FINAL REPORT

Neurosurgical Training Simulator

Team 12

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EXECUTIVE SUMMARY

An intracranial aneurysm is the swelling, or blistering, of a blood vessel deep within the brain. If the aneurysm ruptures and internal bleeding occurs, there is a 40% fatality rate. Of those who survive, 66% suffer serious debilitating complications [1]. Current training methods for this surgery are not ideal, as they do not offer the same conditions as real surgery, and the consequences of a mistake are not accurately represented. The goal of our project is to optimize a neurosurgical simulator on which neurosurgeons can train.

This simulator must anatomically mimic the biological aspects of the human brain, such as tissue materials and fluid behaviors, and the specific user requirements and engineering specifications were determined and listed in Table 1 on page 9. In our benchmarking research, we have found that comprehensive physical simulators for intracranial aneurysm clipping are nonexistent. Only a small number of devices that simulate a limited aspect of the surgery exist. Examples of these include virtual reality simulators, as well as an artificial artery that simulates only the aneurysm.

When approaching the concept generation stage of our project, we divided our design optimization areas into five functional groups: cap securement, brain securement, membrane sealing, tube management, and pressure system. These groups also represent our design drivers and, because these functions are independent of one another, we focused on selecting the best concept for each function. After generating many concepts, we organized them into the appropriate Pugh charts and scored each concept with respect to each specific criterion using a three-point scale to find the best concept for each function.

After selecting concepts for each off our design drivers, we conducted analysis on each design to understand whether or not it would be effective with respect to our design drivers, user requirements, and engineering specifications. To analyze the different ways in which our simulator may fail, we performed an FMEA, or Failure Modes and Effect Analysis. This process allows us to reduce the chance of any failures occurring during product development, while also identifying what aspects of our design may need to be improved in the future.

After all design aspects of our simulator were finalized, we purchased the necessary components and manufactured the simulator, submitting design changes for an unexpected design alterations that we encountered along the way (mainly hole placements). Once the simulator was manufactured and working, validation testing on the prototype was conducted and the results were compared with the predetermined engineering specifications.

Looking at the resulting design and working simulator, our team and sponsor are satisfied with the product of our efforts, both in terms of design and functionality. We are especially pleased with how well the fluid system works and the ease of operation of the device by the user. Although we met our most important specifications, we did not meet some low priority ones such as material selection for the arachnoid and dura membranes as well as for the brain. If we had more time, we would work to meet these specifications as well as make the device more portable and easy to assemble.

TABLE OF CONTENTS

PROBLEM DESCRIPTION

The problem our team has been presented with is to optimize an existing intracranial surgery simulator with the ultimate goal of providing surgeons an effective training method for brain aneurysm surgery. Before being able to perform the procedure on live patients, neurosurgeons currently train by dissecting cadavers and observing experienced neurosurgeons perform the operation. Our sponsor and team believe that an anatomically accurate model that mimics realistic conditions, such as materials and pressures that resemble those in a real brain, will provide surgeons with better training that will ultimately better prepare them to perform the surgery on a live patient. The current prototype is inadequate in three major areas: appropriate pressure systems with regards to the fluids present in the brain, effective sealing of the various membranes, and material selection that accurately represents the components of the brain. We hope to optimize the existing model and incorporate artificial blood vessels that replicate those in the brain, which are being developed by a team at the University of California in San Francisco, to create a simulator on which surgeons can practice their skills in an environment similar to that which they will find when they operate on a live patient.

BACKGROUND

To understand the best way to approach the given problem of optimizing the existing neurosurgical simulator for the purpose of training surgeons in brain aneurysm surgery, extensive background knowledge is required. Especially helpful is understanding the relevant anatomy of the brain and aneurysms, the surgical procedure involved in clipping an aneurysm, current methods of surgical training, and benchmarking.

Relevant Anatomy

A cerebral aneurysm is a weakened area of the wall of an artery located in the brain. Sometimes described as a blister on the artery [1], an aneurysm visually looks like the ballooning of an artery or formation of a bulge. Aneurysms form due to stresses caused on the blood vessel wall by blood flow, which also causes the aneurysm to grow once formed [1].The bulge creates pressure on surrounding tissue, and the weakened artery is at high risk for bursting, releasing blood into the brain and resulting in a stroke [3]. There are various classifications of aneurysm based on their locations, and the one our prototype will train surgeons to address is called a bifurcation aneurysm, shown in Figure 1, which occurs at blood vessel branchings [4].

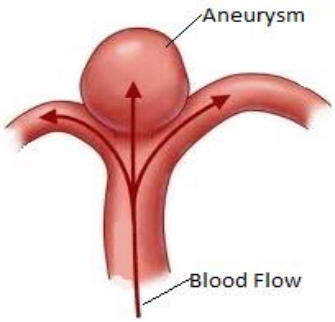


Figure 1. Bifurcation Aneurysm [5]

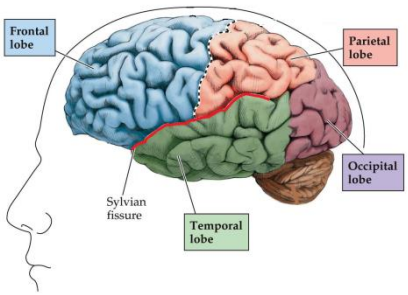


Figure 2. Parts of the Brain [6]

Most aneurysms are located deep in the brain in the Sylvian fissure. The Sylvian fissure, a deep fold in the brain, separates the temporal lobe from the frontal and parietal lobes [7], shown in Figure 2. Brain aneurysms are very difficult to reach surgically because they most often are located deep in the Sylvian fissure [1].

The brain is protected by several layers, the outermost of which is the skin, followed by the skull. The skull surrounds three layers of tissues called the meninges, shown in Figure 3, which protect the brain, from injury and infection, and fold into the Sylvian fissure. The outermost layer of the meninges is the dura mater, a tough material which lines the interior of the skull. Following the dura is a thin membrane called the arachnoid. The innermost layer of the meninges is the pia mater, which lines the brain [8]. In between the arachnoid and the pia mater are the arachnoid trabeculae, which are a sticky, web-like filling of the subarachnoid space [9]. As shown in Figure 4, the blood vessels are surrounded by the arachnoid trabeculae. These blood vessels include both veins, which have a near constant pressure of 10.5+-1.5 mm Hg, and arteries, which have pressures from 70+-20 mm Hg to 120+-30 mm Hg and a pulse of 60-100 beats per minute [1]. Cerebrospinal fluid (CSF) flows in the subarachnoid space and Sylvian fissure, cushioning the brain [10]. The CSF pulsates at a rate of about 10 per minute, with pressures ranging from a low of 0+-1 mm Hg to 4+-1 mm Hg [1].

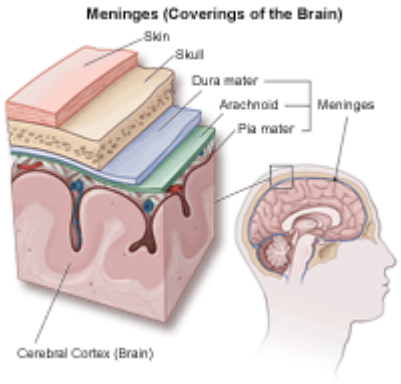


Figure 3. Layers Covering the Brain [11]

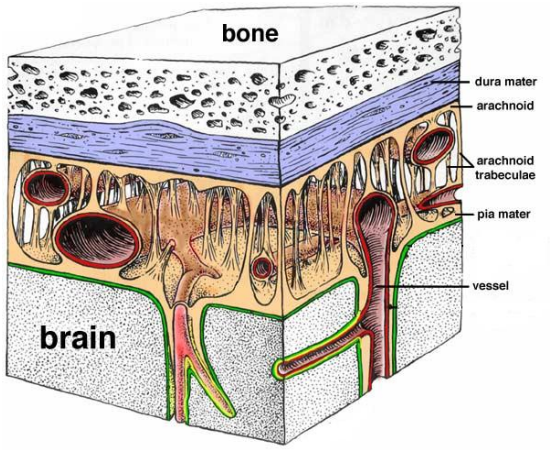


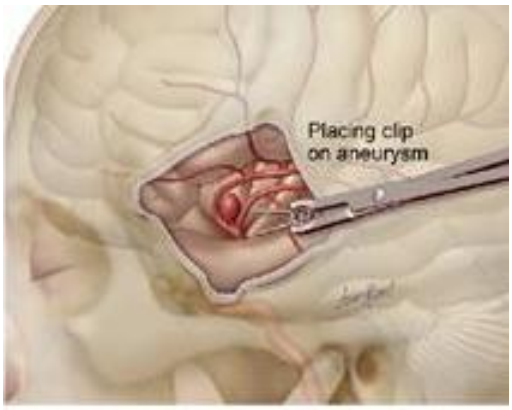
Figure 4. Blood Vessels and Arachnoid Trabeculae [12]

Intracranial Aneurysm Surgery

There are various treatment options for a detected brain aneurysm, the two most common of which are surgical clipping of the aneurysm and endovascular coil placement. Each treatment option presents different risks, and the choice of which treatment to undergo is based on many factors, including the presence of clots, the aneurysm size and location, the aneurysm orientation [13], and the characteristics of the affected artery [14]. Surgical clipping of the aneurysm is the procedure for which our model is intended to provide training.

The goal of aneurysm clipping is to place one or more metallic clips on the neck of the aneurysm, physically preventing blood from entering the affected area and restoring normal blood flow through the vessel [4]. In preparation for surgery, the patient is put under general anesthesia and the head is stabilized. An incision is made behind the hairline and a craniotomy, or the removal of a portion of the skull, is

performed. Next, the dura is cut open so that the only layer left between the surgeon and the aneurysm is the arachnoid. The outer membrane of the arachnoid is opened, and the surgeon carefully cuts through its web-like interior to gain access to the aneurysm, which can take between one and five hours [1]. While draining the pulsing cerebrospinal fluid, the surgeon physically spreads the Sylvian fissure to gain access to the aneurysm, shown in Figure 5. Once the surgeon can physically reach the aneurysm, one or more small clips are fastened to the aneurysm neck, as shown in Figure 6. The size and shape of the clip, which is usually made of Titanium, depends on the size, shape, and orientation of the aneurysm [15]. The layers of the brain are then closed and the bone plate is secured using thin metal plates and screws [16].



Figures 5. Placing Clip on Aneurysm [17]

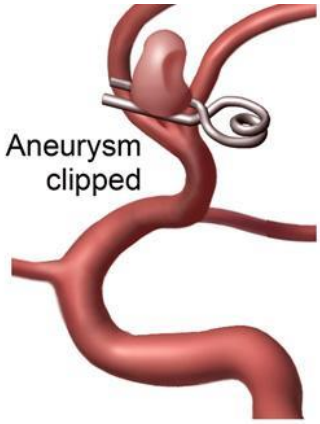


Figure 6. Clipped Aneurysm [17]

There are many risks associated with this type of surgery. Rupture of the aneurysm is of major concern, as it can cause a massive intracerebral hemorrhage, or bleeding into the brain, which may lead to a coma or death.

Available Surgical Training

There are many training methods to help surgeons practice the operation before performing it on a live patient. The most common way of practicing this surgery is on a human cadaver, as it is "the gold standard for anatomic training" [18]. A cadaver is not a perfect simulation of a living human, as it does not have flowing blood, and does not react in the same ways as living body does. Because of this, surgeons must turn to other, more sophisticated methods of practice.

Advanced surgical simulators on which surgeons can practice required surgical techniques exist but are inadequate. Virtual reality simulators use 3D goggles and controllers for surgeons to practice clipping the aneurysm at different orientations [19]. The drawback of this training method is that there is no physical feedback, so it does not give the surgeon the full surgical experience. Another type of training simulator is a 3-dimensional physical model of blood vessels that allows the surgeon to physically place the clips on the aneurysm [20]. Although this can be used to properly train the surgeon on the clipping of the aneurysm, it does not train the surgeon on the full operation, as the surgeon does not have to navigate through the Sylvian fissure or avoid the numerous blood vessels and web-like tissues to reach the aneurysm. The optimal simulator would allow the surgeon to practice each step of the operation and would be seen as "an attractive tool that residents actually enjoy" [21].

Benchmarking

Currently, there are very few simulators available for surgeons on which to practice brain aneurysm surgery, and even fewer that can be used to practice the clipping procedure. There has been progress in the development of virtual brain surgery simulators, but it is difficult to create clinically relevant and useful models [22]. Virtual simulators also fail to give tactile feedback to the surgeon using it, which lessens the effectiveness. Physical models for brain surgery have been developed, but ones specifically made for brain aneurysm surgery are very basic. There has been a patent filed for a general medical training device comprising of at least three elements; the skull, the brain, and at least one membrane separating them [23]. Our project uses a similar concept, but will be more advanced in that it will include multiple membranes, appropriate modeling of the subarachnoid space, and pressure simulations for the cerebrospinal fluid and blood.

A major function our simulator needs to imitate is the vascular system that leads to the brain. There is a patent filed for a flow simulator that creates pulsatile flow by opening and closing valves various amounts [24]. Another patent that was filed involves modeling the vascular system using both a constant-flow and a pulsatile-flow pump [25].

Previous Model

To solve the problem presented to us of creating a model brain to provide surgeons with better training for intracranial aneurysm clipping surgery, we will be optimizing a model developed by a previous team [2]. This model is shown in Figures 7 and 8 [2]. The main features of the model include a 3D printed skull with one opening representative of a craniotomy and another opening to load the brain. The skull is secured to a tripod stand with three axes of motion. The membranes relevant to this surgery are also modeled. The dura layer is made of an exercise resistance band, the arachnoid is made of saran wrap, with artificial spider webs typically used for Halloween as the arachnoid trabeculae. The brain was molded from a 3D scan of a human brain, and molded using silicon. Water was used to fill the plastic wrap bag to mimic the cerebrospinal fluid, and water with red food coloring was pressurized in long balloons to represent blood flowing through veins and arteries. Both these fluid systems were pressurized using a motor and cam system.

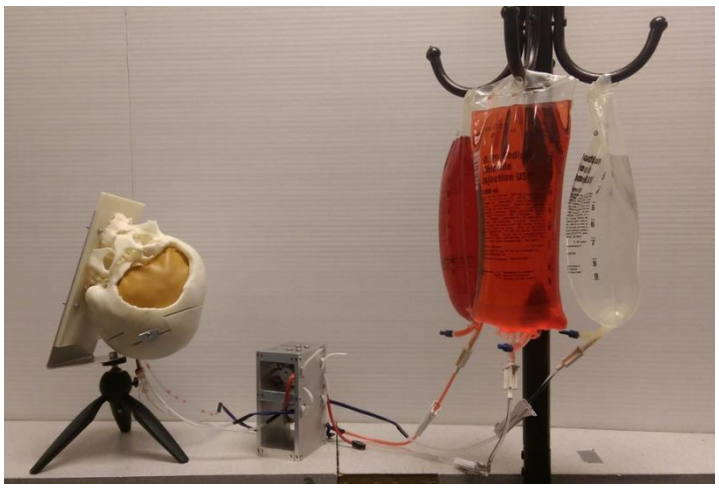


Figure 7. Complete Model [2]

Figure 8. Model Skull [2]

USER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

To create an accurate neurosurgical training simulator for brain aneurysm clipping, our sponsor, Dr. Luis Savastano, supplied us with several qualitative requirements. Since our project is a continuation of a previous team's work, our requirements are a continuation of the previous team's. The previous design is not in a functional state, and the main goal set by Dr. Savastano is to bring the project to a functional level so that it may be tested for validity and accuracy.

From our interview with Dr. Savastano, we determined that the most important issue for us to solve is the sealing of the arachnoid membrane. The arachnoid membrane in the previous model is a single layer that wraps around the brain and is sealed with tape. This sealing technique proved to be inadequate for housing the cerebrospinal fluid (CSF). In addition, the arachnoid is composed of two layers which contain the web-like tissue, the CSF, and the blood vessels. However, the previous model only includes one arachnoid membrane. To determine an appropriate material to use for the arachnoid membrane and method of sealing the arachnoid, we evaluated the material's physical properties, including the necessary stress the seal and material must withstand when the CSF is pressurized to the appropriate value. The quantitative value for this strength is shown in Table 1 on page 10[1].

Another equally important component of our design is to create an anatomically correct fluid system. During surgery, if an artery is cut, the blood will leak out at a frequency related to the patients pulse. Our goal is to develop a system that emulates this pulsating pressure. A change in the artery diameter should be visible to the surgeon, indicative of the patient's heart rate. The CSF located within the arachnoid drips in at a frequency in sync with breathing of the patient, so this will be simulated as well. The values for all of these pressures are reported in Table 1 on page 10 [1].

According to Dr. Savastano, the current brain model is not the correct size or stiffness. The skull from the previous model is the correct size, but the brain is too small and doesn't fit correctly into the skull. To fix this, we will scale the current brain to the correct size such that it will fit appropriately within the skull. The fit is extremely important because the Sylvian fissure, where the target aneurysm is located, is naturally held closed by the pressure of the skull pushing against the brain. When the skull is too small, the Sylvian fissure is naturally open, which is unrealistic and doesn't allow the surgeon to practice opening it to access the aneurysm. The updated brain will be large enough to hold the Sylvian fissure shut, while still fitting within the skull. In addition to being the wrong size, the current model brain is not soft enough. Dr. Savastano requested that the material used should be much softer, as it does not realistically respond to incisions made during surgery. He expects the brain to "leak" out of accidental incisions made on the inner layer of the arachnoid, but the current brain is too hard and does not push through. The quantitative values for these size and material requirements are reported in Table 1 on page 10 [1].

Dr. Savastano also requested that the simulator be simple to set up. Because this will be used to train neurosurgeons, there will likely not be any engineers present to help set up the simulator. For this reason, Dr. Savastano asked that the simulator be simple enough that it could be fully assembled quickly and easily by surgeons. The parameter we chose to use for this requirement is the assembly time, shown in Table 1 [1].

The remaining requirements listed in Table 1 are secondary in importance to the previously mentioned requirements. Dr. Savastano requested us to complete the first two requirements to the best of our ability, and if we have time, to address the remaining requirements. These specifications pertain to the material selection for both the dura mater and the arachnoid mater. The current materials for these membranes are good, but they could be improved. It is our goal to try to find materials that better resemble the materials of the actual membranes. The values for these material properties are shown in Table 1 [2].

Table 1. Engineering specifications for the simulator with corresponding priorities (1=high, 4=low)

Requirement	Priority	Specification				Rationale
Anatomically correct fluids	1	Change in Arterial Diameter:	1.00 ±	0.50	mm	Simulate surgical fluid environment
		Cerebrospinal Fluid Frequency:	3±2 drops every 6.0±1.0 sec			
Ease of assembly	2	Assembly time:	5.00 ±	2.00	min	Allow for quick and easy preparation of the simulator
Anatomically correct brain	3	Elastic Modulus:	1,000.00 ±	300.00	kPa	Simulate surgical environment including the appropriate physical properties of a living patient
		Density:	1,050.00 ±	150.00	kg/m^3	
		Length:	167.00 ±	20.00	mm	
		Width:	140.00 ±	20.00	mm	
		Height:	93.00 ±	10.00	mm	
		Volume:	1,042.00 ±	120.00	cm^3	
Sealing of the arachnoid mater	3	Yield Strength:	18.00 ±	2.00	kPa	Insure against rupture due to CSF pressure
Anatomically correct dura mater	4	Elastic Modulus:	31.00 ±	2.00	MPa	Appropriate material responses when dura incisions are made
		Density:	1,100.00 ±	150.00	kg/m^3	
		Thickness:	1.50 ±	5.00	mm	
Anatomically correct arachnoid mater	4	Elastic Modulus:	1.20 ±	0.20	MPa	Appropriate material responses when arachnoid incisions are made
		Density:	1,350.00 ±	150.00	kg/m^3	
		Thickness:	150.00 ±	50.00	μm	

CONCEPT GENERATION

Before generating a large number of concepts for the simulator design, we created a functional decomposition for our simulator, shown below in Figure 12 on Page 11. This helped us understand the basic functions that each component needed to accomplish.

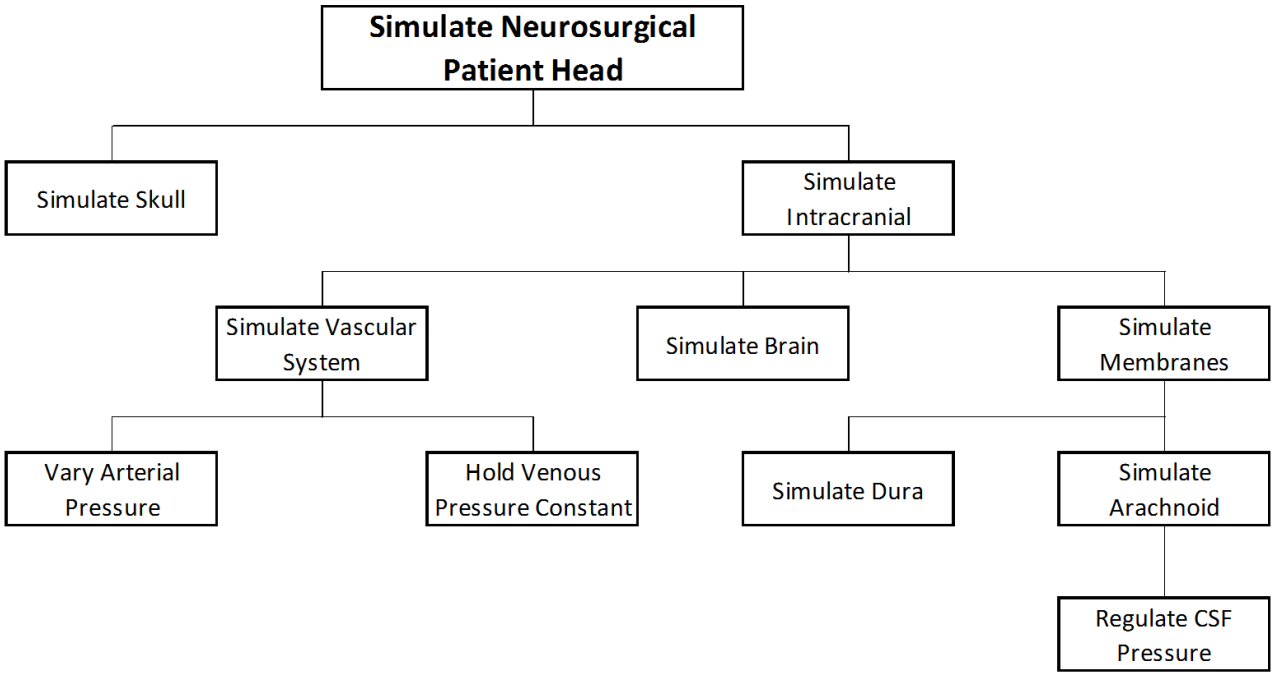


Figure 12. Functional Decomposition

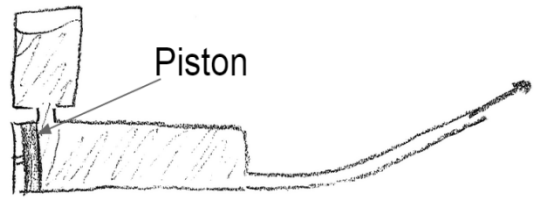
After creating a functional decomposition of our model, we determined the categories that needed optimization to structure our concept generation method. One aspect of our design is the 3D printed skull, for which we defined the two categories of securing the skull cap and securing the brain. Securing the cap involves designing the attachment method that will secure the skull cap onto the base of the skull. The second category, securing the brain, is part of our skull design in that we need to create a mechanism to compress and secure the brain once it is placed in the skull. With regards to the brain membranes, we defined two categories: sealing and tube management. Sealing includes methods and materials used in the creation of the membranes, and tube management involves the design of an interface between vessels on the inside of the membrane and the pressure system outside, without leaking any fluid. Our last category is the pressure system, which should replicate the pulsing of the blood vessels in our model.

