
# NEONATAL 22-23-WEEK PREMATURE INFANT SIMULATION MANIKIN

BME 200/300 - Final Report

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# Abstract

As the rate of preterm births continues to rise, the need for innovation in the field of neonatology grows as well. This project focuses specifically on 22-23-week neonates. These infants are considered extremely premature and resuscitation is critical for many neonates born at this age. These neonates are rare, and thus medical professionals often have minimal experience with these infants. This creates a demand for medical simulation manikins that accurately represent neonates born at this stage of gestation. There are currently no neonatal manikins for infants at this age, with the earliest model representing a neonate born at 25-27-weeks. The design team has been tasked with creating a neonatal simulation manikin that includes three components: IV access, realistic simulation anatomy that allow for proper intubation, and central umbilical line placement. The team's current solution aims to include a realistic skin texture, a chest cavity with a feedback mechanism to show effective intubation, and to create a manikin that is a cost-effective training device to help offset the costs of healthcare. To ensure the group delivers a satisfactory device, mechanical and usability testing will be conducted to assess effectiveness and comfort levels when training with the manikin. With the team's efforts, a neonatal manikin that accurately models a 22-23 week premature infant will be designed to help train medical students and professionals to practice resuscitation when the stakes are not as high and to raise their confidence when conducting this critical procedure.

# Table of Contents

# I. Introduction

## Motivation

The broad goal of the project is to create a neonatal simulation manikin that helps train medical students and professionals on resuscitation procedures for 22-23-week neonatal infants. As the rate of premature births increases, raising by 4% in 2021, resuscitation on these young neonates becomes more commonplace [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 from 31% - 78% [2]. 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 weeks 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 high for infants born before 25 weeks of 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 weeks of gestational age. If a simulation manikin with all necessary components for resuscitation techniques, coupled with realistic skin texture existed, doctors could practice on manikin so that when a real, high-intensity premature delivery occurs, they would be well-versed in resuscitating a 22-23 week neonatal infant. A study conducted by Yamada, et al demonstrates that there is an average error rate of 23% during neonatal resuscitation–which could result in dire consequences such as brain damage, cerebral palsy, pneumonia, respiratory distress syndrome or even death [3, 4]. With the introduction of a cost-effective and realistic simulation manikin, 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 manikins on the market, but none that accurately simulate a 22-23 week premature infant. There are a couple of neonatal infant manikins on the market but none that fully satisfy the client’s desires. Trucorp has a TruBaby X manikin 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 [5]. 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 manikin. 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 of oxygen use or PPV, the 'I' represents intravenous, intraosseous, and intubation, and the 'E' stands for ECG [6]. 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 manikin, 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 and includes a chest cavity that rises and falls, umbilical cord access, and multiple locations for IV insertions [7]. At just 2-3 weeks away from the team's desired infant manikin, 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 weeks of gestational age.

This project is also a continuation of the semester prior. The prior group was able to create a mold design but was unable to create a functioning prototype. Many of the aspects from last semester's design will be carried over to this semester, including the polydimethylsiloxane (PDMS) skin texture and the mold design that was created. However, last semester's team experienced difficulties with the material of the skin interacting negatively with the material of the mold.

**Figure 1**: *Prototype from last semester's group*

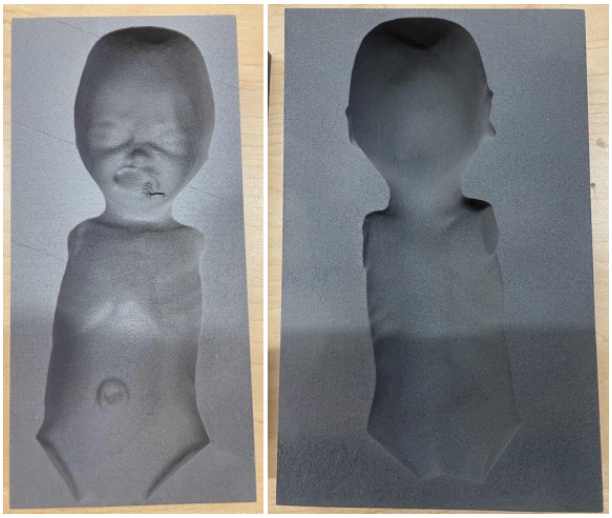

**Figure 2:** *Mold created from Nylon 12 from last semester's group*

## Problem Statement

There are currently no 22-23 week neonatal simulation manikins 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 manikin 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. 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 cage, while different from an adult's thoracic cage where there are distinguishable ribs, an infant has a more cone-like thoracic cage structure [8].

