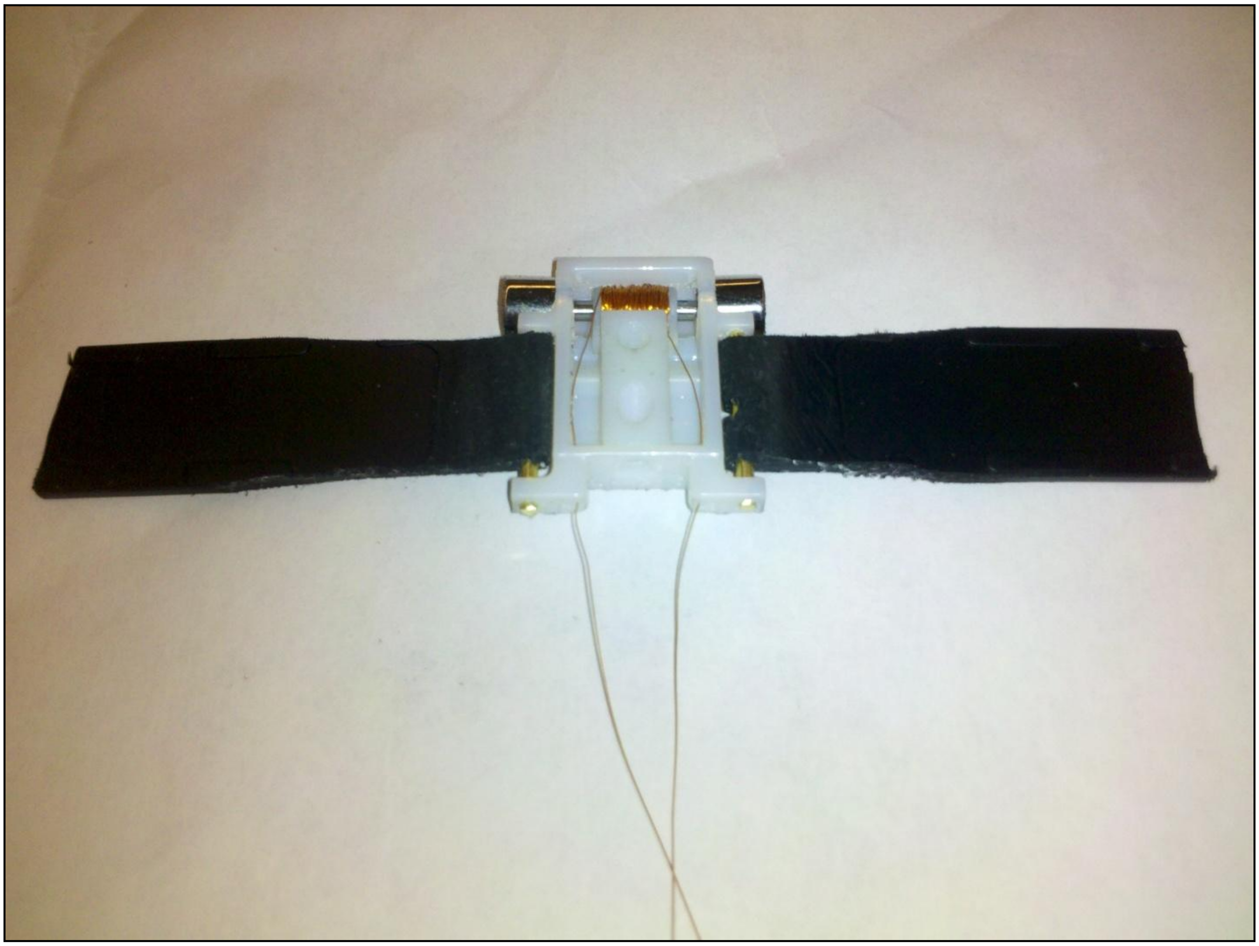
ME 450 Fall 2010: Project 21
Flexible Ultrasound Transducer Fixture for Blood Flow Measurement
Final Report



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EXECUTIVE SUMMARY

Inexpensive and reliable access flow-rate monitoring could significantly reduce the expense, frequency, and morbidity of access thrombosis incidents. One potential inexpensive and accurate method is measuring the changing Doppler signal characteristics as a function of access flow-rate. These measurements are collected using an ultrasound transducer fixed to the patient’s skin above the access. One major issue with this method is maintaining a signal throughout the four hour treatment without any operator intervention. Therefore, we have been tasked with developing an ultrasound transducer positioning system that does not disrupt treatment, minimizes measurement variability, and is operator independent.

Because of the great uncertainty associated with the new ultrasound transducers our sponsors wished to use in this design, we decided to use several design-manufacture-test iterations of prototypes to further define the exact customer requirements and engineering specifications. One constraint that has been constant throughout the project was that the device needed to be geometrically compatible with the current dialysis setup. This meant it had to be less than 6.5 mm in height and 25 mm in width. Another requirement was that the device needed to be able to be used by all dialysis patients. Dialysis patients differ in the location of their access and depth of their access below the skin, so this device needed to be able to fit around a radius of curvature as small as 2.06 cm and also be able to read measurements from accesses between 0.5 and 2 cm below the skin.

The first design iteration was the preliminary prototype. The main objectives of this prototype were to test an in-line orientation of the transducers to see if it could obtain data, and to determine if a static prototype would be acceptable. Through testing this on a phantom access setup, we determined that the in-line orientation worked, and that measurements were too sensitive to lateral movements so an adjustable device allowing at least 3mm of lateral translation would be necessary. We also saw that measurements were different at different depths, so depth adjustment may need to be incorporated in the design.

The secondary prototype was developed to test different angles of transducer orientations relative to the skin, and also to test a concept for lateral adjustment. Testing this prototyped showed that depth adjustment would not be as important as originally thought, and that the different transducer type used had significant implications on the quality of the measurement.

The final prototype tested an electromagnetic actuation concept as a means for lateral adjustment of the transducers. We were able to prove the effectiveness of the magnetic actuation but also identified some areas for future improvement.

Although tremendous steps were made for this project during the duration of this semester, there is still future work needed to fully develop the design before it can be implemented in dialysis clinics. In addition to the software and hardware areas that can be improved, the actual device that will house the transducers and be fixed to the patient could go through more design iterations to test and optimize details such as the transducer orientation relative to the patient’s skin, the transducer type being used, the amount of wire coils used, and the method to ensure a smooth and straight translation of the transducer housing across the patient’s access.

TABLE OF CONTENTS

ABSTRACT

Regular access flow-rate monitoring for hemodialysis patients is known to reduce the frequency of access failure and related emergency hospitalizations. The current accepted method, Indicator Dilution, requires a skilled operator and disrupts dialysis treatment. One potential alternative is using the changing Doppler signal characteristics as a function of access flow-rate. This method requires the precise positioning of an ultrasound transducer on the skin and is currently dependent on an operator making adjustments throughout the treatment. The objective of this project is to develop an ultrasound transducer positioning system that does not disrupt treatment, minimizes measurement variability, and is operator independent.

1 PROJECT DESCRIPTION

The goal of this project is to build an automated ultrasound transducer positioning system for blood flow measurement of patients during hemodialysis treatment. The project is sponsored by Dr. William Weitzel of the University of Michigan Health Services Division of Nephrology, and co-sponsored by Dr. Grant Kruger of the University of Michigan Mechanical Engineering Department.

1.1 Background

In the United States alone, more than 330,000 people suffer from end-stage renal disease (ESRD). Without dialysis treatments three times per week these individuals would die. Before patients begin dialysis, they have a surgery that connects a major artery and vein (frequently the briachial, radial, or ulnar artery). This connection becomes the “access” where blood flows from the body to the dialysis machine and back during treatments. Dialysis patients have high risk of access failure from thrombosis, and these access failure rates due to thrombosis can be significantly reduced when measurements monitoring the blood flow in the access are taken regularly and a corrective action is implemented before clotting.

1.2 Design Problem

Dr. Weitzel and Dr. Kruger have been working with their team to find a way to effectively monitor blood flow in the dialysis patients’ accesses. The team has developed a system to measure the blood flow velocity using ultrasound transducers that are placed on the patient’s skin above his or her access during dialysis treatment. However, positioning this transducer on each patient is a cumbersome task that requires a specialist familiar with the ultrasound program. Even after the transducer is placed on the patient, it can move around on the patient’s skin during the dialysis treatment, leading to a lost ultrasound signal. When this happens, the specialist needs to reposition the transducers so that the ultrasound signal can be read again. Our project objective is to design and manufacture a device that will be operator independent and capable of securing the ultrasound transducers to the patient during treatment to prevent loss of signal.

1.3 Potential Impact

Successfully designing and manufacturing a device that can fix a transducer to a patient so that blood flow can be easily and non-intrusively measured will have a great positive impact on the dialysis community. Doctors will be able to tell when a patient's blood flow through the access is becoming dangerously low and refer them to a remedial treatment before an emergency clot occurs. This will save the patients from having to go to as many emergency treatments for thrombosis and it will reduce costs associated with these potential emergency treatments.

2 INFORMATION SOURCES

Our team has gathered information from several different source areas. We have done background and benchmark research from academic articles, on-site observation at a dialysis clinic where our teams VF Doppler was in use, and discussions with our sponsors, doctors, and clinicians. Since our project with the University of Michigan research team is the first to attempt to secure a transducer for the entire dialysis process, there is limited benchmarking to compare to. While it is not competition, we have benchmarking from a PHD student on the team who showed us the first 'winged' prototype used to attempt to secure the transducer. We were able to see what kind of size the device needs to be, and were also able to hear some of the setbacks of the prototype. We will be able to use that prototype for initial testing and to design alternate prototypes with solutions to the known setbacks. Where we lack benchmarks and comparison data, we will aim to perform extensive testing before design review two with several prototypes to figure out what will and will not work for the design. The following paragraphs provide an insight into the literature sources that we have found and used.

Besides the prototype from our team, we did manage to find one project that had a similar scope as ours, which will be useful in benchmarking. In the article, *Portable directional ultrasonic Doppler blood velocimeter for ambulatory use* [2], a team used a set of Doppler transducers much like ours to measure blood flow through femoral grafts. Just as we will need to do, they made a housing and fixture to hold the transducers at an angle to the skin. In the study, they describe the needs of the fixture to allow for the transmission of ultrasound waves, as well as how they manufactured the device. We will be able to use this article to consider manufacturing and potential design criteria for our device, although their device did not have to fit between access needles, as ours does. Nor does their device allow the transducer to be removed from the fixture, a feature we may want to incorporate.

Another article, *Analysis of Variable Flow Doppler Hemodialysis Access Flow Measurements and Comparison with Ultrasound Dilution* [11], compares the effectiveness of using the VF Doppler device to using a traditional ultrasound device. The article refers to several methods of measuring blood flow, and notes that using the proposed VF Doppler device is the best-suited method in the restricted space available. It also points out a few shortcomings of the transducer and fixture, which we will be able to refer to when considering design aspects.

The use of a diasonics DRF400 Duplex ultrasound scanner to measure volume flow in arterio-venous fistulae in patients undergoing haemodialysis: an analysis of measurement uncertainties [7], considers the accuracy of using Doppler to measure blood flow, but also has an interesting approach to maintaining a good signal. In the article, they secure the transducer to the patient using a clamp, so that the patients are to remain stationary during dialysis. While we intend to allow freedom of movement for the patient, no idea or concept should be struck down during brainstorming and creativity of an early design, so it will be useful insight for our design process.

In order to determine the proper patient compatibility dimensions, we have researched anthropometric data [1]. We concluded that the wrist diameter will be the smallest dimension we will be working with, and that the thigh would be the largest (assumed to be a flat surface). We took the wrist data from a 3rd percentile 12-year-old girl to be the smallest radius arm for our device to fit on. We may continue to search for anthropometric data in order to find data on even smaller wrists so that our device could truly be used on anybody.

In a presentation provided to us, *Dialysis Access Monitoring* [13], we have learned much of the background of the team and project here at the University of Michigan. The presentation goes over the need for a more frequent access monitoring through Doppler readings (three times per treatment, three treatments per week, rather than once per month) in order to more accurately predict and track thrombosis. It also provides some of the more recent history on our specific project, leading up present day. This will be helpful in understanding the value and basis of our project, as well as the results we need to ensure in order to continue research.

In a book called, *Diagnostic Ultrasound: Imaging and Blood Flow Measurements* [10], we were able to discover critical information about how ultrasound technology works and the beam in our transducer. In this book they specifically talk about how Doppler technology works and can interface with blood vessels. They also talk about some of the problems in ultrasonic blood flow technology and state that "a problem in ultrasonic Doppler blood flow measurement is that the blood vessels that produce large reflected echoes are slow moving as well" (p. 105). This can sometimes cause unreliable data. Lastly this book gave us information on blood flow in general and stated that when the blood flow is laminar and has a parabolic flow profile the Doppler reading is optimized if it hits the peak velocity of the parabola. This helps us to realize that we will need to obtain the signal at its peak velocity, in the center of the blood vessel.

We found another source that talks about Doppler Effect called, *Measurement of Blood Flow by Ultrasound: Accuracy and Sources of Error* [3]. In this study Robert Gil, the author, states that "Doppler methods are capable of good absolute accuracy when suitably designed equipment is used in appropriate situations, with systematic errors of 6% of less" (p. 625). He also states that there are potential errors in Doppler methods because of the angle of approach and estimating the blood vessel cross-sectional area. This will be important to keep in mind in regards to our device because the angle at which the fixture holds the device is crucial to the transducer working properly.

Another valuable source that we found was *Retrograde Hemodialysis Access Flow During Dialysis as a Predictor of Access Pathology* [12]. In their study, they "observed 10 patients (9 grafts and 1 fistula) with reversed diastolic flow during dialysis" (p. 1241). They proceeded to report that retrograde access flow could possibly be a specific indicator of access dysfunction and that retrograde access flow happens before recirculation which illustrates that retrograde access flow is more sensitive than recirculation for finding access dysfunction. This report pertains to our project because it adds more background into monitoring accesses and more motivation into finding a reliable way to monitoring accesses during dialysis. It also illustrates that monitoring accesses is important and finding a reliable way to do so will be extremely helpful.

The article, *Intervention Based on Monthly Monitoring Decreases Hemodialysis Access Thrombosis* [9], describes a study where patients received monthly access flow monitoring to evaluate whether the rate of thrombosis would decrease. Whenever a patient was measured at an access flow-rate less than 750 cc/min, they were referred for angioplasty. Throughout the study, 9.7% of the monitored patients developed thrombosis compared to 22% of the control patients. The study did not determine whether more frequent monitoring could provide even better results, but the difference from the control group was determined to be adequate to recommend monthly monitoring for all patients. *Predictive measures of vascular access thrombosis: A prospective study* [6], evaluates varying monitoring methods used to predict access thrombosis. The background explains that intervening before the access reaches thrombosis leads to an increase in overall access lifetime and a decrease in the rate of recurring thrombosis. The conclusion of the study is that measuring access blood flow-rate is the most accurate means of predicting access thrombosis and that a reliable, inexpensive means of doing so could reduce the number of emergency hospitalizations and overall healthcare cost associated with dialysis. Both of these articles provide background information for how the Doppler data is used, and restate the need for a more stable fixture to hold the transducers to the skin for consistent and easy-to-obtain data samples.

In order to continue our project beyond Design Review 1, we needed to design and produce concepts for testing. The following three articles are all on rapid prototyping methods which we investigated and used for our first prototypes:

The first article on prototyping, *Fused Deposition Modelling: A Technology Evaluation*[4], investigates differences between SLA, SLS, and PolyJet manufacturing compared to FDM (Fused Deposition Modelling). From this article, we learned that SLA, SLS, and PolyJet all use materials which may warp, expand, or change properties when exposed to humidity. Since we are exposing our parts to ultrasound gel, and possibly sweat, we will be investigating the long term affects of these liquids on our PolyJet prototypes which have been ordered.

The second article, *A benchmark study on rapid prototyping processes and machines: quantitative comparisons of mechanical properties, accuracy, roughness, speed, and material cost* [5], is a great comparison of several different Rapid Prototyping (RP) techniques. The characteristics most interesting to us which were tested in this study were the strengths, cost, and dimensional accuracies of the technologies. From this study, we found that using the PolyJet technique would be a good choice for our first prototypes.

The final article we researched on RP was, *Experimental analysis of properties of materials for rapid prototyping*[8], which compared 3D printing to PolyJet techniques. This study revealed that the PolyJet technique has better finish and dimensional accuracy than the 3D printing techniques. This further strengthens our confidence in the PolyJet technique to be able to produce our prototypes with accuracy and strength.

3 REQUIREMENTS AND SPECIFICATIONS

3.1 Customer Requirements and Engineering Specifications

After fully understanding the background and problems with the VF Doppler, we were able to define our project requirements. The most important requirement for our device is to make it operator independent. There are typically thirty to forty patients in the dialysis clinic at once and there is one technician who takes care of these patients. Since he cannot be everywhere at once, our requirement is that that once the technician has found a good signal, the technician in the dialysis clinic can secure the VF Doppler with our fixture and not have to readjust the VF Doppler again during treatment. All he will need to do is press a take data button and see the data he needs and will be able to do this for every patient. We translated this into an engineering specification by stating that there should be less than 30% error in the velocity reading due to the device moving and less than 30% error in velocity reading from access depths of 5 to 20 mm.

We were able to come up with these engineering specifications after doing experiments in the Simpson Memorial Institute Laboratory. We were able to generate flow profile curves and found that if the transducers move 2 mm laterally then there is a 40% error in velocity. We do not want our device to move more than 1 mm during treatment, which we found corresponds to about a 30% drop in measured velocity. We also completed testing on different access depths and found that accuracy decreased with increasing access depth.

From testing, we developed the customer requirement that the device should allow lateral adjustment and the engineering specification that the range of lateral adjustment should be 3mm. This is extremely important because if the technician places the device on a patient and the device is not directly over the center of the access, the technician will be able to laterally adjust the position of the transducers to find the optimal signal. Also, if the device moves during treatment, they will be able to make adjustments without having to remove the device from the access and then replace it.

After Design Review 3, we met with our sponsor and were made aware of new customer requirements for our device. Our sponsors asked us to develop a fully-enclosed device using electromagnetic actuation. If the device is compatible with electromagnetic actuation, the maximum signal velocity can be located using a closed-loop feedback system without the need for technician interaction. If the device is fully enclosed it will allow for easier cleaning because the device won't have to be disassembled and reassembled after every use. Instead, the outer surfaces can be wiped down and the device can be used again on another patient.

Another requirement is that the VF Doppler maintains contact with the ultrasound gel throughout treatment. If there is any air in between the transducer and the skin then the transducer will not be able to get a signal. We must ensure that once the gel is applied that the gel does not dry out and that there is always gel in between the transducer and skin. Our engineering specification for this requirement is that the gel does not dry out in 4 hours, which is the typical time for dialysis treatment. If we can enclose the gel so it is not in contact with the air then that will make the gel last longer. We are also looking into other mediums in which the Doppler waves can travel. We are planning on running tests to see how long it takes the gel to dry out when exposed to air.

Once we obtain this data, we will have a better understanding as to whether or not the transducer housing of our fixture needs to enclose the gel or not. We will also test the effect of gel desiccation on signal strength to verify if it is necessary to apply more gel during treatment.

Another important requirement for our device is that it is geometrically compatible with the dialysis set up. Obviously if our device does not fit in the current dialysis set up then it cannot be used. Our engineering specification on this requirement is the height should be less than 6.5 mm, the width of the device should be less than 2 centimeters because the device must fit in between the dialysis needles, and the length of the device should be less than 7.5 centimeters. We have defined the width as the distance parallel to the access and the length as the distance perpendicular to the access.

Our next requirement is that the device should be flexible. Because of the variation in patient body size and access location, the device should be able to fit on something as small as a child's forearm as well as a thigh of a large adult. The engineering specification for this requirement is that the radius of curvature should have a range of 2.06 cm to being able to lay on a flat surface. A radius of curvature of 2.06 cm was calculated from anthropometric data for the wrist size of a 12-year-old girl who was in the 3rd percentile [1].

Another requirement is that the device should be inexpensive. Dialysis clinics would prefer spending as little money as possible because of the already high prices for treatment. The device should cost less than $60.

Our last requirement is that the positioning and fixture device should be durable. We would like to able to use this on multiple patients, and our engineering specification is that the device can withstand 50 procedures. We defined one procedure as cleaning the device with alcohol and lasting through the entire dialysis process. We must also be able to easily remove the transducer from our fixture so that we do not throw away a $700 transducer after fifty uses. Therefore, we have made an additional engineering specification that states that the transducer can be used at least 350 times with our device before it is discarded.

To determine our engineering targets, we used the information given to us from our sponsors, observations from visiting a dialysis clinic, from journal articles and from experiments conducted in the Simpson Memorial Institute Laboratory. From our sponsors we were able to gain critical information such as how how many treatments they would like the device to last for, the cost of the device, and information on the ultrasound gel used in between the transducer and skin. From our time spent at the dialysis clinic, we were able to get a better idea of the confined space where the device has to fit. This gave us critical information in regards to the height, width and freedom of travel. We were also able to gain insight on the dimensional specifications from our sponsors because they have tried building harness devices in the past. Lastly, we were able to gain information on wrist and thigh sizes of children and adults to aid us in creating our radius of curvature specification. From the experiments conducted we were able to understand how much adjustability the device should have and which customer requirements were most important. We gained the knowledge that transducer lateral movement is much more important than depth adjustment.

The relative importance of the project requirements was determined through talking with our sponsors and gaining a greater understanding of the problem at hand by experiments performed in the Simpson Memorial Institute Laboratory. We met with them multiple times to discuss the details of the project and what they felt to be most important. We deduced that the most important requirements are that the device is operator independent, can allow for fine lateral adjustments, is compatible with electromagnetic actuation, can be fully enclosed, maintains full contact with the ultrasound gel, is flexible, and is geometrically compatible with the dialysis set up. Our other requirements, which are durable and low cost, are also important but we felt as though our sponsors highlighted the other requirements more.

3.2 QFD

Our QFD, as seen in Appendix D, was developed by selecting our project requirements and creating engineering specifications that quantified those. After obtaining a detailed list of requirements and specifications, we then talked with our sponsors to obtain any feedback. After making some minor adjustments, we weighed each requirement with a value from one to five in terms of importance. We then began filling in how strongly each project requirements correlated with our engineering specifications by giving rankings of 9, 3, 1, or 0 with 9 being the most strongly correlated and 0 being not correlated at all. Since there are no products currently on the market that attempt what we are planning to do, we did not include a benchmarking section in our QFD. From our QFD we have deduced that our three most important specifications are that the transducers have a lateral freedom of travel of 3 mm, that there is less than a 30% error in the velocity reading due to the device moving and less than 30% error in velocity reading from access depths of 5 to 20 mm . If we can achieve these three critical specifications then our device should be a success. It is very critical that our requirements and specifications are accurate because we are using these as design targets for our project.

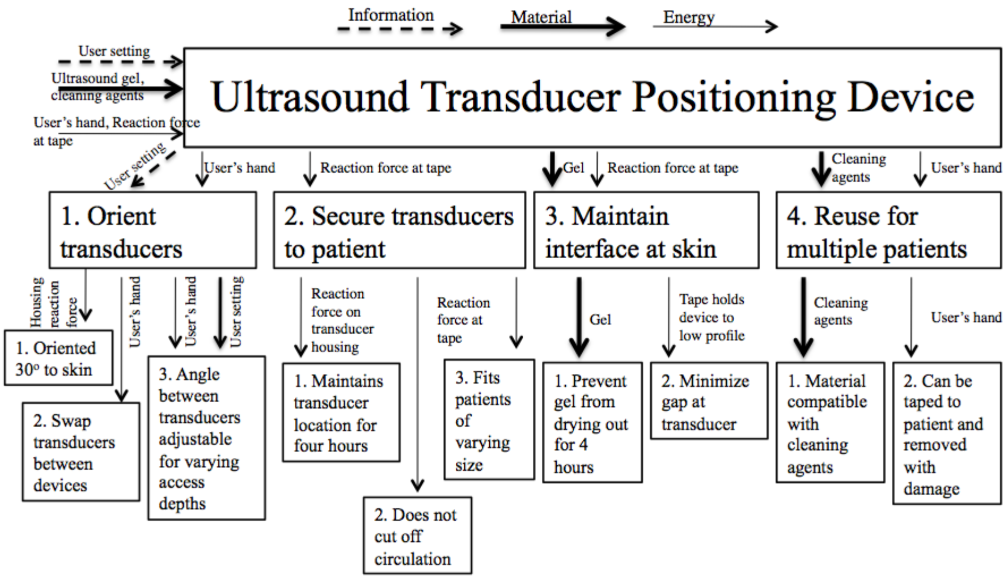
4 CONCEPT GENERATION

Our concept generation was a process involving several steps. We first used our revised customer requirements and engineering specifications to define the overall function of our device. This overall function was then divided into multiple levels of sub-functions using the method of functional decomposition. From the functional decomposition, we defined the sub-components of our device and then generated concepts for these sub-components. Once our concepts were completed, we then moved on to our concept selection process.

4.1 Functional Decomposition

To better evaluate the needs of our design, we used functional decomposition to evaluate the functions of our device. From the revised customer requirements and engineering specifications we were able to define the overall function of our device which was the decomposed into sub-functions and sub-sub-functions. Figure 1 shows a graphical representation of our functional decomposition with information, material, and energy flows.

Figure 1: Functional decomposition down to three levels



The four main sub-functions that we developed were: orienting the transducers, securing the transducers to the patient, maintaining the interface at the skin, and allowing reuse for multiple patients. Most of the energy input to the system is from either the user's hand or the reaction forces at the tape securing the device to the patient. The user also inputs information to the system by selecting the transducer orientations to target a specific access depth. Material enters the system in the form of ultrasound gel and cleaning agents.

The results of our functional decomposition helped us in concisely defining the specific functions that our concepts must meet. These clearly defined functions helped up organize our concepts into categories to meet the customer requirements and engineering specifications.

4.2 Brainstorming

To organize our brainstorming, we first determined the two main sub-components that would be needed to meet our four main sub-functions. The first sub-component, the transducer housing, provides sub-function 1, orienting the transducers. The second sub-component, the housing fixture, provides sub-function 2, securing the transducers to the patient. We also considered whether each sub-component maintained an adequate transducer/skin interface (sub-function 3) and were reusable for multiple patients (sub-function 4). Our group generated 19 housing concepts and 15 fixture concepts.

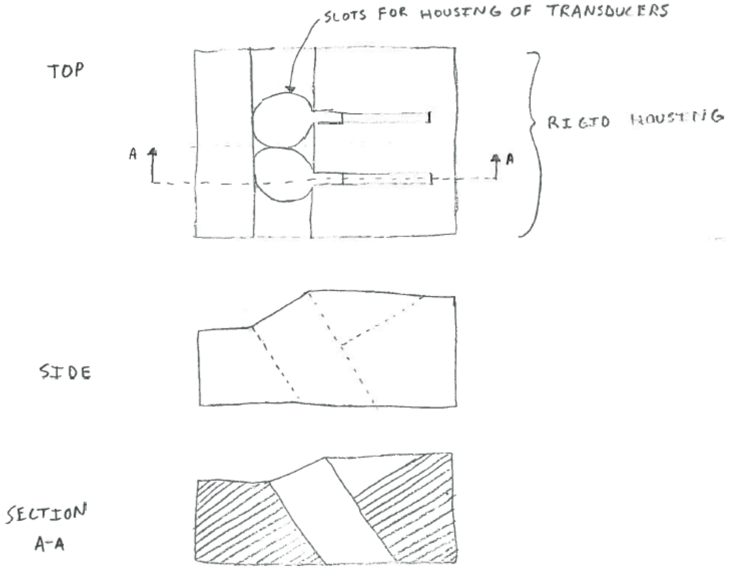
4.2.1 Concepts for housing the transducers

This section highlights the four most distinct and feasible of the 19 housing concepts generated by our group. The concepts vary by transducer orientation and adjustability as well as the mechanical means by which these functions are achieved. The full set of transducer housing concepts is provided in Appendix D.

4.2.1.1 Housing concept 1: Side-by-side transducers

This housing concept is a fixed orientation variation with the transducers mounted side-by-side. The housing would be located so that the access would lie in-between the two transducers. The transducers are oriented at an angle of 30^{o} to the skin and at an angle to each other to target an average access depth. Slots extend from the transducer cavities to route the transducer wires through the housing. Figure 2 on page 13 shows a sketch of the side-by-side concept.

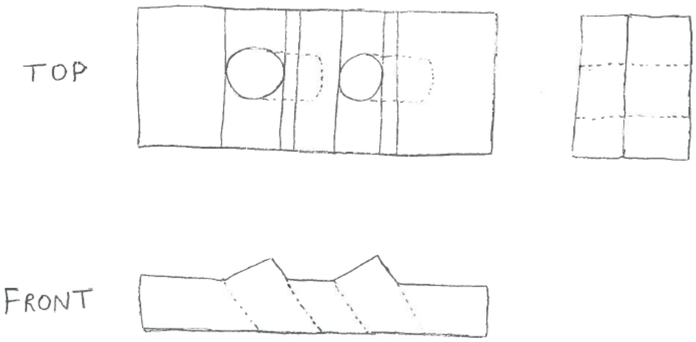
Figure 2: Side-by-side concept provides a fixed transducer orientation



4.2.1.2 Housing concept 2: Longitudinal transducers

This housing concept is a fixed orientation variation with the transducers mounted longitudinally. The housing would be located so that the transducers are both located along the same axis as the access. The transducers are oriented at different angles to the skin to allow the projection paths of the send and receive transducers to intersect at an average access depth. Figure 3 below shows a sketch of the front-to-back concept.

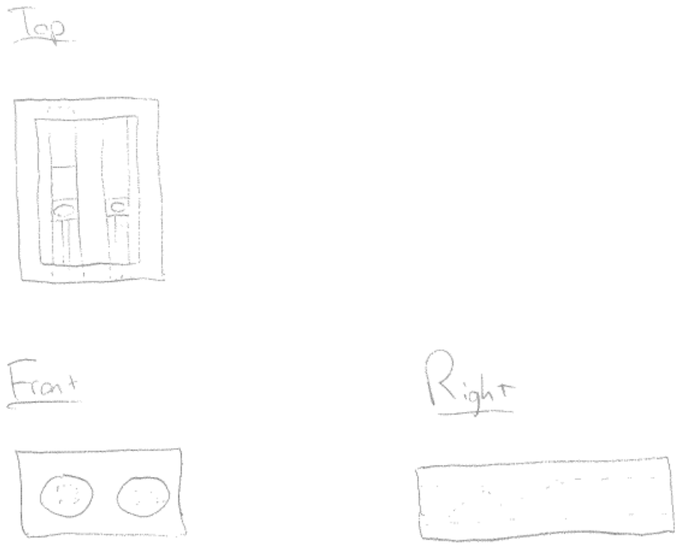
Figure 3: Longitudinal concept provides a fixed transducer orientation



4.2.1.3 Housing concept 3: Adjustable cylinders

This housing concept is an adjustable orientation variation with the transducers mounted side-by-side. The access would lie in-between the two transducers, and different access depths could be targeted by varying the angle between the transducers. By providing the ability to target different access depths, this housing should allow more consistent measurements across a group of patients. Figure 4 shows a sketch of the adjustable cylinder concept.

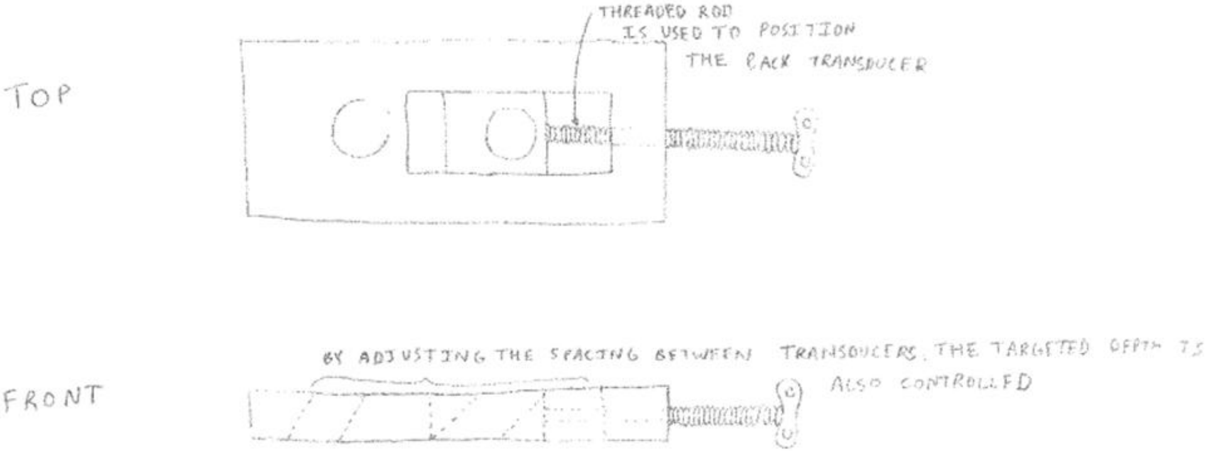
Figure 4: Adjustable cylinder housing can target varying access depths



4.2.1.4 Housing concept 4: Adjustable longitudinal

This housing concept is an adjustable orientation variation with the transducers mounted longitudinally. The transducers are both in line with the access, and one transducer can be translated parallel to the axis to allow targeting of different access depths. Figure 5 shows a sketch of this concept.

