Executive Summary Final

Between Design Review 5 and the Design Expo, we made several major advancements in our project. These included finishing our final prototype, testing that prototype, and performing calculations for validation.

The steps that we took in order to finish fabricating our final prototype were pouring the final silicone base, properly securing the motor shaft, adding Velcro to the securing mechanism, and soldering the wires within the device. The silicone base had to be re-poured because the original was too thick, and the second iteration was too thin and it ripped. The final silicone base was still slightly too thick, but we are confident that if time permitted we would be able to create the ideal silicone base. We also noted that if our motor were more robust, the third silicone base would have functioned properly. We used Loctite to attach the motor shaft to the turning plate because we had problems with the two pieces coming apart when the device was in use. The Velcro that we attached to the securing mechanism is on the straps and is used to roll them to adjust for different patient sizes.

We were able to complete two validation tests between DR5 and the Design Expo. The first validation test that we performed was to gauge whether our device was effective. We could not go through clinical trials, so we attempted to make our device match the metrics of the manual massage performed by a nurse. The massaging device replicated both the speed and pressure applied by Dr. Jody Lori when we asked her to perform the massage for us earlier this semester. The next experiment we did was to test the ease of use of our product. We asked 10 random University of Michigan students to set up our device on one of our team members, without instruction, and we timed how long it took them. Everyone asked was able to set the device up within the allotted time, though no one could do it correctly. We are confident, though, that with minimal explanation of our product, students and medical professionals would be able to set up the massaging device within our specified time. Another test that we performed was to evaluate the comfort of our massager. We asked the same 10 UofM students to rate our device on a 0 to 5 comfort Likert scale. It scored an average of 4.1, which met our user requirement. We weighed the device and found that it was in fact less than 2kg. Finally, we measured the length of our securing mechanism and validated that it would fit the range of women, which we specified. All other validation tests were out of our scope.

Several calculations had to be performed due to the limited scope of our project this semester. We found information supporting the fact that one action potential, caused by shear force, is enough to cause uterine contractions. After calculations, we found that our device causes 36 action potentials, therefore validating that our device should cause the uterus to contract and prevent further bleeding.

Design Review Final Report - Written Report
By: Anna Buzolits, Sarah Geshwender, Taylor Petri, and Jordan Toor
Background
Introduction
Postpartum hemorrhage results in more deaths per year than any other birthing related complication. While in developed countries, such as the United States, the maternal mortality death rate is only 11 per 100,000 births, in underdeveloped countries, such as Africa, the death rate is more than 4,000 per 100,000 births. It is estimated that of those deaths, about 25% of them are caused by postpartum hemorrhage (will be referred to as PPH) [3]. The large discrepancy between developed and underdeveloped countries is largely due to lack of skilled birth attendants underdeveloped countries. Though recent work by the United Nations has decreased worldwide maternal mortality by about 50%, there is still much progress to be made [8]. From the years 1999-2009, the rate of PPH increased by 2.6% in developing countries [3]; this statistic clearly signifies that PPH is still prevalent and can be improved upon.

Postpartum Hemorrhage

Hemorrhage is defined as 500 ml of blood loss during a vaginal birth or 1000 ml of blood loss during a caesarean birth within 24 hours after delivery [1]. The most common cause of PPH is due to uterine atony; this occurs when the uterus fails to contract after delivery. Uterine atony is caused by a loss of muscle tone, which can result from prolonged labor, rushed labor, or multiple deliveries, as well as other things. This cause of PPH is almost completely preventable with the administration of oxytocin or misoprostol, uterotonic drugs administered to help the uterus contract, and the use of uterine massage, also used to help the uterus contract. Uterine massage helps circulate the blood through the uterine muscles and also stimulates the uterus in order to help it contract [8]. These practices can be classified as part of active management during the third stage of labor, which is the worldwide standard of procedures after delivery. Studies show that when oxytocin was administered early in the birthing process, it reduced PPH by almost 25% [3]. Other risk factors for PPH are a retained placenta, placental accreta, and lacerations, though these factors as not as preventable.
Treatment of PPH is possible, but is often difficult. Once PPH has occurred, most patients have already begun to suffer from the effects of severe blood loss, such as loss of consciousness and shock. In this situation, time is critical; it is very important that the source of the hemorrhage is treated as quickly as possible. Finding the source of the hemorrhage for treatment often requires surgery and proves to be difficult, which prolongs the loss of blood. As a result, patients frequently need blood transfusions. In underdeveloped countries, blood supply for transfusions is low, which makes the treatment of PPH even more difficult [3]. Even in the event that a blood transfusion is received, very often the mother will have anemia as a result of the hemorrhage. It is for these reasons that is it both easier and more safe to practice prevention of hemorrhage as opposed to treating it after it already happens.

Uterine Stimulation

After doing much research in regards to the muscular structure of the uterus, we realized that the applied pressure to the muscle is not as important to the contraction of the muscle as the amount of stimulation is. The uterus is characterized by three muscle layers, the middle layer, called the myometrium, is also separated into three layers, the outer-most of which is a smooth muscle referred to as longitudinal muscle (Figure 22, page 22). The longitudinal muscle layer is what is responsible for the contraction of the uterus and therefore the layer we want to target for the purpose of our project. The contractile tissue of the longitudinal layer is made up of two different types of fibers called actin and myosin (Figure 22, page 22); the contact and shear rubbing of 30-40 pairs of these two fibers is what creates the action potential needed to induce contraction throughout the entire muscle layer, though the more contact points there are, the more action potentials will be produced and the faster the muscle layer will contract.

The Problem

Currently, in the Korle-Bu Teaching Hospital in Accra, Ghana, midwives are the only hospital personnel who perform uterine massages as a method of active management of the third stage of labor. However, midwives are often understaffed and are rarely able to perform uterine massage on all patients [3]. Efforts have been made to teach women to perform uterine massage on themselves; however in these cases, it is common for women to stop the massage too early because of discomfort.

One method of preventing uterine atony that currently exists is belt with an inflatable 'bladder' of varying pressure. The belt is placed around the patient's midsection with the 'bladder' over the uterus and a manual pump is used to inflate the bladder, applying a selective pressure to the uterus. However, the final step in operating this device involves manually changing the pressure of the bladder to induce uterine contractions [5]. Therefore, this device does not address the need for a device that can be operated without a nurse or midwife present.
The MamaNatalie birthing simulator, as shown in figure 1, is a teaching device meant for an instructor to wear and it can be used to teach midwives how to prevent PPH. While wearing the simulator, the instructor can control the fetal heart sounds, delivery of the placenta, the position of the baby in the birth tract, uterine firmness, and the intensity and volume of blood loss. Uterine firmness and the delivery of the placenta are two of the three steps as stated earlier required to prevent postpartum hemorrhaging. The instructor can teach students how to properly deliver the placenta and how to massage the uterus in a case where a mother is hemorrhaging. The simulator also provides training on how to properly inject oxytocin. This product is not widely used in low-income settings because at a price of $850 USD [11], it is very expensive.

Figure 1: MamaNatalie birthing simulator [11]

A non-pneumatic anti-shock garment may also be used to treat postpartum hemorrhaging. The main focus of this device is to treat shock that results from severe postpartum hemorrhaging. The garment is placed on a patient and adds external pressure to the body to restore blood pressure, as shown in figure 2. A six-week study in Sialkot, Pakistan [13], found that most of the women suffering from PPH and shock regained healthy arterial pressure within 5 minutes of wearing the garment and continued to wear it for 12 to 36 hours to stop hemorrhaging. This garment costs less than $200 USD [14] and can only be used about 50 times [15] thus making it an impractical option for use in low income areas that have a lot of patients with postpartum hemorrhaging.

Figure 2: Non-pneumatic anti-shock garment [26]

Additionally, there are several existing solutions to preventing postpartum hemorrhage that are invasive, such as the Uniject, the Uterine Electrical Stimulation System, and the tamponade. The Uniject, as shown in figure 3, is a product on the market that comes in single use, prefilled, ready-to-use vials of oxytocin. This is a sanitary way to distribute the drug in low-income settings and its ease of use helps busy midwives. Although the vial is convenient to use, it must be administered by a doctor or midwife because the drug is injected intravenously. In low income hospitals, for example in Korle-Bu Teaching Hospital, they have oxytocin available, but oxytocin injections alone don't always prevent postpartum hemorrhaging. The Uterine Electrical Stimulation System utilizes electrodes coupled to the uterus to provide stimulation current [6]; however, this and other invasive methods of PPH prevention are not ideal for the scope and timeline of this project. There are also balloon or foam tamponades on the market,

as shown in figure 4, that are used to successfully treat postpartum hemorrhage [10]. The device is inserted into the uterus using a catheter and then filled with saline. The tamponade is typically removed after 12- 24 hours if the bleeding has stopped [12]. Although this device has a success rate of 85%, many doctors do not use it anymore because there could be concealed bleeding and infection. The tamponade is also very expensive, costing up to $250 [17], and invasive, making it non ideal for low income countries and not apart of our scope.

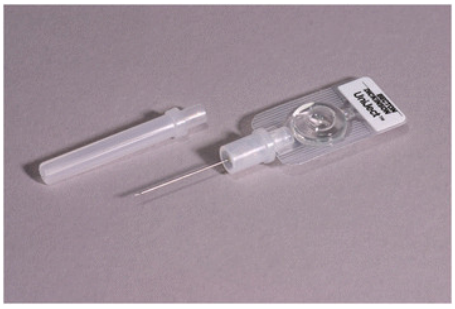

Figure 3: Uniject [27]

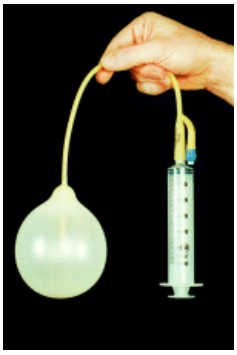

Figure 4: Rusch balloon and catheter tamponade [17]

There are many patents on Chinese medicine preparations [16] that have been proven to prevent post partum hemorrhaging with few toxic side effects. Although these medicine preparations have shown success, they are unnecessary in areas where drugs such as oxytocin and other uterotonic drugs are available.

Specifically in low resource countries where there is a lack of skilled birth attendants, there exists the need for an appropriate means of stimulating uterine contractions to prevent postpartum hemorrhage in hospitals where the number of patients requiring medical attention exceeds the number of available midwives, and a device to address this need has not previously been created.

The myometrium, which forms 90% of the uterine wall, consists of unstriated (smooth) muscles and is responsible for the powerful contractions that occur during labor [28]. Contractions in smooth muscles are associated with the sliding of cells across one another. In order to initiate these contractions, we plan to massage the uterus, which will in turn, slide muscle cells across

one another. More stimulation is correlated with more contractions, without dependence on the amount of pressure provided by the stimulation. [29]

Scope- Hospital and Patients

Because PPH is most prevalent in underdeveloped countries, our primary focus will be hospital settings that are understaffed and overcrowded; we will also assume that the majority of the patients will be expectant mothers who have little to no prenatal care, as these are the most frequent occurrences in low-resource settings [2]. As mentioned previously, it is difficult to diagnose and treat PPH without long term effects for the patient. It is much easier for healthcare professionals and much safer for expectant mothers to practice preventive care as there is less of a risk for PPH and its long term effects so we will be trying to come up with a solution for the prevention of PPH as opposed to the treatment of it.

A member of our project team, Anna Buzolits, spent 8 weeks observing and conducting interviews in the Obstetrics and Gynecology (O&G) department at Korle-Bu Teaching Hospital (KBTH) in Accra, Ghana. While there, she interviewed doctors, nurses, midwives, and the administration who worked at the hospital and gained first-hand experience working in a low-resource setting. Many facts and figures are drawn directly from her experiences as a student shadowing in the labor wards.

Project

The goal of this project will be to conceptualize a device that will be used to stimulate uterine contractions in order to prevent postpartum hemorrhage in low-resource settings. Our scope of practice is hospitals in these types of low-resource settings. We face the challenges of a small budget for the project as well as few health-educated staff members in these settings. As mentioned before, hospitals in these areas are often overcrowded and understaffed [2]; ideally, we need to create a low-cost product that can be operated by almost anyone, regardless of their education level, with very little instruction given.

User Requirements and Engineering Specifications

Ranking	Requirement	Specification
1	Effective	Stimulates uterine contractions by stimulating at least $6.16x10^{-5}$ m^{-2} of the uterus
2	Safe	Is biocompatible according to ISO 10933, ASTM F748-06
		Meets the risk-management standards of ISO 14791 Meets FDA guidelines regarding protective restraints [25]

3	Easy to use	Takes ≤ 2 minutes to set up and begin use
		Includes < 5 separate parts to be assembled
		Takes < 30 minutes for a midwife to understand how to use correctly
4	Durable	Lasts >11,000 uses
		Does not lose functionality after a drop from a height of 2m
		Can be used in temperature between 15-40 C and up to 100% humidity
		Made of a material does not degrade when cleaned with alcohol or chlorine bleach
		Includes spare parts for maintenance [18]
5	Accommodates women of different sizes	Works for women with BMI between 16 and 40 kg/m^2 [19]
6	Low-cost	Costs the hospital < $100
7	Portable	Weighs less than 2 kg
		Includes at least one dimension that is less than 1.25 m wide
8	Easy to clean	Can be cleaned with chlorine or spirits in < 1 minute
		Results in 10^2 to 10^4 log10 reduction in bioburden
9	Appealing	Receives a median score of 3.5 out of 5 on a Likert Scale, indicating that the device is not intimidating to users

Table 1: User Requirements and Engineering Specifications

When interviewed, doctors, nurses, and midwives at the Korle-Bu teaching hospital agreed that the most important quality of a successful solution to the problem at hand would be its ability to prevent PPH. From our research, we have determined that stimulating the myometrium (smooth muscles in the uterus) to contract will prevent postpartum hemorrhage.

