Increased Flow Breast Pump

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Abstract

Current breast pumps on the market are reported to be uncomfortable and require too long of a pumping interval. Additionally, only one known model, the Philips Avent Breast Pump, has introduced mechanical stimulation, and it ignores the motions and physiological relevance of the infant's tongue. The purpose of our breast pump with mechanical stimulation is to improve the comfort and efficiency of breast pumping by providing mechanical stimulation to the nipple. The device uses compression by means of an expanding and contracting latex membrane attached to the breastshield. This provides cushioning for the breast while simultaneously facilitating milk flow by compressing the nipple. It increases the comfort of breast pumping by massaging the nipple similarly to a suckling baby. The breastshield insert is biocompatible and sanitary due to a removable membrane that is discarded after each use, resulting in less cleaning necessary overall. Without access to human subjects, only limited testing could be performed using a Tommee Tippee® bottle, mimicking a nipple. This resulted in the control pump accumulating more liquid than our pump due to our pump's membrane partially inhibiting flow. However, this test does not account for the hormone stimulation that our pump would invoke within a human breast, nor does it account for the hypothesized increase in comfort the membrane provides. Before any final evaluation of the efficiency and comfort of our design, human testing must be conducted to reveal the efficacy of the mechanical stimulation on hormonal release.

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Introduction

Motivation

Breast pumps are essential for most lactating women, especially those who return to work soon after giving birth [1]. They allow the lactating mother to maintain a supply of milk for the baby as well as expel milk periodically throughout the day as necessary to prevent pain [2].

Although there are many products already on the market, women still complain of pain, discomfort, and inefficiency during use [3]. It is hypothesized that a redesign of the pump to imitate a baby's movements will increase oxytocin levels in the lactating woman, therefore increasing milk flow [4]. To achieve this, our device will provide stimulation to the nipple to mimic the cyclical compression provided by a baby during breastfeeding [5].

The two main consumers in need of breast pumps are hospitals and mothers. Mothers are in need of pumps to use both in and out of the home. Hospital-grade pumps tend to be much larger and therefore not as easily transportable [6]. They are comprised of a closed system to eliminate the transmission of diseases when used by multiple women [7]. By the request of our client, the focus will be on designing a pump for individual use. Creating an efficient pump for individual use is especially relevant in today's society, as working and active mothers must store milk for their children when they are not available. Demographically speaking, the majority of consumers are women who have recently delivered children and working mothers who do not have the time to feed their baby throughout the day. Breast pumps allow these women the ability to generate a supply of milk for their infant's later use.

Due to the recent emergence and drive to establish greater women's rights within the workplace, the use and sale of personal breast pumps could see a fairly sizable increase. As part of the 2010 Affordable Care Act, stated in section 4207, employers are now required to allow their employees the opportunity to pump breast milk while at work [8]. Already standing at a worth of 1.2 billion dollars (last noted in 2013), it is expected that with the increased acceptance of public breast pump use, the global breast pump market is estimated to top 2.5 billion dollars by 2022 as this law becomes more socially accepted [9].

Existing Devices

Breast pumps that are currently on the market include the NUK Double Electric Breast Pump, the Medela Freestyle, and the Philips Avent Comfort Double Electric as seen in Figure 1. The NUK Breast Pump is a portable system with silicone breastshields rather than hard plastic. The silicone shield increases the comfort of the device, one of the most common complaints among breast pump users. This breast pump has multi-phase settings and memory to store them and costs $204.99 [10]. A second major competitor, the Medela Freestyle, is a light and portable breast pump. It includes "2-Phase Expression" technology that offers a faster initial pumping speed, similar to a baby's actions when first latched on, and a slower let-down phase. This product costs $399.99 [11]. Another leading breast pump on the market is the Philips Avent Comfort Double Electric. This pump is the only design that attempts to mimic the suckling of a breastfeeding baby, as it offers a gentle stimulation mode that applies cyclic

Figure 1. The Philips Avent Comfort Double Electric Pump [12]

pressure changes in 5 circular domes around the breastshield. This product costs $199.99 [12]. Although all three of these pumps offer desirable components such as portability and comfort, the consumers of these products are commonly not satisfied and demand a pump which will operate more efficiently and with better stimulation.

Problem Statement

Breast pumps are essential for active, lactating women to obtain and store milk for later use. Present breast pumps use periodic suction to induce the milk ejection reflex. However, in addition to suction, babies use their tongue to massage and compress the nipple to draw milk from the breast. Although there are already multiple products already on the market, there are demands from mothers for a more comfortable and efficient pump. The design will consist of a breast pump that mimics the suckling of a human baby by massaging the nipple to increase milk flow.

Background

Physiology

The physiology of breastfeeding involves a multitude of hormones. Prolactin and oxytocin are two hormones found at elevated levels in lactating women [13]. Prolactin is produced prior to birth and peaks as the baby is born. This hormone signals to the breasts to start milk production and is readily available in the body at all times during the lactation period. Unlike prolactin, oxytocin is not readily available in the body. Production of oxytocin begins as soon as the nipple is stimulated and the baby latches on. The milk ejection reflex, commonly referred to as “letdown”, is initiated when oxytocin signals for the contraction of the breast tissue [14]. The milk is then released from the alveoli, which are tiny grape-like ducts that hold the milk as seen in Figure 2. The contraction of the alveoli forces milk out of the nipple. This process does not require suction but instead requires stimulation of the nipple and breast, which is why massage is typically used in conjunction with pumping [15]. Milk can be continuously produced, but without oxytocin, will never be delivered to the nipple. A known inhibitor of oxytocin release is adrenaline, which is another hormone produced by the body when in pain. Research done in 1961 by R. Chaudhury proved that injection of adrenaline blocked the milk ejection reflex in 8 out of 10 lactating rats [15]. It is important that breast pumping is a comfortable experience for the mother in order to stimulate the release of oxytocin and initiate letdown.

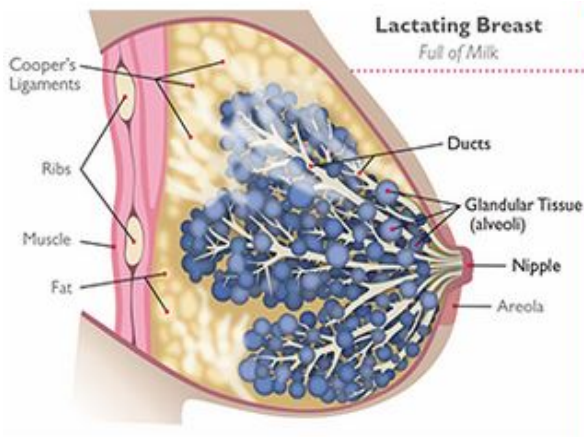


Figure 2. Diagram of the anatomy of the breast.

Breast Pumping & Milk Ejection Reflex

The milk ejection reflex involves the release of milk from milk ducts in the breast tissue to the nipple. An infant latching onto and sucking on the nipple can accomplish this. Breast pumping is another method that is used to stimulate the milk ejection reflex and collect milk for feeding. A general breast pumping procedure is as follows: first, the mother places her nipple in

the center of the breastshield, also known as the flange. Then, she puts the pump on a low setting and pumps for a maximum of 15 minutes on each side. She can compress her breasts using her hands if she is not getting enough flow [16].

The milk ejection reflex can be self-stimulated using several different methods. A warm, wet cloth can be applied to the breast to encourage the reflex. Additionally, the breasts can be massaged in small circular motions, gently stroked in a downward motion toward the nipple, or shaken slightly. Also, gentle rolling of the nipple between the finger and thumb can be helpful. Milk ejection can also be encouraged by thinking about the baby being in her arms or looking at pictures of the baby [17].

There are different physical stimuli that women have reported to aid in the increase of milk flow. Lactation Specialist Sharon Marshall of Meriter Hospital has stated that through her work with nursing mothers, she has found that massage of the nipple, breast, and surrounding areas of the breast can aid in increasing milk flow. This may be due to the physical stimulation that massage provides to the milk-containing alveoli, which are densely packed in the breast and near the nipple (Figure 2). It is also recommended that women engaging in either breastfeeding or breast pumping make sure to relax and control their breathing to assist in optimization of milk flow.

Client information

Professor John Webster is a founding pioneer in the field of biomedical engineering. Although no longer teaching, he invests his time developing an implantable intracranial pressure monitor and a miniature sternal skin-attached hot flash monitor [18]. With inspiration from Dr. Erin Girard, a biomedical engineer from Stanford University, Professor Webster presented this design proposal in hopes of improving the current model of the breast pump.

Design Specifications

Professor Webster and Dr. Girard presented a list of design requirements that are essential to create a breast pump with increased flow. In order for us to complete a successful design, a breast pump must be developed that is faster, more efficient, and has a massage or stimulation component to increase milk flow. The massage or stimulation component must mimic the natural movement of a baby's tongue but must not harm the breast during pumping. Additionally, the device must weigh between three to four kilograms to allow for easy transportation for use at home or in an office setting. The standard flange size of 24 millimeters will be used in the final product. However, there are multiple breastshield sizes available to accommodate variations in breast size. Overall, the breast pump design must be comfortable to wear and use during the breast pumping period.

The budget allotted is $100 for materials this semester. It will be primarily used on new components that will be added to the Medela breast pump that Professor Rogers lent the team for the semester (refer to Appendix A for full Product Design Specifications).

Preliminary Designs

Paint Roller Design

In order to mimic the movement of a baby's tongue on the nipple during breastfeeding, our team came up with a design similar to a small paint roller. This design features a rolling cylinder on a wire that will brush back and forth under the nipple, providing tactile stimulation to increase the flow of milk as shown in Figure 3. The cylinder will be made out of a moist sponge-like material to simulate the texture of the tongue or a soft plastic. It will provide stimulation to the nipple without heavy friction and will be attached to a track through a slit on the underside of the flange. The air pressure generated by the pump will power the roller to slide back and forth on a track.

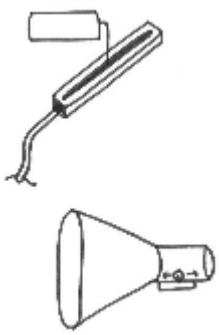


Figure 3. Design alternative 1: Paint Roller Design sketch.

Massage Chair Design

The massage chair design consists of several circular plates positioned throughout the breastshield or on a attachment to the breastshield as an accessory. A pin to the adjacent plates will attach each circular plate and the plates will continuously rotate. There will be small beads held in each plate that will freely roll within the plate. These beads will be the only component of the design that will come in contact with the breast. The plates will receive power from a small motor, located on a belt or in a wearable bra-like garment. The compilation of these design aspects is displayed in Figure 4. This design will promote massage of the breast tissue in order to stimulate the milk ducts, easing the release of milk. The coverage of the massage plates may reduce the need for hand massage of the breast during pumping.

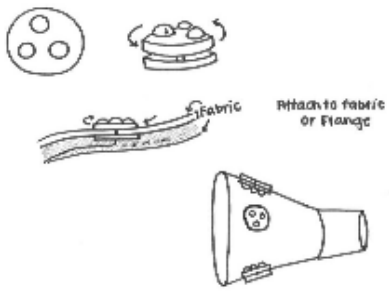


Figure 4. Design alternative 2: Massage Chair Design sketch.

Bead Bracelet Design

Shown in Figure 5, the bead bracelet design consists of many small beads on an elastic band that will move along the length of the breastshield. The bracelet will be fitted over a soft silicone breastshield and will be attached with two hooks. The hooks will run back and forth on a track, powered by the pump, and will pull the bead bracelet up and down the breastshield. The elastic band will hold the beads tight against the breastshield, gently massage the breast as it moves. The motion of the beads toward and away from the nipple will allow the milk ducts to release more milk, therefore increasing the flow rate. This design may also eliminate the need for women to hand massage the breast during pumping.

