External Cephalic Version (ECV) Medical Training Model

Katie Bailey, Kimia Beigzadeh, Lexi Martin, Emma Nottingham, Audrey Wong

Department of Mechanical Engineering: University of Michigan

ME450: Design and Manufacturing III

Sponsor: Dhanu Thiyagarajan, M.D., Michigan Medicine Obstetrics and Gynecology

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TABLE OF CONTENTS:

EXECUTIVE SUMMARY **4**
ABSTRACT **5**
PROJECT INTRODUCTION AND OBJECTIVES **5**
NEED IDENTIFICATION **6**
Breech Presentation and Current Methods of Management 7
External Cephalic Version as a Method of Management 8
Current Perceptions of ECV 9
The Need for a Training Model 10
DESIGN CONTEXT **10**
Contextual Considerations and Power Dynamics 11
Stakeholder Analysis 12
DESIGN PROCESS **14**
BENCHMARKING **16**
USER REQUIREMENTS AND ENGINEERING SPECIFICATIONS **18**
User Requirements 18
Engineering Specifications 20
CONCEPT GENERATION **25**
Virtual Whiteboard Rapid Concept Generation 26
Design Heuristics 29
Morphological Chart 29
CONCEPT SELECTION **31**
Phase 1: Group Vote 32
Phase 2: Comparing to Requirements 34
Phase 3: Full Concept from Narrowed Subfunctions 35
Phase 4: Concept Iteration 38
First Selected Concept **41**
CONCEPT ITERATION & ENGINEERING ANALYSIS **43**
Uterus Model 43
Baby Model 44
Base Design 45
Outer Layer Material Selections 46
Outer Layer to Base Attachment Mechanism 47
FINAL DESIGN **47**
Design Concept 47
Bill of Materials 51
Build Design Prototype 52

VERIFICATION PLANS **52**
VALIDATION PLANS **66**
DISCUSSION **67**
Problem Definition 67
Lessons Learned & Design Critique 67
Risks 69
REFLECTION **69**
RECOMMENDATIONS **72**
CONCLUSION **72**
ACKNOWLEDGEMENTS **73**
OUR TEAM **73**
REFERENCES **76**
APPENDIX A: Concept Generation **82**
APPENDIX B: Concept Selection **86**
APPENDIX C: Concept Iteration & Engineering Analysis **93**
APPENDIX D: Verification Plans **101**
APPENDIX E: Build Design Bill of Materials **110**
APPENDIX F: Fabrication Plan **112**
APPENDIX G: Project Plan **118**

EXECUTIVE SUMMARY

Malpresentation, when a fetus is not in a head-down position in the womb, inhibits spontaneous vaginal birth and often leads to either a cesarean section or breech delivery, resulting in physical, mental, and financial challenges postpartum. Malpresentation, specifically breech presentation, occurs in 3-4% of all pregnancies at term, with 85.1% of fetuses in breech presentation being delivered via cesarean section globally [1][2].

External cephalic version (ECV) is a low-risk medical procedure aimed at correcting the malpositioned fetus, offering a safer alternative to undesirable delivery methods. Presently, there is a significant gap in medical training in the procedure as there is no simulation training model available for ECV, and the procedure is primarily passed down from doctor to doctor through live cases, especially in low- to middle-income countries (LMICs) where there are few doctors trained in ECV. This lack of trained physicians in LMICs like Ghana has led to underutilization of the procedure.

ECV has a general success rate of 58% and is recommended as a safe, cost-effective procedural alternative to both cesarean and vaginal breech delivery, but it has not been implemented in sub-Saharan Africa and other LMICs due to the lack of training, mastery, or undue perception of adverse outcomes [1][17]. Our team's objective is to develop an ECV simulator to train healthcare professionals in Ghana, empowering them with the necessary skills to perform this procedure effectively.

In discussion with our project sponsor and through research, primary, secondary, and tertiary stakeholders were established, most notably being our team, sponsor, and end users of the model (physicians not trained in ECV and Ghanaian medical training centers). Through these stakeholders, our team devised a list of requirements and specifications for our model, with the three primary being to simulate common starting breech positions, to use tactile elements that feel like a pregnant abdomen, and to maintain a low cost, as well as verification plans for each using our team’s knowledge of engineering principles and standards.

Through investigating prior benchmarking models, our team found that none simulate ECV, and satisfy all three primary requirements, furthering the need for our team to develop a model for physicians to learn the procedure. For the duration of this project, we carried out design concept generation, using strategies such as brainstorming and design heuristics, as well as concept selection, using elimination strategies and pugh charts, to choose a primary design for preliminary prototyping. We modeled our preliminary design in CAD and developed a bill of materials for manufacturing.

Our team spent time developing verification and validation plans to gather both quantitative and qualitative data from physical testing, interviews, and verbal feedback. This data verified that our proposed design meets design and requirements developed with our sponsor. Our team continued to iterate on our prototype to meet all those requirements and specifications and created a full model prototype and a fabrication plan for others to replicate.

ABSTRACT

Malpresentation, when a fetus is not head down, inhibits spontaneous vaginal birth and commonly results in cesarean or breech delivery, posing fetal and maternal health risks. External cephalic version (ECV) is a procedure that adjusts a malpositioned fetus, providing a low-risk alternative to allow spontaneous vaginal birth. No clinical ECV simulator exists, so the procedure is taught by experienced physicians in live cases. Because there is a lack of physicians with experience in ECV in Ghana, this experiential learning does not occur and ECV is underutilized. Our group will design a simulator to train Ghanaian physicians on the ECV procedure.

PROJECT INTRODUCTION AND OBJECTIVES

Our team worked with Dr. Dhanu Thiyag and in partnership with the Global Health Design Initiative (GHDI) under the University of Michigan. At the University of Michigan Hospital, Dr. Thiyag specializes in general obstetrics and gynecology. With a background in biomedical engineering, she brought the ECV simulator project to the University of Michigan as a personal project interest derived from her own research. Members of the needs assessment trip to Ghana in the Summer 2023 verified the need for an ECV simulator at the teaching hospitals in partnership with the GHDI.

In initial conversations with our sponsor, we learned that ECV is a procedure that is taught solely in live cases from doctor to doctor, and preliminary research showed that physicians only felt comfortable with the procedure after 20 cases [3]. Although this is a working method of training in more high-income countries where physicians are knowledgeable about the procedure, such as in western Europe and the United States, ECV is not a procedure that is taught in LMICs [23]. This leads to cases of preventable cesarean section or breech deliveries due to fetal malpresentation that could be subverted by the lower-risk procedure. In hospital or clinic settings where resources are limited, minimizing such high-risk surgeries is crucial to saving lives [34]. A more in-depth discussion of our research on these outcomes is outlined in the next section.

The major objective for this project was to create a physical simulator for ECV that can effectively train physicians on the procedure for fetuses in multiple starting breech positions. This simulator had to accurately represent the anatomy of a pregnant torso at term, so our team prioritized mimicking what a physician would feel throughout the ECV procedure. After discussion with our sponsor, a successful project at the end of the semester was a proof of concept, low-fidelity model that accurately simulated the ECV procedure.

Throughout the project, our team focused on developing the scope of our project with our sponsor, determined and ranked our stakeholders, did research to inform project context and need, and developed a concise problem statement. Though the problem statement is relevant to all LMICs, our team narrowed the scope of the project to the country of Ghana for the sake of narrowing the research conducted, as well as leveraging our sponsor and university connections with the teaching hospitals in Ghana. Aside from this, research sources were largely obtained

through databases made available to us as students by the University of Michigan Library as well as working directly with an engineering librarian at the university.

Our team utilized an iterative design process to create our ECV model, as discussed further in the Design Process section of this report. A systematic approach to our process was important to ensure that all aspects of the project were addressed, specifically emphasizing the need to consistently brainstorm, prototype, test, and evaluate our design to create the most successful version possible.

With regard to intellectual property, our team signed the Global Health IP Agreement to address "unmet medical needs in developing nations," as developed by Professor Kathleen Sienko. In our license, we grant "a nonexclusive license, with the right to sublicense, to the Regents of the University of Michigan ("Michigan") under Student's rights in Project Inventions for the purpose of furthering the Global Health Mission." We retain our ownership rights to our project and may commercialize our project and understand that our joint-inventor, our sponsor, may jointly own the project with our team.

NEED IDENTIFICATION

To clearly define our problem based on the true need, our team applied the "5 Whys" root cause analysis [4], creating a linear narrative to understand the broader context of our problem, as seen in Figure 1 below.

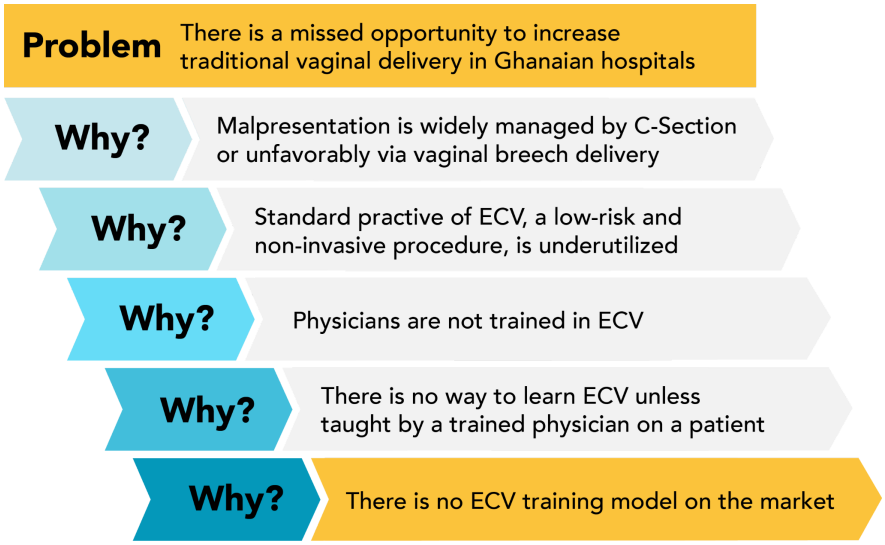


Figure 1. Root Cause Analysis: "5 Whys" Framework

By diverging from our sponsor-identified need for an ECV simulation model, we were able to understand the broader context of malpresentation as a condition, its associated risks, and its management on a global and Ghanaian specific scale. From there, we were able to re-converge using the "5 Whys" framework, which gave us a systematic way to approach our research and problem definition. Through this, we determined that our project need begins with an opportunity to increase rates of spontaneous vaginal deliveries. The resultant "Whys" of this need are discussed in the following sections, beginning with the issue of breech presentation and its current management.

Breech Presentation and Current Methods of Management

Spontaneous vaginal delivery is inhibited when a fetus is exhibiting malpresentation [1]. Malpresentation is a condition defined as when "a fetal part other than the head [engages] the maternal pelvis" [5]. Common fetal orientations are depicted in Figure 2 below.

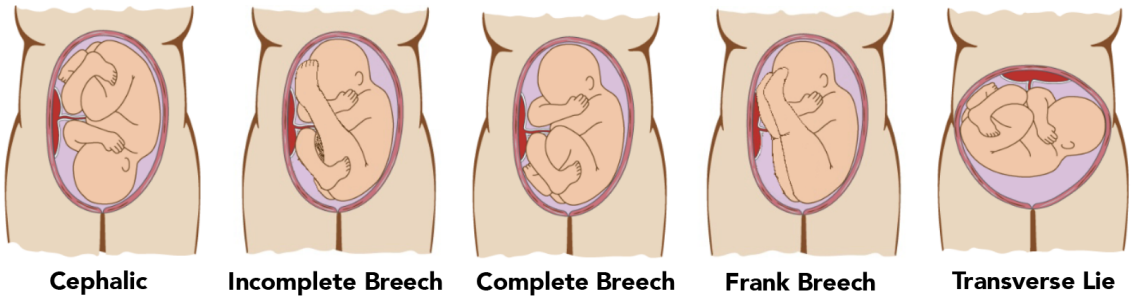


Figure 2. Common fetal orientations [6]

As shown above in Figure 2, general malpresentation orientations include breech, where the fetus is head-up, and transverse lie, where the fetus is oriented sideways in the womb. There are three types of breech presentation: incomplete, where one leg is up and one leg is bent, complete, where both legs are bent, and frank, where both legs are extended towards the fetus' head [1]. Breech presentation is the most commonly encountered fetal malpresentation [5], and occurs in 3-4% of all pregnancies at term. Subsequently, 3-4% of pregnant patients are subject to the concerns associated with breech presentation [1] globally. There is no data that indicates differences in incidence of breech presentation globally versus Ghana.

Breech presentation often leads to a cesarean delivery (CD) or vaginal breech delivery (VBD), subjecting the pregnant patient to potential complications associated with these procedures [13]. CD, also referred to as cesarean section, is delivering the fetus through abdominal incisions, while VBD is delivering the fetus via the vagina while the fetus' buttocks or feet come out first [7]. spontaneous vaginal delivery is the safest option for both fetus and mother. spontaneous vaginal delivery for full-term pregnancies has the lowest associated fetal and maternal morbidities and mortalities of any delivery method. Both CD and VBD have higher risk of complications and can lead to adverse fetal and maternal health outcomes [8].

CD can be a medically-necessary and life-saving method of delivery with growing rates of implementation worldwide; however, data shows that it may not be the favorable procedure in the management of fetuses showing malpresentation. The global prevalence of CD in cases of breech presentation is high, with 85.1% of fetuses in breech presentation delivered via CD [2]. However, CD is associated with increased risk for maternal morbidity and mortality when compared to spontaneous vaginal delivery, particularly in LMICs [10]. Short-term risks of cesarean section include incision infection, placenta accreta, postpartum blood loss, and blood clots [11]. CD also poses long-term health risks in the event of a subsequent pregnancy. According to a study performed by the Department of Obstetrics and Gynecology at University of Helsinki Hospital, CD is associated with "increased risk of having a subsequent abnormal labor and … increases the risk of uterus rupture during subsequent pregnancy and labor, as it increases the risk of postpartum hemorrhage and adverse neonatal outcome" [12]. CD outcomes

are particularly adverse in LMICs compared to those in higher-income countries. According to data compiled by the World Health Organization from 1989-2019, “a quarter of all women who died while giving birth in low- and middle-income countries had undergone cesarean section” (WHO, 2019) [13]. Dr. Soha Sobhy of Queen Mary University of London states that “one in 100 women who has a cesarean section will die” in sub-Saharan Africa, which is 100 times the mortality of women who undergo CD in the United Kingdom [13]. Therefore, spontaneous vaginal delivery leads to more preferable outcomes than cesarean sections in LMICs such as Ghana [37].

Physicians will also conduct VBDs for fetuses exhibiting breech presentation at birth, though mortalities and morbidities associated with this procedure exceed those of CDs and spontaneous vaginal deliveries. Given the breech orientation of the fetus, there is risk of difficulty extracting the fetal body, arms or head. This can lead to injury to the fetus or CD if attempts to dislodge the fetus are unsuccessful [10]. Particularly in LMICs, VBDs are associated with a 10-fold increase in perinatal mortality when compared with spontaneous vaginal deliveries [15]. While VBD is not the primary mode of breech delivery globally, it is the preferred method of breech delivery in Africa, where 73% of fetuses exhibiting breech presentation were delivered by VBD [16]. A clinical study done by the University of Michigan in collaboration with the Department of Obstetrics and Gynaecology at the Komfo Anokye Teaching Hospital in Ghana, 97.7% of physicians reported they believe breech fetuses should be delivered vaginally rather than via cesarean section [16]. This high incidence of VBD in Ghana poses a high incidence of the aforementioned risks associated with the procedure. These adverse health outcomes do not intend to undermine the role of VBDs in LMICs, but rather bring attention to the need for antenatal intervention via procedures like ECV to reduce these complications.

External Cephalic Version as a Method of Management

External cephalic version, also known as ECV, is a procedure used to move the fetus to cephalic position by externally applying pressure, such that the patient can move forward with vaginal delivery [14]. The indications for ECV typically begin at 36 weeks gestation, while the procedure is performed from 37-40 weeks, as the fetus may turn on its own [1]. During ECV, the patient is semi-recumbent, a half-lying down and half-sitting position, and the breech is lifted out of the pelvis while pressure is applied to the fetus’ head to manipulate its body into cephalic position, as demonstrated in Figure 3 below [1].

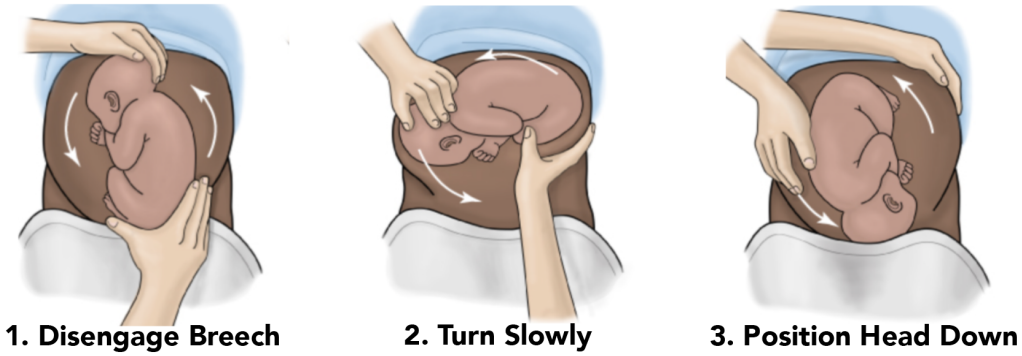


Figure 3. ECV procedure steps [14]

ECV is classified as a low-risk procedure, with a general success rate of 58%, and recommended for pregnant patients without contraindications for a breech-presenting fetus [1]. As outlined in Figure 4 below, a successful ECV allows for a spontaneous vaginal delivery to occur, avoiding the aforementioned risks of CD and VBD.

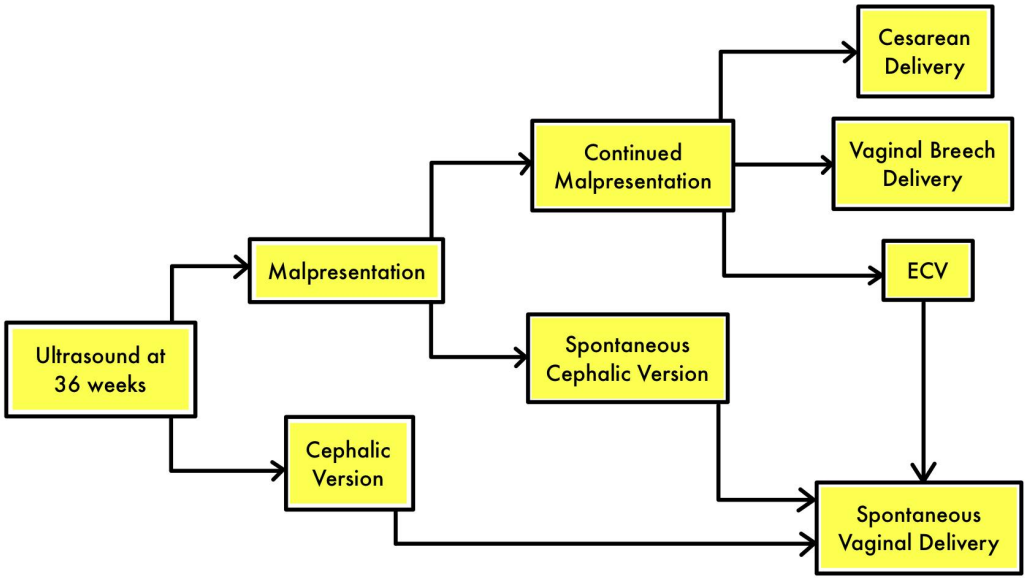


Figure 4. Diagram demonstrating ECV medical process flow

As previously mentioned, spontaneous vaginal delivery is the safest option for both fetus and mother [8]. ECV enables a pregnant patient to have a spontaneous vaginal delivery and is therefore a favorable alternative to CD and VBDs.

Current Perceptions of ECV

Though ECV has been recommended as a safe procedural alternative to both cesarean and vaginal breech delivery, it has not been implemented in sub-Saharan Africa and other LMICs due to the lack of training, mastery, or undue perception of adverse outcomes [17]. As informed by our sponsor and Ghanaian physicians, ECV is an underutilized method to manage breech presentation, as it is currently taught from physician to physician in live cases. Therefore, the training of ECV relies on the presence of experienced doctors to transmit knowledge of the procedure. The lack of physicians experienced in the procedure inhibits the ability of medical residents to attain mastery in ECV and consequently limits their ability to confidently offer it to patients.

Additionally, the pain associated with ECV may deter both patients and physicians away from the procedure. Because ECV requires a significant amount of force to turn the fetus, it is notably painful for the patient, with celebrity and mother Kim Kardashian describing it as “more painful than childbirth” [18]. In a study conducted by the Department of Obstetrics and Gynecology at the Chinese University of Hong Kong, the pain experienced by the patient is significantly higher in unsuccessful ECVs, as well as ECVs deemed difficult by the operator [19].This indicates that, while ECV is an inherently painful procedure, some procedural pain may be mitigated with physician experience and comfort. As physicians become more experienced with ECV, they can

complete the procedure more effectively and in less time, and ultimately decrease the time the patient experiences a high level of discomfort [19].

The Need for a Training Model

Ultimately, ECV is underutilized because physicians rely on experiential training in live cases to learn the procedure. This method of training relies on each teaching hospital or clinical setting to staff a physician with significant experience in ECV, which is an unreliable assumption. While some prototypes used in strictly research settings of an ECV training model exist, there is a need for a model capable of being implemented in training hospitals for medical wide-spread medical use in LMICs.

A training model for ECV will equip physicians to perform a procedure that is comparably less invasive and risky than current methods of managing malpresentation. In a survey of OBGYNs and midwives in Ghana, only 2.5% of respondents cited patient preference as a clinical factor they considered when making the decision of delivery mode for a fetus exhibiting breech presentation [16]. This indicates that much of the health decisions for pregnant patients in Ghana are dependent on physician choice, informed by experience and procedural comfort level. As such, it is imperative that a method of training is introduced in the Ghanaian healthcare setting for ECV so that physicians have the choice of conducting a less resource-intensive procedure that lowers risk for adverse maternal or perinatal outcomes.

To effectively train physicians, a simulation learning model is ideal. From a study conducted on medical students that evaluated knowledge scores comparing simulation based learning with other learning modes, such as textbooks or video recordings, simulation was significantly more effective than other teaching methods, with an associated knowledge score increase of 50%. A growing body of evidence from multiple medical reviews on various fields of medicine have revealed significant improvements in knowledge and procedural comfort as a result of simulations [20]. Additionally, simulation-based learning gives health professionals an opportunity to practice the skills of a procedure without subjecting patients to unnecessary risks [51]. Because of this, a simulation-based model is preferable to training with live patients.

Ultimately, there is a need to provide a mode of training for ECV in LMICs to de-risk pregnancies. A simulation model of ECV aims to increase utilization of ECV, thereby promoting spontaneous vaginal delivery and avoiding adverse health outcomes of alternate delivery methods.

DESIGN CONTEXT

In addition to identifying the need for a simulation model for ECV, it was important for our team to analyze how contextual factors, power dynamics, and identification of key stakeholders may influence our project. Our project did not exist in a vacuum, and in order to practice inclusive design, we had to acknowledge its context and let it inform how we engaged stakeholders.

Contextual Considerations and Power Dynamics

Recognizing our identities as those with minimal knowledge of obstetric practices, Ghanaian culture, and pregnancy allowed us to acknowledge our unfamiliarity with the need to promote spontaneous vaginal delivery in LMICs. Growing up in the United States, we initially lacked understanding of what globally accessible resources are and tend to assume our personal experiences with healthcare are universally shared. A steep learning curve of medical care, particularly in Ghana, had to be addressed to understand how our key stakeholders may be impacted by our solution. We leveraged the expertise of medical professionals at Korle Bu Teaching Hospital and Michigan Medicine to ensure we were considering all key stakeholders of our project and were not exclusively making design decisions from our personal biases and engineering approach. Medical professionals have a greater knowledge about ECV as a procedure, while Ghanaian physicians have a better understanding of practicing obstetrics in Ghana.

We were intentional about ensuring that all cultural, economic, and ethical contexts were considered. An important ethical consideration was the downstream effects of our model on physician's capabilities and patient experiences. A key priority in our design decisions for this project was to create anatomical likeness to a pregnant abdomen. This emphasis on anatomical likeness in our design requirements, discussed later in the report, stems from existing context surrounding the implementation of a teaching simulator. Because we designed a model that will be teaching physicians how to conduct a medical procedure, it was vital that we model patient anatomy as closely as possible. If our model was not accurate to real-life, there runs a greater risk of providers being inappropriately or inadequately trained, which may lead to prolonged pain experienced by the patient for the duration of the procedure. Ultimately, ECV is a painful procedure in which physician expertise and confidence can make the procedure more efficient, thus relieving the patient of excess pain.

Another consideration is the implications of public vs. private healthcare in Ghana. In private hospitals, c-sections are more likely to be emphasized to patients because they cost more, allowing the hospital to make more money [52]. In teaching hospitals, profit is not a motivating factor as they are publically funded, therefore babies are delivered more frequently via VBD when ECV is not offered or not successful [52]. Understanding the economic factors that influence the procedures performed on pregnant women was important to our project as it allowed us to choose the target audience of the model's implementation. Based on public versus private hospital care, our team explored what potential hospital implementation would look like, with likely adoption being seen in public hospitals rather than private, as private hospitals would avoid training doctors on a procedure they do not want to promote. Therefore, our team aimed for our model to be implemented in public Ghanaian teaching hospitals. Additionally, there may be cultural differences in Ghana that influence physician perceptions on performing ECV, including attitudes towards adopting new technology. As Ghana is considered a low-income country, it was also important to consider the cost of our model in feasibility of implementation.

Understanding our positionality was important because our power as designers stems from our identities and privileges. An example of our visible power is found in our decisions of which stakeholders to meet with and how often we did so. We prioritized our sponsor and the aforementioned medical professionals. While it was harder to pinpoint our invisible powers, the

fact that we do not share the same positionality as the customers and beneficiaries of our solution, Ghanaian training centers and physicians respectively, influenced our interactions with them. Finding a balance in listening and learning from our stakeholders while applying what we know as engineers was crucial to the success of our project.

Stakeholder Analysis

To help determine the key individuals, groups, and organizations that impact or are impacted by our problem definition, we leveraged stakeholder and ecosystem mapping frameworks. Stakeholders were categorized in consideration of their proximity to the project's impact and the role they might play related to, as seen in Figure 5 below.

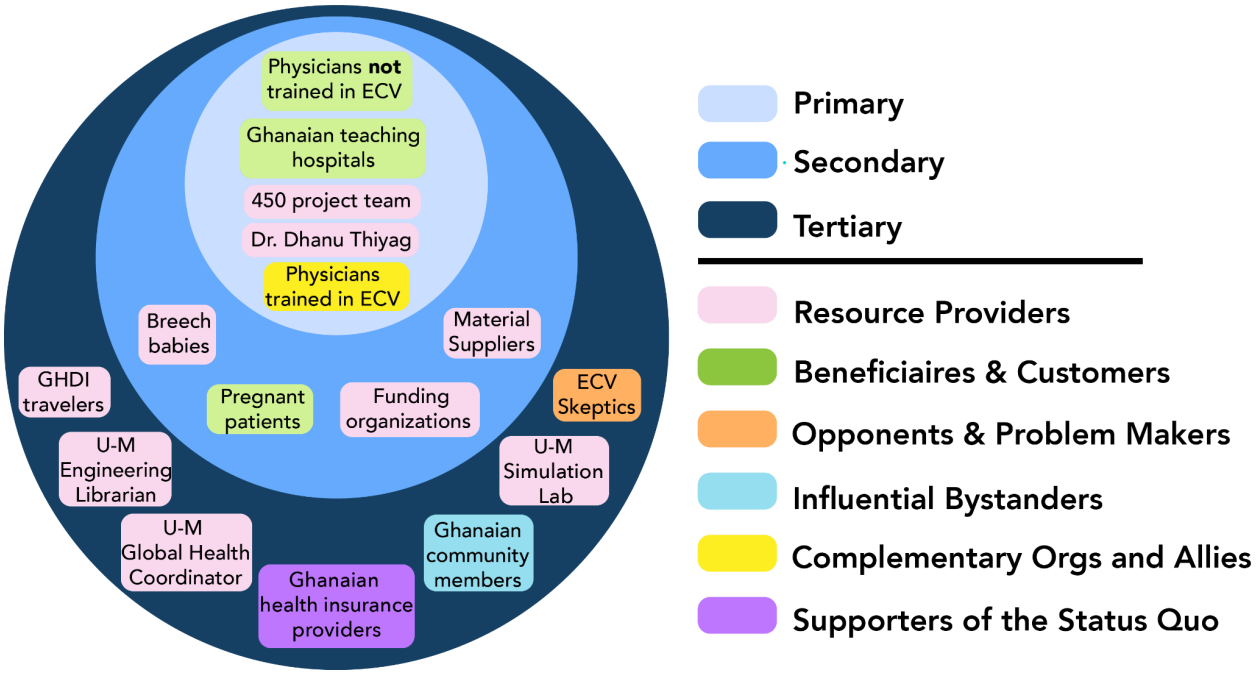


Figure 5. Combined Stakeholder and Ecosystem Map

We implemented a stakeholder map, shown in Figure 5, to place our stakeholders into primary, secondary and tertiary buckets. Primary stakeholders were those directly impacted by the problem and/or the solution development, which included our team, sponsor, and primary customers of our project: physicians not trained in ECV and Ghanaian medical training centers. Our team in tandem with the ME450 instruction staff was a primary stakeholder, as ultimately we were making project decisions by distilling information from all other stakeholders and research. Dr. Thiyag was our project sponsor and acted as a resource provider for us. She was our primary source of information for any questions about the procedure and feedback on our progress. Our team met weekly with her to provide updates, ask questions, and listen to her perspective. Physicians trained in ECV were also a primary stakeholder, as they had knowledge of the procedure and provided feedback on whether our model accurately emulated ECV. We specifically connected with Dr. Kwaku Doffour, an physician in maternal and fetal medicine working in the Korle Bu Teaching Hospital in Accra, Ghana. Dr. Doffour is trained in ECV and trains residents at Korle Bu on the procedure via live patients. Physicians not trained in ECV and Ghanaian teaching hospitals were also primary stakeholders. Physicians not trained in ECV are

the primary end users of the model. Ghanaian teaching hospitals are those partnered with Ghanaian medical schools via education programs for medical residents, and therefore they will be the ones adopting our model for both physicians and medical residents to train. Though midwifery is a large component of the Ghanaian healthcare system, discussion with our sponsor revealed that ECV should only be conducted by physicians. This is because ECV must be done in settings with the infrastructure to support an emergency CD, as that is the worst-case outcome in the case of an unsuccessful procedure.

The secondary stakeholders were those indirectly impacted by the problem and success of the solution. Pregnant patients and breech babies fell into the category of secondary stakeholders as beneficiaries. As we narrowed our problem scope, we recognized that the ultimate goal is to create a training model for physicians, while pregnant patients and breech babies will benefit downstream, as ideally the pregnancy will be de-risked by the availability of the procedure. It was important to consider patient feedback on the procedure and how they may be impacted indirectly by the training device, but counseling and procedural decisions were beyond the scope of the work our team aimed to accomplish. Another secondary stakeholder that acted as a resource provider was funding organizations, or those that will provide funding for Ghanaian teaching hospitals to purchase our model. Given the limited budget of public health facilities in Ghana, future project funding for implementation will likely be sourced via grants for medical simulations or organizations willing to support the purchasing of our product [52]. Material suppliers were also a secondary stakeholder as a resource provider. Given that our product was a physical medical model, material selection was an important consideration and ultimately dictated the physical fidelity of our model.

Lastly, tertiary stakeholders influenced the solution but will not feel the impact of the problem. This was where a lot of expert resources and broader Ghanaian stakeholders were placed. GHDI travelers, the UM Engineering Librarian, UM Global Health Coordinator, and the UM Simulation Lab were all tertiary stakeholders acting as resource providers. GHDI travelers provided us first-hand accounts of the needs assessment performed in Ghana, while the UM Engineering Librarian and UM Global Health Coordinator helped us navigate journals and databases for both medical and cultural information. The UM Simulation Lab provided us with knowledge of existing simulations and understanding what makes a successful simulation model. Ghanaian community members were also tertiary stakeholders, who acted as influential bystanders. Ghanaian community members provided important contextual information, as it is important that our design reflects the needs of its intended community. Finally, ECV skeptics were tertiary stakeholders that may act as opponents to our project once implemented. ECV skeptics was a broad description of stakeholders that included aforementioned groups such as pregnant patients and physicians not trained in ECV. Pregnant patients may inhibit the potential influence of the model if they reject the procedure. Many pregnant patients turn down the option for an ECV due to fear of pain, fear of fetal health risks, or willingness to receive VBD or C-section, therefore limiting physicians ability to perform ECV despite training on our model [1][52]. Additionally, physicians not trained in ECV may be hesitant to adopt a new care preference. As previously mentioned, at the Komfo Anokye Teaching Hospital in Ghana, 97.7% of physicians reported they believe breech fetuses should be delivered vaginally [16]. Given physicians in Ghana have high comfort-level and experience performing VBD, they may act as opponents to performing ECV rather than leaving the fetus breech and performing VBD.

