Pediatric Pulse Oximeter for Low Resource Countries

Baby Ox

Lara Atalay, Saniyah Dar, Coco Francis, Alex Kucinski, and Fatima Shaat

June 8, 2021

Background information

Pulse oximetry is a non-invasive method for measuring the blood's arterial oxygen saturation. It allows for rapid detection in changes of oxygen efficiency being carried by arterial blood to the extremities. Oxygen is a vital component in bodily functions and low levels can have potentially life-threatening consequences. Low oxygen saturation levels may stem from complications within the respiratory system. Respiratory illnesses among children are treatable if appropriately monitored with the correct technology. Baby Ox provides a safe and accessible pediatric pulse oximeter as a solution to accurately monitor the oxygen levels that may be affected by common complications found in children under the age of 5.

After further research on Sudden Infant Death Syndrome (SIDS) this term, we decided to shift the focus of our device to respiratory infections and CCHD. Our device is marketed towards reducing infant mortality, and with the many unknowns of SIDS [2], it's more reasonable to focus on other areas. Respiratory infections are the leading cause of death for children under the age of 5 in low-resource areas and countries. Roughly 1.4 million deaths occur annually due to Acute Lower Respiratory Infections (ALRIs) [3]. A well-known ALRI is pneumonia, an inflammation of one/both of the air sacs in the lungs. Pneumonia is most prevalent in sub-Saharan Africa with roughly 50% of all pneumonia deaths [4]. In 2017, pneumonia itself accounted for 800,000 infant deaths worldwide [5]**.** Pneumonia can result in a below-average level of oxygen in the blood, known as hypoxemia. Hypoxemia is the most common symptom of respiratory illness. In fact, in low-resource areas, 1 in 5 infants are admitted to the hospital due to hypoxia with low oxygen in their tissues which results from hypoxemia [6]. According to the African sector of WHO, there were a total of 5.9 million children under the age of 5 that died in 2015. Unfortunately, more than half of these deaths could have been prevented or treated with simple interventions [1]. Our affordable and sustainable device monitors the patient efficiently so intervention can be possible.

Another possible implication of oxygen deficiency is Critical Congenital Heart Disease (CCHD) [20]. CCHD refers to heart defects that prevent the heart from effectively pumping blood as well as reducing the amount of oxygen delivered to the body [20]. Babies can appear healthy for the first few days, but symptoms eventually become apparent. Failure to treat CCHD can lead to life-threatening conditions. Around 18 per 10,000 infants are born with CCHD [20]. Pulse oximetry can be used as a tool for early diagnosis by attaching the oximeter to both the right hand and one of the feet. This screening evaluates any discrepancy between the two locations on the body that would indicate CCHD. Early detection of this heart disease and quick treatment allows for the babies to survive past infancy and reduce possible heart issues later in their life.

Unfortunately, current and updated medical technology is unavailable to low resource countries due to costs and lack of materials. Low resource areas could systematically use pulse oximeters to improve the quality of infant care. This would also reduce mortality rates for the conditions previously stated that can be prevented with monitoring by an affordable and simple device.

We have not updated our pediatric pulse oximeter competitors from last term. However, we performed further research on specific aspects during our prototyping process. Our first competitor, Lifebox, is a non-profit organization that supplies oximeters to low resource countries. Their oximeter is affordable and durable, which is crucial to our concept. It also has a battery life of up to 36 hours. One of the biggest challenges for oximeters in these areas are broken probes and the inability to replace them. We found a way to address this issue with our prototype. Additional setbacks for the Lifebox include slow readings and inaccuracies if the patient moves [7]. Alternatively, the PPO designed by Zacurate is the best-selling oximeter on Amazon.com (Appendix C.7). This device is highly rated with it's easy to use clip-on design for your finger. However, it recorded inaccurate readings for infants and people of color. It also consists of a display screen on the clip, adding unnecessary weight and bulk to the device making it less desirable for infants [8]. Another oximeter on the market that is worth mentioning is the Owlet Sock by Owlet. This design consists of a wearable sock containing a sensor, making it more suitable for infants. The Owlet Sock includes a Bluetooth option as an additional feature to display the device's data [9]. An app is used to send readings and alerts to parent's smartphones. Electricity is unreliable in low resource countries. The need to access a smartphone significantly decreases the Owlet's availability in these areas.

It's also significant to note the price gap between the Owlet Sock and other oximeters on the market, such as the Zacurate. The Owlet Sock retails at $399 whereas the Zacurate oximeter retails at an average of $20 per device. In hospital settings, a commonly used device is the Nellcor Adhesive Sensor (Appendix C.8). It's an adhesive monitor, resembling a band-aid. This design is suitable for fussy infants, while being versatile for sensor placement. However, the adhesive design raised questions about comfort on the skin, as well as sterility [10]. Its wired design allows for more accessibility in low resource areas.

This term we researched patents relative to our device and discussed two of them closely, a wearable pulse oximeter device and a pediatric sleep positioner [15][16]. The wearable pulse oximeter was used to help influence our design process for an attachment even though it's not directly used for pediatric patients. This patent (Figure 1) incorporates a pulse oximeter bracelet located on the distal end of the ulna bone [15]. The location seems advantageous as newborns do not have enough strength nor comprehension to take off the bracelet, thus keeping it secure on their body as shown in Figure 2.

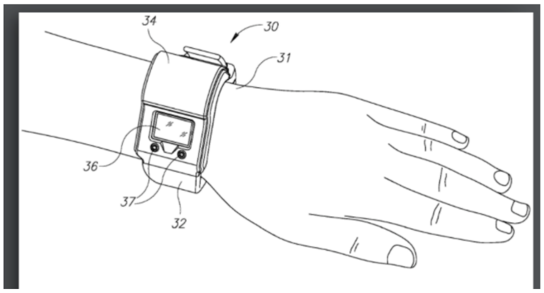


Figure 1. Design for wearable oximeter device from patent. This device is a bracelet fixed on the distal end of the ulna. It consists of two sensors to increase accuracy of oxygen saturation level readings.

