

BMED 456 - BCPAP Infant Interface Redesign

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Neonatal Respiratory Therapy Interface

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Executive Summary

This Final Report reviews and outlines the scope, objectives, and deliverables for the BCPAP Interface Redesign project, aimed at enhancing the functionality, usability, and patient experience of the existing BCPAP interface. It also includes detailed testing results and manufacturing plans for the device prototype. The current system has challenges in universal usability, time constraints, and patient comfort, which this project intends to address effectively. The goal of this project is to reevaluate and redesign the interface of the bubble continuous positive air pressure (BCPAP) machine's attachment site with the infant. Due to the millions of premature neonates and thousands of those suffering from respiratory distress syndrome born every year, and the urgency required when attaching infants to these devices, there exists a need to improve the efficiency and speed of attachment by nurses and respiratory therapists to increase the likelihood of infant survival. This document first provides an introduction and background detailing the necessity of the BCPAP machine and some of the current issues experienced by clinicians when attaching this device. Then, current commercially available devices manufactured by various companies are outlined in addition to the rules, regulations, and codes that the redesigned device will follow. Following this, a preliminary patent search detailing patented BCPAP interface technologies is outlined. An analysis of the current market potential discusses the financial potential of creating a successful, novel device redesign. The objective section clearly states the scope of this project and includes a problem statement, project definition, indications for use, customer requirements, Quality Function Deployment, and engineering specifications. Following this section are photos and descriptions of a more detailed design prototype, as well as manufacturing plans for the prototype, followed by test plans detailing what criteria of the design will be tested and how. The test plans also include the expected outcomes of each test. Photos and descriptions of following iterations are also included, as well as the results for testing of the final prototype and feedback from Dr. Van Scoy and Sierra Vista respiratory therapists. The data presented in this document supports the successful redesign of the BCPAP interface and demonstrates the project developed to meet the goals outlined for the scope of this work. This document has been constructed and agreed upon by the four student biomedical engineers involved in this project.

Introduction

The stakeholders have been updated to include parents.

A Bubble Continuous Positive Airway Pressure (BCPAP) machine is a sophisticated medical device designed to help babies, especially premature, maintain positive pressure in their lungs. It is a crucial device for respiratory support for patients who have Respiratory Distress Syndrome or general breathing difficulties. This machine offers a non-invasive option of delivering a continuous flow of oxygen enriched air, under positive pressure, to help maintain lung function and alleviate respiratory distress. The development of the BCPAP machine has been an invaluable tool used in neonatal intensive care unit (NICU)'s and pediatric wards worldwide. This project aims to redesign the interface of the BCPAP machine to the infant to increase efficiency and ease of attachment in the hospital. The stakeholders in this project are the nurses and

respiratory therapists who routinely attach these medical devices to the patients. Additionally, parents have been identified as stakeholders due to the unsightly and anxiety inducing view that the current interface causes. The background section provides information on the existing information that will impact the project. The objectives section will set the scope of the project. The section discussing Project Management will outline the steps taken by our group to ensure the project remains on task. The conclusion demonstrates the next tangible step in this process, and the appendices provide additional information used to generate this document.

Background

According to the National Library of Medicine, an astounding 15 million babies are born prematurely, and about 1% (150,000) babies will develop Respiratory Distress Syndrome (RDS). Additionally it was determined that neonatal respiratory distress syndrome was the number one cause of death in premature infants (Baldursdottir, Dyer). The BCPAP machine was designed to help infants maintain a positive pressure in their lungs. These babies often have respiratory distress syndrome (RSD) which is a common respiratory disorder that affects premature infants (those often born before 28-32 weeks of gestation. This condition arises because the lungs of premature babies are often underdeveloped, particularly in the alveoli, the tiny air sacs where oxygen and carbon dioxide exchange occurs. In infants with RDS, the lung's alveoli lack the necessary surfactant (a substance that prevents the collapse of the air sacs during exhalation and helps them to expand easily during inhalation). Because the baby's lungs lack surfactant, the affected infants experience significant difficulty in breathing and oxygen exchange (Han). Respiratory distress syndrome has a profound effect on infant mortality and development. It can cause CO₂ build up in the first 48 hours after birth increasing the likelihood of mortality, organ collapse, and other complications. It can cause hypercapnia. RDS is highly prevalent in pre-term babies and is responsible for 50-70% of premature infant death (Liu).

The history behind the BCPAP machine has profusely demonstrated the persistent pursuits of improved healthcare solutions for newborns, especially premature. Previously, babies who had breathing difficulties had to be on ventilation support. This was not a great solution because this often led to irreplaceable damage to the baby's lungs. While the ventilators kept the baby alive, it often caused a series of various problems for the baby's health. When the BCPAP machine was created, it was a great new solution to the problem. The babies that could not maintain a positive pressure in their lungs, now had a way to help them breathe naturally, while not damaging their internal organs.

The BCPAP machine is an innovative apparatus that delivers a continuous stream of oxygen enriched air into a patient's airways, preventing airway collapse and promoting effective lung expansion. The BCPAP machine generates bubbles in the water chamber, which not only ensures a consistent flow of pressure but also humidifies and warms the inspired air, making it gentler on delicate airways. The BCPAP machine plays a vital role in improving oxygenation, reducing the need for more invasive respiratory interventions, and enhancing the overall well-being of patients in need of respiratory support.

While the BCPAP machine has been a fruitful effort in the world of medicine, there are still some issues with the design that have been suggested by nurses who use the device in industry. Based on numerous conversations held with clinicians surrounding this topic as well as observations noted by biomedical engineers in the neonatal intensive care unit (NICU), the following issues have been identified with the BCPAP interface. Firstly, it takes a long time to put on and that it encompasses the majority of the baby's face when they are wearing it. The BCPAP machine takes a long time to put on for a number of reasons. The first reason is because not all premature infants are the same size. Because of this fact, nurses have to measure the circumference of the baby's head, take a nostril measurement, and measure the length of different trunks to best suit the baby. Taking these measurements can often take a long time because the baby fuses around and the measurements are tiny so they can often be hard to read. The amount of time it takes to put on the BCPAP machine on a newborn is crucial because the faster the machine is put on, the faster the baby can start breathing normally. Also, the sooner the baby is put on the BCPAP machine, the sooner the doctors and nurses can take vitals and other important measurements for further testing of the newborn's health. Another problem established with the current BCPAP machine is that the mask and trunk of the machine often encompasses much of the baby's head and face. This can look very daunting and scary to new parents and can be very uncomfortable to the infant because it restricts their movement.

There are currently a number two main interfaces used in hospitals and medical clinics around the world. The first design often uses the U-tube method where two tubes are placed on each side of the baby and are connected by a middle tube that attaches to the baby's nose. The other method commonly used is the use of a trunk where both tubes are connected together that is placed on the front, center part of the baby's face. In both of these commonly used interfaces, there are many parts that need to be connected together which take a long time to assemble and take up a lot of space on the baby's face. Some of the current interface designs are noted in *Table 1*.

Company	Notes
Fisher & Paykel	FlexiTrunk Interface sizing consists of 11 nasal prongs, 4 nasal masks, and 3 nasal tubing lengths ("Fisher & Paykel")
Draeger	BabyFlow Plus has six different sizes and a detachable chinstrap, connected by four velcro straps ("Dräger BabyFlow")
Besmed	The NP-Flow Nasal kit consists of four different bonnet sizes, and seven different nasal prong sizes ("NP-Flow Nasal")
Respiralogics	The Babi.Plus Cannula Kit has 8 different cannula sizes, a cap, and tubing clips ("Babi.Plus nCPAP")

Create-Biotech	Create-Biotech has 8 sizes of nasal prongs, connected by a single velcro strap on the forehead of the infant (“Bubble CPAP”)
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Table 1. Demonstrates the current designs of the BCPAP Infant interface used in industry and compares the different companies that create them.