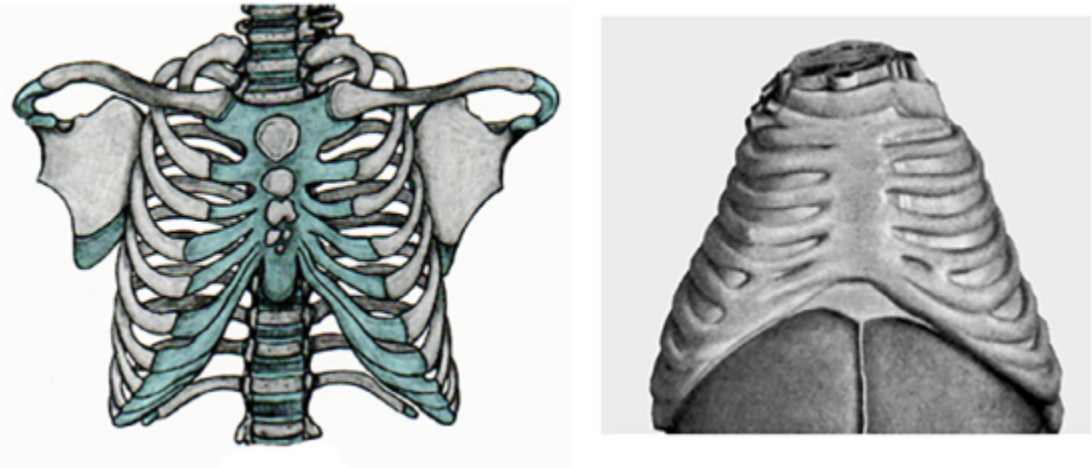

**Figure A**: *A depiction of an adult thoracic cage (left) versus an image of a newborns thoracic cage (right) [8]*

The chest cavity of 22-23 weeks 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 [9]. This means 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 the resuscitation of neonates born extremely prematurely. 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 manikin 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 include having the ability to put a synthetic breathing tube (2.00 -2.50 mm diameter) in the mouth of the manikin, attach a synthetic umbilical cord, and practice vital signs. Additionally, the base has to be pressure resistant and needs expandable lungs to replicate breathing. Some additional design requirements are a shelf life of 3-5 years, the manikin should be less than 30.5 centimeters, and a weight of 400-500 grams (refer to PDS). The client also requests that the skin be made more lifelike, as a premature infant's skin is more malleable than a full-term infant's or an adult's. The average elastic modulus of skin ranges from 0.42 MPa - 0.85 MPa, which a neonatal skin elastic modulus would fall in the lower end of this range [10].

# III. Preliminary Designs

## Polyvinyl Alcohol Casted Mold

Polyvinyl alcohol (PVA) was determined to be an acceptable design for the mold because of its ability to dissolve in water. It is often used as a support structure for 3D printing. As a result, it would be a breakaway mold that could be used when curing the manikin. However, because of its breakaway component, it would not be used multiple times and instead is a single-use mold that would need to be reprinted every time.

## Tough Polylactic Acid

Tough polylactic acid (PLA) was determined to be an acceptable design for the mold because it is one of the most commonly used plastics for 3D printing. It is heat resistant and would be able to withstand the curing process for PDMS which is the material that will be poured and cured in the mold. Additionally, it is durable and can be reused for multiple prototypes.

## Nylon Mold

Nylon was determined to be an acceptable design for the mold because it is extremely heat resistant. It was also the material used in the prior semester for this project. However, the Nylon had

interactions with the PDMS and did not yield the desired results. Thus, it would only be a viable option if PDMS was not the chosen skin material.

## PDMS Coating on Ballistics Gel

This design for the 22-23 week neonatal manikin strikes a balance between the tactile experience and realism that the properties of PDMS provides and the durability and additional realistic properties that ballistics gel provides. Using the mold, the team will first fabricate the ballistics gel base which will serve as the main body and structure of the manikin. 3D printed PVA that is in the shape of the trachea and chest cavity will be placed in the molded ballistics gel before curing in a fashion where it is easily removed afterward. This will leave behind the desired cavities for intubation. Then the team will then cure a thin layer of PDMS over the ballistics gel at room temperature due to the low melting temperature of the ballistics gel.

## PDMS Only

This is the same design for the neonatal manikin as in the semester. This design consists of thin layers of PDMS being cured on top of one another in the mold. Each layer will be cured at 300$^{o}$ for ten minutes at a time. A 3D-printed PVA in the shape of the trachea and chest cavity would be placed in the mod during the curing process, and then removed afterward to leave the cavity behind for intubation.

## Sleeve Coating

This design consists of a PDMS sleeve that can be slipped on and off of a more durable, PVA neonatal manikin. This allows the PDMS covering to be replaced as needed and provides accurate texture to only the locations of the manikin that will be made contact with during intubation.

## Intubation and Shell

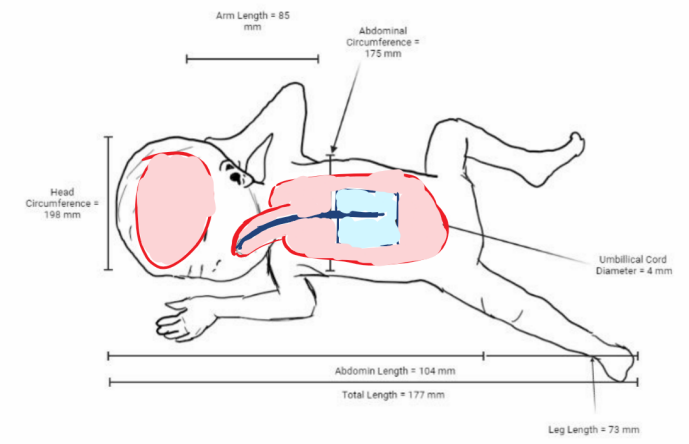


**Figure 3:** *Drawing of the Intubation and Shell design idea.*

This design uses a PLA-printed chest and belly cavity. This allows the chest cavity to have solid support within the manikin. Within this cavity, an infant-sized CPR bag would be placed within it to replicate the lungs. The airways would be molded with silicone to include a realistic mouth and esophagus. This design was previously used in this design project at a different university.

## Balloon Lungs

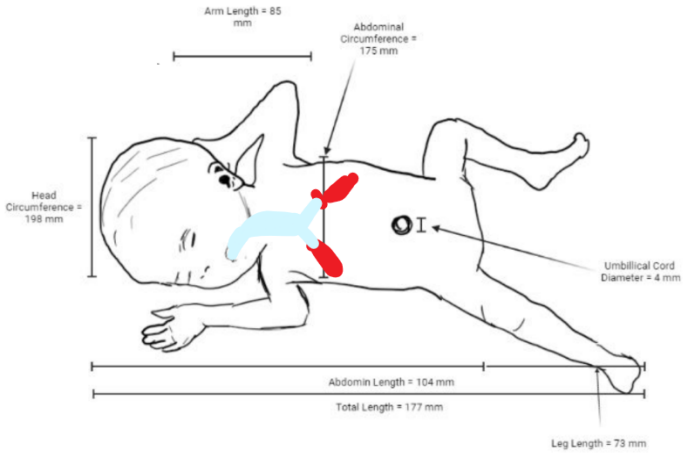


**Figure 4:** *Drawing of the Balloon Lungs design idea.*

The balloon lungs include a breathing tube with T-connectors to mimic airways. These “airways” would be connected to two small balloons which can inflate and deflate to replicate breathing. These balloons

would represent the lungs. This idea is simplistic in that it does not include any skeletal components.

