherapy device that rural district hospital staff with little training could use in the mother's room. Our evolving point of view statement was an invaluable tool to guide the design and invention process and create agreement between partners.

- **The need: to achieve positive social impact, always start with a need (not just a desire).**
- **The users: who are the end users? What other stakeholders must be satisfied?**
- **The context: where and when will your design be used? What else must it interface with?**

You may be familiar with the saying “Design for everyone is design for no one.” At the beginning of each new project, Design that Matters creates a point of view statement to focus the project on the specific need, users, and contexts we will and will NOT design for. During the design of Firefly Newborn Phototherapy, the point of view was an invaluable tool helping us build agreement about project purpose with our implementation partner, Thrive Networks (formally known as East Meets West), and our Vietnamese manufacturing partner, Medical Technology Transfer and Services (MTTS). We focused on treating otherwise healthy newborns with jaundice using a phototherapy device that rural district hospital staff with little training could use in the mother's room.

What Is the Need?

Beginning at the Firefly kick-off meeting, we talked with our manufacturing and implementation partners about whether they envisioned our phototherapy device would treat all jaundiced newborns, or a subset. Approximately 10% of all newborns require phototherapy for jaundice. Some jaundiced newborns have other health conditions in addition like respiratory distress, infection, or complications due to prematurity. Because of this, we would have to marry a lot of constraints in attempting to provide phototherapy to newborns with the widest array of conditions. For example, we would need to ensure the design could fit inside or around an incubator, a device created to keep the sickest babies warm.

Thrive Networks found that around one third of babies in overcrowded national-level Neonatal Intensive Care Units were otherwise healthy newborns with jaundice. These babies were sharing beds and overhead phototherapy lamps with a rotating cast of other newborns, some with infections. The babies were often blocking the light or rolling out of the effective area of the light. Most overhead phototherapy lamps were designed to cast a light on a bed big enough for only one newborn.

Result: In the end, we were all happy that we had focused on otherwise healthy newborns. Departing from designing around an incubator enabled us to create a device that holds only one newborn directly under the lights, increasing effectiveness and possibly decreasing spread of infection.



Top: Two infants share an incubator while receiving phototherapy from an overhead lamp. Bottom: A nurse places a newborn into Firefly.



Who Are the Users?

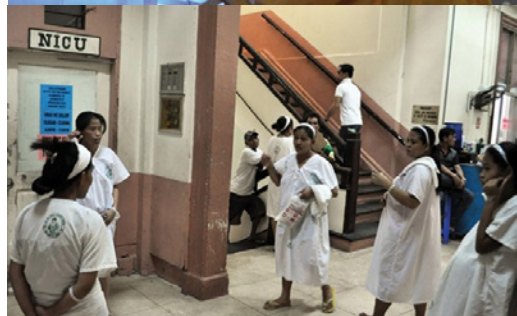
When we began designing Firefly together, Thrive Networks had already provided training and equipment to the over 100 national and provincial level hospitals in Vietnam. They hoped a new, simpler phototherapy device could enable them to expand their Breath of Life newborn health program into rural district hospitals, the lowest level of hospital providing overnight care. They planned to provide training and equipment, but were worried about how best to instill confidence in staff members at these hospitals who may be accustomed to sending all newborns in need of treatment to higher level hospitals. As Luciano Moccia, director of the East Meets West Breath of Life program noted, “Phototherapy will only work in hospitals with the confidence to treat babies.” How could the newly-designed phototherapy device help doctors and nurses with little experience treating jaundice feel good about providing treatment after the trainers had left?

We noticed some interesting behaviors during observations. First, when given a phototherapy device with multiple settings, health care providers in the same hospital had different approaches to choosing power levels for newborns. Second, we would sometimes see newborns lying under phototherapy lamps with a blanket covering them for warmth, blocking the light from reaching their skin. Third, doctors and nurses reported flipping the babies like burgers on a grill to ensure both sides were sufficiently exposed to the light. Ideal phototherapy shines as much blue wavelength light over as much skin as possible. The light passes through the skin to alter a chemical in the blood called Bilirubin so that it can pass through the baby via the urine and stool. Given that blood circulates, it is not necessary to flip the baby to expose different parts of the skin.

