An at Home Cardiorespiratory Monitor in Low Income Countries

Final Report

Sponsors:
Prof. Aubrey Gordon
Ms. Caroline Soyars

Mentor:
Prof. Kathleen Sienko

Group 10

Jake Anderson (jakerand@umich.edu)
Nick Eidsmoe (neidsmoe@umich.edu)
Sydney Gordon (sbgordon@umich.edu)
Rachael Weisman (rweisman@umich.edu)

Executive Summary

Pneumonia is a very common respiratory disease that takes many infants' lives each year. If it goes undetected for too long, it can ultimately lead to death. One of the main causes of pneumonia in infants is Respiratory Syncytial Virus (RSV) [1]. Some of the common symptoms of these diseases are slow breathing, lethargy, and lowered oxygen levels [2]. Many of these symptoms are difficult to detect, especially in infants, where there is a communication barrier. More barriers accumulate in low income countries (LICs), where their access to healthcare is limited and less resourceful. Having the ability to monitor these symptoms will make it easier for parents to detect these deadly diseases in their children.

After talking to our stakeholders, conducting a literature review, and analyzing other devices that address this need, our goal for our project was to create a blood oxygen level monitor for infants in a home setting [3]. This monitor will give parents the ability to continuously monitor their infant's blood oxygen levels while the infant sleeps at night in their home. It also needed to accommodate the needs and resources of the low income countries. This important distinction was what made our project vastly different from the devices currently on the market that were used in homes and hospitals in high income countries (HICs).

Once our problem was initially defined, our group started working on user requirements and specifications based on the needs from our stakeholders and the performance of current devices available. Within our specifications, we took into consideration the conditions in low income countries like unreliable power and the cost of the device [4]. We also defined the intended use of the device and how it would interact with the user. All of these considerations were used to define our problem and aid in our next step in the design process, concept generation.

Our group used common design techniques like Morph charts and SCAMPER to ideate ideas for our problem. We chose techniques that would broaden our solution space by looking at different perspectives, and challenging our original ideas. Our team organized our ideas by anatomical structure to better evaluate our designs. These designs were then evaluated by using a Pugh chart and group discussion to narrow down our concepts to a few selected designs.

With the use case in mind, we created designs that would be suitable for infants to wear while sleeping in hot climates. We wanted our device to still work while an infant rolled around and moved in their sleep. Other considerations we thought about were the usability and barriers to technology and cost in low income countries. With all of those factors, we initially decided on a design that would be a custom sock with a detachable monitoring system. After speaking with stakeholders and doing a cost analysis, we realized that our device would be better suited for a research based environment with a partnered hospital. We modified our original selected design to be a two component device that strapped on the foot and leg. This would help for the hotter climates and use a more effective oximetry, transmissive oximetry.

Once we completed our detailed design, we created a prototype and started performing analyses to fully understand the functionality of our design. We prioritized the functionality of our circuit and how it would interact in the target environment to ensure it would work for the intended users. We currently have a prototype with a functioning circuit that outputs oxygen saturation but the interface and the usability of the device need to be improved before bringing it to low income countries like Nicaragua.

Table of Contents

Problem Description and Background

Respiratory Syncytial Virus Symptoms

RSV is a common respiratory disease that many people get by the age of two. It generally causes cold like symptoms, but in infants, it can cause more severe lung issues. These can lead to many diseases such as pneumonia, bronchitis, or an acute lower respiratory infection (ALRI). In 2005, there were around 33.8 million cases of RSV associated with ALRI in children under five, 3.4 million of these cases required hospitalization. Of those 3.4 million cases, 66,000 to 199,000 children died, 99% of which were in LICs [1].This difference in the outcomes between LICs and HICs is in part due to the difference in technologies available to each country, which is the specific need our device will attempt to address.

Another way to understand the scope of the issue is to investigate the Disability Adjusted Life Years (DALYs) caused by lower and upper respiratory infections and tuberculosis, all of which can be caused by ALRI. DALYs are the years of life lost due to premature mortality and the years of productive life lost due to disability. Respiratory issues make up 15% of all DALYs for children under 5 in LICs [5], which was one of the largest overall effects on DALYs in that setting.

Since most deaths and loss of DALYs are from LICs, we wanted to determine some of the factors that lead to this discrepancy. Some of the largest factors that prevent medical devices from being used in LICs are the cost of the devices, the difficulty of repairing the device, the lack of trained technical staff as well as a lack of reliable electricity [6]. However, the ability of the client to use the devices is generally not the reason that the devices fail. Engineering World Health Interviews revealed that of 331 pieces that could not be returned to the patient or clinical laboratory, none of them were due to a failure to train the users. They were instead due mostly to the inability to repair the devices, or the device being out of a consumable part like a test strip [7].

Most of the symptoms of diseases caused by RSV are testable without using consumable parts. These symptoms vary widely with the specific disease, but some of the more common symptoms in infants include a cough, difficulty breathing, low appetite, lethargy and lowered blood oxygen levels [2]. These symptoms are difficult to distinguish from their more mild and common forms, which can make it difficult for a parent to realize that something is wrong. One of the most reliable ways to determine if the baby is at risk is to measure oxygen levels, which requires a medical device.

Oxygen Level Measurements

Oxygen levels measure the percentage of oxygenated hemoglobin in red blood cells. When the red blood cells interact oxygen the oxygen attaches to the hemoglobin. The oxygenated hemoglobin interacts with organs for them to perform their functions. When organs do not get the appropriate oxygen it is a signal that there is some type of cardiac or vascular diagnosis [32]. Since pneumonia is a cardiovascular disease, measuring blood oxygen levels is an effective way of detecting pneumonia.

There are multiple ways of measuring blood oxygen level. In vitro oximetry is where a blood sample is taken and then analyzed in a lab to determine the amount of oxygenated hemoglobin. This method is not conducive to our problem as it takes discrete measurements of blood oxygen levels and is not meant for an at home setting. In vivo oximetry is another method of measuring oxygen levels in which the oxygen

levels are monitored by blood continuously passing through a catheter. Both of these methods are very accurate for detecting oxygen levels but are not suitable for at home use. Transmissive and reflective oximetry are two other ways of measuring blood oxygen levels that utilize light intensity [32]. Both of these methods are viable for at home use because of their ability to monitor without reliance on large monitors, labs, or blood drawn.

Figure 1. Transmissive Oximetry. A diagram of the mechanism for transmissive oximetry works on a finger. The LED passes light through the finger and the photodiode detects it on the other side [45].

Transmissive oximetry is the type of pulse oximetry that is most widely used in devices. The way transmissive oximetry works is a red and infrared light shines through an extremity, a finger or toe [32]. The amount of light intensity that goes through the extremity is measured through a photodiode. The photodiode then converts the amount of light into a proportional current. The current goes through a band pass filter and amplifier and then code is used to convert that signal into the blood oxygen levels.

Benchmarking

There are many devices that currently monitor oxygen levels. These devices are specialized to the market's resources, settings, and populations. The gold standard for measuring oxygen levels occurs in hospital settings in HICs. These devices although good for their intended uses would not work well for our intended population and setting, at home in LICs. The best way to measure blood oxygen levels is through an arterial blood gases test collected through an indwelling arterial catheter, an in vitro oximetry method. The main reasons this would not be a solution for monitoring infants at home is that the test needs to be analyzed in a lab and does not continuously monitor the oxygen levels [8]. Other solutions used in hospitals like the Masimo and Medtronic baby sensors are also commonly used in hospitals but are reliant on large monitors and are single use [9,10].

There are also products made to accommodate LIC clinics. Lifebox has a portable pulse oximeter that has different probes that accommodate for both adults and children. The pulse oximeter for adults is put on the finger while the one for the children is placed on the foot. Although there are different probes there are still complications with the children moving during the readings [11]. This movement causes inaccurate readings and causes the monitor to be unreliable for infants. This device is also not meant for continuous monitoring as our intended problem requires.

Devices have been made to address the issue of continuous monitoring for infants at home. The two main devices on the market are the Owlet sock and the Wellue Baby02 Baby Oxygen Monitor and intended for HICs. Both of these devices continuously monitor oxygen levels and heart rate. The big drawback from these devices is they are reliant on smartphone and wireless technology which is not reliable in low income countries [12,13].

LICs have very different healthcare systems than HICs and cannot rely on the same technology. Looking specifically at Nicaragua, there are many barriers that need to be considered when designing a blood oxygen level monitor. Many people in rural Nicaragua have a lack of power and internet which creates barriers in alerting the parents [44]. Parents can be located in the same room, the same house in separate rooms, or outside working [41]. This poses the challenge of balancing between the parent hearing the alarm system and the infant hurting their hearing.

There are very few devices that monitor oxygen levels for at home use in LICS. There are two at home fetal monitors, the Moyo and Freeplay Fetal Heart Monitors, that help give requirements and context for the solution to continuous at home monitoring. They give specifications for temperature and humidity in typical LICS [14]. They also give inspiration for how to design for unreliable power [15]. Another device, the Neopenda Vital Signs Monitor, is an infant monitor that records vital signs including blood oxygen levels which is still in its prototype phase [16]. This is a more accurate comparison to a device that resembles what our need is.

There are many devices on the market that address the issue of monitoring oxygen levels. The devices start to narrow down when focused on infant users. As the settings change from LICs to HICs and clinic settings to at home use, the devices change to adapt to the settings and the users within those communities. Table 1 below summarizes the various devices in regards to their monitoring capabilities along with the intended setting.

Table 1. Benchmarking of existing devices and their intended setting of use

Name of Product	Intended Setting	Monitors
Arterial Blood Gas	HIC hospital	oxygen levels and other blood gases
Masimo Sensor	HIC hospital	oxygen levels and heart rate
Medtronic Sensor	HIC hospital	oxygen levels and heart rate
Lifebox Pulse Ox	LIC clinic	oxygen levels and heart rate
Masimo Rad5	LIC clinic	oxygen levels and heart rate
ChARM	LIC clinic	Respiration rate
Owlet	HIC at home	oxygen levels and heart rate
Wellue	HIC at home	oxygen levels and heart rate
Fetal Heart Rate Monitor	LIC at home	fetal heart rate
Moyo Fetal Heart Rate Monitor	LIC at home	fetal heart rate
Neopenda Vital Signs Monitor for Newborns	LIC at home	Heart rate, respiratory rate, blood oxygen saturation, and temperature

Perhaps most important about our benchmarking was the ability to identify "The Gap" in the current marketplace solutions and our specific problem. From the devices benchmarked, we were able to pull a sample of devices and directly compare key components of each. While our requirements and specifications will be discussed in more detail in later sections, a key component of our design is the overall cost to the end consumer. Figure 2, page 7, highlights our intended consumer base and the distinct lack of current solutions on the market.

From this analysis, we determined that a significant amount of lower cost pulse oximeters are used by sports enthusiasts, with an average cost of approximately sixteen dollars (N = 25). Transitioning over to devices applicable for neonatal and pediatric continuous monitoring, the median cost was significantly higher at approximately two hundred dollars (N = 20) with one of the most expensive being the Owlet Sock.

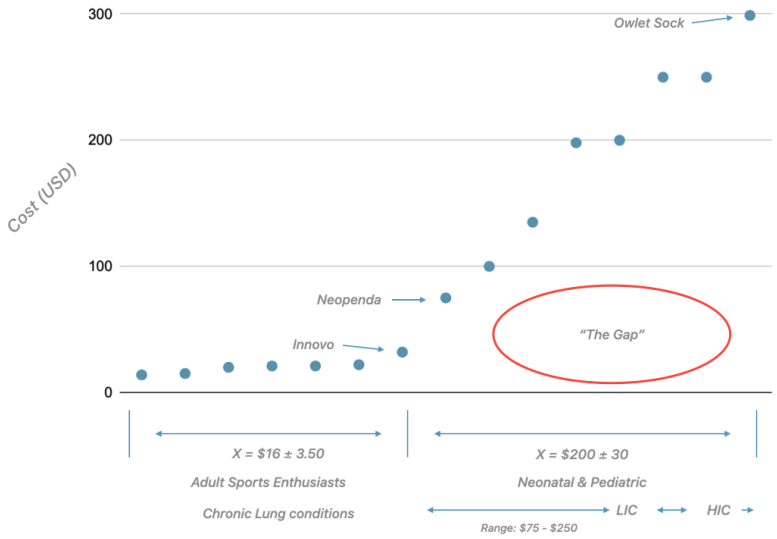


Figure 2. Cost comparison of current market solutions for oximetry monitoring. As indicated, there is a distinct "Gap" for inexpensive neonatal and pediatric overnight monitoring systems. The Owlet Sock (HIC applications) and Neopenda (LIC applications) are specifically highlighted as they are key benchmarks for our team moving forward. Please note that hospital monitoring devices were not included in the above analysis. Additionally, the averages and standard deviations were determined from larger subsets of data while only fifteen randomly selected data points were graphed.

Our next objective was to identify the rationale behind how each product was priced. After a high level feature map was constructed of each product, a more in-depth analysis was conducted of several current market solutions that we felt were the most similar to the direction we intended to go. In Figure 3, page 8, we compared the Innovo Deluxe Pulse Oximeter with the Neopenda Vital Signs Monitor. Neither of these solutions meet all of our requirements and specifications, but they served as a strong foundation for later product development.

Team 10 Reqs	Innovo Deluxe Pulse Oximeter	Neopenda Vital Signs Monitor
Continuous *SpO_2 monitor*	Sampling rate: 10s	Sampling rate: 15s
2 alert thresholds of SpO_2 detection	Singular threshold	Singular threshold
Auditory / *Visual* **Alert**	Auditory & Visual on device	Auditory & Visual on device
PT < $30	Avg: $16; Shown: $30	Avg: $150; shown: $50; MFG cost: $15
Meets WHO **safe**ty guidelines	Meets neither WHO nor FDA	Meets WHO not FDA
Fits *neonatal* & *pediatric* children < 1 y/o	Adult use only	Neonatal only
Rechargable batteries	2x AAA	200 hr continuous use; 250x cycles
Returned to hospital post-use	Not used in hospital settings	Used only @ hospitals by nurse
Minimizes *false positives*	Not calibrated	Factory calibrated
Easy to use	"Plug & play" - AMZN review	Requires additional hat
Simple & *Comforting*	"Sleek design" - AMZN review features	In use in LICs
Transmit data to non-located device	Not capable	Low energy bluetooth to tablet
Local manufacturing capable	Not capable	Shipping cost avg: $25 ; some local manufacturing partners
Durable	Hinge mechanism fatigues	IEC 60601-1 Edition 3.1 (medical electrical equipment safety), ISO 80601-2-56 (ISO 80601-2-61 (pulse oximeter equipment)
1 year use	2 yr	2 yr warranty
Easy cleaning	Water resistant	Snap on / off device

Figure 3. A comparison between the Innovo Deluxe Pulse Oximeter and the Neopenda Vital Signs Monitor. The Innovo device belongs to the group of oximeters heavily used by sports enthusiasts, and thus meets our price target but lacks several key functionality. The Neopenda is specifically designed for neonatal monitoring in LIC hospitals and is still in the prototype phase [16].

It's important to note that the Neopenda Vital Signs Monitor is targeting neonatal monitoring in LIC hospitals and is also still in the prototype phase [16]. This device functions by clipping onto a baby's hat and transmitting the data to a nearby tablet monitored by a nurse. There is no display; however, should a tablet not be available this device has a built in audio alert to notify an attending adult of any problem. This device utilizes a primary manufacturing location in addition to some local partners to keep the manufacturing costs low at fifteen dollars, with a consumer cost of fifty to seventy-five dollars depending on location, etc. An additional comparison between the Wellue Baby O2 and the Owlet sock was conducted in regards to our requirements and can be seen in Appendix 01.

From these benchmarks, we have shown the need for a low cost, constant monitoring pulse oximeter in LICs. However, in order to lower the cost of the device without trading performance, another method had to be taken. We decided to create a pulse oximeter kit designed from open source parts instead of a mass manufactured solution. The process needed and rationale that led us to this decision is detailed in Cost Analysis, page 21. With the influence of these devices, other leading LIC health monitoring devices and our new implementation plan, we were able to formalize the requirements and specifications for our novel device.

Requirements and Specifications

We determined our list of requirements and engineering specifications from our stakeholders, literature reviews, and benchmarking. A full list of our requirements and specifications are below in Table 2. The source column in the table shows the resource for creating the requirement.

First, we interviewed our two stakeholders to understand their constraints. From the interviews, we gained a lot of insight into what the solution should be capable of. For example, 'monitoring oxygen levels' and

‘Reduced cost for LIC’ as seen in the table were provided as constraints from our stakeholders [3]. We utilized the knowledge and experience they have working with LICs. Next, we researched different topics relating to our problem like medical devices in low-income countries. We then created requirements based on common themes we saw across multiple references. For example, ‘Is easy to use for parents’ was a common requirement for at home devices. Literature was also used to determine the specification for the stakeholder’s requirement. The requirement ‘Alerts parent auditory and visually when oxygen level hits warning or dangerous level’ was a stakeholder demand [3]; however, the corresponding values and visual alarm aesthetics in the specification were decided by published literature [18]. Finally, we also used benchmarking to determine specifications. We used existing devices to fill in values for our specifications as seen in the ‘Monitoring oxygen levels’ specification [9,14].

Table 2. List of Requirements and Specifications. Status legend: White, Yellow, and Red stand for complete, missing/incorrect values, and in progress. Source legend: S, B and L stand for Stakeholder, Benchmarking, and Literature.

Priority	Status	REQUIRMENTS	SPECIFICATIONS	SOURCE
I		Monitors oxygen levels	Device is able to determine oxygen level within an accuracy of ± 3% of oxygen level reading	S, B, L [3,9,14,17]
I		Detects oxygen levels at 2 specific thresholds	Warning oxygen level ≤ 95%. Danger oxygen level ≤ 90%.	S [3]
I		Alerts parent auditory and visually when oxygen level hits warning or dangerous level	Audio alert has a sound pressure level ≤ 85 dB at the babies ear. The visual alarm for the more danger level is red, the warning level is yellow, and the normal level is green. The visuals and auditory alarm are part of the monitoring device. The visual and auditory alarms go off when oxygen level is in the appropriate ranges. The parent will also be alerted through an SMS text.	S, L [3,14, 18,47]
I		Reduced cost for LIC	≤ $40 per device	S [3]
I		Is safe	Device is hypoallergenic, meeting the standards set in ISO 10993 - 10:2010, electricially safe, meeting the standards set in NFPA 99, and mechanically safe, meeting the legal requirements set in 16 CFR 1500.49.	S, B, L [3,14,19, 35,36, 37, 38]
I		Fits 0-1 year old babies and infants	Device fits 5th - 95th percentile. The average length range of a baby is 46.1 cm to 79.7 cm from 0-1 yr old. The average weight range of a baby is 2.5 kg to 11.5 kg from 0-1 yr old.	S, L [3,20]
I		Powered by rechargeable batteries	The device is able to operate without external power using a rechargable battery for 2 - 3 days. The battery has an LED indicator for the level of charge, which changes from green to yellow (when less that 25% full) to red (less than 10% full).	S, L [3,4,18]
I		Returned to hospital after 2-3 day use period so it can be reused	The device sends a text message to the parent after 2 - 3 days to remind them to return the device.	S [3]
I		Minimizes false positives	Device has a specificity between 70% and 97%.	B, L [21,22]
I		Is easy to use for parents	No medical training needed and <X seconds for set up procedure time for parents to place device on baby	L [39]
I		Is simple and comforting to parent	Parents have confidence and trust in the device. Avergae Likert Scale ≥ 3 out of a 4 point scale for comfort using the device (1 = will not use device/not comfortable, 4 = no concerns with device, very comfortable)	L [40]
I		Is able to transmit signals to secondary alerting device	Must be able to be heard over X dB of background noise and must be receivable up to Y meters away though Z feet of material	S [41]
I		Is able to be manufactured using local materials and provided to hospitals in an open source kit. Assembled by local physicians.	Device is able to be assembled in < X min and requires limited training All materials are able to be bought locally	S [34]
II		Withstands wear from user and environment	Device is able to be splashed with liquid (water, IPA, etc.) from all directions meeting IP 54 standards. Device is able to function in temperatures from 0°C to 40°C and humitity up to 95%.	S, L, B [3, 14, 25, 42]
II		Functions continuously for 1 year	No repair or replacement parts needed for a minimum of 1 year	S, L [3, 23, 43]
III		Cleaned by the hospital between users	Device is able to be cleaned with at least soapy water	B [14]

In order to focus our efforts, we ranked our specifications I, II, or III by level of importance. The level of importance shows which requirements we should prioritize over others. Level I requirements were must haves in the design. They related to the main and proper function of the device and were strongly requested by our stakeholder. Level II requirements related to the sub-functionalities of the device. They were important to the success of the product but did not relate to the main functionality of the device. Finally, Level III requirements were nice to have. They did not directly relate to functionality of the device but were still important capabilities for our device.

Next, looking at the status column, specifications are listed as white, yellow or red. The white specifications are completed, while the yellow and red specifications are still in progress. The yellow

status refers to specifications that are correctly written but are missing values or the values need to be updated, while the red status indicates the specification was not completed.

The first requirement listed on the table is ‘monitoring oxygen levels’. This requirement was sourced from our stakeholder as one of the main functions of our device, which made it a first priority requirement [3]. According to our stakeholder and additional benchmarking, a drop in blood oxygen level is a symptom of RSV or respiratory illness [3]. The specification was created to ensure the accuracy of monitoring the blood oxygen level. This is important as, according to references, parents have more anxiety from an inaccurate sensor than without one [33]. The 3% accuracy level was determined from similar products we discovered through benchmarking [9]. We wanted our device to be able to compare to the devices currently on the market.

The next requirement is ‘Detects oxygen levels at two specific thresholds’. The requirement and specification were both provided by our stakeholders and aid in how the device will monitor blood oxygen levels, so this requirement was also priority I [3]. Our stakeholder requested to have two blood oxygen levels for the device - a warning level and a danger level - to detect and then alert the parent [3]. This specification currently has a yellow status because it contradicts the accuracy specification in the previous requirement. Since the specification values are our stakeholder’s request, we are hesitant to update the detection levels without receiving her opinion. For this reason, the specification remains in progress.

‘Alerts parent auditory and visually when oxygen level hits warning or dangerous level’ is the next requirement. Alerting the parent of a dip in the baby's blood oxygen levels was another crucial requirement supplied by our stakeholder that supports the main function of the device [3]. The corresponding specification was determined based on benchmarking and literature. We used literature to establish the threshold of sound pressure level that was safe to hear and the visual signals for the alerting systems [18][47]. We also cross referenced the alerting requirements with benchmarking from the Moyo user guide [14]. The Moyo uses a similar color scheme and the same audio and visual alert combo [14]. This requirement and specification was important to ensure the performance of the device so the parent can become aware of the state of their child. In addition, the audio and visual alerting system uses universal signals since this device should be able to be used in different places over the world.

Another main constraint from our stakeholder in order for this device to be successful in Low-Income countries was the cost, so the next requirement is ‘Reduced cost for LIC’ [3]. The initial specification from our stakeholder was ≤ $10 [3]. Our stakeholders initially asked for $10 so the device would be able to be purchased in LICs around the world; however, this value became unfeasible due to the additional device feature requests. For the scope of this project, we also needed to narrow down the use case scenario, so we are able to gather more insight into the environmental context for the device. When we brought up this concern to our stakeholders, we agreed to design this device for Nigaragua and, therefore, are able to bring the price up to $40 [34]. Even so, this requirement and specification was a constraint we focused on as it was a big differentiator from the products currently on the market. For instance, most at-home devices in the US range from $135 to $300 [12][13]. These devices have technology and high

specificity (85.7% for hypoxia) that would also cause for more advanced technology which would drive the prices up for these devices [22].

The next requirement according to Table 2, is ‘Is safe’. This requirement was extremely important especially when creating a device in the medical field. In order for our device to be successful, it needed to meet specific safety standards to assure the parents and doctors that our device is safe to use. We determined the specification based upon benchmarking, standards and federal regulations. Our specification was created to make sure the device is safe to be worn on the skin of a baby electrically and mechanically and would not be a choking hazard. The standards and regulations that we feel are necessary to establish safety in our device are fourfold. First, the device needed to be hypoallergenic by the standards set by the International Organization for Standardization (ISO) [35]. The electrical parameters such as the voltage and current running through the device needed to meet standards set by the International Electrotechnical Commission (IEC) [36]. The device would have to pass the sharp edge test as described by the legal requirements set by the Code of Federal Regulations (CFR) [37]. Lastly, the device needed to be large enough that it would pass the choking test created by the CFR [38].

The next requirement relates to the direct users of the device - ‘Fits 0-1 year old babies and infants’. Based on information from our stakeholders, the age range for this device is 0-1 year old babies because they tended to appear to be asleep when their blood oxygen level dropped. For this reason, it is difficult for the parents to realize there is an underlying concern [3]. In order to support this requirement, we created our specification so our device would be able to fit on most babies based on the length and weight of babies in this age range [20]. This was important in order to understand the size and feasibility constraints of our device.