## Mock Airway and Skeleton

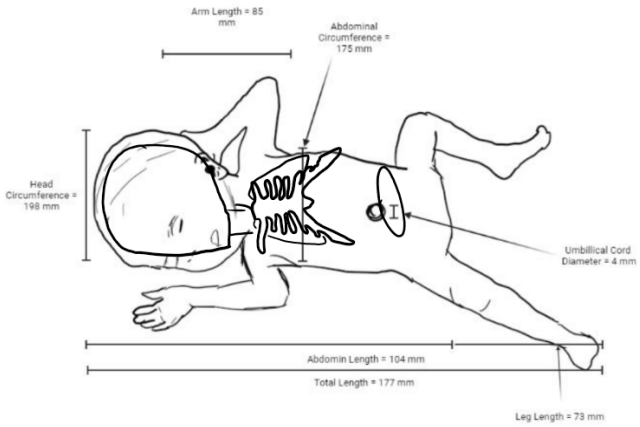


**Figure 5:** *Drawing of Mock Airway and Skeleton design idea.*

The mock airway and skeleton design includes a 3D-printed skull and skeleton within the manikin. This structure would be created out of an elastic-plastic such as polyurethane. Furthermore, there would be accurately sized lung-air bags for the rise and fall of the lungs. The purpose of this design would provide more structural stability as opposed to just the ballistics gel alone and would provide realism to internal components.

# IV. Preliminary Design Evaluation

## Design Matrix

A 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 were evaluated based on the client's requirements, what was most readily accomplishable in a semester, and the amount of background knowledge that the design team has.

Heat resistance is how well the material resists melting when placed in environments with high temperatures. Cost is how cost-effective the material is compared to other alternatives. Durability is how capable the material is to withstand wear and tear depending on what is outlined by the client's specifications. Detail capturing is how well the material will be able to portray smaller intricacies of the

design such as facial features. Feasibility is how capable the team is to create the design over the course of the semester. Ease of use is how easy the material is to turn into the design and how simple usage is by the users.

Each of these criteria was weighed by what the team determined to be most important. Heat resistance was considered the most important because the material must be able to withstand the curing temperatures of the biomaterial. Cost, durability, and detail capturing were the next most important because it was critical to include the most features while withstanding usage over a few years. Keeping the cost low allows for the design to be reproduced as necessary. Feasibility was the next most important aspect because it determines how capable the team is to create and complete the design. Ease of use was least important because the mold is only being used to give the model shape and will not be used after the prototype is created unless needed to create more prototypes.

**Table 1**: *Design matrix evaluating 3 feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 5.*

| | Design 1:<br>PVA Casted Mold | Design 2:<br>Tough PLA | Design 3:<br>Nylon Mold |
|---|---|---|---|
| Heat Resistance (25) | 3/5 (15) | 4/5 (20) | 5/5 (25) |
| Cost (20) | 2/5 (8) | 5/5 (20) | 4/5 (16) |
| Durability (20) | 4/5 (16) | 5/5 (20) | 4/5 (16) |
| Detail Capturing (20) | 4/5 (16) | 5/5 (20) | 4/5 (16) |
| Feasibility (10) | 3/5 (6) | 4/5 (8) | 1/5 (2) |
| Ease of Use (5) | 3/5 (3) | 4/5 (4) | 1/5 (1) |
| Total (100) | 64 | 92 | 76 |

Additionally, the team evaluated various designs for the material and composition of the neonate manikin itself. Six different criteria were used for this evaluation: texture, usability, cost, durability, realism, and feasibility/reproducibility.The texture is how well the material composition replicates the tactile experience of the skin of a premature infant. Usability is how easily the manikin can be used to simulate intubation. Cost is how economical the price of the manikin is compared to other options.

Realism is how realistic the manikin looks and feels. Feasibility/Reproducibility is a measure of how complex the fabrication process will be and how easily it can be repeated with a high degree of precision if necessary.

The team determined that texture, cost, and usability were the most important. This is due to the fact that the client's main complaint about other designs on the market is that they have a very artificial, plastic feel rather than the hydrated and elastic feel of a premature infant. Cost is important due to the fact that another challenge of acquiring neonatal intubation manikins is that they are not accessible. For example, Premature Anne from Laerdal costs $2,999 [7]. The team thus is prioritizing the design of a manikin that is more affordable. Usability was also ranked as the most important due to rollover complications from the previous semester. The most challenging issue was that the previous design had low usability, as it was not easily intubated or handled.

Durability was ranked as the next most important criterion. This is because a large component of determining whether the manikin is functional or not is designing it in such a way that it can handle its function of intubation. This will be done repeatedly to the manikin throughout its lifespan, and thus it must be able to withstand the necessary amount of pressure for intubation many times.

The lowest-ranked criteria were realism and feasibility/reproducibility. This is because, one, the team decided that the aesthetics of the manikin were not as important at this stage of development as the functionality of the manikin. The team also wanted to concentrate efforts on perfecting one fabrication process before fine-tuning it for reproducibility.

**Table 2**: *Design matrix evaluating 3 ideas for the manikin. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 5.*

| | Design 1:<br><br>PDMS Coating on Ballistics Gel | Design 2:<br><br>PDMS Only | Design 3:<br><br>Sleeve Coating<br>-Thicker silicone sleeve on top of hard plastic body |
|---|---|---|---|
| Texture(25) | 5/5 (25) | 3/5 (15) | 4/5 (20) |
| Usability(25) | 5/5 (25) | 3/5 (15) | 4/5 (20) |
| Cost(25) | 4/5 (20) | 5/5 (25) | 2/5 (10) |
| Durability(15) | 4/5 (12) | 2/5 (6) | 3/5 (9) |
| Realism(5) | 4/5 (4) | 2/5 (2) | 5/5 (5) |

| | | | |
|---|---|---|---|
| Feasibility/ Reproducibility (5) | 4/5 (4) | 5/5 (5) | 2/5 (2) |
| Total (100) | 90 | 68 | 66 |

The team also evaluated several design ideas for the inner workings of the manikin. This includes a system for intubation and faux lungs. The designs were evaluated based on five criteria which were ranked based on what the team determined to be most important for the project's functionality. The most important criterion was realism, which is how accurately the airway mechanism mimics breathing (normally and during resuscitation). This also evaluates the accuracy and realism of the structure of the inner workings. Because the manikin is primarily going to be used for intubation, it is critical that the inner workings provide a realistic imitation of breaths and chest rising and falling. This is complemented by usability, which is how easy the manikin's features are to use. The realism is dependent on how simple the breathing mechanism is to operate by the user.

