Vital Signs Acquisition Device
ME 450: Design & Manufacturing III
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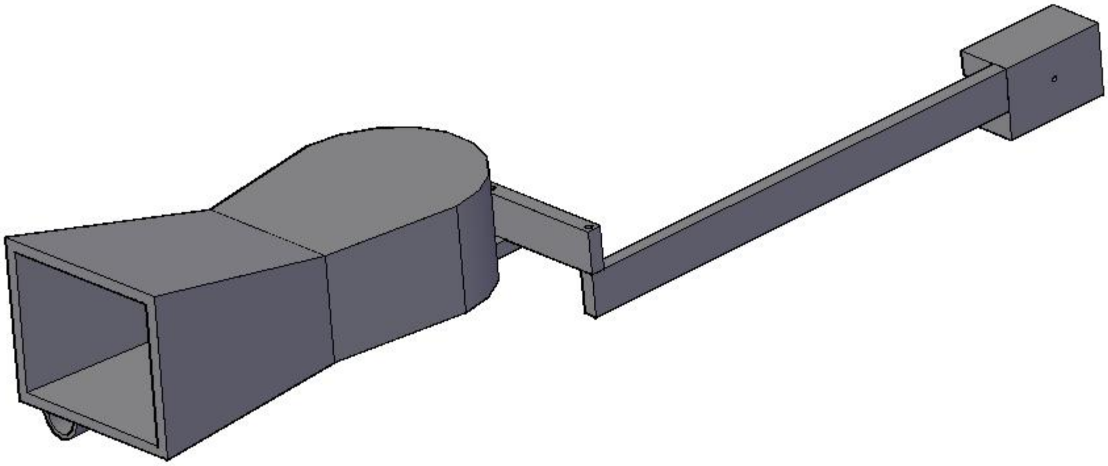


Executive Summary

Our group, ME 450 Team 28, has designed and prototyped a vital signs acquisition device through the sponsorship of Dr. James Goldstein at William Beaumont Hospital in Royal Oak, MI. Currently, the nursing staff at Beaumont Hospital manually measures and records the blood pressure and pulse rate of hospitalized patients using manual sphygmomanometers, wristwatches and clipboards. This procedure is typically performed several times per day, making it labor and resource intensive and often disturbing to patients who are in need of rest for recovery. Additionally, patients in operating rooms, specifically cath labs, often subconsciously move their hands into sterile areas around the groin where catheters are inserted. The purpose of this project was to design a vital signs acquisition device that would automatically record measurements without disturbing the patient while providing light restraint to the patient's arms. The device should incorporate available technologies to comfortably and accurately record the patient's blood pressure, pulse rate, and blood-oxygen levels and automatically read out the measurements.

We first considered the customer requirements and the corresponding engineering specifications. We then brainstormed and sketched a number of different concepts which attempted to satisfy these requirements. By combining the positive aspects of several different designs we produced an alpha design. Upon further feedback from Dr. Goldstein, we refined this into our final design. We visited the cath lab to take measurements of the operating bed and related equipment so we could properly represent the design through dimensioned CAD drawings.

Next, we began the prototyping process for our design. Unfortunately, we realized our final design was impossible to machine using the resources available to us. We modified our design by simplifying the housing shape while keeping the important geometry intact. This allowed us to prototype the design using flat polyethylene pieces, aluminum bar stock, and memory foam blocks. The housing was machined in many different pieces, requiring assembly once they were finished.

Our completed prototype was tested in a cath lab at Beaumont Hospital. It attached securely to the operating table and adequately supported one's arm during brief testing. The prototype was praised for being comfortable and for its range of motion. However, the linkage connections and housing support were not as strong as desired, and the prototype was heavier than it needed to be. Based upon these findings, several improvements could be made to our current design. Some of these improvements would require more time and better facilities, while some were oversights on our part that could be easily corrected.

In conclusion, we feel that our design is a good foundation for a vital signs acquisition device, and fulfills the main customer requirements. We are pleased with what we have accomplished during a semester's worth of work under the constraints of the project. We would like to thank Dr. Goldstein for his sponsorship of this project and hope he is pleased with the progress on his idea.

Introduction

William Beaumont Hospital, in Royal Oak, Michigan, is one of the nation's largest and most advanced hospitals. Here and throughout the country, countless individuals spend time recovering in hospital beds. The vital signs of these patients must be constantly maintained and updated. Under the current system, this means that the patient's pulse, blood pressure, and blood-oxygen content must be manually measured by a nurse several times a day. These measurements are then recorded by hand onto a medical chart. As it is now, this process is inefficient, prone to errors, and most detrimentally, disturbing to the resting patient, who will often awake during the measurement process. Additionally, patients in cath lab operating rooms will commonly move their hands while anesthetized, touching sterile areas and interfering with the procedure.

The goal of this project was to resolve these issues by designing a self-contained, automatic vital-signs acquisition device. This device is able to attach to the hospital bed or operating table, and will interact directly with the patient's arm. The patient's comfort was our first priority – the device is designed to be as unobtrusive as possible. While not providing forceful restraint, the device locks in place, discouraging operating room patients from moving their hands about. In the end, we think our design may greatly improve the vital signs acquisition process.

Engineering Specifications

Many customer requirements were taken into consideration during the design of our device. The most important requirements are that it provides accurate readings and is comfortable to the patient. These requirements are the central focus of our design. To ensure accurate measurements, we designed mechanisms to keep the sensors in their specified locations, relative to the patient's arm. The inner casing was lined with a material that is smooth, soft, and maintains a comfortable temperature, in order to allow the patient to rest comfortably while wearing it. Other requirements included its durability, fixture strength, cost of manufacturing, the ability to be cleaned and removed, and the ability to house any size arm. We chose materials that positively impact each of these requirements. The design was intended to be durable, strong, cheap, light so it can be removed, have unobtrusive wiring so that the wires do not interfere with the doctor, patient or imaging machine, and easily cleanable without causing damage to the housing.

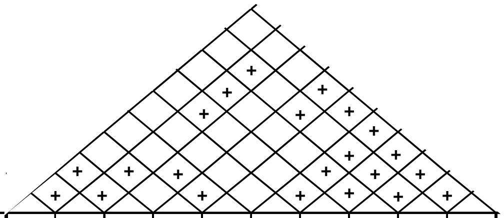
A QFD was used to rank the importance of the customer requirements and design specifications. The QFD for our proposed device is seen in Figure 1. The left column lists all of the customer requirements with the column next to it rating their normalized importance with 1 being high importance and 0 no importance. The top row lists all of the part characteristics. A number was allocated to every box in each row and column corresponding to the relationship between each customer requirement and part characteristic. After the numbers were assigned each row was totaled and multiplied by the relative weight value. This gave us a ranking of the most important customer requirements. In addition, each column was totaled by multiplying the rating number by the relative weight value in corresponding row and summing vertically. This gave us a ranking of the most important part characteristics.

Our specifications were gathered from a number of sources, because there is no known existing item on the market similar to our vital signs acquisition device. Therefore, our specifications were broken into component pieces and researched individually. For instance, the competitor sensor errors were determined from a different source than the dimensions of the competitor restraint system. Ideally, our product specifications should meet or exceed the combined specifications of any other commercially available individual products of comparable price.

The internal temperature target is 22 °C, roughly room temperature. The cath lab rooms are kept cool to optimize computer equipment and keep the doctors comfortable. Therefore, any insulating material to keep the patient's arm warm will suffice. The internal diameter, length, width and height of the housing are based on approximate dimensions of the human arm, and were chosen to meet the needs of a majority of the adult population. Our device sensor error should be no more than 2.5%, which is comparable to existing manual sphygmomanometers and pulse oximeters. The fatigue lifetime was aimed at 50 years, which would certainly exceed any durability expectation from the customer's perspective. The manufacturing and development cost was limited by the budget of this project, set at $400. The weight of the device should be no greater than 10 kg so it can be easily attached, removed, and carried by most anyone. Finally, we hoped to achieve fixture strength of at least 450 N, meaning that the patient would have to exert a single arm force of 100 pounds to dislodge the device from its support. Other components of our design, such as the pin joint locks and the housing should also be able to withstand a considerable force, but assigning more numerical values was not necessary because the goal of the device is not to forcefully restrain the patient but rather create a device which is both pleasing to the touch and guards against compulsive arm movements. However, high fixture strength would be useful to restrain quick, perhaps involuntary movements, especially from large, strong patients.

Figure 1: QFD

1	**Not related**
3	**Weakly related**
5	**Neutral**
7	**Moderately related**
9	**Strongly Related**



	Part Characteristics **Customer Requirements**	**Normalized Importance to Customer (Relative Weight)**	Internal Temperature	Internal Diameter	Sensor Error	Fatigue Lifetime	Manufacturing & Development Cost	Length	Width	Height	Weight	Fixture Strength/Position	**Total - Customer Requirements**	**Rank**	**Current Model**	**Competitor**
USER-PERCEIVED QUALITY	Patient Comfort	**1.0**	9	7	1	2	2	6	6	6	1	4	**44**	**2**	4	4
	Adequate Strength	**0.6**	1	1	1	6	7	1	1	1	4	9	**19.2**	**5**	1	1
	Accurate Vital Sign Measurements	**1.0**	7	5	9	5	6	3	3	3	1	4	**46**	**1**	7	9
	Durable	**0.8**	1	1	5	9	6	2	2	2	5	8	**32.8**	**4**	5	7
	Removablilty	**0.5**	1	1	1	4	2	1	1	1	8	9	**14.5**	**7**	9	9
	Inexpensive	**0.2**	3	1	7	2	9	1	1	1	3	5	**6.6**	**9**	9	1
	Accommodation For Different Arm Sizes	**0.9**	1	9	7	1	1	7	7	7	1	5	**41.4**	**3**	9	9
	Ease of Cleaning	**0.8**	1	3	1	3	1	1	1	1	3	5	**16**	**6**	9	9
	Unobtrusive Wiring	**0.6**	1	1	5	1	1	1	1	1	1	2	**9**	**8**	2	2
	Ease of Manufacturing	**0.1**	1	2	4	3	7	3	3	3	2	7	**3.5**	**10**	9	9
	Units		**°C**	**cm**	**%**	**yrs**	**$**	**cm**	**cm**	**cm**	**kg**	**N**				
	Now		22	7.96	3.2	50	195	30	14.6	14.6	n/a	n/a				
	Competitor		22	11.9	2.5	50	8425	20	24.1	24.1	n/a	n/a				
	Target (Plan)		22	11.5	2.5	50	400	60	22	22	10	450				
	Total		20.9	25.4	27	24.4	22.8	19.9	19.9	19.9	17.1	35.7				
	Rating (%)		9%	11%	12%	10%	10%	9%	9%	9%	7%	15%				
	Ranked Importance		**6**	**3**	**2**	**4**	**5**	**7**	**8**	**9**	**10**	**1**				

Engineering Requirements
- Material used must be comfortable, affordable and durable
- Housing must movable and fixable to accommodate for different arm positions
- Housing must be a proper length, width, and height in order to fit different size arms
- Sensors must be placed to give accurate readings
- Device must be removable from its bedside position
- Wires must be connected in an efficient, organized manner