When thinking about a new interface design for the BCPAP machine, it is important to consider rules, regulations, and industry codes to follow:

- ISO 80601-2-72: This international standard specifies particular requirements for the basic safety and essential performance of respiratory humidifying equipment (including Bubble CPAP interfaces)
- ISO 10993: This standard pertains to the evaluation of biocompatibility for medical devices. It is used to address potential risks related to the materials used in BCPAP interfaces, ensuring that they are safe for contact with the infant's skin or mucous membranes.
- ISO 13485: This standard outlines the requirements for a quality management system specific to the design and manufacture of medical devices. It's essential for ensuring consistent quality and compliance throughout the product development process.
- FDA Regulations (in the United States): This includes adhering to regulations for medical devices, ensuring safety, effectiveness, and quality control.
- CE Marking (in the European Union): It indicates compliance with the European Medical Device Directives or Regulations. These regulations ensure the safety and performance of medical devices.
- Local Healthcare Facility Standards: BCPAP interfaces are typically used in healthcare facilities like neonatal units, so they must also comply with the standards and protocols established by those facilities. These may include guidelines for infection control, cleaning, and maintenance.
- Clinical Guidelines: Following clinical guidelines established by medical organizations and experts in neonatal and pediatric care is crucial. These guidelines often dictate the best practices for using BCPAP interfaces with infants, ensuring their safety and effectiveness.

Objectives

Problem Statement

The aim of this project is to improve the interface between the BCPAP machine and newborn infants so that it is more efficient, requires less components, and maintains the effectiveness and security of the current standard of care.

The scope of the project does not involve modifications to the BCPAP machine itself, which includes the gas delivery trunk which supplies the air to the baby. The project rather focuses on the attachment of such devices to the face of the infant, including but not limited to headgear, bonnets, chinstraps, and attachment sources.

Indications for Use

The Indications for Use have been adjusted to mention patients that qualify for existing BCPAP therapy.

The redesigned BCPAP interface is intended to be combined with existing BCPAP technology to provide respiratory support to neonates. This interface should be used for neonates who qualify as candidates to benefit from BCPAP respiratory therapy. These are outlined as those who can breathe on their own, but have a condition that causes them to require additional respiratory support. This system should be able to be utilized by patients ranging from micro-premature neonates to infants up to 12 pounds.

Customer Requirements & Quality Function Deployment

We have understood the sponsor requirements of this project to be largely focused around time to place, safety on the patients' skin, and not obstructing a large portion of the face and head. Some other wants for this project include not needing an exchange of components, or sizing, adjustable components, and costing as much or lower than current options on the market. We summarized these customer requirements, and translated them into engineering specifications, in the House of Quality chart found below. The full list of the customer requirements are specified in Appendix A-1.

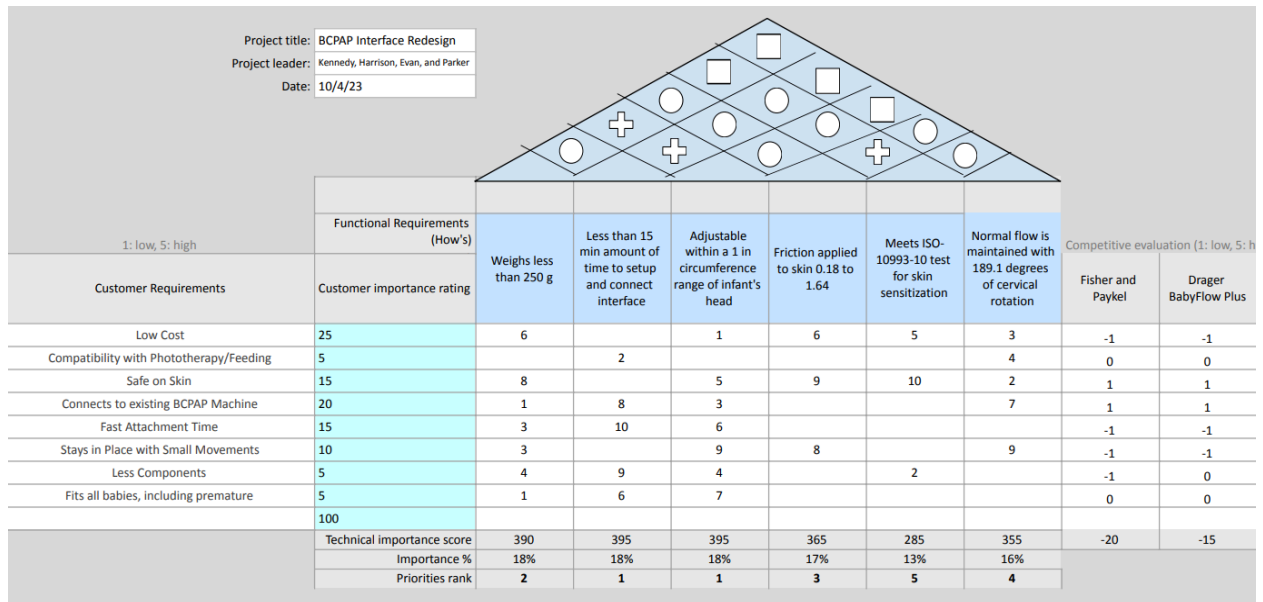


Figure 2. Initial House of Quality diagram for the BCPAP interface

We generated *Table 3* to outline the engineering specification requirements that are pertinent and necessary to the creation of the interface redesign. The compliance column details A, T, and/or S, as analysis, test, inspection, or similarity to existing design.

Engineering Specifications Table

Spec #	Parameter Description	Requirement or Target (units)	Tolerance	Risk	Compliance
1	Weight	250g	Maximum	Low	A, T
2	Time	15 minutes	Maximum	Medium	A, T
3	Adjustability	1 inch	Minimum	Medium	A, T
4	Friction	1.64 N	Maximum	High	A, T, S
5	Safety	Meets ISO 10993	Must meet	Low	T, I
6	Range of Motion	189.1 degrees	Minimum	Low	T

Table 2. *Engineering Specifications and testing plans and risks*

- **Spec 1:** For the safety of the infant users of this device, the weight of the device measured from the trunk and surrounding attachment materials must weigh less than 250g.
- **Spec 2:** The time taken to put on the device must be less than 15 minutes, including any time to size devices. We can test this using an artificial infant model with nurses or laypeople with instructions.
- **Spec 3:** As a main goal of our project, our device must be adjustable to at least one inch around the infant's head. This will be easy to measure, but can also be tested on a variety of infant head sizes.
- **Spec 4:** To reduce skin irritation where the interface comes in contact with the infant's skin, the device should have a force of friction no greater than 1.64 N.
- **Spec 5:** We plan to follow ISO 10993 guidelines for the material(s) of our device to ensure safety on the skin of infants
- **Spec 6:** The device must have a range of motion of at least 189.1 degrees without becoming displaced, to ensure that the interface will be secure while the infant moves.

In this chart, we found some of the most important engineering requirements for this project to be adjustable within a one inch circumference of an infant's head, less than 15 minutes of setup time, and weighing less than 250g. We expect some engineering requirements to change or be added as we move forward with concept creation and evaluation further in this process.

We expect most of these engineering requirements to be tested in relatively inexpensive and efficient manners. The highest risk specifications will be skin sensitization and the friction constant between our device and infant skin, because infant skin is extremely sensitive. Preterm infants are very susceptible to transdermal infection, making these tests important and vital to the safety of infants while using our device.

Project Management

In the design process of our new BCPAP interface, we will focus on several key deliverables and milestones that are essential to developing a successful solution. This process will include meeting at least twice weekly to work on project components. Each project deliverable has an expected timeframe and deadline to ensure that we stay on track and can continue to move forward with the project. The beginning stage of the design process is focused on understanding the problem we hope to solve and the requirements for the project. Next, we will focus on brainstorming and concept development, focusing on ideas that will meet the project requirements and desired function. From there, we will make decisions about the interface design and begin working on a conceptual model, followed by failure mode and effects analysis and risk assessment. The design process for the winter quarter will include prototyping and bench testing of the device. A Gantt chart was utilized to outline the proposed schedule for our project. All reasonable effort will be made to adhere to the chart's schedule, but it is a living document, so adjustments may be made throughout the course of this project. The full Gantt Chart is detailed in Appendix A-2.

Because this project has a solid foundation, including an early-stage prototype, the design process will include building off of prior design ideas, as well as generating new concepts. Early prototyping of the device will also be an option to allow us to visualize design ideas. Utilizing a model infant doll, prototypes will be tested for security and attachment with this model. Additionally, we will seek input from Dr. Van Scoy to get feedback and suggestions from a neonatologist and ensure that our designs are feasible and effectively address the target problems.

Key Deliverable	Timeline
Concept sketches	Oct 18-23
Pugh chart	Oct 23-25
Conceptual model	Oct 27-Nov 1

Critical design review	Nov 15-27
Winter quarter project plan	Nov 29-Dec 5

Table 3. Key deliverables and their expected timelines

The critical path of our design process consists of concept sketches, Pugh matrices, a conceptual model, failure mode and effects analysis, a critical design review report and presentation, and a plan for continuation into the winter quarter.

