



DEPARTMENT OF  
**Biomedical Engineering**  
UNIVERSITY OF WISCONSIN-MADISON

# NEONATAL 22-23-WEEK PREMATURE INFANT SIMULATION MANNEQUIN

BME 200/300 - Preliminary Report

10/12/2022

**Client:** Dr. Timothy Elgin

**Advisor:** Dr. Melissa Skala

## **Team Members:**

Tanishka Sheth	300	Team Leader
Sophia Finn	300	Team Leader
Loukia Agoudemos	300	Communicator
Lael Warren	200	BPAG
Claire Kramar	200	BWIG
Saivarshini Rishi	200	BSAC

## Abstract

Neonatology is an exciting and developing field. Studies and developments based on the various phases of gestation are mitigating complications surrounding birth. This project focuses specifically on 22-23-week neonates. These infants are considered extremely premature and resuscitation is very rarely performed. As the field has developed, it has become possible to resuscitate neonates born this premature. These neonates are rare, and thus medical professionals often have minimal experience with these infants. This creates a demand for medical simulation mannequins that accurately and reliably represent neonates born at this stage of gestation. There are currently no neonatal mannequins for infants born between 22-23 weeks, the earliest model represents a neonate born at 25 weeks. The team has been tasked with creating a neonatal simulation mannequin that includes three critical components. This includes IV access, realistic anatomical aspects that allow for proper intubation, and central umbilical line placement. The team's current solution aims to expand on previous work. The main goals for this semester are to include limbs for IV access, a realistic chest cavity, to allow for the mannequin to be intubated, and to improve how realistic the skin texture is. To ensure the group delivers a satisfactory device, testing will be conducted on mechanical and skin components, and client evaluation will occur many times over the fabrication timeline. With the team's efforts, a neonatal mannequin that accurately models a 22-23 week premature infant will be designed to save lives of at-risk preterm infants and send more home with their families.

## Table of Contents

<b>Abstract</b>	<b>2</b>
<b>Introduction</b>	<b>4</b>
Motivation	4
Existing Devices and Current Methods	4
Problem Statement	5
<b>Background</b>	<b>5</b>
Relevant Biology and Physiology	5
Client Information	6
Design Specifications	6
<b>Preliminary Designs</b>	<b>6</b>
Model with IV Insertion & LED Resuscitation Component	7
Realistic Chest Cavity Model With Intubation	8
Model With Fluid Pockets	9
<b>Preliminary Design Evaluation</b>	<b>10</b>
Design Matrix	10
Proposed Final Design	11
<b>Fabrication/Development Process</b>	<b>12</b>
Materials	12
Methods	12
Testing	12
<b>Results</b>	<b>13</b>
<b>Discussion</b>	<b>13</b>
<b>Conclusions</b>	<b>14</b>
<b>References</b>	<b>16</b>
<b>Appendix</b>	<b>17</b>
Product Design Specification (PDS)	17
Expenses and Purchases	19
Testing Protocols	19

# I. Introduction

## Motivation

The broad goal of the project is to send more families home with their babies, specifically with the babies that are born extremely premature. Infants that are brought home when born extremely premature are unlikely miracles [1]. An extremely premature infant is defined as one who is born before 28 weeks of gestation [2]. At 25 weeks gestational age, the survival rate is around 59% - 86%. At 23 weeks, the survival rate ranges to 31% - 78%. The survival rate for an infant born at 23 weeks of gestation is 1% - 64%, and the survival rate of infants born at 22 weeks drops to less than 10% [2]. This project focuses on infants born at 22-23 week of gestation, who have a relatively low chance of survival. Currently, although it is a hard ethical decision often varying from case to case and parent to parent, doctors are advised not to attempt resuscitation before 25 weeks [2]. Even if the infant manages to survive, the risk of permanent disability is rather high for infants born before 25 weeks gestational age [2]. Further, due to the rarity of extremely premature babies, doctors often do not have experience handling and resuscitating infants at 22-23 week gestational age. If a simulation mannequin with all necessary components for resuscitation techniques, coupled with realistic skin texture existed, doctors could practice on mannequin so that when a real, high intensity premature delivery occurs, they would be well-versed in resuscitating a 22-23 week neonatal infant. With the introduction of a cost-effective and realistic simulation mannequin, extremely premature infants can have a higher rate of survival due to an improved training experience for doctors worldwide.

