6-15-2023

Rhea Breast Pump: Implementation of Biomimicry Technology

Harper Daniels

Leanne James

Laini Reynolds

Courtney Rowe

Julia Yaklich

Santa Clara University

Department of Mechanical Engineering
Department of Bioengineering

I HEREBY RECOMMEND THAT THE THESIS PREPARED UNDER MY SUPERVISION BY

Harper Daniels, Leanne James, Laini Reynolds, Courtney Rowe, Julia Yaklich

ENTITLED

Rhea Breast Pump: Biomimicry Informed Design

BE ACCEPTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREES OF

BACHELOR OF SCIENCE
IN
MECHANICAL ENGINEERING
AND
BACHELOR OF SCIENCE
IN
BIOENGINEERING

Approved: ______________ Date: June 12, 2023
Calvin Tszeng, Thesis Advisor

Approved: ______________ Date: JUNE, 12, 2023
Emre Araci, Thesis Advisor

Approved: Hohyun Lee (Jun 13, 2023 17:51 PDT) Date: 06/13/23
Hohyun Lee, Department Chair, Mechanical Engineering

Approved: Unyoung Kim
Unyoung Kim (Jun 15, 2023 10:35 PDT) Date: 06/15/23
Unyoung Kim, Department Chair, Bioengineering

Rhea Breast Pump: Biomimicry Informed Design

by

Harper Daniels
Leanne James
Laini Reynolds
Courtney Rowe
Julia Yaklich

SENIOR DESIGN PROJECT REPORT

Submitted to
the Department of Mechanical Engineering
and
the Department of Bioengineering

of

SANTA CLARA UNIVERSITY

in Partial Fulfillment of the Requirements
for the degree of
Bachelor of Science in Mechanical Engineering
Bachelor of Science in Bioengineering

Santa Clara, CA
15 June 2023

Abstract

Rhea Breast Pump is an innovative breast pump that implements biomimicry informed technology for a more efficient and comfortable breastfeeding experience. Our design implements a tongue actuator in conjunction with vacuum to mimic the suckling motion of a baby's mouth, a heating element for pain alleviation, and a soft flange to maximize comfort. The development of this device is motivated by the goal of empowering women, specifically nursing mothers, to maintain their independence and individuality while raising a family. Our team, consisting of all female engineers, strongly believes in and supports the notion that women can and should have the freedom to effectively balance both aspects of their lives.

Acknowledgements

We would like to express our deepest gratitude to our advisors, Calvin Tszeng and Emre Araci, for their guidance, patience, and support. Throughout the year, their expertise motivated us to challenge ourselves and innovate with intention. It has been a privilege and honor to work with them.

We would also like to thank the School of Engineering's Undergraduate Program for the funding necessary to make this project possible. Additionally, we would like to acknowledge Rodney Broom and Rebecca Walters for their help in procurement and logo design, respectively.

Contents

List of Figures

List of Tables

Chapter 1: Introduction

As an all-female team, we want to focus our efforts on an overlooked area in women's health. In doing research on female medical devices, we found a gap in the market for adequate breast pumps that fail to cater to the pains mothers undergo during the breastfeeding process. Specifically, the process of breastfeeding and breast pumping for mothers can be painful due to cracked nipples, clogged ducts, and inflammation of breast tissue, also known as mastitis. Despite the discomfort many mothers feel during breast pumping, approximately 85% of mothers use a breast pump during the nursing process, according to the Atlantic [1]. From this research, we concluded that improvements to current pumping solutions are not only possible but necessary in order to alleviate many of the current complaints against them.

1.1 Customer Needs

The global breast pump market size was valued at USD 2.74 billion in 2022 and is projected to grow at a compound annual growth rate (CAGR) of 8.5% from 2023 to 2030 [2]. The demographic for a breast pump is new mothers who choose to feed their baby breast milk. Breast pumps are especially useful when mothers have to be away from their babies for extended periods of time, such as when they return to their jobs. Pumping is also a very helpful tool for mothers who share feeding responsibilities with a co-parent or caregiver. Studies show that low-income mothers are "more likely to rely on infant formula than breastfeeding or start their children on formula earlier" due to the demand to return to work for income [3]. With the recent baby formula shortage, many mothers must pump their own breast milk so that they can feed their babies, increasing the need for breast pumps and growing the potential consumer market [4].

Many newborn mothers struggle with an array of issues surrounding the use of breast pumps. There is a great need for breast pumps to be comfortable. One of the main concerns is the need for mothers to be relaxed while pumping [5]. While nursing, mothers are usually relaxed and bonding with their babies, but pumping can often be uncomfortable and feel unnatural. Additionally, personalized breast pumps with an option to change pumping frequency is desired. Mothers have also expressed a need for easy cleanup after pumping, as there is enough stress and hassle to take care of a baby [5]. Another issue moms have mentioned is the accidental spilling of milk after pumping due to the design of the pump.

In addition to online research, we interviewed a new mom about her experience with breastfeeding. She said she had to move to solely pumping because her baby had issues latching and was dropping in weight. Pumping allows her to measure the amount of breast milk that she produces and the baby consumes. One issue she has with her current pump, Spectra, is that she has to change the settings every 2.5 minutes. She would like a breast pump that could automatically change settings so she wouldn't have to pay attention while pumping. She would also like to have larger cups to catch the breast milk because she often has to stop mid-session to empty the bottle. She does not have a wearable breast pump. She has heard that the suction is not high enough on most wearable pumps so you cannot extract as much milk. Also, wearable pumps are very expensive. Hearing about her first-hand experience was valuable in our research to identify more customer needs.

Based on research and interviews, we organized the observed needs and improvements in Table 1.1. Three stars denote the highest level of need while one star indicates the need is less important.

Table 1.1: Hierarchy of general breastfeeding and customer needs

Group 1 - General Breastfeeding Needs		**Group 2 - Pump Improvements**	
Need	**Rank**	**Need**	**Rank**
Relieve pain of nipple soreness and cracking	***	A comfortable pump with maximum efficiency	***
Unclog the duct	***	A pump that is easy to clean	***
Fix engorgement	***	A pump that fits different nipple sizes	***
Need a steady milk supply	**	A pump that will not spill any breast milk	**
Cure infections	**	A quieter pump	**
Solution for nursing strike	**	Mobility	**
Help with latching issues	**	Personalized pumping frequencies (automatically adjusts)	**
Need constant access to baby or pump	**	Large collection cup	**
A comfortable position	*	A lightweight pump	**
Support from a lactation consultant	*	To not get undressed while pumping	*
Emotional support because breastfeeding can be very taxing on a mom	*	An affordable breast pump	*

Ultimately, we found the physical comfort of new mothers to be the top priority for our target customer. New mothers have just gone through an extremely difficult and challenging experience of carrying a pregnancy to term and then giving birth. A breast pump that alleviates at least some of the discomforts connected to common breastfeeding struggles (nipple soreness/cracking, clogged ducts, engorgement) is at the top of the list of needs. Turning toward the gaps in our target market, we found that an ideal pump must fit a variety of nipple sizes, provide efficient milk extraction, and be easy to clean in order to provide strong value. Overall, this investigation into customer needs provided our team with great insights that shaped our design process.

1.2 Benchmarking Results

After analyzing customer needs, it was found that a pump that provides pain relief, is comfortable for the user, and is able to maximize milk extraction will sufficiently address mothers' concerns with breast pumping. In order to determine our target values for each metric, we collected the benchmarking information of our main competitors, Willow, Elvie, and Medela. This information is summarized in Table 1.2.

Table 1.2: Competitor's benchmarking information and our target values [6, 7, 8]

Metric	Willow	Elvie	Medela	Rhea
Flange Sizes (mm)	17, 19, 21, 24, 27	21, 24, 28	21, 24, 27, 30, 36	21, 24, 27
Suction Levels (kPa)	-33	-40	-36	-13 to -20
Collection Sizes (oz)	4	5	5	5

The Rhea Breast Pump will be designed to provide an alternative to current breast pumps that offers a more comfortable breast pumping experience for mothers. While existing pumps on the market have no way of relieving pain, Rhea will provide pain relief through the addition of a heating element to help relax mothers and act as a warm compress. Mothers can also experience pain if they are using the wrong flange size. The flange is the part of the pump that comes in contact with the breast. While the average flange size in most breast pumps is 24 mm, the final Rhea Breast Pump will include several different flange sizes– 21, 24, and 27 mm– to provide maximum comfort and pumping efficiency.

Current breast pumps on the market use high suction levels to extract milk. However, since Rhea utilizes biomimicry technology, explained in Section 1.5, to maximize milk extraction, it does not require as high of vacuum pressure. The target pressure of the Rhea Breast Pump ranges from -13 to -20 kPa. This will be enough to initialize the flow of milk, while still being comfortable for the mother. With the goal of maximizing milk yield in mind, the collection bottle of Rhea will be the larger size of 5 oz to allow mothers to collect as much milk as possible in one pumping session. Each of these features will be thoroughly explained further in the thesis.

1.3 Biomechanical Understanding of Milk Extraction

1.3.1 Natural Nursing Technology Research

Our research found that natural nursing technology is in the highest demand because it is comfortable and extracts the largest amount of breast milk [9]. It was found that natural nursing technology uses a gentle pumping pattern that is similar to the natural process of breastfeeding [9]. These electric pumps were found to yield a higher milk supply than manual pumps by over twice the amount, where the electric pump yielded greater than 120 mL and the manual pump was found to yield less than 60 mL [9]. As discussed in 1.3, the current pumps on the market only employ negative pressure differential (vacuum) to extract milk, therefore relatively high vacuum pressure is required. After researching the natural breastfeeding process and natural nursing technology, we decided to create a wearable breast pump that mimics a baby's mouth as close as possible in order to improve comfort and efficiency.

1.3.2 Breastfeeding Research

The Institute of Electrical and Electronics Engineers published an academic paper focusing on the biomedical engineering device described as the Bio-Inspired Breastfeeding Simulator I (BIBS). The paper focuses on the creation of a tool intended to improve the biomechanical understanding of breastfeeding shown in Figure 1.1 [10]. Pressure and vacuum values explored in this paper were crucial to our ability to grow a product replicating accurate forces of a baby's mouth.

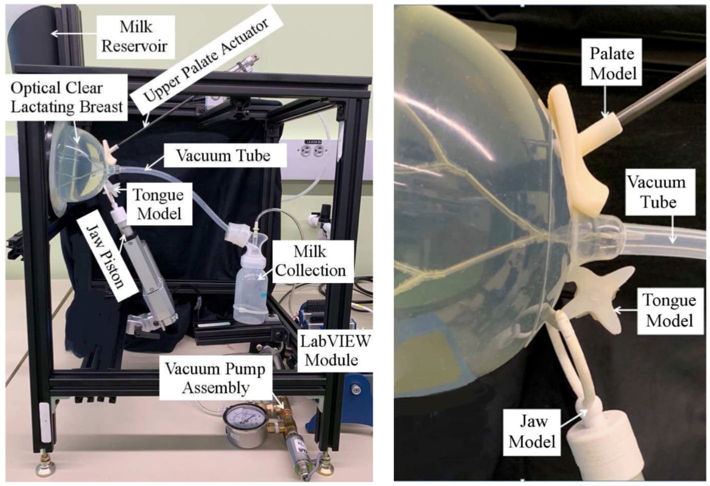


Figure 1.1: Photo of testing apparatus, BIBS [10].

This study broke down the breastfeeding process into different systems including the upper palate actuator, tongue model, jaw piston, and vacuum pump. In terms of pressure, the maximum suction pressure that a baby can create is about 25 kPa and the mean value is around 7 kPa [11]. This is much lower than the suction pressures of other pumps on the market which are around 33 kPa [12]. Because of this, it is concluded that the motion of a baby's mouth improves its efficiency more than just the vacuum pressure when suckling.

During breastfeeding, the nipple and areola are stretched to approximately twice its resting length, is reduced to 70% of its original diameter, and extends as far back as the junction of the hard and soft palates of the baby [13]. Suckling is when the infant places the tongue beneath the nipple, forward over the lower gum in contact with the lower lip, and swallows with the jaws apart and the lips together [14, 15]. While suckling, there is rhythmic coordination between the infant's maxilla (upper jaw), the mandible (lower jaw), and tongue, shown below in Figure 1.2. First, the baby's maxilla and mandible clamp the nipple-areola complex. Second, the tongue extends out and pulls the nipple into the oral cavity. Third, the tongue pushes the nipple into the hard palate. Finally, the baby's upper palate and lower jaw compress the nipple to squeeze out the milk. Maxilla pressure is closer to a constant value (4 kPa) and the mandible fluctuates more (5 kPa to 10 kPa) [10]. Babies suckle about once every 0.7 seconds, resting for an additional half second every 5 sucks to swallow [11].

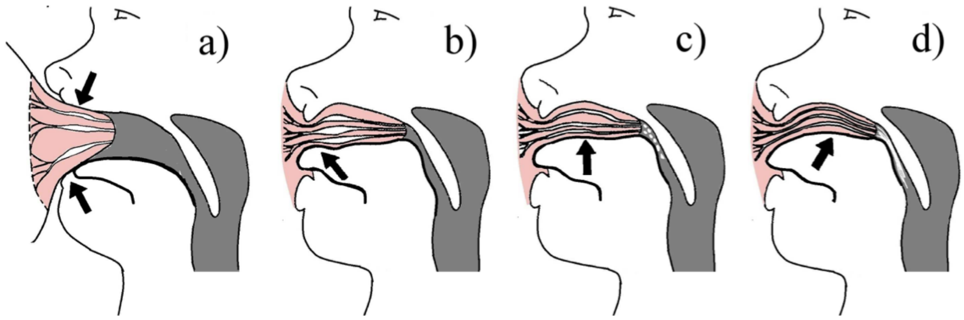


Figure 1.2: Diagram of natural nursing in infants [10].

1.3.3 Warm Compress Research

Many issues causing pain to the mother can occur during breastfeeding. Mastitis, an inflammation of breast tissue that can involve an infection, occurs in 10% of breastfeeding U.S. mothers [16]. Milk ducts can become clogged and painful when breastfeeding. Another common problem for breastfeeding mothers is breast engorgement which includes swelling, tightness, and pain. The treatment for mastitis, breast engorgement, and clogged ducts includes warm compresses. They can help alleviate pain and help induce healing [16]. Along with pain management, warm compresses can also dilate blood vessels and the lactiferous duct which increases milk production [17, 18]. Additionally, the warmth of a baby's mouth during breastfeeding releases oxytocin in the mother. The ducts beneath the areola fill with milk and become wider during a feed, when the oxytocin reflex is active [19].

1.4 Project Approach & Goal

By focusing our project on the needs of mothers, our goal is to create a wearable breast pump that is effective and comfortable. Research leads us to believe that mimicking the natural breastfeeding process as closely as possible will be more effective at extracting milk than current breast pumping solutions. For this reason, Rhea implements biomimicry-inspired technology to satisfy the needs of mothers by mimicking a baby's mouth during breastfeeding. According to our research, the main mechanism of milk extraction in breast pumps on the market today is mainly by vacuum induced pressure differential. Along with vacuum pressure, we aim to mimic the mechanical extraction aspect of the breastfeeding process. Our design implements a traditional vacuum pump along with a mechanical actuator that works together to extract milk. No other breast pumps on the market use a mechanical actuator for extraction. In order to provide a comfortable interface for the mother, we use a softer material for the part of the pump that comes in contact with the breast, the flange. To help with comfort and pain alleviation, there is also a heating element that serves as a warm compress. Additionally, the heating element also intends to mimic the feeling of a baby's mouth which will hopefully elicit a similar oxytocin release in the mother to improve milk extraction and increase milk yield.

Chapter 2:
System Level Overview

This chapter introduces the constraints of the project and key issues surrounding the design process. The final design is introduced to describe the methods used to solve these issues with the given constraints.

2.1 Design Constraints & System Level Issues

For purposes of pain relief, we are implementing a heating element to act as a warm compress. The target temperature range of 40-46℃ is the average optimal temperature for a heating element on the skin of the breast [18, 20]. For proper implementation, it is necessary to ensure that our product will not get too hot while still reaching the target temperature. Additionally, the suction levels of typical pumps on the market are far greater than the suction level induced by a baby in breastfeeding. To make up for this difference, babies apply mechanical forces with their mouths, specifically their tongues, which aid in the milk extraction process. The Rhea Breast Pump aims to replicate one of these additional forces through the addition of a tongue actuator that will apply a force of around 12.5 N. This force is justified in section 6.1.2. The tongue actuator design must accurately mimic this suckling motion without counteracting the mechanical extraction. This may occur if the actuator strikes in the wrong direction down the breast. Similarly, the vacuum pump must be able to induce a suction pressure of at least -7 kPa to adequately mimic the suction applied by a baby. All components must be encompassed together to make the device as compact as possible to reach our ultimate goal of wearability. [18, 20]

Accomplishing these constraints requires developing methods for maintaining a steady temperature for the heating element that can be perceived by the mother through Ecoflex, which is a thermally insulating material. There also is a need for a safety mechanism to ensure that the entire pump does not overheat due to excess heat from the heating element, pump, and motor. Additionally, creating a working tongue actuator that does not strike in the wrong direction is a significant challenge unless a series of gears or a rotary motor is used. Designing a flange that properly fits and forms a tight seal to the breast is another challenge. Finally, encompassing all elements of the design in one wearable device is challenging due to budget and time constraints. The wearability of the design depends on the weight and size of all the components put together, so minimizing dimensions and mass is crucial at all stages of development.

2.2 System Level Design

Figure 2.1 shows an overview of the SolidWorks model of the Rhea prototype. We attempted to make the product as small as possible in order for it to be comfortably wearable. The components are powered by four 9V batteries which are also held in the casing. Starting from the left, we have the conical flange which is the part that comes in contact with the breast. It is made out of soft material and has heating plates embedded into the sides. Below the narrow end, or neck of the flange, the tongue actuator rotates and pushes against the flange in the contact area to compress the breast and simulate the motion of a baby's tongue. In the top right area, the triangle-shaped adapter directs milk from the flange to the bottle. It is connected to a vacuum air pump that is used to initiate the milk extraction process. There is a backflow protector to prevent milk from getting into the pump. The housing completely encases all of these elements so that the user only interfaces with the flange and the removable bottle. Each component will be explained in depth throughout the thesis.

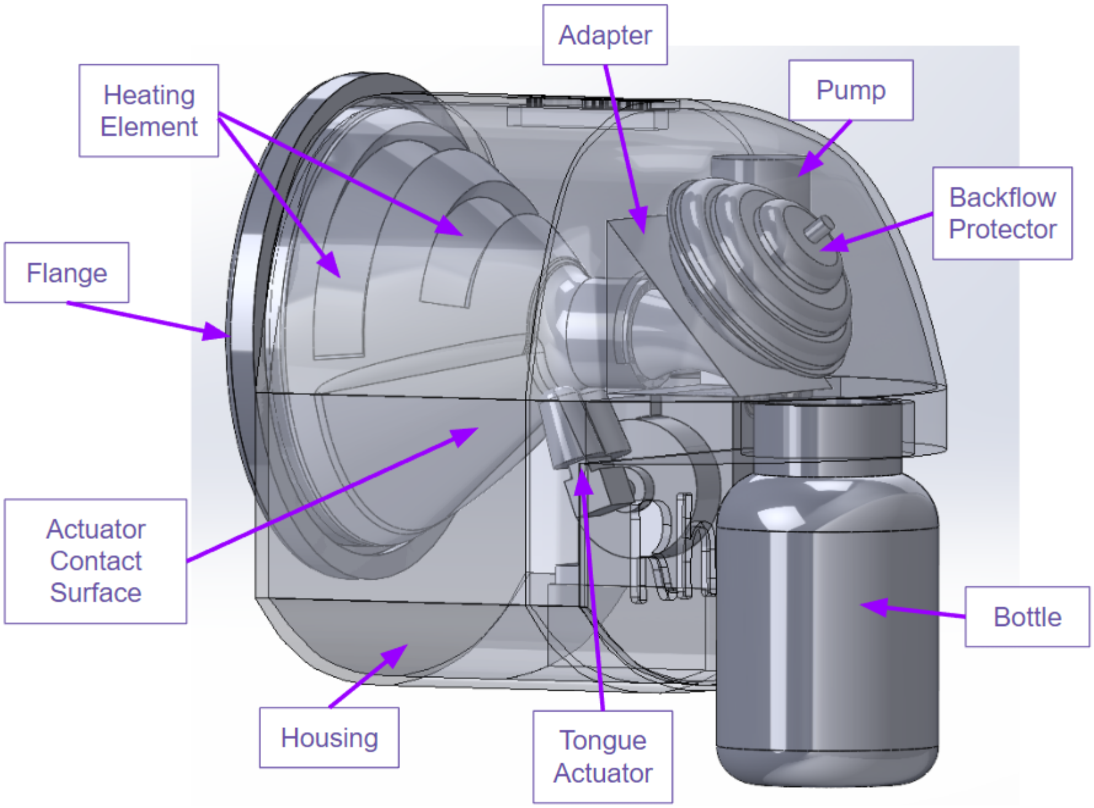


Figure 2.1: SolidWorks model of Rhea prototype component overview.

On the top of the housing, there is one switch and one button Figure 2.2. The switch turns on both the pump and actuator which move together in cycles to mimic the pressure and forces created by a baby's mouth. The cycle replicates 5 suckles, then a pause for swallowing. This cycle repeats until the switch is turned off or for 15 minutes, which is an average length of a pumping session [21]. Next to the switch is a button for modulated heating of the flange to mimic the warmth of a baby's mouth. We created a separate button because we wanted the heating to be an optional feature. When the button is pressed, the flange will heat up for 2 minutes and then the heating plates will cycle on and off to keep the temperature consistent around 40ºC. The heating element automatically turns off after 15 minutes.

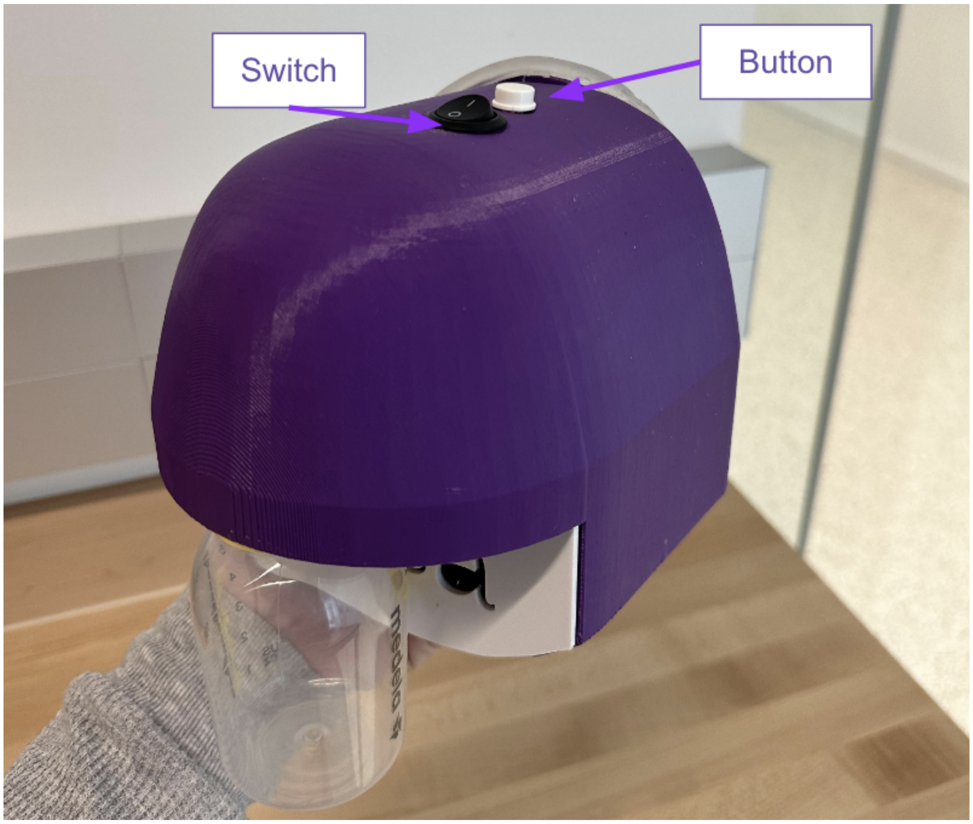


Figure 2.2: Rhea prototype switch and button.

Chapter 3:
Project & Team Management

The project was funded by the School of Engineering. Team members were split into two subgroups to maximize resources in order to accomplish design goals within the time allowed.

3.1 Budgeting

3.1.1 Cost of Research & Development

In total, the project was granted $500 per student with a grand total of $2,500 for the entirety of the senior design process. Overall, approximately $1,100 of the budget was spent. The iterative design process of components such as the flange and casing contributed to the overall budget expenditure of the project. Additionally, medical prosthetics were some of the largest expenses within the budget in order to make up for the inability to conduct human testing experiments. A full budget breakdown can be found in Appendix A.1.

3.1.2 Cost of Physical Model

The cost of material for the final prototype totaled to a value of approximately $150. This includes twenty-nine different materials for the full proof of concept. By using 3D modeling technology and printers, parts including the tongue actuator and casing were able to be iterated upon quickly while in a cheap and customizable way. Costs were also reduced through the use of Arduino-compatible hardware and software utilized to achieve goals in terms of power and coded components. Some of the largest costs for this prototype are Polylactic Acid (PLA), Ecoflex, and the motor. A full budget breakdown of the prototype can be found in Appendix A.2.

3.2 Timeline

The Senior Design process for the team began in June of 2022 and will be completed in June 2023. Table 3.1, shown below, shows the goals set as a team throughout the three-quarter school year. The table is broken down by each ten-week quarter timeline in sequential order. A detailed timeline in the form of a Gantt chart can be found in Appendix B.1.

Table 3.1: A general overview of the project timeline

Summer 2022	Fall 2022	Winter 2023	Spring 2023
Project Brainstorm	Advisor Outreach	Pump Selection	SolidWorks Assembly
Project Selection	Breast Pump Research	Housing Design	Fabrication & Physical Assembly
	Milk-Collection Research	Flange Iterations	Proof of Concept Testing
	Silicone Lab Training	Actuator Design	Conference Preparation
	Safety Report	Connection/Sealing Iterations	Thesis Drafting & Submission

3.3 Design Process

From the beginning, the design process was iterative and collaborative. The summer of 2022 and the early weeks of the fall were spent researching the market of breast pumps and the field of academic research behind the products. Weekly meetings among students and advisors were established to touch base on progress and ideas. Detailed notes of these meetings with delegated task-keeping were crucial as a foundation for clear communication among group members.

Our design process saw many iterations to individual components and connection points, as any thoughtful design process would. Most iterations of individual components had a profound effect on the interactions of the system as a whole. Due to the goal of creating a compact and wearable device, the small three-dimensional space to work within amplified the effects any configuration change would have on the system overall.

3.4 Risk Mitigation

The main hurdle faced for this project was securing adequate time for each iteration of 3D printed items. The printers, located in Santa Clara University's Innovation Zone, were only available for use at given times throughout the week. On top of that, the printers were being used for a multitude of purposes. This meant there was an especially high demand for these limited printers. As a group, it was important to give adequate planning considerations around when to start our prints. With some items, such as the casing, taking upwards of forty hours to complete, we had to account for multiple days in order to procure these parts. On top of that, we would not have access to our part as soon as the print was done but instead at the next open hour and day that the Innovation Zone opened up.

Additionally, the supply of Ecoflex was limited. Originally, we ordered Ecoflex 00-50 for its properties to mold and serve functionally as the material for our flange. As we progressed with flange iterations, there was a need for another order of Ecoflex. Unfortunately, by the time this occurred, Ecoflex 00-50 was no longer available. This was a challenge other bioengineering teams shared with us as well. Subsequently, we opted for Ecoflex 00-45 as the second-best option for our flange due to its similar material properties to Ecoflex 00-50.

