Infant Incubator

F03-Blue Light Therapy Incubators for Neonatal Jaundice in Ghana

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Executive Summary

A serious problem in global healthcare is not simply the absence of existing technology or solutions, but also the accessibility to them. This lack of appropriate equipment is seen in many health facilities in low resource settings in Ghana that treat newborns, especially premature ones. Currently, newborn babies requiring referral management at more equipped hospitals are transported wrapped in sheets as their caregivers travel from one hospital to another, which can take hours to get to. Dr. Okyere-Frempong has brought this problem to attention and wishes to receive a more secure solution that could help save the lives of these infants.

To aid in solving this problem, a transportable incubator needs to be developed that will provide the necessary life support for the infant and sufficient information to their caregivers, while maintaining manufacturability in Ghana. Project development was initiated by the collection of information that has occurred through various sources such as doctors, nurses and biomedical engineers from the US, Ghana, England, and Colombia. Product developers of other low resource solutions to similar problems from around the world were also included during the research phase. This helped create a comprehensive understanding of the requirements necessary for the final product to be considered a functional incubator. The general requirements are to help the infant maintain their body temperature at an adequate level and monitor their basic vital signs at all times.

The specific medical measurements that should be considered related to the internal environment of the incubator, which should remain between 28-39 °C, and 40-70% humidity. According to the research, the baby's temperature should be kept between 36.5-37.5 °C. Additionally, the incubator must be able to read the weight of infants between 0.5-4.0 kgs and heart rates between 40-180 beats per minute. The main mechanical requirements include a hood that is sufficiently large to comfortably fit a newborn infant and a structure that is capable of supporting the weight of its components. The main electrical requirements include 140-230 W of heat that must be produced inside the incubator, the input of the power supply should be designed for 240VAC 50Hz and the output should be 12VDC. Additionally, the monitor should be able to display the appropriate information to the caregiver. The materials and manufacturing techniques considered are materials that have the appropriate physical properties and available processes that the potential manufacturer in Ghana has access to.

Various proofs of concept are described to ensure that all the components perform accurately. First, for mechanical concepts, a prototype for the hood was used to test different design options for the handholes, locks, and grommets. The prototype was also used to test how well the hood would maintain heat with a 200 W heater. The electrical components and the sensors were tested against previously accepted devices. For example, to test the accuracy of

the temperature internal readings, the device was tested against a body thermometer. Additionally, the measurements of the back seat of an average car were used as a guide for the general size to make sure that the main goal of transportation is met.

Moving forward, the goal is to continue testing and finalizing the design. This, in addition to receiving feedback from the main advisor, Dr. Smith and Dr. Okyere-Frempong, will lead to the definition of the final concept which can then be constructed and tested altogether.

Throughout this entire process, comprehensive documentation will be kept in the form of user manuals, pictures, and a publically available website to ensure that the final product is replicable in Ghana. Additionally, Dr. Okyere-Frempong will learn about the skills used by being actively immersed in the construction phase. The final step of this project is to send this documentation back with Dr. Okyere-Frempong.

Glossary

FDA Ghana: Food Drug Administration in Ghana

IEC: International Electrotechnical Commission

Preterm baby: A baby that is born more than 3 weeks before the baby's estimated due date.

Alternatively, it refers to a baby that is born before the 37th week of pregnancy.

Neonate: A newborn baby that is less than 4 weeks/ one month old.

Reflux: When liquid backs up from the stomach into the esophagus.

Main Body

1. Introduction and Background

One of the major problems reported amongst African countries is the high rates of annual infant mortality[1]. At the global level, there is an average of 18 deaths per 1000 live births while the average in Africa is 28 deaths per live births[2]. Although Ghana has made significant progress in reducing neonatal mortality in the last decade going from 39.6 deaths per 100 live births in 2008 to 23.9 deaths per 1000 live births in 2018, the neonatal death rates are still high compared to what the United Nation Sustainable Development Goals (SDGs)[3]. A study was done in the Ashanti Region (the most populated region of the country[4]), which shows that out of 222 newborn babies, 115 of them do not survive past their first 28 days of life. These numbers represent only a small region of the country and reveal a bigger issue; the second biggest cause of newborn death is preterm birth.

The standard method for increasing the chances of preterm birth survival is utilizing an infant incubator. Designed to simulate the environment inside of a mother's womb, it provides thermal support to the infant until they are able to auto-regulate their body temperature. The team is working with Dr. William Okyere-Frempong, the main contact for this project and the founding Medical Superintendent of the Nungua LEKMA Polyclinic, a public health facility in a populous suburb of Accra, Ghana. He raised the concern about the lack of these devices in remote areas of Ghana. He explained how most healthcare centers cannot afford to acquire incubators, and those that can are not able to afford maintenance for repairs. As a result, many premature babies who need an incubator are transported for hours in a car, wrapped in blankets, carried in a caregiver or mother's arms in order to reach the closest hospital with the right resources. He believes an incubator made from affordable materials and manufacturable in Ghana would allow more premature babies to survive.

After researching the features on existing incubators and the various theories that they follow[3], it was defined that the main function of the final design is to provide thermoregulation and a proper sterile environment for the child while they are in need of the incubator. Different ideas have been analyzed, tested, and compared in order to create the ideal design to accomplish this goal. Additionally, working closely with Dr. Okyere-Frempong ensures that when he travels back to his home country, the final product will meet the true user needs and fit into the intended environment.

2. Existing Products/ Prior Art

Infant incubators have evolved significantly since they were first created in 1870 by Dr. Stéphane Tarner, who took the idea of chick incubators and made it into a device that could help premature babies[5]. The current incubators include many intricate features in addition to thermoregulation such as the integration of humidity control, a weighing scale incorporated in the bed of the baby, the space for an x-ray tray, and the option of blue light therapy used to treat jaundice.

The Korle Bu Teaching Hospital, the premier healthcare facility in Accra, Ghana is one of the few hospitals that have access to infant incubators in the entire country. The devices they currently have are from the company Dräger, specifically the Dräger Caleo and the Isolette TI500[6]. The first incubator works by continuously monitoring the baby's temperature. It focuses on insulating the baby and keeping the amount of stress and stimuli to a minimum. The price of the base incubators can range from $3,400 to $5,500. On the other hand, the Isolette TI500 is a mobile intensive care unit that incorporates a double-wall structure to reduce the loss of radiant heat while the baby is being transported. The basic pricing of these incubators ranges between $2,950 to $3,895. It is important to highlight that the baseline price for both of these incubators does not include the additional accessories such as skin temperature probes, the mattress for the bed, baby positioning aids, tubing grommets, ventilation hose holder, oxygen sensor, water tank, air filter, and a rechargeable battery. Additionally, they do not include the international fees for importing them from their country of origin, Germany.

When looking at competitor incubators of the same style, they all tend to be of a similar or greater price and therefore are unaffordable. Due to this international complication, other groups and organizations have designed low-cost incubators. For example, the mOm incubator, an inflatable device designed for easy transport, is meant to be taken to refugee camps found in Europe and treat the infants in the camps. This incubator is meant to focus on the thermoregulation of the baby without the need for humidity[7]. A team from Rice University in Houston, Texas developed a laser cut incubator, Incubaby, for Malawi and other developing countries. It is focused on easy shipping, as a flat packed product, and is made of double wood plywood panels that form a box where the baby can lay and the temperature can be regulated. The cost of it is expected to be between $300 and $400[8].

3. Codes and Standards

There are two compilations of standards that should be considered when developing this product. At the national level in Ghana, there is the Food and Drugs Authority (FDA) of Ghana which is responsible for "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices"[9]. At the international level, there is the International Electrotechnical Commission (IEC), which is in charge of overseeing the regulations of electrical components and their proper usage. Specifically, for the case of an infant incubator, there are the IEC 60601-2-19 and 60601-2-20 which refer specifically to the safety requirements for static infant incubators and the safety requirements for transport infant incubators, respectively[10]. These standards will need to be reviewed in the next phase for this project to understand the factors that play a role in the safety and reliability of the functioning of these devices.

4. Customer Requirements and Engineering Design Specifications

The stakeholder analysis, visualized in **Figure 1** shows that the most important stakeholders when it comes to design considerations for the device are the nurses, doctors, and manufacturers, respectively. The identification of this information is important to direct conversations, research, and prototypes. To ensure full comprehension of the medical, functional, and ergonomic requirements doctors and nurses were contacted. The doctors are the source of the medical and functional knowledge while the nurses are the main users interacting with the device and are the sources of the ergonomic information.

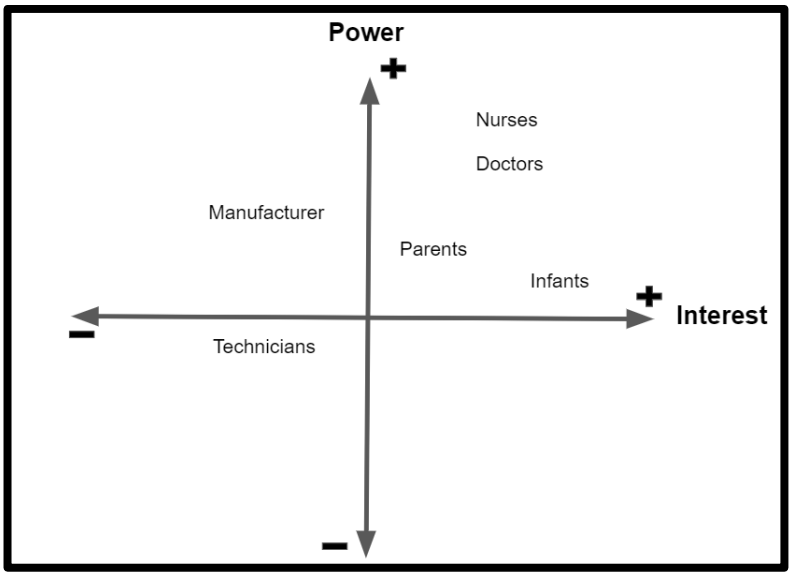

Figure 1: Stakeholder Analysis This graph translates the information from the table in **Appendix A** and helps visualize which stakeholders are more relevant to take into account when designing the device.

Based on the prior art research, **Figure 2** divides the major requirements of the development of the incubator into six major categories and divides those into the corresponding sub-functions. The purpose of this is to organize the various components of the project into the corresponding functional areas.