We would like to implement this to keep the placement of the sensor fixed. Babies are known to fidget, so there is a concern for the sensor moving. This idea also implements two sensors for better transillumination of the blood perfusion in the body [15]. This device was designed to be transportable, due to prior designs limiting mobility or staying in a confined area while being monitored [15]. We incorporated aspects of the bracelet design, as a transportable device is desirable for our customer needs.

Problem Statement

Pediatric medical technology used to help monitor health issues for newborns is scarce in low-resource countries. Respiratory illnesses are common among newborns in these countries. Pulse oximetry is used to help monitor these illnesses but is not very attainable due to lack of transportation and electricity, along with the scarcity of medical resources. An affordable, practical pediatric pulse oximeter that provides accurate oxygen saturation level readings for all skin types would be beneficial for monitoring respiratory illnesses in these countries. This technology would enhance the quality of medical care thus reducing the infant mortality rate in these areas.

Device Customer Requirements

To analyze our customers' needs, we’ve spoken to doctors and a few parents and asked them what they are looking for in a pediatric pulse oximeter. When speaking with Dr. Monaco-Brown at Albany Med, she specified that an oximeter that is versatile on different body parts would be ideal as the doctors often switch the location of the attachment on the child in case one spot isn’t reading well.

We also want to make it easy for clinicians to navigate the device’s readings to understand their child’s oxygen saturation levels. This is vital since our research showed that one of the big challenges in low resource areas are untrained staff. For example, Sub-Saharan Africa has a huge population and disease burden. However, they have only 3% of the world's healthcare workers. This lack of workers makes hospitals more scarce, leaving most of the care to be done at clinics or even just at home, thus making a simple design that’s easy to read more desired.

Due to finding fragility of the probes being another main concern, we rated durability highly on our customer requirement [11]. In low resource areas, we want to limit waste as much as possible and increasing the durability of the attachment, sensors, and console will increase their lifespan while reducing cost. A few of the other desires they expressed for an oximeter include: ability to fit children of different sizes and ages, perform quick and accurate readings for all skin colors, secure and steady placement, can withstand a child pulling it, and is transportable. These customer requirements and some others can be viewed in Appendix A.

Device Functions

While researching more about the quality of medical care in low resource countries, we’ve aimed our product at clinics alone. The potential users narrowed down to clinicians, doctors, and the infant themselves. The updated QFD can be seen in the Appendix (Figure 16). After developing our product this term, the functional requirements have been changed. The challenge of unreliable electricity is addressed by an alternative power source. We've redefined its relationship with the customer's needs knowing its importance to the environment of the device. Aesthetic rating from the infant's perspective has been removed from our requirements. It has been replaced with ensuring no irritation or harm to the child. This is more important as past devices have been known to burn or harm the child. The relationship between this requirement and the customer needs proves it's significance towards our device.

Our device's main function is to measure and monitor oxygen saturation levels through multiple sub-functions. It's known that infants squirm and move which can cause irregular movements. Our device functions to increase available readings during movement. We've focused on the versatility of device placement by adding a specialized-cut. This function allows the device to attach at multiple locations to ensure readings. This addresses any issues the clinician might be experiencing with either limb, from a thumb sucker to a kicker or if one limb isn't reading well. Additional sub-functions and features for our designs can be seen in the Appendix B. The functions consist of: accepting the pediatric appendage, measuring oxygen saturation levels, the ability to monitor constantly, and increased durability of the device.

Securing the pediatric limb, by attaching in the device correctly, also helps secure the confidence of the sensor's readings. The device will accept the appendage size through a latch system for a range of multiple appendage sizes. This negates the concern of irregular readings caused by a loose connection or improper placement. This sub-function is designed to make our device adjustable to different size and aged infants. The most important task will be the ability to observe oxygen saturation levels.

Our device provides constant monitoring of oxygenated blood in the infant as the main function. This is crucial when treating infants with respiratory illnesses as deoxygenated blood is a dangerous threat. To provide this function, we've designed a console/control unit that doesn't have to rely on electricity. This console communicates with the clinician in three ways; a screen to view levels and a dual alert system. The screen shows a digital view of both sensor readings for the clinician to get an exact measurement. The dual alert system consists of a visual and audio alert. The visual alert is used the entire time the device is being applied. The audio alert is utilized only when levels are dangerous and assistance to the patient is recommended or needed. These features assure security and efficiency of the device and the patient. We want our device to be durable for the environment it's in and the patient.

Design Specifications

We took our customer requirements and the functions for our device into consideration when designing our functional decomposition (Appendix B). Since our market is aimed towards low resource settings, affordability is a main focus. Therefore, we've decided our device should not exceed $120. The Lifebox oximeter is $240-250. Due to limited time, it was more practical for us to achieve accuracy of readings during movement by focusing on the sensor's attachment to the body rather than the electrical components. We implemented two sensors in our device to ensure confidence and accuracy. This also allows for one to continue working if the other fails, therefore saving unnecessary panic. Our device keeps track of the accuracy using a confidence feature for each sensor, we aim for a confidence level above 95%. This feature enables doctors to check if the low readings are due to the sensor, rather than automatically assuming the infant is suffering from low oxygen level to prevent unnecessary treatment. According to this feature, doctors and clinicians can adjust the sensor if it's falling off or is displaced, they can also retake the reading. The sensors need to be directly touching the skin for the photosensors to communicate with it. However, to avoid irritation, we have our second device specification, the material encasing the sensors. The material must not harm the infant. Athletic tape can cause irritation if not applied properly. Thus, we've updated the material of our device from athletic tape to cotton fabric to guarantee comfort and safety for the child.

To increase durability, our device has a specification to withstand 2-4 N of pulling force, roughly the amount a child would produce. To increase the longevity of our device, it will be supported with extra protection, refer to QFD Appendix (Figure 16). We want these devices to be working effectively for a long period of time, ideally at least 9 years, as these countries have low resources and unreliable electricity. Our device currently receives power from the computer, when utilized in the future it would work on a 3.3V battery that lasts 24-36 hour.