## Existing Devices and Current Methods

There are a couple of infant mannequins on the market, but none that accurately simulate a 22-23 week premature infant. There are a couple of neonatal infant mannequins on the market but none that fully satisfy the client's desires. Trucorp has a TruBaby X mannequin that simulates a 5 month old infant. TruBaby X has a chest that rises and falls with proper intubation, full chest recoil when performing CPR, multiple insertion points and fluid pockets beneath insertion points to simulate real bodily fluids [3]. Practicing resuscitation techniques on TruBaby X would be ineffective for doctors trying to gain experience resuscitating extremely premature babies due to the larger size of the 5 month infant mannequin. The second competing design is Universal Medical's C.H.A.R.L.I.E, which simulates an infant at birth. C.H.A.R.L.I.E. stands for the first letter of each of its most notable features. The 'C' stands

for compressions and cardiac, the 'H' stands for heat compatible, the 'A' stands for airway and arterial access via the umbilicus, the 'R' means resuscitation, 'L' means laryngeal mask capable for oxygen use or PPV, the 'I' represents intravenous, intraosseous, and intubation, and the 'E' stands for ECG [4].

Although C.H.A.R.L.I.E. simulates an infant at birth, the size is still much bigger than a 22-23 week premature infant. The final competing design, is Laerdal's Premature Anne Mannequin, which is most similar to this semester's project. This design is a 25-week premature baby that can be intubated through the nose and mouth, includes a chest cavity that rises and falls, umbilical cord access, and multiple locations for IV insertions [5]. At just 2-3 weeks away from the team's desired infant mannequin, Premature Anne is still significantly bigger than a 22-23 week premature baby. Further, the skin does not accurately represent the thin, gelatinous skin of an infant at 22-23 week gestational age.

## Problem Statement

There are currently no 22-23 week neonatal simulation mannequins on the market, though it is vital for medical professionals to practice the skills needed to resuscitate an infant at this age. As a result, it is critical to develop a simulation for medical personnel to practice their skills and ease the learning curve to learn in an environment that is less chaotic and high stakes than the first real event. This simulation mannequin must be able to be intubated, support central umbilical line placement, and include IV access. Including a chest cavity and rib structure that allows for additional training in thoracentesis and pericardiocentesis would be ideal.

## II. Background

### Relevant Biology and Physiology

22-23 week premature infants are approximately 1 foot long and weigh between 0.9-1.1 pounds on average. Due to their small size, doctors often do not attempt resuscitation. 11% of births are preterm, yet are the leading cause of mortality in industrialized countries, accounting for 60-80% of deaths. The more premature the infant is, the higher risk for pulmonary abnormalities and infections. Babies born at 22-23 weeks of prematurity are in the canalicular stage of lung development, which is between 23-26 weeks. In this stage is the first big step in being able to complete gas exchange, however the ability to complete the gas exchange circuit does not complete until between 24-26 weeks, meaning infants born at 22-23 weeks are not able to properly breathe on their own. The conducting airways and terminal bronchioles are formed in this stage, which lays the basis for gas exchange. However, neonates born in

this stage are equipped with poor lung elasticity, which reduces the functional residual capacity (FRC) of the lungs. This decreases the lung volume and increases the desaturation of the blood. One similarity that preterm infants have with term infants is their anatomical structure, while scaled down, most preterm infants share the same anatomical features and dimensional ratios. For example, the thoracic cavity, while different from an adult's thoracic cavity where there are distinguishable ribs, an infant has a more cone-like thoracic structure [6]. The chest cavity of 22-23 week premature infants is similar to that of a full term infant, but just much smaller. In addition, they also have gelatinous, sticky skin that tears very easily [7]. Meaning that when life saving operations are performed, the skin is often damaged or torn in the process.

## Client Information

The client, Dr. Timothy Elgin is a neonatal physician affiliated with the UW department of pediatrics, who is passionate about improving the education surrounding resuscitation of neonates born extremely premature. He requires the team to fabricate a prototype model that satisfies the needs of medical professionals training to develop proper resuscitation practices.

## Design Specifications

The customer base for this product is medical schools, and training hospitals that wish to educate their students on the intubation of premature neonatal infants. As it will be used for training, it would be preferable if the mannequin is easy to handle, but maintains accurate difficulty when demonstrating resuscitation in premature infants born at 22-23 weeks of gestation. Due to this, the client's requirements included having the ability to put a synthetic breathing tube (2.00 -2.50 mm diameter) in the mouth of the mannequin, to attach a synthetic umbilical cord, and practice vital signs. Additionally the base had to be pressure resistant, and needed expandable lungs to replicate breathing. Some additional design requirements were a shelf life of 3-5 years, the mannequin should be less than 30.5 centimeters, and a weight of 400-500 grams (refer to PDS). The client also requested that the skin be made more lifelike, as a premature infant's skin is more malleable than a full-term infant or an adult.

## III. Preliminary Designs

## Model with IV Insertion & LED Resuscitation Component

This design for a 22-23 week neonatal mannequin features IV insertion capabilities and electronic resuscitation features, making this model a top-of-the-line resuscitation-training device that is both durable and cost-effective for educational use.