The next few requirements relate to the power source of the device. The first requirement is ‘Powered by rechargeable batteries’. In LICs, including Nigaragua, many households do not have access to electricity [3]. Since our device is for at-home use, the device needs to be battery powered and be recharged at the hospital. Our stakeholder also expressed that the patient should wear the device at-home for 2-3 days [3]. To accommodate this, the specification claims that the battery in the device should be able to last 2-3 days. The specification also includes a visual LED indication so the parent is aware of the battery life. We used literature to determine the standard visual indication and LED colors for the battery signal [18]. Since our device should be able to be used in various locations around the world, our signals need to be universal.

The next requirement, ‘Returned to hospital after 2-3 day use period so it can be reused’, compliments the previous requirement. Our stakeholder wanted the device to be taken home and constantly monitor the baby for 2-3 days. They then wanted the device to be returned to the hospital with the baby, so the baby is able to get rechecked and the device can be given to a new patient to take home [3]. This specification has a red status since we need to reconvene with our stakeholder to understand the best way to communicate this to the parents of the users. We believe the battery dying should be the first indication, but are also considering adding a timer, instructions, or additional alerts. We would like feedback from our stakeholders before making this decision to get insight into the locational factors of Nigaragua and LICs.

As seen from many sources, an inaccurate device provides more anxiety to the parents than no device at all [33]. We needed to make sure our product is as accurate as other current devices so it will be used. Therefore, the next requirement in Table 2 is ‘Minimizes false positives’. The status of this requirement is yellow as we currently have a specificity range from 70% - 97% [22]. This range was based on our benchmarking for devices that measure blood oxygen levels using a pulse oximeter but for hospital use [22].

In order for our device to be successful, our device needs to be easy to use, which is the next requirement. If our device is too complicated and parents are not able to properly place the device on the baby, then the device will be unused and/or unreliable [39]. For this reason, it is important that any parent is able to set up the device on their baby with no issues. In the specification, we wanted the set up time to be < X seconds to define this requirement. This number will be based on current market benchmarks and further research is required, which is why this requirement’s status is yellow.

Similarly, a parent will not put the device on their baby if they are not comfortable with it, so ‘Is simple and comforting to parent’ is the next requirement. The device needs to appear to be simple and non invasive to the parents or they will not allow for the device to be used on their child [40]. As a result, the specification measures parent’s confidence and trust in the device using a Likert scale. We would like most parents to express at least a three out of four on the Likert scale, indicating that they are fairly comfortable and willing to use this device on their baby. (1 = will not use device/not comfortable, 4 = no concerns with device, very comfortable). This requirement is priority I because if the parents do not have confidence or trust in the device, no matter how high the quality and reliability of the device is, the product will not be used without the parent’s consent.

The next two requirements were added based upon feedback from the DR #2 presentation. The first one is ‘Is able to transmit signals to secondary alerting device’. Based on the feedback from our stakeholders, it is possible that the parent would not be in the same room as the baby at all times, so they would like an additional alerting system [42]. This requirement has a red status as more research needs to be done in order to create a complete specification. We still need to figure out how far our device should be able to transmit signals, what materials the walls are made of and how thick of walls the signals should be able to transmit through. Additionally, we have also received contradicting information from our stakeholders about the use of smartphones as the secondary alerting device. Because of this, we need to have follow up conversations with our stakeholders to determine if using a smartphone as the additional alerting system is feasible. If it is not feasible, additional requirements may need to be added and specifications may need to be updated. For example, we would need to increase our cost.

The other requirement is ‘Is able to be manufactured using local materials and provided to hospitals in an open source kit. Assembled by local physicians’. Even with the price increase since DR #1, it is still not feasible to manufacture, mass produce, and distribute the product to LICs in the current price range set by our stakeholder [34]. On the other hand, the cost is a driving factor for making this product available in LICs and a differentiator from other products that currently exist like the Owlet. Therefore, in order to keep the price low, our product will now be open sourced and given to hospitals in a kit form, where the

device will be assembled in the hospital before given to the parents. The status of this requirement is red as we are still creating the specification since this was newly added.

Since our device is going to be used repeatedly and by many users, the following requirement, 'Withstands wear from user and environment', is needed for our device. This requirement was voiced from our stakeholders [3]. To cover the wear from the user, we researched standards to prevent wear. One standard we would like our device to pass is being able to be splashed with liquid. This will help with wear but also cleaning. Based on this, we determined that our device would need to be able to meet IP 54 standards, which would allow it to be splashed from any angle with water as well as not be damaged by small objects scratching the surface of the device[42]. Our stakeholder expressed the extreme environmental conditions in these LICs like high temperatures and humitidity [3]. In order to address these, we made sure that the electronics and other materials will not corrode or rust under these conditions.This requirement is priority II as it does not relate to the direct function of the device, but is still important for the device to work properly.

'Functions continuously for one year' was a direct request from our stakeholder [3]. Because of this, we would like our device to function without repair or replacement parts needed for the one year lifespan. Based on research, an obstacle in LICs for medical devices is not having the proper training or knowledge for fixing medical devices [23]. Since the lifespan for the product is short, the device should be able to work properly for the one year requirement without needing repair [43]. This requirement is also a priority II. We hope to meet our stakeholder demand but this does not affect the function of the device so it was not the top priority.

The last requirement is 'Cleaned by the hospital between users'. Since the device will be used by multiple users, it is important that the device is cleaned at the hospital before it is transferred to a new user. After conducting research and referring to benchmarking, we concluded that other medical devices in LICs are cleaned using soapy water. Even though some devices also claim they are cleaned with bleach and disinfectant, the specification says the device is able to be cleaned with at least soapy water [14]. Our wear requirement supports this specification as the device should be able to withstand liquid splashed on the device. This requirement is priority III because cleaning is important enough that it is a requirement; however, this does not impact the usability or functionality of the device.

In order to evaluate the quality and completeness of our specifications, we referred to Gavin's 8 Dimensions and the contextual categories from the Aranda-Jan paper [26, 27]. Gavin's 8 dimensions are a guide to make sure the requirements and specifications are complete [26]. We have marked each requirement with one of the 8 dimensions to ensure we have covered them. Similarly, we also marked each requirement with all 8 of the contextual factors. These contextual factors are designed to understand the context of designing medical devices for low-income countries [27]. By making sure our requirements and specifications met Gavin's 8 Dimensions and Aranda-Jan's contextual factors, we were able to confirm our requirements are complete, high quality, and considered design requirements specifically for medical devices in low-income countries.

Although there are other products on the market, they all have specific pros and cons depending on their target market. For instance, there are few at-home baby oxygen monitoring devices; however, they are

either very expensive and not designed for low-income countries or they do not have a long enough battery life and are not designed for babies specifically. For these reasons, we are able to use these devices to determine values for our specifications, but we are still able to create a novel device that will fit our target market. Refer to Table 1 for more specific information of the current benchmarking products.

Concept Exploration

Concept Generation and Development

The first step in our concept generation phase was individual brainstorming. This was meant to have team members not be influenced by one another when coming up with concepts and their interpretation of brainstorming. This stage was beneficial because we were able to see that some members brainstormed full solutions while others brainstormed subsystems as seen in Appendix 02. Our team members created designs that were different types of socks, batteries powered on material properties, camera monitors, and pressure mats.

From our initial brainstorming session we identified subfunctions of our design to analyze. Because our group had so many functions and our group decided that a morphological chart would most adequately explore all of our group's solutions. We broke our design into the monitor, housing, audio alert system, visual alert alert system, and power as seen in Appendix 03. For the housing subfunction, we grouped them by anatomical location to better organize our ideas. Our team decided to use a morphological chart as a concept development technique because our device has many components that are not dependent on one another. Having the morphological chart gave us the ability to expand our solution space. We were able to combine designs from our previous sections like a hat that would use a lullabye alarm system to a diaper clip that had a separate device on the parent to alert them.

Each member on the team analyzed the morphological chart to make unique concepts. This limited the bias of our team as we each were looking at the chart from different perspectives. With the new concepts from the morphological chart, SCAMPER and design heuristics cards were used to broaden our solutions space even further as seen in Appendix 04. SCAMPER helped our team look at our existing solutions and analyze our design space from another direction.

Design Heuristic cards were another way for our team to go outside our original solution space and create designs that were more novel. Our team was able to create the most varying designs from design heuristic as seen in Appendix 04. One member created an earmuff design that would be noise cancelling to the baby where the other side was a speaker to the parent. Another member created a stuffed animal design that the baby would hold onto while they are sleeping.

From our concept generation methods our designs fit into categories based on anatomical location. The main locations were head, hand, and foot. These groups were formed because from our research that is where most existing devices measure blood oxygen levels. We did generate concepts outside these groups which were less feasible because of the locations necessary for our monitor.

Figure 4. Arm sleeve design

One of the hand ideas was an arm sleeve idea where the electronics would be detachable from the wearable as seen in Figure 4. The audio alert system would wake up both the baby and the parent. If the alarm was not loud enough for the parent to hear the child waking up and crying would alert the parents. The device would have LEDs on the monitor to visually alert the parents of the warning and danger levels. An advantage of this design was that it would be easy to clean and recharge the device with the removable electronics. A disadvantage of this device was that it would be a choking hazard because infants put their hands in their mouth and the removable electronics can also create small pieces. Other disadvantages were the alert system was dependent on the infant waking up and the arm sleeve in hot weather could cause rashes and discomfort.

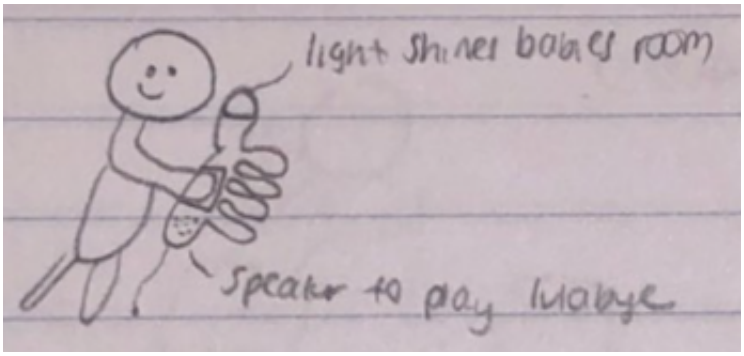


Figure 5. Stuffed animal design

Another idea was a stuffed animal that the infant would hold while they are sleeping as seen in Figure 5. This device would contain both the monitoring system and the alert system in the stuffed animal. There would be two pockets for the infant to put their hands in and that was where the monitor would be placed. The audio alerting system would be a lullaby that the parents would hear but not startle the infant. The visual alerting system would be a light that is incorporated with the stuffed animal that would light up the room when it was signalling and warning or danger level. An advantage to this design was that it was very comforting to the parent compared to other medical device appearance. Another positive of this design was the sound would be soothing to the infant but still alert the parent. Disadvantages to this design would be that stuffed animals were normally not in the cribs of infants 0 - 1 years old and the infant might not continuously hold the stuffed animal all night.

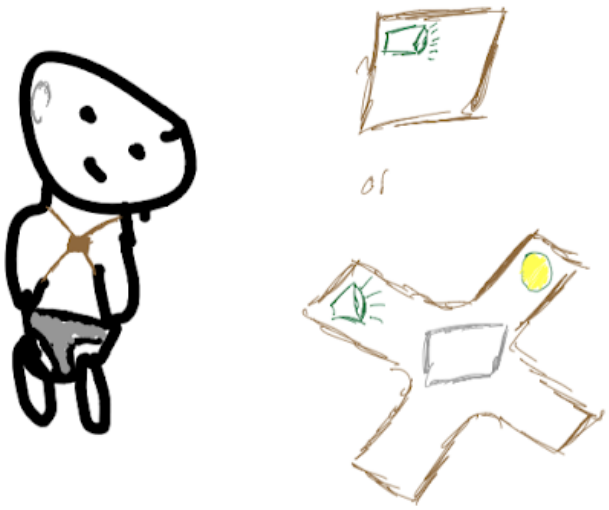


Figure 6. Chest strap design

A design that was more geared toward the climate we are working in was the chest strap design as seen in Figure 6. It has a backpack strap design where it would go around the infant's arms and the monitor would be centered around their chest. The monitor system would be in the shape of an X with the sensor being in the middle. On the top right of the X, the speaker system would alert the parents when the warning levels occurred. There would be one set of LEDS on the top left that would visually warn the parents about the oxygen levels and another set of LEDS on the bottom right that would indicate a low battery. An advantage to this design was that it considers the high humidity and temperatures of the environment where this device would be used. Another advantage of this design was that it was durable and would easily stay on the infant. A negative of this design would be it was reliant on reflexive oximetry which was not commonly used due to accuracy concerns. Another downside would be that if the baby was swaddled or facing downward you would not be able to see or hear the alert well.

There were many more designs that our team generated to explore the solution space. Our team was able to explore the solution space of the housing through SCAMPER and design heuristics. We were able to explore the audio and visual alert systems but still have the opportunity to explore that more if we focus concept development sessions on the electrical components. One of the spaces we have not really explored the solution space for would be the types of sensors and circuits used for the monitor.

Concept Evaluation and Selection

Once our team felt we had explored the solution space, we began to narrow down the solutions that we created. We think that the 55 solutions that we generated fully explored the solution space because they addressed all of the parts of the problem that we had determined from our research and benchmarking. The solutions encompassed the common positions for a pulse oximeter as well as some less common spots for the device. We explored many different ways of keeping the device on the infant as well as different ways of signaling the parent. All of these factors together allowed us to feel that the solution space was fully explored.

We moved on to create a "go no go" check for our designs. This check was a quick way for us to filter out concepts down to the most feasible designs. Since we had so many designs, we again sorted all of our concepts by the location that they were attached to the body. Once we had finished this test, we created a Pugh chart. The Pugh chart can be seen in full in Appendix 05.

We created the criteria for the Pugh chart based on our anticipation of the device's ability to meet our specs. Specifically, our criteria were: durability, whether it could stay on the baby, comfort, the amount of material used, the uniqueness of the solution, how much the parent would accept the device, the cost, the simplicity, feasibility and how well it would in the environment. These criteria were weighted using the different priority levels that the specs had originally. Once we had scored every design, we picked the top three designs, which were an arm sleeve, a shoe and a sock. The sock had the overall highest score, so we selected this after more discussion on the feasibility of making a shoe and concerns over whether an arm sleeve would be comfortable in warm climates.

We also made a second Pugh chart for the battery and sensor combinations. This Pugh chart can be seen in full in Appendix 06. As they were for the other Pugh chart, the criteria were based off from and weighted according to our specs. The criteria for the electronics Pugh chart were durability, cost, simplicity, the size of the device on the baby, rechargeability, electrical safety, lifecycle, cleanliness, bodily harm risk, and environmental context. This led to our final design of the electronics portion of the device being removable and lasting for 2 to 3 days.

Current Design: Design 1.0

Our current design combines the best design for the housing, the sock, with the best design for the electronics, a removable system. This design was the best design as it allows for the baby to be comfortable while they wear the device while also keeping the device safe and secure. When the sensor was removed, the sock could be washed like a normal piece of clothing, making it easy to clean. The sock itself will be made out of a cotton polyester blend while the sensor housing will be medical grade silicone. The electronics will use a 3V, 1200 mAh battery, four photosensors, and infrared and red LED light. This device will cost approximately $20.74 and is detailed in the Bill of Materials, which can be found in Appendix 07.

Pictured below is a CAD model of our device. On the left is the full model with the device and the sock and on the right is the device by itself. The sock itself has a circumference of 4.5 inches, a length of 4.5 inches and a height of 2.5 inches. The sensor device itself was removable and has a length of 1 inch, a width of half an inch and has a height of 0.5 inches. The device works on the top of the foot and was located in the middle between the ankle and the toes. It attaches using small pegs in the base of the device that snap onto the sock and the reflective sensor fits into a small hole in the sock to ensure proper placement. This sensor configuration allows us to meet our primary requirement of being able to measure the baby's oxygen levels and alert the parent at different levels.

a) b)

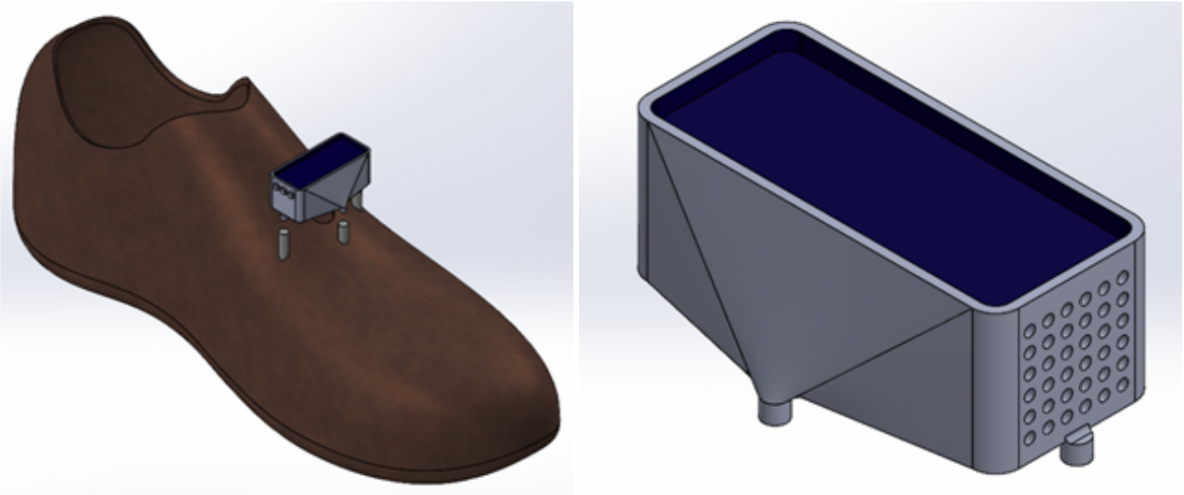


Figure 7: (a)The sock and device in proper position. (b) The CAD model of the device alone.

This device works based on a reflectance oximetry design. In this style of oximeter, light is reflected off thicker tissue or bone and returned to the photodiode in the same device. We felt that this was the superior option over transmissive pulse oximetry as it does not require a second device on the other side of the body part to read the signal. This signal was measured by the onboard microprocessor and the parent was alerted by the speaker and light system that are onboard our device.

From our initial cost analysis, this device meets the $40 cost threshold for the client, but will not produce any profit as it was just below the target price. The enclosed device will make it durable and unlikely to be affected by the environmental conditions. The clasps that ensure proper placement for the sensor also allow for the device to stay on the baby's foot so that it will not be a choking hazard or otherwise hurt the child. Our device was the best solution we have generated because it meets our requirements as they are currently defined. Our red and IR light system with the photodiode meets the requirement 'Monitors Oxygen levels' and along with the software it also meets 'Detects oxygen levels at 2 specific thresholds'. With the addition of the filtering and software measures, we are able to meet the 'Minimizes false positives' requirement. 'Alerts parent auditorily and visually' was met by the onboard speaker and lights. 'Reduced cost' was met by picking the lowest cost components which can be assembled locally to meet the 'Local Manufacturing' requirement. The device has no sharp edges, small parts or hazardous materials exposed which allows it to meet the 'Is Safe' requirement.

Our device uses two standard, off the shelf AAA batteries which meets our 'Powered by rechargeable batteries' requirement. This lifetime for the batteries will allow for it to last for two to three days before it needs to be returned to the hospital, which satisfies the 'Returns to hospital' metric in part. Further ideation for how the device will be encouraged to be returned to the hospital will be developed.

The device meets the 'Is easy to use' requirement as it requires the parent to put a sock on their child and snap the device on, which requires little technical knowledge or difficult skill. The device was 'Simple

and comforting' as our specifications require due to its simple, enclosed design. This enclosed design gives it the durability to meet the 'Withstands wear from user', 'Functions continuously for 1 year' and 'Cleaned by hospital between users' due to the water resistance of the material. Since our device meets all of these requirements and specifications, we feel it was the best design of all concepts we have generated.

Challenges with Design 1.0

The first problems with Design 1.0 came from additional benchmarking done after DR2. We had thought that the reflectance design was a common pulse oximetry device, but in reality it is not frequently used. The reasons for this are twofold. First, the device requires very precise positioning to ensure that it gives proper readings. The device being at a slight angle or wobbling as the baby moves around would likely cause the device to have improper readings. The other reason that these devices are not frequently used is that they have a very low signal to noise ratio, which means that it is more difficult to interrupt your measurements when they are taken. This can be alleviated with signal processing, but this requires additional electrical components which will add cost. However, we also realized that the device was already unable to house all of the components that we need for our device to function and will need to be much larger than Design 1.0 currently had.

The other problem that came up was that the device's alerting system being on the child would either be difficult for the parent to notice if they are not near the parent or loud enough that it would have the potential to harm the infant. In order to fix this, we needed to create some sort of off device signally method, which was not currently possible with Design 1.0. The sock itself was a concern as the potential for it to be too warm or otherwise very uncomfortable in warmer climates was likely.

With all these factors, we determined that Design 1.0 was not feasible, and we needed to go back to our other generated concepts to create our next solution.

Engineering Analysis

We created a list of design drivers to help determine which tests to conduct to analyze the functionality of our device, the requirements, and specifications. In doing so, we decided that cost, safety, circuit analysis, sound/alerting system, usability, monitoring, thermals, and energy were the most important aspects of our device. From these drivers, we created 13 tests to verify our design and current working prototype was functioning correctly. Cost, safety and circuit analysis were initially tested. The cost analysis was a first priority because our cost requirement was a driving factor in our designs. Since we are working with a very small budget, many of design decisions, like component selection and manufacturing process, were determined with cost in mind. These design decisions affected other aspects of the project which is why it was completed first. The next top priority was the safety of the device. It was very important to meet safety standards, not harm the users, and not cause anxiety or stress to parents. For this reason, we conducted a risk analysis and FMEA to determine the highest risks in our design. Based on the analyses, we were able reevaluate our design for safety concerns like adding gauze to make the loose wire flush to the skin. Finally, the last top design driver was circuit analysis. This driver includes many tests, but the first one was determining the circuit components. It was important to pick components that would provide accurate readings, be able to be shipped to Nicaragua, and satisfy our budget. This was a first priority as we needed to purchase the components to create the prototype and conduct tests on our circuit. After

these initial tests were conducted, we continued to test the sound/alerting system, monitoring ability, usability, thermal analysis, and energy consumption.

Circuit Component Selection

This analysis was chosen in order to optimize each individual component of our device for cost and functionality and to test the 'Reduced cost for LIC' requirement. To do this, we researched each component individually to make sure that it would fit our needs and read through manufacturers catalogues to determine the proper component. A high level of depth was chosen for this analysis, as we needed to ensure that the components that we were getting were the best for the price point and met our needs.

Our resistors were selected in order to create a bandpass filter with a frequency of 1.5 Hz and a bandwidth of 1.5 Hz. This small range is to ensure that we are getting only the signal from the photodiode and minimize any external noise. This signal is then strengthened by the amplifier which was selected to have a 300 times amplification of the signal. The two LED lights were selected to have distinct wavelengths to maximize the difference in their intensities.

The largest design consideration came from our photodiode. An ideal photodiode for our device would have a maximum sensitivity only at red and IR wavelengths, 645 to 940 nm. There was no photodiode that was sensitive only at the wavelengths for IR and Red light, so we needed to get a photodiode that was sensitive at many wavelengths. A comparison of photodiodes can be seen below in Figure 8 and Table 3:

a) b) c)

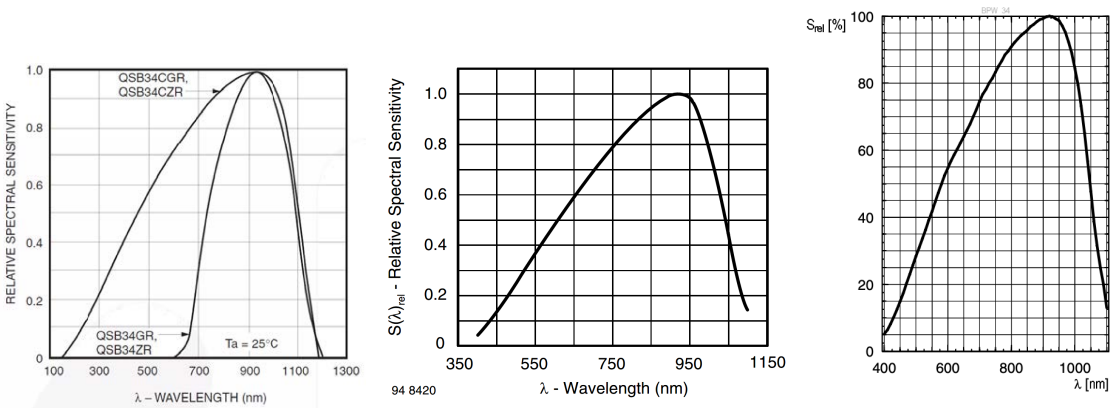


Figure 8(a)(b)(c). a) left, spectral sensitivity of several Fairchild photodiodes. b) middle, spectral sensitivity of a Vishay photodiode. c) right, spectral senstarivey of an OSRAM photodiode.