Concept Generation

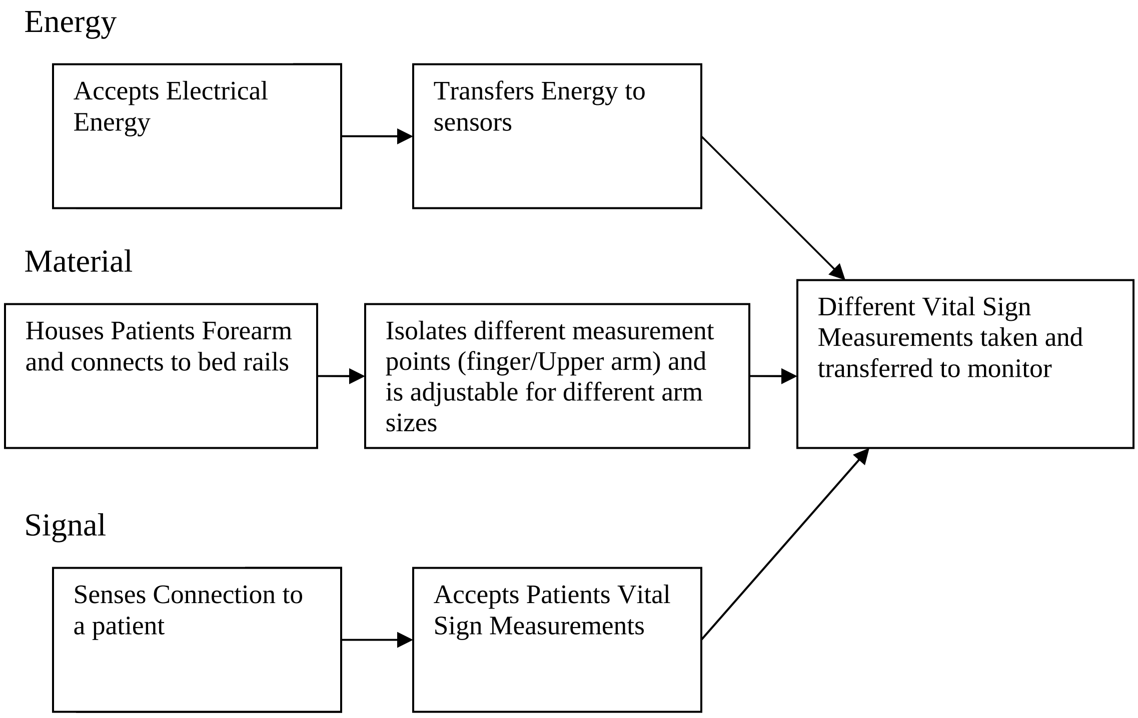
The concept generation process consisted of several brainstorming sessions, conducted both individually and as a group. During these sessions, we outlined the following list of design problems to focus on:

- *How much of the patient's arm will be enclosed by the housing?*
- *Where will the housing attach to the hospital bed?*
- *How will the housing accommodate various arm sizes?*
- *How will the housing be positioned to allow for comfortable arm placement?*
- *How will the housing incorporate the various measurement devices?*

We then attempted to qualitatively answer these in as many ways as possible, through idea generation. We then created a number of design concepts which incorporated several ideas, and graphically represented them through the use of sketches. We narrowed these concepts down to 5 major designs, as described in the following section.

We also created a functional decomposition, showing the energy and signal transfers in the system. Our concepts were designed to accommodate these transfers in an efficient and reliable manner.

Figure 2: Functional Decomposition



Concept Descriptions:

The following section describes in detail 5 major design concepts, which were created following our group brainstorming sessions. These designs were selected because they incorporate a wide range of possible features, and are considerably different from each other. We also felt these designs were the most "fleshed-out," that is, the closest to being usable as a true alpha design. It is these 5 designs that were put through the concept selection process, which is detailed in the following section. Sketches and brief descriptions of all our brainstormed designs, including the 5 detailed below, are located in Appendix A on pg. 18.

Concept 1: "Thor"

This design consists of a single, fixed support and two enclosed housings: one for the upper arm, and one for the lower arm. The area around the patient's elbow is open to allow for air flow. The fixture joining the two cylindrical housings is slightly "bent" to create a natural position for the arm to rest in. This concept would be attached to the bed by hooking over the side-rails. A thin, flat segment would also be placed under the table cushion, and would be firmly in place by the weight of the patient. This design is quite simple, in that it has no moving parts and has a fixed position and orientation.

Concept 2: "The Eel"

This concept features an enclosure for both the upper and lower arm, connected to each other with a ball joint. This allows the upper arm housing to be adjusted to comfortably accommodate different patients. A hinged arm enclosure is also included in the design, allowing for easy insertion and removal of the patient's arm, as well as the ability to easily clean or replace the interior lining. This design would be attached directly to the side of the operating table through the use of clamps.

Concept 3: "The Enclosure 1"

This design is notable for its use of a double-hinged arm enclosure. Hinges are placed on the left and right sides of the enclosure, allowing the patient to insert their arm through the top. The sides are then securely latched into place, allowing for an adjustable yet secure fit. This concept would be attached to the table either with clamps or with a flat, under-the-cushion segment.

Concept 4: "The Dishwasher"

"The Dishwasher" is so named due to its wheeled rollers, which would allow the housing to slide along the length of the bed, similarly to a dishwasher drawer. It would be attached to the bed side-rail, and when un-extended would sit at the patient's side. When in use, it will slide along rollers, and then lock in place. The arm enclosure can also rotate at a pivot point, allowing for custom and comfortable positioning.

Concept 5: "The Charlemagne"

This concept is unique in its use of a support beam, which would run from the operating table side-rail (where it is attached) to the patient's arm. This beam would pivot at two points, allowing for an extensive range of motion. The housing will enclose only the patient's lower arm, with the blood pressure cuff connected to it but open for easy access and adjustment.

Concept Selection Process

Our most basic concepts were generated individually, with our alpha design ultimately consisting of components from several independent designs. When evaluating the concepts generated by individuals, the group as a whole first considered whether the concept would adequately fulfill the most fundamental requirements of the device, checking to see if there were any obvious oversights. We then looked at the most important components of the device and compared our concepts. We discussed where to affix the device to the operating table, how to affix the device to the operating table, how the patient should put his arm into the housing, whether the housing should extend to the upper arm, how the device should accommodate patients of different heights and sizes, and where the sensor wiring should be located in the housing. To analyze the concept differences, we compared our five favorite complete designs using a concept scoring matrix. The devices were named "Thor", "The Eel", "The Charlemagne", "The Enclosure 1" and "The Dishwasher". We combined our favorite traits of each of these models, discussed in more detail below, into our alpha design These five concepts, along with our alpha design, called "Ramrod", are present in the weighted concept scoring matrix shown below in Figure 2.

Figure 3: Concept Scoring Matrix

Selection Criteria	**Weight**	**Concepts**													
		Current Equipment		**Ramrod**		**Thor**		**The Eel**		**The Charlemagne**		**The Enclosure 1**		**The Dishwasher**	
		Rating	Weighted Score	Rating	Weighted Score	Rating	Weighted Score	Rating	Weighted Score	Rating	Weighted Score	Rating	Weighted Score	Rating	Weighted Score
Fixture Strength	**0.10**	3	0.3	5	0.5	3	0.3	3	0.3	4	0.4	3	0.3	5	0.5
Removability	**0.05**	3	0.15	3	0.15	3	0.15	3	0.15	2	0.1	3	0.15	3	0.15
Vital Signs Accuracy	**0.20**	3	0.6	4	0.8	3	0.6	4	0.8	4	0.8	4	0.8	4	0.8
Patient Comfort	**0.15**	3	0.45	5	0.75	4	0.6	5	0.75	5	0.75	5	0.75	4	0.6
Patient Restraint	**0.15**	3	0.45	5	0.75	5	0.75	5	0.75	5	0.75	5	0.75	5	0.75
Inexpensive	**0.05**	3	0.15	2	0.1	2	0.1	2	0.1	2	0.1	2	0.1	1	0.05
Accommodation for Different Arm Sizes	**0.10**	3	0.3	5	0.5	2	0.2	4	0.4	4	0.4	4	0.4	3	0.3
Unobtrusive Wiring	**0.10**	3	0.3	4	0.4	3	0.3	3	0.3	4	0.4	3	0.3	3	0.3
Ease of Manufacture	**0.05**	3	0.15	2	0.1	2	0.1	2	0.1	2	0.1	2	0.1	1	0.05
Ease of Cleaning	**0.05**	3	0.15	2	0.1	2	0.1	2	0.1	2	0.1	2	0.1	2	0.1
Total Score			**3.00**		**4.15**		**3.20**		**3.75**		**3.90**		**3.75**		**3.60**
Rank					**1**		**6**		**3**		**2**		**3**		**5**

The scoring matrix considered ten of the most important product criteria from the perspective of the customer, many of which came directly from our QFD. These criteria were rated with a percentage of 0 to 100 depending on their estimated significance from the perspective of the customer. We assigned ten scores for each of the five designs corresponding to how well that design satisfied the customer requirements. These scores ranged between 1 and 5, with 1 being much poorer than the current equipment, 3 defined as approximately equivalent to the current equipment, and 5 being much better than the current equipment. The scores were then multiplied by the weights of the respective customer requirements and were added down the columns, resulting in a total score for each concept ranged between 1 and 5. The tentative alpha design, which incorporated the best aspects of the different designs, was later added to the scoring matrix, and its scores were similarly weighted and summed to confirm that it was indeed the best design.

All of our concepts significantly improved upon the datum in patient restraint, which the current equipment offers very little of. Also, with a choice of comfortable material and contouring inside the housing, all concepts would be much more comfortable than the plastic guard currently in use. Naturally, more complex vital signs acquisition devices would be more costly than the current guard to varying degrees, as well as more difficult to manufacture and more difficult to clean. Despite some of these universal findings, our concepts differentiated themselves in several different categories.

Thor offers excellent patient restraint due to its single piece upper and lower arm housing, but it would be difficult to adjust the blood pressure cuff and the location of the housing to accommodate for different arm sizes. Thor’s support relies on the patient’s weight for support, and thus its fixture strength and removability are on par with the current equipment.

The Eel uses the same support system as Thor and also encloses the lower and upper arm, offering good patient restraint but mediocre fixture strength. The ball joint near the elbow allows for improved movement between the upper and lower arm. The hinge in the upper arm housing allows for easier blood pressure cuff adjustments. However, it may be tricky to manufacture the housing to incorporate the ball joint and it would be difficult to find a way to lock the ball joint in place when placed in the desired position.

The Charlemagne has the best features to allow for change in housing position to accommodate for different arm sizes. Its three links and two pin joints allow for maximal range of motion, as the housing can move forward and backward, side to side, and rotate. The pin joints may be locked down with wing nuts when put in the proper position, so the design offers superior patient restraint and comfort. The Charlemagne does not extend to the upper arm, but rather has the blood pressure cuff exposed in order to allow for easy adjustments. The conduit through the housing will keep the wiring of both the blood pressure cuff and pulse oximeter much more organized format than the current equipment. As a negative, this design featured a fairly weak and time consuming method of fixture attachment where screw down clamps would be placed over the small metal cylinders connecting the rail to the operating table.

The Enclosure 1 also has roughly the same support system as the current equipment. Its best feature is the double hinged housing over the lower arm, which makes it very easy to insert and remove the patient’s arm from the device while maintaining proper patient restraint. This feature could also conceivably be adjustable to accommodate patients with different arm thicknesses.