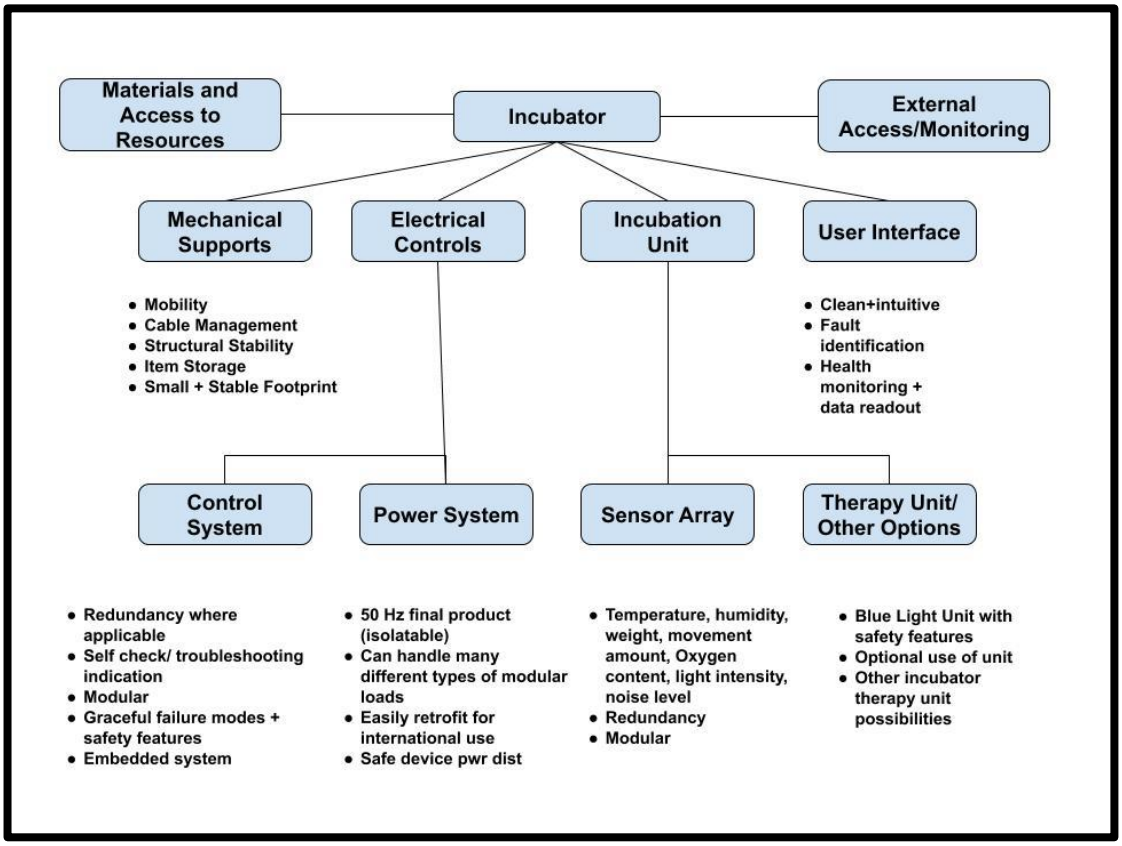

Figure 2: Function Tree The blue boxes are the main functions and the bullets are sub-functions with more detail

The initial, high-level, customer needs and the related engineering specifications are simplified in **Table 1** based on the major functional requirements. This analysis helps determine what will be necessary to prove the overall concepts for a functional final product.

Relationships: Strong 5 Medium 3 Weak 1 None Blank	**Engineering Requirements**	materials	energy consumption	manufacturing	consumer testing	strength tests
Customer Needs						
safety		3				5
low cost		5		5		
reliability		1		1		3
energy efficiency (battery)			5			
appearance		1			3	
mobility		1	1	3		
lifespan		5		3		3

Table 1: Form Chart Ranks the correlation between the customer needs on the left side and engineering requirements on the right.

Finally, the House of Quality seen in **Appendix B** quantifies the features from an engineering standpoint. It takes all the different correlations described before, bringing them together in a comprehensive manner to understand how specific customer needs will be met through the engineering requirements. For example, to be portable, people must be able to lift the device without the use of an additional device. OSHA standards state that any device that weighs greater than 50 lbs, approximately 23 kg, must be lifted by more than one person[11]. Therefore, if the incubator is designed to be lifted by two people, the ideal weight should be no greater than 100 lbs, approximately 46 kgs, when in use.

The numerical values for these requirements are divided into three separate categories: the medical, the mechanical, and the electrical requirements. As observed in **Table 2,** the medical requirements refer to vital signs of the baby since they provide the caregiver with information about the status of their patient. The incubator must be capable of reading the measurements of the baby's status and communicating those values in a concise and understandable format. These values were identified by speaking to various doctors to understand what the normal range of measurements could be and expand the range that the device will be able to read to cover any extreme circumstances that should be alerted to the caregiver.

Medical Requirements		
Part	**Requirement**	**Specifications**
Shell compartment	**Environment Temp**	**31-37 ℃**
	Baby temperature	**31 ℃ < T(baby) < 40℃ - should be measured in at least 2 different locations**
	Humidity	**40% - 77%**
	HR	**120 to 160 beats per minute**
	Weight	**0.5 - 4.0 Kg**
Blue Light	**Wavelength**	**waveband interval 460 to 490 nm**
	Intensity	**30W/cm/nm**

Table 2: Medical Specification Sheet This lists out the most important vital signs that the incubator needs to keep a record of, with specific ranges that it should detect. These values were given by Dr. Okyere-Frempong and were confirmed by his colleagues from Ghana.

The mechanical side of the requirements, seen below in **Table 3,** are all the conditions that the incubator must meet for it to provide the appropriate environment for the treatment of the infant. In other words, they allow for the medical requirements to be met in an accurate and credible method without the concern of external interference. For most incubators, this includes quick access to the baby and keeping consistent communication with the caregiver about the vital signs of the patient. In the case of this incubator prototype, it must provide a safe environment for the child to be transported to another hospital.

Mechanical Requirements (based off of previous incubators)		
Part	**Requirement**	**Specifications**
Hood	**Height**	**30 cm**
	Length	**71 cm**
	Width	**46 cm**
	material	**nonporous and humidity resistant**
Bed (meant to fit the already existing incubator)	**weight to support**	**2.3 kg - 3.2 kg**
	width	**40 cm**
	length	**59 cm**
	max inclination (degrees)	**15 - 30 degrees**

	material - mattress	nonporous and humidity resistant
	material - board	nonporous and humidity resistant
Handles	Weight to carry	designed to be carried by 2 people
Base compartment	length	72 cm
	width	50 cm
	height	22 cm
Stand	length	90 cm
	width	48 cm
Access	hand hole diameters	15 cm
	whole side length	67 cm
	whole side width	42 cm
Monitor	length	18 cm
	width	10 cm

Table 3: Mechanical Specification Sheet This table provides the necessary requirements for the main structure and to maintain the environment for the infant.

The electrical requirements are what ensure the safe and reliable operation of the incubator, allowing it to perform the necessary functions and supplement the medical and mechanical operations of the device. These requirements can be found in **Table 4**. They include those necessary for the computer, sensing array, user interface, heating unit, and power supply. As with most incubators, it includes the ability to read the ambient temperature inside the hood, as well as the body temperature, oxygen saturation, heart rate, and weight of the baby. These readings will be transmitted to a display, which will be used to control the heating unit, illumination, and alarms. The display will provide warnings to the caregiver as the user interface of the incubator. One requirement specific to this incubator is that due to the target country, Ghana, the power supply will have to be compatible with 240V 50Hz Power. The power supply will also need to output enough power to meet the requirements of the computer, sensor array, display, and the heating unit. Based on dimensions from the first version of the design, the heat output required from the heating unit was originally estimated to be in a range from 140W to 230W, shown in section **Appendix C**. This base measurement was used to make a new estimate for the final prototype design, using heaters of 200W-300W capacity.

Electrical Requirements		
Part	**Requirement**	**Specification**
Computer	**Unit**	**Raspberry Pi 4 Model B**
Heating Unit	**Heat Output**	**~ 140W - 230W**
User Interface	**Display**	**Ambient: Temperature and Humidity**
		Patient: Temperature, O2 Sat, Heart Rate, and Weight
		Machine Status: Battery Level, Plugged In Status, Warning Symbol for Alarms
	Control	**Buttons to change temperature settings, turn the illumination on/off and acknowledge alarms**
	Alarms	**Warning symbol on display as well as a speaker for audible feedback, with the option to acknowledge alarm/warning**
Power Supply	**Input**	**240V 50Hz**
	Output	**5-12 VDC ***
	Power Output	**~ 200W - 300W**
Sensing Array	**Ambient (Hood)**	**Temperature, Humidity (at Exhaust)**
	Baby	**Temperature, O2 Saturation, ECG, HR**
	Electrical Compartment	**Temperature**
	Other	**Baby Weight**
		Apnea

Table 4: Electrical Specification Sheet This table includes all the electrical components for the device to function and read vitals. * Will depend on final component supply requirements. Will likely be 24VDC output with voltage regulators downstream of initial power supply

5. Market Research

Various groups were contacted to gain information to help aim the directive of the project. The multiple sources include: Susan Zachariah, M.D. is a Ghana Pediatrician Specialist at the Korle-Bu Teaching Hospital in Akora, Theophilus Ofori is a Biomedical Engineer at Korle-Bu Teaching Hospital in Akora, Alfred Selorm Betepe is a manufacturer in Ghana and CEO of Seloart Group, Irma Raquel Tabares, M.D. is a Pediatrician Neonatologist at PROCAREN UCI-NEONATAL in Caldas, Antioquia, Colombia, James Stubbs, Ph.D., is a Medical Device Company Executive and Biomedical Engineering professor at Georgia Institute of Technology, Matthew Khoory is a co-founder for mOm Incubators and Matthew H. Merves, M.D. is an Assistant Professor of Pediatrics Division of Neonatology Emory University School of Medicine. A full list of sources can be found **in Appendix D**.

Dr. Zachariah's top priorities to be considered are: weigh the baby, monitor temperature, clean mode autoclave, the light source to illuminate the baby, easy to clean and replace, and a need to work without electricity. A current problem she has noticed is the temperature probe for the child reads incorrectly and sets off unnecessary alarms. She also believes setting specific ranges for each child for the alarms would help reduce alarm fatigue. A factor that makes neonatal incubators hard to maintain is the unavailability of replacement parts.

Mr. Ofori provides insight into design considerations. He believes that the ideal humidity range for an incubator is between 80% and 90%. He also notices a need for backup power and switches to allow for manual control of the device due to the power outages that can last up to six hours. He observes that the fan and heating elements break down the most and also that the temperature sensor on the baby is unreliable. For transportation, his top priorities are backup power, oxygen cylinder mount, and humidity as necessary.

Mr. Betepe is a very important source for this project because he will lead the manufacturing of the product in Ghana and knows what is available there. This will heavily influence the parts that are chosen. He has access to a vacuum forming machine, laser cutter, and metal cutter. Plexiglass, aluminum plates, stainless steel, mild steel, and steel plates are available to get in Ghana.

Dr. Tabares provides her experience with transport incubators and explains how they incorporate some humidity into their incubators but also how not having reliable humidity regulation can lead to the creation of an infection inside of the child. In contrast to the heat regulation component of the device, humidity is not an essential part of the functioning of the incubator, rather a nice feature to have. When using a transport incubator, because it is a temporary situation, the need for humidity is not as important as the heat. In her experience, people will transport the babies in whichever way possible even if it is simply in their arms which

could be life-threatening to the child. Therefore, she also observes the need for an incubator that is easily transportable.

Dr. Stubbs has experience working on medical devices and suggests that the IEC 60601 documents mentioned before should be considered. Stubbs also advised regarding best practices while considering material options when designing a medical device.