Table 3. Photodiode selection. The parameters of the photodiodes were used to determine which one would be the most optimal for the device.

Part Number	Peak Wavelength	Sensitivity at 645nm (%)	Sensitivity at 940 nm (%)
Fairchild QSB34CGR	940	80	100
Fairchild QSB34GR	940	5	100
Vishay VBP104SR	920	60	99
Osram BPW34	925	60	99

As Figure 8 and Table 3 show, there was no photodiode that was only sensitive at the wavelengths we desire. This requires us to have additional measures for reducing the effects of ambient light, as our photodiode would be more sensitive at this level than we had initially suspected.

Our initial testing showed that our design was functional. See circuit analysis, page 23, for additional information on how these components were performing in our initial tests. We have high confidence in the analysis we have performed here and the components that we selected because of it. This is because of the meticulous methods that we performed to ensure compatibility for each part as well as cross comparing multiple similar parts to find the best options. This led us to believe that there are no technical issues that we know of that have been overlooked but we would address any issues as they surface. We also have no need for further analysis at the moment but would use these methods when new components are needed for this project.

Cost Analysis

A cost analysis was one of the first analyses completed. We realized cost was the only differentiator between our product and the devices on the market like the Owlet. Since, we would like our product to be <$40 USD, according to our requirements and specifications, we researched many similar products to determine the costs of products currently on the market. All other products are much more expensive and mass produced. For this reason, we decided to speak with additional stakeholders to understand the feasibility of mass production for our price constraint, since this was our original plan at the end of DR2. After speaking with Randy Schwemmin [45] and Jeff Plot [46], we learned that mass producing our product that meets our cost requirement was not feasible. In the medical device industry, the margin target is 80%, so we would need to be able to purchase all our components for $8, which was not possible [46]. For this reason, we looked for guidance from our stakeholders, Professor Sienko and Caroline Soyars. After meeting with them, we decided to change our conceptual implementation plan, which can be seen below in Figure 9 [45,46].

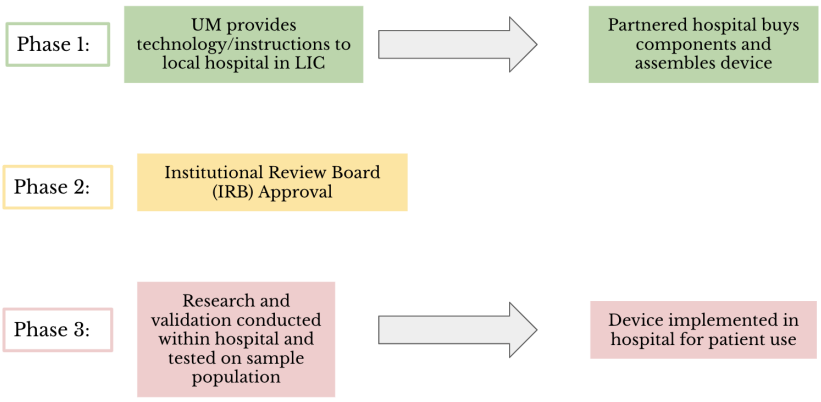


Figure 9. The conceptual implementation plan for our research intended use product.

From these stakeholder conversations, we shifted our product from being mass produced to be a research intended product that uses modular parts. By looking at Phase 1 in Figure 9, the first step in our conceptual implementation plan is to partner with a hospital in an LIC, probably in Nicaragua. We will then provide them with the modular parts needed to create the device and instructions for assembling. The hospital will then be able to purchase components to create as many devices as they would like and they would assemble the devices themselves. We are assuming that the hospital would have electrical technicians available to assemble the devices. Next, Phase 2 is having the hospital receive local IRB approval. This would allow the hospital to use the devices to conduct biomedical research on people. Finally, Phase 3 is having the hospital conduct research and validation testing on a sample population. When the device is up to hospital standards, they will implement it for patient use. This new plan allows the hospital to spend up to $40 USD on purchasing the components because the device is now being used as a research tool and not for profit. Additionally, due to the nature of this process, the project will be handed off to our partners in Nicaragua. More testing will need to be completed to ensure the safety and accuracy of the device. When they receive the device at the partnering hospital, they will be responsible for completing the additional testing to ensure proper use of the device.

In order to make sure the new implementation plan was feasible, we created a bill of materials for the components that would be needed to be purchased by the hospital to make sure the total was <$40. Further, we determined the prices for bulk ordering for the hospitals. Figure 10 below shows the bill of materials and the bulk ordering analysis.

a)

Bill of Materials

	No.	Name	Description	Qty	Component Cost
Electrical	1	Raspberry Pico	Microprocessor	1	$4.00
	2	GSM SIM800L	2G Arduino Module	1	$1.80
	3	MSD LM2596S	Buck Converter	1	$0.45
	4	Li-Po 3.7V battery	1800 mah 6.6Wh	1	$5.75
	5	Display	LCD1602	1	$1.35
	6	Photodiode	512-QSB34CGR	1	$0.68
	7	Alert LED	RGB	1	$0.34
	8	Alert Speaker	CQ Robot CQRLB8O5W-B	1	$4.00
	9	Power Switch	On/Off Switch	1	$0.75
	10	Misc. Wire	24G	-	$1.00
	11	Resistors & Capacitors	Various	-	$1.50
					$21.62
Mechanical	1	Foot 3D print	PLA 40% linear infill 40 mm/s	1	$0.30
	2	Housing 3D print 1	PLA 60% linear infill 40 mm/s	1	$0.80
	3	Housing 3D print 2	PLA 60% linear infill 40 mm/s	1	$0.80
	4	Housing 3D print 3	PLA 60% linear infill 40 mm/s	1	$0.80
	5	Foot Strap	Elastic Gauze 2.5cm W	1	$0.62
	6	Calf Strap	Elastic Gauze 2.5cm W	1	$0.62
	7	M4x15 screws	Mounting (30c/u)	10	$0.48
					$3.94

b)

Bulk Ordering

Qty	1	50	100
Cost Savings Single Unit	-	3%	5%
Shipping to Managua (Total)	$10.00	$140.00	$190.00
Sub-total	$25.56	$1239.66	$2428.20
Taxes (15% flat rate)	$3.83	$185.95	$364.23
Total Expenditure	$39.39	$1565.61	$2982.43
Final USD Cost Single Unit	**$39.39**	**$31.31**	**$29.82**
Final Córdoba Cost Single Unit	C$1374.32	C$1092.41	C$1040.42

Figure 10. BOM (a) and bulk ordering chart (b) for the components of the device.

According to the BOM and bulk ordering chart, the cost to create one device is $39.39. This analysis shows that we are able to meet our cost requirement and specification using the new conceptual implementation plan. Additionally, if the components were bulk ordered for 50 or 100 devices, the cost of each unit would be $31.31 and $29.82, respectively. This analysis used the assumption that the hospital would have access to a 3D printer, soldering iron, oven, wire strippers, and a screwdriver.

This analysis was appropriate as we were able to shift our leading concept to satisfy the cost requirement and specification. We believe that there was a great enough level of detail in this analysis in order to determine that the current leading concept would not satisfy a top requirement and we were able to create a new solution. We could go more in depth by reaching out to suppliers to understand how much it would cost to mass produce our device; however, we were able to come to a conclusion without that level of detail. We also were able to do research to pick accessible components that were in our price range. Our current design plan seems functional. As people continue to develop a circuit prototype and experiment with the current chosen components, we will be able to make adjustments to the BOM when necessary. We also are fairly confident in this analysis. This implementation plan seems reasonable to be done and we believe we have the necessary resources and mentors to help with the process. We will also be able to easily swap out components from the BOM as we continue to develop our prototype. We do need to communicate with hospitals in Nicaragua to make sure they have the necessary supplies stated above that we are assuming they have access to. We also need to make sure they have an electrical technician who is capable of assembling the device. Finally, if any components need to change, we will have to do further cost and bulk order analysis to make sure we are still meeting our cost requirement and specification.

Circuit Analysis

The first analysis that was conducted on the circuit was measuring the voltage going through each component of the circuit. From the measured voltage we will determine the amount of current going through the component of the circuit. This was meant as both a safety test and a functionality test. We

want to make sure there was a safe amount of current going through each component of the circuit. We also don't want to have more power going through the components then they are rated in their datasheet. Physical testing was an appropriate mode of analysis because it measures both current and power are safe for use and want to make sure there was power going through all the components. This analysis makes sure each part of the circuit, as seen in Figure 11, was functioning its purpose of the circuit. We decided it was important to be very detailed to make sure each component of our circuit was physically working and we are keeping the technicians who are putting the circuit together safe. This relates back to our requirement of the device being electrically safe. If we notice that some parts of our circuit are drawing too much current we will change the type of resistors used in our band pass filter and amplifier. This analysis will give our team confidence in whether our circuit physically works because we are measuring the values in question. Once this analysis was complete we were be able to do further analysis on the functionality of our device in terms of reading in values from the sensor and turning them into oxygen levels.

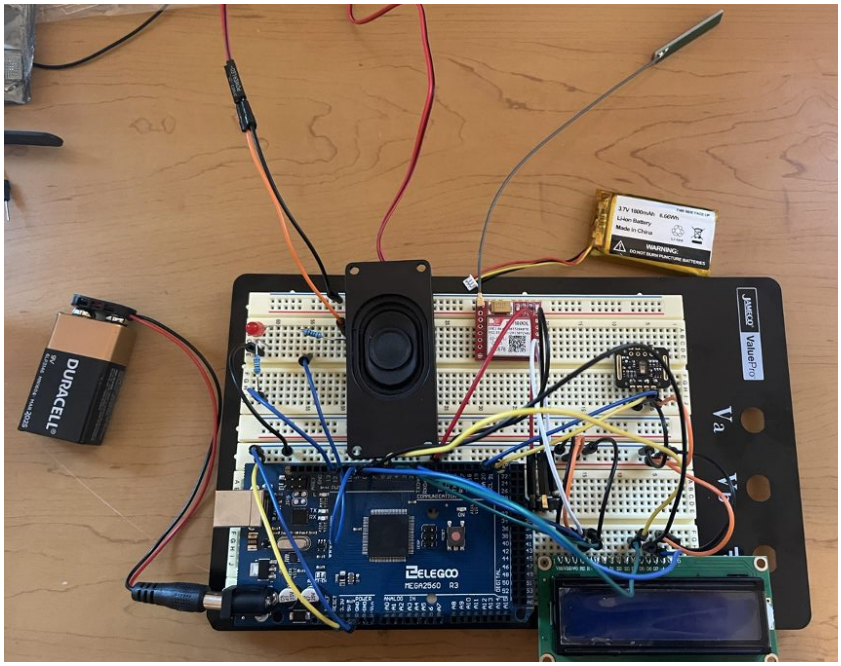


Figure 11. The physical prototype of the circuit

The next test we will conduct for our circuit analysis was comparing the readings of our pulse oximeter prototype to a commercial pulse oximeter. We are still continuing to develop our prototype, so this test has not been completed yet. For this test, we will place our prototype on one hand of a team member and place the commercial pulse oximeter on the other hand of the same team member. This test will help us understand the accuracy and specificity of our sensor. By comparing the readings to the commercial oximeter, we will be able to check accuracy by seeing if our sensor was outputting a similar range of readings to the commercial oximeter. For specificity, we can compare how large the range of readings was in our device to the commercial device. This was important as we are testing two priority I requirements. For accuracy, our specification was 'Device is able to determine oxygen level within an accuracy of ± 3% of oxygen level reading'. By conducting multiple trials of the test described above, we will be able to

have a preliminary accuracy range. Next for specificity, our specification states ‘Device has a specificity between 70% and 97%’. This was the range we have seen across benchmarking, so we would like our device to compare to devices on the market. The commercial pulse oximeter we will be using in this test has a specificity range of 70%-100%. For this reason, by comparing data from both devices, we can get a preliminary understanding if our device was consistent with the commercial pulse oximeter, which has the same specificity range as our device.

We chose this method of testing because it takes little additional effort once the circuit was completed, but will provide an initial starting point for the accuracy and specificity of our device. Since we will gather value data, this method of analysis was appropriate. A greater detail of analysis can be conducted; however this test was just to gain initial data points for our proof of concept. The results of this test will show us the next steps we need to take to improve the accuracy and specificity. We may have to change components in our circuit or continue to conduct more concrete tests to collect more confident data. After conducting this test further analysis will be needed. This test was not to determine the accuracy or specificity range, but only to understand the current ballpark of ranges our device was in for the initial proof of concept.

Sound Analysis

Another analysis that we completed was an analysis on the sound levels. This analysis was to make sure that our device would be safe for the infant and to optimize the distance between the parent and the device. This was to ensure that our device can meet the ‘Alerts parent auditory and visually when oxygen level hits warning or dangerous level’ and ‘is safe’. The two parts of the analysis were analyzing the sound level for the baby and the parent. For the baby, we want to make sure that it was not at a level that will hurt the infant. Based on a WHO report on sound and children, 85 dBA is the lowest sound pressure level that could potentially cause damage to the ear [47]. This number was used as the upper limit for the sound pressure level. In our analysis we assumed that the device would be 50 cm from the baby based on the average length of a newborn baby [48]. The output sound pressure level rated for each speaker was found from the datasheet of all the specifications of the speaker as seen in Table 4. The distance that the parent could hear the device was optimized to be as far as possible so they don’t have to be reliant on the SMS messaging. The level of sound that was used to determine how far the parent can be was 60 dB because that is the level of conversation in a busy place and background music[47]. Looking at both of those parameters the CQRLB8O5W-B speaker was chosen because it was the under 84 dB limit and allows the parent to be around 5 meters away from the device while still hearing the device.

Table 4. Speaker selection. The parameters of the speaker were used to determine which speaker would be the safest to use and loudest for the parent to hear

Part Number	Output Sound Pressure Level rated (dB)	Power and Distance of Output Power	Sound Pressure Level at .5 m (dB)	Distance (m) at 60 dB
AS04516MR-2-LW105-R	86	1 W/ .5 m	86	10.08
CMS-40504N-L152A	100	1 W/ .1 m	86.02	10.16
CMS-28528N-L152B	99	1 W/ .1 m	85.02	9.05
SP-1304	88	.1 W/ .1 m	74.02	2.54
P-1303L	87	.1 W/ .1 m	73.02	2.26
SP-1510	85	.1 W/ .1 m	71.02	1.79
CQRLB8O5W-B	94	1W/.1m	80.02	5.07

This mode of analysing the audio alert for our device was most appropriate because our budget was low so this saved money and time of testing each of these speakers individually. This analysis was done as a high overview to be able to pick a speaker that would not hurt the infant and continue to do testing on the prototype. From this analysis we were able to pick a speaker for our prototype that would be most suitable for our requirements of the audio alert that would be safe for the infant and loud enough for the parent to hear. Based on this analysis it was important to have another alerting feature to warn the parents because the level to not harm the baby the parent would have to be five meters away from the baby. This was also a simplified model as we don't take into account other noises that could dilute the audio and barriers like walls that would reflect the sound. Since we do not know the exact use case and this was a simplified analysis, it was important to have the SMS messaging and the visual alert system as other methods to alert the parents.

Based on this analysis, we are confident that we have a speaker which can notify a parent that was in the same room or in the next room. These results come from the spec sheets of the speakers and the analysis comes from multiple sources so we believe the results are accurate for the assumptions we made. We would still conduct empirical testing on the speaker chosen with background noise and the addition of walls to get a more accurate representation of some of the scenarios parents would be in when they were hearing the alarm.

The next aspect of our design we were testing was the functionality of the alarm system of the device. According to our requirements, we would like our device to 'Alerts parent auditory and visually when oxygen level hits warning or dangerous level'. The specification for this requirement explains the specific harmonic frequency for the alarm levels and the visual alarms protocol. The device's LED should light up green when the oxygen level was in a normal range, orange when the oxygen level was at the warning level, and red when the oxygen level was at the danger level. The device should also make an audio alarm when the oxygen level was in the warning or danger level. We are testing this requirement simply by using the prototype and seeing if the alarm goes off at appropriate oxygen levels and if the corresponding LED color was lit.

By conducting multiple trials and documenting if the alarm sounds and the correct LED lights up, we are determining if our device will be able to function properly. Currently, we have created the circuit with an LED and speaker, but we are still working to refine its ability to read the blood oxygen levels. Once the circuit was able to read the blood oxygen levels, we would be able to conduct trials and record this data. This analysis was appropriate as we will be able to get instant feedback if our circuit was working properly by actually using it. Eventually, we will add more detail to this test, but we will be able to understand the starting point of the circuit we built and if it was able to detect the various oxygen levels we set for the device. We will be able to understand if our vision for the audio and visual alert seems reasonable for the device by seeing it in a proof of concept. This test will help us gain an initial reaction for the alarming system, so then we will be able to conduct further testing to make sure the alarm sound and visual alerts are prominent enough to alarm the parent. We will be able to manipulate different levels of volume and brightness. If our test fails, we may need to do research into different components, troubleshoot the circuit, or adjust the oxygen detection levels.

Motion Analysis

A motion analysis would be performed once the circuit was complete. We will test the device stationary and record the oxygen saturation levels and will then test it with added motion. We will do several different conditions seeing if some motion will affect the readings and others won't. Some of the different conditions we will test are rotational motion, pure linear motion, and combined at different speeds and distances. This will help us determine if our device is able to meet the requirements 'Monitors oxygen levels' and 'Detects oxygen levels at 2 specific thresholds' while the infant is moving with the device on.

This mode of analysis was appropriate for our resources because we don't have an infant to conduct these tests and it is faster than conducting simulations or first principles models. The different types of motion are important to test because infant's movement is unpredictable so we need to test varied motion. When we complete this test and see variance in the oxygen levels we will look into adding an IMU to see how we can modify our device to more accurately measure oxygen levels when our device is in motion. Some technical issues we are overlooking in our design is if blood oxygen levels change due to motion and if that could be the cause of discrepancies and not our device. Because we are looking at such critical values and trends not instant values we do not think this oversight will cause issues in our testing.

Thermal Analysis

Thermal analysis was performed with Ansys Discover Live to ensure design durability (both housing and electrical component wise) over the course of one year at worst case environmental conditions. At this point in time, we aim to function in a wide range of temperature and humidity conditions (0 - 40C and 0 - 95% non-condensing humidity per our stakeholder requirements). We also wish to ensure the infant or consumers are not subject to unsafe temperatures. As we are still working on a physical prototype and aim to stay away from destructive testing, we believe simulations were the next best method of analysis. The results can be seen below in Figure 12:

a) b)

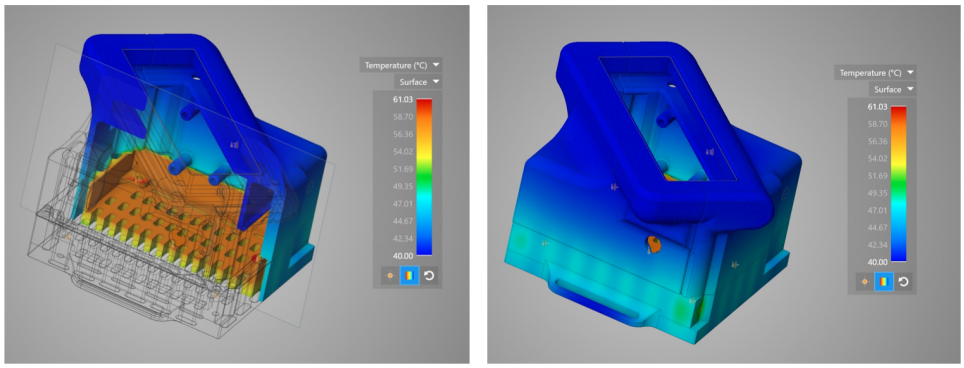


Figure 12. (a) Cross-section view of housing 1 in a 40C ambient temperature condition at max energy out and 95% non-condensing humidity. (b) Showcasing the temperature gradient across the case thickness with a delta of greater than -14C.

At external temperatures of 40C and non-condensing humidity of 95%, this extreme scenario is extremely hot and thus serves more to highlight the temperature drop across the housing 1 thickness. With the bottom potentially against an infant's skin, we are confident that this delta protects the users against any extreme temperature variations that might arise. By ensuring our device functions under these operating conditions we are confident that we meet our stakeholder requirements of 'Durable' and 'Safe'.

Energy Use

Energy analysis will be performed after the submission of the DR3 report after taking measurements with our finalized prototype. At this point in time we are still sourcing one or two remaining components and working on optimizing the code's logic to minimize energy usage while maximizing accuracy. In this analysis, we will confirm that the capacity of the battery was sufficient for steady-state power consumption and was sufficient for multiple SMS communications, as this was the largest potential current draw at any given time.

Ensuring appropriate power and battery capacity is vital towards guaranteeing the device functionality and end user safety. Over the course of 1 year the rechargeable batteries will potentially cycle from full to discharge more than 120 times, which requires us to factor in the battery health. By ensuring we can sufficiently power the device after 120 cycles at max predicted energy use, we are confident that our device will meet our stakeholder requirements of 'Powered by rechargeable batteries', 'Returned to the hospital after 2-3 day use period so it can be reused'.

Assembly Analysis

Assembly analysis will begin after the submission of the DR3 report and preliminary findings will be incorporated into our design exp and final report; however, some work will need to be done by the partner hospital and in LICs. Due to the COVID-19 pandemic, we are unable to trial mass assembly and are relying on low volume builds to inform design iterations. The end goal of this analysis was to meet our 'Is an open source kit [...]' requirement and prove that these can be mass assembled (scale 50-100) by knowledgeable technicians in these regions. As such, we are aiming to run time trials of assembly given

that the person who assembles our devices has access to basic tools such as wire cutters, soldering iron, screwdriver and a 3D printer. We would then track any areas of difficulty and work to iterate through these challenges via clearer assembly instructions or a small change in the overall design.

At this point in time, as we are still working to complete a physical prototype ourselves, and thus we still have work to complete towards this analysis and this requirement. Thus, while we believe our design can and will meet this requirement, we cannot say with confidence that we do until we have completed a first round prototype ourselves. Once our initial prototype was complete, we planned to analyze the process and better refine our assembly instructions.

Electrical Component Deformation

Structural and fatigue analysis was performed with Ansys Discover Live to ensure design durability (both housing and electrical component wise) over the course of one year. A load case of a two meter drop on the corner of the housing was used for impact loading, and a general use case with torsion on the strap loops was used for fatigue. The results can be seen in Figure 13 below:

a) b)

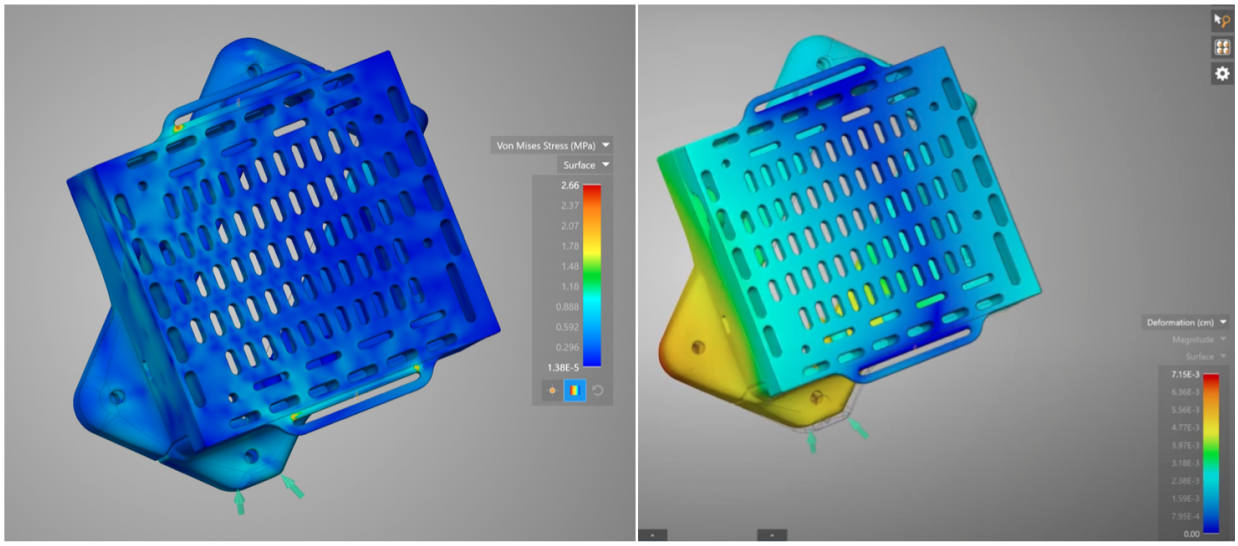


Figure 13. (a) Stress on housing 1 from a two meter drop. With the current planned printing conditions this gives a safety factor of five [49]. (b) Deformation of housing 1 and the electrical components from a two meter drop. With the maximum deformation all electrical components have at least a safety factor of two.

