Designing a Mechanical Housing Component for Neonatal Pulse Oximetry

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Abstract

Current pulse oximeters do not adequately treat neonates as end users due to the unique design challenges they pose. This leads to inadequacies in treatments with pulse oximeters never being prescribed. This problem is magnified within third-world countries where oxygen supplementation is scarce. This capstone aims to create a mechanical housing for a pulse oximeter that would create a secure attachment to a neonate's finger. This was done through an iterative design process where design ideas were considered and then evaluated based on two decision criteria: adaptable towards any diameter size and would have a tight fit on a finger. The final design considerations were a one-sensor model and a zipper-based model that were modeled within Fusion 360 and printed in the Scholar Lab Makerspace at UVA. To consider durability, a stress analysis was conducted to identify areas where the device could break. To evaluate if the design would work for a neonate, an experiment was conducted where the design would be tested on different finger sizes and neonatal movement would be replicated with erratic movements. The Ziploc, which was a proxy for a zipper design had slight variations in positioning but was adaptable towards any diameter size. The ring design, the current pulse oximeter design for smaller fingers, did not adequately address differences in diameter size. Thus, our device addressed the design challenges that neonates pose. Future testing would involve improving the security of fit, conducting more tests with neonates, addressing the limitations of our project, addressing the cost analysis of our pulse oximeter, and integrating the circuit component into the mechanical component of the pulse oximeter.

Keywords: Neonates, Pulse Oximetry, Design, Fusion 360

Introduction

Clinical Problem

The majority of deaths occurring in children under 5 years occur mostly in developing countries. The primary causes of infant mortality in these countries are diarrhoeal disorders and acute respiratory infections (ARIs) [1]. Recent estimates show that the highest contributor to infant mortality rates is pneumonia, and accounts for 28-34% of deaths globally [2]. To assess the health of newborns during emergency admissions to hospitals, it is crucial to collect vital signs, including oxygen saturation and pulse rate. The pulse oximeter is an electronic device that measures the oxygen saturation (SpO2) in the red blood cells. SpO2 is determined by measuring the absorption of infrared light at a specific wavelength and is converted into a concentration value through Beer-Lambert's law. This can be done either via a reflectance model that conducts both transmission and receiving of signals on the same side; or a transmissive model, where two sensors are opposed with one transmitting light and the other receiving light [3]. Existing designs are usually placed on a patient's body part such as finger, palm, sole, toe or earlobe [4]. However, it has been recently estimated that pulse oximetry is unavailable in 51-70% of operating theaters in low-income countries [5], with the primary factor being its high cost. Additionally, neonatal pulse oximeters struggle to provide accurate readings due to infants' erratic movements and random motions. It has been shown that motion can have a negative impact on the signal quality of pulse oximetry and can lead to erroneous readings [6]. Furthermore, over the course of time, from 1 year to 3 years, the diameter of a neonatal finger increases drastically from 10 mm to 15 mm, as shown in Figure 1. Because of this, there is demand for pulse oximeters that account for this diameter constraint as opposed to creating a design specific to each diameter, as it would be very resource-intensive.

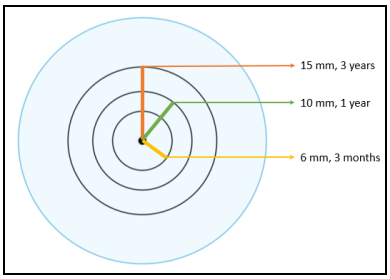


Figure 1: Change in neonatal diameter over time

Current State of Art

The first innovation shown on the left in Figure 2A is intended towards pediatric use taking into consideration that there are various types of finger sizes and allows for the extension of the device to encapsulate the patient's fingers. As per expertise from the clinical advisor, this design was intended for observation during recovery so it is always placed on the patient to have readings throughout recovery instead of a testing measurement. Thus, it won't fall off when the patient moves around. However, the price point is so high at $123.38 that it wouldn't be suitable for lower income countries [7]. Additionally, the material used in this device is less durable hence the device has a lower shelf life.