The next most important criterion was cost. This is because the manikin needs to be low cost in order to create numerous functional prototypes, and be created within the cost constraints of the semester. Durability and feasibility were the lowest because they are not necessary for functionality, but are required for the reproduction of prototypes and extended usage. Durability is important because the manikin should have a shelf life of about 3-5 years, meaning that the inner workings should be able to withstand semi-constant use for this time period. Feasibility and reproducibility are important for the project because the team should be able to develop a prototype within the semester and this prototype should be easy to recreate in future iterations.

**Table 3**: *Design matrix evaluating 3 ideas for the inner workings. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 5.*

| | Design 1: Intubation and Shell | Design 2: Balloon Lungs | Design 3: Mock airway and skeleton |
|---|---|---|---|
| Feedback Mechanism/ Realism (25) | 4/5 (20) | 4/5 (20) | 5/5 (25) |
| Usability(25) | 4/5 (20) | 4/5 (20) | 5/5 (25) |
| Cost (20) | 3/5 (12) | 5/5 (20) | 2/5 (8) |
| Durability (15) | 3/5 (9) | 3/5 (9) | 4/5 (12) |

| | | | |
|---|---|---|---|
| Feasibility/ Reproducibility (15) | 3/5 (9) | 5/5 (15) | 2/5 (6) |
| Total (100) | 70 | 84 | 76 |

## Proposed Final Design

Ultimately, the team chose to combine the highest scoring designs from each matrix to create the final design. The manikin's skin will be created out of ballistics gel which will be coated with a layer of cured PDMS. Ballistics gel will increase the durability of the design while PDMS will maintain the skin-like texture that is required for realism. This model will also include limbs that will allow for IV access. The inner workings will be created by using balloons and tubing to simulate lungs that can rise and fall with the introduction of air. Finally, the mold to create this design will be created from tough PLA, which is heat resistant enough to withstand the curing process and should have no chemical interactions with the skin materials during curing.

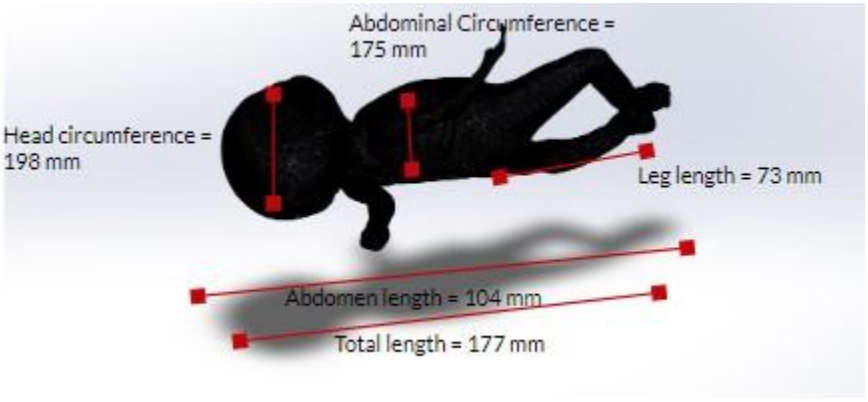


**Figure 6:** *SOLIDWORKS visualization of what the final design should look like after completion*

# V. Fabrication/Development Process

## Materials

The final mold was made of Ultimaker's Tough PLA that was 3D printed from the UW-Madison Makerspace. The mold is composed of two halves that divide the neonate in half along its coronal plane.

This allowed for the chest cavity to be carved out and the inner workings to be placed within each half before sealing both halves together using a gelatin based adhesive. The skin and exterior of the manikin are made up of ballistics gel due to its mechanical and physical properties relating to that of neonate skin. A small tube connected to a T-connector was utilized to simulate the trachea branching off to the lungs in order to allow for intubation practice. The lungs are made of small balloons, to replicate premature development, their elasticity necessary so they can fill and empty with resuscitation. This would give feedback to the user in the form of air entering the lungs and exiting out the mouth.

# Methods

The design team began by using the mold design that was created by one of the members last semester. The mold was made by doing a scan of Laerdal's Premature Anne [7], scaling it down to the anatomically correct size of 6 inches, and extruding two rectangles around the two halves that were sliced. (Refer to Appendix H). The two molds were then 3D printed in the Makerspace. The ballistics gel for the skin and body was created by mixing ballistics gelatin powder with water. The ratio of this is 20% gelatin by mass [11]. The contents were added and stirred in a beaker until fully mixed. The liquid was then sent to solidify in the fridge for two hours. After sitting in the fridge, the ballistics gel was then heated over a hot plate at 260 degrees Fahrenheit while stirring until consistent. Once consistent, it was then degassed in the vacuum degasser for thirty minutes to eliminate bubbling of the gel. While the ballistics gel was degassing, two layers of mold release were applied to the inside of the mold. After degassing, the gel was poured into each half of the mold, and covered with parafilm. Each half was then put in the fridge to set overnight. When each half was solid gelatin, the chest cavity of each half was then hollowed out to make way for the inner workings such as the trachea and lungs. It also allows for the chest cavity to more accurately replicate the fragility of a neonate. After the chest cavity was fully cleared out, the inner workings were to be created. The inner workings were created by using breathing tubing with a T-connector to mimic airways. At the ends of these, two small balloons are attached to mimic lungs. Additionally, the tubing will travel up the trachea to the mouth of the infant to provide a resuscitation avenue. Once this breathing mechanism had been placed in the chest cavity and out the mouth the manikin, both sides of the model needed to be attached. A ballistics gel based glue was created to stay synchronous with the rest of the model [12], and a layer of it was applied to the contact points on each half. The molds were then fastened together and refrigerated once more to allow for the model to be a consistent whole.