This analysis was performed as compared to destructive testing of a prototype, and will be used in conjunction with the physical prototype to determine the minimal amount of material necessary to ensure functionality over the course of a year (without real world testing). Once real world testing begins by a partner hospital, further design iterations may be necessary in order to accomodate the environment. However, at this point in time we believe this analysis helps support the fact that our design meets the ‘Functions continuously for 1 year’, ‘Durable’, and ‘Safe’ requirements as set by our stakeholders.

Risk Analysis

Our Risk Analysis was chosen based on industry standard decision matrices in the industry standard level of detail and was chosen to test our "Is safe" requirement. For the risk analysis, we created a list of the largest concerns for our device and how it can affect the user. From there, we generated a situation that the hazard could occur in as well as the likelihood, the impact it would have on the infant, the level of severity, the technical performance and what actions we have in place to minimize or prevent its effects. This chart can be seen in full in Appendix 07, but two key hazards are reproduced in Figure 14 below.

Hazard	Hazardous Situation	Likelihood	Impact	Level	Technical Preformance	Actions to Minimize
False Positive	The parent may ignore real alerts if false positives are too frequent	High	Serious	4	No technical impact	The signals used by the device must go through several signal processing methods such as a filter and be based off average measurements, not the measurements of that instant
Wire Hazards	The infant may choke or otherwise be harmed by the connecting wire	Medium	Serious	3	Baby may remove wire connections	The device must alert the parent when the wire is removed. Wire acts as a breakaway so it will unplug instead of providing a hazard to baby.

Figure 14. This figure shows two key hazards, the potential for false positives and the harm that our connecting wire can cause.

The false positive hazard was selected as we are concerned by the potential for the device to signal incorrectly that there is a hazard and cause the parent to ignore when a real hazard could occur. We considered this to be a very likely scenario as the device will be taking many measurements and it is an inherent problem with any measurement. It has a serious impact since it can cause the entire device to fail to meet its function and a level 4 classification due to these two factors. It has no effect on technical performance though as the device will continue to function whether this happens or not. To address it we have implemented a bandpass filter in our design as well as creating software measures to make every signal output actually based off from all the measurements taken in 20ms.

The wire hazard was selected as we are concerned by the potential for the infant to choke or otherwise be tangled with the wire. This is only a medium likelihood as the baby could potentially be swaddled or otherwise be in a use case that prevents them from moving around; but since it can harm the infant, these two factors combine to give it a level 3 assignment. If the baby pulls on the wire, this could cause stress on the circuit board causing the device to fail to function. In order to minimize this, the wire connecting the two devices is designed to be a breakaway wire so that any force the baby puts on it will cause it to unplug instead of providing a hazard.

These safety factors had important design consequences but had mostly been addressed earlier in the design process due to our research and stakeholder feedback. This risk analysis did lead us to consider the hazard that the wire running between our devices could cause, which was not a part of our earlier safety considerations as it is a relatively new part of our device. Our current prototype has features that meet the mitigation methods detailed in our risk analysis but will continue to be modified as we think of and discover additional hazards. We feel confident in our current analysis due to the depth of hazards we have generated and the factors that we have in place to mitigate them, but as we do more testing with our prototype we will add any technical issues that we may have overlooked to this analysis and do further analysis to ensure they are addressed as well.

FMEA Analysis

Our Failure Mode and Effects Analysis (FMEA) was chosen based on industry standard decision matrices in the industry standard level of detail and was chosen to test our "Is safe" requirement. We created a list of each component of our device and several modes of failure for each. We then looked at the potential effects of failure, the severity, potential causes, the occurrence, our current controls and how easy it is to detect. These factors are combined to give it a risk priority number (RPN) to weigh the severity of each of these failures. From here we came up with recommended actions to try and solve each problem. This chart can be seen in full in Appendix 08, but the failure methods for the photodiode are reproduced and explained in Figure 15 below.

Component & Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurance	Current Controls	Detection	RPN	Reccomend Action
Photodiode	stops changing output values with change in light	the device wouldn't be able to monitor oxygen levels	8	loose terminal holes, the movement of the device disconnected, overpowered	5	Instructions to build the circuit, check if current is going through it	4	160	Choose a robust photodiode
	placement is off with LEDs	the device wouldn't be able to monitor oxygen levels	8	the device was not put on properly, the device was not put on the proper place on the body	6	Instructions to build the circuit, check if current is going through it	4	192	Have explicit instructions for correct placement, user testing to see where they place the device, and mechanical solution to prevent movement

Figure 15. This figure shows the FMEA analysis for the photodiode.

The photodiode was chosen as it was one of the most critical portions of our device as well as one of the more complex devices. We came up with two potential failure modes. First, that the device was unable to change the output values as the light changes. This was a huge issue for our device as without a functional photodiode no values can be output. This gives it a severity of 8. The potential causes of failure that we came up with were based on concerns in how the device is used, namely that the baby's movement could affect the circuitry by loosening the wire connections or disconnecting the device. It was also possible that the device could provide more power than intended to the photodiode. We considered these factors to collectively have an occurrence of 5. Our current methods of controlling this failure to have proper instructions when building the device and to check the current running through the device before operating it. This factor is relatively easy to detect, giving it a detection of 4 for an overall RPN of 160. In order to prevent this problem, we needed to select a photodiode that would be durable and consistent.

The second failure mode was that the placement is off with the LED which also causes the device to not detect oxygen levels properly, which is rated at an 8 for severity. This can be caused by many of the same things that the previous photodiode failures could, but with a greater emphasis on the baby's movement.

The baby's movement could easily cause the device to move slightly and lose its alignment with the LEDs if proper measures were not taken, giving this an occurrence of 6. Our current controls are the same as when the photodiode was unable to change in light. Clear instructions are given to the technician who builds the circuit as well as a reminder to ensure that the device has no current running through it when idling. These are also relatively easy to detect, giving a weight of 4 for a RPN of 192. To further counteract these , we plan on having explicit instructions for the parent and the technician to show that the device is placed properly as well as seeing how parents place it to see if these instructions are sufficient. Lastly, we plan on developing a mechanical solution on our device to minimize movement.

The photodiode was the FMEA analysis that we learned the most from and had the largest consequence on our design. We are working on methods in addition to instructions to try and mitigate the risk of the photodiode being placed in the wrong location as the device will not work properly in that circumstance. We are currently planning on doing further analysis to determine whether or not we need additional methods to mitigate this problem. The current design is functional but will need changes to ensure that it is functional across less ideal use cases. We have high confidence in the analysis that we have performed here since we performed industry standard analysis on our device. However, there are likely to be methods of failure that we have overlooked as we cannot think of every possible way that our device will fail. As additional methods come to our attention, we will add them to this list and address them.

Summary of Engineering Analysis

There were many aspects of our design that needed to work in order for our device to function properly. The main aspects our group focused on were getting blood oxygen reading, having an alerting system, making the device safe for the infant, and having the device withstand the intended environment. Our engineering analyses for getting blood oxygen reading were focused on getting accurate readings and having the device work while the infant is moving. Another important aspect for our device to work was the parent being alerted that their child is in danger. We completed two analyses that looked at this problem from an analytical and an empirical method. Safe to use and can withstand its environments was also important for our device. We conducted several analyses to ensure those requirements. All of these components together will show the functionality of our device.

Detailed Design Solution

Design 2.0

Design 2.0 was an iteration of one of our previous concepts from our morphological chart (see Appendix 03). This concept was closely modeled after the Wellue Baby02 designed for HIC at-home monitoring and mentioned above in benchmarking. The change in placement of the oximetry sensor results from additional research showing the toe and foot arch region to be one of the most accurate spots for pulse oximetry [51]. An additional change between designs iterations was the change in location of the battery and display. Due to concerns over the weight being placed exclusively on the infant's foot, we decided to locate the majority of the components on the infant's calf (referred to as housing 1 from here on out) and the oximetry sensor (referred to as housing 2 from here on out) on the infant's foot. In order to accommodate this change, we designed the power and signal wires running between housing 1 and 2 to "breakaway" at a certain force. This ensures the infant's safety due to tangling and protects the infant and

the device from undue harm as a result of dropping either housing or entanglement. A 3D rendering of Design 2.0 can be seen below in Figure 16.

a) b)

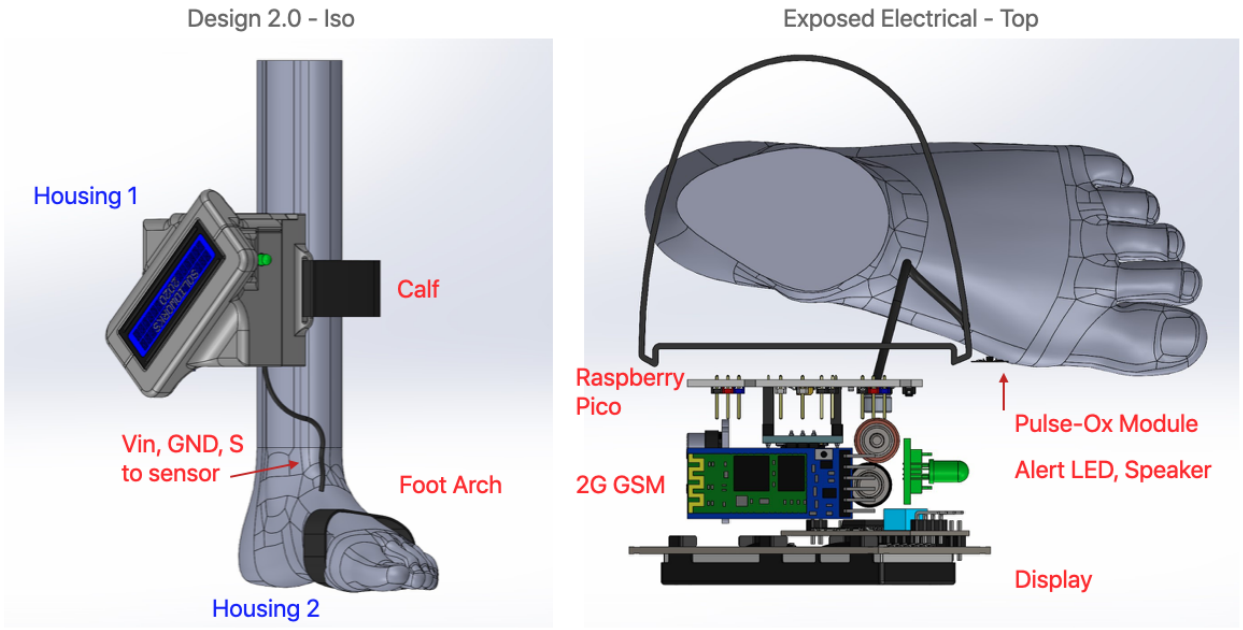


Figure 16. (a) Design 2.0 shown in an isometric view. Highlighted in the figure is housing 1 located on the infant's calf, housing 2 located on the infant's foot arch, and the necessary wires between the two. (b) Top view showing the electronic stackup inside the different housing with labels.

For housing 1, the dimensions are 2.5 x 2.7 x 2.2 inches (LxWxH). Housing 2's dimensions are currently unknown as we are still working on the best way to maintain consistent pressure and location on the infant's foot. Our best estimate was that the device on the foot will be approximately 0.5 x 1.0 x 0.5 inches (LxWxH). Our current idea was to provide the parent with gauze and detailed instructions to ensure that the ensure is placed properly. The device will first be put on by medical technicians at the medical facility, demonstrating how to position both housing 1 and 2. The gauze would be used similar to how hospitals bandage the wound after blood has been drawn but this idea needs testing and development to ensure that this problem is solved.

The overall weight of our device was estimated to be just over one pound, which was on par with our benchmarking results. All housing components will be 3D printed PLA followed by an optional 60C oven annealing to increase the durability of the design (please note that this is not vital to the integrity of the design, but does improve the material properties of the printed components by ~40% [49]).

This device also varies from previous iterations in how it will be manufactured. Design 1.0 was intended to be locally manufactured and implemented using custom components, but our device was not able to be made cheap enough for this solution to be viable. Instead, our device will be made from off the shelf

components bought in bulk by a partner hospital that wants to use this device and assembled by technicians at the hospital. See our cost analysis (p. 21) for a more in-depth overview and explanation of this.

In order to address the concern of our device's signaling system either being too quiet for the parent or harming the infant, our device will have the ability to communicate with non-collocated devices via 2G SMS messaging. The device will send an SMS message to the parent's device to alert them that the baby's oxygen levels have dropped or that the device was not working properly. This alert was also configured for several other conditions, such as if the breakaway cord was disconnected or the sensor was not positioned correctly. The phone number of the parent will be input by the technician at the hospital.

Our device was the best solution we have generated because it meets our requirements as they are currently defined. Our red and IR light system with the photodiode meets the requirement 'Monitors Oxygen levels' and along with the software it also meets 'Detects oxygen levels at 2 specific thresholds'. With the addition of the bandpass filter, amplifier and software measures, we are able to meet the 'Minimizes false positives' requirement. 'Alerts parent auditorily and visually' was met by the onboard speaker and lights as well as the SMS module which also meets the 'Transmit signals to secondary device' requirement. 'Reduced cost' was met by picking the lowest cost components which are assembled locally in hospitals to meet the 'Local Manufacturing' requirement. The device has no sharp edges, small parts or hazardous materials exposed which allows it to meet the 'Is Safe' requirement and the cord was made to break away to ensure it does not harm the infant.

Our device uses two standards off the shelf AAA batteries which meets our 'Powered by rechargeable batteries' requirement. This lifetime for the batteries will allow for it to last for two to three days before it needs to be returned to the hospital, which satisfies the 'Returns to hospital' metric in part. Further ideation for how the device will be encouraged to be returned to the hospital will be developed.

The device meets the 'Is easy to use' requirement as it will have detailed instructions for how and where to place it on the infant as well as only requiring the parent to attach the device to the infant. The device was 'Simple and comforting' as our specifications required due to the two devices reducing the overall device size on the infant as well as the simple design. This enclosed design gives it the durability to meet the 'Withstands wear from user', 'Functions continuously for 1 year' and 'Cleaned by hospital between users' due to the water resistance of the material. Because of these requirements and specifications being better addressed and more fleshed out than the ones that Design 1.0 met, we believe that 2.0 was the superior solution.

Electrical Design

Our circuit needed to be able to do four things primarily. First, it needed to be able to control the red and IR lights. Next, it needs to be able to have the photodiode record the light's intensity and the circuit must be able to process this data and manipulate it using the calibration curve (see Figure 18, below, for this curve) to correspond to the oxygen levels. This curve was treated as linear for our calculations. Lastly, it needs to be able to output visual and auditory alerts at 92 and 95% oxygen levels. Figure 17 below shows the layout of the circuit as well as the connections to the microprocessor.

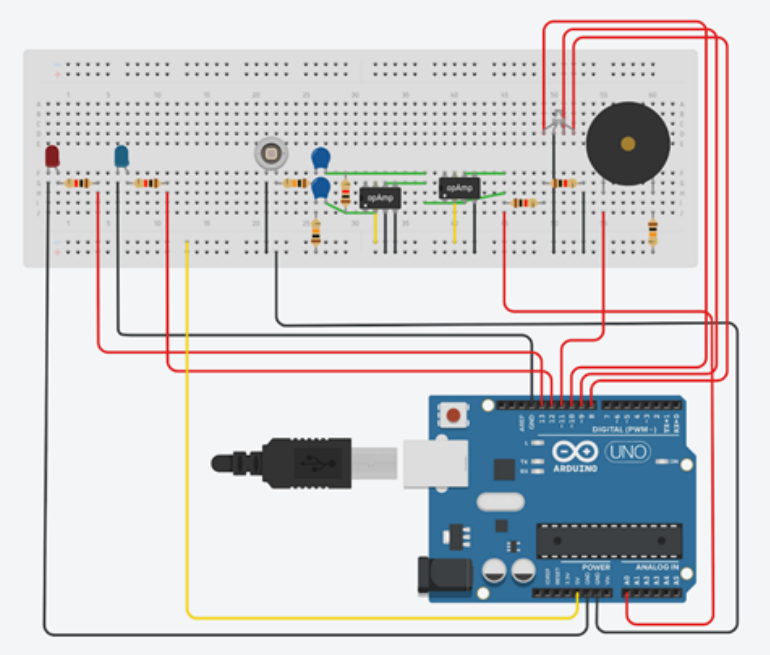


Figure 17. The circuit diagram and Arduino connections for Design 2.0. The red wires are a pin connection to the Arduino, the black wires are grounded connections, the yellow wires are power connections, and the green wires are for internal data connections. Please note that the LCD, SMS module and battery are left off of this diagram to better highlight the pulse-oximetry components.

Figure 17 is missing several components when compared to the prototype model, such as the digital screen, SMS module and battery. These components are excluded from this model and would add visual complexity to the diagram without providing additional insights into how the circuit works since those components are relatively simple to wire.

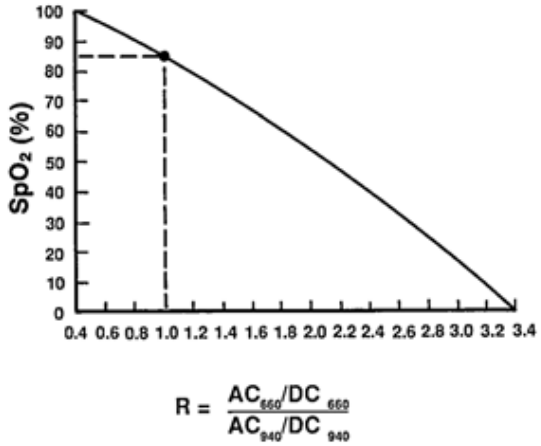


Figure 18. This figure shows the largely linear relationship between R and the oxygen level. R is the ratio of the photo diode's AC/DC measurements for the IR light and the Red light. [50]

In order to reduce the effect of noise and ambient light on the signal, a bandpass filter takes the output of the photodiode. The bandpass filter has a frequency of 1.5 Hz and a bandwidth of 1.5 Hz, but this will be refined down as physical testing gives us the true signals. The bandpass filter's output runs through an amplifier in order to provide even more clarity. Each specific component can be found in Appendix 09 and the rationale behind selecting each specific component can be found in Engineering Analysis page 20.

Code

The code for our project was largely developed based on open-source code from a pulse oximeter project. This code works by first reading in the data from both the IR and red light and stores them in an array. It stores this data for 20 ms and takes the average of the reading. This reading was then used to calculate the ratio of the IR and Red signal which was used with the above calibration curve (Figure 18) to determine the oxygen level. If this level was in the alert range, it sends out the appropriate alert on the device and to the parent using the onboard lights and speaker as well as a SMS message.

Social & Environmental Context Assessment

For Design 2.0 we made sure to implement features that adapts our device for the social and environmental context of Nicaragua. First, most households in Nicaragua have very limited access to electricity. For this reason, we have specifications relating to using rechargeable batteries that last 2-3 days. This was so that the device does not require access to electricity in the household. Next, a big design decision for us was what location on the baby to place the sensor. After debating between hand and foot, we decided to go with a baby's foot. Safety was the main driver in this decision. We did not want the baby to choke or place electrical components in their mouth. This would be more likely with a device on the hand. Next, in Design 1.0, the baby wore a sock over their foot. When iterating Design 2.0, we considered the environmental context more and realized since Nicaragua has a very hot, humid climate, we do not want to add unnecessary warmth to the baby. For this reason, we replaced the sock with a strap for less materials. By changing the to the strap, we moved the electric components to the baby's lower leg, while the sensor on the baby's foot was attached by a wire. We made sure this wire was a breakaway cable, so if the baby gets tangled in the wire, the wire will break off from one of the components. We are also considering creating multiple wire lengths for different sized babies and to accommodate swaddling or other variations of intended use. Another new addition for Design 2.0 was adding a secondary alert system. After learning the parent may not be in the same room as the baby, we did not want to harm the baby by having an extremely loud alarm on the baby's foot. For this reason, we added an additional feature to our design. The device will now send an SMS message to the parents cell phone to not harm the baby. This method was chosen as we learned that most people in Nicaragua have a cell phone but do have a smartphone. We also designed the messaging system to be written in English and Spanish to accommodate the team in the US as well as people in Nicaragua, who are native Spanish speakers.

Verification

Cost

To analyze the cost of our device, we added up the individual costs of each component when bought as individual units as well as when purchased in bulk. We made sure that we had selected components that were both low cost and high performance in our device, which can be seen in the initial cost analysis section on page 21. After we selected all of our components and estimated the dimensions and weight for our final device, we approximated shipping costs to several large cities in Nicaragua. Lastly, we estimated labor costs for our device. Based on our experiences assembling the devices, we estimated that it would take around 90 minutes for the device to be fully assembled. Using a salary of two dollars an hour, which we determined was appropriate from salary data in the country [56], the total cost for our device is as detailed below if bought as a single unit:

Table 5. A Summary of the Bill of Materials.

Component	One Device (USD)
Mechanical (Housing, strap etc)	3.94
Electrical	21.62
Shipping	10
Labor	3
Total Cost	38.56

Our device meets our requirement of being below $40 with a safety factor of 3.6%. This safety factor will grow larger as the amount of devices ordered increases. This solution assumes that the hospital has access to a 3D printer. The cost of the 3D printed components was included within the mechanical section. A detailed Bill of Materials can be found in Figure 10. Due to the improvements gained through bulk ordering and the close parallels to reality with our testing methods, we feel very certain that our device meets this specification.

Risk

Previously, we performed an FMEA analysis as well as a risk analysis for our design. See Appendix 8 for a summary of these analyses for FMEA and appendix 7 for the full analyses of the risk analysis. The highest risk portion of our design was the wire that runs between the two housings. This component could potentially harm the infant if it became tangled and if it came detached would cause the device to stop functioning. This was determined to be a high risk and high likelihood concern for our device. We originally had the only control for this point of failure to be that the wire in between the devices would breakaway when the infant puts force on it, but that only fixed the safety aspect, not the functionality aspect. To fix the functionality, we decided to make use of the texting capability of our device to send an alert to the parent when the chord has been detached. With these two concerns met, the risk has been

reduced to more appropriate levels. We have been unable to test the device due to limitations of the course and the ongoing COVID-19 pandemic, but we felt with relatively high certainty that the device meets the safety requirements specified.

Voltage Through Circuit

There were many components of our circuit that were important for our device to function. We did a high level analysis of the circuit to make sure that each component functions and is safe. We used a multimeter and isolated each component to measure the voltage going through it. As seen in Table 6, there was voltage through all the resistors, capacitors and other components that made up our circuit. This analysis showed that each component of the circuit was being powered correctly.

Table 6. Voltages through each component in the circuit

Components	Voltage
Red LED	2 V
resistor Red LED	3 V
IR LED	2 V
resistor IR LED	3 V
Photocell	2.8 V
resistor 1 - Band Pass Filter	1.3 V
capacitor 1 - Band Pass Filter	3.1 V
capacitor 2 - Band Pass Filter	3.1 V
resistor 2 - Band Pass Filter	.14 V
resistor 3 - Amplifier	1 mV
resistor 4 - Amplifier	1.7 V
resistor 5 - Amplifier	1.7 V

Alerts Parents

There are three components that are involved in alerting the parents. The analysis on the speaker selection was completed based on the sound pressure levels for the infant and for the parent at their respective distances from the device. This analysis can be found on page 26 and explains why our certain speaker was chosen. We also did a qualitative analysis to see what alert system parents would most prefer in a monitoring device for their children. This analysis was done through a survey with parents from high income countries. Most parents prefer a sound alert on a separate monitor to notify if their infant is at a warning level or danger level. The second most popular preference for being alerted was receiving a text message. Based on these responses, we confirmed that the use of our GSM module and texting capabilities in a 2G environment is very important. Although this was not the most popular result it was the answer that was most compatible with the technology accessibility in low income countries. The lack of strong wifi and materials used in their houses prevents two wirelessly connected devices.

Durable

One of the core requirements of our device is the ability to function for up to one year. This takes into account the multiple users throughout the one year span. During this time, the device will potentially be exposed to harsh environmental conditions and will need to be cleaned between users. An additional requirement was to only perform non-destructive testing so that any of our prototypes would not be damaged. Therefore, in order to verify this requirement, we resorted to using Ansys to perform FEA and thermal analysis. The FEA and thermal simulations helped us gain an understanding of how our device would handle repeated use in our target environments. Thus, we believe that our device has sufficient potential to be durable under our intended use case. Unfortunately, due to the on-going pandemic and the time constraints of the class, we were unable to perform any trials with our device or test how multiple devices might perform (i.e. gather any statistics). Therefore, we would encourage additional testing with the creation of multiple devices before field implementation. Running multiple trials after building several devices will take a fair amount of time, as the time needed to 3D print the housing was quite substantial. Once printed, assembly requires approximately ninety minutes, and then test trials can begin.

