A Low Cost Neonatal Incubator for Use in the Developing Setting

1) Abstract

Team Incubaby has designed a low cost neonatal incubator for developing world hospitals. Hypothermia is a leading cause of neonatal death worldwide. However, currently available incubators are too costly, unsafe, or ineffective to treat this deadly condition in the developing world. To address this need, we designed an incubator that meets the following criteria: low cost (<250 USD), temperature adjustable (achieves temperatures between 27 - 37°C), accurate (measures temperatures with less than 2.5% error), insulated (drops only 2°C over 45 minutes in case of power loss), easy to operate, repair, and clean (scores 4/5 on user surveys), safe (abides by IEC standards for alarms), accessible (can be easily shipped or fabricated in country), and has automatic temperature adjustment.

To meet these criteria, we built a double-walled wooden incubator with one acrylic window and an acrylic lid for easy viewing and accessibility. The heating elements are two low-power, safe commercial heating pads, which are easily replaced if needed. The heating pads are in the back wall and floor and provide convective and conductive heat respectively to the neonate. The incubator requires less than 90 watts of power. Thermistors gather temperature data from the infant and a microcontroller uses this data to regulate the heating elements.

The heating capacity of the incubator has been thoroughly tested using a simulation baby ("SimuBaby"): a warm water IV bag. We have shown that the current incubator design can effectively raise a hypothermic SimuBaby (34°C) to non-hypothermic temperatures (37°C) with the microcontroller fêedback system controlling the infant's temperature within +/- 1°C of the set temperature. We have also installed an alarm system, resulting in a highly effective final design.

This summer Rice 360°: Institute for Global Health Technologies will take the incubator to Malawi and gather feedback from physicians and nurses. Ultimately, the incubator will be implemented in Malawian district hospitals for clinical trials and testing.

2) Description of clinical need

Neonates, or newborns under 28 days old, are at the highest risk for mortality compared to all other stages of life. While hypothermia is rarely the direct cause of death in neonates it compounds the effects of common neonatal illnesses. Incubators provide a warm environment for neonates so that their energy can be spent on development rather than producing heat.

In the developing world, many barriers exist to providing high standards of care. The most significant barrier affecting the care of neonates in the developing world is the lack of appropriate medical equipment. Limited resources for device training and repair make advanced equipment difficult to use (Blue, 2014). In addition, nurses may not receive standardized education throughout developing countries, thus necessitating the use of intuitive, hassle-free medical devices (Baumann, n.d.). As a final concern, development of medical devices for low-resource settings is hindered by a lack of local manufacturing capabilities.

A number of incubators are currently on the market, ranging from high-tech devices for the developed world to low-cost solutions for low-resource locations. However, the solutions are either too costly, unsafe, or ineffective for use in the developing world. In the developed world, a commonly used incubator is the GE Giraffe. While this device is customizable, has an integrated humidity system and has a system of alarm buzzers and LEDs, it can cost upwards of \$37,000, making it unaffordable for the developing world (Wentworth, 2002).

In low-resource settings, incubators tend to be much simpler and more affordable than in the developed world, but often lack necessary features, such as temperature feedback and safety precautions. The Hot Cot is the current incubator standard in Malawian hospitals. Inexpensive incandescent light bulbs act as the heating element, and the Hot Cost costs less than 50 USD to produce. However, the device does not offer automated temperature feedback- a user must manually change the temperature by adjusting the bulbs, and the use of the bulbs is a fire hazard without constant supervision (Zwiener, 2009). Finally, the Embrace is a low-cost thermoregulator designed for the developing world that relies on heated phase change wax in an insulated sleeping bag to keep an infant warm. The energy release from the phase change wax allows the Embrace to stay at a constant 37 °C for 4 hours before the wax needs to be reheated. While it is reusable, the design of the Embrace severely restricts physician access and the device must be reheated every 4 hours. During physician access and reheating, the baby is exposed to ambient air ("Embrace Warmer", n.d).

While designing a low-cost incubator has been attempted previously, no prior solution has been fully successful. Therefore, we have designed a low cost incubator with temperature feedback that is proven safe and meets the needs of infants and care providers in the developing world.