## Final Prototype

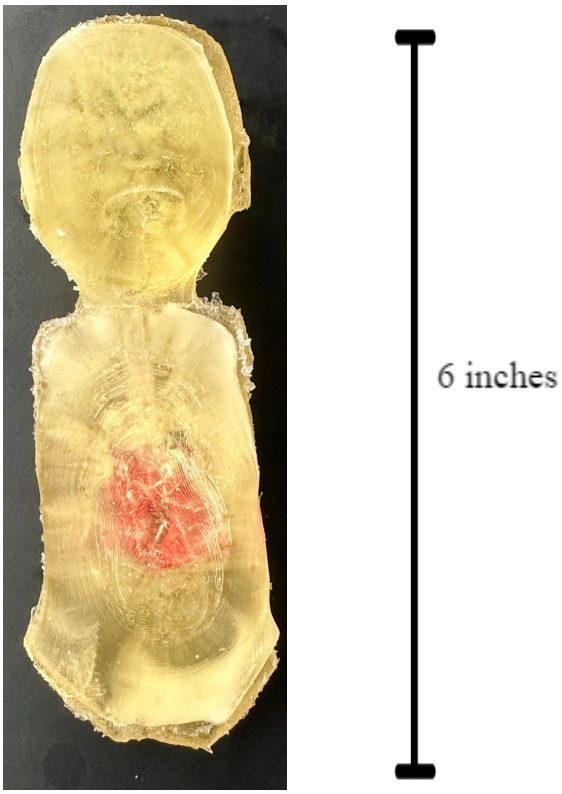


***Figure 7:*** *Final prototype created from ballistics gel with internal components inserted.*

## Testing

Testing conducted during the course of this design project will ensure the best outcome of the final prototype. This will also help the design team identify areas of weakness for future design improvements.

The first testing conducted by the group will involve testing of the chosen skin materials, ballistics gel and ballistics gel with the PDMS. In order to identify the optimal formulation of ballistics gel, gels made with different concentrations of gelatin will be compression tested on a MTS machine. The formulation that best matches the elastic modulus of 0.42 MPa and the physical properties of a 22-23 week neonate's skin will be the formulation the team moves forward in prototyping with [10]. Similar testing will be conducted with the ballistics gel with the PDMS coating with a compressive strength test. The best concentrations for each of the materials will move forward in the prototyping stage.

Next, usability testing will be conducted to assess the effectiveness of the team's prototype. First will be intubation testing. This will involve all members of the design team and the client attempting to intubate the prototype with tubing and place an umbilical line. This will be tested against the control

manikin, Premature Anne. Quantitative data such as time taken to complete this will be assessed as well as qualitative –such as comfort level and success– will be recorded. Other ideas for evaluating the prototype will be continuously considered throughout the project development phase with feedback from the team's client.

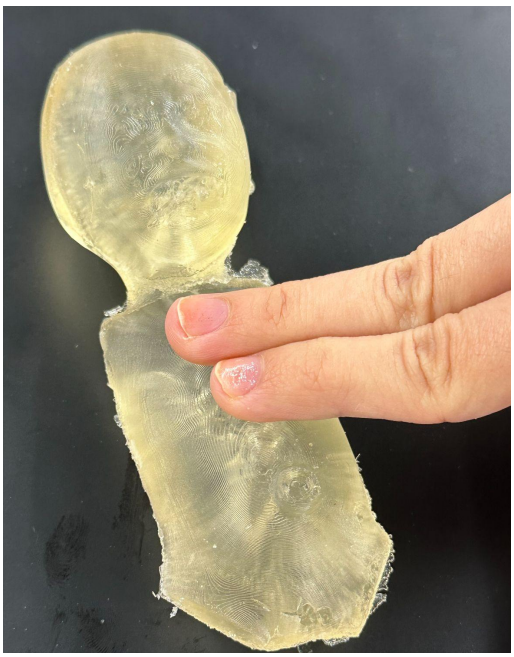

**Figure 8:** *Usability testing conducted on the ballistics gel manikin.*

# VI. Results

The results were analyzed using MATLAB in order to extract the Young's Modulus and Stress vs. Strain curve from the MTS tensile test raw data. This resulted in a Young's Modulus of 727.85 kPa, which is within the desired range for human skin tissue [10]. Due to this, the team decided that the 20% ballistics gel concentration was satisfactory. The team also collected qualitative testing data from a clinician using a survey with various quality ratings, ranging from 1 to 5. The clinician determined that although, in terms of anatomical observations, the lungs were placed slightly too superiorly, the manikin did have realistic tactile properties.

# VII. Discussion

Based on the results that were achieved from testing, it became clear that the original material design of coating ballistics gel with PDMS was going to be too difficult to complete in the duration of the semester. Since the PDMS kept coming off of the ballistics gel during testing, the team decided to move

forward with just using ballistics gel for the prototyped skin. From testing results, the team found that ballistics gel's Young's Modulus fell within the acceptable range for what the Young's Modulus for skin should be [10].

When the team conducted usability testing, the results showed that many of the users appreciated that the ballistics gel was able to replicate the feel of skin in terms of moisture retention and texture. However, users would have preferred the addition of limbs, and for the chest cavity to not have as much stiffness. Based on this evaluation, the team believes that the manikin needs to be changed by either reducing the concentration of gelatin from 20% to closer to 10-15% or by creating a larger chest cavity. This is to allow the manikin's inner workings to inflate and deflate more and decrease how stiff the chest feels. This also decreases the amount of ballistics gel on top of the inner workings which will also provide more visual feedback to the user as the chest rises and falls.