Accuracy of reading with commercial

In order to test the first requirement, monitoring oxygen levels within a 3% accuracy, we compared the readings of our pulse oximeter prototype to a commercial pulse oximeter that also has an accuracy of $\pm 3\%$. To do this, we placed our prototype on a finger of one of the group members. We then placed the commercial pulse oximeter on the other hand of the same group member. We recorded videos of the readings of the serial monitor for our prototype, and recorded a video of the commercial pulse oximeter readings. These videos can be seen in Appendix 15. This test was used to gain an initial understanding into the accuracy of our pulse oximeter. We were able to gage that our pulse oximeter was generally detecting correct blood oxygen levels, but the prototype also reads large outliers frequently. From this test, we determined that our prototype was able to properly monitor blood oxygen levels; however, additional work needs to be done to limit the amount of outliers in the readings. Ideally, we would now try to improve the accuracy of our device and then conduct the test again to see if it limited the outliers. However, due to time constraints we were unable to continue to develop the prototype further. If we had more time, a housing could be made to block out ambient light and make sure the photodiode was properly lined up with the IR light and red LED. Also, the code could be further developed to limit the bad readings.

This method was chosen to test the monitoring ability of our device because it was an extremely simple test that requires very little additional supplies or time. We were able to gain great insight into the accuracy of our device by only purchasing a commercial pulse oximeter and using our device. This test should not be the only test used to evaluate the accuracy of the device as it was only used to get a baseline for the accuracy of readings. Further analysis should be done when the prototype is more developed to determine if the device’s readings are within 3% accuracy.

Readings with motion

A main concern of ours when ensuring the device can properly monitor oxygen levels, one of our requirements, was making sure the device can still accurately read the blood oxygen levels during movement. Since the device will be attached to the baby's foot, we need to make sure that the unpredicted

movement of the baby's foot does not affect the accuracy of the readings. This was also important because to maintain accurate readings, the photodiode needs to be lined up with IR light and red LED. The outline of the test protocol is outlined in the Engineering Analysis section on page 25. Due to time constraints, we were unable to perform this test. We need to develop a housing for our prototype to keep proper alignment between the photodiode and IR light and red LED in order to conduct this test. Without the housing, the components are held manually together, so we are unable to add movement and properly align the components.

Even though the test has not been done, it will require no additional materials and very little time to conduct when the housing is created. It will also provide valuable insight into this concern and help us understand the accuracy of the device in an environment that models use. In future testing, the device could be put on a baby and the blood oxygen levels could be recorded when the baby is stationary and moving.

Alarm goes off at desired thresholds

An additional concern of ours has been the ability to notify the infant's parents that the Spo2 levels had reached a critical threshold. At this point in time, we intend to have three different methods of alert. First, a flashing LED on the side of housing 1, which can be seen in Figure 15. This light was intended to help draw people's attention to the device and infant, and serve as an alert should the infant or parent be hard of hearing. The second alert mechanism was a loudspeaker alert. This sound was intended to help alert people to the baby's needs and also help awaken the baby. The speaker was specifically located to point away from the baby's head so that the noise can be louder for the parents while not imposing a risk to the baby's hearing. This alert method has the added benefit of helping alert those who have difficulty with sight. Lastly, we intend to message the parent's phone via 2G SMS. This would help the parent react to an emergency should they be out of the room or too far away to hear the speaker alert.

Due to the constraints of the class and the on-going pandemic, we were unable to test en-mass the functionality of the alert system. Granted, the most important input to the alert system was the accuracy of the pulse oximeter (we have verified that the alert system works as expected when called for in the software). The one aspect of the alert system that we were unable to verify was the 2G SMS messaging. Both the software and the hardware need to be further developed in order to properly work. We estimate that another four to five hours of development is needed before this functions.

Electrical deformation

In line with the durability of the prototype was ensuring that the electrical components are safely housed and are able to sustain multiple impacts should the device be dropped during use. As such, FEA was performed to measure the total deformation and deflection at each of the mounting locations when experiencing a two meter drop. This deflection was then compared to the total allowable deformation as listed by the component manufacturers. It is worth noting that we were unable to perform any real-world tests to verify the computer simulations, especially as we were tasked with doing only non-destructive testing. As such, we would recommend completing real-world testing before use with any infants. Testing should be done to confirm that the device continues to function as expected after being fatigued and impact loaded, with no damage to the electrical components. By doing this testing, it will minimize the

likelihood of the device being damaged in-field and help ensure that, when an infant's life is at risk, the device will perform as expected.

Instructions

Due to the timing of the course, we were unable to test the instructions to assemble, place on the infant and use our device. These can be found in Appendix 11, 12, and 13 respectively. The instructions that we wrote are based on the research done by Edgar Dale and Jeanne S. Chall [57]. Their research created a way of determining the complexity and readability for instructions based on the words chosen and the sentence structure. Using their formula, our instructions were easy to understand in English, then we would work with experienced translators to make sure that the same was true in Spanish. We thought that this method of creating instructions for our device would provide the best chance of success for proper assembly but cannot say for certain due to the inability to complete validation for this requirement.

Usability

Usability was a very important aspect of our design. If parents are not willing to or don't understand how to use our device, it will not be effective or used on their infant. We distributed a survey with questions relating to the usability of our device to parents in high income countries. We got 66 results with parents who have children ranging from newborns to 25 years old. Parents liked that the monitor was on the leg and it was secure on the infant. They also appreciated that the wire was constrained and not loose for the baby to interact with. Some aspects that they didn't like about the device were that it looks uncomfortable and there are too many components. One of the recommendations they would want to use the device would be to combine the two monitors and place it on the ankle. This could not be done because of the location needed for the transmissive oximetry. Another recommendation parents made was to make the device flatter and smaller which can be made in further iterations of the device. There is still a lot of work to be done on the usability of the device as most parents still don't feel comfortable using the device on their baby. The usability of the device has not been the priority of our current design and if given more time our team would focus more on the usability and modify the device based on parents' preferences.

Discussion and Recommendations

In this section, we will discuss any critiques of our design, highlight the specific strengths and weaknesses along with any changes or recommendations we would advise be made before implementing this in Nicaragua or other low income countries. Both system-level and detailed-level recommendations will be discussed, along with any possible redesigns that we would recommend.

User Input

Throughout the design process, one area that we have significantly lacked was user input. If we were to begin this project again, we would first begin by identifying a local partner or local resource that we could then design our product around. We also believe that we would have benefited greatly by spending several weeks or even a couple months in the target region, building our background knowledge of this project along with building connections in the area before beginning this project. There was a significant cultural and environment knowledge gap between our group and how this device might actually be perceived or used. Even simple concepts such as what the buildings are made out of or how a baby is held may have an impact on the design. Our requirements and specifications were selected without much

end-user input. Thus, by surveying and documenting what the current solutions are to RSV monitoring in LICs, this information could be better incorporated into the final design. At the end of the semester we were able to begin surveying parents; however, these surveys are limited in their usability due to the population sample available to us.

Strengths

There are a number of strengths about this project and design. The need to provide continuous monitoring to infants with RSV in LICs is extremely apparent, and there are few to no current market solutions to address this need. A great challenge that we, as a team, continuously faced throughout the semester concerned the pricing of the device. As shown previously in Figure. 2, there is a distinct price gap. Additional strengths can be found below in Figure 19:

Category	Avg Benchmark	Team 10's Solution	Delta
Weight	2.1 lbs	2.35 lbs	12%
Size (in^3)	12.15	16.88	39%
Price	$175.00	$40.00	77%
Battery Life	16 hours	72 hours	350%

Figure 19. Showcasing the individual strengths and weaknesses of our device as compared to current market solutions.

One significant objective of our design was to create a solution with enough battery capacity to last for multiple days of use without the ability to recharge. This requirement was a challenge for us, as the majority of existing solutions were designed to work for a singular overnight period or with the direct supervision of a medical professional. Additionally, our team began the semester without an in-depth understanding of electromechanical devices. Working together, we were able to create a device that used a multitude of commercially available, rechargeable batteries to power the device. This was all designed with the intent of multiple possible alerts and SMS messaging, which was the single greatest possible power draw in the entire system. Including more batteries proved to add a substantial cost, which was the primary reason why the device was priced at its current point. From our research, we could not find a current market solution with battery life that lasted longer than a single day of use.

This device almost exclusively used commercially available components, which was another strength. Our open-sourced design was created so it could be used and assembled by partner medical facilities in low income countries. As explained in our cost analysis, the only way to come close to forty dollars was to avoid any implementation plan dependent on one company mass producing this device. Through open-source, we predicted that we would reduce the cost by as much as eighty percent. However, mass production does have some benefits over an open-source concept. One such benefit was the ability to use custom components, resulting in a smaller form factor and a reduction in net weight. Additional weaknesses will be discussed in the following section.

Weaknesses

No concept is without weaknesses or areas of potential improvement, and our design was not unique in this. As evident by Figure 19, p. 42, our device was both heavier and larger than current market solutions. If we were to alter our design, we would first look at the form factor and weight to try and reduce that. The leading reason why our form factor and weight was worse than competitors was the battery capacity required to meet all of our requirements. However, there is possibly room for improvement by sourcing batteries from a system level point of view as compared to an individual item. If we were able to find a 9V or 12V battery with sufficient capacity, there could potentially be weight and volume reductions.

Additionally, there are several aspects of the mechanical housing that should be further investigated. As it currently stands, there is a substantial amount of time required to 3D print housing 1 and housing 2. This time would be a significant bottleneck for any partner facility should they attempt to make multiple. It may be worthwhile to investigate commercial solutions such as BUD boxes [54], which one could simply purchase and ship. Conversely, these would certainly be more expensive and less friendly to our end-consumer. For these reasons we elected to go with a 3D printed design; however, there is the possibility of a commercial solution that could work better, we just never found one.

Should the current manufacturing method of 3D printing be continued, further design development can be made to reduce the printing time and increase housing strength. For example, there is no current prototype for housing 2 of our design. There was a preliminary CAD rendering; however, due to the time constraints of the class and a last-second design pivot we were unable to progress further than a rendering. Additionally, housing 1 requires several design modifications to be considered. First, the interaction between the top and bottom of housing 1 needs to be revisited. Currently, there are four prongs where bolts can slide through to constrain the two halves together. However, during physical testing we found these to easily break. As such, we recommend swapping this for a continuous two plus mm lip. This lip would provide additional structural strength. Furthermore, the current Li-Po battery in use was not fully constrained. This battery would either need to be glued in or there would need to be an additional structural component designed in.

Throughout the semester there was significant pushback concerning the breakaway wire between housing 1 and housing 2. We designed our solution to model the Wellue BabyO2 which has a similar functionality, which we reasoned was an appropriate foundation considering it's on the market and has been largely well received. Additionally, the power constraints of the system, combined with the cost requirement, forced us to break the system into two different components. The primary concern with this wire revolved around safety. To combat this, we attempted to use gauze wrap to secure it to the infant's leg. In preliminary surveys, parents seemed largely divided as to whether they would be ok with the wire being constrained like that. Thus, we recommend further research and evaluation in the intended environment and culture, and iterating upon the design based on those findings.

Recommendations

Reflecting upon the above weaknesses and limitations of our design, we recommend having several students continue working on this project before implementation. A team with experience in a variety of engineering disciplines could easily iterate upon and finish this project within the span of a couple of

months. Even better, if these students had experience in the intended LIC, they would be even better prepared to finish this project. Therefore, we recommend a team of two to four students, with experience in designing electromechanical projects (ideally experience gathered in real-world projects outside of the X50 courses). A team of two, dedicated to this project, with proper experience and background knowledge would be able to finish this project within a month or two.

Conclusion

RSV is a common virus that can cause many deadly or debilitating diseases such as Pneumonia, Bronchitis and Tuberculosis. RSV and its related diseases are especially harmful in children under five. RSV-caused diseases have symptoms that include a cough or lethargy, but these symptoms are difficult to measure and interpret as more severe than their common mild version. Instead of having the parent determine the severity of these symptoms, the symptom of choice to measure is the blood oxygen levels of the infant as it is a discrete value instead of a subjective judgement. The downside of this symptom is that it requires an external tool in order to be measured.

RSV infections lead to severe results in LICs, causing many more deaths and loss of Disability Adjusted Life Years (DALYS) than in HICs. In order to minimize these deaths and DALYs, we are designing a blood oxygen monitor for infants to be used in LICs. In order to do this, we met with our stakeholders and performed research in order to better understand and specify the problem. From this information, we created a list of requirements and specifications, which we used to create and generate concepts towards a solution in the near future.

In our concept exploration phase, we created designs that incorporated a measuring system, alert system, and housing. We utilized different design techniques to narrow down our designs and analyzed which one would be the best for our problem. Then we looked into making sure that our device is distinct from the current market designs. We came up with a final detailed design that resembled a sock for infants to wear while they slept.

Based on the new scope of our project being a research based device, we recreated the design to contain two straps, one on the foot and the other on the ankle. Most of the electronics are housed on the strap on the ankle. The LEDs and sensor used for transmissive oximetry are in the second housing on the front of the infant's foot. We started to conduct analysis to test our most critical requirements. We conducted a cost analysis as this was one of our most important gaps to the other benchmarks we found. We also conducted analysis on the circuit functionality, usability, the sound output, the housing performance, and the risk of the device and its components.

After completing these analyses, we were able to see that our device was able to read blood oxygen levels and withstand environmental disturbances. At the stage we are currently at, there is a lot of improvement that needs to be done before bringing it to a low income country for testing. The main part we need to work on is integrating the circuit and housing for better usability. We also need to work on making the device more accurate for it to meet our accuracy specifications. Once improvements are made our device will be able to be implemented in low income countries.

Authors

Jake Anderson: Jake Anderson is a senior studying Mechanical Engineering at the University of Michigan. At the start of his college career Jake worked as the manufacturing and mechanical lead for the University of Michigan Solar Car team's 2017 solar car. After racing in Australia, Jake transitioned to the Baja team and helped lead the manufacturing efforts for the 2018 and 2019 cars. Outside of school, Jake loves photography, hiking and positioned his internships to give him access to the east coast, west coast and the Rockies.

Nick Eidsmoe: Nick is a senior studying Mechanical Engineering and Economics at the University of Michigan. He spends a lot of time volunteering through the FIRST Alumni and Mentors Network at Michigan, or FAMNM for short. FAMNM works with K12 students in the Ann Arbor area to help teach and volunteer in support of STEM education. He also plays tennis and is involved with the ACLU Chapter at University of Michigan. He is from Midland, Michigan and likes to spend time with his dogs.

Sydney Gordon: Sydney Gordon is a senior studying Mechanical Engineering at the University of Michigan. During the school year she works on a project team called MEND through the M-HEAL organization. MEND works on creating fall prevention devices for older adults. She is very interested in the medical devices industry and wants to work on projects that improve people's lives. She is from Sharon, Massachusetts and also likes to play the guitar, be outside, listen to music, and spend time with family and friends.

Rachael Weisman: Rachael Weisman is a senior studying Mechanical Engineering at the University of Michigan. During the school year she works on a project team called MEND through the M-HEAL organization. MEND works on creating a fall prevention assistive device for older adults. She is also an instructor's assistant where she teaches the introductory Design and Manufacturing course at the University of Michigan. She is from West Caldwell, New Jersey and enjoys creating new recipes to bake and cook, learning embroidery, and playing board games with friends and family.

Information Sources

[1] Nair, H., Nokes, D. J., Gessner, B. D., Dherani, M., Madhi, S. A., Singleton, R. J., O'Brien, K. L., Roca, A., Wright, P. F., Bruce, N., Chandran, A., Theodoratou, E., Sutanto, A., Sedyaningsih, E. R., Ngama, M., Munywoki, P. K., Kartasasmita, C., Simões, E. A. F., Rudan, I., Weber, M. W., and Campbell, H., 2010, "Global Burden of Acute Lower Respiratory Infections Due to Respiratory Syncytial Virus in Young Children: A Systematic Review and Meta-Analysis," Lancet, 375(9725), pp. 1545–1555.

[2] Marangu, D., and Zar, H. J., 2019, "Childhood Pneumonia in Low-and-Middle-Income Countries: An Update," Paediatric Respiratory Reviews, 32, pp. 3–9.

[3] Gordon, A., 2021, "Initial Stakeholder Meeting."'

[4] "How to Ensure Medical Devices Help Communities in Low- and Middle-Income Countries" [Online]. Available: https://ssir.org/articles/entry/how_to_ensure_medical_devices_help_communities_in_low_and_middle_income_countries. [Accessed: 28-Jan-2021].

[5] World Health Organization, 2019, "World health statistics 2019: monitoring health for the SDGs, sustainable development goals." [Online]. Available: https://apps.who.int/iris/handle/10665/324835.[Accessed: 28-Jan-2021]

[6] Vasan, A., and Friend, J., 2020, "Medical Devices for Low- and Middle-Income Countries: A Review and Directions for Development," J Med Device, 14(1).

[7] Malkin, R. A., 2007, "Design of Health Care Technologies for the Developing World," Annu Rev Biomed Eng, 9, pp. 567–587.

[8] Di Fiore, J. M., 2004, "Neonatal Cardiorespiratory Monitoring Techniques," Seminars in Neonatology, 9(3), pp. 195–203.

[9] "Masimo - Newborn Care" [Online]. Available: https://www.masimo.com/solutions/acute/newborn/. [Accessed: 03-Feb-2021].

[10] "NellcorTM SpO_2 Nonadhesive Sensors | Medtronic" [Online]. Available: https://www.medtronic.com/covidien/en-us/products/pulse-oximetry/nellcor-spo2-nonadhesive-sensors.html. [Accessed: 03-Feb-2021].

[11] King, C., Boyd, N., Walker, I., Zadutsa, B., Baqui, A. H., Ahmed, S., Islam, M., Kainja, E., Nambiar, B., Wilson, I., and McCollum, E. D., 2018, "Opportunities and Barriers in Paediatric Pulse Oximetry for Pneumonia in Low-Resource Clinical Settings: A Qualitative Evaluation from Malawi and Bangladesh," BMJ Open, 8(1), p. e019177.

[12] “Owlet Smart Sock Monitor for Baby – Owlet Baby Care US” [Online]. Available: https://owletcare.com/products/owlet-smart-sock. [Accessed: 03-Feb-2021].

[13] “BabyO2 Baby Oxygen Monitor – Wellue Health.” [Online]. Available: https://getwellue.com/pages/babyo2-baby-oxygen-monitor. [Accessed: 03-Feb-2021].

[14] “Moyo Fetal Heart Rate Monitor,” Engineering For Change [Online]. Available: https://www.engineeringforchange.org/solutions/product/moyo-fetal-heart-rate-monitor/. [Accessed: 08-Feb-2021].

[15] “Fetal Heart Rate Monitor | Engineering For Change” [Online]. Available: https://www.engineeringforchange.org/solutions/product/fetal-heart-rate-monitor/. [Accessed: 08-Feb-2021].

[16] “Neopenda Vital Signs Monitor for Newborns | Engineering For Change” [Online]. Available: https://www.engineeringforchange.org/solutions/product/neopenda-vital-signs-monitor-for-newborns/. [Accessed: 08-Feb-2021].

[17] Jadavji, T., Law, B., Lebel, M. H., Kennedy, W. A., Gold, R., and Wang, E. E. L., “A Practical Guide for the Diagnosis and Treatment of Pediatric Pneumonia,” CAN MED ASSOC J, p. 9.

[18] Weinger, M. Bret., Gardner-Bonneau, Daryle., Wiklund, M. E., Kelly, L. M., and Taylor & Francis., 2011, *Handbook of Human Factors in Medical Device Design*, CRC Press, Boca Raton, FL :

[19] 14:00-17:00, “ISO 10993-10:2010,” ISO [Online]. Available: https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/04/08/40884.html. [Accessed: 08-Feb-2021].

[20] *WHO Child Growth Standards,* 2006, World Health Organization, Geneva.

[21] Cvach, M., 2012, “Monitor Alarm Fatigue: An Integrative Review,” Biomedical Instrumentation & Technology, **46**(4), pp. 268–77.

[22] “Performance of Three New-Generation Pulse Oximeters during Motion and Low Perfusion in Volunteers - PubMed” [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/22626683/. [Accessed: 08-Feb-2021].

[23] Malkin, R. A., 2007, “Barriers for Medical Devices for the Developing World,” Expert Review of Medical Devices, **4**(6), pp. 759–763.

[24] “Smart Sock Care,” Owlet Baby Care US [Online]. Available: https://owletcare.com/pages/smart-sock-care. [Accessed: 08-Feb-2021].

[25] DAVIS, F., 1989, “PERCEIVED USEFULNESS, PERCEIVED EASE OF USE, AND USER ACCEPTANCE OF INFORMATION TECHNOLOGY,” MIS quarterly, **13**(3), pp. 319–340.

[26] Dieter, G., *Problem Definition and Need Identification*, 2018, pp. 75–115.

[27] “Towards A Framework for Holistic Contextual Design for Low-Resource Settings,” International Journal of Design [Online]. Available: http://www.ijdesign.org/index.php/IJDesign/article/view/2596. [Accessed: 08-Feb-2021].

[28] SparcIt. “4Ps of Creativity: What Are They?” *Medium*, SparcIt Blog, 18 Aug. 2016, medium.com/sparcit-blog/4ps-of-creativity-what-are-they-8e639423f5a1.

[29] Soyars, C., 2021, “Initial Stakeholder Meeting.”

[30]Breznitz, S., 1983, *Cry Wolf: The Psychology of False Alarms*, Lawrence Erlbaum Associates, Hillsdale, N.J.

[31] Görges, M., Markewitz, B. A., and Westenskow, D. R., 2009, “Improving Alarm Performance in the Medical Intensive Care Unit Using Delays and Clinical Context,” Anesth Analg, **108**(5), pp. 1546–1552.

[32] Dr R.S. Khandpur, 2014, “Fundamentals of Medical Instrumentation,” HANDBOOK OF BIOMEDICAL INSTRUMENTATION, THIRD EDITION, McGraw-Hill Education, New York.

[33] Sumra, Husain. “Wearable baby monitors may miss key vital signs, says new medical study” Weable, 24 Aug 2018, https://www.wareable.com/wearable-tech/baby-monitors-miss-vital-signs-6445

[34] Sienko, K., “DR 1 Mentor Meeting”

[35] ISO 10993-10:2010, “Biological evaluation of medical devices”

[36] IEC 60601-1-2:2014, “Medical electrical equipment”

[37] 16 C.F.R. § 1500.49

[38] 16 C.F.R. § 1501.4

[39] Sarvestani, Amirm 2015, “Designing task shifting medical devices for low-resource settings”, https://deepblue.lib.umich.edu/bitstream/handle/2027.42/111571/asabet_1.pdf?sequence=1&isAllowed=y

[40] Zhu, Zhihua; Liu, Tao; Li, Guangyi; Li, Tong; Inoue, Yoshio. 2015. "Wearable Sensor Systems for Infants" *Sensors* 15, no. 2: 3721-3749. https://doi.org/10.3390/s150203721

[41] Gordon, A., 2021, “DR2 Stakeholder Meeting.”

[42] IEC 60529:1989, “Degrees of protection provided by enclosures”

[43] Soyars, C., 2021, “Second Stakeholder Meeting.”

[44] Grogan, L., and Sadanand, A., 2013, “Rural Electrification and Employment in Poor Countries: Evidence from Nicaragua,” World Development, **43**, pp. 252–265.

[45] “Reflectance Pulse Oximetry from SPO Medical | Medgadget” [Online]. Available: https://www.medgadget.com/2007/11/reflectance_pulse_oximetry_from_spo_medical.html. [Accessed: 19-Mar-2021].

[45] Schwemmin, R., 2021, “Initial Stakeholder Meeting.”

[46] Plot, J., 2021, “Initial Stakeholder Meeting.”

[47] Stansfeld, S., 2009, Children and Noise’[Online]. https://www.who.int/ceh/capacity/noise.pdf

[48] “Physical Growth in Newborns | Michigan Medicine” [Online]. Available: https://www.uofmhealth.org/health-library/te6295. [Accessed: 21-Mar-2021].

[49] Travieso-Rodriguez, J Antonio et al. “Mechanical Properties of 3D-Printing Polylactic Acid Parts subjected to Bending Stress and Fatigue Testing.” Materials (Basel, Switzerland) vol. 12,23 3859. 22 Nov. 2019, doi:10.3390/ma12233859

[50] Pologe J.A, 1987, “Pulse oximetry: Technical aspects of machine design” International Anesthesiology Clinic 25:137-153.

[51] Jyotirmoy Das, Amit Aggarwal, Naresh Kumar Arrarwal, 2010, “Pulse oximeter accuracy and precision at five different sensor locations in infants and children with cyanotic heart disease.” https://dx.doi.org/10.4103%2F0019-5049.72642

[52] “What Standards Apply to Medical Devices Manufacturing? | NQA” [Online]. Available: https://www.nqa.com/en-us/certification/sectors/medical-devices-services. [Accessed: 22-Apr-2021].

[53] “ISO - ISO 80601-2-61:2017 - Medical Electrical Equipment — Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment” [Online]. Available: https://www.iso.org/standard/67963.html. [Accessed: 22-Apr-2021].