The specific ways in which we engaged with stakeholders throughout this semester can be found in our project plan in Appendix H.

DESIGN PROCESS

As we began our project, our team evaluated and adopted a design process that fits our anticipated project needs. This semester, our team followed the design process framework shown in Figure 6 below.

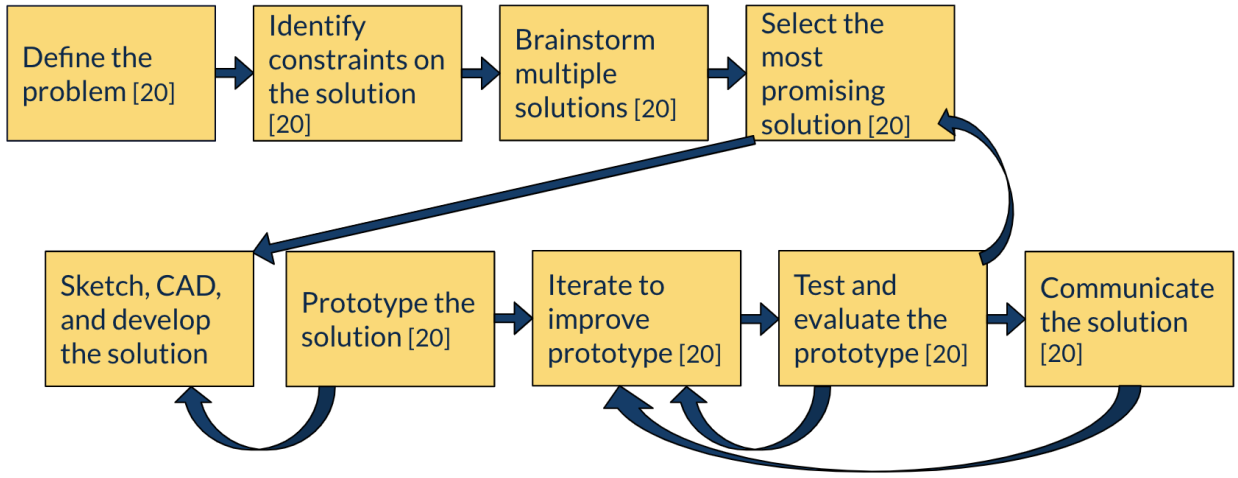


Figure 6. Intended design process, adapted from "The Engineering Design Process: A Taco Party." [21].

Our team considered many different approaches to the design process to find one conducive to our project. The process in Figure 6 was eventually selected for its emphasis on iteration during the prototyping phase. Our model went through several iterations of prototyping as we refined our material selection and explored varying levels of procedural accuracy. Due to our group's limited prior knowledge of materials that tactically and structurally resemble human anatomy, we had to do a few rounds of iteration on the design, with each round concluding in feedback from our group internally, our sponsor, and other physicians. Additionally, due to the importance of tactile elements in our prototype, we performed several rounds of feedback to be integral due to subjectivity that came as a result. Having the many stages of prototyping, testing, communication, and iteration allowed us to address the subjectivity and account for all feedback. Therefore, we felt as though the process pictured above best fits the trajectory of our project. The team defined the problem and identified constraints on the solution with the help of Dr. Thiyag, implementing a problem-based framework to our project.

Our design process continued to evolve by adding "Sketch, CAD, and develop the solution" in between "Select the most promising solution" and "Prototype the solution." Through concept generation and evaluation, our team discovered that there was a lot of work to be done between these steps that greatly affected the proposed prototype. When a design was selected as the most promising, with the process described in the "Concept Generation" section, there was sketching, preliminary CAD creation, and engineering analysis of the idea was performed by our team even before we moved to prototyping and testing to decide if the idea was still feasible when put on

paper. These steps were continued in the proceeding prototyping, iterating, and testing stages, but our team emphasized its initial importance of further developing the idea prior to prototyping.

A range of other design processes were considered to ensure we selected a model that helped us contribute valuable solutions. The design process model our team developed resembles the procedural cycle for systems analysis by Ehrlenspie [22], as seen in Figure 7.

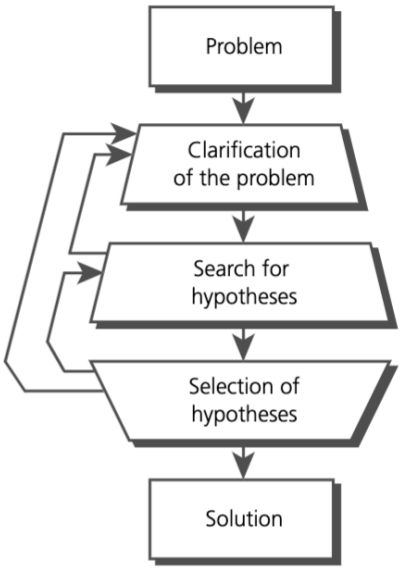


Figure 7. Ehrlenspie's Procedural Cycle for Systems Analysis [22]

The above model emphasizes the iterative process that our team followed, with specific emphasis on the arrows coming from "Selection of hypotheses" to "Search for hypotheses." Even after we have converged on a design concept, we iterated through different solutions to ensure our final model met our requirements.

At the beginning of the semester, however, the team received a project brief that limited prospective solutions significantly, stating there was a need for a physical ECV simulator rather than a broader prompt for a new training method for the procedure. In spite of this, our team worked to re-scope and contextualize the problem through our own research, in conjunction with expert opinion from our sponsor and the travelers on the most recent needs assessment trip to Ghana. We opted to work according to a problem-based design model in order to have a stronger basis for problem context and more robust support for all the developed requirements and specifications. Using the problem-based framework also allowed for more depth of future concept generation.

Our team decided to use a model other than the standard design process introduced as the ME450 Framework, shown below in Figure 9.

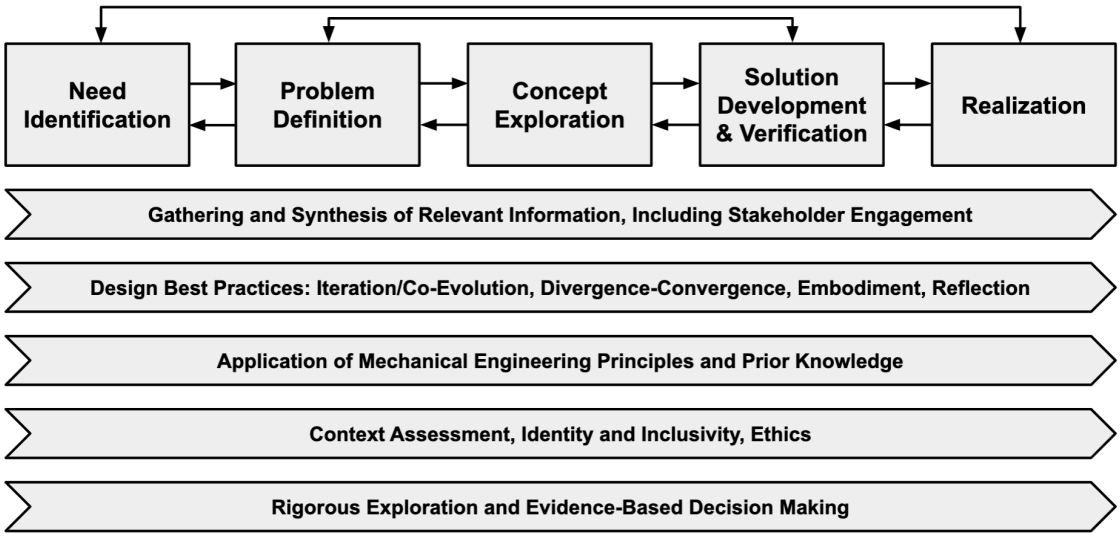


Figure 9. ME450 Design Process Framework

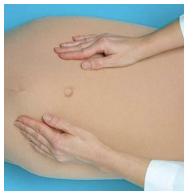
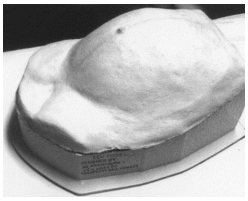
In comparison to the ME450 Framework, our model in Figure 6 resembled the key steps of "Problem Definition," "Concept Exploration," and "Solution Development and Verification". The model we chose was different because it placed more emphasis on time spent in the concept exploration phase, rather than a single block in the process. Our team chose to place the most important aspect of the process on the iteration needed between the selection of an idea, prototyping, and evaluating.

BENCHMARKING

As a part of the problem definition stage of our selected design process, our team evaluated current solutions for both ECV and other obstetric models as benchmarks for our solution. ECV is currently taught from physician to physician in live cases [23], and there is no existing ECV simulator on the market. There have been attempts by researchers to create models, but they were proof of concept benchtop models that were not designed for marketability or distribution.

In our research, we found three medical models to help benchmark our potential solution. These included an abdominal palpation model [24], and two ECV teaching simulations that were created as research for ECV simulation [25][26]. When evaluating each model, we considered four criteria: function, material, cost, and lifetime. Ultimately, the function of the model needed to simulate ECV, and the material needed to mimic the feeling of a pregnant person's abdomen in order to best simulate the procedure. Additionally, the importance of cost and lifetime go hand-in-hand, as a long-lasting, low-cost simulation was imperative to simulation implementation in LMICs. The evaluation of our three models is outlined in Table 1 below.

Table 1: Evaluations of three models

Model	 Benchmark #1 [24]	 Benchmark #2 [25]	 Benchmark #3 [26]
Function	Leopold's Maneuver	ECV (turning)	ECV (disengaging, turning)
Material	Silicone, padded cloth	Silicone, pillowcase, water balloon	Latex, water in latex bag
Cost ($)	1060	100	600
Lifetime (cycles)	1000	20	200

The first model we considered was an abdominal palpation model that is used to teach Leopold's maneuver, a non-invasive procedure used purely to determine the presentation of a fetus. The model is made up of a plastic fetus and pelvis, with a silicone mat and padded cloth cover to simulate the feeling of a pregnant abdomen. Although the model is standardized and available for purchase, teaching Leopold's maneuver does not give the user the ability to practice turning the fetus, which is the main goal of ECV. Additionally, its cost is extremely high and is out of reach for our target audience, even with an extended lifetime.

The second model we evaluated was a lower-fidelity model that was created as research for an easy-to-replicate prototype that could be implemented throughout the western world. The model was constructed with Dragon Skin Smooth-On Silicone™ applied to a pillowcase, with balloons and a plastic fetus. The fetus is placed in a balloon, which is placed inside another balloon filled with water. This series of balloons are placed on a human volunteer's stomach, and are wrapped in the silicone covered pillowcase. ECV is then performed on the volunteer by a practicing physician. Though the monetary cost of the model is low, it comes at the expense of durability, as it's constructed with cheaper materials. Moreover, the model does not contain a pelvis, and therefore does not simulate the disengaging of the breech fetus during the procedure.

The third and final benchmarking model examined is a higher-fidelity model used in research settings, consisting of a fiberglass fetus, base, and pelvis, a latex bag filled with water to represent the uterus, and a latex covering to imitate skin. Several airbags surround the uterus, and with changing pressure can modify the difficulty of disengaging the breech, as well as the difficulty of physically turning the fetus. The model has a flat base that is stabilized when used on a table. While the tactile components of the model are successful in demonstrating varying difficulty in the procedure, the monetary cost is quite high, especially considering it has only been proven to last for 200 procedures.

In both ECV research models, participants acknowledged that the hands-on experience was critical in their learning and understanding of the procedure. Even in the lower-fidelity model, 100% of the users confirmed that the model was at least somewhat effective in increasing their comfort level with ECV [25]. However, none of the aforementioned models holistically simulate ECV while being designed for widespread implementation in a clinical setting. Given that none of the existing models meet all of our considerations, our team had a unique opportunity to create a comprehensive and accessible ECV simulation that can be implemented in LMICs.

USER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

After thoroughly understanding the problem context, existing solutions, and stakeholders, preliminary requirements and subsequent specifications for our model were developed.

User Requirements

To begin developing user requirements, we first identified our stakeholders, as shown in the stakeholder map (Figure 5). We then met with stakeholders at the primary and tertiary levels, especially those identified as resource providers, such as the UM Engineering Librarian Sarah Barbrow and the UM Global Health Coordinator and Librarian Gurpreet Rana for identifying applicable journals and research articles. We also met with Dr. Doffour-Dapaah from Korle-Bu teaching hospital in Ghana, who acted as a primary stakeholder as a physician who performs ECV. Dr. Dhanu Thiyag, our project sponsor and a primary stakeholder, was the main resource for the majority of the project needs and subsequent requirements and specifications. She was our primary informant in scoping the final project goal, specifically in the requirements we aimed to meet in fabricating biological likeness and correctness in our model. She also informed us there are no explicit regulations or standards to be met for a medical simulation model [23]. The critical consideration was validating the model via expert panels, validation checklists, etc. Additionally, we conducted research into the needs in the context of Ghanaian teaching hospitals, which led to cost, repairability, and repeatability considerations. After the needs of various stakeholders were gathered, they were synthesized into a list of requirements, then categorized as high, medium, and low priority, as shown in Table 2.

Table 2. User requirements according to relative priority

High Priority	Medium Priority	Low Priority
Simulates common starting breech positions	Stable	Simulates disengaging from pelvis
Simulates turning of fetus	Long-lasting	Easy to clean and reset
Fetus can be palpated	Compatible with ultrasound gel	Can be repaired locally
Tactile elements feel like pregnant abdomen		
Low-cost		

We prioritized the above requirements according to the needs and expectations expressed by our sponsor. All our discussions on project scope for the semester resulted in the goal of developing a proof of concept model. It needed to accurately simulate the ECV procedure capable of different starting breech positions, verified by physician feedback for accuracy of feel. As such, the main priority for our team was to focus on functionality and biological accuracy for our simulator. Prioritizations were also assigned in consideration of viable implementation in Ghana [23], hence the high prioritization of low-cost. The relative priority of our requirements were reviewed and approved by our project sponsor [23].

Our high priority requirements were essential to the success of our project. The model must simulate common starting breech positions, since this is the primary marker for performing an ECV. The physician must be able to identify the positioning of the fetus in order to properly dislodge the breech and turn the fetus, so simulating this was crucial to prepare physicians for a realistic procedure [1]. Another high priority requirement to achieve physical fidelity was that the model should simulate turning of the fetus, as it must encapsulate the ability of the physician to turn the fetus, which is the main objective of the procedure. Too little pressure will not turn the fetus, and too much pressure may cause harm to the patient. Similarly, it was a high priority that the fetus can be palpated. Being able to identify the fetal features was identified by our sponsor as a critical part of the ECV procedure [23]. Ensuring that tactile elements feel like a pregnant abdomen was also critical for our model, as research shows physical fidelity is key for effective medical models [27]. The model also must be low-cost, given that we were working in a LMIC and the cost of the model will need to be covered by receiving grants or external funding [52].

Our medium priority requirements were those that were moderately essential to the success of our project. ECV involves exerting high magnitudes of force on the abdomen, and therefore our model must remain stable under applied force. This is also important for the safety of the user. Another medium priority requirement was long-lasting to ensure our model can be used for multiple cohorts of medical residents in Ghana. We wanted to limit replacement of the model due to the limited budget in Ghanaian teaching hospitals. The model must also be compatible with ultrasound gel, as ultrasound gel is utilized in a live ECV procedure. Therefore, ultrasound gel will also be used on our simulator, as physical fidelity is key for effective medical models [27].

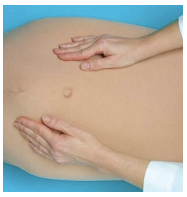
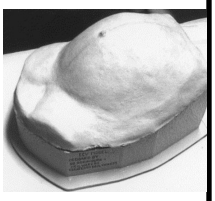
Low priority requirements were those that were not essential to the success of our project this semester, but were still considered. Our model should simulate the disengaging of the fetus from the pelvis, which is the first step of the ECV procedure [14]. Our sponsor indicated this is a less essential component compared to the other elements of the procedure and therefore low priority [23]. Our model should be easy to clean, as ultrasound gel will need to be cleaned from the model between simulation sessions. It should also be easy to reset, as we wanted the model to be user-friendly and easily utilized many times during a training session. Finally, we wanted the model to be locally repairable such that it can be maintained once implemented in Ghana.

It is important to note certain requirements such as maneuvers related to mitigating patient pain or simulating health complications were omitted from our list of requirements. This decision was made in discussion with our sponsor Dr. Dhanu Thiyag when evaluating the essential elements of

a successful medical model. For example, there is less success in cases where it is hard to feel the fetus' head, or when the location of the placenta is in front of the uterus, which also increases the difficulty of feeling the fetus [28]. While these are important factors that may be pertinent to an ECV simulation, they fell beyond the scope of the requirements for this project. This was discussed and affirmed in discussions with our sponsor [23]. However, the successful implementation of this simulator will contribute to overall improved familiarity with the procedure that will ultimately lead to reduced procedure times and less sustained discomfort for the patient. Additionally, our model only focused on the procedure for singleton fetuses, as ECV is not performed on twins [29].

After establishing our requirements, our team revisited the benchmarking process to evaluate to what extent existing products satisfy our user requirements. As shown in Table 3, the previously identified benchmarking models were evaluated against our high priority requirements.

Table 3. Benchmarking models against high priority requirements

	 Benchmark #1	 Benchmark #2	 Benchmark #3	**Our Model**
Simulates common starting breech positions	☑	☑	☑	☑
Simulates turning of the fetus		☑	☑	☑
Fetus can be palpated	☑	☑	☑	☑
Tactile elements feel like pregnant abdomen	☑		☑	☑
Represents pressure used to perform ECV			☑	☑
Low-cost		☑		☑

As seen in Table 3, none of the existing products identified during the benchmarking process met our top requirements, affirming the unique need for our model.

Engineering Specifications

To confirm our model will in fact meet our requirements, we defined engineering specifications. Each of our requirements was translated into engineering parameters through which the

requirements were evaluated and verified. Target values were established in the form of minimal and optimal specifications. Minimal specifications were the minimum value needed to meet the user requirement, while optimal specifications were the ideal values for optimal project performance. Our user requirements and engineering specifications are shown below in Table 4.

Table 4. User requirements and engineering specifications

Priority	Functional Requirement	Minimal Specification	Optimal Specification
High	Simulates common starting breech positions	Simulates 1 breech position	Simulates 3 breech positions
High	Simulates turning of fetus	Requires 28-93 kPa of peak applied pressure	
		Can withstand 93 kPa without damage for 10 minutes	
		Fetus can turn 180°	Fetus can turn 180° in 2 steady state positions (oriented head-down or feet-down)
High	Fetus can be palpated	60-80% can palpate fetal features among 15+ participants surveyed	80-100% can palpate fetal features among 15+ participants surveyed
High	Tactile elements feel like pregnant abdomen	5-point Likert scale score ≥ 3.5 averaged among 15+ clinicians surveyed	5-point Likert scale score ≥ 4.5 averaged among 15+ clinicians surveyed
		-	Elastic modulus of external element 90-110 kPa
		-	Elastic modulus of internal element 9-11 kPa
High	Low-cost	< $350 lifetime cost	≤ $100 lifetime cost
Medium	Stable	Remains static with ≤ 90 N horizontal load	Remains static with ≤ 135 N horizontal load
Medium	Long-lasting	≥ 2,450 cycles with no material failure or fracture	≥ 5,268 cycles with no material failure or fracture
		Non-reactive to 99% isopropyl alcohol	
		Withstands temperatures ranging from 3.8°C to 43.9°C [53]	
		Withstands humidity ranging from 77% - 100% [53]	
Medium	Compatible with ultrasound gel	Water absorption percentage < 5.00% [54]	
Low	Simulates disengaging from pelvis	Fetal starting position should be 1-3 cm depth into pelvis	

Low	Easy to clean and reset	≤ 600 seconds 1 user independently	
Low	Can be repaired locally	Use locally available fasteners	
		Use ≤ 2 non-locally available materials	Use 0 non-locally available materials

Each target value was informed by relevant research and sponsor recommendation. The rationale and data used to justify our specifications are outlined below, organized by the corresponding requirement:

Simulates common starting breech positions
There are three common breech positions. Our minimal specification was that our model will simulate one breech position, as breech position is the basis for performing ECV. Our ideal specification was that our model will be able to simulate all 3.

Simulates turning of fetus
To accurately emulate the turning of the fetus during an ECV, our model must require 28-93 kPa of peak applied pressure. This specification was informed by a study performed by the Department of Obstetrics and Gynecology, Prince of Wales Hospital and The Chinese University of Hong Kong to determine the peak applied contact surface pressure during ECV. The peak applied pressure was found to be in a range of 28-93 kPa, which was applied directly into the specification for our model to require a similar pressure to effectively emulate the procedure [35]. This is a wide range of potential peak pressure and does not account for the variability of pressure applied throughout the duration of the procedure. This data was not available.

To simulate the turning of the fetus, the model must also withstand 93 kPa without damage for 10 minutes. This specification was set according to the maximum pressure our model must withstand of 93 kPa and the average time to perform a live ECV of approximately 10 minutes in the worst-case scenario [35][78]. Therefore, if our model can withstand this pressure for the duration of the procedure, it can withstand the entire range of pressure applied to turn the fetus.

The model must also be able to minimally turn 180°. Optimally, it can only turn and settle in 2 steady state positions (oriented head-down or feet-down), such that if the physician unsuccessfully attempts to turn the fetus it will rotate back to its starting position. When an ECV is performed, the fetus is turned 180° from feet-down to head-down [78]. Additionally, in our team's experience witnessing a live ECV as well as watching online recordings of ECVs, we noted that the fetus often exists in two steady state positions [78]. The physician must continually be turning the fetus or it will slip back into one of two steady state positions, so optimally our model will emulate this.

Fetus can be palpated
To achieve physical fidelity, it is crucial that the fetus can be palpated. Per our sponsor, the fetal features that are palpated during ECV are the head, legs, and spine [23]. Therefore, minimally 60-80% of participants surveyed must be able to palpate the fetus, while optimally 80-100% of

participants surveyed can palpate the fetus. These values arose from the classification of agreement in data collected via human subjects [57]. 60-80% is considered substantial agreement, while 80-100% is considered nearly complete agreement [57].

Tactile elements feel like pregnant abdomen
In order to confirm that the tactile elements of our model feel like a pregnant abdomen, a Likert scale was developed. A Likert scale can be used to evaluate physician opinions of our model. Physicians can agree or disagree on the extent to which the clinical interface material feels like skin, the extent to which internal components accurately mimic anatomy felt during the procedure, etc. Our minimal specification was that the Likert scale score is greater than or equal to a 3.5 among 15 or more clinicians surveyed, while our optimal specification was that the Likert scale score is greater than or equal to a 4.5 among 15 or more clinicians surveyed. In a Likert scale, a score of greater than 3.5 is considered high agreement, while a score of 4.5 and above is optimal [30]. We chose to survey a minimum of 15 clinicians for feedback, as this is the minimal number for usability testing of medical devices [59].

Additionally, material properties informed our material selection for our first full-concept design. Our team performed preliminary research on the elastic modulus of human abdominal skin and compared to the elastic modulus potential material choices. For an outer "skin" layer, we set an optimal specification of the elastic modulus to be between 90-110 kPa. This was because the elastic modulus of pregnant abdominal skin is approximately 100 kPa, and we applied a 10% margin, which is standard acceptable margin of error [79][57]. For an inner "fat" layer, we set an optimal specification of the elastic modulus to be between 9-11 kPa. This is because the elastic modulus of pregnant abdominal fat is approximately 10 kPa, and we applied a 10% margin, which is standard acceptable margin of error [79][57].We did not set a minimal specification, as sponsor opinion was our primary source of verification and material similarity may not always correlate to equivalent material properties. Therefore, it was ideal that there were similarities in material properties, but not essential to the success of our model.

Low-cost
The cost specifications of our model were set per sponsor recommendation. Our target values were deemed reasonable by Dr. Dhanu Thiyag, informed by her connections to medical staff in Ghana and experience with creating low-cost medical models [23]. Our optimal specification was to develop a model under $100, but under $350 was our minimal target. When considering the need for a simulation-based model, it was important to understand the feasibility of these models in low and middle income countries, as many current simulators cost over $100,000 [31].

Stable
Our minimal specification was that our model remains static with an applied horizontal force of 90 N. This value was set according to the push strength of a standing adult male at normal reach and arms extended at 0° from the horizontal [32]. A standing adult male was used as a conservative estimate, as the average push strength of a standing adult male is higher than that of a standing adult female [32]. Our optimal specification was that our model remains static with an applied horizontal force of 135 N, which is the push strength with a 1.5 safety factor applied, a standard safety factor for use with materials where loading and environmental conditions are not severe [33]. Given that the shape of a pregnant abdomen can be likened to that of a

semi-ellipsoid, the primary concern is the model slipping rather than tipping. The length of the lever above the center of mass of a hemisphere cannot be large enough to cause tipping. Therefore, horizontal force was the primary force limit considered. Additionally, the specification for a maximum horizontal force was developed as a "worst-case" scenario. If the horizontal force specification was met, the same magnitude of force can be applied at an angle and still not slide, accounting for the variability of application of angles in the ECV procedure.

Long-lasting
The minimal specification was that the model must withstand 2,450 cycles with no material failure or fracture, while the optimal specification was that the model must withstand 5,268 cycles with no material failure or fracture. These values were calculated as shown in Eq. 1 below:

$$\frac{245\ OBGYN\ residents}{year} \times \frac{20\ OR\ 43\ cycles}{resident} \times 1\ year\ lifespan \times \frac{1}{2\ models} = 2{,}450 \text{ OR } 5{,}268 \text{ cycles}$$

We estimated the number of students utilizing our model by using the average number of OBGYN medical residents per year at the University of Ghana Medical School [34]. The number of cycles each resident will perform was informed by a study published in the Singapore Medical Journal stating that the "learning curve for ECV is sharp and plateaus after the first 20 cases" [3]. Therefore, the minimal number of cycles a resident would perform is 20 cycles before reaching procedural comfort. However, ideally our model can withstand more cycles, as it will likely not achieve exact procedural accuracy. Therefore, our optimal number of cycles was 43 cycles, which is the number of cycles physicians performed before reaching procedural comfort in initial testing on the previously benchmarked high fidelity ECV model, shown as "Benchmark #3" in Table 3 [26]. The target of a one year lifespan was arbitrarily set and approved by our sponsor. Per our sponsor, teaching hospitals will typically purchase at least two training models.

Additionally, to be considered long-lasting, our specification was that our model needs to be non-reactive to 99% isopropyl alcohol, as this is the most commonly utilized cleaning and sterilization solution in clinical settings [53].

Our model must withstand the local environment of Ghana, and the specifications were set to encompass the totality of Ghanaian climate. Our temperature specification was that our model must withstand a range of 3.8°C to 43.9°C. The temperature range our model must withstand was informed by the average range of maximum and minimum daily temperatures in Ghana in the last 71 years, which was between 3.8°C to 43.9°C [53]. Our humidity specification was that our model must withstand a range of 77%-100%. The humidity range was informed by the average maximum and minimum monthly humidity in Ghana, between 77%-100%[53].

Compatible with ultrasound gel
Ultrasound gel is a water-based solution, and therefore the specification was set to be less than 5.00% water absorbency, a standard set for a material to be considered water repellant [54]. If the material was resistant to penetration by water, it was assumed to be resistant to ultrasound gel.

Simulates disengaging from pelvis

In order to accurately simulate disengaging from the pelvis, our fetal starting position must be 1-3 cm deep into the pelvis. This specification was set according to the positioning of the fetus in utero at approximately 37 weeks gestation [58]. The head of the fetus in cephalic position sits approximately 1-3 cm deep into the pelvis at this gestational age, and therefore we assumed the feet of the fetus sits at approximately the same distance in breech position.

Easy to clean and reset
The estimated cycle time was set according to the average time to perform a live ECV of approximately 10 minutes, per estimation by our sponsor. Reliable quantitative data was not available on the time required to perform an ECV. The specifications for reset and cleaning time were set with the intention to be less than or equal to the estimated average cycle time of our model (600 seconds) [35]. Therefore, the minimal specification was that the model can be reset for another training session in 600 seconds or less. This specification was discussed with our sponsor, who affirmed our approach [23].

Can be repaired locally
These specifications were deemed reasonable by our sponsor. Our team aims to use only components that use locally-available fasteners, such that any required tools or replacement fasteners are available. Additionally, we aimed to use minimally less than 2 and optimally 0 non-locally available materials, such that the materials can be repaired or replaced if necessary. In the event that we do use more than 0 non-locally available materials, our team aimed to ensure that the non-locally available materials were the least likely to fail. Therefore, the materials that may need repair or replacement can be sourced locally.

CONCEPT GENERATION

From the Concept Generation Learning Block, each team member each brought 40 ideas to the table, with varying amounts of feasibility and achievement of requirements and specifications. This practice allowed us to exercise divergent concept generation, in which the scope of the initial concept was expanded to generate a large number of possibilities. The individual ideation phase resulted in 120 unique ideas after eliminating duplicate ideas among group members. After consolidating individual ideas, we began our team concept generation, in which individual ideas were expanded upon and novel ideas were generated. Our team used concept generation methods including a Miro virtual whiteboard, design heuristics cards, and a morphological chart [60]. These methods led us to our initial concept selection, and per our chosen design process, we continued to iterate and refine our design. A summary of our concept generation process is depicted in Figure 10 below.

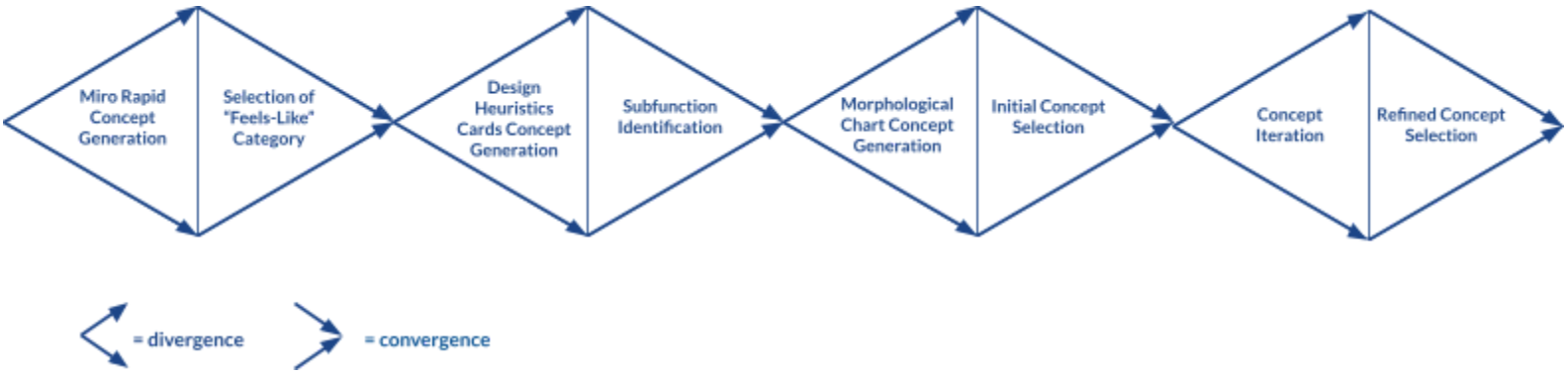


Figure 10. Our team's concept generation process

Our team first used a Miro virtual whiteboard to prioritize quantity over quality and explore divergent thinking. From this, we identified three major design type categories and converged to generate ideas within a "feels-like" model. We then re-diverged within the "feels-like" category to generate more novel concepts by using the design heuristics cards. We then re-converged our process by identifying major subfunctions that our model must have. Subsequently, we re-diverged to generate novel concepts for each subfunction using a morphological chart. This morphological chart could then be used for re-converging to select an "Alpha" design concept. Further iterations occurred as we continued to refine our design needs and evaluate subfunction efficacy.

Virtual Whiteboard Rapid Concept Generation

For the first round of team concept generation, our group aimed to utilize methods that prioritized quantity over quality. Thus we used brainstorming, which allowed for the rapid generation of a high number of ideas, regardless of their feasibility. To promote collaboration, our group used a Miro digital whiteboard and conveyed ideas using drawings, words, and idea iterations, as seen in Figure 11 below.