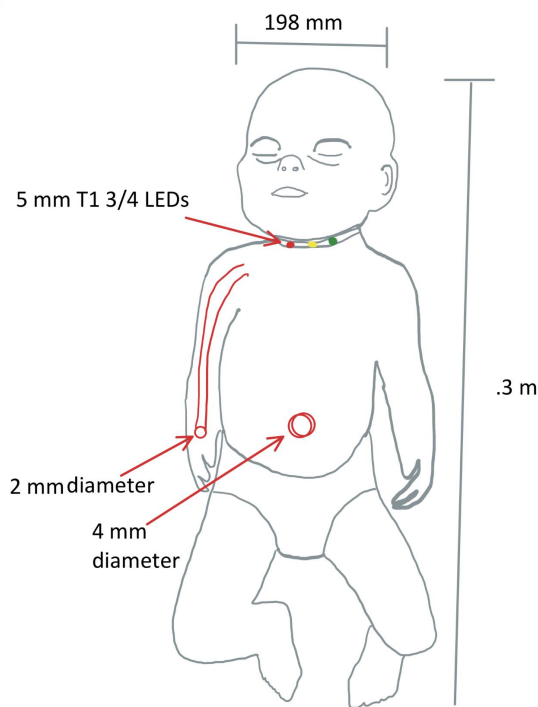


Figure 1: Model with IV Insertion & LED Resuscitation Component

This design features an LED and pressure sensor circuit, connected to the chest cavity, detects proper and improper resuscitation technique via Arduino software [8]. After the sensor picks up on the pressure applied and the Arduino categorizes the resuscitation as proper, approaching improper, or improper, an LED is lit with its respective category. Green shows proper technique; yellow indicates potentially improper technique, and red indicates improper technique. This allows for direct feedback for those training on the device to practice their resuscitation strategies and potentially save more premature neonatal infant lives.

The durability aspect comes from the materials that have a high elastic modulus, and will not wear as easily as more brittle materials. The IV line will be a small tube of plastic that will allow for multiple reinsertions of 2 mm IV line. Additionally, an umbilical line hole will be included for similar umbilical cord insertion. Finally, the skin would be made out of silicone, which, as an elastomeric polymer, can withstand more extensive use in comparison to more gelatinous polymers.

## Realistic Chest Cavity Model With Intubation

This neonatal model includes many physical features, including realistic limbs, chest cavity, and multiple IV insertion points to make the model as realistic to a 22-23 week neonatal as possible, given the design team's time constraint.