3.5 Team Management

Effective team management is essential for creating a cohesive and hardworking team. In order to facilitate this in a bigger team, the team discovered that dividing into two subgroups allowed for equal delegation of responsibilities. Each subgroup had weekly meetings as well as large group meetings to report progress and synthesize the design. The delineation of tasks can be seen in Table 3.2. The first subgroup was a team of three students that focused on biomimicry and consisted of Harper Daniels, Leanne James, and Courtney Rowe. They focused their efforts mainly on the components of the Rhea Breast Pump that were in contact with the human interface such as the flange, heating element, and tongue actuator. The second subgroup was a team of two that focused on the assembly and consisted of Laini Reynolds and Julia Yaklich. They focused their contributions on the other parts of the Rhea Breast Pump such as the vacuum pump, circuitry, and housing.

Table 3.2: Delineation of tasks

Team	**Members**	**Tasks**
Biomimicry	Harper Daniels, Leanne James, Courtney Rowe	Flange, Heating Element, Tongue Actuator
Assembly	Laini Reynolds, Julia Yaklich	Assembly, Housing, Circuitry

Chapter 4:
Comfortable Human Interface Subsystem

This chapter describes the comfortable interface of the breast pump created for the mother. This subsystem consists of two components: (1) flange, (2) heating element.

4.1 Flange Design

The flange is part of the breast pump that comes in contact with the breast. It provides a sealed space for negative pressure differential induced by the vacuum pump. The goal of our flange design is to create a comfortable interface for a mother that replicates the feeling of a baby's mouth tissue. The flange in the Rhea Breast Pump is very different from those in existing pumps. Rather than being made out of hard plastic, it is made out of Ecoflex which is a soft, rubberlike silicone material. Because Ecoflex feels similar to human skin, it was selected to mimic the natural feeling of a baby during breastfeeding which maximizes comfort. It is also able to be molded into a desired shape. Ecoflex is flexible but can still hold its shape under vacuum pressure.

4.1.1 Flange & Mold Design Iterations

The flange shape and dimensions were initially based on the average breast size and flange sizes of existing breast pumps. The first iteration of the flange is shown in Figure 4.1. Since Ecoflex is a platinum-catalyzed silicone material, it starts in a liquid form with a viscosity similar to honey and hardens into a desired shape. A mold is needed to form the desired shape of the flange. The mold is designed in SolidWorks, shown in Figure 4.2, and is 3D printed using PLA. The mold is split up into three pieces to be able to remove the solid flange easily. The first component includes the top and inside of the mold, as shown in purple in Figure 4.3. The cross-section of the bottom parts of the mold can be seen clearly after 3D printing in black in Figure 4.3. As shown in Figure 4.2, there are six holes along the edges that align the mold and hold it in place using small wooden dowels. The bottom of the mold is split into two parts and is also aligned with wooden dowels. More images of flange and mold Iteration 1 can be found in Appendix C.1.

Figure 4.1: Flange Iteration 1 made out of Ecoflex 00-50.

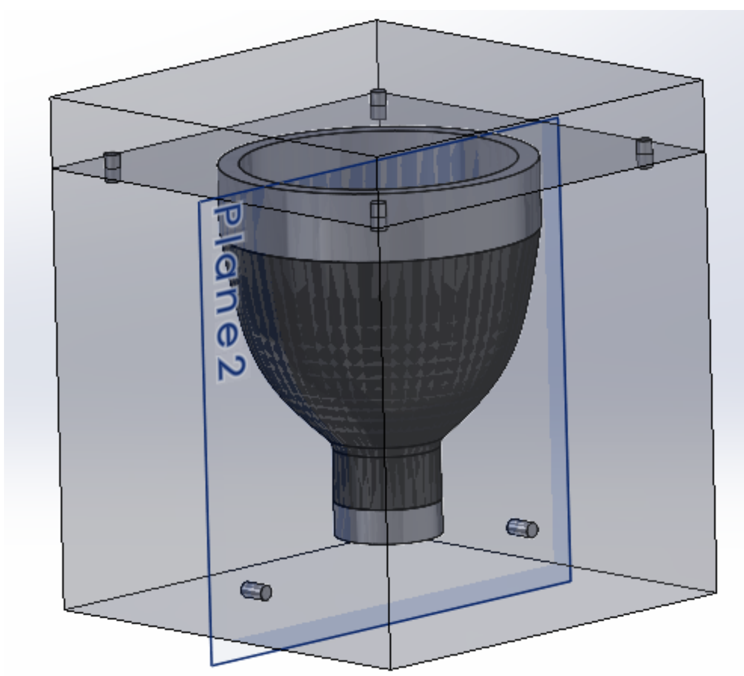


Figure 4.2: SolidWorks model of flange mold Iteration 1 (bottom is split at Plane 2).

Figure 4.3: Bottom half and top of flange mold Iteration 1.

Prior to pouring the material, the mold is coated in Universal Mold Release to make the removal process easier. For the molding process, the two bottom halves of the mold are aligned and attached first. The pieces are secured together with rubber bands. The design of the flange mold requires the Ecoflex to be poured from the top of the mold, so it is necessary for the bottom of the mold to be closed to hold the poured material. A controlled volume equal to that of the flange of liquid Ecoflex 00-50 is poured into the bottom of the mold. Then, the top and inside of the mold are pushed into the liquid to make the desired shape. An additional well to close the bottom of the mold was added to the design to account for this process. The mold design also accounts for an extra inch of overflow material at the top of the flange that will be trimmed after the flange is set. This ensures the mold will not overflow. After the material is cured for three hours, the bottom well is trimmed so that all that remains from the molded material is the desired shape of the flange, with a hole all the way through the piece.

After the first flange was made, it was observed that the flange is too long to create a strong enough suction around an average breast. The second iteration of the flange is shorter in length and includes a lip around the wide opening as shown in Figure 4.4. This lip allows the flange to wrap around the outer housing of the pump and can be seen in the mold in Figure 4.5. This ensures that Ecoflex is the only material coming in contact with the breast to provide optimal comfort for the mother. The narrow end, or neck, of the flange, is made about 5 mm thinner in order for the flange to deform more under pressure and to ensure the tongue actuator is felt on the nipple through the flange. The shape of the flange is also made less round to create a tighter fit to the breast and to maintain a sealed space for vacuum pressure to be applied.

Figure 4.4: Flange Iteration 2 made out of Ecoflex 00-50.

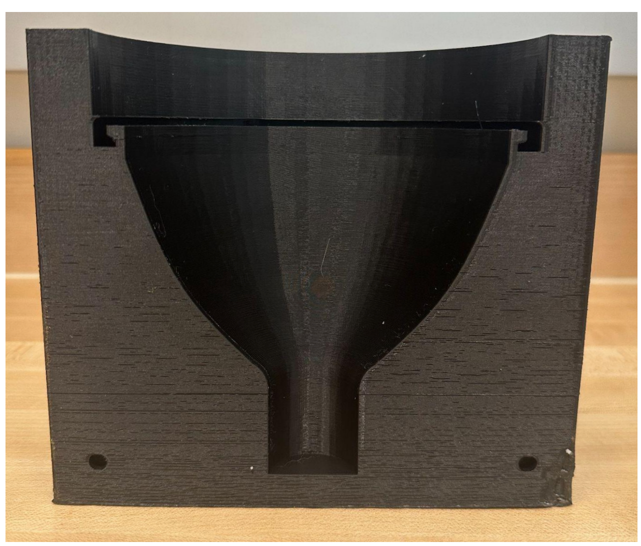


Figure 4.5: Bottom half of flange mold Iteration 2.

In our final iteration, shown in Figure 4.6, the flange is more conical in shape in order to have a tighter fit on the prosthetic breast. This is accomplished by reducing the length to help the flange sit closer to the breast and improve sealing. Additionally, along the bottom part of the flange, where the tongue actuator comes in contact with the flange, the flange thickness is thinner than in other areas. With the flange thinner in the neck and along the bottom, the tongue actuator can be felt better through the flange and be more effective at extracting milk. At this stage in the design process, we decided to embed the heating plates into the flange to create a warm compress. This was done by adding wells to hold the heating plates so that the heat could be felt through the flange. These changes are highlighted in Figure 4.7. Some design features that did not change from the previous iteration were the lip design, the widest diameter of the flange at the location of the lip, and the narrow thickness of the neck. Due to supply shortages, Ecoflex 00-45 is used for the final flange. It has a close stiffness to Ecoflex 00-50 and a photo of it can be found in Appendix C.2.

Figure 4.6: Flange Iteration 3 made out of Ecoflex 00-45.

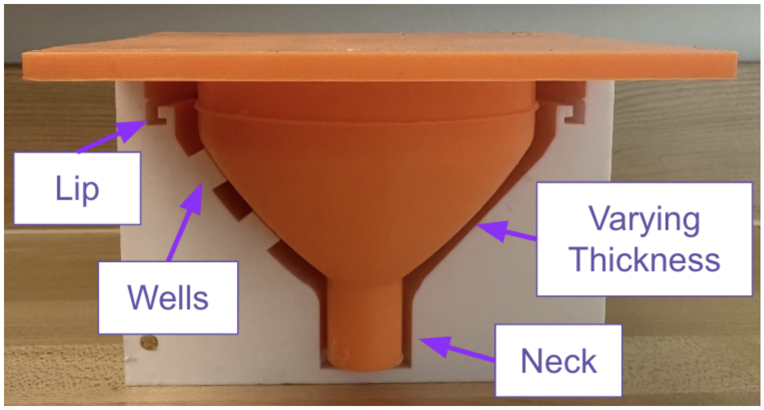


Figure 4.7: Bottom half and top of final flange mold.

4.1.2 Flange Testing

After making each iteration, we tested the fit and seal with the prosthetic breast shown in Figure 4.8 [22]. Mothers have various breast and nipple sizes so a final product would include several different flange sizes, but for the purposes of this project, this prosthetic representing the average size of a breast was used for testing an average flange size. We tested how tight the flange fit onto the prosthetic breast by observing areas where there were gaps between the breast and flange. Throughout our design process, we tried to minimize these gaps.

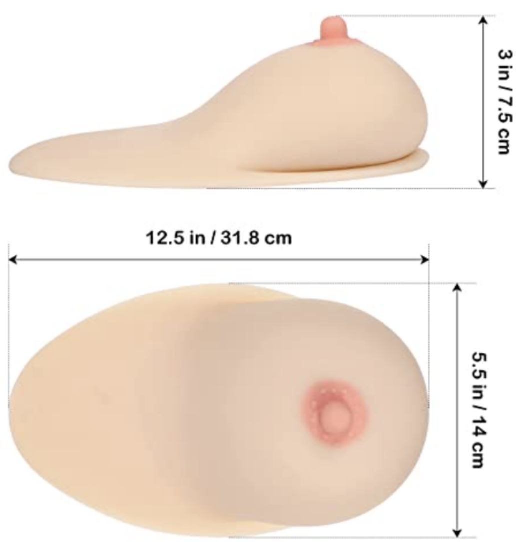


Figure 4.8: Prosthetic breast used for testing [22].

4.1.3 Final Flange Design & Implementation

The final implementation of our flange design can be seen in purple in Figure 4.9. The flange is attached to the triangle adapter using silicone sealant. The outer lip of the flange connects to the PLA housing. The heating wells are filled with heating pads and insulation in order to warm up the flange and create a comfortable interface for the mother.

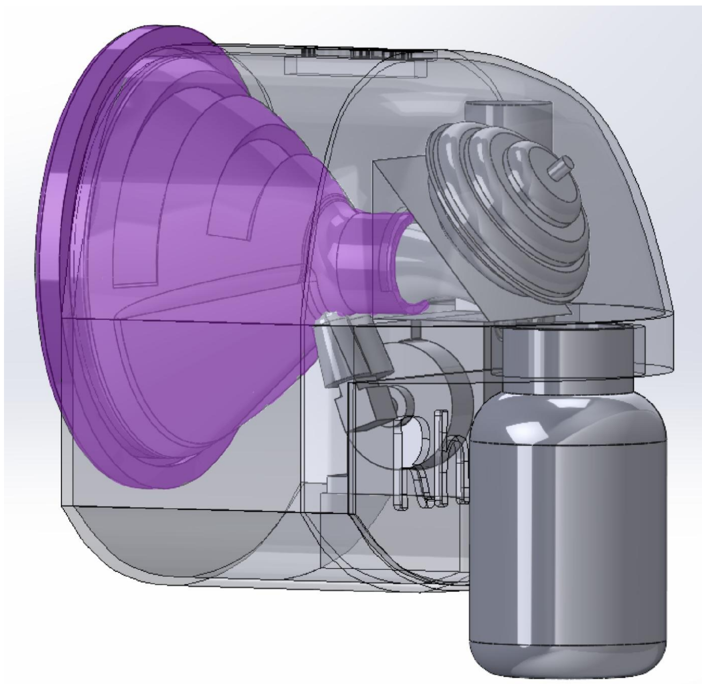


Figure 4.9: SolidWorks model of flange implementation highlighted in purple.

4.2 Heating Element

The heating element serves several purposes in the Rhea Breast Pump. First, it simulates the warmth of a baby's mouth which is lacking in other pumps currently on the market. It is hypothesized that the heating element will help produce a similar oxytocin release that occurs in the natural nursing process. Additionally, the heating element serves as a warm compress for pain relief. Many breastfeeding mothers suffer from ailments such as sore and cracking nipples, clogged ducts, and infections such as mastitis. Warm compresses are common treatments for these problems, so the heating element can help prevent and treat these common painful issues while also simulating the warmth of a baby's mouth [16]. Furthermore, warm compresses can dilate blood vessels and the lactiferous milk duct which increases milk production [17]. To properly achieve the function of a warm compress, the heating element must reach and maintain a desired temperature of 40ºC in a timely manner so that it is effective for an average length of the 15-minute pumping session.

4.2.1 Heating Material Selection Process

For the first iteration of the heating element, the Adafruit EeonTex High-Conductivity Heater Fabric was implemented into our flange design, as shown in Figure 4.10 [23]. This iteration, including the connection of alligator clips to an Arduino Uno board and breadboard circuit, is shown in Figure 4.11. This breadboard circuit has a potentiometer with the ability to turn on and off the heat with a regulating dial and I/O switch. The alligator clips are also connected to a 9V battery and to the cut-out portion of the heating fabric that could be adhered to the Ecoflex flange. This iteration, unfortunately, did not work due to the battery not supplying enough voltage to the fabric, in turn, causing the circuit to generate not enough heat to adequately warm the Ecoflex material. Additionally, the heating fabric only heated up at the location of the applied current. It did not uniformly distribute heat as well which was not ideal for this application.

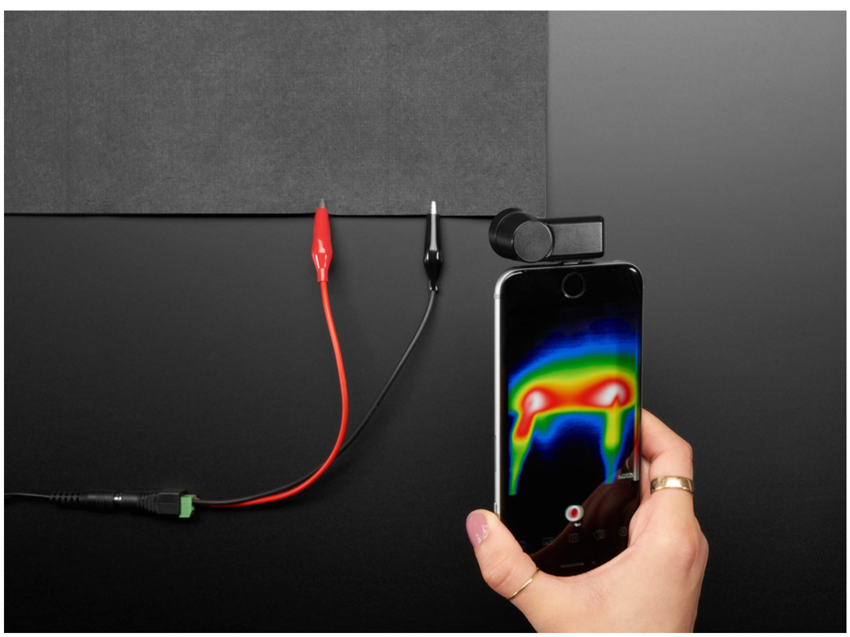


Figure 4.10: Adafruit EeonTex High-Conductivity Heater Fabric - NW170-PI-20 [23].

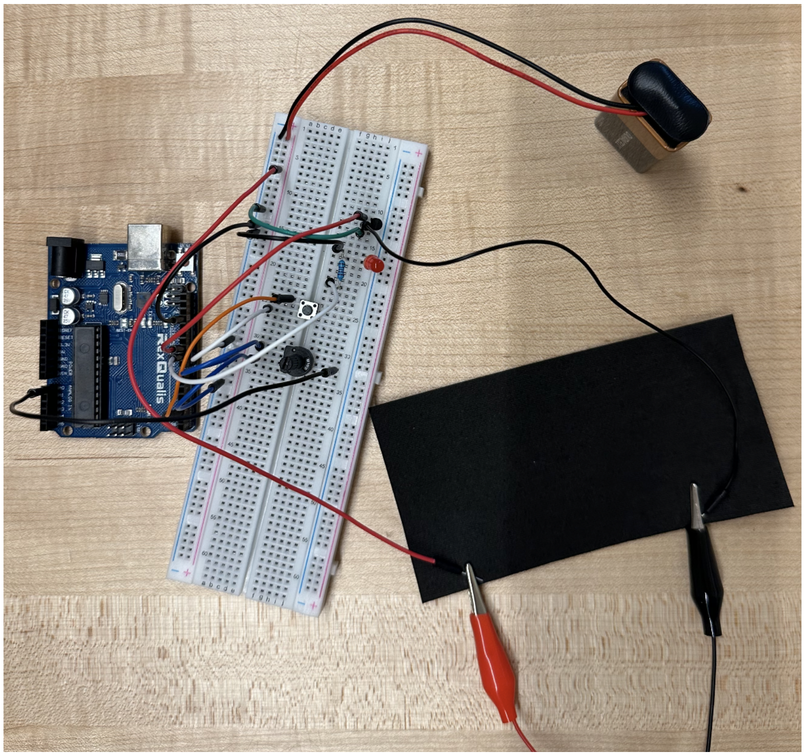


Figure 4.11: Arduino Uno, breadboard with potentiometer and I/O switch, heating fabric, and 9V battery.

For the second iteration of the heating element, the Clayborn Pressure-Sensitive Heating Tape, shown in Figure 4.12, was assessed with the goal of completely embedding the heating tape inside the Ecoflex flange material. With the intention of creating a working prototype, a feedback system with a thermocouple monitor was implemented. A power supply was not used due to its apparent complexity with this application. This material was ultimately not used due to its complexity and the fact that the tape was relatively stiff and difficult to implement into the final flange design. Additionally, there was some concern that the wires might puncture the flange and poke or burn the user.

Figure 4.12: Clayborn Pressure-Sensitive Heating Tape.

The final material considered for the heating element was the Arduino-compatible heating plates shown below in Figure 4.13 [24]. The plates are small, measuring 10 mm by 93 mm. They are made of polyimide and require 12V and 12W of power per plate. They reach a maximum temperature of 150ºC which is well above the required temperature of 40ºC. Since these heating plates were small and flexible enough to be implemented into the flange while also reaching the desired temperature quickly, they were selected for the final design.

Figure 4.13: Heating plates used in the final prototype [24].

4.2.2 Heating Element Testing

Once the heating plates were selected as the material for the heating element, several experiments were conducted to determine specific details for the final design and implementation. The purpose of the first test was to determine the thickness of the flange wells for the final flange design. This test was conducted by layering a heating plate on top of three different thicknesses of Ecoflex, and the temperature across the Ecoflex was measured every 15 seconds for 90 seconds using a thermocouple. A diagram depicting the experimental setup is shown below in Figure 4.14. The results of this experiment are given in Figure 4.15 with a complete list of data points found in Appendix D.1.

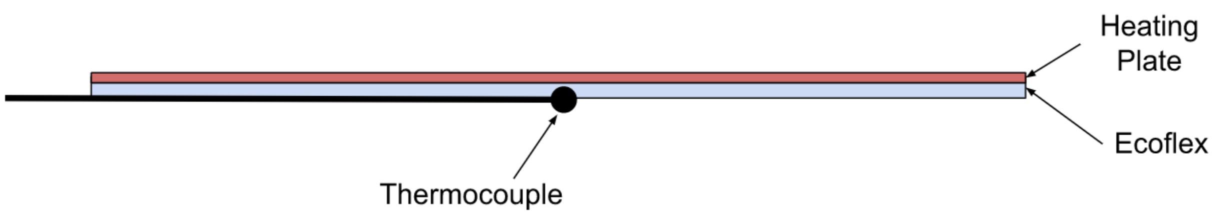


Figure 4.14: Diagram of experimental setup to determine flange thickness.

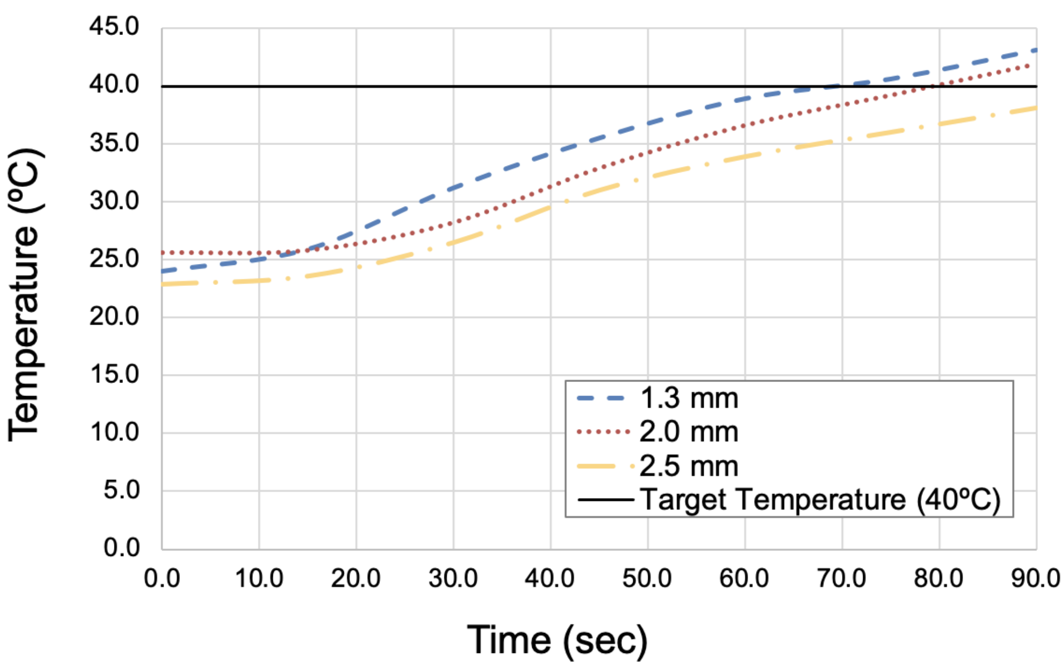


Figure 4.15: Results of flange thickness test.

The results of the flange thickness test showed that after approximately 70 seconds of heating, the temperature across the 1.3 mm and 2.0 mm Ecoflex layers reached the target temperature of 40ºC. The thickest Ecoflex layer with a thickness of 2.5 mm did not reach the target temperature within 90 seconds. Since the results of the two thinner layers were very similar, the thicker layer was selected to maximize the durability of the flange. The final flange well thickness was chosen to be 2.0 mm.

The second experiment was used to determine the best way to hold the temperature of the plates constant at 40ºC while considering the effect of body heat on the recorded temperatures. Additionally, this test sought to establish that adding layers of insulation would mitigate the escape of excess heat from the heating plates to the interior of the breast pump casing. For this test, modulated heating was employed in the hopes of maintaining a steady temperature at 40ºC. The heating pattern began with an initial heating period of 15 seconds followed by a repeated cycle of 10 seconds off and 5 seconds on that repeated 6 times. This experiment recorded temperatures from two thermocouples every 15 seconds. The first thermocouple was placed on top of two layers of insulation. Next, the heating plate was layered between the insulation and the 2.0 mm thick Ecoflex layer. The second thermocouple was placed between the Ecoflex and the skin. A diagram of the experimental setup is shown in Figure 4.16, and a photo of the physical experimental setup is shown in Figure 4.17. The results of the modulated heating test are shown below in Figure 4.18 and the complete set of data points can be found in Appendix D.2.

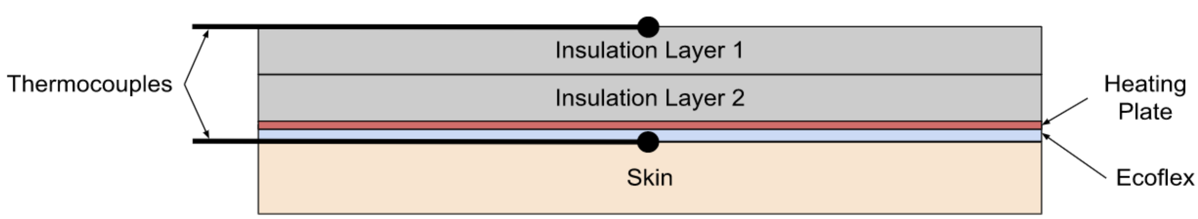


Figure 4.16: Diagram of experimental setup for the modulated heating test.

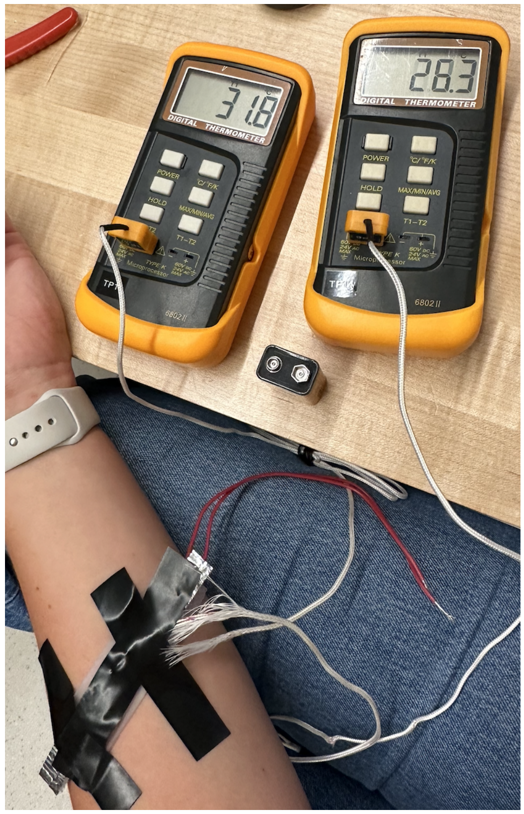


Figure 4.17: Photo of experimental setup for the modulated heating test.

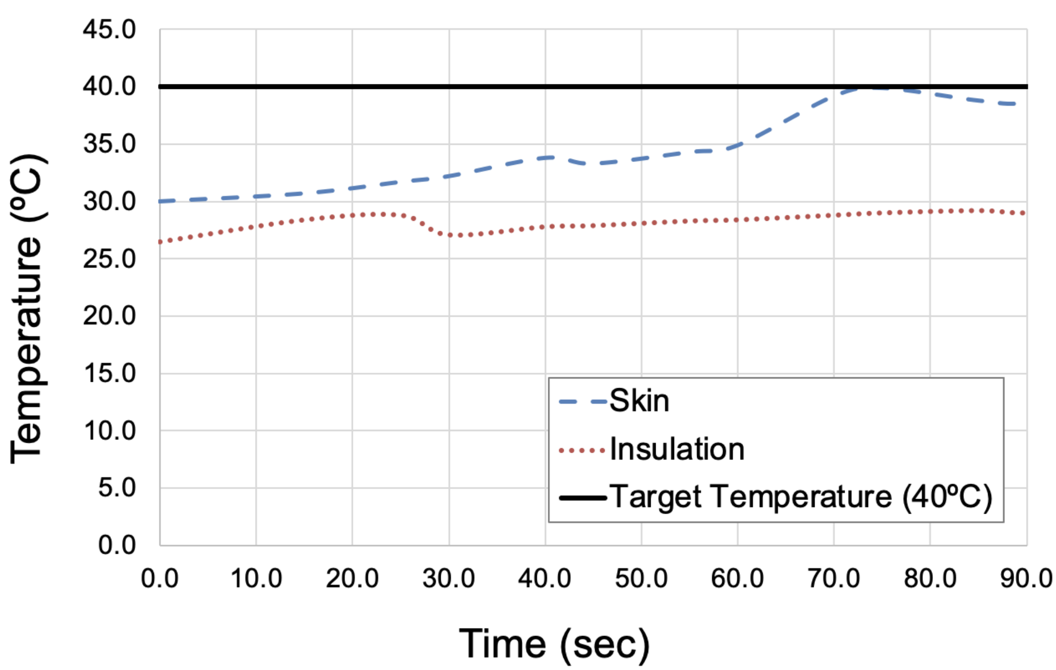


Figure 4.18: Results of modulated heating test.