The Dishwasher has the best fixture location of any of the designs, as it resides on the metal rails running parallel down both sides of the operating bed. This means it will have high fixture strength and could be made adjustable for patients of different arm lengths. However, the enclosure sliding on rails would be difficult to manufacture, difficult to secure, and could fatigue quicker or have defects due to the additional moving parts.

Ramrod, our alpha design, is an amalgamation of these other concepts. It uses the fixture supports from The Dishwasher for optimal fixture strength and position adjustability. It uses the three bar linkage and double pin joints from The Charlemagne in order to accommodate different arm lengths and arm resting angles. Ramrod also features the conduit through the housing from The Charlemagne, where the sphygmomanometer and oximeter wiring exits through the bottom of the housing. Finally, the alpha design incorporates the adjustable double hinged housing from The Enclosure 1 for easy arm insertion and removal. The interior of the housing will be lined with memory foam for patient comfort and proper fit.

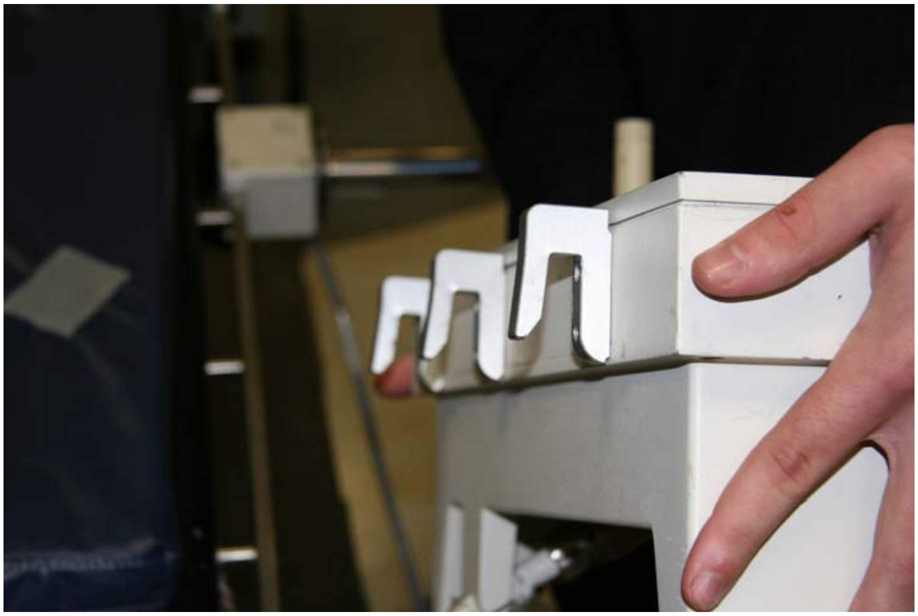
Despite all of the strengths listed above, Ramrod has some disadvantages. Because it rests on the railing, it needs to have a relatively long link to reach from the fixture location to the patient’s hand. This fact, in addition to incorporating the double pin joint system, will require more materials and a more demanding manufacturing process. The housing is not perfect either. Finding a material that may both rotate on a hinge and also be adjustable to accommodate different patient arm thicknesses may prove a challenge. Also, as of yet, there is no definitive decision on what, if any, interior or exterior contouring the housing should have to fit the patients arm. Right now it is represented as half a cylinder.

Nonetheless, we feel that Ramrod is our best concept. This is reflected in the concept scoring matrix, where Ramrod scored 0.25 points higher than its nearest competing design, and scored 1.15 points higher than the current equipment used at the hospital. Consequently, we are continuing forward with Ramrod serving as our tentative alpha design.

Alpha Design Description

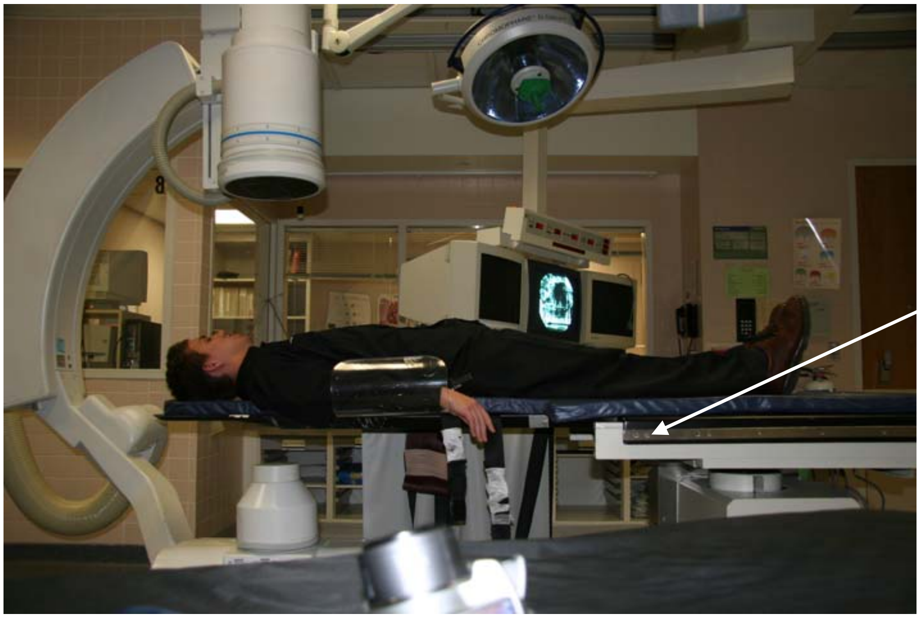
The alpha design “Ramrod” combined components from three designs into once concept. The device will be connected to the railing of the bed on hooks. These hooks will be similar to the ones found on other devices connected to the railing, as seen in Figure 4 below.

Figure 4: Connection Hooks



The connection points are located around the patient's knee as they lay on the table. This can be seen in Figure 5, with the white arrow pointing to the railing.

Figure 5: Operating Bed and Testing Equipment Layout



An aluminum linkage will extend along the bed rail up to a few inches short of the patient's finger tips. This linkage will attach via pin joint to another shorter linkage, which itself extends to the patients finger tip. Here the second linkage also connects via pin joint to the main housing. These pin joints will allow the housing to be rotated to different angles, as well as be translated forward and backward, and side to side. This feature should allow a patient to relax in the most comfortable position depending on their body type. The main housing will have a rectangular base 8-10 inches long and roughly 4 inches wide. This should be large enough to hold any patient's forearm. The patients arm is enclosed in a semi-cylindrical cover around 3 inches in diameter. Soft foam will be placed on the inside of the housing to provide more comfort and a secure fit. The cover will attach to the housing bottom by two hinges. These hinges will allow the cover to open outward on both sides so a patient may slide their arm into position before the cover is closed. The cover will then be locked in place by an adjustable latch so that the arm is secured. The housing will fit snugly around the patient's arm in order to offer adequate restraint and keep the patient's arm warm. In all, the housing will enclose the arm between mid-finger and mid-forearm. This allows a pulse oximeter to be placed onto the patient's index finger. The blood pressure cuff will be attached and adjusted on the patient's exposed upper arm. The wire and tube from the blood pressure cuff will run down the patient's arm to wrist level through the foam on the inside of the housing. The wire from the oximeter will travel to wrist level through the foam. The bottom of the housing will have a small hole at this juncture so that these wires can run down and out through the base of the device and under the bed to the readout monitors. The preliminary CAD drawing is shown in Figures 6a-d.

Figure 6a: Alpha Design Model (Top View)

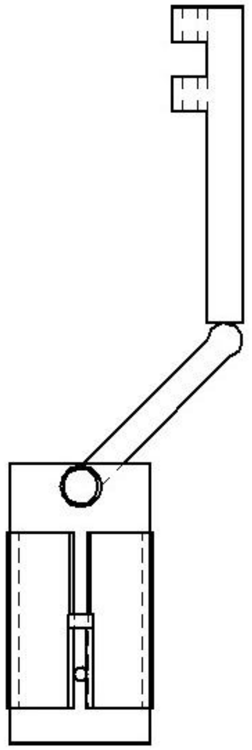


Figure 6b: Alpha Design Model (Front View)

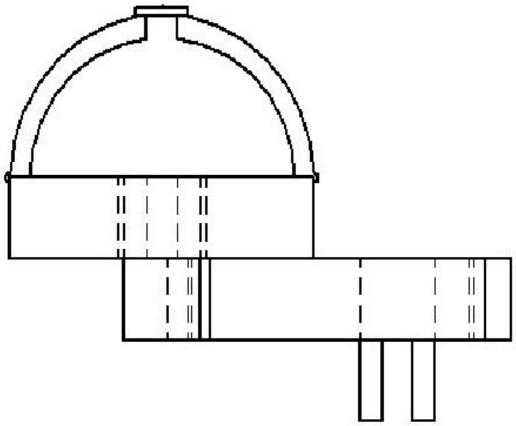


Figure 6c: Alpha Design Model (Side View)

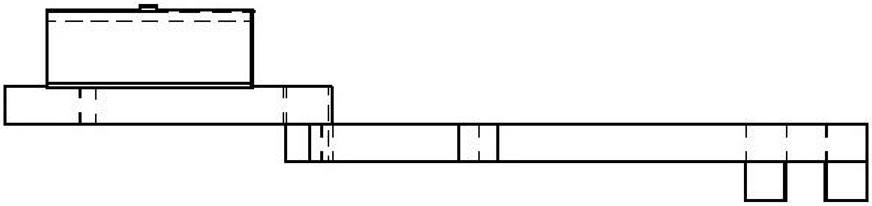
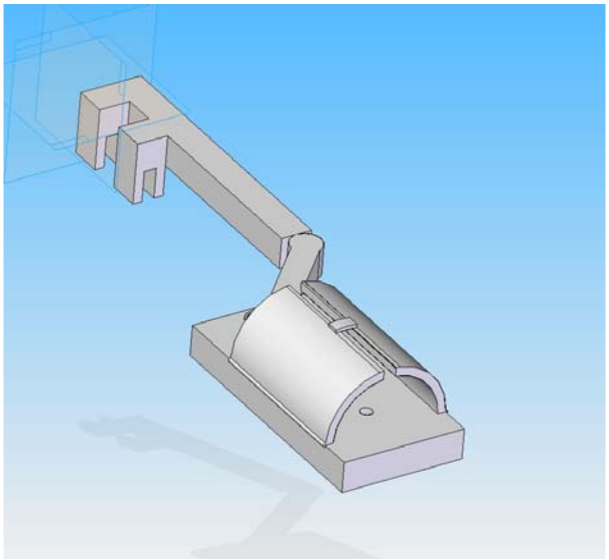


Figure 6d: Alpha Design Model (Isometric Rendering)



Changes to Alpha Design

Upon receiving feedback from Dr. Goldstein and making additional observations in the cath lab, we made several important changes to our alpha design to reach our final design. The housing was deemed to be not aesthetically pleasing; it resembled a restraining device. For legal reasons and patient comfort, the housing was redesigned to look more ergonomic and pleasing. Also, the housing was closed off around the fingers at the suggestion of Dr. Goldstein. The pulse oximeter will be integrated completely inside the housing. The fixture at the operating bed rail was combined from the two smaller hooks shown above to a single slot that uses a large set screw to fix it in place. This change was adopted after seeing a radiation shield attached to the rail using a similar fixture in a cath lab. Finally, we concluded that the middle linkage would be best situated at a right angle to the linkage attached to the rail, thus allowing for both clockwise and counterclockwise rotation of the middle bar without the housing being impeded by the bed.