Figure 5: Adjustable longitudinal concept can target varying access depths



4.2.1.5 Housing Concept 5: Three longitudinal transducers

This housing concept, shown in Figure 6, is very similar to the longitudinal transducers concept except instead of housing two transducers this would hose three transducers. All three transducers would be orientated at different angles to allow different intersection points for the beams. Therefore the front two transducers would allow for shallow accesses and the front and back transducers would allow for deep accesses.

Figure 6: Three longitudinal concept

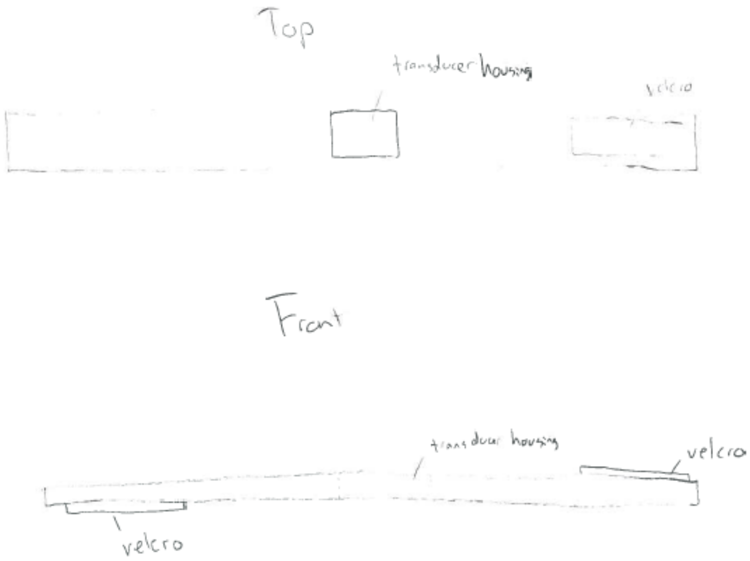
4.2.2 Concepts for securing the housing to the patient

This section highlights the three most distinct and feasible of the 15 fixture concepts generated by our group. The concepts can be used interchangeably with any of the above housing concepts.

4.2.2.1 Fixture concept 1: Velcro band

This fixture concept is a simple Velcro band that wraps around the patients arm or leg to secure the housing. This method would prevent the need to apply tape to the patient, but also raises the concern of affecting the circulation to the limb. Figure 7 shows a sketch of the Velcro band concept.

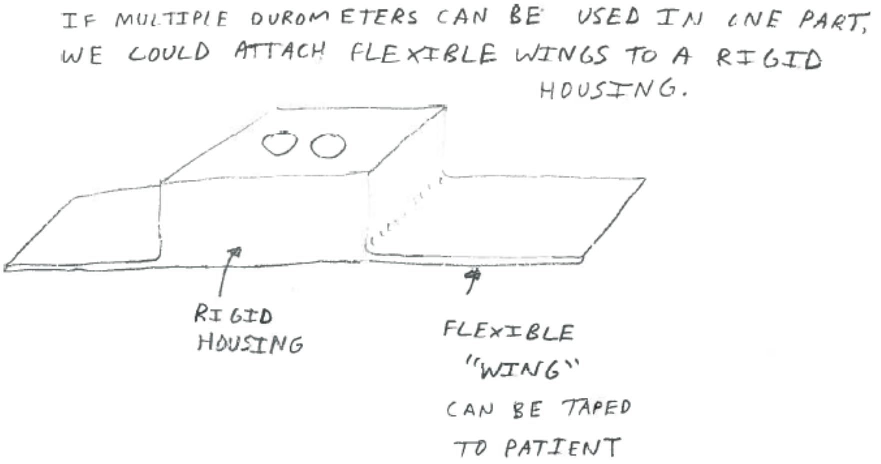
Figure 7: Velcro band can secure housing to patient without tape



4.2.2.2 Fixture concept 2: Flexible wings

This concept involves attaching flexible "wings" to either side of the housing. The wings can bend to fit varying surfaces and would be secured to the patient using tape. For this concept to work, the wings and housing would have to be manufactured as one part with a material of varying durometer. Figure 8 shows a sketch of the flexible wings concept.

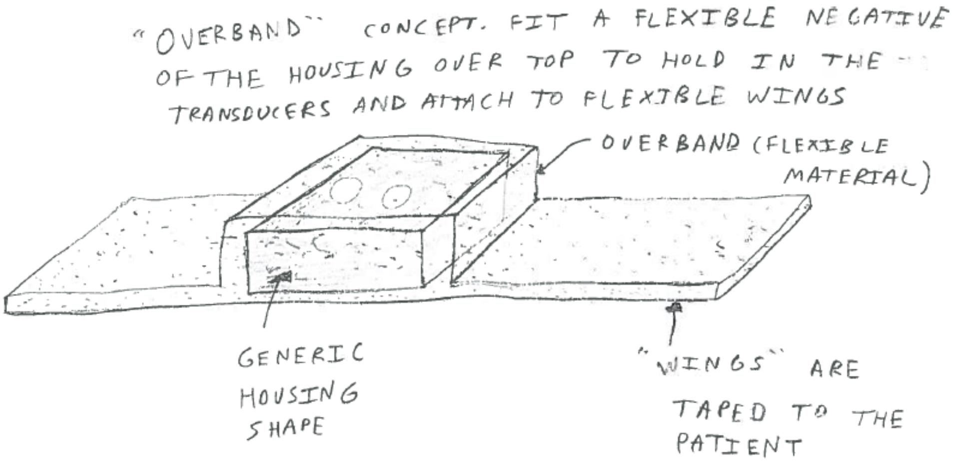
Figure 8: Flexible wings can be taped to patient to secure the housing



4.2.2.3 Fixture concept 3: Flexible "overband"

The "overband" fixture is a flexible negative of the rigid housing. The "overband" mates with the housing and extends outwards with flexible wings that can be taped to the patient. This concept allows the flexible wings to be a separate part from the housing while also holding the transducers in place. Figure 9 shows a sketch of the flexible "overband" concept.

Figure 9: Flexible "overband" holds transducers in housing



4.2.2.3 Fixture concept 4: Hinged Band

The band in this fixture concept is hinged to the housing using watch pins. This concept allows for greater flexibility around small radii of curvature because it creates a hinge point closer to the cover. The cover would be similar to the other concepts and have a negative of the transducer housing to hold the transducers in place. Instead of being made out of a flexible material, the cover would be rigid like the transducer housing.

4.2.3 Concepts for lateral actuation

This section highlights the two most feasible actuation methods. These concepts can be incorporated into any of the concepts talked about above.

4.2.3.1 Lateral Actuation Concept 1: Rotating Rods

This concept involves two rotating rods that would be able to adjust the transducer housing laterally. String would be wrapped around the rotating rods and threaded through a hole in the transducer housing. The thread would be knotted on both ends so that when one of the rods is rotated and the string is taught, it will pull the transducer housing with it. Instead of manually adjusting the rods, it could also be hooked up to a stepper motor that would automatically adjust the device.

4.2.3.2 Lateral Actuation Concept 2: Electromagnetic

Electromagnetic lateral actuation would involve a current being passed through a copper wire between two magnets. The copper wire would be wound around a “winding barrel” that would slide along a ferrous rod. On both ends of the ferrous rod would be magnets that would create a magnetic field between them. When a current is passed through the copper wire, it will create a force that will cause the transducer housing to move along the ferrous rod. The electromagnetic actuation could be used in conjunction with a closed feedback loop that would be able to find the maximum velocity.

5 CONCEPT SELECTION PROCESS

After generating many concepts for fixtures and housings through our brainstorming, we utilized Pugh charts to decide which concept was best for each subcomponent. We then combined the best concept for the fixture with the best concept for the transducer housing to select our overall best concept.

In our Pugh Charts, we graded each concept on how well they met each applicable customer requirement on a scale of zero to one. We also weighted the importance of each customer requirement relative to one another. By summing the products of the weight and grade for each of the customer requirements, we arrived at a number that gave the rating of the concept. The concept with the highest rating was the selected concept.

5.1 Fixture Pugh Chart

Table 1 shows the Pugh Chart for the fixture subcomponent of our device:

Table 1: Pugh Chart for fixture concepts

Customer Requirement	Weight	Velcro band	Flexible Wings	Over-band	Hinged band
Operator Independence	17	1	1	1	1
Effective medium at transducer/skin interface	17	n/a	n/a	n/a	n/a
Geometric compatibility with current dialysis set-up	17	1	1	0.75	1
Flexibility to accommodate the range of patient arm/leg sizes	17	1	1	1	1
Transducer adjustability	17	0	0	1	1
Durable	10	0.75	1	1	1
Inexpensive	5	0.25	1	1	1
Total	**100**	**59.75**	**66**	**78.5**	**83**

As seen in the chart, not all of the customer requirements were relevant to the fixture subcomponent. Having an effective medium and the transducer/skin interface is a requirement independent of the fixture design but specific to the housing design.

5.1.1 Velcro band

See Figure 7 for a sketch of the Velcro band concept. This concept has a band that wraps around the patient's arm or leg, depending on the location of the access. The band allows space to be connected to a housing component. A Velcro strap ensures that the band is tight enough so that the transducers will not move during treatment.

One advantage to this concept is that it will not require tape as a mechanism to secure the device to the patient. Complaints from a previous model used in the clinic indicated that tape can sometimes come loose from a patient and result in the transducers not maintaining a strong signal.

However, several disadvantages to this design lead us to choose against this concept. One disadvantage is that it could potentially cut off blood flow circulation because it is unclear how tight the band will have to fit around the patient to ensure the transducer maintains a signal. This device will also probably be less durable than other devices because it will be continually stretched and have Velcro attached to it. We also anticipate this device will be significantly more expensive because it will need more material than other concepts and separate Velcro pieces attached to it.

5.1.2 Flexible Wings

A model of this design is provided in Figure 8. In this design, the fixture mechanism is two flaps connected to each side of the housing piece. These flaps, or "wings," are then taped to the patient's skin to hold the device in place.

An advantage to this design is that it will be part of the same piece as the housing subcomponent. The manufacturing process is easier and less expensive if there are fewer parts.

A possible disadvantage to this design is it may be a challenge fitting this device to all patients. If the device is all one piece, it might have to be out of the same material. The housing component needs to be a rigid material, so that may mean that the wings would have to be rigid.

5.1.3 Over-band

The over-band concept was used in our preliminary prototype we manufactured to run initial tests on the new cylindrical transducers. A drawing can be seen in Figure 9. In this design, a flexible material will be fit over the housing and then be taped to the patient to secure the housing to the patient.

An advantage to this design is that it will provide a cover to the transducer housing, further preventing the transducers from falling out of the housing and becoming misaligned. A disadvantage to this design is that it may not be able to meet the geometric constraints of the dialysis setup; since the over-band fits on top of the housing, it is difficult to design more than 6.5 mm above the patient's skin, which would not meet our engineering specification required for geometric compatibility with the dialysis setup.

5.1.4 Hinged Band

The hinged band concept was used in the secondary and final prototypes. These prototypes have proven that it works well at fitting around small radii of curvature. As indicated by the highest score on the Pugh chart, this concept is recommended for the fixture component on all future designs.

5.2 Transducer Housing Pugh Chart

Table 2 shows the Pugh Chart used to grade our concepts for the transducer housing subcomponent:

Table 2: Pugh Chart for housing concepts

Customer Requirement	Weight	Longitudinal	Side by side	Adjustable cylinder	Adjustable longitudinal	Three Longidutinal
Operator Independence	17	1	1	0.75	0.75	0.75
Effective medium at transducer/skin interface	17	1	1	1	1	1
Geometric compatibility with current dialysis set-up	17	1	0.5	0.75	0.5	0.75
Flexibility to accommodate the range of patient arm/leg sizes	17	n/a	n/a	n/a	n/a	n/a
Transducer adjustability	17	1	.25	1	0.75	1
Durable	10	1	1	1	0.75	1
Inexpensive	5	1	1	0.75	0.75	1
Total	**100**	**83**	**61.75**	**73.25**	**62.25**	**74.5**

As seen in the chart, these housings were not graded on their flexibility to accommodate the range of patient arm or leg sizes because that customer requirement is specific to the fixture subcomponent.

5.2.1 Longitudinal

The longitudinal concept uses the idea of housing the transducers in line parallel with the blood flow of the access. The angles of the transducers can be optimized in future designs, but for the preliminary prototype the front most transducer is at a 35° angle relative to the skin and the rear most transducer is at a 25° angle relative to the skin. The concept drawing can be seen in Fig. 3.

One advantage to this design idea is that it allows the wires from the transducers to come out of the device from the same side without getting in the way of the dialysis needles.

5.2.2 Side by side

The side by side design was modeled after the previous transducer; the “send” and “receive” transducers were oriented at 10° angles towards each other and at a 30° angle relative to the skin. The drawing is in Figure 2.

An advantage to this design is that we are confident that this orientation of transducers will work. In previous clinical trials with the old transducers, a strong ultrasound reading was achieved at this transducer orientation. However, the main disadvantage that led to a poor score in the Pugh Chart is that this design requires a width that would limit its geometric compatibility with the dialysis setup and lateral transducer adjustability.

5.2.3 Adjustable cylinder

As shown in the model in Figure 4, the housing utilizes a rectangular base with two rotatable parallel cylinders that house the transducers. The transducer housing is oriented at a 30° angle relative to the skin surface within the cylinder, and the cylinder is able to rotate on the axis parallel to the access. This allows the focal point of the intersection of the two transducers to be variable on two degrees of freedom.

The main advantage of this design is that it allows for the adjustability of the transducers. This capability was identified as an important customer requirement by our sponsor, and this design will be able to meet that requirement to a greater degree than the other designs.

Disadvantages of this design are that it will not be completely operator independent because the operator may have to adjust it; it will be more expensive than simple, static designs; and it will be less easy to use than static designs because the operator must know how to adjust the transducers.

5.2.4 Adjustable longitudinal

This concept utilizes the idea of having the transducers along the same axis as the access, but allows for transducer adjustability. The housing for one of the transducers is stationary, but the other housing can move along the same axis as the access. This adjustable housing is adjusted by rotating a screw; the linear movement on the screw threads will move the adjustable transducer housing. A sketch of this design can be seen in Figure 5.

The one main advantage to this design is that the transducer is adjustable. However, it is only adjustable along one axis, which may mean that adjusting the focal point of the transducer ultrasound wave intersection is not as easy. The adjustability on this design also means that it would be less easy to use and less operator independent. Another downside to this design is that the addition of screws to this design makes it less durable and more expensive.

5.2.5 Three Longitudinal transducers

This concept also utilizes the idea of having the transducers along the same axis as the access but allows for different transducer positions. All of the housings for the transducers are stationary similar to the two longitudinal transducer design but there are two focal depths instead of one.

For example if the three transducer housing angles were at 25 degrees in the front and at 45 degrees in the middle and back then you could reach accesses at 7.2 mm and 18 mm which is very advantageous. You would also not have to involve any screws like you do in the adjustable longitudinal design.

A disadvantage of this design is that it only accounts for adjustments in depth and not for adjustments from side to side.

5.3 Lateral Positioning Mechanism Pugh Chart

Testing results from the preliminary prototype showed that the transducer measurements are very sensitive to lateral movements, so it was determined that the final device needed to allow for lateral adjustment of the transducers.

Table 3 shows the Pugh Chart used to grade our concepts for the transducer housing subcomponent:

Table 3: Pugh Chart for lateral positioning mechanism concepts

Customer Requirement	**Weight**	**Rotating Rod**	**Electro-magnetic**
Operator Independence	17	0.75	1
Effective medium at transducer/skin interface	17	n/a	n/a
Geometric compatibility with current dialysis set-up	17	1	1
Flexibility to accommodate the range of patient arm/leg sizes	17	1	1
Transducer adjustability	17	0.75	1
Durable	10	0.75	0.75
Inexpensive	5	0.5	0.5
Total	**100**	**69.5**	**78**

5.3.1 Rotating Rod

The rotating rod was implemented and tested in the secondary prototype. In the secondary prototype, knobs were put on both ends of each rod so that an operator could manually rotate each rod to move the transducer housing to the appropriate location. This concept would also allow a small stepper motor to be attached to the rod so that it could automatically move the position of the transducers.

Although this concept worked at successfully allowing fine adjustment of the transducer position across the access, it proved to be difficult to adjust by hand. It was also unclear how challenging it would be to accurately install a stepper motor to the rod.

5.3.2 Electromagnetic

The electromagnetic concept was tested in the final prototype. At the time we were ready to test this concept, no control system was available to test how our prototype could move back and forth over an access. However, after increasing and decreasing a voltage to the wires, we could apply a force to move the transducers in one direction and allow the spring to push the transducer housing back in place. This concept has the potential to be connected to a controller that would be able to automatically make adjustments to the position of the transducer housing.

As indicated by the results of the Pugh chart, we feel the electromagnetic concept is the best lateral positioning concept. Although our secondary prototype was connected to a DC power supply as a means of actuating the device, future design iterations will be able to be connected to a controller that will be able to automatically adjust the transducers to the optimum signal reading.

6 PARAMETER ANALYSIS

The following subjections describe our design, the engineering analysis we used to come up with our design, the fabrication plan for our design, and the validation plan we will use to ensure our design meets the engineering specifications after it is manufactured. Due to the iterative “design-build-test” nature of our project, the majority of our guidance in selecting parameters for our secondary prototype and final prototype came from experimentation with our preliminary prototype and secondary prototype respectively. We also completed some analytical work to evaluate the expected transducer focus ranges as and the mechanics of the flexible band component.

6.1 Experimental testing with preliminary prototype

We completed preliminary testing in the Simpson Memorial Institute Laboratory using our preliminary prototype. The tests evaluated the effectiveness of the transducers for measurements across a range of flow-rates, the best orientation of the transducers, and the importance of lateral and depth adjustment. The preliminary prototype was a two-part design consisting of a rigid housing and a flexible “over-band”. The rigid housing has four transducer holes, two for the side-by-side orientation and two for the in-line orientation. The flexible over-band secures the transducers in place and is taped to the patient’s arm to secure the device. Figure 10 shows the assembled preliminary prototype while Figure 11 shows the separate components.

Figure 10 Assembled preliminary prototype

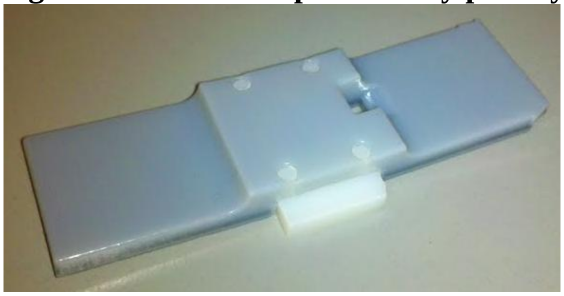
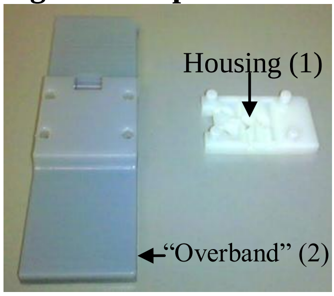


Figure 11 Separate Components



6.1.1 Test set-up

The test set-up in the Simpson Institute lab was provided by our sponsor and consists of three sub-systems: the transducer electrical system, the simulated access or “Phantom access” electrical system, and the Phantom access fluid system. Figure 12 shows a picture of the test set-up and Figure 13 shows a picture of the simulated “Phantom” access. The “Phantom” access simulates a dialysis patient’s access and consists of a 6 mm diameter tube housed beneath 1.25 and 2 cm sections of ballistic gel. The fluid used to simulate blood is a water-glycerin mixture with fine plastic particles.

Figure 12: Simpson Institute lab test set-up

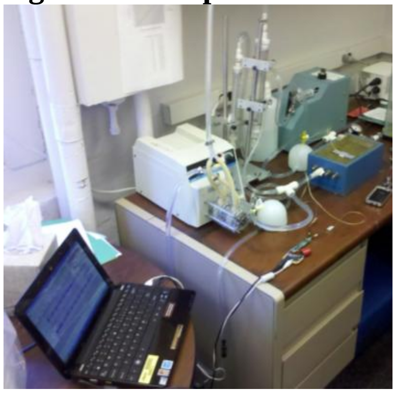


Figure 13: “Phantom” access

Figure 14 shows a simplified schematic of the transducer electrical system. The major components in the transducer electrical system are the netbook, circuit-board, and transducers. Pictures and additional information for these components are provided in Appendix G.

Figure 14: Simplified schematic of the transducer electrical system

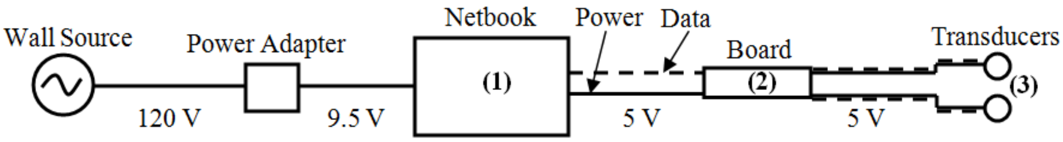


Figure 15 shows a simplified schematic of the Phantom access electrical system. The major components in the Phantom access electrical system are the isolation transformer, pulsatile pump, and continuous pump. Pictures and additional information for these components are provided in Appendix G.

Figure 15: Simplified schematic of the Phantom access electrical system

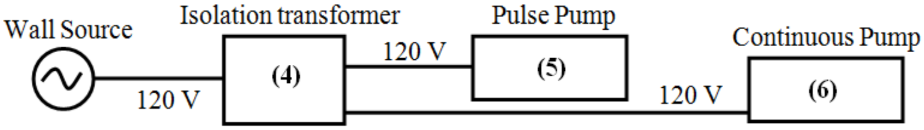
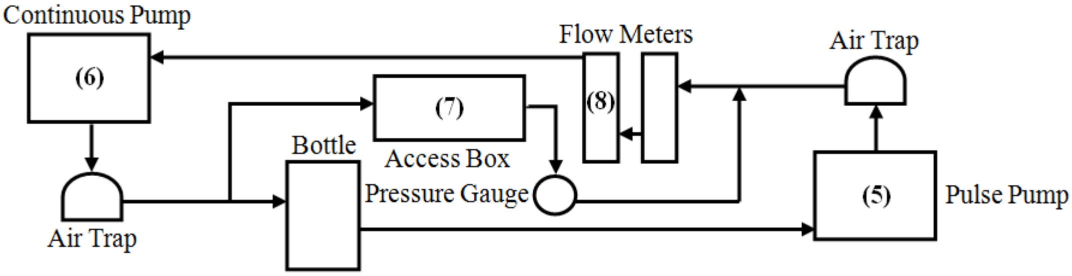


Figure 16 shows a simplified schematic of the Phantom access fluid system. The major components in the Phantom access fluid system are the pulsatile pump, continuous pump, access box, and flow meters. Pictures and additional information for these components are provided in Appendix G.

Figure 16: Simplified schematic of the Phantom access fluid system



6.1.2 Testing the effectiveness of the transducers across a range of flow-rates

Our sponsor asked us to evaluate the effectiveness of the transducers at measuring velocities across a range of flow-rates. To evaluate this, we applied the transducers in the in-line orientation to the simulated access box and collected velocity measurements while varying the flow-rate through the continuous pump from 100m/min to 1500 ml/min. This test was completed at three different locations: the center of the axis, 2 mm from the center of the access, and 3 mm from the center of the simulated access. Figure 17 shows the varying velocities measured at the access center. The velocity increases fairly linearly with flow-rate until around 800 ml/min and then drops off.

Figure 17: Velocity vs. flow-rate at access center

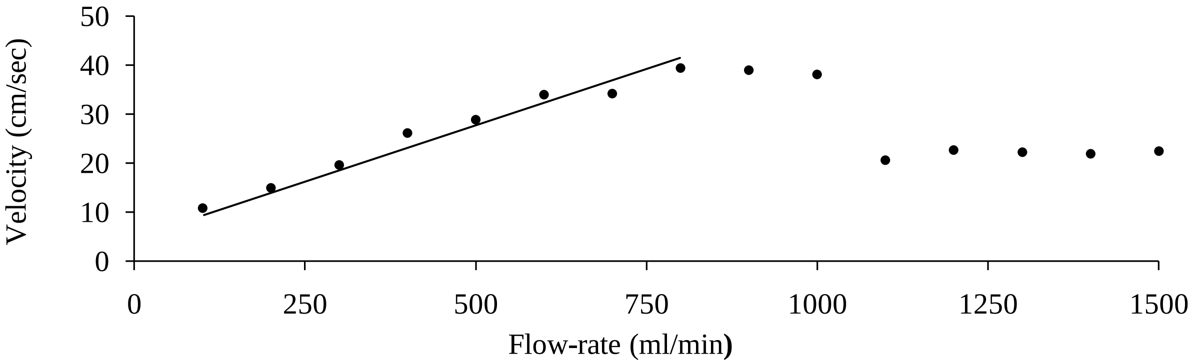


Figure 18 shows the varying velocities measured 2 mm from the access center. The velocity increases fairly linearly with flow-rate until around 1200 ml/min and then drops off.

Figure 18: Velocity vs. flow-rate at 2 mm from the access center

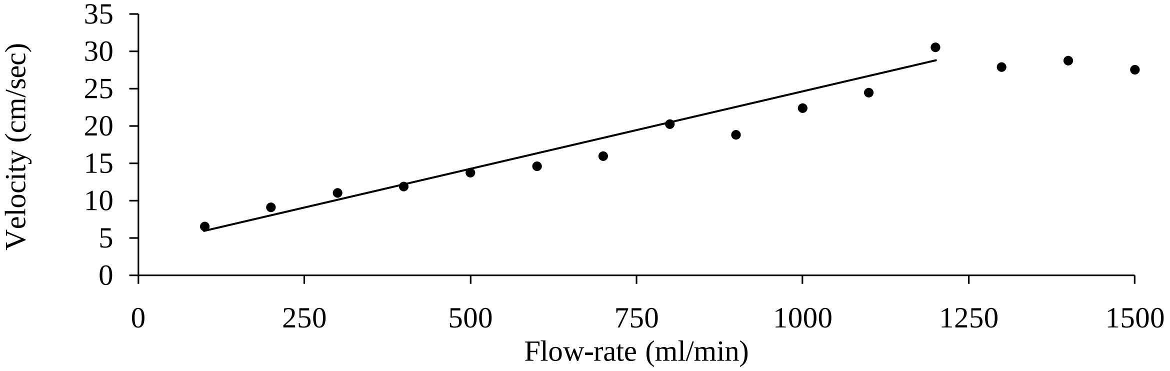
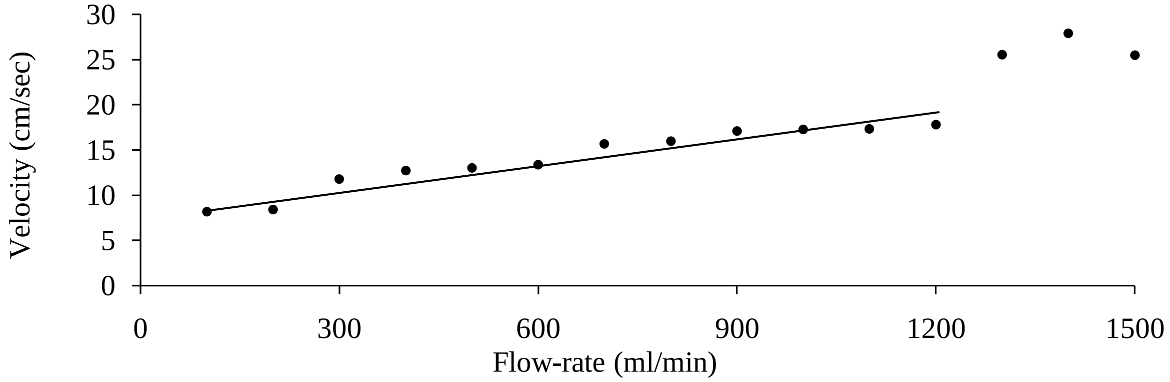


Figure 19 shows the varying velocities measured 3 mm from the access center. The velocity increases fairly linearly with flow-rate until around 1200 ml/min and then increases sharply. At lower flow-rates, all three positions provided a linear velocity vs. flow-rate relationship. At higher flow-rates, the relationship between velocity and flow-rate did not show a consistent trend.

Figure 19: Velocity vs. flow-rate at 3 mm from the access center



Another observation that we made was that the noise of the measured signal greatly increased at the higher flow-rates. Figures 20 and 21 show the large increase in signal noise from lower to higher flow-rates. From our assessment of the velocity measurements and signal noise across varying flow-rates we concluded that the device is most reliable at flow-rates under 900 ml/min. Two possible explanations are that the velocity calculation in the software does not account for the changing flow profile at higher flow-rates or that the flow becomes turbulent enough at high velocities to deviate from unidirectional flow and interfere with the Doppler method of velocity measurement.

Figure 20: Less noisy signal at 100 ml/min

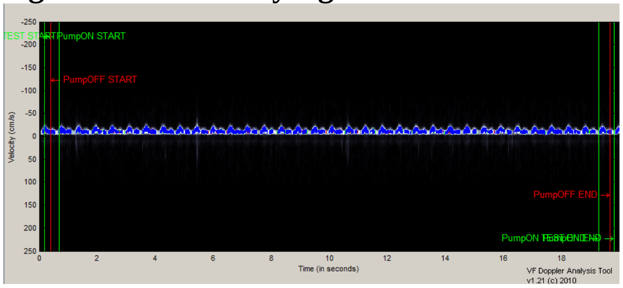
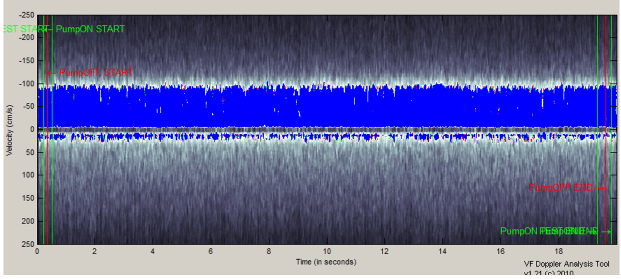


Figure 21: noisier signal at 1500 ml/min



We concluded that the measurements are most reliable below 900 ml/min. This is not expected to be a significant problem as the objective of these measurements is to provide early detection of clotting in accesses. The flow-rate in a clotting access is expected to decrease incrementally from 900ml/min to no flow, so the device should still effectively detect clotting in an access before complete thrombosis occurs.

6.1.3 Testing to determine the best transducer orientation

The second experiment that we completed compared the side-by-side and in-line transducer orientations. For each test run we inserted the transducers in one of the two orientations and applied the device to the phantom access box. We moved the transducers laterally across the access until we obtained the strongest signal, and took that to be the center of the axis. We then displaced the transducer one mm at a time from the center of the access until the signal was lost. The transducer position values are referenced from the side of the access box and show the relative change in position between measurements. We completed two runs at each orientation at each access depth and averaged the measured velocities from the two runs to increase the accuracy of our data. Figure 22 shows the measured velocity profile using the side-by-side orientation while Figure 23 shows the measured velocity profile for the in-line orientation.

Figure 22: Side- by-side orientation

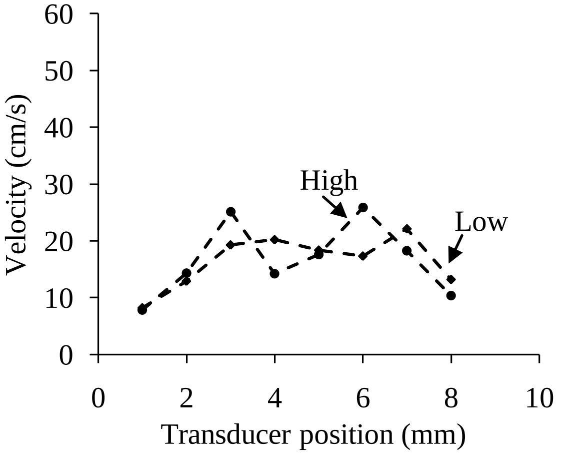
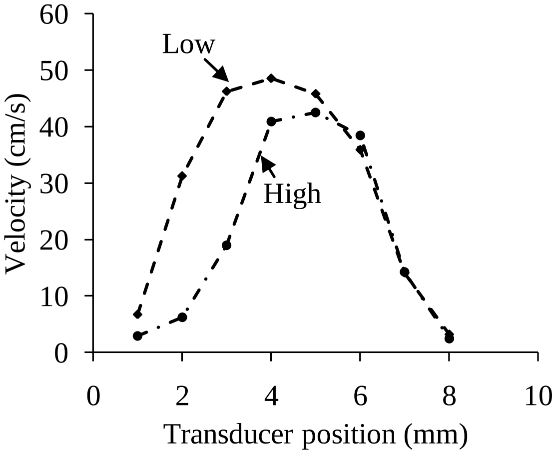


Figure 23: In-line orientation



The in-line testing produced the parabolic velocity profiles that we expected to measure. We believe that the lateral discrepancy between the high and low depth measurements is due to a slight shift in our reference point between test runs. The slightly lower velocity measured at the deeper depth is also expected as the in-line transducers are expected to target a depth of 1.3 cm, much closer to the high velocity center of the shallower access depth of 1.5 cm than the deeper access depth of 2 cm. The velocity profile for the side-by-side transducers does not follow the expected parabolic pattern. The velocity measurements are more consistent across the lateral movement, but there is no clear reason for the measured variances. As the in-line orientation produced consistent results that we could explain, we decided to move forward with the in-line orientation as the more reliable transducer configuration for our next prototype.