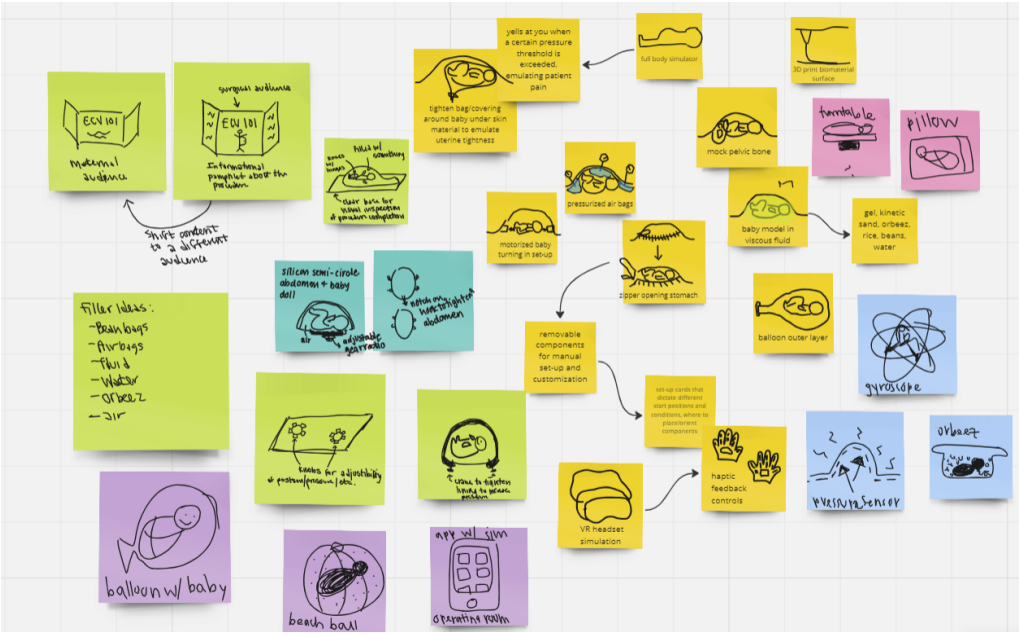


Figure 11. Rapid concept generation using a digital whiteboard

By using the virtual whiteboard, we ended with a wide variety of potential solutions. As evidenced in the arrows in Figure 11, generating one concept often led to many other ideas or notes to expand upon the idea. Some divergent concepts generated during this session included: a virtual reality (VR) training software, a medical pamphlet for physicians detailing the ECV procedure, and using pressurized airbags with a model fetus under a model abdomen, as shown below in Figure 12. Other examples of concepts generated during this phase are located in Appendix A.

Figure 12a highlights a virtual reality (VR) model, where a physician could perform a highly-detailed ECV using VR. Within this model we could include patient interaction and common complications throughout the procedure. Figure 12b highlights a medical pamphlet for both physicians and patients to describe the procedure using text and images. The medical pamphlet could have tactile components so physicians could feel certain aspects of the procedure. Figure 12c highlights a tactile model that contains a baby inside an abdomen, which has pressure bags to vary pressure, mimicking uterine muscles of various strengths.

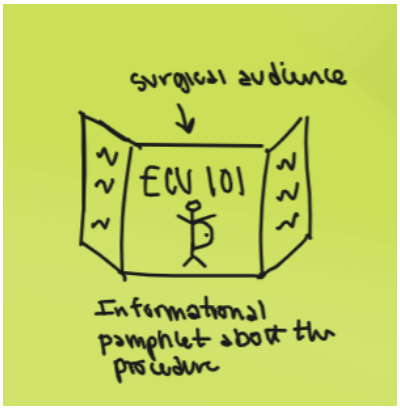


Figure 12a. VR headset simulation concept

Figure 12b. Medical pamphlet for physicians concept

Figure 12c. Pressurized airbags with model fetus and abdomen concept

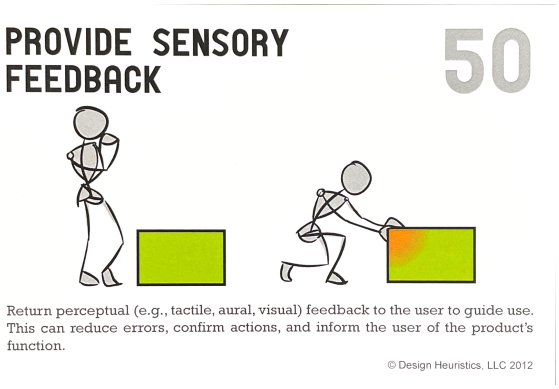
After reflecting on the broad range of ideas brought together via the virtual whiteboard, our team discovered our concepts could be divided into three major categories: a physical "feels-like" model, a virtual model, or a hybrid of tactile and virtual components. Examples of concepts in the "feels-like" category included using pressurized airbags, a medical pamphlet with tactile elements, and a model fetus in a balloon. Examples of virtual models included a VR headset simulation and a mobile app with a virtual operating room. Examples of concepts that utilized both tactile and virtual components included using haptic feedback gloves connected to a computer or a model with pressure sensors on a small piece of skin connected to an ultrasound where the fetus in the ultrasound would shift depending on where pressure was applied.

Once we had this divergent group of ideas sorted into three major categories, we sought to select one major category and continued to explore concepts within that category. Upon reviewing our problem statement, research, and discussing with our sponsor, we decided to move forward with a "feels-like" model. We determined that a "feels-like" model is critical for teaching ECV to physicians and to the success of our project. As previously mentioned, physical fidelity is key for medical simulations [27]. Also, since we were designing for a LMIC, we were not able to rely on Ghanaian teaching hospitals to have access to virtual equipment such as VR headsets, and these were costly items to provide [38]. Each of the concepts that fell within the virtual or hybrid category utilized equipment or materials that were either not readily available in Ghana or very costly. Additionally, upon further analysis of the hybrid options, we did not anticipate any of them fulfilling each requirement and specification. For example, utilizing a small piece of skin connected to a virtual ultrasound did not meet our requirements that *Tactile elements feel like a pregnant abdomen*, as the physicians would not be able to physically palpate the fetus. In discussions with our sponsor, she agreed a "feels-like" model was likely the ideal solution for our problem [23]. For these reasons, we decided to abandon the concepts with virtual components and move towards creating a physical simulation model. In order to continue to create divergent concepts even with a narrowed solution scope, we utilized design heuristics.

Design Heuristics

The design heuristic cards, which provided 77 specific strategies to help generate innovative concepts, were used to aid our concept generation for a "feels-like" model [60]. We reviewed all the design heuristic cards and identified the ones we felt were most relevant to our project scope. For example, "Use Alternative Energy" was eliminated, as we did not identify components within our design that may require energy input. Examples of cards that we identified as relevant to our project include "Provide Sensory Feedback," and "Add Natural Features," as these generated concepts related to the accuracy of a medical procedure. Overall, using design heuristics resulted in 10 design ideas, with 5 being iterations of previous ideas. An example is shown below in Table 5 utilizing the card "Provide Sensory Feedback". More examples of the concepts resulting from using design heuristics can be found in Appendix A.

Table 5. Design Heuristic and corresponding generated concept model

Design Heuristic Card	Concept Generated
	

As shown in Table 5, the card prompting "Provide Sensory Feedback" led to the concept of a full-body simulator with auditory pain indication. This concept showed consideration of patient pain and a way to provide the physician feedback on when to stop the procedure. Many of these heuristics built off of those from the rapid concept generation shown in Figure 11. For example, the idea of a full-body simulator was generated on the Miro virtual whiteboard and the use of design heuristics introduced the idea of auditory pain indication to give sensory feedback. We did not pursue sensory feedback for our model, as our sponsor indicated our model should prioritize mimicking the "feel" of the simulator purely to teach ECV which eliminated the need for auditory pain feedback in our eventual prototype [23].

Morphological Chart

After utilizing the design heuristics, we identified that within the category of a "feels-like" model, many of the concepts focused on designing for a specific subfunction. For example, the use of a silicone layer for the "Cover or Wrap" card was to ensure the model externally feels like skin. However, creating an alert for patient pain with the "Provide Sensory Feedback" card would ensure that it models varying difficulty and emphasize that not every ECV is successful. Therefore, our team identified eight subfunctions that our design must have and created a corresponding morphological chart. These critical subfunctions were generated from both our stakeholder requirements and categories that seemed to naturally emerge during our virtual

whiteboard and design heuristics card sessions. The eight identified subfunctions with descriptions and justifications are highlighted in no particular order in Table 6 below.

Table 6. Subfunctions of physical simulation model

Subfunction	Description & Justification
Externally feels like skin	Per requirement that *Tactile elements feel like pregnant abdomen*
Behaves like abdomen to pressure	Per requirement that *Tactile elements feel like pregnant abdomen*
Models varying difficulty	Per requirement that model *Simulates turning of fetus* ECV is unique to each patient, so must have variable difficulty levels
Fetal model	Per requirement *Simulates common starting breech positions*
Pelvis	Per requirement that *Simulates disengaging from pelvis* First step of an ECV procedure requires disengaging the breech from the pelvis
Base	Per requirement that model is *Stable* Base material informs susceptibility to sliding
Access to inner components	Per requirement that model is *Easy to clean and reset* Need to access fetus/insides to reset model after procedure

Using these subfunctions, we developed a morphological chart by generating concepts for each specific subfunction. Similarly to our initial design generation, we ignored feasibility and generated as many ways to meet the subfunctions as possible. A lot of ideas were pulled from our virtual whiteboard session, as well as from our design heuristics discussion. Our final morphological chart generated over 100,000 possible models. A representative morphological chart is shown in the table below, while the full morphological chart is located in Appendix A.

Table 7. Morphological chart

Subfunctions	Solutions				
Externally feels like skin	silicone	latex	textile/fabric	agar	epoxy resin
Behaves like abdomen to pressure	spring loaded skin layer	memory foam	water bed	balloon	silicone castable foam
Models varying difficulty	one airbag that covers entire abdomen	5 airbags on sides	pull on differently spaced hooks	liquids with different viscosities	torque-adjust able turntable

Fetal model	medical model fetus	poseable stuffed animal (wire)	block with hinges for extremities	doll with velcro to velcro limbs in position	3D printed doll
Pelvis	3D print	halloween decor skeleton	bucket	bowl	medical model pelvis
Base	wood	aluminum	rubber stops	yoga mat	PVC
Easy access to inner components	zipper	sunken base	“fitted sheet”	hooks for skin	velcro

Some notable ideas that highlighted divergent thinking even when working within a list of subfunctions include using a “water-bed” material to emulate the feeling of a pregnant abdomen with amniotic fluid, using a wire-framed stuffed animal to represent the fetus, and using the pelvis of a halloween decor skeleton.

By utilizing a variety of concept generation methods, including rapid concept generation on a virtual whiteboard, design heuristics cards, and a morphological chart, our team was able to successfully generate a high volume concepts to consider. With each concept generation method, we narrowed in on the scope of our design to help focus our thinking. However, we remained divergent in our thinking with each phase to ensure novel and creative ideas were considered.

CONCEPT SELECTION

Moving into concept selection, our team utilized several strategies to narrow down the high number of concepts generated at different stages of concept generation. Our team opted to narrow our concepts in three phases, continually eliminating groups of ideas until a final design was chosen.The primary strategy was to use a morphological chart, as it represented the critical subfunctions of our model and was informed by the ideas generated with the virtual whiteboard and design heuristics cards. We therefore narrowed our ideas from the morphological chart to select a design. An overview of this selection process is shown in Figure 13 below.

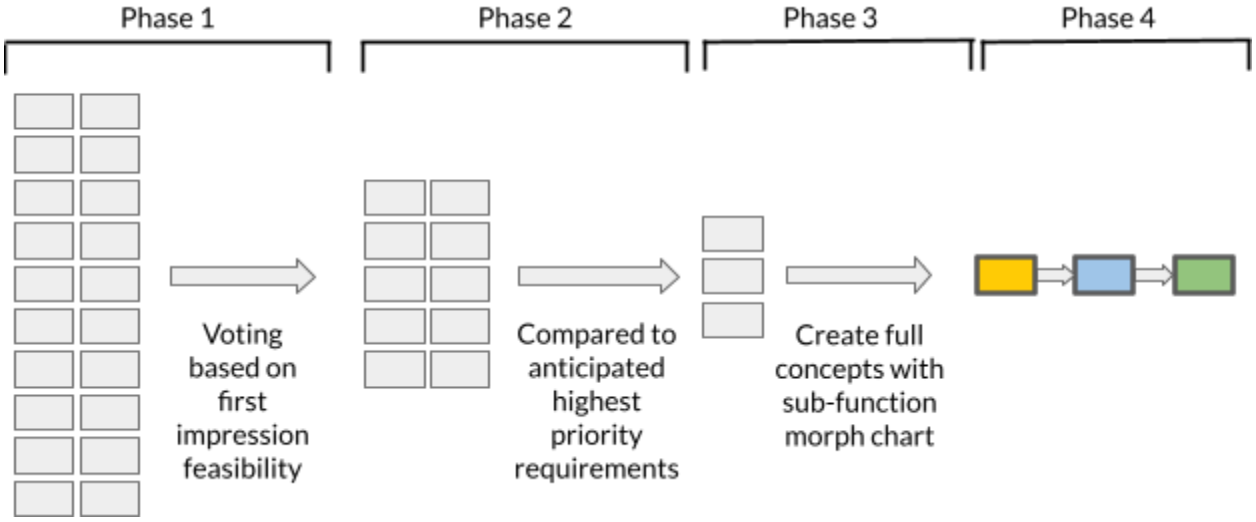


Figure 13. Our team's chosen concept selection process

As shown in Figure 13, we began with a full morphological chart, found in Appendix A, which included any ideas the team had regardless of how realistic or feasible. The phases of this concept selection are described in the proceeding sections. We chose to pursue this strategy over selecting a few specific concepts and narrowing them down from there as our team found that through concept generation, aspects of the model could be "mixed and matched" with each other to create a larger number of concept, which allowed us to then consider which of these aspects were the best in each subfunction category.

Phase 1: Group Vote

In Phase 1, we voted as a group on our first impression feasibility. Each idea from each subfunction was read aloud, and we discussed how it could be implemented in a full model. Considerations for feasibility included cost and effectiveness, but no quantitative values were considered at this time. After discussion, our group of five voted yes or no for the concept remaining in the morphological chart, and the majority ruled. From this discussion, we were able to eliminate ideas and narrow our morphological chart significantly. Examples of concepts eliminated during this phase are shown with strike-throughs in the representative morphological chart in Table 8 below.

Table 8. Phase 3 morphological chart

Subfunctions	Solutions				
Externally feels like skin	silicone	~~latex~~	textile/fabric	~~agar~~	polyurethane
Behaves like abdomen to pressure	~~spring-loaded skin layer~~	memory foam	~~water bed~~	balloon	silicone castable foam
Models varying difficulty	one airbag that covers entire abdomen	5 airbags on sides	pull on differently spaced hooks	~~liquids with different viscosities~~	torque-adjustable turntable
Fetal model	medical model fetus	poseable stuffed animal (wire)	~~block with hinges for extremities~~	doll with velcro position limbs	3d printed doll
Pelvis	3D print	~~halloween decor skeleton~~	bucket	bowl	medical model pelvis
Base	wood	aluminum	rubber stops	~~yoga mat~~	~~PVC~~
Easy access to inner components	zipper	sunken base	~~"fitted sheet"~~	hooks for skin	velcro

As previously mentioned, each of the eliminated concepts was voted on after a group discussion of possible concerns. For example, we eliminated agar as a potential skin material because of its potential to grow microorganisms, while latex was eliminated due to latex allergy concerns. Spring-loaded skin layer and water bed were eliminated because of anticipated difficulty finding or manufacturing these materials. Utilizing liquids with different viscosities was removed because it seemed potentially messy or hazardous, while utilizing multiple different-sized fetuses was removed because it seemed unnecessary to have extra components rather than one fetus. The block with hinges was removed as a model fetus because using flat hinges on a rounded shape would be difficult to implement. Using a Halloween decor skeleton pelvis as our model pelvis was eliminated in an effort to be conscious about our consumption and waste production as the rest of the skeleton model aside from the pelvis would not be utilized. Yoga mat and PVC were eliminated as a base material based on suspected low friction relative to the other concepts. Finally, the "fitted sheet" skin layer was eliminated as it seemed difficult to properly secure during the simulation. The remaining concepts received at least 3 out of 5 yes votes to remain as potential solutions. This voting led to a reduced morphological chart, leading to Phase 2 of our process in which we compared each concept to our user requirements.

Phase 2: Comparing to Requirements

After this initial concept reduction, we took our narrowed-down morphological chart and began to compare ideas directly to our requirements. Once compared, we eliminated possible solutions from the morphological chart that did not meet the requirements, which are seen in Table 9.

Table 9. Phase 2 Morphological Chart

Subfunctions	Solutions			
Externally feels like skin	silicone	~~textile/fabric~~	polyurethane	
Behaves like abdomen to pressure	memory foam	~~balloon~~	silicone castable foam	
Models varying difficulty	~~one airbag that covers entire abdomen~~	5 airbags on sides	pull on differently spaced hooks	torque-adjustable turntable
Fetal model	~~medical model fetus~~	poseable stuffed animal (wire)	doll with velcro to velcro limbs in position	3D printed doll
Pelvis	3D print	bucket	bowl	~~medical model pelvis~~
Base	wood	aluminum	rubber stops	
Easy access to inner components	zipper	~~sunken base~~	hooks for skin	velcro

With each remaining concept in the morphological chart, our team discussed if it would be difficult to achieve any of our requirements with this concept. Textile/fabric was eliminated as a way to model skin due to the requirement that *must be compatible with ultrasound gel*. As fabric is not water repellent, it would absorb the ultrasound gel and therefore is not compatible [55]. A balloon was eliminated as a way to behave like an abdomen to pressure due to the *Long-lasting* requirement, as a balloon is susceptible to tearing or popping. The use of one airbag to model varying difficulty was eliminated due to the requirement that the model requires *Representative pressure used to perform ECV.* It was determined that one airbag will not accurately represent the pressure used to perform ECV, as the pressure varies at different points on the abdomen depending on the five abdominal muscles. A medical model fetus and medical model pelvis were eliminated due to the *Low cost* requirement. Medical model fetuses and pelvises can cost up to $204 and $148, respectively, and therefore did not meet our cost requirement [39][40]. A sunken base was eliminated because of the *Stable* requirement. A sunken base would be a base in which a divot or slot is made such that the abdominal portion can sit or “sink into” and be constrained

by the base on either side. Our team had concerns that this might be difficult to lock such that it does not risk sliding or lifting while the simulation is in progress.

Comparing our morphological chart against our requirements left us with a significantly narrowed subfunction concept list. The remaining elements in the morphological chart seemed promising towards meeting our requirements and therefore remained in the chart.

Phase 3: Full Concept from Narrowed Subfunctions
The narrowed morphological chart resulted in 2-3 concepts remaining for each subfunction, as shown below in Table 10.

Table 10. Phase 3 Morphological Chart

Subfunctions	Solutions		
Externally feels like skin	silicone	polyurethane	
Behaves like abdomen to pressure	memory foam	silicone castable foam	
Models varying difficulty	5 airbags on sides	pull on differently spaced hooks	torque-adjustable turntable
Fetal model	poseable stuffed animal (wire)	doll with velcro to velcro limbs in position	3D printed doll
Pelvis	3D print	bucket	bowl
Base	wood	aluminum	rubber stops
Easy access to inner components	zipper	hooks for skin	velcro

The remaining concepts in Table 10 represented solutions our team believed could be reasonably used for our model. From here, our team explored many possibilities for proceeding with full design concepts. Our team recognized that the specific subfunctions of our model are largely independent of one another, and the design concepts could be used interchangeably within the model. For example, selecting a base material was largely independent of selecting a fetal model in breech positions. Some dependencies existed within the remaining concepts in Table 10, specifically between silicone and silicone castable foam, as utilizing the castable foam was dependent on applying the foam to a layer of silicone. Another dependency existed between the use of hooks to model varying difficulty, as this also dictated that hooks for skin would be used for easy access to inner components. Utilizing hooks would entail attaching cup hooks to our base and attaching grommets to the abdominal part of the model to hook onto the base. To simulate varying difficulty, the hooks could be placed at many distances to stretch the abdominal model variably. Aside from these examples of subfunctions interactions, the concepts were interchangeable, and therefore our team proceeded by creating a Pugh chart for each subfunction

to determine the optimal concept within each subfunction. Our team discussed that, in the event of competing Pugh chart results, such as hooks being an optimal concept for varying difficulty but not easy access or vice versa, we discussed as a team the pros and cons of meeting each subfunction. We evaluated how utilizing a "suboptimal" result in one subfunction may impact our design and if it is permissible to allow another subfunction to be optimal. Thus, our team proceeded with seven subfunction Pugh charts, where each concept was ranked relative to one another to select optimal subfunction components. A representative subfunction Pugh chart is shown below in Table 11, while the remainder of the subfunction Pugh charts are located in Appendix B.

Table 11. Pelvis subfunction Pugh chart

Selection Criteria	Justification	Weight	3D Print	Bucket	Bowl
Low cost	Per *Low cost* requirement	3	-	+	+
Long-lasting	Per *Long-Lasting* requirement	2	0	0	0
Locally repairable	Per *Can be repaired locally* requirement	1	0	+	+
Allows user to disengage breech	Per requirement that *Simulates disengaging from pelvis*	1	+	-	0
Representative width of human pelvis	Per requirement that model *Simulates disengaging from pelvis*	1	+	-	0
Representative depth of human pelvis	Per requirement that model *Simulates disengaging from pelvis*	1	+	-	0
	Total		**0**	**+1**	**+4**

The selection criteria of each Pugh chart was informed by our user requirements and meetings with our sponsor to understand which aspects of each function's design were most crucial. Weights were selected according to the priority levels of the related requirement as outlined in Table 2. High priority requirements were assigned the highest weight of 3, medium priority requirements were assigned a weight of 2, and low priority requirements were assigned the lowest weight of 1. Each subfunction concept was evaluated based on a score system of -, 0, +. If a concept failed to meet the selection criteria, it received a -. If a concept partially achieved the selection criteria, it received a 0. If a concept fully achieved the selection criteria, it received a +.

In the example of Table 11 shown above, our highly weighted selection criteria included allowing the user to disengage the breech and remaining low cost. Disengaging the breech is a key step in performing an ECV and was related to our requirement of simulating common starting breech positions, as the fetus begins in the pelvis. Our team discussed that it may be too difficult to disengage pelvis from a bucket relative to a 3D printed pelvis or bowl, as buckets are more narrow with a greater depth. Low cost was one of our high priority requirements and thus a highly weighted selection criteria. 3D printing such a large anatomical model would likely be

expensive relative to purchasing a bucket or bowl from any local store. Medium weighted selection criteria included representative width and depth of human pelvis, to ensure the model dimensionally represents a human pelvis. Our team determined that a bucket may be too narrow and too deep relative to a 3D printed model or bowl. Long-lasting was a medium weighted criteria, as it was a medium priority requirement. Our team saw no significant differences in anticipated lifespans, and thus they were ranked equally. A pelvic model that was locally available or repairable in Ghana was a low weighted criteria, as this was a low priority requirement. We determined that a bucket or bowl were likely more available or repairable than a 3D printed pelvis.

The remainder of the subfunction concepts were evaluated using similar logic to determine selection criteria and weighting. The highest ranking concept from each subfunction is shown in Table 12 below.

Table 12. Highest ranking subfunction concepts

Subfunction	Selected Concept
Externally feels like skin	silicone
Behaves like abdomen to pressure	silicone castable foam
Models varying difficulty	5 airbags on sides
Fetal model	doll with velcro to velcro limbs in position
Pelvis	bowl
Base	wood, rubber stops
Easy access to inner components	zipper

The selected concepts in Table 12 were then combined to create a full design concept. This design concept acted as an initial design with which we continued to iterate and revisit old concepts as necessary. A sketch of this design concept is shown below in Figure 14.

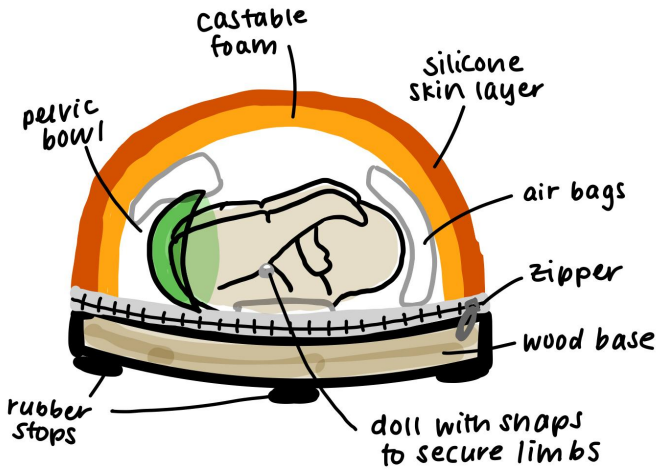


Figure 14. Highest ranked subfunctions design sketch

This design encompassed each of the highest ranked subfunction components. Note that although rubber stops were selected as the optimal concept for the base, rubber stops can not act as a physical stage for the model but rather an additional material for increased stability. Thus, the next highest ranked base material of wood was utilized as the main base, with rubber stops attached as the material to contact any surfaces. With this preliminary design, our team recognized previously eliminated elements of our morphological chart would likely need to be revisited as we received feedback and evaluated against engineering specifications.

The first solution concept that occurred to our team was similar to our selected concept, as our initial assumption for the project was to create a physical simulation model. However, to avoid fixation on this early idea, we employed the aforementioned divergent thinking concepts such as a virtual whiteboard and design heuristics. This divergent thinking allowed our team to explore a wide variety of possible ideas, then reconverge towards a physical simulation model. It also allowed us to identify seven key subfunctions of our design amongst the wide variety of design concepts. Thus, although we arrived at a concept within our initial solution space, the individual elements that composed this design are a result of rigorous concept generation.

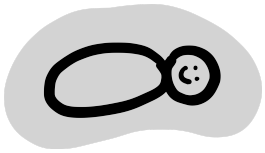
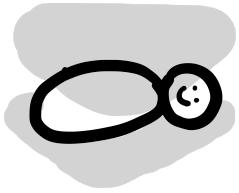
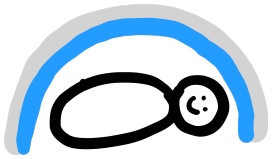
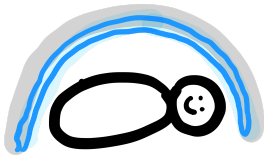
Phase 4: Concept Iteration

In accordance with the iterative nature of our selected design process (Figure 6), our team presented and reviewed this design with our project sponsor Dr. Thiyag to identify any gaps in design or elements that could be improved.

Dr. Thiyag's feedback sparked further concept development within our team, particularly relating to properly mimicking uterine and abdominal muscle. She expressed that these elements and their placement with respect to the fetus heavily influence the pressure that must be exerted and how the fetus will turn [23]. Dr. Thiyag informed us that these elements significantly affect the physician's ability to successfully feel and turn the fetus and are the "crux of performing an ECV" [23]. The abdominal muscles act as a static barrier to the procedure and do not move with physician palpation. The uterine muscles act as a dynamic barrier to the procedure and move as

the physician turns the fetus inside the uterus [23]. However, since they share a function of acting as a physical barrier between the physician and fetus, our team generated concepts that attempted to mimic both sets of muscles. With this sponsor feedback, our team had another brainstorming session in which we identified 5 major concepts to effectively represent uterine and abdominal muscles. All other design elements remained the same as in Figure 13, as they were largely unaffected by the proposed additional elements. These five new concepts are shown below in Table 13.

Table 13. Five new concepts from iteration discussion

#	Concept Sketch	Description
1		Uterus-shaped plastic bag filled with air Model fetus placed inside bag
2		2 uterus-shaped plastic bags filled with gel Model fetus placed between bags
3		Rubber layer underneath castable foam
4		Airbag underneath castable foam
5		“Gel ice-pack” layer underneath castable foam

Our team then evaluated these 5 concepts using a Pugh chart to identify the optimal solutions, as shown below in Table 14. Note that the assigned concept numbers correspond to those defined in Table 13. We elected to do another Pugh chart down-selection to fully evaluate to what extent each concept may fulfill our requirements in a quantified manner.

Table 14. Pugh chart of five new concepts

Selected Criteria	Justification	Weight	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Responds like abdominal muscles to pressure	Per *Tactile elements feel like pregnant abdomen*	3	-	-	+	+	+
Responds like uterine muscles to pressure	Per *Tactile elements feel like pregnant abdomen*	3	+	+	-	-	-
Allows palpation of fetus	Per *Fetus can be palpated*	3	+	+	-	-	+
Low cost	Per *Low Cost* requirement	3	+	+	0	0	+
Long-lasting	Per *Long-lasting* requirement	2	-	0	+	0	0
Locally repairable	Per *Can be repaired locally* requirement	1	+	+	+	+	+
Total			+5	+7	0	-4	+7

Weights were selected according to the priority levels of the related requirement as outlined in Table 2. High priority requirements were assigned the highest weight of 3, medium priority requirements were assigned a weight of 2, and low priority requirements were assigned the lowest weight of 1. Our highest weighted selected criteria included that the concept responds like abdominal or uterine muscles to pressure. These were key criteria identified by our sponsor [23]. Design Concepts 3, 4, and 5 received a + score for fully achieving mimicking abdominal muscles, as they act as static components on our model, similar to abdominal muscles. However, Design Concepts 1 and 2 received a + score for fully achieving mimicking uterine muscles, as they are dynamic components that move relative to the abdomen, similar to uterine muscles.

Another highly weighted criteria was to allow palpation of the fetus. As informed by our sponsor, palpation of the fetus is an essential part of ECV. Our team determined that Concepts 1, 2, and 5 would allow for palpation of the fetus, as gel packs and a plastic bag will likely be easy to manipulate and palpate through. However, Concepts 3 and 4 received a - score, as it may be

difficult to palpate through an air bag or rubber layer. Low cost was a highly weighted criteria because it was a high priority requirement for our project, due to the intended users in LMICs. Concepts 1, 2, and 5 were likely to meet this criteria, as they are relatively low-cost items. Concepts 3 and 4 received a score of 0, as they are more expensive options. Even if they meet our specification, the other concepts were more low cost. Long-lasting was weighted as a medium criteria because it was a medium priority requirement. We anticipated that a rubber material may be more long-lasting than airbag or gel pack components. In particular, Concept 1 received a - score, as a plastic bag is typically a single-use material and not meant to be long-lasting.

Finally, locally available or repairable was a low weighted criteria because it was a low priority requirement for our project. We did not identify any significant availability or repairability differences among each concept and expected that plastic bags, gel packs, air bags, and rubber are all available in Ghana.

As shown above in Table 14, Design Concept 2 (two uterus-shaped plastic bags filled with gel) and Concept 5 ("Gel ice-pack" layer underneath castable foam) were found to be the most optimal in representing uterine and abdominal muscles that a physician feels throughout the procedure when palpating the fetus. Initially, our team was going to attempt to narrow our selection to one concept. However, a closer look at the Pugh chart showed that either of these concepts alone failed to accurately model both the static obstruction that abdominal muscles provide and the dynamic muscles in the uterus that the physician has to palpate through and physically manipulate. Our sponsor expressed the need for both to be represented in our final prototype, so we decided to implement both of these design concepts in order to adequately model both uterine and abdominal muscles in the simulator. Our initial idea that both muscles may be emulated with one design concept was rejected in the results of our Pugh chart, and therefore we proceeded with incorporating the two new concepts.

After incorporating plastic bags filled with gel and a gel layer underneath the castable foam into our design, this design became our current selected "Alpha Design," as described in the following section.

First Selected Concept

The selected "Alpha Design" for the preliminary prototype is seen in Figure 15 below.

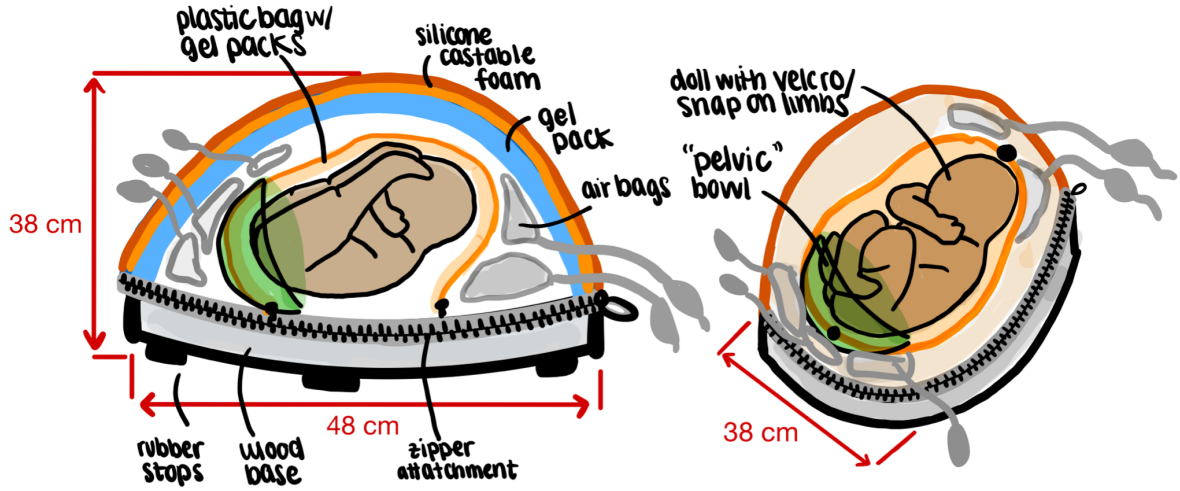


Figure 15. Alpha design drawing

Through iterating on our initial full concept design to include proper representation of uterine and abdominal muscles, our team landed on our Alpha design concept as seen in Figure 15 above. With all of our highest ranked subfunction components, our Alpha design had a wood frame/stage that connected to our abdominal skin layer and muscle subfunction components using a zipper attachment. The outer skin layer was a castable silicone layer with an added castable foam to emulate skin feeling and elastic behavior, with a gel pack layered inside to represent abdominal muscle obstruction. The fetus model was encased in a plastic gel layer emulating the uterus and uterine muscles. This gel layer pouch was fixed onto the base to inhibit translational movement while allowing for malleability and manipulation of its surface, as well as slight turning in response to physician movement. The model fetus was a doll with velcro on limbs in order to secure the legs in different breech positions (e.g. a snap on the model's knee corresponding to a snap on its chest to keep the knee up in complete breech). Various airbags would be implemented under the fetal model to not obstruct physician feeling and palpation, with manual hand pumps that could be used to create variable pressures and adjust procedural difficulty in the simulator. Dimensions of our model were initially estimated by referencing Benchmark 1 (Table 3) with a length, width, and height of 48, 38, and 38 cm respectively [24]. A pre-emptive bill of materials totaling $89.14, and CAD model used for dimensional reference of the Alpha design is located in Appendix C.