Design Parameter Analysis

The dimensions of the connecting linkages were determined by taking measurements of the operating bed. We also considered the position of the patient when lying down on the table. The first linkage is 18” long and travels parallel to the side of the bed to just short of the patient’s finger tips. Because the end radii of the two linkages are 0.5”, the fixture bar is 17.5” long from its end to the pin joint. The second linkage connects the first linkage and housing and is able to rotate and lock in place. This middle linkage is 4.425” long from pin joint to pin joint so that the housing fits closely against the side of the bed. The second bar sits on top of the first bar, while the housing connects below the second bar. This means that the housing sits on the same vertical plane as the first bar, and therefore the patient’s arm will rest at bed level.

The housing consists of three separate pieces that fit together. These pieces were dimensioned using typical sizes for a hand, wrist and forearm. Taking these parameters into consideration we determined the length, width, and height for the hand, wrist and arm portion. For simplicity and ease of manufacturing, we decided the housing should have a flat base and be symmetrical along its length. The thickness of all three pieces is 0.375”

The first piece is a tapered half cylinder that surrounds the patient’s forearm, with internal radius decreasing from 3” at the opening to 2.25” at the wrist. The forearm enclosure is 7” long from the wrist back up the arm. The enclosure increases in radius from the wrist back towards the patients elbow to follow the natural shape of the forearm. The dimensions of this piece should provide enough room for different sized arms and will also allow the foam to fit on the inside without interference to the patient.

The second piece is another tapered half cylinder that encloses the back of the patient’s hand, re-expanding from a 2.25” radius to 3” around the knuckles. The third piece is a quarter-sphere that surrounds the patient’s fingertips and has a 3” internal radius. The second and third pieces combine to form the hand housing from the wrist up to the fingertips. The total length of these sections is 9”, which would provide enough room for long fingers while not being prohibitive for those with short fingers. Depending on the patient’s finger length, they can slide their hand forward or backward over a limited range to reposition their wrist relative to the housing. The internal width was chosen to be 6” maximum for the hand, which would provide enough room for the patient to stretch their fingers if desired. The device was made most narrow at the wrist to provide some resistance when the patient inserts or removes his hand from the housing. Also, the housing features no sharp edges or latches in order to make it visually pleasing.

The inside of the arm housing will be lined with foam. This will be done to provide patient comfort and account for a range of arm and hand sizes. The foam will be 0.5” thick in the hand portion and 1” thick in the forearm portion. This will effectively reduce the inner diameter and make the patient’s arm more secure.

The housing that encloses the arm and hand will be made out of plastic. This is a radiolucent material that will not interfere with the medical imaging equipment during operations. It will also provide adequate strength to support the patient’s arm. The linkages will be made out of aluminum. They will be strong enough to support the arm with only one connection to the bed.   Both materials are light so that they can be removed easily if necessary. Also, both materials are durable and can be easily cleaned.

Final Design Description

The final design consists of three main components: the railing attachment, the arm housing, and the bar linkages connecting them. Dimensioned drawings of these components are shown in the figures below, as well as a 3D view of the entire design.

Figure 7: Railing Attachment

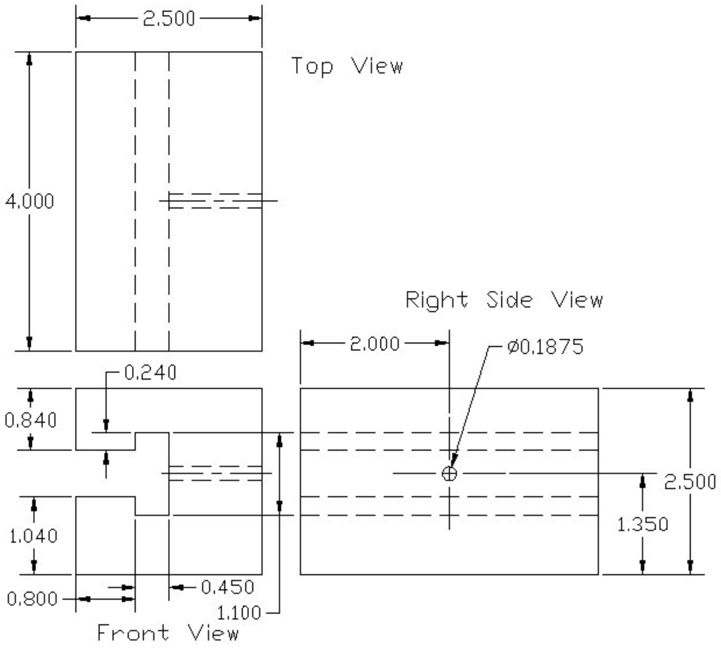


Figure 8: Arm Housing

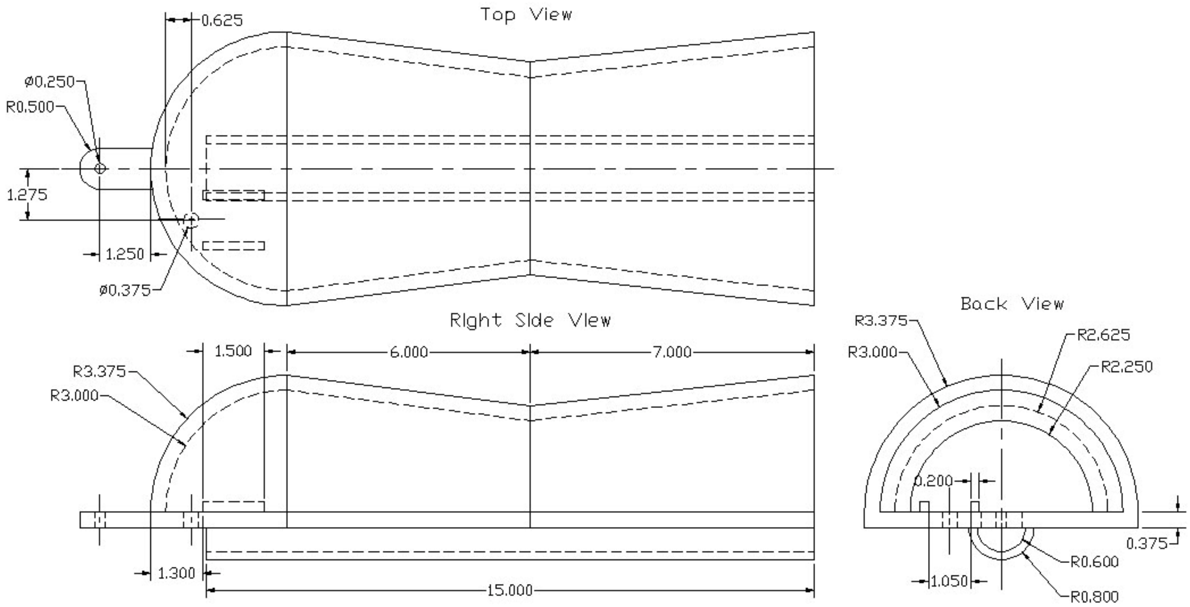
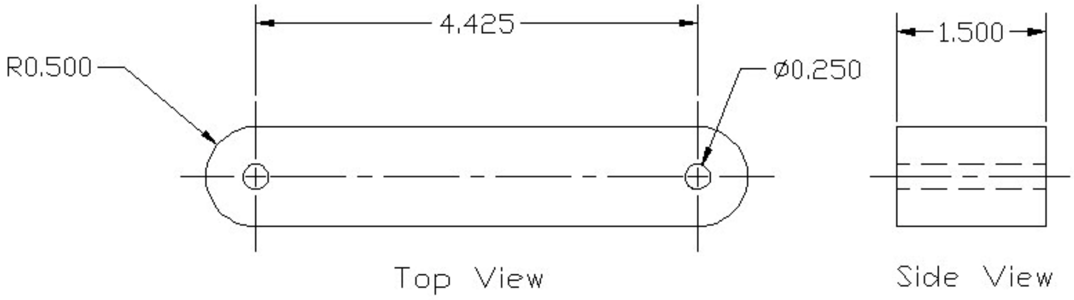
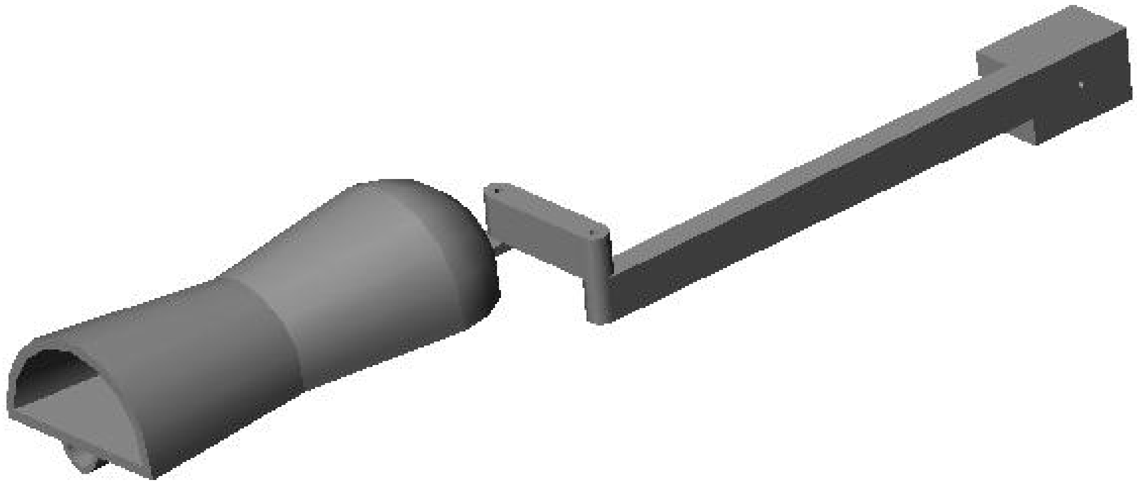


Figure 9: Bar Linkage



Note: Long bar measures 17.5″ from end to pin

Figure 10: 3D Rendering of Final Design



The railing attachment is where the device connects to the side rail of the operating table. It will slide onto the railing, where it will be secured using a screw-in clamp (similar to a set-screw.) This should provide a stable fixture which is also easily adjustable if necessary.

The arm housing serves to contain and support the patient's lower arm while using the device. It has a 6" internal diameter, semi-circular opening where the patient inserts their arm. The housing narrows down to 4.5" internal diameter to match the shape of the patient's lower arm. The housing then expands to its 6" internal diameter again, and ends in a quarter-spherical enclosure. This is the area that the patient's hand will occupy. Note that these dimensions are for the outer "shell" of the housing, which will consist of molded thermoplastic. There will also be a memory foam lining in the interior of the housing (not pictured in the CAD drawing), which will reduce the effective size of the arm opening. The housing interior also contains a slot in which the pulse oximeter will be mounted, and a hole for the sensor's cable to run through. The underside of the housing has a small enclosure for the sphygmomanometer cable, which will run from the cuff on the patient's arm to the front of the arm housing. The arm housing connects to the short bar linkage at the pin joint at the front of the housing.

The two bar linkages are similar to the ones outlined in our alpha design. However, we have changed the geometry by shortening the second bar linkage. When the housing is in its neutral position (flat against the side of the operating table,) the second linkage will be at a right angle to the first linkage and the arm housing. Thus, the housing will be able to translate both backward and forward from its neutral position. As before, the pin joints of the bar linkages will be able to lock in place through the use of a wing nut. The bar linkages will be made of aluminum, and the long bar linkage will be rigidly attached to the railing attachment (welded, or even fabricated of the same piece of aluminum).