Morphology

In order to begin a conceptual design for our product, we decided to break it into different functions that could have different options for production. The three main functions we addressed were tightening, attachment to infant, and attachment to BCPAP. Brainstorming different concepts allowed us to create the following morphology to reference when creating drawings for our device.

Morphology						
Product: BCPAP Interface		Organization Name : BCPAPtastic				
Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
Tightening	Tightening dial with cord	Large Velcro Sections	Small velcro sections pulled by a cord	Double ring belt	Buckle	Bungee straps
Attachment to Infant	Headband	Multiple straps around head	Straps around ears	Strap around base of head		

Attachment to BCPAP	Hole + Connection	Directly attached to trunk from nosepiece	Hole through piece of trunk/nose	Strap over/around trunk		
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Table 4. Morphology with key device functions and corresponding design concepts

Concept Evaluation

Based on the morphology shown by table 4, several concept sketches were developed to provide visualization of various aspects of potential BCPAP interface designs. These concepts were then evaluated using a Pugh chart to determine a leading concept.

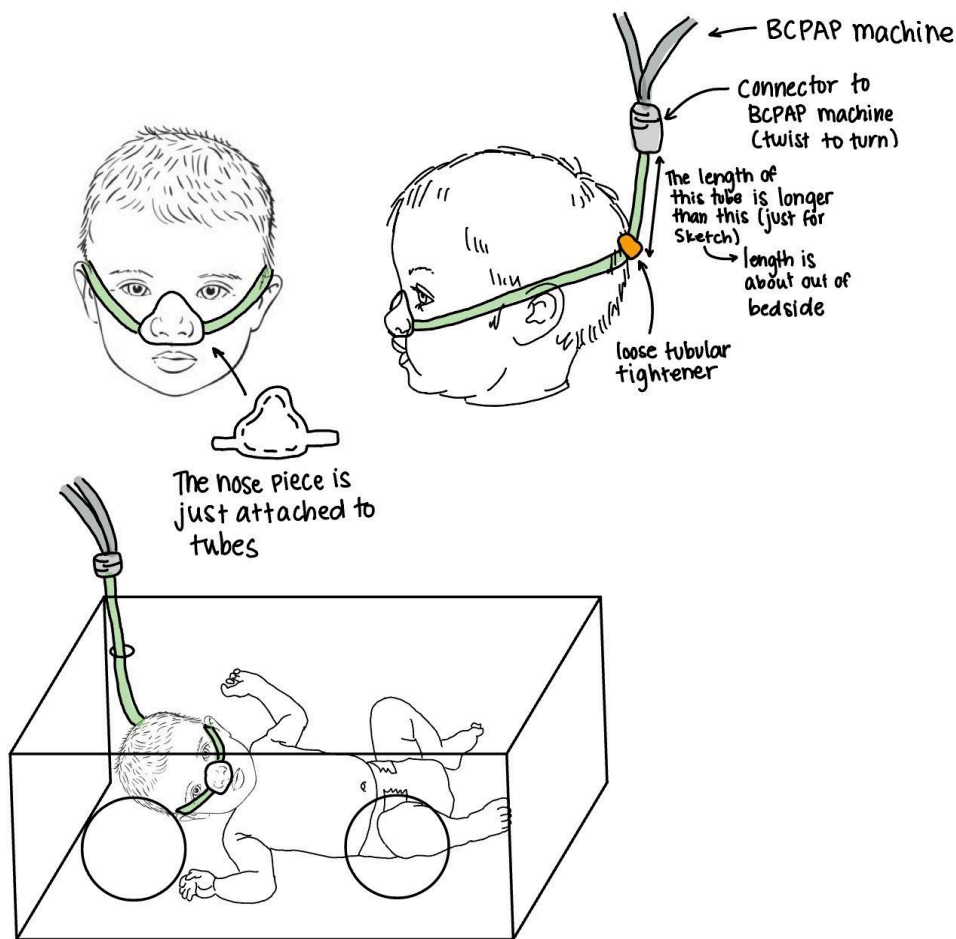


Figure 3. Concept sketch for interface with redesigned trunk connection

This concept was based off of the Neotech RAM Cannula Nasal Oxygen Cannulas, but applies the similar design to the BCPAP machine. It moves the main part of the standard interface away from the baby's face and outside of their crib (sleeping box used in the NICU). The mask will have automatic suction (like a pair of goggles) and maybe a bit of adhesion. The tubes will be bigger but still a soft material for comfort. All

of the pieces are going to be one part in different sizes so that only one measurement needs to be taken. Our different sized masks will be able to just attach to any BCPAP machine.

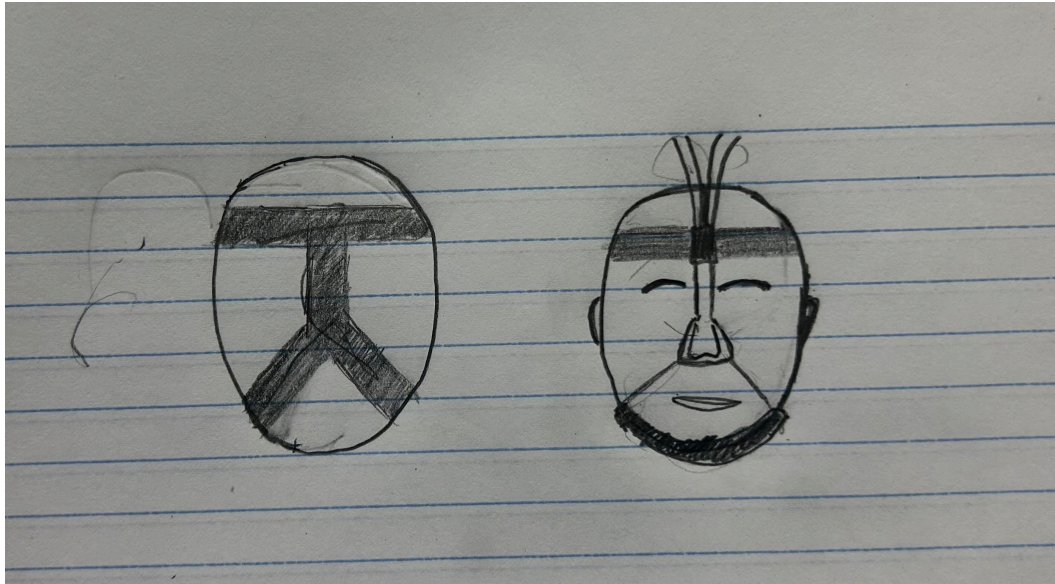


Figure 4. *Concept sketch for redesigned interface with chinstrap*

This concept is based on the trunk connecting to a chinstrap via two adjustable (thinner) straps that are adjustable on the small hooks on the existing trunk/mask. The chinstrap would connect in the back of the head, and move into a T-shaped strap that goes around the trunk on the forehead. This top portion would also have an adjustable component with velcro, that would allow the system to become a single piece, and adjustable on the top and bottom. The idea is that adjusting the trunk-chin straps and the top strap would allow for the components to tighten off of one another and create a secure interface.

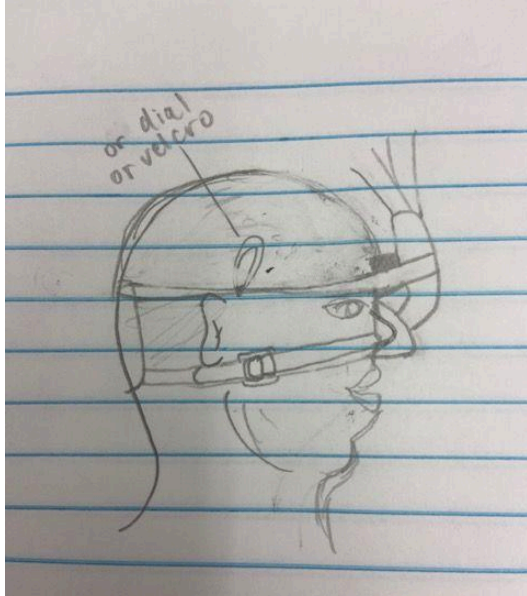


Figure 5. Concept sketch for interface with new adjustment features

This concept consists of two straps joined at the back of the baby's head, with the bottom strap at the base of the head and connecting to the cannula, and the top strap wrapping around the trunk to secure it in place. The straps could be adjusted by a tightening dial with cord embedded in the fabric. The goal of having one strap below the ears and one above is to secure the device and prevent it from sliding up or down with as few straps as possible.