The purpose of this product is to allow for medical professionals to experience realistic training to prepare them for real life neonate procedures. Therefore it is essential that the manikin maintains as much realism as feasible given the time frame and budget constraints. As each individual infant is unique, one potential source of error is that it is impossible to create a manikin that accounts for all variations of neonates. To combat this error our team has decided upon a design that represents characteristics maintained by a majority of 22-23 week old infants, while also considering future work that can be done to potentially create interchangeable parts to diversify our manikin. Another potential source of error is that 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. To minimize this error, the team tested 6 samples to ensure that the average results represented the material the best and would minimize outlier results.

Throughout the group's research/testing, one of the main ethical considerations is that the final product and prototypes are safe to handle and do not pose a threat to the users. Such dangers could potentially include overheating of the electronic components to dangerous temperatures or usage of toxic materials that could harm the user. However since all of the materials used are safe and nontoxic, the manikin can be deemed safe for use by consumers.

# VIII. Conclusions

Medical procedures performed on extremely premature infants are relatively rare as the survival rates for these infants is very low. For this reason, it is essential that medical professionals have adequate training on neonates so that when strenuous situations are encountered they feel more confident in their

capabilities. Currently, there are no simulation manikins on the market representing infants of 22-23 weeks gestation, causing there to be a lack of adequate training for neonatal procedures such as resuscitation, intubation, and IV insertion. Oftentimes, a medical professional's first experience with resuscitation of a neonate this small is in a high stakes and chaotic environment within the hospital. To better prepare medical professionals for these different scenarios, the team has developed design ideas to create a realistic neonatal manikin for simulated practice.

The final design included a simulated neonate body consisting of a torso and head with lung and throat mechanisms mimicking the anatomy of an airway. This manikin was molded using ballistics gel due to its similarity in mechanical and physical properties to that of neonate skin. The team created a 3D printed PLA mold consisting of two halves that the manikin was first cured in separately, allowing for the team to carve out a chest cavity for the airway tubing to be inserted into. The airway consisted of an opening beginning at the infant's mouth that connected to a tube replicating the trachea which then branched off to connect to two balloons representing the lungs. Following insertion of these features, the two halves were sealed together using a gelatin based adhesive to form the whole infant.

The team conducted both usability and mechanical testing on the manikin in order to analyze the anatomical accuracy and functionality of the prototype. Usability testing achieved by having medical professionals fill out a survey following handling of the manikin and completion of procedures such as compressions revealed that while the skin texture was realistic, some of the dimensions varied slightly than that of a true neonate. Mechanical testing accomplished by the utilization of an MTS machine to do both compression and tensile examinations of the ballistics gel revealed that the elasticity of the material correctly mimicked that of a neonate, confirmed by analysis of the young's modulus.

A complication the team experienced while working on this project was trying to find a way to evenly coat the ballistics gel baby with PDMS. This was attempted as a way to make the skin of the manikin even more realistic as PDMS has a more viscous finish similar to that of a neonate. The team attempted to cure PDMS on top of ballistics gel samples using a few different techniques including texturing the ballistics gel surface, however the PDMS refused to fully cure on any of the surfaces causing the team to revert to a fully ballistics gel manikin due to time constraints. In order to combat this issue in the future it would be beneficial for the team to begin material testing earlier on in the semester so that if such an issue arises again, there is adequate time to find a substitute material. There were also challenges encountered when the tubing and balloons intended for the airway mechanism were too large to fit inside the chest cavity they needed to reside in. The team was able to alter these items in order to make them fit to scale, however the airway in turn did not operate as smoothly as planned. This could be avoided in the future by ensuring that the dimensions of materials will be sufficient and appropriate for the prototype prior to ordering them. In addition, there were also some issues with communicating with the client and

their assistants which caused the team to have some difficulty ordering and receiving materials in a timely manner.

In the future, there are a variety of alterations the team would like to make to the manikin in order to make it more realistic and functional for a variety of medical procedures. The addition of limbs in order to allow for IV insertion, thinning of the ballistics gel layer enclosing the chest cavity in order to allow for more realistic compression testing, installation of a resuscitation feedback mechanism in order to confirm effective medical training are a few examples of such moderations that would improve the teams design. In addition, more focus could be placed on the internal components of the manikin for example addition of a ribcage in order to add more structure to the neonate and make compressions more realistic. More usability testing could also be helpful in order to gain more analyzable data on the manikin and for biases amongst medical professionals to have less of an impact on the results.

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# X. Appendix

## A. Product Design Specification (PDS)

### Neonatal 22-23-Week Premature Infant Simulation manikin: PDS

2/10/2023
Client: Dr. Tim Elgin
Advisor: Dr. Kristyn Masters
Team Members: Loukia Agoudemos, Sophia Finn, Tanishka Sheth, Charlie Fisher, and Abbie Schaefer

**Function:**

The simulation manikin must be representative of a premature infant born at 22-23 weeks of gestation. The manikin must be able to be intubated, which means that a breathing tube must be able to be placed into the manikin'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 manikins 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 manikin 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 manikin 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 manikin, 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 manikin 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.

II. According to a study conducted by Dr. Douglas Campbell and colleagues, high-fidelity simulation manikins for neonatal resuscitation prove more effective for practicing intubation on neonates. Such manikins include features such as breathing, crying, seizing, displaying cardiac and respiratory status, etc [1].

III. Standard procedure for neonatal resuscitation include the following:

A. Receive 30 seconds of intermittent positive pressure for adequate resuscitation and minimizing mask leak.

B. Withstand the chest compression pressure of standard chest compression techniques employed– 3 chest compressions to 1 breath. .

1. Force applied by two thumbs at a right angle to the chest with fingers clenched in a fist.

2. Thumbs applying force to the sternum with fingers encircling the chest and back for support.

b. *Safety*:

I. *User Safety* - The manikin is intended to be utilized in a low risk, learning environment. Any electronics included in the manikin must be enclosed and remain at a temperature low enough to ensure that the user is not experiencing any discomfort. Users should be informed of any characteristics of the manikin that are deemed as dangerous prior to operation.

c. *Accuracy and Reliability*:

I. The skin that is included on the manikin must be lifelike and resemble that of an extremely premature infant.

II. The organs, limbs, and other body parts that compose the manikin must replicate a realistic infant in such qualities as material, size, and location on the baby.