Another main specification of our device was for it to work on the hand and foot. Our AMC doctor, Dr. Monaco-Brown, addressed the importance of this feature as sometimes infants have other devices hooked to them or some tests need to be obtained on their hands. Therefore, the device needs to be shifted to the foot to take alternative oxygen saturation readings. Our physician showed us images of infants in the NICU to help us get a better idea. A small premature baby weighs 1-5 pounds with a foot size as small as 1" - 2" and a hand size as small as 2" by 2.25" [14]. Therefore, the material should be able to fit two sensors within these dimensions. The attachment should wrap around the hand and the foot without slipping off. The device will accept the appendage size through its adjustable hooks and clasp that fit a multiple range of hand/foot sizes.

To ensure easy reading and to maximize space on the infant, we decided to design a separate display unit. This would decrease the weight of the attachment on the baby. It also allows the doctor to move the display around in the room to best utilize the small space they have. For an easy to understand control unit, we want to use LEDs, speaker sounds, and the LCD screen to display readings. The audio system uses a speaker to play an alert if the oxygen level is under 93. The recommended sound level for children is 82 decibels or less [12]. Hearing 89 decibels for under 90 minutes is considered safe for children, thus 82 would not harm the child [12]. We aim for the control unit to weigh 1-2 lbs so doctors and clinicians can hold it and position in different places.

Documentation of the Final Design

Originally, we had our product narrowed down to two different designs. The first being a sleep positioner that allowed for the readings to be taken, while keeping the baby on its back, to avoid the baby flipping over and suffocating. The second design combined current pulse oximeters that are on the market, the Owlet sock and the LifeBox. It took the inexpensive console component of the LifeBox and combined it with the attachment style of the Owlet. After conducting more research and consulting with our AMC Mentor, our design completely switched. Our final design consists of three main components, the butterfly attachment, the circuit, and the control unit. The attachment connects the sensors to either the infant's hand or foot. The circuit consists of the LED, LCD screen, speaker and sensors. The control unit surrounds the circuit to show the different components. The design contains two sensors to allow for more accuracy. The user will be able to see the oxygen saturation levels of both sensors, as well as the confidence, to have a better idea of what the level is. The attachment can be connected to either the hand or the foot. While on the hand, the sensors will be on the palm and the inner wrist. When connected to the foot, the sensors will be on the bottom of the foot and the ankle.

The first component, the butterfly attachment, was designed for more stability and mimics the shape of a butterfly style bandaid. This design allows for two points of closure around the infant, so that if one becomes unattached the other will stay on. Pockets were created on the attachment to slide the sensors into (Figure 2). The pocket design allows for the sensors to be taken in and out. With this design, the fabric attachment can be disposable and the sensors can be reused, lowering the cost of the device.

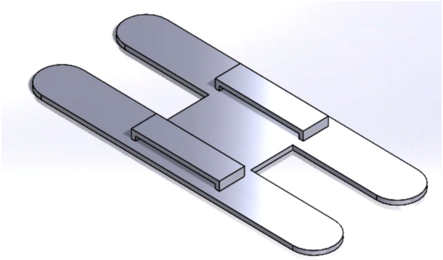


Figure 2. A Solidworks model of the butterfly style attachment.

The main component of our design, the circuit, controls the sensors, LED, LCD screen, and speaker. An Arduino board connects each aspect of the circuit, combined with a code to control the components. A wiring diagram for our overall circuit can be seen in Figure 3. The oxygen saturation levels were split into three sections, green, yellow, and red. When levels are normal, over 96%, the LED will be green and the LCD screen will display the level. When levels drop between 93 and 95, the LED will be yellow, the LCD screen will continue to display the level, and the speaker will play a tone. Dangerous levels below 93 will cause the LED to turn red and the speaker to play a different tone to alert the caretaker to take action. If the sensor falls off, the LED will stay red, the speaker will play the tone, and the LCD screen will display “Check Sensor.”

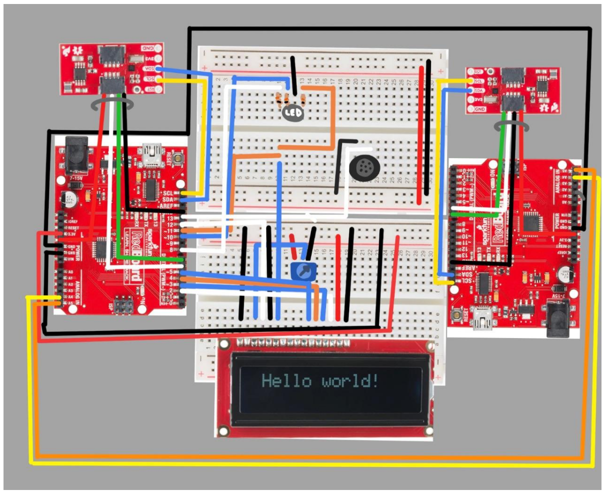


Figure 3. Wiring diagram for the entire circuit.

A console component will also be created to cover the circuit. The LED, LCD screen, and speaker will all be shown on this console so that the user can see each component (Figure 4). It will be made out of an inexpensive material and covered with the same fabric that the butterfly attachment will be made out of. This will protect the circuit and electronics to further the lifespan and durability of the device.

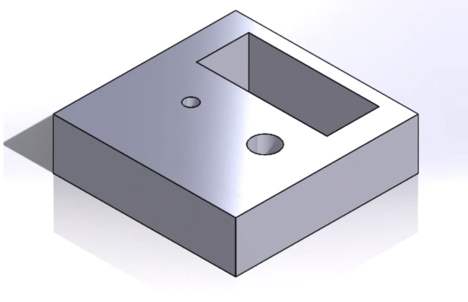


Figure 4. A Solidworks model of the control unit.

Final Prototype

Each of the three components of our design were prototyped. After trial and error of various materials for the butterfly fabric, we landed on a cotton fabric for our final design. Our original plan was to use KT tape, however after more consideration we felt that it would be too irritating on the infant's skin. Instead of using a gel adhesive, we added clasps to the end of each side so that the fabric could be adjustable and would not irritate the skin (Figure 5). The pocket design was used for inserting the sensors into the attachment.