Engineering Changes

Several changes were made to our final design prior to the prototype manufacturing process. These changes were made to facilitate the manufacturing process while retaining the vital functionality of the prototype. As it is, the final design would be impossible for us to manufacture personally in the ME X50 machine shop – for instance, the entirety of the arm housing would require a 5-axis mill to be machined. Given the budget constraint for the project, we decided against outsourcing the fabrication of the prototype. Thus, we decided to modify the final design, making it easier to machine while leaving its functionality largely unchanged. We believe we were justified in making these changes, because our goal was to have a functional, testable prototype – not necessarily an exact fabrication of the final design. Engineering drawings of the modified prototype design are shown in Figures 11a-12c. The engineering changes are labeled by letter on these drawings, corresponding with the following list with descriptions of these changes.

Figure 11a: Prototype Arm Housing (Top View)

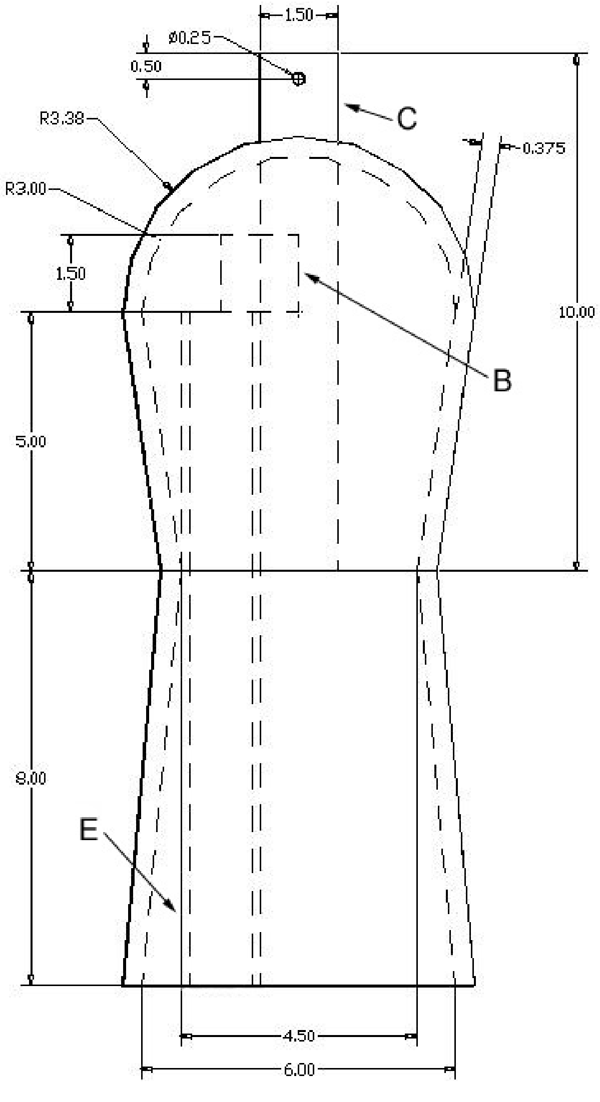


Figure 11b: Prototype Arm Housing (Front View)

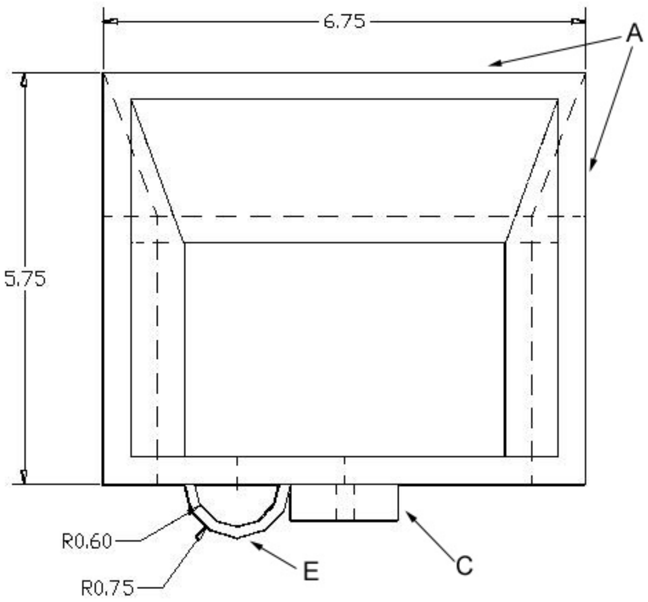


Figure 11c: Prototype Arm Housing (Right Side View)

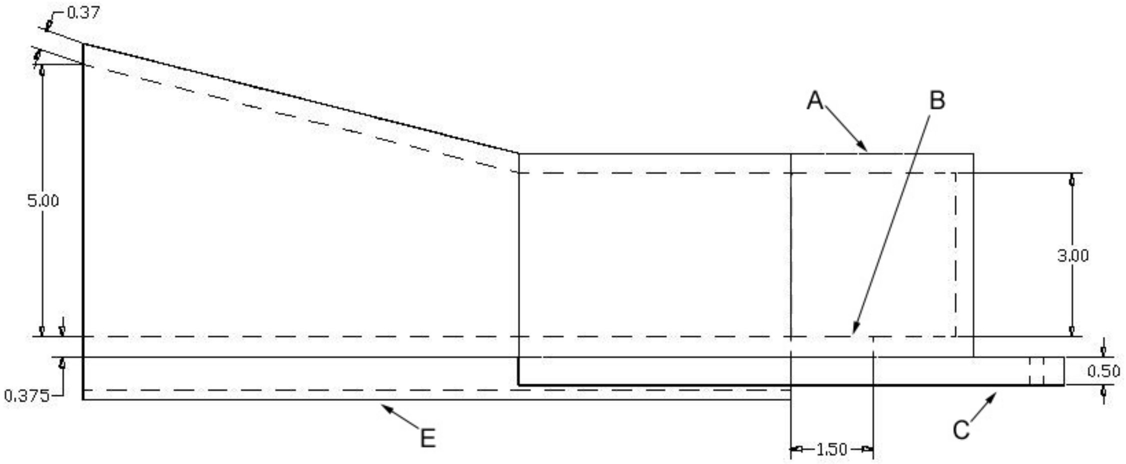


Figure 12a: Railing Attachment and Linkages (Top View)

Figure 12b: Railing Attachment and Linkages (Front View)

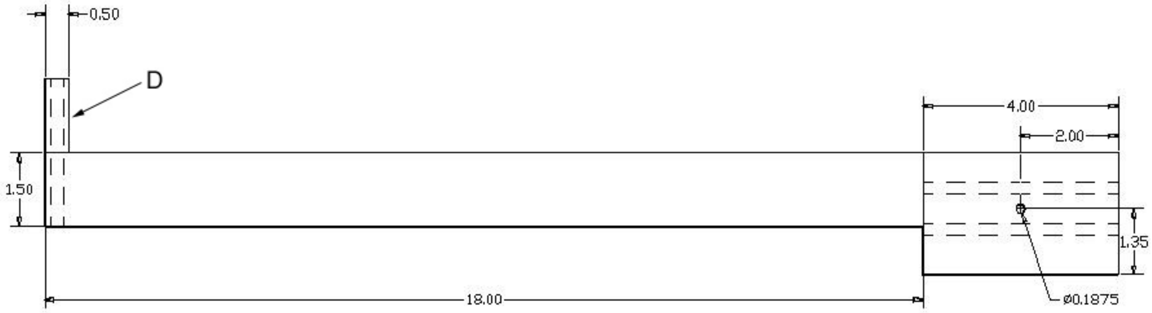
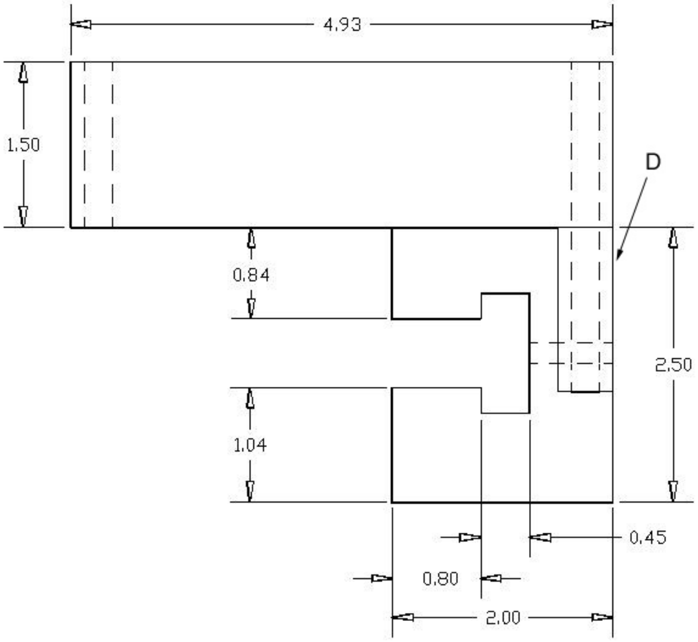


Figure 12c: Railing Attachment and Linkages (Left Side View)



List & Descriptions of Engineering Changes

A) *Sides of Arm Housing*: The sides of the arm housing were changed from semi-conical (semi-circular cross-section with varying radius) to flat panels. This allows the arm housing to be cut from a flat sheet of 3/8” thick polyethylene, as opposed to a complicated 5-axis mill process. Note that the width of the housing is consistent with our final design: the opening has a width of 6”, which narrows down to 4.5” and expands back to 6”, ending with a 3” radius semi-circular enclosure.

B) *Opening for Pulse Oximeter*: In the final design, the pulse oximeter opening is just large enough for the cord, forcing the oximeter to be permanently installed in the arm housing. To allow us to insert a pulse oximeter during testing, we expanded this opening to a 1.5” square. This opening is covered by the memory foam lining, so a slit was cut in the foam, allowing the oximeter to be inserted and removed easily while preventing it from falling out during use.

C) *Arm Housing Support Bar*: A 1.5” by 0.5” by 10” aluminum support bar was added to the underside of the prototype arm housing. This is where the bar linkages attach to the front of the housing, as opposed to an extended piece of plastic. This was added to increase the stability and strength of the prototype – the housing is comprised of multiple pieces of thick, dense polyethylene, and there were concerns that it would be unable to support itself. The production model of our design would be injection modeled out of a lighter, thinner thermoplastic, and this support would be obsolete.

D) *Width of Linkages and Railing Attachment*: The width of the bar linkages was decreased from 1” to 0.5”. This was done to accommodate the materials available to us – one of the group members had access to 1.5” by 0.5” aluminum bar stock. The width of the railing attachment was also decreased by 0.5”, to keep the railing-linkage geometry consistent. The ends of each bar were also changed from rounded to flat, for the sake of easier machining. These rounded edges were largely for aesthetic purposes, and do not affect the performance of the prototype.

E) *Sphygmomanometer Cable Conduit*: The diameter of the sphygmomanometer cable conduit on the underside of the arm housing was changed from 1.6” to 1.5”, to accommodate the available materials, namely 1.5” diameter PVC piping. This slight change will not negatively affect the prototype performance; the conduit is still wide enough to house the cable. Also, due to the addition of the housing support bar, the location of the cable conduit was changed – it is now located directly to the left of the support bar, and runs the length of the housing up to the pulse oximeter opening.