6.1.4 Testing for lateral and depth adjustment with focused and un-focused transducers

The third experiment that we completed compared the effectiveness of focused and un-focused transducers at measuring the access flow velocity at different depths using the in-line orientation. The test procedure was identical to the side-by-side vs. in-line experiment, except that we tested two types of transducers with the same orientation. We found that both types of transducers produced the expected parabolic velocity profiles. From the limited testing that we have been able to complete so far it is not clear whether the focused of unfocused transducers produce more reliable results. However, our second prototype can be used interchangeably with either transducer type. We can complete further testing with that prototype to determine the best transducer type for our application.

While there is some difference between the measured velocities at the high and low depths, lateral movement clearly has a more significant effect on the measured velocity. The depth difference between the high and low transducers is 7.5 mm and results in moderate to no difference in measured velocity. In the lateral direction, any displacement greater than about 1 mm from the center leads to significant drop in measured velocity. Therefore, we concluded that fine lateral adjustment was a higher priority in our second prototype than depth adjustment.

Figure 24: Focused transducers

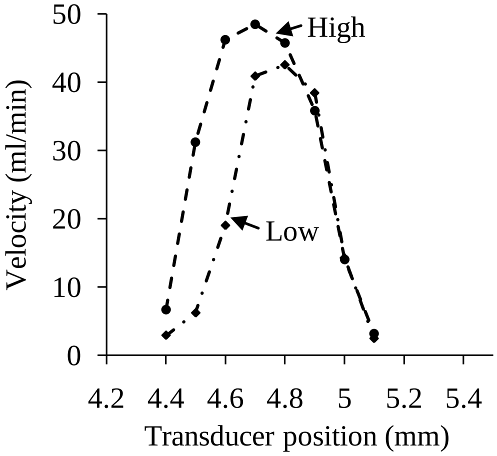
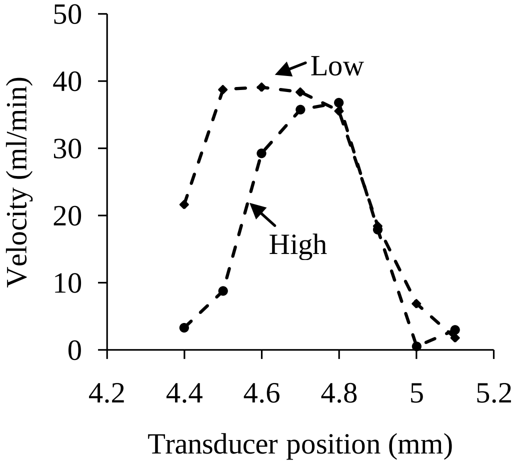


Figure 25: Unfocused transducers



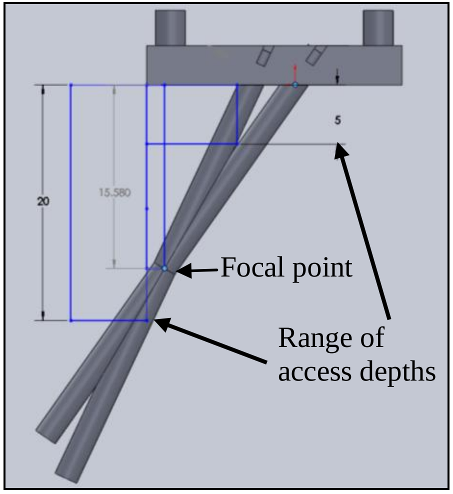
6.2 Analytical assessment of design parameters

We also completed an analytical assessment of some of our design parameters.

6.2.1 Transducer focus depth

We roughly modeled the transducer beams as 2 mm diameter cylinders extending from the faces of the transducers. Our engineering specification on depth range requires that our device be able to target access depths from 0.5 to 2.0 cm. As our simple model in Figure 26 shows, the focus depth of our in-line orientation is about 1.56 cm. However, due to the shape of the beams, there is still some overlap a couple mm both above and below the focus depth. We considered this rough graphical model when deciding what orientations to provide for our second in-line prototype.

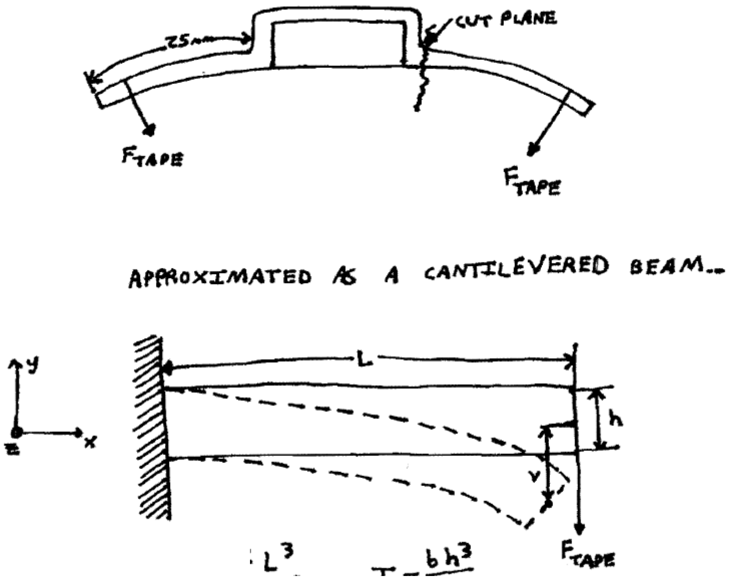
Figure 26: Preliminary prototype focus depth



7.2.2 "Over-band" flexibility

Our initial over-band prototype required more force to deform than we had initially expected. When applied to our arms, the force required to secure the wings was greater than can be provided by medical tape. We identified the main problem to be the thickness of the wings. Therefore, we modeled the wings as a cantilevered beam to better understand the relationship between the band thickness and the force required by the tape. Figure 27 shows a sketch of the analysis where L is the wing length, h is the wing thickness, v is the displacement at the end of the wing, F is the force applied by the tape, and b is the wing width in the out-of-plane direction.

Figure 27: Modeling of over-band wings as cantilevered beams



Equation 1 provides the relationship between the force at the tape and the second moment of inertia, *I*, where *E* is Young's modulus for the material. Equation 2 gives the relationship between the wind thickness and the second moment of inertia. Combining Equations 1 and 2 produces the proportionality in Eq. 3 which shows that the force required to produce a given deformation varies with the cube of the band thickness.

$$v = \frac{FL^3}{3EI} \qquad \text{(Equation 1)}$$

$$I = \frac{bh^3}{12} \qquad \text{(Equation 2)}$$

$$F \propto h^3 v \qquad \text{(Equation 3)}$$

Using this proportionality, we can estimate the expected reduction in taping force for a given reduction in band thickness for our second prototype.

6.3 Experimental testing with secondary prototype

We also completed testing in the Simpson Memorial Institute with our secondary prototype. We performed velocity profile tests on the phantom access setup similar to those performed with the preliminary prototype. In these experiments we tested varying the transducer type (focused or unfocused), transducer orientation (aiming at shallow depth or deep depth) and access depth on the lab setup (9.5 mm or 18 mm). The secondary prototype was designed to improve upon the preliminary prototype and allow for fine lateral adjustment as well as coarse depth adjustment. The design consists of a transducer housing that holds the transducers, a cover that keeps the transducers in place, and watch bands that are taped to the patient to secure the device to the patient (Figure 28). The watch bands are connected to watch pins that go through bored out holes in the cover. Rods on the cover are attached to the transducer housing by a string that positions the transducer housing over a 3mm lateral range when rotated. This prototype has two in-line transducer orientations that focus at depths of 9.7 mm (shallow orientation) and 17.5 mm (deep orientation) (Figure 29).

Figure 28: Secondary Prototype

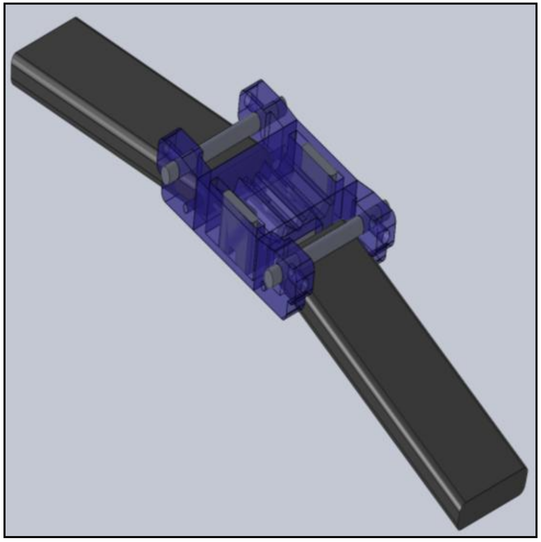
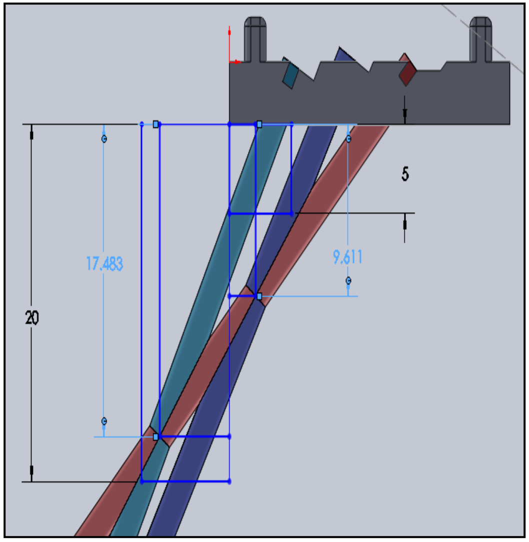


Figure 29: Depth Focus



In our testing, we created flow profiles for the focused transducers in a shallow orientation and shallow depth, deep orientation and deep depth, and deep orientation and shallow depth. For the unfocused transducers, we tested at a shallow orientation and shallow depth as well as a deep orientation and deep depth. From the curves shown in Figure 30 we were able to form conclusions about our secondary prototype that benefitted in the design of the final prototype. We were able to conclude that if the focused transducers are used, we do not need to account for depth adjustment in the design; at the shallow depth, the focused transducers at the shallow orientation (blue curve) and deep orientation (purple curve) both yield similar data in terms of peak velocity. The focused transducers at the deep depth (red curve) also yielded data showing the velocity profile curve of the access, but the magnitudes at each position were lower than when measured at the shallow depths. We believe that the magnitude of the velocity at the deep depth and deep orientation is lower due to the fact that the access is much deeper and results in the transducer beams to travel further. Therefore the receive signal is much weaker and has a lower velocity. We also concluded that we should allow for more than 3 mm of lateral movement based on Figure 31. We noticed that there is a steep drop-off in velocity measured between 1.5 mm away from the center of the access and 2mm away from the center of the access, so in our new design we will try to allow for 4 mm of lateral translation versus only 3 mm of lateral translation in the secondary prototype. Lastly, we have decided to pursue a more efficient way to laterally adjust the transducer housing because we found it difficult to turn the rotating rods during testing.

Figure 30: Secondary Prototype Data

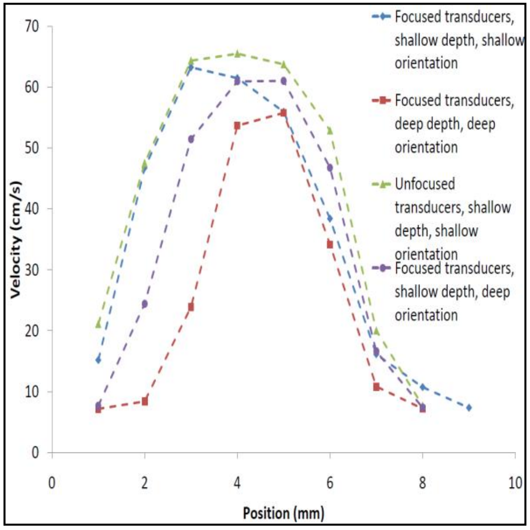
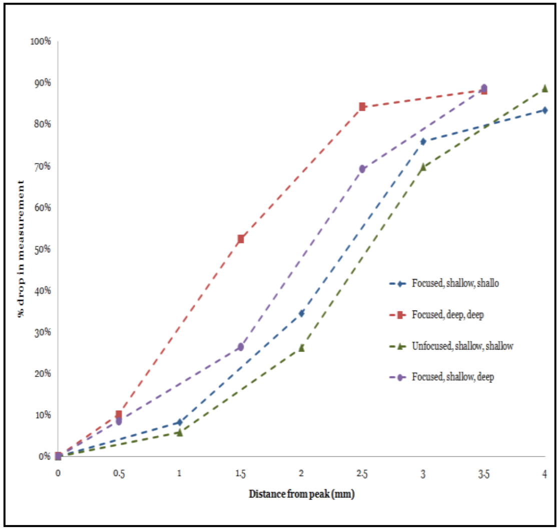


Figure 31: Relative Percent Error Drop



6.4 Analysis Assignment Summary

We also completed three types of analysis on our final design: material and manufacturing process selection, design for environmental sustainability, and design for safety. These types of analysis allowed us to focus in more depth on a couple of the major components in our design. A more detailed description of this analysis is provided in Appendix C.

6.4.1 Material and Manufacturing Process Selection

Using CES EduPack 2010, we completed a material and manufacturing process selection. For the materials selection portion, we searched for materials that would best fit the needs of our housing components and the band pins. To search for a material for the housing components, we searched for materials that met or exceeded the properties of the VeroWhite material used for those components in the final prototype. Then, we limited the results of that search to materials that were compatible with organic solvents (rubbing alcohol for cleaning) and water. From the remaining materials, we selected Polyethersulfone (PES) for its ability to withstand repeated cleaning cycles and its compatibility with injection modling. For the strap hinge pins, we again used the material properties of the current Brass Alloy 260 hinge pins as the minimum standard and searched for materials that were also non-ferrous and less expensive. We found that the only mechanically comparable materials in the same price range were steel and aluminum. However, steel is ferrous and would not work for the application while aluminum is slightly more expensive than brass. Therefore, after our search we still recommend staying with brass strap hinges.

We then used the materials with the CES process selector to determine the best processes for producing the housing components and hinge pins. To match the tolerances of our Objet printed prototype parts, we found that thermoplastic injection molding was the best option. This process has an economic batch size of around 100,000 units while allowing feature sizes of less than 1 mm and tolerances of 0.3 mm. The Brass Alloy 260 hinge pins could be produced through low pressure die casting. This process is recommended because it can produce small parts with tight tolerances, is compatible with low-melting point materials such as brass, and has a lower capital cost relative to other die casting methods.

6.4.2 Design for environmental sustainability

We also completed a design for environmental sustainability analysis for the housing components and strap hinges using SimaPro software and the EcoIndicator 99 system. We found that the largest environmental impact of these two components would be on natural resources, largely due to the use of the Brass Alloy 260. The use of the PES also rated some points for negative human health effects. The greatest emissions impact is in air emissions with the PET producing about 90 grams per unit and the Brass Alloy 260 emitting about 100 grams per unit. PET also produced large amounts of waste and had some impact on water. Overall, the PET parts are associated with greater emissions.

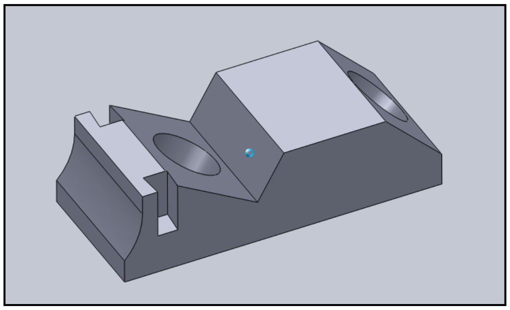
6.4.3 Design for Safety

From the results of Designsafe, we have learned that there is no major risk in using our device because the risk level on all of our hazards is low. The most severe hazard involved in our project is blood borne disease because there is a possibility that blood may get on our device from one of the dialysis needles. In cases where blood gets on our device, we would have standard procedures that either require for that device to be properly discarded or for the device to be rigorously cleaned with alcohol. We would also lower the risk level of unsanitary conditions, bacterial infections and viral infections by cleaning device in between each use with alcohol to ensure that germs do not get passed from patient to patient. In order to prevent a pinch point on the skin, we will train the operators as to how to properly translate the device. Also, this pinch point would be negligible because our device is only translating 3 mm. In order to reduce electrical hazards, we will secure all wiring in a fixed enclosure so it is no exposed to the patients. No electrical equipment will be plugged into a wall outlet so there is no ground connection between the patients and any electrical equipment which could cause an electrical current to pass through them. To avoid reactions between our device and cleaning alcohol, we will only use materials that are compatible with alcohol to ensure patient safety. We will also make sure the technicians ask patients if they have any known allergic reactions to the materials in the ultrasound gel. Since Design Review 3, we have added some modifications to our design. We will now be using electromagnetism to actuate our device and with that comes some safety concerns. In our design, we have fully enclosed the copper wires that the current will be passing through and will not allow more than 0.3 amps of current to flow through the wire. As for the magnets, the magnetic field will not exceed 0.5 Tesla and will be safe for patients. When redoing our analysis in Designsafe, the risk was negligible with these new additions. After doing our analysis in Designsafe, we have found no major safety concerns to the users of our device.

7 CONCEPT DESCRIPTION

Our final design utilized electromagnetic actuation and a spring to translate the transducers side-to-side within a rigid cover. From our testing, we found that we could use just two transducers focused at a deep depth in the inline orientation. Our concept was intended to be a proof of concept for using electromagnetic actuation, and did not include all of the details for the transducers, yet allowed the rough geometry for them. Figure 32 shows the transducer housing.

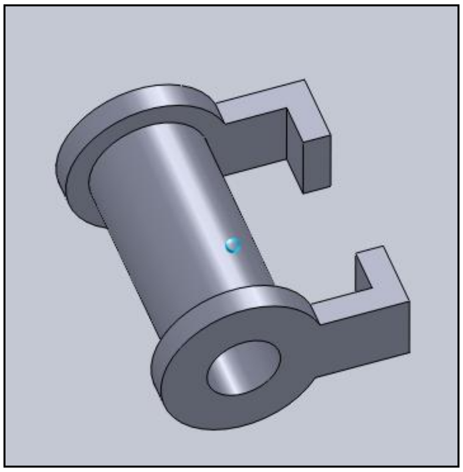
Figure 32: Transducer housing which could allow for two transducers focused at a depth of 17.6mm vertically below the surface of the skin



The transducer housing is low-profile, and allows for an over-band with the negative profile of the top surface, which would hold the transducers in place and still allow for lateral translation. It also includes features on the front which allow for a winding barrel to be affixed to the front of the transducer housing after wire is coiled onto the winding barrel. The two notches for the winding barrel arms have been enlarged and drafted as a consideration to the flow of material into the inside corners which occurs during the rapid prototype process.

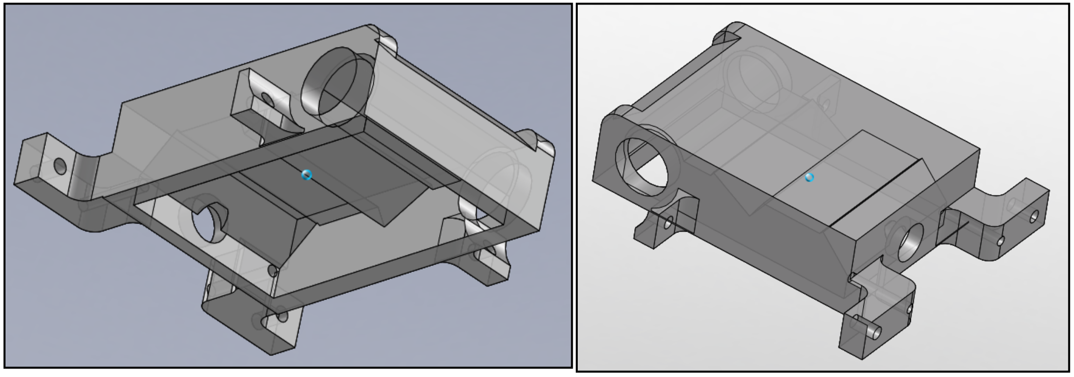
The winding barrel has a 2mm inner diameter that will allow a 2mm ferrous rod to slide within it. This will be the guide track for lateral translation. The barrel has a 3.25mm primary outer diameter to which up to 160 turns of .006" magnetic wire can be coiled around. There are outer flanges which keep the wire in place, and finally extending arms which provide the fixture between the barrel and the transducer housing. The winding barrel will be wound before being attached to the transducer housing for ease of winding, and then later glued in place to the transducer housing. The winding barrel was made as large as possible so that the maximum number of turns of wire could be wound. The more turns of wire, the stronger the electromagnetic force, which is critical with such small components. The wire will extend from both ends of the barrel and be used to connect to a power supply.

Figure 33: Winding barrel which will have magnetic wire coiled around it to provide electric field for electromagnetic system



The winding barrel slides along a 2mm ferrous rod which is centered between two magnets in the cover. The transducer housing/winding barrel/ferrous rod assembly fits inside of the cover, which has a negative profile of the transducer housing and winding barrel to allow for translation while holding the transducers in place. There are four feet which protrude from the cover that hold two rods in place, which secure the watch bands to the cover. These feet were placed as close the cover wall as possible so that the hinge points of the securing bands were as close as possible. A narrower width allows the device to fit a wider range of wrists and radii of curvature. The cover was also designed to be as low profile as possible so that the device would fit within the customer requirements for dimensions, and was able to meet all of the specifications (the feet extend beyond the 25.4mm length requirement by 0.34mm, but the device narrows to 21.74mm where the needles would be located). A slant was cut into the front of the cover in an attempt to lower the front profile of the device since the front needle will be angled. Two holes were introduced to the rear of the cover to allow for the magnet wire to be fed through the device. Once the assembly is near completion, a thin sheet of ultrasound transparent material is glued onto the bottom of the cover, sealing the transducer housing inside. A rubber stopper is placed in the rear of the cover, which seals the system and allows for a syringe to fill the cavity of the cover with fluid while air escapes out of the wire holes. When the cavity is full of fluid, the wire holes are sealed with glue.

Figure 34a and 34b: The lower and upper views of the cover show the negative profile of the transducer housing as well as the band hinge points



The transducer housing, winding barrel, and cover are all created using SLA rapid prototyping, which allows for tight tolerances and complex geometries to be manufactured quickly and easily. The following is a description of the assembly process and the actuation of the device:

Figure 35a and 35b: Winding barrel fits into transducer housing after being would with wire

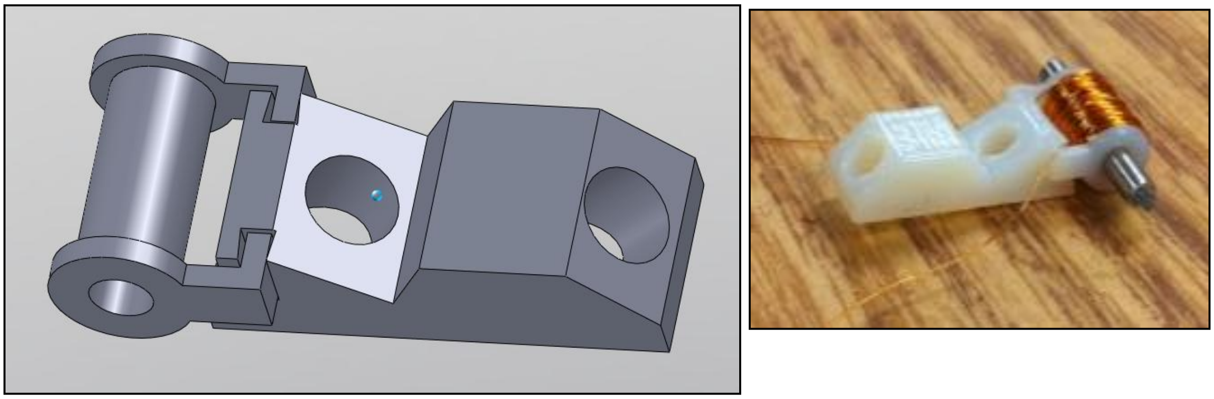
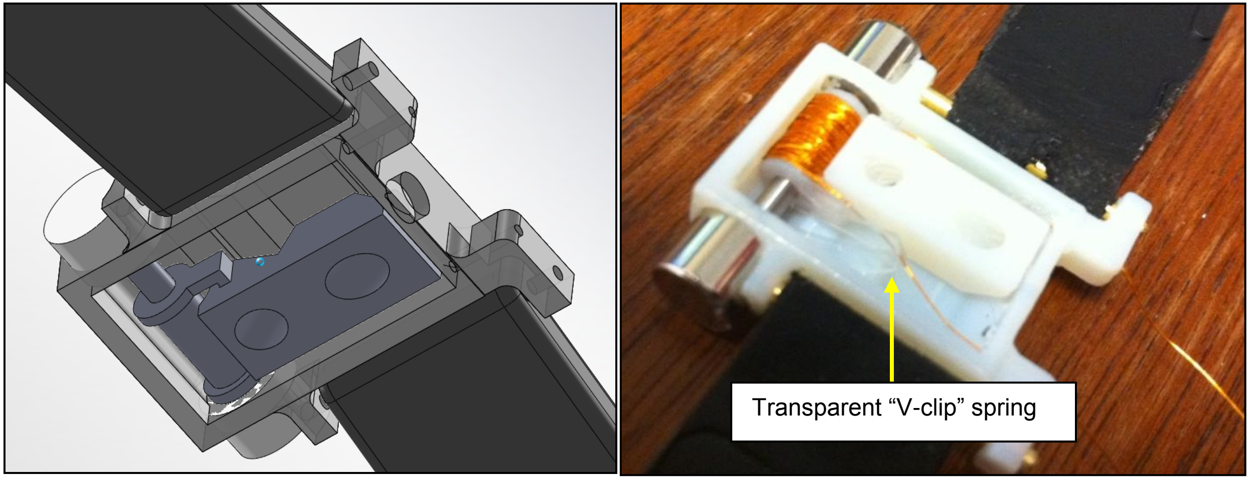
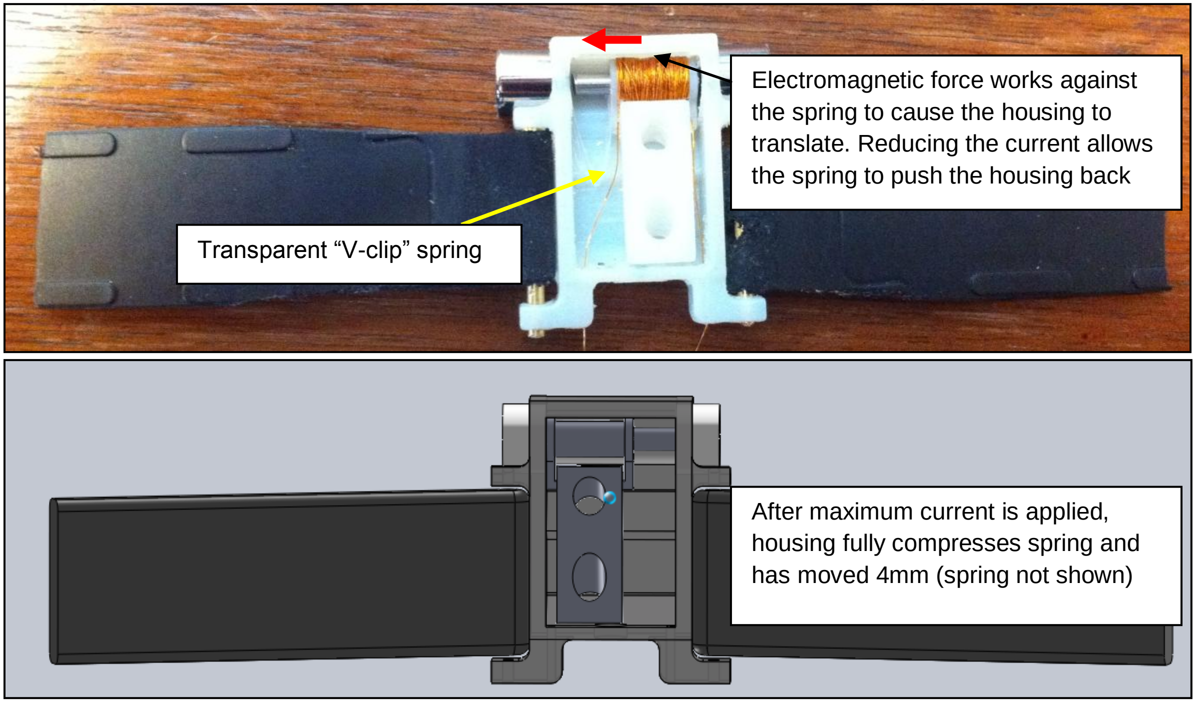


Figure 36a and 36b: Transducer housing/winding barrel assembly is slid over ferrous rod and inserted into the cover, which has a magnet glued into each side and a watch band secured to each side with brass pins. Finally, an ultrasound transparent film (not pictured) is glued onto the bottom surface, and the rubber plug is inserted into the cover and the cavity is filled with fluid, then sealed fully.



The design planned for 160 turns to fit on the coil, but we were able to get 200 turns without the coil becoming too large to fit. We used a “V” shaped piece of plastic as our spring, which resisted the electromagnetic force. In Figure 37, as current is applied to the coil, the electromagnetic force causes the transducer housing to translate, and compress the spring. As more current is applied, the transducer housing translates further, so that the transducers can be programmed to sweep across the surface of the skin, take readings along the translational path, and find the highest velocity of blood flow in the artery.

Figure 37: Current applied to the coil causes the spring to compress, allowing the transducer housing to move anywhere along the track inside the cover from varying electrical input



Electromagnetic force works against the spring to cause the housing to translate. Reducing the current allows the spring to push the housing back

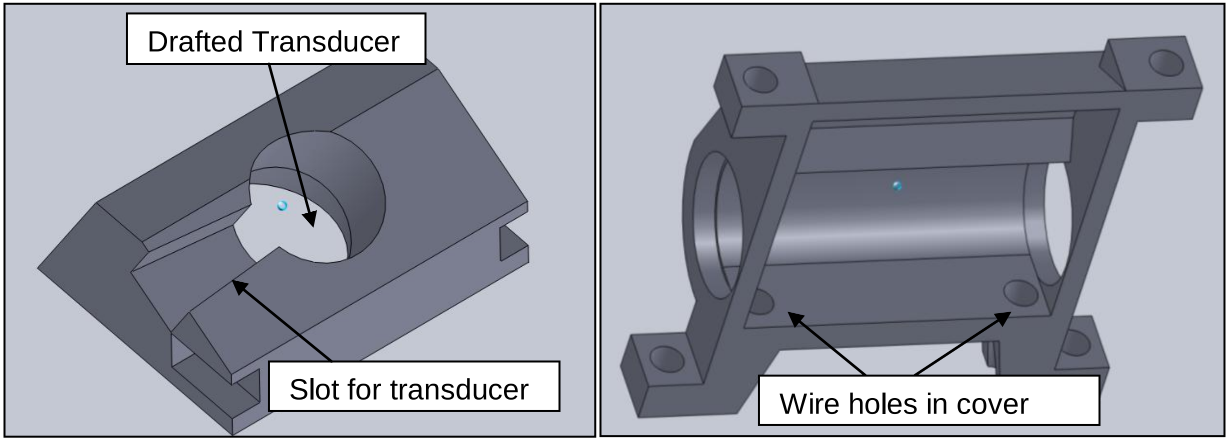
Transparent "V-clip" spring

After maximum current is applied, housing fully compresses spring and has moved 4mm (spring not shown)

8 FINAL DESIGN

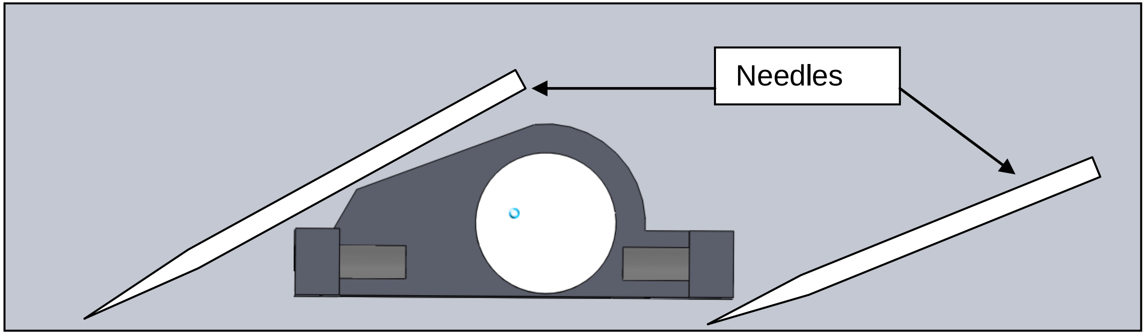
Since our final concept was just a proof of the electromagnetic actuation and the ability to seal the system and fill it with fluid, a final design would have a few differences in order to meet all of the requirements. Primarily, a final design would be designed to actually house transducers. By using a pulse wave transducer instead of continuous wave transducers, we can get a velocity measurement using just one transducer. The final design would ideally use just one transducer in order to save space and allow for a shorter dimension between the two access points. With a single transducer, we would strip the coaxial cable near the transducer. In the coaxial cable, there are two individual wires, each with shielding and protective layers, which are then combined in another shielded and protected covering. It would be this final covering which would be stripped so that the remaining amount of wire is much more flexible, otherwise it may induce extraneous forces inside the cover and cause unreliable actuation. These wires would come out of the side of the transducer housing and then be run out of the cover along with the magnet wires, as shown in Figure 38. The hole for the transducer should also be drafted starting from the edge of the transducer, to allow for more reflected waves to reach the piezoelectric crystal.