Khoory works for a company that is in the process of creating a static inflatable incubator for refugee camps. Khoory's mOm incubator company focuses on the core functionality which includes vitals and temperature stability. To him and his team, humidity is not considered a core function as it creates an infection risk. He mentions how he has seen the use of creative ideas such as humid towels and sponges to introduce humidity in an incubator when the patient is found in an extreme circumstance. Transport incubators have different standards than static and his company also uses the 60601 documents as a reference needed. The biggest challenge his company faces is meeting the standards and regulations.

Dr. Merves allowed for the observation of the cleaning process of a Drager Isolette 8000. This helped the team understand how the airflow and humidity systems are incorporated as well as how the bed tray can be repositioned on a pair of t-bars. One of the nurses from his staff also explained how they view the inside of the incubators in two halves: the clean, head side and the dirty, foot side. These are related to the positioning of the baby where their feet define the dirty side and their head defines the clean side of the incubator. This is important when introducing new equipment into the hood to avoid contaminating sterilized equipment. This information was later taken into account when designing the access points of the incubator to the baby.

The feedback from the sources helps determine the core functions and the preliminary design. Based on the feedback, the incubator will include a weight sensor, temperature control, and a custom alarm system. The humidity system was determined not to be essential and as a potential source of infection if not correctly regulated. As a result of this decision, the humidity will be passively monitored, but not actively regulated. Based on the availability of materials and manufacturing processes, the incubator will ideally be manufactured by laser cutting plexiglass and manipulating aluminum plates. These materials and design processes take into account that not all manufacturers will have access to these tools. To accommodate these cases, instructions for a more manual process will be offered as an alternative.

6. Design Concept Ideation

After collecting the data and narrowing down the requirements, a table was made to better understand how the medical requirements of the incubator might be impacted by the conditions

in which it will be operating. Features found in current, state of the art incubators, are presented and ranked. Those considered to be absolutely necessary and life-supporting are ranked as 1, those which are useful but not entirely life-supporting are ranked as 2, and the features that are nice ideas, but not necessary for this prototype are ranked as 3. The information was presented to a group of doctors with similar backgrounds to that of Dr. Okyere-Frempong. With their feedback, a final decision about the features that are to be included in the final product is shown below in **Table 5,** with the features this phase will include in green. **Appendix E** uses this list to create a variety of possible design ideas. Various combinations of these sketches in addition to the main customer's feedback have been used to create a final image of the concept design.

1 - Absolutely Necessary	2- Extras	3- Completely new

- Sensors:
  - Temperature
  - Humidity
  - HR
  - O2 Saturation
- Mechanical Capacity:
  - Capacity to be on a stand
  - Hand access to baby
- User interaction
  - Instructions Manual
  - User interface
  - Calibration system
- Electrical Requirements
  - O2 Filter
  - Motor Powered Fan
  - Exhaust Fan
  - General Illumination
	- Electrical Requirements
	  - Backup Battery
	  - Interchangeable Power Supply
	  - Redundancy + Maintainable Electrical Components
	- Mechanical Capacity
	- Sensors
	  - Apnea
	  - Weight
		- Dual Chamber
		- Heat Cleaning
		- Blue Light Incorporation
		- Cabinet space
		- BP Sensor

Table 5: Promised Features This table highlights the features from the original table that was developed with the main contact and highlights what the device will include.

The major challenge of this project has not just been to design a new incubator, but to make sure that the materials and techniques necessary to build it are available in Ghana. To make sure that this is the case, the table in **Appendix F** includes a materials list created from those that are used in existing incubators as well as some additional options. Mr. Betepe has

been consulted on the availability of them in Ghana. Plexiglass, aluminum, steel, and wood are the best options based on his ability to obtain them.

For the prototypes, materials were selected based on commonly used components that could easily be found in the United States but could also be replaced with similar alternatives found in Ghana.

7. Concept Selection and Justification

Putting together all the concepts mentioned before and consulting with Dr. Okyere-Frempong, the main design of the incubator was created, shown in **Figure 3**. The device is composed of two main sections: the hood which is the main area where the patient will be treated, and the base which contains the heating/ventilation system as well as the electrical components. The main dimensions of the various parts can be found in the table in **Appendix G.**

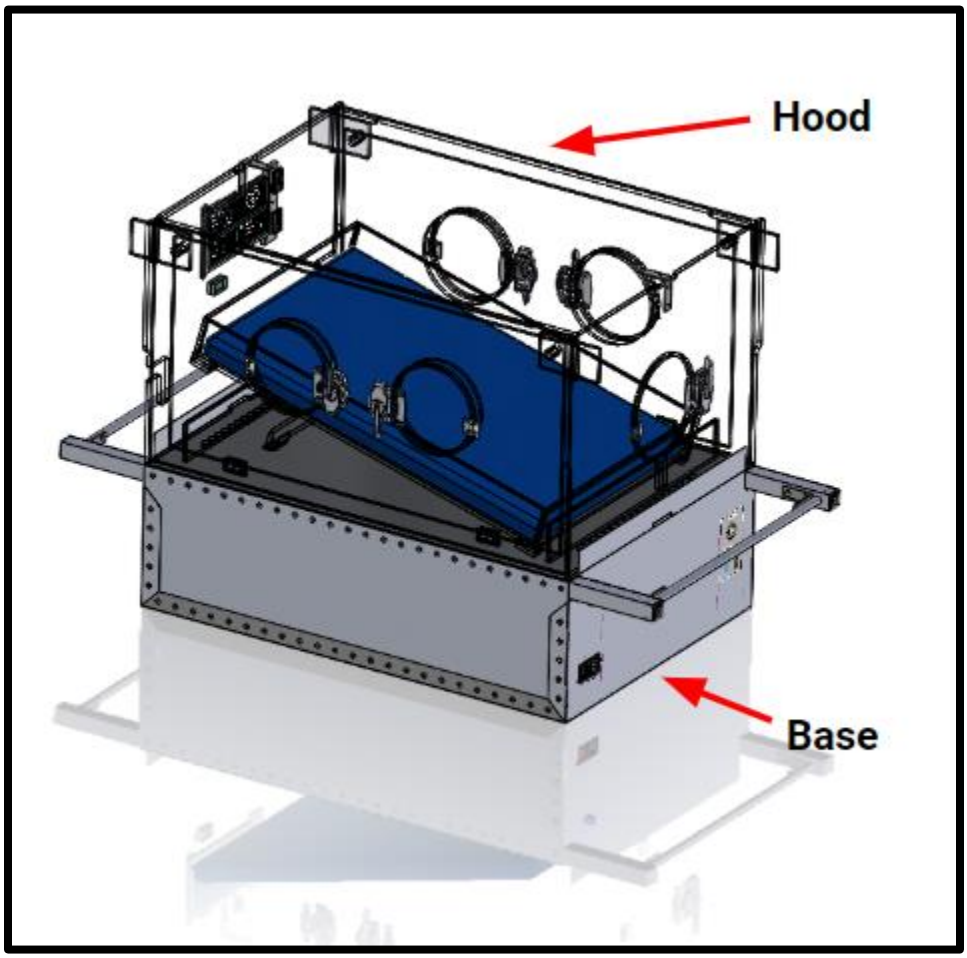

Figure 3: The final concept design for the entire incubator including the base and the hood.

a. Hood of the Incubator

The main goals for the hood are the accessibility to the baby both in the hospital and during transportation as well as providing the patient's essential information to the caregiver. For accessibility to the baby, there are two handholes on each long side of the incubator to allow for quick access during small procedures or when readjusting the baby. This is the preferred option by physicians and has become part of the standard design of modern incubators. To perform a major procedure or to remove the baby from the incubator, the two long sides of the incubator can be entirely opened to provide more access. Additionally, for transportation in a car, a handhole is on one of the short ends of the incubator to meet the need for easy access while sitting next to the incubator. As was suggested by the doctors from Ghana the additional hole is located on the "foot side" rather than the "head-side" of the incubator. All the doors incorporated require a lock system. For this, various options were presented to Dr. Okyere-Frempong that included either using the same plexiglass used for the hood or using cabinetry-style locks that could easily be found locally in Ghana. The final design has a rotating acrylic lock for the long sides of the hood, and the handholes will each have a cabinet lock both as shown in **Figure 4.** Both are options that require enough effort to open but will not be accidentally opened and can be replaced with similar materials if needed in Ghana.

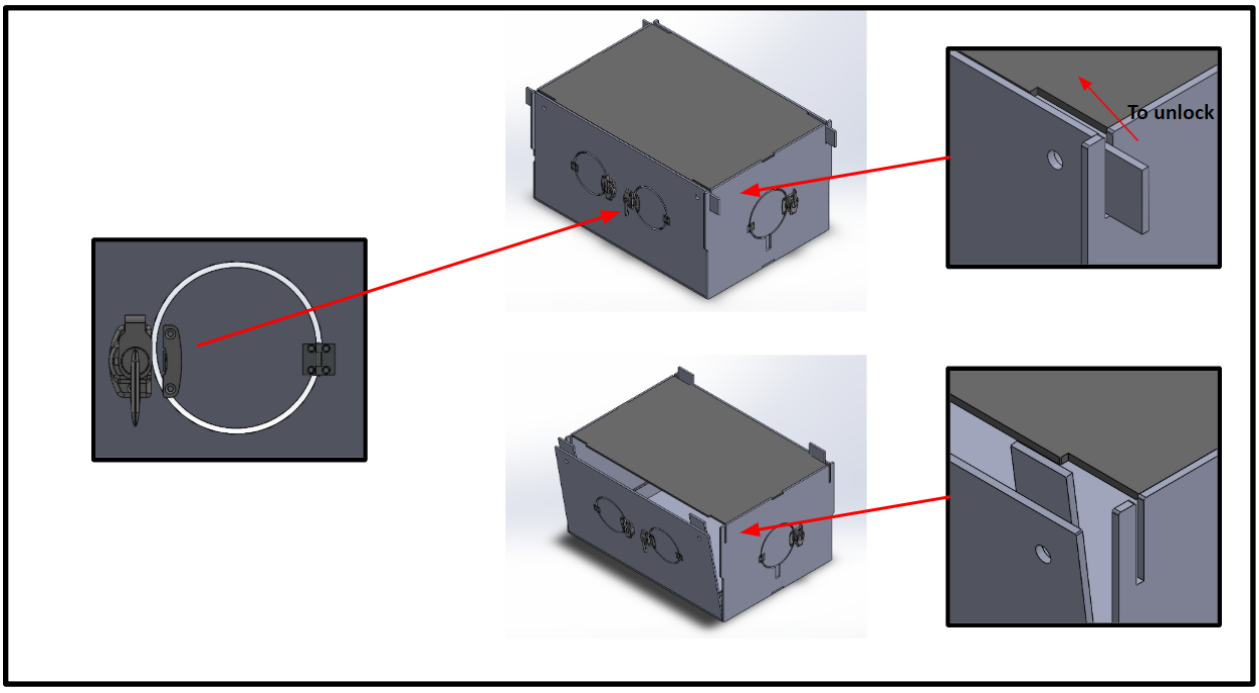

Figure 4: These images represent the two different lock systems that will be used to allow for different levels of accessibility to the baby depending on the needs of the caregiver.

From discussions with the various pediatricians, it was expressed that angling the patient in case of reflux is very important and that most standard incubators have an inclination option. The final design for the inclination mechanism includes a stand that lays flat under the bed tray that is attached to the bottom of the hood with hinges. The stand can be raised and placed into a notch under the bed tray to lift the bed at an angle of approximately 18 degrees (**Figure 5**).