Of second, if not equal, importance to the faculty and staff at KBTH is their patients' safety. As safety is such a broad requirement, several broad specifications were chosen to encompass the solution space. Biocompatibility refers to the interaction of a medical device or component

material to a living system with little to no toxic, injurious, or immunological response. [21] ISO 10993 provides a framework to conduct a biological evaluation of the components and overall device to assess safety. In addition, the device should undergo a systematic risk analysis to ensure risk management is assessed throughout the product life-cycle, which includes design, production, and post-production. Finally, the device should meet FDA guidelines regarding protective restraints. These guidelines entail, for example, displaying clearly visible and easy to interpret instructions and documenting of the length of time for device use in the patient's record. [25]

The midwives working in the labor ward were especially interested in solutions that would take little time to understand and apply in their daily routine. Though the midwives are formally trained at the medical school at Korle-Bu, if a solution was presented to the midwives currently on-staff at KBTH, the best time for them to learn how to use the device would be between patient check-ins. This allows for a maximum of 30 minutes at a time to learn about new equipment in the ward. Ideally, the device should be intuitive enough so that anyone could understand how to use it immediately; Jennifer Agyei, a midwife on the second floor, suggested placing instructions or pictures on the device to clarify how to use it. The specification that limits the number of separate parts to five comes from a statements from the midwives that they would not use a device that required the assembly of multiple parts. Upon observation in the ward, though, it was noticed that there is actually equipment that has up to five separate parts already in use in the ward. This lead to the chosen specification.

Every stakeholder at KBTH immediately noted durability as a requirement for any device to be used at the hospital. Presently, the hospital staff struggles with maintaining the equipment they have; broken equipment is prohibitive in several of the departments and leads to sub-par care in the rest, despite the expertise of the physicians and staff. The annual report of the O&G department from 2014, Korle-Bu sees about 11,000 births per year; the solution produced by this project should be able to last at least one year. The specification stating that the solution should not lose functionality after a fall from two meters comes from the observation that the staff sometimes stores equipment on their refrigerator, which is two meters high, but nowhere taller. The climate in Accra, Ghana, is hot and wet: 15 to 40 degrees celsius and 100% humidity, indoors, is not only possible but likely. The specification to include spare parts was obtained from the World Health Organization, which recommends sending spare parts with equipment to allow it to last at least 2 years if it is not easily accessible in the recipient country. If the devices meets the requirement for 11,000 uses, as stated above, replacement parts would have to amount to one of each individual part that cannot be found in-country.

Dr. Otaka was the original source for the requirement for a device that would work for all the differently sized women at the hospital. The BMI range comes from literature and represents the extremes, from extreme thinness to obesity type III, and is meant to encompass all potential patients. [19]

Low-cost seemed to be an obvious requirement for all interviewed users. The O&G department has a budget of 10,000 Ghana cedi per month, equivalent to about 2,400 USD as of August

2015, to spend on maintenance and purchasing new equipment, but resources remain scarce in the wards. Because even $5 or $10 is too much for many women to pay for her treatments, doctors suggested a solution that would not incur cost for the patients. After benchmarking technology used to treat PPH, a price limit of $100 was determined.

In order for medical equipment to be used to its full potential at the hospital, it must be able to move from patient to patient, who reside in separate rooms during active labor. Therefore, portable is a requirement that could not be overlooked by the midwives who would have to use the device. According to the midwife Jennifer, BP cuffs and fetal heart rate monitors were examples of devices she would consider portable; these devices weigh less than 2kg. She also said that 4kg, the weight of a large newborn, would be too heavy for a device that the midwives would often carry around the ward. When asked about large but light equipment, the midwives stated that would be fine so long as there was a way to move it, such as handles or wheels. The only size restraint they had was the width of the labor room doors, which were 1.25m wide.

Though doctors did not mention it, nurses and midwives were adamant that a new device should be easy to clean. Jennifer Agyei said that she would want to be able to wipe with chlorine bleach or alcohol and know it will be clean enough to use with a different patient. Cleanliness of a medical device is defined as "the removal of foreign materials, most often mixtures of organic soil and microorganisms, from medical instruments" [22] Thus, a device being handled in the hospital environment by several staff members and used with multiple patients should be easily cleaned of most of the microorganisms and bacteria that may accumulate on it before use on or in a patient. The ASTM standard for cleaning medical devices defines cleanliness as the removal of 10^2-10^4 log10 of the bioburden from the device.

A final requirement of importance is that the device be appealing to the patient. Our product will not be successful if it is so unappealing or uncomfortable that a patient is afraid to use it. Once a prototype is developed, our team will generate a Likert Scale to distribute among a random population. Data will be analyzed and a median score of 3.5 out of 5 (with 5 corresponding to most appealing) will indicate that our comfort requirement is met. The median was chosen over the mean because this is recommended when summarizing a small data set with outliers such as Likert Scale data [23].

Concept Generation

In an effort to generate a wide variety of concepts addressing our need statement, each team member individually produced 20 concepts, using a functional decomposition graphic as a guide:

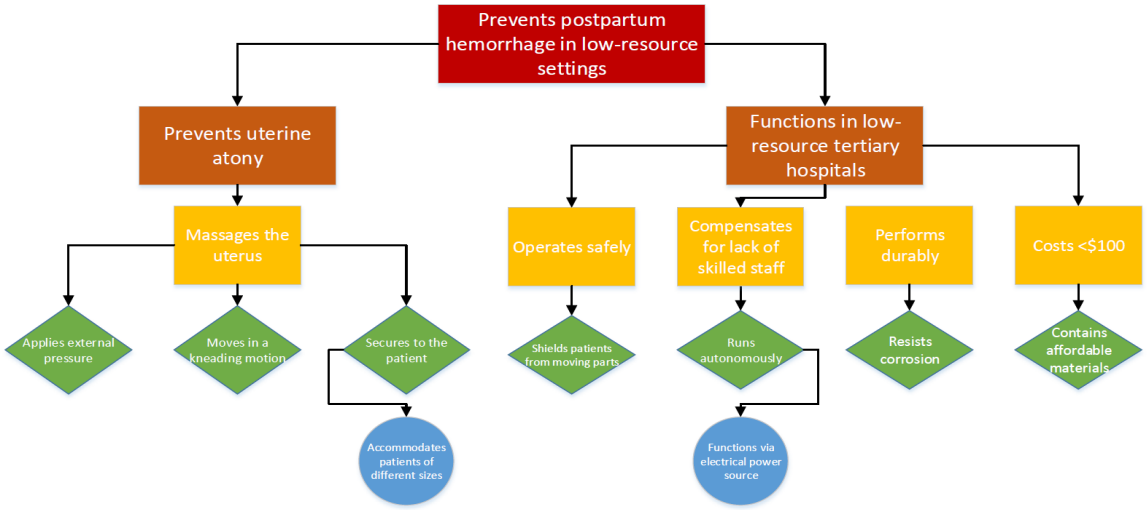

Figure 5: Functional Decomposition Graphic

As a team we created the functional diagram seen in Figure 5 to assess and organize the functions that our final solution should have. From this we each generated 20 concepts that met the requirements and performed as prescribed by this diagram. When we came back together we determined that we had 3 distinct types of solutions: devices that could massage the uterus themselves, designed with the goal of replicating the uterine massaging motion as closely as possible, mechanisms to attach these massaging devices to a patient or the patient's environment, and devices that encouraged uterine atony without actually performing a massage.

One example from our generated concepts that does not actually perform the massage but instead encourages women to massage themselves after they give birth is an apron with handprints where the women should place their hands and apply pressure. It would alert them (with light or sound or mechanical feedback) when they were applying the correct amount of pressure and / or when their uterus was contracting enough for them to cease the massage. This design can be seen in Figure 6.

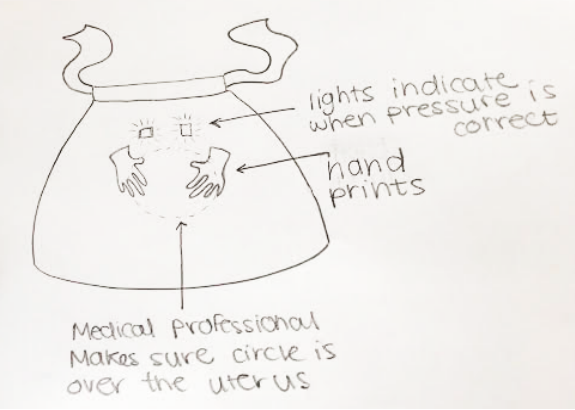

Figure 6: Hand Print Apron

An example of a massaging device that one of our team members developed is an “X” that rotates and applies different amounts of pressure to the patient’s abdomen as it turns. Due to the high coefficient of friction of skin, there would need to be a way to prevent skin damage (not shown here). A sketch of this design can be seen in Figure 7.

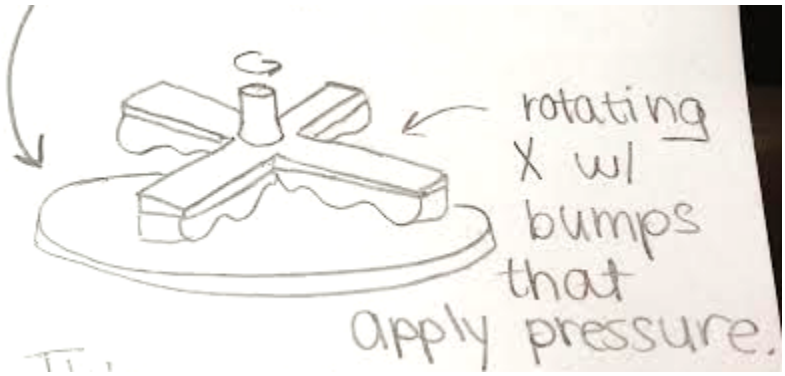

Figure 7: Spinning X

The last category of concepts is attachment mechanisms. Figure 8 shows our idea to use cloth that women bring with them to the hospital, and is readily available in Ghana and other Sub-Saharan countries, to attach the massaging devices to women. This would make them feel more comfortable with the technology and alleviate the need for nurses to clean the cloth because the women would take it home with them to clean or throw it away themselves.

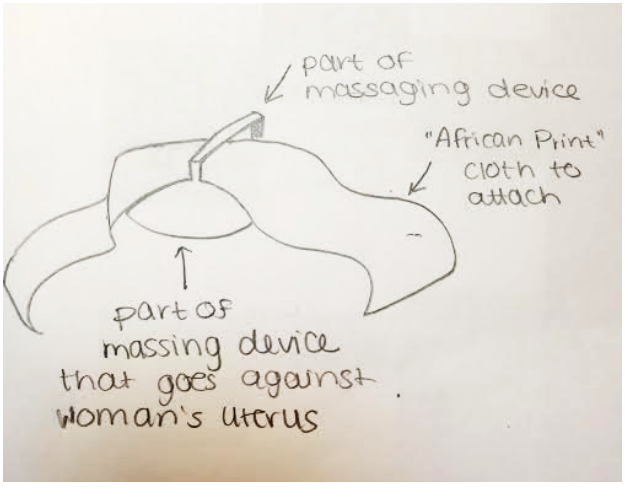

Figure 8: African Cloth Attachment

After we organized our concepts, all of which can be seen in Appendix A, we moved on to scoring the top designs and selecting one design with which to move forward.

Design Selection

We started off with nearly 80 concepts to narrow down. This is obviously a large number of concepts to deal with, so we started by eliminating any concepts that were similar to one another. This helped us narrow down our selection significantly. We were then able to further narrow down our selection by only choosing concepts we would be able to complete financially and technically in the scope of this project. From there, the only ideas that were selected for the charts described below were the ideas we could complete within our time constraints of the semester. In order to select a concept, we made two Pugh charts. One of which had our concepts of different massaging devices to be placed on the surface of the patient's skin in order to massage the uterus [table 2], the other has different attachment mechanisms in which we will use to attach the device to the patient herself or the bed [table 3]. Both of the Pugh charts had nearly the same criteria and weighting system, with the exception of excluding assembly on the attachment mechanism chart because, ideally, the attachment mechanisms will not need to be assembled at all. We found it important to have the same criteria for both charts because both mechanisms will be working together in harmony, so we felt it necessary that they had the same criteria.

The criteria were selected based on our user requirements and specifications, as well as our design drivers. We chose to weigh all of the criteria out of ten and selected the prototype that Anna made over the summer to be our datum, because that is the design we are trying to improve upon. We weighted our criteria based on research we found on laws and regulations of medical devices as well as stakeholder inputs.