Figure 38a and 38b: Transducer housing (a) for single pulse wave transducer and cover (b)



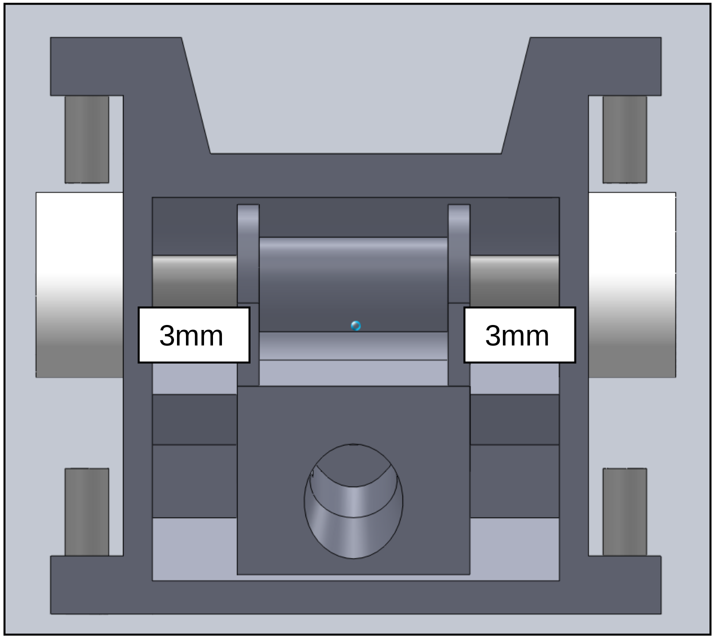
The other major change to a final design would be to increase the size of the wire coil. In this new final design, the wire was coiled around a 3.25mm diameter, coiling to a final diameter of 4.5mm. The final design would again coil around a 3.25 diameter, but have a final diameter of 5.5mm, which should fit at least 280 turns of wire, whereas the concept only allowed for a theoretical 160 turns. Also, the new barrel does not have arms which turn in, and should allow for easier winding and a cleaner winding. The winding barrel diameter can be increased because its position is moved to the rear of the device. Since the needles are always oriented as shown in Figure 39, this will still fit under the needles. In future iterations, this barrel diameter could possibly be increased even further if 280 turns is not enough.

Figure 39: The needles are angled so that the rear of the device can be higher than the front



While the concept of using a spring to return the device was proven, it would be better to have the transducer housing centered in the cover at equilibrium, so that the when the clinician initially places the device, it can sweep in both directions to find the maximum velocity. Because of this requirement, the new design incorporates the use of two springs (exact spring dimensions need to be optimized in further testing) by allowing room for a spring on both sides of the transducer housing. Since the springs are difficult to fully compress, the final design allows for 6mm of travel within the cover, so that even if the springs are 1mm wide when fully compressed, there will be 4mm of travel (3mm is the requirement).

Figure 40: 3mm gaps on each side allow for two springs and up to 6mm of full travel



From our concept testing, we found that the transducer housing was slightly crooked when actuated. This was from the torque introduced by the spring not being fully centered, and a long transducer housing. With this new single transducer housing and dual springs, the spring torques will counteract each other and this problem will be mitigated. Also, we bored the wire barrel hole a bit too large in the concept, and a better fit hole will cause better guidance along the ferrous shaft.

A final change to the final design would be to use 4 pins instead of 2 to hold the bands, since the magnets will be in the middle of the device. The bands can be molded or cut to fit around the magnets, and then the pins can be pushed into place and glued to the cover, so that the bands can hinge freely. Using thinner sidewalls on the cover, the hinge points are still only 18.5mm apart.

From our testing, we found that a stronger electromagnetic force would work better, so this final concept allows for more turns of wire. We also found that the winding barrel was too loose on the guide shaft, so the final concept should be bored to a smaller diameter (on the concept, it was bored to ~2.5mm instead of ~2.1mm). This should create more reliable and consistent translation. Finally, we found that the guide rod did not stay centered, which caused the device to lose some of the translation (from ~3mm of travel to ~1mm of travel after sealing and use) after repeated use and wear. Not depicted in the CAD drawings is a thin washer which should fit around the shaft and fit the profile of the cover to keep the shaft centered on the magnets. The final concept worked using magnetic actuation and a spring to allow for adjustment of the lateral positioning all while the prototype was filled with fluid, so after incorporating all of these improvements, the final design should perform to the ideal requirements very consistently. All of the incorporated changes ensure that the final design is on target. The final parts list is below, with key components shown in figures 41 through 44:

1. Transducer housing
2. Winding Barrel

3. Ferrous Rod
4. 2 Neodymium Magnets (1/4” diameter x ¼” inch thick)
5. Cover
6. 4 brass pins
7. 2 elastomeric bands
8. 1 Pulse Wave Transducer
9. 1 length of magnet wire
10. Ultrasound transparent film
11. Ultrasound transparent fluid

Figure 41a and 41b: ¼”Diameter x ¼”thick magnets (a) and transducer housing (b)

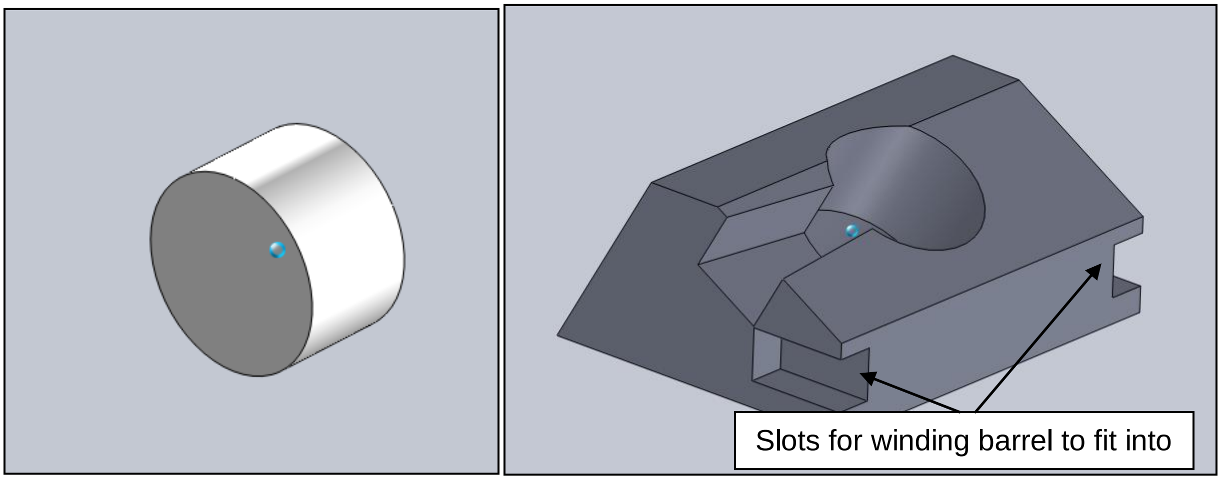


Figure 42a and 42b: Winding barrel (a) and its interface with the transducer housing (b)

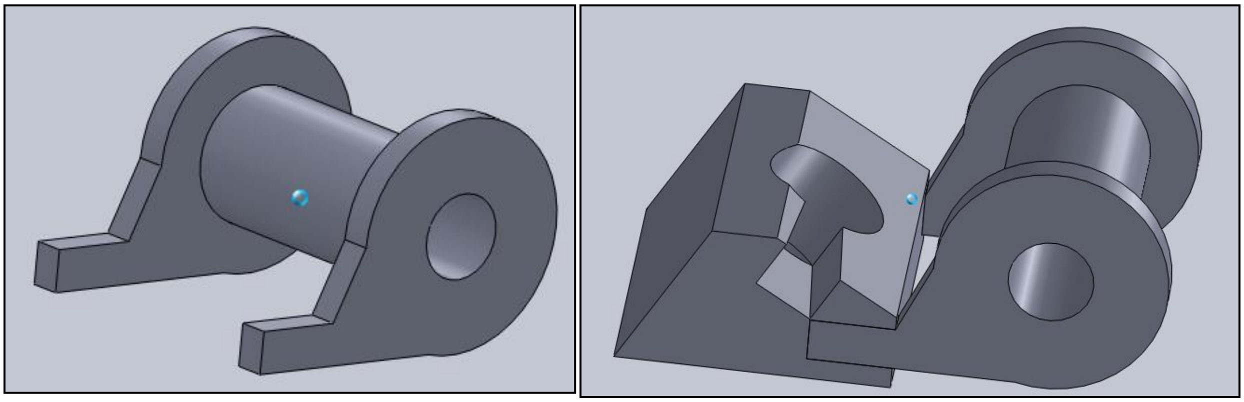


Figure 43a and 43b: Cover (a) and assembly without bands (b) showing pins for bands

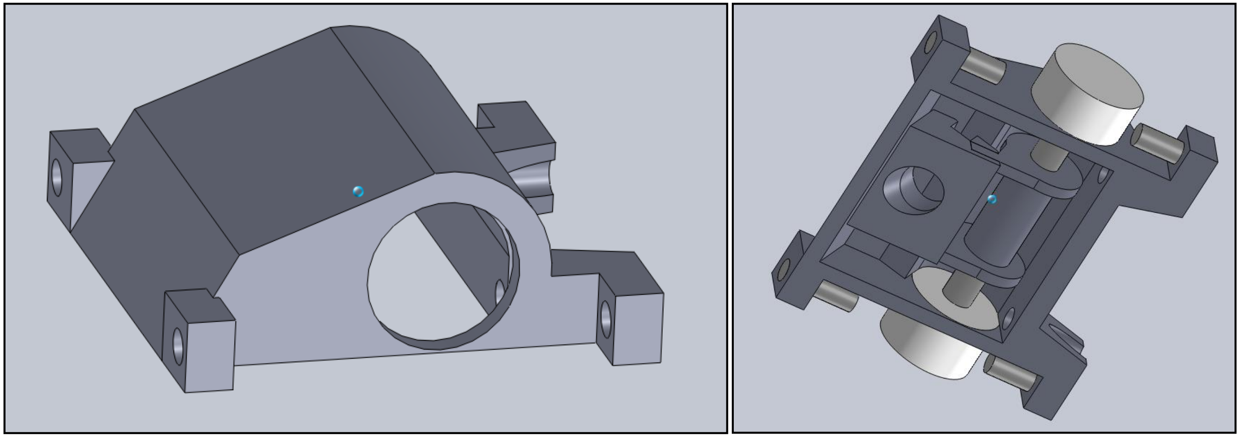
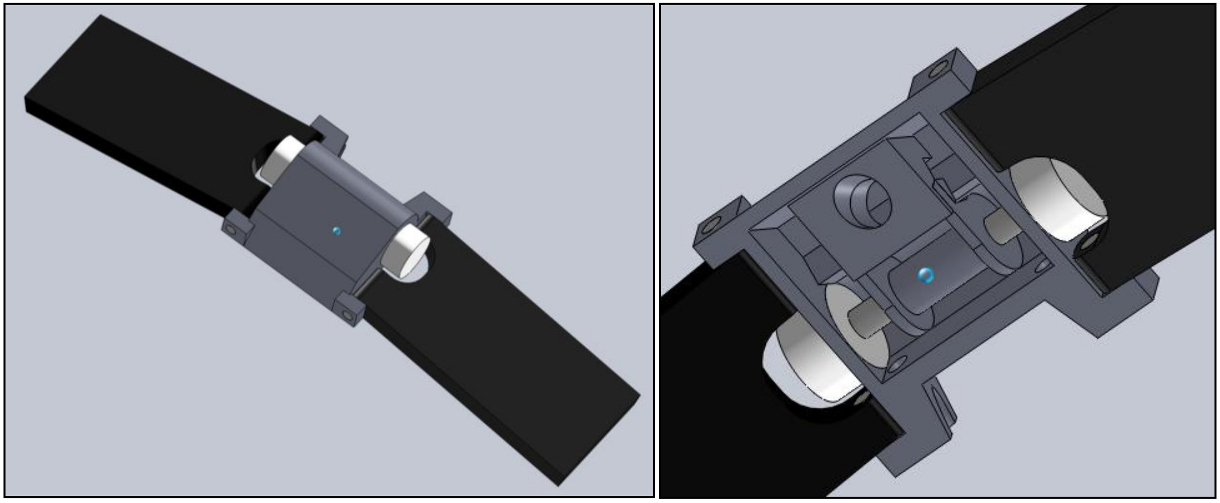


Figure 44a and 44b: final assembly (without springs or ultrasound transparent layer on bottom)



9 FABRICATION PLAN

This device consists of seven main parts: the cover (Figure 12), transducer housing (Figure 10), winding barrel (Figure 11), transducers, coil wire, bottom cover, and band assembly.

In the final prototype, fabrication of the cover, transducer housing, and winding barrel all utilized rapid prototyping through the PolyJet process. For this process, we submitted .STL CAD files to a rapid prototyping company. When submitting this file, we also choose what material we want the CAD model to be fabricated out of; all three of these pieces were made of a Vero material. Parts manufactured through the PolyJet process are made layer by layer. A machine that has information on the CAD model deposits a thin layer of the material in the appropriate shape, and then cures that layer using UV bulbs. After one layer is complete, the machine deposits more material and cures another layer. This process is continued until the entire model is built. A water jet is used on the final product to brush away any support material on the prototype.

In the final design, the cover, winding barrel, and transducer housing will utilize injection molding. Injection molding is less expensive on a mass scale, but it cannot be used for the winding barrel because of the intricate nature of its design.

In this final prototype, the transducers were not a part of the design because the emphasis of this prototype was to prove the electromagnetic actuation concept. However, for the final design the transducers will sit in the holes in the transducer housing. A wire management concept for the transducer wires has not yet been created for the final design, but the wires will probably have to exit the housing through holes in the back or side of the cover.

The coil wire is a 36 gauge copper wire. It has 160 turns around the winding barrel. After the wire is coiled around the winding barrel, the winding barrel is glued to the transducer housing with Super glue. A steel rod is then inserted through the hole of the winding barrel of the assembly, and this assembly is then inserted into the cover (see Figure 14). Magnets are glued to each side of the cover so that the steel rod sits between them. Each end of the copper wire is then threaded through the appropriate hole on the cover.

The bottom cover is an ultrasound transparent film cut to the size of the cover. After the transducer housing-winding barrel assembly is put together and set inside of the cover, the bottom cover is adhered to the bottom of the cover by Super glue. After this dries, water is injected through the hole in the back of the cover. A rubber stopper is then inserted into this hole to prevent water from leaking out.

For the final prototype, the band assembly on each side of the cover consists of a brass spring pin and a plastic watch band. However, if this were to be ultimately produced on a mass scale, injection molding would be utilized for the flexible plastic piece instead of a watch band. The watch pins of band assembly are inserted into the appropriate holes of the cover after the cover is filled with water and sealed.

In terms of adjusting the lateral position of the device, the electromagnetic actuation concept made on the final prototype functions properly and is the best option for lateral positioning of the transducer housing. Although the mechanical adjustment concept with the rods and shaft we made on the secondary prototype worked, the electromagnetic concept is easier to use and more user-friendly. The entire concept still is not final because the final prototype was only connected to a power supply instead of a controller and it could only be actuated in one direction. A better spring mechanism between the cover and the transducer housing could also be developed. The final design could also be improved by having more turns around the winding barrel to generate more force for the same amount of current applied.

Although the final prototype worked properly, the electromagnetic actuation concept could also be improved by design modifications to the transducer housing piece. We noticed that sometimes when we were actuating the device, the transducer housing would not remain perfectly perpendicular to the metal rod axis that was guiding its lateral translation. Having another rod in the back of the transducer housing could help guide its translation so that it would remain straight the whole time.

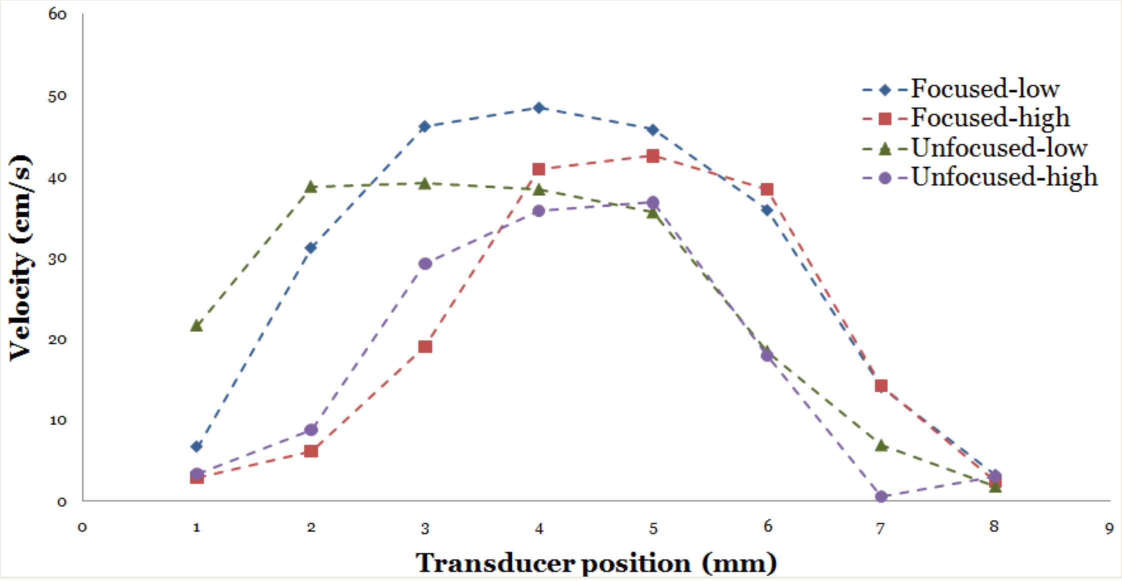
Through manufacturing our prototypes, we've determined that taping the band assembly to the skin is the best method of fixing the device to the patient. The band assembly allows the device to fit on a broader range of patients because the hinges that attach the band to the cover allow the device to fit on a smaller radius of curvature than the flexible over-band concept. It meets the engineering specification of being able to fit around a radius of curvature of around 2 cm.

Although our final prototype was not a fully functional device that was able to house the transducers, the developments of all three of our prototypes throughout this course have lead to significant progress for the VF Doppler project. A working product will be able to be made from minor adjustments to the final prototype mentioned above.

10 VALIDATION RESULTS

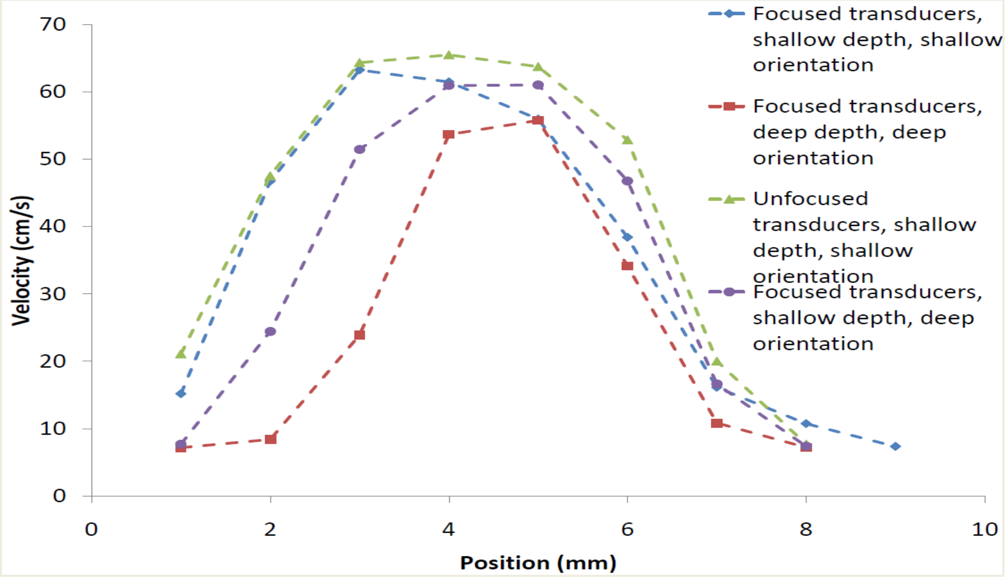
In order to validate whether or not or device worked we ran a series of experiments that tested our engineering specifications. Before validating any engineering specifications, we first ran a series of experiments to help better define what our customer requirements and engineering specifications actually were. In the Simpson Memorial Institute, using a "phantom" access, which was a box of ballistics gel that had a 6 mm tube running through it, and a roller pump, we created a series of flow profile curves at two access depths, 9.5 mm and 18 mm. In order to create the flow profiles curves, we first located where the center of the phantom access was and took a velocity reading to record the maximum velocity. We then laterally translated our device one mm at a time until there was no velocity reading. We also tested to determine the differences between focused and unfocused transducers. We ran testing with a preliminary prototype that had in-line and side by side transducer orientations. We calculated that for the in-line orientation, the transducers beams would intersect at approximately 15.6 mm below the skin. From this testing we deduced that lateral adjustment is extremely important and must be implemented in our next design iteration (Figure 45). We also found that depth adjustment, while important, is not as crucial as lateral adjustment. This testing also told us that the in-line orientation of the transducers was viable. From the testing results we also concluded that there should be less than 30% error in the velocity reading due to the device moving and less than 30% error in velocity reading from access depths of 5 to 20 mm.

Figure 45: Phantom access velocity profile testing results from preliminary prototype



Based on these newly defined customer requirements and engineering specifications we created a new device that would allow for lateral adjustment and had three in-line transducer holes, which allowed us to focus the transducers at different orientations and cover the range of access depths. The two transducers focus depths were 9.6 mm (shallow orientation) and 17.5 mm (deep orientation). With this secondary prototype, we were able to do validation testing on the engineering specification that there should be less than 30% error in velocity reading from access depths of 5 to 20 mm. For this testing, we created flow profiles curves similar to those of our initial testing and in order to validate our engineering specification we tested with the transducers at both orientations and both depths. For example, we tested at shallow orientation, shallow depth; shallow orientation, deep depth; deep orientation, shallow depth; and lastly deep orientation, deep depth. What we learned was that depth adjustment was not as important as previously thought (Figure 46). We found that if the transducers were focused in a deep orientation, then the transducers could obtain good velocity readings at both the shallow and deep depth. When comparing the transducers at shallow orientation and shallow depth with deep orientation and shallow depth there is only a 9% error in velocity which is well within our engineering specification. Also when the transducers are in a deep orientation and at a deep depth, the error in velocity from the maximum is approximately 12%. Since the deep depth was only 18 mm, we added two more mm of ballistics gel on the phantom access to achieve 20 mm and found results very similar to the results at 18 mm. We therefore concluded that only the deep orientation of the transducers was needed for our final design and that this orientation would allow for less than 30% error in velocity readings.

Figure 46: Phantom access velocity profile testing results from secondary prototype



Another engineering specification we wanted to validate was that there should be less than 30% error in the velocity reading due to the device moving. In order to test this, we secured our secondary prototype onto one of our arms and mimicked the motions of dialysis patients during treatment, such as turning the page a magazine or drinking a cup of coffee. Our plan was to first take a velocity reading over the center of one of our arteries to have an initial velocity reading. Then the user would rotate his wrist 180 degrees so that his palm would be facing up and then down. The user would repeat this motion 30 times and then another velocity reading would be taken. We would repeat this test 10-15 times to get a reliable set of data and see if the device moved to cause a velocity error larger than 30%. Unfortunately, due to the fact that the arteries in our forearms and arms are much smaller than those of dialysis patients, we were unable to get a strong initial velocity reading to continue this experiment. What we do know is that since our device allows for 3 mm of lateral movement once secured, if the device moves during treatment it can be adjusted to reduce the error in velocity so that it will not be greater than 30%.

A third engineering specification that we tested was to see if the ultrasound gel used during treatment could last for the entire treatment which is four hours. In order to test this we applied an adequate amount of ultrasound gel to the phantom access and took a velocity reading. We let the gel and our device sit there for four hours and then took another velocity reading. If we were able to get a velocity reading after the four hours then gel does not dry out and if not then more gel would need to be applied during the treatment. From our results, we found that the ultrasound gel does not dry out and does not need to be reapplied during treatment. This is important because the dialysis technician will not have to take the device off the patients arm to apply more gel which is time consuming and may cause error in velocity readings. Instead the device can be left secured to the patients arm through the duration of treatment.

The final experiment we ran was to validate whether or not our device could be electromagnetically actuated and if the device can laterally translate 3 mm. We used our final prototype in order to validate these engineering specifications. We attached the copper wires of our final prototype to a power supply and applied a voltage of approximately 1.5 V which produced a current of 0.3 amps. The current flowing through the wires created a force which allowed our device to translate. From this experiment we found that our device can be electromagnetically actuated and does allow for 3 mm of lateral movement.

Lastly, we were able to validate our geometric constraints, radius of curvature specification and cost per device requirement based on our final prototype. Since we had our parts rapid prototyped at the Medical Innovation Center, we were able to calculate what the cost per device would be if ten devices were ordered. The cost was $26.45 per device and would go down if more were ordered because a bulk of the cost is in the set-up fee. Once we received the parts and assembled them, we measured our device to see if it meets our engineering specifications. We found that the height was 6.4 mm which is less than the specified 6.5 mm, the length, with watch bands, is 6.5 centimeters which is less than the specified 7.5 centimeters and the width of the device, which is the distance between the two needles is 25.8 mm which is slightly greater than the specified distance of 25.4 mm but the final prototype has material cut away where the needles would fit and this distance is 21.7 mm. Since we ended up using watch pins and watch bands to secure the device on the patient, it allowed for much greater flexibility because it created a flexible hinge point that was much closer to the device.

11 DISCUSSION

As we have mentioned throughout this report, the process of completing our project consisted of three iterations of the design-build-test approach of our device. Each subsequent design had specific engineering specifications that we tried to empirically determine based on manufacturing and testing results from the previous prototype. Our final design was not intended to be a fully functional device, but rather it was intended to be another design iteration built to test the electromagnetic actuation concept.

Because each of our prototypes was meant to be learning tools for future prototypes, we discovered several ways we would improve upon the previous designs for the next prototypes.

One design issue that is still unclear is what the best transducer orientation and type are. Tests on the secondary prototype indicated that only one transducer orientation may be needed in the transducer housing because results could be acquired at different access depths from the same transducer orientation (see Figure 46). However, more prototype design and test iterations should be completed to determine the optimum angles of the transducers relative to the surface of the skin because our prototypes only tested a few different orientations. These future prototypes should also test to see whether the focused or unfocused transducer beam profiles yield better results at all access depths.

12 RECOMMENDATIONS

We recognize that the final prototype is not a fully functional design, but through testing we have discovered several areas that can be improved on future design iterations.

As mentioned in the discussion section, more testing on future design iterations could be done to determine the optimum transducer type and angle relative to the skin. It is uncertain if focused transducer beam profiles always yield the best results at all access depths. Although our testing incorporated coherent continuous wave (CCW) transducers, the use of pulse wave (PW) transducers could be advantageous if they can be used in this application. Only one PW transducer would be necessary in the design, whereas two CCW were needed. This would mean that the length of the transducer housing could be shortened, which could allow for more wire turns around the coil or more room in between the dialysis needles on the patient.

The electromagnetic actuation concept can also be improved in future design iterations. More wire turns around the winding barrel would allow the actuation to have a stronger force without applying such a high current. Also, it would be advantageous to the design if the controller were able to apply both positive and negative voltages so that the transducer housing can translate in both directions. More thought could also be given to the material type of the springs between the cover and transducer housing. In the final prototype, the transducer housing did not always remain perpendicular to the rod when translating, so adding another rod to the back of the transducer housing may help in guiding the transducer housing when translating.

13 CONCLUSIONS

We have successfully designed, manufactured, and tested three iterations of working prototypes of our device. The preliminary prototype was crucial in identifying that lateral adjustment was necessary for this device. The secondary prototype was a fully functional prototype, but through testing it we were able to determine that there could be a better way of adjusting the transducers. The final prototype proved that the electromagnetic concept for adjusting the lateral position of the transducers could work well. Moving forward, further iterations of prototypes need to be manufactured and tested to fine-tune the transducer orientation and electromagnetic actuation system before a final design is ready for clinical studies.

14 ACKNOWLEDGEMENTS

The success of our project cannot be attributed to us alone; without the help of the other team members on the VF Doppler team and the Mechanical Engineering department at the University of Michigan we could not have done this work. We would first like to thank our sponsors Dr. Rick Weitzel and Dr. Grant Kruger who were incredibly helpful, insightful, and supportive in all stages and aspects of our project. University of Michigan biomedical engineering PhD candidate Robert Dodde was also helpful in many stages throughout the design process. We’d like to thank the ME 450 graduate student instructor Dan Johnson for all his efforts put forth to this class and ensuring we were following safe testing practices, and the ME 450 instructors Dr. Gordon Krauss, Dr. Albert Shih, and Dr. Kathleen Sienko for their class lectures that helped us in the design process. We’d also like to thank U of M graduate student Mainak Mitra for his help with our final prototype, Ashish Hinger and Chris Diroff for their help testing in the lab, and Preston Andre for insight from his experience working in a dialysis clinic.

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BIOS

Andrew Doss

Andrew is a fourth-year undergraduate mechanical engineering student at the University of Michigan and is originally from Grand Rapids, Michigan. Andrew is also active on campus through Pi Kappa Phi Fraternity and the Undergraduate Student Advisory Board. He chose to study mechanical engineering because of his interest in solving technical problems and is particularly interested in the areas of thermodynamics and fluid mechanics. Andrew has interned in the water heater manufacturing, oil refining, and natural gas production industries. In 2009, he worked at BP’s Texas City Refinery as a maintenance engineering intern. This past summer, he returned to BP as a facilities engineering intern in Houston. There, Andrew completed projects to maintain and improve the safety, reliability, and yields of the gathering system for a natural gas production asset in southwest Kansas. After graduation, Andrew plans to pursue a career in the exploration and production of energy resources. Outside of work, he enjoys playing tennis and volleyball and is currently training for his first triathlon.

Kirk Leonard

Kirk Leonard is a senior in mechanical engineering at the University of Michigan. He has lived 45 minutes away from Ann Arbor his whole life, in Huntington Woods, MI, a northern suburb of Detroit. Growing up in the Metro Detroit area, Kirk has developed an interest in the automotive industry, a major contributor to his pursuit of mechanical engineering. Growing up, Kirk spent his free time building his own skate park. This would be his first exposure to the design process, defining, measuring, and finally constructing each ramp and feature. He also has spent time working with hobby-grade remote control cars, trucks, and airplanes. In a sense, the remote control vehicles were an introduction to engineering systems, blending mechanical and electrical components that were easily modifiable.

Last winter term, Kirk spent 5 months in a Co-Op at Ethicon Endo-Surgery (EES), a biomedical device company under Johnson and Johnson. He was a research engineer at that job, taking part in the design process, and doing extensive testing to develop a breast biopsy device used for cancer evaluation. In his position, Kirk was able to work directly with the team leaders and engineers in the Breast Care division of EES in the design process, and was a co-inventor of a patent for one of the devices.

Kirk also had an internship at Ford Motor Company over the last summer, where he worked in the Automotive Safety Office. In this position, Kirk utilized his team and technical skills to integrate into the company and present important data for the National Highway Traffic Safety Administration (NHTSA) on behalf of Ford Motor Co.

Kirk also works in the University of Michigan Injury Biomechanics Laboratory during the school year. He plans to graduate in May 2011, and pursue a career in the automotive or medical industry, and then to obtain a masters degree within the first few years of employment.