Result: Because of these observations, we simplified the device to go beyond just user-friendly—we made it hard to use wrong.



Top: One of nine rooms with 150 newborns at the Neonatal Intensive Care Unit in National OBGYN Hospital, Vietnam. Bottom: A midwife shows all the equipment she possesses at Tonlebaty, a rural clinic in Cambodia.



Top: Mothers who have recently received c-sections wait outside the NICU to breast feed their babies at Philippines. Bottom: A mother who has recently given birth stands to comfort her baby who receiving overhead phototherapy in Vietnam.

What Is the Context?

Throughout the field research process, we couldn't help but notice how jaundice treatment separated moms and babies during the earliest days of life. In one of the smallest rural hospitals we visited, the nurse confided that she sometimes was the only nurse for the entire hospital during the night. If a baby was receiving phototherapy in the Neonatal Intensive Care Unit, she may not have time to bring the newborn to mom to breast feed all night. Newborns need to eat every 2-3 hours and effective jaundice therapy requires both phototherapy and hydration to produce urine and stool to flush the bilirubin from the body. We saw a tremendous opportunity for technology to facilitate a new treatment context for otherwise-healthy newborns with jaundice in mom's room.

We considered many other possible contexts in conversations with our manufacturing and implementation partners. What about using it in a vehicle to transport jaundiced newborns? Or using in a high-level hospital Neonatal Intensive Care Unit? We explained that planning for these disparate environments would so totally change the design that it could end up not fitting well in any context. We ultimately maintained our focus on mom's room and we are happy with the result!

Result: We created a smaller, more portable device compared to traditional overhead phototherapy that can fit in the room with mom, uniting mother and baby for better bonding, breast feeding, and monitoring.



II: Rapid Prototyping For Refining Product Design

Rapid prototyping is a core human-centered design (HCD) skill. Design that Matters uses prototypes to better communicate with stakeholders across languages and cultures, quickly testing assumptions to efficiently converge on a final solution. This section includes six examples of insights we gained using prototypes.

- **Avoiding overheating in the pursuit of cozy babies**
- **Getting the size just right**
- **Avoiding bumps and bruises**
- **Bringing mom and baby together**
- **Finding firefly's home**
- **Many settings, or no settings?**

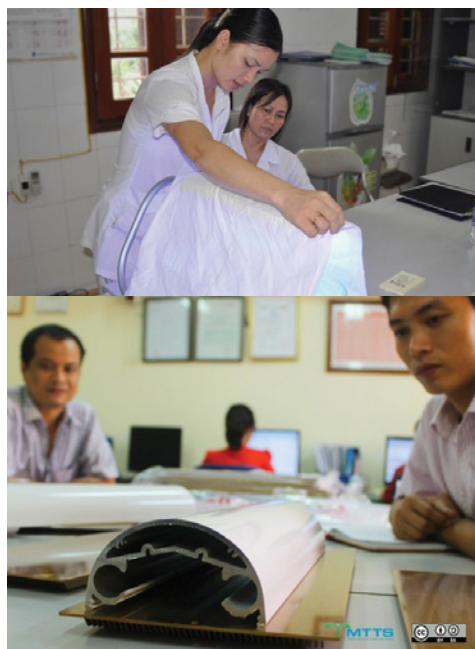
“Fail early to succeed sooner” is a common mantra in the product design world. When you are creating something new and innovative, you take risks. It’s important to test your riskiest assumptions early and often to avoid expensive failures. Prototyping is a great tool for communicating ideas early to get critical feedback from end-users. In designing Firefly, we shared ideas early and often—this helped us work with users of a different culture and language, as well as working in a medical context with which we had little personal experience. hospital staff with little training could use in the mother’s room.