The pulse oximeter developed by LifeBox has a clip to the whole foot instead of a particular finger. While this approach is innovative and targets a different region of the body for the measurement, according to expert clinical opinion from the advisor, the device is not accurate enough and doesn't account for motion artifacts posed by infants too well.

Lastly, the standard neonatal pulse oximeter that is used in most hospitals, including UVA's medical center is the one designed by Masimo. This design is a lightweight adhesive sensor that can be attached to the foot, hand, thumb, toe, or finger. However some limitations with this device is that it is too cumbersome to apply to the neonate if a quick one-time check of vital signs is needed. It is more suitable for surgical scenarios, where constant monitoring is required. Another limitation is that this design is non-reusable and more vulnerable to contamination from the environment, hence lowering its shelf life. Furthermore the price point for this is at $338 for a box of 20 sensors, making it too costly for underserved settings [8].

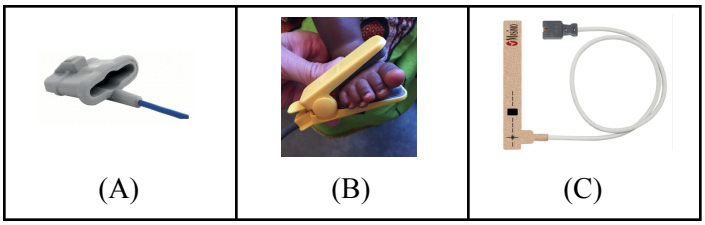


Figure 2: Prior art designs: (A) Pediatric Reusable Soft Sensor [7], (B) Lifebox oximeter [9], (C) Masimo oximeter [8]

Aims

Hence the goal of this project is to design a mechanical housing component for neonatal pulse oximetry sensors that accounts for the various constraints presented: the secureness and stability aspect to reduce influence of motion artifacts from infants; changing of diameter of neonates in first 5 years of life; high cost which makes pulse oximetry unaffordable in underserved countries.

The first aim is to develop a model of a mechanical component that can house a pulse oximetry sensor. This would be accomplished by researching patents to determine key constraints in prior art and identifying a body extremity/location of interest through literature review. Next, the dimensions of the sensors worked with would be measured and a CAD model of our component for chosen extremity would be created using online software tools. Finally, once a design is created, the prototype would be manufactured through 3D printing.

The second aim is to ensure a secure attachment mechanism and to account for varying diameter constraints of neonatal fingers. This would be done by investigating secure attachment methods such as clips, bracelets, straps or buttons and incorporate that into our CAD designs. Once the component is prototyped, a testing protocol would be developed that measures (i) secureness of fit through a quantitative metric and (ii) durability of prototype through force simulations.

The third aim of the project is to reduce the cost of pulse oximeters to be affordable within low income countries. This mandates a design criteria that the pulse oximeter could be used repeatedly and the final cost should be less than the $11.5 per patient over the lifecycle of the device [8], [9], [3]. To reduce the cost of the device, we will conduct durability testing, as mentioned above, to ensure it could be re-used over multiple patients, a cost analysis to identify significant costs, and cost effective supplies.