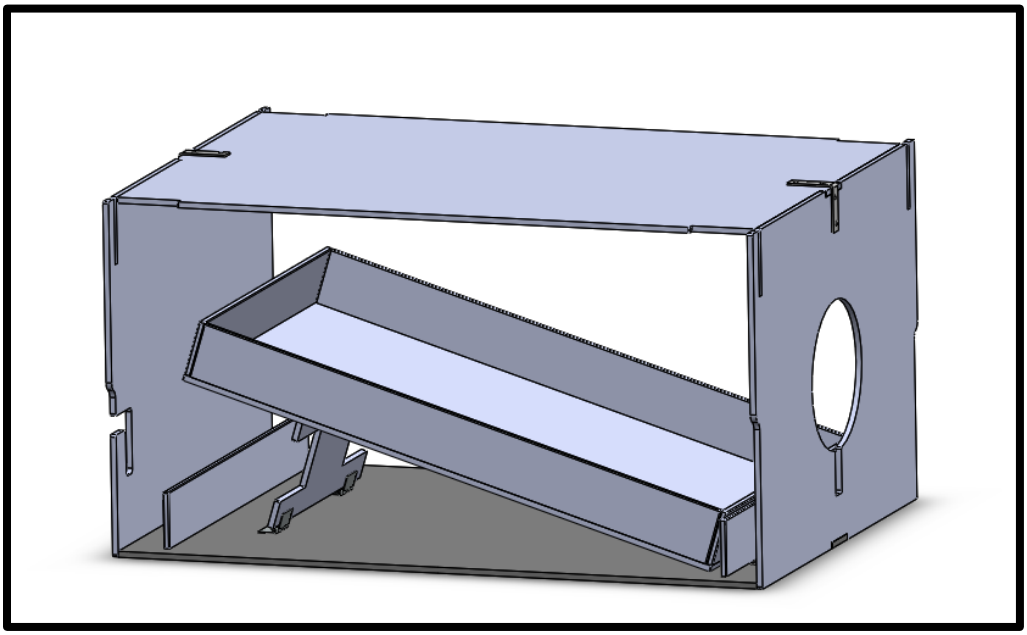

Figure 5: Mechanism of the inclination option of the tray in cases where the baby has reflux.

b. Base Compartment Design

The purpose of the base is to support the hood of the incubator while housing electrical and computer components and maintaining the air circulation in the hood. The base has a structured frame of aluminum square tubes with walls of aluminum sheets. Aluminum is accessible and lightweight making it a top choice for material. For the design of the air duct, a wall on each side of the inside fan and two heaters control the airflow through the incubator, circulating it through the hood via the air holes (**Figure 6**). The air duct walls are made from sheets of zinc-coated metal sheets. Zinc coating maintains antibacterial properties and will prevent contamination. The design of the air duct and the positions of the air holes were created to maintain uniform airflow. The computer and electrical components are placed around the air duct and are connected through the walls with a PVC pipe. Neoprene silicone insulation is placed on the inside surfaces of the air duct and on walls and roof areas surrounding electrical and computer components with the purpose of decreasing thermal leakage. Another purpose that the silicone

serves is to absorb vibrations from moving components such as fans and is commonly used in medical devices. This will help reduce noise to the child. The user interface is placed on the “foot side” of the base, to give the caregiver easy access to the controls.

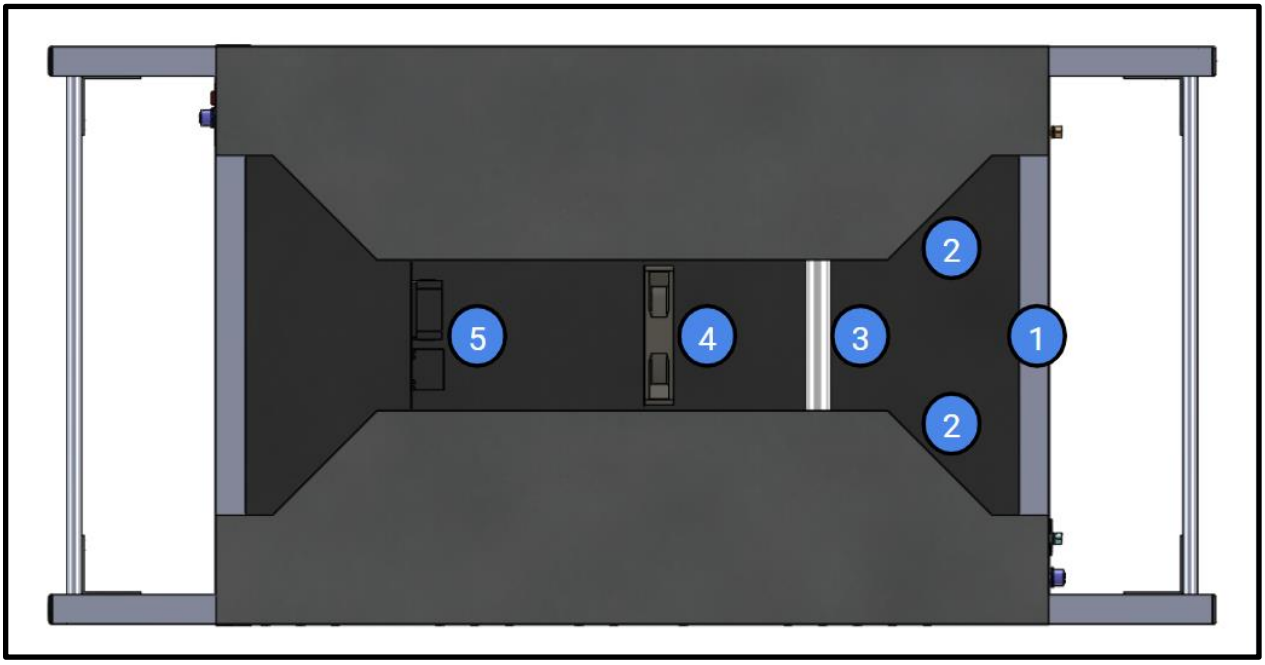

Figure 6: Bottom side of the metal base. 1. Intake air fan 2. Air duct walls 3. PVC pipe 4. Circulation fan 5. 100 W and 200 W heaters.

c. Electrical management

There are three main components that make up the electrical system of the incubator. These include the Vitals Monitor and Display, Thermal Control Interface, and the Power Distribution system. These three components will be interconnected via the control board.

i. Vitals Monitor Display

The information on the display must be carefully organized so that the caregiver can quickly read and understand the status of both the patient and the incubator. As such, the information will be organized into three sections as seen in **Figure 7**. The largest amount of screen space will be dedicated to reporting the status of the patient. These measurements, as seen in the top section of the display, include the patient’s temperature, oxygen saturation, weight, and heart rate.

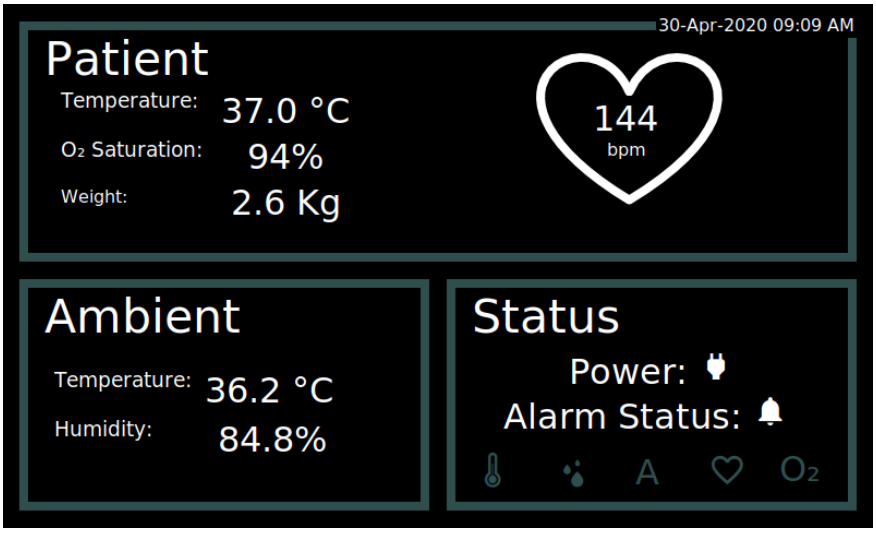

Figure 7: Vitals Monitor Display Layout: This screenshot from the display of the vitals monitor shows how the information from the sensor array will be organized.

The rest of the display is divided into two sections, one to report the ambient environment provided within the incubator, and the other to report the current status of the machine. The section dedicated to the ambient environment, labeled “Ambient” on the display, will report the ambient temperature and humidity within the incubator, as thermoregulation is the most critical function of an incubator. The third section of the display, labeled “Status” on the display, will report a general summary of both the machine’s and the patient’s status. This includes reporting the current power source (AC Power vs. Battery) and alarm status (Muted vs. Unmuted), as well as any warnings triggered by the measurements from either the patient or the environment. These warnings will be displayed as symbols which can be seen in the bottom row of the “Status” section of the display. When a measurement is determined to be outside of the set range, previously defined in the Medical Requirements, the value, as well as the corresponding symbol, will be displayed in red, to alert the caregiver to the source of the alarm. Otherwise, the measurements will be displayed in their default color, and the symbol will be displayed in a dark grey. This layout was reviewed by Dr. Okeyere-Frempong, and his colleagues, who approved of the organization of the display and gave feedback on specific labels to assign to the various readings, as well as the symbols used for warnings.

ii. Temperature Control Interface

A major point of discussion throughout both the ideation and design processes was whether to allow the thermoregulation system to be controlled by the computer, or to design it as a separate, manually controlled system. The final decision for this iteration of the project is to

have thermoregulation be implemented in an isolated system, not controlled by the computer, but to design the control board to allow for the inclusion of this functionality in later iterations. To do this, a connection for a Manual/Computer switch, as well as temperature setpoint and value connections to the Raspberry Pi were added.

This decision was made to avoid introducing a potential point of failure to the thermoregulation system, in the form of the computer. It was discussed that if thermoregulation is controlled solely by the computer, a computer failure would render the incubator nonfunctional. A possible solution to this is to include a switch to choose between manual and computer control of the thermoregulation system. In the event of a computer failure, this switch would automatically go to manual control, to allow continued use of the incubator until the computer can be replaced or repaired. Due to time constraints, it was decided to forgo implementing this solution in the current iteration of this project.