Sean Nimkar

Sean Nimkar is a 4th year mechanical engineering student from Boston, Massachusetts. Sean chose to major in mechanical engineering because he enjoys solving problems and his interest in physics. His future plans are to work in the biomedical industry or to attend graduate school. He interned at a biomedical engineering company in the Boston area this past summer that made ventricular assist devices and sparked his interest in biomedical engineering. In his free time Sean enjoys playing sports particularly basketball.

Dan Oakes

Dan Oakes is a 4th year mechanical engineering student from Perrysburg, Ohio. He originally chose to major in mechanical engineering because of the broad range of possible careers in industrial sectors with a mechanical engineering background, and he will be working for Marathon Oil Company after graduating with a bachelor's degree in May of 2011. He has interned with Marathon Oil Company for the past three summers to gain real-world engineering experience. During 2008 and 2009 he was at Marathon's oil refinery in Detroit, Michigan working in the project engineering department that managed projects within the refinery. This past summer he worked at Marathon's upstream headquarters in Houston, Texas in the Upstream Developments department. Here he worked on a team that coordinated the design, testing, and installation of equipment on two deepwater subsea projects in the Gulf of Mexico. Outside of class, Dan enjoys watching his favorite sports teams, playing sports such as basketball and soccer, traveling, playing the piano, being outdoors, and being an active member in Theta Delta Chi.

APPENDICIES

Appendix A: Bill of Materials

Table A.1: Preliminary prototype bill of materials

Item	Quantity	Source	Catalog Number	Cost	Contact	Notes
Flexible Overband	20	QuickParts	-	$689	quickparts.com	-
Transducer Housing	20	QuickParts	-	$258	quickparts.com	-

Table A.2: Adjustable prototype bill of materials

Item	Quantity	Source	Catalog Number	Cost	Contact	Notes
2mm Stainless Shaft	30 cm	McMaster-Carr	1174K19	$18.15	mcmaster.com	-
2mm Set Screw	25	McMaster-Carr	92015A090	$4.36	mcmaster.com	-
Fishing line	3’	Sponsor’s Lab	-	-	-	-
Resin Strap	1	WatchPrince	HR-MD4-000769	$5.00	thewatchprince.com	-
14/15R Spring Bar	2	WatchPrince	SB14/15X18-NI	$1.50	thewatchprince.com	-
14/15T Spring Bar	2	WatchPrince	SB14/15X15-NI	$1.50	thewatchprince.com	-
16/17R Spring Bar	2	WatchPrince	SB16/17X15	$1.50	thewatchprince.com	-
16/17T Spring Bar	2	WatchPrince	SB16/17X18-NI	$1.50	thewatchprince.com	-
“Swatch” Strap	1	WatchPrince	HR-MD4-000769	$9.95	thewatchprince.com	-
SLA Housing	10	Michigan IC	-	$242.50	734-764-1584	Not quoted separately
SLA Cover	10	Michigan IC	-		734-764-1584	
SLA Knobs	16	Michigan IC	-		734-764-1584	
0.9 mm Allen Key	12	McMaster-Carr	7289A32	$1.92	mcmaster.com	Tool
1.6 mm Drill Bit	2	McMaster-Carr	29355A24	$4.48	mcmaster.com	Tool
2mm Tap	1	McMaster-Carr	8305A77	$13.36	mcmaster.com	Tool

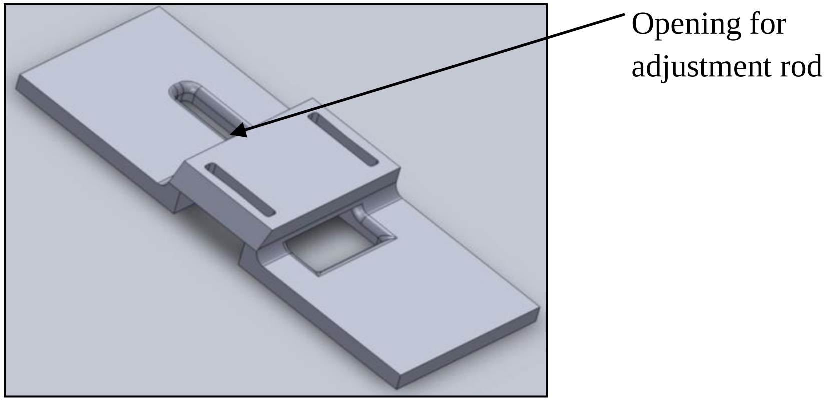
Table A.3: Final prototype bill of materials

Item	Quantity	Source	Catalog Number	Cost	Contact	Notes
1/16” Brass Rod	1’	McMaster-Carr	8859K511	$7.44	mcmaster.com	-
1/4”x 1/4” Magnet	4	McMaster-Carr	8859K511	$13.20	mcmaster.com	-
1/4” x 1/8” Magnet	4	McMaster-Carr	58605K33	$10.12	mcmaster.com	-
2mm D. Steel Rod	1’	McMaster-Carr	8116K57	$2.03	mcmaster.com	-
1/8” Rubber Plug	100	McMaster-Carr	6448K71	$6.29	mcmaster.com	-
Resin Strap	1	WatchPrince	HR-MD4-000769	$5.00	thewatchprince.com	-
36 G Copper Wire	-	Sponsor’s Lab	-	-	-	-
Transparency sheet	1 sheet	Sponsor	-	-	-	-
Objet Housing	10	Michigan IC	-	Invoice not sent to us	734-764-1584	-
Objet Cover	10	Michigan IC	-		734-764-1584	
Objet Coil Barrel	10	Michigan IC	-		734-764-1584	

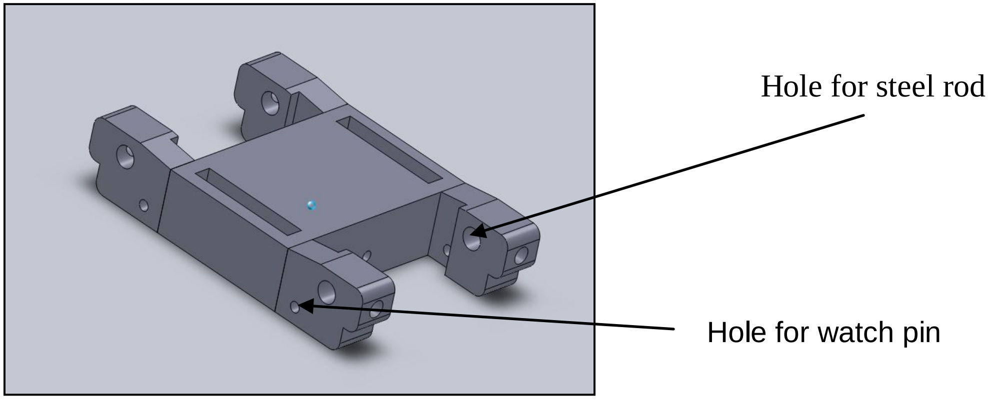
Appendix B: Description of Engineering Changes since Design Review 3

Change in Cover/Change in Fixturing Method:

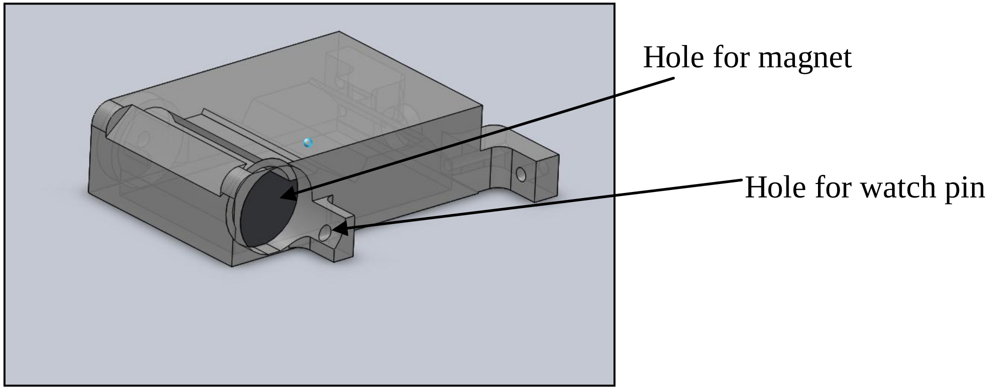
Before Design Review #3:



After Design Review #3:



For Design Expo:

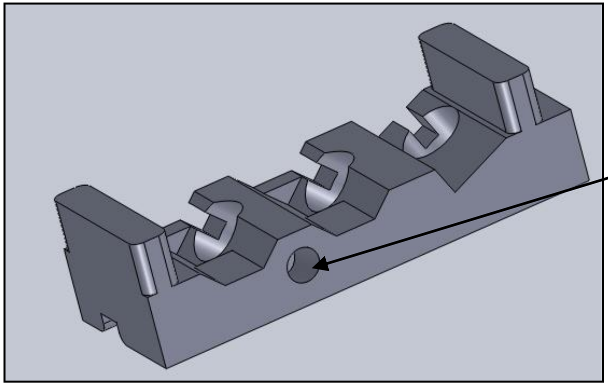


The change in this component of the design was to allow for easier lateral adjustment of the device and more flexibility. Prior to Design Review #3, our transducer housing was manually adjusted using a steel rod that would slide the transducer housing back and forth along the patient's arm. After Design Review #3 and after talking with our sponsors we decided using the steel rod approach would be difficult and redesigned to have adjustable rods that would attached to thread and could be rotated to slide the transducer housing back and forth. We made further revisions to this design before the Design Expo to allow for electromagnetic actuation. Instead of using rotating steel rods, this device would have magnets that would fit into the side of the cover and an electric current would be sent through a coil and cause the device to move.

Another change in this component is in our prototype before Design Review #3, we planned on using flexible bands similar to those in our preliminary prototype. After some deliberation, we concluded it would be more beneficial to use watch pins and watch bands as a way to secure the device. Therefore we created extrusions in both the device after Design Review #3 and the device for the Design Expo.

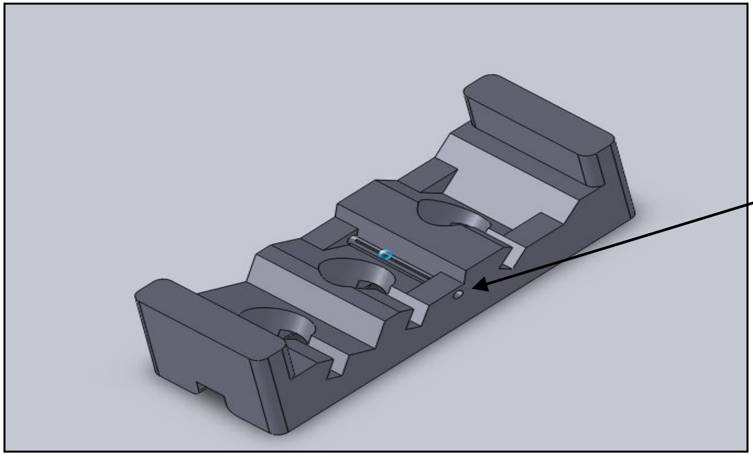
Change in Transducer Housing:

Before Design Review #3:



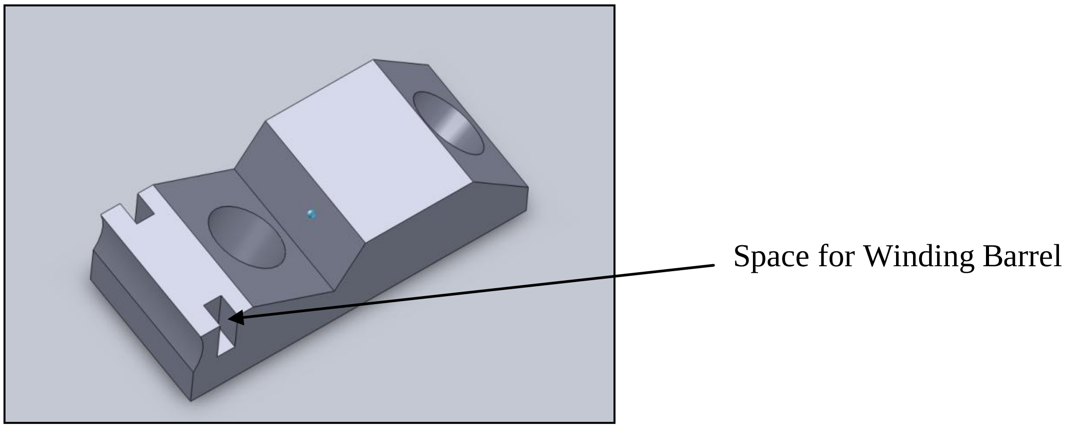
Hole for adjustment rod

After Design Review #3:



Hole for thread

For Design Expo:



Before Design Review #3 there was a hole in the transducer housing that allowed for the adjustable rod to be inserted into. After Design Review #3 we were no longer using an adjustable rod so we had to make changes to our transducer housing to allow for thread to pass through it. In this design, string would be threaded through the hole shown and then knots would be tied on both ends so when the steel rods are rotated the string will be pulled taught and pull on the transducer housing. As can be seen, both of these transducer housings have holes for three transducers because we thought depth adjustment was vital to our design. After doing some experiments, we found our device would be sufficient with only two transducer holes and no depth adjustment as can be seen in our transducer housing for the Design Expo. This transducer housing also has extruded cuts in the front so a winding barrel can be inserted. The winding barrel will be wrapped with copper wire that current can pass through and actuate the device.

Change in Actuation Method:

The prototypes before and after Design Review #3 rely on manual adjustment of either the adjustable rod or rotating rods. In both of these designs it would be difficult to find the maximum velocity reading and maintain that signal throughout dialysis. For the prototype in the Design Expo, it uses electromagnetic actuation which would be done automatically. Electromagnetic lateral actuation involves a current being passed through a copper wire between two magnets. The copper wire would be wound around a “winding barrel” that would slide along a ferrous rod. On both ends of the ferrous rod would be magnets that create a magnetic field between them. When a current is passed through the copper wire, it will create a force that will cause the transducer housing to move along the ferrous rod. The electromagnetic actuation will be used in conjunction with a closed feedback loop that would be able to find the maximum velocity.

Appendix C: Design Analysis Assignment

C.1 Functional Performance

Due to the fine detail, limited known material requirements, and quick turnaround needed in the iterative design-build-test progression of our project, we initially used our engineering judgment to select materials without a formal functional performance. For the final design beyond our prototypes, we have completed a functional performance analysis to recommend materials for the finished product.

Rationale for final prototype materials selection: The nature of our project also constrained us to rapid prototyping materials and the transducer housing, cover, and winding barrel were produced using Objet VeroWhite material. Our primary concern was that the winding barrel and transducer housing could slide smoothly in the cover, so we specified a high stiffness as the most important mechanical property for the prototype. The magnets selected were nickel plated Neodymium-iron-boron magnets and were selected for their very high magnetic-pull-to-size ratio, with nickel plating to resist corrosion and improve the aesthetics of the device. The ferrous shaft between the magnets is composed of A2 Tool Steel to provide a path of low resistance for the magnetic field. Tool steel can experience corrosion, but corrosion resistance is not as much of a concern as the shaft is sealed from exposure to air once in contact with the water inside the device. The wire is insulated-copper with a .152 mm diameter. This allows a large number of turns on a small winding surface, while still providing adequate conductivity. For the straps, we modified a flexible resin watch strap and pinned them to the device using pins. We chose brass pins to ensure that they were non-magnetic and would not interfere with the device. For the bottom surface, we used a piece of overhead transparency for due to its ultrasound transparency. We also selected EPDM rubber plugs for their ability to provide a tight seal at the filling hole after the water was inserted. Water was selected for the filling fluid due to its low viscosity.

Performance and limitations of the selected materials: Overall, the materials that we selected for our device performed well in our experimental testing. While the VeroWhite material had adequate mechanical properties, the final design will require a material with better resistance to water and organic cleaning solvents as VeroWhite is known to degrade with repeated exposure to those substances. Also, we might be able to find a material that would be lower cost and/or more convenient than the current brass watch pins. Therefore, we applied a deeper analysis to these components using CES EduPack 2010.

CES Analysis of the housing components: The transducer housing, winding barrel, and cover all experience similar service conditions and can therefore be produced from a single material. For our final prototype, we produced these materials from Objet's VeroWhite material. As stated above, the material met all mechanical requirements, but was not resistant enough to water and organic solvents (cleaning solutions such as rubbing alcohol) to be practical for the large number of use cycles required for the final device. The mechanical properties for VeroWhite are provided in Table C.1.

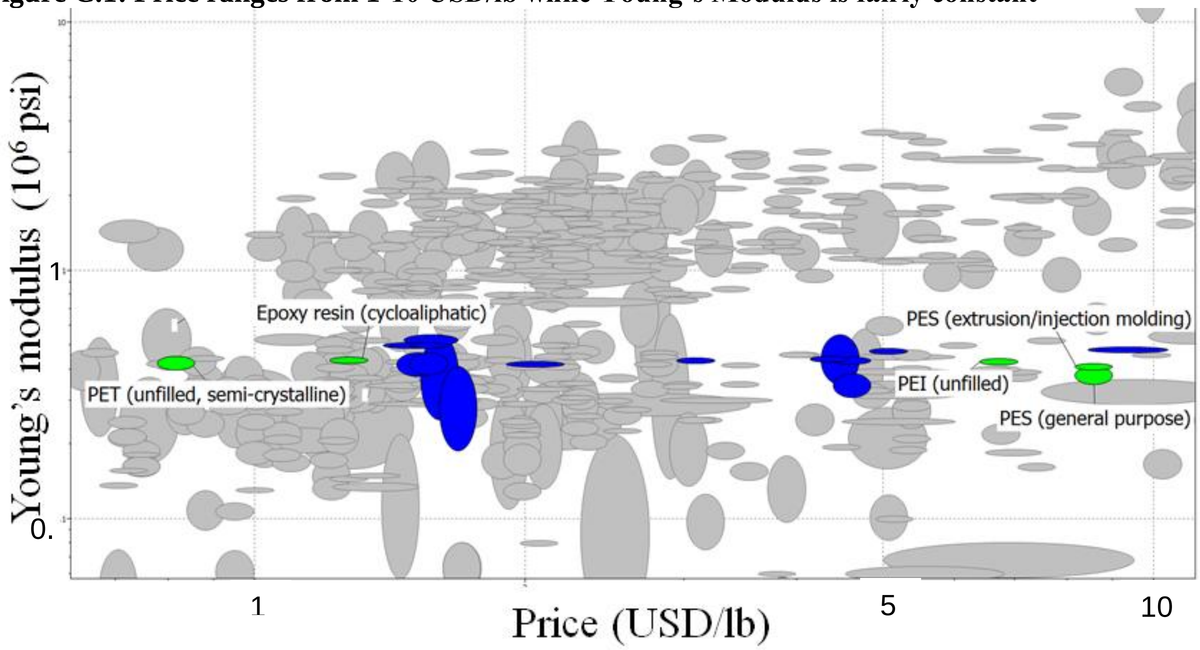
Table C.1: Material Properties for VeroWhite

Property	Tensile Strength (psi)	Young's Modulus (psi)	Flexural Strength (psi)
Value	7221	361775	10817

Provided by Objet using ASTM standards

Injection molding would allow a much broader range of material selection. Therefore, we ran a search in CES for polymers that met or exceeded the mechanical properties of VeroWhite while meeting the additional requirements of compatibility with water, organic solvents, and injection molding processes. From the materials that passed, we selected five materials for further consideration: Polyethylene Terephthalate (PET), Epoxy resin, Polyetherimide (PEI), Polyethersulfone (PES), and Polyethersulfone (extrusion/injection molding). A relative comparison of the Young's Modulus and price variation across these five materials is provided in Figure C.1.

Figure C.1: Price ranges from 1-10 USD/lb while Young's Modulus is fairly constant



These five materials were selected for their variety in composition and cost. While cost is always important, the small size of this device requires very little material per unit and the material cost will be almost negligible with respect to the cost of the transducers and is therefore not an important differentiator in this range. As the material properties were similar, the main differentiating aspect was the compatibility with water and organic solvents.

Table C.2: Comparison of materials on durability

Material	Water durability	Orgo durability
PET	Excellent	Limited use
Resin	Excellent	Limited use
PEI	Excellent	Excellent
PES	Excellent	Limited use
PES (Injection Molding)	Excellent	Limited use

From CES EduPack 2010

At first glance, PEI looked like the material with superior durability. However, it turned out that the compatibility with organic solvents was not the best parameter when assessing the ability to clean the material. The data sheets provided brief summaries of the intended applications of the materials, and the data sheet for PES stated that it was commonly used in medical devices requiring frequent sterilization. Also, PES was listed under a variation specifically labeled for injection molding compatibility. With the new, sealed design the device could simply be wiped down with alcohol between patients and would likely not be exposed to more than “limited use” with rubbing alcohol (an organic solvent). Therefore, we recommend considering Polyethersulfone (PES) as a material that would meet the requirements for the housing components of the final product.

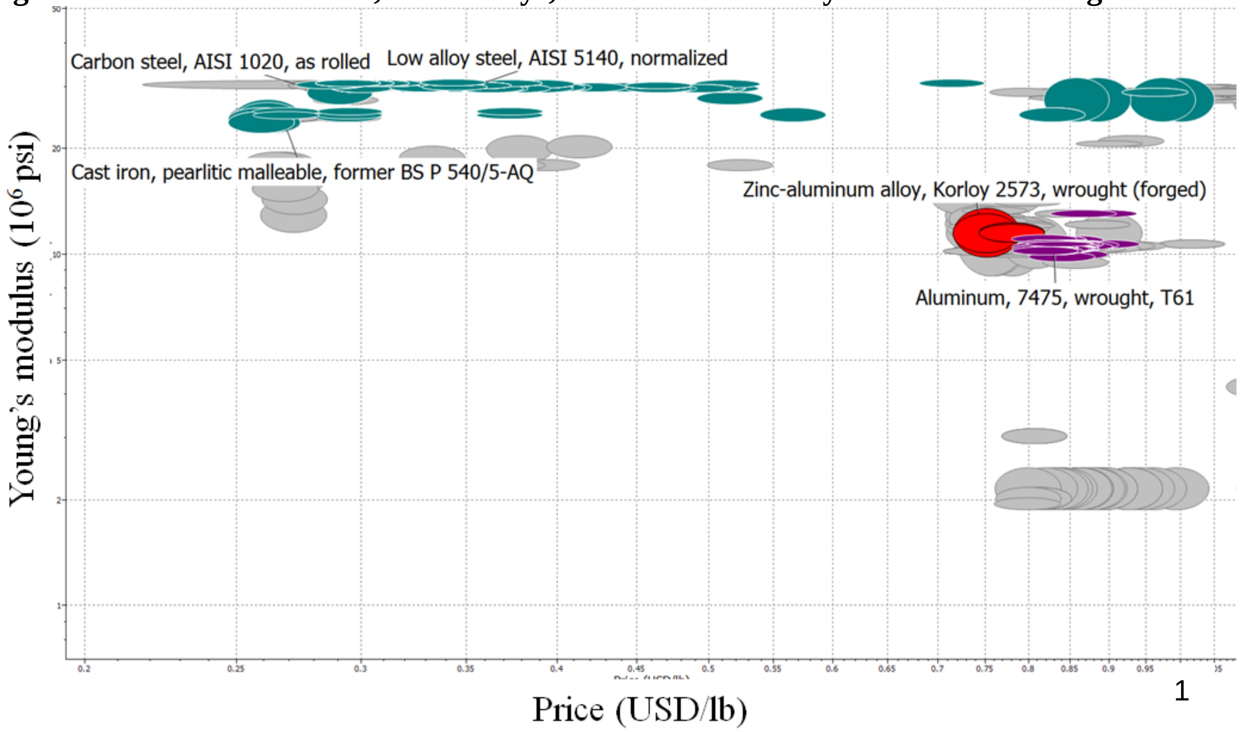
CES Analysis of the watch pins: In searching CES EduPack for an alternative material to Brass 260, I used a similar approach to my first analysis. As the mechanical properties of the first material were adequate, I refined the list to non-magnetic materials that met or exceeded the mechanical properties of Brass 260. The most important parameters were a high Young’s modulus (stiffness), low cost, and high corrosion resistance. The mechanical properties of the Brass 260 Alloy are provided in Table XXX.

Table C.2: Mechanical properties of Brass Alloy 260

Property	Tensile Strength (psi)	Yield Strength (psi)	Young’s Modulus (psi)
Value	61,600	52,200	16,000

After searching CES EduPack for materials with properties similar to Brass 260, CES output the graph shown in Figure C.2. All of the colored figures materials fit the mechanical requirements.

Figure C.2: Steel/iron allows, brass alloys, and aluminum alloys all fall in the range



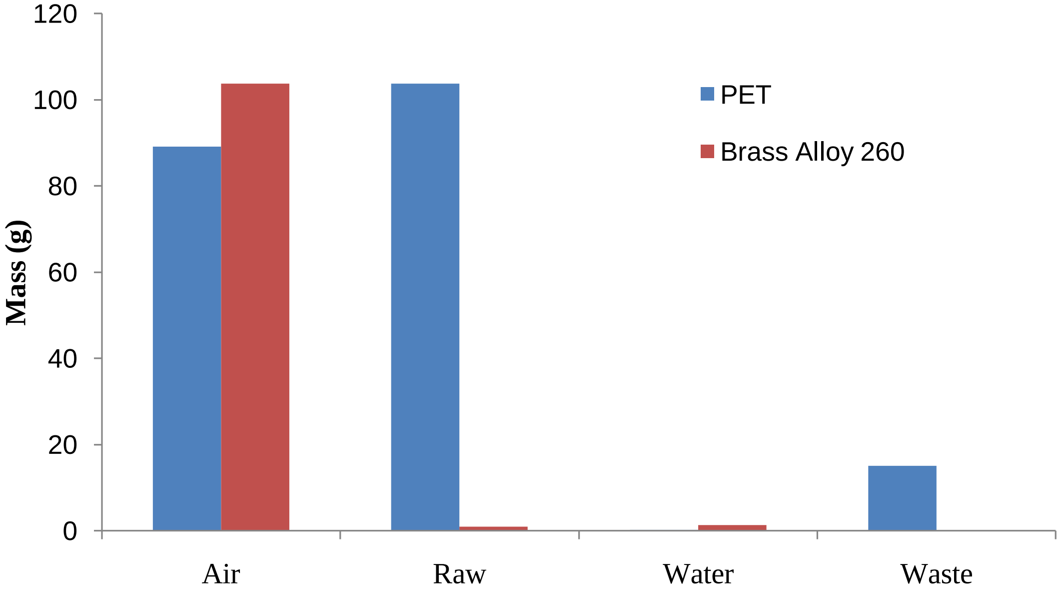
The current market price for Brass 260 is around 1 USD/lb. I again looked at five varying materials from the chart. Some alloys of iron/steel are available at a lower cost, ferrous alloys will not work for this application as they can become magnetized and potentially interfere with the device's actuation. Aluminum is also non-magnetic, but the alloys that I looked at are slightly more expensive than Brass 260. From this analysis it actually appears that there is not a clear alternative that will reduce cost. It is possible that materials with different material properties such as polymers could work for this application, but from an experimental approach the only verified properties are those of Brass 260. Therefore, I would recommend staying with Brass 260 for the non-ferrous watch pins in the final design.

C.2 Environmental Performance

After determining recommended materials for function and cost using CES, we completed an environmental performance assessment using SimaPro. I selected Polyethylene terephtalate fibres as the closest material approximation to Polyethersulfone and a generic Brass as Brass Alloy 260. For each device I calculated that we would require 2.33 grams of PES and 0.214 grams of Brass Alloy 260.

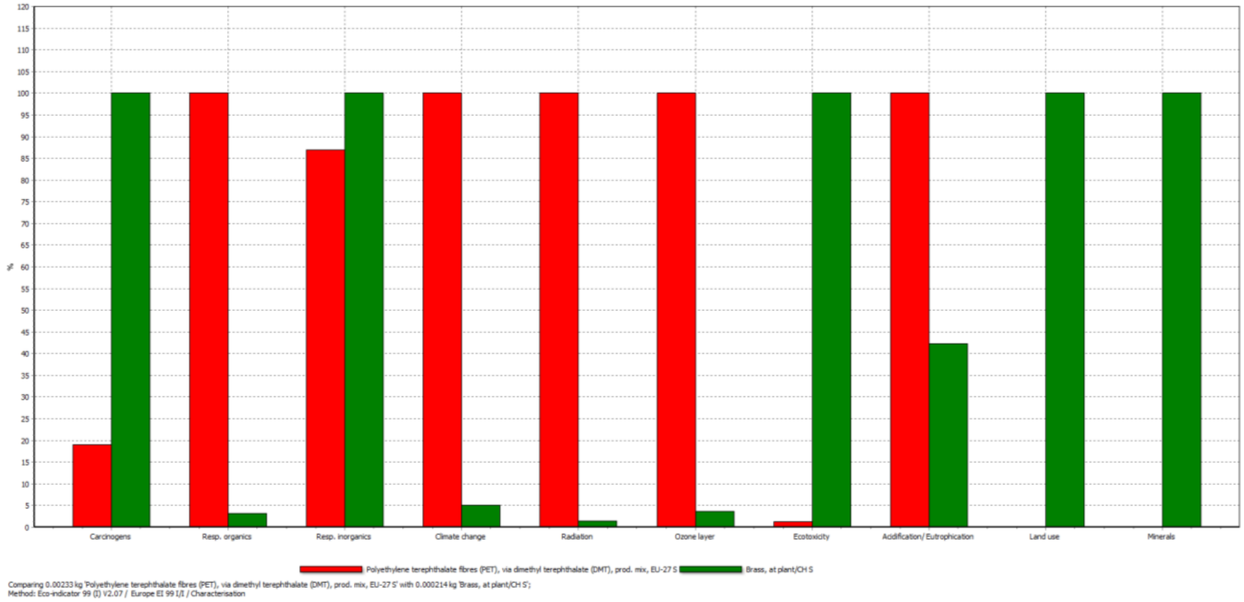
Using SimaPro and the approximated materials with the same masses, we produced a plot of the masses of air emissions, water emissions, use of raw materials, and solid waste. This plot is provided in Figure C.3.

Figure C.3: Comparison of emissions by mass per device for each material



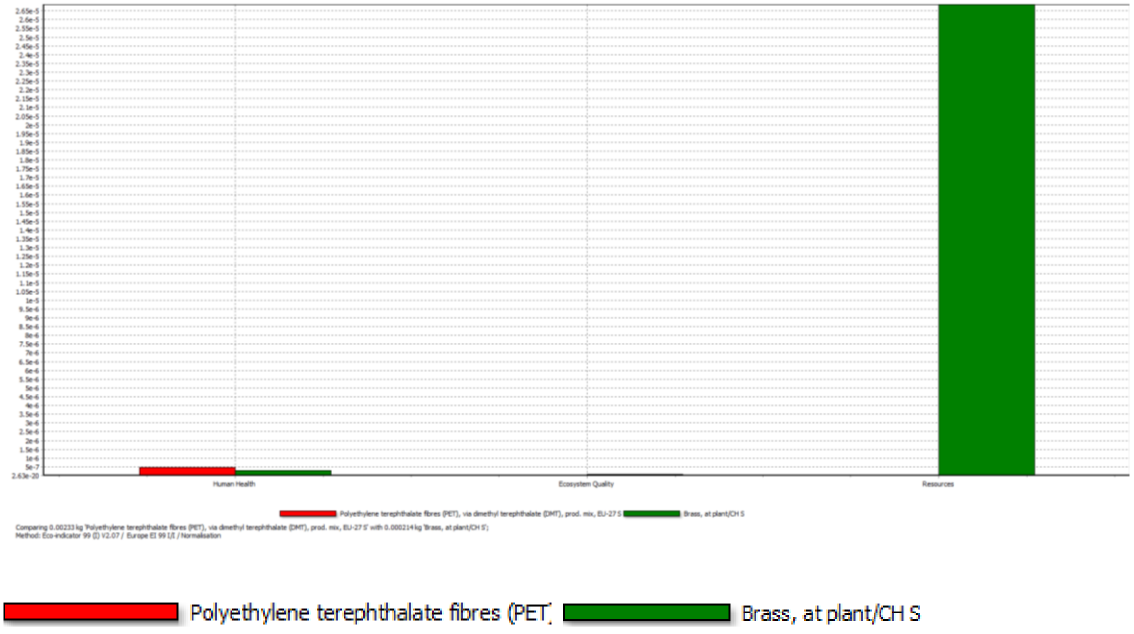
As the plot shows, the PET requires more raw materials, solid waste, and about the same amount of air to produce. It is important to note however that the design uses a larger amount of PET by mass than Brass Alloy 260. Overall, it is clear that the PET parts contribute much more to the environmental impact of the device than the brass components. We also reviewed the relative impacts for each material in disaggregated damage categories as shown in Figure C.4.