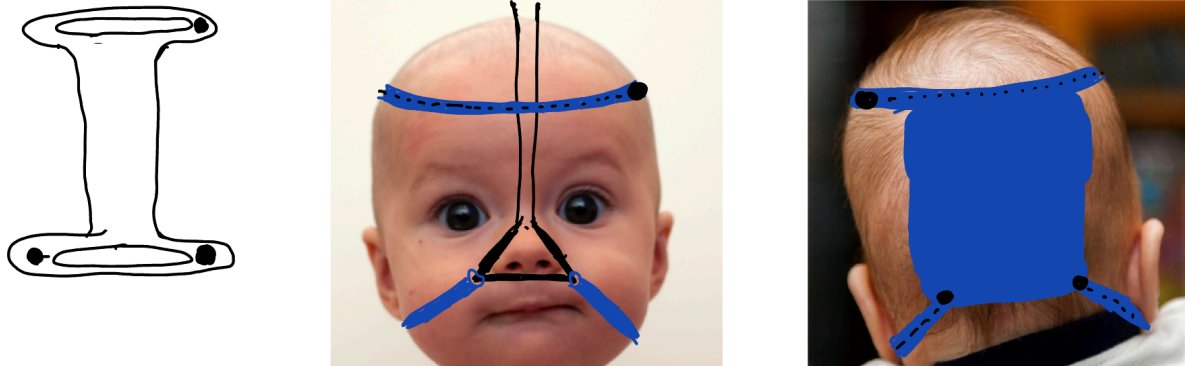


Figure 6. Concept sketch for one-piece adjustable interface

This concept incorporates an attachment piece that is made of one piece of material that has cord sewn in to facilitate tightening of the strap. The tightening component would be similar to the technology used on cycling shoes. This would allow nurses and other clinicians to adjust the device as needed. The straps attaching to the hooks of the mask point downward, preventing 'north south' movements. The larger material on the back of the head would swaddle the infant's head, providing support while the remaining straps are placed and tightened.

These concept ideas were then compared to the basel

Pugh Chart

Issue	Weight	Fischer & Paykel	Chinstrap	Cinch + Straps	Buckle and Cinch	Circle Nose Tube
Low Cost	25	Datum	1	1	1	1
Compatibility with Phototherapy/Feeding	5		1	1	1	1
Safe on Skin	15		0	0	0	0
Connects to existing BCPAP Machine	20		0	0	0	0
Fast Attachment Time	15		0	1	1	1
Stays in Place with Small Movements	10		1	1	1	0
Less Components	5		1	2	1	1
Fits all babies, including premature	5		1	1	1	0
			0	50	70	65

Table 5. Pugh chart comparing four design concepts against Fisher & Paykel datum

Based on our joint Pugh chart, the cinch and straps concept is the current front-runner. This concept has the fewest components and offers improved cost, compatibility, stability, attachment, and fit compared to the baseline Fisher & Paykel interface. It consists of only one component, which wraps around the baby's head and keeps the trunk secured. Reducing the number of components of the interface has the potential to reduce the attachment time and simplify the attachment process. Additionally, it has BOA dials at various locations to allow for precise adjustment to ensure that the trunk is stable and that the interface as a whole fits more comfortably and securely on the baby's face. Compared to the other options, this feels like the best way to move forward with a concept that addresses all of the main concerns of our sponsors and our research.

Conceptual Model

In order to better visualize our conceptual model and explore potential weaknesses in our design, we created an initial, rudimentary real life model using scrap material.

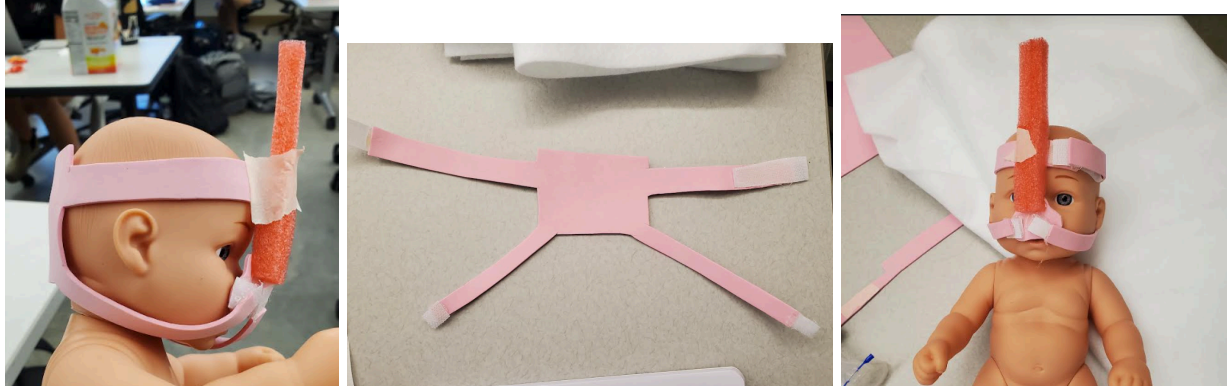


Figure 7. Side view, flattened aerial view, and front view of BCPAP interface model

Shown above are photos of said model, without the connections we will likely be using for our actual model. This process was largely to see if the interface design would fit on an infant head, be secure, and be able to attach to a trunk from the BCPAP machine (seen here in the red foam piece). This process was successful and a learning experience, as the mechanism seemed to be relatively secure, at least for the crude velcro attachments we were using. When holding the model upside down, shaking it, and putting pressure on the interface, it stayed attached to the face fully. Additionally, a snugness test was performed by tugging on the device in four directions. It was observed that the prototype remained firmly attached to the model's face. We expect that when we transition to a better material, with more defined connection points and connection methods, this security will increase even more. One of the concerns that was discussed included the potential for undesirable translation and movement of the device in the north south direction. However, if the device was tightened enough and the lower straps were fastened bilaterally underneath the mandible, this potential was mitigated.

After seeing this model in reality, we also brainstormed an idea to incorporate a bonnet rather than the top strap, with a tightening mechanism more similar to a bungee cord or a drawstring in pants. This could allow for a tighter connection on the top and the ability to connect the trunk of the device, but we have concerns about the ability to make a bonnet one size fits all, and to both tighten and connect to the trunk in one. This is an idea to potentially test once we have a higher functioning prototype created.

Moving forward we intend to obtain a more anatomically correct premature neonate model to test our interface redesign. Additionally, we plan to purchase elastic material to begin testing with fastening strategies.

FMEA

To determine potential ways a BCPAP interface could fail and the effects those failures would have on the patient, we completed failure modes and effects analysis, where we determine the likelihood, detectability, and severity of various failure modes, as well as potential ways to prevent failures and/or mitigate their effects.

Function Affected	Potential Failure Mode	Potential Effect(s) of Failure	OCC	DET	SEV	RPN	Cause of Failure	Recommended Actions
Maintain air tight seal on mask	mask detaches	air leaks from mask seal	5	2	5	50	insecurely fastened mask	Reattach mask per usual and ensure there is a tighter seal from suction in mask
	Baby Rolls +pushes mask off	Loss of air flow, baby loses breathing support	6	1	5	30	insecurely fastened mask	Ensure that rotation does not affect the function of the tubing with additional testing or attachment areas
Maintain airflow through tubing	pinches or kinks in the tubing	Air flow does not reach baby	3	3	3	27	Poor tube management/storage	Check to ensure that the tubing lays flat and flush as to not bend in any obvious places
	gaps in overlaying tubing	Air flow released through small gaps	2	4	3	24	Manufacturing defect or human connection error	Additional testing on connections and fastening in tubing
Prevents Skin Irritation	interface applied too tightly	Pressure Wounds, blood flow loss	7	7	6	294	Applied incorrectly by clinician	Improved instructions for use and/or teachings when given to hospital staff. Create system that alerts applier when proper tension/normal force readings are reached
Stable interface (trunk, mask, tubing) on baby	not properly secured on baby	was not applied tight enough, too loose	8	3	5	120	Applied incorrectly by clinician	Improved instructions for use and/or teachings when given to hospital staff. Create system that alerts applier when proper tension/normal force readings are reached

Table 6. Failure modes and effects analysis of BCPAP interface

Detailed Design

After creating the rudimentary conceptual prototype, we wanted to create a first model of a more detailed design, with some of our application ideas actually integrated in the design. As mentioned before, some of our potential methods of attachments include velcro, buttons and elastic, and a boa-dial adjacent system that could coil the system together. We gathered materials to test each of these, buying buttons, velcro, and boa dials to work with while prototyping. Although the boa dial seems like a promising idea, for the time frame of this quarter, as well as shipping time, any developments made on this idea will have to be done next quarter.