After gaining concept feedback from our manufacturing and implementation partners as well as eighty-eight doctors and nurses at Thrive Networks’ Jaundice Conference in Central Vietnam, we created an alpha prototype. This prototype had “looks-like” aspects of our chosen design: a small and thin top light to provide phototherapy while still allowing good patient visibility, a large base light and a removable clear baby bed, called the bassinets, which would hold the baby right over the light. For lighting, we worked with a noble DtM volunteer who quickly wired together some generic blue LED lights and some white lights to three buttons. Separately, we created a series of concept button graphics and button configurations that could control the lights in different ways. We also brought along a life-size newborn doll for people to simulate use with the prototype. The insights we gained by showing the Firefly alpha prototype to doctors, nurses, technicians, parents and babies at seven hospitals in Vietnam were key to designing the final product which is currently in-use in seven countries.

Avoiding Overheating in the Pursuit of Cozy Babies

At many hospitals we visited, nurses indicated that they would want to drape a sheet over Firefly’s top light to minimize air flow over the baby and keep the baby warmer. Other doctors and nurses we met commonly draped overhead phototherapy devices to keep the light from bothering bystanders’ eyes. What they didn’t know is that draping any of these devices impairs the device’s ability to cool the electronics. This can lead to a variety of ill effects including reducing light bulb life, dim ineffective phototherapy, overheating the baby, or even fire in very extreme cases.

Result: We designed the top light out of thick aluminum and mounted the electronics and lights directly onto it, drawing the heat from the electronics up and away and keeping it cool even when covered by a sheet or blanket.



Left: A nurse uses our alpha prototype to show how she would drape Firefly to keep the light from bothering bystanders, and to keep the baby warmer.

Left: The resulting top light is made of thick metal to ensure heat can escape even when draped.



Getting the Size Just Right

We asked health-care providers whether they thought the bassinet would be cozy for a small newborn, but still comfortably fit a large newborn. Luckily, one of the tallest women in Vietnam was at one of the hospitals the day we visited. She consented to put her big, healthy baby briefly into the bassinet. Sure enough, it was a very tight fit. Other health care providers commented that the walls seemed to be too low for comfort and too steep to easily access the baby for procedures like a blood draw.

Result: We went back to the drawing board, gathering statistics on typical newborn sizes, and resizing the bassinet and the entire device to fit a 90th percentile baby.



We were lucky to meet a tall mom and her above average baby early in the process so we could discover that our bassinet was too small.

Avoiding Bumps and Bruises

We asked doctors, nurses, and parents to try taking a doll in and out of the Firefly alpha prototype to see how they would do it. Even though the bassinet was removable, most preferred to take the baby directly in and out of the device while keeping the bassinet in place. They explained there isn't a lot of space in a Neonatal Intensive Care Unit, especially not tabletop space where they could put the bassinet. However, the top light was so low that our baby doll was getting a lot of bumps and bruises along the way.

Result: We used a tape measure to simulate different light heights and had a variety of health care providers put the baby in and out until we had consensus on the right height. We adjusted the height of the top light higher in the final design.



Left: A mother bumps the baby doll's head while lifting it out of the alpha prototype. Right: A mother safely and comfortably lifts her baby in and out of the final Firefly device with raised top light.



Bringing Mom and Baby Together

One of our hopes was for the new design to be used in the room with mom, bringing mom and baby together for breast feeding, bonding, and to better watch over the baby. Luckily an intrepid mom was willing to give it a try. We placed the device next to her on the bed and she lay next to it with the lights on. She reported that she could lie comfortably next to it and it wasn't too bright for her eyes. She also indicated that she loved the idea of having her baby close during treatment.

Result: We maintained a similar device configuration to enable it to fit on mom's bed.