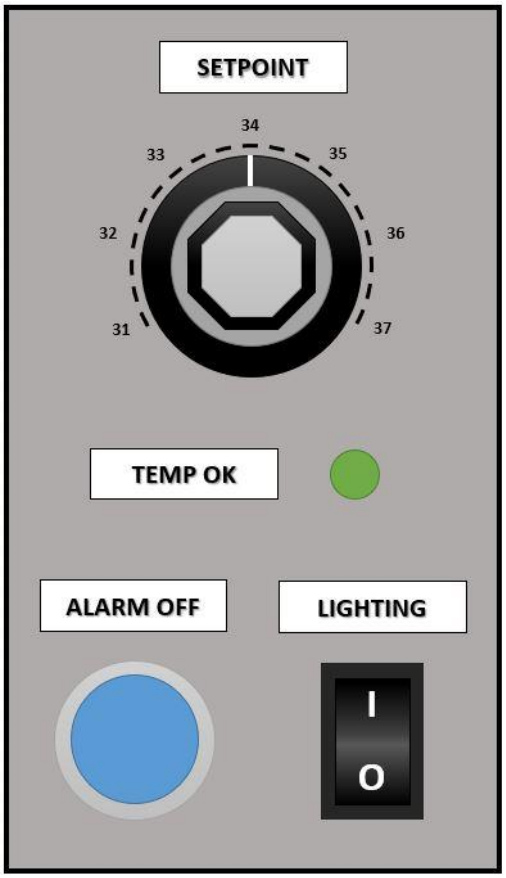

Figure 8: Temperature Control Interface: This mockup shows the thermoregulation interface that operators will use to control the temperature in the incubator.

The temperature control interface shown in **Figure 8** is located at the foot end of the incubator to allow quick access from either side when the incubator is in operation. The

interface contains a setpoint knob that allows the operator to adjust the temperature setpoint between 31-37 Celsius and this knob directly controls a potentiometer in the analog temperature control circuitry. The Green LED in the middle is illuminated when the temperature inside the hood is equal to the temperature setpoint.

The Alarm Off button allows the operator to acknowledge and mute any active system alarms. Acknowledging an alarm will mute the sound but will not clear the alarm from the display screen or the system. Each press of the button acknowledges only one alarm. Lastly, there is a switch to control the power to the lighting.

iii. Power Distribution

The country of Ghana has a power grid that supplies 240VAC at 50Hz while the United States' power grid supplies 120VAC at 60Hz. For this design, an interchangeable power supply was chosen that can operate using either of these inputs to allow for testing and assembly in the United States. When in production, a power supply that only uses 240VAC of the same wattage can be substituted if it is cheaper. This power supply converts the AC input to 12VDC for distribution within the incubator. The low 12V was chosen to minimize hazards related to high voltage. In order to allow for transport of the incubator, as well as mitigate power outages, provision for a battery backup was added as well. Any 12V, deep cycle battery will work. When wall power is supplied and turned on, a relay is closed that connects the 12V from the power supply to the 12V distribution rail. If wall power is turned off or disconnected, the relay connects the 12V supply from the battery instead. The 12V supply is connected to a fuse block that then distributes that voltage to the various devices of the incubator.

One of the 12V connections supplies a 12V to 5V buck converter. This 5V rail provides power to the Raspberry Pi and the monitor. The 12V to 3.3V buck converter on the control board is used to power the sensors and thermoregulation circuitry.

Lastly, M8 and M12 standard panel mount connectors are used to connect the sensors and monitor power. These connectors are waterproof and the cables outside the base can be disconnected for cleaning, storage, and maintenance. (See **Appendix H** for diagrams)

iv. **Control Board**

To allow for easier wiring and sensor connections, a control and breakout board was added to the electrical system. This board connects to the Raspberry Pi's GPIO headers using a

premade cable, to the 12V and 5V rails, and to all of the sensors. The thermoregulation analog circuitry is also located on this board. (See **Appendix I** for diagrams)

8. Industrial Design

One of the main parts of this project was to design a device that can be manufactured in Ghana: a place where they do not usually manufacture medical devices. Therefore various decisions were made in order to minimize the number of possible complications for the manufacturer. The final design is made to be modular and symmetric to facilitate easy manufacturability and repairability. An example of how this is seen is in the hood of the incubator which is a simple design that is not as visually appealing as standard incubators but is easy to assemble and take apart. Similarly, the overall design is symmetrical to reduce time spent on making each side and components like the locks are easy to find and interchangeable with other lock designs.

To make sure that the communication between the incubator and the users is clear, Dr. Okyere-Frempong has been consulted about the necessary visual warnings and alarms that should be included. Also, the design of important instruction labels such as how to position the baby and the number of people necessary to lift the incubator has been considered and will be included in the final prototype of the incubator.

9. Engineering Analyses and Experiments

To test the main concepts and structures that were chosen, a basic prototype of the hood was created in addition to rapid prototypes of the sensors, and some structural aspects such as hinges and locks. As seen in **Figure 9,** the hood prototype incorporates the hinges for the door mechanism as well as the lock mechanisms and the grommet locations. It was used to verify that the shorter ends of the incubator will provide enough support to the longer sides so that when they are locked into them they form a solid structure. Additionally, by creating a model that represented some of the dimensions of the final design it made it easier to receive feedback from the end-user, Dr. Okyere-Frempong.

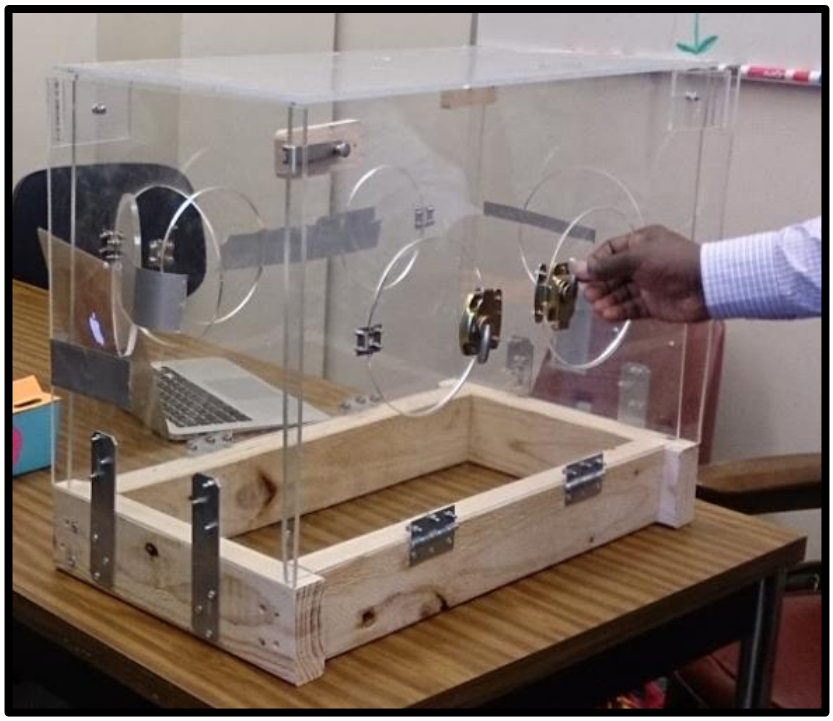

Figure 9: The prototype of the hood with locks, varying hand hole designs, and grommets.

Some of the feedback received from colleagues of Dr. Okyere-Frempong in Ghana brought up the concern of making sure there were no sharp edges that could create occupational hazards for the caregivers. To reduce this risk, liquid silicone was tested on the edges of the handholes as well as in the space designed for the grommets as seen in **Figure 10.** It was demonstrated that the material is adhesive and resistant enough to be used for both functions.

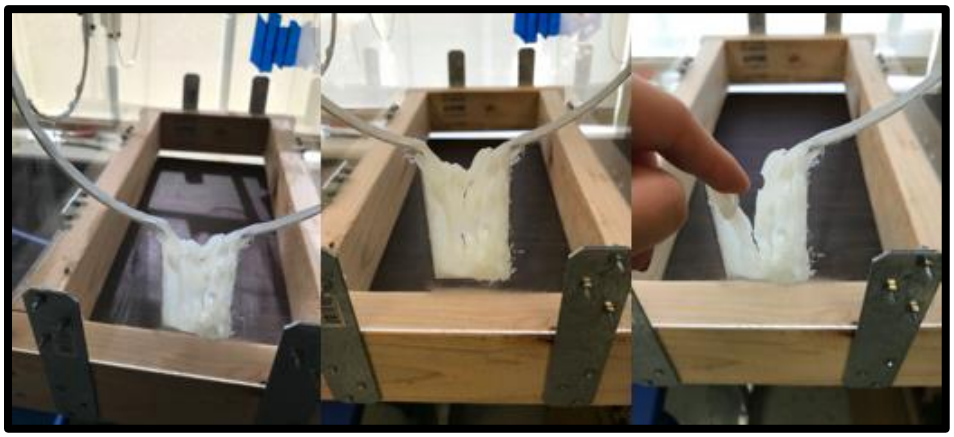

Figure 10: The prototype of using liquid silicone to create a layer of protection on the edges of the incubator. It is also used to create the material in the grommet that keeps the heat from leaving and holding the tubes and cables that need to go into the incubator in place.

This prototype was also used to confirm that a 300W would be required to effectively heat the inside of the incubator to the required temperature as previously defined in the medical requirements. To do this, all gaps were sealed off except for a small area on the bottom of the prototype where a 200 W heater was positioned on top of a fan that brought in fresh air from the outside. Thermometers and temperature sensors were positioned around the inside of the incubator to monitor the effects of the heater on the air. The results of the experiment showed that the 200W heater used would not be sufficient for the required temperature.

The Acrylic hinges, to be used as part of the mattress angling system and interior doors, will be secured without using nuts and bolts in order to avoid extra bacterial growth. Acetone and acrylic cement were both tested in a rapid prototype viewed in **Figure 11** to determine which one is more effective**.** The acrylic cement, when applied properly, provides a more secure bond than the acetone and is the preferred method to be used. However, if acrylic cement is not available, acetone can be used as an alternative. It is important to note that acetone maintains a weaker bond, and takes longer to off-gas.

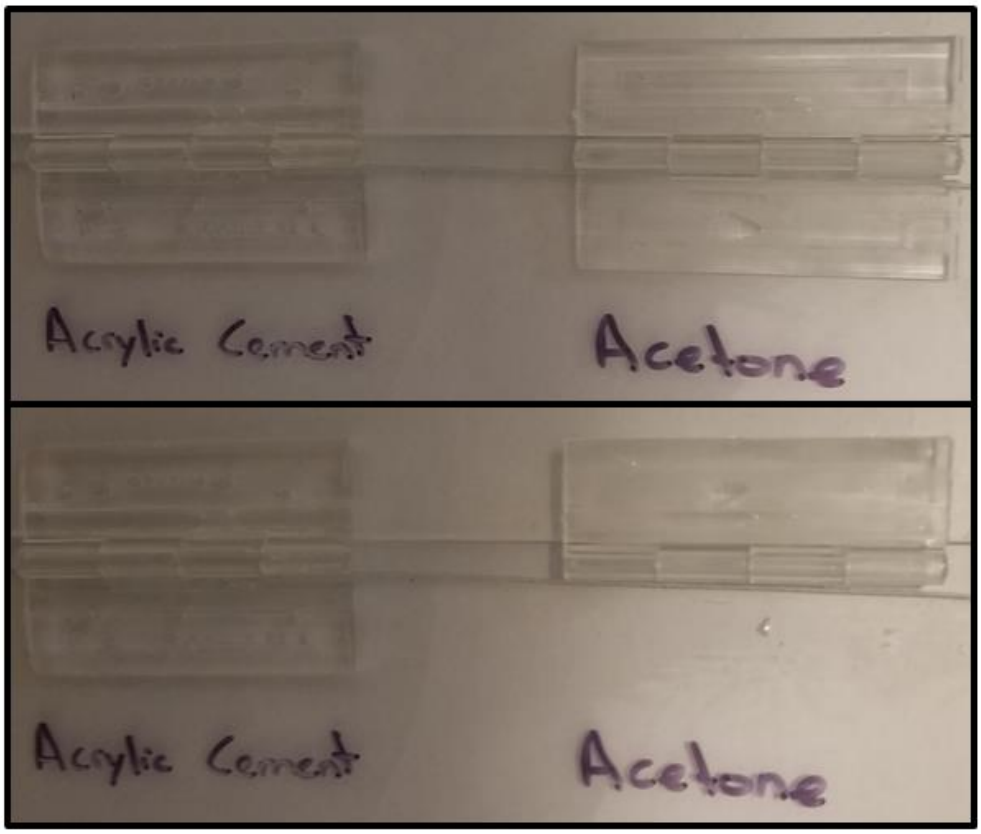

Figure 11: This shows the results of the rapid prototype of the acrylic cement vs. the acetone as a method of adhesion for the acrylic hinges. The top image shows both were set up the same way to connect two sheets of acrylic and the bottom image shows the results after 3 days of letting them dry where the acetone prototype broke off of one side.