From the results obtained, it is clear that the modulated heating system was successful in maintaining a steady temperature of 40ºC. The thermocouple across the Ecoflex reached the desired temperature after just over a minute of heating. Furthermore, it can be seen that the insulation was successful in preventing excess heat from passing through which keeps the interior of the pump as cool as possible.

4.2.3 Final Heating Element Design & Implementation

The SolidWorks model of the final implementation of the heating element is shown below in Figure 4.19 in purple. Figure 4.20 shows a photo of the final implementation. In Figure 4.20, three heating plates are placed in the flange wells and are behind one layer of insulation. For clarity purposes, the second layer of insulation is not shown in the photo.

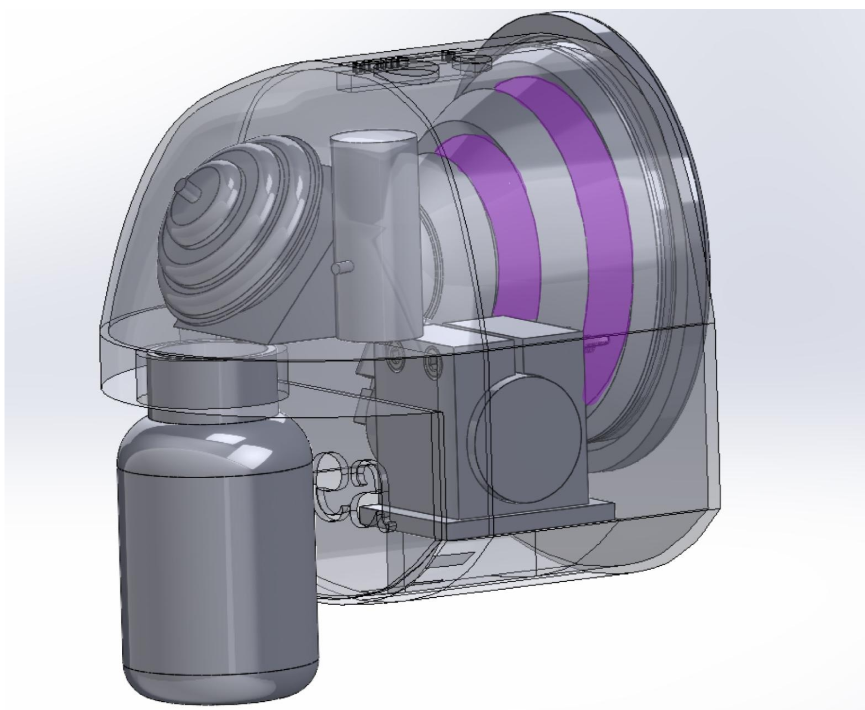


Figure 4.19: SolidWorks model of heating element implementation labeled in purple.

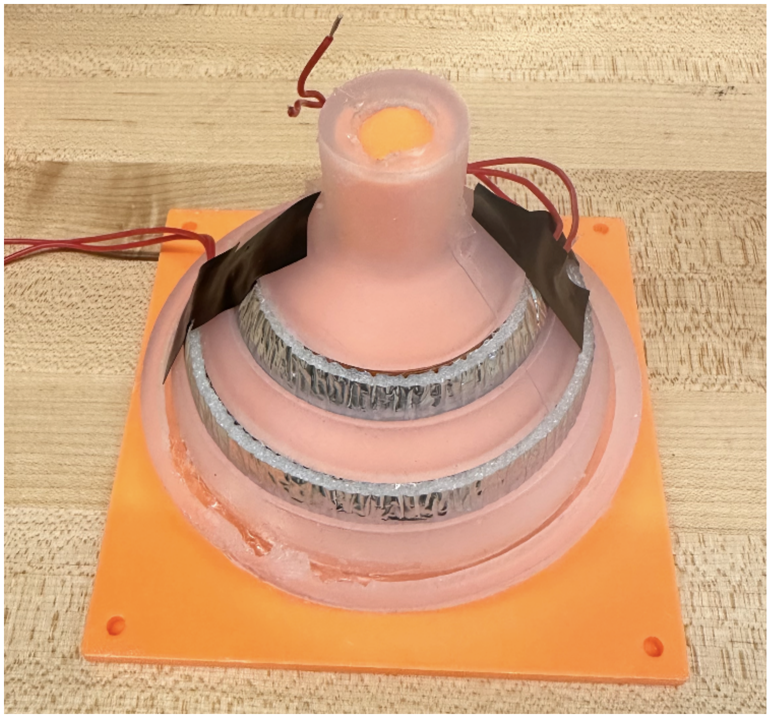


Figure 4.20: Photo of heating element implementation.

The final implementation requires an initial heating period of 2 minutes, then a cycle of 10 seconds off, and 15 seconds on that repeats 31 times to fill the length of an average pumping session. The discrepancy between the modulated heating test results and the final heating pattern is due to the fact that there is a slight gap between the interior layer of the flange in the wells and the heating plates were not anticipated during testing. This gap requires a longer initial heating period to reach and maintain the desired temperature. In future design iterations, the flange wells might be slightly redesigned to better fit the heating plates to prevent the gap and reduce the initial heating period of the final design.

Chapter 5:
Milk Extraction Subsystem

This chapter describes the biomimicry inspired design of milk extraction by using both mechanical extraction and pressure differentials. This subsystem consists of two components: (1) tongue actuator, (2) vacuum pump.

5.1 Milk Extraction by Tongue Actuator

In the natural nursing process, a baby creates mechanical motion through the movement of their tongue which applies between 5-10 kPa of pressure to the nipple [10]. The goal of the tongue actuator in the Rhea Breast Pump is to replicate this motion as closely as possible. A baby's tongue in the natural nursing process works in tandem with suction pressures to mechanically extract milk from the breast. Current breast pumps on the market rely entirely on vacuum pressure differentials to drive milk flow. Based on our research, our team hypothesizes that mechanical extraction in addition to vacuum pressure will improve pumping efficiency while implementing biomimicry technology.

5.1.1 Tongue Actuator Motor

Since a baby's tongue moves cyclically, a rotary motor was selected to replicate this motion. To justify the selection of the motor, several calculations were used to estimate the torque that a baby's tongue applies on the nipple. This torque was then compared to motors on the market before the final motor selection. There is limited data available on the forces that a baby's tongue applies, so the force F was estimated from the pressure, p = 5 kPa, and the estimated contact area A of a tongue. From this, it was determined that the force a baby's tongue applies is approximately 12.5 N.

$$F_{baby} = p \cdot A \tag{5.1}$$

Next, the torque *T* from a baby's tongue was estimated from the estimated length of the tongue *d* and it was found to be 4.08 kgf.cm.

$$T_{baby} = F \cdot d \tag{5.2}$$

The complete calculations for these values can be found in Appendix F.1. A motor was then selected based on this estimated torque, and the final motor has a rated torque of 3.97 kgf.cm which is nearly identical to the estimated torque from a baby [25]. The force that the motor applies from the end of the tongue actuator is 11.68 N. A photo of the motor is shown below in Figure 5.1.

Figure 5.1: Photo of tongue actuator motor [25].

5.1.2 Tongue Actuator Design Iterations

For the tongue actuator, each design iteration was designed in SolidWorks and 3D printed out of PLA. Initial prototypes of this design were modeled after a gear or cam, as seen below in Figure 5.2. The initial thought of this design was to have the actuator strike the nipple at a higher frequency while minimizing the footprint of the design in the pump. However, this design was not feasible long term because it was not thick enough to apply significant force. Additionally, the shape was not similar enough to a tongue which did not satisfy the biomimicry requirements of the project.

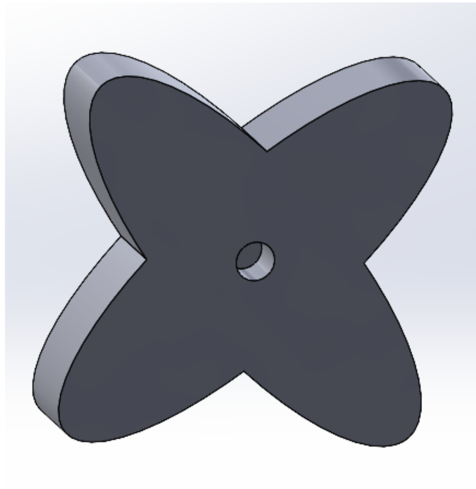


Figure 5.2: SolidWorks model of four-spoke tongue cam actuator design.

A later iteration of the design included two tongue spokes mounted on one beam which would be attached to the motor in the middle, modeled in Figure 5.3. This design is 8 cm long which is much larger than the previous iteration. The tongue parts are shaped much more like a baby's tongue with a well in the middle of the top face in order to improve comfort for the user as the actuator strikes the flange.

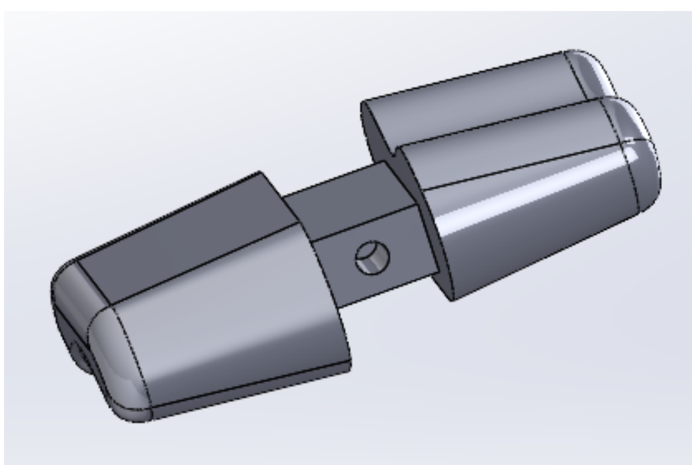


Figure 5.3 SolidWorks model of two-spoke tongue actuator design.

The final tongue actuator design is shown below in Figure 5.4. The actuator has one spoke on which a tongue-like shape is attached, and its length was reduced to 3 cm. The motor spins the actuator from the fixed end so that the tongue tip is the only part of the actuator making contact with the flange. The intention of this design is to simplify the timing process issues from the previous iteration with two tongues. Additionally, the final design reduces the footprint of the actuator to improve the wearability of the pump.

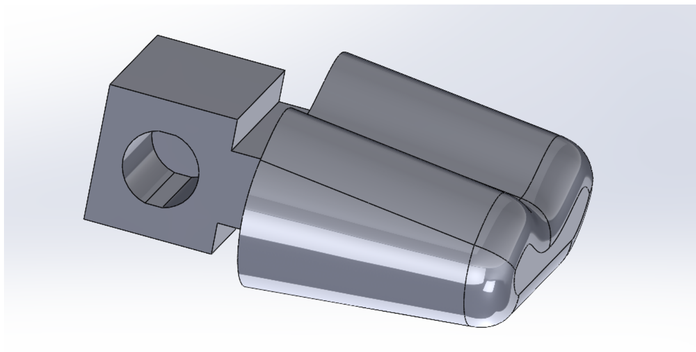


Figure 5.4: SolidWorks model of one spoke tongue actuator design.

5.1.3 Final Tongue Actuator Design & Implementation

The tongue actuator is located on the bottom of the flange at the narrowest part, seen in purple in Figure 5.5.

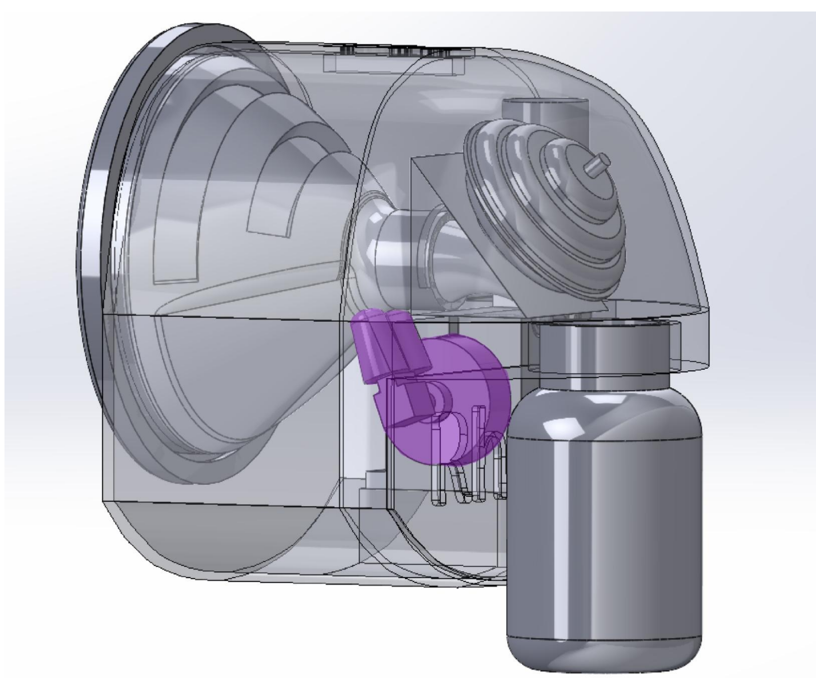


Figure 5.5: SolidWorks model of tongue actuator implementation in the final design.

It consists of a rotary motor and an attached 3D printed tongue that moves in time with the pump to replicate the timing of a baby's natural suckling pattern. It is secured to the casing in a 3D printed support part that is shown in red in the photo of the final actuator design in Figure 5.6.

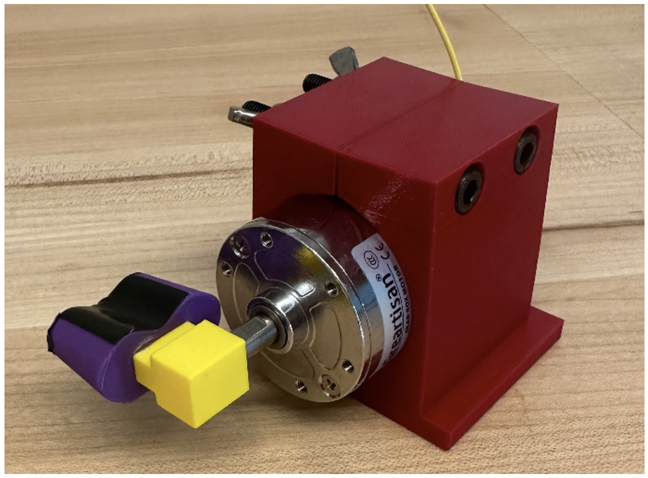


Figure 5.6: Final tongue actuator design.

In the final design, the printed tongue actuator is glued to the motor shaft which is secured by the motor support. It rests on a shelf inside the casing to precisely place the motor at the desired location. The tongue actuator is also lined with electrical tape to reduce friction from the tongue tip on the flange as it strikes.

5.2 Milk Extraction by Vacuum

The vacuum pump is used to replicate the suction of a baby's mouth during the natural nursing process. We evaluated the current breast pumps on the market to gain a better understanding of their milk extraction processes. These pumps only utilize vacuum pressure as a method in which to extract milk. These pumps induce an average of 33 kPa of vacuum pressure [12]. Comparing this value to natural nursing, the maximum pressure from a baby's mouth is only around 25 kPa, and the average pressure from a baby's mouth is even smaller at around 7 kPa [11]. This discrepancy between the pressure of a pump and the pressure from a baby's mouth is due to the fact that current breast pumps do not have any additional extraction forces to draw milk from the breast to the collection area. Biomicry as a concept acknowledges that there are more forces imposed by a baby's mouth that aid in extraction. This means the pumps need a much higher vacuum pressure than in natural nursing.

Considering this, the DC micro vacuum air pump used in the Rhea Breast Pump, shown in Figure 5.7, does not need to induce as much pressure as other breast pumps. While the maximum vacuum level of the pump is 56 kPa, the applied vacuum pressure is only 17 kPa. Made of premium aluminum and plastic, the pump is corrosion-resistant and durable. It is rated for 12 V and has a maximum current of 400 mA. The micro pump is cylindrical in shape, being only 60 mm in length and 24 mm in diameter. This small size enables the breast pump to be wearable and allows mothers to pump without having to be connected to a power outlet. Most importantly, the pump is Arduino-compatible, which allows for easy control over the timing and power of the pump to closely mimic a baby's natural nursing rhythm. [26]

Figure 5.7: DC micro vacuum air pump [26].

5.2.1 Adapter Design Iterations

Another element of the vacuum pump system is an adapter that is used to connect the pump and the flange. Each adapter includes a backflow protector, connected directly to the vacuum air pump, to ensure that no liquid gets into the pump. Throughout the design process, the adapter underwent multiple iterations to make the pumping process as efficient as possible. The first adapter iteration is a large, half-dome-shaped vacuum chamber, highlighted in purple in Figure 5.8.

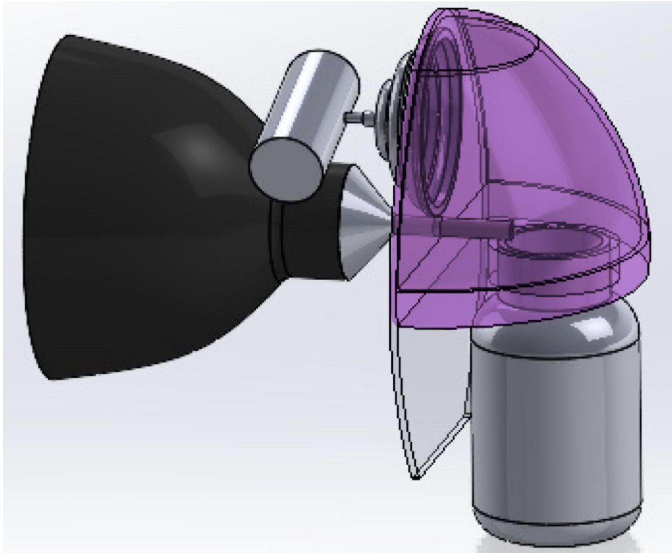


Figure 5.8: SolidWorks model of large vacuum chamber adapter.

In this iteration, the pump, connected to a backflow protector, is located near the top of the adapter. However, this design is too big and forces the pump to vacuum a very large amount of air. To make the adapter smaller and better suited for our wearable pump, the second iteration of the adapter is a small circular disk, shown in Figure 5.9.

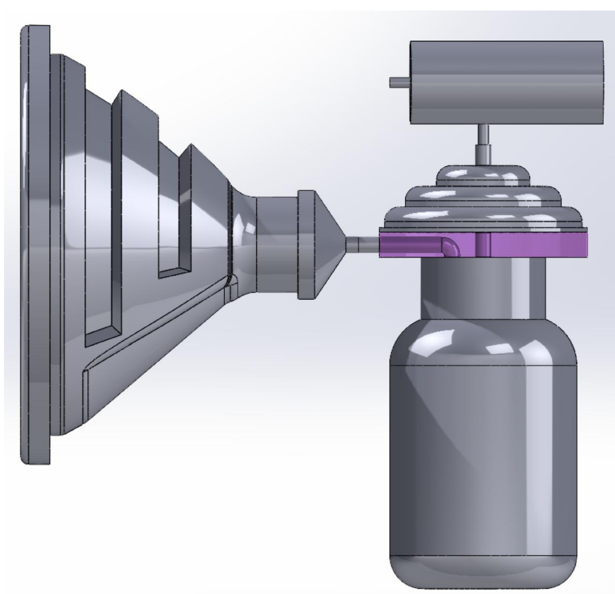


Figure 5.9: SolidWorks model of small circular disk adapter.

This design decreases the amount of air the pump must vacuum which makes it much more efficient. However, the orientation of the backflow protector and pump provides weaker suction than desired. This leads to the final adapter design which is the triangle adapter, seen in Figure 5.10.

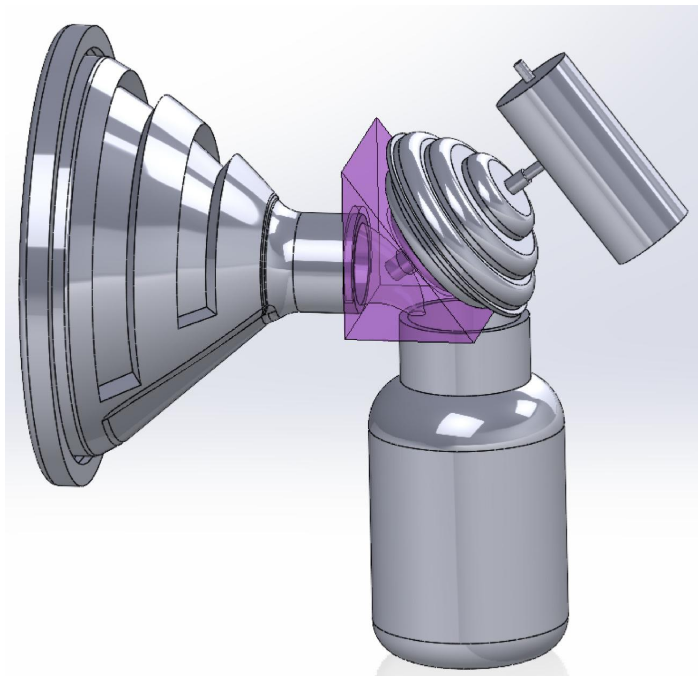


Figure 5.10: SolidWorks model of triangle adapter.

In this design, the backflow protector is at an angle to provide the most suction, since it was found after testing that the vacuum pump applies the highest amount of suction when it is angled more directly towards the neck of the flange. Another notable element of this design is the flange-to-adapter connection. In this final iteration, the flange is connected directly to the triangle adapter, whereas in the first two iterations, a funnel was attached to the end of the flange, and tubing was used to direct the milk to the adapter. The absence of tubing in the final design decreases the volume of air to be vacuumed and takes up less space inside the pump. This triangle adapter is a 3D printed piece that is completely separate from the housing. This makes it easier to attach the backflow protector and flange and ensure everything is properly sealed. This also allows for the manual placement of the adapter and pump, facilitating the assembly process.

5.2.2 Vacuum Pump Testing

Due to liability and safety, no human trials could be conducted. As a result, testing was limited to simplified methods. The vacuum pump was tested using three different techniques. In the first test, the pump was attached directly to the flange using a funnel and tubing. The flange was then placed over a silicone breast, shown earlier in Section 4.1.2 in Figure 4.8, and the pump was turned on. Once the pump was turned on, the flange was observed to collapse down onto the prosthetic breast which created a small compressive force. This indicated that the pump is able to apply enough suction to create a tight seal around the breast so that milk can be extracted. This silicone breast model, however, is solid and does not have the ability to store any liquid. To see how milk would be extracted by the pump, MamaBreast was used [27]. It is a wearable medical device that simulates lactating breasts and is used to help mothers practice breastfeeding. This device is shown in Figure 5.11.

Figure 5.11: MamaBreast medical device [27].

In the second test, the MamaBreast was used in place of the silicone breast and the pump-flange apparatus was kept the same. This test did not provide insightful results, however, due to the limitations of the medical device. The material of the model does not closely mimic the feeling of the skin, making it much harder to create a seal between the device and the flange. It is also very difficult to extract the liquid from the device, even when using hand expression. As a result, the device does not provide a very accurate model of a lactating breast.

In order to test the vacuum pump and measure the vacuum pressure it applies, a small part was designed in SolidWorks and 3D printed in PLA. This part fits perfectly into the flange and is able to create an airtight seal. This allows us to connect a tube and negative pressure gauge to the part and measure the applied pressure within the flange. This apparatus is shown in Figures 5.12 and 5.13.

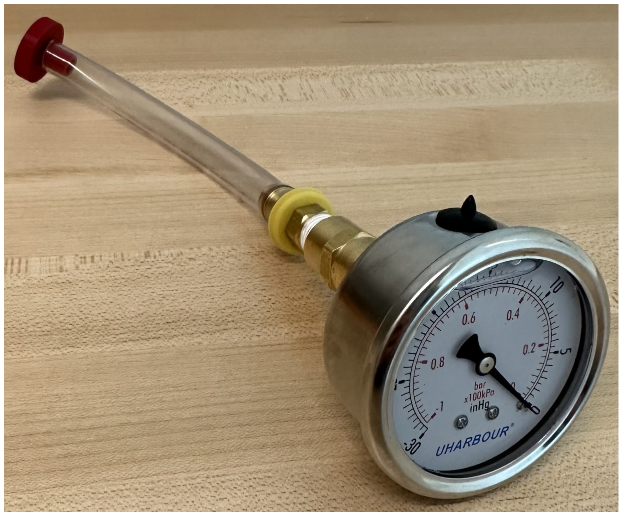


Figure 5.12: Pressure gauge testing apparatus.

Figure 5.13: 3D printed part used to test applied vacuum pressure.

From this test, the applied pressure of the vacuum pump is found to be 17 kPa. This value falls in the middle of our target range, explained in Section 1.3, of 13 to 20 kPa of vacuum pressure.

This means the pump is able to initialize the flow of milk, while still being comfortable for the mother.

5.2.3 Final Adapter Design & Implementation

The final design of the triangle adapter, backflow protector, and pump can be seen in Figure 5.14. In this design, the pump is connected to the backflow protector using tubing. This tubing however is not shown in the figure for simplicity.

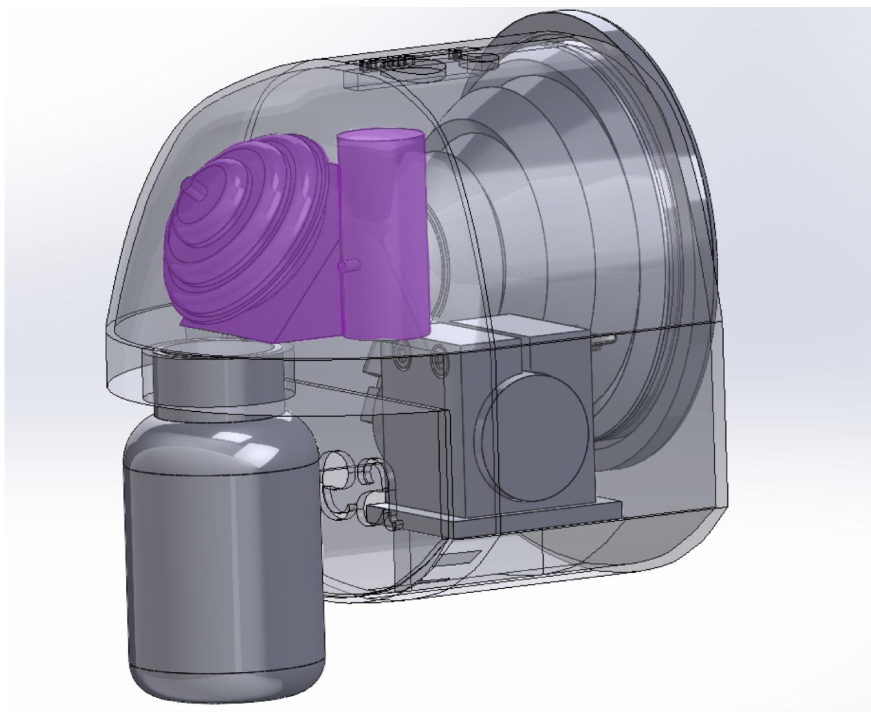


Figure 5.14: SolidWorks model of final pump and adapter design.