We found the most important criterion to our design was its effectiveness, because if it is not effective, then our device loses its purpose entirely; by that reasoning, we weighted it a 10. The next most important factor was safety, because it is obviously extremely important that the patients remain as safe as possible while using the mechanism, for that reason it was rated a 9. Durability of our mechanism was weighted an 8 because it is difficult to fix products in low-resource settings, so we want it to be a durable as possible. Durability was followed by ease of use, ease of cleaning, and being low -cost, which were all weighted 6's. These criteria are important for ensuring that the device remains effective, reduces the spread of infection, and is affordable for a low-resource setting. Portability of the device was weighted a 5, because though it would be nice to be able to have one of these devices in every room of a hospital, it is simply not cost-effective for hospitals in these settings to do so; for that reason, it is important that the device can be easily moved from room to room in order to accommodate all of the patients. Weighted the least, with a 3, is ease of assembly. This was ranked last because though this was a high priority for our stakeholders, we found it more important for the device to have more parts and be more effective, than for the device to have less parts and be less effective. Using this weighting system, we tested our datum against six other designs for the first Pugh Chart. The chart determined that our top three designs were Designs 7, 2, and 3. Design 3 was ranked the lowest of the three with 7 total points. This design was a group of four vibrating petals that would be placed on the woman's skin on top of the uterus and would vibrate for a set amount of time to stimulate blood flow in that area. This design was both durable because

it had no motor mechanism and easy to use because all the user needed to do was to turn it on. This design, however, would not be very effective, as it did not mimic the hand massaging motion. Design 2 had 15 total points and was our second best design. This design was an apron type garment that the woman would wear around her waist with two mitten shaped pockets for her hands over her uterus [Figure 6]. The woman would place her hands in the pockets and would begin to massage her own uterus; within the pockets would be pressure sensors that would light up upon applying the correct amount of pressure. This design did very well in safety, durability, portability, and assembly, but we deemed it not very safe because the woman, most likely not medically trained, would be massaging herself; we also thought it may not be very easy to use for the same reason. Our third and best ranked design was design number 7, a rotary massaging device with a worm gear mechanical set-up, this had 36 points. This device was to be placed on the woman and strapped on to her on the skin, over the uterus [Figure 8]. The massage spheres themselves would be on a tilted axis, as to mimic the motion of a uterine massage done by hand. The worm gear mechanical set-up allows for the device to be thin, as to reduce the risk of it falling over. This design did particularly well in portability, safety, and effectiveness because of its small design and direct mimicry of a human hand. It did not do so well in assembly, because it may be difficult to mesh the gear properly if someone does not have experience doing so.

For our attachment mechanism Pugh chart, we used the same criteria with the same weighting as for the massaging devices, for the criteria used for the massaging devices are just as applicable for these other mechanisms. The only exception is that we did not include assembly in this Pugh chart because, ideally, this mechanism will not need any assembly. The datum we used for the chart was a regular leather belt, because that was the only product currently on the market that resembled the type of mechanism we wanted to build; our datum was tested against 6 other designs.

For the attachment mechanism chart, we used a standard leather belt for our datum because it was the only device on the market that resembled the type of attachment mechanism that we wanted to make. As determined by the chart, our top three mechanisms were designs 1, 2 and 4. Ranked last among the top three was design 2 with 1 point [Appendix A.2]. This design was a bungee cord that would be attached to the bed frame. This design was safe, easy to use, and low cost, but it was not easy to clean due to its absorbent material qualities nor was it very durable because the cords get stretched out easily. We also found that it may not be very safe, because in the event that one of the cords slipped or because detached from the bed, it could whip and injure someone. Ranked second in our top three was design 4 with 5 points [Appendix A.2], this was an African print cloth that was to be wrapped around the woman and the mechanism and tucked in around her to secure it. This was ranked highly because it's safe, easy to use, and many people in low-resource settings already own them, so they're a low cost option. Where this mechanism ranked low was in its effectiveness and in its durability; because they are just tucked in around the women, they could come untucked very easily and because they are so cheap, they often don't keep very well. Our top ranked mechanism was design 1, with 15 points [Appendix A.2]. This design was similar to a large TheraBand that could be wrapped around the woman and the mechanism and tightened with an adjustable clip. This

design was safe, effective, easy to clean, and low cost, the only categories it faltered in was in ease of use and durability. The use of the adjustable clasp might be difficult to use if it has not been used before and because the bands are so cheap, they can tear easily.

Description		Anna's Prototype	Swashplate + Pistons	Hand-Mitt	Vibrating Petals	Rotating X	Weighted Belt	Wheels	Worm Gear with
Sketch									
Criteria	Weight	Datum	Design 1	Design 2	Design 3	Design 4	Design 5	Design 6	Design 7
Effective	10	0	0	-	-	0	--	0	0
Safe	9	0	0	+	0	0	+	0	+
Easy to Use	6	0	0	-	0	0	+	0	0
Durable	8	0	-	+	+	-	+	-	+
Low-cost	6	0	-	+	+	0	+	0	+
Portable	5	0	0	+	0	0	-	0	++
Assembly	3	0	-	+	+	0	+	-	-
Easy to Clean	6	0	0	0	0	0	0	0	+
+		0	0	31	17	0	32	0	39
0		53	36	6	26	45	6	42	16
-		0	17	16	10	8	25	11	3
Total		0	-17	**15**	**7**	-8	**7**	-11	36

Table 2: Massage mechanism Pugh Chart

Description		Regular leather belt	Theraband	Bungee Cord	Hard Plastic Rectangles	African Print Cloth	Rolly Poly Bed Attachment	Hanger
Sketch								
Criteria	Weight	Datum	Design 1	Design 2	Design 3	Design 4	Design 5	Design 6
Effective	10	0	+	+	0	-	0	-
Safe	9	0	+	-	-	+	-	+
Easy to Use	8	0	-	+	0	+	+	-
Durable	8	0	-	-	-	-	0	-
Low-cost	6	0	+	+	+	+	0	-
Portable	5	0	0	0	0	0	-	-
Easy to Clean	6	0	+	-	+	0	+	-
+		0	31	24	12	23	14	0
0		52	5	5	23	11	24	9
-		0	16	23	17	18	14	43
Total		0	**15**	**1**	-5	**5**	0	-43

Table 3: Attachment mechanism Pugh Chart

Design Drivers

Drivers	Importance	Design driver analysis	Validation
Can provide stimulation to induce uterine contractions.	If the device does not apply stimulation to the uterus, the uterus will not contract, rendering the device useless.	Engineering analysis to determine how much power is needed to rotate the plate.	Test physical prototype.
Wont injure the patient	We don't want to injure the patient using the device.	Determind coeffecient of fricton bethween materials and skin. Using force found in the first desing driver and calculate amount of force from the belt onto the skin. Also place the moving parts in a closed off housing to prevent fingers getting caught in the parts.	Test physical prototype.
Ease of use	The midwives and doctors want a device that they don't need to spend too much time learning how to properly use the device.	Talk to hospital staff, see what they constitute as easy to use.	Give prototype to someone on our team and see if they can figure out how to use it.

Table 4: Design Drivers

There are three major design drivers for our problem. The first driver is that the massaging device must provide stimulation to the uterus to induce contractions. The uterus is a soft muscle, so stimulation is all that is needed to cause it to contract [28]. Our current massaging plate has three large balls on it to provide stimulation but not too much pressure. We plan to meet with a group of doctors and nurses from the Department of Gynecology at the University of Michigan hospital to find out what kind of massaging plate they recommend.

Our second design driver is that the device is easy to use. Midwives and doctors in low-income areas do not have an abundance of time to figure out how to operate a new device, nor do they have time for lengthy set up processes. In order to make an easy to use uterus massager, we will only have two independent pieces; the massaging device and the securing mechanism. The massaging device will also have simple sticker instructions to demonstrate use. These instructions will be made up of visuals to avoid a language barrier and will make it quick and easy for the midwives to learn how to use the massager. In order to determine if our device is easy to use, we will give it to another student with no prior knowledge of the device or our project and ask them to set it up. By giving it to a third party who only knows that it is a massager that is supposed to be placed on a woman to prevent post partum hemorrhaging, we can determine if the stickers we placed on the mechanism are simple enough to follow and that the massager is easy to set up. We will also time how long it takes for the student to figure out how to use it to determine if it meets the less than 30-minute time frame defined in our user specs.

Our third design driver is that both the massager we create as well as the securing mechanism must be safe to use on patients. To ensure this, we must use materials that are biocompatible and proven safe to come in contact with skin. The materials we use must also be able to withstand many cleanings with harsh chemicals to sanitize the massager and attachment. We must also be careful not to apply too much pressure to the uterus. To test this, we have concluded that the amount of pressure on the uterus must not exceed 2 psi, because that is the largest amount pressure applied by a healthcare professional while administering the massage. We placed a fabric with a low coefficient of friction to sit between the rotating plate and the

silicone cover because if the plate is moving against the silicone there will be too much friction; this may cause the motor to stall, which could, in turn, overheat the motor and burn the patient.

Concept Description

Our concept has remained the same for the securing device and the massager, except for a minor change in the structure of the housing. The housing will still resemble a short wide bowl, except there is a divot on the inside and an easily removable cover for the divot. This divot will house the batteries so that they are easily accessible by removing the cover plate. The motor will be mounted on the other side of the battery pack. We will drill holes into the plastic so that we can just screw the motor to divot. The massaging plate will be connected to the motor via a threaded rod. From our engineering analysis, we determined that we require a 200:1 Pololu gearmotor with a 90° output. The gearmotor with the 90° output will eliminate the need for additional gears. We will use a silicone cover (figure 13) with nylon glued to the inside to cover the massaging plate. We need to use silicon-epoxy to secure the nylon fabric to the silicone cover to significantly reduce the amount of friction generated, thus preventing the motor from stalling. Covering the bottom of the massaging unit will also make it biocompatible and safe to use on the skin. It will keep debris from getting caught up in the moving parts and it will protect the patient from getting their fingers pinched by the moving parts. We decided to power our massaging device using four AA batteries because they are readily available in Ghana and there is no need for power cords, which could make it more challenging for the midwives to clean quickly. Dr. Johnson initially recommended that we use AA batteries and our engineering analysis determined that four AA batteries would yield at least 71 15-minute massaging sessions, which we deemed as sufficient.

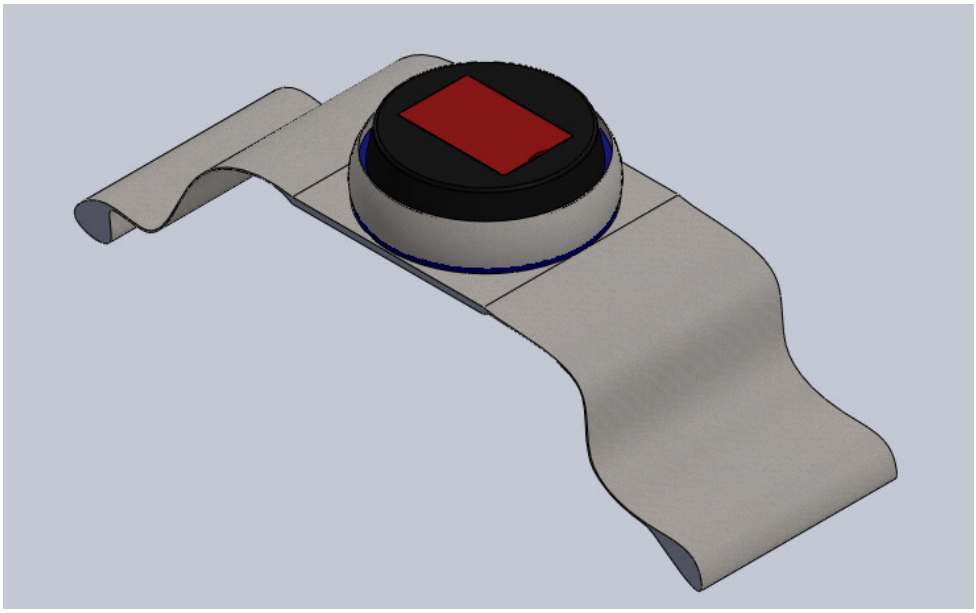

Figure 9: Massaging device inside the securing mechanism.