Figure 5. Prototype of Attachment

Two different circuits were built, one for each sensor. Each circuit consisted of the LCD screen, LED, and speaker. Figure 6 shows the circuit for sensor 1 and Figure 7 shows the circuit for sensor 2. Each component functioned as we planned, with the red, yellow, and green meaning different levels.

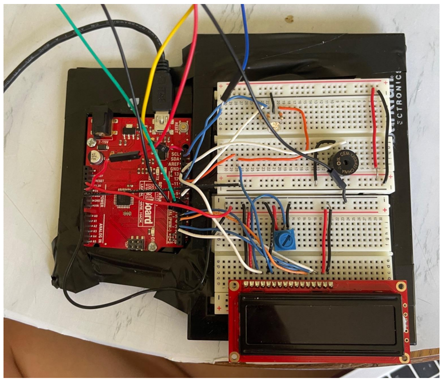


Figure 6. Circuit for Sensor 1.

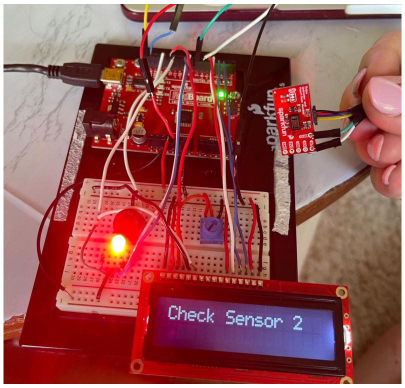


Figure 7. Circuit for Sensor 2.

For the control unit, we stuck with our original design. We wanted to make it out of a lightweight and affordable material, so we used cardboard and covered it with the same fabric as the attachment. The LCD screen, speaker, and LED, fit well into the unit (Figure 8). The purpose of this console was to enclose all of the circuitry while allowing for the components that need to be monitored to be seen.

Figure 8. Prototype of control unit.

Although the two boards were built separately, communication between the boards would need to happen. To show this, we built a separate circuit showing that the two boards can communicate (Figure 9). Ideally, this would be attached to the sensors.

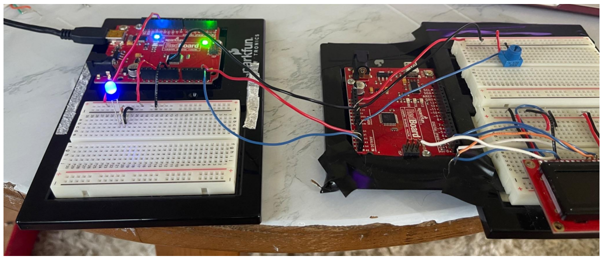


Figure 9. Communication between the two boards.

Design Validation

When designing a pulse oximeter to diagnose oxygen levels, it is critical to validate that the readings are accurate. The way that we achieved this was by testing how accurate the sensor readings were when doing different activities. First, we took measurements while sitting. The readings of each sensor were recorded and graphed (Figure 10). In this case, for a normal, healthy person the readings shouldn't change. In our test, both sensors 1 and 2 fluctuated a few times but remained within the healthy parameters.

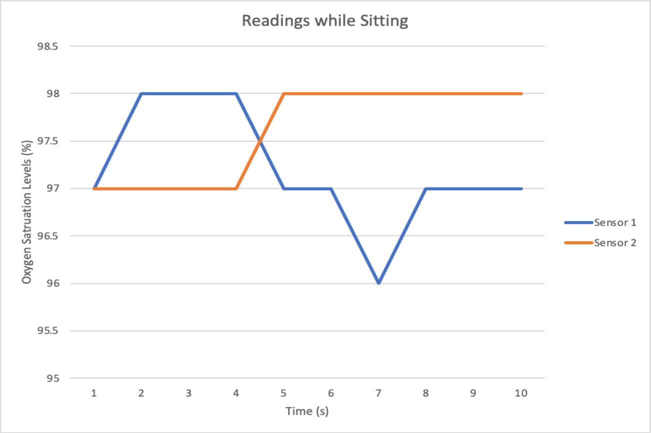


Figure 10. Test results of readings while sitting down.

We also tested the levels after 30 seconds of physical activity. In this case, the levels should be lower than that of sitting. Our sensors did produce values lower than the sitting readings (Figure 11). Like the other test, the sensors did fluctuate in values.

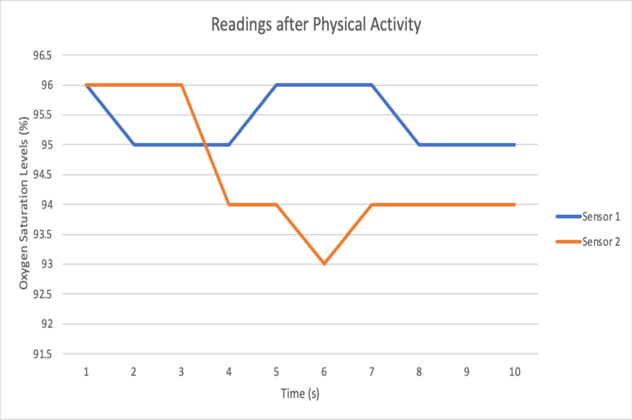


Figure 11. Test results of readings after 30 seconds of physical activity.

The last test conducted consisted of trying to take readings while walking, to see if movement affected its accuracy. When walking, the sensor could detect that there was pressure being placed on it, however it was not able to produce a blood oxygen level reading. The tests completed showed that the majority of the time when stationary, the sensors gave out accurate readings. Although they did fluctuate every once in a while. This was vital information to analyze as our sensors will be placed on infants who could potentially move and affect the readings, however, our tests were done on adult subjects so we would need to complete further testing on infants to see if they have the strength to move the sensors enough.