Chapter 6:
System Integration & Testing

The flange, heating element, tongue actuator, and vacuum pump were integrated into the system using circuitry that was completely encased in the housing.

6.1 Circuitry

After creating all of the physical designs, the vacuum pump and tongue actuator are integrated using circuitry. As seen in the functional diagram in Figure 7.1, the pump and tongue actuator work in tandem to increase milk yield. A detailed schematic of this circuit can be found in Appendix E.1.

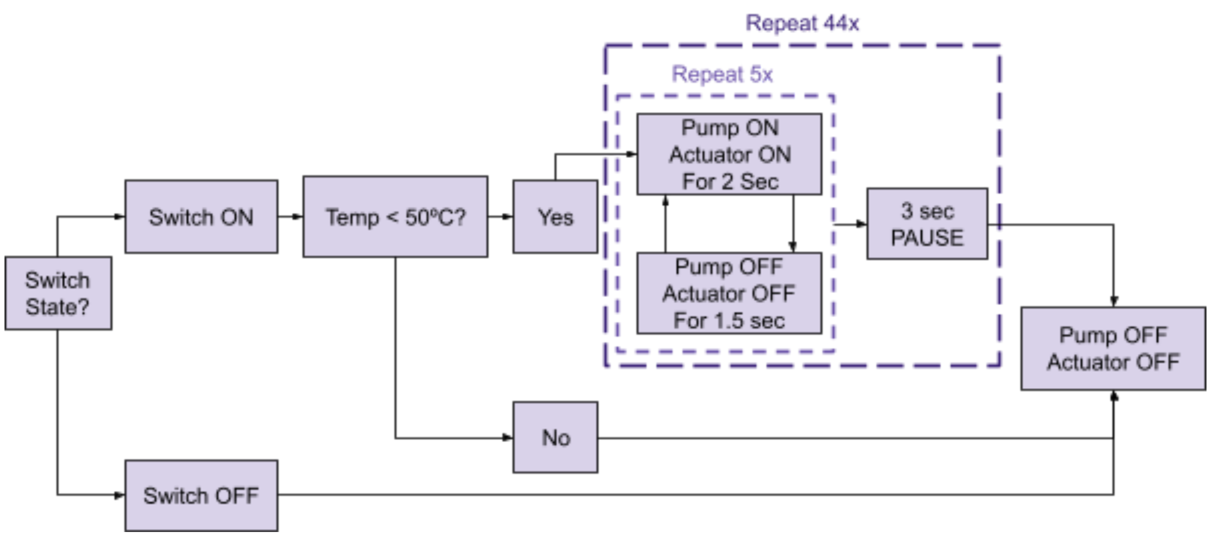


Figure 6.1: Functional diagram of vacuum pump and tongue actuator circuit.

An on/off rocker switch is used to turn on the circuit, initiating the pump and actuator cycles. In one cycle, the pump and actuator turn on for 2 seconds and then turn off for 1.5 seconds. These cycles are repeated with a 3-second pause every five cycles to simulate the swallowing of a baby. This entire sequence is repeated 44 times to fill the length of an average pumping session which is about 15 minutes [21]. However, the nursing mother is able to stop the pumping session at any time by turning the switch to the off position. The code for this circuit is shown in Appendix F.2

A DHT11 temperature and humidity sensor is also implemented in this circuit to monitor the temperature inside the casing. It is coded to automatically turn off the circuit if the temperature reaches a threshold of 50ºC. This value is based on the operating temperatures of the circuit elements. The sensor is vital, as it keeps the pump and actuator from overheating, and ensures the mother's safety while she is pumping. The heating element is in a separate circuit, shown in Figure 6.2. Refer to Appendix E.2 for a detailed schematic.

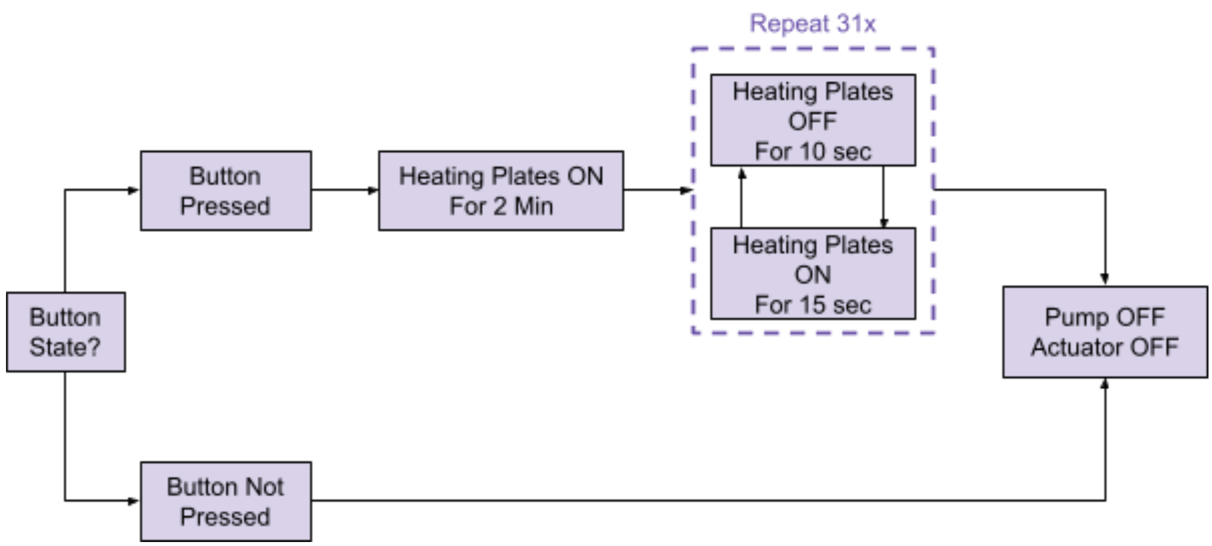


Figure 6.2: Functional diagram of heating element circuit.

As discussed previously, the results of various tests are used to determine the best timing of the heating plates. These results show that modulated heating is the most effective method in maintaining a steady temperature of around 40ºC with the technology we have available to us. Accordingly, after the button is pressed, the heating plates are initially turned on for 2 minutes. Once that period of heating is complete, the plates turn off for 10 seconds, then turn on for 15 seconds. These modulated heating cycles are repeated 31 times to fill the length of the pumping session. The heating then automatically turns off until the button is pressed again. The code for this circuit can be found in Appendix F.3. In future iterations, the heating plates could be controlled by a potentiometer to provide a more customizable user interface and allow mothers to adjust the heating to their desired temperature. This circuit could also be integrated into the pump and actuator circuit to minimize the number of electrical elements within the pump and allow for the temperature sensor to turn off all of the circuitry components.

In both circuits, an Arduino Nano board is used to control the timing and power of each element. The small boards are ideal for decreasing the weight and size of the pump, aiding in the wearable design. Each circuit is powered by two 9V batteries– one powering the Arduino board and one powering the individual elements. Since each Arduino board only provides a maximum of 5V, each board is provided with 14V of power in total.

6.2 Housing

The housing underwent many iterations throughout the design process. The challenge of holding all components and circuitry in a wearable design called for detailed plans for providing the space for each component. A single 3D PLA print can be viewed in Figure 6.3 with an online 3D rendering from a different vantage point found in Figure 6.4. The quarter sphere section which holds the yellow bottle lid was created that size to hold the pump and backflow protector within. The flat shelf located inside the housing serves as a stabilization platform for the motor in order for it to impact the flange at the desired force and location. In the full assembly of the pump, the motor stand was glued to this flat shelf. Further customization can be noted in the flat walls as well as the width of the device. Those features were implemented to enable proper alignment of the tongue actuator with the flange as well as the inclusion of the motor's flat and large diameter face. The curved bottom of the casing minimizes size while leaving the minimum space for the tongue actuator to rotate a full three-hundred sixty degrees.

The opening, shown in Figure 6.3, was intentionally implemented for access to the inner devices of the prototype to help with installation and adjustments to ensure the success of the technology. Ideally, the final product would seal off all electronic circuits and permanent components from the user's access. The holes visible in Figure 6.4 hold the switch and button to activate the two features and circuits respectively. Lastly, the flange sits around the circular lip, shown in Figure 6.4, in order to stabilize the Ecoflex flange while also ensuring the only skin interaction material is the soft Ecoflex on the user. This opening is off-center in order to align with the tongue actuator placement in the casing which enabled the smallest possible dimensions of the current iterations. Currently, these dimensions sit at approximately 13x14x15 cm.

Figure 6.3: 3D single PLA print of housing design showing the outer facing bottle connection and accessibility opening.

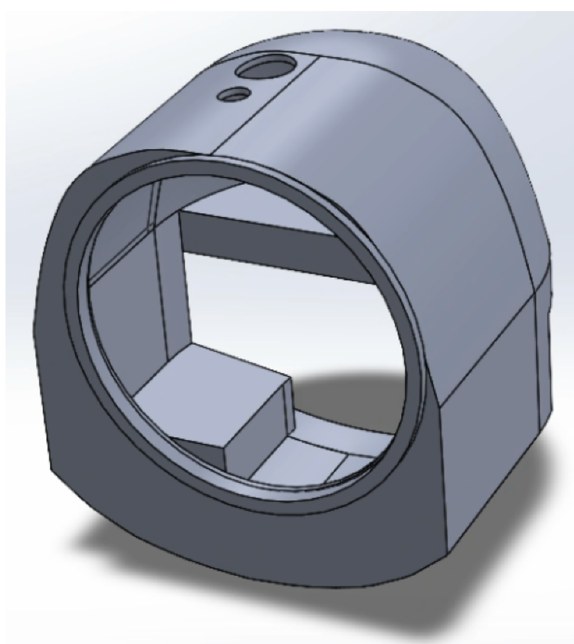


Figure 6.4: SolidWorks model of casing showing the flange lip and interfacing side with a view into the internal build of the device.

6.3 Physical Assembly

The final prototype assembly can be seen in Figure 6.5. The left side of the photo shows the flange lip for a visual representation of the side of the Rhea Breast Pump Prototype that interfaces directly with the mother's breast. Other components, observable from the outside, include the milk bottle attached to the casing in front of the white Rhea logo plate. In market-ready design, these would be the only accessible features to the user. The rest would remain sealed and insulated away for safety purposes. This final prototype runs on a total of four 9V batteries. In an ideal and manufactured version of this prototype, a rechargeable battery would be incorporated into the human interface to support the wearability aspect.

The 3D SolidWorks model rendering of the physical assembly is shown below in Figure 6.6. The inner placement of components is clearly displayed in this image. Key orientations of respective components include the alignment of the tongue actuator on the flange. Additionally, the positioning of the neck of the flange into the triangle adapter proved successful in transporting milk toward the bottle. This triangle adapter was the result of numerous iterations in consideration of how it transports milk as well as in terms of how it exists within the housing. It seals the opening connection between the bottle and the casing. It also seals the neck of the flange. The triangle width and height were determined to fulfill these roles while taking up minimal spacing in the case. The angle at which the backflow protector sits on the triangle was also influenced by the minimal space held in the quarter-sphere casing. The angular position of the backflow protector and pump also proved key in inflicting the pressure differential effects onto the flange and breast tissue. This entire apparatus was secured to its respective interacting parts as well as the casing with sealant glue.

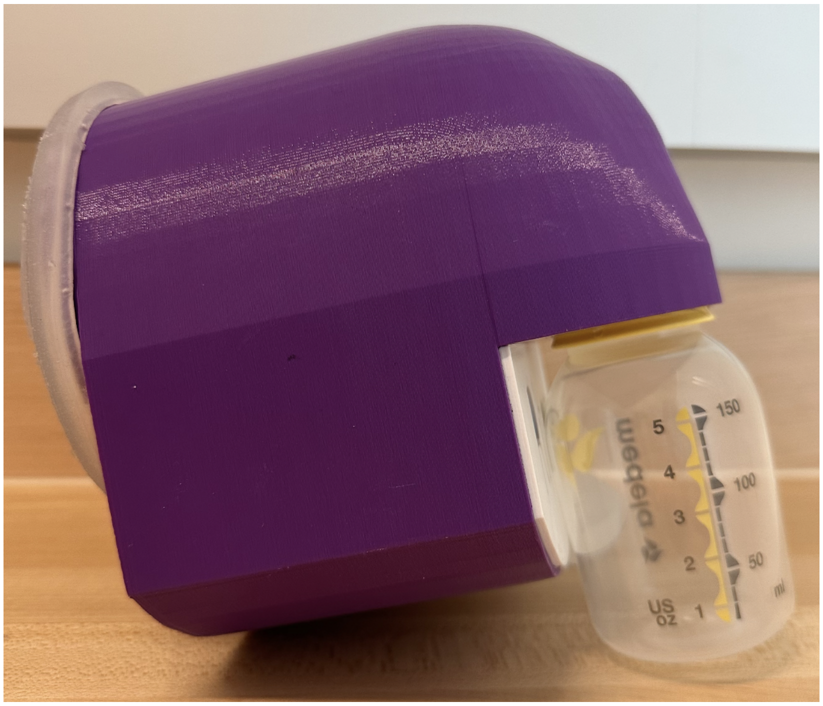


Figure 6.5: Full physical assembly.

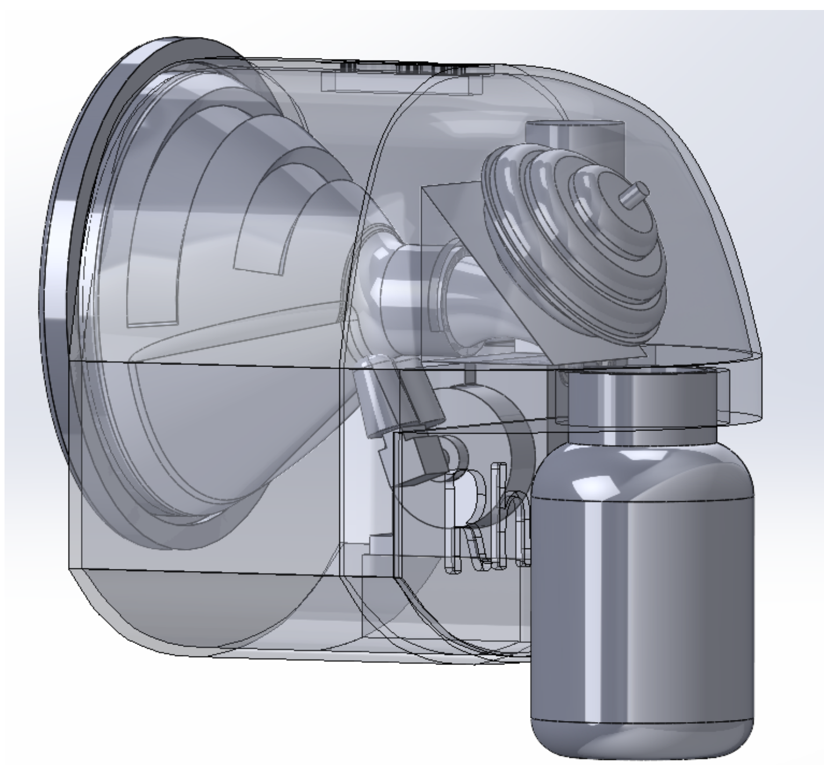


Figure 6.6: SolidWorks model of physical assembly with a view of inner component placement.

6.4 Prototype Testing

Testing the completed prototype was a challenging task since there are no adequate breastfeeding prosthetics available on the market that simulated all the necessary components at once. For our design, we required a prosthetic that was able to create a good seal to the flange, was the correct size and shape, and had liquid flowing through to mimic milk flow. The silicone breast model was adequate in creating a good seal and was the proper size, but it did not have liquid-flowing capabilities [22]. Additionally, the nipple of the silicone breast model did not deform in the same way that real breasts deform under pressure. The MamaBreast medical device was able to produce a milk flow, but the fabric material prevented a proper seal from forming which made it impossible to test the vacuum pump capabilities of the product [27]. Some homemade prosthetics such as a latex glove filled with water were also tested, but those results were also not meaningful since it was difficult to properly test all elements of the breast pump at once. Due to these challenges, our group focused our efforts on testing individual components instead.

Chapter 7:
Analysis & Modeling

Modeling is necessary to better understand the milk extraction process and the interaction between the breast tissue and the flange. Hand calculations and FEM software are employed for these purposes.

7.1 Theoretical Modeling

In order to gain a better understanding of the milk extraction process, analysis through simplified pressure gradient modeling is carried out. This modeling is used to analyze how the pressure gradient produced by the pump drives the milk flow and milk extraction. In Figure 7.1, a simplified model of the breast and flange can be seen, along with a line representing the pressure *P* within the model.

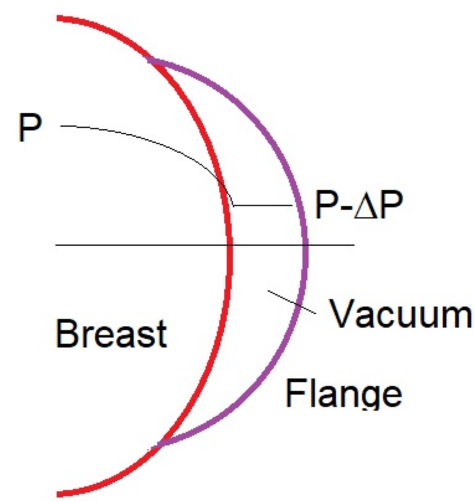


Figure 7.1: Simplified breast and flange model.

The governing equation, Darcy's Law (Eq. 7.1), can be used to understand how milk is extracted by vacuum [28]. This equation is a measurement of the flow rate *Q*, where *K* is the conductivity of the material and *A* is the area.

$$Q = - KA\frac{dP}{dx} \quad (7.1)$$

From this equation, it can be seen that the milk flow rate is directly proportional to the pressure gradient $\frac{dP}{dx}$ which drives the milk extraction. Considering this, the factors that contribute to pressure gradient and therefore what factors affect milk extraction and flow rate are analyzed further. The focus of this analysis is the pressure gradient along the centerline of the breast. This allows the breast to be approximated as a flat, semi-infinite porous-elastic solid with a negative pressure applied at the flange boundary [13]. This model is shown in Figure 7.2.

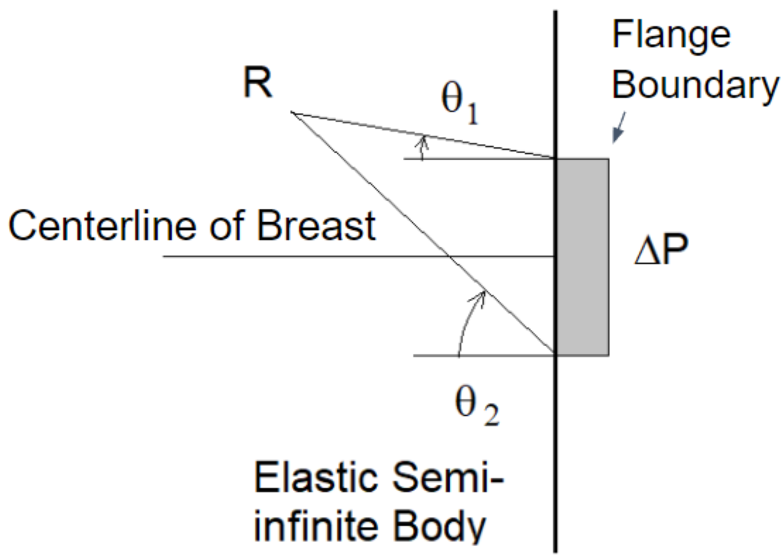


Figure 7.2: Flat breast and flange boundary model.

From the classic solution of a stress field by a point load, the pressure at point *R* in the model can be found (Eq. 7.2) [29].

$$P(\vec{r}) = \frac{\Delta P}{2\pi}(\theta_1 - \theta_2) \quad (7.2)$$

In this equation, ΔP represents the pressure differential due to the applied vacuum and θ is the angle from the horizontal flange boundary. Using this equation, the pressure distribution along the centerline of the breast can be evaluated for various flange sizes and plotted to visually represent the pressure within the breast. The pressure distribution plot, evaluated at 17 kPa of vacuum pressure, is shown in Figure 7.3. In this plot, the uniform atmospheric pressure is removed, making the atmospheric pressure equal to 0 MPa. A detailed table of this data can be found in Appendix G.1.

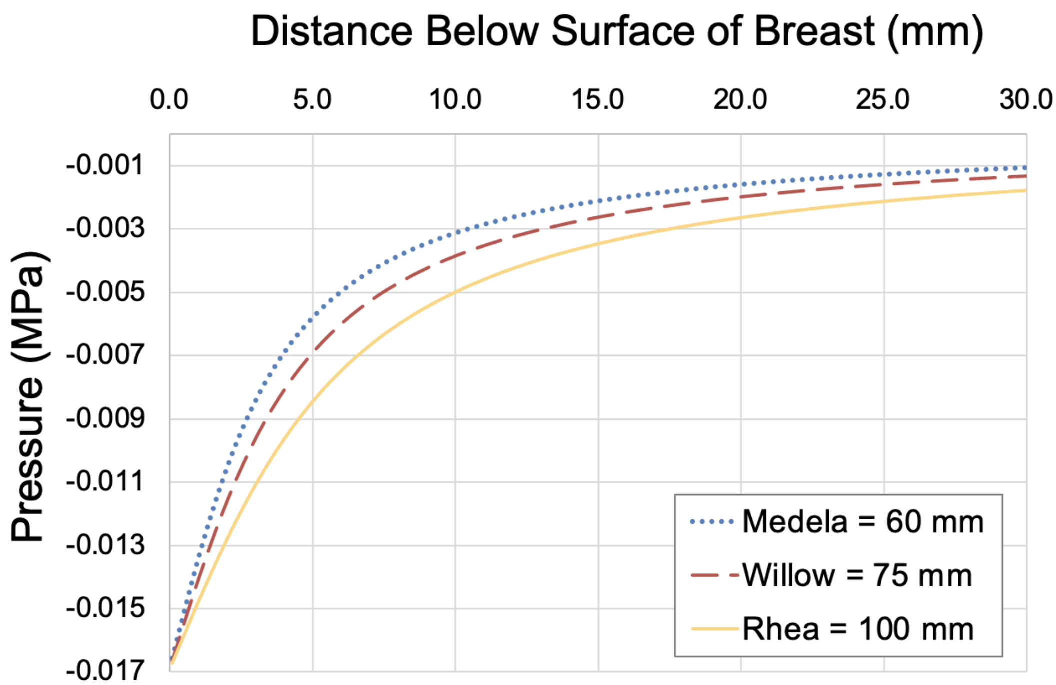


Figure 7.3: Plot of pressure distribution along centerline of breast for 3 flange sizes.

The pressure distribution is calculated for three different flange sizes: 60 mm, 75 mm, and 100 mm. These flange sizes are chosen to evaluate how the flange of the Rhea Breast Pump, at 100 mm in diameter, compares to the flanges of current breast pumps on the market like Medela and Willow, at 60 mm and 75 mm respectively. From this plot, it can be seen that for a fixed vacuum pressure, the vacuum effect is able to penetrate deeper into the breast as the flange size is increased. This analysis supports the use of a larger flange size in the Rhea Breast Pump.

To find the pressure gradient along the surface of the breast, the derivative of Eq. 7.2 can be taken with respect to the distance beneath the surface x (Eq. 7.3).

$$\frac{dP}{dx} = -\frac{4\Delta P}{\pi L} \tag{7.3}$$

From this equation it can be seen that the pressure gradient is directly proportional to the pressure differential ΔP. This means that for a given flange size L, as the pressure differential is increased, the pressure gradient increases, and the milk flow rate is increased. Therefore, it can be concluded that the milk flow rate is linearly proportional to the pressure differential. However, this result is conflicting with the previous analysis, indicating that a smaller flange size increases the pressure differential. Ultimately, the role of flange size must be further studied using FEM analysis.

7.2 COMSOL Multiphysics Modeling

COMSOL Multiphysics is a finite element analysis application software that provides a comprehensive environment for solving complex scientific and engineering problems. One of the areas of application of this software is solid mechanics. This module is designed to provide users with tools for modeling and simulating the mechanical behavior of solid materials under different loads and deformations. Within this module, users can simulate a wide range of solid mechanics phenomena, including von Mises stress analysis, deformation analysis, and displacement analysis.

One of the main features of the solid mechanics module in COMSOL Multiphysics is the ability to model and simulate nonlinear material behavior. Nonlinear material behavior is common in many real-world applications, and it can significantly affect the performance and safety of structures and components. Another significant feature of the solid mechanics component is the ability to visualize simulation results. The software includes post-processing tools that allow users to analyze and understand simulated data. Users can create animations, graphs, and other visualizations to help them understand the behavior of solid materials under different loads and deformations.

COMSOL Multiphysics is used to quantify the behavior of deformation and displacement between the Ecoflex-molded flange and human breast tissue in a two-dimensional format. For this quantification of data, locating the correct areas of fixed constraint, boundary load, free points, and contact points are critical to the accuracy of the results output from this application.

Displacement analysis plays a crucial role in understanding the behavior of the physical system of the breast tissue and the Ecoflex flange [13]. It can provide valuable insight into the deformation and movement of an actual human breast which is an extremely important component of the experimentation process of the Rhea Breast Pump. COMSOL Multiphysics offers an extensive range of tools and capabilities for studying displacement phenomena.

7.2.1 Material & Geometrical Parameters of Model

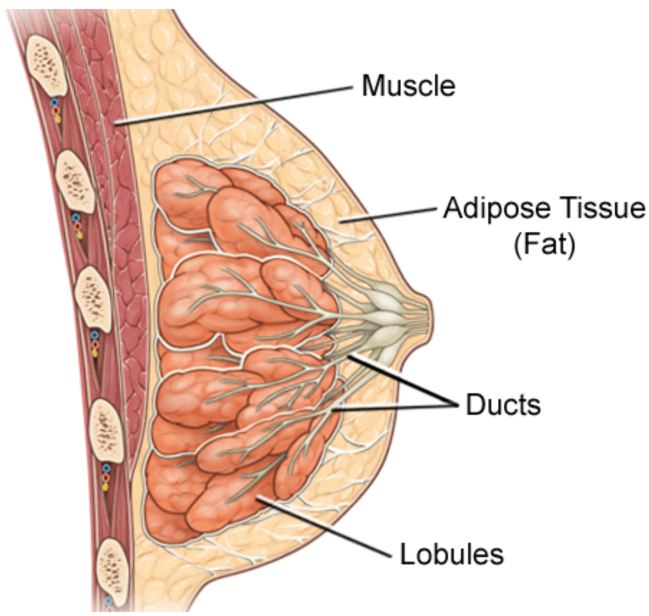


Figure 7.4: Physiological model of breast tissue [30].

A physiological model of a breast is shown above in Figure 7.4. Breast tissue contains components such as muscle, adipose fat, milk ducts, and lobules. A breast is a complex structure and can be classified as a non-homogeneous material with multiple layers possessing both viscous and elastic properties. A simple two-dimensional model of the adipose fat layer with the other breast components modeled as a hollow cavity serves as the basis for the COMSOL Multiphysics model. This is used to model the deformation characteristics of the fat tissue under a vacuum.

The intention of modeling this in COMSOL Multiphysics is to establish a preliminary model of breast deformation associated with our design of Rhea. It is important to note that this model does not examine every aspect of our design thoroughly, as the iterations of COMSOL Multiphysics modeling will soon prove to be useful. A graphical representation of this COMSOL Multiphysics two-dimensional model is shown below in Figure 7.5.