III. The manikin 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 manikins is between 3 to 5 years of frequent usage.

II. If deemed necessary, certain parts of the manikin can be replaced without requiring full manikin renewal.

e. *Shelf Life*:

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

II. It is essential that the materials and components of the manikin will not deteriorate in the storage environment over several years.

f. *Operating Environment*:

I. The manikin will be used as a training model in hospitals and teaching facilities. This includes such

areas as simulation centers and classrooms. The manikin will encounter temperatures rarely straying from room temperature (68 °F and 77 °F) in these environments.

g. *Ergonomics*:

I. The medical personnel using the simulation manikin must be able to perform resuscitation procedures without hindrance.

II. The manikin should be easy to use without exceedingly complicated electronic components that must be manipulated by the user.

h. *Size*:

I. The length of the manikin should be roughly 1 foot when measuring from the "head" of the manikin to the opposing end near the feet.

i. *Weight*:

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

j. *Materials*:

I. The manikin must involve a skin-like material on the external surface. It is essential that the materials of the manikin simulate real human anatomy in such qualities as texture, thickness, and finish. Electronic components should also be encased within this material. The materials must be non-toxic and be safe to be in contact with human skin over prolonged periods of time.

k. *Aesthetics*, *Appearance, and Finish:*

I. The manikin 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. Market prices of competing models as well as the cost of materials and labor will be considered when assigning a retail value to the manikin.

**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[2].

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 and hospitals that wish to educate their students on the intubation of neonatal infants. The students and medical professionals using the product would prefer if the manikin 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 manikin 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 manikin does not incorrectly train medical students in how to intubate the neonatal infant patient.

d. *Competition*:

I. There are many other neonatal intubation manikins on the market today. These include, but are not limited to, models from Universal Medical Inc.[5], Laerdal Company[4], and Trucorp[6]. However none of the current models on the market represent infants younger than 25 weeks of gestation.

**References**

*any quantitative information without references came directly from the client, Dr. Elgin*

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# B. Expenses and Purchases

**Expenses**

| Item | Description | Manufacturer | Part Number | Date | QTY | Cost Each | Total | Link |
|---|---|---|---|---|---|---|---|---|
| **Component 1** | | | | | | | | |
| Gelatin Powder | 1lb of unflavored gelatin | Knox | B001UOW7D8 | 3/23 | 1 | 19.49 | 19.49 | gelatin |
| **Component 2** | | | | | | | | |
| Mold | PLA mold used for fabrication | UW Makerspace | N/A | 4/21 | 1 | 25.00 | 25.00 | N/A |
| **Component 3** | | | | | | | | |
| Balloons | Colorful balloons | Hafree Store | B0BDRDCJLL | 4/21 | 1 | 7.37 | 7.37 | balloons |
| **Component 4** | | | | | | | | |
| ⅜” T-connector | Plastic T-connector | ANPTGHT Store | aww-123100690 | 4/21 | 1 | 6.99 | 6.99 | connect |
| **Component 5** | | | | | | | | |
| Nasopharyngeal Airway | Nasopharyngeal Airway 28F with Lubricant | Rusch Inc | B074BDN6G8 | 4/21 | 1 | 12.99 | 12.99 | airway |
| **TOTAL:** | | | | | | | | **$71.84** |

# C. MATLAB Tension Analysis Code

```
% Close figures and clear out other variables that have been assigned
close all;
clear all;
% Load your data file, replacing the '...' below with your filename
file="CompressionTest.txt";
data=load(file);
% Extract the columns of interest from your data
displacement = data(:, 1) * 1000; % [mm]
load = data(:, 2);              % [N]
time = data(:, 3);              % [s]
sample_rate = 45869 / 458.984;
area = 2.642;
data_coords = readmatrix("CompressionTest.txt", "range", "A12:C45869");
[b, a] = butter(4,1/(0.5*sample_rate), 'low');
filtered_data = filtfilt(b,a,data_coords);
filtered_time=filtered_data(:,3);
filtered_force = filtered_data(:,2);
filtered_displacement = filtered_data(:,1);
stress = filtered_force ./ area;
strain = filtered_displacement ./ 52.7;
% Record the first and last frame of the linear region of the loading curve
```

```
j1 = 200;    % replace with your value
j2 = 800;    % replace with your value
% Plot stress vs strain curve
figure;
plot(strain, stress);
xlabel('Strain [-]');
ylabel('Stress [MPa]');
title('Stress vs Strain Curve');
% Plot linear region
hold on;
plot(strain(j1:j2), stress(j1:j2), 'o');
xlabel('Strain [-]');
ylabel('Stress [MPa]');
title('Stress vs Strain Curve');
% Fit linear region and display equation
p = polyfit(strain(j1:j2), stress(j1:j2), 1);
fitline = polyval(p, strain(j1:j2));
plot(strain(j1:j2), fitline, 'r');
legend('Data', 'Linear Region', 'Linear Fit');
equation = ['y = ', num2str(p(1)), 'x + ', num2str(p(2))];
text(0.1, 1.5, equation);
% Plot load vs time curve
figure;
plot(filtered_time, stress);
xlabel('Time [s]');
ylabel('Stress [MPa]');
title('Stress vs Time Curve');
```

## D. Clinician Experience Survey

| | |
|---|---|
| How was the overall intubating experience? | Highlight the rating 1-5 (5 being the best):<br>5 4 3 2 1 |
| How was the overall compression experience? | Highlight the rating 1-5 (5 being the best):<br>5 4 3 2 1 |

| | |
|---|---|
| How accurate was the manikin compared to a 22-23 week neonate in terms of size? | Highlight the rating 1-5 (5 being the best):<br>5 4 3 2 1 |
| How accurate was the manikin compared to a 22-23 week neonate in terms of skin texture and quality? | Highlight the rating 1-5 (5 being the best):<br>5 4 3 2 1 |
| How accurate was the manikin compared to a 22-23 week neonate in terms of anatomical features? | Highlight the rating 1-5 (5 being the best):<br>5 4 3 2 1 |
| If you could add one portion to make it more realistic, what would it be? | List your suggestion below: (write N/A if not applicable) |