Manufacturing Plan

The manufacturing of the prototype involved machining and assembling two primary components: the housing, made of polyethylene, and the linkages and fixture, made of aluminum.

Housing

The housing is divided into 12 easy to machine pieces. The top and bottom are comprised of three separate pieces each, while the side walls consist of five pieces. The top pieces were cut to shape from a sheet of polyethylene using the band saw. They were then milled down to proper thickness to ensure the pieces were even and the edges were square. The bottom and side wall sections were machined in the same fashion. For both the bottom front and middle sections, two ¼" holes were drilled into the material using the mill. These are needed in order to attach the housing to the arm housing support bar. The semi-cylindrical front wall was machined using a CNC 5-axis mill. The conduit running along the bottom of the housing was machined out of 1.5" diameter PVC tubing. The tube was cut to size and then cut in half lengthwise using the band saw and filed to produce a flat surface.

Fixture/Linkages

The fixture piece was ordered already cut to size. The opening at the back of the fixture was milled to the depth where the slot begins using an edge mill. The slot for the operating bed rail was then machined using a slot cutting tool. A ¼" hole was drilled through the front of the fixture where a screw-in clamp is used to lock the device to the bed rail.

The first linkage running parallel to the bed was made from a bar of aluminum which was ordered to the proper dimensions. It was welded to the fixture to form a single solid support. A ¼" hole was drilled in the end farthest from the fixture. This allows a ¼-20 screw to fit through the hole and into another threaded hole on the second linkage below.

The second linkage, which runs at a right angle from the first linkage towards the bed, was also made from a bar of aluminum ordered to proper dimensions. Holes were drilled and threaded on each end of the linkage.

The arm housing support bar was also made from aluminum. This bar was cut to length from spare aluminum using a band saw. A hole was drilled and threaded through the end of the bar that connects to the second linkage. Two other holes were drilled through the bar so the connector piece can be attached to the housing.

All pieces were sanded using a file and sandpaper in order to eliminate all sharp edges and excess material. The aluminum pieces were polished for aesthetic purposes. The polyethylene and PVC pipe were roughed up using 120 grit sandpaper and then primed and painted (using spray paint) before assembly. Memory foam was cut to shape using templates and a utility knife and then glued to the interior side of the pieces. The pieces were aligned and glued together using quick-grip and wet/dry epoxy to form the complete housing. Once assembled, the housing was once again painted and a clear coating was applied to keep the paint from peeling.

Test Results

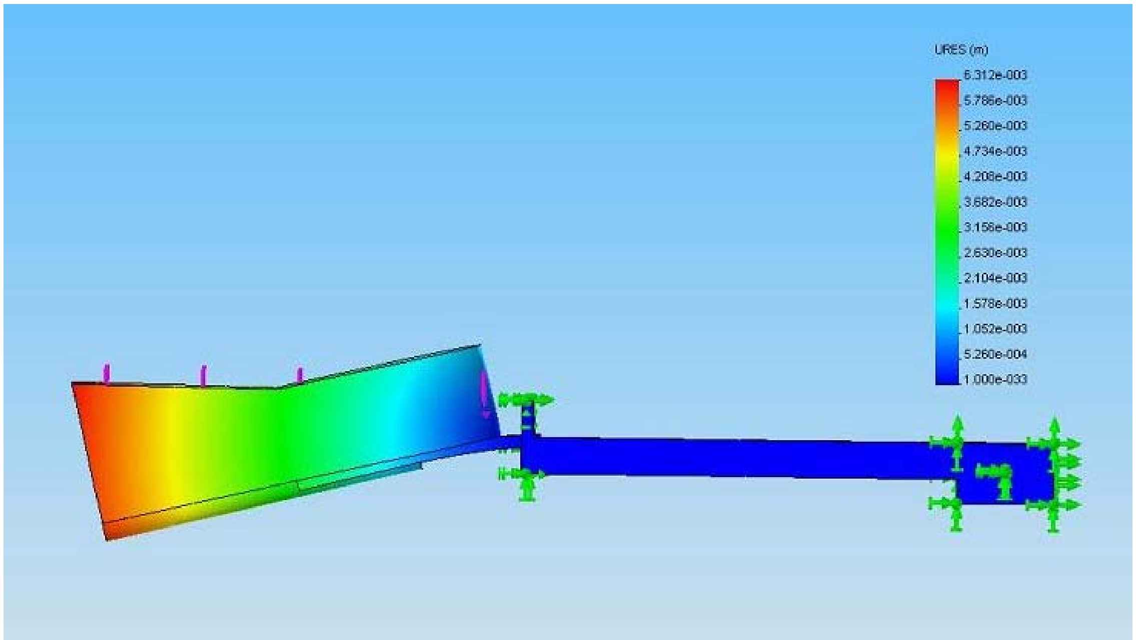
Our final design was validated primarily through the use of a functional prototype. The prototype was not an exact representation of the design we had in mind, but was nonetheless close to it and demonstrated the important characteristics of our design so as to be legitimate as a working model. We took the prototype to Dr. Goldstein's office to be critiqued and tested in the cath lab.

On the whole, the prototype performed adequately during its brief testing. The fixture piece did not fit onto the railing in the first cath lab we went to, but fit well onto the railing in a second cath lab. This means that the bed railing is not consistent in all cath labs, and the current design may only fit onto some of the cath lab beds. Once attached to the proper size bed railing, the fixture was more than strong enough to support the entire device. The fixture was easily adjustable by just loosening the set screw and sliding it, but ran into a range of motion problem when it was obstructed by nuts protruding from the bed rail's base.

The geometry of the linkages was correct in that it left the device flush against the bed while in a neutral position, but ultimately the housing sat too low. The prototype was usable in its current form but would optimally have been raised about two inches. The mechanics of the prototype allowed for the desired range of motion, allowing both the short linkage and the housing itself to rotate. The size of the housing was adequate for its purpose. It was large enough to allow bigger people to fit their hands through the wrist narrowing while still providing a sense of enclosure and passive restraint.

The ½" thick linkages with ¼" screws were strong enough to support the patient's arm, but both would ideally be thicker, as there was some shear deflection at the pin joints when a force was applied. The housing itself was quite sturdy despite having been glued together out of eleven different pieces. We were somewhat gentle with the prototype as we did not want to damage it, so we used SolidWorks to simulate the application of stronger forces on our final design. A force of 70 lb pushing down uniformly on the housing causes a maximum deflection of 6.312 mm at the forearm end of the housing. This deflection is shown exaggerated in Figure 13 below. This is an acceptable deflection, and the design would be able to withstand comparable forces in the lab without the threat of failure. In reality, our prototype would deflect considerably more than this due to inexact machining, but this analysis was nonetheless useful in validating our final design.

Figure 13: Deflection of Housing Under a Uniform 70 lb Load



Many of our design criteria were qualitative rather than quantitative, and none more so than the aesthetics of the device. Dr. Goldstein seemed content with the general design of the housing, but its overall aesthetic appeal is too subjective to interpret a definitive result. Also, our final design would ideally look much sleeker than the model. However, everyone who tested the device, including Dr. Goldstein, a cath lab technician, and ourselves, thought the memory foam lining was very comfortable and inviting.

The pulse oximeter fit properly through the square hole in the bottom of the housing and through the slit cut into the memory foam lining at that same location. We needed to remove the aluminum connector piece, though, as it partially obstructed the opening in the housing. The conduit on the bottom appeared large enough to accommodate the sphygmomanometer wiring, although the doctor told us this was of secondary importance.

Discussion

In retrospect, there are many improvements which could be made to our design and our prototype. Some of these improvements would require a larger budget and better prototyping facilities, but some improvements could be made by others in our same situation, using our hindsight as guidance.

The most significant changes would be made to the design of the arm housing. Our final design had a housing composed of semi-conical segments of varying radius. However the wrist opening was too small in height to accommodate for patients with larger arms. Ultimately, the semi- conical design was not a good choice because the anatomical structure of the human forearm is more akin to a full cylinder than half of one. The prototype housing was not perfect either. Because of limited manufacturing facilities we decided to build our housing out of eleven different pieces, all but one of them flat. Consequently our housing had sharp corners and little ergonomic contouring. This method also resulted in the pieces being glued together and creating seams in the housing which produced a somewhat unpolished finish. For commercial production, we'd have a modified take on our prototype as a final design. It would still keep the vertical walls and semi-circular front, but would either incorporate filleted edges with a flat top or shorter vertical walls with a rounded top. This was not really possible for our prototype due to the limited degrees of freedom for the mills available. Ideally the device would be injection molded. Injection molding, or any method that does not require gluing, would also allow for a reduced thickness of the housing, therefore reducing the device weight.

Future designs could also incorporate some sort of finger separation at the front of the housing. This would also provide a mechanism to keep the pulse oximeter properly aligned with the index finger. The method of feeding the pulse oximeter through the bottom of the housing suffices, but a future design would need to relocate or reshape the connector piece so it does not need to be removed to insert or remove the pulse oximeter.

The housing could be raised to an optimal bedside position simply by changing the height of the bars and/or by connecting the housing to the top of the second linkage instead of beneath it. Dr. Goldstein discussed being able to raise or lower the device vertically to accommodate different patients. However, this would require the addition of a new mechanism that was not considered for our designs. Dr. Goldstein also suggested welding the long bar linkage to the bed side of the fixture, shortening the long bar and aligning the second bar to angle in toward the bed. We considered this geometry in our early designs. It would reduce the practical range of motion of the housing (without moving the fixture), but would beneficially reduce the profile of the device.

The fixture could be made to fit different size railings by being made of two separate pieces instead of a single piece. Each half of the fixture could have a shallow slot milled into its surface and would enclose around the bar. Screws through the top and bottom of the fixture would allow for the thickness of the slot to be adjusted so suit the bed railing. This fixture would be more difficult to attach and remove because it would require multiple screws to be tightened rather than just one. An easy alteration that could be made is to reduce the thickness of the back, or open end, of the fixture so that it is not obstructed from sliding by the nuts on the bed railing.

Each individual element of the device, i.e. the fixture, the linkages and the housing, was strong enough, but the connections need to be improved before any real application. Thicker bars would allow for the use of thicker screws and would also increase the contact area between the two bars. We could also look at using a connector piece with an even larger surface area to provide more support to the front of the housing.

Despite all of the potential for improvements, there were many successful aspects of our prototype. The memory foam lining on the inside of the housing was very pleasing to the touch. The interior of the housing was correctly proportioned to accommodate large arms without creating a sense of restraint while not being too cavernous for smaller arms. The slot was machined well to accommodate the rail size we had measured. Finally, both the pulse oximeter opening and the sphygmomanometer conduit fulfilled their requirements.

Recommendations

We believe that our design is quite successful in creating a comfortable and secure interaction with the patient's arm and the operating table. However, there are a number of improvements that can be made, and additional development time would likely result in a much-improved final product. To begin with, the improvements discussed in the Discussion section should be implemented. Also, the integration of the sensory equipment with the design should be refined. At the moment, the pulse oximeter is crudely placed within the arm housing, and is not mounted or supported in any way. We were unable to implement such a support into our design because we had no access to a pulse oximeter outside of Beaumont Hospital. We recommend that Dr. Goldstein provide a future team with a pulse oximeter at the beginning of the semester, assuming the project will be continued. Finally, we think that an accurate model of the final design should be fabricated using the exact materials and dimensions to be used during production. This can be outsourced to a prototype production company, and would allow for a detailed stress-strain analysis of the prototype. In summary, we think that our design is an excellent groundwork which should be built upon and refined prior to being manufactured as a commercial product.