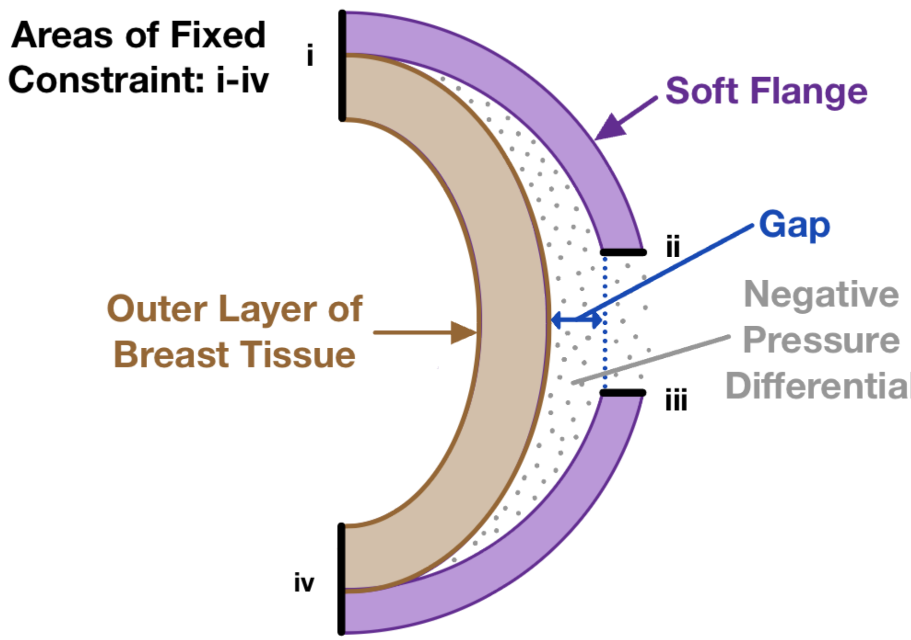


Figure 7.5: COMSOL Multiphysics two-dimensional model representation of the interaction between the breast tissue and Ecoflex-molded flange.

The outer layer of breast tissue is the light brown section, this is also known as the adipose fat layer, and the soft flange is the purple section. The points of fixed constraint are shown in black from sections *i* to *iv* and the gap variable used is the section between the flange and breast tissue indicated with blue arrows. In this situation, the negative pressure is applied to both the breast tissue and flange which is illustrated as the grey dotted area shown.

7.2.2 Comparison of a Rigid & Soft Flange

The model in Figure 7.5 is analyzed through COMSOL Multiphysics for two different rigidities of the flange, as seen in Figure 7.6 and 7.7. These are 2D-planar models with the use of a simple linear elastic material model and a single mesh. Material properties for the flange material used and other polymers for reference are shown in Appendix G.2. The two models in Figure 7.6 use a rigid flange material whereas the models in Figure 7.7 use a soft flange material. The amplitude of the vacuum pressure is varied from 20 to 40 kPa and the gap length is constant for all models at 0.8 cm. This value characterizes the space between the breast tissue and the flange and is an approximation of the gap length measured when Rhea is in contact with the silicone breast [22].

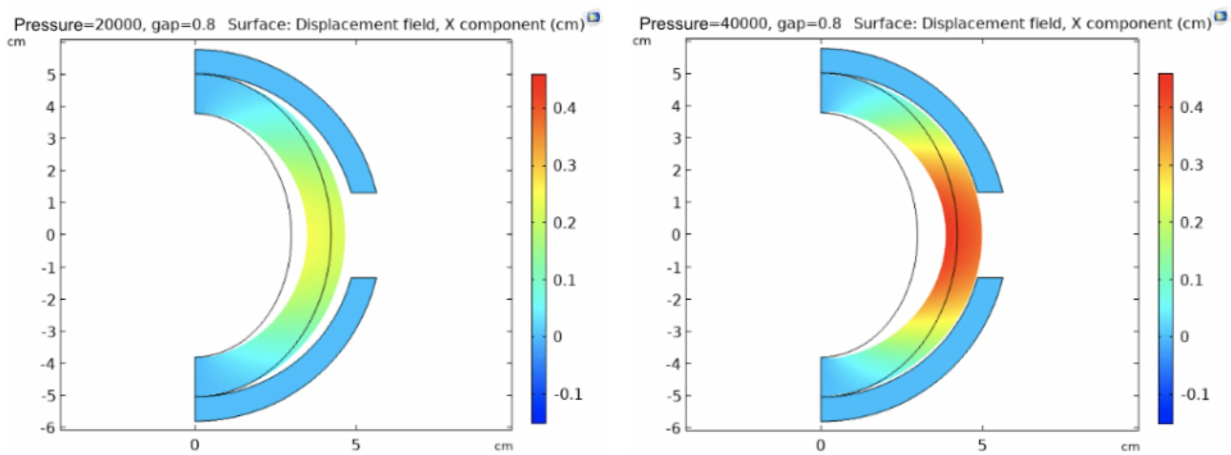


Figure 7.6: COMSOL Multiphysics model of rigid flange material for 20 kPa and 40 kPa.

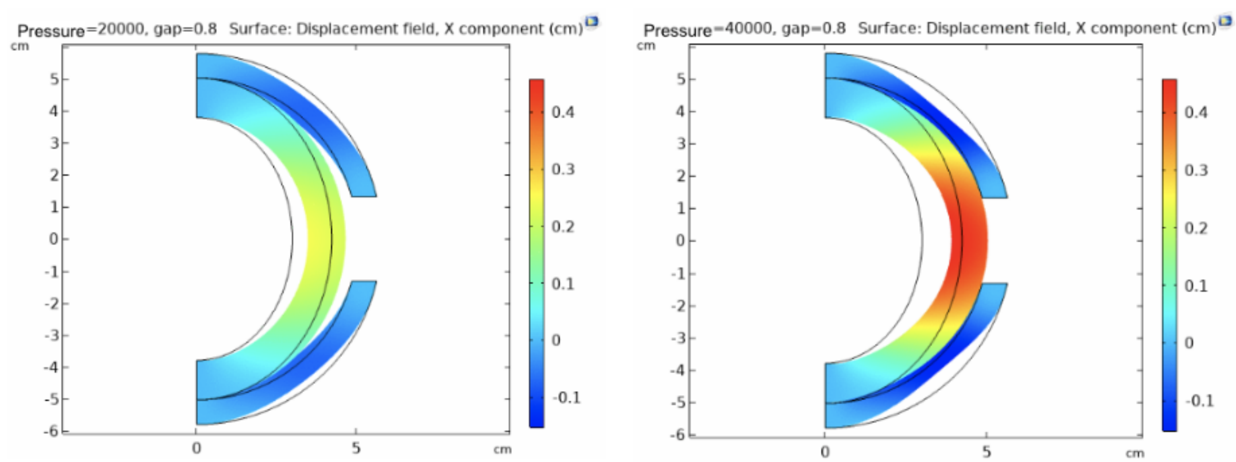


Figure 7.7: COMSOL Multiphysics model of soft flange material for 20 kPa and 40 kPa.

Figure 7.6 and 7.7 shows the displacement in the x-direction. As seen for a rigid flange material, there is no flange deformation which allows the breast to deform freely under a vacuum. For a soft flange material, the flange deforms into the breast which is shown by the flange movement in the figure. These areas of deformation are indicated in dark blue, showing a displacement of 0.1 cm in the negative x-direction. Consequently, the flange applies compressive forces to the breast for a soft flange material. This compression could potentially be beneficial and be used to improve milk extraction, so this was explored with further analysis.

7.2.3 Model of Breast Tissue Displacement

In this model, the vacuum on the breast tissue and on the flange is controlled separately. As seen in Figure 7.8 below, the breast vacuum is zero and the flange vacuum is varied from 10 to 50 kPa at 20 kPa intervals. The gap length used in these models is constant at 0.4 cm in order to illustrate a much clearer displacement. It is evident in these models that flange deformation alone causes a significant deformation of the breast tissue.

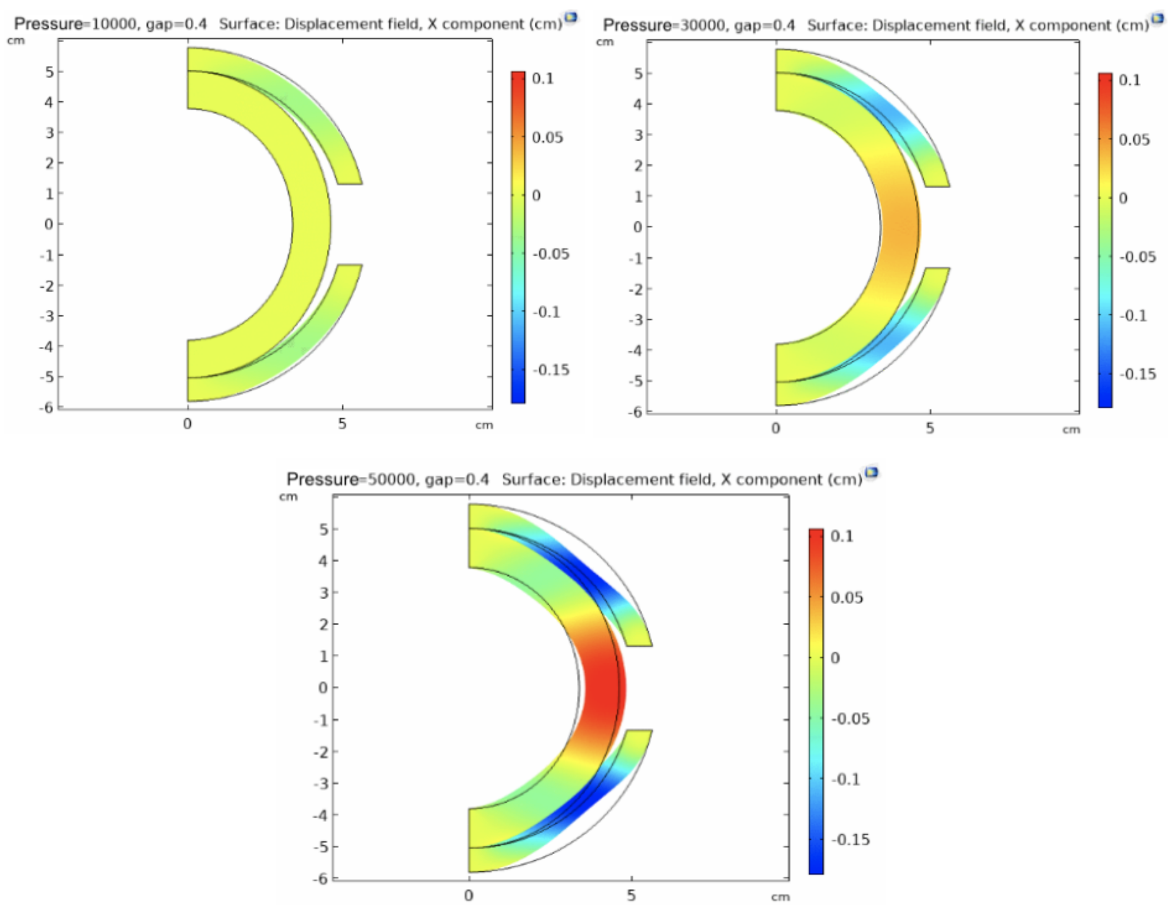


Figure 7.8: COMSOL Multiphysics model when flange vacuum is 10, 30, and 50 kPa.

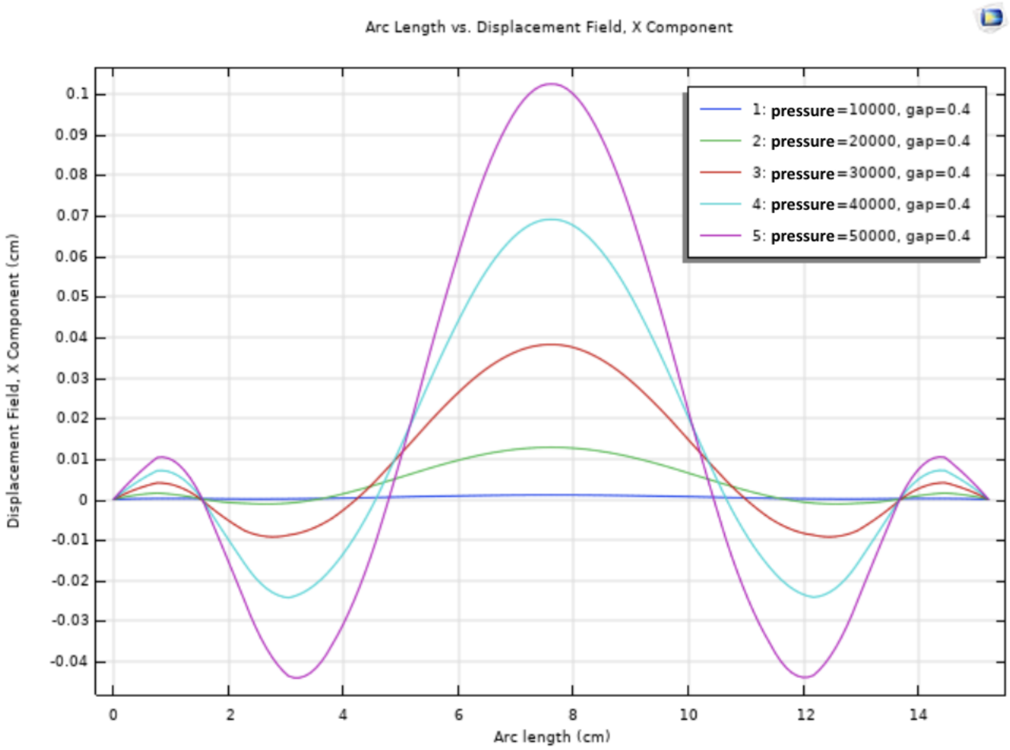


Figure 7.9: Arc Length vs. Displacement Field (x-component).

The line plot in Figure 7.9 represents the displacement of breast tissue along the external boundary for the COMSOL Multiphysics model. There is a considerable amount of compression of the breast tissue along the arc at the 3 cm and 12 cm points. Additionally, in the middle of the breast tissue where the nipple is located, there is the highest positive displacement in the x-direction. This can clearly be seen in the red portion in Figure 7.8 and as the highest amplitude in the line plot in Figure 7.9. This compression could be used to increase milk extraction efficiency because the soft flange is free to collapse on the breast and apply these compressive forces.

7.2.4 Conical Modeling of the Breast Tissue & Flange Interaction

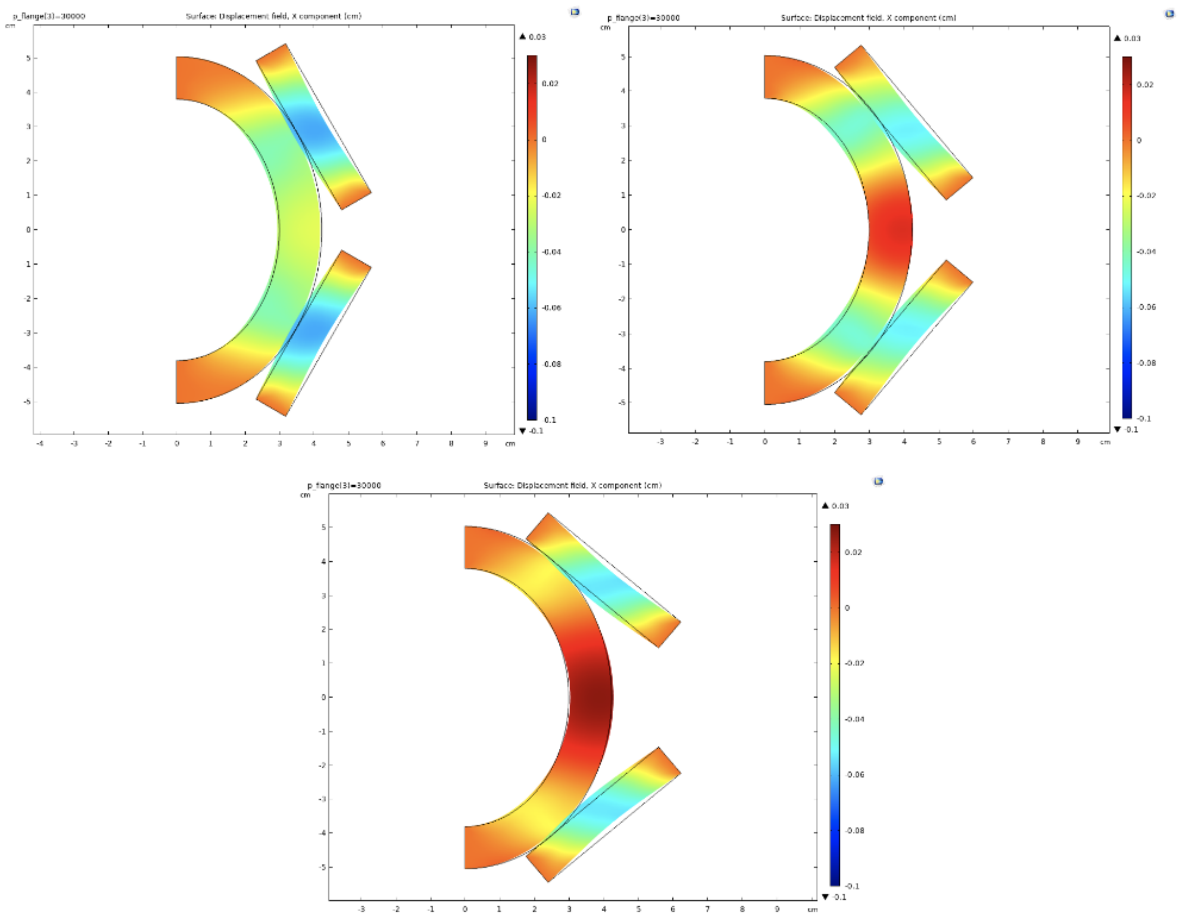


Figure 7.10: COMSOL Multiphysics conical-shaped Flange at 30º, 40º, and 50º at 30 kPa.

In order to provide further geometrical models to account for the final flange shape, three different conical models were created with COMSOL Multiphysics. Figure 7.10 shows displacement in the x-direction for an applied pressure of 30 kPa and varying flange angles of 30º, 40º, and 50º from a vertical y-axis. As the flange angle increases, the displacement in the center of the breast tissue increases, and the flange displacement in the negative x-direction, shown in blue, decreases. These angle differences, especially as they get higher, are significant as they help us better understand the movement of the breast, and therefore the subsequent characterization of milk extraction. This means that milk extraction can be potentially increased when breast displacement increases.

Chapter 8:
Professional Issues & Constraints

Professional issues that exist beyond the design process are cleanability, wearability, and manufacturability. These elements are lacking in our design, but would be addressed in a final prototype. They will be discussed in more detail throughout this chapter.

8.1 Cleanability

Cleanability is an essential aspect of a breast pump. In a final product, cleanability must be thoroughly accounted for, especially because the Center for Disease Control and Prevention issued a report in March of 2023 "urging parents and caregivers to carefully clean and sanitize breast pump equipment, after an infant died last year from a rare bacterial infection linked to a contaminated breast pump" [31]. Breast pumps must be washed multiple times a day so it is important that this process is as quick and easy as possible. However, despite our best efforts, we struggled to create a fully cleanable breast pump for our project due to design and material constraints. Ideally, in a final product, all parts that come in contact with milk would be removable and dishwasher safe to ensure proper sanitization. In future work on this project, cleanability must be seriously considered and efforts to make cleaning easier should be prioritized, such as making the flange removable.

8.2 Wearability

The final prototype is approximately 13x14x15 cm in size and weighs 0.45 kg. Ideally, a wearable device would be lighter and more compact in size. Future improvements for wearability could include a redesign of the tongue actuator to not require a full 360° rotation in order to condense space. Also, a custom milk collection cup in a shape that better conforms to the casing could be implemented. Ultimately, wearability holds a high priority in design considerations because of the benefits it provides to the user. The ability to pump hands-free and without being tied to an outlet allows mothers an increased degree of autonomy and independence. Whether they are returning to work or have demands to fulfill personally, mothers will be empowered to do more of what they hold as valuable without the guilt felt from the experience of having to prioritize nursing with the stressors of life.

8.3 Manufacturability

A mass production of the Rhea Breast Pump for the market would require large-scale manufacturing processes. Key elements to produce would include the flange with ideally multiple size offerings to expand customization for the client, condensed circuitry, the implementation of a rechargeable battery and charging cord, and a variety of aesthetic options for the housing. Some housing variations could include customizable colors including a wide assortment of skin tone shades. In future iterations, we would focus on designing for manufacturability.

Chapter 9:
Impact & Engineering Standards

Engineering standards are necessary to consider throughout the design process. These standards include the environmental impact of the product, ethical considerations, professional guidelines, and the safety of the device.

9.1 Environmental Impact

The Rhea Breast Pump, like other breast pumps, helps to support breastfeeding mothers by offering convenience and flexibility. However, it is critical to examine the environmental impact associated with the production, usage, and disposal of breast pumps as breast pump companies like Medela have [32]. Soft silicone parts cannot be recycled, however, bottles and bottlenecks, bottle sealing discs, bottle caps, valves, and the backflow protector casing can all be recycled [33]. The environmental implications of breast pumps like Rhea are understandably important to the consumer who values sustainable infant feeding practices in order to minimize the ecological footprint.

9.1.1 Energy Consumption Concerns

The Rhea Breast Pump relies on four 9V batteries to operate and two circuits, so the total life cycle environmental costs of producing, using, and disposing of this equipment are of concern [34]. Using rechargeable batteries or exploring other renewable energy sources for powering the Rhea Breast Pump are some of the potential strategies for reducing energy consumption. This is something that can be implemented in further iterations of the design and is a solid goal for the product before it can go on the market.

9.1.2 Considerations of Waste Generation

Additionally, some breast pumps generate waste, sometimes in the form of disposable parts, packaging materials, and discarded breast milk containers. The accumulation of this waste production means exploiting energy sources and leaving a large carbon footprint [35]. To minimize the use of single-use breast milk storage bags that go into landfills, the Rhea Breast pump contains reusable parts such as a bottle that can be screwed and unscrewed for cleaning purposes [36]. Also, the lifespan and durability of breast pumps influence their environmental impact. Longer-lasting and more durable breast pumps reduce the need for frequent replacements, thereby reducing resource consumption and waste generation.

9.2 Ethical Considerations

9.2.1 Designing with Empathy

Despite the significant healthcare advances in the past few decades, there is still a wide gap in research and treatment in women's health, such as maternal and menstrual health [37]. As an all-female team, we are passionate about bridging that gap. Through extensive online research and interviews, we found many problems with the existing breast pump options. Most importantly, they are uncomfortable, not as effective as breastfeeding, and hard to fit each mother. We found that collecting the highest yield of milk is most important to mothers and we believe, based on research, that mimicking the natural nursing process will lead to the highest milk collection. The Rhea Breast Pump combines features, designs, and materials all with the intention to alleviate these issues.

Ultimately, this device is intended to provide comfort to new mothers during a wonderful, but stressful transition in their life. It empowers mothers by helping them maintain their independence and individuality while raising children. Considering the rights lens from "A Framework for Ethical Decision Making," all humans have dignity and the ability to choose freely what they do with their lives [38]. Women, a marginalized group, deserve to be treated as an end in themselves rather than a means to an end. For these reasons, our product is centered around user experience and comfort in addition to maximizing milk production. We differ from other brands on the market because we consider our customer's needs as the top priority in design. When we embarked on the journey of project brainstorming and selection, each member of our team was shocked to find how little innovation in the breast pump industry considered the mother's holistic experience. From loud pumps to painful amounts of pressure inflicted, it appears on the surface that no modular breast pump solution has challenged itself to go above the bare minimum in a goal to accommodate the mother. We refused to settle for achieving the bare minimum outcome of a pump's function.

9.2.2 BSEM Guidelines

In addition to prioritizing the customers in our design, this project is beneficial for emphasizing the ethical responsibilities of an engineer. Considering the BSEM ethical guidelines, it is important for us as engineers to promote the accessibility of biomedical technology [39]. For the purposes of our project, this means testing out different shapes and sizes to accommodate any person who might use our device. We hope for our breast pump to be completely size-inclusive, meaning that the ideal final product will have several different flange sizes available commercially. Additionally, in later prototypes of the Rhea Breast Pump, human testing will be necessary before going to market. The BSEM guidelines state that during human testing, human subjects must be treated as "intrinsically valuable rather than instrumental in service of research and development goals" [39]. At all stages of the testing and development process, our goal as a team is to serve our customers as well as possible in order to create the best product. Our group mission has always been to benefit women's healthcare by designing for their needs and comfort; that mindset would not stop at the human testing stage where our product will be tested on the same women we want to serve.

9.2.3 ASME Guidelines

The ASME ethical guidelines have also proven helpful in our design process as we navigate the skills needed to be a good engineer. One in particular that we have tried to prioritize in this project is the need to consider environmental impact and sustainable development in design [40]. In order to create the most sustainable design possible, we have tried to limit the use of single-use plastics.

9.2.4 Future Opportunities to Reinforce Ethical Features

While our aim is to design the Rhea Breast Pump as ethically as possible, we must also acknowledge the ethical pitfalls in our project. One of the most apparent challenges our project must face includes testing on humans. Biomedical research involving the participation of humans requires extensive amounts of time to carry out the tedious process of getting approval from the National Institutes of Health (NIH) for a clinical trial. Once granted approval, the researchers must ensure the proposed trials meet the NIH's rules and regulations, requiring even more time and resources. Additionally, biomedical research involving human testing includes several ethical implications. These implications may compromise "such values as dignity, bodily integrity, autonomy, and privacy" [41]. Accordingly, in all clinical trials and research that involves humans, it is essential that humans come first. The safety, integrity, and privacy of the test subjects must be the top priority and should not be put at risk. Without human testing and the feedback we would receive from the same women we intend to serve, it cannot be confirmed through feedback that the Rhea Breast Pump design has achieved solutions to the challenges we have taken on through our design.

A secondary challenge that our project faces is the price. Our original aim was to ensure our pump is accessible to all mothers by keeping the price as low as possible. However, despite our best intentions, the Rhea Breast Pump may be just as expensive as existing pumps on the market due to its additional heating and tongue actuator features. As a result of this raised price, our pump may not be as easily accessible for mothers of lower socioeconomic status, limiting the number of mothers we are able to serve. For example, mothers in impoverished countries may not be able to afford Rhea. In future designs, this issue could be tackled and the price could be decreased by finding cheaper materials and more cost-effective manufacturing techniques. This would allow for more accessibility and enable more mothers to be able to pump.

9.3 Health & Safety

The top priority in regard to the Rhea Breast Pump is the health and safety of mothers using the device. Rhea should be a comfortable and proper fit in order to prevent discomfort, pain, and potential damage to breast tissue or nipple. Rhea must also fit properly to create a positive pumping experience and reduce the risk of injury. Our design only allows the breast tissue to come into contact with the soft Ecoflex material to keep the mother safe from the other components. Additionally, there is a safety sensor to ensure that the Rhea breast pump never gets too hot. This ensures that the breast tissue will never get burned or cause additional discomfort.

Chapter 10: Conclusion & Outlook

As a team, we began our project with an interest in the fluidic extraction of breast pumps. It was not until we put the user at the center of our brainstorming that our project came to life. This led us to implement a pump, actuator, and heating element into a biomimicry-guided design. Research, analysis, and many iterations guided us to our final functioning prototype that combined all devices into a wearable experience.

Looking forward, we would like to expand our design by using more expansive knowledge of fluidic milk extraction, not just from the nipple outward but from the entire nursing biology of a human breast. Additionally, the pursuit of a patent for the combination of technology we produced could establish legal backing for those involved with the design to build on it further in the future. Regardless of the future endeavors of our group, each member will carry this experience forward with them as a valuable reminder to design with empathy and advocate for underrepresented needs in the work we contribute to as engineers.

References

[1] Lowrey, A., The Atlantic, cited 2019. Pumping Milk and Nursing Are Not the Same. https://www.theatlantic.com/ideas/archive/2019/07/exclusive-pumping-research/594580/

[2] “Breast Pump Market Size, Share & Growth [2023 Report].” *Breast Pump Market Size, Share & Growth [2023 Report]*, 2021, www.grandviewresearch.com/industry-analysis/breast-pumps-market.