[54] https://www.budind.com

[55] “THE 17 GOALS | Sustainable Development,” *United Nations*. [Online]. Available: https://sdgs.un.org/goals.

[56] Anderson, Lykke, Hernani-Limarino, Werner. 2017. "Living Wage Report"

[57] Dale, Edgar; Chall, Jeanne S, 1948. "A Formula for Predicting Readability". Educational Research Bulletin Vol. 27, No. 2, pp. 37-54

[58]“Dark Skin Decreases the Accuracy of Pulse Oximeters at Low Oxygen Saturation: The Effects of Oximeter Probe Type and Gender - PubMed” [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/18048893/. [Accessed: 25-Apr-2021].

Appendices

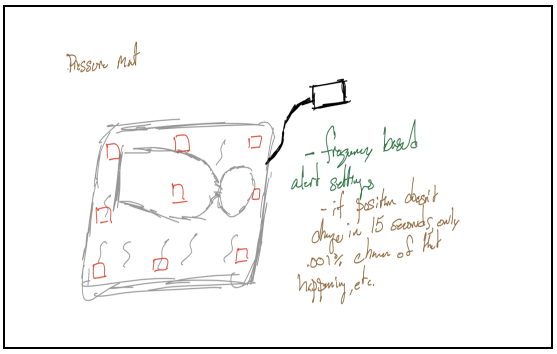
Appendix 01: Wellue BabyO2 and Owlet Sock 3 Benchmarking

Team 10 Reqs	 Wellue Baby O2	 Owlet Sock 3
Continuous *SpO_2 monitor*		
2 alert thresholds of SpO_2 detection	Multiple thresholds	Multiple thresholds
Auditory / *Visual* **Alert**	Auditory & Visual on smartphone OR device	Auditory & Visual on smartphone
PT < **$30**	$135	$299.00
Meets WHO **safe**ty guidelines		
Fits *neonatal* & *pediatric* children < 1 y/o	Neonatal & Pediatric	Neonatal & Pediatric
Rechargable batteries	16 hr rechargeable	16 hr rechargeable
Returned to hospital post-use	Not used in hospital settings	Not used in hospital settings
Minimizes *false positives*	Factory calibrated	Factory calibrated
Easy to use	3 steps to use	3 steps to use
Simple & *Comforting*	"Sleek design" - AMZN review features	In use in LICs
Transmit data to non-located device	Bluetooth	Bluetooth
Local manufacturing capable	Not capable	Not capable
Durable	IP 22	
1 year use	1 yr	1 yr
Easy cleaning	Per reviews	Per reviews

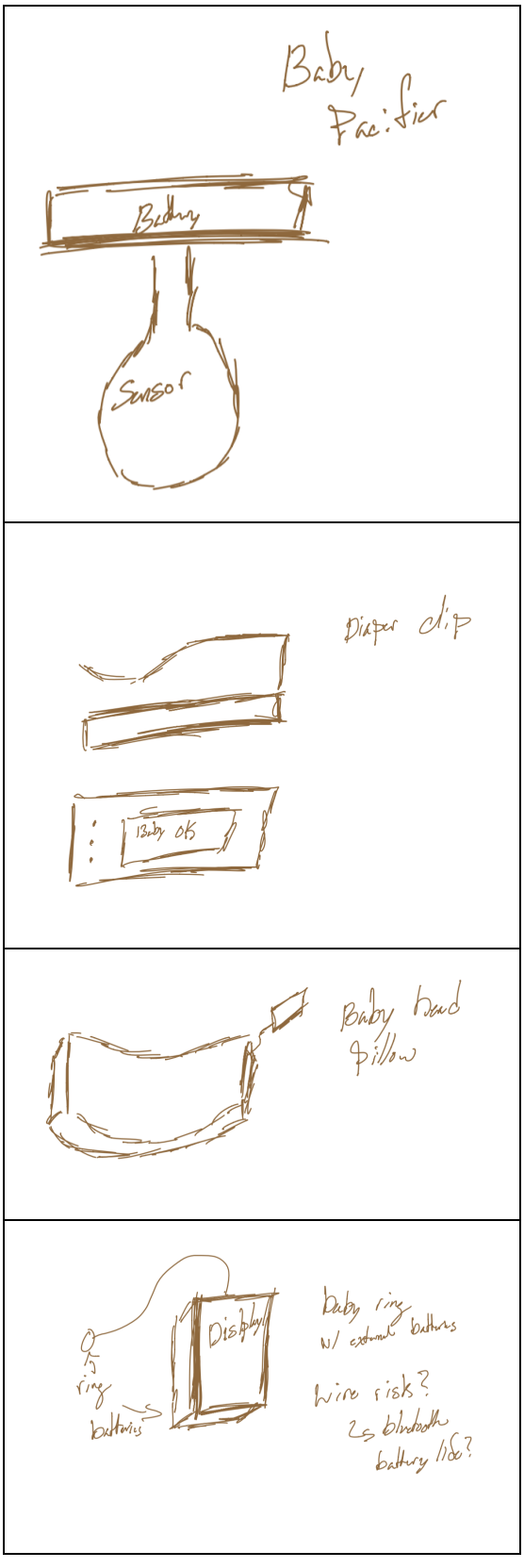
Figure 20. A comparison between the Wellue BabyO2 and the Owlet Sock 3 in regards to our team's requirements and specifications. Both of these devices were designed for neonatal and pediatric monitoring in HICs. As such, many of the features we wish to include in our design also show up in these devices, with the exception of the overall cost. The Owlet Sock 3 was one of the most expensive on-market devices we've benchmarked to-date for at-home pediatric monitoring.

Appendix 02: Solutions from Concept Generation

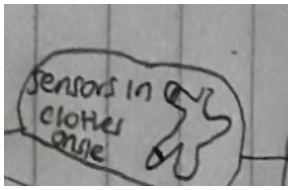
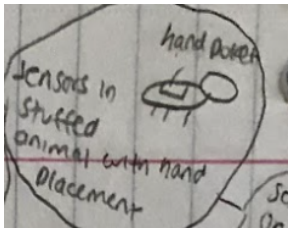
Full Concept Solutions

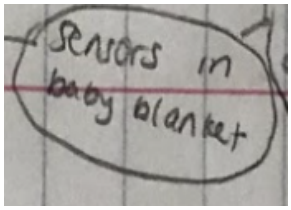
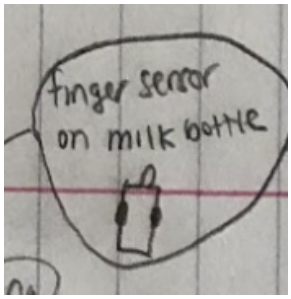
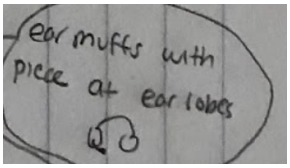
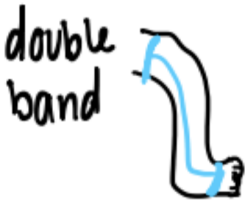
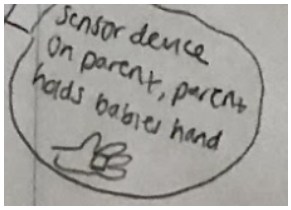
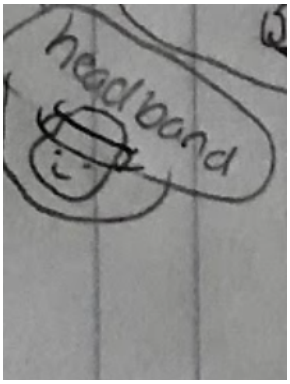
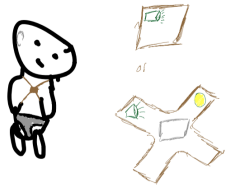
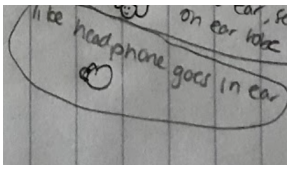
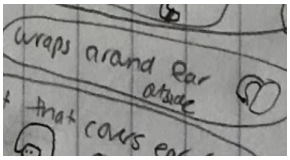


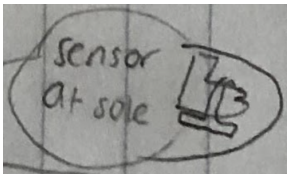

Sports Bands
- silicon or Velcro band
- wrist, arm, leg, foot, hand, chest
Baby Mitten
Camera tracking movement or breath expansion


Baby Pacifier
Battery
Sensor
Diaper clip
Baby OK
Baby head pillow
Display
ring
batteries
baby ring w/ external batteries
wire risks?
bluetooth
battery life?

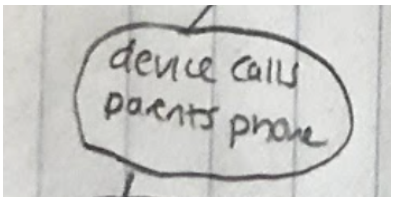
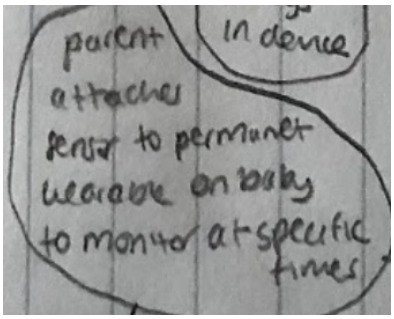
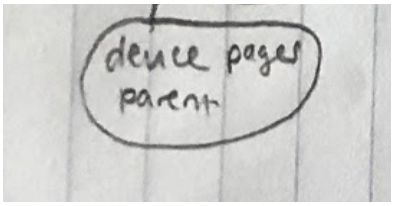
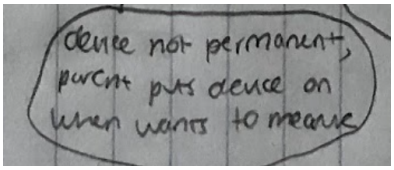
Housing Solutions

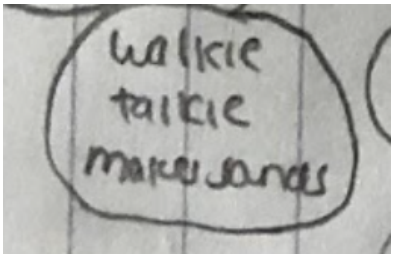
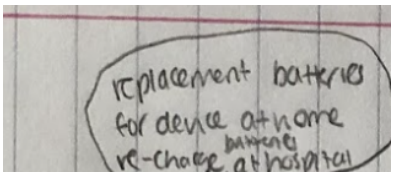
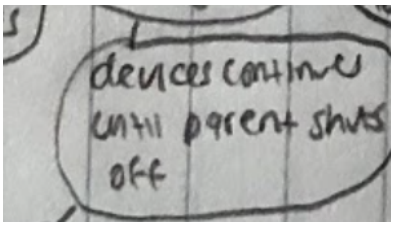
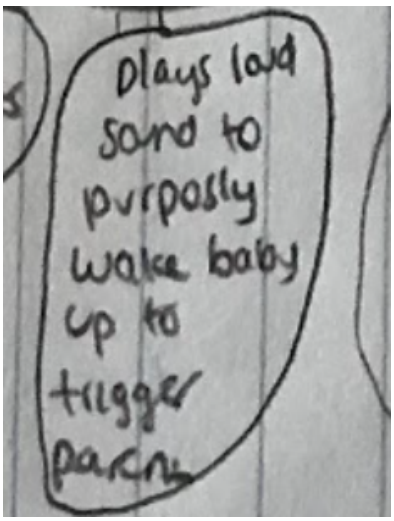
Head/Ear	Hand/Finger	Foot/Toe	Miscellaneous
			
			
			

 strap on	 velcro	 velcro	 sensors in baby blanket
 Slip on	 bracelet	 one band	 finger sensor on milk bottle
 ear muffs with piece at ear lobes	 double band (wellve)	 double band	 sensor device on parent, parent holds babies hand
 headband			
 headphone goes in ear			
 wraps around ear			

Battery and Alert Systems Solutions

Audio Alert	Visual Alert	Battery
- Sound adults can hear that infant cant	- friendship lamp - white when green - yellow/red when warning	battery on device
- sounds that make baby's go to sleep - like meditation	- light that lights up whole room - all the time - intermittent	· battery on device and charged in crib mattress
		-non traditional material properties
		have battery last longe 3 days and have it shut off and aler battery lasted 3

 walkie talkie makes sounds		 replacement batteries for device at home batteries re-charge at hospital
 devices continue until parent shuts off		
 plays loud sound to purposly wake baby up to trigger parent		

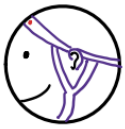
Appendix 03: Morphological Chart

Sub-functions	Solutions-->						
Monitor	Baby is always wearing the device, sensor always in the device	parent attaches/turns on sensor to permenant wearable	Swaps out sensor and battery when dies	Device is not permanent, parent puts it on when they want to measure	camera is monitoring baby's movement	pressure sensor monitoring baby's movement	
Housing							
head/ear	headband - slip on	headband - velco	headband - button on	s-lock headband (bike helmet)	earmuffs - piece goes into earlobe	hat that covers your ears	hearing aid - wraps around ear
OR Finger/Hand (sensor at palm or around finger)	bracelet - slip on	double band - slip on	braclet - button	bracelet - velcro	mitten - slip on	mitten - cross over	mitten - wrap around (ace bandage)
OR foot/toes (sensor at sole or toes)	strap around the sole - slip on	double band - slip on	sock - slip on	sock - cross over	sock - wrap around (ace bandage)	sock - velcro (like velcro shoes)	toe ring
OR misc.	baby onesie with two sensors	shirt	pants	jacket	blanket	pressure mat	diaper clip on
Audio Alert System (sounds are continuous until parent shuts off or peroidic)	sound adults can hear but infant cant - on baby monitor	lulabye - keeps baby asleep but wakes parent - on baby monitor	device that moves and wakes up parents in room	sound of outdoor sounds but louder - on baby monitor	plays a song - on baby monitor	sound to wake up baby to alert parent - on baby monitor	seperate monitor that makes sound
Visual Alert System (combined or individual LED colors/signals)(continuous or periodic)	LED on device	LED on separate monitor	LED on parent wearable	light up the whole room	lamp in parent's room that changes color		
Power	battery in foam bottom of shoe	battery lasts longer than three days but shuts down to return to hospital	battery on device lasts 2-3 days	charging dock/portable charger - lasts 2 - 3 days and returned to hospital, parent recharges device at home	battery on crib - wireless charger	non-traditional material properties charger	solar powered recharge

Sub-functions									
Monitor									
Housing									
head/ear	headphone - wraps around and goes into ear (beats)	airpods	strap-on hat (strap underneath chin)						
OR Finger/Hand (sensor at palm or around finger)	mitten - velcro (like velcro shoes)	alligator clip for multiple fingers	ring	finger splint					
OR foot/toes (sensor at sole or toes)	shoe with sensor on the sole								
OR misc.	diaper	finger sensor on milk bottle	sensor in stuffed animal with hand pockets	belt	arm belt	pacifier	sensor on baby rattle	sensor on parent's hand and baby hold's parent	sensor on parent's finger and baby hold's parent finger
Audio Alert System (sounds are continuous until parent shuts off or peroidic)	device on parent makes sound	device calls parent's phone	device pages parent	walkie talkie that makes sound					
Visual Alert System (combined or individual LED colors/signals)(continuous or periodic)									
Power	small replacement rechargable batteries at home for 2 - 3 days, charged at hospital	kinetic energy to recharge it	solar powered recharge - watch face can generate power						

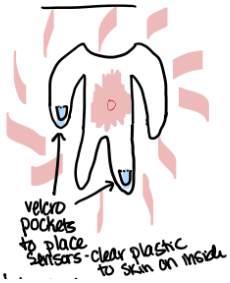
APPENDIX 04: Solutions from Concept Development

Noise cancelling headphone for baby



head band with chin strap - device is permenent
monitoring in ear
alarm system on forehead
audio alert: loud sound for parents to wake up
visual alarm: LED on device
battery: charge daily - portable charger

Onesie



sensor is put in onesie in two locations
- ~~Palm~~ finger
- Sole foot

lulabye is played loudly for parents to hear
LED lights up the whole room
battery lasts for 2-3 days

blanket

device is attached to the blanket
Sound to wake up baby
separate monitor with parent that makes sound
parent monitor shows light signals
battery is solar powered outside

Smart sock

measures on sole
device is attached in sock
device plays sounds to wake baby/parent up
LED lights up the whole room
battery lasts for more than 2-3 days
but shuts off after 3 days

bracelet

measures palm
device is attached to bracelet
LED lights up the whole room
plays sands like crickets but louder
Kinetic energy/nontraditional power

arm sleeve

Compression sock

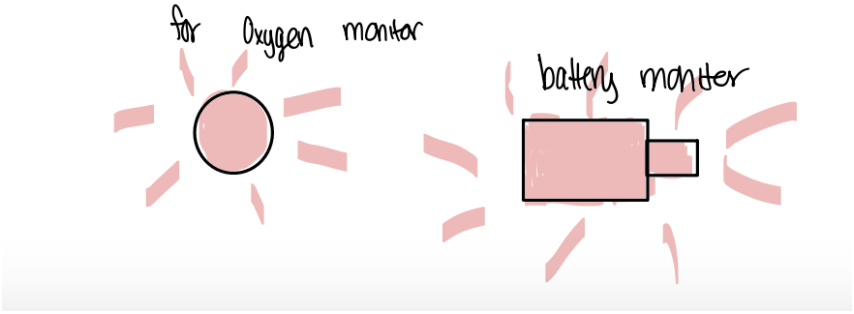
arm blanket

Shirt

pants

16: allow user to rearrange
have the double band
work for both sole and palm

77: visually distinguish functions



71: use human generated powered

hand crank strap for power

or something where they
can hook up to their
foot while walking to clinic

61: Slide

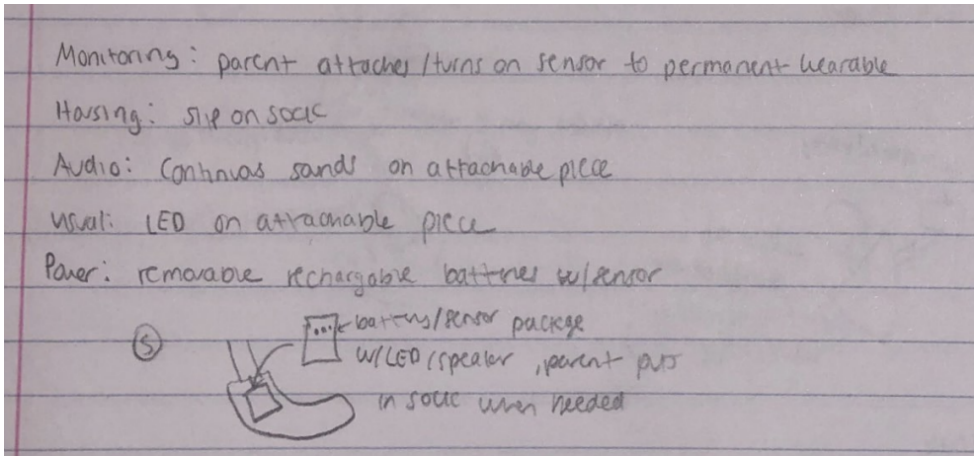
have bracelet to slide
to orient light and
pulse ox sensor

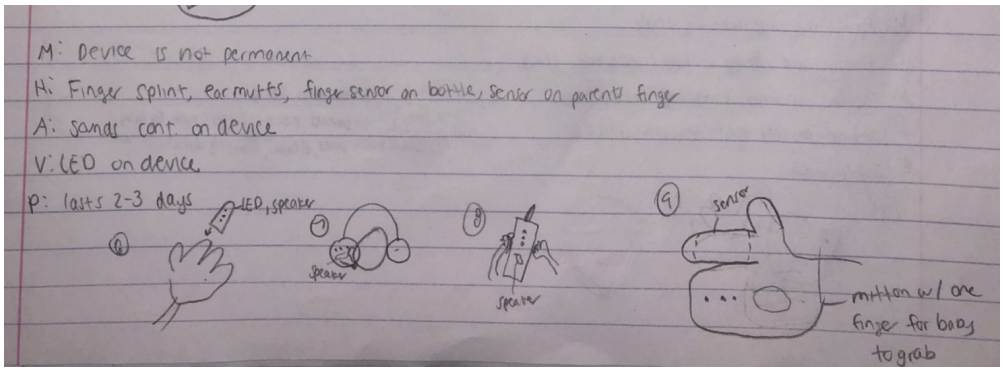
56: roll

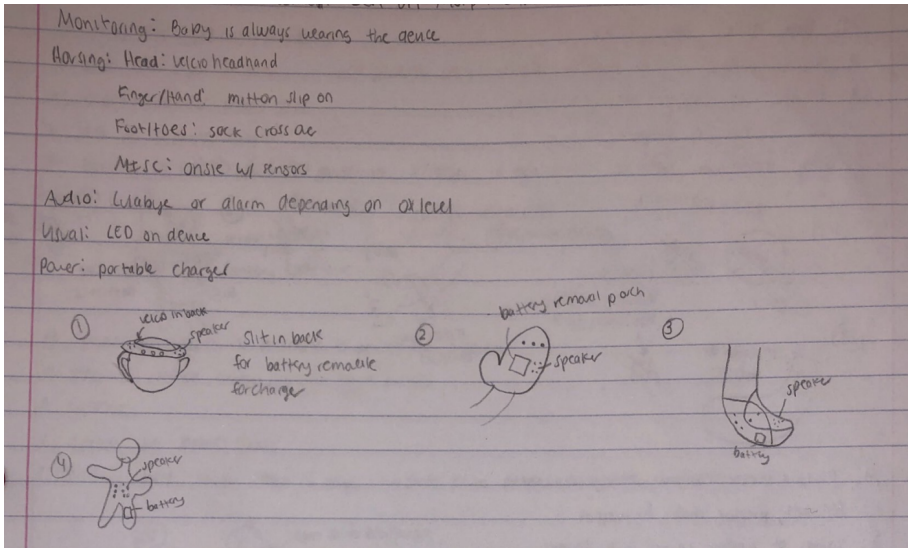
Slap bracelet/zipties style
make it adaptable

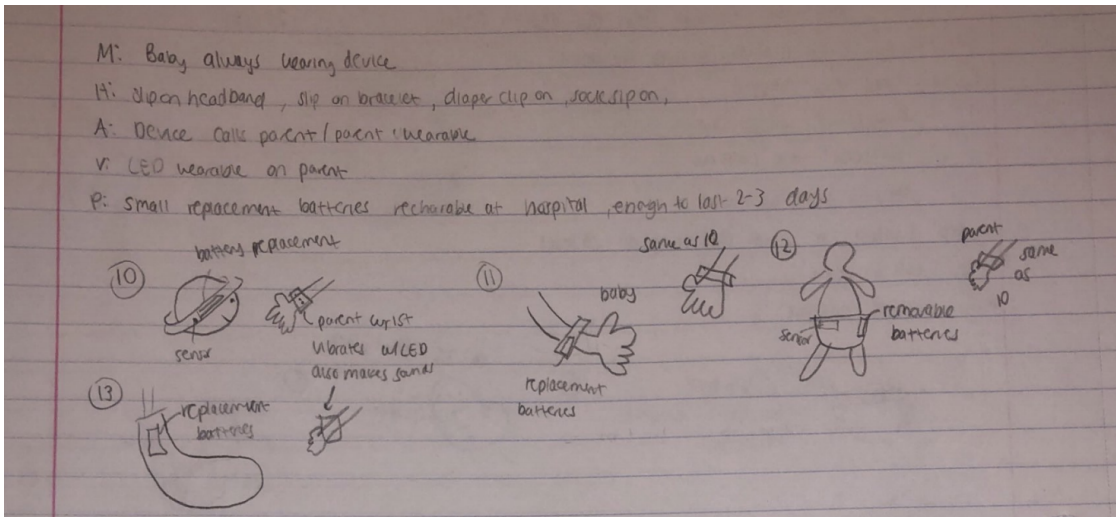
47: mirror array

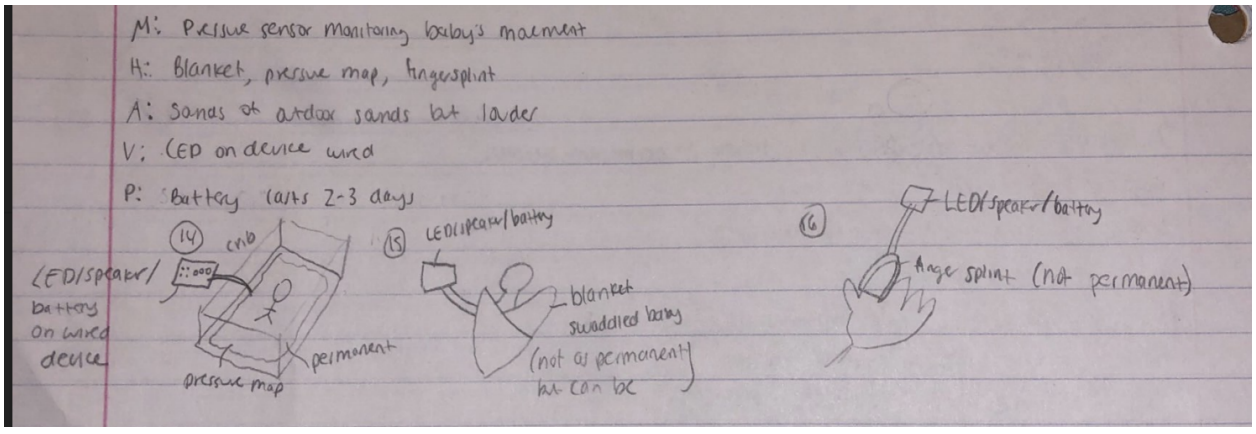
Clip-on for mitten/sock






Monitoring: Baby is always wearing the device
Housing: Head: velcro headband
Finger/Hand: mitten slip on
Feet/toes: sock crossover
Misc: onsie w/ sensors
Audio: Lullaby or alarm depending on dB level
Visual: LED on device
Power: portable charger
velcro in back
speaker
Slit in back for battery removable for charger
battery removal porch
speaker
speaker
battery
speaker
battery