As such, we decided to make a more detailed design and more realistic prototype based on the button-based approach. We want to test the potential of the button-based idea, as a switch to velcro would be an easy change should the button idea fail or not seem to improve the standard of care. We believe that either way should be an improvement, and are testing the changes made based on one another.

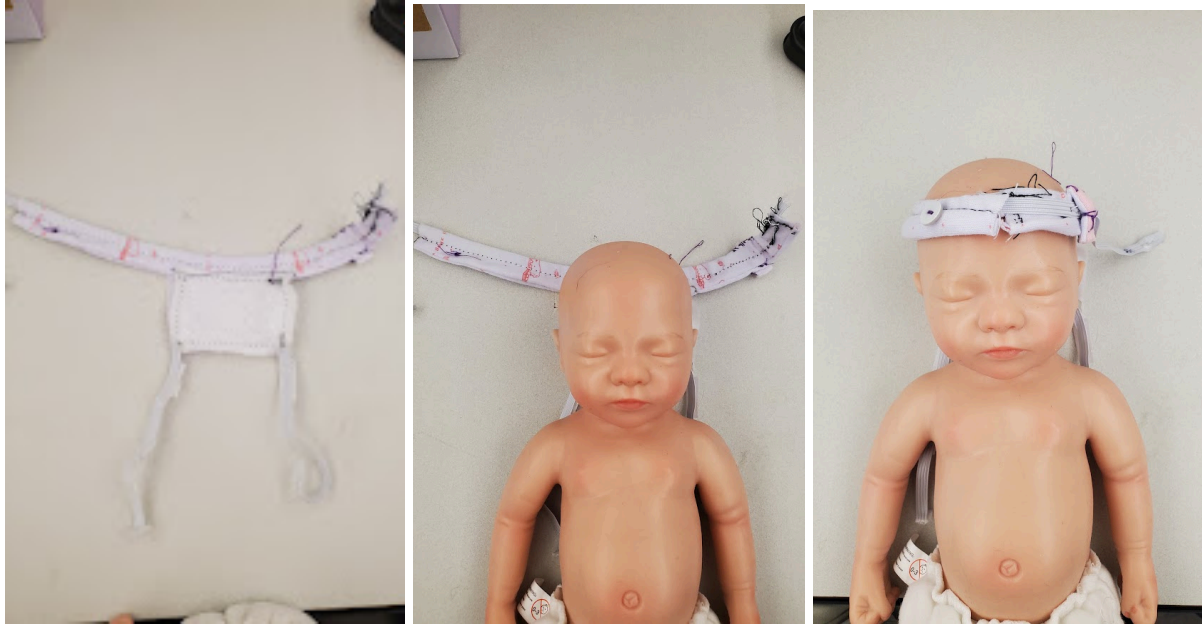


Figure 7. Flat view, and button attachment to baby model with new prototype

The new prototype includes the same solid back piece, with a sewn top part containing an elastic material. The elastic material is sewn on one end to the blanket material to lock it into the system. A button is sewn on one end, and various small holes are cut on the other end as a way to size the system for the baby's head. The top piece can be strapped across the forehead, and fit into the button hole that best fits with the baby's head size. The smaller elastic straps connect to the mask hooks that exist already on BCPAP masks, and loop around to velcro back down to the bulk blanket square on the back of the head, as seen in the figure below.

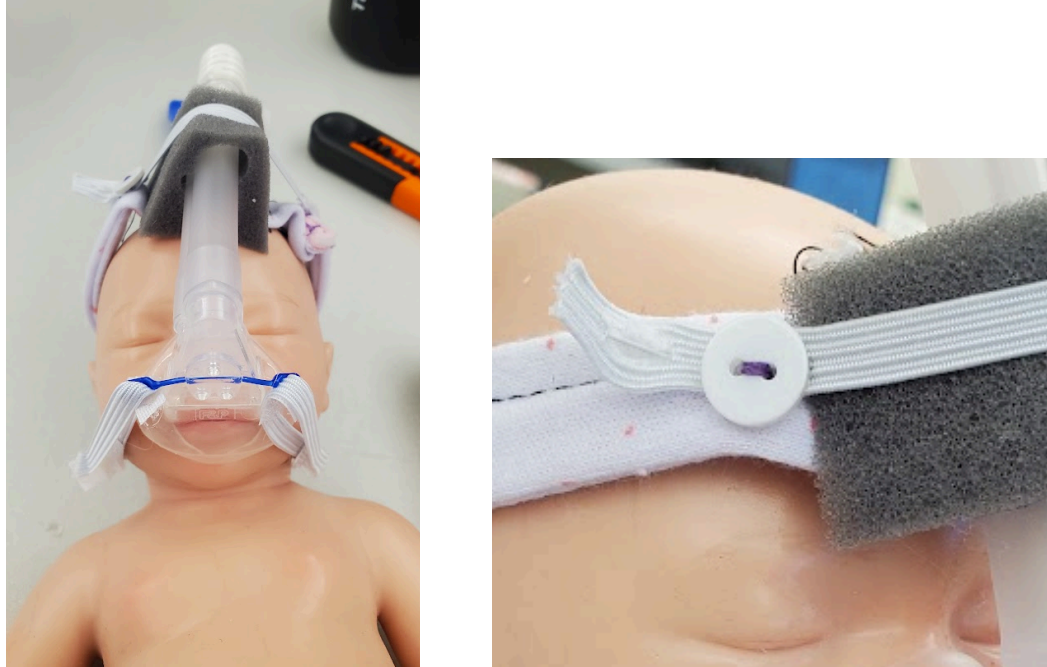


Figure 8. *Loops attaching to the mask (left) and close up of button attachment with mask (right)*

While this prototype is obviously still not at a quality ready for true production or testing, creation of this more usable, self-sufficient prototype gives us as a team confidence about our design and how we can move forward next quarter. We plan on getting better material, likely NeoFoam, and can use similar concepts seen here once we have that material.

Test Plans

Although our next step is to create a better prototype for testing that will be closer to where we want our final model to end up, we have started to think about some tests that we want to perform to demonstrate the efficacy and safety of our device. Some tests are to make sure the device will function as planned, in a safe manner in regards to the neonates, and some tests are to see if our device will be an improvement over the current standard of care.

Specification	Test Type	Sample Size	Facility	Equipment
Fast interface setup	Time trial	10	Sierra Vista Regional Medical Center	Interface prototype, BCPAP machine, neonate

				model, stopwatch
Flow maintained without leak	Air flow maintenance	5	192-330	BCPAP trunk, air pump, clear container, ruler, water
Flow maintained with cervical rotation	Air flow maintenance	5	192-330	BCPAP trunk, air pump, clear container, ruler, water
Adjustability	Measurements	10	192-330	Interface prototype, tape measure
Weight	Measurements	1	192-330	Interface prototype, scale

Table 7. Detailed testing plans

Fast Interface Setup: A crucial part of our device is creating a BCPAP attachment that is quicker to put on than the standard, so testing the time to put the device on will be crucial. We plan on using connections with Dr. VanScoy and Dr. Turbow to connect with respiratory therapists and nurses who can test putting our device on compared to the one they currently use. We expect it to take less than 15 minutes on average and be faster than the current standard of care.

Flow Maintained without Leaks: The prototype will be placed on a neonate model and secured to the trunk and mask. Air will be supplied (6L/min) through one end of the trunk tubing while the other end is submerged in water at a depth of 10mm. Water will be observed for bubbling. This will be repeated for setups by 5 different people to ensure that the mask does not leak. We expect that the flow will be maintained to continue bubbling at 10 mmH₂O in all trials.