Figure C.4: Relative impacts in Disaggregated Damage Categories



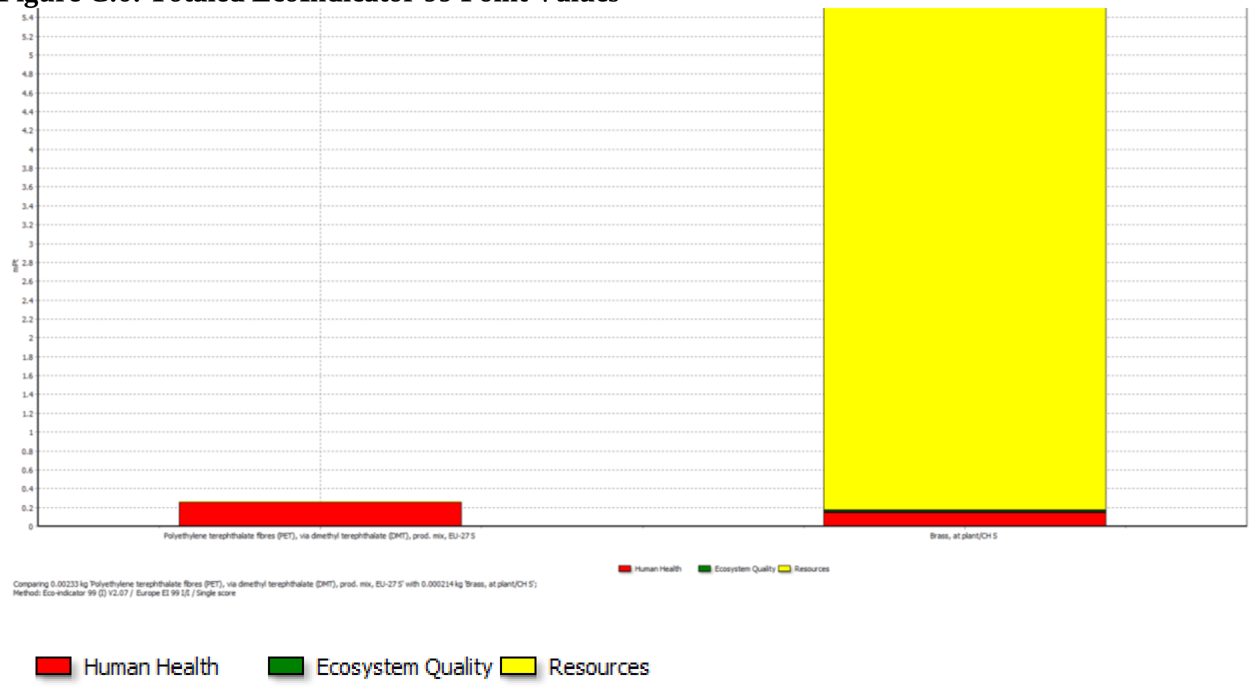
In this view, the environmental impact is fairly split between the two materials. The PET is worse in organics, climate change, radiation, ozone layer, and, acidification while the brass is worse in carcinogens, resp. inorganics, ecotoxicity, land use, and minerals. By combining these into categories, the comparison becomes more clear. Figure C.5 provides a comparison of the environmental impacts aggregated into human health, ecosystem quality and resources.

Figure C.5: Aggregated effects of PET and Brass on the environment



In the aggregated view, it becomes more clear that the largest environmental impact of this device is in the consumption of resources, with brass far surpassing the PET in resources consumed while PET has a larger impact on human health than brass. To make the comparison between the materials even more clear, we generated one more plot showing a side by side comparison with the totaled EcoIndicator 99 point values (Figure C.6).

Figure C.6: Totaled EcoIndicator 99 Point Values



As expected from the previous plot the EcoIndicator 99 total for the brass is much larger due to the large impact on environmental resources. The total for brass is about 5.4 mPt while the PET total is 0.3 mPt. However, if human health was valued far more than environmental resources the PET could be more equal in impact. However, when the whole life cycle is considered the issue of recyclability becomes more significant with the brass being reusable while polymers are generally less likely to be reused. This could potentially reduce the resource impact of using brass relative to PET. With the large margin between the brass and PET in environmental impact, even with lifecycle considerations, it is likely that brass will have the greater environmental impact. Also, in absolute terms the impact of these materials for this application seems reasonable. There is almost no negative effect on the ecosystem quality, and the effects on human health and resources may only look as large as they do in relation to the very small ecosystem quality impact. As the environmental impact of these materials seems modest and the functional fit of these materials is so positive, we believe that these are good material recommendations overall.

C.3 Manufacturing Process Selection

C.3.1 Determining production volume

Roughly 0.1% of people will suffer from kidney failure in their lives and require dialysis in order to stay alive. Of people who have end stage renal disease and require dialysis to live, it is likely that only those in developed countries would receive the treatment. Our device would be likely to only be used in advanced dialysis clinics that have the computer technology to run the software that is capable of measuring blood flow from ultrasound transducers through our device. Let us estimate that of the entire world's population, only 1 billion people live in developed countries in proximity to an advanced dialysis clinic that has access to enough technology to run the appropriate software for our device. If 0.1% of these people go to dialysis clinics for treatment, that would be 1 million patients who would use our device. Dialysis clinics would probably only buy roughly one device for every five patients because not all patients are at the clinic receiving treatment at the same time. According to these assumptions, if a working final product is developed, there could be a global demand for up to 200,000 of these devices.

C.3.2 Determining processes

The two materials selected using the CES Materials Selector are polyethersulfone and brass alloy 260. The polyethersulfone is the plastic that would be used for the cover, transducer housing, and winding barrel. The brass alloy 260 is used for the band hinge pins.

For the polyethersulfone, injection molding (thermoplastic) is the process that will be used for the plastic pieces. There were several processes that could be used for plastic materials where the economic batch size was on the magnitude of 100,000, but thermoplastic injection molding was the only process that could have minimum feature sizes of less than 1mm and tolerances of less than 0.3mm.

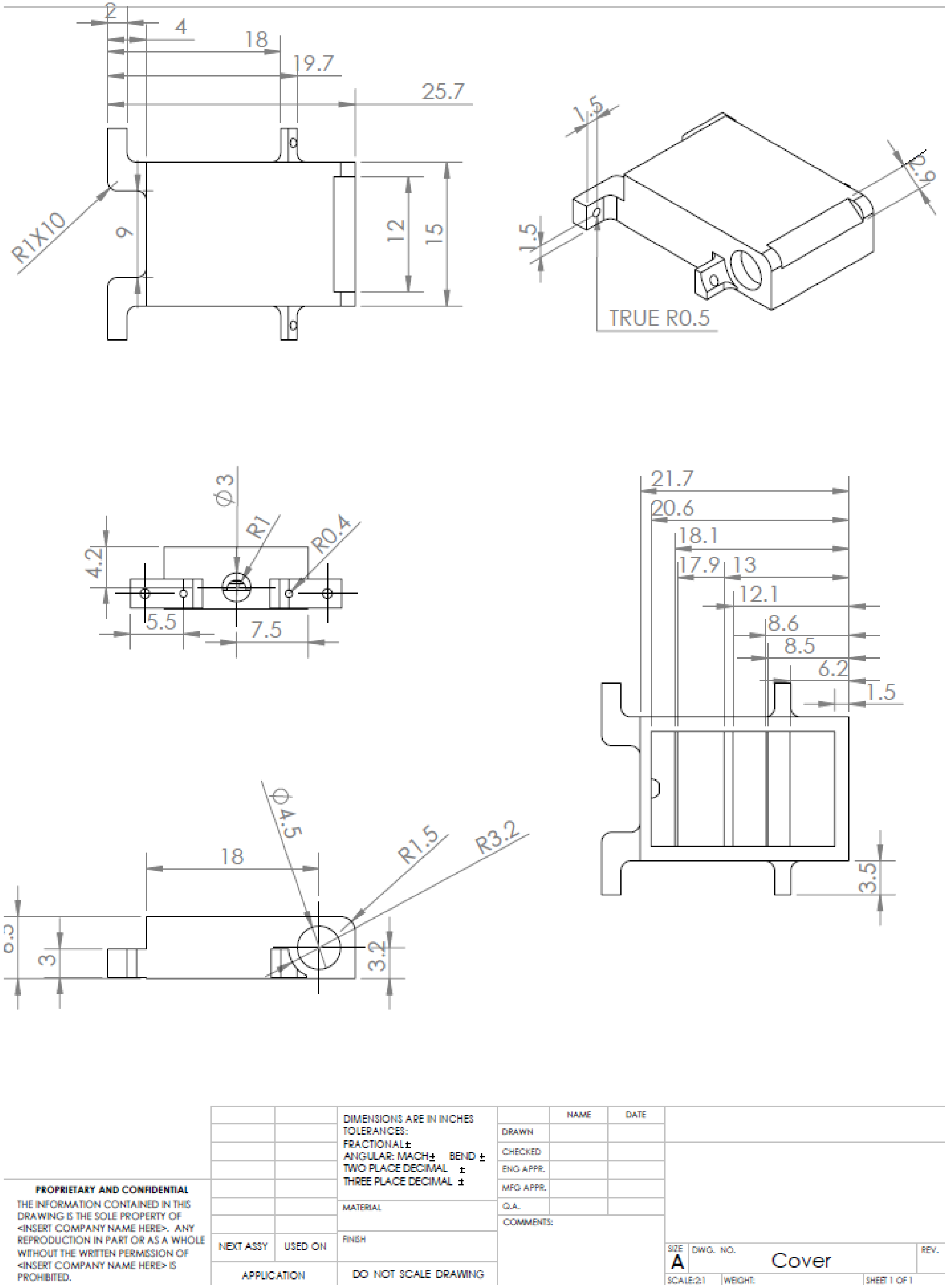
The band hinge pins made of brass alloy 260 will use low pressure die casting. A die casting method is the most economic process for making the magnitude of parts that we need. Low pressure die casting is the most appropriate process for these pins because it can make pieces as small as these pins, it can do very tight tolerances, it is appropriate for metals like brass with low melting points, and it has a relatively low capital cost relative to other die casting methods.

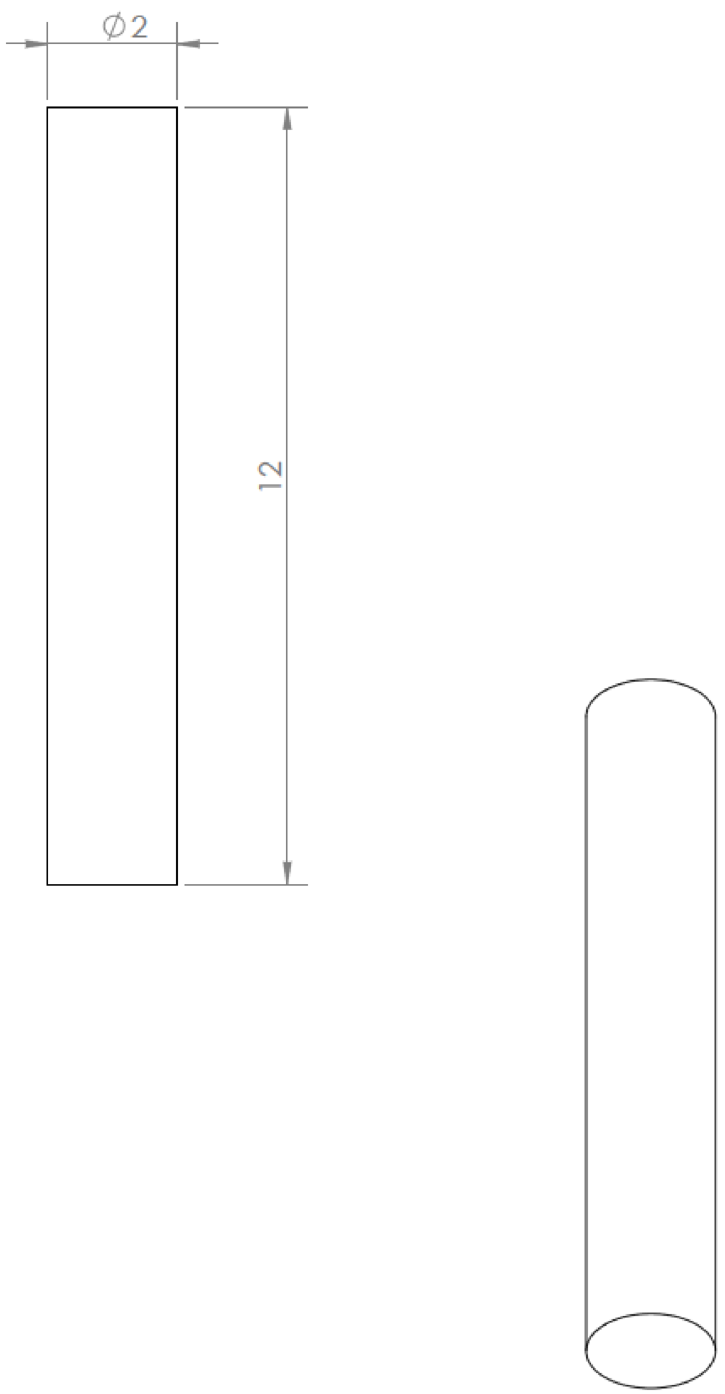
Appendix D: QFD

Customer Needs	Weight	Height (Less than .65 cm)	Width (Less than 2.5 cm)	Length (Less than 7.5 cm)	Cost (Less than $60)	Radius of Curvature (2.06 cm to flat surface)	Can withstand 50 cycles	Less than 30% error in initial velocity reading due to device moving	Gel gets velocity reading for four hours	Less than 30% error in velocity reading from access depth of 5 to 20 mm	Transducer freedom of travel (3 mm)
Maintains signal/Operator Independent	5	1	1	1	1	1	1	9	3	9	9
Maintains interface with gel	5					3	1	3	9	3	3
Low Cost	3				9		3				
Geometrically compatible with dialysis set-up	5	9	9	9		3		3		1	3
Flexible	5	3	3	3		9	1	1		3	1
Durability	3	1	1	1	3	1	9				
Fully Enclosed	4	3	3	3							
Compatible with electro-magnetic actuation	5							9			9
Transducer adjustability	5		3					9		3	9
Total		80	95	80	41	83	51	170	60	95	170

Appendix E: Engineering Drawings

E.1: Engineering drawings of concept





NEXT ASSY | USED ON

APPLICATION

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

FINISH

DO NOT SCALE DRAWING

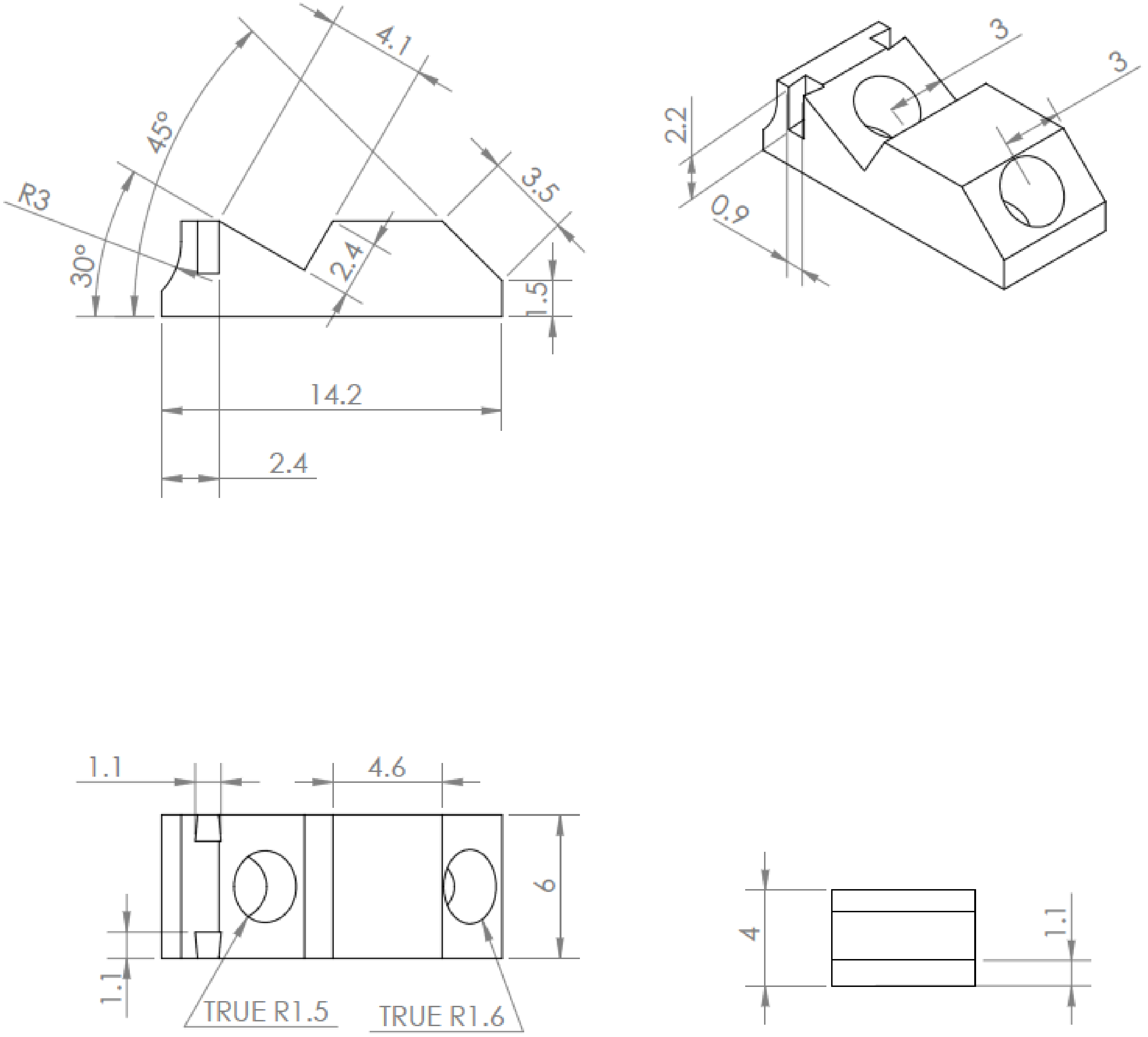
	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SIZE
A

DWG. NO.
FerroRod

SCALE:10:1
WEIGHT:
SHEET 1 OF 1



PROPRIETARY AND CONFIDENTIAL

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NEXT ASSY
USED ON
APPLICATION

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

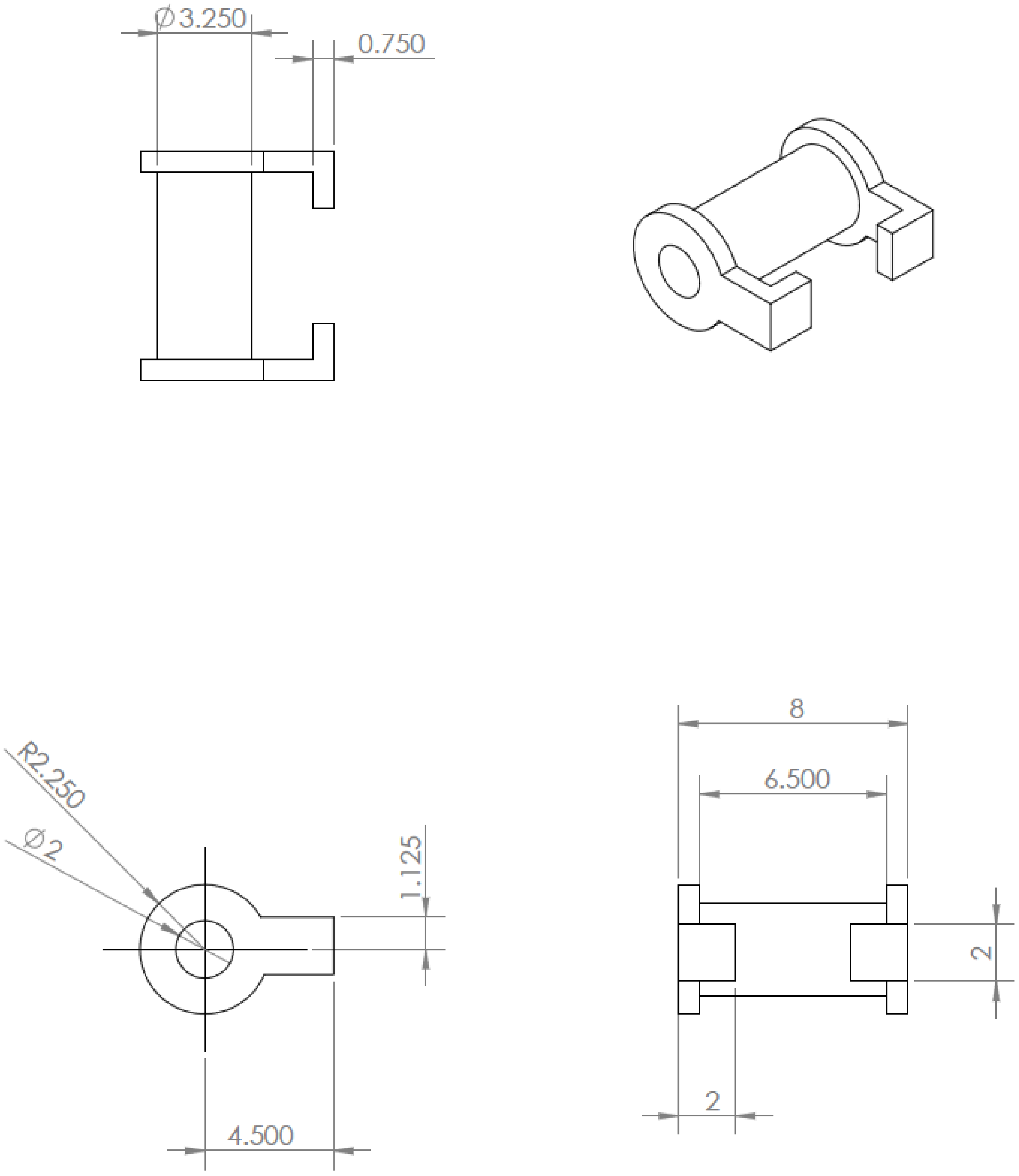
FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SIZE A
DWG. NO. Two hole housing2
REV.
SCALE:2:1
WEIGHT:
SHEET 1 OF 1

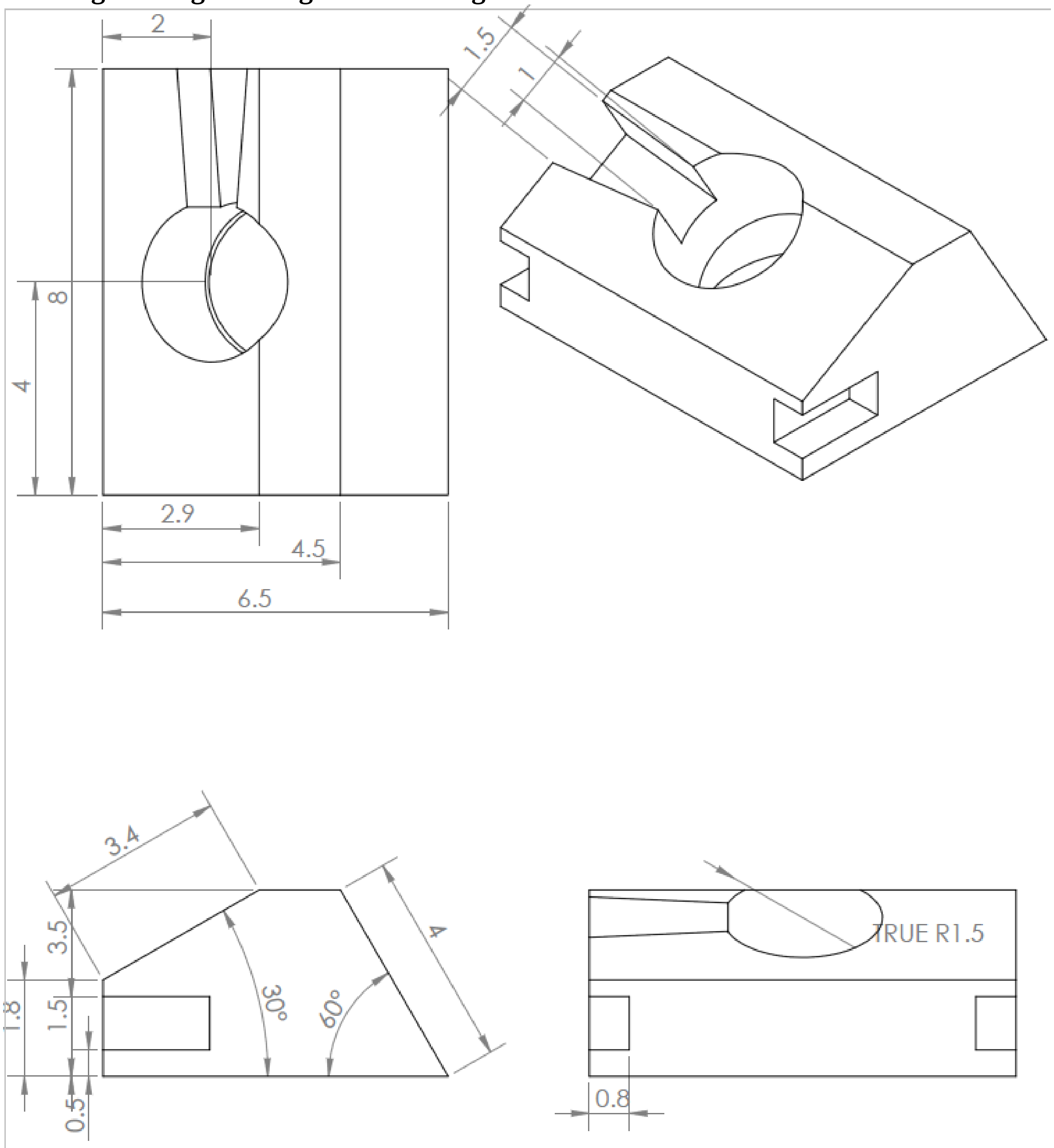


		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL± ANGULAR: MACH± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±		NAME	DATE
			DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		MATERIAL	Q.A.		
NEXT ASSY	USED ON	FINISH	COMMENTS:		
APPLICATION		DO NOT SCALE DRAWING			

SIZE	DWG. NO.	REV.
A	Winding Barrel	

SCALE:5:1 WEIGHT: SHEET 1 OF 1

E.2: Engineering drawings of final design



PROPRIETARY AND CONFIDENTIAL

NEXT ASSY	USED ON
APPLICATION	

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

FINISH

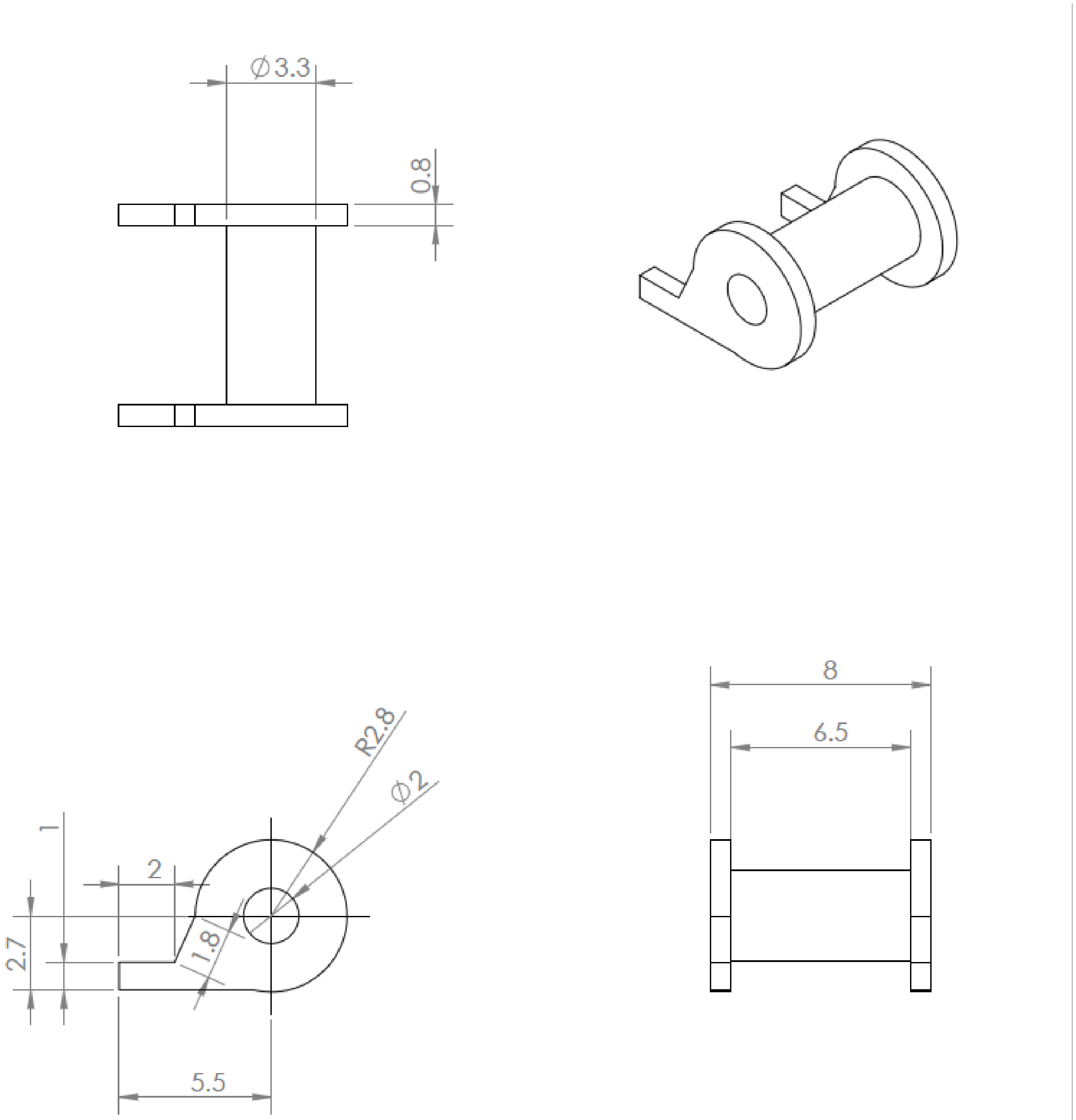
DO NOT SCALE DRAWING

	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SIZE	DWG. NO.	REV.
A	Housing	

SCALE:10:1 WEIGHT: SHEET 1 OF 1



NEXT ASSY
USED ON
APPLICATION

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL±
ANGULAR: MACH± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

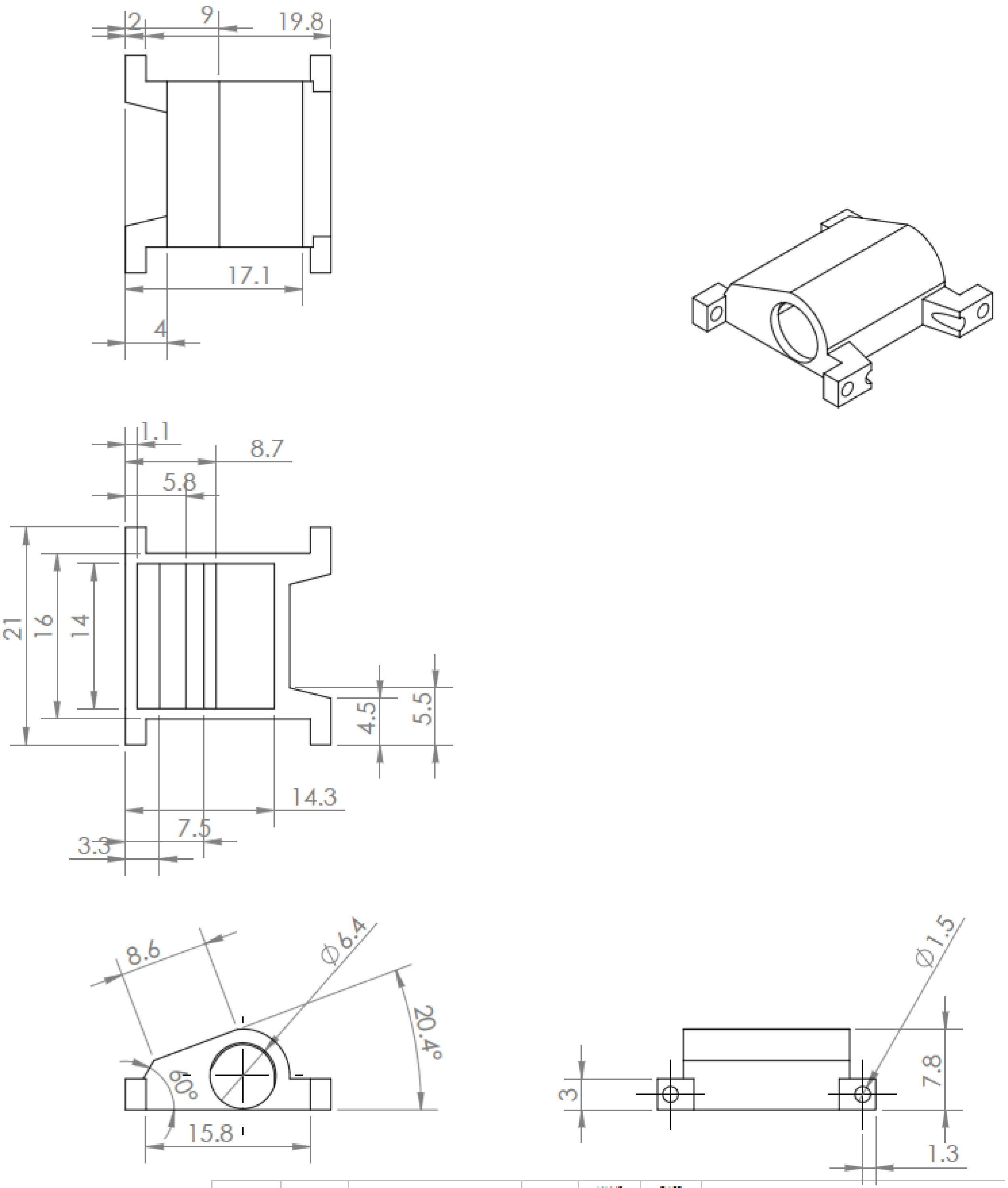
FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SIZE A
DWG. NO. Barrel
REV.
SCALE:5:1
WEIGHT:
SHEET 1 OF 1