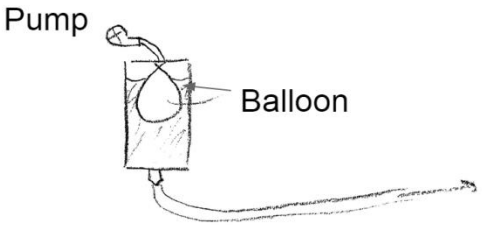
After defining the categories for which we needed to generate concepts, we individually brainstormed designs for each category. We came together as a group to present our ideas after coming up with a list and sketches of our various brainstormed designs. When we met, we were able to bounce new ideas off of each other and come up with even more potential design solutions for each category. The resulting concepts are presented in Table 2 on Page 12.

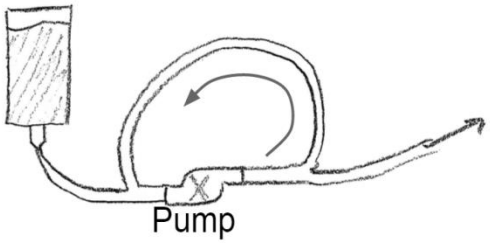
Table 2. Concept Generation

CATEGORY	GENERATED CONCEPTS						
Securing Cap	Hinge + Latch	Hinge + Bolt	Hinge + Pin	Hinge + Elastic	Hinge + Velcro	All Velcro	All Bolt
Securing Brain	Rigid Arm	Inflatable Pad	Fill				
Pressure System	Current Model	Sensor Control	Reservoir + Valve	Piston + Reservoir	Temp.	Balloon	Pump + Artery
Sealing	Heat Seal	No Seal	Fold Edges	Bag	Spray Adhesive	"Press n Seal"	Pinch Hinge
Tube	Foam	Snap	Grommet	Clip	Poke Tube		

For each of our categories we came up with a broad variety of concepts, making sure not to discredit seemingly illogical ideas at first thought. These concepts varied greatly, with one idea using a piston chamber, another using temperature change, another inflating a balloon in a reservoir, and a fourth using a pump. The piston system, shown in Figure 13, will connect a piston to the artery so that when the piston is compressed, the volume in the artery rises, and the pressure will drop when the piston is retracted. The idea behind the temperature change concept is to have a temperature controlled reservoir. When the temperature of the reservoir is increased, the specific volume of the fluid increases, resulting in a volume increase in the artery. Inflating a balloon in the reservoir, shown in Figure 14, will have a similar effect; when the balloon inflates fluid must flow into the artery, increasing the volume. The balloon can then be deflated, causing the desired volume fluctuations. Another concept we had was a pump system, shown in Figure 15, which would use a pump to change the pressure in a feedback tube with the arterial system stemming from it. For more documentation of our concepts, reference Appendix A.







CONCEPT SELECTION

Once we generated concepts for each of our five functions, we used Pugh charts, one per function, to score the ideas. For each function, we determined a list of criteria we thought important when considering different design options, and proceeded to assign weights to each criteria. The weights assigned for the various criteria in each Pugh chart had to add up to 1. We set this restriction so that we were forced to evaluate the trade-off between different criteria and how much of a priority they were, as giving one criterion a larger weight meant that the others had to be a smaller one. This proved to be beneficial because, after all of the criteria and weights for each Pugh chart were discussed and generated, our team had a good understanding of our areas of focus for each function in the simulator.

Next, we organized our generated concepts into the appropriate Pugh charts and scored each concepts with respect to each specific criterion using a three-point scale. When deciding on what datum to use in concept scoring, we had several viable options. We considered a base scale, in which the previous model would be scored as 0 and each generated concept would score a positive value (1 or 2) if it provided an improvement on the old model, and a negative value (-1 or -2) if it was not as effective. Another option was a 1 to 10 scale, which we liked because it allowed for a lot of variability and small degrees of differentiation between concepts for each criteria. However, we soon realized that we did not have enough real knowledge of how each concept would actually perform to assign a concept a 6 instead of a 7, for example. To avoid this issue, our team decided to use a three point scale, in which a score of 1 meant that the concept did not adequately meet the respective criteria, a score of 2 meant that the concept did meet the criteria but that our team was unsure about whether or not the concept would practically work, and a score of 3 meant that the concept fully met the criteria and that our team believed it would address the criteria well. To assign scores to each concept, we first scored all concepts individually and then came together as a team to discuss scoring and assign final values.

Securing the Skull Cap

To evaluate the validity of our concepts for securing the skull cap, a set of criteria were created and assigned weights in order of importance, as seen in Table 3 on page 14. First, the ease of use of the skull cap was given high priority because the surgeon must be able to load the simulation easily and effectively. Next, the cap must be durable and robust to ensure that repeated uses of the simulator yield consistent, accurate results. And lastly, the manufacturability and cost were set to have the lowest weight because we would like for it to be easy to manufacture to reduce possible manufacturing errors, and reduce any costs that may unnecessarily raise the price of the simulator.

Table 3: The Pugh chart for securing the skull cap

Criteria	Weight	A	B	C	D	E	F	G
Ease of Use	0.4	3	2	2	3	3	2	1
Durability	0.2	2	2	1	2	1	1	3
Robustness	0.2	1	1	1	2	2	2	1
Manufactuability	0.1	1	3	3	3	2	3	3
Cost	0.1	3	3	3	3	3	3	3
TOTAL	1	2.2	2.0	1.8	2.6	2.3	2.0	1.8

A. Hinge + Latch
B. Hinge + Bolt
C. Hinge + Pin
D. Hinge + Elastic
E. Hinge + Velcro
F. All Velcro
G. All Bolt

All of the concepts that incorporated the hinge were very easy for the user to operate compared to the concepts that did not use a hinge. However, the hinge is potentially difficult to manufacture, and may break, so the concepts that do not utilize the hinge may last longer. In the end we chose the hinge with an elastic band, (D), because it was the simplest concept that utilized the hinge. This concept is very intuitive for the surgeon to set up, and it makes it very easy to assemble the simulator, an important user requirement.

Securing the Brain

To evaluate the validity of our concepts for securing the brain, a set of criteria were created and assigned weights in order of importance as seen in Table 4 on page 15. First, the effectiveness of the securing mechanism was given high priority because the brain must be pressurized against the craniotomy as it would be in a living patient. Next, robustness was considered to ensure that a slight error in placing the brain will not negatively affect the simulation. And lastly, the manufacturability and number of parts were set to have the lowest weight because we would like for it to be easy to manufacture to reduce possible manufacturing errors, and have minimal parts to allow this portion of our project to be as simple as possible.

Table 4: The Pugh chart for securing the brain

Criteria	**Weight**	**A**	**B**	**C**
Effectiveness	0.5	3	2	2
Robustness	0.3	2	3	1
Number of Parts	0.1	2	2	3
Manufacturability	0.1	1	2	2
TOTAL	1	2.4	2.3	1.8

A. Rigid Arm + Foam
B. Inflatable Pad
C. Print Fill

We believe that the three concepts were fairly effective, with the rigid arm and foam being the most effective as it could be crafted to perfectly compress the brain. In terms of robustness however, the inflatable pad would work regardless of any minor errors in the placement of the brain, even though it requires extra work during setup, while the other two concepts may not work as well when the brain is incorrectly inserted. The print fill consists of no extra parts, so the simplicity was desirable, but this concept was not quite as effective. We decided on the concept with the rigid arm and foam, (A), because it will consistently compress the brain, while requiring no extra work during setup. This ease of setup was an important user requirement.

Arterial Pressure System

To evaluate the validity of our concepts for the arterial pressure system, a set of criteria were created and assigned weights in order of importance, as seen in Table 5. First, the visible pulsation was given high priority because the surgeon must see the arteries moving during the surgery, so that they are representative of a real surgery. Next, the pressure system must be easy to set up as a surgeon will be performing setup, and they may not understand complex mechanical systems. And lastly, the manufacturability, response to cut, and durability were set to have the lowest weight because we would like for it to be easy to manufacture to reduce possible manufacturing errors, make sure it is fairly realistic when an artery is cut, and durable enough to allow this pressure system to be used extensively.

Table 5: The Pugh chart for the arterial pressure system

Criteria	**Weight**	**A**	**B**	**C**	**D**	**E**	**F**	**G**
Visible Pulsation	0.4	1	2	3	3	1	1	2
Ease of set up	0.3	2	1	1	2	1	2	1
Response to Cut	0.1	1	2	3	3	1	1	2
Durability	0.1	1	2	1	2	1	1	2
Manufacturability	0.1	2	1	3	2	2	3	1
TOTAL	1	1.4	1.6	2.2	2.5	1.1	1.5	1.6

A. Current Model
B. Sensor Control
C. Reservoir + Valve
D. Piston + Reservoir
E. Temp.
F. Balloon Pump + Artery

All of the concepts that utilized a pump or motor outside of the reservoir are much easier to manufacture and understand. However, some of the designs, like the current model, the sensor control, the temperature, and the balloon are difficult to understand how they exactly work, while also being difficult to set up. Because of this, we decided on the concept with the piston and the reservoir, (D). This concept is simple to understand and setup should respond correctly to the cut artery, and will be very user friendly in the final product. The simplicity, along with the effective response to the cut artery, satisfy user requirements, making this a very favorable concept.

Membrane Sealing

To evaluate the validity of our concepts for membrane sealing, a set of criteria were created and assigned weights in order of importance, as seen in Table 6. First, the ease of sealing the actual membrane was given high priority because the surgeon must be able to seal the membrane without much trouble. Equally important is that the membrane seal does not leak during the simulation. A live patient would not have leaking membranes, so to be realistic, our simulator cannot leak. The other two criteria are not as important because they are only how the material of the seal feels, and how it looks compared to their anatomic counterparts. If possible, the material should look and feel like the actual membrane, but it is not the highest importance.

Table 6: The Pugh chart for membrane sealing

Criteria	Weight	A	B	C	D	E	F	G
User Ease of sealing	0.4	1	1	2	2	2	3	1
Leak Prevention	0.4	2	1	1	1	2	3	1
Material Realism	0.1	3	2	3	2	3	2	1
Aesthetics	0.1	3	3	2	2	2	2	1
TOTAL	1	1.8	1.3	1.7	1.6	2.1	2.8	1

A. Heat Seal
B. No Seal
C. Fold Edges
D. Bag
E. Spray Adhesive
F. "Press n Seal"
G. Pinch Hinge

All of the concepts either successfully prevented leaking, or allowed leaking. The concepts that leaked were obviously not considered for the final design, and out of the remaining concepts, the “press n seal” was the easiest to seal. The fact that this concept is simple to seal, while also holding water made it our selected concept. It satisfied the user requirement of ease of assembly, along with the membrane being successfully sealed, so it works well as a final design.

Sealing Tube Management

To evaluate the validity of our concepts for sealing tube management, a set of criteria were created and assigned weights in order of importance as seen in Table 7. First, the ease of use of sealing tube management was given high priority because the surgeon must be able to load the tubes into the membrane and easily seal them in. Next, the concept must effective seal the membrane around the tubes to ensure there is no leaking at this interface. And lastly, the tube interference, manufacturability, and durability were set to have the lowest weight because we would like for this concept to not block or compress the tubes in anyway during the sealing. We would like it to be easy to manufacture to reduce possible manufacturing errors, while also being durable enough to use over several simulations and the part does not need to be replaced.

Table 7: The Pugh chart for sealing tube management

Criteria	Weight	A	B	C	D	E
Ease of Use	0.4	1	1	1	2	1
Effectiveness	0.3	2	3	2	3	1
Tube Interference	0.1	3	2	2	2	3
Manufacturability	0.1	2	2	2	2	3
Durability	0.1	1	2	2	2	1
TOTAL	1	1.6	1.9	1.6	2.3	1.4

A. Foam
B. Snap
C. Grommet
D. Clip
E. Poke Tube

All of the concepts seemed to be fairly effective, but they were not all easy to use. Many concepts required precise manipulation of the tubes to create this interface, which may be difficult for the surgeon to perform. Because of this, we decided to use the concept that was the easiest to utilize. This concept was the clip, (D). The clip is simple to use, and effectively seals the membranes while allowing the tubes to enter. This satisfies the user requirements pertaining to membrane sealing, as well as ease of setup, making it a great concept for this functional group.

Overview of Final Design

We selected each of our final concepts for the sub-functions, and combined them together into our complete chosen design. Starting in the top left of Figure 16 on page 18, there is the cap mounted to the skull base using a hinge. Attached to the skull cap is an arm with a foam pad mounted to it, which articulates closed to secure the brain in place. Within the skull is the brain sealed inside the "Press 'n Seal" membrane, with the clip for tube management at the membrane - tube interface. The end of the tube inside the skull connects to the artery, and the other end connects to the piston. By controlling the bore and stroke length of the piston, we will control the visible pulsations of the artery. There is also a reservoir connected to the piston, so that if the artery is cut fluid will continue to leak until it is repaired by the surgeon.

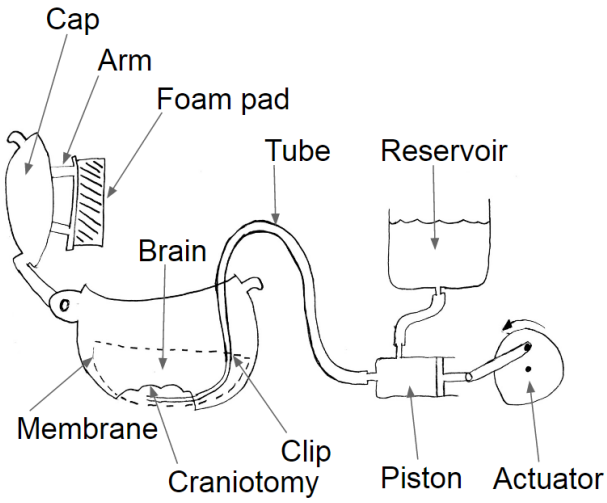


Figure 16: Complete chosen design

KEY DESIGN DRIVERS AND CHALLENGES

Since DR2, we have refined a few of our design drivers. We are focusing on six design drivers, which correlate to one per design area needing to be optimized from the previous model. Our design drivers include needing to produce visually realistic vascular pulsing, meaning that the blood vessels need to visibly contract and expand. With regards to the skull, our design drivers are that there needs to be a way to extract and replace the brain between simulations, and that it has to accommodate for a realistic positioning of the brain in the skull. Another driver is that the brain has to consist of a material that is tactually realistic, so that our simulator is more realistic to the real human head. The last two drivers are that the membranes have to prevent any sort of leaking, and that the interface between the membranes and the tubing has to be impermeable.

As we progress through the stages of our project, we face a few key challenges. We continue to struggle with finding a balance between realism and simplicity in the design of our simulator. Additionally, we expect the transition from chosen designs and CAD modelling to initial manufacturing of the different components of our simulator to be very challenging. When creating and evaluating our computer models, our team has tried to objectively critique each design with respect to potential manufacturing and functionality issues, especially using FMEA. Although we have tried to predict and correct any potential issues, we expect to encounter problems when moving from computer simulated to physical products.

Along these lines, we expect to encounter challenges when comparing the results of our theoretical and empirical analysis to evaluations of our manufactured system. For example, we expect the membrane system not to leak when containing water because of our empirical tests of the material and sealing method, which consisted of sealing a water pouch in the membrane material and seeing if it leaked

anywhere along the seal. Although the membrane material in our simulator will not have to seal fluid at a higher pressure than what was tested in our experiment, the positioning and shape of the water pouch in our simulator is different from that used in our experiment. These differences could affect the membrane sealing and possibly result in leaking, even though our experiment shows that it shouldn't.

Lastly, the iterative nature of the process of designing our simulator has presented and will likely continue to present some challenges. In creating CAD models of our chosen design concept, we found several opportunities for improvement on our chosen design. Discussing these potential changes and moving forward with them took time that we hadn't planned for, which made adhering to our project plan and internal deadlines difficult, as we wanted to continue to optimize our design but also adhere to our demanding timeline. We expect to spend time continuously improving our designs, computer models, and manufactured components in the future, which presents a challenge we will have to prepare for when faced with balancing project improvement with project deadlines.

DESIGN MOCKUP

To give us an idea of what our design would look like in total, we created physical mockups for each of our five chosen concepts. We created a box to represent the skull, and added a hinge and extrusions for a rubber-band to hold the box shut, as seen below in Figure 17. We also added an arm with a platform to the inside of the cap portion to represent the mechanism we plan to use to secure the brain, as can be seen in Figure 18 on page 22. While creating our mockup of the skull, we gained insight in creating the arm and hinge so that the arm is large enough to be able to push a brain against the side, while still allowing the top to be opened without the arm hitting the wall.

Figure 17: Skull cap utilizes hinge to cap allow interior accessibility

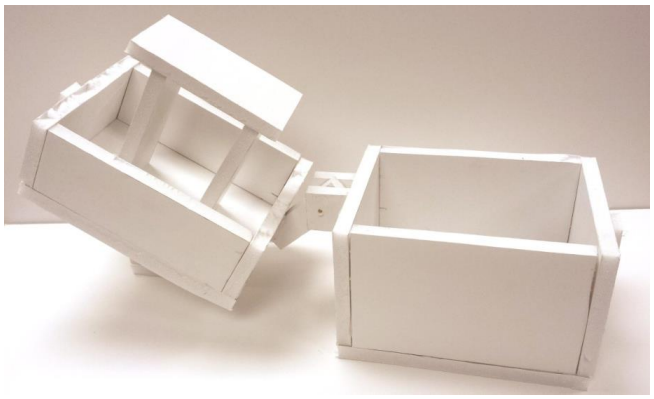


Figure 18: A foam pad mounted to the inside of the skull holds brain in place when closed.

To simulate our concept for the interface between the inside and outside of the membrane, we created a clip with three holes in it for the tubes, as can be seen below in Figure 19.

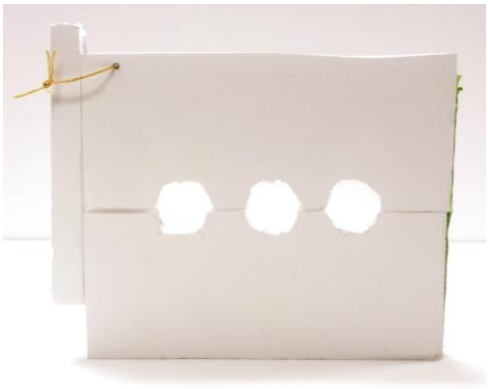


Figure 19: Three hole clamp design allows tubes through while preventing leakage.

Figure 21: “Press n Seal” Pouch.

For our chosen sealing concept, we created a pouch of water out of “press n seal”, as can be seen below in Figure 21.

The mockup for our chosen pressure concept can be seen below in Figure 20. It consists of two parts, the piston chamber, and the piston itself attached to a rotating cam. There is also a dowel coming out of the top of the piston chamber, representing where the reservoir would connect. While creating this mock up, we realized that we would need another linkage in our piston mechanism to keep the piston going in a horizontal motion.

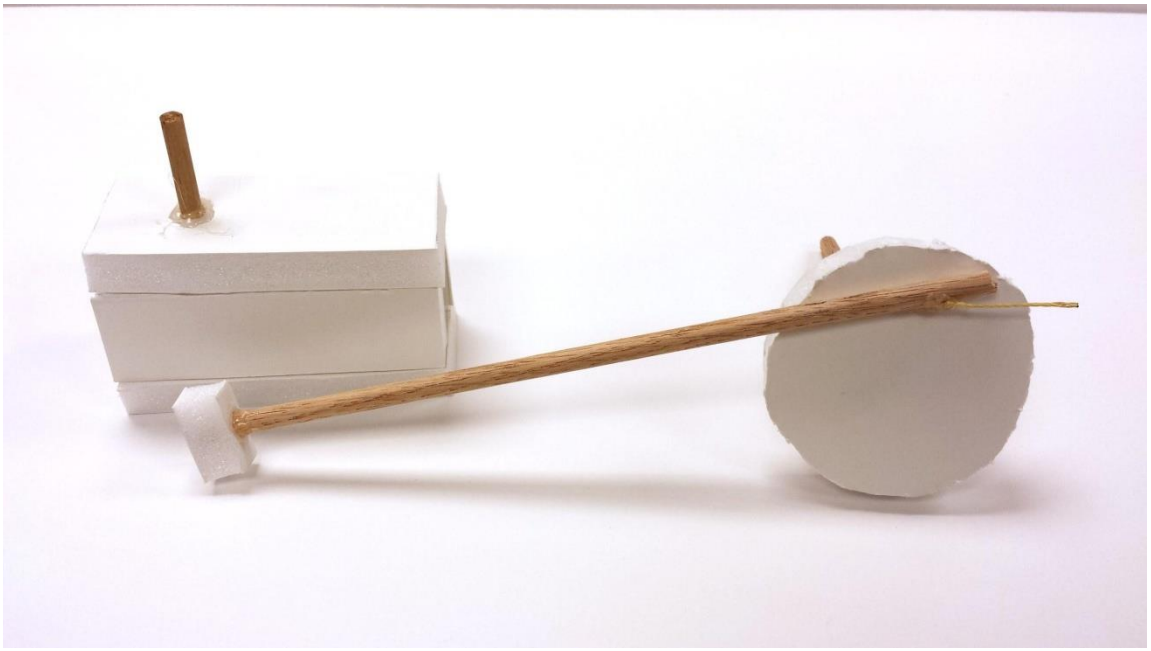


Figure 20: Mockup of the pressure system

After the initial mockup was created, it was refined in order to better reflect our chosen design. The overall mockup is shown in Figure 22. The updated mockup components are the syringe, which was originally our piston and cylinder, tubing connecting the motor and syringe to the skull, and a reservoir connecting to the tubing.

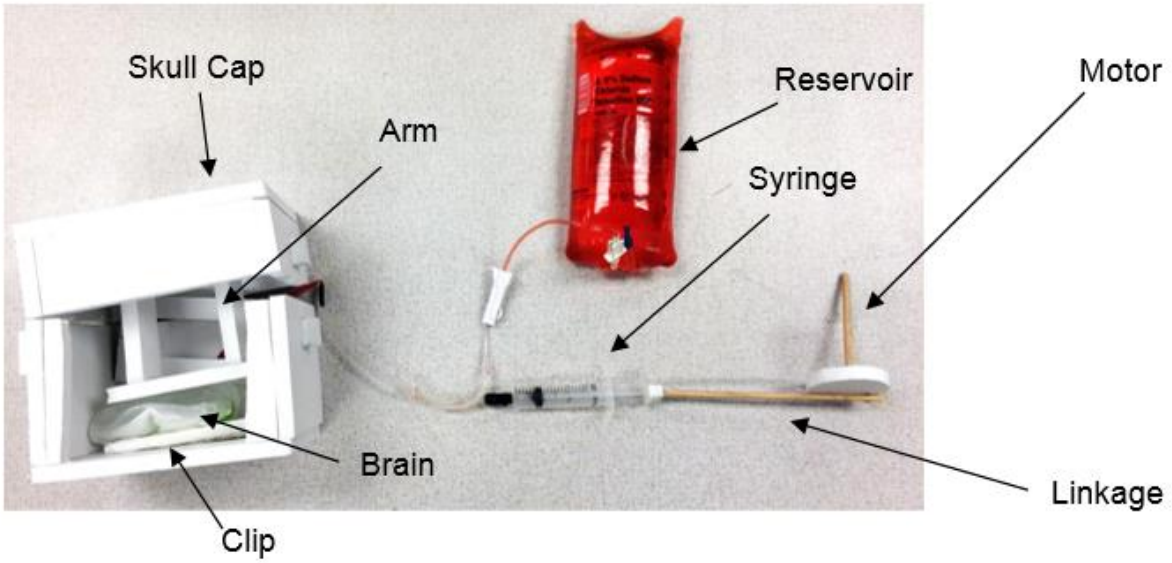


Figure 22. Overall Refined Mockup

We updated the "tube management" clip mockup, shown in Figure 23. This reflects the design change we made to this part, which was to remove the circular extrusions for the tubes and replaced them with a gap to accommodate pieces of rubber foam.