In implementing the sensor array, each sensor was individually tested with the computer prior to being integrated with the Vitals Monitor. The sensors which are currently implemented are the patient temperature, ambient temperature, ambient humidity, and apnea. The functionality of the patient temperature sensor was verified by using it to read temperatures of various objects to ensure the readings were within a reasonably believable range. The sensor was then used to read the body temperature of a healthy subject, and the reading compared against a digital body thermometer. Ambient temperature sensors were tested in the same way, as well as being used to monitor various water temperatures. To test the ambient humidity sensor it was used to record the humidity in various environments, both indoors and outdoors, and compared against humidity readings from various stand-alone humidity sensors. The readings for all of these sensors were determined to be valid and reliable based on these experiments. The apnea sensor was tested with weights at the or close to the 2 ends of the

range of the expected baby weights (0.5 Kg and 4.5 Kg) and measures whether there is a change in pressure from the baby's breathing movements. It is set to trigger an alarm after 20 seconds of detecting no movement.

The last sensor that will be incorporated into future iterations of the incubator is the weight sensor. Due to COVID-19 circumstances, the parts to be able to program and test them entirely could not be ordered in time. However, a single load cell with a capacity of 10 Kgs was wired and programmed to report the data on the monitor. It was tested with various gym weights that were less than the maximum capacity. Ideally, the load sensors for the incubator would have a maximum capacity of 5 Kgs which would make them more sensitive to the smaller range of weights expected.

10. Summary & Future Work/ Project Deliverables

The Gantt chart below, **Figure 12,** was used as the guide for the work for this iteration of the project. It was used to monitor the progress against the expected timeline and was modified due to the circumstances related to COVID-19. These circumstances led to needing to mostly rely on CAD analysis and the creation of work instructions without too much physical prototyping.

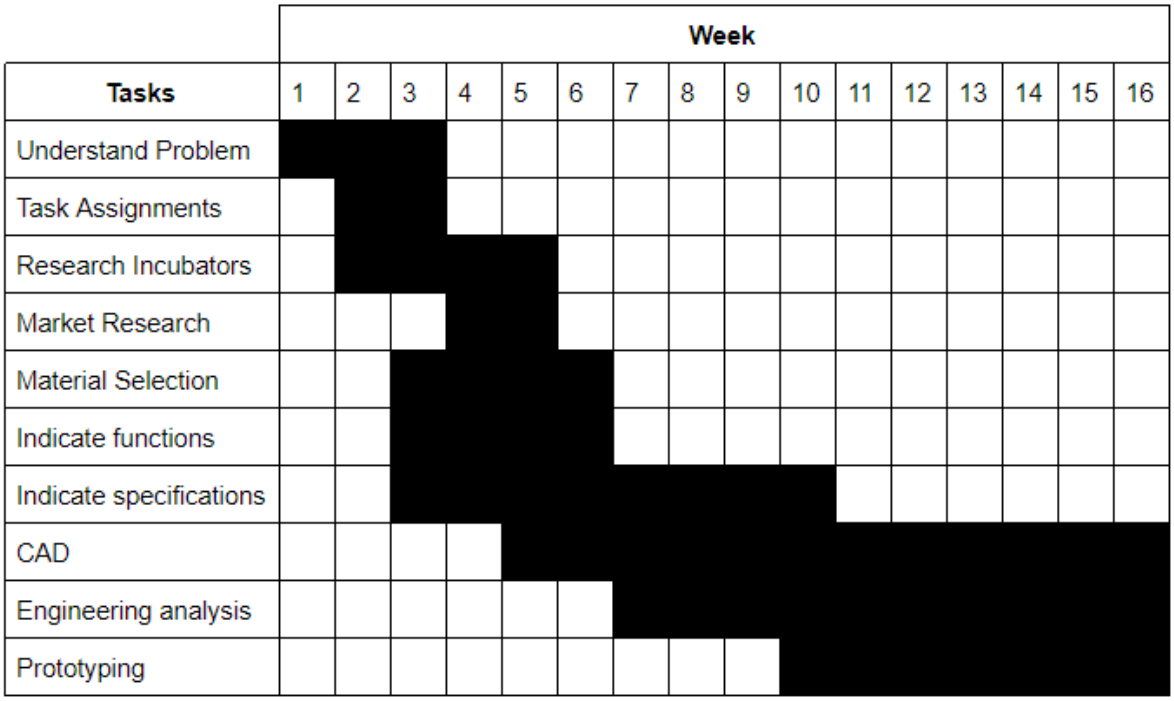

Figure 12: Gantt Chart shows the general schedule for the team for this iteration.

A documentation package of resources has been provided on the team's Senior Design website for Dr. Okyere-Frempong to retrieve when he returns to Ghana. Physical prototypes and CAD models were used to create manufacturing work instructions. This documentation will be supplied to Dr. Okyere-Frempong so that a development may continue in Ghana. As the prototypes are modified, the work instructions will be edited to reflect those changes. The end goal is to create a standard process for building multiple incubators with the same specifications and engineering requirements. There is also a full set of diagrams and drawings that allow for the recreation of the different pieces in Ghana. Finally, there is a user manual with all the instructions on how to interpret the various symbols, interfaces, and alarms that the incubator has. All documentation and project deliverables are available on the project website (currently hosted at http://ece4012y202002.ece.gatech.edu/sd20p01/). The site includes links to the following pages: Home, Deliverables, Documentation, GitHub, and Team. The Home page contains a brief summary of the project, to introduce site visitors to the incubator. The Deliverables page hosts the links to all of the required deliverable files. The Documentation page hosts all the final documentation for the incubator, such as the work instructions and user manual. The GitHub page redirects to the GitHub repository containing the source code for the Vitals Monitor, as well as installation scripts to automate the computer setup process. This repository is currently private but will be made public upon completion of the project. The Team page contains images of each of the team members, including Dr. Whit Smith and Dr. Okyere-Frempong.

Upon Dr. Okyere-Frempong's return to Ghana, the website will be moved to a public GitHub Pages site, hosted within the same public repository that hosts the Vitals Monitor source code. The deliverables and documentation pages will also be merged together, to avoid confusion of external visitors to the site. Moving forward, the idea is to create a functional prototype that can support the virtual analysis done and work towards getting approval from the necessary regulatory systems. The goal of this is to promote further research and development of this prototype and eventually gain the certifications required to utilize the product for infants in international hospitals.

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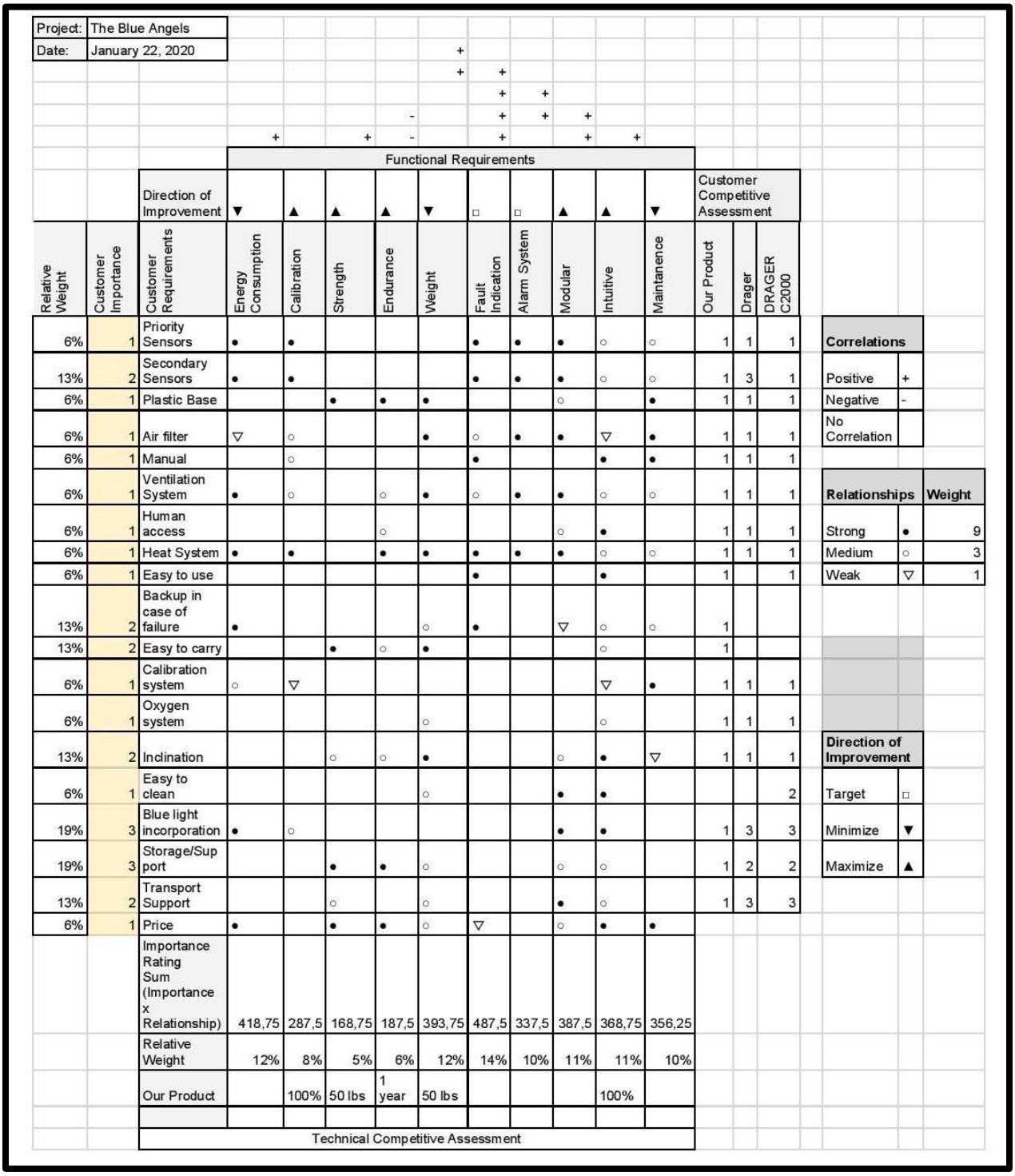
Appendices

Appendix A: Stakeholder Analysis

Stakeholder	Interests	Impact/Effect	Power	Interest
Infants	survival needs	components required to maintain vitals	1	5
Doctors	general infant progression	simple data access	4	4
Nurses	daily infant care	user input / interface	4	5
Technicians	maintenance	component simplicity/lifespan	2	2
Parents	infant survival	visibility and access	2	4
Manufacturer	manufacturing	manufacturability	3	2

Stakeholder Analysis: This table ranks the relative amount of power and interest of the various stakeholders in relation to their role when interacting with the neonatal incubator.