Ethical Considerations

We had to be careful while designing a device for infants since they have sensitive and weak bodies. Therefore, in every step of our design and research we had to ensure that it was ethically and medically suitable for infants. Due to that we had to adjust our design a few times. Initially we were focusing on SIDS, however after further research we found that the FDA doesn't approve of any device that claims to have treated SIDS or decrease the risk of it [18]. Additionally, the American Academy of Pediatricians warns parents and doctors from such devices [21]. Also, our initial sketches included a sleep positioner as a part of the overall design, we had to research what doctors say about that as well as refer back to the FDA. We ended up not going in that direction due to many concerns and the FDA's warnings about sleep positioners. We had to keep in mind the main recommendations for infants' cribs/ hospital beds. Another point where we had to ethically consider is the sport tape. Even though it was cheap and secured a good attachment, we had to think about it in terms of the baby's comfort and safety. Testing is a challenge in our project as we can just test on children , therefore we performed tests on a doll rather than an infant.

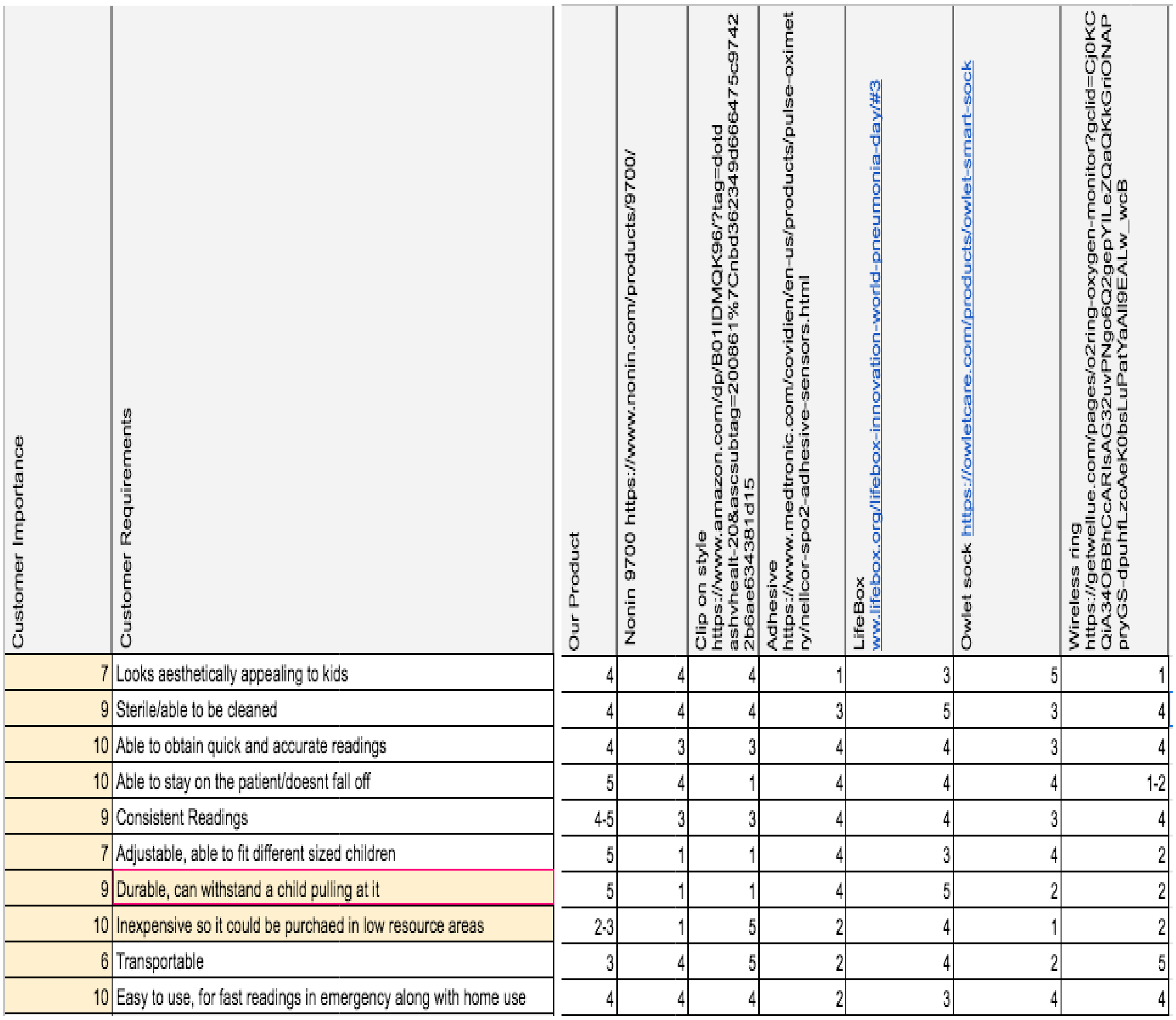
Anticipated Regulatory Pathway and/or Standards That Impact Design

The FDA considers pulse oximeters as Class 2 medical devices meaning it would need a 510(k) in order to be allowed on the market. This means the FDA needs to be "notified" 90 days before proposing to begin marketing a device, this allows the FDA to determine if it is new and requires a new proof of safety or if it is substantially equivalent to a preexisting device on the market. This 510(k) requires a standard fee of $10,566. With our device focusing on use in clinics and diagnosing medical illnesses, it is considered a prescription oximeter according to the FDA [17], this means that our oximeter would be required to undergo clinical testing to confirm its accuracy before being available on the market. The clinical studies evaluate the mean accuracy of the readings in comparison to the arterial blood gas saturation readings. The required mean accrauсy to be cleared by the FDA is within 2-3% of the arterial blood gas saturation. [17].

Conclusions and Future Work

It would be appropriate to perform ample testing on our design for infant wear and tear as well as measuring their overall comfort and safety while attached to the device. While our prototype is made up of feasible materials it is important to gather the proper supplies to make our device not only affordable but durable and sanitary. These resources would be considerably easy to clean and water resistant as well as resistant to electrical fires or overheating. These requirements would be to ensure the safety of the delicate infants. In order to evolve our design we would also consider modifying the extension of the sensor's wires in order to give the device greater flexibility. This refinement would elevate the functionality of our device for clinical use. With more research and development, we could upgrade our device to attach directly to monitors already available and in use in clinical settings. This would furthermore increase feasibility, affordability, and practicality. These accomplishments would aim to create a more ideal wearable device and increase our product's demand. By emphasizing these areas of focus we are better able to create a marketable product that is globally recognized and accessible. By doing so, we are able to effectively offer our device's service to areas of need, specifically targeting low-resource hospital settings. These are areas which have the greatest demand for medical devices and care with greater mortality rates compared to other areas. Greater development has shown to only increase our product's versatility and adaptability through refinement. Therefore it is inevitable that our prototype would reach greater marketable value through further collaboration. Ultimately, our final product would achieve each area highlighted by our problem statement and suit the desired needs of the appropriate clinical setting without failure.