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NEXT ASSY
USED ON
APPLICATION

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

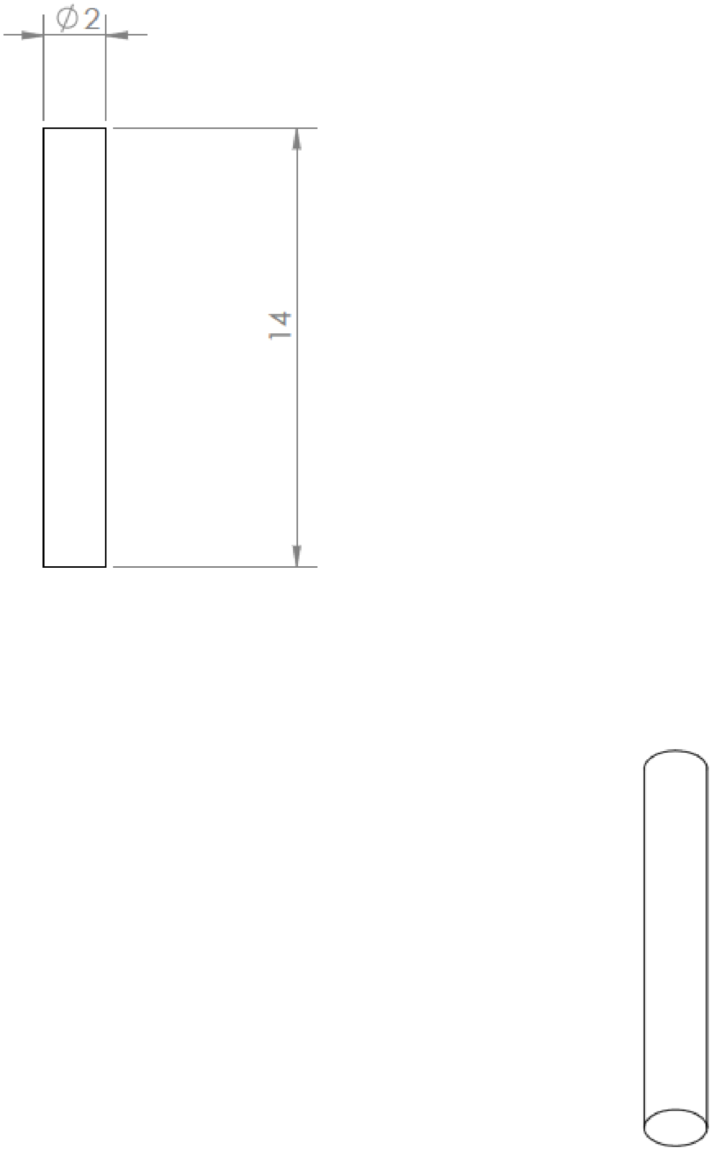
FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SIZE A
DWG. NO.
Cover
REV.
SCALE:2:1
WEIGHT:
SHEET 1 OF 1



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NEXT ASSY | USED ON

APPLICATION

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

FINISH

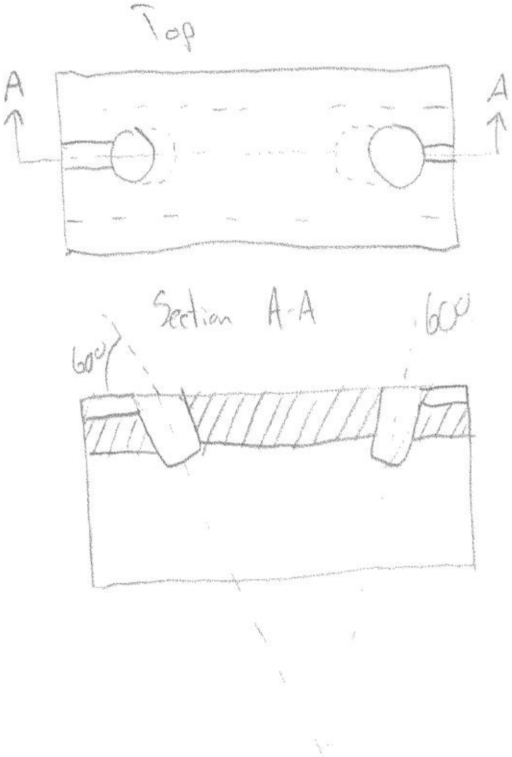
DO NOT SCALE DRAWING

	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SIZE A
DWG. NO. Rod
REV.
SCALE:5:1
WEIGHT:
SHEET 1 OF 1

Appendix F: Other Concepts Generated



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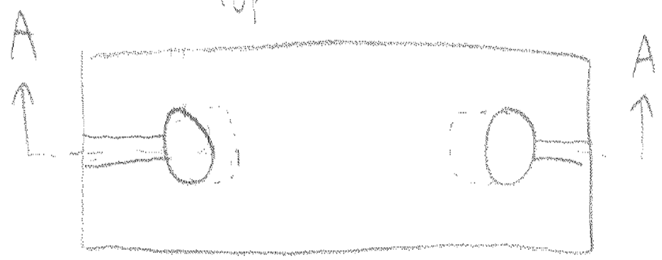
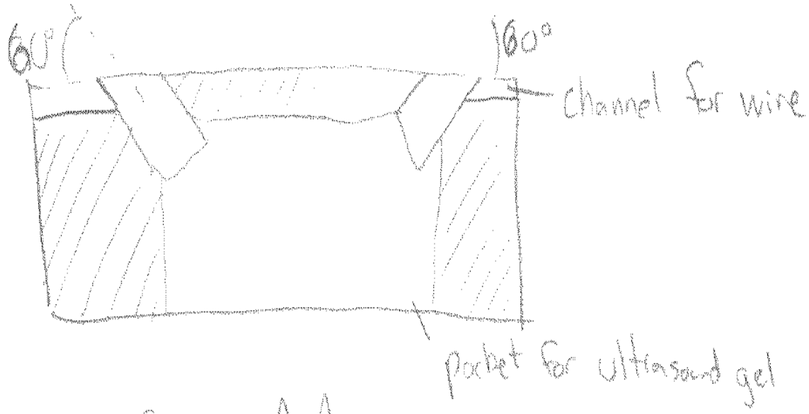
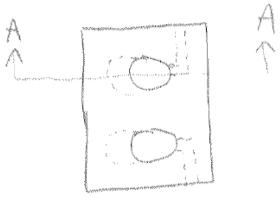
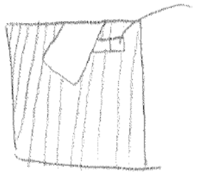




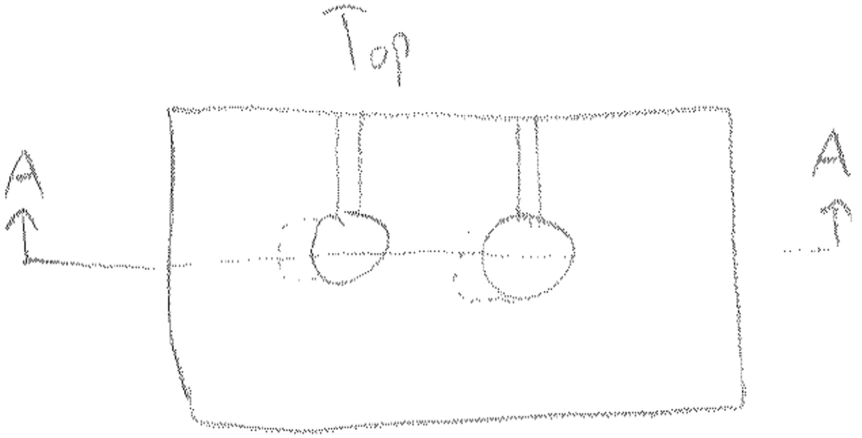
Section A-A

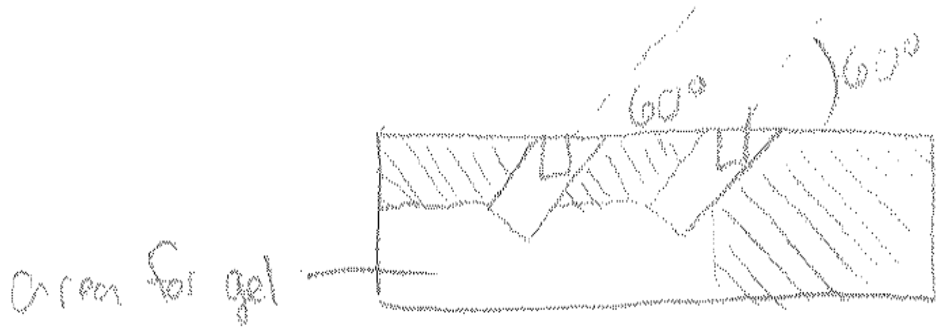
Top



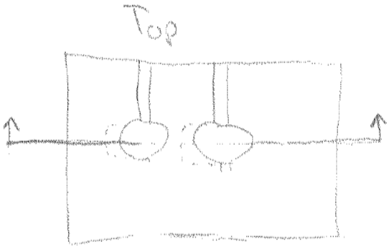

Path for wire keeps it in place

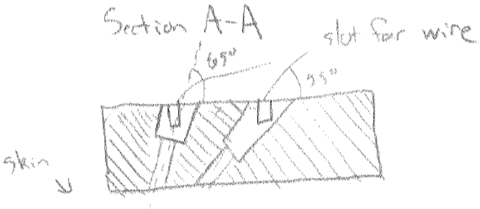
Section A-A





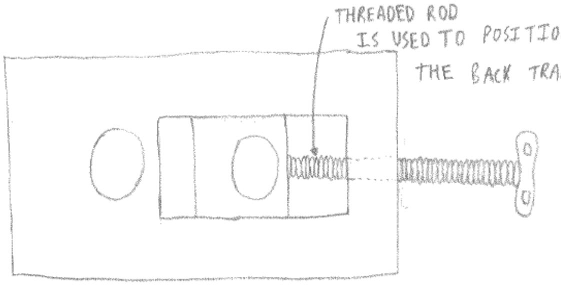
Section A-A





Transducers are in line with access

TOP

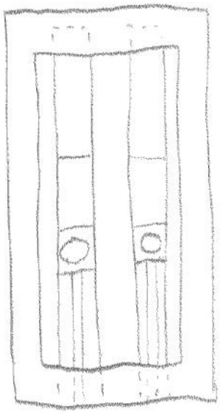


THREADED ROD IS USED TO POSITION THE BACK TRANSDUCER

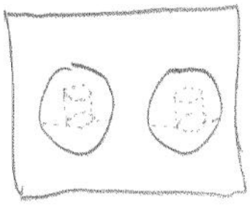
FRONT

BY ADJUSTING THE SPACING BETWEEN TRANSDUCERS, THE TARGETED DEPTH IS ALSO CONTROLLED

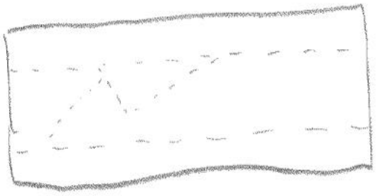
Top

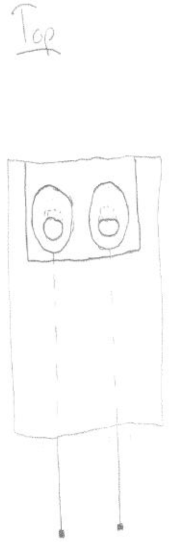


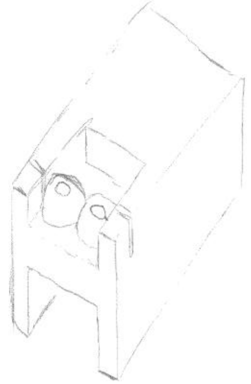
Front

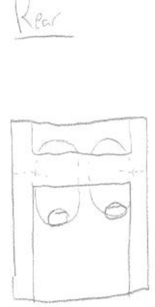


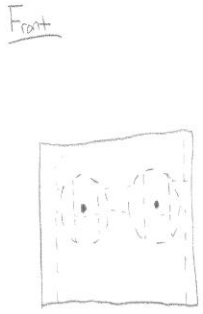
Right

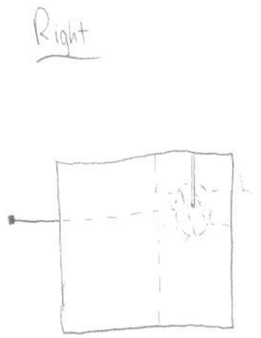



Top

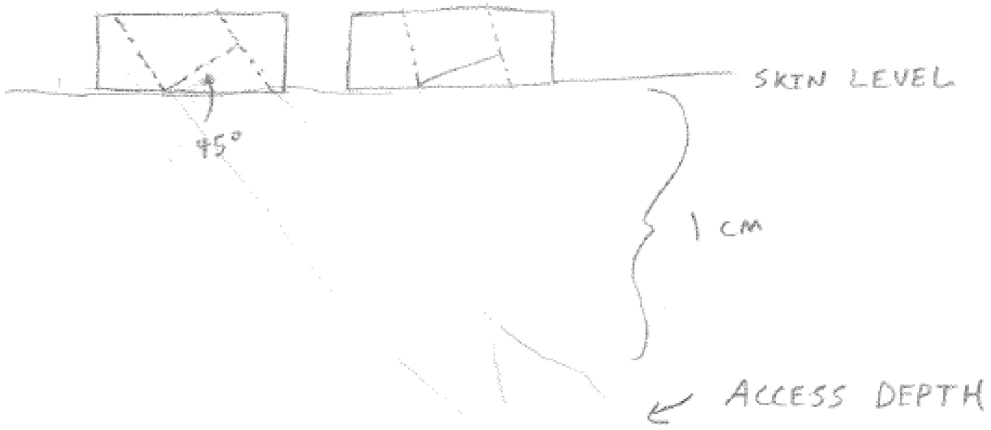


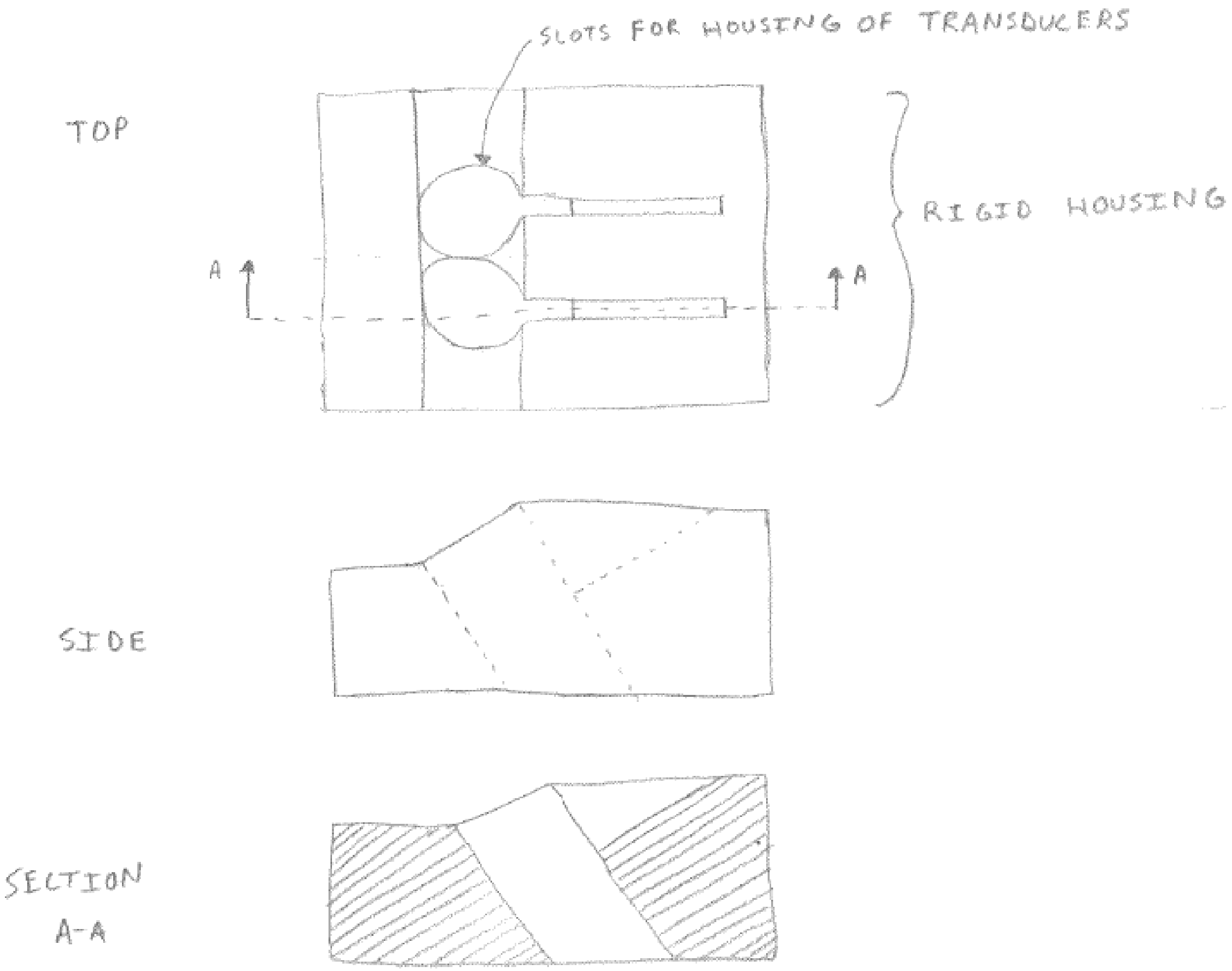

Rear


Front

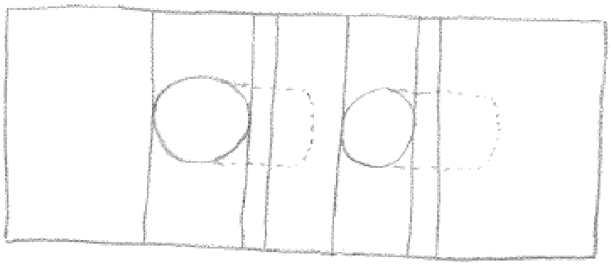

Right

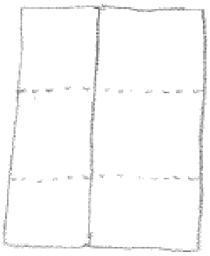
IF THE TRANSDUCERS ARE
HOUSED SEPERATELY AND IN LINE,
THEY CAN BE MOVED CLOSER TOGETHER
OR FARTHER APART TO TARGET THE OPTIMAL ACCESS DEPTH