Appendix B: House of Quality



Project:	The Blue Angels																				
Date:	January 22, 2020																				
								+													
								+		+											
										+		+									
							-			+		+		+							
			+			+	-			+				+		+					
			Functional Requirements																		
		Direction of Improvement	▼	▲	▲	▲	▼	□	□	▲	▲	▼	Customer Competitive Assessment								
Relative Weight	Customer Importance	Customer Requirements	Energy Consumption	Calibration	Strength	Endurance	Weight	Fault Indication	Alarm System	Modular	Intuitive	Maintanence	Our Product	Drager	DRAGER C2000						
6%	1	Priority Sensors	●	●				●	●	●	○	○	1	1	1	Correlations					
13%	2	Secondary Sensors	●	●				●	●	●	○	○	1	3	1	Positive	+				
6%	1	Plastic Base			●	●	●			○		●	1	1	1	Negative	-				
6%	1	Air filter	▽	○			●	○	●	●	▽	●	1	1	1	No Correlation					
6%	1	Manual		○				●			●	●	1	1	1						
6%	1	Ventilation System	●	○		○	●	○	●	●	○	○	1	1	1	Relationships		Weight			
6%	1	Human access				○				○	●		1	1	1	Strong	●	9			
6%	1	Heat System	●	●		●	●	●	●	●	○	○	1	1	1	Medium	○	3			
6%	1	Easy to use						●			●		1		1	Weak	▽	1			
13%	2	Backup in case of failure	●				○	●		▽	○	○	1								
13%	2	Easy to carry			●	○	●				○		1								
6%	1	Calibration system	○	▽							▽	●	1	1	1						
6%	1	Oxygen system					○				○		1	1	1						
13%	2	Inclination			○	○	●			○	●	▽	1	1	1	Direction of Improvement					
6%	1	Easy to clean					○			●	●				2	Target	□				
19%	3	Blue light incorporation	●	○						●	●		1	3	3	Minimize	▼				
19%	3	Storage/Support			●	●	○			○	○		1	2	2	Maximize	▲				
13%	2	Transport Support			○		○			●	○		1	3	3						
6%	1	Price	●		●	●	○	▽		○	●	●									
		Importance Rating Sum (Importance x Relationship)	418,75	287,5	168,75	187,5	393,75	487,5	337,5	387,5	368,75	356,25									
		Relative Weight	12%	8%	5%	6%	12%	14%	10%	11%	11%	10%									
		Our Product		100%	50 lbs	1 year	50 lbs				100%										
		Technical Competitive Assessment																			

House of Quality: The customer needs are listed on the left side in descending order of importance. The engineering requirements are listed at the top. The left ranks and compares to already existing products. The Importance ratings are listed at the bottom.

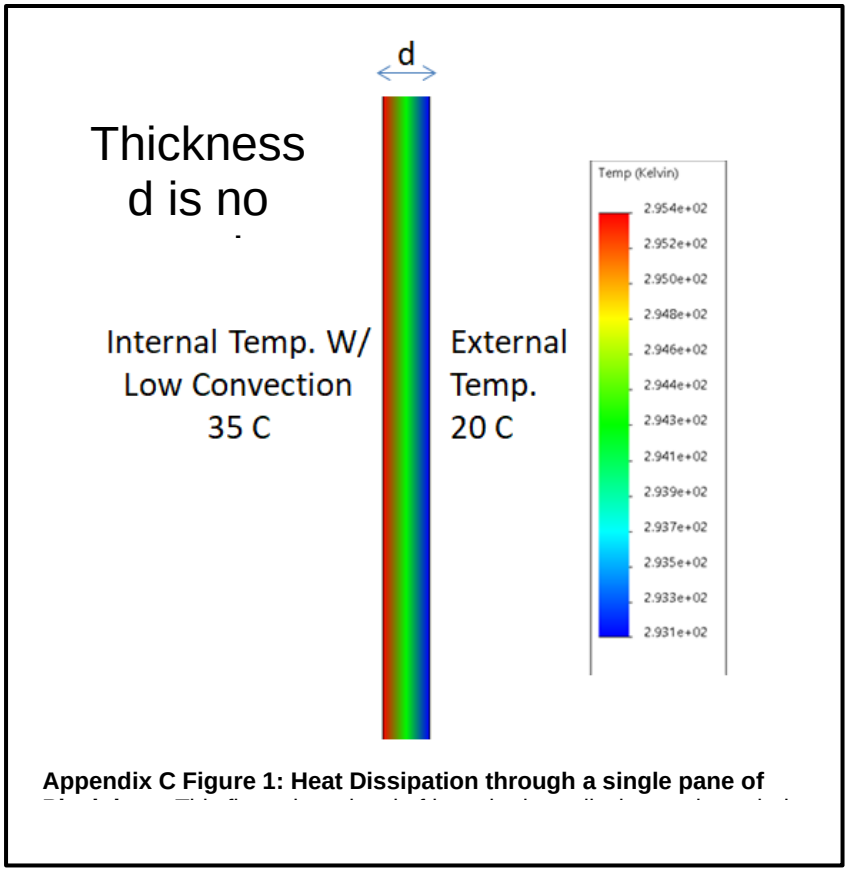
Appendix C: Thermal Analysis

Equations 1-4 are one way to calculate power. Equations 2,3 and 4 calculate the thermal resistance for a double-pane[12] plexiglass plate, a single-pane plexiglass end plate[13], and the top/bottom single-pane plate[14] respectively. These equations are used in equation 1 to calculate the total heat transfer of the plexiglass hood. The assumption is that $1/4$ inch plexiglass is used for each layer. It also assumes that there are no holes in the system, meaning that the hand doors and grommets used would have to have similar thermal properties to plexiglass, and leave little to no room for air to escape. The results showed 139.73 Watts is dissipated through the Plexiglass.

Because one of the main functions of the incubator is to regulate the infant's temperature, it is important to do a thermal analysis of the system and determine what levels of insulation and what amounts of energy are needed. The first thermodynamic evaluations determine an estimated power that the required components need to maintain heat. The goal is to maintain 35°C within the incubator assuming that the minimum external air temp would be 20°C.

The second thermodynamic estimation is evaluated using Solidworks and can be viewed in **Figure 1 of Appendix C**, with the same assumptions that a full model without holes is being used. The heat transfer coefficient inside of the incubator is estimated to be $10\ \frac{W}{m^2K}$, assuming low-speed airflow over the surface of the plexiglass [13], meaning that there is minor forced convection. The external air is assumed to be static, meaning that natural convection would take place. The results show that the heat power dissipated through the plexiglass is approximately 230.93 Watts.

The hand calculated model and the CAD model have two different sets of results because different assumptions are made to best simplify each model. The hand calculations take into account the double-pane, which would be the best-case scenario. Neither takes holes or differences in the thickness of plexiglass into account. Thus the final estimated range of required power is 140 Watts to 230 Watts, where 230 would be the worst-case and 140 is an ideal scenario.



Appendix C Figure 1: Heat Dissipation through a single pane of

$$Q = 2 * \left(\frac{T_{amb1} - T_{amb2}}{R_{tot1}} + \frac{T_{amb1} - T_{amb2}}{R_{tot2}} + \frac{T_{amb1} - T_{amb2}}{R_{tot3}}\right) (1)$$

$$R_{tot1} = \frac{1}{h_1 A_1} + \frac{L}{k_1 A_1} + \frac{L}{k_2 A_1} + \frac{L}{k_1 A_1} + \frac{1}{h_2 A_1} (2)$$

$$R_{tot2} = \frac{1}{h_1 A_2} + \frac{L}{k_1 A_2} + \frac{1}{h_2 A_2} (3)$$

$$R_{tot3} = \frac{1}{h_1 A_3} + \frac{L}{k_1 A_3} + \frac{1}{h_2 A_3} (4)$$

A_1- Area of the double-paned plate, meter

A_2 - Area of the single-paned endplate, meter

A_3- Area of single-paned top and bottom plate, meter

h_1- Heating transfer coefficient for low-speed airflow, $\frac{W}{m^2 K}$

h_2 - Heating transfer coefficient for medium speed airflow, $\frac{W}{m^2 K}$

k_1- Thermal conductivity of plexiglass, $\frac{W}{m^2 K}$

k_2- Thermal conductivity of air, $\frac{W}{m^2 K}$

L- thickness of the plexiglass, meter

R_{tot1}- resistance of double-paned plate, $\frac{K}{W}$

R_{tot2} - resistance of single-paned endplate, $\frac{K}{W}$

R_{tot3}- resistance of single-paned top plate and bottom plate, $\frac{K}{W}$

T_{amb1}- the temperature of ambient outside air, Celcius

T_{amb2}- the temperature of ambient air inside, Celcius

Appendix D: Sources of Information

James Stubbs
Medical Device Company Executive & Investor
Professor - Ga Tech Biomedical Engineering

Matthew H. Merves, MD
Assistant Professor of Pediatrics
Division of Neonatology
Emory University School of Medicine

Irma Raquel Tabares, MD
Pediatrician Neonatologist
PROCAREN UCI-NEONATAL
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Matthew Khoory
Co-founder mOm Incubators

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Biomedical Engineer
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Alfred Selorm Betepe
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CEO Seloart Group

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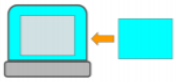
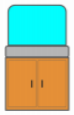
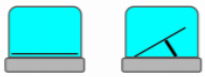
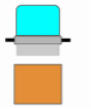
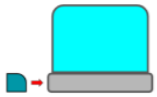
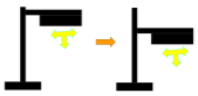
Ghana

William Obeng, MD
Consultant Paediatrician
Ghana

Appendix E: Morph Chart

Function	Option 1	Option 2	Option 3	Option 4	Option 5
open/close/access	entire top removes	front panel slides into place	Front panel on hinges	hand holes	Top comes off
					
Lock Shut	pins tapered	latch	snapfit	lock in place	Slide latch
					
Storage	cabinets	drawers			
					
Mobility	wheels	handles			
					
Added height	set on table	stand			
					
Tilt	prop up	rotate on shaft/sphere	prop up mattress holder (lawn chair) https://www.aliexpress.	https://www.youtube.com/watch?v=slUtiqh-bLM	https://www.youtube.com/watch?v=6aMWvBw5JPs
					
detach from stand	mobile compartment				
					
water container	combined w/ humidifier				
					
Adjustable Blue Ligh	Up and down	angle			
					
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	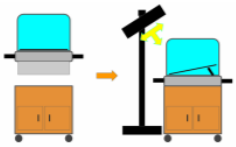	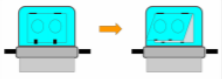			
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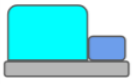
					

Appendix F: Material Selection

The initial material table, shown below, weighs the pros and cons of potential materials. The additional table below shows materials that were selected for the final prototype and their corresponding quantities. Materials were selected based on commonly used components that could easily be found here, in the United States, but could also be replaced with similar alternatives found in Ghana.