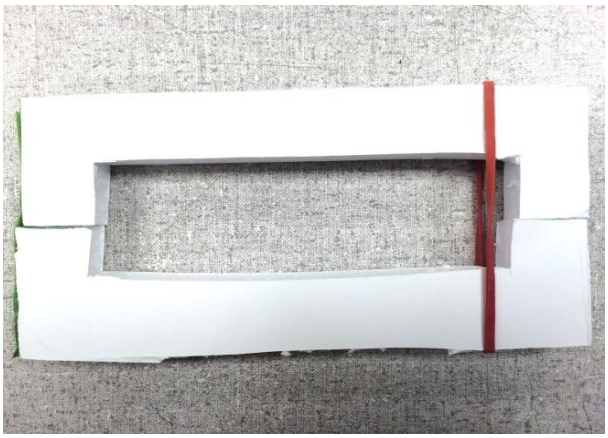


Figure 23. Updated Tube Management Clip

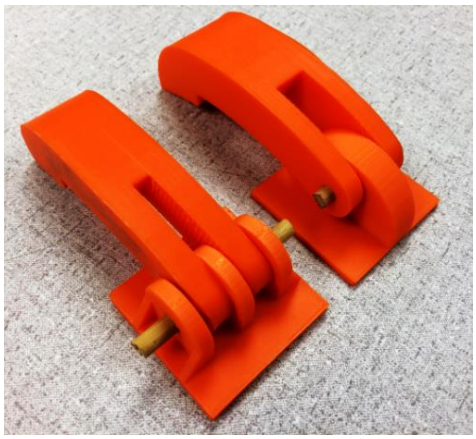


Figure 24. Two 3D Printed Hinge Designs

In an effort to determine which hinge design is best for use in our simulator, we 3D printed two of our hinge designs. One design we printed has three "knuckles", shown in Figure 24 on the left, while the other has one, shown in Figure 24 on the right. Creating these models helped us to better visualize how the hinge would function as an integrated component of our design.

DESIGN DESCRIPTION

Membrane Sealing

For membrane sealing we chose to use our "press n seal" design, shown in Figure 26. To create the simulated arachnoid membrane, one layer of press n seal will be placed on top of the brain with the sticky side facing out. This first layer will run along the brain into the Sylvian fissure, the fold in the brain where the aneurysm is located. We will then add our webbing and blood vessels into the fissure, and then wrap a second layer of press n seal around the brain with the sticky side facing down. This layer does not fold into the fissure, but rather provides tension around the brain so that the fissure remains closed until it is forced open by the surgeon. The seal is created from the sticky side of the top layer of material adhering to the sticky side of the bottom layer of material.

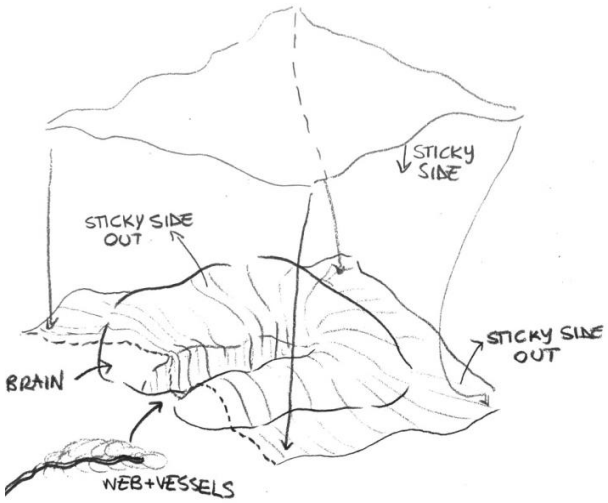


Figure 26: "Press n Seal" design

Tube Management

For tube management, the design we chose to move forward with is a clip with room to accommodate two foam pieces. This component serves the purpose of organizing the tubes entering the skull. The surgeon using the simulator will not interact with this component. The clip was designed in Solidworks with a hinge on one end. The foam pieces are placed on the top and bottom arms of the clip. The tubes are placed on the foam of one arm, and the clip is closed, securing the two arms together. When the clip is shut, the foam is compressed around the tubes, creating a watertight seal. The foam pads pressed against each other also creates a watertight seal to keep the CSF inside of the membrane. To secure the clip when it is closed, we chose to use an elastic band. The Solidworks model of our tube management clip can be seen below in Figure 27.

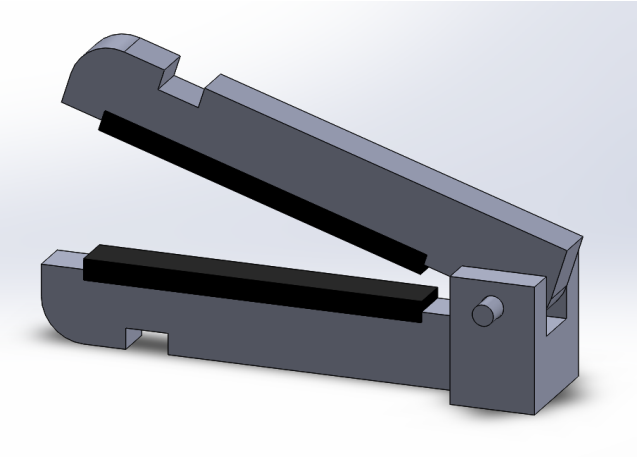


Figure 27: Tube Management Clip design

Cap Securement

To secure the cap onto the skull, we used a three knuckle hinge that will be rigidly attached to the skull and 3D printed as one piece. This hinge was designed in Solidworks and imported into Mimics, then placed onto the skull in the appropriate position, interfering with the skull. Then, the combination of the hinge and the skull will be merged into a single mesh so that it can be 3D printed as one solid piece. This process will be repeated for the part of the hinge that is attached to the cap. A brass rod will be used as the hinge pin. A picture of the hinge in Mimics is shown in Figure 28.

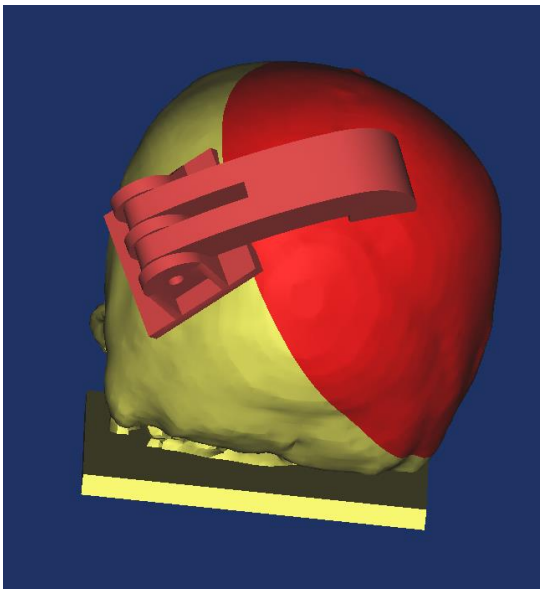


Figure 28: Hinge for cap securement

Brain Securement

For brain securement, we decided to use the arm with a layer of foam at the end of it. We created the arm in Solidworks, and then imported it into Mimics to see how it looked when placed inside of the skull. We will attach a foam pad to the arm so that when the cap is closed the arm and foam pad press against the brain securing it against the skull. An image of the arm placed on the skull cap in Mimics can be seen below in Figure 29.

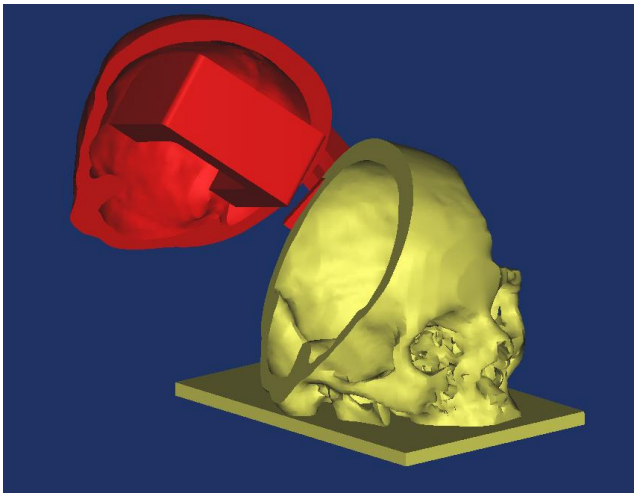


Figure 29: Arm inside of the skull cap

Brain Material

We chose to move forward with a silicone mix (Ecoflex 010) containing 40% mineral oil. It is important for the material we use to create our model brain out of to have the same feel as a real brain does, as we are trying to create a simulator that accurately represents the physical environment surgeons would find in a real patient.

Pressure System

The pressure system is an electro-mechanical system, and we must design it such that the mechanical portion is well streamlined with the electrical portion. At its most basic, the mechanical system consists of a motor connected to the plunger of a syringe via a linkage assembly as seen in Figure 25. The linkage will consist of two arms; the drive arm is rigidly attached to the driveshaft and the free arm connects the drive arm to the plunger. As the drive shaft rotates, the linkage will turn the rotational motion into linear motion and cause the plunger to move inside the syringe, displacing a set amount of fluid with each rotation. The tip of the syringe is connected to a network of tubes, which ultimately lead to a reservoir and the artery. The main tube connects the syringe to the artery, and the secondary tube connects to the main tube with a T valve. There is a one way valve in the secondary tube which allows water from the reservoir to flow into the main tube, but not in the reverse direction. This reservoir and valve system allows the design to meet our engineering specification that if the artery is cut, it needs to continually leak fluid. Driving the mechanical system will be the electrical circuit. The basic concept of our pressure system can be seen in Figure 25.

In order to meet our engineering requirement that the system must pulse at the same rate as a human heart rate, it is necessary that we have a control system. We have decided to go with a very simple control system, consisting of a power supply, a 3 way switch, a high resistance resistor and a low resistance resistor. The power loop will consist of the motor, power supply, and switch, and the switch will control whether the loop is open, connected to the small resistor, or connected to the large resistor. Both the motor and the resistor act as resistors, so what we have is a simple voltage divider. When the switch completes the loop with the small resistor, most of the voltage will flow to the motor, causing it to run at the high speed. When the switch completes the loop with the large resistor, only a little voltage will flow to the motor, causing it to run at a low speed. The high speed setting will be tuned to run at 65 Hz, similar to the human heartbeat rate, and the low speed setting will be used to prime the system.

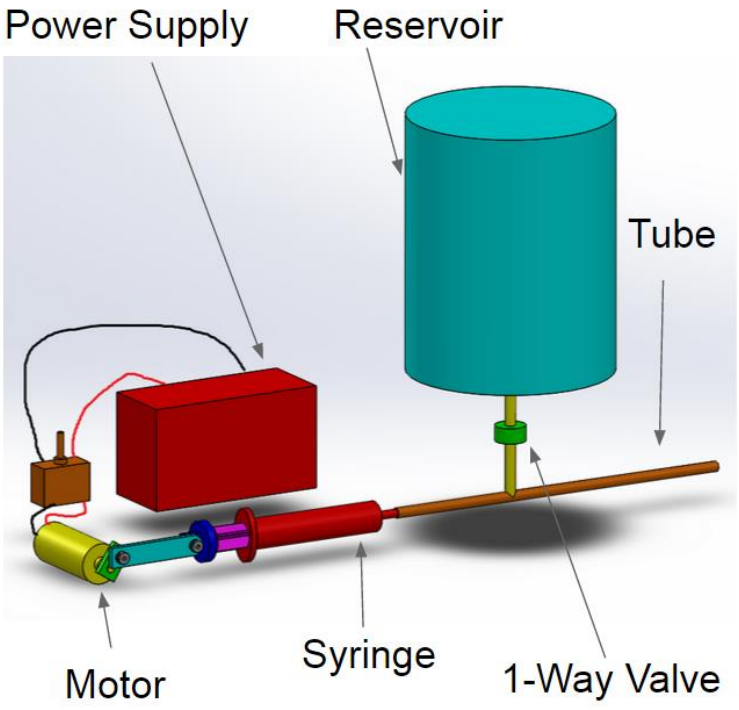


Figure 25: Basic pressure system concept

Design updates since the initial concept was determined revolved around the components of the pressure system. The final pressure system is shown in Figure 37. For ease of use and presentation, the pressure system components will be contained in a box, as shown in Figure 38.

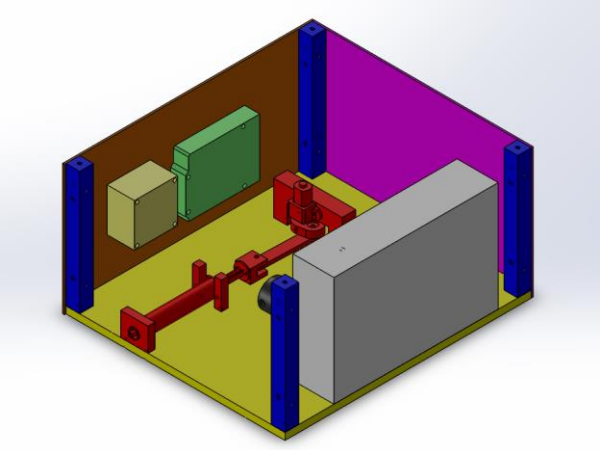


Figure 37: Final Pressure System Design

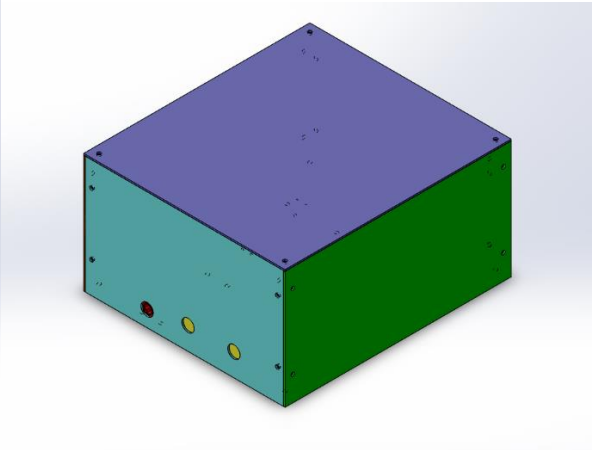


Figure 38: Final Pressure System Box

An exploded view of the overall pressure system with individually labeled components is shown in Figure 39, with the label legend presented in Table 12.

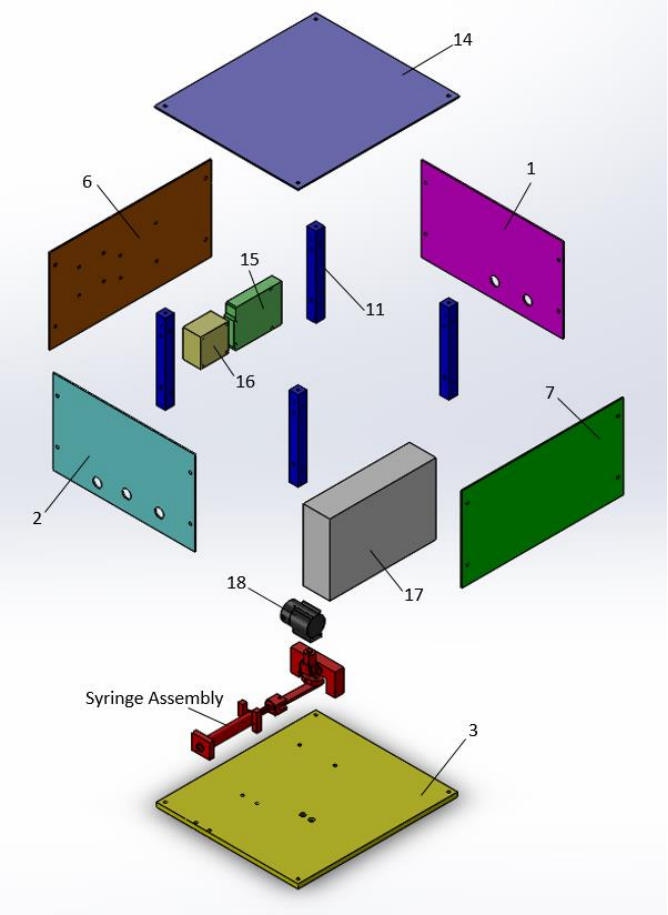


Figure 39: Exploded View, Pressure System

Part #	Description	QTY
1	2 Hole Back Wall	1
2	3 Hole Short Wall	1
3	Base Plate	1
4	Driven Linkage	1
5	Free Linkage	1
6	Long Wall with Arduino	1
7	Long Wall	1
8	Motor Bracket Bracket	1
9	Motor Vertical Support	2
10	Round Part Motor Mount	1
11	Support Beam	4
12	Syringe	1
13	Syringe Linkage Adapter	1
14	Top Plate	1
15	Arduino	1
16	H-Bridge	1
17	Power Supply	1
18	Solenoid Pinch Valve	1
19	Motor Mount	1
20	Motor	1

Table 12: Component Label Numbers

The syringe sub assembly shown in Figure 39 is presented as an exploded view in Figure 40, using the same numbering system as presented in Table 12.

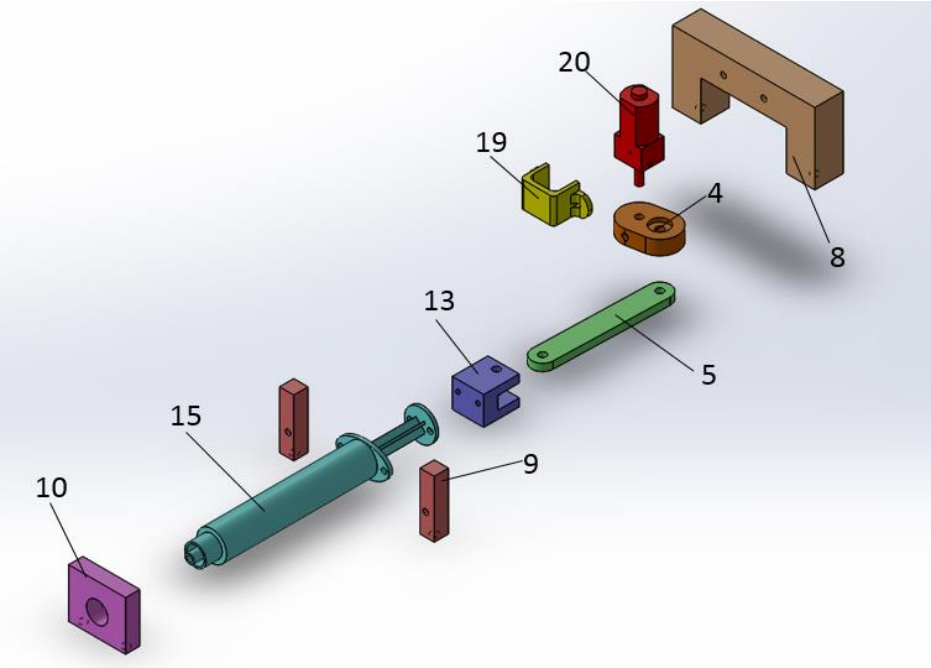


Figure 40: Explode View, Syringe Assembly

For detailed engineering drawings of all manufactured parts, see Appendix D. For the manufacturing plans of these parts, see Appendix E.

ENGINEERING ANALYSIS

We performed analysis, either theoretical or empirical, on the aspects of our product design that addressed each design driver. The purpose of conducting this analysis is to objectively determine whether or not our chosen designs will be functional and effective.

Fluid Volume

The key requirements for the pressure system are to create visible pulsations of the blood vessels in the brain, and to continue to do so even if the surgeon accidentally cuts the vessel.

To test the first requirement, we first performed calculations on the amount of volume needed to fill the balloon representing the blood vessel as well as the amount of additional volume needed to see visible pulsations. In performing this analysis, we made a few key assumptions, including considering water an incompressible fluid, there is no pressure change in the fluid due to height variations, the syringe walls are rigid, and that the balloon material is elastic and expands uniformly. We measured the diameter and length of the balloon filled with water at atmospheric pressure, and calculated the volume using Equation 1. We then calculated the volume that would result from different diameters, using Equation 2. The change in volume and change in diameter were calculated using Equation 3 and Equation 4.

$$V_0 = \pi D_0^2 L/4 \quad \text{(Eq. 1)}$$
$$V = \pi D^2 L/4 \quad \text{(Eq. 2)}$$
$$\Delta V = V - V_0 \quad \text{(Eq. 3)}$$
$$\Delta D = D - D_0 \quad \text{(Eq.4)}$$

where V is volume (mm^3), D is the diameter (mm), and L is length (295 ± 10 mm), D_0 is the original diameter, and V_0 is the original volume. These dimensions are shown in Figure 30.

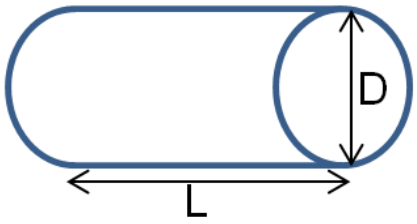


Figure 30. Cylindrical Blood Vessel Approximation

We then calculated the additional volume of fluid we would need to inject into the tube to obtain a specified change in diameter in Table 8.

Table 8: Calculated volume change for various diameter changes

Desired Diameter Change (mm)	0.50	1.00	1.50	2.00	2.50
Calculated Volume Change (mL)	0.99	2.10	3.32	4.66	6.11

As reported in Table 8, our calculations show that we would need to add 2.10 mL of water to obtain a 1.00 mm change in balloon diameter, which meets our engineering specification for visible pulsation.

To assess the validity of our calculations, we tested them in lab. We used a balloon like the one we will be using for our simulator and filled it with water, measuring the volume to be 3.1 ± 0.3 mL. We then filled a syringe with water and attached it to the balloon, making sure not to trap any air during this process. We injected different volumes of water into the balloon and observed the diameter change. These values are reported in Table 9.

Table 9. Observed diameter change for various volume changes

Desired Diameter Change (mm)	0.50	1.00	1.50	2.00	2.50
Calculated Volume Change (mL)	0.43	0.66	0.75	0.89	0.99

The results of the theoretical and experimental analyses we conducted and reported in Table 8 and Table 9 are illustrated in Figure 31 on page 30. As shown in Figure 31, the experimental and theoretical values do not correlate exactly, mainly due to assumptions that were made during the theoretical portion of the

analysis. However, the small discrepancies in diameter change are not significant enough to be of concern for the purpose of our system, which is to create visible diameter changes for the surgeon.