Materials/Methods

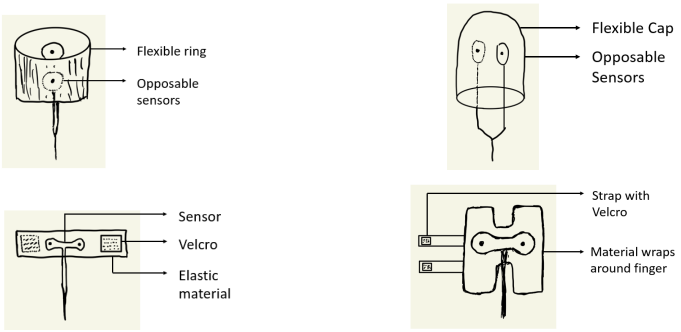


Figure 3: Initial drawings of pulse oximetry housing

Iterative Design Process

The process from initial sketches to final prototypes took a time period of 4 months, since it was crucial to get an understanding of what pulse oximeter designs could be pursued and hone in on the design ideas that would become our potential final prototypes by applying our design constraints based on the clinical needs that neonates had. Within the initial sketches, a survey of pulse oximeter designs was conducted as shown in Figure 3. This survey included designs similar to existing market designs and included other designs developed through brainstorming sessions or through modifications to current existing pulse oximeter designs. Some of the initial brainstorming process also took into consideration a warming element or kid friendly aesthetic, but this was discontinued with a focus on the mechanical housing for a pulse oximeter. Through this survey, it was realized that these pulse oximeter designs, similar to existing market designs, were not adequate for our purposes. Though, this exercise was helpful within the design process of how pulse oximeters could attach to fingers which did show up within our final prototypes.

Once an understanding of potential design ideas were present within the current market, then the design considerations neonates posed were considered more heavily. This was done first through the utilization of an electronic component that would only require only one sensor where the sender and receiver of the signal would be collocated at the same area. The electronic component used is from SparkFun and how it's configured within the housing unit is shown within Figure 4.

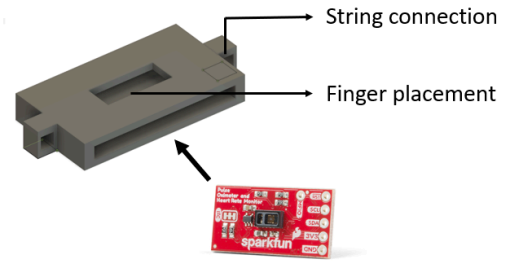


Figure 4: Prototype of one-sensor housing with Sparkfun sensor

This opened up the potential design ideas since the sender and receiver didn't have to be diametrically opposed. For example, now the pulse oximeter could just be a patch that would be applied to the top of the forehead. In our case, we still used the finger for pulse oximeter readings to create a standard between the different designs. Initial designs had a slot that the circuit from Sparkfun would slide into. Then, a cap was created to ensure that it wouldn't fall out during testing, advancing the stability of the design beyond creating a divot for the sensor and receiver hoping it would fit snugly within. Once that was created, it was understood that there would be wires that would have to attach to the circuit component, so another housing unit was created that looked significantly different from the initial design shown in Figure 5. After that the design stayed constant while tweaks were made to the sizing of the housing unit for string or other areas to create a snug fit for the circuit component.

The two sensor design was thought of much later within the design process. The main constraint within the two sensor design was how to take into consideration a variable diameter while keeping the opposing leads at the same location. For this to occur, there would be some part of the design that would act as a belt or where the sensor is located the material should be able to expand to accommodate any finger size. Initial thoughts considered using a rubber band material that would enlarge when force is applied but maintain an opposing force for equilibrium. Another thought was to create a reservoir for extra material that the sensors would be diametrically opposed to while the extra material would be tucked away

somewhere else so that there would be a secure fit established. Though, a final breakthrough was established that replicated a Ziploc.

Essentially, there would be a furrow and ridge that could be snapped into place, and the sensors would be lined up in the middle. This would allow for a variation in size where a bigger hole could be created through unsnapping parts of the furrow and ridge but would still provide a stable connection.

Final Prototypes

Final CAD iterations of the zipperlock and one sensor housing were created using Autodesk Fusion 360 software as shown in Figure 5A and B respectively. Each iteration was printed using polylactic acid (PLA) in the UVA's Maker Space found within Shannon Library.