M: Baby always wearing device
H: Velcro headband, slip on bracelet, diaper clip on, sock slip on,
A: Device calls parent / parent wearable
V: LED wearable on parent
P: Small replacement batteries rechargable at hospital, enough to last 2-3 days
battery replacement
sensor
parent wrist vibrates w/ LED also makes sound
replacement batteries
baby
replacement batteries
same as 10
sensor
rechargable batteries
parent
same as 10


M: Pressure sensor monitoring baby's movement
H: Blanket, pressure map, fingersplint
A: Sounds at outdoor sounds but louder
V: LED on device wired
P: Battery lasts 2-3 days
LED/speaker/battery on wired device
crib
permanent
pressure map
LED/speaker/battery
blanket swaddled baby
(not as permanent but can be
LED/speaker/battery
Finger splint (not permanent)

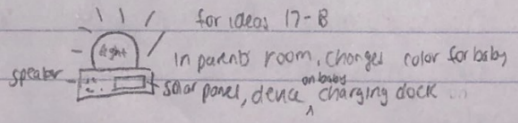
M: Baby is always wearing device

H: Hearing aid, strap on hat (under/outh chin)

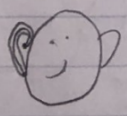
A: separate monitor (or lamp) makes sonas

V: Lamp in parents room that changes color

P: Solarpowered



17



18

M: Baby is always wearing device

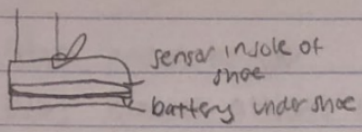
H: shoe with sensor on sole

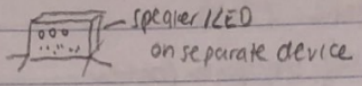
A: separate monitor makes sound

V: LED on separate monitor

P: Battery in foam bottom of shoe

19





M: parent attaches/turns on sensor to permanent wearable

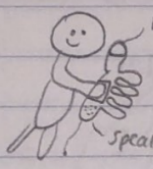
H: sensor in stuffed animal with hand pockets

A: lullabye

V: Lights up babies room

P: Battery lasts longer than 3 days but shuts down to return to hospital

20

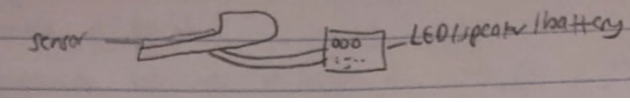


450 2/15/21 Concept Development

SCAMPER

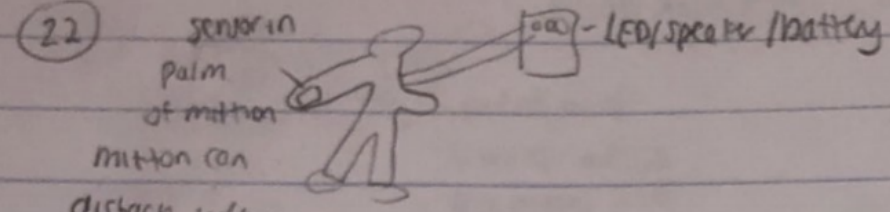
Eliminate: instead of a whole shoe (19), temporary slipper on babies foot

(21)



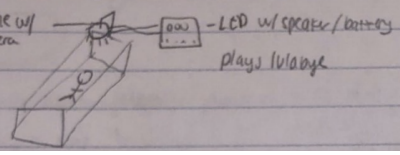
Combine: combine onsie + mittons (2+4)

(22)



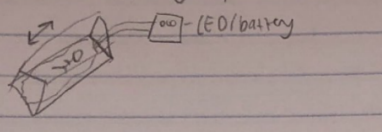
Add to Other Uses: Baby mobile (spins above babies head) use camera to scan baby

(23)



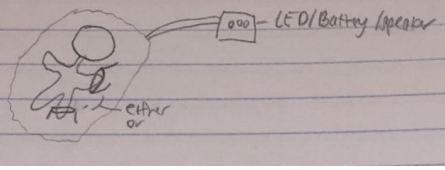
Card 2: Add Motion

(24) Shake crib to make baby up so it cries, sensor in mat of crib



Card 15: Attach product to user

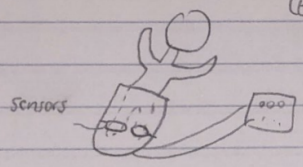
(25) baby blanket attaches to one foot or hand of baby w/ sensor, LED/speaker wired



Card 27: cover or wrap

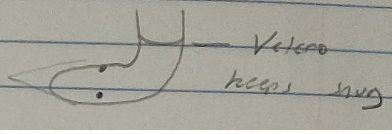
(26) baby sack covers babies waist down, two foot loops in sack

LED/speaker/battery wired attached



↳ 43: Multi function → durable enough for baby/toddler to walk/crawl with on

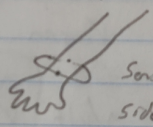
Combination 4: Swap out sensor when battery dies, Sock (Velcro), lullabye, light on device



↓ #22 Surface Properties Band is soft and warm

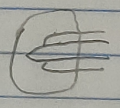
Combination 2: Parent attaches/turns on sensor to parent wearable, bracelet velcro, nature noises, lamp in parent room, battery lasts

Color of lamp + bracelet color, in case they have more than 1 kid

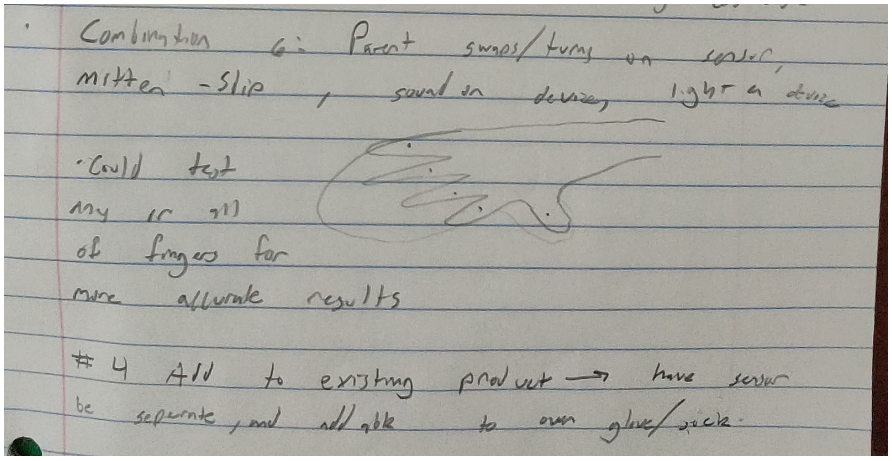


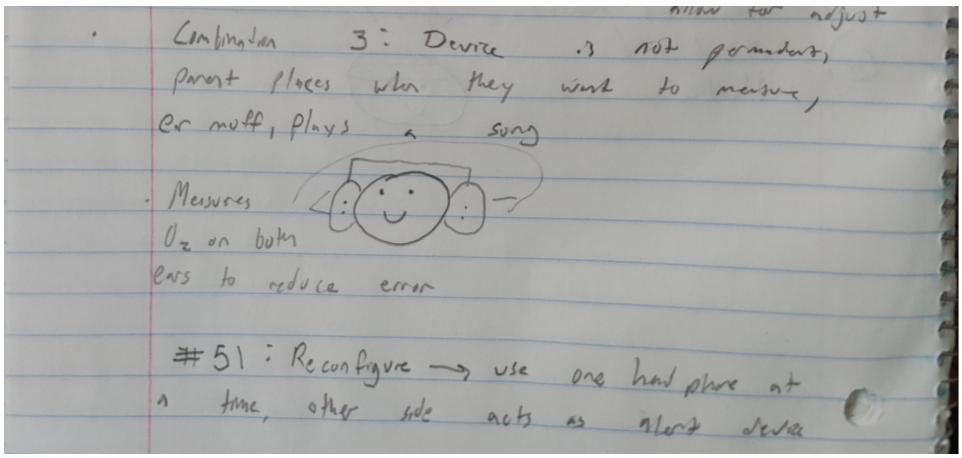
Combination 5: Not parent device, alligator clip, Sound on device, light on device

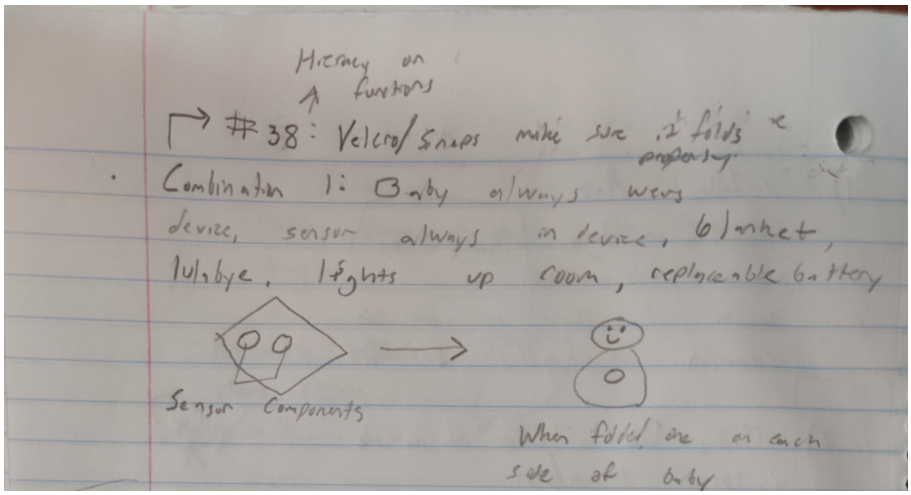
- Soft Clip onto >1 fingers, measures on all



#33: Expose Interior: Transparent design to allow parent to line up finger (s) easier


Combination 6: Parent swaps/turns on sensor, mitten - slip, sound on device, light on device
· Could test any or all of fingers for more accurate results
#4 Add to existing product → have sensor be separate, and able to own glove/sock.


Combination 3: Device is not permadent, parent places when they want to measure, ear muff, plays a song
· Measures O2 on both ears to reduce error
#51: Reconfigure → use one headphone at a time, other side acts as alert device


Hierarchy on functions
#38: Velcro/Snaps make sure it folds properly
Combination 1: Baby always wears device, sensor always in device, blanket, lullaby, lights up room, replaceable battery
Sensor Components
When folded are on each side of baby

Appendix 05: Housing Pugh Chart

	Concept (1-5)	Headband	Headband with Chin Strap	Earmuffs	Mitten	Bracelet
Specs						
Durable	3	0	1	-1	1	0
Stays on Baby	5	0	1	-1	0	1
Comfort	4	0	-1	1	0	1
Minimal Material	2	0	-1	0	1	1
Unique	1	0	0	1	1	1
Parent's Acceptance	4	0	0	1	1	-1
Cost	3	0	-1	0	0	0
Simplicity	4	0	0	0	0	-1
Feasability	5	0	0	-1	0	-1
Environmental Context	3	0	0	-1	-1	1
Totals:		0	-1	-7	7	2

Arm Sleeve	Multi-finger clip	Shoe	Wrap Sock	Sock	Swaddle Blanket
-1	1	1	0	0	0
1	-1	1	1	1	1
1	-1	0	1	1	1
-1	-1	-1	-1	-1	-1
1	-1	1	-1	-1	1
1	-1	1	1	1	0
0	0	-1	0	0	-1
0	1	1	-1	-1	-1
1	1	0	1	1	0
-1	0	0	0	0	-1
11	-4	12	11	11	-2

Pacifier	Chest Strap	Stuffed Animal	Vibrating Mat
0	1	1	1
-1	1	-1	0
1	0	1	1
0	-1	-1	-1
1	1	1	1
-1	0	1	1
0	0	-1	-1
-1	0	-1	-1
-1	0	0	-1
0	0	0	0
-13	7	-2	-2

Appendix 06: Battery Pugh Chart

Concept -->	Weighting (1-5)	LED/Speaker/Battery in device and batteries last 2-3 days	LED/Speaker/Battery in device and batteries last longer than 2-3 days but device shuts off at 2-3 days	LED/Speaker in device but removable batteries that are replaced with new batteries (batteries charged at hospital)
Specs				
Durability	4	0	0	-1
Cost	4	0	-1	0
Simplicity	2	0	-1	-1
Size on baby	3	0	-1	1
rechargability	5	0	1	1
Electrical Safety	5	0	0	0
Lifecycle	3	0	1	0
Cleanliness	3	0	0	-1
Bodily harm risk	5	0	0	0
Environmental Context	3	0	0	-1
Totals		0	-1	-4

LED/Speaker in device but removable batteries that charge in portable charger	LED/Speaker/Batteries are removable and lasts 2-3 days	LED/Speaker on vibrating bracelet parents wears connected bluetooth	LED/Speaker/Battery is connected to the device by wires and in separate housing	LED/Speaker/Battery is separate device through bluetooth (can be in babies room or parents)	Device is solarpowered - can be added to another design
-1	0	-1	-1	1	-1
-1	1	-1	1	-1	1
-1	1	-1	1	-1	1
1	0	1	1	1	0
1	1	-1	1	-1	1
0	0	0	0	1	0
0	0	0	0	0	1
-1	1	0	1	0	0
0	0	0	-1	1	0
0	0	0	0	-1	-1
-5	14	-12	8	3	7

Appendix 07: Risk Analysis

Hazard	Hazardous Situation	Likelihood	Impact	Level	Technical Preformance	Actions to Minimize
Electric Shocks	When using or assembling the device, the user could be shocked due to the device being asssembled wrong or broken.	Medium	Serious	4	If the device shock the infant, they could be severely harmed. Additionally, the device may not function properly.	Insolated device housing, minimze electrical componenets
Overheats	The device will get hot as it is used and could burn the infant.	Medium	Moderate	3	Some concerns on functionality if device gets hot enough to melt solder, otherwise little impact.	Ensure proper airflow, heat sinks if testing deems nessecariy
Cuts	The device could have sharp edges that may cut the infant.	Low	Minor	1	No technical impact	Ensure that device is made of soft material with smooth edges
Choking	The infant may swallow the device if it comes off the foot.	High	Catastrophic	5	If the infant swallows the device, the infant is in serious danger to their life. The device will obviously not be able to give readings if the child swallows it or is unable to breathe.	The device must be securly mounted and large enough that a child cannot swallow it regardless of the angle.
Hearing Damage	The alarm may hurt the infact if it is too loud.	Medium	Serious	3	No technical impact	The alarm system must not be near the baby to thurt them, or must be well below the dangerous levels.
Light Damage	The lights may hurt the infant if it is too bright	Low	Serious	2	No technical impact	The light must be obscured from the baby's eyes so as not to hurt them.

False Positive	The parent may ignore real alerts if false positives are too frequent	High	Serious	4	No technical impact	The signals used by the device must go through several signal processing methods such as a filter and be based off average measurements, not the measurements of that instant
False Negative	The infant may be harmed if the device fails to properly read oxygen levels	High	Serious	4	No technical impact	The device must check oxygen level frequently to ensure that the readings are not tainted by any one bad reading
Wire Hazards	The infant may choke or otherwise be harmed by the connecting wire	Medium	Serious	3	Baby may remove wire connections	The device must alert the parent when the wire is removed. Wire acts as a breakaway so it will unplug instead of providing a hazard to baby.

Appendix 08: FMEA Analysis

Component & Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurance	Current Controls	Detection	RPN	Reccomend Action
Red LED	too much power	the LED stops working and only the IR LED is used to read intensity	2	the circuit was assembled incorrectly	3	Instructions to build the circuit, simulation circuit, measure current through LED	2	12	Make sure to check the circuit before each use
	open circuit/loose wire	the LED stops working and only the IR LED is used to read intensity	2	the movement of the device made one of the wires loose, loose terminal holes	3	the housing of the device	2	12	Make sure to check the circuit before each use
IR LED	too much power	the LED stops working and only the red LED is used to read intensity	2	someone assembled the circuit incorrectly	3	Instructions to build the circuit, simulation circuit, measure current through LED	9	54	Make sure to check the circuit before each use
	open circuit/loose wire	the LED stops working and only the red LED is used to read intensity	2	the movement of the device made one of the wires loose, loose terminal holes	3	the housing of the device	9	54	Make sure to check the circuit before each use
Photodiode	stops changing output values with change in light	the device wouldn't be able to monitor oxygen levels	8	loose terminal holes, the movement of the device disconnected, overpowered	5	Instructions to build the circuit, check if current is going through it	4	160	Choose a robust photodiode
	placement is off with LEDs	the device wouldn't be able to monitor oxygen levels	8	the device was not put on properly, the device was not put on the proper place on the body	6	Instructions to build the circuit, check if current is going through it	4	192	Have explicit instructions for correct placement, user testing to see where they place the device, and mechanical solution to prevent movement
Op Amp	too much power	the filter and amplification of the system would not working and the readings would be hard to measure oxygen levels	7	someone assembled the circuit incorrectly	3	Instructions to build the circuit, simulation circuit, measure current through Op Amp	4	84	Make sure to check the circuit before each use
Microcontroller	too much power	the circuit is not able to time the lights and convert the change in current to oxygen levels	7	someone assembled the circuit incorrectly	3	Instructions to build the circuit, simulation circuit, measure current through circuit	4	84	Make sure to check the circuit before each use
Battery	battery is dead	the device would need new batteries for use	9	the battery was used from the device	4	replacement batteries	1	36	Check amount of battery before use
Timing of Lights	too much ambient light	skewed changes in current and can have inaccurate oxygen level readings	7	the housing lets too much light in, the device is put on incorrectly	3	instructions on how to put the device on	7	147	test code repeatedly before use
	not enough time to get intensity reading	won't be able to calculate oxygen level readings	7	the microcontroller was not responding to the code correctly	2	there is none currently	8	112	test code repeatedly before use

Component & Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurance	Current Controls	Detection	RPN	Reccomend Action
Reading in Intensity	the conversion from current to blood oxygen levels is wrong	give inaccurate readings to the device	7	amplifier or pass filter isn't working correctly	2	Instructions to build the circuit	7	98	test code repeatedly before use
Strap	the strap falls off the infant	the device is not reading blood oxygen levels of the infant	2	device wasn't secured enough	8	instructions on how to put the device on	1	16	choose a material that won't easily slip
	the strap breaks	the device is not reading blood oxygen levels of the infant	2	device was put on too tight, the device was assembled wrong	4	there is none currently	1	8	Choose a robust material for the strap
Alarm Speaker	the speaker is too loud and hurts the infant's ears	parent is not audiotory alerted that their infant needs attention	5	there is too much power going through the speaker	2	Instructions to build the circuit, simulation circuit, measure current through speaker	7	70	Make sure to check the circuit before each use
	the speaker doesn't output soound	parent is not audiotory alerted that their infant needs attention	6	loose terminal holes, the movement of the device disconnected, overpowered	3	Instructions to build the circuit, simulation circuit, measure current through speaker	4	72	Make sure to check the circuit before each use
Alarm LED	too much power	parent is not visually alerted that their infant needs attention	5	someone assembled the circuit incorrectly	3	Instructions to build the circuit	4	60	Make sure to check the circuit before each use
	open circuit/loose wire	parent is not visually alerted that their infant needs attention	5	the movement of the device made one of the wires loose	3	the housing of the device	4	60	Make sure to check the circuit before each use
GSM Module	isn't able to send message to phone	parent isnt notified that their infant needs attention if they aren't in hearing distance of the audio alarm	5	input the wrong number, not strong enough bandwidth	6	the alert and visual alarm	6	180	Test the SMS connection to phone in clinic
Housing	the housing crack	the electronics are exposed to infant	1	device falling	3	there are none currently	1	3	Test the housing properties before use
	the housing melts	the electronics are exposed to infant	1	temperature too high	1	there are none currently	2	2	Test the housing properties before use

Appendix 09: Component List

Resistors	Quantity
100 ohms	4
8 kohms	1
16 kohms	1
62 kohms	1
300 kohms	1
1 kohms	1
10 kohms	1

Capacitors	Quantity
10 uF	2

Op Amp	Quantity
LM324N Quad Op Amp	1

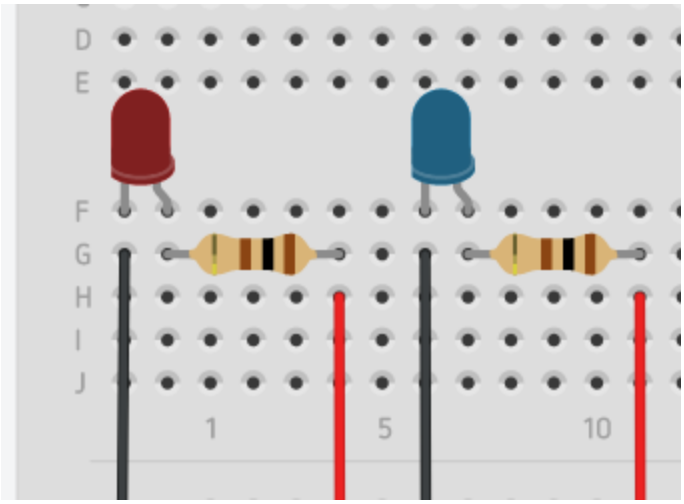
Light	Quantity
Red	1
IR	1
Multi Color	1

Miscellaneous	Quantity
Speaker	1
Raspberry Pico	1
Speaker	1
AA Battery	2
Photodiode	1

Appendix 11: Assembly Instructions

Step 1:

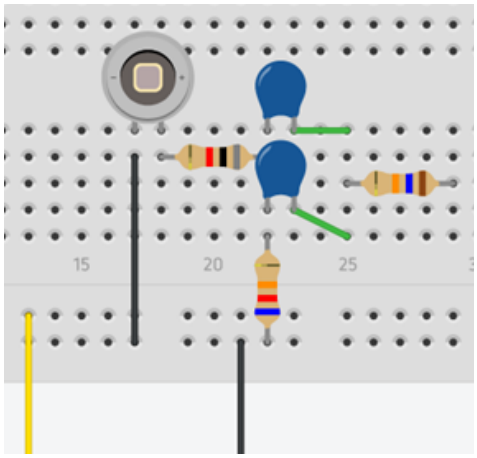
Place the IR Light (represented as a blue light) and Red Light and 100 ohm resistors onto the small breadboard as seen below.



The black wires go to ground on the microcontroller and the red ones go to a pin. Make sure that the pins that each light go to are properly specified in the code.

Each light needs a 100-ohm resistor placed as seen above to prevent them from receiving too much current.

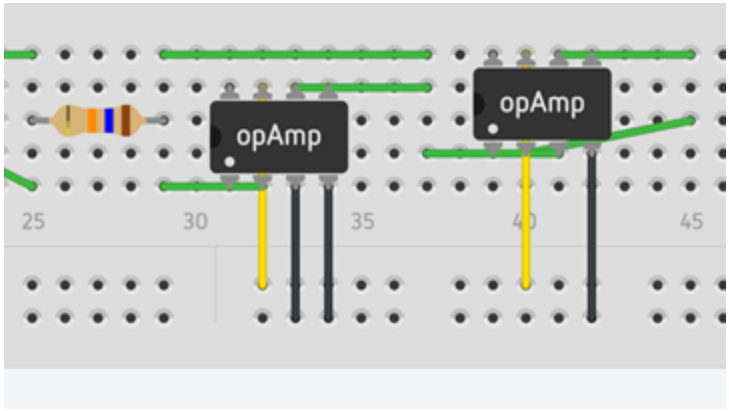
Step 2:



Connect a black wire from the ground on the microcontroller to the bottom row and use a yellow wire to connect the 5V pin to the top row. Yellow wires will represent power connections and black will represent ground connection. Green wires represent internal circuit connection.