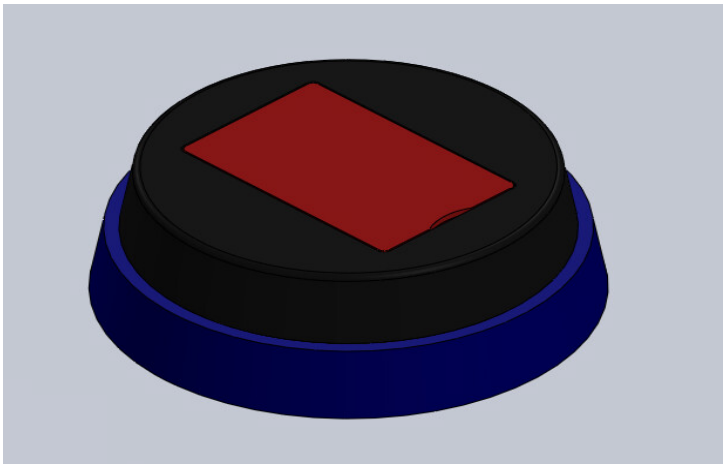

Figure 10: Massaging mechanism

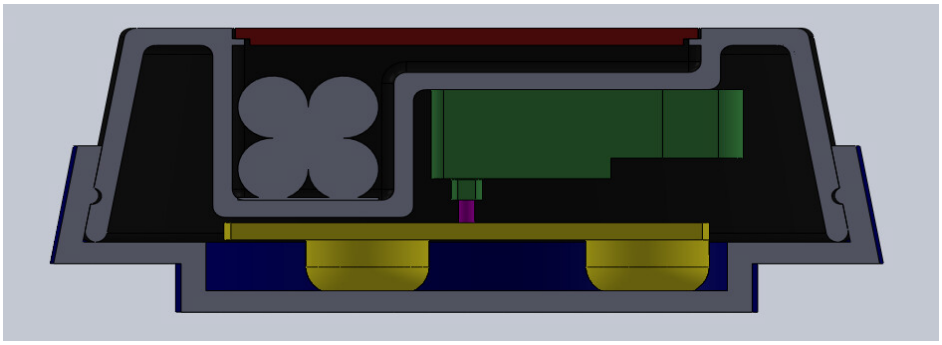

Figure 11: Cross-sectional view of massaging mechanism

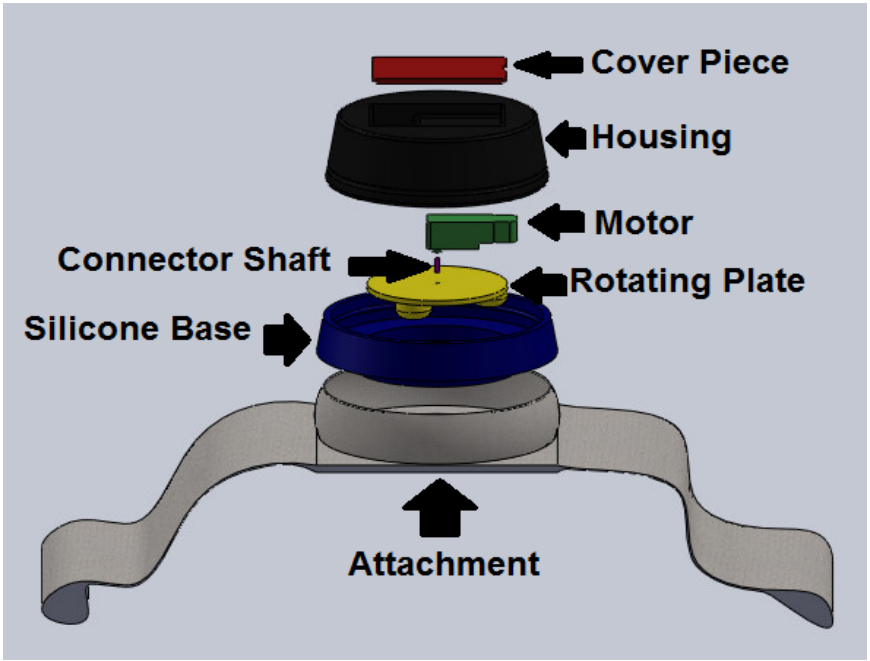

Figure 12: Exploded Assembly view of the massaging device and attachment mechanism

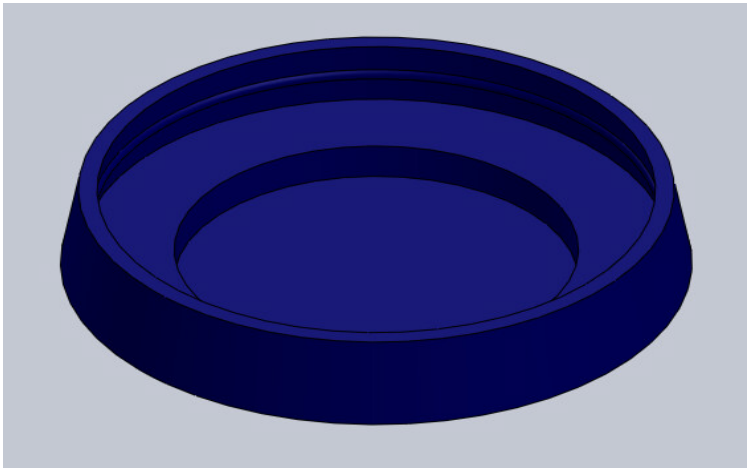

Figure 13: Silicon cover

Our securing mechanism will be a vinyl cloth with weights on the ends, as shown in figure 14. The weighted cloth will be easier for midwives to place on a patient and it will be more comfortable for the patients then a belt would be. The ends of the cloth will have weights sewn inside them. Sewing the weights inside the material will keep the overall part count low and it will ensure that the weights are not lost while the device is transported from patient to patient. To adjust for patients of different sizes, the midwives can just roll the weight sup so that the securing mechanism reaches the desired length. The securing mechanism will contain a pouch that will fit the massaging device, as shown in figure 14. The bottom of the pouch and the top of the pouch will have openings, so that the on/off switch and battery packs are accessible from the top and the silicone on the bottom of the massaging device is against the patient's skin, creating enough friction so that the massing device stays fixed on the woman's uterus.

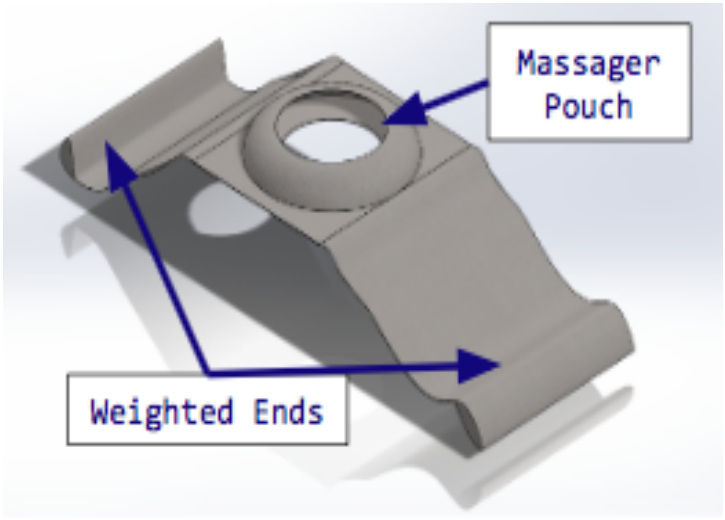

Figure 14: CAD model of securing mechanism with pouch.

Engineering Analysis

Theoretical Modeling

Stall Torque

In order to analyze our first and part of our last design drivers, which were the ability to stimulate the uterus, and the mechanism being safe for the patient, we did a torque analysis. In order for the uterus to be stimulated, our mechanism requires a rotating massaging plate, if the plate does not rotate, the uterus will not be stimulated. By doing this torque analysis, we were able to find how much torque our motor could tolerate before it would stall. As shown in Figure 19, we used force analysis to determine the net force and normal force no the body using Equation 1, where *m* (kg) is mass, *a* (m/s^2) is acceleration, and *F* (N) is force on the body:

$$F_{Net} = \left(m_{Weights} + m_{Mechainsm}\right)a = F_{Normal} \quad \text{(Equation 1)}$$

We then used F_{Normal} to find the force of friction on each individual ball. We used this as an opportunity to explore biocompatible materials with different coefficients of friction in order to material that would give us the lowest friction force. By using a low coefficient of friction material, we significantly reduced the possibility of the motor stalling and overheating and therefore reduced the risk of burning the patient. We settled on using nylon as our fabric of choice because it is biocompatible, easy to clean, and has a low coefficient of friction. To calculate the friction force, $F_{Friction}$ (N), we used Equation 2, where μ (um) is the coefficient of friction of nylon (Figure 20):

$$F_{Friction} = F_{Normal}\mu_{Nylon} \quad \text{(Equation 2)}$$

Finally, with these variables we were able to find the torque that our mechanism will produce. We first found the torque on one of the balls, $T_{1\ ball}$ (N-m), by using Equation 3, we then used this to find the total torque on all three of the balls by using Equation 4, where *d* (m) is the distance between the point of application of the friction force and the location of the shaft (moment arm), which can be seen in Figure 21:

$$\mathrm{T}_{1\ ball} = F_{Friction}d \quad \text{(Equation 3)}$$

$$\mathrm{T}_{Total} = 3\mathrm{T}_{1\ ball} = 0.0534Nm \quad \text{(Equation 4)}$$

From this equation we were able to find the total torque to be 0.0534N-m, which is much lower than we expected. Because our torque was so low, we able to choose a motor with a low stall

torque, which opened a world of opportunities for us in terms of shapes and sizes of our motor. We now have the potential to make our housing much smaller and to perhaps have it powered more easily by battery, while still having a safe mechanism for the patient. This torque is a great base analysis for the torque of our mechanism, but we will probably need to reconsider it once we do more research pertaining to the optimum rpm of our rotating massager.

Applied Pressure

Another design driver we had, in regards to safety, was that our pressure does not exceed 2 psi on the patient's uterus. To analyze this driver, we needed to do a pressure analysis of our mechanism. In order to do this, we used the F_{Net} and F_{Normal} calculated previously. We then found the area of each of the balls on the massaging plate, as that is where the pressure will be concentrated while the mechanism is in use. We found this for each individual ball by using Equation 5, where A (m^2) is the total area of the balls, r (m) is the radius of one of the balls:

$$A_{Total} = 3(\pi r^2) \qquad \text{(Equation 5)}$$

We then did a pressure analysis using this area by using Equation 6, where P (N/m^2) is the total pressure that the device exerts on the patient:

$$P_{Total} = \frac{F_{Normal}}{A_{Total}} = 7087.44 \ \frac{N}{m^2} \qquad \text{(Equation 6)}$$

We found that the total pressure exerted on the patient would be 7087.44 N/m^2, when converted, this is 1.03 psi, which is much less than our threshold number of 2 psi. From this test, we concluded that we were not subjecting the uterus to harmful amounts of pressure. This pressure test, though valid now with our current design, may need to be redone if we decide that a different shape and size of massager and plate would be more optimal.

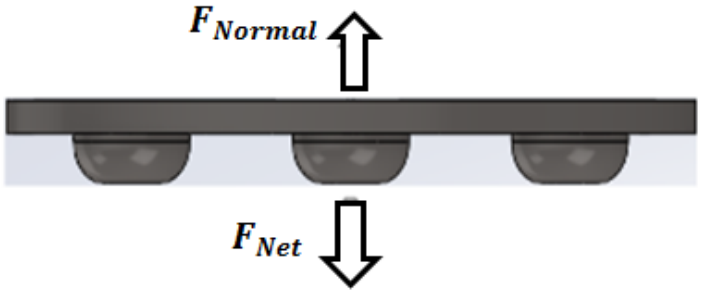

Figure 15: Force analysis on entire plate

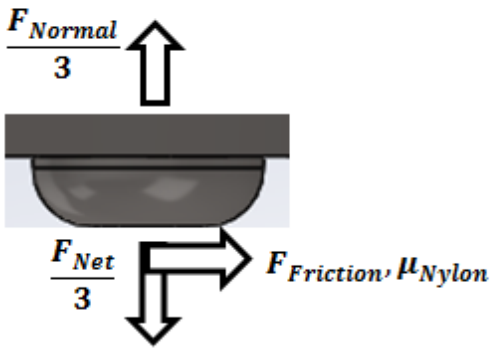

Figure 16: Force analysis on one single ball

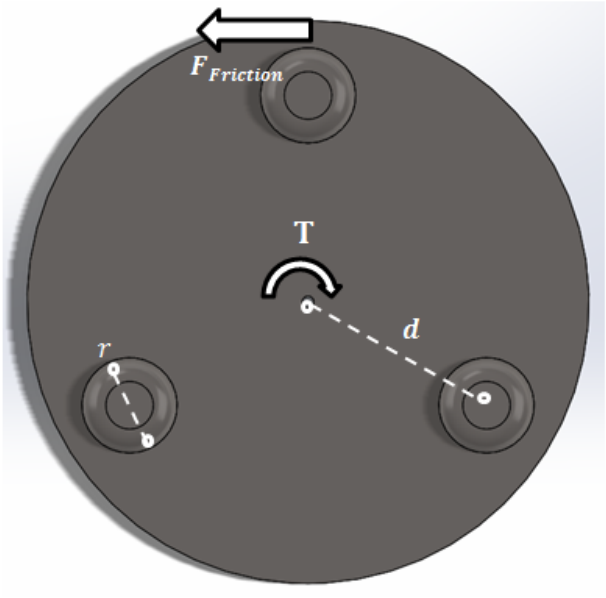

Figure 17: Friction force and torque on plate

Required Stimulation Area

It is from our uterine stimulation information that we were able to find the area of uterus that we needed to stimulate in order to produce contraction in the uterus. The largest area we would need to stimulate in order to produce one action potential would be the area of 40

myosin-actin (Figure 22) fiber pairs lined up next to one another. We used the size of each fiber and found the area it would take in order to stimulate 40 contact points using equation 7 where *A* is area (m^2), *L* is length of fiber (m), and *w* is width of fiber (m):

$$A_{Contact} = 40((Lw)_{Myosin}+(Lw)_{Actin}) \quad \text{(Equation 7)}$$

We found the area of contact to be $6.16x10^{-5}$ m^{-2}, which is the area is would take to create one action potential. Our massaging semicircles will make contact with an area of $1.52x10^{-3}$ m^2, which means we will be stimulating enough area to produce 24.67 action potentials which means that the uterus will contract much more quickly than with one action potential.