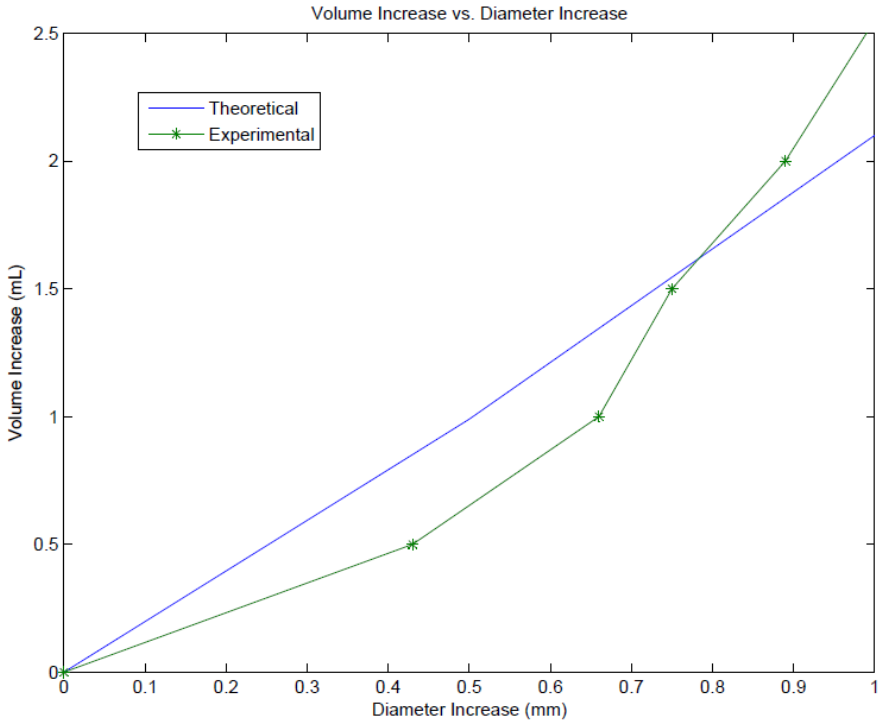


Figure 31. Volume Increase vs. Diameter Increase, Theoretical and Empirical

To help in determining what size motor to use, we measured the forces needed to compress the syringe. We used a set-up similar to that for determining the volume fluctuations, with the balloon we will be using in our design connected to the syringe. The syringe was held vertically so that the plunger was in contact with a metric scale and it was compressed to set volume displacements. We recorded the readings in Table 10 and multiplied them by gravity to get the force.

Table 10: Force required to compress the syringe as a function of volume displaced.

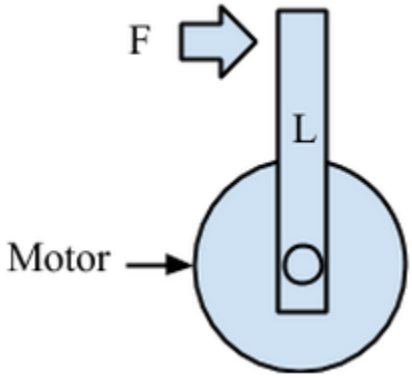
Volume Displaced	Force on 5 mL Syringe (N)	Force on 12 mL Syringe (N)
0.5 mL	2.98 ± 0.76	4.77 ± 0.18
1.0 mL	4.63 ± 0.10	6.73 ± 0.53
1.5 mL	5.81 ± 0.29	7.74 ± 0.21
2.0 mL	6.01 ± 0.36	8.45 ± 0.78

With these forces, we will be able to determine the torque necessary for our motor and choose an adequately sized motor.

Motor Analysis

To determine what size motor to use, we first measured the force necessary to depress the plunger of the syringe 1 mL. We chose 1 mL because this creates the visible change in diameter of the artery that our sponsor requested. At 1 mL, it required 4.63 +- .10 N. However, this only measures the static force required to hold the plunger depressed, and doesn't account for the force required to overcome

friction as the plunger is sliding. To account for this, we assumed the force of friction to be similar to the static force and used twice the static force, 9.62 N, in our calculations. We modeled the linkage attached to the motor drive shaft as a lever arm and multiplied it by the force to determine the torque, as shown in Eq. 5 and Figure 32,



$$T = F*L \qquad \text{Eq. 5}$$

Figure 32: Motor analysis model

where *T* is the torque, *F* is the force, and *L* is the length. With F = 9.62 N and L = 4.5mm, the required torque is 41.67 N-mm, or 5.9 oz-in. To insure the robustness of our design, we used a safety factor of 2. Therefore, we must find a motor that can supply at least 11.8 oz-in of torque at 65 RPM, where 65 RPM is the speed given to us by our sponsor as the average resting heart rate.

We analyzed a selection of micro gearmotors from Pololu using a torque-speed curve to determine which was the right fit for our project. One such calculation is shown in Figure 33.

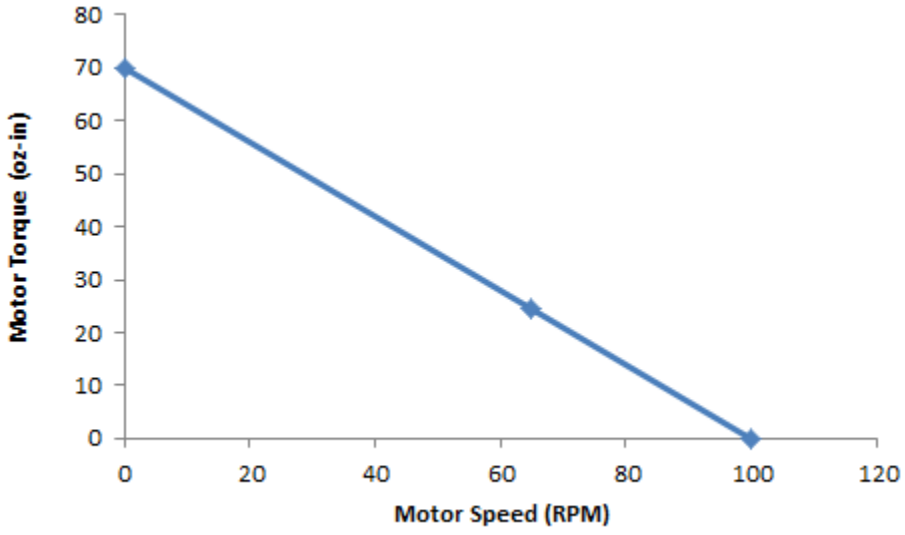


Figure 33: The 298:1 Micro Metal Gearmotor HP provides 24.5 oz-in torque at 65 RPM

The 298:1 high powered micro gearmotor provides 24.5 oz-in of torque at 65 RPM, which exceeds the power our application needs. However, their next smaller motor only provided 6.1 oz-in torque at 65 RPM, which is not enough. We therefore chose the 298:1 gearmotor to power the syringe.

Membrane Sealing

To determine whether our membrane sealing system will be effective in properly sealing the fluids in our simulator, we decided to perform an experiment using our chosen sealing method to see if it could withstand the pressure of the fluid that will be inside of it. The membrane just has to be able to hold water at very low pressures, and mainly prevent water from leaking through the bottom of the membrane due to gravity acting on it. To do this, we decided to join two 20cm by 20cm sheets of "press n seal" with a bubble of water between them (of 5-10 cm in diameter), as shown in Figure 32.

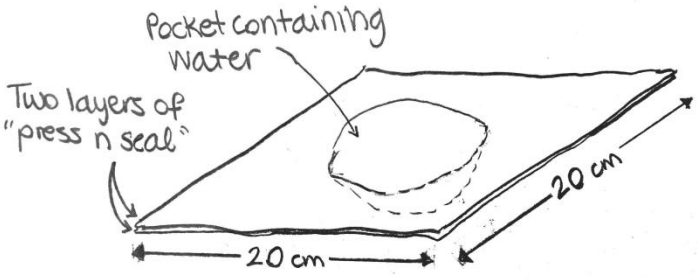


Figure 32: Experimental Set-up

Figure 33: Vertical Orientation

We held this set up in all orientations to see if the fluid would leak at any point, and then repeated it twice more to ensure it would be consistent, one of which is shown in Figure 33. The fluid did not leak, and since the membrane system will only contain the non-pressurized CSF, we believe our membrane system will be effective at sealing the water inside of it.

Tube Management

For tube management, we had to make sure that the seal between the two pieces of rubber foam would be strong enough to keep water from leaking through while not restricting flow in the tubes. We chose a foam that is compressible enough to place around the tubes and will be able to compress against itself to create a seal. We tested this by taking two pieces of foam and pressing them together, and then checking if water could pass through the seal. No water passed through the seal, confirming that our method will work.

Cap Securement

The key component for securing the cap to the skull is the hinge which will attach it and allow the cap to open and close. To determine the optimal size hinge necessary to support the skull cap, we analyzed the stresses it would be subjected to during normal operation. We determined the typical force exerted on the hinge by the weight and size of the skull cap, as well as the efforts required to move it. This was calculated to be 10 N. We then calculated the axial stress from bending and determined the maximum stress that would occur, using Eq. 5, and compared this to the yield stress of the ABS plastic we will be 3D printing the hinge from. The free body diagram and isometric of the hinge can be seen in Figure 34 on

page 32. The hinge was approximated as a 2.54 x 2.54 x 1.27 cm rectangle with the force being applied at the top.

$$\sigma = \frac{My}{I} \qquad \text{(Eq. 5)}$$

In Eq. 5, σ is stress, M is moment, y is the distance from the central axis, and I is the moment of inertia.

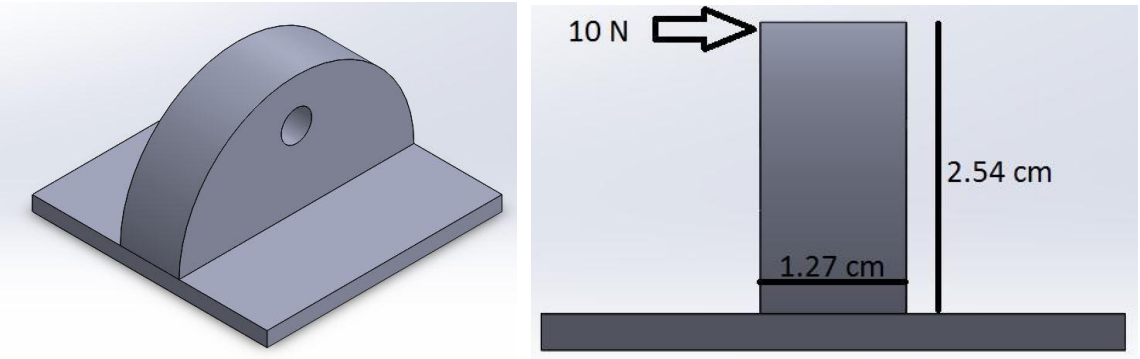


Figure 34: Left: isometric view of hinge base. Right: Forces and dimensions of hinge.

We determined the maximum stress in the hinge base to be 15.5 MPa. The yield stress of the ABS plastic is 39 MPa, giving this design a safety factor of 2.5. With this safety factor, we are confident our design will be strong enough.

Brain Securement

The key analysis we needed to perform for the securement of the brain was determining how long the arm needed to be. The arm needed to be long enough to be able to push against the brain but also short enough so that the skull is able to open without interference with the arm. We first measured an approximate length from the previous skull to give us a start, then imported a prototype arm into Mimics. From our measurements, we found that the arm would have to be around 2.5 inches. The prototype arm on the cap can be seen below in Figure 35. We then rotated the cap open and closed to make sure that the arm did not intersect with the skull, and that the arm will be long enough the reach the brain. The closed brain with the arm inside of it can be seen below in Figure 36. Since the goal of the arm is to simply press the brain up against the side of the skull, no analysis on the pressure the brain will be under was necessary.

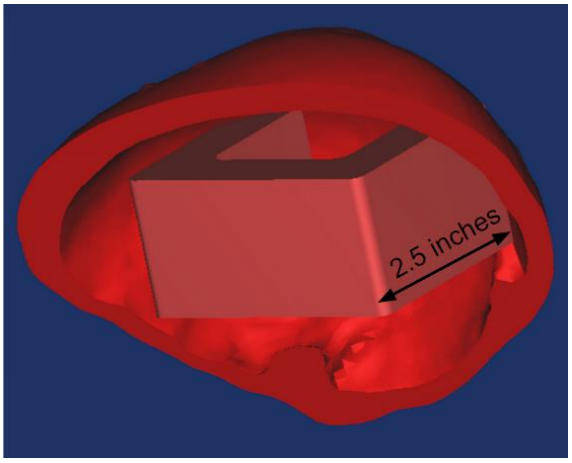


Figure 35: From measurements, our arm needed to be approximately 2.5 inches

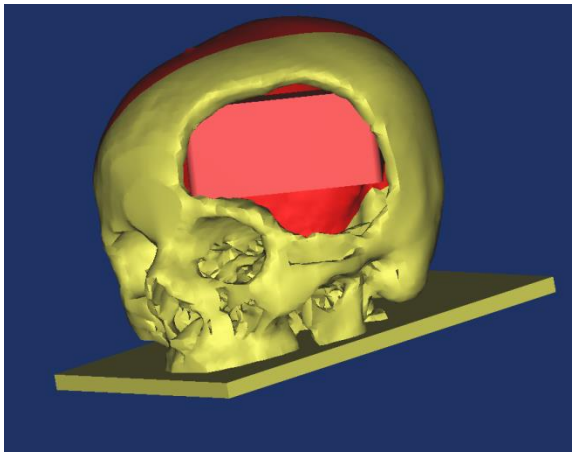


Figure 36: Image of the arm placed inside of the skull.

Brain Material

The goal of our project is to provide neurosurgeons with a tool that will better train them to operate on real patients, so it is important that our simulator accurately mimics the brain conditions during surgery, which includes choosing the appropriate material for the model brain. To create a material that would accurately model the material of the real brain, we made several samples of silicone of different hardness and presented them to our sponsor for evaluation of this criterion. The materials and evaluations are presented in Table 11. Our sponsor is a practicing Neurosurgeon, and our team feels comfortable using his evaluation of the material representativeness of the real brain as a guide in choosing the material we will use.

Table 11. Brain materials and evaluations

Material	Evaluation	Reasoning	Comments
Ecofles 010 - 0% mineral oil	Unsatisfactory	Too hard	+ Easy to make
Ecofles 010 - 20% mineral oil	Unsatisfactory	Too hard	+ Easy to make
Ecofles 010 - 40% mineral oil	Satisfactory	Slightly too hard	+ Easy to make
Agarose Gel	Excellent	Very Realistic	- Must be refrigerated
Heat-treated Silicone	Excellent	Very Realistic	- Difficult to make

In choosing a material for the brain to move ahead with, we considered our sponsor's material evaluation and any significant pros or cons that would go with using that material, beyond the material's representativeness of the real brain. We immediately ruled out the Ecoflex with 0 and 20% mineral oil because they felt too hard compared to the real brain. We also ruled out the Agarose Gel, because it has to stay refrigerated when not in use and goes bad after a certain period of time. We want to create a simulator that is easy to use and prepare by the user, and refrigerating the material and having to throw it out and replace it after a certain period of time overcomplicates the use of our machine. We ultimately decided to move forward with the Ecoflex 010 with 40% mineral oil, because it was satisfactory to our sponsor and is easy to make. The process to make it is also relatively inexpensive, which is important because we are still trying to find the optimal size of the brain for our given skull model and will most likely have to go through several iterations of the brain mold and model in order to find the correct size. Because it is relatively inexpensive to make, several iterations of our design are within our budget. If there is enough time and money left and we have found the best brain size, we will consider making a mold out of the heat-treated silicone, as it is the material that best represents the material of the real brain.

FAILURE MODES EEFFECTS ANALYSIS

To analyze the different ways in which our simulator may fail, we performed an FMEA, or Failure Modes and Effect Analysis. This process allows us to reduce the chance of any failures occurring during product development, while also providing us with what aspects of our may need to be improved in the future. Our simulator was broken down into five functional groups. Each function was then analyzed, and all possible failure modes of each group were listed. The effects of each of these failures was recorded, and the effects were also scaled according to their severity of failure, with a higher number being a more severe failure. Then we determined how likely it was for each failure to occur, with a higher number being more likely to occur. After that we ranked how likely it was that we could detect the failure before shipping it to the customer. A high number here means that we would very likely not identify the failure before sending it to the customers. Lastly, we calculated the risk priority number (RPN) for each failure as the product of the severity, probability, and detection rate of the failure mode. The larger the RPN value, the higher priority the risk. By analyzing the RPN values, the misalignment of the brain was found to be the largest risk. We will take action to minimize this risk by providing a diagram showing the correct orientation of the brain. A detailed table of the FMEA process can be found in Appendix B.

VALIDATION

To determine if the simulator satisfied the engineering specifications obtained from its sponsor, a series of validation tests were run. The result of each of these tests are shown in Table 12.

Arterial Diameter Fluctuation

To validate that the simulator had visually pulsating arteries, pulsating at the appropriate rate, a video of the pulsating artery in front of a scale was taken and analyzed. The video was analyzed (Figure 37) to determine the change in arterial diameter, as well as the rate of arterial pulsation.

Figure 37.

Cerebrospinal Fluid

To validate that the simulator had CSF realistically flowing into the operating area, the tube supplying the CSF was isolated and analyzed while the system was running. The volume of drops per cycle was recorded, as well as the frequency of the drops.

Ease of Assembly

To validate that the simulator was simple to set up, an instruction manual was created and the total assembly time using the instruction manual was recorded. This assembly time was only recorded for team members, but in the future the simulator should be given to a lab technician to setup to obtain a more realistic assembly time.

Sealing of Arachnoid Mater

To validate that the simulator had an arachnoid mater that could sufficiently contain realistic pressures caused by CSF, the membrane was sealed, then wrapped with a pressure cuff that pressurized the membrane until rupture. The pressure that the membrane ruptured was recorded.

Anatomically Correct Brain

To validate that the simulator had an anatomically correct brain, several different measurements were taken. First, a cube of the silicone material that was used for the brain was taken and compressed at an arbitrary force. The total compression of the material was measured. Using these values in conjunction with equations 1, 2, and 3, the Elastic Modulus of the brain was calculated.

$$\sigma = \frac{F}{A} \quad Eq.1 \qquad \epsilon = \frac{\Delta x}{x} \quad Eq.2 \qquad E = \frac{\sigma}{\epsilon} \quad Eq.3$$

Next, the volume of the brain was obtained by measuring the amount of water it took to fill the mold used to manufacture the brain. Using this volume with the mass of the brain obtained from a scale, the density was calculated.

Anatomically Correct Membranes

To validate that the simulator had anatomically correct membranes, an arbitrary tensile force was placed on the membrane, and the amount that the membrane stretched was measured. Using these values in conjunction with equations 1, 2, and 3, the Elastic Modulus of each membrane was calculated. The thickness of each membrane was measured using a micrometer.

Table 12. Validation Results Summary

Requirement	Property	Specification	Actual
Anatomically Correct Fluid System	Change in Arterial Diameter:	1.0 ± 0.5 mm	0.7 ± 0.5 mm
	Arterial Pulse Frequency:	80 ± 20 BPM	78 ± 6 BPM
	CSF Volume:	3 ± 1 drops	3 ± 2 drops
	CSF Frequency:	10 ± 1 BPM	10 ± 1 BPM
Ease of Assembly	Assembly Time:	5 ± 2 min	10 ± 2 min
Anatomically Correct Brain	Elastic Modulus:	1000 ± 300 kPa	55 ± 15 kPa
	Volume:	1050 ± 150 cm^3	948 ± 46 cm^3
	Density:	1042 ± 120 kg/m^3	860 ± 43 kg/m^3
Sealing of the Arachnoid Mater	Minimum Yield Strength:	18 ± 2 kPa	25 ± 1 kPa
Anatomically Correct Dura Mater	Elastic Modulus:	31 ± 2 MPa	870 ± 61 kPa
	Thickness:	1.5 ± 5.0 mm	1.0 ± 0.1 mm
Anatomically Correct Arachnoid Mater	Elastic Modulus:	1.2 ± 0.2 MPa	39.4 ± 14.8 MPa
	Thickness:	150.0 ± 50.0 µm	25.4 ± 1.3 µm

Although some of these values do not satisfy the engineering specification, we are not too concerned. When the simulator was presented to its sponsor, he was satisfied with the material selection. The engineering specifications may have had too strict error bounds, because the simulator's sponsor was satisfied if the materials adequately resembled the anatomic materials.

In the future, this simulator should be further validated by practicing neurosurgeons. The surgeons will perform a mock surgery on the model, then fill out a survey to determine the validity of the model based on the LIKERT scale. The simulator can then further be improved based on the input of the surgeons.

FINAL SIMULATOR

The manufactured prototype of the final design is shown in Figure 38 and can be broken up into three main sections: a brain wrapped in membranes, a skull, and a fluid control system.

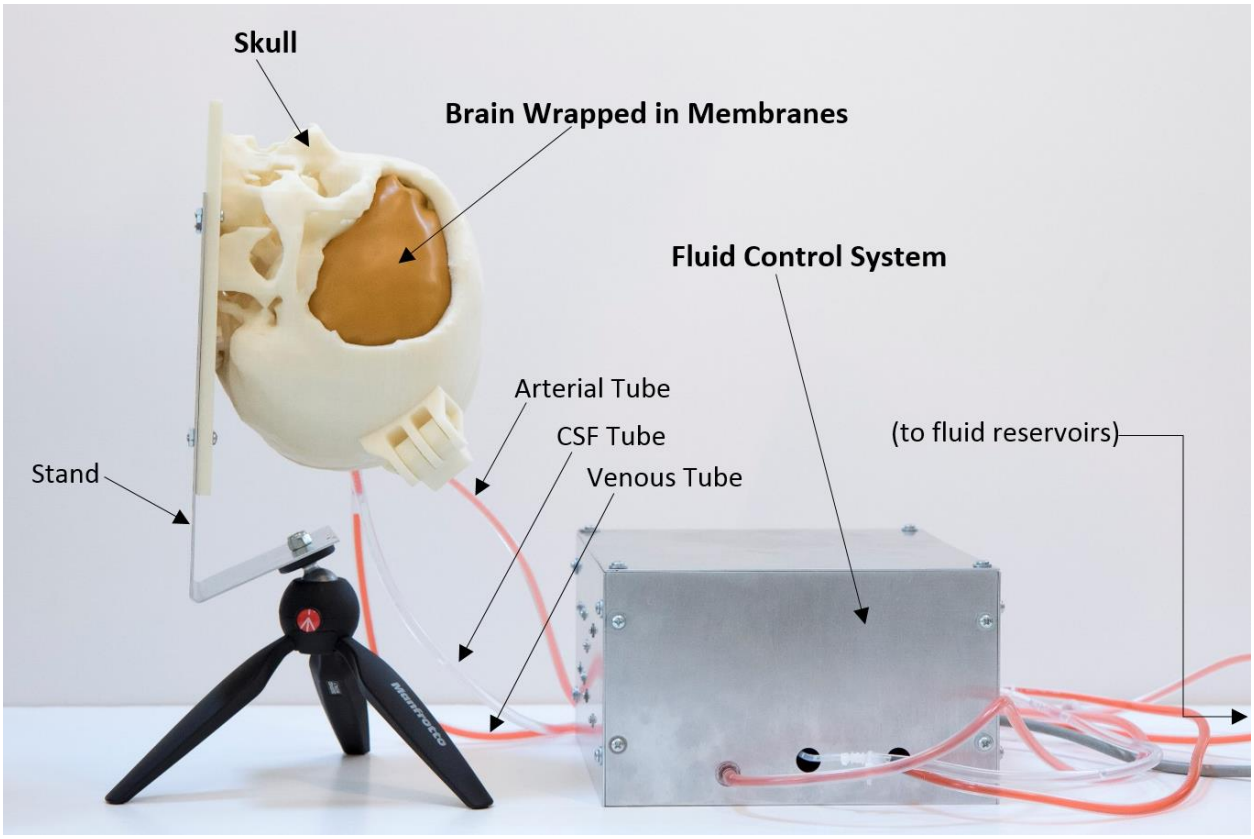


Figure 38. Manufactured Prototype of Final Design

The mock brain in the simulator is made of a 40% mineral oil silicone mix, and it is initially covered in a layer of Press'n Seal to mimic the innermost arachnoid membrane. Within the Sylvian fissure of the simulator's brain are two balloons, representing one artery and one vein, sprayed with adhesive and wrapped in cotton, which simulate the sticky arachnoid trabeculae found in the human brain. The open end of a tube carrying water, or mock cerebrospinal fluid, is placed at the end of the Sylvian fissure to allow fluid to drip into the surgeon's work area, as it would during real surgery. This system is tightly wrapped with another layer of Press'n Seal, representing the outer arachnoid mater, and then in a piece of resistance band rubber, which represents the dura mater. The wrapped brain is positioned and placed in a 3D printed skull via the opening of the skull cap, which is hinged to the skull and closed by placing an elastic band on two pins (one on the cap and one on the skull), as shown in Figure 39. Once the brain is placed in the skull, the skull cap is closed and the brain is held secure by the brain securement plate.

