



Motivation

A pneumothorax occurs when air or liquid enters the pleural cavity, the space between the visceral and parietal pleura, caused from the rupture of a bullae or a trauma related injury to the chest¹. Neonates are more susceptible to a pneumothorax due to the need for respiratory support. While risks of the condition are high, a thoracostomy is performed to alleviate pressure build-up. Medical training devices bridge the gap between learning surgical skills and performing them in the real world. Training devices provide physicians with the opportunity to practice skills confidently to ensure a patient is cared for properly². Current training devices target adult patients and provide uses from intubation to thoracostomy simulations, causing a lack of training when procedures are necessary for neonates.

This project is required to fulfill the need for a neonatal sized training device that can realistically simulate a pneumothorax and feedback that occurs after a thoracotomy procedure is performed successfully. The primary objectives to fulfill this obligation are to generate a realistic sized device that accurately replicates a neonatal infant. The device will properly train physicians on how to perform the necessary thoracostomy procedures and is both reusable and durable to ensure a long lifetime of use.



Customer Expectation

Parkview Mirro Center for Research and Innovation requested a variety of components to be integrated into the trainer to ensure there is a realistic experience for training physicians. There was a major emphasis placed on reusability, durability, and realism due to the limitation of quality for in-house neonatal trainers.

Palpable Ribs

Landmark Regions

Positive Air Feedback

Reusable

As Small as Possible

Table 1: Phase 1 Project Scope Tasks

Tasks	Designation
Ribcage Design	А
Airtight Seal/Membrane Design	А
Skin (Permanent & Patches)	А
Positive Air Feedback	А
Validation Testing	А
Negative Air Feedback	В
Cost Optimization	В
Carrying Case	С
Embroidered Scrubs for Trainer	С

Validation

The neonatal thoracostomy trainer was validated by trained physicians to show that the thoracostomy model provides a realistic experience compared to a neonatal patient. All three physicians (Neonatologist, Respiratory Therapist, and Podiatrist) with different levels of training strongly agreed the trainer is both anatomically correct and serves as a good learning tool for future physicians. Their responses corresponded to a 5-point Likert scale survey after using the trainer, which helped distinguish if any further remediations would be required to optimize the design.



Image 2: Neonatologist performing thoracostomy procedures on trainer to validate realism

Neonatal Thoracostomy Trainer

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Design Components

3D Modeling

Ribcage and Membrane Boxes: The pneumothorax boxes were modeled using SolidWorks[™] and added onto an open-source rib cage model. To increase accessibility, a hinge was integrated into the spine. The back of the boxes were also modeled in Solidworks with a force fit design and force sensors/tubing openings. Final model was 3D printed using PLA+.

Circuit Casing: A casing for the electrical components was modeled in SolidWorks[™] with an opening for the solenoid, wires, LEDs, and battery. Final model was 3D printed using PLA.

Permanent Skin: A permanent skin was modeled in Blender to be placed on top of the internal components to include the necessary anatomical regions needed for procedure success. Final model was 3D printed using Polyjet Elastic on the Stratasys.



Image 3: Modified ribcage 3D mode *Dimensions in inches

mage 4: Permanent

0.164 m

skin 3D model

Consumables

Skin Patches: Realistic skin patches were created using shore OO-30 silicone, silicone pigment, and mesh. They were validated to have a realistic puncture resistance and ability to palpate ribs underneath. Each patch has an epidermis, fat (with mesh), and muscle layer totaling a thickness of 0.48 cm. Each patch can be reused 20-30 times.

Parafilm (Membrane): Parafilm was determined to be the best material to replicate the pleural membrane while keeping an airtight seal after puncture. Each piece can be reused 3 times for needle decompression and once for chest tube insertion.

Image 5: Completed prototype with rib cage, membrane boxes, skin patches, permanent skin, feedback system, and compressor

Feedback System

Positive Feedback: When physicians perform a thoracostomy, they must be able to remove air with a syringe attached to the originally inserted needle/chest tube. To model this air, a compressor outfitted to a solenoid pressurizes the boxes after pressing the button on the front of the electrical casing. A blue LED lights up when the button is pressed to indicate air is entering the membrane boxes. Pressurization takes 5-10 seconds.



Negative Feedback: To help physicians know if the needle is inserted too far into the box, a force center was placed on the back that triggers a red LED if depressed. The sensor is sensitive enough to detect a needle poke, but not too sensitive to be set off by incoming air pressure within the box.

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Testing

Material Testing

Hardness: Performed to ensure silicone patches simulated the neonatal skin mechanical properties, with a range of shore <u>OO-10 & OO-30³</u>. Used ASTM D2240. A silicone sample size of n=30, containing 3 layers with a total thickness of 4.8 mm, were tested utilizing a shore OO durometer. Average hardness was OO-31.47± 1.53. A P-value of 7.12×10^{-14} was obtained through a one-way ANOVA and compared to $\alpha = 0.05$.

Puncture Resistance: Utilized to further analyze the accuracy of the silicone samples simulating neonatal skin. The standards ASTM F1306 and F2878-19 were used to create a protocol and testing apparatus. Using an Instron machine, a 3D printed novel stabilizing apparatus, and a 3D printed novel probe containing a 25G needle, found the maximum force required to puncture through silicone samples with a thickness of 4.84 cm. N=30 silicone samples were required with a target maximum force of 0.5 N to 1 N^{4,5}. An average of 0.6221± **0.102** N was determined, with a P-value of 5.03×10^{-13} obtained from a one-way ANOVA and compared to $\alpha = 0.05$.





imensions in inches*

Drop Testing

To ensure the trainer would withstand long term use, drop testing was performed to assess points of weakness. Standard MIL-STN-180 was used as a guideline to determine that the model needed dropped on all 6 faces 6 times for a value of n=36. The 3D printed internals received no damage while the 3D printed skin had a small fracture at the bottom edge leading to a conclusion on no necessary structural remediations.

Conclusion			
Customer Requirements	Completed	Additional Features	Cor
Palpable Ribs		Negative Feedback	
Landmark regions		system	
Positive Air Feedback		Positive Blood Feedback	
Reusable		Scrubs	
As Small as Possible		Case	

References

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Image 6: 3D printed membrane boxes with integrated sensor & tubing

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