[3] Frances Stead Sellers, “Formula Shortage is Worse for Low-Income Families, High-Risk Infants,” The Washington Post, May 18, 2022 https://www.washingtonpost.com/health/2022/05/18/baby-formula-shortage-impact/

[4] Osub Ahmed, Emily DiMatteo, Marc Jarsulic, Caroline Medina, Arohi Pathak, and Jill Rosenthan, “The National Baby Formula Shortage and the Inequitable U.S. Food System.” Center for American Progress, 26 May 2022, https://www.americanprogress.org/article/the-national-baby-formula-shortage-and-the-inequitable-u-s-food-system/.

[5] D'Ignazio, Catherine, et al. "A Feminist HCI Approach to Designing Postpartum Technologies: " When I first saw a breast pump I was wondering if it was a joke"." Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems. 2016.

[6] “Home Page - August: Willow: Hands Free & Wearable Breast Pump.” Willow, 27 Apr. 2023, https://onewillow.com/.

[7] “Elvie Pump: Silent, Wearable, Smart Breast Pump.” Elvie.

[8] “Breastfeeding Education, Tools, and Support.” Medela, https://medela.us/breastfeeding.

[9] Rini, Susilo, et al. “Type Of Breast Pump And The Affect To Pain Scale, Milk Production, And Pumping Time In Breastfeeding Mothers.” Jurnal Kebidanan Dan Kesehatan Tradisional, vol. 7, no. 1, Mar. 2022, pp. 18–29, https://doi.org/10.37341/jkkt.v0i0.299.

[10] Jiang, Lin, and Fatemeh Hassanipour. "Bio-Inspired Breastfeeding Simulator (BIBS): A Tool for Studying the Infant Feeding Mechanism." *IEEE Transactions on Biomedical Engineering*, vol. 67, no. 11, 2020, pp. 3242–3252, https://doi.org/10.1109/tbme.2020.2980545.

[11] Prieto CR;Cardenas H;Salvatierra AM;Boza C;Montes CG;Croxatto HB; "Sucking Pressure and Its Relationship to Milk Transfer during Breastfeeding in Humans." Journal of Reproduction and Fertility, U.S. National Library of Medicine, https://pubmed.ncbi.nlm.nih.gov/8958830/.

[12] Carrane, Lauren. "What Are the Best Suction Settings to Use on a Breast Pump?" Neb Medical, 15 Aug. 2022, https://www.nebmedical.com/what-are-the-best-suction-settings-to-use-on-a-breast-pump/#:~:text=Electric%20breast%20pumps%20are%20generally,between%20200%20to%20300%20mmHg.

[13] Zoppou C, Barry SI, Mercer GN. Dynamics of human milk extraction: a comparative study of breastfeeding and breast pumping. Bull Math Biol. 1997 Sep;59(5):953-73. doi: 10.1007/BF02460001. PMID: 9281906.

[14] Dana Feştilă, Mircea Ghergie, Daiana Matiz, Alexandrina Muntean, and Alin Şerb Nescu, "Suckling and non-nutritive sucking habit: what should we know?" Clujul Medical, 87(1):11-4, 2014 January 30, doi: 10.15386/cjm.2014.8872.871.df1mg2.

[15] "Baby-Friendly Hospital Initiative: Revised, Updated and Expanded for Integrated Care." Geneva: World Health Organization, Session 6 HOW MILK GETS FROM BREAST TO BABY, 2009, https://www.ncbi.nlm.nih.gov/books/NBK153490/.

[16] Priscilla Tait, Nipple pain in breastfeeding women: causes, treatment, and prevention strategies, Journal of Midwifery & Women's Health, Volume 45, Issue 3, 2000, Pages 212-215, ISSN 1526-9523,

[17] Wahyuningsih, Melania, Liliana Anita, The effectiveness of warm compress on breast milk production among postpartum mothers in Tegalrejo Health Center, July 2019

[18] Yigit, Feride, et al. "Does Warming the Breasts Affect the Amount of Breastmilk Production?" *Research Gate*, Mar. 2012, www.researchgate.net/publication/221712891_Does_Warming_the_Breasts_Affect_the_Amount_of_Breastmilk_Production.

[19] Infant and Young Child Feeding: Model Chapter for Textbooks for Medical Students and Allied Health Professionals. Geneva: World Health Organization; 2009. SESSION 2, The physiological basis of breastfeeding.

[20] Arora, Smriti, et al. "A Comparison of Cabbage Leaves vs. Hot and Cold Compresses in the Treatment of Breast Engorgement." *Indian Journal of Community Medicine*, vol. 33, no. 3, July 2008, p. 160, https://doi.org/10.4103/0970-0218.42053.

[21] "Your Guide to Pumping & Storing While Breastfeeding." Baptist Health, 15 Sept. 2021, www.baptist-health.com/blog/your-guide-to-pumping-storing-while-breastfeeding/#:~:text=A%20pumping%20session%20will%20take,per%2024%20hours.

[22] Amazon.com: Iplusmile Human Female Silicone Breast Silicone Women. Accessed 10 May 2023.

[23] Industries, Adafruit. "EeonTex High-Conductivity Heater Fabric." Adafruit Industries Blog RSS, www.adafruit.com/product/3670. Accessed 25 May 2023.

[24] Amazon.com: 4 PCS Film Heater Plate Adhesive Pad, Icstation PI Heating Elements Film 12V 12W Strip Heater Adhesive Polyimide Heater Plate 10mmx93mm, Accessed 10 May 2023.

[25] Greartisan DC 12V 50RPM Gear Motor High Torque Electric Micro Speed Reduction Geared Motor Centric Output Shaft 37mm Diameter Gearbox, Amazon

[26] Eilumduo Air Pump - DC 6V Micro Vacuum Pump, Electric Mini Air Pumping Booster for Treatment Instrument 1.5L-3.2L/Minute, Amazon

[27] Vegard.landen. “Mamabreast.” Laerdal Global Health, 20 Feb. 2023, shop.laerdalglobalhealth.com/product/mamabreast/.

[28] White, Frank M., and Henry Xue. Fluid Mechanics. McGraw-Hill, 2021.

[29] Theory of Elasticity, 1951, Timoshenko, p.92-93.

[30] Stanford Medicine Children's Health - Lucile Packard Children's Hospital Stanford, https://www.stanfordchildrens.org/en/topic/default?id=anatomy-of-the-breasts-85-P00132

[31] Pearson, Catherine. “What Parents Should Know about Bacteria and Breast Pumps.” The New York Times, 3 Mar. 2023, www.nytimes.com/2023/03/03/well/family/breast-pumps-bacteria-infection.html?unlocked_article_code=E-P2xsS_F0Cgi0RA7c-ptX8vvp3U9Th0tJhZmlSKvsS-ibKc49jXEE8S_Giu-GVmvyPUEmVXPtiQJVG_a3C01gOvOYmJujFUXS4VxIy5n5iy1IQUYm0vpJo3cGmkU1G-BvV5bLwJGzYbOnEO4MpqnneO0cJ9jOqhmjoK4GWQV_B-VbiG2UVK3Oh7uPrUrKRB6BrRDjn76zezX6OXkTjlL-US1U7-0gkm2ZBFW-HsVT8ae6vmfGLHwiWdUvhw1_N8iCod8_WMk37f84yLZgNhgeV15L1dwQlhorwq-djQRx0GzmYRjy4c_8rTtZyLdiYc2ovKahNSrwgzEz3jnI4KH9V9a3omT9VXhKG7Jg3j&smid=url-share.

[32] “Planet.” *Medela*, www.medela.com/company/medelacares/medela-cares-planet. Accessed 7 June 2023.

[33] API, Shopify. “Spectra’s Breast Pump Recycling Guide.” *Spectra Baby Australia*, 19 Oct. 2017, spectra-baby.com.au/blogs/all/spectras-breast-pump-recycling-guide/.

[34] Becker, Genevieve, and Yvonne Ryan-Fogarty. “Reliance on Pumped Mother’s Milk Has an Environmental Impact.” *Children (Basel, Switzerland)*, 10 Sept. 2016, www.ncbi.nlm.nih.gov/pmc/articles/PMC5039474/#:~:text=High%2Dtech%20pumps%20contain%20plastic,ultimately%20end%20up%20as%20waste.

[35] “Breastfeeding and the Environment.” *Elacta*, 2 July 2020, www.elacta.eu/news/breastfeeding-and-the-environment/#:~:text=Bottles%2C%20teats%2C%20pumps%2C%20packages,leaving%20a%20large%20carbon%20footprint.

[36] "5 Tips to Make Your Pumping Journey More Environmentally-Friendly." *Medium*, 25 Aug. 2021, medium.com/milkstork/5-tips-to-make-your-pumping-journey-more-environmentally-friendly-d997fb336fcf.

[37] "Why Is Women's Healthcare Globally so Often Overlooked?" *World Economic Forum*, www.weforum.org/agenda/2023/01/women-health-gap-davos-2023/#:~:text=Despite%20healthcare%20advances%20in%20the,differently%20in%20women%20than%20men. Accessed 7 June 2023.

[38] University, Santa Clara. "A Framework for Ethical Decision Making." *Markkula Center for Applied Ethics*, www.scu.edu/ethics/ethics-resources/a-framework-for-ethical-decision-making/. Accessed 7 June 2023.

[39] *Novi Ams*, assets.noviams.com/novi-file-uploads/bmes/PDFs_and_Documents/Governance/BMES_Code_of_Ethics_2021_-_Revised_October_2021.pdf. Accessed 7 June 2023.

[40] *Society Policy Ethics Code of Ethics of Engineers - ASME*, www.asme.org/getmedia/3e165b2b-f7e7-4106-a772-5f0586d2268e/p-15-7-ethics.pdf. Accessed 7 June 2023.

[41] Kapp, M B. "Ethical and Legal Issues in Research Involving Human Subjects: Do You Want A Piece of Me?" *Journal of Clinical Pathology*, Apr. 2006, www.ncbi.nlm.nih.gov/pmc/articles/PMC1860367/#:~:text=The%20conduct%20of%20biomedical%20research,integrity%2C%20autonomy%2C%20and%20privacy.

Appendix A:

Detailed Project Budget

A.1 Cost of Research & Development

Table A.1: Research & design the total budget with links

Items	Unit Price	Quantity	Total Cost
Breastfeeding Simulator	$299.00	1	$299.00
Pump	$8.99	1	$8.99
Ecoflex 00-50	$34.49	1	$34.49
Universal Mold Release	$21.69	1	$21.69
Breast Model Amazon	$39.99	1	$39.99
Linear Actuators	$28.99	1	$28.99
Backflow Protector	$18.99	1	$18.99
Heater Fabric	$14.95	1	$14.95
Bottle Collar Rings	$15.99	1	$15.99
5 oz Bottles	$15.32	1	$15.32
Transistors	$18.99	1	$18.99
Ecoflex 00-45	$38.80	2	$77.60
Tubing	$7.59	1	$7.59
Super Glue	$2.86	2	$5.72
Backup Pumps	$8.99	2	$17.98
Aligator Clips	$4.99	1	$4.99
Glue Remover	$6.90	1	$6.90
Battery Clips	$6.99	1	$6.99
Baby Formula	$16.15	1	$16.15
Backup Motors	$9.68	1	$9.68
Pliers	$6.59	1	$6.59
Backflow Protector	$18.99	1	$18.99
9V Batteries	$12.17	1	$12.17
Electrical Tape	$2.99	1	$2.99
Epoxy	$5.54	1	$5.54
Multimeter	$11.99	1	$11.99
Circuit Wires	$12.99	1	$12.99
New Motor 1	$9.27	2	$18.54

Items	Unit Price	Quantity	Total Cost
New Motor 2 (24V and 120 rpm)	$14.99	1	$14.99
New Motor 3 (12V and 50 rpm)	$14.99	1	$14.99
Screws	$9.49	1	$9.49
Arduino Nano	$22.99	1	$22.99
Thermal Glue	$11.99	1	$11.99
Mini Soldering Board	$8.99	1	$8.99
Electric Hand Warmers	$24.99	2	$49.98
Backflow Protector	$18.99	1	$18.99
Freeze Spray	$38.99	1	$38.99
New Motor 3 (12V and 50 rpm)	$14.99	1	$14.99
Heater Fabric	$14.95	1	$0.00
Insulation	$17.95	1	$17.95
Temperature Controller	$7.99	1	$7.99
Heating Plate	$16.59	1	$16.59
Long Heating Plate	$11.99	1	$11.99
Battery Clips	$6.99	1	$6.99
Diodes	$4.90	1	$4.90
Soldering Kit	$14.85	2	$23.98
Arduino Nano	$22.99	1	$22.99
9V Batteries	$12.99	1	$12.99
M/F Wires	$6.98	1	$11.99
		Total:	**$1,105.54**

A.2 Cost of Physical Model

Table A.2: Final prototype budget

Items	Total Cost
EcoFlex 45	$15.52
PLA	$33.74
Universal Mold Release	$1.81
Backflow Protector	$4.75
Bottle Collar Rings	$2.67
Baby Bottle	$5.11
Transistors	$1.14
Silicon Tubing	$0.13
Super Glue	$1.43
Pump	$8.99
Battery Clips	$3.50

Items	**Total Cost**
9V Batteries	$6.09
Electrical Tape	$0.04
Epoxy/Sealant	$2.77
Circuit Wires	$0.35
Motor	$14.99
Screws	$0.38
Arduino Nano	$15.33
Thermal Glue	$6.00
Mini Soldering Board	$3.60
Insulation	$0.11
Long Heating Plate	$8.99
DHT11 Temp. Controller	$2.00
Diodes	$0.59
Solder	$5.39
M/F Wires	$0.58
Switch	$1.40
Button	$0.56
M5 Wing Nuts	$2.50
Total:	**$150.42**

Appendix B:

Project Timeline

B.1 Gantt Chart

Breast Pump: Senior Design 22-23

PROJECT TEAM	Courtney Rowe, Leanne James, Laini Reynolds, Julia Yaklich, Harper Daniels
ASSEMBLY TEAM	Julia Yaklich, Laini Reynolds
BIOMIMICRY TEAM	Courtney Rowe, Harper Daniels, Leanne James

TASK TITLE	TASK OWNER	START	END	DURATION (WEEKS)
Project Planning				
Market Research	Everyone	Week 1	Week 4	4
Customer Needs	Everyone	Week 2	Week 3	2
Funding Request	Everyone	Week 5	Week 5	1
Project Proposal	Everyone	Week 6	Week 6	1
Safety Report	Everyone	Week 7	Week 7	1
Interface Research	Biomimicry Team	Week 8	Week 9	2
Pump Research	Everyone	Week 8	Week 9	2
Milk Collection Research	Assembly Team	Week 8	Week 9	2
Silicon Lab Training	Biomimicry Team	Week 9	Week 9	1
CDR Report	Everyone	Week 9	Week 10	2
Fall Final Presentations	Everyone	Week 9	Finals	3
Preliminary Design				
Maker Lab Training	Everyone	Week 1	Week 1	1
Analyze purchased Willow	Everyone	Week 1	Week 2	2
Pump Selection	Assembly Team	Week 2	Week 2	1
Housing Desing	Assembly Team	Week 2	Week 3	2
Connections Design	Assembly Team	Week 1	Week 3	3
Flange Design	Biomimicry Team	Week 1	Week 3	3
Heating Element Design	Biomimicry Team	Week 1	Week 3	3
Actuator/Soft Robotics Design	Biomimicry Team	Week 1	Week 3	3
Solidworks Design	Everyone	Week 2	Week 5	4
Prototyping				
Functional Prototyping	Everyone	Week 4	Week 8	5
Aesthetic Prototyping	Everyone	Week 7	Week 9	3
Testing Protocol	Assembly Team	Week 7	Week 7	1
Testing	Everyone	Week 8	Week 10	3
Design Iterations				
Iterate based on Test Results	Everyone	Week 1	Week 3	3
Presentation	Everyone	Week 4	Week 6	3
Report	Everyone	Week 6	Week 10	5

Figure B.1: Complete team Gantt chart.

Appendix C:

Supplemental Flange Visuals

C.1 Flange Mold & Renderings

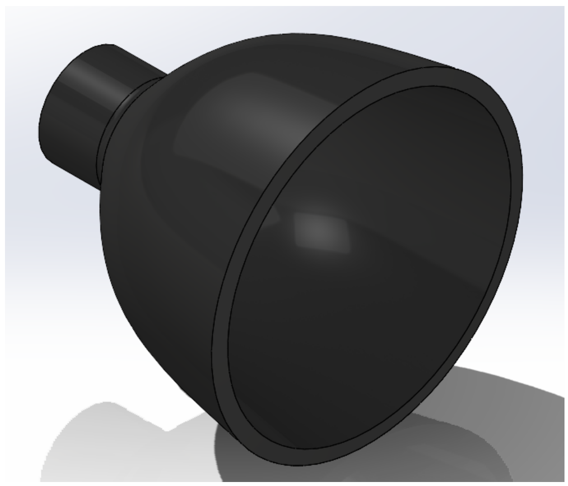


Figure C.1: SolidWorks model of flange Iteration 1.

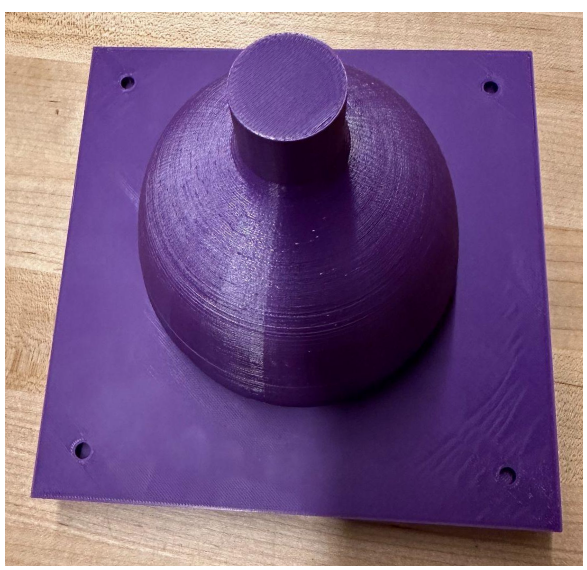


Figure C.2: Top of flange mold Iteration 1.

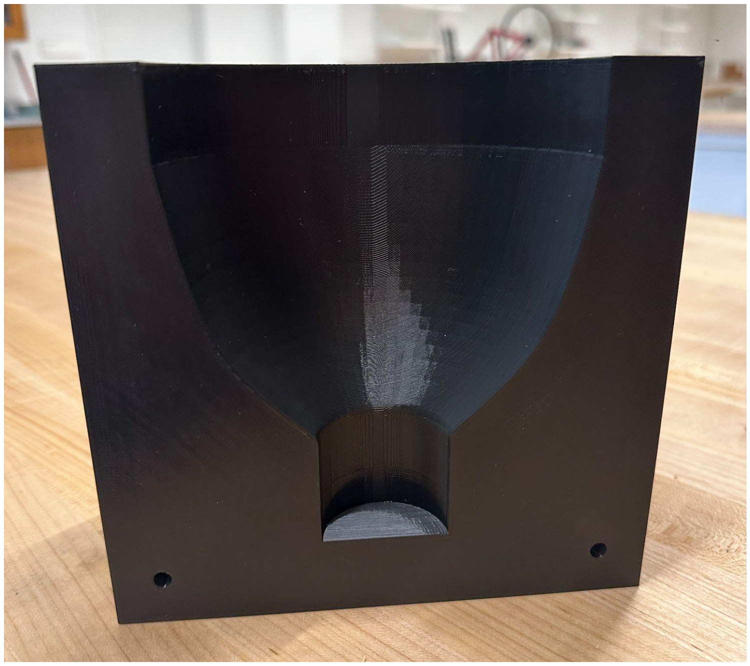


Figure C.3: Bottom half of flange mold Iteration 1.

C.2 Ecoflex Material

Figure C.4: Photo of EcoFlex 00-45.

Appendix D:

Heating Test Results

D.1 Ecoflex Thickness Test

Table D.1: Flange thickness test results

Time Intervals (sec)	Temperature at 1.3 mm (ºC)	Temperature at 2.0 mm (ºC)	Temperature at 2.5 mm (ºC)
0.00	24.0	25.6	22.9
15.00	25.9	25.8	23.6
30.00	31.2	28.2	26.5
45.00	35.5	32.9	31.0
60.00	38.9	36.6	33.9
75.00	40.6	39.2	36.0
90.00	43.1	41.9	38.1

D.2 Modulated Heating Test

Table D.2: Modulated heating test results

Status of Applied Heat	Time (sec)	Temperature on skin (ºC)	Temperature through insulation (ºC)
On	0.00	30.0	26.5
On	15.00	30.7	28.4
Off	25.00	31.7	28.8
On	30.00	32.2	27.1
Off	40.00	33.8	27.8
On	45.00	33.3	27.9
Off	55.00	34.3	28.3

Status of Applied Heat	Time (sec)	Temperature on skin (ºC)	Temperature through insulation (ºC)
On	60.00	34.9	28.4
Off	70.00	39.2	28.8
On	75.00	39.9	29.0
Off	85.00	38.8	29.2
On	90.00	38.6	29.0
Off	100.00	39.9	29.3
On	105.00	40.2	29.6

Appendix E:

Drawings & Schematics

E.1 Vacuum Pump & Tongue Actuator Circuit

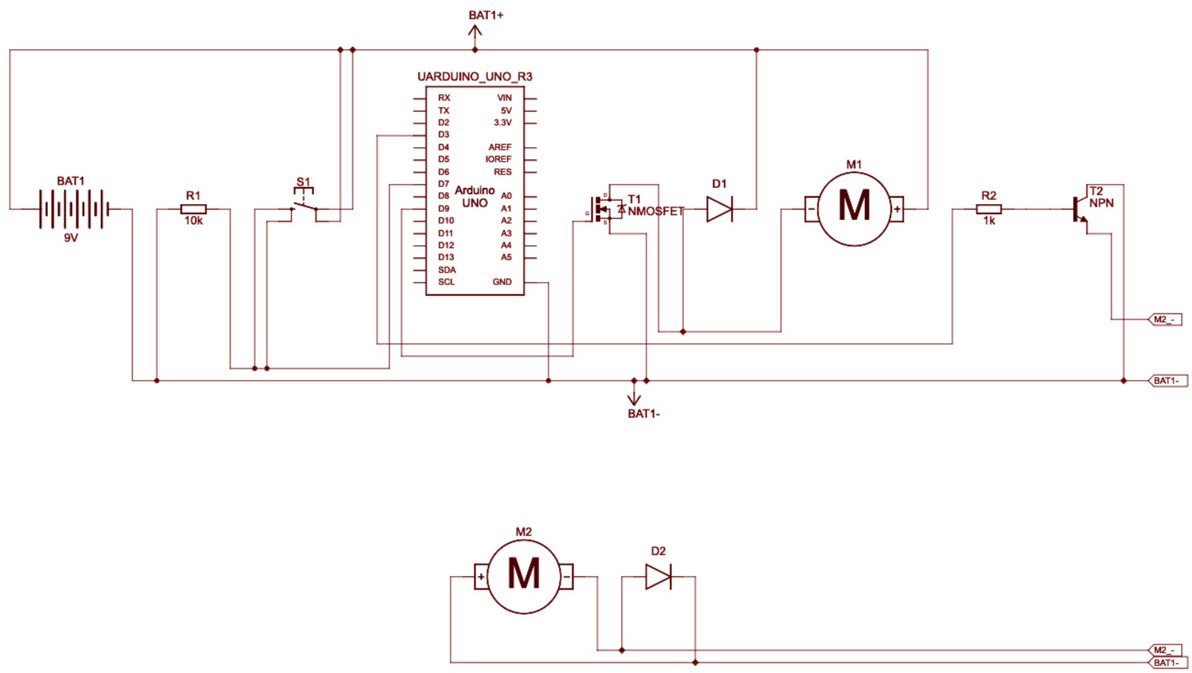


Figure E.1: Detailed schematic of vacuum pump and tongue actuator circuit.

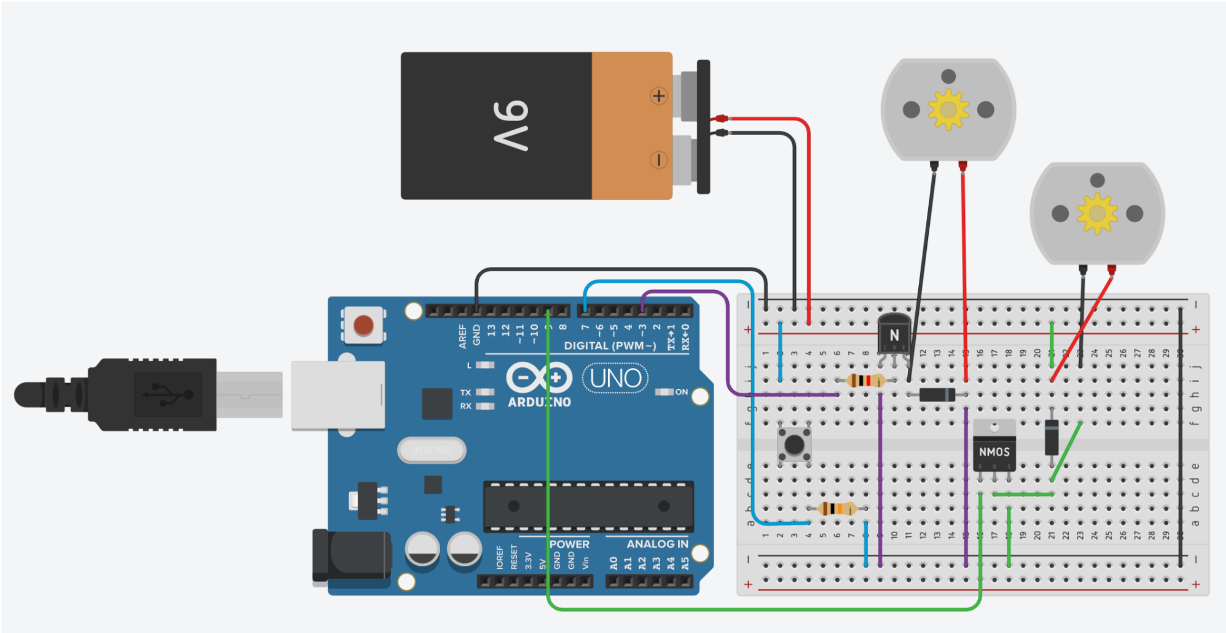


Figure E.2: Online simulation of vacuum pump and tongue actuator circuit.

E.2 Heating Element Circuit

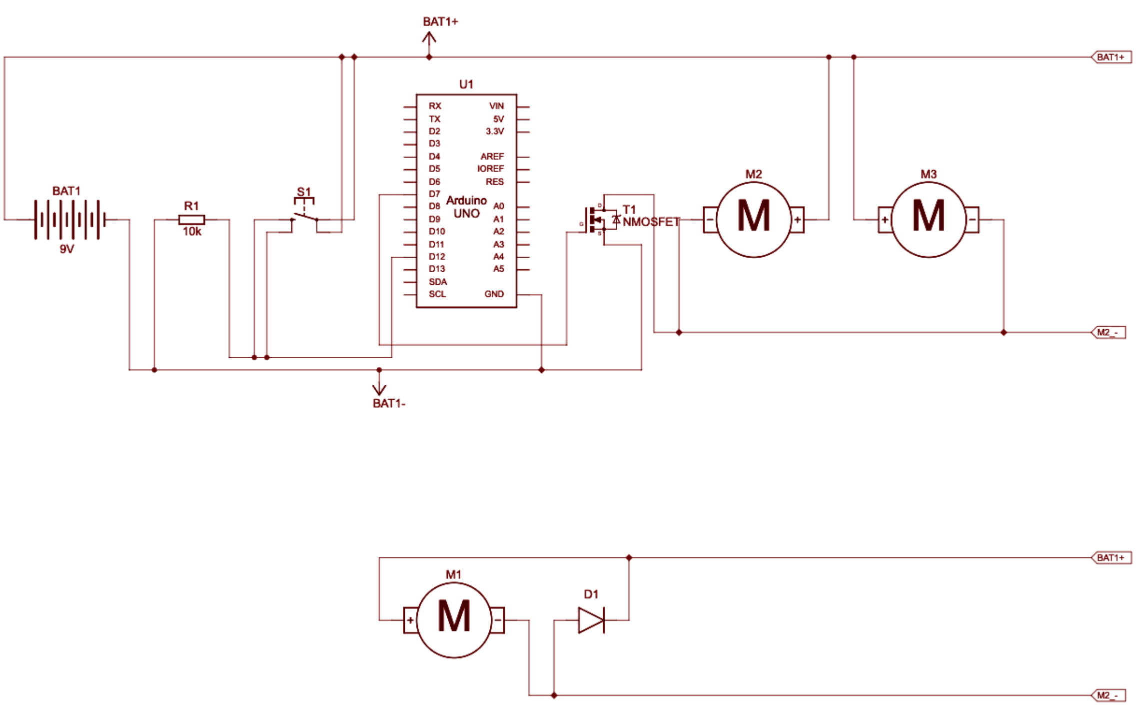


Figure E.3: Detailed schematic of heating element circuit.