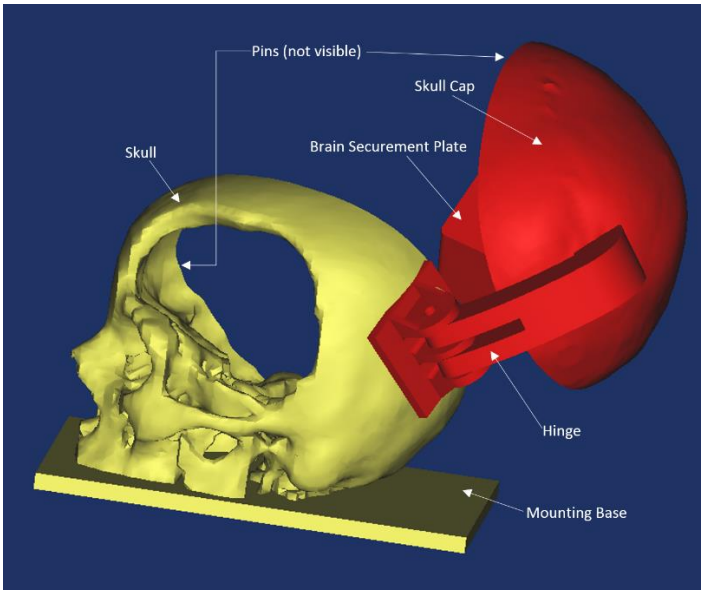


Figure 39. Skull Design

The three tubes in the brain are connected to the fluid control system, shown in Figure 40. To create visible arterial pulsations, a 298:1 micro gear motor connected to the 5V output of the power supply pushes fluid into and out of the arterial tube via the syringe assembly. If the surgeon accidentally cuts the artery in the simulator, a reservoir (IV bag) connected to the arterial tube with a one way valve continues to replenish the system with fluid so that the mock blood (red water) will continue to flow out of the cut artery. The vein tube is simply run through the fluid system housing and connected to a pressurized IV bag containing red water. To control the frequency and amount of water being dripped into the brain, a normally closed solenoid pinch valve controlled by an arduino and connected to the 12V output of the power supply is opened at the correct frequency to allow fluid to flow.

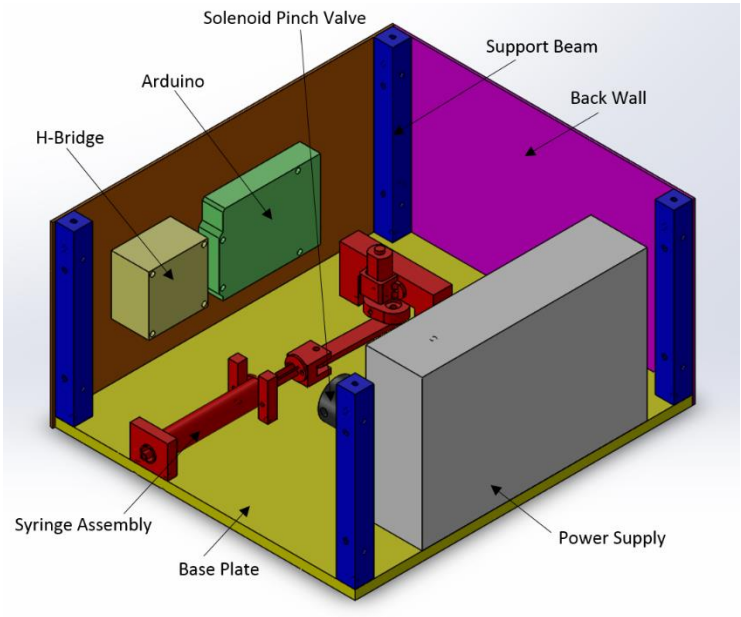


Figure 40. Fluid Control System

DISCUSSION

Our team is satisfied with most aspects of our design, and we feel that we have created a high quality working simulator. However, there are several aspects of our model that could be improved, and we would take several step towards this if we had more time to do future work on the project.

Design Critique

There are multiple parts of our design that we are satisfied with. The first is the simple user interface, which consists the user needing prepare the brain and membranes, place them into the skull, connect the vessels to the tubing coming out of the fluid control housing, and turning on a single switch to run the device. The second great feature is that all moving parts of the control system are enclosed within the housing. This helps with both the ease and simplicity of assembling the simulator for each use as well as safety, as the housing shields anything from interfering with the electrical and moving mechanical components of the fluid system. Overall, our sponsor was very pleased with the improvements we made on the previous prototype, both with respect to our design and the physical prototype.

Although we are pleased with the overall product we have created and with the fact that our simulator meets some important engineering specifications as set at the beginning of the term, it does not meet all of them. All engineering specifications were met in regards to the user requirements of having anatomically correct fluid systems and adequate sealing of the arachnoid mater. One design specification we did not meet, which was considered of relatively high priority, was an assembly time of 5+-2 minutes, as we got an assembly time of 10 +- 2 minutes during our validation testing. In looking at the gap between the specification and the actual result, we believe that the result is still acceptable, considering assembly time does not affect the function of the simulator in training the resident neurosurgeon (because it will already have been set up by a lab technician by the time it gets to the neurosurgeon). Additionally, we are satisfied with this result because it is a big improvement over the assembly time for the previous simulator, which was of over 20 minutes.

Another user requirement we did not fully meet the specifications of is an anatomically correct brain. We met the engineering specification for density, were close to meeting the specification for volume (this could have been due to the way we printed the brain), and we were very far from meeting the correct value for the brain's elastic modulus. The elastic modulus of the brain is an important material property, and there is more work to be done in order to meet this specification. Although the brain is not directly involved in the surgery (the neurosurgeon should never cut the actual brain of a patient), it is important in our efforts to simulate the biological environment of a patient that the surgeon would find in the operating room. Not being able to meet the elastic modulus specification was due in part to our sponsor not wanting to spend the financial resources needed to produce a brain out of a more appropriate, but more expensive material, and not having enough time to find other, more cost effective, alternatives. Lastly, we did not meet the specifications we set for the user requirements of an anatomically correct dura mater and an anatomically correct arachnoid mater. This did not concern us as these were low priority, secondary, stretch goals. In the future, it would be beneficial for the simulator to have more appropriate and biologically representative materials for these two membranes.

Future Work

If our team had more time and resources, there are several steps we would take to improve the design and functionality of our simulator. These include implementing additional measures to ensure the safety of the fluid system housing, as this component is metal (conductive) and houses electrical and

liquid components. We would also focus on meeting our engineering specifications for a reduced assembly time and material selections to meet those set for the brain, arachnoid mater, and dura mater properties.

Beyond satisfying the engineering specifications that our simulator failed to meet, our team would also use additional time to optimize the portability of the simulator. Currently, the simulator is difficult to carry because it consists of the heavy skull, the large fluid housing box, and three IV bag "reservoirs", along with all the tubing that goes with each component. Ideally, the fluid box would be much smaller and the fluid reservoirs would be integrated with the box, so that the whole simulator would become easier to carry.

Lastly, with more time our team would find an effective way to connect the mock blood vessels provided by the research team at UCSF to our fluid system. Because we received the vessels after Design Expo (received on April 17th), we did not have the opportunity to see how they behave on our simulator. With more time, we would like to connect them to our prototype and to produce a more anatomically accurate and therefore better simulator.

ACKNOWLEDGEMENTS

Special thanks to the sponsor, Dr. Luis Savastano, and to Professor Dr. Kannatey-Asibu for guiding us through this project. Also thanks to Dan Johnson, Toby Donajkowski, as well as everyone in Dr. Albert Shih's lab for helping in the development of this project. Lastly, thanks to the team who previously worked on this project: Danielle Kyser, Rianna Penn, Rosalie Shyu, and Rachel Vitale.

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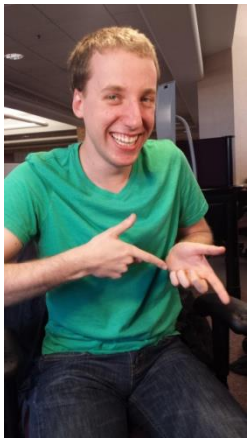
AUTHORS



Nick Bosio
I am from Brighton, Michigan, which is located around 20 minutes north of Ann Arbor. Most of my free time is spent hanging out with my friends, just having fun. I originally studied at the University of Toledo for my first year of college, studying bioengineering. I decided to transfer to the University of Michigan and to also change my major to mechanical engineering. I still hope to obtain my master's degree in biomedical engineering with a focus on biomechanics, as the medical field has always interested me. My dream is to improve other's quality of life through the projects that I work on throughout my career.

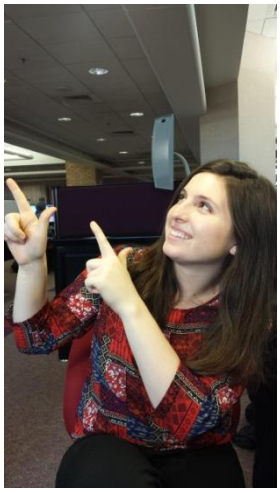
Mike Padilla
I was born and raised in Bloomfield Hills, where I spent much of my childhood playing sports and exploring the outdoors. I chose mechanical engineering as my field of study because I have always enjoyed building with my hands and problem solving. When I was younger, I would have lots of remote controlled cars, boats, and helicopters which would inevitably break when I crashed them. My dad would teach me how to fix them, whether that involved glue or replacing parts. My interest in problem solving has translated to my ME career, where I now apply it to design problems. This past summer I interned at Ford in their Product Development sector, and I look forward to returning there this summer. In my free time I enjoy photography and playing the piano around campus.

Alex Price

I grew up in Brighton, Michigan, a small town about twenty minutes north of Ann Arbor. I grew up playing all sorts of sports, and learning to play piano and guitar. I am always looking to find new hobbies to pick up and improve upon. Recently, I began rock climbing in a gym, and plan on taking this hobby to the outdoors in this coming summer. There is so much of the world that goes unseen because it is off of the beaten path. Outside of my personal hobbies, I have always found math and physical sciences to be very interesting. This, along with my desire to better the quality of life of others through the healthcare system has inspired me to become an engineer focused on BioMechanics. I love working with biological models, and the new technologies involving 3D-printing biological tissues is extremely exciting. My ideal career would be heavily involved in the healthcare industry, while still utilizing my interest in physics and mathematics.

Sara Rusignuolo

I grew up in a suburb of Milan before moving to upstate New York in middle school, and one of my favorite things is going back to visit family and friends in Italy. Outside of class I enjoy reading and swimming, and I absolutely love football Saturdays. I chose to study Mechanical Engineering at Michigan because of my love for mathematics and physics and because of all of the groundbreaking research that happens at the University in this field. I was originally planning on going to medical school after obtaining my degree, but soon realized that I would be able to pursue a career in the medical field in which I could apply my Mechanical Engineering background. After graduation, I hope to obtain a Master's degree in Mechanical Engineering and then go to work in industry, ideally in medical products.



APPENDIX A: CONCEPT GENERATION

CAP SECUREMENT

Hinge and Latch. The first idea we had for securing the cap utilized a hinge and a latch. The hinge would be on one side of the cap, allowing the cap to rotate into position or to expose the opening. The latch would be on the other side and would be a simple way to secure the cap. This concept can be seen below in Figure A1.

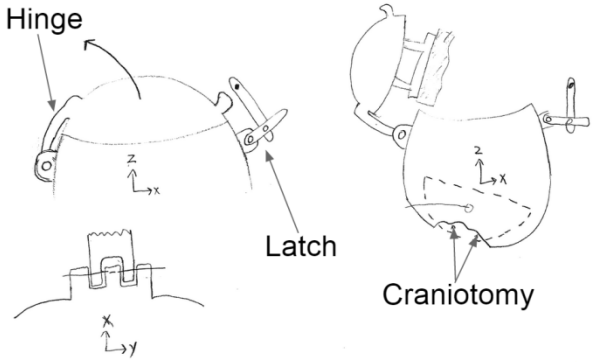


Figure A1: Hinge and Latch

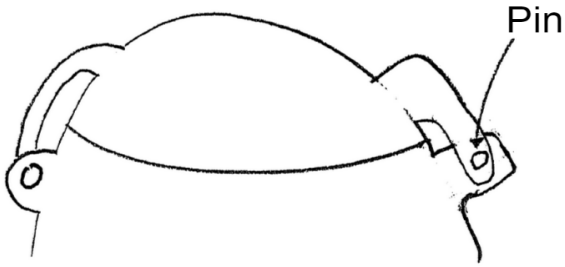


Figure A2: Hinge and Pin

Hinge and Pin. Another idea we had uses the same hinge mechanism, but uses a pin to secure the cap instead. This concept can be seen below in Figure A2.

Hinge and Nut/Bolt. Another idea we had utilized the same hinge mechanism, but instead of having a latch on the other side there would be a nut and bolt that would secure the cap in place.

Hinge and Elastic Band. Another idea we had uses a hinge on one side, coupled with an elastic band that holds the cap up against the skull by holding two extrusions tightly together. This concept can be seen on page 41 in Figure A3.

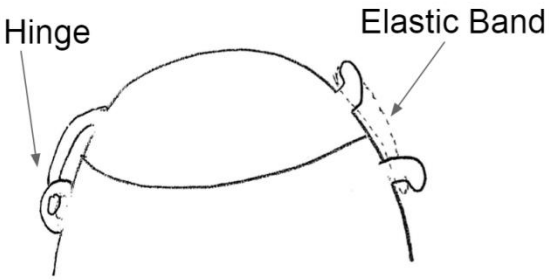


Figure A3: Hinge and Elastic

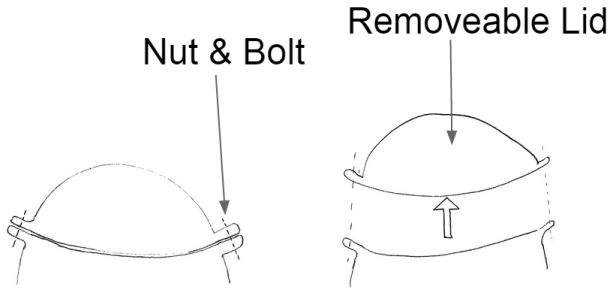


Figure A4: All Nut and Bolt

Complete Nut/Bolt. One final idea we had was to have a separate cap with extrusions on both the cap and the skull. These extrusions would be aligned, and then a bolt would be placed through them, securing the cap. This concept can be seen above in Figure A4.

Hinge and Velcro. Another idea we had was to use a hinge on one side, with a velcro strap on the other. The velcro would be a simple to use mechanism to secure the cap to the skull.

Complete Velcro. Another idea we had was to have a completely separate cap not connected by a hinge. Instead, there would be multiple velcro straps on the cap that would attach to the skull, securing the entire cap in place.

BRAIN SECUREMENT

Arm and Foam Pad. One idea we had for securing the brain was a rigid arm that connects to the cap that we would place on the skull. When the cap is closed, the arm would articulate so that it presses up against the brain, securing it against the skull. This concept also incorporates a foam layer on the end of the arm to account for variations in the position of the brain when it is loaded. This concept can be seen below in Figure A5.

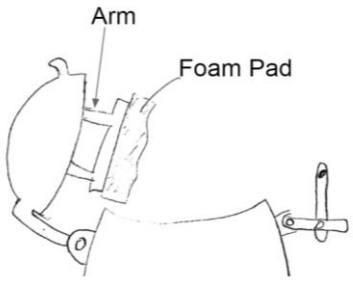


Figure A5: Arm and Foam

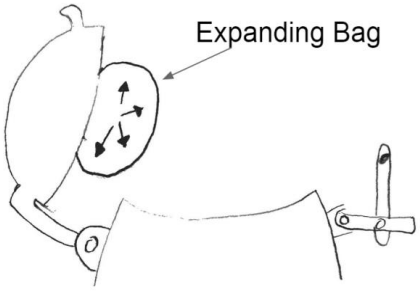


Figure A6: Expanding Bag

Expanding Bag. Another idea we had for securing the brain was to have an inflatable bag on the cap. The bag would be inflated once the cap was secured, and eventually would inflate to the point where it pushes up against the brain, causing the brain to be secured against the skull. This concept can be seen on page 41 in Figure A6.

Solid Fill. One last idea we had for securing the brain was to fill the empty half of the skull instead of leaving it hollow, forcing the brain to be pressed up against the outside of the skull.

MEMBRANE SEALING

Heat Sealing Saran Wrap. The first idea we had for membrane sealing involved heat sealing two layers of saran wrap together, as can be seen in Figure A7. The first layer would be placed on the brain and inside the Sylvian fissure, and another layer would be placed on top, with the layers being heat sealed together on all edges.

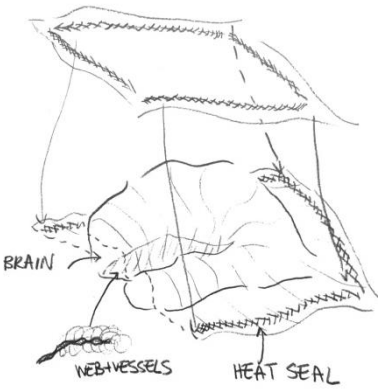


Figure A7: Hinge and Elastic

No Seal. Another idea we had for sealing the membranes was to have no seal at all, and instead position the brain in the skull such that the pressure of the brain against the skull would keep the membranes watertight.

Fold Seal. Another idea we had for sealing was to use saran wrap, and to roll or fold it on the edges to keep it sealed and watertight.

Bag. Another idea we had was to use newspaper bags as our membrane, which are already sealed on three sides, removing the need for us to seal the other sides.

Spray Adhesive. Another idea we had to seal the membranes together was to use a spray adhesive, which can be seen below in Figure A8.

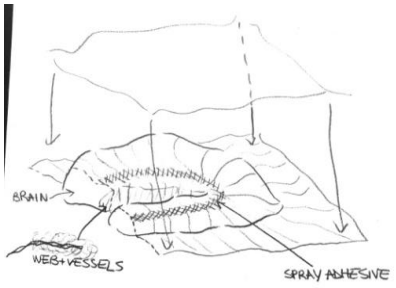


Figure A8: Spray Adhesive

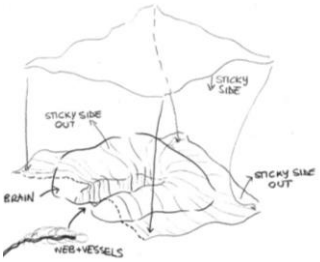


Figure A9: Press n Seal

Press n Seal. Another idea we had was using "press n seal" to seal the membranes together. One layer would be placed on top of the brain with the sticky side facing up, and another layer would be placed onto that, as seen on page 42 in Figure A9.

Mechanical Seal. One final idea we had for sealing the membranes was to have a device made of two pieces that are the outline of the shape we would like to seal. The pieces would be placed on opposite sides of the membranes, and would be snapped together, sealing the membranes together.

TUBE MANAGEMENT

Foam. The first idea we had for sealing the interface where the tubes enter the membrane was to use some sort of foam to fill the space between the tubes and the membrane, creating a seal.

Mechanical Snap. Another idea we had was to have a two piece mechanism made of plastic, where one piece snaps into the other, creating a seal. The two pieces would have holes in them for the tubes to go through. This concept can be seen below in Figure A10.

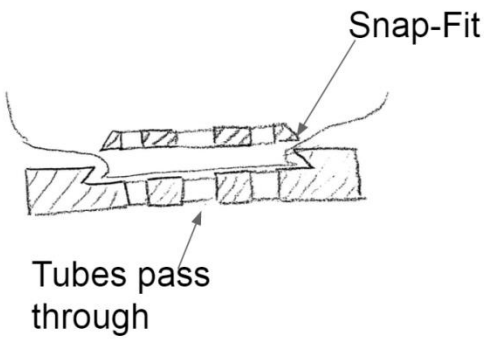


Figure A10: Mechanical Snap

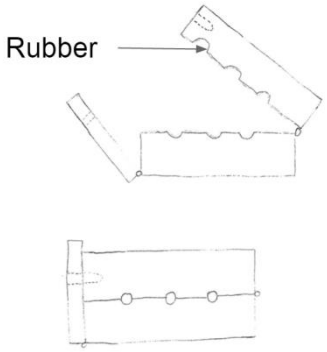


Figure A11: Three Hole Clip

Three Hole Clip. Another idea we had was to use a clip with three holes in it for the tubes to go through. The clip would open and allow the tubes to be placed in half circle indents, while also collecting the open end of the membrane, and then would be closed, sealing the area around the tubes. The inner surfaces of the clip would have a layer of rubber to ensure sealing. This concept can be seen above in Figure A11.

Grommet. Another idea we had was to use a grommet, which functions exactly the same as the mechanical snap, but is made out of rubber instead of plastic.

Poke Holes. One final idea we had was to have completely sealed membranes, and then to poke the tubes through, creating a watertight seal due to the polymers that make up the membrane layers.

PRESSURE SYSTEM

Cam. The first concept we had for the pressure system was the model developed by the previous team, using pressurized fluid reservoirs and a rotating cam to force fluctuations in pressure.

Sensor. Another concept we came up with for the pressure system uses a pump connected to the artery with a feedback loop to the pump to regulate the pressure.

Two Reservoirs. Another concept we came up with for the pressure system incorporates two reservoirs, one at the high pressure and one at the low pressure. A valve would then be used to switch between the high and low pressure reservoirs to simulate pulsatile flow.

Piston and Reservoir. Another concept we came up with for the pressure system uses a piston connected to a reservoir to push fluid in and out of the system. By controlling the amount of fluid displaced by the piston, we could control the change in the arterial diameter. This concept can be seen below in Figure A12.