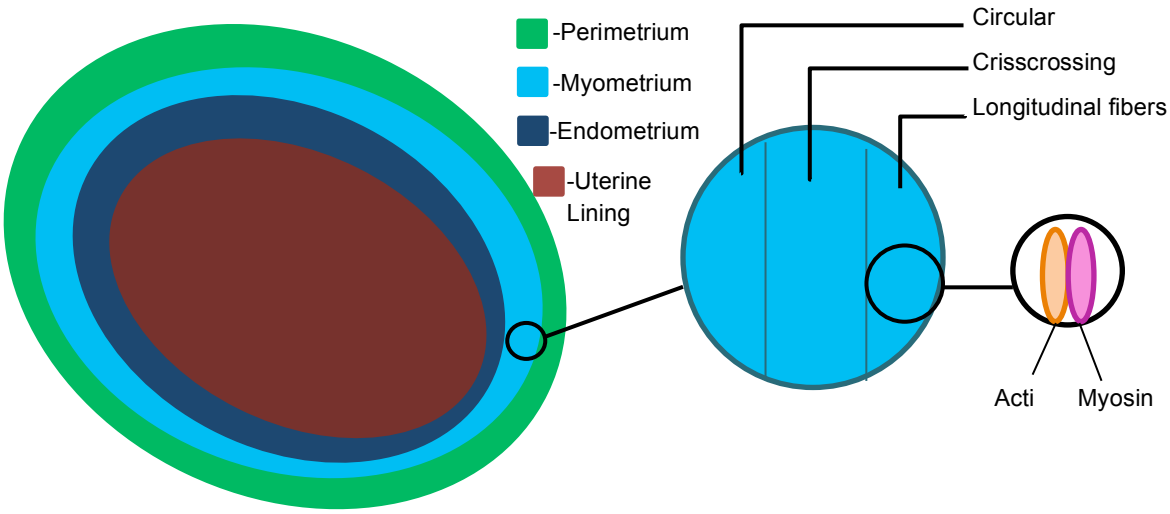

Figure 18: Breakdown of uterine muscle layers

Required Battery Life

In order to determine that four AA batteries are the best choice to power our device, we had to perform an analysis to determine how long the batteries would last. The first step is to determine angular acceleration that is desired. We recorded videos of a nurse performing the

massage and determined the average rotations per minute her hand made. Using Equation 8, we converted the rpm to angular velocity, ω (radians/second).

$$\omega = rpm * \frac{2\pi}{60} = 40.67 * \frac{2\pi}{60} = 4.26\, rad/sec \quad \text{(Equation 8)}$$

Using Equation 9, we are able to determine the power output, P_{out}(watts), which is needed in order to rotate the plate.

$$P_{out} = \omega * T_{total} \quad \text{(Equation 9)}$$

The power that is inputted into the motor equals the power out of the motor, giving us Equation 10 We then used the relationship between the input power, P_{in} (Watts), current required to rotate the plate, $I_{required}$(Amps), and voltage supplied by the batteries, *V* (V), (Equation 11) to establish a relationship between the angular velocity, torque, voltage and current required to rotate the plate (Equation 12). We know the voltage from the four AA batteries (6V) and we can use angular velocity found in Equation 8 and the total torque found in Equation 4 to determine the current required current.

$$P_{in} = P_{out} \quad \text{(Equation 10)}$$

$$P_{in} = V * I_{required} \quad \text{(Equation 11)}$$

$$V * I_{required} = \omega * T_{total} \quad \text{(Equation 12)}$$

$$I_{required} = \frac{\omega * T_{total}}{V} = \frac{4.26 * 0.0178}{6} = 0.0126 \text{ Amps}$$

The next step is to calculate the total current of the system, I_{total}(Amps) using equation 13, which is the free run current of the motor, $I_{free\,run}$(Amps), plus the required current. The free run current is 70mA and was found in the motor specs [29].

$$I_{total} = I_{free\,run} + I_{required} \quad \text{(Equation 13)}$$

$$I_{total} = 0.07 + 0.0126 = 0.0826 \text{ Amps}$$

Finally, we used Equation 14 to determine how long the batteries will last, where *BL* represents the battery life in hours. The discharge rate is the same as the total current of the system. The total current was closest to a discharge rate of 100mA and we took the average of amp-hours,

AH (Amp-hours) at this rate [30] to be the amp-hours of the batteries. Multiplying by 0.7 accounts for the fact that our device will not be 100% efficient.

$$BL = \frac{AH}{I_{total}} * 0.7 \qquad \text{(Equation 14)}$$

$$BL = \frac{2.1}{0.0826} * 0.7 = 17.8 \text{ hours} = 71 \text{ 15-minute intervals}$$

Converting the total hours into 15-minute intervals gives us the amount of full massaging cycles that will be provided by four batteries.

Empirical Testing

To determine the desired speed, motion, and force applied by our massage plate, we observed the uterine massage performed by Dr. Jody Lory at the School of Nursing. We took a video recording of her performing the massage on a scale three separate times and took our data from these video recordings.

Additional empirical testing that we intended to perform previously involved utilizing the expertise of doctors and nurses at the University of Michigan Department of Obstetrics and Gynecology. We hoped to acquire a variety of different massage heads commonly used on the market and present them to our panel of experts and to then use the Delphi Method and incorporate multiple rounds of interviews and utilize a facilitator to provide an anonymous summary of results from previous rounds of interviews. This way, our experts would be presented the massage heads in different orders in each round, and they would utilize the expertise of their peers to converge their assessment until ideally, one specific massage head was chosen as the best at replicating uterine massage. However; due to the busy schedule of our contact at the UM Hospital, we were not able to schedule this testing during this semester. Looking forward to the next steps of this project, this type of testing is something we intend to pursue.

We plan to perform additional empirical testing once we have our final prototype. This testing will be performed to demonstrate that our product is easy to use and appealing. The prototype will be brought to a random population with no prior knowledge of function and will be asked to set up and use the device using only the attached stickers, which pictorially indicate setup and use. Additionally, a Likert Scale will be generated and distributed to the random population and we will use this data to analyze whether or not our product meets our user requirement for 'appealing' (see User Requirements and Engineering Specifications section).

Prototype Construction

We will 3D print the housing unit, as shown in figure 19. By 3D printing the housing, we can create mounts for the motor and the massaging plate, which will make assembling and manufacturing easier.

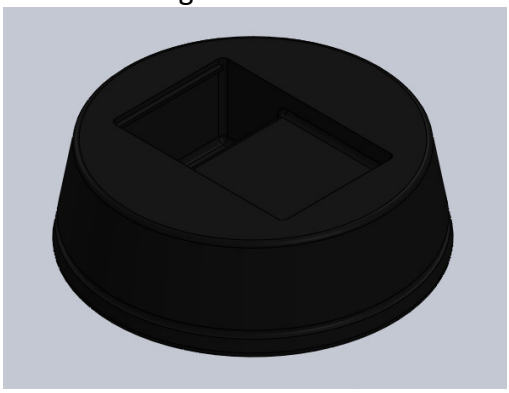

Figure 19: Housing unit

This bowl will house the Pololu 200:1 Plastic Gearmotor with a 90° output. Using gearmotor with a 90° output will eliminate the need for an additional gear. The gearmotor will turn our massaging plate. As of right now our massaging plate is a small circle the size of the uterus with three balls attached. The plate will move in a circular motion, providing the massage to stimulate the uterus. The massaging device will be battery powered, requiring four AA batteries. We were initially thinking to place the four batteries together, as shown in the mockup (figure 20), but while designing in CAD we decided to place the batteries in groups of two, as shown in 13. Separating the batteries into two pairs allows us to have a smaller housing device. The batteries will be located within the housing, but there will be a cover to access them from the top of the massaging device. The on-off switch will also be on the top of the housing. To make the silicone cover, we will 3D print a mold and then pour melted silicone into the mold. We will then use silicone-epoxy to stick the nylon to the silicone cover.

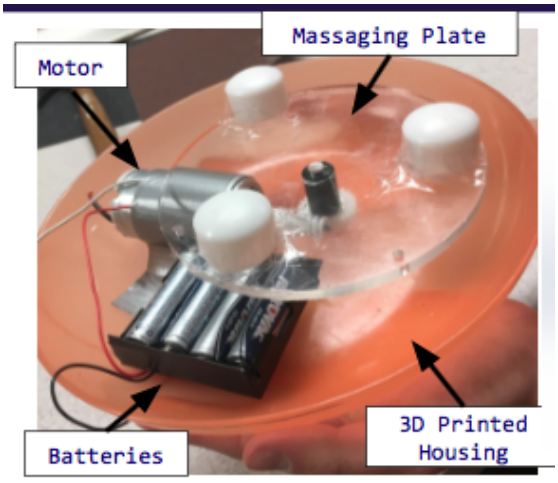

Figure 20: Mockup of massaging device

We made the securing mechanism mockup as shown in figure 21. We left a large pouch for the massaging device to sit in, but we realized that the pouch is too large and will have to be smaller for future prototypes. We also learned that we will need to find a way to secure the massaging device inside the pouch on the securing mechanism. We want to have the top and the bottom of the massaging device exposed so that the on/off switch and batteries are easily accessible and we want the silicone on the bottom of the massager to come in contact with the patient's skin because the friction generated from the skin-to- silicone contact will help keeping the massager in place. We are still unsure of how we will keep debris from getting caught between the open holes of the pouch and the massager.

We also learned from the mockup that the securing device does not have to be this large. The width only needs to be slightly greater than the diameter of the bottom of the massager.

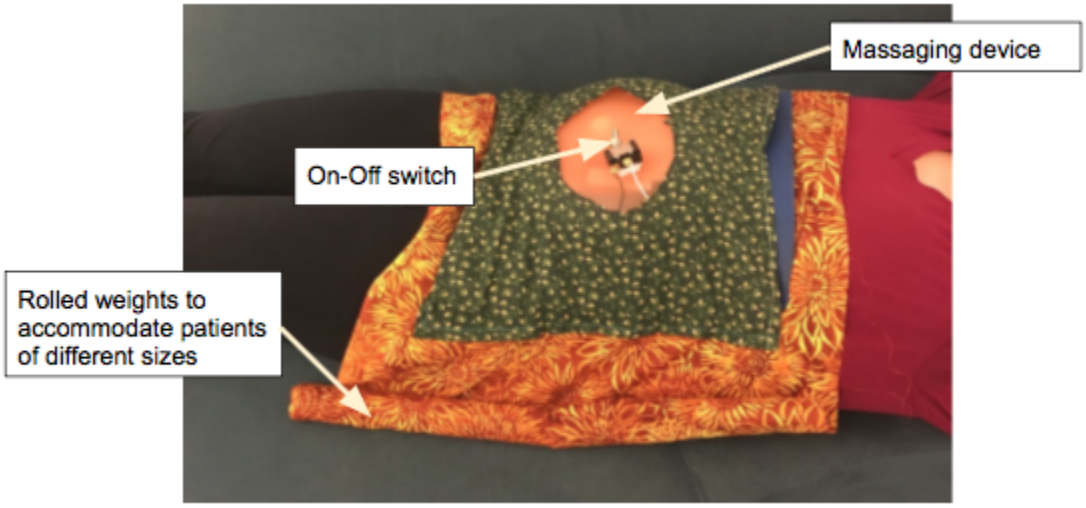

Figure 21: Securing mechanism mockup

FMEA/Risk Analysis

In order to perform a Failure Mode and Effects Analysis (FMEA), we first identified the major components and then went about analyzing how they each might fail. The components that we examined include the motor, the turning plate, the housing, the attachment mechanism, the attachment and the power supply. For each of these components, we generated a table, which included six metrics: hazard, likelihood, impact, level, technical performance, and action to minimize the hazard. The hazard is simply how the device could fail and cause negative effects. The likelihood is “low,” “medium,” or “high” based on our team’s consensus of how often each hazard might occur. Impact is “low,” “moderate,” or “serious” depending on how much the hazard would affect the user if it occurred. Level is a ranking between zero and five that corresponds to the combination of impact and likelihood. Technical performance describes exactly how the hazard might occur. Action to minimize describes how we as a design team will attempt to prevent the hazard from happening. Table 5 shows our FMEA for our device.