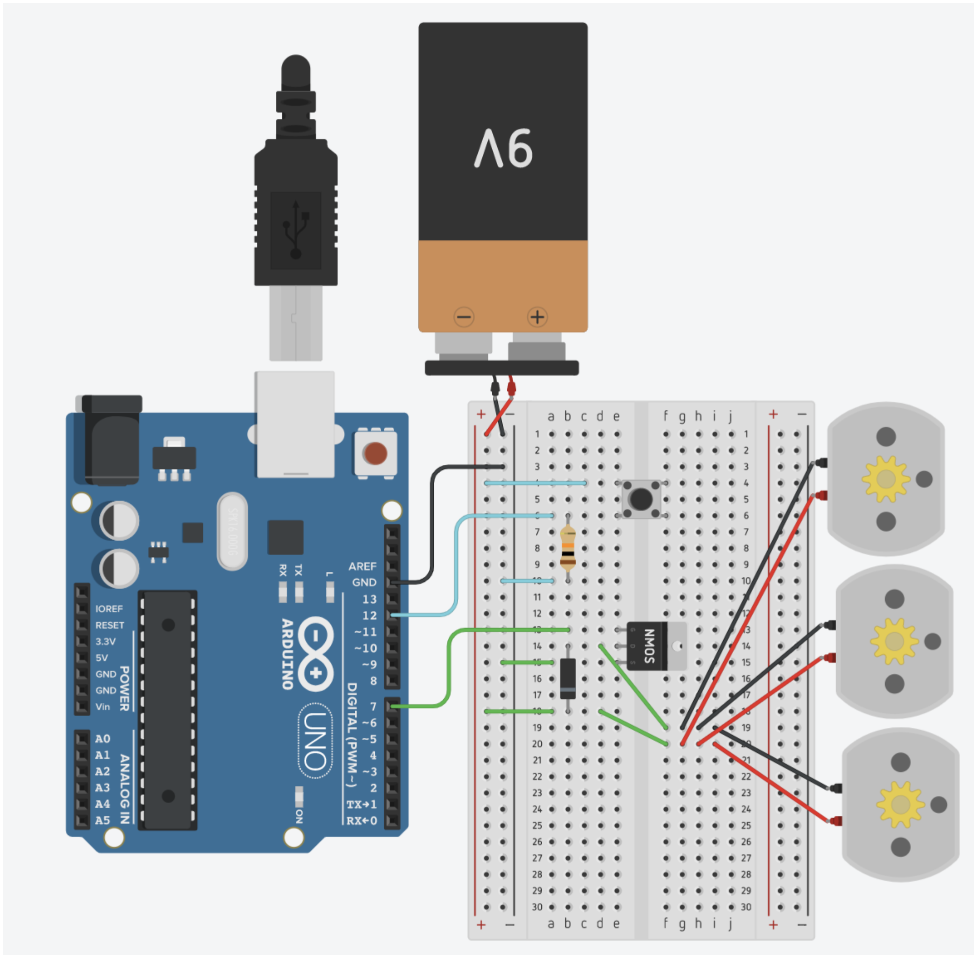


Figure E.4: Online simulation of heating element circuit.

Appendix F:

Code & Calculations

F.1 Torque Calculations

$$p = 5\,kPa = 5000\,N/m^2$$

$$A = 2.5\,cm \cdot 0.1\,cm = 0.0025\,m^2$$

$$F = p \cdot A$$

$$F = 5000\,N/m^2 \cdot 0.0025\,m^2 = 12.5\,N$$

$$T = 3.97\,kgf.cm = F \cdot d$$

$$F = \frac{3.97\,kgf.cm}{1.3125\,in} \cdot \frac{1\,in}{2.54\,cm} = 1.191\,kgf \cdot 9.81\,m/s^2 = 11.68\,N$$

F.2 Vacuum Pump & Tongue Actuator Circuit Code

```
#include <dht.h>

// Define Variables & Pin Numbers
int Pump = 9;
int button = 8;
int buttonState = 0;
int Motor = 6;

dht tempsens;
#define temp 5

void setup()
{
  pinMode(button, INPUT);
  pinMode(Pump, OUTPUT);
  pinMode(Motor, OUTPUT);
  Serial.begin(9600);
}
```

```
void loop()
{
  // Read Switch State
  int buttonstate = digitalRead(button);

  // Switch in ON Position
  if (buttonstate == HIGH)
  {
    for (int total = 1; total <= 44; total++)
    {
      delay(500);

      // Turn on Pump & Actuator
      for (int cycle = 1; cycle <= 5; cycle++)
      {
        // Check Switch State & Temperature
        int chk = tempsens.read11(temp);
        Serial.println(tempsens.temperature);
        if ((digitalRead(button) == HIGH) && (tempsens.temperature < 45)) {
          analogWrite(Pump, 255);
          analogWrite(Motor, 255);
          delay(2000);
          analogWrite(Pump, 0);
          analogWrite(Motor, 0);
          delay(1500);
        }
        else {
          return;
        }
      }
      // 3 Second Pause to Simulate Swallow
      delay(3000);
    }
  }

  // Switch in OFF Position
  else {
    analogWrite(Pump, 0);
    analogWrite(Motor, 0);
  }
}
```

F.3 Heating Element Circuit Code

```
// Define Variables & Pin Numbers
int heat = 4;
int button = 5;

void setup() {
```

```
  pinMode(heat,OUTPUT);
  pinMode(button,INPUT);
}

void loop() {
  // Read Button State
  int buttonState = digitalRead(button);

  // Button is Pressed
  if (buttonState == HIGH)
  {
    // Initial Heating Period
    digitalWrite(heat,HIGH);
    delay(120000);

    // Modulated Heating Cycle
    for (int cycle = 1; cycle < 31; cycle++)
    {
      digitalWrite(heat,LOW);
      delay(10000);
      digitalWrite(heat,HIGH);
      delay(15000);
    }
    digitalWrite(heat,LOW);
  }

  // Button is Not Pressed
  else {
    digitalWrite(heat,LOW);
  }
}
```

Appendix G:
Analysis & Modeling Supplemental Materials

G.1 Pressure Differential Data

Table G.1: Pressure gradient along centerline of breast for three different flange sizes

Distance Below Surface (mm)	Flange Size		
	Medela = 60 mm	Willow = 75 mm	Rhea = 100 mm
0.1	-0.0166	-0.0166	-0.0167
1.1	-0.0131	-0.0139	-0.0146
2.1	-0.0103	-0.0114	-0.0126
3.1	-0.0083	-0.0095	-0.0109
4.1	-0.0068	-0.0080	-0.0095
5.1	-0.0057	-0.0068	-0.0084
6.1	-0.0049	-0.0059	-0.0074
7.1	-0.0043	-0.0052	-0.0066
8.1	-0.0038	-0.0047	-0.0060
9.1	-0.0034	-0.0042	-0.0054
10.1	-0.0031	-0.0038	-0.0050
11.1	-0.0028	-0.0035	-0.0046
12.1	-0.0026	-0.0032	-0.0042
13.1	-0.0024	-0.0030	-0.0039
14.1	-0.0023	-0.0028	-0.0037
15.1	-0.0021	-0.0026	-0.0034
16.1	-0.0020	-0.0025	-0.0032
17.1	-0.0019	-0.0023	-0.0031

Distance Below Surface (mm)	Flange Size		
	Medela = 60 mm	Willow = 75 mm	Rhea = 100 mm
18.1	-0.0018	-0.0022	-0.0029
19.1	-0.0017	-0.0021	-0.0028
20.1	-0.0016	-0.0020	-0.0026
21.1	-0.0015	-0.0019	-0.0025
22.1	-0.0015	-0.0018	-0.0024
23.1	-0.0014	-0.0017	-0.0023
24.1	-0.0013	-0.0017	-0.0022
25.1	-0.0013	-0.0016	-0.0021
26.1	-0.0012	-0.0015	-0.0020
27.1	-0.0012	-0.0015	-0.0020
28.1	-0.0011	-0.0014	-0.0019
29.1	-0.0011	-0.0014	-0.0018
30.1	-0.0011	-0.0013	-0.0018

G.2 COMSOL Multiphysics Material Properties

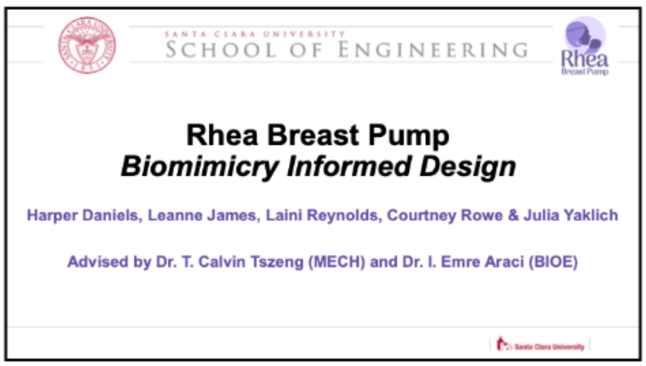
Table G.2: Young’s modulus and Poisson’s ratio of four different polymers

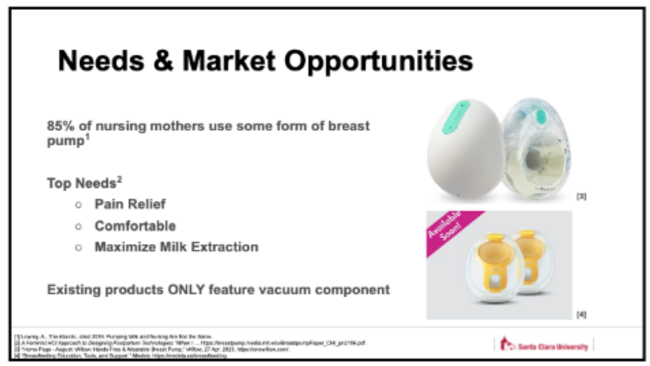
Material	Young’s Modulus (kPa)	Poisson’s Ratio
Ecoflex	130	0.49
Polystyrene	3,300,000	0.35
Polyvinyl Chloride	2,900,000	0.40
Polyethylene	1,000,000	0.43

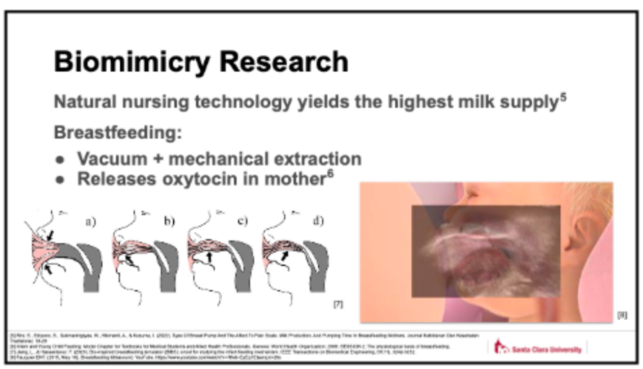
Appendix H:

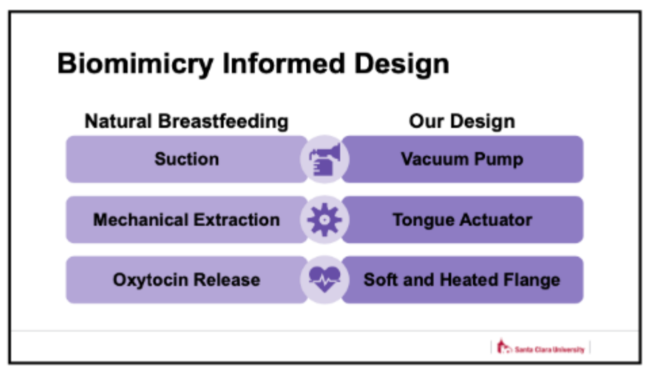
Senior Design Conference Materials

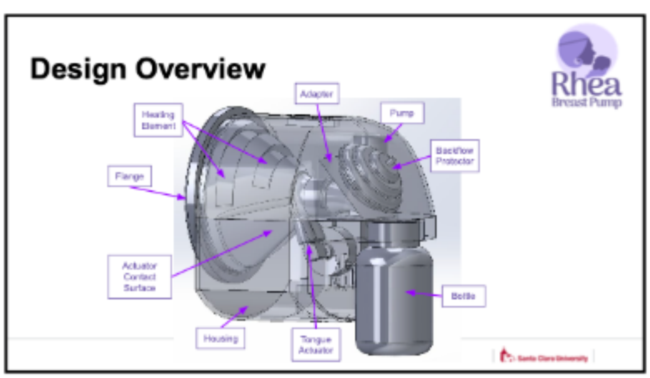
H.1 SDC Slides

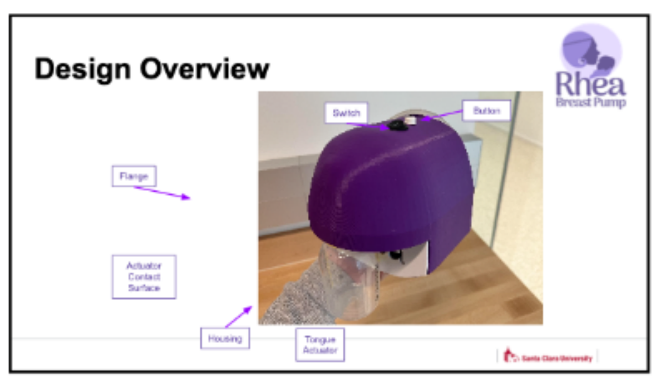


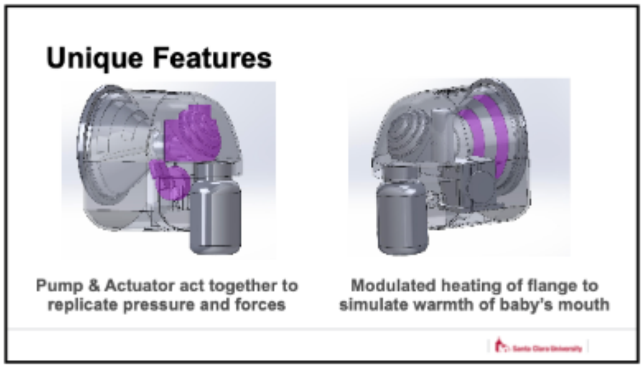


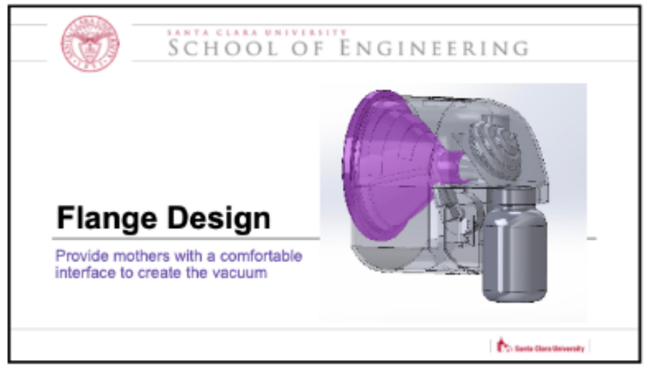


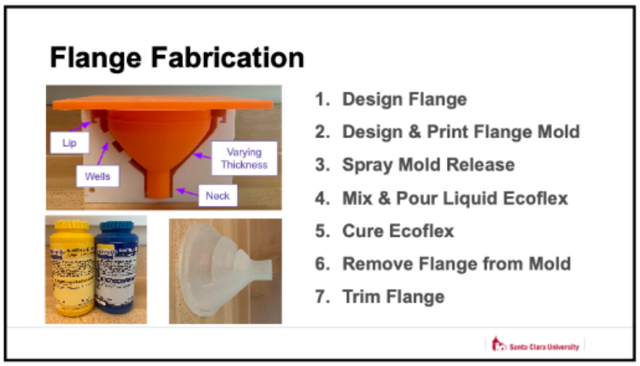


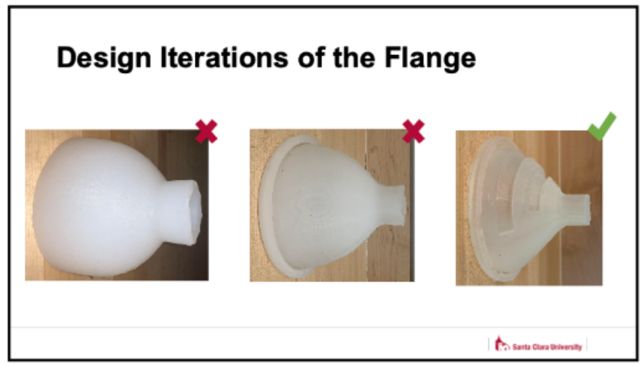


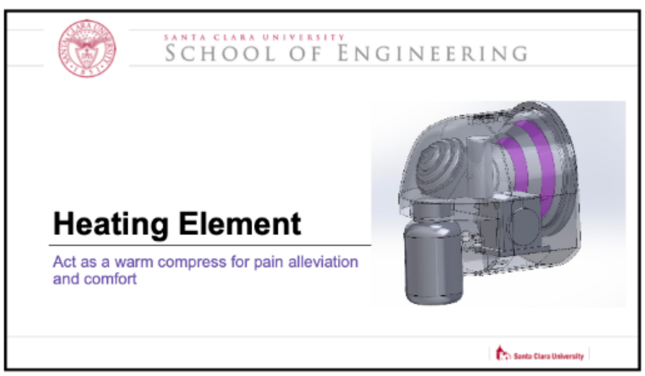


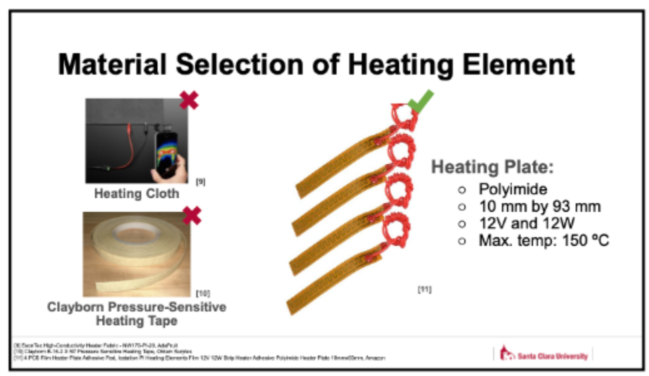

Unique Features
Pump & Actuator act together to replicate pressure and forces
Modulated heating of flange to simulate warmth of baby's mouth

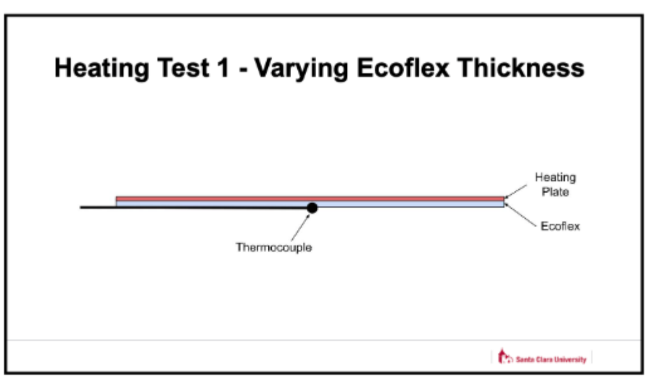

SANTA CLARA UNIVERSITY
SCHOOL OF ENGINEERING
Flange Design
Provide mothers with a comfortable interface to create the vacuum

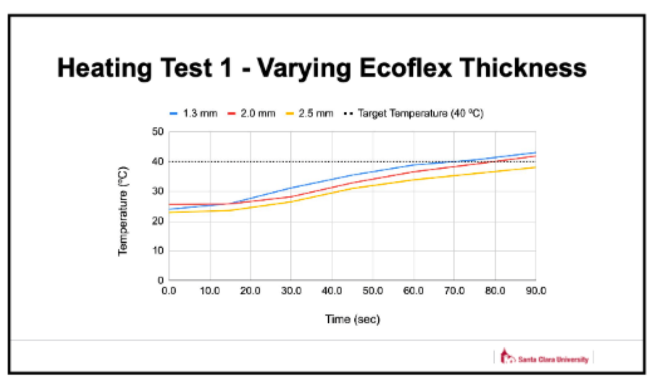

Flange Fabrication
Lip
Varying Thickness
Wells
Neck
1. Design Flange
2. Design & Print Flange Mold
3. Spray Mold Release
4. Mix & Pour Liquid Ecoflex
5. Cure Ecoflex
6. Remove Flange from Mold
7. Trim Flange

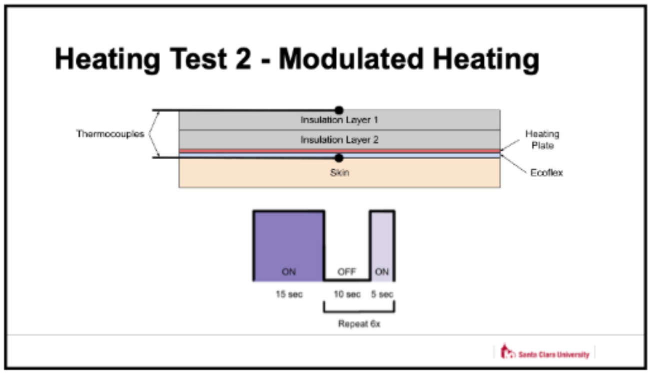

Design Iterations of the Flange

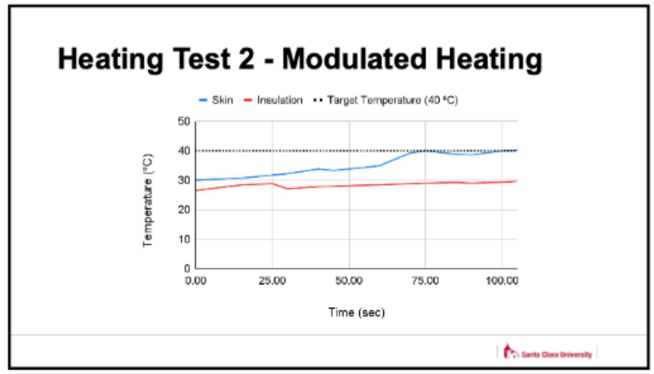

SANTA CLARA UNIVERSITY
SCHOOL OF ENGINEERING
Heating Element
Act as a warm compress for pain alleviation and comfort

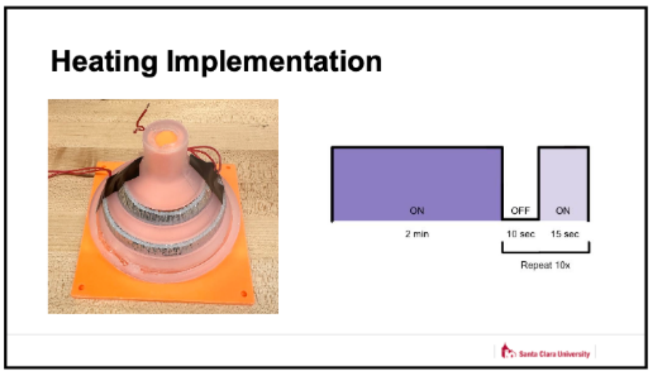

Material Selection of Heating Element
Heating Cloth
[9]
Clayborn Pressure-Sensitive Heating Tape
[10]
[11]
Heating Plate:
Polyimide
10 mm by 93 mm
12V and 12W
Max. temp: 150 °C

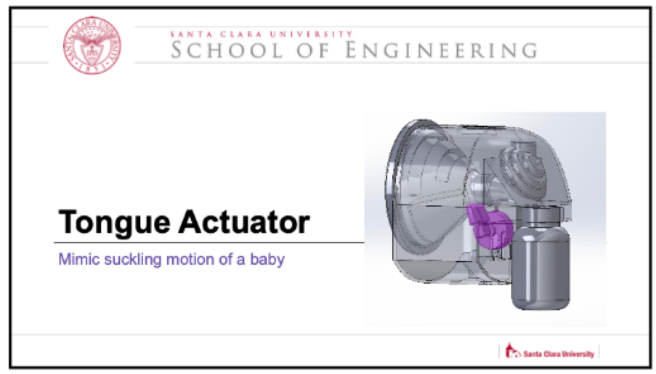

Heating Test 1 - Varying Ecoflex Thickness
Heating Plate
Ecoflex
Thermocouple

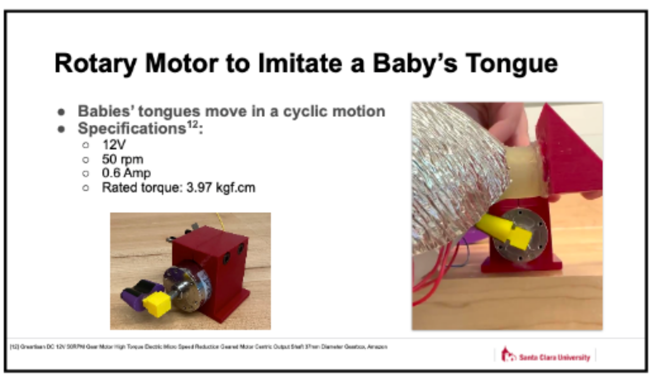

Heating Test 1 - Varying Ecoflex Thickness
1.3 mm
2.0 mm
2.5 mm
Target Temperature (40 °C)
Temperature (°C)
0
10
20
30
40
50
0.0
10.0
20.0
30.0
40.0
50.0
60.0
70.0
80.0
90.0
Time (sec)

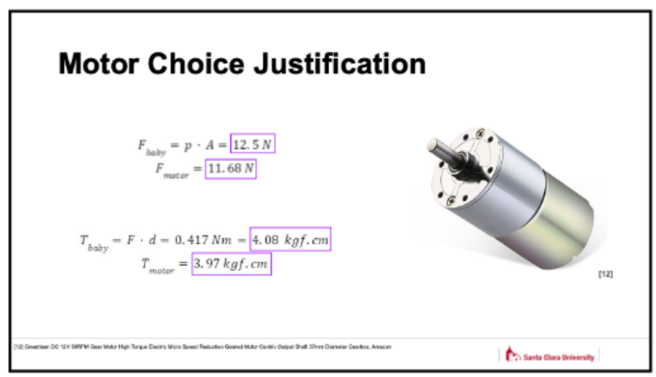

Heating Test 2 - Modulated Heating
Thermocouples
Insulation Layer 1
Insulation Layer 2
Heating Plate
Skin
Ecoflex
ON
OFF
ON
15 sec
10 sec
5 sec
Repeat 6x
Santa Clara University