Flow Maintenance with Cervical Rotation: The prototype will be placed on a neonate model and secured to the trunk and mask. Air will be supplied (6L/min) through one end of the trunk tubing while the other end is submerged in water at a depth of 10mm. Water will be observed bubbling with the neonate models head facing forward. This will be

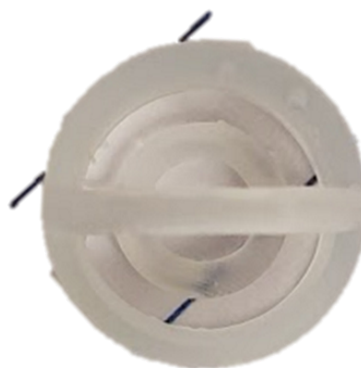
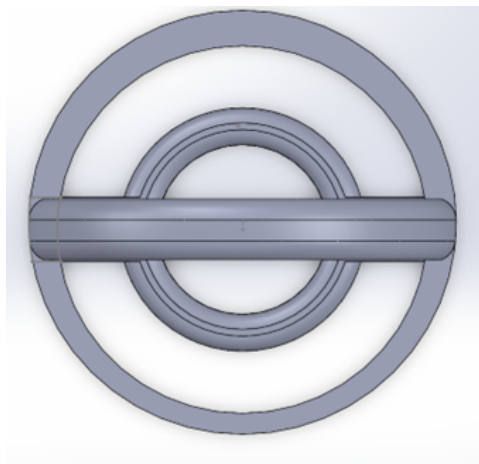
repeated with the head rotated 45 and 90 degrees to the left and right. We expect enough airflow to maintain bubbling at 10 mmH₂O for all head positions.

Adjustability: For a given circumference within range of a neonate's head, the top strap of the interface will be adjusted as closely as possible to that size. This will be repeated for 10 different sizes to ensure that a snug, secure fit can be provided for various head sizes. We expect the interface will be able to be adjusted within 1 inch of any circumference.

Weight: Weigh the prototype on a scale. Maximum limit will be 250g.

Device Modifications

Since the previous design, we have refined the materials used for our current prototype, and added a 3-D printed hook that can attach to the existing mask hooks. Because we want our interface to be able to connect to the existing mask used for most BCPAP machines (Fisher & Paykel), an important step is creating a hook that can attach the lower part of the interface to hooks on the masks. From practitioner feedback, we learned that the existing small hook is often hard to hold with gloves on, tricky to attach to the hook, and can cause issues and cost time. We aimed to create a hook that can be as fool-proof as possible using a ring design, making it slightly bigger so it can be held easier, and containing a ring so that if inserted, it can hook on easily no matter the orientation that the hook is inserted on. Below is a 3-D printed model of the hook, and the part itself printed.



In regards to the material part of the interface, we have created a device using the same manufacturing instructions as above, made using two different types of neoprene sewn together. The more refined, sleek material makes the mask stick better to the baby's face, and allows for a good amount of flexibility, while still maintaining its integrity. The

one modification is the addition of a long velcro strap along the top of the device, which will be pulled up before application and pressed down along the mask trunk.



Detailed Testing Plan

Our testing plan involves material and force testing performed within our group, and the outsourcing of our device to medical professionals who can provide better feedback about the actual attachment of our device, potential problems, and areas of improvement. The testing tree below outlines our plan of testing and revising as we move forward with our device.

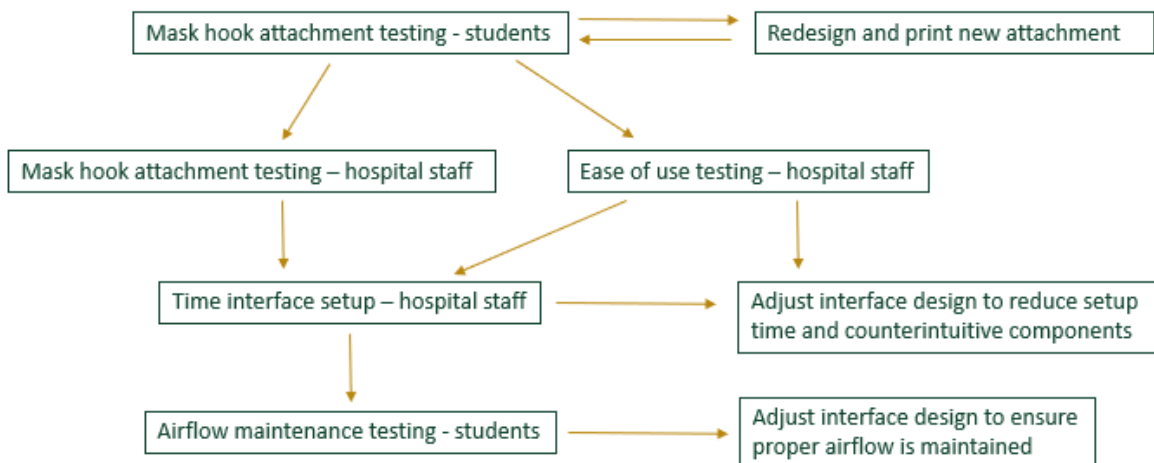


Figure 10. Detailed testing plan tree and adjustment plan.

Mask Hook Attachment Test

Our initial tests and tests to be performed first are tests with our 3-D printed mask attachment. Our initial print had an extremely weak ring, and broke the first time we tried to attach it to the hook. After modifications, we expect to have new pieces to test within the week. Our test plan will be as follows:

Participants will include our own group as well as other members of our senior project class. We will instruct the participants to insert the hook and secure attachment of the connecting strings. After successful attachment, we will have participants remove and reattach the hook until failure, or until 20 attempts have been successful. During these trials, we will keep track of attempts needed to attach the hook (per trial), and amount of cycles to failure.

Our goal is to have the number of attempts be within an average of 1.25, meaning more often than not the hook attaches on the first try. We also of course aim for failure to not occur, and we can have a successful hook.

Once this is successful, we will repeat these trials for hospital staff, as they will be the most accurate models of who will be using the device. In addition to the same measurements explained above, we will also be asking for qualitative feedback on ease of use of the device and comparisons to the current hook attachment that they use. These trials can give us an idea on if our modified hook actually improves the practitioner's ability to attach the interface quicker.

Interface Time Test

Once the hook has been tested both internally and with hospital staff, we aim to test the time attachment of our full device, with the BCPAP mask attached, to a model baby vs the current standard of care.

Our participants in this study will be nurses and respiratory therapists at Sierra Vista Regional Medical Center. Exact number of participants will be variable depending on scheduling and availability, but we aim to have a minimum of 3 participants. We will have participants first attach the current mask and interface that they use to get a baseline measurement of how fast they attach the mask. We will then perform a demonstration of our mask, and then ask them to attach it three times. The hope is that the multiple trials, and almost "practice" with our device, will alleviate the factor that is the practitioner's familiarity with the current device.

We also are considering performing a test with students in our class where we demonstrate the current device and have them attach it, and demonstrate our device

and have them attach it, to see the time it takes to attach our device with participants with no practice with either. We would randomize which device they try first to eliminate the element of practice between the two devices.

While timing will give us quantitative data, we also expect qualitative feedback from the hospital staff on ease of use, potential improvements, and subjective comments on their thoughts on our device vs the one they normally use. These, as well as the timing data, should give us an idea on the performance of our device and how many modifications are needed.

We expect to need two rounds of testing within the hospital, and have planned our testing schedule accordingly to perform testing, make modifications, and test again before the end of this quarter.

Air Flow Testing

This test is designed to ensure that our mask will provide secure airflow when attached to the BCPAP mask. Necessary equipment for this test will be a spirometer found in the BMED lab (38-133). We will attach the mask to the model baby's face using our interface, and attach the spirometer to the two tubes in the BCPAP trunk. We will then pump air through one of the tubes, and the spirometer will compare the amount of air in to the amount of air out. We expect the air out to be at worst 90% of the air in (with some losses due to flow through the tube and a potential slightly imperfect seal.

We also recognize that these spirometers are meant for much larger air flows than will be provided by the baby's small tidal volumes, so the spirometer may not be an effective method of gathering data. If we determine that the spirometer does not give us a good enough model of a baby breathing, we have a backup plan that would give us less specific, but still useful, data.

This plan involves blowing up a medical balloon with a designated amount of air, to the maximum that the balloon could be blown up. We would attach this to the end of a tube and release the air, while a replica deflated balloon will be attached to the other tube. We would see if the second balloon inflates, and if so, we can get an estimate of the inflation rate compared to the first balloon. While these results would not be as specific as the first method, they would give us a good idea if we have a tight seal.