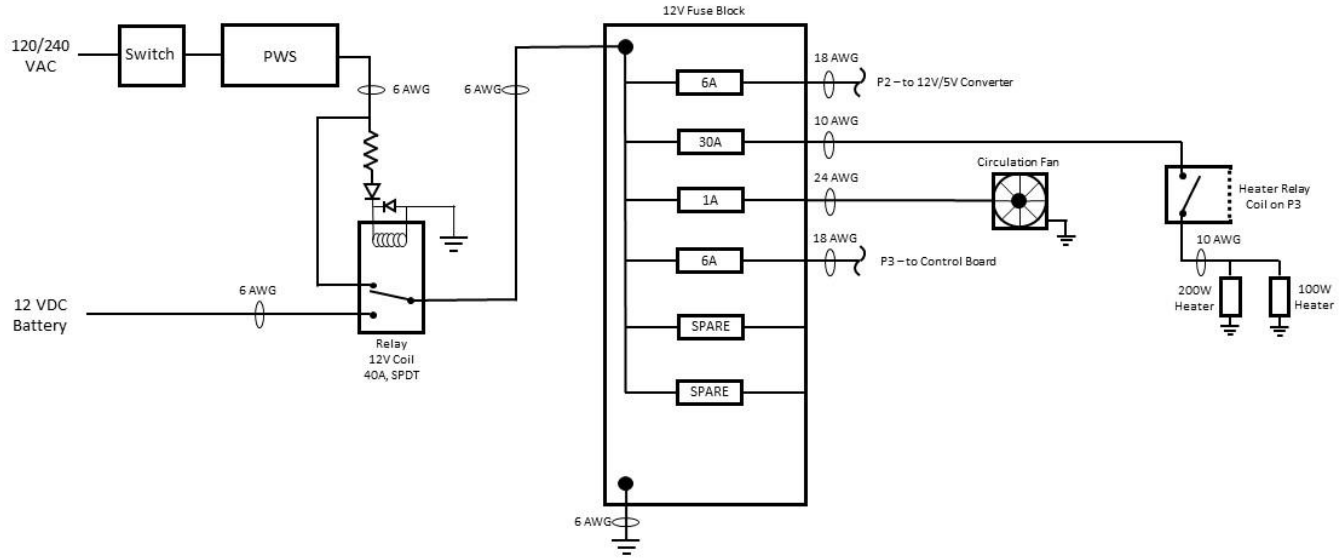
Material	Pros	Cons
Resin	**- Strong - Usually, thermoset and won't change with heat after formed - Most are considered non-toxic once set**	**- Requires us to create a silicone mold (which would be hard to replicate and maintain) - Would need large quantities(probably mailed in)**
Wood	**- Easy to acquired - Easy to work with**	**- Easily damaged by heat or liquid**
Plexiglass/acrylic	**- Can be ordered in sheets - The material used in some current incubators - Can be glued together or use manual fasteners - Decent thermal and electrical insulator - Impact and water-resistant - Clear - Melting point is 320 F**	**- Can be expensive - May need to be mailed in**
Metal	**- Higher-strength - Can be formed/bent**	**- Can be damaged by oxidation - Can have shaper/dangerous edges**
Plastics (Acetal/HDPE/LDPE)	**- Can be molded into the base of the incubator chamber**	**- May be difficult to have the proper shape and size**
Polystyrene	**- Can it be used to create a model to mold plexiglass around possibly? - Melting point 410F**	
Parchment paper	**- Can heat plastics up without them sticking to the surface below**	

Materials List: This table compares materials that have been considered for the design of the incubator.

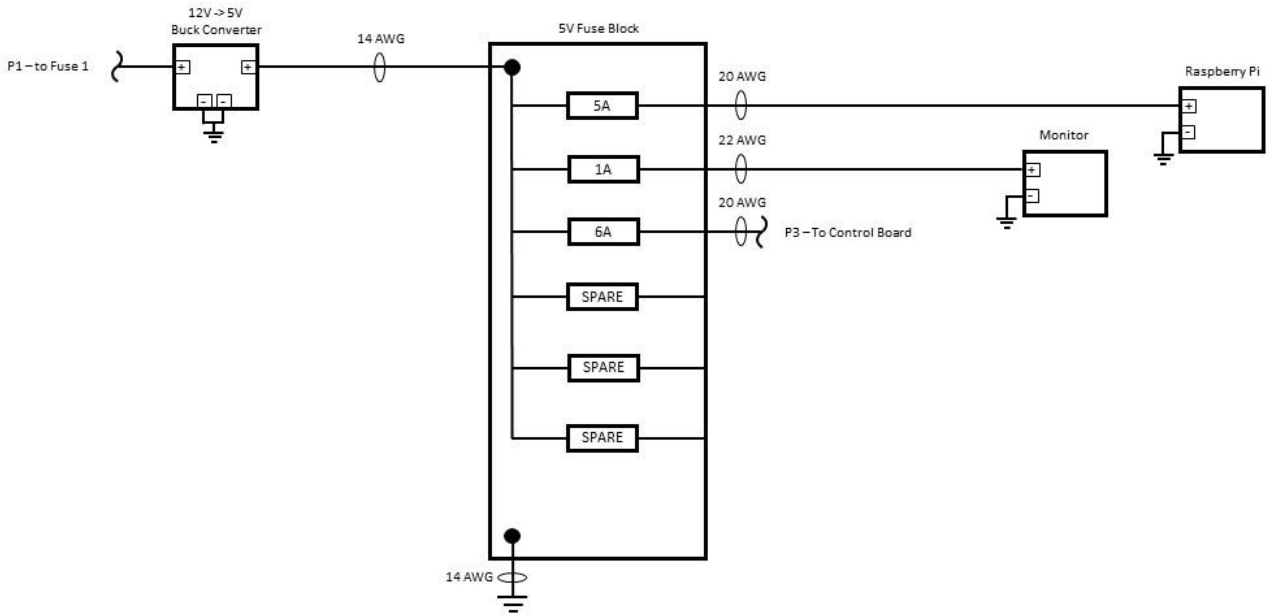
Appendix G: Incubator Hood Dimensions

Part	Actual Length	Actual Height
Top Plate	71.75 cm	48.3 cm
Short Ends	38 cm	52 cm
Exterior Long Ends	70.48 cm	37.3 cm
Interior Long Ends	66 cm	33 cm
Base Plate	71.75 cm	49.75 cm
Tray Base	60.5 cm	41.25 cm
Tray Stand	24 cm	12 cm

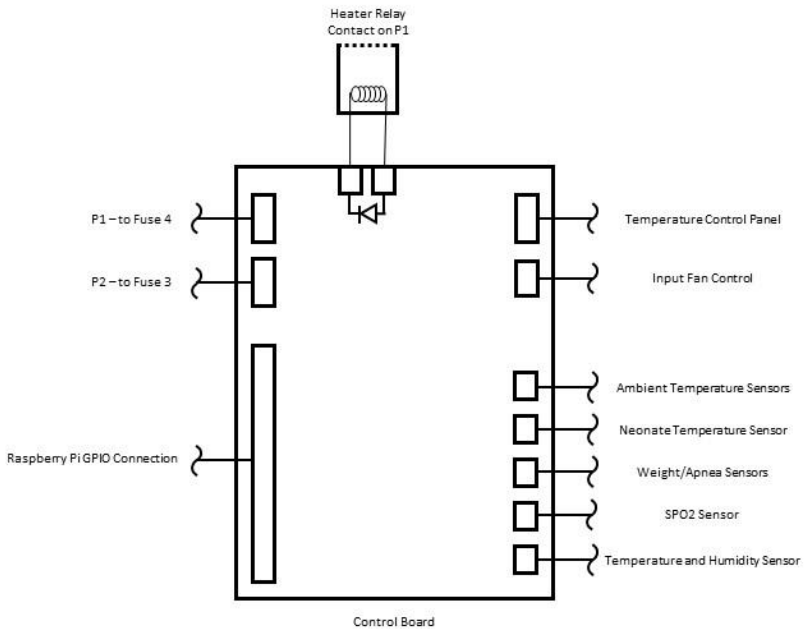
Appendix H: Electrical Wiring Diagrams



GT4823 – Infant Incubator
12V Power Distribution
Designer: Noah Daugherty | Date: 4/12/2020

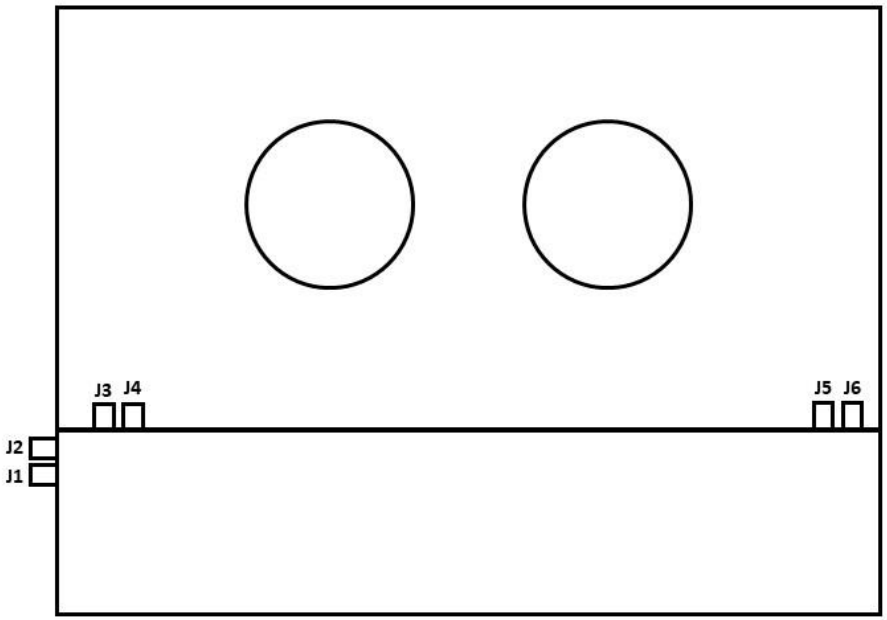


GT4823 – Infant Incubator
5V Power Distribution
Designer: Noah Daugherty | Date: 4/12/2020



GT4823 – Infant Incubator
Control Board I/O
Designer: Noah Daugherty | Date: 4/12/2020

pe	Connection
8 ire	Monitor
8 ire	Temp/Humidity Sensor
8 ire	Neonatal Temp Sensor
12 wire	Weight/Apnea Sensor
?	SpO2 Sensor
12 ire	Ambient Temp Sensors



Head

Incubator Side View

Foot

GT4823 – Infant Incubator
Sensor Connector Layout
Designer: Noah Daugherty | Date: 4/12/2020

Appendix I: Vitals Monitor Schematic