Conclusions

At first glance our project appeared to be relatively straightforward. However, as no comparable device exists commercially, there was very little groundwork on which to base our initial designs. As the device is composed of several independent components, the functionality of each of these depended on each other. Thus, a single alteration to the design could positively or negatively impact a seemingly unrelated design aspect. Several of the challenges we encountered involved difficulties integrating the components of our design. Ultimately we found the housing design, which needed to combine physical and visual aesthetics with mechanical functionality, the most challenging component to design. However, we believe we were able to adequately overcome these challenges and produce a functional prototype, even as limitations in the facilities available to us forced us to modify our final design. Our prototype conveyed the main aspects of our final design, validating some of them during testing while also exposing design weaknesses. We identified several changes we would make to our design, given the chance, and believe improvements must be made prior to its potential commercialization.

Acknowledgements

Firstly, we would like to thank Dr. Goldstein for sponsoring this project. We appreciate not only his financing of this project, but also the time he took from his busy schedule to give us access to the cath lab and provide us with design inspiration and feedback.

Thanks also to Mark Pica at Beaumont Hospital for his help organizing the project from the sponsor’s end. We would like to thank section leader Scott Miller for his critiques at our design reviews and for being accommodating with design review scheduling. Michael Schreiber was extremely helpful in both providing prototyping materials and assisting us with the fabrication process. Thanks also to Marv Cressey in the X50 machine shop for providing assistance and advice during the manufacturing process. Finally, thanks to professor Shih for organizing and coordinating the many ME450 projects.

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http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8026204&dopt=Abstract

http://www.egeneralmedical.com/gedp1100.html

Appendices

Appendix A: Concept Generation Sketches

Figure A.1a: Dishwasher (Top View)

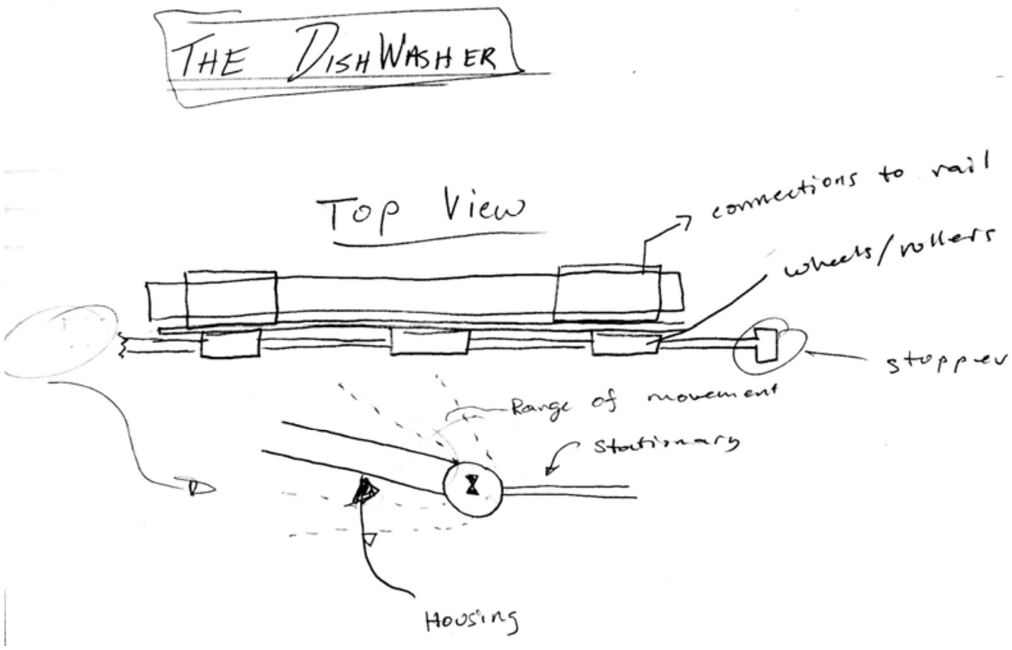


Figure A.1b: Dishwasher (Roller Extension)

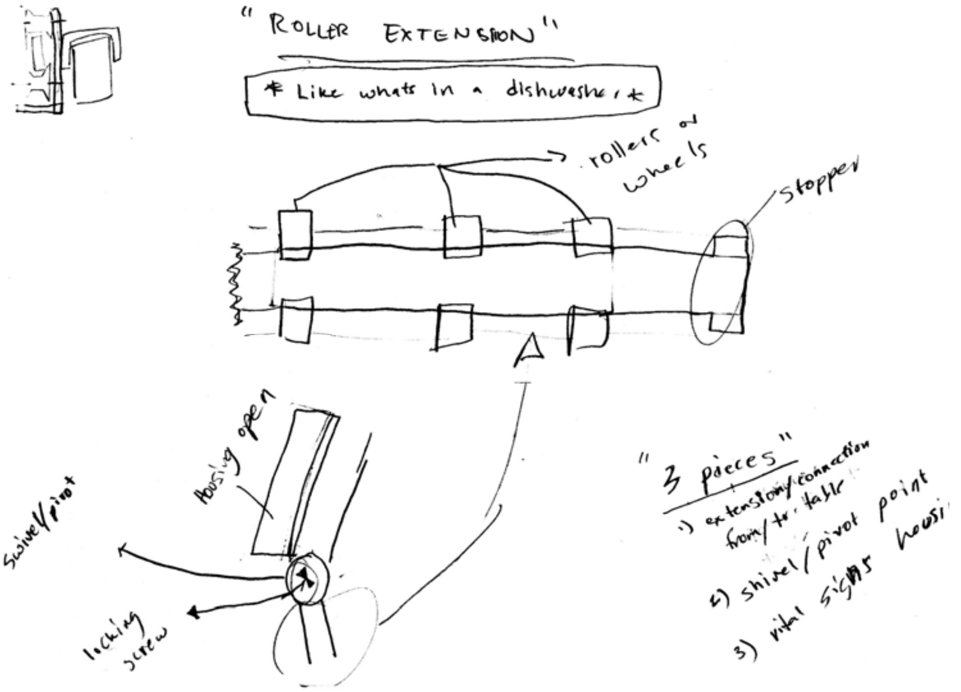


Figure A.1c: Dishwasher (Hinged Housing)