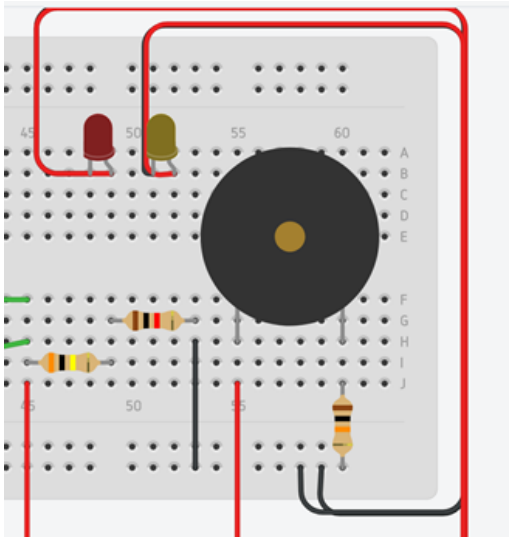
Place the photodiode and connect the black wire (ground) to the negative terminal. The positive terminal outputs to an 8 kOhm resistor, which is in series with the two 10 uF capacitors in series as pictured above. Running to the ground is a 62 kOhm resistor and connected to the two green wires is a 16 kOhm resistor.

Step 3:



Connect the 16 kOhm resistor added in step 2's output to the two points seen in this image then connect the two op amps as shown. The bottom green wire connects to pin 2 on the first op amp and the yellow wire connects to pin 7 on both op amps. Pins 3 and 4 on the first op amp are both connected to ground. Pin 6 is the output for the first op amp and is the input to the second op amp. That green wire is connected to pin 2 of the second op amp. Pin 4 connects to the ground and pin 6 is the output of the second op amp. Pin 3 is connected in parallel to the output of pin 6.

Step 4:



The first resistor (300 kOhms) is connected to a pin and the outputs of the op amp. The Second resistor is 1 kohm and connected to ground.

The speaker's positive terminal is connected to a pin and the negative is connected to a 10 kohm resistor to ground.

Connect two more lights to act as the signals with 1 kOhm resistors (not pictured above).

Appendix 12: Placement Instructions

To place the device, line up the smaller housing with the base of the infant's toes. The infant's foot should be in between the two pieces. Wrap the device with gauze to secure it. Next, decide whether the larger housing will be on the infant or set in a secure location off the infant. If the device is attached to the infant, secure the wire between the two devices to the infant using gauze.

Appendix 13: Usage Instructions

Once the device has been placed, readings will start to be taken. If the infant's oxygen levels drop below normal, a light will glow and a tone will play. If the infant's oxygen level's drop critically below normal, a light will glow, a tone will play and an SMS message will be sent (if enabled).

Appendix 14: Previous Version of the Report

Project Plan, Status and Challenges

Currently, we are moving into the testing phase for the remainder of our top priority design drivers and creating the plan for moving into the secondary and tertiary drivers. These tests vary from using our device in certain circumstances to see how they affect its performance to creating the instructions to ensure that our device is easy for the technicians to assemble. As it has been throughout the project, our largest challenges revolve around the requirement for us to work remotely and the inability for us to directly contact potential users. Our ability to prototype has been greatly affected by the later as it makes troubleshooting our designs much more difficult than if we were all able to see and interact with each device. To try and alleviate this, we are making two separate circuits to have a comparison between the two devices' performance. This required us to spend a large portion of our budget to make sure that each group had the pieces as well as spare components for likely to fail portions, but even with this extra expense we are well under budget. Other main issues include the large amount of circuitry that will be in the small housing and how many of our problems are codependent. These challenges are ones that we are still working on addressing. Our work on addressing these concerns as well as continuing our testing can be seen below in Figure 18.

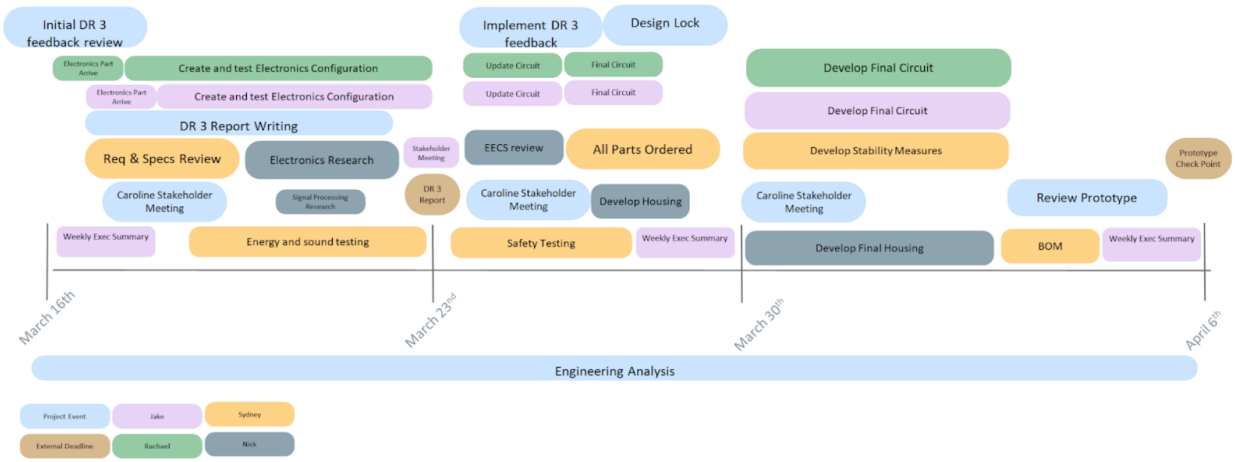


Figure 18. Timeline between design review 3 and the prototype checkpoint. Significant work is planned to address the challenges we will encounter before the end of the semester and responsibilities have been divided to address this.

As Figure 18 shows, over the next week we will work on continuing to develop our final circuit. This will be done with tight communication between the two groups so as to ensure that the circuits are working as intended. The other two members will ensure that all parts are being ordered for the final design as well as developing the housing. While these parts are being developed, safety testing as well as circuit performance will be tested.

In the last week before the review, we will have the final circuit developed in its final form as well as take into account the feedback that we will receive from DR 3. We will make sure that our team meets the challenges of working remotely and creates the product that best meets our stakeholder's needs and requirements as well as any additional feedback they have on our design.

Incorporation of DR 3 Presentation Feedback

One main concern brought up by multiple stakeholders after our DR3 presentation, was making sure our risk analysis covered false negatives and positives. This is extremely important for the functionality and safety of our device. If the device gives many false positives or negatives, the baby could be in distress without the parent knowing or a parent could be alarmed and have unnecessary worry and stress. From this feedback, we made sure to include this in our risk analysis which can be seen in Appendix 08. Next, we also received feedback from DR2 to incorporate social and environmental consideration from Nicaragua in the design and document it in the report. Although, we had already incorporated some features, we did more thoroughly consider the context when iterating to Design 2.0. The social and environmental considerations can be seen in the corresponding section above. Finally, we were also told to look into the weight of our device after the DR3 presentation. After checking with our benchmarking sources, we concluded that the weight of our device is on par with other devices on the market.

Incorporation of DR 2 Presentation Feedback

Alerting Process

Currently, our device alerts the parent by light and sound that are attached to the device worn by the infant. This brought up concern that the alarm would need to be loud enough that the parent could hear it even if they are outside or in a different room, but also not hurt the infant. We are currently looking into several different systems for doing this. First, we would communicate to the parent's phone through either a Bluetooth signal or an SMS signal. This of course requires the parent to have a phone but will keep the cost of the device down. The other solution would be creating a wearable device for the parent that can receive a signal from the infant's monitor but the cost of such a device is a large concern.

Safety

Our device had some safety concerns for the infant. The device, if detached from the sock, could potentially serve as a choking hazard. To combat this, we have added a requirement that our device meets the federal regulations for a child's toy. By meeting this standard as well as the existing safety related standards, we can ensure that our device will not hurt the infant even if it comes detached or is damaged.

Owlet Smart Sock Differentiators

Especially with the addition of the off device signally, our device is largely identical to the Owlet Smart Sock, which was a point of concern from our sponsors. We are looking into several ways to differentiate this device, such as making it an open source, kit-based design. Additionally, we are looking into Owlet's patents again to see if a non-open-source solution is viable without infringing on their patents.

Incorporation of DR 1 Presentation Feedback

False Positives

False positives are a significant concern to our device. Frequent alarms can cause the parent to begin to ignore the alarms when they do go off, regardless of whether they are serious or not in what is known as the "cry wolf effect" [30]. We researched several means to attempt to lower the false positive rate of our device. One way that came up to mitigate this was to base alarms on trends instead of raw data [22]. Another way to mitigate false positives is to have a delay after the device has been placed onto the child, as repositioning of the sensor can often create false alarms [31]. An ideal alarm would combine these methods together in order to create the smallest possible number of false positives.

Low Income at Home Devices

Looking into devices that operate in the same setting as ours is very important to see how they were designed to meet the needs of the users. There were three main monitoring devices, Moyo Fetal Heart Monitor, Freeplay Fetal Heart Monitor and Neopenda Vital Signs Monitor, that helped us better understand how to define our problem and design our device in the context of at home use in low income countries [14,15,16]. The operating temperature and humidity were important factors in determining the environment conditions our product should work under [14]. The different types of power sources will also be helpful when deciding what type of power we will use in our device. One device used hand cranked power and the other used a rechargeable battery to power their monitors because of the lack of

reliable and steady electricity [14,15]. It also helped to put our stakeholder needs in perspective like the cost and lifespan of these devices [14,15,16]. These differed from our specifications and might need to be changed due to feasibility. All of this information helped define our setting and made it easier to start designing our device.

Specifications Updates

After our DR1 presentation, we received feedback to incorporate into our specifications. First, we changed the syntax of our specifications to be uniform. Next, it was brought to our attention that the accuracy tolerance in the 'Monitoring oxygen levels' specification contradicts the specification in the 'Device detects oxygen levels at 2 specific thresholds' as seen in Table 2. After looking into additional benchmarking, we have decided to keep the 3% accuracy tolerance. The specification for the oxygen level thresholds were determined by our stakeholder. Since these values are contradicting, we changed the status of the threshold requirement from complete to in progress so we can reconvene with our stakeholder to adjust the threshold specification. We also added additional details into the 'Alerts parent when oxygen level hits warning or dangerous level', 'Users for the device', 'Baby should not be able to remove device', and 'Battery Indication' specifications to make them more complete.

Stakeholder Engagement

Currently for our project, we have two University of Michigan stakeholders: Professor Aubree Gordon, who is an assistant professor of Epidemiology, and Caroline Soyars, who works for the Global Design Initiative. Thus far, we have interviewed each stakeholder once to help us further define our problem and understand their requirements for our project [3,29]. Since this is Professor Gordon's project and she discovered the need for the problem when she was in Nicaragua, she was able to give us her expectations for the solution and answer questions we had about the need and the problem [3]. This helped us narrow down our problem statement and define our stakeholder requirements. Next, we interviewed Caroline, who is financially sponsoring our project. She was able to educate us on additional resources and people to reach out to. She also reviewed our initial requirements and specifications and gave us useful feedback [29]. From these two interviews, our team was able to gain further insight into the expectations of our solution and new areas to research. Based upon this information, we created our initial list of requirements and specifications for DR1 and will continue to reach out to new people who could provide us additional information.

In order to keep our stakeholders informed this semester, we have decided to conduct bi-weekly Zoom meetings with each stakeholder and send them each an executive summary every Friday to continue the communication regularly. We will be meeting with them bi-weekly to ask additional questions that arise about our problem statement and requirements, and also to look for feedback on our progress. In addition to providing feedback and direction, our stakeholders should also be present during our brainstorming sessions to add diversity to our idea generation. They also will be invited to be involved in idea selection to help the team set priorities for the functionality of the solution ideas. Finally, they will be invited to help us test out potential prototypes and provide feedback.

As we begin to reach out to additional people recommended to us, we hope to gain another stakeholder or two to acquire new perspectives in the medical and manufacturing industry. Ideally, we would also have

stakeholders in low-income countries to also gather their input and test a prototype in the appropriate setting. Due to COVID-19 and the scope of this class, we will not be able to travel to a low-income country to experience the problem and additional barriers. We may have the opportunity to call colleagues of Prof. Gordon in Nicaragua. This would be very beneficial to gain their perspective and feedback; however, the language barrier is a challenge.

In addition to travel constraints and language barriers, we have additional challenges with interacting with our stakeholders. Due to the ongoing pandemic, we are unable to meet with our stakeholders in person and will only be conducting online Zoom meetings. Because of this, it will be difficult to conduct virtual brainstorming sessions, explain potential idea solutions and share and test prototypes. We also have a limited amount of time to spend with our stakeholders, so we will have to conduct efficient meetings and only discuss priorities. Even though we have challenges, interacting with our stakeholders is extremely important and beneficial. They provide critical insight into the direction of the project and set constraints based on their expertise in their respective fields. As the project progresses, they will continue to support us and provide feedback. Hopefully, they will be able to share our work with low-income countries and continue to work on this project after the semester.

Our stakeholders have had limited involvement in our product design process since our last design review. We have met with Caroline Soyars who has been able to guide us through narrowing down and defining our specifications to better understand our problem and the specifications our solution needs to follow. We were able to gain a better understanding of the use case of our device and the barriers of the use case from professor Gordon at design review two which will help us guide our new design process and our future concepts.

Our team has formed a new plan for working with our stakeholders for the project. Our time with professor Gordon is limited so we will show our current design selections and have information prepared to be able to get guidance on how to proceed with the project. Our plan is to have enough designs and content prepared for her to guide us in the direction that will best fit her experience with the users in Nicaragua. We plan to have Caroline help us from a more broad perspective of having global health experience in other low income countries. We will seek guidance from her to see how our device would be feasible in low income countries and how users would interact with the device. This will help us differentiate our devices from current devices that are already on the market.

The benefits of working with our stakeholders have been gaining and understanding of the environment of low income countries and the barriers and challenges they face. They have both worked in global health settings in various low income countries so they have more context for the situation than the articles our team has read and the individuals on the team's experiences. Caroline has also helped us find information on our project whether it was giving people to contact whoo have more knowledge in the field or sending us information sources that would give us different perspectives or new information about our specifications.

Our biggest challenge to date with our stakeholders has been navigating the aggressive design schedule along with the busy schedules of both working professionals and students. In recognition of this, our team

has scheduled bi-weekly meetings with key stakeholders to block out this time in everyone's schedules. We intend to pre-plan the agenda and specifically target the most pressing issues to maximize the information we obtain from our stakeholders. By adapting to and considering everyone's unique scheduling demands, we believe we will be able to successfully keep our stakeholders involved while also meeting the needs of our team.

After DR2, we interacted with two additional stakeholders, Randy Schwemmin [45] and Jeff Plot [46]. Both of these stakeholders have knowledge about mass production and manufacturing. We met with both of them to gain insight for our cost analysis to understand if it would be feasible to mass produce our product with our low cost requirements. They helped us understand that it was not possible, which helped us create our second iteration of our final design.

If we had more time and resources, we would communicate with people in Nicaragua. We would talk to doctors and electrical technicians in a hospital in Nicaragua to understand what they are capable of assembling together and gather their feedback of our current design. We would also like to interview parents of babies in Nicaragua but also could speak to parents here in the US. Their feedback would be valuable to understand their comfort level with using the device on their baby. Additionally, for the parents in Nicaragua, their feedback would be helpful to understand if they think the device is feasible for their living environment.

Appendix 15: Accuracy of Device

The link to the video can be viewed here.
https://drive.google.com/file/d/1bUXw4R2h6FfwjYB1Mxyaw4vpSCAU5HDX/view?usp=sharing

Appendix 16: Supplemental Appendix

Engineering Standards

In the medical device industry it is important to follow engineering standards to ensure your device is safe to use on people. Standards are important to make sure devices being put on the market are meeting the same criteria across different companies. This is especially important in the medical device industry because these devices can be life or death to a patient, so it is important that they are held under some standard to make it easier for health care workers to appropriately treat their patients.

Common standards that are used in the medical device industry are ISO 9001 and ISO 13485. ISO 9001 helps main manufacturing quality throughout the whole manufacturing site while keeping cost low. The low cost is important to our device to tailor to low income countries, but our product will not be manufactured in a facility rather than at the partnered hospital [52]. ISO 13485 is meant specifically for medical device manufacturers while ISO 9001 is a general standard. This standard helps with quality control as well as risk management [52]. While both are very common and important in the medical device industry, neither of these apply to our research model of a medical device.

At our stage in the design process engineering standards were only used to define our specifications. We used ISO 10993 - 10:2010 to define our safety specification and IP 54 to satisfy our environment specification. Standards are important for medical devices, most standards are related to the

manufacturing processes and the accuracy of the device. Because we have not finished working on the accuracy of the device and the manufacturing process will be done in the hospital, we have not incorporated engineering standards into our project. We also looked into standards that are associated with blood oxygen levels and pulse oximetry, and were able to find ISO 80601-2-61:2017, which discusses the safety and performance of pulse oximeters [53]. If our team had more time we would look into this standard to see how we can incorporate into our design.

Engineering Inclusivity

During this project, our team worked to develop an inclusive design. We were a team of four University of Michigan undergraduate students. From this alone, our team shared multiple social identities like education level and age, but we also differed in identities like gender. Even though there were some differences, we were missing key points of view, which is part of the reason we interacted with our stakeholders. Our stakeholders were very educated experienced individuals with different backgrounds and expertise. This allowed us to gain more perspectives. For example, our team has never been to Nicaragua or has designed a product for a LIC. Our stakeholder, Professor Gordon, has experience in this area and gave us insight into the culture and environment. Professor Gordon helped us define the problem properly using her experience in Nicaragua. She was able to guide our design to be feasible for an LIC. Another gap in our perspective from our identities was being a parent. None of our team members are parents and since we are designing a product for a baby this perspective is very important. One of our stakeholders, Professor Sienko, is a parent and was able to emphasize the importance of user testing to understand the parent's point of view of our device. Because of this, we created a survey that we sent out to parents to get parent's feedback and the likelihood they would use our device. In addition to stakeholder interaction, our social identities also did affect our ability to make design decisions. For instance, our original design direction was to mass produce the product. After seeking out advice from multiple stakeholders who are manufacturing experts, we realized this was not a feasible direction for our project given the design constraints. We had to take a step back and learn more about the design space to rethink our design decisions.

Social power also played a role in our project. Since this project was a class, there were many visual forms of power. We had specific deliverables, scheduling, and project requirements that were required for the class. Our stakeholders held hidden power as well. Professor Gordon, Caroline Soyars, and Professor Sienko all held power in making design decisions in our project. Since Professor Gordon was our primary stakeholder, we created most of the requirements and specifications off of her expertise and what she wanted for the device. Additionally, Caroline Soyars and Professor Sienko met with our team regularly, and we always looked to them for guidance and tried to incorporate all their feedback. We also have invisible power. So far, we have decided to focus on Nicaragua. Ideally, we would like to target all LICs, but due to time constraints and the scope of the project, we had to limit our use case. We are also only focusing on babies between 0-1 years old. This could portray that the problem only affects 0-1 year old babies in Nicaragua, although that is not true.

When working with our stakeholders, we tried to avoid creating a closed space and strived for a claimed space. During stakeholder meetings, we made sure to create an open environment for feedback. We wanted our stakeholders to be part of the decision making process; however, due to the busy schedules of

our stakeholders, we did have to make decisions without their input at times. Even when we made design decisions without their initial input, we always kept them up to date with the design decisions and asked for feedback.

Since this project is still in the early stages of development, most of the design decisions were at the local level of influence. Although national and global level of influence has not directly affected the design decisions in this stage, they will become prominent levels of influence as the project progresses. When the time comes to conduct clinical trials of our device and receive IRB approval in Nicaragua, the project will be influenced greatly globally.

Overall, our team worked hard to make an inclusive design. We reached out to additional stakeholders or experts when we felt we needed more perspectives. We also conducted user surveys for parents and asked for feedback from another ME450 team to gain additional point of views and feedback. We were also accommodating to the feedback we received and worked with our stakeholders to make design decisions. Even though we worked to make the design inclusive, there are still areas for improvement. In the future, we should get stakeholders in Nicaragua to further understand their perspective and gain their influence. We can also interview more parents and try to get in contact with parents in Nicaragua. We should talk to the technicians, who will be assembling these devices, to understand what they are capable of. Finally, we should look more into the requirements to receive an IRB approval in Nicaragua to modify the design under global influence.

Environmental Context Assessment

We believe that our project does make significant progress towards an unmet and important social challenge. Although adding a new product to the market creates substantial resource costs, our device's purpose outweighs the costs. According to the Sustainable Development Goals from the United Nations, our device will help target goal 3, good health and well-being, and goal 10, reduce inequalities [55]. These are very important global sustainability goals that the project is working to help achieve. In relation to goal 3, our project will be able to help babies struggling with RSV and respiratory illness. This device could save lives by alerting parents when their baby is in distress and allow them to get their child to the hospital for medical attention. Even though this product is currently on a smaller scale, in an ideal scenario, this device would be used in many hospitals across many LICs. This project will help reduce inequalities, goal 10, because we are targeting LICs. This technology and concept already exists in high income countries; however, the products currently available are extremely expensive. For this reason, creating a low cost wearable pulse oximeter specifically designed for LICs will help people in LICs to have access to this technology.

We believe our project will not lead to undesirable consequences in its lifecycle that overshadow the social benefits. First, our product will not require mass production, so we will not need a manufacturing plant to create and assemble the components. The components are all 'off the shelf' and able to be shipped to LICs from their supplier, so we are reducing any additional transportation costs and pollutants if they had to be shipped to a manufacturing plant first. This also reduces additional manufacturing and assembly costs, CO_2 emissions, and energy consumption by not needing a manufacturing plant. We will have labor costs to pay the hospital technicians to assemble each device individually. There is

significantly more time required to assemble each device unlike if it was mass produced, but since it will be assembled by hand, we are reducing pollution. For lifespan, our product should be able to be used for 1 year with a rechargeable battery life that lasts up to 3 days. This is a shorter lifespan and will require a decent amount of energy to recharge the batteries. More research should be done to investigate the exact amount of energy consumption required. The device will also easily be able to be fixed as the assembling technicians work in the hospital and this is a modular device. The device will be able to be disposed of after 1 year, but the batteries will need to be disposed of properly. The waste created will also need to be further investigated.

Social Context Assessment

There are inherent risks in having a wearable device, especially on an infant. However, we feel that the safety requirements that we have developed prevent an undesirable consequence to the infant from our device. There are no known issues with our device that could cause it to hurt the infant or the environment over the course of its life cycle.

The system is not likely to be adopted and self-sustaining in the market, but that was not the intention of our device. Our device was not intended to make any profit as it was an open source kit design instead of a mass manufactured solution. The product has a clear need, and there is no market solution close to our price point, making adoption likely in cases that have the capacity to do so.

The device will not be so successful that it will cause planetary or social systems to be worse off. Our device does not produce more waste than other devices, and it is more replaceable than any other similar devices on the market due to its ability to swap out individual components when they fail. Social systems will only improve as a result of our device as it is intended to fill a need in low income countries that is currently met in high income countries. The environmental impact of our design is non-trivial as it uses a plastic shell and batteries that will require proper disposal. However, both of these components are intended to be reused many times over the lifespan of the device, minimizing their environmental impact.

Our technology is largely resilient to disruptions. The sustainability in our device comes from its reusability and replaceability. Unlike current market solutions, individual parts can be easily replaced if they are malfunctioning or broken, giving the device much resistance in disruptions. The only large concern would be if the parts and all comparable equivalents are no longer being produced commercially, but the components will likely be produced for many decades to come.

These factors combine into allowing us to feel proud of the minimal negative environmental and social issues that our device has. Our device has a clear need and meets that need in a way that is both accessible and reusable so that it can continue to function without issue. If there is an issue, it can be easily fixed due to the modular nature of our design, which we feel allows it to address the social and environmental concerns around the problem.

Ethical Decision Making

The largest ethical factors with our device were how to address the continuous feedback we received in regards to making the device safe for the infant wearing it. We initially created a design that had no hazardous materials or sharp edges, but had to refine our design several times as new hazards were

discovered such as choking hazards, alerts being too loud and tangling the baby in the wires. To address these concerns, we looked at the ethical codes of the NSPE and ASME as well as our own moral codes to realize that these problems would have to be addressed. These problems caused us to spend a lot of time developing new concepts and solutions that could have been used to create more accurate or consistent results, but morally and ethically we made the correct choice by focusing on safety.

The largest ethical concern that we were unable to address in our design is a flaw in Pulse Oximetry in general: the technology works better for people with lighter skin than for people with darker skin[58]. There are currently no well accepted solutions to this problem in academia or that we were able to test. One of the proposed solutions was to attempt to make different calibration curves that could be selected by the technicians at the same time the phone number is inputted, but this also has its own ethical concerns. These concerns include but were not limited to parents not feeling comfortable with the question of what their baby's skin tone is and potential bias from the technicians. More research was needed to determine a solution to this concern.