Final Design

Following a meeting with Dr. Van Scoy at Sierra Vista Regional Medical Center on March 7, 2024, we created our final design based on the feedback we received. The first update to our previous prototype was making the top velcro strap thinner and more

narrow to allow it to better keep the trunk secured. In addition, we covered the back of the main panel in soft velcro to allow the elastic to attach to any location to optimize adjustability. This velcro will also allow clinicians to secure any additional tubing to the interface via velcro to keep it out of the way. Lastly, we made final adjustments to the tolerances of our mask hook attachments and printed them on the Polyjet printer using VeroBlack™ polymer. While ideally these pieces would be changed in the future to include rounded edges and stronger material, we are happy with the fit of the pieces and have decided to use them as the final iteration for our prototype.



Figure 11. Front view of final design with updated velcro strap and mask hook attachments



Figure 12. Back view of final design with soft velcro panel

This final design, as well as the pictured neonate model, will be utilized for all of our

testing as detailed in the next section.

Prototype Manufacturing Plans

Our final design consists of a panel of neoprene, velcro for attachment and adjustability, elastic for attachment to the mask, and two 3D-printed mask hook attachment pieces. Neoprene was selected as the primary material because it is sturdy enough to provide stability, gentle enough for babies' skin, and will prevent the device from slipping.

We have created the following steps and figure as a written and visual plan of how we intend to create our model:

1. Cut out panel from neoprene
2. Glue soft velcro to cover backside of panel
3. Sew elastic strips onto bottom ends of neoprene
4. Sew velcro circles onto ends of elastic
5. String elastic through loop of mask hook attachment
6. Attach velcro piece to short arm of top neoprene
7. Sew velcro strip onto top strap for trunk attachment
8. Clean up any fabric fraying, loose strings, etc.



Figure 9: *Flattened view of design showing neoprene shape and elastic and velcro locations*

In the future, an automated sewing process would be employed to speed up manufacturing, and a higher-resolution 3D printer would be used, allowing for rounded edges on the mask hook attachment pieces.

Testing

Mask Air Leak

At Sierra Vista Regional Medical Center, with the help of Dr. Van Scoy and a respiratory therapist, the final prototype of our device was properly attached, and connected to a BCPAP machine and our model neonate baby. The BCPAP was set to provide eight liters of pressure, and both Dr. Van Scoy and the RT confirmed that no leak was occurring. Testing this on a real BCPAP machine gives us confidence in the seal that our interface holds.

Pass/Fail: Pass



Figure 13. Model baby connected to BCPAP machine using our final prototype interface

Time Trial

This test was conducted at Sierra Vista Regional Medical Center, with two respiratory therapists as our participants. Participants were given instructions on how to apply our device, and were given a trial run first to understand how the application worked. This was done to try to even the testing between our redesign and the current model that they have applied hundreds of times. The participants then applied the current model while being timed, followed by the redesign while being timed. Results were compiled in Table 8 below.

Table 8. Results from time trial comparing current and redesigned interface setup times

Participant	Fisher & Paykel (s)	Participant	Redesigned Interface (s)
1	105.7	2	72.7
1	137.0	2	51.5
1	105.4	2	47.5
2	96.7	1	56.7
2	85.5	1	49.8
Average	106.1	Average	55.5

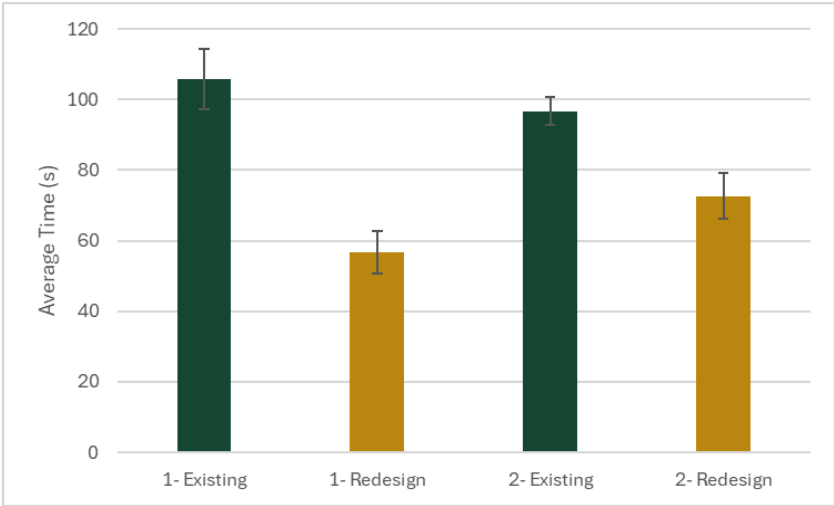


Figure 12. Individual Participant Data for Timed Test. Averages for each participant were taken when applying both designs, and plotted separately. Both participants showed a statistically significant decrease for the redesigned interface than the existing ($p < 0.05$).

The results received in this first part of the timed test demonstrated a notable decrease in average time to attach for the redesign, with an average of 52.4 less seconds taken to attach, a 47.7% decrease. Looking into individual participant averages, we see that regardless of the participants, the significant decrease remained. Participant 1 had an average 62.8 second decrease when attaching the redesign. Participant 2's difference was less, at 33.9 seconds, but both marked significant differences from the existing model. These results are positive for the efficacy and usefulness of the redesign, especially considering that the timed tests were the participants' second or third time attaching the redesigned mask ever, compared to having hundreds of real-life applications with the current model.

Figure 13 below depicts the combined average time in seconds it took to attach the existing device compared to the redesigned model.

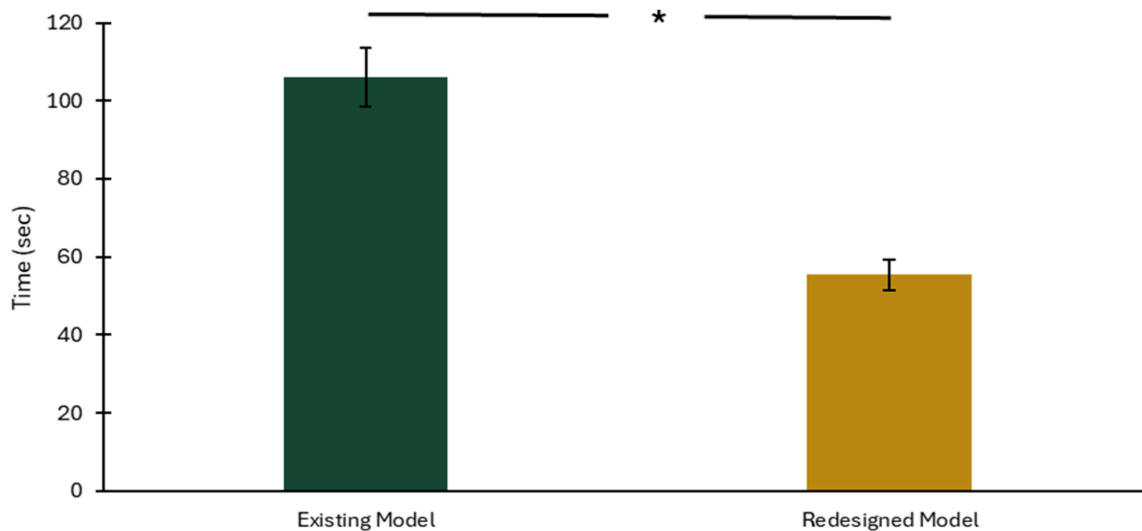


Figure 13. Combined Participant Data for Timed Test. An average of all participant times were compiled (*, $p < 0.05$).

After the initial round of time trials, additional attachment times were measured for the redesigned interface as shown in table 9 below. The first measured setup with the trunk already attached to the proper tubing and with the mask piece added ahead of time. This time trial was included to take into account the length of setup when respiratory therapists know in advance that an infant will need BCPAP, as they can have this aspect of the system prepared in advance. The second trial included head measurement as an added step. While this step is not necessary for placement of our design, respiratory therapists will take this measurement during BCPAP setup to prevent nurses from needing to remove the interface for later measurements.

Table 9. Time trial results for additional setup criteria

Setup Condition	Setup Time (s)
Pre-attached trunk	39.8
With head measurement	47.9

The setup time for the redesigned interface with the pre-attached trunk was just over 25% faster than the average setup time including trunk attachment, indicating that under circumstances when the need for BCPAP is known in advance, setup will be faster than the average time obtained during the initial time trial. With the additional step of taking

the infant's head measurement, the time to place the redesigned interface was still under half that of the Fisher & Paykel model.

Instructions for Use

The following steps describe how to place our final design on an infant using the Fisher and Paykel trunk and connecting to the existing BCPAP machine.