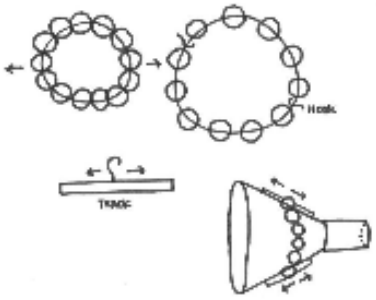


Figure 5. Design alternative 3: Bead Bracelet Design sketch

Preliminary Design Evaluation

Design Matrix

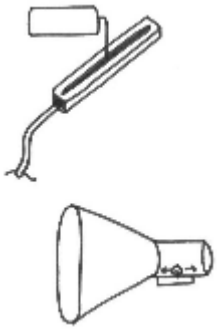
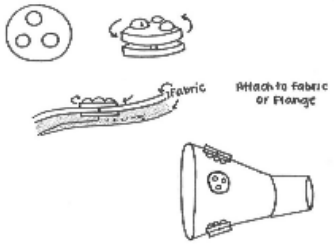
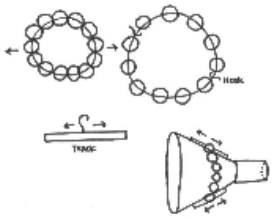
Design	Paint Roller		Massage Chair		Bead Bracelet	
Criteria (Weight)						
Comfort (25)	3/5	15	4/5	20	5/5	25
Milkability (20)	5/5	20	2/5	8	3/5	12
Ergonomics(15)	2/5	6	3/5	9	5/5	15
Safety (15)	4/5	12	5/5	15	5/5	15
Weight/Bulk (10)	4/5	8	3/5	6	4/5	8
Cost (5)	3/5	3	1/5	1	4/5	4
Ease of Fabrication (5)	2/5	2	2/5	2	3/5	3
Durability (5)	3/5	3	5/5	5	4/5	4
Total (100)		**69**		**66**		**86**

Table 1. Design matrix used to evaluate our three initial design ideas.

Design Criteria

We ranked our designs based on the following criteria: comfort, milkability, ergonomics, safety, weight/bulk, cost, ease of fabrication, and durability as highlighted in our Design Matrix, Table 1 above. Comfort was weighted the highest because in order to induce letdown, the user must be comfortable and relaxed. Adrenaline as a result of discomfort can block the release of oxytocin, impairing initiation of the milk ejection reflex. The next criterion that we considered was milkability. Milkability refers to the success of receiving milk in the most efficient way possible, which is one of the main goals of our design. Ergonomics and safety received equal rankings because we find those equally important – the design must be sleek and discrete as well as safe for the user. In addition, it must also be lightweight and portable, making the pump easier for working mothers to use. Current breast pump models range from $200 - $400, so we are aiming to create a more affordable device. Ease of fabrication and durability were ranked lowest among our considered criteria. We are aware that all of our designs are going to be equally difficult to fabricate because we are dealing with a small and isolated area, human contact, and electrical components. The lifetime of the breast pump will be based on how long the user wishes to pump and how many children she plans on having.

Proposed Preliminary Design

After evaluating the three designs featured in the design matrix, we concluded that the bead bracelet design is our proposed final design, shown to the right in Figure 6. This design outcompeted the other two in many of the criteria categories and achieved a score of 86 out of 100. It was chosen based on the comfort and simplicity of the design. The bead bracelet design is lightweight, minimally invasive, and offers effective stimulation to increase milk flow.

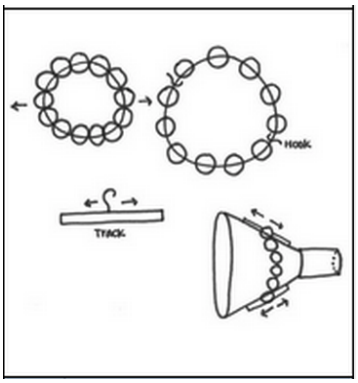


Figure 6. Final Preliminary Design.

Prototype Research

Prior to implementing our final design, there was research done on several other methods and ideas for creating the desired mechanical effects with the breast pump. These ideas included using gears to power two pumps with one motor and using an ultrasonic distance sensor to detect the oscillations of one pump to control the compression pattern with a second pump.

The first method explored included the use of gears. We wanted to use one motor to power two separate pumps with one pump oscillating at half the frequency of the other. In-depth research of gears was conducted to determine proper gear ratio, size, placement, and materials to optimize the performance of the pump motor while creating the most space efficient, cost effective, and reliable product. It was discovered that gear material was a category that was typically and erroneously overlooked. Plastics can easily delaminate and bend, and gear teeth can readily fracture off of the gear face so it was determined that gears made of nylon or a lightweight metal would be used [19]. Upon further investigation, it was determined that using gears to power two pumps with one motor was unfeasible due to the incredible difficulty of proper gear placement and budgetary concerns regarding the use of a more credible gear material.

The second method explored involved the use of two pumps powered separately. In order to control the compression-suction rhythm of the breastshield, we wanted to monitor the oscillations of one pump to control a second pump. The first way we thought to do this was with an ultrasonic distance sensor. When the arm of the pump passes in front of the sensor, the change in distance is measured. This information will be used to control when the secondary pump is on or off. Our team found Arduino code that relays the distances detected by the ultrasonic distance sensor to the Arduino at a high frequency. We found our code on Arduino Playground and modified it slightly to fit our needs [20]. After implementing the sensor, testing was conducted to determine whether the sensor was accurate enough for our design. We determined that the sensor was unreliable and would be too difficult to mount.

Proposed Final Design

After meeting with Professor Paul Thompson, a dairy specialist, and visiting the dairy barns on campus, our design evolved into a vastly different model featuring components similar to an industrial dairy pump. Our final prototype features a latex membrane, alternating suction and compression, and software to control various electrical components. The latex membrane is soft to the touch and will stimulate the nipple by gentle but firm compression. The alternating

compression and suction will be achieved by the use of two pumps. The secondary pump will be turned on and off in accordance to the status of the primary pump to create several patterns for suction and compression. These patterns are meant to mimic the industrial dairy pump and will inflate and deflate the latex membrane to act as a massage stimulus. This device offers many advantages over other breast pumps on the market. The design integrates unique features to provide increased comfort for the user and aid in milk expression while maintaining a hygienic and user-friendly interface.

Fabrication and Development Process

Materials

2 Medela Pump In Style Advanced Breast Pumps
1 Breastshield
1 Arduino Uno
1 Beefcake Relay
1 Force Sensitive Resistor (FSR)
3 DC Power cords (Two 9 V, One 5 V)
1 Breastpump bag
1 USB Cord
1 Black box for electronics housing
2 10 kΩ resistors
1 Toggle switch
1 Latex Membrane
Several jumper wires
Breast pump tubing

Electronics Setup

The Arduino will be used to communicate between the force sensitive resistor, the relay, and the breast pumps. An FSR is a variable-resistance resistor and will alter the voltage delivered to the Arduino each time that it is tapped. As the arm of the primary breast pump motor rotates, it will come in contact with the FSR once per oscillation. When the arm contacts the FSR, the FSR will signal back to the Arduino, which will in turn signal to the relay to turn the secondary pump on or off. Turning the secondary motor on and off will allow the user to control the compression rhythm. The overall electrical component layout can be seen in Figure 7.

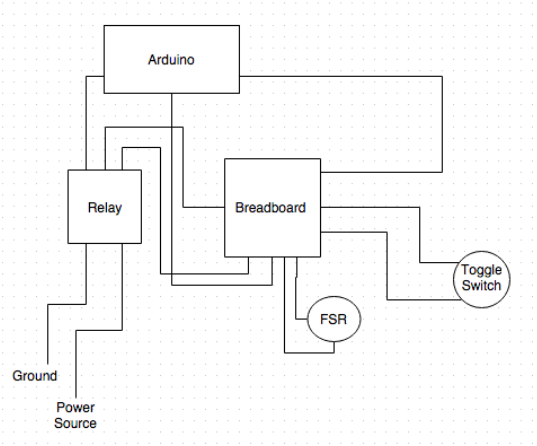


Figure 7. High-level schematic of electronics setup.

Two Medela Pump In Style Advanced breast pumps were extracted from the bags that they were housed in. The power cord for one of the pumps was cut and stripped and the positive wire was connected to the relay so that the power may be controlled through the relay. The rest of the power cord will plug directly into one of the breast pumps as usual. The relay is connected to an Arduino Uno so that the Arduino can control the status of the relay to control

the power. An FSR was adhered to a hard surface inside the housing of the primary breast pump near the motor arm. Each time the pump completes an oscillation, the FSR will be tapped, changing the voltage delivered to the Arduino.There is a toggle switch for the user to change the compression rhythm. Currently there are two different patterns for the compression and suction. These options will be clinically tested to determine which is more comfortable and effective and more compression patterns can be easily incorporated.

Breastshield Assembly

The breastshield used in this design is a cone-shaped piece of hard plastic which is placed on the breast while pumping. A hole was drilled in the flange of the breastshield approximately 3 cm from the top of the flange. A 7/32 – 1 sized drill bit was used to drill the hole; this size is exactly the size of the breast pump tubing that is used to connect the breastshield to the pump. After the hole was drilled, the remaining plastic was shaved away to make for a clean insertion. A breast pump tube was then inserted into the hole and was secured tightly using non-toxic super glue; an air tight seal is necessary for proper membrane movement. Latex rubber tubing was then added to the inside of the breast flange. The latex was stretched over the wide end of the breastshield and pulled down through the flange and glued to create an air tight seal. The nipple will be in contact with the latex during pumping. The full protocol can be found in Appendix D, part.

Final Prototype

Our final design shown in Figure 8 features a latex membrane, two pumps, and an Arduino microcontroller connecting a force sensitive resistor and relay to control the power of one pump. The breast pump design incorporates two pump motors. The primary pump is used for direct suction to collect the breast milk into an attached container and the second pump is attached to the breastshield. The pump attached to the breastshield serves to move the membrane by increasing and reducing the pressure in the space between the membrane and breastshield. This causes the membrane to expand and contract, producing periodic compression. Synchronizing the two pump motors produces periodic compression. The primary pump is on at all times of use and the second pump functions during specific cycles of the regular pump. The pumps are synchronized this way to maintain a comfortable suction and compression rhythm for the user.

The breastshield used in this design is a cone-shaped piece of hard plastic, which is placed on the breast while pumping. The shield features a small hole in the side of the shield at the end attached to the continuous vacuum. Tubing is inserted into this hole, which is then connected to the pump and motor. The membrane is stretched around this breastshield to create an airtight seal. The membrane used is similar to a long, tubular balloon that is affordable and easy to manufacture. This feature provides a clean, isolated

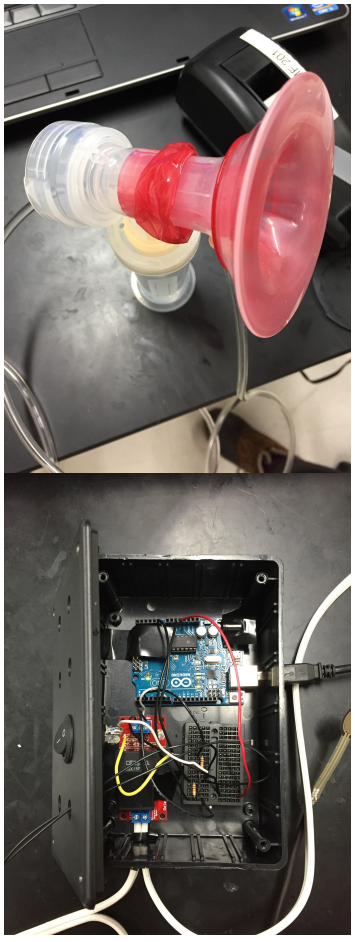


Figure 8. Pictures of final design.

pathway for milk discharge into the bottle.