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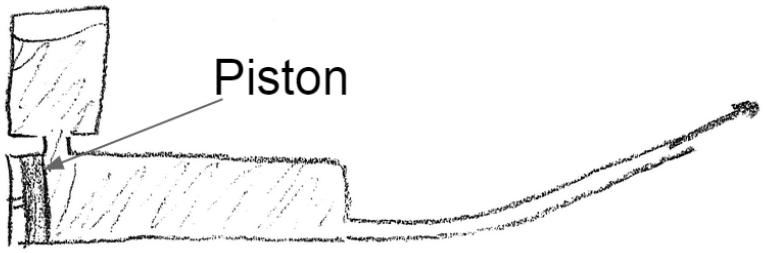


Figure A12: Piston and Reservoir

Temperature. Another idea we had for the pressure system was to modify the temperature of the reservoirs to create changes in pressure.

Balloon in Reservoir. Another idea we had was to insert a balloon inside of the fluid reservoir, and to inflate and deflate the balloon to create changes in pressure of the fluid. This concept can be seen below in Figure A13.

Pump. One final idea we had for the pressure system was to have a pump constantly pumping fluid through a fork. One path would lead back towards the reservoir and the other would lead to the blood vessels. This concept can be seen below in Figure A14.

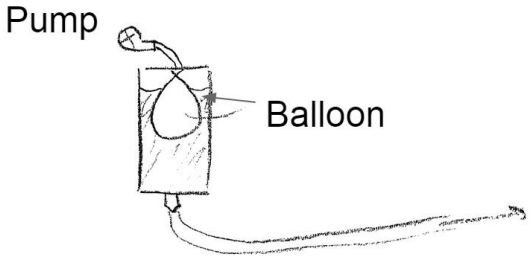


Figure A13: Balloon in Reservoir

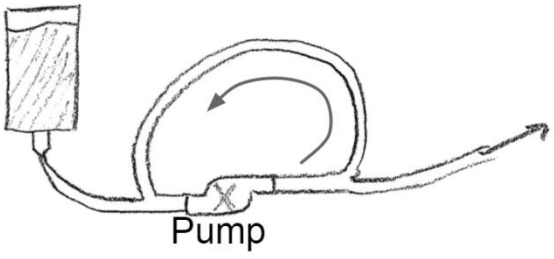


Figure A14: Pump

APPENDIX B: FMEA AND RISK ANALYSIS

Function Description	Failure Mode				*Potential Cause(s)/ Mechanism(s) of Failure	O	Current Design Controls	Det	R.P.N.
	*Potential Failure Mode	*Potential Effects	*Sev	Cls					
Securing the Skull Cap									
Cap is held in place when shut	Cap fails to close	Brain is not secured Simulator not suitable for use	8		Blockage	4	Foam pad for adjustability	2	64
					Brain is misaligned	6	Foam pad for adjustability	3	144
					Fatigue failure	2	Designed to prevent fracture	1	16
					Cap fractures	2	Designed to prevent fracture	1	16
					Hinge fractures	3	Designed to prevent fracture	1	24
	Cap is not held shut	Brain is not secured Simulator not suitable for use	7		Blockage	4	Foam pad for adjustability	2	56
					Brain is misaligned	6	Foam pad for adjustability	3	126
					Elastics ecurement strap breaks	5	Spare straps	1	35
Securing the Brain									
Brain is held in place when shut and Sylvian fissure is held closed	Securement arm on skull cap fractures	Brain is not held in place Simulator does not function	8		Stresses too high	2	Designed to prevent fracture	1	16
					Brain is misaligned	6	Crainiotomy orients brain	3	144
					Unintentional debris/ objects obstruct motion	4	Easily cleaned components	2	64
	Foam pad on securment arm falls off	Brain is not held in place Simulator does not function	5		Adhesive not durable enough	3	Designed to be durable	2	30
					Foam removed by user	2	Adhesive prevents removal	1	10
					High temperatures reduce adhesive strength	3	Designed to withstand room temperatures	3	45

Function Description	Failure Mode				*Potential Cause(s)/ Mechanism(s) of Failure		Current Design Controls		
	*Potential Failure Mode	*Potential Effects	*Sev	Cls		O		Det	R.P.N.
Arterial Pressure System Electro-mechanical system which varies the volume of fluid in the artery, such that a visible change in the diamter of the artery can be observed.									
	No electrical power	System does not function correctly Motor and control system do not function	8						
					Power supply fails	1	Utilizes consistent power source	1	8
					Not plugged in	2	Uses a common plug	1	16
	Syringe breaks	Fluid leakage Insufficient volume fluctuations applied to artery Collateral system damage Noise	4						
					Tubing ruptures	2	Designed against rupture	1	8
					Tubing Connection Leaks	4	Designed to prevent leakage	3	48
					Piston Leaks	4	Designed to prevent leakage	3	48
					Reservoir Leaks	2	Designed to prevent leakage	3	24
	Cam and or follower fracture	Piston does not function and does not supply volume fluctuations	8						
					Blockage in Piston	5	Easily cleanable	2	80
					Cam attached incorrectly	3	Easily made connection	2	48
Membrane Sealing Membranes around the brain should form a watertight seal									
	Membrane ruptures prior to surgery	Fluid leakage Unrealistic CSF pressure	7						
					Brain misaligned	6	Crainiotomy aligns brain	2	84
					Brain incorrectly wrapped	5	Easily able to rewrap	3	105
	Membrane seal separates	Fluid leakage CSF fluid not contained	7						
					Brain incorrectly wrapped	5	Easily able to rewrap	2	70
					Debris between membrane layers	4	Easily cleanable	2	56
					High temperature reduces sealing strength	2	Designed to withstand room temperatures	3	42
Sealing Tube Management At the interface of the membrane, the tubes must enter without any leakage of fluid.									
	Membrane is not sealed at interface	Fluid leakage CSF fluid not contained	7						
					Hinge malfunction	2	Designed to be robust	3	42
					Debris interferes with clip	5	Easily cleanable	2	70
					Clip fractures	4	Designed against fracture	1	28
	Tubing is not secured at interface	Fluid leakage CSF fluid not contained	7						
					Hinge malfunction	2	Designed to be robust	3	42
					Debris interferes with tubing	5	Easily cleanable	2	70
					Clip fractures	4	Designed against fracture	1	28
	Clip compresses tubing	Unrealistic pressure changes due to compressed tubes	3						
					Tubing incorrectly placed	4	Location specified on clip	2	24
					Debris interferes with clip	5	Easily cleanable	2	30

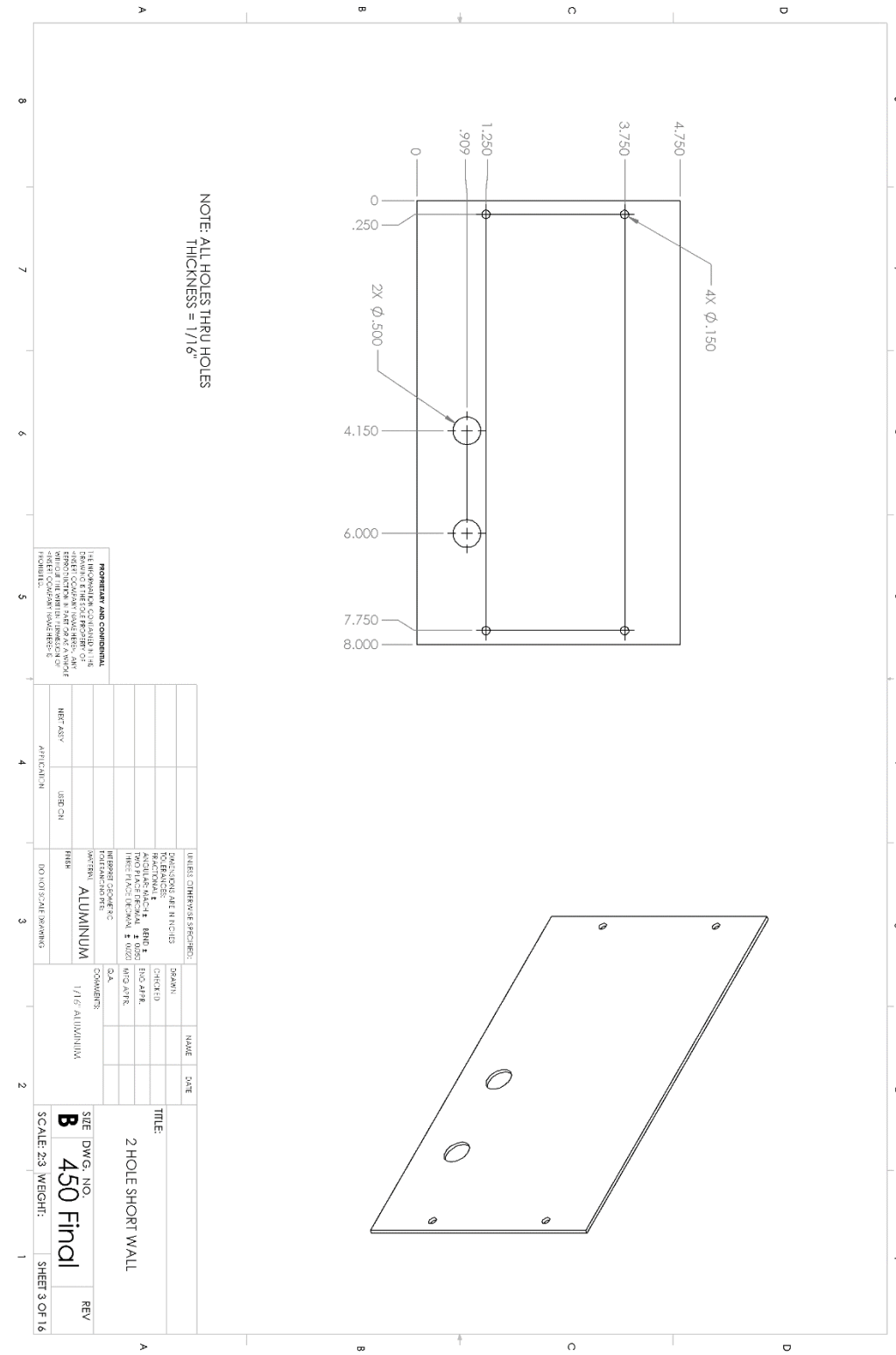
APPENDIX C: BILL OF MATERIALS

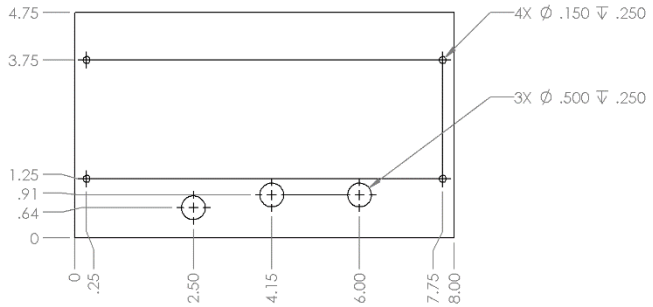
Part #	Component	Qty	Manufacturer	Cost
1	Model Skull Base	1	3D Printed*	-
2	Model Skull Cap	1	3D Printed*	-
3	Model Brain	1	Silicone Molded	-
4	Driven Linkage	2	Milled	-
5	Free Linkage	2	Milled	-
6	Sheet Metal	1	Bending	-
7	Adult Sphygomanometer	2	Hospital	-
8	Water Reservoirs	2	Hospital	-
9	Fluid Tubes	2	Hospital	-
10	Press n Seal	1	Glad	$ 3.49
11	Rubber Band	2	Home Depot	$ 0.98
12	Electrical Tape	1	Home Depot	$ 4.99
13	Wire	1	Home Depot	$ 4.98
14	Coat Rack	1	King's Brand	$26.64
15	Tripod	1	Manfrotto	$24.88
16	Check Valve	2	McMaster Carr	$ 5.84
17	Shoulder Bolt	2	McMaster Carr	$ 1.90
18	Nut	2	McMaster Carr	$ 3.31
19	Brass Rod	2	McMaster Carr	$ 1.01
20	Power Supply	1	MPJA	$14.95
21	Animal Balloons	2	Qualatex	$ 0.38
22	Elastic Band	1	Theraband	$ 8.19
23	tubing	1	McMaster Carr	$ 3.25
24	3 mL syringe	1	McMaster Carr	$ 7.12
25	1 mL syringe	1	McMaster Carr	$ 6.57
26	Rubber Foam	1	Home Depot	$ 4.99
27	Check Valve	1	McMaster Carr	$ 5.84
28	Foam Cushion - Table	1	Joann	$ 2.99
29	Motor - 298:1 Micro HP	1	Pololu	$15.95
30	Web for arachnoid	1	Amazon	$ 9.80
31	Motor - 298:1 Micro MP	1	Pololu	$15.95
32	Motor Mount Bracket	1	Pololu	$ 4.99
33	Nylon Tight-Seal Barbed Tube Fitting	1	mcmaster	$ 7.10
34	Quick-Turn Tube Coupling, Clear Barbed Socket	1	mcmaster	$ 8.86
35	Tight-Seal Barbed Tube Fitting	1	mcmaster	$ 8.95

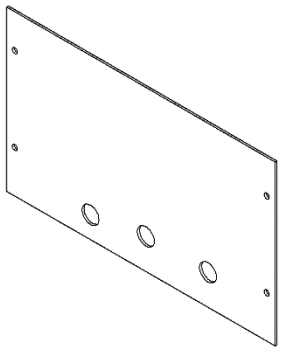
Part #	Component	Qty	Manufacturer	Cost
36	Super-Flow Polyethylene Barbed Tube Fitting	1	mcmaster	$ 5.53
37	3 mL syringe	1	Amazon	$ 7.25
38	1/8" shoulder screw >.475	2	McMaster	$ 8.78
39	1/8" shoulder screw >.3125	2	McMaster	$ 6.32
40	1/8" brass rod, 1/2 ft	1	McMaster	$ 1.65
41	1/4" brass rod, 1/2 ft	1	McMaster	$ 4.06
42	flathead screws, 6-32 x 5/8"	1	Mcmaster	$ 3.71
43	nylock nuts, 4-40	1	Mcmaster	$ 2.74
44	1/16" to 1/8" tube adapter	1	Mcmaster	$ 4.21
45	2-56 x 3/4" Machine screw	1	Mcmaster	$ 4.27
46	4-40 x 1/8" Set Screw	1	Mcmaster	$ 3.31
47	#2 Hex Nut	1	Mcmaster	$ 0.90
48	2-56, 5/16" length	1	Mcmaster	$ 3.28
49	nylon washers, #5	1	Mcmaster	$ 6.75
50	Solenoid pinch valve; 12 VDC	1	Cole Palmer	$79.00
51	mounting clip	1	Cole palmer	$ 5.00
52	mounting flange	1	Cole Palmer	$ 3.00
53	Power Supply	1	Mean Well	$29.20
54	#6 Flathead bolt	12	X50 Assembly Room	-
55	#6 Panhead bolt	20	X50 Assembly Room	-
56	#6 Hex Nut	16	X50 Assembly Room	-
57	#6 Washer	36	X50 Assembly Room	-

*3D Printing supplied by Dr. Shih's Lab

APPENDIX D: ENGINEERING DRAWINGS







NOTE: ALL HOLES THRU HOLES
THICKNESS = 1/16"

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			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	QA		
		MATERIAL ALUMINUM	COMMENTS: 1/16" ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

PROPRIETARY AND CONFIDENTIAL

THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.

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3 HOLE SHORT WALL

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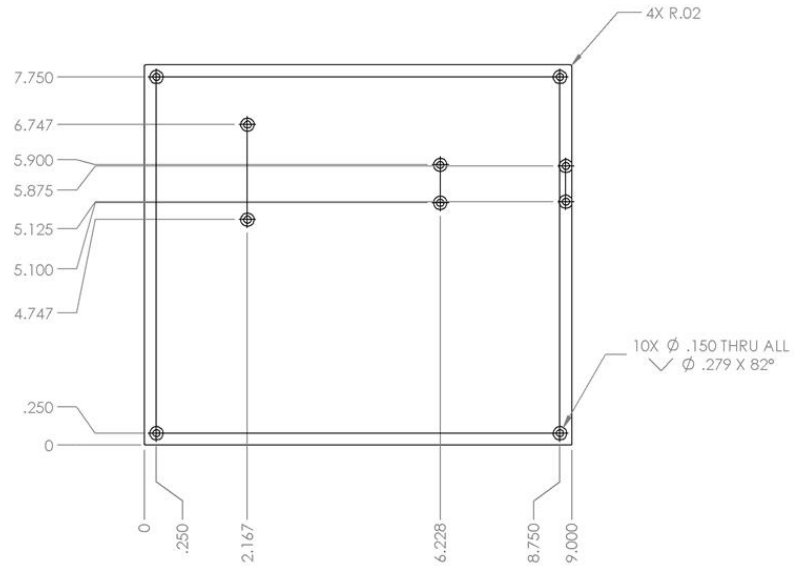

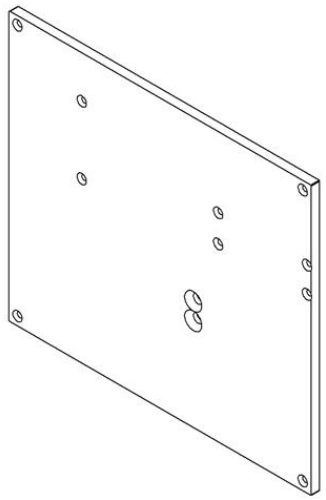

NOTE: THICKNESS = 1/4"

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APPLICATION		DO NOT SCALE DRAWING			

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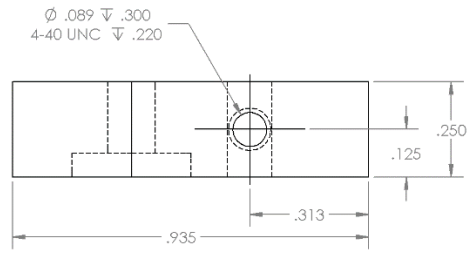
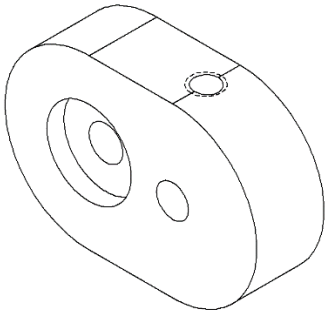
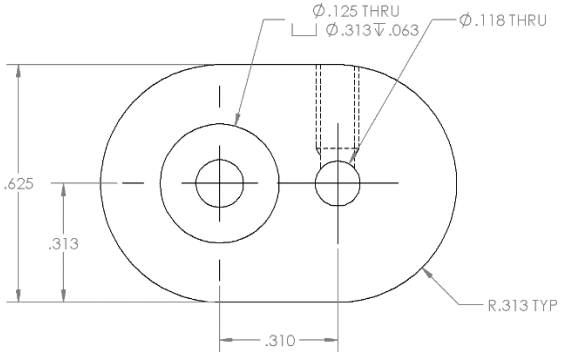
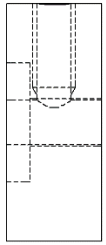
B	450 Final	

SCALE: 1:2 | WEIGHT: | SHEET 2 OF 16







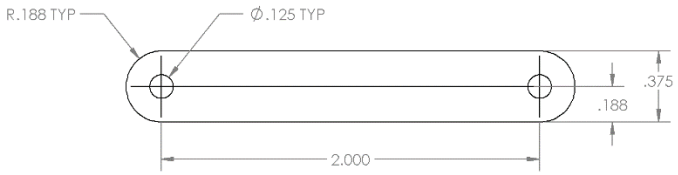


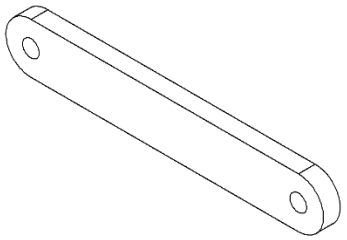
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/4" ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE: DRIVEN LINKAGE 1 ML

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 4:1 | WEIGHT: | SHEET 9 OF 16





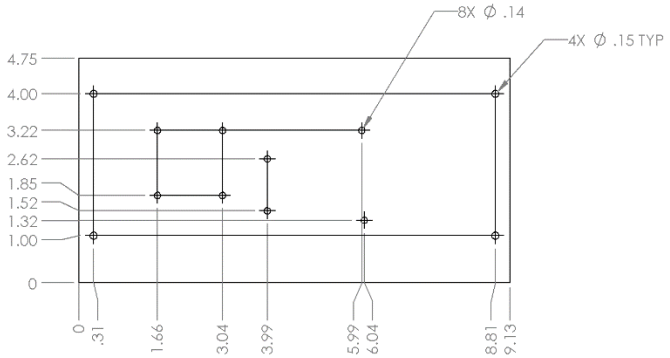
NOTE: ALL HOLES THRU HOLES
THICKNESS = 1/8"

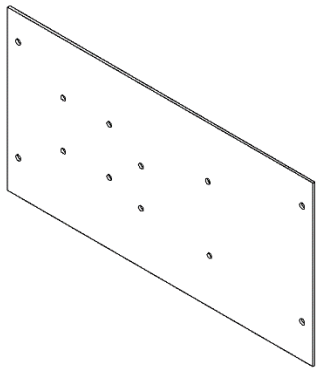
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.000	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/8" ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE: FREE LINKAGE

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 2:1 | WEIGHT: | SHEET 10 OF 16





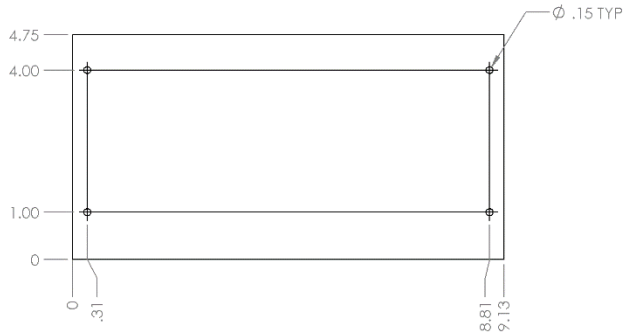
NOTE: ALL HOLES THRU HOLES
THICKNESS = 1/16"

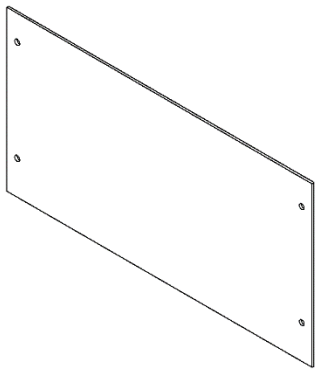
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/16" ALUMINUM		
		FINISH			
NEXT ASSY	USED ON				
APPLICATION		DO NOT SCALE DRAWING			

TITLE:
LONG WALL WITH ARDUINO

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 1:2 WEIGHT: SHEET 6 OF 16





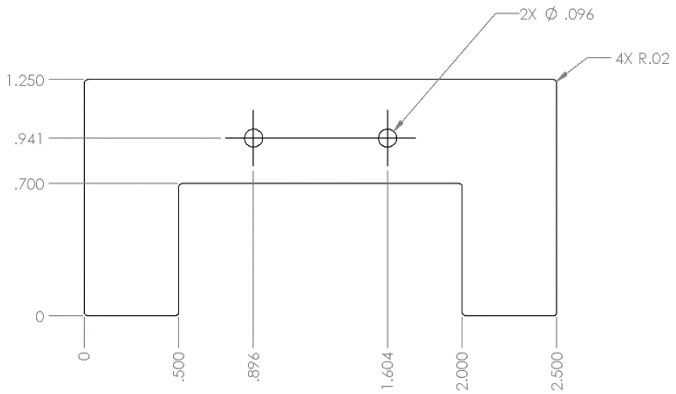
NOTE: ALL HOLES THRU HOLES
THICKNESS = 1/16"