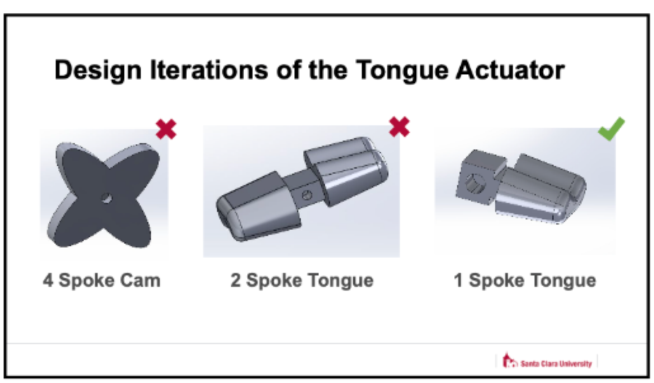

Heating Test 2 - Modulated Heating
Skin
Insulation
Target Temperature (40 °C)
Temperature (°C)
50
40
30
20
10
0
0.00
25.00
50.00
75.00
100.00
Time (sec)
Santa Clara University

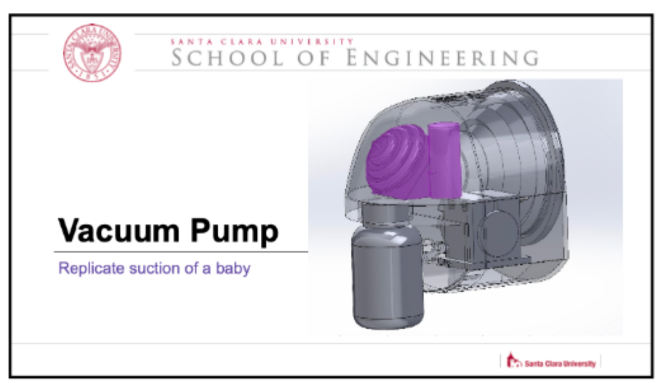

Heating Implementation
ON
OFF
ON
2 min
10 sec
15 sec
Repeat 10x
Santa Clara University

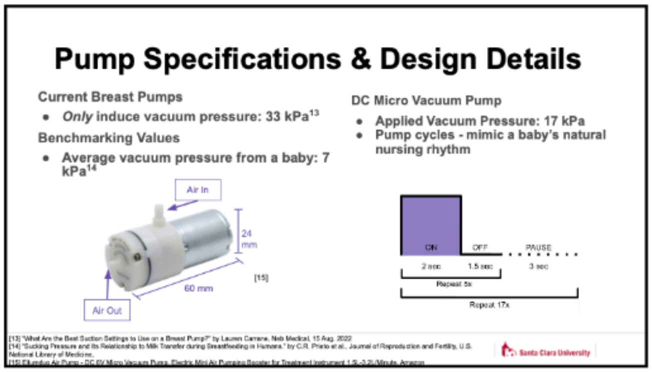

SANTA CLARA UNIVERSITY
SCHOOL OF ENGINEERING
Tongue Actuator
Mimic suckling motion of a baby
Santa Clara University

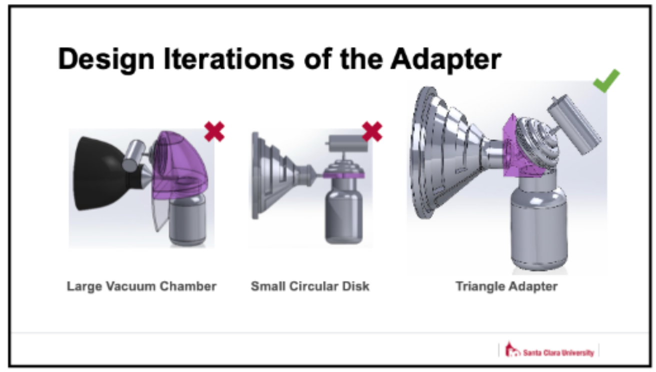

Rotary Motor to Imitate a Baby's Tongue
Babies' tongues move in a cyclic motion
Specifications[12]:
12V
50 rpm
0.6 Amp
Rated torque: 3.97 kgf.cm
[12] Greartisan DC 12V 50RPM Gear Motor High Torque Electric Micro Speed Reduction Geared Motor Centric Output Shaft 37mm Diameter Gearbox, Amazon
Santa Clara University

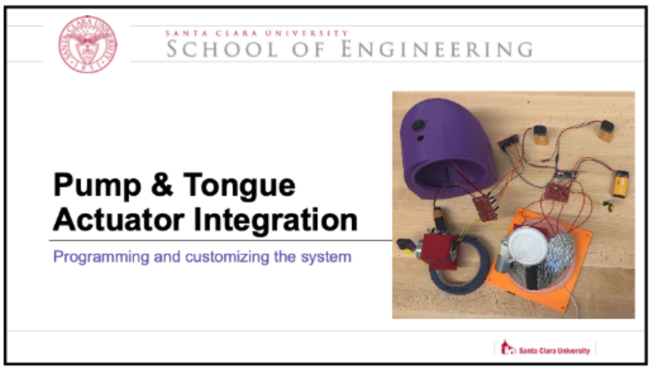

Motor Choice Justification
$F_{baby} = p \cdot A = 12.5\,N$
$F_{motor} = 11.68\,N$
$T_{baby} = F \cdot d = 0.417\,Nm = 4.08\ kgf.cm$
$T_{motor} = 3.97\,kgf.cm$
[12]
Santa Clara University

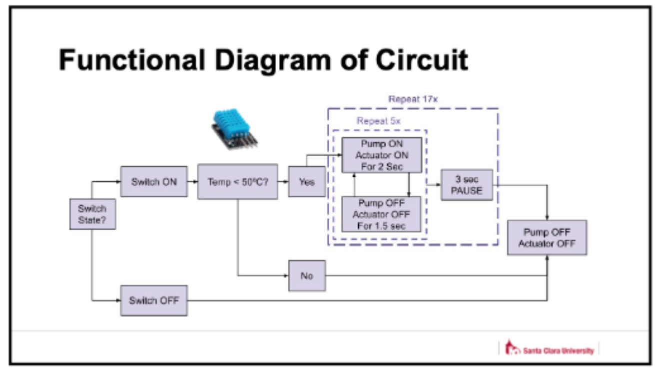

Design Iterations of the Tongue Actuator
4 Spoke Cam
2 Spoke Tongue
1 Spoke Tongue
Santa Clara University

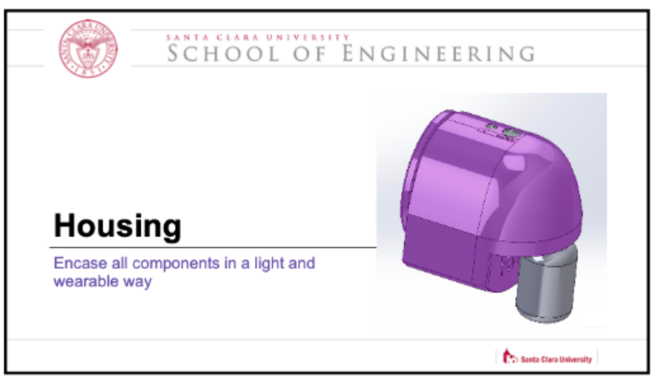

SANTA CLARA UNIVERSITY
SCHOOL OF ENGINEERING
Vacuum Pump
Replicate suction of a baby
Santa Clara University

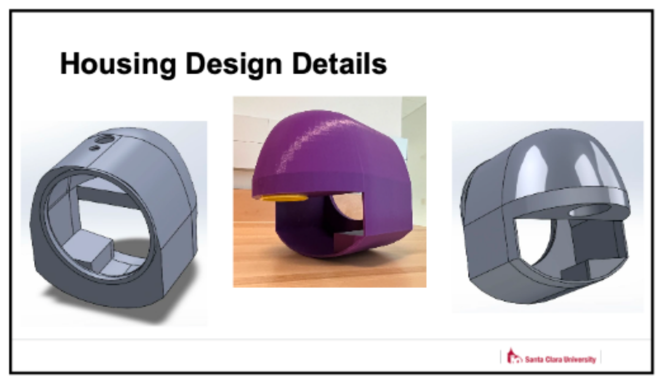


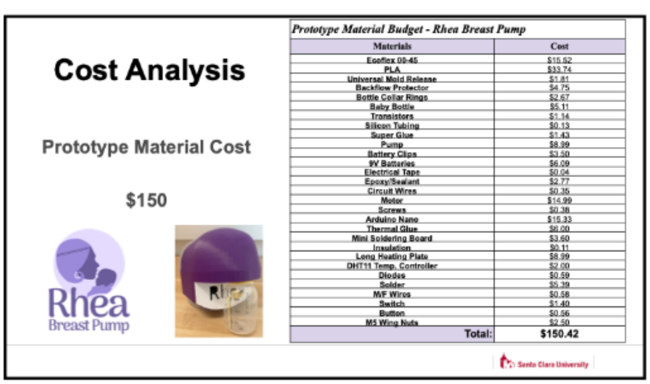






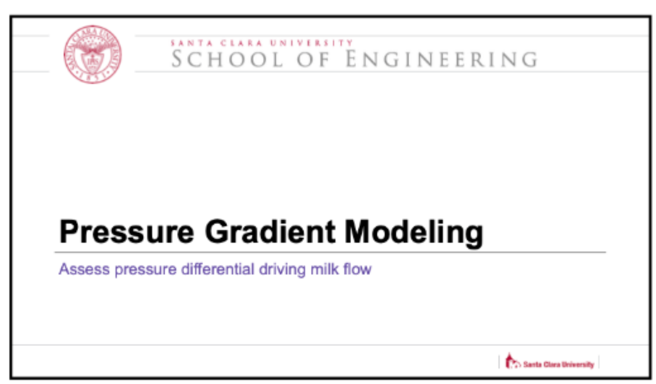


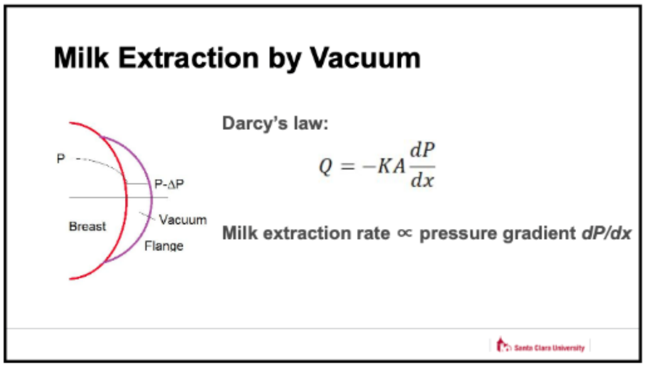


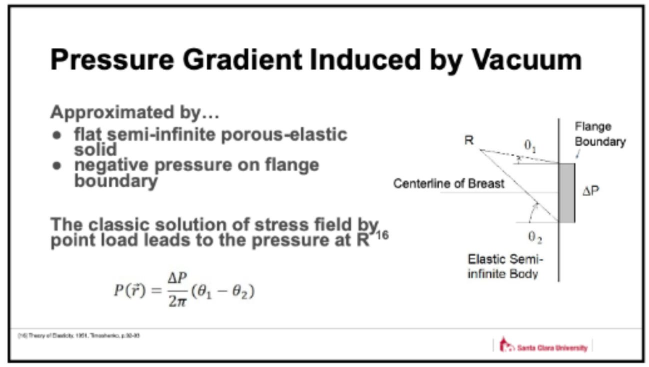


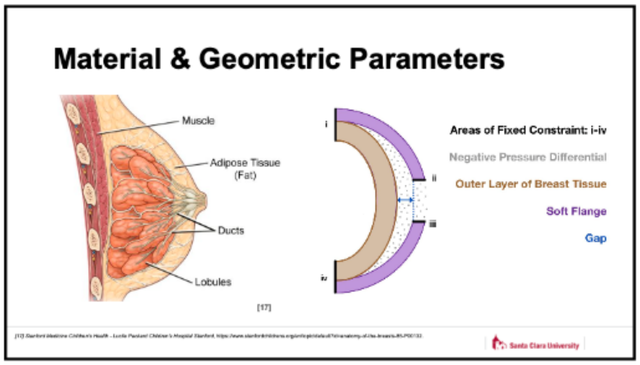
Prototype Material Budget - Rhea Breast Pump

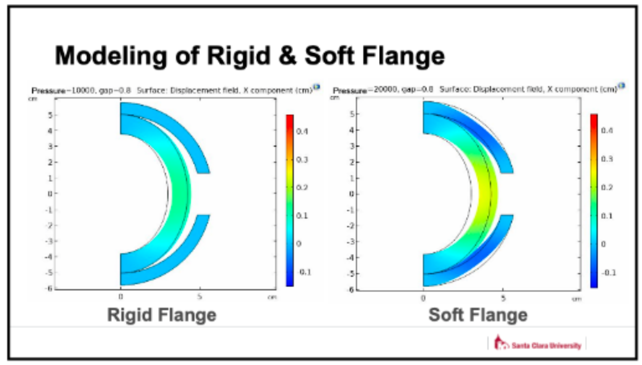
Materials	Cost
Ecoflex 00-45	$15.62
PLA	$33.74
Universal Mold Release	$1.81
Backflow Protector	$4.75
Bottle Collar Rings	$2.67
Baby Bottle	$5.11
Transistors	$1.14
Silicon Tubing	$0.13
Super Glue	$1.43
Pump	$8.99
Battery Clips	$3.50
9V Batteries	$6.09
Electrical Tape	$0.04
Epoxy/Sealant	$2.77
Circuit Wires	$0.35
Motor	$14.99
Screws	$0.38
Arduino Nano	$15.33
Thermal Glue	$6.00
Mini Soldering Board	$3.60
Insulation	$0.11
Long Heating Plate	$8.99
DHT11 Temp. Controller	$2.00
Diodes	$0.59
Solder	$5.39
M/F Wires	$0.58
Switch	$1.40
Button	$0.56
M5 Wing Nuts	$2.50
Total:	$150.42

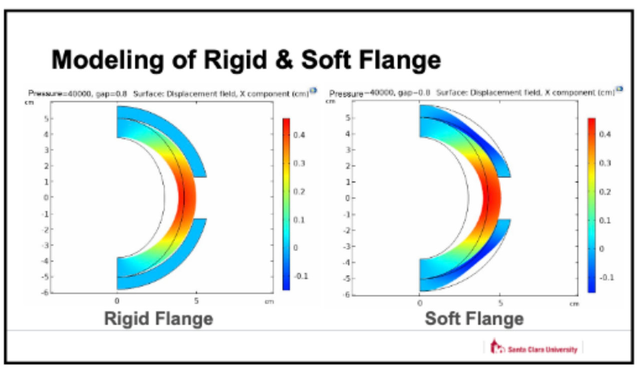


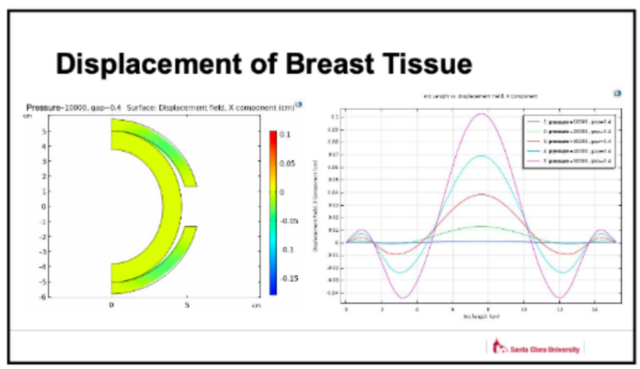

Milk Extraction by Vacuum
P
P-ΔP
Breast
Vacuum
Flange
Darcy's law:
$Q = -KA\frac{dP}{dx}$
Milk extraction rate ∝ pressure gradient *dP/dx*
Santa Clara University

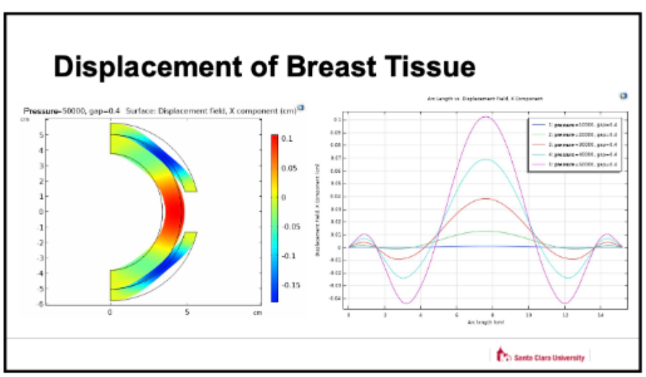

Pressure Gradient Induced by Vacuum
Approximated by…
● flat semi-infinite porous-elastic solid
● negative pressure on flange boundary
The classic solution of stress field by point load leads to the pressure at R[16]
$P(\vec{r}) = \frac{\Delta P}{2\pi}(\theta_1 - \theta_2)$
R
θ_1
θ_2
Flange Boundary
Centerline of Breast
ΔP
Elastic Semi-infinite Body
Santa Clara University

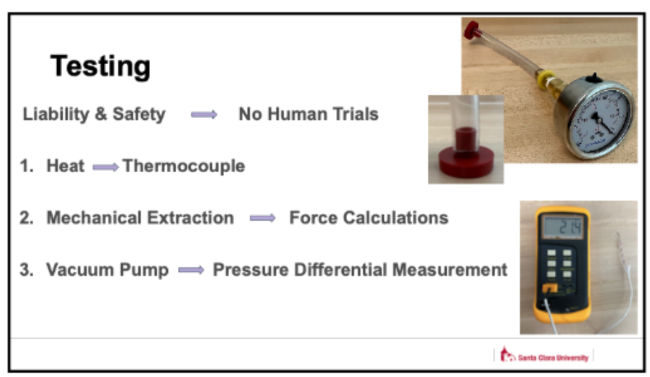

Material & Geometric Parameters
Muscle
Adipose Tissue (Fat)
Ducts
Lobules
[17]
i
ii
iii
iv
Areas of Fixed Constraint: i-iv
Negative Pressure Differential
Outer Layer of Breast Tissue
Soft Flange
Gap
Santa Clara University

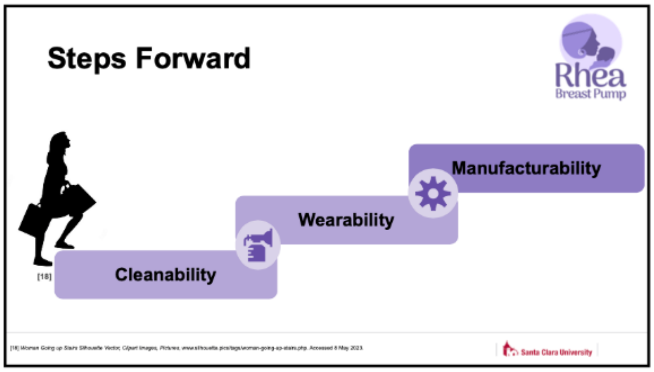

Modeling of Rigid & Soft Flange
Rigid Flange
Soft Flange
Santa Clara University

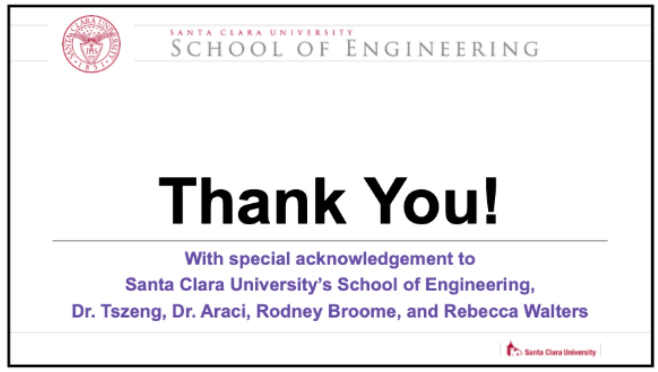

Modeling of Rigid & Soft Flange
Rigid Flange
Soft Flange
Santa Clara University

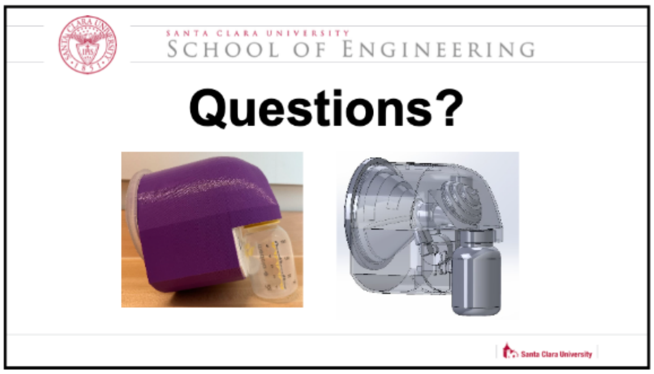

Displacement of Breast Tissue
Santa Clara University

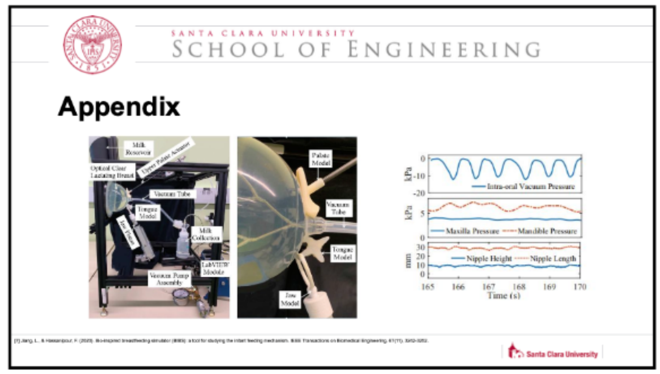

Displacement of Breast Tissue
Santa Clara University

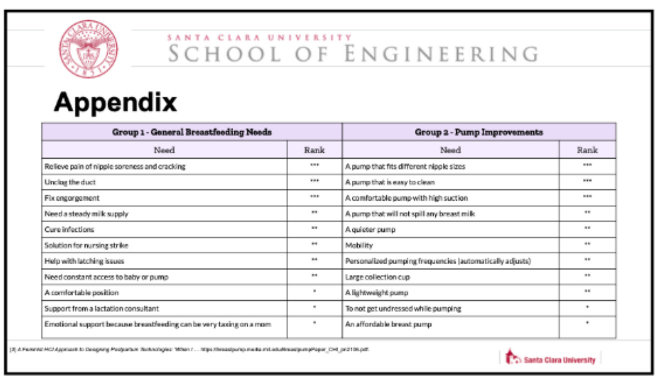

Testing
Liability & Safety → No Human Trials
1. Heat → Thermocouple
2. Mechanical Extraction → Force Calculations
3. Vacuum Pump → Pressure Differential Measurement
Santa Clara University



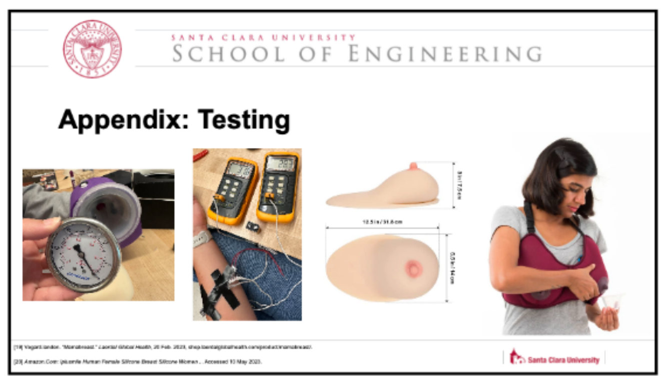


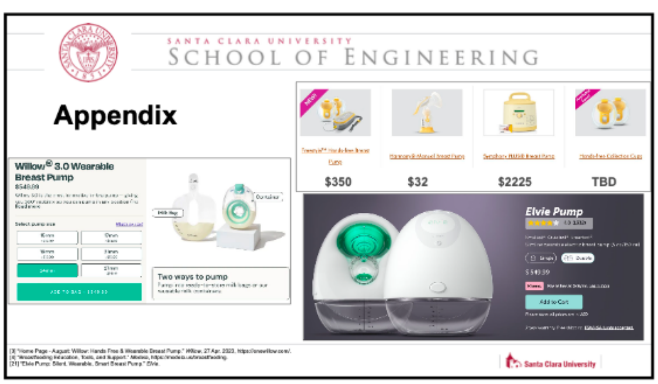


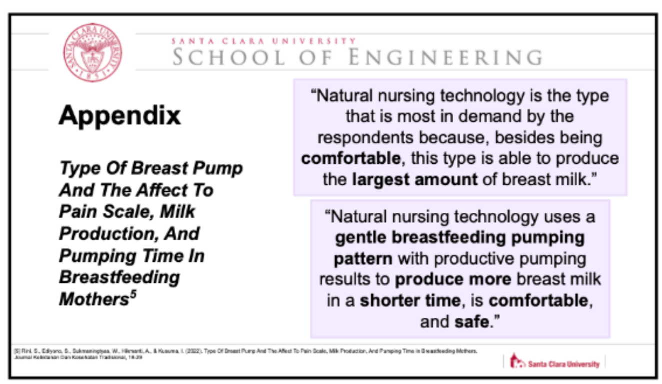




Group 1 - General Breastfeeding Needs		Group 2 - Pump Improvements	
Need	Rank	Need	Rank
Relieve pain of nipple soreness and cracking	***	A pump that fits different nipple sizes	***
Unclog the duct	***	A pump that is easy to clean	***
Fix engorgement	***	A comfortable pump with high suction	***
Need a steady milk supply	**	A pump that will not spill any breast milk	**
Cure infections	**	A quieter pump	**
Solution for nursing strike	**	Mobility	**
Help with latching issues	**	Personalized pumping frequencies (automatically adjusts)	**
Need constant access to baby or pump	**	Large collection cup	**
A comfortable position	*	A lightweight pump	**
Support from a lactation consultant	*	To not get undressed while pumping	*
Emotional support because breastfeeding can be very taxing on a mom	*	An affordable breast pump	*







SANTA CLARA UNIVERSITY
SCHOOL OF ENGINEERING

Appendix - Heating Element

- Mastitis occurs in 10% of breastfeeding U.S. mothers when bacteria found on the skin or saliva enters breast tissue through a milk duct or crack in the skin[22]
- Predominantly caused by Staphylococcus aureus bacteria
- Most common complication is a breast abscess that needs to be surgically drained by a physician
- Warm compress can help alleviate pain along with helping inducing healing
- Study conducted found that warm compress relieves breast engorgement.
- Warm compress can dilate blood vessels and the lactiferous duct. This increases milk production[23]
    - Lactiferous duct enlarges to form a lactiferous sinus, which serves as a reservoir for milk

[22] Priscilla Tait, Nipple pain in breastfeeding women: causes, treatment, and prevention strategies, Journal of Midwifery & Women's Health, Volume 45, Issue 3, 2000, Pages 212-215, ISSN 1526-9523,
[23] Wahyuningsih, Melania, Liliana Anita. The effectiveness of warm compress on breast milk production among postpartum mothers in Tegalrejo Health Center, July 2019

Santa Clara University

Rhea Breast Pump Final Thesis

Final Audit Report 2023-06-15

Created:	2023-06-13
By:	Darcy Yaley (dyaley@scu.edu)
Status:	Signed
Transaction ID:	CBJCHBCAABAAEWHT7H5FCHOGmevv-YtW2xS0oMSrrvXi

"Rhea Breast Pump Final Thesis" History

Document created by Darcy Yaley (dyaley@scu.edu)
2023-06-13 - 11:45:18 PM GMT

Document emailed to hlee@scu.edu for signature
2023-06-13 - 11:46:23 PM GMT

Email viewed by hlee@scu.edu
2023-06-14 - 0:50:42 AM GMT

Signer hlee@scu.edu entered name at signing as Hohyun Lee
2023-06-14 - 0:51:10 AM GMT

Document e-signed by Hohyun Lee (hlee@scu.edu)
Signature Date: 2023-06-14 - 0:51:12 AM GMT - Time Source: server

Document emailed to ukim@scu.edu for signature
2023-06-14 - 0:51:13 AM GMT

Email viewed by ukim@scu.edu
2023-06-15 - 5:34:16 PM GMT

Signer ukim@scu.edu entered name at signing as Unyoung Kim
2023-06-15 - 5:35:04 PM GMT

Document e-signed by Unyoung Kim (ukim@scu.edu)
Signature Date: 2023-06-15 - 5:35:06 PM GMT - Time Source: server

Agreement completed.
2023-06-15 - 5:35:06 PM GMT