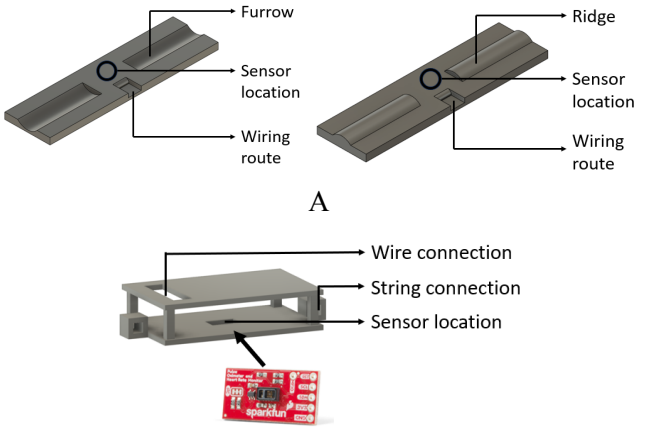


Figure 5: CAD designs of final prototypes. A. two sensor zipperlock design with furrow and ridge components. B. one-sensor housing component with sparkfun sensor

Proposed Testing

Finite Element Analysis (FEA) was proposed as a method to test the durability of the final prototypes developed. A stress-strain study would be conducted where a force of 0.75 N, which simulates a force exerted by a neonatal finger, was applied on the regions of the prototype in contact with the finger. For the zipperlock design the force would be applied in the center of the furrow and ridge components acting perpendicularly. This is because the finger would be sandwiched hence creating an applied force on one component and a reaction force acting on the other. A constraint was set to be on the sides of the zipperlock design because that region would be untouched and fixed for the most part. Likewise for the one-sensor design, a 0.75 N force was applied vertically upwards at the bottom region of the housing, because this is where the finger would be in contact with the sensor. After the simulations for each prototype are complete, the major stress and strain points would be evaluated and observed so that those areas of the design can be further iterated on.

To determine if there was a secure attachment, neonatal movement would have to be replicated and the scope of what a secure attachment is would have to be defined. For our purposes, a secure attachment would indicate a lack of deviation from the initial positioning of the device. A deviation could occur within two directions, the horizontal and vertical direction. A horizontal direction would indicate a rotation of the pulse oximeter along the finger as shown in Figure 6. Whereas, vertical deviation would indicate the pulse oximeter traveled up or down the length of the fingers as shown in Figure 6.

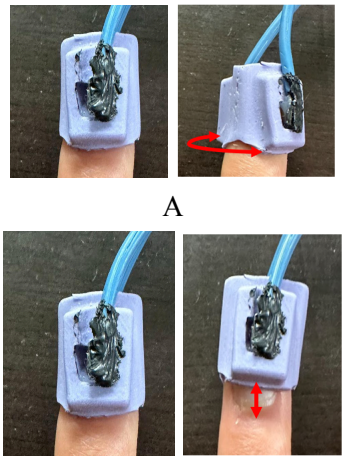


Figure 6: Secureness testing - visualization of position deviation (marked in red). A. Horizontal displacement (rotation along finger) B. Vertical displacement (movement up or down)

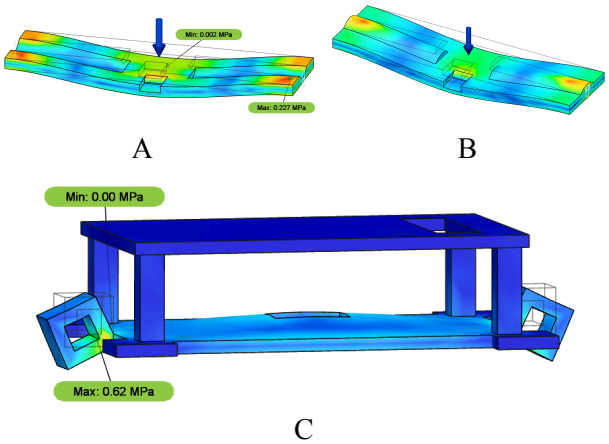
A ziploc was used as a proxy for the zipper design during testing since the zipper design couldn't snap together due to the 3d printed material used. This was an assumption made that the ziploc would work in a similar fashion to the

zipper design. The ring design was the previous minimum viable product that Dr.Mori used within his clinic and this would be the comparable standard. The ring design is shown within Figure 6. The one sensor model was not tested, since the housing unit+the sensor wasn't stable due to three reasons: the flat surface of the housing unit could not sit properly on the finger, the size was still bulky for the finger, and the sensor didn't have a snug fit within the housing unit.