Component Testing

Breast Pump Testing

The mechanical function of the breast pump was tested to confirm that both pumps were working correctly to retrieve and store liquid as desired. A variety of conditions were tested to evaluate our prototype throughout fabrication. The conditions include: (A) suction pump only with no membrane; (B) suction pump with membrane, and compression pump every third cycle; (C) suction pump with membrane, and compression pumping every other cycle; (D) suction pump only with membrane; and (E) no suction or compression. A detailed testing protocol can be found in Appendix D, part 3: Testing Protocol.

Electronic Component Testing

Each electrical component was tested separately to ensure our final prototype would function as expected. The three electrical components tested were the force sensitive resistor, the Beefcake relay, and the toggle switch. After testing, all components were combined and tested with the final Arduino code and two breast pumps. Testing, Arduino code, and assembly can be found in further detail in Appendix D.

Experimental Design

An Institutional Review Board application has been filled out to receive permission for human subject testing. See Appendix F for the full application. The application is currently being reviewed, and if approved, the experimental protocol would be as follows:

Purpose:

The purpose of this study is to test the mechanical stimulation applied to the nipple by a modified breast pump to initiate the hormonal response in order to increase letdown and subsequently increase milk flow of the human breast during lactation. Current breast pump models use periodic suction to induce the expression of milk; additionally, infants use their tongue to massage the nipple to increase milk flow.

Materials:

- 2 Medela Pump In Style Advanced Breast Pumps
- 1 Breastshield
- 1 Arduino Uno
- 1 USB Cable
- 2 10 kΩ Resistors
- 1 Toggle Switch
- 1 Beefcake Relay
- 1 Force Sensitive Resistor, 0.5”
- 1 Small Breadboard
- 1 Black box for electronics housing
- 3 DC Power cords (Two 9 V, One 5 V)
- 1 Breastpump bag
- 1 Latex Membrane
- Several jumper wires

- Breast pump tubing

The modified breast pump features a primary and secondary pump that provide variable suction and compression to the nipple. The modified breastshield is fitted with a latex membrane that contracts and expands, compressing the nipple to mimic the natural motion of an infant's tongue. A microprocessor, relay, and force sensitive resistor are used to regulate the secondary pump that moves the membrane. These electronic components sense each oscillation of the primary pump and turn the secondary pump on and off accordingly to control the pattern of suction and compression.

Methods:

Permission to conduct our study will be based on approval from the Institutional Review Board. Subjects will be given a complete overview of the purpose and procedure and will then provide written consent. Participation will be voluntary, yet selective based on lactation, and participants are allowed to leave the study at any time.

Subjects will be brought in on a volunteer basis on two subsequent days during times that they would normally be breast pumping in order to perform milk collections, but will be asked to refrain from pumping for a minimum of four hours before the two testing days. The subjects will be randomized to an extent; it is necessary to test subjects that are lactating because milk flow cannot be induced in non-lactating mothers.

To obtain baseline data for comparison, subjects will be divided into two groups: It is suggested that all subjects have been breast pumping for a minimum of three months to ensure ease of use of the breast pumps. Additionally, it is essential that the subjects have not suffered from common yeast infections so that the nipples are not tender or sensitive and to ensure that infection not be transmitted between users despite sterilization.

On the first day, group 1 will pump for 15 minutes using the standard Medela pump. The milk collected will be measured and they will be qualitatively asked to rate the comfort and overall experience. Group 2 will do the same with the modified pump. On day 2, the two groups will switch to the other pump, and the same data will be collected, and participants will be asked which pump they preferred overall.

Results:

The most useful quantitative data will be the volume of milk extracted during the testing period. Volume measurements will be taken for both conditions to determine how well the modified pump induces the letdown response. Qualitatively, subjects will compare the comfort and ease of use of the two models. The full Experimental Protocol can be found in Appendix D.

Additionally, we have documented our design and ideas through the Wisconsin Alumni Research Foundation, which can be seen in full in Appendix E.

Results

The purpose of the testing conducted on the device was to ensure that the mechanical components of the prototype were functioning properly. Six sets of data were collected to analyze the efficiency and overall performance of the pump. Statistical analysis was executed using Rstudio to determine if there is a difference between the effectiveness of the original breast pump configuration and the modified prototype. The effectiveness of the pump was

determined by measuring the volume per unit time of liquid pumped from a bottle. See Appendix D for detailed testing protocols and Appendix E for the full code used in R.

Using QQ Plots and a boxplot of the data, it was determined that the data has a normal distribution with unequal variances. Because of this, a two-sample Welch T-Test was conducted using R, which resulted in a p-value of 1.518e-10. The null hypothesis was rejected and we concluded that the original breast pump and modified prototype yielded different volumes of liquid. The mean and standard deviation of the standard pump and the modified prototype are summarized in Table 2 below:

Table 2. Standard deviation and mean values of testing results

	Standard Pump	Prototype
Mean (mL/min)	21.25	8.22
Standard Deviation	1.52	2.05

Unfortunately, there were several factors of variability in our testing. One factor that varied and posed a great threat to the accuracy and consistency of our results is the type of latex used and how it was applied. Pumping for long durations can put strain on the latex material, occasionally causing the membrane to tear. During testing, it was not possible to use the same latex membrane throughout all trials due to the length of the trials. The two latex membranes used throughout the trials varied in elasticity and thickness. It is possible that this variance may have affected the pressure applied to the bottle during testing. The placement of the latex on the breastshield also had potential to affect the applied pressure. The latex is manually stretched over the shield prior to pumping. Therefore, a tighter stretch will result in higher pressure applied to the breast. This problem can be resolved by manufacturing customizable latex parts. Another source of error stems from the hole drilled in the shield. The tubing was glued into the shield, but was never tested for airtightness. This can be fixed by ensuring the tubing is flush with the hole or manufacturing a breastshield in the future with a fitted component for tube insertion.

The tests conducted on the pump are not an accurate representation of the performance of the pump because it does not take into account physiological factors. The prototype is designed to modulate hormone release with the intention of increasing the rate of milk flow. The success of the prototype cannot be determined until experiments are implemented using lactating women.

Discussion

The limited testing conducted, based on an inability to perform human testing, revealed that our prototype possibly reduced the flow of liquid from the bottle. The latex membrane was effectively inhibiting flow by obstructing the exit of the breast flange. As noted earlier, the testing method fails to emulate what would occur with a human breast due to the lack of hormonal response. The mechanical stimulation is hypothesized to release oxytocin to promote letdown and milk ejection, which would compensate for the slight resistance caused by the membrane. In addition, the membrane increases comfort for the user by providing more cushion than the

hard plastic standard breastshield provides, which will allow the user to relax and have an overall more satisfying experience.

The most commonly used breast pump models are listed above in the Competing Designs section. However, there are some patents out that feature a membrane around the nipple to mechanically stimulate it. The first design features a nipple membrane to mimic infant motions while the second design features pulsating suctions [21][22]. Overall, our prototype is unique and features different setups than the current models and filed patents. With the latex membrane and the variable suction, our prototype is more physiologically accurate and allows for more control by the mother.

Unfortunately, our breast pump prototype is not an entirely ideal design. It is wasteful in that it requires two motors rather than just one. Negative consequences of this include that it adds substantial weight to the final product and it significantly raises the price of fabrication. Although the disposable latex membrane will reduce the amount of sanitization between pumping periods, there will be an additional cost along the way as the membranes are discarded each time. The design should incorporate a material that is not only safe for human skin as it is currently, but also safe to come in contact with milk. Additionally, until we are able to perform human testing, we will not know the exact compression and suction patterns that work best. Human testing would allow us to assign a variety of settings based on user preference. Finally, there are many electrical components involved in the control of our pump design which bare risk of damage in the case that milk comes in contact with them. However, we have enclosed everything into a plastic casing that will not require any alterations once packed into the bag.

Throughout the semester, with much trial and error, we changed our final design multiple times. After talking with Professor Thompson, we took a much more electromechanical pathway to incorporate stimulation of the nipple into our design. Overall, our goals have remained the same: to mechanically stimulate the nipple and to use suction along with compression to induce letdown. Our design began with the idea of using gears to power both pump arms using a single motor; the gears would have two different sizes to coordinate with the variations in suction. Unfortunately, we determined that the setup of the gears would not fit correctly into the housing and while we hoped that the different sizes of the gears would lead to different frequencies among the two pumps, we noticed that it would only slow the suction of one pump, rather than resulting in differing suction frequencies.

In addition to how we synchronized the pumps, another major alteration was a change in the material used for the breastshield membrane. Our team originally decided to use a thin silicone sheet for the membrane. We chose this material because silicone is biocompatible and flexible. However, a silicone sheet that is thin enough to meet our needs was difficult to find. After acquiring a thin, small sheet of silicone from another design team, we concluded that we did not have enough of the material to cover the breastshield and that the material may not expand and contract as desired due to thickness and stiffness. Another observation we made was that the silicone could lead to issues with sanitation. A permanent membrane would need to be cleaned regularly and could increase the amount of bacteria within the breastshield. Additionally, if the membrane were to crack or tear, an entire new breastshield would need to be purchased.

After experimenting with different types of rubber including nitrile rubber and portions of rubber gloves, we found a feasible material. We purchased latex rubber tubing and stretched this over the entire breastshield. The elasticity of the material creates an airtight seal and holds the tubing in place on the outside of the shield. The material can also be adjusted to control the degree of compression. One great benefit that comes from using this material is disposability. This material can be discarded and replaced after each use, reducing the risk of infection and the amount of cleaning required. This material has the elasticity and flexibility to provide gentle but firm stimulation to the breast and cushioning against the hard plastic.

Conclusion

Our team was challenged with the task of creating a breast pump that worked to increase milk flow and improve comfort for the user. To do this, the physiological elements of milk stimulation by breast compression were explored. A two-pump system was created where one pump was assigned to administer suction and the other assigned to stimulate the breast with compression.

This design uses compression by means of an expanding and contracting membrane attached to the breastshield. There are currently no breast pumps on the market that provide compression to the breast and nipple this way. This type of stimulation simulates the compression that a baby provides with the tongue and hard palate during breast feeding. Tactile stimulation of the nipple is thought to have a positive effect on oxytocin levels, which is known to stimulate the let down response. Though our limited testing showed that the standard pump extracted a higher volume of liquid than our prototype, we are awaiting human testing trials to fully evaluate the success of our design based on the specifications of our client, which include a more comfortable experience for the user as well as a more efficient pump.

Many of our design ideas were ambitious and had a lot of potential. However, with limited time, budget, and resources, we chose a much more feasible and approachable design. With more time and supplies, we would consider using two force sensitive resistors – one in the primary and one in the secondary pump to better regulate the compression pattern. More specifically, by doing this we could more sensitively measure when one cycle has happened in the compression pump as opposed to the time delay method we are using currently. Additionally, we hope to reach more of our design goals by harnessing the power from a single pump rather than using two pumps. This would involve more research in mechanical engineering but would reduce the overall product weight and cost. Although the latex membrane is non-toxic, latex allergies are common, so it would be necessary to find an all-natural material to use inside the breastshield. Ideally, after obtaining IRB approval and performing human subject testing; we could receive user feedback and determine the most natural compression-suction patterns to increase the comfort and milkability of our breast pump design.