3) Design, including a discussion of the innovative aspects

Our team prototyped an incubator with a double-walled housing, tested different heating elements, and selected the most effective temperature probes. We then prototyped six scaled-down models of the double-walled housing to optimize a design that can be easily assembled and provides infant access. Next, a full-scale model was created that was used for our heating element testing. We tested a variety of thermistors and RTDs against the Oakton Temp 300 precision thermometer in order to find a temperature probe that was both low-cost and accurate. The most important testing we did was to determine which heating element was best suited to our incubator. We prioritized heat-up time, temperature adjustability, and infant safety. A hair dryer, heating pad, and halogen bulb space heater were tested for efficacy in the heating element's ability to heat the open space as well as to heat a 1kg bag of water from 35C to 37C. Testing revealed that the heating pad is the optimal heating element due to its low power consumption and lower operating temperature, providing a safer environment for the infant.

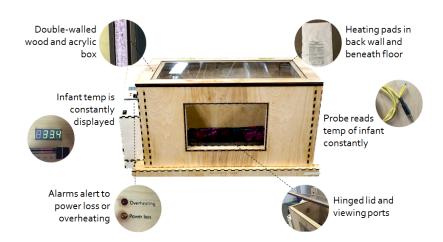


Figure 1 Incubator features and image

The novelties of our invention include temperature feedback, low-cost, operational simplicity, and the option for flat-pack shipping. Current warming technologies often lack temperature feedback. Our device regulates temperature automatically based on the infant's temperature. Using a low-cost microcontroller, PD control and high-precision thermistors, we accomplish a high degree of accuracy for a much lower cost than conventional servo-controlled models. In addition, the use of double walls in the incubator design cuts heating costs by increasing insulation and reducing power consumption. Finally, since the incubator is assembled from laser cut pieces, it can be flat-packed and efficiently shipped or produced in country and assembled with minimal tools. Our incubator also improves upon existing technologies with infant accessibility. The front and top acrylic walls allow for complete visibility of the infant and the lid is easily opened for top access. Thus, a healthcare provider can view and handle the infant and additional devices, such as feeding tubes, can be easily connected.

Additionally, the affordability of our incubator makes it a unique solution. With a bill of materials under \$250, hospitals will be able to purchase these incubators and provide for more children at a lower cost. Furthermore, hospitals will not need to spend money fixing expensive, donated incubators. Finally, our incubator is made of materials that can be found in many developing countries, so it could also be produced in country, further saving costs.

4) Evidence of working prototype (results/graphics obtained with the designed solution)

In order to ensure that our incubator met our design criteria and functioned as desired, we developed and performed a number of tests. A brief overview of these tests is presented here.

Temperature Reading Accuracy

To determine the accuracy of the temperature probes, we placed 5 of our thermistors and in a hot water bath with a high-accuracy submersible temperature probe. This test was run for a total of n = 3 times with the water bath at 5 different temperatures (23, 29, 35, 37, and 39°C +/- 1°C), representing a range of temperatures over which our incubator operates. The average error results from these tests can be seen in **Table 1**.

	Probe 1	Probe 2	Probe 3	Probe 4	Probe 5	Average
AVERAGE:	1.35%	1.07%	1.48%	0.97%	1.39%	1.25%

 Table 1
 Temperature
 Probe
 Accuracy
 Data

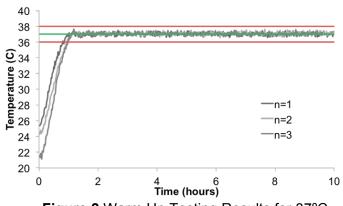
SimuBaby Testing Set Up

To perform the tests that addressed incubator temperature, we used a simulation baby ("SimuBaby") made from an IV bag. We filled the IV bag with hot water and connected it to a water pump in a hot water bath. The circulating warm water simulated an infant capable of generating some body heat. SimuBaby demonstrated both how the incubator would heat up with a warm, radiating body contributing to the internal temperature and if the incubator was be capable of heating a hypothermic infant.

To test the efficacy of this set up, we compared the heat loss from SimuBaby over time with the heat loss of an uncirculating, heated IV bag over time. The uncirculating, heated IV bag lost heat at a rate of 5°C/hour while SimuBaby lost heat at a rate of only 1°C/hour which is more similar to a hypothermic infant, which maintains a low, relatively constant level of heat.