For testing protocol, the zipper and ring design were both attached to the finger. Once a secure fit was established, three lines were drawn using a marker. One line was at the top of the design from an eagle perspective facing the finger to be used later to indicate any horizontal movement. Two other lines were placed on the finger above and below where the design was attached on a vertical dimension to indicate any vertical movement. Once the lines were established, then the finger was moved in an erratic fashion to mimicate the movement of a neonate while making sure that the movement wasn't too fast or had sudden change in movements. After 15 seconds of erratic movement that was assumed to emulate a neonatal movement, the horizontal deviation and vertical deviation was measured using a ruler and a protractor.

Results

FEA Simulations



A B C

Figure 7: FEA stress simulation results. A: Furrow component for zipperlock design, B: Ridge component, C: One-sensor housing

The stress design revealed for both the one sensor and two sensor design that the greatest stress would occur at attachment points and also where the sensor was located as shown in Figure 7A, B, C. It was interesting to see that those results were observed uniformly between the sensor designs and would prompt future work into checking if that is observed among other designs.

The two-sensor design had the greatest stresses at the ends of the connection points between the furrow and the ridge. From a physics perspective, this outcome is validated, since if a stress was applied at the middle, the ends would experience greater levels of stress. Since the stress simulation was not conducted with both of the pieces being connected, if the pieces were connected, then maybe the stress would be more centralized at the place where force is applied. This would be included within considerations of future work.

For the one sensor design, the final use case was a close replication to the forces applied within the FEA simulation. The greatest application of force would be within the boxes included in the housing component where the string would be looped through. And with that being the site of the greatest force, the greatest stresses were also observed at that location at the hinge between the box and the other housing component. This information would be very helpful in determining how to ensure that the box that has a string looped through,which is how the sensor attaches to the finger, would not snap easily. There was also a greater amount of stress located at the sensor. The force application downwards on the housing component for the string potentially created an opposing force upwards on the bottom of the device with it being fixed that led to a bulging at the sensor. This could potentially create issues within the functioning of the device, since the sensor wouldn't be flush with the skin causing issues within the measurements.

Secureness Testing

Trial	Horizontal	Vertical
Pinky Finger		
1	2 degrees	2 mm
2	6 degrees	.5 mm
3	4 degrees	1 mm
Middle Finger		
1	0 degrees	0 mm
2	2 degrees	0 mm
3	2 degrees	0 mm

A

Trial	Horizontal	Vertical
Pinky Finger		
1	0 degrees	0 mm
2	0 degrees	0 mm
3	0 degrees	0 mm
Middle Finger*		
1	-	-
2	-	-
3	-	-

B

Table 1: Measurements of secureness metrics (deviation) for A: zipperlock design and B: existing ring design. *ring design could not fit on middle finger

For the secureness of fit tests, the data did reveal some trends, but some statistical tests would have to be run to ensure the trends were significant. That would require more testing, which would be conducted within future work with repeated trials with neonates after getting a fully functional working prototype and IRB approval. Though, based on the data that was collected, there were some trends. As the finger diameter increased shown by the difference between the middle and pinky finger data, there was less variation as shown in Table 1. Both did not show a significant difference in variation that would affect the pulse oximeter readings. However, that could not be evaluated since only the mechanical part of the pulse oximeter was created within this project. When a fully functional pulse oximeter is created, the deviations in positioning could be evaluated to determine if it has a significant effect on pulse oximeter readings.

The ring design had no deviations in positioning for either the horizontal rotation or vertical movement. Though, this only applied to the pinky finger. When trials were run with the middle finger, the ring design was able to be placed on the finger. But, during the duration of erratic movements, the ring fell off. This serves as a really good illustration of how the unique design challenges neonates pose, the erratic movements and change in diameter, would not work for a design that normally works perfectly.