	Hazard	Likelihood	Impact	Level (0-5)	Technical Performance	Action to Minimize Hazard
Motor	Overheats	Medium	Serious	5	Plastic casing and possibly gears would in danger of melting, in which case device would not function. Patient could be in danger of getting burnt	Make sure torque calculations are carefully performed to ensure motor does not stall. Consider high temperatures in environment of use
	Motor injures skin	Low	Serious	2	Patient, nurse, or engineer performing maintenance could shear their skin if they were to take apart the device and touch the moving motor	Adequately secure casing so motor is not exposed
	Motor won't spin	Low	Low	1	Device would not function	Ensure motor encasing securely holds all motor parts
Rotating Plate	Crack/Break	Medium	Low	3	Could stab patient in the uterus	Make plate of material that can withstand force calculated during force analysis
	Plate tilts off axis	Low	Low	1	This would apply uneven pressure as it spins, leading to inadequate massaging	Ensure design takes plate alignment into account
Housing	Breaks or cracks	Low	Moderate	3	This would allow openings for debris and fingers to get caught between the gears, or could create friction on patient's skin	Perform calculations to account for drop force
	Material degrades	Medium	Low	1	Cleaning agents could cause material to degrade, exposing moving parts of the mechanism	Ensure materials that do not degrade with common hospital cleaning agents are chosen
	Bacteria caught in housing	Low	Low	1	Bacteria could build up in crevices, and potentially spread infection to patients and healthcare professionals	Ensure design leaves no holes or openings that cannot easily be wiped down with a cloth
Weighted Vest	Causes too much pressure on the uterus	Low	Moderate	2	Could cause the motor to stall due to more friction	Calculate pressure on uterus due to weights to ensure does not exceed 2 psi
	Does not secure mechanism to uterus	Low	High	3	The device will not be effective in its ability to stimulate uterine contractions	Many empirical tests in order to make sure the device works under many different conditions and positions
Power Supply	Could cause electrocution	Medium	High	4	Could shock user	Utilize currents and voltages no greater than those that are commonly used in hospitals

Table 5. FMEA

The hazard that we saw as the highest risk associated with our project is that the motor may overheat for any reason, including excess torque. This overheating may lead to the housing melting, the motor melting, and/or the overall device becoming hot to the touch. We see this hazard as medium likelihood due to the fact that it will be used by stakeholders who probably have no knowledge of how motorized devices function. The impact that this would have is serious because in the worst case scenario a patient or medical care provider could get burned by the device. In order to prevent this overheating, we will do torque calculations for the load the motor will be responsible for counteracting and we will take the high temperatures of the climate in Ghana into consideration. This risk does not require us to make any changes to our design, but it will require that we keep the amount of torque we will be applying in mind

throughout the process. Further discussion of the FMEA that we performed can be found in Appendix C.

Manufacturing Plan

Our design contains very few parts that require machining. Many components of our mechanism (geared motor, batteries and battery holder, wiring, switch, magnets for pouch in attachment mechanism, weights for attachment mechanism) have been or will be purchased from stock. We have also purchased the vinyl and nylon material which will be sewn to make the attachment mechanism and low coefficient friction layer on the silicone base, respectively. Other parts of our design are the device housing, lid, and massage plate, which have been 3d printed. The pros of 3D printing far outweigh the cons for our design. Because we are 3D printing the device casing, we have been able to incorporate a battery door, a hole for the on-off switch, and geometries to easily mount the motor and battery pack to our device. We will 3D print negative molds, which we will pour silicone into for the silicone base so we can achieve the lip design that easily fits on to the casing. Another reason we chose to make these designs such that they must be 3D printed is potential mass manufacturing of our product. Both the device housing and silicone base would be injection molded in the case of mass production. Our designs for both of these parts require minimal assembly, which would decrease cost and potential quality issues during mass production. For example, if we were to simply use a hemispherical dome for the device housing, mass production would require an additional assembly step of securing the motor and battery pack mounts to this housing. Additionally, the design of our silicone base requires no screws or additional parts to secure the base to the housing. Had we chosen a simpler design that did not require 3D printing, we would likely increase the per piece cost during mass production by adding additional off-the-shelf parts and additional assembly steps. The cons of 3D printing for both of these parts will likely be a rough surface finish that requires sanding, and the possibility of multiple rounds of printing until a high quality part is produced. Additionally, we will have to consult with experts and think critically when designing parts that are 3D printed because we must consider where supports are needed. Our 3D printed housing and rotating plate can be seen, assembled, in Figure 22.

Figure 22: 3D printed turning plate and housing, viewed from the bottom.

To manufacture the shaft used to connect the motor and the massaging plate, we used a ½ in steel shaft. We first used the lather to cut it down to 0.4in. We then used the lathe to make a 0.2in deep, 0.161in diameter hole into one side of the shaft, we then tapped that hole with a #29 tap for the massaging plate. On the other side of the shaft, we made a 0.2in deep, 0.275in diameter hole for the motor shaft. On the motor shaft side, we then used the mill to make two 0.098in diameter through holes located on either side of the shaft for #4-40 set screws.

To manufacture the silicone base, OOMOO 30 silicone was poured into a two-piece mold and allowed to cure. Part one of the two-piece mold was created by laser cutting a disk and a ring of ¼" thick acrylic. Both pieces of acrylic had the same outer diameter and the ring was aligned and secured on top of the disc with adhesive bonding spray, to allow 0.25" of depth for the silicone to protrude out of the securing mechanism, allowing it to make better contact with the patient's skin. Tape was secured around these pieces to contain the poured silicone (see Figure 23).

Figure 23: Part one of the two-piece mold

Part two of the two-piece mold included two more discs of laser cut acrylic secured to the inside of the 3D printed housing. The disc seen at the top of Figure 21 (.5" thick) had smaller diameter to offer .5" of depth for the balls on the massage plate to rotate in.


Figure 24: Part two of the two-piece mold

A thin layer of silicone was poured in part one of the two-piece mold and then a ruler was secured to the part two of the two-piece mold and set at an elevated position inside part one, and silicone was poured to fill in the sides of the mold. Silicone was poured to a height above the lip in the casing. See Figure 25. Figure 26 shows the silicone base after curing for 6 hours.


Figure 25: Two-piece mold fully assembled


Figure 26: Silicone covering (purple) with nylon insert (green)

The securing mechanism was sewn out of a light blue vinyl fabric, as shown in figure 27. The massaging device is sitting in the pouch of the securing mechanism and a zipper is keeping it shut. The weights are shown rolled up on the side, to account for the varying sizes of women.

Figure 27: Securing mechanism on a volunteer

Bill of Materials

Made in House

#	Description	Material	Manufacturing Processes	Assembly Processes
1	Device Housing and battery cover	ABS	3D Printing	NA
2	Silicone Base	OOMOO 30 Silicone	Laser cutting acrylic for mold, pouring silicone into mold and allowing to cure	Secure to device housing
3	Massage Mechanism Plate	ABS	3D Printing	Secure to Shaft
4	Motor Shaft Attachment	Steel	Lathe to correct inner and outer diameter, milled set-screw hole, hand-tapped.	NA

Off-The-Shelf Parts

#	Description	Manufacturer	Part Number	Cost
5	200:1 Plastic Gearmotor, 90 degree output	Pololu	1120	5.75
6	Side-by-Side Spring Battery Holder (2)	McMaster Carr	7712K12	1.38
7	Wiring	(mechatronics lab)	NA	0

8	Switch	(mechatronics lab)	NA	0
9	Magnets	Joann Fabrics	TBD	4.99
10	Weights for Attachment Mechanism	TBD	TBD	TBD
11	Nylon Sheet	Joann Fabrics	TBD	4.52
12	Vinyl Sheet	Joann Fabrics	TBD	10.11

Validation

Requirement	**Specification**	**Validation Protocol**	**Status**
Effective	Measure angular velocity of plate, compare with data from Dr. Lori's massage	Plate rotates at 150 rpm	✓
	Determine that pressure applied to uterus is less than 13,900 N/m2	Device applies 4,877 N/m2	✓
Safe	Use biocompatible materials		out of scope
Easy to use	Takes ≤ 2 minutes to set up and begin use	Took 10 students an average of 41 seconds to set up	✓
	Includes < 5 separate parts for midwives to assemble	Device contains 3 separate parts	✓

Durable	Lasts > 11,000 uses	Build test fixture that would expedite wear on device	out of scope
	Can be dropped from a height of 2m	Drop device from a height of 2 m	out of scope
	Materials do not degrade from cleaning solutions used in hospitals	Soak materials in the cleaning solution	out of scope
	Device has sufficient battery life	Can run for 1,065 minutes	
Accommodates women of different sizes	Securing mechanism is at least 1326 mm long [19]	Belt is 1330 mm long	
Portable	Weighs less than 2 kg	Weighs 1.67 kg	
Appealing	Receives a median score of 3.5 out of 5 on a Likert Scale	Scored an average 4.1 amongst 10 students	

Table 6: Validation Testing

To validate the Effective user requirement, initial did theoretical calculations to determine the amount of surface area that must be stimulated to induce uterine contractions (see Engineering Analysis). Additionally, because there is currently limited literature on uterine massage, we gathered quantifiable data from Dr. Jody Lori of the University of Michigan School of Nursing.

Dr. Lori performed the massage on a scale while we videotaped her hand motion and the scale readings. This testing was repeated three times. We were then able to gather the average normal force (which was converted to a pressure value by dividing by area) and rotational velocity values from each of the three trials, and determine the average as a reference that we would attempt to replicate with our device. After production of our final prototype, we determined rotational velocity and pressure using the same methods and found that our device rotates at 150rpm, which closely replicates our reference value of 122rpm. Additionally, the pressure applied to the device was found to be 4,877 N/m2, which is well below 13,900 N/m2, or the amount of pressure that would cause harm to the uterus [9].

To validate the Safe user requirement, we intend to ultimately confirm that all exposed materials are biocompatible. Although we are not using medical grade materials for our prototype for this project, we have confirmed that as this project progresses, all chosen exposed materials will indeed be biocompatible.

In validating that our device is easy to use, we have confirmed that our product will contain only three parts when delivered to the hospital: the casing with motor and massage plate assembled, the silicone base, and the securing mechanism. Therefore, this requirement is met. We also conducted 'ease of use' testing by gathering a random sample of 10 students who were unfamiliar with our product and giving them the device to set up on a patient and adjust it to accommodate the patient's size. The only information they were given was that the device massaged the uterus and the location of the uterus on the patient. It took this sample of students an average of 41 seconds to set up the device so our user requirement is met. To validate durability, we calculated the battery life of the product to be 1,065 minutes (see Engineering Analysis) but all other testing was out of scope due to the prototype being manufactured out of materials and methods that would not be used in the final production product.

To validate that our product accommodates women of different sizes, we gathered anthropometric data on abdominal circumference during the third trimester of pregnancy from the UM Transportation Research Institute and the maximum was found to be 1326 mm [31]. This maximum size constraint is met with our design, which features a belt that is 1330 mm long. There is no need to calculate minimum size constraint due to the adjustable design of our securing mechanism. We were able to validate portability because our device weighs 1.67 kg, which is less than our 2kg benchmark. Additionally, when gathering the random sample of 10 students for ease of use testing, we were also able to validate appealingness. The average score that this sample rated our device on how appealing it would be to a patient was 4.1 out of 5, which meets our requirement. Additionally, we have confirmed that the price of all purchased parts and material and the labor cost associated with our manufacturing processes (considering injection molding for the housing and plate as opposed to printing) is under $100 per product. We are confident that were our product to be mass produced, this price would be well under the benchmark due to the fact that our highest cost was 3D printing, and injection molding would significantly bring down cost.

There are several validation tests that we would perform were we given more time or a larger budget. The first being reduction in bioburden, which falls under the safety requirement. Given a larger scope of this project, chemical testing on how well this product is cleaned after use in a hospital setting would be performed.

Additionally, were we able to manufacture our device out of medical grade materials and utilize mass production fabrication techniques (injection molding), we would perform further validation testing. We would create a test fixture that would expedite wear on the device and determine if it lasts more than 11,000 uses. Specifically, we would be concerned with the life of the nylon secured to the silicone as we would expect this to be our first sign of wear. If we had more time, a further way to validate that our product is effective in stimulating uterine contractions would be to conduct pre-clinical and clinical trials. If we had the budget to produce our product out of medical grade silicone, nylon, and plastic, we would be able to soak materials in cleaning spirits to confirm that it doesn't degrade. Given the resources and availability of materials and manufacturing methods used in mass production, we would perform drop testing from a height of 2m on samples to validate durability.

More information about our validation testing can be found in Appendix D.

Design Critique

The device met all of the user specifications, but after building the final prototype, there are a few design critiques. In order to select the motor for the device, engineering calculations were used to determine the force necessary to turn the massaging plate. These engineering calculations did not account for the extra force added by the silicone cover, nor did the motor selection account for human added pressure. Almost every person who saw the working prototype would put their hand over the rotating plate and press down. This showed that although mathematically the device worked, the motor selection didn't account for human interaction. Moving forward, the motor in the current design would be replaced with a motor with a greater stall torque so that the plate would still rotate with a silicone cover and a person pressing down on it.