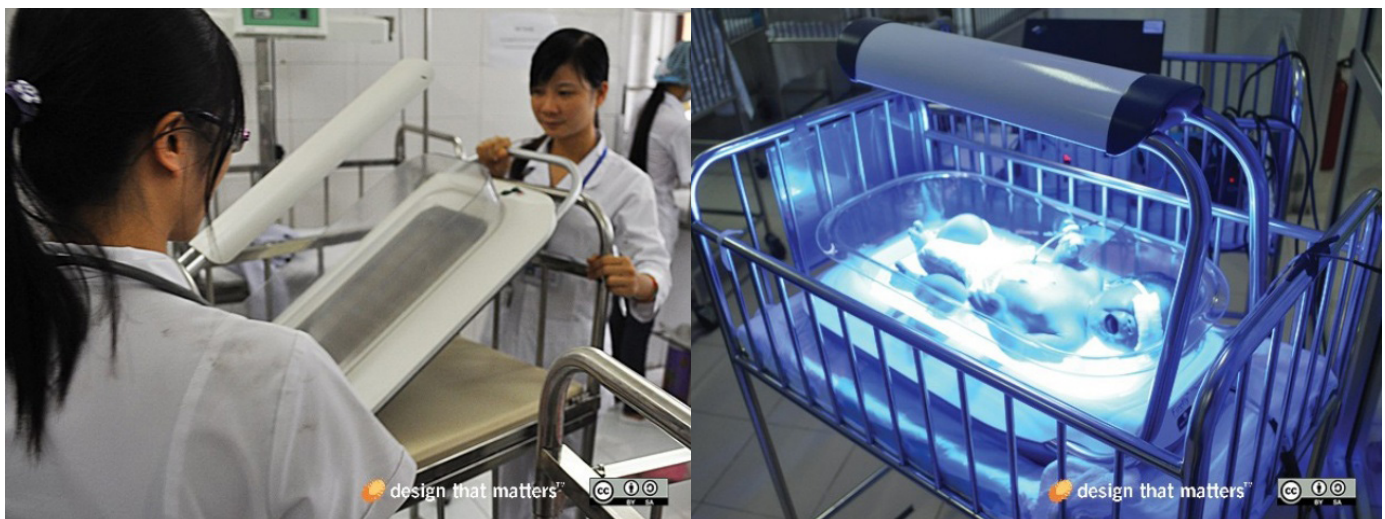


Left: A mother provides positive feedback while lying next to the Firefly alpha prototype in bed with the light turned on. Right: In the Philippines, the first mother and baby benefit from treatment in mom's room.

Finding Firefly's Home

Neonatal Intensive Care Units (NICU) in low resource hospitals are busy places. At National OBGYN Hospital in Hanoi, where the first baby was treated with Firefly, there were 9 rooms and 150 newborns. At all the hospitals we visited across many countries, one of the scarcest resources was counter space. When we asked nurses to show us where they would keep Firefly in the NICU, she picked it up and tried placing it in one of the standard infant cots. Unfortunately, the device was just a couple inches too long to fit inside the rails! The experience repeated itself at hospital after hospital. There was a standard-sized infant cot, so we took measurements.

Result: We ensured the final design would not be so long, and that it would leave extra room to hold onto the device while lifting it in and out of a typical infant cot.



Left: Nurses in Vietnam discover the Firefly alpha prototype is too long after attempting to put it on their typical infant cot. Right: The final Firefly design fits neatly within the typical-sized cot in Vietnam.



Many Settings, or No Settings?

We asked health care providers at each hospital to consider a variety of different lighting control options. The main question: did most health care providers want multiple levels of brightness, and separate control of the top and bottom lights, or just one button that could turn both lights on and off with a single brightness? The various buttons and icons led to a discussion about the settings they used on their current overhead phototherapy devices. Most existing devices offered either two or three different brightness levels. Through these interviews, we discovered even staff at the same hospital had different approaches to which brightness setting they would choose. Some would always leave the phototherapy on low because they wanted the bulbs to last longer; others would occasionally put it on high for patients with severe jaundice; and still others had never realized there were multiple settings to choose from. In multiple hospitals, we noticed newborns laying under white lights and looked closer to find the device included an option for a white observation light. At one hospital, I asked the nearest nurse if she knew the child was not receiving treatment. She explained to me that this was a white light phototherapy unit. Unfortunately, the overwhelmed staff had never discovered that they were not providing any phototherapy because the device had always been in patient observation mode.