Discussion

Impact

Two new pulse oximeter designs were created that widened the possibilities of existing pulse oximeter designs. As seen within the results, there were slight deviations with the zipper based design with a Ziploc as proxy. It is true that a Ziploc could work better than the zipper based design that we came up with based on the inclusion of a sensor and other considerations, but that is the standard that is being aimed for. And within this type of design, it can be adaptable towards any diameter which is a strength that currently other designs such as the ring design doesn't address. The stress analysis also revealed weak points within the design which can be used for further development of the device. Within this project, the unique design challenges that neonates pose was adequately addressed. There were slight deviations in the positioning of the design indicating a secure attachment with movement of the finger, and it was adaptable towards any finger size. This advancement would hopefully reduce the prevalence of a lack of diagnosis with pulse oximeters due to the inaccuracy in readings with the device advancing the treatment for neonates by modifying the pulse oximeter, a device that was not designed taking into neonates as potential end users, to address design challenges that neonates pose. This would hopefully advance the treatment of neonates within lower income countries by creating a pulse oximeter that can be adequately used for diagnosis.

Limitations

Within the scope of the project there were various limitations that limited what could have been accomplished. These limitations were associated with the material, neonatal testing, and delays in testing.

Material

a. ***One sensor model***
   The material used for the one sensor model was able to create a housing component that would encase the SparkFun pulse oximeter. However, it was not a secure fit even with variations in the spacing for the sensor, height of the device, and other measurements. Thus, another material that would have been more flexible/malleable could have created a better snap for the sparkfun pulse oximeter by creating an encasing that would have been better able to wrap around the pulse oximeter.
b. ***Two sensor model***
   For the two sensor model, there was a problem with being able to make the furrow and ridge of the plastic snap together. This could have been due to issues with the measurements used for the

furrow and ridge, but at the same time, due to the rigidity of PLA, there wouldn't have been a connection that could have been established like a Ziploc does. Future considerations of different materials such as thermoplastic urethane (TPU) and silicone might be considered.

Neonatal Testing

During testing, there was an attempt to replicate neonatal movement. However, the testing was conducted on an adult finger and it still did not consider neonates rubbing the pulse oximeter on other parts of their body or attempts at removal. To further validate if the designs would work, conducting testing on neonates and running statistical tests would establish if the new designs are an improvement on previous existing designs.

Delay in Testing

There were issues that arose during the scope of the project with delays in acquiring the SparkFun pulse oximeter, which set our project back two-three weeks. Due to the setback, the testing procedure occurred later resulting in a rushed testing period that attempted to get some data to work with. If there was extra time given, then better testing procedures could have taken place to test on multiple people with their own definitions of erratic movements, more data could have been populated, and statistical tests could have been conducted with more data being present.

Next Steps

Some of our next steps would include addressing the limitations within our project. Primarily, we would like to experiment with different types of materials and design processes to create designs that are more flexible and durable. In addition, testing would happen with neonates to validate our design for the intended end user.

Another next step would be addressing the third aim that addresses the cost component. Accurate diagnosis with a pulse oximeter is magnified within developing countries since oxygen supplementation is a scarce resource. Thus, to ensure our pulse oximeter is used within the implementation of proper administration of oxygen to patients that need it, it also has to be affordable within lower income countries. Thus, once a final design has been validated through testing, we would also want to run a cost analysis and examine the production methods to ensure that our device would be affordable for patients within lower income countries. Part of our testing included durability with the FEA analysis, since if the device broke during testing or transportation, a significant cost would be the transportation fees. Thus, part of the FEA analysis was to ensure the device would be intended for multiple uses to reduce the lifetime cost of the device, and this would be further expanded upon with other durability testing that would expand upon the simulations run within Fusion 360.