Our selected concept was chosen due to heavy sponsor influence because of their position as a knowledgeable stakeholder on ECV. An 'objective' selection process (one without the input of our sponsor) might have pointed to a different solution as we did not have the knowledge or experience required to inform robust design decisions for the simulator. These considerations were used independently to down-select in the Pugh chart above according to our ranked requirements. Therefore, we were able to still carry out engineering methods and analysis in the scope of the information we were given.

CONCEPT ITERATION & ENGINEERING ANALYSIS

After selecting our initial "Alpha Design" concept, we explored how this design may meet our requirements and specifications by leveraging our working knowledge from coursework in statics, mechanics, and mechanical behavior of materials, as well as stakeholder engagement. As outlined in our team's design process (Fig. 6), we anticipated the need to continually iterate our design as we conducted engineering analysis and accounted for stakeholder feedback. Further, although the lack of existing ECV simulators was an opportunity for our team to make a novel device, this made it difficult to anticipate how unique components may work together. Therefore, our first selected "Alpha" design (Fig. 15) underwent continuous iteration to best meet our requirements and specifications. Detailed below is the evolution of our selected concept and corresponding engineering analysis.

Uterus Model

In assessing the uterus design, varying ECV difficulty remained a point of interest that we have been continually iterating to ensure it meets our project specifications and sponsor desires. Our original "Alpha" design had the fetus model surrounded by a bag of gel packs, which were then surrounded by air bags on the top and sides of the abdomen to mimic major abdominal muscles that could be filled with varying amounts of air to change the difficulty of the procedure. As our team continued to discuss this design, there were concerns that it may be too difficult to turn the fetus if it is "sandwiched" between gel packs. Per our high priority requirement *Simulates turning of fetus*, it was critical that our fetus has room to physically turn 180°, which may be difficult if surrounded too tightly by gel packs. Additionally, there were concerns that it may be difficult to palpate the fetus with inflated airbags and two layers of gel packs, as *Fetus can be palpated* was one of our high priority requirements. In discussion with our sponsor, these concerns with the "Alpha" design were confirmed. She also expressed that it may be of higher fidelity to have something completely enclosing our fetal model that contributes to the varying difficulty, similar to a real pregnant uterus [23].

Our team conceptualized using a beach ball to mimic the uterus, which could be inflated to different levels in order to change the difficulty, as shown in the concept sketch in Figure 16 below.

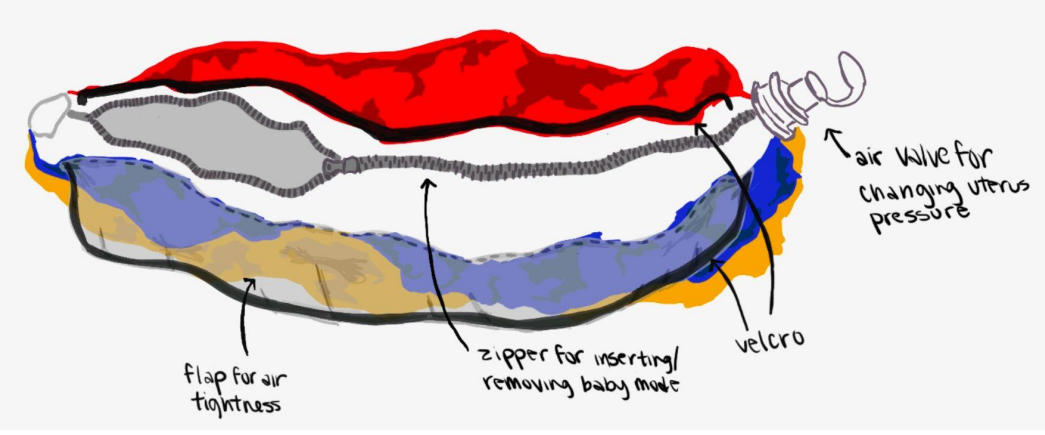


Figure 16. Concept sketch of beach ball uterus model

As shown in Figure 16, this design would require us to alter a beach ball to our needs. We would attach a zipper to the ball to make the fetus model inside easily accessible. Then, a flap of velcro

would be attached to enclose the zipper to keep it airtight. As we began prototyping, we encountered significant difficulty keeping the model airtight. Therefore, we were unable to vary the amount of air in the beach ball, and it would not withstand the pressure used to simulate ECV. A detailed account of the prototyping process for the beach ball is located in Appendix C.

Looking back at our initial concept generation for ways to model the uterus, we reevaluated the idea of using a plastic bag. The press-to-close aspect of the bags would ensure easy access to the fetus model inside, and the bag is thin enough that it would not disrupt the palpation of the fetus. Though the plastic bag, due to elastic deformation properties and overall material thickness, would be the weakest part of our model, it would also be the cheapest and easiest to replace, at less than $1.00 per bag [61]. Confirmation with our sponsor led us to move forward with using McMaster Carr press-to-close bags as our current solution. We calculated the properly sized press-to-close bags using an estimate of the total intra-uterine volume (TIUV) at 37 weeks gestation, and we determined a 12”x13” press-to-close bag will best fit our dimensional needs [81]. The details of this estimation are located in Appendix C. To achieve the correct shape, we heat sealed the edges of the rectangular bag. We planned to fill the bag with varying amounts of water to change the difficulty of the procedure as a result of discussion with our sponsor. Unlike the beach ball, the plastic bags do not have an existing valve to easily calibrate how much air would be pumped into the bag. However, it would be feasible to measure and pour a calibrated amount of water into the bag. Additionally, amniotic fluid is quite similar to the viscosity of water at 37 weeks gestation, so our team had high confidence that it would be a successful design choice [86].

Baby Model

Our initial concept was to purchase a soft-bodied baby doll and add snap buttons or velcro to position the limbs into various breech positions. A 20” length baby doll was purchased and snap buttons were sewn onto its body as shown in Figure 17.

Figure 17. Fetal model in breech positions

However, our fetal model did not match fetal dimensions at 37 weeks gestation, with a head circumference of approximately 32.6 cm and a length in breech position of approximately 28 cm [87]. Additionally, our sponsor identified the main features needed to palpate the fetus included the head, spine, and legs/buttocks [23]. This fetal model was soft-bodied and therefore did not have a hard spine to palpate and could not be submerged in water per our updated uterus model. The baby doll also had a hollow head that would concave when pressure was applied, unlike a live fetus head. For these reasons, our team sought a new concept for our fetal model. We chose

to craft a do-it-yourself model made out of a bocce ball, plastic grocery bags, and duct tape. A detailed description of how this fetal model was created can be found in the fabrication plan in Appendix F. These materials are waterproof and could be tailored to our specified dimensions. The bocce ball will remain firm when palpated. This option was selected in lieu of other mechanisms from our concept generation phase due material availability as household items and the X50 Lab. Given the budget constraints of the project, this do-it-yourself fetal model was the best concept readily available to use for our model with no extra cost.

Base Design

In order to determine if our model met our stability requirement, we performed a simple force analysis on potential table-base interface materials from our concept generation. We wanted to determine which table-base interface material would best restrict model movement while minimizing total weight. Full assumptions and calculations performed are detailed in Appendix C. Our analysis revealed that using rubber stops as the table-base interface material would best restrict movement throughout the procedure while minimizing weight to remain static. We opted to move forward with rubber stops as the interface material, but still had to select a material for our actual base. Considering that even with rubber stops we still needed our model to weigh at least 14.33 kgs, we initially looked to using aluminum as our main base material, as it contributed a lot of weight to our design. However, our aluminum base design would cost $177.25, which surpassed our optimal cost specification of $100 and was over half of our minimal specification of $350. The bill of materials for this base is shown in Appendix C. Because of the high cost, we reevaluated other base materials, specifically plywood. The cost comparison of the two materials based on needed dimensions is shown in Table 15 below.

Table 15. Cost analysis of base materials

Aluminum	BC Plywood
$177.25	$9.46

Since cost is a high priority requirement, we decided to move forward with BC plywood as our base material. Additionally, we pivoted to using an anti-slip mat, which was still made of the previously selected rubber material but would cover the entire surface area of the base. The friction coefficient for the anti-slip mat was determined to be 0.8 [64], and the new force our model could withstand before slipping was calculated to be 64 N. Though this was still less than our minimum specification, the friction coefficient was conservative, so we planned to verify the stability through experimental testing with different options for an anti-slip mat, as discussed further in our verification plans.

Outer Layer Material Selections

Our original outer layer selection was based on literature review of a research model used at Drexel University [65]. However, this combination of silicone and castable foam was fairly expensive and had an elastic modulus of approximately 600 kPa, nearly 6x our specification. Our team also recognized that we may have downselected our outer layer materials too quickly. This realization occurred when discussing as a team the subjectivity of our specifications and how many tactile elements relied on physical samples or prototypes to know if they would be successful. Theoretical analysis was not as effective as physically feeling the materials and then downselecting. Therefore, we decided to reevaluate the outer layer selection and purchase samples of many materials.

Through literature review, we determined that silicone rubber is used in medical models for skin, fat, and muscle imitation [42]. From here, we identified a common distributor for silicone rubbers with well-documented material properties, Smooth-On. Using our specifications for elastic moduli, we determined EcoFlex 00-50 best meets our external layer specification, while EcoFlex 00-20 best meets our internal layer specification. The detailed comparison of elastic moduli of the selected silicones can be found in Appendix C. We chose to order trial sizes and move forward with these silicone rubbers for our materials. We also recognized that the selected silicone rubbers may be costly, so we sought lower-cost materials, specifically for the thicker layer meant to mimic fat and muscle, as this will be more costly to use silicone rubber. Our sponsor identified soft foam and gel ice packs as potential materials that may be likened to the palpation of a pregnant abdomen.

We created 6 possible combinations of layers to emulate the layers of a pregnant abdomen. These layers feature EcoFlex 00-50 as the outer layer and variations of EcoFlex 00-20, soft foam, and gel ice packs. EcoFlex 00-50 was selected as the outer layer for each combination, as we felt confident it would be successful. It is the thinnest layer, so we anticipated it would remain affordable to cast. Our sponsor expressed that the inner layers contribute most significantly to the feeling of palpation, so we prioritized testing these variations [23]. Full details of each combination of layers and how they were chosen can be found in Appendix C. We visited the UM Simulation Center and compared their feeling to Victoria, a medical birthing simulator. We

had each team member palpate each sample and select the combination they felt best resembles the feeling of Victoria. The combination of EcoFlex 00-50 and 2.54 cm EcoFlex 00-20 as well as EcoFlex 00-50, 0.64 cm soft foam, and a gel ice pack felt the most akin to Victoria's abdomen. Since both samples were equally comparable to an existing high-fidelity medical model, we decided to evaluate the cost of both options. Since both options utilized EcoFlex 00-50, only the cost of the inner layers were included. The cost difference between both combinations is shown in Table 16 below, with more detailed calculations in Appendix C.

Table 16. Cost analysis of outer layer materials

EcoFlex 00-20	Gel Packs + Foam
$197.50	$43.39

As seen in Table 16, Ecoflex 00-20 was more expensive than gel packs and foam. Since low-cost was a high priority requirement for our model, we moved forward with an outer layer consisting of a thin layer of Ecoflex 00-50, 0.64 cm foam layer, and a gel pack underneath.

Outer Layer to Base Attachment Mechanism

Further analysis of a zipper as the attachment mechanism of our outer layers to the base revealed some concerns of failure. We were unsure if sewing a zipper to the Ecoflex would result in strength reduction of the material, and had concerns of being able to attach a 2 cm thick layer to a single zipper. Because of these concerns, we opted to use a hose clamp as our attachment mechanism, so as to not damage the structural integrity of the silicone and to have greater flexibility in securing our layers. The hose clamp allows for removal of the outer layers in the case that internal components need to be replaced or repaired. The hose clamp was selected in lieu of other mechanisms from our concept generation phase due its availability in the X50 Lab. Given the budget constraints of the project, the hose clamp was the best mechanism readily available to use for our model with no extra cost.

FINAL DESIGN

Through the continuous iteration and engineering analysis performed as highlighted in section above, we developed a new final design including the improved subcomponent selections.

Design Concept

An exposed view of our final design concept can be seen in Figure 18 below.

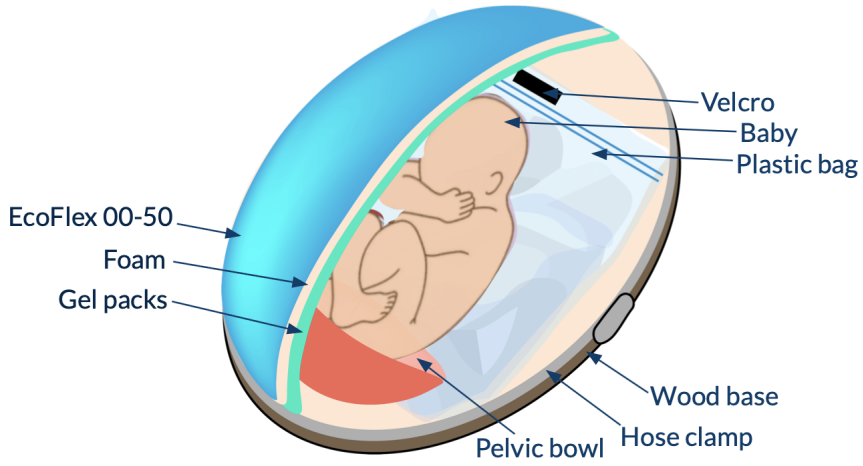


Figure 18. Exposed isometric view of final design concept

Attached to the plywood base of our model is a layer of foam. The plastic pelvic bowl sits within it, and the uterus subsystem was fixed to the foam via velcro. The uterus subsystem partially sat inside the pelvic bowl given the flexibility of the plastic bag and formability of the water. The baby was a do-it-yourself fetus model created using common materials, as detailed in the fabrication plan in Appendix F. From there, the skin subsystem made up of EcoFlex 00-50 silicone, foam, and gel packs was attached to the base using a hose clamp. The outer silicone layer is what was clamped down to base, while the foam and gel pack were secured underneath. Front and side views of the model as well as high level dimensions can be seen in the figure below. Design justification and further detailed dimensions will be discussed with the CAD model, while the engineering drawings of the final design concept are seen in Figure 19 below.

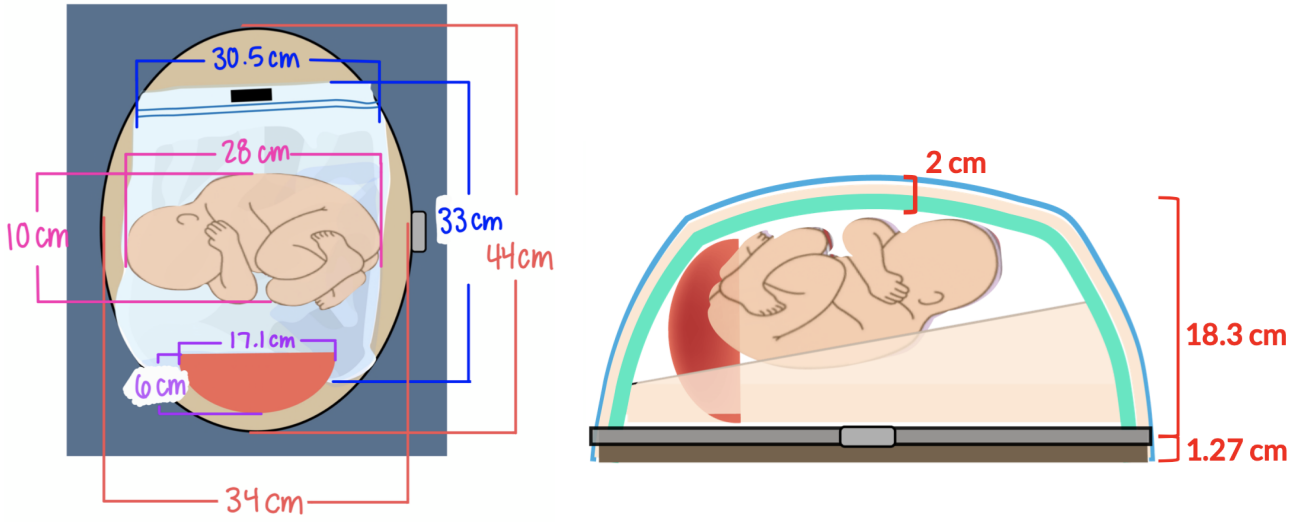


Figure 19. Engineering drawings of final design concept

In virtually modeling our simulator, we ran into issues regarding the accurate modeling of anatomy. Organic shapes are naturally more difficult to recreate in CAD software, so we

conducted a lot of research into literature for help in dimensions and relative proportioning, but ultimately found the most utility in taking measurements of the abdomen of a birthing simulator provided by the Michigan Simulation Center. From information gathered during sponsor interviews, literature review, and taking our own measurements, we created a full, accurate 3D model using SolidWorks in Figure 20 below.

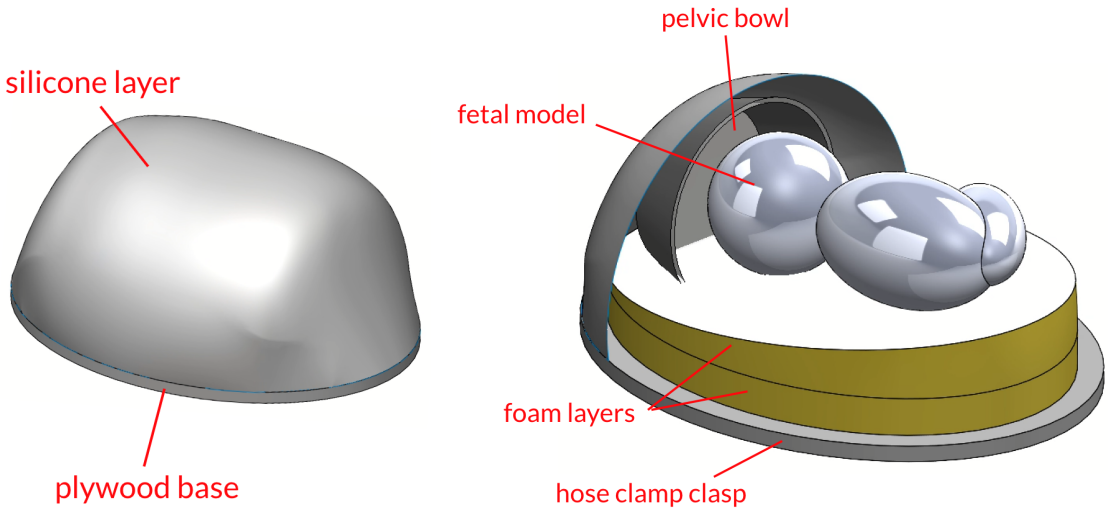


Figure 20. CAD visualization of final design concept

In the left image, the external view of the prototype is shown, where a silicone layer was stretched over the inner components atop the elliptical plywood base. This silicone layer was dimensioned and modeled by taking the outer arc measurements along the length of the abdomen of a birthing simulator from the University of Michigan Simulation Center, then creating a surface across the arcs. The right image displays the inner components of the simulator, including a bowl to emulate a pelvis, and foam layers to hold it in place as well as elevate the fetal model. The plywood base and foam layers were shaped as ellipses as in Figure 21 below, based on dimensions taken from the same birthing simulator.

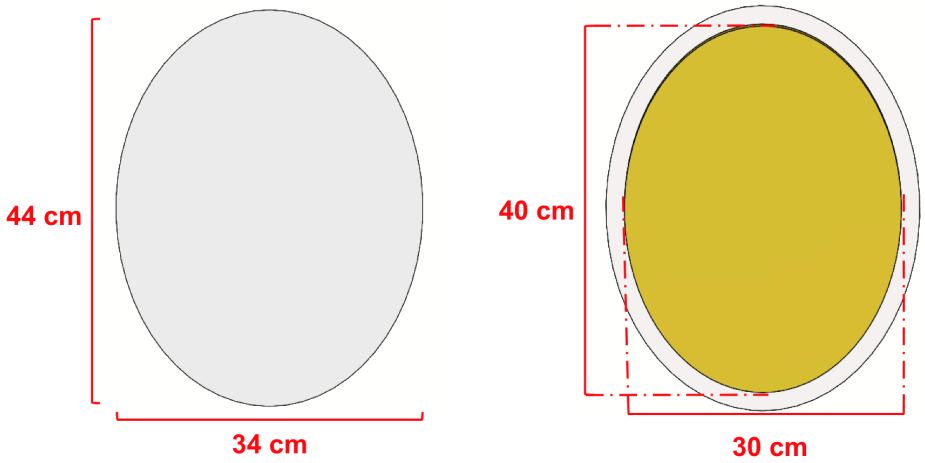


Figure 21. Top view of plywood base and foam layers

As shown, the foam layers were 4 cm shorter in both the horizontal and vertical directions to make room for silicone and other layers that comprise the skin. The foam layers were glued on top of the plywood base to elevate and hold the fetal model and pelvis bowl in place. Both inner components are shown below in Figure 22.

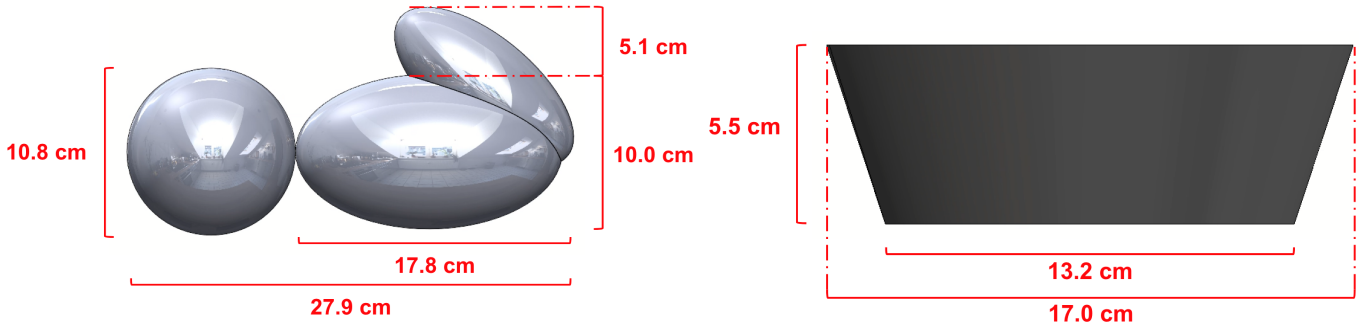


Figure 22. Fetal model and pelvis bowl, side view

The fetal model was dimensioned based on the fetal biometry of a 50th percentile fetus at 37 weeks' gestation. The bowl that will act as the pelvis was a Target brand bowl with a top (open) diameter of 17.0 cm, bottom diameter of 13.2 cm, and depth of 5.5 cm [67]. This bowl was placed in a slot cut into the base foam layers so it stayed rigidly in place even while experiencing palpation. Its depth and outer circumference were akin to that of an anatomical pelvis, where the transverse diameter of the pelvis inlet and outlet is typically 13 cm [84]. The dimensions of the foam are shown in Figure 23 below.

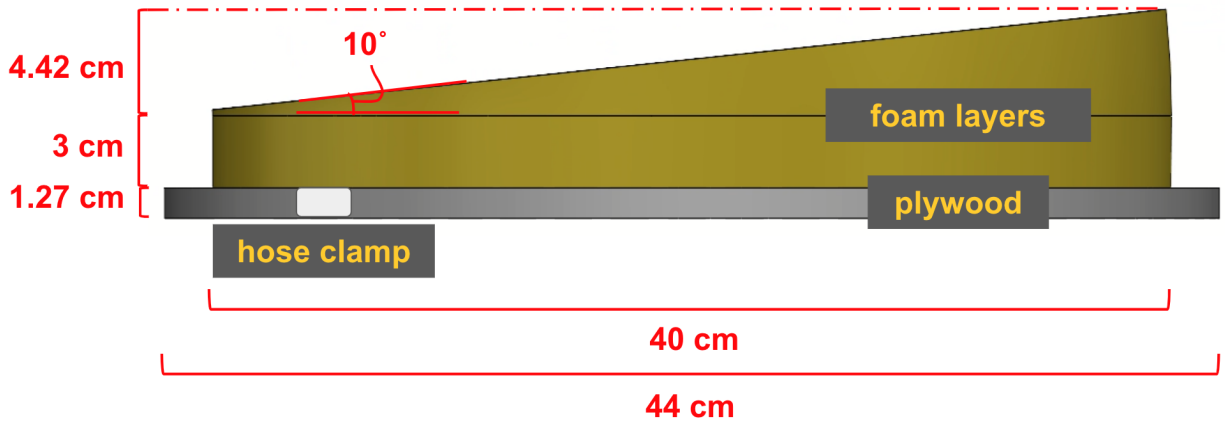


Figure 23. Side view of CAD base with dimensions

In the figure above, the side view of the base and all attached layers can be seen. On top of the laser-cut plywood base, the foam layers elevated and held the inner components. The 3 cm layer provided adequate depth for the bowl to rest in without exceeding the bounds of the silicone as dimensioned from the birthing model, and the 10˚ incline on the second layer of foam helped to position the fetal model such that the curvature of the mother's spine in supine position was accounted for [85].

Bill of Materials

A bill of materials for our final design is shown below in Table 17.

Table 17. Final design bill of materials

Part Title	Material	Dimension(s)	Supplier*	Qty.	Cost	Notes
Pelvis	Plastic	6.75" dia, 2.62" depth	Target	1	$0.50	subject to change due to sponsor feedback
Fetus body	Plastic bags	N/A	N/A	30	$0.00	common free product, assuming negligible cost
Fetus body	Duct tape	1.88" x 15 yds.	Amazon	1	$3.94	any strong, waterproof tape is sufficient
Fetus head	Coated foam	4" dia	Joann Fabrics	1	$2.63	any spherical object ~4" dia is sufficient
Base	Wood	24" x 24" x 15/26"	Home Depot	1	$9.46	dimensions of wood will be reduced post-machining
Base non slip mat	Neoprene	24" x 15"	Amazon	1	$14.99	
Hose clamp	304 Stainless steel	15’ length, 1/2" width	Amazon	1	$9.99	15 ft available, will cut to length required by model
Silicone rubber	EcoFlex 00-50	1 lb	Smooth On	2	$61.48	
Gel packs	Soft reusable ice packs	12.2" x 4.7"	Amazon	2	$35.60	packs of 2, total quantity of 4
Base Foam	32 ILD/ 1.40 lbs cu/ft	.5" x 24"x 72"	Joann Fabrics	1	$13.49	
Velcro	Industrial strength velcro	4" x 2"	Menards	1	$9.97	
Uterus	Heavy duty LDPE plastic	16" x 18"	Amazon	1	$0.98	Pack of 12, cost is price per bag
Outer Layer Foam	Airtex High Density Foam	1/2" x 24"	Joann Fabrics	1	$7.79	
				Total Cost:	**$170.82**	

The calculated total material cost for our final simulator was $170.82 as shown above. This remained below our minimum cost specification of $350. Overall, the greatest cost for our device components stemmed from the outer layer material components.

With our final design completed, it was imperative that we began manufacturing our subsystems and full design quickly, as most of our requirements were subjective and required physical verification in lieu of theoretical analysis. We were able to manufacture several of our subsystems individually throughout the semester, and combined them into our full prototype at the end of the semester.

Build Design Prototype

With the final design built, the team was able to see how each designed part or off the shelf component interacted with each other when all assembled. We were also able to gather feedback from our sponsor and test our specifications. Since our build design is our final design, we were able to directly evaluate the performance of our final design with our sponsor. Shown below in Figure 23 is the prototype our team was able to build during the course of this semester. More detailed component-level photos and our manufacturing plan can be found in Appendix F.

Figure 23. Final design prototype, fully assembled (left) and internal view (right)

The build proved that all elements of our design could work cohesively to achieve the objective of modeling the ECV procedure. Due to the critical interaction between components, the feasibility and performance of our final design was impossible to evaluate without having the whole model built and tested by our sponsor.

The build demonstrates great engineering value, as there is no ECV simulator or model commercially available. The work done by our team this semester ultimately provides an alternative training method and is a novel design that emphasizes do-it-yourself fabrication and widespread accessibility in its low cost and easily-sourceable materials.

VERIFICATION PLANS

As we continued to prototype and manufacture our model, we verified the success of our model with respect to our requirements and specifications. Our team completed our verification plans

for most specifications prior to the end of the semester. Some specifications need to be verified in future work due to time constraints and pending design changes. A table of requirements and respective verification methods is shown below in Table 18.

Table 18. Plans to meet minimal specifications via testing, material choice, or design intent

Requirement	Minimal Specification	Verification Method	Date / Compliance?
Simulates common starting breech positions	Simulates 1 common starting breech position	Verified through design/inspection	Nov 28 - passed
Simulates turning of fetus	Requires 28-93 kPa of peak applied pressure	Experimental/physical test	Nov 28 - passed
	Can withstand 93 kPa without damage for 10 minutes	Experimental/physical test	Dec 8 - passed
	Fetus can turn 180˚	Inspection	Nov 30 - passed
Fetus can be palpated	60-80% can palpate features among 15+ participants survey	User testing	Nov 13 - passed
Tactile elements feel like pregnant abdomen	5-point Likert scale score ≥ 3.5 averaged among 15+ clinicians surveyed	User testing	Nov 30 -passed with sponsor
Low-cost	< $350 lifetime cost	Verified by design/analysis	Nov 20 - passed
Stable	Remains static ≤ 90 N horizontal load	Experimental/physical test	Nov 20 - passed
Long-lasting	≥ 2,450 cycles with no material fracture or failure	Experimental/physical test	Not yet verified - future work
	Non-reactive to 99% isopropyl alcohol	Inherent to material choice	Dec 8 - passed

		Confirm with experimental test	
	Withstands temperatures ranging from 3.8˚C to 43.9˚C [53]	Inherent to material choice	Nov 20 - passed via literature review
	Withstands humidity ranging from 77-100% [53]	Inherent to material choice	Not yet verified - future work
Compatible with ultrasound gel	Water absorption percentage < 5.00% [54]	Experimental/physical test	Nov 20 - passed
Simulates disengaging from pelvis	Fetal starting position should be 1-3 cm depth into pelvis	Inspection/experimental /physical test	Not yet verified - future work
Easy to clean and reset	≤ 600 seconds	User testing	Dec 8 - passed
Can be repaired locally	Use ≤ 2 non-locally available materials	Verified by design/inspection	Not yet verified - future work

Detailed below are our team's working plans for testing and verifying each of our minimal specifications.

Requirement	**Minimal Specification**
Simulates common starting breech positions	Simulate 1 common starting breech position

To verify that the model meets this specification, we confirmed with our sponsor that the model does an adequate job of representing the breech position. This specification was met with our fetal model, as shown in Figure 24 below.

Figure 24. Fetal model in breech position (left) and in full model assembly (right)

This fetal model met the minimal specification of simulating 1 common breech position.

Requirement	Minimal Specification
Simulates turning of fetus	Requires 28-93 kPa of peak applied pressure

In order to ensure that our model requires 28-93 kPa of peak applied pressure, our team developed a testing setup that determined the volume of water inside the plastic bag that met the specified range of applied pressure. We placed our fetal model in its bag on a scale and recorded the peak applied pressure for incrementally increasing amounts of water. We established a range of water that could be added to the bag to properly simulate the difficulty of turning the fetus. For this test, we assumed the full model would increase the amount of pressure required to turn the fetus. The outer layers would likely make it more difficult to turn the fetus. Therefore, if we achieved the upper limit of 93 kPa of peak applied pressure with only the uterus bag, then the upper limit of 93 kPa could be achieved in our full model. The testing setup for this verification plan is shown below in Figure 25.

Figure 25. Testing setup to determine required pressure

Using the test setup shown in Figure 25, we recorded the peak applied pressure for volumes of water ranging from 0.50 to 1.75 L in increasing increments of 0.25 L. Three trials were run at each volume increment. The results of this experiment are summarized below in Figure 26. The full data set and pressure calculations are detailed in Appendix D.