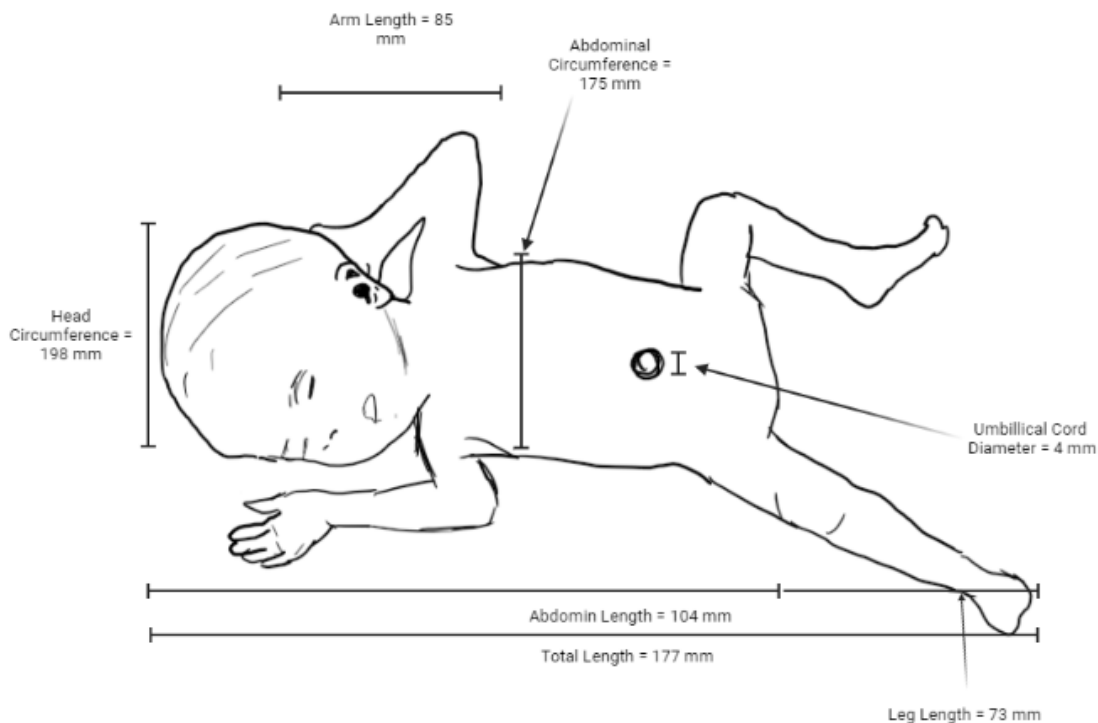


Figure 2: Realistic Chest Cavity with Intubation Model

This mannequin features a composite of polymers for the skin to make the mannequin's skin model as accurate as possible to premature infant skin. The inner layers of the skin model will be made of a gelatinous polymer such as a hydrogel made out of gelatine, agar, or polyvinyl alcohol. The outside of the gelatinous polymer will be sealed with an elastomer—such as silicone or polyurethane—that allows for the hydrogel to be more durable, stretchable, skin-like, and prevents evaporation of the water used to make the gelatinous polymer. This mannequin will also have airbrushing and realistic coloration to make the mannequin as life-like as possible. Additionally, limbs will have a skeleton system with realistic joints to allow for accurate movements.



The chest cavity of the mannequin will be a realistic, air-bag system. It will also feature an accurate ribcage to encapsulate the mannequin's respiratory system. The mannequin will also include IV insertion and intubation holes in the umbilical cord and mouth. Electronics that allow for mimicking the rise and fall of breathing will also be included

### Model With Fluid Pockets

This model is very similar to the realistic chest cavity model with the composite polymer skin and electronic respiration system. The main difference is the inclusion of liquid proof pockets that allow liquids to be drawn through the IV insertion lines and umbilical cords, allowing those who work with neonates to practice drawing fluids from neonatal infants in critical condition.

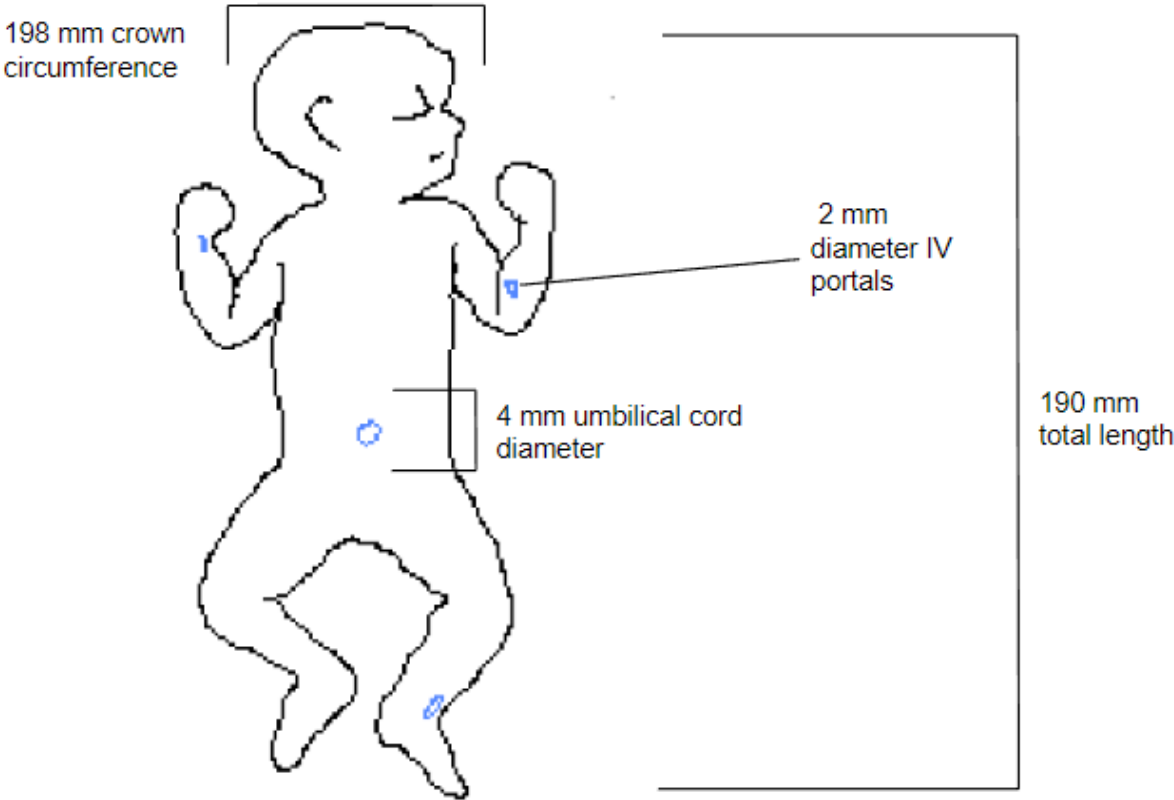


Figure 3: Model with Fluid Pockets

## IV. Preliminary Design Evaluation

### Design Matrix

The design matrix is a tool employed by the design team to evaluate preliminary designs in terms of important selected criteria. The criteria chosen by the design team was evaluated based on the client's requirements, what was most readily accomplishable in a semester, and by the amount of background knowledge that the design team has.