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Appendix Table of Contents

A. Product Design Specifications

Title: Increased Flow Breast Pump

Function:

There are numerous reasons nursing women choose to use breast pumps over naturally breastfeeding. One huge advantage is the convenience of collecting milk while away from the baby, allowing opportunity to pump milk at a convenient time and place to store for later infant consumption. It is quite common for mothers to use a breast pump at work so that they have milk readily available later in the day, which opens up time to spend on other activities. However, breast pumps do have some disadvantages compared to natural breastfeeding. They can be uncomfortable to use, even causing pain and distress at times. Furthermore, it takes significantly more time to collect milk when pumping as opposed to breastfeeding. Breast pumps currently on the market focus on suction magnitude, rate, and cycle, but do not take into consideration the inherent behavior of the baby's mouth while feeding. The baby's tongue massages the nipple, which increases the milk flow rate from the breast. Some breast pump designs attempt to mimic the movement of the infant's tongue by altering pressure in the breastshield, but there is still ample room for improvement in the industry to increase breast milk flow using massaging and stimulation [1]. Enhancing this mechanical aspect of a breast pump design will decrease the time a mother has to spend pumping, while at the same time lowering the discomfort and pain a mother experiences during the pumping process.

Client Needs and Requirements:

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance Requirements

The breast pump must function faster and more efficiently than current products on the market, utilizing a massage or stimulation to increase flow rate.

b. Safety

The device will exhibit massage apparatus stability to ensure the mechanical stimulus does no harm to the breast. It will have a maximum suction magnitude to prevent over-suction, which could result in discomfort. There will be no exposed wires or moving parts, and the motor used will have a safety factor ensuring its normal operating conditions are much lower than its maximum operating specifications to prevent overheating and malfunction.

c. Accuracy and Reliability

The massage function must work properly for the duration of each pumping session, accurately applying stimulation as close to infant tongue massaging as possible.

d. Life in Service

The device will function at its optimal performance rate for one year [5].

e. Shelf Life

The breast pump can be stored before use indefinitely.

f. Operating Environment

The breast pump will be portable and will be mainly used at home or in an office setting.

g. Ergonomics

The breast pump will be comfortable to wear and use and will maintain its durability

throughout its lifetime of one year. It will be used in a sitting position, but will weigh light enough for easy transport.

h. Size

The breastshield will be made in one size - 24 millimeters. However, the size could be altered for future application to 21, 27, 30, or 36 millimeters.

i. Weight

It is expected to weigh between 3 and 4 kilograms.

j. Materials

The current list of materials include:

2 Medela Pump In Style Advanced Breast Pumps
1 Breastshield
1 Arduino Uno
1 USB cable
1 Beefcake Relay
1 Force Sensitive Resistor
3 DC Power cords (Two 9 V, One 5 V)
1 Breastpump bag
2 10 kΩ resistors
1 Extension cord
1 Toggle switch
1 Latex Membrane
1 Black box for electronics housing
1 Small Breadboard
Several jumper wires
Breast pump tubing

k. Aesthetics, Appearance, and Finish

The breast pump will be portable, have a discreet and lightweight latex massage compression insert, and will have a pleasant and comfortable looking finish.

2. Production Characteristics:

a. Quantity:

The product consists of one breastshield, two pumps enclosed in a single bag, one replaceable latex membrane, and breast pump tubing

b. Target Product Cost:

The top-rated breast pumps on the market range from $100-$400.

3. Miscellaneous:

a. Standards and Specifications:

The breast pump device will mimic an infant suckling onto the nipple. It will be competitively priced with current models on the market, and will pump the same amount of milk as a current model does in less time. Breast pumps are medical devices that are regulated by the Food and Drug Administration [4].

b. Customer:

Nursing women and hospitals are the customers.

c. Patient-Related Concerns:

Concerns include nipple irritation, mastitis (infection of the breast tissue), milk quantity, and pumping duration.

d. Competition:

Philips Avent Comfort Double Electric

The Philips Avent breast pump offers a gentle stimulation mode that simulates a baby suckling with cyclic pressure changes in 5 circles around the breastshield. This product is $199.99 [1].

Medela Freestyle

The Medela Freestyle is a light and portable breast pump that is on the market today. It includes “2-Phase Expression” technology that offers a faster initial pumping speed, similar to a baby’s actions when first latched on, and a slower let-down phase. This product costs $399.99 [3].

NUK Double Electric Breast Pump

The NUK breast pump is a portable system with silicone breastshields instead of hard plastic. This breast pump has multi-phase settings and memory to store them. This product costs $204.99 [2].

References

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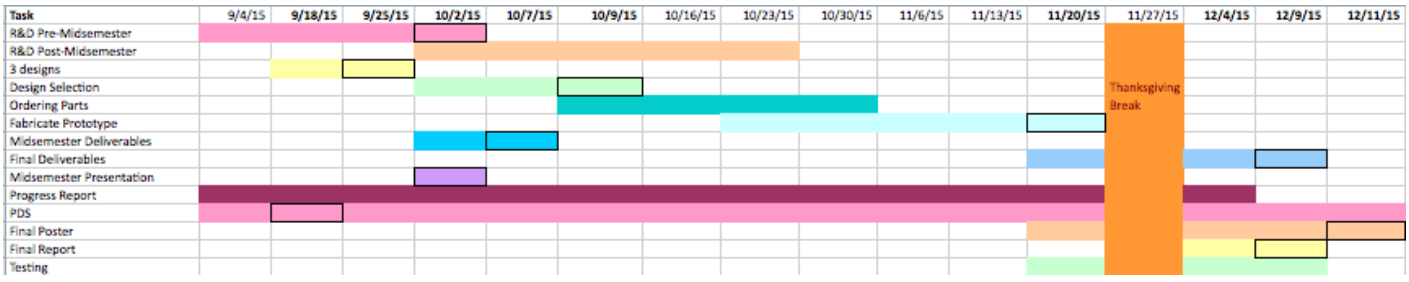
B. Gantt Chart

Table 3. Gantt Chart schedule of Fall 2015



C. Expense Report

Table 4. Expense report for Fall 2015

Item	Quantity	Cost	Link (if applicable)
Plastic breastshield	1	$4.99 (donated)	http://www.amazon.com/Medela-PersonalFit-Breastshields-pack-Large/dp/B000A88JYQ/ref=sr_1_7?ie=UTF8&qid=1448461286&sr=8-7&keywords=plastic+breast+shield
Medela Pump in Style Advanced Breast Pump	2	$719.98 (donated)	http://www.medelabreastfeedingus.com/products/714/pump-in-style-advanced---on-the-go-tote-solution-set
Arduino Uno	1	$24.95 (donated)	https://www.sparkfun.com/products/11021
Beefcake Relay	1	$7.95 (donated)	https://www.sparkfun.com/products/11042
Nitrile Rubber Sheet	1	$10.80	http://www.mscdirect.com/product/details/31935117
Silicone Sheet	1	Donated	
Force Sensitive Resistor	1	$7.95 (donated)	https://www.sparkfun.com/products/9376
Latex Rubber Tube	1	$14.75 for box	
10 kΩ resistor	2	Borrowed	
Extension Cord	1	Borrowed	
USB Cable	1	Borrowed	https://www.sparkfun.com/products/512
Small Breadboard (Red)	1	Borrowed	https://www.sparkfun.com/products/12044
Black box	1	Borrowed	
Total:	15	$25.55	

D. Fabrication and Experimental Protocols

1. Breastshield Assembly

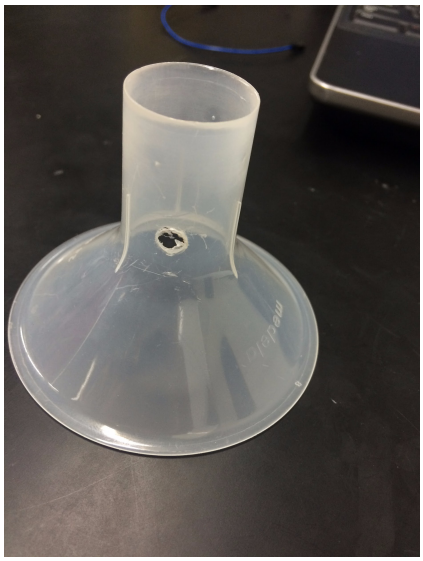


Figure 9. Drilled breast shield.

Purpose:

The purpose of altering the breastshield is to allow for the addition of another tube to create the vacuum suction and variation in suction for the mechanical stimulation of the nipple.

Materials:

- Medela breastshield
- Drill press
- 7/32 - 1 drill bit
- 1 breast pump tube
- Non-toxic super glue
- Latex rubber tubing

Methods:

A hole was drilled in the flange of the breastshield approximately 4 cm from the top of the flange. A 7/32 - 1 sized drill bit was used to drill the hole; this size is exactly the size of the breast pump tubing that is used to connect the breastshield to the pump. After the hole was drilled, the remaining plastic was shaved away using a utility knife to make for a clean insertion. A breast pump tube was then inserted into the hole and was secured tightly using non-toxic super glue; an air-tight seal is necessary in creating the variation of the suctions for the mechanical stimulation.

Latex rubber tubing was then added to the inside of the breast flange. The latex was stretched over the wide end of the breastshield and pulled down through the flange and glued to create an air tight seal. The nipple will be in contact with the latex during pumping.

2. Electronics Setup

Electronics Protocol

Purpose:

The purpose of the electronics setup is to allow for the control of the variations in suctions through the use of a microcontroller, relay, and force sensitive resistor.

Materials:

- 1 Arduino Uno
- 1 USB Cable
- 1 Force Sensitive Resistor, 0.5” (FSR)
- 1 Beefcake Relay
- 2 Breast Pump Power Cords
- 1 Extension Cord
- 1 Toggle Switch
- 2 10 kΩ Resistors
- Jumper Wires
- 1 Black box for housing

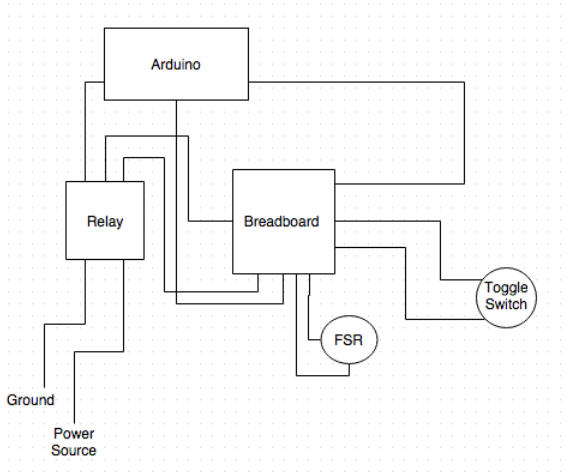


Figure 10. High-level schematic of electronics setup.

- 1 Small Breadboard

Methods:

The Arduino will be used to communicate between the force sensitive resistor, the relay, and the breast pump. As the arm of the breast pump motor rotates about it axis, it will make contact with the FSR. When the arm contacts the FSR, the FSR will signal back to the Arduino, which will in turn signal to the relay to turn on and off the pump. This electronic setup will be controlling one breast pump motor. Turning on and off one motor will allow for the variation and oscillation of the two different suction caused by the two breast pumps.