Result: Given that there is no known way to overdose on phototherapy, we wanted to give every baby the best chance at a successful treatment. We decided to provide one button and one power setting with both lights providing intensive phototherapy. We also excluded the white patient observation light.



Top: Health care providers in Vietnam consider an array of different button option on paper. Bottom: The resulting simple, one-button Firefly control panel.



III: Safety and Regulations

Does United States FDA regulatory approval mean a medical device is safe and effective in low resource settings? The short answer is no. In developing countries, 95% of western medical equipment is broken within 5 years. In fact, only 30% of this donated equipment is ever even turned on. To enable Firefly phototherapy to work well in remote hospitals, we had to develop a novel cooling solution and a more robust electrical system that exceed FDA requirements.

- **A More Sustainable Cooling Solution:** Firefly uses a unique fully-sealed design with no moving parts to keep cool and use less energy in hot climates.
- **A More Robust Electrical System:** Firefly uses an external power supply so it can continue functioning during wide power fluctuations.

One of the common questions I am asked when I tell someone I am designing a medical device for the developing world, is whether we will be seeking FDA approval. The United States Food and Drug Administration (FDA) regulates medical devices ranging from complicated, high-risk medical devices, like artificial hearts, to simple, low-risk devices, like tongue depressors, as well as devices that fall somewhere in between, like sutures. FDA can regulate medical devices before and after they reach the marketplace.

Europe requires medical devices to get CE Mark certification. These requirements mainly focus on quality manufacturing processes and design practices like choosing safe materials and minimizing radiation coming from a device. In contrast, gaining FDA approval allowing use in the United States is known to be the most expensive and time-intensive medical device regulatory process in the world because of the unique requirement to evaluate efficacy.

For example, take the bank of broken, high-tech newborn incubators I saw while visiting National OBGYN Hospital, Vietnam. Our extended Firefly team was preparing to treat the first patient in the nine-room Neonatal Intensive Care Unit (NICU). The Firefly room was also used to observed all newborns shortly after birth and to treat the newborns with minor health issues. I noticed many newborns in the room lying inside incubators, traditionally used to provide enclosed, warm environments for critical or intensive care and at odds with the low-intensity care needed for the room's newborns. I asked a nurse why some babies were in incubators and others in open beds. She said that they were broken incubators used simply to provide additional bed and storage space in this room. Some incubators had blown fuses due to power spikes, while others had undiagnosed failures that rendered them useless as anything but spare bedding. Many of these burnt-out devices passed FDA approval and so should therefore technically be considered effective, but there are so many ways a device can fail in a low resource setting. These incubators had become no more than fancy and cumbersome beds.



Don't be fooled by the phototherapy lamps shining from above; the four non-working incubators that sit along the walls are used as hard to clean beds for the well-baby room at a national hospital in Vietnam.



To design Firefly, we began our detailed engineering design process by pouring over the phototherapy standards used in the FDA approval and CE Mark certification processes. These standards are helpful in that they lay out how bright and uniform the light must be in order to provide clinically effective phototherapy. However, we knew early in the design process that just meeting the FDA and CE Mark standards would not yield a device appropriate for low resource settings. DtM's partnership with Thrive Networks and Vietnamese manufacturer MTTS was essential to go above and beyond.

Together, Thrive Networks and MTTS have over a decade of experience designing and manufacturing successful newborn health technologies for the poor. In close partnership with hundreds of hospitals in Vietnam, they discovered early on that Western devices fail due to poor training as well as environmental factors including heat, dust, and irregular electrical power. Our manufacturing and implementation partners are continually learning from hospitals, designing and releasing equipment, visiting to learn from any failures, fixing the equipment, and then redesigning the next generation of equipment to even better meet the challenges. Every piece of equipment they build also goes through a basic functionality test before it leaves MTTS. These tests have been custom designed to predict whether equipment will endure in the low resource environment. MTTS and DtM collaborated to recreate this same process for Firefly.