Texture is how accurately the skin model on the mannequin mimics that of true premature neonatal skin. Usability is how effective the mannequin serves as a training device. This concerns whether it has the proper design components for educational purposes or not. This criteria also determines if the mannequin is durable enough for training use. Cost is how cost effective the design is to make in comparison to competitors with more costly mannequins. Size and weight refers to how accurately the model portrays 22-23 week neonatal dimensions/weight. Realism is how life-like the mannequin is, and finally feasibility and reproducibility is how effectively the design team can fabricate the model during the time constraint of the semester.

Each of these criteria were weighted by what was determined to be the most important criteria which were texture, usability, and cost. The next highest criteria were size and weight, which, while important for the mannequin, these dimensions could be impacted by the inclusion of external bulky electronics and mechanical components. The lowest criteria were realism and feasibility given a general lack of research in this realm, and the fact that the team will be making one final prototype during the span of the semester.

**Table 1:** Design Matrix. Evaluation of feasible design ideas amongst different criteria.  
Highlighted areas indicate the highest score per category. Scores out of 5.

	Design 1: Model with IV Insertion & LED Resuscitation Component	Design 2: Realistic Chest Cavity Model w/ Intubation	Design 3: Model w/ Fluid Pockets
Texture(25)	3/5 (15)	5/5 (25)	4/5 (20)
Usability(25)	4/5 (20)	2/5 (10)	3/5 (15)
Cost(25)	2/5 (10)	3/5 (15)	2/5 (10)
Size/Weight(15)	3/5 (9)	2/5 (6)	3/5 (9)
Realism(5)	4/5 (4)	5/5 (5)	4/5 (4)
Feasibility/ Reproducibility (5)	3/5 (3)	2/5 (2)	2/5 (2)
Total (100)	61	63	60

## Proposed Final Design

Ultimately, the team chose Design 2: Realistic Chest Cavity Model with Intubation. This design scored the highest based on the e design matrix criteria. This model's hydrogel and elastomer composite skin, in combination with realistic joints and additional details in the skin design, would give it the most realistic texture. It is the most cost efficient, as fluid pockets pose the threat of damage in Design 3, and Design 1 is more costly due to the amount of sensors and lights that would need to be purchased. Design 2 is more realistic overall than either of the other designs. Design 1 becomes too heavy with the inclusion of all proposed electronics. Design 3, due to its fluid pocket, cannot include some of the necessary electronic components for realism.

## V. Fabrication/Development Process

### Materials

The final design intends to use a hydrogel hybrid for the neonatal skin. This will be accomplished using a rigid mold that the hydrogel (either gelatine, agar, or polyvinyl alcohol) and elastomer polymer (silicone or polyurethane) will be set on and then peeled off of. The elastomer and hydrogel will be layered on top with a stiff backing layered over the entire complex. The material may also be dyed to a shade resembling human skin, as the hydrogel elastomer includes channels in its material, allowing for the flow of dye [9]. The hydrogel hybrid will be cured with either heat or ultraviolet light. This is contingent on results from material testing during the fabrication process.

For the realistic joints the team would like to incorporate in the prototype, ball and stick joints made from high-density plastic will be used. The team has decided to accomplish the electronics portion of the project using Arduino products for the sake of simplicity, given that half of the team is already familiar with Arduino. The Sparkfun Pressure Sensor breakout will be used within the chest cavity [10].

### Methods

The design team will start by using the prior design team's mold, and adapt it to include limbs using Solidworks. One half of the mold will be one half of the mannequin with respect to the sagittal plane and two such molds for each mannequin/prototype that will be put together to make a full mannequin. The molds will also take into consideration how the two halves will be attached together—either through a zipper or a hydrogel-compatible glue, like a tissue adhesive. The team will then conduct necessary preparations of the chemicals for the elastomer polymer hybrid hydrogel. This skin mixture will then be put in the mold to set. Afterwards, joints and hollow areas will be inserted for formation of proper cavities needed for the design. After the mold is made, using the zipper attachment as an entryway point, the team will insert the respiration system via a plastic bag breathing mechanism on the inside of the thoracic cavity, enabling “respiratory” movement. Once the mechanism is in place, the electronic components would be inserted and wired into the mannequin. Much of the details of this methods section is intentionally left ambiguous, as the team has not been able to receive approval for purchases and this can not settle on which fabrication methods are the most effective.