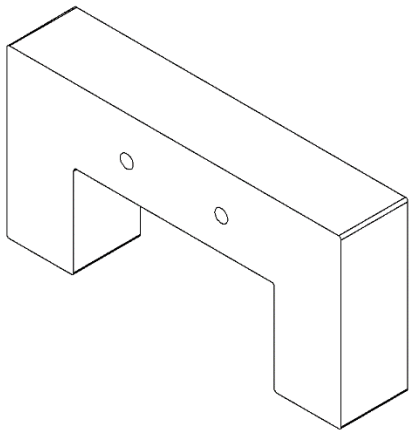
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.010 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/16" ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE:
LONG WALL

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 1:2 | WEIGHT: | SHEET 5 OF 16





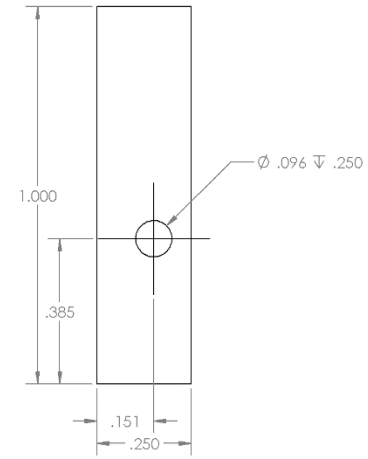
NOTE: ALL HOLES THRU HOLES
THICKNESS = 1/2"

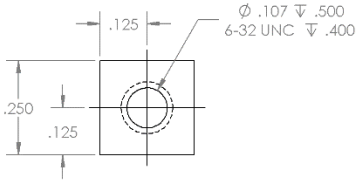
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/2" ALUMINUM		
		FINISH			
NEXT ASSY	USED ON				
APPLICATION		DO NOT SCALE DRAWING			

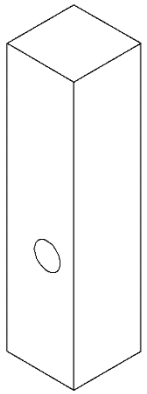
TITLE:
MOTOR BRACKET BRACKET

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 2:1 | WEIGHT: | SHEET 11 OF 16





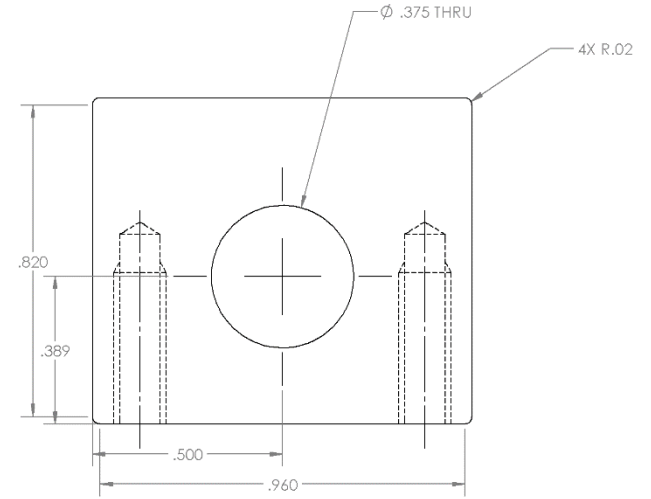


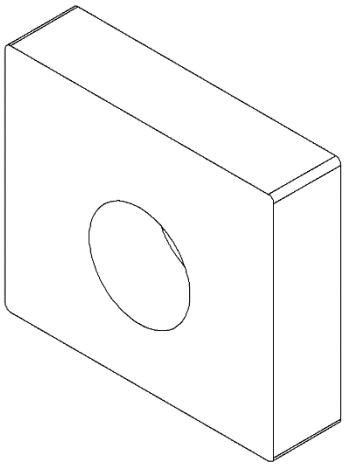
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/4" SQUARE STOCK ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

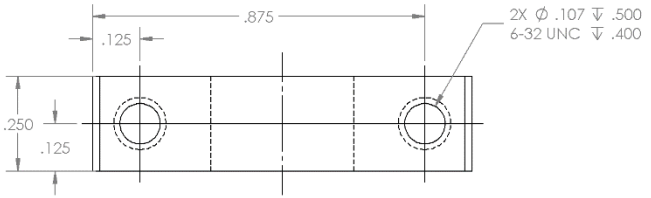
TITLE:
MOTOR VERTICAL SUPPORT

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 4:1 | WEIGHT: | SHEET 14 OF 16





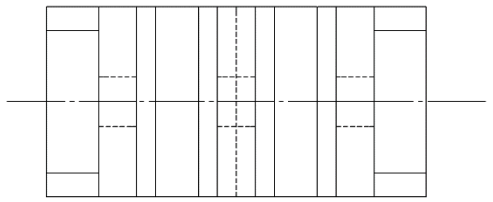


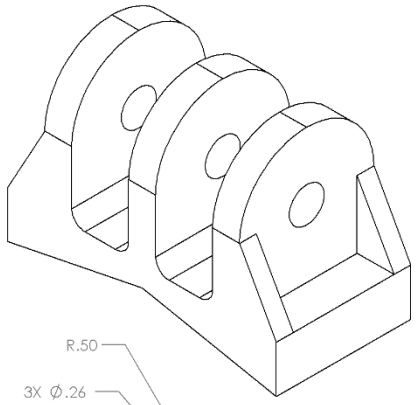
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.000	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/4" ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

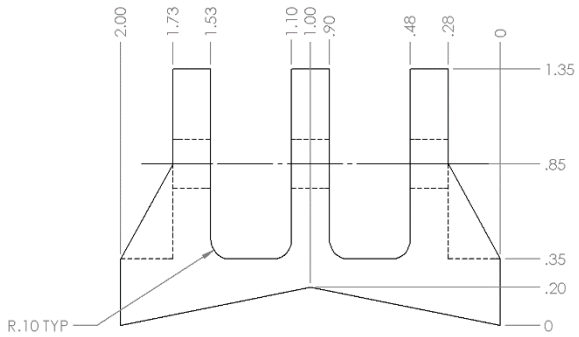
TITLE:
ROUND PART MOTOR MOUNT

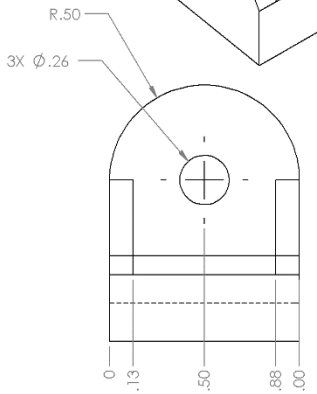
SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 4:1 | WEIGHT: | SHEET 13 OF 16







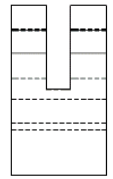


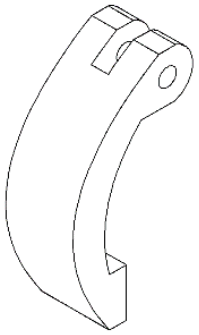
				NAME	DATE
		UNLESS OTHERWISE SPECIFIED:			
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	QA		
		MATERIAL	COMMENTS:		
		FINISH			
NEXT ASSY	USED ON				
APPLICATION		DO NOT SCALE DRAWING			

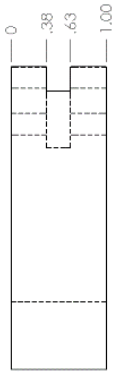
TITLE:

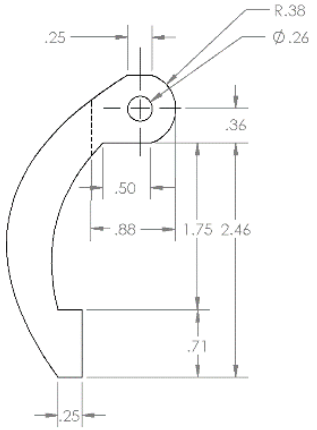
SIZE **B** | DWG. NO. Skull Hinge | REV

SCALE: 2:1 | WEIGHT: | SHEET 3 OF 3







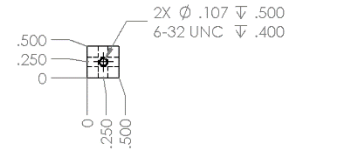


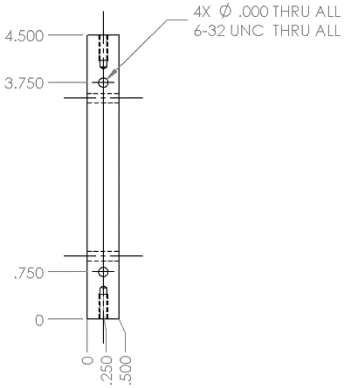
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DEC MAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	QUA.		
		MATERIAL	COMMENTS:		
		FINISH			
NEXT ASSY	USED ON				
APPLICATION		DO NOT SCALE DRAWING			

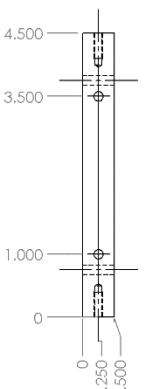
TITLE:

SIZE B | DWG. NO. Skull Hinge | REV

SCALE: 1:1 | WEIGHT: | SHEET 2 OF 3





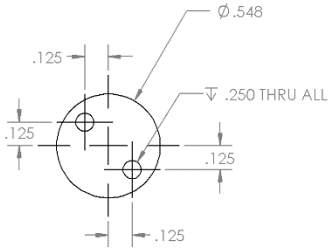


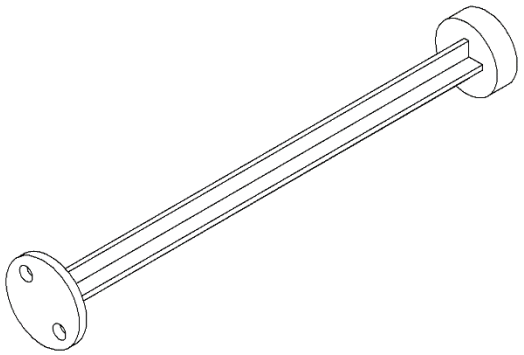
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/2" SQUARE STOCK ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE:
SUPPORT BEAM

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 2:3 | WEIGHT: | SHEET 8 OF 16



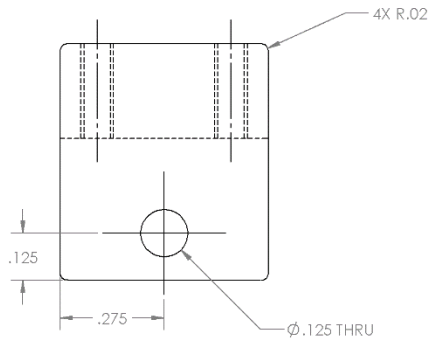


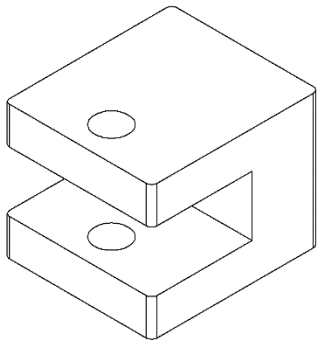
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
			Q.A.		
		INTERPRET GEOMETRIC TOLERANCING PER:	COMMENTS:		
		MATERIAL PLASTIC	HOLES MADE IN SUPPLIED SYRINGE		
		FINISH			
NEXT ASSY	USED ON				
APPLICATION		DO NOT SCALE DRAWING			

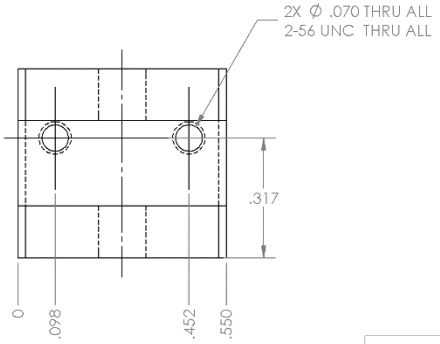
TITLE:
SYRINGE INNER

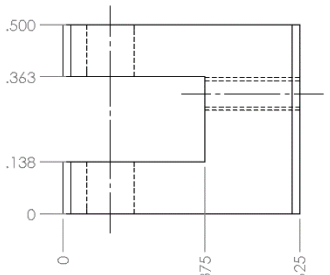
SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 2:1 | WEIGHT: | SHEET 16 OF 16









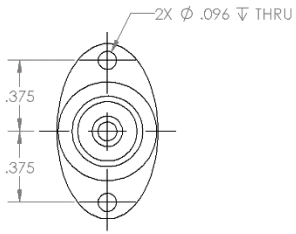
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± 0.050 THREE PLACE DECIMAL ± 0.020	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL ALUMINUM	COMMENTS: 1/2" ALUMINUM		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

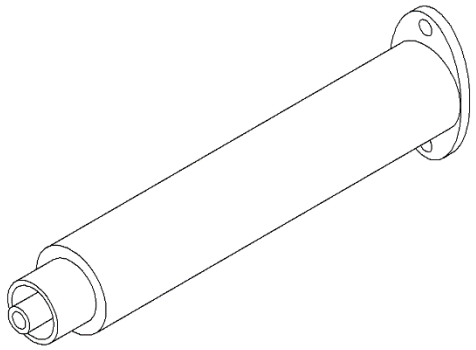
TITLE:

SYRINGE LINKAGE ADAPTER

SIZE	DWG. NO.	REV
B	450 Final	

SCALE: 4:1 | WEIGHT: | SHEET 12 OF 16





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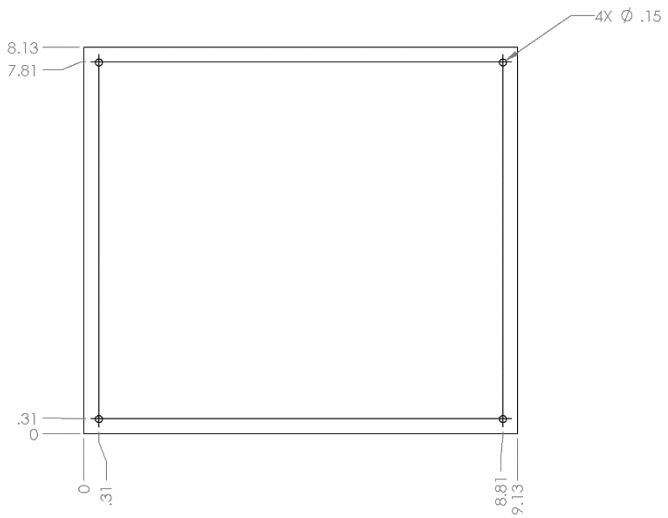

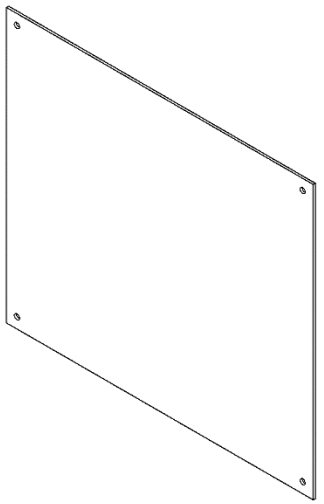

NOTE: ALL HOLES THRU HOLES
THICKNESS = 1/16"

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TOP PLATE

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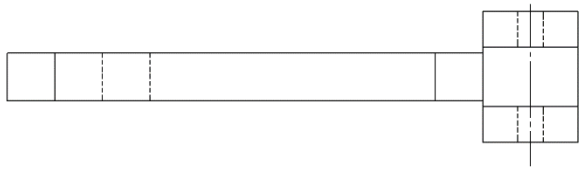

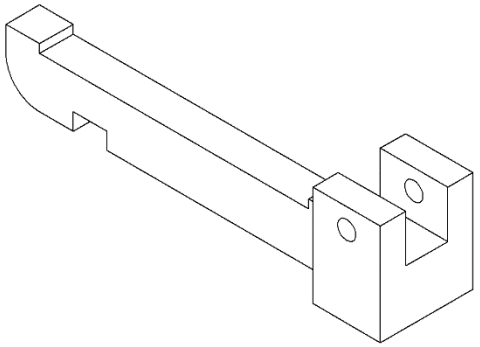

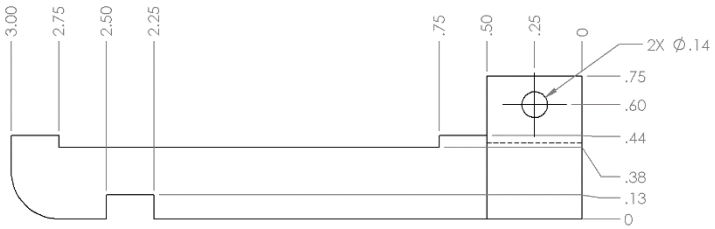

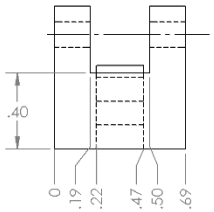

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THE INFORMATION CONTAINED IN THE DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.

TITLE:

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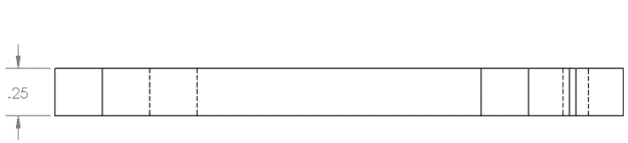

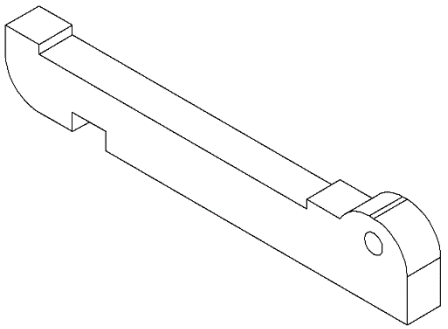

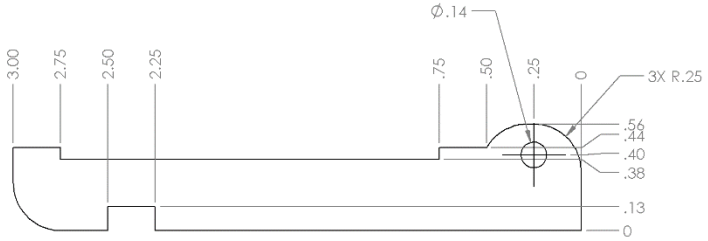

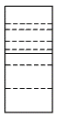

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APPLICATION		DO NOT SCALE DRAWING			

TITLE:

SIZE	DWG. NO.	REV
B	Tube Clip	
SCALE: 1:1	WEIGHT:	SHEET 3 OF 3

APPENDIX E: MANUFACTURING PLANS

Manufacturing Plan

Part Number: ME450-001 — Revision Date: 3/19/15

Part Name: 2 Hole Back Wall

Team Name: Team 12

Raw Material Stock: 1/16" Aluminum Sheet

Step #	*Process Description*	*Machine*	*Fixtures*	*Tool(s)*	*Speed (RPM)*
1	Cut part to length of 8"	Metal Shear			
2	Cut part to width of 4.75"	Metal Shear			
3	Centerdrill and drill the four 0.15" holes	Drill Press	Vise	Center drill, Drill bit #25	1400 RPM or less
4	Centerdrill and drill the two .50" holes	Drill Press	Vise	.50" Drill bit, Center drill	600 RPM or less
5	Break all edges by hand			File	

Part Number: ME450-002 — Revision Date: 2/19/15

Part Name: 3 Hole Short Wall

Team Name: Team 12

Raw Material Stock: 1/16" Aluminum Sheet

Step #	*Process Description*	*Machine*	*Fixtures*	*Tool(s)*	*Speed (RPM)*
1	Cut part to length of 8"	Metal Shear			
2	Cut part to width of 4.75"	Metal Shear			
3	Centerdrill and drill the four 0.15" holes	Drill Press	Vise	Center drill, Drill bit #25	1400 RPM or less
4	Centerdrill and drill the three .50" holes	Drill Press	Vise	.50" Drill bit, Center drill	600 RPM or less
5	Break all edges by hand			File	

Part Number: ME450-003				Revision Date: 3/19/15	
Part Name: Base Plate					
Team Name: Team 12					
Raw Material Stock: 1/4" Thick Aluminum Stock					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut the outline of the part using the waterjet	Waterjet Cutting Machine			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the nine 0.15" holes, then countersink them	Mill	Vise	Center drill, Drill bit #25, Drill chuck, 82 degree chamfer	1400 RPM or less
4	Break all edges by hand			File	

Part Number: ME450-004				Revision Date: 3/19/15	
Part Name: Driven Linkage					
Team Name: Team 12					
Raw Material Stock: 1/4" Aluminum Plate					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut the outline of the part using the waterjet	Waterjet Cutting Machine			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the 0.118" Hole	Mill	Vise	Center drill, Drill bit #32, Drill chuck	1600 RPM or less
4	Ream the .118" hole	Mill	Vise	Drikk chuck, 0.12" fractional reamer	100 RPM
5	Centerdrill and drill the .125 hole	Mill	Vise	Center Drill, Drill Chuck, Drill bit #31	1600 RPM or less
6	Ream the .125" hole	Mill	Vise	Drill chuck, 0.125" fractional reamer	100 RPM
7	Centerdrill and drill the .09" hole	Mill	Vise	Center drill, Drill bit #43, Drill chuck	1600 RPM or less
8	Tap .09" hole using #4-40 hand tap			Hand Tap, #4-40 Tap drill	
9	Break all edges by hand			File	

Part Number: ME450-005				Revision Date: 3/19/15	
Part Name: Free Linkage					
Team Name: Team 12					
Raw Material Stock: 1/8" Aluminum Plate					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut the outline of the part using the waterjet	Waterjet Cutting Machine			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the .125 hole	Mill	Vise	Center Drill, Drill Chuck, Drill bit #31	1600 RPM or less
4	Ream the .125" hole	Mill	Vise	Drill chuck, 0.125" fractional reamer	100 RPM
5	Break all edges by hand			File	

Part Number: ME450-006				Revision Date: 3/19/15	
Part Name: Long Wall with Arduino					
Team Name: Team 12					
Raw Material Stock: 1/16" Aluminum Sheet					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut part to length of 9.13"	Metal Shear			
2	Cut part to width of 4.75"	Metal Shear			
3	Centerdrill and drill the four 0.15" holes	Drill Press	Vise	Center drill, Drill bit #25	1400 RPM or less
4	Centerdrill and drill the eight 0.14" holes	Drill press	Vise	Center drill, Drill bit # 29	1400 RPM or less
5	Break all edges by hand			File	

Part Number: ME450-007				Revision Date: 3/19/15	
Part Name: Long Wall					
Team Name: Team 12					
Raw Material Stock: 1/16" Aluminum Sheet					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut part to length of 9.13"	Metal Shear			
2	Cut part to width of 4.75"	Metal Shear			
3	Centerdrill and drill the four 0.15" holes	Drill Press	Vise	Center drill, Drill bit #25	1400 RPM or less
4	Break all edges by hand			File	

Part Number: ME450-008				Revision Date: 3/19/15	
Part Name: Motor Bracket Bracket					
Team Name: Team 12					
Raw Material Stock: 1/2" Aluminum Plate					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut the outline of the part using the waterjet	Waterjet Cutting Machine			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the two 0.10" holes	Mill	Vise	Center drill, Drill bit #41, Drill chuck	1600 RPM or less
4	Centerdrill and drill the .11" hole	Mill	Vise	Center drill, Drill bit #36, Drill chuck	1600 RPM or less
5	Tap .11" hole using #6-32 hand tap			Hand Tap, #6-32 Tap drill	
6	Break all edges by hand			File	