Left: Firefly manufacturer MTTS submits a series of new Firefly devices to the “burn-in test” at their offices in Vietnam. Photo courtesy Michael O'Brien of MTTS. Right: The vent for the Natus NeoBlue LED Overhead Phototherapy, one of the most popular phototherapy devices used in the United States. An internal fan helps move air through this vent to cool the electronics.

In order to design a device for success in low resource environments, we took two important steps. First, we poured over the phototherapy standards that FDA and CE Mark use to validate a medical device for use in high resource hospitals with climate control, filtered air, and smooth floors. After that, DtM used our human-centered design techniques to interview MTTS staff in-depth about their experiences in these environments. We invited MTTS to tell us stories of equipment failures and successes, encouraged them to dig up old photos to jog the memory, brought MTTS staff with us on hospital visits, and created a steady line of communication through a series of regular Skype calls to pass on new stories. Building on the best practices for phototherapy design in the first world alongside what we learned from our conversations with MTTS staff, DtM created a unique design that prevent bugs, dust, and liquids from entering and enables Firefly to keep operating during broad power fluctuations.



A More Sustainable Cooling Solution

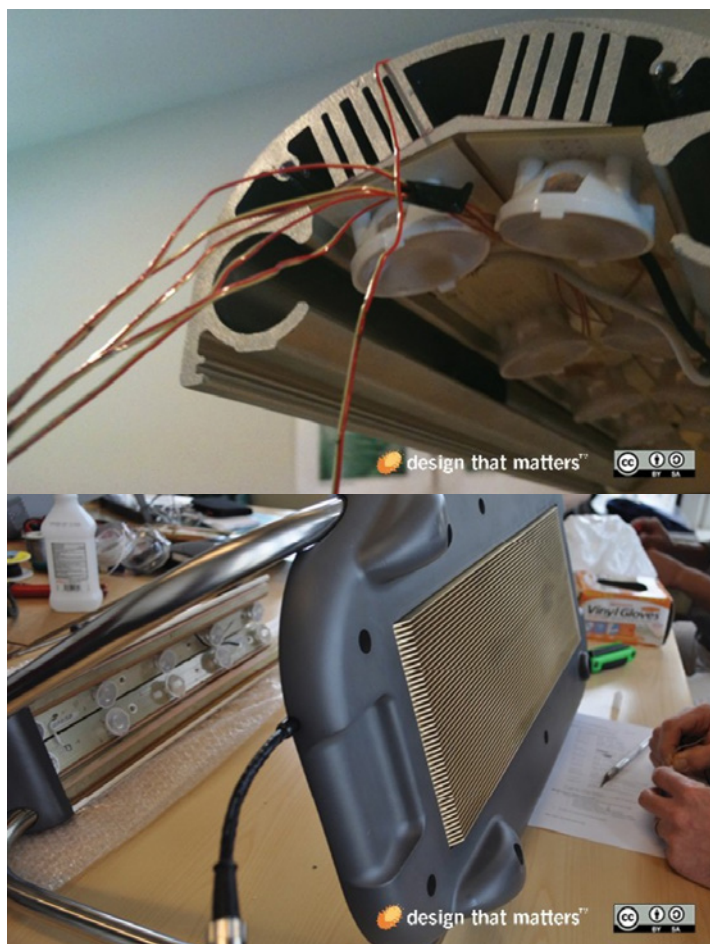
Typically, devices with electronics have holes. You may never have noticed, but if you look at your computer, most will have a series of perforations. Most devices with electronics also make a purring sound. For many electronic devices, both of these features are due to the need to keep the electronics cool. The purring sound is usually a fan, and the holes enable it to blow hot air out and bring cool air in. These features keep the device from becoming dangerously hot to touch, and also to ensure the electronic components can perform optimally.