Arduino Code:

```
int fsrPin = 0;     // the FSR and 10K pulldown are connected to a0
int fsrReading;     // the analog reading from the FSR resistor divider
int fsrVoltage;     // the analog reading converted to voltage
int button = 2;    //Connect the button to pin 2 in Arduino
int beefcakeRelay = 7; //Connect the beefcake to pin 7 in Arduino
int stimCycleTime = 1000; //1 second delay for compression pump to cycle
unsigned long fsrResistance;  // The voltage converted to resistance, can be very big so make "long"
int cycleNumber = 0; //Initialze cycles to zero to start
boolean stimRate = true; //Default set the stimRate to be the default every other cycle for mechanical stimulation
int thresholdVoltage = 5; //This is arbitrary but is adequate to verify voltage changed enough
 void setup(void) {
  Serial.begin(9600);
  digitalWrite(beefcakeRelay, LOW); //Start with the beefcake relay off aka the mechanical stimulation pump off
  //Set the cycle to the alternate cycle if the button is on by changing stimRate to false indicating alternate cycle
}
void loop(void) {
  fsrReading = analogRead(fsrPin);  //Analog read in from the force resistor
  Serial.print("Analog reading = ");
  Serial.println(fsrReading);
  // analog voltage reading ranges from about 0 to 1023 which maps to 0V to 5V (= 5000mV)
  fsrVoltage = map(fsrReading, 0, 1023, 0, 5000);
  Serial.print("Voltage reading in mV = ");
  Serial.println(fsrVoltage);
  if (fsrVoltage == 0) {
    Serial.println("No pressure");
  } else {
    // The voltage = Vcc * R / (R + FSR) where R = 10K and Vcc = 5V
    // so FSR = ((Vcc - V) * R) / V
    fsrResistance = 5000 - fsrVoltage;     // fsrVoltage is in millivolts so 5V = 5000mV
    fsrResistance *= 10000;                // 10K resistor
    fsrResistance /= fsrVoltage;
```

```
    Serial.print("FSR resistance in ohms = ");
    Serial.println(fsrResistance);
  }
  //Check to see which cycle mode to put it in
  if (digitalRead(button) == HIGH) {
   stimRate = false; //This will enable the cycle to be every 3 cycles as opposed to default every
other cycle for mechanical stimulation
  } else stimRate = true;
  //Check to see if force was detected meaning a cycle has started
  if (fsrVoltage > thresholdVoltage) {
     cycleNumber++;
     Serial.print("cycleNumber = ");
     Serial.println(cycleNumber);
     //Check if cycle happened twice in a row to indicate it is time to start mechanical stimulation,
     //if in default mode
     if (stimRate) {
       if (cycleNumber % 2 == 0) {
         digitalWrite(beefcakeRelay, HIGH); //Turn on mechanical pump
         Serial.println("relay turned on"); //Verify relay turned on
         delay(stimCycleTime); //Wait for mechanical pump to go one cycle
         Serial.println("waiting stimCycleTime for default");
         digitalWrite(beefcakeRelay, LOW); //Turn off mechanical pump
         Serial.println("relay turned off"); //Verify relay turned off
       }
       if (cycleNumber == 2) {
            cycleNumber = 0;
       }
     }
     else {
       //Check if cycle happened three times to indicate it is time to start mechanical stimulation if
in alternate mode
         if (cycleNumber % 3 == 0) {
            digitalWrite(beefcakeRelay, HIGH); //Turn on mechanical pump
            Serial.println("relay turned on"); /Verify the relay turned on
            delay(stimCycleTime); //Wait for mechanical pump to go one cycle
            Serial.println("Waiting stimCycleTime for alternate"); //Test print
            digitalWrite(beefcakeRelay, LOW); //Turn off mechanical pump
            Serial.println("relay turned off"); //Verify the relay turned off
         }
         if (cycleNumber == 3) {
               cycleNumber = 0; //Prevent cycleNumber from being too high of a number over time
         }
      }
  }
```

```
  delay(10); //This is the overall delay before the loop starts over
}
```

3. Testing Protocol

a. Breastshield Membrane and Pump Testing Protocol

Purpose:

The purpose of this testing protocol is to measure the volume of liquid that is taken from a Tommee Tippee® baby bottle by the breast pump under a series of different conditions. The conditions include: (A) suction pump only with no membrane; (B) suction pump with membrane, and compression pump every third cycle; (C) suction pump with membrane, and compression pumping every other cycle; (D) suction pump only with membrane; and (E) no suction or compression.

Materials:

- 2 Medela Breast Pumps
- Electronics - Arduino, Relay, Force Sensitive Resistor
- Tommee Tippee® baby bottle
- Breast Pump tubing
- Latex Membrane

Methods:

For each trial, the Tommee Tippee® baby bottle was filled with 120 mL of water. The pumps were turned on and the bottle was pumped for one minute. The primary suction pump was set to full pressure, and the compression pump was set to half power. When the pumping period ended, the volume of water extracted from the baby bottle by the breast pump was measured using a pipet and recorded. Each condition was tested 10 times.

Statistical analysis will be completed using RStudio. The mean and standard deviation of each condition will be calculated. The focus of our statistical analysis will be to determine if there is a statistical significance between the liquid extraction of using (A) suction only, no membrane; and (B) suction, compression every third, with membrane. Condition A is the original breast pump before modifications. Condition B is the final state of the prototype.

Results:

The data from breastshield and pump testing is summarized in the table below.

Breastshield Membrane and Pump Testing Data

Trial No.	**A** Suction only, no Membrane (mL)	**B** Suction, Compression every 3rd, w/ Membrane (mL)	**C** Suction, Compression every other w/ Membrane (mL)	**D** Suction only w/ Membrane (mL)	**E** No Suction or Compression (mL)
1	18	9.9	5.8	6.2	1.8

2	21	8.4	5	6.9	1.6
3	23.3	11.2	4.7	6.2	1.4
4	21.1	6	4.9	7.5	1.5
5	20.2	10.7	8.7	6.6	0.8
6	22.9	7	6.3	5.2	2.1
7	22.5	6.7	4.1	6	0.6
8	20.6	8.5	9.2	7.4	1.6
9	21.4	5.6	6.9	6.3	1.2
10	21.5	N/A	6.3	5.7	1.4
Mean	21.25	8.22	6.19	6.4	1.4
Standard Deviation	1.52	2.05	1.69	0.72	0.44

Statistical Analysis:

All calculations were completed using RStudio. The purpose of the testing is to determine if Condition A (suction pump only, no membrane) and Condition B (suction pump, compression every 3rd pump with membrane) produce different volumes of liquid. The null and alternate hypotheses are as follows:

H_0: $\mu_A = \mu_B$

H_A: $\mu_A \neq \mu_B$

R was used to make a QQ plot of Deviations and a Boxplot of Deviations for conditions A and B to determine if the data is normally distributed and if the conditions have equal variances.

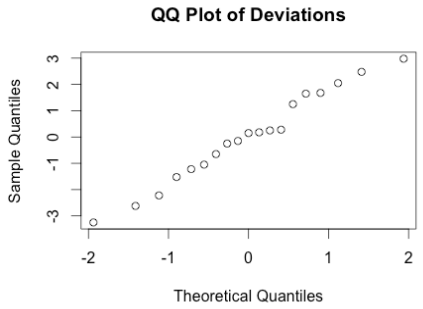


Figure 11. QQ Plot of Deviations

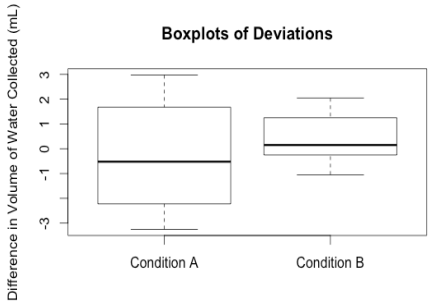


Figure 12. Boxplot of Deviations

The QQ plot confirmed that the data has a normal distribution. The boxplot shows that the two conditions do not have equal variances. Therefore, a Welch T-Test with a p-value of .05 will be performed in R to test the stated hypotheses. The output from R is as follows:

```
        Welch Two Sample t-test
data:  P and M
t = 15.61, df = 14.679, p-value = 1.518e-10
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
11.24548 14.81007
sample estimates:
mean of x mean of y
21.250000  8.222222
```

The p-value is 1.518e-10. Therefore, the null is rejected. It can be concluded that condition A and condition B result in different volumes of liquid collection. Condition A, the original pump, produces a larger amount of liquid than Condition B, our prototype, when tested using a Tommee Tippee® Bottle.

All code written in R is available in Appendix E: Statistical Analysis Code.

Unfortunately, this testing does not include the human breast and therefore is missing a key component of the entire breast feeding process: the oxytocin and other hormones, comfort, and the tactile stimulation of the nipple itself.

b. Electronic Component Testing Protocol

Purpose:

The purpose of this testing protocol is to ensure that every electrical component worked properly and accurately prior to circuit assembly.

Materials:

- Arduino Uno
- USB cord
- Jumper wires
- Two 10 kΩ resistors
- Beefcake relay
- Toggle switch
- Small breadboard
- 0.5” Force sensitive resistor
- Extension cord
- 2 Power cords
- 1 Black box for electronics housing

Methods:

Each electrical component was tested separately to ensure our final prototype would function as expected. The three electrical components tested were the force sensitive resistor, the Beefcake relay, and the toggle switch. After testing, all components were combined and tested with the final Arduino code and two breast pumps.

FSR Testing

One lead of the FSR was attached to the 5 V pin of the Arduino and the second lead was connected to the A0 pin, a 10 kΩ resistor, and ground. The FSR was tested with varying forces including constant loading and with fast, intermittent loading like the FSR would experience as the arm made contact. The FSR would communicate a voltage of zero with no force to the Arduino and a voltage greater than a thousand millivolts with force. We concluded that with a sampling rate of 100Hz, the FSR was accurate enough to detect a quick, light tap. The code that we used to test the FSR individually was found on Arduino Playground and modified. The code is as follows:

```
int fsrPin = 0;     // FSR connected to A0
int fsrReading;     // the analog reading from the FSR resistor divider
int fsrVoltage;     // the analog reading converted to voltage
void setup() {
        Serial.begin(9600);   // We'll send debugging information via the Serial monitor
}
void loop() {
         fsrReading = analogRead(fsrPin);
        // analog voltage reading ranges from about 0 to 1023 which maps to 0V to 5V
         fsrVoltage = map(fsrReading, 0, 1023, 0, 5000);
        Serial.print("Voltage reading in mV = ");
        Serial.println(fsrVoltage);
         if (fsrVoltage == 0) {
                Serial.println("No pressure");
         }
        delay(1000);
}
```

Toggle Switch Testing

The toggle switch allows the user to change the compression rhythm. When the switch if off, the secondary motor pumps once every two oscillations of the primary motor and every three oscillations when on. A toggle switch has two terminals allowing for current to flow through the switch when on and blocking current when the switch is turned off. One terminal was connected to the 5 V supplied by the Arduino. The second terminal was connected to pin 2, a 10 kΩ resistor, and ground. We tested the function of the switch by measuring the voltage delivered to the Arduino when on and when off. We concluded that the switch was functioning properly prior to installation in the final circuit. The code that we used to test the toggle switch is as follows:

```
int switch = 2;         // pin number that switch is connected to
int state;          // state of switch (HIGH/LOW)
void setup()
{
         pinMode(switch, INPUT);      //est. that pin is reading from switch
         Serial.begin(9600);    // start serial communication
}
void loop()
{
```

```
        state = digitalRead(switch);
    Serial.print(state);
    delay(500);
    }
```

Relay Testing

The relay was connected to the 5 V supplied by the Arduino, pin 7, and ground. The relay was tested at different frequencies to determine if it functioned properly. We listened for a clicking sound, which signifies that the relay arm is moving to open and close the circuit. The code used for relay testing is as follows:

```
int relay = 7; // Initializes the relay pin
void setup() {
        pinMode(relay, OUTPUT); //Assigns the relay pin as an output signal
}
void loop() {
        digitalWrite(relay,LOW);
        delay(1000); // clicks every second
        digitalWrite(relay, HIGH);
        delay(1000);
}
```

Results:

After all components were deemed functional individually, the final circuit was assembled. All circuit components were attached exactly as they were during testing and the final circuit was tested with the final code and two pumps.