### Testing

Testing will include two areas of testing: skin texture and breathing mechanism. Skin testing will compare different skin models/samples (differing in chemical composition percentages) as well as a control (the exact composition of the skin of the mannequin from the previous group that had the highest resemblance) that will assess different criteria. These observations will mostly be qualitative. Additionally, tensile testing should be conducted on the skin materials to determine the elasticity of the polymer hybrid.

Two tests related to the mobility of the chest cavity will also be completed: timing and the minimum and maximum heights of the chest cavity during each “breath”. Testing for timing will ensure that the time duration of each breath is relatively consistent and at the correct targeted rate. The testing for maximum and minimum heights for each breath would verify consistency between each breath (depending on what kind of breathing is to be defined: normal or restrained). Normal breathing would achieve approximately similar maximum heights and similar minimum heights while restrained breathing will have lower maximums. Finally, testing and evaluation of the design by the client will be conducted at many points during the project timeline.

## **VI. Results**

Results will be analyzed using standard deviation, statistical significance and percent error (this will mostly pertain to the testing surrounding mobility of the chest cavity that include timing and maximum/minimum heights of the thoracic cavity). The results are pending so this portion is yet to be completed after testing. If proper shear strength and tearing is witnessed while performing skin testing, the team will move forward with the final skin composition. If testing proves the material to be inadequate, the team will reevaluate. If the team determines that the breathing and chest cavity movements are equivalent to what is defined in literature, then the team will move on with that finalized chest design. If the values received from testing are insufficient, then the team will determine new shaping for future prototypes.

## **VII. Discussion**

During the group’s research/testing, one of the main ethical considerations is that the final product and prototypes must be safe to handle and not pose any dangers, such as overheating of the electric components to dangerous temperatures and usage of toxic chemicals that might harm the person.

In the skin quality/texture testing, if the group finds that the skin is damaged or any noticeable deformations occur, the team might have to change the chemical composition of the material by adjusting the ratio of materials of the hydrogel and/or the elastomer solutions. Overall the skin sample that is most stable and durable during these tests will be used for the final prototype. In the timing testing of the thoracic cavity, if the team finds that timings are too slow or too fast, the team will have to adjust the software and other electronic components. This would include increasing the sensitivity of the components that push the chest cavity outward. For the results of testing for the maximum and minimum heights of the chest cavity during each inhalation/exhalation, the team would adjust the spring elasticity variable depending on whether the team would like to achieve higher or lower heights. Possible sources of error in results could arise from inaccurate readings of the height (twice during each breath) due to the fast paced data acquisition and estimation of the heights at a centimeter/millimeter level. Another possible source of error could be from inaccurate timings (mostly in milliseconds) because of difficulty in differentiating exactly when the chest cavity height reaches highest and lowest values. The analysis of the skin testing can include MTS testing which could result in possible sources of error due to placement and amount of force being used to shear.

## **VIII. Conclusions**

Neonatal resuscitation in infants born extremely premature is relatively rare as the survival rate for these infants is very low. Currently, there are no simulation mannequins on the market specific to 22-23 weeks gestation, which does not allow medical professionals the ability to practice medical procedures including resuscitation and IV insertion. Oftentimes, a medical professional's first experience with a neonate this small requiring resuscitation is in a high stakes and chaotic environment within the hospital. To increase confidence and reduce stress, the team has developed design ideas to create a realistic mannequin that includes aspects for medical professionals to practice.

The final design seeks to include realistic skin by including gelatinous, elastomer skin. This will be developed by sandwiching a gelatinous layer—which could be agar, gelatine, or polyvinyl alcohol—between an elastomer material, such as silicone or polyurethane. Additionally, the team will create a new mold that includes limbs which will be vital to the inclusion of IV access ports on the mannequin's feet and arms. This will allow for the insertion of a 2mm IV tube. By including electronics, such as a pressure sensor, the mannequin will include an accurate rise and fall of the neonate's chest as though it was breathing, and also allow for feedback on the user's resuscitation techniques. Market research was

conducted, and the proposed final design was chosen after comparison to competing designs on the market. The team developed three design ideas, and determined a final design based on weighted scores in various design criteria. The previous team was able to create a mold and develop an adequate design, though it did not include any of the criteria that was discussed above. Thus, the team has worked to create a design to improve on the previous group's successes and shortcomings.

If the team was able to do this portion of the project again, there would have been a greater emphasis on design meetings where each team member can discuss different components of the design that were deemed important. The team fell back on design ideas from previous groups fairly often, instead. This would have additionally facilitated further discussion and team building at the beginning of the semester.