In a U.S. hospital, electro-mechanical medical devices share these same cooling solutions. However, when these devices are taken to low resource contexts, they run into trouble. The interior fills with dust and insects. The fans are often the first thing to break, causing the electronics to overheat and burnout in the warm environment. A DtM friend in India quipped, “You haven’t really tested a piece of electronic technology for distribution in Asia until you’ve trained a cockroach to climb in and pee on every single little component on the inside.”

Instead of fans, another way to keep electronics cool is by exposing a large surface area to the air. You may have noticed cooling fins on other home electronics like your refrigerator. Metal cooling fins increase the amount of area exposed to the air and increase conduction compared to a flat, plastic outer surface. In order to completely seal Firefly, DtM designed a novel passive cooling system for the top and the bottom. The top light was easier to design because heat rises: we manufacture the top light from an aluminum extrusion that has sufficient surface area on top to enable heat from the top lights to rise upward and away from the device. The bottom light was more difficult because any rising heat could directly contribute to overheating the newborn in the bassinet. For this issue, we designed a tilted bottom surface and installed cooling fins. Because hot air rises, air from the lowest part of the device rises up along the fins, cooling the base electronics and enabling the majority of the heat to rise off the rear.



DtM used rubber o-rings to create a seal around the metal tubes where they enter the base of the device. This helps keep bugs and dust out of the device.



Top: The inside of the Firefly top light, showing the metal housing that helps wick heat out the top. Bottom: The cooling fins are mounted on a slanted surface on the bottom of Firefly to pull heat down from the electronics and then air moves the heat off the rear.



A More Robust Electrical System

A Duke University study found that up to 98% of medical equipment sent to developing countries is broken within five years. There are many causes, but one of the major issues is fluctuating power sources. Electrical power in Myanmar is 220v at 50Hz. Brownouts, blackouts, and voltage fluctuations are common, especially in the dry season. The typical Nigerian building experiences power failure or voltage fluctuations about seven times per week, each lasting for about two hours and without the benefit of prior warning. To enable Firefly to ride the waves, we knew we needed a serious power supply. However, the power supply is one of the main components generating heat in a device. Could we point to any existing examples of technology that were already good at working through power fluctuations and could solve the heat problem?

The answer? Laptops! During field research in hospitals in eight countries throughout Southeast Asia, we were always able to use our laptops! Most laptop power cords include a “brick” - that is the power supply. Reading the numbers on the brick, we could see it could accommodate a range of voltages for input. In the end, we were able to find an existing off-the-shelf power supply integrated with a power cable that is CE Mark certified for medical use, can accommodate 100-240 Volts AC, and keeps the hot power supply outside of our sealed device and away from the baby, just like a laptop power cord!

The evidence was laid out in front of us; FDA approval and CE Mark certification focus on hospitals with big resources. To design Firefly to work well in low resource contexts, DtM leveraged field experience to go beyond known phototherapy standards in order to deliver a device that meets a higher standard of care. In June 2014, Firefly received its certificate of free-sale from the Ministry of Health in Vietnam, a type of regulatory approval that enables distribution to 11 ASEAN member nations. Firefly is currently in the process of CE Mark certification, and we are also considering FDA approval to enable the device to reach western markets, creating new revenue streams and beneficial product pricing structures that will enable us to reach many more in the developing world. We are proud to partner with Thrive Networks and manufacturer MTTS and their joint vision of designing devices that really work in hospitals with few resources. Our partners will continue to monitor Firefly in the field, ready in case anything needs to be fixed, constantly learning what improvements we might make for the next generation.

Other references include the general IEC/ISO medical device standards and specific infant phototherapy standard used to design and evaluate medical electrical equipment for CE Mark and FDA Approvals. Design that Matters designed with these standards in mind, and then found where we needed to go above and beyond.



The laptop-like power supply from our Firefly clinical evaluation model prevents Firefly from burning out during a power surge, and relocates the hot power supply outside of the device and away from the baby.