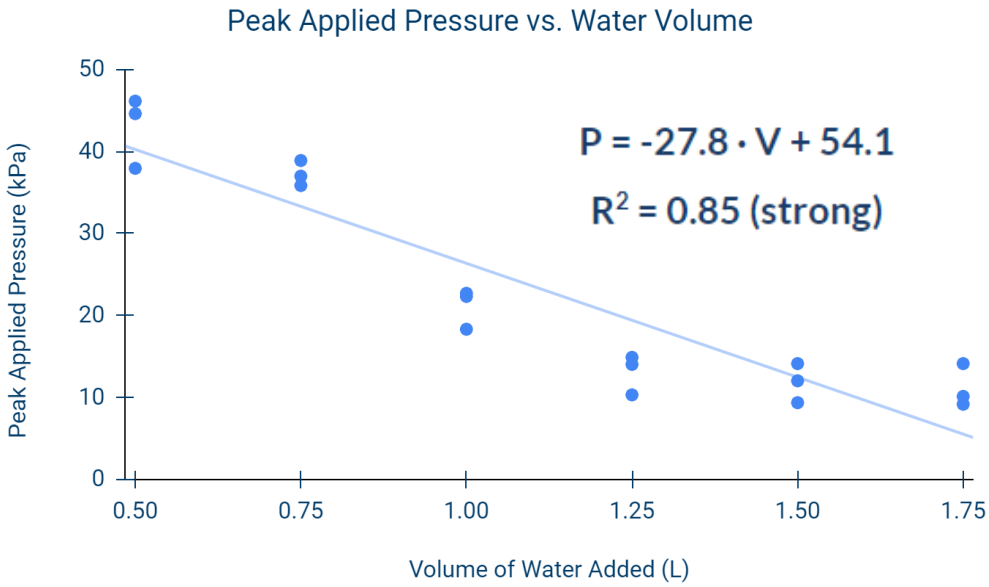


Figure 26. Results of testing required pressure

As shown in Figure 26, as the volume of water inside the bag was increased, the pressure required to turn the fetus decreased. The experiment resulted in a strongly linear correlation between peak applied pressure and volume of water added. By using the equation of the linear

fit, the volume of water corresponding to our required pressure values was calculated to be approximately [0 L, 0.94 L]. The average volume of amniotic fluid at 37 weeks gestation is between 0.5 and 1 L, which confirmed that our model achieved physical likeness of a live ECV. However, our team had concerns that the bag may have experienced plastic deformation in successive trials. Trials were conducted in increasing increments beginning with 0.50 L. As the number of trials increased, our team noted that the bag seemed to be losing structure and plastically deforming as the fetus was turning and stretching it. This may have influenced the testing results. These plastic bags were 2 mm in thickness, so we recommend that bags of 6 mm thickness are used. We anticipated that thicker bags would be more durable and less susceptible to deformation. Further work for verifying this specification would include retesting with the thicker bags, and retesting with the full model to confirm the pressure specifications would still be met and to recalibrate the water volume range.

Requirement	Minimal Specification
Simulates turning of fetus	Can withstand 93 kPa without damage for 10 minutes

To test if our model can withstand 93 kPa without damage for 10 minutes, our team developed a testing setup that emulates the surface area of two human hands exerting pressure on our model. First, we filled our bag with our fetal model and 0.94 L of water, which was the upper-end of experimentally determined water volume for our model. The surface area used was the approximate surface area of the pads of four human hands, as it is typical for two physicians to perform the procedure. Then, we determined the height of steel weights to be placed on the foam is approximately 2 cm, which corresponded to 93 kPa of pressure. We assumed 93 kPa represented our “worst-case scenario” pressure since it was the upper limit of our peak applied pressure specification. This testing setup is shown below in Figure 32. Full calculations to determine surface contact area and required height of steel weights are located in Appendix D. Our team did not take a picture of the testing set-up but a representation is seen in Figure 27 below.

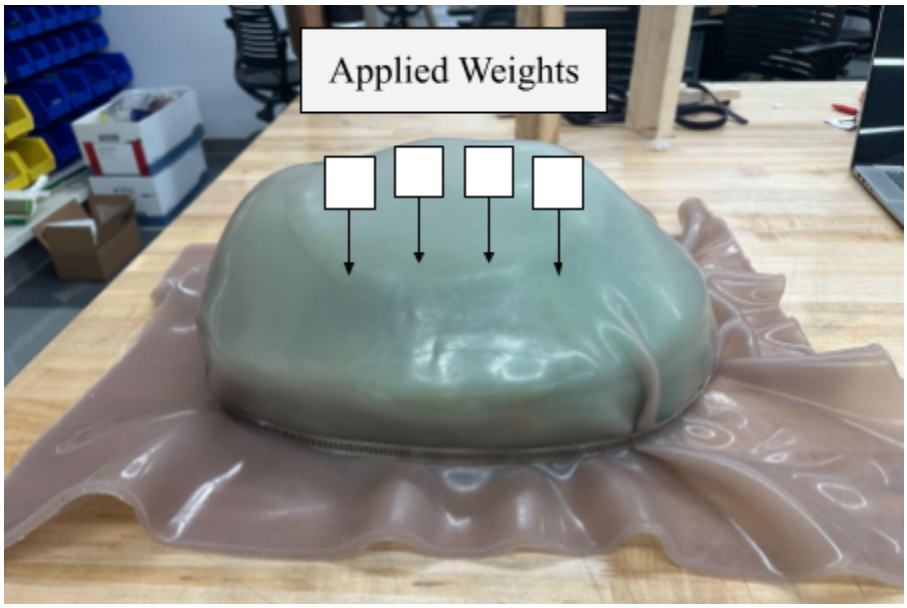


Figure 27. Testing setup to determine if bag can withstand required pressure

To evaluate our specification, we set a timer for 10 minutes, then visually inspected the bag to identify if any leaking occurred. We also inspected the gel pack layer for any signs of popping or leaking. Our primary concerns for this verification test were the uterus bag and gel packs, as these were the components of our model with liquid elements and therefore susceptible to popping or leaking. After testing, there was no visible damage to any components, including both the gel pack and plastic bag. Future work to further verify this specification could include testing that simulates applying 93 kPa from different angles on our model, as this testing exerted a purely vertical load on the model.

Requirement	Minimal Specification
Simulates turning of fetus	Fetus can turn 180˚

Given that our fetal model and uterus bag were designed to be dimensionally accurate, we had high confidence that this specification could be met. This specification was met concurrently with the testing to determine the required peak applied pressure as discussed on pg. 55, 56, and 57. During this testing, the fetus was able to turn 180˚ during each of the 18 trials conducted, and therefore this specification was considered to be met.

Requirement	Minimal Specification
Fetus can be palpated	60-80% can palpate features among 15+ participants surveyed

In order to determine if fetal features were distinguishable underneath our outer layers, we developed a user testing setup composed of two objects underneath our outer layers. The two shapes were a rectangular lego and a cylindrical spool of thread, chosen based on their distinct features. Both shapes were placed under a gel pack, ½" foam, and Ecoflex 00-50. A figure of the testing setup is shown in Figure 28 below.

Figure 28. Palpation testing setup

The setup was presented to 15 individuals. Each individual was told to identify the lego and the spool of thread by palpating the model with as much force as needed. We opted to tell the users what they were feeling for, as in practice, physicians know if they're feeling for the head or the butt of the fetus. From the survey, 86.7% of participants were able to correctly locate and distinguish between the lego and the spool of thread, which met and exceeded our minimal specification of 60-80% of participants being able to identify fetal features within our model.

For this verification, we assumed that anyone was capable of palpating the sample, and that 15+ participants would be statistically significant [59]. We also assumed that the identification of the smaller objects would scale in a full-size model, and that the effect of the uterus press-to-close bag was negligible on palpation of fetal features. We also tested with our sponsor with our full model, who confirmed palpation ability with a fetal model inside the uterus bag.

Requirement	Minimal Specification
Tactile elements feel like pregnant abdomen	5-point Likert scale score ≥ 3.5 averaged among 15+ clinicians surveyed

Physician feedback is crucial to certify that the model does feel like a pregnant abdomen. Therefore, we created a small test sample of the intended skin material. According to our outlined specification in Table 4, this material will be presented to a group of 15+ physicians for them to palpate, with a supplementing 5-point Likert scale survey. We first presented our model to our project sponsor. A representative survey question is shown in Figure 29 below.

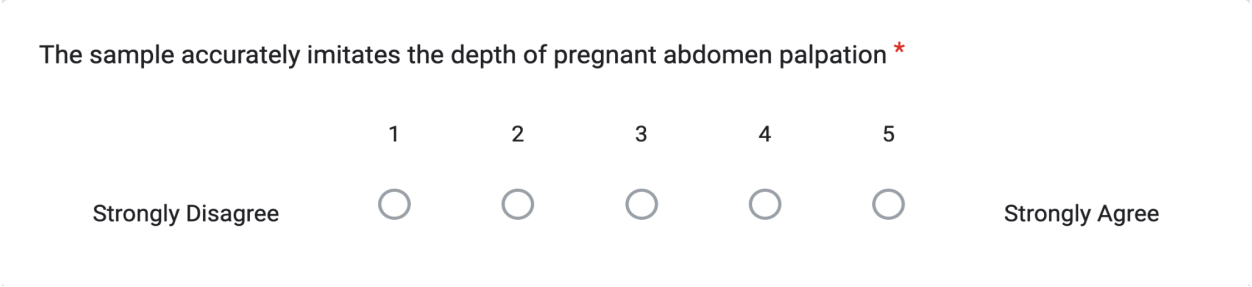


Figure 29. Example survey question for Likert scale verification

The Likert survey consists of 4 questions, evaluating the external feel, compressibility, and palpation elements of the model. The full Likert survey our team developed can be found in Appendix D. To meet our minimal specification, the results from the Likert scale must have an average of 3.5 or greater. If the feedback shows that our model does not meet our tactile feel requirement, our design should be iterated based on their feedback, then repeating the same process with the same Likert scale survey.

We presented our model and this survey to Dr. Thiyag. She evaluated the extent to which this specification is met and awarded our model an average score of 3.75, meeting our minimal specification [23]. Her individual responses are shown in Appendix D. Dr. Thiyag has also expressed confidence in collecting data from 15+ physicians in future work with our model [23].

Requirement	Minimal Specification
Low-cost	< $350 lifetime cost

To calculate the manufacturing cost of the model, we carefully examined our chosen materials and created a preliminary BOM, shown in Appendix D. The bill of materials projected a material cost for our model of $170.82. Assuming our minimal specification of 2,450 cycles, the cost per use was approximately $0.07. We note that our current model was created with materials that were easily accessible to us, not necessarily to Ghana. Therefore, future work includes changing materials as necessary for manufacturing in Ghana to ensure it is as affordable and accessible as possible.

Requirement	Minimal Specification
Stable	Remains static with ≤ 90 N horizontal load

To verify the stability of our model, we experimentally found the load at which our model would slip against our non-slip mat. To test, we placed the fully-constructed base on top of the non-slip mat, and added a weight of 6.3 kg on top of the base. This weight was determined by subtracting our projected full model weight of approximately 8.2 kg , detailed in Appendix C, from the weight of our base. We then pushed on our model with a force gauge until the point our model slipped, and recorded the maximum force during the test. We conducted testing for two non-slip material options. We purchased the thin, white, non-slip kitchen mat as well as a thicker, black, 30-Duro rubber. The testing setups for both material choices are shown below in Figure 30.

Figure 30. Stability testing setup with thin non-slip kitchen mat (left) and thicker 30-Duro rubber (right)

We pushed on the model with a force gauge until slipping occurred. The results of this testing are shown below in Table 19.

Table 19. Slip forces of non-slip kitchen mat and 30-Duro rubber

Material	Slip Force (N)	Static at ≥ 90 N?
Non-slip kitchen mat	37.5	No
30-Duro rubber	100	Yes

As shown in Table 19, the non-slip drawer liner mat slipped at 37.5 N of applied force and therefore does not meet our minimal specification of providing enough friction for the base to remain static with 90 N of push force. We performed additional trials at higher weights, and the non-slip kitchen mat still failed the specification, confirming the material would not meet our specification even if our final model weighed more than estimated. These additional trials are detailed in Appendix D. We observed that 100 N of horizontal load applied to our model on

30-Duro rubber did not cause the model to slip, which surpassed our minimal specification of remaining static against 90 N of push force. We also conducted trials with lower weights, including 2.3 kg of added weight and 0 kg of added weight to confirm that the material will meet our specification, even if our final model weighed less than estimated. These additional trials are detailed in Appendix D. The 30-Duro rubber kept the base stable at a force of greater than 90 N, even when no additional weight was added to our wooden base. Therefore, our model met our stable requirement.

Requirement	Minimal Specification
Long-lasting	≥ 2,450 cycles with no material fracture or failure

The most definitive way to verify our specification of 2,450 cycles with no material fracture or failure would be to apply a maximum procedural pressure of 93 kPa to our model with a force gauge 2,450 times, then inspect the materials for signs of failure or fracture. However, the total time to perform this testing is not feasible within the remaining time in the semester. Therefore, although we are confident that many of our components will withstand 2,450 cycles, this specification may require further cycle testing to verify.

The ASTM D430 Standard outlines 3 ways to test for fatigue in rubber [47]. Using the DeMattia flexing machine outlined in the standard, the bending and extension fatigue life of silicone rubber were both found to be 3106 cycles [48]. The extension and bending performed on the sample in these tests were larger than what we intended to inflict on our model during use, so we have confidence that our model will endure our requirement of 2,450 cycles. However, we anticipate that the fetal model and plastic bags may not last 2,450 cycles. For these materials, we evaluated the replaceability. The plastic bags have a low cost and are easily replaceable. Therefore, if they do not last 2,450 cycles, we recommend they get replaced more frequently and subsequently extend the lifetime of our model. Materials such as the wood and foam base and pelvic bowl are not directly being subjected to cyclic loading during the ECV procedure.

Requirement	Minimal Specification
Long-lasting	Non-reactive to 99% isopropyl alcohol

To test our specification that our model was non-reactive to 99% isopropyl alcohol, we submerged a small sample of our outer layer, EcoFlex 00-50, in 99% isopropyl alcohol for approximately 23 hours. This time was estimated according to the number of cycles our model must withstand and how long it took 30 participants to wipe down our outer material, approximately 33.7 seconds, as outlined in our verification of *Easy to clean and reset*. The resulting calculation is shown below in Eq. 1.

$$time\ submerged = \frac{33.7\ s}{cycle} \times 2,450\ cycles \times \frac{1\ hr}{3600\ s} = 23\ \text{hrs} \quad [1]$$

We only tested this specification with our outer layer material, as it was the only surface that needed to be wiped down between uses. After submerging our sample for 23 hours, it was inspected for any degradation or damage. The sample before and after testing is shown below in Figure 31.

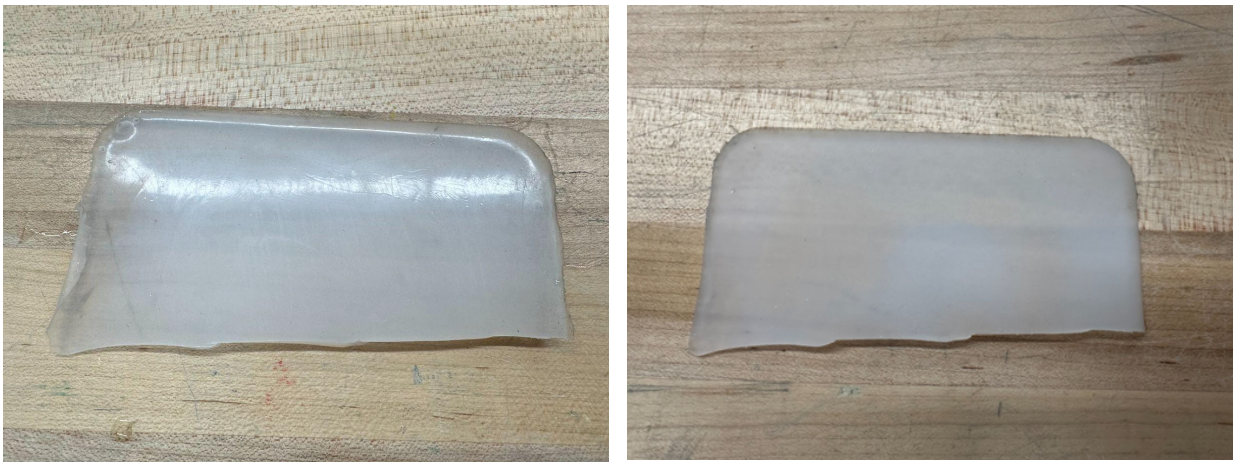


Figure 31. EcoFlex 00-50 sample before testing (left) and after testing (right)

As evidenced in Figure 31, the EcoFlex 00-50 showed no major signs of degradation, and therefore the specification was considered to be met. We did note that the isopropyl alcohol appeared to remove the shine or glossiness of the silicone rubber to a more matte texture. However, this did not seem to affect the strength of the material and made it less susceptible to dirt and grime sticking to the material.

Requirement	Minimal Specification
Long-lasting	Withstands temperatures ranging from 3.8˚C to 43.9˚C [53]

Our temperature specification is inherently verified by our material selections. Each of our selected materials was rated for operating temperatures that met our specification range of 3.8˚C to 43.9˚C, as outlined in Table 20 [53].

Table 20. Verification of temperature specifications

Material	Operating Temperatures (°C)
Ecoflex 00-50	[-54, 232] [68]
Foam	[-29, 82] [61]
Gel packs	[-12, 60] [80]
Pelvic bowl	[0, 120] [69]

Fetus model	[-10, 60] [69]
Uterus bag	[-50, 80] [69]
Velcro	[-18, 49] [70]
Non slip mat	[-18, 52] [71]
Wood base	[-1 49] [72]
Hose clamp	[-196, 850] [73]

Requirement	Minimal Specification
Long-lasting	Withstands humidity ranging from 77-100% [53]

Literature review did not reveal clear humidity ranges of our model's materials. Future work to verify this specification may include meeting with Ghanaian physicians to gain a clear understanding of what is currently used in hospitals and correlate those materials to our model's in order to confirm their longevity in Ghana's humidity. Additionally, a testing setup could be constructed to evaluate how well the outer layer of EcoFlex 00-50 protects the internal components from humidity. The outer layer could be subjected to humidities between 77-100%, checking the moisture level of the top and underside before and after with a moisture meter. If the topside exhibits no signs of degradation, it can withstand the humidity. If the moisture level of the underside does not change after being subjected to high humidity, then it can be concluded that the internal components will not be affected by the humidity. Our team was not able to complete this testing due to budget and time constraints, so future work will need to be done to verify this specification.

Requirement	Minimal Specification
Compatible with ultrasound gel	Water absorption percentage < 5.00% [54]

Using the outermost layer of our model, we completed the ASTM D570 standard test to determine the water absorption of Ecoflex 00-50. We first weighed the initial 8.9"x3.7"x0.12" piece of Ecoflex 00-50, and then submerged the sample in water for two hours. After two hours, we reweighed the sample and calculated the water absorption using the Equation 2:

$$water\ absorption = \frac{wet\ weight - conditioned\ weight}{conditioned\ weight} \times 100 \qquad [74][2]$$

The conditioned weight of our sample was 0.212 lbs, and the wet weight was 0.216 lbs. The water absorption percentage of Ecoflex 00-50 was calculated to be 1.89%, which was less than our specification of 5.00%. We assumed that ultrasound gel would only be interacting with the Ecoflex 00-50, so we did not test the water absorption of any other material.

Requirement	Minimal Specification
Simulates disengaging from fetus	Fetal starting position should be 1-3 cm depth into pelvis

To ensure that we meet this specification, we worked with our project sponsor to confirm that the fetus can be disengaged and the procedure can be completed with this starting position. After testing with our full model, Dr. Thiyag informed us that our current design does not accurately reflect the actual procedure, so future work on this model should include changing the pelvis subfunction design choice and reevaluating this specification [23].

Requirement	Minimal Specification
Easy to clean and reset	≤ 600 seconds

We performed time studies in order to verify our easy to clean and reset specifications. Cleaning referred to removing all ultrasound gel from the abdomen, and resetting referred to removing the outer layers, manipulating the fetus into the starting breech position, and repositioning all necessary inner components. 30 time trials were conducted of someone performing the operation of cleaning or resetting [41]. Participants were given a step-by-step description of what cleaning or resetting the model entails, detailed in Appendix D. A team member was present for each trial, so a demonstration of the steps was given to participants and clarifications were given as needed. These time trials were tested on a variety of participants, not a particular group, under the assumption that most adults have previously wiped down a surface and can reset the model with no clinical ECV experience. A summary of these results are shown below in Table 21, with full data located in Appendix D.

Table 21. Average clean and reset time

Procedure	Average Time (s)
Clean	33.7
Reset	322
Total (Clean + Reset)	356

As shown in Table 21, the total average time to clean and reset the model was 356 seconds, meeting our minimal specification of ≤ 600 seconds. It should be noted that participants were tasked with cleaning water off of the EcoFlex 00-50. In reality, users would clean the ultrasound gel used in the procedure, but due to budget constraints we did not obtain ultrasound gel. While using ultrasound gel may increase the time to clean since it is more viscous than water, we do not anticipate it adding enough time to make the total time exceed our specification of 600 seconds. Additionally, while observing these time trials, our team noted that the most time-consuming and arduous aspect of resetting the model was undoing and redoing the hose clamp by hand.

Therefore, future work on this model may include an alternate clamping mechanism that is more user-friendly and easier to reset.

Requirement	Minimal Specification
Can be repaired locally	Use ≤ 2 non-locally available materials

As previously mentioned, our current build prototype was constructed according to materials available to us in Ann Arbor, MI, USA. Our sponsor expressed confidence that many of our materials will be locally available or easily obtainable in Ghana, such as wood, foam, a bowl, etc [23]. However, future work on this model should include working with Ghanaian physicians and local suppliers to certify that all materials are locally available.

It is likely that beyond this semester, this design will continue to be iterated, and specifications should be reverified as needed.

VALIDATION PLANS

Although simulator validation is beyond the scope of the semester, we have outlined a few key steps for future validation of our device. We hope to implement the methodology of summative usability testing in order to measure usability and validate our prototype, ensuring that the model accurately portrays patient anatomy and the ECV procedure as a whole. We also want to demonstrate that the simulator is safe to use from a human factors standpoint. We hope to make the usability test as realistic as possible, where we will fabricate a simulated use environment representative of Ghanaian teaching hospital conditions, find participants representative of the end users with relevant expertise and experience, and promote smooth and natural workflows for the duration of the testing.

In creating a simulated use environment for the validation of our device, the team would need to find space usable for long periods of time that allows for customization of temperature and humidity, along with a table that can hold the simulator. To find participants representative of the end users, Dr. Thiyag's network would be leveraged to find willing OB-GYN physicians local to Ann Arbor who are willing to participate in the study of device usability and efficacy. Simply asking a physician participant to do ECV on the device is a good method for gathering general impressions for the simulator, but fails to evaluate smaller functions that the device will have in detail, such as each individual step of performing an ECV. To address this, the team would create segmented tasks for each participant to follow (e.g. 1. Lift the fetus out of the pelvis; 2. Palpate to identify the head…) in addition to asking the participant to carry out more natural tasks (e.g. Conduct the ECV procedure on this model). This is also beneficial for data gathering, as the team conducting the validation can ask for impressions after each segmented task, rather than ask for all participant feedback at the end of a longer period.

Throughout the usability test, the team should collect data on simulator effectiveness, task time, and general user satisfaction. This can be a combination of Likert ratings and qualitative data taken from participant commentary and interviewing. Because human subjects are participating in the process of data collection, the team carrying out validation must apply for the Michigan

Institutional Review Board (IRB) approval, as required by federal regulations and university policy when human participants are needed for a research study. For the IRB, the team would have to submit detailed device descriptions, test plans, consent forms, and risk analysis for the participants. Given Dr. Thiyag's past experience in medical simulator validation, she would be a primary resource and the acting Principal Investigator for the project.

However, there are some validation protocols that can be done locally with Dr. Thiyag as the representative user. For example, the cleaning and resetting specification can be evaluated by recording Dr. Thiyag as she wipes down and resets the simulator to her preference, for multiple timed trials. Along with recording the time it takes for her to do this, we would be able to take down her live impressions of the process and receive qualitative data in terms of what she finds is or is not effective, intuitive, and efficient.

DISCUSSION

This section discusses some project considerations outside the scope of the semester, as well as design critiques and lessons learned throughout the semester. User risk is also outlined.

Problem Definition

Our team worked diligently to best utilize our time and resources, as evidenced by our detailed project plan in Appendix H. However, there are aspects of our project that could have been improved or explored further. In general, our team struggled with budget constraints. Given the heavy emphasis on testing design choices with physical prototypes, the iteration of our design required us to limit what materials could be purchased. An expanded budget perhaps would have allowed our team to explore more design concepts in depth. Given more time and resources, our team could have sought to verify all specifications. One of the specifications we were not able to verify was that our model must withstand $\geq$ 2,450 cycles with no material fracture or failure. Given the complex machinery associated with formal cyclic testing and the extensive amount of time required for our team to conduct 2,450 cycles, the specification was not verified with testing. Additionally, we were not able to verify the specification that our model must withstand humidity ranging from 77-100%. Humidity testing would require a moisture meter and a testing environment that can simulate high humidities. We did not have access to these resources within this semester but this specification could be verified given more time and resources. Other verification such as whether the fetal starting position is 1-3 cm depth into the pelvis. Given more time and an increased budget for purchasing materials, we could have redesigned the pelvis according to sponsor feedback and performed the relevant verification testing. Finally, our team could have performed testing to get quantitative data about the time it takes to perform ECV, as literature on this value does not exist. ECVs did not occur frequently enough at Michigan Medicine throughout the semester for us to record any substantial data, and we relied on sponsor estimates for these values.

Lessons Learned & Design Critique

Now that our final design has been built and verified, we have evaluated its strengths and weaknesses based on sponsor feedback and its response to multiple uses over the course of Design Expo.

Strong aspects to our design are the base and fetus model. The first principles modeling held true empirically in response to force exerted on the model during verification testing, and the prototype did not slip whatsoever when used by passersby. The 30-Duro rubber base was extremely effective in holding the base in place even with users' full bodyweight pushing on the model in efforts to turn the fetus. The fetus also adequately represented key features as specified by our sponsor, and participants were able to palpate and accurately identify those features as they attempted to turn the fetus in the model.

The greatest inaccuracy in our model was the modeling of the pelvis with the bowl. Our sponsor gave the feedback that it was too large and not flexible enough to palpate through. We also observed passersby struggle to palpate with the pelvic bowl in the way, opting to push from other angles to disengage the fetal model from breech.

One particular issue we observed was damage to the outer silicone layer as a result of the tightness of the hose clamp holding all components to the base, shown in Figure 32 below.

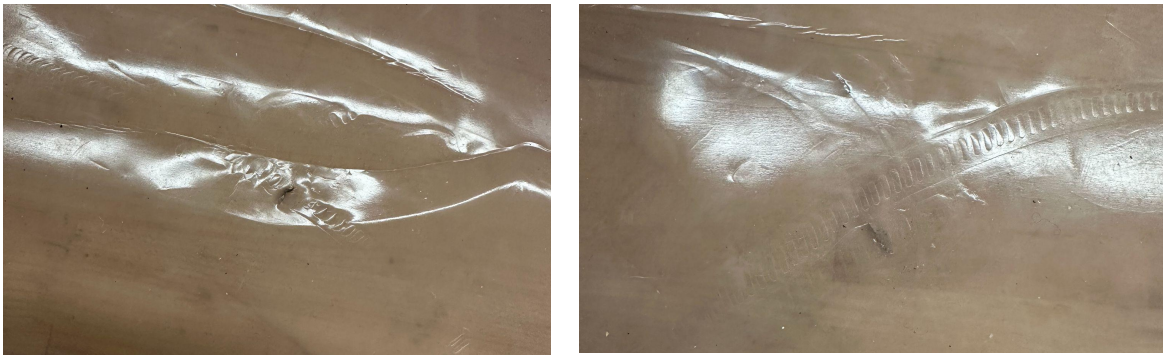


Figure 32. Damage on EcoFlex 00-50 due to hose clamp

As shown above, the hose clamp left visible indentations and even punctured the cast silicone layer, despite its marketed durability and resistance to tearing. While the hose clamp worked well in tightly holding the skin layer in place throughout multiple uses and strong push forces, the damage it does to the outer layer lowers its viability as a clamping mechanism significantly. Furthermore, it was much more difficult to handle than expected, with tightening and loosening taking minutes even using a drill. The hose clamp length was purposely cut in excess to provide room for loosening, but the end was sharp and difficult to handle when tightening and loosening.

Another area of concern is durability of the press-to-close plastic bag that will be used for the uterus. While we are still testing the durability and leaking for this component, this is still an area of concern for our model given it is the weakest part. If the bag were to pop or stretch during use, other components in the model would risk water exposure. This could lead to mold growth or degradation of the softer components.

Another critique of our design is the cost of the silicone rubber. Our team was faced with minimizing cost for maximized accessibility, while still maintaining anatomical accuracy and

structural integrity. Though silicone was an effective design choice, it is the most expensive component in our model, and we recognize that paying $80 for this component is not ideal.

A major obstacle our team faced during prototyping was in troubleshooting the casting of our silicone layer. Due to our limited budget, we hesitated to use large amounts of the EcoFlex due to its aforementioned high cost. Thus, we initially decided to cast the silicone to near-net shape, leading to the various explorations in casting options with clay and papier mache done throughout the semester. Once those options failed, we were left with no more casting silicone and had to source additional silicone outside of Ann Arbor to cast into a flat sheet. Even casting that took significant time and energy, as cleaning and setting up an adequately smooth surface required three people and significant planning. The budget constraint limited our confidence to iterate and explore different options, though we could have considered the flat sheet as a viable option for the final prototype sooner. We also could have iterated through smaller samples earlier in the semester, because when we seriously acknowledged flat sheet casting there was very little time to implement in time for Design Expo.

Risks

Our final design and prototype is made of primarily soft materials and components that do not pose much harm to the user, if any. Because the base has been proven to not slip due to push force, there is little to no risk of the user falling due to slipping or model collapse. The hose clamp poses some concern for user safety, as its end is sharp and difficult to handle and may cause cuts. However, this design aspect is subject to change in future work. If water leaks within the model, the soft components may absorb the moisture, leading to unfavorable mold or bacterial growth. To mitigate this risk, our team updated our press-to-close bags from a 2 mm thickness to a 6 mm thickness, providing more durability.

REFLECTION

As we began our initial project research, it became apparent that considering the global and societal impacts of our project would be imperative to our success. A lot of thought and effort was put into fully understanding the context of our project so we could best solve the problem at hand, and these perspectives have remained consistent.

Regarding global context, we acknowledged the potential for broader applicability in other low- and middle-income countries (LMICs), although the training model was designed for Ghana where there is a shortage of trained physicians. The model's DIY nature and adaptability to locally available materials open opportunities for implementation beyond Ghana.

With respect to economic impacts, we examined the distinction between private and public healthcare in Ghana. As our model promotes a cheaper alternative to CDs, we aimed for implementation in teaching hospitals, which are publicly funded and less likely to be motivated by cost. As Ghana is a low-income country, we wanted to ensure that the model was accessible for consumers in Ghana by designing a low-cost model that can be manufactured domestically, which drove our material choices. Our model’s accessibility has both a positive economic and societal impact.

Public health and safety were relevant to our project as it is a medical training model. ECV is a relatively safe procedure that often does not involve surgery or heavy anesthesia, and fetal heart rate is monitored throughout to ensure the safety of the baby. ECV is also cheaper compared to a C-section, which benefits the patient. We acknowledge that there is a gap in the societal and economic impacts of the disposal of our model, which was not heavily considered throughout the project but should be considered in the future.

When characterizing the potential societal impacts of our design, we utilized stakeholders maps to gain a greater understanding of who our model was influencing. Interactions with stakeholders influenced decisions throughout the design process and gave us a better understanding of problem context. We also created a bill of materials to help us understand the acquisition cost of our model as it contributes significantly to overall life cycle cost.

Cultural, privilege, identity, and stylistic similarities and differences
We were very fortunate to enter this project as great friends with pre-established confidence that we could work together. While we had a general understanding of each other's work styles, cultures and identities coming into the semester, the required discussions on social context, multidisciplinary project work, and tight timelines inevitably presented roadblocks and highlighted our differences in approach to overcome them.

Addressing cultural, privilege, identity, and stylistic differences, the team comprised both system- and detail-oriented thinkers. Collaboration involved navigating differences in approach, leveraging individual strengths, especially when addressing conflicting ideas for components. On a personal note, in discussions during DR1 with our families and each other, we learned that each of our mothers had experience with C-section delivery or an ECV. This was a unique situation that provided us all with a personal tie to the project and a newfound appreciation for the engineering goal. Being a team of women in engineering, it is important for us to contribute to equitable solutions.

Positionality as designers remained consistent since DR1. Regular interactions with the sponsor, stakeholders, and acknowledgment of differences in positionality ensured a balanced and receptive approach. An initial challenge for us was overcoming our bias of what a successful model looked like. Before we began concept generation, we were interested in pursuing highly engineered solutions that would have been costly, which can be attributed to the privileges we had only being exposed to high-end obstetric training models at Michigan Medicine. After discussions with Dr. Dhanu and Dr. Doffour, we recognized that for a non-surgical, lower-risk procedure, and for successful implementation in Ghanaian teaching hospitals, a model that is benchmarked to a high-fidelity birthing simulator is unrealistic and unnecessary. Our perspective of our engineering challenge changed, to creating a low cost, “do it yourself” model that could be assembled, purchased, and trained on.

Inclusion and Equity
In considering inclusion and equity, we see the importance of addressing our power as designers as it stems from our identities and privileges. We met with our sponsor weekly to discuss the progression of the project, and heavily relied on her feedback and input. We also remained aware of how our differences in positionality with our stakeholders was an invisible power we had to

continuously acknowledge. Overall, we balanced listening and learning with our stakeholders, and are happy with the final build design we were able to engineer this semester.