The final step in our project would be integrating the circuit component of the pulse oximeter within the mechanical component that was the main focus within this capstone paper. This would include modifications of the sensor and the circuit component within the one sensor design to determine if the sensor could occupy a smaller surface area. In addition, by including the circuit component, we would be able to see if there are other fluctuations that would occur during neonatal movement that weren't considered within the secure attachment fit. An assumption within our project was to equate a secure attachment with an accurate reading, however that might not be the case or the variables used to determine a secure attachment weren't all encompassing. By including the circuit component within the final design, we would be able to validate our final design and create a fully functional product.

End matter

Author Contribution and Notes

Jayeesh designed and 3D printed the one sensor housing component; envisioned the idea of the zipperlock. Anirudh created the initial sketches; CAD designed and 3D printed the final zipperlock design.

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References

[1] Z. A. Bhutta, "Dealing with childhood pneumonia in developing countries: how can we make a difference?," *Arch. Dis. Child.*, vol. 92, no. 4, pp. 286–288, Apr. 2007, doi: 10.1136/adc.2006.111849.

[2] T. Wardlaw, P. Salama, E. W. Johansson, and E. Mason, "Pneumonia: the leading killer of children," *Lancet Lond. Engl.*, vol. 368, no. 9541, pp. 1048–1050, Sep. 2006, doi: 10.1016/S0140-6736(06)69334-3.

[3] H. Lee, H. Ko, and J. Lee, "Reflectance pulse oximetry: Practical issues and limitations," *ICT Express*, vol. 2, no. 4, pp. 195–198, Dec. 2016, doi: 10.1016/j.icte.2016.10.004.

[4] J. Das, A. Aggarwal, and N. K. Aggarwal, “Pulse oximeter accuracy and precision at five different sensor locations in infants and children with cyanotic heart disease,” *Indian J. Anaesth.*, vol. 54, no. 6, pp. 531–534, 2010, doi: 10.4103/0019-5049.72642.

[5] S. L. Burn, P. J. Chilton, A. A. Gawande, and R. J. Lilford, “Peri-operative pulse oximetry in low-income countries: a cost–effectiveness analysis,” *Bull. World Health Organ.*, vol. 92, no. 12, pp. 858–867, Dec. 2014, doi: 10.2471/BLT.14.137315.

[6] A. Dormishian, A. Schott, A. C. Aguilar, E. Bancalari, and N. Claure, “Pulse Oximetry Reliability for Detection of Hypoxemia under Motion in Extremely Premature Infants,” *Pediatr. Res.*, vol. 93, no. 1, pp. 118–124, Jan. 2023, doi: 10.1038/s41390-022-02258-7.

[7] “MAXTEC, Oximeter Systems and Modules, Pediatric Reusable Soft Sensor - 33JT89|R123P23-002 - Grainger.” Accessed: Nov. 07, 2023. [Online]. Available: https://www.grainger.com/product/33JT89?gucid=N:N:PS:Paid:GGL:CSM-2295:4P7A1P:20501231&gad_source=1&gclid=CjwKCAiA3aeqBhBzEiwAxFiOBohgm0EzMXzmtfohp5_zj8TyHCrwFqTuPHMJrf2NGteguQJtLtunxhoCC_EQAvD_BwE&gclsrc=aw.ds

[8] “Masimo LNCS Neo Neonatal SpO2 Adhesive Sensor 18 in | AED.US.” Accessed: Nov. 07, 2023. [Online]. Available: https://www.aed.us/masimo-lncs-neo-neonatal-spo2-adhesive-sensor?&utm_id=17816802395&gad_source=1&gclid=CjwKCAiA3aeqBhBzEiwAxFiOBosR9Bpljap9fEyXy6sbApomBepUVpYAQ7j0JRsMFfUXQMe6NRLayBoCJvQQAvD_BwE

[9] “Pulse Oximetry use and Pneumonia,” Lifebox. Accessed: Nov. 07, 2023. [Online]. Available: https://www.lifebox.org/our-work/pulse-oximetry/pneumonia/