Part Number: ME450-009				Revision Date: 3/19/15	
Part Name: Motor Vertical Support					
Team Name: Team 12					
Raw Material Stock: 1/4" Aluminum Square stock					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut stock to length of 1.13"	Bandsaw			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the .10" hole	Mill	Vise	Center drill, Drill bit #41, Drill chuck	1600 RPM or less
4	Centerdrill and drill the .11" hole	Mill	Vise	Center drill, Drill bit #36, Drill chuck	1600 RPM or less
5	Tap .11" hole using #6-32 hand tap			Hand Tap, #6-32 Tap drill	
6	Break all edges by hand			File	

Part Number: ME450-010				Revision Date: 3/19/15	
Part Name: Round Part Motor Mount					
Team Name: Team 12					
Raw Material Stock: 1/4" Aluminum plate					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut the outline of the part using the waterjet	Waterjet			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the .38" hole	Mill	Vise	Center drill, 3/8" Drill bit, Drill chuck	800 RPM or less
4	Centerdrill and drill the two .11" holes	Mill	Vise	Center drill, Drill bit #36, Drill chuck	1600 RPM or less
5	Tap .11" holes using #6-32 hand tap			Hand Tap, #6-32 Tap drill	
6	Break all edges by hand			File	

Part Number: ME450-011				Revision Date: 3/19/15	
Part Name: Support Beam					
Team Name: Team 12					
Raw Material Stock: 1/2" Aluminum Square stock					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut stock to length of 4.63"	Bandsaw			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the 2 .11" holes	Mill	Vise	Center drill, Drill bit #36, Drill chuck	1600 RPM or less
4	Tap .11" hole using #6-32 hand tap	Mill	Vise	Hand Tap, #6-32 Tap drill	
5	Centerdrill and drill the 4 0.15" holes	Mill	Vise	Center Drill, Drill chuck Drill bit #25	1400 RPM or less
6	Break all edges by hand			File	

Part Number: ME450-012				Revision Date: 3/19/15	
Part Name: Syring Inner					
Team Name: Team 12					
Raw Material Stock: 3 mL syringe					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
2	Centerdrill and drill the two .10" holes	Mill	Vise	Center drill, Drill bit #41, Drill chuck	900 RPM or less
3	Break all edges by hand			File	

Part Number: ME450-013				Revision Date: 3/19/15	
Part Name: Sryinge Linkage Adapter					
Team Name: Team 12					
Raw Material Stock: 1/2" Aluminum Plate					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut outline of part using waterjet	Waterjet			
2	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
3	Centerdrill and drill the .125 hole	Mill	Vise	Center Drill, Drill Chuck, Drill bit #31	1600 RPM or less
4	Ream the .125" hole	Mill	Vise	Drill chuck, 0.125" fractional reamer	100 RPM
5	Centerdrill and drill the two 0.07" holes	Mill	Vise	Center Drill, Drill chuck Drill bit #25	1400 RPM or less
6	Mill out gap in part with 1/8" endmill	Mill	Vise	Collet, 1/8" endmill	1800 RPM or less
7	Tap .07" hole using #2-56 hand tap	Mill	Vise	Hand Tap, #2-56 tap	
8	Break all edges by hand			File	

Part Number: ME450-014				Revision Date: 3/19/15	
Part Name: Sryinge Outer					
Team Name: Team 12					
Raw Material Stock: 3 mL syringe					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Find datum lines for X and Y.	Mill	Vise	Edge finder, Drill chuck	900 RPM
2	Centerdrill and drill the two .10" holes	Mill	Vise	Center drill, Drill bit #41, Drill chuck	900 RPM or less
3	Break all edges by hand			File	

Part Number: ME450-015				Revision Date: 3/19/15	
Part Name: Top plate					
Team Name: Team 12					
Raw Material Stock: 1/16" Aluminum Sheet					
Step #	***Process Description***	***Machine***	***Fixtures***	***Tool(s)***	***Speed (RPM)***
1	Cut part to length of 9.13"	Metal Shear			
2	Cut part to width of 8.13"	Metal Shear			
3	Centerdrill and drill the four 0.15" holes	Drill Press	Vise	Center drill, Drill bit #25	1400 RPM or less
4	Break all edges by hand			File	

APPENDIX F: ENGINEERING CHANGES

Engineering Change Notice

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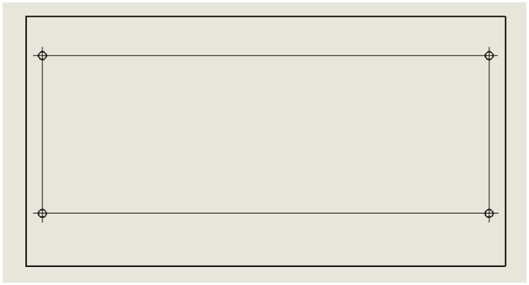

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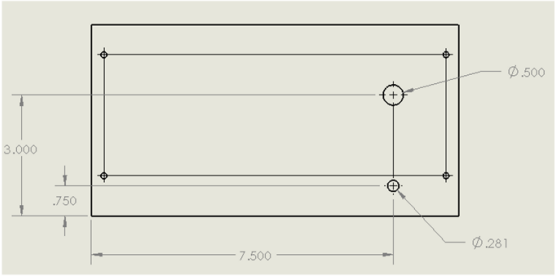
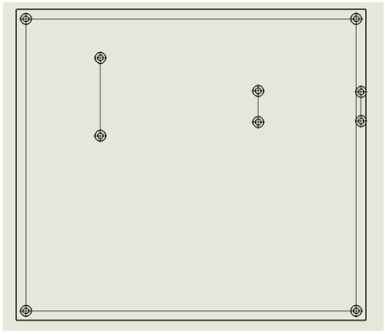


Notes:

Part:	Long Wall	
Description:	New holes for toggle switch and power cord.	
Engineer:	Alex Price	3/31/2015
Authorized:	Professor Asibu	4/2/2015

Engineering Change Notice

Was:



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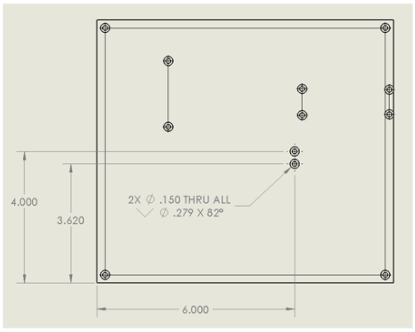

Notes: Same as all other holes on the part

Part:	Base Plate	
Description:	Updated location for securing the solenoid mount	
Engineer:	Alex Price	3/31/2015
Authorized:	Professor Asibu	4/2/2015

APPENDIX G: VALIDATION PROTOCOL

Table G1: Anatomically Correct Fluid System

	Priority	Specification	Rationale
Anatomically correct fluids	1	Change in Arterial Diameter: 1.00 ± 0.50 mm Cerebrospinal Fluid Frequency: 3±2 drops every 6.0±1.0 sec	Simulate surgical fluid environment

To validate this user requirements, we will measure the change in diameter of the blood vessel. To do this, we will use our simulator, a metric ruler, and a video recorder. We will start to run our simulator, with the metric ruler held behind the fluctuating arterial balloon. We will place a camera in front of the balloon so that it captures the moving balloon in front of the metric ruler. To acquire our data, we will take various frames from the video recording (ones with the vessel fully expanded and ones with the vessel fully contracted) and measure the vessel diameter change. We will take several measurements of the vessel diameter and calculate the mean diameter change and the various standard deviations. We will then calculate the percent confidence with which we can confirm the diameter change to be 1mm, as defined in the engineering specifications.

Table G2: Ease of Assembly

Requirement	Priority	Specification	Rationale
Ease of assembly	2	Assembly time: 5.00 ± 2.00 min	Allow for quick and easy preparation of the simulator

To evaluate the ease of assembly of our simulator, we will measure its assembly time. To do this, we will ask at least three lab technicians to assemble our simulator (from the point from which they would have to realistically assemble it). We will measure the time it takes each technician to assemble the simulator using a stopwatch. After acquiring the data, we will run statistical analysis on it, calculating the mean, standard deviation, and confidence level for the engineering specification having been met.

Table G3: Anatomically Correct Brain

Requirement	Priority	Specification	Rationale
Anatomically correct brain	3	Elastic Modulus: 1,000.00 ± 300.00 kPa Density: 1,050.00 ± 150.00 kg/m^3 Length: 167.00 ± 20.00 mm Width: 140.00 ± 20.00 mm Height: 93.00 ± 10.00 mm Volume: 1,042.00 ± 120.00 cm^3	Simulate surgical environment including the appropriate physical properties of a living patient

For evaluate the density the brain, we will use a scale to obtain the mass and compute the volume by water displacement. The remaining dimensions will be calculated using a caliper. The Elastic Modulus is more complicated, and we will be using a compressive force gauge to push on a one inch test cube of brain material. We will push it an arbitrary force, then measure displacement to obtain the strain. By comparing the strain and the force, we can obtain the value for stress divided by strain, which results in the Elastic Modulus. After acquiring the data, we will run statistical analysis on it, calculating the mean, standard deviation, and confidence level for the engineering specification having been met.

Table G4: Sealing of the Arachnoid Mater

Requirement	Priority	Specification	Rationale
Sealing of the arachnoid mater	3	Yield Strength: 18.00 ± 2.00 kPa	Insure against rupture due to CSF pressure

To evaluate the yield strength of the arachnoid mater, we will seal the membrane, then fill it with pressure until the membrane leaks. We will insert a tube that is attached to a reservoir of water into the sealed membrane. Then, a pressure cuff will be wrapped around the reservoir, and the pressure on the reservoir will be slowly increased. Thus, the pressure in the membrane will be increased. The pressure will be increased until the membrane leaks, and that pressure will be recorded. After acquiring the data, we will run statistical analysis on it, calculating the mean, standard deviation, and confidence level for the engineering specification having been met.

Table G5: Anatomically Correct Dura and Arachnoid Mater

Requirement	Priority	Specification					Rationale
Anatomically correct dura mater	4	Elastic Modulus:	31.00	±	2.00	MPa	Appropriate material responses when dura incisions are made
		Density:	1,100.00	±	150.00	kg/m^3	
		Thickness:	1.50	±	5.00	mm	
Anatomically correct arachnoid mater	4	Elastic Modulus:	1.20	±	0.20	MPa	Appropriate material responses when arachnoid incisions are made
		Density:	1,350.00	±	150.00	kg/m^3	
		Thickness:	150.00	±	50.00	μm	

For evaluate the density and the thickness of these membranes, we will simply use a scale to obtain the mass and compute the volume by water displacement for the density, and a caliper for the thickness. The Elastic Modulus is more complicated, and we will be using a tensile force gauge to pull one side of the membrane, with the other side secured. We will pull it an arbitrary distance, then measure that distance to obtain the strain. By comparing the strain and the force, we can obtain the value for stress divided by strain, which results in the Elastic Modulus. After acquiring the data, we will run statistical analysis on it, calculating the mean, standard deviation, and confidence level for the engineering specification having been met.

APPENDIX H: ETHICAL DESIGN

Nick Bosio

In our project of making a simulator for brain aneurysm surgery, taking ethics into account is extremely important. In the Mechanical Engineering Code of Ethics, the first canon states that "Engineers shall hold paramount the safety, health and welfare of the public in the performance of their professional duties." [1] Since our project will be used to train surgeons on how to perform a dangerous surgery on live patients, it needs to be a realistic as possible to provide proper training. If our simulator is not accurate, it could actually lead to more harm than good, as surgeons could be trained incorrectly.

Due to the possible negative outcomes of incorrectly training surgeons on this surgery, our prototype will be tested by many experienced neurosurgeons and feedback will be given based on their experience with it. Only after the simulator is deemed acceptable will it be able to be used to train neurosurgeons for the surgery. To ensure that we are doing our due diligence in creating an accurate simulator, we have met continuously with our sponsor, a resident neurosurgeon to receive feedback on what he feels could be improved still.

Another aspect of our project that we had to think ethically about is the safety of our user, the neurosurgeon. Since our project incorporates an electrical system to control fluid flow, we had to be careful in the way we set up everything together. While we don't foresee any fluid leaking from our tubes inside the enclosure, we have taken precautions to ensure the safety of the user. Our first idea was to make sure that all tube connections happen outside of the enclosure, as the connections are the most common place for the tubes to leak. We also added rubber rings to all of the holes in the walls of the enclosure, to make sure that the tubes don't tear from rubbing on the metal edge.
We have also consulted with reputable individuals over the course of our project for advice on how to design certain aspects. By using advice we received from Luis Savastano, Dan Johnson, Toby Donajkowski, and our various ME 450 professors, we were able to make sure that our simulator was as good as we could make it.

Mike Padilla

Ethics are an integral part of being an engineer, and in particular, being a good mechanical engineer. In designing our neurosurgical training simulator, our team has considered the ethics of our decisions both in a direct sense, and in an indirect sense.

The first Fundamental Principle from the Code of Ethics of Engineers, ASME, states that engineers will use "their knowledge and skill for the enhancement of human welfare." Since the beginning of our project, we have directly attempted to adhere to this principle. Our project is to enable resident neurosurgeons to be better trained before operating on their patients. At the start, we looked for a design which would help meet this Principle in several areas, namely, the realism and ease of use. In order for this design to actually enhance current medical technology, and therefore human welfare, it needs to add benefit to the training experience of doctors. We met with our sponsor, a neurosurgeon, and completed extensive research to learn about the surgery and its relevant anatomy so that we could incorporate this knowledge into a design that was realistic where it needed to be. Some of the goals we strived to meet for this were a realistic fluid system, brain, and meninges. Secondly, once the design was realistic, it needed to be convenient to use so that clients will purchase it. Even if a design serves the correct purpose, if it isn't desirable to the end user and therefore isn't implemented,

it has little benefit. To achieve this, we put a strong emphasis on the ease of assembly of the simulator, in large part because that is an important aspect of a good design, but also because it will indirectly help improve the current medical training technology. Our ethical behavior was not constrained to our design process, however.

Most every decision we made was rooted in ethical thinking, if even at the subconscious level. We did not always stop and ask ourselves if this decision is for the good of our end users. However, we have been trained to be ethical engineers for four years at the University of Michigan, and because of this, acted accordingly. When interacting with our sponsor, my team and I were always honest and respectful. We took care to represent mechanical engineers in a prestigious manner. In this sense, we took an indirect approach, as well as a direct approach, to ethical design by continually incorporating the Code of Ethics of Engineers as well as our inner feeling of what was right.

Alex Price

Making a surgical simulator obviously has significant ethical implications. If we as engineers were to create a simulator that in inherently inaccurate to a real surgery, it could result in failed surgery, meaning our design has caused the death of an individual. For this reason, we have been heavily involved with our sponsor in making sure that the simulator is as accurate as we could make it within our ability.

To ensure the accuracy of our model, each component has been validated by our sponsor to be realistic. For the skull, we have utilized a 3D scan of a skull chosen by our sponsor, and recreated as a 1:1 model. The brain material was hand chosen from a variety of options, as were the materials for the membranes surrounding the brain. The pressure system has also been verified to be realistic, resulting in consequences similar to what would be seen in the operating room. All of these validations have given us confidence that our simulator will be able to accurately and efficiently train surgeons to perform this surgery.

The Code of Ethics for Mechanical Engineers wants to ensure that we are creating products to the best of our ability, and doing it for the greater good of the world. By creating a simulator that can potentially train surgeons to perform a difficult surgery with a greater success rate, we are saving the lives of those unfortunate people that have been affected with a brain aneurysm. Our final design has the potential to train surgeons for years to come, and help them save lives in surgeries around the world.

Sara Rusignuolo

Our team has addressed ethics in every step of our senior design project. We have followed the Code of Ethics of Engineers as set by the American Society of Mechanical Engineers (ASME).

Throughout the semester have abided by the code's three driving principles. The first is to use our knowledge for the enhancement of human welfare, which we are doing through our project's goal, which is to provide surgeons with better training methods in hopes of increasing patient survival rates for intracranial aneurysm surgery. The second principle is to be honest, impartial, and serve our clients with fidelity. We have done this throughout the semester, as we have reported all successes and failures in our design and prototyping to our sponsor, keeping our design process and methods transparent. We have contributed to the third principle, which is to strive to increase the competence

and prestige of the engineering profession, by doing a professional and quality job while representing the significant contributions engineers can make to non-engineering fields, such as medicine.

The selection of our final design involved various ethics considerations, and our team has acted in accordance with the fundamental canons of ASME"s code of ethics, with a few in particular. The second canon begins with "Engineers shall perform services only in the areas of their competence," which we have done in that we have sought the support of experts in any area we did not have the proper knowledge. For example, we contacted graduate students in Dr. Albert Shih's research lab for help in making the silicone brain material as well as 3D printing various components in our design. Most importantly, we worked very closely with Toby Donajkowski in the mechatronics lab to ensure that our control systems and wiring were safe for the user to operate. While we have worked to make the electrical portions of our simulator operate, there is still a concern whenever mixing water and electricity in close proximity. In recognition of this, we will provide ample warnings regarding hazards of such a device, and will continue to work to improve its safety. Another way in which we applied the code of ethics is our benchmark and patent documentation of existing systems from which we drew ideas. The fifth fundamental canon in ASME's code states that "Engineers shall respect the proprietary information and intellectual property rights of others." We worked very closely with Dan Johnson in Dr. Shih's research lab, which is filled with medical devices that accomplish similar high level tasks as ours. With respect to both the devices present at the University of Michigan and found online, our team has infringed any intellectual property rights, as we have no intent of patenting or commercializing any part of our project with a design that drew on an existing idea in any way.

APPENDIX I: ENVIRONMENTAL IMPACT

Nick Bosio

When looking at the environmental impact of our project, there is only so much that can be improved while still offering a realistic surgery simulation. Since the surgery simulation is a destructive process, as the membranes are being cut through, the materials used for the membranes need to be discarded after each simulation attempt. Additionally, the spiderwebs we use for the arachnoid trabeculae will need to be discarded after each surgery, and the balloons we use for the veins and arteries will need to be discarded if they are cut during the surgery. Ideally, the membrane materials would be recyclable, but as of right now the elastic rubber and Press n Seal we are using for the membranes are not. One improvement that could be made in the future is finding a material that can be recycled, and still closely mimics the dura and the arachnoid membranes.

When looking at our overall project, we have tried to make it as reusable as possible. Both the skull and the brain are meant to be reusable for as long as needed. Also, the tubes and the fluid reservoirs are meant to be reusable, leaving only a few non-reusable parts. Overall, our simulator is not the best in terms of reusability and environmental impact for our material selection, but there is a limit to how good environmentally it can be while still providing an accurate surgery experience.

Since our project is powered electrically, it does use a non-trivial amount of electricity. Since the surgery can take hours, our simulator will be running for hours as well, which is not great in terms of electricity usage, but there is no other real option for us in terms of having a working, accurate simulator.

Mike Padilla

Our team was presented with the problem of optimizing a neurosurgical training simulator, and in doing so had the opportunity to affect the environmental impact of the design. There are many types of materials in our design, ranging from aluminum and steel, to 3D printed material and plastic tubing, to a silicon mold, and more. Each of these has their own environmental impact, with some of them being reusable and or recyclable, and other being less environmentally friendly.

Aluminum is one of the primary materials used in our proposed solution. To create new aluminum from ore in the ground is an extremely energy intensive process, requiring 7 times as much energy as it takes to process steel. If this were the whole story for aluminum, it would be bad for our environmental impact. However, aluminum is highly recyclable, and it takes 20 times less energy to recycle aluminum than to create it initially. The other primary material used in our design is the ABS plastic used by 3D printers. Plastic is a large environmental concern because it does not biodegrade like many other materials. Fortunately, it is also possible to recycle ABS plastic, and due to the high cost of virgin ABS it is an economically viable option. Many of the other components of our proposed solution have the ability to be recycled, such as steel fasteners and DC motors. These materials can be taken to a recycling facility or a scrap yard.

Looking back at our design, there are several actions we could have taken to reduce our environmental impact. First, we could have looked for recycled materials to use. The aluminum and plastic we used did not say it was recycled and I think it is likely that they were virgin materials, which require more energy to process but can be higher quality. Secondly, we could have optimized our design so that we used fewer nonrenewable materials. This could have been done by reducing the

size of the aluminum sheets we used, or replacing it with a material such as wood. Moving forward, we can include an end of life plan for our project. It is likely that when it is done being used, it will be thrown out and make its way to a landfill. However, if we stipulate that the metals, plastic, and motor should be recycled at the end of its life, it is possible to reduce the negative environmental impact.

Alex Price

Environmentally, our product is not that friendly, but that was a tradeoff that had to be made in order to create a realistic surgery simulator. The skull is 3D printed, a low energy cost manufacturing process, but it is not recyclable. However, this skull will be reused for the entire lifecycle of the simulator. The same is true for the silicone brain. The manufacturing of the brain is not that expensive, but still, it is not a recyclable material. The pressure system is assembled simply using a mill, and will last through the lifecycle as well.

The least environmentally friendly part of the simulator lies in the membranes. Because this is a surgical simulator, the membranes will inevitable be cut for every single surgery. This is a necessity to realistically simulate the surgery, but it means that the membranes must be replaced between every surgery. An elastic resistance band, and a piece of Press n Seal must be replaced each time a surgery is practiced, along with the webbing within the membranes.

When the simulator reaches the end of its life, there is very little that can be done to recycle components. The pressure system can be scrapped for parts, such as the tubing, connectors, the electronics, and the aluminum. Unfortunately, the skull and the brain will just be thrown away, as they are not made of materials that can be easily recycled. To create a simulator that trains surgeons to perform this difficult surgery, we had to sacrifice the environmental friendliness of our final design.

Sara Rusignuolo

When we took on our assigned project, our team did not take environmental impact as a focus in our design. In material selection for our simulator, we did not focus on environmentally friendly choices, but rather what material has the best properties for our intended use.

Our simulator uses materials that, if disposed of in the incorrect way, can be potentially harmful to the environment. Additionally, many of the materials that are for single use in our simulator are not recyclable. This is mainly a concern for the brain membranes, which are cut during every surgery and disposed of every time. The benefit of the membrane materials is that they are inexpensive, which was important for us from a practical perspective.

The other materials we used in our simulator are not necessarily very environmentally friendly, but are not disposable and will be used for the lifetime of the simulator. The mold needed to create the silicon brain and the skull are 3D printed out of plastic, which uses a good amount of energy (and time) to make. These are necessary components of the simulator and our team couldn’t determine a better way to manufacture such unique and detailed components without a 3D printer. Similarly, the brain is made out of a silicon mineral oil mix, which is not considered an especially environmentally friendly material. Again, we chose this material because it met the material properties needed in our

simulator. Because it is reusable for every surgical simulation, it is not of huge concern environmentally.

Lastly, our simulator has to be plugged into the wall, receiving about 120 Volts, for use. If the simulator is an accurate representation of the intracranial surgery we are trying to replicate, it should take the surgeon several hours to practice on our device. This means that the simulator will be plugged in and using energy for this entire time. Because it is a medical device and we were not concerned with potential negative impact as much as we were with the potential benefits this could have in improving surgery survival rates, this is a compromise we were comfortable making.

In retrospect, we had the opportunity to make several design choices keeping environmental impact as a higher priority. This includes material selection and power method. While our proposed solution does not have obvious and large scale negative environmental effects, it is not designed to be environmentally friendly, which is a drawback to our simulator design.