Our team prioritized a collaborative approach, with emphasis on being receptive, when seeking input from our project sponsor, Ghanaian physicians, and peers. For knowledge gaps in the details of the procedure for example that are not readily available online, their feedback was critical to our progress. In DR1, we cited a wide range of pressure exerted during the procedure, but discussions with our sponsor revealed nuances, such as pressure variation with procedure stages and fetus positioning. Discussions with our sponsor revealed that pressure applied on the patient's abdomen does in fact vary with different parts of the procedure, as well as with fetus positioning in relation to the uterus, which changed how we evaluated each sub-component of the simulator in the down-selection process. While opinions varied among stakeholders, including Dr. Doffour emphasizing breech disengagement, we recognized the importance of all perspectives. It was crucial that we relied on our ability to make the best decisions for our project, and thoroughly communicated with our project sponsor to gain her opinions, as the creation of the training model was specifically for her to implement. We placed her insight the highest when making design decisions and dealing with disagreements, but also had confidence in utilizing our own experience when engineering issues arose.

Ethical considerations

During our initial research and creation of our stakeholder map, the ethical issue of patient privacy arose. Interaction with patients who received an ECV to gauge their opinions would have been valuable, but privacy stipulations prevented our team from doing so. To manage this, we sourced patient feedback from online discourse and forums, as per recommendation from our professor.

As we approached the end of the semester, we still had several verification tests that needed to be completed. With final exams, other projects, and design expo being complete, it was hard for our group to overcome the notion that our project was finished. Though it may have been easier to fabricate data to verify the remainder of our specifications, we understood the significance of engineering ethics and made the effort to accurately test and verify as many specifications as we could before handing off our project to our sponsor.

If our model entered the marketplace with inaccuracies in regard to patient anatomy, there is potential for ECVs to be taught incorrectly, and therefore performed incorrectly on patients. This could lead to a myriad of ethical issues, such as increasing patient pain during the procedure, and leading to higher risks on the mother and baby. It was our responsibility to ensure through verification and validation testing that our model is accurate to our specifications before market implementation.

At the University of Michigan, our ethical decisions are guided by the engineering honor code, and professionally by multiple codes of ethics. However, in our daily life, there isn't a set ethical standard we are forced to follow. Our personal ethics are shaped by the way we were raised, and are different for each of us. Though there is no direct code to follow, our personal and professional ethics are similar in that we each strive to put forth our best effort in everything we

do. We felt a strong obligation to hold ourselves and our project to a very high standard because of both our personal and professional ethics.

RECOMMENDATIONS

In presenting our model to Dr. Thiyag, our team received several recommendations to improve its functionality and fidelity. Upon her observation, the pelvis representation using the bowl inhibited palpation of the model fetus for determination of the breech position and turning as the plastic of the selected bowl was too hard. It was suggested that the bowl be exchanged for a more flexible bowl, such as one made of silicone, that one can more easily palpate through. Options from online sources, such as Target and Amazon, to remedy this have been found within budget but no formal design changes were made by our team.

Our sponsor also expressed the need for an assembly manual for the model, as it is meant to be built by physicians themselves. This manual would include manufacturing instructions for the individual components, as well as directions on how to assemble and reset the model. Additionally, it would include a basic tutorial on how to perform the procedure. While this is a recommendation expressed to our team by our sponsor, she does not expect it to be completed by our team specifically, but rather by the team during the model's eventual implementation.

As discussed in the design critique section, the hose clamp posed issues to the integrity of the silicone and risk to the end user of the model. In future iterations, our team recommends that the hose clamp be exchanged for an adjustable belt made of cloth or a different soft material.

Additionally, future teams may seek cheaper alternatives to silicone for the outer skin layer, such as fabric or felt. These materials were suggested by our sponsor in the initial stages of prototyping, so barring any issues with palpation of the fetus model, they may prove sufficient for the model. If fabric or felt is selected as a replacement, a revision to requirements and specifications, such as "compatible with ultrasound gel" will be necessary.

Lastly, in considering the risk of the plastic bag filled with water opening inside of the model, our team emphasizes the ability of the model to be taken apart, which will allow users to dry components individually to prevent mold growth. We recommend using accessible tools, such as a hair dryer fan to ensure complete dryness.

CONCLUSION

A need was identified for an ECV simulation model to give users an opportunity to practice ECV in a low-risk environment and help increase the comfort level of the procedure amongst physicians. Increasing the comfort level with the procedure was expected to lead to physicians offering ECV as an option, promoting spontaneous vaginal birth. Working with our project sponsor and conducting our own research, we identified the key requirements, specification, and overall needs of an ECV training simulator that could be implemented in Ghanaian teaching hospitals. We spent time meeting with Ghanaian physicians, as well as other stakeholders, to continue fleshing out our design requirements and ensure our solution addressed all the needs

within our problem scope. Since DR1, we generated a myriad of novel solutions and moved our focus to our highest quality and most unique solution, evaluating it against our stakeholder requirements and specifications. Since DR2, we then centered our efforts on the more technical aspects of our design: 3D modeling, prototyping, and verifying our specifications to ensure that our solution accurately addressed our initial problem statement. Our team progressed through the prototyping stage and worked on finalizing the design through iteration of the original "Alpha" concept. Additionally, we worked through verification testing and made plans for validation testing as our model came together. At the conclusion of this project, our team has completed a final prototype for the model, which will be passed on to another team for further iteration, testing, and eventual implementation.

ACKNOWLEDGEMENTS

Our team acknowledges Dr. Julia Kramer, Dr. Dhanu Thiagarajan, undergraduate machine shop, Prof. Jon Estrada, Dr. DeBlanc, Dr. Doffour, Gurpreet Rana, Sara Barbrow, Dr. Marzano, the UM Medical Simulation Center, and Dr. Kira Barton for all their help and expertise this semester. We could not have done this project without them!

OUR TEAM





Katie Bailey **Kimia Beigzadeh** **Lexi Martin** **Emma Nottingham** **Audrey Wong**

Katie Bailey:
Katie is a senior in Mechanical Engineering with a concentration in energy and sustainability at the University of Michigan. Originally from Albany, New York, Katie has always been interested in math and science, as well as art and design, as a result of her dad being an engineer and her mom being an art teacher. This drew her to mechanical engineering, which allowed her to participate in design and manufacturing classes. She has always been interested in sustainability and renewable energy, which brought her to join BLUElab Woven Wind at UM, a project team that builds and manufactures small-scale wind turbines, and pursue a concentration in energy through her ME degree. She has also interned at a solar start-up, Urban Energy, and as a nuclear engineering intern at GE Hitachi Nuclear Energy. Outside of school, Katie is an avid cook and runner. She had a blast running the Ann Arbor Marathon at the beginning of October and has since begun training for the biggest race of the year, the Big House 5K. Shortly after this report is submitted, Katie will be heading to Steamboat Springs, CO for a ski trip with some friends before heading home for a restful break!

Kimia Beigzadeh:

Kimia is a senior in Mechanical Engineering at the University of Michigan. She is originally from Midland, Michigan. She has an older brother that recently graduated from Michigan as well, and comes from a family of engineers. Her original interest in mechanical engineering stems from her love for art and design at a young age, and as she completed her highschool career, this interest developed into the intersection of science and the arts due to her focuses on physics and math. She hopes to work in product design in the future. At University, Kimia is involved in her consulting group, MECC, as a project manager and is the photographer for her professional engineering fraternity. She has also interned at Steelcase for the past two summers, working in product development engineering in their ancillary division. In her freetime, she can often be found reading books, taking photos, and making pottery. She looks forward to making a new set of plates as soon as she gets back into the studio. Kimia has since been pressured into running. Kimia ran two miles straight last week, a new personal record! She plans to run the Big House 5K with Katie Bailey in the spring. She is excited to begin training with her family over winter break!

Lexi Martin:
Lexi is a senior in mechanical engineering at the University of Michigan. She was born and raised in Michigan, and spent her childhood living in Grand Rapids and across the downriver area. She has one younger sister, and two half brothers who are both under six years old, and they are the highlight of her life. When deciding to study mechanical engineering, Lexi looked up to her grandpa, who is a mechanical engineer, as she has never met anyone who has loved his job and his life as much as he does. Manufacturing is a big passion of hers. She spent the past two summers interning as a manufacturing engineer; one summer in the automotive industry and her second in the office furniture industry. She spent her first internship specifically working as a manufacturing controls engineer, which she thoroughly enjoyed, and hopes to work as a controls engineer someday in the future. When Lexi isn't working diligently on ME 450, she enjoys watching football with her roommates, spending time with her peers in Pi Tau Sigma (planning the next National Convention!), and playing tuba in the Michigan Marching Band. Since DR1, Lexi has trained to do 10 push-ups in a row. And since DR2, Lexi's flag football team has made it to the championship and is looking to take home the win for the first time in the team's history. As the semester wraps up, Lexi is looking forward to traveling to Pasadena for the Rose Bowl this break. She will partake in a 5 mile parade holding a tuba, and will eat (hopefully) many In-and-Out burgers after.

Emma Nottingham:
Emma is a senior in Mechanical Engineering at the University of Michigan. She is originally from Saint Louis, Missouri. She has six siblings and grew up playing soccer, sewing, and singing. Since DR1, she has completed the Detroit International Half-Marathon with her grandmother and siblings! And now, since DR2, she has entered the lottery for the Chicago Marathon 2024! Fingers crossed! During the upcoming holiday break, Emma gets to see her 5 year old cousin's basketball team, the Swish Kabobs, play in their final game of the season. Her original interest in mechanical engineering began with expressing creativity as a child. She loved to create and build through putting together LEGO sets with her older brother, upcycling clothing, and making scrapbooks and collages. In high school, she participated in various career exploration opportunities to shadow engineers in a variety of fields - aerospace, biomedical, mechanical, etc. She eventually realized that mechanical engineering gave the opportunity to

express creativity in a technically challenging and meaningful way. Emma has continued to grow in this desire throughout her time at UM. She has been involved in several bio-design project teams on campus through Medlaunch. She has also interned at Tesla Motors working on low-voltage component fixtures. In the future, she hopes to obtain a master's degree in Mechanical Engineering and has an interest in working in controls engineering or product development in the future.

Audrey Wong:
Audrey is a senior studying Mechanical Engineering at the University of Michigan. She grew up in southeast Michigan with an engineer and teacher for parents who inspired her to learn and take on difficult problems. Alongside playing sports and spending time with friends, Audrey is an avid lover of food (with the exception of pickles and olives) and highly dependent on coffee. She always had fun building and fixing things with her father in the garage, and eventually joined her high school robotics team where she learned how to translate design concepts into fully-fledged robots. Throughout her college career, she has pursued a targeted interest in engineering for biomedical applications through doing research under the University of Michigan Medical School, joining an M-HEAL project team developing a medical treatment device, and interning at Medtronic developing heart valve replacement implants. In the future, she hopes to work in the research and development of medical device implants somewhere with warmer weather. Since DR1, Audrey has been able to achieve her lifelong goal of doing one (1) unassisted push-up! Since DR 2, Audrey spent a period of 40 hours without caffeine, which is a semester record of no caffeine ingestion! During the upcoming break, Audrey will be going to Texas with her family to eat through the holidays.

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APPENDIX A: Concept Generation

The team generated many design concepts prior to any concept selection methods, using various strategies introduced by the learning block. Firstly, the team generated numerous ideas using a whiteboard, which are pictured and described below. These showed a wide range of ideas using divergent thinking and allowed us to remain open to all solutions.

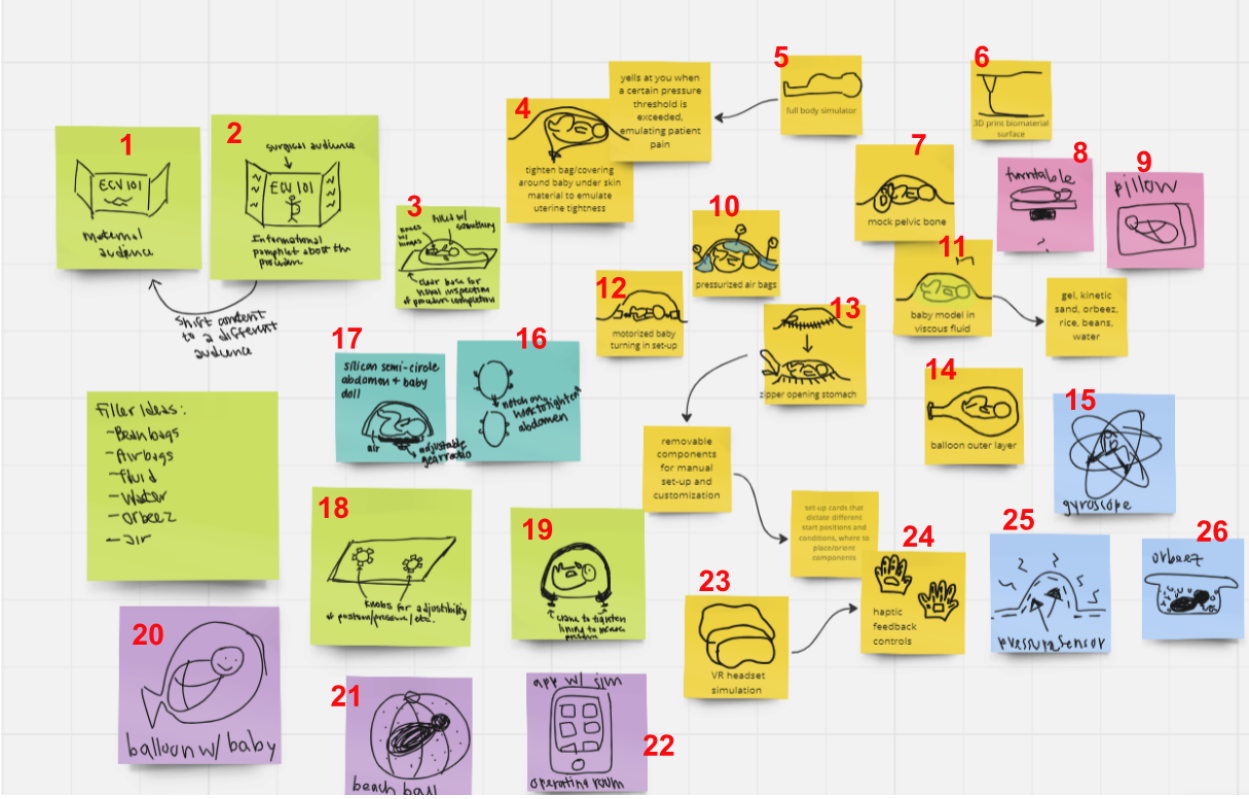


Figure A1. Whiteboard design concept generation

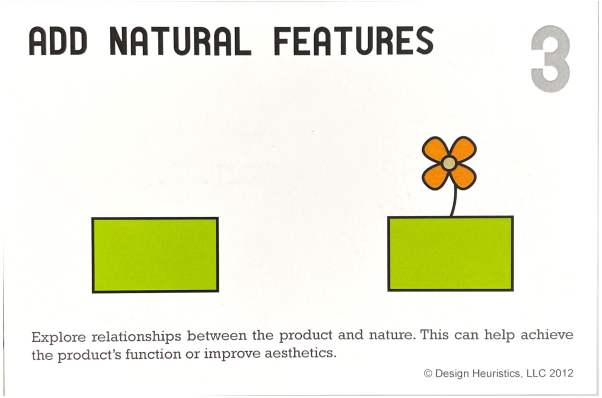
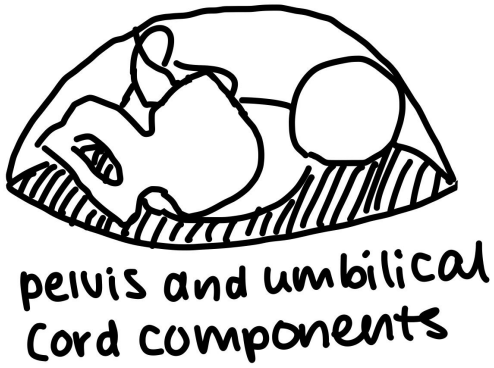
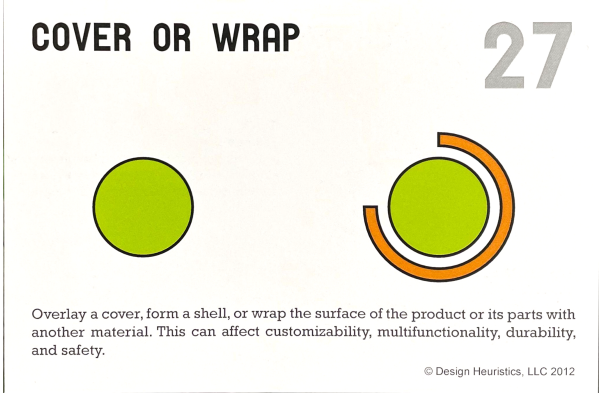
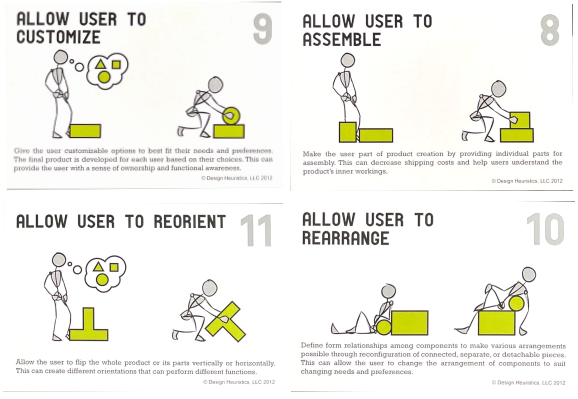
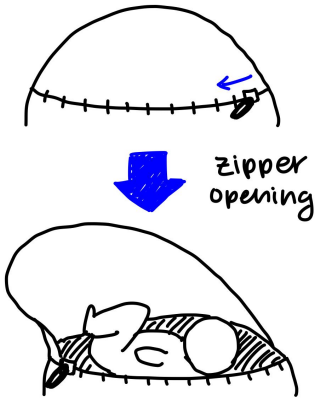
As shown above in Figure A1, we started off with many ideas without thought for feasibility, cost, or realistic implementation. These concepts were a mix of ideas for functions, full prototypes, and other methods of teaching ECV. The whiteboard allowed us to enter a divergent thinking space, and the numbered sticky notes above are briefly described:

1. An ECV pamphlet is distributed to a maternal audience and counseling is done to provide information and emphasize benefits of the procedure.
2. In addition to the maternal counseling guide, a pamphlet or in-depth tutorial for medical providers on how to conduct the procedure, different complications associated, and other information about the procedure.
3. A full prototype model where the fetal model is within a fluid-filled abdominal shape, where the base is clear such that the physician can look inside to check on positioning at the end of the procedure.
4. A bag holding the fetal model that can be tightened or loosened to adjust the difficulty of turning procedure.
5. A full-body simulator that gives an auditory indication once a pressure threshold is exceeded, simulating a patient's reaction to pain from the procedure.

6. Outer skin layer is a biomaterial that is 3D printed, beneficial for rapid prototyping and iteration of material.
7. A mock pelvic bone to hold the fetal model in place such that the user can physically "disengage breech" as would be done at the start of the procedure on a live patient.
8. A turntable on which the fetal model rests on top of that can support rotation of the fetus, as well as be adjusted for difficulty and increased resistance.
9. Fetal model inside a pillowcase that emulates skin layer.
10. Pressurized air bags to change inner volume available for turning and maneuverability, allows for difficulty adjustment.
11. Viscous fluid inside abdomen to mimic amniotic fluid and resistance felt in turning procedure.
12. An abdomen simulator where the fetus is motorized, so it can manipulate itself into different breech positions without any need for human interaction with the model.
13. An abdomen simulation where a zipper allows for easy access of the model's inner components, so the user can easily reset the simulator.
14. A balloon acts as the uterus surrounding the fetus, and the fetus is turned inside the balloon.
15. Gyroscope moves the fetus in three dimensions, with capabilities for rotation.
16. Notches are used to tighten skin around the abdomen model to simulate the changes in uterine tightness and procedural difficulty.
17. Silicone skin layer that simulates many skin mechanical properties.
18. Physical knobs to adjust fetal positioning, set-up, or other inner components.
19. A fetus inside a pillow that can be turned to practice turning a baby inside the uterus. It would be completely opaque and allow you to practice relying on the feel of the fetus.
20. A fetus inside a balloon that can be turned to practice turning a baby inside the uterus.
21. Similar to a fetus in a balloon, a beach ball can be inflated/deflated to increase/decrease difficulty of the ECV procedure.
22. A phone game that lets you simulate ECV. As you go up in levels, the procedure becomes more difficult to perform.

We also used design heuristics to develop subfunction ideas. An additional example of the use of design heuristics is shown in Table A1 below.

Table A1. Concepts generated using design heuristics cards

Design Heuristic Card	Concept Generated
	
	
	

The card prompting "Add Natural Features" led to considerations to include a model pelvis and umbilical cord components. This could better emulate natural biological elements of a pregnant patient. A discussion with Dr. Kwaku Douffour revealed that though an umbilical cord could be a determining factor in terms of whether an ECV is successful, there is no way of knowing

whether that is the case until the procedure begins. In light of this information, we have opted to omit the umbilical cord as a vital component of our model. The card “Cover or Wrap” allowed us to consider what may act as an outer “skin” layer to cover a model fetus. This led to the concept of a silicone layer over a hemispheric shell, such that there is a shell providing structural support but a silicone layer to mimic skin. Several cards related to accessibility in our design including allowing the user to customize, assemble, reorient, and rearrange led to the concept of a zipper opening such that internal components can be accessed.

The design heuristic cards helped generate the subfunctions evaluated in the morphological chart. Our full morphological chart is shown below, in Table A2.

Table A2. Full morphological chart resulting in 100,000+ potential design concepts.

Subfunctions	**Solutions**									
Externally feels like skin	silicone	latex	rubber	foam ball						
Behaves like abdomen to pressure	spring loaded skin	compressible foam	memory foam	water bed	balloon	elastic	ball	linear damper		
Models varying difficulty	one big air bag	5 bags for muscles	spaced hooks	fluid	both air and liquid as fluid resistances to pressure	beans	rice	sand	bean bag/stuffing	
Fetal model	buy medical model	wire form with doll components	3d print extremities	block baby, hinges	baby doll, velcro/snap	papier mache				
Pelvis	3D print	bucket	bowl	papier mache	steal from halloween skeleton	soup mug	spider decor	basket	pillow	small pet bed
Base	wood frame	aluminum frame	non slip sock material	yoga mat bottom	rubber bottom grip	clamp	superglue	command strips		
Easy access to inner components	Zipper	Sunken base	"Fitted sheet" skin layer							

APPENDIX B: Concept Selection

Phase 3: Full Concept from Narrowed Subfunctions

Below are the remainder of the subfunction Pugh charts, where each concept was ranked relative to one another to select optimal subfunction components.

The first requirement we down-selected concepts for was "Externally feels like skin," shown below in Table B1.

Table B1. Externally feels like skin

Selection Criteria	Justification	Weight	Silicone	Polyurethane
Elastic modulus similar to that of human skin	Per *Tactile elements feel like pregnant abdomen* requirement	3	+	-
Low cost	Per *Low cost* requirement	3	-	0
Long-lasting	Per *Long-lasting* requirement	2	+	0
Easy to clean	Per *Easy to clean & reset* requirement	1	+	-
Locally available or repairable	Per *Can be repaired locally requirement*	1	-	0
Total			**2**	**-4**

We assigned the highest weight to the selection criterias of "elastic modulus similar to that of human skin" and "low cost," as the elastic modulus informed our high-priority requirement that external components feel like a pregnant abdomen and low cost was another high-priority requirement. The selection criterion "long-lasting" was one that is vital for implementation and consistent use in a teaching hospital, but not necessarily for a functional prototype; as such, this was weighted lower than the highest weighting criteria. For similar reasons, the "easy to clean" and "locally available or repairable" criteria were ranked the lowest. Through this Pugh chart, we elected that silicone was the best material to act as an outer material mimicking skin.

The next Pugh chart addressed the requirement "Behaves like abdomen to pressure."

Table B2. Behaves like abdomen to pressure

Selection Criteria	Justification	Weight	Memory Foam	Silicone Castable Foam
Unobstructive to fetal palpation	Per *Fetus can be palpated* requirement	3	+	+
Low cost	Per *Low cost* requirement	3	-	+
Lead time for prototyping	Per internal time constraints	2	-	0
Long-lasting	Per *Long-lasting* requirement	2	+	0
Locally available or repairable	Per *Can be repaired locally* requirement	1	-	-
Total			**-1**	**+5**

The highest weighted selection criteria were “unobstructive to fetal palpation” and “low cost,” as any material used to emulate abdomen behavior could not excessively obstruct feeling and palpation of the fetal model inside, and low cost was another high priority requirement. We weighted “lead time for prototyping” with a value of 2, since we were on a tight timeline for the semester. “Long-lasting” was also assigned a weight of 2 for considerations of sustainable implementation in a Ghanaian teaching hospital, and “locally available or repairable” was weighted with a 1 because of its lack of impact on device functionality. We opted to use silicone castable foam for this material based on the result of the Pugh chart.

The next requirement we addressed was “Models varying difficulty” for the ECV procedure, shown below in Table B3.

Table B3. Models varying difficulty

Selection Criteria	Justification	Weight	5 airbags on sides	pull on differently spaced hooks	torque-adjustable turntable
User-adjustable	Per *Simulates turning of fetus*	3	0	0	-
Low cost	Per *Low cost* requirement	3	0	0	-
Quantifiable adjustment metrics	Per *Simulates turning of fetus*	3	0	-	0
Long-lasting	Per *Long-lasting* requirement	2	0	0	0
Locally available or repairable	Per *Can be repaired locally* requirement	1	0	0	-
Total			**0**	**-3**	**-7**

The highest weighted selection criteria for this requirement were "user-adjustable" and "low cost." From discussions with our sponsor, we want to prioritize implementation of adjustable difficulty levels for our simulator so practicing groups can gain familiarity with the procedure in various conditions and grow a sense of adaptability when treating patients. We want the mechanism for difficulty adjustment to have quantifiable adjustment metrics so data collected from testing can be analyzed and quantifiable adjustments can be made accordingly, so this criterion was assigned a weight of 2. The "low cost," "long-lasting," and "locally available or repairable" criteria were assigned the same weights as in the Pugh charts prior for the same reasons. As a result, the airbags solution won over the other two concepts.

The next Pugh chart shown below in Table B4 addressed the requirement of being able to simulate breech positions.

Table B4. Fetal model

Selection Criteria	Justification	Weight	poseable stuffed animal (wire)	doll with velcro to velcro limbs in position	3D printed doll
User-adjustable	Per *Simulates turning of fetus* requirement	3	+	+	-
Low cost	Per *Low cost* requirement	3	0	0	0
Long-lasting	Per *Long-lasting* requirement	2	-	+	-
Locally available or repairable	Per *Can be repaired locally* requirement	1	-	+	-
Total			**0**	**+3**	**-3**

User-adjustability was assigned the highest weight for this Pugh chart because the user must be able to conduct ECV with the fetal model at different breech positions. After discussion with our sponsor, the easiest and most cost-effective way of implementing this requirement was to have a fetal model that can be adjusted to emulate the breech positions such that the user can change the starting position as necessary. The other selection criteria were assigned the same weights as previously for the same reasons. From this Pugh chart, we selected the doll with velcro to velcro limbs in position to emulate breech positions in our simulator.

In the next Pugh chart, we downselected the base material for our simulator. We defined the base to be interfaces between the stage holding simulator inner components and the examination table.

Table B5. Base

Selection Criteria	Justification	Weight	wood	aluminum	rubber stops
High coefficient of friction	Per *Stable* requirement	3	-	-	+
Low cost	Per *Low cost* requirement	3	+	-	+
Weight	Per *Stable Requirement*	3	-	+	-
Locally available or repairable	Per *Can be repaired locally* requirement	1	0	0	0
Total			**-3**	**-3**	**+3**

Unique to this Pugh chart was the "high coefficient of friction" criterion. This was assigned a weight of 3 because the most pertinent requirement for the base was to prevent slipping and provide for a stable foundation on which the procedure could be carried out. All other selection criteria were assigned the same weights as in previous Pugh charts for the same reasons. From this down selection, rubber stops came out to be the ideal component to function as a non-slip base for the simulator.

The last requirement we addressed in a Pugh chart was "Easy access to inner components." From discussions with our sponsor, we agreed that access to inner components of the simulator was vital for the sake of set-up and inner components maintenance. A pugh chart of easy to access inner components is seen in Figure B6 below.

Table B6. Easy access to inner components

Selection Criteria	Justification	Weight	zipper	hooks for skin	velcro
Withstands pressure used during simulation	Per *Simulates turning of fetus*	3	+	-	-
Low cost	Per *Low cost* requirement	3	+	0	0
No tearing of other materials	Per *Long-lasting* requirement	2	0	-	0
Locally available or repairable	Per *Can be repaired locally* requirement	1	0	0	0
Total			**6**	**-5**	**-3**

The most highly weighted selection criterion shown above was that the mechanism for opening and closing of the simulator "withstands pressure used during simulation." Specifically, the inner components had to be held securely inside the simulator even with high pressures applied, and whatever mechanism was being used could not be at risk for bursting open or breaking. The other selection criterion unique to this Pugh chart was "no tearing of other materials," meaning the mechanism could not risk damage to other components of the simulator, such as ripping the outer skin layer. From this Pugh chart, the zipper mechanism for our simulator was chosen to be the accessway for the physician in our final design concept.

First Selected Concept

A preliminary BOM to assess the feasibility of our selected concepts is shown below in Table B7.

Table B7. Preliminary BOM for first selected “Alpha Design”

Part #	Part Title	Material	Dimension(s)	Supplier	Qty	Price	Notes
1	Pelvis	Plastic	6.75” dia, 2.6” length	Target	1	$0.50	
2	Fetus	Plastic	14" length	Target	1	$9.99	
3	Base	Wood	4 ft. x 8 ft.	Lowes	1	$12.48	
4	Base stops	Rubber	2 in. width	Ace Hardware	1	$4.00	4 pack of stops
5	Zipper	Nylon	10 yd length	Amazon	1	$8.69	
6	Silicone skin/castable foam	Dragon Skin FX-Pro	-	Blick	1	$35.53	
7	Gel packs		11"x5"	Amazon	2	$17.95	2 pack
					Total Cost:	**$89.14**	

The selected materials resulted in a projected cost of $89.14. This total evolved as our design was continuously iterated and engineering analysis informed precise quantities and dimensions needed. However, it provided a baseline cost that provided our team with confidence that our model would meet our low-cost specification. Our team continued to evaluate materials for purchasing and make decisions by considering cost and lead time. Additionally, our team developed a preliminary CAD model of our “Alpha Design”, as shown below in Figure B1.

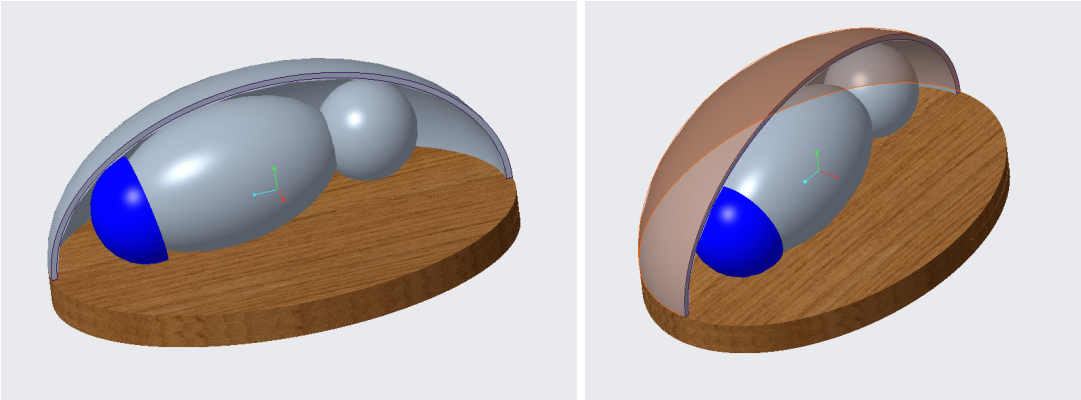


Figure B1. Preliminary CAD model of Alpha concept

Given that our model largely contained complex surfaced components and a fetal model, our CAD model best served us to justify the positioning, dimensions and size of our model. This was also updated as we iterated and improved our design.

APPENDIX C: Concept Iteration & Engineering Analysis

Uterus Model: Beach Ball Prototyping

To create a proof-of-concept model for the beach ball uterus model, our team purchased a multi-pack of 10 mini beach balls. Then, we would scale up to the properly-sized model. As previously stated, the beach ball concept was ultimately unsuccessful. The first step in creating the beach ball prototype was to attach the zipper, which was successful with careful sewing techniques, as shown in Figure C1.

Figure C1. Attachment of zipper to beach ball

However, in order to attach the zipper, the beach ball had to be cut along its entire circumference. Therefore, our team had to attempt to reseal the rest of the beach ball once the zipper was attached. We attempted to heat seal and use vinyl cement to reconstruct the beach ball. The beach ball with vinyl cement lining the edges is shown in Figure C2.