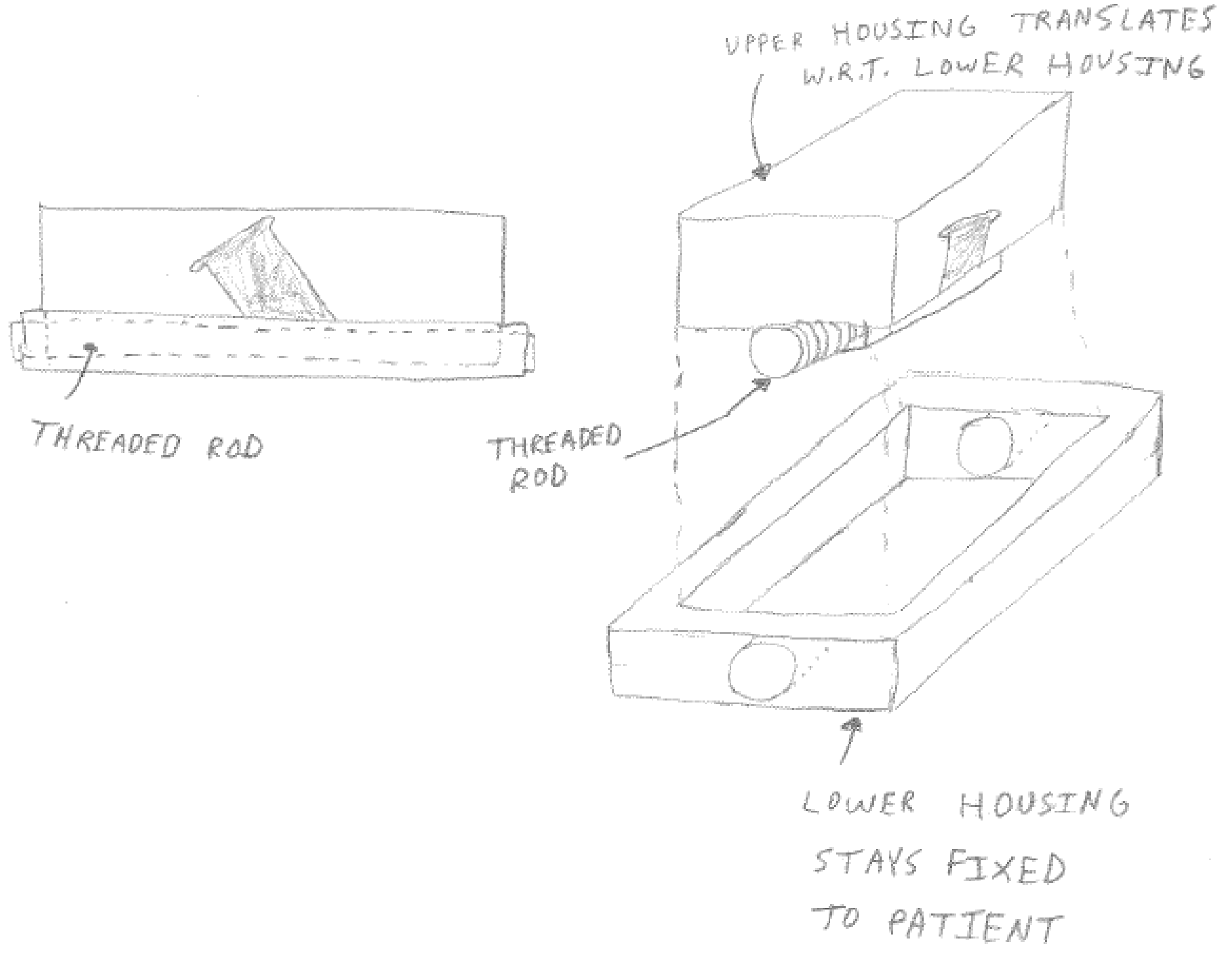

SLOTS FOR HOUSING OF TRANSDUCERS
TOP
RIGID HOUSING
A
A
SIDE
SECTION
A-A

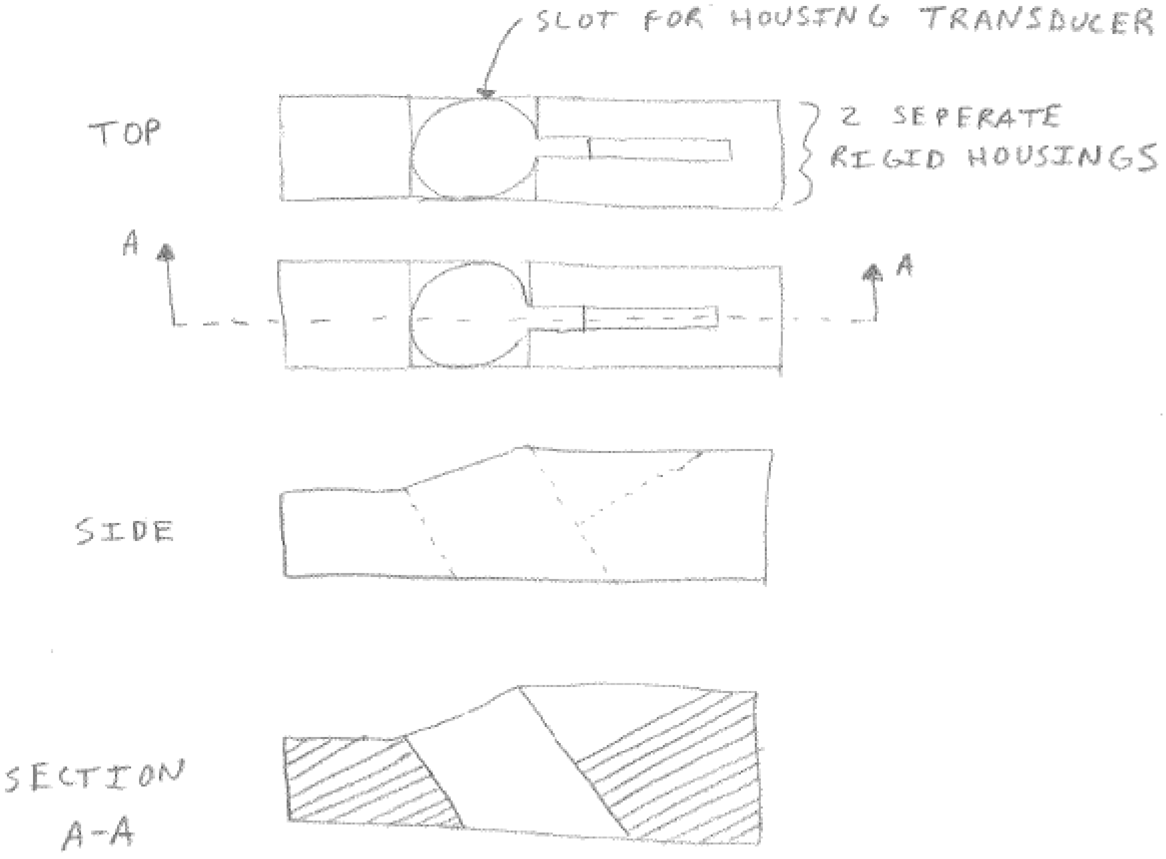
TOP

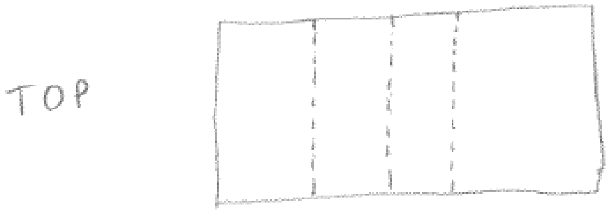


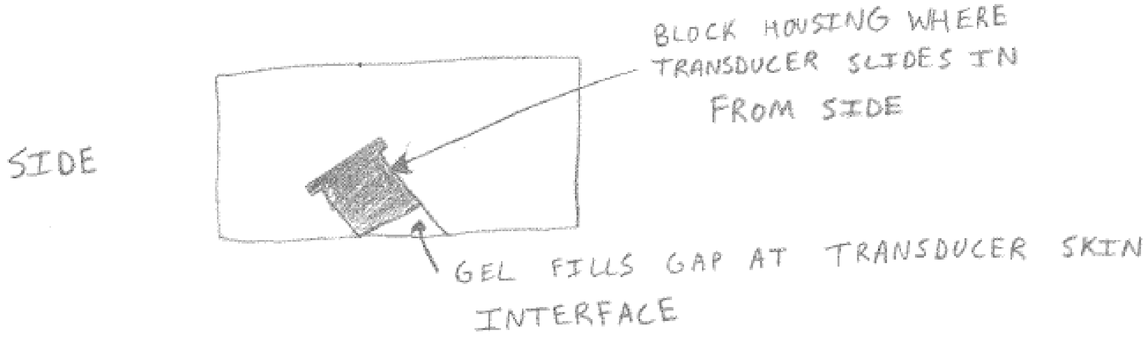


FRONT

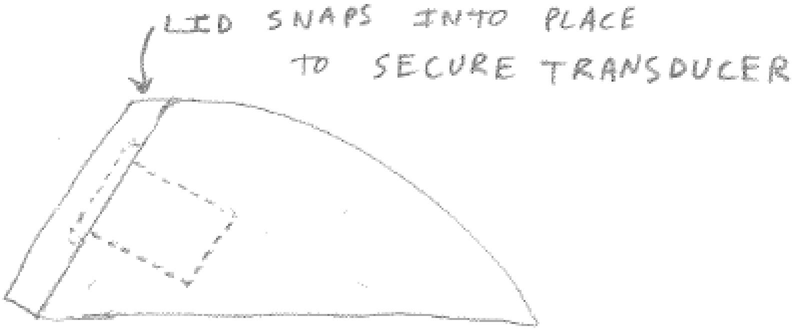

THREADED ROD
UPPER HOUSING TRANSLATES W.R.T. LOWER HOUSING
THREADED ROD
LOWER HOUSING STAYS FIXED TO PATIENT


SLOT FOR HOUSING TRANSDUCER
TOP
2 SEPERATE
RIGID HOUSINGS
A
A
SIDE
SECTION
A-A

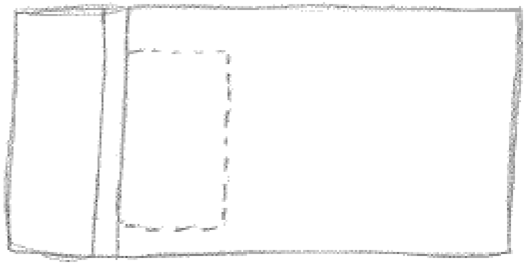

TOP

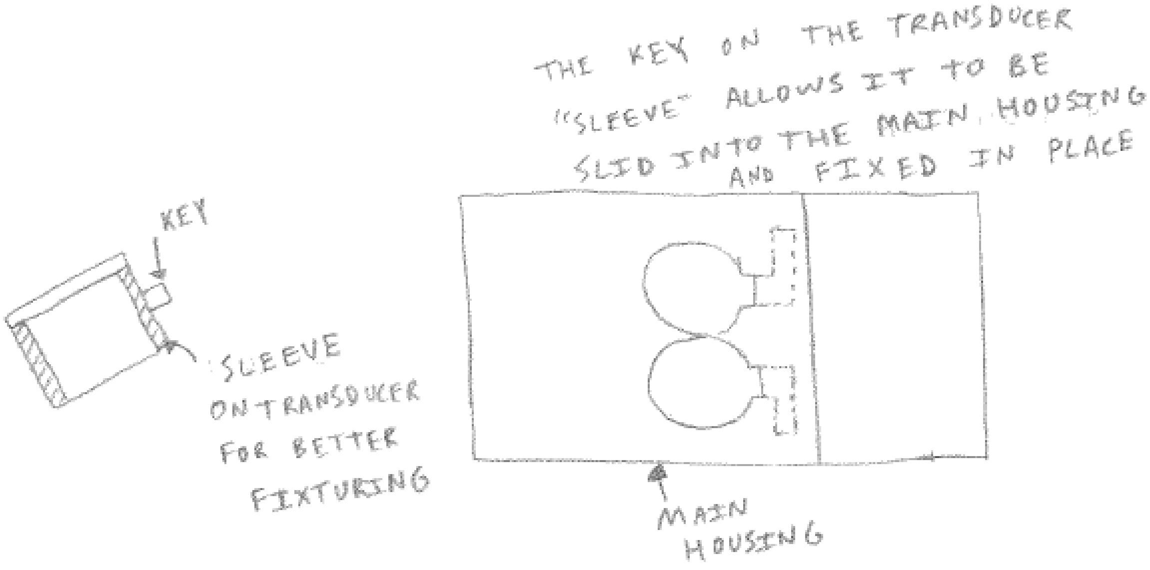

SIDE
BLOCK HOUSING WHERE TRANSDUCER SLIDES IN FROM SIDE
GEL FILLS GAP AT TRANSDUCER SKIN INTERFACE

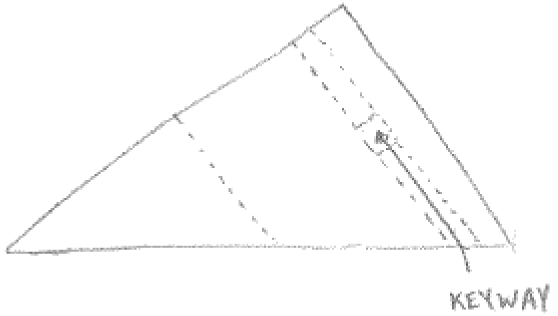
SIDE

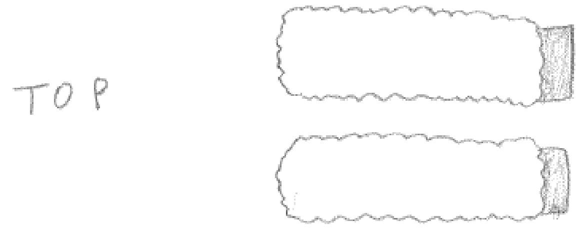


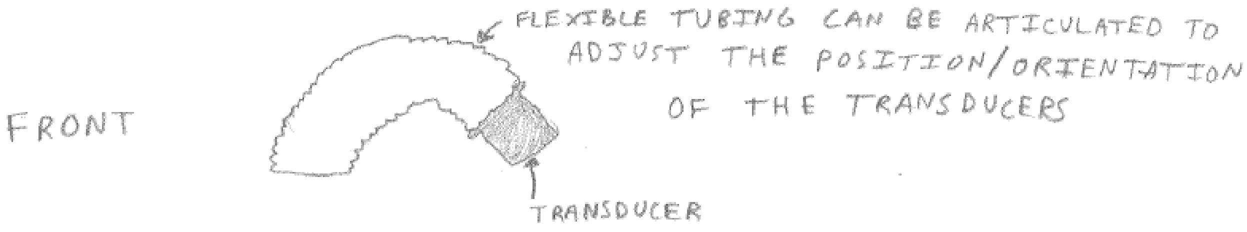
TOP

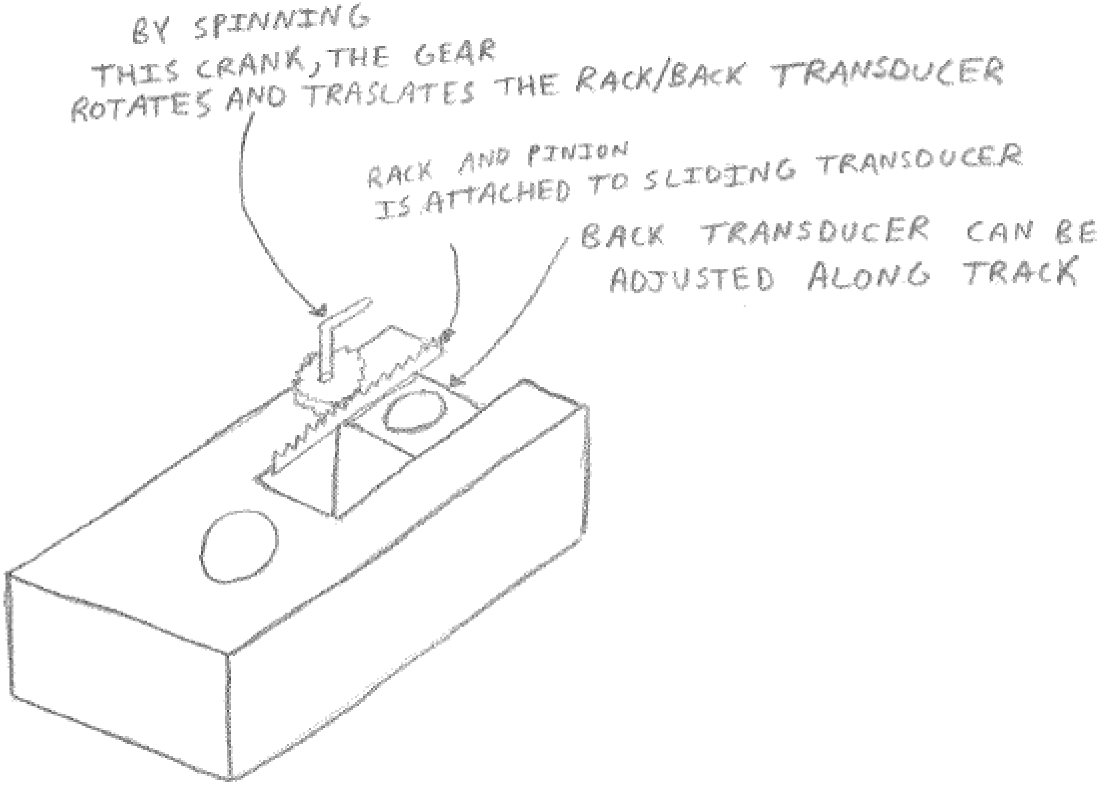


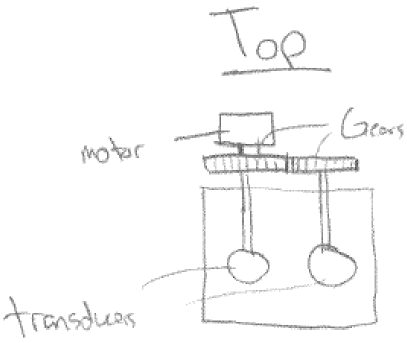

THE KEY ON THE TRANSDUCER "SLEEVE" ALLOWS IT TO BE SLID INTO THE MAIN HOUSING AND FIXED IN PLACE
KEY
SLEEVE ON TRANSDUCER FOR BETTER FIXTURING
MAIN HOUSING

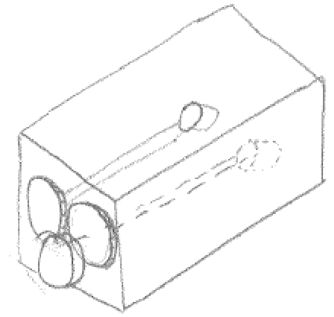

KEYWAY


TOP

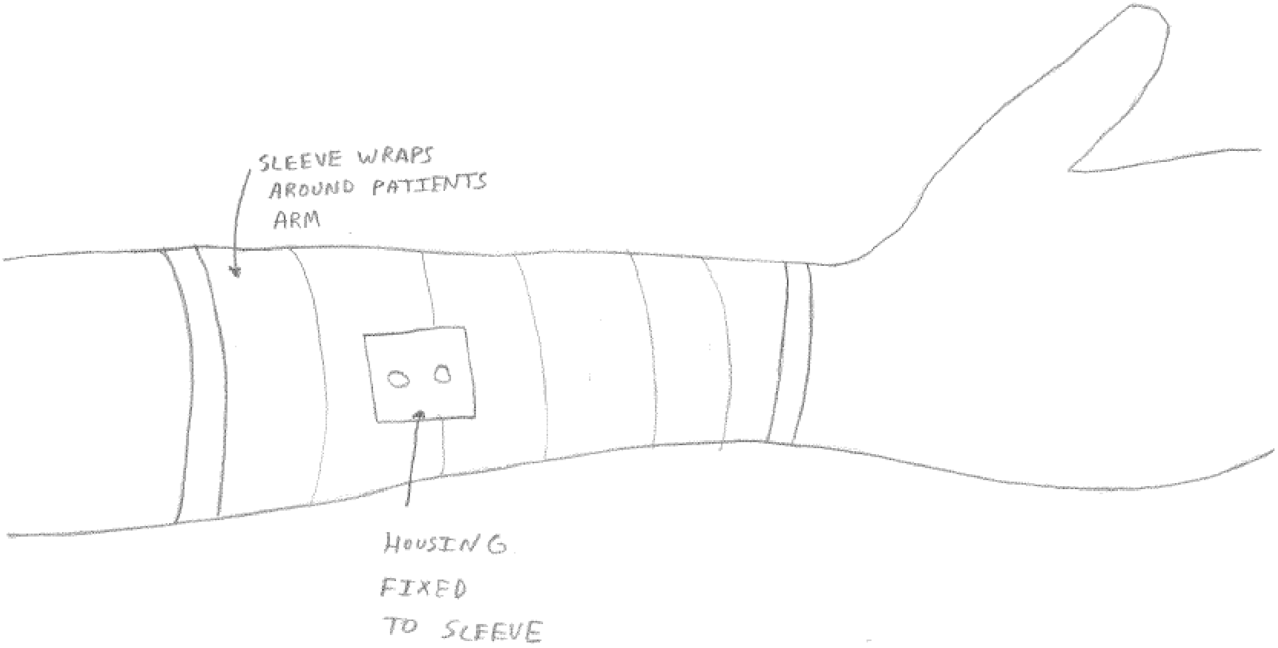

FRONT
FLEXIBLE TUBING CAN BE ARTICULATED TO ADJUST THE POSITION/ORIENTATION OF THE TRANSDUCERS
TRANSDUCER

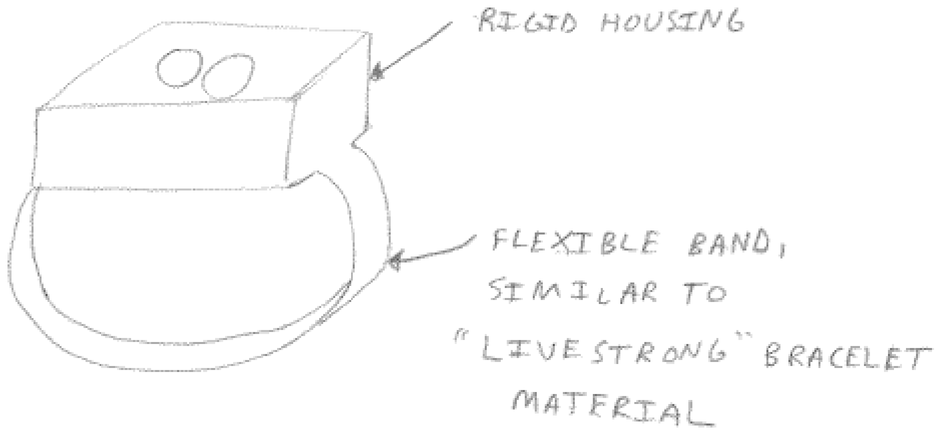

BY SPINNING THIS CRANK, THE GEAR ROTATES AND TRASLATES THE RACK/BACK TRANSDUCER
RACK AND PINION IS ATTACHED TO SLIDING TRANSDUCER
BACK TRANSDUCER CAN BE ADJUSTED ALONG TRACK



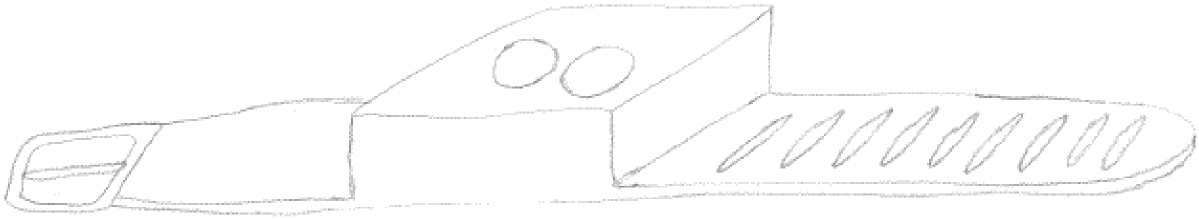


Motor can rotate transducers towards each other or away from each other

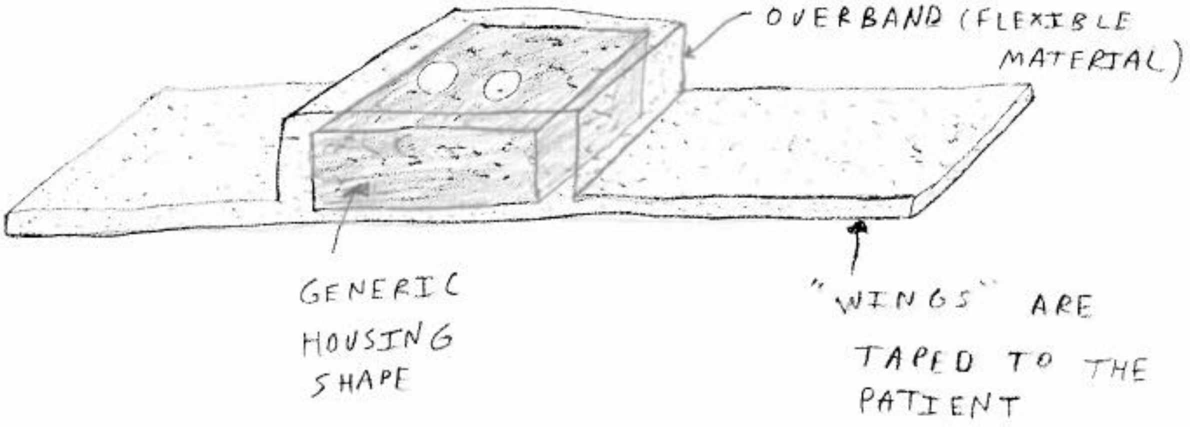

SLEEVE WRAPS
AROUND PATIENTS
ARM
HOUSING
FIXED
TO SLEEVE

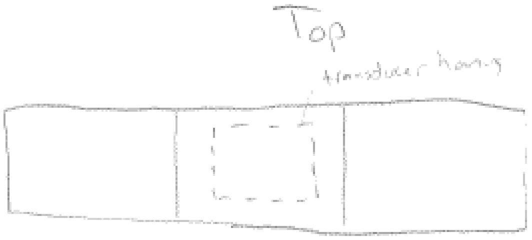

RIGID HOUSING
FLEXIBLE BAND, SIMILAR TO "LIVESTRONG" BRACELET MATERIAL

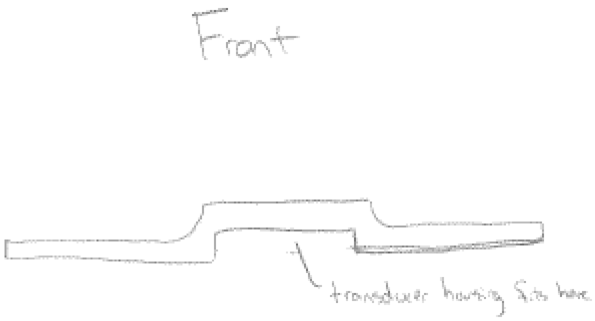
"WATCH STRAP" CONCEPT



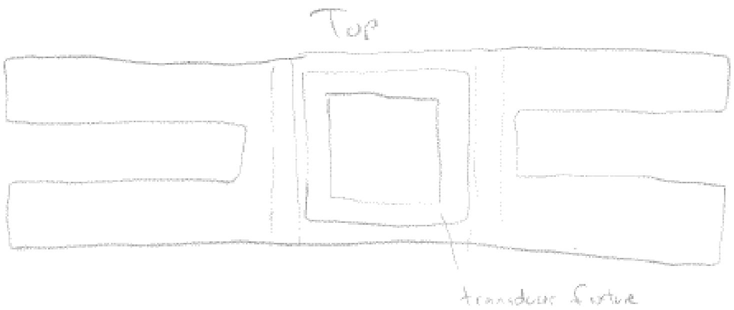
"OVERBAND" CONCEPT. FIT A FLEXIBLE NEGATIVE OF THE HOUSING OVER TOP TO HOLD IN THE TRANSDUCERS AND ATTACH TO FLEXIBLE WINGS



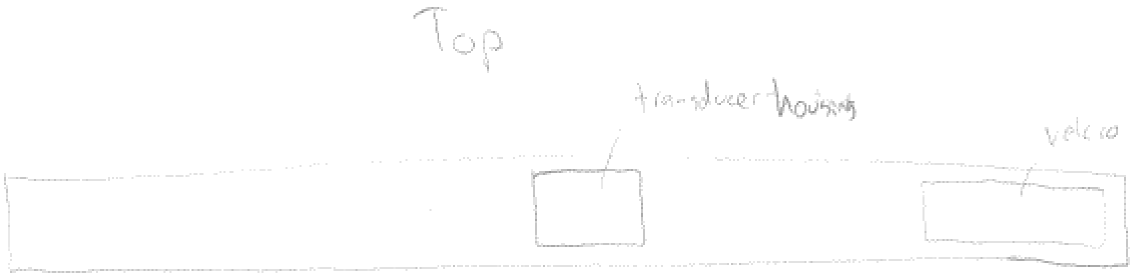




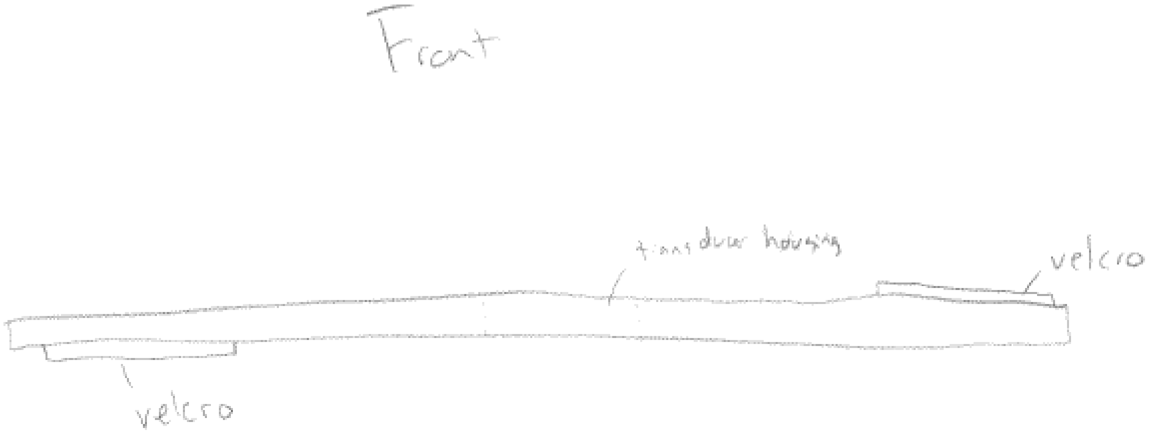
Fixture is taped to skin and covers transducer housing



Put tape on each of
the four "wings" to
secure it to the skin

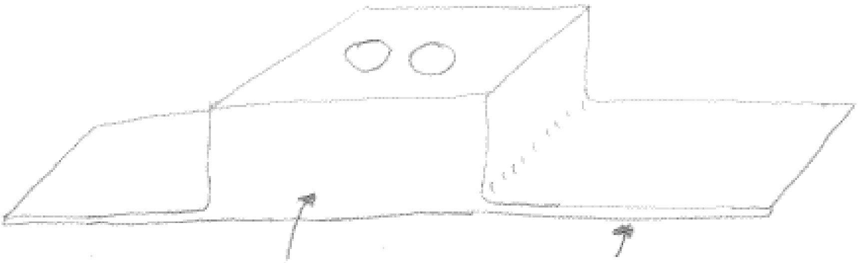

Top

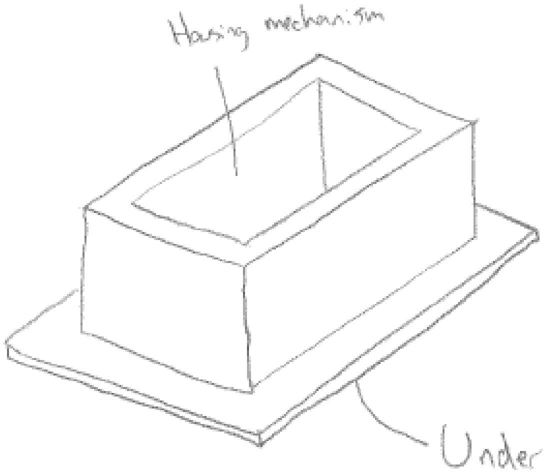
transducer housing
velcro


Front

transducer housing
velcro
velcro

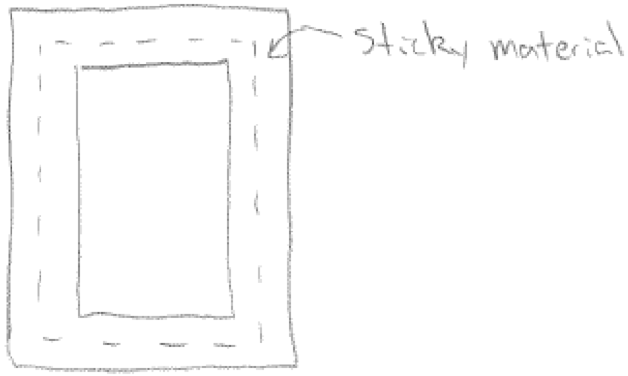
IF MULTIPLE DUROMETERS CAN BE USED IN ONE PART, WE COULD ATTACH FLEXIBLE WINGS TO A RIGID HOUSING.

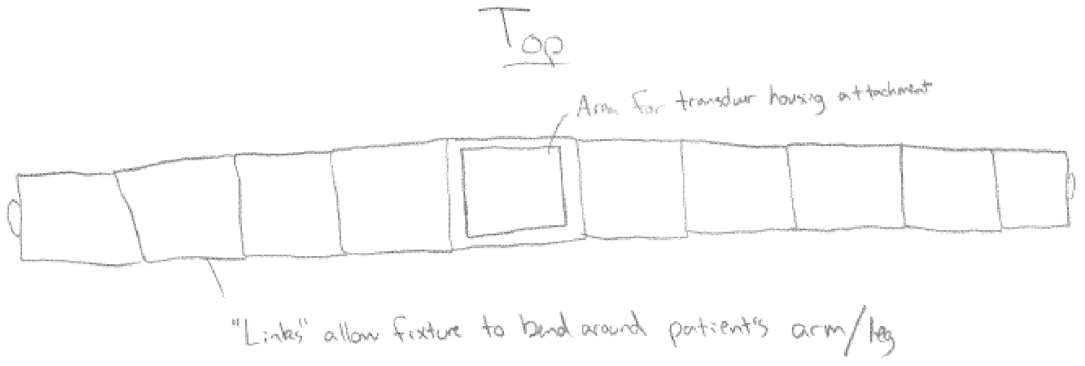


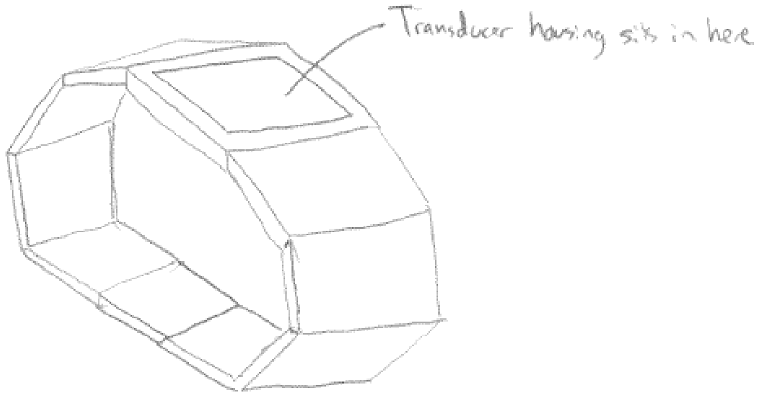


Under side has very sticky surface so that it adheres to the patient throughout the entire treatment

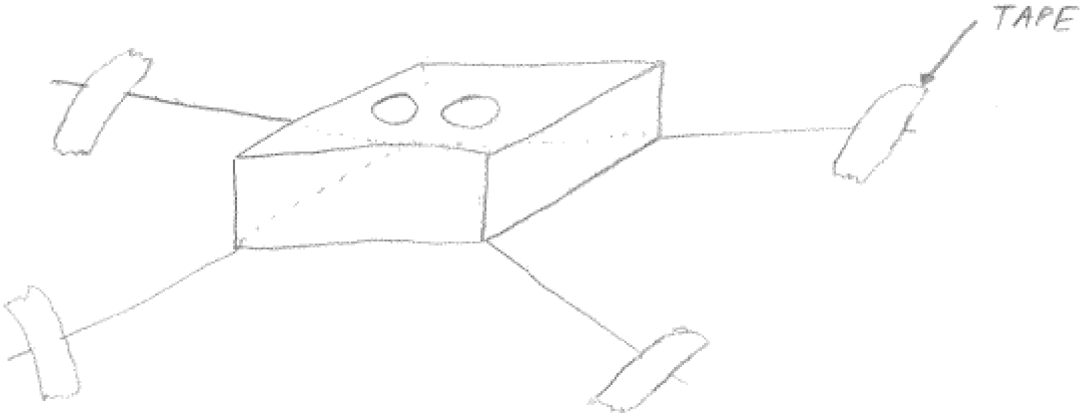
Bottom view



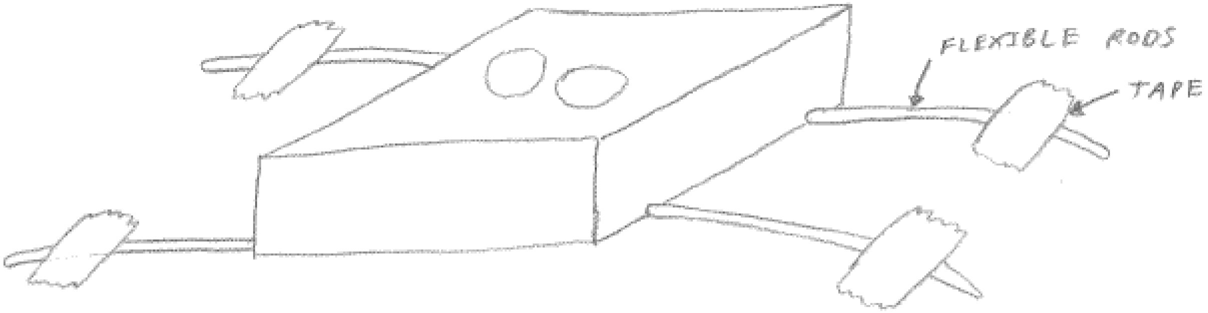

Top
Area for transduer housing attachment
"Links" allow fixture to bend around patient's arm/leg

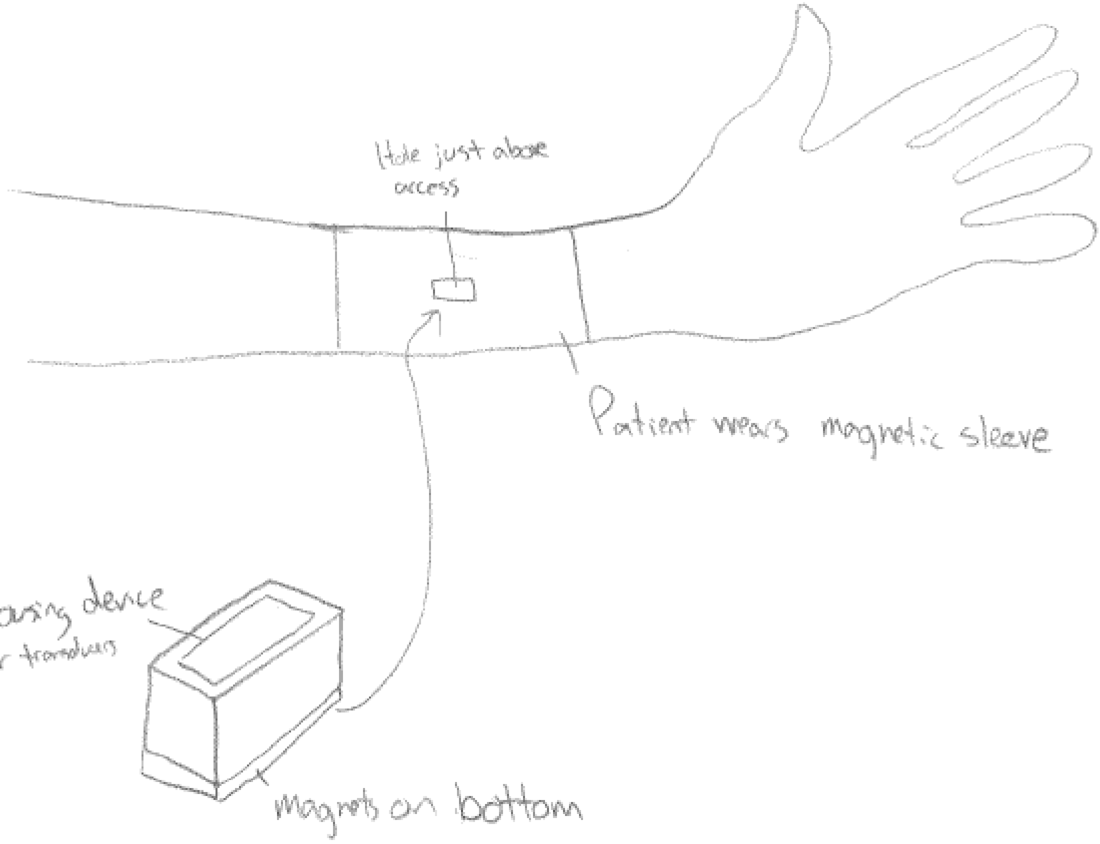

Transducer housing sits in here

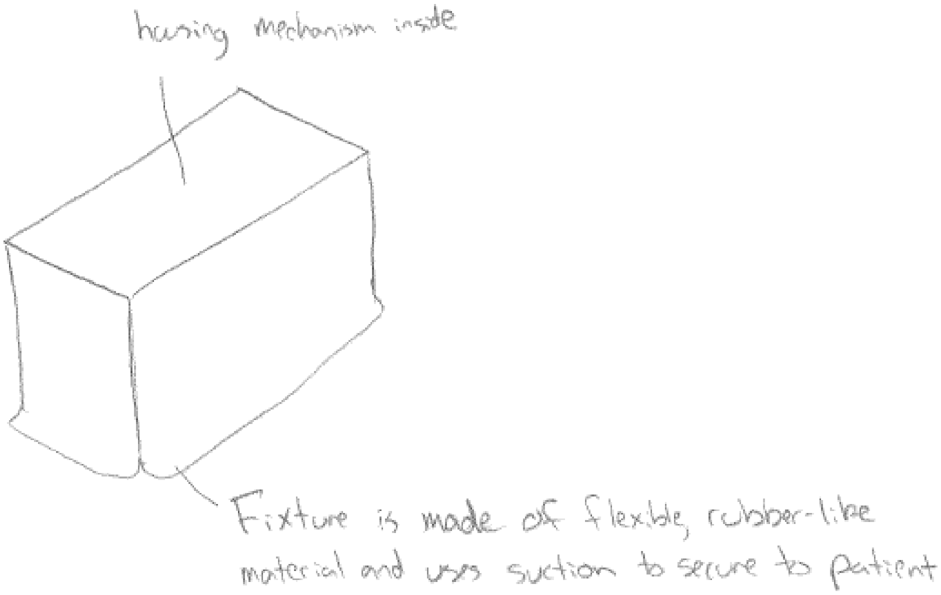
4 Lines are pulled taught from the corners of the transducer housing and taped down to the patient



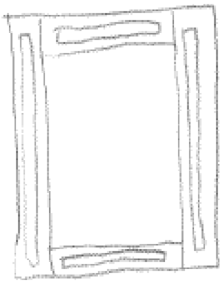
THIS FIXTURING METHOD USES FOUR
FLEXIBLE RODS TAPED TO THE PATIENT



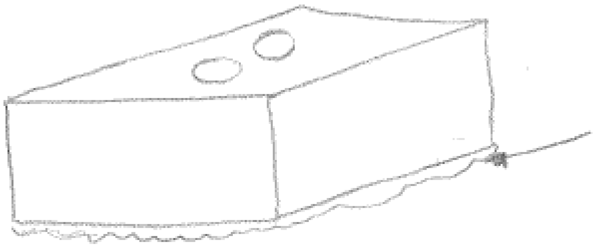

Hole just above access
Patient wears magnetic sleeve
Housing device for transducers
magnets on bottom


housing mechanism inside
Fixture is made of flexible, rubber-like material and uses suction to secure to patient

Bottom



FIXTURING BY ADHESIVE



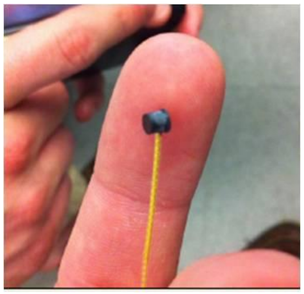
APPLY A SKIN-SAFE ADHESIVE THAT CAN BE REMOVED WITH A SOLVENT

Appendix G: Picture of Lab Equipment

G.1 ASUS Eee PC netbook

ASUS Eee PC Netbook
SN 340571

G.2 Transducer



Transducer

Custom manufactured by Blaytek.

G.3 Isolation Transformer

Islatran Isolation Transformer
Model: LRAM-102
Input: 120 V
Output: 120 V
Freq: 60 Hz
SN: 100078

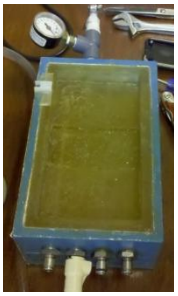
G.4 Pulse Pump

Harvard Apparatus Pulsatile Blood Pump
Model: 1405-048
Max Current: 1 A (fuse)
CAT # 55-1838
Input: 115 V, 50-60 Hz.

G.5 Continuous Pump

Masterflex Console Drive
Cole-Oarmer Instrument Company
Model No. 7520-40
6 - 600 RPM
Manufactured by Barrant Co.

G.6 Access



Box that simulates access.
Has four 6 mm diameter vessels at 1.25 – 2 cm depth from surface.

G.7 Flow meters

Gravity type flow meter