Appendix A



Customer Importance	Customer Requirements	Our Product	Nonin 9700 https://www.nonin.com/products/9700/	Clip on style https://www.amazon.com/dp/B01IDMQK96/?tag=dotd ashvhealt-20&ascsubtag=200861%7Cnbd362349d66475c9742 2b6ae634381d15	Adhesive https://www.medtronic.com/covidien/en-us/products/pulse-oximet ry/nellcor-spo2-adhesive-sensors.html	LifeBox ww.lifebox.org/lifebox-innovation-world-pneumonia-day/#3	Owlet sock https://owletcare.com/products/owlet-smart-sock	Wireless ring https://getwellue.com/pages/o2ring-oxygen-monitor?gclid=Cj0KC QiA34OBBhCcARIsAG32uvPNgo6Q2gepYILeZQaQKkGriONAP pryGS-dpuhfLzcAeK0bsLuPatYaAlI9EALw_wcB
7	Looks aesthetically appealing to kids	4	4	4	1	3	5	1
9	Sterile/able to be cleaned	4	4	4	3	5	3	4
10	Able to obtain quick and accurate readings	4	3	3	4	4	3	4
10	Able to stay on the patient/doesnt fall off	5	4	1	4	4	4	1-2
9	Consistent Readings	4-5	3	3	4	4	3	4
7	Adjustable, able to fit different sized children	5	1	1	4	3	4	2
9	Durable, can withstand a child pulling at it	5	1	1	4	5	2	2
10	Inexpensive so it could be purchaed in low resource areas	2-3	1	5	2	4	1	2
6	Transportable	3	4	5	2	4	2	5
10	Easy to use, for fast readings in emergency along with home use	4	4	4	2	3	4	4

Figure 12. QFD

QFD customer requirements and different competitors evaluated and ranked according to these requirements. The Lifebox and Owlet sock oximeters are considered as our two main competitors. In addition, affordability and durability have high ranking since they are the two main challenges for pediatric pulse oximeters accessibility in low resource areas.