Figure C2. Resealing the beach ball with vinyl cement

However, along the edges that were resealed, the PVC plastic material of the beach ball lost much of its integrity. Furthermore, our team attempted to place a velcro flap over a slit in the beach ball as a proof of concept for the flap to make the ball airtight. However, as indicated by the thumbs-down seen in Figure C3 below, this was unsuccessful.

Figure C3. Testing airtightness of velcro flap

The velcro was not airtight, and it was difficult to properly secure it around the beach ball. After several attempts at prototyping, our team ultimately decided to move forward with other concepts.

Uterus Model: Dimension Calculations

In order to estimate the dimensions of our uterus model, the total intrauterine volume (TIUV) was calculated based on the assumption that the shape of the uterus is an ellipsoid [81]. A representative ellipsoid is shown below in Figure C4. [75]

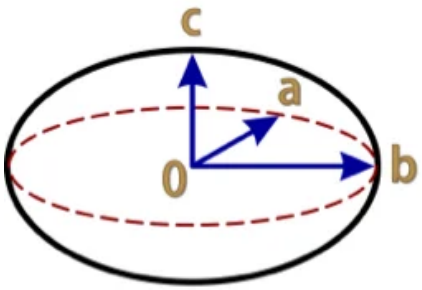


Figure C4. Prolate ellipsoid used to estimate uterine dimensions

The dimensions of A, B, and C were approximated using uterine dimensions at 37 weeks gestation, where

$$A = 8.831\ mm/week \cdot 37\ weeks = 327 \text{ mm [82]}$$
$$B = 7.912\ mm/week \cdot 37\ weeks = 293 \text{ mm [82]}$$
$$C = 2.795\ mm/week \cdot 37\ weeks = 103 \text{ mm [82]}$$

A prolate ellipsoid volume is equal to the product of the length (A), transverse diameter (B), the anterior-posterior diameter (C), and a constant. The resulting equation and calculated volume is shown in Equation C1 below [81].

$$TIUV = 0.5233 \cdot A \cdot B \cdot C = 0.5233 \cdot 327mm \cdot 293mm \cdot 103mm \approx 5\ L \qquad [C1]$$

Therefore, we selected our press-to-close bags that have at least a 5 L capacity and dimensions such that the width was approximately the transverse diameter of the uterus and the length was approximately the length of the uterus.

Base Design: Material Selection

As mentioned in the main body of the report, our team wanted to determine which table-base interface material would best restrict model movement while minimizing total weight. For this analysis, we assumed that our model would be used on a medical grade, stainless steel table [45], which gave a more conservative coefficient of friction than other table materials [46], and evaluated how the table interacted with our selected material. Coefficients of friction for each interface material with respect to stainless steel were found [46], and a free-body diagram of our model is shown below in Figure C5.

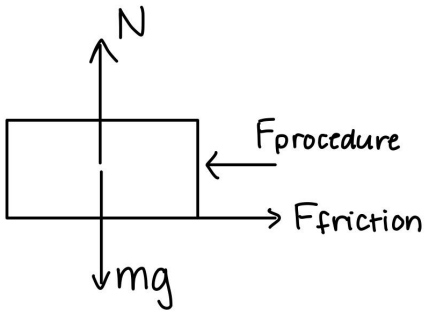


Figure C5. FBD of simulator

We utilized Newton's 2nd law to determine the required weight to ensure stability for each interface material, with a minimum procedural force of 90N, and a maximum procedural force of 135N, as outlined in our specifications. The materials of interest and their respective properties are outlined in Table C1 below.

Table C1. Materials and respective required mass

Material	μ	Required m_{min} (kg)	Required m_{max} (kg)
Wood	0.41 [46]	22.38	37.29
Rubber Stops	0.64 [46]	14.33	23.89
PVC	0.20 [46]	45.87	76.45

Our analysis revealed that using rubber stops as the table-base interface material would best restrict movement throughout the procedure while minimizing weight to remain static. We opted to move forward with rubber stops as the interface material, but still had to select a material for our actual base.

Even with rubber stops we still needed our model to weigh at least 14.33 kgs, so we looked to using aluminum as our main base material, as it contributed a lot of weight to our design. Rubber stops could be placed under the aluminum base to prevent slipping. This base design is shown below in Figure C6.

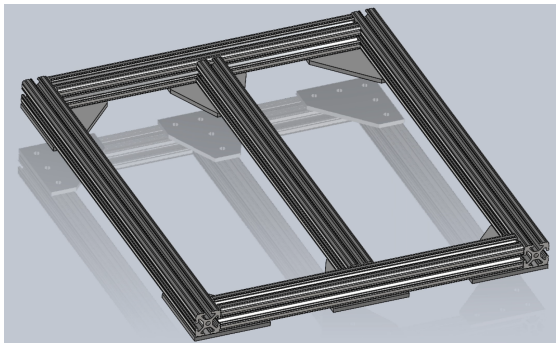


Figure C6. Original base design

This base weighed 9 kg [63], which helped our model meet our weight requirement to ensure stability. However, a cost analysis revealed that a base made completely of aluminum would cost $177.25, which surpassed our optimal cost specification of $100 and was over half of our minimal specification of $350. The resultant bill of materials for this design is detailed below in Table C2.

Table C2. Bill of materials for aluminum frame base

Component	McMaster #	Unit Price ($)	Quantity	Cost ($)
1.5x1.5” 80/20 Hollow single rail, 1.5 ft.	47065T102	15.31ea	3	45.93
1.5x1.5” 80/20 Hollow single rail, 2 ft.	47065T102	18.38ea	2	36.76
90 degree angle	47065T271	13.34ea	4	53.36
Tee surface bracket	47065T279	13.93ea	2	27.86
T-slotted framing fasteners	6000N201	6.67/pack of 4	2	13.34
			Total Cost	**$177.25**

As evidenced in Table C2, a cost of $177.25 would comprise a significant portion of our budget for the semester as well as the low-cost specification of our model. Therefore, we proceeded with the cheaper alternative of a wood base.

Base Design: Estimated weight of model

As mentioned in the main body of our report, we used an estimated weight of our model to calculate the force the full model could withstand without slipping. The densities, volumes, and total mass of the model are outlined below in Table C3.

Table C3. Estimated weight of current design

Material	Density	Volume	Mass	Mass (kg)
Ziploc Bag	-	-	33 g	0.033
Ecoflex 00-50	26 in^3/lb	73.51 in^3	2.827 lbs	1.285
Foam	32 kg/m^3	0.002409 m^3	0.0771 kg	0.077
Gel Packs	1.12 g/cm^3	2409.96 cm^3	2699.16 g	2.699
Plywood	0.65 g/cm^3	2896.58 cm^3	1882.78 g	1.883
Hose Clamp	-	-	0.788 lbs	0.358
Baby	-	-	3 lbs	1.364
Bowl/Pelvis	-	-	1 lb	0.455
			Total Mass	**8.153 kgs**

Using the densities and respective volumes of some elements, as well as the actual weight of others, we were able to estimate our full model weight to be 8.153 kgs and used this estimate throughout our force calculations.

Outer Layer Materials: Layer Downselection
As discussed in the main body of this report, we selected EcoFlex 00-50 and EcoFlex 00-20 as the silicone rubbers that best meet our specifications for elastic moduli, as shown in Table C4 below.

Table C4. Mechanical properties of selected silicones

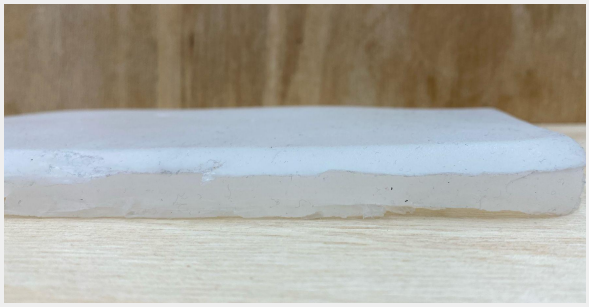
Material Choice	Elastic Modulus	Per Specification
EcoFlex 00-50	83 kPa	90-110 kPa
EcoFlex 00-20	55 kPa	9-11 kPa

Though the elastic moduli of silicone and human skin are not identical, these selections best fulfilled our specifications. The EcoFlex 00-50 has the highest elastic modulus among available products at 83 kPa, which is the closest to our specification of an elastic modulus of the external layer between 90-110 kPa. Additionally, the EcoFlex 00-20 has the lowest elastic modulus among available products at 55 kPa, which is the closest to our specification of an elastic modulus of the internal layer between 9-11 kPa. Although both of these material selections are outside of our specification range, they are well-documented on the Smooth-On website for application in prosthetics and medical models. Further discussion with Professor Jon Estrada and a soft materials lab tour gave us the opportunity to feel both EcoFlex 00-50 and EcoFlex 00-20 [66].

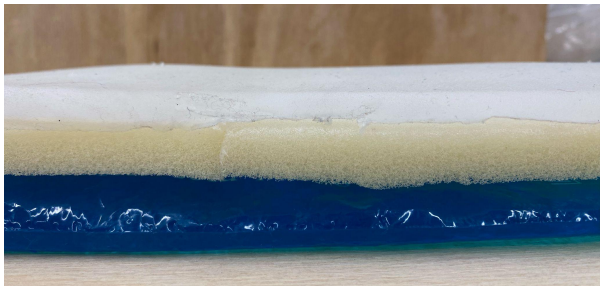
Using these silicone rubbers as well as gel packs and soft foam, our team created 6 possible combinations of layers to emulate the layers of a pregnant abdomen. These layers feature EcoFlex 00-50 as the outer layer and variations of EcoFlex 00-20, soft foam, and gel ice packs. EcoFlex 00-50 was selected as the outer layer for each combination, as we felt confident it would be successful. Since it is the thinnest layer, we anticipated it would remain affordable to cast. We also anticipated the inner layers to contribute most significantly to the feeling of palpation, so we prioritized testing these variations.

Using these silicone rubbers as well as gel packs and soft foam which were identified by our sponsor as potential low-cost materials, we created 6 possible combinations of layers to emulate the layers of a pregnant abdomen. These combinations were chosen based on sponsor discussion as well as our own research in materials previously used to emulate skin, fat, and muscle layers. The thicknesses of these layers were informed by the average thicknesses of pregnant abdominal skin, fat, and muscle, which ranges from approximately 1.5-2.0 cm [83]. The details of these layers are shown below in Table C5.

Table C5. Outer layer combinations for testing

Sample Components	Image
0.31 cm Ecoflex 00-50 1.27 cm Ecoflex 00-20	
0.31 cm Ecoflex 00-50 2.54 cm Ecoflex 00-20	
0.31 cm Ecoflex 00-50 0.64 cm soft foam	
0.31 cm Ecoflex 00-50 1.27 cm soft foam	
0.31 cm Ecoflex 00-50 1 cm Gel pack	

0.31 cm Ecoflex 00-50
0.64 cm soft foam
1 cm Gel pack



Each of these layers was brought to the simulation center for comparison to a high-fidelity birthing simulator. As mentioned in the main body of the report, our team identified two samples that could be likened to the feeling of a pregnant abdomen. One selection was 1.3 cm thick EcoFlex 00-20 layered under EcoFlex 00-50, while the other selection was 0.64 cm thick soft foam and 1 cm thick gel ice packs. Our team compared the projected material costs to determine which combination to select, as low-cost was a high priority requirement for our model. Since EcoFlex 00-50 was used in both samples, this cost was not included in the comparison. First, we estimated the volume of EcoFlex 00-20 and the area of foam and gel packs would be required for our model. These were estimated by using an ellipse approximation, where the surface area was approximately 2400 cm^2, found using our CAD model. To estimate the volume of EcoFlex 00-20, we assumed a uniform thickness of 1.3 cm, leading to a volume of approximately 3,120 cm^3. Using the casting estimator available on the Smooth-On website, we determined that our model would require 7.32 lbs, as shown below in Figure C7 [76].

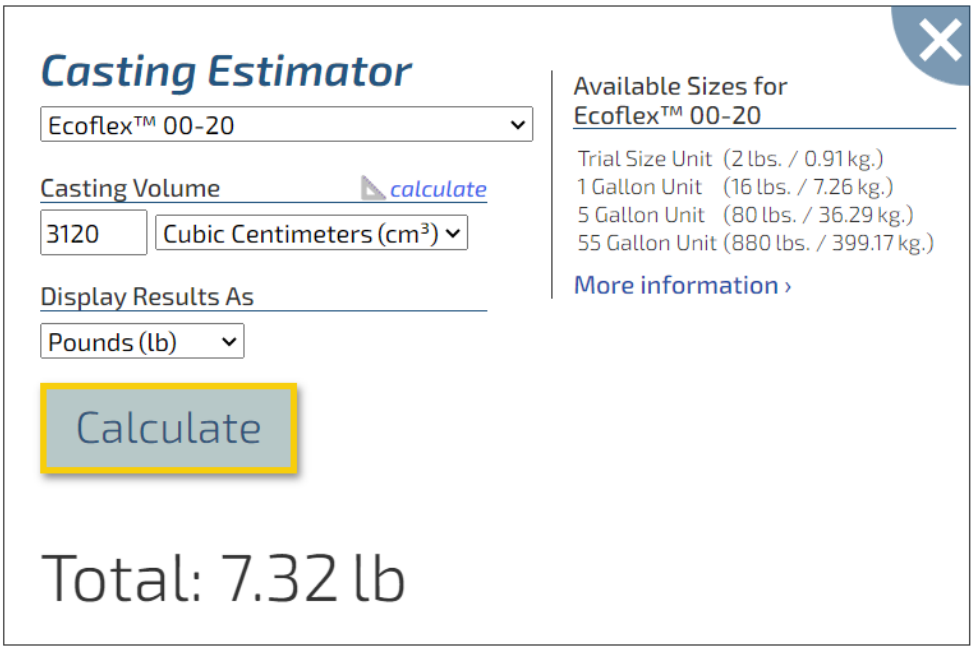


Figure C7. Screenshot of Smooth-On Casting Estimator

Figure C7 shows that our model would require the 1 gallon unit of EcoFlex 00-20, which retails at $197.50.

To estimate the cost of the gel packs, we used a gel pack of 12.5”x4.7”, which retails at $8.90 [77]. In order to cover our base area, we required 4 gel packs at a total cost of $35.60. The cost of foam to cover our surface area would cost $7.79. Therefore, the total cost for the foam and gel packs would be $43.39. Since the foam and gel packs were more cost effective, this is the concept we selected.

APPENDIX D: Verification Plans

Simulates Turning of Fetus: Requires 28-93 kPa peak applied pressure

Peak applied pressure was calculated first using Newton's Second Law to convert mass into pressure using an acceleration due to gravity of 9.81 m/s^2. Then this force was converted into pressure using the estimated contact area of the pads of two hands. This value arises from the aforementioned study of the pressure used to perform ECV, approximately 10.3 cm^2 [35]. The resultant data is shown below in Table D1.

Table D1. Peak Applied Pressure Calculations

Volume Water Added (L)	Max Applied Mass (kg)	Max Applied Force (N)	Peak Applied Pressure (kPa)
0.5	3.98	39.04	37.93
0.5	4.68	45.91	44.60
0.5	4.84	47.48	46.12
0.75	4.08	40.02	38.88
0.75	3.88	38.06	36.97
0.75	3.76	36.89	35.83
1	2.34	22.96	22.30
1	2.38	23.35	22.68
1	1.92	18.84	18.30
1.25	1.56	15.30	14.87
1.25	1.08	10.59	10.29
1.25	1.47	14.42	14.01
1.5	1.48	14.52	14.10
1.5	0.98	9.61	9.34
1.5	1.26	12.36	12.01
1.75	1.48	14.52	14.10
1.75	0.96	9.42	9.15
1.75	1.06	10.40	10.10

The calculated peak applied pressure values were within the 28-93 kPa specification range.

Simulates Turning of Fetus: Can withstand 93 kPa without damage for 10 minutes

To calculate the height of steel equivalent to 93 kPa, we used the estimated contact area of the pads of four hands 20.6 cm^2, or 0.00206 m^2, as typically two physicians perform the procedure [35]. Using this area and 93 kPa, the required force was calculated to be approximately 191 N, or 43 lbf. Using Newton's Second Law and an acceleration due to gravity of 32.2 ft/s^2, the weight of steel needed was found to be approximately 1.3 lbm, or 0.62 kg. Assuming a density of steel

of approximately 7850 kg/m^3, the volume of steel needed was approximately 0.00008 m^3. Dividing the volume by the area gave a total height of steel required of 8 cm. Assuming this weight was divided evenly among each of four hands, the height of steel needed was approximately 2 cm per area. These calculations are shown below in Equations D1 and D2.

$$F = P \cdot A = 93000\,Pa \cdot 0.00206\,m^2 = 191\,N \cdot 0.225 = 21.5\,lbf$$

$$m = \frac{F}{a} = \frac{21.5\,lbf}{32.2\,ft/s^2} = 1.3\,lbm \cdot 0.454 = 0.62\,kg$$

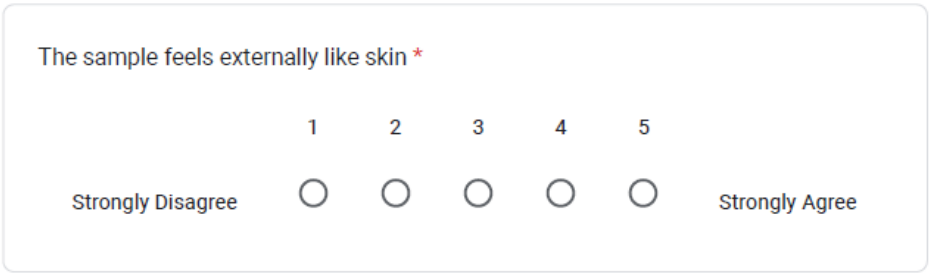
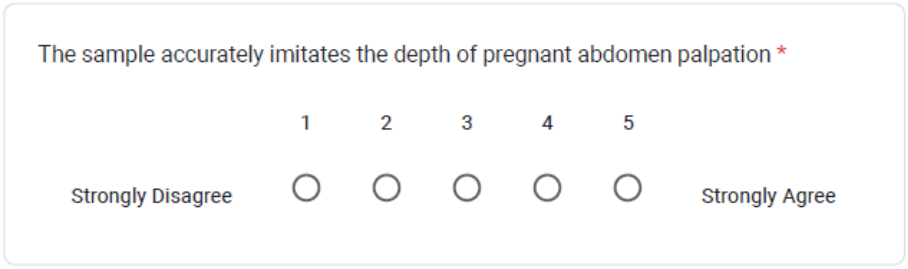
$$V = \frac{m}{\rho} = \frac{0.62\,kg}{7850\,kg/m^3} = 0.00008\,m^3$$

$$h = \frac{V}{A} = \frac{0.00008\,m^3}{0.00206\,m^2} = 0.08\,m = 8\,cm$$

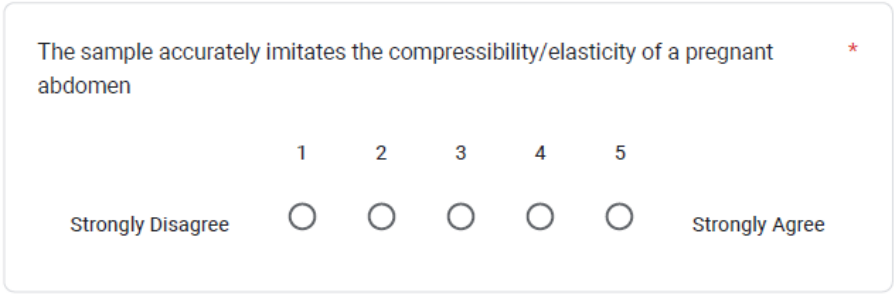
Tactile Elements Feel Like Pregnant Abdomen: 5-point Likert scale score ≥ 3.5 averaged among 15+ clinicians surveyed

To verify our outer layers accurately mimic a pregnant abdomen, a Likert scale was used to test with our sponsor and can be used to test with other physicians. The full questionnaire each physician will fill out is shown below in Table D2.

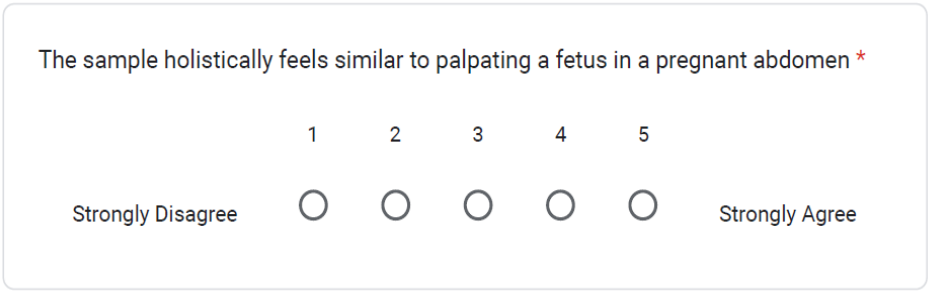
Table D2. Likert scale survey for physician feedback

Question Intent	Survey Question
Survey the extent to which the EcoFlex 00-50 outer layer resembles pregnant abdominal skin	
Survey the extent to which the total depth of our sample resembles the depth of a pregnant abdomen	

Survey the extent to which the compressibility of our sample resembles the compressibility of a pregnant abdomen



Survey overall impressions of the sample in relation to palpation of a pregnant abdomen



The results in the Likert scale survey will be averaged and must meet or exceed an average score of 3.5.

The results of the Likert scale survey with our sponsor are shown in Table D3 below.

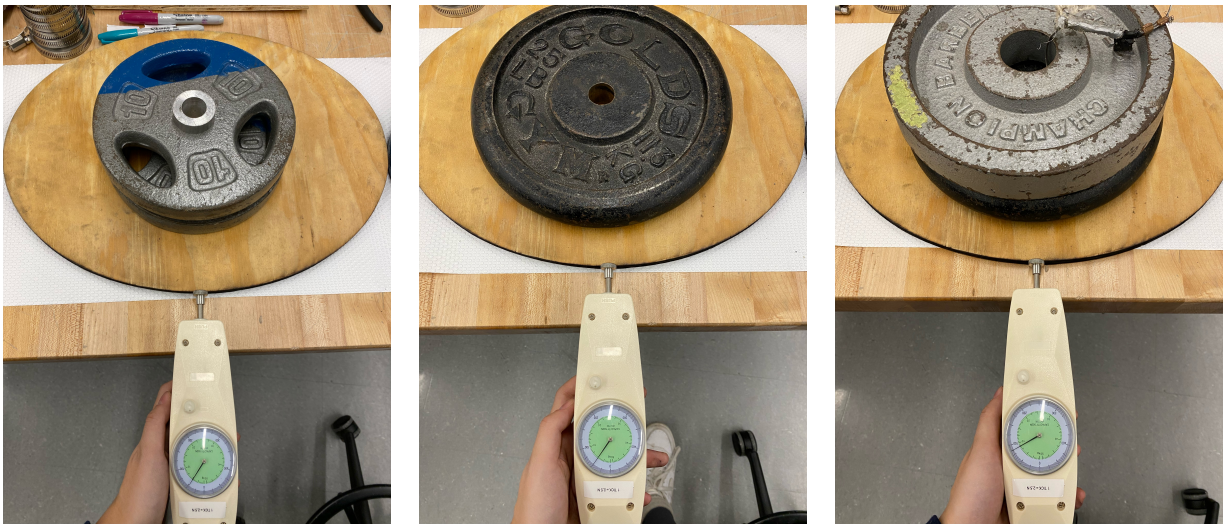
Table D3. Dr. Thiyag's Likert scale responses

Survey Question	Sponsor Score
The sample externally feels like skin	3.0
The sample accurately imitates the the depth of pregnant abdomen palpation	4.0
The sample accurately imitates the compressibility/elasticity of a pregnant abdomen	4.0
The sample holistically feels similar to palpating a fetus in a pregnant abdomen	4.0
Average Score:	**3.75**

It should be noted that the individual score of "The sample externally feels like skin" received a score of 3.0 from our sponsor. This is below our specification of 3.5. However, we utilized an external layer of silicone rubber, which is a commonly used material to resemble human skin [42]. Therefore, although this did not receive a score above 3.5, there may not be other low-cost, accessible materials to use as a replacement. Further, our sponsor expressed that, when evaluating the tactility of the model, the external layer is less important than the overall feeling of palpation, for which related questions received a score greater than a 3.5.

Stable: Remains static with ≤ 90 N horizontal load

To confirm that the white non-slip mat would not meet our minimum specification to remain static with a 90 N horizontal load, our team conducted trials with overestimations of our projected model weight. As shown in the main body of the report, the white non-slip mat did not meet our minimal specification when the approximate projected weight was loaded onto it. We performed additional tests, as the added weight was an estimated model weight, and we sought to determine if the non-slip kitchen mat met our specifications if our model weight was higher than estimated. We added weights of approximately 9.1 kg, 11.3 kg, and 22.7 kg, as shown in the setups in Figure D1 below.



9.1 kg 11.3 kg 22.7 kg

Figure D1. White non-slip mat trials with overestimations of weight

Our team pushed on our model with a horizontal force using the force gauge to identify the force the base can withstand using overestimations of weight. The results of these tests are shown below in Table D4.

Table D4. Slip force of non-slip mat with varying weights

Added Weight (kg)	Slip Force (N)
9.1	47.5
11.3	50.0
22.7	85.0

As shown in Table D4, even when adding a weight of 22.7 kg to our base, the base still slipped at a force of 85.0 N, which was less than our minimal specification of 90 N. Therefore, we opted to move forward with testing another non-slip solution, 30-Duro rubber. The results of this test are detailed in the main body of the report, showing that the 30-Duro rubber met our minimal force specification of 90 N. For the 30-Duro rubber, we also conducted trials with lower weights, including 2.3 kg of added weight and 0 kg of added weight, as shown in Figure D2 below. This

was to confirm that the material will meet our specification, even if our final model weighed less than estimated.

2.3 kg

0 kg

Figure D2. 30-Duro rubber trials with underestimations of weight

The results of these trials are shown in Table D5 below.

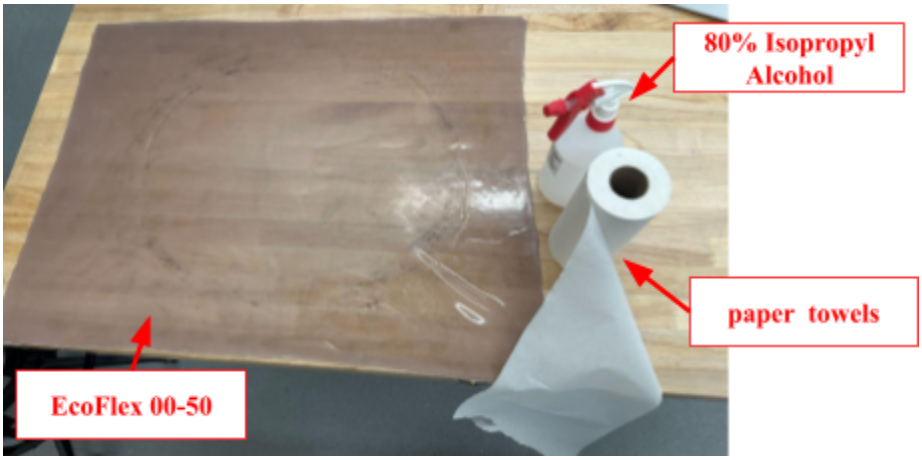
Table D5. Slip force of base on 30-Duro rubber with varying weight

Added Weight (kg)	Force Applied (N)
0	102.5 N
2.3	105.0 N

As shown in Table D5, the 30-Duro rubber kept the base stable at a force of greater than 90 N, even when no additional weight was added to our wooden base. In both cases, a greater force was applied to the base atop the rubber, and the base did not slip in both cases. In testing, the table on which the base and rubber were moved before the base slipped.

Easy to Clean and Reset: ≤ 600 seconds

To verify the time required to clean and reset our model, participants were given a step-by-step description of what cleaning or resetting the model entails. A team member was present for each trial, so clarifications were given as needed to participants. The instructions given to participants to clean the model is shown below in Figure D3.



Task: Clean surface of EcoFlex 00-50 silicone rubber. Prior to testing a team member will spray water over the entire surface. Your objective is to clean the surface of the silicone rubber by ensuring all the water is wiped off the surface.

Materials:

- 80% Isopropyl Alcohol
- Paper Towels
- Timer
- EcoFlex 00-50 Silicone Rubber

Instructions:

1. Spray down the entire surface with spray bottle of 80% Isopropyl Alcohol
2. Gather paper towels
3. Wipe down the surface with the paper towel
4. When you feel all the water is wiped from the surface, say “Stop” out loud to confirm to the team member that you have finished cleaning the surface, and the timer will be stopped
5. A team member will inspect to confirm there is no remaining water or isopropyl alcohol on the surface
6. Repeat trials as needed if surface was not sufficiently cleaned

Figure D3. Cleaning instructions

The instructions given to participants to reset the model is shown below in Figure D4.

Task: Reset the fetus model so it is ready for another training session. Before conducting each trial, a team member will demonstrate the resetting process to familiarize participants with how our model works.

Materials:

- Measuring cup
- Water
- Flathead screwdriver
- Timer
- ECV training model

Instructions:

1. Undo hose clamp with flathead screwdriver. Loosen enough that the hose clamp can be easily lifted from the model
2. Lift outer layers of silicone rubber, foam, and gel packs from the model
3. Open the plastic bag and remove the fetal model
4. Pour existing water in the plastic bag into a sink
5. Measure the desired amount of water with a measuring cup (for this trial use 0.94 L) and pour into the plastic bag
6. Place the fetal model back into the plastic bag and close
7. Place the plastic bag back into the pelvis model with the fetal model's feet/buttocks down
8. Place the gel pack layer back onto the model
9. Place the foam layer back onto the model
10. Place the silicone rubber layer back onto the model, ensuring that it is sufficiently covering each side
11. Resecure the hose clamp onto the silicone rubber using a flathead screwdriver. As you are tightening the hose clamp, pull on the edges of the silicone rubber to mitigate folding and ensure it is secure

Figure D4. Resetting instructions

Data was collected for 30 trials for both cleaning and resetting. Both cleaning and resetting occurred by the same participant for each trial. For example, in Trial 1, the participant was first

asked to clean the model, then asked to reset the model, then these results were both recorded under Trial 1. The resulting data is shown below in Table D6.

Table D6. Clean and reset time trials

Trial (#)	Clean Time (s)	Reset Time (s)	Total Time (s)
1	49.9	449	499
2	25.5	416	442
3	40.1	258	298
4	37.6	263	301
5	34.9	362	397
6	34.3	344	378
7	22.5	369	392
8	30.2	246	276
9	28.5	436	465
10	24.8	249	274
11	26.3	257	283
12	34.7	317	352
13	36.2	326	362
14	40.8	322	363
15	45.9	202	248
16	30.2	420	450
17	21.9	216	238
18	44.8	296	341
19	31.8	428	460
20	34.4	355	389
21	20.3	301	321
22	37.7	285	323
23	37.5	324	362
24	46.3	408	454
25	41.2	278	319
26	22.5	446	469
27	28.7	286	315

28	31.1	222	253
29	39.8	339	379
30	31.2	246	277
Average Time (s)	**33.7**	**322**	**356**

As shown in Table D6, the average time to clean our model was 33.7 seconds, while the average time to clean our model was 322 seconds, resulting in a total average time of approximately 356 seconds.

APPENDIX E: Build Design Bill of Materials

Table E1 shows the bill of materials for our current build design. Note that this is the same bill of materials as our final design bill of materials, as our build design is our final design.

Table E1. Build design bill of materials

Part Title	Material	Dimension(s)	Supplier*	Qty.	Cost	Notes
Pelvis	Plastic	6.75" dia, 2.62" depth	Target	1	$0.50	subject to change due to sponsor feedback
Fetus body	Plastic grocery bags	N/A	N/A	30	$0.00	common free product, assuming negligible cost
Fetus body	Duct tape	1.88" x 15 yds.	Amazon	1	$3.94	any strong, waterproof tape is sufficient
Fetus head	Coated foam	4" dia	Joanns	1	$2.63	any spherical object ~4" dia is sufficient
Base	Wood	24" x 24" x 15/26"	Home Depot	1	$9.46	dimensions of wood will be reduced post-machining
Base non slip mat	Neoprene	24" x 15"	Amazon	1	$14.99	
Hose clamp	304 Stainless steel	15 ft length, 1/2" thick	Amazon	1	$9.99	15 ft available, will cut to length required by model
Silicone rubber	EcoFlex 00-50	1 lb	Smooth On	2	$61.48	
Gel packs	Soft reusable ice packs	12.2" x 4.7"	Amazon	2	$35.60	packs of 2, total quantity of 4
Base Foam	32 ILD/ 1.40 lbs cu/ft	.5" x 24"x 72"	Joanns	1	$13.49	
Velcro	Industrial strength velcro	4" x 2"	Menards	1	$9.97	
Uterus	Heavy duty LDPE plastic	16" x 18"	Amazon	1	$0.98	Pack of 12, cost is price per bag

Outer Layer Foam	Airtex High Density Foam	1/2" x 24"	Joanns	1	$7.79	
				Total Cost:	**$170.82**	

APPENDIX F: Fabrication Plan

Given that the majority of our components are purchasable items (e.g. thick bags to act as the uterus, bowl to act as a pelvis, plastic bags and tape for the fetus model), the main components that require manufacturing or other means of fabrication are the base, foam, and "skin" layers.