4. Experimental Protocol

Increased Flow Breast Pump Experimental Protocol

Purpose:

The purpose of this study is to test a mechanical stimulation applied to the nipple by a modified breast pump to initiate the hormonal response in order to increase letdown and subsequently increase milk flow of the human breast during lactation. Current breast pump models use periodic suction to induce the expression of milk; additionally, infants use their tongue to massage the nipple to increase milk flow.

Materials:

- 2 Medela Pump In Style Advanced Breast Pumps
- 1 Breastshield
- Breast pump tubing
- 1 Arduino Uno
- 1 Beefcake Relay
- 1 Toggle switch
- 1 Force Sensitive Resistor
- 2 Power cords
- 2 10 kΩ resistors

- 1 bag for housing both pumps
- 1 Latex membrane
- Several jumper wires
- 1 Black plastic box

The modified breast pump features an oscillating suction with variable suctions to induce massage movement of the nipple. Within the breastshield, there is a tube of silicone that will move with the variable pressures and this will be in contact with the nipple to mimic the natural motion of the infant's tongue. A microprocessor, a relay, and a force sensitive resistor are used to create the variable pressure. The FSR reports a change in voltage to the Arduino each time it comes in contact with the arm of the pump. The Arduino signals to the relay to turn off one of the pumps. The other pump remains pumping and as the other pump turns on and off, variable suction is achieved.

Methods:

Subjects will be brought in on a volunteer basis on two subsequent days during times that they would normally be breast pumping in order to perform milk collections, but will be asked to refrain from pumping for a minimum of four hours before the two testing days. The subjects will be randomized to an extent; it is necessary to test subjects that are lactating because milk flow cannot be induced in non-lactating mothers.

To obtain baseline data for comparison, subjects will be divided into two groups: It is suggested that all subjects have been breast pumping for a minimum of three months to ensure ease of use of the breast pumps. Additionally, it is essential that the subjects have not suffered from common yeast infections so that the nipples are not tender or sensitive and to ensure that infection not be transmitted between users despite sterilization.

On the first day, group 1 will pump for 15 minutes using the standard Medela pump. The milk collected will be measured and they will be qualitatively asked to rate the comfort and overall experience. Group 2 will do the same with the modified pump. On day 2, the two groups will switch to the other pump, and the same data will be collected, and they will be asked which pump they preferred overall.

Results:

The most useful quantitative data will be the volume of milk pumped during the testing period. Quantitatively, subjects will compare the comfort and ease of use of the two models; preferences will be based on these aspects.

E. Statistical Analysis Code

The code used to run a Welch T-Test for two independent populations and a bootstrap test was written in R, and is as follows:

```
#P refers to primary pump only
#M refers to primary pump and membrane
#Data:
P <- c(18,21,23.3,21.1,20.2,22.9,22.5,20.6,21.4,21.5)
M <- c(9.9,8.4,11.2,6,10.7,7,6.7,8.5,5.6)
#compute summary stats#
summary(M)
sd(M)
```

```
summary(P)
sd(P)
#qq plots#
Mdev <- M - mean(M)
Pdev <- P - mean(P)
alldev <- c(Mdev, Pdev)
qqnorm(alldev, main = "QQ Plot of Deviations")
#boxplots#
all <- c(P, M)
group <- c(rep("Condition A", 10), rep("Condition B", 9))
boxplot(alldev ~ group, main = "Boxplots of Deviations", ylab = "Difference in Volume of
Water Collected (mL)")
#t-test#
t.test(P, M,var.equal = F, alternate="less")
```

F. Institutional Review Board Application and Intention Disclosure Report

1. Institutional Review Board Application

1.1 Indicate the appropriate IRB. NOTE:
If you are unsure which IRB to select, please refer to the guidance or contact an IRB office for assistance.
For studies that may qualify for review by the commercial (e.g., Western) IRB or NCI Central IRB, select the Health Sciences IRB below.
* Education and Social/Behavioral Science IRB Health Sciences IRB
Minimal Risk IRB (Health Sciences)
1.2 Provide a short, lay-terms study title. * Breast Pump
1.3 Provide the full, formal study title. NOTE: This is the title that will appear in correspondence.
* Increased Flow Breast Pump
1.4 Is this study being transferred from another institution? * No
1.5 Identify the Principal Investigator. * MADALYN PECHMANN
1.6 Identify the points of contact for this study (limit of four).
NOTE:
Points of contact can edit the application and will receive email notifications about this submission. For the HS and MR IRBs only, points of contact can also submit materials on behalf of the PI.
If the PI is serving as a study point of contact, indicate that here.
*MADALYN PECHMANN
JEREMY ROGERS
PI STATUS
Principal Investigator: MADALYN PECHMANN
2.1 Select which of the following criteria describe(s) how the person identified as the PI meets UW-Madison requirements to serve as PI:
*PI has a UW-Madison faculty appointment (generally 50% or more). This includes faculty with a full-time UW-Madison position but who hold a $0 UW-Madison appointment only because their position is funded by the federal government

2.1.1 If the PI does not meet any of the above criteria and an exception to allow the individual to serve as PI is being requested, indicate below why an exception is being sought and the person's qualifications to serve as PI. NOTE: Campus policy does not allow student researchers to serve as PI.
2.1.2 If required, upload “Request for Approval to Serve as Principal Investigator on a Human Subjects Protocol.
STUDY TEAM
NOTE: All members of the study team (key personnel) must be listed on this page. Study team members can be listed as having either edit/email access or read-only access, but all study team members (apart from the PI and POC) must be listed in one category or the other.
If the study team includes anyone (including students) who is not affiliated with (e.g., employed by, holds an appointment at) the UW-Madison, UWHC, or Madison VA (Wm S. Middleton VA Hospital) AND for whom you are requesting that UW-Madison serve as IRB of record, these individuals must be listed in either 3.1 or 3.2. If the study team includes anyone who is not affiliated
with the UW-Madison, UWHC, or Madison VA (Wm. S. Middleton VA Hospital) for whom you are NOT requesting that UW- Madison serve as IRB of record, DO NOT list these individuals in either 3.1 or 3.2. The study protocol must include all external collaborators and their roles in this study.
3.1 Identify study team members with edit/email access. NOTE: Study team members listed here will be able to edit the application and receive email notifications regarding this study. Only the PI and Point of Contact can formally submit materials to the IRB.
THERESE BESSER
CONNOR FORD
HEATHER SHUMAKER
3.2 Identify study team members with read-only access. NOTE: Study team members listed here will be able to read the application but will not be able to edit the application or receive email notifications.
STUDY TEAM: ROLES
NOTE: Depending on the nature of the study or project, it is possible that some or all study team members will not fit into the categories below. If this is the case, select Not Applicable.
4.1 Identify the study team members who will be involved in identification and recruitment of subjects for this study, if applicable.
Person
CONNOR FORD
4.2 Identify the study team members who will be responsible for obtaining informed consent, if applicable.
Person
HEATHER SHUMAKER
4.3 Identify the study team members who will be intervening or interacting with subjects (e.g., administering surveys, conducting physical interventions), if applicable.
Person
THERESE BESSER

4.4 Identify the primary point of contact for this study. NOTE: If the PI is serving as the primary point of contact, indicate that here.
* MADALYN PECHMANN
PROJECT SPONSORSHIP AND BILLING INFORMATION
6.1 Does this submission primarily represent a trainee project? * Yes
6.1.1 If yes, identify the student(s)/trainee(s).
Student/Trainee
View THERESE BESSER
View CONNOR FORD
View HEATHER SHUMAKER
Category Course
6.2 Is this an investigator-initiated project?
Student pursuing a UW degree (e.g. graduate, undergraduate student) Student pursuing a UW degree (e.g. graduate, undergraduate student) Student pursuing a UW degree (e.g. graduate, undergraduate student)
BME 200 BME 300 BME 300
NOTE: The UW-Madison Health Sciences IRBs define investigator-initiated research as research that is originated and designed by individuals, independently of any sponsor or funding agency. Such research is not conducted under the auspices of a formal sponsor, such as a pharmaceutical company, and the protocol is not developed or generated by a funding agency (e.g., National Cancer Institute, Cystic Fibrosis Foundation)
To be considered investigator-initiated research, the following must apply:
The project receives no or very limited industry funding or support (e.g., support is limited to the provision of the drug or device)
If an IND or IDE exists, it is held by an individual investigator and not a study sponsor
* No
FUNDING: GENERAL
7.1 Identify the organization through which the PI will conduct the study. NOTE: If you are requesting the UW-Madison defer to another IRB, select the organization with which the PI is affiliated.
*Madison VA (Wm. S. Middleton VA Hospital) University of Wisconsin Hospital and Clinics (UWHC) University of Wisconsin-Madison
7.1.1 If the University of Wisconsin-Madison, identify the specific department or organization unit under which the research study will be conducted:
7.2 Are you or do you plan on receiving funding to support this project (includes internal UW-Madison/UWHC/UWMF funds)? * No
7.2.1 If the answer to 7.2 is Yes, will any of the funding be administered by the University of Wisconsin-Madison AND be at least one of the following types of accounts: 133 (not federally sponsored), 144 (federally sponsored), 233 (gift account), or 135 (WARF gift account). NOTE: For a 136 revenue account, please answer No to this question.
No
7.2.2 If the answer to 7.2 is Yes, will any of the funding be administered by the Madison VA (Wm. S. Middleton VA Hospital) or the UWHC?
No

CONFLICT OF INTEREST (COI)

13.1 Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a financial interest in an entity that (a) sponsors the study or (b) owns or licenses technology tested or evaluated in the study (including any agent, device, or software) that meets or exceeds one of the thresholds below:

(a) Compensation of $20,000 or more in a calendar year from a publicly traded or privately held business entity;
(b) An ownership interest in a publicly traded business entity valued at $20,000 or more or a 5% or greater equity interest; (c) Any ownership interest in a privately held business entity whatever the value;
(d) A combination of compensation and ownership interest in a publicly traded business entity valued at $20,000 or more;
(e) A leadership position in a business entity (Leadership positions are positions with fiduciary responsibility, including senior managers (e.g., presidents, vice presidents, etc.) and members of boards of directors). Scientific advisory board membership is not a leadership position.

* No
13.1.1 If yes, identify the personnel who have this interest
Person
13.1.2 Upload the COI management plan(s).
13.2 Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a proprietary interest in the research, such as royalties, patents, trademarks, copyright, or licensing agreement, that is relevant to this research study (including any agent, device, or software being evaluated as part of the research study)? NOTE: If this proprietary interest is managed through WARF, select Not Applicable.
No
13.2.1 If yes, identify the personnel who have this interest. Person
13.2.2 Upload the COI management plan(s).
13.3 Do ANY of the study team involved in the design or conduct of the research study have a financial interest that requires disclosure to the sponsor or funding source?
* No
13.3.1 If yes, identify the personnel who have this interest.