Moving forward, the team will develop the new mannequin components and fuse them together into a prototype. After completion of the prototype, the group will perform testing to determine whether the mannequin is functioning as desired. Once this is complete, the group will determine what revisions can be made to the final design and then move on to final testing. Once this is completed, final changes including visual appeal and realism will be made.

## IX. References

- [1] “A miracle preemie: Yishan's story,” *Children's Minnesota*, 25-Nov-2020. [Online]. Available: <https://www.childrensmn.org/2020/11/12/extremely-premature-infant-miracle-baby/>. [Accessed: 05-Oct-2022].
- [2] A. Cavolo, B. Dierckx de Casterlé, G. Naulaers, and C. Gastmans, “Physicians’ Attitudes on Resuscitation of Extremely Premature Infants: A Systematic Review,” *Pediatrics*, vol. 143, no. 6, p. e20183972, Jun. 2019, doi: 10.1542/peds.2018-3972.
- [3] “Trubaby x: Infant CPR manikin: Pediatric manikin,” *Trucorp*, 16-Aug-2022. [Online]. Available: <https://trucorp.com/product/trubabyx/>. [Accessed: 05-Oct-2022].
- [4] “Life/form C.H.A.R.L.I.E. neonatal resuscitation simulator without interactive ECG Simulator,” *Universal Medical*. [Online]. Available: <https://www.universalmedicalinc.com/life-form-c-h-a-r-l-i-e-neonatal-resuscitation-simulator-without-interactive-ecg-simulator.html>. [Accessed: 05-Oct-2022].
- [5] “Premature anne,” *Laerdal Medical*. [Online]. Available: <https://laerdal.com/us/products/simulation-training/obstetrics-pediatrics/premature-anne/>. [Accessed: 05-Oct-2022].
- [6] J. A. Vilensky and C. A. Suárez-Quian, “Newborn anatomy,” *Clinical Anatomy*, vol. 35, no. 1, pp. 15–18, 2022, doi: 10.1002/ca.23774. [Online]. Available: <https://onlinelibrary.wiley.com/doi/10.1002/ca.23774>. [Accessed: Sep. 22, 2022]
- [7] R. P. Davis and G. B. Mychaliska, “Neonatal pulmonary physiology,” *Seminars in Pediatric Surgery*, 16-Oct-2013. [Online]. Available: [https://www.sciencedirect.com/science/article/abs/pii/S1055858613000577?fr=RR-2&ref=pdf\\_download&rr=757bc0682e10635c](https://www.sciencedirect.com/science/article/abs/pii/S1055858613000577?fr=RR-2&ref=pdf_download&rr=757bc0682e10635c). [Accessed: 11-Oct-2022].
- [8] “5mm LED technical specifications and power characteristics,” *Make*, 20-Aug-2022. [Online]. Available: [https://www.make-it.ca/5mm-led-specifications/#:~:text=The%205mm%20LED%20can%20be,common%20size%20of%20LED%20available](https://www.make-it.ca/5mm-led-specifications/#:~:text=The%205mm%20LED%20can%20be,common%20size%20of%20LED%20available.). [Accessed: 05-Oct-2022].
- [9] J. Chu, “Tough New Hydrogel Doesn’t Dry Out,” *MIT News*, June 2016. <https://news.mit.edu/2016/tough-hydrogel-hybrid-artificial-skin-0627>
- [10] “Digital Pressure Sensor,” Arduino Workshop, 2021. <https://create.arduino.cc/projecthub/sarful/digital-pressure-sensor-arduino-workshop-0e43ae>



# X. Appendix

## A. Product Design Specification (PDS)

### **Function:**

The simulation mannequin must be representative of a premature infant born at 22-23 weeks of gestation. The mannequin must be able to be intubated, which means that a breathing tube must be able to be placed into the mannequin's trachea. Additionally, the chest cavity and rib cage must be created so as to include further procedural training for medical professionals in thoracentesis and pericardiocentesis. As there is a lack of simulation mannequins for infants born this premature, it is critical to develop one that allows for medical personnel to be able to practice resuscitation techniques. Using a simulation mannequin with similar characteristics and technology that makes it seem more lifelike allows the medical professionals to practice in a less chaotic and stressful environment. It is essential for medical personnel to have access to a training mannequin such as this as it will allow neonatology to further advance and resuscitation to be possible for infants born at even younger gestational times.

### **Client requirements:**

- I. Length should be less than 30.5 cm
- II. Improve skin texture of previous models
- III. Ability to put synthetic breathing tube (2.00 -2.50 mm diameter) in mouth of mannequin, to attach a synthetic umbilical cord, and to be able to practice vital signs
- IV. Base has to be able to handle breathing mask and bag practice, therefore pressure resistant
- V. Weight around 400-500 grams
- VI. Expandable lungs that replicate neonatal breathing
- VII. The more prototypes the better

### **Design requirements:**

#### **1. Physical and Operational Characteristics**

##### *a. Performance requirements:*

- I. The mannequin must be able to last between 3-5 years and production cost must remain low to maintain reproducibility. It should also maintain similar characteristics to a real infant born at 22-23 weeks of gestation and include anatomically relevant structures.