## E. Fabrication Protocol

a. Mix 160 mL of water and 40 g of ballistics gel powder into a beaker to make 200 mL of ballistics gel
b. Stir the mixture in a beaker until fully liquid
c. Let sit in fridge for 2 hours
d. Heat ballistics gel in a beaker over a hot plate at 260 degrees Fahrenheit while stirring, until consistent
e. Put the beaker in a vacuum degasser for 30 minutes to eliminate bubbles
f. Apply a layer of “Smooth-On Universal Mold Release”, to the inside of each half of the Tough Polylactic Acid (PLA) mold of the baby

g. Let sit for two minutes
h. Apply second layer of Smooth On to each half
i. Let sit for two minutes
j. Pour 70 mL of previously made ballistics gel into each half of the mold.
k. Cover each half in parafilm covering
l. Put it in the fridge for 24 hours
m. Removed from fridge
n. Hollow out the chest cavity of the model
o. Put lungs with t-connector in cavity and run it through the mouth hole
p. Acquire beaker to make gelatin based glue
q. Mix 15 g of gelatin powder with 240 mL of cold water in a bowl.
r. Once the gelatin powder is completely dissolved, add in 15 mL of boiling water, stirring continuously until the mixture is blended.
s. Allow glue to cool and thicken.
t. Spread a layer of glue on each half of the ballistics gel
u. Press together each half of the ballistics gel neonate and refrigerate again.
v. Wait a couple hours and the model is complete

## F. Tensile Testing Protocol

a. Make cylindrical sample of ballistics gel in petri dish
b. Use a scalpel to cut sample into three dog bone shape, smaller samples
c. Measure the samples' dimensions, specifically width and thickness (mm)
d. Put tension grips into MTS machine
e. Fasten one sample into each end of the grips
f. Set the program onto tensile testing and add the measurements for the specified sample
g. Start the program and let it run until the sample breaks
h. Save the data for future analysis
i. Repeat steps 4-8 for the other two samples

## G. Compression Testing Protocol

a. Select 3 samples of ballistics gel of appropriate thickness and area for use on the MTS machine in ECB, and do your best to ensure that the sample is as uniform as possible within the sample and among the other samples.
b. Equip appropriate compression testing plate heads onto the MTS testing loads.
c. Power up the MTS machine and open the MTS software. Open a new test.

d. For each sample, conduct the following...
    i. Measure and record the length, width, and thickness of the agar sample.
    ii. Put this information in the appropriate text-entry prompts in the MTS software for your new test.
    iii. Place the sample centered on the compression plates.
    iv. Double-check that everything is looking right before you run the test.
    v. Unlock the machine and select run test.
    vi. Collect compression testing data until failure-- should look like a sudden dip in displacement.
    vii. Stop the machine and take picture of a sample where you believe failure to be located.
e. Use data analysis to identify elastic modulus and failure load following this example.
    i. Elastic Modulus and Ultimate Strength --Yield point does not apply to the elastic material.

## H. 3D model of the PLA mold

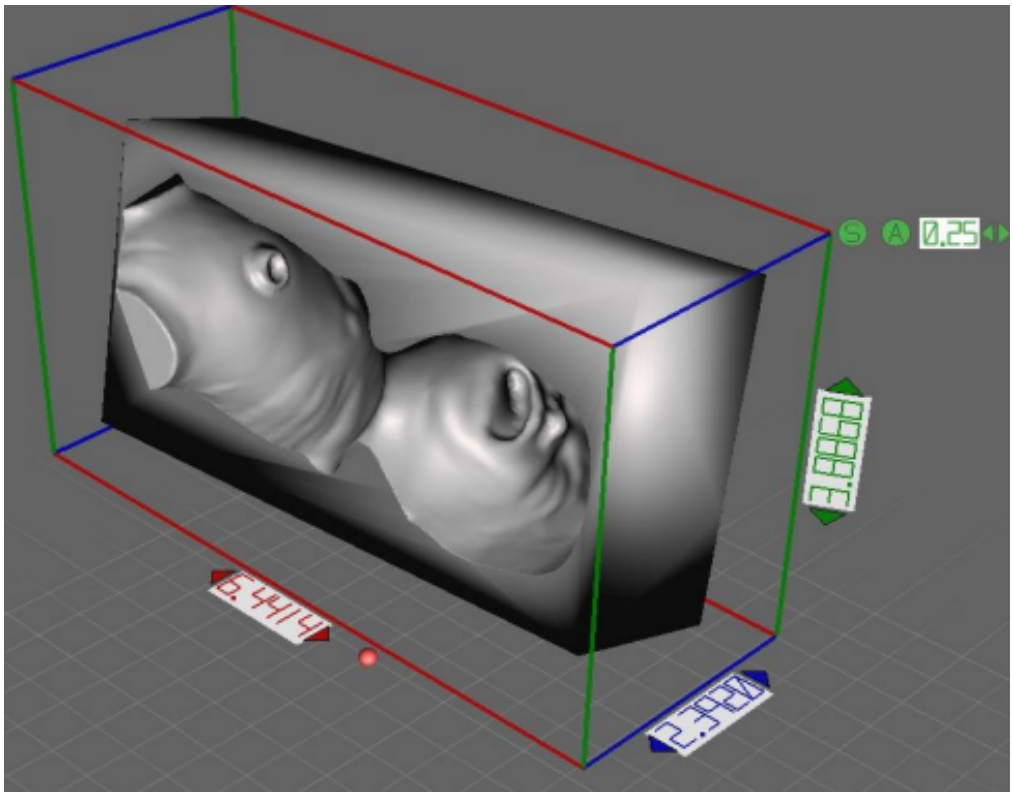


Figure 9: 3D model of PLA mold with Laerdal's Premature Anne Scan [7]