CONFLICT OF INTEREST (COI): CONTINUED

14.1 In addition to the sponsor(s) of this study or project, are other companies or business entities involved or potentially affected in a significant way by this study or project?
*No
14.1.1 If yes, list those companies/business entities.
14.1.2 If yes, describe the nature of each company/business entity's involvement.
14.2 Do ANY of the study team involved in the design or conduct of the study or project have any other financial interest that the investigator believes may interfere with his or her ability to protect subjects?
* No
14.2.1 If yes, identify the personnel who have this interest.

14.3 Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?
* No
14.3.1 If yes, describe the nature of the incentive.

DETERMINATION OF VA STATUS

15.1 Indicate if any of the following apply to this study or project:
* None of the above

SCIENTIFIC REVIEW: UW CARBONE CANCER CENTER (UWCCC) PROTOCOL REVIEW MONITORING COMMITTEE (PRMC) AND CLINICAL AND TRANSLATIONAL RESEARCH CORE (CTRC)

17.1 Is the scientific question of the protocol cancer related? * No
17.2 Are you specifically targeting cancer patients for enrollment in this study? * No
17.3 Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients? * No
17.4 Will this study use the Clinical and Translational Research Core (CTRC)?
NOTE: If the answer to this question is Yes, you must upload a copy of the CTRC application to the Submit activity form. You will see the Submit activity form when you click on the Submit link to submit the completed IRB application.
* No

SCIENTIFIC REVIEW: OTHER

18.1 Does this study require scientific review by ICTR Scientific Review Committees? NOTE: If none of the options in 18.1.1
18.1 Does this study require scientific review by ICTR Scientific Review Committees? NOTE: If none of the options in 18.1.1 apply, scientific review is required.
* No
18.1.1 If no, select why scientific review is not required
There are no items to display

ICTR SUPPORT SERVICES

19.1 Select all of the research support services available through the Institute for Clinical and Translational Research (ICTR) that you consulted while preparing this study or project for submission. If none of these services were used, select Not Applicable.
*Not Applicable
19.1.1 If other, specify.
19.2 Is this study coordinated by the Office of Clinical Trials?
* No

CLINICALTRIALS.GOV REGISTRATION

NOTE: Registration at Clinicaltrials.gov may be required in the following situations:
Per FDA regulations, most studies involving the testing of a drug, biologic, or device must be registered.
If publications resulting from this study will be published in a member journal of the International Committee of Medical Journal Editors (ICMJE) or in a publication that adheres to the standards of the ICMJE, the study must be registered.
Click on the help link above for additional information on these requirements.
20.1 Does this study need to be registered at Clinicaltrials.gov? * YesNo

20.1.1 If yes, who has or will register the study prior to the enrollment of the first subject? 3.
20.1.1.1 If other, specify.

TYPE OF APPLICATION

1. 1.1 Indicate the type of application:
* Initial review application: Full review

STUDY LOCATION: GENERAL

1.1 Is this a multi-site study? NOTE: A multi-site study involves at least one site or individual NOT affiliated with the UW- Madison/UW Health/Madison VA (Wm. S. Middleton VA Hospital). Select Yes if this study:
Will be conducted at sites outside the UW
Includes study team members NOT affliated with the UW
Involves sending or receving samples/data/images to/from collaborators outside the UW
* Yes
1.1.1 If yes, does the study have a coordinating center? NOTE: A lead site or coordinating center is typically responsible for coordinating activities at all other sites, receiving and analyzing data, and developing and updating the study protocol as needed. No
1.1.1.1 If yes to question 1.1.1, is the UW-Madison/Madison VA (Wm. S. Middleton VA Hospital) serving as the coordinating center?
Yes
1.1.1.2 If no to question
1.1.1. how is it being ensured that all sites have IRB approval prior to initiating study activities?
1.2 Will UW-Madison , Madison VA (Wm. S. Middleton VA Hospital), or UWHC personnel or personnel under UW-Madison IRB purview conduct research activities at sites outside of the US?
* Yes
1.2.1 If yes, specify.
There are no items to display

STUDY LOCATION(S): UW-MADISON SITES

3.1 Select the UW-Madison/UW Health/Madison VA (Wm. S. Middleton VA Hospital) location(s) at which this study will occur. Check all that apply:
Other UW-Madison/UW Health location (s)
3.1.1 If other, specify.

STUDY SUMMARY

1.1 Upload the stand-alone scientific protocol associated with this application. NOTE: A protocol is required for the types of studies listed below. This list is NOT exhaustive and the IRB may request a protocol in other cases as appropriate.
All multi-site studies (regardless of risk level)
All studies requiring scientific review
All studies involving drugs or devices
All studies posing more than minimal risk to subjects
1.1.1 If no protocol was uploaded, select the reason(s) below. There are no items to display
1.1.1.1 If other, provide a justification.
1.2 Will study activities involve interaction and/or communication with human subjects, even if only to obtain informed consent?

* Yes
1.3 Provide the expected duration of the study (i.e., the time from IRB approval to completion of all study activities).
* 6 months
SPECIAL CONSIDERATIONS AND PROCEDURES
2.1 If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.
Not Applicable
RESEARCH DESIGN AND PROCEDURES
1.1 What is the overall purpose of this project or study?
* To mechanically stimulate the nipple in order to increase lactation.
1.2 What are the specific aims of this project or study?
* Mechanically stimulate the nipple to increase milk flow through the use of suction and heating elements that mimic the natural actions of an infant
1.3 Background: What prior information or knowledge exists to support the conduct of this project or study?
* There is no other work of this type, however, it was brought to our attention because many mothers endure pain while breast pumping and wish it to be a more comfortable and natural process
1.4 Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved.
* We will be asking mothers to use the current breast pump model and then use ours and see if they find our design more comfortable and more effective.
1.5 Will subjects be randomized?
* Yes
RESEARCH DESIGN AND PROCEDURES: CONTINUED
NOTE: Depending on the nature of your study or project, these questions may not apply. If this is the case, select Not Applicable.
2.1 Describe the current alternatives to participation in this research study, including treatments subjects could undergo outside of the research study. If there is no accepted treatment or no effective treatment, state this.
Using the current breast pump models
Not Applicable
2.2 Describe how this patient population is treated clinically
Not Applicable
2.3 List the procedures that will be performed solely for research purposes (i.e., those that are not performed as part of standard of care).
Not Applicable
RISKS AND BENEFITS: GENERAL
1.1 Describe any potential direct benefits to subjects. If there are no direct benefits, state this.
* The direct benefits to our subjects include increased milk flow and increased comfort while breast pump
1.2 Describe the potential benefits of this research to society.
* Allows women to spend less time pumping and more time to do normal daily activities

1.3 Does this study involve direct physical intervention with subjects? NOTE: A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject's body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.
* Yes
1.4 Will subjects incur any costs as a result of study participation (e.g., pharmacy preparation fees, payment for a device, billing of study procedures to subject's insurance)? * No
1.4.1 If yes, describe any costs. NOTE: Costs to subjects must be included in the consent form.
RISKS: PHYSICAL INTERVENTIONS
2.1 Describe the most common or frequent physical risks expected related to study participation.
* It is normal for mothers to experience pain while pumping and it is possible for the nipple to become infected
2.2 Describe any risks which are rare, but serious, or irreversible and any late effects (e.g., secondary cancers). * Should not have any serious effects
2.3 Does this protocol involve physical interventions (e.g., blood draws, exercise testing, allergy testing) that will NOT be conducted in a clinical setting (i.e., hospital or medical clinic)?
* Yes
2.4 Do any of the study procedures pose significant physical risk to females who are or may be pregnant (either as study subjects or as partners of study subjects) or to a fetus? * No
RISK/BENEFIT ANALYSIS
4.1 Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).
* No psychological risks
4.2 Describe how ALL the risks of the study will be minimized.
* Low suction pressure, comfortable breastshield
4.3 Explain why the risks to the subjects are reasonable in relation to the anticipated benefits
* We do not wish to have the mothers be uncomfortable while breast pumping, but if they were to experience pain, it would be at the cost of increasing the milk flow
4.4 Describe the provisions in place to identify and address unanticipated problems or complications.
* We will stop pumping if the mother experiences more than normal pain
4.5 Does this study constitute minimal risk research? NOTE: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
* Yes
4.5.1 If no, describe the data and safety monitoring plan for this study. NOTE: If a formal Data Safety Monitoring Board or Data Monitoring Committee exists, provide a general description of the committee or board's membership (e.g., number of members, expertise, and whether members are independent of the sponsors/researchers) and the expected frequency of their meetings.
SUBJECT POPULATION: GENERAL

1.1 Provide the total number of subjects required from all study locations. NOTE: You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.
* 15
1.2 Provide the number of subjects that will be recruited at sites under UW-Madison purview. NOTE: You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number. * 15
1.3 Provide a formal statistical justification for sample size and analysis of results. If a formal justification does not exist, explain why and provide a rationale for the sample size. NOTE: To supplement your response, you can upload a word document with the statistical justification at the end of this application.
* N/A
1.4 Describe the main inclusion criteria.
* Lactating mothers
1.5 Describe the main exclusion criteria.
* Mothers who are not lactating, those whom have HIV
1.6 If any racial/ethnic group will be targeted for or excluded from this study, identify the group that will be targeted or excluded and provide justification for this. If this does not apply to your study, select Not Applicable.
Not Applicable
1.7 If men or women will be targeted for or excluded from this study, identify which sex will be targeted or excluded and provide justification for this. If this does not apply to your study, select Not Applicable.
Women
SUBJECT POPULATION: VULNERABLE GROUP CHECKLIST
2.1 If your study involves *targeted* enrollment of any of the following populations, additional information may be needed. Check all that apply. NOTE: If inclusion of any of these populations is only *incidental*, do not select that population. If none apply, check "None of the above."

*None of the above
SUBJECT IDENTIFICATION AND RECRUITMENT: GENERAL
1.1 From what sources or by what methods will subjects be identified and/or recruited?
*Identification in clinical practice: Investigator's own
1.1.1 If other, specify.
RECRUITMENT METHODS
2.1 Describe the recruitment plan for this study. NOTE: This description should address what methods will be used, when and how often they will be used, and how many times potential subjects will be contacted.
Contact mommy support groups and hospitals for access to breast feeding mothers
2.2 If any advertisements will be posted, list locations and describe what advertisements will be posted at which locations. NOTE: Study teams must obtain permission from each location prior to posting recruitment materials.
Obtain permission to post ads in local hospitals and provide lactation specialists with our contact if they have any interested mothers

2.3 Upload copies of recruitment flyers. NOTE: Recruitment flyers are any advertisement that will be posted in public locations.
2.4 Upload copies of any other recruitment materials, including scripts, brochures, or advertisements (radio, newspaper, mailed letters, etc.).
2.5 Are you using an IRB approved recruitment database to disseminate recruitment materials or to contact subjects?
* Yes
2.5.1 If yes, provide the IRB protocol number of the recruitment database.
2.5.2 Describe what will be disseminated to individuals who agreed to be included in the recruitment database.
2.5.3 If the recruitment database is not the investigator's own, upload a letter of support for the use of the database.
SUBJECT RECRUITMENT: CONTINUED
1. 3.1 Will subjects be paid or offered other material inducements to participate in the study? * No
3.2 Will subjects undergo a preliminary phone screen to determine basic eligibility? * Yes
SUBJECT SCREENING
4.1 Describe the procedures subjects will undergo as part of screening to determine eligiblity. * We will call them and ask if they are lactating
4.2 Describe any study procedures that will be conducted before written informed consent is obtained from subjects(e.g., phone screening, fasting, discontinuing medications, etc.).
* See if they are lactating
Phone SCREENING
7.1 Upload a copy of the phone screening questionnaire. NOTE: If the screening questions are part of a previously upoaded phone script, you do not need to upload the questionnaire again here.
7.2 Will you be retaining phone screen data from subjects who do not enroll in the study? NOTE: If you are retaining phone screen data, the previously uploaded phone script should address this and include HIPAA authorization language for maintaining PHI.
*No
7.2.1 Describe the purpose of retaining the phone screen data.
7.2.2 Describe where the phone screen data will be maintained. If these data will be retained in a recruitment database, indicate whether the development of a recruitment database is the purpose of this study OR provide the IRB protocol number of the database.
PRIVACY AND CONFIDENTIALITY
1.1 Describe the precautions that will be used to ensure subject *privacy* is protected (e.g., research intervention is conducted in a private room; collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research).
* Research will be done in a private room
1.2 Select how subjects are identified in the research records. Check all that apply:
*Directly: Information identifying subjects is stored directly on data records
1.3 Describe the measures that will be implemented by your research team to safeguard the identifiable subject information from unauthorized use or disclosure for both paper and electronic forms of information. Include how and where data will be stored.