Wooden base

1. Create a part file for the base, sketching an ellipse of major axis dimension 44 cm and minor axis 34 cm.
2. Export the created part file as a .DXF onto a USB, load onto laser cutting software in Mechanical Engineering Undergraduate Machine Shop desktop.
3. Create laser pathing and tune processing parameters.
4. Obtain 15/36 or 1/2 inch-thick plywood, at least 1.5 x 2 ft. in dimension.
5. Place plywood stock into the cutting box and make sure the corner is squared. Manually adjust the laser head to 25 mm gap from the stock surface.
6. Run the program to laser cut the base shape into the wood. Make multiple runs as necessary with lower input thickness dimension for faster runs, and do not move the piece until it is done being cut.
7. Punch/push out the ellipse from rectangular stock, and sand the sides to prevent splinters. If necessary, use a knife to cut the piece out.

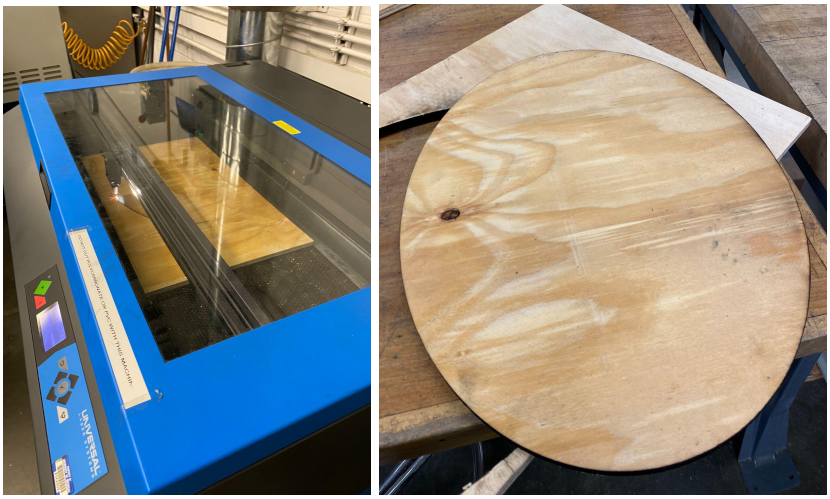


Figure F1. Laser cutting of plywood base

Foam Layers

1. Obtain a thick piece (around 7 cm thick) of soft 32-ILD foam. Sketch out an ellipse to dimension according to the engineering drawing, with major axis value of 40 cm and minor axis value of 30 cm.
2. With a box cutter or X-ACTO knife, cut out an ellipse tracing the sketch. The cut does not need to be very precise, as long as this layer is a smaller ellipse than the base.

Figure F2. Ellipse cut-out of foam

3. On the long side of the elliptical prism, as oriented in Figure 25, mark 3 cm above the bottom on the left end and 7.42 cm above the bottom on the right end. Draw a line connecting these two points to create a 10˚ angle from the horizontal. Repeat mirrored on the other side.
4. Using a box cutter or X-ACTO knife, cut along this line through the entirety of the foam to create the supine position angle.

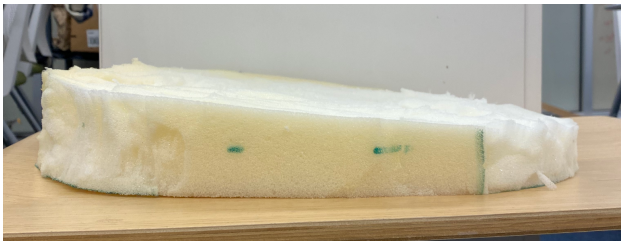


Figure F3. Foam layer side view with 10˚ angle cut from 3 cm above bottom

5. Glue foam layer to the center of the plywood base with Gorilla Glue or equivalent. Make sure there is at least 2 cm of space between foam layer and plywood circumference. Carve off excess foam as necessary.

Skin Layer - Silicone

1. Clean a level, smooth surface on which to cast silicone (at least 70 x 90 cm). Any surface is suitable as long as it does not inhibit curing. Options include a plastic sheet, plastic wrap, or tabletop.
2. Mark out casting surface area of 62 x 80 cm with marker or masking tape.

Table F1. Calculations for surface area for sheet casting

Equations	Purpose

$34 \cdot 44 = 1496\ cm^2$	Ellipse major and minor axis, multiplied for rectangular area
$1496\ cm^2 + 2(924\ cm^2) + 2(714\ cm^2) = 4772\ cm^2$	Add sides of projected rectangle according to maximum model height
$44 = 34x \Rightarrow x = 1.29$	Ratio between side lengths
$a = xb,\ ab = 4772$	Scale sides to get new projected rectangle
$a = 60.72\ cm,\ b = 78.58\ cm$	Dimensions to cast sheet

3. Create a physical border to hold in the casting silicone with aluminum foil for walls and clay to seal gaps and corners. Clay inhibits curing, so add an acrylic paint layer to any clay that will come in contact with the silicone.
4. Mix equal volume of EcoFlex 00-50 Part A and B into a large bowl for a total of 3.5 lb of silicone. If adding color dye or pigment, first mix pigment into Part A before adding and mixing in Part B. Pour, and spread fully mixed castable silicone across the casting surface.

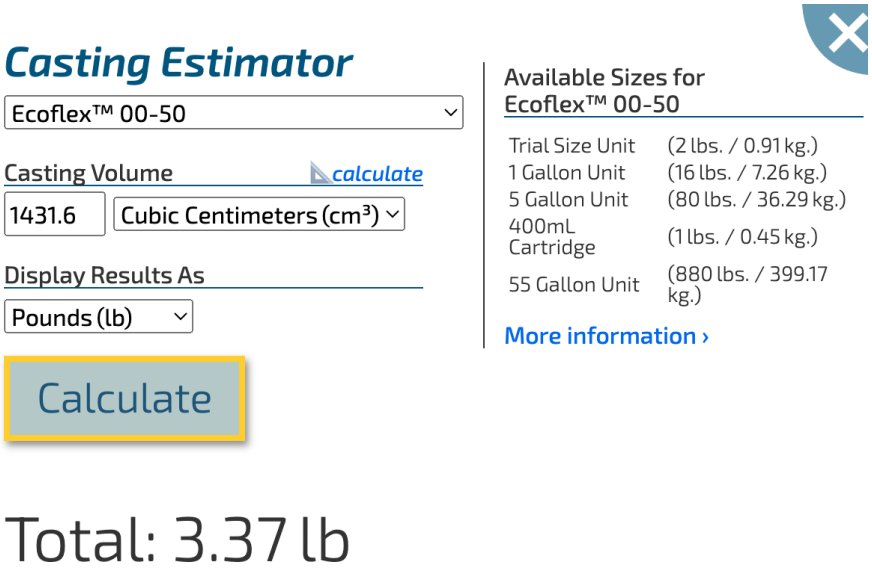


Figure F4. Casting estimator calculating amount of silicone necessary [76]

5. Let cure for 4 hours. After all air bubbles rise to the surface of the spread silicone, a heat gun can be used to expedite curing time.
6. Remove cured silicone from the casting surface.

Skin Layer - Foam

1. From a sheet of high-density Airtex foam, use scissors to cut out an ellipse of 2410 cm^2 that can cover inner components entirely.
2. Cut the resulting ellipse into pieces to create panels, shown below.

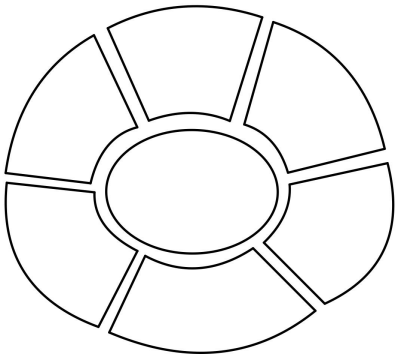


Figure F5. Diagram of high-density Airtex foam cut into panels making up an ellipse

3. Sew panels together so they come together in a shell shape. Cut excess foam. Attached foam layers should be shaped to form a shell around inner components.

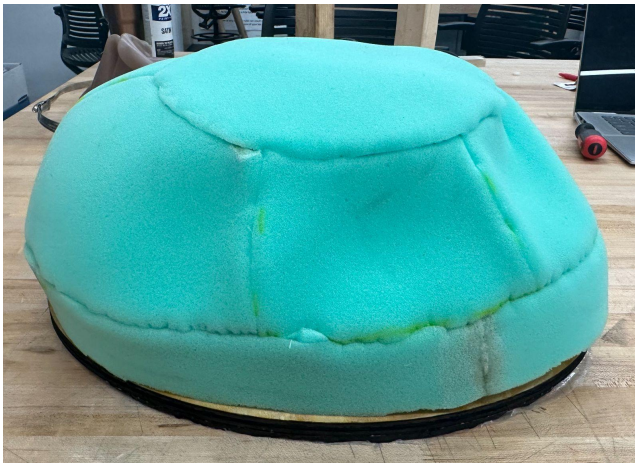


Figure F6. Sewed foam layers positioned on base over inner components

Fetal Model

1. Obtain 30 plastic bags, 5 plastic butter knives, 1 bocce ball, and a roll of duct tape.
2. Flatten 20 plastic bags and stack them on top of each other. Roll the bags to create a cylindrical shape. Secure with duct tape.

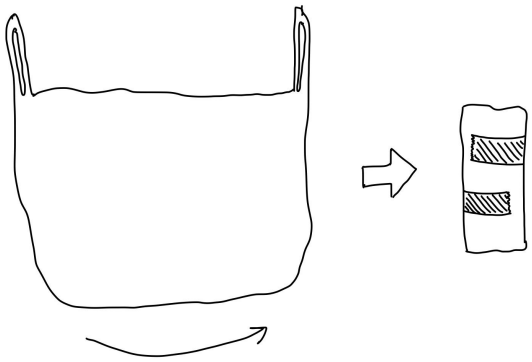


Figure F7. Creating abdomen of fetus

3. Flatten 5 plastic bags and stack them on top of each other. Fold in half. Roll the bags to create a cylindrical shape. Secure with duct tape. Repeat.

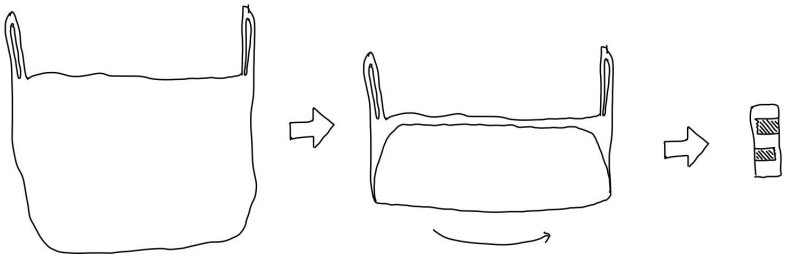


Figure F8. Creating legs of fetus

4. Duct tape 5 plastic butter knives directly on top of each other. Slide the assembly into the abdomen of the model.

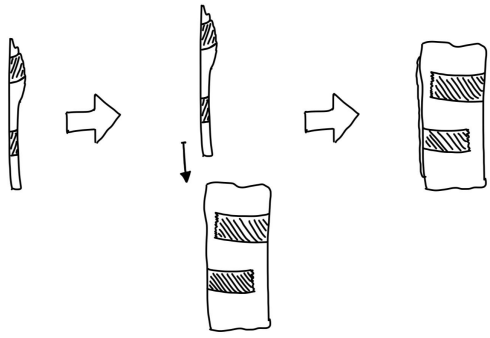


Figure F9. Creating and inserting the spine of the fetus. Knives could be substituted for any thin object of the same length.

5. Tape the legs of the model onto the abdomen on the face opposite the butter knife assembly near the butt of the model.
6. Tape the bocce ball opposite the legs.

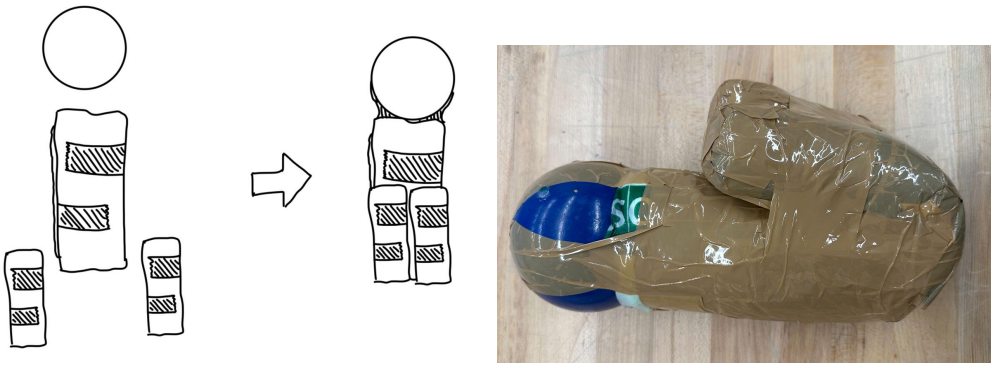


Figure F10. Final assembly of full model sketch (left) and physical prototype (right)

Pelvic Bowl

1. Obtain a bowl (37 oz. plastic bowl, Target) with diameter 6.75” and height 2.62”.
2. Cut off ⅓ of the bowl so it can rest on a flat edge, on its side. Options are to use a hacksaw or bandsaw with a serrated blade.
3. Position on top of base foam layer and glue to fix in place.

Figure F11. Pelvic bowl, cut and glued onto base foam layer

Skin Layer - Gel Packs

1. Obtain four gel packs (each 12.2" x 4.7").
2. Heat seal down the middle of the long edge of each gel pack to split gel into two sides of the pack, shown below. Repeat for three additional gel packs.

Figure F12. Gel pack, heat sealed down the middle through long edge

3. Along the long edge of each gel pack, heat seal to another gel pack for a total of four attached to each other, enough to cover the length of the model abdomen.

Figure F13. Four gel packs heat sealed vertically (left), gel array over inner components (right)

APPENDIX G: Project Plan

A team schedule, as seen in Figure G1 at the end of this section, was established and broken down by week to outline recurring tasks for our lab meetings, ME450-specific deadlines, as well as project-specific tasks. This schedule included the deadline and task assignment to team members. For ease of use, the schedule also allowed team members to link documents and notes pertinent to tasks. The project schedule was updated constantly, as the projected timeline of the project shifted during the prototyping phase. Key project tasks and stakeholder meetings that occurred throughout the semester are highlighted in Table G1.

Table G1. Unique project tasks and key stakeholder meetings.

Date	Task	Significance
9/18/23	Met with Gurpreet Rana	Provided important Ghanaian specific obstetric data resources.
10/01/23	Met with Dr. Doffour-Dapaah	Clearly identified needs with an

		OBGYN at Korle Bu Teaching hospital.
10/04/23	Met with Dr. Marzano	Discussed OB GYN simulation models available at UM
10/30	Watched a live ECV performed at Michigan Hospital	Allowed for first-hand observation, consultation with doctors performing procedure
11/1	Uterus prototyping and preliminary evaluations	Preliminary evaluation and assembly of samples for testing
11/3	Materials consultation with Prof. Estrada	Information collection with expert in biomaterials
11/4	Selected & purchased/obtained materials for skin outer and inner layers	Preliminary evaluation and assembly of samples for testing
11/9	Visited UM simulation center to see existing pregnancy simulation technology	Measurement collection, medical-grade silicone skin comparison
11/13	Finished base CAD	Subsystem necessary for full assembly and testing
11/14 - 12/12	Monitored sponsor testing of model	Verify our technical requirements and specifications are met

The initial tasks of our project were to narrow the project scope and revise the problem statement accordingly based on preliminary research and conversations with our project sponsor. Additionally, we prioritized developing a list of stakeholders across UM and in Ghana, which was aided by meeting with Gurpreet Rana, Global Health Coordinator in Taubman Health Sciences Library at UM, and became a milestone task as she was able to connect us with physicians at Korle-Bu and Komfo Anokye teaching hospitals in Ghana. We are also meeting with Dr. Doffour-Dapaah, a physician in obstetrics and gynecology at Korle Bu teaching hospital in Ghana in order to further contextualize the need in Ghana.

Further milestones that were critical during the prototyping phase were connecting with the UM Medical Simulation Center to learn about existing simulation technology in the OBGYN space and seeing a real ECV performed in the UM hospital to gain a further understanding of the

procedure. Two team members had the opportunity to witness an ECV performed, as well as discuss the procedure directly with the resident performing it.

The next steps of the project included concept generation and preliminary design creation. Firstly, our team needed to complete concept generation, which involved several strategies like brainstorming, morphological matrices, and design heuristics. These tasks were completed by our team as a collective, as collaboration in brainstorming has been successful for team members in the past and allowed us to develop a creative set of possible solutions. Once completed, our team evaluated the generated ideas against the requirements and specifications, problem statement, design constraints, and novelty. These were critical tasks that needed to be completed prior to prototyping, iterating, testing, and communication of our design, as seen in the developed design process in Figure 6.

Most recently, we have been working on prototyping, as well as verification and validation testing with the strategies discussed thus far. As the end of the semester approached and our team became occupied with final exams and projects, we devised a “final push” schedule with the tasks necessary to complete within the scope of the project as established with our sponsor.

While our team was constrained on budget and time, we completed the necessary tasks. Our team successfully demonstrated our abilities to communicate with each other and our stakeholders, as well as complete milestone tasks completely and on-time. Our full documentation of semester tasks is shown below in Figure G1.

Week	Task	Who	Category	Start	Duration	Done?
1	Reach out to sponsor, schedule meeting 1	Audrey	Stakeholder Engagement	9/5	9/5	Yes
2	20+ research articles	Topics by person	Research	9/5	9/19	Yes
1	Agenda for Kramer meeting	Audrey	Dr. Kramer Engagement	9/6	9/6	Yes
2	New revision of problem statement for peer review	All	Prep for DR PPT/Report	9/6	9/6	Yes
2	Tentative plan for reaching out to stakeholders	Katie	Stakeholder Engagement	9/6	9/6	Yes
1	Team Contract	All	Course Deadlines	9/7	9/7	Yes
2	Agenda for Kramer meeting (9/12)	Emma	Dr. Kramer Engagement	9/10	9/10	Yes
2	Complete project problem statement	All	Prep for DR PPT/Report	9/10	9/17	Yes
2	Flesh out project schedule for rest of the semester	All	Prep for DR PPT/Report	9/12	9/14	Yes
2	List of stakeholders (ranked, subject to change)	All	Stakeholder Engagement	9/12	9/12	Yes

2	Presentation to class of stakeholders and problem statement	All	Course Deadlines	9/12	9/12	Yes
2	Meet with Sarah Barbrow	All	Stakeholder Engagement	9/13	9/13	Yes
2	Fill in research gaps	All	Research	9/14	9/21	Yes
2	Reach out to additional stakeholders, set up meetings	Katie	Stakeholder Engagement	9/14	9/30	Yes
2	Develop contact list	Katie	Stakeholder Engagement	9/14	9/21	Yes
2	Table of requirements and specifications	Kimia, Lexi	Prep for DR PPT/Report	9/14	9/21	Yes
2	Develop list of questions for physicians	Audrey, Emma	Stakeholder Engagement	9/14	9/21	Yes
2	Rough draft DR 1 presentation	All	Prep for DR PPT/Report	9/14	9/19	Yes
2	Presentation to class of current reqs/specs list	All	Course Deadlines	9/14	9/14	Yes
	Agenda for Kramer meeting (9/14)	Audrey, Emma	Dr. Kramer Engagement	9/12	9/12	Yes
3	Meet with Gurpreet Rana	Kimia, Katie, Lexi, Audrey	Stakeholder Engagement	9/18	9/18	Yes
4	Connect with Ghanian physicians	Audrey, Kimia, Lexi	Stakeholder Engagement	9/18	10/10	Yes
4	Connect with UM OBGYN simulation center	Emma, Katie	Stakeholder Engagement	9/18	10/10	Yes
3	Final Revisions for DR1 presentation	Assignments in Slides	Prep for DR PPT/Report	9/19	9/21	Yes
3	Review draft DR 1 presentation with Kramer	All	Dr. Kramer Engagement	9/19	9/19	Yes
3	Final DR 1 presentation	All	Course Deadlines	9/20	9/21	Yes
3	Rough draft DR 1 report	Assignments in DR1 tab	Prep for DR PPT/Report	9/22	9/26	Yes
4	Design concept generation (individual)	All	Concept Development	9/24	9/26	Yes
4	DR 1 report revisions	All	Prep for DR PPT/Report	9/26	9/28	Yes
4	Design concept selection	All	Concept Development	9/26	9/26	Yes
4	Review presentation feedback with Kramer	All	Dr. Kramer Engagement	9/26	9/26	Yes
4	DR 1 report due	All	Course Deadlines	9/28	9/28	Yes
4	Plans and questions for DR 2	Audrey	Prep for DR PPT/Report	9/28	9/30	Yes

5	DR 1 finish updating	Emma, Katie	Prep for DR PPT/Report	9/29	10/18	Yes
4	Initial engineering analysis for selected design	Lexi	Prototyping & Analysis	10/1	10/10	Yes
5	Meet with Kwaku Doffour Dapaah	All	Stakeholder Engagement	10/1	10/1	Yes
5	Define a clear plan for our project direction	All	Prep for DR PPT/Report	10/1	10/1	Yes
6	DR 2 presentation draft	All	Prep for DR PPT/Report	10/3	10/10	Yes
8	Begin drafting CAD drawings and model	Kimia	Concept Development	10/9	11/10	Yes
6	DR 2 presentation	All	Course Deadlines	10/10	10/10	Yes
7	Review and update DR 2 presentation based on feedback	All	Prep for DR PPT/Report	10/10	10/19	Yes
6	Rough draft of DR 2 report	All	Prep for DR PPT/Report	10/11	10/19	Yes
7	Update DR 2 report based on presentation feedback	All	Prep for DR PPT/Report	10/12	10/19	Yes
6	DR 2 draft/review with Kramer	All	Dr. Kramer Engagement	10/19	10/19	Yes
7	DR 2 report due	All	Course Deadlines	10/19	10/19	Yes
7	Review and update DR 2 report based on feedback	All	Prep for DR PPT/Report	10/20	11/14	Yes
7	Reevaluate project timeline	Emma	Prep for DR PPT/Report	10/20	10/22	Yes
8	Reach out to Michigan Medicine / BME for CAD files	Audrey	Stakeholder Engagement	10/20	10/20	Yes
9	Define analysis plan for each engineering specification	Lexi	Prototyping & Analysis	10/20	11/14	Yes
9	Develop validation method	Emma	Prototyping & Analysis	10/20	11/14	Yes
8	Construct a "threat analysis" of our current problem situation	All	Prep for DR PPT/Report	10/22	11/14	Yes
8	Meet with Dr. David Marzano for simulation consultation	All	Stakeholder Engagement	10/26	10/26	Yes
8	Meet with Professor Barton for quantitative testing consultation	All	Stakeholder Engagement	10/26	10/26	Yes
8	Research compressiveness of abdomen		Research	10/27	11/01	Yes
8	Select & obtain/purchase materials for abdominal layer samples	All	Purchasing	10/27	11/02	Yes

8	Construct samples of abdominal layers for physician feedback	Katie	Prototyping & Analysis	10/27	11/02	Yes
8	Develop Likert scale Google Form for physician feedback	Lexi	Prototyping & Analysis	10/27	11/02	Yes
8	Obtain & interpret feedback, make decision on material choices	Lexi	Prototyping & Analysis	10/27	11/30	Yes
8	Order selected abdominal materials	All	Purchasing	11/10	11/14	Yes
8	Order beach ball	Emma	Purchasing	10/27	10/27	Yes
8	Order gel packs for material testing	Emma	Purchasing	10/27	10/27	Yes
8	Order baby doll	Emma	Purchasing	10/27	10/27	Yes
8	Alter beach ball	Emma, Kimia	Prototyping & Analysis	10/27	11/02	Yes
8	Develop detailed drawings & manufacturing plan for base	Audrey	Concept Development	10/27	11/02	Yes
8	Order materials for base testing	Audrey	Purchasing	10/27	11/03	Yes
8	Feedback meetings with Dhanu, Kramer, stakeholders, doctors	All	Stakeholder Engagement	10/25	11/21	Yes
8	Plans and questions for DR 3	All	Prep for DR PPT/Report	10/24	11/13	Yes
9	Visit UM simulation center to see existing tech	All	Stakeholder Engagement	10/26	11/14	Yes
9	See a real ECV performed at hospital	All	Research	10/29	11/14	Yes
9	Material sample meeting with Estrada	All	Prototyping & Analysis			Yes
9	Machine Shop consultation	Audrey	Prototyping & Analysis	10/30	10/30	Yes
9	Reach out to contacts from Estrada for materials research		Prototyping & Analysis			Yes
9	DR 3 presentation draft	All	Prep for DR PPT/Report	11/02	11/13	Yes
10	DR 3 report rough draft	All	Prep for DR PPT/Report	11/9	11/21	Yes
10	Design Expo Poster Abstract Submission	All	Course Deadlines	10/27	11/7	Yes
10	Review draft DR 3 presentation with Kramer	All	Dr. Kramer Engagement	11/9	11/9	Yes
10	Finalize CAD model	Kimia	Concept Development	11/10	11/13	Yes
11	DR 3 Presentation	All	Course Deadlines	11/14	11/14	Yes
10	Design expo poster rough draft	All	Course Deadlines	11/15	11/19	Yes
11	Further prototyping of iterated alpha design	All	Prototyping & Analysis	11/15	11/21	Yes

11	Further testing of iterated alpha design	All	Prototyping & Analysis	11/18	11/29	Yes
11	Feedback meetings with Dhanu, Kramer, stakeholders, doctors	All	Stakeholder Engagement	11/15	11/21	Yes
11	Review and update DR 3 presentation with feedback	All	Prep for DR PPT/Report	11/15	11/21	Yes
11	Kramer feedback on DR 3 presentation	All	Dr. Kramer Engagement	11/16	11/16	Yes
11	Revise poster based on DR 3 feedback	All	Prep for DR PPT/Report	11/19	11/21	Yes
11	Base manufacturing	Audrey	Prototyping & Analysis	11/20	11/27	Yes
11	DR 3 report revisions	All	Prep for DR PPT/Report	11/20	11/21	Yes
12	DR 3 report due	All	Course Deadlines	11/21	11/21	Yes
12	Design expo poster due	All	Course Deadlines	11/27	11/27	Yes
13	Full-scale silicone setting and assembly	All	Prototyping & Analysis	11/27	11/27	Yes
13	Practice for design expo presentation	All	Prep for DR PPT/Report	11/28	11/30	Yes
13	Design expo	All	Course Deadlines	11/30	11/30	Yes
14	Review Kramer feedback from DR 3 report and design expo	All	Dr. Kramer Engagement	12/01	12/12	Yes
14	Complete final prototype	All	Prototyping & Analysis	12/4	12/4	Yes
14	Write assembly manual for end user	All	Prototyping & Analysis	12/4	12/4	Yes
14	Complete testing on final prototype	All	Prototyping & Analysis	11/30	12/12	Yes
14	Plans and questions for final report	All	Prep for DR PPT/Report	12/01	12/04	Yes
14	Final Report Drafting	All	Prep for DR PPT/Report	12/01	12/12	Yes
15	Final Report DUE	All	Course Deadlines	12/12	12/12	Yes!!!

Figure G1. Semester schedule and task assignments.

The tasks in Figure G1 are outlined in a Gantt chart format below. Each section was broken up based on relevance to each design report (DR) for ME450: DR1 (Figure G2), DR2 (Figure G3), DR3 (Figure G4), and final report (Figure G5). The Gantt chart allowed for the visualization of tasks and how they related to each other over the course of the project.

Figure G2. Gantt chart from project start to DR1 report due date

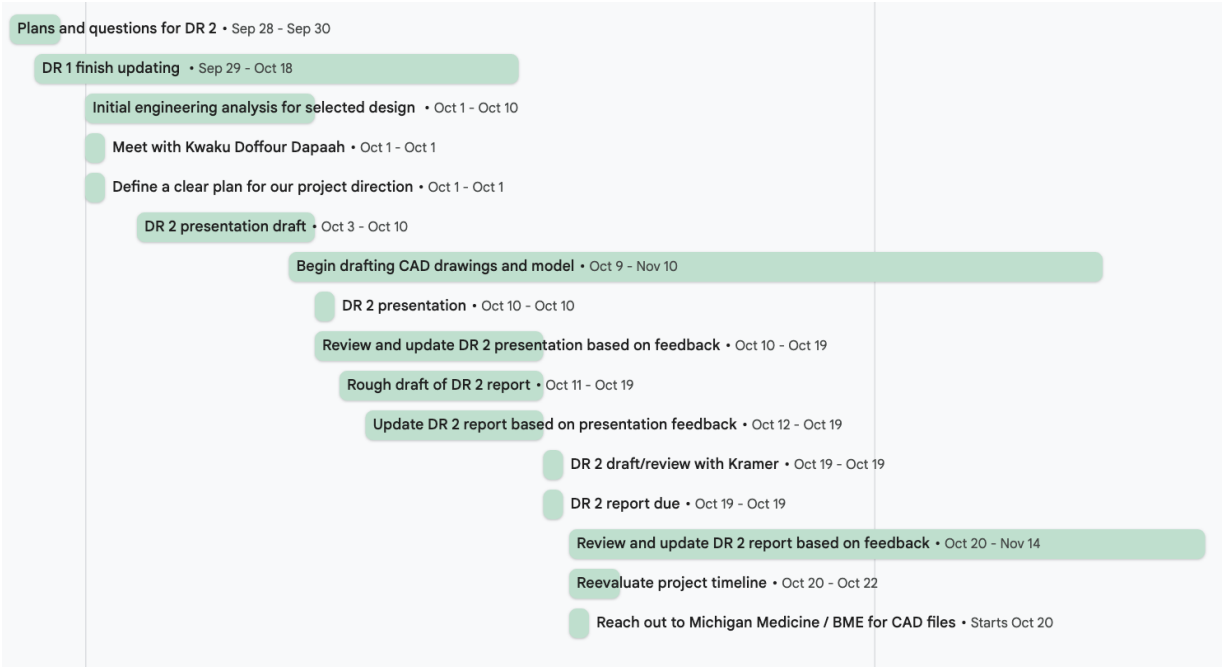


Figure G3. Gantt chart from DR1 report to DR2 report due dates

Figure G4. Gantt chart from DR2 report to DR3 report due dates

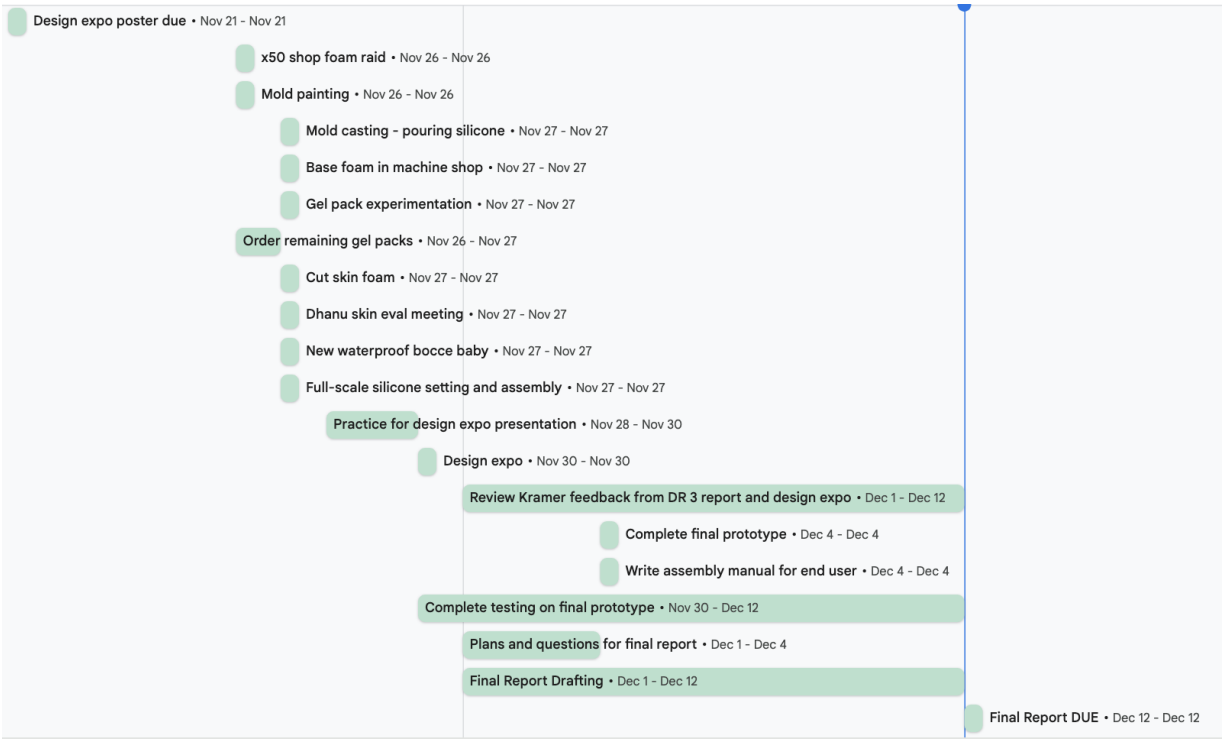


Figure G5. Gantt chart from DR3 report to final report due dates

Overall, we were able to successfully complete all tasks outlined in our project plan and create a full prototype of our final design.