Heating Testing

The first test we performed was to measure the amount of time the incubator took to heat, as well as its ability to keep the mattress at a steady temperature. In this test, we set the SimuBaby to 34°C, placed it in the incubator and attached one temperature probe to the rice mattress. Three tests were performed at each set temperature: 27°C, 32°C, and 37°C. The Arduino Uno microcontroller was used to regulated the temperature collected temperature data every second from the mattress temperature probe. The graphed data for 37°C is shown below in **Figure 2** and is representative of all three tests.





For all tests the green line is the set value and the red lines are the upper/lower bounds *Temperature measured is mattress temperature These results demonstrated that the PID microcontroller code enabled the incubator to oscillate under a tight range (+/- 1°C) at a range of temperatures (27, 32, 37°C) and that the incubator warms in just over 60 minutes (average to heat to 37°C was 67 minutes). Additionally, the incubator remained within an appropriate temperature range (+/- 1°C) for over 8 hours (**Figure 2**) with no user intervention. While we recommend that healthcare providers check on the infant at least every 2 hours, this demonstrates that the incubator is capable of safely regulating temperature during that interim time. These heat up tests show that the incubator can heat to and maintain a versatile range of temperatures, from low to high, which is important due to the varying infant and environmental conditions.

Heat Retention

Following heat-up testing, we tested the cool-down of the incubator. For this testing, we simulated a power loss, during which the heating pads will not be on, but it is still critical that the incubator retain heat for the infant. To run this test, the incubator was heated to 37°C, unplugged and then the ambient air temperature was monitored over time. The ambient air in the incubator dropped an average of 2.03°C in 45 minutes reaching the goal of 2°C in 45 minutes. The data was gathered using the microcontroller and can be seen in **Table 2**.

Test	n=1	n=2	n=3	Average
Delta Temperature	1.78 °C	2.38 °C	1.93 °C	2.031 °C

Table 2 Data from Heat Retention Testing: demonstrating minimal heat loss from incubator

Automated Temperature Feedback

After measuring the ability of our incubator to operate over a wide range of temperatures, the next step was to determine if our temperature feedback system worked with SimuBaby. Testing was performed on the SimuBaby (IV bag) at 34°C with a temperature sensor attached to the top of SimuBaby. SimuBaby was then placed in the incubator for 3 hours. The incubator autonomously ran with a set desired temperature of 37°C for 3 hours. As seen in **Figure 2**, this demonstrated that the microcontroller feedback system was accurately able to raise the infant's temperature to the desired 37°C and maintain that temperature within a +/- 1°C range. Additionally, this test demonstrated that the infant's temperature did not decrease when in the incubator, even initially, meaning that our incubator heats up quickly.

Additionally, to demonstrate that in case of overheating the incubator temperature will decrease, we placed a hyperthermic SimuBaby in the incubator. After the 37°C test, we increased the temperature of SimuBaby to a body temperature of 38°C using hot water, leaving SimuBaby in the hot incubator. The resulting data demonstrated that, if the SimuBaby's temperature goes over 37°C, the incubator temperature plateaus or decreases so that the infant does not hit a temperature higher than 39°C or lower than 36°C. The results of these tests can be seen in **Figure 3.**

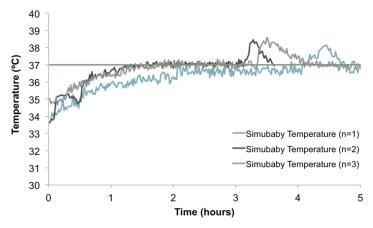


Figure 3 Temperature Feedback

Incubator able to maintain infant at appropriate body temperature without significant deviation from the set temperature. It is also able to cool an overheated baby

SimuBaby was made hyperthermic after 4, 3, and 3.5 hours for trials 1, 2 and 3 (respectively)

Current status

Currently, the incubator is a functional prototype, capable of heating a simulation infant, retaining heat without power, and using alarms to alert the user to power failure or hyperthermia. Though the device works well, there are still several features that must be optimized before it is ready for use with patients, including improving insulation and ventilation capabilities, integrating temperature probes with infant body temperature band, and adding a weaning setting for infants. This summer, interns from Rice 360 will be taking a version of the device to Queen Elizabeth Central Hospital (QECH) in Blantyre, Malawi. There, they will obtain feedback from nurses and physicians on the function and aesthetics of the device. Associates from Rice 360 will then incorporate this feedback to optimize the device and make it ready for clinical testing and, ultimately, implementation.

<u>Sources</u>

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