1. Place device under infant's head velcro side down, with square panel centered on the head and elastic at the bottom.
2. Detach velcro strap from top neoprene strap.
3. Secure neoprene strap around infant's forehead via velcro.
4. Attach trunk tubing to BCPAP machine.
5. Place trunk on infant with mask over the nose and place velcro strap over foam to secure.
6. Attach the mask hook attachment pieces to the mask by sliding each blue hook through inner ring and pulling back to latch.
7. Pull elastic through mask hook attachment loop until tight enough and velcro ends to backside.

These steps may vary if the trunk is attached to the machine in advance, if head measurements are taken during setup, or if other circumstances necessitate deviations.

Conclusion

After finalizing a prototype and performing real-life timing and attachment tests with clinicians, we can say that our prototype has made significant progress in developing a new attachment to the BCPAP system. Our team accomplished all of the specifications we set out to meet, including keeping the system to a single component, decreasing the time to attach by 25%, keeping access to the top of the head open, and maximizing the adjustability of the device. Testing these parameters revealed successful outcomes for these specifications, including a 47.7% decrease in time to attach. We have confidence in the future application of the product. After using our device, clinicians called it "a step ahead of what we do now" and said it was "simpler than what we do". This encouraging feedback supplements the quantitative evidence of our improved device with qualitative, demonstrating the effectiveness and overall satisfaction with our device.

Future Directions

Some final feedback from clinicians revealed needs to secure the top of the head. This can be accomplished with a small strap across the head to keep access to the head open while providing downward force to keep the mask on during movement. Implementing a measurement system on the inside of the device may help clinicians with sizing and the need to cut off ends of the device.

In regards to material and printing, more high resolution 3-D printing would be needed to remove sharp edges from the mask hook attachment and increase strength. Future iterations if mass produced would include an injection molded mask hook attachment made of a hardened plastic. The base layer of neoprene would have to come from a more reliable source than ours for effective reproduction.

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Works Cited

- Aly, Hany. "BUBBLE CPAP for Prevention of Chronic Lung Disease in Premature Infants." *Cleveland Clinic*, 27 Jan. 2020, consultqd.clevelandclinic.org/bubble-cpap-for-prevention-of-chronic-lung-disease-in-premature-infants/.
- "Babi.Plus nCPAP Kit." Respiralogics, https://www.respiralogics.com/content/babi_nCPAP_kit.html
- Baldursdottir, Sonja, et al. "Basic principles of neonatal bubble CPAP: effects on CPAP delivery and imposed work of breathing when altering the original design." *NCBI*, 11 February 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7547905/>. Accessed 15 October 2023.
- "Bubble CPAP." Create Biotech, <https://www.create-biotech.com/en/product-277113/Bubble-CPAP-Nasal-Cannula.html>
- "Dräger BabyFlow plus Consumables and Accessories." Dräger, 2 January 2016, <https://www.draeger.com/products/content/babyflow-plus-pi-9072932-en.pdf>
- Dyer, Janet. "Neonatal Respiratory Distress Syndrome: Tackling A Worldwide Problem." *National Library of Medicine*, NCBI, 9 January 2019, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6336202/>. Accessed 15 October 2023.
- "Fisher & Paykel Healthcare - FlexiTrunk Midline." Fisher & Paykel Healthcare, www.fphcare.com/us/hospital/infant-respiratory/cpap/flexitrunk-midline/.
- Hamilton, Brady, et al. "Births: Provisional Data for 2021." *Center for Disease Control*, www.cdc.gov/nchs/data/vsrr/vsrr020.pdf. Accessed 16 Oct. 2023.
- Han, SeungHye, and Rama K Mallampalli. "The Role of Surfactant in Lung Disease and Host Defense against Pulmonary Infections." *Annals of the American Thoracic Society* vol. 12,5 (2015): 765-74. doi:10.1513/AnnalsATS.201411-507FR
- "How Many Babies Are Born a Year?" *UNICEF DATA*, 18 May 2022, data.unicef.org/how-many/how-many-babies-are-born-a-year/.
- "How to set up the F & P BCPAP Device." YouTube, uploaded by SuzanneFelicity, 22 October 2014, www.youtube.com/watch?app=desktop&v=eXpaSnE-4NU.
- "ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process." *ISO*, August 2018, <https://www.iso.org/standard/68936.html>. Accessed 16 October 2023.
- "ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes." *ISO*, March 2016, <https://www.iso.org/standard/59752.html>. Accessed 16 October 2023.
- "ISO 80601-2-72:2015 - Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients." *ISO*, September 2015, <https://www.iso.org/standard/61389.html>. Accessed 16 October 2023.
- Liu, Lin, and Quanmin Deng. "Profound Effect of Pulmonary Surfactant on the Treatment of Preterm Infants with Respiratory Distress Syndrome." *Contrast media & molecular imaging* vol. 2022 4166994. 3 Oct. 2022, doi:10.1155/2022/4166994
- "Medical Devices." *FDA*, <https://www.fda.gov/medical-devices>. Accessed 16 October 2023.

"NP-Flow Nasal CPAP Kit." Besmed, <https://www.besmed.com/en/product318.htm>

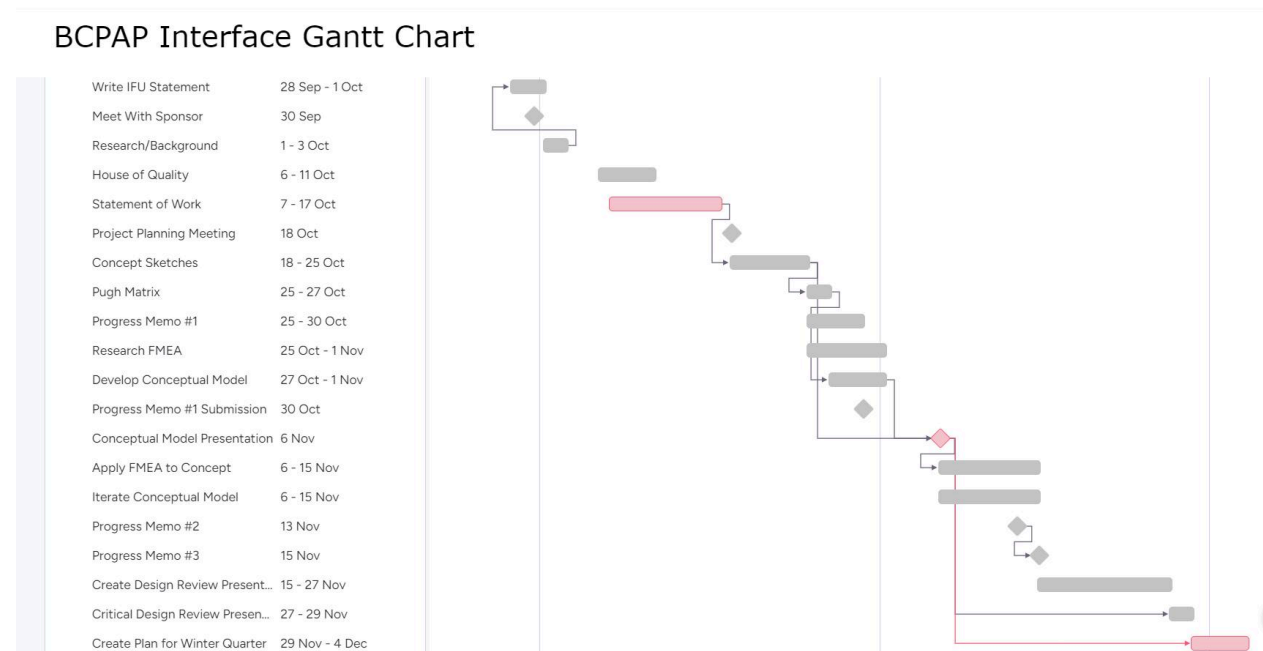
"Patent Public Search." USPTO, <https://ppubs.uspto.gov/pubwebapp/>. Accessed 16 October 2023.

"Premature Birth." Beacon Health System,

https://www.beaconhealthsystem.org/library/diseases-and-conditions/premature-birth?content_id=CON-20376713

Appendix

A-1: Gantt Chart



A-2: Sponsor Needs and Wants

Must Have:

- Placed in <20 minutes
- Doesn't cause skin irritation
- Weighs <250g
- Doesn't obstruct majority of face/head
- Secure & can be used long term
- Can be used for premature infants
- Successfully attaches to BCPAP machine

Nice to Have:

- Doesn't require exchange of components
- Adjustable components
- Minimal training requirements
- Costs as much or less than existing technology
- Can be put on by one person