* Data will be stored privately and all subjects will be deidentified before anything is published
1.4 Are you planning to retain data collected for this study for purposes not described in this application (e.g., future unrelated research project)? * No
1.4.1 If yes, do you confirm that any future uses not described in this application will be submitted separately for IRB review?
Yes
PRIVACY AND CONFIDENTIALITY: CONTINUED
2.1 Will data be stored on laptops or portable devices? * Yes
2.1.1 If yes, what additional safeguards have been put in place (e.g., link for coded data will be stored separately, data will be deidentified) to protect these data from risk of breach of confidentiality (e.g., theft of laptop, loss of portable device)? NOTE: Consult with your IT department about security of data storage on laptops or portable devices.
Data will be deidentified
2.2 Will subject data, specimens, or images be shared outside the UW-Madison, the Madison VA (Wm. S. Middleton VA Hospital), or UWHC (including UWMF clinics)? NOTE: This is not referring to industry-sponsored clinical trials or cooperative group studies. For such studies, select Not Applicable.
No
INFORMED CONSENT: GENERAL
1.1 What consent process or waivers of consent are you requesting for this study?
* Consent process with signed consent documentation
INFORMED CONSENT: OVERVIEW
6.1 Describe when the consent process will occur. * When we have access to lactating mothers
6.2 Describe where the consent process will occur. * In UW hospital or Meriter
6.3 Describe how you will ensure potential subjects are given sufficient time to consider participation. * Mothers can lactate for as long as they desire
6.4 Do you confirm that all study personnel responsible for obtaining informed consent have the following qualifications:
Are familiar with the details of the study;
Will ensure subjects are provided with sufficient information to make an informed and voluntary decision about study participation;
Are familiar with UW-Madison policies regarding informed consent.
* Yes
6.5 Upload all consent documents and, if applicable, information sheets (e.g., consent form, assent form, translated consent documents). NOTE: If the main consent document for this study is over 5 pages long and/or if the CTRC will be used for this study, an information sheet MUST also be uploaded.
HIPAA: GENERAL
NOTE: For guidance on the HIPAA privacy rule, including what constitutes individually identifiable information and Protected Health Information (PHI), refer to the HIPAA website. If the purpose of this study or project is to create a database or registry, contact the HIPAA Privacy Officer to determine whether it needs to be registered
1.1 Will the research involve the access, collection, use, or disclosure of individually identifiable information? * No

1.1.1 If yes, are you or any member of the study team conducting the study under a Madison VA (Wm. S. Middleton VA Hospital), UWHC, or UW Medical Foundation appointment or an appointment that is within the UW-Madison Health Care Component (HCC)? NOTE: The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only).
Yes No
SUPPLEMENTAL INFORMATION
1.1 Does this submission represent a replacement of a protocol previously approved by a UW-Madison IRB (e.g., one closed under the campus Five Year Renewal Policy)?
No
1.1.1 If yes, please provide the reason for the replacement (e.g., IRB required closure due to Five Year Renewal Policy):
1.1.2 If yes, provide the previous number assigned to this protocol by the UW-Madison IRB that approved the study:
2.1 Provide any additional relevant documents (e.g., supplemental statistical justification information), if applicable.
2.2 Describe what additional documents were added in 2.1.
FINAL PAGE
1. 1.1 Do you certify that (1) the information presented in this application is accurate; and (2) if the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement?
* Yes
To complete and submit this application to the IRB office, please follow the steps below:
1. Select Hide/Show Errors at the top of this page to identify any omissions in the application;
2. Select Finish or Exit on this page to return to the study workspace;
3. To submit this application to the IRB office, click the Submit activity in the study workspace.
NOTE: The Submit activity is only available to certain study team members.
STUDENT/TRAINEE DETAIL
Student/Trainee:
* THERESE BESSER
Indicate the category of the student/trainee.
* Student pursuing a UW degree (e.g. graduate, undergraduate student) If other, specify.
Course of program for which this project is being completed. * BME 200
STUDENT/TRAINEE DETAIL
Student/Trainee:
* CONNOR FORD
Indicate the category of the student/trainee.
* Student pursuing a UW degree (e.g. graduate, undergraduate student) If other, specify.
Course of program for which this project is being completed. * BME 300
STUDENT/TRAINEE DETAIL
Student/Trainee:
* HEATHER SHUMAKER
Indicate the category of the student/trainee.

* Student pursuing a UW degree (e.g. graduate, undergraduate student) If other, specify. Course of program for which this project is being completed. * BME 300

2. Wisconsin Alumni Research Foundation Intention Disclosure Report

UW-Madison Invention Disclosure Report	Date: Dec. 4, 2015 WARF Case No.

Information in this report is supplied by the investigators pursuant to obligations of researchers specified in the UW-Madison, Office of the Vice Chancellor for Research and Graduate Education, Intellectual Property Policies and Procedures for University Research: (https://research.wisc.edu/projectagreementsip/intellectualprop/ippolicies/).

If you have questions about completing this document contact your WARF Intellectual Property Manager, 263-2500, or Becky Bound, Office of the Vice Chancellor for Research and Graduate Education, 263-2877. Please distribute copies to all individuals who worked on this invention as identified in the inventor information section of this document.

Invention Summary

Title of invention: Breast Pump with Mechanical Stimulation

Technical abstract of the invention (or attach a publication or draft). This will be provided, when required, to sponsoring agencies.

The purpose of the Breast Pump with Mechanical Stimulation is to improve the comfort and efficiency of breast pumping by providing mechanical stimulation to the nipple during breast pumping. The device uses compression by means of an expanding and contracting membrane attached to a breastshield. This device provides cushioning for the breast while simultaneously facilitating milk flow by compressing the nipple. The breastshield design is biocompatible and sanitary due to a removable latex or nitrile membrane that should be discarded after each use. The disposable membrane will reduce the cleaning necessary after each use. The breastshield design increases the comfort of breast pumping by massaging the nipple similarly to a suckling baby.

The breast pump design incorporates two pump motors. The primary pump is used for direct suction to collect the breast milk into an attached container. The second pump is attached to the breastshield. The pump attached to the breastshield serves to move the membrane by increasing and reducing the pressure in the space between the membrane

and breastshield. This causes the membrane to expand and contract, producing periodic compression. Periodic compression is produced by synchronizing the two pump motors. The primary pump is on at all times of use and the second pump functions during specific cycles of the regular pump. The pumps are synchronized this way to maintain a comfortable suction and compression rhythm for the user.

The breastshield used in this design is a cone-shaped piece of hard plastic which is placed on the breast while pumping. The shield features a small hole in the side of the shield at the end attached to the continuous vacuum. Tubing is inserted into this hole, which is then connected to the pump and motor. The membrane is stretched around this breastshield to create an airtight seal. The membrane used is similar to a long, tubular balloon that is affordable and easy to manufacture. This feature provides a clean, isolated pathway for milk discharge into the bottle. The altered breastshield and membrane design can be seen below in Figure 1.

This device offers many advantages over other breast pumps on the market. The design integrates unique features to provide increased comfort for the user and aid in milk expression while maintaining a hygienic and user-friendly interface.

Figure 1: Membrane and Altered Shield

What makes this invention superior to existing technology?
This invention provides mechanical stimulation to the nipple during breast pumping. This design uses compression by means of an expanding and contracting membrane attached to the breastshield. There are currently no breast pumps on the market that provide compression to the breast and nipple this way. This type of compression simulates the compression that a baby provides with the tongue and hard palate during breast feeding. Tactile stimulation of the nipple is thought to have a positive effect on oxytocin levels which is known to stimulate the let down response.

The invention was conceived of at least as early as:
September 25, 2015

When was the invention shown to work?
December 1, 2015

Have you disclosed this invention to anyone in a non-confidential manner?
If so, when and to whom?

If not, do you anticipate such a disclosure in the next six months (when and to whom)?
Yes, the design will be presented on Friday, December 12, 2015 to students and staff in the department of Biomedical Engineering to fulfill the BME 200/300 design requirement.

Inventor Information
Note: Should royalty payments be made to the department(s) at any point, the distribution will be determined based on the departments listed below and any additional information provided by inventors, as this is expected to reflect the unit in which the work was done.

Names of Inventors: Please include the names of all University of Wisconsin and any non-University personnel who contributed to this invention.

Inventor A

First name:	Heather

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Additional department/center:	N/A
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Home phone number:	651-788-3553
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Inventor B

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Work phone number:	N/A
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Inventor E

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Home phone number:	630-797-1810
E-mail address:	enethery@wisc.edu

Is any inventor employed by or affiliated with:

	Yes	**No**
USDA		**X**
USDA/Forest Products Lab		**X**
Veterans Administration		**X**
UW Hospitals and Clinics	**X** Connor Ford holds an unpaid research position at Pearce Laboratory. The	

	Laboratory. The PI, Dr. Robert Pearce, is Chair of Anesthesiology at UW Hospital and Clinics.	
Howard Hughes Medical Institute		**X**
Any organization or company other than the UW Madison		**X**

Funding and Materials

To look up your funding sources see http://www.rsp.wisc.edu/services/admin/awards.cfm
A grant, contract or cooperative agreement is a source of funds if the invention was conceived or reduced to practice in the performance of work sponsored by the funding agreement.

Which federal funds (144-accounts) contributed to making this invention?

	Sponsoring Agency	Grant, Contract or Agreement Number	UW Account Number
Primary	**N/A**		144-
Secondary	**N/A**		144-

(expand as needed for more sources)

Which non-federal funds contributed to making this invention?

Sponsoring Agency	Grant, Contract or Agreement Number	UW Account Number
N/A		
N/A		
N/A		

(expand as needed for more sources)

Check if any other agreements are relevant to this invention (list):

Check Here	Agreement Type	Other parties to agreement, and description of agreement
	Material transfer agreement	
	Confidentiality agreement	
	Collaboration agreement	
	Research agreement	
	Consortia agreement or funding	
	Consulting agreement	
	Other	

If none, check here____**X**_____

(expand as needed for more sources)

Name of person completing this form:	
Phone:	
e-mail address:	

In submitting this form you are accepting the responsibility for the accuracy of the information supplied and for ensuring that all inventors will be provided with copies of this form.

Submit this report to the Wisconsin Alumni Research Foundation:

- By e-mail to the appropriate Intellectual Property Manager
- Through WARF's website at http://www.warf.org/for-uw-inventors/disclose-an-invention/disclose-an-invention.cmsx http://www.warf.org/contact/idr.jsp
- By mail Attn: Docket Clerk P.O. Box 7365 Madison, WI 53707