Appendix B

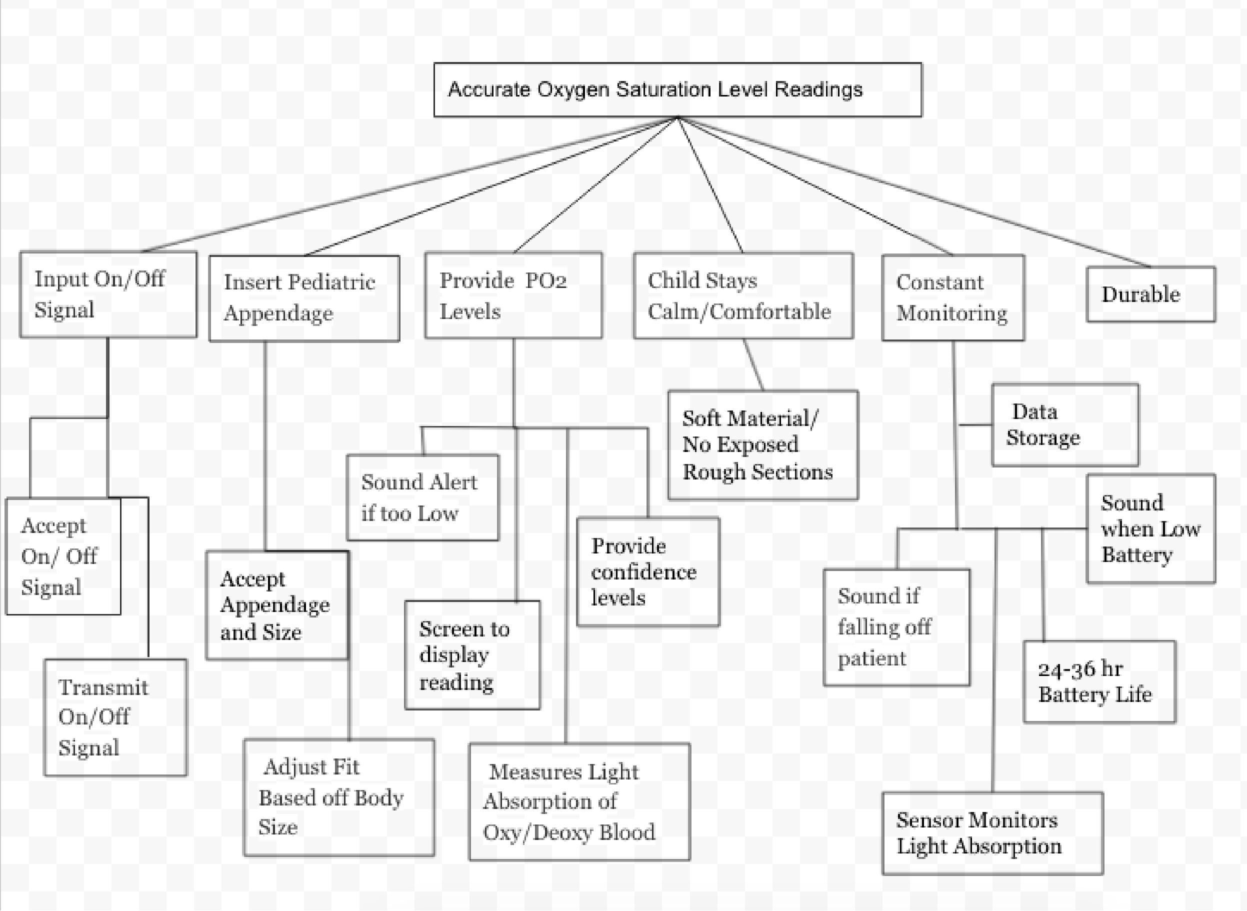


Figure 13. Functional Decomposition

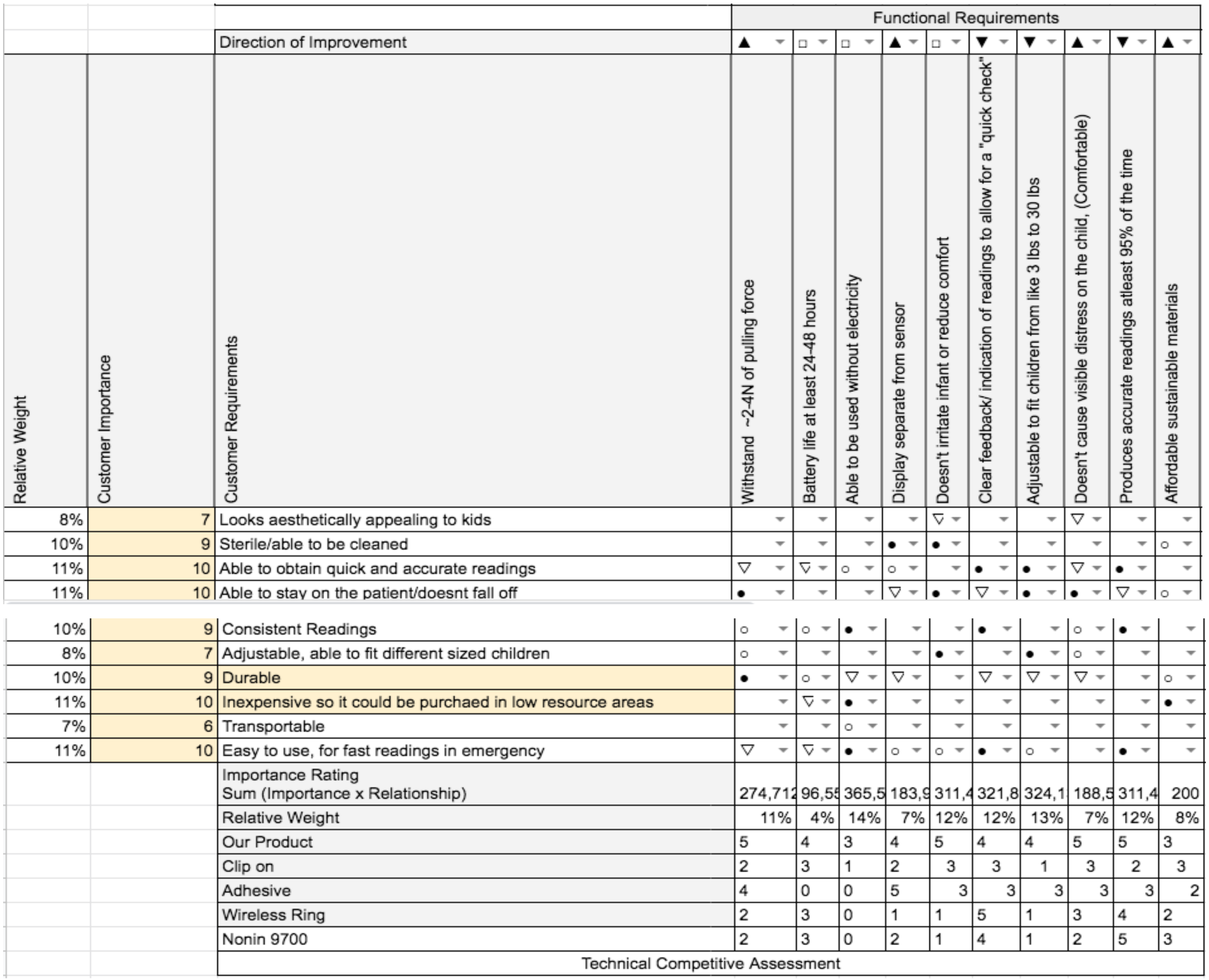
The functional decomposition consists of our device's main functions and the sub-functions needed to occur to satisfy our main function. Each sub-function has features added to optimize our devices usage.

Appendix C

Figure 14.
Zacurate clip-on style oximeter. High selling on amazon, but not suitable for infants. The oxygen saturation level is displayed on the screen.

Figure 15.
Nellcor adhesive sensor, its a band-aid style and its commonly used in hospital settings. It fits children of different ages but could be irritating to the skin.

Appendix D



			Functional Requirements									
		Direction of Improvement	▲	□	□	▲	□	▼	▼	▲	▼	▲
Relative Weight	Customer Importance	Customer Requirements	Withstand ~2-4N of pulling force	Battery life at least 24-48 hours	Able to be used without electricity	Display separate from sensor	Doesn't irritate infant or reduce comfort	Clear feedback/ indication of readings to allow for a "quick check"	Adjustable to fit children from like 3 lbs to 30 lbs	Doesn't cause visible distress on the child, (Comfortable)	Produces accurate readings atleast 95% of the time	Affordable sustainable materials
8%	7	Looks aesthetically appealing to kids					▽			▽		
10%	9	Sterile/able to be cleaned				●	●					○
11%	10	Able to obtain quick and accurate readings	▽	▽	○	○		●	●	▽	●	
11%	10	Able to stay on the patient/doesnt fall off	●			▽	●	▽	●	●	▽	○
10%	9	Consistent Readings	○	○	●			●		○	●	
8%	7	Adjustable, able to fit different sized children	○				●		●	○		
10%	9	Durable	●	○	▽	▽		▽	▽	▽		○
11%	10	Inexpensive so it could be purchaed in low resource areas		▽	●							●
7%	6	Transportable			○							
11%	10	Easy to use, for fast readings in emergency	▽	▽	●	○	○	●	○		●	
		Importance Rating Sum (Importance x Relationship)	274,712	96,55	365,5	183,9	311,4	321,8	324,1	188,5	311,4	200
		Relative Weight	11%	4%	14%	7%	12%	12%	13%	7%	12%	8%
		Our Product	5	4	3	4	5	4	4	5	5	3
		Clip on	2	3	1	2	3	3	1	3	2	3
		Adhesive	4	0	0	5	3	3	3	3	3	2
		Wireless Ring	2	3	0	1	1	5	1	3	4	2
		Nonin 9700	2	3	0	2	1	4	1	2	5	3
		Technical Competitive Assessment										

Figure 16. Updated Pediatric Pulse Oximeter QFD
List of functional requirements according to what's desired from the device to achieve, the main ones are highlighted. This figure also shows engineering specification targets rated according to their importance.