##### *b. Safety:*

- I. *User Safety* - Any electronics included in the mannequin must be enclosed and remain at a temperature low enough to ensure that the user is not experiencing any discomfort.

##### *c. Accuracy and Reliability:*

- I. The skin that is included on the mannequin must be lifelike and resemble that of an extremely

premature infant.

- II. The mannequin should be an accurate anatomical representation of an infant born at 22-23 weeks of gestation.

d. *Life in Service:*

- I. Typical use for simulation mannequins is between 3 to 5 years of frequent usage.

e. *Shelf Life:*

- I. Batteries and electronics within the mannequin must be able to last for the full lifetime of the model.

f. *Operating Environment:*

- I. The mannequin will be used as a training model in hospitals and teaching facilities.

g. *Ergonomics:*

- I. The medical personnel using the simulation mannequin must be able to perform resuscitation procedures without hindrance.
- II. The mannequin should be easy to use without exceedingly complicated electronic components that must be manipulated by the user.

h. *Size:*

- I. The length of the mannequin should be roughly 1 foot when measuring from the “head” of the mannequin to the opposite side.

i. *Weight:*

- I. The mannequin should be between 400 and 500 grams which does not include added electrical components.

j. *Materials:*

- I. The mannequin must involve a skin-like material on the external surface. Electronic components should also be encased within this material.

k. *Aesthetics, Appearance, and Finish:*

- I. The mannequin must look similar to an infant born between 22-23 weeks of gestation in both size and shape.
- II. Additional aesthetics should not add any adverse effects to the experience nor add any extra weight.

## 2. Production Characteristics

a. *Quantity:*

- I. The client requires a single prototype. With successful creation of one prototype, more will be needed.

b. *Target Product Cost:*

- I. Cost should be low enough to be reproducible, and be created within a couple thousand dollars.

### 3. Miscellaneous

#### a. *Standards and Specifications*

- I. ISO 13485: This standard states that the organization must ensure quality medical devices from design to manufacturing and so on. This is achieved through ethical design that puts the customer and patient first, following standards, having adequate documentation, and so on[1].
- II. ISO 14971: This standard states that risk management and design with risk considerations must be conducted by the design team. This involves risk evaluation and the implementation of risk control by the design team [3].

#### b. *Customer:*

- I. The customer base for this product is medical schools that wish to educate their students on the intubation of neonatal infants. The students and medical professionals using the product would prefer if the mannequin is easy to handle but at the same time reflect the higher difficulties in resuscitation for premature infants of 22-23 weeks of gestational age.

#### c. *Patient-related concerns:*

- I. The patients that this mannikin is supposed to simulate, the neonatal infant, would best benefit from this device if it is quite comparable to their likeness. Therefore, the patient-related concern is that the neonatal infant mannikin does not incorrectly train medical students in how to intubate the neonatal infant patient.

#### d. *Competition:*

- I. There are many other neonatal intubation mannequins on the market today. These include, but are not limited to, models from Universal Medical Inc.[5], Laerdal Company [4], and Trucorp[5].

## B. Expenses and Purchases

The team has not yet made any purchases.

## C. Testing Protocols

### Skin

1. Obtain slightly varying samples of the skin
2. Compare sample's texture with texture of control
3. Add 0.25 mL of water to small portion of sample and note any changes in texture and appearance (right away and after an hour)
4. Expose a small portion of the sample in sunlight for 2 hours and make note of any changes
5. Stretch the skin gently and make note of the ease of elasticity, difference in appearance/texture, and any tearing if it is present
6. Repeat steps 3-5 for all samples and the control

## Breathing

### Timing

1. Initiation of the breathing/mobility of chest cavity
2. Start the timer immediately following initiation
3. Lap the timer at the start of each breath and continue this for 1 minute
4. Stop the mobility of the chest cavity at the end of the 1 minute
5. Record the total number of breaths during that one minute
6. Repeat steps 1-5 for a total of 5 runs

### Maximum/Minimum heights of chest cavity

1. Record the height of the topmost portion of the chest cavity
2. Initiation of the breathing/mobility of chest cavity
3. During the breath, record the height of the topmost portion of the chest cavity at “peak” of breath (should be highest height achieved during inhalation)
4. Record the height of the topmost portion of the chest cavity at the end of exhalation (should be the lowest height achieved during exhalation)
5. Repeat steps 3-4 for a total of 15 breaths or runs