Another critique of the design is that the silicone cover was thicker than the design called for. The team members poured the silicone themselves and performed multiple iterations, so it did not make financial sense to spend so much money on medical grade silicone. The silicone used was much weaker than medical grade silicone; therefore it was not possible to make the cover as thin as desired without it tearing as soon as the massaging balls came into contact with it. In future work, the silicone cover will be made of medical grade silicone so it would be possible achieve the desired thinness without the massaging balls tearing the cover. The pouring of the silicone was expected to be the greatest hurdle of the prototype and these results were not surprising.

Future Work

The next step in the project would be to send it over to the Korle-Bu Teaching Hospital in Ghana. There will be a summer internship that is a continuation of Anna's internship this past summer. The UM students will take our prototype to the KBTH where they can see how the doctors and midwives react to the device. Here they can gather feedback and see what changes should be made, especially whether a timer switch should replace the current button- switch. When the students return from Ghana, either they will make a new prototype, or perhaps the device will be an ME 450 project again. From that point, students will reach out to other hospitals to generate an interest in our device. From there, the device will go into mass production. Once the device is in mass production, the final validation tests, as mentioned previously, will be performed. Then the device will undergo preclinical and clinical trials before it's implemented in low-income hospitals across the globe.

ACKNOWLEDGMENTS

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Author Biographies

Anna Buzolits (Sponsor Contact)

Anna is a senior in mechanical engineering at the University of Michigan in Ann Arbor, MI with prior experience with both design ethnography and Ghanaian culture, as she studied appropriate technology in Kumasi, Ghana for six weeks in 2013. Anna has experience with the design process in the form of three design classes, in which she learned about the design process, computer-aided design, and prototyping. She has been an instructional assistant for a freshman-level design class for three semesters and is a member of UofM's Pi Tau Sigma mechanical engineering honor society. Recently, Anna has completed a Global Health Design Internship on the very topic of this project and she joined a research team working in the Smart Materials and Structures Design Lab at UofM.She is also on the executive board for the FIRST Alumni and Mentor Network at Michigan, an organization that seeks to act as a liaison between UofM and FIRST®. In the future, Anna hopes to receive her PhD. in mechanical engineering and become a professor.

Jordan Toor (Safety Officer)

Jordan is studying at the University of Michigan and is a senior in mechanical engineering. She has experience being in the medical field at UofM hospital through job shadowing and volunteering. She also spent two years working in a prosthesis lab sponsored by the U of M Surgical department, where she was the primary researcher on a project focusing on somatosensory stimulation at the peripheral nerve interface. Most recently, she studied sustainable engineering for eight weeks in Troyes, France where she completed multiple projects involving the design process and prototyping. Currently, Jordan is a member of the executive board of the University's Club Gymnastics Team, where she is serving her second year as president. After graduating, she hopes to pursue her dreams of becoming a doctor by attending medical school.

Taylor Petri (Facilitator and Treasurer)

Taylor is a senior studying Mechanical Engineering at the University of Michigan. She has had the opportunity to participate in three years of research in Shuichi Takayama's Biomedical Engineering Lab and piloted a variety of projects involving microfluidic devices, soft lithography fabrication, cell culture, and analysis of material parameters in cellular constructs. Additionally, Taylor has had the opportunity to gain industry experience through two internships in a Supplier Development Quality Engineering role for the metals commodity at Stryker Medical. Currently, Taylor is Tour Manager and a member of the executive board of the Women's Glee Club at the University of Michigan and also serves as president of Midnight Blue, an a cappella group within the Women's Glee Club. After graduating, Taylor will work as a Supplier Development Quality Engineering at Stryker Medical in Kalamazoo, Michigan.

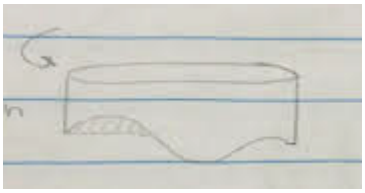
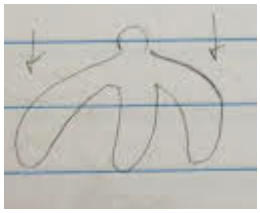
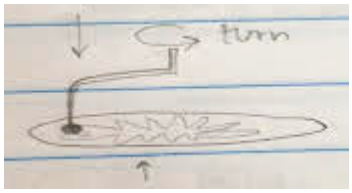
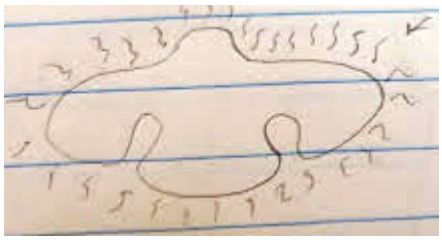
Sarah Geshwender (Portfolio Manager)

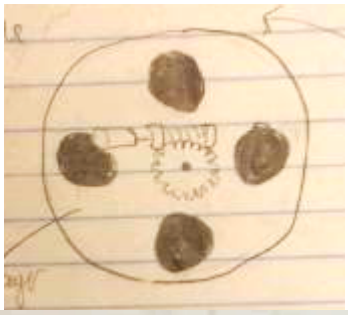
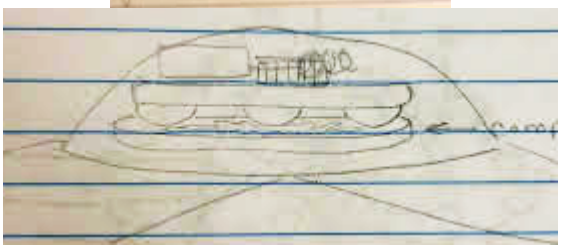
Sarah is a senior studying Mechanical Engineering at the University of Michigan. She spent last summer interning at Hill Mechanical in Chicago, IL, where she ran load calculations on buildings in order to determine the heating, ventilation, and air conditioning needs of new and existing construction projects, focusing specifically on office buildings and candy factories. She would also calculate the stress placed on plumbing fixtures and help to design the plumbing systems of high rise apartment buildings. Additionally, Sarah is very interested in sustainable practices and is working towards completing her certificate in sustainability through the college of engineering. She hopes that after completing her degree she can put her mechanical and sustainable knowledge to help develop environmentally friendly products. Formerly a member of the service fraternity Alpha Phi Omega, she enjoys working with kids in her spare time.

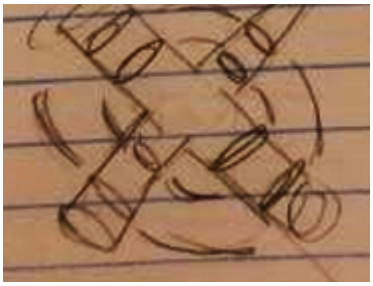
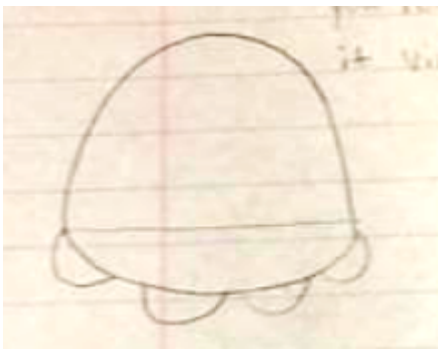
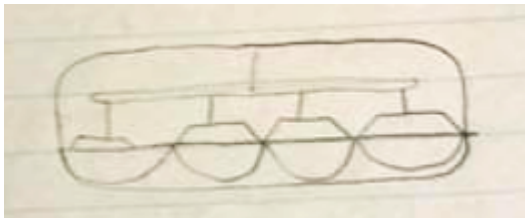
Appendix

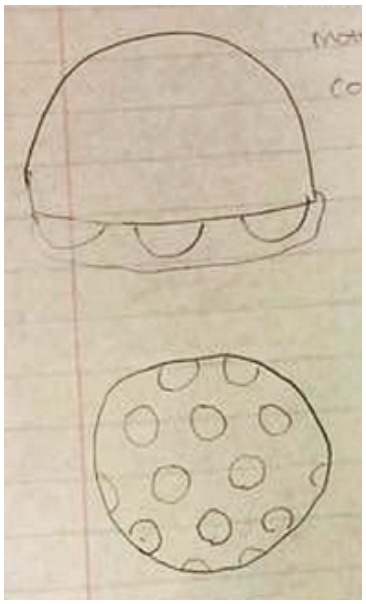
A. Full List of solutions generated during the ideation process

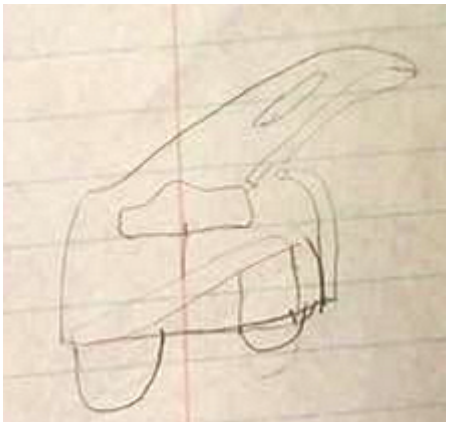
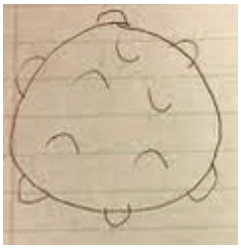
A.1. Massage Apparati

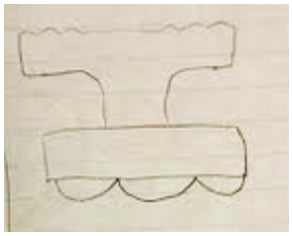
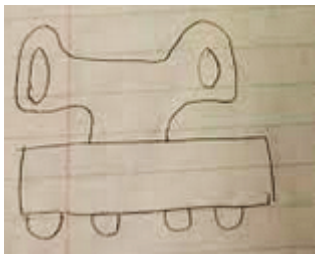
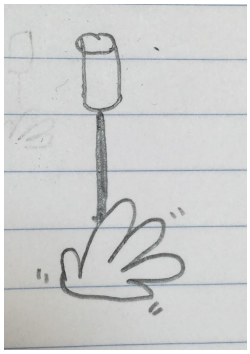
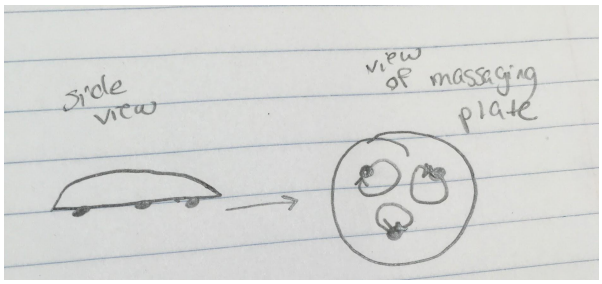
Sketch	Description
	Cylinder with attached spheres; this would spin in place on a compliant mechanism or flexible (low friction) material to massage the patient's abdomen.
	Custom rotating piece; this would spin in place on a compliant mechanism or flexible (low friction) material to massage the patient's abdomen.
	Claw with varying pressure: this would tilt around its axis to apply different pressure around the abdomen.
	Compliant mechanism + single rotating point: this would simply push down one part of the compliant mechanism at a time, applying pressure to the woman's abdomen.
	Vibrating petals: this would sit on the woman's abdomen and vibrate the uterus.

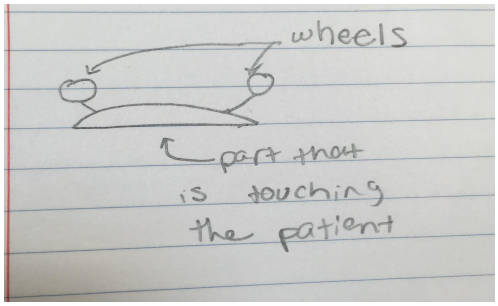
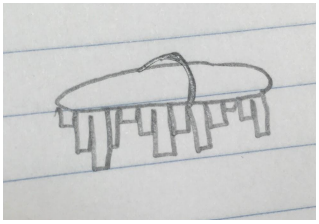
	Cup: this would tilt around its axis to apply smooth but varying pressure around the abdomen.
	Double spinner: two rotating pieces apply pressure on two different sides of the abdomen.
 	Worm gear, 4 balls, plate: a compact design that incorporates a cylinder with spheres on it pressing on a flexible material that touches the woman's abdomen.
 	Replaceable spinning protrusions: these would work like the spheres in several of the other concepts, but they would be removable and individually replaceable.

	Rotating X: has varying height; when it turns it applies different amounts of pressure around the abdomen.
	Hemispherical housing: to go over any of the other concepts.
	Hemispherical vibrating massager: vibrates on the abdomen.
	Piston swashplate thin massager: a tilted plate goes around and pushes down pistons onto the abdomen.