References

[1] “Child health,” *World Health Organization*. [Online]. Available: https://www.afro.who.int/health-topics/child-health. [Accessed: 25-Mar-2021].

[2] I. K. Ndu, “Sudden infant death syndrome: an unrecognized killer in developing countries,” *Pediatric health, medicine and therapeutics*, 03-Feb-2016. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683278/. [Accessed: 24-Mar-2021].

[3] J. Guo, M. Ma, C. Xiao, C. Zhang, J. Chen, H. Lin, Y. DU, and M. Liu, “Association of Air Pollution and Mortality of Acute Lower Respiratory Tract Infections in Shenyang, China: A Time Series Analysis Study,” *Iranian journal of public health*, Sep-2018. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6174054/. [Accessed: 24-Mar-2021].

[4] A.-A. Seidu, K. S. Dickson, B. O. Ahinkorah, H. Amu, E. K. M. Darteh, and A. Kumi-Kyereme, “Prevalence and determinants of Acute Lower Respiratory Infections among children under-five years in sub–Saharan Africa: Evidence from demographic and health surveys,” *SSM - Population Health*, 04-Jul-2019. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S2352827319300461. [Accessed: 24-Mar-2021].

[5] L. M. Niessen, A. ten Hove, H. Hilderink, M. Weber, K. Mulholland, and M. Ezzati, “Comparative impact assessment of child pneumonia interventions,” *Bulletin of the World Health Organization*. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/19565126/. [Accessed: 24-Mar-2021].

[6] C. King, N. Boyd, I. Walker, B. Zadutsa, A. H. Baqui, S. Ahmed, M. Islam, E. Kainja, B. Nambiar, I. Wilson, and E. D. McCollum, “Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical settings: a qualitative evaluation from Malawi and Bangladesh,” *BMJ Open*, 01-Jan-2018. [Online]. Available: https://bmjopen.bmj.com/content/8/1/e019177. [Accessed: 24-Mar-2021].

[7] “Lifebox, Oximetry Innovation and Paediatric Pneumonia.” *Lifebox*, 4 Dec. 2017, www.lifebox.org/lifebox-innovation-world-pneumonia-day/#3.

[8] Zacurate Digital Fingertip Pulse Oximeter for Chizacurate.com/products/digital-fingertip-pulse-oximeter-for-children.

[9] “Owlet Smart Sock.” *Owlet Baby Care US*, owletcare.com/products/owlet-smart-sock.

[10] *Cpapusa.com*, www.cpapusa.com/nellcor-oxicliq-pediatric-adhesive-disposable-sensor-10-50-kg-24-box.html.

[11] Herbert, Lara J., and Iain H. Wilson. “Pulse Oximetry in Low-Resource Settings.” *European Respiratory Society*, European Respiratory Society, 1 Dec. 2012, breathe.ersjournals.com/content/9/2/90.

[12] J. Blijlevens, C. Thurgood, P. Hekkert, L.-L. Chen, H. Leder, and T. W. Whitfield, “The Aesthetic Pleasure in Design Scale: The development of a scale to measure aesthetic pleasure for designed artifacts.,” *Psychology of Aesthetics, Creativity, and the Arts*, vol. 11, no. 1, pp. 86–98, 2017.

[13] “Research on Back Sleeping And SIDS,” Eunice Kennedy Shriver National Institute of Child Health and Human Development. [Online]. Available: https://safetosleep.nichd.nih.gov/research/science/backsleeping. [Accessed: 25-Mar-2021].

[14] “PREMATURE AND NEWBORN SIZE CHART.” *SIZE CHART*, www.touchinglittlelives.org/size.html.

[15] *Eisen, L., Fine, I. and Goldinov, L. (2012) Wearable Pulse Oximetry Device. US Patent Application No. 14/239578. - References - Scientific Research Publishing*, www.scirp.org/reference/referencespapers.aspx?referenceid=1715034.

[16] J. Lord, “Formable sleep positioner along with method for adjusting same,” 04-Sept-2008.“US6877176B2 - Infant Support System.” *Google Patents*, Google, patents.google.com/patent/US6877176B2/en.

[17] Center for Devices and Radiological Health, “Pulse Oximeter Accuracy and Limitations,” *U.S. Food and Drug Administration*. [Online]. Available: https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication. [Accessed: 08-Jun-2021].

[18] Center for Devices and Radiological Health. “Baby Products with SIDS Prevention Claims.” *U.S. Food and Drug Administration*, FDA, www.fda.gov/medical-devices/products-and-medical-procedures/baby-products-sids-prevention-claims.

[19] Commissioner, Office of the. “Do Not Use Infant Sleep Positioners Due to the Risk of Suffocation.” U.S. Food and Drug Administration, FDA, www.fda.gov/consumers/consumer-updates/do-not-use-infant-sleep-positioners-due-risk-

suffocation#:~:text=The%20U.S.%20Food%20and%20Drug,that%20can%20lead%20to%20death.

[20] "Critical congenital heart disease: MedlinePlus Genetics," *MedlinePlus*, 18-Aug-2020. [Online]. Available: https://medlineplus.gov/genetics/condition/critical-congenital-heart-disease/. [Accessed: 09-Jun-2021].

[21] Korioth, Trisha. "Health Alerts: Infant Sleep Positioners, Bouncer Seats, and More." American Academy of Pediatrics, 29 May 2021, www.aappublications.org/news/2017/10/17/HealthAlerts101717.