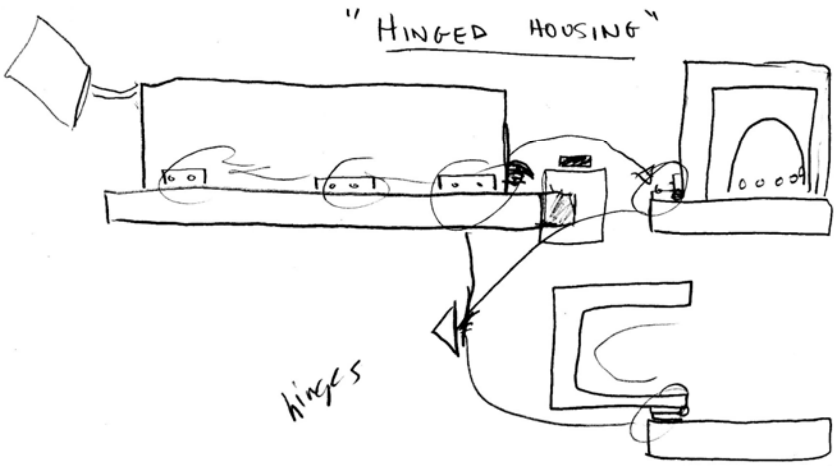


Figure A.2: Double Stamp

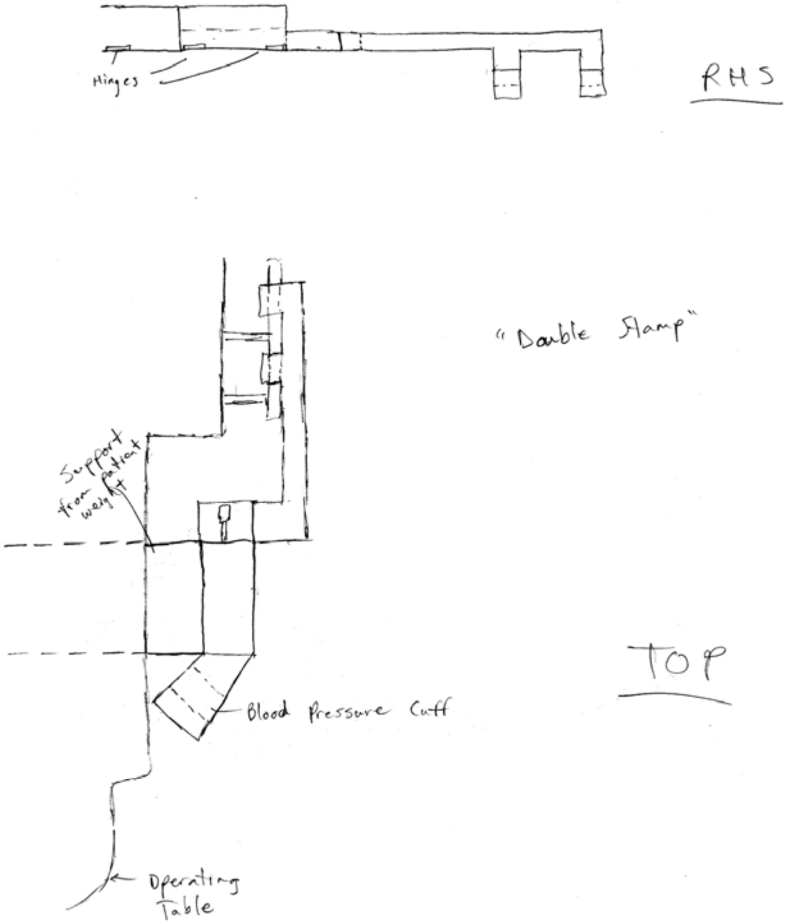


Figure A.3: Duo

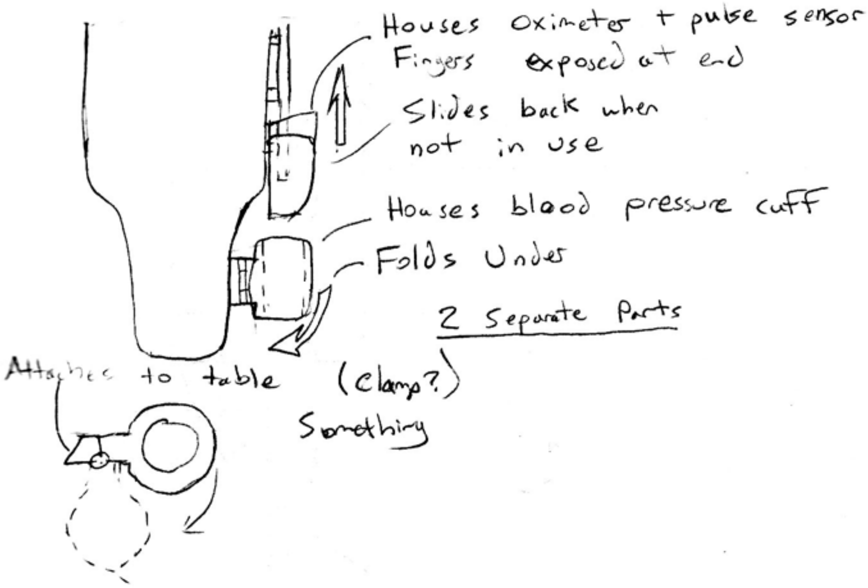


Figure A.4: The Charlemagne

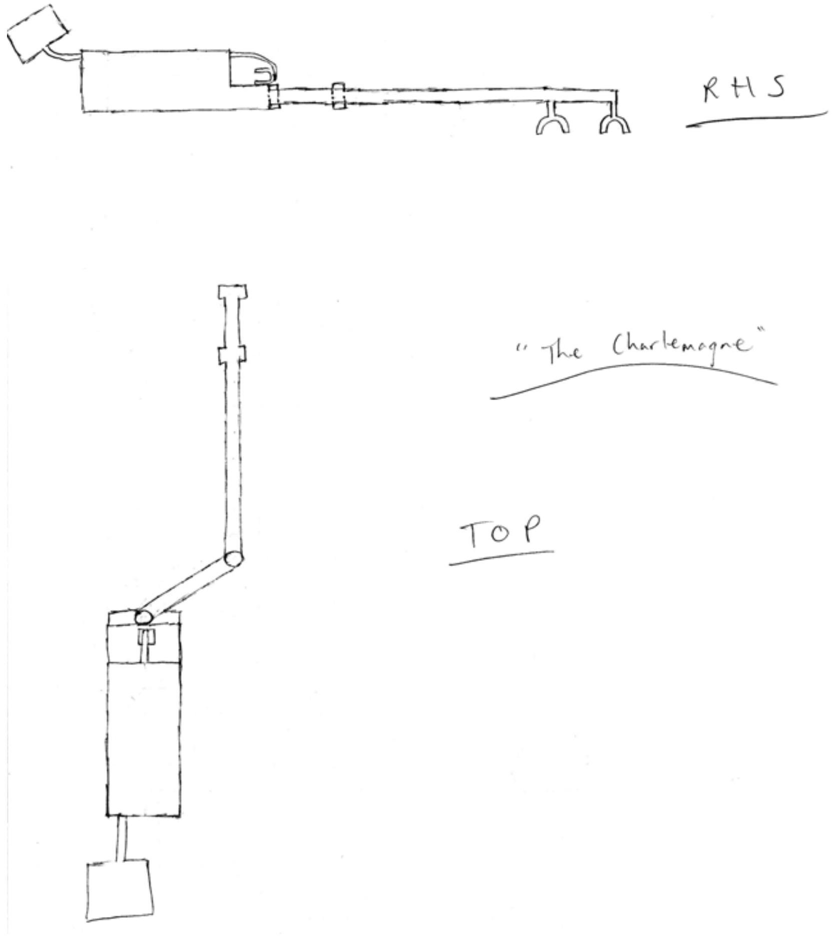


Figure A.5: The Eel

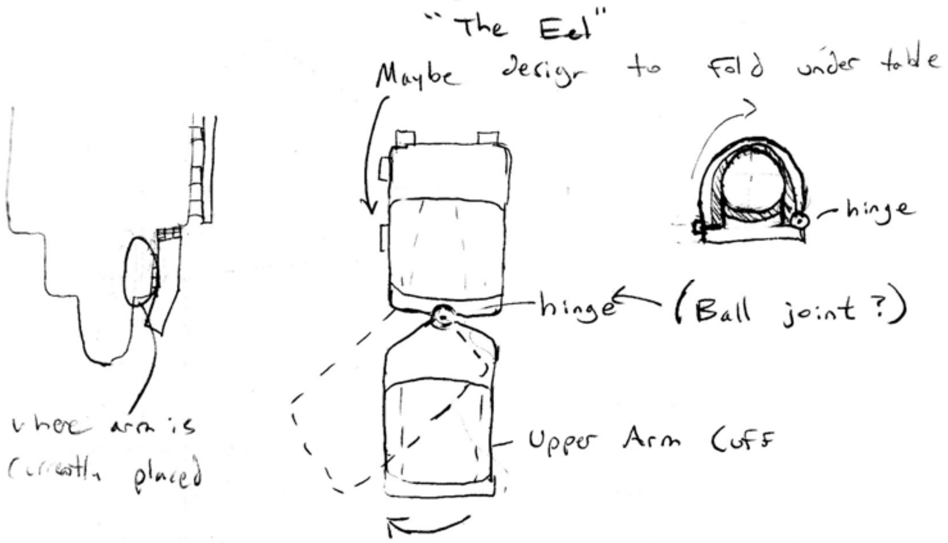


Figure A.6: The Enclosure 1

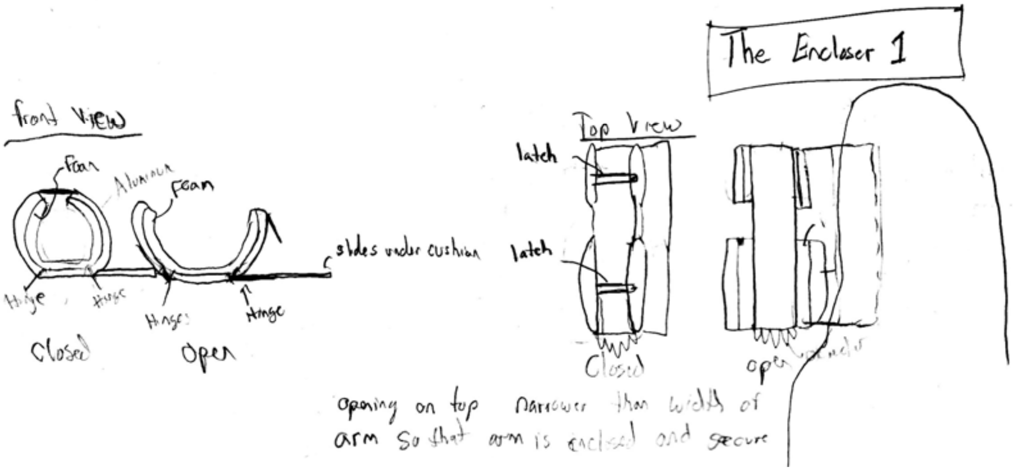


Figure A.7: The Enclosure 2

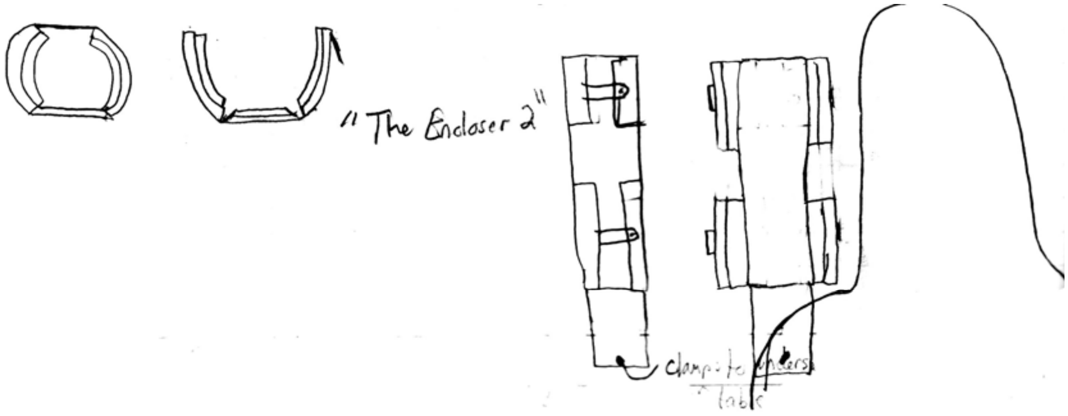


Figure A.8: The Hatchet

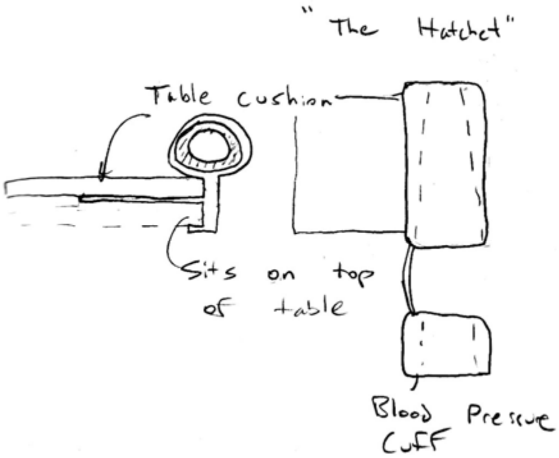


Figure A.9: The Mag-1000

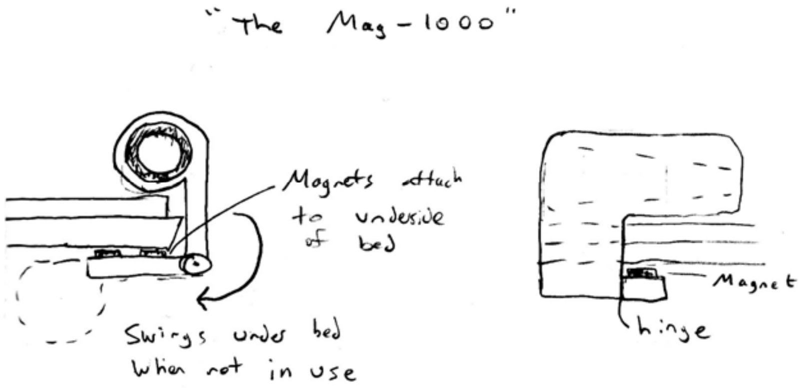
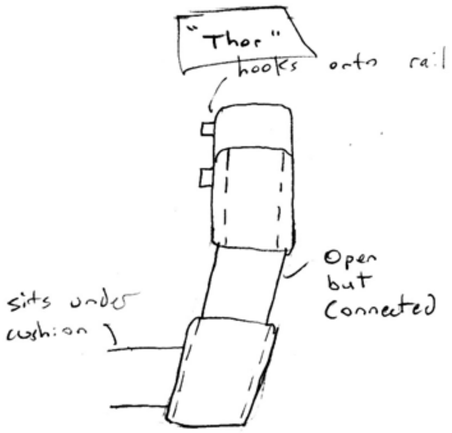


Figure A.10: Thor



Appendix B: Bill of Materials

Quantity	Part Description	Purchased From	Part Number	Price (each)
2	18" 6061 T-651 Aluminum Bar	Lapeer Industries		\$0.00
2	4.5" 6061 T-651 Aluminum Bar	Lapeer Industries		\$0.00
3	8"X 5.5"X 5.5" Polyethylene Block	Lapeer Industries		\$58.34
2	24"X 12"X $^{1}/_{4}$" Foam Sheet	Foam Order*		\$6.21
2	24"X 12"X $^{3}/_{8}$" Foam Sheet	Foam Order*		\$6.21
4	1/4"-20 Thread, 2" Length	McMaster-Carr**	93005A581	\$6.44
1	1/4"-20 Thread, 1.5" Length	McMaster-Carr**	93005A552	\$4.88
2	1/4"-20 Thread, 1.25" Length	University of Michigan		\$0.00
1	Primer/SLR B-I-N Spray	Jack's Hardware		\$6.29
1	Blue Enamel Spray Paint	Jack's Hardware		\$4.68
2	Quick-Grip Glue	Meijer		\$3.98

Total = \$249.41

*http://www.foamorder.com
**http://www.mcmaster.com

Appendix C: Prototype Component Engineering Drawings