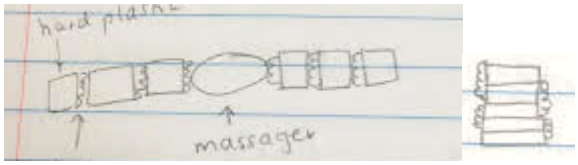
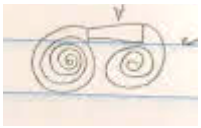
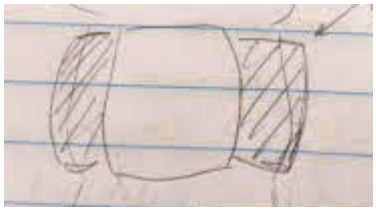
	Vibrating massager with cover.
	Hand-held rotating massager

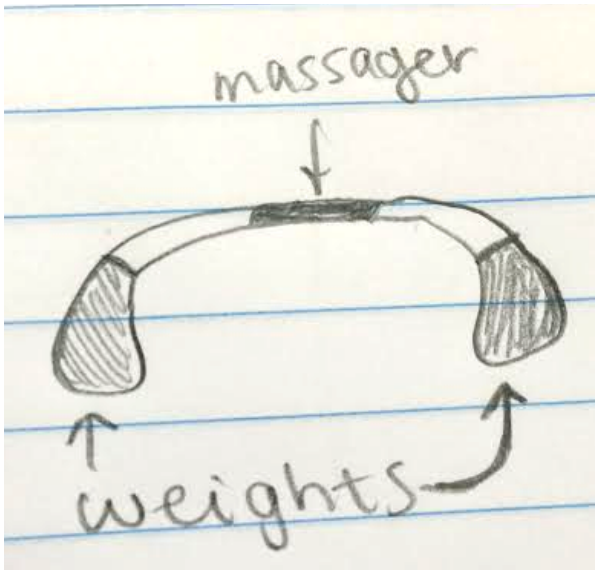
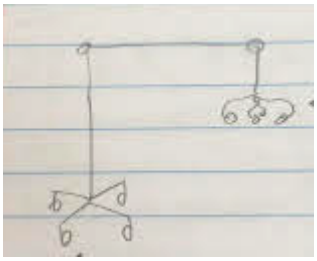
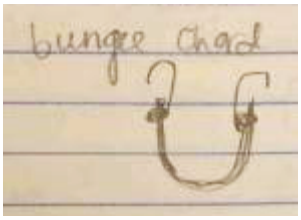
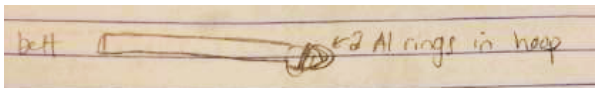
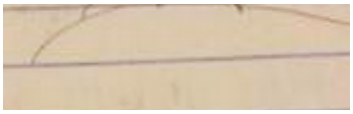
	Handheld swashplate massager
	Manually operated ball massager: user would roll this over the abdomen themselves.
	Ball massager with handle (see above)
	Battery-powered ball massager: the bumpy ball would roll itself on the woman's abdomen.
	Hand-held pressure massager: to be rubbed on the abdomen.

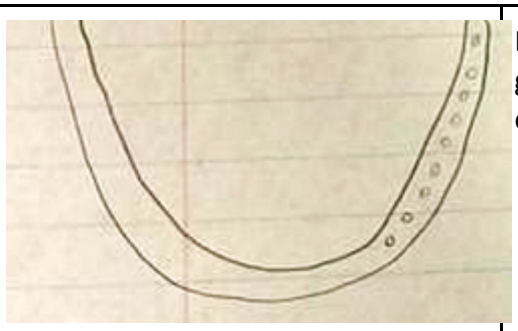
	Different handle design
	Different handle design
	Hand-held rocker massager
	Massaging mechanism in the shape of a hand to exactly replicate the midwives massage.
	Massaging mechanism with three small balls rotating in three small circles

	Massaging device that is already weighted so a securing mechanism is not needed. It has wheels for ease of transport.
	Handheld massaging device that moves in a wave like motion, applying varying pressure to the uterus.

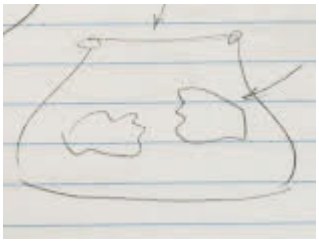
A.2. Attachment Mechanisms

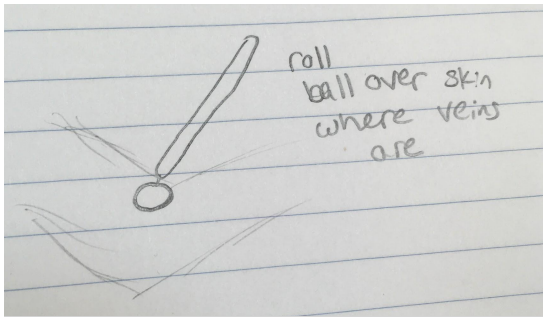
	Fold-able, hard-plastic belt; this is several hard plastic rectangles held together with flexible plastic wire or (?). It would be easy to clean and could fold up for easy storage.
	Rollable, bed-attached belt; this belt is attached to (but removable from) the bed frame. When it is needed, the midwife would pull it across the patient and attach it to the other side of the bed.
	Wide “African print” cloth; this wide cloth would be brought with the patient when she comes into the hospital and attached to the massage apparatus. It would then wrap around the patient’s back during use.

	Weighted belt; this belt is heavy on each end to keep the massager in contact with the patient without having to go behind her back.
	Reach-over bar; this would be wheeled from room to room and be adjusted up and down to put the right amount of pressure on the woman's abdomen via the attached massaging apparatus.
	Bungee cords: these would attach to a massager and then to the bed. Four would make the device the most stable.
	
	
	Suction Cups
	Breast-pump suction

	Belt: this attaches to the massager and then goes around the woman's back; self-explanatory.
	Double belt: similar to belt but able to attach to the bed.
	Theraband: stretchable, cleanable rubber that attaches to the massager and tightens around the woman.

A.3. Non-massaging Solutions

	Weights; these weights would just rest on the patient's abdomen, applying uniform pressure on the uterus.
	Instructional apron; this would be worn by the patient who would then know where to put her hands and how hard to press while she gives herself the massage. It could also be used by bystanders who are not skilled birth attendants.

	A device to help midwives and doctors find veins quicker in order to administer the oxytocin quicker. Shaped like a pen with a ball attached to a pressure sensor. The ball rolls on the skin and detects the change in pressure when a vein is found.
	A uterus simulator. Doctors and midwives can use this to teach others how to massage the uterus. Similar to MamaNatalie Birthing Simulator, but less complex and therefore cheaper.

B. DR2 Peer Feedback

Positive aspects of the presentation:

- We gave enough background information our presentation
- Good background information about the teaching hospital in Ghana
- Good variety of concepts
- Motivation for project is clear and powerful
- Good explanation of concept generation process and the different categories of concepts

Negative aspects of the presentation:

- Not all the tables and drawings were legible
- Introduction/ background/ scope could have been more of an update
- Concept design drawings should be more clear
- Labels for the mockup picture would facilitate the design explanation
- Avoid “um”
- Should include some benchmarking in the presentation
- Should consolidate background info/scope/ problem into shorter section
- Include how the chosen concepts evolved from the top designs
- Slides were text heavy

Technical questions or comments:

- Someone liked the apron with hand prints and pressure sensors
- How would you sense where the uterus is?
- Can the african cloth secure the device?

- How will device be powered?
- Consider cultural acceptability of flashes and sounds for the pressure alert system
- How will you attach the band if the patient is lying down/immobile
- How do you verify that this device simulates a real massage?
- Will we have to add a safety factor to the pressure sensor?

C. FMEA Discussion

The next potential hazard for the motor is that, if exposed, the motor rod may touch someone's skin and cause skin damage. This issue is categorized by low likelihood and serious impact, because the motor should never be exposed to the user but, in the event that it is, the consequences could be severe. These consequences would most likely be sheared skin. To prevent this from happening we will design the massaging apparatus so that the motor is not exposed. The final motor failure mode is if the motor simply will not spin, due to faulty wiring, misalignment of the gears within the motor, etc… This would mean the our device could not function and therefore could not help prevent PPH. The likelihood of this event is low because we are buying our motor from a reputable source, and the impact is low because, if necessary, the woman could massage her own uterus, though this would be less effective. We will prevent this by ordering the correct motor according to our motor analysis and by securing the motor to the housing well.

We came up with two failure modes to analyze for the rotating plate in our mechanism. The first is that the plate could crack or break somehow. This is of medium likelihood due to the fact that medical devices are not handled very gently in many settings and may be stored high off the ground from where they could fall and break. The impact of this failure is low because the broken plate would still be enclosed inside the housing and the silicon base. The level, therefore, is 3. In order to prevent this failure we will choose an impact-resistant material to build the plate. Next, the plate could tilt off-axis and therefore apply uneven pressure as it spins around. This is categorized as low for both likelihood and impact because, though it will not necessarily replicate the motion that we are looking for, we have no data on the best method for massaging the uterus and therefore the uterus will still be stimulated we just do not know how well. To prevent this we will design a secure mechanism for attaching the plate to the motor.

The first potential failure mode for the housing is that it could break or crack. This could allow debris, bacteria, fingers, and fluids to get inside the housing and onto the electronics. This is of

low likelihood because we will perform calculations for the impact when the mechanism is dropped and choose a material accordingly, but if it did occur it would have a moderate impact because the motor and the spinning plate could be compromised. The next failure mode is if the material degrades due to the cleaning agents. This is moderately likely due to the nature of chlorine bleach and methylated spirits, but the impact would most likely be low because the degradation would be gradual and easily seen. To prevent this we will choose a material that is most resistant to the corrosive cleaning substances. Finally, bacteria could get caught in the material of the housing. The likelihood of this is low due to the frequency of cleaning at the hospital, and the impact is low because every patient takes many antibiotics during their stay at the hospital, but it could potentially spread infection between patients. Our design will use the minimum number of small crevices and other locations that bacteria could not be reached by the cleaning agents.

The first of the two failure modes for the weighted cloth is it it applies too much pressure to the uterus. This could virtually only happen if we design incorrectly or if someone is pushing down on the device externally, thus the likelihood is low. The impact, however, is moderate because if it did happen it could cause internal damage to the patient. It could also render the massaging device useless. To minimize this hazard we will do pressure calculations to ensure that, on its own, the device does not apply more pressure than a light massage (2PSI). Next, there is the failure mode that occurs if the device is not secured to the patient well enough. This would mean that the device could not massage the uterus but might massage other parts of the abdomen. The likelihood is low because we will use the high coefficient of friction of silicon against skin to keep the device in place. The impact is moderate because it would render the device useless but the device would not injure any user.

The failure mode for the power supply is that it could electrocute a user. The likelihood of this is low, because the power supply will be enclosed in the housing, but the impact is serious because electrocution is serious. In order to prevent this failure mode, we will use currents and voltages similar to other devices of the same type and we will solder the electrical connections so nothing comes loose. We will also enclose the power supply in the housing so no user could touch them.

D. Validation Protocol and Results

The following tests are those which we have performed, plan to perform, or would perform given a larger project scope.

Don’t require timely testing

1. Confirm that all exposed materials are biocompatible

a. Although we are not using medical grade materials for our prototype for this project, we have confirmed that as this project progresses, all materials exposed will indeed be biocompatible.

2. Confirm that costs less than $100

. We have confirmed that the price of all purchased parts and material and the labor cost associated with our manufacturing processes (considering injection molding for the housing and plate as opposed to printing) is under $100 per product. We are confident that were our product to be mass produced, this price would be well under the benchmark due to the fact that our highest cost was 3D printing, and injection molding would significantly bring down cost.

3. Confirm that weighs less than 2kg

. We have confirmed that the product meets our weight requirement.

4. Confirm that assembly contains less than 5 separate parts when delivered to hospital

. We have confirmed that our product will contain only three parts when delivered to the hospital: the casing with motor and massage plate assembled, the silicone base, and the securing mechanism.

May require timely testing

5. Easy to use tests to confirm that takes less than 2 minutes to set up and begin using and takes less than 30 minutes for a midwife to understand how to use it.

a. We will perform this testing using the protocol described in Validation Protocol Expectations

6. Appealing test confirms that score of 3.5 out of 5 on a likert scale is achieved

. We will perform this testing using the protocol described in Validation Protocol Expectations

7. Perform calculations to confirm that belt accommodates women of sizes stated in our specifications.

. We have gathered anthropometric data on abdominal circumference during the third trimester of pregnancy from the UM Transportation Research Institute and the maximum was found to be 1326 mm [31]. This maximum size constraint is met with our design. There is no need to calculate minimum size constraint due to the adjustable design of our securing mechanism.

8. Compare to quantitative values of device to those obtained from nurses.

. We will take speed and pressure values from our functioning device to compare them to those obtained from nurses.

No way to verify within the scope of this class

1. Reduction in bioburden

a. Given a larger scope of this project, chemical testing on how well this product is cleaned after use in a hospital setting would be performed.

2. lasts >11,000 uses

. If we had more time, we would create a test fixture that would expedite wear on the device. Specifically, we would be concerned with the life of the nylon secured to the silicone as we would expect this to be our first sign of wear.

3. stimulates uterine contractions

. If we had more time, a further way to validate this requirement would be to conduct clinical trials to confirm that our product does indeed stimulate uterine contractions and therefore prevents uterine atony.

4. Soak material in cleaning spirits to confirm that it doesn't degrade

. If we had the budget to produce our product out of medical grade silicone, nylon, and plastic, we would be able to perform testing to confirm that our product meets this requirement.

5. Drop test from 2m

. Given the resources and availability of materials and manufacturing methods used in mass production, we would perform drop testing on samples to validate

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